**Anhang 4-G: Post-hoc Analysen inklusive der Analysen, die nicht zur Ableitung des Zusatznutzens herangezogen werden**

Es werden in Anhang 4-G die folgenden Analysen dargestellt:

- Analysen für den Datenschnitt zum 04.01.2021
    - Einschließlich der Sensitivitätsanalyse zum EORTC QLQ-C30 um ≥ 10 Punkte (Datenschnitt zum 04.01.2021)
- Abbildungen für den Datenschnitt zum 04.01.2021
    - Einschließlich der Kaplan-Meier-Kurven für Subgruppenanalysen ohne signifikanten Interaktionsterm (Datenschnitt zum 04.01.2021)
- Analysen für den Datenschnitt zum 04.01.2022
- Abbildungen für den Datenschnitt zum 04.01.2022

Table 1.1.1. Demographics and Baseline Characteristics
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Age (years) | | | |
| n | 196 | 183 | 379 |
| Mean (SD) | 49.6 (10.96) | 50.4 (11.45) | 50.0 (11.19) |
| Median | 50.0 | 50.0 | 50.0 |
| Q1 : Q3 | 41.0 : 58.5 | 43.0 : 56.0 | 42.0 : 57.0 |
| Min : Max | 22 : 75 | 28 : 87 | 22 : 87 |
| Age Groups (years), n (%) | | | |
| <65 | 180 (91.8%) | 163 (89.1%) | 343 (90.5%) |
| >=65 | 16 (8.2%) | 20 (10.9%) | 36 (9.5%) |
| Age Groups (years), n (%) | | | |
| <65 | 180 (91.8%) | 163 (89.1%) | 343 (90.5%) |
| >=65 and <75 | 15 (7.7%) | 14 (7.7%) | 29 (7.7%) |
| >=75 | 1 (0.5%) | 6 (3.3%) | 7 (1.8%) |

Data cut-off as of Jan 4th, 2021.
ECOG, Geographic Region are based on clinical database.

Table 1.1.1. Demographics and Baseline Characteristics
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Race, n (%) | | | |
| White | 136 (69.4%) | 123 (67.2%) | 259 (68.3%) |
| Black or African American | 9 (4.6%) | 12 (6.6%) | 21 (5.5%) |
| Asian | 41 (20.9%) | 38 (20.8%) | 79 (20.8%) |
| American Indian or Alaska Native | 0 | 1 (0.5%) | 1 (0.3%) |
| Other | 6 (3.1%) | 3 (1.6%) | 9 (2.4%) |
| Unknown | 1 (0.5%) | 1 (0.5%) | 2 (0.5%) |
| Not Reported | 3 (1.5%) | 5 (2.7%) | 8 (2.1%) |
| Ethnicity, n (%) | | | |
| Not Hispanic or Latino | 150 (76.5%) | 138 (75.4%) | 288 (76.0%) |
| Hispanic or Latino | 40 (20.4%) | 38 (20.8%) | 78 (20.6%) |
| Not Reported | 6 (3.1%) | 7 (3.8%) | 13 (3.4%) |
| Geographic region, n (%) | | | |
| North America | 22 (11.2%) | 25 (13.7%) | 47 (12.4%) |
| Asia | 36 (18.4%) | 35 (19.1%) | 71 (18.7%) |
| Rest of World | 138 (70.4%) | 123 (67.2%) | 261 (68.9%) |

Data cut-off as of Jan 4th, 2021.
ECOG, Geographic Region are based on clinical database.

Table 1.1.1. Demographics and Baseline Characteristics
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Height (cm) | | | |
| n | 196 | 183 | 379 |
| Mean (SD) | 160.81 (6.582) | 160.54 (6.879) | 160.68 (6.719) |
| Median | 160.40 | 160.00 | 160.00 |
| Q1 : Q3 | 156.00 : 165.00 | 156.00 : 165.00 | 156.00 : 165.00 |
| Min : Max | 147.0 : 178.0 | 137.0 : 181.0 | 137.0 : 181.0 |
| Body Weight (kg) | | | |
| n | 196 | 183 | 379 |
| Mean (SD) | 67.00 (17.283) | 64.64 (16.326) | 65.86 (16.847) |
| Median | 65.00 | 62.00 | 63.50 |
| Q1 : Q3 | 53.00 : 77.80 | 52.50 : 75.00 | 52.70 : 76.00 |
| Min : Max | 36.6 : 128.7 | 35.0 : 120.0 | 35.0 : 128.7 |
| BMI (kg/m2) | | | |
| n | 196 | 183 | 379 |
| Mean (SD) | 25.868 (6.3681) | 25.010 (5.7981) | 25.454 (6.1066) |
| Median | 24.890 | 24.090 | 24.570 |
| Q1 : Q3 | 21.330 : 29.060 | 20.500 : 28.520 | 21.090 : 28.880 |
| Min : Max | 14.17 : 49.00 | 15.43 : 43.73 | 14.17 : 49.00 |

Data cut-off as of Jan 4th, 2021.
ECOG, Geographic Region are based on clinical database.

Table 1.1.1. Demographics and Baseline Characteristics
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| ECOG performance status, n (%) | | | |
| 0 | 83 (42.3%) | 69 (37.7%) | 152 (40.1%) |
| 1 | 113 (57.7%) | 114 (62.3%) | 227 (59.9%) |

Data cut-off as of Jan 4th, 2021.
ECOG, Geographic Region are based on clinical database.

Table 5.1.1. Overall Survival
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Number of deaths, n (%) | 119 (60.7%) | 131 (71.6%) |
| Number of censored patients, n (%) | 77 (39.3%) | 52 (28.4%) |
| | | |
| Median (95% CI), (Months) [a] | 12.7 (8.9, 15.2) | 8.0 (7.0, 9.7) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0025 | |
| HR (95% CI) [b][d] | 0.677 (0.525, 0.873) | |
| HR P-Value [b][d] | 0.0026 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 66.6 (59.5, 72.7) | 63.4 (55.7, 70.2) |
| 12 months | 53.6 (46.2, 60.5) | 33.3 (25.9, 40.9) |
| 18 months | 33.9 (26.0, 41.9) | 16.7 (10.7, 23.9) |
| 24 months | 23.0 (15.0, 32.0) | 10.3 (5.0, 18.0) |
| 30 months | 23.0 (15.0, 32.0) | 8.3 (3.3, 16.1) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 5.1.2. Progression-free Survival
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Number of events, n (%) | 160 (81.6%) | 165 (90.2%) |
| Progressive Disease, n (%) | 135 (68.9%) | 130 (71.0%) |
| Number of deaths, n (%) | 25 (12.8%) | 35 (19.1%) |
| Number of censored patients, n (%) | 36 (18.4%) | 18 (9.8%) |
| | | |
| Median (95% CI), (Months) [a] | 2.8 (2.3, 3.9) | 2.9 (2.7, 3.7) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0214 | |
| HR (95% CI) [b][d] | 0.772 (0.616, 0.967) | |
| HR P-Value [b][d] | 0.0245 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.5 (27.9, 41.2) | 24.8 (18.6, 31.5) |
| 12 months | 22.6 (16.8, 29.0) | 8.1 (4.5, 13.0) |
| 18 months | 15.0 (9.6, 21.6) | NE (NE, NE) |
| 24 months | 10.6 (5.6, 17.5) | NE (NE, NE) |
| 30 months | 7.1 (2.2, 16.1) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 5.1.3. Kaplan-Meier Estimation of Duration of Response
(Full Analysis Set Exclude Patients Assigned to Gemcitabine - Patients with Confirmed CR or PR)

| | Cemiplimab (N=31) | Chemotherapy (N=13) |
|---|---|---|
| KM Estimation of Duration of Response (CR or PR) [a] | | |
| n | 31 | 13 |
| Number of events, n (%) | 9 (29.0%) | 11 (84.6%) |
| Number of censored patients, n (%) | 22 (71.0%) | 2 (15.4%) |
| Median (95% CI), (months) [a] | 17.3 (16.2, NE) | 7.5 (3.7, 9.9) |
| Stratified log-rank test 1-sided p-value [b][c] | <0.0001 | |
| HR (95% CI) [b][d] | 0.105 (0.032, 0.340) | |
| HR P-Value [b][d] | 0.0002 | |
| Estimated Event-Free Probability, % (95% CI) [a] | | |
| 6 months | 90.2 (72.6, 96.7) | 74.6 (39.8, 91.1) |
| 12 months | 85.5 (65.1, 94.4) | 0.0 (NE, NE) |
| 18 months | 38.8 (10.1, 67.7) | 0.0 (NE, NE) |
| 24 months | 38.8 (10.1, 67.7) | 0.0 (NE, NE) |
| 30 months | 19.4 (1.2, 54.3) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on patients with confirmed CR or PR.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 46 (23.5%) | 34 (18.6%) |
| Censored Patients, n (%) | 150 (76.5%) | 149 (81.4%) |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 4.21) | 3.45 (2.69, 7.26) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.3970 | |
| HR (95% CI) [b][d] | 1.229 (0.778, 1.940) | |
| HR P-Value [b][d] | 0.3768 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.4 (9.8, 35.9) | 36.1 (21.6, 50.7) |
| 12 months | 14.3 (3.7, 31.5) | 24.1 (6.8, 46.9) |
| 18 months | 14.3 (3.7, 31.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 54 (27.6%) | 37 (20.2%) |
| Censored Patients, n (%) | 142 (72.4%) | 146 (79.8%) |
| Median (95% CI), (Months) [a] | 2.83 (1.91, 4.17) | 2.96 (1.81, 4.40) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.8744 | |
| HR (95% CI) [b][d] | 1.041 (0.670, 1.618) | |
| HR P-Value [b][d] | 0.8590 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.6 (22.4, 45.2) | 26.6 (12.8, 42.5) |
| 12 months | 18.4 (8.3, 31.5) | NE (NE, NE) |
| 18 months | 18.4 (8.3, 31.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 52 (26.5%) | 29 (15.8%) |
| Censored Patients, n (%) | 144 (73.5%) | 154 (84.2%) |
| Median (95% CI), (Months) [a] | 2.83 (1.61, 4.14) | 3.12 (2.10, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1885 | |
| HR (95% CI) [b][d] | 1.374 (0.853, 2.215) | |
| HR P-Value [b][d] | 0.1916 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.3 (10.7, 34.2) | 40.7 (25.8, 55.0) |
| 12 months | 12.2 (4.2, 24.6) | 40.7 (25.8, 55.0) |
| 18 months | 8.1 (1.8, 20.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 31 (15.8%) | 17 (9.3%) |
| Censored Patients, n (%) | 165 (84.2%) | 166 (90.7%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 2.83) | 1.81 (1.48, 5.59) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.4537 | |
| HR (95% CI) [b][d] | 1.304 (0.668, 2.545) | |
| HR P-Value [b][d] | 0.4360 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 16.1 (5.8, 31.1) | 22.3 (6.4, 44.2) |
| 12 months | 4.0 (0.3, 16.8) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 42 (21.4%) | 24 (13.1%) |
| Censored Patients, n (%) | 154 (78.6%) | 159 (86.9%) |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 4.21) | 5.06 (2.10, 9.69) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0666 | |
| HR (95% CI) [b][d] | 1.633 (0.967, 2.758) | |
| HR P-Value [b][d] | 0.0663 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.2 (14.3, 39.8) | 45.2 (27.6, 61.3) |
| 12 months | 11.7 (3.4, 25.5) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 71 (36.2%) | 35 (19.1%) |
| Censored Patients, n (%) | 125 (63.8%) | 148 (80.9%) |
| Median (95% CI), (Months) [a] | 2.96 (2.07, 4.24) | 5.06 (3.12, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0273 | |
| HR (95% CI) [b][d] | 1.609 (1.060, 2.442) | |
| HR P-Value [b][d] | 0.0254 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.2 (23.1, 43.6) | 43.0 (28.4, 56.8) |
| 12 months | 18.2 (9.1, 29.8) | NE (NE, NE) |
| 18 months | 15.2 (6.7, 26.9) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 77 (39.3%) | 42 (23.0%) |
| Censored Patients, n (%) | 119 (60.7%) | 141 (77.0%) |
| Median (95% CI), (Months) [a] | 4.21 (2.86, 5.68) | 7.26 (5.91, 14.69) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0108 | |
| HR (95% CI) [b][d] | 1.639 (1.120, 2.398) | |
| HR P-Value [b][d] | 0.0110 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.5 (25.6, 45.5) | 60.6 (48.6, 70.5) |
| 12 months | 26.6 (16.5, 37.8) | 41.2 (24.0, 57.7) |
| 18 months | 22.2 (11.5, 35.0) | 0.0 (NE, NE) |
| 24 months | 11.1 (1.3, 32.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 48 (24.5%) | 37 (20.2%) |
| Censored Patients, n (%) | 148 (75.5%) | 146 (79.8%) |
| Median (95% CI), (Months) [a] | 2.92 (2.33, 4.67) | 3.45 (2.56, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.4315 | |
| HR (95% CI) [b][d] | 1.197 (0.771, 1.856) | |
| HR P-Value [b][d] | 0.4228 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 31.7 (20.2, 43.9) | 46.0 (33.2, 57.9) |
| 12 months | 25.4 (14.0, 38.3) | 32.7 (15.7, 51.0) |
| 18 months | 25.4 (14.0, 38.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 35 (17.9%) | 26 (14.2%) |
| Censored Patients, n (%) | 161 (82.1%) | 157 (85.8%) |
| Median (95% CI), (Months) [a] | 1.91 (1.58, 3.22) | 2.83 (1.64, 4.37) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.3998 | |
| HR (95% CI) [b][d] | 1.273 (0.739, 2.193) | |
| HR P-Value [b][d] | 0.3840 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 16.4 (5.8, 31.7) | 15.0 (4.2, 32.2) |
| 12 months | 12.3 (3.4, 27.2) | NE (NE, NE) |
| 18 months | 6.2 (0.6, 22.1) | NE (NE, NE) |
| 24 months | 6.2 (0.6, 22.1) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 81 (41.3%) | 60 (32.8%) |
| Censored Patients, n (%) | 115 (58.7%) | 123 (67.2%) |
| Median (95% CI), (Months) [a] | 2.79 (1.64, 4.21) | 3.02 (2.56, 5.22) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.2167 | |
| HR (95% CI) [b][d] | 1.265 (0.891, 1.794) | |
| HR P-Value [b][d] | 0.1883 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.1 (18.8, 38.0) | 32.8 (22.0, 44.0) |
| 12 months | 13.0 (5.2, 24.4) | 21.7 (10.1, 36.0) |
| 18 months | 8.6 (2.1, 21.0) | NE (NE, NE) |
| 24 months | 8.6 (2.1, 21.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 53 (27.0%) | 21 (11.5%) |
| Censored Patients, n (%) | 143 (73.0%) | 162 (88.5%) |
| Median (95% CI), (Months) [a] | 5.62 (4.27, NE) | NE (7.00, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0005 | |
| HR (95% CI) [b][d] | 2.455 (1.463, 4.119) | |
| HR P-Value [b][d] | 0.0007 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.8 (36.5, 58.2) | 78.5 (66.7, 86.6) |
| 12 months | 43.2 (31.5, 54.4) | 58.0 (39.1, 72.9) |
| 18 months | 43.2 (31.5, 54.4) | NE (NE, NE) |
| 24 months | 32.4 (14.0, 52.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-10pts.sas (23JAN23:11:39:20, yingyuan.lin)

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 77 (39.3%) | 36 (19.7%) |
| Censored Patients, n (%) | 119 (60.7%) | 147 (80.3%) |
| Median (95% CI), (Months) [a] | 4.90 (2.99, 7.43) | 9.59 (7.06, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0050 | |
| HR (95% CI) [b][d] | 1.775 (1.188, 2.653) | |
| HR P-Value [b][d] | 0.0051 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.8 (36.4, 54.7) | 65.6 (54.1, 74.8) |
| 12 months | 38.0 (28.2, 47.7) | 49.3 (29.4, 66.4) |
| 18 months | 26.5 (14.6, 40.0) | NE (NE, NE) |
| 24 months | 19.9 (7.7, 36.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 71 (36.2%) | 31 (16.9%) |
| Censored Patients, n (%) | 125 (63.8%) | 152 (83.1%) |
| Median (95% CI), (Months) [a] | 2.99 (1.91, 4.67) | NE (4.21, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0064 | |
| HR (95% CI) [b][d] | 1.821 (1.182, 2.805) | |
| HR P-Value [b][d] | 0.0066 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.8 (19.1, 39.2) | 54.7 (41.2, 66.4) |
| 12 months | 19.7 (10.7, 30.8) | 54.7 (41.2, 66.4) |
| 18 months | 19.7 (10.7, 30.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 69 (35.2%) | 40 (21.9%) |
| Censored Patients, n (%) | 127 (64.8%) | 143 (78.1%) |
| Median (95% CI), (Months) [a] | 1.84 (1.58, 2.83) | 4.17 (2.79, 7.26) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0059 | |
| HR (95% CI) [b][d] | 1.778 (1.181, 2.676) | |
| HR P-Value [b][d] | 0.0058 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 19.0 (10.6, 29.3) | 42.9 (29.7, 55.4) |
| 12 months | 10.9 (3.9, 21.9) | 29.4 (13.3, 47.6) |
| 18 months | 10.9 (3.9, 21.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 55 (28.1%) | 32 (17.5%) |
| Censored Patients, n (%) | 141 (71.9%) | 151 (82.5%) |
| Median (95% CI), (Months) [a] | 2.92 (2.73, 5.45) | 5.03 (3.02, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.2023 | |
| HR (95% CI) [b][d] | 1.359 (0.869, 2.125) | |
| HR P-Value [b][d] | 0.1788 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.2 (20.8, 44.2) | 44.9 (29.3, 59.2) |
| 12 months | 19.7 (9.2, 33.1) | NE (NE, NE) |
| 18 months | 19.7 (9.2, 33.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 80 (40.8%) | 84 (45.9%) |
| Censored Patients, n (%) | 116 (59.2%) | 99 (54.1%) |
| Median (95% CI), (Months) [a] | 5.68 (4.21, 8.41) | 3.12 (2.56, 4.40) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0006 | |
| HR (95% CI) [b][d] | 0.579 (0.421, 0.796) | |
| HR P-Value [b][d] | 0.0008 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.7 (38.6, 56.3) | 27.9 (19.1, 37.4) |
| 12 months | 35.4 (25.9, 45.1) | 4.6 (0.4, 18.0) |
| 18 months | 31.5 (21.8, 41.6) | 4.6 (0.4, 18.0) |
| 24 months | 31.5 (21.8, 41.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 90 (45.9%) | 72 (39.3%) |
| Censored Patients, n (%) | 106 (54.1%) | 111 (60.7%) |
| Median (95% CI), (Months) [a] | 5.59 (3.09, 7.23) | 3.19 (2.92, 5.22) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.2853 | |
| HR (95% CI) [b][d] | 0.845 (0.615, 1.161) | |
| HR P-Value [b][d] | 0.2992 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.1 (36.0, 53.6) | 39.5 (30.0, 48.8) |
| 12 months | 27.6 (18.5, 37.6) | 30.3 (18.4, 43.1) |
| 18 months | 16.7 (7.8, 28.4) | 30.3 (18.4, 43.1) |
| 24 months | 16.7 (7.8, 28.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 74 (37.8%) | 65 (35.5%) |
| Censored Patients, n (%) | 122 (62.2%) | 118 (64.5%) |
| Median (95% CI), (Months) [a] | 8.21 (5.68, 10.09) | 4.40 (3.06, 6.97) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0549 | |
| HR (95% CI) [b][d] | 0.715 (0.506, 1.010) | |
| HR P-Value [b][d] | 0.0572 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.0 (47.8, 65.2) | 44.1 (33.8, 53.9) |
| 12 months | 39.5 (29.2, 49.7) | 25.2 (11.2, 41.9) |
| 18 months | 23.7 (12.3, 37.1) | 16.8 (4.2, 36.5) |
| 24 months | 23.7 (12.3, 37.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 58 (29.6%) | 48 (26.2%) |
| Censored Patients, n (%) | 138 (70.4%) | 135 (73.8%) |
| Median (95% CI), (Months) [a] | 8.44 (7.10, 18.04) | 8.84 (5.55, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.3232 | |
| HR (95% CI) [b][d] | 0.822 (0.556, 1.216) | |
| HR P-Value [b][d] | 0.3264 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.4 (57.9, 75.2) | 54.6 (43.1, 64.7) |
| 12 months | 40.6 (29.1, 51.7) | 42.4 (27.6, 56.5) |
| 18 months | 40.6 (29.1, 51.7) | NE (NE, NE) |
| 24 months | 34.8 (21.0, 49.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 69 (35.2%) | 62 (33.9%) |
| Censored Patients, n (%) | 127 (64.8%) | 121 (66.1%) |
| Median (95% CI), (Months) [a] | 7.62 (5.65, 19.29) | 5.85 (4.37, 9.89) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1074 | |
| HR (95% CI) [b][d] | 0.749 (0.524, 1.071) | |
| HR P-Value [b][d] | 0.1127 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.4 (45.0, 62.9) | 49.5 (38.8, 59.4) |
| 12 months | 40.2 (29.6, 50.5) | 20.7 (8.0, 37.6) |
| 18 months | 40.2 (29.6, 50.5) | 10.4 (1.1, 32.3) |
| 24 months | 33.5 (19.3, 48.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 68 (34.7%) | 64 (35.0%) |
| Censored Patients, n (%) | 128 (65.3%) | 119 (65.0%) |
| Median (95% CI), (Months) [a] | 7.33 (5.62, 13.83) | 5.32 (3.48, 7.10) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0620 | |
| HR (95% CI) [b][d] | 0.715 (0.501, 1.021) | |
| HR P-Value [b][d] | 0.0650 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.4 (46.9, 64.9) | 43.6 (33.1, 53.6) |
| 12 months | 43.5 (32.8, 53.8) | 26.7 (12.4, 43.4) |
| 18 months | 35.7 (24.0, 47.5) | 26.7 (12.4, 43.4) |
| 24 months | 19.0 (5.1, 39.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 111 (56.6%) | 97 (53.0%) |
| Censored Patients, n (%) | 85 (43.4%) | 86 (47.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.71, 3.22) | 1.97 (1.68, 2.86) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1600 | |
| HR (95% CI) [b][d] | 0.818 (0.616, 1.087) | |
| HR P-Value [b][d] | 0.1660 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.7 (21.2, 36.6) | 26.7 (18.7, 35.2) |
| 12 months | 15.9 (9.1, 24.4) | 0.0 (NE, NE) |
| 18 months | 15.9 (9.1, 24.4) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 58 (29.6%) | 45 (24.6%) |
| Censored Patients, n (%) | 138 (70.4%) | 138 (75.4%) |
| Median (95% CI), (Months) [a] | 10.12 (5.72, NE) | 8.84 (6.67, 11.93) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.4058 | |
| HR (95% CI) [b][d] | 0.848 (0.569, 1.263) | |
| HR P-Value [b][d] | 0.4172 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.3 (49.5, 67.9) | 63.7 (52.5, 72.9) |
| 12 months | 47.1 (36.3, 57.3) | 30.4 (14.0, 48.6) |
| 18 months | 47.1 (36.3, 57.3) | 22.8 (7.6, 42.8) |
| 24 months | 34.9 (19.0, 51.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 70 (35.7%) | 82 (44.8%) |
| Censored Patients, n (%) | 126 (64.3%) | 101 (55.2%) |
| Median (95% CI), (Months) [a] | 7.79 (6.28, 11.99) | 2.96 (1.77, 5.16) |
| Stratified log-rank test 2-sided p-value [b][c] | <0.0001 | |
| HR (95% CI) [b][d] | 0.437 (0.313, 0.611) | |
| HR P-Value [b][d] | <0.0001 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.7 (50.4, 67.8) | 35.8 (26.5, 45.2) |
| 12 months | 39.5 (29.3, 49.6) | 8.9 (0.9, 28.8) |
| 18 months | 34.2 (23.3, 45.5) | 8.9 (0.9, 28.8) |
| 24 months | 34.2 (23.3, 45.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 85 (43.4%) | 91 (49.7%) |
| Censored Patients, n (%) | 111 (56.6%) | 92 (50.3%) |
| Median (95% CI), (Months) [a] | 4.30 (2.92, 5.82) | 2.79 (1.77, 2.92) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0027 | |
| HR (95% CI) [b][d] | 0.633 (0.466, 0.860) | |
| HR P-Value [b][d] | 0.0034 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.0 (30.0, 47.9) | 20.7 (13.3, 29.3) |
| 12 months | 27.9 (19.0, 37.4) | 5.6 (0.6, 20.0) |
| 18 months | 25.3 (16.2, 35.4) | 5.6 (0.6, 20.0) |
| 24 months | 25.3 (16.2, 35.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 89 (45.4%) | 83 (45.4%) |
| Censored Patients, n (%) | 107 (54.6%) | 100 (54.6%) |
| Median (95% CI), (Months) [a] | 6.18 (5.29, 10.45) | 4.14 (2.86, 4.83) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0028 | |
| HR (95% CI) [b][d] | 0.619 (0.449, 0.853) | |
| HR P-Value [b][d] | 0.0034 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.5 (42.5, 59.7) | 34.4 (25.2, 43.8) |
| 12 months | 33.6 (24.2, 43.2) | 9.4 (2.0, 23.9) |
| 18 months | 15.4 (7.2, 26.4) | 9.4 (2.0, 23.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 87 (44.4%) | 84 (45.9%) |
| Censored Patients, n (%) | 109 (55.6%) | 99 (54.1%) |
| Median (95% CI), (Months) [a] | 5.82 (4.37, 7.10) | 3.45 (2.79, 4.40) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0705 | |
| HR (95% CI) [b][d] | 0.752 (0.548, 1.032) | |
| HR P-Value [b][d] | 0.0774 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.5 (37.3, 55.1) | 32.7 (23.6, 42.1) |
| 12 months | 28.4 (19.5, 38.0) | 12.9 (3.6, 28.2) |
| 18 months | 23.5 (14.3, 34.0) | 12.9 (3.6, 28.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 91 (46.4%) | 89 (48.6%) |
| Censored Patients, n (%) | 105 (53.6%) | 94 (51.4%) |
| Median (95% CI), (Months) [a] | 4.27 (2.83, 8.34) | 2.83 (1.84, 3.48) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0020 | |
| HR (95% CI) [b][d] | 0.621 (0.456, 0.847) | |
| HR P-Value [b][d] | 0.0026 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.7 (33.8, 51.3) | 27.0 (18.4, 36.3) |
| 12 months | 33.5 (24.5, 42.7) | 3.9 (0.4, 15.5) |
| 18 months | 19.7 (10.8, 30.5) | 3.9 (0.4, 15.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 76 (38.8%) | 78 (42.6%) |
| Censored Patients, n (%) | 120 (61.2%) | 105 (57.4%) |
| Median (95% CI), (Months) [a] | 5.75 (4.37, 11.27) | 4.21 (2.86, 5.65) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0094 | |
| HR (95% CI) [b][d] | 0.650 (0.467, 0.905) | |
| HR P-Value [b][d] | 0.0106 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.6 (39.3, 57.3) | 36.1 (26.4, 45.8) |
| 12 months | 39.6 (29.9, 49.0) | 17.8 (8.3, 30.2) |
| 18 months | 33.8 (23.0, 45.0) | 8.9 (1.1, 27.6) |
| 24 months | 11.3 (1.0, 35.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 78 (39.8%) | 70 (38.3%) |
| Censored Patients, n (%) | 118 (60.2%) | 113 (61.7%) |
| Median (95% CI), (Months) [a] | 4.40 (3.19, 7.95) | 4.30 (2.89, 7.00) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1950 | |
| HR (95% CI) [b][d] | 0.806 (0.578, 1.124) | |
| HR P-Value [b][d] | 0.2039 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.0 (32.7, 51.1) | 45.0 (35.0, 54.5) |
| 12 months | 34.4 (24.3, 44.7) | 21.9 (10.7, 35.7) |
| 18 months | 25.0 (15.0, 36.3) | 16.5 (5.9, 31.7) |
| 24 months | 16.7 (5.1, 34.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 31 (15.8%) | 20 (10.9%) |
| Censored Patients, n (%) | 165 (84.2%) | 163 (89.1%) |
| Median (95% CI), (Months) [a] | 12.52 (4.21, NE) | NE (5.65, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.3533 | |
| HR (95% CI) [b][d] | 1.329 (0.734, 2.408) | |
| HR P-Value [b][d] | 0.3474 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.2 (43.5, 68.7) | 64.1 (48.6, 76.0) |
| 12 months | 52.0 (36.1, 65.7) | 58.8 (41.0, 72.8) |
| 18 months | 30.3 (12.0, 51.1) | NE (NE, NE) |
| 24 months | 30.3 (12.0, 51.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 28 (14.3%) | 19 (10.4%) |
| Censored Patients, n (%) | 168 (85.7%) | 164 (89.6%) |
| Median (95% CI), (Months) [a] | 17.97 (9.72, NE) | NE (5.65, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.6835 | |
| HR (95% CI) [b][d] | 0.887 (0.483, 1.628) | |
| HR P-Value [b][d] | 0.6976 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.0 (61.4, 81.6) | 65.1 (49.5, 77.0) |
| 12 months | 61.9 (47.3, 73.6) | NE (NE, NE) |
| 18 months | 43.0 (20.7, 63.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 30 (15.3%) | 21 (11.5%) |
| Censored Patients, n (%) | 166 (84.7%) | 162 (88.5%) |
| Median (95% CI), (Months) [a] | 9.72 (5.72, NE) | NE (3.12, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.4387 | |
| HR (95% CI) [b][d] | 0.792 (0.439, 1.429) | |
| HR P-Value [b][d] | 0.4394 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.7 (48.7, 73.9) | 56.6 (40.6, 69.8) |
| 12 months | 39.6 (22.7, 56.0) | 56.6 (40.6, 69.8) |
| 18 months | 33.0 (15.8, 51.3) | NE (NE, NE) |
| 24 months | 33.0 (15.8, 51.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 23 (11.7%) | 13 (7.1%) |
| Censored Patients, n (%) | 173 (88.3%) | 170 (92.9%) |
| Median (95% CI), (Months) [a] | 6.11 (1.58, 11.40) | 2.33 (1.48, 7.00) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.8039 | |
| HR (95% CI) [b][d] | 0.918 (0.413, 2.043) | |
| HR P-Value [b][d] | 0.8348 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.2 (32.6, 65.5) | 40.6 (18.8, 61.6) |
| 12 months | 25.5 (9.8, 44.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 30 (15.3%) | 13 (7.1%) |
| Censored Patients, n (%) | 166 (84.7%) | 170 (92.9%) |
| Median (95% CI), (Months) [a] | 8.97 (4.21, 11.83) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1241 | |
| HR (95% CI) [b][d] | 1.702 (0.863, 3.357) | |
| HR P-Value [b][d] | 0.1247 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.7 (43.8, 70.9) | 71.1 (54.1, 82.7) |
| 12 months | 32.3 (16.1, 49.6) | 71.1 (54.1, 82.7) |
| 18 months | 24.2 (8.5, 44.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 30 (15.3%) | 17 (9.3%) |
| Censored Patients, n (%) | 166 (84.7%) | 166 (90.7%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (8.67, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.7364 | |
| HR (95% CI) [b][d] | 1.111 (0.604, 2.044) | |
| HR P-Value [b][d] | 0.7344 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.4 (62.4, 81.6) | 75.2 (61.4, 84.7) |
| 12 months | 61.6 (47.8, 72.8) | 65.5 (46.6, 79.1) |
| 18 months | 56.5 (40.3, 69.9) | NE (NE, NE) |
| 24 months | 56.5 (40.3, 69.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 39 (19.9%) | 22 (12.0%) |
| Censored Patients, n (%) | 157 (80.1%) | 161 (88.0%) |
| Median (95% CI), (Months) [a] | 21.88 (11.17, NE) | 14.69 (8.97, 14.69) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.3269 | |
| HR (95% CI) [b][d] | 1.312 (0.770, 2.234) | |
| HR P-Value [b][d] | 0.3176 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.7 (64.4, 80.8) | 81.1 (71.3, 87.9) |
| 12 months | 61.7 (49.4, 71.8) | 67.7 (48.9, 80.9) |
| 18 months | 58.9 (45.9, 69.7) | 0.0 (NE, NE) |
| 24 months | 49.1 (28.1, 67.1) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 26 (13.3%) | 20 (10.9%) |
| Censored Patients, n (%) | 170 (86.7%) | 163 (89.1%) |
| Median (95% CI), (Months) [a] | NE (13.86, NE) | NE (8.80, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.8304 | |
| HR (95% CI) [b][d] | 0.936 (0.513, 1.710) | |
| HR P-Value [b][d] | 0.8302 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.5 (51.4, 75.0) | 73.1 (60.6, 82.2) |
| 12 months | 64.5 (51.4, 75.0) | 54.1 (27.8, 74.5) |
| 18 months | 54.2 (36.5, 68.9) | NE (NE, NE) |
| 24 months | 54.2 (36.5, 68.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 24 (12.2%) | 18 (9.8%) |
| Censored Patients, n (%) | 172 (87.8%) | 165 (90.2%) |
| Median (95% CI), (Months) [a] | 7.92 (2.07, 25.53) | 4.47 (2.79, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.7935 | |
| HR (95% CI) [b][d] | 0.909 (0.465, 1.775) | |
| HR P-Value [b][d] | 0.7790 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.4 (36.5, 67.7) | 44.7 (26.0, 61.7) |
| 12 months | 41.6 (24.5, 57.9) | NE (NE, NE) |
| 18 months | 35.6 (18.3, 53.4) | NE (NE, NE) |
| 24 months | 35.6 (18.3, 53.4) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 50 (25.5%) | 34 (18.6%) |
| Censored Patients, n (%) | 146 (74.5%) | 149 (81.4%) |
| Median (95% CI), (Months) [a] | 11.17 (6.93, NE) | NE (6.67, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.7176 | |
| HR (95% CI) [b][d] | 1.100 (0.700, 1.729) | |
| HR P-Value [b][d] | 0.6801 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.4 (50.9, 70.2) | 62.0 (50.0, 71.9) |
| 12 months | 48.1 (35.5, 59.6) | 56.9 (43.9, 68.0) |
| 18 months | 34.8 (19.5, 50.6) | 56.9 (43.9, 68.0) |
| 24 months | 34.8 (19.5, 50.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 31 (15.8%) | 10 (5.5%) |
| Censored Patients, n (%) | 165 (84.2%) | 173 (94.5%) |
| Median (95% CI), (Months) [a] | NE (15.24, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0182 | |
| HR (95% CI) [b][d] | 2.333 (1.133, 4.804) | |
| HR P-Value [b][d] | 0.0215 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.0 (62.3, 81.0) | 88.6 (77.9, 94.3) |
| 12 months | 64.3 (51.4, 74.5) | 81.4 (65.6, 90.4) |
| 18 months | 58.9 (42.9, 71.8) | NE (NE, NE) |
| 24 months | 58.9 (42.9, 71.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 36 (18.4%) | 17 (9.3%) |
| Censored Patients, n (%) | 160 (81.6%) | 166 (90.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1323 | |
| HR (95% CI) [b][d] | 1.570 (0.873, 2.821) | |
| HR P-Value [b][d] | 0.1318 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.5 (66.7, 82.2) | 85.6 (76.4, 91.4) |
| 12 months | 69.4 (59.2, 77.5) | 72.2 (52.5, 84.9) |
| 18 months | 65.3 (52.4, 75.5) | NE (NE, NE) |
| 24 months | 65.3 (52.4, 75.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 42 (21.4%) | 15 (8.2%) |
| Censored Patients, n (%) | 154 (78.6%) | 168 (91.8%) |
| Median (95% CI), (Months) [a] | 12.48 (6.97, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0358 | |
| HR (95% CI) [b][d] | 1.904 (1.039, 3.490) | |
| HR P-Value [b][d] | 0.0373 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.4 (51.3, 71.6) | 79.9 (68.0, 87.8) |
| 12 months | 53.1 (40.3, 64.3) | 76.5 (62.6, 85.8) |
| 18 months | 46.0 (31.6, 59.1) | NE (NE, NE) |
| 24 months | 46.0 (31.6, 59.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 42 (21.4%) | 24 (13.1%) |
| Censored Patients, n (%) | 154 (78.6%) | 159 (86.9%) |
| Median (95% CI), (Months) [a] | 8.44 (3.09, NE) | NE (7.06, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1114 | |
| HR (95% CI) [b][d] | 1.511 (0.908, 2.514) | |
| HR P-Value [b][d] | 0.1122 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.5 (43.7, 65.7) | 69.5 (56.6, 79.2) |
| 12 months | 45.1 (32.0, 57.3) | 55.7 (37.7, 70.5) |
| 18 months | 40.1 (25.5, 54.2) | NE (NE, NE) |
| 24 months | 40.1 (25.5, 54.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 35 (17.9%) | 18 (9.8%) |
| Censored Patients, n (%) | 161 (82.1%) | 165 (90.2%) |
| Median (95% CI), (Months) [a] | 12.58 (5.45, NE) | NE (7.03, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1517 | |
| HR (95% CI) [b][d] | 1.524 (0.854, 2.719) | |
| HR P-Value [b][d] | 0.1542 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.9 (48.8, 71.1) | 71.0 (55.3, 82.1) |
| 12 months | 52.1 (37.9, 64.5) | 58.6 (37.0, 75.0) |
| 18 months | 46.9 (30.9, 61.3) | NE (NE, NE) |
| 24 months | 46.9 (30.9, 61.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 49 (25.0%) | 53 (29.0%) |
| Censored Patients, n (%) | 147 (75.0%) | 130 (71.0%) |
| Median (95% CI), (Months) [a] | NE (10.38, NE) | 9.17 (4.83, 9.72) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0043 | |
| HR (95% CI) [b][d] | 0.559 (0.373, 0.837) | |
| HR P-Value [b][d] | 0.0048 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.2 (62.4, 78.3) | 57.3 (47.1, 66.3) |
| 12 months | 58.6 (47.9, 67.8) | 32.8 (17.4, 49.1) |
| 18 months | 56.6 (45.5, 66.2) | 32.8 (17.4, 49.1) |
| 24 months | 50.3 (34.7, 63.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 47 (24.0%) | 51 (27.9%) |
| Censored Patients, n (%) | 149 (76.0%) | 132 (72.1%) |
| Median (95% CI), (Months) [a] | 17.05 (13.83, NE) | 8.90 (5.68, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0049 | |
| HR (95% CI) [b][d] | 0.553 (0.363, 0.842) | |
| HR P-Value [b][d] | 0.0058 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.7 (66.2, 81.4) | 56.1 (45.6, 65.3) |
| 12 months | 67.7 (57.6, 75.9) | 47.8 (34.6, 59.8) |
| 18 months | 46.9 (32.5, 60.0) | 47.8 (34.6, 59.8) |
| 24 months | 46.9 (32.5, 60.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 40 (20.4%) | 43 (23.5%) |
| Censored Patients, n (%) | 156 (79.6%) | 140 (76.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 11.50 (7.00, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0280 | |
| HR (95% CI) [b][d] | 0.612 (0.392, 0.954) | |
| HR P-Value [b][d] | 0.0301 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.7 (67.2, 82.3) | 67.6 (57.5, 75.8) |
| 12 months | 66.0 (55.6, 74.5) | 39.6 (19.7, 59.0) |
| 18 months | 62.9 (51.0, 72.6) | 29.7 (10.1, 52.5) |
| 24 months | 62.9 (51.0, 72.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 24 (12.2%) | 21 (11.5%) |
| Censored Patients, n (%) | 172 (87.8%) | 162 (88.5%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1509 | |
| HR (95% CI) [b][d] | 0.637 (0.342, 1.185) | |
| HR P-Value [b][d] | 0.1545 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.8 (81.6, 93.3) | 81.2 (71.6, 87.8) |
| 12 months | 75.5 (63.9, 83.8) | 72.4 (56.2, 83.4) |
| 18 months | 72.1 (58.7, 81.8) | 72.4 (56.2, 83.4) |
| 24 months | 66.5 (49.4, 79.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 35 (17.9%) | 41 (22.4%) |
| Censored Patients, n (%) | 161 (82.1%) | 142 (77.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 10.35 (6.74, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0074 | |
| HR (95% CI) [b][d] | 0.533 (0.333, 0.852) | |
| HR P-Value [b][d] | 0.0086 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.0 (70.8, 85.1) | 64.7 (54.0, 73.5) |
| 12 months | 71.1 (60.7, 79.2) | 49.2 (31.9, 64.4) |
| 18 months | 64.6 (51.1, 75.3) | 49.2 (31.9, 64.4) |
| 24 months | 64.6 (51.1, 75.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 36 (18.4%) | 37 (20.2%) |
| Censored Patients, n (%) | 160 (81.6%) | 146 (79.8%) |
| Median (95% CI), (Months) [a] | 20.80 (16.85, NE) | NE (8.84, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0271 | |
| HR (95% CI) [b][d] | 0.578 (0.352, 0.947) | |
| HR P-Value [b][d] | 0.0296 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.8 (75.1, 88.3) | 70.6 (60.5, 78.5) |
| 12 months | 72.2 (61.5, 80.4) | 53.8 (37.4, 67.7) |
| 18 months | 61.5 (47.4, 72.9) | 53.8 (37.4, 67.7) |
| 24 months | 47.5 (26.9, 65.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 79 (40.3%) | 74 (40.4%) |
| Censored Patients, n (%) | 117 (59.7%) | 109 (59.6%) |
| Median (95% CI), (Months) [a] | 10.12 (5.72, 12.45) | 4.40 (2.89, 7.39) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0172 | |
| HR (95% CI) [b][d] | 0.673 (0.483, 0.938) | |
| HR P-Value [b][d] | 0.0196 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.6 (46.8, 63.5) | 46.7 (37.2, 55.7) |
| 12 months | 42.0 (32.4, 51.2) | 20.3 (9.0, 34.8) |
| 18 months | 34.0 (23.7, 44.5) | 20.3 (9.0, 34.8) |
| 24 months | 29.7 (18.3, 42.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 37 (18.9%) | 36 (19.7%) |
| Censored Patients, n (%) | 159 (81.1%) | 147 (80.3%) |
| Median (95% CI), (Months) [a] | NE (13.93, NE) | 11.50 (7.06, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0088 | |
| HR (95% CI) [b][d] | 0.531 (0.328, 0.861) | |
| HR P-Value [b][d] | 0.0102 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.7 (69.9, 85.3) | 71.6 (61.1, 79.8) |
| 12 months | 66.5 (55.3, 75.6) | 40.0 (20.7, 58.6) |
| 18 months | 59.4 (46.5, 70.1) | 40.0 (20.7, 58.6) |
| 24 months | 52.0 (33.8, 67.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 39 (19.9%) | 44 (24.0%) |
| Censored Patients, n (%) | 157 (80.1%) | 139 (76.0%) |
| Median (95% CI), (Months) [a] | NE (14.59, NE) | 11.93 (8.90, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0016 | |
| HR (95% CI) [b][d] | 0.485 (0.306, 0.768) | |
| HR P-Value [b][d] | 0.0020 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.1 (73.1, 86.9) | 65.2 (55.0, 73.7) |
| 12 months | 65.6 (54.6, 74.6) | 38.2 (14.8, 61.6) |
| 18 months | 57.5 (44.1, 68.8) | 38.2 (14.8, 61.6) |
| 24 months | 57.5 (44.1, 68.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 52 (26.5%) | 60 (32.8%) |
| Censored Patients, n (%) | 144 (73.5%) | 123 (67.2%) |
| Median (95% CI), (Months) [a] | 19.15 (10.18, NE) | 5.95 (4.17, 11.07) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0017 | |
| HR (95% CI) [b][d] | 0.543 (0.368, 0.802) | |
| HR P-Value [b][d] | 0.0021 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.4 (58.2, 75.0) | 48.8 (38.6, 58.2) |
| 12 months | 54.8 (43.7, 64.6) | 26.9 (12.1, 44.2) |
| 18 months | 53.0 (41.7, 63.0) | 26.9 (12.1, 44.2) |
| 24 months | 37.8 (19.3, 56.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 56 (28.6%) | 64 (35.0%) |
| Censored Patients, n (%) | 140 (71.4%) | 119 (65.0%) |
| Median (95% CI), (Months) [a] | 15.34 (10.45, NE) | 6.67 (4.63, 9.72) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0002 | |
| HR (95% CI) [b][d] | 0.492 (0.336, 0.721) | |
| HR P-Value [b][d] | 0.0003 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.7 (62.1, 77.8) | 52.1 (42.0, 61.2) |
| 12 months | 57.0 (46.3, 66.2) | 26.9 (13.5, 42.4) |
| 18 months | 48.5 (36.7, 59.4) | 21.6 (8.8, 38.0) |
| 24 months | 37.4 (21.6, 53.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 55 (28.1%) | 63 (34.4%) |
| Censored Patients, n (%) | 141 (71.9%) | 120 (65.6%) |
| Median (95% CI), (Months) [a] | 11.20 (8.54, NE) | 6.67 (4.40, 9.72) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0005 | |
| HR (95% CI) [b][d] | 0.519 (0.356, 0.757) | |
| HR P-Value [b][d] | 0.0006 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.3 (65.7, 81.1) | 52.3 (42.3, 61.3) |
| 12 months | 50.0 (39.2, 59.9) | 31.1 (16.9, 46.4) |
| 18 months | 45.2 (33.5, 56.1) | 31.1 (16.9, 46.4) |
| 24 months | 45.2 (33.5, 56.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 54 (27.6%) | 59 (32.2%) |
| Censored Patients, n (%) | 142 (72.4%) | 124 (67.8%) |
| Median (95% CI), (Months) [a] | 14.26 (11.99, NE) | 8.54 (4.27, 11.93) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0012 | |
| HR (95% CI) [b][d] | 0.535 (0.364, 0.787) | |
| HR P-Value [b][d] | 0.0015 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.3 (61.5, 77.4) | 52.8 (42.7, 61.9) |
| 12 months | 60.1 (49.6, 69.1) | 32.2 (18.0, 47.3) |
| 18 months | 43.3 (30.8, 55.2) | 32.2 (18.0, 47.3) |
| 24 months | 43.3 (30.8, 55.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 47 (24.0%) | 53 (29.0%) |
| Censored Patients, n (%) | 149 (76.0%) | 130 (71.0%) |
| Median (95% CI), (Months) [a] | 20.17 (13.93, 20.83) | 8.02 (5.68, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0013 | |
| HR (95% CI) [b][d] | 0.508 (0.333, 0.775) | |
| HR P-Value [b][d] | 0.0017 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.7 (67.1, 82.4) | 58.4 (48.1, 67.3) |
| 12 months | 62.7 (51.7, 71.8) | 42.5 (29.8, 54.6) |
| 18 months | 54.6 (41.6, 65.9) | 42.5 (29.8, 54.6) |
| 24 months | 27.7 (10.6, 48.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 47 (24.0%) | 41 (22.4%) |
| Censored Patients, n (%) | 149 (76.0%) | 142 (77.6%) |
| Median (95% CI), (Months) [a] | 16.76 (11.20, NE) | 9.72 (8.05, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0988 | |
| HR (95% CI) [b][d] | 0.689 (0.441, 1.076) | |
| HR P-Value [b][d] | 0.1015 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (62.1, 78.8) | 72.6 (63.3, 79.9) |
| 12 months | 56.8 (45.2, 66.9) | 39.7 (21.5, 57.4) |
| 18 months | 47.9 (34.4, 60.1) | 39.7 (21.5, 57.4) |
| 24 months | 41.9 (26.1, 56.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 20 (10.2%) | 14 (7.7%) |
| Censored Patients, n (%) | 176 (89.8%) | 169 (92.3%) |
| Median (95% CI), (Months) [a] | 13.31 (11.10, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.5567 | |
| HR (95% CI) [b][d] | 1.254 (0.603, 2.610) | |
| HR P-Value [b][d] | 0.5451 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.1 (59.2, 82.9) | 72.1 (56.1, 83.1) |
| 12 months | 66.5 (47.4, 80.0) | 72.1 (56.1, 83.1) |
| 18 months | 38.8 (14.6, 62.7) | NE (NE, NE) |
| 24 months | 38.8 (14.6, 62.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-10pts.sas (23JAN23:11:39:38, yingyuan.lin)

Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 21 (10.7%) | 10 (5.5%) |
| Censored Patients, n (%) | 175 (89.3%) | 173 (94.5%) |
| Median (95% CI), (Months) [a] | 17.97 (12.52, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.7847 | |
| HR (95% CI) [b][d] | 1.116 (0.509, 2.450) | |
| HR P-Value [b][d] | 0.7838 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.0 (71.4, 89.0) | 80.5 (64.3, 89.9) |
| 12 months | 69.6 (53.8, 80.9) | NE (NE, NE) |
| 18 months | 48.4 (22.7, 70.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-10pts.sas (23JAN23:11:39:38, yingyuan.lin)

Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 19 (9.7%) | 14 (7.7%) |
| Censored Patients, n (%) | 177 (90.3%) | 169 (92.3%) |
| Median (95% CI), (Months) [a] | 15.31 (9.72, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.4291 | |
| HR (95% CI) [b][d] | 0.748 (0.360, 1.556) | |
| HR P-Value [b][d] | 0.4372 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.5 (63.5, 86.7) | 72.9 (57.8, 83.3) |
| 12 months | 53.4 (31.9, 70.8) | 72.9 (57.8, 83.3) |
| 18 months | 44.5 (21.5, 65.2) | NE (NE, NE) |
| 24 months | 44.5 (21.5, 65.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-10pts.sas (23JAN23:11:39:38, yingyuan.lin)

Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 18 (9.2%) | 7 (3.8%) |
| Censored Patients, n (%) | 178 (90.8%) | 176 (96.2%) |
| Median (95% CI), (Months) [a] | 8.34 (2.83, 14.26) | NE (1.54, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.4657 | |
| HR (95% CI) [b][d] | 1.502 (0.536, 4.203) | |
| HR P-Value [b][d] | 0.4388 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.5 (40.3, 74.3) | 56.8 (29.0, 77.2) |
| 12 months | 32.7 (12.6, 54.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 22 (11.2%) | 7 (3.8%) |
| Censored Patients, n (%) | 174 (88.8%) | 176 (96.2%) |
| Median (95% CI), (Months) [a] | 11.33 (8.34, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1205 | |
| HR (95% CI) [b][d] | 2.005 (0.820, 4.902) | |
| HR P-Value [b][d] | 0.1274 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.0 (55.2, 82.1) | 85.4 (71.6, 92.8) |
| 12 months | 39.0 (19.4, 58.3) | 85.4 (71.6, 92.8) |
| 18 months | 29.3 (10.0, 51.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 19 (9.7%) | 8 (4.4%) |
| Censored Patients, n (%) | 177 (90.3%) | 175 (95.6%) |
| Median (95% CI), (Months) [a] | NE (16.39, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.4700 | |
| HR (95% CI) [b][d] | 1.364 (0.585, 3.179) | |
| HR P-Value [b][d] | 0.4721 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.3 (71.6, 89.2) | 89.4 (78.7, 94.9) |
| 12 months | 74.2 (60.1, 83.9) | 81.9 (59.5, 92.6) |
| 18 months | 68.0 (49.3, 81.0) | NE (NE, NE) |
| 24 months | 68.0 (49.3, 81.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 26 (13.3%) | 11 (6.0%) |
| Censored Patients, n (%) | 170 (86.7%) | 172 (94.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1294 | |
| HR (95% CI) [b][d] | 1.734 (0.849, 3.544) | |
| HR P-Value [b][d] | 0.1310 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.0 (73.4, 88.0) | 90.5 (82.3, 95.0) |
| 12 months | 72.9 (60.5, 82.0) | 79.0 (56.8, 90.7) |
| 18 months | 69.6 (55.8, 79.8) | NE (NE, NE) |
| 24 months | 69.6 (55.8, 79.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 15 (7.7%) | 11 (6.0%) |
| Censored Patients, n (%) | 181 (92.3%) | 172 (94.0%) |
| Median (95% CI), (Months) [a] | NE (14.95, NE) | NE (8.97, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.8475 | |
| HR (95% CI) [b][d] | 0.925 (0.412, 2.077) | |
| HR P-Value [b][d] | 0.8501 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.2 (67.7, 88.3) | 83.9 (72.0, 91.1) |
| 12 months | 80.2 (67.7, 88.3) | 69.9 (36.1, 88.2) |
| 18 months | 67.3 (45.3, 82.0) | NE (NE, NE) |
| 24 months | 67.3 (45.3, 82.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 17 (8.7%) | 13 (7.1%) |
| Censored Patients, n (%) | 179 (91.3%) | 170 (92.9%) |
| Median (95% CI), (Months) [a] | 12.06 (6.97, NE) | NE (2.79, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.9462 | |
| HR (95% CI) [b][d] | 0.970 (0.435, 2.163) | |
| HR P-Value [b][d] | 0.9414 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.4 (51.5, 80.5) | 62.8 (44.0, 76.9) |
| 12 months | 53.3 (32.9, 70.0) | NE (NE, NE) |
| 18 months | 45.7 (24.0, 65.0) | NE (NE, NE) |
| 24 months | 45.7 (24.0, 65.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 35 (17.9%) | 18 (9.8%) |
| Censored Patients, n (%) | 161 (82.1%) | 165 (90.2%) |
| Median (95% CI), (Months) [a] | 17.05 (11.17, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.2063 | |
| HR (95% CI) [b][d] | 1.478 (0.814, 2.684) | |
| HR P-Value [b][d] | 0.1996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.4 (62.9, 81.3) | 77.1 (65.3, 85.3) |
| 12 months | 60.3 (46.0, 71.9) | 77.1 (65.3, 85.3) |
| 18 months | 43.6 (24.3, 61.5) | 77.1 (65.3, 85.3) |
| 24 months | 43.6 (24.3, 61.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 20 (10.2%) | 2 (1.1%) |
| Censored Patients, n (%) | 176 (89.8%) | 181 (98.9%) |
| Median (95% CI), (Months) [a] | NE (15.24, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0021 | |
| HR (95% CI) [b][d] | 7.169 (1.656, 31.034) | |
| HR P-Value [b][d] | 0.0084 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.0 (71.6, 88.9) | 97.8 (91.3, 99.4) |
| 12 months | 74.4 (60.7, 83.9) | 97.8 (91.3, 99.4) |
| 18 months | 68.2 (49.7, 81.1) | NE (NE, NE) |
| 24 months | 68.2 (49.7, 81.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 19 (9.7%) | 5 (2.7%) |
| Censored Patients, n (%) | 177 (90.3%) | 178 (97.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0342 | |
| HR (95% CI) [b][d] | 2.844 (1.038, 7.789) | |
| HR P-Value [b][d] | 0.0420 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (79.8, 92.4) | 95.3 (88.9, 98.0) |
| 12 months | 82.2 (72.2, 88.9) | 95.3 (88.9, 98.0) |
| 18 months | 77.4 (62.5, 86.9) | NE (NE, NE) |
| 24 months | 77.4 (62.5, 86.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 25 (12.8%) | 9 (4.9%) |
| Censored Patients, n (%) | 171 (87.2%) | 174 (95.1%) |
| Median (95% CI), (Months) [a] | NE (12.48, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1040 | |
| HR (95% CI) [b][d] | 1.900 (0.869, 4.154) | |
| HR P-Value [b][d] | 0.1076 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.8 (68.1, 86.2) | 88.6 (78.2, 94.3) |
| 12 months | 67.1 (52.0, 78.3) | 84.8 (70.7, 92.5) |
| 18 months | 58.0 (40.1, 72.3) | NE (NE, NE) |
| 24 months | 58.0 (40.1, 72.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 25 (12.8%) | 15 (8.2%) |
| Censored Patients, n (%) | 171 (87.2%) | 168 (91.8%) |
| Median (95% CI), (Months) [a] | NE (13.44, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.2100 | |
| HR (95% CI) [b][d] | 1.522 (0.791, 2.929) | |
| HR P-Value [b][d] | 0.2083 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.2 (61.9, 81.6) | 79.6 (67.8, 87.5) |
| 12 months | 65.9 (51.1, 77.2) | 74.3 (57.8, 85.1) |
| 18 months | 58.6 (38.9, 73.9) | NE (NE, NE) |
| 24 months | 58.6 (38.9, 73.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 5.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 21 (10.7%) | 13 (7.1%) |
| Censored Patients, n (%) | 175 (89.3%) | 170 (92.9%) |
| Median (95% CI), (Months) [a] | NE (12.58, NE) | NE (8.48, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.5445 | |
| HR (95% CI) [b][d] | 1.246 (0.616, 2.521) | |
| HR P-Value [b][d] | 0.5412 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.9 (65.5, 85.0) | 78.9 (63.0, 88.5) |
| 12 months | 70.4 (56.1, 80.8) | 65.1 (40.9, 81.4) |
| 18 months | 63.4 (43.8, 77.7) | NE (NE, NE) |
| 24 months | 63.4 (43.8, 77.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 25 (12.8%) | 31 (16.9%) |
| Censored Patients, n (%) | 171 (87.2%) | 152 (83.1%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (9.69, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0053 | |
| HR (95% CI) [b][d] | 0.464 (0.267, 0.806) | |
| HR P-Value [b][d] | 0.0064 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.4 (74.9, 89.3) | 72.6 (62.5, 80.4) |
| 12 months | 74.2 (62.6, 82.7) | 59.9 (40.2, 74.9) |
| 18 months | 74.2 (62.6, 82.7) | 59.9 (40.2, 74.9) |
| 24 months | 66.0 (45.4, 80.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 17 (8.7%) | 27 (14.8%) |
| Censored Patients, n (%) | 179 (91.3%) | 156 (85.2%) |
| Median (95% CI), (Months) [a] | NE (17.05, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0011 | |
| HR (95% CI) [b][d] | 0.334 (0.168, 0.665) | |
| HR P-Value [b][d] | 0.0018 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.2 (84.4, 95.1) | 72.4 (61.1, 80.9) |
| 12 months | 91.2 (84.4, 95.1) | 69.2 (56.5, 78.9) |
| 18 months | 68.2 (47.9, 82.0) | 69.2 (56.5, 78.9) |
| 24 months | 68.2 (47.9, 82.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 15 (7.7%) | 19 (10.4%) |
| Censored Patients, n (%) | 181 (92.3%) | 164 (89.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0692 | |
| HR (95% CI) [b][d] | 0.531 (0.265, 1.063) | |
| HR P-Value [b][d] | 0.0740 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.8 (80.8, 93.6) | 83.1 (74.0, 89.3) |
| 12 months | 83.0 (72.2, 89.9) | 74.9 (58.7, 85.5) |
| 18 months | 83.0 (72.2, 89.9) | 74.9 (58.7, 85.5) |
| 24 months | 83.0 (72.2, 89.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 11 (5.6%) | 5 (2.7%) |
| Censored Patients, n (%) | 185 (94.4%) | 178 (97.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.8428 | |
| HR (95% CI) [b][d] | 1.121 (0.361, 3.483) | |
| HR P-Value [b][d] | 0.8428 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.8 (88.4, 97.7) | 95.2 (88.7, 98.0) |
| 12 months | 88.6 (77.7, 94.3) | 95.2 (88.7, 98.0) |
| 18 months | 84.5 (69.9, 92.4) | 95.2 (88.7, 98.0) |
| 24 months | 78.0 (57.1, 89.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 18 (9.2%) | 18 (9.8%) |
| Censored Patients, n (%) | 178 (90.8%) | 165 (90.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1034 | |
| HR (95% CI) [b][d] | 0.571 (0.288, 1.133) | |
| HR P-Value [b][d] | 0.1092 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.3 (80.7, 93.0) | 82.4 (72.4, 89.1) |
| 12 months | 84.8 (75.5, 90.8) | 75.5 (56.7, 87.0) |
| 18 months | 77.0 (61.5, 86.9) | 75.5 (56.7, 87.0) |
| 24 months | 77.0 (61.5, 86.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 20 (10.2%) | 20 (10.9%) |
| Censored Patients, n (%) | 176 (89.8%) | 163 (89.1%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0416 | |
| HR (95% CI) [b][d] | 0.496 (0.250, 0.985) | |
| HR P-Value [b][d] | 0.0453 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.1 (85.8, 95.7) | 82.4 (72.9, 88.8) |
| 12 months | 85.7 (76.0, 91.6) | 75.4 (61.1, 85.0) |
| 18 months | 73.0 (56.7, 84.0) | 75.4 (61.1, 85.0) |
| 24 months | 56.3 (30.9, 75.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 44 (22.4%) | 49 (26.8%) |
| Censored Patients, n (%) | 152 (77.6%) | 134 (73.2%) |
| Median (95% CI), (Months) [a] | 20.17 (12.45, NE) | 10.28 (4.44, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0058 | |
| HR (95% CI) [b][d] | 0.552 (0.359, 0.847) | |
| HR P-Value [b][d] | 0.0066 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.0 (64.9, 81.0) | 57.0 (46.4, 66.3) |
| 12 months | 62.1 (50.5, 71.7) | 43.1 (26.2, 58.9) |
| 18 months | 50.3 (36.0, 63.0) | 43.1 (26.2, 58.9) |
| 24 months | 44.0 (27.2, 59.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 19 (9.7%) | 8 (4.4%) |
| Censored Patients, n (%) | 177 (90.3%) | 175 (95.6%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.9052 | |
| HR (95% CI) [b][d] | 1.052 (0.441, 2.513) | |
| HR P-Value [b][d] | 0.9083 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.1 (83.2, 95.3) | 91.5 (83.5, 95.7) |
| 12 months | 80.2 (68.3, 88.0) | 91.5 (83.5, 95.7) |
| 18 months | 71.6 (56.7, 82.1) | 91.5 (83.5, 95.7) |
| 24 months | 62.6 (39.9, 78.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 12 (6.1%) | 20 (10.9%) |
| Censored Patients, n (%) | 184 (93.9%) | 163 (89.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (11.07, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0024 | |
| HR (95% CI) [b][d] | 0.309 (0.140, 0.685) | |
| HR P-Value [b][d] | 0.0038 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.4 (88.4, 97.4) | 84.0 (75.0, 89.9) |
| 12 months | 87.1 (76.5, 93.1) | 70.5 (45.2, 85.8) |
| 18 months | 83.6 (70.3, 91.3) | 70.5 (45.2, 85.8) |
| 24 months | 83.6 (70.3, 91.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 32 (16.3%) | 33 (18.0%) |
| Censored Patients, n (%) | 164 (83.7%) | 150 (82.0%) |
| Median (95% CI), (Months) [a] | 20.17 (19.15, NE) | NE (8.97, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0369 | |
| HR (95% CI) [b][d] | 0.584 (0.349, 0.977) | |
| HR P-Value [b][d] | 0.0407 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.2 (71.5, 86.5) | 66.6 (55.2, 75.8) |
| 12 months | 68.6 (56.5, 78.0) | 53.4 (33.5, 69.8) |
| 18 months | 66.3 (53.7, 76.2) | 53.4 (33.5, 69.8) |
| 24 months | 47.4 (23.3, 68.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 25 (12.8%) | 31 (16.9%) |
| Censored Patients, n (%) | 171 (87.2%) | 152 (83.1%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (9.92, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0050 | |
| HR (95% CI) [b][d] | 0.454 (0.259, 0.798) | |
| HR P-Value [b][d] | 0.0061 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.7 (77.6, 91.0) | 73.4 (63.0, 81.3) |
| 12 months | 78.7 (68.0, 86.1) | 63.3 (45.0, 76.9) |
| 18 months | 72.0 (57.8, 82.1) | 50.6 (23.8, 72.4) |
| 24 months | 55.5 (31.1, 74.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 34 (17.3%) | 32 (17.5%) |
| Censored Patients, n (%) | 162 (82.7%) | 151 (82.5%) |
| Median (95% CI), (Months) [a] | NE (13.90, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0746 | |
| HR (95% CI) [b][d] | 0.633 (0.382, 1.050) | |
| HR P-Value [b][d] | 0.0765 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.8 (78.2, 90.9) | 71.3 (60.8, 79.5) |
| 12 months | 63.5 (51.1, 73.5) | 65.1 (51.8, 75.6) |
| 18 months | 57.4 (43.3, 69.1) | 65.1 (51.8, 75.6) |
| 24 months | 57.4 (43.3, 69.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-10pts.sas (23JAN23:11:39:43, yingyuan.lin)

Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 29 (14.8%) | 37 (20.2%) |
| Censored Patients, n (%) | 167 (85.2%) | 146 (79.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0081 | |
| HR (95% CI) [b][d] | 0.515 (0.312, 0.849) | |
| HR P-Value [b][d] | 0.0092 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (72.9, 87.2) | 65.3 (55.0, 73.8) |
| 12 months | 77.4 (67.5, 84.7) | 65.3 (55.0, 73.8) |
| 18 months | 66.4 (52.3, 77.2) | 65.3 (55.0, 73.8) |
| 24 months | 66.4 (52.3, 77.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-10pts.sas (23JAN23:11:39:43, yingyuan.lin)

Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 31 (15.8%) | 30 (16.4%) |
| Censored Patients, n (%) | 165 (84.2%) | 153 (83.6%) |
| Median (95% CI), (Months) [a] | 20.80 (20.17, NE) | NE (NE, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.0653 | |
| HR (95% CI) [b][d] | 0.602 (0.348, 1.041) | |
| HR P-Value [b][d] | 0.0694 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.1 (77.5, 90.3) | 71.5 (60.9, 79.8) |
| 12 months | 74.7 (63.6, 82.9) | 67.8 (54.8, 77.7) |
| 18 months | 65.1 (50.2, 76.6) | 67.8 (54.8, 77.7) |
| 24 months | 38.6 (15.4, 61.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-10pts.sas (23JAN23:11:39:43, yingyuan.lin)

Table 5.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Patients with event, n (%) | 26 (13.3%) | 22 (12.0%) |
| Censored Patients, n (%) | 170 (86.7%) | 161 (88.0%) |
| Median (95% CI), (Months) [a] | NE (16.76, NE) | NE (11.33, NE) |
| Stratified log-rank test 2-sided p-value [b][c] | 0.1988 | |
| HR (95% CI) [b][d] | 0.670 (0.363, 1.238) | |
| HR P-Value [b][d] | 0.2012 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.1 (76.6, 90.6) | 83.6 (75.3, 89.2) |
| 12 months | 73.7 (61.5, 82.5) | 65.8 (39.4, 82.9) |
| 18 months | 62.0 (45.3, 75.0) | 65.8 (39.4, 82.9) |
| 24 months | 54.3 (33.5, 71.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-10pts.sas (23JAN23:11:39:43, yingyuan.lin)

Table 6.1.1. Observed Duration of Response
(Full Analysis Set Exclude Patients Assigned to Gemcitabine - Patients with Confirmed CR or PR)

| | Cemiplimab (N=31) | Chemotherapy (N=13) |
|---|---|---|
| Observed Duration of Response (CR or PR) (months) [a] | | |
| n | 31 | 13 |
| Mean (SD) | 11.66 (6.619) | 6.89 (2.953) |
| Median | 9.69 | 7.16 |
| Q1 : Q3 | 7.13 : 15.38 | 4.57 : 9.66 |
| Min : Max | 3.9 : 32.7 | 2.7 : 11.8 |
| Observed Duration of Response (CR or PR), n (%) [a] | | |
| <6 months | 5 (16.1%) | 5 (38.5%) |
| >=6 months | 26 (83.9%) | 8 (61.5%) |
| >=12 months | 11 (35.5%) | 0 |
| >=18 months | 3 (9.7%) | 0 |
| >=24 months | 2 (6.5%) | 0 |
| >=30 months | 1 (3.2%) | 0 |
| >=36 months | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
[a] Based on patients with confirmed CR or PR.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Global Health Status/Qol | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 172 (94.0%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 45 (91.8%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |
| | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Global Health Status/Qol | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |
| Physical Functioning | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 173 (94.5%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 46 (93.9%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Physical Functioning | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |
| | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Role Functioning | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 173 (94.5%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 46 (93.9%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |
| | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Role Functioning | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |
| Emotional Functioning | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 172 (94.0%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 45 (91.8%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Emotional Functioning | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |
| | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Cognitive Functioning | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 172 (94.0%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 45 (91.8%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |
| | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Cognitive Functioning | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |
| Social Functioning | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 172 (94.0%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 45 (91.8%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Social Functioning | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |
| | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Fatigue | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 173 (94.5%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 46 (93.9%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |
| | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Fatigue | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |
| Nausea And Vomiting | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 173 (94.5%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 46 (93.9%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Nausea And Vomiting | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |
| | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Pain | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 173 (94.5%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 69 (93.2%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 46 (93.9%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |
| | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Pain | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |
| Dyspnoea | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 173 (94.5%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 142 (95.9%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 68 (91.9%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 46 (93.9%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 22 (95.7%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Dyspnoea | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |
| | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Insomnia | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 173 (94.5%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 69 (93.2%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 46 (93.9%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |
| | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Insomnia | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |
| Appetite Loss | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 173 (94.5%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 112 (94.1%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 69 (93.2%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 46 (93.9%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Appetite Loss | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |
| | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Constipation | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 173 (94.5%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 46 (93.9%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |
| | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Constipation | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |
| Diarrhoea | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 172 (94.0%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 45 (91.8%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 70 (98.6%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Diarrhoea | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |
| | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 89 (86.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Financial Difficulties | BASELINE | Expected, n | 196 | 183 |
| | | Evaluable score, n (%) | 192 (98.0%) | 172 (94.0%) |
| | CYCLE 2 DAY 1 | Expected, n | 148 | 119 |
| | | Evaluable score, n (%) | 143 (96.6%) | 113 (95.0%) |
| | CYCLE 3 DAY 1 | Expected, n | 106 | 74 |
| | | Evaluable score, n (%) | 103 (97.2%) | 70 (94.6%) |
| | CYCLE 4 DAY 1 | Expected, n | 85 | 49 |
| | | Evaluable score, n (%) | 78 (91.8%) | 45 (91.8%) |
| | CYCLE 5 DAY 1 | Expected, n | 71 | 32 |
| | | Evaluable score, n (%) | 69 (97.2%) | 29 (90.6%) |
| | CYCLE 6 DAY 1 | Expected, n | 62 | 23 |
| | | Evaluable score, n (%) | 60 (96.8%) | 23 (100%) |
| | CYCLE 7 DAY 1 | Expected, n | 47 | 13 |
| | | Evaluable score, n (%) | 46 (97.9%) | 12 (92.3%) |
| | CYCLE 8 DAY 1 | Expected, n | 44 | 9 |
| | | Evaluable score, n (%) | 43 (97.7%) | 8 (88.9%) |
| | CYCLE 9 DAY 1 | Expected, n | 41 | 6 |
| | | Evaluable score, n (%) | 41 (100%) | 6 (100%) |
| | CYCLE 10 DAY 1 | Expected, n | 38 | 3 |
| | | Evaluable score, n (%) | 37 (97.4%) | 3 (100%) |
| | CYCLE 11 DAY 1 | Expected, n | 28 | 1 |
| | | Evaluable score, n (%) | 27 (96.4%) | 1 (100%) |
| | CYCLE 12 DAY 1 | Expected, n | 23 | 1 |
| | | Evaluable score, n (%) | 21 (91.3%) | 1 (100%) |

Data cut-off as of Jan 4th, 2021.

Table 8.1.1. PRO Completion Rate on the EORTC QLQ-C30
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| Category | | | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|---|---|
| Financial Difficulties | CYCLE 13 DAY 1 | Expected, n | 19 | 1 |
| | | Evaluable score, n (%) | 19 (100%) | 1 (100%) |
| | CYCLE 14 DAY 1 | Expected, n | 16 | 1 |
| | | Evaluable score, n (%) | 15 (93.8%) | 1 (100%) |
| | CYCLE 15 DAY 1 | Expected, n | 10 | 0 |
| | | Evaluable score, n (%) | 9 (90.0%) | 0 |
| | CYCLE 16 DAY 1 | Expected, n | 7 | 0 |
| | | Evaluable score, n (%) | 7 (100%) | 0 |
| | FOLLOW UP VISIT 1 | Expected, n | 115 | 103 |
| | | Evaluable score, n (%) | 87 (75.7%) | 90 (87.4%) |
| | FOLLOW UP VISIT 2 | Expected, n | 49 | 48 |
| | | Evaluable score, n (%) | 36 (73.5%) | 38 (79.2%) |

Data cut-off as of Jan 4th, 2021.

Table 9.4.1. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 GHS/QoL
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 59.9 (21.58) | 57.7 (18.95) |
| Baseline Mean (SD) | 58.9 (23.58) | 64.7 (19.22) |
| Median | 61 | 58 |
| Min : Max | 0 : 100 | 8 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | 1.0 (20.35) | -7.0 (18.06) |
| Median | 0 | -7 |
| Min : Max | -67 : 83 | -58 : 43 |
| LS Mean (SE) (95% CI) | 1.14 (1.87) (-2.55, 4.84) | -5.78 (2.30) (-10.31, -1.25) |
| LS Mean Difference vs. Chemotherapy (SE) | 6.92 (2.41) | |
| 95% CI | (2.15, 11.69) | |
| Two-sided P-value * | 0.0048 | |
| Hedges'g (95% CI) | 0.36 (0.11, 0.60) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.1. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 GHS/QoL
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 57.7 (24.02) | 59.5 (20.83) |
| Baseline Mean (SD) | 58.9 (23.58) | 64.7 (19.22) |
| Median | 58 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | -1.2 (21.14) | -5.8 (19.48) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | -75 : 42 |
| LS Mean (SE) (95% CI) | -3.27 (2.00) (-7.20, 0.67) | -5.43 (2.07) (-9.50, -1.36) |
| LS Mean Difference vs. Chemotherapy (SE) | 2.16 (2.37) | |
| 95% CI | (-2.50, 6.82) | |
| Two-sided P-value * | 0.3613 | |
| Hedges'g (95% CI) | 0.11 (-0.13, 0.36) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.1. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 GHS/QoL
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 63.6 (22.88) | 60.0 (21.58) |
| Baseline Mean (SD) | 58.9 (23.58) | 64.7 (19.22) |
| Median | 67 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 4.1 (22.94) | -6.3 (19.49) |
| Median | 0 | 0 |
| Min : Max | -50 : 100 | -75 : 33 |
| LS Mean (SE) (95% CI) | 1.01 (2.19) (-3.31, 5.33) | -7.12 (2.43) (-11.90, -2.34) |
| LS Mean Difference vs. Chemotherapy (SE) | 8.13 (2.81) | |
| 95% CI | (2.58, 13.67) | |
| Two-sided P-value * | 0.0043 | |
| Hedges'g (95% CI) | 0.44 (0.14, 0.75) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.1. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 GHS/QoL
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 67.8 (19.67) | 61.5 (23.79) |
| Baseline Mean (SD) | 58.9 (23.58) | 64.7 (19.22) |
| Median | 67 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 4.3 (20.33) | -6.7 (25.78) |
| Median | 0 | 0 |
| Min : Max | -50 : 67 | -83 : 42 |
| LS Mean (SE) (95% CI) | 3.24 (2.41) (-1.51, 7.99) | -6.20 (2.99) (-12.09, -0.31) |
| LS Mean Difference vs. Chemotherapy (SE) | 9.44 (3.43) | |
| 95% CI | (2.66, 16.22) | |
| Two-sided P-value * | 0.0067 | |
| Hedges'g (95% CI) | 0.50 (0.13, 0.87) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.1. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 GHS/QoL
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 66.4 (20.56) | 61.4 (20.82) |
| Baseline Mean (SD) | 58.9 (23.58) | 64.7 (19.22) |
| Median | 67 | 67 |
| Min : Max | 25 : 100 | 17 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 1.7 (20.93) | -4.4 (28.09) |
| Median | 0 | 0 |
| Min : Max | -50 : 67 | -67 : 58 |
| LS Mean (SE) (95% CI) | 1.45 (2.61) (-3.71, 6.60) | -6.09 (3.64) (-13.29, 1.11) |
| LS Mean Difference vs. Chemotherapy (SE) | 7.54 (4.11) | |
| 95% CI | (-0.61, 15.69) | |
| Two-sided P-value * | 0.0695 | |
| Hedges'g (95% CI) | 0.39 (-0.04, 0.82) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.1. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 GHS/QoL
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 65.3 (23.68) | 64.5 (19.17) |
| Baseline Mean (SD) | 58.9 (23.58) | 64.7 (19.22) |
| Median | 67 | 67 |
| Min : Max | 0 : 100 | 33 : 100 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 1.0 (18.89) | -1.8 (21.17) |
| Median | 0 | 0 |
| Min : Max | -33 : 67 | -42 : 50 |
| LS Mean (SE) (95% CI) | -0.45 (2.64) (-5.68, 4.77) | -5.66 (3.88) (-13.34, 2.03) |
| LS Mean Difference vs. Chemotherapy (SE) | 5.20 (4.34) | |
| 95% CI | (-3.41, 13.82) | |
| Two-sided P-value * | 0.2335 | |
| Hedges'g (95% CI) | 0.29 (-0.19, 0.77) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.1. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 GHS/QoL
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 71.1 (17.71) | 66.0 (20.55) |
| Baseline Mean (SD) | 58.9 (23.58) | 64.7 (19.22) |
| Median | 67 | 67 |
| Min : Max | 33 : 100 | 33 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 6.2 (22.89) | 4.9 (22.60) |
| Median | 0 | 8 |
| Min : Max | -33 : 67 | -42 : 33 |
| LS Mean (SE) (95% CI) | 4.88 (2.74) (-0.55, 10.31) | -4.16 (4.67) (-13.46, 5.13) |
| LS Mean Difference vs. Chemotherapy (SE) | 9.05 (5.13) | |
| 95% CI | (-1.18, 19.27) | |
| Two-sided P-value * | 0.0821 | |
| Hedges'g (95% CI) | 0.55 (-0.09, 1.20) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.2. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Physical Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 71.7 (22.78) | 67.5 (21.76) |
| Baseline Mean (SD) | 73.0 (21.55) | 75.2 (21.51) |
| Median | 76 | 71 |
| Min : Max | 0 : 100 | 7 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | -1.3 (16.96) | -7.6 (13.80) |
| Median | 0 | -7 |
| Min : Max | -67 : 56 | -47 : 40 |
| LS Mean (SE) (95% CI) | 0.01 (1.74) (-3.41, 3.44) | -8.74 (2.09) (-12.86, -4.63) |
| LS Mean Difference vs. Chemotherapy (SE) | 8.76 (2.24) | |
| 95% CI | (4.34, 13.18) | |
| Two-sided P-value * | 0.0001 | |
| Hedges'g (95% CI) | 0.49 (0.24, 0.74) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.2. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Physical Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 70.7 (24.54) | 68.4 (22.05) |
| Baseline Mean (SD) | 73.0 (21.55) | 75.2 (21.51) |
| Median | 73 | 73 |
| Min : Max | 0 : 100 | 7 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | -2.3 (17.68) | -7.1 (14.52) |
| Median | 0 | -7 |
| Min : Max | -67 : 53 | -47 : 40 |
| LS Mean (SE) (95% CI) | -2.72 (1.75) (-6.16, 0.73) | -7.05 (1.80) (-10.59, -3.52) |
| LS Mean Difference vs. Chemotherapy (SE) | 4.34 (2.02) | |
| 95% CI | (0.36, 8.31) | |
| Two-sided P-value * | 0.0326 | |
| Hedges'g (95% CI) | 0.27 (0.02, 0.52) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.2. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Physical Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 76.1 (22.48) | 71.2 (20.81) |
| Baseline Mean (SD) | 73.0 (21.55) | 75.2 (21.51) |
| Median | 80 | 75 |
| Min : Max | 7 : 100 | 20 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 1.9 (18.13) | -6.4 (15.18) |
| Median | 0 | -7 |
| Min : Max | -47 : 60 | -53 : 40 |
| LS Mean (SE) (95% CI) | 0.05 (1.89) (-3.68, 3.77) | -6.56 (2.07) (-10.64, -2.47) |
| LS Mean Difference vs. Chemotherapy (SE) | 6.60 (2.35) | |
| 95% CI | (1.96, 11.24) | |
| Two-sided P-value * | 0.0055 | |
| Hedges'g (95% CI) | 0.43 (0.12, 0.74) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.2. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Physical Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 78.1 (20.66) | 73.9 (19.57) |
| Baseline Mean (SD) | 73.0 (21.55) | 75.2 (21.51) |
| Median | 80 | 77 |
| Min : Max | 0 : 100 | 20 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 2.6 (17.57) | -6.8 (13.81) |
| Median | 0 | -7 |
| Min : Max | -47 : 67 | -40 : 27 |
| LS Mean (SE) (95% CI) | 2.19 (2.00) (-1.76, 6.15) | -7.11 (2.40) (-11.84, -2.38) |
| LS Mean Difference vs. Chemotherapy (SE) | 9.30 (2.71) | |
| 95% CI | (3.94, 14.67) | |
| Two-sided P-value * | 0.0008 | |
| Hedges'g (95% CI) | 0.62 (0.25, 0.99) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.2. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Physical Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 76.1 (19.97) | 69.8 (20.47) |
| Baseline Mean (SD) | 73.0 (21.55) | 75.2 (21.51) |
| Median | 80 | 73 |
| Min : Max | 27 : 100 | 33 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | -0.6 (17.02) | -7.8 (13.91) |
| Median | 0 | -7 |
| Min : Max | -53 : 40 | -40 : 33 |
| LS Mean (SE) (95% CI) | -1.48 (2.09) (-5.61, 2.66) | -8.92 (2.74) (-14.34, -3.50) |
| LS Mean Difference vs. Chemotherapy (SE) | 7.45 (3.09) | |
| 95% CI | (1.33, 13.56) | |
| Two-sided P-value * | 0.0174 | |
| Hedges'g (95% CI) | 0.52 (0.08, 0.95) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.2. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Physical Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 78.4 (20.39) | 71.3 (22.24) |
| Baseline Mean (SD) | 73.0 (21.55) | 75.2 (21.51) |
| Median | 80 | 80 |
| Min : Max | 20 : 100 | 27 : 100 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 1.2 (17.87) | -8.4 (19.30) |
| Median | 0 | 0 |
| Min : Max | -33 : 47 | -47 : 13 |
| LS Mean (SE) (95% CI) | 0.45 (2.37) (-4.23, 5.14) | -9.15 (3.42) (-15.92, -2.37) |
| LS Mean Difference vs. Chemotherapy (SE) | 9.60 (3.85) | |
| 95% CI | (1.96, 17.24) | |
| Two-sided P-value * | 0.0144 | |
| Hedges'g (95% CI) | 0.60 (0.11, 1.08) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.2. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Physical Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 81.3 (16.37) | 67.2 (28.35) |
| Baseline Mean (SD) | 73.0 (21.55) | 75.2 (21.51) |
| Median | 80 | 73 |
| Min : Max | 40 : 100 | 20 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 3.4 (17.74) | -7.2 (21.55) |
| Median | 0 | -3 |
| Min : Max | -47 : 60 | -60 : 13 |
| LS Mean (SE) (95% CI) | 1.59 (2.63) (-3.64, 6.82) | -13.67 (4.43) (-22.49, -4.86) |
| LS Mean Difference vs. Chemotherapy (SE) | 15.26 (4.92) | |
| 95% CI | (5.46, 25.06) | |
| Two-sided P-value * | 0.0027 | |
| Hedges'g (95% CI) | 0.97 (0.32, 1.63) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.3. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Role Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 67.8 (28.52) | 61.9 (28.08) |
| Baseline Mean (SD) | 66.7 (30.62) | 71.6 (30.43) |
| Median | 72 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | 1.1 (26.46) | -9.7 (22.73) |
| Median | 0 | -7 |
| Min : Max | -83 : 97 | -67 : 83 |
| LS Mean (SE) (95% CI) | 2.41 (2.36) (-2.24, 7.07) | -10.58 (2.82) (-16.15, -5.02) |
| LS Mean Difference vs. Chemotherapy (SE) | 13.00 (2.96) | |
| 95% CI | (7.14, 18.86) | |
| Two-sided P-value * | <0.0001 | |
| Hedges'g (95% CI) | 0.54 (0.29, 0.79) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.3. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Role Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 66.3 (31.60) | 63.4 (30.85) |
| Baseline Mean (SD) | 66.7 (30.62) | 71.6 (30.43) |
| Median | 67 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | -0.4 (27.96) | -8.6 (24.91) |
| Median | 0 | 0 |
| Min : Max | -83 : 83 | -100 : 50 |
| LS Mean (SE) (95% CI) | -2.38 (2.59) (-7.47, 2.71) | -8.92 (2.68) (-14.20, -3.64) |
| LS Mean Difference vs. Chemotherapy (SE) | 6.54 (3.10) | |
| 95% CI | (0.43, 12.65) | |
| Two-sided P-value * | 0.0359 | |
| Hedges'g (95% CI) | 0.26 (0.02, 0.51) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.3. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Role Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 72.1 (28.93) | 66.0 (29.06) |
| Baseline Mean (SD) | 66.7 (30.62) | 71.6 (30.43) |
| Median | 75 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 3.1 (29.36) | -7.5 (27.72) |
| Median | 0 | 0 |
| Min : Max | -83 : 100 | -100 : 100 |
| LS Mean (SE) (95% CI) | 0.48 (2.83) (-5.09, 6.04) | -8.58 (3.14) (-14.76, -2.39) |
| LS Mean Difference vs. Chemotherapy (SE) | 9.05 (3.64) | |
| 95% CI | (1.87, 16.24) | |
| Two-sided P-value * | 0.0138 | |
| Hedges'g (95% CI) | 0.38 (0.07, 0.69) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.3. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Role Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 75.9 (24.01) | 68.1 (29.98) |
| Baseline Mean (SD) | 66.7 (30.62) | 71.6 (30.43) |
| Median | 67 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 4.1 (28.20) | -9.1 (29.55) |
| Median | 0 | 0 |
| Min : Max | -67 : 100 | -67 : 100 |
| LS Mean (SE) (95% CI) | 3.65 (2.99) (-2.25, 9.55) | -8.56 (3.67) (-15.79, -1.33) |
| LS Mean Difference vs. Chemotherapy (SE) | 12.21 (4.19) | |
| 95% CI | (3.93, 20.48) | |
| Two-sided P-value * | 0.0041 | |
| Hedges'g (95% CI) | 0.53 (0.16, 0.90) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.3. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Role Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 74.3 (26.87) | 66.1 (28.19) |
| Baseline Mean (SD) | 66.7 (30.62) | 71.6 (30.43) |
| Median | 67 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 2.1 (28.08) | -5.6 (30.11) |
| Median | 0 | 0 |
| Min : Max | -50 : 100 | -50 : 100 |
| LS Mean (SE) (95% CI) | 0.88 (3.20) (-5.44, 7.19) | -9.06 (4.37) (-17.69, -0.42) |
| LS Mean Difference vs. Chemotherapy (SE) | 9.93 (4.95) | |
| 95% CI | (0.13, 19.74) | |
| Two-sided P-value * | 0.0470 | |
| Hedges'g (95% CI) | 0.43 (0.00, 0.86) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.3. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Role Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 79.5 (25.35) | 63.0 (34.80) |
| Baseline Mean (SD) | 66.7 (30.62) | 71.6 (30.43) |
| Median | 100 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 5.5 (27.84) | -11.6 (35.33) |
| Median | 0 | 0 |
| Min : Max | -67 : 100 | -100 : 100 |
| LS Mean (SE) (95% CI) | 4.19 (3.48) (-2.70, 11.07) | -16.53 (5.02) (-26.48, -6.58) |
| LS Mean Difference vs. Chemotherapy (SE) | 20.72 (5.69) | |
| 95% CI | (9.44, 31.99) | |
| Two-sided P-value * | 0.0004 | |
| Hedges'g (95% CI) | 0.87 (0.38, 1.37) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.3. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Role Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 82.3 (19.16) | 63.9 (30.84) |
| Baseline Mean (SD) | 66.7 (30.62) | 71.6 (30.43) |
| Median | 83 | 67 |
| Min : Max | 33 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 8.2 (19.93) | -11.1 (25.95) |
| Median | 0 | 0 |
| Min : Max | -33 : 67 | -67 : 33 |
| LS Mean (SE) (95% CI) | 7.68 (3.12) (1.46, 13.89) | -11.86 (5.37) (-22.58, -1.15) |
| LS Mean Difference vs. Chemotherapy (SE) | 19.54 (5.81) | |
| 95% CI | (7.92, 31.16) | |
| Two-sided P-value * | 0.0013 | |
| Hedges'g (95% CI) | 1.05 (0.39, 1.71) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.4. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Emotional Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 75.1 (21.88) | 73.2 (21.69) |
| Baseline Mean (SD) | 71.8 (25.28) | 76.6 (22.54) |
| Median | 79 | 75 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | 3.3 (18.97) | -3.4 (16.91) |
| Median | 0 | -0 |
| Min : Max | -50 : 61 | -75 : 50 |
| LS Mean (SE) (95% CI) | 5.07 (1.79) (1.54, 8.60) | -1.23 (2.20) (-5.56, 3.10) |
| LS Mean Difference vs. Chemotherapy (SE) | 6.30 (2.33) | |
| 95% CI | (1.70, 10.91) | |
| Two-sided P-value * | 0.0077 | |
| Hedges'g (95% CI) | 0.34 (0.09, 0.58) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.4. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Emotional Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 74.6 (23.67) | 74.2 (22.38) |
| Baseline Mean (SD) | 71.8 (25.28) | 76.6 (22.54) |
| Median | 75 | 75 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 2.8 (19.75) | -2.9 (18.36) |
| Median | 0 | 0 |
| Min : Max | -50 : 58 | -75 : 50 |
| LS Mean (SE) (95% CI) | 3.91 (1.87) (0.24, 7.59) | 0.06 (1.92) (-3.72, 3.84) |
| LS Mean Difference vs. Chemotherapy (SE) | 3.85 (2.18) | |
| 95% CI | (-0.44, 8.14) | |
| Two-sided P-value * | 0.0783 | |
| Hedges'g (95% CI) | 0.22 (-0.03, 0.47) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.4. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Emotional Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 78.3 (21.50) | 75.0 (21.91) |
| Baseline Mean (SD) | 71.8 (25.28) | 76.6 (22.54) |
| Median | 83 | 75 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 5.1 (21.34) | -0.8 (18.96) |
| Median | 0 | 0 |
| Min : Max | -42 : 75 | -50 : 58 |
| LS Mean (SE) (95% CI) | 6.02 (2.04) (2.00, 10.04) | 1.06 (2.25) (-3.37, 5.49) |
| LS Mean Difference vs. Chemotherapy (SE) | 4.96 (2.58) | |
| 95% CI | (-0.12, 10.04) | |
| Two-sided P-value * | 0.0558 | |
| Hedges'g (95% CI) | 0.29 (-0.01, 0.60) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.4. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Emotional Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 77.6 (21.92) | 71.9 (27.08) |
| Baseline Mean (SD) | 71.8 (25.28) | 76.6 (22.54) |
| Median | 83 | 75 |
| Min : Max | 17 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 2.9 (21.86) | -5.0 (21.35) |
| Median | 0 | 0 |
| Min : Max | -75 : 50 | -75 : 50 |
| LS Mean (SE) (95% CI) | 4.56 (2.41) (-0.19, 9.30) | -3.30 (2.98) (-9.18, 2.59) |
| LS Mean Difference vs. Chemotherapy (SE) | 7.86 (3.48) | |
| 95% CI | (0.98, 14.73) | |
| Two-sided P-value * | 0.0255 | |
| Hedges'g (95% CI) | 0.41 (0.05, 0.78) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.4. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Emotional Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 77.5 (19.57) | 68.9 (24.36) |
| Baseline Mean (SD) | 71.8 (25.28) | 76.6 (22.54) |
| Median | 83 | 75 |
| Min : Max | 25 : 100 | 25 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 1.4 (22.43) | -6.7 (16.72) |
| Median | 0 | -4 |
| Min : Max | -58 : 50 | -58 : 25 |
| LS Mean (SE) (95% CI) | 3.67 (2.36) (-0.98, 8.32) | -5.38 (3.23) (-11.76, 1.00) |
| LS Mean Difference vs. Chemotherapy (SE) | 9.05 (3.65) | |
| 95% CI | (1.81, 16.28) | |
| Two-sided P-value * | 0.0147 | |
| Hedges'g (95% CI) | 0.53 (0.10, 0.96) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.4. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Emotional Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 78.8 (22.54) | 76.4 (19.73) |
| Baseline Mean (SD) | 71.8 (25.28) | 76.6 (22.54) |
| Median | 83 | 75 |
| Min : Max | 0 : 100 | 17 : 100 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 2.3 (21.20) | -1.1 (16.72) |
| Median | 0 | 0 |
| Min : Max | -50 : 50 | -50 : 33 |
| LS Mean (SE) (95% CI) | 4.79 (2.53) (-0.21, 9.79) | 0.62 (3.76) (-6.84, 8.07) |
| LS Mean Difference vs. Chemotherapy (SE) | 4.17 (4.22) | |
| 95% CI | (-4.21, 12.55) | |
| Two-sided P-value * | 0.3251 | |
| Hedges'g (95% CI) | 0.24 (-0.24, 0.72) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.4. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Emotional Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 81.6 (17.97) | 72.9 (28.23) |
| Baseline Mean (SD) | 71.8 (25.28) | 76.6 (22.54) |
| Median | 83 | 83 |
| Min : Max | 33 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 4.6 (24.13) | -1.4 (22.43) |
| Median | 0 | 0 |
| Min : Max | -50 : 67 | -50 : 33 |
| LS Mean (SE) (95% CI) | 7.48 (2.86) (1.81, 13.16) | -0.44 (4.80) (-9.98, 9.11) |
| LS Mean Difference vs. Chemotherapy (SE) | 7.92 (5.34) | |
| 95% CI | (-2.72, 18.55) | |
| Two-sided P-value * | 0.1423 | |
| Hedges'g (95% CI) | 0.47 (-0.17, 1.11) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.5. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Cognitive Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 80.3 (22.23) | 80.0 (20.92) |
| Baseline Mean (SD) | 80.6 (24.28) | 84.8 (21.58) |
| Median | 85 | 83 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | -0.4 (18.37) | -4.7 (17.00) |
| Median | 0 | 0 |
| Min : Max | -83 : 53 | -50 : 44 |
| LS Mean (SE) (95% CI) | 0.47 (1.79) (-3.05, 4.00) | -4.88 (2.18) (-9.18, -0.59) |
| LS Mean Difference vs. Chemotherapy (SE) | 5.36 (2.32) | |
| 95% CI | (0.77, 9.94) | |
| Two-sided P-value * | 0.0224 | |
| Hedges'g (95% CI) | 0.29 (0.04, 0.53) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.5. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Cognitive Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 80.4 (24.66) | 81.7 (21.24) |
| Baseline Mean (SD) | 80.6 (24.28) | 84.8 (21.58) |
| Median | 83 | 83 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | -0.2 (19.55) | -3.7 (17.78) |
| Median | 0 | 0 |
| Min : Max | -83 : 50 | -50 : 50 |
| LS Mean (SE) (95% CI) | -0.36 (1.87) (-4.04, 3.32) | -2.44 (1.93) (-6.24, 1.36) |
| LS Mean Difference vs. Chemotherapy (SE) | 2.08 (2.20) | |
| 95% CI | (-2.26, 6.42) | |
| Two-sided P-value * | 0.3469 | |
| Hedges'g (95% CI) | 0.12 (-0.13, 0.37) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.5. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Cognitive Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 82.2 (21.14) | 82.6 (18.35) |
| Baseline Mean (SD) | 80.6 (24.28) | 84.8 (21.58) |
| Median | 83 | 83 |
| Min : Max | 0 : 100 | 33 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 1.1 (19.23) | -2.8 (17.36) |
| Median | 0 | 0 |
| Min : Max | -50 : 50 | -33 : 50 |
| LS Mean (SE) (95% CI) | 0.06 (1.92) (-3.73, 3.85) | -2.22 (2.14) (-6.42, 1.99) |
| LS Mean Difference vs. Chemotherapy (SE) | 2.28 (2.39) | |
| 95% CI | (-2.43, 7.00) | |
| Two-sided P-value * | 0.3406 | |
| Hedges'g (95% CI) | 0.15 (-0.16, 0.45) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.5. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Cognitive Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 83.3 (21.41) | 82.2 (22.30) |
| Baseline Mean (SD) | 80.6 (24.28) | 84.8 (21.58) |
| Median | 83 | 83 |
| Min : Max | 0 : 100 | 17 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 1.0 (18.88) | -3.0 (20.50) |
| Median | 0 | 0 |
| Min : Max | -50 : 50 | -67 : 50 |
| LS Mean (SE) (95% CI) | 0.71 (2.14) (-3.51, 4.93) | -2.95 (2.60) (-8.08, 2.17) |
| LS Mean Difference vs. Chemotherapy (SE) | 3.67 (2.96) | |
| 95% CI | (-2.19, 9.52) | |
| Two-sided P-value * | 0.2178 | |
| Hedges'g (95% CI) | 0.23 (-0.14, 0.59) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.5. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Cognitive Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 83.6 (20.56) | 79.4 (22.18) |
| Baseline Mean (SD) | 80.6 (24.28) | 84.8 (21.58) |
| Median | 83 | 83 |
| Min : Max | 0 : 100 | 33 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 0.7 (19.34) | -6.1 (21.21) |
| Median | 0 | 0 |
| Min : Max | -50 : 67 | -50 : 33 |
| LS Mean (SE) (95% CI) | 0.20 (2.25) (-4.25, 4.64) | -4.71 (3.04) (-10.71, 1.30) |
| LS Mean Difference vs. Chemotherapy (SE) | 4.90 (3.43) | |
| 95% CI | (-1.89, 11.69) | |
| Two-sided P-value * | 0.1553 | |
| Hedges'g (95% CI) | 0.31 (-0.12, 0.74) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.5. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Cognitive Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 83.6 (22.87) | 77.5 (25.43) |
| Baseline Mean (SD) | 80.6 (24.28) | 84.8 (21.58) |
| Median | 100 | 83 |
| Min : Max | 0 : 100 | 17 : 100 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | -0.3 (18.63) | -8.0 (27.46) |
| Median | 0 | 0 |
| Min : Max | -50 : 67 | -83 : 33 |
| LS Mean (SE) (95% CI) | -0.11 (2.64) (-5.34, 5.12) | -7.45 (3.89) (-15.16, 0.26) |
| LS Mean Difference vs. Chemotherapy (SE) | 7.34 (4.41) | |
| 95% CI | (-1.42, 16.10) | |
| Two-sided P-value * | 0.0995 | |
| Hedges'g (95% CI) | 0.40 (-0.09, 0.88) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.5. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Cognitive Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 86.5 (19.24) | 69.4 (29.16) |
| Baseline Mean (SD) | 80.6 (24.28) | 84.8 (21.58) |
| Median | 100 | 75 |
| Min : Max | 0 : 100 | 17 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 2.5 (19.96) | -16.7 (29.30) |
| Median | 0 | -17 |
| Min : Max | -33 : 67 | -67 : 33 |
| LS Mean (SE) (95% CI) | 2.33 (2.73) (-3.09, 7.75) | -9.53 (4.64) (-18.75, -0.31) |
| LS Mean Difference vs. Chemotherapy (SE) | 11.86 (5.13) | |
| 95% CI | (1.64, 22.09) | |
| Two-sided P-value * | 0.0235 | |
| Hedges'g (95% CI) | 0.73 (0.08, 1.37) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.6. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Social Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 76.2 (25.24) | 72.8 (24.80) |
| Baseline Mean (SD) | 74.2 (29.75) | 77.4 (25.86) |
| Median | 83 | 70 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | 2.0 (25.40) | -4.6 (20.99) |
| Median | 0 | 0 |
| Min : Max | -83 : 83 | -72 : 50 |
| LS Mean (SE) (95% CI) | 1.77 (2.17) (-2.51, 6.04) | -3.23 (2.49) (-8.13, 1.67) |
| LS Mean Difference vs. Chemotherapy (SE) | 4.99 (2.61) | |
| 95% CI | (-0.16, 10.15) | |
| Two-sided P-value * | 0.0574 | |
| Hedges'g (95% CI) | 0.24 (-0.01, 0.48) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.6. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Social Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 76.9 (27.99) | 73.6 (26.79) |
| Baseline Mean (SD) | 74.2 (29.75) | 77.4 (25.86) |
| Median | 83 | 67 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 2.7 (26.16) | -4.3 (24.48) |
| Median | 0 | 0 |
| Min : Max | -83 : 67 | -100 : 67 |
| LS Mean (SE) (95% CI) | 1.89 (2.41) (-2.85, 6.62) | -3.67 (2.48) (-8.56, 1.21) |
| LS Mean Difference vs. Chemotherapy (SE) | 5.56 (2.85) | |
| 95% CI | (-0.05, 11.18) | |
| Two-sided P-value * | 0.0522 | |
| Hedges'g (95% CI) | 0.24 (0.00, 0.49) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.6. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Social Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 77.8 (27.08) | 76.1 (26.08) |
| Baseline Mean (SD) | 74.2 (29.75) | 77.4 (25.86) |
| Median | 92 | 83 |
| Min : Max | 0 : 100 | 17 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 2.5 (32.28) | -2.8 (24.23) |
| Median | 0 | 0 |
| Min : Max | -83 : 100 | -67 : 50 |
| LS Mean (SE) (95% CI) | 1.34 (2.73) (-4.04, 6.72) | -3.08 (3.04) (-9.07, 2.91) |
| LS Mean Difference vs. Chemotherapy (SE) | 4.42 (3.56) | |
| 95% CI | (-2.60, 11.44) | |
| Two-sided P-value * | 0.2158 | |
| Hedges'g (95% CI) | 0.19 (-0.11, 0.49) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.6. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Social Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 79.2 (23.94) | 78.9 (24.20) |
| Baseline Mean (SD) | 74.2 (29.75) | 77.4 (25.86) |
| Median | 83 | 83 |
| Min : Max | 0 : 100 | 17 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 0.0 (24.15) | -1.5 (21.56) |
| Median | 0 | 0 |
| Min : Max | -67 : 50 | -67 : 33 |
| LS Mean (SE) (95% CI) | 0.37 (2.62) (-4.80, 5.53) | -1.04 (3.17) (-7.30, 5.22) |
| LS Mean Difference vs. Chemotherapy (SE) | 1.41 (3.58) | |
| 95% CI | (-5.66, 8.48) | |
| Two-sided P-value * | 0.6936 | |
| Hedges'g (95% CI) | 0.07 (-0.29, 0.44) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.6. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Social Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 81.2 (21.96) | 70.6 (30.22) |
| Baseline Mean (SD) | 74.2 (29.75) | 77.4 (25.86) |
| Median | 83 | 83 |
| Min : Max | 17 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 0.2 (21.14) | -5.0 (21.06) |
| Median | 0 | 0 |
| Min : Max | -50 : 50 | -67 : 33 |
| LS Mean (SE) (95% CI) | 1.40 (2.63) (-3.80, 6.60) | -4.71 (3.50) (-11.63, 2.21) |
| LS Mean Difference vs. Chemotherapy (SE) | 6.11 (3.88) | |
| 95% CI | (-1.58, 13.80) | |
| Two-sided P-value * | 0.1183 | |
| Hedges'g (95% CI) | 0.34 (-0.09, 0.77) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.6. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Social Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 80.9 (25.61) | 76.8 (26.47) |
| Baseline Mean (SD) | 74.2 (29.75) | 77.4 (25.86) |
| Median | 100 | 83 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | -1.4 (20.25) | 0.7 (23.29) |
| Median | 0 | 0 |
| Min : Max | -50 : 50 | -50 : 50 |
| LS Mean (SE) (95% CI) | -0.49 (2.79) (-6.00, 5.03) | -1.41 (3.83) (-8.98, 6.16) |
| LS Mean Difference vs. Chemotherapy (SE) | 0.92 (4.29) | |
| 95% CI | (-7.57, 9.42) | |
| Two-sided P-value * | 0.8298 | |
| Hedges'g (95% CI) | 0.05 (-0.43, 0.53) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.6. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Social Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 85.8 (17.37) | 75.0 (26.11) |
| Baseline Mean (SD) | 74.2 (29.75) | 77.4 (25.86) |
| Median | 100 | 75 |
| Min : Max | 33 : 100 | 33 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 1.4 (22.21) | -1.4 (32.92) |
| Median | 0 | 0 |
| Min : Max | -50 : 67 | -67 : 50 |
| LS Mean (SE) (95% CI) | 6.09 (2.94) (0.28, 11.90) | -5.45 (4.82) (-15.06, 4.15) |
| LS Mean Difference vs. Chemotherapy (SE) | 11.55 (5.29) | |
| 95% CI | (1.00, 22.09) | |
| Two-sided P-value * | 0.0324 | |
| Hedges'g (95% CI) | 0.68 (0.04, 1.33) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.7. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Fatigue
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 37.4 (25.24) | 44.1 (23.56) |
| Baseline Mean (SD) | 36.8 (26.51) | 33.8 (25.91) |
| Median | 33 | 39 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | 0.6 (22.59) | 10.4 (20.26) |
| Median | 2 | 9 |
| Min : Max | -78 : 67 | -33 : 78 |
| LS Mean (SE) (95% CI) | 0.63 (2.23) (-3.78, 5.03) | 11.92 (2.70) (6.61, 17.24) |
| LS Mean Difference vs. Chemotherapy (SE) | -11.30 (2.91) | |
| 95% CI | (-17.04, -5.56) | |
| Two-sided P-value * | 0.0001 | |
| Hedges'g (95% CI) | -0.48 (-0.73, -0.23) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.7. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Fatigue
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 38.8 (27.87) | 42.4 (24.56) |
| Baseline Mean (SD) | 36.8 (26.51) | 33.8 (25.91) |
| Median | 33 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 2.1 (21.83) | 9.0 (21.37) |
| Median | 0 | 0 |
| Min : Max | -78 : 67 | -44 : 78 |
| LS Mean (SE) (95% CI) | 3.90 (2.19) (-0.42, 8.22) | 9.72 (2.25) (5.29, 14.15) |
| LS Mean Difference vs. Chemotherapy (SE) | -5.82 (2.52) | |
| 95% CI | (-10.79, -0.86) | |
| Two-sided P-value * | 0.0217 | |
| Hedges'g (95% CI) | -0.29 (-0.54, -0.04) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.7. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Fatigue
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 31.4 (24.69) | 39.7 (23.05) |
| Baseline Mean (SD) | 36.8 (26.51) | 33.8 (25.91) |
| Median | 33 | 33 |
| Min : Max | 0 : 100 | 0 : 89 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | -4.1 (26.99) | 8.7 (21.49) |
| Median | 0 | 11 |
| Min : Max | -100 : 56 | -44 : 56 |
| LS Mean (SE) (95% CI) | -0.52 (2.44) (-5.32, 4.28) | 10.87 (2.69) (5.57, 16.17) |
| LS Mean Difference vs. Chemotherapy (SE) | -11.39 (3.08) | |
| 95% CI | (-17.46, -5.32) | |
| Two-sided P-value * | 0.0003 | |
| Hedges'g (95% CI) | -0.57 (-0.87, -0.26) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.7. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Fatigue
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 30.6 (23.28) | 37.8 (27.00) |
| Baseline Mean (SD) | 36.8 (26.51) | 33.8 (25.91) |
| Median | 33 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | -1.6 (27.45) | 10.3 (22.10) |
| Median | 0 | 11 |
| Min : Max | -89 : 67 | -44 : 78 |
| LS Mean (SE) (95% CI) | -0.52 (2.71) (-5.87, 4.83) | 9.68 (3.27) (3.24, 16.13) |
| LS Mean Difference vs. Chemotherapy (SE) | -10.20 (3.77) | |
| 95% CI | (-17.65, -2.76) | |
| Two-sided P-value * | 0.0075 | |
| Hedges'g (95% CI) | -0.49 (-0.86, -0.13) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.7. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Fatigue
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 29.8 (23.67) | 40.4 (29.10) |
| Baseline Mean (SD) | 36.8 (26.51) | 33.8 (25.91) |
| Median | 33 | 33 |
| Min : Max | 0 : 89 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | -0.5 (23.96) | 9.6 (22.55) |
| Median | 0 | 11 |
| Min : Max | -78 : 67 | -44 : 56 |
| LS Mean (SE) (95% CI) | -0.81 (2.84) (-6.43, 4.80) | 11.05 (3.82) (3.50, 18.59) |
| LS Mean Difference vs. Chemotherapy (SE) | -11.86 (4.33) | |
| 95% CI | (-20.42, -3.30) | |
| Two-sided P-value * | 0.0070 | |
| Hedges'g (95% CI) | -0.59 (-1.02, -0.15) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.7. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Fatigue
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 31.5 (26.85) | 40.6 (27.75) |
| Baseline Mean (SD) | 36.8 (26.51) | 33.8 (25.91) |
| Median | 33 | 33 |
| Min : Max | 0 : 89 | 0 : 89 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 1.3 (23.32) | 10.1 (26.36) |
| Median | 0 | 0 |
| Min : Max | -89 : 56 | -33 : 78 |
| LS Mean (SE) (95% CI) | 1.91 (3.16) (-4.35, 8.17) | 14.84 (4.58) (5.77, 23.90) |
| LS Mean Difference vs. Chemotherapy (SE) | -12.92 (5.19) | |
| 95% CI | (-23.23, -2.62) | |
| Two-sided P-value * | 0.0145 | |
| Hedges'g (95% CI) | -0.60 (-1.08, -0.11) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.7. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Fatigue
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 29.3 (20.91) | 43.5 (27.40) |
| Baseline Mean (SD) | 36.8 (26.51) | 33.8 (25.91) |
| Median | 33 | 39 |
| Min : Max | 0 : 78 | 0 : 89 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 0.0 (24.52) | 12.0 (23.43) |
| Median | 0 | 6 |
| Min : Max | -89 : 33 | -11 : 67 |
| LS Mean (SE) (95% CI) | -0.20 (3.17) (-6.49, 6.09) | 15.39 (5.20) (5.06, 25.71) |
| LS Mean Difference vs. Chemotherapy (SE) | -15.59 (5.75) | |
| 95% CI | (-27.03, -4.14) | |
| Two-sided P-value * | 0.0082 | |
| Hedges'g (95% CI) | -0.85 (-1.50, -0.20) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.8. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Nausea / Vomiting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 11.3 (19.76) | 19.1 (20.40) |
| Baseline Mean (SD) | 9.6 (19.58) | 10.0 (19.84) |
| Median | 0 | 17 |
| Min : Max | 0 : 100 | 0 : 83 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | 1.7 (17.47) | 9.1 (21.49) |
| Median | 0 | 3 |
| Min : Max | -83 : 83 | -92 : 67 |
| LS Mean (SE) (95% CI) | 0.52 (1.73) (-2.90, 3.94) | 7.38 (2.04) (3.34, 11.41) |
| LS Mean Difference vs. Chemotherapy (SE) | -6.86 (2.11) | |
| 95% CI | (-11.03, -2.68) | |
| Two-sided P-value * | 0.0015 | |
| Hedges'g (95% CI) | -0.40 (-0.65, -0.15) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.8. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Nausea / Vomiting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 11.5 (22.91) | 19.3 (21.54) |
| Baseline Mean (SD) | 9.6 (19.58) | 10.0 (19.84) |
| Median | 0 | 17 |
| Min : Max | 0 : 100 | 0 : 83 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 1.9 (19.46) | 9.7 (22.68) |
| Median | 0 | 0 |
| Min : Max | -50 : 83 | -83 : 67 |
| LS Mean (SE) (95% CI) | 1.49 (2.04) (-2.52, 5.49) | 10.03 (2.11) (5.87, 14.19) |
| LS Mean Difference vs. Chemotherapy (SE) | -8.54 (2.46) | |
| 95% CI | (-13.39, -3.69) | |
| Two-sided P-value * | 0.0006 | |
| Hedges'g (95% CI) | -0.43 (-0.68, -0.18) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.8. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Nausea / Vomiting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 8.0 (17.82) | 14.6 (21.44) |
| Baseline Mean (SD) | 9.6 (19.58) | 10.0 (19.84) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | -0.8 (21.92) | 5.4 (26.39) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -100 : 83 |
| LS Mean (SE) (95% CI) | -0.65 (2.22) (-5.02, 3.73) | 6.35 (2.49) (1.45, 11.25) |
| LS Mean Difference vs. Chemotherapy (SE) | -7.00 (2.89) | |
| 95% CI | (-12.71, -1.29) | |
| Two-sided P-value * | 0.0165 | |
| Hedges'g (95% CI) | -0.37 (-0.68, -0.06) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.8. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Nausea / Vomiting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 7.2 (15.35) | 17.8 (19.69) |
| Baseline Mean (SD) | 9.6 (19.58) | 10.0 (19.84) |
| Median | 0 | 17 |
| Min : Max | 0 : 67 | 0 : 67 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | -1.0 (19.07) | 9.4 (21.84) |
| Median | 0 | 0 |
| Min : Max | -100 : 50 | -33 : 67 |
| LS Mean (SE) (95% CI) | -1.28 (2.15) (-5.52, 2.97) | 7.98 (2.62) (2.82, 13.15) |
| LS Mean Difference vs. Chemotherapy (SE) | -9.26 (2.94) | |
| 95% CI | (-15.07, -3.45) | |
| Two-sided P-value * | 0.0020 | |
| Hedges'g (95% CI) | -0.57 (-0.94, -0.20) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.8. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Nausea / Vomiting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 8.1 (14.40) | 17.8 (27.31) |
| Baseline Mean (SD) | 9.6 (19.58) | 10.0 (19.84) |
| Median | 0 | 0 |
| Min : Max | 0 : 67 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 1.0 (12.65) | 6.7 (25.75) |
| Median | 0 | 0 |
| Min : Max | -33 : 50 | -67 : 50 |
| LS Mean (SE) (95% CI) | 0.83 (2.30) (-3.72, 5.37) | 8.14 (3.11) (2.00, 14.29) |
| LS Mean Difference vs. Chemotherapy (SE) | -7.31 (3.50) | |
| 95% CI | (-14.26, -0.37) | |
| Two-sided P-value * | 0.0391 | |
| Hedges'g (95% CI) | -0.45 (-0.88, -0.01) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.8. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Nausea / Vomiting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 9.8 (17.04) | 13.0 (21.29) |
| Baseline Mean (SD) | 9.6 (19.58) | 10.0 (19.84) |
| Median | 0 | 0 |
| Min : Max | 0 : 67 | 0 : 83 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 3.3 (17.16) | 2.9 (26.90) |
| Median | 0 | 0 |
| Min : Max | -50 : 67 | -67 : 83 |
| LS Mean (SE) (95% CI) | 2.24 (2.59) (-2.89, 7.37) | 5.50 (3.82) (-2.07, 13.08) |
| LS Mean Difference vs. Chemotherapy (SE) | -3.26 (4.31) | |
| 95% CI | (-11.84, 5.31) | |
| Two-sided P-value * | 0.4511 | |
| Hedges'g (95% CI) | -0.18 (-0.66, 0.30) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.8. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Nausea / Vomiting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 7.4 (14.67) | 12.5 (14.43) |
| Baseline Mean (SD) | 9.6 (19.58) | 10.0 (19.84) |
| Median | 0 | 17 |
| Min : Max | 0 : 67 | 0 : 50 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 1.1 (17.17) | 5.6 (8.21) |
| Median | 0 | 0 |
| Min : Max | -50 : 50 | 0 : 17 |
| LS Mean (SE) (95% CI) | 0.49 (2.44) (-4.36, 5.33) | 6.26 (3.94) (-1.59, 14.10) |
| LS Mean Difference vs. Chemotherapy (SE) | -5.77 (4.32) | |
| 95% CI | (-14.40, 2.86) | |
| Two-sided P-value * | 0.1865 | |
| Hedges'g (95% CI) | -0.42 (-1.06, 0.22) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.9. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Pain
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 33.2 (29.62) | 40.6 (27.99) |
| Baseline Mean (SD) | 36.4 (31.98) | 35.4 (32.23) |
| Median | 28 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | -3.2 (28.23) | 5.3 (24.98) |
| Median | 0 | 3 |
| Min : Max | -93 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | -6.12 (2.60) (-11.26, -0.99) | 6.32 (3.17) (0.08, 12.57) |
| LS Mean Difference vs. Chemotherapy (SE) | -12.45 (3.41) | |
| 95% CI | (-19.18, -5.71) | |
| Two-sided P-value * | 0.0004 | |
| Hedges'g (95% CI) | -0.45 (-0.70, -0.20) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.9. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Pain
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 35.1 (31.74) | 39.2 (30.04) |
| Baseline Mean (SD) | 36.4 (31.98) | 35.4 (32.23) |
| Median | 33 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | -1.3 (28.29) | 4.7 (25.63) |
| Median | 0 | 0 |
| Min : Max | -83 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | -1.31 (2.63) (-6.49, 3.87) | 4.08 (2.70) (-1.24, 9.40) |
| LS Mean Difference vs. Chemotherapy (SE) | -5.39 (3.06) | |
| 95% CI | (-11.42, 0.65) | |
| Two-sided P-value * | 0.0799 | |
| Hedges'g (95% CI) | -0.22 (-0.47, 0.03) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.9. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Pain
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 69/2 |
| Mean (SD) | 27.9 (30.41) | 35.4 (29.40) |
| Baseline Mean (SD) | 36.4 (31.98) | 35.4 (32.23) |
| Median | 17 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 69/2 |
| Mean (SD) | -7.2 (35.76) | 4.5 (27.02) |
| Median | 0 | 0 |
| Min : Max | -100 : 83 | -67 : 83 |
| LS Mean (SE) (95% CI) | -5.34 (3.11) (-11.47, 0.78) | 3.87 (3.49) (-3.00, 10.74) |
| LS Mean Difference vs. Chemotherapy (SE) | -9.21 (4.09) | |
| 95% CI | (-17.27, -1.15) | |
| Two-sided P-value * | 0.0253 | |
| Hedges'g (95% CI) | -0.34 (-0.65, -0.04) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.9. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Pain
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 20.6 (22.25) | 33.3 (27.67) |
| Baseline Mean (SD) | 36.4 (31.98) | 35.4 (32.23) |
| Median | 17 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | -10.5 (28.92) | 4.3 (29.90) |
| Median | 0 | 0 |
| Min : Max | -100 : 50 | -67 : 67 |
| LS Mean (SE) (95% CI) | -10.42 (2.87) (-16.08, -4.76) | 3.68 (3.42) (-3.07, 10.43) |
| LS Mean Difference vs. Chemotherapy (SE) | -14.10 (3.83) | |
| 95% CI | (-21.68, -6.53) | |
| Two-sided P-value * | 0.0003 | |
| Hedges'g (95% CI) | -0.67 (-1.04, -0.30) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.9. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Pain
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 24.5 (25.49) | 33.9 (32.31) |
| Baseline Mean (SD) | 36.4 (31.98) | 35.4 (32.23) |
| Median | 17 | 33 |
| Min : Max | 0 : 83 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | -4.0 (28.01) | 1.1 (26.60) |
| Median | 0 | 0 |
| Min : Max | -100 : 50 | -67 : 50 |
| LS Mean (SE) (95% CI) | -6.05 (3.25) (-12.46, 0.36) | 5.51 (4.38) (-3.15, 14.16) |
| LS Mean Difference vs. Chemotherapy (SE) | -11.55 (4.94) | |
| 95% CI | (-21.34, -1.76) | |
| Two-sided P-value * | 0.0212 | |
| Hedges'g (95% CI) | -0.50 (-0.93, -0.07) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.9. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Pain
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 24.3 (28.80) | 28.3 (30.33) |
| Baseline Mean (SD) | 36.4 (31.98) | 35.4 (32.23) |
| Median | 17 | 17 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | -2.7 (30.76) | 0.7 (29.51) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | -5.23 (3.74) (-12.63, 2.16) | 6.13 (5.32) (-4.39, 16.66) |
| LS Mean Difference vs. Chemotherapy (SE) | -11.36 (6.05) | |
| 95% CI | (-23.36, 0.63) | |
| Two-sided P-value * | 0.0632 | |
| Hedges'g (95% CI) | -0.45 (-0.93, 0.03) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.9. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Pain
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 18.8 (22.95) | 37.5 (34.17) |
| Baseline Mean (SD) | 36.4 (31.98) | 35.4 (32.23) |
| Median | 17 | 33 |
| Min : Max | 0 : 67 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | -6.4 (25.67) | 4.2 (37.01) |
| Median | 0 | 0 |
| Min : Max | -67 : 50 | -50 : 83 |
| LS Mean (SE) (95% CI) | -8.40 (3.98) (-16.31, -0.49) | 14.67 (6.62) (1.51, 27.83) |
| LS Mean Difference vs. Chemotherapy (SE) | -23.07 (7.38) | |
| 95% CI | (-37.78, -8.36) | |
| Two-sided P-value * | 0.0025 | |
| Hedges'g (95% CI) | -0.98 (-1.64, -0.32) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.10. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Dyspnoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 141 | 115 |
| Mean (SD) | 18.6 (25.21) | 19.7 (22.87) |
| Baseline Mean (SD) | 17.3 (24.75) | 15.9 (20.87) |
| Median | 8 | 11 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 141 | 115 |
| Mean (SD) | 1.4 (24.06) | 3.8 (21.23) |
| Median | 0 | 0 |
| Min : Max | -67 : 100 | -67 : 67 |
| LS Mean (SE) (95% CI) | 1.75 (2.35) (-2.89, 6.38) | 4.52 (2.81) (-1.02, 10.06) |
| LS Mean Difference vs. Chemotherapy (SE) | -2.77 (3.00) | |
| 95% CI | (-8.71, 3.16) | |
| Two-sided P-value * | 0.3576 | |
| Hedges'g (95% CI) | -0.11 (-0.36, 0.13) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.10. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Dyspnoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 141/0 | 113/0 |
| Mean (SD) | 18.4 (26.55) | 18.9 (24.75) |
| Baseline Mean (SD) | 17.3 (24.75) | 15.9 (20.87) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 141/0 | 113/0 |
| Mean (SD) | 1.2 (25.95) | 2.7 (22.77) |
| Median | 0 | 0 |
| Min : Max | -67 : 100 | -67 : 67 |
| LS Mean (SE) (95% CI) | 1.95 (2.43) (-2.84, 6.74) | 3.11 (2.50) (-1.81, 8.03) |
| LS Mean Difference vs. Chemotherapy (SE) | -1.16 (2.83) | |
| 95% CI | (-6.73, 4.42) | |
| Two-sided P-value * | 0.6825 | |
| Hedges'g (95% CI) | -0.05 (-0.30, 0.20) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.10. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Dyspnoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 68/2 |
| Mean (SD) | 16.0 (26.42) | 18.1 (23.87) |
| Baseline Mean (SD) | 17.3 (24.75) | 15.9 (20.87) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 68/2 |
| Mean (SD) | -0.7 (24.36) | 3.8 (21.64) |
| Median | 0 | 0 |
| Min : Max | -67 : 100 | -67 : 67 |
| LS Mean (SE) (95% CI) | 0.69 (2.59) (-4.43, 5.80) | 4.34 (2.89) (-1.34, 10.03) |
| LS Mean Difference vs. Chemotherapy (SE) | -3.66 (3.26) | |
| 95% CI | (-10.08, 2.77) | |
| Two-sided P-value * | 0.2630 | |
| Hedges'g (95% CI) | -0.17 (-0.48, 0.13) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.10. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Dyspnoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 15.2 (21.11) | 18.1 (26.02) |
| Baseline Mean (SD) | 17.3 (24.75) | 15.9 (20.87) |
| Median | 0 | 0 |
| Min : Max | 0 : 67 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 0.4 (22.04) | 5.1 (28.08) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | 0.49 (2.73) (-4.90, 5.88) | 5.24 (3.27) (-1.21, 11.68) |
| LS Mean Difference vs. Chemotherapy (SE) | -4.74 (3.70) | |
| 95% CI | (-12.06, 2.58) | |
| Two-sided P-value * | 0.2024 | |
| Hedges'g (95% CI) | -0.23 (-0.60, 0.13) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.10. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Dyspnoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 18.1 (24.53) | 17.8 (27.31) |
| Baseline Mean (SD) | 17.3 (24.75) | 15.9 (20.87) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 3.3 (23.50) | 2.2 (33.83) |
| Median | 0 | 0 |
| Min : Max | -33 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | 4.01 (3.17) (-2.25, 10.27) | 3.72 (4.38) (-4.94, 12.38) |
| LS Mean Difference vs. Chemotherapy (SE) | 0.29 (4.98) | |
| 95% CI | (-9.57, 10.15) | |
| Two-sided P-value * | 0.9537 | |
| Hedges'g (95% CI) | 0.01 (-0.42, 0.44) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.10. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Dyspnoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 22/1 |
| Mean (SD) | 16.4 (23.27) | 17.4 (24.35) |
| Baseline Mean (SD) | 17.3 (24.75) | 15.9 (20.87) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 67 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 22/1 |
| Mean (SD) | 2.2 (20.06) | 1.4 (29.26) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | 2.18 (2.94) (-3.63, 8.00) | 4.73 (4.07) (-3.31, 12.78) |
| LS Mean Difference vs. Chemotherapy (SE) | -2.55 (4.56) | |
| 95% CI | (-11.59, 6.49) | |
| Two-sided P-value * | 0.5768 | |
| Hedges'g (95% CI) | -0.13 (-0.61, 0.35) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.10. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Dyspnoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 13.5 (20.45) | 16.7 (22.47) |
| Baseline Mean (SD) | 17.3 (24.75) | 15.9 (20.87) |
| Median | 0 | 0 |
| Min : Max | 0 : 67 | 0 : 67 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | -0.7 (23.56) | 0.0 (24.62) |
| Median | 0 | 0 |
| Min : Max | -67 : 33 | -67 : 33 |
| LS Mean (SE) (95% CI) | 1.15 (3.38) (-5.56, 7.87) | 5.97 (5.39) (-4.74, 16.68) |
| LS Mean Difference vs. Chemotherapy (SE) | -4.81 (6.00) | |
| 95% CI | (-16.78, 7.15) | |
| Two-sided P-value * | 0.4253 | |
| Hedges'g (95% CI) | -0.25 (-0.89, 0.38) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.11. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Insomnia
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 30.5 (28.77) | 38.5 (30.79) |
| Baseline Mean (SD) | 31.5 (34.56) | 29.3 (30.64) |
| Median | 26 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | -1.0 (27.15) | 9.2 (30.93) |
| Median | 0 | 0 |
| Min : Max | -80 : 67 | -83 : 100 |
| LS Mean (SE) (95% CI) | 0.09 (2.82) (-5.47, 5.66) | 7.77 (3.30) (1.27, 14.27) |
| LS Mean Difference vs. Chemotherapy (SE) | -7.67 (3.51) | |
| 95% CI | (-14.61, -0.74) | |
| Two-sided P-value * | 0.0303 | |
| Hedges'g (95% CI) | -0.27 (-0.52, -0.02) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.11. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Insomnia
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 31.0 (32.65) | 36.9 (32.54) |
| Baseline Mean (SD) | 31.5 (34.56) | 29.3 (30.64) |
| Median | 33 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | -0.5 (27.21) | 8.3 (32.59) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -67 : 100 |
| LS Mean (SE) (95% CI) | 1.06 (2.91) (-4.66, 6.79) | 8.25 (2.98) (2.37, 14.12) |
| LS Mean Difference vs. Chemotherapy (SE) | -7.19 (3.35) | |
| 95% CI | (-13.78, -0.59) | |
| Two-sided P-value * | 0.0328 | |
| Hedges'g (95% CI) | -0.27 (-0.52, -0.02) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.11. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Insomnia
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 69/2 |
| Mean (SD) | 26.1 (29.15) | 30.0 (31.95) |
| Baseline Mean (SD) | 31.5 (34.56) | 29.3 (30.64) |
| Median | 33 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 69/2 |
| Mean (SD) | -4.2 (33.72) | 4.2 (35.60) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -100 : 100 |
| LS Mean (SE) (95% CI) | -2.24 (3.27) (-8.68, 4.20) | 6.57 (3.64) (-0.60, 13.74) |
| LS Mean Difference vs. Chemotherapy (SE) | -8.81 (4.17) | |
| 95% CI | (-17.03, -0.59) | |
| Two-sided P-value * | 0.0358 | |
| Hedges'g (95% CI) | -0.32 (-0.63, -0.02) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.11. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Insomnia
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 31.3 (29.03) | 36.2 (35.01) |
| Baseline Mean (SD) | 31.5 (34.56) | 29.3 (30.64) |
| Median | 33 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 2.1 (35.10) | 12.3 (37.42) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -67 : 100 |
| LS Mean (SE) (95% CI) | 3.75 (3.56) (-3.26, 10.76) | 12.83 (4.31) (4.33, 21.32) |
| LS Mean Difference vs. Chemotherapy (SE) | -9.08 (4.96) | |
| 95% CI | (-18.88, 0.72) | |
| Two-sided P-value * | 0.0692 | |
| Hedges'g (95% CI) | -0.33 (-0.70, 0.03) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.11. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Insomnia
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 24.8 (24.53) | 33.3 (35.02) |
| Baseline Mean (SD) | 31.5 (34.56) | 29.3 (30.64) |
| Median | 33 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | -1.0 (32.09) | 6.7 (41.43) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | -67 : 100 |
| LS Mean (SE) (95% CI) | -0.68 (3.42) (-7.43, 6.08) | 8.73 (4.47) (-0.09, 17.56) |
| LS Mean Difference vs. Chemotherapy (SE) | -9.41 (5.01) | |
| 95% CI | (-19.32, 0.50) | |
| Two-sided P-value * | 0.0625 | |
| Hedges'g (95% CI) | -0.40 (-0.83, 0.03) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.11. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Insomnia
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 25.1 (28.97) | 26.1 (26.51) |
| Baseline Mean (SD) | 31.5 (34.56) | 29.3 (30.64) |
| Median | 33 | 33 |
| Min : Max | 0 : 100 | 0 : 67 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 1.1 (33.87) | -4.3 (27.16) |
| Median | 0 | 0 |
| Min : Max | -67 : 100 | -67 : 33 |
| LS Mean (SE) (95% CI) | 0.66 (3.72) (-6.70, 8.02) | 5.91 (5.19) (-4.36, 16.18) |
| LS Mean Difference vs. Chemotherapy (SE) | -5.25 (5.85) | |
| 95% CI | (-16.86, 6.36) | |
| Two-sided P-value * | 0.3713 | |
| Hedges'g (95% CI) | -0.22 (-0.70, 0.27) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.11. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Insomnia
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 22.0 (28.04) | 27.8 (31.25) |
| Baseline Mean (SD) | 31.5 (34.56) | 29.3 (30.64) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 3.5 (33.50) | -2.8 (26.43) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | -33 : 67 |
| LS Mean (SE) (95% CI) | -1.99 (4.25) (-10.40, 6.42) | 4.31 (7.08) (-9.77, 18.39) |
| LS Mean Difference vs. Chemotherapy (SE) | -6.30 (7.88) | |
| 95% CI | (-22.01, 9.42) | |
| Two-sided P-value * | 0.4272 | |
| Hedges'g (95% CI) | -0.25 (-0.89, 0.38) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.12. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Appetite loss
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 114 |
| Mean (SD) | 24.1 (28.46) | 31.8 (27.13) |
| Baseline Mean (SD) | 21.8 (29.19) | 22.5 (28.91) |
| Median | 13 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 114 |
| Mean (SD) | 2.3 (27.94) | 9.3 (29.16) |
| Median | 0 | 0 |
| Min : Max | -78 : 100 | -67 : 100 |
| LS Mean (SE) (95% CI) | -1.61 (2.47) (-6.49, 3.27) | 9.77 (2.94) (3.96, 15.59) |
| LS Mean Difference vs. Chemotherapy (SE) | -11.38 (3.03) | |
| 95% CI | (-17.39, -5.38) | |
| Two-sided P-value * | 0.0003 | |
| Hedges'g (95% CI) | -0.47 (-0.72, -0.22) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.12. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Appetite loss
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 112/0 |
| Mean (SD) | 24.6 (31.43) | 28.6 (29.97) |
| Baseline Mean (SD) | 21.8 (29.19) | 22.5 (28.91) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 112/0 |
| Mean (SD) | 2.8 (29.31) | 6.8 (31.68) |
| Median | 0 | 0 |
| Min : Max | -67 : 100 | -67 : 100 |
| LS Mean (SE) (95% CI) | 2.03 (2.86) (-3.59, 7.66) | 6.64 (2.97) (0.80, 12.49) |
| LS Mean Difference vs. Chemotherapy (SE) | -4.61 (3.44) | |
| 95% CI | (-11.39, 2.17) | |
| Two-sided P-value * | 0.1819 | |
| Hedges'g (95% CI) | -0.17 (-0.42, 0.08) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.12. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Appetite loss
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 69/1 |
| Mean (SD) | 17.0 (28.04) | 30.0 (31.67) |
| Baseline Mean (SD) | 21.8 (29.19) | 22.5 (28.91) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 69/1 |
| Mean (SD) | -3.9 (29.40) | 9.5 (30.64) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | -2.69 (3.11) (-8.82, 3.45) | 10.34 (3.48) (3.49, 17.20) |
| LS Mean Difference vs. Chemotherapy (SE) | -13.03 (4.04) | |
| 95% CI | (-21.00, -5.06) | |
| Two-sided P-value * | 0.0015 | |
| Hedges'g (95% CI) | -0.50 (-0.80, -0.19) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.12. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Appetite loss
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 18.1 (26.90) | 34.1 (29.39) |
| Baseline Mean (SD) | 21.8 (29.19) | 22.5 (28.91) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | -1.6 (32.87) | 13.0 (32.57) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | -67 : 100 |
| LS Mean (SE) (95% CI) | -1.54 (3.38) (-8.21, 5.14) | 12.18 (4.17) (3.96, 20.40) |
| LS Mean Difference vs. Chemotherapy (SE) | -13.72 (4.81) | |
| 95% CI | (-23.24, -4.20) | |
| Two-sided P-value * | 0.0050 | |
| Hedges'g (95% CI) | -0.52 (-0.89, -0.15) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.12. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Appetite loss
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 18.6 (27.59) | 30.0 (26.77) |
| Baseline Mean (SD) | 21.8 (29.19) | 22.5 (28.91) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 1.0 (27.79) | 6.7 (34.35) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | -0.72 (3.46) (-7.57, 6.12) | 9.99 (4.83) (0.42, 19.55) |
| LS Mean Difference vs. Chemotherapy (SE) | -10.71 (5.46) | |
| 95% CI | (-21.54, 0.12) | |
| Two-sided P-value * | 0.0525 | |
| Hedges'g (95% CI) | -0.42 (-0.85, 0.01) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.12. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Appetite loss
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 18.0 (25.51) | 27.5 (21.68) |
| Baseline Mean (SD) | 21.8 (29.19) | 22.5 (28.91) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 67 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 0.0 (26.53) | 8.7 (20.64) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | -33 : 33 |
| LS Mean (SE) (95% CI) | -1.06 (3.22) (-7.43, 5.31) | 10.24 (4.61) (1.10, 19.38) |
| LS Mean Difference vs. Chemotherapy (SE) | -11.30 (5.08) | |
| 95% CI | (-21.39, -1.20) | |
| Two-sided P-value * | 0.0287 | |
| Hedges'g (95% CI) | -0.53 (-1.02, -0.05) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.12. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Appetite loss
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 12.1 (20.17) | 27.8 (31.25) |
| Baseline Mean (SD) | 21.8 (29.19) | 22.5 (28.91) |
| Median | 0 | 33 |
| Min : Max | 0 : 67 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | -5.0 (25.04) | 8.3 (20.72) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | 0 : 67 |
| LS Mean (SE) (95% CI) | -5.67 (3.41) (-12.45, 1.11) | 9.24 (5.67) (-2.06, 20.55) |
| LS Mean Difference vs. Chemotherapy (SE) | -14.92 (6.18) | |
| 95% CI | (-27.26, -2.58) | |
| Two-sided P-value * | 0.0186 | |
| Hedges'g (95% CI) | -0.76 (-1.40, -0.11) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.13. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Constipation
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 24.4 (30.79) | 31.0 (31.33) |
| Baseline Mean (SD) | 23.2 (29.44) | 24.9 (31.17) |
| Median | 11 | 27 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | 1.2 (31.78) | 6.1 (28.75) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -83 : 67 |
| LS Mean (SE) (95% CI) | -0.74 (2.95) (-6.58, 5.09) | 5.67 (3.43) (-1.09, 12.43) |
| LS Mean Difference vs. Chemotherapy (SE) | -6.41 (3.64) | |
| 95% CI | (-13.60, 0.78) | |
| Two-sided P-value * | 0.0800 | |
| Hedges'g (95% CI) | -0.22 (-0.47, 0.03) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.13. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Constipation
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 23.7 (33.12) | 27.7 (32.40) |
| Baseline Mean (SD) | 23.2 (29.44) | 24.9 (31.17) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 0.5 (33.68) | 2.9 (30.39) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -100 : 67 |
| LS Mean (SE) (95% CI) | -0.15 (3.13) (-6.32, 6.02) | 3.70 (3.23) (-2.66, 10.05) |
| LS Mean Difference vs. Chemotherapy (SE) | -3.85 (3.66) | |
| 95% CI | (-11.05, 3.35) | |
| Two-sided P-value * | 0.2936 | |
| Hedges'g (95% CI) | -0.13 (-0.38, 0.12) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.13. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Constipation
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 17.3 (25.58) | 28.2 (34.11) |
| Baseline Mean (SD) | 23.2 (29.44) | 24.9 (31.17) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | -4.2 (29.17) | 8.5 (34.60) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -100 : 100 |
| LS Mean (SE) (95% CI) | -2.96 (3.30) (-9.47, 3.55) | 8.85 (3.66) (1.65, 16.05) |
| LS Mean Difference vs. Chemotherapy (SE) | -11.81 (4.11) | |
| 95% CI | (-19.93, -3.69) | |
| Two-sided P-value * | 0.0046 | |
| Hedges'g (95% CI) | -0.44 (-0.75, -0.13) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.13. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Constipation
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | 14.0 (25.20) | 29.7 (37.34) |
| Baseline Mean (SD) | 23.2 (29.44) | 24.9 (31.17) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 46/0 |
| Mean (SD) | -8.6 (28.76) | 12.3 (33.23) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | -5.89 (3.52) (-12.83, 1.05) | 10.31 (4.24) (1.94, 18.69) |
| LS Mean Difference vs. Chemotherapy (SE) | -16.20 (4.81) | |
| 95% CI | (-25.71, -6.69) | |
| Two-sided P-value * | 0.0010 | |
| Hedges'g (95% CI) | -0.61 (-0.98, -0.24) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.13. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Constipation
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 20.5 (26.79) | 23.3 (34.07) |
| Baseline Mean (SD) | 23.2 (29.44) | 24.9 (31.17) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | -1.0 (30.55) | 5.6 (26.38) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | 0.60 (3.55) (-6.41, 7.61) | 3.91 (4.70) (-5.37, 13.18) |
| LS Mean Difference vs. Chemotherapy (SE) | -3.30 (5.22) | |
| 95% CI | (-13.65, 7.04) | |
| Two-sided P-value * | 0.5283 | |
| Hedges'g (95% CI) | -0.14 (-0.56, 0.29) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.13. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Constipation
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 21.3 (30.45) | 17.4 (26.34) |
| Baseline Mean (SD) | 23.2 (29.44) | 24.9 (31.17) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 0.5 (34.69) | 2.9 (19.88) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -67 : 33 |
| LS Mean (SE) (95% CI) | 3.02 (3.93) (-4.76, 10.79) | 4.00 (5.52) (-6.92, 14.91) |
| LS Mean Difference vs. Chemotherapy (SE) | -0.98 (6.21) | |
| 95% CI | (-13.30, 11.34) | |
| Two-sided P-value * | 0.8750 | |
| Hedges'g (95% CI) | -0.04 (-0.52, 0.44) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.13. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Constipation
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 16.3 (25.89) | 13.9 (26.43) |
| Baseline Mean (SD) | 23.2 (29.44) | 24.9 (31.17) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 67 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | -0.7 (31.46) | -2.8 (22.29) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -67 : 33 |
| LS Mean (SE) (95% CI) | 0.91 (3.93) (-6.87, 8.70) | 3.24 (6.01) (-8.66, 15.15) |
| LS Mean Difference vs. Chemotherapy (SE) | -2.33 (6.63) | |
| 95% CI | (-15.51, 10.85) | |
| Two-sided P-value * | 0.7261 | |
| Hedges'g (95% CI) | -0.11 (-0.74, 0.52) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.14. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Diarhoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 10.2 (15.84) | 12.2 (18.66) |
| Baseline Mean (SD) | 9.4 (19.99) | 7.0 (17.93) |
| Median | 0 | 0 |
| Min : Max | 0 : 78 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | 0.8 (18.18) | 5.2 (21.28) |
| Median | 0 | 0 |
| Min : Max | -78 : 50 | -67 : 100 |
| LS Mean (SE) (95% CI) | 2.44 (1.66) (-0.84, 5.72) | 3.16 (2.08) (-0.94, 7.27) |
| LS Mean Difference vs. Chemotherapy (SE) | -0.72 (2.20) | |
| 95% CI | (-5.08, 3.63) | |
| Two-sided P-value * | 0.7430 | |
| Hedges'g (95% CI) | -0.04 (-0.29, 0.21) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.14. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Diarhoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 10.1 (19.85) | 11.5 (21.26) |
| Baseline Mean (SD) | 9.4 (19.99) | 7.0 (17.93) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 0.7 (20.42) | 4.4 (22.05) |
| Median | 0 | 0 |
| Min : Max | -33 : 100 | -67 : 100 |
| LS Mean (SE) (95% CI) | 1.13 (1.90) (-2.61, 4.87) | 3.41 (1.99) (-0.50, 7.32) |
| LS Mean Difference vs. Chemotherapy (SE) | -2.29 (2.35) | |
| 95% CI | (-6.91, 2.34) | |
| Two-sided P-value * | 0.3314 | |
| Hedges'g (95% CI) | -0.12 (-0.37, 0.13) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.14. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Diarhoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 6.5 (14.86) | 9.9 (17.27) |
| Baseline Mean (SD) | 9.4 (19.99) | 7.0 (17.93) |
| Median | 0 | 0 |
| Min : Max | 0 : 67 | 0 : 67 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | -2.9 (19.40) | 3.8 (23.60) |
| Median | 0 | 0 |
| Min : Max | -100 : 33 | -100 : 67 |
| LS Mean (SE) (95% CI) | -2.44 (1.85) (-6.09, 1.21) | 2.45 (2.10) (-1.69, 6.59) |
| LS Mean Difference vs. Chemotherapy (SE) | -4.89 (2.36) | |
| 95% CI | (-9.55, -0.24) | |
| Two-sided P-value * | 0.0396 | |
| Hedges'g (95% CI) | -0.32 (-0.62, -0.01) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.14. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Diarhoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 10.3 (20.84) | 11.1 (23.57) |
| Baseline Mean (SD) | 9.4 (19.99) | 7.0 (17.93) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | -0.4 (23.86) | 4.4 (27.15) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -67 : 100 |
| LS Mean (SE) (95% CI) | 1.28 (2.56) (-3.77, 6.33) | 4.64 (3.25) (-1.78, 11.07) |
| LS Mean Difference vs. Chemotherapy (SE) | -3.36 (3.87) | |
| 95% CI | (-11.01, 4.29) | |
| Two-sided P-value * | 0.3866 | |
| Hedges'g (95% CI) | -0.16 (-0.52, 0.21) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.14. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Diarhoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 13.3 (22.98) | 11.1 (25.27) |
| Baseline Mean (SD) | 9.4 (19.99) | 7.0 (17.93) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 70/0 | 29/1 |
| Mean (SD) | 4.8 (25.56) | 5.6 (29.14) |
| Median | 0 | 0 |
| Min : Max | -33 : 100 | -33 : 100 |
| LS Mean (SE) (95% CI) | 4.79 (3.03) (-1.21, 10.78) | 3.72 (4.50) (-5.21, 12.64) |
| LS Mean Difference vs. Chemotherapy (SE) | 1.07 (5.21) | |
| 95% CI | (-9.27, 11.40) | |
| Two-sided P-value * | 0.8379 | |
| Hedges'g (95% CI) | 0.04 (-0.38, 0.47) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.14. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Diarhoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 16.4 (24.05) | 7.2 (14.06) |
| Baseline Mean (SD) | 9.4 (19.99) | 7.0 (17.93) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 33 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 7.7 (28.80) | 0.0 (17.41) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -33 : 33 |
| LS Mean (SE) (95% CI) | 8.28 (3.00) (2.34, 14.23) | 0.60 (4.51) (-8.34, 9.53) |
| LS Mean Difference vs. Chemotherapy (SE) | 7.69 (5.20) | |
| 95% CI | (-2.64, 18.01) | |
| Two-sided P-value * | 0.1426 | |
| Hedges'g (95% CI) | 0.35 (-0.13, 0.84) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.14. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Diarhoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 10.6 (17.18) | 11.1 (16.41) |
| Baseline Mean (SD) | 9.4 (19.99) | 7.0 (17.93) |
| Median | 0 | 0 |
| Min : Max | 0 : 67 | 0 : 33 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 1.4 (25.02) | 5.6 (19.25) |
| Median | 0 | 0 |
| Min : Max | -100 : 33 | -33 : 33 |
| LS Mean (SE) (95% CI) | 1.60 (2.73) (-3.82, 7.03) | 4.16 (5.03) (-5.89, 14.22) |
| LS Mean Difference vs. Chemotherapy (SE) | -2.56 (5.54) | |
| 95% CI | (-13.64, 8.52) | |
| Two-sided P-value * | 0.6458 | |
| Hedges'g (95% CI) | -0.14 (-0.78, 0.49) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.15. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Financial Problems
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| OVERALL | | |
| n | 142 | 115 |
| Mean (SD) | 26.0 (30.18) | 27.5 (30.73) |
| Baseline Mean (SD) | 28.4 (33.91) | 30.1 (34.76) |
| Median | 12 | 25 |
| Min : Max | 0 : 100 | 0 : 100 |
| Overall Absolute Change from BASELINE | | |
| n | 142 | 115 |
| Mean (SD) | -2.4 (25.46) | -2.6 (22.81) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -67 : 67 |
| LS Mean (SE) (95% CI) | -4.58 (2.64) (-9.78, 0.62) | -1.42 (3.13) (-7.59, 4.75) |
| LS Mean Difference vs. Chemotherapy (SE) | -3.16 (3.45) | |
| 95% CI | (-9.97, 3.65) | |
| Two-sided P-value * | 0.3613 | |
| Hedges'g (95% CI) | -0.11 (-0.36, 0.13) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.15. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Financial Problems
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | 25.1 (32.54) | 26.8 (33.29) |
| Baseline Mean (SD) | 28.4 (33.91) | 30.1 (34.76) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 2 DAY 1 | | |
| n/n1 | 142/0 | 113/0 |
| Mean (SD) | -3.3 (24.57) | -2.9 (23.38) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -67 : 100 |
| LS Mean (SE) (95% CI) | -5.47 (2.46) (-10.31, -0.63) | -4.19 (2.50) (-9.12, 0.74) |
| LS Mean Difference vs. Chemotherapy (SE) | -1.28 (2.78) | |
| 95% CI | (-6.76, 4.19) | |
| Two-sided P-value * | 0.6453 | |
| Hedges'g (95% CI) | -0.06 (-0.30, 0.19) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.15. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Financial Problems
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | 23.2 (31.39) | 28.2 (33.64) |
| Baseline Mean (SD) | 28.4 (33.91) | 30.1 (34.76) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 3 DAY 1 | | |
| n/n1 | 102/0 | 70/1 |
| Mean (SD) | -6.5 (30.05) | -5.2 (29.09) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -100 : 67 |
| LS Mean (SE) (95% CI) | -6.86 (2.94) (-12.65, -1.07) | -5.64 (3.31) (-12.15, 0.88) |
| LS Mean Difference vs. Chemotherapy (SE) | -1.22 (3.82) | |
| 95% CI | (-8.77, 6.32) | |
| Two-sided P-value * | 0.7494 | |
| Hedges'g (95% CI) | -0.05 (-0.35, 0.25) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.15. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Financial Problems
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | 26.7 (34.73) | 29.6 (37.08) |
| Baseline Mean (SD) | 28.4 (33.91) | 30.1 (34.76) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 4 DAY 1 | | |
| n/n1 | 78/3 | 45/0 |
| Mean (SD) | -1.6 (32.45) | 2.2 (25.03) |
| Median | 0 | 0 |
| Min : Max | -100 : 100 | -67 : 100 |
| LS Mean (SE) (95% CI) | -2.42 (3.29) (-8.91, 4.08) | -0.85 (4.00) (-8.74, 7.04) |
| LS Mean Difference vs. Chemotherapy (SE) | -1.57 (4.69) | |
| 95% CI | (-10.84, 7.71) | |
| Two-sided P-value * | 0.7389 | |
| Hedges'g (95% CI) | -0.06 (-0.43, 0.30) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.15. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Financial Problems
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 5 DAY 1 | | |
| n/n1 | 69/1 | 29/1 |
| Mean (SD) | 21.9 (27.74) | 36.7 (40.45) |
| Baseline Mean (SD) | 28.4 (33.91) | 30.1 (34.76) |
| Median | 0 | 33 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 5 DAY 1 | | |
| n/n1 | 69/1 | 29/1 |
| Mean (SD) | -3.8 (28.68) | 5.6 (27.80) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -67 : 67 |
| LS Mean (SE) (95% CI) | -4.78 (3.14) (-10.96, 1.41) | 2.94 (4.04) (-5.03, 10.91) |
| LS Mean Difference vs. Chemotherapy (SE) | -7.72 (4.62) | |
| 95% CI | (-16.85, 1.42) | |
| Two-sided P-value * | 0.0972 | |
| Hedges'g (95% CI) | -0.36 (-0.79, 0.07) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.15. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Financial Problems
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | 23.0 (27.58) | 27.5 (37.13) |
| Baseline Mean (SD) | 28.4 (33.91) | 30.1 (34.76) |
| Median | 0 | 0 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 6 DAY 1 | | |
| n/n1 | 60/1 | 23/0 |
| Mean (SD) | -2.7 (31.21) | -1.4 (32.53) |
| Median | 0 | 0 |
| Min : Max | -100 : 67 | -100 : 67 |
| LS Mean (SE) (95% CI) | -3.32 (3.55) (-10.34, 3.70) | -2.35 (5.05) (-12.34, 7.64) |
| LS Mean Difference vs. Chemotherapy (SE) | -0.98 (5.76) | |
| 95% CI | (-12.39, 10.44) | |
| Two-sided P-value * | 0.8659 | |
| Hedges'g (95% CI) | -0.04 (-0.52, 0.44) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 9.4.15. Least Square Mean Estimates of Changes from Baseline of EORTC QLQ-C30 Financial Problems
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | 22.0 (28.89) | 30.6 (36.12) |
| Baseline Mean (SD) | 28.4 (33.91) | 30.1 (34.76) |
| Median | 0 | 17 |
| Min : Max | 0 : 100 | 0 : 100 |
| Absolute Change from BASELINE to CYCLE 7 DAY 1 | | |
| n/n1 | 46/1 | 12/0 |
| Mean (SD) | -1.4 (30.26) | 5.6 (27.83) |
| Median | 0 | 0 |
| Min : Max | -67 : 67 | -33 : 67 |
| LS Mean (SE) (95% CI) | -4.64 (3.69) (-11.93, 2.66) | 1.56 (5.81) (-9.95, 13.07) |
| LS Mean Difference vs. Chemotherapy (SE) | -6.20 (6.50) | |
| 95% CI | (-19.10, 6.70) | |
| Two-sided P-value * | 0.3426 | |
| Hedges'g (95% CI) | -0.30 (-0.94, 0.34) | |

Data cut-off as of Jan 4th, 2021.
n/n1 (where n is number of patients with data available and n1 is number of patients imputed by LOCF)
Note: LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only.
* The dependent variable for the Mixed Model Repeated Measures (MMRM) model is change from baseline of PRO scores and the predictors are the corresponding baseline PROscores, treatment, visit, geographic region, Histology, treatment by visit, and baseline PRO scores by visit interactions.
Scheduled visits with less than 10 patients in either arm, unscheduled visits, and off-treatment visits are not included in the analysis.

Table 12.2.1. Time to First Any Treatment-Emergent Adverse Events
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 173 (88.7%) | 152 (88.4%) |
| Censored Patients, n (%) | 22 (11.3%) | 20 (11.6%) |
| Median (95% CI), (Months) [a] | 0.56 (0.39, 0.72) | 0.23 (0.13, 0.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0009 | |
| HR (95% CI) [c] | 0.685 (0.549, 0.857) | |
| HR P-Value [c] | 0.0009 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 11.8 (7.5, 17.3) | 9.9 (5.5, 16.0) |
| 12 months | 7.3 (3.7, 12.5) | 0.0 (NE, NE) |
| 18 months | 5.8 (2.5, 11.2) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.2. Time to First Any Serious Treatment-Emergent Adverse Events
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 56 (28.7%) | 52 (30.2%) |
| Censored Patients, n (%) | 139 (71.3%) | 120 (69.8%) |
| Median (95% CI), (Months) [a] | NE (13.63, NE) | NE (7.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1887 | |
| HR (95% CI) [c] | 0.774 (0.528, 1.135) | |
| HR P-Value [c] | 0.1898 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.5 (63.6, 78.1) | 64.2 (54.3, 72.5) |
| 12 months | 62.5 (52.3, 71.1) | 57.4 (44.5, 68.4) |
| 18 months | 53.7 (40.6, 65.1) | 57.4 (44.5, 68.4) |
| 24 months | 53.7 (40.6, 65.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 94 (48.2%) | 87 (50.6%) |
| Censored Patients, n (%) | 101 (51.8%) | 85 (49.4%) |
| Median (95% CI), (Months) [a] | 7.16 (4.80, 13.83) | 3.61 (1.87, 11.56) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0165 | |
| HR (95% CI) [c] | 0.694 (0.515, 0.936) | |
| HR P-Value [c] | 0.0165 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.9 (45.9, 61.3) | 45.3 (36.5, 53.7) |
| 12 months | 45.5 (36.5, 54.0) | 29.7 (12.5, 49.2) |
| 18 months | 33.2 (22.8, 44.0) | 29.7 (12.5, 49.2) |
| 24 months | 29.5 (18.4, 41.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3)
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 24 (12.3%) | 0 |
| Censored Patients, n (%) | 171 (87.7%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| HR (95% CI) [c] | 24000477 (0.000, NE) | |
| HR P-Value [c] | 0.9881 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.3 (77.9, 90.3) | 100.0 (100.0, 100.0) |
| 12 months | 82.6 (74.4, 88.4) | 100.0 (100.0, 100.0) |
| 18 months | 78.5 (66.0, 86.9) | 100.0 (100.0, 100.0) |
| 24 months | 78.5 (66.0, 86.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2)
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 3 (1.5%) | 0 |
| Censored Patients, n (%) | 192 (98.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1033 | |
| HR (95% CI) [c] | 26324080 (0.000, NE) | |
| HR P-Value [c] | 0.9957 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 98.5 (95.3, 99.5) | 100.0 (100.0, 100.0) |
| 12 months | 98.5 (95.3, 99.5) | 100.0 (100.0, 100.0) |
| 18 months | 98.5 (95.3, 99.5) | 100.0 (100.0, 100.0) |
| 24 months | 98.5 (95.3, 99.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2)
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3476 | |
| HR (95% CI) [c] | 26258353 (0.000, NE) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.5 (96.4, 99.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 20 (10.3%) | 8 (4.7%) |
| Censored Patients, n (%) | 175 (89.7%) | 164 (95.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2754 | |
| HR (95% CI) [c] | 1.588 (0.686, 3.676) | |
| HR P-Value [c] | 0.2799 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.2 (82.1, 93.7) | 95.0 (89.6, 97.7) |
| 12 months | 85.2 (76.6, 90.9) | 90.0 (73.5, 96.5) |
| 18 months | 74.6 (58.8, 85.1) | 90.0 (73.5, 96.5) |
| 24 months | 74.6 (58.8, 85.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Number of deaths, n (%) | 111 (61.7%) | 116 (71.2%) |
| Number of censored patients, n (%) | 69 (38.3%) | 47 (28.8%) |
| Median (95% CI), (Months) [a] | 12.3 (8.0, 14.6) | 8.0 (6.9, 9.5) |
| Stratified log-rank test 1-sided p-value [b] | 0.00408 | |
| HR (95% CI) [c] | 0.703 (0.541, 0.914) | |
| HR P-Value [c] | 0.0084 | |
| Heterogeneity p-value [d] | 0.3143 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 65.3 (57.8, 71.8) | 64.1 (55.8, 71.2) |
| 12 months | 52.9 (45.2, 60.1) | 33.2 (25.4, 41.2) |
| 18 months | 31.0 (22.9, 39.4) | 16.4 (10.1, 24.0) |
| 24 months | 20.9 (12.9, 30.1) | 9.4 (4.0, 17.5) |
| 30 months | 20.9 (12.9, 30.1) | 9.4 (4.0, 17.5) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Number of deaths, n (%) | 8 (50.0%) | 15 (75.0%) |
| Number of censored patients, n (%) | 8 (50.0%) | 5 (25.0%) |
| Median (95% CI), (Months) [a] | 19.1 (7.0, 30.4) | 11.2 (3.2, 13.8) |
| Stratified log-rank test 1-sided p-value [b] | 0.02629 | |
| HR (95% CI) [c] | 0.417 (0.168, 1.037) | |
| HR P-Value [c] | 0.0598 | |
| Heterogeneity p-value [d] | 0.3143 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (52.5, 93.5) | 58.4 (33.8, 76.7) |
| 12 months | 61.9 (33.9, 80.8) | 35.1 (14.7, 56.4) |
| 18 months | 61.9 (33.9, 80.8) | 18.7 (3.9, 42.1) |
| 24 months | 46.4 (15.3, 73.1) | 18.7 (3.9, 42.1) |
| 30 months | 46.4 (15.3, 73.1) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Number of deaths, n (%) | 82 (60.3%) | 89 (72.4%) |
| Number of censored patients, n (%) | 54 (39.7%) | 34 (27.6%) |
| Median (95% CI), (Months) [a] | 12.7 (8.9, 15.2) | 8.0 (6.5, 10.0) |
| Stratified log-rank test 1-sided p-value [b] | 0.00494 | |
| HR (95% CI) [c] | 0.674 (0.499, 0.911) | |
| HR P-Value [c] | 0.0103 | |
| Heterogeneity p-value [d] | 0.9051 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 66.9 (58.3, 74.1) | 61.9 (52.4, 70.1) |
| 12 months | 54.3 (45.4, 62.4) | 33.4 (24.6, 42.4) |
| 18 months | 32.5 (23.3, 42.0) | 17.2 (10.1, 25.9) |
| 24 months | 25.5 (15.9, 36.2) | 14.7 (7.7, 23.9) |
| 30 months | 25.5 (15.9, 36.2) | 11.1 (4.3, 21.5) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Number of deaths, n (%) | 37 (61.7%) | 42 (70.0%) |
| Number of censored patients, n (%) | 23 (38.3%) | 18 (30.0%) |
| Median (95% CI), (Months) [a] | 12.1 (7.0, 19.7) | 8.8 (6.4, 11.3) |
| Stratified log-rank test 1-sided p-value [b] | 0.03734 | |
| HR (95% CI) [c] | 0.664 (0.422, 1.044) | |
| HR P-Value [c] | 0.0764 | |
| Heterogeneity p-value [d] | 0.9051 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 65.6 (51.9, 76.3) | 66.7 (52.4, 77.5) |
| 12 months | 51.4 (37.4, 63.8) | 32.7 (19.6, 46.5) |
| 18 months | 36.8 (22.5, 51.1) | 14.8 (5.5, 28.4) |
| 24 months | 20.4 (8.4, 36.2) | 3.7 (0.3, 15.5) |
| 30 months | 20.4 (8.4, 36.2) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Number of deaths, n (%) | 12 (54.5%) | 15 (60.0%) |
| Number of censored patients, n (%) | 10 (45.5%) | 10 (40.0%) |
| Median (95% CI), (Months) [a] | 15.3 (3.9, NE) | 7.0 (4.5, 17.3) |
| Stratified log-rank test 1-sided p-value [b] | 0.15826 | |
| HR (95% CI) [c] | 0.679 (0.317, 1.455) | |
| HR P-Value [c] | 0.3195 | |
| Heterogeneity p-value [d] | 0.6927 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (44.6, 83.4) | 62.6 (38.8, 79.3) |
| 12 months | 62.5 (38.5, 79.3) | 36.1 (16.0, 56.7) |
| 18 months | 35.5 (14.1, 57.8) | 24.1 (7.9, 45.0) |
| 24 months | 35.5 (14.1, 57.8) | 24.1 (7.9, 45.0) |
| 30 months | 35.5 (14.1, 57.8) | 24.1 (7.9, 45.0) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Number of deaths, n (%) | 26 (66.7%) | 23 (63.9%) |
| Number of censored patients, n (%) | 13 (33.3%) | 13 (36.1%) |
| Median (95% CI), (Months) [a] | 12.5 (7.0, 20.8) | 8.7 (5.8, 13.2) |
| Stratified log-rank test 1-sided p-value [b] | 0.07542 | |
| HR (95% CI) [c] | 0.655 (0.366, 1.170) | |
| HR P-Value [c] | 0.1529 | |
| Heterogeneity p-value [d] | 0.6927 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 71.1 (53.9, 82.8) | 67.6 (48.1, 81.1) |
| 12 months | 51.2 (34.1, 66.0) | 38.9 (20.3, 57.2) |
| 18 months | 36.5 (20.2, 53.0) | 11.7 (2.2, 30.1) |
| 24 months | 22.8 (9.2, 40.1) | 5.8 (0.4, 22.9) |
| 30 months | 22.8 (9.2, 40.1) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Number of deaths, n (%) | 44 (57.9%) | 49 (74.2%) |
| Number of censored patients, n (%) | 32 (42.1%) | 17 (25.8%) |
| Median (95% CI), (Months) [a] | 13.9 (8.9, 15.8) | 8.2 (5.7, 11.3) |
| Stratified log-rank test 1-sided p-value [b] | 0.00423 | |
| HR (95% CI) [c] | 0.578 (0.383, 0.873) | |
| HR P-Value [c] | 0.0091 | |
| Heterogeneity p-value [d] | 0.6927 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 69.7 (58.1, 78.7) | 63.1 (49.9, 73.8) |
| 12 months | 58.6 (46.5, 68.8) | 33.9 (21.9, 46.3) |
| 18 months | 32.7 (20.1, 46.0) | 10.9 (3.5, 23.1) |
| 24 months | 25.2 (12.9, 39.6) | 10.9 (3.5, 23.1) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Number of deaths, n (%) | 37 (62.7%) | 44 (78.6%) |
| Number of censored patients, n (%) | 22 (37.3%) | 12 (21.4%) |
| Median (95% CI), (Months) [a] | 7.5 (5.3, 17.3) | 7.7 (5.4, 10.5) |
| Stratified log-rank test 1-sided p-value [b] | 0.23576 | |
| HR (95% CI) [c] | 0.852 (0.549, 1.320) | |
| HR P-Value [c] | 0.4720 | |
| Heterogeneity p-value [d] | 0.6927 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 58.9 (45.2, 70.3) | 62.0 (47.9, 73.3) |
| 12 months | 45.0 (31.5, 57.6) | 29.4 (17.8, 42.0) |
| 18 months | 32.2 (18.4, 46.9) | 22.7 (12.2, 35.0) |
| 24 months | 12.1 (1.2, 36.5) | 7.1 (0.8, 23.8) |
| 30 months | 12.1 (1.2, 36.5) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Number of deaths, n (%) | 95 (59.0%) | 97 (70.8%) |
| Number of censored patients, n (%) | 66 (41.0%) | 40 (29.2%) |
| Median (95% CI), (Months) [a] | 12.9 (8.9, 15.3) | 8.2 (7.4, 10.3) |
| Stratified log-rank test 1-sided p-value [b] | 0.00357 | |
| HR (95% CI) [c] | 0.678 (0.510, 0.901) | |
| HR P-Value [c] | 0.0075 | |
| Heterogeneity p-value [d] | 0.9571 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (60.4, 74.8) | 67.2 (58.3, 74.6) |
| 12 months | 53.7 (45.5, 61.3) | 34.5 (25.8, 43.2) |
| 18 months | 35.3 (26.5, 44.2) | 16.3 (9.4, 24.7) |
| 24 months | 25.2 (16.0, 35.5) | 12.5 (6.3, 21.1) |
| 30 months | 25.2 (16.0, 35.5) | 9.4 (3.5, 18.9) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Number of deaths, n (%) | 24 (68.6%) | 34 (73.9%) |
| Number of censored patients, n (%) | 11 (31.4%) | 12 (26.1%) |
| | | |
| Median (95% CI), (Months) [a] | 12.1 (4.7, 17.9) | 6.2 (4.3, 11.4) |
| Stratified log-rank test 1-sided p-value [b] | 0.09875 | |
| HR (95% CI) [c] | 0.709 (0.419, 1.199) | |
| HR P-Value [c] | 0.1998 | |
| Heterogeneity p-value [d] | 0.9571 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 59.0 (40.8, 73.3) | 51.6 (35.5, 65.6) |
| 12 months | 52.8 (34.9, 67.9) | 30.1 (16.6, 44.7) |
| 18 months | 28.1 (12.6, 46.1) | 17.6 (7.1, 31.8) |
| 24 months | 14.1 (2.9, 33.8) | 5.9 (0.5, 21.7) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Number of deaths, n (%) | 49 (55.1%) | 60 (70.6%) |
| Number of censored patients, n (%) | 40 (44.9%) | 25 (29.4%) |
| Median (95% CI), (Months) [a] | 15.3 (8.1, 20.4) | 6.7 (4.5, 8.7) |
| Stratified log-rank test 1-sided p-value [b] | 0.00015 | |
| HR (95% CI) [c] | 0.498 (0.340, 0.732) | |
| HR P-Value [c] | 0.0004 | |
| Heterogeneity p-value [d] | 0.0278 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 70.8 (60.1, 79.0) | 52.7 (40.9, 63.2) |
| 12 months | 54.0 (42.6, 64.1) | 24.8 (14.8, 36.1) |
| 18 months | 39.3 (26.4, 51.9) | 11.6 (4.5, 22.3) |
| 24 months | 25.0 (12.6, 39.5) | 7.7 (1.9, 19.1) |
| 30 months | 25.0 (12.6, 39.5) | 7.7 (1.9, 19.1) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Number of deaths, n (%) | 70 (65.4%) | 71 (72.4%) |
| Number of censored patients, n (%) | 37 (34.6%) | 27 (27.6%) |
| Median (95% CI), (Months) [a] | 12.3 (6.6, 14.6) | 9.4 (7.7, 11.8) |
| Stratified log-rank test 1-sided p-value [b] | 0.17683 | |
| HR (95% CI) [c] | 0.855 (0.614, 1.190) | |
| HR P-Value [c] | 0.3529 | |
| Heterogeneity p-value [d] | 0.0278 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 63.1 (53.1, 71.5) | 72.1 (61.8, 80.1) |
| 12 months | 53.0 (43.0, 62.1) | 39.7 (29.4, 49.7) |
| 18 months | 30.2 (20.6, 40.3) | 20.7 (12.2, 30.6) |
| 24 months | 22.4 (12.7, 33.8) | 12.1 (4.5, 23.6) |
| 30 months | 22.4 (12.7, 33.8) | 8.0 (1.9, 20.1) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Number of deaths, n (%) | 37 (44.6%) | 45 (65.2%) |
| Number of censored patients, n (%) | 46 (55.4%) | 24 (34.8%) |
| Median (95% CI), (Months) [a] | 17.9 (13.5, NE) | 9.6 (8.0, 13.2) |
| Stratified log-rank test 1-sided p-value [b] | 0.00070 | |
| HR (95% CI) [c] | 0.495 (0.319, 0.769) | |
| HR P-Value [c] | 0.0017 | |
| Heterogeneity p-value [d] | 0.0791 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 78.2 (67.6, 85.6) | 76.4 (63.9, 85.0) |
| 12 months | 67.0 (55.3, 76.3) | 40.6 (27.4, 53.4) |
| 18 months | 49.0 (35.1, 61.4) | 19.9 (9.4, 33.3) |
| 24 months | 41.7 (27.0, 55.7) | 13.3 (4.7, 26.3) |
| 30 months | 41.7 (27.0, 55.7) | 9.9 (2.8, 22.6) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Number of deaths, n (%) | 82 (72.6%) | 86 (75.4%) |
| Number of censored patients, n (%) | 31 (27.4%) | 28 (24.6%) |
| Median (95% CI), (Months) [a] | 7.7 (5.5, 12.1) | 7.0 (5.4, 8.5) |
| Stratified log-rank test 1-sided p-value [b] | 0.11496 | |
| HR (95% CI) [c] | 0.830 (0.613, 1.125) | |
| HR P-Value [c] | 0.2297 | |
| Heterogeneity p-value [d] | 0.0791 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 58.1 (48.4, 66.6) | 55.7 (45.7, 64.5) |
| 12 months | 43.9 (34.5, 53.0) | 28.7 (20.2, 37.9) |
| 18 months | 23.7 (15.1, 33.3) | 14.8 (8.2, 23.2) |
| 24 months | 9.4 (2.9, 20.5) | 6.5 (0.9, 20.5) |
| 30 months | NE (NE, NE) | 6.5 (0.9, 20.5) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Number of deaths, n (%) | 68 (58.1%) | 72 (74.2%) |
| Number of censored patients, n (%) | 49 (41.9%) | 25 (25.8%) |
| Median (95% CI), (Months) [a] | 13.3 (8.9, 17.0) | 7.7 (6.2, 9.5) |
| Stratified log-rank test 1-sided p-value [b] | 0.00095 | |
| HR (95% CI) [c] | 0.590 (0.422, 0.826) | |
| HR P-Value [c] | 0.0021 | |
| Heterogeneity p-value [d] | 0.1965 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 68.3 (59.0, 75.9) | 61.8 (51.0, 70.8) |
| 12 months | 54.1 (44.3, 62.8) | 30.0 (20.5, 40.1) |
| 18 months | 36.8 (26.6, 47.1) | 14.7 (7.4, 24.5) |
| 24 months | 24.7 (13.7, 37.4) | 0.0 (NE, NE) |
| 30 months | 24.7 (13.7, 37.4) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Number of deaths, n (%) | 50 (64.9%) | 59 (68.6%) |
| Number of censored patients, n (%) | 27 (35.1%) | 27 (31.4%) |
| | | |
| Median (95% CI), (Months) [a] | 12.1 (6.2, 15.3) | 8.8 (6.9, 11.8) |
| Stratified log-rank test 1-sided p-value [b] | 0.15379 | |
| HR (95% CI) [c] | 0.822 (0.564, 1.199) | |
| HR P-Value [c] | 0.3094 | |
| Heterogeneity p-value [d] | 0.1965 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 63.1 (51.2, 72.8) | 65.5 (53.8, 74.9) |
| 12 months | 51.5 (39.5, 62.2) | 37.4 (26.2, 48.6) |
| 18 months | 28.6 (16.8, 41.6) | 19.1 (10.2, 30.2) |
| 24 months | 19.1 (8.7, 32.4) | 14.3 (6.5, 25.2) |
| 30 months | 19.1 (8.7, 32.4) | 11.5 (4.4, 22.4) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Number of deaths, n (%) | 12 (46.2%) | 12 (63.2%) |
| Number of censored patients, n (%) | 14 (53.8%) | 7 (36.8%) |
| | | |
| Median (95% CI), (Months) [a] | 15.8 (11.2, NE) | 11.8 (6.9, 14.9) |
| Stratified log-rank test 1-sided p-value [b] | 0.01691 | |
| HR (95% CI) [c] | 0.420 (0.184, 0.957) | |
| HR P-Value [c] | 0.0390 | |
| Heterogeneity p-value [d] | 0.8592 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 88.5 (68.4, 96.1) | 82.6 (55.2, 94.1) |
| 12 months | 70.4 (47.2, 84.8) | 43.3 (17.0, 67.4) |
| 18 months | 36.9 (14.8, 59.4) | 13.0 (1.0, 40.9) |
| 24 months | 36.9 (14.8, 59.4) | 13.0 (1.0, 40.9) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Number of deaths, n (%) | 73 (61.3%) | 84 (75.7%) |
| Number of censored patients, n (%) | 46 (38.7%) | 27 (24.3%) |
| Median (95% CI), (Months) [a] | 12.5 (7.5, 15.3) | 7.7 (6.4, 9.8) |
| Stratified log-rank test 1-sided p-value [b] | 0.01388 | |
| HR (95% CI) [c] | 0.703 (0.513, 0.963) | |
| HR P-Value [c] | 0.0284 | |
| Heterogeneity p-value [d] | 0.8592 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 65.2 (55.8, 73.0) | 62.5 (52.6, 71.0) |
| 12 months | 52.3 (42.8, 61.0) | 30.9 (22.1, 40.1) |
| 18 months | 34.8 (25.0, 44.8) | 17.6 (10.3, 26.5) |
| 24 months | 21.6 (11.7, 33.4) | 11.2 (4.8, 20.6) |
| 30 months | 21.6 (11.7, 33.4) | 11.2 (4.8, 20.6) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Number of deaths, n (%) | 14 (70.0%) | 11 (52.4%) |
| Number of censored patients, n (%) | 6 (30.0%) | 10 (47.6%) |
| | | |
| Median (95% CI), (Months) [a] | 7.0 (3.9, 15.0) | 6.5 (4.4, 8.8) |
| Stratified log-rank test 1-sided p-value [b] | 0.20065 | |
| HR (95% CI) [c] | 0.706 (0.312, 1.598) | |
| HR P-Value [c] | 0.4035 | |
| Heterogeneity p-value [d] | 0.8592 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 59.2 (34.7, 77.2) | 51.8 (24.3, 73.7) |
| 12 months | 48.5 (25.4, 68.2) | 22.2 (4.0, 49.5) |
| 18 months | 27.7 (9.3, 50.0) | 11.1 (0.7, 37.9) |
| 24 months | 20.8 (5.4, 42.9) | NE (NE, NE) |
| 30 months | 20.8 (5.4, 42.9) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Number of deaths, n (%) | 20 (64.5%) | 24 (75.0%) |
| Number of censored patients, n (%) | 11 (35.5%) | 8 (25.0%) |
| | | |
| Median (95% CI), (Months) [a] | 10.3 (3.4, 22.8) | 7.6 (5.2, 13.2) |
| Stratified log-rank test 1-sided p-value [b] | 0.18954 | |
| HR (95% CI) [c] | 0.759 (0.408, 1.410) | |
| HR P-Value [c] | 0.3823 | |
| Heterogeneity p-value [d] | 0.8592 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 58.1 (39.0, 73.1) | 61.3 (42.0, 75.8) |
| 12 months | 46.8 (28.2, 63.4) | 41.4 (24.0, 58.0) |
| 18 months | 31.2 (12.2, 52.4) | 17.2 (5.2, 35.2) |
| 24 months | 23.4 (6.9, 45.5) | 0.0 (NE, NE) |
| 30 months | 23.4 (6.9, 45.5) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Number of events, n (%) | 148 (82.2%) | 146 (89.6%) |
| Progressive Disease, n (%) | 126 (70.0%) | 115 (70.6%) |
| Number of deaths, n (%) | 22 (12.2%) | 31 (19.0%) |
| Number of censored patients, n (%) | 32 (17.8%) | 17 (10.4%) |
| | | |
| Median (95% CI), (Months) [a] | 2.8 (1.8, 3.9) | 2.9 (2.7, 4.0) |
| Stratified log-rank test 1-sided p-value [b] | 0.02591 | |
| HR (95% CI) [c] | 0.796 (0.631, 1.005) | |
| HR P-Value [c] | 0.0553 | |
| Heterogeneity p-value [d] | 0.0911 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.6 (26.8, 40.6) | 25.4 (18.8, 32.6) |
| 12 months | 21.1 (15.2, 27.7) | 7.4 (3.8, 12.5) |
| 18 months | 13.7 (8.4, 20.4) | NE (NE, NE) |
| 24 months | 8.7 (4.0, 15.8) | NE (NE, NE) |
| 30 months | 4.4 (0.6, 14.8) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Number of events, n (%) | 12 (75.0%) | 19 (95.0%) |
| Progressive Disease, n (%) | 9 (56.3%) | 15 (75.0%) |
| Number of deaths, n (%) | 3 (18.8%) | 4 (20.0%) |
| Number of censored patients, n (%) | 4 (25.0%) | 1 (5.0%) |
| Median (95% CI), (Months) [a] | 4.0 (1.8, 30.4) | 2.5 (1.4, 4.6) |
| Stratified log-rank test 1-sided p-value [b] | 0.02007 | |
| HR (95% CI) [c] | 0.451 (0.206, 0.986) | |
| HR P-Value [c] | 0.0461 | |
| Heterogeneity p-value [d] | 0.0911 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.8 (19.8, 65.6) | 20.0 (6.2, 39.3) |
| 12 months | 37.5 (15.4, 59.8) | 13.3 (2.6, 32.7) |
| 18 months | 25.0 (5.5, 51.5) | 0.0 (NE, NE) |
| 24 months | 25.0 (5.5, 51.5) | 0.0 (NE, NE) |
| 30 months | 25.0 (5.5, 51.5) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Number of events, n (%) | 111 (81.6%) | 114 (92.7%) |
| Progressive Disease, n (%) | 90 (66.2%) | 84 (68.3%) |
| Number of deaths, n (%) | 21 (15.4%) | 30 (24.4%) |
| Number of censored patients, n (%) | 25 (18.4%) | 9 (7.3%) |
| | | |
| Median (95% CI), (Months) [a] | 3.8 (2.7, 5.6) | 3.0 (2.2, 4.1) |
| Stratified log-rank test 1-sided p-value [b] | 0.00170 | |
| HR (95% CI) [c] | 0.672 (0.514, 0.879) | |
| HR P-Value [c] | 0.0037 | |
| Heterogeneity p-value [d] | 0.1721 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.9 (30.7, 47.0) | 27.7 (19.9, 36.1) |
| 12 months | 26.0 (18.8, 33.8) | 9.9 (5.2, 16.2) |
| 18 months | 15.8 (9.3, 23.9) | NE (NE, NE) |
| 24 months | 9.2 (3.7, 17.9) | NE (NE, NE) |
| 30 months | 4.6 (0.6, 16.0) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Number of events, n (%) | 49 (81.7%) | 51 (85.0%) |
| Progressive Disease, n (%) | 45 (75.0%) | 46 (76.7%) |
| Number of deaths, n (%) | 4 (6.7%) | 5 (8.3%) |
| Number of censored patients, n (%) | 11 (18.3%) | 9 (15.0%) |
| Median (95% CI), (Months) [a] | 1.8 (1.4, 2.8) | 2.9 (2.7, 3.5) |
| Stratified log-rank test 1-sided p-value [b] | 0.44299 | |
| HR (95% CI) [c] | 1.033 (0.694, 1.539) | |
| HR P-Value [c] | 0.8724 | |
| Heterogeneity p-value [d] | 0.1721 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.1 (14.1, 35.7) | 18.2 (9.2, 29.6) |
| 12 months | 14.4 (6.2, 25.8) | 3.0 (0.3, 12.8) |
| 18 months | 14.4 (6.2, 25.8) | 0.0 (NE, NE) |
| 24 months | 14.4 (6.2, 25.8) | 0.0 (NE, NE) |
| 30 months | 14.4 (6.2, 25.8) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Number of events, n (%) | 19 (86.4%) | 20 (80.0%) |
| Progressive Disease, n (%) | 16 (72.7%) | 16 (64.0%) |
| Number of deaths, n (%) | 3 (13.6%) | 4 (16.0%) |
| Number of censored patients, n (%) | 3 (13.6%) | 5 (20.0%) |
| Median (95% CI), (Months) [a] | 2.3 (1.6, 5.7) | 2.8 (1.6, 6.5) |
| Stratified log-rank test 1-sided p-value [b] | 0.48355 | |
| HR (95% CI) [c] | 1.016 (0.535, 1.931) | |
| HR P-Value [c] | 0.9610 | |
| Heterogeneity p-value [d] | 0.5576 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.3 (11.1, 46.4) | 36.4 (17.4, 55.7) |
| 12 months | 20.5 (6.2, 40.3) | 15.6 (4.0, 34.1) |
| 18 months | 13.6 (2.7, 33.5) | NE (NE, NE) |
| 24 months | 13.6 (2.7, 33.5) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Number of events, n (%) | 33 (84.6%) | 28 (77.8%) |
| Progressive Disease, n (%) | 30 (76.9%) | 25 (69.4%) |
| Number of deaths, n (%) | 3 (7.7%) | 3 (8.3%) |
| Number of censored patients, n (%) | 6 (15.4%) | 8 (22.2%) |
| | | |
| Median (95% CI), (Months) [a] | 2.7 (1.4, 3.9) | 2.8 (1.7, 4.1) |
| Stratified log-rank test 1-sided p-value [b] | 0.42881 | |
| HR (95% CI) [c] | 0.963 (0.576, 1.609) | |
| HR P-Value [c] | 0.8848 | |
| Heterogeneity p-value [d] | 0.5576 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.3 (13.7, 40.8) | 20.0 (8.1, 35.6) |
| 12 months | 15.4 (6.0, 28.6) | 12.0 (3.3, 26.8) |
| 18 months | 15.4 (6.0, 28.6) | 0.0 (NE, NE) |
| 24 months | 15.4 (6.0, 28.6) | 0.0 (NE, NE) |
| 30 months | 15.4 (6.0, 28.6) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Number of events, n (%) | 61 (80.3%) | 63 (95.5%) |
| Progressive Disease, n (%) | 49 (64.5%) | 48 (72.7%) |
| Number of deaths, n (%) | 12 (15.8%) | 15 (22.7%) |
| Number of censored patients, n (%) | 15 (19.7%) | 3 (4.5%) |
| | | |
| Median (95% CI), (Months) [a] | 3.5 (1.8, 6.8) | 2.8 (1.6, 4.1) |
| Stratified log-rank test 1-sided p-value [b] | 0.00303 | |
| HR (95% CI) [c] | 0.602 (0.417, 0.867) | |
| HR P-Value [c] | 0.0065 | |
| Heterogeneity p-value [d] | 0.5576 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.8 (29.7, 51.5) | 24.1 (14.4, 35.2) |
| 12 months | 27.7 (17.9, 38.3) | 6.4 (2.1, 14.3) |
| 18 months | 17.2 (8.2, 29.0) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Number of events, n (%) | 47 (79.7%) | 54 (96.4%) |
| Progressive Disease, n (%) | 40 (67.8%) | 41 (73.2%) |
| Number of deaths, n (%) | 7 (11.9%) | 13 (23.2%) |
| Number of censored patients, n (%) | 12 (20.3%) | 2 (3.6%) |
| Median (95% CI), (Months) [a] | 2.9 (1.5, 5.5) | 3.2 (2.7, 4.5) |
| Stratified log-rank test 1-sided p-value [b] | 0.14198 | |
| HR (95% CI) [c] | 0.811 (0.547, 1.203) | |
| HR P-Value [c] | 0.2971 | |
| Heterogeneity p-value [d] | 0.5576 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.2 (22.3, 46.4) | 23.6 (13.5, 35.4) |
| 12 months | 22.0 (12.0, 33.8) | 6.1 (1.6, 14.9) |
| 18 months | 11.8 (3.9, 24.4) | 0.0 (NE, NE) |
| 24 months | 11.8 (3.9, 24.4) | 0.0 (NE, NE) |
| 30 months | 11.8 (3.9, 24.4) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Number of events, n (%) | 130 (80.7%) | 126 (92.0%) |
| Progressive Disease, n (%) | 111 (68.9%) | 99 (72.3%) |
| Number of deaths, n (%) | 19 (11.8%) | 27 (19.7%) |
| Number of censored patients, n (%) | 31 (19.3%) | 11 (8.0%) |
| | | |
| Median (95% CI), (Months) [a] | 2.8 (2.3, 4.0) | 3.0 (2.7, 4.1) |
| Stratified log-rank test 1-sided p-value [b] | 0.00323 | |
| HR (95% CI) [c] | 0.707 (0.549, 0.911) | |
| HR P-Value [c] | 0.0072 | |
| Heterogeneity p-value [d] | 0.2068 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.6 (28.2, 43.0) | 24.9 (17.8, 32.6) |
| 12 months | 24.6 (18.0, 31.8) | 8.1 (4.1, 13.9) |
| 18 months | 16.6 (10.4, 24.0) | 0.0 (NE, NE) |
| 24 months | 11.2 (5.5, 19.1) | 0.0 (NE, NE) |
| 30 months | 7.5 (2.2, 17.2) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Number of events, n (%) | 30 (85.7%) | 39 (84.8%) |
| Progressive Disease, n (%) | 24 (68.6%) | 31 (67.4%) |
| Number of deaths, n (%) | 6 (17.1%) | 8 (17.4%) |
| Number of censored patients, n (%) | 5 (14.3%) | 7 (15.2%) |
| Median (95% CI), (Months) [a] | 2.7 (1.4, 5.6) | 2.8 (1.8, 3.2) |
| Stratified log-rank test 1-sided p-value [b] | 0.45833 | |
| HR (95% CI) [c] | 1.028 (0.637, 1.659) | |
| HR P-Value [c] | 0.9101 | |
| Heterogeneity p-value [d] | 0.2068 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.4 (15.4, 44.9) | 24.4 (12.7, 38.2) |
| 12 months | 13.1 (4.2, 27.0) | 8.1 (2.1, 19.4) |
| 18 months | 8.7 (1.8, 22.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Number of events, n (%) | 73 (82.0%) | 75 (88.2%) |
| Progressive Disease, n (%) | 59 (66.3%) | 59 (69.4%) |
| Number of deaths, n (%) | 14 (15.7%) | 16 (18.8%) |
| Number of censored patients, n (%) | 16 (18.0%) | 10 (11.8%) |
| | | |
| Median (95% CI), (Months) [a] | 3.0 (1.8, 4.0) | 2.3 (1.7, 2.8) |
| Stratified log-rank test 1-sided p-value [b] | 0.00179 | |
| HR (95% CI) [c] | 0.615 (0.442, 0.856) | |
| HR P-Value [c] | 0.0039 | |
| Heterogeneity p-value [d] | 0.1121 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.0 (19.9, 38.6) | 12.0 (5.9, 20.5) |
| 12 months | 19.0 (11.2, 28.4) | 2.7 (0.5, 8.3) |
| 18 months | 19.0 (11.2, 28.4) | 0.0 (NE, NE) |
| 24 months | 9.5 (2.4, 22.6) | 0.0 (NE, NE) |
| 30 months | 4.7 (0.4, 18.1) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Number of events, n (%) | 87 (81.3%) | 90 (91.8%) |
| Progressive Disease, n (%) | 76 (71.0%) | 71 (72.4%) |
| Number of deaths, n (%) | 11 (10.3%) | 19 (19.4%) |
| Number of censored patients, n (%) | 20 (18.7%) | 8 (8.2%) |
| Median (95% CI), (Months) [a] | 2.7 (1.6, 4.1) | 4.0 (3.0, 5.2) |
| Stratified log-rank test 1-sided p-value [b] | 0.12406 | |
| HR (95% CI) [c] | 0.840 (0.621, 1.137) | |
| HR P-Value [c] | 0.2593 | |
| Heterogeneity p-value [d] | 0.1121 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.0 (29.7, 48.2) | 34.8 (25.4, 44.4) |
| 12 months | 25.5 (17.4, 34.3) | 12.4 (6.5, 20.3) |
| 18 months | 13.9 (7.3, 22.5) | NE (NE, NE) |
| 24 months | 11.9 (5.7, 20.6) | NE (NE, NE) |
| 30 months | 11.9 (5.7, 20.6) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Number of events, n (%) | 63 (75.9%) | 62 (89.9%) |
| Progressive Disease, n (%) | 56 (67.5%) | 56 (81.2%) |
| Number of deaths, n (%) | 7 (8.4%) | 6 (8.7%) |
| Number of censored patients, n (%) | 20 (24.1%) | 7 (10.1%) |
| | | |
| Median (95% CI), (Months) [a] | 3.9 (2.6, 4.3) | 2.8 (2.1, 3.0) |
| Stratified log-rank test 1-sided p-value [b] | 0.00539 | |
| HR (95% CI) [c] | 0.630 (0.440, 0.903) | |
| HR P-Value [c] | 0.0120 | |
| Heterogeneity p-value [d] | 0.0514 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.5 (26.3, 46.9) | 25.0 (15.2, 36.0) |
| 12 months | 27.3 (18.1, 37.4) | 5.7 (1.5, 13.8) |
| 18 months | 23.1 (14.1, 33.5) | 0.0 (NE, NE) |
| 24 months | 23.1 (14.1, 33.5) | 0.0 (NE, NE) |
| 30 months | 15.4 (4.8, 31.6) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Number of events, n (%) | 97 (85.8%) | 103 (90.4%) |
| Progressive Disease, n (%) | 79 (69.9%) | 74 (64.9%) |
| Number of deaths, n (%) | 18 (15.9%) | 29 (25.4%) |
| Number of censored patients, n (%) | 16 (14.2%) | 11 (9.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.6 (1.6, 3.1) | 3.3 (2.6, 4.1) |
| Stratified log-rank test 1-sided p-value [b] | 0.14709 | |
| HR (95% CI) [c] | 0.861 (0.649, 1.143) | |
| HR P-Value [c] | 0.3012 | |
| Heterogeneity p-value [d] | 0.0514 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.9 (24.4, 41.7) | 24.6 (16.9, 33.1) |
| 12 months | 18.7 (11.7, 27.0) | 9.4 (4.7, 16.1) |
| 18 months | 8.1 (2.9, 16.9) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Number of events, n (%) | 92 (78.6%) | 89 (91.8%) |
| Progressive Disease, n (%) | 77 (65.8%) | 69 (71.1%) |
| Number of deaths, n (%) | 15 (12.8%) | 20 (20.6%) |
| Number of censored patients, n (%) | 25 (21.4%) | 8 (8.2%) |
| | | |
| Median (95% CI), (Months) [a] | 2.8 (1.6, 4.3) | 3.5 (2.9, 4.5) |
| Stratified log-rank test 1-sided p-value [b] | 0.03894 | |
| HR (95% CI) [c] | 0.768 (0.570, 1.034) | |
| HR P-Value [c] | 0.0824 | |
| Heterogeneity p-value [d] | 0.6795 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.9 (29.1, 46.6) | 27.3 (18.7, 36.7) |
| 12 months | 24.4 (16.7, 33.0) | 9.8 (4.7, 17.2) |
| 18 months | 14.2 (6.7, 24.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Number of events, n (%) | 67 (87.0%) | 76 (88.4%) |
| Progressive Disease, n (%) | 57 (74.0%) | 61 (70.9%) |
| Number of deaths, n (%) | 10 (13.0%) | 15 (17.4%) |
| Number of censored patients, n (%) | 10 (13.0%) | 10 (11.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.8 (1.9, 3.9) | 2.7 (1.7, 2.9) |
| Stratified log-rank test 1-sided p-value [b] | 0.03907 | |
| HR (95% CI) [c] | 0.741 (0.529, 1.038) | |
| HR P-Value [c] | 0.0810 | |
| Heterogeneity p-value [d] | 0.6795 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.8 (19.1, 39.2) | 21.7 (13.4, 31.4) |
| 12 months | 18.8 (10.8, 28.5) | 5.9 (2.0, 13.1) |
| 18 months | 13.2 (6.3, 22.6) | 0.0 (NE, NE) |
| 24 months | 10.5 (4.2, 20.2) | 0.0 (NE, NE) |
| 30 months | 7.0 (1.8, 17.4) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Number of events, n (%) | 20 (76.9%) | 16 (84.2%) |
| Progressive Disease, n (%) | 16 (61.5%) | 13 (68.4%) |
| Number of deaths, n (%) | 4 (15.4%) | 3 (15.8%) |
| Number of censored patients, n (%) | 6 (23.1%) | 3 (15.8%) |
| | | |
| Median (95% CI), (Months) [a] | 6.9 (1.9, 13.8) | 4.2 (1.6, 8.3) |
| Stratified log-rank test 1-sided p-value [b] | 0.09698 | |
| HR (95% CI) [c] | 0.639 (0.323, 1.264) | |
| HR P-Value [c] | 0.1978 | |
| Heterogeneity p-value [d] | 0.6165 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.8 (33.3, 70.6) | 35.3 (14.5, 57.0) |
| 12 months | 32.0 (14.7, 50.8) | 15.7 (3.1, 37.4) |
| 18 months | 19.2 (5.5, 39.0) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Number of events, n (%) | 92 (77.3%) | 102 (91.9%) |
| Progressive Disease, n (%) | 80 (67.2%) | 83 (74.8%) |
| Number of deaths, n (%) | 12 (10.1%) | 19 (17.1%) |
| Number of censored patients, n (%) | 27 (22.7%) | 9 (8.1%) |
| | | |
| Median (95% CI), (Months) [a] | 3.0 (2.3, 4.2) | 2.9 (2.6, 3.7) |
| Stratified log-rank test 1-sided p-value [b] | 0.00906 | |
| HR (95% CI) [c] | 0.710 (0.533, 0.945) | |
| HR P-Value [c] | 0.0189 | |
| Heterogeneity p-value [d] | 0.6165 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.8 (27.2, 44.4) | 25.4 (17.6, 34.0) |
| 12 months | 24.5 (16.8, 32.9) | 7.6 (3.4, 14.0) |
| 18 months | 17.8 (10.5, 26.7) | NE (NE, NE) |
| 24 months | 11.9 (5.0, 22.0) | NE (NE, NE) |
| 30 months | 11.9 (5.0, 22.0) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Number of events, n (%) | 19 (95.0%) | 16 (76.2%) |
| Progressive Disease, n (%) | 16 (80.0%) | 10 (47.6%) |
| Number of deaths, n (%) | 3 (15.0%) | 6 (28.6%) |
| Number of censored patients, n (%) | 1 (5.0%) | 5 (23.8%) |
| | | |
| Median (95% CI), (Months) [a] | 2.2 (1.3, 4.1) | 2.3 (1.7, 5.4) |
| Stratified log-rank test 1-sided p-value [b] | 0.39833 | |
| HR (95% CI) [c] | 0.923 (0.456, 1.868) | |
| HR P-Value [c] | 0.8228 | |
| Heterogeneity p-value [d] | 0.6165 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.0 (9.1, 44.9) | 25.9 (8.1, 48.3) |
| 12 months | 20.0 (6.2, 39.3) | 6.5 (0.4, 25.4) |
| 18 months | 10.0 (1.7, 27.2) | 0.0 (NE, NE) |
| 24 months | 10.0 (1.7, 27.2) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.2.2. Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Number of events, n (%) | 29 (93.5%) | 31 (96.9%) |
| Progressive Disease, n (%) | 23 (74.2%) | 24 (75.0%) |
| Number of deaths, n (%) | 6 (19.4%) | 7 (21.9%) |
| Number of censored patients, n (%) | 2 (6.5%) | 1 (3.1%) |
| | | |
| Median (95% CI), (Months) [a] | 1.5 (1.4, 2.7) | 2.8 (1.5, 4.1) |
| Stratified log-rank test 1-sided p-value [b] | 0.29456 | |
| HR (95% CI) [c] | 1.157 (0.691, 1.936) | |
| HR P-Value [c] | 0.5791 | |
| Heterogeneity p-value [d] | 0.6165 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 19.4 (7.9, 34.6) | 16.1 (5.9, 30.9) |
| 12 months | 9.7 (2.5, 22.9) | 6.5 (1.1, 18.6) |
| 18 months | 9.7 (2.5, 22.9) | 0.0 (NE, NE) |
| 24 months | 9.7 (2.5, 22.9) | 0.0 (NE, NE) |
| 30 months | 9.7 (2.5, 22.9) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.3.1. Overall Survival by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: <1%

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Number of deaths, n (%) | 21 (72.4%) | 22 (73.3%) |
| Number of censored patients, n (%) | 8 (27.6%) | 8 (26.7%) |
| Median (95% CI), (Months) [a] | 6.3 (3.3, 15.0) | 8.2 (3.9, 15.7) |
| Stratified log-rank test 1-sided p-value [b] | 0.30555 | |
| HR (95% CI) [c] | 1.169 (0.632, 2.160) | |
| HR P-Value [c] | 0.6189 | |
| Heterogeneity p-value [d] | 0.1807 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 51.7 (32.5, 67.9) | 57.2 (37.1, 73.0) |
| 12 months | 43.9 (25.4, 61.0) | 42.4 (24.0, 59.6) |
| 18 months | 9.4 (0.8, 31.3) | 17.7 (5.2, 36.1) |
| 24 months | NE (NE, NE) | 8.8 (0.8, 29.4) |
| 30 months | NE (NE, NE) | 8.8 (0.8, 29.4) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.3.1. Overall Survival by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: >=1%

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Number of deaths, n (%) | 31 (50.0%) | 33 (66.0%) |
| Number of censored patients, n (%) | 31 (50.0%) | 17 (34.0%) |
| Median (95% CI), (Months) [a] | 13.9 (8.0, NE) | 8.8 (6.9, 11.4) |
| Stratified log-rank test 1-sided p-value [b] | 0.03234 | |
| HR (95% CI) [c] | 0.632 (0.387, 1.033) | |
| HR P-Value [c] | 0.0670 | |
| Heterogeneity p-value [d] | 0.1807 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 69.2 (56.1, 79.1) | 65.6 (50.0, 77.4) |
| 12 months | 55.9 (42.0, 67.6) | 35.3 (21.1, 49.8) |
| 18 months | 41.4 (26.7, 55.5) | 21.3 (9.0, 37.1) |
| 24 months | 41.4 (26.7, 55.5) | 14.2 (3.5, 32.1) |
| 30 months | NE (NE, NE) | 14.2 (3.5, 32.1) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.3.1. Overall Survival by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Number of deaths, n (%) | 67 (63.8%) | 76 (73.8%) |
| Number of censored patients, n (%) | 38 (36.2%) | 27 (26.2%) |
| Median (95% CI), (Months) [a] | 13.5 (8.1, 16.7) | 7.7 (6.4, 9.6) |
| Stratified log-rank test 1-sided p-value [b] | 0.00105 | |
| HR (95% CI) [c] | 0.593 (0.424, 0.830) | |
| HR P-Value [c] | 0.0023 | |
| Heterogeneity p-value [d] | 0.1807 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 69.3 (59.4, 77.2) | 64.3 (53.8, 73.0) |
| 12 months | 55.2 (45.0, 64.2) | 29.7 (20.4, 39.6) |
| 18 months | 36.0 (25.5, 46.6) | 14.8 (7.8, 24.0) |
| 24 months | 17.6 (8.3, 29.8) | 9.5 (3.4, 19.4) |
| 30 months | 17.6 (8.3, 29.8) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.3.2. Progression-free Survival by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: <1%

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Number of events, n (%) | 24 (82.8%) | 28 (93.3%) |
| Progressive Disease, n (%) | 20 (69.0%) | 18 (60.0%) |
| Number of deaths, n (%) | 4 (13.8%) | 10 (33.3%) |
| Number of censored patients, n (%) | 5 (17.2%) | 2 (6.7%) |
| Median (95% CI), (Months) [a] | 1.7 (1.4, 3.9) | 3.1 (2.0, 5.4) |
| Stratified log-rank test 1-sided p-value [b] | 0.22241 | |
| HR (95% CI) [c] | 1.250 (0.712, 2.194) | |
| HR P-Value [c] | 0.4377 | |
| Heterogeneity p-value [d] | 0.1953 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.6 (13.1, 44.3) | 32.1 (16.1, 49.3) |
| 12 months | 8.3 (0.8, 27.9) | 10.7 (2.7, 25.1) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.3.2. Progression-free Survival by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: >=1%

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Number of events, n (%) | 52 (83.9%) | 45 (90.0%) |
| Progressive Disease, n (%) | 42 (67.7%) | 36 (72.0%) |
| Number of deaths, n (%) | 10 (16.1%) | 9 (18.0%) |
| Number of censored patients, n (%) | 10 (16.1%) | 5 (10.0%) |
| Median (95% CI), (Months) [a] | 3.0 (1.6, 5.5) | 3.7 (1.7, 4.6) |
| Stratified log-rank test 1-sided p-value [b] | 0.15804 | |
| HR (95% CI) [c] | 0.813 (0.541, 1.222) | |
| HR P-Value [c] | 0.3193 | |
| Heterogeneity p-value [d] | 0.1953 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.0 (24.2, 47.9) | 26.5 (14.8, 39.7) |
| 12 months | 18.5 (9.4, 29.8) | 10.1 (3.4, 21.2) |
| 18 months | 13.5 (5.7, 24.6) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 17.3.2. Progression-free Survival by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Number of events, n (%) | 84 (80.0%) | 92 (89.3%) |
| Progressive Disease, n (%) | 73 (69.5%) | 76 (73.8%) |
| Number of deaths, n (%) | 11 (10.5%) | 16 (15.5%) |
| Number of censored patients, n (%) | 21 (20.0%) | 11 (10.7%) |
| | | |
| Median (95% CI), (Months) [a] | 3.0 (2.5, 4.1) | 2.8 (2.3, 3.4) |
| Stratified log-rank test 1-sided p-value [b] | 0.00461 | |
| HR (95% CI) [c] | 0.670 (0.493, 0.910) | |
| HR P-Value [c] | 0.0104 | |
| Heterogeneity p-value [d] | 0.1953 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.5 (26.4, 44.7) | 21.8 (14.2, 30.5) |
| 12 months | 27.5 (19.2, 36.3) | 6.3 (2.4, 12.8) |
| 18 months | 17.2 (9.6, 26.7) | NE (NE, NE) |
| 24 months | 14.3 (6.9, 24.4) | NE (NE, NE) |
| 30 months | 9.6 (2.7, 21.8) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 18 (10.0%) | 12 (7.4%) |
| Censored Patients, n (%) | 162 (90.0%) | 151 (92.6%) |
| Median (95% CI), (Months) [a] | 16.62 (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5976 | |
| HR (95% CI) [c] | 1.224 (0.582, 2.575) | |
| HR P-Value [c] | 0.5943 | |
| Heterogeneity p-value [d] | 0.4542 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.4 (59.2, 83.4) | 75.7 (60.7, 85.6) |
| 12 months | 65.3 (43.7, 80.3) | 75.7 (60.7, 85.6) |
| 18 months | 40.8 (13.3, 67.1) | NE (NE, NE) |
| 24 months | 40.8 (13.3, 67.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 18 (10.0%) | 10 (6.1%) |
| Censored Patients, n (%) | 162 (90.0%) | 153 (93.9%) |
| Median (95% CI), (Months) [a] | 17.97 (12.52, NE) | NE (6.28, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8862 | |
| HR (95% CI) [c] | 1.061 (0.475, 2.372) | |
| HR P-Value [c] | 0.8845 | |
| Heterogeneity p-value [d] | 0.9906 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.1 (69.6, 88.6) | 78.9 (61.6, 89.0) |
| 12 months | 70.0 (53.1, 81.8) | NE (NE, NE) |
| 18 months | 48.8 (18.3, 73.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 16 (8.9%) | 13 (8.0%) |
| Censored Patients, n (%) | 164 (91.1%) | 150 (92.0%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5000 | |
| HR (95% CI) [c] | 0.775 (0.370, 1.625) | |
| HR P-Value [c] | 0.5003 | |
| Heterogeneity p-value [d] | 0.5738 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.1 (61.9, 86.8) | 73.2 (57.7, 83.8) |
| 12 months | 51.6 (27.4, 71.3) | 73.2 (57.7, 83.8) |
| 18 months | 51.6 (27.4, 71.3) | NE (NE, NE) |
| 24 months | 51.6 (27.4, 71.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 15 (8.3%) | 6 (3.7%) |
| Censored Patients, n (%) | 165 (91.7%) | 157 (96.3%) |
| Median (95% CI), (Months) [a] | 9.72 (1.58, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7234 | |
| HR (95% CI) [c] | 1.201 (0.456, 3.158) | |
| HR P-Value [c] | 0.7109 | |
| Heterogeneity p-value [d] | 0.5547 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.5 (37.0, 73.5) | 62.6 (34.2, 81.5) |
| 12 months | 30.7 (9.4, 55.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 20 (11.1%) | 7 (4.3%) |
| Censored Patients, n (%) | 160 (88.9%) | 156 (95.7%) |
| Median (95% CI), (Months) [a] | 11.83 (8.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1488 | |
| HR (95% CI) [c] | 1.893 (0.784, 4.569) | |
| HR P-Value [c] | 0.1559 | |
| Heterogeneity p-value [d] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.5 (53.1, 81.2) | 83.6 (68.4, 91.9) |
| 12 months | 44.8 (24.0, 63.6) | 83.6 (68.4, 91.9) |
| 18 months | 33.6 (11.9, 57.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 18 (10.0%) | 8 (4.9%) |
| Censored Patients, n (%) | 162 (90.0%) | 155 (95.1%) |
| Median (95% CI), (Months) [a] | NE (16.39, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4880 | |
| HR (95% CI) [c] | 1.351 (0.578, 3.160) | |
| HR P-Value [c] | 0.4876 | |
| Heterogeneity p-value [d] | 0.9908 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.8 (69.4, 88.3) | 88.5 (77.1, 94.4) |
| 12 months | 74.0 (59.1, 84.2) | 79.7 (54.1, 91.9) |
| 18 months | 66.6 (45.7, 81.0) | NE (NE, NE) |
| 24 months | 66.6 (45.7, 81.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 25 (13.9%) | 10 (6.1%) |
| Censored Patients, n (%) | 155 (86.1%) | 153 (93.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0934 | |
| HR (95% CI) [c] | 1.874 (0.893, 3.933) | |
| HR P-Value [c] | 0.0966 | |
| Heterogeneity p-value [d] | 0.5598 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.7 (72.8, 87.9) | 90.5 (81.7, 95.2) |
| 12 months | 71.7 (58.3, 81.4) | 78.0 (53.9, 90.4) |
| 18 months | 67.9 (52.9, 79.0) | NE (NE, NE) |
| 24 months | 67.9 (52.9, 79.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 14 (7.8%) | 11 (6.7%) |
| Censored Patients, n (%) | 166 (92.2%) | 152 (93.3%) |
| Median (95% CI), (Months) [a] | NE (14.95, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9351 | |
| HR (95% CI) [c] | 0.968 (0.428, 2.191) | |
| HR P-Value [c] | 0.9384 | |
| Heterogeneity p-value [d] | 0.9916 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.3 (67.1, 88.6) | 82.8 (70.2, 90.4) |
| 12 months | 80.3 (67.1, 88.6) | 69.0 (35.9, 87.4) |
| 18 months | 64.9 (40.0, 81.5) | NE (NE, NE) |
| 24 months | 64.9 (40.0, 81.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 14 (7.8%) | 12 (7.4%) |
| Censored Patients, n (%) | 166 (92.2%) | 151 (92.6%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8040 | |
| HR (95% CI) [c] | 0.907 (0.411, 2.000) | |
| HR P-Value [c] | 0.8086 | |
| Heterogeneity p-value [d] | 0.5680 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.0 (50.2, 80.6) | 63.3 (43.7, 77.7) |
| 12 months | 61.2 (40.1, 76.8) | NE (NE, NE) |
| 18 months | 52.5 (28.5, 71.8) | NE (NE, NE) |
| 24 months | 52.5 (28.5, 71.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:01:24, yingyuan.lin)

Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 32 (17.8%) | 17 (10.4%) |
| Censored Patients, n (%) | 148 (82.2%) | 146 (89.6%) |
| Median (95% CI), (Months) [a] | 16.76 (8.61, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2099 | |
| HR (95% CI) [c] | 1.470 (0.811, 2.662) | |
| HR P-Value [c] | 0.2040 | |
| Heterogeneity p-value [d] | 0.8414 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.8 (64.4, 82.5) | 76.4 (63.8, 85.2) |
| 12 months | 59.7 (44.3, 72.2) | 76.4 (63.8, 85.2) |
| 18 months | 47.3 (27.2, 65.0) | 76.4 (63.8, 85.2) |
| 24 months | 47.3 (27.2, 65.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 19 (10.6%) | 2 (1.2%) |
| Censored Patients, n (%) | 161 (89.4%) | 161 (98.8%) |
| Median (95% CI), (Months) [a] | NE (15.24, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0028 | |
| HR (95% CI) [c] | 6.859 (1.588, 29.629) | |
| HR P-Value [c] | 0.0099 | |
| Heterogeneity p-value [d] | 0.9922 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.4 (70.2, 88.7) | 97.5 (90.4, 99.4) |
| 12 months | 72.6 (57.6, 83.1) | 97.5 (90.4, 99.4) |
| 18 months | 64.6 (42.8, 79.8) | NE (NE, NE) |
| 24 months | 64.6 (42.8, 79.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 18 (10.0%) | 4 (2.5%) |
| Censored Patients, n (%) | 162 (90.0%) | 159 (97.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0231 | |
| HR (95% CI) [c] | 3.303 (1.109, 9.841) | |
| HR P-Value [c] | 0.0319 | |
| Heterogeneity p-value [d] | 0.3418 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.4 (79.3, 92.5) | 96.1 (89.9, 98.5) |
| 12 months | 81.7 (71.0, 88.7) | 96.1 (89.9, 98.5) |
| 18 months | 75.8 (58.8, 86.6) | NE (NE, NE) |
| 24 months | 75.8 (58.8, 86.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 23 (12.8%) | 9 (5.5%) |
| Censored Patients, n (%) | 157 (87.2%) | 154 (94.5%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2004 | |
| HR (95% CI) [c] | 1.659 (0.761, 3.619) | |
| HR P-Value [c] | 0.2032 | |
| Heterogeneity p-value [d] | 0.9888 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.3 (65.7, 85.4) | 87.5 (76.0, 93.7) |
| 12 months | 65.9 (49.1, 78.3) | 82.8 (66.9, 91.6) |
| 18 months | 54.7 (34.5, 71.0) | NE (NE, NE) |
| 24 months | 54.7 (34.5, 71.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 24 (13.3%) | 13 (8.0%) |
| Censored Patients, n (%) | 156 (86.7%) | 150 (92.0%) |
| Median (95% CI), (Months) [a] | NE (13.44, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1647 | |
| HR (95% CI) [c] | 1.617 (0.820, 3.188) | |
| HR P-Value [c] | 0.1652 | |
| Heterogeneity p-value [d] | 0.5108 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.2 (61.6, 81.8) | 79.7 (67.4, 87.8) |
| 12 months | 65.9 (50.9, 77.2) | 79.7 (67.4, 87.8) |
| 18 months | 58.5 (38.8, 73.9) | NE (NE, NE) |
| 24 months | 58.5 (38.8, 73.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 20 (11.1%) | 13 (8.0%) |
| Censored Patients, n (%) | 160 (88.9%) | 150 (92.0%) |
| Median (95% CI), (Months) [a] | NE (12.58, NE) | NE (7.03, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4677 | |
| HR (95% CI) [c] | 1.303 (0.644, 2.636) | |
| HR P-Value [c] | 0.4619 | |
| Heterogeneity p-value [d] | 0.9901 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.4 (61.9, 83.2) | 77.2 (60.3, 87.6) |
| 12 months | 70.2 (55.4, 80.9) | 61.9 (36.4, 79.7) |
| 18 months | 61.4 (39.2, 77.6) | NE (NE, NE) |
| 24 months | 61.4 (39.2, 77.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 2 (10.0%) |
| Censored Patients, n (%) | 14 (87.5%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 13.31 (4.21, NE) | 5.65 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5637 | |
| HR (95% CI) [c] | 0.500 (0.045, 5.514) | |
| HR P-Value [c] | 0.5715 | |
| Heterogeneity p-value [d] | 0.4542 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (5.4, 94.5) | 40.0 (1.1, 82.9) |
| 12 months | 66.7 (5.4, 94.5) | NE (NE, NE) |
| 18 months | 33.3 (0.9, 77.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 0 |
| Censored Patients, n (%) | 13 (81.3%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | 14.09 (1.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4058 | |
| HR (95% CI) [c] | 40063401 (0.000, NE) | |
| HR P-Value [c] | 0.9982 | |
| Heterogeneity p-value [d] | 0.9906 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.9 (43.3, 98.4) | 100.0 (100.0, 100.0) |
| 12 months | 66.7 (16.0, 91.4) | NE (NE, NE) |
| 18 months | 44.4 (6.0, 79.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 1 (5.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 15.31 (2.69, NE) | NE (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9237 | |
| HR (95% CI) [c] | 1.126 (0.099, 12.811) | |
| HR P-Value [c] | 0.9237 | |
| Heterogeneity p-value [d] | 0.5738 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.3 (27.3, 97.5) | 66.7 (5.4, 94.5) |
| 12 months | 55.6 (7.3, 87.6) | NE (NE, NE) |
| 18 months | 27.8 (1.0, 70.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 1 (5.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 6.97 (1.58, 14.26) | 4.40 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4504 | |
| HR (95% CI) [c] | 0.354 (0.021, 5.893) | |
| HR P-Value [c] | 0.4689 | |
| Heterogeneity p-value [d] | 0.5547 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (12.8, 96.1) | 0.0 (NE, NE) |
| 12 months | 37.5 (1.1, 80.8) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 0 |
| Censored Patients, n (%) | 14 (87.5%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | 9.15 (6.97, 11.33) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4795 | |
| HR (95% CI) [c] | 1.2816E8 (0.000, NE) | |
| HR P-Value [c] | 0.9991 | |
| Heterogeneity p-value [d] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 0 |
| Censored Patients, n (%) | 15 (93.8%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3865 | |
| HR (95% CI) [c] | 62193133 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.9908 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 18 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 24 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 1 (5.0%) |
| Censored Patients, n (%) | 15 (93.8%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | NE (4.21, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9731 | |
| HR (95% CI) [c] | 1.049 (0.066, 16.781) | |
| HR P-Value [c] | 0.9731 | |
| Heterogeneity p-value [d] | 0.5598 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.3 (27.3, 97.5) | 90.9 (50.8, 98.7) |
| 12 months | 83.3 (27.3, 97.5) | NE (NE, NE) |
| 18 months | 83.3 (27.3, 97.5) | NE (NE, NE) |
| 24 months | 83.3 (27.3, 97.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 0 |
| Censored Patients, n (%) | 15 (93.8%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (2.89, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4386 | |
| HR (95% CI) [c] | 52829214 (0.000, NE) | |
| HR P-Value [c] | 0.9985 | |
| Heterogeneity p-value [d] | 0.9916 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (20.4, 96.9) | 100.0 (100.0, 100.0) |
| 12 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 18 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 1 (5.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 6.97 (1.41, 7.92) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5577 | |
| HR (95% CI) [c] | 1.955 (0.200, 19.147) | |
| HR P-Value [c] | 0.5647 | |
| Heterogeneity p-value [d] | 0.5680 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (12.8, 96.1) | 50.0 (0.6, 91.0) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 1 (5.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 17.05 (4.21, NE) | NE (1.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6071 | |
| HR (95% CI) [c] | 1.860 (0.168, 20.570) | |
| HR P-Value [c] | 0.6128 | |
| Heterogeneity p-value [d] | 0.8414 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.0 (12.6, 88.2) | 83.3 (27.3, 97.5) |
| 12 months | 60.0 (12.6, 88.2) | NE (NE, NE) |
| 18 months | 40.0 (5.2, 75.3) | NE (NE, NE) |
| 24 months | 40.0 (5.2, 75.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 0 |
| Censored Patients, n (%) | 15 (93.8%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3778 | |
| HR (95% CI) [c] | 64047725 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.9922 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.9 (43.3, 98.4) | 100.0 (100.0, 100.0) |
| 12 months | 88.9 (43.3, 98.4) | NE (NE, NE) |
| 18 months | 88.9 (43.3, 98.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 1 (5.0%) |
| Censored Patients, n (%) | 15 (93.8%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | NE (4.21, NE) | NE (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9703 | |
| HR (95% CI) [c] | 0.949 (0.059, 15.181) | |
| HR P-Value [c] | 0.9703 | |
| Heterogeneity p-value [d] | 0.3418 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (38.7, 98.1) | 88.9 (43.3, 98.4) |
| 12 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 18 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 24 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 0 |
| Censored Patients, n (%) | 14 (87.5%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2662 | |
| HR (95% CI) [c] | 53921138 (0.000, NE) | |
| HR P-Value [c] | 0.9978 | |
| Heterogeneity p-value [d] | 0.9888 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.9 (50.8, 98.7) | 100.0 (100.0, 100.0) |
| 12 months | 72.7 (24.1, 93.1) | NE (NE, NE) |
| 18 months | 72.7 (24.1, 93.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 2 (10.0%) |
| Censored Patients, n (%) | 15 (93.8%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | NE (1.41, NE) | 7.06 (1.48, 7.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8084 | |
| HR (95% CI) [c] | 1.414 (0.085, 23.573) | |
| HR P-Value [c] | 0.8092 | |
| Heterogeneity p-value [d] | 0.5108 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 75.0 (12.8, 96.1) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 0 |
| Censored Patients, n (%) | 15 (93.8%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4795 | |
| HR (95% CI) [c] | 47145826 (0.000, NE) | |
| HR P-Value [c] | 0.9985 | |
| Heterogeneity p-value [d] | 0.9901 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 18 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 16 (11.8%) | 7 (5.7%) |
| Censored Patients, n (%) | 120 (88.2%) | 116 (94.3%) |
| Median (95% CI), (Months) [a] | 16.62 (12.52, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2073 | |
| HR (95% CI) [c] | 1.784 (0.720, 4.420) | |
| HR P-Value [c] | 0.2108 | |
| Heterogeneity p-value [d] | 0.1221 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.4 (52.5, 81.3) | 80.5 (63.0, 90.4) |
| 12 months | 69.4 (52.5, 81.3) | 80.5 (63.0, 90.4) |
| 18 months | 40.5 (15.4, 64.6) | NE (NE, NE) |
| 24 months | 40.5 (15.4, 64.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 15 (11.0%) | 7 (5.7%) |
| Censored Patients, n (%) | 121 (89.0%) | 116 (94.3%) |
| Median (95% CI), (Months) [a] | 17.97 (12.52, NE) | NE (6.28, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7021 | |
| HR (95% CI) [c] | 1.206 (0.467, 3.111) | |
| HR P-Value [c] | 0.6988 | |
| Heterogeneity p-value [d] | 0.8059 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.7 (67.0, 89.2) | 80.8 (59.9, 91.5) |
| 12 months | 73.3 (56.4, 84.5) | NE (NE, NE) |
| 18 months | 46.4 (17.0, 71.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 13 (9.6%) | 11 (8.9%) |
| Censored Patients, n (%) | 123 (90.4%) | 112 (91.1%) |
| Median (95% CI), (Months) [a] | 11.10 (8.48, NE) | NE (3.12, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3759 | |
| HR (95% CI) [c] | 0.691 (0.303, 1.577) | |
| HR P-Value [c] | 0.3802 | |
| Heterogeneity p-value [d] | 0.4529 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.1 (63.4, 89.8) | 67.7 (48.2, 81.2) |
| 12 months | 49.4 (25.0, 69.9) | 67.7 (48.2, 81.2) |
| 18 months | 49.4 (25.0, 69.9) | NE (NE, NE) |
| 24 months | 49.4 (25.0, 69.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 11 (8.1%) | 5 (4.1%) |
| Censored Patients, n (%) | 125 (91.9%) | 118 (95.9%) |
| Median (95% CI), (Months) [a] | 11.40 (1.58, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8205 | |
| HR (95% CI) [c] | 0.901 (0.299, 2.719) | |
| HR P-Value [c] | 0.8536 | |
| Heterogeneity p-value [d] | 0.4209 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.3 (48.8, 85.2) | 52.5 (18.8, 78.0) |
| 12 months | 43.2 (16.3, 67.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 12 (8.8%) | 2 (1.6%) |
| Censored Patients, n (%) | 124 (91.2%) | 121 (98.4%) |
| Median (95% CI), (Months) [a] | 11.83 (8.48, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0374 | |
| HR (95% CI) [c] | 4.383 (0.966, 19.882) | |
| HR P-Value [c] | 0.0554 | |
| Heterogeneity p-value [d] | 0.1281 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.0 (58.4, 89.2) | 93.9 (77.2, 98.5) |
| 12 months | 45.5 (20.6, 67.5) | 93.9 (77.2, 98.5) |
| 18 months | 45.5 (20.6, 67.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 12 (8.8%) | 6 (4.9%) |
| Censored Patients, n (%) | 124 (91.2%) | 117 (95.1%) |
| Median (95% CI), (Months) [a] | NE (16.39, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9015 | |
| HR (95% CI) [c] | 1.067 (0.392, 2.905) | |
| HR P-Value [c] | 0.8996 | |
| Heterogeneity p-value [d] | 0.2998 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.0 (74.1, 92.7) | 88.6 (74.2, 95.2) |
| 12 months | 79.7 (64.7, 88.9) | 78.8 (49.8, 92.1) |
| 18 months | 71.8 (49.0, 85.7) | NE (NE, NE) |
| 24 months | 71.8 (49.0, 85.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 18 (13.2%) | 6 (4.9%) |
| Censored Patients, n (%) | 118 (86.8%) | 117 (95.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1348 | |
| HR (95% CI) [c] | 2.024 (0.794, 5.159) | |
| HR P-Value [c] | 0.1396 | |
| Heterogeneity p-value [d] | 0.7800 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.5 (73.5, 90.0) | 92.0 (81.7, 96.6) |
| 12 months | 75.7 (62.2, 85.0) | 81.8 (51.1, 94.2) |
| 18 months | 71.9 (56.6, 82.6) | NE (NE, NE) |
| 24 months | 71.9 (56.6, 82.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 12 (8.8%) | 4 (3.3%) |
| Censored Patients, n (%) | 124 (91.2%) | 119 (96.7%) |
| Median (95% CI), (Months) [a] | NE (13.86, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1706 | |
| HR (95% CI) [c] | 2.212 (0.693, 7.060) | |
| HR P-Value [c] | 0.1801 | |
| Heterogeneity p-value [d] | 0.0250 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.4 (61.4, 87.4) | 91.9 (76.9, 97.3) |
| 12 months | 77.4 (61.4, 87.4) | 73.5 (26.6, 93.1) |
| 18 months | 60.9 (35.0, 79.1) | NE (NE, NE) |
| 24 months | 60.9 (35.0, 79.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 12 (8.8%) | 8 (6.5%) |
| Censored Patients, n (%) | 124 (91.2%) | 115 (93.5%) |
| Median (95% CI), (Months) [a] | 12.06 (1.71, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9451 | |
| HR (95% CI) [c] | 0.977 (0.388, 2.462) | |
| HR P-Value [c] | 0.9603 | |
| Heterogeneity p-value [d] | 0.9408 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (47.5, 82.1) | 62.4 (37.8, 79.5) |
| 12 months | 55.9 (32.8, 73.9) | NE (NE, NE) |
| 18 months | 46.6 (22.1, 68.0) | NE (NE, NE) |
| 24 months | 46.6 (22.1, 68.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 26 (19.1%) | 13 (10.6%) |
| Censored Patients, n (%) | 110 (80.9%) | 110 (89.4%) |
| Median (95% CI), (Months) [a] | 16.76 (8.61, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4121 | |
| HR (95% CI) [c] | 1.334 (0.680, 2.619) | |
| HR P-Value [c] | 0.4023 | |
| Heterogeneity p-value [d] | 0.6753 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.1 (62.8, 83.8) | 74.8 (59.8, 84.9) |
| 12 months | 59.1 (42.5, 72.3) | 74.8 (59.8, 84.9) |
| 18 months | 40.0 (19.4, 59.9) | 74.8 (59.8, 84.9) |
| 24 months | 40.0 (19.4, 59.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 15 (11.0%) | 2 (1.6%) |
| Censored Patients, n (%) | 121 (89.0%) | 121 (98.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0121 | |
| HR (95% CI) [c] | 5.433 (1.234, 23.933) | |
| HR P-Value [c] | 0.0253 | |
| Heterogeneity p-value [d] | 0.9909 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.8 (68.6, 88.6) | 96.7 (87.4, 99.2) |
| 12 months | 78.3 (65.3, 86.9) | 96.7 (87.4, 99.2) |
| 18 months | 71.2 (51.1, 84.2) | NE (NE, NE) |
| 24 months | 71.2 (51.1, 84.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 14 (10.3%) | 2 (1.6%) |
| Censored Patients, n (%) | 122 (89.7%) | 121 (98.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0204 | |
| HR (95% CI) [c] | 4.922 (1.108, 21.867) | |
| HR P-Value [c] | 0.0362 | |
| Heterogeneity p-value [d] | 0.2249 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (78.4, 92.9) | 96.8 (87.8, 99.2) |
| 12 months | 82.5 (70.5, 89.9) | 96.8 (87.8, 99.2) |
| 18 months | 76.1 (57.3, 87.5) | NE (NE, NE) |
| 24 months | 76.1 (57.3, 87.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 20 (14.7%) | 5 (4.1%) |
| Censored Patients, n (%) | 116 (85.3%) | 118 (95.9%) |
| Median (95% CI), (Months) [a] | NE (12.48, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0539 | |
| HR (95% CI) [c] | 2.568 (0.953, 6.924) | |
| HR P-Value [c] | 0.0623 | |
| Heterogeneity p-value [d] | 0.1808 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.4 (66.4, 86.6) | 93.0 (82.4, 97.3) |
| 12 months | 67.9 (51.5, 79.8) | 88.4 (71.6, 95.5) |
| 18 months | 58.1 (38.8, 73.3) | NE (NE, NE) |
| 24 months | 58.1 (38.8, 73.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 17 (12.5%) | 13 (10.6%) |
| Censored Patients, n (%) | 119 (87.5%) | 110 (89.4%) |
| Median (95% CI), (Months) [a] | NE (8.44, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9117 | |
| HR (95% CI) [c] | 0.962 (0.465, 1.990) | |
| HR P-Value [c] | 0.9160 | |
| Heterogeneity p-value [d] | 0.0586 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.8 (62.3, 85.0) | 73.4 (57.6, 84.1) |
| 12 months | 66.9 (49.2, 79.6) | 66.7 (46.4, 80.8) |
| 18 months | 57.3 (33.3, 75.5) | NE (NE, NE) |
| 24 months | 57.3 (33.3, 75.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 17 (12.5%) | 8 (6.5%) |
| Censored Patients, n (%) | 119 (87.5%) | 115 (93.5%) |
| Median (95% CI), (Months) [a] | NE (7.23, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2574 | |
| HR (95% CI) [c] | 1.623 (0.699, 3.765) | |
| HR P-Value [c] | 0.2598 | |
| Heterogeneity p-value [d] | 0.4578 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.4 (59.4, 83.1) | 81.3 (64.3, 90.8) |
| 12 months | 65.9 (49.4, 78.2) | 73.9 (50.8, 87.4) |
| 18 months | 65.9 (49.4, 78.2) | NE (NE, NE) |
| 24 months | 65.9 (49.4, 78.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 4 (6.7%) | 7 (11.7%) |
| Censored Patients, n (%) | 56 (93.3%) | 53 (88.3%) |
| Median (95% CI), (Months) [a] | 11.10 (NE, NE) | NE (1.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3331 | |
| HR (95% CI) [c] | 0.548 (0.159, 1.885) | |
| HR P-Value [c] | 0.3401 | |
| Heterogeneity p-value [d] | 0.1221 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.3 (52.5, 94.3) | 50.4 (16.8, 76.8) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 6 (10.0%) | 3 (5.0%) |
| Censored Patients, n (%) | 54 (90.0%) | 57 (95.0%) |
| Median (95% CI), (Months) [a] | NE (7.03, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9721 | |
| HR (95% CI) [c] | 0.975 (0.236, 4.024) | |
| HR P-Value [c] | 0.9720 | |
| Heterogeneity p-value [d] | 0.8059 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.7 (61.5, 93.7) | 80.2 (50.1, 93.2) |
| 12 months | 57.4 (21.7, 81.7) | NE (NE, NE) |
| 18 months | 57.4 (21.7, 81.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 6 (10.0%) | 3 (5.0%) |
| Censored Patients, n (%) | 54 (90.0%) | 57 (95.0%) |
| Median (95% CI), (Months) [a] | 15.31 (4.27, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7785 | |
| HR (95% CI) [c] | 1.218 (0.290, 5.107) | |
| HR P-Value [c] | 0.7874 | |
| Heterogeneity p-value [d] | 0.4529 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.0 (41.4, 87.5) | 83.3 (56.8, 94.3) |
| 12 months | 71.0 (41.4, 87.5) | NE (NE, NE) |
| 18 months | 35.5 (1.7, 76.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 7 (11.7%) | 2 (3.3%) |
| Censored Patients, n (%) | 53 (88.3%) | 58 (96.7%) |
| Median (95% CI), (Months) [a] | 3.45 (1.48, 8.34) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6419 | |
| HR (95% CI) [c] | 1.475 (0.295, 7.383) | |
| HR P-Value [c] | 0.6361 | |
| Heterogeneity p-value [d] | 0.4209 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.0 (8.5, 64.0) | 62.5 (14.2, 89.3) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 10 (16.7%) | 5 (8.3%) |
| Censored Patients, n (%) | 50 (83.3%) | 55 (91.7%) |
| Median (95% CI), (Months) [a] | 8.34 (1.91, 15.31) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8972 | |
| HR (95% CI) [c] | 1.071 (0.340, 3.375) | |
| HR P-Value [c] | 0.9073 | |
| Heterogeneity p-value [d] | 0.1281 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.7 (27.8, 77.8) | 66.0 (36.5, 84.3) |
| 12 months | 22.7 (1.6, 58.9) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 7 (11.7%) | 2 (3.3%) |
| Censored Patients, n (%) | 53 (88.3%) | 58 (96.7%) |
| Median (95% CI), (Months) [a] | NE (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1722 | |
| HR (95% CI) [c] | 2.903 (0.585, 14.422) | |
| HR P-Value [c] | 0.1924 | |
| Heterogeneity p-value [d] | 0.2998 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.7 (41.5, 86.2) | 91.4 (69.7, 97.8) |
| 12 months | 58.1 (26.8, 79.9) | NE (NE, NE) |
| 18 months | 58.1 (26.8, 79.9) | NE (NE, NE) |
| 24 months | 58.1 (26.8, 79.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 8 (13.3%) | 5 (8.3%) |
| Censored Patients, n (%) | 52 (86.7%) | 55 (91.7%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4172 | |
| HR (95% CI) [c] | 1.586 (0.515, 4.882) | |
| HR P-Value [c] | 0.4216 | |
| Heterogeneity p-value [d] | 0.7800 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.6 (57.8, 89.0) | 87.9 (70.2, 95.4) |
| 12 months | 64.7 (32.9, 84.3) | 70.3 (27.5, 90.8) |
| 18 months | 64.7 (32.9, 84.3) | NE (NE, NE) |
| 24 months | 64.7 (32.9, 84.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 3 (5.0%) | 7 (11.7%) |
| Censored Patients, n (%) | 57 (95.0%) | 53 (88.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1084 | |
| HR (95% CI) [c] | 0.346 (0.089, 1.340) | |
| HR P-Value [c] | 0.1243 | |
| Heterogeneity p-value [d] | 0.0250 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.8 (61.4, 95.3) | 69.9 (46.6, 84.5) |
| 12 months | 85.8 (61.4, 95.3) | NE (NE, NE) |
| 18 months | 85.8 (61.4, 95.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 5 (8.3%) | 5 (8.3%) |
| Censored Patients, n (%) | 55 (91.7%) | 55 (91.7%) |
| Median (95% CI), (Months) [a] | 7.92 (1.91, NE) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9117 | |
| HR (95% CI) [c] | 0.932 (0.268, 3.241) | |
| HR P-Value [c] | 0.9116 | |
| Heterogeneity p-value [d] | 0.9408 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.9 (31.0, 86.2) | 64.2 (33.3, 83.6) |
| 12 months | 33.0 (1.7, 74.1) | NE (NE, NE) |
| 18 months | 33.0 (1.7, 74.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 9 (15.0%) | 5 (8.3%) |
| Censored Patients, n (%) | 51 (85.0%) | 55 (91.7%) |
| Median (95% CI), (Months) [a] | NE (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2197 | |
| HR (95% CI) [c] | 1.968 (0.659, 5.878) | |
| HR P-Value [c] | 0.2254 | |
| Heterogeneity p-value [d] | 0.6753 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.7 (44.0, 84.2) | 82.1 (61.3, 92.4) |
| 12 months | 68.7 (44.0, 84.2) | NE (NE, NE) |
| 18 months | 68.7 (44.0, 84.2) | NE (NE, NE) |
| 24 months | 68.7 (44.0, 84.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 5 (8.3%) | 0 |
| Censored Patients, n (%) | 55 (91.7%) | 60 (100.0%) |
| Median (95% CI), (Months) [a] | 11.10 (7.00, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0490 | |
| HR (95% CI) [c] | 67242314 (0.000, NE) | |
| HR P-Value [c] | 0.9965 | |
| Heterogeneity p-value [d] | 0.9909 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.7 (55.1, 95.5) | 100.0 (100.0, 100.0) |
| 12 months | 48.4 (8.7, 80.6) | NE (NE, NE) |
| 18 months | 48.4 (8.7, 80.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 5 (8.3%) | 3 (5.0%) |
| Censored Patients, n (%) | 55 (91.7%) | 57 (95.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6080 | |
| HR (95% CI) [c] | 1.446 (0.345, 6.061) | |
| HR P-Value [c] | 0.6139 | |
| Heterogeneity p-value [d] | 0.2249 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.9 (63.4, 95.0) | 92.3 (78.0, 97.5) |
| 12 months | 79.3 (53.6, 91.7) | NE (NE, NE) |
| 18 months | 79.3 (53.6, 91.7) | NE (NE, NE) |
| 24 months | 79.3 (53.6, 91.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 5 (8.3%) | 4 (6.7%) |
| Censored Patients, n (%) | 55 (91.7%) | 56 (93.3%) |
| Median (95% CI), (Months) [a] | NE (5.55, NE) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7602 | |
| HR (95% CI) [c] | 0.814 (0.217, 3.053) | |
| HR P-Value [c] | 0.7606 | |
| Heterogeneity p-value [d] | 0.1808 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.7 (42.5, 91.3) | 76.4 (46.7, 90.9) |
| 12 months | 60.5 (23.1, 84.2) | NE (NE, NE) |
| 18 months | 60.5 (23.1, 84.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 8 (13.3%) | 2 (3.3%) |
| Censored Patients, n (%) | 52 (86.7%) | 58 (96.7%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0213 | |
| HR (95% CI) [c] | 5.154 (1.092, 24.338) | |
| HR P-Value [c] | 0.0384 | |
| Heterogeneity p-value [d] | 0.0586 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.2 (44.0, 82.5) | 91.3 (69.3, 97.8) |
| 12 months | 67.2 (44.0, 82.5) | NE (NE, NE) |
| 18 months | 67.2 (44.0, 82.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 4 (6.7%) | 5 (8.3%) |
| Censored Patients, n (%) | 56 (93.3%) | 55 (91.7%) |
| Median (95% CI), (Months) [a] | 12.58 (NE, NE) | 8.48 (5.88, 8.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4624 | |
| HR (95% CI) [c] | 0.586 (0.136, 2.535) | |
| HR P-Value [c] | 0.4746 | |
| Heterogeneity p-value [d] | 0.4578 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.5 (59.1, 95.4) | 71.6 (33.0, 90.5) |
| 12 months | 85.5 (59.1, 95.4) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 1 (4.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4600 | |
| HR (95% CI) [c] | 2.481 (0.225, 27.387) | |
| HR P-Value [c] | 0.4584 | |
| Heterogeneity p-value [d] | 0.7840 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (25.8, 92.0) | 80.0 (20.4, 96.9) |
| 12 months | 71.4 (25.8, 92.0) | 80.0 (20.4, 96.9) |
| 18 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 24 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 0 | 0 |
| Censored Patients, n (%) | 22 (100.0%) | 25 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.9946 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 4 (16.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | 2.35 (1.54, 3.12) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0091 | |
| HR (95% CI) [c] | 0.090 (0.010, 0.841) | |
| HR P-Value [c] | 0.0347 | |
| Heterogeneity p-value [d] | 0.2355 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.0 (47.3, 98.5) | 0.0 (NE, NE) |
| 12 months | 60.0 (7.6, 90.4) | 0.0 (NE, NE) |
| 18 months | 60.0 (7.6, 90.4) | 0.0 (NE, NE) |
| 24 months | 60.0 (7.6, 90.4) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 2 (8.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | 1.58 (1.41, NE) | 4.40 (2.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2526 | |
| HR (95% CI) [c] | 2.931 (0.472, 18.218) | |
| HR P-Value [c] | 0.2487 | |
| Heterogeneity p-value [d] | 0.6960 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 1 (4.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (1.54, NE) | NE (2.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2202 | |
| HR (95% CI) [c] | 3.753 (0.388, 36.300) | |
| HR P-Value [c] | 0.2533 | |
| Heterogeneity p-value [d] | 0.8241 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.1 (15.1, 84.7) | 88.9 (43.3, 98.4) |
| 12 months | 57.1 (15.1, 84.7) | 88.9 (43.3, 98.4) |
| 18 months | 57.1 (15.1, 84.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 3 (12.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 8.67 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2097 | |
| HR (95% CI) [c] | 0.260 (0.027, 2.507) | |
| HR P-Value [c] | 0.2440 | |
| Heterogeneity p-value [d] | 0.2813 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 74.1 (28.9, 93.0) |
| 12 months | 91.7 (53.9, 98.8) | NE (NE, NE) |
| 18 months | 91.7 (53.9, 98.8) | NE (NE, NE) |
| 24 months | 91.7 (53.9, 98.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 0 |
| Censored Patients, n (%) | 20 (90.9%) | 25 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1490 | |
| HR (95% CI) [c] | 83857150 (0.000, NE) | |
| HR P-Value [c] | 0.9977 | |
| Heterogeneity p-value [d] | 0.9996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.6 (51.2, 95.9) | 100.0 (100.0, 100.0) |
| 12 months | 84.6 (51.2, 95.9) | 100.0 (100.0, 100.0) |
| 18 months | 84.6 (51.2, 95.9) | NE (NE, NE) |
| 24 months | 84.6 (51.2, 95.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (4.0%) |
| Censored Patients, n (%) | 22 (100.0%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3711 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.5346 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 90.0 (47.3, 98.5) |
| 12 months | 100.0 (100.0, 100.0) | 90.0 (47.3, 98.5) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 1 (4.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7262 | |
| HR (95% CI) [c] | 1.633 (0.102, 26.111) | |
| HR P-Value [c] | 0.7288 | |
| Heterogeneity p-value [d] | 0.3255 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 12 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 18 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 24 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 5 (22.7%) | 3 (12.0%) |
| Censored Patients, n (%) | 17 (77.3%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | 16.76 (1.61, 16.76) | NE (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3307 | |
| HR (95% CI) [c] | 2.009 (0.479, 8.431) | |
| HR P-Value [c] | 0.3404 | |
| Heterogeneity p-value [d] | 0.8958 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.7 (21.6, 83.1) | 64.3 (24.5, 87.1) |
| 12 months | 58.7 (21.6, 83.1) | 64.3 (24.5, 87.1) |
| 18 months | 0.0 (NE, NE) | 64.3 (24.5, 87.1) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 0 |
| Censored Patients, n (%) | 20 (90.9%) | 25 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1732 | |
| HR (95% CI) [c] | 74929519 (0.000, NE) | |
| HR P-Value [c] | 0.9977 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.1 (52.3, 96.1) | 100.0 (100.0, 100.0) |
| 12 months | 85.1 (52.3, 96.1) | 100.0 (100.0, 100.0) |
| 18 months | 85.1 (52.3, 96.1) | NE (NE, NE) |
| 24 months | 85.1 (52.3, 96.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 1 (4.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (5.68, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8881 | |
| HR (95% CI) [c] | 0.818 (0.050, 13.417) | |
| HR P-Value [c] | 0.8883 | |
| Heterogeneity p-value [d] | 0.7366 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (38.7, 98.1) | 93.3 (61.3, 99.0) |
| 12 months | 87.5 (38.7, 98.1) | 93.3 (61.3, 99.0) |
| 18 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 24 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 0 | 0 |
| Censored Patients, n (%) | 22 (100.0%) | 25 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.9993 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 2 (8.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6455 | |
| HR (95% CI) [c] | 0.582 (0.053, 6.436) | |
| HR P-Value [c] | 0.6586 | |
| Heterogeneity p-value [d] | 0.1181 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (38.7, 98.1) | 75.0 (29.8, 93.4) |
| 12 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 18 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 24 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 1 (4.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4862 | |
| HR (95% CI) [c] | 2.208 (0.199, 24.468) | |
| HR P-Value [c] | 0.5188 | |
| Heterogeneity p-value [d] | 0.5903 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.5 (14.2, 89.3) | 75.0 (12.8, 96.1) |
| 12 months | 62.5 (14.2, 89.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 3 (7.7%) | 1 (2.8%) |
| Censored Patients, n (%) | 36 (92.3%) | 35 (97.2%) |
| Median (95% CI), (Months) [a] | 11.10 (4.27, 11.10) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4455 | |
| HR (95% CI) [c] | 2.357 (0.244, 22.804) | |
| HR P-Value [c] | 0.4590 | |
| Heterogeneity p-value [d] | 0.7840 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.0 (45.7, 95.6) | 90.0 (47.3, 98.5) |
| 12 months | 0.0 (NE, NE) | 90.0 (47.3, 98.5) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 4 (10.3%) | 1 (2.8%) |
| Censored Patients, n (%) | 35 (89.7%) | 35 (97.2%) |
| Median (95% CI), (Months) [a] | NE (7.03, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8038 | |
| HR (95% CI) [c] | 1.327 (0.142, 12.438) | |
| HR P-Value [c] | 0.8045 | |
| Heterogeneity p-value [d] | 0.9946 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.2 (66.2, 97.5) | 87.5 (38.7, 98.1) |
| 12 months | 64.2 (24.2, 87.0) | NE (NE, NE) |
| 18 months | 64.2 (24.2, 87.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 3 (7.7%) | 2 (5.6%) |
| Censored Patients, n (%) | 36 (92.3%) | 34 (94.4%) |
| Median (95% CI), (Months) [a] | 15.31 (4.27, NE) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8731 | |
| HR (95% CI) [c] | 0.835 (0.117, 5.941) | |
| HR P-Value [c] | 0.8574 | |
| Heterogeneity p-value [d] | 0.2355 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.9 (35.4, 94.2) | 83.3 (48.2, 95.6) |
| 12 months | 77.9 (35.4, 94.2) | NE (NE, NE) |
| 18 months | 39.0 (1.4, 81.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 4 (10.3%) | 2 (5.6%) |
| Censored Patients, n (%) | 35 (89.7%) | 34 (94.4%) |
| Median (95% CI), (Months) [a] | 8.34 (1.48, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7248 | |
| HR (95% CI) [c] | 0.724 (0.119, 4.393) | |
| HR P-Value [c] | 0.7259 | |
| Heterogeneity p-value [d] | 0.6960 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.6 (13.2, 82.5) | 53.3 (6.8, 86.3) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 2 (5.6%) |
| Censored Patients, n (%) | 34 (87.2%) | 34 (94.4%) |
| Median (95% CI), (Months) [a] | 11.33 (2.99, 15.31) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6311 | |
| HR (95% CI) [c] | 0.621 (0.087, 4.420) | |
| HR P-Value [c] | 0.6343 | |
| Heterogeneity p-value [d] | 0.8241 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.5 (39.3, 94.5) | 72.9 (27.6, 92.5) |
| 12 months | 33.1 (1.5, 74.6) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 1 (2.8%) |
| Censored Patients, n (%) | 34 (87.2%) | 35 (97.2%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2289 | |
| HR (95% CI) [c] | 3.544 (0.395, 31.785) | |
| HR P-Value [c] | 0.2582 | |
| Heterogeneity p-value [d] | 0.2813 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.6 (51.5, 91.6) | 92.9 (59.1, 99.0) |
| 12 months | 62.9 (25.5, 85.4) | NE (NE, NE) |
| 18 months | 62.9 (25.5, 85.4) | NE (NE, NE) |
| 24 months | 62.9 (25.5, 85.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 2 (5.1%) | 1 (2.8%) |
| Censored Patients, n (%) | 37 (94.9%) | 35 (97.2%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8410 | |
| HR (95% CI) [c] | 1.284 (0.111, 14.830) | |
| HR P-Value [c] | 0.8414 | |
| Heterogeneity p-value [d] | 0.9996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.4 (66.6, 99.2) | 95.5 (71.9, 99.3) |
| 12 months | 78.7 (31.8, 95.1) | 95.5 (71.9, 99.3) |
| 18 months | 78.7 (31.8, 95.1) | NE (NE, NE) |
| 24 months | 78.7 (31.8, 95.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 2 (5.1%) | 3 (8.3%) |
| Censored Patients, n (%) | 37 (94.9%) | 33 (91.7%) |
| Median (95% CI), (Months) [a] | NE (2.89, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4824 | |
| HR (95% CI) [c] | 0.531 (0.088, 3.194) | |
| HR P-Value [c] | 0.4895 | |
| Heterogeneity p-value [d] | 0.5346 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.8 (41.0, 95.0) | 66.7 (27.2, 88.1) |
| 12 months | 80.8 (41.0, 95.0) | NE (NE, NE) |
| 18 months | 80.8 (41.0, 95.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 1 (2.6%) | 3 (8.3%) |
| Censored Patients, n (%) | 38 (97.4%) | 33 (91.7%) |
| | | |
| Median (95% CI), (Months) [a] | NE (1.91, NE) | 1.56 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0276 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9973 | |
| Heterogeneity p-value [d] | 0.3255 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 12 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 18 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 4 (10.3%) | 1 (2.8%) |
| Censored Patients, n (%) | 35 (89.7%) | 35 (97.2%) |
| Median (95% CI), (Months) [a] | NE (6.93, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3792 | |
| HR (95% CI) [c] | 2.642 (0.283, 24.696) | |
| HR P-Value [c] | 0.3941 | |
| Heterogeneity p-value [d] | 0.8958 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.1 (65.0, 95.7) | 93.3 (61.3, 99.0) |
| 12 months | 76.2 (43.3, 91.5) | NE (NE, NE) |
| 18 months | 76.2 (43.3, 91.5) | NE (NE, NE) |
| 24 months | 76.2 (43.3, 91.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 3 (7.7%) | 0 |
| Censored Patients, n (%) | 36 (92.3%) | 36 (100.0%) |
| Median (95% CI), (Months) [a] | NE (7.00, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3092 | |
| HR (95% CI) [c] | 39775071 (0.000, NE) | |
| HR P-Value [c] | 0.9977 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.9 (50.8, 98.7) | 100.0 (100.0, 100.0) |
| 12 months | 53.0 (8.5, 85.0) | 100.0 (100.0, 100.0) |
| 18 months | 53.0 (8.5, 85.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 3 (7.7%) | 2 (5.6%) |
| Censored Patients, n (%) | 36 (92.3%) | 34 (94.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8262 | |
| HR (95% CI) [c] | 1.209 (0.202, 7.243) | |
| HR P-Value [c] | 0.8353 | |
| Heterogeneity p-value [d] | 0.7366 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.7 (63.8, 95.6) | 90.9 (68.3, 97.6) |
| 12 months | 86.7 (63.8, 95.6) | 90.9 (68.3, 97.6) |
| 18 months | 86.7 (63.8, 95.6) | NE (NE, NE) |
| 24 months | 86.7 (63.8, 95.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 4 (10.3%) | 1 (2.8%) |
| Censored Patients, n (%) | 35 (89.7%) | 35 (97.2%) |
| Median (95% CI), (Months) [a] | 12.48 (8.34, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7015 | |
| HR (95% CI) [c] | 1.536 (0.169, 13.993) | |
| HR P-Value [c] | 0.7036 | |
| Heterogeneity p-value [d] | 0.9993 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.7 (58.1, 96.9) | 85.7 (33.4, 97.9) |
| 12 months | 70.2 (25.7, 91.2) | 85.7 (33.4, 97.9) |
| 18 months | 35.1 (1.4, 77.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 3 (7.7%) | 2 (5.6%) |
| Censored Patients, n (%) | 36 (92.3%) | 34 (94.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8086 | |
| HR (95% CI) [c] | 1.247 (0.208, 7.469) | |
| HR P-Value [c] | 0.8089 | |
| Heterogeneity p-value [d] | 0.1181 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.5 (52.3, 93.7) | 83.1 (47.2, 95.5) |
| 12 months | 81.5 (52.3, 93.7) | 83.1 (47.2, 95.5) |
| 18 months | 81.5 (52.3, 93.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 4 (10.3%) | 1 (2.8%) |
| Censored Patients, n (%) | 35 (89.7%) | 35 (97.2%) |
| Median (95% CI), (Months) [a] | NE (1.45, NE) | NE (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1661 | |
| HR (95% CI) [c] | 4.225 (0.471, 37.881) | |
| HR P-Value [c] | 0.1979 | |
| Heterogeneity p-value [d] | 0.5903 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.5 (48.8, 90.4) | 88.9 (43.3, 98.4) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 8 (10.5%) | 2 (3.0%) |
| Censored Patients, n (%) | 68 (89.5%) | 64 (97.0%) |
| Median (95% CI), (Months) [a] | 16.62 (13.31, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4146 | |
| HR (95% CI) [c] | 1.927 (0.388, 9.583) | |
| HR P-Value [c] | 0.4228 | |
| Heterogeneity p-value [d] | 0.7840 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.9 (51.9, 88.0) | 86.3 (54.7, 96.5) |
| 12 months | 74.9 (51.9, 88.0) | NE (NE, NE) |
| 18 months | 37.4 (6.4, 70.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 12 (15.8%) | 4 (6.1%) |
| Censored Patients, n (%) | 64 (84.2%) | 62 (93.9%) |
| Median (95% CI), (Months) [a] | 17.97 (8.61, NE) | NE (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9678 | |
| HR (95% CI) [c] | 1.033 (0.310, 3.441) | |
| HR P-Value [c] | 0.9583 | |
| Heterogeneity p-value [d] | 0.9946 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.9 (60.7, 89.4) | 80.1 (49.4, 93.3) |
| 12 months | 67.5 (44.9, 82.5) | NE (NE, NE) |
| 18 months | 34.3 (7.8, 63.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 9 (11.8%) | 3 (4.5%) |
| Censored Patients, n (%) | 67 (88.2%) | 63 (95.5%) |
| Median (95% CI), (Months) [a] | 9.72 (5.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5402 | |
| HR (95% CI) [c] | 1.518 (0.398, 5.784) | |
| HR P-Value [c] | 0.5408 | |
| Heterogeneity p-value [d] | 0.2355 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.4 (47.4, 87.0) | 84.1 (58.3, 94.6) |
| 12 months | 47.0 (20.0, 70.2) | 84.1 (58.3, 94.6) |
| 18 months | 47.0 (20.0, 70.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 6 (7.9%) | 3 (4.5%) |
| Censored Patients, n (%) | 70 (92.1%) | 63 (95.5%) |
| Median (95% CI), (Months) [a] | 11.40 (6.97, 14.26) | NE (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7017 | |
| HR (95% CI) [c] | 0.753 (0.165, 3.434) | |
| HR P-Value [c] | 0.7144 | |
| Heterogeneity p-value [d] | 0.6960 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.7 (56.4, 96.5) | 68.6 (30.5, 88.7) |
| 12 months | 37.9 (6.0, 71.6) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 7 (9.2%) | 0 |
| Censored Patients, n (%) | 69 (90.8%) | 66 (100.0%) |
| Median (95% CI), (Months) [a] | 11.83 (8.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0809 | |
| HR (95% CI) [c] | 18210291 (0.000, NE) | |
| HR P-Value [c] | 0.9945 | |
| Heterogeneity p-value [d] | 0.8241 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.2 (65.0, 95.7) | 100.0 (100.0, 100.0) |
| 12 months | 44.4 (13.1, 72.3) | 100.0 (100.0, 100.0) |
| 18 months | 44.4 (13.1, 72.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 5 (6.6%) | 2 (3.0%) |
| Censored Patients, n (%) | 71 (93.4%) | 64 (97.0%) |
| Median (95% CI), (Months) [a] | NE (16.39, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9252 | |
| HR (95% CI) [c] | 0.921 (0.166, 5.117) | |
| HR P-Value [c] | 0.9252 | |
| Heterogeneity p-value [d] | 0.2813 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.9 (81.1, 98.7) | 89.1 (61.5, 97.3) |
| 12 months | 82.4 (55.8, 93.8) | 89.1 (61.5, 97.3) |
| 18 months | 68.7 (32.0, 88.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 13 (17.1%) | 5 (7.6%) |
| Censored Patients, n (%) | 63 (82.9%) | 61 (92.4%) |
| Median (95% CI), (Months) [a] | NE (11.17, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3896 | |
| HR (95% CI) [c] | 1.588 (0.558, 4.517) | |
| HR P-Value [c] | 0.3858 | |
| Heterogeneity p-value [d] | 0.9996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.8 (67.0, 89.3) | 87.5 (69.4, 95.2) |
| 12 months | 67.0 (46.9, 80.9) | 70.0 (27.5, 90.6) |
| 18 months | 67.0 (46.9, 80.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 7 (9.2%) | 2 (3.0%) |
| Censored Patients, n (%) | 69 (90.8%) | 64 (97.0%) |
| Median (95% CI), (Months) [a] | 14.95 (13.86, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4589 | |
| HR (95% CI) [c] | 1.834 (0.360, 9.344) | |
| HR P-Value [c] | 0.4652 | |
| Heterogeneity p-value [d] | 0.5346 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.3 (54.6, 90.6) | 94.7 (68.1, 99.2) |
| 12 months | 78.3 (54.6, 90.6) | 63.2 (7.0, 92.4) |
| 18 months | 49.0 (14.7, 76.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 9 (11.8%) | 3 (4.5%) |
| Censored Patients, n (%) | 67 (88.2%) | 63 (95.5%) |
| Median (95% CI), (Months) [a] | 9.72 (1.64, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5414 | |
| HR (95% CI) [c] | 1.512 (0.395, 5.783) | |
| HR P-Value [c] | 0.5459 | |
| Heterogeneity p-value [d] | 0.3255 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (40.4, 83.4) | 66.3 (26.6, 88.0) |
| 12 months | 49.4 (22.1, 71.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 15 (19.7%) | 6 (9.1%) |
| Censored Patients, n (%) | 61 (80.3%) | 60 (90.9%) |
| Median (95% CI), (Months) [a] | 17.05 (8.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7277 | |
| HR (95% CI) [c] | 1.195 (0.453, 3.147) | |
| HR P-Value [c] | 0.7190 | |
| Heterogeneity p-value [d] | 0.8958 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.5 (58.5, 86.4) | 78.0 (56.6, 89.7) |
| 12 months | 52.3 (29.6, 70.8) | 78.0 (56.6, 89.7) |
| 18 months | 39.2 (13.9, 64.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 9 (11.8%) | 2 (3.0%) |
| Censored Patients, n (%) | 67 (88.2%) | 64 (97.0%) |
| Median (95% CI), (Months) [a] | NE (15.24, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2189 | |
| HR (95% CI) [c] | 2.562 (0.542, 12.109) | |
| HR P-Value [c] | 0.2351 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.9 (61.4, 90.2) | 93.5 (76.1, 98.3) |
| 12 months | 75.4 (55.5, 87.3) | 93.5 (76.1, 98.3) |
| 18 months | 64.6 (36.4, 82.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 8 (10.5%) | 0 |
| Censored Patients, n (%) | 68 (89.5%) | 66 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0229 | |
| HR (95% CI) [c] | 20816884 (0.000, NE) | |
| HR P-Value [c] | 0.9933 | |
| Heterogeneity p-value [d] | 0.7366 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.7 (73.9, 93.5) | 100.0 (100.0, 100.0) |
| 12 months | 82.5 (66.6, 91.3) | 100.0 (100.0, 100.0) |
| 18 months | 82.5 (66.6, 91.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 13 (17.1%) | 4 (6.1%) |
| Censored Patients, n (%) | 63 (82.9%) | 62 (93.9%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1505 | |
| HR (95% CI) [c] | 2.235 (0.728, 6.856) | |
| HR P-Value [c] | 0.1597 | |
| Heterogeneity p-value [d] | 0.9993 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.3 (50.2, 81.0) | 89.6 (71.0, 96.5) |
| 12 months | 63.1 (43.3, 77.6) | 80.6 (51.6, 93.2) |
| 18 months | 63.1 (43.3, 77.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 9 (11.8%) | 7 (10.6%) |
| Censored Patients, n (%) | 67 (88.2%) | 59 (89.4%) |
| Median (95% CI), (Months) [a] | NE (8.34, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5760 | |
| HR (95% CI) [c] | 0.754 (0.278, 2.049) | |
| HR P-Value [c] | 0.5800 | |
| Heterogeneity p-value [d] | 0.1181 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.8 (58.8, 88.8) | 70.0 (46.3, 84.8) |
| 12 months | 70.0 (45.8, 85.0) | 70.0 (46.3, 84.8) |
| 18 months | 52.5 (18.0, 78.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 11 (14.5%) | 7 (10.6%) |
| Censored Patients, n (%) | 65 (85.5%) | 59 (89.4%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8459 | |
| HR (95% CI) [c] | 1.101 (0.425, 2.854) | |
| HR P-Value [c] | 0.8434 | |
| Heterogeneity p-value [d] | 0.5903 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.6 (55.0, 85.5) | 73.4 (49.1, 87.4) |
| 12 months | 61.5 (38.7, 78.0) | 61.2 (29.9, 81.8) |
| 18 months | 61.5 (38.7, 78.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 7 (11.9%) | 10 (17.9%) |
| Censored Patients, n (%) | 52 (88.1%) | 46 (82.1%) |
| Median (95% CI), (Months) [a] | 12.52 (2.83, NE) | NE (1.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7328 | |
| HR (95% CI) [c] | 0.844 (0.303, 2.352) | |
| HR P-Value [c] | 0.7451 | |
| Heterogeneity p-value [d] | 0.7840 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.2 (35.7, 84.8) | 52.1 (28.0, 71.6) |
| 12 months | 66.2 (35.7, 84.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 5 (8.5%) | 5 (8.9%) |
| Censored Patients, n (%) | 54 (91.5%) | 51 (91.1%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7624 | |
| HR (95% CI) [c] | 1.205 (0.348, 4.170) | |
| HR P-Value [c] | 0.7685 | |
| Heterogeneity p-value [d] | 0.9946 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.0 (45.5, 88.2) | 73.2 (44.3, 88.8) |
| 12 months | 73.0 (45.5, 88.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 5 (8.5%) | 5 (8.9%) |
| Censored Patients, n (%) | 54 (91.5%) | 51 (91.1%) |
| Median (95% CI), (Months) [a] | 11.10 (11.10, NE) | NE (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5222 | |
| HR (95% CI) [c] | 0.652 (0.175, 2.437) | |
| HR P-Value [c] | 0.5253 | |
| Heterogeneity p-value [d] | 0.2355 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.6 (53.6, 92.0) | 73.9 (47.7, 88.3) |
| 12 months | 39.8 (1.5, 81.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 5 (8.5%) | 0 |
| Censored Patients, n (%) | 54 (91.5%) | 56 (100.0%) |
| Median (95% CI), (Months) [a] | 4.21 (1.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.6960 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.0 (9.8, 69.7) | NE (NE, NE) |
| 12 months | 40.0 (9.8, 69.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 7 (11.9%) | 4 (7.1%) |
| Censored Patients, n (%) | 52 (88.1%) | 52 (92.9%) |
| Median (95% CI), (Months) [a] | 5.59 (1.58, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1600 | |
| HR (95% CI) [c] | 2.341 (0.679, 8.076) | |
| HR P-Value [c] | 0.1782 | |
| Heterogeneity p-value [d] | 0.8241 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.5 (5.9, 68.5) | 74.5 (45.4, 89.6) |
| 12 months | 17.8 (0.9, 53.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 8 (13.6%) | 2 (3.6%) |
| Censored Patients, n (%) | 51 (86.4%) | 54 (96.4%) |
| Median (95% CI), (Months) [a] | NE (5.59, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0940 | |
| HR (95% CI) [c] | 3.461 (0.734, 16.314) | |
| HR P-Value [c] | 0.1166 | |
| Heterogeneity p-value [d] | 0.2813 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.1 (38.9, 81.1) | 93.3 (75.9, 98.3) |
| 12 months | 64.1 (38.9, 81.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 9 (15.3%) | 5 (8.9%) |
| Censored Patients, n (%) | 50 (84.7%) | 51 (91.1%) |
| Median (95% CI), (Months) [a] | NE (12.65, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3182 | |
| HR (95% CI) [c] | 1.749 (0.577, 5.299) | |
| HR P-Value [c] | 0.3228 | |
| Heterogeneity p-value [d] | 0.9996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.9 (52.9, 86.7) | 86.6 (67.4, 94.9) |
| 12 months | 73.9 (52.9, 86.7) | 74.2 (39.9, 90.8) |
| 18 months | 59.1 (26.1, 81.4) | NE (NE, NE) |
| 24 months | 59.1 (26.1, 81.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 6 (10.2%) | 5 (8.9%) |
| Censored Patients, n (%) | 53 (89.8%) | 51 (91.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8259 | |
| HR (95% CI) [c] | 1.142 (0.348, 3.745) | |
| HR P-Value [c] | 0.8266 | |
| Heterogeneity p-value [d] | 0.5346 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.7 (54.4, 89.1) | 79.6 (57.4, 91.1) |
| 12 months | 76.7 (54.4, 89.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 6 (10.2%) | 6 (10.7%) |
| Censored Patients, n (%) | 53 (89.8%) | 50 (89.3%) |
| Median (95% CI), (Months) [a] | 7.92 (1.45, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9902 | |
| HR (95% CI) [c] | 0.991 (0.318, 3.091) | |
| HR P-Value [c] | 0.9879 | |
| Heterogeneity p-value [d] | 0.3255 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.7 (29.9, 84.5) | 61.2 (33.0, 80.4) |
| 12 months | 31.9 (1.7, 72.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 11 (18.6%) | 8 (14.3%) |
| Censored Patients, n (%) | 48 (81.4%) | 48 (85.7%) |
| Median (95% CI), (Months) [a] | NE (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4021 | |
| HR (95% CI) [c] | 1.501 (0.590, 3.819) | |
| HR P-Value [c] | 0.3943 | |
| Heterogeneity p-value [d] | 0.8958 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.9 (45.9, 82.5) | 72.8 (51.2, 86.1) |
| 12 months | 67.9 (45.9, 82.5) | NE (NE, NE) |
| 18 months | 54.3 (24.2, 76.9) | NE (NE, NE) |
| 24 months | 54.3 (24.2, 76.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 6 (10.2%) | 0 |
| Censored Patients, n (%) | 53 (89.8%) | 56 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0105 | |
| HR (95% CI) [c] | 88612115 (0.000, NE) | |
| HR P-Value [c] | 0.9960 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.7 (56.5, 90.5) | 100.0 (100.0, 100.0) |
| 12 months | 78.7 (56.5, 90.5) | NE (NE, NE) |
| 18 months | 78.7 (56.5, 90.5) | NE (NE, NE) |
| 24 months | 78.7 (56.5, 90.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 7 (11.9%) | 2 (3.6%) |
| Censored Patients, n (%) | 52 (88.1%) | 54 (96.4%) |
| Median (95% CI), (Months) [a] | NE (15.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1754 | |
| HR (95% CI) [c] | 2.885 (0.580, 14.350) | |
| HR P-Value [c] | 0.1955 | |
| Heterogeneity p-value [d] | 0.7366 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.9 (74.8, 96.2) | 93.9 (77.4, 98.5) |
| 12 months | 77.3 (52.3, 90.2) | NE (NE, NE) |
| 18 months | 51.5 (9.7, 82.8) | NE (NE, NE) |
| 24 months | 51.5 (9.7, 82.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 8 (13.6%) | 4 (7.1%) |
| Censored Patients, n (%) | 51 (86.4%) | 52 (92.9%) |
| Median (95% CI), (Months) [a] | 13.83 (9.86, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6213 | |
| HR (95% CI) [c] | 1.379 (0.386, 4.931) | |
| HR P-Value [c] | 0.6211 | |
| Heterogeneity p-value [d] | 0.9993 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.7 (57.6, 92.0) | 85.1 (64.2, 94.3) |
| 12 months | 58.8 (26.5, 80.9) | NE (NE, NE) |
| 18 months | 29.4 (1.7, 69.2) | NE (NE, NE) |
| 24 months | 29.4 (1.7, 69.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 12 (20.3%) | 4 (7.1%) |
| Censored Patients, n (%) | 47 (79.7%) | 52 (92.9%) |
| Median (95% CI), (Months) [a] | 8.44 (1.48, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0130 | |
| HR (95% CI) [c] | 3.859 (1.234, 12.066) | |
| HR P-Value [c] | 0.0202 | |
| Heterogeneity p-value [d] | 0.1181 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.1 (36.6, 74.6) | 88.0 (67.2, 96.0) |
| 12 months | 38.7 (9.4, 68.4) | NE (NE, NE) |
| 18 months | 38.7 (9.4, 68.4) | NE (NE, NE) |
| 24 months | 38.7 (9.4, 68.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 4 (6.8%) | 4 (7.1%) |
| Censored Patients, n (%) | 55 (93.2%) | 52 (92.9%) |
| Median (95% CI), (Months) [a] | NE (12.58, NE) | NE (5.88, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5198 | |
| HR (95% CI) [c] | 0.614 (0.137, 2.751) | |
| HR P-Value [c] | 0.5239 | |
| Heterogeneity p-value [d] | 0.5903 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.9 (61.6, 95.4) | 79.3 (43.7, 93.7) |
| 12 months | 85.9 (61.6, 95.4) | NE (NE, NE) |
| 18 months | 64.4 (18.4, 89.2) | NE (NE, NE) |
| 24 months | 64.4 (18.4, 89.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 18 (11.2%) | 11 (8.0%) |
| Censored Patients, n (%) | 143 (88.8%) | 126 (92.0%) |
| | | |
| Median (95% CI), (Months) [a] | 13.31 (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8686 | |
| HR (95% CI) [c] | 1.068 (0.496, 2.301) | |
| HR P-Value [c] | 0.8658 | |
| Heterogeneity p-value [d] | 0.6989 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.2 (58.2, 83.6) | 71.0 (52.4, 83.5) |
| 12 months | 65.9 (45.2, 80.3) | 71.0 (52.4, 83.5) |
| 18 months | 37.7 (13.7, 61.9) | NE (NE, NE) |
| 24 months | 37.7 (13.7, 61.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 19 (11.8%) | 7 (5.1%) |
| Censored Patients, n (%) | 142 (88.2%) | 130 (94.9%) |
| Median (95% CI), (Months) [a] | 17.97 (9.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5689 | |
| HR (95% CI) [c] | 1.301 (0.529, 3.199) | |
| HR P-Value [c] | 0.5664 | |
| Heterogeneity p-value [d] | 0.4225 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.8 (70.0, 89.3) | 84.0 (67.4, 92.6) |
| 12 months | 67.4 (49.9, 80.0) | NE (NE, NE) |
| 18 months | 46.1 (21.2, 68.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 18 (11.2%) | 8 (5.8%) |
| Censored Patients, n (%) | 143 (88.8%) | 129 (94.2%) |
| Median (95% CI), (Months) [a] | 11.10 (8.48, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7648 | |
| HR (95% CI) [c] | 1.140 (0.489, 2.660) | |
| HR P-Value [c] | 0.7611 | |
| Heterogeneity p-value [d] | 0.1142 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.5 (61.3, 86.4) | 77.2 (58.7, 88.2) |
| 12 months | 49.4 (27.3, 68.1) | 77.2 (58.7, 88.2) |
| 18 months | 41.1 (18.8, 62.3) | NE (NE, NE) |
| 24 months | 41.1 (18.8, 62.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 17 (10.6%) | 3 (2.2%) |
| Censored Patients, n (%) | 144 (89.4%) | 134 (97.8%) |
| Median (95% CI), (Months) [a] | 8.34 (1.58, 14.26) | NE (2.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2351 | |
| HR (95% CI) [c] | 2.098 (0.603, 7.295) | |
| HR P-Value [c] | 0.2439 | |
| Heterogeneity p-value [d] | 0.0530 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.5 (35.9, 72.8) | 74.9 (39.1, 91.5) |
| 12 months | 27.4 (8.3, 50.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 19 (11.8%) | 5 (3.6%) |
| Censored Patients, n (%) | 142 (88.2%) | 132 (96.4%) |
| Median (95% CI), (Months) [a] | 11.33 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0606 | |
| HR (95% CI) [c] | 2.541 (0.927, 6.961) | |
| HR P-Value [c] | 0.0697 | |
| Heterogeneity p-value [d] | 0.4786 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.3 (54.1, 83.0) | 87.8 (72.7, 94.8) |
| 12 months | 37.6 (16.6, 58.8) | 87.8 (72.7, 94.8) |
| 18 months | 28.2 (8.9, 51.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 17 (10.6%) | 8 (5.8%) |
| Censored Patients, n (%) | 144 (89.4%) | 129 (94.2%) |
| Median (95% CI), (Months) [a] | NE (16.39, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8457 | |
| HR (95% CI) [c] | 1.090 (0.463, 2.569) | |
| HR P-Value [c] | 0.8437 | |
| Heterogeneity p-value [d] | 0.9898 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (69.1, 89.1) | 85.7 (71.9, 93.1) |
| 12 months | 71.2 (54.6, 82.6) | 76.2 (49.4, 90.0) |
| 18 months | 64.7 (44.4, 79.2) | NE (NE, NE) |
| 24 months | 64.7 (44.4, 79.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 23 (14.3%) | 8 (5.8%) |
| Censored Patients, n (%) | 138 (85.7%) | 129 (94.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0858 | |
| HR (95% CI) [c] | 2.017 (0.895, 4.546) | |
| HR P-Value [c] | 0.0907 | |
| Heterogeneity p-value [d] | 0.5300 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.9 (74.0, 89.0) | 90.5 (80.8, 95.4) |
| 12 months | 72.5 (58.8, 82.3) | 85.2 (68.0, 93.6) |
| 18 months | 68.9 (53.8, 79.9) | NE (NE, NE) |
| 24 months | 68.9 (53.8, 79.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 13 (8.1%) | 8 (5.8%) |
| Censored Patients, n (%) | 148 (91.9%) | 129 (94.2%) |
| Median (95% CI), (Months) [a] | NE (14.95, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8872 | |
| HR (95% CI) [c] | 1.068 (0.431, 2.642) | |
| HR P-Value [c] | 0.8874 | |
| Heterogeneity p-value [d] | 0.8763 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.8 (65.5, 88.6) | 82.3 (67.4, 90.9) |
| 12 months | 79.8 (65.5, 88.6) | 82.3 (67.4, 90.9) |
| 18 months | 65.8 (42.2, 81.7) | NE (NE, NE) |
| 24 months | 65.8 (42.2, 81.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 15 (9.3%) | 8 (5.8%) |
| Censored Patients, n (%) | 146 (90.7%) | 129 (94.2%) |
| Median (95% CI), (Months) [a] | 12.06 (2.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5974 | |
| HR (95% CI) [c] | 1.264 (0.527, 3.031) | |
| HR P-Value [c] | 0.5999 | |
| Heterogeneity p-value [d] | 0.3413 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.9 (50.0, 80.5) | 71.5 (50.4, 84.9) |
| 12 months | 56.0 (34.4, 73.0) | NE (NE, NE) |
| 18 months | 46.7 (22.9, 67.5) | NE (NE, NE) |
| 24 months | 46.7 (22.9, 67.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 31 (19.3%) | 14 (10.2%) |
| Censored Patients, n (%) | 130 (80.7%) | 123 (89.8%) |
| Median (95% CI), (Months) [a] | 16.76 (8.61, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2409 | |
| HR (95% CI) [c] | 1.477 (0.777, 2.811) | |
| HR P-Value [c] | 0.2343 | |
| Heterogeneity p-value [d] | 0.9006 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.9 (61.5, 81.5) | 75.6 (61.4, 85.2) |
| 12 months | 59.5 (43.7, 72.3) | 75.6 (61.4, 85.2) |
| 18 months | 42.6 (23.1, 60.9) | NE (NE, NE) |
| 24 months | 42.6 (23.1, 60.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 19 (11.8%) | 2 (1.5%) |
| Censored Patients, n (%) | 142 (88.2%) | 135 (98.5%) |
| Median (95% CI), (Months) [a] | NE (15.24, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0037 | |
| HR (95% CI) [c] | 6.546 (1.516, 28.271) | |
| HR P-Value [c] | 0.0118 | |
| Heterogeneity p-value [d] | 0.9934 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.2 (69.9, 88.6) | 97.2 (89.3, 99.3) |
| 12 months | 72.3 (57.3, 82.8) | 97.2 (89.3, 99.3) |
| 18 months | 66.3 (47.4, 79.7) | NE (NE, NE) |
| 24 months | 66.3 (47.4, 79.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 18 (11.2%) | 3 (2.2%) |
| Censored Patients, n (%) | 143 (88.8%) | 134 (97.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0131 | |
| HR (95% CI) [c] | 4.183 (1.225, 14.287) | |
| HR P-Value [c] | 0.0224 | |
| Heterogeneity p-value [d] | 0.1331 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.4 (76.6, 91.1) | 96.2 (88.5, 98.8) |
| 12 months | 81.6 (71.1, 88.6) | 96.2 (88.5, 98.8) |
| 18 months | 76.5 (61.0, 86.5) | NE (NE, NE) |
| 24 months | 76.5 (61.0, 86.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 23 (14.3%) | 6 (4.4%) |
| Censored Patients, n (%) | 138 (85.7%) | 131 (95.6%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0711 | |
| HR (95% CI) [c] | 2.257 (0.913, 5.583) | |
| HR P-Value [c] | 0.0780 | |
| Heterogeneity p-value [d] | 0.2825 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.7 (64.8, 85.1) | 90.0 (77.0, 95.8) |
| 12 months | 63.1 (46.4, 75.8) | 85.2 (67.7, 93.7) |
| 18 months | 58.5 (40.8, 72.7) | NE (NE, NE) |
| 24 months | 58.5 (40.8, 72.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 21 (13.0%) | 11 (8.0%) |
| Censored Patients, n (%) | 140 (87.0%) | 126 (92.0%) |
| Median (95% CI), (Months) [a] | NE (13.44, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3298 | |
| HR (95% CI) [c] | 1.442 (0.693, 3.001) | |
| HR P-Value [c] | 0.3276 | |
| Heterogeneity p-value [d] | 0.7628 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.8 (60.3, 81.9) | 80.8 (67.0, 89.3) |
| 12 months | 68.5 (53.6, 79.5) | 74.1 (53.8, 86.5) |
| 18 months | 60.9 (40.4, 76.2) | NE (NE, NE) |
| 24 months | 60.9 (40.4, 76.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 19 (11.8%) | 9 (6.6%) |
| Censored Patients, n (%) | 142 (88.2%) | 128 (93.4%) |
| Median (95% CI), (Months) [a] | NE (7.23, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1943 | |
| HR (95% CI) [c] | 1.687 (0.762, 3.731) | |
| HR P-Value [c] | 0.1970 | |
| Heterogeneity p-value [d] | 0.2000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.5 (60.4, 82.9) | 77.1 (58.1, 88.4) |
| 12 months | 65.0 (48.0, 77.7) | 77.1 (58.1, 88.4) |
| 18 months | 65.0 (48.0, 77.7) | NE (NE, NE) |
| 24 months | 65.0 (48.0, 77.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 3 (6.5%) |
| Censored Patients, n (%) | 33 (94.3%) | 43 (93.5%) |
| Median (95% CI), (Months) [a] | NE (1.41, NE) | NE (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4754 | |
| HR (95% CI) [c] | 1.914 (0.319, 11.488) | |
| HR P-Value [c] | 0.4777 | |
| Heterogeneity p-value [d] | 0.6989 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (19.5, 90.4) | 77.5 (44.8, 92.3) |
| 12 months | 66.7 (19.5, 90.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 3 (6.5%) |
| Censored Patients, n (%) | 33 (94.3%) | 43 (93.5%) |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7693 | |
| HR (95% CI) [c] | 0.765 (0.127, 4.617) | |
| HR P-Value [c] | 0.7700 | |
| Heterogeneity p-value [d] | 0.4225 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.3 (48.2, 95.6) | 65.0 (17.7, 89.8) |
| 12 months | 83.3 (48.2, 95.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 1 (2.9%) | 6 (13.0%) |
| Censored Patients, n (%) | 34 (97.1%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | NE (2.69, NE) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1730 | |
| HR (95% CI) [c] | 0.255 (0.031, 2.117) | |
| HR P-Value [c] | 0.2055 | |
| Heterogeneity p-value [d] | 0.1142 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.7 (33.4, 97.9) | 62.5 (34.9, 81.1) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 1 (2.9%) | 4 (8.7%) |
| Censored Patients, n (%) | 34 (97.1%) | 42 (91.3%) |
| Median (95% CI), (Months) [a] | NE (1.45, NE) | 1.54 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1593 | |
| HR (95% CI) [c] | 0.241 (0.027, 2.173) | |
| HR P-Value [c] | 0.2045 | |
| Heterogeneity p-value [d] | 0.0530 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (20.4, 96.9) | 20.0 (0.8, 58.2) |
| 12 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 2 (4.3%) |
| Censored Patients, n (%) | 32 (91.4%) | 44 (95.7%) |
| Median (95% CI), (Months) [a] | 8.48 (1.54, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7804 | |
| HR (95% CI) [c] | 1.291 (0.213, 7.834) | |
| HR P-Value [c] | 0.7810 | |
| Heterogeneity p-value [d] | 0.4786 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.0 (22.5, 91.8) | 75.0 (31.5, 93.1) |
| 12 months | 46.7 (7.1, 80.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 0 |
| Censored Patients, n (%) | 33 (94.3%) | 46 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1041 | |
| HR (95% CI) [c] | 1.0993E8 (0.000, NE) | |
| HR P-Value [c] | 0.9977 | |
| Heterogeneity p-value [d] | 0.9898 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.2 (55.0, 96.4) | 100.0 (100.0, 100.0) |
| 12 months | 86.2 (55.0, 96.4) | 100.0 (100.0, 100.0) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 3 (6.5%) |
| Censored Patients, n (%) | 32 (91.4%) | 43 (93.5%) |
| Median (95% CI), (Months) [a] | NE (4.34, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9551 | |
| HR (95% CI) [c] | 1.047 (0.209, 5.258) | |
| HR P-Value [c] | 0.9551 | |
| Heterogeneity p-value [d] | 0.5300 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.1 (47.9, 92.8) | 90.5 (67.0, 97.5) |
| 12 months | 79.1 (47.9, 92.8) | 60.3 (8.0, 90.4) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 3 (6.5%) |
| Censored Patients, n (%) | 33 (94.3%) | 43 (93.5%) |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | 8.97 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7146 | |
| HR (95% CI) [c] | 0.697 (0.100, 4.848) | |
| HR P-Value [c] | 0.7156 | |
| Heterogeneity p-value [d] | 0.8763 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.8 (42.3, 94.9) | 87.5 (58.6, 96.7) |
| 12 months | 80.8 (42.3, 94.9) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 5 (10.9%) |
| Censored Patients, n (%) | 33 (94.3%) | 41 (89.1%) |
| Median (95% CI), (Months) [a] | 7.92 (1.45, NE) | 2.22 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3113 | |
| HR (95% CI) [c] | 0.360 (0.041, 3.127) | |
| HR P-Value [c] | 0.3541 | |
| Heterogeneity p-value [d] | 0.3413 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 12 months | 37.5 (1.1, 80.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 4 (8.7%) |
| Censored Patients, n (%) | 31 (88.6%) | 42 (91.3%) |
| Median (95% CI), (Months) [a] | NE (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7139 | |
| HR (95% CI) [c] | 1.300 (0.318, 5.309) | |
| HR P-Value [c] | 0.7146 | |
| Heterogeneity p-value [d] | 0.9006 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.5 (44.8, 92.3) | 82.8 (60.1, 93.2) |
| 12 months | 66.5 (31.8, 86.4) | 82.8 (60.1, 93.2) |
| 18 months | NE (NE, NE) | 82.8 (60.1, 93.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 1 (2.9%) | 0 |
| Censored Patients, n (%) | 34 (97.1%) | 46 (100.0%) |
| Median (95% CI), (Months) [a] | NE (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3778 | |
| HR (95% CI) [c] | 64047725 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.9934 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.9 (43.3, 98.4) | 100.0 (100.0, 100.0) |
| 12 months | 88.9 (43.3, 98.4) | 100.0 (100.0, 100.0) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 1 (2.9%) | 2 (4.3%) |
| Censored Patients, n (%) | 34 (97.1%) | 44 (95.7%) |
| Median (95% CI), (Months) [a] | NE (8.44, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4738 | |
| HR (95% CI) [c] | 0.410 (0.034, 5.007) | |
| HR P-Value [c] | 0.4848 | |
| Heterogeneity p-value [d] | 0.1331 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 91.7 (70.6, 97.8) |
| 12 months | 87.5 (38.7, 98.1) | 91.7 (70.6, 97.8) |
| 18 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 3 (6.5%) |
| Censored Patients, n (%) | 33 (94.3%) | 43 (93.5%) |
| Median (95% CI), (Months) [a] | 13.83 (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5569 | |
| HR (95% CI) [c] | 0.514 (0.053, 4.941) | |
| HR P-Value [c] | 0.5641 | |
| Heterogeneity p-value [d] | 0.2825 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 83.9 (57.9, 94.5) |
| 12 months | 91.7 (53.9, 98.8) | 83.9 (57.9, 94.5) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 4 (8.7%) |
| Censored Patients, n (%) | 31 (88.6%) | 42 (91.3%) |
| Median (95% CI), (Months) [a] | 8.44 (1.41, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4497 | |
| HR (95% CI) [c] | 1.728 (0.423, 7.058) | |
| HR P-Value [c] | 0.4464 | |
| Heterogeneity p-value [d] | 0.7628 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.7 (37.1, 90.3) | 76.6 (48.8, 90.5) |
| 12 months | 48.5 (8.8, 80.6) | 76.6 (48.8, 90.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 4 (8.7%) |
| Censored Patients, n (%) | 33 (94.3%) | 42 (91.3%) |
| Median (95% CI), (Months) [a] | NE (12.58, NE) | 8.48 (7.03, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1146 | |
| HR (95% CI) [c] | 0.192 (0.020, 1.818) | |
| HR P-Value [c] | 0.1502 | |
| Heterogeneity p-value [d] | 0.2000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (59.1, 99.0) | 85.2 (51.9, 96.2) |
| 12 months | 92.9 (59.1, 99.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 10 (11.2%) | 3 (3.5%) |
| Censored Patients, n (%) | 79 (88.8%) | 82 (96.5%) |
| Median (95% CI), (Months) [a] | NE (4.27, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3267 | |
| HR (95% CI) [c] | 1.910 (0.517, 7.066) | |
| HR P-Value [c] | 0.3320 | |
| Heterogeneity p-value [d] | 0.4146 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.3 (49.9, 83.7) | 76.0 (37.8, 92.5) |
| 12 months | 70.3 (49.9, 83.7) | NE (NE, NE) |
| 18 months | 52.7 (18.8, 78.3) | NE (NE, NE) |
| 24 months | 52.7 (18.8, 78.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 6 (6.7%) | 5 (5.9%) |
| Censored Patients, n (%) | 83 (93.3%) | 80 (94.1%) |
| Median (95% CI), (Months) [a] | 17.97 (14.09, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2191 | |
| HR (95% CI) [c] | 0.448 (0.120, 1.672) | |
| HR P-Value [c] | 0.2319 | |
| Heterogeneity p-value [d] | 0.0743 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.8 (72.6, 95.6) | 67.5 (32.4, 87.2) |
| 12 months | 88.8 (72.6, 95.6) | NE (NE, NE) |
| 18 months | 38.0 (1.5, 80.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 7 (7.9%) | 5 (5.9%) |
| Censored Patients, n (%) | 82 (92.1%) | 80 (94.1%) |
| Median (95% CI), (Months) [a] | 11.10 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4594 | |
| HR (95% CI) [c] | 0.635 (0.191, 2.112) | |
| HR P-Value [c] | 0.4589 | |
| Heterogeneity p-value [d] | 0.6726 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.1 (53.6, 90.7) | 77.3 (53.7, 89.9) |
| 12 months | 47.3 (9.6, 78.7) | NE (NE, NE) |
| 18 months | 47.3 (9.6, 78.7) | NE (NE, NE) |
| 24 months | 47.3 (9.6, 78.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 10 (11.2%) | 4 (4.7%) |
| Censored Patients, n (%) | 79 (88.8%) | 81 (95.3%) |
| Median (95% CI), (Months) [a] | 4.21 (1.58, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7375 | |
| HR (95% CI) [c] | 1.241 (0.388, 3.972) | |
| HR P-Value [c] | 0.7163 | |
| Heterogeneity p-value [d] | 0.8739 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.6 (23.0, 68.7) | 51.1 (14.1, 79.5) |
| 12 months | 35.7 (11.6, 61.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 12 (13.5%) | 1 (1.2%) |
| Censored Patients, n (%) | 77 (86.5%) | 84 (98.8%) |
| Median (95% CI), (Months) [a] | 11.83 (4.21, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0910 | |
| HR (95% CI) [c] | 5.039 (0.631, 40.260) | |
| HR P-Value [c] | 0.1272 | |
| Heterogeneity p-value [d] | 0.2720 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.3 (48.4, 85.4) | 91.7 (53.9, 98.8) |
| 12 months | 40.4 (14.1, 65.8) | NE (NE, NE) |
| 18 months | 20.2 (1.5, 54.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 9 (10.1%) | 2 (2.4%) |
| Censored Patients, n (%) | 80 (89.9%) | 83 (97.6%) |
| Median (95% CI), (Months) [a] | NE (16.39, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4086 | |
| HR (95% CI) [c] | 1.909 (0.401, 9.081) | |
| HR P-Value [c] | 0.4165 | |
| Heterogeneity p-value [d] | 0.5510 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.0 (68.6, 93.2) | 92.6 (72.8, 98.1) |
| 12 months | 74.3 (52.1, 87.4) | 92.6 (72.8, 98.1) |
| 18 months | 55.7 (18.9, 81.5) | NE (NE, NE) |
| 24 months | 55.7 (18.9, 81.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 14 (15.7%) | 3 (3.5%) |
| Censored Patients, n (%) | 75 (84.3%) | 82 (96.5%) |
| Median (95% CI), (Months) [a] | NE (12.65, NE) | 8.97 (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0696 | |
| HR (95% CI) [c] | 3.036 (0.863, 10.685) | |
| HR P-Value [c] | 0.0837 | |
| Heterogeneity p-value [d] | 0.3030 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.4 (59.6, 84.5) | 93.9 (76.9, 98.5) |
| 12 months | 74.4 (59.6, 84.5) | 46.9 (0.9, 88.6) |
| 18 months | 66.1 (44.0, 81.2) | NE (NE, NE) |
| 24 months | 66.1 (44.0, 81.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 6 (6.7%) | 2 (2.4%) |
| Censored Patients, n (%) | 83 (93.3%) | 83 (97.6%) |
| Median (95% CI), (Months) [a] | NE (14.95, NE) | 8.97 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6526 | |
| HR (95% CI) [c] | 1.467 (0.274, 7.853) | |
| HR P-Value [c] | 0.6545 | |
| Heterogeneity p-value [d] | 0.5879 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.4 (64.5, 92.8) | 95.5 (71.9, 99.3) |
| 12 months | 83.4 (64.5, 92.8) | 0.0 (NE, NE) |
| 18 months | 71.5 (39.4, 88.6) | 0.0 (NE, NE) |
| 24 months | 71.5 (39.4, 88.6) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 7 (7.9%) | 6 (7.1%) |
| Censored Patients, n (%) | 82 (92.1%) | 79 (92.9%) |
| Median (95% CI), (Months) [a] | 12.06 (1.58, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5820 | |
| HR (95% CI) [c] | 0.734 (0.230, 2.346) | |
| HR P-Value [c] | 0.6025 | |
| Heterogeneity p-value [d] | 0.6597 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.2 (50.0, 88.9) | 53.6 (22.4, 77.0) |
| 12 months | 65.8 (36.8, 83.9) | NE (NE, NE) |
| 18 months | 49.3 (16.0, 76.1) | NE (NE, NE) |
| 24 months | 49.3 (16.0, 76.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 16 (18.0%) | 3 (3.5%) |
| Censored Patients, n (%) | 73 (82.0%) | 82 (96.5%) |
| Median (95% CI), (Months) [a] | NE (8.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0361 | |
| HR (95% CI) [c] | 3.494 (1.008, 12.107) | |
| HR P-Value [c] | 0.0485 | |
| Heterogeneity p-value [d] | 0.1485 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.1 (51.1, 80.2) | 89.2 (69.7, 96.4) |
| 12 months | 62.8 (43.9, 76.9) | 89.2 (69.7, 96.4) |
| 18 months | 53.8 (30.5, 72.4) | NE (NE, NE) |
| 24 months | 53.8 (30.5, 72.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 7 (7.9%) | 0 |
| Censored Patients, n (%) | 82 (92.1%) | 85 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0392 | |
| HR (95% CI) [c] | 19761570 (0.000, NE) | |
| HR P-Value [c] | 0.9938 | |
| Heterogeneity p-value [d] | 0.9907 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.0 (75.0, 94.5) | 100.0 (100.0, 100.0) |
| 12 months | 83.1 (65.5, 92.2) | 100.0 (100.0, 100.0) |
| 18 months | 83.1 (65.5, 92.2) | NE (NE, NE) |
| 24 months | 83.1 (65.5, 92.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:01:24, yingyuan.lin)

Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 14 (15.7%) | 2 (2.4%) |
| Censored Patients, n (%) | 75 (84.3%) | 83 (97.6%) |
| Median (95% CI), (Months) [a] | NE (15.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0632 | |
| HR (95% CI) [c] | 3.746 (0.840, 16.708) | |
| HR P-Value [c] | 0.0834 | |
| Heterogeneity p-value [d] | 0.3622 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.5 (68.9, 89.4) | 95.1 (81.9, 98.8) |
| 12 months | 73.3 (56.2, 84.6) | 95.1 (81.9, 98.8) |
| 18 months | 61.1 (32.5, 80.6) | NE (NE, NE) |
| 24 months | 61.1 (32.5, 80.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 12 (13.5%) | 1 (1.2%) |
| Censored Patients, n (%) | 77 (86.5%) | 84 (98.8%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0433 | |
| HR (95% CI) [c] | 6.331 (0.812, 49.350) | |
| HR P-Value [c] | 0.0782 | |
| Heterogeneity p-value [d] | 0.1466 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.2 (65.0, 89.3) | 96.6 (77.9, 99.5) |
| 12 months | 64.5 (36.9, 82.4) | 96.6 (77.9, 99.5) |
| 18 months | 51.6 (21.0, 75.5) | NE (NE, NE) |
| 24 months | 51.6 (21.0, 75.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 10 (11.2%) | 4 (4.7%) |
| Censored Patients, n (%) | 79 (88.8%) | 81 (95.3%) |
| Median (95% CI), (Months) [a] | NE (13.44, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4505 | |
| HR (95% CI) [c] | 1.583 (0.484, 5.181) | |
| HR P-Value [c] | 0.4478 | |
| Heterogeneity p-value [d] | 0.8126 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.5 (61.2, 88.7) | 83.6 (61.3, 93.7) |
| 12 months | 71.9 (50.4, 85.4) | 83.6 (61.3, 93.7) |
| 18 months | 59.9 (30.4, 80.2) | NE (NE, NE) |
| 24 months | 59.9 (30.4, 80.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 12 (13.5%) | 3 (3.5%) |
| Censored Patients, n (%) | 77 (86.5%) | 82 (96.5%) |
| Median (95% CI), (Months) [a] | NE (7.23, NE) | NE (7.03, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2945 | |
| HR (95% CI) [c] | 1.965 (0.546, 7.072) | |
| HR P-Value [c] | 0.3012 | |
| Heterogeneity p-value [d] | 0.3073 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.0 (60.3, 87.4) | 96.0 (74.8, 99.4) |
| 12 months | 65.6 (43.8, 80.6) | NE (NE, NE) |
| 18 months | 52.5 (23.5, 75.0) | NE (NE, NE) |
| 24 months | 52.5 (23.5, 75.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 10 (9.3%) | 11 (11.2%) |
| Censored Patients, n (%) | 97 (90.7%) | 87 (88.8%) |
| Median (95% CI), (Months) [a] | 13.31 (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8444 | |
| HR (95% CI) [c] | 0.913 (0.372, 2.241) | |
| HR P-Value [c] | 0.8425 | |
| Heterogeneity p-value [d] | 0.4146 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.3 (57.3, 88.7) | 68.9 (50.4, 81.7) |
| 12 months | 66.2 (37.1, 84.3) | 68.9 (50.4, 81.7) |
| 18 months | 33.1 (5.8, 65.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 15 (14.0%) | 5 (5.1%) |
| Censored Patients, n (%) | 92 (86.0%) | 93 (94.9%) |
| Median (95% CI), (Months) [a] | 12.52 (7.03, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1618 | |
| HR (95% CI) [c] | 2.061 (0.730, 5.817) | |
| HR P-Value [c] | 0.1718 | |
| Heterogeneity p-value [d] | 0.0743 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.2 (60.1, 86.5) | 87.3 (69.4, 95.1) |
| 12 months | 55.1 (33.2, 72.5) | NE (NE, NE) |
| 18 months | 48.3 (25.9, 67.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 12 (11.2%) | 9 (9.2%) |
| Censored Patients, n (%) | 95 (88.8%) | 89 (90.8%) |
| Median (95% CI), (Months) [a] | 15.31 (8.48, NE) | NE (3.12, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8338 | |
| HR (95% CI) [c] | 0.915 (0.377, 2.221) | |
| HR P-Value [c] | 0.8448 | |
| Heterogeneity p-value [d] | 0.6726 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.7 (59.7, 88.4) | 70.1 (49.1, 83.7) |
| 12 months | 52.4 (25.4, 73.8) | 70.1 (49.1, 83.7) |
| 18 months | 39.3 (12.6, 65.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 8 (7.5%) | 3 (3.1%) |
| Censored Patients, n (%) | 99 (92.5%) | 95 (96.9%) |
| Median (95% CI), (Months) [a] | 11.40 (3.45, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9026 | |
| HR (95% CI) [c] | 0.920 (0.223, 3.787) | |
| HR P-Value [c] | 0.9075 | |
| Heterogeneity p-value [d] | 0.8739 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.1 (42.7, 89.1) | 61.0 (20.2, 85.8) |
| 12 months | 37.6 (10.0, 66.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 10 (9.3%) | 6 (6.1%) |
| Censored Patients, n (%) | 97 (90.7%) | 92 (93.9%) |
| Median (95% CI), (Months) [a] | 11.33 (5.59, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3449 | |
| HR (95% CI) [c] | 1.625 (0.584, 4.517) | |
| HR P-Value [c] | 0.3522 | |
| Heterogeneity p-value [d] | 0.2720 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.0 (44.8, 85.3) | 81.4 (63.1, 91.2) |
| 12 months | 38.3 (11.6, 65.1) | 81.4 (63.1, 91.2) |
| 18 months | 38.3 (11.6, 65.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 10 (9.3%) | 6 (6.1%) |
| Censored Patients, n (%) | 97 (90.7%) | 92 (93.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5845 | |
| HR (95% CI) [c] | 1.331 (0.479, 3.696) | |
| HR P-Value [c] | 0.5835 | |
| Heterogeneity p-value [d] | 0.5510 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.2 (64.1, 89.6) | 87.3 (71.8, 94.6) |
| 12 months | 74.8 (55.5, 86.7) | 76.4 (45.5, 91.2) |
| 18 months | 74.8 (55.5, 86.7) | NE (NE, NE) |
| 24 months | 74.8 (55.5, 86.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 12 (11.2%) | 8 (8.2%) |
| Censored Patients, n (%) | 95 (88.8%) | 90 (91.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5802 | |
| HR (95% CI) [c] | 1.290 (0.523, 3.182) | |
| HR P-Value [c] | 0.5801 | |
| Heterogeneity p-value [d] | 0.3030 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.0 (79.1, 94.3) | 88.3 (76.7, 94.3) |
| 12 months | 73.1 (54.0, 85.3) | 82.7 (64.7, 92.1) |
| 18 months | 73.1 (54.0, 85.3) | NE (NE, NE) |
| 24 months | 73.1 (54.0, 85.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 9 (8.4%) | 9 (9.2%) |
| Censored Patients, n (%) | 98 (91.6%) | 89 (90.8%) |
| Median (95% CI), (Months) [a] | NE (13.86, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9463 | |
| HR (95% CI) [c] | 0.970 (0.380, 2.477) | |
| HR P-Value [c] | 0.9487 | |
| Heterogeneity p-value [d] | 0.5879 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.8 (57.3, 88.3) | 78.9 (63.3, 88.5) |
| 12 months | 76.8 (57.3, 88.3) | 78.9 (63.3, 88.5) |
| 18 months | 64.0 (32.8, 83.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 10 (9.3%) | 7 (7.1%) |
| Censored Patients, n (%) | 97 (90.7%) | 91 (92.9%) |
| Median (95% CI), (Months) [a] | 9.72 (1.91, NE) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7696 | |
| HR (95% CI) [c] | 1.137 (0.431, 3.003) | |
| HR P-Value [c] | 0.7952 | |
| Heterogeneity p-value [d] | 0.6597 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.6 (39.6, 80.1) | 67.0 (42.9, 82.7) |
| 12 months | 45.4 (19.7, 68.1) | NE (NE, NE) |
| 18 months | 45.4 (19.7, 68.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 19 (17.8%) | 15 (15.3%) |
| Censored Patients, n (%) | 88 (82.2%) | 83 (84.7%) |
| Median (95% CI), (Months) [a] | 16.76 (8.61, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7943 | |
| HR (95% CI) [c] | 1.101 (0.554, 2.188) | |
| HR P-Value [c] | 0.7846 | |
| Heterogeneity p-value [d] | 0.1485 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.0 (62.4, 86.5) | 71.4 (56.0, 82.2) |
| 12 months | 58.3 (37.8, 74.1) | 71.4 (56.0, 82.2) |
| 18 months | 36.4 (12.2, 61.6) | 71.4 (56.0, 82.2) |
| 24 months | 36.4 (12.2, 61.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 13 (12.1%) | 2 (2.0%) |
| Censored Patients, n (%) | 94 (87.9%) | 96 (98.0%) |
| Median (95% CI), (Months) [a] | NE (15.24, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0130 | |
| HR (95% CI) [c] | 5.446 (1.215, 24.404) | |
| HR P-Value [c] | 0.0268 | |
| Heterogeneity p-value [d] | 0.9907 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.7 (61.6, 87.7) | 96.5 (86.9, 99.1) |
| 12 months | 69.3 (50.1, 82.3) | 96.5 (86.9, 99.1) |
| 18 months | 59.4 (33.9, 77.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 5 (4.7%) | 3 (3.1%) |
| Censored Patients, n (%) | 102 (95.3%) | 95 (96.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5108 | |
| HR (95% CI) [c] | 1.609 (0.384, 6.741) | |
| HR P-Value [c] | 0.5152 | |
| Heterogeneity p-value [d] | 0.3622 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.2 (82.1, 97.5) | 95.4 (86.3, 98.5) |
| 12 months | 90.5 (77.8, 96.1) | 95.4 (86.3, 98.5) |
| 18 months | 90.5 (77.8, 96.1) | NE (NE, NE) |
| 24 months | 90.5 (77.8, 96.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 13 (12.1%) | 8 (8.2%) |
| Censored Patients, n (%) | 94 (87.9%) | 90 (91.8%) |
| Median (95% CI), (Months) [a] | NE (9.86, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6378 | |
| HR (95% CI) [c] | 1.239 (0.508, 3.020) | |
| HR P-Value [c] | 0.6376 | |
| Heterogeneity p-value [d] | 0.1466 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.5 (61.0, 87.6) | 84.5 (69.7, 92.4) |
| 12 months | 67.1 (46.5, 81.3) | 79.2 (60.3, 89.8) |
| 18 months | 60.4 (37.7, 77.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 15 (14.0%) | 11 (11.2%) |
| Censored Patients, n (%) | 92 (86.0%) | 87 (88.8%) |
| Median (95% CI), (Months) [a] | NE (8.34, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3333 | |
| HR (95% CI) [c] | 1.469 (0.674, 3.201) | |
| HR P-Value [c] | 0.3328 | |
| Heterogeneity p-value [d] | 0.8126 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.8 (52.5, 80.5) | 76.9 (61.2, 86.9) |
| 12 months | 60.2 (37.7, 76.8) | 69.2 (47.0, 83.6) |
| 18 months | 60.2 (37.7, 76.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 9 (8.4%) | 10 (10.2%) |
| Censored Patients, n (%) | 98 (91.6%) | 88 (89.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (5.88, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8720 | |
| HR (95% CI) [c] | 1.081 (0.439, 2.663) | |
| HR P-Value [c] | 0.8648 | |
| Heterogeneity p-value [d] | 0.3073 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.4 (60.0, 87.9) | 69.1 (47.1, 83.5) |
| 12 months | 77.4 (60.0, 87.9) | 69.1 (47.1, 83.5) |
| 18 months | 77.4 (60.0, 87.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 9 (10.8%) | 6 (8.7%) |
| Censored Patients, n (%) | 74 (89.2%) | 63 (91.3%) |
| Median (95% CI), (Months) [a] | NE (4.21, NE) | NE (2.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7991 | |
| HR (95% CI) [c] | 0.875 (0.309, 2.479) | |
| HR P-Value [c] | 0.8017 | |
| Heterogeneity p-value [d] | 0.4433 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.1 (45.8, 82.8) | 61.9 (33.3, 81.1) |
| 12 months | 68.1 (45.8, 82.8) | 61.9 (33.3, 81.1) |
| 18 months | 54.5 (24.2, 77.2) | NE (NE, NE) |
| 24 months | 54.5 (24.2, 77.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 8 (9.6%) | 4 (5.8%) |
| Censored Patients, n (%) | 75 (90.4%) | 65 (94.2%) |
| Median (95% CI), (Months) [a] | 17.97 (8.61, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5137 | |
| HR (95% CI) [c] | 0.644 (0.173, 2.393) | |
| HR P-Value [c] | 0.5115 | |
| Heterogeneity p-value [d] | 0.4049 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.6 (70.3, 95.2) | 77.7 (50.7, 91.1) |
| 12 months | 75.0 (50.0, 88.7) | NE (NE, NE) |
| 18 months | 41.7 (8.4, 73.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 9 (10.8%) | 5 (7.2%) |
| Censored Patients, n (%) | 74 (89.2%) | 64 (92.8%) |
| Median (95% CI), (Months) [a] | 11.10 (6.97, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7306 | |
| HR (95% CI) [c] | 0.820 (0.265, 2.533) | |
| HR P-Value [c] | 0.7296 | |
| Heterogeneity p-value [d] | 0.7182 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.6 (57.5, 91.1) | 69.9 (42.0, 86.3) |
| 12 months | 45.5 (14.3, 72.7) | 69.9 (42.0, 86.3) |
| 18 months | 30.3 (5.4, 61.5) | NE (NE, NE) |
| 24 months | 30.3 (5.4, 61.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 10 (12.0%) | 4 (5.8%) |
| Censored Patients, n (%) | 73 (88.0%) | 65 (94.2%) |
| Median (95% CI), (Months) [a] | 6.97 (1.58, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8943 | |
| HR (95% CI) [c] | 0.940 (0.287, 3.078) | |
| HR P-Value [c] | 0.9192 | |
| Heterogeneity p-value [d] | 0.7115 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.9 (29.3, 74.6) | 50.8 (15.7, 78.1) |
| 12 months | 30.5 (6.7, 59.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 7 (8.4%) | 4 (5.8%) |
| Censored Patients, n (%) | 76 (91.6%) | 65 (94.2%) |
| Median (95% CI), (Months) [a] | 11.33 (4.27, NE) | NE (1.94, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8718 | |
| HR (95% CI) [c] | 1.108 (0.317, 3.875) | |
| HR P-Value [c] | 0.8719 | |
| Heterogeneity p-value [d] | 0.1503 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.5 (49.9, 91.1) | 72.5 (42.1, 88.8) |
| 12 months | 23.3 (1.1, 62.1) | 72.5 (42.1, 88.8) |
| 18 months | 23.3 (1.1, 62.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 9 (10.8%) | 3 (4.3%) |
| Censored Patients, n (%) | 74 (89.2%) | 66 (95.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4083 | |
| HR (95% CI) [c] | 1.736 (0.466, 6.462) | |
| HR P-Value [c] | 0.4108 | |
| Heterogeneity p-value [d] | 0.8629 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (62.6, 89.9) | 88.4 (67.9, 96.1) |
| 12 months | 75.3 (55.9, 87.0) | 88.4 (67.9, 96.1) |
| 18 months | 75.3 (55.9, 87.0) | NE (NE, NE) |
| 24 months | 75.3 (55.9, 87.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 9 (10.8%) | 6 (8.7%) |
| Censored Patients, n (%) | 74 (89.2%) | 63 (91.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8721 | |
| HR (95% CI) [c] | 0.915 (0.320, 2.621) | |
| HR P-Value [c] | 0.8693 | |
| Heterogeneity p-value [d] | 0.1028 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.1 (72.8, 93.1) | 87.1 (71.3, 94.5) |
| 12 months | 81.3 (64.0, 90.8) | 72.6 (35.2, 90.6) |
| 18 months | 75.5 (54.6, 87.7) | NE (NE, NE) |
| 24 months | 75.5 (54.6, 87.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 6 (7.2%) | 4 (5.8%) |
| Censored Patients, n (%) | 77 (92.8%) | 65 (94.2%) |
| | | |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9342 | |
| HR (95% CI) [c] | 1.053 (0.295, 3.762) | |
| HR P-Value [c] | 0.9362 | |
| Heterogeneity p-value [d] | 0.8608 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.8 (60.4, 90.4) | 87.3 (65.6, 95.7) |
| 12 months | 79.8 (60.4, 90.4) | 58.2 (8.7, 88.7) |
| 18 months | 79.8 (60.4, 90.4) | NE (NE, NE) |
| 24 months | 79.8 (60.4, 90.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 5 (6.0%) | 4 (5.8%) |
| Censored Patients, n (%) | 78 (94.0%) | 65 (94.2%) |
| Median (95% CI), (Months) [a] | NE (1.71, NE) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8102 | |
| HR (95% CI) [c] | 0.839 (0.218, 3.234) | |
| HR P-Value [c] | 0.7983 | |
| Heterogeneity p-value [d] | 0.6565 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.5 (38.9, 87.8) | 64.3 (29.8, 85.1) |
| 12 months | 61.7 (30.5, 82.2) | NE (NE, NE) |
| 18 months | 61.7 (30.5, 82.2) | NE (NE, NE) |
| 24 months | 61.7 (30.5, 82.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 16 (19.3%) | 7 (10.1%) |
| Censored Patients, n (%) | 67 (80.7%) | 62 (89.9%) |
| Median (95% CI), (Months) [a] | 16.76 (8.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6751 | |
| HR (95% CI) [c] | 1.215 (0.490, 3.014) | |
| HR P-Value [c] | 0.6740 | |
| Heterogeneity p-value [d] | 0.6656 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.0 (55.9, 84.4) | 77.0 (57.5, 88.4) |
| 12 months | 58.4 (37.6, 74.4) | 77.0 (57.5, 88.4) |
| 18 months | 43.2 (20.5, 64.2) | NE (NE, NE) |
| 24 months | 43.2 (20.5, 64.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 7 (8.4%) | 1 (1.4%) |
| Censored Patients, n (%) | 76 (91.6%) | 68 (98.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1227 | |
| HR (95% CI) [c] | 4.502 (0.554, 36.601) | |
| HR P-Value [c] | 0.1593 | |
| Heterogeneity p-value [d] | 0.4628 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.5 (64.3, 91.0) | 96.3 (76.5, 99.5) |
| 12 months | 81.5 (64.3, 91.0) | 96.3 (76.5, 99.5) |
| 18 months | 81.5 (64.3, 91.0) | NE (NE, NE) |
| 24 months | 81.5 (64.3, 91.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 8 (9.6%) | 0 |
| Censored Patients, n (%) | 75 (90.4%) | 69 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0304 | |
| HR (95% CI) [c] | 21176031 (0.000, NE) | |
| HR P-Value [c] | 0.9937 | |
| Heterogeneity p-value [d] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.8 (73.8, 93.6) | 100.0 (100.0, 100.0) |
| 12 months | 86.8 (73.8, 93.6) | 100.0 (100.0, 100.0) |
| 18 months | 78.1 (53.0, 90.8) | NE (NE, NE) |
| 24 months | 78.1 (53.0, 90.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 9 (10.8%) | 4 (5.8%) |
| Censored Patients, n (%) | 74 (89.2%) | 65 (94.2%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8755 | |
| HR (95% CI) [c] | 1.102 (0.335, 3.626) | |
| HR P-Value [c] | 0.8731 | |
| Heterogeneity p-value [d] | 0.3414 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.4 (69.9, 94.2) | 82.4 (58.2, 93.3) |
| 12 months | 68.9 (44.0, 84.4) | 82.4 (58.2, 93.3) |
| 18 months | 61.2 (34.9, 79.6) | NE (NE, NE) |
| 24 months | 61.2 (34.9, 79.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 10 (12.0%) | 6 (8.7%) |
| Censored Patients, n (%) | 73 (88.0%) | 63 (91.3%) |
| Median (95% CI), (Months) [a] | NE (3.09, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3226 | |
| HR (95% CI) [c] | 1.652 (0.600, 4.547) | |
| HR P-Value [c] | 0.3310 | |
| Heterogeneity p-value [d] | 0.8854 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.6 (49.1, 81.9) | 79.5 (59.7, 90.3) |
| 12 months | 68.6 (49.1, 81.9) | 79.5 (59.7, 90.3) |
| 18 months | 68.6 (49.1, 81.9) | NE (NE, NE) |
| 24 months | 68.6 (49.1, 81.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 9 (10.8%) | 8 (11.6%) |
| Censored Patients, n (%) | 74 (89.2%) | 61 (88.4%) |
| Median (95% CI), (Months) [a] | NE (7.23, NE) | 8.48 (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3098 | |
| HR (95% CI) [c] | 0.604 (0.226, 1.619) | |
| HR P-Value [c] | 0.3164 | |
| Heterogeneity p-value [d] | 0.0980 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.1 (65.8, 92.1) | 72.9 (48.9, 87.0) |
| 12 months | 71.1 (47.6, 85.5) | 29.2 (1.7, 68.9) |
| 18 months | 60.9 (32.8, 80.2) | NE (NE, NE) |
| 24 months | 60.9 (32.8, 80.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 11 (9.7%) | 8 (7.0%) |
| Censored Patients, n (%) | 102 (90.3%) | 106 (93.0%) |
| Median (95% CI), (Months) [a] | 13.31 (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7736 | |
| HR (95% CI) [c] | 1.153 (0.438, 3.033) | |
| HR P-Value [c] | 0.7732 | |
| Heterogeneity p-value [d] | 0.4433 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.9 (58.9, 88.9) | 77.1 (57.4, 88.6) |
| 12 months | 62.3 (27.4, 84.1) | 77.1 (57.4, 88.6) |
| 18 months | 20.8 (1.1, 58.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 13 (11.5%) | 6 (5.3%) |
| Censored Patients, n (%) | 100 (88.5%) | 108 (94.7%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (6.28, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3834 | |
| HR (95% CI) [c] | 1.553 (0.575, 4.194) | |
| HR P-Value [c] | 0.3848 | |
| Heterogeneity p-value [d] | 0.4049 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.0 (62.8, 87.6) | 82.3 (60.0, 92.8) |
| 12 months | 66.8 (45.6, 81.2) | NE (NE, NE) |
| 18 months | 59.3 (35.8, 76.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 10 (8.8%) | 9 (7.9%) |
| Censored Patients, n (%) | 103 (91.2%) | 105 (92.1%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5049 | |
| HR (95% CI) [c] | 0.730 (0.287, 1.852) | |
| HR P-Value [c] | 0.5070 | |
| Heterogeneity p-value [d] | 0.7182 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.3 (56.2, 88.0) | 74.5 (55.1, 86.4) |
| 12 months | 61.0 (35.1, 79.2) | NE (NE, NE) |
| 18 months | 61.0 (35.1, 79.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 8 (7.1%) | 3 (2.6%) |
| Censored Patients, n (%) | 105 (92.9%) | 111 (97.4%) |
| Median (95% CI), (Months) [a] | 9.72 (3.45, NE) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7523 | |
| HR (95% CI) [c] | 1.251 (0.318, 4.917) | |
| HR P-Value [c] | 0.7486 | |
| Heterogeneity p-value [d] | 0.7115 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.7 (35.5, 84.3) | 64.6 (23.0, 87.8) |
| 12 months | 35.0 (6.8, 66.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 15 (13.3%) | 3 (2.6%) |
| Censored Patients, n (%) | 98 (86.7%) | 111 (97.4%) |
| Median (95% CI), (Months) [a] | 9.72 (5.59, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0291 | |
| HR (95% CI) [c] | 3.715 (1.053, 13.106) | |
| HR P-Value [c] | 0.0413 | |
| Heterogeneity p-value [d] | 0.1503 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.3 (46.2, 81.6) | 91.7 (76.3, 97.2) |
| 12 months | 44.1 (22.3, 64.0) | 91.7 (76.3, 97.2) |
| 18 months | 29.4 (7.1, 56.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 10 (8.8%) | 5 (4.4%) |
| Censored Patients, n (%) | 103 (91.2%) | 109 (95.6%) |
| Median (95% CI), (Months) [a] | NE (16.39, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7726 | |
| HR (95% CI) [c] | 1.178 (0.388, 3.579) | |
| HR P-Value [c] | 0.7728 | |
| Heterogeneity p-value [d] | 0.8629 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.1 (68.6, 92.4) | 89.9 (74.7, 96.2) |
| 12 months | 73.9 (52.9, 86.6) | NE (NE, NE) |
| 18 months | 63.3 (35.3, 81.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 17 (15.0%) | 5 (4.4%) |
| Censored Patients, n (%) | 96 (85.0%) | 109 (95.6%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0195 | |
| HR (95% CI) [c] | 3.120 (1.147, 8.487) | |
| HR P-Value [c] | 0.0259 | |
| Heterogeneity p-value [d] | 0.1028 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.9 (66.1, 87.3) | 92.9 (81.7, 97.3) |
| 12 months | 64.6 (44.8, 78.8) | 85.7 (62.2, 95.1) |
| 18 months | 64.6 (44.8, 78.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 9 (8.0%) | 7 (6.1%) |
| Censored Patients, n (%) | 104 (92.0%) | 107 (93.9%) |
| Median (95% CI), (Months) [a] | NE (13.86, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9760 | |
| HR (95% CI) [c] | 1.018 (0.357, 2.905) | |
| HR P-Value [c] | 0.9730 | |
| Heterogeneity p-value [d] | 0.8608 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.8 (62.4, 90.8) | 81.8 (65.1, 91.0) |
| 12 months | 80.8 (62.4, 90.8) | 81.8 (65.1, 91.0) |
| 18 months | 55.4 (21.8, 79.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 12 (10.6%) | 9 (7.9%) |
| Censored Patients, n (%) | 101 (89.4%) | 105 (92.1%) |
| Median (95% CI), (Months) [a] | 9.72 (2.83, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9722 | |
| HR (95% CI) [c] | 1.017 (0.417, 2.479) | |
| HR P-Value [c] | 0.9701 | |
| Heterogeneity p-value [d] | 0.6565 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.4 (45.8, 81.9) | 62.0 (38.5, 78.7) |
| 12 months | 48.1 (21.6, 70.5) | NE (NE, NE) |
| 18 months | 32.1 (7.0, 61.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 19 (16.8%) | 11 (9.6%) |
| Censored Patients, n (%) | 94 (83.2%) | 103 (90.4%) |
| Median (95% CI), (Months) [a] | 17.05 (11.17, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1966 | |
| HR (95% CI) [c] | 1.645 (0.778, 3.479) | |
| HR P-Value [c] | 0.1928 | |
| Heterogeneity p-value [d] | 0.6656 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.9 (61.2, 84.3) | 77.3 (61.5, 87.2) |
| 12 months | 62.9 (42.0, 78.0) | 77.3 (61.5, 87.2) |
| 18 months | 41.9 (9.9, 72.1) | 77.3 (61.5, 87.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 13 (11.5%) | 1 (0.9%) |
| Censored Patients, n (%) | 100 (88.5%) | 113 (99.1%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0051 | |
| HR (95% CI) [c] | 10.505 (1.361, 81.080) | |
| HR P-Value [c] | 0.0241 | |
| Heterogeneity p-value [d] | 0.4628 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.6 (67.6, 91.1) | 98.5 (89.6, 99.8) |
| 12 months | 68.1 (46.6, 82.5) | 98.5 (89.6, 99.8) |
| 18 months | 54.5 (24.4, 77.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 11 (9.7%) | 5 (4.4%) |
| Censored Patients, n (%) | 102 (90.3%) | 109 (95.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1895 | |
| HR (95% CI) [c] | 2.002 (0.695, 5.770) | |
| HR P-Value [c] | 0.1987 | |
| Heterogeneity p-value [d] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.7 (78.2, 94.3) | 92.2 (82.1, 96.7) |
| 12 months | 77.1 (59.2, 87.9) | 92.2 (82.1, 96.7) |
| 18 months | 77.1 (59.2, 87.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 16 (14.2%) | 5 (4.4%) |
| Censored Patients, n (%) | 97 (85.8%) | 109 (95.6%) |
| Median (95% CI), (Months) [a] | NE (8.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0589 | |
| HR (95% CI) [c] | 2.569 (0.933, 7.073) | |
| HR P-Value [c] | 0.0679 | |
| Heterogeneity p-value [d] | 0.3414 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.3 (57.6, 84.0) | 91.7 (79.3, 96.9) |
| 12 months | 67.2 (47.8, 80.8) | NE (NE, NE) |
| 18 months | 56.0 (29.3, 76.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 15 (13.3%) | 9 (7.9%) |
| Censored Patients, n (%) | 98 (86.7%) | 105 (92.1%) |
| Median (95% CI), (Months) [a] | NE (8.34, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5343 | |
| HR (95% CI) [c] | 1.313 (0.566, 3.048) | |
| HR P-Value [c] | 0.5263 | |
| Heterogeneity p-value [d] | 0.8854 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.6 (62.0, 86.2) | 79.7 (63.0, 89.4) |
| 12 months | 62.7 (39.6, 79.0) | NE (NE, NE) |
| 18 months | 50.1 (22.0, 73.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 12 (10.6%) | 5 (4.4%) |
| Censored Patients, n (%) | 101 (89.4%) | 109 (95.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0909 | |
| HR (95% CI) [c] | 2.391 (0.842, 6.792) | |
| HR P-Value [c] | 0.1016 | |
| Heterogeneity p-value [d] | 0.0980 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.9 (55.1, 83.3) | 83.9 (60.8, 94.0) |
| 12 months | 71.9 (55.1, 83.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 14 (12.0%) | 9 (9.3%) |
| Censored Patients, n (%) | 103 (88.0%) | 88 (90.7%) |
| Median (95% CI), (Months) [a] | 13.31 (4.27, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8187 | |
| HR (95% CI) [c] | 1.109 (0.459, 2.678) | |
| HR P-Value [c] | 0.8181 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.1 (48.9, 81.4) | 72.5 (52.7, 85.0) |
| 12 months | 59.6 (35.8, 77.0) | NE (NE, NE) |
| 18 months | 35.8 (10.7, 62.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 13 (11.1%) | 6 (6.2%) |
| Censored Patients, n (%) | 104 (88.9%) | 91 (93.8%) |
| Median (95% CI), (Months) [a] | 17.97 (9.72, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8497 | |
| HR (95% CI) [c] | 0.902 (0.321, 2.540) | |
| HR P-Value [c] | 0.8455 | |
| Heterogeneity p-value [d] | 0.6175 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.9 (69.0, 92.0) | 75.1 (49.1, 89.2) |
| 12 months | 68.7 (46.9, 83.0) | NE (NE, NE) |
| 18 months | 42.5 (15.1, 67.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 12 (10.3%) | 9 (9.3%) |
| Censored Patients, n (%) | 105 (89.7%) | 88 (90.7%) |
| | | |
| Median (95% CI), (Months) [a] | 9.72 (6.97, NE) | NE (3.12, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5267 | |
| HR (95% CI) [c] | 0.752 (0.311, 1.815) | |
| HR P-Value [c] | 0.5257 | |
| Heterogeneity p-value [d] | 0.9822 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.5 (55.5, 87.5) | 70.0 (49.2, 83.5) |
| 12 months | 47.3 (22.5, 68.8) | NE (NE, NE) |
| 18 months | 47.3 (22.5, 68.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 12 (10.3%) | 4 (4.1%) |
| Censored Patients, n (%) | 105 (89.7%) | 93 (95.9%) |
| Median (95% CI), (Months) [a] | 9.72 (3.45, NE) | NE (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7294 | |
| HR (95% CI) [c] | 0.821 (0.254, 2.652) | |
| HR P-Value [c] | 0.7411 | |
| Heterogeneity p-value [d] | 0.4459 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.8 (45.1, 83.9) | 52.5 (15.0, 80.4) |
| 12 months | 36.1 (12.8, 60.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 16 (13.7%) | 4 (4.1%) |
| Censored Patients, n (%) | 101 (86.3%) | 93 (95.9%) |
| Median (95% CI), (Months) [a] | 9.72 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2215 | |
| HR (95% CI) [c] | 1.997 (0.643, 6.203) | |
| HR P-Value [c] | 0.2316 | |
| Heterogeneity p-value [d] | 0.9201 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.5 (52.5, 85.1) | 85.9 (66.5, 94.5) |
| 12 months | 40.1 (19.2, 60.3) | NE (NE, NE) |
| 18 months | 30.1 (10.0, 53.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 8 (6.8%) | 4 (4.1%) |
| Censored Patients, n (%) | 109 (93.2%) | 93 (95.9%) |
| Median (95% CI), (Months) [a] | NE (16.39, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9528 | |
| HR (95% CI) [c] | 1.038 (0.298, 3.612) | |
| HR P-Value [c] | 0.9530 | |
| Heterogeneity p-value [d] | 0.6992 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.8 (76.5, 96.6) | 89.4 (73.5, 96.0) |
| 12 months | 76.3 (54.0, 88.8) | 89.4 (73.5, 96.0) |
| 18 months | 65.4 (35.7, 83.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 19 (16.2%) | 8 (8.2%) |
| Censored Patients, n (%) | 98 (83.8%) | 89 (91.8%) |
| Median (95% CI), (Months) [a] | NE (11.17, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2139 | |
| HR (95% CI) [c] | 1.700 (0.735, 3.931) | |
| HR P-Value [c] | 0.2150 | |
| Heterogeneity p-value [d] | 0.8577 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.8 (65.4, 86.2) | 88.0 (74.5, 94.5) |
| 12 months | 63.3 (45.8, 76.4) | NE (NE, NE) |
| 18 months | 63.3 (45.8, 76.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 10 (8.5%) | 7 (7.2%) |
| Censored Patients, n (%) | 107 (91.5%) | 90 (92.8%) |
| Median (95% CI), (Months) [a] | NE (13.86, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8500 | |
| HR (95% CI) [c] | 0.905 (0.324, 2.527) | |
| HR P-Value [c] | 0.8488 | |
| Heterogeneity p-value [d] | 0.8442 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.8 (61.0, 89.1) | 84.1 (67.9, 92.5) |
| 12 months | 78.8 (61.0, 89.1) | NE (NE, NE) |
| 18 months | 62.0 (35.0, 80.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 13 (11.1%) | 8 (8.2%) |
| Censored Patients, n (%) | 104 (88.9%) | 89 (91.8%) |
| Median (95% CI), (Months) [a] | 9.72 (1.91, NE) | NE (3.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8039 | |
| HR (95% CI) [c] | 1.115 (0.450, 2.760) | |
| HR P-Value [c] | 0.8139 | |
| Heterogeneity p-value [d] | 0.4261 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.9 (44.4, 80.7) | 66.0 (42.2, 81.8) |
| 12 months | 46.6 (23.7, 66.7) | NE (NE, NE) |
| 18 months | 37.3 (14.8, 60.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 21 (17.9%) | 12 (12.4%) |
| Censored Patients, n (%) | 96 (82.1%) | 85 (87.6%) |
| Median (95% CI), (Months) [a] | 16.76 (8.61, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3765 | |
| HR (95% CI) [c] | 1.387 (0.676, 2.845) | |
| HR P-Value [c] | 0.3728 | |
| Heterogeneity p-value [d] | 0.8273 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.0 (58.9, 83.0) | 74.5 (58.1, 85.3) |
| 12 months | 59.7 (40.9, 74.2) | 74.5 (58.1, 85.3) |
| 18 months | 37.3 (12.7, 62.4) | 74.5 (58.1, 85.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 18 (15.4%) | 1 (1.0%) |
| Censored Patients, n (%) | 99 (84.6%) | 96 (99.0%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0009 | |
| HR (95% CI) [c] | 13.653 (1.814, 102.765) | |
| HR P-Value [c] | 0.0111 | |
| Heterogeneity p-value [d] | 0.1690 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.1 (59.2, 84.3) | 98.0 (86.9, 99.7) |
| 12 months | 62.8 (44.9, 76.3) | 98.0 (86.9, 99.7) |
| 18 months | 55.0 (33.3, 72.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 14 (12.0%) | 4 (4.1%) |
| Censored Patients, n (%) | 103 (88.0%) | 93 (95.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0570 | |
| HR (95% CI) [c] | 2.813 (0.924, 8.564) | |
| HR P-Value [c] | 0.0686 | |
| Heterogeneity p-value [d] | 0.9753 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.0 (72.5, 91.0) | 93.6 (83.6, 97.6) |
| 12 months | 74.8 (59.3, 85.1) | 93.6 (83.6, 97.6) |
| 18 months | 74.8 (59.3, 85.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 19 (16.2%) | 5 (5.2%) |
| Censored Patients, n (%) | 98 (83.8%) | 92 (94.8%) |
| Median (95% CI), (Months) [a] | NE (8.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0401 | |
| HR (95% CI) [c] | 2.711 (1.005, 7.309) | |
| HR P-Value [c] | 0.0488 | |
| Heterogeneity p-value [d] | 0.2059 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.8 (54.6, 80.8) | 88.0 (72.7, 95.0) |
| 12 months | 62.2 (45.0, 75.4) | 88.0 (72.7, 95.0) |
| 18 months | 55.3 (35.0, 71.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 20 (17.1%) | 8 (8.2%) |
| Censored Patients, n (%) | 97 (82.9%) | 89 (91.8%) |
| Median (95% CI), (Months) [a] | 13.44 (3.09, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0422 | |
| HR (95% CI) [c] | 2.319 (1.013, 5.310) | |
| HR P-Value [c] | 0.0465 | |
| Heterogeneity p-value [d] | 0.0587 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.0 (48.2, 76.1) | 83.1 (67.5, 91.6) |
| 12 months | 52.4 (32.7, 68.8) | 73.9 (47.8, 88.3) |
| 18 months | 41.9 (19.0, 63.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 11 (9.4%) | 9 (9.3%) |
| Censored Patients, n (%) | 106 (90.6%) | 88 (90.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (7.03, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7685 | |
| HR (95% CI) [c] | 1.144 (0.474, 2.764) | |
| HR P-Value [c] | 0.7649 | |
| Heterogeneity p-value [d] | 0.4654 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.2 (56.9, 85.4) | 74.8 (53.9, 87.3) |
| 12 months | 69.6 (50.6, 82.4) | NE (NE, NE) |
| 18 months | 69.6 (50.6, 82.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 6 (7.8%) | 5 (5.8%) |
| Censored Patients, n (%) | 71 (92.2%) | 81 (94.2%) |
| Median (95% CI), (Months) [a] | 12.52 (12.52, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8387 | |
| HR (95% CI) [c] | 1.131 (0.345, 3.708) | |
| HR P-Value [c] | 0.8388 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (57.2, 91.4) | 71.3 (40.6, 88.1) |
| 12 months | 80.0 (57.2, 91.4) | 71.3 (40.6, 88.1) |
| 18 months | 40.0 (1.5, 82.0) | NE (NE, NE) |
| 24 months | 40.0 (1.5, 82.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 8 (10.4%) | 4 (4.7%) |
| Censored Patients, n (%) | 69 (89.6%) | 82 (95.3%) |
| Median (95% CI), (Months) [a] | NE (7.03, NE) | NE (6.28, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4531 | |
| HR (95% CI) [c] | 1.593 (0.474, 5.352) | |
| HR P-Value [c] | 0.4512 | |
| Heterogeneity p-value [d] | 0.6175 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.0 (60.8, 89.4) | 86.0 (61.8, 95.4) |
| 12 months | 71.8 (48.7, 85.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 6 (7.8%) | 5 (5.8%) |
| Censored Patients, n (%) | 71 (92.2%) | 81 (94.2%) |
| Median (95% CI), (Months) [a] | 15.31 (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6804 | |
| HR (95% CI) [c] | 0.768 (0.221, 2.660) | |
| HR P-Value [c] | 0.6766 | |
| Heterogeneity p-value [d] | 0.9822 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.5 (60.9, 93.7) | 77.2 (52.5, 90.1) |
| 12 months | 62.6 (18.9, 87.7) | 77.2 (52.5, 90.1) |
| 18 months | 41.8 (6.5, 75.7) | NE (NE, NE) |
| 24 months | 41.8 (6.5, 75.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 6 (7.8%) | 3 (3.5%) |
| Censored Patients, n (%) | 71 (92.2%) | 83 (96.5%) |
| Median (95% CI), (Months) [a] | 4.21 (1.45, NE) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4247 | |
| HR (95% CI) [c] | 1.741 (0.434, 6.979) | |
| HR P-Value [c] | 0.4341 | |
| Heterogeneity p-value [d] | 0.4459 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.4 (10.3, 66.8) | 58.3 (18.0, 84.4) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 6 (7.8%) | 3 (3.5%) |
| Censored Patients, n (%) | 71 (92.2%) | 83 (96.5%) |
| | | |
| Median (95% CI), (Months) [a] | 11.33 (2.99, 11.33) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1521 | |
| HR (95% CI) [c] | 2.648 (0.659, 10.638) | |
| HR P-Value [c] | 0.1699 | |
| Heterogeneity p-value [d] | 0.9201 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.3 (37.2, 85.4) | 84.6 (59.1, 94.8) |
| 12 months | 0.0 (NE, NE) | 84.6 (59.1, 94.8) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 11 (14.3%) | 4 (4.7%) |
| Censored Patients, n (%) | 66 (85.7%) | 82 (95.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2689 | |
| HR (95% CI) [c] | 1.902 (0.601, 6.015) | |
| HR P-Value [c] | 0.2739 | |
| Heterogeneity p-value [d] | 0.6992 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.7 (51.8, 83.3) | 89.5 (70.6, 96.5) |
| 12 months | 70.7 (51.8, 83.3) | 59.7 (8.4, 89.8) |
| 18 months | 70.7 (51.8, 83.3) | NE (NE, NE) |
| 24 months | 70.7 (51.8, 83.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 7 (9.1%) | 3 (3.5%) |
| Censored Patients, n (%) | 70 (90.9%) | 83 (96.5%) |
| Median (95% CI), (Months) [a] | NE (12.65, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2698 | |
| HR (95% CI) [c] | 2.104 (0.542, 8.170) | |
| HR P-Value [c] | 0.2826 | |
| Heterogeneity p-value [d] | 0.8577 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.4 (73.8, 94.2) | 93.6 (81.4, 97.9) |
| 12 months | 87.4 (73.8, 94.2) | 93.6 (81.4, 97.9) |
| 18 months | 76.5 (46.2, 91.1) | NE (NE, NE) |
| 24 months | 76.5 (46.2, 91.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 5 (6.5%) | 4 (4.7%) |
| Censored Patients, n (%) | 72 (93.5%) | 82 (95.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7399 | |
| HR (95% CI) [c] | 1.249 (0.335, 4.655) | |
| HR P-Value [c] | 0.7404 | |
| Heterogeneity p-value [d] | 0.8442 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.6 (60.7, 92.1) | 84.0 (62.5, 93.7) |
| 12 months | 81.6 (60.7, 92.1) | 84.0 (62.5, 93.7) |
| 18 months | 81.6 (60.7, 92.1) | NE (NE, NE) |
| 24 months | 81.6 (60.7, 92.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 4 (5.2%) | 5 (5.8%) |
| Censored Patients, n (%) | 73 (94.8%) | 81 (94.2%) |
| Median (95% CI), (Months) [a] | NE (1.64, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6475 | |
| HR (95% CI) [c] | 0.738 (0.198, 2.754) | |
| HR P-Value [c] | 0.6511 | |
| Heterogeneity p-value [d] | 0.4261 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.1 (44.0, 89.6) | 55.5 (22.8, 79.1) |
| 12 months | 74.1 (44.0, 89.6) | NE (NE, NE) |
| 18 months | 74.1 (44.0, 89.6) | NE (NE, NE) |
| 24 months | 74.1 (44.0, 89.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 13 (16.9%) | 6 (7.0%) |
| Censored Patients, n (%) | 64 (83.1%) | 80 (93.0%) |
| Median (95% CI), (Months) [a] | NE (8.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3006 | |
| HR (95% CI) [c] | 1.676 (0.631, 4.447) | |
| HR P-Value [c] | 0.2998 | |
| Heterogeneity p-value [d] | 0.8273 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.2 (57.7, 86.3) | 81.7 (63.4, 91.4) |
| 12 months | 63.5 (41.0, 79.3) | 81.7 (63.4, 91.4) |
| 18 months | 52.9 (26.3, 73.8) | NE (NE, NE) |
| 24 months | 52.9 (26.3, 73.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 2 (2.6%) | 1 (1.2%) |
| Censored Patients, n (%) | 75 (97.4%) | 85 (98.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6957 | |
| HR (95% CI) [c] | 1.609 (0.145, 17.806) | |
| HR P-Value [c] | 0.6984 | |
| Heterogeneity p-value [d] | 0.1690 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.5 (74.3, 98.5) | 97.5 (83.5, 99.6) |
| 12 months | 93.5 (74.3, 98.5) | 97.5 (83.5, 99.6) |
| 18 months | 93.5 (74.3, 98.5) | NE (NE, NE) |
| 24 months | 93.5 (74.3, 98.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 4 (5.2%) | 1 (1.2%) |
| Censored Patients, n (%) | 73 (94.8%) | 85 (98.8%) |
| Median (95% CI), (Months) [a] | NE (15.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4154 | |
| HR (95% CI) [c] | 2.487 (0.259, 23.928) | |
| HR P-Value [c] | 0.4301 | |
| Heterogeneity p-value [d] | 0.9753 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.4 (83.5, 98.2) | 97.8 (85.6, 99.7) |
| 12 months | 94.4 (83.5, 98.2) | 97.8 (85.6, 99.7) |
| 18 months | 82.6 (45.6, 95.5) | NE (NE, NE) |
| 24 months | 82.6 (45.6, 95.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 5 (6.5%) | 4 (4.7%) |
| Censored Patients, n (%) | 72 (93.5%) | 82 (95.3%) |
| Median (95% CI), (Months) [a] | NE (9.86, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7745 | |
| HR (95% CI) [c] | 0.827 (0.220, 3.106) | |
| HR P-Value [c] | 0.7781 | |
| Heterogeneity p-value [d] | 0.2059 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.1 (80.2, 97.7) | 89.7 (70.9, 96.6) |
| 12 months | 67.9 (28.9, 88.6) | 80.7 (51.6, 93.3) |
| 18 months | 67.9 (28.9, 88.6) | NE (NE, NE) |
| 24 months | 67.9 (28.9, 88.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 5 (6.5%) | 7 (8.1%) |
| Censored Patients, n (%) | 72 (93.5%) | 79 (91.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4528 | |
| HR (95% CI) [c] | 0.646 (0.205, 2.036) | |
| HR P-Value [c] | 0.4553 | |
| Heterogeneity p-value [d] | 0.0587 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.9 (67.1, 93.5) | 75.3 (54.7, 87.5) |
| 12 months | 84.9 (67.1, 93.5) | 75.3 (54.7, 87.5) |
| 18 months | 84.9 (67.1, 93.5) | NE (NE, NE) |
| 24 months | 84.9 (67.1, 93.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 10 (13.0%) | 4 (4.7%) |
| Censored Patients, n (%) | 67 (87.0%) | 82 (95.3%) |
| Median (95% CI), (Months) [a] | NE (7.23, NE) | 8.48 (8.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3770 | |
| HR (95% CI) [c] | 1.709 (0.526, 5.549) | |
| HR P-Value [c] | 0.3728 | |
| Heterogeneity p-value [d] | 0.4654 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.3 (62.3, 89.2) | 87.5 (65.1, 95.9) |
| 12 months | 70.5 (45.5, 85.6) | 43.8 (1.1, 85.8) |
| 18 months | 52.9 (17.9, 79.0) | NE (NE, NE) |
| 24 months | 52.9 (17.9, 79.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 4 (15.4%) | 0 |
| Censored Patients, n (%) | 22 (84.6%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 11.10 (4.21, 16.62) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4862 | |
| HR (95% CI) [c] | 13389421 (0.000, NE) | |
| HR P-Value [c] | 0.9975 | |
| Heterogeneity p-value [d] | 0.9671 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.5 (39.3, 94.5) | 100.0 (100.0, 100.0) |
| 12 months | 39.8 (1.3, 82.1) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 0 |
| Censored Patients, n (%) | 21 (80.8%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 12.52 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4041 | |
| HR (95% CI) [c] | 12874197 (0.000, NE) | |
| HR P-Value [c] | 0.9970 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (59.1, 99.0) | 100.0 (100.0, 100.0) |
| 12 months | 63.7 (21.6, 87.6) | NE (NE, NE) |
| 18 months | 31.8 (4.7, 65.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 4 (15.4%) | 0 |
| Censored Patients, n (%) | 22 (84.6%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 9.72 (5.72, 9.72) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.2485 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 0 |
| Censored Patients, n (%) | 20 (76.9%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 6.97 (1.45, 9.72) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1088 | |
| HR (95% CI) [c] | 47396897 (0.000, NE) | |
| HR P-Value [c] | 0.9967 | |
| Heterogeneity p-value [d] | 0.9627 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.5 (22.9, 86.1) | 100.0 (100.0, 100.0) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 3 (11.5%) | 0 |
| Censored Patients, n (%) | 23 (88.5%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 9.72 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.9713 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 42.9 (5.8, 77.7) | NE (NE, NE) |
| 18 months | 42.9 (5.8, 77.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 3 (11.5%) | 1 (5.3%) |
| Censored Patients, n (%) | 23 (88.5%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (2.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8920 | |
| HR (95% CI) [c] | 1.170 (0.120, 11.376) | |
| HR P-Value [c] | 0.8921 | |
| Heterogeneity p-value [d] | 0.9573 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (59.1, 99.0) | 83.3 (27.3, 97.5) |
| 12 months | 53.1 (8.3, 85.1) | NE (NE, NE) |
| 18 months | 53.1 (8.3, 85.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 0 |
| Censored Patients, n (%) | 21 (80.8%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 9.72 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1224 | |
| HR (95% CI) [c] | 46754109 (0.000, NE) | |
| HR P-Value [c] | 0.9968 | |
| Heterogeneity p-value [d] | 0.9920 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.4 (60.3, 97.1) | 100.0 (100.0, 100.0) |
| 12 months | 38.7 (6.0, 72.5) | NE (NE, NE) |
| 18 months | 38.7 (6.0, 72.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 4 (15.4%) | 1 (5.3%) |
| Censored Patients, n (%) | 22 (84.6%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | 13.86 (1.58, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9698 | |
| HR (95% CI) [c] | 1.045 (0.108, 10.068) | |
| HR P-Value [c] | 0.9698 | |
| Heterogeneity p-value [d] | 0.8357 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.0 (22.6, 87.5) | 75.0 (12.8, 96.1) |
| 12 months | 64.0 (22.6, 87.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 1 (5.3%) |
| Censored Patients, n (%) | 21 (80.8%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | 8.34 (1.58, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7134 | |
| HR (95% CI) [c] | 1.512 (0.174, 13.105) | |
| HR P-Value [c] | 0.7075 | |
| Heterogeneity p-value [d] | 0.8708 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (28.2, 87.8) | 66.7 (5.4, 94.5) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 2 (10.5%) |
| Censored Patients, n (%) | 21 (80.8%) | 17 (89.5%) |
| Median (95% CI), (Months) [a] | 11.17 (4.21, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8205 | |
| HR (95% CI) [c] | 1.215 (0.218, 6.786) | |
| HR P-Value [c] | 0.8245 | |
| Heterogeneity p-value [d] | 0.9765 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.1 (41.4, 91.8) | 84.4 (50.4, 95.9) |
| 12 months | 38.0 (6.0, 71.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 0 |
| Censored Patients, n (%) | 20 (76.9%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 11.10 (5.62, 15.24) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1734 | |
| HR (95% CI) [c] | 45709289 (0.000, NE) | |
| HR P-Value [c] | 0.9972 | |
| Heterogeneity p-value [d] | 0.7278 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.1 (35.2, 91.0) | 100.0 (100.0, 100.0) |
| 12 months | 40.6 (7.4, 73.1) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 2 (7.7%) | 0 |
| Censored Patients, n (%) | 24 (92.3%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2770 | |
| HR (95% CI) [c] | 52478210 (0.000, NE) | |
| HR P-Value [c] | 0.9979 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.7 (61.4, 97.1) | 100.0 (100.0, 100.0) |
| 12 months | 88.7 (61.4, 97.1) | NE (NE, NE) |
| 18 months | 88.7 (61.4, 97.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 7 (26.9%) | 1 (5.3%) |
| Censored Patients, n (%) | 19 (73.1%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | 8.34 (4.24, NE) | NE (1.18, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5875 | |
| HR (95% CI) [c] | 1.788 (0.216, 14.814) | |
| HR P-Value [c] | 0.5901 | |
| Heterogeneity p-value [d] | 0.7581 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.0 (35.5, 84.7) | 83.3 (27.3, 97.5) |
| 12 months | 26.4 (1.6, 65.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 3 (11.5%) | 0 |
| Censored Patients, n (%) | 23 (88.5%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | NE (3.09, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1628 | |
| HR (95% CI) [c] | 55827972 (0.000, NE) | |
| HR P-Value [c] | 0.9973 | |
| Heterogeneity p-value [d] | 0.4358 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.1 (44.4, 95.3) | 100.0 (100.0, 100.0) |
| 12 months | 54.7 (8.6, 86.2) | NE (NE, NE) |
| 18 months | 54.7 (8.6, 86.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 3 (11.5%) | 1 (5.3%) |
| Censored Patients, n (%) | 23 (88.5%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | NE (3.09, NE) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7078 | |
| HR (95% CI) [c] | 1.540 (0.158, 14.976) | |
| HR P-Value [c] | 0.7101 | |
| Heterogeneity p-value [d] | 0.9269 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.1 (47.2, 95.5) | 87.5 (38.7, 98.1) |
| 12 months | 66.5 (24.1, 88.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 12 (10.1%) | 12 (10.8%) |
| Censored Patients, n (%) | 107 (89.9%) | 99 (89.2%) |
| | | |
| Median (95% CI), (Months) [a] | NE (12.52, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7661 | |
| HR (95% CI) [c] | 1.134 (0.507, 2.540) | |
| HR P-Value [c] | 0.7592 | |
| Heterogeneity p-value [d] | 0.9671 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.7 (50.5, 82.6) | 66.9 (48.0, 80.3) |
| 12 months | 69.7 (50.5, 82.6) | 66.9 (48.0, 80.3) |
| 18 months | 55.7 (25.6, 77.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 13 (10.9%) | 7 (6.3%) |
| Censored Patients, n (%) | 106 (89.1%) | 104 (93.7%) |
| Median (95% CI), (Months) [a] | NE (17.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6759 | |
| HR (95% CI) [c] | 1.226 (0.478, 3.145) | |
| HR P-Value [c] | 0.6715 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.6 (61.5, 86.4) | 74.3 (51.3, 87.6) |
| 12 months | 72.1 (54.8, 83.7) | NE (NE, NE) |
| 18 months | 54.1 (19.6, 79.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 9 (7.6%) | 13 (11.7%) |
| Censored Patients, n (%) | 110 (92.4%) | 98 (88.3%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0857 | |
| HR (95% CI) [c] | 0.467 (0.193, 1.132) | |
| HR P-Value [c] | 0.0920 | |
| Heterogeneity p-value [d] | 0.2485 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.8 (61.5, 90.0) | 61.8 (42.5, 76.3) |
| 12 months | 58.5 (25.5, 81.0) | NE (NE, NE) |
| 18 months | 58.5 (25.5, 81.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 10 (8.4%) | 4 (3.6%) |
| Censored Patients, n (%) | 109 (91.6%) | 107 (96.4%) |
| Median (95% CI), (Months) [a] | 11.40 (1.58, NE) | 4.40 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5302 | |
| HR (95% CI) [c] | 0.685 (0.202, 2.321) | |
| HR P-Value [c] | 0.5432 | |
| Heterogeneity p-value [d] | 0.9627 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.8 (36.3, 78.3) | 27.3 (1.3, 67.8) |
| 12 months | 48.7 (20.7, 71.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 14 (11.8%) | 6 (5.4%) |
| Censored Patients, n (%) | 105 (88.2%) | 105 (94.6%) |
| Median (95% CI), (Months) [a] | 11.83 (5.59, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2262 | |
| HR (95% CI) [c] | 1.818 (0.679, 4.867) | |
| HR P-Value [c] | 0.2343 | |
| Heterogeneity p-value [d] | 0.9713 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.4 (46.2, 81.7) | 82.3 (64.6, 91.7) |
| 12 months | 44.9 (19.5, 67.6) | 82.3 (64.6, 91.7) |
| 18 months | 30.0 (6.6, 58.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 15 (12.6%) | 5 (4.5%) |
| Censored Patients, n (%) | 104 (87.4%) | 106 (95.5%) |
| Median (95% CI), (Months) [a] | NE (16.39, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2024 | |
| HR (95% CI) [c] | 1.933 (0.690, 5.411) | |
| HR P-Value [c] | 0.2096 | |
| Heterogeneity p-value [d] | 0.9573 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.2 (58.8, 84.6) | 90.5 (76.0, 96.4) |
| 12 months | 70.8 (54.6, 82.2) | NE (NE, NE) |
| 18 months | 60.7 (35.9, 78.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 17 (14.3%) | 8 (7.2%) |
| Censored Patients, n (%) | 102 (85.7%) | 103 (92.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1888 | |
| HR (95% CI) [c] | 1.761 (0.753, 4.115) | |
| HR P-Value [c] | 0.1915 | |
| Heterogeneity p-value [d] | 0.9920 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.7 (66.6, 86.8) | 87.5 (75.2, 93.9) |
| 12 months | 74.5 (59.8, 84.6) | 81.2 (61.4, 91.5) |
| 18 months | 69.6 (52.1, 81.7) | NE (NE, NE) |
| 24 months | 69.6 (52.1, 81.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 9 (7.6%) | 8 (7.2%) |
| Censored Patients, n (%) | 110 (92.4%) | 103 (92.8%) |
| Median (95% CI), (Months) [a] | NE (14.95, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8159 | |
| HR (95% CI) [c] | 0.893 (0.335, 2.381) | |
| HR P-Value [c] | 0.8217 | |
| Heterogeneity p-value [d] | 0.8357 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.0 (68.5, 91.2) | 79.7 (63.3, 89.4) |
| 12 months | 83.0 (68.5, 91.2) | 79.7 (63.3, 89.4) |
| 18 months | 73.8 (48.2, 88.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 9 (7.6%) | 8 (7.2%) |
| Censored Patients, n (%) | 110 (92.4%) | 103 (92.8%) |
| Median (95% CI), (Months) [a] | 12.06 (2.83, NE) | NE (3.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9323 | |
| HR (95% CI) [c] | 1.049 (0.392, 2.803) | |
| HR P-Value [c] | 0.9241 | |
| Heterogeneity p-value [d] | 0.8708 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.8 (47.4, 85.2) | 69.0 (46.9, 83.4) |
| 12 months | 61.9 (35.2, 80.3) | NE (NE, NE) |
| 18 months | 49.6 (20.3, 73.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 27 (22.7%) | 14 (12.6%) |
| Censored Patients, n (%) | 92 (77.3%) | 97 (87.4%) |
| Median (95% CI), (Months) [a] | 16.76 (8.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1792 | |
| HR (95% CI) [c] | 1.578 (0.821, 3.035) | |
| HR P-Value [c] | 0.1716 | |
| Heterogeneity p-value [d] | 0.9765 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.0 (55.9, 79.0) | 70.6 (54.5, 81.9) |
| 12 months | 59.3 (43.6, 71.9) | 70.6 (54.5, 81.9) |
| 18 months | 37.2 (16.0, 58.7) | 70.6 (54.5, 81.9) |
| 24 months | 37.2 (16.0, 58.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 12 (10.1%) | 1 (0.9%) |
| Censored Patients, n (%) | 107 (89.9%) | 110 (99.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0063 | |
| HR (95% CI) [c] | 9.985 (1.298, 76.819) | |
| HR P-Value [c] | 0.0271 | |
| Heterogeneity p-value [d] | 0.7278 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.4 (68.1, 89.6) | 98.2 (88.0, 99.7) |
| 12 months | 78.3 (63.7, 87.6) | 98.2 (88.0, 99.7) |
| 18 months | 78.3 (63.7, 87.6) | NE (NE, NE) |
| 24 months | 78.3 (63.7, 87.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 15 (12.6%) | 5 (4.5%) |
| Censored Patients, n (%) | 104 (87.4%) | 106 (95.5%) |
| Median (95% CI), (Months) [a] | NE (15.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1161 | |
| HR (95% CI) [c] | 2.228 (0.800, 6.204) | |
| HR P-Value [c] | 0.1252 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.0 (74.0, 91.6) | 92.2 (82.1, 96.7) |
| 12 months | 77.5 (63.8, 86.5) | 92.2 (82.1, 96.7) |
| 18 months | 69.7 (48.4, 83.6) | NE (NE, NE) |
| 24 months | 69.7 (48.4, 83.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 16 (13.4%) | 6 (5.4%) |
| Censored Patients, n (%) | 103 (86.6%) | 105 (94.6%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2373 | |
| HR (95% CI) [c] | 1.773 (0.679, 4.629) | |
| HR P-Value [c] | 0.2419 | |
| Heterogeneity p-value [d] | 0.7581 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.9 (63.4, 87.2) | 86.3 (71.5, 93.7) |
| 12 months | 68.3 (49.2, 81.5) | 86.3 (71.5, 93.7) |
| 18 months | 54.4 (30.9, 72.9) | NE (NE, NE) |
| 24 months | 54.4 (30.9, 72.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 18 (15.1%) | 8 (7.2%) |
| Censored Patients, n (%) | 101 (84.9%) | 103 (92.8%) |
| Median (95% CI), (Months) [a] | NE (8.44, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1095 | |
| HR (95% CI) [c] | 1.970 (0.851, 4.561) | |
| HR P-Value [c] | 0.1134 | |
| Heterogeneity p-value [d] | 0.4358 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.7 (53.6, 79.8) | 82.3 (66.3, 91.2) |
| 12 months | 63.5 (45.7, 76.8) | 74.1 (49.8, 87.9) |
| 18 months | 52.9 (28.3, 72.5) | NE (NE, NE) |
| 24 months | 52.9 (28.3, 72.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 14 (11.8%) | 6 (5.4%) |
| Censored Patients, n (%) | 105 (88.2%) | 105 (94.6%) |
| Median (95% CI), (Months) [a] | NE (12.58, NE) | NE (8.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2056 | |
| HR (95% CI) [c] | 1.856 (0.704, 4.892) | |
| HR P-Value [c] | 0.2114 | |
| Heterogeneity p-value [d] | 0.9269 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (55.2, 82.6) | 82.0 (58.6, 92.9) |
| 12 months | 71.4 (55.2, 82.6) | NE (NE, NE) |
| 18 months | 62.5 (39.2, 79.0) | NE (NE, NE) |
| 24 months | 62.5 (39.2, 79.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 0 |
| Censored Patients, n (%) | 19 (95.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (13.31, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.9671 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 50.0 (0.6, 91.0) | NE (NE, NE) |
| 24 months | 50.0 (0.6, 91.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 19 (95.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (1.84, NE) | 6.28 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7456 | |
| HR (95% CI) [c] | 0.632 (0.039, 10.307) | |
| HR P-Value [c] | 0.7477 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (20.4, 96.9) | 100.0 (100.0, 100.0) |
| 12 months | 80.0 (20.4, 96.9) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 0 |
| Censored Patients, n (%) | 19 (95.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (1.38, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5127 | |
| HR (95% CI) [c] | 43334290 (0.000, NE) | |
| HR P-Value [c] | 0.9986 | |
| Heterogeneity p-value [d] | 0.2485 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.7 (33.4, 97.9) | NE (NE, NE) |
| 12 months | 85.7 (33.4, 97.9) | NE (NE, NE) |
| 18 months | 85.7 (33.4, 97.9) | NE (NE, NE) |
| 24 months | 85.7 (33.4, 97.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 0 |
| Censored Patients, n (%) | 20 (100.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.9627 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 100.0 (100.0, 100.0) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 0 |
| Censored Patients, n (%) | 18 (90.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | 4.27 (1.84, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0753 | |
| HR (95% CI) [c] | 3.8288E8 (0.000, NE) | |
| HR P-Value [c] | 0.9986 | |
| Heterogeneity p-value [d] | 0.9713 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (0.9, 77.4) | 100.0 (100.0, 100.0) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (4.8%) |
| Censored Patients, n (%) | 20 (100.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1025 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9987 | |
| Heterogeneity p-value [d] | 0.9573 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 66.7 (5.4, 94.5) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 0 |
| Censored Patients, n (%) | 19 (95.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (2.86, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5271 | |
| HR (95% CI) [c] | 41864210 (0.000, NE) | |
| HR P-Value [c] | 0.9986 | |
| Heterogeneity p-value [d] | 0.9920 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.0 (47.3, 98.5) | 100.0 (100.0, 100.0) |
| 12 months | 90.0 (47.3, 98.5) | NE (NE, NE) |
| 18 months | 90.0 (47.3, 98.5) | NE (NE, NE) |
| 24 months | 90.0 (47.3, 98.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 0 |
| Censored Patients, n (%) | 20 (100.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.8357 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 19 (95.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (1.41, NE) | 2.56 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5924 | |
| HR (95% CI) [c] | 0.471 (0.028, 7.858) | |
| HR P-Value [c] | 0.6004 | |
| Heterogeneity p-value [d] | 0.8708 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.3 (27.3, 97.5) | 0.0 (NE, NE) |
| 12 months | 83.3 (27.3, 97.5) | 0.0 (NE, NE) |
| 18 months | 83.3 (27.3, 97.5) | 0.0 (NE, NE) |
| 24 months | 83.3 (27.3, 97.5) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 0 |
| Censored Patients, n (%) | 19 (95.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (1.61, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3496 | |
| HR (95% CI) [c] | 70862853 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.9765 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (38.7, 98.1) | 100.0 (100.0, 100.0) |
| 12 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 0 |
| Censored Patients, n (%) | 19 (95.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3865 | |
| HR (95% CI) [c] | 62193134 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.7278 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 100.0 (100.0, 100.0) |
| 12 months | 91.7 (53.9, 98.8) | NE (NE, NE) |
| 18 months | 91.7 (53.9, 98.8) | NE (NE, NE) |
| 24 months | 91.7 (53.9, 98.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 0 |
| Censored Patients, n (%) | 20 (100.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 19 (95.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 6.28 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4402 | |
| HR (95% CI) [c] | 0.338 (0.019, 5.949) | |
| HR P-Value [c] | 0.4586 | |
| Heterogeneity p-value [d] | 0.7581 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (59.1, 99.0) | 100.0 (100.0, 100.0) |
| 12 months | 92.9 (59.1, 99.0) | 0.0 (NE, NE) |
| 18 months | 92.9 (59.1, 99.0) | 0.0 (NE, NE) |
| 24 months | 92.9 (59.1, 99.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 19 (95.0%) | 19 (90.5%) |
| Median (95% CI), (Months) [a] | NE (1.48, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5601 | |
| HR (95% CI) [c] | 0.497 (0.045, 5.491) | |
| HR P-Value [c] | 0.5681 | |
| Heterogeneity p-value [d] | 0.4358 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.9 (43.3, 98.4) | NE (NE, NE) |
| 12 months | 88.9 (43.3, 98.4) | NE (NE, NE) |
| 18 months | 88.9 (43.3, 98.4) | NE (NE, NE) |
| 24 months | 88.9 (43.3, 98.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (4.8%) |
| Censored Patients, n (%) | 20 (100.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3173 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.9269 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 2 (6.3%) |
| Censored Patients, n (%) | 28 (90.3%) | 30 (93.8%) |
| Median (95% CI), (Months) [a] | NE (1.84, NE) | NE (2.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5418 | |
| HR (95% CI) [c] | 1.734 (0.289, 10.392) | |
| HR P-Value [c] | 0.5469 | |
| Heterogeneity p-value [d] | 0.9671 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.3 (24.5, 87.1) | 81.5 (43.5, 95.1) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 2 (6.3%) |
| Censored Patients, n (%) | 29 (93.5%) | 30 (93.8%) |
| Median (95% CI), (Months) [a] | 7.03 (7.03, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9294 | |
| HR (95% CI) [c] | 1.093 (0.154, 7.768) | |
| HR P-Value [c] | 0.9293 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 84.4 (50.4, 95.9) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 1 (3.1%) |
| Censored Patients, n (%) | 26 (83.9%) | 31 (96.9%) |
| Median (95% CI), (Months) [a] | 15.31 (2.07, 15.31) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2514 | |
| HR (95% CI) [c] | 3.356 (0.373, 30.161) | |
| HR P-Value [c] | 0.2798 | |
| Heterogeneity p-value [d] | 0.2485 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.2 (30.4, 85.8) | 91.7 (53.9, 98.8) |
| 12 months | 65.2 (30.4, 85.8) | 91.7 (53.9, 98.8) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 3 (9.4%) |
| Censored Patients, n (%) | 29 (93.5%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.45, 2.83) | 1.51 (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8676 | |
| HR (95% CI) [c] | 0.862 (0.142, 5.232) | |
| HR P-Value [c] | 0.8717 | |
| Heterogeneity p-value [d] | 0.9627 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 40.0 (5.2, 75.3) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 1 (3.1%) |
| Censored Patients, n (%) | 28 (90.3%) | 31 (96.9%) |
| Median (95% CI), (Months) [a] | 11.33 (1.45, 11.33) | NE (1.94, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3112 | |
| HR (95% CI) [c] | 3.046 (0.315, 29.417) | |
| HR P-Value [c] | 0.3356 | |
| Heterogeneity p-value [d] | 0.9713 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (19.5, 90.4) | 80.0 (20.4, 96.9) |
| 12 months | 0.0 (NE, NE) | 80.0 (20.4, 96.9) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 1 (3.2%) | 1 (3.1%) |
| Censored Patients, n (%) | 30 (96.8%) | 31 (96.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8903 | |
| HR (95% CI) [c] | 0.823 (0.051, 13.184) | |
| HR P-Value [c] | 0.8905 | |
| Heterogeneity p-value [d] | 0.9573 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.2 (70.7, 99.3) | 93.8 (63.2, 99.1) |
| 12 months | 95.2 (70.7, 99.3) | 93.8 (63.2, 99.1) |
| 18 months | 95.2 (70.7, 99.3) | NE (NE, NE) |
| 24 months | 95.2 (70.7, 99.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 3 (9.4%) |
| Censored Patients, n (%) | 28 (90.3%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7008 | |
| HR (95% CI) [c] | 1.373 (0.271, 6.963) | |
| HR P-Value [c] | 0.7019 | |
| Heterogeneity p-value [d] | 0.9920 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.7 (52.7, 93.9) | 90.9 (68.3, 97.6) |
| 12 months | 81.7 (52.7, 93.9) | 60.6 (8.0, 90.6) |
| 18 months | 81.7 (52.7, 93.9) | NE (NE, NE) |
| 24 months | 81.7 (52.7, 93.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 2 (6.3%) |
| Censored Patients, n (%) | 29 (93.5%) | 30 (93.8%) |
| Median (95% CI), (Months) [a] | NE (1.84, NE) | 8.97 (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2123 | |
| HR (95% CI) [c] | 4.109 (0.370, 45.611) | |
| HR P-Value [c] | 0.2498 | |
| Heterogeneity p-value [d] | 0.8357 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.3 (15.1, 90.2) | 92.9 (59.1, 99.0) |
| 12 months | NE (NE, NE) | 46.4 (0.9, 88.3) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 3 (9.4%) |
| Censored Patients, n (%) | 29 (93.5%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | 1.91 (1.45, NE) | 2.14 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7560 | |
| HR (95% CI) [c] | 0.758 (0.125, 4.606) | |
| HR P-Value [c] | 0.7637 | |
| Heterogeneity p-value [d] | 0.8708 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.5 (1.1, 80.8) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 2 (6.3%) |
| Censored Patients, n (%) | 29 (93.5%) | 30 (93.8%) |
| Median (95% CI), (Months) [a] | NE (5.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9084 | |
| HR (95% CI) [c] | 0.891 (0.125, 6.354) | |
| HR P-Value [c] | 0.9083 | |
| Heterogeneity p-value [d] | 0.9765 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.7 (37.7, 95.4) | 88.9 (62.4, 97.1) |
| 12 months | 80.7 (37.7, 95.4) | 88.9 (62.4, 97.1) |
| 18 months | 80.7 (37.7, 95.4) | NE (NE, NE) |
| 24 months | 80.7 (37.7, 95.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 1 (3.2%) | 1 (3.1%) |
| Censored Patients, n (%) | 30 (96.8%) | 31 (96.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9098 | |
| HR (95% CI) [c] | 1.174 (0.073, 18.819) | |
| HR P-Value [c] | 0.9099 | |
| Heterogeneity p-value [d] | 0.7278 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (59.1, 99.0) | 94.4 (66.6, 99.2) |
| 12 months | NE (NE, NE) | 94.4 (66.6, 99.2) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 0 |
| Censored Patients, n (%) | 29 (93.5%) | 32 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1379 | |
| HR (95% CI) [c] | 88981491 (0.000, NE) | |
| HR P-Value [c] | 0.9977 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.4 (66.8, 97.5) | 100.0 (100.0, 100.0) |
| 12 months | 90.4 (66.8, 97.5) | 100.0 (100.0, 100.0) |
| 18 months | 90.4 (66.8, 97.5) | NE (NE, NE) |
| 24 months | 90.4 (66.8, 97.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 1 (3.2%) | 1 (3.1%) |
| Censored Patients, n (%) | 30 (96.8%) | 31 (96.9%) |
| Median (95% CI), (Months) [a] | NE (1.84, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8211 | |
| HR (95% CI) [c] | 1.375 (0.086, 22.009) | |
| HR P-Value [c] | 0.8219 | |
| Heterogeneity p-value [d] | 0.7581 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.0 (47.3, 98.5) | 93.8 (63.2, 99.1) |
| 12 months | NE (NE, NE) | 93.8 (63.2, 99.1) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 5 (15.6%) |
| Censored Patients, n (%) | 28 (90.3%) | 27 (84.4%) |
| Median (95% CI), (Months) [a] | NE (1.84, NE) | NE (2.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7220 | |
| HR (95% CI) [c] | 0.772 (0.184, 3.234) | |
| HR P-Value [c] | 0.7228 | |
| Heterogeneity p-value [d] | 0.4358 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.7 (32.9, 89.8) | 65.7 (35.5, 84.3) |
| 12 months | NE (NE, NE) | 65.7 (35.5, 84.3) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.5a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts sensitivity sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 5 (15.6%) |
| Censored Patients, n (%) | 27 (87.1%) | 27 (84.4%) |
| Median (95% CI), (Months) [a] | 7.23 (7.23, NE) | 7.03 (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8834 | |
| HR (95% CI) [c] | 0.905 (0.237, 3.454) | |
| HR P-Value [c] | 0.8835 | |
| Heterogeneity p-value [d] | 0.9269 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.7 (53.1, 93.8) | 75.2 (46.1, 90.0) |
| 12 months | NE (NE, NE) | 37.6 (1.6, 79.4) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 22 (12.2%) | 29 (17.8%) |
| Censored Patients, n (%) | 158 (87.8%) | 134 (82.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0118 | |
| HR (95% CI) [c] | 0.491 (0.279, 0.863) | |
| HR P-Value [c] | 0.0135 | |
| Heterogeneity p-value [d] | 0.6765 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.1 (73.9, 89.3) | 72.1 (61.4, 80.3) |
| 12 months | 72.2 (59.3, 81.7) | 57.7 (36.3, 74.2) |
| 18 months | 72.2 (59.3, 81.7) | 57.7 (36.3, 74.2) |
| 24 months | 72.2 (59.3, 81.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 15 (8.3%) | 25 (15.3%) |
| Censored Patients, n (%) | 165 (91.7%) | 138 (84.7%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0014 | |
| HR (95% CI) [c] | 0.346 (0.176, 0.681) | |
| HR P-Value [c] | 0.0021 | |
| Heterogeneity p-value [d] | 0.8416 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.1 (83.7, 95.2) | 73.8 (62.8, 82.0) |
| 12 months | 91.1 (83.7, 95.2) | 70.3 (57.3, 80.0) |
| 18 months | 68.4 (46.1, 83.0) | 70.3 (57.3, 80.0) |
| 24 months | 68.4 (46.1, 83.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 12 (6.7%) | 19 (11.7%) |
| Censored Patients, n (%) | 168 (93.3%) | 144 (88.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0206 | |
| HR (95% CI) [c] | 0.432 (0.208, 0.897) | |
| HR P-Value [c] | 0.0244 | |
| Heterogeneity p-value [d] | 0.9872 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.3 (80.7, 94.2) | 81.3 (71.4, 88.1) |
| 12 months | 85.1 (74.1, 91.7) | 72.1 (54.4, 83.8) |
| 18 months | 85.1 (74.1, 91.7) | 72.1 (54.4, 83.8) |
| 24 months | 85.1 (74.1, 91.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 11 (6.1%) | 5 (3.1%) |
| Censored Patients, n (%) | 169 (93.9%) | 158 (96.9%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7243 | |
| HR (95% CI) [c] | 1.219 (0.405, 3.674) | |
| HR P-Value [c] | 0.7248 | |
| Heterogeneity p-value [d] | 0.9999 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.2 (87.2, 97.4) | 94.7 (87.5, 97.8) |
| 12 months | 87.0 (74.6, 93.6) | 94.7 (87.5, 97.8) |
| 18 months | 82.1 (65.2, 91.3) | 94.7 (87.5, 97.8) |
| 24 months | 73.9 (49.3, 87.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 12 (6.7%) | 16 (9.8%) |
| Censored Patients, n (%) | 168 (93.3%) | 147 (90.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0669 | |
| HR (95% CI) [c] | 0.492 (0.227, 1.067) | |
| HR P-Value [c] | 0.0725 | |
| Heterogeneity p-value [d] | 0.1247 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.2 (85.2, 95.9) | 84.3 (74.8, 90.4) |
| 12 months | 88.1 (78.3, 93.7) | 76.6 (55.9, 88.5) |
| 18 months | 82.3 (64.4, 91.7) | 76.6 (55.9, 88.5) |
| 24 months | 82.3 (64.4, 91.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 17 (9.4%) | 20 (12.3%) |
| Censored Patients, n (%) | 163 (90.6%) | 143 (87.7%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0409 | |
| HR (95% CI) [c] | 0.498 (0.252, 0.984) | |
| HR P-Value [c] | 0.0448 | |
| Heterogeneity p-value [d] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.2 (85.5, 95.9) | 80.8 (70.6, 87.8) |
| 12 months | 84.8 (74.1, 91.4) | 73.3 (58.1, 83.7) |
| 18 months | 73.8 (56.3, 85.2) | 73.3 (58.1, 83.7) |
| 24 months | 61.5 (32.5, 81.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 38 (21.1%) | 43 (26.4%) |
| Censored Patients, n (%) | 142 (78.9%) | 120 (73.6%) |
| Median (95% CI), (Months) [a] | 16.62 (11.24, NE) | 10.28 (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0075 | |
| HR (95% CI) [c] | 0.545 (0.347, 0.856) | |
| HR P-Value [c] | 0.0084 | |
| Heterogeneity p-value [d] | 0.8615 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.6 (64.9, 81.9) | 58.4 (47.4, 67.8) |
| 12 months | 62.4 (49.8, 72.7) | 46.7 (28.8, 62.8) |
| 18 months | 48.9 (33.3, 62.7) | 46.7 (28.8, 62.8) |
| 24 months | 48.9 (33.3, 62.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 19 (10.6%) | 8 (4.9%) |
| Censored Patients, n (%) | 161 (89.4%) | 155 (95.1%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6369 | |
| HR (95% CI) [c] | 1.226 (0.523, 2.874) | |
| HR P-Value [c] | 0.6390 | |
| Heterogeneity p-value [d] | 0.9999 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.0 (81.4, 94.8) | 90.5 (81.7, 95.3) |
| 12 months | 77.5 (64.2, 86.3) | 90.5 (81.7, 95.3) |
| 18 months | 67.0 (50.3, 79.3) | 90.5 (81.7, 95.3) |
| 24 months | 55.9 (30.3, 75.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 10 (5.6%) | 20 (12.3%) |
| Censored Patients, n (%) | 170 (94.4%) | 143 (87.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0016 | |
| HR (95% CI) [c] | 0.298 (0.135, 0.658) | |
| HR P-Value [c] | 0.0027 | |
| Heterogeneity p-value [d] | 0.9889 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.7 (88.4, 97.7) | 82.3 (72.6, 88.8) |
| 12 months | 88.5 (77.5, 94.4) | 67.4 (40.2, 84.3) |
| 18 months | 84.3 (69.2, 92.4) | 67.4 (40.2, 84.3) |
| 24 months | 84.3 (69.2, 92.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 27 (15.0%) | 31 (19.0%) |
| Censored Patients, n (%) | 153 (85.0%) | 132 (81.0%) |
| Median (95% CI), (Months) [a] | NE (19.15, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0195 | |
| HR (95% CI) [c] | 0.535 (0.314, 0.912) | |
| HR P-Value [c] | 0.0215 | |
| Heterogeneity p-value [d] | 0.2983 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.6 (72.4, 88.0) | 65.1 (52.8, 74.9) |
| 12 months | 67.8 (54.2, 78.2) | 50.2 (29.0, 68.2) |
| 18 months | 65.1 (50.9, 76.1) | 50.2 (29.0, 68.2) |
| 24 months | 54.2 (30.4, 73.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 22 (12.2%) | 29 (17.8%) |
| Censored Patients, n (%) | 158 (87.8%) | 134 (82.2%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (12.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0034 | |
| HR (95% CI) [c] | 0.429 (0.240, 0.768) | |
| HR P-Value [c] | 0.0044 | |
| Heterogeneity p-value [d] | 0.5607 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.2 (77.7, 91.6) | 71.4 (60.1, 80.0) |
| 12 months | 78.1 (66.3, 86.1) | 67.8 (54.7, 77.9) |
| 18 months | 69.6 (53.1, 81.3) | 54.2 (26.7, 75.3) |
| 24 months | 58.0 (31.4, 77.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 28 (15.6%) | 29 (17.8%) |
| Censored Patients, n (%) | 152 (84.4%) | 134 (82.2%) |
| Median (95% CI), (Months) [a] | NE (13.90, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0410 | |
| HR (95% CI) [c] | 0.576 (0.338, 0.984) | |
| HR P-Value [c] | 0.0434 | |
| Heterogeneity p-value [d] | 0.3827 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.7 (79.8, 92.6) | 70.2 (58.9, 78.9) |
| 12 months | 64.7 (51.0, 75.5) | 67.1 (54.5, 76.9) |
| 18 months | 57.1 (41.0, 70.3) | 67.1 (54.5, 76.9) |
| 24 months | 57.1 (41.0, 70.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 25 (13.9%) | 36 (22.1%) |
| Censored Patients, n (%) | 155 (86.1%) | 127 (77.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0038 | |
| HR (95% CI) [c] | 0.471 (0.280, 0.793) | |
| HR P-Value [c] | 0.0047 | |
| Heterogeneity p-value [d] | 0.1453 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.9 (73.1, 88.0) | 62.8 (51.8, 71.9) |
| 12 months | 77.3 (66.3, 85.1) | 62.8 (51.8, 71.9) |
| 18 months | 67.5 (52.2, 78.9) | 62.8 (51.8, 71.9) |
| 24 months | 67.5 (52.2, 78.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 27 (15.0%) | 27 (16.6%) |
| Censored Patients, n (%) | 153 (85.0%) | 136 (83.4%) |
| Median (95% CI), (Months) [a] | 20.80 (15.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0947 | |
| HR (95% CI) [c] | 0.626 (0.359, 1.091) | |
| HR P-Value [c] | 0.0983 | |
| Heterogeneity p-value [d] | 0.9767 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.3 (77.3, 90.6) | 71.4 (60.4, 79.8) |
| 12 months | 73.3 (60.8, 82.3) | 71.4 (60.4, 79.8) |
| 18 months | 61.0 (43.7, 74.5) | 71.4 (60.4, 79.8) |
| 24 months | 48.8 (23.4, 70.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 23 (12.8%) | 20 (12.3%) |
| Censored Patients, n (%) | 157 (87.2%) | 143 (87.7%) |
| Median (95% CI), (Months) [a] | NE (16.66, NE) | NE (11.33, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2536 | |
| HR (95% CI) [c] | 0.697 (0.374, 1.301) | |
| HR P-Value [c] | 0.2570 | |
| Heterogeneity p-value [d] | 0.9224 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.6 (76.7, 91.3) | 83.7 (74.9, 89.6) |
| 12 months | 72.3 (58.7, 82.1) | 65.5 (39.0, 82.7) |
| 18 months | 57.8 (38.8, 72.9) | 65.5 (39.0, 82.7) |
| 24 months | 57.8 (38.8, 72.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 2 (10.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 20.17 (20.17, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8717 | |
| HR (95% CI) [c] | 0.851 (0.119, 6.063) | |
| HR P-Value [c] | 0.8718 | |
| Heterogeneity p-value [d] | 0.6765 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.1 (52.3, 96.1) | 79.5 (39.3, 94.5) |
| 12 months | 85.1 (52.3, 96.1) | NE (NE, NE) |
| 18 months | 85.1 (52.3, 96.1) | NE (NE, NE) |
| 24 months | 42.6 (1.2, 84.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 2 (10.0%) |
| Censored Patients, n (%) | 14 (87.5%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | NE (17.05, NE) | NE (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3847 | |
| HR (95% CI) [c] | 0.359 (0.032, 3.997) | |
| HR P-Value [c] | 0.4046 | |
| Heterogeneity p-value [d] | 0.8416 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.3 (56.6, 98.9) | 60.0 (12.6, 88.2) |
| 12 months | 92.3 (56.6, 98.9) | NE (NE, NE) |
| 18 months | 69.2 (16.3, 92.8) | NE (NE, NE) |
| 24 months | 69.2 (16.3, 92.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 0 |
| Censored Patients, n (%) | 13 (81.3%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (2.92, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1821 | |
| HR (95% CI) [c] | 59743399 (0.000, NE) | |
| HR P-Value [c] | 0.9975 | |
| Heterogeneity p-value [d] | 0.9872 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.6 (48.0, 95.7) | 100.0 (100.0, 100.0) |
| 12 months | 69.6 (29.7, 89.8) | NE (NE, NE) |
| 18 months | 69.6 (29.7, 89.8) | NE (NE, NE) |
| 24 months | 69.6 (29.7, 89.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 0 | 0 |
| Censored Patients, n (%) | 16 (100.0%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.9999 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 2 (10.0%) |
| Censored Patients, n (%) | 10 (62.5%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 14.26 (4.37, NE) | NE (4.37, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5013 | |
| HR (95% CI) [c] | 1.738 (0.332, 9.091) | |
| HR P-Value [c] | 0.5128 | |
| Heterogeneity p-value [d] | 0.1247 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.0 (24.8, 79.8) | 64.3 (15.1, 90.2) |
| 12 months | 57.0 (24.8, 79.8) | NE (NE, NE) |
| 18 months | 45.6 (15.7, 71.7) | NE (NE, NE) |
| 24 months | 45.6 (15.7, 71.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 0 |
| Censored Patients, n (%) | 13 (81.3%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | 20.17 (14.65, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3938 | |
| HR (95% CI) [c] | 22332085 (0.000, NE) | |
| HR P-Value [c] | 0.9976 | |
| Heterogeneity p-value [d] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.9 (50.8, 98.7) | 100.0 (100.0, 100.0) |
| 12 months | 90.9 (50.8, 98.7) | NE (NE, NE) |
| 18 months | 72.7 (24.1, 93.1) | NE (NE, NE) |
| 24 months | 36.4 (1.3, 78.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 6 (30.0%) |
| Censored Patients, n (%) | 10 (62.5%) | 14 (70.0%) |
| Median (95% CI), (Months) [a] | 20.17 (1.58, NE) | 5.68 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4582 | |
| HR (95% CI) [c] | 0.640 (0.190, 2.155) | |
| HR P-Value [c] | 0.4714 | |
| Heterogeneity p-value [d] | 0.8615 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.1 (34.8, 86.9) | 47.0 (13.2, 75.5) |
| 12 months | 56.7 (23.7, 80.0) | NE (NE, NE) |
| 18 months | 56.7 (23.7, 80.0) | NE (NE, NE) |
| 24 months | 28.4 (1.7, 67.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 0 | 0 |
| Censored Patients, n (%) | 16 (100.0%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.9999 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 0 |
| Censored Patients, n (%) | 14 (87.5%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (9.89, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3744 | |
| HR (95% CI) [c] | 48191714 (0.000, NE) | |
| HR P-Value [c] | 0.9982 | |
| Heterogeneity p-value [d] | 0.9889 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 100.0 (100.0, 100.0) |
| 12 months | 78.6 (36.1, 94.4) | NE (NE, NE) |
| 18 months | 78.6 (36.1, 94.4) | NE (NE, NE) |
| 24 months | 78.6 (36.1, 94.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 2 (10.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 20.17 (2.92, 20.17) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6032 | |
| HR (95% CI) [c] | 1.568 (0.284, 8.672) | |
| HR P-Value [c] | 0.6062 | |
| Heterogeneity p-value [d] | 0.2983 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.1 (36.7, 87.3) | 81.5 (43.5, 95.1) |
| 12 months | 69.1 (36.7, 87.3) | NE (NE, NE) |
| 18 months | 69.1 (36.7, 87.3) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 2 (10.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 20.17 (5.55, NE) | 9.92 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5718 | |
| HR (95% CI) [c] | 0.553 (0.069, 4.408) | |
| HR P-Value [c] | 0.5761 | |
| Heterogeneity p-value [d] | 0.5607 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.1 (44.4, 95.3) | 90.9 (50.8, 98.7) |
| 12 months | 82.1 (44.4, 95.3) | 0.0 (NE, NE) |
| 18 months | 82.1 (44.4, 95.3) | 0.0 (NE, NE) |
| 24 months | 41.0 (1.3, 83.3) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 3 (15.0%) |
| Censored Patients, n (%) | 10 (62.5%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6035 | |
| HR (95% CI) [c] | 1.457 (0.361, 5.878) | |
| HR P-Value [c] | 0.5973 | |
| Heterogeneity p-value [d] | 0.3827 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.1 (36.7, 87.3) | 82.1 (44.4, 95.3) |
| 12 months | 50.4 (20.4, 74.4) | NE (NE, NE) |
| 18 months | 50.4 (20.4, 74.4) | NE (NE, NE) |
| 24 months | 50.4 (20.4, 74.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 1 (5.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | NE (4.37, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3953 | |
| HR (95% CI) [c] | 2.610 (0.270, 25.211) | |
| HR P-Value [c] | 0.4070 | |
| Heterogeneity p-value [d] | 0.1453 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.2 (40.7, 91.4) | 90.0 (47.3, 98.5) |
| 12 months | 75.2 (40.7, 91.4) | NE (NE, NE) |
| 18 months | 60.2 (22.5, 84.1) | NE (NE, NE) |
| 24 months | 60.2 (22.5, 84.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 3 (15.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | 20.17 (4.37, 20.83) | 8.54 (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3577 | |
| HR (95% CI) [c] | 0.439 (0.072, 2.662) | |
| HR P-Value [c] | 0.3706 | |
| Heterogeneity p-value [d] | 0.9767 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.1 (47.2, 95.5) | 73.3 (24.3, 93.4) |
| 12 months | 83.1 (47.2, 95.5) | NE (NE, NE) |
| 18 months | 83.1 (47.2, 95.5) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 2 (10.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 20.17 (4.27, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7960 | |
| HR (95% CI) [c] | 0.771 (0.107, 5.546) | |
| HR P-Value [c] | 0.7966 | |
| Heterogeneity p-value [d] | 0.9224 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.5 (39.3, 94.5) | 81.5 (43.5, 95.1) |
| 12 months | 79.5 (39.3, 94.5) | NE (NE, NE) |
| 18 months | 79.5 (39.3, 94.5) | NE (NE, NE) |
| 24 months | 39.8 (1.3, 82.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 18 (13.2%) | 20 (16.3%) |
| Censored Patients, n (%) | 118 (86.8%) | 103 (83.7%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (9.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0553 | |
| HR (95% CI) [c] | 0.531 (0.274, 1.026) | |
| HR P-Value [c] | 0.0595 | |
| Heterogeneity p-value [d] | 0.6507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.5 (72.8, 90.2) | 71.7 (58.5, 81.4) |
| 12 months | 73.6 (59.6, 83.4) | 62.8 (40.7, 78.6) |
| 18 months | 73.6 (59.6, 83.4) | 62.8 (40.7, 78.6) |
| 24 months | 61.4 (33.6, 80.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 12 (8.8%) | 17 (13.8%) |
| Censored Patients, n (%) | 124 (91.2%) | 106 (86.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0203 | |
| HR (95% CI) [c] | 0.412 (0.190, 0.892) | |
| HR P-Value [c] | 0.0244 | |
| Heterogeneity p-value [d] | 0.8453 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.6 (80.6, 94.5) | 75.4 (62.1, 84.6) |
| 12 months | 89.6 (80.6, 94.5) | 71.4 (56.1, 82.2) |
| 18 months | 75.3 (54.7, 87.5) | 71.4 (56.1, 82.2) |
| 24 months | 75.3 (54.7, 87.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 9 (6.6%) | 13 (10.6%) |
| Censored Patients, n (%) | 127 (93.4%) | 110 (89.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0468 | |
| HR (95% CI) [c] | 0.425 (0.179, 1.013) | |
| HR P-Value [c] | 0.0536 | |
| Heterogeneity p-value [d] | 0.4147 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.1 (83.1, 96.5) | 82.0 (70.2, 89.5) |
| 12 months | 84.5 (71.0, 92.1) | 74.6 (53.8, 87.0) |
| 18 months | 84.5 (71.0, 92.1) | 74.6 (53.8, 87.0) |
| 24 months | 84.5 (71.0, 92.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 10 (7.4%) | 2 (1.6%) |
| Censored Patients, n (%) | 126 (92.6%) | 121 (98.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1870 | |
| HR (95% CI) [c] | 2.733 (0.579, 12.902) | |
| HR P-Value [c] | 0.2041 | |
| Heterogeneity p-value [d] | 0.0638 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.7 (84.1, 96.7) | 96.7 (87.4, 99.2) |
| 12 months | 84.6 (70.8, 92.2) | 96.7 (87.4, 99.2) |
| 18 months | 79.6 (61.9, 89.7) | 96.7 (87.4, 99.2) |
| 24 months | 79.6 (61.9, 89.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 10 (7.4%) | 8 (6.5%) |
| Censored Patients, n (%) | 126 (92.6%) | 115 (93.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6970 | |
| HR (95% CI) [c] | 0.828 (0.319, 2.149) | |
| HR P-Value [c] | 0.6983 | |
| Heterogeneity p-value [d] | 0.6241 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.9 (82.3, 95.4) | 87.7 (76.2, 93.8) |
| 12 months | 88.2 (77.4, 94.0) | 87.7 (76.2, 93.8) |
| 18 months | 84.0 (69.1, 92.1) | 87.7 (76.2, 93.8) |
| 24 months | 84.0 (69.1, 92.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 15 (11.0%) | 12 (9.8%) |
| Censored Patients, n (%) | 121 (89.0%) | 111 (90.2%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3782 | |
| HR (95% CI) [c] | 0.699 (0.314, 1.556) | |
| HR P-Value [c] | 0.3801 | |
| Heterogeneity p-value [d] | 0.4059 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.0 (82.6, 95.4) | 82.4 (70.3, 89.9) |
| 12 months | 84.5 (72.7, 91.5) | 82.4 (70.3, 89.9) |
| 18 months | 73.9 (56.9, 85.0) | 82.4 (70.3, 89.9) |
| 24 months | 63.3 (36.9, 81.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 32 (23.5%) | 32 (26.0%) |
| Censored Patients, n (%) | 104 (76.5%) | 91 (74.0%) |
| Median (95% CI), (Months) [a] | 20.17 (11.20, NE) | 10.28 (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0209 | |
| HR (95% CI) [c] | 0.554 (0.332, 0.923) | |
| HR P-Value [c] | 0.0233 | |
| Heterogeneity p-value [d] | 0.8052 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.5 (63.5, 82.6) | 59.7 (46.7, 70.4) |
| 12 months | 58.4 (44.2, 70.2) | 40.4 (19.5, 60.5) |
| 18 months | 50.5 (34.6, 64.5) | 40.4 (19.5, 60.5) |
| 24 months | 42.1 (22.6, 60.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 15 (11.0%) | 5 (4.1%) |
| Censored Patients, n (%) | 121 (89.0%) | 118 (95.9%) |
| Median (95% CI), (Months) [a] | NE (14.00, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5108 | |
| HR (95% CI) [c] | 1.410 (0.501, 3.966) | |
| HR P-Value [c] | 0.5147 | |
| Heterogeneity p-value [d] | 0.4445 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.6 (79.2, 95.0) | 91.4 (80.3, 96.4) |
| 12 months | 77.0 (62.0, 86.7) | 91.4 (80.3, 96.4) |
| 18 months | 65.5 (47.1, 78.8) | 91.4 (80.3, 96.4) |
| 24 months | 65.5 (47.1, 78.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 9 (6.6%) | 11 (8.9%) |
| Censored Patients, n (%) | 127 (93.4%) | 112 (91.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0448 | |
| HR (95% CI) [c] | 0.389 (0.151, 1.005) | |
| HR P-Value [c] | 0.0512 | |
| Heterogeneity p-value [d] | 0.3663 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.4 (87.9, 98.3) | 85.8 (74.2, 92.5) |
| 12 months | 85.7 (72.0, 93.0) | 68.7 (28.8, 89.3) |
| 18 months | 81.4 (64.7, 90.7) | 68.7 (28.8, 89.3) |
| 24 months | 81.4 (64.7, 90.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 19 (14.0%) | 21 (17.1%) |
| Censored Patients, n (%) | 117 (86.0%) | 102 (82.9%) |
| Median (95% CI), (Months) [a] | 20.17 (19.15, NE) | 11.07 (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0186 | |
| HR (95% CI) [c] | 0.460 (0.238, 0.892) | |
| HR P-Value [c] | 0.0216 | |
| Heterogeneity p-value [d] | 0.3192 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.2 (75.2, 91.4) | 68.3 (54.0, 79.0) |
| 12 months | 72.4 (57.7, 82.7) | 47.8 (21.5, 70.2) |
| 18 months | 72.4 (57.7, 82.7) | 47.8 (21.5, 70.2) |
| 24 months | 48.2 (19.4, 72.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 19 (14.0%) | 22 (17.9%) |
| Censored Patients, n (%) | 117 (86.0%) | 101 (82.1%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | 12.71 (9.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0101 | |
| HR (95% CI) [c] | 0.433 (0.225, 0.832) | |
| HR P-Value [c] | 0.0121 | |
| Heterogeneity p-value [d] | 0.7972 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.1 (76.5, 91.9) | 72.6 (59.6, 82.1) |
| 12 months | 76.8 (63.6, 85.8) | 58.8 (35.3, 76.3) |
| 18 months | 68.5 (51.4, 80.6) | 44.1 (15.7, 69.7) |
| 24 months | 57.1 (30.8, 76.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 24 (17.6%) | 23 (18.7%) |
| Censored Patients, n (%) | 112 (82.4%) | 100 (81.3%) |
| Median (95% CI), (Months) [a] | NE (10.12, NE) | NE (8.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0601 | |
| HR (95% CI) [c] | 0.572 (0.318, 1.030) | |
| HR P-Value [c] | 0.0627 | |
| Heterogeneity p-value [d] | 0.5452 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.7 (77.5, 92.3) | 69.8 (56.6, 79.7) |
| 12 months | 60.3 (45.4, 72.4) | 61.1 (44.0, 74.4) |
| 18 months | 60.3 (45.4, 72.4) | 61.1 (44.0, 74.4) |
| 24 months | 60.3 (45.4, 72.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 22 (16.2%) | 20 (16.3%) |
| Censored Patients, n (%) | 114 (83.8%) | 103 (83.7%) |
| Median (95% CI), (Months) [a] | NE (14.26, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2095 | |
| HR (95% CI) [c] | 0.672 (0.359, 1.258) | |
| HR P-Value [c] | 0.2142 | |
| Heterogeneity p-value [d] | 0.1132 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.9 (70.5, 87.9) | 71.4 (58.7, 80.8) |
| 12 months | 75.8 (63.3, 84.6) | 71.4 (58.7, 80.8) |
| 18 months | 62.0 (45.1, 75.0) | 71.4 (58.7, 80.8) |
| 24 months | 62.0 (45.1, 75.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 22 (16.2%) | 15 (12.2%) |
| Censored Patients, n (%) | 114 (83.8%) | 108 (87.8%) |
| Median (95% CI), (Months) [a] | NE (15.34, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6989 | |
| HR (95% CI) [c] | 0.875 (0.442, 1.734) | |
| HR P-Value [c] | 0.7030 | |
| Heterogeneity p-value [d] | 0.0924 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.3 (74.8, 90.4) | 80.8 (69.5, 88.3) |
| 12 months | 72.5 (58.7, 82.4) | 75.1 (57.9, 86.0) |
| 18 months | 64.4 (47.5, 77.1) | 75.1 (57.9, 86.0) |
| 24 months | 53.7 (29.1, 73.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 16 (11.8%) | 15 (12.2%) |
| Censored Patients, n (%) | 120 (88.2%) | 108 (87.8%) |
| Median (95% CI), (Months) [a] | NE (16.76, NE) | NE (11.33, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1170 | |
| HR (95% CI) [c] | 0.554 (0.262, 1.172) | |
| HR P-Value [c] | 0.1222 | |
| Heterogeneity p-value [d] | 0.3221 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.2 (78.5, 93.8) | 83.2 (72.7, 90.0) |
| 12 months | 78.2 (64.0, 87.3) | 63.4 (28.6, 84.7) |
| 18 months | 67.8 (48.0, 81.3) | 63.4 (28.6, 84.7) |
| 24 months | 56.5 (29.4, 76.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 7 (11.7%) | 11 (18.3%) |
| Censored Patients, n (%) | 53 (88.3%) | 49 (81.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0912 | |
| HR (95% CI) [c] | 0.443 (0.168, 1.165) | |
| HR P-Value [c] | 0.0989 | |
| Heterogeneity p-value [d] | 0.6507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.2 (67.9, 92.6) | 74.5 (57.6, 85.5) |
| 12 months | 77.2 (54.5, 89.5) | 55.9 (19.8, 81.1) |
| 18 months | 77.2 (54.5, 89.5) | NE (NE, NE) |
| 24 months | 77.2 (54.5, 89.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 5 (8.3%) | 10 (16.7%) |
| Censored Patients, n (%) | 55 (91.7%) | 50 (83.3%) |
| Median (95% CI), (Months) [a] | 16.85 (12.45, NE) | NE (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0096 | |
| HR (95% CI) [c] | 0.197 (0.051, 0.759) | |
| HR P-Value [c] | 0.0183 | |
| Heterogeneity p-value [d] | 0.8453 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.6 (83.5, 98.9) | 65.0 (39.4, 81.9) |
| 12 months | 95.6 (83.5, 98.9) | 65.0 (39.4, 81.9) |
| 18 months | 31.9 (1.3, 73.8) | NE (NE, NE) |
| 24 months | 31.9 (1.3, 73.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 6 (10.0%) | 6 (10.0%) |
| Censored Patients, n (%) | 54 (90.0%) | 54 (90.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8021 | |
| HR (95% CI) [c] | 0.865 (0.279, 2.687) | |
| HR P-Value [c] | 0.8023 | |
| Heterogeneity p-value [d] | 0.4147 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.9 (58.5, 91.0) | 85.8 (68.8, 93.9) |
| 12 months | 79.9 (58.5, 91.0) | 75.1 (44.8, 90.3) |
| 18 months | 79.9 (58.5, 91.0) | NE (NE, NE) |
| 24 months | 79.9 (58.5, 91.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 1 (1.7%) | 3 (5.0%) |
| Censored Patients, n (%) | 59 (98.3%) | 57 (95.0%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0751 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9956 | |
| Heterogeneity p-value [d] | 0.0638 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 92.7 (79.0, 97.6) |
| 12 months | 100.0 (100.0, 100.0) | 92.7 (79.0, 97.6) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 8 (13.3%) | 10 (16.7%) |
| Censored Patients, n (%) | 52 (86.7%) | 50 (83.3%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | 9.17 (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1438 | |
| HR (95% CI) [c] | 0.488 (0.182, 1.305) | |
| HR P-Value [c] | 0.1529 | |
| Heterogeneity p-value [d] | 0.6241 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (61.4, 91.6) | 70.5 (46.7, 85.2) |
| 12 months | 75.1 (51.9, 88.2) | 47.0 (9.9, 78.2) |
| 18 months | 56.3 (18.8, 82.1) | NE (NE, NE) |
| 24 months | 56.3 (18.8, 82.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 5 (8.3%) | 8 (13.3%) |
| Censored Patients, n (%) | 55 (91.7%) | 52 (86.7%) |
| Median (95% CI), (Months) [a] | 20.80 (16.85, NE) | NE (7.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0333 | |
| HR (95% CI) [c] | 0.255 (0.066, 0.983) | |
| HR P-Value [c] | 0.0472 | |
| Heterogeneity p-value [d] | 0.4059 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.7 (80.5, 98.7) | 82.3 (63.7, 91.9) |
| 12 months | 88.4 (64.9, 96.6) | 56.4 (22.0, 80.6) |
| 18 months | 66.3 (18.0, 90.6) | NE (NE, NE) |
| 24 months | 44.2 (6.4, 78.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 12 (20.0%) | 17 (28.3%) |
| Censored Patients, n (%) | 48 (80.0%) | 43 (71.7%) |
| Median (95% CI), (Months) [a] | 16.53 (12.45, NE) | NE (2.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1035 | |
| HR (95% CI) [c] | 0.531 (0.245, 1.150) | |
| HR P-Value [c] | 0.1086 | |
| Heterogeneity p-value [d] | 0.8052 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.3 (55.5, 84.9) | 50.6 (30.1, 67.9) |
| 12 months | 73.3 (55.5, 84.9) | 50.6 (30.1, 67.9) |
| 18 months | 48.9 (17.3, 74.7) | NE (NE, NE) |
| 24 months | 48.9 (17.3, 74.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 4 (6.7%) | 3 (5.0%) |
| Censored Patients, n (%) | 56 (93.3%) | 57 (95.0%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7898 | |
| HR (95% CI) [c] | 0.802 (0.157, 4.087) | |
| HR P-Value [c] | 0.7902 | |
| Heterogeneity p-value [d] | 0.4445 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.4 (83.0, 98.8) | 92.3 (78.0, 97.5) |
| 12 months | 89.1 (65.5, 96.9) | 92.3 (78.0, 97.5) |
| 18 months | 89.1 (65.5, 96.9) | NE (NE, NE) |
| 24 months | 66.8 (17.9, 91.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 3 (5.0%) | 9 (15.0%) |
| Censored Patients, n (%) | 57 (95.0%) | 51 (85.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0308 | |
| HR (95% CI) [c] | 0.259 (0.069, 0.966) | |
| HR P-Value [c] | 0.0443 | |
| Heterogeneity p-value [d] | 0.3663 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.4 (78.1, 97.5) | 80.8 (65.2, 89.9) |
| 12 months | 92.4 (78.1, 97.5) | 64.6 (28.4, 86.0) |
| 18 months | 92.4 (78.1, 97.5) | NE (NE, NE) |
| 24 months | 92.4 (78.1, 97.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 13 (21.7%) | 12 (20.0%) |
| Censored Patients, n (%) | 47 (78.3%) | 48 (80.0%) |
| Median (95% CI), (Months) [a] | NE (10.97, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7647 | |
| HR (95% CI) [c] | 0.885 (0.400, 1.959) | |
| HR P-Value [c] | 0.7627 | |
| Heterogeneity p-value [d] | 0.3192 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.3 (50.9, 82.0) | 65.5 (46.4, 79.1) |
| 12 months | 61.6 (39.0, 77.9) | 65.5 (46.4, 79.1) |
| 18 months | 51.3 (25.4, 72.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 6 (10.0%) | 9 (15.0%) |
| Censored Patients, n (%) | 54 (90.0%) | 51 (85.0%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1287 | |
| HR (95% CI) [c] | 0.440 (0.147, 1.317) | |
| HR P-Value [c] | 0.1419 | |
| Heterogeneity p-value [d] | 0.7972 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.2 (64.5, 93.5) | 76.3 (58.8, 87.1) |
| 12 months | 84.2 (64.5, 93.5) | 76.3 (58.8, 87.1) |
| 18 months | 84.2 (64.5, 93.5) | NE (NE, NE) |
| 24 months | 63.2 (19.1, 88.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 10 (16.7%) | 9 (15.0%) |
| Censored Patients, n (%) | 50 (83.3%) | 51 (85.0%) |
| Median (95% CI), (Months) [a] | 16.85 (8.21, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6486 | |
| HR (95% CI) [c] | 0.800 (0.311, 2.054) | |
| HR P-Value [c] | 0.6423 | |
| Heterogeneity p-value [d] | 0.5452 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.0 (66.9, 92.7) | 76.2 (58.6, 87.0) |
| 12 months | 72.3 (49.3, 86.2) | 76.2 (58.6, 87.0) |
| 18 months | 41.3 (8.8, 72.5) | NE (NE, NE) |
| 24 months | 41.3 (8.8, 72.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 7 (11.7%) | 17 (28.3%) |
| Censored Patients, n (%) | 53 (88.3%) | 43 (71.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0132 | |
| HR (95% CI) [c] | 0.345 (0.143, 0.833) | |
| HR P-Value [c] | 0.0180 | |
| Heterogeneity p-value [d] | 0.1132 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.9 (67.1, 91.5) | 54.0 (36.0, 68.9) |
| 12 months | 82.9 (67.1, 91.5) | 54.0 (36.0, 68.9) |
| 18 months | 82.9 (67.1, 91.5) | NE (NE, NE) |
| 24 months | 82.9 (67.1, 91.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 9 (15.0%) | 15 (25.0%) |
| Censored Patients, n (%) | 51 (85.0%) | 45 (75.0%) |
| Median (95% CI), (Months) [a] | 20.80 (15.44, NE) | 5.88 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0077 | |
| HR (95% CI) [c] | 0.294 (0.113, 0.764) | |
| HR P-Value [c] | 0.0120 | |
| Heterogeneity p-value [d] | 0.0924 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.9 (70.8, 94.4) | 48.5 (25.0, 68.5) |
| 12 months | 80.6 (59.0, 91.6) | 48.5 (25.0, 68.5) |
| 18 months | 64.5 (27.1, 86.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 10 (16.7%) | 7 (11.7%) |
| Censored Patients, n (%) | 50 (83.3%) | 53 (88.3%) |
| Median (95% CI), (Months) [a] | 16.66 (8.25, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9186 | |
| HR (95% CI) [c] | 1.052 (0.386, 2.864) | |
| HR P-Value [c] | 0.9217 | |
| Heterogeneity p-value [d] | 0.3221 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.0 (57.0, 88.5) | 84.2 (68.2, 92.6) |
| 12 months | 59.9 (32.5, 79.1) | 67.4 (28.3, 88.4) |
| 18 months | 44.9 (14.9, 71.4) | NE (NE, NE) |
| 24 months | 44.9 (14.9, 71.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 2 (8.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | NE (7.26, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7887 | |
| HR (95% CI) [c] | 1.283 (0.206, 7.989) | |
| HR P-Value [c] | 0.7891 | |
| Heterogeneity p-value [d] | 0.3130 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.3 (61.3, 99.0) | 86.6 (55.2, 96.6) |
| 12 months | 62.2 (19.9, 87.0) | 86.6 (55.2, 96.6) |
| 18 months | 62.2 (19.9, 87.0) | 86.6 (55.2, 96.6) |
| 24 months | 62.2 (19.9, 87.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 4 (16.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | NE (13.93, NE) | 7.16 (5.78, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4108 | |
| HR (95% CI) [c] | 0.529 (0.113, 2.469) | |
| HR P-Value [c] | 0.4176 | |
| Heterogeneity p-value [d] | 0.8796 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (58.6, 96.7) | 71.3 (30.9, 90.7) |
| 12 months | 87.5 (58.6, 96.7) | 47.5 (8.1, 80.2) |
| 18 months | 65.6 (17.7, 90.3) | 47.5 (8.1, 80.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 3 (12.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | NE (7.26, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4755 | |
| HR (95% CI) [c] | 0.520 (0.085, 3.164) | |
| HR P-Value [c] | 0.4777 | |
| Heterogeneity p-value [d] | 0.6928 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 80.8 (50.5, 93.6) |
| 12 months | 68.6 (21.3, 91.2) | 80.8 (50.5, 93.6) |
| 18 months | 68.6 (21.3, 91.2) | 80.8 (50.5, 93.6) |
| 24 months | 68.6 (21.3, 91.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 1 (4.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (16.76, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5995 | |
| HR (95% CI) [c] | 0.465 (0.025, 8.517) | |
| HR P-Value [c] | 0.6061 | |
| Heterogeneity p-value [d] | 0.9727 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 92.3 (56.6, 98.9) |
| 12 months | 100.0 (100.0, 100.0) | 92.3 (56.6, 98.9) |
| 18 months | 75.0 (12.8, 96.1) | 92.3 (56.6, 98.9) |
| 24 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 0 | 0 |
| Censored Patients, n (%) | 22 (100.0%) | 25 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.8678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 18 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 2 (8.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | NE (12.52, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4244 | |
| HR (95% CI) [c] | 0.378 (0.032, 4.453) | |
| HR P-Value [c] | 0.4396 | |
| Heterogeneity p-value [d] | 0.4472 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 88.9 (62.4, 97.1) |
| 12 months | 100.0 (100.0, 100.0) | 88.9 (62.4, 97.1) |
| 18 months | 80.0 (20.4, 96.9) | 88.9 (62.4, 97.1) |
| 24 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 5 (20.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | 7.10 (4.30, NE) | 10.28 (2.96, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8065 | |
| HR (95% CI) [c] | 1.161 (0.351, 3.843) | |
| HR P-Value [c] | 0.8066 | |
| Heterogeneity p-value [d] | 0.4254 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.3 (30.2, 83.0) | 77.6 (44.7, 92.4) |
| 12 months | 49.8 (18.3, 75.2) | 29.1 (1.4, 69.9) |
| 18 months | 49.8 (18.3, 75.2) | 29.1 (1.4, 69.9) |
| 24 months | 49.8 (18.3, 75.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 1 (4.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (5.95, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7257 | |
| HR (95% CI) [c] | 1.523 (0.143, 16.196) | |
| HR P-Value [c] | 0.7274 | |
| Heterogeneity p-value [d] | 0.9390 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (38.7, 98.1) | 93.3 (61.3, 99.0) |
| 12 months | 87.5 (38.7, 98.1) | 93.3 (61.3, 99.0) |
| 18 months | 52.5 (12.2, 82.1) | 93.3 (61.3, 99.0) |
| 24 months | 52.5 (12.2, 82.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 3 (12.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | NE (7.26, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3488 | |
| HR (95% CI) [c] | 0.411 (0.062, 2.725) | |
| HR P-Value [c] | 0.3569 | |
| Heterogeneity p-value [d] | 0.9466 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 83.0 (55.9, 94.2) |
| 12 months | 68.6 (21.3, 91.2) | 83.0 (55.9, 94.2) |
| 18 months | 68.6 (21.3, 91.2) | 83.0 (55.9, 94.2) |
| 24 months | 68.6 (21.3, 91.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 4 (18.2%) | 2 (8.0%) |
| Censored Patients, n (%) | 18 (81.8%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | NE (8.38, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5672 | |
| HR (95% CI) [c] | 1.636 (0.296, 9.050) | |
| HR P-Value [c] | 0.5730 | |
| Heterogeneity p-value [d] | 0.1398 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.1 (57.3, 96.6) | 84.0 (48.7, 95.9) |
| 12 months | 54.4 (14.8, 82.4) | 84.0 (48.7, 95.9) |
| 18 months | 54.4 (14.8, 82.4) | 84.0 (48.7, 95.9) |
| 24 months | 54.4 (14.8, 82.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 2 (8.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | NE (5.95, NE) | NE (9.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8512 | |
| HR (95% CI) [c] | 0.828 (0.115, 5.958) | |
| HR P-Value [c] | 0.8514 | |
| Heterogeneity p-value [d] | 0.8173 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.0 (42.3, 95.5) | 92.3 (56.6, 98.9) |
| 12 months | 82.0 (42.3, 95.5) | 61.5 (7.4, 91.3) |
| 18 months | 82.0 (42.3, 95.5) | 61.5 (7.4, 91.3) |
| 24 months | 82.0 (42.3, 95.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 4 (18.2%) | 5 (20.0%) |
| Censored Patients, n (%) | 18 (81.8%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | NE (10.09, NE) | 8.54 (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5842 | |
| HR (95% CI) [c] | 0.691 (0.181, 2.635) | |
| HR P-Value [c] | 0.5882 | |
| Heterogeneity p-value [d] | 0.1034 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.6 (53.0, 93.7) | 70.9 (37.7, 88.6) |
| 12 months | 65.3 (25.6, 87.5) | 47.3 (8.9, 79.3) |
| 18 months | 65.3 (25.6, 87.5) | 47.3 (8.9, 79.3) |
| 24 months | 65.3 (25.6, 87.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 1 (4.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9737 | |
| HR (95% CI) [c] | 0.954 (0.059, 15.318) | |
| HR P-Value [c] | 0.9737 | |
| Heterogeneity p-value [d] | 0.9265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.8 (63.2, 99.1) | 91.7 (53.9, 98.8) |
| 12 months | 93.8 (63.2, 99.1) | 91.7 (53.9, 98.8) |
| 18 months | 93.8 (63.2, 99.1) | 91.7 (53.9, 98.8) |
| 24 months | 93.8 (63.2, 99.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 5 (22.7%) | 4 (16.0%) |
| Censored Patients, n (%) | 17 (77.3%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | 13.93 (7.10, NE) | NE (8.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9881 | |
| HR (95% CI) [c] | 0.990 (0.258, 3.796) | |
| HR P-Value [c] | 0.9887 | |
| Heterogeneity p-value [d] | 0.0855 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (58.6, 96.7) | 80.8 (50.5, 93.6) |
| 12 months | 62.5 (25.3, 85.1) | 60.6 (17.9, 86.4) |
| 18 months | 46.9 (12.8, 75.7) | 60.6 (17.9, 86.4) |
| 24 months | 46.9 (12.8, 75.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 4 (18.2%) | 2 (8.0%) |
| Censored Patients, n (%) | 18 (81.8%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | 16.76 (5.95, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4887 | |
| HR (95% CI) [c] | 1.827 (0.324, 10.290) | |
| HR P-Value [c] | 0.4946 | |
| Heterogeneity p-value [d] | 0.6413 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.0 (35.3, 90.9) | 88.9 (62.4, 97.1) |
| 12 months | 73.0 (35.3, 90.9) | 88.9 (62.4, 97.1) |
| 18 months | 48.6 (8.6, 81.0) | 88.9 (62.4, 97.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 8 (20.5%) | 6 (16.7%) |
| Censored Patients, n (%) | 31 (79.5%) | 30 (83.3%) |
| Median (95% CI), (Months) [a] | NE (9.92, NE) | 9.17 (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6600 | |
| HR (95% CI) [c] | 0.787 (0.266, 2.329) | |
| HR P-Value [c] | 0.6654 | |
| Heterogeneity p-value [d] | 0.3130 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.7 (52.4, 86.6) | 77.9 (54.7, 90.2) |
| 12 months | 65.5 (40.1, 82.2) | 38.9 (1.5, 80.8) |
| 18 months | 65.5 (40.1, 82.2) | NE (NE, NE) |
| 24 months | 65.5 (40.1, 82.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 3 (7.7%) | 5 (13.9%) |
| Censored Patients, n (%) | 36 (92.3%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | 16.85 (12.45, NE) | NE (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0036 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9945 | |
| Heterogeneity p-value [d] | 0.8796 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 62.7 (25.4, 85.2) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 46.7 (7.1, 80.3) | NE (NE, NE) |
| 24 months | 46.7 (7.1, 80.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 3 (8.3%) |
| Censored Patients, n (%) | 34 (87.2%) | 33 (91.7%) |
| Median (95% CI), (Months) [a] | NE (5.78, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8922 | |
| HR (95% CI) [c] | 1.105 (0.262, 4.664) | |
| HR P-Value [c] | 0.8922 | |
| Heterogeneity p-value [d] | 0.6928 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.8 (49.8, 89.6) | 91.1 (68.8, 97.7) |
| 12 months | 75.8 (49.8, 89.6) | 68.3 (17.4, 92.0) |
| 18 months | 75.8 (49.8, 89.6) | NE (NE, NE) |
| 24 months | 75.8 (49.8, 89.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 2 (5.1%) | 2 (5.6%) |
| Censored Patients, n (%) | 37 (94.9%) | 34 (94.4%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4562 | |
| HR (95% CI) [c] | 0.415 (0.038, 4.576) | |
| HR P-Value [c] | 0.4726 | |
| Heterogeneity p-value [d] | 0.9727 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 96.8 (79.2, 99.5) | 91.8 (70.9, 97.9) |
| 12 months | 96.8 (79.2, 99.5) | 91.8 (70.9, 97.9) |
| 18 months | 96.8 (79.2, 99.5) | NE (NE, NE) |
| 24 months | 77.4 (23.6, 95.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 7 (19.4%) |
| Censored Patients, n (%) | 32 (82.1%) | 29 (80.6%) |
| Median (95% CI), (Months) [a] | NE (7.62, NE) | 9.17 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1676 | |
| HR (95% CI) [c] | 0.465 (0.152, 1.423) | |
| HR P-Value [c] | 0.1795 | |
| Heterogeneity p-value [d] | 0.8678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.1 (57.4, 91.5) | 69.0 (42.1, 85.3) |
| 12 months | 73.4 (48.2, 87.7) | 34.5 (1.8, 75.6) |
| 18 months | 58.7 (24.8, 81.6) | NE (NE, NE) |
| 24 months | 58.7 (24.8, 81.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 5 (13.9%) |
| Censored Patients, n (%) | 34 (87.2%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (7.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0954 | |
| HR (95% CI) [c] | 0.298 (0.067, 1.327) | |
| HR P-Value [c] | 0.1122 | |
| Heterogeneity p-value [d] | 0.4472 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.4 (72.5, 98.0) | 80.2 (54.9, 92.2) |
| 12 months | 85.2 (58.7, 95.3) | 53.5 (9.5, 84.7) |
| 18 months | 68.2 (26.3, 89.6) | NE (NE, NE) |
| 24 months | 51.1 (13.2, 80.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 9 (23.1%) | 11 (30.6%) |
| Censored Patients, n (%) | 30 (76.9%) | 25 (69.4%) |
| Median (95% CI), (Months) [a] | NE (12.45, NE) | 5.68 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0659 | |
| HR (95% CI) [c] | 0.418 (0.161, 1.084) | |
| HR P-Value [c] | 0.0728 | |
| Heterogeneity p-value [d] | 0.4254 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.1 (52.8, 86.9) | 39.4 (13.7, 64.6) |
| 12 months | 74.1 (52.8, 86.9) | NE (NE, NE) |
| 18 months | 51.9 (21.5, 75.6) | NE (NE, NE) |
| 24 months | 51.9 (21.5, 75.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 3 (7.7%) | 1 (2.8%) |
| Censored Patients, n (%) | 36 (92.3%) | 35 (97.2%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9628 | |
| HR (95% CI) [c] | 1.061 (0.090, 12.515) | |
| HR P-Value [c] | 0.9628 | |
| Heterogeneity p-value [d] | 0.9390 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 96.8 (79.2, 99.5) | 95.0 (69.5, 99.3) |
| 12 months | 89.3 (60.2, 97.5) | 95.0 (69.5, 99.3) |
| 18 months | 89.3 (60.2, 97.5) | NE (NE, NE) |
| 24 months | 71.5 (25.6, 92.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 3 (7.7%) | 4 (11.1%) |
| Censored Patients, n (%) | 36 (92.3%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4133 | |
| HR (95% CI) [c] | 0.538 (0.120, 2.406) | |
| HR P-Value [c] | 0.4174 | |
| Heterogeneity p-value [d] | 0.9466 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.9 (69.1, 96.3) | 82.6 (60.1, 93.1) |
| 12 months | 88.9 (69.1, 96.3) | 82.6 (60.1, 93.1) |
| 18 months | 88.9 (69.1, 96.3) | NE (NE, NE) |
| 24 months | 88.9 (69.1, 96.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 12 (30.8%) | 6 (16.7%) |
| Censored Patients, n (%) | 27 (69.2%) | 30 (83.3%) |
| Median (95% CI), (Months) [a] | 12.45 (2.89, NE) | NE (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4374 | |
| HR (95% CI) [c] | 1.467 (0.547, 3.938) | |
| HR P-Value [c] | 0.4468 | |
| Heterogeneity p-value [d] | 0.1398 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.4 (35.9, 74.0) | 68.9 (43.0, 84.9) |
| 12 months | 57.4 (35.9, 74.0) | 68.9 (43.0, 84.9) |
| 18 months | 47.8 (23.7, 68.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 4 (10.3%) | 5 (13.9%) |
| Censored Patients, n (%) | 35 (89.7%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | 12.71 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1147 | |
| HR (95% CI) [c] | 0.319 (0.072, 1.411) | |
| HR P-Value [c] | 0.1321 | |
| Heterogeneity p-value [d] | 0.8173 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.1 (63.8, 95.8) | 82.0 (58.6, 92.9) |
| 12 months | 87.1 (63.8, 95.8) | 82.0 (58.6, 92.9) |
| 18 months | 87.1 (63.8, 95.8) | 0.0 (NE, NE) |
| 24 months | 69.7 (26.8, 90.6) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 5 (13.9%) |
| Censored Patients, n (%) | 32 (82.1%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | NE (13.90, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6906 | |
| HR (95% CI) [c] | 0.779 (0.232, 2.617) | |
| HR P-Value [c] | 0.6858 | |
| Heterogeneity p-value [d] | 0.1034 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (60.0, 91.9) | 77.0 (53.2, 89.8) |
| 12 months | 81.3 (60.0, 91.9) | 77.0 (53.2, 89.8) |
| 18 months | 52.2 (16.2, 79.3) | NE (NE, NE) |
| 24 months | 52.2 (16.2, 79.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 9 (25.0%) |
| Censored Patients, n (%) | 32 (82.1%) | 27 (75.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (1.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2115 | |
| HR (95% CI) [c] | 0.534 (0.199, 1.436) | |
| HR P-Value [c] | 0.2139 | |
| Heterogeneity p-value [d] | 0.9265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (54.4, 87.3) | 56.1 (31.9, 74.7) |
| 12 months | 75.0 (54.4, 87.3) | 56.1 (31.9, 74.7) |
| 18 months | 75.0 (54.4, 87.3) | NE (NE, NE) |
| 24 months | 75.0 (54.4, 87.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 9 (23.1%) | 9 (25.0%) |
| Censored Patients, n (%) | 30 (76.9%) | 27 (75.0%) |
| Median (95% CI), (Months) [a] | 20.80 (7.62, NE) | 5.68 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0509 | |
| HR (95% CI) [c] | 0.365 (0.128, 1.043) | |
| HR P-Value [c] | 0.0599 | |
| Heterogeneity p-value [d] | 0.0855 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.1 (60.0, 91.8) | 43.9 (15.0, 69.9) |
| 12 months | 73.7 (48.4, 88.0) | NE (NE, NE) |
| 18 months | 61.4 (29.7, 82.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 4 (11.1%) |
| Censored Patients, n (%) | 32 (82.1%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | NE (8.25, NE) | 11.33 (11.33, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9074 | |
| HR (95% CI) [c] | 0.922 (0.257, 3.316) | |
| HR P-Value [c] | 0.9014 | |
| Heterogeneity p-value [d] | 0.6413 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.1 (53.2, 89.8) | 85.7 (62.0, 95.2) |
| 12 months | 69.4 (42.6, 85.5) | NE (NE, NE) |
| 18 months | 55.5 (23.1, 78.9) | NE (NE, NE) |
| 24 months | 55.5 (23.1, 78.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 11 (14.5%) | 13 (19.7%) |
| Censored Patients, n (%) | 65 (85.5%) | 53 (80.3%) |
| Median (95% CI), (Months) [a] | 20.17 (20.17, NE) | 9.69 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0243 | |
| HR (95% CI) [c] | 0.390 (0.167, 0.910) | |
| HR P-Value [c] | 0.0295 | |
| Heterogeneity p-value [d] | 0.3130 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.8 (66.1, 90.7) | 63.9 (44.2, 78.2) |
| 12 months | 72.3 (52.1, 85.1) | NE (NE, NE) |
| 18 months | 72.3 (52.1, 85.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 7 (9.2%) | 10 (15.2%) |
| Censored Patients, n (%) | 69 (90.8%) | 56 (84.8%) |
| Median (95% CI), (Months) [a] | NE (17.05, NE) | NE (5.82, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0324 | |
| HR (95% CI) [c] | 0.348 (0.126, 0.959) | |
| HR P-Value [c] | 0.0414 | |
| Heterogeneity p-value [d] | 0.8796 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.0 (72.7, 94.1) | 68.9 (48.4, 82.6) |
| 12 months | 87.0 (72.7, 94.1) | 68.9 (48.4, 82.6) |
| 18 months | 76.1 (45.9, 90.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 4 (5.3%) | 6 (9.1%) |
| Censored Patients, n (%) | 72 (94.7%) | 60 (90.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0576 | |
| HR (95% CI) [c] | 0.299 (0.080, 1.111) | |
| HR P-Value [c] | 0.0714 | |
| Heterogeneity p-value [d] | 0.6928 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (79.0, 97.7) | 83.3 (63.8, 92.9) |
| 12 months | 87.4 (67.0, 95.6) | 66.7 (27.6, 88.0) |
| 18 months | 87.4 (67.0, 95.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 4 (5.3%) | 2 (3.0%) |
| Censored Patients, n (%) | 72 (94.7%) | 64 (97.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9874 | |
| HR (95% CI) [c] | 0.986 (0.175, 5.557) | |
| HR P-Value [c] | 0.9873 | |
| Heterogeneity p-value [d] | 0.9727 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (79.0, 97.7) | 92.7 (73.7, 98.1) |
| 12 months | 87.7 (68.1, 95.6) | 92.7 (73.7, 98.1) |
| 18 months | 87.7 (68.1, 95.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 7 (9.2%) | 4 (6.1%) |
| Censored Patients, n (%) | 69 (90.8%) | 62 (93.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9701 | |
| HR (95% CI) [c] | 1.024 (0.292, 3.588) | |
| HR P-Value [c] | 0.9706 | |
| Heterogeneity p-value [d] | 0.8678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.1 (74.9, 94.6) | 87.5 (69.3, 95.3) |
| 12 months | 88.1 (74.9, 94.6) | 87.5 (69.3, 95.3) |
| 18 months | 80.1 (55.9, 91.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 10 (13.2%) | 4 (6.1%) |
| Censored Patients, n (%) | 66 (86.8%) | 62 (93.9%) |
| Median (95% CI), (Months) [a] | NE (14.65, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8916 | |
| HR (95% CI) [c] | 1.089 (0.317, 3.740) | |
| HR P-Value [c] | 0.8921 | |
| Heterogeneity p-value [d] | 0.4472 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.1 (75.2, 94.5) | 86.9 (67.0, 95.2) |
| 12 months | 82.9 (64.8, 92.2) | 86.9 (67.0, 95.2) |
| 18 months | 68.8 (42.4, 84.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 19 (25.0%) | 14 (21.2%) |
| Censored Patients, n (%) | 57 (75.0%) | 52 (78.8%) |
| Median (95% CI), (Months) [a] | 16.62 (7.29, NE) | 8.34 (3.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2189 | |
| HR (95% CI) [c] | 0.643 (0.314, 1.315) | |
| HR P-Value [c] | 0.2263 | |
| Heterogeneity p-value [d] | 0.4254 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.5 (54.6, 81.7) | 60.6 (40.7, 75.6) |
| 12 months | 57.7 (38.4, 72.9) | 48.5 (22.3, 70.5) |
| 18 months | 46.1 (21.4, 67.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 9 (11.8%) | 4 (6.1%) |
| Censored Patients, n (%) | 67 (88.2%) | 62 (93.9%) |
| Median (95% CI), (Months) [a] | NE (12.48, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8601 | |
| HR (95% CI) [c] | 0.893 (0.265, 3.013) | |
| HR P-Value [c] | 0.8554 | |
| Heterogeneity p-value [d] | 0.9390 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.9 (77.2, 96.5) | 86.9 (68.1, 95.0) |
| 12 months | 72.7 (50.5, 86.2) | 86.9 (68.1, 95.0) |
| 18 months | 66.7 (43.1, 82.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 4 (5.3%) | 7 (10.6%) |
| Censored Patients, n (%) | 72 (94.7%) | 59 (89.4%) |
| | | |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 11.07 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0217 | |
| HR (95% CI) [c] | 0.233 (0.062, 0.883) | |
| HR P-Value [c] | 0.0321 | |
| Heterogeneity p-value [d] | 0.9466 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.5 (80.6, 97.9) | 80.7 (59.1, 91.6) |
| 12 months | 88.6 (69.8, 96.0) | 0.0 (NE, NE) |
| 18 months | 88.6 (69.8, 96.0) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 11 (14.5%) | 13 (19.7%) |
| Censored Patients, n (%) | 65 (85.5%) | 53 (80.3%) |
| Median (95% CI), (Months) [a] | 19.15 (19.15, NE) | 8.97 (5.59, 11.07) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0070 | |
| HR (95% CI) [c] | 0.309 (0.126, 0.756) | |
| HR P-Value [c] | 0.0101 | |
| Heterogeneity p-value [d] | 0.1398 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.3 (69.3, 92.3) | 60.1 (37.8, 76.5) |
| 12 months | 74.4 (54.0, 86.7) | 0.0 (NE, NE) |
| 18 months | 74.4 (54.0, 86.7) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 11 (14.5%) | 13 (19.7%) |
| Censored Patients, n (%) | 65 (85.5%) | 53 (80.3%) |
| Median (95% CI), (Months) [a] | 20.17 (20.17, NE) | NE (4.37, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0149 | |
| HR (95% CI) [c] | 0.360 (0.154, 0.844) | |
| HR P-Value [c] | 0.0188 | |
| Heterogeneity p-value [d] | 0.8173 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.3 (71.1, 92.8) | 59.3 (38.4, 75.2) |
| 12 months | 72.5 (52.4, 85.2) | 59.3 (38.4, 75.2) |
| 18 months | 72.5 (52.4, 85.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 10 (13.2%) | 14 (21.2%) |
| Censored Patients, n (%) | 66 (86.8%) | 52 (78.8%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (3.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0018 | |
| HR (95% CI) [c] | 0.284 (0.123, 0.655) | |
| HR P-Value [c] | 0.0031 | |
| Heterogeneity p-value [d] | 0.1034 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.6 (76.3, 96.5) | 54.8 (33.6, 71.8) |
| 12 months | 67.1 (46.1, 81.4) | 54.8 (33.6, 71.8) |
| 18 months | 67.1 (46.1, 81.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 10 (13.2%) | 9 (13.6%) |
| Censored Patients, n (%) | 66 (86.8%) | 57 (86.4%) |
| Median (95% CI), (Months) [a] | NE (14.26, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2810 | |
| HR (95% CI) [c] | 0.602 (0.237, 1.529) | |
| HR P-Value [c] | 0.2859 | |
| Heterogeneity p-value [d] | 0.9265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.5 (67.4, 91.0) | 73.2 (54.1, 85.4) |
| 12 months | 82.5 (67.4, 91.0) | 73.2 (54.1, 85.4) |
| 18 months | 68.4 (43.2, 84.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 12 (15.8%) | 4 (6.1%) |
| Censored Patients, n (%) | 64 (84.2%) | 62 (93.9%) |
| Median (95% CI), (Months) [a] | 20.17 (20.17, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3458 | |
| HR (95% CI) [c] | 1.735 (0.545, 5.521) | |
| HR P-Value [c] | 0.3509 | |
| Heterogeneity p-value [d] | 0.0855 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.2 (70.0, 90.9) | 88.0 (70.6, 95.4) |
| 12 months | 72.8 (52.8, 85.4) | 88.0 (70.6, 95.4) |
| 18 months | 72.8 (52.8, 85.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 7 (9.2%) | 6 (9.1%) |
| Censored Patients, n (%) | 69 (90.8%) | 60 (90.9%) |
| Median (95% CI), (Months) [a] | NE (16.62, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1425 | |
| HR (95% CI) [c] | 0.410 (0.121, 1.394) | |
| HR P-Value [c] | 0.1534 | |
| Heterogeneity p-value [d] | 0.6413 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.1 (80.1, 97.7) | 82.9 (65.2, 92.1) |
| 12 months | 82.8 (60.9, 93.0) | 82.9 (65.2, 92.1) |
| 18 months | 70.9 (38.3, 88.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 3 (5.1%) | 10 (17.9%) |
| Censored Patients, n (%) | 56 (94.9%) | 46 (82.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0192 | |
| HR (95% CI) [c] | 0.241 (0.066, 0.877) | |
| HR P-Value [c] | 0.0309 | |
| Heterogeneity p-value [d] | 0.3130 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.5 (70.0, 96.6) | 71.2 (51.9, 83.9) |
| 12 months | 89.5 (70.0, 96.6) | 71.2 (51.9, 83.9) |
| 18 months | 89.5 (70.0, 96.6) | NE (NE, NE) |
| 24 months | 89.5 (70.0, 96.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 4 (6.8%) | 8 (14.3%) |
| Censored Patients, n (%) | 55 (93.2%) | 48 (85.7%) |
| Median (95% CI), (Months) [a] | NE (13.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1914 | |
| HR (95% CI) [c] | 0.445 (0.128, 1.549) | |
| HR P-Value [c] | 0.2032 | |
| Heterogeneity p-value [d] | 0.8796 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.4 (80.8, 97.8) | 79.7 (63.1, 89.4) |
| 12 months | 93.4 (80.8, 97.8) | 79.7 (63.1, 89.4) |
| 18 months | 80.0 (40.5, 94.7) | NE (NE, NE) |
| 24 months | 80.0 (40.5, 94.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 4 (6.8%) | 7 (12.5%) |
| Censored Patients, n (%) | 55 (93.2%) | 49 (87.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3831 | |
| HR (95% CI) [c] | 0.583 (0.171, 1.992) | |
| HR P-Value [c] | 0.3894 | |
| Heterogeneity p-value [d] | 0.6928 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.6 (69.5, 95.3) | 79.2 (60.8, 89.7) |
| 12 months | 87.6 (69.5, 95.3) | 79.2 (60.8, 89.7) |
| 18 months | 87.6 (69.5, 95.3) | NE (NE, NE) |
| 24 months | 87.6 (69.5, 95.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 4 (6.8%) | 0 |
| Censored Patients, n (%) | 55 (93.2%) | 56 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1299 | |
| HR (95% CI) [c] | 23128256 (0.000, NE) | |
| HR P-Value [c] | 0.9956 | |
| Heterogeneity p-value [d] | 0.9727 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.1 (77.2, 98.6) | 100.0 (100.0, 100.0) |
| 12 months | 79.8 (51.0, 92.7) | 100.0 (100.0, 100.0) |
| 18 months | 79.8 (51.0, 92.7) | NE (NE, NE) |
| 24 months | 79.8 (51.0, 92.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 4 (6.8%) | 7 (12.5%) |
| Censored Patients, n (%) | 55 (93.2%) | 49 (87.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1955 | |
| HR (95% CI) [c] | 0.445 (0.127, 1.566) | |
| HR P-Value [c] | 0.2072 | |
| Heterogeneity p-value [d] | 0.8678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.4 (72.3, 96.9) | 77.8 (56.6, 89.5) |
| 12 months | 83.9 (60.1, 94.2) | 77.8 (56.6, 89.5) |
| 18 months | 83.9 (60.1, 94.2) | NE (NE, NE) |
| 24 months | 83.9 (60.1, 94.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 4 (6.8%) | 9 (16.1%) |
| Censored Patients, n (%) | 55 (93.2%) | 47 (83.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1162 | |
| HR (95% CI) [c] | 0.400 (0.123, 1.307) | |
| HR P-Value [c] | 0.1293 | |
| Heterogeneity p-value [d] | 0.4472 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.4 (79.1, 98.6) | 77.1 (58.0, 88.3) |
| 12 months | 83.2 (59.1, 93.8) | 68.5 (43.3, 84.3) |
| 18 months | 83.2 (59.1, 93.8) | NE (NE, NE) |
| 24 months | 83.2 (59.1, 93.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 10 (16.9%) | 19 (33.9%) |
| Censored Patients, n (%) | 49 (83.1%) | 37 (66.1%) |
| Median (95% CI), (Months) [a] | NE (11.20, NE) | NE (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0198 | |
| HR (95% CI) [c] | 0.399 (0.179, 0.890) | |
| HR P-Value [c] | 0.0249 | |
| Heterogeneity p-value [d] | 0.4254 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.8 (68.6, 93.0) | 53.5 (36.5, 67.9) |
| 12 months | 64.7 (38.8, 81.9) | 53.5 (36.5, 67.9) |
| 18 months | 51.8 (21.7, 75.3) | NE (NE, NE) |
| 24 months | 51.8 (21.7, 75.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 4 (6.8%) | 2 (3.6%) |
| Censored Patients, n (%) | 55 (93.2%) | 54 (96.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6199 | |
| HR (95% CI) [c] | 1.545 (0.273, 8.742) | |
| HR P-Value [c] | 0.6224 | |
| Heterogeneity p-value [d] | 0.9390 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (64.9, 96.0) | 94.1 (78.3, 98.5) |
| 12 months | 80.8 (54.7, 92.7) | 94.1 (78.3, 98.5) |
| 18 months | 80.8 (54.7, 92.7) | NE (NE, NE) |
| 24 months | 80.8 (54.7, 92.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:01:53, yingyuan.lin)

Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 3 (5.1%) | 6 (10.7%) |
| Censored Patients, n (%) | 56 (94.9%) | 50 (89.3%) |
| Median (95% CI), (Months) [a] | NE (14.59, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1374 | |
| HR (95% CI) [c] | 0.349 (0.083, 1.477) | |
| HR P-Value [c] | 0.1528 | |
| Heterogeneity p-value [d] | 0.9466 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 97.9 (85.8, 99.7) | 88.4 (74.2, 95.0) |
| 12 months | 91.8 (66.7, 98.2) | 81.0 (57.7, 92.2) |
| 18 months | 76.5 (32.8, 93.7) | NE (NE, NE) |
| 24 months | 76.5 (32.8, 93.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 5 (8.5%) | 12 (21.4%) |
| Censored Patients, n (%) | 54 (91.5%) | 44 (78.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0308 | |
| HR (95% CI) [c] | 0.316 (0.106, 0.944) | |
| HR P-Value [c] | 0.0391 | |
| Heterogeneity p-value [d] | 0.1398 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.8 (73.2, 97.1) | 66.5 (47.9, 79.7) |
| 12 months | 77.3 (50.5, 90.7) | 66.5 (47.9, 79.7) |
| 18 months | 77.3 (50.5, 90.7) | NE (NE, NE) |
| 24 months | 77.3 (50.5, 90.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 8 (13.6%) | 11 (19.6%) |
| Censored Patients, n (%) | 51 (86.4%) | 45 (80.4%) |
| Median (95% CI), (Months) [a] | NE (14.55, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1551 | |
| HR (95% CI) [c] | 0.500 (0.188, 1.330) | |
| HR P-Value [c] | 0.1647 | |
| Heterogeneity p-value [d] | 0.8173 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.3 (69.1, 94.3) | 74.7 (57.3, 85.9) |
| 12 months | 80.2 (58.1, 91.4) | 67.9 (46.4, 82.3) |
| 18 months | 50.1 (15.0, 77.8) | NE (NE, NE) |
| 24 months | 50.1 (15.0, 77.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 13 (22.0%) | 8 (14.3%) |
| Censored Patients, n (%) | 46 (78.0%) | 48 (85.7%) |
| Median (95% CI), (Months) [a] | 11.20 (8.28, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5508 | |
| HR (95% CI) [c] | 1.318 (0.533, 3.256) | |
| HR P-Value [c] | 0.5502 | |
| Heterogeneity p-value [d] | 0.1034 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.5 (68.3, 92.9) | 83.2 (67.8, 91.7) |
| 12 months | 46.3 (23.6, 66.4) | 76.8 (55.9, 88.7) |
| 18 months | 46.3 (23.6, 66.4) | NE (NE, NE) |
| 24 months | 46.3 (23.6, 66.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 11 (18.6%) | 18 (32.1%) |
| Censored Patients, n (%) | 48 (81.4%) | 38 (67.9%) |
| Median (95% CI), (Months) [a] | 14.55 (11.24, NE) | NE (1.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0300 | |
| HR (95% CI) [c] | 0.427 (0.193, 0.942) | |
| HR P-Value [c] | 0.0351 | |
| Heterogeneity p-value [d] | 0.9265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.8 (60.1, 89.5) | 51.8 (33.9, 67.0) |
| 12 months | 66.9 (43.4, 82.4) | 51.8 (33.9, 67.0) |
| 18 months | 46.8 (19.2, 70.5) | NE (NE, NE) |
| 24 months | 46.8 (19.2, 70.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 5 (8.5%) | 13 (23.2%) |
| Censored Patients, n (%) | 54 (91.5%) | 43 (76.8%) |
| Median (95% CI), (Months) [a] | NE (15.34, NE) | NE (5.88, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0142 | |
| HR (95% CI) [c] | 0.261 (0.083, 0.822) | |
| HR P-Value [c] | 0.0218 | |
| Heterogeneity p-value [d] | 0.0855 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.5 (72.8, 96.9) | 65.5 (47.1, 78.9) |
| 12 months | 82.3 (54.8, 93.9) | 65.5 (47.1, 78.9) |
| 18 months | 65.8 (25.9, 87.8) | NE (NE, NE) |
| 24 months | 65.8 (25.9, 87.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 8 (13.6%) | 10 (17.9%) |
| Censored Patients, n (%) | 51 (86.4%) | 46 (82.1%) |
| Median (95% CI), (Months) [a] | NE (9.59, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4793 | |
| HR (95% CI) [c] | 0.708 (0.268, 1.867) | |
| HR P-Value [c] | 0.4851 | |
| Heterogeneity p-value [d] | 0.6413 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.2 (65.6, 93.2) | 80.5 (64.8, 89.8) |
| 12 months | 63.1 (36.2, 81.2) | 64.1 (37.2, 81.8) |
| 18 months | 63.1 (36.2, 81.2) | NE (NE, NE) |
| 24 months | 63.1 (36.2, 81.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 20 (12.4%) | 24 (17.5%) |
| Censored Patients, n (%) | 141 (87.6%) | 113 (82.5%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0106 | |
| HR (95% CI) [c] | 0.454 (0.244, 0.844) | |
| HR P-Value [c] | 0.0126 | |
| Heterogeneity p-value [d] | 0.6215 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.6 (75.4, 90.6) | 72.9 (61.2, 81.7) |
| 12 months | 75.4 (62.5, 84.4) | 55.6 (31.0, 74.5) |
| 18 months | 75.4 (62.5, 84.4) | NE (NE, NE) |
| 24 months | 66.0 (42.6, 81.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 15 (9.3%) | 20 (14.6%) |
| Censored Patients, n (%) | 146 (90.7%) | 117 (85.4%) |
| Median (95% CI), (Months) [a] | NE (17.05, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0078 | |
| HR (95% CI) [c] | 0.383 (0.184, 0.798) | |
| HR P-Value [c] | 0.0103 | |
| Heterogeneity p-value [d] | 0.7055 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.6 (81.6, 94.2) | 73.4 (60.4, 82.7) |
| 12 months | 89.6 (81.6, 94.2) | 69.3 (54.2, 80.3) |
| 18 months | 70.4 (48.8, 84.2) | NE (NE, NE) |
| 24 months | 70.4 (48.8, 84.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 14 (8.7%) | 13 (9.5%) |
| Censored Patients, n (%) | 147 (91.3%) | 124 (90.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3099 | |
| HR (95% CI) [c] | 0.675 (0.314, 1.451) | |
| HR P-Value [c] | 0.3141 | |
| Heterogeneity p-value [d] | 0.2290 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.4 (79.7, 93.5) | 84.0 (73.3, 90.7) |
| 12 months | 81.5 (69.3, 89.3) | 80.2 (66.4, 88.8) |
| 18 months | 81.5 (69.3, 89.3) | NE (NE, NE) |
| 24 months | 81.5 (69.3, 89.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 9 (5.6%) | 4 (2.9%) |
| Censored Patients, n (%) | 152 (94.4%) | 133 (97.1%) |
| | | |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9841 | |
| HR (95% CI) [c] | 1.013 (0.287, 3.577) | |
| HR P-Value [c] | 0.9842 | |
| Heterogeneity p-value [d] | 0.6284 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.6 (87.2, 97.8) | 94.8 (86.6, 98.1) |
| 12 months | 89.6 (77.9, 95.3) | 94.8 (86.6, 98.1) |
| 18 months | 85.1 (68.9, 93.3) | NE (NE, NE) |
| 24 months | 78.0 (55.1, 90.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 14 (8.7%) | 14 (10.2%) |
| Censored Patients, n (%) | 147 (91.3%) | 123 (89.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1644 | |
| HR (95% CI) [c] | 0.581 (0.267, 1.263) | |
| HR P-Value [c] | 0.1704 | |
| Heterogeneity p-value [d] | 0.5084 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.4 (81.3, 94.1) | 83.8 (72.7, 90.7) |
| 12 months | 87.6 (78.6, 93.0) | 74.5 (49.8, 88.3) |
| 18 months | 78.6 (61.0, 88.9) | NE (NE, NE) |
| 24 months | 78.6 (61.0, 88.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 18 (11.2%) | 15 (10.9%) |
| Censored Patients, n (%) | 143 (88.8%) | 122 (89.1%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1384 | |
| HR (95% CI) [c] | 0.574 (0.273, 1.206) | |
| HR P-Value [c] | 0.1431 | |
| Heterogeneity p-value [d] | 0.5925 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.7 (83.2, 94.9) | 83.2 (72.0, 90.3) |
| 12 months | 84.6 (73.8, 91.2) | 73.4 (54.7, 85.4) |
| 18 months | 70.8 (53.2, 82.8) | NE (NE, NE) |
| 24 months | 62.9 (40.4, 78.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 35 (21.7%) | 42 (30.7%) |
| Censored Patients, n (%) | 126 (78.3%) | 95 (69.3%) |
| Median (95% CI), (Months) [a] | 20.17 (16.53, NE) | 8.34 (3.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0006 | |
| HR (95% CI) [c] | 0.446 (0.278, 0.717) | |
| HR P-Value [c] | 0.0008 | |
| Heterogeneity p-value [d] | 0.0417 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.7 (64.7, 82.3) | 50.9 (38.7, 61.9) |
| 12 months | 62.8 (50.0, 73.1) | 35.0 (14.6, 56.4) |
| 18 months | 55.4 (40.4, 68.0) | NE (NE, NE) |
| 24 months | 48.4 (30.2, 64.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 16 (9.9%) | 8 (5.8%) |
| Censored Patients, n (%) | 145 (90.1%) | 129 (94.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9674 | |
| HR (95% CI) [c] | 0.981 (0.407, 2.363) | |
| HR P-Value [c] | 0.9654 | |
| Heterogeneity p-value [d] | 0.9906 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.5 (81.5, 95.3) | 89.3 (79.5, 94.6) |
| 12 months | 79.6 (66.3, 88.1) | 89.3 (79.5, 94.6) |
| 18 months | 69.9 (53.5, 81.5) | NE (NE, NE) |
| 24 months | 69.9 (53.5, 81.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 10 (6.2%) | 14 (10.2%) |
| Censored Patients, n (%) | 151 (93.8%) | 123 (89.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0128 | |
| HR (95% CI) [c] | 0.343 (0.142, 0.824) | |
| HR P-Value [c] | 0.0168 | |
| Heterogeneity p-value [d] | 0.7995 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.3 (87.4, 97.5) | 85.4 (74.6, 91.9) |
| 12 months | 87.7 (76.2, 93.9) | 64.9 (28.6, 86.2) |
| 18 months | 83.7 (68.8, 91.9) | NE (NE, NE) |
| 24 months | 83.7 (68.8, 91.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 25 (15.5%) | 26 (19.0%) |
| Censored Patients, n (%) | 136 (84.5%) | 111 (81.0%) |
| Median (95% CI), (Months) [a] | 20.17 (19.15, NE) | NE (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0319 | |
| HR (95% CI) [c] | 0.539 (0.303, 0.957) | |
| HR P-Value [c] | 0.0348 | |
| Heterogeneity p-value [d] | 0.3532 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.2 (71.4, 87.9) | 65.3 (52.0, 75.8) |
| 12 months | 69.4 (55.8, 79.5) | 52.3 (26.0, 73.2) |
| 18 months | 69.4 (55.8, 79.5) | NE (NE, NE) |
| 24 months | 49.5 (24.0, 70.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 19 (11.8%) | 22 (16.1%) |
| Censored Patients, n (%) | 142 (88.2%) | 115 (83.9%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | 12.71 (12.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0121 | |
| HR (95% CI) [c] | 0.444 (0.232, 0.851) | |
| HR P-Value [c] | 0.0144 | |
| Heterogeneity p-value [d] | 0.6652 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.0 (78.2, 92.4) | 75.7 (63.9, 84.1) |
| 12 months | 78.4 (66.1, 86.7) | 71.9 (57.9, 81.9) |
| 18 months | 74.7 (60.2, 84.5) | NE (NE, NE) |
| 24 months | 66.4 (44.3, 81.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 26 (16.1%) | 26 (19.0%) |
| Censored Patients, n (%) | 135 (83.9%) | 111 (81.0%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0377 | |
| HR (95% CI) [c] | 0.556 (0.317, 0.975) | |
| HR P-Value [c] | 0.0404 | |
| Heterogeneity p-value [d] | 0.1184 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.0 (76.3, 90.6) | 68.2 (55.6, 77.9) |
| 12 months | 67.4 (54.1, 77.6) | 64.9 (51.2, 75.7) |
| 18 months | 63.4 (48.5, 75.1) | NE (NE, NE) |
| 24 months | 63.4 (48.5, 75.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 25 (15.5%) | 27 (19.7%) |
| Censored Patients, n (%) | 136 (84.5%) | 110 (80.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0649 | |
| HR (95% CI) [c] | 0.595 (0.340, 1.041) | |
| HR P-Value [c] | 0.0691 | |
| Heterogeneity p-value [d] | 0.4596 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.5 (70.1, 86.3) | 67.5 (55.8, 76.7) |
| 12 months | 77.3 (66.8, 84.8) | 67.5 (55.8, 76.7) |
| 18 months | 68.3 (54.0, 79.0) | NE (NE, NE) |
| 24 months | 68.3 (54.0, 79.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 27 (16.8%) | 20 (14.6%) |
| Censored Patients, n (%) | 134 (83.2%) | 117 (85.4%) |
| Median (95% CI), (Months) [a] | 20.83 (15.44, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2643 | |
| HR (95% CI) [c] | 0.707 (0.382, 1.308) | |
| HR P-Value [c] | 0.2688 | |
| Heterogeneity p-value [d] | 0.2719 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.3 (77.0, 90.8) | 73.2 (60.4, 82.4) |
| 12 months | 73.1 (60.5, 82.3) | 73.2 (60.4, 82.4) |
| 18 months | 62.6 (46.4, 75.1) | NE (NE, NE) |
| 24 months | 43.8 (19.6, 65.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 19 (11.8%) | 16 (11.7%) |
| Censored Patients, n (%) | 142 (88.2%) | 121 (88.3%) |
| Median (95% CI), (Months) [a] | NE (16.76, NE) | NE (11.33, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0972 | |
| HR (95% CI) [c] | 0.548 (0.267, 1.126) | |
| HR P-Value [c] | 0.1014 | |
| Heterogeneity p-value [d] | 0.2172 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (78.4, 93.0) | 85.1 (75.5, 91.1) |
| 12 months | 75.8 (62.1, 85.1) | 56.7 (19.7, 82.0) |
| 18 months | 66.9 (49.1, 79.7) | NE (NE, NE) |
| 24 months | 58.5 (35.8, 75.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 5 (14.3%) | 7 (15.2%) |
| Censored Patients, n (%) | 30 (85.7%) | 39 (84.8%) |
| Median (95% CI), (Months) [a] | NE (4.34, NE) | NE (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5632 | |
| HR (95% CI) [c] | 0.711 (0.225, 2.251) | |
| HR P-Value [c] | 0.5617 | |
| Heterogeneity p-value [d] | 0.6215 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.2 (47.7, 90.5) | 71.0 (47.3, 85.5) |
| 12 months | 66.6 (35.7, 85.2) | 71.0 (47.3, 85.5) |
| 18 months | 66.6 (35.7, 85.2) | 71.0 (47.3, 85.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 7 (15.2%) |
| Censored Patients, n (%) | 33 (94.3%) | 39 (84.8%) |
| Median (95% CI), (Months) [a] | NE (12.45, NE) | NE (5.78, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0682 | |
| HR (95% CI) [c] | 0.251 (0.051, 1.237) | |
| HR P-Value [c] | 0.0894 | |
| Heterogeneity p-value [d] | 0.7055 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 68.5 (42.2, 84.8) |
| 12 months | 100.0 (100.0, 100.0) | 68.5 (42.2, 84.8) |
| 18 months | NE (NE, NE) | 68.5 (42.2, 84.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 1 (2.9%) | 6 (13.0%) |
| Censored Patients, n (%) | 34 (97.1%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0705 | |
| HR (95% CI) [c] | 0.174 (0.021, 1.467) | |
| HR P-Value [c] | 0.1079 | |
| Heterogeneity p-value [d] | 0.2290 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 80.3 (58.8, 91.3) |
| 12 months | 91.7 (53.9, 98.8) | 60.2 (19.2, 85.6) |
| 18 months | NE (NE, NE) | 60.2 (19.2, 85.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 1 (2.2%) |
| Censored Patients, n (%) | 33 (94.3%) | 45 (97.8%) |
| Median (95% CI), (Months) [a] | NE (10.12, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5590 | |
| HR (95% CI) [c] | 2.060 (0.174, 24.340) | |
| HR P-Value [c] | 0.5661 | |
| Heterogeneity p-value [d] | 0.6284 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.2 (70.7, 99.3) | 96.3 (76.5, 99.5) |
| 12 months | 84.7 (47.4, 96.4) | 96.3 (76.5, 99.5) |
| 18 months | 84.7 (47.4, 96.4) | 96.3 (76.5, 99.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 4 (8.7%) |
| Censored Patients, n (%) | 31 (88.6%) | 42 (91.3%) |
| | | |
| Median (95% CI), (Months) [a] | NE (10.12, NE) | NE (4.63, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9061 | |
| HR (95% CI) [c] | 0.918 (0.224, 3.772) | |
| HR P-Value [c] | 0.9060 | |
| Heterogeneity p-value [d] | 0.5084 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.8 (55.0, 94.2) | 76.6 (47.8, 90.8) |
| 12 months | 72.5 (39.6, 89.4) | 76.6 (47.8, 90.8) |
| 18 months | 72.5 (39.6, 89.4) | 76.6 (47.8, 90.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 5 (10.9%) |
| Censored Patients, n (%) | 33 (94.3%) | 41 (89.1%) |
| Median (95% CI), (Months) [a] | 20.80 (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1187 | |
| HR (95% CI) [c] | 0.210 (0.024, 1.817) | |
| HR P-Value [c] | 0.1563 | |
| Heterogeneity p-value [d] | 0.5925 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 79.9 (57.7, 91.2) |
| 12 months | 90.9 (50.8, 98.7) | 79.9 (57.7, 91.2) |
| 18 months | 90.9 (50.8, 98.7) | 79.9 (57.7, 91.2) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 9 (25.7%) | 7 (15.2%) |
| Censored Patients, n (%) | 26 (74.3%) | 39 (84.8%) |
| Median (95% CI), (Months) [a] | 12.45 (4.30, NE) | NE (8.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5958 | |
| HR (95% CI) [c] | 1.306 (0.480, 3.555) | |
| HR P-Value [c] | 0.6013 | |
| Heterogeneity p-value [d] | 0.0417 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.1 (43.2, 85.0) | 77.6 (56.8, 89.3) |
| 12 months | 60.4 (32.8, 79.7) | 62.1 (26.9, 84.1) |
| 18 months | NE (NE, NE) | 62.1 (26.9, 84.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 0 |
| Censored Patients, n (%) | 32 (91.4%) | 46 (100.0%) |
| Median (95% CI), (Months) [a] | 20.80 (9.66, 20.80) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2766 | |
| HR (95% CI) [c] | 53641093 (0.000, NE) | |
| HR P-Value [c] | 0.9979 | |
| Heterogeneity p-value [d] | 0.9906 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.8 (63.2, 99.1) | 100.0 (100.0, 100.0) |
| 12 months | 83.3 (46.2, 95.8) | 100.0 (100.0, 100.0) |
| 18 months | 83.3 (46.2, 95.8) | 100.0 (100.0, 100.0) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 6 (13.0%) |
| Censored Patients, n (%) | 33 (94.3%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | NE (8.77, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1733 | |
| HR (95% CI) [c] | 0.341 (0.067, 1.729) | |
| HR P-Value [c] | 0.1941 | |
| Heterogeneity p-value [d] | 0.7995 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.0 (69.5, 99.3) | 78.3 (57.9, 89.7) |
| 12 months | 84.4 (47.2, 96.3) | 78.3 (57.9, 89.7) |
| 18 months | 84.4 (47.2, 96.3) | 78.3 (57.9, 89.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 7 (20.0%) | 7 (15.2%) |
| Censored Patients, n (%) | 28 (80.0%) | 39 (84.8%) |
| Median (95% CI), (Months) [a] | 12.45 (10.12, NE) | NE (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8811 | |
| HR (95% CI) [c] | 0.920 (0.317, 2.669) | |
| HR P-Value [c] | 0.8776 | |
| Heterogeneity p-value [d] | 0.3532 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.8 (51.1, 89.2) | 72.3 (47.8, 86.7) |
| 12 months | 66.3 (37.4, 84.2) | 54.2 (18.3, 80.2) |
| 18 months | NE (NE, NE) | 54.2 (18.3, 80.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 6 (17.1%) | 9 (19.6%) |
| Censored Patients, n (%) | 29 (82.9%) | 37 (80.4%) |
| | | |
| Median (95% CI), (Months) [a] | 20.80 (14.55, 20.80) | 9.92 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2535 | |
| HR (95% CI) [c] | 0.530 (0.175, 1.607) | |
| HR P-Value [c] | 0.2618 | |
| Heterogeneity p-value [d] | 0.6652 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.6 (51.9, 91.5) | 65.5 (41.3, 81.7) |
| 12 months | 78.6 (51.9, 91.5) | 43.7 (9.7, 74.6) |
| 18 months | 52.4 (9.5, 83.7) | 43.7 (9.7, 74.6) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 8 (22.9%) | 6 (13.0%) |
| Censored Patients, n (%) | 27 (77.1%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | 10.12 (7.26, NE) | NE (8.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6760 | |
| HR (95% CI) [c] | 1.259 (0.427, 3.709) | |
| HR P-Value [c] | 0.6762 | |
| Heterogeneity p-value [d] | 0.1184 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.5 (67.0, 97.5) | 82.1 (62.2, 92.1) |
| 12 months | 40.7 (13.0, 67.3) | 61.6 (19.3, 86.7) |
| 18 months | NE (NE, NE) | 61.6 (19.3, 86.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 10 (21.7%) |
| Censored Patients, n (%) | 31 (88.6%) | 36 (78.3%) |
| Median (95% CI), (Months) [a] | NE (10.12, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0809 | |
| HR (95% CI) [c] | 0.366 (0.114, 1.177) | |
| HR P-Value [c] | 0.0917 | |
| Heterogeneity p-value [d] | 0.4596 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.2 (65.9, 97.5) | 57.1 (34.1, 74.7) |
| 12 months | 80.1 (46.9, 93.7) | 57.1 (34.1, 74.7) |
| 18 months | 53.4 (8.9, 85.0) | 57.1 (34.1, 74.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 10 (21.7%) |
| Censored Patients, n (%) | 31 (88.6%) | 36 (78.3%) |
| Median (95% CI), (Months) [a] | 20.80 (NE, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0689 | |
| HR (95% CI) [c] | 0.320 (0.088, 1.168) | |
| HR P-Value [c] | 0.0845 | |
| Heterogeneity p-value [d] | 0.2719 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.0 (55.3, 94.3) | 65.1 (43.4, 80.2) |
| 12 months | 83.0 (55.3, 94.3) | 52.1 (23.4, 74.7) |
| 18 months | 83.0 (55.3, 94.3) | 52.1 (23.4, 74.7) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 7 (20.0%) | 6 (13.0%) |
| Censored Patients, n (%) | 28 (80.0%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | 16.66 (4.17, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5970 | |
| HR (95% CI) [c] | 1.344 (0.448, 4.034) | |
| HR P-Value [c] | 0.5978 | |
| Heterogeneity p-value [d] | 0.2172 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.3 (43.6, 87.1) | 78.2 (57.7, 89.6) |
| 12 months | 62.4 (33.1, 81.7) | 78.2 (57.7, 89.6) |
| 18 months | NE (NE, NE) | 78.2 (57.7, 89.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 11 (12.4%) | 14 (16.5%) |
| Censored Patients, n (%) | 78 (87.6%) | 71 (83.5%) |
| Median (95% CI), (Months) [a] | NE (10.18, NE) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0147 | |
| HR (95% CI) [c] | 0.373 (0.164, 0.849) | |
| HR P-Value [c] | 0.0188 | |
| Heterogeneity p-value [d] | 0.4845 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.2 (68.9, 92.4) | 66.2 (48.9, 78.8) |
| 12 months | 66.3 (45.0, 81.0) | 66.2 (48.9, 78.8) |
| 18 months | 66.3 (45.0, 81.0) | NE (NE, NE) |
| 24 months | 66.3 (45.0, 81.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 7 (7.9%) | 9 (10.6%) |
| Censored Patients, n (%) | 82 (92.1%) | 76 (89.4%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0761 | |
| HR (95% CI) [c] | 0.395 (0.136, 1.141) | |
| HR P-Value [c] | 0.0861 | |
| Heterogeneity p-value [d] | 0.7931 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (81.2, 96.5) | 74.3 (53.0, 87.1) |
| 12 months | 91.7 (81.2, 96.5) | 74.3 (53.0, 87.1) |
| 18 months | 61.9 (18.3, 87.3) | NE (NE, NE) |
| 24 months | 61.9 (18.3, 87.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 6 (6.7%) | 8 (9.4%) |
| Censored Patients, n (%) | 83 (93.3%) | 77 (90.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0872 | |
| HR (95% CI) [c] | 0.399 (0.134, 1.183) | |
| HR P-Value [c] | 0.0976 | |
| Heterogeneity p-value [d] | 0.5136 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.7 (76.6, 95.7) | 79.4 (60.7, 89.9) |
| 12 months | 86.1 (70.6, 93.8) | 52.9 (10.0, 83.9) |
| 18 months | 86.1 (70.6, 93.8) | NE (NE, NE) |
| 24 months | 86.1 (70.6, 93.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 6 (6.7%) | 2 (2.4%) |
| Censored Patients, n (%) | 83 (93.3%) | 83 (97.6%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9604 | |
| HR (95% CI) [c] | 1.044 (0.190, 5.719) | |
| HR P-Value [c] | 0.9607 | |
| Heterogeneity p-value [d] | 0.8247 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.4 (80.2, 97.9) | 94.0 (77.9, 98.5) |
| 12 months | 81.4 (56.7, 92.8) | 94.0 (77.9, 98.5) |
| 18 months | 81.4 (56.7, 92.8) | NE (NE, NE) |
| 24 months | 65.1 (26.4, 87.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 12 (13.5%) | 7 (8.2%) |
| Censored Patients, n (%) | 77 (86.5%) | 78 (91.8%) |
| | | |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7686 | |
| HR (95% CI) [c] | 0.865 (0.326, 2.294) | |
| HR P-Value [c] | 0.7705 | |
| Heterogeneity p-value [d] | 0.2349 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.7 (70.6, 91.3) | 78.0 (55.8, 89.9) |
| 12 months | 75.8 (58.2, 86.7) | 78.0 (55.8, 89.9) |
| 18 months | 60.6 (27.4, 82.4) | NE (NE, NE) |
| 24 months | 60.6 (27.4, 82.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 7 (7.9%) | 7 (8.2%) |
| Censored Patients, n (%) | 82 (92.1%) | 78 (91.8%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1950 | |
| HR (95% CI) [c] | 0.486 (0.160, 1.476) | |
| HR P-Value [c] | 0.2028 | |
| Heterogeneity p-value [d] | 0.6313 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.9 (84.9, 98.3) | 84.1 (69.1, 92.2) |
| 12 months | 84.6 (67.5, 93.2) | 84.1 (69.1, 92.2) |
| 18 months | 67.7 (28.0, 88.7) | NE (NE, NE) |
| 24 months | 67.7 (28.0, 88.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 17 (19.1%) | 21 (24.7%) |
| Censored Patients, n (%) | 72 (80.9%) | 64 (75.3%) |
| Median (95% CI), (Months) [a] | NE (11.24, NE) | 4.40 (2.89, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0076 | |
| HR (95% CI) [c] | 0.416 (0.213, 0.810) | |
| HR P-Value [c] | 0.0099 | |
| Heterogeneity p-value [d] | 0.1600 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.0 (59.4, 84.1) | 47.2 (30.1, 62.6) |
| 12 months | 64.7 (46.1, 78.3) | 47.2 (30.1, 62.6) |
| 18 months | 55.5 (31.7, 73.9) | NE (NE, NE) |
| 24 months | 55.5 (31.7, 73.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 7 (7.9%) | 3 (3.5%) |
| Censored Patients, n (%) | 82 (92.1%) | 82 (96.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9212 | |
| HR (95% CI) [c] | 1.073 (0.265, 4.350) | |
| HR P-Value [c] | 0.9212 | |
| Heterogeneity p-value [d] | 0.6421 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.8 (78.7, 97.0) | 90.5 (72.7, 96.9) |
| 12 months | 79.1 (58.7, 90.2) | 90.5 (72.7, 96.9) |
| 18 months | 79.1 (58.7, 90.2) | NE (NE, NE) |
| 24 months | 79.1 (58.7, 90.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 8 (9.0%) | 10 (11.8%) |
| Censored Patients, n (%) | 81 (91.0%) | 75 (88.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0897 | |
| HR (95% CI) [c] | 0.448 (0.173, 1.158) | |
| HR P-Value [c] | 0.0975 | |
| Heterogeneity p-value [d] | 0.6033 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.8 (76.2, 94.9) | 73.8 (52.1, 86.8) |
| 12 months | 81.6 (64.9, 90.9) | 73.8 (52.1, 86.8) |
| 18 months | 81.6 (64.9, 90.9) | NE (NE, NE) |
| 24 months | 81.6 (64.9, 90.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:01:53, yingyuan.lin)

Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 16 (18.0%) | 17 (20.0%) |
| Censored Patients, n (%) | 73 (82.0%) | 68 (80.0%) |
| Median (95% CI), (Months) [a] | 19.15 (10.12, NE) | 8.97 (3.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0340 | |
| HR (95% CI) [c] | 0.464 (0.224, 0.959) | |
| HR P-Value [c] | 0.0382 | |
| Heterogeneity p-value [d] | 0.5800 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.4 (58.6, 84.8) | 57.2 (38.3, 72.1) |
| 12 months | 59.5 (39.1, 75.0) | 38.1 (9.6, 67.2) |
| 18 months | 59.5 (39.1, 75.0) | NE (NE, NE) |
| 24 months | 39.7 (9.7, 69.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:01:53, yingyuan.lin)

Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 11 (12.4%) | 11 (12.9%) |
| Censored Patients, n (%) | 78 (87.6%) | 74 (87.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (5.82, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0843 | |
| HR (95% CI) [c] | 0.472 (0.197, 1.129) | |
| HR P-Value [c] | 0.0915 | |
| Heterogeneity p-value [d] | 0.9760 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.0 (67.4, 90.5) | 67.1 (44.6, 82.1) |
| 12 months | 72.9 (53.8, 85.1) | 67.1 (44.6, 82.1) |
| 18 months | 72.9 (53.8, 85.1) | NE (NE, NE) |
| 24 months | 72.9 (53.8, 85.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 13 (14.6%) | 13 (15.3%) |
| Censored Patients, n (%) | 76 (85.4%) | 72 (84.7%) |
| Median (95% CI), (Months) [a] | NE (10.12, NE) | NE (5.82, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0348 | |
| HR (95% CI) [c] | 0.422 (0.185, 0.963) | |
| HR P-Value [c] | 0.0405 | |
| Heterogeneity p-value [d] | 0.2754 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.7 (71.2, 92.2) | 62.1 (39.8, 78.1) |
| 12 months | 68.6 (48.9, 82.0) | 62.1 (39.8, 78.1) |
| 18 months | 54.9 (25.1, 77.1) | NE (NE, NE) |
| 24 months | 54.9 (25.1, 77.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 13 (14.6%) | 14 (16.5%) |
| Censored Patients, n (%) | 76 (85.4%) | 71 (83.5%) |
| Median (95% CI), (Months) [a] | NE (11.24, NE) | NE (4.27, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1261 | |
| HR (95% CI) [c] | 0.552 (0.255, 1.196) | |
| HR P-Value [c] | 0.1318 | |
| Heterogeneity p-value [d] | 0.8785 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.3 (66.8, 88.8) | 64.9 (47.4, 77.9) |
| 12 months | 69.8 (49.8, 83.0) | 64.9 (47.4, 77.9) |
| 18 months | 69.8 (49.8, 83.0) | NE (NE, NE) |
| 24 months | 69.8 (49.8, 83.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 14 (15.7%) | 6 (7.1%) |
| Censored Patients, n (%) | 75 (84.3%) | 79 (92.9%) |
| Median (95% CI), (Months) [a] | NE (11.24, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7429 | |
| HR (95% CI) [c] | 1.179 (0.438, 3.176) | |
| HR P-Value [c] | 0.7440 | |
| Heterogeneity p-value [d] | 0.1120 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.0 (71.3, 91.4) | 84.2 (67.7, 92.7) |
| 12 months | 67.2 (47.0, 81.2) | 84.2 (67.7, 92.7) |
| 18 months | 57.6 (32.3, 76.4) | NE (NE, NE) |
| 24 months | 57.6 (32.3, 76.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 13 (14.6%) | 9 (10.6%) |
| Censored Patients, n (%) | 76 (85.4%) | 76 (89.4%) |
| Median (95% CI), (Months) [a] | NE (16.76, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6681 | |
| HR (95% CI) [c] | 0.825 (0.345, 1.972) | |
| HR P-Value [c] | 0.6650 | |
| Heterogeneity p-value [d] | 0.9730 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.6 (62.9, 87.0) | 78.6 (62.4, 88.4) |
| 12 months | 74.6 (59.1, 84.9) | 78.6 (62.4, 88.4) |
| 18 months | 64.0 (37.8, 81.4) | NE (NE, NE) |
| 24 months | 64.0 (37.8, 81.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 14 (13.1%) | 17 (17.3%) |
| Censored Patients, n (%) | 93 (86.9%) | 81 (82.7%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1512 | |
| HR (95% CI) [c] | 0.587 (0.282, 1.223) | |
| HR P-Value [c] | 0.1550 | |
| Heterogeneity p-value [d] | 0.4845 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.7 (71.2, 90.0) | 76.7 (63.7, 85.6) |
| 12 months | 79.2 (65.3, 88.0) | 61.4 (37.5, 78.4) |
| 18 months | 79.2 (65.3, 88.0) | 61.4 (37.5, 78.4) |
| 24 months | 66.0 (35.1, 84.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 10 (9.3%) | 18 (18.4%) |
| Censored Patients, n (%) | 97 (90.7%) | 80 (81.6%) |
| Median (95% CI), (Months) [a] | NE (17.05, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0055 | |
| HR (95% CI) [c] | 0.323 (0.140, 0.742) | |
| HR P-Value [c] | 0.0078 | |
| Heterogeneity p-value [d] | 0.7931 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.9 (80.3, 95.9) | 71.2 (56.8, 81.5) |
| 12 months | 90.9 (80.3, 95.9) | 66.7 (50.3, 78.8) |
| 18 months | 69.9 (46.0, 84.8) | 66.7 (50.3, 78.8) |
| 24 months | 69.9 (46.0, 84.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 9 (8.4%) | 11 (11.2%) |
| Censored Patients, n (%) | 98 (91.6%) | 87 (88.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3412 | |
| HR (95% CI) [c] | 0.651 (0.268, 1.585) | |
| HR P-Value [c] | 0.3445 | |
| Heterogeneity p-value [d] | 0.5136 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.1 (76.1, 94.3) | 84.9 (73.6, 91.7) |
| 12 months | 81.1 (65.0, 90.3) | 80.9 (66.3, 89.7) |
| 18 months | 81.1 (65.0, 90.3) | 80.9 (66.3, 89.7) |
| 24 months | 81.1 (65.0, 90.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 5 (4.7%) | 3 (3.1%) |
| Censored Patients, n (%) | 102 (95.3%) | 95 (96.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8461 | |
| HR (95% CI) [c] | 1.160 (0.258, 5.209) | |
| HR P-Value [c] | 0.8464 | |
| Heterogeneity p-value [d] | 0.8247 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.8 (87.0, 98.7) | 95.7 (87.2, 98.6) |
| 12 months | 92.6 (79.6, 97.4) | 95.7 (87.2, 98.6) |
| 18 months | 86.4 (64.8, 95.2) | 95.7 (87.2, 98.6) |
| 24 months | 86.4 (64.8, 95.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 6 (5.6%) | 11 (11.2%) |
| Censored Patients, n (%) | 101 (94.4%) | 87 (88.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0732 | |
| HR (95% CI) [c] | 0.403 (0.145, 1.125) | |
| HR P-Value [c] | 0.0826 | |
| Heterogeneity p-value [d] | 0.2349 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.0 (81.1, 96.7) | 84.6 (72.6, 91.6) |
| 12 months | 92.0 (81.1, 96.7) | 76.9 (55.0, 89.1) |
| 18 months | 86.2 (66.9, 94.7) | 76.9 (55.0, 89.1) |
| 24 months | 86.2 (66.9, 94.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 13 (12.1%) | 13 (13.3%) |
| Censored Patients, n (%) | 94 (87.9%) | 85 (86.7%) |
| Median (95% CI), (Months) [a] | 20.80 (20.17, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1855 | |
| HR (95% CI) [c] | 0.569 (0.244, 1.324) | |
| HR P-Value [c] | 0.1906 | |
| Heterogeneity p-value [d] | 0.6313 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.8 (79.6, 95.0) | 82.0 (69.0, 89.9) |
| 12 months | 86.6 (73.8, 93.4) | 72.5 (53.7, 84.6) |
| 18 months | 73.6 (53.8, 86.0) | 72.5 (53.7, 84.6) |
| 24 months | 46.0 (14.6, 73.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 27 (25.2%) | 28 (28.6%) |
| Censored Patients, n (%) | 80 (74.8%) | 70 (71.4%) |
| Median (95% CI), (Months) [a] | 16.53 (11.10, NE) | 10.28 (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1400 | |
| HR (95% CI) [c] | 0.662 (0.381, 1.150) | |
| HR P-Value [c] | 0.1433 | |
| Heterogeneity p-value [d] | 0.1600 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.5 (60.9, 82.7) | 62.7 (49.2, 73.6) |
| 12 months | 59.9 (44.4, 72.4) | 43.0 (20.7, 63.6) |
| 18 months | 46.0 (27.9, 62.3) | 43.0 (20.7, 63.6) |
| 24 months | 34.5 (13.2, 57.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 12 (11.2%) | 5 (5.1%) |
| Censored Patients, n (%) | 95 (88.8%) | 93 (94.9%) |
| Median (95% CI), (Months) [a] | NE (14.00, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6548 | |
| HR (95% CI) [c] | 1.281 (0.431, 3.804) | |
| HR P-Value [c] | 0.6556 | |
| Heterogeneity p-value [d] | 0.6421 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.3 (78.0, 95.9) | 92.1 (81.8, 96.7) |
| 12 months | 80.8 (64.3, 90.2) | 92.1 (81.8, 96.7) |
| 18 months | 67.3 (46.6, 81.5) | 92.1 (81.8, 96.7) |
| 24 months | 53.9 (24.4, 76.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 4 (3.7%) | 10 (10.2%) |
| Censored Patients, n (%) | 103 (96.3%) | 88 (89.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0059 | |
| HR (95% CI) [c] | 0.193 (0.054, 0.682) | |
| HR P-Value [c] | 0.0107 | |
| Heterogeneity p-value [d] | 0.6033 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 98.8 (91.7, 99.8) | 89.1 (79.3, 94.4) |
| 12 months | 91.8 (74.8, 97.5) | 72.4 (40.7, 89.0) |
| 18 months | 86.1 (63.9, 95.1) | 72.4 (40.7, 89.0) |
| 24 months | 86.1 (63.9, 95.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 16 (15.0%) | 16 (16.3%) |
| Censored Patients, n (%) | 91 (85.0%) | 82 (83.7%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2733 | |
| HR (95% CI) [c] | 0.671 (0.326, 1.380) | |
| HR P-Value [c] | 0.2783 | |
| Heterogeneity p-value [d] | 0.5800 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.5 (73.5, 91.2) | 72.8 (57.8, 83.2) |
| 12 months | 74.9 (59.3, 85.2) | 62.4 (37.2, 79.8) |
| 18 months | 71.1 (54.3, 82.7) | 62.4 (37.2, 79.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 14 (13.1%) | 20 (20.4%) |
| Censored Patients, n (%) | 93 (86.9%) | 78 (79.6%) |
| Median (95% CI), (Months) [a] | 20.80 (20.17, NE) | 12.71 (9.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0101 | |
| HR (95% CI) [c] | 0.385 (0.181, 0.818) | |
| HR P-Value [c] | 0.0131 | |
| Heterogeneity p-value [d] | 0.9760 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.6 (78.1, 94.3) | 75.9 (63.6, 84.5) |
| 12 months | 82.9 (69.1, 90.9) | 63.7 (42.4, 78.9) |
| 18 months | 72.5 (52.4, 85.3) | 47.8 (17.4, 73.2) |
| 24 months | 45.3 (14.5, 72.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 21 (19.6%) | 19 (19.4%) |
| Censored Patients, n (%) | 86 (80.4%) | 79 (80.6%) |
| Median (95% CI), (Months) [a] | NE (10.09, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5100 | |
| HR (95% CI) [c] | 0.809 (0.430, 1.521) | |
| HR P-Value [c] | 0.5098 | |
| Heterogeneity p-value [d] | 0.2754 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.6 (76.3, 92.7) | 75.5 (63.0, 84.3) |
| 12 months | 60.0 (43.5, 73.1) | 67.1 (50.3, 79.3) |
| 18 months | 55.4 (37.8, 69.9) | 67.1 (50.3, 79.3) |
| 24 months | 55.4 (37.8, 69.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 16 (15.0%) | 23 (23.5%) |
| Censored Patients, n (%) | 91 (85.0%) | 75 (76.5%) |
| Median (95% CI), (Months) [a] | NE (14.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0356 | |
| HR (95% CI) [c] | 0.500 (0.258, 0.969) | |
| HR P-Value [c] | 0.0400 | |
| Heterogeneity p-value [d] | 0.8785 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.0 (70.2, 89.5) | 65.6 (52.3, 76.0) |
| 12 months | 82.0 (70.2, 89.5) | 65.6 (52.3, 76.0) |
| 18 months | 64.3 (44.5, 78.7) | 65.6 (52.3, 76.0) |
| 24 months | 64.3 (44.5, 78.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 17 (15.9%) | 24 (24.5%) |
| Censored Patients, n (%) | 90 (84.1%) | 74 (75.5%) |
| Median (95% CI), (Months) [a] | 20.80 (15.34, NE) | NE (8.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0143 | |
| HR (95% CI) [c] | 0.438 (0.222, 0.865) | |
| HR P-Value [c] | 0.0173 | |
| Heterogeneity p-value [d] | 0.1120 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.9 (75.2, 92.3) | 65.8 (52.3, 76.3) |
| 12 months | 80.1 (66.2, 88.7) | 61.4 (46.0, 73.6) |
| 18 months | 69.7 (49.9, 82.9) | 61.4 (46.0, 73.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 13 (12.1%) | 13 (13.3%) |
| Censored Patients, n (%) | 94 (87.9%) | 85 (86.7%) |
| Median (95% CI), (Months) [a] | 20.17 (16.62, NE) | NE (11.33, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1654 | |
| HR (95% CI) [c] | 0.561 (0.245, 1.282) | |
| HR P-Value [c] | 0.1706 | |
| Heterogeneity p-value [d] | 0.9730 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.9 (81.6, 96.6) | 86.5 (76.4, 92.5) |
| 12 months | 74.1 (55.3, 85.9) | 61.9 (27.6, 83.6) |
| 18 months | 61.7 (38.8, 78.2) | 61.9 (27.6, 83.6) |
| 24 months | 46.3 (16.6, 71.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 12 (14.5%) | 13 (18.8%) |
| Censored Patients, n (%) | 71 (85.5%) | 56 (81.2%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | 9.69 (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0383 | |
| HR (95% CI) [c] | 0.424 (0.184, 0.976) | |
| HR P-Value [c] | 0.0437 | |
| Heterogeneity p-value [d] | 0.8265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.2 (72.2, 92.4) | 76.3 (60.9, 86.3) |
| 12 months | 75.0 (57.9, 86.0) | 45.8 (13.5, 73.7) |
| 18 months | 75.0 (57.9, 86.0) | NE (NE, NE) |
| 24 months | 64.3 (37.3, 82.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 7 (8.4%) | 13 (18.8%) |
| Censored Patients, n (%) | 76 (91.6%) | 56 (81.2%) |
| Median (95% CI), (Months) [a] | NE (16.53, NE) | NE (5.82, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0040 | |
| HR (95% CI) [c] | 0.252 (0.092, 0.688) | |
| HR P-Value [c] | 0.0072 | |
| Heterogeneity p-value [d] | 0.3700 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.0 (84.7, 97.7) | 66.5 (47.3, 80.1) |
| 12 months | 94.0 (84.7, 97.7) | 66.5 (47.3, 80.1) |
| 18 months | 73.5 (44.3, 89.0) | NE (NE, NE) |
| 24 months | 73.5 (44.3, 89.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 9 (10.8%) | 10 (14.5%) |
| Censored Patients, n (%) | 74 (89.2%) | 59 (85.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0842 | |
| HR (95% CI) [c] | 0.454 (0.181, 1.137) | |
| HR P-Value [c] | 0.0918 | |
| Heterogeneity p-value [d] | 0.9643 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.4 (73.8, 94.2) | 82.2 (67.3, 90.8) |
| 12 months | 76.2 (57.8, 87.4) | 62.8 (31.8, 82.8) |
| 18 months | 76.2 (57.8, 87.4) | NE (NE, NE) |
| 24 months | 76.2 (57.8, 87.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 6 (7.2%) | 2 (2.9%) |
| Censored Patients, n (%) | 77 (92.8%) | 67 (97.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8654 | |
| HR (95% CI) [c] | 1.157 (0.215, 6.235) | |
| HR P-Value [c] | 0.8655 | |
| Heterogeneity p-value [d] | 0.8516 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 96.2 (85.0, 99.1) | 95.4 (82.8, 98.8) |
| 12 months | 84.9 (66.1, 93.8) | 95.4 (82.8, 98.8) |
| 18 months | 78.4 (55.1, 90.6) | NE (NE, NE) |
| 24 months | 78.4 (55.1, 90.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 11 (13.3%) | 11 (15.9%) |
| Censored Patients, n (%) | 72 (86.7%) | 58 (84.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1861 | |
| HR (95% CI) [c] | 0.566 (0.240, 1.332) | |
| HR P-Value [c] | 0.1922 | |
| Heterogeneity p-value [d] | 0.6326 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.1 (71.3, 91.5) | 76.3 (59.6, 86.8) |
| 12 months | 77.6 (61.9, 87.5) | 61.0 (27.7, 82.7) |
| 18 months | 77.6 (61.9, 87.5) | NE (NE, NE) |
| 24 months | 77.6 (61.9, 87.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 7 (8.4%) | 7 (10.1%) |
| Censored Patients, n (%) | 76 (91.6%) | 62 (89.9%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0413 | |
| HR (95% CI) [c] | 0.305 (0.092, 1.008) | |
| HR P-Value [c] | 0.0516 | |
| Heterogeneity p-value [d] | 0.4139 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 98.5 (89.6, 99.8) | 89.3 (75.9, 95.4) |
| 12 months | 88.2 (70.3, 95.6) | 71.0 (40.0, 88.0) |
| 18 months | 83.8 (63.9, 93.2) | NE (NE, NE) |
| 24 months | 62.8 (30.8, 83.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 22 (26.5%) | 15 (21.7%) |
| Censored Patients, n (%) | 61 (73.5%) | 54 (78.3%) |
| Median (95% CI), (Months) [a] | 20.17 (11.24, NE) | NE (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3778 | |
| HR (95% CI) [c] | 0.732 (0.366, 1.464) | |
| HR P-Value [c] | 0.3782 | |
| Heterogeneity p-value [d] | 0.2045 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.5 (63.2, 85.6) | 65.5 (48.0, 78.4) |
| 12 months | 64.8 (48.7, 76.9) | 65.5 (48.0, 78.4) |
| 18 months | 51.0 (32.1, 67.1) | NE (NE, NE) |
| 24 months | 40.8 (18.6, 62.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 11 (13.3%) | 3 (4.3%) |
| Censored Patients, n (%) | 72 (86.7%) | 66 (95.7%) |
| Median (95% CI), (Months) [a] | NE (14.00, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5731 | |
| HR (95% CI) [c] | 1.455 (0.391, 5.421) | |
| HR P-Value [c] | 0.5760 | |
| Heterogeneity p-value [d] | 0.5260 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.6 (78.7, 96.8) | 93.3 (80.7, 97.8) |
| 12 months | 77.6 (59.0, 88.5) | 93.3 (80.7, 97.8) |
| 18 months | 66.9 (44.8, 81.7) | NE (NE, NE) |
| 24 months | 57.3 (31.2, 76.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 10 (12.0%) | 10 (14.5%) |
| Censored Patients, n (%) | 73 (88.0%) | 59 (85.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0722 | |
| HR (95% CI) [c] | 0.438 (0.174, 1.100) | |
| HR P-Value [c] | 0.0788 | |
| Heterogeneity p-value [d] | 0.1700 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.9 (81.2, 96.6) | 78.1 (59.4, 88.9) |
| 12 months | 78.8 (61.5, 89.0) | 62.4 (27.5, 84.2) |
| 18 months | 73.2 (52.8, 85.8) | NE (NE, NE) |
| 24 months | 73.2 (52.8, 85.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 19 (22.9%) | 12 (17.4%) |
| Censored Patients, n (%) | 64 (77.1%) | 57 (82.6%) |
| Median (95% CI), (Months) [a] | 20.17 (10.18, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5890 | |
| HR (95% CI) [c] | 0.814 (0.385, 1.722) | |
| HR P-Value [c] | 0.5904 | |
| Heterogeneity p-value [d] | 0.1590 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.4 (66.3, 87.8) | 75.8 (58.2, 86.8) |
| 12 months | 61.6 (43.5, 75.4) | 50.5 (19.5, 75.2) |
| 18 months | 57.5 (39.0, 72.2) | NE (NE, NE) |
| 24 months | 46.0 (21.6, 67.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 13 (15.7%) | 11 (15.9%) |
| Censored Patients, n (%) | 70 (84.3%) | 58 (84.1%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | 12.71 (12.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0996 | |
| HR (95% CI) [c] | 0.492 (0.208, 1.163) | |
| HR P-Value [c] | 0.1060 | |
| Heterogeneity p-value [d] | 0.6339 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.3 (72.3, 92.5) | 74.6 (55.0, 86.6) |
| 12 months | 74.6 (57.2, 85.8) | 74.6 (55.0, 86.6) |
| 18 months | 74.6 (57.2, 85.8) | NE (NE, NE) |
| 24 months | 53.3 (24.6, 75.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 13 (15.7%) | 11 (15.9%) |
| Censored Patients, n (%) | 70 (84.3%) | 58 (84.1%) |
| Median (95% CI), (Months) [a] | NE (13.90, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1685 | |
| HR (95% CI) [c] | 0.562 (0.245, 1.287) | |
| HR P-Value [c] | 0.1728 | |
| Heterogeneity p-value [d] | 0.6667 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.3 (77.3, 95.1) | 73.7 (55.2, 85.4) |
| 12 months | 69.6 (51.3, 82.1) | 73.7 (55.2, 85.4) |
| 18 months | 65.0 (45.5, 78.9) | NE (NE, NE) |
| 24 months | 65.0 (45.5, 78.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 15 (18.1%) | 15 (21.7%) |
| Censored Patients, n (%) | 68 (81.9%) | 54 (78.3%) |
| Median (95% CI), (Months) [a] | NE (14.26, NE) | NE (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1259 | |
| HR (95% CI) [c] | 0.570 (0.275, 1.180) | |
| HR P-Value [c] | 0.1301 | |
| Heterogeneity p-value [d] | 0.7540 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.7 (66.6, 88.0) | 66.2 (49.9, 78.3) |
| 12 months | 72.7 (56.9, 83.6) | 66.2 (49.9, 78.3) |
| 18 months | 67.1 (48.2, 80.4) | NE (NE, NE) |
| 24 months | 67.1 (48.2, 80.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 17 (20.5%) | 9 (13.0%) |
| Censored Patients, n (%) | 66 (79.5%) | 60 (87.0%) |
| Median (95% CI), (Months) [a] | 20.80 (13.93, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7638 | |
| HR (95% CI) [c] | 0.878 (0.372, 2.069) | |
| HR P-Value [c] | 0.7654 | |
| Heterogeneity p-value [d] | 0.2172 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.6 (74.7, 93.1) | 77.4 (59.3, 88.2) |
| 12 months | 70.6 (53.3, 82.5) | 77.4 (59.3, 88.2) |
| 18 months | 65.9 (47.1, 79.4) | NE (NE, NE) |
| 24 months | 37.7 (13.9, 61.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 16 (19.3%) | 7 (10.1%) |
| Censored Patients, n (%) | 67 (80.7%) | 62 (89.9%) |
| Median (95% CI), (Months) [a] | 20.17 (16.66, NE) | NE (11.33, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8007 | |
| HR (95% CI) [c] | 1.132 (0.445, 2.877) | |
| HR P-Value [c] | 0.7949 | |
| Heterogeneity p-value [d] | 0.1366 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.1 (66.7, 88.5) | 90.2 (77.9, 95.8) |
| 12 months | 73.9 (58.4, 84.4) | 64.1 (25.1, 86.7) |
| 18 months | 60.5 (38.0, 77.0) | NE (NE, NE) |
| 24 months | 48.4 (21.3, 71.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 13 (11.5%) | 18 (15.8%) |
| Censored Patients, n (%) | 100 (88.5%) | 96 (84.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1162 | |
| HR (95% CI) [c] | 0.564 (0.275, 1.158) | |
| HR P-Value [c] | 0.1186 | |
| Heterogeneity p-value [d] | 0.8265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.7 (68.8, 89.7) | 69.9 (55.6, 80.4) |
| 12 months | 73.8 (56.7, 85.0) | 69.9 (55.6, 80.4) |
| 18 months | 73.8 (56.7, 85.0) | 69.9 (55.6, 80.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 10 (8.8%) | 14 (12.3%) |
| Censored Patients, n (%) | 103 (91.2%) | 100 (87.7%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0693 | |
| HR (95% CI) [c] | 0.461 (0.196, 1.083) | |
| HR P-Value [c] | 0.0756 | |
| Heterogeneity p-value [d] | 0.3700 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.6 (76.8, 94.6) | 76.9 (62.4, 86.4) |
| 12 months | 88.6 (76.8, 94.6) | 71.8 (54.1, 83.7) |
| 18 months | 61.7 (30.4, 82.2) | 71.8 (54.1, 83.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 6 (5.3%) | 9 (7.9%) |
| Censored Patients, n (%) | 107 (94.7%) | 105 (92.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3426 | |
| HR (95% CI) [c] | 0.610 (0.217, 1.716) | |
| HR P-Value [c] | 0.3491 | |
| Heterogeneity p-value [d] | 0.9643 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.1 (80.9, 96.0) | 83.6 (70.4, 91.3) |
| 12 months | 91.1 (80.9, 96.0) | 83.6 (70.4, 91.3) |
| 18 months | 91.1 (80.9, 96.0) | 83.6 (70.4, 91.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 5 (4.4%) | 3 (2.6%) |
| Censored Patients, n (%) | 108 (95.6%) | 111 (97.4%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6774 | |
| HR (95% CI) [c] | 1.360 (0.318, 5.818) | |
| HR P-Value [c] | 0.6785 | |
| Heterogeneity p-value [d] | 0.8516 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.4 (82.9, 97.5) | 95.2 (85.4, 98.5) |
| 12 months | 93.4 (82.9, 97.5) | 95.2 (85.4, 98.5) |
| 18 months | 93.4 (82.9, 97.5) | 95.2 (85.4, 98.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 7 (6.2%) | 7 (6.1%) |
| Censored Patients, n (%) | 106 (93.8%) | 107 (93.9%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5246 | |
| HR (95% CI) [c] | 0.701 (0.233, 2.108) | |
| HR P-Value [c] | 0.5274 | |
| Heterogeneity p-value [d] | 0.6326 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.5 (82.3, 96.9) | 87.5 (73.8, 94.3) |
| 12 months | 92.5 (82.3, 96.9) | 87.5 (73.8, 94.3) |
| 18 months | 73.2 (38.6, 90.3) | 87.5 (73.8, 94.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 13 (11.5%) | 13 (11.4%) |
| Censored Patients, n (%) | 100 (88.5%) | 101 (88.6%) |
| Median (95% CI), (Months) [a] | NE (14.65, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4430 | |
| HR (95% CI) [c] | 0.732 (0.330, 1.625) | |
| HR P-Value [c] | 0.4436 | |
| Heterogeneity p-value [d] | 0.4139 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.0 (74.6, 92.5) | 77.2 (62.7, 86.6) |
| 12 months | 83.3 (70.5, 90.9) | 77.2 (62.7, 86.6) |
| 18 months | 60.2 (32.4, 79.6) | 77.2 (62.7, 86.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 22 (19.5%) | 34 (29.8%) |
| Censored Patients, n (%) | 91 (80.5%) | 80 (70.2%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | 4.40 (2.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0041 | |
| HR (95% CI) [c] | 0.453 (0.260, 0.789) | |
| HR P-Value [c] | 0.0052 | |
| Heterogeneity p-value [d] | 0.2045 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.6 (58.1, 81.4) | 49.6 (35.5, 62.3) |
| 12 months | 58.5 (40.0, 73.1) | 27.1 (7.6, 51.6) |
| 18 months | 50.2 (28.2, 68.6) | 27.1 (7.6, 51.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 8 (7.1%) | 5 (4.4%) |
| Censored Patients, n (%) | 105 (92.9%) | 109 (95.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9904 | |
| HR (95% CI) [c] | 1.005 (0.316, 3.195) | |
| HR P-Value [c] | 0.9939 | |
| Heterogeneity p-value [d] | 0.5260 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.7 (78.5, 96.2) | 90.0 (76.9, 95.9) |
| 12 months | 82.9 (65.2, 92.0) | 90.0 (76.9, 95.9) |
| 18 months | 77.3 (56.5, 89.1) | 90.0 (76.9, 95.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 2 (1.8%) | 10 (8.8%) |
| Censored Patients, n (%) | 111 (98.2%) | 104 (91.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0117 | |
| HR (95% CI) [c] | 0.176 (0.038, 0.807) | |
| HR P-Value [c] | 0.0254 | |
| Heterogeneity p-value [d] | 0.1700 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 96.9 (88.3, 99.2) | 87.8 (77.8, 93.5) |
| 12 months | 96.9 (88.3, 99.2) | 82.6 (66.3, 91.5) |
| 18 months | 96.9 (88.3, 99.2) | 82.6 (66.3, 91.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 13 (11.5%) | 21 (18.4%) |
| Censored Patients, n (%) | 100 (88.5%) | 93 (81.6%) |
| Median (95% CI), (Months) [a] | 19.15 (19.15, NE) | NE (5.59, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0259 | |
| HR (95% CI) [c] | 0.452 (0.221, 0.927) | |
| HR P-Value [c] | 0.0302 | |
| Heterogeneity p-value [d] | 0.1590 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.4 (68.3, 89.5) | 59.1 (43.3, 71.9) |
| 12 months | 76.9 (60.6, 87.1) | 59.1 (43.3, 71.9) |
| 18 months | 76.9 (60.6, 87.1) | 59.1 (43.3, 71.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 12 (10.6%) | 20 (17.5%) |
| Censored Patients, n (%) | 101 (89.4%) | 94 (82.5%) |
| Median (95% CI), (Months) [a] | NE (15.34, NE) | NE (9.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0169 | |
| HR (95% CI) [c] | 0.416 (0.198, 0.874) | |
| HR P-Value [c] | 0.0205 | |
| Heterogeneity p-value [d] | 0.6339 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.3 (74.6, 92.8) | 71.6 (58.1, 81.4) |
| 12 months | 83.5 (70.5, 91.1) | 53.9 (26.0, 75.4) |
| 18 months | 67.5 (41.1, 84.0) | 53.9 (26.0, 75.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 21 (18.6%) | 21 (18.4%) |
| Censored Patients, n (%) | 92 (81.4%) | 93 (81.6%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3378 | |
| HR (95% CI) [c] | 0.742 (0.400, 1.376) | |
| HR P-Value [c] | 0.3433 | |
| Heterogeneity p-value [d] | 0.6667 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.9 (71.6, 90.1) | 69.1 (55.1, 79.5) |
| 12 months | 58.4 (40.6, 72.6) | 60.3 (42.8, 73.9) |
| 18 months | 50.1 (28.6, 68.2) | 60.3 (42.8, 73.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 14 (12.4%) | 22 (19.3%) |
| Censored Patients, n (%) | 99 (87.6%) | 92 (80.7%) |
| Median (95% CI), (Months) [a] | NE (14.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0364 | |
| HR (95% CI) [c] | 0.483 (0.240, 0.970) | |
| HR P-Value [c] | 0.0409 | |
| Heterogeneity p-value [d] | 0.7540 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.3 (71.8, 90.5) | 64.7 (50.7, 75.7) |
| 12 months | 83.3 (71.8, 90.5) | 64.7 (50.7, 75.7) |
| 18 months | 65.1 (41.7, 81.1) | 64.7 (50.7, 75.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 14 (12.4%) | 21 (18.4%) |
| Censored Patients, n (%) | 99 (87.6%) | 93 (81.6%) |
| Median (95% CI), (Months) [a] | NE (15.34, NE) | NE (8.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0359 | |
| HR (95% CI) [c] | 0.483 (0.241, 0.970) | |
| HR P-Value [c] | 0.0409 | |
| Heterogeneity p-value [d] | 0.2172 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.9 (72.6, 90.8) | 67.3 (53.1, 78.1) |
| 12 months | 79.9 (65.5, 88.8) | 61.7 (44.3, 75.1) |
| 18 months | 62.2 (35.0, 80.6) | 61.7 (44.3, 75.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 10 (8.8%) | 15 (13.2%) |
| Censored Patients, n (%) | 103 (91.2%) | 99 (86.8%) |
| Median (95% CI), (Months) [a] | NE (11.20, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0736 | |
| HR (95% CI) [c] | 0.475 (0.207, 1.088) | |
| HR P-Value [c] | 0.0782 | |
| Heterogeneity p-value [d] | 0.1366 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.7 (78.7, 96.0) | 78.4 (66.0, 86.8) |
| 12 months | 71.4 (48.6, 85.5) | 73.5 (57.4, 84.4) |
| 18 months | 62.5 (35.9, 80.6) | 73.5 (57.4, 84.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 15 (12.8%) | 18 (18.6%) |
| Censored Patients, n (%) | 102 (87.2%) | 79 (81.4%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0333 | |
| HR (95% CI) [c] | 0.468 (0.229, 0.957) | |
| HR P-Value [c] | 0.0375 | |
| Heterogeneity p-value [d] | 0.7554 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.3 (70.5, 89.8) | 67.7 (52.6, 78.9) |
| 12 months | 76.2 (61.7, 85.9) | 67.7 (52.6, 78.9) |
| 18 months | 76.2 (61.7, 85.9) | 67.7 (52.6, 78.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 9 (7.7%) | 14 (14.4%) |
| Censored Patients, n (%) | 108 (92.3%) | 83 (85.6%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0035 | |
| HR (95% CI) [c] | 0.268 (0.106, 0.680) | |
| HR P-Value [c] | 0.0056 | |
| Heterogeneity p-value [d] | 0.8507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.8 (83.6, 97.7) | 74.3 (59.4, 84.4) |
| 12 months | 93.8 (83.6, 97.7) | 74.3 (59.4, 84.4) |
| 18 months | 64.1 (37.4, 81.8) | 74.3 (59.4, 84.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 7 (6.0%) | 13 (13.4%) |
| Censored Patients, n (%) | 110 (94.0%) | 84 (86.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0143 | |
| HR (95% CI) [c] | 0.327 (0.128, 0.836) | |
| HR P-Value [c] | 0.0196 | |
| Heterogeneity p-value [d] | 0.1177 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.1 (78.8, 95.5) | 79.5 (65.6, 88.2) |
| 12 months | 86.7 (72.9, 93.8) | 65.4 (40.6, 81.9) |
| 18 months | 86.7 (72.9, 93.8) | 65.4 (40.6, 81.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 8 (6.8%) | 2 (2.1%) |
| Censored Patients, n (%) | 109 (93.2%) | 95 (97.9%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4341 | |
| HR (95% CI) [c] | 1.891 (0.375, 9.543) | |
| HR P-Value [c] | 0.4407 | |
| Heterogeneity p-value [d] | 0.2855 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.9 (84.0, 97.7) | 96.7 (87.0, 99.2) |
| 12 months | 87.4 (72.2, 94.6) | 96.7 (87.0, 99.2) |
| 18 months | 81.1 (59.9, 91.8) | 96.7 (87.0, 99.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 12 (10.3%) | 9 (9.3%) |
| Censored Patients, n (%) | 105 (89.7%) | 88 (90.7%) |
| | | |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5695 | |
| HR (95% CI) [c] | 0.770 (0.312, 1.897) | |
| HR P-Value [c] | 0.5694 | |
| Heterogeneity p-value [d] | 0.4493 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.9 (76.8, 93.9) | 85.1 (72.6, 92.2) |
| 12 months | 82.3 (68.3, 90.5) | 85.1 (72.6, 92.2) |
| 18 months | 70.6 (48.6, 84.6) | 85.1 (72.6, 92.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 14 (12.0%) | 11 (11.3%) |
| Censored Patients, n (%) | 103 (88.0%) | 86 (88.7%) |
| Median (95% CI), (Months) [a] | 20.17 (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1753 | |
| HR (95% CI) [c] | 0.554 (0.234, 1.314) | |
| HR P-Value [c] | 0.1802 | |
| Heterogeneity p-value [d] | 0.3182 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.5 (85.0, 97.3) | 79.6 (65.0, 88.6) |
| 12 months | 83.0 (68.5, 91.3) | 79.6 (65.0, 88.6) |
| 18 months | 64.5 (42.5, 79.8) | 79.6 (65.0, 88.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 28 (23.9%) | 26 (26.8%) |
| Censored Patients, n (%) | 89 (76.1%) | 71 (73.2%) |
| Median (95% CI), (Months) [a] | 16.53 (11.10, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0755 | |
| HR (95% CI) [c] | 0.602 (0.343, 1.058) | |
| HR P-Value [c] | 0.0779 | |
| Heterogeneity p-value [d] | 0.2488 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.1 (61.7, 83.1) | 61.3 (47.3, 72.6) |
| 12 months | 57.2 (41.4, 70.2) | 51.1 (33.5, 66.2) |
| 18 months | 42.2 (24.1, 59.3) | 51.1 (33.5, 66.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 11 (9.4%) | 5 (5.2%) |
| Censored Patients, n (%) | 106 (90.6%) | 92 (94.8%) |
| Median (95% CI), (Months) [a] | NE (14.00, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7841 | |
| HR (95% CI) [c] | 0.853 (0.277, 2.626) | |
| HR P-Value [c] | 0.7816 | |
| Heterogeneity p-value [d] | 0.6193 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.8 (84.5, 98.3) | 90.5 (78.1, 96.0) |
| 12 months | 80.8 (64.4, 90.1) | 90.5 (78.1, 96.0) |
| 18 months | 67.1 (46.2, 81.4) | 90.5 (78.1, 96.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 7 (6.0%) | 10 (10.3%) |
| Censored Patients, n (%) | 110 (94.0%) | 87 (89.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1076 | |
| HR (95% CI) [c] | 0.450 (0.167, 1.217) | |
| HR P-Value [c] | 0.1158 | |
| Heterogeneity p-value [d] | 0.8379 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.2 (84.1, 97.2) | 86.9 (76.2, 93.0) |
| 12 months | 87.6 (74.2, 94.3) | 80.7 (61.9, 90.9) |
| 18 months | 87.6 (74.2, 94.3) | 80.7 (61.9, 90.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 19 (16.2%) | 16 (16.5%) |
| Censored Patients, n (%) | 98 (83.8%) | 81 (83.5%) |
| Median (95% CI), (Months) [a] | 19.15 (19.15, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2490 | |
| HR (95% CI) [c] | 0.665 (0.330, 1.342) | |
| HR P-Value [c] | 0.2547 | |
| Heterogeneity p-value [d] | 0.6010 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.0 (66.7, 87.2) | 68.5 (51.4, 80.6) |
| 12 months | 70.7 (55.8, 81.3) | 54.8 (25.8, 76.5) |
| 18 months | 70.7 (55.8, 81.3) | 54.8 (25.8, 76.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 16 (13.7%) | 19 (19.6%) |
| Censored Patients, n (%) | 101 (86.3%) | 78 (80.4%) |
| Median (95% CI), (Months) [a] | 20.17 (15.34, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0069 | |
| HR (95% CI) [c] | 0.382 (0.186, 0.785) | |
| HR P-Value [c] | 0.0088 | |
| Heterogeneity p-value [d] | 0.8733 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.8 (75.7, 93.0) | 72.9 (59.5, 82.5) |
| 12 months | 75.7 (60.3, 85.7) | 50.5 (19.0, 75.5) |
| 18 months | 65.9 (46.4, 79.7) | 50.5 (19.0, 75.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.

[a] Based on Kaplan-Meier method.

[b] Two-sided p-value is from unstratified log-rank test.

[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 21 (17.9%) | 19 (19.6%) |
| Censored Patients, n (%) | 96 (82.1%) | 78 (80.4%) |
| Median (95% CI), (Months) [a] | NE (10.12, NE) | NE (8.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1057 | |
| HR (95% CI) [c] | 0.588 (0.306, 1.128) | |
| HR P-Value [c] | 0.1103 | |
| Heterogeneity p-value [d] | 0.8005 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.3 (75.7, 92.5) | 73.9 (60.9, 83.1) |
| 12 months | 60.8 (44.6, 73.6) | 63.7 (45.1, 77.5) |
| 18 months | 55.3 (37.1, 70.1) | 63.7 (45.1, 77.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 17 (14.5%) | 25 (25.8%) |
| Censored Patients, n (%) | 100 (85.5%) | 72 (74.2%) |
| Median (95% CI), (Months) [a] | NE (14.26, NE) | NE (4.27, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0023 | |
| HR (95% CI) [c] | 0.372 (0.192, 0.719) | |
| HR P-Value [c] | 0.0033 | |
| Heterogeneity p-value [d] | 0.2877 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.3 (73.1, 91.1) | 58.7 (44.5, 70.4) |
| 12 months | 78.1 (63.8, 87.3) | 58.7 (44.5, 70.4) |
| 18 months | 61.4 (41.8, 76.1) | 58.7 (44.5, 70.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 19 (16.2%) | 19 (19.6%) |
| Censored Patients, n (%) | 98 (83.8%) | 78 (80.4%) |
| Median (95% CI), (Months) [a] | 20.17 (15.34, NE) | NE (8.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0636 | |
| HR (95% CI) [c] | 0.530 (0.268, 1.050) | |
| HR P-Value [c] | 0.0687 | |
| Heterogeneity p-value [d] | 0.9173 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.9 (74.3, 91.4) | 70.0 (55.5, 80.6) |
| 12 months | 73.2 (57.6, 83.8) | 64.2 (46.1, 77.6) |
| 18 months | 58.3 (38.0, 74.0) | 64.2 (46.1, 77.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 16 (13.7%) | 11 (11.3%) |
| Censored Patients, n (%) | 101 (86.3%) | 86 (88.7%) |
| Median (95% CI), (Months) [a] | NE (16.62, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8019 | |
| HR (95% CI) [c] | 0.904 (0.406, 2.013) | |
| HR P-Value [c] | 0.8049 | |
| Heterogeneity p-value [d] | 0.4868 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.8 (75.1, 92.1) | 84.4 (72.7, 91.4) |
| 12 months | 73.4 (57.3, 84.3) | 79.5 (63.1, 89.2) |
| 18 months | 66.7 (46.2, 80.9) | 79.5 (63.1, 89.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 10 (13.0%) | 13 (15.1%) |
| Censored Patients, n (%) | 67 (87.0%) | 73 (84.9%) |
| Median (95% CI), (Months) [a] | NE (11.43, NE) | NE (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2097 | |
| HR (95% CI) [c] | 0.592 (0.258, 1.362) | |
| HR P-Value [c] | 0.2179 | |
| Heterogeneity p-value [d] | 0.7554 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.9 (70.6, 92.6) | 78.4 (64.2, 87.5) |
| 12 months | 70.0 (48.1, 84.1) | 53.7 (22.1, 77.5) |
| 18 months | 70.0 (48.1, 84.1) | NE (NE, NE) |
| 24 months | 70.0 (48.1, 84.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 7 (9.1%) | 13 (15.1%) |
| Censored Patients, n (%) | 70 (90.9%) | 73 (84.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (7.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0534 | |
| HR (95% CI) [c] | 0.411 (0.162, 1.043) | |
| HR P-Value [c] | 0.0613 | |
| Heterogeneity p-value [d] | 0.8507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.2 (77.5, 95.0) | 69.4 (50.3, 82.4) |
| 12 months | 89.2 (77.5, 95.0) | 63.1 (41.6, 78.6) |
| 18 months | 79.3 (50.8, 92.4) | NE (NE, NE) |
| 24 months | 79.3 (50.8, 92.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 8 (10.4%) | 6 (7.0%) |
| Censored Patients, n (%) | 69 (89.6%) | 80 (93.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8781 | |
| HR (95% CI) [c] | 1.088 (0.374, 3.163) | |
| HR P-Value [c] | 0.8774 | |
| Heterogeneity p-value [d] | 0.1177 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.4 (71.5, 93.8) | 87.8 (74.8, 94.4) |
| 12 months | 76.3 (54.7, 88.5) | 87.8 (74.8, 94.4) |
| 18 months | 76.3 (54.7, 88.5) | NE (NE, NE) |
| 24 months | 76.3 (54.7, 88.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 3 (3.9%) | 3 (3.5%) |
| Censored Patients, n (%) | 74 (96.1%) | 83 (96.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7481 | |
| HR (95% CI) [c] | 0.767 (0.152, 3.878) | |
| HR P-Value [c] | 0.7487 | |
| Heterogeneity p-value [d] | 0.2855 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 96.0 (84.3, 99.0) | 93.1 (79.8, 97.7) |
| 12 months | 90.0 (67.4, 97.2) | 93.1 (79.8, 97.7) |
| 18 months | 90.0 (67.4, 97.2) | NE (NE, NE) |
| 24 months | 90.0 (67.4, 97.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 6 (7.8%) | 9 (10.5%) |
| Censored Patients, n (%) | 71 (92.2%) | 77 (89.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2124 | |
| HR (95% CI) [c] | 0.522 (0.184, 1.483) | |
| HR P-Value [c] | 0.2223 | |
| Heterogeneity p-value [d] | 0.4493 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.6 (75.8, 94.9) | 79.3 (61.2, 89.6) |
| 12 months | 88.6 (75.8, 94.9) | 66.1 (33.9, 85.3) |
| 18 months | 88.6 (75.8, 94.9) | NE (NE, NE) |
| 24 months | 88.6 (75.8, 94.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 5 (6.5%) | 9 (10.5%) |
| Censored Patients, n (%) | 72 (93.5%) | 77 (89.5%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0896 | |
| HR (95% CI) [c] | 0.373 (0.114, 1.223) | |
| HR P-Value [c] | 0.1035 | |
| Heterogeneity p-value [d] | 0.3182 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.6 (79.1, 96.8) | 86.0 (72.5, 93.1) |
| 12 months | 91.6 (79.1, 96.8) | 69.4 (41.0, 86.1) |
| 18 months | 91.6 (79.1, 96.8) | NE (NE, NE) |
| 24 months | 68.7 (17.8, 92.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 15 (19.5%) | 23 (26.7%) |
| Censored Patients, n (%) | 62 (80.5%) | 63 (73.3%) |
| Median (95% CI), (Months) [a] | NE (12.45, NE) | 10.28 (2.89, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0188 | |
| HR (95% CI) [c] | 0.464 (0.240, 0.896) | |
| HR P-Value [c] | 0.0222 | |
| Heterogeneity p-value [d] | 0.2488 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.6 (59.7, 84.6) | 51.5 (34.8, 65.8) |
| 12 months | 71.2 (55.3, 82.3) | 38.6 (15.4, 61.6) |
| 18 months | 64.1 (43.4, 78.9) | NE (NE, NE) |
| 24 months | 64.1 (43.4, 78.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 8 (10.4%) | 3 (3.5%) |
| Censored Patients, n (%) | 69 (89.6%) | 83 (96.5%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4258 | |
| HR (95% CI) [c] | 1.723 (0.443, 6.701) | |
| HR P-Value [c] | 0.4322 | |
| Heterogeneity p-value [d] | 0.6193 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.5 (69.5, 93.4) | 92.8 (79.3, 97.6) |
| 12 months | 78.9 (57.0, 90.5) | 92.8 (79.3, 97.6) |
| 18 months | 78.9 (57.0, 90.5) | NE (NE, NE) |
| 24 months | 59.2 (19.2, 84.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 5 (6.5%) | 10 (11.6%) |
| Censored Patients, n (%) | 72 (93.5%) | 76 (88.4%) |
| Median (95% CI), (Months) [a] | NE (14.59, NE) | NE (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0267 | |
| HR (95% CI) [c] | 0.301 (0.099, 0.919) | |
| HR P-Value [c] | 0.0349 | |
| Heterogeneity p-value [d] | 0.8379 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 96.0 (84.6, 99.0) | 79.7 (62.4, 89.7) |
| 12 months | 85.2 (60.3, 95.0) | 63.8 (27.9, 85.3) |
| 18 months | 74.5 (41.8, 90.6) | NE (NE, NE) |
| 24 months | 74.5 (41.8, 90.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 13 (16.9%) | 17 (19.8%) |
| Censored Patients, n (%) | 64 (83.1%) | 69 (80.2%) |
| Median (95% CI), (Months) [a] | NE (10.97, NE) | NE (5.82, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1439 | |
| HR (95% CI) [c] | 0.586 (0.284, 1.211) | |
| HR P-Value [c] | 0.1491 | |
| Heterogeneity p-value [d] | 0.6010 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.2 (66.8, 89.9) | 63.3 (46.6, 76.1) |
| 12 months | 60.6 (35.5, 78.5) | 52.8 (28.7, 72.1) |
| 18 months | 51.9 (26.0, 72.7) | NE (NE, NE) |
| 24 months | 51.9 (26.0, 72.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 9 (11.7%) | 12 (14.0%) |
| Censored Patients, n (%) | 68 (88.3%) | 74 (86.0%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (12.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1665 | |
| HR (95% CI) [c] | 0.535 (0.217, 1.316) | |
| HR P-Value [c] | 0.1731 | |
| Heterogeneity p-value [d] | 0.8733 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.7 (69.2, 91.7) | 74.5 (56.8, 85.9) |
| 12 months | 83.7 (69.2, 91.7) | 74.5 (56.8, 85.9) |
| 18 months | 83.7 (69.2, 91.7) | NE (NE, NE) |
| 24 months | 62.7 (19.8, 87.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 13 (16.9%) | 13 (15.1%) |
| Censored Patients, n (%) | 64 (83.1%) | 73 (84.9%) |
| | | |
| Median (95% CI), (Months) [a] | NE (10.09, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4457 | |
| HR (95% CI) [c] | 0.739 (0.339, 1.611) | |
| HR P-Value [c] | 0.4471 | |
| Heterogeneity p-value [d] | 0.8005 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.9 (71.6, 92.2) | 68.3 (50.0, 81.1) |
| 12 months | 67.2 (46.4, 81.4) | 68.3 (50.0, 81.1) |
| 18 months | 58.8 (34.4, 76.8) | NE (NE, NE) |
| 24 months | 58.8 (34.4, 76.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 12 (15.6%) | 12 (14.0%) |
| Censored Patients, n (%) | 65 (84.4%) | 74 (86.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6429 | |
| HR (95% CI) [c] | 0.830 (0.373, 1.848) | |
| HR P-Value [c] | 0.6478 | |
| Heterogeneity p-value [d] | 0.2877 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.1 (61.4, 85.9) | 74.3 (58.9, 84.7) |
| 12 months | 76.1 (61.4, 85.9) | 74.3 (58.9, 84.7) |
| 18 months | 76.1 (61.4, 85.9) | NE (NE, NE) |
| 24 months | 76.1 (61.4, 85.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 12 (15.6%) | 11 (12.8%) |
| Censored Patients, n (%) | 65 (84.4%) | 75 (87.2%) |
| Median (95% CI), (Months) [a] | 20.83 (20.80, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4565 | |
| HR (95% CI) [c] | 0.725 (0.307, 1.713) | |
| HR P-Value [c] | 0.4641 | |
| Heterogeneity p-value [d] | 0.9173 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.7 (71.5, 92.1) | 73.3 (55.5, 84.9) |
| 12 months | 77.3 (60.6, 87.6) | 73.3 (55.5, 84.9) |
| 18 months | 77.3 (60.6, 87.6) | NE (NE, NE) |
| 24 months | 38.6 (6.7, 71.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 10 (13.0%) | 11 (12.8%) |
| Censored Patients, n (%) | 67 (87.0%) | 75 (87.2%) |
| Median (95% CI), (Months) [a] | NE (16.66, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1566 | |
| HR (95% CI) [c] | 0.517 (0.205, 1.304) | |
| HR P-Value [c] | 0.1625 | |
| Heterogeneity p-value [d] | 0.4868 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.5 (66.7, 92.3) | 82.4 (68.7, 90.4) |
| 12 months | 72.7 (50.6, 86.1) | 57.6 (23.9, 80.9) |
| 18 months | 51.9 (23.1, 74.6) | NE (NE, NE) |
| 24 months | 51.9 (23.1, 74.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 4 (21.1%) |
| Censored Patients, n (%) | 21 (80.8%) | 15 (78.9%) |
| Median (95% CI), (Months) [a] | NE (7.26, NE) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5494 | |
| HR (95% CI) [c] | 0.669 (0.174, 2.573) | |
| HR P-Value [c] | 0.5589 | |
| Heterogeneity p-value [d] | 0.6494 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.5 (55.4, 92.4) | 67.7 (33.8, 86.9) |
| 12 months | 71.6 (42.2, 87.8) | NE (NE, NE) |
| 18 months | 71.6 (42.2, 87.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 2 (7.7%) | 5 (26.3%) |
| Censored Patients, n (%) | 24 (92.3%) | 14 (73.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (2.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0376 | |
| HR (95% CI) [c] | 0.206 (0.040, 1.067) | |
| HR P-Value [c] | 0.0598 | |
| Heterogeneity p-value [d] | 0.6584 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.1 (58.8, 97.0) | 55.9 (21.3, 80.4) |
| 12 months | 88.1 (58.8, 97.0) | NE (NE, NE) |
| 18 months | 88.1 (58.8, 97.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 3 (11.5%) | 2 (10.5%) |
| Censored Patients, n (%) | 23 (88.5%) | 17 (89.5%) |
| Median (95% CI), (Months) [a] | NE (7.26, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5080 | |
| HR (95% CI) [c] | 0.538 (0.084, 3.453) | |
| HR P-Value [c] | 0.5131 | |
| Heterogeneity p-value [d] | 0.2774 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.1 (62.2, 97.2) | 90.9 (50.8, 98.7) |
| 12 months | 80.2 (48.3, 93.5) | NE (NE, NE) |
| 18 months | 80.2 (48.3, 93.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (5.3%) |
| Censored Patients, n (%) | 26 (100.0%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2207 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.2029 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 93.8 (63.2, 99.1) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 3 (15.8%) |
| Censored Patients, n (%) | 21 (80.8%) | 16 (84.2%) |
| Median (95% CI), (Months) [a] | NE (5.72, NE) | NE (1.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9895 | |
| HR (95% CI) [c] | 1.010 (0.241, 4.230) | |
| HR P-Value [c] | 0.9895 | |
| Heterogeneity p-value [d] | 0.5191 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.2 (45.4, 88.4) | 79.1 (47.9, 92.8) |
| 12 months | 73.2 (45.4, 88.4) | NE (NE, NE) |
| 18 months | 73.2 (45.4, 88.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 4 (15.4%) | 1 (5.3%) |
| Censored Patients, n (%) | 22 (84.6%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | NE (12.48, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6366 | |
| HR (95% CI) [c] | 1.699 (0.176, 16.360) | |
| HR P-Value [c] | 0.6466 | |
| Heterogeneity p-value [d] | 0.2003 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.4 (58.3, 94.8) | 90.9 (50.8, 98.7) |
| 12 months | 84.4 (58.3, 94.8) | NE (NE, NE) |
| 18 months | 70.3 (32.5, 89.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 8 (30.8%) | 7 (36.8%) |
| Censored Patients, n (%) | 18 (69.2%) | 12 (63.2%) |
| Median (95% CI), (Months) [a] | NE (4.24, NE) | 5.68 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2081 | |
| HR (95% CI) [c] | 0.515 (0.180, 1.475) | |
| HR P-Value [c] | 0.2164 | |
| Heterogeneity p-value [d] | 0.7551 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.4 (37.0, 81.1) | 47.9 (15.1, 75.0) |
| 12 months | 50.7 (21.0, 74.4) | NE (NE, NE) |
| 18 months | 50.7 (21.0, 74.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 3 (11.5%) | 3 (15.8%) |
| Censored Patients, n (%) | 23 (88.5%) | 16 (84.2%) |
| Median (95% CI), (Months) [a] | NE (9.76, NE) | NE (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0856 | |
| HR (95% CI) [c] | 0.170 (0.017, 1.663) | |
| HR P-Value [c] | 0.1278 | |
| Heterogeneity p-value [d] | 0.4382 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 74.9 (39.1, 91.5) |
| 12 months | 76.4 (30.9, 94.0) | NE (NE, NE) |
| 18 months | 61.1 (19.5, 86.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 2 (7.7%) | 2 (10.5%) |
| Censored Patients, n (%) | 24 (92.3%) | 17 (89.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3328 | |
| HR (95% CI) [c] | 0.369 (0.046, 2.972) | |
| HR P-Value [c] | 0.3489 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.5 (71.9, 99.3) | 87.4 (58.1, 96.7) |
| 12 months | 85.9 (51.1, 96.6) | NE (NE, NE) |
| 18 months | 85.9 (51.1, 96.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 2 (10.5%) |
| Censored Patients, n (%) | 21 (80.8%) | 17 (89.5%) |
| Median (95% CI), (Months) [a] | NE (5.72, NE) | NE (5.59, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7214 | |
| HR (95% CI) [c] | 1.356 (0.261, 7.058) | |
| HR P-Value [c] | 0.7175 | |
| Heterogeneity p-value [d] | 0.2208 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.0 (47.4, 88.6) | 74.3 (24.5, 93.9) |
| 12 months | 74.0 (47.4, 88.6) | NE (NE, NE) |
| 18 months | 74.0 (47.4, 88.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 3 (11.5%) | 3 (15.8%) |
| Censored Patients, n (%) | 23 (88.5%) | 16 (84.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5191 | |
| HR (95% CI) [c] | 0.594 (0.120, 2.947) | |
| HR P-Value [c] | 0.5238 | |
| Heterogeneity p-value [d] | 0.9224 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.7 (64.2, 95.5) | 80.0 (50.0, 93.1) |
| 12 months | 86.7 (64.2, 95.5) | NE (NE, NE) |
| 18 months | 86.7 (64.2, 95.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 5 (26.3%) |
| Censored Patients, n (%) | 20 (76.9%) | 14 (73.7%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3845 | |
| HR (95% CI) [c] | 0.588 (0.175, 1.971) | |
| HR P-Value [c] | 0.3894 | |
| Heterogeneity p-value [d] | 0.5121 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.2 (51.1, 89.5) | 64.2 (33.3, 83.6) |
| 12 months | 65.3 (34.5, 84.3) | NE (NE, NE) |
| 18 months | 65.3 (34.5, 84.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 7 (36.8%) |
| Censored Patients, n (%) | 21 (80.8%) | 12 (63.2%) |
| Median (95% CI), (Months) [a] | NE (12.48, NE) | 4.30 (1.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0619 | |
| HR (95% CI) [c] | 0.330 (0.096, 1.133) | |
| HR P-Value [c] | 0.0781 | |
| Heterogeneity p-value [d] | 0.9196 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (57.5, 92.6) | 40.0 (13.0, 66.3) |
| 12 months | 81.3 (57.5, 92.6) | NE (NE, NE) |
| 18 months | 67.8 (32.6, 87.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 9 (34.6%) | 6 (31.6%) |
| Censored Patients, n (%) | 17 (65.4%) | 13 (68.4%) |
| Median (95% CI), (Months) [a] | 9.76 (4.21, NE) | 5.68 (1.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6319 | |
| HR (95% CI) [c] | 0.787 (0.271, 2.289) | |
| HR P-Value [c] | 0.6605 | |
| Heterogeneity p-value [d] | 0.3265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.4 (44.4, 83.7) | 45.0 (13.5, 72.8) |
| 12 months | 47.9 (19.5, 71.7) | NE (NE, NE) |
| 18 months | 47.9 (19.5, 71.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 3 (11.5%) | 2 (10.5%) |
| Censored Patients, n (%) | 23 (88.5%) | 17 (89.5%) |
| Median (95% CI), (Months) [a] | 16.62 (9.76, 16.62) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3834 | |
| HR (95% CI) [c] | 0.360 (0.033, 3.968) | |
| HR P-Value [c] | 0.4038 | |
| Heterogeneity p-value [d] | 0.6899 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.7 (68.1, 99.2) | 84.4 (49.3, 96.0) |
| 12 months | 75.8 (24.4, 94.7) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 14 (11.8%) | 14 (12.6%) |
| Censored Patients, n (%) | 105 (88.2%) | 97 (87.4%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1905 | |
| HR (95% CI) [c] | 0.601 (0.278, 1.296) | |
| HR P-Value [c] | 0.1940 | |
| Heterogeneity p-value [d] | 0.6494 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.3 (75.0, 92.7) | 78.1 (65.1, 86.7) |
| 12 months | 75.4 (60.2, 85.5) | 78.1 (65.1, 86.7) |
| 18 months | 75.4 (60.2, 85.5) | 78.1 (65.1, 86.7) |
| 24 months | 62.8 (33.8, 81.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 10 (8.4%) | 15 (13.5%) |
| Censored Patients, n (%) | 109 (91.6%) | 96 (86.5%) |
| Median (95% CI), (Months) [a] | NE (17.05, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0165 | |
| HR (95% CI) [c] | 0.360 (0.152, 0.854) | |
| HR P-Value [c] | 0.0205 | |
| Heterogeneity p-value [d] | 0.6584 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.6 (83.8, 96.7) | 75.7 (61.0, 85.4) |
| 12 months | 92.6 (83.8, 96.7) | 71.2 (54.4, 82.8) |
| 18 months | 68.4 (42.3, 84.6) | 71.2 (54.4, 82.8) |
| 24 months | 68.4 (42.3, 84.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 9 (7.6%) | 8 (7.2%) |
| Censored Patients, n (%) | 110 (92.4%) | 103 (92.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6634 | |
| HR (95% CI) [c] | 0.807 (0.307, 2.119) | |
| HR P-Value [c] | 0.6627 | |
| Heterogeneity p-value [d] | 0.2774 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.5 (78.8, 94.9) | 87.2 (75.7, 93.4) |
| 12 months | 83.3 (68.9, 91.4) | 87.2 (75.7, 93.4) |
| 18 months | 83.3 (68.9, 91.4) | 87.2 (75.7, 93.4) |
| 24 months | 83.3 (68.9, 91.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 8 (6.7%) | 1 (0.9%) |
| Censored Patients, n (%) | 111 (93.3%) | 110 (99.1%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1530 | |
| HR (95% CI) [c] | 4.219 (0.501, 35.554) | |
| HR P-Value [c] | 0.1856 | |
| Heterogeneity p-value [d] | 0.2029 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.1 (87.3, 98.2) | 98.6 (90.7, 99.8) |
| 12 months | 89.1 (75.3, 95.4) | 98.6 (90.7, 99.8) |
| 18 months | 83.2 (62.8, 92.9) | 98.6 (90.7, 99.8) |
| 24 months | 74.8 (48.2, 89.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 10 (8.4%) | 8 (7.2%) |
| Censored Patients, n (%) | 109 (91.6%) | 103 (92.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4913 | |
| HR (95% CI) [c] | 0.713 (0.271, 1.879) | |
| HR P-Value [c] | 0.4940 | |
| Heterogeneity p-value [d] | 0.5191 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.1 (83.1, 96.4) | 84.9 (70.9, 92.5) |
| 12 months | 87.4 (75.4, 93.8) | 84.9 (70.9, 92.5) |
| 18 months | 75.7 (53.3, 88.4) | 84.9 (70.9, 92.5) |
| 24 months | 75.7 (53.3, 88.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 10 (8.4%) | 14 (12.6%) |
| Censored Patients, n (%) | 109 (91.6%) | 97 (87.4%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0309 | |
| HR (95% CI) [c] | 0.395 (0.166, 0.943) | |
| HR P-Value [c] | 0.0364 | |
| Heterogeneity p-value [d] | 0.2003 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.9 (87.0, 98.1) | 79.5 (66.5, 87.9) |
| 12 months | 85.8 (72.8, 92.9) | 74.5 (57.8, 85.4) |
| 18 months | 79.2 (58.7, 90.3) | 74.5 (57.8, 85.4) |
| 24 months | 67.9 (37.6, 85.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 27 (22.7%) | 29 (26.1%) |
| Censored Patients, n (%) | 92 (77.3%) | 82 (73.9%) |
| Median (95% CI), (Months) [a] | 20.17 (14.55, NE) | 10.28 (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0338 | |
| HR (95% CI) [c] | 0.555 (0.320, 0.965) | |
| HR P-Value [c] | 0.0369 | |
| Heterogeneity p-value [d] | 0.7551 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.1 (64.5, 84.4) | 59.7 (46.4, 70.8) |
| 12 months | 64.3 (50.0, 75.5) | 44.1 (21.8, 64.4) |
| 18 months | 50.8 (33.0, 66.1) | 44.1 (21.8, 64.4) |
| 24 months | 42.3 (21.9, 61.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 12 (10.1%) | 3 (2.7%) |
| Censored Patients, n (%) | 107 (89.9%) | 108 (97.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2080 | |
| HR (95% CI) [c] | 2.240 (0.619, 8.115) | |
| HR P-Value [c] | 0.2193 | |
| Heterogeneity p-value [d] | 0.4382 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.6 (80.0, 95.8) | 95.3 (86.2, 98.5) |
| 12 months | 78.6 (63.9, 87.9) | 95.3 (86.2, 98.5) |
| 18 months | 74.2 (57.3, 85.3) | 95.3 (86.2, 98.5) |
| 24 months | 74.2 (57.3, 85.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 7 (5.9%) | 13 (11.7%) |
| Censored Patients, n (%) | 112 (94.1%) | 98 (88.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0122 | |
| HR (95% CI) [c] | 0.308 (0.117, 0.808) | |
| HR P-Value [c] | 0.0166 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 96.5 (89.4, 98.9) | 82.1 (69.8, 89.7) |
| 12 months | 88.0 (73.4, 94.9) | 78.0 (62.8, 87.5) |
| 18 months | 82.5 (62.9, 92.4) | 78.0 (62.8, 87.5) |
| 24 months | 82.5 (62.9, 92.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 14 (11.8%) | 19 (17.1%) |
| Censored Patients, n (%) | 105 (88.2%) | 92 (82.9%) |
| Median (95% CI), (Months) [a] | 20.17 (19.15, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0089 | |
| HR (95% CI) [c] | 0.384 (0.183, 0.806) | |
| HR P-Value [c] | 0.0114 | |
| Heterogeneity p-value [d] | 0.2208 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.8 (79.7, 95.0) | 66.8 (52.1, 77.8) |
| 12 months | 75.0 (58.5, 85.6) | 66.8 (52.1, 77.8) |
| 18 months | 75.0 (58.5, 85.6) | 66.8 (52.1, 77.8) |
| 24 months | 50.0 (19.6, 74.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 16 (13.4%) | 18 (16.2%) |
| Censored Patients, n (%) | 103 (86.6%) | 93 (83.8%) |
| Median (95% CI), (Months) [a] | NE (15.34, NE) | 12.71 (9.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0302 | |
| HR (95% CI) [c] | 0.460 (0.224, 0.943) | |
| HR P-Value [c] | 0.0340 | |
| Heterogeneity p-value [d] | 0.9224 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.6 (76.2, 92.7) | 75.2 (61.2, 84.7) |
| 12 months | 78.9 (65.3, 87.7) | 62.3 (39.3, 78.7) |
| 18 months | 68.7 (49.3, 81.9) | 46.7 (16.7, 72.4) |
| 24 months | 58.9 (33.5, 77.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 20 (16.8%) | 15 (13.5%) |
| Censored Patients, n (%) | 99 (83.2%) | 96 (86.5%) |
| Median (95% CI), (Months) [a] | NE (11.20, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5186 | |
| HR (95% CI) [c] | 0.797 (0.399, 1.593) | |
| HR P-Value [c] | 0.5206 | |
| Heterogeneity p-value [d] | 0.5121 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.1 (81.0, 95.0) | 79.0 (65.7, 87.6) |
| 12 months | 64.6 (48.9, 76.5) | 70.2 (52.3, 82.5) |
| 18 months | 58.7 (40.3, 73.2) | 70.2 (52.3, 82.5) |
| 24 months | 58.7 (40.3, 73.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 18 (15.1%) | 21 (18.9%) |
| Censored Patients, n (%) | 101 (84.9%) | 90 (81.1%) |
| Median (95% CI), (Months) [a] | NE (14.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0743 | |
| HR (95% CI) [c] | 0.558 (0.291, 1.068) | |
| HR P-Value [c] | 0.0780 | |
| Heterogeneity p-value [d] | 0.9196 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.0 (72.4, 89.8) | 68.6 (55.6, 78.5) |
| 12 months | 77.7 (64.6, 86.4) | 68.6 (55.6, 78.5) |
| 18 months | 64.2 (45.3, 78.1) | 68.6 (55.6, 78.5) |
| 24 months | 64.2 (45.3, 78.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 14 (11.8%) | 20 (18.0%) |
| Censored Patients, n (%) | 105 (88.2%) | 91 (82.0%) |
| Median (95% CI), (Months) [a] | NE (15.44, NE) | NE (8.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0068 | |
| HR (95% CI) [c] | 0.375 (0.180, 0.782) | |
| HR P-Value [c] | 0.0089 | |
| Heterogeneity p-value [d] | 0.3265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.2 (80.4, 95.2) | 71.0 (57.7, 80.8) |
| 12 months | 80.3 (66.2, 89.0) | 65.9 (49.5, 78.1) |
| 18 months | 69.6 (49.3, 83.1) | 65.9 (49.5, 78.1) |
| 24 months | 58.0 (30.0, 78.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 16 (13.4%) | 16 (14.4%) |
| Censored Patients, n (%) | 103 (86.6%) | 95 (85.6%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | NE (11.33, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2051 | |
| HR (95% CI) [c] | 0.630 (0.307, 1.294) | |
| HR P-Value [c] | 0.2083 | |
| Heterogeneity p-value [d] | 0.6899 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.5 (72.0, 90.6) | 81.3 (70.0, 88.7) |
| 12 months | 73.5 (58.8, 83.6) | 54.5 (19.7, 79.7) |
| 18 months | 73.5 (58.8, 83.6) | 54.5 (19.7, 79.7) |
| 24 months | 63.0 (37.7, 80.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 17 (85.0%) | 18 (85.7%) |
| | | |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | 3.48 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5150 | |
| HR (95% CI) [c] | 0.582 (0.112, 3.019) | |
| HR P-Value [c] | 0.5194 | |
| Heterogeneity p-value [d] | 0.6494 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.2 (42.7, 91.7) | 26.7 (1.0, 68.6) |
| 12 months | 76.2 (42.7, 91.7) | NE (NE, NE) |
| 18 months | 76.2 (42.7, 91.7) | NE (NE, NE) |
| 24 months | 76.2 (42.7, 91.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 4 (20.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 16 (80.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | 13.93 (1.61, NE) | 3.48 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4836 | |
| HR (95% CI) [c] | 0.563 (0.111, 2.864) | |
| HR P-Value [c] | 0.4891 | |
| Heterogeneity p-value [d] | 0.6584 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.1 (39.1, 90.9) | 26.7 (1.0, 68.6) |
| 12 months | 74.1 (39.1, 90.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 4 (19.0%) |
| Censored Patients, n (%) | 19 (95.0%) | 17 (81.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 3.15 (1.51, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0080 | |
| HR (95% CI) [c] | 0.076 (0.008, 0.755) | |
| HR P-Value [c] | 0.0278 | |
| Heterogeneity p-value [d] | 0.2774 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (59.1, 99.0) | 0.0 (NE, NE) |
| 12 months | 92.9 (59.1, 99.0) | 0.0 (NE, NE) |
| 18 months | 92.9 (59.1, 99.0) | 0.0 (NE, NE) |
| 24 months | 92.9 (59.1, 99.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 19 (95.0%) | 19 (90.5%) |
| Median (95% CI), (Months) [a] | NE (10.09, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0200 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9971 | |
| Heterogeneity p-value [d] | 0.2029 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 53.3 (6.8, 86.3) |
| 12 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 18 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 24 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 18 (90.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (5.75, NE) | NE (3.15, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9679 | |
| HR (95% CI) [c] | 0.951 (0.082, 11.063) | |
| HR P-Value [c] | 0.9679 | |
| Heterogeneity p-value [d] | 0.5191 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.2 (16.3, 92.8) | 75.0 (12.8, 96.1) |
| 12 months | 69.2 (16.3, 92.8) | NE (NE, NE) |
| 18 months | 69.2 (16.3, 92.8) | NE (NE, NE) |
| 24 months | 69.2 (16.3, 92.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (25.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 15 (75.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | 12.52 (1.58, NE) | NE (3.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4408 | |
| HR (95% CI) [c] | 2.375 (0.246, 22.947) | |
| HR P-Value [c] | 0.4547 | |
| Heterogeneity p-value [d] | 0.2003 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.7 (36.3, 90.4) | 75.0 (12.8, 96.1) |
| 12 months | 72.7 (36.3, 90.4) | NE (NE, NE) |
| 18 months | 24.2 (1.1, 64.1) | NE (NE, NE) |
| 24 months | 24.2 (1.1, 64.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (25.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 15 (75.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | 7.29 (1.48, NE) | 3.48 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9514 | |
| HR (95% CI) [c] | 1.046 (0.244, 4.493) | |
| HR P-Value [c] | 0.9517 | |
| Heterogeneity p-value [d] | 0.7551 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.8 (37.8, 87.6) | 26.7 (1.0, 68.6) |
| 12 months | 46.6 (9.0, 78.4) | NE (NE, NE) |
| 18 months | 46.6 (9.0, 78.4) | NE (NE, NE) |
| 24 months | 46.6 (9.0, 78.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 0 |
| Censored Patients, n (%) | 18 (90.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (4.37, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4795 | |
| HR (95% CI) [c] | 17343980 (0.000, NE) | |
| HR P-Value [c] | 0.9977 | |
| Heterogeneity p-value [d] | 0.4382 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (38.7, 98.1) | 100.0 (100.0, 100.0) |
| 12 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 18 months | 58.3 (7.7, 89.3) | NE (NE, NE) |
| 24 months | 58.3 (7.7, 89.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 19 (95.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (3.15, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6832 | |
| HR (95% CI) [c] | 0.563 (0.035, 9.186) | |
| HR P-Value [c] | 0.6871 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (59.1, 99.0) | 75.0 (12.8, 96.1) |
| 12 months | 92.9 (59.1, 99.0) | NE (NE, NE) |
| 18 months | 92.9 (59.1, 99.0) | NE (NE, NE) |
| 24 months | 92.9 (59.1, 99.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 4 (20.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 16 (80.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | 3.48 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5359 | |
| HR (95% CI) [c] | 0.599 (0.117, 3.079) | |
| HR P-Value [c] | 0.5399 | |
| Heterogeneity p-value [d] | 0.2208 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.1 (44.2, 92.1) | 32.8 (1.3, 75.2) |
| 12 months | 51.4 (9.1, 83.2) | NE (NE, NE) |
| 18 months | 51.4 (9.1, 83.2) | NE (NE, NE) |
| 24 months | 51.4 (9.1, 83.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 17 (85.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | NE (7.23, NE) | 3.48 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4123 | |
| HR (95% CI) [c] | 0.505 (0.096, 2.655) | |
| HR P-Value [c] | 0.4196 | |
| Heterogeneity p-value [d] | 0.9224 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.4 (50.4, 95.9) | 33.3 (1.3, 75.8) |
| 12 months | 63.3 (17.4, 88.7) | NE (NE, NE) |
| 18 months | 63.3 (17.4, 88.7) | NE (NE, NE) |
| 24 months | 63.3 (17.4, 88.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 4 (19.0%) |
| Censored Patients, n (%) | 17 (85.0%) | 17 (81.0%) |
| Median (95% CI), (Months) [a] | NE (7.23, NE) | 3.48 (0.20, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0159 | |
| HR (95% CI) [c] | 0.104 (0.011, 0.956) | |
| HR P-Value [c] | 0.0456 | |
| Heterogeneity p-value [d] | 0.5121 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (59.1, 99.0) | 22.5 (0.9, 62.2) |
| 12 months | 55.7 (13.0, 84.5) | NE (NE, NE) |
| 18 months | 55.7 (13.0, 84.5) | NE (NE, NE) |
| 24 months | 55.7 (13.0, 84.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 18 (90.0%) | 19 (90.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7388 | |
| HR (95% CI) [c] | 0.715 (0.099, 5.181) | |
| HR P-Value [c] | 0.7400 | |
| Heterogeneity p-value [d] | 0.9196 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.4 (50.4, 95.9) | 66.7 (16.0, 91.4) |
| 12 months | 84.4 (50.4, 95.9) | NE (NE, NE) |
| 18 months | 84.4 (50.4, 95.9) | NE (NE, NE) |
| 24 months | 84.4 (50.4, 95.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 17 (85.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (3.09, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8551 | |
| HR (95% CI) [c] | 1.252 (0.112, 13.999) | |
| HR P-Value [c] | 0.8554 | |
| Heterogeneity p-value [d] | 0.3265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.5 (43.5, 95.1) | 90.0 (47.3, 98.5) |
| 12 months | 81.5 (43.5, 95.1) | NE (NE, NE) |
| 18 months | 54.3 (8.6, 85.9) | NE (NE, NE) |
| 24 months | 54.3 (8.6, 85.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 17 (85.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | 16.76 (2.89, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5262 | |
| HR (95% CI) [c] | 0.402 (0.022, 7.267) | |
| HR P-Value [c] | 0.5373 | |
| Heterogeneity p-value [d] | 0.6899 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.9 (43.3, 98.4) | NE (NE, NE) |
| 12 months | 66.7 (16.0, 91.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 10 (31.3%) |
| Censored Patients, n (%) | 28 (90.3%) | 22 (68.8%) |
| Median (95% CI), (Months) [a] | NE (5.72, NE) | 9.17 (2.79, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0300 | |
| HR (95% CI) [c] | 0.263 (0.072, 0.959) | |
| HR P-Value [c] | 0.0431 | |
| Heterogeneity p-value [d] | 0.6494 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.6 (42.1, 92.8) | 67.0 (44.3, 82.1) |
| 12 months | 77.6 (42.1, 92.8) | 0.0 (NE, NE) |
| 18 months | 77.6 (42.1, 92.8) | 0.0 (NE, NE) |
| 24 months | 77.6 (42.1, 92.8) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 1 (3.2%) | 4 (12.5%) |
| Censored Patients, n (%) | 30 (96.8%) | 28 (87.5%) |
| Median (95% CI), (Months) [a] | NE (12.45, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1301 | |
| HR (95% CI) [c] | 0.212 (0.023, 1.925) | |
| HR P-Value [c] | 0.1680 | |
| Heterogeneity p-value [d] | 0.6584 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 82.2 (58.7, 93.0) |
| 12 months | 100.0 (100.0, 100.0) | 82.2 (58.7, 93.0) |
| 18 months | 50.0 (0.6, 91.0) | NE (NE, NE) |
| 24 months | 50.0 (0.6, 91.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 5 (15.6%) |
| Censored Patients, n (%) | 29 (93.5%) | 27 (84.4%) |
| Median (95% CI), (Months) [a] | NE (5.78, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3973 | |
| HR (95% CI) [c] | 0.496 (0.095, 2.598) | |
| HR P-Value [c] | 0.4065 | |
| Heterogeneity p-value [d] | 0.2774 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.6 (42.8, 95.8) | 81.3 (56.6, 92.7) |
| 12 months | 82.6 (42.8, 95.8) | 54.2 (9.4, 85.3) |
| 18 months | 82.6 (42.8, 95.8) | NE (NE, NE) |
| 24 months | 82.6 (42.8, 95.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 1 (3.1%) |
| Censored Patients, n (%) | 29 (93.5%) | 31 (96.9%) |
| Median (95% CI), (Months) [a] | NE (5.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5410 | |
| HR (95% CI) [c] | 2.083 (0.188, 23.071) | |
| HR P-Value [c] | 0.5499 | |
| Heterogeneity p-value [d] | 0.2029 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.7 (42.0, 95.4) | 94.4 (66.6, 99.2) |
| 12 months | 81.7 (42.0, 95.4) | 94.4 (66.6, 99.2) |
| 18 months | 81.7 (42.0, 95.4) | NE (NE, NE) |
| 24 months | 81.7 (42.0, 95.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 1 (3.2%) | 6 (18.8%) |
| Censored Patients, n (%) | 30 (96.8%) | 26 (81.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 9.17 (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0637 | |
| HR (95% CI) [c] | 0.171 (0.021, 1.423) | |
| HR P-Value [c] | 0.1023 | |
| Heterogeneity p-value [d] | 0.5191 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.0 (69.5, 99.3) | 76.5 (51.3, 89.8) |
| 12 months | 95.0 (69.5, 99.3) | 38.2 (1.6, 80.0) |
| 18 months | 95.0 (69.5, 99.3) | NE (NE, NE) |
| 24 months | 95.0 (69.5, 99.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 1 (3.2%) | 4 (12.5%) |
| Censored Patients, n (%) | 30 (96.8%) | 28 (87.5%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (7.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0410 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9968 | |
| Heterogeneity p-value [d] | 0.2003 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 86.1 (62.1, 95.4) |
| 12 months | 100.0 (100.0, 100.0) | 64.6 (18.4, 89.3) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 50.0 (0.6, 91.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 10 (31.3%) |
| Censored Patients, n (%) | 27 (87.1%) | 22 (68.8%) |
| Median (95% CI), (Months) [a] | 12.45 (5.72, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0635 | |
| HR (95% CI) [c] | 0.349 (0.109, 1.117) | |
| HR P-Value [c] | 0.0760 | |
| Heterogeneity p-value [d] | 0.7551 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.6 (42.1, 92.8) | 56.3 (33.3, 74.1) |
| 12 months | 77.6 (42.1, 92.8) | 56.3 (33.3, 74.1) |
| 18 months | 38.8 (1.4, 81.0) | NE (NE, NE) |
| 24 months | 38.8 (1.4, 81.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 2 (6.3%) |
| Censored Patients, n (%) | 29 (93.5%) | 30 (93.8%) |
| Median (95% CI), (Months) [a] | 20.80 (20.80, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5637 | |
| HR (95% CI) [c] | 0.500 (0.045, 5.514) | |
| HR P-Value [c] | 0.5715 | |
| Heterogeneity p-value [d] | 0.4382 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.0 (69.5, 99.3) | 88.4 (60.3, 97.1) |
| 12 months | 95.0 (69.5, 99.3) | 88.4 (60.3, 97.1) |
| 18 months | 95.0 (69.5, 99.3) | NE (NE, NE) |
| 24 months | 47.5 (0.8, 89.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 4 (12.5%) |
| Censored Patients, n (%) | 29 (93.5%) | 28 (87.5%) |
| Median (95% CI), (Months) [a] | NE (5.72, NE) | 11.07 (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3819 | |
| HR (95% CI) [c] | 0.476 (0.087, 2.612) | |
| HR P-Value [c] | 0.3926 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.4 (47.2, 96.3) | 88.0 (67.3, 96.0) |
| 12 months | 84.4 (47.2, 96.3) | NE (NE, NE) |
| 18 months | 84.4 (47.2, 96.3) | NE (NE, NE) |
| 24 months | 84.4 (47.2, 96.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 9 (29.0%) | 9 (28.1%) |
| Censored Patients, n (%) | 22 (71.0%) | 23 (71.9%) |
| Median (95% CI), (Months) [a] | 5.72 (2.07, 12.45) | 8.97 (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7528 | |
| HR (95% CI) [c] | 1.169 (0.448, 3.053) | |
| HR P-Value [c] | 0.7494 | |
| Heterogeneity p-value [d] | 0.2208 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.4 (21.9, 72.1) | 67.0 (42.3, 83.0) |
| 12 months | 49.4 (21.9, 72.1) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 7 (21.9%) |
| Censored Patients, n (%) | 28 (90.3%) | 25 (78.1%) |
| Median (95% CI), (Months) [a] | 20.80 (5.55, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0625 | |
| HR (95% CI) [c] | 0.249 (0.052, 1.206) | |
| HR P-Value [c] | 0.0842 | |
| Heterogeneity p-value [d] | 0.9224 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.8 (36.5, 93.9) | 71.0 (48.4, 85.1) |
| 12 months | 77.8 (36.5, 93.9) | 71.0 (48.4, 85.1) |
| 18 months | 77.8 (36.5, 93.9) | NE (NE, NE) |
| 24 months | 38.9 (1.4, 81.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 8 (25.0%) |
| Censored Patients, n (%) | 26 (83.9%) | 24 (75.0%) |
| Median (95% CI), (Months) [a] | 13.90 (5.72, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2397 | |
| HR (95% CI) [c] | 0.510 (0.165, 1.572) | |
| HR P-Value [c] | 0.2411 | |
| Heterogeneity p-value [d] | 0.5121 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.8 (39.5, 89.7) | 64.2 (40.4, 80.5) |
| 12 months | 72.8 (39.5, 89.7) | 64.2 (40.4, 80.5) |
| 18 months | 36.4 (1.6, 78.2) | NE (NE, NE) |
| 24 months | 36.4 (1.6, 78.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 7 (21.9%) |
| Censored Patients, n (%) | 27 (87.1%) | 25 (78.1%) |
| Median (95% CI), (Months) [a] | NE (5.59, NE) | NE (3.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3787 | |
| HR (95% CI) [c] | 0.579 (0.169, 1.986) | |
| HR P-Value [c] | 0.3845 | |
| Heterogeneity p-value [d] | 0.9196 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.1 (35.0, 87.8) | 68.5 (44.4, 83.8) |
| 12 months | 69.1 (35.0, 87.8) | 68.5 (44.4, 83.8) |
| 18 months | 69.1 (35.0, 87.8) | NE (NE, NE) |
| 24 months | 69.1 (35.0, 87.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 3 (9.4%) |
| Censored Patients, n (%) | 26 (83.9%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | 20.80 (20.80, 20.83) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9229 | |
| HR (95% CI) [c] | 1.082 (0.218, 5.373) | |
| HR P-Value [c] | 0.9228 | |
| Heterogeneity p-value [d] | 0.3265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.1 (60.2, 95.0) | 86.1 (62.5, 95.3) |
| 12 months | 85.1 (60.2, 95.0) | 86.1 (62.5, 95.3) |
| 18 months | 85.1 (60.2, 95.0) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
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Table 18.2.6a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts sensitivity sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 3 (9.4%) |
| Censored Patients, n (%) | 27 (87.1%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | 16.66 (4.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8317 | |
| HR (95% CI) [c] | 1.203 (0.243, 5.963) | |
| HR P-Value [c] | 0.8211 | |
| Heterogeneity p-value [d] | 0.6899 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.2 (42.1, 91.8) | 88.1 (67.6, 96.0) |
| 12 months | 76.2 (42.1, 91.8) | 88.1 (67.6, 96.0) |
| 18 months | 38.1 (1.5, 80.1) | NE (NE, NE) |
| 24 months | 38.1 (1.5, 80.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored
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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 41 (22.8%) | 30 (18.4%) |
| Censored Patients, n (%) | 139 (77.2%) | 133 (81.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 4.27) | 3.32 (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1737 | |
| HR (95% CI) [c] | 1.394 (0.869, 2.236) | |
| HR P-Value [c] | 0.1682 | |
| Heterogeneity p-value [d] | 0.6054 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.3 (8.7, 37.6) | 41.8 (27.2, 55.7) |
| 12 months | NE (NE, NE) | 27.9 (8.0, 52.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 48 (26.7%) | 34 (20.9%) |
| Censored Patients, n (%) | 132 (73.3%) | 129 (79.1%) |
| Median (95% CI), (Months) [a] | 2.83 (1.91, 3.06) | 2.92 (1.81, 4.83) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8095 | |
| HR (95% CI) [c] | 1.066 (0.682, 1.665) | |
| HR P-Value [c] | 0.7799 | |
| Heterogeneity p-value [d] | 0.7909 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 31.2 (19.6, 43.5) | 28.8 (14.1, 45.3) |
| 12 months | 19.4 (8.3, 33.9) | NE (NE, NE) |
| 18 months | 19.4 (8.3, 33.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 47 (26.1%) | 26 (16.0%) |
| Censored Patients, n (%) | 133 (73.9%) | 137 (84.0%) |
| Median (95% CI), (Months) [a] | 2.07 (1.58, 2.99) | 3.12 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0858 | |
| HR (95% CI) [c] | 1.516 (0.938, 2.452) | |
| HR P-Value [c] | 0.0895 | |
| Heterogeneity p-value [d] | 0.5568 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 18.8 (8.2, 32.7) | 42.8 (27.2, 57.5) |
| 12 months | 11.3 (3.2, 24.8) | 42.8 (27.2, 57.5) |
| 18 months | 11.3 (3.2, 24.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 28 (15.6%) | 16 (9.8%) |
| Censored Patients, n (%) | 152 (84.4%) | 147 (90.2%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 2.83) | 2.30 (1.48, 5.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6192 | |
| HR (95% CI) [c] | 1.194 (0.642, 2.223) | |
| HR P-Value [c] | 0.5749 | |
| Heterogeneity p-value [d] | 0.4362 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 12.8 (3.7, 27.8) | 23.6 (6.7, 46.2) |
| 12 months | 4.3 (0.3, 17.5) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 40 (22.2%) | 21 (12.9%) |
| Censored Patients, n (%) | 140 (77.8%) | 142 (87.1%) |
| Median (95% CI), (Months) [a] | 2.83 (1.64, 3.02) | 5.06 (2.10, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0461 | |
| HR (95% CI) [c] | 1.716 (1.007, 2.925) | |
| HR P-Value [c] | 0.0472 | |
| Heterogeneity p-value [d] | 0.5243 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.0 (13.0, 38.9) | 46.5 (28.1, 63.0) |
| 12 months | 12.5 (3.7, 27.0) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 66 (36.7%) | 30 (18.4%) |
| Censored Patients, n (%) | 114 (63.3%) | 133 (81.6%) |
| Median (95% CI), (Months) [a] | 2.96 (1.91, 4.24) | 5.39 (4.24, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0071 | |
| HR (95% CI) [c] | 1.812 (1.173, 2.799) | |
| HR P-Value [c] | 0.0074 | |
| Heterogeneity p-value [d] | 0.1144 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.7 (20.5, 41.5) | 48.9 (33.5, 62.6) |
| 12 months | 18.9 (9.2, 31.2) | NE (NE, NE) |
| 18 months | 15.1 (6.1, 27.9) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 71 (39.4%) | 39 (23.9%) |
| Censored Patients, n (%) | 109 (60.6%) | 124 (76.1%) |
| Median (95% CI), (Months) [a] | 3.09 (2.83, 5.59) | 7.10 (5.91, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0109 | |
| HR (95% CI) [c] | 1.664 (1.122, 2.466) | |
| HR P-Value [c] | 0.0112 | |
| Heterogeneity p-value [d] | 0.9976 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.6 (25.4, 45.9) | 59.9 (47.3, 70.4) |
| 12 months | 28.8 (18.5, 40.0) | 38.8 (21.0, 56.3) |
| 18 months | 23.1 (11.3, 37.2) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 44 (24.4%) | 33 (20.2%) |
| Censored Patients, n (%) | 136 (75.6%) | 130 (79.8%) |
| Median (95% CI), (Months) [a] | 2.92 (1.71, 5.06) | 4.47 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2000 | |
| HR (95% CI) [c] | 1.344 (0.856, 2.112) | |
| HR P-Value [c] | 0.1995 | |
| Heterogeneity p-value [d] | 0.1290 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.2 (21.0, 46.0) | 49.4 (36.0, 61.5) |
| 12 months | 25.9 (13.7, 39.8) | 35.1 (16.7, 54.2) |
| 18 months | 25.9 (13.7, 39.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 31 (17.2%) | 24 (14.7%) |
| Censored Patients, n (%) | 149 (82.8%) | 139 (85.3%) |
| Median (95% CI), (Months) [a] | 1.91 (1.58, 2.96) | 2.83 (1.64, 4.47) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3599 | |
| HR (95% CI) [c] | 1.297 (0.754, 2.231) | |
| HR P-Value [c] | 0.3469 | |
| Heterogeneity p-value [d] | 0.6988 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 14.9 (4.3, 31.5) | 16.4 (4.6, 34.6) |
| 12 months | 14.9 (4.3, 31.5) | NE (NE, NE) |
| 18 months | 7.4 (0.7, 25.7) | NE (NE, NE) |
| 24 months | 7.4 (0.7, 25.7) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 76 (42.2%) | 54 (33.1%) |
| Censored Patients, n (%) | 104 (57.8%) | 109 (66.9%) |
| Median (95% CI), (Months) [a] | 2.79 (1.64, 4.24) | 3.02 (2.43, 5.39) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1882 | |
| HR (95% CI) [c] | 1.279 (0.901, 1.815) | |
| HR P-Value [c] | 0.1692 | |
| Heterogeneity p-value [d] | 0.2921 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.4 (18.9, 38.7) | 34.8 (23.4, 46.4) |
| 12 months | 11.4 (3.7, 23.7) | 25.3 (12.2, 40.7) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 50 (27.8%) | 18 (11.0%) |
| Censored Patients, n (%) | 130 (72.2%) | 145 (89.0%) |
| Median (95% CI), (Months) [a] | 4.96 (3.06, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0004 | |
| HR (95% CI) [c] | 2.576 (1.499, 4.427) | |
| HR P-Value [c] | 0.0006 | |
| Heterogeneity p-value [d] | 0.2015 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.3 (34.7, 57.2) | 77.9 (65.4, 86.4) |
| 12 months | 41.2 (29.0, 52.9) | 62.9 (43.1, 77.5) |
| 18 months | 41.2 (29.0, 52.9) | NE (NE, NE) |
| 24 months | 30.9 (13.2, 50.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 73 (40.6%) | 31 (19.0%) |
| Censored Patients, n (%) | 107 (59.4%) | 132 (81.0%) |
| Median (95% CI), (Months) [a] | 4.57 (2.99, 6.97) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0020 | |
| HR (95% CI) [c] | 1.937 (1.267, 2.961) | |
| HR P-Value [c] | 0.0023 | |
| Heterogeneity p-value [d] | 0.1505 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.3 (34.6, 53.6) | 65.1 (52.9, 74.9) |
| 12 months | 36.0 (26.0, 46.2) | 59.7 (43.9, 72.4) |
| 18 months | 23.9 (12.1, 37.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 64 (35.6%) | 26 (16.0%) |
| Censored Patients, n (%) | 116 (64.4%) | 137 (84.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 4.27) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0011 | |
| HR (95% CI) [c] | 2.111 (1.337, 3.333) | |
| HR P-Value [c] | 0.0013 | |
| Heterogeneity p-value [d] | 0.0673 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.6 (16.7, 37.5) | 58.1 (44.0, 69.9) |
| 12 months | 20.9 (11.3, 32.6) | 58.1 (44.0, 69.9) |
| 18 months | 20.9 (11.3, 32.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 67 (37.2%) | 38 (23.3%) |
| Censored Patients, n (%) | 113 (62.8%) | 125 (76.7%) |
| Median (95% CI), (Months) [a] | 1.84 (1.58, 2.83) | 4.17 (2.79, 7.26) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0030 | |
| HR (95% CI) [c] | 1.819 (1.219, 2.714) | |
| HR P-Value [c] | 0.0034 | |
| Heterogeneity p-value [d] | 0.8654 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 18.7 (10.3, 28.9) | 43.2 (29.7, 55.9) |
| 12 months | 10.7 (3.8, 21.6) | 29.6 (13.3, 48.0) |
| 18 months | 10.7 (3.8, 21.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 50 (27.8%) | 30 (18.4%) |
| Censored Patients, n (%) | 130 (72.2%) | 133 (81.6%) |
| Median (95% CI), (Months) [a] | 2.92 (2.73, 4.96) | 5.03 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1307 | |
| HR (95% CI) [c] | 1.427 (0.905, 2.251) | |
| HR P-Value [c] | 0.1258 | |
| Heterogeneity p-value [d] | 0.8813 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 31.3 (19.4, 43.9) | 45.4 (29.5, 60.0) |
| 12 months | 19.5 (8.3, 34.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 4 (20.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 16 (80.0%) |
| Median (95% CI), (Months) [a] | 2.84 (1.41, NE) | 4.37 (1.48, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8000 | |
| HR (95% CI) [c] | 1.188 (0.314, 4.489) | |
| HR P-Value [c] | 0.7993 | |
| Heterogeneity p-value [d] | 0.6054 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 16.7 (0.8, 51.7) | 0.0 (NE, NE) |
| 12 months | 16.7 (0.8, 51.7) | 0.0 (NE, NE) |
| 18 months | 16.7 (0.8, 51.7) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 3 (15.0%) |
| Censored Patients, n (%) | 10 (62.5%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | 6.97 (1.41, NE) | 2.99 (1.48, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5892 | |
| HR (95% CI) [c] | 0.677 (0.150, 3.048) | |
| HR P-Value [c] | 0.6112 | |
| Heterogeneity p-value [d] | 0.7909 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.9 (16.4, 78.8) | 0.0 (NE, NE) |
| 12 months | 17.3 (0.9, 52.0) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 3 (15.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | 4.34 (2.69, 15.31) | 4.27 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7109 | |
| HR (95% CI) [c] | 0.752 (0.166, 3.410) | |
| HR P-Value [c] | 0.7118 | |
| Heterogeneity p-value [d] | 0.5568 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.7 (5.6, 76.7) | 26.7 (1.0, 68.6) |
| 12 months | 20.8 (0.9, 59.5) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 1 (5.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 4.27 (1.58, 6.97) | 1.64 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6949 | |
| HR (95% CI) [c] | 0.702 (0.062, 7.918) | |
| HR P-Value [c] | 0.7751 | |
| Heterogeneity p-value [d] | 0.4362 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (5.8, 84.5) | 0.0 (NE, NE) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 3 (15.0%) |
| Censored Patients, n (%) | 14 (87.5%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | 4.93 (2.89, 6.97) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5579 | |
| HR (95% CI) [c] | 0.493 (0.045, 5.429) | |
| HR P-Value [c] | 0.5633 | |
| Heterogeneity p-value [d] | 0.5243 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (0.6, 91.0) | NE (NE, NE) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 5 (25.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 15 (75.0%) |
| Median (95% CI), (Months) [a] | 6.97 (1.41, NE) | 3.02 (0.20, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1714 | |
| HR (95% CI) [c] | 0.387 (0.091, 1.645) | |
| HR P-Value [c] | 0.1984 | |
| Heterogeneity p-value [d] | 0.1144 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (28.2, 87.8) | 0.0 (NE, NE) |
| 12 months | 22.2 (1.1, 60.8) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 3 (15.0%) |
| Censored Patients, n (%) | 10 (62.5%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | 5.68 (1.45, NE) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4322 | |
| HR (95% CI) [c] | 1.738 (0.430, 7.020) | |
| HR P-Value [c] | 0.4378 | |
| Heterogeneity p-value [d] | 0.9976 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.4 (6.6, 70.1) | 68.8 (29.1, 89.3) |
| 12 months | 18.7 (1.0, 54.6) | NE (NE, NE) |
| 18 months | 18.7 (1.0, 54.6) | NE (NE, NE) |
| 24 months | 18.7 (1.0, 54.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 4 (20.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 16 (80.0%) |
| Median (95% CI), (Months) [a] | 3.48 (2.89, NE) | 2.25 (1.45, 2.99) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0314 | |
| HR (95% CI) [c] | 0.180 (0.032, 1.020) | |
| HR P-Value [c] | 0.0527 | |
| Heterogeneity p-value [d] | 0.1290 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 20.0 (0.8, 58.2) | 0.0 (NE, NE) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 2 (10.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.41, 6.97) | 2.92 (1.48, 4.37) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9741 | |
| HR (95% CI) [c] | 0.952 (0.157, 5.778) | |
| HR P-Value [c] | 0.9570 | |
| Heterogeneity p-value [d] | 0.6988 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.0 (0.9, 66.5) | 0.0 (NE, NE) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 6 (30.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 14 (70.0%) |
| Median (95% CI), (Months) [a] | 3.25 (1.41, NE) | 3.02 (0.20, 6.74) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6468 | |
| HR (95% CI) [c] | 0.755 (0.227, 2.518) | |
| HR P-Value [c] | 0.6477 | |
| Heterogeneity p-value [d] | 0.2921 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.5 (1.2, 60.2) | 17.1 (0.8, 52.6) |
| 12 months | 22.5 (1.2, 60.2) | 0.0 (NE, NE) |
| 18 months | 22.5 (1.2, 60.2) | 0.0 (NE, NE) |
| 24 months | 22.5 (1.2, 60.2) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 3 (15.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | 7.16 (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8997 | |
| HR (95% CI) [c] | 0.902 (0.180, 4.508) | |
| HR P-Value [c] | 0.8995 | |
| Heterogeneity p-value [d] | 0.2015 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.6 (16.6, 87.0) | 83.3 (27.3, 97.5) |
| 12 months | 60.6 (16.6, 87.0) | NE (NE, NE) |
| 18 months | 60.6 (16.6, 87.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 5 (25.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 15 (75.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | 7.06 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7528 | |
| HR (95% CI) [c] | 0.809 (0.217, 3.025) | |
| HR P-Value [c] | 0.7532 | |
| Heterogeneity p-value [d] | 0.1505 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.5 (25.8, 84.0) | 69.3 (31.2, 89.1) |
| 12 months | 61.5 (25.8, 84.0) | NE (NE, NE) |
| 18 months | 61.5 (25.8, 84.0) | NE (NE, NE) |
| 24 months | 61.5 (25.8, 84.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 7 (43.8%) | 5 (25.0%) |
| Censored Patients, n (%) | 9 (56.3%) | 15 (75.0%) |
| Median (95% CI), (Months) [a] | 5.68 (1.45, 8.48) | 3.01 (1.18, 4.37) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2468 | |
| HR (95% CI) [c] | 0.466 (0.120, 1.803) | |
| HR P-Value [c] | 0.2685 | |
| Heterogeneity p-value [d] | 0.0673 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.8 (13.5, 74.9) | 0.0 (NE, NE) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 2 (10.0%) |
| Censored Patients, n (%) | 14 (87.5%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | NE (1.41, NE) | 2.99 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6043 | |
| HR (95% CI) [c] | 1.797 (0.237, 13.608) | |
| HR P-Value [c] | 0.5702 | |
| Heterogeneity p-value [d] | 0.8654 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 2 (10.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 5.95 (1.41, NE) | 2.99 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9651 | |
| HR (95% CI) [c] | 1.069 (0.177, 6.469) | |
| HR P-Value [c] | 0.9424 | |
| Heterogeneity p-value [d] | 0.8813 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.0 (6.6, 73.4) | NE (NE, NE) |
| 12 months | 20.0 (1.0, 57.3) | NE (NE, NE) |
| 18 months | 20.0 (1.0, 57.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Appetite loss - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 35 (25.7%) | 23 (18.7%) |
| Censored Patients, n (%) | 101 (74.3%) | 100 (81.3%) |
| Median (95% CI), (Months) [a] | 2.83 (1.61, 4.17) | 3.12 (2.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1543 | |
| HR (95% CI) [c] | 1.471 (0.869, 2.492) | |
| HR P-Value [c] | 0.1509 | |
| Heterogeneity p-value [d] | 0.4887 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 17.2 (6.8, 31.6) | 38.5 (21.8, 55.0) |
| 12 months | 11.5 (2.8, 27.1) | 25.7 (6.9, 50.0) |
| 18 months | 11.5 (2.8, 27.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 36 (26.5%) | 27 (22.0%) |
| Censored Patients, n (%) | 100 (73.5%) | 96 (78.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.64, 6.97) | 2.99 (1.64, 4.83) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6376 | |
| HR (95% CI) [c] | 0.894 (0.533, 1.498) | |
| HR P-Value [c] | 0.6697 | |
| Heterogeneity p-value [d] | 0.3461 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.3 (23.7, 50.9) | 21.7 (6.8, 41.9) |
| 12 months | 20.5 (8.2, 36.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 38 (27.9%) | 22 (17.9%) |
| Censored Patients, n (%) | 98 (72.1%) | 101 (82.1%) |
| | | |
| Median (95% CI), (Months) [a] | 1.84 (1.58, 3.91) | 3.12 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1529 | |
| HR (95% CI) [c] | 1.468 (0.867, 2.485) | |
| HR P-Value [c] | 0.1529 | |
| Heterogeneity p-value [d] | 0.9910 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 14.5 (5.2, 28.3) | 32.8 (16.3, 50.3) |
| 12 months | 7.2 (1.4, 19.9) | 32.8 (16.3, 50.3) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 21 (15.4%) | 12 (9.8%) |
| Censored Patients, n (%) | 115 (84.6%) | 111 (90.2%) |
| Median (95% CI), (Months) [a] | 1.61 (1.45, 4.21) | 1.81 (1.48, 5.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6768 | |
| HR (95% CI) [c] | 0.884 (0.430, 1.817) | |
| HR P-Value [c] | 0.7374 | |
| Heterogeneity p-value [d] | 0.2385 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.0 (8.2, 42.2) | 18.7 (3.1, 44.5) |
| 12 months | 5.8 (0.4, 22.7) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 29 (21.3%) | 15 (12.2%) |
| Censored Patients, n (%) | 107 (78.7%) | 108 (87.8%) |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 3.02) | 9.69 (2.30, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0345 | |
| HR (95% CI) [c] | 1.962 (1.045, 3.683) | |
| HR P-Value [c] | 0.0361 | |
| Heterogeneity p-value [d] | 0.2664 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.4 (9.9, 38.1) | 50.0 (27.7, 68.9) |
| 12 months | 12.4 (3.0, 29.1) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 52 (38.2%) | 26 (21.1%) |
| Censored Patients, n (%) | 84 (61.8%) | 97 (78.9%) |
| Median (95% CI), (Months) [a] | 2.89 (1.84, 4.34) | 4.40 (2.89, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3046 | |
| HR (95% CI) [c] | 1.295 (0.805, 2.084) | |
| HR P-Value [c] | 0.2857 | |
| Heterogeneity p-value [d] | 0.1109 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.9 (22.5, 45.7) | 39.4 (23.0, 55.4) |
| 12 months | 22.0 (11.3, 35.0) | NE (NE, NE) |
| 18 months | 18.3 (8.2, 31.7) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 59 (43.4%) | 29 (23.6%) |
| Censored Patients, n (%) | 77 (56.6%) | 94 (76.4%) |
| Median (95% CI), (Months) [a] | 3.09 (2.79, 4.34) | 6.93 (3.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0229 | |
| HR (95% CI) [c] | 1.679 (1.074, 2.624) | |
| HR P-Value [c] | 0.0230 | |
| Heterogeneity p-value [d] | 0.8782 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.5 (19.0, 40.8) | 55.2 (39.8, 68.2) |
| 12 months | 24.5 (14.3, 36.2) | NE (NE, NE) |
| 18 months | 18.4 (7.4, 33.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Financial Problems - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 34 (25.0%) | 28 (22.8%) |
| Censored Patients, n (%) | 102 (75.0%) | 95 (77.2%) |
| Median (95% CI), (Months) [a] | 2.92 (1.58, 4.53) | 2.86 (1.64, 8.80) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6006 | |
| HR (95% CI) [c] | 1.147 (0.695, 1.893) | |
| HR P-Value [c] | 0.5903 | |
| Heterogeneity p-value [d] | 0.5794 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.6 (17.5, 44.8) | 39.4 (24.6, 54.0) |
| 12 months | 23.0 (10.8, 37.9) | 25.4 (9.4, 45.1) |
| 18 months | 23.0 (10.8, 37.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 25 (18.4%) | 16 (13.0%) |
| Censored Patients, n (%) | 111 (81.6%) | 107 (87.0%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 2.96) | 3.19 (1.58, 5.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1758 | |
| HR (95% CI) [c] | 1.572 (0.832, 2.971) | |
| HR P-Value [c] | 0.1634 | |
| Heterogeneity p-value [d] | 0.2980 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 14.5 (3.9, 31.7) | 14.6 (2.7, 35.9) |
| 12 months | 9.7 (1.8, 26.0) | NE (NE, NE) |
| 18 months | 9.7 (1.8, 26.0) | NE (NE, NE) |
| 24 months | 9.7 (1.8, 26.0) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 60 (44.1%) | 40 (32.5%) |
| Censored Patients, n (%) | 76 (55.9%) | 83 (67.5%) |
| Median (95% CI), (Months) [a] | 2.79 (1.61, 4.21) | 2.89 (1.74, 5.03) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5092 | |
| HR (95% CI) [c] | 1.164 (0.778, 1.740) | |
| HR P-Value [c] | 0.4603 | |
| Heterogeneity p-value [d] | 0.8093 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.0 (16.7, 38.4) | 30.2 (17.6, 43.8) |
| 12 months | 10.1 (3.1, 22.0) | 19.8 (7.4, 36.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 40 (29.4%) | 16 (13.0%) |
| Censored Patients, n (%) | 96 (70.6%) | 107 (87.0%) |
| Median (95% CI), (Months) [a] | 5.62 (3.06, NE) | NE (6.93, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0127 | |
| HR (95% CI) [c] | 2.068 (1.155, 3.702) | |
| HR P-Value [c] | 0.0145 | |
| Heterogeneity p-value [d] | 0.5807 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.8 (33.7, 58.8) | 78.7 (64.2, 87.9) |
| 12 months | 41.3 (27.9, 54.1) | 52.7 (31.1, 70.4) |
| 18 months | 41.3 (27.9, 54.1) | NE (NE, NE) |
| 24 months | 27.5 (8.1, 51.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 56 (41.2%) | 21 (17.1%) |
| Censored Patients, n (%) | 80 (58.8%) | 102 (82.9%) |
| Median (95% CI), (Months) [a] | 4.21 (2.86, 7.43) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0022 | |
| HR (95% CI) [c] | 2.174 (1.310, 3.606) | |
| HR P-Value [c] | 0.0026 | |
| Heterogeneity p-value [d] | 0.1530 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.1 (32.2, 53.6) | 66.9 (52.2, 78.0) |
| 12 months | 36.3 (24.9, 47.7) | 60.8 (42.6, 74.9) |
| 18 months | 22.7 (8.7, 40.6) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 54 (39.7%) | 20 (16.3%) |
| Censored Patients, n (%) | 82 (60.3%) | 103 (83.7%) |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 4.24) | NE (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0018 | |
| HR (95% CI) [c] | 2.230 (1.334, 3.728) | |
| HR P-Value [c] | 0.0022 | |
| Heterogeneity p-value [d] | 0.2035 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.9 (17.3, 39.4) | 57.8 (41.2, 71.3) |
| 12 months | 19.5 (9.7, 31.7) | 57.8 (41.2, 71.3) |
| 18 months | 19.5 (9.7, 31.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Social Functioning - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 48 (35.3%) | 30 (24.4%) |
| Censored Patients, n (%) | 88 (64.7%) | 93 (75.6%) |
| Median (95% CI), (Months) [a] | 2.07 (1.58, 2.83) | 3.06 (2.14, 5.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1717 | |
| HR (95% CI) [c] | 1.383 (0.875, 2.186) | |
| HR P-Value [c] | 0.1655 | |
| Heterogeneity p-value [d] | 0.0392 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.8 (12.5, 34.9) | 31.6 (16.2, 48.3) |
| 12 months | 16.6 (7.4, 29.1) | 19.0 (5.8, 37.8) |
| 18 months | 16.6 (7.4, 29.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 42 (30.9%) | 19 (15.4%) |
| Censored Patients, n (%) | 94 (69.1%) | 104 (84.6%) |
| | | |
| Median (95% CI), (Months) [a] | 3.09 (1.58, 5.45) | 5.03 (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1251 | |
| HR (95% CI) [c] | 1.546 (0.894, 2.673) | |
| HR P-Value [c] | 0.1187 | |
| Heterogeneity p-value [d] | 0.5398 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.7 (18.2, 44.0) | 45.7 (25.2, 64.0) |
| 12 months | 18.1 (7.8, 31.8) | NE (NE, NE) |
| 18 months | 18.1 (7.8, 31.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 11 (18.3%) | 11 (18.3%) |
| Censored Patients, n (%) | 49 (81.7%) | 49 (81.7%) |
| Median (95% CI), (Months) [a] | 4.27 (1.58, NE) | 4.34 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8295 | |
| HR (95% CI) [c] | 1.101 (0.467, 2.595) | |
| HR P-Value [c] | 0.8264 | |
| Heterogeneity p-value [d] | 0.4887 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 22.3 (1.8, 57.3) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 18 (30.0%) | 10 (16.7%) |
| Censored Patients, n (%) | 42 (70.0%) | 50 (83.3%) |
| Median (95% CI), (Months) [a] | 2.76 (1.64, 2.96) | 2.92 (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2867 | |
| HR (95% CI) [c] | 1.544 (0.701, 3.401) | |
| HR P-Value [c] | 0.2813 | |
| Heterogeneity p-value [d] | 0.3461 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.5 (6.0, 43.2) | 32.4 (10.7, 56.7) |
| 12 months | 10.8 (0.9, 34.8) | NE (NE, NE) |
| 18 months | 10.8 (0.9, 34.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 14 (23.3%) | 7 (11.7%) |
| Censored Patients, n (%) | 46 (76.7%) | 53 (88.3%) |
| Median (95% CI), (Months) [a] | 2.99 (1.91, 15.31) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5016 | |
| HR (95% CI) [c] | 1.349 (0.535, 3.403) | |
| HR P-Value [c] | 0.5256 | |
| Heterogeneity p-value [d] | 0.9910 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.6 (20.9, 64.4) | 57.1 (28.9, 77.7) |
| 12 months | 29.1 (6.8, 56.6) | NE (NE, NE) |
| 18 months | 14.5 (1.0, 44.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 10 (16.7%) | 5 (8.3%) |
| Censored Patients, n (%) | 50 (83.3%) | 55 (91.7%) |
| Median (95% CI), (Months) [a] | 1.58 (1.38, 1.91) | 2.23 (1.45, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1682 | |
| HR (95% CI) [c] | 2.200 (0.664, 7.288) | |
| HR P-Value [c] | 0.1969 | |
| Heterogeneity p-value [d] | 0.2385 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 33.3 (4.6, 67.6) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 13 (21.7%) | 9 (15.0%) |
| Censored Patients, n (%) | 47 (78.3%) | 51 (85.0%) |
| Median (95% CI), (Months) [a] | 2.99 (1.54, 8.54) | 2.10 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9377 | |
| HR (95% CI) [c] | 1.027 (0.424, 2.486) | |
| HR P-Value [c] | 0.9535 | |
| Heterogeneity p-value [d] | 0.2664 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.1 (12.9, 60.2) | 35.0 (10.9, 60.8) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 19 (31.7%) | 9 (15.0%) |
| Censored Patients, n (%) | 41 (68.3%) | 51 (85.0%) |
| Median (95% CI), (Months) [a] | 2.99 (1.84, 7.00) | 5.65 (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0077 | |
| HR (95% CI) [c] | 2.849 (1.278, 6.351) | |
| HR P-Value [c] | 0.0105 | |
| Heterogeneity p-value [d] | 0.1109 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.6 (9.7, 51.1) | 48.0 (20.5, 71.2) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 18 (30.0%) | 13 (21.7%) |
| Censored Patients, n (%) | 42 (70.0%) | 47 (78.3%) |
| Median (95% CI), (Months) [a] | 6.01 (2.89, 21.88) | 7.26 (7.10, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2691 | |
| HR (95% CI) [c] | 1.503 (0.727, 3.108) | |
| HR P-Value [c] | 0.2715 | |
| Heterogeneity p-value [d] | 0.8782 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.7 (35.7, 70.3) | 70.6 (51.4, 83.4) |
| 12 months | 30.4 (7.4, 58.1) | 42.4 (12.8, 69.9) |
| 18 months | 30.4 (7.4, 58.1) | 0.0 (NE, NE) |
| 24 months | 15.2 (1.0, 46.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 14 (23.3%) | 9 (15.0%) |
| Censored Patients, n (%) | 46 (76.7%) | 51 (85.0%) |
| Median (95% CI), (Months) [a] | 2.96 (1.64, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3106 | |
| HR (95% CI) [c] | 1.537 (0.663, 3.563) | |
| HR P-Value [c] | 0.3163 | |
| Heterogeneity p-value [d] | 0.5794 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.6 (12.0, 55.4) | 59.9 (36.2, 77.2) |
| 12 months | 32.6 (12.0, 55.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 10 (16.7%) | 10 (16.7%) |
| Censored Patients, n (%) | 50 (83.3%) | 50 (83.3%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 5.59) | 2.56 (1.48, 4.47) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6297 | |
| HR (95% CI) [c] | 0.799 (0.323, 1.973) | |
| HR P-Value [c] | 0.6260 | |
| Heterogeneity p-value [d] | 0.2980 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 17.4 (1.2, 49.9) | NE (NE, NE) |
| 12 months | 17.4 (1.2, 49.9) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 21 (35.0%) | 20 (33.3%) |
| Censored Patients, n (%) | 39 (65.0%) | 40 (66.7%) |
| | | |
| Median (95% CI), (Months) [a] | 1.94 (1.58, NE) | 4.30 (2.43, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3735 | |
| HR (95% CI) [c] | 1.328 (0.717, 2.458) | |
| HR P-Value [c] | 0.3671 | |
| Heterogeneity p-value [d] | 0.8093 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.5 (14.9, 51.6) | 35.6 (16.6, 55.2) |
| 12 months | 32.5 (14.9, 51.6) | NE (NE, NE) |
| 18 months | 32.5 (14.9, 51.6) | NE (NE, NE) |
| 24 months | 32.5 (14.9, 51.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 13 (21.7%) | 5 (8.3%) |
| Censored Patients, n (%) | 47 (78.3%) | 55 (91.7%) |
| Median (95% CI), (Months) [a] | NE (2.96, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0260 | |
| HR (95% CI) [c] | 3.062 (1.085, 8.642) | |
| HR P-Value [c] | 0.0345 | |
| Heterogeneity p-value [d] | 0.5807 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.7 (30.1, 69.6) | 78.6 (54.8, 90.8) |
| 12 months | 51.7 (30.1, 69.6) | NE (NE, NE) |
| 18 months | 51.7 (30.1, 69.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 21 (35.0%) | 15 (25.0%) |
| Censored Patients, n (%) | 39 (65.0%) | 45 (75.0%) |
| Median (95% CI), (Months) [a] | 6.01 (2.99, NE) | 9.59 (4.24, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6097 | |
| HR (95% CI) [c] | 1.189 (0.608, 2.326) | |
| HR P-Value [c] | 0.6137 | |
| Heterogeneity p-value [d] | 0.1530 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.4 (33.0, 67.0) | 63.5 (44.4, 77.5) |
| 12 months | 40.4 (21.6, 58.6) | NE (NE, NE) |
| 18 months | 30.3 (10.9, 52.6) | NE (NE, NE) |
| 24 months | 30.3 (10.9, 52.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 17 (28.3%) | 11 (18.3%) |
| Censored Patients, n (%) | 43 (71.7%) | 49 (81.7%) |
| | | |
| Median (95% CI), (Months) [a] | 4.63 (1.91, 9.92) | 4.21 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6706 | |
| HR (95% CI) [c] | 1.185 (0.549, 2.556) | |
| HR P-Value [c] | 0.6650 | |
| Heterogeneity p-value [d] | 0.2035 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.1 (10.7, 52.4) | 47.9 (24.7, 67.8) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 21 (35.0%) | 10 (16.7%) |
| Censored Patients, n (%) | 39 (65.0%) | 50 (83.3%) |
| Median (95% CI), (Months) [a] | 1.64 (1.48, 2.96) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0012 | |
| HR (95% CI) [c] | 3.298 (1.527, 7.120) | |
| HR P-Value [c] | 0.0024 | |
| Heterogeneity p-value [d] | 0.0392 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 7.7 (0.6, 28.0) | 60.3 (38.4, 76.6) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 13 (21.7%) | 13 (21.7%) |
| Censored Patients, n (%) | 47 (78.3%) | 47 (78.3%) |
| Median (95% CI), (Months) [a] | 2.89 (1.64, NE) | 5.06 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7275 | |
| HR (95% CI) [c] | 1.138 (0.526, 2.458) | |
| HR P-Value [c] | 0.7430 | |
| Heterogeneity p-value [d] | 0.5398 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.7 (21.5, 62.5) | 43.8 (20.7, 64.8) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 1 (4.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | 1.68 (1.58, 7.10) | NE (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0221 | |
| HR (95% CI) [c] | 8.273 (0.988, 69.261) | |
| HR P-Value [c] | 0.0513 | |
| Heterogeneity p-value [d] | 0.3328 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.4 (1.2, 58.6) | 80.0 (20.4, 96.9) |
| 12 months | 0.0 (NE, NE) | 80.0 (20.4, 96.9) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 5 (20.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | 4.57 (1.38, NE) | 3.37 (1.41, 4.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2819 | |
| HR (95% CI) [c] | 0.410 (0.077, 2.180) | |
| HR P-Value [c] | 0.2959 | |
| Heterogeneity p-value [d] | 0.9171 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 0.0 (NE, NE) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 7 (31.8%) | 5 (20.0%) |
| Censored Patients, n (%) | 15 (68.2%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | 1.61 (1.58, NE) | 1.58 (1.45, 3.12) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1727 | |
| HR (95% CI) [c] | 0.471 (0.143, 1.548) | |
| HR P-Value [c] | 0.2151 | |
| Heterogeneity p-value [d] | 0.2239 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 0.0 (NE, NE) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 4 (18.2%) | 3 (12.0%) |
| Censored Patients, n (%) | 18 (81.8%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | 1.58 (1.41, 3.02) | 2.32 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2439 | |
| HR (95% CI) [c] | 2.526 (0.544, 11.727) | |
| HR P-Value [c] | 0.2370 | |
| Heterogeneity p-value [d] | 0.8743 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | NE (NE, NE) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 5 (20.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | 4.57 (1.38, NE) | 4.30 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7215 | |
| HR (95% CI) [c] | 1.267 (0.351, 4.582) | |
| HR P-Value [c] | 0.7178 | |
| Heterogeneity p-value [d] | 0.6779 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 17.8 (0.9, 52.9) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 8 (36.4%) | 6 (24.0%) |
| Censored Patients, n (%) | 14 (63.6%) | 19 (76.0%) |
| Median (95% CI), (Months) [a] | 2.96 (1.41, 20.93) | 3.02 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7888 | |
| HR (95% CI) [c] | 1.164 (0.389, 3.479) | |
| HR P-Value [c] | 0.7859 | |
| Heterogeneity p-value [d] | 0.4154 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.9 (12.6, 65.0) | NE (NE, NE) |
| 12 months | 38.9 (12.6, 65.0) | NE (NE, NE) |
| 18 months | 38.9 (12.6, 65.0) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 9 (40.9%) | 4 (16.0%) |
| Censored Patients, n (%) | 13 (59.1%) | 21 (84.0%) |
| | | |
| Median (95% CI), (Months) [a] | 2.96 (1.58, 8.48) | NE (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0616 | |
| HR (95% CI) [c] | 2.970 (0.903, 9.766) | |
| HR P-Value [c] | 0.0731 | |
| Heterogeneity p-value [d] | 0.5024 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.7 (6.0, 59.1) | 55.4 (16.1, 82.6) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 4 (18.2%) | 5 (20.0%) |
| Censored Patients, n (%) | 18 (81.8%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | 7.10 (1.64, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4394 | |
| HR (95% CI) [c] | 0.587 (0.153, 2.248) | |
| HR P-Value [c] | 0.4371 | |
| Heterogeneity p-value [d] | 0.3568 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.9 (27.6, 92.5) | 50.0 (18.4, 75.3) |
| 12 months | NE (NE, NE) | 50.0 (18.4, 75.3) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 4 (18.2%) | 4 (16.0%) |
| Censored Patients, n (%) | 18 (81.8%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | 2.96 (1.58, 25.53) | 2.92 (1.58, 5.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9012 | |
| HR (95% CI) [c] | 0.953 (0.205, 4.435) | |
| HR P-Value [c] | 0.9508 | |
| Heterogeneity p-value [d] | 0.1803 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.0 (1.2, 71.9) | 0.0 (NE, NE) |
| 12 months | 30.0 (1.2, 71.9) | 0.0 (NE, NE) |
| 18 months | 30.0 (1.2, 71.9) | 0.0 (NE, NE) |
| 24 months | 30.0 (1.2, 71.9) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 8 (36.4%) | 11 (44.0%) |
| Censored Patients, n (%) | 14 (63.6%) | 14 (56.0%) |
| Median (95% CI), (Months) [a] | 2.96 (1.58, 5.65) | 2.43 (1.54, 3.02) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7362 | |
| HR (95% CI) [c] | 0.838 (0.330, 2.130) | |
| HR P-Value [c] | 0.7102 | |
| Heterogeneity p-value [d] | 0.7187 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 19.0 (3.1, 45.2) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 7 (31.8%) | 3 (12.0%) |
| Censored Patients, n (%) | 15 (68.2%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | 4.57 (1.58, NE) | 7.16 (4.30, 7.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1599 | |
| HR (95% CI) [c] | 2.419 (0.612, 9.563) | |
| HR P-Value [c] | 0.2078 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.0 (11.3, 66.5) | 85.7 (33.4, 97.9) |
| 12 months | 39.0 (11.3, 66.5) | 0.0 (NE, NE) |
| 18 months | 39.0 (11.3, 66.5) | 0.0 (NE, NE) |
| 24 months | 39.0 (11.3, 66.5) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 7 (31.8%) | 3 (12.0%) |
| Censored Patients, n (%) | 15 (68.2%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | 5.68 (2.96, 18.20) | NE (5.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2927 | |
| HR (95% CI) [c] | 2.160 (0.516, 9.035) | |
| HR P-Value [c] | 0.2917 | |
| Heterogeneity p-value [d] | 0.3505 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.7 (10.8, 69.5) | 65.0 (17.7, 89.8) |
| 12 months | 40.7 (10.8, 69.5) | NE (NE, NE) |
| 18 months | 40.7 (10.8, 69.5) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 4 (16.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | 7.10 (1.58, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8831 | |
| HR (95% CI) [c] | 1.116 (0.293, 4.259) | |
| HR P-Value [c] | 0.8722 | |
| Heterogeneity p-value [d] | 0.3968 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.3 (15.3, 77.8) | 52.6 (14.8, 80.5) |
| 12 months | 33.6 (5.7, 66.0) | NE (NE, NE) |
| 18 months | 33.6 (5.7, 66.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 5 (22.7%) | 4 (16.0%) |
| Censored Patients, n (%) | 17 (77.3%) | 21 (84.0%) |
| | | |
| Median (95% CI), (Months) [a] | 2.28 (1.38, NE) | 4.09 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3290 | |
| HR (95% CI) [c] | 1.929 (0.514, 7.236) | |
| HR P-Value [c] | 0.3298 | |
| Heterogeneity p-value [d] | 0.0439 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (5.6, 65.8) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 5 (22.7%) | 2 (8.0%) |
| Censored Patients, n (%) | 17 (77.3%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | 1.58 (1.51, 3.02) | NE (2.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0116 | |
| HR (95% CI) [c] | 7.116 (1.318, 38.408) | |
| HR P-Value [c] | 0.0225 | |
| Heterogeneity p-value [d] | 0.3597 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 55.6 (7.3, 87.6) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 5 (13.9%) |
| Censored Patients, n (%) | 32 (82.1%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | 4.27 (1.45, NE) | 3.32 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8028 | |
| HR (95% CI) [c] | 1.160 (0.367, 3.668) | |
| HR P-Value [c] | 0.8009 | |
| Heterogeneity p-value [d] | 0.3328 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 46.7 (15.0, 73.7) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 13 (33.3%) | 7 (19.4%) |
| Censored Patients, n (%) | 26 (66.7%) | 29 (80.6%) |
| Median (95% CI), (Months) [a] | 2.07 (1.51, NE) | 2.92 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8863 | |
| HR (95% CI) [c] | 1.077 (0.422, 2.745) | |
| HR P-Value [c] | 0.8772 | |
| Heterogeneity p-value [d] | 0.9171 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.6 (16.3, 59.1) | 22.9 (3.5, 52.2) |
| 12 months | 28.2 (8.8, 51.8) | NE (NE, NE) |
| 18 months | 28.2 (8.8, 51.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 6 (16.7%) |
| Censored Patients, n (%) | 32 (82.1%) | 30 (83.3%) |
| Median (95% CI), (Months) [a] | 10.45 (1.64, NE) | 3.02 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5751 | |
| HR (95% CI) [c] | 0.696 (0.222, 2.186) | |
| HR P-Value [c] | 0.5352 | |
| Heterogeneity p-value [d] | 0.2239 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.9 (29.8, 81.7) | 46.7 (16.8, 72.2) |
| 12 months | 40.6 (8.3, 72.2) | NE (NE, NE) |
| 18 months | 20.3 (1.1, 57.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 5 (13.9%) |
| Censored Patients, n (%) | 32 (82.1%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | 1.64 (1.45, 2.83) | 1.54 (1.45, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6802 | |
| HR (95% CI) [c] | 1.256 (0.358, 4.409) | |
| HR P-Value [c] | 0.7215 | |
| Heterogeneity p-value [d] | 0.8743 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 20.0 (0.8, 58.2) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 5 (13.9%) |
| Censored Patients, n (%) | 32 (82.1%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | 2.99 (1.41, NE) | 3.50 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6293 | |
| HR (95% CI) [c] | 0.727 (0.210, 2.522) | |
| HR P-Value [c] | 0.6156 | |
| Heterogeneity p-value [d] | 0.6779 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.4 (16.5, 75.9) | 33.3 (5.6, 65.8) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 13 (33.3%) | 6 (16.7%) |
| Censored Patients, n (%) | 26 (66.7%) | 30 (83.3%) |
| Median (95% CI), (Months) [a] | 4.24 (1.91, 8.41) | 5.39 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4163 | |
| HR (95% CI) [c] | 1.525 (0.549, 4.232) | |
| HR P-Value [c] | 0.4178 | |
| Heterogeneity p-value [d] | 0.4154 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.7 (15.2, 63.5) | 39.2 (7.7, 71.1) |
| 12 months | 13.2 (0.9, 42.3) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 10 (25.6%) | 5 (13.9%) |
| Censored Patients, n (%) | 29 (74.4%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | 21.88 (2.89, NE) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2486 | |
| HR (95% CI) [c] | 1.884 (0.630, 5.634) | |
| HR P-Value [c] | 0.2573 | |
| Heterogeneity p-value [d] | 0.5024 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.3 (35.7, 76.7) | 73.6 (46.4, 88.5) |
| 12 months | 59.3 (35.7, 76.7) | NE (NE, NE) |
| 18 months | 59.3 (35.7, 76.7) | NE (NE, NE) |
| 24 months | 29.7 (1.9, 68.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 9 (23.1%) | 3 (8.3%) |
| Censored Patients, n (%) | 30 (76.9%) | 33 (91.7%) |
| | | |
| Median (95% CI), (Months) [a] | 2.89 (1.41, 5.06) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0376 | |
| HR (95% CI) [c] | 3.649 (0.982, 13.564) | |
| HR P-Value [c] | 0.0533 | |
| Heterogeneity p-value [d] | 0.3568 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 12.8 (0.7, 42.2) | 66.7 (27.2, 88.1) |
| 12 months | 12.8 (0.7, 42.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 4 (10.3%) | 4 (11.1%) |
| Censored Patients, n (%) | 35 (89.7%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | 1.91 (1.41, 12.55) | 1.56 (1.45, 1.64) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2138 | |
| HR (95% CI) [c] | 0.332 (0.059, 1.860) | |
| HR P-Value [c] | 0.2099 | |
| Heterogeneity p-value [d] | 0.1803 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.0 (5.2, 75.3) | 0.0 (NE, NE) |
| 12 months | 40.0 (5.2, 75.3) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 14 (35.9%) | 8 (22.2%) |
| Censored Patients, n (%) | 25 (64.1%) | 28 (77.8%) |
| Median (95% CI), (Months) [a] | 2.99 (1.48, NE) | 6.67 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3132 | |
| HR (95% CI) [c] | 1.556 (0.652, 3.717) | |
| HR P-Value [c] | 0.3194 | |
| Heterogeneity p-value [d] | 0.7187 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.4 (14.6, 55.4) | 51.0 (17.2, 77.2) |
| 12 months | 34.4 (14.6, 55.4) | NE (NE, NE) |
| 18 months | 34.4 (14.6, 55.4) | NE (NE, NE) |
| 24 months | 34.4 (14.6, 55.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 8 (20.5%) | 2 (5.6%) |
| Censored Patients, n (%) | 31 (79.5%) | 34 (94.4%) |
| Median (95% CI), (Months) [a] | NE (2.99, NE) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1207 | |
| HR (95% CI) [c] | 3.189 (0.676, 15.045) | |
| HR P-Value [c] | 0.1429 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.9 (33.4, 77.5) | 81.7 (42.0, 95.4) |
| 12 months | 58.9 (33.4, 77.5) | 81.7 (42.0, 95.4) |
| 18 months | 58.9 (33.4, 77.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 12 (30.8%) | 9 (25.0%) |
| Censored Patients, n (%) | 27 (69.2%) | 27 (75.0%) |
| Median (95% CI), (Months) [a] | 12.39 (2.89, NE) | 7.06 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9675 | |
| HR (95% CI) [c] | 1.016 (0.419, 2.464) | |
| HR P-Value [c] | 0.9712 | |
| Heterogeneity p-value [d] | 0.3505 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.7 (28.8, 70.4) | 62.5 (38.1, 79.6) |
| 12 months | 51.7 (28.8, 70.4) | NE (NE, NE) |
| 18 months | 38.8 (13.7, 63.7) | NE (NE, NE) |
| 24 months | 38.8 (13.7, 63.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 11 (28.2%) | 5 (13.9%) |
| Censored Patients, n (%) | 28 (71.8%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | 4.67 (1.45, 9.92) | 3.02 (1.18, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9591 | |
| HR (95% CI) [c] | 1.036 (0.353, 3.041) | |
| HR P-Value [c] | 0.9485 | |
| Heterogeneity p-value [d] | 0.3968 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.3 (9.1, 58.7) | 46.7 (15.0, 73.7) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 14 (35.9%) | 7 (19.4%) |
| Censored Patients, n (%) | 25 (64.1%) | 29 (80.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.51, 4.67) | 3.06 (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2428 | |
| HR (95% CI) [c] | 1.710 (0.681, 4.295) | |
| HR P-Value [c] | 0.2536 | |
| Heterogeneity p-value [d] | 0.0439 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 17.4 (3.2, 41.2) | 48.2 (20.8, 71.2) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 6 (16.7%) |
| Censored Patients, n (%) | 32 (82.1%) | 30 (83.3%) |
| Median (95% CI), (Months) [a] | NE (1.45, NE) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7087 | |
| HR (95% CI) [c] | 1.236 (0.414, 3.688) | |
| HR P-Value [c] | 0.7043 | |
| Heterogeneity p-value [d] | 0.3597 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.6 (29.3, 76.8) | 50.3 (18.7, 75.5) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 19 (25.0%) | 10 (15.2%) |
| Censored Patients, n (%) | 57 (75.0%) | 56 (84.8%) |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 4.53) | 4.37 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4312 | |
| HR (95% CI) [c] | 1.371 (0.635, 2.958) | |
| HR P-Value [c] | 0.4213 | |
| Heterogeneity p-value [d] | 0.3328 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.7 (8.5, 41.1) | 43.1 (16.3, 67.7) |
| 12 months | 22.7 (8.5, 41.1) | NE (NE, NE) |
| 18 months | 22.7 (8.5, 41.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 26 (34.2%) | 12 (18.2%) |
| Censored Patients, n (%) | 50 (65.8%) | 54 (81.8%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.96) | 4.17 (1.51, 6.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8408 | |
| HR (95% CI) [c] | 0.941 (0.463, 1.912) | |
| HR P-Value [c] | 0.8658 | |
| Heterogeneity p-value [d] | 0.9171 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.4 (16.8, 49.2) | 28.5 (6.4, 56.4) |
| 12 months | 10.8 (2.0, 28.1) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 23 (30.3%) | 9 (13.6%) |
| Censored Patients, n (%) | 53 (69.7%) | 57 (86.4%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.51, 4.34) | 3.45 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0877 | |
| HR (95% CI) [c] | 1.935 (0.892, 4.195) | |
| HR P-Value [c] | 0.0946 | |
| Heterogeneity p-value [d] | 0.2239 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 14.7 (3.9, 32.3) | 38.1 (13.3, 63.0) |
| 12 months | 4.9 (0.4, 20.0) | 38.1 (13.3, 63.0) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 13 (17.1%) | 9 (13.6%) |
| Censored Patients, n (%) | 63 (82.9%) | 57 (86.4%) |
| Median (95% CI), (Months) [a] | 2.33 (1.45, 5.65) | 1.66 (1.41, 6.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7581 | |
| HR (95% CI) [c] | 1.173 (0.481, 2.861) | |
| HR P-Value [c] | 0.7259 | |
| Heterogeneity p-value [d] | 0.8743 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 18.5 (3.2, 43.6) | 26.7 (4.8, 56.3) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 18 (23.7%) | 7 (10.6%) |
| Censored Patients, n (%) | 58 (76.3%) | 59 (89.4%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 3.02) | 9.69 (1.77, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1640 | |
| HR (95% CI) [c] | 1.863 (0.771, 4.500) | |
| HR P-Value [c] | 0.1667 | |
| Heterogeneity p-value [d] | 0.6779 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.1 (11.5, 47.4) | 58.1 (28.0, 79.3) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 26 (34.2%) | 12 (18.2%) |
| Censored Patients, n (%) | 50 (65.8%) | 54 (81.8%) |
| Median (95% CI), (Months) [a] | 2.99 (1.84, 4.96) | 4.40 (1.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5522 | |
| HR (95% CI) [c] | 1.229 (0.618, 2.443) | |
| HR P-Value [c] | 0.5561 | |
| Heterogeneity p-value [d] | 0.4154 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.7 (17.3, 49.1) | 39.7 (15.9, 62.9) |
| 12 months | 19.6 (6.2, 38.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 36 (47.4%) | 19 (28.8%) |
| Censored Patients, n (%) | 40 (52.6%) | 47 (71.2%) |
| | | |
| Median (95% CI), (Months) [a] | 3.09 (2.79, 5.59) | 6.93 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5045 | |
| HR (95% CI) [c] | 1.216 (0.695, 2.129) | |
| HR P-Value [c] | 0.4937 | |
| Heterogeneity p-value [d] | 0.5024 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.2 (16.1, 43.6) | 52.1 (33.7, 67.7) |
| 12 months | 25.5 (12.9, 40.2) | NE (NE, NE) |
| 18 months | 17.0 (4.7, 36.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 19 (25.0%) | 14 (21.2%) |
| Censored Patients, n (%) | 57 (75.0%) | 52 (78.8%) |
| Median (95% CI), (Months) [a] | 3.22 (1.58, 4.53) | 2.79 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7288 | |
| HR (95% CI) [c] | 1.135 (0.569, 2.265) | |
| HR P-Value [c] | 0.7193 | |
| Heterogeneity p-value [d] | 0.3568 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.6 (8.8, 42.4) | 36.9 (16.7, 57.5) |
| 12 months | 23.6 (8.8, 42.4) | NE (NE, NE) |
| 18 months | 23.6 (8.8, 42.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 16 (21.1%) | 7 (10.6%) |
| Censored Patients, n (%) | 60 (78.9%) | 59 (89.4%) |
| Median (95% CI), (Months) [a] | 1.68 (1.45, 3.22) | 3.45 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1334 | |
| HR (95% CI) [c] | 1.968 (0.806, 4.805) | |
| HR P-Value [c] | 0.1373 | |
| Heterogeneity p-value [d] | 0.1803 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 13.3 (2.3, 34.0) | 17.0 (1.1, 50.0) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 34 (44.7%) | 13 (19.7%) |
| Censored Patients, n (%) | 42 (55.3%) | 53 (80.3%) |
| Median (95% CI), (Months) [a] | 2.99 (1.84, 4.96) | 5.75 (1.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1539 | |
| HR (95% CI) [c] | 1.595 (0.838, 3.033) | |
| HR P-Value [c] | 0.1549 | |
| Heterogeneity p-value [d] | 0.7187 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.4 (18.5, 47.0) | 48.8 (26.0, 68.2) |
| 12 months | 14.4 (4.2, 30.5) | 48.8 (26.0, 68.2) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 23 (30.3%) | 7 (10.6%) |
| Censored Patients, n (%) | 53 (69.7%) | 59 (89.4%) |
| Median (95% CI), (Months) [a] | 4.96 (2.86, NE) | NE (6.93, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0293 | |
| HR (95% CI) [c] | 2.490 (1.067, 5.811) | |
| HR P-Value [c] | 0.0349 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.8 (20.6, 54.9) | 79.9 (56.5, 91.6) |
| 12 months | 32.4 (15.7, 50.4) | 57.1 (24.6, 79.9) |
| 18 months | 32.4 (15.7, 50.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 34 (44.7%) | 9 (13.6%) |
| Censored Patients, n (%) | 42 (55.3%) | 57 (86.4%) |
| Median (95% CI), (Months) [a] | 4.21 (2.83, 13.86) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0068 | |
| HR (95% CI) [c] | 2.675 (1.276, 5.609) | |
| HR P-Value [c] | 0.0092 | |
| Heterogeneity p-value [d] | 0.3505 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.0 (29.1, 56.1) | 75.9 (56.9, 87.3) |
| 12 months | 36.1 (21.9, 50.4) | 63.2 (32.7, 82.8) |
| 18 months | 13.5 (1.3, 39.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 30 (39.5%) | 11 (16.7%) |
| Censored Patients, n (%) | 46 (60.5%) | 55 (83.3%) |
| | | |
| Median (95% CI), (Months) [a] | 3.06 (1.61, 4.96) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1456 | |
| HR (95% CI) [c] | 1.659 (0.831, 3.314) | |
| HR P-Value [c] | 0.1513 | |
| Heterogeneity p-value [d] | 0.3968 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.2 (16.3, 45.4) | 52.1 (27.2, 72.2) |
| 12 months | 21.1 (8.6, 37.5) | 52.1 (27.2, 72.2) |
| 18 months | 21.1 (8.6, 37.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 28 (36.8%) | 16 (24.2%) |
| Censored Patients, n (%) | 48 (63.2%) | 50 (75.8%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 3.09) | 2.79 (1.51, 7.26) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8110 | |
| HR (95% CI) [c] | 1.075 (0.579, 1.996) | |
| HR P-Value [c] | 0.8184 | |
| Heterogeneity p-value [d] | 0.0439 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.7 (10.8, 39.5) | 39.8 (17.1, 61.9) |
| 12 months | 15.8 (5.4, 31.2) | 19.9 (3.7, 45.3) |
| 18 months | 15.8 (5.4, 31.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 25 (32.9%) | 13 (19.7%) |
| Censored Patients, n (%) | 51 (67.1%) | 53 (80.3%) |
| | | |
| Median (95% CI), (Months) [a] | 4.96 (2.83, 6.97) | 3.45 (1.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9904 | |
| HR (95% CI) [c] | 1.017 (0.513, 2.018) | |
| HR P-Value [c] | 0.9608 | |
| Heterogeneity p-value [d] | 0.3597 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.2 (18.6, 52.2) | 45.9 (23.0, 66.2) |
| 12 months | 13.7 (3.0, 32.4) | NE (NE, NE) |
| 18 months | 13.7 (3.0, 32.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 14 (23.7%) | 18 (32.1%) |
| Censored Patients, n (%) | 45 (76.3%) | 38 (67.9%) |
| | | |
| Median (95% CI), (Months) [a] | 2.73 (1.45, 5.95) | 1.68 (1.48, 4.34) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9415 | |
| HR (95% CI) [c] | 0.981 (0.477, 2.017) | |
| HR P-Value [c] | 0.9574 | |
| Heterogeneity p-value [d] | 0.3328 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | NE (NE, NE) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 12 (20.3%) | 13 (23.2%) |
| Censored Patients, n (%) | 47 (79.7%) | 43 (76.8%) |
| Median (95% CI), (Months) [a] | 2.83 (1.54, NE) | 4.83 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6015 | |
| HR (95% CI) [c] | 1.237 (0.562, 2.723) | |
| HR P-Value [c] | 0.5967 | |
| Heterogeneity p-value [d] | 0.9171 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.0 (13.7, 57.5) | 27.9 (6.5, 55.1) |
| 12 months | 35.0 (13.7, 57.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 15 (25.4%) | 9 (16.1%) |
| Censored Patients, n (%) | 44 (74.6%) | 47 (83.9%) |
| Median (95% CI), (Months) [a] | 2.79 (1.48, 2.99) | 4.50 (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1113 | |
| HR (95% CI) [c] | 2.000 (0.846, 4.731) | |
| HR P-Value [c] | 0.1144 | |
| Heterogeneity p-value [d] | 0.2239 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 10.4 (0.7, 35.4) | 48.4 (22.2, 70.5) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 7 (11.9%) | 0 |
| Censored Patients, n (%) | 52 (88.1%) | 56 (100.0%) |
| Median (95% CI), (Months) [a] | 1.45 (1.38, 9.82) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7389 | |
| HR (95% CI) [c] | 1422744 (0.000, NE) | |
| HR P-Value [c] | 0.9968 | |
| Heterogeneity p-value [d] | 0.8743 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (7.8, 62.3) | NE (NE, NE) |
| 12 months | 16.7 (1.1, 49.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 11 (18.6%) | 7 (12.5%) |
| Censored Patients, n (%) | 48 (81.4%) | 49 (87.5%) |
| | | |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 5.59) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1349 | |
| HR (95% CI) [c] | 2.050 (0.789, 5.324) | |
| HR P-Value [c] | 0.1406 | |
| Heterogeneity p-value [d] | 0.6779 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 13.6 (0.9, 43.0) | 55.6 (28.6, 75.9) |
| 12 months | 13.6 (0.9, 43.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 24 (40.7%) | 11 (19.6%) |
| Censored Patients, n (%) | 35 (59.3%) | 45 (80.4%) |
| Median (95% CI), (Months) [a] | 2.79 (1.45, 4.34) | NE (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0172 | |
| HR (95% CI) [c] | 2.349 (1.144, 4.824) | |
| HR P-Value [c] | 0.0200 | |
| Heterogeneity p-value [d] | 0.4154 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.5 (12.9, 46.4) | 50.4 (25.1, 71.2) |
| 12 months | 14.3 (2.9, 34.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 22 (37.3%) | 14 (25.0%) |
| Censored Patients, n (%) | 37 (62.7%) | 42 (75.0%) |
| Median (95% CI), (Months) [a] | 2.92 (1.54, 6.01) | 7.26 (2.99, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0528 | |
| HR (95% CI) [c] | 1.933 (0.984, 3.799) | |
| HR P-Value [c] | 0.0558 | |
| Heterogeneity p-value [d] | 0.5024 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.5 (17.2, 54.3) | 66.0 (46.7, 79.7) |
| 12 months | 18.9 (4.3, 41.5) | 39.6 (12.2, 66.5) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 16 (27.1%) | 15 (26.8%) |
| Censored Patients, n (%) | 43 (72.9%) | 41 (73.2%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.54, NE) | 2.99 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7119 | |
| HR (95% CI) [c] | 1.148 (0.565, 2.329) | |
| HR P-Value [c] | 0.7030 | |
| Heterogeneity p-value [d] | 0.3568 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.8 (21.6, 59.3) | 46.2 (25.5, 64.6) |
| 12 months | 40.8 (21.6, 59.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 11 (18.6%) | 11 (19.6%) |
| Censored Patients, n (%) | 48 (81.4%) | 45 (80.4%) |
| Median (95% CI), (Months) [a] | 2.73 (1.45, 5.59) | 1.68 (1.45, 4.47) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5754 | |
| HR (95% CI) [c] | 1.283 (0.546, 3.015) | |
| HR P-Value [c] | 0.5670 | |
| Heterogeneity p-value [d] | 0.1803 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 20.4 (3.7, 46.3) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 25 (42.4%) | 28 (50.0%) |
| Censored Patients, n (%) | 34 (57.6%) | 28 (50.0%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 5.95) | 2.83 (1.51, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5564 | |
| HR (95% CI) [c] | 1.221 (0.708, 2.107) | |
| HR P-Value [c] | 0.4724 | |
| Heterogeneity p-value [d] | 0.7187 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.9 (8.5, 45.6) | 21.0 (9.0, 36.4) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 15 (25.4%) | 9 (16.1%) |
| Censored Patients, n (%) | 44 (74.6%) | 47 (83.9%) |
| Median (95% CI), (Months) [a] | 19.45 (2.79, 19.45) | NE (6.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1486 | |
| HR (95% CI) [c] | 1.858 (0.801, 4.310) | |
| HR P-Value [c] | 0.1491 | |
| Heterogeneity p-value [d] | 0.9900 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.1 (41.9, 75.7) | 73.6 (53.4, 86.1) |
| 12 months | 51.0 (26.6, 70.9) | NE (NE, NE) |
| 18 months | 51.0 (26.6, 70.9) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 24 (40.7%) | 15 (26.8%) |
| Censored Patients, n (%) | 35 (59.3%) | 41 (73.2%) |
| Median (95% CI), (Months) [a] | 4.90 (1.48, NE) | 9.59 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1350 | |
| HR (95% CI) [c] | 1.651 (0.864, 3.156) | |
| HR P-Value [c] | 0.1291 | |
| Heterogeneity p-value [d] | 0.3505 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.6 (30.8, 62.6) | 58.0 (38.3, 73.4) |
| 12 months | 32.6 (16.0, 50.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 24 (40.7%) | 11 (19.6%) |
| Censored Patients, n (%) | 35 (59.3%) | 45 (80.4%) |
| Median (95% CI), (Months) [a] | 1.84 (1.45, 2.92) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0019 | |
| HR (95% CI) [c] | 2.995 (1.459, 6.150) | |
| HR P-Value [c] | 0.0028 | |
| Heterogeneity p-value [d] | 0.3968 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 18.0 (5.5, 36.4) | 60.8 (39.4, 76.6) |
| 12 months | 18.0 (5.5, 36.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 22 (37.3%) | 13 (23.2%) |
| Censored Patients, n (%) | 37 (62.7%) | 43 (76.8%) |
| Median (95% CI), (Months) [a] | 1.45 (1.45, 1.54) | 4.17 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0007 | |
| HR (95% CI) [c] | 3.390 (1.640, 7.007) | |
| HR P-Value [c] | 0.0010 | |
| Heterogeneity p-value [d] | 0.0439 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 47.0 (26.4, 65.1) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 18 (30.5%) | 11 (19.6%) |
| Censored Patients, n (%) | 41 (69.5%) | 45 (80.4%) |
| Median (95% CI), (Months) [a] | 2.83 (1.48, 4.34) | 5.03 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1628 | |
| HR (95% CI) [c] | 1.699 (0.800, 3.609) | |
| HR P-Value [c] | 0.1676 | |
| Heterogeneity p-value [d] | 0.3597 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.9 (10.4, 46.7) | 38.0 (13.1, 63.2) |
| 12 months | 26.9 (10.4, 46.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 42 (26.1%) | 29 (21.2%) |
| Censored Patients, n (%) | 119 (73.9%) | 108 (78.8%) |
| Median (95% CI), (Months) [a] | 2.83 (1.68, 4.21) | 3.12 (1.74, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4135 | |
| HR (95% CI) [c] | 1.225 (0.762, 1.970) | |
| HR P-Value [c] | 0.4012 | |
| Heterogeneity p-value [d] | 0.6338 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.0 (9.8, 37.3) | 30.6 (16.1, 46.5) |
| 12 months | 14.7 (3.8, 32.5) | 20.4 (5.5, 41.8) |
| 18 months | 14.7 (3.8, 32.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 46 (28.6%) | 27 (19.7%) |
| Censored Patients, n (%) | 115 (71.4%) | 110 (80.3%) |
| Median (95% CI), (Months) [a] | 2.83 (1.91, 4.57) | 2.99 (1.91, 5.78) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9832 | |
| HR (95% CI) [c] | 1.014 (0.623, 1.650) | |
| HR P-Value [c] | 0.9564 | |
| Heterogeneity p-value [d] | 0.7205 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.0 (21.9, 46.5) | 28.2 (12.2, 46.8) |
| 12 months | 18.1 (7.8, 31.7) | NE (NE, NE) |
| 18 months | 18.1 (7.8, 31.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 46 (28.6%) | 19 (13.9%) |
| Censored Patients, n (%) | 115 (71.4%) | 118 (86.1%) |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 4.14) | 4.27 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0228 | |
| HR (95% CI) [c] | 1.855 (1.082, 3.180) | |
| HR P-Value [c] | 0.0246 | |
| Heterogeneity p-value [d] | 0.0606 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 19.9 (9.0, 33.8) | 44.7 (26.8, 61.2) |
| 12 months | 11.9 (3.5, 25.9) | 44.7 (26.8, 61.2) |
| 18 months | 7.9 (1.6, 21.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 27 (16.8%) | 12 (8.8%) |
| Censored Patients, n (%) | 134 (83.2%) | 125 (91.2%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 2.83) | 2.30 (1.45, 5.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5213 | |
| HR (95% CI) [c] | 1.270 (0.639, 2.526) | |
| HR P-Value [c] | 0.4957 | |
| Heterogeneity p-value [d] | 0.2033 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 10.9 (2.3, 27.1) | 22.0 (4.2, 48.5) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 36 (22.4%) | 20 (14.6%) |
| Censored Patients, n (%) | 125 (77.6%) | 117 (85.4%) |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 4.21) | 5.06 (2.10, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0971 | |
| HR (95% CI) [c] | 1.595 (0.918, 2.771) | |
| HR P-Value [c] | 0.0977 | |
| Heterogeneity p-value [d] | 0.9186 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.9 (14.0, 41.6) | 44.7 (25.4, 62.3) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 61 (37.9%) | 27 (19.7%) |
| Censored Patients, n (%) | 100 (62.1%) | 110 (80.3%) |
| Median (95% CI), (Months) [a] | 2.96 (2.79, 4.24) | 5.06 (3.12, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0559 | |
| HR (95% CI) [c] | 1.571 (0.995, 2.480) | |
| HR P-Value [c] | 0.0526 | |
| Heterogeneity p-value [d] | 0.7789 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.5 (23.6, 45.6) | 39.8 (22.9, 56.2) |
| 12 months | 16.2 (6.8, 29.1) | NE (NE, NE) |
| 18 months | 12.1 (3.9, 25.3) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 70 (43.5%) | 35 (25.5%) |
| Censored Patients, n (%) | 91 (56.5%) | 102 (74.5%) |
| Median (95% CI), (Months) [a] | 3.09 (2.79, 4.96) | 7.26 (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0047 | |
| HR (95% CI) [c] | 1.794 (1.192, 2.701) | |
| HR P-Value [c] | 0.0051 | |
| Heterogeneity p-value [d] | 0.3689 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.2 (19.6, 41.5) | 56.6 (42.9, 68.2) |
| 12 months | 23.0 (13.0, 34.7) | NE (NE, NE) |
| 18 months | 18.4 (8.3, 31.6) | NE (NE, NE) |
| 24 months | 9.2 (1.1, 28.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 42 (26.1%) | 30 (21.9%) |
| Censored Patients, n (%) | 119 (73.9%) | 107 (78.1%) |
| Median (95% CI), (Months) [a] | 2.96 (1.84, 4.67) | 2.86 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6046 | |
| HR (95% CI) [c] | 1.132 (0.709, 1.810) | |
| HR P-Value [c] | 0.6032 | |
| Heterogeneity p-value [d] | 0.5976 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.0 (17.7, 43.3) | 40.8 (26.5, 54.6) |
| 12 months | 22.5 (10.9, 36.7) | 35.0 (19.5, 50.9) |
| 18 months | 22.5 (10.9, 36.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 32 (19.9%) | 20 (14.6%) |
| Censored Patients, n (%) | 129 (80.1%) | 117 (85.4%) |
| Median (95% CI), (Months) [a] | 1.91 (1.58, 2.96) | 3.19 (1.68, 4.47) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2765 | |
| HR (95% CI) [c] | 1.378 (0.780, 2.432) | |
| HR P-Value [c] | 0.2691 | |
| Heterogeneity p-value [d] | 0.6715 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 17.8 (6.4, 33.9) | 17.8 (4.9, 37.3) |
| 12 months | 13.4 (3.7, 29.1) | NE (NE, NE) |
| 18 months | 6.7 (0.6, 23.6) | NE (NE, NE) |
| 24 months | 6.7 (0.6, 23.6) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 69 (42.9%) | 47 (34.3%) |
| Censored Patients, n (%) | 92 (57.1%) | 90 (65.7%) |
| Median (95% CI), (Months) [a] | 2.79 (1.64, 4.17) | 2.99 (2.43, 5.39) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4673 | |
| HR (95% CI) [c] | 1.166 (0.803, 1.694) | |
| HR P-Value [c] | 0.4198 | |
| Heterogeneity p-value [d] | 0.4626 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.8 (17.9, 38.5) | 31.3 (19.6, 43.8) |
| 12 months | 15.9 (6.9, 28.4) | 18.5 (7.0, 34.3) |
| 18 months | 10.6 (2.7, 24.7) | NE (NE, NE) |
| 24 months | 10.6 (2.7, 24.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 48 (29.8%) | 19 (13.9%) |
| Censored Patients, n (%) | 113 (70.2%) | 118 (86.1%) |
| Median (95% CI), (Months) [a] | 5.62 (4.17, 19.45) | NE (6.93, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0033 | |
| HR (95% CI) [c] | 2.186 (1.282, 3.730) | |
| HR P-Value [c] | 0.0041 | |
| Heterogeneity p-value [d] | 0.6621 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.2 (32.8, 56.7) | 75.0 (61.3, 84.5) |
| 12 months | 39.5 (26.7, 52.0) | 57.2 (38.0, 72.5) |
| 18 months | 39.5 (26.7, 52.0) | NE (NE, NE) |
| 24 months | 29.6 (12.5, 49.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 72 (44.7%) | 29 (21.2%) |
| Censored Patients, n (%) | 89 (55.3%) | 108 (78.8%) |
| Median (95% CI), (Months) [a] | 4.21 (2.96, 6.01) | 9.59 (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0019 | |
| HR (95% CI) [c] | 1.977 (1.279, 3.056) | |
| HR P-Value [c] | 0.0021 | |
| Heterogeneity p-value [d] | 0.0911 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.0 (31.0, 50.6) | 64.4 (51.0, 75.0) |
| 12 months | 33.8 (23.8, 44.2) | NE (NE, NE) |
| 18 months | 22.4 (11.2, 36.0) | NE (NE, NE) |
| 24 months | 15.0 (4.1, 32.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 66 (41.0%) | 25 (18.2%) |
| Censored Patients, n (%) | 95 (59.0%) | 112 (81.8%) |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 4.27) | NE (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0105 | |
| HR (95% CI) [c] | 1.819 (1.147, 2.886) | |
| HR P-Value [c] | 0.0110 | |
| Heterogeneity p-value [d] | 0.6142 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.2 (16.5, 37.0) | 52.5 (37.1, 65.9) |
| 12 months | 16.3 (7.8, 27.6) | 52.5 (37.1, 65.9) |
| 18 months | 16.3 (7.8, 27.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Social Functioning - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 59 (36.6%) | 34 (24.8%) |
| Censored Patients, n (%) | 102 (63.4%) | 103 (75.2%) |
| Median (95% CI), (Months) [a] | 2.33 (1.58, 2.86) | 3.06 (2.56, 7.00) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1196 | |
| HR (95% CI) [c] | 1.400 (0.915, 2.141) | |
| HR P-Value [c] | 0.1210 | |
| Heterogeneity p-value [d] | 0.0017 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 20.7 (11.5, 31.9) | 35.9 (21.5, 50.4) |
| 12 months | 11.8 (4.2, 23.8) | NE (NE, NE) |
| 18 months | 11.8 (4.2, 23.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 46 (28.6%) | 27 (19.7%) |
| Censored Patients, n (%) | 115 (71.4%) | 110 (80.3%) |
| Median (95% CI), (Months) [a] | 2.92 (2.73, 5.45) | 3.45 (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2704 | |
| HR (95% CI) [c] | 1.315 (0.817, 2.118) | |
| HR P-Value [c] | 0.2590 | |
| Heterogeneity p-value [d] | 0.5788 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.3 (16.8, 42.9) | 39.1 (22.3, 55.7) |
| 12 months | 18.6 (7.9, 32.8) | NE (NE, NE) |
| 18 months | 18.6 (7.9, 32.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 5 (10.9%) |
| Censored Patients, n (%) | 31 (88.6%) | 41 (89.1%) |
| | | |
| Median (95% CI), (Months) [a] | 4.93 (1.41, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6217 | |
| HR (95% CI) [c] | 1.447 (0.339, 6.169) | |
| HR P-Value [c] | 0.6176 | |
| Heterogeneity p-value [d] | 0.6338 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.0 (1.2, 64.6) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 8 (22.9%) | 10 (21.7%) |
| Censored Patients, n (%) | 27 (77.1%) | 36 (78.3%) |
| Median (95% CI), (Months) [a] | 1.86 (1.38, NE) | 2.83 (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5740 | |
| HR (95% CI) [c] | 1.269 (0.499, 3.227) | |
| HR P-Value [c] | 0.6164 | |
| Heterogeneity p-value [d] | 0.7205 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (10.3, 58.8) | 18.3 (1.4, 50.7) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 6 (17.1%) | 10 (21.7%) |
| Censored Patients, n (%) | 29 (82.9%) | 36 (78.3%) |
| | | |
| Median (95% CI), (Months) [a] | 3.91 (1.45, 10.45) | 1.58 (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2597 | |
| HR (95% CI) [c] | 0.528 (0.175, 1.591) | |
| HR P-Value [c] | 0.2560 | |
| Heterogeneity p-value [d] | 0.0606 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 31.7 (4.9, 64.7) | 29.2 (6.6, 57.2) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 5 (10.9%) |
| Censored Patients, n (%) | 31 (88.6%) | 41 (89.1%) |
| | | |
| Median (95% CI), (Months) [a] | 1.64 (1.45, NE) | 1.54 (1.45, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5651 | |
| HR (95% CI) [c] | 0.707 (0.187, 2.675) | |
| HR P-Value [c] | 0.6092 | |
| Heterogeneity p-value [d] | 0.2033 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.0 (5.2, 75.3) | 20.0 (0.8, 58.2) |
| 12 months | 20.0 (0.8, 58.2) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 6 (17.1%) | 4 (8.7%) |
| Censored Patients, n (%) | 29 (82.9%) | 42 (91.3%) |
| | | |
| Median (95% CI), (Months) [a] | 1.56 (1.31, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2042 | |
| HR (95% CI) [c] | 2.201 (0.609, 7.961) | |
| HR P-Value [c] | 0.2289 | |
| Heterogeneity p-value [d] | 0.9186 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 18.8 (1.1, 53.5) | 50.8 (15.7, 78.1) |
| 12 months | 18.8 (1.1, 53.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 10 (28.6%) | 8 (17.4%) |
| Censored Patients, n (%) | 25 (71.4%) | 38 (82.6%) |
| Median (95% CI), (Months) [a] | 2.07 (1.41, NE) | NE (2.89, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1246 | |
| HR (95% CI) [c] | 2.042 (0.803, 5.195) | |
| HR P-Value [c] | 0.1339 | |
| Heterogeneity p-value [d] | 0.7789 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.0 (7.1, 52.2) | 50.3 (23.4, 72.2) |
| 12 months | 27.0 (7.1, 52.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 7 (20.0%) | 7 (15.2%) |
| Censored Patients, n (%) | 28 (80.0%) | 39 (84.8%) |
| Median (95% CI), (Months) [a] | 11.10 (2.89, NE) | 14.69 (7.10, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9664 | |
| HR (95% CI) [c] | 1.019 (0.355, 2.925) | |
| HR P-Value [c] | 0.9715 | |
| Heterogeneity p-value [d] | 0.3689 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.1 (32.7, 80.5) | 76.8 (52.8, 89.6) |
| 12 months | 40.7 (8.8, 71.8) | 51.2 (9.8, 82.4) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 6 (17.1%) | 7 (15.2%) |
| Censored Patients, n (%) | 29 (82.9%) | 39 (84.8%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.41, NE) | 8.80 (1.64, 8.80) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5262 | |
| HR (95% CI) [c] | 1.432 (0.472, 4.343) | |
| HR P-Value [c] | 0.5258 | |
| Heterogeneity p-value [d] | 0.5976 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.9 (12.7, 67.9) | 61.9 (33.8, 80.9) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 6 (13.0%) |
| Censored Patients, n (%) | 32 (91.4%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | 2.81 (1.41, 4.17) | 2.22 (1.45, 2.83) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7428 | |
| HR (95% CI) [c] | 0.779 (0.153, 3.977) | |
| HR P-Value [c] | 0.7637 | |
| Heterogeneity p-value [d] | 0.6715 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 12 (34.3%) | 13 (28.3%) |
| Censored Patients, n (%) | 23 (65.7%) | 33 (71.7%) |
| | | |
| Median (95% CI), (Months) [a] | 1.64 (1.38, 6.97) | 3.02 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2634 | |
| HR (95% CI) [c] | 1.571 (0.709, 3.481) | |
| HR P-Value [c] | 0.2657 | |
| Heterogeneity p-value [d] | 0.4626 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.2 (8.4, 54.2) | 39.9 (17.1, 62.0) |
| 12 months | 0.0 (NE, NE) | 39.9 (17.1, 62.0) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 5 (14.3%) | 2 (4.3%) |
| Censored Patients, n (%) | 30 (85.7%) | 44 (95.7%) |
| | | |
| Median (95% CI), (Months) [a] | NE (1.64, NE) | 7.16 (7.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1500 | |
| HR (95% CI) [c] | 3.187 (0.605, 16.779) | |
| HR P-Value [c] | 0.1715 | |
| Heterogeneity p-value [d] | 0.6621 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.5 (30.8, 81.8) | 94.4 (66.6, 99.2) |
| 12 months | 61.5 (30.8, 81.8) | 47.2 (0.8, 88.9) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 5 (14.3%) | 7 (15.2%) |
| Censored Patients, n (%) | 30 (85.7%) | 39 (84.8%) |
| Median (95% CI), (Months) [a] | NE (4.30, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5635 | |
| HR (95% CI) [c] | 0.704 (0.219, 2.256) | |
| HR P-Value [c] | 0.5543 | |
| Heterogeneity p-value [d] | 0.0911 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.9 (45.6, 89.9) | 70.0 (46.8, 84.6) |
| 12 months | 62.4 (28.6, 83.7) | 70.0 (46.8, 84.6) |
| 18 months | 62.4 (28.6, 83.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 5 (14.3%) | 6 (13.0%) |
| Censored Patients, n (%) | 30 (85.7%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | NE (1.41, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6922 | |
| HR (95% CI) [c] | 1.273 (0.387, 4.190) | |
| HR P-Value [c] | 0.6913 | |
| Heterogeneity p-value [d] | 0.6142 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (15.2, 77.5) | 61.7 (32.2, 81.3) |
| 12 months | 50.0 (15.2, 77.5) | 61.7 (32.2, 81.3) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 10 (28.6%) | 6 (13.0%) |
| Censored Patients, n (%) | 25 (71.4%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | 1.45 (1.38, 1.64) | NE (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| HR (95% CI) [c] | 6.771 (2.410, 19.022) | |
| HR P-Value [c] | 0.0003 | |
| Heterogeneity p-value [d] | 0.0017 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 65.5 (38.4, 82.9) |
| 12 months | NE (NE, NE) | 65.5 (38.4, 82.9) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 9 (25.7%) | 5 (10.9%) |
| Censored Patients, n (%) | 26 (74.3%) | 41 (89.1%) |
| Median (95% CI), (Months) [a] | 3.61 (1.45, NE) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2027 | |
| HR (95% CI) [c] | 2.043 (0.666, 6.265) | |
| HR P-Value [c] | 0.2113 | |
| Heterogeneity p-value [d] | 0.5788 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.7 (16.4, 65.4) | 65.6 (34.9, 84.5) |
| 12 months | 27.8 (5.8, 56.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 25 (28.1%) | 12 (14.1%) |
| Censored Patients, n (%) | 64 (71.9%) | 73 (85.9%) |
| Median (95% CI), (Months) [a] | 3.09 (1.61, 4.86) | 3.45 (1.61, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4120 | |
| HR (95% CI) [c] | 1.347 (0.672, 2.700) | |
| HR P-Value [c] | 0.4011 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 20.1 (5.2, 41.8) | 34.9 (11.6, 59.7) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 24 (27.0%) | 17 (20.0%) |
| Censored Patients, n (%) | 65 (73.0%) | 68 (80.0%) |
| | | |
| Median (95% CI), (Months) [a] | 2.99 (1.84, 6.97) | 1.81 (1.51, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1207 | |
| HR (95% CI) [c] | 0.603 (0.314, 1.160) | |
| HR P-Value [c] | 0.1295 | |
| Heterogeneity p-value [d] | 0.0919 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.2 (19.0, 53.7) | 0.0 (NE, NE) |
| 12 months | 14.5 (2.8, 35.1) | 0.0 (NE, NE) |
| 18 months | 14.5 (2.8, 35.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 24 (27.0%) | 11 (12.9%) |
| Censored Patients, n (%) | 65 (73.0%) | 74 (87.1%) |
| Median (95% CI), (Months) [a] | 2.79 (1.61, 4.96) | 3.45 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5579 | |
| HR (95% CI) [c] | 1.236 (0.602, 2.541) | |
| HR P-Value [c] | 0.5638 | |
| Heterogeneity p-value [d] | 0.6370 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.1 (8.8, 41.3) | 38.1 (14.2, 62.2) |
| 12 months | 11.5 (2.2, 29.4) | NE (NE, NE) |
| 18 months | 11.5 (2.2, 29.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 17 (19.1%) | 8 (9.4%) |
| Censored Patients, n (%) | 72 (80.9%) | 77 (90.6%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 3.02) | 1.81 (1.41, 7.00) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8423 | |
| HR (95% CI) [c] | 1.121 (0.481, 2.612) | |
| HR P-Value [c] | 0.7910 | |
| Heterogeneity p-value [d] | 0.8898 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 19.7 (5.5, 40.3) | 27.3 (4.9, 57.1) |
| 12 months | 6.6 (0.5, 25.3) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 19 (21.3%) | 8 (9.4%) |
| Censored Patients, n (%) | 70 (78.7%) | 77 (90.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 4.57) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1656 | |
| HR (95% CI) [c] | 1.792 (0.781, 4.108) | |
| HR P-Value [c] | 0.1683 | |
| Heterogeneity p-value [d] | 0.9245 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.0 (11.9, 48.7) | 52.3 (26.5, 72.9) |
| 12 months | 15.5 (3.3, 36.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 35 (39.3%) | 15 (17.6%) |
| Censored Patients, n (%) | 54 (60.7%) | 70 (82.4%) |
| Median (95% CI), (Months) [a] | 4.17 (2.07, 4.96) | 5.03 (2.56, 7.00) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5101 | |
| HR (95% CI) [c] | 1.227 (0.664, 2.265) | |
| HR P-Value [c] | 0.5136 | |
| Heterogeneity p-value [d] | 0.2646 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.1 (16.5, 44.9) | 34.1 (11.5, 58.6) |
| 12 months | 17.2 (6.2, 32.8) | 0.0 (NE, NE) |
| 18 months | 17.2 (6.2, 32.8) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 35 (39.3%) | 14 (16.5%) |
| Censored Patients, n (%) | 54 (60.7%) | 71 (83.5%) |
| Median (95% CI), (Months) [a] | 4.21 (2.79, 5.75) | 14.69 (3.68, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0536 | |
| HR (95% CI) [c] | 1.833 (0.982, 3.421) | |
| HR P-Value [c] | 0.0569 | |
| Heterogeneity p-value [d] | 0.8645 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.8 (21.1, 48.7) | 67.1 (49.5, 79.7) |
| 12 months | 34.8 (21.1, 48.7) | 67.1 (49.5, 79.7) |
| 18 months | 23.2 (6.7, 45.3) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 20 (22.5%) | 14 (16.5%) |
| Censored Patients, n (%) | 69 (77.5%) | 71 (83.5%) |
| Median (95% CI), (Months) [a] | 3.22 (1.64, 7.26) | 2.79 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8516 | |
| HR (95% CI) [c] | 0.935 (0.470, 1.857) | |
| HR P-Value [c] | 0.8467 | |
| Heterogeneity p-value [d] | 0.3306 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.5 (22.1, 56.5) | 42.6 (21.6, 62.1) |
| 12 months | 28.2 (12.0, 47.0) | NE (NE, NE) |
| 18 months | 28.2 (12.0, 47.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 15 (16.9%) | 11 (12.9%) |
| Censored Patients, n (%) | 74 (83.1%) | 74 (87.1%) |
| Median (95% CI), (Months) [a] | 3.22 (1.45, 6.97) | 3.45 (1.58, 4.47) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8952 | |
| HR (95% CI) [c] | 0.965 (0.426, 2.186) | |
| HR P-Value [c] | 0.9320 | |
| Heterogeneity p-value [d] | 0.3640 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.6 (8.9, 54.2) | 10.6 (0.6, 36.8) |
| 12 months | 19.7 (3.7, 45.1) | NE (NE, NE) |
| 18 months | 9.9 (0.6, 34.6) | NE (NE, NE) |
| 24 months | 9.9 (0.6, 34.6) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 36 (40.4%) | 17 (20.0%) |
| Censored Patients, n (%) | 53 (59.6%) | 68 (80.0%) |
| Median (95% CI), (Months) [a] | 4.17 (1.64, 5.65) | 5.03 (2.43, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2132 | |
| HR (95% CI) [c] | 1.456 (0.814, 2.606) | |
| HR P-Value [c] | 0.2059 | |
| Heterogeneity p-value [d] | 0.4170 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.0 (15.4, 44.1) | 41.2 (20.0, 61.4) |
| 12 months | 7.9 (0.8, 26.6) | 30.9 (10.3, 54.5) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 25 (28.1%) | 5 (5.9%) |
| Censored Patients, n (%) | 64 (71.9%) | 80 (94.1%) |
| Median (95% CI), (Months) [a] | 4.96 (2.89, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0068 | |
| HR (95% CI) [c] | 3.495 (1.332, 9.169) | |
| HR P-Value [c] | 0.0110 | |
| Heterogeneity p-value [d] | 0.3336 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.4 (31.8, 61.6) | 85.6 (64.6, 94.6) |
| 12 months | 47.4 (31.8, 61.6) | 71.3 (34.0, 90.0) |
| 18 months | 47.4 (31.8, 61.6) | NE (NE, NE) |
| 24 months | 31.6 (8.8, 58.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 38 (42.7%) | 12 (14.1%) |
| Censored Patients, n (%) | 51 (57.3%) | 73 (85.9%) |
| Median (95% CI), (Months) [a] | 4.27 (2.83, 8.77) | 9.59 (4.47, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0398 | |
| HR (95% CI) [c] | 1.967 (1.021, 3.789) | |
| HR P-Value [c] | 0.0431 | |
| Heterogeneity p-value [d] | 0.6614 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.8 (29.8, 55.2) | 69.5 (49.8, 82.8) |
| 12 months | 35.3 (21.5, 49.5) | 34.8 (1.8, 75.6) |
| 18 months | 23.6 (6.8, 46.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 30 (33.7%) | 10 (11.8%) |
| Censored Patients, n (%) | 59 (66.3%) | 75 (88.2%) |
| Median (95% CI), (Months) [a] | 4.17 (1.64, 6.97) | NE (2.43, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0689 | |
| HR (95% CI) [c] | 1.927 (0.940, 3.950) | |
| HR P-Value [c] | 0.0731 | |
| Heterogeneity p-value [d] | 0.9391 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.4 (18.9, 50.5) | 59.1 (35.3, 76.7) |
| 12 months | 18.4 (5.9, 36.5) | 59.1 (35.3, 76.7) |
| 18 months | 18.4 (5.9, 36.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 32 (36.0%) | 15 (17.6%) |
| Censored Patients, n (%) | 57 (64.0%) | 70 (82.4%) |
| | | |
| Median (95% CI), (Months) [a] | 1.84 (1.51, 2.96) | 5.06 (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0122 | |
| HR (95% CI) [c] | 2.166 (1.168, 4.017) | |
| HR P-Value [c] | 0.0142 | |
| Heterogeneity p-value [d] | 0.6009 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 15.8 (5.2, 31.6) | 43.5 (21.9, 63.5) |
| 12 months | 0.0 (NE, NE) | 32.7 (11.1, 56.6) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 27 (30.3%) | 11 (12.9%) |
| Censored Patients, n (%) | 62 (69.7%) | 74 (87.1%) |
| Median (95% CI), (Months) [a] | 4.24 (2.83, 6.97) | 5.03 (2.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6843 | |
| HR (95% CI) [c] | 1.162 (0.569, 2.375) | |
| HR P-Value [c] | 0.6800 | |
| Heterogeneity p-value [d] | 0.4897 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.2 (21.0, 53.4) | 40.0 (13.8, 65.5) |
| 12 months | 19.9 (6.4, 38.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 21 (19.6%) | 22 (22.4%) |
| Censored Patients, n (%) | 86 (80.4%) | 76 (77.6%) |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 4.53) | 3.32 (1.77, 7.26) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3457 | |
| HR (95% CI) [c] | 1.336 (0.733, 2.433) | |
| HR P-Value [c] | 0.3444 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.8 (7.4, 43.1) | 36.8 (19.9, 53.8) |
| 12 months | 22.8 (7.4, 43.1) | 24.5 (6.5, 48.4) |
| 18 months | 22.8 (7.4, 43.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 30 (28.0%) | 20 (20.4%) |
| Censored Patients, n (%) | 77 (72.0%) | 78 (79.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 2.83) | 4.17 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1761 | |
| HR (95% CI) [c] | 1.506 (0.845, 2.684) | |
| HR P-Value [c] | 0.1646 | |
| Heterogeneity p-value [d] | 0.0919 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.9 (16.9, 45.9) | 38.0 (20.0, 55.9) |
| 12 months | 19.3 (6.6, 37.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 28 (26.2%) | 18 (18.4%) |
| Censored Patients, n (%) | 79 (73.8%) | 80 (81.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.14) | 3.12 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1735 | |
| HR (95% CI) [c] | 1.512 (0.830, 2.756) | |
| HR P-Value [c] | 0.1770 | |
| Heterogeneity p-value [d] | 0.6370 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 19.8 (6.3, 38.7) | 41.3 (23.1, 58.7) |
| 12 months | 13.2 (2.7, 32.3) | 41.3 (23.1, 58.7) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 14 (13.1%) | 9 (9.2%) |
| Censored Patients, n (%) | 93 (86.9%) | 89 (90.8%) |
| Median (95% CI), (Months) [a] | 1.61 (1.45, 4.21) | 2.33 (1.45, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7190 | |
| HR (95% CI) [c] | 1.173 (0.497, 2.768) | |
| HR P-Value [c] | 0.7159 | |
| Heterogeneity p-value [d] | 0.8898 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 10.4 (0.8, 34.6) | 22.2 (3.4, 51.3) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 23 (21.5%) | 16 (16.3%) |
| Censored Patients, n (%) | 84 (78.5%) | 82 (83.7%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 5.59) | 4.53 (1.94, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1897 | |
| HR (95% CI) [c] | 1.542 (0.806, 2.950) | |
| HR P-Value [c] | 0.1905 | |
| Heterogeneity p-value [d] | 0.9245 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.6 (8.1, 41.4) | 40.8 (18.8, 61.8) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 36 (33.6%) | 20 (20.4%) |
| Censored Patients, n (%) | 71 (66.4%) | 78 (79.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 8.41) | 5.39 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0169 | |
| HR (95% CI) [c] | 1.958 (1.125, 3.408) | |
| HR P-Value [c] | 0.0175 | |
| Heterogeneity p-value [d] | 0.2646 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.7 (23.6, 51.6) | 47.7 (29.6, 63.8) |
| 12 months | 21.5 (8.2, 38.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 42 (39.3%) | 28 (28.6%) |
| Censored Patients, n (%) | 65 (60.7%) | 70 (71.4%) |
| Median (95% CI), (Months) [a] | 4.21 (2.83, 6.01) | 7.10 (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0315 | |
| HR (95% CI) [c] | 1.692 (1.047, 2.734) | |
| HR P-Value [c] | 0.0317 | |
| Heterogeneity p-value [d] | 0.8645 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.1 (22.4, 50.1) | 57.9 (42.7, 70.4) |
| 12 months | 19.2 (7.3, 35.2) | NE (NE, NE) |
| 18 months | 19.2 (7.3, 35.2) | NE (NE, NE) |
| 24 months | 19.2 (7.3, 35.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 28 (26.2%) | 23 (23.5%) |
| Censored Patients, n (%) | 79 (73.8%) | 75 (76.5%) |
| Median (95% CI), (Months) [a] | 2.92 (1.58, 4.67) | 3.45 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1641 | |
| HR (95% CI) [c] | 1.479 (0.851, 2.570) | |
| HR P-Value [c] | 0.1654 | |
| Heterogeneity p-value [d] | 0.3306 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.8 (10.8, 41.7) | 48.3 (32.4, 62.5) |
| 12 months | 24.8 (10.8, 41.7) | 40.2 (21.4, 58.4) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 20 (18.7%) | 15 (15.3%) |
| Censored Patients, n (%) | 87 (81.3%) | 83 (84.7%) |
| Median (95% CI), (Months) [a] | 1.91 (1.45, 2.83) | 2.83 (1.48, 4.37) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1825 | |
| HR (95% CI) [c] | 1.569 (0.796, 3.092) | |
| HR P-Value [c] | 0.1935 | |
| Heterogeneity p-value [d] | 0.3640 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 6.8 (0.5, 25.5) | 18.4 (3.9, 41.4) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 45 (42.1%) | 43 (43.9%) |
| Censored Patients, n (%) | 62 (57.9%) | 55 (56.1%) |
| Median (95% CI), (Months) [a] | 2.33 (1.54, 3.09) | 2.89 (1.71, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5922 | |
| HR (95% CI) [c] | 1.137 (0.747, 1.730) | |
| HR P-Value [c] | 0.5498 | |
| Heterogeneity p-value [d] | 0.4170 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.5 (16.6, 41.5) | 28.6 (16.8, 41.7) |
| 12 months | 17.8 (6.4, 33.8) | 18.4 (6.8, 34.4) |
| 18 months | 17.8 (6.4, 33.8) | NE (NE, NE) |
| 24 months | 17.8 (6.4, 33.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 28 (26.2%) | 16 (16.3%) |
| Censored Patients, n (%) | 79 (73.8%) | 82 (83.7%) |
| Median (95% CI), (Months) [a] | 5.68 (3.06, NE) | NE (6.93, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0307 | |
| HR (95% CI) [c] | 1.945 (1.051, 3.600) | |
| HR P-Value [c] | 0.0341 | |
| Heterogeneity p-value [d] | 0.3336 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.8 (32.9, 62.9) | 75.1 (59.6, 85.4) |
| 12 months | 39.9 (23.5, 55.9) | 51.8 (29.3, 70.2) |
| 18 months | 39.9 (23.5, 55.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 39 (36.4%) | 24 (24.5%) |
| Censored Patients, n (%) | 68 (63.6%) | 74 (75.5%) |
| Median (95% CI), (Months) [a] | 5.68 (2.99, 13.86) | NE (5.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0598 | |
| HR (95% CI) [c] | 1.636 (0.978, 2.738) | |
| HR P-Value [c] | 0.0607 | |
| Heterogeneity p-value [d] | 0.6614 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.7 (35.4, 60.8) | 64.1 (49.7, 75.4) |
| 12 months | 40.4 (26.7, 53.6) | NE (NE, NE) |
| 18 months | 29.9 (15.0, 46.4) | NE (NE, NE) |
| 24 months | 29.9 (15.0, 46.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 41 (38.3%) | 21 (21.4%) |
| Censored Patients, n (%) | 66 (61.7%) | 77 (78.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.61, 4.67) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0178 | |
| HR (95% CI) [c] | 1.881 (1.111, 3.185) | |
| HR P-Value [c] | 0.0187 | |
| Heterogeneity p-value [d] | 0.9391 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.8 (13.3, 38.2) | 52.4 (35.7, 66.6) |
| 12 months | 20.7 (9.6, 34.7) | 52.4 (35.7, 66.6) |
| 18 months | 20.7 (9.6, 34.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 37 (34.6%) | 25 (25.5%) |
| Censored Patients, n (%) | 70 (65.4%) | 73 (74.5%) |
| Median (95% CI), (Months) [a] | 1.91 (1.51, 2.83) | 3.06 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0412 | |
| HR (95% CI) [c] | 1.693 (1.016, 2.822) | |
| HR P-Value [c] | 0.0434 | |
| Heterogeneity p-value [d] | 0.6009 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.5 (10.2, 35.4) | 43.3 (27.5, 58.1) |
| 12 months | 17.9 (7.5, 31.9) | NE (NE, NE) |
| 18 months | 17.9 (7.5, 31.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 28 (26.2%) | 21 (21.4%) |
| Censored Patients, n (%) | 79 (73.8%) | 77 (78.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 5.45) | 5.06 (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0744 | |
| HR (95% CI) [c] | 1.677 (0.951, 2.958) | |
| HR P-Value [c] | 0.0740 | |
| Heterogeneity p-value [d] | 0.4897 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.1 (12.1, 44.6) | 46.7 (28.1, 63.4) |
| 12 months | 20.3 (6.6, 39.1) | NE (NE, NE) |
| 18 months | 20.3 (6.6, 39.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Appetite loss - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 19 (22.9%) | 11 (15.9%) |
| Censored Patients, n (%) | 64 (77.1%) | 58 (84.1%) |
| | | |
| Median (95% CI), (Months) [a] | 3.09 (1.58, 5.95) | 3.32 (1.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8927 | |
| HR (95% CI) [c] | 1.058 (0.496, 2.257) | |
| HR P-Value [c] | 0.8835 | |
| Heterogeneity p-value [d] | 0.4820 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.1 (9.6, 46.3) | 29.0 (9.3, 52.5) |
| 12 months | 13.0 (1.2, 39.1) | NE (NE, NE) |
| 18 months | 13.0 (1.2, 39.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 22 (26.5%) | 15 (21.7%) |
| Censored Patients, n (%) | 61 (73.5%) | 54 (78.3%) |
| | | |
| Median (95% CI), (Months) [a] | 3.06 (1.91, 6.97) | 2.43 (1.51, 2.96) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1067 | |
| HR (95% CI) [c] | 0.570 (0.286, 1.136) | |
| HR P-Value [c] | 0.1100 | |
| Heterogeneity p-value [d] | 0.0549 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.1 (19.9, 54.5) | 21.3 (6.1, 42.4) |
| 12 months | 19.9 (6.2, 39.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 22 (26.5%) | 8 (11.6%) |
| Censored Patients, n (%) | 61 (73.5%) | 61 (88.4%) |
| Median (95% CI), (Months) [a] | 2.07 (1.58, 4.24) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2498 | |
| HR (95% CI) [c] | 1.591 (0.702, 3.606) | |
| HR P-Value [c] | 0.2663 | |
| Heterogeneity p-value [d] | 0.6124 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.1 (7.9, 40.7) | 51.9 (26.3, 72.5) |
| 12 months | 14.8 (3.2, 34.4) | 51.9 (26.3, 72.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Diarhoea - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 18 (21.7%) | 8 (11.6%) |
| Censored Patients, n (%) | 65 (78.3%) | 61 (88.4%) |
| Median (95% CI), (Months) [a] | 1.64 (1.48, 4.17) | 1.54 (1.41, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6372 | |
| HR (95% CI) [c] | 0.817 (0.352, 1.898) | |
| HR P-Value [c] | 0.6382 | |
| Heterogeneity p-value [d] | 0.3702 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 15.8 (3.9, 34.9) | 22.2 (3.4, 51.3) |
| 12 months | 5.3 (0.4, 21.4) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 14 (16.9%) | 7 (10.1%) |
| Censored Patients, n (%) | 69 (83.1%) | 62 (89.9%) |
| Median (95% CI), (Months) [a] | 2.83 (1.61, 5.72) | 9.69 (1.58, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2767 | |
| HR (95% CI) [c] | 1.639 (0.660, 4.066) | |
| HR P-Value [c] | 0.2867 | |
| Heterogeneity p-value [d] | 0.9262 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.0 (7.0, 48.5) | 59.2 (30.5, 79.4) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 30 (36.1%) | 13 (18.8%) |
| Censored Patients, n (%) | 53 (63.9%) | 56 (81.2%) |
| Median (95% CI), (Months) [a] | 4.21 (2.79, 8.41) | 5.39 (2.89, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4052 | |
| HR (95% CI) [c] | 1.326 (0.681, 2.582) | |
| HR P-Value [c] | 0.4071 | |
| Heterogeneity p-value [d] | 0.4183 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.0 (24.8, 54.7) | 36.2 (8.9, 65.3) |
| 12 months | 27.4 (11.7, 45.9) | NE (NE, NE) |
| 18 months | 18.3 (4.4, 39.7) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 34 (41.0%) | 15 (21.7%) |
| Censored Patients, n (%) | 49 (59.0%) | 54 (78.3%) |
| | | |
| Median (95% CI), (Months) [a] | 4.21 (2.83, 5.75) | 14.69 (6.93, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0451 | |
| HR (95% CI) [c] | 1.842 (1.002, 3.386) | |
| HR P-Value [c] | 0.0491 | |
| Heterogeneity p-value [d] | 0.7872 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.7 (19.3, 46.8) | 69.2 (52.7, 80.9) |
| 12 months | 28.0 (14.6, 43.2) | 57.7 (31.3, 77.1) |
| 18 months | 28.0 (14.6, 43.2) | 0.0 (NE, NE) |
| 24 months | 28.0 (14.6, 43.2) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 21 (25.3%) | 14 (20.3%) |
| Censored Patients, n (%) | 62 (74.7%) | 55 (79.7%) |
| | | |
| Median (95% CI), (Months) [a] | 2.96 (2.07, 7.10) | 2.99 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9029 | |
| HR (95% CI) [c] | 0.959 (0.480, 1.915) | |
| HR P-Value [c] | 0.9063 | |
| Heterogeneity p-value [d] | 0.4563 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.9 (17.7, 52.7) | 38.6 (17.9, 59.1) |
| 12 months | 20.9 (6.3, 41.2) | NE (NE, NE) |
| 18 months | 20.9 (6.3, 41.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 12 (14.5%) | 8 (11.6%) |
| Censored Patients, n (%) | 71 (85.5%) | 61 (88.4%) |
| Median (95% CI), (Months) [a] | 1.71 (1.45, 4.17) | 2.56 (1.48, 5.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8529 | |
| HR (95% CI) [c] | 1.094 (0.430, 2.778) | |
| HR P-Value [c] | 0.8507 | |
| Heterogeneity p-value [d] | 0.6974 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.2 (4.2, 48.8) | 0.0 (NE, NE) |
| 12 months | 11.1 (0.7, 37.5) | 0.0 (NE, NE) |
| 18 months | 11.1 (0.7, 37.5) | 0.0 (NE, NE) |
| 24 months | 11.1 (0.7, 37.5) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 33 (39.8%) | 19 (27.5%) |
| Censored Patients, n (%) | 50 (60.2%) | 50 (72.5%) |
| Median (95% CI), (Months) [a] | 4.21 (1.84, 5.65) | 5.22 (2.43, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3929 | |
| HR (95% CI) [c] | 1.278 (0.726, 2.249) | |
| HR P-Value [c] | 0.3953 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.5 (16.7, 45.4) | 43.1 (24.0, 60.8) |
| 12 months | 18.1 (6.7, 33.8) | 30.8 (13.0, 50.6) |
| 18 months | 18.1 (6.7, 33.8) | NE (NE, NE) |
| 24 months | 18.1 (6.7, 33.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 25 (30.1%) | 6 (8.7%) |
| Censored Patients, n (%) | 58 (69.9%) | 63 (91.3%) |
| | | |
| Median (95% CI), (Months) [a] | 4.96 (2.83, NE) | NE (6.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0115 | |
| HR (95% CI) [c] | 3.011 (1.228, 7.380) | |
| HR P-Value [c] | 0.0160 | |
| Heterogeneity p-value [d] | 0.4614 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.2 (28.1, 59.1) | 82.9 (60.3, 93.3) |
| 12 months | 40.2 (24.1, 55.8) | 59.2 (25.4, 81.9) |
| 18 months | 40.2 (24.1, 55.8) | NE (NE, NE) |
| 24 months | 26.8 (7.4, 51.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 37 (44.6%) | 12 (17.4%) |
| Censored Patients, n (%) | 46 (55.4%) | 57 (82.6%) |
| Median (95% CI), (Months) [a] | 4.57 (2.96, 12.39) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0202 | |
| HR (95% CI) [c] | 2.142 (1.110, 4.134) | |
| HR P-Value [c] | 0.0231 | |
| Heterogeneity p-value [d] | 0.5342 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.1 (29.9, 55.6) | 70.1 (51.6, 82.7) |
| 12 months | 37.3 (23.9, 50.7) | 60.1 (34.6, 78.4) |
| 18 months | 32.0 (17.7, 47.2) | NE (NE, NE) |
| 24 months | 21.3 (5.9, 42.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 27 (32.5%) | 11 (15.9%) |
| Censored Patients, n (%) | 56 (67.5%) | 58 (84.1%) |
| Median (95% CI), (Months) [a] | 4.67 (1.91, 5.68) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2376 | |
| HR (95% CI) [c] | 1.513 (0.750, 3.052) | |
| HR P-Value [c] | 0.2473 | |
| Heterogeneity p-value [d] | 0.5144 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.4 (15.8, 46.4) | 55.8 (33.5, 73.2) |
| 12 months | 22.2 (9.3, 38.4) | 55.8 (33.5, 73.2) |
| 18 months | 22.2 (9.3, 38.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 28 (33.7%) | 18 (26.1%) |
| Censored Patients, n (%) | 55 (66.3%) | 51 (73.9%) |
| Median (95% CI), (Months) [a] | 2.33 (1.58, 2.96) | 3.06 (1.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1130 | |
| HR (95% CI) [c] | 1.604 (0.884, 2.911) | |
| HR P-Value [c] | 0.1198 | |
| Heterogeneity p-value [d] | 0.5388 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 15.5 (5.2, 30.7) | 36.8 (18.4, 55.4) |
| 12 months | 10.3 (2.2, 25.7) | 36.8 (18.4, 55.4) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 22 (26.5%) | 14 (20.3%) |
| Censored Patients, n (%) | 61 (73.5%) | 55 (79.7%) |
| Median (95% CI), (Months) [a] | 4.96 (2.83, 7.23) | 3.32 (2.14, 8.31) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7536 | |
| HR (95% CI) [c] | 0.900 (0.455, 1.784) | |
| HR P-Value [c] | 0.7637 | |
| Heterogeneity p-value [d] | 0.1278 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.7 (24.4, 59.8) | 46.3 (24.9, 65.3) |
| 12 months | 24.4 (8.7, 44.2) | 0.0 (NE, NE) |
| 18 months | 24.4 (8.7, 44.2) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 27 (23.9%) | 23 (20.2%) |
| Censored Patients, n (%) | 86 (76.1%) | 91 (79.8%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.61, 4.27) | 4.37 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1676 | |
| HR (95% CI) [c] | 1.492 (0.850, 2.621) | |
| HR P-Value [c] | 0.1634 | |
| Heterogeneity p-value [d] | 0.4820 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.5 (7.9, 39.3) | 40.8 (23.0, 57.9) |
| 12 months | NE (NE, NE) | 27.2 (7.2, 52.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 32 (28.3%) | 22 (19.3%) |
| Censored Patients, n (%) | 81 (71.7%) | 92 (80.7%) |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 2.96) | 4.30 (1.91, 6.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2284 | |
| HR (95% CI) [c] | 1.428 (0.822, 2.480) | |
| HR P-Value [c] | 0.2060 | |
| Heterogeneity p-value [d] | 0.0549 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.4 (19.6, 47.8) | 31.4 (13.2, 51.6) |
| 12 months | 20.0 (6.7, 38.5) | NE (NE, NE) |
| 18 months | 20.0 (6.7, 38.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 30 (26.5%) | 21 (18.4%) |
| Censored Patients, n (%) | 83 (73.5%) | 93 (81.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.34) | 3.12 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4065 | |
| HR (95% CI) [c] | 1.277 (0.724, 2.250) | |
| HR P-Value [c] | 0.3983 | |
| Heterogeneity p-value [d] | 0.6124 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.2 (7.8, 38.9) | 34.7 (17.4, 52.8) |
| 12 months | 10.6 (2.0, 27.6) | NE (NE, NE) |
| 18 months | 10.6 (2.0, 27.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 13 (11.5%) | 9 (7.9%) |
| Censored Patients, n (%) | 100 (88.5%) | 105 (92.1%) |
| Median (95% CI), (Months) [a] | 1.46 (1.45, 3.02) | 2.92 (1.48, 6.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5546 | |
| HR (95% CI) [c] | 1.359 (0.564, 3.271) | |
| HR P-Value [c] | 0.4943 | |
| Heterogeneity p-value [d] | 0.3702 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.4 (5.4, 44.4) | 25.3 (4.1, 55.2) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 28 (24.8%) | 17 (14.9%) |
| Censored Patients, n (%) | 85 (75.2%) | 97 (85.1%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.21) | 4.53 (2.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1197 | |
| HR (95% CI) [c] | 1.624 (0.880, 2.995) | |
| HR P-Value [c] | 0.1208 | |
| Heterogeneity p-value [d] | 0.9262 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.2 (12.8, 43.9) | 37.9 (17.3, 58.5) |
| 12 months | 10.9 (2.1, 27.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 41 (36.3%) | 22 (19.3%) |
| Censored Patients, n (%) | 72 (63.7%) | 92 (80.7%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.34) | 5.06 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0126 | |
| HR (95% CI) [c] | 1.948 (1.157, 3.281) | |
| HR P-Value [c] | 0.0121 | |
| Heterogeneity p-value [d] | 0.4183 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.9 (15.3, 42.1) | 43.6 (26.1, 59.9) |
| 12 months | 12.0 (3.4, 26.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 43 (38.1%) | 27 (23.7%) |
| Censored Patients, n (%) | 70 (61.9%) | 87 (76.3%) |
| Median (95% CI), (Months) [a] | 3.25 (2.79, 7.43) | 7.10 (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0745 | |
| HR (95% CI) [c] | 1.571 (0.964, 2.560) | |
| HR P-Value [c] | 0.0700 | |
| Heterogeneity p-value [d] | 0.7872 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.3 (26.7, 53.6) | 54.5 (38.0, 68.3) |
| 12 months | 26.5 (12.5, 42.8) | NE (NE, NE) |
| 18 months | 19.8 (6.8, 37.8) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 27 (23.9%) | 23 (20.2%) |
| Censored Patients, n (%) | 86 (76.1%) | 91 (79.8%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.53) | 3.45 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2326 | |
| HR (95% CI) [c] | 1.412 (0.808, 2.465) | |
| HR P-Value [c] | 0.2258 | |
| Heterogeneity p-value [d] | 0.4563 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.4 (14.7, 45.8) | 49.2 (32.9, 63.6) |
| 12 months | 29.4 (14.7, 45.8) | 35.0 (15.9, 54.9) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 23 (20.4%) | 18 (15.8%) |
| Censored Patients, n (%) | 90 (79.6%) | 96 (84.2%) |
| Median (95% CI), (Months) [a] | 2.07 (1.45, 3.22) | 2.92 (1.64, 3.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3978 | |
| HR (95% CI) [c] | 1.317 (0.705, 2.462) | |
| HR P-Value [c] | 0.3873 | |
| Heterogeneity p-value [d] | 0.6974 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 12.9 (2.5, 32.1) | 18.1 (4.9, 37.8) |
| 12 months | 12.9 (2.5, 32.1) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 48 (42.5%) | 41 (36.0%) |
| Censored Patients, n (%) | 65 (57.5%) | 73 (64.0%) |
| Median (95% CI), (Months) [a] | 1.94 (1.54, 3.25) | 2.89 (1.91, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3918 | |
| HR (95% CI) [c] | 1.233 (0.807, 1.884) | |
| HR P-Value [c] | 0.3331 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.0 (16.2, 41.1) | 27.0 (14.6, 40.9) |
| 12 months | 11.7 (2.6, 28.2) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 28 (24.8%) | 15 (13.2%) |
| Censored Patients, n (%) | 85 (75.2%) | 99 (86.8%) |
| | | |
| Median (95% CI), (Months) [a] | 7.43 (4.17, NE) | NE (7.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0311 | |
| HR (95% CI) [c] | 1.978 (1.055, 3.708) | |
| HR P-Value [c] | 0.0335 | |
| Heterogeneity p-value [d] | 0.4614 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.6 (35.9, 65.3) | 76.5 (60.9, 86.5) |
| 12 months | 46.5 (29.5, 61.8) | NE (NE, NE) |
| 18 months | 46.5 (29.5, 61.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 40 (35.4%) | 24 (21.1%) |
| Censored Patients, n (%) | 73 (64.6%) | 90 (78.9%) |
| | | |
| Median (95% CI), (Months) [a] | 4.90 (2.89, 13.86) | 9.59 (5.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0805 | |
| HR (95% CI) [c] | 1.585 (0.950, 2.645) | |
| HR P-Value [c] | 0.0779 | |
| Heterogeneity p-value [d] | 0.5342 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.9 (36.9, 61.6) | 63.1 (48.1, 74.8) |
| 12 months | 39.3 (25.0, 53.4) | NE (NE, NE) |
| 18 months | 21.0 (5.3, 43.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 44 (38.9%) | 20 (17.5%) |
| Censored Patients, n (%) | 69 (61.1%) | 94 (82.5%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.24) | NE (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0070 | |
| HR (95% CI) [c] | 2.072 (1.217, 3.528) | |
| HR P-Value [c] | 0.0073 | |
| Heterogeneity p-value [d] | 0.5144 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.1 (17.6, 43.5) | 53.5 (36.2, 68.0) |
| 12 months | 20.1 (8.1, 35.8) | NE (NE, NE) |
| 18 months | 20.1 (8.1, 35.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 41 (36.3%) | 22 (19.3%) |
| Censored Patients, n (%) | 72 (63.7%) | 92 (80.7%) |
| Median (95% CI), (Months) [a] | 1.58 (1.48, 2.83) | 4.17 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0107 | |
| HR (95% CI) [c] | 1.962 (1.163, 3.309) | |
| HR P-Value [c] | 0.0116 | |
| Heterogeneity p-value [d] | 0.5388 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.9 (13.7, 38.0) | 48.3 (30.8, 63.8) |
| 12 months | 13.3 (3.4, 30.0) | NE (NE, NE) |
| 18 months | 13.3 (3.4, 30.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 33 (29.2%) | 18 (15.8%) |
| Censored Patients, n (%) | 80 (70.8%) | 96 (84.2%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.34) | 5.06 (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0279 | |
| HR (95% CI) [c] | 1.906 (1.069, 3.398) | |
| HR P-Value [c] | 0.0289 | |
| Heterogeneity p-value [d] | 0.1278 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.2 (11.0, 40.2) | 44.7 (24.2, 63.3) |
| 12 months | 16.1 (4.1, 35.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 26 (22.2%) | 20 (20.6%) |
| Censored Patients, n (%) | 91 (77.8%) | 77 (79.4%) |
| | | |
| Median (95% CI), (Months) [a] | 3.91 (1.84, 4.86) | 2.79 (1.61, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9182 | |
| HR (95% CI) [c] | 1.040 (0.580, 1.867) | |
| HR P-Value [c] | 0.8951 | |
| Heterogeneity p-value [d] | 0.1698 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 20.9 (7.6, 38.7) | 38.6 (20.4, 56.5) |
| 12 months | 20.9 (7.6, 38.7) | NE (NE, NE) |
| 18 months | 20.9 (7.6, 38.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 31 (26.5%) | 21 (21.6%) |
| Censored Patients, n (%) | 86 (73.5%) | 76 (78.4%) |
| Median (95% CI), (Months) [a] | 2.83 (1.91, 6.97) | 2.92 (1.74, 4.83) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6870 | |
| HR (95% CI) [c] | 0.901 (0.509, 1.595) | |
| HR P-Value [c] | 0.7193 | |
| Heterogeneity p-value [d] | 0.6526 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.9 (24.4, 53.2) | 18.2 (4.3, 39.8) |
| 12 months | 16.7 (4.9, 34.6) | NE (NE, NE) |
| 18 months | 16.7 (4.9, 34.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 31 (26.5%) | 19 (19.6%) |
| Censored Patients, n (%) | 86 (73.5%) | 78 (80.4%) |
| Median (95% CI), (Months) [a] | 2.69 (1.58, 3.91) | 2.10 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6036 | |
| HR (95% CI) [c] | 1.158 (0.652, 2.059) | |
| HR P-Value [c] | 0.6163 | |
| Heterogeneity p-value [d] | 0.3904 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.0 (9.0, 38.5) | 36.9 (19.3, 54.7) |
| 12 months | 11.0 (2.2, 27.8) | NE (NE, NE) |
| 18 months | 11.0 (2.2, 27.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 21 (17.9%) | 9 (9.3%) |
| Censored Patients, n (%) | 96 (82.1%) | 88 (90.7%) |
| | | |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 2.83) | 2.07 (1.41, 5.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9503 | |
| HR (95% CI) [c] | 1.048 (0.475, 2.314) | |
| HR P-Value [c] | 0.9073 | |
| Heterogeneity p-value [d] | 0.7066 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.3 (7.4, 40.1) | 12.5 (0.7, 41.8) |
| 12 months | 5.3 (0.4, 21.4) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 27 (23.1%) | 13 (13.4%) |
| Censored Patients, n (%) | 90 (76.9%) | 84 (86.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 6.97) | 4.30 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3747 | |
| HR (95% CI) [c] | 1.358 (0.693, 2.660) | |
| HR P-Value [c] | 0.3728 | |
| Heterogeneity p-value [d] | 0.2433 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.8 (18.7, 51.4) | 48.0 (25.6, 67.2) |
| 12 months | 15.2 (4.2, 32.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 38 (32.5%) | 19 (19.6%) |
| Censored Patients, n (%) | 79 (67.5%) | 78 (80.4%) |
| | | |
| Median (95% CI), (Months) [a] | 2.89 (1.84, 6.97) | 5.03 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0536 | |
| HR (95% CI) [c] | 1.720 (0.990, 2.987) | |
| HR P-Value [c] | 0.0541 | |
| Heterogeneity p-value [d] | 0.9320 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.1 (24.7, 51.4) | 49.9 (31.1, 66.1) |
| 12 months | 14.3 (4.1, 30.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 48 (41.0%) | 28 (28.9%) |
| Censored Patients, n (%) | 69 (59.0%) | 69 (71.1%) |
| | | |
| Median (95% CI), (Months) [a] | 3.25 (2.83, 5.68) | 7.10 (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1509 | |
| HR (95% CI) [c] | 1.417 (0.884, 2.270) | |
| HR P-Value [c] | 0.1473 | |
| Heterogeneity p-value [d] | 0.3245 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.4 (21.2, 46.1) | 55.4 (40.9, 67.6) |
| 12 months | 23.5 (11.8, 37.4) | NE (NE, NE) |
| 18 months | 17.6 (6.4, 33.4) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 29 (24.8%) | 21 (21.6%) |
| Censored Patients, n (%) | 88 (75.2%) | 76 (78.4%) |
| Median (95% CI), (Months) [a] | 2.83 (1.71, 4.67) | 3.45 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4104 | |
| HR (95% CI) [c] | 1.267 (0.722, 2.224) | |
| HR P-Value [c] | 0.4096 | |
| Heterogeneity p-value [d] | 0.8880 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.4 (14.8, 43.6) | 49.9 (32.9, 64.8) |
| 12 months | 28.4 (14.8, 43.6) | NE (NE, NE) |
| 18 months | 28.4 (14.8, 43.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 23 (19.7%) | 17 (17.5%) |
| Censored Patients, n (%) | 94 (80.3%) | 80 (82.5%) |
| Median (95% CI), (Months) [a] | 2.73 (1.45, 3.22) | 2.92 (1.58, 4.47) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4020 | |
| HR (95% CI) [c] | 1.316 (0.698, 2.484) | |
| HR P-Value [c] | 0.3962 | |
| Heterogeneity p-value [d] | 0.6203 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 16.9 (4.7, 35.6) | 18.1 (4.7, 38.6) |
| 12 months | 11.3 (2.1, 29.3) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Pain - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 46 (39.3%) | 38 (39.2%) |
| Censored Patients, n (%) | 71 (60.7%) | 59 (60.8%) |
| Median (95% CI), (Months) [a] | 3.09 (1.84, 4.34) | 2.83 (1.71, 4.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9041 | |
| HR (95% CI) [c] | 1.038 (0.674, 1.601) | |
| HR P-Value [c] | 0.8642 | |
| Heterogeneity p-value [d] | 0.3311 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.5 (14.6, 40.0) | 26.4 (14.4, 40.0) |
| 12 months | 12.9 (3.3, 29.1) | 26.4 (14.4, 40.0) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 35 (29.9%) | 14 (14.4%) |
| Censored Patients, n (%) | 82 (70.1%) | 83 (85.6%) |
| | | |
| Median (95% CI), (Months) [a] | 4.67 (2.83, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0053 | |
| HR (95% CI) [c] | 2.367 (1.272, 4.404) | |
| HR P-Value [c] | 0.0065 | |
| Heterogeneity p-value [d] | 0.9695 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.1 (26.0, 53.8) | 73.3 (57.0, 84.2) |
| 12 months | 40.1 (26.0, 53.8) | 59.2 (36.0, 76.4) |
| 18 months | 40.1 (26.0, 53.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 44 (37.6%) | 20 (20.6%) |
| Censored Patients, n (%) | 73 (62.4%) | 77 (79.4%) |
| Median (95% CI), (Months) [a] | 6.01 (2.99, 12.39) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0390 | |
| HR (95% CI) [c] | 1.749 (1.024, 2.987) | |
| HR P-Value [c] | 0.0407 | |
| Heterogeneity p-value [d] | 0.9727 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.2 (37.9, 61.3) | 66.5 (52.2, 77.4) |
| 12 months | 40.0 (27.0, 52.7) | 66.5 (52.2, 77.4) |
| 18 months | 18.7 (4.7, 39.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 44 (37.6%) | 19 (19.6%) |
| Censored Patients, n (%) | 73 (62.4%) | 78 (80.4%) |
| | | |
| Median (95% CI), (Months) [a] | 3.06 (1.84, 5.68) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0353 | |
| HR (95% CI) [c] | 1.791 (1.044, 3.074) | |
| HR P-Value [c] | 0.0344 | |
| Heterogeneity p-value [d] | 0.8278 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.0 (18.0, 42.9) | 55.4 (37.8, 69.9) |
| 12 months | 21.2 (10.5, 34.4) | 55.4 (37.8, 69.9) |
| 18 months | 21.2 (10.5, 34.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 43 (36.8%) | 20 (20.6%) |
| Censored Patients, n (%) | 74 (63.2%) | 77 (79.4%) |
| Median (95% CI), (Months) [a] | 1.61 (1.48, 2.33) | 7.00 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0004 | |
| HR (95% CI) [c] | 2.535 (1.487, 4.323) | |
| HR P-Value [c] | 0.0006 | |
| Heterogeneity p-value [d] | 0.0866 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 14.7 (6.3, 26.3) | 51.2 (33.4, 66.5) |
| 12 months | 9.8 (2.6, 22.9) | 41.0 (19.2, 61.7) |
| 18 months | 9.8 (2.6, 22.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 28 (23.9%) | 20 (20.6%) |
| Censored Patients, n (%) | 89 (76.1%) | 77 (79.4%) |
| | | |
| Median (95% CI), (Months) [a] | 3.09 (2.83, 6.97) | 3.12 (2.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6379 | |
| HR (95% CI) [c] | 1.152 (0.647, 2.052) | |
| HR P-Value [c] | 0.6304 | |
| Heterogeneity p-value [d] | 0.2148 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.0 (20.8, 51.3) | 41.7 (23.1, 59.3) |
| 12 months | 27.4 (13.2, 43.7) | NE (NE, NE) |
| 18 months | 27.4 (13.2, 43.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 20 (26.0%) | 14 (16.3%) |
| Censored Patients, n (%) | 57 (74.0%) | 72 (83.7%) |
| | | |
| Median (95% CI), (Months) [a] | 2.79 (1.48, 4.17) | 4.37 (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0291 | |
| HR (95% CI) [c] | 2.163 (1.065, 4.390) | |
| HR P-Value [c] | 0.0327 | |
| Heterogeneity p-value [d] | 0.1698 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.6 (12.4, 47.2) | 36.7 (15.1, 58.8) |
| 12 months | 0.0 (NE, NE) | 18.4 (1.5, 50.2) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 22 (28.6%) | 16 (18.6%) |
| Censored Patients, n (%) | 55 (71.4%) | 70 (81.4%) |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 4.96) | 3.02 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6380 | |
| HR (95% CI) [c] | 1.163 (0.605, 2.235) | |
| HR P-Value [c] | 0.6514 | |
| Heterogeneity p-value [d] | 0.6526 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.6 (11.7, 46.2) | 40.2 (20.2, 59.5) |
| 12 months | 22.1 (7.8, 40.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 20 (26.0%) | 10 (11.6%) |
| Censored Patients, n (%) | 57 (74.0%) | 76 (88.4%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.96) | 4.50 (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1299 | |
| HR (95% CI) [c] | 1.791 (0.831, 3.862) | |
| HR P-Value [c] | 0.1372 | |
| Heterogeneity p-value [d] | 0.3904 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.6 (6.1, 43.1) | 45.6 (20.9, 67.5) |
| 12 months | 14.4 (2.6, 35.6) | 45.6 (20.9, 67.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 10 (13.0%) | 8 (9.3%) |
| Censored Patients, n (%) | 67 (87.0%) | 78 (90.7%) |
| | | |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 4.17) | 1.54 (1.41, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3727 | |
| HR (95% CI) [c] | 1.573 (0.563, 4.398) | |
| HR P-Value [c] | 0.3877 | |
| Heterogeneity p-value [d] | 0.7066 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 33.8 (8.0, 62.7) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 15 (19.5%) | 11 (12.8%) |
| Censored Patients, n (%) | 62 (80.5%) | 75 (87.2%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.45, 3.02) | 5.06 (2.30, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0097 | |
| HR (95% CI) [c] | 2.793 (1.239, 6.300) | |
| HR P-Value [c] | 0.0133 | |
| Heterogeneity p-value [d] | 0.2433 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 7.5 (0.5, 28.4) | 44.3 (19.0, 67.1) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 32 (41.6%) | 16 (18.6%) |
| Censored Patients, n (%) | 45 (58.4%) | 70 (81.4%) |
| | | |
| Median (95% CI), (Months) [a] | 2.96 (1.58, 4.24) | 5.06 (2.89, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0807 | |
| HR (95% CI) [c] | 1.722 (0.936, 3.169) | |
| HR P-Value [c] | 0.0807 | |
| Heterogeneity p-value [d] | 0.9320 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.6 (10.3, 39.9) | 33.0 (12.4, 55.4) |
| 12 months | 17.7 (5.7, 35.0) | NE (NE, NE) |
| 18 months | 17.7 (5.7, 35.0) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 28 (36.4%) | 14 (16.3%) |
| Censored Patients, n (%) | 49 (63.6%) | 72 (83.7%) |
| | | |
| Median (95% CI), (Months) [a] | 4.30 (2.79, NE) | 14.69 (5.91, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0177 | |
| HR (95% CI) [c] | 2.147 (1.125, 4.094) | |
| HR P-Value [c] | 0.0204 | |
| Heterogeneity p-value [d] | 0.3245 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.7 (23.6, 55.3) | 66.5 (44.2, 81.6) |
| 12 months | 34.7 (18.7, 51.3) | 53.2 (23.6, 75.9) |
| 18 months | 34.7 (18.7, 51.3) | 0.0 (NE, NE) |
| 24 months | 34.7 (18.7, 51.3) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 18 (23.4%) | 16 (18.6%) |
| Censored Patients, n (%) | 59 (76.6%) | 70 (81.4%) |
| Median (95% CI), (Months) [a] | 4.17 (1.64, 7.26) | 2.99 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6606 | |
| HR (95% CI) [c] | 1.162 (0.591, 2.284) | |
| HR P-Value [c] | 0.6632 | |
| Heterogeneity p-value [d] | 0.8880 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.6 (19.5, 59.1) | 41.6 (22.6, 59.6) |
| 12 months | 19.8 (4.0, 44.3) | 41.6 (22.6, 59.6) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 12 (15.6%) | 9 (10.5%) |
| Censored Patients, n (%) | 65 (84.4%) | 77 (89.5%) |
| Median (95% CI), (Months) [a] | 1.64 (1.45, 5.59) | 2.79 (1.58, 5.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7867 | |
| HR (95% CI) [c] | 1.136 (0.458, 2.817) | |
| HR P-Value [c] | 0.7830 | |
| Heterogeneity p-value [d] | 0.6203 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 14.7 (1.1, 44.4) | 0.0 (NE, NE) |
| 12 months | 14.7 (1.1, 44.4) | 0.0 (NE, NE) |
| 18 months | 14.7 (1.1, 44.4) | 0.0 (NE, NE) |
| 24 months | 14.7 (1.1, 44.4) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 34 (44.2%) | 22 (25.6%) |
| Censored Patients, n (%) | 43 (55.8%) | 64 (74.4%) |
| Median (95% CI), (Months) [a] | 1.94 (1.54, 4.96) | 5.39 (2.69, 6.74) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1688 | |
| HR (95% CI) [c] | 1.475 (0.858, 2.534) | |
| HR P-Value [c] | 0.1595 | |
| Heterogeneity p-value [d] | 0.3311 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.7 (16.3, 44.3) | 42.0 (22.8, 60.0) |
| 12 months | 13.2 (3.1, 30.7) | 14.0 (1.3, 41.2) |
| 18 months | 13.2 (3.1, 30.7) | NE (NE, NE) |
| 24 months | 13.2 (3.1, 30.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 18 (23.4%) | 7 (8.1%) |
| Censored Patients, n (%) | 59 (76.6%) | 79 (91.9%) |
| | | |
| Median (95% CI), (Months) [a] | 7.43 (4.17, NE) | NE (6.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0553 | |
| HR (95% CI) [c] | 2.320 (0.957, 5.620) | |
| HR P-Value [c] | 0.0624 | |
| Heterogeneity p-value [d] | 0.9695 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.2 (38.6, 72.1) | 85.6 (64.7, 94.6) |
| 12 months | 45.8 (25.8, 63.7) | 55.5 (23.8, 78.6) |
| 18 months | 45.8 (25.8, 63.7) | NE (NE, NE) |
| 24 months | 22.9 (1.9, 57.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 32 (41.6%) | 16 (18.6%) |
| Censored Patients, n (%) | 45 (58.4%) | 70 (81.4%) |
| | | |
| Median (95% CI), (Months) [a] | 4.37 (2.83, 18.20) | 7.26 (5.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0506 | |
| HR (95% CI) [c] | 1.821 (0.993, 3.337) | |
| HR P-Value [c] | 0.0525 | |
| Heterogeneity p-value [d] | 0.9727 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.3 (24.8, 53.4) | 64.7 (44.9, 78.9) |
| 12 months | 35.3 (20.8, 50.2) | NE (NE, NE) |
| 18 months | 35.3 (20.8, 50.2) | NE (NE, NE) |
| 24 months | 23.6 (6.7, 46.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 26 (33.8%) | 12 (14.0%) |
| Censored Patients, n (%) | 51 (66.2%) | 74 (86.0%) |
| | | |
| Median (95% CI), (Months) [a] | 2.92 (1.58, 4.96) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0509 | |
| HR (95% CI) [c] | 1.955 (0.985, 3.878) | |
| HR P-Value [c] | 0.0552 | |
| Heterogeneity p-value [d] | 0.8278 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.8 (12.1, 44.1) | 53.8 (32.1, 71.3) |
| 12 months | 17.9 (4.5, 38.5) | 53.8 (32.1, 71.3) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 25 (32.5%) | 20 (23.3%) |
| Censored Patients, n (%) | 52 (67.5%) | 66 (76.7%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.51, 4.96) | 2.99 (1.64, 7.26) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5823 | |
| HR (95% CI) [c] | 1.184 (0.649, 2.160) | |
| HR P-Value [c] | 0.5821 | |
| Heterogeneity p-value [d] | 0.0866 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 26.0 (10.9, 44.1) | 34.3 (16.8, 52.6) |
| 12 months | 13.9 (3.0, 32.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 27 (35.1%) | 12 (14.0%) |
| Censored Patients, n (%) | 50 (64.9%) | 74 (86.0%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.51, 5.75) | 5.06 (3.32, 8.31) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0709 | |
| HR (95% CI) [c] | 1.882 (0.947, 3.740) | |
| HR P-Value [c] | 0.0711 | |
| Heterogeneity p-value [d] | 0.2148 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.7 (9.4, 45.8) | 48.6 (21.4, 71.4) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 7 (26.9%) | 1 (5.3%) |
| Censored Patients, n (%) | 19 (73.1%) | 18 (94.7%) |
| | | |
| Median (95% CI), (Months) [a] | 3.91 (1.45, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6763 | |
| HR (95% CI) [c] | 1.526 (0.176, 13.200) | |
| HR P-Value [c] | 0.7011 | |
| Heterogeneity p-value [d] | 0.9768 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.8 (8.6, 61.8) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 11 (42.3%) | 3 (15.8%) |
| Censored Patients, n (%) | 15 (57.7%) | 16 (84.2%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.48, 6.97) | 2.92 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9667 | |
| HR (95% CI) [c] | 0.980 (0.264, 3.637) | |
| HR P-Value [c] | 0.9755 | |
| Heterogeneity p-value [d] | 0.6010 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.7 (13.0, 59.4) | 30.0 (1.2, 71.9) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 10 (38.5%) | 3 (15.8%) |
| Censored Patients, n (%) | 16 (61.5%) | 16 (84.2%) |
| | | |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 3.91) | 1.58 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5631 | |
| HR (95% CI) [c] | 1.471 (0.388, 5.579) | |
| HR P-Value [c] | 0.5704 | |
| Heterogeneity p-value [d] | 0.4653 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.2 (3.3, 49.3) | NE (NE, NE) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 8 (30.8%) | 2 (10.5%) |
| Censored Patients, n (%) | 18 (69.2%) | 17 (89.5%) |
| | | |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 6.11) | 4.25 (2.92, 5.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7346 | |
| HR (95% CI) [c] | 1.401 (0.275, 7.148) | |
| HR P-Value [c] | 0.6851 | |
| Heterogeneity p-value [d] | 0.9691 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.0 (3.7, 55.8) | 0.0 (NE, NE) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 0 |
| Censored Patients, n (%) | 20 (76.9%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 8.34 (2.83, 9.72) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3689 | |
| HR (95% CI) [c] | 13114956 (0.000, NE) | |
| HR P-Value [c] | 0.9968 | |
| Heterogeneity p-value [d] | 0.7559 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.6 (30.5, 88.7) | 100.0 (100.0, 100.0) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 10 (38.5%) | 3 (15.8%) |
| Censored Patients, n (%) | 16 (61.5%) | 16 (84.2%) |
| | | |
| Median (95% CI), (Months) [a] | 2.51 (1.45, 9.72) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1835 | |
| HR (95% CI) [c] | 2.351 (0.643, 8.591) | |
| HR P-Value [c] | 0.1962 | |
| Heterogeneity p-value [d] | 0.5396 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.9 (17.7, 66.0) | 53.3 (12.5, 82.7) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 10 (38.5%) | 3 (15.8%) |
| Censored Patients, n (%) | 16 (61.5%) | 16 (84.2%) |
| Median (95% CI), (Months) [a] | 5.59 (2.83, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2694 | |
| HR (95% CI) [c] | 2.014 (0.553, 7.331) | |
| HR P-Value [c] | 0.2884 | |
| Heterogeneity p-value [d] | 0.3408 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.4 (12.8, 64.0) | 76.9 (44.2, 91.9) |
| 12 months | 38.4 (12.8, 64.0) | NE (NE, NE) |
| 18 months | 38.4 (12.8, 64.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 10 (38.5%) | 2 (10.5%) |
| Censored Patients, n (%) | 16 (61.5%) | 17 (89.5%) |
| Median (95% CI), (Months) [a] | 1.71 (1.45, 5.59) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3460 | |
| HR (95% CI) [c] | 2.002 (0.431, 9.300) | |
| HR P-Value [c] | 0.3757 | |
| Heterogeneity p-value [d] | 0.7622 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 13.6 (1.0, 42.6) | 50.0 (5.8, 84.5) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 8 (30.8%) | 3 (15.8%) |
| Censored Patients, n (%) | 18 (69.2%) | 16 (84.2%) |
| Median (95% CI), (Months) [a] | 1.71 (1.45, 4.90) | 2.83 (1.45, 5.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9882 | |
| HR (95% CI) [c] | 0.976 (0.247, 3.851) | |
| HR P-Value [c] | 0.9720 | |
| Heterogeneity p-value [d] | 0.9614 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 16.7 (1.1, 49.3) | 0.0 (NE, NE) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 10 (38.5%) | 6 (31.6%) |
| Censored Patients, n (%) | 16 (61.5%) | 13 (68.4%) |
| | | |
| Median (95% CI), (Months) [a] | 4.21 (1.45, 11.17) | 5.22 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9797 | |
| HR (95% CI) [c] | 1.020 (0.362, 2.874) | |
| HR P-Value [c] | 0.9705 | |
| Heterogeneity p-value [d] | 0.7742 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.1 (10.5, 61.5) | 44.7 (13.6, 72.3) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 7 (26.9%) | 1 (5.3%) |
| Censored Patients, n (%) | 19 (73.1%) | 18 (94.7%) |
| | | |
| Median (95% CI), (Months) [a] | 5.62 (2.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1530 | |
| HR (95% CI) [c] | 4.046 (0.497, 32.955) | |
| HR P-Value [c] | 0.1916 | |
| Heterogeneity p-value [d] | 0.8645 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.8 (14.7, 72.8) | 90.9 (50.8, 98.7) |
| 12 months | 45.8 (14.7, 72.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 12 (46.2%) | 5 (26.3%) |
| Censored Patients, n (%) | 14 (53.8%) | 14 (73.7%) |
| Median (95% CI), (Months) [a] | 4.21 (1.58, NE) | 7.06 (2.83, 7.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5873 | |
| HR (95% CI) [c] | 1.356 (0.469, 3.922) | |
| HR P-Value [c] | 0.5736 | |
| Heterogeneity p-value [d] | 0.9081 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.2 (23.8, 66.0) | 65.6 (30.8, 86.0) |
| 12 months | 46.2 (23.8, 66.0) | 0.0 (NE, NE) |
| 18 months | 30.8 (7.4, 58.7) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 8 (30.8%) | 3 (15.8%) |
| Censored Patients, n (%) | 18 (69.2%) | 16 (84.2%) |
| | | |
| Median (95% CI), (Months) [a] | 6.97 (1.58, NE) | NE (1.18, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2382 | |
| HR (95% CI) [c] | 0.437 (0.108, 1.767) | |
| HR P-Value [c] | 0.2455 | |
| Heterogeneity p-value [d] | 0.1246 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.8 (28.0, 76.6) | NE (NE, NE) |
| 12 months | 41.9 (13.5, 68.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 8 (30.8%) | 4 (21.1%) |
| Censored Patients, n (%) | 18 (69.2%) | 15 (78.9%) |
| Median (95% CI), (Months) [a] | 2.96 (1.51, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9444 | |
| HR (95% CI) [c] | 0.915 (0.274, 3.056) | |
| HR P-Value [c] | 0.8850 | |
| Heterogeneity p-value [d] | 0.3038 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.5 (14.1, 62.8) | NE (NE, NE) |
| 12 months | 38.5 (14.1, 62.8) | NE (NE, NE) |
| 18 months | 38.5 (14.1, 62.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 7 (26.9%) | 3 (15.8%) |
| Censored Patients, n (%) | 19 (73.1%) | 16 (84.2%) |
| Median (95% CI), (Months) [a] | 6.97 (1.51, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8100 | |
| HR (95% CI) [c] | 0.849 (0.205, 3.507) | |
| HR P-Value [c] | 0.8209 | |
| Heterogeneity p-value [d] | 0.7970 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.5 (20.6, 74.4) | 62.5 (22.9, 86.1) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 25 (21.0%) | 26 (23.4%) |
| Censored Patients, n (%) | 94 (79.0%) | 85 (76.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 5.72) | 3.12 (1.68, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4295 | |
| HR (95% CI) [c] | 1.256 (0.722, 2.184) | |
| HR P-Value [c] | 0.4192 | |
| Heterogeneity p-value [d] | 0.9768 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 11.8 (0.9, 37.6) | 33.2 (17.4, 49.8) |
| 12 months | 11.8 (0.9, 37.6) | 22.1 (5.9, 44.7) |
| 18 months | 11.8 (0.9, 37.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 33 (27.7%) | 22 (19.8%) |
| Censored Patients, n (%) | 86 (72.3%) | 89 (80.2%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.57) | 2.99 (1.58, 5.78) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7666 | |
| HR (95% CI) [c] | 1.093 (0.630, 1.899) | |
| HR P-Value [c] | 0.7510 | |
| Heterogeneity p-value [d] | 0.6010 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.5 (18.6, 47.2) | 21.2 (5.2, 44.3) |
| 12 months | 19.5 (7.6, 35.5) | NE (NE, NE) |
| 18 months | 19.5 (7.6, 35.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 28 (23.5%) | 20 (18.0%) |
| Censored Patients, n (%) | 91 (76.5%) | 91 (82.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.14) | 3.12 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3425 | |
| HR (95% CI) [c] | 1.324 (0.742, 2.364) | |
| HR P-Value [c] | 0.3427 | |
| Heterogeneity p-value [d] | 0.4653 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 18.0 (5.7, 35.8) | 33.3 (15.5, 52.3) |
| 12 months | 12.0 (2.4, 29.8) | NE (NE, NE) |
| 18 months | 12.0 (2.4, 29.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 19 (16.0%) | 8 (7.2%) |
| Censored Patients, n (%) | 100 (84.0%) | 103 (92.8%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 3.02) | 1.64 (1.45, 2.33) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8920 | |
| HR (95% CI) [c] | 0.944 (0.406, 2.194) | |
| HR P-Value [c] | 0.8933 | |
| Heterogeneity p-value [d] | 0.9691 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 13.0 (2.6, 31.9) | 14.8 (0.8, 46.8) |
| 12 months | 6.5 (0.5, 24.6) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 29 (24.4%) | 20 (18.0%) |
| Censored Patients, n (%) | 90 (75.6%) | 91 (82.0%) |
| | | |
| Median (95% CI), (Months) [a] | 1.84 (1.51, 4.21) | 4.30 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1009 | |
| HR (95% CI) [c] | 1.605 (0.906, 2.846) | |
| HR P-Value [c] | 0.1050 | |
| Heterogeneity p-value [d] | 0.7559 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 15.2 (4.3, 32.3) | 30.5 (12.3, 51.1) |
| 12 months | 10.1 (1.9, 26.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 45 (37.8%) | 23 (20.7%) |
| Censored Patients, n (%) | 74 (62.2%) | 88 (79.3%) |
| | | |
| Median (95% CI), (Months) [a] | 2.86 (1.61, 4.17) | 5.06 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0107 | |
| HR (95% CI) [c] | 1.926 (1.159, 3.199) | |
| HR P-Value [c] | 0.0114 | |
| Heterogeneity p-value [d] | 0.5396 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.5 (13.8, 39.0) | 43.0 (25.5, 59.5) |
| 12 months | 14.6 (5.3, 28.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 51 (42.9%) | 26 (23.4%) |
| Censored Patients, n (%) | 68 (57.1%) | 85 (76.6%) |
| Median (95% CI), (Months) [a] | 2.99 (1.64, 5.68) | 7.26 (5.06, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0044 | |
| HR (95% CI) [c] | 1.980 (1.229, 3.191) | |
| HR P-Value [c] | 0.0050 | |
| Heterogeneity p-value [d] | 0.3408 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (21.3, 45.7) | 59.1 (43.0, 72.0) |
| 12 months | 20.7 (9.7, 34.5) | 39.9 (20.0, 59.1) |
| 18 months | 13.8 (3.7, 30.4) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 30 (25.2%) | 26 (23.4%) |
| Censored Patients, n (%) | 89 (74.8%) | 85 (76.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.64, 5.06) | 2.99 (1.64, 8.80) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5230 | |
| HR (95% CI) [c] | 1.190 (0.703, 2.014) | |
| HR P-Value [c] | 0.5173 | |
| Heterogeneity p-value [d] | 0.7622 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.7 (19.4, 48.6) | 42.0 (26.7, 56.6) |
| 12 months | 33.7 (19.4, 48.6) | 27.6 (10.5, 47.9) |
| 18 months | 33.7 (19.4, 48.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 19 (16.0%) | 19 (17.1%) |
| Censored Patients, n (%) | 100 (84.0%) | 92 (82.9%) |
| Median (95% CI), (Months) [a] | 2.83 (1.45, 4.17) | 2.92 (1.58, 4.37) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4955 | |
| HR (95% CI) [c] | 1.265 (0.662, 2.417) | |
| HR P-Value [c] | 0.4769 | |
| Heterogeneity p-value [d] | 0.9614 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 10.2 (0.8, 33.6) | 17.5 (4.7, 37.0) |
| 12 months | 10.2 (0.8, 33.6) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 56 (47.1%) | 44 (39.6%) |
| Censored Patients, n (%) | 63 (52.9%) | 67 (60.4%) |
| Median (95% CI), (Months) [a] | 1.61 (1.48, 2.99) | 2.89 (1.71, 3.12) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3255 | |
| HR (95% CI) [c] | 1.247 (0.836, 1.859) | |
| HR P-Value [c] | 0.2786 | |
| Heterogeneity p-value [d] | 0.7742 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.1 (13.6, 36.3) | 23.1 (12.1, 36.2) |
| 12 months | 6.1 (0.7, 20.9) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 39 (32.8%) | 16 (14.4%) |
| Censored Patients, n (%) | 80 (67.2%) | 95 (85.6%) |
| Median (95% CI), (Months) [a] | 4.27 (2.79, 7.43) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0019 | |
| HR (95% CI) [c] | 2.460 (1.369, 4.422) | |
| HR P-Value [c] | 0.0026 | |
| Heterogeneity p-value [d] | 0.8645 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.9 (28.4, 54.8) | 74.4 (58.6, 84.9) |
| 12 months | 35.4 (21.9, 49.2) | 55.3 (34.9, 71.7) |
| 18 months | 35.4 (21.9, 49.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 52 (43.7%) | 28 (25.2%) |
| Censored Patients, n (%) | 67 (56.3%) | 83 (74.8%) |
| | | |
| Median (95% CI), (Months) [a] | 4.30 (2.89, 6.05) | 9.59 (4.47, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0713 | |
| HR (95% CI) [c] | 1.537 (0.967, 2.444) | |
| HR P-Value [c] | 0.0690 | |
| Heterogeneity p-value [d] | 0.9081 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.5 (30.9, 53.6) | 57.0 (42.4, 69.1) |
| 12 months | 31.9 (20.6, 43.8) | NE (NE, NE) |
| 18 months | 17.7 (5.0, 36.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 47 (39.5%) | 21 (18.9%) |
| Censored Patients, n (%) | 72 (60.5%) | 90 (81.1%) |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 4.17) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0033 | |
| HR (95% CI) [c] | 2.145 (1.278, 3.599) | |
| HR P-Value [c] | 0.0039 | |
| Heterogeneity p-value [d] | 0.1246 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 20.8 (10.1, 34.1) | 52.4 (35.9, 66.5) |
| 12 months | 13.9 (5.0, 27.1) | NE (NE, NE) |
| 18 months | 13.9 (5.0, 27.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 45 (37.8%) | 25 (22.5%) |
| Censored Patients, n (%) | 74 (62.2%) | 86 (77.5%) |
| Median (95% CI), (Months) [a] | 1.58 (1.48, 2.79) | 4.17 (2.79, 7.26) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0005 | |
| HR (95% CI) [c] | 2.382 (1.448, 3.920) | |
| HR P-Value [c] | 0.0006 | |
| Heterogeneity p-value [d] | 0.3038 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 13.4 (4.6, 27.0) | 41.2 (24.6, 57.0) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 38 (31.9%) | 20 (18.0%) |
| Censored Patients, n (%) | 81 (68.1%) | 91 (82.0%) |
| | | |
| Median (95% CI), (Months) [a] | 2.73 (1.58, 2.92) | 3.45 (2.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0460 | |
| HR (95% CI) [c] | 1.743 (1.009, 3.009) | |
| HR P-Value [c] | 0.0462 | |
| Heterogeneity p-value [d] | 0.7970 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.2 (11.4, 37.5) | 35.3 (16.1, 55.3) |
| 12 months | 15.5 (5.6, 29.8) | NE (NE, NE) |
| 18 months | 15.5 (5.6, 29.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 0 |
| Censored Patients, n (%) | 14 (70.0%) | 21 (100.0%) |
| | | |
| Median (95% CI), (Months) [a] | 4.53 (1.41, 7.10) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1753 | |
| HR (95% CI) [c] | 53641560 (0.000, NE) | |
| HR P-Value [c] | 0.9974 | |
| Heterogeneity p-value [d] | 0.9768 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.6 (4.1, 61.2) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 4 (19.0%) |
| Censored Patients, n (%) | 18 (90.0%) | 17 (81.0%) |
| Median (95% CI), (Months) [a] | NE (1.41, NE) | 2.43 (1.77, 6.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3098 | |
| HR (95% CI) [c] | 0.422 (0.076, 2.342) | |
| HR P-Value [c] | 0.3239 | |
| Heterogeneity p-value [d] | 0.6010 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.5 (14.2, 89.3) | 40.0 (5.2, 75.3) |
| 12 months | 62.5 (14.2, 89.3) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 4 (20.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 16 (80.0%) | 19 (90.5%) |
| | | |
| Median (95% CI), (Months) [a] | 5.85 (1.38, NE) | 2.10 (1.45, 2.10) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5635 | |
| HR (95% CI) [c] | 0.593 (0.099, 3.565) | |
| HR P-Value [c] | 0.5676 | |
| Heterogeneity p-value [d] | 0.4653 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.6 (1.4, 69.1) | 0.0 (NE, NE) |
| 12 months | 28.6 (1.4, 69.1) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 2 (9.5%) |
| Censored Patients, n (%) | 20 (100.0%) | 19 (90.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 6.28 (1.81, 6.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5637 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9987 | |
| Heterogeneity p-value [d] | 0.9691 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 66.7 (5.4, 94.5) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 18 (90.0%) | 19 (90.5%) |
| Median (95% CI), (Months) [a] | 1.84 (1.51, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3209 | |
| HR (95% CI) [c] | 2.630 (0.363, 19.067) | |
| HR P-Value [c] | 0.3386 | |
| Heterogeneity p-value [d] | 0.7559 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (0.9, 77.4) | 62.5 (14.2, 89.3) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (25.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 15 (75.0%) | 19 (90.5%) |
| | | |
| Median (95% CI), (Months) [a] | 20.93 (1.41, 20.93) | 2.56 (0.20, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9489 | |
| HR (95% CI) [c] | 0.946 (0.173, 5.172) | |
| HR P-Value [c] | 0.9489 | |
| Heterogeneity p-value [d] | 0.5396 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.3 (23.0, 82.1) | 40.0 (1.1, 82.9) |
| 12 months | 58.3 (23.0, 82.1) | NE (NE, NE) |
| 18 months | 58.3 (23.0, 82.1) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 8 (40.0%) | 5 (23.8%) |
| Censored Patients, n (%) | 12 (60.0%) | 16 (76.2%) |
| Median (95% CI), (Months) [a] | 3.25 (1.51, NE) | 2.43 (0.20, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6941 | |
| HR (95% CI) [c] | 0.784 (0.245, 2.509) | |
| HR P-Value [c] | 0.6815 | |
| Heterogeneity p-value [d] | 0.3408 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.7 (6.0, 59.1) | NE (NE, NE) |
| 12 months | 29.7 (6.0, 59.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 4 (20.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 16 (80.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | 7.10 (3.48, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2469 | |
| HR (95% CI) [c] | 0.370 (0.066, 2.082) | |
| HR P-Value [c] | 0.2594 | |
| Heterogeneity p-value [d] | 0.7622 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.1 (17.2, 83.7) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (25.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 15 (75.0%) | 20 (95.2%) |
| | | |
| Median (95% CI), (Months) [a] | 1.82 (1.41, 25.53) | 2.56 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2841 | |
| HR (95% CI) [c] | 3.135 (0.346, 28.356) | |
| HR P-Value [c] | 0.3093 | |
| Heterogeneity p-value [d] | 0.9614 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (4.6, 67.6) | 0.0 (NE, NE) |
| 12 months | 33.3 (4.6, 67.6) | 0.0 (NE, NE) |
| 18 months | 33.3 (4.6, 67.6) | 0.0 (NE, NE) |
| 24 months | 33.3 (4.6, 67.6) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (25.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 15 (75.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | 3.25 (1.54, NE) | 2.43 (0.20, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8622 | |
| HR (95% CI) [c] | 0.879 (0.206, 3.757) | |
| HR P-Value [c] | 0.8623 | |
| Heterogeneity p-value [d] | 0.7742 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.4 (13.6, 71.9) | NE (NE, NE) |
| 12 months | 44.4 (13.6, 71.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 0 |
| Censored Patients, n (%) | 18 (90.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2286 | |
| HR (95% CI) [c] | 60575344 (0.000, NE) | |
| HR P-Value [c] | 0.9978 | |
| Heterogeneity p-value [d] | 0.8645 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.5 (46.1, 95.3) | 100.0 (100.0, 100.0) |
| 12 months | 82.5 (46.1, 95.3) | NE (NE, NE) |
| 18 months | 82.5 (46.1, 95.3) | NE (NE, NE) |
| 24 months | 82.5 (46.1, 95.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 0 |
| Censored Patients, n (%) | 14 (70.0%) | 21 (100.0%) |
| | | |
| Median (95% CI), (Months) [a] | 18.20 (1.54, 18.20) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0385 | |
| HR (95% CI) [c] | 69778007 (0.000, NE) | |
| HR P-Value [c] | 0.9964 | |
| Heterogeneity p-value [d] | 0.9081 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.2 (20.4, 78.9) | 100.0 (100.0, 100.0) |
| 12 months | 54.2 (20.4, 78.9) | NE (NE, NE) |
| 18 months | 54.2 (20.4, 78.9) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 9 (45.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 11 (55.0%) | 18 (85.7%) |
| | | |
| Median (95% CI), (Months) [a] | 3.25 (1.48, NE) | 3.32 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5668 | |
| HR (95% CI) [c] | 1.479 (0.384, 5.694) | |
| HR P-Value [c] | 0.5692 | |
| Heterogeneity p-value [d] | 0.1246 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.7 (12.9, 62.8) | NE (NE, NE) |
| 12 months | 28.3 (7.3, 54.3) | NE (NE, NE) |
| 18 months | 28.3 (7.3, 54.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 14 (70.0%) | 19 (90.5%) |
| Median (95% CI), (Months) [a] | 1.84 (1.41, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0891 | |
| HR (95% CI) [c] | 3.692 (0.743, 18.348) | |
| HR P-Value [c] | 0.1103 | |
| Heterogeneity p-value [d] | 0.3038 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (7.8, 62.3) | NE (NE, NE) |
| 12 months | 33.3 (7.8, 62.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 18 (90.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | 5.95 (1.41, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9372 | |
| HR (95% CI) [c] | 1.118 (0.070, 17.956) | |
| HR P-Value [c] | 0.9371 | |
| Heterogeneity p-value [d] | 0.7970 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.0 (1.1, 82.9) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 7 (21.9%) |
| Censored Patients, n (%) | 23 (74.2%) | 25 (78.1%) |
| | | |
| Median (95% CI), (Months) [a] | 2.79 (1.58, NE) | 3.32 (1.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2734 | |
| HR (95% CI) [c] | 1.761 (0.631, 4.917) | |
| HR P-Value [c] | 0.2802 | |
| Heterogeneity p-value [d] | 0.9768 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 38.5 (12.2, 64.8) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 8 (25.0%) |
| Censored Patients, n (%) | 23 (74.2%) | 24 (75.0%) |
| | | |
| Median (95% CI), (Months) [a] | 2.79 (1.51, NE) | 4.17 (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7954 | |
| HR (95% CI) [c] | 1.147 (0.427, 3.083) | |
| HR P-Value [c] | 0.7855 | |
| Heterogeneity p-value [d] | 0.6010 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 30.6 (6.3, 60.3) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 10 (32.3%) | 4 (12.5%) |
| Censored Patients, n (%) | 21 (67.7%) | 28 (87.5%) |
| Median (95% CI), (Months) [a] | 2.83 (1.45, 15.31) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1952 | |
| HR (95% CI) [c] | 2.175 (0.656, 7.213) | |
| HR P-Value [c] | 0.2040 | |
| Heterogeneity p-value [d] | 0.4653 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 19.6 (1.5, 53.4) | 61.9 (27.0, 83.9) |
| 12 months | 19.6 (1.5, 53.4) | 61.9 (27.0, 83.9) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 5 (15.6%) |
| Censored Patients, n (%) | 27 (87.1%) | 27 (84.4%) |
| Median (95% CI), (Months) [a] | 1.68 (1.45, 2.83) | 1.45 (1.41, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8333 | |
| HR (95% CI) [c] | 0.871 (0.215, 3.522) | |
| HR P-Value [c] | 0.8464 | |
| Heterogeneity p-value [d] | 0.9691 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 20.0 (0.8, 58.2) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 2 (6.3%) |
| Censored Patients, n (%) | 26 (83.9%) | 30 (93.8%) |
| Median (95% CI), (Months) [a] | 2.10 (1.45, 2.89) | 9.69 (1.94, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0411 | |
| HR (95% CI) [c] | 7.167 (0.813, 63.212) | |
| HR P-Value [c] | 0.0762 | |
| Heterogeneity p-value [d] | 0.7559 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 80.0 (20.4, 96.9) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 11 (35.5%) | 7 (21.9%) |
| Censored Patients, n (%) | 20 (64.5%) | 25 (78.1%) |
| Median (95% CI), (Months) [a] | 4.37 (2.79, 8.41) | 5.39 (1.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7611 | |
| HR (95% CI) [c] | 1.163 (0.441, 3.069) | |
| HR P-Value [c] | 0.7603 | |
| Heterogeneity p-value [d] | 0.5396 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.1 (12.9, 60.3) | 37.0 (7.5, 68.3) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 8 (25.0%) |
| Censored Patients, n (%) | 23 (74.2%) | 24 (75.0%) |
| | | |
| Median (95% CI), (Months) [a] | 4.96 (1.94, NE) | 6.93 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7931 | |
| HR (95% CI) [c] | 1.139 (0.427, 3.040) | |
| HR P-Value [c] | 0.7944 | |
| Heterogeneity p-value [d] | 0.3408 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.2 (18.0, 70.7) | 68.6 (45.0, 83.7) |
| 12 months | 46.2 (18.0, 70.7) | NE (NE, NE) |
| 18 months | 46.2 (18.0, 70.7) | NE (NE, NE) |
| 24 months | 46.2 (18.0, 70.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 6 (18.8%) |
| Censored Patients, n (%) | 27 (87.1%) | 26 (81.3%) |
| | | |
| Median (95% CI), (Months) [a] | 2.89 (1.45, NE) | NE (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7928 | |
| HR (95% CI) [c] | 1.185 (0.333, 4.224) | |
| HR P-Value [c] | 0.7930 | |
| Heterogeneity p-value [d] | 0.7622 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.3 (1.0, 64.6) | 58.3 (29.3, 78.9) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 3 (9.4%) |
| Censored Patients, n (%) | 28 (90.3%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | 1.68 (1.41, 1.91) | 2.14 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3902 | |
| HR (95% CI) [c] | 2.127 (0.352, 12.866) | |
| HR P-Value [c] | 0.4110 | |
| Heterogeneity p-value [d] | 0.9614 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | NE (NE, NE) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 10 (32.3%) | 7 (21.9%) |
| Censored Patients, n (%) | 21 (67.7%) | 25 (78.1%) |
| Median (95% CI), (Months) [a] | 4.24 (1.94, NE) | 6.67 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2753 | |
| HR (95% CI) [c] | 1.705 (0.641, 4.536) | |
| HR P-Value [c] | 0.2849 | |
| Heterogeneity p-value [d] | 0.7742 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.6 (8.1, 55.6) | 59.4 (27.9, 80.9) |
| 12 months | 29.6 (8.1, 55.6) | 44.6 (13.5, 72.2) |
| 18 months | 29.6 (8.1, 55.6) | NE (NE, NE) |
| 24 months | 29.6 (8.1, 55.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 4 (12.5%) |
| Censored Patients, n (%) | 26 (83.9%) | 28 (87.5%) |
| Median (95% CI), (Months) [a] | 4.96 (2.83, NE) | 6.93 (4.37, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5107 | |
| HR (95% CI) [c] | 1.550 (0.415, 5.786) | |
| HR P-Value [c] | 0.5140 | |
| Heterogeneity p-value [d] | 0.8645 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.8 (16.0, 75.5) | 78.5 (45.9, 92.7) |
| 12 months | NE (NE, NE) | 39.2 (1.4, 81.4) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 7 (22.6%) | 3 (9.4%) |
| Censored Patients, n (%) | 24 (77.4%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1029 | |
| HR (95% CI) [c] | 2.924 (0.754, 11.339) | |
| HR P-Value [c] | 0.1208 | |
| Heterogeneity p-value [d] | 0.9081 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.6 (27.8, 77.7) | 83.1 (55.3, 94.4) |
| 12 months | 56.6 (27.8, 77.7) | 83.1 (55.3, 94.4) |
| 18 months | 56.6 (27.8, 77.7) | NE (NE, NE) |
| 24 months | 56.6 (27.8, 77.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 7 (22.6%) | 4 (12.5%) |
| Censored Patients, n (%) | 24 (77.4%) | 28 (87.5%) |
| | | |
| Median (95% CI), (Months) [a] | 2.79 (1.48, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0822 | |
| HR (95% CI) [c] | 2.818 (0.815, 9.742) | |
| HR P-Value [c] | 0.1016 | |
| Heterogeneity p-value [d] | 0.1246 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 16.6 (0.9, 50.4) | 69.6 (35.2, 88.2) |
| 12 months | NE (NE, NE) | 69.6 (35.2, 88.2) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 10 (32.3%) | 9 (28.1%) |
| Censored Patients, n (%) | 21 (67.7%) | 23 (71.9%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 4.67) | 2.14 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7390 | |
| HR (95% CI) [c] | 1.165 (0.471, 2.880) | |
| HR P-Value [c] | 0.7411 | |
| Heterogeneity p-value [d] | 0.3038 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 10.5 (0.6, 37.0) | 40.2 (16.0, 63.6) |
| 12 months | 0.0 (NE, NE) | 40.2 (16.0, 63.6) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.1a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 8 (25.0%) |
| Censored Patients, n (%) | 23 (74.2%) | 24 (75.0%) |
| | | |
| Median (95% CI), (Months) [a] | 4.96 (1.84, NE) | 8.31 (2.14, 8.31) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6410 | |
| HR (95% CI) [c] | 1.278 (0.461, 3.546) | |
| HR P-Value [c] | 0.6376 | |
| Heterogeneity p-value [d] | 0.7970 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.6 (13.5, 70.9) | 58.3 (31.0, 78.0) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:18, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 72 (40.0%) | 78 (47.9%) |
| Censored Patients, n (%) | 108 (60.0%) | 85 (52.1%) |
| Median (95% CI), (Months) [a] | 5.62 (4.21, 8.41) | 2.99 (2.56, 4.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0013 | |
| HR (95% CI) [c] | 0.590 (0.425, 0.818) | |
| HR P-Value [c] | 0.0015 | |
| Heterogeneity p-value [d] | 0.8870 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.2 (36.6, 55.3) | 28.4 (19.4, 38.2) |
| 12 months | 36.4 (26.3, 46.6) | 4.3 (0.4, 17.4) |
| 18 months | 31.4 (20.9, 42.5) | 4.3 (0.4, 17.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 83 (46.1%) | 64 (39.3%) |
| Censored Patients, n (%) | 97 (53.9%) | 99 (60.7%) |
| Median (95% CI), (Months) [a] | 5.59 (2.99, 6.97) | 3.19 (2.92, 6.08) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5930 | |
| HR (95% CI) [c] | 0.917 (0.660, 1.274) | |
| HR P-Value [c] | 0.6058 | |
| Heterogeneity p-value [d] | 0.2397 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.8 (34.4, 52.9) | 40.2 (30.2, 50.1) |
| 12 months | 25.1 (15.6, 35.8) | 29.8 (16.8, 43.9) |
| 18 months | 12.0 (4.0, 24.7) | 29.8 (16.8, 43.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 65 (36.1%) | 61 (37.4%) |
| Censored Patients, n (%) | 115 (63.9%) | 102 (62.6%) |
| Median (95% CI), (Months) [a] | 8.21 (5.68, 12.06) | 4.34 (3.02, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0646 | |
| HR (95% CI) [c] | 0.718 (0.504, 1.025) | |
| HR P-Value [c] | 0.0681 | |
| Heterogeneity p-value [d] | 0.2425 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.2 (48.4, 66.7) | 42.3 (31.6, 52.5) |
| 12 months | 40.2 (29.1, 51.0) | 23.7 (10.4, 40.0) |
| 18 months | 24.3 (11.7, 39.3) | 15.8 (4.0, 34.8) |
| 24 months | 24.3 (11.7, 39.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 53 (29.4%) | 44 (27.0%) |
| Censored Patients, n (%) | 127 (70.6%) | 119 (73.0%) |
| Median (95% CI), (Months) [a] | 8.41 (7.00, 18.04) | 8.84 (5.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4112 | |
| HR (95% CI) [c] | 0.845 (0.563, 1.267) | |
| HR P-Value [c] | 0.4154 | |
| Heterogeneity p-value [d] | 0.8034 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.4 (57.3, 75.6) | 54.7 (42.7, 65.2) |
| 12 months | 38.2 (26.0, 50.3) | 40.4 (24.3, 56.0) |
| 18 months | 38.2 (26.0, 50.3) | NE (NE, NE) |
| 24 months | 31.8 (17.5, 47.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 60 (33.3%) | 55 (33.7%) |
| Censored Patients, n (%) | 120 (66.7%) | 108 (66.3%) |
| Median (95% CI), (Months) [a] | 10.09 (5.65, NE) | 5.85 (4.37, 9.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1241 | |
| HR (95% CI) [c] | 0.749 (0.515, 1.088) | |
| HR P-Value [c] | 0.1292 | |
| Heterogeneity p-value [d] | 0.5912 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.5 (46.6, 65.3) | 49.1 (37.7, 59.5) |
| 12 months | 41.5 (29.9, 52.7) | 24.5 (9.9, 42.5) |
| 18 months | 41.5 (29.9, 52.7) | 12.2 (1.2, 36.7) |
| 24 months | 33.2 (17.1, 50.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 63 (35.0%) | 57 (35.0%) |
| Censored Patients, n (%) | 117 (65.0%) | 106 (65.0%) |
| Median (95% CI), (Months) [a] | 7.33 (5.59, 13.83) | 5.32 (3.48, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0920 | |
| HR (95% CI) [c] | 0.732 (0.507, 1.057) | |
| HR P-Value [c] | 0.0958 | |
| Heterogeneity p-value [d] | 0.1941 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.6 (45.6, 64.5) | 45.9 (35.0, 56.1) |
| 12 months | 42.8 (31.5, 53.7) | 28.1 (13.0, 45.5) |
| 18 months | 33.7 (21.3, 46.5) | 28.1 (13.0, 45.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 98 (54.4%) | 87 (53.4%) |
| Censored Patients, n (%) | 82 (45.6%) | 76 (46.6%) |
| Median (95% CI), (Months) [a] | 2.89 (1.91, 4.14) | 1.97 (1.64, 2.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0473 | |
| HR (95% CI) [c] | 0.748 (0.557, 1.004) | |
| HR P-Value [c] | 0.0531 | |
| Heterogeneity p-value [d] | 0.4092 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.0 (22.0, 38.4) | 26.6 (18.2, 35.7) |
| 12 months | 15.0 (7.8, 24.4) | 0.0 (NE, NE) |
| 18 months | 15.0 (7.8, 24.4) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 53 (29.4%) | 42 (25.8%) |
| Censored Patients, n (%) | 127 (70.6%) | 121 (74.2%) |
| Median (95% CI), (Months) [a] | 10.12 (5.62, 20.80) | 8.84 (6.14, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6235 | |
| HR (95% CI) [c] | 0.904 (0.599, 1.364) | |
| HR P-Value [c] | 0.6300 | |
| Heterogeneity p-value [d] | 0.9234 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.2 (47.7, 67.3) | 63.4 (51.7, 73.1) |
| 12 months | 45.5 (33.8, 56.5) | 28.5 (12.6, 46.8) |
| 18 months | 45.5 (33.8, 56.5) | 21.4 (6.9, 41.0) |
| 24 months | 29.3 (11.6, 49.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 65 (36.1%) | 75 (46.0%) |
| Censored Patients, n (%) | 115 (63.9%) | 88 (54.0%) |
| Median (95% CI), (Months) [a] | 7.43 (5.68, 10.38) | 2.96 (1.68, 5.19) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| HR (95% CI) [c] | 0.502 (0.357, 0.706) | |
| HR P-Value [c] | <0.0001 | |
| Heterogeneity p-value [d] | 0.3826 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.1 (47.3, 65.8) | 36.2 (26.5, 46.0) |
| 12 months | 36.8 (26.0, 47.5) | 7.4 (0.6, 26.3) |
| 18 months | 34.1 (23.2, 45.4) | 7.4 (0.6, 26.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 78 (43.3%) | 79 (48.5%) |
| Censored Patients, n (%) | 102 (56.7%) | 84 (51.5%) |
| Median (95% CI), (Months) [a] | 4.27 (2.89, 5.68) | 2.83 (1.94, 2.99) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0147 | |
| HR (95% CI) [c] | 0.679 (0.494, 0.932) | |
| HR P-Value [c] | 0.0165 | |
| Heterogeneity p-value [d] | 0.0398 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.0 (27.6, 46.4) | 22.8 (14.6, 32.1) |
| 12 months | 25.6 (16.4, 35.9) | 6.2 (0.6, 21.7) |
| 18 months | 22.8 (13.5, 33.6) | 6.2 (0.6, 21.7) |
| 24 months | 22.8 (13.5, 33.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 79 (43.9%) | 75 (46.0%) |
| Censored Patients, n (%) | 101 (56.1%) | 88 (54.0%) |
| Median (95% CI), (Months) [a] | 6.18 (4.90, 10.45) | 3.48 (2.83, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0039 | |
| HR (95% CI) [c] | 0.623 (0.449, 0.864) | |
| HR P-Value [c] | 0.0045 | |
| Heterogeneity p-value [d] | 0.6314 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.9 (42.4, 60.6) | 33.8 (24.2, 43.7) |
| 12 months | 34.3 (24.3, 44.6) | 10.5 (2.3, 26.0) |
| 18 months | 16.5 (7.6, 28.3) | 10.5 (2.3, 26.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 77 (42.8%) | 75 (46.0%) |
| Censored Patients, n (%) | 103 (57.2%) | 88 (54.0%) |
| Median (95% CI), (Months) [a] | 5.82 (4.90, 7.95) | 3.35 (2.73, 4.63) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0708 | |
| HR (95% CI) [c] | 0.747 (0.540, 1.032) | |
| HR P-Value [c] | 0.0766 | |
| Heterogeneity p-value [d] | 0.9207 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.4 (37.6, 56.6) | 34.7 (25.0, 44.5) |
| 12 months | 28.0 (18.4, 38.3) | 13.4 (3.7, 29.3) |
| 18 months | 22.2 (12.6, 33.6) | 13.4 (3.7, 29.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 82 (45.6%) | 82 (50.3%) |
| Censored Patients, n (%) | 98 (54.4%) | 81 (49.7%) |
| Median (95% CI), (Months) [a] | 4.37 (2.83, 8.34) | 2.79 (1.81, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0013 | |
| HR (95% CI) [c] | 0.598 (0.435, 0.823) | |
| HR P-Value [c] | 0.0016 | |
| Heterogeneity p-value [d] | 0.4287 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.5 (33.1, 51.6) | 25.8 (17.0, 35.5) |
| 12 months | 33.4 (23.9, 43.3) | 3.6 (0.3, 14.8) |
| 18 months | 18.5 (9.6, 29.6) | 3.6 (0.3, 14.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 67 (37.2%) | 71 (43.6%) |
| Censored Patients, n (%) | 113 (62.8%) | 92 (56.4%) |
| Median (95% CI), (Months) [a] | 5.82 (4.34, 11.27) | 4.14 (2.56, 5.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0065 | |
| HR (95% CI) [c] | 0.626 (0.445, 0.882) | |
| HR P-Value [c] | 0.0074 | |
| Heterogeneity p-value [d] | 0.6678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.9 (40.0, 59.1) | 37.5 (27.5, 47.5) |
| 12 months | 39.5 (29.1, 49.6) | 16.7 (6.9, 30.1) |
| 18 months | 32.6 (20.8, 44.9) | 8.3 (1.0, 26.6) |
| 24 months | 16.3 (1.8, 43.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 70 (38.9%) | 65 (39.9%) |
| Censored Patients, n (%) | 110 (61.1%) | 98 (60.1%) |
| Median (95% CI), (Months) [a] | 4.40 (2.96, 7.95) | 4.27 (2.89, 7.00) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3079 | |
| HR (95% CI) [c] | 0.841 (0.599, 1.181) | |
| HR P-Value [c] | 0.3166 | |
| Heterogeneity p-value [d] | 0.8955 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.1 (31.3, 50.6) | 43.6 (33.1, 53.6) |
| 12 months | 31.2 (20.1, 42.8) | 19.2 (8.5, 33.3) |
| 18 months | 21.4 (10.7, 34.4) | 14.4 (4.8, 29.2) |
| 24 months | 21.4 (10.7, 34.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 8 (50.0%) | 6 (30.0%) |
| Censored Patients, n (%) | 8 (50.0%) | 14 (70.0%) |
| Median (95% CI), (Months) [a] | 7.06 (1.58, NE) | 4.40 (1.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4939 | |
| HR (95% CI) [c] | 0.669 (0.211, 2.120) | |
| HR P-Value [c] | 0.4949 | |
| Heterogeneity p-value [d] | 0.8870 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.4 (30.2, 81.9) | 21.9 (1.3, 58.8) |
| 12 months | 35.1 (11.1, 60.7) | NE (NE, NE) |
| 18 months | 35.1 (11.1, 60.7) | NE (NE, NE) |
| 24 months | 35.1 (11.1, 60.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 7 (43.8%) | 8 (40.0%) |
| Censored Patients, n (%) | 9 (56.3%) | 12 (60.0%) |
| Median (95% CI), (Months) [a] | 7.29 (1.58, NE) | 4.21 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4011 | |
| HR (95% CI) [c] | 0.641 (0.229, 1.798) | |
| HR P-Value [c] | 0.3985 | |
| Heterogeneity p-value [d] | 0.2397 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.3 (27.2, 77.6) | 35.9 (11.7, 61.3) |
| 12 months | 45.0 (16.8, 70.0) | NE (NE, NE) |
| 18 months | 45.0 (16.8, 70.0) | NE (NE, NE) |
| 24 months | 45.0 (16.8, 70.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 9 (56.3%) | 4 (20.0%) |
| Censored Patients, n (%) | 7 (43.8%) | 16 (80.0%) |
| Median (95% CI), (Months) [a] | 4.34 (1.58, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4333 | |
| HR (95% CI) [c] | 1.629 (0.484, 5.484) | |
| HR P-Value [c] | 0.4305 | |
| Heterogeneity p-value [d] | 0.2425 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.4 (19.3, 69.9) | 64.5 (29.8, 85.3) |
| 12 months | 34.8 (10.2, 61.4) | NE (NE, NE) |
| 18 months | 23.2 (4.1, 51.2) | NE (NE, NE) |
| 24 months | 23.2 (4.1, 51.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 4 (20.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 16 (80.0%) |
| Median (95% CI), (Months) [a] | NE (2.92, NE) | NE (1.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7305 | |
| HR (95% CI) [c] | 0.790 (0.205, 3.037) | |
| HR P-Value [c] | 0.7310 | |
| Heterogeneity p-value [d] | 0.8034 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (35.0, 87.0) | 54.7 (15.9, 82.0) |
| 12 months | 56.8 (23.8, 80.0) | NE (NE, NE) |
| 18 months | 56.8 (23.8, 80.0) | NE (NE, NE) |
| 24 months | 56.8 (23.8, 80.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 9 (56.3%) | 7 (35.0%) |
| Censored Patients, n (%) | 7 (43.8%) | 13 (65.0%) |
| Median (95% CI), (Months) [a] | 5.72 (1.48, NE) | 6.74 (2.89, 9.92) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9994 | |
| HR (95% CI) [c] | 1.014 (0.370, 2.778) | |
| HR P-Value [c] | 0.9778 | |
| Heterogeneity p-value [d] | 0.5912 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.7 (11.9, 62.3) | 54.7 (22.1, 78.6) |
| 12 months | 27.5 (6.9, 53.7) | 0.0 (NE, NE) |
| 18 months | 27.5 (6.9, 53.7) | 0.0 (NE, NE) |
| 24 months | 27.5 (6.9, 53.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 7 (35.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 13 (65.0%) |
| Median (95% CI), (Months) [a] | 7.29 (2.92, NE) | 4.27 (1.48, 5.78) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1247 | |
| HR (95% CI) [c] | 0.387 (0.110, 1.357) | |
| HR P-Value [c] | 0.1378 | |
| Heterogeneity p-value [d] | 0.1941 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.3 (29.6, 85.2) | 0.0 (NE, NE) |
| 12 months | 48.2 (14.1, 76.3) | 0.0 (NE, NE) |
| 18 months | 48.2 (14.1, 76.3) | 0.0 (NE, NE) |
| 24 months | 48.2 (14.1, 76.3) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 13 (81.3%) | 10 (50.0%) |
| Censored Patients, n (%) | 3 (18.8%) | 10 (50.0%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 4.27) | 1.77 (1.64, 8.54) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6510 | |
| HR (95% CI) [c] | 1.221 (0.523, 2.854) | |
| HR P-Value [c] | 0.6443 | |
| Heterogeneity p-value [d] | 0.4092 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 16.7 (2.9, 40.2) | 26.4 (6.5, 52.2) |
| 12 months | 16.7 (2.9, 40.2) | 0.0 (NE, NE) |
| 18 months | 16.7 (2.9, 40.2) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 3 (15.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | NE (4.17, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9291 | |
| HR (95% CI) [c] | 1.068 (0.252, 4.515) | |
| HR P-Value [c] | 0.9291 | |
| Heterogeneity p-value [d] | 0.9234 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.8 (34.4, 86.9) | 64.2 (22.5, 87.6) |
| 12 months | 56.5 (23.5, 79.9) | NE (NE, NE) |
| 18 months | 56.5 (23.5, 79.9) | NE (NE, NE) |
| 24 months | 56.5 (23.5, 79.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 7 (35.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 13 (65.0%) |
| Median (95% CI), (Months) [a] | 17.71 (2.92, NE) | 2.89 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0248 | |
| HR (95% CI) [c] | 0.244 (0.066, 0.901) | |
| HR P-Value [c] | 0.0343 | |
| Heterogeneity p-value [d] | 0.3826 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.9 (49.4, 95.7) | 29.7 (5.1, 60.9) |
| 12 months | 62.9 (28.0, 84.5) | NE (NE, NE) |
| 18 months | 42.0 (8.0, 74.2) | NE (NE, NE) |
| 24 months | 42.0 (8.0, 74.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 7 (43.8%) | 12 (60.0%) |
| Censored Patients, n (%) | 9 (56.3%) | 8 (40.0%) |
| Median (95% CI), (Months) [a] | 8.71 (1.51, NE) | 1.71 (1.51, 1.77) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0146 | |
| HR (95% CI) [c] | 0.295 (0.106, 0.821) | |
| HR P-Value [c] | 0.0194 | |
| Heterogeneity p-value [d] | 0.0398 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.2 (25.8, 77.0) | 0.0 (NE, NE) |
| 12 months | 44.1 (16.1, 69.3) | 0.0 (NE, NE) |
| 18 months | 44.1 (16.1, 69.3) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 10 (62.5%) | 8 (40.0%) |
| Censored Patients, n (%) | 6 (37.5%) | 12 (60.0%) |
| Median (95% CI), (Months) [a] | 5.72 (1.58, 16.07) | 5.78 (1.61, 9.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5874 | |
| HR (95% CI) [c] | 0.759 (0.281, 2.055) | |
| HR P-Value [c] | 0.5881 | |
| Heterogeneity p-value [d] | 0.6314 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.5 (21.0, 71.5) | 40.7 (13.5, 66.8) |
| 12 months | 29.1 (7.6, 55.3) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 10 (62.5%) | 9 (45.0%) |
| Censored Patients, n (%) | 6 (37.5%) | 11 (55.0%) |
| Median (95% CI), (Months) [a] | 3.48 (1.45, NE) | 4.21 (1.51, 5.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9257 | |
| HR (95% CI) [c] | 0.968 (0.387, 2.419) | |
| HR P-Value [c] | 0.9444 | |
| Heterogeneity p-value [d] | 0.9207 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.4 (13.4, 60.1) | 16.2 (1.2, 47.6) |
| 12 months | 27.3 (7.5, 52.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 9 (56.3%) | 7 (35.0%) |
| Censored Patients, n (%) | 7 (43.8%) | 13 (65.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.45, NE) | 4.40 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8000 | |
| HR (95% CI) [c] | 1.149 (0.425, 3.104) | |
| HR P-Value [c] | 0.7841 | |
| Heterogeneity p-value [d] | 0.4287 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.6 (18.2, 66.7) | 39.1 (10.6, 67.5) |
| 12 months | 32.7 (9.7, 58.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 9 (56.3%) | 7 (35.0%) |
| Censored Patients, n (%) | 7 (43.8%) | 13 (65.0%) |
| Median (95% CI), (Months) [a] | 5.55 (1.58, 20.83) | 5.68 (1.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7665 | |
| HR (95% CI) [c] | 0.853 (0.307, 2.365) | |
| HR P-Value [c] | 0.7596 | |
| Heterogeneity p-value [d] | 0.6678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.9 (14.9, 64.2) | 28.0 (4.7, 59.0) |
| 12 months | 39.9 (14.9, 64.2) | NE (NE, NE) |
| 18 months | 39.9 (14.9, 64.2) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 8 (50.0%) | 5 (25.0%) |
| Censored Patients, n (%) | 8 (50.0%) | 15 (75.0%) |
| Median (95% CI), (Months) [a] | 4.34 (1.58, 20.17) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9767 | |
| HR (95% CI) [c] | 1.006 (0.306, 3.307) | |
| HR P-Value [c] | 0.9926 | |
| Heterogeneity p-value [d] | 0.8955 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.5 (19.5, 73.8) | 56.6 (24.7, 79.4) |
| 12 months | 49.5 (19.5, 73.8) | NE (NE, NE) |
| 18 months | 39.6 (12.8, 65.8) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 56 (41.2%) | 55 (44.7%) |
| Censored Patients, n (%) | 80 (58.8%) | 68 (55.3%) |
| Median (95% CI), (Months) [a] | 6.21 (4.37, 9.76) | 3.48 (2.30, 4.60) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0076 | |
| HR (95% CI) [c] | 0.600 (0.409, 0.880) | |
| HR P-Value [c] | 0.0089 | |
| Heterogeneity p-value [d] | 0.8566 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.1 (39.0, 60.1) | 27.5 (16.8, 39.2) |
| 12 months | 36.2 (25.1, 47.4) | 5.5 (0.5, 21.0) |
| 18 months | 31.2 (20.0, 43.0) | 5.5 (0.5, 21.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 67 (49.3%) | 46 (37.4%) |
| Censored Patients, n (%) | 69 (50.7%) | 77 (62.6%) |
| Median (95% CI), (Months) [a] | 5.59 (2.99, 7.23) | 4.17 (2.92, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9084 | |
| HR (95% CI) [c] | 0.982 (0.673, 1.435) | |
| HR P-Value [c] | 0.9262 | |
| Heterogeneity p-value [d] | 0.2208 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.3 (33.7, 54.3) | 45.1 (33.6, 56.0) |
| 12 months | 25.7 (15.6, 37.1) | 31.7 (16.0, 48.8) |
| 18 months | 13.5 (5.2, 25.8) | 31.7 (16.0, 48.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 53 (39.0%) | 39 (31.7%) |
| Censored Patients, n (%) | 83 (61.0%) | 84 (68.3%) |
| Median (95% CI), (Months) [a] | 8.28 (5.59, 12.06) | 4.83 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5278 | |
| HR (95% CI) [c] | 0.876 (0.574, 1.336) | |
| HR P-Value [c] | 0.5374 | |
| Heterogeneity p-value [d] | 0.2293 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.1 (48.2, 68.5) | 46.2 (32.9, 58.4) |
| 12 months | 39.2 (26.9, 51.2) | 39.8 (26.1, 53.2) |
| 18 months | 17.6 (6.0, 34.1) | 19.9 (2.0, 51.3) |
| 24 months | 17.6 (6.0, 34.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 44 (32.4%) | 31 (25.2%) |
| Censored Patients, n (%) | 92 (67.6%) | 92 (74.8%) |
| Median (95% CI), (Months) [a] | 8.34 (7.00, NE) | NE (4.63, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8905 | |
| HR (95% CI) [c] | 0.969 (0.610, 1.541) | |
| HR P-Value [c] | 0.8953 | |
| Heterogeneity p-value [d] | 0.3908 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.8 (54.6, 75.0) | 54.0 (40.4, 65.8) |
| 12 months | 39.3 (26.7, 51.6) | 54.0 (40.4, 65.8) |
| 18 months | 39.3 (26.7, 51.6) | NE (NE, NE) |
| 24 months | 39.3 (26.7, 51.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 48 (35.3%) | 39 (31.7%) |
| Censored Patients, n (%) | 88 (64.7%) | 84 (68.3%) |
| Median (95% CI), (Months) [a] | 8.44 (5.65, NE) | 6.74 (4.50, 10.35) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3919 | |
| HR (95% CI) [c] | 0.831 (0.540, 1.280) | |
| HR P-Value [c] | 0.4018 | |
| Heterogeneity p-value [d] | 0.5740 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.0 (44.7, 65.8) | 51.2 (37.8, 63.1) |
| 12 months | 39.6 (27.3, 51.6) | 25.4 (8.5, 46.7) |
| 18 months | 39.6 (27.3, 51.6) | 12.7 (1.1, 38.7) |
| 24 months | 39.6 (27.3, 51.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 50 (36.8%) | 39 (31.7%) |
| Censored Patients, n (%) | 86 (63.2%) | 84 (68.3%) |
| Median (95% CI), (Months) [a] | 7.33 (5.62, 13.83) | 5.65 (4.34, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3996 | |
| HR (95% CI) [c] | 0.836 (0.545, 1.284) | |
| HR P-Value [c] | 0.4142 | |
| Heterogeneity p-value [d] | 0.1069 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.5 (47.3, 68.1) | 46.6 (33.5, 58.6) |
| 12 months | 42.1 (29.6, 54.0) | 35.3 (17.8, 53.4) |
| 18 months | 32.8 (19.9, 46.3) | 35.3 (17.8, 53.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 76 (55.9%) | 62 (50.4%) |
| Censored Patients, n (%) | 60 (44.1%) | 61 (49.6%) |
| Median (95% CI), (Months) [a] | 2.92 (2.10, 4.34) | 1.84 (1.68, 2.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0927 | |
| HR (95% CI) [c] | 0.750 (0.532, 1.059) | |
| HR P-Value [c] | 0.1021 | |
| Heterogeneity p-value [d] | 0.5220 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.3 (21.2, 39.9) | 26.9 (17.3, 37.4) |
| 12 months | 17.3 (9.3, 27.4) | NE (NE, NE) |
| 18 months | 17.3 (9.3, 27.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 37 (27.2%) | 26 (21.1%) |
| Censored Patients, n (%) | 99 (72.8%) | 97 (78.9%) |
| Median (95% CI), (Months) [a] | 10.12 (6.87, NE) | 8.84 (6.70, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8125 | |
| HR (95% CI) [c] | 0.941 (0.568, 1.559) | |
| HR P-Value [c] | 0.8135 | |
| Heterogeneity p-value [d] | 0.9970 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.0 (50.1, 71.8) | 66.1 (51.8, 77.1) |
| 12 months | 49.7 (36.7, 61.5) | 39.6 (19.3, 59.4) |
| 18 months | 49.7 (36.7, 61.5) | 26.4 (6.5, 52.4) |
| 24 months | 49.7 (36.7, 61.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 51 (37.5%) | 53 (43.1%) |
| Censored Patients, n (%) | 85 (62.5%) | 70 (56.9%) |
| Median (95% CI), (Months) [a] | 7.26 (5.72, 11.99) | 2.99 (1.77, 5.95) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0012 | |
| HR (95% CI) [c] | 0.527 (0.355, 0.782) | |
| HR P-Value [c] | 0.0014 | |
| Heterogeneity p-value [d] | 0.4475 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.0 (47.9, 68.5) | 37.9 (26.6, 49.0) |
| 12 months | 38.0 (26.3, 49.6) | 16.8 (4.0, 37.2) |
| 18 months | 34.2 (21.8, 46.9) | 16.8 (4.0, 37.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 62 (45.6%) | 58 (47.2%) |
| Censored Patients, n (%) | 74 (54.4%) | 65 (52.8%) |
| Median (95% CI), (Months) [a] | 4.21 (2.89, 5.82) | 2.79 (1.77, 3.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0294 | |
| HR (95% CI) [c] | 0.672 (0.466, 0.967) | |
| HR P-Value [c] | 0.0325 | |
| Heterogeneity p-value [d] | 0.5000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.5 (29.1, 49.7) | 21.4 (12.3, 32.1) |
| 12 months | 27.4 (17.4, 38.3) | 9.6 (1.2, 28.8) |
| 18 months | 24.6 (14.7, 35.9) | 9.6 (1.2, 28.8) |
| 24 months | 24.6 (14.7, 35.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 64 (47.1%) | 56 (45.5%) |
| Censored Patients, n (%) | 72 (52.9%) | 67 (54.5%) |
| Median (95% CI), (Months) [a] | 6.05 (4.90, 9.69) | 3.48 (2.10, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0171 | |
| HR (95% CI) [c] | 0.641 (0.443, 0.928) | |
| HR P-Value [c] | 0.0185 | |
| Heterogeneity p-value [d] | 0.9234 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.6 (39.8, 60.4) | 34.1 (23.4, 45.2) |
| 12 months | 30.9 (20.4, 42.0) | 14.3 (3.5, 32.5) |
| 18 months | 17.5 (8.3, 29.6) | 14.3 (3.5, 32.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 60 (44.1%) | 54 (43.9%) |
| Censored Patients, n (%) | 76 (55.9%) | 69 (56.1%) |
| Median (95% CI), (Months) [a] | 5.95 (4.90, 8.34) | 3.68 (2.73, 4.63) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0702 | |
| HR (95% CI) [c] | 0.712 (0.489, 1.036) | |
| HR P-Value [c] | 0.0761 | |
| Heterogeneity p-value [d] | 0.4281 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.9 (38.0, 58.9) | 36.2 (25.2, 47.2) |
| 12 months | 32.1 (21.5, 43.1) | 21.1 (8.7, 37.2) |
| 18 months | 26.3 (15.6, 38.4) | 21.1 (8.7, 37.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 64 (47.1%) | 61 (49.6%) |
| Censored Patients, n (%) | 72 (52.9%) | 62 (50.4%) |
| Median (95% CI), (Months) [a] | 4.44 (2.83, 8.34) | 2.89 (1.84, 4.27) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0092 | |
| HR (95% CI) [c] | 0.623 (0.433, 0.897) | |
| HR P-Value [c] | 0.0108 | |
| Heterogeneity p-value [d] | 0.9789 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.3 (31.7, 52.6) | 27.6 (17.3, 38.9) |
| 12 months | 31.9 (21.5, 42.8) | 4.0 (0.3, 16.2) |
| 18 months | 17.1 (7.7, 29.6) | 4.0 (0.3, 16.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 54 (39.7%) | 50 (40.7%) |
| Censored Patients, n (%) | 82 (60.3%) | 73 (59.3%) |
| Median (95% CI), (Months) [a] | 5.75 (4.37, 11.27) | 4.53 (2.96, 6.97) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0728 | |
| HR (95% CI) [c] | 0.703 (0.474, 1.043) | |
| HR P-Value [c] | 0.0798 | |
| Heterogeneity p-value [d] | 0.3682 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.6 (37.5, 58.8) | 41.5 (29.5, 53.2) |
| 12 months | 37.9 (26.6, 49.1) | 17.3 (5.9, 33.7) |
| 18 months | 34.1 (22.1, 46.5) | 8.7 (0.9, 28.3) |
| 24 months | 17.0 (1.9, 45.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 52 (38.2%) | 48 (39.0%) |
| Censored Patients, n (%) | 84 (61.8%) | 75 (61.0%) |
| Median (95% CI), (Months) [a] | 4.90 (4.21, 11.99) | 4.63 (2.79, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1653 | |
| HR (95% CI) [c] | 0.759 (0.510, 1.129) | |
| HR P-Value [c] | 0.1738 | |
| Heterogeneity p-value [d] | 0.3474 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.0 (34.6, 56.6) | 46.8 (34.9, 57.8) |
| 12 months | 35.6 (23.2, 48.1) | 23.4 (10.4, 39.4) |
| 18 months | 29.1 (16.8, 42.5) | 15.6 (3.9, 34.3) |
| 24 months | 19.4 (5.7, 39.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 24 (40.0%) | 29 (48.3%) |
| Censored Patients, n (%) | 36 (60.0%) | 31 (51.7%) |
| Median (95% CI), (Months) [a] | 5.55 (2.86, NE) | 2.86 (1.68, 5.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0491 | |
| HR (95% CI) [c] | 0.580 (0.335, 1.005) | |
| HR P-Value [c] | 0.0522 | |
| Heterogeneity p-value [d] | 0.8566 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.6 (26.2, 58.0) | 28.3 (14.1, 44.4) |
| 12 months | 35.5 (17.9, 53.6) | NE (NE, NE) |
| 18 months | 35.5 (17.9, 53.6) | NE (NE, NE) |
| 24 months | 35.5 (17.9, 53.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 23 (38.3%) | 26 (43.3%) |
| Censored Patients, n (%) | 37 (61.7%) | 34 (56.7%) |
| Median (95% CI), (Months) [a] | 5.78 (2.92, NE) | 2.99 (2.56, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1564 | |
| HR (95% CI) [c] | 0.665 (0.376, 1.176) | |
| HR P-Value [c] | 0.1610 | |
| Heterogeneity p-value [d] | 0.2208 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.4 (30.2, 62.9) | 25.4 (10.8, 42.9) |
| 12 months | 35.1 (16.9, 54.0) | NE (NE, NE) |
| 18 months | 35.1 (16.9, 54.0) | NE (NE, NE) |
| 24 months | 35.1 (16.9, 54.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 21 (35.0%) | 26 (43.3%) |
| Censored Patients, n (%) | 39 (65.0%) | 34 (56.7%) |
| Median (95% CI), (Months) [a] | 6.18 (2.96, NE) | 2.89 (2.56, 11.50) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1173 | |
| HR (95% CI) [c] | 0.632 (0.354, 1.127) | |
| HR P-Value [c] | 0.1199 | |
| Heterogeneity p-value [d] | 0.2293 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.5 (32.0, 66.4) | 39.9 (24.0, 55.3) |
| 12 months | 39.7 (21.1, 57.9) | 11.1 (0.9, 36.0) |
| 18 months | 39.7 (21.1, 57.9) | NE (NE, NE) |
| 24 months | 39.7 (21.1, 57.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 14 (23.3%) | 17 (28.3%) |
| Censored Patients, n (%) | 46 (76.7%) | 43 (71.7%) |
| Median (95% CI), (Months) [a] | 10.45 (8.44, NE) | 8.48 (5.16, 8.87) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1058 | |
| HR (95% CI) [c] | 0.547 (0.260, 1.148) | |
| HR P-Value [c] | 0.1109 | |
| Heterogeneity p-value [d] | 0.3908 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.0 (51.1, 83.9) | 55.1 (32.8, 72.7) |
| 12 months | 47.3 (22.5, 68.7) | NE (NE, NE) |
| 18 months | 47.3 (22.5, 68.7) | NE (NE, NE) |
| 24 months | 23.7 (1.8, 59.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 21 (35.0%) | 23 (38.3%) |
| Censored Patients, n (%) | 39 (65.0%) | 37 (61.7%) |
| Median (95% CI), (Months) [a] | 7.62 (2.96, NE) | 4.47 (2.83, 9.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2079 | |
| HR (95% CI) [c] | 0.682 (0.373, 1.247) | |
| HR P-Value [c] | 0.2139 | |
| Heterogeneity p-value [d] | 0.5740 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.4 (32.4, 66.0) | 47.2 (29.7, 62.8) |
| 12 months | 43.2 (23.6, 61.5) | NE (NE, NE) |
| 18 months | 43.2 (23.6, 61.5) | NE (NE, NE) |
| 24 months | 21.6 (1.9, 55.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 18 (30.0%) | 25 (41.7%) |
| Censored Patients, n (%) | 42 (70.0%) | 35 (58.3%) |
| Median (95% CI), (Months) [a] | 5.68 (4.47, NE) | 4.27 (1.77, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0145 | |
| HR (95% CI) [c] | 0.466 (0.250, 0.870) | |
| HR P-Value [c] | 0.0164 | |
| Heterogeneity p-value [d] | 0.1069 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.6 (30.4, 66.2) | 40.0 (23.8, 55.7) |
| 12 months | 49.6 (30.4, 66.2) | 0.0 (NE, NE) |
| 18 months | 49.6 (30.4, 66.2) | 0.0 (NE, NE) |
| 24 months | 24.8 (2.0, 60.8) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 35 (58.3%) | 35 (58.3%) |
| Censored Patients, n (%) | 25 (41.7%) | 25 (41.7%) |
| Median (95% CI), (Months) [a] | 1.68 (1.54, 3.02) | 2.10 (1.54, 2.96) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6539 | |
| HR (95% CI) [c] | 0.897 (0.560, 1.438) | |
| HR P-Value [c] | 0.6518 | |
| Heterogeneity p-value [d] | 0.5220 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.5 (13.3, 39.6) | 26.5 (13.6, 41.4) |
| 12 months | 13.6 (3.4, 30.9) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 21 (35.0%) | 19 (31.7%) |
| Censored Patients, n (%) | 39 (65.0%) | 41 (68.3%) |
| Median (95% CI), (Months) [a] | 7.62 (4.17, 20.80) | 6.67 (5.22, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7063 | |
| HR (95% CI) [c] | 0.887 (0.467, 1.687) | |
| HR P-Value [c] | 0.7157 | |
| Heterogeneity p-value [d] | 0.9970 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.0 (34.8, 68.3) | 60.3 (41.4, 74.9) |
| 12 months | 41.8 (22.6, 59.9) | 15.8 (1.1, 47.3) |
| 18 months | 41.8 (22.6, 59.9) | NE (NE, NE) |
| 24 months | 20.9 (4.4, 45.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 19 (31.7%) | 29 (48.3%) |
| Censored Patients, n (%) | 41 (68.3%) | 31 (51.7%) |
| Median (95% CI), (Months) [a] | 10.38 (4.21, NE) | 2.86 (1.54, 5.75) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0011 | |
| HR (95% CI) [c] | 0.373 (0.202, 0.688) | |
| HR P-Value [c] | 0.0016 | |
| Heterogeneity p-value [d] | 0.4475 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.6 (43.7, 75.2) | 29.4 (13.0, 48.0) |
| 12 months | 44.8 (24.7, 63.0) | 0.0 (NE, NE) |
| 18 months | 33.6 (12.1, 56.9) | 0.0 (NE, NE) |
| 24 months | 33.6 (12.1, 56.9) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 23 (38.3%) | 33 (55.0%) |
| Censored Patients, n (%) | 37 (61.7%) | 27 (45.0%) |
| Median (95% CI), (Months) [a] | 5.52 (2.07, 6.97) | 2.56 (1.58, 2.99) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0215 | |
| HR (95% CI) [c] | 0.540 (0.316, 0.921) | |
| HR P-Value [c] | 0.0237 | |
| Heterogeneity p-value [d] | 0.5000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.0 (18.4, 53.9) | 20.3 (8.8, 35.2) |
| 12 months | 28.8 (11.7, 48.5) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 25 (41.7%) | 27 (45.0%) |
| Censored Patients, n (%) | 35 (58.3%) | 33 (55.0%) |
| Median (95% CI), (Months) [a] | 8.41 (2.73, 14.03) | 4.14 (2.86, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1018 | |
| HR (95% CI) [c] | 0.624 (0.350, 1.112) | |
| HR P-Value [c] | 0.1098 | |
| Heterogeneity p-value [d] | 0.9234 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.8 (38.5, 68.5) | 35.0 (18.5, 52.0) |
| 12 months | 43.2 (24.4, 60.6) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 27 (45.0%) | 30 (50.0%) |
| Censored Patients, n (%) | 33 (55.0%) | 30 (50.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 6.97) | 3.02 (2.56, 5.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7318 | |
| HR (95% CI) [c] | 0.917 (0.543, 1.549) | |
| HR P-Value [c] | 0.7460 | |
| Heterogeneity p-value [d] | 0.4281 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.7 (26.2, 58.2) | 24.7 (10.5, 41.9) |
| 12 months | 18.7 (5.4, 38.0) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 27 (45.0%) | 28 (46.7%) |
| Censored Patients, n (%) | 33 (55.0%) | 32 (53.3%) |
| Median (95% CI), (Months) [a] | 2.99 (1.64, 19.29) | 2.56 (1.61, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1537 | |
| HR (95% CI) [c] | 0.673 (0.388, 1.167) | |
| HR P-Value [c] | 0.1589 | |
| Heterogeneity p-value [d] | 0.9789 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.5 (28.8, 59.1) | 27.0 (13.1, 43.0) |
| 12 months | 39.0 (22.4, 55.2) | 0.0 (NE, NE) |
| 18 months | 29.2 (11.1, 50.2) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 22 (36.7%) | 28 (46.7%) |
| Censored Patients, n (%) | 38 (63.3%) | 32 (53.3%) |
| Median (95% CI), (Months) [a] | 5.55 (2.86, 20.83) | 2.96 (1.97, 5.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0341 | |
| HR (95% CI) [c] | 0.541 (0.303, 0.965) | |
| HR P-Value [c] | 0.0375 | |
| Heterogeneity p-value [d] | 0.3682 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.4 (31.9, 64.8) | 22.9 (8.3, 41.7) |
| 12 months | 45.0 (27.2, 61.2) | NE (NE, NE) |
| 18 months | 36.0 (16.3, 56.2) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 26 (43.3%) | 22 (36.7%) |
| Censored Patients, n (%) | 34 (56.7%) | 38 (63.3%) |
| Median (95% CI), (Months) [a] | 3.19 (2.83, 4.86) | 4.27 (2.43, 8.05) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8284 | |
| HR (95% CI) [c] | 1.064 (0.601, 1.886) | |
| HR P-Value [c] | 0.8310 | |
| Heterogeneity p-value [d] | 0.3474 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.5 (18.3, 49.4) | 39.8 (21.8, 57.3) |
| 12 months | 33.5 (18.3, 49.4) | 15.9 (1.5, 44.9) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 9 (40.9%) | 12 (48.0%) |
| Censored Patients, n (%) | 13 (59.1%) | 13 (52.0%) |
| Median (95% CI), (Months) [a] | 4.37 (1.54, NE) | 2.92 (2.10, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5241 | |
| HR (95% CI) [c] | 0.756 (0.313, 1.823) | |
| HR P-Value [c] | 0.5329 | |
| Heterogeneity p-value [d] | 0.7230 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.0 (19.4, 67.8) | 23.0 (5.9, 46.7) |
| 12 months | 30.0 (6.5, 58.8) | 23.0 (5.9, 46.7) |
| 18 months | 30.0 (6.5, 58.8) | 23.0 (5.9, 46.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 10 (45.5%) | 6 (24.0%) |
| Censored Patients, n (%) | 12 (54.5%) | 19 (76.0%) |
| Median (95% CI), (Months) [a] | 2.96 (1.61, NE) | 7.16 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2321 | |
| HR (95% CI) [c] | 1.855 (0.670, 5.139) | |
| HR P-Value [c] | 0.2345 | |
| Heterogeneity p-value [d] | 0.5209 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.4 (11.5, 62.3) | 68.1 (39.0, 85.5) |
| 12 months | 36.4 (11.5, 62.3) | 45.4 (9.3, 76.9) |
| 18 months | 18.2 (1.3, 51.1) | 45.4 (9.3, 76.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 11 (50.0%) | 7 (28.0%) |
| Censored Patients, n (%) | 11 (50.0%) | 18 (72.0%) |
| Median (95% CI), (Months) [a] | 5.68 (2.83, 16.76) | NE (1.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4662 | |
| HR (95% CI) [c] | 1.414 (0.542, 3.685) | |
| HR P-Value [c] | 0.4788 | |
| Heterogeneity p-value [d] | 0.5256 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.4 (23.7, 70.8) | 61.4 (35.4, 79.5) |
| 12 months | 37.1 (11.9, 62.9) | 61.4 (35.4, 79.5) |
| 18 months | 12.4 (0.8, 40.8) | 61.4 (35.4, 79.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 7 (28.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 18 (72.0%) |
| | | |
| Median (95% CI), (Months) [a] | NE (7.03, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1049 | |
| HR (95% CI) [c] | 0.341 (0.087, 1.335) | |
| HR P-Value [c] | 0.1225 | |
| Heterogeneity p-value [d] | 0.5522 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.8 (63.2, 99.1) | 53.2 (25.5, 74.8) |
| 12 months | 62.5 (19.9, 87.2) | 53.2 (25.5, 74.8) |
| 18 months | 62.5 (19.9, 87.2) | NE (NE, NE) |
| 24 months | 62.5 (19.9, 87.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 9 (36.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 16 (64.0%) |
| Median (95% CI), (Months) [a] | 10.09 (2.99, NE) | 5.68 (2.43, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2517 | |
| HR (95% CI) [c] | 0.545 (0.190, 1.561) | |
| HR P-Value [c] | 0.2583 | |
| Heterogeneity p-value [d] | 0.9751 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.6 (21.0, 80.2) | 41.9 (13.3, 68.7) |
| 12 months | 37.1 (6.9, 69.2) | 21.0 (1.4, 56.4) |
| 18 months | 37.1 (6.9, 69.2) | 21.0 (1.4, 56.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 5 (22.7%) | 7 (28.0%) |
| Censored Patients, n (%) | 17 (77.3%) | 18 (72.0%) |
| | | |
| Median (95% CI), (Months) [a] | 12.65 (4.27, NE) | 6.14 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3774 | |
| HR (95% CI) [c] | 0.598 (0.189, 1.896) | |
| HR P-Value [c] | 0.3824 | |
| Heterogeneity p-value [d] | 0.0212 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.2 (26.3, 84.4) | 59.5 (28.0, 80.9) |
| 12 months | 62.2 (26.3, 84.4) | 47.6 (17.3, 73.1) |
| 18 months | 46.6 (13.0, 75.1) | 47.6 (17.3, 73.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 12 (54.5%) | 16 (64.0%) |
| Censored Patients, n (%) | 10 (45.5%) | 9 (36.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 5.82) | 1.81 (1.64, 2.56) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4848 | |
| HR (95% CI) [c] | 0.753 (0.348, 1.630) | |
| HR P-Value [c] | 0.4721 | |
| Heterogeneity p-value [d] | 0.9618 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 16.9 (3.0, 40.7) | 13.3 (2.3, 34.0) |
| 12 months | 16.9 (3.0, 40.7) | NE (NE, NE) |
| 18 months | 16.9 (3.0, 40.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 5 (22.7%) | 4 (16.0%) |
| Censored Patients, n (%) | 17 (77.3%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | NE (2.96, NE) | NE (5.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4825 | |
| HR (95% CI) [c] | 1.607 (0.429, 6.023) | |
| HR P-Value [c] | 0.4812 | |
| Heterogeneity p-value [d] | 0.4689 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.3 (30.2, 83.0) | 67.3 (30.7, 87.6) |
| 12 months | 62.3 (30.2, 83.0) | 67.3 (30.7, 87.6) |
| 18 months | 62.3 (30.2, 83.0) | 67.3 (30.7, 87.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 6 (24.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 19 (76.0%) |
| Median (95% CI), (Months) [a] | 7.26 (4.27, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8773 | |
| HR (95% CI) [c] | 0.910 (0.291, 2.845) | |
| HR P-Value [c] | 0.8707 | |
| Heterogeneity p-value [d] | 0.4607 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.5 (32.7, 87.1) | 64.1 (35.3, 82.8) |
| 12 months | 40.5 (10.5, 69.6) | 64.1 (35.3, 82.8) |
| 18 months | 40.5 (10.5, 69.6) | 64.1 (35.3, 82.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 11 (50.0%) | 11 (44.0%) |
| Censored Patients, n (%) | 11 (50.0%) | 14 (56.0%) |
| Median (95% CI), (Months) [a] | 4.29 (1.58, 7.10) | 2.10 (1.64, 2.83) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7330 | |
| HR (95% CI) [c] | 0.881 (0.376, 2.065) | |
| HR P-Value [c] | 0.7703 | |
| Heterogeneity p-value [d] | 0.9577 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (11.4, 57.4) | 24.0 (6.3, 47.9) |
| 12 months | 25.0 (6.5, 49.4) | 24.0 (6.3, 47.9) |
| 18 months | 25.0 (6.5, 49.4) | 24.0 (6.3, 47.9) |
| 24 months | 25.0 (6.5, 49.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 11 (50.0%) | 10 (40.0%) |
| Censored Patients, n (%) | 11 (50.0%) | 15 (60.0%) |
| | | |
| Median (95% CI), (Months) [a] | 5.95 (1.58, 16.76) | 5.68 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9946 | |
| HR (95% CI) [c] | 1.005 (0.420, 2.404) | |
| HR P-Value [c] | 0.9916 | |
| Heterogeneity p-value [d] | 0.8727 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.1 (19.2, 66.6) | 35.3 (12.1, 59.7) |
| 12 months | 44.1 (19.2, 66.6) | 35.3 (12.1, 59.7) |
| 18 months | 22.1 (4.1, 49.0) | 35.3 (12.1, 59.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 14 (63.6%) | 15 (60.0%) |
| Censored Patients, n (%) | 8 (36.4%) | 10 (40.0%) |
| Median (95% CI), (Months) [a] | 2.89 (1.58, 7.10) | 2.30 (1.64, 2.73) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3907 | |
| HR (95% CI) [c] | 0.721 (0.335, 1.553) | |
| HR P-Value [c] | 0.4031 | |
| Heterogeneity p-value [d] | 0.4246 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.6 (12.9, 56.0) | 13.3 (2.3, 34.1) |
| 12 months | 20.2 (5.1, 42.3) | 13.3 (2.3, 34.1) |
| 18 months | 13.4 (2.3, 34.5) | 13.3 (2.3, 34.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 11 (50.0%) | 13 (52.0%) |
| Censored Patients, n (%) | 11 (50.0%) | 12 (48.0%) |
| Median (95% CI), (Months) [a] | 4.37 (1.58, 14.06) | 2.10 (1.64, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4854 | |
| HR (95% CI) [c] | 0.756 (0.334, 1.711) | |
| HR P-Value [c] | 0.5028 | |
| Heterogeneity p-value [d] | 0.9973 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.6 (10.1, 57.8) | 22.6 (4.8, 48.4) |
| 12 months | 32.6 (10.1, 57.8) | 11.3 (0.8, 37.7) |
| 18 months | 16.3 (1.2, 47.2) | 11.3 (0.8, 37.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 8 (36.4%) | 12 (48.0%) |
| Censored Patients, n (%) | 14 (63.6%) | 13 (52.0%) |
| Median (95% CI), (Months) [a] | 5.82 (1.64, NE) | 2.43 (1.64, 4.53) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2288 | |
| HR (95% CI) [c] | 0.575 (0.232, 1.426) | |
| HR P-Value [c] | 0.2325 | |
| Heterogeneity p-value [d] | 0.1787 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.3 (18.7, 71.5) | 27.3 (8.8, 50.0) |
| 12 months | 31.5 (6.4, 61.6) | 27.3 (8.8, 50.0) |
| 18 months | 31.5 (6.4, 61.6) | 27.3 (8.8, 50.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 8 (36.4%) | 7 (28.0%) |
| Censored Patients, n (%) | 14 (63.6%) | 18 (72.0%) |
| | | |
| Median (95% CI), (Months) [a] | 7.95 (1.61, NE) | 6.14 (2.43, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7253 | |
| HR (95% CI) [c] | 1.200 (0.432, 3.331) | |
| HR P-Value [c] | 0.7261 | |
| Heterogeneity p-value [d] | 0.7967 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.4 (22.2, 75.8) | 62.4 (33.7, 81.5) |
| 12 months | 39.3 (11.4, 66.9) | 49.9 (19.7, 74.3) |
| 18 months | 26.2 (4.5, 56.0) | 49.9 (19.7, 74.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 18 (46.2%) | 16 (44.4%) |
| Censored Patients, n (%) | 21 (53.8%) | 20 (55.6%) |
| | | |
| Median (95% CI), (Months) [a] | 4.17 (2.79, 10.38) | 4.67 (1.58, 9.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3504 | |
| HR (95% CI) [c] | 0.725 (0.365, 1.442) | |
| HR P-Value [c] | 0.3593 | |
| Heterogeneity p-value [d] | 0.7230 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.2 (18.7, 55.8) | 36.9 (16.0, 58.1) |
| 12 months | 27.9 (9.7, 49.7) | 0.0 (NE, NE) |
| 18 months | 27.9 (9.7, 49.7) | 0.0 (NE, NE) |
| 24 months | 27.9 (9.7, 49.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 18 (46.2%) | 15 (41.7%) |
| Censored Patients, n (%) | 21 (53.8%) | 21 (58.3%) |
| | | |
| Median (95% CI), (Months) [a] | 2.96 (2.79, NE) | 4.24 (1.58, 5.22) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6226 | |
| HR (95% CI) [c] | 0.849 (0.427, 1.690) | |
| HR P-Value [c] | 0.6419 | |
| Heterogeneity p-value [d] | 0.5209 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.2 (16.0, 53.3) | 23.4 (6.6, 46.2) |
| 12 months | 34.2 (16.0, 53.3) | NE (NE, NE) |
| 18 months | 34.2 (16.0, 53.3) | NE (NE, NE) |
| 24 months | 34.2 (16.0, 53.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 13 (33.3%) | 14 (38.9%) |
| Censored Patients, n (%) | 26 (66.7%) | 22 (61.1%) |
| Median (95% CI), (Months) [a] | 6.18 (2.83, NE) | 6.67 (1.58, 14.13) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2582 | |
| HR (95% CI) [c] | 0.647 (0.302, 1.383) | |
| HR P-Value [c] | 0.2611 | |
| Heterogeneity p-value [d] | 0.5256 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.2 (31.9, 71.9) | 52.6 (30.5, 70.7) |
| 12 months | 47.4 (25.0, 66.9) | 17.5 (1.1, 50.9) |
| 18 months | 47.4 (25.0, 66.9) | 0.0 (NE, NE) |
| 24 months | 47.4 (25.0, 66.9) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 12 (30.8%) | 10 (27.8%) |
| Censored Patients, n (%) | 27 (69.2%) | 26 (72.2%) |
| Median (95% CI), (Months) [a] | 10.45 (4.30, NE) | 8.84 (4.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4016 | |
| HR (95% CI) [c] | 0.686 (0.284, 1.656) | |
| HR P-Value [c] | 0.4023 | |
| Heterogeneity p-value [d] | 0.5522 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.6 (47.5, 83.9) | 53.5 (27.5, 73.9) |
| 12 months | 41.3 (15.3, 65.9) | NE (NE, NE) |
| 18 months | 41.3 (15.3, 65.9) | NE (NE, NE) |
| 24 months | 20.6 (1.5, 55.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 17 (43.6%) | 13 (36.1%) |
| Censored Patients, n (%) | 22 (56.4%) | 23 (63.9%) |
| | | |
| Median (95% CI), (Months) [a] | 5.72 (2.89, 19.29) | 6.67 (1.97, 9.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4573 | |
| HR (95% CI) [c] | 0.758 (0.363, 1.583) | |
| HR P-Value [c] | 0.4608 | |
| Heterogeneity p-value [d] | 0.9751 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.3 (26.6, 65.4) | 53.9 (30.4, 72.6) |
| 12 months | 34.5 (15.0, 55.0) | 0.0 (NE, NE) |
| 18 months | 34.5 (15.0, 55.0) | 0.0 (NE, NE) |
| 24 months | 17.2 (1.6, 47.6) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 11 (28.2%) | 15 (41.7%) |
| Censored Patients, n (%) | 28 (71.8%) | 21 (58.3%) |
| Median (95% CI), (Months) [a] | 20.80 (4.50, NE) | 3.06 (1.54, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0029 | |
| HR (95% CI) [c] | 0.296 (0.127, 0.686) | |
| HR P-Value [c] | 0.0046 | |
| Heterogeneity p-value [d] | 0.0212 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.4 (41.6, 80.2) | 42.1 (21.5, 61.5) |
| 12 months | 55.2 (29.5, 74.9) | 0.0 (NE, NE) |
| 18 months | 55.2 (29.5, 74.9) | 0.0 (NE, NE) |
| 24 months | 36.8 (8.4, 66.8) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 24 (61.5%) | 19 (52.8%) |
| Censored Patients, n (%) | 15 (38.5%) | 17 (47.2%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.61, 5.72) | 2.56 (1.54, 4.44) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3328 | |
| HR (95% CI) [c] | 0.735 (0.397, 1.360) | |
| HR P-Value [c] | 0.3268 | |
| Heterogeneity p-value [d] | 0.9618 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.5 (16.3, 49.9) | 29.1 (11.4, 49.6) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 15 (38.5%) | 12 (33.3%) |
| Censored Patients, n (%) | 24 (61.5%) | 24 (66.7%) |
| Median (95% CI), (Months) [a] | 10.45 (4.96, NE) | 6.67 (2.96, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2951 | |
| HR (95% CI) [c] | 0.656 (0.295, 1.458) | |
| HR P-Value [c] | 0.3007 | |
| Heterogeneity p-value [d] | 0.4689 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.3 (40.7, 78.0) | 60.2 (35.8, 77.8) |
| 12 months | 45.4 (23.7, 64.9) | 20.6 (1.6, 54.9) |
| 18 months | 45.4 (23.7, 64.9) | NE (NE, NE) |
| 24 months | 27.3 (8.1, 51.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 14 (35.9%) | 16 (44.4%) |
| Censored Patients, n (%) | 25 (64.1%) | 20 (55.6%) |
| Median (95% CI), (Months) [a] | 8.54 (4.17, NE) | 4.67 (1.54, 9.95) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0272 | |
| HR (95% CI) [c] | 0.443 (0.213, 0.921) | |
| HR P-Value [c] | 0.0292 | |
| Heterogeneity p-value [d] | 0.4607 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.0 (40.1, 77.8) | 35.5 (14.2, 57.7) |
| 12 months | 35.8 (14.9, 57.4) | 0.0 (NE, NE) |
| 18 months | 35.8 (14.9, 57.4) | 0.0 (NE, NE) |
| 24 months | 35.8 (14.9, 57.4) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 17 (43.6%) | 19 (52.8%) |
| Censored Patients, n (%) | 22 (56.4%) | 17 (47.2%) |
| Median (95% CI), (Months) [a] | 2.92 (2.07, 6.97) | 2.83 (1.54, 3.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0787 | |
| HR (95% CI) [c] | 0.559 (0.289, 1.081) | |
| HR P-Value [c] | 0.0838 | |
| Heterogeneity p-value [d] | 0.9577 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.5 (16.1, 55.5) | 13.5 (2.7, 32.8) |
| 12 months | 26.6 (8.6, 48.9) | 0.0 (NE, NE) |
| 18 months | 26.6 (8.6, 48.9) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 17 (43.6%) | 16 (44.4%) |
| Censored Patients, n (%) | 22 (56.4%) | 20 (55.6%) |
| | | |
| Median (95% CI), (Months) [a] | 8.41 (2.89, 16.85) | 4.44 (1.77, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1000 | |
| HR (95% CI) [c] | 0.552 (0.268, 1.136) | |
| HR P-Value [c] | 0.1064 | |
| Heterogeneity p-value [d] | 0.8727 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.3 (32.8, 70.1) | 31.9 (11.9, 54.1) |
| 12 months | 38.0 (16.9, 59.2) | 0.0 (NE, NE) |
| 18 months | 14.3 (1.2, 42.6) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 20 (51.3%) | 17 (47.2%) |
| Censored Patients, n (%) | 19 (48.7%) | 19 (52.8%) |
| | | |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 6.97) | 4.14 (1.54, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9983 | |
| HR (95% CI) [c] | 1.003 (0.525, 1.918) | |
| HR P-Value [c] | 0.9927 | |
| Heterogeneity p-value [d] | 0.4246 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.4 (20.4, 57.9) | 29.6 (10.6, 51.6) |
| 12 months | 16.4 (3.3, 38.5) | 7.4 (0.5, 27.8) |
| 18 months | 16.4 (3.3, 38.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 20 (51.3%) | 16 (44.4%) |
| Censored Patients, n (%) | 19 (48.7%) | 20 (55.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.64, 19.29) | 3.68 (1.54, 7.20) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3295 | |
| HR (95% CI) [c] | 0.713 (0.360, 1.410) | |
| HR P-Value [c] | 0.3306 | |
| Heterogeneity p-value [d] | 0.9973 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.2 (23.1, 58.5) | 32.0 (12.9, 53.0) |
| 12 months | 34.3 (16.1, 53.4) | 0.0 (NE, NE) |
| 18 months | 34.3 (16.1, 53.4) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 20 (51.3%) | 16 (44.4%) |
| Censored Patients, n (%) | 19 (48.7%) | 20 (55.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.89 (2.07, 13.90) | 2.96 (1.68, 5.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3397 | |
| HR (95% CI) [c] | 0.720 (0.365, 1.419) | |
| HR P-Value [c] | 0.3423 | |
| Heterogeneity p-value [d] | 0.1787 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.5 (21.2, 57.3) | 20.6 (4.5, 44.9) |
| 12 months | 34.6 (17.0, 52.9) | NE (NE, NE) |
| 18 months | 23.0 (5.9, 46.8) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 19 (48.7%) | 11 (30.6%) |
| Censored Patients, n (%) | 20 (51.3%) | 25 (69.4%) |
| Median (95% CI), (Months) [a] | 4.40 (2.89, 12.78) | 5.72 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9888 | |
| HR (95% CI) [c] | 0.985 (0.460, 2.109) | |
| HR P-Value [c] | 0.9688 | |
| Heterogeneity p-value [d] | 0.7967 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.2 (16.2, 53.0) | 45.1 (19.1, 68.2) |
| 12 months | 34.2 (16.2, 53.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 29 (38.2%) | 28 (42.4%) |
| Censored Patients, n (%) | 47 (61.8%) | 38 (57.6%) |
| | | |
| Median (95% CI), (Months) [a] | 7.03 (4.44, 11.53) | 3.48 (1.91, 4.27) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0063 | |
| HR (95% CI) [c] | 0.478 (0.277, 0.825) | |
| HR P-Value [c] | 0.0080 | |
| Heterogeneity p-value [d] | 0.7230 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.5 (40.1, 68.3) | 21.0 (8.2, 37.8) |
| 12 months | 33.8 (18.4, 50.0) | 0.0 (NE, NE) |
| 18 months | 33.8 (18.4, 50.0) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 33 (43.4%) | 23 (34.8%) |
| Censored Patients, n (%) | 43 (56.6%) | 43 (65.2%) |
| | | |
| Median (95% CI), (Months) [a] | 5.59 (4.24, 8.77) | 3.15 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4324 | |
| HR (95% CI) [c] | 0.809 (0.474, 1.380) | |
| HR P-Value [c] | 0.4359 | |
| Heterogeneity p-value [d] | 0.5209 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.0 (31.3, 59.5) | 44.1 (28.1, 58.9) |
| 12 months | 27.1 (12.9, 43.5) | 39.2 (22.8, 55.2) |
| 18 months | 27.1 (12.9, 43.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 27 (35.5%) | 17 (25.8%) |
| Censored Patients, n (%) | 49 (64.5%) | 49 (74.2%) |
| Median (95% CI), (Months) [a] | 9.86 (5.59, 14.65) | 4.83 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3467 | |
| HR (95% CI) [c] | 0.738 (0.392, 1.391) | |
| HR P-Value [c] | 0.3477 | |
| Heterogeneity p-value [d] | 0.5256 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.1 (45.9, 73.3) | 40.6 (19.8, 60.5) |
| 12 months | 40.9 (23.3, 57.7) | NE (NE, NE) |
| 18 months | 23.3 (6.0, 47.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 26 (34.2%) | 14 (21.2%) |
| Censored Patients, n (%) | 50 (65.8%) | 52 (78.8%) |
| Median (95% CI), (Months) [a] | 8.41 (6.97, NE) | NE (3.38, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9069 | |
| HR (95% CI) [c] | 0.962 (0.496, 1.862) | |
| HR P-Value [c] | 0.9073 | |
| Heterogeneity p-value [d] | 0.5522 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.6 (51.5, 78.0) | 56.7 (36.0, 72.9) |
| 12 months | 35.5 (19.3, 52.2) | 56.7 (36.0, 72.9) |
| 18 months | 35.5 (19.3, 52.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 27 (35.5%) | 18 (27.3%) |
| Censored Patients, n (%) | 49 (64.5%) | 48 (72.7%) |
| Median (95% CI), (Months) [a] | 8.44 (4.44, NE) | 10.35 (3.35, 12.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5033 | |
| HR (95% CI) [c] | 0.816 (0.441, 1.508) | |
| HR P-Value [c] | 0.5161 | |
| Heterogeneity p-value [d] | 0.9751 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.4 (43.5, 70.7) | 54.6 (36.0, 69.9) |
| 12 months | 40.9 (24.5, 56.7) | 27.3 (2.1, 64.8) |
| 18 months | 40.9 (24.5, 56.7) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 31 (40.8%) | 15 (22.7%) |
| Censored Patients, n (%) | 45 (59.2%) | 51 (77.3%) |
| Median (95% CI), (Months) [a] | 7.16 (2.99, 13.83) | NE (4.60, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3262 | |
| HR (95% CI) [c] | 1.370 (0.733, 2.560) | |
| HR P-Value [c] | 0.3243 | |
| Heterogeneity p-value [d] | 0.0212 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.9 (39.1, 66.6) | 55.3 (35.5, 71.3) |
| 12 months | 33.3 (17.3, 50.2) | 55.3 (35.5, 71.3) |
| 18 months | 26.7 (11.1, 45.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 38 (50.0%) | 27 (40.9%) |
| Censored Patients, n (%) | 38 (50.0%) | 39 (59.1%) |
| Median (95% CI), (Months) [a] | 3.22 (1.71, 4.90) | 2.89 (1.77, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3910 | |
| HR (95% CI) [c] | 0.812 (0.491, 1.342) | |
| HR P-Value [c] | 0.4163 | |
| Heterogeneity p-value [d] | 0.9618 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.5 (19.8, 45.8) | 30.8 (16.2, 46.5) |
| 12 months | 27.9 (14.9, 42.4) | 0.0 (NE, NE) |
| 18 months | 27.9 (14.9, 42.4) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 22 (28.9%) | 16 (24.2%) |
| Censored Patients, n (%) | 54 (71.1%) | 50 (75.8%) |
| Median (95% CI), (Months) [a] | NE (5.13, NE) | 10.35 (3.48, 12.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3084 | |
| HR (95% CI) [c] | 0.715 (0.373, 1.369) | |
| HR P-Value [c] | 0.3115 | |
| Heterogeneity p-value [d] | 0.4689 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.6 (44.2, 72.1) | 60.7 (41.6, 75.2) |
| 12 months | 53.6 (37.7, 67.1) | 34.7 (8.4, 63.6) |
| 18 months | 53.6 (37.7, 67.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 24 (31.6%) | 27 (40.9%) |
| Censored Patients, n (%) | 52 (68.4%) | 39 (59.1%) |
| Median (95% CI), (Months) [a] | 10.09 (6.93, NE) | 2.89 (1.58, 5.19) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0003 | |
| HR (95% CI) [c] | 0.354 (0.196, 0.639) | |
| HR P-Value [c] | 0.0006 | |
| Heterogeneity p-value [d] | 0.4607 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.1 (53.3, 79.1) | 29.0 (14.2, 45.5) |
| 12 months | 48.0 (31.0, 63.1) | NE (NE, NE) |
| 18 months | 40.0 (20.7, 58.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 32 (42.1%) | 29 (43.9%) |
| Censored Patients, n (%) | 44 (57.9%) | 37 (56.1%) |
| Median (95% CI), (Months) [a] | 4.27 (2.99, NE) | 2.83 (1.77, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0772 | |
| HR (95% CI) [c] | 0.637 (0.383, 1.060) | |
| HR P-Value [c] | 0.0825 | |
| Heterogeneity p-value [d] | 0.9577 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.6 (25.8, 53.1) | 26.1 (12.4, 42.1) |
| 12 months | 36.3 (22.5, 50.2) | 0.0 (NE, NE) |
| 18 months | 36.3 (22.5, 50.2) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 34 (44.7%) | 26 (39.4%) |
| Censored Patients, n (%) | 42 (55.3%) | 40 (60.6%) |
| Median (95% CI), (Months) [a] | 6.18 (4.86, 10.45) | 3.48 (1.81, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0277 | |
| HR (95% CI) [c] | 0.552 (0.322, 0.947) | |
| HR P-Value [c] | 0.0308 | |
| Heterogeneity p-value [d] | 0.8727 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.8 (38.7, 66.7) | 31.9 (16.4, 48.6) |
| 12 months | 26.0 (12.7, 41.4) | 0.0 (NE, NE) |
| 18 months | 17.3 (4.6, 36.8) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 29 (38.2%) | 27 (40.9%) |
| Censored Patients, n (%) | 47 (61.8%) | 39 (59.1%) |
| Median (95% CI), (Months) [a] | 7.06 (4.86, NE) | 3.45 (1.81, 4.99) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0397 | |
| HR (95% CI) [c] | 0.572 (0.333, 0.982) | |
| HR P-Value [c] | 0.0428 | |
| Heterogeneity p-value [d] | 0.4246 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.6 (39.6, 67.2) | 33.5 (18.0, 49.8) |
| 12 months | 38.1 (22.7, 53.3) | NE (NE, NE) |
| 18 months | 38.1 (22.7, 53.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 33 (43.4%) | 28 (42.4%) |
| Censored Patients, n (%) | 43 (56.6%) | 38 (57.6%) |
| | | |
| Median (95% CI), (Months) [a] | 5.72 (2.83, 10.45) | 3.19 (2.07, 4.83) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0492 | |
| HR (95% CI) [c] | 0.595 (0.351, 1.010) | |
| HR P-Value [c] | 0.0547 | |
| Heterogeneity p-value [d] | 0.9973 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.5 (32.9, 60.7) | 21.5 (8.6, 38.0) |
| 12 months | 33.7 (19.2, 48.8) | 0.0 (NE, NE) |
| 18 months | 25.7 (12.2, 41.5) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 33 (43.4%) | 22 (33.3%) |
| Censored Patients, n (%) | 43 (56.6%) | 44 (66.7%) |
| Median (95% CI), (Months) [a] | 5.13 (3.09, 20.76) | 5.65 (3.02, 12.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8511 | |
| HR (95% CI) [c] | 0.954 (0.551, 1.652) | |
| HR P-Value [c] | 0.8661 | |
| Heterogeneity p-value [d] | 0.1787 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.4 (28.3, 55.8) | 46.9 (28.9, 63.1) |
| 12 months | 35.5 (21.1, 50.1) | 33.5 (15.1, 53.2) |
| 18 months | 35.5 (21.1, 50.1) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 26 (34.2%) | 21 (31.8%) |
| Censored Patients, n (%) | 50 (65.8%) | 45 (68.2%) |
| Median (95% CI), (Months) [a] | 4.90 (4.27, NE) | 7.39 (2.89, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2430 | |
| HR (95% CI) [c] | 0.711 (0.397, 1.275) | |
| HR P-Value [c] | 0.2528 | |
| Heterogeneity p-value [d] | 0.7967 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.6 (33.3, 62.4) | 53.3 (35.3, 68.3) |
| 12 months | 44.2 (28.2, 59.1) | 21.3 (4.1, 47.2) |
| 18 months | 44.2 (28.2, 59.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 24 (40.7%) | 28 (50.0%) |
| Censored Patients, n (%) | 35 (59.3%) | 28 (50.0%) |
| Median (95% CI), (Months) [a] | 5.82 (2.89, 13.96) | 2.99 (1.68, 5.55) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0465 | |
| HR (95% CI) [c] | 0.569 (0.323, 1.002) | |
| HR P-Value [c] | 0.0508 | |
| Heterogeneity p-value [d] | 0.7230 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.8 (30.1, 61.8) | 30.5 (15.9, 46.5) |
| 12 months | 43.4 (27.0, 58.8) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 29 (49.2%) | 28 (50.0%) |
| Censored Patients, n (%) | 30 (50.8%) | 28 (50.0%) |
| Median (95% CI), (Months) [a] | 6.97 (2.83, 11.07) | 2.96 (2.86, 4.60) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1601 | |
| HR (95% CI) [c] | 0.674 (0.385, 1.181) | |
| HR P-Value [c] | 0.1681 | |
| Heterogeneity p-value [d] | 0.5209 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.2 (37.4, 68.3) | 31.3 (17.0, 46.8) |
| 12 months | 25.2 (10.3, 43.4) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 23 (39.0%) | 27 (48.2%) |
| Censored Patients, n (%) | 36 (61.0%) | 29 (51.8%) |
| Median (95% CI), (Months) [a] | 8.21 (2.79, 15.11) | 2.99 (2.79, 4.60) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2807 | |
| HR (95% CI) [c] | 0.737 (0.418, 1.301) | |
| HR P-Value [c] | 0.2931 | |
| Heterogeneity p-value [d] | 0.5256 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.7 (39.6, 70.6) | 33.1 (18.3, 48.7) |
| 12 months | 34.9 (18.0, 52.3) | 14.5 (1.5, 40.9) |
| 18 months | 23.2 (6.1, 46.7) | NE (NE, NE) |
| 24 months | 23.2 (6.1, 46.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 17 (28.8%) | 17 (30.4%) |
| Censored Patients, n (%) | 42 (71.2%) | 39 (69.6%) |
| Median (95% CI), (Months) [a] | 7.36 (5.29, NE) | 8.48 (5.55, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9886 | |
| HR (95% CI) [c] | 1.006 (0.513, 1.973) | |
| HR P-Value [c] | 0.9856 | |
| Heterogeneity p-value [d] | 0.5522 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.5 (37.6, 73.0) | 54.6 (34.4, 71.0) |
| 12 months | 41.1 (21.2, 60.1) | NE (NE, NE) |
| 18 months | 41.1 (21.2, 60.1) | NE (NE, NE) |
| 24 months | 41.1 (21.2, 60.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 19 (32.2%) | 22 (39.3%) |
| Censored Patients, n (%) | 40 (67.8%) | 34 (60.7%) |
| Median (95% CI), (Months) [a] | 11.93 (4.14, NE) | 5.85 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5636 | |
| HR (95% CI) [c] | 0.835 (0.447, 1.562) | |
| HR P-Value [c] | 0.5729 | |
| Heterogeneity p-value [d] | 0.9751 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.8 (35.2, 67.7) | 47.5 (30.0, 63.1) |
| 12 months | 45.3 (25.3, 63.3) | NE (NE, NE) |
| 18 months | 45.3 (25.3, 63.3) | NE (NE, NE) |
| 24 months | 45.3 (25.3, 63.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 21 (35.6%) | 27 (48.2%) |
| Censored Patients, n (%) | 38 (64.4%) | 29 (51.8%) |
| Median (95% CI), (Months) [a] | 7.06 (4.17, NE) | 4.30 (2.86, 5.32) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0572 | |
| HR (95% CI) [c] | 0.570 (0.313, 1.036) | |
| HR P-Value [c] | 0.0652 | |
| Heterogeneity p-value [d] | 0.0212 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.5 (33.6, 66.8) | 27.7 (13.3, 44.2) |
| 12 months | 39.7 (20.7, 58.2) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 37 (62.7%) | 35 (62.5%) |
| Censored Patients, n (%) | 22 (37.3%) | 21 (37.5%) |
| | | |
| Median (95% CI), (Months) [a] | 2.79 (1.48, 2.96) | 1.68 (1.54, 2.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6332 | |
| HR (95% CI) [c] | 0.905 (0.565, 1.450) | |
| HR P-Value [c] | 0.6792 | |
| Heterogeneity p-value [d] | 0.9618 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.6 (13.8, 39.2) | 27.5 (14.9, 41.6) |
| 12 months | 9.8 (2.1, 24.5) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 16 (27.1%) | 13 (23.2%) |
| Censored Patients, n (%) | 43 (72.9%) | 43 (76.8%) |
| | | |
| Median (95% CI), (Months) [a] | 6.87 (4.21, NE) | 8.84 (5.55, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6134 | |
| HR (95% CI) [c] | 1.225 (0.585, 2.565) | |
| HR P-Value [c] | 0.5909 | |
| Heterogeneity p-value [d] | 0.4689 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.2 (35.3, 72.8) | 67.1 (44.6, 82.1) |
| 12 months | 37.5 (17.2, 57.9) | 20.9 (1.6, 55.3) |
| 18 months | 37.5 (17.2, 57.9) | NE (NE, NE) |
| 24 months | 37.5 (17.2, 57.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 26 (44.1%) | 33 (58.9%) |
| Censored Patients, n (%) | 33 (55.9%) | 23 (41.1%) |
| Median (95% CI), (Months) [a] | 5.62 (2.99, 11.99) | 1.68 (1.54, 4.60) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0201 | |
| HR (95% CI) [c] | 0.541 (0.318, 0.920) | |
| HR P-Value [c] | 0.0235 | |
| Heterogeneity p-value [d] | 0.4607 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.7 (28.2, 59.8) | 30.8 (17.0, 45.6) |
| 12 months | 28.9 (12.5, 47.7) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 25 (42.4%) | 32 (57.1%) |
| Censored Patients, n (%) | 34 (57.6%) | 24 (42.9%) |
| Median (95% CI), (Months) [a] | 5.52 (1.84, 9.66) | 2.83 (1.54, 4.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0324 | |
| HR (95% CI) [c] | 0.552 (0.316, 0.965) | |
| HR P-Value [c] | 0.0370 | |
| Heterogeneity p-value [d] | 0.9577 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.6 (26.8, 60.9) | 16.9 (6.3, 31.9) |
| 12 months | 20.1 (6.5, 38.9) | NE (NE, NE) |
| 18 months | 13.4 (2.7, 32.5) | NE (NE, NE) |
| 24 months | 13.4 (2.7, 32.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 27 (45.8%) | 31 (55.4%) |
| Censored Patients, n (%) | 32 (54.2%) | 25 (44.6%) |
| Median (95% CI), (Months) [a] | 5.82 (2.86, 14.03) | 3.02 (1.77, 8.38) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0554 | |
| HR (95% CI) [c] | 0.589 (0.338, 1.027) | |
| HR P-Value [c] | 0.0622 | |
| Heterogeneity p-value [d] | 0.8727 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.7 (33.2, 64.2) | 37.1 (22.7, 51.5) |
| 12 months | 35.4 (18.3, 53.0) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 24 (40.7%) | 25 (44.6%) |
| Censored Patients, n (%) | 35 (59.3%) | 31 (55.4%) |
| Median (95% CI), (Months) [a] | 5.95 (4.37, 11.20) | 4.34 (2.86, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6012 | |
| HR (95% CI) [c] | 0.863 (0.483, 1.540) | |
| HR P-Value [c] | 0.6178 | |
| Heterogeneity p-value [d] | 0.4246 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.6 (29.4, 63.7) | 41.9 (25.5, 57.5) |
| 12 months | 26.7 (10.5, 46.0) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 27 (45.8%) | 32 (57.1%) |
| Censored Patients, n (%) | 32 (54.2%) | 24 (42.9%) |
| Median (95% CI), (Months) [a] | 2.99 (2.79, 11.99) | 1.77 (1.54, 4.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0545 | |
| HR (95% CI) [c] | 0.594 (0.343, 1.028) | |
| HR P-Value [c] | 0.0626 | |
| Heterogeneity p-value [d] | 0.9973 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.8 (24.0, 56.9) | 30.2 (16.3, 45.3) |
| 12 months | 32.4 (16.6, 49.4) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 15 (25.4%) | 28 (50.0%) |
| Censored Patients, n (%) | 44 (74.6%) | 28 (50.0%) |
| Median (95% CI), (Months) [a] | 15.34 (5.72, NE) | 4.34 (1.68, 6.70) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0017 | |
| HR (95% CI) [c] | 0.368 (0.191, 0.708) | |
| HR P-Value [c] | 0.0027 | |
| Heterogeneity p-value [d] | 0.1787 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.8 (47.5, 80.4) | 37.4 (21.4, 53.3) |
| 12 months | 52.8 (32.3, 69.7) | NE (NE, NE) |
| 18 months | 42.2 (18.8, 64.1) | NE (NE, NE) |
| 24 months | 42.2 (18.8, 64.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 25 (42.4%) | 31 (55.4%) |
| Censored Patients, n (%) | 34 (57.6%) | 25 (44.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 11.93) | 2.92 (1.68, 4.63) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6136 | |
| HR (95% CI) [c] | 0.888 (0.519, 1.519) | |
| HR P-Value [c] | 0.6637 | |
| Heterogeneity p-value [d] | 0.7967 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.2 (18.2, 50.9) | 30.7 (16.8, 45.7) |
| 12 months | 20.5 (6.4, 40.1) | 10.5 (1.1, 32.4) |
| 18 months | 13.7 (2.7, 33.4) | NE (NE, NE) |
| 24 months | 13.7 (2.7, 33.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 67 (41.6%) | 67 (48.9%) |
| Censored Patients, n (%) | 94 (58.4%) | 70 (51.1%) |
| Median (95% CI), (Months) [a] | 5.82 (4.37, 9.76) | 3.15 (2.56, 4.60) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0009 | |
| HR (95% CI) [c] | 0.559 (0.394, 0.793) | |
| HR P-Value [c] | 0.0011 | |
| Heterogeneity p-value [d] | 0.6387 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.1 (39.1, 58.4) | 27.3 (17.4, 38.1) |
| 12 months | 34.6 (24.2, 45.2) | 0.0 (NE, NE) |
| 18 months | 31.9 (21.3, 43.0) | 0.0 (NE, NE) |
| 24 months | 31.9 (21.3, 43.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 76 (47.2%) | 56 (40.9%) |
| Censored Patients, n (%) | 85 (52.8%) | 81 (59.1%) |
| Median (95% CI), (Months) [a] | 5.59 (2.99, 7.29) | 4.17 (2.92, 6.08) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4431 | |
| HR (95% CI) [c] | 0.876 (0.617, 1.243) | |
| HR P-Value [c] | 0.4576 | |
| Heterogeneity p-value [d] | 0.9873 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.5 (34.8, 53.8) | 40.5 (29.7, 50.9) |
| 12 months | 26.6 (16.8, 37.5) | 27.8 (13.8, 43.7) |
| 18 months | 19.0 (9.0, 31.8) | NE (NE, NE) |
| 24 months | 19.0 (9.0, 31.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 62 (38.5%) | 55 (40.1%) |
| Censored Patients, n (%) | 99 (61.5%) | 82 (59.9%) |
| Median (95% CI), (Months) [a] | 8.21 (5.59, 14.65) | 4.17 (2.99, 5.19) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0308 | |
| HR (95% CI) [c] | 0.667 (0.459, 0.969) | |
| HR P-Value [c] | 0.0335 | |
| Heterogeneity p-value [d] | 0.1014 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.3 (46.4, 65.1) | 38.1 (26.7, 49.3) |
| 12 months | 41.6 (30.2, 52.6) | 16.4 (4.0, 36.3) |
| 18 months | 27.0 (14.3, 41.5) | 0.0 (NE, NE) |
| 24 months | 27.0 (14.3, 41.5) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 47 (29.2%) | 40 (29.2%) |
| Censored Patients, n (%) | 114 (70.8%) | 97 (70.8%) |
| Median (95% CI), (Months) [a] | 8.54 (7.03, NE) | 8.84 (4.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1545 | |
| HR (95% CI) [c] | 0.736 (0.480, 1.127) | |
| HR P-Value [c] | 0.1583 | |
| Heterogeneity p-value [d] | 0.1226 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.6 (58.3, 76.9) | 50.1 (37.1, 61.9) |
| 12 months | 42.8 (30.2, 54.8) | 40.1 (24.3, 55.4) |
| 18 months | 42.8 (30.2, 54.8) | NE (NE, NE) |
| 24 months | 42.8 (30.2, 54.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 61 (37.9%) | 48 (35.0%) |
| Censored Patients, n (%) | 100 (62.1%) | 89 (65.0%) |
| Median (95% CI), (Months) [a] | 7.23 (5.59, 11.93) | 5.85 (4.37, 9.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2261 | |
| HR (95% CI) [c] | 0.791 (0.537, 1.164) | |
| HR P-Value [c] | 0.2339 | |
| Heterogeneity p-value [d] | 0.6107 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.8 (42.6, 62.1) | 48.5 (36.0, 59.9) |
| 12 months | 38.4 (27.2, 49.5) | 23.0 (8.1, 42.3) |
| 18 months | 38.4 (27.2, 49.5) | 0.0 (NE, NE) |
| 24 months | 32.0 (18.0, 46.8) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 62 (38.5%) | 44 (32.1%) |
| Censored Patients, n (%) | 99 (61.5%) | 93 (67.9%) |
| Median (95% CI), (Months) [a] | 7.16 (5.55, 11.99) | 7.10 (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4390 | |
| HR (95% CI) [c] | 0.857 (0.577, 1.274) | |
| HR P-Value [c] | 0.4458 | |
| Heterogeneity p-value [d] | 0.0153 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.6 (43.2, 62.9) | 50.9 (38.8, 61.8) |
| 12 months | 38.7 (27.3, 49.9) | 29.2 (10.8, 50.5) |
| 18 months | 30.3 (18.6, 42.9) | NE (NE, NE) |
| 24 months | 22.7 (9.3, 39.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 94 (58.4%) | 77 (56.2%) |
| Censored Patients, n (%) | 67 (41.6%) | 60 (43.8%) |
| | | |
| Median (95% CI), (Months) [a] | 2.89 (1.64, 4.21) | 2.07 (1.71, 2.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1186 | |
| HR (95% CI) [c] | 0.789 (0.581, 1.073) | |
| HR P-Value [c] | 0.1305 | |
| Heterogeneity p-value [d] | 0.8403 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.4 (19.4, 36.0) | 25.9 (17.1, 35.4) |
| 12 months | 15.9 (8.4, 25.6) | 0.0 (NE, NE) |
| 18 months | 15.9 (8.4, 25.6) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 48 (29.8%) | 40 (29.2%) |
| Censored Patients, n (%) | 113 (70.2%) | 97 (70.8%) |
| Median (95% CI), (Months) [a] | 18.89 (5.55, NE) | 7.06 (5.91, 11.50) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2918 | |
| HR (95% CI) [c] | 0.797 (0.521, 1.222) | |
| HR P-Value [c] | 0.2985 | |
| Heterogeneity p-value [d] | 0.1088 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.5 (46.7, 66.8) | 61.9 (49.3, 72.2) |
| 12 months | 50.6 (39.3, 60.9) | 16.9 (3.4, 39.1) |
| 18 months | 50.6 (39.3, 60.9) | NE (NE, NE) |
| 24 months | 44.3 (29.1, 58.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 62 (38.5%) | 68 (49.6%) |
| Censored Patients, n (%) | 99 (61.5%) | 69 (50.4%) |
| Median (95% CI), (Months) [a] | 7.43 (5.82, 10.38) | 2.96 (1.77, 4.93) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| HR (95% CI) [c] | 0.434 (0.302, 0.622) | |
| HR P-Value [c] | <0.0001 | |
| Heterogeneity p-value [d] | 0.8637 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.0 (48.8, 67.8) | 31.6 (21.4, 42.4) |
| 12 months | 37.4 (26.6, 48.2) | 0.0 (NE, NE) |
| 18 months | 31.8 (20.4, 43.7) | 0.0 (NE, NE) |
| 24 months | 31.8 (20.4, 43.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 71 (44.1%) | 70 (51.1%) |
| Censored Patients, n (%) | 90 (55.9%) | 67 (48.9%) |
| Median (95% CI), (Months) [a] | 4.34 (2.92, 5.82) | 2.56 (1.77, 2.96) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0068 | |
| HR (95% CI) [c] | 0.634 (0.453, 0.887) | |
| HR P-Value [c] | 0.0079 | |
| Heterogeneity p-value [d] | 0.8962 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.9 (28.1, 47.6) | 23.3 (14.6, 33.2) |
| 12 months | 29.5 (19.8, 39.8) | 0.0 (NE, NE) |
| 18 months | 26.5 (16.6, 37.6) | 0.0 (NE, NE) |
| 24 months | 26.5 (16.6, 37.6) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 76 (47.2%) | 62 (45.3%) |
| Censored Patients, n (%) | 85 (52.8%) | 75 (54.7%) |
| Median (95% CI), (Months) [a] | 6.18 (5.55, 9.69) | 4.37 (2.86, 6.08) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0118 | |
| HR (95% CI) [c] | 0.641 (0.451, 0.911) | |
| HR P-Value [c] | 0.0131 | |
| Heterogeneity p-value [d] | 0.9111 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.8 (42.1, 60.7) | 39.6 (28.8, 50.3) |
| 12 months | 34.2 (24.1, 44.6) | 6.3 (0.5, 23.5) |
| 18 months | 16.7 (7.8, 28.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 72 (44.7%) | 70 (51.1%) |
| Censored Patients, n (%) | 89 (55.3%) | 67 (48.9%) |
| Median (95% CI), (Months) [a] | 6.05 (5.55, 8.21) | 3.02 (2.56, 4.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0058 | |
| HR (95% CI) [c] | 0.628 (0.448, 0.881) | |
| HR P-Value [c] | 0.0070 | |
| Heterogeneity p-value [d] | 0.0072 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (40.1, 59.2) | 29.9 (20.2, 40.2) |
| 12 months | 30.9 (21.1, 41.3) | 8.2 (0.9, 26.1) |
| 18 months | 25.4 (15.2, 36.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 77 (47.8%) | 69 (50.4%) |
| Censored Patients, n (%) | 84 (52.2%) | 68 (49.6%) |
| Median (95% CI), (Months) [a] | 4.27 (2.83, 8.34) | 2.96 (2.10, 4.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0201 | |
| HR (95% CI) [c] | 0.676 (0.481, 0.950) | |
| HR P-Value [c] | 0.0240 | |
| Heterogeneity p-value [d] | 0.2927 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.6 (32.0, 51.0) | 29.5 (19.5, 40.2) |
| 12 months | 33.6 (23.8, 43.6) | 0.0 (NE, NE) |
| 18 months | 19.1 (9.6, 31.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 66 (41.0%) | 59 (43.1%) |
| Censored Patients, n (%) | 95 (59.0%) | 78 (56.9%) |
| Median (95% CI), (Months) [a] | 5.72 (4.21, 11.27) | 4.53 (2.92, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0682 | |
| HR (95% CI) [c] | 0.720 (0.502, 1.032) | |
| HR P-Value [c] | 0.0735 | |
| Heterogeneity p-value [d] | 0.1882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.8 (36.7, 56.2) | 39.4 (28.0, 50.6) |
| 12 months | 39.0 (28.7, 49.2) | 16.4 (6.3, 30.7) |
| 18 months | 35.1 (23.6, 46.8) | 0.0 (NE, NE) |
| 24 months | 11.7 (1.0, 36.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 67 (41.6%) | 56 (40.9%) |
| Censored Patients, n (%) | 94 (58.4%) | 81 (59.1%) |
| Median (95% CI), (Months) [a] | 4.47 (2.96, 7.95) | 4.27 (2.89, 7.00) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1775 | |
| HR (95% CI) [c] | 0.783 (0.545, 1.125) | |
| HR P-Value [c] | 0.1862 | |
| Heterogeneity p-value [d] | 0.6878 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.6 (31.4, 51.4) | 43.0 (31.5, 54.0) |
| 12 months | 32.9 (22.1, 44.0) | 11.0 (2.3, 27.8) |
| 18 months | 25.3 (14.8, 37.1) | NE (NE, NE) |
| 24 months | 16.9 (5.1, 34.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 13 (37.1%) | 17 (37.0%) |
| Censored Patients, n (%) | 22 (62.9%) | 29 (63.0%) |
| Median (95% CI), (Months) [a] | 4.17 (2.79, NE) | 2.99 (1.54, 5.32) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4232 | |
| HR (95% CI) [c] | 0.741 (0.357, 1.538) | |
| HR P-Value [c] | 0.4212 | |
| Heterogeneity p-value [d] | 0.6387 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.0 (19.8, 61.2) | 29.5 (12.0, 49.5) |
| 12 months | 41.0 (19.8, 61.2) | 29.5 (12.0, 49.5) |
| 18 months | NE (NE, NE) | 29.5 (12.0, 49.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 14 (40.0%) | 16 (34.8%) |
| Censored Patients, n (%) | 21 (60.0%) | 30 (65.2%) |
| Median (95% CI), (Months) [a] | 5.78 (2.83, 12.48) | 2.96 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7171 | |
| HR (95% CI) [c] | 0.879 (0.427, 1.807) | |
| HR P-Value [c] | 0.7250 | |
| Heterogeneity p-value [d] | 0.9873 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.4 (23.7, 68.0) | 37.7 (19.1, 56.2) |
| 12 months | 31.6 (11.0, 54.9) | 37.7 (19.1, 56.2) |
| 18 months | 0.0 (NE, NE) | 37.7 (19.1, 56.2) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 12 (34.3%) | 10 (21.7%) |
| Censored Patients, n (%) | 23 (65.7%) | 36 (78.3%) |
| Median (95% CI), (Months) [a] | 6.97 (2.96, 15.11) | NE (2.89, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4734 | |
| HR (95% CI) [c] | 1.358 (0.583, 3.164) | |
| HR P-Value [c] | 0.4780 | |
| Heterogeneity p-value [d] | 0.1014 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.3 (35.0, 79.6) | 65.7 (44.3, 80.5) |
| 12 months | 28.7 (8.2, 53.6) | 56.3 (30.9, 75.5) |
| 18 months | 0.0 (NE, NE) | 56.3 (30.9, 75.5) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 11 (31.4%) | 8 (17.4%) |
| Censored Patients, n (%) | 24 (68.6%) | 38 (82.6%) |
| | | |
| Median (95% CI), (Months) [a] | 7.36 (2.83, 18.04) | NE (4.63, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3907 | |
| HR (95% CI) [c] | 1.505 (0.588, 3.851) | |
| HR P-Value [c] | 0.3937 | |
| Heterogeneity p-value [d] | 0.1226 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.7 (32.6, 78.9) | 70.1 (46.1, 85.0) |
| 12 months | 29.9 (7.9, 56.2) | 52.6 (18.0, 78.6) |
| 18 months | 29.9 (7.9, 56.2) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 8 (22.9%) | 14 (30.4%) |
| Censored Patients, n (%) | 27 (77.1%) | 32 (69.6%) |
| | | |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | 9.89 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2895 | |
| HR (95% CI) [c] | 0.615 (0.250, 1.512) | |
| HR P-Value [c] | 0.2895 | |
| Heterogeneity p-value [d] | 0.6107 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.9 (40.0, 81.6) | 52.2 (30.5, 70.1) |
| 12 months | 54.1 (25.9, 75.6) | 17.4 (1.1, 50.6) |
| 18 months | NE (NE, NE) | 17.4 (1.1, 50.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 6 (17.1%) | 20 (43.5%) |
| Censored Patients, n (%) | 29 (82.9%) | 26 (56.5%) |
| Median (95% CI), (Months) [a] | 20.80 (4.50, 20.80) | 3.32 (1.77, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0019 | |
| HR (95% CI) [c] | 0.238 (0.089, 0.637) | |
| HR P-Value [c] | 0.0043 | |
| Heterogeneity p-value [d] | 0.0153 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.9 (44.6, 87.4) | 26.0 (10.4, 44.9) |
| 12 months | 71.9 (44.6, 87.4) | 20.8 (7.0, 39.6) |
| 18 months | 71.9 (44.6, 87.4) | 20.8 (7.0, 39.6) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 17 (48.6%) | 20 (43.5%) |
| Censored Patients, n (%) | 18 (51.4%) | 26 (56.5%) |
| | | |
| Median (95% CI), (Months) [a] | 2.79 (1.48, 8.34) | 1.64 (1.54, 3.02) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4366 | |
| HR (95% CI) [c] | 0.765 (0.390, 1.499) | |
| HR P-Value [c] | 0.4349 | |
| Heterogeneity p-value [d] | 0.8403 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.4 (17.4, 55.7) | 30.8 (14.4, 48.8) |
| 12 months | 18.2 (4.9, 38.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 10 (28.6%) | 5 (10.9%) |
| Censored Patients, n (%) | 25 (71.4%) | 41 (89.1%) |
| Median (95% CI), (Months) [a] | 10.12 (4.30, 20.80) | NE (5.22, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3698 | |
| HR (95% CI) [c] | 1.639 (0.548, 4.906) | |
| HR P-Value [c] | 0.3771 | |
| Heterogeneity p-value [d] | 0.1088 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.4 (39.6, 85.6) | 70.1 (41.1, 86.8) |
| 12 months | 30.8 (8.2, 57.4) | 70.1 (41.1, 86.8) |
| 18 months | 30.8 (8.2, 57.4) | 70.1 (41.1, 86.8) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 8 (22.9%) | 14 (30.4%) |
| Censored Patients, n (%) | 27 (77.1%) | 32 (69.6%) |
| | | |
| Median (95% CI), (Months) [a] | NE (4.17, NE) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1753 | |
| HR (95% CI) [c] | 0.545 (0.227, 1.305) | |
| HR P-Value [c] | 0.1730 | |
| Heterogeneity p-value [d] | 0.8637 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.9 (38.5, 81.1) | 50.2 (30.8, 66.8) |
| 12 months | 53.3 (25.2, 75.0) | 50.2 (30.8, 66.8) |
| 18 months | NE (NE, NE) | 50.2 (30.8, 66.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 14 (40.0%) | 21 (45.7%) |
| Censored Patients, n (%) | 21 (60.0%) | 25 (54.3%) |
| | | |
| Median (95% CI), (Months) [a] | 4.21 (1.68, 9.72) | 2.83 (1.64, 3.02) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1022 | |
| HR (95% CI) [c] | 0.562 (0.281, 1.127) | |
| HR P-Value [c] | 0.1048 | |
| Heterogeneity p-value [d] | 0.8962 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.8 (22.3, 65.0) | 11.9 (2.3, 30.3) |
| 12 months | 23.0 (6.4, 45.7) | 6.0 (0.4, 23.1) |
| 18 months | NE (NE, NE) | 6.0 (0.4, 23.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 13 (37.1%) | 21 (45.7%) |
| Censored Patients, n (%) | 22 (62.9%) | 25 (54.3%) |
| | | |
| Median (95% CI), (Months) [a] | 10.45 (1.68, 14.55) | 2.96 (1.77, 4.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2521 | |
| HR (95% CI) [c] | 0.666 (0.328, 1.351) | |
| HR P-Value [c] | 0.2602 | |
| Heterogeneity p-value [d] | 0.9111 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (26.7, 69.6) | 18.0 (5.4, 36.5) |
| 12 months | 30.0 (8.8, 55.1) | 18.0 (5.4, 36.5) |
| 18 months | 0.0 (NE, NE) | 18.0 (5.4, 36.5) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 15 (42.9%) | 14 (30.4%) |
| Censored Patients, n (%) | 20 (57.1%) | 32 (69.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.76 (1.45, 5.95) | 4.63 (1.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0733 | |
| HR (95% CI) [c] | 1.929 (0.928, 4.010) | |
| HR P-Value [c] | 0.0783 | |
| Heterogeneity p-value [d] | 0.0072 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 22.3 (5.1, 46.8) | 43.3 (21.6, 63.3) |
| 12 months | 11.1 (0.8, 36.7) | 32.5 (11.0, 56.4) |
| 18 months | NE (NE, NE) | 32.5 (11.0, 56.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 14 (40.0%) | 20 (43.5%) |
| Censored Patients, n (%) | 21 (60.0%) | 26 (56.5%) |
| Median (95% CI), (Months) [a] | 4.21 (2.79, 14.55) | 1.64 (1.54, 4.27) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0392 | |
| HR (95% CI) [c] | 0.473 (0.231, 0.968) | |
| HR P-Value [c] | 0.0406 | |
| Heterogeneity p-value [d] | 0.2927 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.6 (25.2, 68.6) | 17.4 (4.9, 36.4) |
| 12 months | 33.3 (12.3, 56.2) | 17.4 (4.9, 36.4) |
| 18 months | 22.2 (4.7, 47.8) | 17.4 (4.9, 36.4) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 10 (28.6%) | 19 (41.3%) |
| Censored Patients, n (%) | 25 (71.4%) | 27 (58.7%) |
| Median (95% CI), (Months) [a] | 10.45 (4.27, NE) | 2.96 (1.54, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0203 | |
| HR (95% CI) [c] | 0.400 (0.181, 0.887) | |
| HR P-Value [c] | 0.0240 | |
| Heterogeneity p-value [d] | 0.1882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.0 (32.2, 78.2) | 25.8 (10.5, 44.2) |
| 12 months | 45.0 (20.2, 67.1) | 25.8 (10.5, 44.2) |
| 18 months | NE (NE, NE) | 25.8 (10.5, 44.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 11 (31.4%) | 14 (30.4%) |
| Censored Patients, n (%) | 24 (68.6%) | 32 (69.6%) |
| | | |
| Median (95% CI), (Months) [a] | 4.21 (2.83, NE) | 6.14 (1.61, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9170 | |
| HR (95% CI) [c] | 0.956 (0.432, 2.111) | |
| HR P-Value [c] | 0.9106 | |
| Heterogeneity p-value [d] | 0.6878 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.0 (20.6, 65.3) | 50.5 (29.9, 67.9) |
| 12 months | 44.0 (20.6, 65.3) | 44.8 (24.4, 63.4) |
| 18 months | NE (NE, NE) | 44.8 (24.4, 63.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 34 (38.2%) | 36 (42.4%) |
| Censored Patients, n (%) | 55 (61.8%) | 49 (57.6%) |
| Median (95% CI), (Months) [a] | 5.72 (2.99, 12.88) | 2.56 (1.77, 4.21) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0059 | |
| HR (95% CI) [c] | 0.516 (0.318, 0.835) | |
| HR P-Value [c] | 0.0071 | |
| Heterogeneity p-value [d] | 0.4242 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.3 (33.2, 60.1) | 21.3 (9.8, 35.7) |
| 12 months | 36.0 (21.2, 51.1) | NE (NE, NE) |
| 18 months | 31.5 (16.8, 47.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 42 (47.2%) | 27 (31.8%) |
| Censored Patients, n (%) | 47 (52.8%) | 58 (68.2%) |
| Median (95% CI), (Months) [a] | 4.47 (2.83, 7.33) | 4.21 (2.56, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9060 | |
| HR (95% CI) [c] | 0.974 (0.597, 1.587) | |
| HR P-Value [c] | 0.9145 | |
| Heterogeneity p-value [d] | 0.4632 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.3 (27.2, 53.0) | 39.3 (23.7, 54.6) |
| 12 months | 19.3 (6.8, 36.5) | 23.6 (6.5, 46.6) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 33 (37.1%) | 22 (25.9%) |
| Censored Patients, n (%) | 56 (62.9%) | 63 (74.1%) |
| Median (95% CI), (Months) [a] | 8.77 (2.96, 16.76) | 4.83 (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9895 | |
| HR (95% CI) [c] | 1.004 (0.577, 1.746) | |
| HR P-Value [c] | 0.9895 | |
| Heterogeneity p-value [d] | 0.3712 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.5 (40.0, 65.3) | 46.7 (29.3, 62.4) |
| 12 months | 46.2 (31.2, 59.9) | 37.4 (17.3, 57.6) |
| 18 months | 21.5 (5.3, 44.9) | NE (NE, NE) |
| 24 months | 21.5 (5.3, 44.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 27 (30.3%) | 16 (18.8%) |
| Censored Patients, n (%) | 62 (69.7%) | 69 (81.2%) |
| Median (95% CI), (Months) [a] | 8.44 (5.72, NE) | 8.48 (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9753 | |
| HR (95% CI) [c] | 1.011 (0.540, 1.893) | |
| HR P-Value [c] | 0.9729 | |
| Heterogeneity p-value [d] | 0.5185 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.9 (49.3, 75.3) | 59.3 (40.3, 73.9) |
| 12 months | 35.4 (17.9, 53.4) | 47.4 (22.2, 69.1) |
| 18 months | 35.4 (17.9, 53.4) | NE (NE, NE) |
| 24 months | 35.4 (17.9, 53.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 31 (34.8%) | 21 (24.7%) |
| Censored Patients, n (%) | 58 (65.2%) | 64 (75.3%) |
| | | |
| Median (95% CI), (Months) [a] | 10.45 (5.65, NE) | 6.67 (3.06, 9.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4715 | |
| HR (95% CI) [c] | 0.814 (0.459, 1.444) | |
| HR P-Value [c] | 0.4819 | |
| Heterogeneity p-value [d] | 0.9183 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.7 (39.4, 66.0) | 55.6 (38.6, 69.6) |
| 12 months | 36.2 (19.7, 52.9) | 0.0 (NE, NE) |
| 18 months | 36.2 (19.7, 52.9) | 0.0 (NE, NE) |
| 24 months | 36.2 (19.7, 52.9) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 27 (30.3%) | 24 (28.2%) |
| Censored Patients, n (%) | 62 (69.7%) | 61 (71.8%) |
| | | |
| Median (95% CI), (Months) [a] | 12.65 (5.62, NE) | 4.83 (2.96, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0714 | |
| HR (95% CI) [c] | 0.597 (0.338, 1.057) | |
| HR P-Value [c] | 0.0766 | |
| Heterogeneity p-value [d] | 0.5450 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.7 (45.2, 71.6) | 42.6 (25.0, 59.1) |
| 12 months | 52.9 (37.2, 66.3) | 0.0 (NE, NE) |
| 18 months | 40.3 (21.7, 58.2) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 45 (50.6%) | 39 (45.9%) |
| Censored Patients, n (%) | 44 (49.4%) | 46 (54.1%) |
| Median (95% CI), (Months) [a] | 3.22 (1.61, 5.72) | 1.97 (1.68, 2.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0176 | |
| HR (95% CI) [c] | 0.592 (0.379, 0.927) | |
| HR P-Value [c] | 0.0218 | |
| Heterogeneity p-value [d] | 0.1331 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.8 (20.7, 45.3) | 20.4 (9.7, 34.0) |
| 12 months | 17.5 (6.9, 32.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 27 (30.3%) | 13 (15.3%) |
| Censored Patients, n (%) | 62 (69.7%) | 72 (84.7%) |
| Median (95% CI), (Months) [a] | 10.12 (4.96, NE) | NE (5.22, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6940 | |
| HR (95% CI) [c] | 1.144 (0.583, 2.244) | |
| HR P-Value [c] | 0.6949 | |
| Heterogeneity p-value [d] | 0.3678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.9 (44.0, 71.1) | 66.6 (47.0, 80.3) |
| 12 months | 43.1 (26.0, 59.0) | 58.3 (34.7, 75.9) |
| 18 months | 43.1 (26.0, 59.0) | NE (NE, NE) |
| 24 months | 28.7 (7.8, 54.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 34 (38.2%) | 31 (36.5%) |
| Censored Patients, n (%) | 55 (61.8%) | 54 (63.5%) |
| | | |
| Median (95% CI), (Months) [a] | 7.03 (5.59, 9.69) | 2.89 (1.64, 5.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0073 | |
| HR (95% CI) [c] | 0.504 (0.303, 0.841) | |
| HR P-Value [c] | 0.0086 | |
| Heterogeneity p-value [d] | 0.5826 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.0 (37.6, 64.7) | 32.4 (17.9, 47.7) |
| 12 months | 31.1 (17.3, 45.9) | 0.0 (NE, NE) |
| 18 months | 31.1 (17.3, 45.9) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 36 (40.4%) | 37 (43.5%) |
| Censored Patients, n (%) | 53 (59.6%) | 48 (56.5%) |
| Median (95% CI), (Months) [a] | 4.21 (2.79, 7.00) | 2.10 (1.64, 2.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0091 | |
| HR (95% CI) [c] | 0.542 (0.339, 0.867) | |
| HR P-Value [c] | 0.0106 | |
| Heterogeneity p-value [d] | 0.4265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.3 (24.1, 50.5) | 14.2 (5.1, 27.8) |
| 12 months | 30.2 (16.9, 44.6) | NE (NE, NE) |
| 18 months | 30.2 (16.9, 44.6) | NE (NE, NE) |
| 24 months | 30.2 (16.9, 44.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 39 (43.8%) | 34 (40.0%) |
| Censored Patients, n (%) | 50 (56.2%) | 51 (60.0%) |
| Median (95% CI), (Months) [a] | 5.95 (2.86, 9.69) | 3.38 (2.56, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0139 | |
| HR (95% CI) [c] | 0.552 (0.339, 0.897) | |
| HR P-Value [c] | 0.0165 | |
| Heterogeneity p-value [d] | 0.7913 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.7 (36.1, 61.9) | 27.2 (13.7, 42.7) |
| 12 months | 25.3 (11.9, 41.2) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 38 (42.7%) | 32 (37.6%) |
| Censored Patients, n (%) | 51 (57.3%) | 53 (62.4%) |
| Median (95% CI), (Months) [a] | 5.82 (3.48, 7.95) | 3.02 (2.10, 4.34) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0435 | |
| HR (95% CI) [c] | 0.611 (0.374, 0.998) | |
| HR P-Value [c] | 0.0491 | |
| Heterogeneity p-value [d] | 0.4006 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.6 (29.7, 56.7) | 24.6 (11.6, 40.2) |
| 12 months | 28.1 (15.0, 42.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 39 (43.8%) | 35 (41.2%) |
| Censored Patients, n (%) | 50 (56.2%) | 50 (58.8%) |
| Median (95% CI), (Months) [a] | 4.17 (1.68, 5.95) | 2.56 (1.77, 3.38) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0676 | |
| HR (95% CI) [c] | 0.651 (0.406, 1.043) | |
| HR P-Value [c] | 0.0744 | |
| Heterogeneity p-value [d] | 0.9583 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.4 (22.5, 48.4) | 19.8 (8.2, 35.1) |
| 12 months | 26.5 (13.5, 41.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 37 (41.6%) | 24 (28.2%) |
| Censored Patients, n (%) | 52 (58.4%) | 61 (71.8%) |
| Median (95% CI), (Months) [a] | 5.75 (3.09, 10.45) | 4.27 (2.10, 8.02) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5341 | |
| HR (95% CI) [c] | 0.848 (0.500, 1.437) | |
| HR P-Value [c] | 0.5406 | |
| Heterogeneity p-value [d] | 0.2605 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.1 (32.7, 58.5) | 43.1 (25.8, 59.3) |
| 12 months | 31.9 (18.4, 46.2) | NE (NE, NE) |
| 18 months | 31.9 (18.4, 46.2) | NE (NE, NE) |
| 24 months | 31.9 (18.4, 46.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 38 (42.7%) | 23 (27.1%) |
| Censored Patients, n (%) | 51 (57.3%) | 62 (72.9%) |
| Median (95% CI), (Months) [a] | 4.27 (2.83, 5.82) | 6.14 (2.96, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5945 | |
| HR (95% CI) [c] | 1.157 (0.687, 1.946) | |
| HR P-Value [c] | 0.5840 | |
| Heterogeneity p-value [d] | 0.1695 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.5 (23.9, 49.2) | 54.8 (38.1, 68.7) |
| 12 months | 28.1 (14.6, 43.2) | 22.7 (5.3, 47.4) |
| 18 months | 28.1 (14.6, 43.2) | NE (NE, NE) |
| 24 months | 28.1 (14.6, 43.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 46 (43.0%) | 48 (49.0%) |
| Censored Patients, n (%) | 61 (57.0%) | 50 (51.0%) |
| Median (95% CI), (Months) [a] | 5.82 (4.14, 9.76) | 4.27 (2.86, 5.32) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0358 | |
| HR (95% CI) [c] | 0.647 (0.428, 0.980) | |
| HR P-Value [c] | 0.0396 | |
| Heterogeneity p-value [d] | 0.4242 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.3 (36.2, 59.4) | 32.2 (20.3, 44.6) |
| 12 months | 35.1 (22.9, 47.5) | 6.4 (0.5, 24.0) |
| 18 months | 31.6 (19.2, 44.7) | 6.4 (0.5, 24.0) |
| 24 months | 31.6 (19.2, 44.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 48 (44.9%) | 45 (45.9%) |
| Censored Patients, n (%) | 59 (55.1%) | 53 (54.1%) |
| | | |
| Median (95% CI), (Months) [a] | 5.82 (2.99, 8.41) | 3.15 (2.83, 7.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2702 | |
| HR (95% CI) [c] | 0.797 (0.528, 1.204) | |
| HR P-Value [c] | 0.2810 | |
| Heterogeneity p-value [d] | 0.4632 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.8 (36.4, 60.0) | 39.5 (27.8, 51.0) |
| 12 months | 32.6 (20.4, 45.3) | 35.1 (22.3, 48.2) |
| 18 months | 19.7 (8.1, 35.1) | 35.1 (22.3, 48.2) |
| 24 months | 19.7 (8.1, 35.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 41 (38.3%) | 43 (43.9%) |
| Censored Patients, n (%) | 66 (61.7%) | 55 (56.1%) |
| Median (95% CI), (Months) [a] | 8.21 (5.68, 14.65) | 4.17 (2.92, 6.97) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0600 | |
| HR (95% CI) [c] | 0.662 (0.429, 1.022) | |
| HR P-Value [c] | 0.0626 | |
| Heterogeneity p-value [d] | 0.3712 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.1 (47.4, 70.6) | 42.4 (29.7, 54.5) |
| 12 months | 36.8 (23.5, 50.2) | 22.2 (7.8, 41.3) |
| 18 months | 26.3 (12.4, 42.6) | 11.1 (1.1, 34.6) |
| 24 months | 26.3 (12.4, 42.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:11:59:50, yingyuan.lin)

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 31 (29.0%) | 32 (32.7%) |
| Censored Patients, n (%) | 76 (71.0%) | 66 (67.3%) |
| Median (95% CI), (Months) [a] | 8.54 (7.00, NE) | 8.84 (5.55, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2341 | |
| HR (95% CI) [c] | 0.739 (0.447, 1.222) | |
| HR P-Value [c] | 0.2383 | |
| Heterogeneity p-value [d] | 0.5185 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.0 (56.8, 79.9) | 51.9 (37.3, 64.7) |
| 12 months | 42.9 (27.8, 57.2) | 40.4 (22.9, 57.2) |
| 18 months | 42.9 (27.8, 57.2) | NE (NE, NE) |
| 24 months | 32.2 (13.0, 53.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 38 (35.5%) | 41 (41.8%) |
| Censored Patients, n (%) | 69 (64.5%) | 57 (58.2%) |
| Median (95% CI), (Months) [a] | 6.93 (4.44, NE) | 5.68 (4.27, 9.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2322 | |
| HR (95% CI) [c] | 0.761 (0.486, 1.193) | |
| HR P-Value [c] | 0.2344 | |
| Heterogeneity p-value [d] | 0.9183 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.6 (41.7, 65.8) | 46.6 (33.1, 59.1) |
| 12 months | 41.7 (28.0, 54.8) | 22.3 (8.6, 40.0) |
| 18 months | 41.7 (28.0, 54.8) | 11.2 (1.1, 34.2) |
| 24 months | 27.8 (8.1, 52.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 41 (38.3%) | 40 (40.8%) |
| Censored Patients, n (%) | 66 (61.7%) | 58 (59.2%) |
| Median (95% CI), (Months) [a] | 7.16 (4.44, 15.34) | 5.32 (3.06, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2280 | |
| HR (95% CI) [c] | 0.762 (0.487, 1.192) | |
| HR P-Value [c] | 0.2340 | |
| Heterogeneity p-value [d] | 0.5450 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.7 (40.7, 65.1) | 44.1 (31.1, 56.3) |
| 12 months | 37.2 (23.5, 50.9) | 33.4 (17.8, 49.8) |
| 18 months | 33.1 (19.2, 47.6) | 33.4 (17.8, 49.8) |
| 24 months | 16.5 (3.8, 37.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 66 (61.7%) | 58 (59.2%) |
| Censored Patients, n (%) | 41 (38.3%) | 40 (40.8%) |
| Median (95% CI), (Months) [a] | 2.79 (1.58, 2.92) | 1.97 (1.64, 2.96) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7881 | |
| HR (95% CI) [c] | 0.955 (0.668, 1.365) | |
| HR P-Value [c] | 0.7998 | |
| Heterogeneity p-value [d] | 0.1331 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.8 (15.7, 34.9) | 30.2 (19.8, 41.3) |
| 12 months | 14.1 (6.5, 24.6) | 0.0 (NE, NE) |
| 18 months | 14.1 (6.5, 24.6) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 31 (29.0%) | 32 (32.7%) |
| Censored Patients, n (%) | 76 (71.0%) | 66 (67.3%) |
| Median (95% CI), (Months) [a] | 7.66 (5.52, NE) | 7.06 (5.91, 11.50) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3522 | |
| HR (95% CI) [c] | 0.790 (0.477, 1.306) | |
| HR P-Value [c] | 0.3574 | |
| Heterogeneity p-value [d] | 0.3678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.9 (46.3, 71.1) | 62.4 (48.3, 73.7) |
| 12 months | 49.5 (35.1, 62.4) | 22.6 (6.9, 43.6) |
| 18 months | 49.5 (35.1, 62.4) | 15.0 (2.9, 36.2) |
| 24 months | 39.6 (19.7, 59.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 36 (33.6%) | 51 (52.0%) |
| Censored Patients, n (%) | 71 (66.4%) | 47 (48.0%) |
| Median (95% CI), (Months) [a] | 10.09 (6.93, NE) | 2.99 (1.68, 5.95) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0002 | |
| HR (95% CI) [c] | 0.437 (0.281, 0.678) | |
| HR P-Value [c] | 0.0002 | |
| Heterogeneity p-value [d] | 0.5826 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.3 (53.0, 75.2) | 38.0 (26.2, 49.6) |
| 12 months | 46.2 (32.0, 59.2) | 11.3 (1.2, 34.5) |
| 18 months | 38.1 (23.1, 52.9) | 11.3 (1.2, 34.5) |
| 24 months | 38.1 (23.1, 52.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 49 (45.8%) | 54 (55.1%) |
| Censored Patients, n (%) | 58 (54.2%) | 44 (44.9%) |
| Median (95% CI), (Months) [a] | 5.55 (2.83, 6.97) | 2.83 (1.77, 3.32) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0387 | |
| HR (95% CI) [c] | 0.666 (0.450, 0.986) | |
| HR P-Value [c] | 0.0426 | |
| Heterogeneity p-value [d] | 0.4265 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.8 (28.7, 52.4) | 24.6 (14.6, 35.9) |
| 12 months | 26.5 (15.2, 39.4) | 7.4 (0.7, 25.3) |
| 18 months | 22.1 (10.8, 36.0) | 7.4 (0.7, 25.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 50 (46.7%) | 49 (50.0%) |
| Censored Patients, n (%) | 57 (53.3%) | 49 (50.0%) |
| Median (95% CI), (Months) [a] | 6.97 (4.44, 13.77) | 4.27 (2.73, 5.78) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0495 | |
| HR (95% CI) [c] | 0.667 (0.443, 1.004) | |
| HR P-Value [c] | 0.0525 | |
| Heterogeneity p-value [d] | 0.7913 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.6 (40.4, 63.4) | 38.1 (26.3, 49.8) |
| 12 months | 37.7 (25.3, 50.1) | 16.7 (3.9, 37.1) |
| 18 months | 17.4 (7.6, 30.5) | 16.7 (3.9, 37.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 49 (45.8%) | 52 (53.1%) |
| Censored Patients, n (%) | 58 (54.2%) | 46 (46.9%) |
| Median (95% CI), (Months) [a] | 5.82 (2.79, 8.28) | 4.14 (2.73, 5.91) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3860 | |
| HR (95% CI) [c] | 0.844 (0.569, 1.253) | |
| HR P-Value [c] | 0.4006 | |
| Heterogeneity p-value [d] | 0.4006 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.6 (36.4, 59.7) | 37.2 (25.6, 48.8) |
| 12 months | 28.7 (17.2, 41.2) | 14.7 (3.9, 32.2) |
| 18 months | 25.1 (13.7, 38.2) | 14.7 (3.9, 32.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 52 (48.6%) | 54 (55.1%) |
| Censored Patients, n (%) | 55 (51.4%) | 44 (44.9%) |
| Median (95% CI), (Months) [a] | 4.44 (2.83, 11.99) | 3.19 (1.77, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0114 | |
| HR (95% CI) [c] | 0.603 (0.404, 0.902) | |
| HR P-Value [c] | 0.0138 | |
| Heterogeneity p-value [d] | 0.9583 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.0 (35.9, 59.1) | 31.3 (19.9, 43.4) |
| 12 months | 37.7 (25.6, 49.7) | 4.5 (0.4, 17.8) |
| 18 months | 18.8 (8.8, 31.7) | 4.5 (0.4, 17.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 39 (36.4%) | 54 (55.1%) |
| Censored Patients, n (%) | 68 (63.6%) | 44 (44.9%) |
| Median (95% CI), (Months) [a] | 6.97 (4.30, 20.76) | 4.14 (2.10, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0037 | |
| HR (95% CI) [c] | 0.540 (0.353, 0.828) | |
| HR P-Value [c] | 0.0047 | |
| Heterogeneity p-value [d] | 0.2605 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.9 (37.7, 62.6) | 33.3 (22.1, 44.9) |
| 12 months | 46.1 (32.8, 58.4) | 15.8 (6.1, 29.7) |
| 18 months | 35.1 (19.3, 51.4) | 7.9 (0.9, 25.7) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 40 (37.4%) | 47 (48.0%) |
| Censored Patients, n (%) | 67 (62.6%) | 51 (52.0%) |
| Median (95% CI), (Months) [a] | 4.90 (4.21, 12.78) | 4.21 (2.79, 7.00) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0626 | |
| HR (95% CI) [c] | 0.667 (0.433, 1.026) | |
| HR P-Value [c] | 0.0656 | |
| Heterogeneity p-value [d] | 0.1695 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.8 (33.4, 59.1) | 40.0 (28.0, 51.8) |
| 12 months | 39.5 (25.2, 53.4) | 21.2 (8.5, 37.7) |
| 18 months | 23.0 (10.1, 39.0) | 14.1 (3.4, 32.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 31 (37.3%) | 35 (50.7%) |
| Censored Patients, n (%) | 52 (62.7%) | 34 (49.3%) |
| Median (95% CI), (Months) [a] | 8.41 (5.59, NE) | 4.17 (1.97, 5.32) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0006 | |
| HR (95% CI) [c] | 0.423 (0.254, 0.703) | |
| HR P-Value [c] | 0.0009 | |
| Heterogeneity p-value [d] | 0.1339 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.7 (44.7, 70.3) | 28.3 (15.1, 43.1) |
| 12 months | 43.1 (27.8, 57.5) | 0.0 (NE, NE) |
| 18 months | 38.8 (23.2, 54.0) | 0.0 (NE, NE) |
| 24 months | 38.8 (23.2, 54.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 43 (51.8%) | 27 (39.1%) |
| Censored Patients, n (%) | 40 (48.2%) | 42 (60.9%) |
| Median (95% CI), (Months) [a] | 5.72 (2.96, 8.77) | 4.67 (2.96, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8143 | |
| HR (95% CI) [c] | 1.062 (0.654, 1.725) | |
| HR P-Value [c] | 0.8079 | |
| Heterogeneity p-value [d] | 0.3403 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.8 (31.0, 55.9) | 44.2 (29.2, 58.1) |
| 12 months | 27.3 (14.5, 41.7) | 44.2 (29.2, 58.1) |
| 18 months | 17.0 (5.8, 33.4) | NE (NE, NE) |
| 24 months | 17.0 (5.8, 33.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 30 (36.1%) | 30 (43.5%) |
| Censored Patients, n (%) | 53 (63.9%) | 39 (56.5%) |
| Median (95% CI), (Months) [a] | 10.09 (5.68, 16.76) | 4.17 (2.89, 11.50) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0220 | |
| HR (95% CI) [c] | 0.550 (0.327, 0.927) | |
| HR P-Value [c] | 0.0248 | |
| Heterogeneity p-value [d] | 0.1043 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.0 (47.0, 72.4) | 46.0 (30.4, 60.2) |
| 12 months | 44.3 (28.2, 59.2) | 18.1 (4.0, 40.4) |
| 18 months | 29.5 (12.1, 49.4) | NE (NE, NE) |
| 24 months | 29.5 (12.1, 49.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 24 (28.9%) | 18 (26.1%) |
| Censored Patients, n (%) | 59 (71.1%) | 51 (73.9%) |
| Median (95% CI), (Months) [a] | 10.38 (7.10, NE) | 8.48 (5.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2616 | |
| HR (95% CI) [c] | 0.698 (0.371, 1.313) | |
| HR P-Value [c] | 0.2653 | |
| Heterogeneity p-value [d] | 0.5996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.2 (61.8, 84.5) | 55.5 (35.7, 71.5) |
| 12 months | 49.4 (32.0, 64.6) | 29.6 (6.7, 57.8) |
| 18 months | 49.4 (32.0, 64.6) | NE (NE, NE) |
| 24 months | 41.1 (21.3, 60.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 37 (44.6%) | 28 (40.6%) |
| Censored Patients, n (%) | 46 (55.4%) | 41 (59.4%) |
| Median (95% CI), (Months) [a] | 6.28 (4.37, 11.93) | 6.67 (3.15, 9.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2727 | |
| HR (95% CI) [c] | 0.756 (0.456, 1.252) | |
| HR P-Value [c] | 0.2775 | |
| Heterogeneity p-value [d] | 0.8628 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.7 (38.2, 63.6) | 54.3 (38.8, 67.5) |
| 12 months | 33.6 (19.7, 48.1) | 16.9 (3.3, 39.6) |
| 18 months | 33.6 (19.7, 48.1) | 0.0 (NE, NE) |
| 24 months | 25.2 (9.9, 44.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 28 (33.7%) | 25 (36.2%) |
| Censored Patients, n (%) | 55 (66.3%) | 44 (63.8%) |
| Median (95% CI), (Months) [a] | 12.65 (7.06, NE) | 6.14 (2.99, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0245 | |
| HR (95% CI) [c] | 0.525 (0.297, 0.928) | |
| HR P-Value [c] | 0.0267 | |
| Heterogeneity p-value [d] | 0.2506 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.8 (50.7, 75.8) | 50.3 (32.8, 65.5) |
| 12 months | 51.5 (35.2, 65.5) | 18.6 (1.7, 50.0) |
| 18 months | 43.8 (27.2, 59.2) | NE (NE, NE) |
| 24 months | 29.2 (8.0, 54.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 54 (65.1%) | 37 (53.6%) |
| Censored Patients, n (%) | 29 (34.9%) | 32 (46.4%) |
| Median (95% CI), (Months) [a] | 2.99 (2.79, 4.60) | 2.56 (1.68, 6.14) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4152 | |
| HR (95% CI) [c] | 0.838 (0.547, 1.286) | |
| HR P-Value [c] | 0.4191 | |
| Heterogeneity p-value [d] | 0.4438 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.0 (19.1, 41.7) | 38.1 (24.5, 51.6) |
| 12 months | 12.3 (4.4, 24.5) | 0.0 (NE, NE) |
| 18 months | 12.3 (4.4, 24.5) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 25 (30.1%) | 17 (24.6%) |
| Censored Patients, n (%) | 58 (69.9%) | 52 (75.4%) |
| Median (95% CI), (Months) [a] | 20.80 (5.72, NE) | 11.50 (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7396 | |
| HR (95% CI) [c] | 0.901 (0.482, 1.684) | |
| HR P-Value [c] | 0.7431 | |
| Heterogeneity p-value [d] | 0.9363 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.3 (47.9, 73.8) | 70.4 (52.4, 82.6) |
| 12 months | 52.6 (36.8, 66.2) | 39.1 (15.1, 62.7) |
| 18 months | 52.6 (36.8, 66.2) | NE (NE, NE) |
| 24 months | 43.8 (23.8, 62.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 35 (42.2%) | 31 (44.9%) |
| Censored Patients, n (%) | 48 (57.8%) | 38 (55.1%) |
| Median (95% CI), (Months) [a] | 7.79 (5.72, 10.38) | 4.67 (1.64, 9.95) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0034 | |
| HR (95% CI) [c] | 0.476 (0.287, 0.789) | |
| HR P-Value [c] | 0.0040 | |
| Heterogeneity p-value [d] | 0.6356 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.0 (47.1, 72.2) | 42.0 (26.9, 56.3) |
| 12 months | 31.2 (17.8, 45.7) | 0.0 (NE, NE) |
| 18 months | 31.2 (17.8, 45.7) | 0.0 (NE, NE) |
| 24 months | 31.2 (17.8, 45.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 40 (48.2%) | 39 (56.5%) |
| Censored Patients, n (%) | 43 (51.8%) | 30 (43.5%) |
| Median (95% CI), (Months) [a] | 4.30 (2.83, 7.00) | 2.56 (1.64, 2.99) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0150 | |
| HR (95% CI) [c] | 0.578 (0.368, 0.906) | |
| HR P-Value [c] | 0.0170 | |
| Heterogeneity p-value [d] | 0.5876 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.2 (26.4, 51.7) | 21.3 (10.3, 34.9) |
| 12 months | 30.0 (17.3, 43.7) | 0.0 (NE, NE) |
| 18 months | 30.0 (17.3, 43.7) | 0.0 (NE, NE) |
| 24 months | 30.0 (17.3, 43.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 37 (44.6%) | 33 (47.8%) |
| Censored Patients, n (%) | 46 (55.4%) | 36 (52.2%) |
| Median (95% CI), (Months) [a] | 8.41 (5.65, 11.99) | 4.14 (1.84, 5.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0012 | |
| HR (95% CI) [c] | 0.442 (0.267, 0.733) | |
| HR P-Value [c] | 0.0016 | |
| Heterogeneity p-value [d] | 0.1211 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.6 (45.9, 71.0) | 34.4 (20.5, 48.8) |
| 12 months | 34.5 (20.4, 49.0) | 0.0 (NE, NE) |
| 18 months | 21.7 (9.0, 38.0) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 43 (51.8%) | 40 (58.0%) |
| Censored Patients, n (%) | 40 (48.2%) | 29 (42.0%) |
| Median (95% CI), (Months) [a] | 5.82 (2.86, 7.95) | 3.35 (1.97, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0132 | |
| HR (95% CI) [c] | 0.575 (0.368, 0.899) | |
| HR P-Value [c] | 0.0152 | |
| Heterogeneity p-value [d] | 0.2974 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.4 (29.2, 55.1) | 21.4 (9.9, 35.8) |
| 12 months | 26.4 (14.4, 39.9) | 4.3 (0.3, 17.5) |
| 18 months | 18.5 (7.6, 33.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 46 (55.4%) | 33 (47.8%) |
| Censored Patients, n (%) | 37 (44.6%) | 36 (52.2%) |
| Median (95% CI), (Months) [a] | 4.37 (2.07, 8.41) | 2.79 (1.77, 4.44) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1282 | |
| HR (95% CI) [c] | 0.699 (0.437, 1.120) | |
| HR P-Value [c] | 0.1368 | |
| Heterogeneity p-value [d] | 0.6756 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.4 (27.9, 52.5) | 28.1 (14.6, 43.3) |
| 12 months | 29.6 (17.6, 42.7) | 0.0 (NE, NE) |
| 18 months | 21.1 (9.3, 36.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 34 (41.0%) | 29 (42.0%) |
| Censored Patients, n (%) | 49 (59.0%) | 40 (58.0%) |
| Median (95% CI), (Months) [a] | 6.93 (4.34, 20.83) | 4.63 (2.96, 7.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2262 | |
| HR (95% CI) [c] | 0.730 (0.437, 1.219) | |
| HR P-Value [c] | 0.2292 | |
| Heterogeneity p-value [d] | 0.6030 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.8 (36.9, 63.2) | 41.8 (25.8, 57.0) |
| 12 months | 42.3 (28.1, 55.9) | 28.6 (12.1, 47.7) |
| 18 months | 38.1 (23.4, 52.6) | 0.0 (NE, NE) |
| 24 months | 19.0 (1.9, 49.9) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 38 (45.8%) | 27 (39.1%) |
| Censored Patients, n (%) | 45 (54.2%) | 42 (60.9%) |
| Median (95% CI), (Months) [a] | 7.95 (2.96, 12.78) | 6.14 (2.96, 8.05) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3570 | |
| HR (95% CI) [c] | 0.791 (0.475, 1.317) | |
| HR P-Value [c] | 0.3671 | |
| Heterogeneity p-value [d] | 0.9694 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.7 (38.1, 63.7) | 52.2 (36.0, 66.1) |
| 12 months | 39.0 (24.5, 53.2) | 25.5 (8.2, 47.4) |
| 18 months | 24.8 (12.0, 40.0) | NE (NE, NE) |
| 24 months | 12.4 (1.4, 36.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 49 (43.4%) | 49 (43.0%) |
| Censored Patients, n (%) | 64 (56.6%) | 65 (57.0%) |
| Median (95% CI), (Months) [a] | 4.21 (2.89, 6.21) | 2.92 (2.10, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1586 | |
| HR (95% CI) [c] | 0.753 (0.504, 1.126) | |
| HR P-Value [c] | 0.1673 | |
| Heterogeneity p-value [d] | 0.1339 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.4 (26.6, 50.1) | 27.5 (16.3, 39.8) |
| 12 months | 29.0 (17.6, 41.4) | 7.3 (0.6, 25.8) |
| 18 months | 25.4 (14.0, 38.5) | 7.3 (0.6, 25.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 47 (41.6%) | 45 (39.5%) |
| Censored Patients, n (%) | 66 (58.4%) | 69 (60.5%) |
| Median (95% CI), (Months) [a] | 5.59 (4.24, 7.29) | 3.02 (2.10, 4.37) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1884 | |
| HR (95% CI) [c] | 0.761 (0.502, 1.153) | |
| HR P-Value [c] | 0.1975 | |
| Heterogeneity p-value [d] | 0.3403 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.2 (33.5, 57.9) | 35.4 (23.3, 47.7) |
| 12 months | 28.2 (16.0, 41.8) | 21.9 (8.7, 38.9) |
| 18 months | 16.1 (4.4, 34.4) | 21.9 (8.7, 38.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 44 (38.9%) | 35 (30.7%) |
| Censored Patients, n (%) | 69 (61.1%) | 79 (69.3%) |
| Median (95% CI), (Months) [a] | 6.97 (3.19, 9.86) | 4.60 (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9976 | |
| HR (95% CI) [c] | 1.004 (0.640, 1.575) | |
| HR P-Value [c] | 0.9876 | |
| Heterogeneity p-value [d] | 0.1043 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.6 (41.1, 64.5) | 42.4 (28.6, 55.4) |
| 12 months | 35.9 (22.8, 49.2) | 38.5 (24.4, 52.4) |
| 18 months | 19.1 (6.4, 37.0) | 38.5 (24.4, 52.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 34 (30.1%) | 30 (26.3%) |
| Censored Patients, n (%) | 79 (69.9%) | 84 (73.7%) |
| Median (95% CI), (Months) [a] | 7.43 (5.55, 10.45) | 8.87 (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8672 | |
| HR (95% CI) [c] | 0.960 (0.586, 1.573) | |
| HR P-Value [c] | 0.8718 | |
| Heterogeneity p-value [d] | 0.5996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.5 (45.5, 71.0) | 53.5 (39.2, 65.9) |
| 12 months | 32.5 (18.3, 47.6) | 47.6 (30.8, 62.6) |
| 18 months | 32.5 (18.3, 47.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 32 (28.3%) | 34 (29.8%) |
| Censored Patients, n (%) | 81 (71.7%) | 80 (70.2%) |
| Median (95% CI), (Months) [a] | 10.45 (5.55, NE) | 5.68 (4.37, 10.35) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2958 | |
| HR (95% CI) [c] | 0.773 (0.474, 1.262) | |
| HR P-Value [c] | 0.3035 | |
| Heterogeneity p-value [d] | 0.8628 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.0 (43.6, 68.4) | 45.8 (31.4, 59.2) |
| 12 months | 48.0 (33.3, 61.3) | 22.9 (5.2, 48.0) |
| 18 months | 48.0 (33.3, 61.3) | 22.9 (5.2, 48.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 40 (35.4%) | 39 (34.2%) |
| Censored Patients, n (%) | 73 (64.6%) | 75 (65.8%) |
| Median (95% CI), (Months) [a] | 5.59 (3.19, 7.33) | 4.40 (2.86, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4761 | |
| HR (95% CI) [c] | 0.854 (0.547, 1.335) | |
| HR P-Value [c] | 0.4897 | |
| Heterogeneity p-value [d] | 0.2506 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.0 (34.8, 60.0) | 37.9 (24.9, 50.9) |
| 12 months | 36.0 (22.4, 49.7) | 28.5 (11.8, 47.7) |
| 18 months | 27.0 (10.9, 46.1) | 28.5 (11.8, 47.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 57 (50.4%) | 60 (52.6%) |
| Censored Patients, n (%) | 56 (49.6%) | 54 (47.4%) |
| Median (95% CI), (Months) [a] | 2.10 (1.58, 3.02) | 1.77 (1.61, 2.83) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1560 | |
| HR (95% CI) [c] | 0.777 (0.538, 1.123) | |
| HR P-Value [c] | 0.1796 | |
| Heterogeneity p-value [d] | 0.4438 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.3 (17.4, 38.2) | 18.3 (9.7, 29.0) |
| 12 months | 20.5 (11.1, 31.8) | NE (NE, NE) |
| 18 months | 20.5 (11.1, 31.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 33 (29.2%) | 28 (24.6%) |
| Censored Patients, n (%) | 80 (70.8%) | 86 (75.4%) |
| Median (95% CI), (Months) [a] | 6.97 (4.86, NE) | 7.00 (4.37, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7857 | |
| HR (95% CI) [c] | 0.934 (0.560, 1.558) | |
| HR P-Value [c] | 0.7938 | |
| Heterogeneity p-value [d] | 0.9363 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.3 (43.3, 69.0) | 58.2 (43.0, 70.6) |
| 12 months | 42.5 (27.5, 56.7) | 25.9 (6.6, 51.0) |
| 18 months | 42.5 (27.5, 56.7) | 25.9 (6.6, 51.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 35 (31.0%) | 51 (44.7%) |
| Censored Patients, n (%) | 78 (69.0%) | 63 (55.3%) |
| Median (95% CI), (Months) [a] | 8.54 (4.47, NE) | 2.86 (1.68, 4.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0007 | |
| HR (95% CI) [c] | 0.477 (0.308, 0.739) | |
| HR P-Value [c] | 0.0009 | |
| Heterogeneity p-value [d] | 0.6356 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.5 (45.5, 69.3) | 31.9 (20.6, 43.8) |
| 12 months | 48.5 (34.6, 61.0) | 18.2 (5.3, 37.4) |
| 18 months | 36.4 (19.1, 53.9) | 18.2 (5.3, 37.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 45 (39.8%) | 52 (45.6%) |
| Censored Patients, n (%) | 68 (60.2%) | 62 (54.4%) |
| Median (95% CI), (Months) [a] | 4.27 (2.89, 6.97) | 2.83 (1.77, 3.02) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0413 | |
| HR (95% CI) [c] | 0.661 (0.441, 0.990) | |
| HR P-Value [c] | 0.0446 | |
| Heterogeneity p-value [d] | 0.5876 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.2 (26.7, 51.4) | 20.7 (11.4, 31.9) |
| 12 months | 26.9 (15.4, 39.8) | 9.3 (1.2, 28.2) |
| 18 months | 21.5 (9.8, 36.3) | 9.3 (1.2, 28.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 52 (46.0%) | 50 (43.9%) |
| Censored Patients, n (%) | 61 (54.0%) | 64 (56.1%) |
| | | |
| Median (95% CI), (Months) [a] | 4.90 (2.83, 10.45) | 4.27 (2.79, 5.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2832 | |
| HR (95% CI) [c] | 0.810 (0.545, 1.204) | |
| HR P-Value [c] | 0.2975 | |
| Heterogeneity p-value [d] | 0.1211 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.4 (32.4, 55.6) | 35.1 (23.3, 47.1) |
| 12 months | 33.0 (21.1, 45.4) | 11.7 (2.5, 28.6) |
| 18 months | 9.6 (1.9, 24.9) | 11.7 (2.5, 28.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 44 (38.9%) | 44 (38.6%) |
| Censored Patients, n (%) | 69 (61.1%) | 70 (61.4%) |
| Median (95% CI), (Months) [a] | 6.05 (2.53, 8.28) | 3.48 (2.83, 7.00) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6347 | |
| HR (95% CI) [c] | 0.908 (0.595, 1.386) | |
| HR P-Value [c] | 0.6544 | |
| Heterogeneity p-value [d] | 0.2974 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.1 (37.6, 61.4) | 40.8 (28.6, 52.7) |
| 12 months | 30.3 (17.7, 43.8) | 23.3 (6.9, 45.2) |
| 18 months | 30.3 (17.7, 43.8) | 23.3 (6.9, 45.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 45 (39.8%) | 56 (49.1%) |
| Censored Patients, n (%) | 68 (60.2%) | 58 (50.9%) |
| Median (95% CI), (Months) [a] | 4.27 (2.83, 12.48) | 2.83 (1.77, 4.27) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0084 | |
| HR (95% CI) [c] | 0.588 (0.392, 0.881) | |
| HR P-Value [c] | 0.0100 | |
| Heterogeneity p-value [d] | 0.6756 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.0 (32.4, 56.7) | 26.3 (15.8, 38.1) |
| 12 months | 37.3 (24.6, 50.0) | 5.3 (0.6, 19.1) |
| 18 months | 18.5 (7.3, 33.6) | 5.3 (0.6, 19.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 42 (37.2%) | 49 (43.0%) |
| Censored Patients, n (%) | 71 (62.8%) | 65 (57.0%) |
| Median (95% CI), (Months) [a] | 5.72 (3.48, 15.34) | 3.02 (1.77, 4.60) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0165 | |
| HR (95% CI) [c] | 0.604 (0.397, 0.921) | |
| HR P-Value [c] | 0.0191 | |
| Heterogeneity p-value [d] | 0.6030 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.7 (33.9, 58.5) | 32.2 (20.4, 44.6) |
| 12 months | 37.6 (24.9, 50.2) | 13.9 (4.6, 28.4) |
| 18 months | 28.2 (11.8, 47.2) | 13.9 (4.6, 28.4) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 40 (35.4%) | 43 (37.7%) |
| Censored Patients, n (%) | 73 (64.6%) | 71 (62.3%) |
| Median (95% CI), (Months) [a] | 4.21 (2.83, 4.86) | 3.48 (1.77, 7.00) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5513 | |
| HR (95% CI) [c] | 0.882 (0.573, 1.358) | |
| HR P-Value [c] | 0.5693 | |
| Heterogeneity p-value [d] | 0.9694 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 31.7 (19.5, 44.5) | 39.0 (26.2, 51.5) |
| 12 months | 31.7 (19.5, 44.5) | 17.7 (5.6, 35.4) |
| 18 months | 31.7 (19.5, 44.5) | 17.7 (5.6, 35.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 48 (41.0%) | 46 (47.4%) |
| Censored Patients, n (%) | 69 (59.0%) | 51 (52.6%) |
| | | |
| Median (95% CI), (Months) [a] | 5.72 (4.21, 11.53) | 3.15 (2.10, 4.44) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0134 | |
| HR (95% CI) [c] | 0.595 (0.392, 0.905) | |
| HR P-Value [c] | 0.0151 | |
| Heterogeneity p-value [d] | 0.8233 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.7 (35.7, 58.7) | 29.3 (17.6, 42.0) |
| 12 months | 36.3 (24.1, 48.5) | 7.3 (0.6, 26.2) |
| 18 months | 30.6 (18.6, 43.5) | 7.3 (0.6, 26.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 53 (45.3%) | 39 (40.2%) |
| Censored Patients, n (%) | 64 (54.7%) | 58 (59.8%) |
| Median (95% CI), (Months) [a] | 5.82 (4.50, 7.29) | 4.17 (2.92, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3794 | |
| HR (95% CI) [c] | 0.831 (0.545, 1.266) | |
| HR P-Value [c] | 0.3884 | |
| Heterogeneity p-value [d] | 0.8896 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.2 (36.0, 59.3) | 43.4 (30.6, 55.6) |
| 12 months | 26.4 (15.3, 38.9) | 30.1 (12.6, 49.9) |
| 18 months | 15.3 (5.5, 29.6) | 30.1 (12.6, 49.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 44 (37.6%) | 39 (40.2%) |
| Censored Patients, n (%) | 73 (62.4%) | 58 (59.8%) |
| Median (95% CI), (Months) [a] | 6.97 (4.47, 14.65) | 4.17 (2.99, 5.19) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1105 | |
| HR (95% CI) [c] | 0.702 (0.452, 1.091) | |
| HR P-Value [c] | 0.1156 | |
| Heterogeneity p-value [d] | 0.6599 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.8 (43.6, 66.4) | 36.3 (23.2, 49.4) |
| 12 months | 41.2 (27.9, 54.0) | 29.3 (16.4, 43.4) |
| 18 months | 22.8 (9.4, 39.7) | 29.3 (16.4, 43.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 37 (31.6%) | 29 (29.9%) |
| Censored Patients, n (%) | 80 (68.4%) | 68 (70.1%) |
| | | |
| Median (95% CI), (Months) [a] | 8.34 (5.72, 10.38) | 8.84 (5.55, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7516 | |
| HR (95% CI) [c] | 0.924 (0.566, 1.508) | |
| HR P-Value [c] | 0.7517 | |
| Heterogeneity p-value [d] | 0.5111 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.8 (49.7, 73.3) | 55.8 (41.1, 68.2) |
| 12 months | 34.1 (20.6, 48.2) | 43.4 (24.8, 60.6) |
| 18 months | 34.1 (20.6, 48.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 36 (30.8%) | 34 (35.1%) |
| Censored Patients, n (%) | 81 (69.2%) | 63 (64.9%) |
| Median (95% CI), (Months) [a] | 11.93 (5.72, NE) | 5.68 (4.37, 10.35) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1721 | |
| HR (95% CI) [c] | 0.718 (0.444, 1.162) | |
| HR P-Value [c] | 0.1774 | |
| Heterogeneity p-value [d] | 0.5117 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.6 (46.2, 69.2) | 45.6 (31.0, 59.0) |
| 12 months | 48.2 (34.3, 60.7) | 22.8 (5.2, 47.8) |
| 18 months | 48.2 (34.3, 60.7) | 22.8 (5.2, 47.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 46 (39.3%) | 37 (38.1%) |
| Censored Patients, n (%) | 71 (60.7%) | 60 (61.9%) |
| Median (95% CI), (Months) [a] | 7.00 (4.27, 9.99) | 5.55 (3.48, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3808 | |
| HR (95% CI) [c] | 0.827 (0.532, 1.284) | |
| HR P-Value [c] | 0.3967 | |
| Heterogeneity p-value [d] | 0.1724 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.8 (38.7, 61.8) | 42.4 (28.6, 55.6) |
| 12 months | 36.1 (23.5, 48.9) | 22.6 (5.8, 46.1) |
| 18 months | 26.8 (13.4, 42.2) | 22.6 (5.8, 46.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 67 (57.3%) | 54 (55.7%) |
| Censored Patients, n (%) | 50 (42.7%) | 43 (44.3%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.64, 3.06) | 2.07 (1.64, 2.96) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6974 | |
| HR (95% CI) [c] | 0.936 (0.651, 1.345) | |
| HR P-Value [c] | 0.7195 | |
| Heterogeneity p-value [d] | 0.2054 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.1 (14.3, 33.2) | 26.8 (16.6, 38.0) |
| 12 months | 17.2 (9.2, 27.4) | NE (NE, NE) |
| 18 months | 17.2 (9.2, 27.4) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 34 (29.1%) | 27 (27.8%) |
| Censored Patients, n (%) | 83 (70.9%) | 70 (72.2%) |
| Median (95% CI), (Months) [a] | 7.62 (5.13, NE) | 7.06 (5.55, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6930 | |
| HR (95% CI) [c] | 0.903 (0.541, 1.507) | |
| HR P-Value [c] | 0.6972 | |
| Heterogeneity p-value [d] | 0.8485 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.5 (45.2, 69.6) | 63.5 (48.8, 74.9) |
| 12 months | 45.2 (30.9, 58.4) | 30.2 (10.9, 52.4) |
| 18 months | 45.2 (30.9, 58.4) | 30.2 (10.9, 52.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 38 (32.5%) | 42 (43.3%) |
| Censored Patients, n (%) | 79 (67.5%) | 55 (56.7%) |
| Median (95% CI), (Months) [a] | 9.89 (5.72, NE) | 4.60 (2.86, 8.38) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0070 | |
| HR (95% CI) [c] | 0.544 (0.347, 0.853) | |
| HR P-Value [c] | 0.0080 | |
| Heterogeneity p-value [d] | 0.6819 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.7 (46.5, 69.1) | 38.5 (25.5, 51.2) |
| 12 months | 46.7 (33.2, 59.0) | 22.0 (6.2, 43.8) |
| 18 months | 41.5 (26.4, 55.8) | 22.0 (6.2, 43.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Pain - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 56 (47.9%) | 49 (50.5%) |
| Censored Patients, n (%) | 61 (52.1%) | 48 (49.5%) |
| Median (95% CI), (Months) [a] | 4.21 (1.84, 5.72) | 2.89 (2.10, 4.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3007 | |
| HR (95% CI) [c] | 0.820 (0.556, 1.210) | |
| HR P-Value [c] | 0.3174 | |
| Heterogeneity p-value [d] | 0.0216 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.7 (22.7, 44.9) | 22.4 (12.1, 34.6) |
| 12 months | 23.9 (14.1, 35.2) | 9.8 (1.2, 29.6) |
| 18 months | 20.0 (10.0, 32.4) | 9.8 (1.2, 29.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 53 (45.3%) | 46 (47.4%) |
| Censored Patients, n (%) | 64 (54.7%) | 51 (52.6%) |
| Median (95% CI), (Months) [a] | 6.05 (4.86, 11.53) | 4.27 (2.83, 5.78) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0556 | |
| HR (95% CI) [c] | 0.676 (0.450, 1.016) | |
| HR P-Value [c] | 0.0598 | |
| Heterogeneity p-value [d] | 0.9547 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.2 (39.4, 61.7) | 35.0 (22.5, 47.7) |
| 12 months | 37.4 (25.5, 49.3) | 9.2 (0.8, 30.6) |
| 18 months | 13.3 (4.0, 28.4) | 9.2 (0.8, 30.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 51 (43.6%) | 45 (46.4%) |
| Censored Patients, n (%) | 66 (56.4%) | 52 (53.6%) |
| Median (95% CI), (Months) [a] | 5.82 (2.89, 7.03) | 3.48 (2.86, 6.97) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4276 | |
| HR (95% CI) [c] | 0.854 (0.569, 1.281) | |
| HR P-Value [c] | 0.4455 | |
| Heterogeneity p-value [d] | 0.4513 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.4 (31.4, 54.7) | 39.3 (27.2, 51.3) |
| 12 months | 27.2 (16.3, 39.3) | 20.4 (6.0, 40.7) |
| 18 months | 27.2 (16.3, 39.3) | 20.4 (6.0, 40.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 52 (44.4%) | 53 (54.6%) |
| Censored Patients, n (%) | 65 (55.6%) | 44 (45.4%) |
| Median (95% CI), (Months) [a] | 4.21 (2.83, 8.34) | 3.02 (2.07, 4.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0455 | |
| HR (95% CI) [c] | 0.677 (0.456, 1.005) | |
| HR P-Value [c] | 0.0527 | |
| Heterogeneity p-value [d] | 0.5664 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.0 (30.4, 53.2) | 26.3 (15.3, 38.6) |
| 12 months | 35.8 (24.3, 47.4) | 4.1 (0.3, 16.6) |
| 18 months | 23.3 (12.0, 36.8) | 4.1 (0.3, 16.6) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 40 (34.2%) | 51 (52.6%) |
| Censored Patients, n (%) | 77 (65.8%) | 46 (47.4%) |
| Median (95% CI), (Months) [a] | 5.82 (4.30, NE) | 3.02 (2.10, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0055 | |
| HR (95% CI) [c] | 0.560 (0.369, 0.852) | |
| HR P-Value [c] | 0.0067 | |
| Heterogeneity p-value [d] | 0.3288 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.5 (36.8, 60.9) | 34.6 (22.9, 46.6) |
| 12 months | 43.2 (30.5, 55.2) | 13.1 (4.2, 27.2) |
| 18 months | 36.0 (20.1, 52.2) | 13.1 (4.2, 27.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 50 (42.7%) | 41 (42.3%) |
| Censored Patients, n (%) | 67 (57.3%) | 56 (57.7%) |
| | | |
| Median (95% CI), (Months) [a] | 4.21 (2.83, 4.86) | 4.21 (2.79, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7610 | |
| HR (95% CI) [c] | 0.941 (0.620, 1.427) | |
| HR P-Value [c] | 0.7748 | |
| Heterogeneity p-value [d] | 0.4683 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.8 (23.6, 46.2) | 42.0 (29.3, 54.2) |
| 12 months | 28.3 (16.8, 41.1) | 19.1 (6.0, 37.7) |
| 18 months | 28.3 (16.8, 41.1) | 19.1 (6.0, 37.7) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 30 (39.0%) | 38 (44.2%) |
| Censored Patients, n (%) | 47 (61.0%) | 48 (55.8%) |
| | | |
| Median (95% CI), (Months) [a] | 6.21 (2.89, NE) | 2.99 (1.77, 5.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0229 | |
| HR (95% CI) [c] | 0.577 (0.356, 0.935) | |
| HR P-Value [c] | 0.0256 | |
| Heterogeneity p-value [d] | 0.8233 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.3 (35.7, 63.3) | 27.1 (14.8, 41.1) |
| 12 months | 38.4 (23.8, 52.7) | 0.0 (NE, NE) |
| 18 months | 38.4 (23.8, 52.7) | 0.0 (NE, NE) |
| 24 months | 38.4 (23.8, 52.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 35 (45.5%) | 33 (38.4%) |
| Censored Patients, n (%) | 42 (54.5%) | 53 (61.6%) |
| Median (95% CI), (Months) [a] | 2.99 (2.73, 9.76) | 2.96 (1.77, 5.22) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5977 | |
| HR (95% CI) [c] | 0.883 (0.548, 1.424) | |
| HR P-Value [c] | 0.6106 | |
| Heterogeneity p-value [d] | 0.8896 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.5 (28.9, 55.4) | 34.4 (21.1, 48.2) |
| 12 months | 31.5 (16.0, 48.2) | 30.1 (16.7, 44.8) |
| 18 months | 21.0 (5.6, 43.0) | NE (NE, NE) |
| 24 months | 21.0 (5.6, 43.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 29 (37.7%) | 26 (30.2%) |
| Censored Patients, n (%) | 48 (62.3%) | 60 (69.8%) |
| Median (95% CI), (Months) [a] | 8.21 (2.99, 16.76) | 6.67 (2.83, 14.13) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6230 | |
| HR (95% CI) [c] | 0.877 (0.512, 1.501) | |
| HR P-Value [c] | 0.6319 | |
| Heterogeneity p-value [d] | 0.6599 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.2 (44.5, 71.1) | 54.5 (38.7, 67.8) |
| 12 months | 37.1 (20.9, 53.4) | 29.4 (9.6, 52.8) |
| 18 months | 27.8 (10.5, 48.4) | NE (NE, NE) |
| 24 months | 27.8 (10.5, 48.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 20 (26.0%) | 19 (22.1%) |
| Censored Patients, n (%) | 57 (74.0%) | 67 (77.9%) |
| Median (95% CI), (Months) [a] | 18.04 (7.43, NE) | 8.48 (4.63, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3311 | |
| HR (95% CI) [c] | 0.728 (0.382, 1.390) | |
| HR P-Value [c] | 0.3360 | |
| Heterogeneity p-value [d] | 0.5111 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.3 (58.7, 83.5) | 52.9 (34.3, 68.6) |
| 12 months | 52.3 (32.3, 68.9) | 42.4 (19.6, 63.6) |
| 18 months | 52.3 (32.3, 68.9) | NE (NE, NE) |
| 24 months | 41.8 (18.8, 63.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 32 (41.6%) | 28 (32.6%) |
| Censored Patients, n (%) | 45 (58.4%) | 58 (67.4%) |
| | | |
| Median (95% CI), (Months) [a] | 5.95 (2.99, 11.27) | 6.67 (4.17, 9.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6163 | |
| HR (95% CI) [c] | 0.879 (0.526, 1.471) | |
| HR P-Value [c] | 0.6238 | |
| Heterogeneity p-value [d] | 0.5117 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.6 (34.9, 62.7) | 55.0 (39.7, 68.0) |
| 12 months | 28.4 (13.1, 45.8) | 17.6 (3.5, 40.8) |
| 18 months | 28.4 (13.1, 45.8) | 0.0 (NE, NE) |
| 24 months | 28.4 (13.1, 45.8) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 21 (27.3%) | 27 (31.4%) |
| Censored Patients, n (%) | 56 (72.7%) | 59 (68.6%) |
| Median (95% CI), (Months) [a] | 12.65 (5.95, 20.80) | 4.83 (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0244 | |
| HR (95% CI) [c] | 0.510 (0.281, 0.927) | |
| HR P-Value [c] | 0.0271 | |
| Heterogeneity p-value [d] | 0.1724 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.9 (49.7, 78.0) | 45.7 (29.8, 60.2) |
| 12 months | 54.1 (33.6, 70.8) | 36.3 (20.0, 52.9) |
| 18 months | 47.3 (26.0, 66.0) | NE (NE, NE) |
| 24 months | 15.8 (1.1, 47.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 42 (54.5%) | 43 (50.0%) |
| Censored Patients, n (%) | 35 (45.5%) | 43 (50.0%) |
| | | |
| Median (95% CI), (Months) [a] | 2.96 (1.61, 5.95) | 1.77 (1.61, 2.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0310 | |
| HR (95% CI) [c] | 0.627 (0.406, 0.969) | |
| HR P-Value [c] | 0.0357 | |
| Heterogeneity p-value [d] | 0.2054 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.9 (23.3, 48.5) | 26.6 (14.7, 40.0) |
| 12 months | 10.6 (2.1, 27.1) | 0.0 (NE, NE) |
| 18 months | 10.6 (2.1, 27.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 24 (31.2%) | 18 (20.9%) |
| Censored Patients, n (%) | 53 (68.8%) | 68 (79.1%) |
| | | |
| Median (95% CI), (Months) [a] | 10.45 (4.96, NE) | 11.50 (5.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9406 | |
| HR (95% CI) [c] | 0.979 (0.527, 1.820) | |
| HR P-Value [c] | 0.9468 | |
| Heterogeneity p-value [d] | 0.8485 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.4 (43.8, 71.9) | 64.0 (45.4, 77.7) |
| 12 months | 47.7 (30.3, 63.2) | 34.9 (10.9, 60.6) |
| 18 months | 47.7 (30.3, 63.2) | NE (NE, NE) |
| 24 months | 31.8 (8.6, 58.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 32 (41.6%) | 40 (46.5%) |
| Censored Patients, n (%) | 45 (58.4%) | 46 (53.5%) |
| Median (95% CI), (Months) [a] | 7.10 (5.59, 10.09) | 1.68 (1.54, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0004 | |
| HR (95% CI) [c] | 0.425 (0.262, 0.690) | |
| HR P-Value [c] | 0.0005 | |
| Heterogeneity p-value [d] | 0.6819 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.9 (44.7, 72.1) | 32.5 (20.0, 45.7) |
| 12 months | 26.9 (12.5, 43.6) | 0.0 (NE, NE) |
| 18 months | 20.1 (6.8, 38.5) | 0.0 (NE, NE) |
| 24 months | 20.1 (6.8, 38.5) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 28 (36.4%) | 42 (48.8%) |
| Censored Patients, n (%) | 49 (63.6%) | 44 (51.2%) |
| | | |
| Median (95% CI), (Months) [a] | 5.52 (2.89, NE) | 1.77 (1.58, 2.79) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0002 | |
| HR (95% CI) [c] | 0.401 (0.246, 0.654) | |
| HR P-Value [c] | 0.0002 | |
| Heterogeneity p-value [d] | 0.0216 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.3 (31.0, 60.3) | 17.5 (8.2, 29.8) |
| 12 months | 31.5 (14.6, 50.0) | 0.0 (NE, NE) |
| 18 months | 31.5 (14.6, 50.0) | 0.0 (NE, NE) |
| 24 months | 31.5 (14.6, 50.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 36 (46.8%) | 37 (43.0%) |
| Censored Patients, n (%) | 41 (53.2%) | 49 (57.0%) |
| | | |
| Median (95% CI), (Months) [a] | 6.97 (2.79, 10.45) | 3.45 (1.77, 5.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0496 | |
| HR (95% CI) [c] | 0.626 (0.389, 1.007) | |
| HR P-Value [c] | 0.0534 | |
| Heterogeneity p-value [d] | 0.9547 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.4 (36.0, 63.1) | 33.4 (20.1, 47.3) |
| 12 months | 23.5 (10.2, 39.9) | 9.9 (0.9, 32.5) |
| 18 months | 14.1 (4.0, 30.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 35 (45.5%) | 39 (45.3%) |
| Censored Patients, n (%) | 42 (54.5%) | 47 (54.7%) |
| Median (95% CI), (Months) [a] | 7.10 (1.68, 8.44) | 3.45 (1.77, 4.63) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0539 | |
| HR (95% CI) [c] | 0.634 (0.395, 1.019) | |
| HR P-Value [c] | 0.0599 | |
| Heterogeneity p-value [d] | 0.4513 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.9 (36.5, 63.7) | 22.6 (10.6, 37.3) |
| 12 months | 27.6 (13.5, 43.7) | 7.1 (0.7, 24.2) |
| 18 months | 13.8 (3.0, 32.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 38 (49.4%) | 36 (41.9%) |
| Censored Patients, n (%) | 39 (50.6%) | 50 (58.1%) |
| Median (95% CI), (Months) [a] | 4.44 (2.07, 10.45) | 1.97 (1.54, 3.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0214 | |
| HR (95% CI) [c] | 0.571 (0.353, 0.925) | |
| HR P-Value [c] | 0.0228 | |
| Heterogeneity p-value [d] | 0.5664 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.2 (29.3, 56.4) | 28.1 (15.4, 42.3) |
| 12 months | 27.8 (14.1, 43.2) | 0.0 (NE, NE) |
| 18 months | 13.2 (3.2, 30.4) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 34 (44.2%) | 27 (31.4%) |
| Censored Patients, n (%) | 43 (55.8%) | 59 (68.6%) |
| Median (95% CI), (Months) [a] | 5.75 (2.92, 13.90) | 4.53 (2.56, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2969 | |
| HR (95% CI) [c] | 0.756 (0.445, 1.284) | |
| HR P-Value [c] | 0.3007 | |
| Heterogeneity p-value [d] | 0.3288 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.7 (34.3, 61.6) | 37.8 (21.4, 54.1) |
| 12 months | 35.8 (21.2, 50.6) | 32.4 (16.2, 49.8) |
| 18 months | 31.3 (16.8, 46.9) | 0.0 (NE, NE) |
| 24 months | 10.4 (0.9, 34.1) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 27 (35.1%) | 29 (33.7%) |
| Censored Patients, n (%) | 50 (64.9%) | 57 (66.3%) |
| | | |
| Median (95% CI), (Months) [a] | 11.99 (2.96, 12.85) | 5.72 (1.77, 8.05) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1747 | |
| HR (95% CI) [c] | 0.694 (0.407, 1.183) | |
| HR P-Value [c] | 0.1795 | |
| Heterogeneity p-value [d] | 0.4683 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.7 (38.9, 68.0) | 48.5 (32.5, 62.8) |
| 12 months | 44.7 (26.6, 61.2) | 23.7 (7.7, 44.7) |
| 18 months | 19.1 (5.4, 39.3) | NE (NE, NE) |
| 24 months | 19.1 (5.4, 39.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 14 (53.8%) | 12 (63.2%) |
| Censored Patients, n (%) | 12 (46.2%) | 7 (36.8%) |
| | | |
| Median (95% CI), (Months) [a] | 5.59 (1.58, NE) | 4.37 (1.51, 5.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2568 | |
| HR (95% CI) [c] | 0.640 (0.289, 1.420) | |
| HR P-Value [c] | 0.2724 | |
| Heterogeneity p-value [d] | 0.7712 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.3 (22.4, 64.2) | 16.7 (2.7, 41.1) |
| 12 months | 27.7 (8.6, 51.1) | 0.0 (NE, NE) |
| 18 months | 27.7 (8.6, 51.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 11 (42.3%) | 13 (68.4%) |
| Censored Patients, n (%) | 15 (57.7%) | 6 (31.6%) |
| | | |
| Median (95% CI), (Months) [a] | 7.33 (4.90, NE) | 2.92 (1.45, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0144 | |
| HR (95% CI) [c] | 0.377 (0.167, 0.855) | |
| HR P-Value [c] | 0.0195 | |
| Heterogeneity p-value [d] | 0.1250 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.1 (29.9, 74.4) | 24.8 (7.0, 48.1) |
| 12 months | 36.7 (13.2, 60.9) | NE (NE, NE) |
| 18 months | 36.7 (13.2, 60.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 10 (38.5%) | 9 (47.4%) |
| Censored Patients, n (%) | 16 (61.5%) | 10 (52.6%) |
| Median (95% CI), (Months) [a] | 6.97 (4.21, NE) | 4.17 (1.54, 6.97) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0719 | |
| HR (95% CI) [c] | 0.428 (0.169, 1.087) | |
| HR P-Value [c] | 0.0744 | |
| Heterogeneity p-value [d] | 0.3967 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.8 (28.8, 73.5) | 42.4 (15.4, 67.4) |
| 12 months | 44.9 (19.9, 67.2) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 8 (30.8%) | 7 (36.8%) |
| Censored Patients, n (%) | 18 (69.2%) | 12 (63.2%) |
| Median (95% CI), (Months) [a] | 7.33 (4.21, NE) | 8.84 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2301 | |
| HR (95% CI) [c] | 0.541 (0.194, 1.510) | |
| HR P-Value [c] | 0.2405 | |
| Heterogeneity p-value [d] | 0.1702 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.7 (49.1, 88.8) | 55.8 (25.1, 78.2) |
| 12 months | 49.8 (22.5, 72.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 13 (50.0%) | 8 (42.1%) |
| Censored Patients, n (%) | 13 (50.0%) | 11 (57.9%) |
| | | |
| Median (95% CI), (Months) [a] | 5.65 (1.58, NE) | 2.83 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8170 | |
| HR (95% CI) [c] | 0.914 (0.378, 2.210) | |
| HR P-Value [c] | 0.8420 | |
| Heterogeneity p-value [d] | 0.7976 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.4 (13.9, 56.2) | 47.3 (21.1, 69.7) |
| 12 months | 34.4 (13.9, 56.2) | NE (NE, NE) |
| 18 months | 34.4 (13.9, 56.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 11 (42.3%) | 8 (42.1%) |
| Censored Patients, n (%) | 15 (57.7%) | 11 (57.9%) |
| | | |
| Median (95% CI), (Months) [a] | 7.33 (2.53, NE) | 8.84 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5701 | |
| HR (95% CI) [c] | 0.772 (0.309, 1.928) | |
| HR P-Value [c] | 0.5791 | |
| Heterogeneity p-value [d] | 0.6287 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.2 (35.4, 76.8) | 55.5 (28.3, 75.9) |
| 12 months | 42.3 (18.1, 64.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 19 (73.1%) | 13 (68.4%) |
| Censored Patients, n (%) | 7 (26.9%) | 6 (31.6%) |
| Median (95% CI), (Months) [a] | 1.58 (1.51, 4.90) | 1.54 (1.45, 1.97) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6083 | |
| HR (95% CI) [c] | 0.828 (0.408, 1.681) | |
| HR P-Value [c] | 0.6023 | |
| Heterogeneity p-value [d] | 0.7059 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 15.9 (4.1, 34.7) | 26.7 (8.3, 49.6) |
| 12 months | 10.6 (1.8, 28.3) | 0.0 (NE, NE) |
| 18 months | 10.6 (1.8, 28.3) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 8 (42.1%) |
| Censored Patients, n (%) | 21 (80.8%) | 11 (57.9%) |
| Median (95% CI), (Months) [a] | NE (5.55, NE) | 6.14 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0600 | |
| HR (95% CI) [c] | 0.356 (0.116, 1.095) | |
| HR P-Value [c] | 0.0717 | |
| Heterogeneity p-value [d] | 0.1886 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.3 (37.7, 86.2) | 55.2 (27.7, 76.0) |
| 12 months | 68.3 (37.7, 86.2) | NE (NE, NE) |
| 18 months | 68.3 (37.7, 86.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 7 (26.9%) | 12 (63.2%) |
| Censored Patients, n (%) | 19 (73.1%) | 7 (36.8%) |
| Median (95% CI), (Months) [a] | NE (2.99, NE) | 1.58 (1.48, 5.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0022 | |
| HR (95% CI) [c] | 0.239 (0.089, 0.643) | |
| HR P-Value [c] | 0.0046 | |
| Heterogeneity p-value [d] | 0.1122 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.7 (48.8, 86.8) | 19.6 (3.6, 44.9) |
| 12 months | 62.3 (33.4, 81.6) | NE (NE, NE) |
| 18 months | 62.3 (33.4, 81.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 12 (46.2%) | 11 (57.9%) |
| Censored Patients, n (%) | 14 (53.8%) | 8 (42.1%) |
| Median (95% CI), (Months) [a] | 5.72 (1.58, NE) | 2.83 (1.51, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1159 | |
| HR (95% CI) [c] | 0.519 (0.224, 1.198) | |
| HR P-Value [c] | 0.1244 | |
| Heterogeneity p-value [d] | 0.8147 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.9 (23.2, 66.1) | 15.3 (1.2, 44.9) |
| 12 months | 39.4 (17.7, 60.5) | NE (NE, NE) |
| 18 months | 39.4 (17.7, 60.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 14 (53.8%) | 11 (57.9%) |
| Censored Patients, n (%) | 12 (46.2%) | 8 (42.1%) |
| | | |
| Median (95% CI), (Months) [a] | 4.21 (1.58, NE) | 4.67 (1.48, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4994 | |
| HR (95% CI) [c] | 0.774 (0.348, 1.721) | |
| HR P-Value [c] | 0.5297 | |
| Heterogeneity p-value [d] | 0.6239 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.7 (19.5, 62.6) | 37.7 (13.1, 62.7) |
| 12 months | 27.8 (9.4, 50.0) | 0.0 (NE, NE) |
| 18 months | 27.8 (9.4, 50.0) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 16 (61.5%) | 12 (63.2%) |
| Censored Patients, n (%) | 10 (38.5%) | 7 (36.8%) |
| Median (95% CI), (Months) [a] | 5.59 (1.58, 7.95) | 2.79 (1.51, 5.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2382 | |
| HR (95% CI) [c] | 0.638 (0.297, 1.372) | |
| HR P-Value [c] | 0.2504 | |
| Heterogeneity p-value [d] | 0.9025 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.7 (24.0, 65.1) | 22.6 (4.6, 48.8) |
| 12 months | 22.9 (7.4, 43.3) | NE (NE, NE) |
| 18 months | 22.9 (7.4, 43.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 15 (57.7%) | 12 (63.2%) |
| Censored Patients, n (%) | 11 (42.3%) | 7 (36.8%) |
| Median (95% CI), (Months) [a] | 2.07 (1.58, 12.48) | 2.83 (1.48, 4.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2094 | |
| HR (95% CI) [c] | 0.618 (0.281, 1.361) | |
| HR P-Value [c] | 0.2326 | |
| Heterogeneity p-value [d] | 0.9181 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.3 (18.2, 58.2) | 10.9 (0.7, 37.5) |
| 12 months | 31.9 (13.1, 52.6) | 0.0 (NE, NE) |
| 18 months | 25.5 (8.7, 46.5) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 14 (53.8%) | 10 (52.6%) |
| Censored Patients, n (%) | 12 (46.2%) | 9 (47.4%) |
| Median (95% CI), (Months) [a] | 4.21 (1.51, NE) | 5.16 (1.58, 6.97) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8331 | |
| HR (95% CI) [c] | 1.111 (0.493, 2.507) | |
| HR P-Value [c] | 0.7991 | |
| Heterogeneity p-value [d] | 0.0951 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.5 (13.0, 53.7) | 32.6 (9.3, 58.9) |
| 12 months | 32.5 (13.0, 53.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 12 (46.2%) | 8 (42.1%) |
| Censored Patients, n (%) | 14 (53.8%) | 11 (57.9%) |
| Median (95% CI), (Months) [a] | 4.21 (1.58, NE) | 4.21 (1.45, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6862 | |
| HR (95% CI) [c] | 0.837 (0.340, 2.059) | |
| HR P-Value [c] | 0.6987 | |
| Heterogeneity p-value [d] | 0.8903 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.0 (16.9, 60.6) | 43.3 (15.0, 69.0) |
| 12 months | 29.2 (9.1, 53.2) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 51 (42.9%) | 51 (45.9%) |
| Censored Patients, n (%) | 68 (57.1%) | 60 (54.1%) |
| | | |
| Median (95% CI), (Months) [a] | 5.62 (4.14, 10.38) | 2.96 (1.91, 4.60) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0121 | |
| HR (95% CI) [c] | 0.605 (0.406, 0.902) | |
| HR P-Value [c] | 0.0136 | |
| Heterogeneity p-value [d] | 0.7712 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.6 (35.2, 57.3) | 27.6 (16.7, 39.5) |
| 12 months | 35.5 (24.1, 47.0) | 7.4 (0.7, 25.8) |
| 18 months | 30.2 (18.9, 42.3) | 7.4 (0.7, 25.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 58 (48.7%) | 43 (38.7%) |
| Censored Patients, n (%) | 61 (51.3%) | 68 (61.3%) |
| | | |
| Median (95% CI), (Months) [a] | 5.59 (2.96, 8.41) | 4.17 (2.86, 7.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7427 | |
| HR (95% CI) [c] | 0.937 (0.626, 1.402) | |
| HR P-Value [c] | 0.7516 | |
| Heterogeneity p-value [d] | 0.1250 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.9 (34.5, 56.5) | 40.3 (28.1, 52.2) |
| 12 months | 27.2 (16.2, 39.5) | 24.2 (7.1, 46.6) |
| 18 months | 10.4 (2.4, 25.4) | 24.2 (7.1, 46.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 47 (39.5%) | 36 (32.4%) |
| Censored Patients, n (%) | 72 (60.5%) | 75 (67.6%) |
| Median (95% CI), (Months) [a] | 8.21 (2.99, 12.06) | 4.83 (3.02, 14.13) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9976 | |
| HR (95% CI) [c] | 1.003 (0.647, 1.556) | |
| HR P-Value [c] | 0.9881 | |
| Heterogeneity p-value [d] | 0.3967 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.5 (45.0, 66.5) | 49.4 (36.3, 61.3) |
| 12 months | 38.5 (26.4, 50.6) | 37.2 (18.7, 55.8) |
| 18 months | 30.3 (17.0, 44.7) | 24.8 (6.3, 49.5) |
| 24 months | 30.3 (17.0, 44.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 40 (33.6%) | 27 (24.3%) |
| Censored Patients, n (%) | 79 (66.4%) | 84 (75.7%) |
| | | |
| Median (95% CI), (Months) [a] | 8.41 (6.97, 10.38) | 8.87 (5.72, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7361 | |
| HR (95% CI) [c] | 1.089 (0.664, 1.784) | |
| HR P-Value [c] | 0.7361 | |
| Heterogeneity p-value [d] | 0.1702 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.1 (51.7, 74.1) | 57.5 (42.3, 70.0) |
| 12 months | 33.3 (20.1, 47.1) | 45.7 (27.0, 62.7) |
| 18 months | 33.3 (20.1, 47.1) | NE (NE, NE) |
| 24 months | 33.3 (20.1, 47.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 40 (33.6%) | 37 (33.3%) |
| Censored Patients, n (%) | 79 (66.4%) | 74 (66.7%) |
| | | |
| Median (95% CI), (Months) [a] | 10.45 (5.72, NE) | 5.85 (4.37, 9.92) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1222 | |
| HR (95% CI) [c] | 0.698 (0.440, 1.107) | |
| HR P-Value [c] | 0.1265 | |
| Heterogeneity p-value [d] | 0.7976 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.3 (47.2, 69.5) | 48.7 (34.6, 61.3) |
| 12 months | 42.8 (29.3, 55.6) | 20.3 (6.2, 40.1) |
| 18 months | 42.8 (29.3, 55.6) | 20.3 (6.2, 40.1) |
| 24 months | 34.2 (17.0, 52.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 45 (37.8%) | 43 (38.7%) |
| Censored Patients, n (%) | 74 (62.2%) | 68 (61.3%) |
| Median (95% CI), (Months) [a] | 7.16 (4.50, 15.34) | 4.40 (2.96, 5.78) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0487 | |
| HR (95% CI) [c] | 0.651 (0.423, 1.003) | |
| HR P-Value [c] | 0.0516 | |
| Heterogeneity p-value [d] | 0.6287 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.1 (40.0, 62.8) | 36.4 (23.9, 49.0) |
| 12 months | 40.9 (28.3, 53.1) | 22.7 (6.8, 44.1) |
| 18 months | 33.6 (20.2, 47.5) | 22.7 (6.8, 44.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 69 (58.0%) | 57 (51.4%) |
| Censored Patients, n (%) | 50 (42.0%) | 54 (48.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.92 (1.64, 4.27) | 1.84 (1.64, 2.89) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1669 | |
| HR (95% CI) [c] | 0.782 (0.544, 1.123) | |
| HR P-Value [c] | 0.1831 | |
| Heterogeneity p-value [d] | 0.7059 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.7 (21.1, 40.7) | 25.8 (15.7, 37.1) |
| 12 months | 16.0 (8.1, 26.2) | 0.0 (NE, NE) |
| 18 months | 16.0 (8.1, 26.2) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 34 (28.6%) | 22 (19.8%) |
| Censored Patients, n (%) | 85 (71.4%) | 89 (80.2%) |
| Median (95% CI), (Months) [a] | 10.45 (6.87, NE) | 10.35 (6.70, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7348 | |
| HR (95% CI) [c] | 1.103 (0.639, 1.904) | |
| HR P-Value [c] | 0.7236 | |
| Heterogeneity p-value [d] | 0.1886 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.0 (51.4, 74.1) | 68.2 (52.6, 79.6) |
| 12 months | 48.0 (34.1, 60.6) | 33.5 (11.3, 57.8) |
| 18 months | 48.0 (34.1, 60.6) | 33.5 (11.3, 57.8) |
| 24 months | 41.1 (24.3, 57.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 46 (38.7%) | 54 (48.6%) |
| Censored Patients, n (%) | 73 (61.3%) | 57 (51.4%) |
| Median (95% CI), (Months) [a] | 8.54 (5.68, 14.03) | 2.56 (1.64, 4.60) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0003 | |
| HR (95% CI) [c] | 0.477 (0.318, 0.715) | |
| HR P-Value [c] | 0.0003 | |
| Heterogeneity p-value [d] | 0.1122 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.7 (47.0, 68.6) | 34.7 (23.7, 46.0) |
| 12 months | 38.7 (26.7, 50.6) | 14.0 (3.4, 32.1) |
| 18 months | 35.7 (23.5, 48.1) | 14.0 (3.4, 32.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 51 (42.9%) | 52 (46.8%) |
| Censored Patients, n (%) | 68 (57.1%) | 59 (53.2%) |
| | | |
| Median (95% CI), (Months) [a] | 5.52 (2.92, 7.00) | 2.83 (1.71, 3.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0144 | |
| HR (95% CI) [c] | 0.617 (0.416, 0.915) | |
| HR P-Value [c] | 0.0163 | |
| Heterogeneity p-value [d] | 0.8147 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.2 (29.6, 52.4) | 23.5 (13.5, 35.2) |
| 12 months | 28.7 (17.6, 40.8) | 8.8 (1.1, 27.3) |
| 18 months | 25.1 (14.0, 37.9) | 8.8 (1.1, 27.3) |
| 24 months | 25.1 (14.0, 37.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 57 (47.9%) | 48 (43.2%) |
| Censored Patients, n (%) | 62 (52.1%) | 63 (56.8%) |
| | | |
| Median (95% CI), (Months) [a] | 7.06 (5.55, 11.53) | 4.37 (2.96, 5.78) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0580 | |
| HR (95% CI) [c] | 0.682 (0.456, 1.019) | |
| HR P-Value [c] | 0.0619 | |
| Heterogeneity p-value [d] | 0.6239 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.7 (42.4, 63.7) | 36.6 (24.7, 48.5) |
| 12 months | 34.8 (23.3, 46.7) | 16.3 (3.9, 36.3) |
| 18 months | 13.4 (4.8, 26.4) | 16.3 (3.9, 36.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 50 (42.0%) | 46 (41.4%) |
| Censored Patients, n (%) | 69 (58.0%) | 65 (58.6%) |
| Median (95% CI), (Months) [a] | 6.05 (5.62, 8.44) | 3.78 (2.86, 5.91) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3289 | |
| HR (95% CI) [c] | 0.820 (0.545, 1.235) | |
| HR P-Value [c] | 0.3424 | |
| Heterogeneity p-value [d] | 0.9025 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.3 (38.4, 61.1) | 37.4 (25.5, 49.3) |
| 12 months | 30.3 (18.8, 42.6) | 23.0 (6.9, 44.6) |
| 18 months | 26.5 (14.9, 39.7) | 23.0 (6.9, 44.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 56 (47.1%) | 51 (45.9%) |
| Censored Patients, n (%) | 63 (52.9%) | 60 (54.1%) |
| Median (95% CI), (Months) [a] | 4.27 (2.83, 9.69) | 2.96 (1.71, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0453 | |
| HR (95% CI) [c] | 0.671 (0.452, 0.998) | |
| HR P-Value [c] | 0.0488 | |
| Heterogeneity p-value [d] | 0.9181 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.8 (32.4, 54.7) | 32.8 (21.2, 45.0) |
| 12 months | 34.2 (23.0, 45.7) | 9.4 (2.0, 23.9) |
| 18 months | 17.2 (7.3, 30.5) | 9.4 (2.0, 23.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 40 (33.6%) | 48 (43.2%) |
| Censored Patients, n (%) | 79 (66.4%) | 63 (56.8%) |
| Median (95% CI), (Months) [a] | 8.28 (5.72, NE) | 3.19 (1.84, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0005 | |
| HR (95% CI) [c] | 0.468 (0.302, 0.723) | |
| HR P-Value [c] | 0.0006 | |
| Heterogeneity p-value [d] | 0.0951 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.2 (44.9, 67.7) | 33.5 (21.5, 45.9) |
| 12 months | 46.4 (33.9, 58.0) | 13.4 (3.3, 30.7) |
| 18 months | 41.2 (26.9, 55.1) | 13.4 (3.3, 30.7) |
| 24 months | 20.6 (2.0, 52.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 49 (41.2%) | 47 (42.3%) |
| Censored Patients, n (%) | 70 (58.8%) | 64 (57.7%) |
| Median (95% CI), (Months) [a] | 4.40 (3.19, 8.61) | 2.96 (1.71, 6.14) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1862 | |
| HR (95% CI) [c] | 0.762 (0.508, 1.144) | |
| HR P-Value [c] | 0.1898 | |
| Heterogeneity p-value [d] | 0.8903 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.4 (28.7, 51.8) | 38.8 (26.9, 50.5) |
| 12 months | 31.9 (19.8, 44.7) | 20.0 (8.2, 35.6) |
| 18 months | 25.5 (13.8, 39.0) | 20.0 (8.2, 35.6) |
| 24 months | 17.0 (4.9, 35.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 5 (23.8%) |
| Censored Patients, n (%) | 14 (70.0%) | 16 (76.2%) |
| Median (95% CI), (Months) [a] | 4.37 (1.45, NE) | 3.15 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7138 | |
| HR (95% CI) [c] | 0.787 (0.231, 2.675) | |
| HR P-Value [c] | 0.7007 | |
| Heterogeneity p-value [d] | 0.7712 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.9 (16.7, 72.6) | 20.0 (1.0, 57.3) |
| 12 months | 46.9 (16.7, 72.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 9 (45.0%) | 6 (28.6%) |
| Censored Patients, n (%) | 11 (55.0%) | 15 (71.4%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 7.29) | 2.56 (1.51, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5577 | |
| HR (95% CI) [c] | 0.712 (0.235, 2.151) | |
| HR P-Value [c] | 0.5466 | |
| Heterogeneity p-value [d] | 0.1250 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.9 (9.1, 59.7) | 0.0 (NE, NE) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 8 (40.0%) | 6 (28.6%) |
| Censored Patients, n (%) | 12 (60.0%) | 15 (71.4%) |
| Median (95% CI), (Months) [a] | 14.65 (2.83, 16.76) | 2.56 (1.51, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0213 | |
| HR (95% CI) [c] | 0.206 (0.048, 0.883) | |
| HR P-Value [c] | 0.0334 | |
| Heterogeneity p-value [d] | 0.3967 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.5 (34.1, 86.6) | 0.0 (NE, NE) |
| 12 months | 50.6 (15.3, 78.1) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (25.0%) | 7 (33.3%) |
| Censored Patients, n (%) | 15 (75.0%) | 14 (66.7%) |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | 2.83 (1.64, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0551 | |
| HR (95% CI) [c] | 0.328 (0.099, 1.082) | |
| HR P-Value [c] | 0.0672 | |
| Heterogeneity p-value [d] | 0.1702 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.8 (32.4, 86.6) | 13.5 (0.7, 44.4) |
| 12 months | 50.1 (14.8, 77.8) | NE (NE, NE) |
| 18 months | 50.1 (14.8, 77.8) | NE (NE, NE) |
| 24 months | 50.1 (14.8, 77.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 14 (70.0%) | 18 (85.7%) |
| | | |
| Median (95% CI), (Months) [a] | 7.23 (1.58, NE) | NE (1.81, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5183 | |
| HR (95% CI) [c] | 1.576 (0.392, 6.337) | |
| HR P-Value [c] | 0.5219 | |
| Heterogeneity p-value [d] | 0.7976 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.5 (22.8, 79.1) | 55.6 (14.1, 83.8) |
| 12 months | 27.8 (1.7, 66.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 7 (35.0%) | 4 (19.0%) |
| Censored Patients, n (%) | 13 (65.0%) | 17 (81.0%) |
| | | |
| Median (95% CI), (Months) [a] | 4.27 (1.58, 12.65) | 3.48 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9151 | |
| HR (95% CI) [c] | 1.054 (0.294, 3.778) | |
| HR P-Value [c] | 0.9355 | |
| Heterogeneity p-value [d] | 0.6287 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.8 (17.1, 76.0) | 42.3 (7.3, 75.4) |
| 12 months | 24.9 (1.5, 63.0) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 10 (50.0%) | 8 (38.1%) |
| Censored Patients, n (%) | 10 (50.0%) | 13 (61.9%) |
| Median (95% CI), (Months) [a] | 1.87 (1.48, 4.86) | 2.56 (1.64, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6381 | |
| HR (95% CI) [c] | 1.243 (0.487, 3.172) | |
| HR P-Value [c] | 0.6497 | |
| Heterogeneity p-value [d] | 0.7059 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 12.0 (0.7, 40.8) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 9 (45.0%) | 4 (19.0%) |
| Censored Patients, n (%) | 11 (55.0%) | 17 (81.0%) |
| | | |
| Median (95% CI), (Months) [a] | 4.37 (1.51, 5.13) | 7.06 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3585 | |
| HR (95% CI) [c] | 1.758 (0.529, 5.845) | |
| HR P-Value [c] | 0.3572 | |
| Heterogeneity p-value [d] | 0.1886 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 13.8 (0.8, 44.0) | 54.7 (13.7, 83.2) |
| 12 months | 13.8 (0.8, 44.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 14 (70.0%) | 18 (85.7%) |
| | | |
| Median (95% CI), (Months) [a] | 10.09 (4.27, 17.71) | 4.93 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9968 | |
| HR (95% CI) [c] | 1.003 (0.219, 4.592) | |
| HR P-Value [c] | 0.9968 | |
| Heterogeneity p-value [d] | 0.1122 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.3 (18.8, 82.1) | 43.8 (6.0, 78.5) |
| 12 months | 28.1 (1.5, 68.1) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 8 (40.0%) | 8 (38.1%) |
| Censored Patients, n (%) | 12 (60.0%) | 13 (61.9%) |
| | | |
| Median (95% CI), (Months) [a] | 3.48 (1.45, NE) | 2.10 (1.64, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3742 | |
| HR (95% CI) [c] | 0.617 (0.219, 1.741) | |
| HR P-Value [c] | 0.3618 | |
| Heterogeneity p-value [d] | 0.8147 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.7 (14.1, 67.6) | 11.1 (0.6, 38.8) |
| 12 months | 20.8 (1.5, 55.9) | NE (NE, NE) |
| 18 months | 20.8 (1.5, 55.9) | NE (NE, NE) |
| 24 months | 20.8 (1.5, 55.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 8 (40.0%) | 5 (23.8%) |
| Censored Patients, n (%) | 12 (60.0%) | 16 (76.2%) |
| | | |
| Median (95% CI), (Months) [a] | 4.86 (1.48, NE) | 2.56 (0.20, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8023 | |
| HR (95% CI) [c] | 0.868 (0.269, 2.803) | |
| HR P-Value [c] | 0.8125 | |
| Heterogeneity p-value [d] | 0.6239 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.9 (7.5, 66.7) | 22.5 (1.1, 61.3) |
| 12 months | 35.9 (7.5, 66.7) | NE (NE, NE) |
| 18 months | 18.0 (1.0, 52.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 10 (50.0%) | 7 (33.3%) |
| Censored Patients, n (%) | 10 (50.0%) | 14 (66.7%) |
| Median (95% CI), (Months) [a] | 2.89 (1.45, 16.76) | 2.56 (0.20, 7.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7057 | |
| HR (95% CI) [c] | 0.823 (0.301, 2.253) | |
| HR P-Value [c] | 0.7044 | |
| Heterogeneity p-value [d] | 0.9025 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.0 (4.8, 53.1) | 19.0 (1.0, 55.1) |
| 12 months | 25.0 (4.8, 53.1) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 7 (35.0%) | 6 (28.6%) |
| Censored Patients, n (%) | 13 (65.0%) | 15 (71.4%) |
| | | |
| Median (95% CI), (Months) [a] | 4.37 (1.48, NE) | 2.56 (0.20, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5440 | |
| HR (95% CI) [c] | 0.708 (0.231, 2.171) | |
| HR P-Value [c] | 0.5457 | |
| Heterogeneity p-value [d] | 0.9181 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.5 (15.6, 68.9) | 18.8 (1.0, 54.5) |
| 12 months | 43.5 (15.6, 68.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 9 (45.0%) | 5 (23.8%) |
| Censored Patients, n (%) | 11 (55.0%) | 16 (76.2%) |
| | | |
| Median (95% CI), (Months) [a] | 3.48 (1.51, 11.27) | 7.06 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5234 | |
| HR (95% CI) [c] | 1.422 (0.459, 4.406) | |
| HR P-Value [c] | 0.5420 | |
| Heterogeneity p-value [d] | 0.0951 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.0 (1.5, 56.1) | 51.4 (16.0, 78.6) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 7 (35.0%) | 4 (19.0%) |
| Censored Patients, n (%) | 13 (65.0%) | 17 (81.0%) |
| Median (95% CI), (Months) [a] | 2.89 (1.58, NE) | 3.48 (0.20, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9213 | |
| HR (95% CI) [c] | 1.064 (0.308, 3.673) | |
| HR P-Value [c] | 0.9214 | |
| Heterogeneity p-value [d] | 0.8903 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.2 (1.5, 60.0) | NE (NE, NE) |
| 12 months | 23.2 (1.5, 60.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 9 (29.0%) | 16 (50.0%) |
| Censored Patients, n (%) | 22 (71.0%) | 16 (50.0%) |
| Median (95% CI), (Months) [a] | 6.93 (2.79, NE) | 2.79 (1.51, 9.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0477 | |
| HR (95% CI) [c] | 0.447 (0.196, 1.017) | |
| HR P-Value [c] | 0.0550 | |
| Heterogeneity p-value [d] | 0.7712 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.7 (30.4, 77.6) | 41.6 (21.8, 60.4) |
| 12 months | 48.1 (20.9, 71.0) | 0.0 (NE, NE) |
| 18 months | 48.1 (20.9, 71.0) | 0.0 (NE, NE) |
| 24 months | 48.1 (20.9, 71.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 12 (38.7%) | 10 (31.3%) |
| Censored Patients, n (%) | 19 (61.3%) | 22 (68.8%) |
| Median (95% CI), (Months) [a] | 5.72 (2.79, NE) | NE (2.33, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6751 | |
| HR (95% CI) [c] | 1.202 (0.519, 2.785) | |
| HR P-Value [c] | 0.6680 | |
| Heterogeneity p-value [d] | 0.1250 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.2 (13.6, 59.7) | 56.1 (33.4, 73.7) |
| 12 months | 36.2 (13.6, 59.7) | 56.1 (33.4, 73.7) |
| 18 months | 36.2 (13.6, 59.7) | NE (NE, NE) |
| 24 months | 36.2 (13.6, 59.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 9 (29.0%) | 14 (43.8%) |
| Censored Patients, n (%) | 22 (71.0%) | 18 (56.3%) |
| Median (95% CI), (Months) [a] | 6.18 (2.10, NE) | 4.17 (2.56, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4056 | |
| HR (95% CI) [c] | 0.700 (0.302, 1.625) | |
| HR P-Value [c] | 0.4066 | |
| Heterogeneity p-value [d] | 0.3967 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.0 (24.9, 74.8) | 39.3 (16.3, 61.9) |
| 12 months | 42.4 (15.6, 67.3) | 0.0 (NE, NE) |
| 18 months | 42.4 (15.6, 67.3) | 0.0 (NE, NE) |
| 24 months | 42.4 (15.6, 67.3) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 7 (21.9%) |
| Censored Patients, n (%) | 26 (83.9%) | 25 (78.1%) |
| | | |
| Median (95% CI), (Months) [a] | 18.04 (5.72, NE) | NE (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3120 | |
| HR (95% CI) [c] | 0.534 (0.155, 1.837) | |
| HR P-Value [c] | 0.3197 | |
| Heterogeneity p-value [d] | 0.1702 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.0 (41.0, 90.3) | 62.9 (36.8, 80.6) |
| 12 months | 74.0 (41.0, 90.3) | 62.9 (36.8, 80.6) |
| 18 months | 74.0 (41.0, 90.3) | NE (NE, NE) |
| 24 months | 37.0 (1.6, 78.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 10 (32.3%) | 14 (43.8%) |
| Censored Patients, n (%) | 21 (67.7%) | 18 (56.3%) |
| | | |
| Median (95% CI), (Months) [a] | 6.93 (2.79, NE) | 6.67 (2.56, 12.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4366 | |
| HR (95% CI) [c] | 0.725 (0.321, 1.641) | |
| HR P-Value [c] | 0.4408 | |
| Heterogeneity p-value [d] | 0.7976 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.4 (33.2, 75.6) | 51.5 (29.2, 69.9) |
| 12 months | 47.8 (22.3, 69.5) | 19.3 (1.5, 52.7) |
| 18 months | 47.8 (22.3, 69.5) | 0.0 (NE, NE) |
| 24 months | 47.8 (22.3, 69.5) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 9 (28.1%) |
| Censored Patients, n (%) | 26 (83.9%) | 23 (71.9%) |
| Median (95% CI), (Months) [a] | 20.80 (20.80, NE) | 7.10 (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1387 | |
| HR (95% CI) [c] | 0.425 (0.131, 1.381) | |
| HR P-Value [c] | 0.1546 | |
| Heterogeneity p-value [d] | 0.6287 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.4 (53.2, 92.0) | 57.0 (28.0, 78.0) |
| 12 months | 79.4 (53.2, 92.0) | 38.0 (8.1, 68.9) |
| 18 months | 79.4 (53.2, 92.0) | NE (NE, NE) |
| 24 months | 39.7 (1.5, 81.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 13 (41.9%) | 19 (59.4%) |
| Censored Patients, n (%) | 18 (58.1%) | 13 (40.6%) |
| | | |
| Median (95% CI), (Months) [a] | 2.83 (1.64, NE) | 2.56 (1.54, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1704 | |
| HR (95% CI) [c] | 0.612 (0.302, 1.242) | |
| HR P-Value [c] | 0.1741 | |
| Heterogeneity p-value [d] | 0.7059 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.6 (24.3, 63.2) | 34.2 (16.3, 53.0) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 10 (32.3%) | 11 (34.4%) |
| Censored Patients, n (%) | 21 (67.7%) | 21 (65.6%) |
| | | |
| Median (95% CI), (Months) [a] | 6.93 (2.96, NE) | 6.67 (2.96, 12.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4412 | |
| HR (95% CI) [c] | 0.709 (0.291, 1.725) | |
| HR P-Value [c] | 0.4483 | |
| Heterogeneity p-value [d] | 0.1886 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.7 (30.2, 76.4) | 59.1 (34.3, 77.3) |
| 12 months | 48.6 (22.6, 70.4) | 29.6 (5.6, 59.7) |
| 18 months | 48.6 (22.6, 70.4) | 0.0 (NE, NE) |
| 24 months | 24.3 (1.8, 60.9) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 11 (35.5%) | 13 (40.6%) |
| Censored Patients, n (%) | 20 (64.5%) | 19 (59.4%) |
| Median (95% CI), (Months) [a] | 6.93 (1.94, NE) | 5.19 (1.48, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3702 | |
| HR (95% CI) [c] | 0.686 (0.304, 1.548) | |
| HR P-Value [c] | 0.3635 | |
| Heterogeneity p-value [d] | 0.1122 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.2 (28.2, 74.3) | 46.5 (22.9, 67.2) |
| 12 months | 21.7 (1.6, 56.8) | 0.0 (NE, NE) |
| 18 months | 21.7 (1.6, 56.8) | 0.0 (NE, NE) |
| 24 months | 21.7 (1.6, 56.8) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 14 (45.2%) | 20 (62.5%) |
| Censored Patients, n (%) | 17 (54.8%) | 12 (37.5%) |
| Median (95% CI), (Months) [a] | 2.83 (1.51, 5.55) | 2.56 (1.45, 3.32) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5876 | |
| HR (95% CI) [c] | 0.828 (0.415, 1.653) | |
| HR P-Value [c] | 0.5924 | |
| Heterogeneity p-value [d] | 0.8147 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.3 (4.7, 45.7) | 18.9 (6.1, 37.2) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 10 (32.3%) | 19 (59.4%) |
| Censored Patients, n (%) | 21 (67.7%) | 13 (40.6%) |
| | | |
| Median (95% CI), (Months) [a] | 6.97 (2.86, NE) | 2.10 (1.48, 4.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0158 | |
| HR (95% CI) [c] | 0.395 (0.181, 0.863) | |
| HR P-Value [c] | 0.0199 | |
| Heterogeneity p-value [d] | 0.6239 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.5 (30.2, 77.4) | 28.9 (12.4, 47.9) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 11 (35.5%) | 19 (59.4%) |
| Censored Patients, n (%) | 20 (64.5%) | 13 (40.6%) |
| Median (95% CI), (Months) [a] | 2.86 (1.64, NE) | 3.02 (1.74, 4.99) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2523 | |
| HR (95% CI) [c] | 0.651 (0.307, 1.381) | |
| HR P-Value [c] | 0.2633 | |
| Heterogeneity p-value [d] | 0.9025 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.1 (26.6, 68.2) | 27.8 (10.5, 48.4) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 13 (41.9%) | 20 (62.5%) |
| Censored Patients, n (%) | 18 (58.1%) | 12 (37.5%) |
| Median (95% CI), (Months) [a] | 5.72 (1.94, 20.80) | 2.79 (1.48, 3.35) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0771 | |
| HR (95% CI) [c] | 0.527 (0.256, 1.085) | |
| HR P-Value [c] | 0.0821 | |
| Heterogeneity p-value [d] | 0.9181 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.4 (19.1, 64.1) | 20.0 (6.2, 39.3) |
| 12 months | 21.2 (1.7, 55.4) | 0.0 (NE, NE) |
| 18 months | 21.2 (1.7, 55.4) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 13 (41.9%) | 15 (46.9%) |
| Censored Patients, n (%) | 18 (58.1%) | 17 (53.1%) |
| Median (95% CI), (Months) [a] | 5.55 (1.94, 20.83) | 4.17 (2.10, 12.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5629 | |
| HR (95% CI) [c] | 0.798 (0.365, 1.746) | |
| HR P-Value [c] | 0.5721 | |
| Heterogeneity p-value [d] | 0.0951 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.9 (17.4, 64.9) | 42.7 (22.2, 61.8) |
| 12 months | 41.9 (17.4, 64.9) | 28.5 (7.1, 55.0) |
| 18 months | 21.0 (1.6, 55.2) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 10 (32.3%) | 11 (34.4%) |
| Censored Patients, n (%) | 21 (67.7%) | 21 (65.6%) |
| Median (95% CI), (Months) [a] | 12.78 (2.83, 13.90) | 6.67 (5.72, 12.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6148 | |
| HR (95% CI) [c] | 0.802 (0.320, 2.007) | |
| HR P-Value [c] | 0.6372 | |
| Heterogeneity p-value [d] | 0.8903 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.6 (33.5, 77.0) | 62.5 (34.5, 81.2) |
| 12 months | 58.6 (33.5, 77.0) | 31.2 (5.6, 62.4) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 27 (15.0%) | 18 (11.0%) |
| Censored Patients, n (%) | 153 (85.0%) | 145 (89.0%) |
| Median (95% CI), (Months) [a] | 12.52 (3.91, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4277 | |
| HR (95% CI) [c] | 1.278 (0.699, 2.336) | |
| HR P-Value [c] | 0.4263 | |
| Heterogeneity p-value [d] | 0.9897 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.0 (43.7, 70.0) | 66.6 (51.3, 78.0) |
| 12 months | 51.6 (33.9, 66.7) | 60.5 (42.0, 74.8) |
| 18 months | 32.2 (11.3, 55.6) | NE (NE, NE) |
| 24 months | 32.2 (11.3, 55.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 25 (13.9%) | 18 (11.0%) |
| Censored Patients, n (%) | 155 (86.1%) | 145 (89.0%) |
| Median (95% CI), (Months) [a] | 17.97 (9.72, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7133 | |
| HR (95% CI) [c] | 0.893 (0.478, 1.668) | |
| HR P-Value [c] | 0.7223 | |
| Heterogeneity p-value [d] | 0.8186 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.1 (58.7, 80.5) | 65.0 (48.7, 77.2) |
| 12 months | 61.4 (45.9, 73.7) | NE (NE, NE) |
| 18 months | 42.8 (16.9, 66.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 26 (14.4%) | 19 (11.7%) |
| Censored Patients, n (%) | 154 (85.6%) | 144 (88.3%) |
| Median (95% CI), (Months) [a] | 9.72 (5.72, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6568 | |
| HR (95% CI) [c] | 0.871 (0.479, 1.583) | |
| HR P-Value [c] | 0.6512 | |
| Heterogeneity p-value [d] | 0.8369 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.8 (47.9, 74.5) | 58.5 (42.1, 71.7) |
| 12 months | 37.9 (19.4, 56.3) | 58.5 (42.1, 71.7) |
| 18 months | 37.9 (19.4, 56.3) | NE (NE, NE) |
| 24 months | 37.9 (19.4, 56.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 20 (11.1%) | 12 (7.4%) |
| Censored Patients, n (%) | 160 (88.9%) | 151 (92.6%) |
| Median (95% CI), (Months) [a] | 4.21 (1.58, 11.40) | 2.30 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5758 | |
| HR (95% CI) [c] | 0.820 (0.395, 1.702) | |
| HR P-Value [c] | 0.5948 | |
| Heterogeneity p-value [d] | 0.7572 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.1 (28.8, 63.5) | 43.3 (20.3, 64.5) |
| 12 months | 22.8 (7.1, 43.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 28 (15.6%) | 12 (7.4%) |
| Censored Patients, n (%) | 152 (84.4%) | 151 (92.6%) |
| Median (95% CI), (Months) [a] | 8.97 (3.02, 15.31) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1398 | |
| HR (95% CI) [c] | 1.674 (0.840, 3.333) | |
| HR P-Value [c] | 0.1429 | |
| Heterogeneity p-value [d] | 0.5622 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.8 (41.6, 69.4) | 69.7 (51.4, 82.2) |
| 12 months | 36.6 (19.6, 53.7) | 69.7 (51.4, 82.2) |
| 18 months | 27.4 (10.0, 48.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 29 (16.1%) | 16 (9.8%) |
| Censored Patients, n (%) | 151 (83.9%) | 147 (90.2%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7283 | |
| HR (95% CI) [c] | 1.117 (0.601, 2.078) | |
| HR P-Value [c] | 0.7261 | |
| Heterogeneity p-value [d] | 0.7142 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (59.9, 80.2) | 75.2 (60.7, 85.0) |
| 12 months | 60.4 (45.8, 72.1) | 63.7 (42.7, 78.8) |
| 18 months | 54.3 (36.8, 68.9) | NE (NE, NE) |
| 24 months | 54.3 (36.8, 68.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 37 (20.6%) | 21 (12.9%) |
| Censored Patients, n (%) | 143 (79.4%) | 142 (87.1%) |
| Median (95% CI), (Months) [a] | 21.88 (11.17, NE) | 14.69 (8.97, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3594 | |
| HR (95% CI) [c] | 1.296 (0.751, 2.236) | |
| HR P-Value [c] | 0.3523 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.7 (63.0, 80.2) | 80.3 (69.8, 87.4) |
| 12 months | 62.0 (49.5, 72.3) | 65.8 (46.0, 79.9) |
| 18 months | 58.8 (45.3, 70.0) | 0.0 (NE, NE) |
| 24 months | 44.1 (18.0, 67.6) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 24 (13.3%) | 20 (12.3%) |
| Censored Patients, n (%) | 156 (86.7%) | 143 (87.7%) |
| Median (95% CI), (Months) [a] | NE (13.86, NE) | NE (8.80, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9575 | |
| HR (95% CI) [c] | 0.984 (0.537, 1.803) | |
| HR P-Value [c] | 0.9584 | |
| Heterogeneity p-value [d] | 0.9885 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.0 (51.2, 75.8) | 71.4 (58.4, 81.0) |
| 12 months | 65.0 (51.2, 75.8) | 52.9 (27.3, 73.2) |
| 18 months | 52.5 (32.9, 68.9) | NE (NE, NE) |
| 24 months | 52.5 (32.9, 68.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 20 (11.1%) | 17 (10.4%) |
| Censored Patients, n (%) | 160 (88.9%) | 146 (89.6%) |
| Median (95% CI), (Months) [a] | 9.72 (2.07, 25.53) | 4.47 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6524 | |
| HR (95% CI) [c] | 0.858 (0.440, 1.673) | |
| HR P-Value [c] | 0.6526 | |
| Heterogeneity p-value [d] | 0.4020 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.3 (35.3, 68.4) | 43.7 (24.4, 61.6) |
| 12 months | 47.9 (29.2, 64.5) | NE (NE, NE) |
| 18 months | 41.1 (21.6, 59.7) | NE (NE, NE) |
| 24 months | 41.1 (21.6, 59.7) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 46 (25.6%) | 32 (19.6%) |
| Censored Patients, n (%) | 134 (74.4%) | 131 (80.4%) |
| Median (95% CI), (Months) [a] | 11.17 (6.93, NE) | NE (5.85, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5533 | |
| HR (95% CI) [c] | 1.155 (0.733, 1.822) | |
| HR P-Value [c] | 0.5340 | |
| Heterogeneity p-value [d] | 0.8391 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.3 (51.6, 71.2) | 60.3 (47.7, 70.8) |
| 12 months | 47.1 (33.6, 59.5) | 57.4 (44.2, 68.6) |
| 18 months | 37.3 (21.4, 53.2) | 57.4 (44.2, 68.6) |
| 24 months | 37.3 (21.4, 53.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:21, yingyuan.lin)

Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 29 (16.1%) | 9 (5.5%) |
| Censored Patients, n (%) | 151 (83.9%) | 154 (94.5%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0186 | |
| HR (95% CI) [c] | 2.402 (1.131, 5.099) | |
| HR P-Value [c] | 0.0226 | |
| Heterogeneity p-value [d] | 0.7586 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.2 (60.8, 80.8) | 87.4 (75.7, 93.7) |
| 12 months | 62.3 (48.4, 73.5) | 82.8 (66.7, 91.6) |
| 18 months | 55.4 (37.0, 70.4) | NE (NE, NE) |
| 24 months | 55.4 (37.0, 70.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 35 (19.4%) | 14 (8.6%) |
| Censored Patients, n (%) | 145 (80.6%) | 149 (91.4%) |
| Median (95% CI), (Months) [a] | NE (15.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0415 | |
| HR (95% CI) [c] | 1.898 (1.017, 3.542) | |
| HR P-Value [c] | 0.0442 | |
| Heterogeneity p-value [d] | 0.1006 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.2 (64.9, 81.4) | 85.4 (75.7, 91.4) |
| 12 months | 67.7 (57.0, 76.3) | 81.3 (67.8, 89.6) |
| 18 months | 62.9 (48.7, 74.2) | NE (NE, NE) |
| 24 months | 62.9 (48.7, 74.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 39 (21.7%) | 14 (8.6%) |
| Censored Patients, n (%) | 141 (78.3%) | 149 (91.4%) |
| Median (95% CI), (Months) [a] | 12.48 (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0325 | |
| HR (95% CI) [c] | 1.935 (1.046, 3.579) | |
| HR P-Value [c] | 0.0353 | |
| Heterogeneity p-value [d] | 0.9976 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.2 (48.4, 70.1) | 79.0 (66.0, 87.4) |
| 12 months | 51.2 (37.4, 63.5) | 74.8 (59.4, 85.1) |
| 18 months | 42.6 (27.0, 57.3) | NE (NE, NE) |
| 24 months | 42.6 (27.0, 57.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 41 (22.8%) | 22 (13.5%) |
| Censored Patients, n (%) | 139 (77.2%) | 141 (86.5%) |
| Median (95% CI), (Months) [a] | 8.44 (3.09, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0666 | |
| HR (95% CI) [c] | 1.623 (0.964, 2.731) | |
| HR P-Value [c] | 0.0684 | |
| Heterogeneity p-value [d] | 0.5378 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.1 (43.1, 65.5) | 69.1 (55.8, 79.1) |
| 12 months | 44.8 (31.6, 57.1) | 59.1 (41.2, 73.3) |
| 18 months | 39.8 (25.3, 54.0) | NE (NE, NE) |
| 24 months | 39.8 (25.3, 54.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 34 (18.9%) | 18 (11.0%) |
| Censored Patients, n (%) | 146 (81.1%) | 145 (89.0%) |
| Median (95% CI), (Months) [a] | 10.45 (3.09, NE) | NE (7.03, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1071 | |
| HR (95% CI) [c] | 1.606 (0.902, 2.858) | |
| HR P-Value [c] | 0.1074 | |
| Heterogeneity p-value [d] | 0.9884 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.0 (44.1, 67.9) | 68.9 (52.4, 80.7) |
| 12 months | 49.3 (34.3, 62.7) | 55.3 (32.8, 73.0) |
| 18 months | 43.1 (26.1, 59.1) | NE (NE, NE) |
| 24 months | 43.1 (26.1, 59.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 2 (10.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 4.21 (1.45, NE) | 5.65 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6772 | |
| HR (95% CI) [c] | 1.447 (0.242, 8.670) | |
| HR P-Value [c] | 0.6858 | |
| Heterogeneity p-value [d] | 0.9897 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.4 (6.6, 78.5) | 40.0 (1.1, 82.9) |
| 12 months | 44.4 (6.6, 78.5) | NE (NE, NE) |
| 18 months | 22.2 (1.0, 61.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 1 (5.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 14.09 (1.41, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8804 | |
| HR (95% CI) [c] | 0.830 (0.073, 9.459) | |
| HR P-Value [c] | 0.8805 | |
| Heterogeneity p-value [d] | 0.8186 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.9 (43.3, 98.4) | 66.7 (5.4, 94.5) |
| 12 months | 66.7 (16.0, 91.4) | NE (NE, NE) |
| 18 months | 44.4 (6.0, 79.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 2 (10.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 6.97 (2.69, NE) | 4.27 (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8598 | |
| HR (95% CI) [c] | 0.850 (0.140, 5.175) | |
| HR P-Value [c] | 0.8600 | |
| Heterogeneity p-value [d] | 0.8369 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.5 (14.2, 89.3) | 33.3 (0.9, 77.4) |
| 12 months | 41.7 (5.6, 76.7) | NE (NE, NE) |
| 18 months | 20.8 (0.9, 59.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 1 (5.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 6.97 (1.58, 14.26) | 4.40 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4504 | |
| HR (95% CI) [c] | 0.354 (0.021, 5.893) | |
| HR P-Value [c] | 0.4689 | |
| Heterogeneity p-value [d] | 0.7572 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (12.8, 96.1) | 0.0 (NE, NE) |
| 12 months | 37.5 (1.1, 80.8) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 1 (5.0%) |
| Censored Patients, n (%) | 14 (87.5%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 9.15 (6.97, 11.33) | NE (1.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8964 | |
| HR (95% CI) [c] | 1.225 (0.058, 25.979) | |
| HR P-Value [c] | 0.8965 | |
| Heterogeneity p-value [d] | 0.5622 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 83.3 (27.3, 97.5) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 1 (5.0%) |
| Censored Patients, n (%) | 15 (93.8%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9191 | |
| HR (95% CI) [c] | 0.866 (0.054, 13.945) | |
| HR P-Value [c] | 0.9192 | |
| Heterogeneity p-value [d] | 0.7142 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 75.0 (12.8, 96.1) |
| 12 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 18 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 24 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 1 (5.0%) |
| Censored Patients, n (%) | 14 (87.5%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | NE (4.21, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7828 | |
| HR (95% CI) [c] | 1.419 (0.117, 17.239) | |
| HR P-Value [c] | 0.7837 | |
| Heterogeneity p-value [d] | 0.9764 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.3 (27.3, 97.5) | 90.9 (50.8, 98.7) |
| 12 months | 62.5 (14.2, 89.3) | NE (NE, NE) |
| 18 months | 62.5 (14.2, 89.3) | NE (NE, NE) |
| 24 months | 62.5 (14.2, 89.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 0 |
| Censored Patients, n (%) | 14 (87.5%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (2.89, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2457 | |
| HR (95% CI) [c] | 57562993 (0.000, NE) | |
| HR P-Value [c] | 0.9978 | |
| Heterogeneity p-value [d] | 0.9885 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.0 (12.6, 88.2) | 100.0 (100.0, 100.0) |
| 12 months | 60.0 (12.6, 88.2) | NE (NE, NE) |
| 18 months | 60.0 (12.6, 88.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 1 (5.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 4.22 (1.41, 7.92) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3465 | |
| HR (95% CI) [c] | 2.574 (0.284, 23.323) | |
| HR P-Value [c] | 0.4006 | |
| Heterogeneity p-value [d] | 0.4020 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (5.8, 84.5) | 50.0 (0.6, 91.0) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 2 (10.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 17.05 (1.45, NE) | NE (1.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6894 | |
| HR (95% CI) [c] | 1.440 (0.238, 8.695) | |
| HR P-Value [c] | 0.6910 | |
| Heterogeneity p-value [d] | 0.8391 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.5 (12.2, 82.1) | 83.3 (27.3, 97.5) |
| 12 months | 52.5 (12.2, 82.1) | NE (NE, NE) |
| 18 months | 35.0 (4.9, 69.3) | NE (NE, NE) |
| 24 months | 35.0 (4.9, 69.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 1 (5.0%) |
| Censored Patients, n (%) | 14 (87.5%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | NE (6.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5860 | |
| HR (95% CI) [c] | 1.931 (0.173, 21.526) | |
| HR P-Value [c] | 0.5926 | |
| Heterogeneity p-value [d] | 0.7586 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.8 (42.3, 94.9) | 100.0 (100.0, 100.0) |
| 12 months | 80.8 (42.3, 94.9) | NE (NE, NE) |
| 18 months | 80.8 (42.3, 94.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 3 (15.0%) |
| Censored Patients, n (%) | 15 (93.8%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | NE (4.21, NE) | 9.59 (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1984 | |
| HR (95% CI) [c] | 0.250 (0.026, 2.440) | |
| HR P-Value [c] | 0.2329 | |
| Heterogeneity p-value [d] | 0.1006 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (38.7, 98.1) | 88.9 (43.3, 98.4) |
| 12 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 18 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 24 months | 87.5 (38.7, 98.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 1 (5.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | NE (1.45, NE) | NE (1.18, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5421 | |
| HR (95% CI) [c] | 1.995 (0.207, 19.201) | |
| HR P-Value [c] | 0.5500 | |
| Heterogeneity p-value [d] | 0.9976 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.8 (44.7, 95.1) | 87.5 (38.7, 98.1) |
| 12 months | 65.5 (23.6, 88.3) | NE (NE, NE) |
| 18 months | 65.5 (23.6, 88.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 2 (10.0%) |
| Censored Patients, n (%) | 15 (93.8%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | NE (1.41, NE) | 7.06 (1.48, 7.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8084 | |
| HR (95% CI) [c] | 1.414 (0.085, 23.573) | |
| HR P-Value [c] | 0.8092 | |
| Heterogeneity p-value [d] | 0.5378 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 75.0 (12.8, 96.1) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 0 |
| Censored Patients, n (%) | 15 (93.8%) | 20 (100.0%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4795 | |
| HR (95% CI) [c] | 47145826 (0.000, NE) | |
| HR P-Value [c] | 0.9985 | |
| Heterogeneity p-value [d] | 0.9884 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 18 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 22 (16.2%) | 11 (8.9%) |
| Censored Patients, n (%) | 114 (83.8%) | 112 (91.1%) |
| Median (95% CI), (Months) [a] | 12.52 (3.09, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1874 | |
| HR (95% CI) [c] | 1.635 (0.784, 3.413) | |
| HR P-Value [c] | 0.1900 | |
| Heterogeneity p-value [d] | 0.3454 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.1 (39.5, 69.7) | 73.1 (55.1, 84.8) |
| 12 months | 56.1 (39.5, 69.7) | 66.4 (44.9, 81.2) |
| 18 months | 32.7 (12.8, 54.5) | NE (NE, NE) |
| 24 months | 32.7 (12.8, 54.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 20 (14.7%) | 13 (10.6%) |
| Censored Patients, n (%) | 116 (85.3%) | 110 (89.4%) |
| Median (95% CI), (Months) [a] | 17.97 (8.61, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8846 | |
| HR (95% CI) [c] | 0.953 (0.459, 1.982) | |
| HR P-Value [c] | 0.8980 | |
| Heterogeneity p-value [d] | 0.6388 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.7 (57.4, 82.0) | 66.0 (46.5, 79.8) |
| 12 months | 65.1 (49.0, 77.2) | NE (NE, NE) |
| 18 months | 41.2 (15.8, 65.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 21 (15.4%) | 17 (13.8%) |
| Censored Patients, n (%) | 115 (84.6%) | 106 (86.2%) |
| Median (95% CI), (Months) [a] | 9.72 (4.96, NE) | 4.50 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3980 | |
| HR (95% CI) [c] | 0.755 (0.393, 1.448) | |
| HR P-Value [c] | 0.3972 | |
| Heterogeneity p-value [d] | 0.2860 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.8 (46.2, 75.6) | 48.3 (29.5, 64.8) |
| 12 months | 38.8 (19.8, 57.4) | 48.3 (29.5, 64.8) |
| 18 months | 38.8 (19.8, 57.4) | NE (NE, NE) |
| 24 months | 38.8 (19.8, 57.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 15 (11.0%) | 9 (7.3%) |
| Censored Patients, n (%) | 121 (89.0%) | 114 (92.7%) |
| Median (95% CI), (Months) [a] | 6.97 (1.48, 14.26) | 2.33 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4218 | |
| HR (95% CI) [c] | 0.721 (0.306, 1.702) | |
| HR P-Value [c] | 0.4559 | |
| Heterogeneity p-value [d] | 0.5639 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.3 (37.5, 75.7) | 35.4 (11.3, 60.9) |
| 12 months | 32.9 (12.4, 55.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 19 (14.0%) | 5 (4.1%) |
| Censored Patients, n (%) | 117 (86.0%) | 118 (95.9%) |
| Median (95% CI), (Months) [a] | 8.97 (3.02, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0162 | |
| HR (95% CI) [c] | 3.194 (1.181, 8.635) | |
| HR P-Value [c] | 0.0221 | |
| Heterogeneity p-value [d] | 0.0547 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.7 (42.5, 74.8) | 85.3 (68.1, 93.7) |
| 12 months | 35.4 (16.3, 55.2) | 85.3 (68.1, 93.7) |
| 18 months | 35.4 (16.3, 55.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 20 (14.7%) | 11 (8.9%) |
| Censored Patients, n (%) | 116 (85.3%) | 112 (91.1%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9855 | |
| HR (95% CI) [c] | 1.008 (0.478, 2.129) | |
| HR P-Value [c] | 0.9826 | |
| Heterogeneity p-value [d] | 0.6089 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.5 (64.9, 86.0) | 79.3 (63.2, 88.9) |
| 12 months | 65.7 (49.7, 77.7) | 66.0 (41.9, 82.0) |
| 18 months | 59.2 (39.7, 74.2) | NE (NE, NE) |
| 24 months | 59.2 (39.7, 74.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 26 (19.1%) | 10 (8.1%) |
| Censored Patients, n (%) | 110 (80.9%) | 113 (91.9%) |
| Median (95% CI), (Months) [a] | NE (12.65, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1099 | |
| HR (95% CI) [c] | 1.817 (0.870, 3.797) | |
| HR P-Value [c] | 0.1121 | |
| Heterogeneity p-value [d] | 0.4467 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.5 (64.7, 83.4) | 86.4 (75.4, 92.8) |
| 12 months | 66.4 (53.2, 76.7) | 76.8 (50.6, 90.3) |
| 18 months | 63.1 (48.8, 74.4) | NE (NE, NE) |
| 24 months | 63.1 (48.8, 74.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 18 (13.2%) | 13 (10.6%) |
| Censored Patients, n (%) | 118 (86.8%) | 110 (89.4%) |
| Median (95% CI), (Months) [a] | NE (5.59, NE) | NE (8.80, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7864 | |
| HR (95% CI) [c] | 1.108 (0.533, 2.307) | |
| HR P-Value [c] | 0.7830 | |
| Heterogeneity p-value [d] | 0.6672 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.6 (49.7, 77.5) | 75.0 (59.2, 85.3) |
| 12 months | 65.6 (49.7, 77.5) | 51.4 (21.4, 75.0) |
| 18 months | 51.7 (30.1, 69.6) | NE (NE, NE) |
| 24 months | 51.7 (30.1, 69.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 16 (11.8%) | 10 (8.1%) |
| Censored Patients, n (%) | 120 (88.2%) | 113 (91.9%) |
| Median (95% CI), (Months) [a] | 9.72 (1.64, 25.53) | 5.06 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9462 | |
| HR (95% CI) [c] | 0.979 (0.430, 2.228) | |
| HR P-Value [c] | 0.9596 | |
| Heterogeneity p-value [d] | 0.9294 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.0 (37.6, 73.8) | 49.0 (24.4, 69.8) |
| 12 months | 47.5 (26.9, 65.7) | NE (NE, NE) |
| 18 months | 39.6 (18.5, 60.1) | NE (NE, NE) |
| 24 months | 39.6 (18.5, 60.1) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 35 (25.7%) | 20 (16.3%) |
| Censored Patients, n (%) | 101 (74.3%) | 103 (83.7%) |
| Median (95% CI), (Months) [a] | 11.17 (8.34, NE) | NE (5.85, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5376 | |
| HR (95% CI) [c] | 1.201 (0.689, 2.093) | |
| HR P-Value [c] | 0.5191 | |
| Heterogeneity p-value [d] | 0.8388 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.2 (52.9, 75.1) | 64.5 (49.4, 76.2) |
| 12 months | 48.5 (33.6, 61.8) | 61.1 (45.3, 73.6) |
| 18 months | 32.8 (16.0, 50.7) | 61.1 (45.3, 73.6) |
| 24 months | 32.8 (16.0, 50.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 22 (16.2%) | 5 (4.1%) |
| Censored Patients, n (%) | 114 (83.8%) | 118 (95.9%) |
| Median (95% CI), (Months) [a] | NE (15.24, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0145 | |
| HR (95% CI) [c] | 3.171 (1.194, 8.421) | |
| HR P-Value [c] | 0.0206 | |
| Heterogeneity p-value [d] | 0.4025 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.6 (61.2, 82.5) | 94.0 (82.0, 98.1) |
| 12 months | 68.9 (55.5, 79.0) | 84.4 (63.5, 93.8) |
| 18 months | 62.6 (44.8, 76.1) | NE (NE, NE) |
| 24 months | 62.6 (44.8, 76.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 24 (17.6%) | 7 (5.7%) |
| Censored Patients, n (%) | 112 (82.4%) | 116 (94.3%) |
| Median (95% CI), (Months) [a] | NE (15.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0340 | |
| HR (95% CI) [c] | 2.438 (1.044, 5.697) | |
| HR P-Value [c] | 0.0395 | |
| Heterogeneity p-value [d] | 0.1498 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.9 (67.6, 85.2) | 89.6 (77.8, 95.3) |
| 12 months | 71.4 (59.1, 80.5) | 84.6 (67.3, 93.2) |
| 18 months | 65.9 (49.6, 78.0) | NE (NE, NE) |
| 24 months | 65.9 (49.6, 78.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 30 (22.1%) | 6 (4.9%) |
| Censored Patients, n (%) | 106 (77.9%) | 117 (95.1%) |
| Median (95% CI), (Months) [a] | 13.83 (9.86, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0035 | |
| HR (95% CI) [c] | 3.443 (1.424, 8.321) | |
| HR P-Value [c] | 0.0060 | |
| Heterogeneity p-value [d] | 0.0374 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.8 (53.4, 75.6) | 90.0 (77.0, 95.9) |
| 12 months | 57.0 (42.4, 69.1) | 85.5 (68.4, 93.8) |
| 18 months | 48.7 (32.5, 63.2) | NE (NE, NE) |
| 24 months | 48.7 (32.5, 63.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 28 (20.6%) | 19 (15.4%) |
| Censored Patients, n (%) | 108 (79.4%) | 104 (84.6%) |
| Median (95% CI), (Months) [a] | 8.61 (4.96, NE) | 7.26 (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8332 | |
| HR (95% CI) [c] | 1.067 (0.593, 1.920) | |
| HR P-Value [c] | 0.8277 | |
| Heterogeneity p-value [d] | 0.0372 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.4 (48.8, 73.4) | 63.8 (47.0, 76.6) |
| 12 months | 48.8 (33.0, 62.9) | 47.3 (27.2, 65.0) |
| 18 months | 41.8 (23.8, 58.9) | NE (NE, NE) |
| 24 months | 41.8 (23.8, 58.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 26 (19.1%) | 8 (6.5%) |
| Censored Patients, n (%) | 110 (80.9%) | 115 (93.5%) |
| Median (95% CI), (Months) [a] | 10.45 (4.96, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0266 | |
| HR (95% CI) [c] | 2.406 (1.085, 5.335) | |
| HR P-Value [c] | 0.0307 | |
| Heterogeneity p-value [d] | 0.1528 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.6 (45.1, 71.4) | 81.3 (64.3, 90.8) |
| 12 months | 49.4 (33.4, 63.5) | 73.9 (50.8, 87.4) |
| 18 months | 49.4 (33.4, 63.5) | NE (NE, NE) |
| 24 months | 49.4 (33.4, 63.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 9 (15.0%) | 9 (15.0%) |
| Censored Patients, n (%) | 51 (85.0%) | 51 (85.0%) |
| Median (95% CI), (Months) [a] | 11.10 (1.91, 11.10) | 5.65 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8981 | |
| HR (95% CI) [c] | 0.938 (0.371, 2.372) | |
| HR P-Value [c] | 0.8921 | |
| Heterogeneity p-value [d] | 0.3454 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.4 (35.4, 78.2) | 43.0 (14.7, 68.9) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 8 (13.3%) | 6 (10.0%) |
| Censored Patients, n (%) | 52 (86.7%) | 54 (90.0%) |
| Median (95% CI), (Months) [a] | NE (7.03, NE) | NE (2.43, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5243 | |
| HR (95% CI) [c] | 0.708 (0.241, 2.084) | |
| HR P-Value [c] | 0.5310 | |
| Heterogeneity p-value [d] | 0.6388 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.4 (51.0, 87.9) | 61.9 (33.6, 81.0) |
| 12 months | 51.0 (20.1, 75.5) | NE (NE, NE) |
| 18 months | 51.0 (20.1, 75.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 9 (15.0%) | 4 (6.7%) |
| Censored Patients, n (%) | 51 (85.0%) | 56 (93.3%) |
| Median (95% CI), (Months) [a] | 10.45 (2.99, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5647 | |
| HR (95% CI) [c] | 1.415 (0.423, 4.735) | |
| HR P-Value [c] | 0.5731 | |
| Heterogeneity p-value [d] | 0.2860 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.4 (34.1, 80.2) | 74.1 (43.0, 89.9) |
| 12 months | 41.0 (8.9, 71.9) | NE (NE, NE) |
| 18 months | 20.5 (1.1, 57.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 8 (13.3%) | 4 (6.7%) |
| Censored Patients, n (%) | 52 (86.7%) | 56 (93.3%) |
| Median (95% CI), (Months) [a] | 3.14 (1.48, 8.34) | 3.89 (1.45, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8862 | |
| HR (95% CI) [c] | 0.907 (0.262, 3.143) | |
| HR P-Value [c] | 0.8782 | |
| Heterogeneity p-value [d] | 0.5639 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.0 (7.1, 57.8) | 50.0 (11.1, 80.4) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 11 (18.3%) | 8 (13.3%) |
| Censored Patients, n (%) | 49 (81.7%) | 52 (86.7%) |
| Median (95% CI), (Months) [a] | 8.34 (1.91, 15.31) | 5.06 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5882 | |
| HR (95% CI) [c] | 0.759 (0.285, 2.024) | |
| HR P-Value [c] | 0.5820 | |
| Heterogeneity p-value [d] | 0.0547 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.9 (26.5, 75.0) | 40.0 (12.9, 66.4) |
| 12 months | 21.6 (1.6, 56.8) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 10 (16.7%) | 6 (10.0%) |
| Censored Patients, n (%) | 50 (83.3%) | 54 (90.0%) |
| Median (95% CI), (Months) [a] | NE (4.21, NE) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4663 | |
| HR (95% CI) [c] | 1.465 (0.520, 4.123) | |
| HR P-Value [c] | 0.4696 | |
| Heterogeneity p-value [d] | 0.6089 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.9 (36.2, 78.6) | 66.1 (36.2, 84.5) |
| 12 months | 50.8 (24.0, 72.5) | NE (NE, NE) |
| 18 months | 50.8 (24.0, 72.5) | NE (NE, NE) |
| 24 months | 50.8 (24.0, 72.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 13 (21.7%) | 12 (20.0%) |
| Censored Patients, n (%) | 47 (78.3%) | 48 (80.0%) |
| Median (95% CI), (Months) [a] | 11.10 (4.27, NE) | 7.26 (7.10, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9837 | |
| HR (95% CI) [c] | 1.008 (0.450, 2.260) | |
| HR P-Value [c] | 0.9837 | |
| Heterogeneity p-value [d] | 0.4467 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.6 (48.9, 82.0) | 72.4 (52.9, 84.9) |
| 12 months | 38.1 (8.4, 68.7) | 48.3 (18.7, 72.9) |
| 18 months | 38.1 (8.4, 68.7) | 0.0 (NE, NE) |
| 24 months | 19.0 (1.1, 54.3) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 8 (13.3%) | 7 (11.7%) |
| Censored Patients, n (%) | 52 (86.7%) | 53 (88.3%) |
| Median (95% CI), (Months) [a] | NE (4.67, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9362 | |
| HR (95% CI) [c] | 0.956 (0.346, 2.643) | |
| HR P-Value [c] | 0.9306 | |
| Heterogeneity p-value [d] | 0.6672 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.5 (33.0, 78.4) | 69.9 (46.6, 84.5) |
| 12 months | 59.5 (33.0, 78.4) | NE (NE, NE) |
| 18 months | 59.5 (33.0, 78.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 8 (13.3%) | 8 (13.3%) |
| Censored Patients, n (%) | 52 (86.7%) | 52 (86.7%) |
| Median (95% CI), (Months) [a] | 5.59 (1.91, NE) | 3.65 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8664 | |
| HR (95% CI) [c] | 0.915 (0.342, 2.446) | |
| HR P-Value [c] | 0.8587 | |
| Heterogeneity p-value [d] | 0.9294 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.2 (11.9, 67.6) | 37.5 (11.4, 64.2) |
| 12 months | 20.1 (1.3, 55.0) | NE (NE, NE) |
| 18 months | 20.1 (1.3, 55.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 15 (25.0%) | 14 (23.3%) |
| Censored Patients, n (%) | 45 (75.0%) | 46 (76.7%) |
| Median (95% CI), (Months) [a] | NE (1.91, NE) | 6.67 (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6221 | |
| HR (95% CI) [c] | 1.210 (0.583, 2.510) | |
| HR P-Value [c] | 0.6093 | |
| Heterogeneity p-value [d] | 0.8388 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.6 (30.7, 69.0) | 57.7 (37.0, 73.8) |
| 12 months | 51.6 (30.7, 69.0) | NE (NE, NE) |
| 18 months | 51.6 (30.7, 69.0) | NE (NE, NE) |
| 24 months | 51.6 (30.7, 69.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 9 (15.0%) | 5 (8.3%) |
| Censored Patients, n (%) | 51 (85.0%) | 55 (91.7%) |
| Median (95% CI), (Months) [a] | 11.10 (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3852 | |
| HR (95% CI) [c] | 1.621 (0.539, 4.878) | |
| HR P-Value [c] | 0.3904 | |
| Heterogeneity p-value [d] | 0.4025 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.1 (45.1, 85.4) | 78.6 (54.8, 90.8) |
| 12 months | 40.1 (8.6, 71.1) | NE (NE, NE) |
| 18 months | 40.1 (8.6, 71.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 12 (20.0%) | 10 (16.7%) |
| Censored Patients, n (%) | 48 (80.0%) | 50 (83.3%) |
| Median (95% CI), (Months) [a] | NE (5.68, NE) | 9.59 (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9720 | |
| HR (95% CI) [c] | 1.015 (0.436, 2.361) | |
| HR P-Value [c] | 0.9725 | |
| Heterogeneity p-value [d] | 0.1498 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.5 (48.7, 82.0) | 78.1 (60.1, 88.7) |
| 12 months | 63.2 (42.2, 78.4) | NE (NE, NE) |
| 18 months | 63.2 (42.2, 78.4) | NE (NE, NE) |
| 24 months | 63.2 (42.2, 78.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 12 (20.0%) | 9 (15.0%) |
| Censored Patients, n (%) | 48 (80.0%) | 51 (85.0%) |
| Median (95% CI), (Months) [a] | 5.55 (4.63, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8696 | |
| HR (95% CI) [c] | 0.931 (0.391, 2.215) | |
| HR P-Value [c] | 0.8713 | |
| Heterogeneity p-value [d] | 0.0374 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.4 (24.2, 69.0) | 57.2 (32.9, 75.6) |
| 12 months | 38.7 (15.1, 62.1) | NE (NE, NE) |
| 18 months | 38.7 (15.1, 62.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 14 (23.3%) | 5 (8.3%) |
| Censored Patients, n (%) | 46 (76.7%) | 55 (91.7%) |
| Median (95% CI), (Months) [a] | 4.67 (1.58, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0037 | |
| HR (95% CI) [c] | 4.065 (1.454, 11.362) | |
| HR P-Value [c] | 0.0075 | |
| Heterogeneity p-value [d] | 0.0372 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 31.3 (10.2, 55.5) | 79.8 (57.7, 91.1) |
| 12 months | 31.3 (10.2, 55.5) | NE (NE, NE) |
| 18 months | 31.3 (10.2, 55.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 9 (15.0%) | 10 (16.7%) |
| Censored Patients, n (%) | 51 (85.0%) | 50 (83.3%) |
| Median (95% CI), (Months) [a] | 12.58 (2.89, 12.58) | 8.48 (5.06, 8.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7375 | |
| HR (95% CI) [c] | 0.850 (0.332, 2.175) | |
| HR P-Value [c] | 0.7347 | |
| Heterogeneity p-value [d] | 0.1528 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.1 (41.6, 81.1) | 54.5 (26.2, 75.9) |
| 12 months | 65.1 (41.6, 81.1) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 1 (4.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2032 | |
| HR (95% CI) [c] | 3.979 (0.413, 38.378) | |
| HR P-Value [c] | 0.2324 | |
| Heterogeneity p-value [d] | 0.8338 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.1 (17.2, 83.7) | 80.0 (20.4, 96.9) |
| 12 months | 57.1 (17.2, 83.7) | 80.0 (20.4, 96.9) |
| 18 months | 57.1 (17.2, 83.7) | NE (NE, NE) |
| 24 months | 57.1 (17.2, 83.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 2 (8.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | NE (2.96, NE) | NE (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6878 | |
| HR (95% CI) [c] | 0.613 (0.055, 6.807) | |
| HR P-Value [c] | 0.6907 | |
| Heterogeneity p-value [d] | 0.9245 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (12.8, 96.1) | 75.0 (31.5, 93.1) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 4 (18.2%) | 4 (16.0%) |
| Censored Patients, n (%) | 18 (81.8%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | 8.48 (1.58, NE) | 2.35 (1.54, 3.12) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0423 | |
| HR (95% CI) [c] | 0.197 (0.035, 1.113) | |
| HR P-Value [c] | 0.0659 | |
| Heterogeneity p-value [d] | 0.5403 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.5 (23.6, 88.3) | 0.0 (NE, NE) |
| 12 months | 43.6 (7.3, 76.9) | 0.0 (NE, NE) |
| 18 months | 43.6 (7.3, 76.9) | 0.0 (NE, NE) |
| 24 months | 43.6 (7.3, 76.9) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 3 (12.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | 1.58 (1.41, NE) | 3.37 (2.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4083 | |
| HR (95% CI) [c] | 2.072 (0.405, 10.618) | |
| HR P-Value [c] | 0.3820 | |
| Heterogeneity p-value [d] | 0.6155 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 2 (8.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | NE (1.54, NE) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4464 | |
| HR (95% CI) [c] | 1.984 (0.329, 11.964) | |
| HR P-Value [c] | 0.4550 | |
| Heterogeneity p-value [d] | 0.2449 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.1 (15.1, 84.7) | 80.0 (40.9, 94.6) |
| 12 months | 57.1 (15.1, 84.7) | 80.0 (40.9, 94.6) |
| 18 months | 57.1 (15.1, 84.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 3 (12.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | NE (2.96, NE) | 8.67 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4456 | |
| HR (95% CI) [c] | 0.505 (0.084, 3.029) | |
| HR P-Value [c] | 0.4543 | |
| Heterogeneity p-value [d] | 0.1777 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.5 (43.5, 95.1) | 74.1 (28.9, 93.0) |
| 12 months | 81.5 (43.5, 95.1) | NE (NE, NE) |
| 18 months | 81.5 (43.5, 95.1) | NE (NE, NE) |
| 24 months | 81.5 (43.5, 95.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 1 (4.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (2.96, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2861 | |
| HR (95% CI) [c] | 3.208 (0.333, 30.876) | |
| HR P-Value [c] | 0.3130 | |
| Heterogeneity p-value [d] | 0.8809 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.2 (40.7, 91.4) | 91.7 (53.9, 98.8) |
| 12 months | 75.2 (40.7, 91.4) | 91.7 (53.9, 98.8) |
| 18 months | 75.2 (40.7, 91.4) | NE (NE, NE) |
| 24 months | 75.2 (40.7, 91.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 2 (8.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | NE (2.96, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5621 | |
| HR (95% CI) [c] | 0.496 (0.044, 5.562) | |
| HR P-Value [c] | 0.5698 | |
| Heterogeneity p-value [d] | 0.8493 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.7 (33.4, 97.9) | 80.0 (40.9, 94.6) |
| 12 months | 85.7 (33.4, 97.9) | 80.0 (40.9, 94.6) |
| 18 months | 85.7 (33.4, 97.9) | NE (NE, NE) |
| 24 months | 85.7 (33.4, 97.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 2 (8.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 23 (92.0%) |
| Median (95% CI), (Months) [a] | 25.53 (1.58, 25.53) | 5.06 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6698 | |
| HR (95% CI) [c] | 0.590 (0.051, 6.848) | |
| HR P-Value [c] | 0.6729 | |
| Heterogeneity p-value [d] | 0.1690 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 12 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 18 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 24 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 5 (22.7%) | 5 (20.0%) |
| Censored Patients, n (%) | 17 (77.3%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | 16.76 (1.61, 16.76) | NE (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7316 | |
| HR (95% CI) [c] | 1.242 (0.359, 4.305) | |
| HR P-Value [c] | 0.7321 | |
| Heterogeneity p-value [d] | 0.9878 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.7 (21.6, 83.1) | 54.3 (21.5, 78.4) |
| 12 months | 58.7 (21.6, 83.1) | 54.3 (21.5, 78.4) |
| 18 months | 0.0 (NE, NE) | 54.3 (21.5, 78.4) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 0 |
| Censored Patients, n (%) | 19 (86.4%) | 25 (100.0%) |
| Median (95% CI), (Months) [a] | NE (2.96, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1050 | |
| HR (95% CI) [c] | 71259022 (0.000, NE) | |
| HR P-Value [c] | 0.9972 | |
| Heterogeneity p-value [d] | 0.9402 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.7 (41.3, 91.6) | 100.0 (100.0, 100.0) |
| 12 months | 75.7 (41.3, 91.6) | 100.0 (100.0, 100.0) |
| 18 months | 75.7 (41.3, 91.6) | NE (NE, NE) |
| 24 months | 75.7 (41.3, 91.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 1 (4.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (5.68, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7232 | |
| HR (95% CI) [c] | 1.542 (0.138, 17.287) | |
| HR P-Value [c] | 0.7252 | |
| Heterogeneity p-value [d] | 0.4603 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.2 (40.3, 94.8) | 93.3 (61.3, 99.0) |
| 12 months | 80.2 (40.3, 94.8) | 93.3 (61.3, 99.0) |
| 18 months | 80.2 (40.3, 94.8) | NE (NE, NE) |
| 24 months | 80.2 (40.3, 94.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (4.0%) |
| Censored Patients, n (%) | 22 (100.0%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (2.43, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2689 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.3916 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 88.9 (43.3, 98.4) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 3 (12.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6101 | |
| HR (95% CI) [c] | 0.631 (0.103, 3.877) | |
| HR P-Value [c] | 0.6193 | |
| Heterogeneity p-value [d] | 0.0791 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.9 (27.6, 92.5) | 50.0 (7.9, 82.8) |
| 12 months | 72.9 (27.6, 92.5) | NE (NE, NE) |
| 18 months | 72.9 (27.6, 92.5) | NE (NE, NE) |
| 24 months | 72.9 (27.6, 92.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 1 (4.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 24 (96.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4862 | |
| HR (95% CI) [c] | 2.208 (0.199, 24.468) | |
| HR P-Value [c] | 0.5188 | |
| Heterogeneity p-value [d] | 0.9827 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.5 (14.2, 89.3) | 75.0 (12.8, 96.1) |
| 12 months | 62.5 (14.2, 89.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 3 (8.3%) |
| Censored Patients, n (%) | 34 (87.2%) | 33 (91.7%) |
| Median (95% CI), (Months) [a] | 11.10 (1.91, 11.10) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7556 | |
| HR (95% CI) [c] | 1.237 (0.294, 5.196) | |
| HR P-Value [c] | 0.7715 | |
| Heterogeneity p-value [d] | 0.8338 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.6 (38.7, 88.0) | 68.6 (30.5, 88.7) |
| 12 months | 0.0 (NE, NE) | 68.6 (30.5, 88.7) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 3 (8.3%) |
| Censored Patients, n (%) | 34 (87.2%) | 33 (91.7%) |
| Median (95% CI), (Months) [a] | NE (7.03, NE) | NE (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5063 | |
| HR (95% CI) [c] | 0.616 (0.142, 2.670) | |
| HR P-Value [c] | 0.5173 | |
| Heterogeneity p-value [d] | 0.9245 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.2 (60.8, 95.0) | 67.5 (29.1, 88.2) |
| 12 months | 60.6 (23.8, 84.0) | NE (NE, NE) |
| 18 months | 60.6 (23.8, 84.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 3 (8.3%) |
| Censored Patients, n (%) | 34 (87.2%) | 33 (91.7%) |
| Median (95% CI), (Months) [a] | 10.45 (2.07, NE) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9835 | |
| HR (95% CI) [c] | 0.971 (0.213, 4.427) | |
| HR P-Value [c] | 0.9702 | |
| Heterogeneity p-value [d] | 0.5403 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.9 (34.2, 90.4) | 71.4 (33.7, 90.1) |
| 12 months | 48.0 (8.5, 80.3) | NE (NE, NE) |
| 18 months | 24.0 (1.1, 63.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 4 (11.1%) |
| Censored Patients, n (%) | 34 (87.2%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | 2.83 (1.48, NE) | 1.54 (1.45, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3088 | |
| HR (95% CI) [c] | 0.482 (0.120, 1.943) | |
| HR P-Value [c] | 0.3048 | |
| Heterogeneity p-value [d] | 0.6155 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.9 (9.8, 73.4) | 40.0 (5.2, 75.3) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 4 (11.1%) |
| Censored Patients, n (%) | 34 (87.2%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | 11.33 (2.99, 15.31) | 5.06 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1453 | |
| HR (95% CI) [c] | 0.300 (0.055, 1.643) | |
| HR P-Value [c] | 0.1652 | |
| Heterogeneity p-value [d] | 0.2449 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.5 (39.3, 94.5) | 41.7 (7.2, 74.7) |
| 12 months | 33.1 (1.5, 74.6) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 6 (15.4%) | 5 (13.9%) |
| Censored Patients, n (%) | 33 (84.6%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | NE (2.99, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7632 | |
| HR (95% CI) [c] | 0.830 (0.239, 2.885) | |
| HR P-Value [c] | 0.7700 | |
| Heterogeneity p-value [d] | 0.1777 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.9 (47.6, 88.4) | 51.1 (15.1, 78.7) |
| 12 months | 59.2 (24.6, 82.2) | NE (NE, NE) |
| 18 months | 59.2 (24.6, 82.2) | NE (NE, NE) |
| 24 months | 59.2 (24.6, 82.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 4 (11.1%) |
| Censored Patients, n (%) | 34 (87.2%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | 21.88 (9.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7360 | |
| HR (95% CI) [c] | 0.786 (0.193, 3.198) | |
| HR P-Value [c] | 0.7366 | |
| Heterogeneity p-value [d] | 0.8809 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.8 (62.1, 95.2) | 78.5 (51.1, 91.6) |
| 12 months | 71.5 (33.3, 90.3) | 78.5 (51.1, 91.6) |
| 18 months | 71.5 (33.3, 90.3) | NE (NE, NE) |
| 24 months | 47.7 (8.4, 80.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 3 (8.3%) |
| Censored Patients, n (%) | 34 (87.2%) | 33 (91.7%) |
| Median (95% CI), (Months) [a] | 5.06 (1.51, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6972 | |
| HR (95% CI) [c] | 1.325 (0.316, 5.561) | |
| HR P-Value [c] | 0.7006 | |
| Heterogeneity p-value [d] | 0.8493 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.0 (16.1, 75.6) | 66.7 (27.2, 88.1) |
| 12 months | 49.0 (16.1, 75.6) | NE (NE, NE) |
| 18 months | 49.0 (16.1, 75.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 2 (5.1%) | 4 (11.1%) |
| Censored Patients, n (%) | 37 (94.9%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | NE (1.48, NE) | 1.56 (1.45, 1.64) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0328 | |
| HR (95% CI) [c] | 0.121 (0.013, 1.118) | |
| HR P-Value [c] | 0.0627 | |
| Heterogeneity p-value [d] | 0.1690 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.0 (12.6, 88.2) | 0.0 (NE, NE) |
| 12 months | 60.0 (12.6, 88.2) | 0.0 (NE, NE) |
| 18 months | 60.0 (12.6, 88.2) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 8 (20.5%) | 5 (13.9%) |
| Censored Patients, n (%) | 31 (79.5%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | NE (4.67, NE) | 6.67 (5.39, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9557 | |
| HR (95% CI) [c] | 1.035 (0.330, 3.251) | |
| HR P-Value [c] | 0.9528 | |
| Heterogeneity p-value [d] | 0.9878 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.0 (43.7, 83.6) | 67.0 (26.3, 88.7) |
| 12 months | 59.5 (33.0, 78.4) | NE (NE, NE) |
| 18 months | 59.5 (33.0, 78.4) | NE (NE, NE) |
| 24 months | 59.5 (33.0, 78.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 5 (12.8%) | 2 (5.6%) |
| Censored Patients, n (%) | 34 (87.2%) | 34 (94.4%) |
| Median (95% CI), (Months) [a] | 11.10 (5.55, NE) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7886 | |
| HR (95% CI) [c] | 1.254 (0.239, 6.588) | |
| HR P-Value [c] | 0.7890 | |
| Heterogeneity p-value [d] | 0.9402 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.4 (49.7, 93.4) | 81.7 (42.0, 95.4) |
| 12 months | 46.9 (8.9, 78.9) | 81.7 (42.0, 95.4) |
| 18 months | 46.9 (8.9, 78.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 6 (15.4%) | 6 (16.7%) |
| Censored Patients, n (%) | 33 (84.6%) | 30 (83.3%) |
| Median (95% CI), (Months) [a] | NE (5.06, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6841 | |
| HR (95% CI) [c] | 0.788 (0.253, 2.453) | |
| HR P-Value [c] | 0.6803 | |
| Heterogeneity p-value [d] | 0.4603 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.2 (47.3, 86.8) | 77.6 (54.0, 90.1) |
| 12 months | 72.2 (47.3, 86.8) | 58.2 (18.9, 83.9) |
| 18 months | 72.2 (47.3, 86.8) | NE (NE, NE) |
| 24 months | 72.2 (47.3, 86.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 4 (11.1%) |
| Censored Patients, n (%) | 32 (82.1%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | 12.48 (4.67, NE) | NE (1.18, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5776 | |
| HR (95% CI) [c] | 0.704 (0.204, 2.431) | |
| HR P-Value [c] | 0.5794 | |
| Heterogeneity p-value [d] | 0.3916 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.0 (33.6, 84.3) | 57.1 (21.7, 81.5) |
| 12 months | 52.0 (19.8, 76.8) | 57.1 (21.7, 81.5) |
| 18 months | 26.0 (1.6, 64.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 4 (11.1%) |
| Censored Patients, n (%) | 32 (82.1%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5416 | |
| HR (95% CI) [c] | 1.448 (0.423, 4.954) | |
| HR P-Value [c] | 0.5550 | |
| Heterogeneity p-value [d] | 0.0791 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.0 (22.7, 74.9) | 70.7 (39.4, 87.9) |
| 12 months | 52.0 (22.7, 74.9) | 70.7 (39.4, 87.9) |
| 18 months | 52.0 (22.7, 74.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 6 (15.4%) | 4 (11.1%) |
| Censored Patients, n (%) | 33 (84.6%) | 32 (88.9%) |
| Median (95% CI), (Months) [a] | NE (1.45, NE) | NE (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4081 | |
| HR (95% CI) [c] | 1.716 (0.481, 6.123) | |
| HR P-Value [c] | 0.4057 | |
| Heterogeneity p-value [d] | 0.9827 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.7 (34.6, 81.5) | 64.2 (27.8, 85.8) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 11 (14.5%) | 6 (9.1%) |
| Censored Patients, n (%) | 65 (85.5%) | 60 (90.9%) |
| Median (95% CI), (Months) [a] | 13.31 (4.21, NE) | NE (4.37, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8830 | |
| HR (95% CI) [c] | 0.925 (0.327, 2.613) | |
| HR P-Value [c] | 0.8827 | |
| Heterogeneity p-value [d] | 0.8338 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.9 (40.4, 78.9) | 69.9 (40.0, 86.9) |
| 12 months | 62.9 (40.4, 78.9) | NE (NE, NE) |
| 18 months | 31.4 (6.0, 62.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 15 (19.7%) | 7 (10.6%) |
| Censored Patients, n (%) | 61 (80.3%) | 59 (89.4%) |
| Median (95% CI), (Months) [a] | 14.09 (6.97, NE) | 6.28 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6323 | |
| HR (95% CI) [c] | 0.802 (0.310, 2.078) | |
| HR P-Value [c] | 0.6500 | |
| Heterogeneity p-value [d] | 0.9245 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.9 (51.0, 82.7) | 62.3 (33.1, 81.7) |
| 12 months | 59.8 (38.8, 75.7) | NE (NE, NE) |
| 18 months | 30.4 (7.3, 58.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 14 (18.4%) | 8 (12.1%) |
| Censored Patients, n (%) | 62 (81.6%) | 58 (87.9%) |
| Median (95% CI), (Months) [a] | 9.72 (1.84, NE) | 4.27 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9324 | |
| HR (95% CI) [c] | 0.957 (0.394, 2.327) | |
| HR P-Value [c] | 0.9235 | |
| Heterogeneity p-value [d] | 0.5403 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.4 (33.5, 72.7) | 47.6 (20.5, 70.6) |
| 12 months | 36.0 (15.3, 57.3) | 47.6 (20.5, 70.6) |
| 18 months | 36.0 (15.3, 57.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 9 (11.8%) | 6 (9.1%) |
| Censored Patients, n (%) | 67 (88.2%) | 60 (90.9%) |
| Median (95% CI), (Months) [a] | 9.72 (1.45, 14.26) | 4.40 (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4322 | |
| HR (95% CI) [c] | 0.654 (0.217, 1.970) | |
| HR P-Value [c] | 0.4503 | |
| Heterogeneity p-value [d] | 0.6155 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.7 (42.5, 88.8) | 50.0 (18.4, 75.3) |
| 12 months | 28.3 (5.0, 58.6) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 12 (15.8%) | 3 (4.5%) |
| Censored Patients, n (%) | 64 (84.2%) | 63 (95.5%) |
| | | |
| Median (95% CI), (Months) [a] | 9.72 (2.99, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2064 | |
| HR (95% CI) [c] | 2.244 (0.620, 8.119) | |
| HR P-Value [c] | 0.2179 | |
| Heterogeneity p-value [d] | 0.2449 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.7 (41.5, 80.6) | 81.1 (51.4, 93.6) |
| 12 months | 33.0 (10.4, 58.0) | 81.1 (51.4, 93.6) |
| 18 months | 33.0 (10.4, 58.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 9 (11.8%) | 6 (9.1%) |
| Censored Patients, n (%) | 67 (88.2%) | 60 (90.9%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3956 | |
| HR (95% CI) [c] | 0.629 (0.217, 1.828) | |
| HR P-Value [c] | 0.3943 | |
| Heterogeneity p-value [d] | 0.1777 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.7 (68.5, 93.9) | 72.3 (44.5, 87.8) |
| 12 months | 66.2 (39.4, 83.3) | 63.3 (33.7, 82.4) |
| 18 months | 55.1 (25.7, 77.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 19 (25.0%) | 9 (13.6%) |
| Censored Patients, n (%) | 57 (75.0%) | 57 (86.4%) |
| Median (95% CI), (Months) [a] | NE (7.43, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4963 | |
| HR (95% CI) [c] | 1.328 (0.595, 2.963) | |
| HR P-Value [c] | 0.4882 | |
| Heterogeneity p-value [d] | 0.8809 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.2 (56.6, 81.7) | 77.8 (60.0, 88.4) |
| 12 months | 55.8 (37.6, 70.6) | 62.2 (27.6, 83.9) |
| 18 months | 55.8 (37.6, 70.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 11 (14.5%) | 9 (13.6%) |
| Censored Patients, n (%) | 65 (85.5%) | 57 (86.4%) |
| Median (95% CI), (Months) [a] | 14.95 (4.14, NE) | 8.97 (1.81, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6211 | |
| HR (95% CI) [c] | 0.795 (0.318, 1.983) | |
| HR P-Value [c] | 0.6221 | |
| Heterogeneity p-value [d] | 0.8493 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.7 (41.4, 79.4) | 66.1 (43.4, 81.4) |
| 12 months | 63.7 (41.4, 79.4) | 44.1 (9.9, 74.8) |
| 18 months | 39.8 (12.9, 66.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 11 (14.5%) | 4 (6.1%) |
| Censored Patients, n (%) | 65 (85.5%) | 62 (93.9%) |
| Median (95% CI), (Months) [a] | 6.97 (1.64, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5805 | |
| HR (95% CI) [c] | 1.389 (0.430, 4.491) | |
| HR P-Value [c] | 0.5829 | |
| Heterogeneity p-value [d] | 0.1690 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.0 (29.8, 74.5) | 56.8 (21.3, 81.3) |
| 12 months | 40.7 (17.4, 63.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 21 (27.6%) | 8 (12.1%) |
| Censored Patients, n (%) | 55 (72.4%) | 58 (87.9%) |
| Median (95% CI), (Months) [a] | 10.45 (5.85, NE) | NE (2.89, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5426 | |
| HR (95% CI) [c] | 1.296 (0.566, 2.972) | |
| HR P-Value [c] | 0.5397 | |
| Heterogeneity p-value [d] | 0.9878 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.6 (47.7, 77.2) | 71.2 (50.0, 84.7) |
| 12 months | 40.2 (21.4, 58.4) | 71.2 (50.0, 84.7) |
| 18 months | 30.2 (10.8, 52.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 14 (18.4%) | 4 (6.1%) |
| Censored Patients, n (%) | 62 (81.6%) | 62 (93.9%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2191 | |
| HR (95% CI) [c] | 1.996 (0.649, 6.144) | |
| HR P-Value [c] | 0.2280 | |
| Heterogeneity p-value [d] | 0.9402 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.5 (52.4, 82.8) | 87.6 (64.6, 96.1) |
| 12 months | 62.2 (42.6, 76.7) | 76.7 (43.2, 91.9) |
| 18 months | 53.3 (29.9, 72.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 14 (18.4%) | 4 (6.1%) |
| Censored Patients, n (%) | 62 (81.6%) | 62 (93.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1593 | |
| HR (95% CI) [c] | 2.186 (0.716, 6.679) | |
| HR P-Value [c] | 0.1698 | |
| Heterogeneity p-value [d] | 0.4603 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.4 (63.4, 86.6) | 90.5 (72.6, 96.9) |
| 12 months | 70.0 (53.3, 81.7) | 79.2 (45.1, 93.4) |
| 18 months | 70.0 (53.3, 81.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 20 (26.3%) | 5 (7.6%) |
| Censored Patients, n (%) | 56 (73.7%) | 61 (92.4%) |
| Median (95% CI), (Months) [a] | 6.97 (2.33, NE) | NE (6.28, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0344 | |
| HR (95% CI) [c] | 2.767 (1.038, 7.376) | |
| HR P-Value [c] | 0.0418 | |
| Heterogeneity p-value [d] | 0.3916 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.4 (36.6, 67.6) | 83.2 (59.4, 93.7) |
| 12 months | 49.3 (32.1, 64.4) | 74.9 (46.5, 89.6) |
| 18 months | 49.3 (32.1, 64.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 17 (22.4%) | 11 (16.7%) |
| Censored Patients, n (%) | 59 (77.6%) | 55 (83.3%) |
| Median (95% CI), (Months) [a] | 8.61 (3.09, NE) | 7.26 (2.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7796 | |
| HR (95% CI) [c] | 0.896 (0.416, 1.929) | |
| HR P-Value [c] | 0.7783 | |
| Heterogeneity p-value [d] | 0.0791 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.9 (43.3, 76.0) | 64.9 (42.6, 80.3) |
| 12 months | 45.1 (24.6, 63.5) | 44.5 (18.0, 68.2) |
| 18 months | 33.8 (12.1, 57.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 17 (22.4%) | 7 (10.6%) |
| Censored Patients, n (%) | 59 (77.6%) | 59 (89.4%) |
| Median (95% CI), (Months) [a] | 7.23 (3.09, NE) | NE (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2941 | |
| HR (95% CI) [c] | 1.613 (0.663, 3.926) | |
| HR P-Value [c] | 0.2922 | |
| Heterogeneity p-value [d] | 0.9827 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.0 (40.1, 73.8) | 73.4 (49.1, 87.4) |
| 12 months | 42.3 (21.9, 61.4) | 61.2 (29.9, 81.8) |
| 18 months | 42.3 (21.9, 61.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 12 (20.3%) | 10 (17.9%) |
| Censored Patients, n (%) | 47 (79.7%) | 46 (82.1%) |
| Median (95% CI), (Months) [a] | 2.83 (1.45, NE) | NE (1.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2993 | |
| HR (95% CI) [c] | 1.583 (0.664, 3.775) | |
| HR P-Value [c] | 0.3001 | |
| Heterogeneity p-value [d] | 0.8338 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 39.4 (15.2, 63.0) | 52.1 (28.0, 71.6) |
| 12 months | 39.4 (15.2, 63.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 7 (11.9%) | 7 (12.5%) |
| Censored Patients, n (%) | 52 (88.1%) | 49 (87.5%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (4.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6892 | |
| HR (95% CI) [c] | 1.229 (0.430, 3.510) | |
| HR P-Value [c] | 0.6998 | |
| Heterogeneity p-value [d] | 0.9245 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.5 (40.1, 82.2) | 63.8 (36.8, 81.7) |
| 12 months | 65.5 (40.1, 82.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 7 (11.9%) | 6 (10.7%) |
| Censored Patients, n (%) | 52 (88.1%) | 50 (89.3%) |
| Median (95% CI), (Months) [a] | 11.10 (2.99, NE) | NE (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7729 | |
| HR (95% CI) [c] | 0.846 (0.272, 2.630) | |
| HR P-Value [c] | 0.7726 | |
| Heterogeneity p-value [d] | 0.5403 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.3 (38.9, 83.6) | 65.7 (37.5, 83.5) |
| 12 months | 33.2 (1.8, 73.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 6 (10.2%) | 0 |
| Censored Patients, n (%) | 53 (89.8%) | 56 (100.0%) |
| Median (95% CI), (Months) [a] | 3.45 (1.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | NE | |
| HR (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NE | |
| Heterogeneity p-value [d] | 0.6155 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (7.8, 62.3) | NE (NE, NE) |
| 12 months | 33.3 (7.8, 62.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 10 (16.9%) | 4 (7.1%) |
| Censored Patients, n (%) | 49 (83.1%) | 52 (92.9%) |
| Median (95% CI), (Months) [a] | 4.21 (1.45, 8.48) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0340 | |
| HR (95% CI) [c] | 3.312 (1.032, 10.629) | |
| HR P-Value [c] | 0.0442 | |
| Heterogeneity p-value [d] | 0.2449 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.3 (5.0, 57.0) | 74.5 (45.4, 89.6) |
| 12 months | 13.7 (0.8, 44.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 13 (22.0%) | 3 (5.4%) |
| Censored Patients, n (%) | 46 (78.0%) | 53 (94.6%) |
| Median (95% CI), (Months) [a] | 6.97 (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0260 | |
| HR (95% CI) [c] | 3.752 (1.068, 13.178) | |
| HR P-Value [c] | 0.0391 | |
| Heterogeneity p-value [d] | 0.1777 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.2 (33.3, 72.6) | 90.0 (72.1, 96.7) |
| 12 months | 49.7 (27.9, 68.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 12 (20.3%) | 8 (14.3%) |
| Censored Patients, n (%) | 47 (79.7%) | 48 (85.7%) |
| Median (95% CI), (Months) [a] | 12.65 (4.34, NE) | 14.69 (7.10, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5569 | |
| HR (95% CI) [c] | 1.323 (0.529, 3.311) | |
| HR P-Value [c] | 0.5496 | |
| Heterogeneity p-value [d] | 0.8809 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.8 (48.4, 82.4) | 83.4 (64.1, 92.9) |
| 12 months | 61.1 (37.6, 78.1) | 62.6 (30.8, 83.0) |
| 18 months | 48.9 (21.2, 71.9) | 0.0 (NE, NE) |
| 24 months | 48.9 (21.2, 71.9) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 9 (15.3%) | 6 (10.7%) |
| Censored Patients, n (%) | 50 (84.7%) | 50 (89.3%) |
| Median (95% CI), (Months) [a] | NE (2.92, NE) | NE (8.80, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5054 | |
| HR (95% CI) [c] | 1.422 (0.506, 3.998) | |
| HR P-Value [c] | 0.5044 | |
| Heterogeneity p-value [d] | 0.8493 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (47.2, 82.3) | 79.6 (57.4, 91.1) |
| 12 months | 68.2 (47.2, 82.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 9 (15.3%) | 8 (14.3%) |
| Censored Patients, n (%) | 50 (84.7%) | 48 (85.7%) |
| Median (95% CI), (Months) [a] | 5.59 (1.45, NE) | 4.47 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6769 | |
| HR (95% CI) [c] | 1.222 (0.468, 3.192) | |
| HR P-Value [c] | 0.6818 | |
| Heterogeneity p-value [d] | 0.1690 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.4 (7.1, 65.1) | 45.3 (19.1, 68.5) |
| 12 months | 17.2 (1.0, 51.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 16 (27.1%) | 16 (28.6%) |
| Censored Patients, n (%) | 43 (72.9%) | 40 (71.4%) |
| Median (95% CI), (Months) [a] | 12.65 (1.58, NE) | 6.74 (4.27, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6773 | |
| HR (95% CI) [c] | 1.190 (0.586, 2.415) | |
| HR P-Value [c] | 0.6303 | |
| Heterogeneity p-value [d] | 0.9878 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.7 (35.1, 70.6) | 54.1 (35.0, 69.8) |
| 12 months | 54.7 (35.1, 70.6) | NE (NE, NE) |
| 18 months | 43.7 (20.0, 65.4) | NE (NE, NE) |
| 24 months | 43.7 (20.0, 65.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 9 (15.3%) | 4 (7.1%) |
| Censored Patients, n (%) | 50 (84.7%) | 52 (92.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1054 | |
| HR (95% CI) [c] | 2.562 (0.787, 8.337) | |
| HR P-Value [c] | 0.1181 | |
| Heterogeneity p-value [d] | 0.9402 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.5 (50.9, 84.7) | 89.2 (69.7, 96.5) |
| 12 months | 71.5 (50.9, 84.7) | NE (NE, NE) |
| 18 months | 71.5 (50.9, 84.7) | NE (NE, NE) |
| 24 months | 71.5 (50.9, 84.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 14 (23.7%) | 6 (10.7%) |
| Censored Patients, n (%) | 45 (76.3%) | 50 (89.3%) |
| Median (95% CI), (Months) [a] | 15.41 (6.01, NE) | NE (9.59, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1549 | |
| HR (95% CI) [c] | 2.017 (0.763, 5.334) | |
| HR P-Value [c] | 0.1571 | |
| Heterogeneity p-value [d] | 0.4603 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.0 (56.1, 84.3) | 83.4 (63.6, 92.9) |
| 12 months | 62.7 (42.3, 77.7) | NE (NE, NE) |
| 18 months | 41.8 (9.9, 72.0) | NE (NE, NE) |
| 24 months | 41.8 (9.9, 72.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 15 (25.4%) | 5 (8.9%) |
| Censored Patients, n (%) | 44 (74.6%) | 51 (91.1%) |
| Median (95% CI), (Months) [a] | 11.10 (2.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0700 | |
| HR (95% CI) [c] | 2.514 (0.893, 7.079) | |
| HR P-Value [c] | 0.0810 | |
| Heterogeneity p-value [d] | 0.3916 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.9 (39.6, 75.4) | 82.3 (61.8, 92.4) |
| 12 months | 43.7 (20.5, 64.9) | NE (NE, NE) |
| 18 months | 21.9 (1.8, 56.4) | NE (NE, NE) |
| 24 months | 21.9 (1.8, 56.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 16 (27.1%) | 6 (10.7%) |
| Censored Patients, n (%) | 43 (72.9%) | 50 (89.3%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0041 | |
| HR (95% CI) [c] | 3.683 (1.430, 9.490) | |
| HR P-Value [c] | 0.0069 | |
| Heterogeneity p-value [d] | 0.0791 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.1 (25.7, 62.7) | 78.7 (55.9, 90.6) |
| 12 months | 30.1 (7.8, 56.8) | NE (NE, NE) |
| 18 months | 30.1 (7.8, 56.8) | NE (NE, NE) |
| 24 months | 30.1 (7.8, 56.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 10 (16.9%) | 6 (10.7%) |
| Censored Patients, n (%) | 49 (83.1%) | 50 (89.3%) |
| Median (95% CI), (Months) [a] | 12.58 (2.86, NE) | NE (5.88, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6477 | |
| HR (95% CI) [c] | 1.266 (0.450, 3.562) | |
| HR P-Value [c] | 0.6550 | |
| Heterogeneity p-value [d] | 0.9827 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.1 (42.0, 79.7) | 71.6 (41.0, 88.2) |
| 12 months | 64.1 (42.0, 79.7) | NE (NE, NE) |
| 18 months | 48.1 (17.3, 73.7) | NE (NE, NE) |
| 24 months | 48.1 (17.3, 73.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 28 (17.4%) | 17 (12.4%) |
| Censored Patients, n (%) | 133 (82.6%) | 120 (87.6%) |
| Median (95% CI), (Months) [a] | 12.52 (4.21, NE) | NE (4.37, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6685 | |
| HR (95% CI) [c] | 1.145 (0.621, 2.110) | |
| HR P-Value [c] | 0.6640 | |
| Heterogeneity p-value [d] | 0.3949 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.8 (43.4, 69.8) | 60.9 (43.3, 74.6) |
| 12 months | 52.1 (35.0, 66.6) | 55.4 (36.2, 70.9) |
| 18 months | 29.7 (11.3, 51.0) | NE (NE, NE) |
| 24 months | 29.7 (11.3, 51.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 26 (16.1%) | 13 (9.5%) |
| Censored Patients, n (%) | 135 (83.9%) | 124 (90.5%) |
| Median (95% CI), (Months) [a] | 17.97 (8.61, NE) | NE (6.28, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8844 | |
| HR (95% CI) [c] | 1.057 (0.532, 2.101) | |
| HR P-Value [c] | 0.8737 | |
| Heterogeneity p-value [d] | 0.1861 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.3 (58.5, 80.7) | 70.7 (53.7, 82.4) |
| 12 months | 58.7 (42.9, 71.6) | NE (NE, NE) |
| 18 months | 40.2 (19.0, 60.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 26 (16.1%) | 14 (10.2%) |
| Censored Patients, n (%) | 135 (83.9%) | 123 (89.8%) |
| | | |
| Median (95% CI), (Months) [a] | 9.72 (5.72, NE) | NE (3.12, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9844 | |
| HR (95% CI) [c] | 0.993 (0.514, 1.918) | |
| HR P-Value [c] | 0.9836 | |
| Heterogeneity p-value [d] | 0.5243 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.0 (47.8, 74.8) | 58.6 (39.4, 73.6) |
| 12 months | 40.6 (22.5, 58.0) | 58.6 (39.4, 73.6) |
| 18 months | 33.8 (15.8, 53.0) | NE (NE, NE) |
| 24 months | 33.8 (15.8, 53.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 20 (12.4%) | 8 (5.8%) |
| Censored Patients, n (%) | 141 (87.6%) | 129 (94.2%) |
| Median (95% CI), (Months) [a] | 4.21 (1.58, 11.40) | 2.33 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9113 | |
| HR (95% CI) [c] | 0.955 (0.413, 2.209) | |
| HR P-Value [c] | 0.9141 | |
| Heterogeneity p-value [d] | 0.3343 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.4 (29.5, 64.9) | 48.5 (21.0, 71.5) |
| 12 months | 23.4 (7.2, 44.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 27 (16.8%) | 11 (8.0%) |
| Censored Patients, n (%) | 134 (83.2%) | 126 (92.0%) |
| | | |
| Median (95% CI), (Months) [a] | 8.34 (2.99, 11.83) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0923 | |
| HR (95% CI) [c] | 1.837 (0.898, 3.758) | |
| HR P-Value [c] | 0.0956 | |
| Heterogeneity p-value [d] | 0.7042 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.4 (40.4, 69.7) | 70.2 (51.0, 83.1) |
| 12 months | 29.8 (13.3, 48.3) | 70.2 (51.0, 83.1) |
| 18 months | 22.3 (7.3, 42.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 28 (17.4%) | 14 (10.2%) |
| Censored Patients, n (%) | 133 (82.6%) | 123 (89.8%) |
| Median (95% CI), (Months) [a] | NE (8.97, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8590 | |
| HR (95% CI) [c] | 1.064 (0.555, 2.040) | |
| HR P-Value [c] | 0.8519 | |
| Heterogeneity p-value [d] | 0.6600 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.2 (58.9, 80.3) | 73.1 (56.2, 84.3) |
| 12 months | 56.7 (41.1, 69.6) | 60.7 (38.1, 77.2) |
| 18 months | 51.6 (34.4, 66.3) | NE (NE, NE) |
| 24 months | 51.6 (34.4, 66.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 34 (21.1%) | 17 (12.4%) |
| Censored Patients, n (%) | 127 (78.9%) | 120 (87.6%) |
| Median (95% CI), (Months) [a] | 21.88 (12.65, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2517 | |
| HR (95% CI) [c] | 1.416 (0.784, 2.556) | |
| HR P-Value [c] | 0.2489 | |
| Heterogeneity p-value [d] | 0.8085 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.1 (64.2, 81.7) | 78.8 (67.1, 86.7) |
| 12 months | 63.0 (50.1, 73.4) | 74.1 (58.9, 84.4) |
| 18 months | 59.8 (46.0, 71.2) | NE (NE, NE) |
| 24 months | 49.9 (28.2, 68.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 24 (14.9%) | 15 (10.9%) |
| Censored Patients, n (%) | 137 (85.1%) | 122 (89.1%) |
| Median (95% CI), (Months) [a] | NE (5.59, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6726 | |
| HR (95% CI) [c] | 1.151 (0.598, 2.215) | |
| HR P-Value [c] | 0.6744 | |
| Heterogeneity p-value [d] | 0.4472 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.6 (47.1, 73.2) | 70.7 (56.0, 81.3) |
| 12 months | 61.6 (47.1, 73.2) | 70.7 (56.0, 81.3) |
| 18 months | 50.8 (32.5, 66.5) | NE (NE, NE) |
| 24 months | 50.8 (32.5, 66.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 22 (13.7%) | 12 (8.8%) |
| Censored Patients, n (%) | 139 (86.3%) | 125 (91.2%) |
| Median (95% CI), (Months) [a] | 6.97 (2.07, 25.53) | NE (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5972 | |
| HR (95% CI) [c] | 1.212 (0.590, 2.489) | |
| HR P-Value [c] | 0.6006 | |
| Heterogeneity p-value [d] | 0.1901 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.5 (33.9, 66.6) | 53.3 (31.2, 71.2) |
| 12 months | 42.5 (24.6, 59.4) | NE (NE, NE) |
| 18 months | 35.5 (17.0, 54.5) | NE (NE, NE) |
| 24 months | 35.5 (17.0, 54.5) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 44 (27.3%) | 27 (19.7%) |
| Censored Patients, n (%) | 117 (72.7%) | 110 (80.3%) |
| Median (95% CI), (Months) [a] | 11.17 (5.85, NE) | NE (5.39, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6053 | |
| HR (95% CI) [c] | 1.148 (0.706, 1.868) | |
| HR P-Value [c] | 0.5780 | |
| Heterogeneity p-value [d] | 0.9854 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.7 (48.3, 69.4) | 60.5 (46.7, 71.8) |
| 12 months | 48.7 (35.2, 60.9) | 54.3 (39.4, 67.0) |
| 18 months | 34.9 (19.1, 51.2) | NE (NE, NE) |
| 24 months | 34.9 (19.1, 51.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 29 (18.0%) | 10 (7.3%) |
| Censored Patients, n (%) | 132 (82.0%) | 127 (92.7%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0467 | |
| HR (95% CI) [c] | 2.054 (0.996, 4.236) | |
| HR P-Value [c] | 0.0513 | |
| Heterogeneity p-value [d] | 0.9894 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.9 (60.4, 80.6) | 86.1 (73.5, 93.0) |
| 12 months | 61.8 (47.8, 73.1) | 77.7 (59.9, 88.3) |
| 18 months | 56.7 (40.2, 70.1) | NE (NE, NE) |
| 24 months | 56.7 (40.2, 70.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 34 (21.1%) | 14 (10.2%) |
| Censored Patients, n (%) | 127 (78.9%) | 123 (89.8%) |
| Median (95% CI), (Months) [a] | NE (15.41, NE) | NE (9.59, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0992 | |
| HR (95% CI) [c] | 1.691 (0.903, 3.165) | |
| HR P-Value [c] | 0.1007 | |
| Heterogeneity p-value [d] | 0.3593 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.6 (62.8, 80.2) | 85.4 (74.6, 91.8) |
| 12 months | 67.5 (56.7, 76.2) | 69.5 (46.8, 84.0) |
| 18 months | 63.3 (49.9, 74.1) | NE (NE, NE) |
| 24 months | 63.3 (49.9, 74.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 40 (24.8%) | 10 (7.3%) |
| Censored Patients, n (%) | 121 (75.2%) | 127 (92.7%) |
| Median (95% CI), (Months) [a] | 11.10 (5.06, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0074 | |
| HR (95% CI) [c] | 2.511 (1.252, 5.037) | |
| HR P-Value [c] | 0.0095 | |
| Heterogeneity p-value [d] | 0.0693 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.6 (46.7, 68.6) | 83.6 (70.4, 91.2) |
| 12 months | 48.1 (34.6, 60.4) | 79.2 (62.9, 88.9) |
| 18 months | 44.7 (30.7, 57.7) | NE (NE, NE) |
| 24 months | 44.7 (30.7, 57.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 38 (23.6%) | 20 (14.6%) |
| Censored Patients, n (%) | 123 (76.4%) | 117 (85.4%) |
| Median (95% CI), (Months) [a] | 8.34 (2.96, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1913 | |
| HR (95% CI) [c] | 1.436 (0.833, 2.473) | |
| HR P-Value [c] | 0.1925 | |
| Heterogeneity p-value [d] | 0.7625 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.0 (40.4, 64.1) | 67.3 (52.1, 78.6) |
| 12 months | 44.4 (30.8, 57.2) | 51.3 (31.4, 68.0) |
| 18 months | 39.5 (24.7, 53.9) | NE (NE, NE) |
| 24 months | 39.5 (24.7, 53.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 29 (18.0%) | 14 (10.2%) |
| Censored Patients, n (%) | 132 (82.0%) | 123 (89.8%) |
| Median (95% CI), (Months) [a] | NE (4.96, NE) | NE (5.88, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1147 | |
| HR (95% CI) [c] | 1.665 (0.879, 3.153) | |
| HR P-Value [c] | 0.1174 | |
| Heterogeneity p-value [d] | 0.8798 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.2 (44.3, 69.7) | 67.2 (48.8, 80.2) |
| 12 months | 51.4 (36.3, 64.6) | 67.2 (48.8, 80.2) |
| 18 months | 51.4 (36.3, 64.6) | NE (NE, NE) |
| 24 months | 51.4 (36.3, 64.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 3 (6.5%) |
| Censored Patients, n (%) | 32 (91.4%) | 43 (93.5%) |
| Median (95% CI), (Months) [a] | NE (1.41, NE) | NE (2.69, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2199 | |
| HR (95% CI) [c] | 2.648 (0.530, 13.241) | |
| HR P-Value [c] | 0.2356 | |
| Heterogeneity p-value [d] | 0.3949 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (11.1, 80.4) | 77.5 (44.8, 92.3) |
| 12 months | 50.0 (11.1, 80.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 6 (13.0%) |
| Censored Patients, n (%) | 33 (94.3%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | 5.65 (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2357 | |
| HR (95% CI) [c] | 0.390 (0.078, 1.941) | |
| HR P-Value [c] | 0.2502 | |
| Heterogeneity p-value [d] | 0.1861 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.3 (48.2, 95.6) | 46.3 (14.1, 73.9) |
| 12 months | 83.3 (48.2, 95.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 7 (15.2%) |
| Censored Patients, n (%) | 31 (88.6%) | 39 (84.8%) |
| Median (95% CI), (Months) [a] | 10.45 (1.45, NE) | NE (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4198 | |
| HR (95% CI) [c] | 0.574 (0.147, 2.243) | |
| HR P-Value [c] | 0.4244 | |
| Heterogeneity p-value [d] | 0.5243 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.0 (20.2, 85.8) | 50.0 (20.2, 74.1) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 5 (10.9%) |
| Censored Patients, n (%) | 32 (91.4%) | 41 (89.1%) |
| Median (95% CI), (Months) [a] | 6.11 (1.45, NE) | 1.54 (1.45, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3717 | |
| HR (95% CI) [c] | 0.554 (0.130, 2.354) | |
| HR P-Value [c] | 0.4232 | |
| Heterogeneity p-value [d] | 0.3343 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.0 (12.6, 88.2) | 20.0 (0.8, 58.2) |
| 12 months | 30.0 (1.2, 71.9) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 2 (4.3%) |
| Censored Patients, n (%) | 32 (91.4%) | 44 (95.7%) |
| Median (95% CI), (Months) [a] | 8.48 (1.54, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7804 | |
| HR (95% CI) [c] | 1.291 (0.213, 7.834) | |
| HR P-Value [c] | 0.7810 | |
| Heterogeneity p-value [d] | 0.7042 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.0 (22.5, 91.8) | 75.0 (31.5, 93.1) |
| 12 months | 46.7 (7.1, 80.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 3 (6.5%) |
| Censored Patients, n (%) | 33 (94.3%) | 43 (93.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8698 | |
| HR (95% CI) [c] | 0.863 (0.144, 5.170) | |
| HR P-Value [c] | 0.8722 | |
| Heterogeneity p-value [d] | 0.6600 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.2 (55.0, 96.4) | 80.9 (50.9, 93.5) |
| 12 months | 86.2 (55.0, 96.4) | 80.9 (50.9, 93.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 5 (14.3%) | 5 (10.9%) |
| Censored Patients, n (%) | 30 (85.7%) | 41 (89.1%) |
| Median (95% CI), (Months) [a] | 11.10 (4.34, NE) | 8.97 (7.10, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9690 | |
| HR (95% CI) [c] | 0.976 (0.280, 3.401) | |
| HR P-Value [c] | 0.9690 | |
| Heterogeneity p-value [d] | 0.8085 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.9 (44.2, 89.4) | 90.5 (67.0, 97.5) |
| 12 months | 49.2 (9.4, 80.9) | 48.3 (7.5, 81.4) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 5 (10.9%) |
| Censored Patients, n (%) | 33 (94.3%) | 41 (89.1%) |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | 8.80 (8.80, 8.97) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2408 | |
| HR (95% CI) [c] | 0.354 (0.060, 2.101) | |
| HR P-Value [c] | 0.2532 | |
| Heterogeneity p-value [d] | 0.4472 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.8 (42.3, 94.9) | 80.8 (51.4, 93.4) |
| 12 months | 80.8 (42.3, 94.9) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 6 (13.0%) |
| Censored Patients, n (%) | 33 (94.3%) | 40 (87.0%) |
| Median (95% CI), (Months) [a] | 7.92 (1.45, NE) | 2.22 (1.45, 2.83) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1373 | |
| HR (95% CI) [c] | 0.230 (0.026, 2.018) | |
| HR P-Value [c] | 0.1848 | |
| Heterogeneity p-value [d] | 0.1901 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (12.8, 96.1) | 0.0 (NE, NE) |
| 12 months | 37.5 (1.1, 80.8) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 6 (17.1%) | 7 (15.2%) |
| Censored Patients, n (%) | 29 (82.9%) | 39 (84.8%) |
| Median (95% CI), (Months) [a] | 10.45 (1.64, NE) | NE (5.22, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9102 | |
| HR (95% CI) [c] | 1.063 (0.351, 3.225) | |
| HR P-Value [c] | 0.9135 | |
| Heterogeneity p-value [d] | 0.9854 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.0 (41.1, 88.6) | 67.2 (40.8, 83.8) |
| 12 months | 49.4 (18.1, 74.7) | 67.2 (40.8, 83.8) |
| 18 months | NE (NE, NE) | 67.2 (40.8, 83.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 0 |
| Censored Patients, n (%) | 33 (94.3%) | 46 (100.0%) |
| Median (95% CI), (Months) [a] | NE (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1745 | |
| HR (95% CI) [c] | 75128195 (0.000, NE) | |
| HR P-Value [c] | 0.9977 | |
| Heterogeneity p-value [d] | 0.9894 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.1 (44.4, 95.3) | 100.0 (100.0, 100.0) |
| 12 months | 82.1 (44.4, 95.3) | 100.0 (100.0, 100.0) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 3 (6.5%) |
| Censored Patients, n (%) | 33 (94.3%) | 43 (93.5%) |
| Median (95% CI), (Months) [a] | NE (8.44, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6041 | |
| HR (95% CI) [c] | 0.617 (0.098, 3.882) | |
| HR P-Value [c] | 0.6071 | |
| Heterogeneity p-value [d] | 0.3593 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.1 (65.0, 99.1) | 86.3 (62.8, 95.4) |
| 12 months | 82.4 (42.6, 95.7) | 86.3 (62.8, 95.4) |
| 18 months | 82.4 (42.6, 95.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 5 (10.9%) |
| Censored Patients, n (%) | 33 (94.3%) | 41 (89.1%) |
| Median (95% CI), (Months) [a] | 13.83 (NE, NE) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2071 | |
| HR (95% CI) [c] | 0.274 (0.032, 2.357) | |
| HR P-Value [c] | 0.2385 | |
| Heterogeneity p-value [d] | 0.0693 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 67.8 (37.7, 85.6) |
| 12 months | 91.7 (53.9, 98.8) | 67.8 (37.7, 85.6) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 4 (8.7%) |
| Censored Patients, n (%) | 31 (88.6%) | 42 (91.3%) |
| Median (95% CI), (Months) [a] | 8.44 (1.41, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4497 | |
| HR (95% CI) [c] | 1.728 (0.423, 7.058) | |
| HR P-Value [c] | 0.4464 | |
| Heterogeneity p-value [d] | 0.7625 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.7 (37.1, 90.3) | 76.6 (48.8, 90.5) |
| 12 months | 48.5 (8.8, 80.6) | 76.6 (48.8, 90.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 6 (17.1%) | 4 (8.7%) |
| Censored Patients, n (%) | 29 (82.9%) | 42 (91.3%) |
| Median (95% CI), (Months) [a] | 12.58 (1.58, NE) | 8.48 (7.03, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9554 | |
| HR (95% CI) [c] | 0.960 (0.233, 3.962) | |
| HR P-Value [c] | 0.9554 | |
| Heterogeneity p-value [d] | 0.8798 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (40.6, 88.2) | 85.2 (51.9, 96.2) |
| 12 months | 59.5 (26.5, 81.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 16 (18.0%) | 6 (7.1%) |
| Censored Patients, n (%) | 73 (82.0%) | 79 (92.9%) |
| Median (95% CI), (Months) [a] | 12.52 (3.91, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3132 | |
| HR (95% CI) [c] | 1.630 (0.632, 4.203) | |
| HR P-Value [c] | 0.3124 | |
| Heterogeneity p-value [d] | 0.6819 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.1 (35.0, 69.8) | 66.3 (35.4, 85.0) |
| 12 months | 54.1 (35.0, 69.8) | NE (NE, NE) |
| 18 months | 40.6 (15.5, 64.7) | NE (NE, NE) |
| 24 months | 40.6 (15.5, 64.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 10 (11.2%) | 10 (11.8%) |
| Censored Patients, n (%) | 79 (88.8%) | 75 (88.2%) |
| Median (95% CI), (Months) [a] | 17.97 (14.09, NE) | 5.65 (1.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0770 | |
| HR (95% CI) [c] | 0.443 (0.175, 1.126) | |
| HR P-Value [c] | 0.0873 | |
| Heterogeneity p-value [d] | 0.0490 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.3 (57.3, 87.7) | 49.0 (23.2, 70.5) |
| 12 months | 76.3 (57.3, 87.7) | NE (NE, NE) |
| 18 months | 32.7 (1.8, 73.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 13 (14.6%) | 7 (8.2%) |
| Censored Patients, n (%) | 76 (85.4%) | 78 (91.8%) |
| Median (95% CI), (Months) [a] | 10.45 (4.96, NE) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6942 | |
| HR (95% CI) [c] | 0.821 (0.315, 2.140) | |
| HR P-Value [c] | 0.6869 | |
| Heterogeneity p-value [d] | 0.9981 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.9 (41.0, 78.6) | 62.4 (34.8, 81.1) |
| 12 months | 31.8 (7.3, 60.5) | NE (NE, NE) |
| 18 months | 31.8 (7.3, 60.5) | NE (NE, NE) |
| 24 months | 31.8 (7.3, 60.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 13 (14.6%) | 7 (8.2%) |
| Censored Patients, n (%) | 76 (85.4%) | 78 (91.8%) |
| Median (95% CI), (Months) [a] | 2.83 (1.48, 6.97) | 2.30 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8916 | |
| HR (95% CI) [c] | 0.959 (0.381, 2.413) | |
| HR P-Value [c] | 0.9298 | |
| Heterogeneity p-value [d] | 0.6996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.4 (19.6, 62.1) | 37.9 (10.1, 66.3) |
| 12 months | 24.9 (7.1, 48.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 14 (15.7%) | 5 (5.9%) |
| Censored Patients, n (%) | 75 (84.3%) | 80 (94.1%) |
| Median (95% CI), (Months) [a] | 8.97 (2.99, NE) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5788 | |
| HR (95% CI) [c] | 1.357 (0.465, 3.960) | |
| HR P-Value [c] | 0.5760 | |
| Heterogeneity p-value [d] | 0.6599 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.0 (41.7, 79.6) | 69.8 (41.7, 86.2) |
| 12 months | 36.2 (12.8, 60.6) | NE (NE, NE) |
| 18 months | 18.1 (1.4, 50.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 16 (18.0%) | 7 (8.2%) |
| Censored Patients, n (%) | 73 (82.0%) | 78 (91.8%) |
| Median (95% CI), (Months) [a] | 16.39 (6.97, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8820 | |
| HR (95% CI) [c] | 1.071 (0.434, 2.638) | |
| HR P-Value [c] | 0.8823 | |
| Heterogeneity p-value [d] | 0.9389 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.2 (55.6, 83.4) | 76.2 (53.5, 88.9) |
| 12 months | 59.6 (40.3, 74.5) | 66.7 (38.6, 84.2) |
| 18 months | 44.7 (16.9, 69.4) | NE (NE, NE) |
| 24 months | 44.7 (16.9, 69.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 20 (22.5%) | 9 (10.6%) |
| Censored Patients, n (%) | 69 (77.5%) | 76 (89.4%) |
| Median (95% CI), (Months) [a] | 21.88 (12.65, NE) | 8.97 (8.97, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4460 | |
| HR (95% CI) [c] | 1.370 (0.612, 3.065) | |
| HR P-Value [c] | 0.4439 | |
| Heterogeneity p-value [d] | 0.8468 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.3 (50.3, 76.7) | 81.5 (64.6, 90.8) |
| 12 months | 65.3 (50.3, 76.7) | 40.7 (1.4, 82.7) |
| 18 months | 58.0 (38.3, 73.4) | 0.0 (NE, NE) |
| 24 months | 38.7 (9.6, 68.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 9 (10.1%) | 9 (10.6%) |
| Censored Patients, n (%) | 80 (89.9%) | 76 (89.4%) |
| Median (95% CI), (Months) [a] | NE (14.95, NE) | 8.80 (1.81, 8.97) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1954 | |
| HR (95% CI) [c] | 0.529 (0.199, 1.410) | |
| HR P-Value [c] | 0.2030 | |
| Heterogeneity p-value [d] | 0.1098 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.5 (53.7, 85.8) | 70.7 (48.1, 84.8) |
| 12 months | 73.5 (53.7, 85.8) | 0.0 (NE, NE) |
| 18 months | 63.0 (35.6, 81.3) | 0.0 (NE, NE) |
| 24 months | 63.0 (35.6, 81.3) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 10 (11.2%) | 9 (10.6%) |
| Censored Patients, n (%) | 79 (88.8%) | 76 (89.4%) |
| Median (95% CI), (Months) [a] | 12.06 (1.58, 25.53) | 3.68 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2257 | |
| HR (95% CI) [c] | 0.550 (0.202, 1.501) | |
| HR P-Value [c] | 0.2432 | |
| Heterogeneity p-value [d] | 0.2979 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.6 (36.0, 80.7) | 18.5 (1.3, 52.1) |
| 12 months | 54.8 (28.1, 75.2) | NE (NE, NE) |
| 18 months | 41.1 (13.5, 67.4) | NE (NE, NE) |
| 24 months | 41.1 (13.5, 67.4) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 20 (22.5%) | 10 (11.8%) |
| Censored Patients, n (%) | 69 (77.5%) | 75 (88.2%) |
| Median (95% CI), (Months) [a] | 12.65 (4.96, NE) | NE (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5738 | |
| HR (95% CI) [c] | 1.263 (0.583, 2.736) | |
| HR P-Value [c] | 0.5539 | |
| Heterogeneity p-value [d] | 0.8681 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.2 (45.5, 75.1) | 71.2 (51.6, 84.0) |
| 12 months | 51.7 (32.4, 68.0) | 63.3 (39.6, 79.8) |
| 18 months | 44.3 (23.6, 63.1) | NE (NE, NE) |
| 24 months | 44.3 (23.6, 63.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 13 (14.6%) | 3 (3.5%) |
| Censored Patients, n (%) | 76 (85.4%) | 82 (96.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1085 | |
| HR (95% CI) [c] | 2.691 (0.764, 9.470) | |
| HR P-Value [c] | 0.1231 | |
| Heterogeneity p-value [d] | 0.9213 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.9 (59.6, 85.1) | 91.4 (68.5, 97.9) |
| 12 months | 70.8 (53.8, 82.5) | 78.3 (39.1, 93.9) |
| 18 months | 70.8 (53.8, 82.5) | NE (NE, NE) |
| 24 months | 70.8 (53.8, 82.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 20 (22.5%) | 7 (8.2%) |
| Censored Patients, n (%) | 69 (77.5%) | 78 (91.8%) |
| Median (95% CI), (Months) [a] | NE (8.44, NE) | 9.59 (9.59, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3469 | |
| HR (95% CI) [c] | 1.523 (0.635, 3.656) | |
| HR P-Value [c] | 0.3461 | |
| Heterogeneity p-value [d] | 0.9148 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.6 (58.1, 81.5) | 82.7 (63.6, 92.3) |
| 12 months | 64.4 (48.5, 76.6) | 41.3 (1.4, 83.4) |
| 18 months | 53.7 (29.5, 72.8) | NE (NE, NE) |
| 24 months | 53.7 (29.5, 72.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 17 (19.1%) | 4 (4.7%) |
| Censored Patients, n (%) | 72 (80.9%) | 81 (95.3%) |
| Median (95% CI), (Months) [a] | 13.83 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1162 | |
| HR (95% CI) [c] | 2.362 (0.785, 7.107) | |
| HR P-Value [c] | 0.1261 | |
| Heterogeneity p-value [d] | 0.6651 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.9 (50.9, 80.0) | 81.4 (56.0, 93.0) |
| 12 months | 54.5 (31.4, 72.8) | 81.4 (56.0, 93.0) |
| 18 months | 43.6 (18.5, 66.5) | NE (NE, NE) |
| 24 months | 43.6 (18.5, 66.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 16 (18.0%) | 9 (10.6%) |
| Censored Patients, n (%) | 73 (82.0%) | 76 (89.4%) |
| | | |
| Median (95% CI), (Months) [a] | 13.44 (4.96, NE) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7030 | |
| HR (95% CI) [c] | 1.184 (0.514, 2.729) | |
| HR P-Value [c] | 0.6915 | |
| Heterogeneity p-value [d] | 0.4429 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.0 (45.3, 77.7) | 67.1 (43.6, 82.6) |
| 12 months | 53.3 (32.8, 70.1) | 55.9 (27.6, 77.0) |
| 18 months | 44.4 (22.0, 64.8) | NE (NE, NE) |
| 24 months | 44.4 (22.0, 64.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 17 (19.1%) | 4 (4.7%) |
| Censored Patients, n (%) | 72 (80.9%) | 81 (95.3%) |
| Median (95% CI), (Months) [a] | 10.45 (4.96, NE) | NE (7.03, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1892 | |
| HR (95% CI) [c] | 2.073 (0.686, 6.264) | |
| HR P-Value [c] | 0.1962 | |
| Heterogeneity p-value [d] | 0.4472 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.0 (49.5, 79.6) | 91.6 (70.4, 97.8) |
| 12 months | 49.9 (28.5, 68.1) | NE (NE, NE) |
| 18 months | 39.9 (17.1, 62.1) | NE (NE, NE) |
| 24 months | 39.9 (17.1, 62.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 15 (14.0%) | 14 (14.3%) |
| Censored Patients, n (%) | 92 (86.0%) | 84 (85.7%) |
| Median (95% CI), (Months) [a] | 13.31 (2.73, NE) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6925 | |
| HR (95% CI) [c] | 1.161 (0.548, 2.459) | |
| HR P-Value [c] | 0.6965 | |
| Heterogeneity p-value [d] | 0.6819 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.2 (40.0, 75.6) | 61.9 (42.9, 76.2) |
| 12 months | 51.6 (28.4, 70.7) | 55.0 (33.8, 72.0) |
| 18 months | 25.8 (5.1, 54.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 18 (16.8%) | 9 (9.2%) |
| Censored Patients, n (%) | 89 (83.2%) | 89 (90.8%) |
| Median (95% CI), (Months) [a] | 12.52 (6.97, NE) | NE (6.28, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3625 | |
| HR (95% CI) [c] | 1.463 (0.644, 3.324) | |
| HR P-Value [c] | 0.3631 | |
| Heterogeneity p-value [d] | 0.0490 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.9 (53.7, 81.4) | 74.7 (55.1, 86.7) |
| 12 months | 50.6 (30.4, 67.7) | NE (NE, NE) |
| 18 months | 44.3 (23.8, 63.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 17 (15.9%) | 14 (14.3%) |
| Censored Patients, n (%) | 90 (84.1%) | 84 (85.7%) |
| Median (95% CI), (Months) [a] | 9.72 (2.99, NE) | NE (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7445 | |
| HR (95% CI) [c] | 0.890 (0.433, 1.829) | |
| HR P-Value [c] | 0.7508 | |
| Heterogeneity p-value [d] | 0.9981 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.8 (43.8, 77.0) | 53.0 (32.9, 69.6) |
| 12 months | 42.4 (20.6, 62.8) | 53.0 (32.9, 69.6) |
| 18 months | 31.8 (10.6, 55.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 10 (9.3%) | 6 (6.1%) |
| Censored Patients, n (%) | 97 (90.7%) | 92 (93.9%) |
| Median (95% CI), (Months) [a] | 9.72 (1.91, 14.26) | 4.40 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3796 | |
| HR (95% CI) [c] | 0.618 (0.211, 1.815) | |
| HR P-Value [c] | 0.3813 | |
| Heterogeneity p-value [d] | 0.6996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.9 (32.7, 80.3) | 44.4 (13.6, 71.9) |
| 12 months | 31.3 (8.5, 57.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 16 (15.0%) | 8 (8.2%) |
| Censored Patients, n (%) | 91 (85.0%) | 90 (91.8%) |
| Median (95% CI), (Months) [a] | 8.34 (2.33, NE) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0962 | |
| HR (95% CI) [c] | 2.042 (0.869, 4.797) | |
| HR P-Value [c] | 0.1014 | |
| Heterogeneity p-value [d] | 0.6599 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.3 (32.4, 70.4) | 71.9 (49.6, 85.6) |
| 12 months | 29.2 (9.3, 52.7) | 71.9 (49.6, 85.6) |
| 18 months | 29.2 (9.3, 52.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 14 (13.1%) | 10 (10.2%) |
| Censored Patients, n (%) | 93 (86.9%) | 88 (89.8%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8344 | |
| HR (95% CI) [c] | 1.093 (0.481, 2.483) | |
| HR P-Value [c] | 0.8318 | |
| Heterogeneity p-value [d] | 0.9389 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.3 (59.6, 85.6) | 74.4 (55.2, 86.3) |
| 12 months | 65.3 (45.5, 79.4) | 65.1 (39.3, 82.1) |
| 18 months | 65.3 (45.5, 79.4) | NE (NE, NE) |
| 24 months | 65.3 (45.5, 79.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 19 (17.8%) | 13 (13.3%) |
| Censored Patients, n (%) | 88 (82.2%) | 85 (86.7%) |
| Median (95% CI), (Months) [a] | NE (11.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5452 | |
| HR (95% CI) [c] | 1.249 (0.613, 2.547) | |
| HR P-Value [c] | 0.5401 | |
| Heterogeneity p-value [d] | 0.8468 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.5 (70.1, 88.9) | 81.0 (67.7, 89.2) |
| 12 months | 60.5 (42.6, 74.4) | 71.4 (52.7, 83.8) |
| 18 months | 60.5 (42.6, 74.4) | NE (NE, NE) |
| 24 months | 60.5 (42.6, 74.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 17 (15.9%) | 11 (11.2%) |
| Censored Patients, n (%) | 90 (84.1%) | 87 (88.8%) |
| Median (95% CI), (Months) [a] | 13.86 (4.67, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2344 | |
| HR (95% CI) [c] | 1.583 (0.737, 3.398) | |
| HR P-Value [c] | 0.2388 | |
| Heterogeneity p-value [d] | 0.1098 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.9 (39.7, 72.3) | 74.5 (58.4, 85.1) |
| 12 months | 57.9 (39.7, 72.3) | 74.5 (58.4, 85.1) |
| 18 months | 48.2 (25.5, 67.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 14 (13.1%) | 9 (9.2%) |
| Censored Patients, n (%) | 93 (86.9%) | 89 (90.8%) |
| Median (95% CI), (Months) [a] | 4.90 (1.71, NE) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5256 | |
| HR (95% CI) [c] | 1.287 (0.555, 2.985) | |
| HR P-Value [c] | 0.5561 | |
| Heterogeneity p-value [d] | 0.2979 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.2 (25.6, 66.0) | 55.8 (31.9, 74.3) |
| 12 months | 33.7 (13.9, 54.9) | NE (NE, NE) |
| 18 months | 33.7 (13.9, 54.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 30 (28.0%) | 24 (24.5%) |
| Censored Patients, n (%) | 77 (72.0%) | 74 (75.5%) |
| Median (95% CI), (Months) [a] | 8.61 (4.67, NE) | NE (5.22, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6339 | |
| HR (95% CI) [c] | 1.145 (0.666, 1.970) | |
| HR P-Value [c] | 0.6234 | |
| Heterogeneity p-value [d] | 0.8681 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.5 (46.5, 71.9) | 57.8 (42.7, 70.2) |
| 12 months | 45.8 (29.5, 60.7) | 53.9 (38.1, 67.4) |
| 18 months | 28.6 (10.1, 50.5) | 53.9 (38.1, 67.4) |
| 24 months | 28.6 (10.1, 50.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 18 (16.8%) | 7 (7.1%) |
| Censored Patients, n (%) | 89 (83.2%) | 91 (92.9%) |
| Median (95% CI), (Months) [a] | NE (7.43, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0700 | |
| HR (95% CI) [c] | 2.216 (0.917, 5.357) | |
| HR P-Value [c] | 0.0772 | |
| Heterogeneity p-value [d] | 0.9213 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.5 (55.8, 82.4) | 87.2 (73.0, 94.3) |
| 12 months | 60.1 (42.0, 74.2) | 82.4 (64.2, 91.9) |
| 18 months | 51.5 (29.4, 69.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 16 (15.0%) | 10 (10.2%) |
| Censored Patients, n (%) | 91 (85.0%) | 88 (89.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3059 | |
| HR (95% CI) [c] | 1.509 (0.684, 3.330) | |
| HR P-Value [c] | 0.3084 | |
| Heterogeneity p-value [d] | 0.9148 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.3 (67.0, 87.4) | 87.0 (75.3, 93.4) |
| 12 months | 74.1 (60.3, 83.8) | 78.2 (60.3, 88.8) |
| 18 months | 74.1 (60.3, 83.8) | NE (NE, NE) |
| 24 months | 74.1 (60.3, 83.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 25 (23.4%) | 11 (11.2%) |
| Censored Patients, n (%) | 82 (76.6%) | 87 (88.8%) |
| Median (95% CI), (Months) [a] | 12.48 (4.90, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0917 | |
| HR (95% CI) [c] | 1.827 (0.896, 3.728) | |
| HR P-Value [c] | 0.0975 | |
| Heterogeneity p-value [d] | 0.6651 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.4 (43.4, 70.7) | 78.6 (63.4, 88.0) |
| 12 months | 50.6 (34.2, 64.9) | 73.7 (55.7, 85.3) |
| 18 months | 45.6 (28.3, 61.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 26 (24.3%) | 15 (15.3%) |
| Censored Patients, n (%) | 81 (75.7%) | 83 (84.7%) |
| Median (95% CI), (Months) [a] | 5.06 (1.91, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0546 | |
| HR (95% CI) [c] | 1.850 (0.979, 3.495) | |
| HR P-Value [c] | 0.0581 | |
| Heterogeneity p-value [d] | 0.4429 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.4 (33.0, 62.2) | 71.1 (55.3, 82.2) |
| 12 months | 38.1 (21.3, 54.7) | 56.0 (32.5, 74.1) |
| 18 months | 38.1 (21.3, 54.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 18 (16.8%) | 14 (14.3%) |
| Censored Patients, n (%) | 89 (83.2%) | 84 (85.7%) |
| Median (95% CI), (Months) [a] | NE (2.73, NE) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2243 | |
| HR (95% CI) [c] | 1.541 (0.766, 3.101) | |
| HR P-Value [c] | 0.2251 | |
| Heterogeneity p-value [d] | 0.4472 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.6 (36.9, 69.3) | 59.9 (39.3, 75.5) |
| 12 months | 54.6 (36.9, 69.3) | 59.9 (39.3, 75.5) |
| 18 months | 54.6 (36.9, 69.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 11 (13.3%) | 8 (11.6%) |
| Censored Patients, n (%) | 72 (86.7%) | 61 (88.4%) |
| Median (95% CI), (Months) [a] | 12.52 (2.83, NE) | 4.37 (2.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6455 | |
| HR (95% CI) [c] | 0.808 (0.323, 2.021) | |
| HR P-Value [c] | 0.6486 | |
| Heterogeneity p-value [d] | 0.1521 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.1 (40.8, 77.6) | 48.7 (22.8, 70.5) |
| 12 months | 62.1 (40.8, 77.6) | 48.7 (22.8, 70.5) |
| 18 months | 49.7 (22.4, 72.1) | NE (NE, NE) |
| 24 months | 49.7 (22.4, 72.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 11 (13.3%) | 6 (8.7%) |
| Censored Patients, n (%) | 72 (86.7%) | 63 (91.3%) |
| Median (95% CI), (Months) [a] | 17.97 (8.61, NE) | NE (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5206 | |
| HR (95% CI) [c] | 0.707 (0.245, 2.039) | |
| HR P-Value [c] | 0.5215 | |
| Heterogeneity p-value [d] | 0.7422 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.2 (57.8, 88.5) | 69.4 (44.0, 85.0) |
| 12 months | 66.1 (43.3, 81.5) | NE (NE, NE) |
| 18 months | 36.7 (8.1, 67.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 14 (16.9%) | 5 (7.2%) |
| Censored Patients, n (%) | 69 (83.1%) | 64 (92.8%) |
| Median (95% CI), (Months) [a] | 8.48 (2.83, 15.31) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5244 | |
| HR (95% CI) [c] | 1.394 (0.494, 3.935) | |
| HR P-Value [c] | 0.5300 | |
| Heterogeneity p-value [d] | 0.1766 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.0 (37.3, 76.7) | 69.9 (42.0, 86.3) |
| 12 months | 34.3 (11.3, 59.0) | 69.9 (42.0, 86.3) |
| 18 months | 22.8 (4.4, 49.7) | NE (NE, NE) |
| 24 months | 22.8 (4.4, 49.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 14 (16.9%) | 7 (10.1%) |
| Censored Patients, n (%) | 69 (83.1%) | 62 (89.9%) |
| Median (95% CI), (Months) [a] | 2.33 (1.48, 11.40) | 2.30 (1.45, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5425 | |
| HR (95% CI) [c] | 0.758 (0.301, 1.912) | |
| HR P-Value [c] | 0.5578 | |
| Heterogeneity p-value [d] | 0.9963 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.1 (20.4, 62.5) | 33.3 (7.8, 62.3) |
| 12 months | 20.1 (4.4, 43.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 9 (10.8%) | 4 (5.8%) |
| Censored Patients, n (%) | 74 (89.2%) | 65 (94.2%) |
| Median (95% CI), (Months) [a] | 11.33 (2.33, NE) | NE (1.94, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5194 | |
| HR (95% CI) [c] | 1.483 (0.449, 4.896) | |
| HR P-Value [c] | 0.5181 | |
| Heterogeneity p-value [d] | 0.7084 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.3 (42.3, 84.5) | 72.5 (42.1, 88.8) |
| 12 months | 20.5 (1.1, 57.0) | 72.5 (42.1, 88.8) |
| 18 months | 20.5 (1.1, 57.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 13 (15.7%) | 6 (8.7%) |
| Censored Patients, n (%) | 70 (84.3%) | 63 (91.3%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (5.39, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6582 | |
| HR (95% CI) [c] | 1.247 (0.471, 3.298) | |
| HR P-Value [c] | 0.6564 | |
| Heterogeneity p-value [d] | 0.9004 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.0 (53.8, 82.7) | 71.9 (44.2, 87.6) |
| 12 months | 66.8 (48.6, 79.9) | 71.9 (44.2, 87.6) |
| 18 months | 66.8 (48.6, 79.9) | NE (NE, NE) |
| 24 months | 66.8 (48.6, 79.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 14 (16.9%) | 10 (14.5%) |
| Censored Patients, n (%) | 69 (83.1%) | 59 (85.5%) |
| Median (95% CI), (Months) [a] | NE (12.65, NE) | 14.69 (8.97, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7276 | |
| HR (95% CI) [c] | 0.862 (0.376, 1.976) | |
| HR P-Value [c] | 0.7257 | |
| Heterogeneity p-value [d] | 0.1305 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.7 (62.5, 86.1) | 80.0 (63.7, 89.6) |
| 12 months | 72.4 (56.0, 83.5) | 66.7 (34.5, 85.7) |
| 18 months | 67.2 (48.5, 80.4) | 0.0 (NE, NE) |
| 24 months | 67.2 (48.5, 80.4) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 11 (13.3%) | 6 (8.7%) |
| Censored Patients, n (%) | 72 (86.7%) | 63 (91.3%) |
| Median (95% CI), (Months) [a] | NE (4.67, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5578 | |
| HR (95% CI) [c] | 1.343 (0.495, 3.644) | |
| HR P-Value [c] | 0.5626 | |
| Heterogeneity p-value [d] | 0.6905 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.1 (41.6, 77.2) | 80.0 (58.4, 91.1) |
| 12 months | 62.1 (41.6, 77.2) | 53.3 (9.7, 84.4) |
| 18 months | 62.1 (41.6, 77.2) | NE (NE, NE) |
| 24 months | 62.1 (41.6, 77.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 6 (7.2%) | 6 (8.7%) |
| Censored Patients, n (%) | 77 (92.8%) | 63 (91.3%) |
| Median (95% CI), (Months) [a] | 25.53 (1.71, 25.53) | 4.47 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2265 | |
| HR (95% CI) [c] | 0.471 (0.137, 1.623) | |
| HR P-Value [c] | 0.2330 | |
| Heterogeneity p-value [d] | 0.1806 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.5 (38.9, 87.8) | 21.4 (1.1, 59.2) |
| 12 months | 61.7 (30.5, 82.2) | NE (NE, NE) |
| 18 months | 61.7 (30.5, 82.2) | NE (NE, NE) |
| 24 months | 61.7 (30.5, 82.2) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 22 (26.5%) | 15 (21.7%) |
| Censored Patients, n (%) | 61 (73.5%) | 54 (78.3%) |
| Median (95% CI), (Months) [a] | 8.61 (4.96, NE) | 6.67 (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5346 | |
| HR (95% CI) [c] | 0.810 (0.414, 1.582) | |
| HR P-Value [c] | 0.5370 | |
| Heterogeneity p-value [d] | 0.2384 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.0 (44.5, 73.9) | 56.1 (35.6, 72.4) |
| 12 months | 48.7 (30.8, 64.5) | 42.1 (20.5, 62.3) |
| 18 months | 36.1 (17.3, 55.4) | NE (NE, NE) |
| 24 months | 36.1 (17.3, 55.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 13 (15.7%) | 4 (5.8%) |
| Censored Patients, n (%) | 70 (84.3%) | 65 (94.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (6.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1990 | |
| HR (95% CI) [c] | 2.054 (0.669, 6.310) | |
| HR P-Value [c] | 0.2087 | |
| Heterogeneity p-value [d] | 0.5950 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (51.1, 80.4) | 86.9 (64.3, 95.6) |
| 12 months | 68.2 (51.1, 80.4) | 74.5 (39.0, 91.2) |
| 18 months | 68.2 (51.1, 80.4) | NE (NE, NE) |
| 24 months | 68.2 (51.1, 80.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 17 (20.5%) | 5 (7.2%) |
| Censored Patients, n (%) | 66 (79.5%) | 64 (92.8%) |
| Median (95% CI), (Months) [a] | NE (15.41, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1309 | |
| HR (95% CI) [c] | 2.134 (0.780, 5.839) | |
| HR P-Value [c] | 0.1400 | |
| Heterogeneity p-value [d] | 0.5302 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.3 (58.6, 82.1) | 88.6 (71.7, 95.7) |
| 12 months | 72.3 (58.6, 82.1) | 79.8 (52.0, 92.5) |
| 18 months | 65.1 (45.3, 79.2) | NE (NE, NE) |
| 24 months | 65.1 (45.3, 79.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 16 (19.3%) | 6 (8.7%) |
| Censored Patients, n (%) | 67 (80.7%) | 63 (91.3%) |
| Median (95% CI), (Months) [a] | 12.48 (5.06, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5001 | |
| HR (95% CI) [c] | 1.381 (0.537, 3.551) | |
| HR P-Value [c] | 0.5035 | |
| Heterogeneity p-value [d] | 0.4314 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.2 (49.2, 80.0) | 75.4 (52.3, 88.4) |
| 12 months | 53.6 (33.5, 70.0) | 75.4 (52.3, 88.4) |
| 18 months | 47.6 (27.1, 65.6) | NE (NE, NE) |
| 24 months | 47.6 (27.1, 65.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 18 (21.7%) | 10 (14.5%) |
| Censored Patients, n (%) | 65 (78.3%) | 59 (85.5%) |
| Median (95% CI), (Months) [a] | 5.06 (2.33, NE) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1407 | |
| HR (95% CI) [c] | 1.766 (0.814, 3.829) | |
| HR P-Value [c] | 0.1500 | |
| Heterogeneity p-value [d] | 0.7918 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.2 (28.0, 62.7) | 65.6 (44.7, 80.2) |
| 12 months | 41.1 (22.9, 58.5) | 65.6 (44.7, 80.2) |
| 18 months | 41.1 (22.9, 58.5) | NE (NE, NE) |
| 24 months | 41.1 (22.9, 58.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 13 (15.7%) | 9 (13.0%) |
| Censored Patients, n (%) | 70 (84.3%) | 60 (87.0%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | 8.48 (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6831 | |
| HR (95% CI) [c] | 0.838 (0.351, 2.002) | |
| HR P-Value [c] | 0.6905 | |
| Heterogeneity p-value [d] | 0.1091 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (52.8, 83.7) | 70.4 (47.2, 84.9) |
| 12 months | 61.1 (40.0, 76.7) | 28.2 (1.7, 67.4) |
| 18 months | 52.4 (28.4, 71.7) | NE (NE, NE) |
| 24 months | 52.4 (28.4, 71.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 20 (17.7%) | 12 (10.5%) |
| Censored Patients, n (%) | 93 (82.3%) | 102 (89.5%) |
| Median (95% CI), (Months) [a] | 11.10 (3.02, 16.62) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1814 | |
| HR (95% CI) [c] | 1.643 (0.787, 3.430) | |
| HR P-Value [c] | 0.1866 | |
| Heterogeneity p-value [d] | 0.1521 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.4 (34.8, 68.8) | 71.5 (52.8, 83.8) |
| 12 months | 42.7 (19.8, 63.9) | 64.4 (42.0, 80.0) |
| 18 months | 14.2 (1.0, 44.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 17 (15.0%) | 13 (11.4%) |
| Censored Patients, n (%) | 96 (85.0%) | 101 (88.6%) |
| Median (95% CI), (Months) [a] | NE (6.97, NE) | NE (4.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9975 | |
| HR (95% CI) [c] | 1.007 (0.480, 2.112) | |
| HR P-Value [c] | 0.9851 | |
| Heterogeneity p-value [d] | 0.7422 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.8 (55.6, 81.6) | 63.2 (43.0, 77.9) |
| 12 months | 60.6 (41.3, 75.2) | NE (NE, NE) |
| 18 months | 53.8 (32.6, 71.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 16 (14.2%) | 16 (14.0%) |
| Censored Patients, n (%) | 97 (85.8%) | 98 (86.0%) |
| Median (95% CI), (Months) [a] | 10.45 (5.72, NE) | 4.50 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2142 | |
| HR (95% CI) [c] | 0.634 (0.308, 1.306) | |
| HR P-Value [c] | 0.2165 | |
| Heterogeneity p-value [d] | 0.1766 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.3 (45.4, 78.1) | 49.4 (29.6, 66.5) |
| 12 months | 45.0 (23.3, 64.5) | NE (NE, NE) |
| 18 months | 45.0 (23.3, 64.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 9 (8.0%) | 6 (5.3%) |
| Censored Patients, n (%) | 104 (92.0%) | 108 (94.7%) |
| Median (95% CI), (Months) [a] | 8.34 (1.48, 14.26) | 4.40 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6007 | |
| HR (95% CI) [c] | 0.750 (0.257, 2.190) | |
| HR P-Value [c] | 0.5987 | |
| Heterogeneity p-value [d] | 0.9963 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.2 (31.6, 79.9) | 48.5 (16.4, 74.9) |
| 12 months | 32.1 (6.4, 62.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 21 (18.6%) | 9 (7.9%) |
| Censored Patients, n (%) | 92 (81.4%) | 105 (92.1%) |
| Median (95% CI), (Months) [a] | 8.34 (2.99, 15.31) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1010 | |
| HR (95% CI) [c] | 1.925 (0.868, 4.267) | |
| HR P-Value [c] | 0.1069 | |
| Heterogeneity p-value [d] | 0.7084 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.4 (34.8, 68.9) | 70.3 (48.7, 84.2) |
| 12 months | 35.1 (17.6, 53.2) | 70.3 (48.7, 84.2) |
| 18 months | 23.4 (6.0, 47.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 17 (15.0%) | 11 (9.6%) |
| Censored Patients, n (%) | 96 (85.0%) | 103 (90.4%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9758 | |
| HR (95% CI) [c] | 0.991 (0.455, 2.161) | |
| HR P-Value [c] | 0.9828 | |
| Heterogeneity p-value [d] | 0.9004 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.5 (60.2, 85.6) | 75.8 (57.7, 87.0) |
| 12 months | 58.8 (39.3, 73.9) | NE (NE, NE) |
| 18 months | 50.4 (27.9, 69.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 25 (22.1%) | 12 (10.5%) |
| Censored Patients, n (%) | 88 (77.9%) | 102 (89.5%) |
| Median (95% CI), (Months) [a] | 11.10 (7.43, 21.88) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0953 | |
| HR (95% CI) [c] | 1.811 (0.901, 3.641) | |
| HR P-Value [c] | 0.0953 | |
| Heterogeneity p-value [d] | 0.1305 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.0 (59.1, 81.5) | 81.6 (67.5, 90.1) |
| 12 months | 49.7 (30.6, 66.2) | 70.0 (48.5, 83.9) |
| 18 months | 49.7 (30.6, 66.2) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 15 (13.3%) | 14 (12.3%) |
| Censored Patients, n (%) | 98 (86.7%) | 100 (87.7%) |
| Median (95% CI), (Months) [a] | 14.95 (5.59, NE) | NE (8.80, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8417 | |
| HR (95% CI) [c] | 0.926 (0.435, 1.975) | |
| HR P-Value [c] | 0.8432 | |
| Heterogeneity p-value [d] | 0.6905 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (48.7, 79.7) | 68.7 (52.0, 80.7) |
| 12 months | 66.7 (48.7, 79.7) | 57.3 (31.0, 76.7) |
| 18 months | 45.8 (19.3, 69.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 18 (15.9%) | 12 (10.5%) |
| Censored Patients, n (%) | 95 (84.1%) | 102 (89.5%) |
| Median (95% CI), (Months) [a] | 4.90 (1.64, 12.06) | 3.68 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5956 | |
| HR (95% CI) [c] | 1.214 (0.576, 2.555) | |
| HR P-Value [c] | 0.6102 | |
| Heterogeneity p-value [d] | 0.1806 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.1 (24.0, 62.5) | 49.5 (27.9, 67.9) |
| 12 months | 31.5 (13.1, 51.9) | NE (NE, NE) |
| 18 months | 21.0 (4.9, 44.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 28 (24.8%) | 19 (16.7%) |
| Censored Patients, n (%) | 85 (75.2%) | 95 (83.3%) |
| Median (95% CI), (Months) [a] | 11.17 (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2346 | |
| HR (95% CI) [c] | 1.444 (0.802, 2.600) | |
| HR P-Value [c] | 0.2205 | |
| Heterogeneity p-value [d] | 0.2384 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.2 (49.6, 74.0) | 65.2 (50.0, 76.8) |
| 12 months | 49.0 (31.1, 64.7) | 65.2 (50.0, 76.8) |
| 18 months | 32.7 (8.7, 59.9) | 65.2 (50.0, 76.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 18 (15.9%) | 6 (5.3%) |
| Censored Patients, n (%) | 95 (84.1%) | 108 (94.7%) |
| Median (95% CI), (Months) [a] | 15.24 (7.43, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0388 | |
| HR (95% CI) [c] | 2.585 (1.016, 6.581) | |
| HR P-Value [c] | 0.0463 | |
| Heterogeneity p-value [d] | 0.5950 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.3 (62.9, 86.7) | 89.9 (76.0, 95.9) |
| 12 months | 60.0 (40.1, 75.2) | 84.6 (65.4, 93.6) |
| 18 months | 48.0 (22.1, 70.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 19 (16.8%) | 12 (10.5%) |
| Censored Patients, n (%) | 94 (83.2%) | 102 (89.5%) |
| Median (95% CI), (Months) [a] | NE (8.44, NE) | NE (9.59, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3580 | |
| HR (95% CI) [c] | 1.409 (0.682, 2.911) | |
| HR P-Value [c] | 0.3537 | |
| Heterogeneity p-value [d] | 0.5302 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.1 (67.3, 87.1) | 83.6 (71.1, 91.0) |
| 12 months | 65.5 (48.7, 78.0) | 67.2 (38.5, 84.7) |
| 18 months | 65.5 (48.7, 78.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 26 (23.0%) | 9 (7.9%) |
| Censored Patients, n (%) | 87 (77.0%) | 105 (92.1%) |
| Median (95% CI), (Months) [a] | 13.83 (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0193 | |
| HR (95% CI) [c] | 2.422 (1.130, 5.193) | |
| HR P-Value [c] | 0.0230 | |
| Heterogeneity p-value [d] | 0.4314 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.6 (46.4, 72.2) | 82.1 (66.7, 90.8) |
| 12 months | 55.6 (39.2, 69.2) | NE (NE, NE) |
| 18 months | 46.3 (25.1, 65.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 24 (21.2%) | 14 (12.3%) |
| Censored Patients, n (%) | 89 (78.8%) | 100 (87.7%) |
| Median (95% CI), (Months) [a] | 8.44 (3.06, NE) | 7.26 (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3341 | |
| HR (95% CI) [c] | 1.394 (0.714, 2.723) | |
| HR P-Value [c] | 0.3307 | |
| Heterogeneity p-value [d] | 0.7918 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.1 (48.7, 74.6) | 73.0 (56.2, 84.2) |
| 12 months | 47.7 (29.0, 64.2) | NE (NE, NE) |
| 18 months | 38.2 (17.2, 59.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 22 (19.5%) | 9 (7.9%) |
| Censored Patients, n (%) | 91 (80.5%) | 105 (92.1%) |
| Median (95% CI), (Months) [a] | 10.45 (2.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0255 | |
| HR (95% CI) [c] | 2.369 (1.085, 5.175) | |
| HR P-Value [c] | 0.0305 | |
| Heterogeneity p-value [d] | 0.1091 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.9 (36.4, 66.9) | 72.4 (50.5, 85.8) |
| 12 months | 45.3 (26.0, 62.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 20 (17.1%) | 10 (10.3%) |
| Censored Patients, n (%) | 97 (82.9%) | 87 (89.7%) |
| Median (95% CI), (Months) [a] | 11.10 (2.83, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2777 | |
| HR (95% CI) [c] | 1.536 (0.703, 3.357) | |
| HR P-Value [c] | 0.2815 | |
| Heterogeneity p-value [d] | 0.4436 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.8 (34.6, 68.1) | 70.6 (51.3, 83.4) |
| 12 months | 46.2 (26.6, 63.8) | NE (NE, NE) |
| 18 months | 27.7 (8.7, 51.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 18 (15.4%) | 11 (11.3%) |
| Censored Patients, n (%) | 99 (84.6%) | 86 (88.7%) |
| Median (95% CI), (Months) [a] | 14.09 (8.61, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5818 | |
| HR (95% CI) [c] | 0.800 (0.363, 1.764) | |
| HR P-Value [c] | 0.5808 | |
| Heterogeneity p-value [d] | 0.8159 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.6 (58.2, 84.1) | 58.7 (36.2, 75.6) |
| 12 months | 60.3 (40.9, 75.0) | NE (NE, NE) |
| 18 months | 37.3 (13.8, 61.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 17 (14.5%) | 13 (13.4%) |
| Censored Patients, n (%) | 100 (85.5%) | 84 (86.6%) |
| Median (95% CI), (Months) [a] | 9.72 (5.72, NE) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4812 | |
| HR (95% CI) [c] | 0.765 (0.368, 1.590) | |
| HR P-Value [c] | 0.4725 | |
| Heterogeneity p-value [d] | 0.6431 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.8 (45.0, 77.6) | 55.9 (35.4, 72.2) |
| 12 months | 40.0 (19.2, 60.1) | NE (NE, NE) |
| 18 months | 40.0 (19.2, 60.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 16 (13.7%) | 7 (7.2%) |
| Censored Patients, n (%) | 101 (86.3%) | 90 (92.8%) |
| Median (95% CI), (Months) [a] | 6.97 (1.58, 11.40) | 2.33 (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3651 | |
| HR (95% CI) [c] | 0.661 (0.264, 1.652) | |
| HR P-Value [c] | 0.3756 | |
| Heterogeneity p-value [d] | 0.5642 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.0 (34.8, 74.1) | 36.0 (9.0, 64.8) |
| 12 months | 27.2 (9.5, 48.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 22 (18.8%) | 6 (6.2%) |
| Censored Patients, n (%) | 95 (81.2%) | 91 (93.8%) |
| Median (95% CI), (Months) [a] | 8.48 (2.99, 15.31) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1061 | |
| HR (95% CI) [c] | 2.109 (0.836, 5.323) | |
| HR P-Value [c] | 0.1140 | |
| Heterogeneity p-value [d] | 0.4857 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.6 (40.4, 73.0) | 78.1 (57.4, 89.5) |
| 12 months | 32.5 (15.5, 50.7) | NE (NE, NE) |
| 18 months | 24.4 (8.3, 44.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 15 (12.8%) | 6 (6.2%) |
| Censored Patients, n (%) | 102 (87.2%) | 91 (93.8%) |
| Median (95% CI), (Months) [a] | NE (9.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4695 | |
| HR (95% CI) [c] | 1.428 (0.544, 3.752) | |
| HR P-Value [c] | 0.4692 | |
| Heterogeneity p-value [d] | 0.3539 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.4 (66.9, 90.0) | 87.5 (71.8, 94.7) |
| 12 months | 60.6 (40.4, 75.9) | 80.7 (58.2, 91.9) |
| 18 months | 52.0 (28.6, 71.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 25 (21.4%) | 15 (15.5%) |
| Censored Patients, n (%) | 92 (78.6%) | 82 (84.5%) |
| Median (95% CI), (Months) [a] | 21.88 (9.72, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7023 | |
| HR (95% CI) [c] | 1.144 (0.592, 2.212) | |
| HR P-Value [c] | 0.6883 | |
| Heterogeneity p-value [d] | 0.5771 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.6 (60.1, 81.7) | 77.7 (63.8, 86.8) |
| 12 months | 55.6 (38.8, 69.4) | NE (NE, NE) |
| 18 months | 55.6 (38.8, 69.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 16 (13.7%) | 13 (13.4%) |
| Censored Patients, n (%) | 101 (86.3%) | 84 (86.6%) |
| Median (95% CI), (Months) [a] | NE (5.59, NE) | 8.97 (8.80, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6823 | |
| HR (95% CI) [c] | 0.854 (0.399, 1.830) | |
| HR P-Value [c] | 0.6845 | |
| Heterogeneity p-value [d] | 0.6235 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.5 (48.3, 78.3) | 71.4 (54.1, 83.2) |
| 12 months | 65.5 (48.3, 78.3) | NE (NE, NE) |
| 18 months | 51.6 (29.5, 69.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 16 (13.7%) | 11 (11.3%) |
| Censored Patients, n (%) | 101 (86.3%) | 86 (88.7%) |
| Median (95% CI), (Months) [a] | 7.92 (1.91, NE) | NE (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9444 | |
| HR (95% CI) [c] | 1.021 (0.465, 2.243) | |
| HR P-Value [c] | 0.9580 | |
| Heterogeneity p-value [d] | 0.5662 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.4 (34.5, 72.0) | 50.3 (27.3, 69.5) |
| 12 months | 39.1 (19.3, 58.6) | NE (NE, NE) |
| 18 months | 31.3 (12.3, 52.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Pain - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 26 (22.2%) | 19 (19.6%) |
| Censored Patients, n (%) | 91 (77.8%) | 78 (80.4%) |
| Median (95% CI), (Months) [a] | 16.76 (8.34, NE) | NE (5.22, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7136 | |
| HR (95% CI) [c] | 1.125 (0.618, 2.046) | |
| HR P-Value [c] | 0.7006 | |
| Heterogeneity p-value [d] | 0.9342 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.3 (51.2, 76.3) | 61.7 (45.9, 74.2) |
| 12 months | 53.4 (36.3, 67.8) | 61.7 (45.9, 74.2) |
| 18 months | 33.4 (11.7, 57.0) | 61.7 (45.9, 74.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 25 (21.4%) | 5 (5.2%) |
| Censored Patients, n (%) | 92 (78.6%) | 92 (94.8%) |
| Median (95% CI), (Months) [a] | 15.24 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0029 | |
| HR (95% CI) [c] | 3.897 (1.484, 10.237) | |
| HR P-Value [c] | 0.0058 | |
| Heterogeneity p-value [d] | 0.0615 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.8 (50.5, 75.9) | 90.9 (76.8, 96.6) |
| 12 months | 55.0 (38.9, 68.4) | 84.8 (63.6, 94.2) |
| 18 months | 48.1 (29.3, 64.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 22 (18.8%) | 8 (8.2%) |
| Censored Patients, n (%) | 95 (81.2%) | 89 (91.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0431 | |
| HR (95% CI) [c] | 2.258 (1.004, 5.078) | |
| HR P-Value [c] | 0.0489 | |
| Heterogeneity p-value [d] | 0.2253 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.3 (62.3, 83.0) | 86.8 (74.9, 93.3) |
| 12 months | 66.2 (51.9, 77.1) | 86.8 (74.9, 93.3) |
| 18 months | 66.2 (51.9, 77.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 28 (23.9%) | 8 (8.2%) |
| Censored Patients, n (%) | 89 (76.1%) | 89 (91.8%) |
| Median (95% CI), (Months) [a] | 13.83 (4.67, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0144 | |
| HR (95% CI) [c] | 2.584 (1.173, 5.692) | |
| HR P-Value [c] | 0.0185 | |
| Heterogeneity p-value [d] | 0.3234 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.9 (43.8, 69.7) | 82.1 (66.7, 90.8) |
| 12 months | 51.6 (36.6, 64.7) | 82.1 (66.7, 90.8) |
| 18 months | 45.9 (29.0, 61.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 29 (24.8%) | 11 (11.3%) |
| Censored Patients, n (%) | 88 (75.2%) | 86 (88.7%) |
| Median (95% CI), (Months) [a] | 4.67 (1.84, 13.44) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0075 | |
| HR (95% CI) [c] | 2.520 (1.253, 5.069) | |
| HR P-Value [c] | 0.0096 | |
| Heterogeneity p-value [d] | 0.0352 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.8 (33.3, 61.0) | 78.3 (62.1, 88.2) |
| 12 months | 39.1 (23.5, 54.4) | 62.6 (37.2, 80.2) |
| 18 months | 31.3 (14.3, 49.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 18 (15.4%) | 11 (11.3%) |
| Censored Patients, n (%) | 99 (84.6%) | 86 (88.7%) |
| Median (95% CI), (Months) [a] | NE (2.92, NE) | NE (7.03, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2611 | |
| HR (95% CI) [c] | 1.535 (0.725, 3.253) | |
| HR P-Value [c] | 0.2631 | |
| Heterogeneity p-value [d] | 0.6915 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.0 (42.0, 72.5) | 70.7 (50.6, 83.8) |
| 12 months | 55.3 (38.0, 69.6) | NE (NE, NE) |
| 18 months | 55.3 (38.0, 69.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 11 (14.3%) | 10 (11.6%) |
| Censored Patients, n (%) | 66 (85.7%) | 76 (88.4%) |
| Median (95% CI), (Months) [a] | 12.52 (3.02, NE) | 7.26 (2.96, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9795 | |
| HR (95% CI) [c] | 1.007 (0.427, 2.374) | |
| HR P-Value [c] | 0.9874 | |
| Heterogeneity p-value [d] | 0.4436 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.2 (42.0, 78.4) | 56.6 (31.4, 75.6) |
| 12 months | 63.2 (42.0, 78.4) | 42.5 (14.5, 68.4) |
| 18 months | 31.6 (1.9, 71.4) | NE (NE, NE) |
| 24 months | 31.6 (1.9, 71.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 10 (13.0%) | 8 (9.3%) |
| Censored Patients, n (%) | 67 (87.0%) | 78 (90.7%) |
| Median (95% CI), (Months) [a] | NE (7.03, NE) | NE (6.28, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9963 | |
| HR (95% CI) [c] | 1.010 (0.395, 2.579) | |
| HR P-Value [c] | 0.9837 | |
| Heterogeneity p-value [d] | 0.8159 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.7 (51.9, 84.5) | 72.8 (50.6, 86.2) |
| 12 months | 65.2 (42.8, 80.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 12 (15.6%) | 8 (9.3%) |
| Censored Patients, n (%) | 65 (84.4%) | 78 (90.7%) |
| Median (95% CI), (Months) [a] | 11.10 (4.14, NE) | NE (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9873 | |
| HR (95% CI) [c] | 0.990 (0.396, 2.474) | |
| HR P-Value [c] | 0.9820 | |
| Heterogeneity p-value [d] | 0.6431 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.9 (40.8, 80.0) | 58.2 (32.0, 77.3) |
| 12 months | 40.0 (12.9, 66.3) | 58.2 (32.0, 77.3) |
| 18 months | 26.6 (4.9, 55.9) | NE (NE, NE) |
| 24 months | 26.6 (4.9, 55.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 7 (9.1%) | 6 (7.0%) |
| Censored Patients, n (%) | 70 (90.9%) | 80 (93.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.45, NE) | 2.30 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8949 | |
| HR (95% CI) [c] | 1.071 (0.358, 3.200) | |
| HR P-Value [c] | 0.9028 | |
| Heterogeneity p-value [d] | 0.5642 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.1 (9.1, 61.6) | 44.4 (13.6, 71.9) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 8 (10.4%) | 7 (8.1%) |
| Censored Patients, n (%) | 69 (89.6%) | 79 (91.9%) |
| Median (95% CI), (Months) [a] | 11.33 (2.99, 11.33) | NE (2.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4496 | |
| HR (95% CI) [c] | 1.474 (0.533, 4.074) | |
| HR P-Value [c] | 0.4548 | |
| Heterogeneity p-value [d] | 0.4857 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.6 (30.1, 77.6) | 64.5 (38.0, 82.0) |
| 12 months | 0.0 (NE, NE) | 64.5 (38.0, 82.0) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 15 (19.5%) | 11 (12.8%) |
| Censored Patients, n (%) | 62 (80.5%) | 75 (87.2%) |
| Median (95% CI), (Months) [a] | NE (5.59, NE) | 8.67 (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9274 | |
| HR (95% CI) [c] | 0.970 (0.443, 2.121) | |
| HR P-Value [c] | 0.9384 | |
| Heterogeneity p-value [d] | 0.3539 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.4 (44.3, 76.0) | 60.5 (37.5, 77.3) |
| 12 months | 62.4 (44.3, 76.0) | 40.3 (9.4, 70.5) |
| 18 months | 62.4 (44.3, 76.0) | NE (NE, NE) |
| 24 months | 62.4 (44.3, 76.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 14 (18.2%) | 7 (8.1%) |
| Censored Patients, n (%) | 63 (81.8%) | 79 (91.9%) |
| Median (95% CI), (Months) [a] | NE (12.65, NE) | 14.69 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2750 | |
| HR (95% CI) [c] | 1.654 (0.660, 4.142) | |
| HR P-Value [c] | 0.2828 | |
| Heterogeneity p-value [d] | 0.5771 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.4 (58.9, 84.7) | 85.6 (69.5, 93.6) |
| 12 months | 70.7 (54.0, 82.2) | 85.6 (69.5, 93.6) |
| 18 months | 61.8 (38.6, 78.5) | 0.0 (NE, NE) |
| 24 months | 61.8 (38.6, 78.5) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 9 (11.7%) | 7 (8.1%) |
| Censored Patients, n (%) | 68 (88.3%) | 79 (91.9%) |
| Median (95% CI), (Months) [a] | NE (5.06, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5886 | |
| HR (95% CI) [c] | 1.312 (0.488, 3.525) | |
| HR P-Value [c] | 0.5901 | |
| Heterogeneity p-value [d] | 0.6235 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.2 (43.9, 81.3) | 75.6 (55.3, 87.6) |
| 12 months | 66.2 (43.9, 81.3) | 75.6 (55.3, 87.6) |
| 18 months | 66.2 (43.9, 81.3) | NE (NE, NE) |
| 24 months | 66.2 (43.9, 81.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 8 (10.4%) | 7 (8.1%) |
| Censored Patients, n (%) | 69 (89.6%) | 79 (91.9%) |
| Median (95% CI), (Months) [a] | 5.59 (1.48, 25.53) | 2.79 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6593 | |
| HR (95% CI) [c] | 0.782 (0.267, 2.293) | |
| HR P-Value [c] | 0.6546 | |
| Heterogeneity p-value [d] | 0.5662 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.9 (21.2, 73.2) | 24.7 (1.7, 62.1) |
| 12 months | 49.9 (21.2, 73.2) | NE (NE, NE) |
| 18 months | 49.9 (21.2, 73.2) | NE (NE, NE) |
| 24 months | 49.9 (21.2, 73.2) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:21, yingyuan.lin)

Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 23 (29.9%) | 15 (17.4%) |
| Censored Patients, n (%) | 54 (70.1%) | 71 (82.6%) |
| Median (95% CI), (Months) [a] | 8.34 (2.07, NE) | 6.74 (4.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6415 | |
| HR (95% CI) [c] | 1.177 (0.611, 2.267) | |
| HR P-Value [c] | 0.6268 | |
| Heterogeneity p-value [d] | 0.9342 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.7 (40.3, 70.2) | 62.4 (42.9, 76.9) |
| 12 months | 41.9 (23.4, 59.4) | 48.5 (26.2, 67.6) |
| 18 months | 34.9 (16.3, 54.3) | NE (NE, NE) |
| 24 months | 34.9 (16.3, 54.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 6 (7.8%) | 5 (5.8%) |
| Censored Patients, n (%) | 71 (92.2%) | 81 (94.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (6.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8285 | |
| HR (95% CI) [c] | 0.876 (0.265, 2.899) | |
| HR P-Value [c] | 0.8286 | |
| Heterogeneity p-value [d] | 0.0615 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.7 (66.3, 93.6) | 85.6 (64.7, 94.6) |
| 12 months | 79.4 (58.2, 90.7) | 76.1 (46.6, 90.7) |
| 18 months | 79.4 (58.2, 90.7) | NE (NE, NE) |
| 24 months | 79.4 (58.2, 90.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 13 (16.9%) | 9 (10.5%) |
| Censored Patients, n (%) | 64 (83.1%) | 77 (89.5%) |
| Median (95% CI), (Months) [a] | NE (15.41, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8976 | |
| HR (95% CI) [c] | 0.949 (0.396, 2.271) | |
| HR P-Value [c] | 0.9064 | |
| Heterogeneity p-value [d] | 0.2253 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.4 (63.9, 87.6) | 83.7 (66.4, 92.6) |
| 12 months | 75.0 (59.2, 85.3) | 56.4 (26.1, 78.3) |
| 18 months | 65.6 (41.2, 81.8) | NE (NE, NE) |
| 24 months | 65.6 (41.2, 81.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 13 (16.9%) | 7 (8.1%) |
| Censored Patients, n (%) | 64 (83.1%) | 79 (91.9%) |
| Median (95% CI), (Months) [a] | 11.10 (5.06, NE) | NE (6.28, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5416 | |
| HR (95% CI) [c] | 1.334 (0.531, 3.353) | |
| HR P-Value [c] | 0.5401 | |
| Heterogeneity p-value [d] | 0.3234 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.1 (48.7, 81.4) | 76.9 (54.9, 89.1) |
| 12 months | 49.6 (23.7, 71.1) | 69.2 (43.6, 84.9) |
| 18 months | 49.6 (23.7, 71.1) | NE (NE, NE) |
| 24 months | 49.6 (23.7, 71.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 13 (16.9%) | 13 (15.1%) |
| Censored Patients, n (%) | 64 (83.1%) | 73 (84.9%) |
| Median (95% CI), (Months) [a] | NE (4.96, NE) | 7.26 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6181 | |
| HR (95% CI) [c] | 0.819 (0.376, 1.780) | |
| HR P-Value [c] | 0.6137 | |
| Heterogeneity p-value [d] | 0.0352 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.5 (43.7, 79.2) | 58.9 (38.3, 74.6) |
| 12 months | 51.3 (28.3, 70.3) | 47.1 (21.4, 69.2) |
| 18 months | 51.3 (28.3, 70.3) | NE (NE, NE) |
| 24 months | 51.3 (28.3, 70.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 17 (22.1%) | 7 (8.1%) |
| Censored Patients, n (%) | 60 (77.9%) | 79 (91.9%) |
| Median (95% CI), (Months) [a] | 10.45 (3.02, NE) | 8.48 (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2521 | |
| HR (95% CI) [c] | 1.694 (0.694, 4.137) | |
| HR P-Value [c] | 0.2470 | |
| Heterogeneity p-value [d] | 0.6915 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.6 (44.2, 76.4) | 72.1 (44.3, 87.6) |
| 12 months | 44.5 (19.9, 66.6) | 36.0 (1.7, 77.5) |
| 18 months | 33.4 (10.4, 58.8) | NE (NE, NE) |
| 24 months | 33.4 (10.4, 58.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 0 |
| Censored Patients, n (%) | 21 (80.8%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 11.10 (3.91, 16.62) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4409 | |
| HR (95% CI) [c] | 12721546 (0.000, NE) | |
| HR P-Value [c] | 0.9972 | |
| Heterogeneity p-value [d] | 0.9995 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.7 (33.7, 89.5) | 100.0 (100.0, 100.0) |
| 12 months | 35.4 (1.6, 77.1) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 0 |
| Censored Patients, n (%) | 20 (76.9%) | 19 (100.0%) |
| | | |
| Median (95% CI), (Months) [a] | 12.52 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3165 | |
| HR (95% CI) [c] | 13120799 (0.000, NE) | |
| HR P-Value [c] | 0.9964 | |
| Heterogeneity p-value [d] | 0.6074 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.7 (53.9, 96.2) | 100.0 (100.0, 100.0) |
| 12 months | 58.8 (20.9, 83.5) | NE (NE, NE) |
| 18 months | 29.4 (4.5, 61.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 1 (5.3%) |
| Censored Patients, n (%) | 20 (76.9%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | 6.97 (3.91, 9.72) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9971 | |
| HR (95% CI) [c] | 1.004 (0.091, 11.097) | |
| HR P-Value [c] | 0.9971 | |
| Heterogeneity p-value [d] | 0.1248 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.6 (19.3, 85.9) | NE (NE, NE) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 7 (26.9%) | 0 |
| Censored Patients, n (%) | 19 (73.1%) | 19 (100.0%) |
| | | |
| Median (95% CI), (Months) [a] | 6.54 (1.45, 9.72) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0849 | |
| HR (95% CI) [c] | 46573620 (0.000, NE) | |
| HR P-Value [c] | 0.9964 | |
| Heterogeneity p-value [d] | 0.3236 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.5 (22.9, 86.1) | 100.0 (100.0, 100.0) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 4 (15.4%) | 0 |
| Censored Patients, n (%) | 22 (84.6%) | 19 (100.0%) |
| | | |
| Median (95% CI), (Months) [a] | 9.72 (2.99, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6374 | |
| HR (95% CI) [c] | 4515512 (0.000, NE) | |
| HR P-Value [c] | 0.9973 | |
| Heterogeneity p-value [d] | 0.7937 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.9 (43.3, 98.4) | 100.0 (100.0, 100.0) |
| 12 months | 38.1 (5.7, 72.3) | NE (NE, NE) |
| 18 months | 38.1 (5.7, 72.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 1 (5.3%) |
| Censored Patients, n (%) | 21 (80.8%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | 9.72 (6.97, NE) | NE (2.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5287 | |
| HR (95% CI) [c] | 2.040 (0.237, 17.573) | |
| HR P-Value [c] | 0.5163 | |
| Heterogeneity p-value [d] | 0.9037 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.7 (53.9, 96.2) | 83.3 (27.3, 97.5) |
| 12 months | 24.5 (1.1, 64.5) | NE (NE, NE) |
| 18 months | 24.5 (1.1, 64.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 1 (5.3%) |
| Censored Patients, n (%) | 20 (76.9%) | 18 (94.7%) |
| | | |
| Median (95% CI), (Months) [a] | 9.72 (6.97, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2752 | |
| HR (95% CI) [c] | 3.077 (0.368, 25.756) | |
| HR P-Value [c] | 0.2998 | |
| Heterogeneity p-value [d] | 0.8266 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.5 (56.7, 94.5) | 92.3 (56.6, 98.9) |
| 12 months | 36.5 (6.0, 69.8) | NE (NE, NE) |
| 18 months | 36.5 (6.0, 69.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 1 (5.3%) |
| Censored Patients, n (%) | 20 (76.9%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | 13.86 (1.58, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5903 | |
| HR (95% CI) [c] | 1.752 (0.204, 15.015) | |
| HR P-Value [c] | 0.6090 | |
| Heterogeneity p-value [d] | 0.5780 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.9 (18.2, 76.6) | 75.0 (12.8, 96.1) |
| 12 months | 50.9 (18.2, 76.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 2 (10.5%) |
| Censored Patients, n (%) | 20 (76.9%) | 17 (89.5%) |
| | | |
| Median (95% CI), (Months) [a] | 6.97 (1.58, NE) | 2.83 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8531 | |
| HR (95% CI) [c] | 0.872 (0.174, 4.371) | |
| HR P-Value [c] | 0.8675 | |
| Heterogeneity p-value [d] | 0.9643 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.3 (17.7, 79.6) | 33.3 (0.9, 77.4) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 3 (15.8%) |
| Censored Patients, n (%) | 20 (76.9%) | 16 (84.2%) |
| Median (95% CI), (Months) [a] | 11.17 (3.09, NE) | NE (5.22, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9617 | |
| HR (95% CI) [c] | 1.034 (0.243, 4.395) | |
| HR P-Value [c] | 0.9643 | |
| Heterogeneity p-value [d] | 0.9939 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.3 (39.2, 88.5) | 67.5 (24.8, 89.6) |
| 12 months | 35.7 (5.9, 68.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 7 (26.9%) | 0 |
| Censored Patients, n (%) | 19 (73.1%) | 19 (100.0%) |
| | | |
| Median (95% CI), (Months) [a] | 11.10 (4.90, 15.24) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1277 | |
| HR (95% CI) [c] | 45635175 (0.000, NE) | |
| HR P-Value [c] | 0.9968 | |
| Heterogeneity p-value [d] | 1.0000 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (33.6, 87.4) | 100.0 (100.0, 100.0) |
| 12 months | 37.9 (7.3, 69.8) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 4 (15.4%) | 2 (10.5%) |
| Censored Patients, n (%) | 22 (84.6%) | 17 (89.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9341 | |
| HR (95% CI) [c] | 1.075 (0.196, 5.905) | |
| HR P-Value [c] | 0.9341 | |
| Heterogeneity p-value [d] | 0.8935 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.2 (55.1, 92.1) | 92.9 (59.1, 99.0) |
| 12 months | 80.2 (55.1, 92.1) | NE (NE, NE) |
| 18 months | 80.2 (55.1, 92.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 8 (30.8%) | 2 (10.5%) |
| Censored Patients, n (%) | 18 (69.2%) | 17 (89.5%) |
| Median (95% CI), (Months) [a] | 6.97 (4.24, NE) | NE (1.18, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9665 | |
| HR (95% CI) [c] | 1.018 (0.213, 4.873) | |
| HR P-Value [c] | 0.9820 | |
| Heterogeneity p-value [d] | 0.5507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.9 (33.2, 81.2) | 66.7 (19.5, 90.4) |
| 12 months | 24.8 (1.6, 62.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 0 |
| Censored Patients, n (%) | 20 (76.9%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | 8.34 (1.51, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0469 | |
| HR (95% CI) [c] | 56327424 (0.000, NE) | |
| HR P-Value [c] | 0.9962 | |
| Heterogeneity p-value [d] | 0.7883 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.5 (30.8, 81.8) | 100.0 (100.0, 100.0) |
| 12 months | 41.0 (8.5, 72.5) | NE (NE, NE) |
| 18 months | 41.0 (8.5, 72.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 1 (5.3%) |
| Censored Patients, n (%) | 21 (80.8%) | 18 (94.7%) |
| | | |
| Median (95% CI), (Months) [a] | NE (3.09, NE) | NE (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3863 | |
| HR (95% CI) [c] | 2.511 (0.291, 21.666) | |
| HR P-Value [c] | 0.4025 | |
| Heterogeneity p-value [d] | 0.9882 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.6 (33.1, 86.1) | 87.5 (38.7, 98.1) |
| 12 months | 53.3 (19.7, 78.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 17 (14.3%) | 15 (13.5%) |
| Censored Patients, n (%) | 102 (85.7%) | 96 (86.5%) |
| Median (95% CI), (Months) [a] | 12.52 (2.83, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4515 | |
| HR (95% CI) [c] | 1.309 (0.651, 2.632) | |
| HR P-Value [c] | 0.4495 | |
| Heterogeneity p-value [d] | 0.9995 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.2 (38.8, 71.9) | 63.1 (44.8, 76.8) |
| 12 months | 57.2 (38.8, 71.9) | 57.4 (37.4, 73.0) |
| 18 months | 45.7 (21.5, 67.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 17 (14.3%) | 13 (11.7%) |
| Censored Patients, n (%) | 102 (85.7%) | 98 (88.3%) |
| Median (95% CI), (Months) [a] | 17.97 (8.61, NE) | NE (4.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7627 | |
| HR (95% CI) [c] | 0.900 (0.430, 1.884) | |
| HR P-Value [c] | 0.7808 | |
| Heterogeneity p-value [d] | 0.6074 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.4 (54.3, 80.4) | 58.6 (38.1, 74.3) |
| 12 months | 65.3 (48.8, 77.7) | NE (NE, NE) |
| 18 months | 49.0 (18.8, 73.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 14 (11.8%) | 16 (14.4%) |
| Censored Patients, n (%) | 105 (88.2%) | 95 (85.6%) |
| Median (95% CI), (Months) [a] | 11.10 (8.48, NE) | 4.50 (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1079 | |
| HR (95% CI) [c] | 0.544 (0.256, 1.155) | |
| HR P-Value [c] | 0.1130 | |
| Heterogeneity p-value [d] | 0.1248 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.1 (50.7, 81.8) | 47.2 (27.1, 64.9) |
| 12 months | 44.3 (18.9, 67.2) | NE (NE, NE) |
| 18 months | 44.3 (18.9, 67.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 12 (10.1%) | 8 (7.2%) |
| Censored Patients, n (%) | 107 (89.9%) | 103 (92.8%) |
| Median (95% CI), (Months) [a] | 11.40 (1.48, NE) | 2.30 (1.45, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0453 | |
| HR (95% CI) [c] | 0.393 (0.152, 1.019) | |
| HR P-Value [c] | 0.0546 | |
| Heterogeneity p-value [d] | 0.3236 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.9 (30.2, 71.3) | 13.9 (0.7, 45.2) |
| 12 months | 42.4 (18.0, 65.1) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 20 (16.8%) | 11 (9.9%) |
| Censored Patients, n (%) | 99 (83.2%) | 100 (90.1%) |
| Median (95% CI), (Months) [a] | 8.97 (2.99, 15.31) | NE (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2550 | |
| HR (95% CI) [c] | 1.544 (0.728, 3.278) | |
| HR P-Value [c] | 0.2578 | |
| Heterogeneity p-value [d] | 0.7937 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.6 (36.0, 69.9) | 65.3 (44.6, 79.9) |
| 12 months | 36.4 (16.1, 57.1) | 65.3 (44.6, 79.9) |
| 18 months | 24.3 (5.7, 49.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 20 (16.8%) | 12 (10.8%) |
| Censored Patients, n (%) | 99 (83.2%) | 99 (89.2%) |
| Median (95% CI), (Months) [a] | NE (8.97, NE) | NE (8.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7675 | |
| HR (95% CI) [c] | 1.116 (0.539, 2.313) | |
| HR P-Value [c] | 0.7672 | |
| Heterogeneity p-value [d] | 0.9037 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.8 (53.9, 79.7) | 75.5 (58.4, 86.4) |
| 12 months | 63.0 (47.3, 75.2) | NE (NE, NE) |
| 18 months | 54.0 (32.2, 71.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 26 (21.8%) | 15 (13.5%) |
| Censored Patients, n (%) | 93 (78.2%) | 96 (86.5%) |
| Median (95% CI), (Months) [a] | 21.88 (11.17, NE) | 14.69 (7.26, 14.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4270 | |
| HR (95% CI) [c] | 1.309 (0.682, 2.513) | |
| HR P-Value [c] | 0.4179 | |
| Heterogeneity p-value [d] | 0.8266 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.8 (58.5, 80.1) | 78.2 (64.2, 87.3) |
| 12 months | 61.6 (46.5, 73.6) | 68.1 (48.7, 81.5) |
| 18 months | 57.5 (41.2, 70.7) | 0.0 (NE, NE) |
| 24 months | 43.1 (17.1, 66.9) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 15 (12.6%) | 14 (12.6%) |
| Censored Patients, n (%) | 104 (87.4%) | 97 (87.4%) |
| Median (95% CI), (Months) [a] | NE (14.95, NE) | NE (8.80, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7335 | |
| HR (95% CI) [c] | 0.881 (0.419, 1.852) | |
| HR P-Value [c] | 0.7380 | |
| Heterogeneity p-value [d] | 0.5780 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.3 (54.5, 81.5) | 69.3 (52.9, 80.9) |
| 12 months | 70.3 (54.5, 81.5) | 57.7 (31.3, 77.1) |
| 18 months | 62.5 (41.0, 78.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 12 (10.1%) | 12 (10.8%) |
| Censored Patients, n (%) | 107 (89.9%) | 99 (89.2%) |
| Median (95% CI), (Months) [a] | 7.92 (2.73, NE) | 5.06 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9251 | |
| HR (95% CI) [c] | 0.964 (0.424, 2.190) | |
| HR P-Value [c] | 0.9304 | |
| Heterogeneity p-value [d] | 0.9643 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.3 (32.4, 74.7) | 49.5 (27.3, 68.3) |
| 12 months | 49.3 (25.4, 69.4) | NE (NE, NE) |
| 18 months | 39.4 (15.7, 62.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 35 (29.4%) | 25 (22.5%) |
| Censored Patients, n (%) | 84 (70.6%) | 86 (77.5%) |
| | | |
| Median (95% CI), (Months) [a] | 10.45 (4.34, 17.05) | NE (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5966 | |
| HR (95% CI) [c] | 1.168 (0.694, 1.965) | |
| HR P-Value [c] | 0.5584 | |
| Heterogeneity p-value [d] | 0.9939 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.0 (47.1, 70.7) | 56.6 (41.9, 68.9) |
| 12 months | 48.1 (33.4, 61.4) | 53.3 (38.1, 66.3) |
| 18 months | 30.2 (13.1, 49.4) | 53.3 (38.1, 66.3) |
| 24 months | 30.2 (13.1, 49.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 19 (16.0%) | 8 (7.2%) |
| Censored Patients, n (%) | 100 (84.0%) | 103 (92.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1050 | |
| HR (95% CI) [c] | 1.960 (0.857, 4.480) | |
| HR P-Value [c] | 0.1108 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.6 (60.5, 83.0) | 86.6 (71.9, 93.9) |
| 12 months | 68.0 (53.3, 78.9) | 77.7 (58.3, 88.9) |
| 18 months | 68.0 (53.3, 78.9) | NE (NE, NE) |
| 24 months | 68.0 (53.3, 78.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 28 (23.5%) | 14 (12.6%) |
| Censored Patients, n (%) | 91 (76.5%) | 97 (87.4%) |
| Median (95% CI), (Months) [a] | NE (8.44, NE) | NE (9.59, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2250 | |
| HR (95% CI) [c] | 1.498 (0.783, 2.865) | |
| HR P-Value [c] | 0.2222 | |
| Heterogeneity p-value [d] | 0.8935 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.0 (59.3, 79.8) | 80.2 (67.3, 88.5) |
| 12 months | 62.7 (49.7, 73.2) | 66.1 (41.2, 82.4) |
| 18 months | 56.4 (39.3, 70.4) | NE (NE, NE) |
| 24 months | 56.4 (39.3, 70.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 26 (21.8%) | 9 (8.1%) |
| Censored Patients, n (%) | 93 (78.2%) | 102 (91.9%) |
| Median (95% CI), (Months) [a] | 13.83 (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0522 | |
| HR (95% CI) [c] | 2.107 (0.978, 4.541) | |
| HR P-Value [c] | 0.0571 | |
| Heterogeneity p-value [d] | 0.5507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.3 (49.2, 74.5) | 80.1 (64.8, 89.2) |
| 12 months | 55.5 (39.3, 69.1) | 80.1 (64.8, 89.2) |
| 18 months | 44.2 (25.4, 61.4) | NE (NE, NE) |
| 24 months | 44.2 (25.4, 61.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 27 (22.7%) | 17 (15.3%) |
| Censored Patients, n (%) | 92 (77.3%) | 94 (84.7%) |
| Median (95% CI), (Months) [a] | 8.44 (1.84, NE) | 7.26 (5.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2875 | |
| HR (95% CI) [c] | 1.397 (0.757, 2.577) | |
| HR P-Value [c] | 0.2844 | |
| Heterogeneity p-value [d] | 0.7883 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.3 (39.3, 67.0) | 65.5 (48.1, 78.3) |
| 12 months | 46.8 (30.8, 61.2) | 45.9 (24.0, 65.4) |
| 18 months | 39.0 (20.6, 57.0) | NE (NE, NE) |
| 24 months | 39.0 (20.6, 57.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 24 (20.2%) | 11 (9.9%) |
| Censored Patients, n (%) | 95 (79.8%) | 100 (90.1%) |
| Median (95% CI), (Months) [a] | 12.58 (2.83, NE) | NE (5.88, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1293 | |
| HR (95% CI) [c] | 1.740 (0.843, 3.592) | |
| HR P-Value [c] | 0.1344 | |
| Heterogeneity p-value [d] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.2 (40.0, 68.1) | 68.6 (47.2, 82.7) |
| 12 months | 50.6 (34.2, 64.9) | NE (NE, NE) |
| 18 months | 44.3 (26.2, 60.9) | NE (NE, NE) |
| 24 months | 44.3 (26.2, 60.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 4 (20.0%) | 0 |
| Censored Patients, n (%) | 16 (80.0%) | 21 (100.0%) |
| | | |
| Median (95% CI), (Months) [a] | 13.31 (1.48, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3008 | |
| HR (95% CI) [c] | 49188031 (0.000, NE) | |
| HR P-Value [c] | 0.9979 | |
| Heterogeneity p-value [d] | 0.9995 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.6 (13.2, 82.5) | NE (NE, NE) |
| 12 months | 53.6 (13.2, 82.5) | NE (NE, NE) |
| 18 months | 26.8 (1.3, 67.0) | NE (NE, NE) |
| 24 months | 26.8 (1.3, 67.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 19 (95.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | NE (1.84, NE) | 6.28 (1.81, 6.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2144 | |
| HR (95% CI) [c] | 0.260 (0.027, 2.547) | |
| HR P-Value [c] | 0.2472 | |
| Heterogeneity p-value [d] | 0.6074 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (20.4, 96.9) | 60.0 (12.6, 88.2) |
| 12 months | 80.0 (20.4, 96.9) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 18 (90.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (1.38, NE) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9671 | |
| HR (95% CI) [c] | 0.951 (0.086, 10.500) | |
| HR P-Value [c] | 0.9671 | |
| Heterogeneity p-value [d] | 0.1248 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 12 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 18 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 24 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (4.8%) |
| Censored Patients, n (%) | 20 (100.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (1.81, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5637 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9987 | |
| Heterogeneity p-value [d] | 0.3236 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | NE (NE, NE) | 66.7 (5.4, 94.5) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 18 (90.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | 4.27 (1.84, NE) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2541 | |
| HR (95% CI) [c] | 3.713 (0.332, 41.497) | |
| HR P-Value [c] | 0.2868 | |
| Heterogeneity p-value [d] | 0.7937 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (0.9, 77.4) | 80.0 (20.4, 96.9) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (4.8%) |
| Censored Patients, n (%) | 20 (100.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1025 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9987 | |
| Heterogeneity p-value [d] | 0.9037 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 66.7 (5.4, 94.5) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 24 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 18 (90.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (2.86, NE) | NE (2.43, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9536 | |
| HR (95% CI) [c] | 1.074 (0.096, 12.004) | |
| HR P-Value [c] | 0.9536 | |
| Heterogeneity p-value [d] | 0.8266 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.1 (47.2, 95.5) | 83.3 (27.3, 97.5) |
| 12 months | 83.1 (47.2, 95.5) | NE (NE, NE) |
| 18 months | 83.1 (47.2, 95.5) | NE (NE, NE) |
| 24 months | 83.1 (47.2, 95.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 18 (90.0%) | 19 (90.5%) |
| Median (95% CI), (Months) [a] | NE (3.48, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3672 | |
| HR (95% CI) [c] | 0.378 (0.044, 3.280) | |
| HR P-Value [c] | 0.3775 | |
| Heterogeneity p-value [d] | 0.5780 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 12 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 18 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 24 months | 71.4 (25.8, 92.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 4 (20.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 16 (80.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | 13.80 (1.41, 25.53) | 2.56 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5854 | |
| HR (95% CI) [c] | 1.870 (0.190, 18.357) | |
| HR P-Value [c] | 0.5912 | |
| Heterogeneity p-value [d] | 0.9643 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (11.1, 80.4) | 0.0 (NE, NE) |
| 12 months | 50.0 (11.1, 80.4) | 0.0 (NE, NE) |
| 18 months | 50.0 (11.1, 80.4) | 0.0 (NE, NE) |
| 24 months | 50.0 (11.1, 80.4) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 1 (4.8%) |
| Censored Patients, n (%) | 17 (85.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (1.54, NE) | NE (2.43, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4401 | |
| HR (95% CI) [c] | 2.376 (0.247, 22.895) | |
| HR P-Value [c] | 0.4541 | |
| Heterogeneity p-value [d] | 0.9939 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (28.2, 87.8) | 75.0 (12.8, 96.1) |
| 12 months | 66.7 (28.2, 87.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 0 |
| Censored Patients, n (%) | 18 (90.0%) | 21 (100.0%) |
| | | |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2286 | |
| HR (95% CI) [c] | 60575344 (0.000, NE) | |
| HR P-Value [c] | 0.9978 | |
| Heterogeneity p-value [d] | 1.0000 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.5 (46.1, 95.3) | 100.0 (100.0, 100.0) |
| 12 months | 82.5 (46.1, 95.3) | NE (NE, NE) |
| 18 months | 82.5 (46.1, 95.3) | NE (NE, NE) |
| 24 months | 82.5 (46.1, 95.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 0 |
| Censored Patients, n (%) | 19 (95.0%) | 21 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3613 | |
| HR (95% CI) [c] | 67878667 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.8935 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 100.0 (100.0, 100.0) |
| 12 months | 91.7 (53.9, 98.8) | NE (NE, NE) |
| 18 months | 91.7 (53.9, 98.8) | NE (NE, NE) |
| 24 months | 91.7 (53.9, 98.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 4 (20.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 16 (80.0%) | 19 (90.5%) |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | 6.28 (2.43, 6.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9471 | |
| HR (95% CI) [c] | 0.943 (0.168, 5.289) | |
| HR P-Value [c] | 0.9471 | |
| Heterogeneity p-value [d] | 0.5507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.7 (34.4, 86.7) | 80.0 (20.4, 96.9) |
| 12 months | 67.7 (34.4, 86.7) | 0.0 (NE, NE) |
| 18 months | 67.7 (34.4, 86.7) | 0.0 (NE, NE) |
| 24 months | 67.7 (34.4, 86.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 18 (90.0%) | 19 (90.5%) |
| Median (95% CI), (Months) [a] | NE (1.48, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9043 | |
| HR (95% CI) [c] | 0.886 (0.123, 6.364) | |
| HR P-Value [c] | 0.9041 | |
| Heterogeneity p-value [d] | 0.7883 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.8 (36.5, 93.9) | NE (NE, NE) |
| 12 months | 77.8 (36.5, 93.9) | NE (NE, NE) |
| 18 months | 77.8 (36.5, 93.9) | NE (NE, NE) |
| 24 months | 77.8 (36.5, 93.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (4.8%) |
| Censored Patients, n (%) | 20 (100.0%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3173 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 5 (15.6%) |
| Censored Patients, n (%) | 26 (83.9%) | 27 (84.4%) |
| Median (95% CI), (Months) [a] | NE (1.84, NE) | NE (2.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7982 | |
| HR (95% CI) [c] | 1.176 (0.340, 4.067) | |
| HR P-Value [c] | 0.7984 | |
| Heterogeneity p-value [d] | 0.9995 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.9 (19.8, 76.7) | 56.4 (24.4, 79.3) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 3 (9.4%) |
| Censored Patients, n (%) | 27 (87.1%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | 7.03 (1.91, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6457 | |
| HR (95% CI) [c] | 1.434 (0.320, 6.420) | |
| HR P-Value [c] | 0.6376 | |
| Heterogeneity p-value [d] | 0.6074 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (33.7, 90.1) | 73.9 (37.9, 91.0) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 3 (9.4%) |
| Censored Patients, n (%) | 23 (74.2%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | 4.96 (1.84, 15.31) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2307 | |
| HR (95% CI) [c] | 2.265 (0.575, 8.931) | |
| HR P-Value [c] | 0.2426 | |
| Heterogeneity p-value [d] | 0.1248 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.7 (7.7, 67.6) | 71.3 (34.4, 89.8) |
| 12 months | 36.7 (7.7, 67.6) | 71.3 (34.4, 89.8) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 4 (12.5%) |
| Censored Patients, n (%) | 27 (87.1%) | 28 (87.5%) |
| | | |
| Median (95% CI), (Months) [a] | 1.68 (1.45, 2.83) | 1.51 (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5013 | |
| HR (95% CI) [c] | 1.690 (0.375, 7.627) | |
| HR P-Value [c] | 0.4947 | |
| Heterogeneity p-value [d] | 0.3236 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 40.0 (5.2, 75.3) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 1 (3.1%) |
| Censored Patients, n (%) | 27 (87.1%) | 31 (96.9%) |
| Median (95% CI), (Months) [a] | 2.10 (1.45, 11.33) | NE (1.94, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1555 | |
| HR (95% CI) [c] | 4.309 (0.479, 38.741) | |
| HR P-Value [c] | 0.1924 | |
| Heterogeneity p-value [d] | 0.7937 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.4 (6.6, 78.5) | 80.0 (20.4, 96.9) |
| 12 months | 0.0 (NE, NE) | 80.0 (20.4, 96.9) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 3 (9.4%) |
| Censored Patients, n (%) | 26 (83.9%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | NE (4.96, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6233 | |
| HR (95% CI) [c] | 1.429 (0.341, 5.982) | |
| HR P-Value [c] | 0.6252 | |
| Heterogeneity p-value [d] | 0.9037 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.8 (40.9, 86.6) | 70.3 (30.1, 90.2) |
| 12 months | 69.8 (40.9, 86.6) | 70.3 (30.1, 90.2) |
| 18 months | 69.8 (40.9, 86.6) | NE (NE, NE) |
| 24 months | 69.8 (40.9, 86.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 5 (16.1%) | 5 (15.6%) |
| Censored Patients, n (%) | 26 (83.9%) | 27 (84.4%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | NE (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6849 | |
| HR (95% CI) [c] | 1.295 (0.371, 4.524) | |
| HR P-Value [c] | 0.6857 | |
| Heterogeneity p-value [d] | 0.8266 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (35.9, 85.3) | 81.8 (58.4, 92.8) |
| 12 months | 66.7 (35.9, 85.3) | 54.6 (9.4, 85.6) |
| 18 months | 66.7 (35.9, 85.3) | NE (NE, NE) |
| 24 months | 66.7 (35.9, 85.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 3 (9.4%) |
| Censored Patients, n (%) | 28 (90.3%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | 4.67 (1.84, NE) | 8.97 (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2029 | |
| HR (95% CI) [c] | 3.032 (0.504, 18.250) | |
| HR P-Value [c] | 0.2257 | |
| Heterogeneity p-value [d] | 0.5780 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.9 (5.8, 77.7) | 86.7 (56.4, 96.5) |
| 12 months | NE (NE, NE) | 43.3 (1.2, 85.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 2 (6.5%) | 3 (9.4%) |
| Censored Patients, n (%) | 29 (93.5%) | 29 (90.6%) |
| Median (95% CI), (Months) [a] | 1.91 (1.45, NE) | 2.14 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7560 | |
| HR (95% CI) [c] | 0.758 (0.125, 4.606) | |
| HR P-Value [c] | 0.7637 | |
| Heterogeneity p-value [d] | 0.9643 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.5 (1.1, 80.8) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 6 (19.4%) | 5 (15.6%) |
| Censored Patients, n (%) | 25 (80.6%) | 27 (84.4%) |
| | | |
| Median (95% CI), (Months) [a] | NE (4.67, NE) | NE (5.39, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8463 | |
| HR (95% CI) [c] | 1.125 (0.343, 3.693) | |
| HR P-Value [c] | 0.8464 | |
| Heterogeneity p-value [d] | 0.9939 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.5 (26.3, 78.3) | 72.2 (39.5, 89.2) |
| 12 months | 56.5 (26.3, 78.3) | 54.2 (16.5, 81.2) |
| 18 months | 56.5 (26.3, 78.3) | NE (NE, NE) |
| 24 months | 56.5 (26.3, 78.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 2 (6.3%) |
| Censored Patients, n (%) | 28 (90.3%) | 30 (93.8%) |
| Median (95% CI), (Months) [a] | NE (4.67, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5519 | |
| HR (95% CI) [c] | 1.711 (0.285, 10.258) | |
| HR P-Value [c] | 0.5566 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.6 (30.9, 89.4) | 85.9 (52.9, 96.4) |
| 12 months | NE (NE, NE) | 85.9 (52.9, 96.4) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 1 (3.1%) |
| Censored Patients, n (%) | 28 (90.3%) | 31 (96.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2585 | |
| HR (95% CI) [c] | 3.411 (0.355, 32.825) | |
| HR P-Value [c] | 0.2881 | |
| Heterogeneity p-value [d] | 0.8935 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.4 (50.1, 94.1) | 93.3 (61.3, 99.0) |
| 12 months | 81.4 (50.1, 94.1) | 93.3 (61.3, 99.0) |
| 18 months | 81.4 (50.1, 94.1) | NE (NE, NE) |
| 24 months | 81.4 (50.1, 94.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 4 (12.9%) | 2 (6.3%) |
| Censored Patients, n (%) | 27 (87.1%) | 30 (93.8%) |
| Median (95% CI), (Months) [a] | NE (1.84, NE) | NE (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2237 | |
| HR (95% CI) [c] | 2.749 (0.503, 15.028) | |
| HR P-Value [c] | 0.2433 | |
| Heterogeneity p-value [d] | 0.5507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.3 (17.3, 79.8) | 83.3 (46.2, 95.8) |
| 12 months | NE (NE, NE) | 83.3 (46.2, 95.8) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 7 (22.6%) | 5 (15.6%) |
| Censored Patients, n (%) | 24 (77.4%) | 27 (84.4%) |
| Median (95% CI), (Months) [a] | 4.96 (1.84, 8.61) | NE (2.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2503 | |
| HR (95% CI) [c] | 1.941 (0.614, 6.139) | |
| HR P-Value [c] | 0.2588 | |
| Heterogeneity p-value [d] | 0.7883 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 37.7 (9.6, 66.6) | 65.7 (35.5, 84.3) |
| 12 months | 0.0 (NE, NE) | 65.7 (35.5, 84.3) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.3a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts sustained improvement

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 6 (19.4%) | 5 (15.6%) |
| Censored Patients, n (%) | 25 (80.6%) | 27 (84.4%) |
| Median (95% CI), (Months) [a] | 7.23 (1.84, NE) | 7.03 (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6108 | |
| HR (95% CI) [c] | 1.373 (0.412, 4.576) | |
| HR P-Value [c] | 0.6062 | |
| Heterogeneity p-value [d] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.6 (29.7, 84.4) | 75.2 (46.1, 90.0) |
| 12 months | NE (NE, NE) | 37.6 (1.6, 79.4) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 45 (25.0%) | 50 (30.7%) |
| Censored Patients, n (%) | 135 (75.0%) | 113 (69.3%) |
| Median (95% CI), (Months) [a] | NE (10.18, NE) | 8.90 (4.83, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0083 | |
| HR (95% CI) [c] | 0.579 (0.384, 0.873) | |
| HR P-Value [c] | 0.0091 | |
| Heterogeneity p-value [d] | 0.9192 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.7 (60.2, 77.3) | 56.6 (45.9, 65.9) |
| 12 months | 56.5 (44.9, 66.6) | 29.7 (14.3, 46.9) |
| 18 months | 54.1 (42.0, 64.7) | 29.7 (14.3, 46.9) |
| 24 months | 54.1 (42.0, 64.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 43 (23.9%) | 45 (27.6%) |
| Censored Patients, n (%) | 137 (76.1%) | 118 (72.4%) |
| Median (95% CI), (Months) [a] | 16.53 (12.88, NE) | 8.90 (5.22, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0126 | |
| HR (95% CI) [c] | 0.582 (0.378, 0.896) | |
| HR P-Value [c] | 0.0139 | |
| Heterogeneity p-value [d] | 0.4269 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.3 (65.2, 81.4) | 58.1 (47.4, 67.5) |
| 12 months | 66.2 (55.2, 75.1) | 48.8 (34.6, 61.5) |
| 18 months | 45.2 (29.9, 59.3) | 48.8 (34.6, 61.5) |
| 24 months | 45.2 (29.9, 59.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 35 (19.4%) | 41 (25.2%) |
| Censored Patients, n (%) | 145 (80.6%) | 122 (74.8%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 11.50 (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0146 | |
| HR (95% CI) [c] | 0.569 (0.359, 0.901) | |
| HR P-Value [c] | 0.0162 | |
| Heterogeneity p-value [d] | 0.2130 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.3 (67.3, 83.1) | 66.0 (55.3, 74.7) |
| 12 months | 67.2 (56.4, 75.9) | 37.5 (18.4, 56.7) |
| 18 months | 63.3 (50.1, 73.8) | 28.1 (9.6, 50.4) |
| 24 months | 63.3 (50.1, 73.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 22 (12.2%) | 20 (12.3%) |
| Censored Patients, n (%) | 158 (87.8%) | 143 (87.7%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1908 | |
| HR (95% CI) [c] | 0.659 (0.351, 1.236) | |
| HR P-Value [c] | 0.1936 | |
| Heterogeneity p-value [d] | 0.7747 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.6 (82.0, 94.0) | 80.3 (70.0, 87.4) |
| 12 months | 74.1 (61.2, 83.3) | 70.5 (52.9, 82.5) |
| 18 months | 70.0 (54.8, 80.9) | 70.5 (52.9, 82.5) |
| 24 months | 63.0 (43.0, 77.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 28 (15.6%) | 35 (21.5%) |
| Censored Patients, n (%) | 152 (84.4%) | 128 (78.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0135 | |
| HR (95% CI) [c] | 0.532 (0.319, 0.886) | |
| HR P-Value [c] | 0.0153 | |
| Heterogeneity p-value [d] | 0.5135 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.2 (74.1, 88.0) | 66.7 (55.7, 75.6) |
| 12 months | 73.1 (61.7, 81.5) | 51.1 (31.6, 67.6) |
| 18 months | 68.2 (53.2, 79.3) | 51.1 (31.6, 67.6) |
| 24 months | 68.2 (53.2, 79.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 33 (18.3%) | 35 (21.5%) |
| Censored Patients, n (%) | 147 (81.7%) | 128 (78.5%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0325 | |
| HR (95% CI) [c] | 0.588 (0.359, 0.963) | |
| HR P-Value [c] | 0.0349 | |
| Heterogeneity p-value [d] | 0.8355 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.0 (73.7, 87.8) | 69.4 (58.8, 77.8) |
| 12 months | 69.9 (58.2, 78.9) | 50.8 (33.3, 65.9) |
| 18 months | 60.8 (45.9, 72.8) | 50.8 (33.3, 65.9) |
| 24 months | 50.7 (28.3, 69.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 70 (38.9%) | 64 (39.3%) |
| Censored Patients, n (%) | 110 (61.1%) | 99 (60.7%) |
| Median (95% CI), (Months) [a] | 10.12 (5.72, 12.45) | 4.40 (2.96, 8.34) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0343 | |
| HR (95% CI) [c] | 0.691 (0.488, 0.979) | |
| HR P-Value [c] | 0.0373 | |
| Heterogeneity p-value [d] | 0.6794 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.9 (46.6, 64.2) | 48.7 (38.8, 58.0) |
| 12 months | 41.4 (31.2, 51.4) | 23.5 (10.5, 39.4) |
| 18 months | 32.5 (21.6, 43.8) | 23.5 (10.5, 39.4) |
| 24 months | 32.5 (21.6, 43.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 35 (19.4%) | 35 (21.5%) |
| Censored Patients, n (%) | 145 (80.6%) | 128 (78.5%) |
| Median (95% CI), (Months) [a] | 20.80 (12.48, NE) | 10.35 (6.70, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0224 | |
| HR (95% CI) [c] | 0.574 (0.354, 0.930) | |
| HR P-Value [c] | 0.0240 | |
| Heterogeneity p-value [d] | 0.7639 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.2 (68.8, 85.1) | 69.7 (58.4, 78.4) |
| 12 months | 64.1 (51.8, 74.1) | 37.3 (18.8, 55.8) |
| 18 months | 55.5 (41.2, 67.6) | 37.3 (18.8, 55.8) |
| 24 months | 46.2 (26.0, 64.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 35 (19.4%) | 43 (26.4%) |
| Censored Patients, n (%) | 145 (80.6%) | 120 (73.6%) |
| Median (95% CI), (Months) [a] | NE (14.59, NE) | 11.07 (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0021 | |
| HR (95% CI) [c] | 0.491 (0.309, 0.780) | |
| HR P-Value [c] | 0.0026 | |
| Heterogeneity p-value [d] | 0.2043 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (71.4, 86.3) | 62.9 (52.2, 71.9) |
| 12 months | 65.5 (53.7, 75.0) | 35.4 (13.3, 58.6) |
| 18 months | 59.9 (46.6, 70.9) | 35.4 (13.3, 58.6) |
| 24 months | 59.9 (46.6, 70.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 46 (25.6%) | 52 (31.9%) |
| Censored Patients, n (%) | 134 (74.4%) | 111 (68.1%) |
| Median (95% CI), (Months) [a] | 19.15 (10.18, NE) | 6.47 (4.21, 11.07) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0053 | |
| HR (95% CI) [c] | 0.566 (0.376, 0.850) | |
| HR P-Value [c] | 0.0061 | |
| Heterogeneity p-value [d] | 0.5831 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.0 (58.3, 76.0) | 50.0 (39.0, 60.1) |
| 12 months | 53.2 (41.1, 64.0) | 26.0 (10.9, 44.0) |
| 18 months | 51.1 (38.8, 62.1) | 26.0 (10.9, 44.0) |
| 24 months | 42.6 (24.5, 59.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 50 (27.8%) | 58 (35.6%) |
| Censored Patients, n (%) | 130 (72.2%) | 105 (64.4%) |
| Median (95% CI), (Months) [a] | 14.55 (10.45, NE) | 6.08 (4.37, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0003 | |
| HR (95% CI) [c] | 0.491 (0.331, 0.727) | |
| HR P-Value [c] | 0.0004 | |
| Heterogeneity p-value [d] | 0.9345 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.8 (62.8, 79.1) | 50.5 (39.8, 60.2) |
| 12 months | 55.9 (44.4, 66.0) | 30.2 (15.8, 46.0) |
| 18 months | 45.7 (32.7, 57.8) | 24.2 (10.1, 41.5) |
| 24 months | 38.1 (21.3, 54.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 47 (26.1%) | 57 (35.0%) |
| Censored Patients, n (%) | 133 (73.9%) | 106 (65.0%) |
| Median (95% CI), (Months) [a] | 13.90 (8.61, NE) | 6.24 (4.17, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0004 | |
| HR (95% CI) [c] | 0.496 (0.334, 0.737) | |
| HR P-Value [c] | 0.0005 | |
| Heterogeneity p-value [d] | 0.4200 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.2 (67.1, 83.1) | 51.5 (40.9, 61.1) |
| 12 months | 50.6 (38.7, 61.3) | 31.3 (16.9, 46.8) |
| 18 months | 44.6 (31.7, 56.8) | 31.3 (16.9, 46.8) |
| 24 months | 44.6 (31.7, 56.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 48 (26.7%) | 56 (34.4%) |
| Censored Patients, n (%) | 132 (73.3%) | 107 (65.6%) |
| Median (95% CI), (Months) [a] | 14.06 (11.24, NE) | 6.77 (4.21, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0010 | |
| HR (95% CI) [c] | 0.519 (0.349, 0.773) | |
| HR P-Value [c] | 0.0012 | |
| Heterogeneity p-value [d] | 0.3381 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.0 (61.7, 78.5) | 50.1 (39.6, 59.7) |
| 12 months | 59.1 (47.5, 68.9) | 31.0 (16.8, 46.3) |
| 18 months | 41.8 (28.4, 54.6) | 31.0 (16.8, 46.3) |
| 24 months | 41.8 (28.4, 54.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 40 (22.2%) | 49 (30.1%) |
| Censored Patients, n (%) | 140 (77.8%) | 114 (69.9%) |
| Median (95% CI), (Months) [a] | 20.76 (11.24, NE) | 7.06 (5.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0012 | |
| HR (95% CI) [c] | 0.496 (0.321, 0.765) | |
| HR P-Value [c] | 0.0016 | |
| Heterogeneity p-value [d] | 0.4103 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.6 (68.6, 84.3) | 57.3 (46.6, 66.7) |
| 12 months | 62.1 (49.9, 72.1) | 42.6 (29.6, 55.0) |
| 18 months | 51.7 (36.8, 64.8) | 42.6 (29.6, 55.0) |
| 24 months | 34.5 (14.6, 55.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Patients with event, n (%) | 42 (23.3%) | 37 (22.7%) |
| Censored Patients, n (%) | 138 (76.7%) | 126 (77.3%) |
| Median (95% CI), (Months) [a] | 16.66 (10.09, NE) | 9.72 (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1481 | |
| HR (95% CI) [c] | 0.717 (0.455, 1.130) | |
| HR P-Value [c] | 0.1512 | |
| Heterogeneity p-value [d] | 0.7449 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.8 (62.0, 79.5) | 73.4 (63.6, 80.9) |
| 12 months | 54.7 (42.0, 65.8) | 38.7 (20.2, 56.8) |
| 18 months | 43.8 (29.0, 57.7) | 38.7 (20.2, 56.8) |
| 24 months | 43.8 (29.0, 57.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 3 (15.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | 20.17 (7.03, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6936 | |
| HR (95% CI) [c] | 0.709 (0.140, 3.583) | |
| HR P-Value [c] | 0.6774 | |
| Heterogeneity p-value [d] | 0.9192 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.1 (52.3, 96.1) | 68.2 (29.7, 88.6) |
| 12 months | 74.5 (38.7, 91.3) | NE (NE, NE) |
| 18 months | 74.5 (38.7, 91.3) | NE (NE, NE) |
| 24 months | 37.2 (1.5, 79.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 6 (30.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 14 (70.0%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | 5.78 (1.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2097 | |
| HR (95% CI) [c] | 0.419 (0.104, 1.685) | |
| HR P-Value [c] | 0.2207 | |
| Heterogeneity p-value [d] | 0.4269 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.6 (47.2, 92.5) | 41.0 (11.0, 69.8) |
| 12 months | 78.6 (47.2, 92.5) | NE (NE, NE) |
| 18 months | 58.9 (17.6, 85.1) | NE (NE, NE) |
| 24 months | 58.9 (17.6, 85.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 2 (10.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4516 | |
| HR (95% CI) [c] | 1.880 (0.354, 9.979) | |
| HR P-Value [c] | 0.4588 | |
| Heterogeneity p-value [d] | 0.2130 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.6 (37.8, 87.4) | 83.1 (47.2, 95.5) |
| 12 months | 58.0 (25.2, 80.7) | NE (NE, NE) |
| 18 months | 58.0 (25.2, 80.7) | NE (NE, NE) |
| 24 months | 58.0 (25.2, 80.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 1 (5.0%) |
| Censored Patients, n (%) | 14 (87.5%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | NE (5.29, NE) | NE (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7862 | |
| HR (95% CI) [c] | 1.395 (0.125, 15.593) | |
| HR P-Value [c] | 0.7871 | |
| Heterogeneity p-value [d] | 0.7747 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.6 (48.0, 95.7) | 90.0 (47.3, 98.5) |
| 12 months | 83.6 (48.0, 95.7) | NE (NE, NE) |
| 18 months | 83.6 (48.0, 95.7) | NE (NE, NE) |
| 24 months | 83.6 (48.0, 95.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 7 (43.8%) | 6 (30.0%) |
| Censored Patients, n (%) | 9 (56.3%) | 14 (70.0%) |
| Median (95% CI), (Months) [a] | 14.26 (1.58, NE) | 5.65 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6235 | |
| HR (95% CI) [c] | 0.751 (0.239, 2.362) | |
| HR P-Value [c] | 0.6249 | |
| Heterogeneity p-value [d] | 0.5135 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.6 (22.9, 75.7) | 48.2 (14.1, 76.3) |
| 12 months | 52.6 (22.9, 75.7) | NE (NE, NE) |
| 18 months | 42.1 (14.6, 67.8) | NE (NE, NE) |
| 24 months | 42.1 (14.6, 67.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 3 (18.8%) | 2 (10.0%) |
| Censored Patients, n (%) | 13 (81.3%) | 18 (90.0%) |
| Median (95% CI), (Months) [a] | 20.17 (14.65, NE) | NE (1.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4580 | |
| HR (95% CI) [c] | 0.414 (0.037, 4.581) | |
| HR P-Value [c] | 0.4723 | |
| Heterogeneity p-value [d] | 0.8355 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.9 (50.8, 98.7) | 83.3 (48.2, 95.6) |
| 12 months | 90.9 (50.8, 98.7) | NE (NE, NE) |
| 18 months | 72.7 (24.1, 93.1) | NE (NE, NE) |
| 24 months | 36.4 (1.3, 78.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 9 (56.3%) | 10 (50.0%) |
| Censored Patients, n (%) | 7 (43.8%) | 10 (50.0%) |
| Median (95% CI), (Months) [a] | 7.29 (1.48, NE) | 2.89 (1.71, 8.54) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3013 | |
| HR (95% CI) [c] | 0.592 (0.228, 1.537) | |
| HR P-Value [c] | 0.2812 | |
| Heterogeneity p-value [d] | 0.6794 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.5 (25.2, 74.0) | 32.1 (8.8, 58.8) |
| 12 months | 43.8 (17.9, 67.2) | 0.0 (NE, NE) |
| 18 months | 43.8 (17.9, 67.2) | 0.0 (NE, NE) |
| 24 months | 21.9 (1.6, 57.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 2 (12.5%) | 1 (5.0%) |
| Censored Patients, n (%) | 14 (87.5%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | NE (5.55, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8192 | |
| HR (95% CI) [c] | 1.325 (0.118, 14.882) | |
| HR P-Value [c] | 0.8197 | |
| Heterogeneity p-value [d] | 0.7639 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.5 (45.1, 95.5) | 91.7 (53.9, 98.8) |
| 12 months | 82.5 (45.1, 95.5) | NE (NE, NE) |
| 18 months | 82.5 (45.1, 95.5) | NE (NE, NE) |
| 24 months | 82.5 (45.1, 95.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 4 (25.0%) | 1 (5.0%) |
| Censored Patients, n (%) | 12 (75.0%) | 19 (95.0%) |
| Median (95% CI), (Months) [a] | 17.71 (7.03, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7217 | |
| HR (95% CI) [c] | 1.523 (0.148, 15.657) | |
| HR P-Value [c] | 0.7235 | |
| Heterogeneity p-value [d] | 0.2043 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (53.9, 98.8) | 92.3 (56.6, 98.9) |
| 12 months | 68.7 (30.2, 88.9) | NE (NE, NE) |
| 18 months | 45.8 (8.2, 78.4) | NE (NE, NE) |
| 24 months | 45.8 (8.2, 78.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 8 (40.0%) |
| Censored Patients, n (%) | 10 (62.5%) | 12 (60.0%) |
| Median (95% CI), (Months) [a] | 20.17 (2.92, 20.17) | 2.83 (1.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1898 | |
| HR (95% CI) [c] | 0.474 (0.154, 1.459) | |
| HR P-Value [c] | 0.1929 | |
| Heterogeneity p-value [d] | 0.5831 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.2 (31.5, 82.3) | 36.9 (12.5, 62.0) |
| 12 months | 62.2 (31.5, 82.3) | NE (NE, NE) |
| 18 months | 62.2 (31.5, 82.3) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 6 (30.0%) |
| Censored Patients, n (%) | 10 (62.5%) | 14 (70.0%) |
| Median (95% CI), (Months) [a] | 20.17 (2.83, NE) | 9.59 (1.77, 9.92) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2926 | |
| HR (95% CI) [c] | 0.520 (0.153, 1.770) | |
| HR P-Value [c] | 0.2952 | |
| Heterogeneity p-value [d] | 0.9345 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.9 (32.3, 82.6) | 65.1 (30.6, 85.6) |
| 12 months | 62.9 (32.3, 82.6) | 0.0 (NE, NE) |
| 18 months | 62.9 (32.3, 82.6) | 0.0 (NE, NE) |
| 24 months | 31.4 (1.8, 71.8) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 8 (50.0%) | 6 (30.0%) |
| Censored Patients, n (%) | 8 (50.0%) | 14 (70.0%) |
| Median (95% CI), (Months) [a] | 8.44 (1.58, NE) | 8.54 (1.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9562 | |
| HR (95% CI) [c] | 1.037 (0.357, 3.008) | |
| HR P-Value [c] | 0.9471 | |
| Heterogeneity p-value [d] | 0.4200 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.4 (28.7, 78.2) | 59.8 (28.5, 81.0) |
| 12 months | 41.9 (16.5, 65.6) | NE (NE, NE) |
| 18 months | 41.9 (16.5, 65.6) | NE (NE, NE) |
| 24 months | 41.9 (16.5, 65.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 3 (15.0%) |
| Censored Patients, n (%) | 10 (62.5%) | 17 (85.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7191 | |
| HR (95% CI) [c] | 1.294 (0.306, 5.465) | |
| HR P-Value [c] | 0.7263 | |
| Heterogeneity p-value [d] | 0.3381 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.5 (33.1, 83.0) | 80.0 (40.9, 94.6) |
| 12 months | 63.5 (33.1, 83.0) | NE (NE, NE) |
| 18 months | 50.8 (19.5, 75.5) | NE (NE, NE) |
| 24 months | 50.8 (19.5, 75.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 7 (43.8%) | 4 (20.0%) |
| Censored Patients, n (%) | 9 (56.3%) | 16 (80.0%) |
| Median (95% CI), (Months) [a] | 20.17 (3.48, 20.83) | 8.54 (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8438 | |
| HR (95% CI) [c] | 0.876 (0.233, 3.286) | |
| HR P-Value [c] | 0.8439 | |
| Heterogeneity p-value [d] | 0.4103 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.3 (31.7, 82.4) | 67.7 (24.9, 89.6) |
| 12 months | 62.3 (31.7, 82.4) | NE (NE, NE) |
| 18 months | 62.3 (31.7, 82.4) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Patients with event, n (%) | 5 (31.3%) | 4 (20.0%) |
| Censored Patients, n (%) | 11 (68.8%) | 16 (80.0%) |
| Median (95% CI), (Months) [a] | 20.17 (2.76, NE) | NE (1.71, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8157 | |
| HR (95% CI) [c] | 0.836 (0.208, 3.366) | |
| HR P-Value [c] | 0.8010 | |
| Heterogeneity p-value [d] | 0.7449 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.3 (34.0, 86.5) | 64.8 (31.0, 85.2) |
| 12 months | 67.3 (34.0, 86.5) | NE (NE, NE) |
| 18 months | 67.3 (34.0, 86.5) | NE (NE, NE) |
| 24 months | 33.7 (1.7, 74.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 34 (25.0%) | 33 (26.8%) |
| Censored Patients, n (%) | 102 (75.0%) | 90 (73.2%) |
| Median (95% CI), (Months) [a] | 20.17 (10.18, NE) | 9.69 (4.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0466 | |
| HR (95% CI) [c] | 0.610 (0.373, 0.998) | |
| HR P-Value [c] | 0.0488 | |
| Heterogeneity p-value [d] | 0.6012 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.2 (61.3, 80.5) | 59.6 (46.7, 70.3) |
| 12 months | 59.4 (46.7, 70.0) | 33.1 (14.5, 53.1) |
| 18 months | 56.7 (43.5, 67.9) | 33.1 (14.5, 53.1) |
| 24 months | 47.2 (27.0, 65.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 33 (24.3%) | 34 (27.6%) |
| Censored Patients, n (%) | 103 (75.7%) | 89 (72.4%) |
| Median (95% CI), (Months) [a] | NE (13.83, NE) | 8.90 (5.78, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0272 | |
| HR (95% CI) [c] | 0.577 (0.352, 0.948) | |
| HR P-Value [c] | 0.0298 | |
| Heterogeneity p-value [d] | 0.9652 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.6 (63.1, 81.5) | 58.9 (46.5, 69.4) |
| 12 months | 68.1 (56.4, 77.3) | 47.1 (30.1, 62.3) |
| 18 months | 51.8 (36.1, 65.4) | 47.1 (30.1, 62.3) |
| 24 months | 51.8 (36.1, 65.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 26 (19.1%) | 26 (21.1%) |
| Censored Patients, n (%) | 110 (80.9%) | 97 (78.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 14.13 (6.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0965 | |
| HR (95% CI) [c] | 0.627 (0.359, 1.095) | |
| HR P-Value [c] | 0.1008 | |
| Heterogeneity p-value [d] | 0.8976 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.5 (69.7, 86.5) | 68.0 (55.0, 78.0) |
| 12 months | 68.2 (55.7, 77.9) | 56.8 (39.6, 70.8) |
| 18 months | 64.5 (50.2, 75.6) | 37.8 (9.8, 66.6) |
| 24 months | 64.5 (50.2, 75.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 18 (13.2%) | 11 (8.9%) |
| Censored Patients, n (%) | 118 (86.8%) | 112 (91.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9454 | |
| HR (95% CI) [c] | 1.027 (0.476, 2.217) | |
| HR P-Value [c] | 0.9452 | |
| Heterogeneity p-value [d] | 0.1823 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (78.2, 93.0) | 84.4 (73.3, 91.2) |
| 12 months | 74.6 (61.1, 84.0) | 84.4 (73.3, 91.2) |
| 18 months | 70.2 (54.3, 81.5) | 84.4 (73.3, 91.2) |
| 24 months | 70.2 (54.3, 81.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 21 (15.4%) | 24 (19.5%) |
| Censored Patients, n (%) | 115 (84.6%) | 99 (80.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (10.35, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0530 | |
| HR (95% CI) [c] | 0.557 (0.305, 1.018) | |
| HR P-Value [c] | 0.0571 | |
| Heterogeneity p-value [d] | 0.9044 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.2 (73.8, 89.4) | 68.6 (55.6, 78.5) |
| 12 months | 74.3 (61.5, 83.3) | 56.2 (34.3, 73.3) |
| 18 months | 70.7 (56.4, 81.1) | 56.2 (34.3, 73.3) |
| 24 months | 70.7 (56.4, 81.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 27 (19.9%) | 23 (18.7%) |
| Censored Patients, n (%) | 109 (80.1%) | 100 (81.3%) |
| Median (95% CI), (Months) [a] | NE (14.65, NE) | NE (8.90, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2117 | |
| HR (95% CI) [c] | 0.694 (0.390, 1.237) | |
| HR P-Value [c] | 0.2157 | |
| Heterogeneity p-value [d] | 0.3561 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.1 (72.6, 88.5) | 70.5 (57.8, 80.0) |
| 12 months | 69.9 (56.9, 79.6) | 61.3 (42.8, 75.3) |
| 18 months | 61.1 (46.0, 73.2) | 61.3 (42.8, 75.3) |
| 24 months | 52.4 (31.4, 69.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 56 (41.2%) | 48 (39.0%) |
| Censored Patients, n (%) | 80 (58.8%) | 75 (61.0%) |
| Median (95% CI), (Months) [a] | 9.69 (5.72, 14.55) | 4.40 (2.83, 8.54) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0542 | |
| HR (95% CI) [c] | 0.682 (0.459, 1.014) | |
| HR P-Value [c] | 0.0585 | |
| Heterogeneity p-value [d] | 0.8942 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.2 (45.6, 65.5) | 47.1 (35.6, 57.8) |
| 12 months | 39.3 (28.1, 50.4) | 25.9 (12.1, 42.1) |
| 18 months | 34.0 (22.5, 46.0) | 25.9 (12.1, 42.1) |
| 24 months | 28.4 (15.3, 42.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 24 (17.6%) | 18 (14.6%) |
| Censored Patients, n (%) | 112 (82.4%) | 105 (85.4%) |
| Median (95% CI), (Months) [a] | NE (13.93, NE) | NE (8.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2685 | |
| HR (95% CI) [c] | 0.703 (0.377, 1.314) | |
| HR P-Value [c] | 0.2696 | |
| Heterogeneity p-value [d] | 0.3789 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.5 (70.9, 88.6) | 77.3 (64.3, 86.0) |
| 12 months | 68.6 (54.8, 79.0) | 55.6 (32.8, 73.4) |
| 18 months | 58.3 (42.1, 71.5) | 55.6 (32.8, 73.4) |
| 24 months | 58.3 (42.1, 71.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 29 (21.3%) | 26 (21.1%) |
| Censored Patients, n (%) | 107 (78.7%) | 97 (78.9%) |
| Median (95% CI), (Months) [a] | NE (14.59, NE) | 11.07 (8.90, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0851 | |
| HR (95% CI) [c] | 0.618 (0.356, 1.073) | |
| HR P-Value [c] | 0.0874 | |
| Heterogeneity p-value [d] | 0.2844 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.0 (71.3, 87.7) | 68.5 (55.9, 78.1) |
| 12 months | 64.4 (51.3, 74.8) | 49.3 (23.3, 70.9) |
| 18 months | 56.8 (41.2, 69.7) | 49.3 (23.3, 70.9) |
| 24 months | 56.8 (41.2, 69.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 37 (27.2%) | 39 (31.7%) |
| Censored Patients, n (%) | 99 (72.8%) | 84 (68.3%) |
| Median (95% CI), (Months) [a] | 19.15 (10.12, NE) | 6.47 (4.21, 11.07) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0093 | |
| HR (95% CI) [c] | 0.544 (0.341, 0.868) | |
| HR P-Value [c] | 0.0107 | |
| Heterogeneity p-value [d] | 0.9529 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.6 (57.7, 77.3) | 50.2 (37.6, 61.5) |
| 12 months | 54.8 (41.8, 65.9) | 27.9 (11.5, 47.2) |
| 18 months | 54.8 (41.8, 65.9) | 27.9 (11.5, 47.2) |
| 24 months | 36.5 (15.8, 57.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 41 (30.1%) | 42 (34.1%) |
| Censored Patients, n (%) | 95 (69.9%) | 81 (65.9%) |
| Median (95% CI), (Months) [a] | 14.55 (9.82, NE) | 7.00 (4.40, 9.92) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0035 | |
| HR (95% CI) [c] | 0.518 (0.330, 0.811) | |
| HR P-Value [c] | 0.0041 | |
| Heterogeneity p-value [d] | 0.6278 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.9 (60.5, 79.0) | 53.2 (40.9, 64.0) |
| 12 months | 55.0 (42.6, 65.9) | 32.2 (16.4, 49.1) |
| 18 months | 46.8 (33.3, 59.3) | 24.1 (8.6, 43.9) |
| 24 months | 39.0 (21.7, 56.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 42 (30.9%) | 41 (33.3%) |
| Censored Patients, n (%) | 94 (69.1%) | 82 (66.7%) |
| Median (95% CI), (Months) [a] | 10.09 (8.44, NE) | 7.00 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0132 | |
| HR (95% CI) [c] | 0.577 (0.371, 0.896) | |
| HR P-Value [c] | 0.0144 | |
| Heterogeneity p-value [d] | 0.5014 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.5 (63.2, 81.4) | 53.8 (41.6, 64.5) |
| 12 months | 45.2 (32.9, 56.7) | 36.0 (20.6, 51.7) |
| 18 months | 45.2 (32.9, 56.7) | 36.0 (20.6, 51.7) |
| 24 months | 45.2 (32.9, 56.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 41 (30.1%) | 38 (30.9%) |
| Censored Patients, n (%) | 95 (69.9%) | 85 (69.1%) |
| Median (95% CI), (Months) [a] | 13.96 (10.45, NE) | 8.54 (4.27, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0267 | |
| HR (95% CI) [c] | 0.600 (0.380, 0.949) | |
| HR P-Value [c] | 0.0290 | |
| Heterogeneity p-value [d] | 0.2936 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.0 (59.2, 78.5) | 55.9 (43.4, 66.7) |
| 12 months | 56.8 (44.2, 67.6) | 36.0 (20.3, 51.9) |
| 18 months | 38.7 (25.0, 52.3) | 36.0 (20.3, 51.9) |
| 24 months | 38.7 (25.0, 52.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 34 (25.0%) | 31 (25.2%) |
| Censored Patients, n (%) | 102 (75.0%) | 92 (74.8%) |
| Median (95% CI), (Months) [a] | 20.17 (10.45, NE) | 8.84 (6.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0719 | |
| HR (95% CI) [c] | 0.632 (0.380, 1.050) | |
| HR P-Value [c] | 0.0766 | |
| Heterogeneity p-value [d] | 0.1449 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.8 (65.3, 83.4) | 67.5 (55.5, 76.9) |
| 12 months | 60.1 (46.9, 71.0) | 45.7 (28.4, 61.5) |
| 18 months | 53.4 (38.6, 66.1) | 45.7 (28.4, 61.5) |
| 24 months | 33.4 (12.1, 56.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Patients with event, n (%) | 28 (20.6%) | 30 (24.4%) |
| Censored Patients, n (%) | 108 (79.4%) | 93 (75.6%) |
| Median (95% CI), (Months) [a] | 20.17 (11.99, NE) | 9.72 (7.39, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0107 | |
| HR (95% CI) [c] | 0.501 (0.292, 0.861) | |
| HR P-Value [c] | 0.0123 | |
| Heterogeneity p-value [d] | 0.0433 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.2 (67.5, 85.8) | 70.7 (59.0, 79.6) |
| 12 months | 62.5 (48.2, 73.8) | 35.7 (15.6, 56.6) |
| 18 months | 54.1 (37.6, 68.0) | 35.7 (15.6, 56.6) |
| 24 months | 45.1 (24.3, 63.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 15 (25.0%) | 20 (33.3%) |
| Censored Patients, n (%) | 45 (75.0%) | 40 (66.7%) |
| Median (95% CI), (Months) [a] | NE (9.92, NE) | 6.67 (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0652 | |
| HR (95% CI) [c] | 0.532 (0.269, 1.052) | |
| HR P-Value [c] | 0.0697 | |
| Heterogeneity p-value [d] | 0.6012 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.8 (53.6, 81.3) | 53.1 (35.6, 67.8) |
| 12 months | 58.2 (37.5, 74.1) | 34.1 (12.4, 57.5) |
| 18 months | 58.2 (37.5, 74.1) | NE (NE, NE) |
| 24 months | 58.2 (37.5, 74.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 14 (23.3%) | 17 (28.3%) |
| Censored Patients, n (%) | 46 (76.7%) | 43 (71.7%) |
| Median (95% CI), (Months) [a] | 16.53 (11.07, NE) | 5.68 (4.24, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0671 | |
| HR (95% CI) [c] | 0.500 (0.234, 1.066) | |
| HR P-Value [c] | 0.0726 | |
| Heterogeneity p-value [d] | 0.9652 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.1 (61.7, 88.1) | 48.6 (28.0, 66.4) |
| 12 months | 66.5 (44.5, 81.4) | 48.6 (28.0, 66.4) |
| 18 months | 22.2 (1.5, 58.2) | NE (NE, NE) |
| 24 months | 22.2 (1.5, 58.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 14 (23.3%) | 17 (28.3%) |
| Censored Patients, n (%) | 46 (76.7%) | 43 (71.7%) |
| Median (95% CI), (Months) [a] | NE (5.78, NE) | 11.50 (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2808 | |
| HR (95% CI) [c] | 0.678 (0.332, 1.382) | |
| HR P-Value [c] | 0.2844 | |
| Heterogeneity p-value [d] | 0.8976 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.6 (47.0, 79.0) | 66.4 (49.0, 79.1) |
| 12 months | 60.9 (41.4, 75.7) | 17.2 (1.1, 50.3) |
| 18 months | 60.9 (41.4, 75.7) | NE (NE, NE) |
| 24 months | 60.9 (41.4, 75.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 6 (10.0%) | 10 (16.7%) |
| Censored Patients, n (%) | 54 (90.0%) | 50 (83.3%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | 8.87 (8.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0351 | |
| HR (95% CI) [c] | 0.321 (0.106, 0.970) | |
| HR P-Value [c] | 0.0440 | |
| Heterogeneity p-value [d] | 0.1823 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.5 (77.8, 97.6) | 74.6 (53.4, 87.2) |
| 12 months | 78.3 (50.8, 91.5) | 49.8 (18.9, 74.7) |
| 18 months | 78.3 (50.8, 91.5) | NE (NE, NE) |
| 24 months | 58.7 (18.3, 84.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 14 (23.3%) | 17 (28.3%) |
| Censored Patients, n (%) | 46 (76.7%) | 43 (71.7%) |
| Median (95% CI), (Months) [a] | 16.85 (7.62, NE) | 6.67 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1329 | |
| HR (95% CI) [c] | 0.576 (0.277, 1.196) | |
| HR P-Value [c] | 0.1387 | |
| Heterogeneity p-value [d] | 0.9044 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.1 (51.1, 81.7) | 56.3 (35.8, 72.5) |
| 12 months | 63.8 (44.0, 78.2) | 32.2 (7.8, 60.3) |
| 18 months | 47.9 (17.8, 73.0) | NE (NE, NE) |
| 24 months | 47.9 (17.8, 73.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 9 (15.0%) | 14 (23.3%) |
| Censored Patients, n (%) | 51 (85.0%) | 46 (76.7%) |
| Median (95% CI), (Months) [a] | 20.80 (16.85, NE) | 8.05 (7.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0254 | |
| HR (95% CI) [c] | 0.364 (0.145, 0.915) | |
| HR P-Value [c] | 0.0316 | |
| Heterogeneity p-value [d] | 0.3561 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.2 (67.7, 92.7) | 70.9 (53.0, 83.0) |
| 12 months | 78.6 (58.2, 89.8) | 36.4 (10.6, 63.5) |
| 18 months | 58.9 (19.4, 84.3) | NE (NE, NE) |
| 24 months | 39.3 (6.6, 72.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 23 (38.3%) | 26 (43.3%) |
| Censored Patients, n (%) | 37 (61.7%) | 34 (56.7%) |
| Median (95% CI), (Months) [a] | 12.45 (2.83, NE) | 5.68 (2.56, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1561 | |
| HR (95% CI) [c] | 0.661 (0.369, 1.182) | |
| HR P-Value [c] | 0.1625 | |
| Heterogeneity p-value [d] | 0.8942 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.2 (39.4, 68.5) | 44.4 (26.3, 61.0) |
| 12 months | 50.6 (33.8, 65.2) | 11.9 (1.1, 36.9) |
| 18 months | 33.8 (12.9, 56.2) | NE (NE, NE) |
| 24 months | 33.8 (12.9, 56.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 13 (21.7%) | 18 (30.0%) |
| Censored Patients, n (%) | 47 (78.3%) | 42 (70.0%) |
| Median (95% CI), (Months) [a] | 20.80 (7.62, NE) | 6.67 (5.22, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0537 | |
| HR (95% CI) [c] | 0.488 (0.231, 1.029) | |
| HR P-Value [c] | 0.0594 | |
| Heterogeneity p-value [d] | 0.3789 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.1 (53.6, 84.3) | 62.6 (43.5, 76.9) |
| 12 months | 61.7 (40.4, 77.3) | 16.4 (1.1, 48.6) |
| 18 months | 61.7 (40.4, 77.3) | NE (NE, NE) |
| 24 months | 46.3 (17.0, 71.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 10 (16.7%) | 18 (30.0%) |
| Censored Patients, n (%) | 50 (83.3%) | 42 (70.0%) |
| Median (95% CI), (Months) [a] | NE (10.38, NE) | 7.26 (5.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0104 | |
| HR (95% CI) [c] | 0.365 (0.164, 0.811) | |
| HR P-Value [c] | 0.0134 | |
| Heterogeneity p-value [d] | 0.2844 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.2 (63.8, 90.8) | 58.3 (38.7, 73.5) |
| 12 months | 70.0 (47.6, 84.2) | 23.3 (1.8, 59.1) |
| 18 months | 60.0 (32.7, 79.1) | NE (NE, NE) |
| 24 months | 60.0 (32.7, 79.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 15 (25.0%) | 21 (35.0%) |
| Censored Patients, n (%) | 45 (75.0%) | 39 (65.0%) |
| Median (95% CI), (Months) [a] | 12.45 (4.40, NE) | 4.67 (2.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1088 | |
| HR (95% CI) [c] | 0.582 (0.297, 1.140) | |
| HR P-Value [c] | 0.1143 | |
| Heterogeneity p-value [d] | 0.9529 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.8 (48.0, 78.8) | 47.3 (30.4, 62.5) |
| 12 months | 58.5 (37.1, 74.9) | 23.7 (2.1, 58.6) |
| 18 months | 48.8 (24.3, 69.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 15 (25.0%) | 22 (36.7%) |
| Censored Patients, n (%) | 45 (75.0%) | 38 (63.3%) |
| Median (95% CI), (Months) [a] | 20.80 (10.45, NE) | 6.67 (3.02, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0150 | |
| HR (95% CI) [c] | 0.439 (0.221, 0.871) | |
| HR P-Value [c] | 0.0186 | |
| Heterogeneity p-value [d] | 0.6278 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.6 (53.0, 82.6) | 50.1 (32.2, 65.6) |
| 12 months | 64.1 (43.4, 79.0) | 16.1 (1.4, 46.1) |
| 18 months | 55.0 (30.4, 74.1) | NE (NE, NE) |
| 24 months | 41.2 (14.2, 66.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 13 (21.7%) | 22 (36.7%) |
| Censored Patients, n (%) | 47 (78.3%) | 38 (63.3%) |
| Median (95% CI), (Months) [a] | 16.85 (8.21, NE) | 5.22 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0155 | |
| HR (95% CI) [c] | 0.422 (0.206, 0.865) | |
| HR P-Value [c] | 0.0184 | |
| Heterogeneity p-value [d] | 0.5014 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.5 (60.6, 87.8) | 49.3 (31.5, 64.9) |
| 12 months | 66.7 (45.5, 81.2) | 19.7 (1.8, 51.7) |
| 18 months | 38.1 (8.7, 68.4) | NE (NE, NE) |
| 24 months | 38.1 (8.7, 68.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 13 (21.7%) | 21 (35.0%) |
| Censored Patients, n (%) | 47 (78.3%) | 39 (65.0%) |
| Median (95% CI), (Months) [a] | NE (14.03, NE) | 4.44 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0318 | |
| HR (95% CI) [c] | 0.471 (0.233, 0.952) | |
| HR P-Value [c] | 0.0360 | |
| Heterogeneity p-value [d] | 0.2936 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.5 (55.2, 82.8) | 46.6 (29.5, 62.0) |
| 12 months | 71.5 (55.2, 82.8) | 23.3 (2.0, 58.0) |
| 18 months | 61.3 (36.1, 79.1) | NE (NE, NE) |
| 24 months | 61.3 (36.1, 79.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 13 (21.7%) | 22 (36.7%) |
| Censored Patients, n (%) | 47 (78.3%) | 38 (63.3%) |
| Median (95% CI), (Months) [a] | 20.80 (15.44, NE) | 5.16 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0026 | |
| HR (95% CI) [c] | 0.332 (0.156, 0.705) | |
| HR P-Value [c] | 0.0041 | |
| Heterogeneity p-value [d] | 0.1449 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.8 (57.9, 86.9) | 37.1 (18.5, 55.7) |
| 12 months | 70.4 (50.1, 83.7) | 30.9 (13.3, 50.5) |
| 18 months | 56.3 (25.4, 78.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Patients with event, n (%) | 19 (31.7%) | 11 (18.3%) |
| Censored Patients, n (%) | 41 (68.3%) | 49 (81.7%) |
| Median (95% CI), (Months) [a] | 8.25 (3.19, NE) | NE (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3538 | |
| HR (95% CI) [c] | 1.429 (0.671, 3.042) | |
| HR P-Value [c] | 0.3545 | |
| Heterogeneity p-value [d] | 0.0433 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.9 (38.0, 70.4) | 76.5 (59.5, 87.0) |
| 12 months | 43.5 (23.6, 61.8) | 53.5 (22.7, 76.9) |
| 18 months | 32.6 (11.7, 55.7) | NE (NE, NE) |
| 24 months | 32.6 (11.7, 55.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 5 (22.7%) | 6 (24.0%) |
| Censored Patients, n (%) | 17 (77.3%) | 19 (76.0%) |
| Median (95% CI), (Months) [a] | NE (3.19, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7076 | |
| HR (95% CI) [c] | 0.794 (0.238, 2.652) | |
| HR P-Value [c] | 0.7082 | |
| Heterogeneity p-value [d] | 0.9347 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.4 (48.8, 92.9) | 65.2 (38.0, 82.8) |
| 12 months | 53.0 (18.4, 78.8) | 65.2 (38.0, 82.8) |
| 18 months | 53.0 (18.4, 78.8) | 65.2 (38.0, 82.8) |
| 24 months | 53.0 (18.4, 78.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 6 (24.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 19 (76.0%) |
| Median (95% CI), (Months) [a] | 14.06 (5.82, NE) | 7.16 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5800 | |
| HR (95% CI) [c] | 0.721 (0.226, 2.304) | |
| HR P-Value [c] | 0.5815 | |
| Heterogeneity p-value [d] | 0.2004 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.7 (37.9, 88.3) | 61.8 (28.2, 83.3) |
| 12 months | 70.7 (37.9, 88.3) | 41.2 (8.1, 73.2) |
| 18 months | 35.3 (5.9, 68.3) | 41.2 (8.1, 73.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 7 (28.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 18 (72.0%) |
| Median (95% CI), (Months) [a] | NE (3.19, NE) | NE (1.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5364 | |
| HR (95% CI) [c] | 0.701 (0.234, 2.101) | |
| HR P-Value [c] | 0.5254 | |
| Heterogeneity p-value [d] | 0.8402 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (46.3, 89.8) | 61.4 (35.4, 79.5) |
| 12 months | 51.4 (19.3, 76.4) | 61.4 (35.4, 79.5) |
| 18 months | 51.4 (19.3, 76.4) | 61.4 (35.4, 79.5) |
| 24 months | 51.4 (19.3, 76.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 4 (16.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | NE (16.76, NE) | NE (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0819 | |
| HR (95% CI) [c] | 0.164 (0.017, 1.580) | |
| HR P-Value [c] | 0.1179 | |
| Heterogeneity p-value [d] | 0.6511 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 74.3 (44.6, 89.6) |
| 12 months | 100.0 (100.0, 100.0) | 74.3 (44.6, 89.6) |
| 18 months | 75.0 (12.8, 96.1) | 74.3 (44.6, 89.6) |
| 24 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 1 (4.5%) | 5 (20.0%) |
| Censored Patients, n (%) | 21 (95.5%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (2.73, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1087 | |
| HR (95% CI) [c] | 0.204 (0.024, 1.752) | |
| HR P-Value [c] | 0.1474 | |
| Heterogeneity p-value [d] | 0.7410 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.3 (61.3, 99.0) | 65.5 (33.4, 85.0) |
| 12 months | 93.3 (61.3, 99.0) | 65.5 (33.4, 85.0) |
| 18 months | 93.3 (61.3, 99.0) | 65.5 (33.4, 85.0) |
| 24 months | 93.3 (61.3, 99.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 2 (9.1%) | 5 (20.0%) |
| Censored Patients, n (%) | 20 (90.9%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | NE (12.52, NE) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1693 | |
| HR (95% CI) [c] | 0.329 (0.063, 1.733) | |
| HR P-Value [c] | 0.1898 | |
| Heterogeneity p-value [d] | 0.7082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.3 (56.6, 98.9) | 77.0 (49.7, 90.7) |
| 12 months | 92.3 (56.6, 98.9) | 64.2 (30.2, 84.9) |
| 18 months | 73.8 (24.5, 93.7) | 64.2 (30.2, 84.9) |
| 24 months | 73.8 (24.5, 93.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 8 (36.4%) | 11 (44.0%) |
| Censored Patients, n (%) | 14 (63.6%) | 14 (56.0%) |
| Median (95% CI), (Months) [a] | 5.95 (2.83, NE) | 6.14 (2.10, 10.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5035 | |
| HR (95% CI) [c] | 0.731 (0.292, 1.828) | |
| HR P-Value [c] | 0.5025 | |
| Heterogeneity p-value [d] | 0.6578 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (22.1, 72.7) | 54.2 (28.8, 73.9) |
| 12 months | 40.0 (14.1, 65.1) | 16.9 (1.3, 48.6) |
| 18 months | 40.0 (14.1, 65.1) | 16.9 (1.3, 48.6) |
| 24 months | 40.0 (14.1, 65.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 3 (12.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 22 (88.0%) |
| Median (95% CI), (Months) [a] | NE (5.95, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5540 | |
| HR (95% CI) [c] | 0.602 (0.110, 3.279) | |
| HR P-Value [c] | 0.5571 | |
| Heterogeneity p-value [d] | 0.8973 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.5 (38.7, 98.1) | 80.8 (51.4, 93.4) |
| 12 months | 87.5 (38.7, 98.1) | 80.8 (51.4, 93.4) |
| 18 months | 52.5 (12.2, 82.1) | 80.8 (51.4, 93.4) |
| 24 months | 52.5 (12.2, 82.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 3 (13.6%) | 4 (16.0%) |
| Censored Patients, n (%) | 19 (86.4%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | NE (5.82, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3831 | |
| HR (95% CI) [c] | 0.501 (0.105, 2.396) | |
| HR P-Value [c] | 0.3868 | |
| Heterogeneity p-value [d] | 0.6100 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.9 (43.3, 98.4) | 78.6 (52.5, 91.4) |
| 12 months | 61.0 (20.2, 85.8) | 78.6 (52.5, 91.4) |
| 18 months | 61.0 (20.2, 85.8) | 78.6 (52.5, 91.4) |
| 24 months | 61.0 (20.2, 85.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 6 (24.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 19 (76.0%) |
| Median (95% CI), (Months) [a] | 11.43 (5.82, NE) | NE (1.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7672 | |
| HR (95% CI) [c] | 0.843 (0.270, 2.634) | |
| HR P-Value [c] | 0.7684 | |
| Heterogeneity p-value [d] | 0.7269 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.2 (40.8, 88.9) | 58.7 (30.0, 79.0) |
| 12 months | 45.1 (13.1, 73.3) | 58.7 (30.0, 79.0) |
| 18 months | 45.1 (13.1, 73.3) | 58.7 (30.0, 79.0) |
| 24 months | 45.1 (13.1, 73.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 6 (24.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 19 (76.0%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | 9.92 (2.73, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7294 | |
| HR (95% CI) [c] | 0.815 (0.256, 2.595) | |
| HR P-Value [c] | 0.7299 | |
| Heterogeneity p-value [d] | 0.2082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.9 (36.3, 85.3) | 64.7 (32.5, 84.4) |
| 12 months | 66.9 (36.3, 85.3) | 43.1 (8.6, 74.9) |
| 18 months | 53.5 (20.9, 77.9) | 43.1 (8.6, 74.9) |
| 24 months | 53.5 (20.9, 77.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 8 (36.4%) | 10 (40.0%) |
| Censored Patients, n (%) | 14 (63.6%) | 15 (60.0%) |
| Median (95% CI), (Months) [a] | 10.09 (1.64, NE) | 4.40 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4523 | |
| HR (95% CI) [c] | 0.698 (0.271, 1.798) | |
| HR P-Value [c] | 0.4561 | |
| Heterogeneity p-value [d] | 0.0518 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.7 (34.6, 81.5) | 48.2 (23.6, 69.2) |
| 12 months | 43.0 (15.9, 67.9) | 32.2 (7.4, 61.0) |
| 18 months | 43.0 (15.9, 67.9) | 32.2 (7.4, 61.0) |
| 24 months | 43.0 (15.9, 67.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 4 (18.2%) | 5 (20.0%) |
| Censored Patients, n (%) | 18 (81.8%) | 20 (80.0%) |
| Median (95% CI), (Months) [a] | NE (14.06, NE) | NE (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5284 | |
| HR (95% CI) [c] | 0.649 (0.167, 2.514) | |
| HR P-Value [c] | 0.5313 | |
| Heterogeneity p-value [d] | 0.8483 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (52.5, 93.5) | 75.8 (47.3, 90.2) |
| 12 months | 81.3 (52.5, 93.5) | 60.6 (24.5, 83.7) |
| 18 months | 65.0 (25.5, 87.3) | 60.6 (24.5, 83.7) |
| 24 months | 65.0 (25.5, 87.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 7 (28.0%) |
| Censored Patients, n (%) | 16 (72.7%) | 18 (72.0%) |
| Median (95% CI), (Months) [a] | 13.93 (5.82, NE) | 8.54 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5366 | |
| HR (95% CI) [c] | 0.706 (0.232, 2.147) | |
| HR P-Value [c] | 0.5399 | |
| Heterogeneity p-value [d] | 0.3160 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.8 (44.2, 92.6) | 64.2 (36.8, 82.2) |
| 12 months | 55.6 (22.1, 79.5) | 48.1 (16.0, 74.7) |
| 18 months | 41.7 (11.5, 70.2) | 48.1 (16.0, 74.7) |
| 24 months | 41.7 (11.5, 70.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Patients with event, n (%) | 7 (31.8%) | 4 (16.0%) |
| Censored Patients, n (%) | 15 (68.2%) | 21 (84.0%) |
| Median (95% CI), (Months) [a] | 7.95 (3.19, NE) | NE (6.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4617 | |
| HR (95% CI) [c] | 1.589 (0.458, 5.509) | |
| HR P-Value [c] | 0.4655 | |
| Heterogeneity p-value [d] | 0.1762 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.0 (25.9, 80.3) | 81.5 (52.3, 93.7) |
| 12 months | 46.4 (16.3, 72.3) | 67.9 (31.0, 88.0) |
| 18 months | 31.0 (5.8, 61.6) | 67.9 (31.0, 88.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 12 (30.8%) | 11 (30.6%) |
| Censored Patients, n (%) | 27 (69.2%) | 25 (69.4%) |
| Median (95% CI), (Months) [a] | NE (2.89, NE) | 6.67 (4.44, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2874 | |
| HR (95% CI) [c] | 0.636 (0.274, 1.477) | |
| HR P-Value [c] | 0.2924 | |
| Heterogeneity p-value [d] | 0.9347 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.5 (45.2, 79.8) | 57.6 (33.4, 75.8) |
| 12 months | 50.9 (27.4, 70.3) | 21.6 (1.5, 57.1) |
| 18 months | 50.9 (27.4, 70.3) | NE (NE, NE) |
| 24 months | 50.9 (27.4, 70.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 8 (20.5%) | 10 (27.8%) |
| Censored Patients, n (%) | 31 (79.5%) | 26 (72.2%) |
| Median (95% CI), (Months) [a] | 16.85 (12.45, NE) | 5.68 (4.24, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0265 | |
| HR (95% CI) [c] | 0.314 (0.107, 0.924) | |
| HR P-Value [c] | 0.0355 | |
| Heterogeneity p-value [d] | 0.2004 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.7 (61.3, 92.0) | 43.6 (17.5, 67.3) |
| 12 months | 81.7 (61.3, 92.0) | NE (NE, NE) |
| 18 months | 38.1 (7.2, 70.2) | NE (NE, NE) |
| 24 months | 38.1 (7.2, 70.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 8 (20.5%) | 9 (25.0%) |
| Censored Patients, n (%) | 31 (79.5%) | 27 (75.0%) |
| Median (95% CI), (Months) [a] | NE (5.78, NE) | 7.00 (6.67, 14.13) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2040 | |
| HR (95% CI) [c] | 0.539 (0.205, 1.418) | |
| HR P-Value [c] | 0.2106 | |
| Heterogeneity p-value [d] | 0.8402 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.7 (46.7, 85.5) | 79.1 (56.6, 90.8) |
| 12 months | 64.9 (40.2, 81.4) | 23.7 (1.4, 61.8) |
| 18 months | 64.9 (40.2, 81.4) | 0.0 (NE, NE) |
| 24 months | 64.9 (40.2, 81.4) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 6 (15.4%) | 5 (13.9%) |
| Censored Patients, n (%) | 33 (84.6%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | NE (10.45, NE) | NE (5.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3602 | |
| HR (95% CI) [c] | 0.553 (0.152, 2.003) | |
| HR P-Value [c] | 0.3667 | |
| Heterogeneity p-value [d] | 0.6511 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.8 (68.5, 96.3) | 78.2 (49.9, 91.7) |
| 12 months | 71.0 (39.8, 88.1) | 52.1 (9.4, 83.6) |
| 18 months | 71.0 (39.8, 88.1) | NE (NE, NE) |
| 24 months | 56.8 (22.2, 80.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 11 (28.2%) | 10 (27.8%) |
| Censored Patients, n (%) | 28 (71.8%) | 26 (72.2%) |
| Median (95% CI), (Months) [a] | 16.85 (5.72, NE) | 6.67 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2185 | |
| HR (95% CI) [c] | 0.576 (0.235, 1.408) | |
| HR P-Value [c] | 0.2264 | |
| Heterogeneity p-value [d] | 0.7410 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.7 (46.5, 82.0) | 62.6 (37.8, 79.8) |
| 12 months | 62.1 (39.8, 78.1) | 23.5 (1.5, 60.5) |
| 18 months | 49.7 (22.1, 72.3) | NE (NE, NE) |
| 24 months | 49.7 (22.1, 72.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 8 (20.5%) | 8 (22.2%) |
| Censored Patients, n (%) | 31 (79.5%) | 28 (77.8%) |
| Median (95% CI), (Months) [a] | 20.80 (9.07, NE) | 7.10 (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0519 | |
| HR (95% CI) [c] | 0.343 (0.112, 1.050) | |
| HR P-Value [c] | 0.0609 | |
| Heterogeneity p-value [d] | 0.7082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.8 (64.1, 94.1) | 72.8 (48.8, 86.9) |
| 12 months | 70.5 (43.1, 86.4) | 24.3 (1.2, 63.7) |
| 18 months | 56.4 (23.3, 79.8) | NE (NE, NE) |
| 24 months | 42.3 (11.9, 70.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 15 (38.5%) | 16 (44.4%) |
| Censored Patients, n (%) | 24 (61.5%) | 20 (55.6%) |
| Median (95% CI), (Months) [a] | 12.45 (2.89, NE) | 4.44 (1.77, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0182 | |
| HR (95% CI) [c] | 0.401 (0.184, 0.875) | |
| HR P-Value [c] | 0.0217 | |
| Heterogeneity p-value [d] | 0.6578 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.4 (43.5, 77.9) | 35.6 (12.6, 59.8) |
| 12 months | 51.2 (29.4, 69.4) | 0.0 (NE, NE) |
| 18 months | 35.8 (14.4, 58.0) | 0.0 (NE, NE) |
| 24 months | 35.8 (14.4, 58.0) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 10 (25.6%) | 11 (30.6%) |
| Censored Patients, n (%) | 29 (74.4%) | 25 (69.4%) |
| Median (95% CI), (Months) [a] | 20.80 (7.62, NE) | 6.67 (2.96, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0848 | |
| HR (95% CI) [c] | 0.463 (0.188, 1.138) | |
| HR P-Value [c] | 0.0932 | |
| Heterogeneity p-value [d] | 0.8973 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.7 (50.4, 86.2) | 64.6 (40.1, 81.2) |
| 12 months | 59.6 (34.7, 77.7) | 22.1 (1.6, 57.7) |
| 18 months | 59.6 (34.7, 77.7) | NE (NE, NE) |
| 24 months | 47.7 (20.0, 71.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 7 (17.9%) | 10 (27.8%) |
| Censored Patients, n (%) | 32 (82.1%) | 26 (72.2%) |
| Median (95% CI), (Months) [a] | NE (7.79, NE) | 11.93 (4.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0578 | |
| HR (95% CI) [c] | 0.393 (0.145, 1.063) | |
| HR P-Value [c] | 0.0658 | |
| Heterogeneity p-value [d] | 0.6100 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.1 (57.9, 91.4) | 58.9 (34.0, 77.1) |
| 12 months | 66.6 (40.2, 83.4) | 29.4 (1.9, 68.5) |
| 18 months | 66.6 (40.2, 83.4) | NE (NE, NE) |
| 24 months | 66.6 (40.2, 83.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 12 (30.8%) | 12 (33.3%) |
| Censored Patients, n (%) | 27 (69.2%) | 24 (66.7%) |
| | | |
| Median (95% CI), (Months) [a] | 12.45 (2.89, NE) | 4.67 (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4239 | |
| HR (95% CI) [c] | 0.720 (0.320, 1.618) | |
| HR P-Value [c] | 0.4263 | |
| Heterogeneity p-value [d] | 0.7269 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.4 (35.9, 74.0) | 47.6 (25.2, 67.0) |
| 12 months | 57.4 (35.9, 74.0) | 23.8 (1.9, 59.5) |
| 18 months | 47.8 (23.7, 68.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 8 (20.5%) | 14 (38.9%) |
| Censored Patients, n (%) | 31 (79.5%) | 22 (61.1%) |
| Median (95% CI), (Months) [a] | NE (10.45, NE) | 5.16 (2.83, 12.71) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0024 | |
| HR (95% CI) [c] | 0.258 (0.102, 0.657) | |
| HR P-Value [c] | 0.0045 | |
| Heterogeneity p-value [d] | 0.2082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.4 (55.7, 89.4) | 47.9 (24.6, 68.0) |
| 12 months | 68.8 (42.1, 85.0) | 18.0 (1.4, 50.3) |
| 18 months | 68.8 (42.1, 85.0) | 0.0 (NE, NE) |
| 24 months | 55.0 (23.0, 78.5) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 10 (25.6%) | 15 (41.7%) |
| Censored Patients, n (%) | 29 (74.4%) | 21 (58.3%) |
| Median (95% CI), (Months) [a] | 16.85 (9.07, NE) | 4.67 (2.56, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0088 | |
| HR (95% CI) [c] | 0.337 (0.144, 0.787) | |
| HR P-Value [c] | 0.0120 | |
| Heterogeneity p-value [d] | 0.0518 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.5 (54.8, 87.6) | 41.9 (20.0, 62.5) |
| 12 months | 68.6 (44.9, 83.7) | 14.0 (1.2, 41.6) |
| 18 months | 44.1 (14.5, 70.6) | NE (NE, NE) |
| 24 months | 44.1 (14.5, 70.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 9 (23.1%) | 12 (33.3%) |
| Censored Patients, n (%) | 30 (76.9%) | 24 (66.7%) |
| Median (95% CI), (Months) [a] | NE (2.89, NE) | 4.44 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0986 | |
| HR (95% CI) [c] | 0.487 (0.204, 1.161) | |
| HR P-Value [c] | 0.1045 | |
| Heterogeneity p-value [d] | 0.8483 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.4 (49.3, 82.8) | 46.9 (24.4, 66.7) |
| 12 months | 69.4 (49.3, 82.8) | 23.5 (1.9, 59.0) |
| 18 months | 69.4 (49.3, 82.8) | NE (NE, NE) |
| 24 months | 69.4 (49.3, 82.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 13 (33.3%) | 14 (38.9%) |
| Censored Patients, n (%) | 26 (66.7%) | 22 (61.1%) |
| Median (95% CI), (Months) [a] | 20.80 (5.55, NE) | 4.44 (1.97, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0185 | |
| HR (95% CI) [c] | 0.384 (0.168, 0.875) | |
| HR P-Value [c] | 0.0228 | |
| Heterogeneity p-value [d] | 0.3160 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.7 (45.0, 81.4) | 30.6 (9.9, 54.5) |
| 12 months | 60.6 (37.8, 77.3) | NE (NE, NE) |
| 18 months | 50.5 (24.8, 71.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Patients with event, n (%) | 13 (33.3%) | 5 (13.9%) |
| Censored Patients, n (%) | 26 (66.7%) | 31 (86.1%) |
| Median (95% CI), (Months) [a] | 16.66 (2.96, NE) | 11.33 (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4151 | |
| HR (95% CI) [c] | 1.541 (0.539, 4.404) | |
| HR P-Value [c] | 0.4199 | |
| Heterogeneity p-value [d] | 0.1762 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.2 (37.1, 74.4) | 85.7 (62.0, 95.2) |
| 12 months | 52.4 (30.8, 70.1) | NE (NE, NE) |
| 18 months | 41.9 (18.2, 64.2) | NE (NE, NE) |
| 24 months | 41.9 (18.2, 64.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 19 (25.0%) | 19 (28.8%) |
| Censored Patients, n (%) | 57 (75.0%) | 47 (71.2%) |
| Median (95% CI), (Months) [a] | 20.17 (7.26, NE) | 9.69 (3.15, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0287 | |
| HR (95% CI) [c] | 0.487 (0.252, 0.943) | |
| HR P-Value [c] | 0.0328 | |
| Heterogeneity p-value [d] | 0.9347 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.5 (57.4, 83.0) | 52.0 (33.8, 67.4) |
| 12 months | 58.7 (41.0, 72.8) | NE (NE, NE) |
| 18 months | 58.7 (41.0, 72.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 14 (18.4%) | 18 (27.3%) |
| Censored Patients, n (%) | 62 (81.6%) | 48 (72.7%) |
| Median (95% CI), (Months) [a] | NE (17.05, NE) | NE (3.15, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0123 | |
| HR (95% CI) [c] | 0.413 (0.201, 0.846) | |
| HR P-Value [c] | 0.0156 | |
| Heterogeneity p-value [d] | 0.2004 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.5 (63.4, 86.7) | 55.1 (37.3, 69.7) |
| 12 months | 74.5 (59.5, 84.7) | 50.5 (32.2, 66.2) |
| 18 months | 65.2 (41.3, 81.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 11 (14.5%) | 11 (16.7%) |
| Censored Patients, n (%) | 65 (85.5%) | 55 (83.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 8.97 (5.19, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1208 | |
| HR (95% CI) [c] | 0.514 (0.219, 1.211) | |
| HR P-Value [c] | 0.1282 | |
| Heterogeneity p-value [d] | 0.8402 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.9 (69.4, 90.8) | 68.5 (46.6, 82.9) |
| 12 months | 74.9 (57.2, 86.1) | 49.3 (21.3, 72.4) |
| 18 months | 74.9 (57.2, 86.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 10 (13.2%) | 6 (9.1%) |
| Censored Patients, n (%) | 66 (86.8%) | 60 (90.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7907 | |
| HR (95% CI) [c] | 0.870 (0.310, 2.441) | |
| HR P-Value [c] | 0.7907 | |
| Heterogeneity p-value [d] | 0.6511 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.9 (74.5, 94.5) | 82.4 (64.6, 91.8) |
| 12 months | 73.4 (54.6, 85.4) | 82.4 (64.6, 91.8) |
| 18 months | 73.4 (54.6, 85.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 12 (15.8%) | 9 (13.6%) |
| Censored Patients, n (%) | 64 (84.2%) | 57 (86.4%) |
| | | |
| Median (95% CI), (Months) [a] | NE (14.26, NE) | 10.35 (10.35, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4414 | |
| HR (95% CI) [c] | 0.705 (0.286, 1.737) | |
| HR P-Value [c] | 0.4478 | |
| Heterogeneity p-value [d] | 0.7410 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.5 (70.3, 91.2) | 77.6 (59.5, 88.3) |
| 12 months | 76.3 (59.5, 86.9) | 38.8 (1.6, 80.5) |
| 18 months | 69.4 (47.8, 83.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 14 (18.4%) | 9 (13.6%) |
| Censored Patients, n (%) | 62 (81.6%) | 57 (86.4%) |
| Median (95% CI), (Months) [a] | 20.17 (14.65, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5355 | |
| HR (95% CI) [c] | 0.759 (0.313, 1.840) | |
| HR P-Value [c] | 0.5410 | |
| Heterogeneity p-value [d] | 0.7082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.9 (69.5, 90.8) | 73.1 (53.4, 85.5) |
| 12 months | 74.9 (57.3, 86.1) | 73.1 (53.4, 85.5) |
| 18 months | 62.1 (38.7, 78.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 28 (36.8%) | 21 (31.8%) |
| Censored Patients, n (%) | 48 (63.2%) | 45 (68.2%) |
| | | |
| Median (95% CI), (Months) [a] | 9.69 (4.90, 20.17) | 4.17 (2.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1541 | |
| HR (95% CI) [c] | 0.662 (0.370, 1.184) | |
| HR P-Value [c] | 0.1640 | |
| Heterogeneity p-value [d] | 0.6578 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.5 (43.6, 70.7) | 47.2 (29.9, 62.7) |
| 12 months | 44.2 (27.7, 59.4) | 32.4 (13.7, 52.8) |
| 18 months | 35.3 (16.5, 54.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 16 (21.1%) | 11 (16.7%) |
| Censored Patients, n (%) | 60 (78.9%) | 55 (83.3%) |
| Median (95% CI), (Months) [a] | NE (9.76, NE) | 10.35 (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2779 | |
| HR (95% CI) [c] | 0.646 (0.294, 1.421) | |
| HR P-Value [c] | 0.2773 | |
| Heterogeneity p-value [d] | 0.8973 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.2 (66.0, 89.0) | 72.8 (53.9, 85.0) |
| 12 months | 62.1 (43.0, 76.3) | 43.2 (9.7, 73.9) |
| 18 months | 56.9 (36.9, 72.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 15 (19.7%) | 16 (24.2%) |
| Censored Patients, n (%) | 61 (80.3%) | 50 (75.8%) |
| Median (95% CI), (Months) [a] | NE (17.71, NE) | 11.07 (4.93, 11.07) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0210 | |
| HR (95% CI) [c] | 0.426 (0.202, 0.898) | |
| HR P-Value [c] | 0.0249 | |
| Heterogeneity p-value [d] | 0.6100 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.7 (70.6, 91.2) | 58.0 (38.6, 73.1) |
| 12 months | 67.7 (50.1, 80.2) | 0.0 (NE, NE) |
| 18 months | 58.0 (33.8, 76.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 19 (25.0%) | 23 (34.8%) |
| Censored Patients, n (%) | 57 (75.0%) | 43 (65.2%) |
| Median (95% CI), (Months) [a] | 19.15 (10.18, NE) | 5.82 (3.48, 10.35) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0017 | |
| HR (95% CI) [c] | 0.369 (0.192, 0.707) | |
| HR P-Value [c] | 0.0026 | |
| Heterogeneity p-value [d] | 0.7269 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.6 (55.8, 81.3) | 44.9 (27.0, 61.2) |
| 12 months | 62.3 (44.8, 75.7) | 0.0 (NE, NE) |
| 18 months | 62.3 (44.8, 75.7) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 21 (27.6%) | 22 (33.3%) |
| Censored Patients, n (%) | 55 (72.4%) | 44 (66.7%) |
| Median (95% CI), (Months) [a] | 20.17 (9.69, NE) | 4.40 (2.99, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0020 | |
| HR (95% CI) [c] | 0.382 (0.204, 0.718) | |
| HR P-Value [c] | 0.0028 | |
| Heterogeneity p-value [d] | 0.2082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.2 (60.7, 85.0) | 43.1 (25.8, 59.3) |
| 12 months | 52.3 (34.6, 67.3) | 25.5 (6.8, 50.0) |
| 18 months | 52.3 (34.6, 67.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 19 (25.0%) | 24 (36.4%) |
| Censored Patients, n (%) | 57 (75.0%) | 42 (63.6%) |
| Median (95% CI), (Months) [a] | NE (8.34, NE) | 4.70 (3.02, 7.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0002 | |
| HR (95% CI) [c] | 0.328 (0.176, 0.609) | |
| HR P-Value [c] | 0.0004 | |
| Heterogeneity p-value [d] | 0.0518 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.1 (63.6, 87.4) | 39.6 (22.6, 56.1) |
| 12 months | 53.1 (35.6, 67.9) | 28.9 (12.9, 47.1) |
| 18 months | 53.1 (35.6, 67.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 20 (26.3%) | 17 (25.8%) |
| Censored Patients, n (%) | 56 (73.7%) | 49 (74.2%) |
| Median (95% CI), (Months) [a] | 14.26 (9.69, NE) | 9.72 (3.38, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0935 | |
| HR (95% CI) [c] | 0.568 (0.290, 1.112) | |
| HR P-Value [c] | 0.0988 | |
| Heterogeneity p-value [d] | 0.8483 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.5 (56.2, 82.2) | 52.9 (33.7, 68.9) |
| 12 months | 60.2 (42.4, 74.1) | 39.7 (15.1, 63.7) |
| 18 months | 45.4 (26.0, 62.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 19 (25.0%) | 13 (19.7%) |
| Censored Patients, n (%) | 57 (75.0%) | 53 (80.3%) |
| Median (95% CI), (Months) [a] | 20.17 (10.18, 20.76) | NE (6.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4912 | |
| HR (95% CI) [c] | 0.774 (0.371, 1.614) | |
| HR P-Value [c] | 0.4950 | |
| Heterogeneity p-value [d] | 0.3160 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.8 (59.5, 83.7) | 71.0 (53.6, 82.9) |
| 12 months | 60.0 (40.9, 74.7) | 58.6 (36.6, 75.2) |
| 18 months | 60.0 (40.9, 74.7) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Patients with event, n (%) | 13 (17.1%) | 13 (19.7%) |
| Censored Patients, n (%) | 63 (82.9%) | 53 (80.3%) |
| Median (95% CI), (Months) [a] | 20.17 (16.62, NE) | 9.72 (7.39, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0301 | |
| HR (95% CI) [c] | 0.414 (0.182, 0.943) | |
| HR P-Value [c] | 0.0357 | |
| Heterogeneity p-value [d] | 0.1762 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.0 (66.5, 89.7) | 73.6 (56.2, 85.0) |
| 12 months | 72.0 (53.2, 84.3) | 37.9 (10.9, 65.3) |
| 18 months | 61.7 (35.3, 80.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 13 (22.0%) | 17 (30.4%) |
| Censored Patients, n (%) | 46 (78.0%) | 39 (69.6%) |
| Median (95% CI), (Months) [a] | NE (6.21, NE) | 8.90 (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0985 | |
| HR (95% CI) [c] | 0.543 (0.260, 1.135) | |
| HR P-Value [c] | 0.1047 | |
| Heterogeneity p-value [d] | 0.9347 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.9 (52.8, 83.1) | 59.1 (40.7, 73.5) |
| 12 months | 67.2 (48.5, 80.4) | 31.5 (7.1, 60.4) |
| 18 months | 59.7 (37.5, 76.3) | NE (NE, NE) |
| 24 months | 59.7 (37.5, 76.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 19 (32.2%) | 17 (30.4%) |
| Censored Patients, n (%) | 40 (67.8%) | 39 (69.6%) |
| Median (95% CI), (Months) [a] | 12.88 (6.51, NE) | 8.90 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7546 | |
| HR (95% CI) [c] | 0.899 (0.457, 1.770) | |
| HR P-Value [c] | 0.7589 | |
| Heterogeneity p-value [d] | 0.2004 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.0 (50.5, 80.4) | 59.6 (42.3, 73.3) |
| 12 months | 50.2 (30.4, 67.1) | 49.7 (26.7, 69.1) |
| 18 months | 37.6 (18.0, 57.3) | NE (NE, NE) |
| 24 months | 37.6 (18.0, 57.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 15 (25.4%) | 16 (28.6%) |
| Censored Patients, n (%) | 44 (74.6%) | 40 (71.4%) |
| Median (95% CI), (Months) [a] | 15.11 (6.97, NE) | 11.50 (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6334 | |
| HR (95% CI) [c] | 0.841 (0.408, 1.735) | |
| HR P-Value [c] | 0.6395 | |
| Heterogeneity p-value [d] | 0.8402 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.9 (51.6, 81.1) | 62.5 (44.6, 76.0) |
| 12 months | 59.7 (40.3, 74.7) | 29.0 (2.0, 67.4) |
| 18 months | 44.8 (17.0, 69.5) | NE (NE, NE) |
| 24 months | 44.8 (17.0, 69.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 7 (11.9%) | 6 (10.7%) |
| Censored Patients, n (%) | 52 (88.1%) | 50 (89.3%) |
| Median (95% CI), (Months) [a] | NE (11.24, NE) | NE (8.87, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8102 | |
| HR (95% CI) [c] | 0.872 (0.282, 2.702) | |
| HR P-Value [c] | 0.8130 | |
| Heterogeneity p-value [d] | 0.6511 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.2 (68.7, 94.3) | 84.6 (65.6, 93.5) |
| 12 months | 73.1 (47.8, 87.6) | 72.5 (39.7, 89.4) |
| 18 months | 73.1 (47.8, 87.6) | NE (NE, NE) |
| 24 months | 73.1 (47.8, 87.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 11 (18.6%) | 17 (30.4%) |
| Censored Patients, n (%) | 48 (81.4%) | 39 (69.6%) |
| Median (95% CI), (Months) [a] | NE (11.93, NE) | NE (4.60, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0972 | |
| HR (95% CI) [c] | 0.523 (0.240, 1.141) | |
| HR P-Value [c] | 0.1034 | |
| Heterogeneity p-value [d] | 0.7410 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.3 (58.9, 87.1) | 56.5 (38.2, 71.3) |
| 12 months | 63.8 (40.7, 79.8) | 51.3 (32.3, 67.5) |
| 18 months | 63.8 (40.7, 79.8) | NE (NE, NE) |
| 24 months | 63.8 (40.7, 79.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 12 (20.3%) | 15 (26.8%) |
| Censored Patients, n (%) | 47 (79.7%) | 41 (73.2%) |
| Median (95% CI), (Months) [a] | NE (7.06, NE) | 8.90 (5.55, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3063 | |
| HR (95% CI) [c] | 0.674 (0.310, 1.465) | |
| HR P-Value [c] | 0.3191 | |
| Heterogeneity p-value [d] | 0.7082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.6 (60.9, 87.9) | 64.6 (46.1, 78.2) |
| 12 months | 60.8 (37.6, 77.6) | 43.1 (15.8, 68.1) |
| 18 months | 60.8 (37.6, 77.6) | NE (NE, NE) |
| 24 months | 60.8 (37.6, 77.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 28 (47.5%) | 26 (46.4%) |
| Censored Patients, n (%) | 31 (52.5%) | 30 (53.6%) |
| Median (95% CI), (Months) [a] | 5.82 (1.58, 11.99) | 4.40 (1.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6381 | |
| HR (95% CI) [c] | 0.888 (0.512, 1.537) | |
| HR P-Value [c] | 0.6704 | |
| Heterogeneity p-value [d] | 0.6578 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.6 (33.3, 62.3) | 47.1 (31.5, 61.1) |
| 12 months | 32.5 (17.1, 48.8) | 20.2 (1.9, 52.4) |
| 18 months | 26.0 (10.9, 44.1) | NE (NE, NE) |
| 24 months | 26.0 (10.9, 44.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 8 (13.6%) | 11 (19.6%) |
| Censored Patients, n (%) | 51 (86.4%) | 45 (80.4%) |
| Median (95% CI), (Months) [a] | NE (9.66, NE) | 11.50 (5.55, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2025 | |
| HR (95% CI) [c] | 0.552 (0.217, 1.404) | |
| HR P-Value [c] | 0.2122 | |
| Heterogeneity p-value [d] | 0.8973 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.2 (56.9, 88.8) | 71.6 (49.5, 85.3) |
| 12 months | 71.2 (48.7, 85.2) | 26.9 (1.8, 65.0) |
| 18 months | 71.2 (48.7, 85.2) | NE (NE, NE) |
| 24 months | 71.2 (48.7, 85.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 14 (23.7%) | 14 (25.0%) |
| Censored Patients, n (%) | 45 (76.3%) | 42 (75.0%) |
| Median (95% CI), (Months) [a] | 14.59 (11.99, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4262 | |
| HR (95% CI) [c] | 0.733 (0.340, 1.579) | |
| HR P-Value [c] | 0.4277 | |
| Heterogeneity p-value [d] | 0.6100 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.1 (58.1, 85.9) | 70.7 (53.0, 82.8) |
| 12 months | 62.5 (39.5, 78.9) | 54.0 (27.9, 74.3) |
| 18 months | 45.6 (20.7, 67.6) | NE (NE, NE) |
| 24 months | 45.6 (20.7, 67.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 15 (25.4%) | 19 (33.9%) |
| Censored Patients, n (%) | 44 (74.6%) | 37 (66.1%) |
| | | |
| Median (95% CI), (Months) [a] | 11.99 (5.82, NE) | 4.60 (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2065 | |
| HR (95% CI) [c] | 0.640 (0.318, 1.287) | |
| HR P-Value [c] | 0.2103 | |
| Heterogeneity p-value [d] | 0.7269 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.4 (49.6, 81.4) | 50.0 (32.9, 64.8) |
| 12 months | 47.5 (26.2, 66.2) | 50.0 (32.9, 64.8) |
| 18 months | 47.5 (26.2, 66.2) | NE (NE, NE) |
| 24 months | 47.5 (26.2, 66.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 21 (35.6%) | 22 (39.3%) |
| Censored Patients, n (%) | 38 (64.4%) | 34 (60.7%) |
| Median (95% CI), (Months) [a] | 14.03 (5.55, NE) | 8.90 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2645 | |
| HR (95% CI) [c] | 0.704 (0.376, 1.319) | |
| HR P-Value [c] | 0.2737 | |
| Heterogeneity p-value [d] | 0.2082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.7 (44.7, 74.9) | 57.1 (40.8, 70.5) |
| 12 months | 51.6 (32.3, 67.8) | 31.1 (10.2, 55.1) |
| 18 months | 28.2 (9.2, 51.1) | NE (NE, NE) |
| 24 months | 28.2 (9.2, 51.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 18 (30.5%) | 14 (25.0%) |
| Censored Patients, n (%) | 41 (69.5%) | 42 (75.0%) |
| Median (95% CI), (Months) [a] | 9.82 (8.21, NE) | 9.72 (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8637 | |
| HR (95% CI) [c] | 1.067 (0.522, 2.185) | |
| HR P-Value [c] | 0.8581 | |
| Heterogeneity p-value [d] | 0.0518 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.4 (56.9, 85.6) | 71.4 (54.7, 82.8) |
| 12 months | 37.8 (18.9, 56.7) | 43.9 (10.2, 74.3) |
| 18 months | 37.8 (18.9, 56.7) | NE (NE, NE) |
| 24 months | 37.8 (18.9, 56.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 21 (35.6%) | 25 (44.6%) |
| Censored Patients, n (%) | 38 (64.4%) | 31 (55.4%) |
| Median (95% CI), (Months) [a] | 11.99 (2.99, 14.55) | 4.30 (1.68, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0404 | |
| HR (95% CI) [c] | 0.532 (0.286, 0.988) | |
| HR P-Value [c] | 0.0458 | |
| Heterogeneity p-value [d] | 0.8483 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.5 (46.5, 77.8) | 45.1 (28.8, 60.0) |
| 12 months | 46.0 (26.2, 63.7) | 24.1 (8.0, 44.9) |
| 18 months | 13.8 (1.3, 40.7) | NE (NE, NE) |
| 24 months | 13.8 (1.3, 40.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 9 (15.3%) | 19 (33.9%) |
| Censored Patients, n (%) | 50 (84.7%) | 37 (66.1%) |
| Median (95% CI), (Months) [a] | NE (11.24, NE) | 8.02 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0079 | |
| HR (95% CI) [c] | 0.337 (0.145, 0.783) | |
| HR P-Value [c] | 0.0114 | |
| Heterogeneity p-value [d] | 0.3160 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.1 (69.2, 94.1) | 58.1 (40.0, 72.4) |
| 12 months | 69.3 (45.0, 84.5) | 39.9 (19.5, 59.7) |
| 18 months | 55.4 (23.9, 78.4) | NE (NE, NE) |
| 24 months | 55.4 (23.9, 78.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Patients with event, n (%) | 14 (23.7%) | 19 (33.9%) |
| Censored Patients, n (%) | 45 (76.3%) | 37 (66.1%) |
| Median (95% CI), (Months) [a] | 11.93 (6.97, NE) | 8.05 (2.96, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1807 | |
| HR (95% CI) [c] | 0.614 (0.297, 1.271) | |
| HR P-Value [c] | 0.1888 | |
| Heterogeneity p-value [d] | 0.1762 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.1 (57.3, 86.3) | 61.8 (45.0, 74.7) |
| 12 months | 40.3 (17.1, 62.6) | 32.8 (8.3, 60.6) |
| 18 months | 40.3 (17.1, 62.6) | NE (NE, NE) |
| 24 months | 40.3 (17.1, 62.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 40 (24.8%) | 43 (31.4%) |
| Censored Patients, n (%) | 121 (75.2%) | 94 (68.6%) |
| Median (95% CI), (Months) [a] | NE (10.38, NE) | 8.90 (4.83, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0033 | |
| HR (95% CI) [c] | 0.519 (0.332, 0.809) | |
| HR P-Value [c] | 0.0038 | |
| Heterogeneity p-value [d] | 0.3749 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.4 (62.8, 79.9) | 56.5 (44.7, 66.7) |
| 12 months | 58.9 (47.0, 69.0) | 24.7 (9.3, 44.0) |
| 18 months | 58.9 (47.0, 69.0) | NE (NE, NE) |
| 24 months | 51.5 (34.0, 66.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 42 (26.1%) | 40 (29.2%) |
| Censored Patients, n (%) | 119 (73.9%) | 97 (70.8%) |
| Median (95% CI), (Months) [a] | 17.05 (14.06, NE) | 8.90 (4.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0258 | |
| HR (95% CI) [c] | 0.602 (0.383, 0.946) | |
| HR P-Value [c] | 0.0279 | |
| Heterogeneity p-value [d] | 0.5556 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.5 (62.0, 79.0) | 56.9 (45.0, 67.1) |
| 12 months | 64.8 (53.9, 73.8) | 46.0 (30.4, 60.2) |
| 18 months | 48.6 (33.5, 62.2) | NE (NE, NE) |
| 24 months | 48.6 (33.5, 62.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 33 (20.5%) | 34 (24.8%) |
| Censored Patients, n (%) | 128 (79.5%) | 103 (75.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 11.50 (6.97, 14.13) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0418 | |
| HR (95% CI) [c] | 0.607 (0.372, 0.989) | |
| HR P-Value [c] | 0.0450 | |
| Heterogeneity p-value [d] | 0.5693 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.6 (66.5, 82.6) | 66.0 (54.3, 75.5) |
| 12 months | 66.7 (55.4, 75.8) | 34.7 (11.7, 59.4) |
| 18 months | 66.7 (55.4, 75.8) | NE (NE, NE) |
| 24 months | 66.7 (55.4, 75.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 21 (13.0%) | 20 (14.6%) |
| Censored Patients, n (%) | 140 (87.0%) | 117 (85.4%) |
| | | |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (8.87, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0812 | |
| HR (95% CI) [c] | 0.568 (0.299, 1.081) | |
| HR P-Value [c] | 0.0849 | |
| Heterogeneity p-value [d] | 0.1606 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.7 (79.5, 92.8) | 77.2 (65.7, 85.3) |
| 12 months | 76.3 (64.0, 84.8) | 66.5 (47.8, 79.9) |
| 18 months | 72.4 (58.0, 82.6) | NE (NE, NE) |
| 24 months | 66.4 (47.9, 79.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 30 (18.6%) | 31 (22.6%) |
| Censored Patients, n (%) | 131 (81.4%) | 106 (77.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 10.35 (6.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0411 | |
| HR (95% CI) [c] | 0.588 (0.350, 0.987) | |
| HR P-Value [c] | 0.0446 | |
| Heterogeneity p-value [d] | 0.8182 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.5 (69.6, 85.0) | 67.3 (55.1, 76.9) |
| 12 months | 73.3 (62.8, 81.3) | 45.9 (24.1, 65.3) |
| 18 months | 65.8 (51.0, 77.0) | NE (NE, NE) |
| 24 months | 65.8 (51.0, 77.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 32 (19.9%) | 26 (19.0%) |
| Censored Patients, n (%) | 129 (80.1%) | 111 (81.0%) |
| Median (95% CI), (Months) [a] | NE (14.65, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1178 | |
| HR (95% CI) [c] | 0.649 (0.376, 1.123) | |
| HR P-Value [c] | 0.1221 | |
| Heterogeneity p-value [d] | 0.3016 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.9 (73.5, 87.9) | 73.4 (61.9, 82.0) |
| 12 months | 71.0 (59.2, 79.9) | 51.5 (30.2, 69.3) |
| 18 months | 59.3 (44.2, 71.6) | NE (NE, NE) |
| 24 months | 52.7 (34.3, 68.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 65 (40.4%) | 63 (46.0%) |
| Censored Patients, n (%) | 96 (59.6%) | 74 (54.0%) |
| Median (95% CI), (Months) [a] | 9.69 (5.59, 16.62) | 3.38 (2.56, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0026 | |
| HR (95% CI) [c] | 0.583 (0.406, 0.835) | |
| HR P-Value [c] | 0.0033 | |
| Heterogeneity p-value [d] | 0.0565 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.0 (45.4, 63.6) | 40.5 (30.1, 50.8) |
| 12 months | 43.1 (32.7, 53.1) | 9.7 (1.0, 30.5) |
| 18 months | 38.0 (26.9, 49.1) | NE (NE, NE) |
| 24 months | 33.3 (20.7, 46.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 32 (19.9%) | 31 (22.6%) |
| Censored Patients, n (%) | 129 (80.1%) | 106 (77.4%) |
| Median (95% CI), (Months) [a] | NE (13.93, NE) | 10.35 (6.70, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0217 | |
| HR (95% CI) [c] | 0.555 (0.334, 0.924) | |
| HR P-Value [c] | 0.0237 | |
| Heterogeneity p-value [d] | 0.5643 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.1 (67.2, 84.4) | 71.9 (60.3, 80.7) |
| 12 months | 66.6 (54.5, 76.1) | 28.6 (8.9, 52.4) |
| 18 months | 58.5 (44.6, 70.0) | NE (NE, NE) |
| 24 months | 58.5 (44.6, 70.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 36 (22.4%) | 36 (26.3%) |
| Censored Patients, n (%) | 125 (77.6%) | 101 (73.7%) |
| Median (95% CI), (Months) [a] | NE (14.03, NE) | 11.07 (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0052 | |
| HR (95% CI) [c] | 0.504 (0.309, 0.823) | |
| HR P-Value [c] | 0.0061 | |
| Heterogeneity p-value [d] | 0.5227 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.5 (70.5, 86.1) | 63.4 (51.3, 73.2) |
| 12 months | 63.4 (51.4, 73.2) | 21.9 (1.8, 56.3) |
| 18 months | 54.5 (40.2, 66.7) | NE (NE, NE) |
| 24 months | 54.5 (40.2, 66.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 43 (26.7%) | 49 (35.8%) |
| Censored Patients, n (%) | 118 (73.3%) | 88 (64.2%) |
| | | |
| Median (95% CI), (Months) [a] | 19.15 (10.97, NE) | 5.82 (4.17, 11.07) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0017 | |
| HR (95% CI) [c] | 0.514 (0.336, 0.786) | |
| HR P-Value [c] | 0.0022 | |
| Heterogeneity p-value [d] | 0.4050 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.0 (56.8, 75.3) | 46.9 (35.5, 57.6) |
| 12 months | 55.1 (42.9, 65.7) | 20.0 (4.9, 42.4) |
| 18 months | 55.1 (42.9, 65.7) | NE (NE, NE) |
| 24 months | 39.4 (19.9, 58.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 47 (29.2%) | 47 (34.3%) |
| Censored Patients, n (%) | 114 (70.8%) | 90 (65.7%) |
| Median (95% CI), (Months) [a] | 20.17 (10.18, NE) | 7.00 (5.16, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0021 | |
| HR (95% CI) [c] | 0.522 (0.342, 0.796) | |
| HR P-Value [c] | 0.0025 | |
| Heterogeneity p-value [d] | 0.7558 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.3 (60.8, 77.8) | 56.0 (44.2, 66.2) |
| 12 months | 57.4 (46.0, 67.3) | 25.8 (9.6, 45.6) |
| 18 months | 50.3 (37.8, 61.6) | NE (NE, NE) |
| 24 months | 44.7 (29.6, 58.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 46 (28.6%) | 52 (38.0%) |
| Censored Patients, n (%) | 115 (71.4%) | 85 (62.0%) |
| Median (95% CI), (Months) [a] | 16.85 (8.61, NE) | 5.82 (3.68, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0005 | |
| HR (95% CI) [c] | 0.494 (0.329, 0.743) | |
| HR P-Value [c] | 0.0007 | |
| Heterogeneity p-value [d] | 0.2642 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.5 (63.0, 80.0) | 49.4 (38.2, 59.6) |
| 12 months | 51.7 (40.1, 62.1) | 26.8 (10.9, 45.8) |
| 18 months | 48.7 (36.3, 59.9) | NE (NE, NE) |
| 24 months | 48.7 (36.3, 59.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 46 (28.6%) | 46 (33.6%) |
| Censored Patients, n (%) | 115 (71.4%) | 91 (66.4%) |
| Median (95% CI), (Months) [a] | 14.26 (12.48, NE) | 8.54 (4.24, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0060 | |
| HR (95% CI) [c] | 0.555 (0.361, 0.851) | |
| HR P-Value [c] | 0.0070 | |
| Heterogeneity p-value [d] | 0.8385 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.5 (58.8, 76.4) | 53.7 (42.1, 64.0) |
| 12 months | 61.4 (50.2, 70.8) | 24.7 (9.0, 44.3) |
| 18 months | 44.5 (31.1, 57.1) | NE (NE, NE) |
| 24 months | 44.5 (31.1, 57.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 40 (24.8%) | 39 (28.5%) |
| Censored Patients, n (%) | 121 (75.2%) | 98 (71.5%) |
| Median (95% CI), (Months) [a] | 20.17 (13.93, NE) | 8.02 (5.88, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0095 | |
| HR (95% CI) [c] | 0.546 (0.342, 0.870) | |
| HR P-Value [c] | 0.0109 | |
| Heterogeneity p-value [d] | 0.5910 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.3 (65.8, 82.5) | 60.1 (47.9, 70.3) |
| 12 months | 63.1 (51.1, 72.9) | 42.7 (27.9, 56.7) |
| 18 months | 54.0 (39.8, 66.2) | NE (NE, NE) |
| 24 months | 31.5 (12.7, 52.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Patients with event, n (%) | 39 (24.2%) | 34 (24.8%) |
| Censored Patients, n (%) | 122 (75.8%) | 103 (75.2%) |
| Median (95% CI), (Months) [a] | 20.17 (11.20, NE) | 9.40 (7.39, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0354 | |
| HR (95% CI) [c] | 0.598 (0.368, 0.971) | |
| HR P-Value [c] | 0.0376 | |
| Heterogeneity p-value [d] | 0.1808 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.3 (62.3, 80.1) | 70.9 (59.9, 79.3) |
| 12 months | 57.0 (44.4, 67.8) | 28.5 (9.8, 50.8) |
| 18 months | 50.3 (36.1, 62.9) | NE (NE, NE) |
| 24 months | 44.0 (27.3, 59.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 9 (25.7%) | 10 (21.7%) |
| Censored Patients, n (%) | 26 (74.3%) | 36 (78.3%) |
| Median (95% CI), (Months) [a] | 12.88 (4.17, NE) | NE (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7397 | |
| HR (95% CI) [c] | 0.856 (0.345, 2.121) | |
| HR P-Value [c] | 0.7369 | |
| Heterogeneity p-value [d] | 0.3749 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.6 (39.4, 81.5) | 60.4 (38.3, 76.8) |
| 12 months | 56.5 (30.3, 76.2) | 60.4 (38.3, 76.8) |
| 18 months | 45.2 (18.1, 69.2) | 60.4 (38.3, 76.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 5 (14.3%) | 11 (23.9%) |
| Censored Patients, n (%) | 30 (85.7%) | 35 (76.1%) |
| Median (95% CI), (Months) [a] | 13.83 (12.45, NE) | NE (2.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0647 | |
| HR (95% CI) [c] | 0.377 (0.129, 1.102) | |
| HR P-Value [c] | 0.0748 | |
| Heterogeneity p-value [d] | 0.5556 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.3 (61.3, 99.0) | 53.2 (30.2, 71.8) |
| 12 months | 84.8 (51.2, 96.0) | 53.2 (30.2, 71.8) |
| 18 months | NE (NE, NE) | 53.2 (30.2, 71.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 7 (20.0%) | 9 (19.6%) |
| Censored Patients, n (%) | 28 (80.0%) | 37 (80.4%) |
| Median (95% CI), (Months) [a] | 15.11 (5.78, NE) | 8.97 (6.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6366 | |
| HR (95% CI) [c] | 0.786 (0.290, 2.135) | |
| HR P-Value [c] | 0.6373 | |
| Heterogeneity p-value [d] | 0.5693 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.9 (49.0, 90.8) | 73.5 (52.3, 86.4) |
| 12 months | 61.5 (32.6, 81.0) | 49.0 (16.8, 75.2) |
| 18 months | NE (NE, NE) | 49.0 (16.8, 75.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 1 (2.2%) |
| Censored Patients, n (%) | 32 (91.4%) | 45 (97.8%) |
| Median (95% CI), (Months) [a] | NE (10.12, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3917 | |
| HR (95% CI) [c] | 2.674 (0.261, 27.386) | |
| HR P-Value [c] | 0.4073 | |
| Heterogeneity p-value [d] | 0.1606 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.2 (70.7, 99.3) | 96.3 (76.5, 99.5) |
| 12 months | 74.1 (36.7, 91.4) | 96.3 (76.5, 99.5) |
| 18 months | 74.1 (36.7, 91.4) | 96.3 (76.5, 99.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 5 (14.3%) | 10 (21.7%) |
| Censored Patients, n (%) | 30 (85.7%) | 36 (78.3%) |
| Median (95% CI), (Months) [a] | NE (10.12, NE) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1665 | |
| HR (95% CI) [c] | 0.469 (0.157, 1.403) | |
| HR P-Value [c] | 0.1757 | |
| Heterogeneity p-value [d] | 0.8182 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.8 (55.0, 94.2) | 55.6 (32.2, 73.8) |
| 12 months | 62.1 (29.0, 83.3) | 55.6 (32.2, 73.8) |
| 18 months | 62.1 (29.0, 83.3) | 55.6 (32.2, 73.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 4 (11.4%) | 11 (23.9%) |
| Censored Patients, n (%) | 31 (88.6%) | 35 (76.1%) |
| Median (95% CI), (Months) [a] | 20.80 (6.97, 20.80) | NE (3.32, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0377 | |
| HR (95% CI) [c] | 0.280 (0.078, 1.008) | |
| HR P-Value [c] | 0.0515 | |
| Heterogeneity p-value [d] | 0.3016 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.1 (60.2, 96.9) | 61.8 (40.1, 77.6) |
| 12 months | 80.1 (49.4, 93.3) | 55.0 (32.0, 73.0) |
| 18 months | 80.1 (49.4, 93.3) | 55.0 (32.0, 73.0) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 14 (40.0%) | 11 (23.9%) |
| Censored Patients, n (%) | 21 (60.0%) | 35 (76.1%) |
| Median (95% CI), (Months) [a] | 10.12 (2.79, 14.55) | 8.54 (1.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5970 | |
| HR (95% CI) [c] | 1.240 (0.557, 2.763) | |
| HR P-Value [c] | 0.5980 | |
| Heterogeneity p-value [d] | 0.0565 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.3 (35.0, 75.8) | 69.9 (48.6, 83.7) |
| 12 months | 38.9 (17.3, 60.1) | 44.0 (18.0, 67.5) |
| 18 months | NE (NE, NE) | 44.0 (18.0, 67.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 5 (14.3%) | 5 (10.9%) |
| Censored Patients, n (%) | 30 (85.7%) | 41 (89.1%) |
| Median (95% CI), (Months) [a] | 20.80 (9.66, 20.80) | NE (5.22, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4515 | |
| HR (95% CI) [c] | 0.603 (0.160, 2.278) | |
| HR P-Value [c] | 0.4560 | |
| Heterogeneity p-value [d] | 0.5643 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.1 (57.3, 96.6) | 70.1 (41.1, 86.8) |
| 12 months | 67.7 (33.8, 86.9) | 70.1 (41.1, 86.8) |
| 18 months | 67.7 (33.8, 86.9) | 70.1 (41.1, 86.8) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 8 (17.4%) |
| Censored Patients, n (%) | 32 (91.4%) | 38 (82.6%) |
| Median (95% CI), (Months) [a] | NE (8.77, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1565 | |
| HR (95% CI) [c] | 0.392 (0.103, 1.498) | |
| HR P-Value [c] | 0.1710 | |
| Heterogeneity p-value [d] | 0.5227 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.0 (65.6, 97.4) | 71.6 (51.2, 84.7) |
| 12 months | 80.0 (46.8, 93.7) | 71.6 (51.2, 84.7) |
| 18 months | 80.0 (46.8, 93.7) | 71.6 (51.2, 84.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 9 (25.7%) | 11 (23.9%) |
| Censored Patients, n (%) | 26 (74.3%) | 35 (76.1%) |
| Median (95% CI), (Months) [a] | 12.45 (4.21, NE) | 8.97 (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5338 | |
| HR (95% CI) [c] | 0.753 (0.308, 1.841) | |
| HR P-Value [c] | 0.5339 | |
| Heterogeneity p-value [d] | 0.4050 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.9 (44.6, 85.3) | 56.9 (34.6, 74.2) |
| 12 months | 55.1 (28.6, 75.3) | 42.7 (15.4, 67.9) |
| 18 months | NE (NE, NE) | 42.7 (15.4, 67.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 9 (25.7%) | 17 (37.0%) |
| Censored Patients, n (%) | 26 (74.3%) | 29 (63.0%) |
| Median (95% CI), (Months) [a] | 14.55 (5.55, 20.80) | 4.17 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0375 | |
| HR (95% CI) [c] | 0.414 (0.175, 0.980) | |
| HR P-Value [c] | 0.0449 | |
| Heterogeneity p-value [d] | 0.7558 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.2 (48.3, 88.5) | 39.8 (21.2, 57.8) |
| 12 months | 55.6 (26.4, 77.2) | 26.5 (6.8, 51.8) |
| 18 months | 37.1 (7.9, 67.9) | 26.5 (6.8, 51.8) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 9 (25.7%) | 11 (23.9%) |
| Censored Patients, n (%) | 26 (74.3%) | 35 (76.1%) |
| Median (95% CI), (Months) [a] | 8.48 (6.93, NE) | 8.54 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5769 | |
| HR (95% CI) [c] | 0.776 (0.317, 1.901) | |
| HR P-Value [c] | 0.5796 | |
| Heterogeneity p-value [d] | 0.2642 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.2 (60.6, 95.0) | 63.2 (40.2, 79.4) |
| 12 months | 38.3 (12.4, 64.4) | 40.6 (13.6, 66.6) |
| 18 months | NE (NE, NE) | 40.6 (13.6, 66.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 8 (22.9%) | 13 (28.3%) |
| Censored Patients, n (%) | 27 (77.1%) | 33 (71.7%) |
| | | |
| Median (95% CI), (Months) [a] | 14.55 (6.97, NE) | 4.30 (1.61, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1527 | |
| HR (95% CI) [c] | 0.525 (0.216, 1.279) | |
| HR P-Value [c] | 0.1563 | |
| Heterogeneity p-value [d] | 0.8385 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.7 (54.3, 91.9) | 48.2 (27.6, 66.1) |
| 12 months | 56.4 (28.1, 77.2) | 48.2 (27.6, 66.1) |
| 18 months | 37.6 (8.2, 68.2) | 48.2 (27.6, 66.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 7 (20.0%) | 14 (30.4%) |
| Censored Patients, n (%) | 28 (80.0%) | 32 (69.6%) |
| Median (95% CI), (Months) [a] | 20.80 (6.97, 20.80) | 8.54 (1.61, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0641 | |
| HR (95% CI) [c] | 0.412 (0.157, 1.084) | |
| HR P-Value [c] | 0.0725 | |
| Heterogeneity p-value [d] | 0.5910 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.8 (50.7, 91.2) | 51.1 (31.0, 68.1) |
| 12 months | 61.3 (31.8, 81.1) | 40.9 (18.2, 62.6) |
| 18 months | 61.3 (31.8, 81.1) | 40.9 (18.2, 62.6) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Patients with event, n (%) | 8 (22.9%) | 7 (15.2%) |
| Censored Patients, n (%) | 27 (77.1%) | 39 (84.8%) |
| Median (95% CI), (Months) [a] | 16.66 (3.19, NE) | NE (6.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5784 | |
| HR (95% CI) [c] | 1.335 (0.481, 3.707) | |
| HR P-Value [c] | 0.5792 | |
| Heterogeneity p-value [d] | 0.1808 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.8 (38.8, 83.1) | 78.2 (57.7, 89.6) |
| 12 months | 57.6 (30.0, 77.7) | 70.4 (45.3, 85.6) |
| 18 months | NE (NE, NE) | 70.4 (45.3, 85.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 20 (22.5%) | 26 (30.6%) |
| Censored Patients, n (%) | 69 (77.5%) | 59 (69.4%) |
| | | |
| Median (95% CI), (Months) [a] | 12.88 (7.26, NE) | 4.83 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0005 | |
| HR (95% CI) [c] | 0.356 (0.193, 0.654) | |
| HR P-Value [c] | 0.0009 | |
| Heterogeneity p-value [d] | 0.0883 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.0 (61.5, 85.6) | 43.6 (27.5, 58.6) |
| 12 months | 52.9 (33.9, 68.7) | 25.8 (7.1, 50.1) |
| 18 months | 48.1 (28.9, 64.8) | NE (NE, NE) |
| 24 months | 48.1 (28.9, 64.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 20 (22.5%) | 20 (23.5%) |
| Censored Patients, n (%) | 69 (77.5%) | 65 (76.5%) |
| Median (95% CI), (Months) [a] | 16.85 (11.93, NE) | 6.08 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0300 | |
| HR (95% CI) [c] | 0.496 (0.260, 0.946) | |
| HR P-Value [c] | 0.0334 | |
| Heterogeneity p-value [d] | 0.8188 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.9 (61.3, 84.3) | 53.1 (34.6, 68.5) |
| 12 months | 66.5 (48.7, 79.3) | 36.2 (13.8, 59.4) |
| 18 months | 40.8 (15.0, 65.5) | NE (NE, NE) |
| 24 months | 40.8 (15.0, 65.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 15 (16.9%) | 18 (21.2%) |
| Censored Patients, n (%) | 74 (83.1%) | 67 (78.8%) |
| Median (95% CI), (Months) [a] | NE (15.11, NE) | 8.97 (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0343 | |
| HR (95% CI) [c] | 0.474 (0.233, 0.964) | |
| HR P-Value [c] | 0.0394 | |
| Heterogeneity p-value [d] | 0.2418 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.7 (64.4, 86.5) | 60.2 (42.6, 74.0) |
| 12 months | 74.6 (60.2, 84.4) | 35.7 (9.0, 64.3) |
| 18 months | 63.9 (38.2, 81.2) | NE (NE, NE) |
| 24 months | 63.9 (38.2, 81.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 14 (15.7%) | 7 (8.2%) |
| Censored Patients, n (%) | 75 (84.3%) | 78 (91.8%) |
| | | |
| Median (95% CI), (Months) [a] | 18.10 (10.45, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6177 | |
| HR (95% CI) [c] | 0.784 (0.302, 2.040) | |
| HR P-Value [c] | 0.6184 | |
| Heterogeneity p-value [d] | 0.3118 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.3 (72.7, 93.4) | 78.4 (58.4, 89.5) |
| 12 months | 61.2 (40.2, 76.8) | 78.4 (58.4, 89.5) |
| 18 months | 61.2 (40.2, 76.8) | NE (NE, NE) |
| 24 months | 49.0 (22.2, 71.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 20 (22.5%) | 16 (18.8%) |
| Censored Patients, n (%) | 69 (77.5%) | 69 (81.2%) |
| Median (95% CI), (Months) [a] | 16.85 (10.45, NE) | NE (4.47, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2035 | |
| HR (95% CI) [c] | 0.642 (0.322, 1.283) | |
| HR P-Value [c] | 0.2102 | |
| Heterogeneity p-value [d] | 0.3798 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.9 (63.0, 84.9) | 60.7 (41.7, 75.2) |
| 12 months | 59.5 (40.7, 74.0) | 53.1 (31.4, 70.8) |
| 18 months | 47.6 (22.3, 69.2) | NE (NE, NE) |
| 24 months | 47.6 (22.3, 69.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 12 (13.5%) | 15 (17.6%) |
| Censored Patients, n (%) | 77 (86.5%) | 70 (82.4%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | 8.90 (6.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0169 | |
| HR (95% CI) [c] | 0.393 (0.178, 0.869) | |
| HR P-Value [c] | 0.0210 | |
| Heterogeneity p-value [d] | 0.1898 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.7 (77.4, 94.5) | 68.5 (51.1, 80.8) |
| 12 months | 75.9 (59.2, 86.5) | 46.7 (17.4, 71.8) |
| 18 months | 60.7 (27.6, 82.4) | NE (NE, NE) |
| 24 months | 60.7 (27.6, 82.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 30 (33.7%) | 32 (37.6%) |
| Censored Patients, n (%) | 59 (66.3%) | 53 (62.4%) |
| Median (95% CI), (Months) [a] | 10.45 (5.82, NE) | 2.92 (1.77, 6.14) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0034 | |
| HR (95% CI) [c] | 0.475 (0.283, 0.797) | |
| HR P-Value [c] | 0.0048 | |
| Heterogeneity p-value [d] | 0.0534 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.4 (45.5, 70.8) | 35.9 (21.9, 50.2) |
| 12 months | 46.0 (30.4, 60.2) | 19.3 (6.4, 37.2) |
| 18 months | 39.4 (22.1, 56.2) | NE (NE, NE) |
| 24 months | 39.4 (22.1, 56.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 16 (18.0%) | 11 (12.9%) |
| Censored Patients, n (%) | 73 (82.0%) | 74 (87.1%) |
| Median (95% CI), (Months) [a] | NE (9.89, NE) | NE (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3953 | |
| HR (95% CI) [c] | 0.712 (0.322, 1.570) | |
| HR P-Value [c] | 0.3992 | |
| Heterogeneity p-value [d] | 0.7239 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.4 (63.0, 86.7) | 71.2 (50.9, 84.3) |
| 12 months | 62.3 (43.6, 76.3) | 62.3 (37.0, 79.8) |
| 18 months | 62.3 (43.6, 76.3) | NE (NE, NE) |
| 24 months | 62.3 (43.6, 76.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 18 (20.2%) | 19 (22.4%) |
| Censored Patients, n (%) | 71 (79.8%) | 66 (77.6%) |
| Median (95% CI), (Months) [a] | NE (9.69, NE) | 8.90 (4.93, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0150 | |
| HR (95% CI) [c] | 0.442 (0.225, 0.868) | |
| HR P-Value [c] | 0.0177 | |
| Heterogeneity p-value [d] | 0.6475 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.3 (64.2, 87.3) | 54.5 (35.2, 70.3) |
| 12 months | 59.6 (42.2, 73.3) | 36.4 (9.3, 65.0) |
| 18 months | 59.6 (42.2, 73.3) | NE (NE, NE) |
| 24 months | 59.6 (42.2, 73.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 24 (27.0%) | 26 (30.6%) |
| Censored Patients, n (%) | 65 (73.0%) | 59 (69.4%) |
| Median (95% CI), (Months) [a] | 10.18 (5.72, NE) | 4.17 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0170 | |
| HR (95% CI) [c] | 0.502 (0.281, 0.895) | |
| HR P-Value [c] | 0.0194 | |
| Heterogeneity p-value [d] | 0.7870 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.0 (47.0, 73.9) | 40.2 (24.8, 55.1) |
| 12 months | 49.6 (32.3, 64.7) | 26.8 (7.5, 51.1) |
| 18 months | 49.6 (32.3, 64.7) | NE (NE, NE) |
| 24 months | 33.1 (8.9, 60.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 23 (25.8%) | 27 (31.8%) |
| Censored Patients, n (%) | 66 (74.2%) | 58 (68.2%) |
| Median (95% CI), (Months) [a] | NE (9.82, NE) | 5.16 (3.35, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0005 | |
| HR (95% CI) [c] | 0.362 (0.201, 0.654) | |
| HR P-Value [c] | 0.0007 | |
| Heterogeneity p-value [d] | 0.2663 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.7 (55.7, 80.1) | 41.8 (24.8, 58.0) |
| 12 months | 51.4 (34.0, 66.3) | 10.6 (0.8, 34.9) |
| 18 months | 51.4 (34.0, 66.3) | NE (NE, NE) |
| 24 months | 51.4 (34.0, 66.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 23 (25.8%) | 25 (29.4%) |
| Censored Patients, n (%) | 66 (74.2%) | 60 (70.6%) |
| Median (95% CI), (Months) [a] | 16.85 (7.95, NE) | 4.67 (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0028 | |
| HR (95% CI) [c] | 0.415 (0.229, 0.752) | |
| HR P-Value [c] | 0.0037 | |
| Heterogeneity p-value [d] | 0.3226 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.8 (57.7, 82.0) | 39.1 (22.3, 55.5) |
| 12 months | 53.5 (36.8, 67.6) | 33.5 (16.9, 51.1) |
| 18 months | 42.8 (20.6, 63.4) | NE (NE, NE) |
| 24 months | 42.8 (20.6, 63.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 20 (22.5%) | 23 (27.1%) |
| Censored Patients, n (%) | 69 (77.5%) | 62 (72.9%) |
| Median (95% CI), (Months) [a] | NE (10.12, NE) | 4.83 (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0183 | |
| HR (95% CI) [c] | 0.483 (0.260, 0.897) | |
| HR P-Value [c] | 0.0213 | |
| Heterogeneity p-value [d] | 0.4155 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.2 (59.7, 82.8) | 48.9 (32.5, 63.5) |
| 12 months | 56.3 (37.8, 71.3) | 36.7 (14.7, 59.2) |
| 18 months | 56.3 (37.8, 71.3) | NE (NE, NE) |
| 24 months | 56.3 (37.8, 71.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 23 (25.8%) | 14 (16.5%) |
| Censored Patients, n (%) | 66 (74.2%) | 71 (83.5%) |
| Median (95% CI), (Months) [a] | 15.44 (10.18, NE) | 8.02 (5.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5723 | |
| HR (95% CI) [c] | 0.821 (0.413, 1.634) | |
| HR P-Value [c] | 0.5750 | |
| Heterogeneity p-value [d] | 0.1153 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.0 (57.1, 81.1) | 68.3 (49.3, 81.4) |
| 12 months | 53.3 (35.7, 68.1) | 48.6 (21.4, 71.3) |
| 18 months | 45.7 (25.6, 63.7) | NE (NE, NE) |
| 24 months | 45.7 (25.6, 63.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Patients with event, n (%) | 24 (27.0%) | 17 (20.0%) |
| Censored Patients, n (%) | 65 (73.0%) | 68 (80.0%) |
| Median (95% CI), (Months) [a] | 16.76 (5.95, NE) | 7.39 (6.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3553 | |
| HR (95% CI) [c] | 0.741 (0.391, 1.406) | |
| HR P-Value [c] | 0.3595 | |
| Heterogeneity p-value [d] | 0.9778 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.2 (49.8, 75.4) | 69.6 (53.1, 81.3) |
| 12 months | 54.4 (38.0, 68.1) | 30.9 (7.1, 59.4) |
| 18 months | 46.6 (26.9, 64.1) | NE (NE, NE) |
| 24 months | 46.6 (26.9, 64.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 29 (27.1%) | 27 (27.6%) |
| Censored Patients, n (%) | 78 (72.9%) | 71 (72.4%) |
| | | |
| Median (95% CI), (Months) [a] | NE (11.43, NE) | 9.72 (9.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4118 | |
| HR (95% CI) [c] | 0.799 (0.468, 1.365) | |
| HR P-Value [c] | 0.4123 | |
| Heterogeneity p-value [d] | 0.0883 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.4 (55.3, 76.8) | 65.9 (52.7, 76.1) |
| 12 months | 60.9 (47.8, 71.7) | 39.5 (19.1, 59.4) |
| 18 months | 60.9 (47.8, 71.7) | 39.5 (19.1, 59.4) |
| 24 months | 50.8 (29.0, 69.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 27 (25.2%) | 31 (31.6%) |
| Censored Patients, n (%) | 80 (74.8%) | 67 (68.4%) |
| Median (95% CI), (Months) [a] | 17.05 (13.93, NE) | NE (4.60, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0568 | |
| HR (95% CI) [c] | 0.597 (0.349, 1.021) | |
| HR P-Value [c] | 0.0596 | |
| Heterogeneity p-value [d] | 0.8188 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.5 (62.6, 83.1) | 57.5 (44.5, 68.5) |
| 12 months | 68.0 (54.7, 78.1) | 53.9 (39.8, 66.0) |
| 18 months | 49.0 (31.7, 64.2) | 53.9 (39.8, 66.0) |
| 24 months | 49.0 (31.7, 64.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 25 (23.4%) | 25 (25.5%) |
| Censored Patients, n (%) | 82 (76.6%) | 73 (74.5%) |
| Median (95% CI), (Months) [a] | NE (9.89, NE) | 11.93 (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3547 | |
| HR (95% CI) [c] | 0.768 (0.437, 1.347) | |
| HR P-Value [c] | 0.3572 | |
| Heterogeneity p-value [d] | 0.2418 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.1 (62.1, 82.8) | 72.0 (59.3, 81.4) |
| 12 months | 60.4 (46.1, 72.0) | 42.0 (17.5, 65.0) |
| 18 months | 60.4 (46.1, 72.0) | 28.0 (6.1, 56.1) |
| 24 months | 60.4 (46.1, 72.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 10 (9.3%) | 14 (14.3%) |
| Censored Patients, n (%) | 97 (90.7%) | 84 (85.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1505 | |
| HR (95% CI) [c] | 0.545 (0.236, 1.263) | |
| HR P-Value [c] | 0.1569 | |
| Heterogeneity p-value [d] | 0.3118 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.0 (81.7, 95.7) | 82.4 (70.5, 89.8) |
| 12 months | 85.4 (72.4, 92.6) | 71.0 (50.5, 84.2) |
| 18 months | 79.7 (61.1, 90.1) | 71.0 (50.5, 84.2) |
| 24 months | 79.7 (61.1, 90.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 15 (14.0%) | 25 (25.5%) |
| Censored Patients, n (%) | 92 (86.0%) | 73 (74.5%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (6.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0185 | |
| HR (95% CI) [c] | 0.465 (0.243, 0.893) | |
| HR P-Value [c] | 0.0214 | |
| Heterogeneity p-value [d] | 0.3798 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.5 (69.9, 89.0) | 67.0 (53.6, 77.3) |
| 12 months | 79.3 (67.0, 87.4) | 50.9 (30.6, 68.0) |
| 18 months | 74.3 (58.1, 85.0) | 50.9 (30.6, 68.0) |
| 24 months | 74.3 (58.1, 85.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 24 (22.4%) | 22 (22.4%) |
| Censored Patients, n (%) | 83 (77.6%) | 76 (77.6%) |
| Median (95% CI), (Months) [a] | 20.17 (12.52, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3017 | |
| HR (95% CI) [c] | 0.725 (0.393, 1.339) | |
| HR P-Value [c] | 0.3046 | |
| Heterogeneity p-value [d] | 0.1898 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.1 (66.5, 86.1) | 71.9 (59.0, 81.4) |
| 12 months | 69.8 (55.5, 80.3) | 57.8 (38.9, 72.7) |
| 18 months | 59.4 (42.5, 72.8) | 57.8 (38.9, 72.7) |
| 24 months | 37.1 (12.9, 61.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 49 (45.8%) | 42 (42.9%) |
| Censored Patients, n (%) | 58 (54.2%) | 56 (57.1%) |
| Median (95% CI), (Months) [a] | 7.23 (2.99, 12.45) | 8.34 (3.15, 10.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4470 | |
| HR (95% CI) [c] | 0.849 (0.555, 1.299) | |
| HR P-Value [c] | 0.4514 | |
| Heterogeneity p-value [d] | 0.0534 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.2 (40.5, 62.6) | 53.2 (40.8, 64.2) |
| 12 months | 38.5 (26.5, 50.3) | 18.8 (4.7, 40.2) |
| 18 months | 29.5 (17.4, 42.7) | 18.8 (4.7, 40.2) |
| 24 months | 22.1 (8.9, 39.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 21 (19.6%) | 25 (25.5%) |
| Censored Patients, n (%) | 86 (80.4%) | 73 (74.5%) |
| Median (95% CI), (Months) [a] | 20.80 (13.93, NE) | 11.50 (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0292 | |
| HR (95% CI) [c] | 0.516 (0.282, 0.944) | |
| HR P-Value [c] | 0.0319 | |
| Heterogeneity p-value [d] | 0.7239 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.7 (67.3, 87.9) | 71.8 (58.5, 81.5) |
| 12 months | 69.3 (54.3, 80.3) | 34.0 (13.4, 56.1) |
| 18 months | 57.8 (40.1, 71.9) | 34.0 (13.4, 56.1) |
| 24 months | 46.2 (22.0, 67.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 21 (19.6%) | 25 (25.5%) |
| Censored Patients, n (%) | 86 (80.4%) | 73 (74.5%) |
| Median (95% CI), (Months) [a] | NE (14.59, NE) | 11.93 (11.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0371 | |
| HR (95% CI) [c] | 0.525 (0.284, 0.971) | |
| HR P-Value [c] | 0.0400 | |
| Heterogeneity p-value [d] | 0.6475 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.0 (72.3, 89.8) | 70.5 (58.1, 79.9) |
| 12 months | 70.3 (55.5, 81.0) | 38.2 (9.2, 67.9) |
| 18 months | 57.5 (39.1, 72.1) | 38.2 (9.2, 67.9) |
| 24 months | 57.5 (39.1, 72.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 28 (26.2%) | 34 (34.7%) |
| Censored Patients, n (%) | 79 (73.8%) | 64 (65.3%) |
| Median (95% CI), (Months) [a] | 20.17 (11.43, NE) | 10.35 (4.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0275 | |
| HR (95% CI) [c] | 0.565 (0.337, 0.947) | |
| HR P-Value [c] | 0.0304 | |
| Heterogeneity p-value [d] | 0.7870 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.3 (59.2, 80.4) | 54.2 (40.8, 65.8) |
| 12 months | 58.4 (43.8, 70.5) | 29.0 (10.6, 50.6) |
| 18 months | 55.5 (40.5, 68.1) | 29.0 (10.6, 50.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 33 (30.8%) | 37 (37.8%) |
| Censored Patients, n (%) | 74 (69.2%) | 61 (62.2%) |
| Median (95% CI), (Months) [a] | 15.34 (9.79, NE) | 9.72 (4.63, 12.71) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0197 | |
| HR (95% CI) [c] | 0.559 (0.340, 0.918) | |
| HR P-Value [c] | 0.0216 | |
| Heterogeneity p-value [d] | 0.2663 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.3 (59.4, 80.2) | 57.3 (44.9, 68.0) |
| 12 months | 60.2 (46.6, 71.5) | 34.7 (15.9, 54.3) |
| 18 months | 47.2 (31.7, 61.1) | 26.0 (8.5, 47.9) |
| 24 months | 29.5 (10.6, 51.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 32 (29.9%) | 38 (38.8%) |
| Censored Patients, n (%) | 75 (70.1%) | 60 (61.2%) |
| Median (95% CI), (Months) [a] | 11.20 (8.34, NE) | 7.06 (4.70, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0458 | |
| HR (95% CI) [c] | 0.618 (0.383, 0.997) | |
| HR P-Value [c] | 0.0485 | |
| Heterogeneity p-value [d] | 0.3226 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.2 (64.7, 84.5) | 58.9 (46.6, 69.3) |
| 12 months | 47.5 (33.3, 60.5) | 32.5 (15.3, 51.1) |
| 18 months | 43.9 (29.2, 57.6) | 32.5 (15.3, 51.1) |
| 24 months | 43.9 (29.2, 57.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 34 (31.8%) | 36 (36.7%) |
| Censored Patients, n (%) | 73 (68.2%) | 62 (63.3%) |
| Median (95% CI), (Months) [a] | 14.03 (11.99, NE) | 8.54 (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0420 | |
| HR (95% CI) [c] | 0.607 (0.373, 0.989) | |
| HR P-Value [c] | 0.0452 | |
| Heterogeneity p-value [d] | 0.4155 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.8 (55.4, 77.4) | 55.1 (42.1, 66.3) |
| 12 months | 61.1 (47.7, 72.1) | 31.4 (14.3, 50.1) |
| 18 months | 36.8 (22.2, 51.6) | 31.4 (14.3, 50.1) |
| 24 months | 36.8 (22.2, 51.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 24 (22.4%) | 39 (39.8%) |
| Censored Patients, n (%) | 83 (77.6%) | 59 (60.2%) |
| Median (95% CI), (Months) [a] | 20.76 (13.93, 20.83) | 6.97 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0004 | |
| HR (95% CI) [c] | 0.384 (0.221, 0.667) | |
| HR P-Value [c] | 0.0007 | |
| Heterogeneity p-value [d] | 0.1153 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.8 (68.0, 87.7) | 53.3 (40.8, 64.4) |
| 12 months | 69.8 (55.3, 80.4) | 39.0 (25.0, 52.7) |
| 18 months | 60.7 (42.9, 74.5) | 39.0 (25.0, 52.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Patients with event, n (%) | 23 (21.5%) | 24 (24.5%) |
| Censored Patients, n (%) | 84 (78.5%) | 74 (75.5%) |
| Median (95% CI), (Months) [a] | 16.66 (11.20, NE) | 11.33 (9.40, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1328 | |
| HR (95% CI) [c] | 0.632 (0.346, 1.153) | |
| HR P-Value [c] | 0.1349 | |
| Heterogeneity p-value [d] | 0.9778 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.0 (65.5, 86.5) | 74.3 (62.6, 82.9) |
| 12 months | 59.6 (42.9, 72.9) | 42.5 (18.7, 64.7) |
| 18 months | 49.7 (31.1, 65.8) | 42.5 (18.7, 64.7) |
| 24 months | 37.2 (14.3, 60.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 20 (24.1%) | 21 (30.4%) |
| Censored Patients, n (%) | 63 (75.9%) | 48 (69.6%) |
| Median (95% CI), (Months) [a] | NE (11.43, NE) | 9.17 (4.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0132 | |
| HR (95% CI) [c] | 0.452 (0.238, 0.860) | |
| HR P-Value [c] | 0.0156 | |
| Heterogeneity p-value [d] | 0.4676 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.6 (65.7, 87.1) | 60.3 (44.0, 73.3) |
| 12 months | 63.9 (47.6, 76.4) | 32.9 (10.6, 57.6) |
| 18 months | 59.9 (42.7, 73.5) | NE (NE, NE) |
| 24 months | 51.4 (29.8, 69.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 20 (24.1%) | 21 (30.4%) |
| Censored Patients, n (%) | 63 (75.9%) | 48 (69.6%) |
| Median (95% CI), (Months) [a] | 16.53 (12.88, NE) | NE (4.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0331 | |
| HR (95% CI) [c] | 0.505 (0.266, 0.957) | |
| HR P-Value [c] | 0.0363 | |
| Heterogeneity p-value [d] | 0.6422 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.3 (65.9, 86.7) | 52.6 (35.7, 67.0) |
| 12 months | 74.6 (60.1, 84.5) | 52.6 (35.7, 67.0) |
| 18 months | 49.9 (29.1, 67.6) | NE (NE, NE) |
| 24 months | 49.9 (29.1, 67.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 15 (18.1%) | 23 (33.3%) |
| Censored Patients, n (%) | 68 (81.9%) | 46 (66.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 8.97 (5.19, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0008 | |
| HR (95% CI) [c] | 0.337 (0.174, 0.654) | |
| HR P-Value [c] | 0.0013 | |
| Heterogeneity p-value [d] | 0.0316 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.3 (66.9, 88.7) | 65.8 (49.9, 77.8) |
| 12 months | 68.0 (51.2, 80.1) | 26.0 (7.7, 49.4) |
| 18 months | 68.0 (51.2, 80.1) | NE (NE, NE) |
| 24 months | 68.0 (51.2, 80.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 11 (13.3%) | 7 (10.1%) |
| Censored Patients, n (%) | 72 (86.7%) | 62 (89.9%) |
| Median (95% CI), (Months) [a] | NE (16.76, NE) | NE (8.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5157 | |
| HR (95% CI) [c] | 0.722 (0.268, 1.944) | |
| HR P-Value [c] | 0.5188 | |
| Heterogeneity p-value [d] | 0.7864 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.0 (78.6, 95.5) | 82.9 (64.5, 92.3) |
| 12 months | 76.2 (58.4, 87.1) | 71.1 (39.5, 88.2) |
| 18 months | 70.3 (49.6, 83.8) | NE (NE, NE) |
| 24 months | 70.3 (49.6, 83.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 18 (21.7%) | 20 (29.0%) |
| Censored Patients, n (%) | 65 (78.3%) | 49 (71.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 9.17 (4.63, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0445 | |
| HR (95% CI) [c] | 0.518 (0.270, 0.995) | |
| HR P-Value [c] | 0.0483 | |
| Heterogeneity p-value [d] | 0.6705 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.3 (63.5, 85.1) | 63.2 (47.1, 75.6) |
| 12 months | 66.9 (51.1, 78.6) | 41.4 (18.7, 62.8) |
| 18 months | 66.9 (51.1, 78.6) | NE (NE, NE) |
| 24 months | 66.9 (51.1, 78.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 14 (16.9%) | 14 (20.3%) |
| Censored Patients, n (%) | 69 (83.1%) | 55 (79.7%) |
| Median (95% CI), (Months) [a] | NE (20.17, NE) | 8.84 (7.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0255 | |
| HR (95% CI) [c] | 0.411 (0.184, 0.916) | |
| HR P-Value [c] | 0.0297 | |
| Heterogeneity p-value [d] | 0.4511 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.1 (81.1, 95.9) | 79.8 (65.5, 88.6) |
| 12 months | 74.6 (56.8, 85.9) | 47.8 (20.0, 71.2) |
| 18 months | 70.9 (52.4, 83.3) | NE (NE, NE) |
| 24 months | 53.2 (27.3, 73.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 36 (43.4%) | 25 (36.2%) |
| Censored Patients, n (%) | 47 (56.6%) | 44 (63.8%) |
| Median (95% CI), (Months) [a] | 11.24 (7.10, 20.17) | 6.67 (4.44, 11.50) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2095 | |
| HR (95% CI) [c] | 0.713 (0.418, 1.216) | |
| HR P-Value [c] | 0.2142 | |
| Heterogeneity p-value [d] | 0.4700 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.0 (50.1, 73.5) | 59.8 (43.3, 72.9) |
| 12 months | 46.5 (32.5, 59.4) | 23.7 (7.3, 45.4) |
| 18 months | 36.6 (22.3, 51.0) | NE (NE, NE) |
| 24 months | 29.3 (13.6, 46.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 18 (21.7%) | 15 (21.7%) |
| Censored Patients, n (%) | 65 (78.3%) | 54 (78.3%) |
| Median (95% CI), (Months) [a] | NE (13.93, NE) | 11.93 (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1073 | |
| HR (95% CI) [c] | 0.563 (0.277, 1.143) | |
| HR P-Value [c] | 0.1119 | |
| Heterogeneity p-value [d] | 0.9097 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (66.6, 88.5) | 72.6 (54.5, 84.4) |
| 12 months | 67.8 (51.2, 79.8) | 40.3 (15.5, 64.2) |
| 18 months | 58.4 (39.3, 73.4) | NE (NE, NE) |
| 24 months | 50.1 (27.9, 68.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 22 (26.5%) | 18 (26.1%) |
| Censored Patients, n (%) | 61 (73.5%) | 51 (73.9%) |
| Median (95% CI), (Months) [a] | NE (10.38, NE) | 11.93 (5.82, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0607 | |
| HR (95% CI) [c] | 0.541 (0.282, 1.036) | |
| HR P-Value [c] | 0.0640 | |
| Heterogeneity p-value [d] | 0.5618 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.9 (68.5, 88.8) | 62.8 (44.8, 76.3) |
| 12 months | 57.1 (40.9, 70.4) | 33.5 (7.4, 63.1) |
| 18 months | 53.1 (36.2, 67.4) | NE (NE, NE) |
| 24 months | 53.1 (36.2, 67.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 25 (30.1%) | 21 (30.4%) |
| Censored Patients, n (%) | 58 (69.9%) | 48 (69.6%) |
| Median (95% CI), (Months) [a] | 12.45 (10.12, NE) | 11.07 (4.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1290 | |
| HR (95% CI) [c] | 0.631 (0.345, 1.152) | |
| HR P-Value [c] | 0.1340 | |
| Heterogeneity p-value [d] | 0.3699 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.1 (58.7, 81.8) | 60.6 (44.1, 73.6) |
| 12 months | 52.5 (35.6, 66.8) | 26.9 (5.9, 54.5) |
| 18 months | 49.0 (32.1, 63.8) | NE (NE, NE) |
| 24 months | 39.2 (18.5, 59.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 23 (27.7%) | 24 (34.8%) |
| Censored Patients, n (%) | 60 (72.3%) | 45 (65.2%) |
| Median (95% CI), (Months) [a] | 20.17 (9.82, NE) | 6.67 (4.40, 12.71) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0033 | |
| HR (95% CI) [c] | 0.414 (0.226, 0.758) | |
| HR P-Value [c] | 0.0043 | |
| Heterogeneity p-value [d] | 0.6082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.9 (63.7, 85.8) | 52.1 (35.3, 66.5) |
| 12 months | 59.4 (43.0, 72.5) | 34.7 (13.3, 57.4) |
| 18 months | 55.5 (38.4, 69.5) | NE (NE, NE) |
| 24 months | 39.6 (18.7, 59.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 21 (25.3%) | 27 (39.1%) |
| Censored Patients, n (%) | 62 (74.7%) | 42 (60.9%) |
| Median (95% CI), (Months) [a] | NE (9.82, NE) | 5.82 (4.17, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0006 | |
| HR (95% CI) [c] | 0.373 (0.208, 0.671) | |
| HR P-Value [c] | 0.0010 | |
| Heterogeneity p-value [d] | 0.1299 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.4 (67.6, 88.5) | 49.5 (33.4, 63.7) |
| 12 months | 58.1 (41.7, 71.5) | 27.5 (10.3, 48.1) |
| 18 months | 54.3 (37.3, 68.5) | NE (NE, NE) |
| 24 months | 54.3 (37.3, 68.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 25 (30.1%) | 19 (27.5%) |
| Censored Patients, n (%) | 58 (69.9%) | 50 (72.5%) |
| Median (95% CI), (Months) [a] | 17.77 (11.24, NE) | 11.93 (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2079 | |
| HR (95% CI) [c] | 0.676 (0.366, 1.249) | |
| HR P-Value [c] | 0.2110 | |
| Heterogeneity p-value [d] | 0.4563 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.5 (58.4, 81.1) | 58.2 (41.5, 71.7) |
| 12 months | 59.4 (43.7, 72.1) | 46.6 (22.5, 67.6) |
| 18 months | 46.1 (28.3, 62.2) | NE (NE, NE) |
| 24 months | 46.1 (28.3, 62.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 21 (25.3%) | 18 (26.1%) |
| Censored Patients, n (%) | 62 (74.7%) | 51 (73.9%) |
| Median (95% CI), (Months) [a] | 20.80 (11.24, NE) | NE (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1007 | |
| HR (95% CI) [c] | 0.576 (0.295, 1.123) | |
| HR P-Value [c] | 0.1051 | |
| Heterogeneity p-value [d] | 0.8280 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.3 (66.2, 87.8) | 63.7 (46.7, 76.6) |
| 12 months | 64.7 (48.3, 77.1) | 53.5 (34.1, 69.5) |
| 18 months | 60.4 (42.8, 74.1) | NE (NE, NE) |
| 24 months | 34.5 (13.0, 57.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Patients with event, n (%) | 25 (30.1%) | 14 (20.3%) |
| Censored Patients, n (%) | 58 (69.9%) | 55 (79.7%) |
| Median (95% CI), (Months) [a] | 16.76 (10.09, NE) | 11.33 (7.39, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7760 | |
| HR (95% CI) [c] | 0.908 (0.458, 1.800) | |
| HR P-Value [c] | 0.7823 | |
| Heterogeneity p-value [d] | 0.2648 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.3 (57.7, 81.2) | 81.9 (68.0, 90.2) |
| 12 months | 57.1 (41.2, 70.2) | 45.8 (19.2, 69.1) |
| 18 months | 46.7 (28.6, 63.0) | NE (NE, NE) |
| 24 months | 37.4 (17.0, 57.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 29 (25.7%) | 32 (28.1%) |
| Censored Patients, n (%) | 84 (74.3%) | 82 (71.9%) |
| Median (95% CI), (Months) [a] | NE (6.21, NE) | 8.90 (4.60, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1521 | |
| HR (95% CI) [c] | 0.690 (0.415, 1.145) | |
| HR P-Value [c] | 0.1506 | |
| Heterogeneity p-value [d] | 0.4676 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.7 (51.9, 74.9) | 55.2 (41.7, 66.8) |
| 12 months | 54.7 (40.3, 67.0) | 32.2 (13.0, 53.2) |
| 18 months | 54.7 (40.3, 67.0) | 32.2 (13.0, 53.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 27 (23.9%) | 30 (26.3%) |
| Censored Patients, n (%) | 86 (76.1%) | 84 (73.7%) |
| Median (95% CI), (Months) [a] | 16.85 (11.07, NE) | 8.90 (4.60, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0871 | |
| HR (95% CI) [c] | 0.630 (0.369, 1.075) | |
| HR P-Value [c] | 0.0902 | |
| Heterogeneity p-value [d] | 0.6422 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (58.7, 80.9) | 58.4 (44.8, 69.8) |
| 12 months | 61.5 (46.8, 73.3) | 44.6 (26.3, 61.4) |
| 18 months | 42.8 (22.6, 61.7) | 44.6 (26.3, 61.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 25 (22.1%) | 20 (17.5%) |
| Censored Patients, n (%) | 88 (77.9%) | 94 (82.5%) |
| Median (95% CI), (Months) [a] | NE (15.11, NE) | NE (6.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8187 | |
| HR (95% CI) [c] | 1.074 (0.594, 1.945) | |
| HR P-Value [c] | 0.8127 | |
| Heterogeneity p-value [d] | 0.0316 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.3 (60.6, 81.0) | 68.7 (54.8, 79.2) |
| 12 months | 64.9 (51.4, 75.5) | 64.9 (49.5, 76.6) |
| 18 months | 58.4 (40.6, 72.6) | 64.9 (49.5, 76.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 13 (11.5%) | 14 (12.3%) |
| Censored Patients, n (%) | 100 (88.5%) | 100 (87.7%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4172 | |
| HR (95% CI) [c] | 0.727 (0.337, 1.570) | |
| HR P-Value [c] | 0.4171 | |
| Heterogeneity p-value [d] | 0.7864 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.4 (76.1, 93.6) | 79.7 (67.1, 87.9) |
| 12 months | 75.0 (58.5, 85.7) | 72.5 (52.2, 85.3) |
| 18 months | 75.0 (58.5, 85.7) | 72.5 (52.2, 85.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 17 (15.0%) | 21 (18.4%) |
| Censored Patients, n (%) | 96 (85.0%) | 93 (81.6%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (10.35, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1216 | |
| HR (95% CI) [c] | 0.598 (0.309, 1.159) | |
| HR P-Value [c] | 0.1275 | |
| Heterogeneity p-value [d] | 0.6705 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.7 (70.2, 89.1) | 66.3 (51.6, 77.5) |
| 12 months | 75.7 (61.4, 85.4) | 53.1 (25.9, 74.3) |
| 18 months | 59.9 (34.5, 78.2) | 53.1 (25.9, 74.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 22 (19.5%) | 23 (20.2%) |
| Censored Patients, n (%) | 91 (80.5%) | 91 (79.8%) |
| Median (95% CI), (Months) [a] | NE (12.48, NE) | NE (5.55, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2947 | |
| HR (95% CI) [c] | 0.728 (0.400, 1.325) | |
| HR P-Value [c] | 0.2987 | |
| Heterogeneity p-value [d] | 0.4511 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.8 (62.3, 83.7) | 63.5 (49.1, 74.9) |
| 12 months | 70.0 (56.3, 80.1) | 55.6 (35.6, 71.6) |
| 18 months | 50.6 (28.1, 69.3) | 55.6 (35.6, 71.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 43 (38.1%) | 49 (43.0%) |
| Censored Patients, n (%) | 70 (61.9%) | 65 (57.0%) |
| Median (95% CI), (Months) [a] | 5.82 (2.92, 14.55) | 2.89 (1.77, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0390 | |
| HR (95% CI) [c] | 0.649 (0.426, 0.987) | |
| HR P-Value [c] | 0.0431 | |
| Heterogeneity p-value [d] | 0.4700 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.6 (36.5, 59.7) | 36.8 (25.2, 48.4) |
| 12 months | 37.4 (24.2, 50.5) | 17.8 (5.2, 36.7) |
| 18 months | 32.0 (17.9, 47.1) | 17.8 (5.2, 36.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 19 (16.8%) | 21 (18.4%) |
| Censored Patients, n (%) | 94 (83.2%) | 93 (81.6%) |
| Median (95% CI), (Months) [a] | NE (10.45, NE) | 10.35 (6.70, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1233 | |
| HR (95% CI) [c] | 0.609 (0.322, 1.152) | |
| HR P-Value [c] | 0.1272 | |
| Heterogeneity p-value [d] | 0.9097 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.0 (65.0, 86.6) | 70.7 (56.6, 80.9) |
| 12 months | 65.6 (49.3, 77.8) | 45.2 (20.7, 67.0) |
| 18 months | 61.3 (43.7, 74.8) | 45.2 (20.7, 67.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 17 (15.0%) | 26 (22.8%) |
| Censored Patients, n (%) | 96 (85.0%) | 88 (77.2%) |
| Median (95% CI), (Months) [a] | NE (17.71, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0254 | |
| HR (95% CI) [c] | 0.496 (0.265, 0.928) | |
| HR P-Value [c] | 0.0284 | |
| Heterogeneity p-value [d] | 0.5618 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (69.6, 88.9) | 66.8 (53.9, 76.9) |
| 12 months | 76.4 (63.0, 85.4) | 55.9 (37.0, 71.2) |
| 18 months | 62.0 (38.4, 78.8) | 55.9 (37.0, 71.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 27 (23.9%) | 39 (34.2%) |
| Censored Patients, n (%) | 86 (76.1%) | 75 (65.8%) |
| Median (95% CI), (Months) [a] | 19.15 (5.82, NE) | 4.21 (2.83, 10.35) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0090 | |
| HR (95% CI) [c] | 0.520 (0.315, 0.858) | |
| HR P-Value [c] | 0.0105 | |
| Heterogeneity p-value [d] | 0.3699 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.0 (49.7, 73.8) | 40.0 (27.4, 52.3) |
| 12 months | 57.2 (42.7, 69.4) | 28.2 (11.9, 47.2) |
| 18 months | 57.2 (42.7, 69.4) | 28.2 (11.9, 47.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 33 (29.2%) | 40 (35.1%) |
| Censored Patients, n (%) | 80 (70.8%) | 74 (64.9%) |
| Median (95% CI), (Months) [a] | 14.55 (8.34, NE) | 6.08 (3.38, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0171 | |
| HR (95% CI) [c] | 0.565 (0.351, 0.910) | |
| HR P-Value [c] | 0.0189 | |
| Heterogeneity p-value [d] | 0.6082 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 65.5 (53.2, 75.3) | 52.1 (39.3, 63.4) |
| 12 months | 55.2 (41.1, 67.3) | 23.4 (8.8, 42.0) |
| 18 months | 41.4 (24.6, 57.5) | 23.4 (8.8, 42.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 34 (30.1%) | 36 (31.6%) |
| Censored Patients, n (%) | 79 (69.9%) | 78 (68.4%) |
| Median (95% CI), (Months) [a] | 8.48 (7.26, NE) | 7.00 (3.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1632 | |
| HR (95% CI) [c] | 0.714 (0.443, 1.151) | |
| HR P-Value [c] | 0.1672 | |
| Heterogeneity p-value [d] | 0.1299 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.9 (56.3, 78.5) | 54.2 (41.3, 65.4) |
| 12 months | 43.1 (28.7, 56.6) | 35.8 (17.6, 54.5) |
| 18 months | 36.9 (21.0, 53.0) | 35.8 (17.6, 54.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 29 (25.7%) | 40 (35.1%) |
| Censored Patients, n (%) | 84 (74.3%) | 74 (64.9%) |
| Median (95% CI), (Months) [a] | 13.96 (10.45, NE) | 4.83 (2.96, 8.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0054 | |
| HR (95% CI) [c] | 0.501 (0.304, 0.824) | |
| HR P-Value [c] | 0.0065 | |
| Heterogeneity p-value [d] | 0.4563 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.2 (56.5, 78.9) | 49.3 (36.5, 60.8) |
| 12 months | 61.6 (47.4, 73.0) | 27.8 (13.1, 44.6) |
| 18 months | 41.2 (24.2, 57.4) | 27.8 (13.1, 44.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 26 (23.0%) | 35 (30.7%) |
| Censored Patients, n (%) | 87 (77.0%) | 79 (69.3%) |
| Median (95% CI), (Months) [a] | 15.44 (9.76, 20.76) | 6.97 (3.19, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0090 | |
| HR (95% CI) [c] | 0.504 (0.298, 0.854) | |
| HR P-Value [c] | 0.0109 | |
| Heterogeneity p-value [d] | 0.8280 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.7 (60.2, 81.9) | 54.6 (41.3, 66.2) |
| 12 months | 61.3 (46.0, 73.5) | 36.1 (20.6, 51.8) |
| 18 months | 47.7 (27.3, 65.5) | 36.1 (20.6, 51.8) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Patients with event, n (%) | 22 (19.5%) | 27 (23.7%) |
| Censored Patients, n (%) | 91 (80.5%) | 87 (76.3%) |
| Median (95% CI), (Months) [a] | 16.62 (9.59, NE) | 9.40 (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0905 | |
| HR (95% CI) [c] | 0.611 (0.344, 1.087) | |
| HR P-Value [c] | 0.0936 | |
| Heterogeneity p-value [d] | 0.2648 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.6 (57.9, 81.5) | 65.6 (52.3, 75.9) |
| 12 months | 56.4 (38.6, 70.9) | 38.4 (17.3, 59.4) |
| 18 months | 49.4 (29.2, 66.7) | 38.4 (17.3, 59.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 28 (23.9%) | 31 (32.0%) |
| Censored Patients, n (%) | 89 (76.1%) | 66 (68.0%) |
| Median (95% CI), (Months) [a] | 20.17 (10.38, NE) | 8.90 (4.30, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0070 | |
| HR (95% CI) [c] | 0.486 (0.285, 0.829) | |
| HR P-Value [c] | 0.0081 | |
| Heterogeneity p-value [d] | 0.4145 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.1 (58.1, 79.2) | 53.9 (40.0, 66.0) |
| 12 months | 62.3 (48.5, 73.4) | 27.0 (8.4, 50.0) |
| 18 months | 59.0 (44.4, 71.0) | 27.0 (8.4, 50.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 30 (25.6%) | 27 (27.8%) |
| Censored Patients, n (%) | 87 (74.4%) | 70 (72.2%) |
| Median (95% CI), (Months) [a] | 16.85 (12.88, NE) | 8.90 (5.78, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0388 | |
| HR (95% CI) [c] | 0.565 (0.326, 0.978) | |
| HR P-Value [c] | 0.0413 | |
| Heterogeneity p-value [d] | 0.5404 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.0 (63.2, 83.5) | 60.6 (46.6, 71.9) |
| 12 months | 64.4 (50.7, 75.2) | 49.3 (29.7, 66.2) |
| 18 months | 42.0 (25.1, 58.1) | 49.3 (29.7, 66.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 22 (18.8%) | 26 (26.8%) |
| Censored Patients, n (%) | 95 (81.2%) | 71 (73.2%) |
| Median (95% CI), (Months) [a] | NE (15.11, NE) | 8.97 (5.19, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0411 | |
| HR (95% CI) [c] | 0.553 (0.310, 0.986) | |
| HR P-Value [c] | 0.0445 | |
| Heterogeneity p-value [d] | 0.3110 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.7 (65.3, 84.8) | 63.6 (49.6, 74.6) |
| 12 months | 69.8 (56.6, 79.7) | 47.1 (28.8, 63.4) |
| 18 months | 65.2 (49.4, 77.1) | 47.1 (28.8, 63.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 15 (12.8%) | 14 (14.4%) |
| Censored Patients, n (%) | 102 (87.2%) | 83 (85.6%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (8.87, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1723 | |
| HR (95% CI) [c] | 0.589 (0.273, 1.269) | |
| HR P-Value [c] | 0.1765 | |
| Heterogeneity p-value [d] | 0.6156 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.8 (78.4, 94.4) | 80.7 (67.9, 88.8) |
| 12 months | 75.4 (60.0, 85.6) | 66.6 (43.1, 82.2) |
| 18 months | 70.1 (51.5, 82.6) | 66.6 (43.1, 82.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 19 (16.2%) | 23 (23.7%) |
| Censored Patients, n (%) | 98 (83.8%) | 74 (76.3%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | 10.35 (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0224 | |
| HR (95% CI) [c] | 0.483 (0.255, 0.914) | |
| HR P-Value [c] | 0.0253 | |
| Heterogeneity p-value [d] | 0.5947 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.0 (69.6, 88.4) | 63.4 (48.8, 74.8) |
| 12 months | 72.7 (58.4, 82.8) | 47.5 (18.8, 71.8) |
| 18 months | 62.5 (43.0, 76.9) | 47.5 (18.8, 71.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 25 (21.4%) | 22 (22.7%) |
| Censored Patients, n (%) | 92 (78.6%) | 75 (77.3%) |
| Median (95% CI), (Months) [a] | 20.17 (12.52, NE) | NE (8.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0971 | |
| HR (95% CI) [c] | 0.603 (0.329, 1.104) | |
| HR P-Value [c] | 0.1014 | |
| Heterogeneity p-value [d] | 0.4679 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.2 (70.6, 88.3) | 67.2 (53.1, 77.9) |
| 12 months | 70.1 (56.4, 80.2) | 51.8 (29.3, 70.3) |
| 18 months | 54.4 (36.2, 69.4) | 51.8 (29.3, 70.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 48 (41.0%) | 38 (39.2%) |
| Censored Patients, n (%) | 69 (59.0%) | 59 (60.8%) |
| Median (95% CI), (Months) [a] | 7.29 (4.86, 16.53) | 8.34 (2.96, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2953 | |
| HR (95% CI) [c] | 0.792 (0.510, 1.230) | |
| HR P-Value [c] | 0.2991 | |
| Heterogeneity p-value [d] | 0.2056 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.4 (41.7, 63.7) | 50.8 (38.2, 62.1) |
| 12 months | 41.2 (29.0, 53.0) | 32.7 (17.2, 49.1) |
| 18 months | 30.4 (17.4, 44.4) | 32.7 (17.2, 49.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 19 (16.2%) | 22 (22.7%) |
| Censored Patients, n (%) | 98 (83.8%) | 75 (77.3%) |
| Median (95% CI), (Months) [a] | NE (13.93, NE) | 10.35 (6.70, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0081 | |
| HR (95% CI) [c] | 0.427 (0.224, 0.815) | |
| HR P-Value [c] | 0.0098 | |
| Heterogeneity p-value [d] | 0.1914 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.0 (72.6, 90.9) | 70.4 (55.9, 80.8) |
| 12 months | 71.5 (56.7, 82.1) | 41.5 (18.7, 63.1) |
| 18 months | 59.4 (41.3, 73.7) | 41.5 (18.7, 63.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 21 (17.9%) | 24 (24.7%) |
| Censored Patients, n (%) | 96 (82.1%) | 73 (75.3%) |
| Median (95% CI), (Months) [a] | NE (17.71, NE) | NE (7.26, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0477 | |
| HR (95% CI) [c] | 0.548 (0.300, 1.002) | |
| HR P-Value [c] | 0.0507 | |
| Heterogeneity p-value [d] | 0.6642 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.1 (66.9, 86.0) | 66.2 (52.3, 76.9) |
| 12 months | 70.9 (57.6, 80.8) | 53.8 (33.5, 70.4) |
| 18 months | 65.0 (47.5, 78.0) | 53.8 (33.5, 70.4) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 34 (29.1%) | 33 (34.0%) |
| Censored Patients, n (%) | 83 (70.9%) | 64 (66.0%) |
| | | |
| Median (95% CI), (Months) [a] | 19.15 (6.97, NE) | 5.95 (4.21, 10.35) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0653 | |
| HR (95% CI) [c] | 0.632 (0.385, 1.039) | |
| HR P-Value [c] | 0.0704 | |
| Heterogeneity p-value [d] | 0.5097 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.7 (50.4, 72.8) | 48.4 (34.2, 61.2) |
| 12 months | 54.3 (41.2, 65.7) | 24.1 (6.1, 48.5) |
| 18 months | 54.3 (41.2, 65.7) | 24.1 (6.1, 48.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 32 (27.4%) | 36 (37.1%) |
| Censored Patients, n (%) | 85 (72.6%) | 61 (62.9%) |
| Median (95% CI), (Months) [a] | 20.17 (9.82, NE) | 7.00 (3.48, 9.92) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0020 | |
| HR (95% CI) [c] | 0.464 (0.282, 0.764) | |
| HR P-Value [c] | 0.0026 | |
| Heterogeneity p-value [d] | 0.5165 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.1 (58.4, 79.0) | 53.0 (39.5, 64.7) |
| 12 months | 59.3 (45.9, 70.4) | 23.1 (7.2, 44.2) |
| 18 months | 51.6 (36.2, 65.0) | 23.1 (7.2, 44.2) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 33 (28.2%) | 36 (37.1%) |
| Censored Patients, n (%) | 84 (71.8%) | 61 (62.9%) |
| Median (95% CI), (Months) [a] | 11.20 (8.44, NE) | 7.00 (3.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0068 | |
| HR (95% CI) [c] | 0.514 (0.315, 0.840) | |
| HR P-Value [c] | 0.0080 | |
| Heterogeneity p-value [d] | 0.7796 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.7 (61.9, 82.4) | 55.0 (42.1, 66.2) |
| 12 months | 49.0 (35.2, 61.5) | 31.4 (12.8, 52.1) |
| 18 months | 44.6 (29.6, 58.5) | 31.4 (12.8, 52.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 30 (25.6%) | 40 (41.2%) |
| Censored Patients, n (%) | 87 (74.4%) | 57 (58.8%) |
| Median (95% CI), (Months) [a] | 14.55 (11.24, NE) | 4.44 (3.19, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0002 | |
| HR (95% CI) [c] | 0.403 (0.245, 0.665) | |
| HR P-Value [c] | 0.0004 | |
| Heterogeneity p-value [d] | 0.0653 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.0 (60.1, 80.9) | 46.0 (32.9, 58.2) |
| 12 months | 62.9 (49.2, 73.8) | 24.5 (10.9, 41.0) |
| 18 months | 46.9 (31.2, 61.2) | 24.5 (10.9, 41.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 25 (21.4%) | 38 (39.2%) |
| Censored Patients, n (%) | 92 (78.6%) | 59 (60.8%) |
| Median (95% CI), (Months) [a] | 20.17 (13.93, NE) | 6.97 (3.19, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0001 | |
| HR (95% CI) [c] | 0.362 (0.212, 0.618) | |
| HR P-Value [c] | 0.0002 | |
| Heterogeneity p-value [d] | 0.0642 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.6 (65.7, 85.8) | 53.6 (40.6, 65.0) |
| 12 months | 65.0 (50.2, 76.5) | 32.6 (18.1, 48.0) |
| 18 months | 51.8 (33.7, 67.1) | 32.6 (18.1, 48.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Patients with event, n (%) | 29 (24.8%) | 21 (21.6%) |
| Censored Patients, n (%) | 88 (75.2%) | 76 (78.4%) |
| Median (95% CI), (Months) [a] | 20.17 (9.76, NE) | 9.72 (8.90, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6543 | |
| HR (95% CI) [c] | 0.877 (0.491, 1.569) | |
| HR P-Value [c] | 0.6585 | |
| Heterogeneity p-value [d] | 0.3989 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.9 (57.7, 79.2) | 74.6 (62.1, 83.5) |
| 12 months | 56.8 (42.1, 69.1) | 43.9 (19.4, 66.1) |
| 18 months | 51.7 (35.1, 65.9) | 43.9 (19.4, 66.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 21 (27.3%) | 22 (25.6%) |
| Censored Patients, n (%) | 56 (72.7%) | 64 (74.4%) |
| Median (95% CI), (Months) [a] | NE (7.03, NE) | 9.17 (4.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3539 | |
| HR (95% CI) [c] | 0.755 (0.413, 1.377) | |
| HR P-Value [c] | 0.3591 | |
| Heterogeneity p-value [d] | 0.4145 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.3 (58.1, 82.3) | 61.6 (46.0, 74.0) |
| 12 months | 52.2 (34.7, 67.1) | 39.5 (17.1, 61.2) |
| 18 months | 52.2 (34.7, 67.1) | NE (NE, NE) |
| 24 months | 52.2 (34.7, 67.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 16 (20.8%) | 24 (27.9%) |
| Censored Patients, n (%) | 61 (79.2%) | 62 (72.1%) |
| Median (95% CI), (Months) [a] | NE (12.45, NE) | 7.16 (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0446 | |
| HR (95% CI) [c] | 0.526 (0.278, 0.997) | |
| HR P-Value [c] | 0.0490 | |
| Heterogeneity p-value [d] | 0.5404 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.8 (62.5, 85.0) | 50.2 (34.2, 64.2) |
| 12 months | 75.8 (62.5, 85.0) | 45.6 (29.0, 60.8) |
| 18 months | 56.2 (28.4, 76.8) | NE (NE, NE) |
| 24 months | 56.2 (28.4, 76.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 18 (23.4%) | 17 (19.8%) |
| Censored Patients, n (%) | 59 (76.6%) | 69 (80.2%) |
| Median (95% CI), (Months) [a] | NE (8.28, NE) | 11.93 (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5962 | |
| HR (95% CI) [c] | 0.836 (0.428, 1.631) | |
| HR P-Value [c] | 0.5987 | |
| Heterogeneity p-value [d] | 0.3110 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.4 (58.9, 83.5) | 73.3 (57.9, 83.8) |
| 12 months | 58.8 (40.7, 73.1) | 45.1 (17.9, 69.1) |
| 18 months | 58.8 (40.7, 73.1) | NE (NE, NE) |
| 24 months | 58.8 (40.7, 73.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 9 (11.7%) | 7 (8.1%) |
| Censored Patients, n (%) | 68 (88.3%) | 79 (91.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9368 | |
| HR (95% CI) [c] | 0.961 (0.354, 2.609) | |
| HR P-Value [c] | 0.9383 | |
| Heterogeneity p-value [d] | 0.6156 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.6 (76.0, 94.8) | 81.9 (64.8, 91.2) |
| 12 months | 74.4 (53.1, 87.1) | 81.9 (64.8, 91.2) |
| 18 months | 74.4 (53.1, 87.1) | NE (NE, NE) |
| 24 months | 74.4 (53.1, 87.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 16 (20.8%) | 18 (20.9%) |
| Censored Patients, n (%) | 61 (79.2%) | 68 (79.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 9.17 (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2889 | |
| HR (95% CI) [c] | 0.695 (0.352, 1.375) | |
| HR P-Value [c] | 0.2962 | |
| Heterogeneity p-value [d] | 0.5947 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.5 (61.9, 84.9) | 66.7 (50.0, 78.9) |
| 12 months | 68.1 (51.1, 80.2) | 47.6 (24.7, 67.5) |
| 18 months | 68.1 (51.1, 80.2) | NE (NE, NE) |
| 24 months | 68.1 (51.1, 80.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 10 (13.0%) | 15 (17.4%) |
| Censored Patients, n (%) | 67 (87.0%) | 71 (82.6%) |
| Median (95% CI), (Months) [a] | NE (20.80, NE) | NE (7.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0675 | |
| HR (95% CI) [c] | 0.466 (0.201, 1.079) | |
| HR P-Value [c] | 0.0748 | |
| Heterogeneity p-value [d] | 0.4679 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 86.9 (74.4, 93.6) | 75.0 (59.7, 85.2) |
| 12 months | 75.3 (52.9, 88.1) | 57.2 (34.1, 74.8) |
| 18 months | 75.3 (52.9, 88.1) | NE (NE, NE) |
| 24 months | 56.4 (19.0, 82.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 30 (39.0%) | 36 (41.9%) |
| Censored Patients, n (%) | 47 (61.0%) | 50 (58.1%) |
| Median (95% CI), (Months) [a] | 9.69 (4.27, NE) | 2.96 (1.77, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0146 | |
| HR (95% CI) [c] | 0.549 (0.335, 0.900) | |
| HR P-Value [c] | 0.0175 | |
| Heterogeneity p-value [d] | 0.2056 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.3 (45.4, 70.7) | 41.4 (27.1, 55.2) |
| 12 months | 41.6 (25.7, 56.9) | 13.6 (3.0, 32.1) |
| 18 months | 37.5 (21.6, 53.3) | NE (NE, NE) |
| 24 months | 37.5 (21.6, 53.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 18 (23.4%) | 14 (16.3%) |
| Censored Patients, n (%) | 59 (76.6%) | 72 (83.7%) |
| Median (95% CI), (Months) [a] | 20.80 (9.89, NE) | 11.93 (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7350 | |
| HR (95% CI) [c] | 0.886 (0.435, 1.802) | |
| HR P-Value [c] | 0.7374 | |
| Heterogeneity p-value [d] | 0.1914 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.7 (54.9, 81.8) | 73.4 (56.3, 84.7) |
| 12 months | 57.4 (37.9, 72.8) | 45.2 (17.8, 69.4) |
| 18 months | 57.4 (37.9, 72.8) | NE (NE, NE) |
| 24 months | 43.0 (16.3, 67.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 18 (23.4%) | 20 (23.3%) |
| Censored Patients, n (%) | 59 (76.6%) | 66 (76.7%) |
| Median (95% CI), (Months) [a] | 14.59 (9.69, NE) | 11.93 (5.82, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0609 | |
| HR (95% CI) [c] | 0.537 (0.278, 1.037) | |
| HR P-Value [c] | 0.0641 | |
| Heterogeneity p-value [d] | 0.6642 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.1 (71.9, 92.4) | 63.9 (47.5, 76.4) |
| 12 months | 55.8 (35.7, 71.9) | 34.1 (7.6, 63.8) |
| 18 months | 43.9 (23.3, 62.9) | NE (NE, NE) |
| 24 months | 43.9 (23.3, 62.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 18 (23.4%) | 27 (31.4%) |
| Censored Patients, n (%) | 59 (76.6%) | 59 (68.6%) |
| Median (95% CI), (Months) [a] | 11.99 (9.89, NE) | 5.82 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0237 | |
| HR (95% CI) [c] | 0.507 (0.278, 0.923) | |
| HR P-Value [c] | 0.0262 | |
| Heterogeneity p-value [d] | 0.5097 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.3 (58.2, 83.6) | 48.3 (33.5, 61.7) |
| 12 months | 47.8 (25.3, 67.3) | 30.2 (11.0, 52.3) |
| 18 months | 41.0 (19.2, 61.8) | NE (NE, NE) |
| 24 months | 41.0 (19.2, 61.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 24 (31.2%) | 28 (32.6%) |
| Censored Patients, n (%) | 53 (68.8%) | 58 (67.4%) |
| Median (95% CI), (Months) [a] | 14.03 (9.69, NE) | 6.67 (4.40, 12.71) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0533 | |
| HR (95% CI) [c] | 0.579 (0.330, 1.016) | |
| HR P-Value [c] | 0.0569 | |
| Heterogeneity p-value [d] | 0.5165 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.9 (56.5, 81.2) | 51.4 (36.0, 64.9) |
| 12 months | 50.8 (32.2, 66.6) | 32.6 (14.1, 52.6) |
| 18 months | 40.6 (22.1, 58.4) | NE (NE, NE) |
| 24 months | 30.5 (11.1, 52.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 22 (28.6%) | 27 (31.4%) |
| Censored Patients, n (%) | 55 (71.4%) | 59 (68.6%) |
| Median (95% CI), (Months) [a] | 13.90 (8.21, NE) | 5.82 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0684 | |
| HR (95% CI) [c] | 0.592 (0.335, 1.048) | |
| HR P-Value [c] | 0.0718 | |
| Heterogeneity p-value [d] | 0.7796 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.6 (60.7, 84.2) | 49.1 (33.4, 63.1) |
| 12 months | 50.0 (32.2, 65.4) | 33.5 (15.5, 52.5) |
| 18 months | 43.8 (24.9, 61.2) | NE (NE, NE) |
| 24 months | 43.8 (24.9, 61.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 24 (31.2%) | 19 (22.1%) |
| Censored Patients, n (%) | 53 (68.8%) | 67 (77.9%) |
| Median (95% CI), (Months) [a] | 14.03 (9.69, NE) | 11.93 (3.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7112 | |
| HR (95% CI) [c] | 0.890 (0.481, 1.646) | |
| HR P-Value [c] | 0.7107 | |
| Heterogeneity p-value [d] | 0.0653 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.6 (52.1, 77.6) | 62.1 (46.2, 74.5) |
| 12 months | 53.4 (35.4, 68.5) | 49.7 (24.2, 70.8) |
| 18 months | 35.6 (16.7, 55.2) | NE (NE, NE) |
| 24 months | 35.6 (16.7, 55.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 22 (28.6%) | 15 (17.4%) |
| Censored Patients, n (%) | 55 (71.4%) | 71 (82.6%) |
| Median (95% CI), (Months) [a] | 20.76 (7.26, NE) | NE (5.68, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8956 | |
| HR (95% CI) [c] | 0.957 (0.484, 1.892) | |
| HR P-Value [c] | 0.9002 | |
| Heterogeneity p-value [d] | 0.0642 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.1 (57.7, 82.3) | 65.7 (47.8, 78.7) |
| 12 months | 58.0 (40.5, 72.1) | 61.0 (42.0, 75.5) |
| 18 months | 58.0 (40.5, 72.1) | NE (NE, NE) |
| 24 months | 23.2 (4.4, 50.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Patients with event, n (%) | 18 (23.4%) | 20 (23.3%) |
| Censored Patients, n (%) | 59 (76.6%) | 66 (76.7%) |
| Median (95% CI), (Months) [a] | 16.66 (9.59, NE) | 8.05 (6.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0848 | |
| HR (95% CI) [c] | 0.560 (0.287, 1.092) | |
| HR P-Value [c] | 0.0890 | |
| Heterogeneity p-value [d] | 0.3989 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.8 (56.6, 83.7) | 69.8 (54.5, 80.8) |
| 12 months | 54.8 (34.7, 71.1) | 37.6 (15.7, 59.6) |
| 18 months | 39.2 (17.6, 60.3) | NE (NE, NE) |
| 24 months | 39.2 (17.6, 60.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 7 (26.9%) | 9 (47.4%) |
| Censored Patients, n (%) | 19 (73.1%) | 10 (52.6%) |
| Median (95% CI), (Months) [a] | NE (4.21, NE) | 4.67 (4.21, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0513 | |
| HR (95% CI) [c] | 0.379 (0.137, 1.047) | |
| HR P-Value [c] | 0.0613 | |
| Heterogeneity p-value [d] | 0.4671 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.5 (48.3, 86.7) | 36.1 (11.5, 61.9) |
| 12 months | 64.4 (37.7, 82.0) | 0.0 (NE, NE) |
| 18 months | 64.4 (37.7, 82.0) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 11 (57.9%) |
| Censored Patients, n (%) | 21 (80.8%) | 8 (42.1%) |
| Median (95% CI), (Months) [a] | NE (7.33, NE) | 4.67 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0016 | |
| HR (95% CI) [c] | 0.204 (0.069, 0.603) | |
| HR P-Value [c] | 0.0040 | |
| Heterogeneity p-value [d] | 0.1210 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.2 (52.6, 91.9) | 35.5 (12.8, 59.3) |
| 12 months | 71.2 (42.5, 87.4) | NE (NE, NE) |
| 18 months | 71.2 (42.5, 87.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 5 (26.3%) |
| Censored Patients, n (%) | 21 (80.8%) | 14 (73.7%) |
| Median (95% CI), (Months) [a] | NE (7.26, NE) | 7.00 (2.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2011 | |
| HR (95% CI) [c] | 0.444 (0.124, 1.592) | |
| HR P-Value [c] | 0.2125 | |
| Heterogeneity p-value [d] | 0.1880 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.1 (56.7, 92.6) | 80.2 (49.6, 93.3) |
| 12 months | 73.0 (44.9, 88.4) | NE (NE, NE) |
| 18 months | 73.0 (44.9, 88.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 1 (3.8%) | 4 (21.1%) |
| Censored Patients, n (%) | 25 (96.2%) | 15 (78.9%) |
| Median (95% CI), (Months) [a] | NE (7.33, NE) | 8.84 (5.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0188 | |
| HR (95% CI) [c] | 0.107 (0.011, 0.991) | |
| HR P-Value [c] | 0.0491 | |
| Heterogeneity p-value [d] | 0.0330 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 76.2 (40.7, 92.1) |
| 12 months | 88.9 (43.3, 98.4) | NE (NE, NE) |
| 18 months | 88.9 (43.3, 98.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 4 (21.1%) |
| Censored Patients, n (%) | 20 (76.9%) | 15 (78.9%) |
| Median (95% CI), (Months) [a] | NE (5.72, NE) | NE (1.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9072 | |
| HR (95% CI) [c] | 0.926 (0.261, 3.287) | |
| HR P-Value [c] | 0.9059 | |
| Heterogeneity p-value [d] | 0.9467 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.8 (43.3, 85.7) | 74.5 (45.0, 89.7) |
| 12 months | 69.8 (43.3, 85.7) | NE (NE, NE) |
| 18 months | 69.8 (43.3, 85.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 4 (21.1%) |
| Censored Patients, n (%) | 20 (76.9%) | 15 (78.9%) |
| Median (95% CI), (Months) [a] | NE (7.33, NE) | 8.84 (2.92, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4800 | |
| HR (95% CI) [c] | 0.619 (0.163, 2.361) | |
| HR P-Value [c] | 0.4830 | |
| Heterogeneity p-value [d] | 0.8569 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.9 (56.0, 92.5) | 79.4 (48.3, 93.0) |
| 12 months | 72.8 (44.5, 88.3) | NE (NE, NE) |
| 18 months | 60.7 (28.2, 82.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 10 (38.5%) | 10 (52.6%) |
| Censored Patients, n (%) | 16 (61.5%) | 9 (47.4%) |
| Median (95% CI), (Months) [a] | 11.10 (4.21, NE) | 5.68 (1.45, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0742 | |
| HR (95% CI) [c] | 0.447 (0.180, 1.110) | |
| HR P-Value [c] | 0.0828 | |
| Heterogeneity p-value [d] | 0.7151 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.2 (30.8, 74.1) | 40.0 (12.9, 66.4) |
| 12 months | 44.1 (18.3, 67.4) | 0.0 (NE, NE) |
| 18 months | 44.1 (18.3, 67.4) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 4 (15.4%) | 8 (42.1%) |
| Censored Patients, n (%) | 22 (84.6%) | 11 (57.9%) |
| Median (95% CI), (Months) [a] | NE (9.76, NE) | 6.14 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0020 | |
| HR (95% CI) [c] | 0.123 (0.026, 0.590) | |
| HR P-Value [c] | 0.0088 | |
| Heterogeneity p-value [d] | 0.2669 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.6 (51.2, 95.9) | 55.2 (27.7, 76.0) |
| 12 months | 70.5 (30.6, 90.2) | NE (NE, NE) |
| 18 months | 56.4 (18.9, 82.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 3 (11.5%) | 7 (36.8%) |
| Censored Patients, n (%) | 23 (88.5%) | 12 (63.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0114 | |
| HR (95% CI) [c] | 0.193 (0.047, 0.784) | |
| HR P-Value [c] | 0.0215 | |
| Heterogeneity p-value [d] | 0.1972 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.4 (66.8, 97.5) | 52.9 (24.5, 75.0) |
| 12 months | 81.4 (50.1, 94.1) | NE (NE, NE) |
| 18 months | 81.4 (50.1, 94.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 5 (26.3%) |
| Censored Patients, n (%) | 21 (80.8%) | 14 (73.7%) |
| | | |
| Median (95% CI), (Months) [a] | NE (5.72, NE) | NE (4.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3579 | |
| HR (95% CI) [c] | 0.565 (0.162, 1.967) | |
| HR P-Value [c] | 0.3694 | |
| Heterogeneity p-value [d] | 0.3201 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.0 (47.4, 88.6) | 56.3 (21.4, 80.7) |
| 12 months | 74.0 (47.4, 88.6) | NE (NE, NE) |
| 18 months | 74.0 (47.4, 88.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 5 (19.2%) | 10 (52.6%) |
| Censored Patients, n (%) | 21 (80.8%) | 9 (47.4%) |
| Median (95% CI), (Months) [a] | NE (8.34, NE) | 5.16 (1.51, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0035 | |
| HR (95% CI) [c] | 0.218 (0.072, 0.662) | |
| HR P-Value [c] | 0.0071 | |
| Heterogeneity p-value [d] | 0.3632 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.5 (55.4, 92.4) | 44.8 (18.1, 68.6) |
| 12 months | 70.4 (39.6, 87.6) | 0.0 (NE, NE) |
| 18 months | 70.4 (39.6, 87.6) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 11 (42.3%) | 10 (52.6%) |
| Censored Patients, n (%) | 15 (57.7%) | 9 (47.4%) |
| Median (95% CI), (Months) [a] | 8.34 (4.90, NE) | 2.83 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0944 | |
| HR (95% CI) [c] | 0.482 (0.201, 1.155) | |
| HR P-Value [c] | 0.1017 | |
| Heterogeneity p-value [d] | 0.5081 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.5 (43.0, 83.3) | 40.7 (16.5, 63.9) |
| 12 months | 40.5 (17.7, 62.4) | NE (NE, NE) |
| 18 months | 40.5 (17.7, 62.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 7 (26.9%) | 10 (52.6%) |
| Censored Patients, n (%) | 19 (73.1%) | 9 (47.4%) |
| Median (95% CI), (Months) [a] | NE (4.90, NE) | 4.24 (1.58, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0076 | |
| HR (95% CI) [c] | 0.267 (0.094, 0.757) | |
| HR P-Value [c] | 0.0130 | |
| Heterogeneity p-value [d] | 0.5585 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.5 (48.4, 88.8) | 27.7 (6.9, 54.0) |
| 12 months | 63.9 (33.3, 83.3) | 0.0 (NE, NE) |
| 18 months | 53.2 (22.7, 76.5) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 11 (42.3%) | 10 (52.6%) |
| Censored Patients, n (%) | 15 (57.7%) | 9 (47.4%) |
| Median (95% CI), (Months) [a] | 7.26 (4.21, NE) | 5.16 (1.58, 6.97) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1873 | |
| HR (95% CI) [c] | 0.566 (0.234, 1.372) | |
| HR P-Value [c] | 0.2079 | |
| Heterogeneity p-value [d] | 0.8703 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.4 (32.0, 75.0) | 32.6 (9.3, 58.9) |
| 12 months | 39.5 (15.6, 62.9) | NE (NE, NE) |
| 18 months | 39.5 (15.6, 62.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (23.1%) | 3 (15.8%) |
| Censored Patients, n (%) | 20 (76.9%) | 16 (84.2%) |
| Median (95% CI), (Months) [a] | 16.62 (7.95, 16.62) | 9.72 (4.21, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5566 | |
| HR (95% CI) [c] | 0.631 (0.135, 2.959) | |
| HR P-Value [c] | 0.5596 | |
| Heterogeneity p-value [d] | 0.4819 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.1 (55.9, 94.3) | 84.4 (49.3, 96.0) |
| 12 months | 58.2 (22.2, 82.2) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 31 (26.1%) | 26 (23.4%) |
| Censored Patients, n (%) | 88 (73.9%) | 85 (76.6%) |
| Median (95% CI), (Months) [a] | 20.17 (10.18, NE) | NE (8.90, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2756 | |
| HR (95% CI) [c] | 0.744 (0.436, 1.270) | |
| HR P-Value [c] | 0.2787 | |
| Heterogeneity p-value [d] | 0.4671 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.1 (60.5, 80.8) | 64.3 (51.2, 74.8) |
| 12 months | 57.8 (44.3, 69.2) | 50.7 (30.4, 67.8) |
| 18 months | 54.9 (40.9, 66.9) | 50.7 (30.4, 67.8) |
| 24 months | 45.8 (25.8, 63.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 29 (24.4%) | 29 (26.1%) |
| Censored Patients, n (%) | 90 (75.6%) | 82 (73.9%) |
| Median (95% CI), (Months) [a] | 17.05 (13.83, NE) | 8.90 (5.78, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0396 | |
| HR (95% CI) [c] | 0.570 (0.331, 0.981) | |
| HR P-Value [c] | 0.0424 | |
| Heterogeneity p-value [d] | 0.1210 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.7 (65.6, 84.6) | 58.7 (45.0, 70.1) |
| 12 months | 68.3 (55.1, 78.3) | 48.3 (30.4, 64.2) |
| 18 months | 45.5 (28.0, 61.4) | 48.3 (30.4, 64.2) |
| 24 months | 45.5 (28.0, 61.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 26 (21.8%) | 21 (18.9%) |
| Censored Patients, n (%) | 93 (78.2%) | 90 (81.1%) |
| Median (95% CI), (Months) [a] | NE (15.11, NE) | 14.13 (11.50, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6341 | |
| HR (95% CI) [c] | 0.869 (0.483, 1.562) | |
| HR P-Value [c] | 0.6384 | |
| Heterogeneity p-value [d] | 0.1880 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.2 (64.1, 83.3) | 72.6 (59.7, 81.9) |
| 12 months | 64.8 (51.6, 75.3) | 55.8 (27.1, 77.1) |
| 18 months | 59.8 (43.9, 72.5) | 37.2 (8.0, 68.0) |
| 24 months | 59.8 (43.9, 72.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 17 (14.3%) | 9 (8.1%) |
| Censored Patients, n (%) | 102 (85.7%) | 102 (91.9%) |
| Median (95% CI), (Months) [a] | NE (18.10, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8565 | |
| HR (95% CI) [c] | 1.081 (0.466, 2.505) | |
| HR P-Value [c] | 0.8559 | |
| Heterogeneity p-value [d] | 0.0330 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.7 (79.1, 94.1) | 86.8 (74.4, 93.4) |
| 12 months | 74.6 (60.1, 84.5) | 80.1 (59.6, 90.9) |
| 18 months | 69.6 (52.3, 81.7) | 80.1 (59.6, 90.9) |
| 24 months | 62.7 (41.5, 78.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 19 (16.0%) | 24 (21.6%) |
| Censored Patients, n (%) | 100 (84.0%) | 87 (78.4%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (6.74, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0173 | |
| HR (95% CI) [c] | 0.476 (0.255, 0.890) | |
| HR P-Value [c] | 0.0201 | |
| Heterogeneity p-value [d] | 0.9467 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.1 (74.0, 90.5) | 64.3 (50.1, 75.4) |
| 12 months | 74.6 (61.1, 84.0) | 53.7 (34.1, 69.8) |
| 18 months | 64.6 (45.7, 78.3) | 53.7 (34.1, 69.8) |
| 24 months | 64.6 (45.7, 78.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 22 (18.5%) | 24 (21.6%) |
| Censored Patients, n (%) | 97 (81.5%) | 87 (78.4%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (8.05, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0504 | |
| HR (95% CI) [c] | 0.552 (0.302, 1.010) | |
| HR P-Value [c] | 0.0540 | |
| Heterogeneity p-value [d] | 0.8569 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.7 (72.4, 89.4) | 67.8 (54.3, 78.0) |
| 12 months | 70.0 (56.4, 80.1) | 54.4 (35.4, 69.9) |
| 18 months | 64.6 (47.7, 77.3) | 54.4 (35.4, 69.9) |
| 24 months | 55.4 (32.5, 73.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 50 (42.0%) | 40 (36.0%) |
| Censored Patients, n (%) | 69 (58.0%) | 71 (64.0%) |
| Median (95% CI), (Months) [a] | 10.12 (5.82, 16.53) | 6.14 (2.96, 11.50) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2403 | |
| HR (95% CI) [c] | 0.777 (0.504, 1.198) | |
| HR P-Value [c] | 0.2531 | |
| Heterogeneity p-value [d] | 0.7151 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.5 (46.3, 67.2) | 52.3 (39.9, 63.4) |
| 12 months | 42.1 (30.4, 53.4) | 22.4 (5.7, 45.9) |
| 18 months | 33.3 (21.0, 46.0) | 22.4 (5.7, 45.9) |
| 24 months | 27.7 (14.5, 42.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 19 (16.0%) | 17 (15.3%) |
| Censored Patients, n (%) | 100 (84.0%) | 94 (84.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 11.50 (8.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1969 | |
| HR (95% CI) [c] | 0.646 (0.330, 1.265) | |
| HR P-Value [c] | 0.2027 | |
| Heterogeneity p-value [d] | 0.2669 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.5 (72.5, 90.4) | 77.0 (62.8, 86.4) |
| 12 months | 69.9 (55.5, 80.4) | 47.2 (20.3, 70.2) |
| 18 months | 66.0 (50.2, 77.9) | 47.2 (20.3, 70.2) |
| 24 months | 66.0 (50.2, 77.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 26 (21.8%) | 26 (23.4%) |
| Censored Patients, n (%) | 93 (78.2%) | 85 (76.6%) |
| Median (95% CI), (Months) [a] | NE (11.99, NE) | NE (8.90, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0773 | |
| HR (95% CI) [c] | 0.605 (0.344, 1.062) | |
| HR P-Value [c] | 0.0802 | |
| Heterogeneity p-value [d] | 0.1972 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.4 (69.8, 87.6) | 67.6 (54.8, 77.5) |
| 12 months | 63.6 (49.5, 74.7) | 58.4 (41.1, 72.2) |
| 18 months | 56.5 (40.7, 69.5) | 58.4 (41.1, 72.2) |
| 24 months | 56.5 (40.7, 69.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 30 (25.2%) | 31 (27.9%) |
| Censored Patients, n (%) | 89 (74.8%) | 80 (72.1%) |
| Median (95% CI), (Months) [a] | 19.15 (10.97, NE) | 10.35 (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0344 | |
| HR (95% CI) [c] | 0.574 (0.341, 0.967) | |
| HR P-Value [c] | 0.0370 | |
| Heterogeneity p-value [d] | 0.3201 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.4 (60.7, 81.2) | 54.0 (40.5, 65.7) |
| 12 months | 56.3 (42.0, 68.3) | 44.1 (26.5, 60.3) |
| 18 months | 56.3 (42.0, 68.3) | 44.1 (26.5, 60.3) |
| 24 months | 37.5 (16.0, 59.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 36 (30.3%) | 36 (32.4%) |
| Censored Patients, n (%) | 83 (69.7%) | 75 (67.6%) |
| Median (95% CI), (Months) [a] | 14.55 (10.45, NE) | 8.90 (4.63, 12.71) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0170 | |
| HR (95% CI) [c] | 0.558 (0.343, 0.908) | |
| HR P-Value [c] | 0.0188 | |
| Heterogeneity p-value [d] | 0.3632 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.0 (61.0, 80.4) | 55.8 (42.8, 67.0) |
| 12 months | 57.4 (44.1, 68.6) | 37.0 (20.2, 54.0) |
| 18 months | 45.0 (30.1, 58.7) | 27.8 (10.2, 48.7) |
| 24 months | 38.5 (21.9, 54.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 30 (25.2%) | 29 (26.1%) |
| Censored Patients, n (%) | 89 (74.8%) | 82 (73.9%) |
| Median (95% CI), (Months) [a] | 16.85 (9.07, NE) | 9.72 (5.82, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1281 | |
| HR (95% CI) [c] | 0.668 (0.394, 1.130) | |
| HR P-Value [c] | 0.1323 | |
| Heterogeneity p-value [d] | 0.5081 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.0 (69.2, 87.3) | 62.9 (49.8, 73.4) |
| 12 months | 54.2 (40.2, 66.3) | 47.9 (28.5, 64.9) |
| 18 months | 49.3 (33.6, 63.2) | 47.9 (28.5, 64.9) |
| 24 months | 49.3 (33.6, 63.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 34 (28.6%) | 33 (29.7%) |
| Censored Patients, n (%) | 85 (71.4%) | 78 (70.3%) |
| Median (95% CI), (Months) [a] | 14.06 (11.99, NE) | 8.84 (4.27, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0311 | |
| HR (95% CI) [c] | 0.581 (0.353, 0.958) | |
| HR P-Value [c] | 0.0332 | |
| Heterogeneity p-value [d] | 0.5585 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.8 (62.6, 82.1) | 58.2 (45.3, 69.1) |
| 12 months | 61.2 (47.7, 72.2) | 41.4 (24.8, 57.2) |
| 18 months | 38.9 (23.5, 54.0) | 41.4 (24.8, 57.2) |
| 24 months | 38.9 (23.5, 54.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 22 (18.5%) | 28 (25.2%) |
| Censored Patients, n (%) | 97 (81.5%) | 83 (74.8%) |
| Median (95% CI), (Months) [a] | 20.76 (15.34, NE) | 8.84 (6.70, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0021 | |
| HR (95% CI) [c] | 0.402 (0.221, 0.732) | |
| HR P-Value [c] | 0.0029 | |
| Heterogeneity p-value [d] | 0.8703 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.1 (74.6, 91.5) | 64.3 (51.1, 74.8) |
| 12 months | 70.2 (55.9, 80.6) | 47.5 (29.7, 63.4) |
| 18 months | 60.8 (42.9, 74.7) | 47.5 (29.7, 63.4) |
| 24 months | 38.0 (13.1, 63.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Patients with event, n (%) | 27 (22.7%) | 28 (25.2%) |
| Censored Patients, n (%) | 92 (77.3%) | 83 (74.8%) |
| Median (95% CI), (Months) [a] | 20.17 (11.93, NE) | 9.40 (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0721 | |
| HR (95% CI) [c] | 0.608 (0.351, 1.052) | |
| HR P-Value [c] | 0.0754 | |
| Heterogeneity p-value [d] | 0.4819 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.4 (60.4, 81.4) | 69.1 (56.7, 78.6) |
| 12 months | 58.2 (43.6, 70.2) | 34.7 (12.7, 58.1) |
| 18 months | 58.2 (43.6, 70.2) | 34.7 (12.7, 58.1) |
| 24 months | 49.9 (30.1, 66.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 5 (23.8%) |
| Censored Patients, n (%) | 17 (85.0%) | 16 (76.2%) |
| | | |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | 3.15 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1919 | |
| HR (95% CI) [c] | 0.384 (0.088, 1.671) | |
| HR P-Value [c] | 0.2021 | |
| Heterogeneity p-value [d] | 0.4671 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.2 (42.7, 91.7) | 20.0 (1.0, 57.3) |
| 12 months | 76.2 (42.7, 91.7) | NE (NE, NE) |
| 18 months | 76.2 (42.7, 91.7) | NE (NE, NE) |
| 24 months | 76.2 (42.7, 91.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 5 (23.8%) |
| Censored Patients, n (%) | 14 (70.0%) | 16 (76.2%) |
| Median (95% CI), (Months) [a] | 13.93 (1.61, NE) | 3.15 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4467 | |
| HR (95% CI) [c] | 0.610 (0.174, 2.142) | |
| HR P-Value [c] | 0.4409 | |
| Heterogeneity p-value [d] | 0.1210 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.2 (28.8, 81.3) | 20.0 (1.0, 57.3) |
| 12 months | 60.2 (28.8, 81.3) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 6 (28.6%) |
| Censored Patients, n (%) | 17 (85.0%) | 15 (71.4%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | 2.56 (1.51, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0213 | |
| HR (95% CI) [c] | 0.206 (0.048, 0.883) | |
| HR P-Value [c] | 0.0334 | |
| Heterogeneity p-value [d] | 0.1880 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.1 (44.2, 92.1) | 0.0 (NE, NE) |
| 12 months | 77.1 (44.2, 92.1) | 0.0 (NE, NE) |
| 18 months | 77.1 (44.2, 92.1) | 0.0 (NE, NE) |
| 24 months | 77.1 (44.2, 92.1) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 6 (28.6%) |
| Censored Patients, n (%) | 17 (85.0%) | 15 (71.4%) |
| Median (95% CI), (Months) [a] | NE (10.09, NE) | 2.83 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0211 | |
| HR (95% CI) [c] | 0.180 (0.036, 0.909) | |
| HR P-Value [c] | 0.0380 | |
| Heterogeneity p-value [d] | 0.0330 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.1 (52.3, 96.1) | 27.0 (4.1, 58.4) |
| 12 months | 68.1 (25.1, 89.9) | NE (NE, NE) |
| 18 months | 68.1 (25.1, 89.9) | NE (NE, NE) |
| 24 months | 68.1 (25.1, 89.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 17 (85.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | NE (5.75, NE) | NE (1.81, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5470 | |
| HR (95% CI) [c] | 0.608 (0.118, 3.121) | |
| HR P-Value [c] | 0.5507 | |
| Heterogeneity p-value [d] | 0.9467 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.5 (17.5, 88.8) | 55.6 (14.1, 83.8) |
| 12 months | 63.5 (17.5, 88.8) | NE (NE, NE) |
| 18 months | 63.5 (17.5, 88.8) | NE (NE, NE) |
| 24 months | 63.5 (17.5, 88.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (25.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 15 (75.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | 12.52 (1.58, NE) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8441 | |
| HR (95% CI) [c] | 0.834 (0.168, 4.151) | |
| HR P-Value [c] | 0.8246 | |
| Heterogeneity p-value [d] | 0.8569 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.7 (36.3, 90.4) | 56.3 (14.7, 84.2) |
| 12 months | 72.7 (36.3, 90.4) | NE (NE, NE) |
| 18 months | 24.2 (1.1, 64.1) | NE (NE, NE) |
| 24 months | 24.2 (1.1, 64.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 8 (40.0%) | 8 (38.1%) |
| Censored Patients, n (%) | 12 (60.0%) | 13 (61.9%) |
| Median (95% CI), (Months) [a] | 4.86 (1.48, NE) | 2.56 (1.64, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4648 | |
| HR (95% CI) [c] | 0.687 (0.251, 1.881) | |
| HR P-Value [c] | 0.4653 | |
| Heterogeneity p-value [d] | 0.7151 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.8 (12.4, 68.1) | 12.0 (0.7, 40.8) |
| 12 months | 27.2 (4.8, 57.2) | NE (NE, NE) |
| 18 months | 27.2 (4.8, 57.2) | NE (NE, NE) |
| 24 months | 27.2 (4.8, 57.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 14 (70.0%) | 18 (85.7%) |
| | | |
| Median (95% CI), (Months) [a] | 5.13 (4.37, NE) | 7.06 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9879 | |
| HR (95% CI) [c] | 0.989 (0.236, 4.150) | |
| HR P-Value [c] | 0.9879 | |
| Heterogeneity p-value [d] | 0.2669 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.7 (16.5, 76.2) | 72.9 (27.6, 92.5) |
| 12 months | 49.7 (16.5, 76.2) | NE (NE, NE) |
| 18 months | 33.1 (5.9, 64.9) | NE (NE, NE) |
| 24 months | 33.1 (5.9, 64.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 2 (10.0%) | 3 (14.3%) |
| Censored Patients, n (%) | 18 (90.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | NE (17.71, NE) | 4.93 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1326 | |
| HR (95% CI) [c] | 0.206 (0.021, 2.000) | |
| HR P-Value [c] | 0.1730 | |
| Heterogeneity p-value [d] | 0.1972 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.9 (59.1, 99.0) | 43.8 (6.0, 78.5) |
| 12 months | 92.9 (59.1, 99.0) | NE (NE, NE) |
| 18 months | 61.9 (7.3, 91.6) | NE (NE, NE) |
| 24 months | 61.9 (7.3, 91.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (25.0%) | 8 (38.1%) |
| Censored Patients, n (%) | 15 (75.0%) | 13 (61.9%) |
| Median (95% CI), (Months) [a] | 8.38 (1.58, NE) | 2.10 (1.64, 3.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0332 | |
| HR (95% CI) [c] | 0.277 (0.080, 0.952) | |
| HR P-Value [c] | 0.0416 | |
| Heterogeneity p-value [d] | 0.3201 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.5 (34.1, 86.6) | 11.1 (0.6, 38.8) |
| 12 months | 45.0 (8.7, 77.0) | NE (NE, NE) |
| 18 months | 45.0 (8.7, 77.0) | NE (NE, NE) |
| 24 months | 45.0 (8.7, 77.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 4 (19.0%) |
| Censored Patients, n (%) | 14 (70.0%) | 17 (81.0%) |
| | | |
| Median (95% CI), (Months) [a] | 7.23 (1.58, NE) | 3.48 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6524 | |
| HR (95% CI) [c] | 0.748 (0.202, 2.776) | |
| HR P-Value [c] | 0.6643 | |
| Heterogeneity p-value [d] | 0.3632 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.4 (21.2, 79.9) | 29.2 (1.4, 70.2) |
| 12 months | 41.6 (11.2, 70.4) | NE (NE, NE) |
| 18 months | 41.6 (11.2, 70.4) | NE (NE, NE) |
| 24 months | 41.6 (11.2, 70.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 7 (33.3%) |
| Censored Patients, n (%) | 14 (70.0%) | 14 (66.7%) |
| Median (95% CI), (Months) [a] | 8.54 (3.48, NE) | 3.48 (0.20, 7.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0121 | |
| HR (95% CI) [c] | 0.220 (0.062, 0.786) | |
| HR P-Value [c] | 0.0198 | |
| Heterogeneity p-value [d] | 0.5081 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.1 (31.6, 86.2) | 16.9 (0.8, 51.5) |
| 12 months | 39.7 (10.3, 68.7) | 0.0 (NE, NE) |
| 18 months | 39.7 (10.3, 68.7) | 0.0 (NE, NE) |
| 24 months | 39.7 (10.3, 68.7) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 4 (20.0%) | 4 (19.0%) |
| Censored Patients, n (%) | 16 (80.0%) | 17 (81.0%) |
| Median (95% CI), (Months) [a] | NE (1.58, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5800 | |
| HR (95% CI) [c] | 0.674 (0.165, 2.748) | |
| HR P-Value [c] | 0.5822 | |
| Heterogeneity p-value [d] | 0.5585 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.3 (37.0, 87.3) | 50.0 (13.7, 78.5) |
| 12 months | 69.3 (37.0, 87.3) | NE (NE, NE) |
| 18 months | 69.3 (37.0, 87.3) | NE (NE, NE) |
| 24 months | 69.3 (37.0, 87.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (30.0%) | 5 (23.8%) |
| Censored Patients, n (%) | 14 (70.0%) | 16 (76.2%) |
| Median (95% CI), (Months) [a] | 5.13 (3.09, NE) | 7.06 (1.45, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4556 | |
| HR (95% CI) [c] | 0.617 (0.178, 2.143) | |
| HR P-Value [c] | 0.4477 | |
| Heterogeneity p-value [d] | 0.8703 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.7 (14.8, 77.3) | 51.4 (16.0, 78.6) |
| 12 months | 49.7 (14.8, 77.3) | NE (NE, NE) |
| 18 months | 33.1 (5.5, 65.6) | NE (NE, NE) |
| 24 months | 33.1 (5.5, 65.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (25.0%) | 2 (9.5%) |
| Censored Patients, n (%) | 15 (75.0%) | 19 (90.5%) |
| | | |
| Median (95% CI), (Months) [a] | 16.76 (2.89, NE) | NE (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6552 | |
| HR (95% CI) [c] | 0.661 (0.106, 4.123) | |
| HR P-Value [c] | 0.6572 | |
| Heterogeneity p-value [d] | 0.4819 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.4 (28.5, 89.1) | NE (NE, NE) |
| 12 months | 51.3 (13.8, 79.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 13 (40.6%) |
| Censored Patients, n (%) | 23 (74.2%) | 19 (59.4%) |
| | | |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | 6.67 (1.77, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1388 | |
| HR (95% CI) [c] | 0.520 (0.214, 1.263) | |
| HR P-Value [c] | 0.1486 | |
| Heterogeneity p-value [d] | 0.4671 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.0 (35.4, 81.4) | 59.3 (37.4, 75.7) |
| 12 months | 54.0 (26.0, 75.4) | 0.0 (NE, NE) |
| 18 months | 54.0 (26.0, 75.4) | 0.0 (NE, NE) |
| 24 months | 54.0 (26.0, 75.4) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 7 (22.6%) | 6 (18.8%) |
| Censored Patients, n (%) | 24 (77.4%) | 26 (81.3%) |
| Median (95% CI), (Months) [a] | 12.45 (2.96, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8497 | |
| HR (95% CI) [c] | 1.114 (0.373, 3.331) | |
| HR P-Value [c] | 0.8466 | |
| Heterogeneity p-value [d] | 0.1210 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.0 (49.3, 86.9) | 73.9 (50.7, 87.4) |
| 12 months | 73.0 (49.3, 86.9) | 73.9 (50.7, 87.4) |
| 18 months | 36.5 (1.7, 77.9) | NE (NE, NE) |
| 24 months | 36.5 (1.7, 77.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 6 (19.4%) | 11 (34.4%) |
| Censored Patients, n (%) | 25 (80.6%) | 21 (65.6%) |
| Median (95% CI), (Months) [a] | NE (5.78, NE) | 6.67 (4.17, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3872 | |
| HR (95% CI) [c] | 0.645 (0.236, 1.757) | |
| HR P-Value [c] | 0.3908 | |
| Heterogeneity p-value [d] | 0.1880 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 69.7 (39.1, 87.1) | 61.1 (35.5, 79.1) |
| 12 months | 59.8 (28.5, 81.0) | 16.3 (1.0, 49.1) |
| 18 months | 59.8 (28.5, 81.0) | NE (NE, NE) |
| 24 months | 59.8 (28.5, 81.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 2 (6.3%) |
| Censored Patients, n (%) | 28 (90.3%) | 30 (93.8%) |
| Median (95% CI), (Months) [a] | NE (5.72, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6161 | |
| HR (95% CI) [c] | 1.575 (0.263, 9.451) | |
| HR P-Value [c] | 0.6191 | |
| Heterogeneity p-value [d] | 0.0330 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.3 (42.5, 93.2) | 88.9 (62.4, 97.1) |
| 12 months | 78.3 (42.5, 93.2) | 88.9 (62.4, 97.1) |
| 18 months | 78.3 (42.5, 93.2) | NE (NE, NE) |
| 24 months | 78.3 (42.5, 93.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 7 (22.6%) | 10 (31.3%) |
| Censored Patients, n (%) | 24 (77.4%) | 22 (68.8%) |
| | | |
| Median (95% CI), (Months) [a] | NE (2.96, NE) | 6.67 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3833 | |
| HR (95% CI) [c] | 0.651 (0.245, 1.728) | |
| HR P-Value [c] | 0.3891 | |
| Heterogeneity p-value [d] | 0.9467 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.6 (48.5, 86.8) | 64.5 (40.8, 80.7) |
| 12 months | 63.5 (35.9, 81.8) | 24.2 (1.5, 61.7) |
| 18 months | 63.5 (35.9, 81.8) | NE (NE, NE) |
| 24 months | 63.5 (35.9, 81.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 3 (9.7%) | 6 (18.8%) |
| Censored Patients, n (%) | 28 (90.3%) | 26 (81.3%) |
| Median (95% CI), (Months) [a] | 20.80 (20.80, NE) | NE (7.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1487 | |
| HR (95% CI) [c] | 0.330 (0.067, 1.640) | |
| HR P-Value [c] | 0.1754 | |
| Heterogeneity p-value [d] | 0.8569 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.7 (70.6, 97.8) | 77.6 (53.9, 90.1) |
| 12 months | 91.7 (70.6, 97.8) | 58.2 (18.9, 83.9) |
| 18 months | 91.7 (70.6, 97.8) | NE (NE, NE) |
| 24 months | 45.8 (1.0, 87.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 11 (35.5%) | 16 (50.0%) |
| Censored Patients, n (%) | 20 (64.5%) | 16 (50.0%) |
| Median (95% CI), (Months) [a] | 12.45 (2.10, NE) | 4.17 (1.77, 7.39) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1747 | |
| HR (95% CI) [c] | 0.591 (0.274, 1.277) | |
| HR P-Value [c] | 0.1809 | |
| Heterogeneity p-value [d] | 0.7151 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.0 (30.0, 73.0) | 46.9 (26.4, 65.0) |
| 12 months | 54.0 (30.0, 73.0) | 18.8 (3.6, 43.2) |
| 18 months | 27.0 (1.9, 64.8) | NE (NE, NE) |
| 24 months | 27.0 (1.9, 64.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 8 (25.0%) |
| Censored Patients, n (%) | 23 (74.2%) | 24 (75.0%) |
| | | |
| Median (95% CI), (Months) [a] | 20.80 (4.96, NE) | 11.93 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6661 | |
| HR (95% CI) [c] | 0.797 (0.286, 2.227) | |
| HR P-Value [c] | 0.6659 | |
| Heterogeneity p-value [d] | 0.2669 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.4 (44.7, 85.8) | 68.9 (43.1, 84.8) |
| 12 months | 61.6 (33.7, 80.5) | 34.4 (6.1, 66.6) |
| 18 months | 61.6 (33.7, 80.5) | NE (NE, NE) |
| 24 months | 30.8 (1.8, 70.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 8 (25.0%) |
| Censored Patients, n (%) | 23 (74.2%) | 24 (75.0%) |
| Median (95% CI), (Months) [a] | 7.79 (5.72, NE) | 11.07 (5.19, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8062 | |
| HR (95% CI) [c] | 0.886 (0.328, 2.390) | |
| HR P-Value [c] | 0.8109 | |
| Heterogeneity p-value [d] | 0.1972 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.8 (41.1, 85.4) | 70.9 (43.5, 86.8) |
| 12 months | 44.2 (14.0, 71.3) | 0.0 (NE, NE) |
| 18 months | 44.2 (14.0, 71.3) | 0.0 (NE, NE) |
| 24 months | 44.2 (14.0, 71.3) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 12 (38.7%) | 16 (50.0%) |
| Censored Patients, n (%) | 19 (61.3%) | 16 (50.0%) |
| Median (95% CI), (Months) [a] | 4.27 (1.64, 12.45) | 4.40 (2.79, 11.07) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7400 | |
| HR (95% CI) [c] | 0.887 (0.410, 1.919) | |
| HR P-Value [c] | 0.7608 | |
| Heterogeneity p-value [d] | 0.3201 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.1 (17.2, 62.1) | 44.2 (23.6, 63.0) |
| 12 months | 40.1 (17.2, 62.1) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 9 (29.0%) | 14 (43.8%) |
| Censored Patients, n (%) | 22 (71.0%) | 18 (56.3%) |
| | | |
| Median (95% CI), (Months) [a] | 6.97 (5.55, NE) | 6.67 (1.77, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0893 | |
| HR (95% CI) [c] | 0.478 (0.199, 1.146) | |
| HR P-Value [c] | 0.0980 | |
| Heterogeneity p-value [d] | 0.3632 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.8 (31.2, 79.7) | 50.4 (29.3, 68.3) |
| 12 months | 47.8 (18.6, 72.4) | 16.8 (1.1, 49.3) |
| 18 months | 47.8 (18.6, 72.4) | NE (NE, NE) |
| 24 months | 23.9 (1.6, 60.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 17 (53.1%) |
| Censored Patients, n (%) | 23 (74.2%) | 15 (46.9%) |
| Median (95% CI), (Months) [a] | 13.90 (4.83, NE) | 4.14 (1.97, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0221 | |
| HR (95% CI) [c] | 0.390 (0.167, 0.908) | |
| HR P-Value [c] | 0.0291 | |
| Heterogeneity p-value [d] | 0.5081 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.3 (34.4, 81.1) | 37.8 (17.8, 57.7) |
| 12 months | 62.3 (34.4, 81.1) | 9.4 (0.7, 33.0) |
| 18 months | 31.2 (1.8, 71.2) | NE (NE, NE) |
| 24 months | 31.2 (1.8, 71.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 9 (29.0%) | 12 (37.5%) |
| Censored Patients, n (%) | 22 (71.0%) | 20 (62.5%) |
| Median (95% CI), (Months) [a] | NE (2.10, NE) | 11.93 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5733 | |
| HR (95% CI) [c] | 0.779 (0.327, 1.854) | |
| HR P-Value [c] | 0.5723 | |
| Heterogeneity p-value [d] | 0.5585 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.1 (25.8, 71.7) | 52.0 (28.7, 70.9) |
| 12 months | 51.1 (25.8, 71.7) | 34.6 (8.3, 63.7) |
| 18 months | 51.1 (25.8, 71.7) | NE (NE, NE) |
| 24 months | 51.1 (25.8, 71.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 8 (25.8%) | 10 (31.3%) |
| Censored Patients, n (%) | 23 (74.2%) | 22 (68.8%) |
| Median (95% CI), (Months) [a] | 20.80 (2.07, 20.83) | 6.67 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3745 | |
| HR (95% CI) [c] | 0.639 (0.232, 1.763) | |
| HR P-Value [c] | 0.3870 | |
| Heterogeneity p-value [d] | 0.8703 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.1 (49.5, 87.0) | 61.2 (38.5, 77.7) |
| 12 months | 73.1 (49.5, 87.0) | 48.9 (21.5, 71.7) |
| 18 months | 73.1 (49.5, 87.0) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.2.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Patients with event, n (%) | 9 (29.0%) | 8 (25.0%) |
| Censored Patients, n (%) | 22 (71.0%) | 24 (75.0%) |
| Median (95% CI), (Months) [a] | 16.66 (2.83, NE) | 7.39 (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7548 | |
| HR (95% CI) [c] | 1.177 (0.441, 3.141) | |
| HR P-Value [c] | 0.7447 | |
| Heterogeneity p-value [d] | 0.4819 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.4 (30.7, 75.8) | 76.7 (55.3, 88.8) |
| 12 months | 56.4 (30.7, 75.8) | 46.0 (13.1, 74.4) |
| 18 months | 28.2 (1.9, 66.8) | NE (NE, NE) |
| 24 months | 28.2 (1.9, 66.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-no-pdl1.sas (23JAN23:12:00:51, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Appetite loss - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 21 (20.0%) | 25 (24.3%) |
| Censored Patients, n (%) | 84 (80.0%) | 78 (75.7%) |
| Median (95% CI), (Months) [a] | 3.09 (1.48, 7.10) | 2.86 (1.68, 3.45) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8709 | |
| HR (95% CI) [c] | 0.965 (0.534, 1.744) | |
| HR P-Value [c] | 0.9059 | |
| Heterogeneity p-value [d] | 0.1965 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.7 (6.7, 50.6) | 29.6 (14.8, 46.0) |
| 12 months | 12.9 (1.0, 40.4) | NE (NE, NE) |
| 18 months | 12.9 (1.0, 40.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 30 (28.6%) | 20 (19.4%) |
| Censored Patients, n (%) | 75 (71.4%) | 83 (80.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 7.00) | 2.99 (2.56, 5.78) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4970 | |
| HR (95% CI) [c] | 1.235 (0.692, 2.205) | |
| HR P-Value [c] | 0.4750 | |
| Heterogeneity p-value [d] | 0.5791 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.8 (21.1, 50.9) | 27.9 (11.3, 47.4) |
| 12 months | 20.5 (7.6, 37.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Constipation - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 23 (21.9%) | 17 (16.5%) |
| Censored Patients, n (%) | 82 (78.1%) | 86 (83.5%) |
| Median (95% CI), (Months) [a] | 2.69 (1.61, 5.88) | 3.45 (1.54, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4059 | |
| HR (95% CI) [c] | 1.300 (0.688, 2.458) | |
| HR P-Value [c] | 0.4185 | |
| Heterogeneity p-value [d] | 0.6921 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.9 (11.9, 48.5) | 43.4 (24.0, 61.3) |
| 12 months | 21.7 (6.6, 42.2) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Diarhoea - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 17 (16.2%) | 6 (5.8%) |
| Censored Patients, n (%) | 88 (83.8%) | 97 (94.2%) |
| Median (95% CI), (Months) [a] | 1.48 (1.45, 1.64) | 1.54 (1.45, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6582 | |
| HR (95% CI) [c] | 1.234 (0.481, 3.163) | |
| HR P-Value [c] | 0.6615 | |
| Heterogeneity p-value [d] | 0.8681 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 14.0 (2.8, 34.1) | 28.6 (4.1, 61.2) |
| 12 months | 7.0 (0.5, 26.2) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 21 (20.0%) | 12 (11.7%) |
| Censored Patients, n (%) | 84 (80.0%) | 91 (88.3%) |
| Median (95% CI), (Months) [a] | 2.33 (1.51, 5.59) | 5.06 (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1954 | |
| HR (95% CI) [c] | 1.601 (0.784, 3.266) | |
| HR P-Value [c] | 0.1961 | |
| Heterogeneity p-value [d] | 0.2010 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 28.8 (12.1, 48.0) | 46.2 (22.6, 67.0) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 35 (33.3%) | 15 (14.6%) |
| Censored Patients, n (%) | 70 (66.7%) | 88 (85.4%) |
| Median (95% CI), (Months) [a] | 2.92 (1.45, 5.55) | NE (3.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0186 | |
| HR (95% CI) [c] | 2.095 (1.133, 3.876) | |
| HR P-Value [c] | 0.0184 | |
| Heterogeneity p-value [d] | 0.4904 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.1 (20.9, 49.6) | 54.0 (33.0, 71.0) |
| 12 months | 22.3 (9.6, 38.3) | NE (NE, NE) |
| 18 months | 22.3 (9.6, 38.3) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Fatigue - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 39 (37.1%) | 18 (17.5%) |
| Censored Patients, n (%) | 66 (62.9%) | 85 (82.5%) |
| Median (95% CI), (Months) [a] | 4.30 (2.79, 6.01) | 14.69 (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0013 | |
| HR (95% CI) [c] | 2.454 (1.401, 4.298) | |
| HR P-Value [c] | 0.0017 | |
| Heterogeneity p-value [d] | 0.0384 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.8 (23.3, 50.4) | 69.9 (55.3, 80.6) |
| 12 months | 27.0 (12.5, 43.8) | 69.9 (55.3, 80.6) |
| 18 months | 27.0 (12.5, 43.8) | 0.0 (NE, NE) |
| 24 months | 27.0 (12.5, 43.8) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Financial Problems - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 27 (25.7%) | 19 (18.4%) |
| Censored Patients, n (%) | 78 (74.3%) | 84 (81.6%) |
| Median (95% CI), (Months) [a] | 2.92 (1.84, 4.53) | 7.00 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1214 | |
| HR (95% CI) [c] | 1.595 (0.882, 2.884) | |
| HR P-Value [c] | 0.1223 | |
| Heterogeneity p-value [d] | 0.2908 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.1 (11.5, 41.4) | 53.5 (35.6, 68.4) |
| 12 months | 16.7 (5.7, 32.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 16 (15.2%) | 16 (15.5%) |
| Censored Patients, n (%) | 89 (84.8%) | 87 (84.5%) |
| Median (95% CI), (Months) [a] | 1.58 (1.41, 4.17) | 2.56 (1.48, 3.45) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5208 | |
| HR (95% CI) [c] | 1.269 (0.626, 2.572) | |
| HR P-Value [c] | 0.5088 | |
| Heterogeneity p-value [d] | 0.6792 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 10.5 (0.8, 34.5) | 17.8 (3.7, 40.5) |
| 12 months | 10.5 (0.8, 34.5) | NE (NE, NE) |
| 18 months | 10.5 (0.8, 34.5) | NE (NE, NE) |
| 24 months | 10.5 (0.8, 34.5) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Pain - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 46 (43.8%) | 37 (35.9%) |
| Censored Patients, n (%) | 59 (56.2%) | 66 (64.1%) |
| Median (95% CI), (Months) [a] | 1.94 (1.58, 4.27) | 2.83 (2.10, 4.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2887 | |
| HR (95% CI) [c] | 1.286 (0.832, 1.987) | |
| HR P-Value [c] | 0.2572 | |
| Heterogeneity p-value [d] | 0.8943 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.4 (12.5, 36.4) | 33.8 (20.9, 47.2) |
| 12 months | 13.0 (3.5, 29.1) | NE (NE, NE) |
| 18 months | 13.0 (3.5, 29.1) | NE (NE, NE) |
| 24 months | 13.0 (3.5, 29.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 31 (29.5%) | 10 (9.7%) |
| Censored Patients, n (%) | 74 (70.5%) | 93 (90.3%) |
| Median (95% CI), (Months) [a] | 5.68 (2.86, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0045 | |
| HR (95% CI) [c] | 2.723 (1.329, 5.580) | |
| HR P-Value [c] | 0.0062 | |
| Heterogeneity p-value [d] | 0.8507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.5 (35.3, 62.2) | 77.1 (60.1, 87.5) |
| 12 months | 46.2 (31.7, 59.6) | NE (NE, NE) |
| 18 months | 46.2 (31.7, 59.6) | NE (NE, NE) |
| 24 months | 23.1 (2.1, 57.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 37 (35.2%) | 20 (19.4%) |
| Censored Patients, n (%) | 68 (64.8%) | 83 (80.6%) |
| Median (95% CI), (Months) [a] | 6.01 (2.89, NE) | NE (7.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0442 | |
| HR (95% CI) [c] | 1.753 (1.011, 3.040) | |
| HR P-Value [c] | 0.0456 | |
| Heterogeneity p-value [d] | 0.5014 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.2 (38.4, 62.7) | 67.8 (53.4, 78.7) |
| 12 months | 43.4 (29.9, 56.1) | NE (NE, NE) |
| 18 months | 43.4 (29.9, 56.1) | NE (NE, NE) |
| 24 months | 28.9 (8.4, 53.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Role Functioning - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 37 (35.2%) | 13 (12.6%) |
| Censored Patients, n (%) | 68 (64.8%) | 90 (87.4%) |
| Median (95% CI), (Months) [a] | 2.92 (1.61, 5.06) | NE (4.21, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0038 | |
| HR (95% CI) [c] | 2.484 (1.317, 4.683) | |
| HR P-Value [c] | 0.0049 | |
| Heterogeneity p-value [d] | 0.3276 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.5 (16.7, 43.5) | 63.9 (44.9, 77.8) |
| 12 months | 22.5 (10.7, 36.9) | NE (NE, NE) |
| 18 months | 22.5 (10.7, 36.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Social Functioning - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 33 (31.4%) | 22 (21.4%) |
| Censored Patients, n (%) | 72 (68.6%) | 81 (78.6%) |
| Median (95% CI), (Months) [a] | 1.61 (1.45, 2.33) | 4.17 (2.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0053 | |
| HR (95% CI) [c] | 2.150 (1.245, 3.714) | |
| HR P-Value [c] | 0.0060 | |
| Heterogeneity p-value [d] | 0.3140 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 20.7 (8.8, 36.0) | 46.5 (30.1, 61.4) |
| 12 months | 7.8 (0.8, 26.1) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Insomnia - 10 pts improvement

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 31 (29.5%) | 19 (18.4%) |
| Censored Patients, n (%) | 74 (70.5%) | 84 (81.6%) |
| Median (95% CI), (Months) [a] | 2.83 (1.64, 7.23) | 3.32 (2.86, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4196 | |
| HR (95% CI) [c] | 1.278 (0.714, 2.288) | |
| HR P-Value [c] | 0.4080 | |
| Heterogeneity p-value [d] | 0.8423 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 35.4 (20.0, 51.1) | 37.4 (18.2, 56.7) |
| 12 months | 18.9 (6.1, 37.2) | NE (NE, NE) |
| 18 months | 18.9 (6.1, 37.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Appetite loss - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 8 (27.6%) | 3 (10.0%) |
| Censored Patients, n (%) | 21 (72.4%) | 27 (90.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.41, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1764 | |
| HR (95% CI) [c] | 2.435 (0.636, 9.320) | |
| HR P-Value [c] | 0.1939 | |
| Heterogeneity p-value [d] | 0.1965 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.9 (3.5, 50.3) | 53.6 (13.2, 82.5) |
| 12 months | NE (NE, NE) | 53.6 (13.2, 82.5) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 8 (27.6%) | 6 (20.0%) |
| Censored Patients, n (%) | 21 (72.4%) | 24 (80.0%) |
| Median (95% CI), (Months) [a] | 2.07 (1.45, NE) | 1.77 (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6036 | |
| HR (95% CI) [c] | 0.747 (0.254, 2.201) | |
| HR P-Value [c] | 0.5969 | |
| Heterogeneity p-value [d] | 0.5791 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.6 (4.7, 54.4) | NE (NE, NE) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Constipation - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 7 (24.1%) | 2 (6.7%) |
| Censored Patients, n (%) | 22 (75.9%) | 28 (93.3%) |
| Median (95% CI), (Months) [a] | 3.91 (1.51, 5.85) | NE (0.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1707 | |
| HR (95% CI) [c] | 2.905 (0.581, 14.519) | |
| HR P-Value [c] | 0.1940 | |
| Heterogeneity p-value [d] | 0.6921 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 0.0 (NE, NE) | 70.0 (22.5, 91.8) |
| 12 months | 0.0 (NE, NE) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Diarhoea - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 3 (10.3%) | 4 (13.3%) |
| Censored Patients, n (%) | 26 (89.7%) | 26 (86.7%) |
| Median (95% CI), (Months) [a] | 4.17 (1.91, 6.11) | 1.58 (1.41, 7.00) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6623 | |
| HR (95% CI) [c] | 0.696 (0.136, 3.568) | |
| HR P-Value [c] | 0.6639 | |
| Heterogeneity p-value [d] | 0.8681 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 33.3 (0.9, 77.4) | 25.0 (0.9, 66.5) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 5 (17.2%) | 5 (16.7%) |
| Censored Patients, n (%) | 24 (82.8%) | 25 (83.3%) |
| Median (95% CI), (Months) [a] | 2.79 (1.38, NE) | 1.77 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8210 | |
| HR (95% CI) [c] | 0.867 (0.249, 3.022) | |
| HR P-Value [c] | 0.8232 | |
| Heterogeneity p-value [d] | 0.2010 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.1 (10.3, 70.7) | 17.1 (0.8, 52.6) |
| 12 months | 41.1 (10.3, 70.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 11 (37.9%) | 7 (23.3%) |
| Censored Patients, n (%) | 18 (62.1%) | 23 (76.7%) |
| Median (95% CI), (Months) [a] | 1.91 (1.58, 4.17) | 5.03 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1479 | |
| HR (95% CI) [c] | 1.992 (0.764, 5.195) | |
| HR P-Value [c] | 0.1586 | |
| Heterogeneity p-value [d] | 0.4904 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 24.8 (6.1, 49.8) | 43.4 (12.7, 71.3) |
| 12 months | 12.4 (0.9, 39.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Fatigue - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 5 (17.2%) | 9 (30.0%) |
| Censored Patients, n (%) | 24 (82.8%) | 21 (70.0%) |
| Median (95% CI), (Months) [a] | NE (2.79, NE) | 5.91 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2894 | |
| HR (95% CI) [c] | 0.559 (0.187, 1.671) | |
| HR P-Value [c] | 0.2980 | |
| Heterogeneity p-value [d] | 0.0384 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.7 (34.1, 83.9) | 48.1 (18.6, 72.7) |
| 12 months | 64.7 (34.1, 83.9) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Financial Problems - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 5 (17.2%) | 6 (20.0%) |
| Censored Patients, n (%) | 24 (82.8%) | 24 (80.0%) |
| Median (95% CI), (Months) [a] | NE (1.45, NE) | 2.89 (1.38, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5012 | |
| HR (95% CI) [c] | 0.661 (0.202, 2.169) | |
| HR P-Value [c] | 0.4950 | |
| Heterogeneity p-value [d] | 0.2908 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.0 (17.2, 76.1) | 40.0 (12.3, 67.0) |
| 12 months | 50.0 (17.2, 76.1) | 40.0 (12.3, 67.0) |
| 18 months | 50.0 (17.2, 76.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 5 (17.2%) | 3 (10.0%) |
| Censored Patients, n (%) | 24 (82.8%) | 27 (90.0%) |
| Median (95% CI), (Months) [a] | 1.58 (1.31, NE) | 4.47 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2800 | |
| HR (95% CI) [c] | 2.193 (0.519, 9.269) | |
| HR P-Value [c] | 0.2856 | |
| Heterogeneity p-value [d] | 0.6792 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 21.4 (1.2, 58.6) | 27.8 (1.0, 70.0) |
| 12 months | NE (NE, NE) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Pain - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 8 (27.6%) | 9 (30.0%) |
| Censored Patients, n (%) | 21 (72.4%) | 21 (70.0%) |
| Median (95% CI), (Months) [a] | 6.97 (1.91, NE) | 5.03 (1.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9909 | |
| HR (95% CI) [c] | 1.007 (0.387, 2.621) | |
| HR P-Value [c] | 0.9884 | |
| Heterogeneity p-value [d] | 0.8943 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.2 (31.7, 83.2) | 36.7 (12.1, 62.2) |
| 12 months | NE (NE, NE) | 18.4 (1.4, 51.2) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 4 (13.8%) | 4 (13.3%) |
| Censored Patients, n (%) | 25 (86.2%) | 26 (86.7%) |
| Median (95% CI), (Months) [a] | NE (1.61, NE) | NE (7.00, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3501 | |
| HR (95% CI) [c] | 1.895 (0.453, 7.926) | |
| HR P-Value [c] | 0.3812 | |
| Heterogeneity p-value [d] | 0.8507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.3 (31.3, 86.5) | 90.9 (50.8, 98.7) |
| 12 months | 66.3 (31.3, 86.5) | 53.0 (17.0, 79.7) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 8 (27.6%) | 3 (10.0%) |
| Censored Patients, n (%) | 21 (72.4%) | 27 (90.0%) |
| Median (95% CI), (Months) [a] | 6.05 (2.83, NE) | NE (5.91, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0370 | |
| HR (95% CI) [c] | 3.805 (0.993, 14.584) | |
| HR P-Value [c] | 0.0512 | |
| Heterogeneity p-value [d] | 0.5014 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 51.6 (23.4, 74.0) | 74.2 (38.2, 91.2) |
| 12 months | NE (NE, NE) | 74.2 (38.2, 91.2) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Role Functioning - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 10 (34.5%) | 6 (20.0%) |
| Censored Patients, n (%) | 19 (65.5%) | 24 (80.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.48, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3340 | |
| HR (95% CI) [c] | 1.642 (0.594, 4.538) | |
| HR P-Value [c] | 0.3390 | |
| Heterogeneity p-value [d] | 0.3276 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 25.1 (5.2, 52.3) | 51.9 (22.2, 75.1) |
| 12 months | NE (NE, NE) | 51.9 (22.2, 75.1) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Social Functioning - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 9 (31.0%) | 5 (16.7%) |
| Censored Patients, n (%) | 20 (69.0%) | 25 (83.3%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 4.17) | 7.00 (1.41, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0809 | |
| HR (95% CI) [c] | 2.625 (0.853, 8.075) | |
| HR P-Value [c] | 0.0923 | |
| Heterogeneity p-value [d] | 0.3140 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 15.9 (1.1, 46.9) | 62.5 (27.6, 84.2) |
| 12 months | NE (NE, NE) | 46.9 (13.5, 75.1) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Insomnia - 10 pts improvement

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 5 (17.2%) | 4 (13.3%) |
| Censored Patients, n (%) | 24 (82.8%) | 26 (86.7%) |
| Median (95% CI), (Months) [a] | 5.45 (1.45, NE) | NE (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6812 | |
| HR (95% CI) [c] | 1.301 (0.348, 4.858) | |
| HR P-Value [c] | 0.6956 | |
| Heterogeneity p-value [d] | 0.8423 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.4 (10.7, 72.0) | 52.6 (14.8, 80.5) |
| 12 months | 42.4 (10.7, 72.0) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Appetite loss - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 17 (27.4%) | 6 (12.0%) |
| Censored Patients, n (%) | 45 (72.6%) | 44 (88.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.61, 4.86) | 7.26 (1.68, 7.26) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0392 | |
| HR (95% CI) [c] | 2.761 (1.007, 7.569) | |
| HR P-Value [c] | 0.0484 | |
| Heterogeneity p-value [d] | 0.1965 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 11.7 (1.0, 36.9) | 51.1 (15.2, 78.7) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Cognitive Functioning - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 16 (25.8%) | 11 (22.0%) |
| Censored Patients, n (%) | 46 (74.2%) | 39 (78.0%) |
| Median (95% CI), (Months) [a] | 2.96 (1.64, 6.97) | 4.17 (1.48, 6.28) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6071 | |
| HR (95% CI) [c] | 0.804 (0.361, 1.789) | |
| HR P-Value [c] | 0.5929 | |
| Heterogeneity p-value [d] | 0.5791 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 29.0 (9.3, 52.6) | 33.3 (9.7, 59.6) |
| 12 months | 9.7 (0.7, 33.8) | 0.0 (NE, NE) |
| 18 months | 9.7 (0.7, 33.8) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Constipation - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 22 (35.5%) | 10 (20.0%) |
| Censored Patients, n (%) | 40 (64.5%) | 40 (80.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.24) | 2.86 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5101 | |
| HR (95% CI) [c] | 1.300 (0.614, 2.749) | |
| HR P-Value [c] | 0.4931 | |
| Heterogeneity p-value [d] | 0.6921 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 19.8 (5.9, 39.4) | 23.4 (4.6, 50.5) |
| 12 months | 6.6 (0.5, 25.0) | 23.4 (4.6, 50.5) |
| 18 months | 6.6 (0.5, 25.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Diarhoea - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 11 (17.7%) | 7 (14.0%) |
| Censored Patients, n (%) | 51 (82.3%) | 43 (86.0%) |
| Median (95% CI), (Months) [a] | 2.20 (1.45, 5.65) | 2.30 (1.41, 5.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8459 | |
| HR (95% CI) [c] | 0.958 (0.361, 2.544) | |
| HR P-Value [c] | 0.9310 | |
| Heterogeneity p-value [d] | 0.8681 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 12.5 (0.9, 39.9) | 15.9 (0.8, 49.6) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Dyspnoea - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 16 (25.8%) | 7 (14.0%) |
| Censored Patients, n (%) | 46 (74.2%) | 43 (86.0%) |
| Median (95% CI), (Months) [a] | 2.86 (1.64, 4.57) | 9.69 (2.89, 9.69) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0543 | |
| HR (95% CI) [c] | 2.363 (0.961, 5.811) | |
| HR P-Value [c] | 0.0610 | |
| Heterogeneity p-value [d] | 0.2010 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 17.4 (3.5, 40.3) | 55.5 (22.2, 79.4) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Emotional Functioning - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 25 (40.3%) | 13 (26.0%) |
| Censored Patients, n (%) | 37 (59.7%) | 37 (74.0%) |
| Median (95% CI), (Months) [a] | 4.24 (2.79, 6.97) | 4.40 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6721 | |
| HR (95% CI) [c] | 1.160 (0.587, 2.294) | |
| HR P-Value [c] | 0.6686 | |
| Heterogeneity p-value [d] | 0.4904 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 31.7 (14.8, 50.0) | 29.9 (10.2, 52.7) |
| 12 months | 10.6 (0.8, 34.8) | NE (NE, NE) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Fatigue - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 33 (53.2%) | 15 (30.0%) |
| Censored Patients, n (%) | 29 (46.8%) | 35 (70.0%) |
| Median (95% CI), (Months) [a] | 2.96 (1.84, 4.24) | 4.30 (1.58, 7.26) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5650 | |
| HR (95% CI) [c] | 1.201 (0.642, 2.245) | |
| HR P-Value [c] | 0.5669 | |
| Heterogeneity p-value [d] | 0.0384 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.2 (9.9, 39.7) | 49.5 (27.6, 68.1) |
| 12 months | 13.9 (3.9, 30.1) | 0.0 (NE, NE) |
| 18 months | 9.3 (1.7, 24.8) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Financial Problems - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 16 (25.8%) | 12 (24.0%) |
| Censored Patients, n (%) | 46 (74.2%) | 38 (76.0%) |
| Median (95% CI), (Months) [a] | 2.96 (1.54, NE) | 1.81 (1.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8856 | |
| HR (95% CI) [c] | 0.949 (0.449, 2.007) | |
| HR P-Value [c] | 0.8912 | |
| Heterogeneity p-value [d] | 0.2908 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.9 (11.0, 53.5) | 33.2 (12.6, 55.6) |
| 12 months | 30.9 (11.0, 53.5) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Nausea / Vomiting - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 14 (22.6%) | 7 (14.0%) |
| Censored Patients, n (%) | 48 (77.4%) | 43 (86.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.58, 4.90) | 2.92 (1.48, 5.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9528 | |
| HR (95% CI) [c] | 1.030 (0.404, 2.627) | |
| HR P-Value [c] | 0.9511 | |
| Heterogeneity p-value [d] | 0.6792 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 20.0 (3.7, 45.6) | 0.0 (NE, NE) |
| 12 months | 10.0 (0.7, 34.9) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Pain - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 27 (43.5%) | 14 (28.0%) |
| Censored Patients, n (%) | 35 (56.5%) | 36 (72.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.54, 4.21) | 5.39 (1.51, 6.74) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4443 | |
| HR (95% CI) [c] | 1.298 (0.674, 2.501) | |
| HR P-Value [c] | 0.4360 | |
| Heterogeneity p-value [d] | 0.8943 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 20.7 (6.9, 39.6) | 31.9 (9.6, 57.2) |
| 12 months | 10.4 (1.0, 32.9) | 21.2 (3.9, 47.7) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Physical Functioning - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 18 (29.0%) | 7 (14.0%) |
| Censored Patients, n (%) | 44 (71.0%) | 43 (86.0%) |
| Median (95% CI), (Months) [a] | 4.90 (2.96, 7.43) | NE (4.37, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0529 | |
| HR (95% CI) [c] | 2.335 (0.967, 5.635) | |
| HR P-Value [c] | 0.0593 | |
| Heterogeneity p-value [d] | 0.8507 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.1 (16.1, 56.6) | 75.2 (49.0, 89.2) |
| 12 months | 27.0 (8.6, 49.8) | 54.8 (24.3, 77.5) |
| 18 months | 27.0 (8.6, 49.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Global health status / QoL - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 32 (51.6%) | 13 (26.0%) |
| Censored Patients, n (%) | 30 (48.4%) | 37 (74.0%) |
| Median (95% CI), (Months) [a] | 4.21 (2.83, 5.68) | 7.26 (2.79, 9.59) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4335 | |
| HR (95% CI) [c] | 1.308 (0.678, 2.522) | |
| HR P-Value [c] | 0.4227 | |
| Heterogeneity p-value [d] | 0.5014 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 34.1 (18.9, 49.9) | 59.8 (38.3, 75.9) |
| 12 months | 29.2 (14.4, 45.8) | 0.0 (NE, NE) |
| 18 months | 12.2 (2.5, 30.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Role Functioning - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 24 (38.7%) | 12 (24.0%) |
| Censored Patients, n (%) | 38 (61.3%) | 38 (76.0%) |
| Median (95% CI), (Months) [a] | 4.24 (1.64, 5.72) | 4.30 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5860 | |
| HR (95% CI) [c] | 1.211 (0.605, 2.426) | |
| HR P-Value [c] | 0.5886 | |
| Heterogeneity p-value [d] | 0.3276 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.8 (11.6, 46.8) | 36.9 (13.5, 60.8) |
| 12 months | 10.4 (0.9, 33.5) | 36.9 (13.5, 60.8) |
| 18 months | 10.4 (0.9, 33.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Social Functioning - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 27 (43.5%) | 13 (26.0%) |
| Censored Patients, n (%) | 35 (56.5%) | 37 (74.0%) |
| Median (95% CI), (Months) [a] | 2.83 (1.84, 3.06) | 3.12 (1.51, 5.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5560 | |
| HR (95% CI) [c] | 1.231 (0.634, 2.390) | |
| HR P-Value [c] | 0.5396 | |
| Heterogeneity p-value [d] | 0.3140 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 18.0 (6.1, 35.1) | 21.3 (3.9, 47.9) |
| 12 months | 12.0 (2.6, 29.4) | NE (NE, NE) |
| 18 months | 12.0 (2.6, 29.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:15:57, yingyuan.lin)

Table 18.3.1a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Insomnia - 10 pts improvement

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 19 (30.6%) | 9 (18.0%) |
| Censored Patients, n (%) | 43 (69.4%) | 41 (82.0%) |
| Median (95% CI), (Months) [a] | 2.92 (1.54, 4.96) | 8.31 (1.48, 8.31) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2250 | |
| HR (95% CI) [c] | 1.631 (0.736, 3.615) | |
| HR P-Value [c] | 0.2282 | |
| Heterogeneity p-value [d] | 0.8423 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 20.6 (4.9, 43.9) | 61.8 (37.0, 79.2) |
| 12 months | NE (NE, NE) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 47 (44.8%) | 42 (40.8%) |
| Censored Patients, n (%) | 58 (55.2%) | 61 (59.2%) |
| Median (95% CI), (Months) [a] | 5.55 (2.89, 10.38) | 4.60 (2.86, 5.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2627 | |
| HR (95% CI) [c] | 0.786 (0.512, 1.207) | |
| HR P-Value [c] | 0.2714 | |
| Heterogeneity p-value [d] | 0.0678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.3 (32.2, 55.7) | 36.7 (23.6, 49.8) |
| 12 months | 33.9 (22.1, 46.0) | 7.9 (0.6, 28.0) |
| 18 months | 27.4 (15.6, 40.5) | 7.9 (0.6, 28.0) |
| 24 months | 27.4 (15.6, 40.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 51 (48.6%) | 40 (38.8%) |
| Censored Patients, n (%) | 54 (51.4%) | 63 (61.2%) |
| Median (95% CI), (Months) [a] | 5.82 (2.99, 8.41) | 4.24 (2.96, 5.22) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4592 | |
| HR (95% CI) [c] | 0.853 (0.556, 1.307) | |
| HR P-Value [c] | 0.4639 | |
| Heterogeneity p-value [d] | 0.8723 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 46.5 (34.2, 57.9) | 36.0 (23.1, 49.1) |
| 12 months | 26.9 (15.6, 39.6) | 24.0 (7.1, 46.3) |
| 18 months | 10.2 (2.3, 25.2) | 24.0 (7.1, 46.3) |
| 24 months | 10.2 (2.3, 25.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Constipation - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 42 (40.0%) | 45 (43.7%) |
| Censored Patients, n (%) | 63 (60.0%) | 58 (56.3%) |
| Median (95% CI), (Months) [a] | 8.28 (5.59, 14.65) | 2.99 (2.79, 5.19) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0289 | |
| HR (95% CI) [c] | 0.619 (0.400, 0.958) | |
| HR P-Value [c] | 0.0312 | |
| Heterogeneity p-value [d] | 0.2364 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.5 (46.0, 69.1) | 36.0 (23.3, 48.8) |
| 12 months | 38.1 (25.0, 51.0) | 15.2 (3.9, 33.5) |
| 18 months | 22.8 (9.5, 39.6) | 15.2 (3.9, 33.5) |
| 24 months | 22.8 (9.5, 39.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 28 (26.7%) | 28 (27.2%) |
| Censored Patients, n (%) | 77 (73.3%) | 75 (72.8%) |
| Median (95% CI), (Months) [a] | 10.45 (7.10, NE) | 8.48 (5.16, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0717 | |
| HR (95% CI) [c] | 0.606 (0.349, 1.051) | |
| HR P-Value [c] | 0.0744 | |
| Heterogeneity p-value [d] | 0.2877 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.6 (57.5, 80.4) | 51.9 (34.8, 66.6) |
| 12 months | 49.8 (34.3, 63.4) | NE (NE, NE) |
| 18 months | 49.8 (34.3, 63.4) | NE (NE, NE) |
| 24 months | 39.8 (19.4, 59.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 43 (41.0%) | 32 (31.1%) |
| Censored Patients, n (%) | 62 (59.0%) | 71 (68.9%) |
| Median (95% CI), (Months) [a] | 5.72 (4.14, 11.27) | 6.67 (4.37, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8254 | |
| HR (95% CI) [c] | 1.056 (0.661, 1.688) | |
| HR P-Value [c] | 0.8198 | |
| Heterogeneity p-value [d] | 0.1072 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.1 (36.6, 60.4) | 53.3 (38.6, 66.0) |
| 12 months | 31.4 (18.9, 44.8) | 25.3 (6.1, 50.9) |
| 18 months | 31.4 (18.9, 44.8) | 25.3 (6.1, 50.9) |
| 24 months | 31.4 (18.9, 44.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 34 (32.4%) | 39 (37.9%) |
| Censored Patients, n (%) | 71 (67.6%) | 64 (62.1%) |
| Median (95% CI), (Months) [a] | 11.99 (5.62, 20.80) | 4.83 (2.99, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0145 | |
| HR (95% CI) [c] | 0.549 (0.337, 0.895) | |
| HR P-Value [c] | 0.0161 | |
| Heterogeneity p-value [d] | 0.4439 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.2 (48.1, 71.9) | 44.5 (30.8, 57.4) |
| 12 months | 47.7 (33.0, 60.9) | 12.8 (1.2, 38.6) |
| 18 months | 37.7 (21.2, 54.2) | 12.8 (1.2, 38.6) |
| 24 months | 18.9 (1.8, 49.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Fatigue - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 62 (59.0%) | 54 (52.4%) |
| Censored Patients, n (%) | 43 (41.0%) | 49 (47.6%) |
| Median (95% CI), (Months) [a] | 2.79 (1.61, 4.21) | 1.77 (1.61, 2.92) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3159 | |
| HR (95% CI) [c] | 0.827 (0.567, 1.205) | |
| HR P-Value [c] | 0.3230 | |
| Heterogeneity p-value [d] | 0.6200 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 27.1 (17.3, 37.9) | 31.6 (20.6, 43.3) |
| 12 months | 12.6 (4.9, 24.1) | NE (NE, NE) |
| 18 months | 12.6 (4.9, 24.1) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 35 (33.3%) | 26 (25.2%) |
| Censored Patients, n (%) | 70 (66.7%) | 77 (74.8%) |
| Median (95% CI), (Months) [a] | 7.62 (4.50, NE) | 6.70 (5.55, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9127 | |
| HR (95% CI) [c] | 0.973 (0.577, 1.642) | |
| HR P-Value [c] | 0.9197 | |
| Heterogeneity p-value [d] | 0.5419 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.8 (42.3, 67.3) | 63.4 (47.8, 75.4) |
| 12 months | 41.7 (28.1, 54.8) | 23.1 (5.5, 47.6) |
| 18 months | 41.7 (28.1, 54.8) | 23.1 (5.5, 47.6) |
| 24 months | 31.3 (13.0, 51.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 41 (39.0%) | 47 (45.6%) |
| Censored Patients, n (%) | 64 (61.0%) | 56 (54.4%) |
| Median (95% CI), (Months) [a] | 7.26 (5.68, 11.99) | 4.60 (1.64, 5.95) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0015 | |
| HR (95% CI) [c] | 0.498 (0.321, 0.771) | |
| HR P-Value [c] | 0.0018 | |
| Heterogeneity p-value [d] | 0.7081 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.3 (46.3, 70.1) | 34.9 (22.0, 48.1) |
| 12 months | 35.3 (22.4, 48.4) | 9.7 (0.8, 32.2) |
| 18 months | 25.1 (11.4, 41.4) | 9.7 (0.8, 32.2) |
| 24 months | 25.1 (11.4, 41.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Pain - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 46 (43.8%) | 56 (54.4%) |
| Censored Patients, n (%) | 59 (56.2%) | 47 (45.6%) |
| Median (95% CI), (Months) [a] | 5.52 (2.89, 7.10) | 2.83 (1.74, 3.02) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0008 | |
| HR (95% CI) [c] | 0.509 (0.341, 0.759) | |
| HR P-Value [c] | 0.0009 | |
| Heterogeneity p-value [d] | 0.5518 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.7 (32.2, 56.4) | 16.8 (8.2, 28.0) |
| 12 months | 28.6 (16.8, 41.4) | 5.2 (0.6, 18.6) |
| 18 months | 24.5 (12.8, 38.2) | 5.2 (0.6, 18.6) |
| 24 months | 24.5 (12.8, 38.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 46 (43.8%) | 45 (43.7%) |
| Censored Patients, n (%) | 59 (56.2%) | 58 (56.3%) |
| Median (95% CI), (Months) [a] | 9.63 (5.55, 11.99) | 3.45 (2.83, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0204 | |
| HR (95% CI) [c] | 0.604 (0.392, 0.931) | |
| HR P-Value [c] | 0.0225 | |
| Heterogeneity p-value [d] | 0.4138 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.3 (43.9, 67.0) | 39.6 (27.2, 51.7) |
| 12 months | 35.2 (22.3, 48.4) | 10.1 (0.9, 33.0) |
| 18 months | 14.1 (4.2, 29.7) | 10.1 (0.9, 33.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 51 (48.6%) | 48 (46.6%) |
| Censored Patients, n (%) | 54 (51.4%) | 55 (53.4%) |
| Median (95% CI), (Months) [a] | 5.68 (2.83, 7.10) | 3.68 (2.79, 5.68) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3946 | |
| HR (95% CI) [c] | 0.843 (0.563, 1.264) | |
| HR P-Value [c] | 0.4091 | |
| Heterogeneity p-value [d] | 0.4846 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 42.2 (30.0, 54.0) | 36.5 (24.1, 48.9) |
| 12 months | 24.2 (13.8, 36.3) | 7.9 (0.7, 27.1) |
| 18 months | 15.6 (5.8, 29.8) | 7.9 (0.7, 27.1) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 50 (47.6%) | 51 (49.5%) |
| Censored Patients, n (%) | 55 (52.4%) | 52 (50.5%) |
| Median (95% CI), (Months) [a] | 4.17 (2.83, 11.99) | 3.02 (1.77, 4.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0355 | |
| HR (95% CI) [c] | 0.650 (0.431, 0.978) | |
| HR P-Value [c] | 0.0388 | |
| Heterogeneity p-value [d] | 0.9136 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.7 (32.6, 56.1) | 27.7 (16.4, 40.3) |
| 12 months | 36.2 (24.2, 48.3) | 4.6 (0.4, 18.5) |
| 18 months | 13.6 (3.6, 30.2) | 4.6 (0.4, 18.5) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 43 (41.0%) | 50 (48.5%) |
| Censored Patients, n (%) | 62 (59.0%) | 53 (51.5%) |
| Median (95% CI), (Months) [a] | 5.75 (4.21, 11.27) | 2.96 (1.97, 5.16) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0035 | |
| HR (95% CI) [c] | 0.535 (0.350, 0.820) | |
| HR P-Value [c] | 0.0040 | |
| Heterogeneity p-value [d] | 0.4283 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.9 (35.2, 59.5) | 32.3 (20.3, 44.9) |
| 12 months | 37.6 (25.2, 50.0) | 10.8 (2.5, 26.1) |
| 18 months | 29.5 (16.3, 44.0) | 10.8 (2.5, 26.1) |
| 24 months | 14.8 (1.6, 41.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Insomnia - 10 pts deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 47 (44.8%) | 43 (41.7%) |
| Censored Patients, n (%) | 58 (55.2%) | 60 (58.3%) |
| Median (95% CI), (Months) [a] | 4.34 (2.96, 11.93) | 4.30 (1.97, 6.67) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2608 | |
| HR (95% CI) [c] | 0.784 (0.513, 1.200) | |
| HR P-Value [c] | 0.2631 | |
| Heterogeneity p-value [d] | 0.4860 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.1 (30.8, 54.9) | 42.8 (29.8, 55.2) |
| 12 months | 33.2 (20.8, 46.1) | 15.5 (3.5, 35.4) |
| 18 months | 21.1 (10.3, 34.6) | 15.5 (3.5, 35.4) |
| 24 months | 10.6 (1.2, 31.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 7 (24.1%) | 15 (50.0%) |
| Censored Patients, n (%) | 22 (75.9%) | 15 (50.0%) |
| Median (95% CI), (Months) [a] | NE (2.83, NE) | 1.68 (1.58, 2.99) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0045 | |
| HR (95% CI) [c] | 0.285 (0.113, 0.718) | |
| HR P-Value [c] | 0.0077 | |
| Heterogeneity p-value [d] | 0.0678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.1 (25.3, 74.8) | 12.0 (2.0, 31.7) |
| 12 months | 53.1 (25.3, 74.8) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 11 (37.9%) | 13 (43.3%) |
| Censored Patients, n (%) | 18 (62.1%) | 17 (56.7%) |
| | | |
| Median (95% CI), (Months) [a] | 5.59 (1.58, NE) | 1.64 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4738 | |
| HR (95% CI) [c] | 0.738 (0.329, 1.656) | |
| HR P-Value [c] | 0.4617 | |
| Heterogeneity p-value [d] | 0.8723 | |
| | | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.5 (23.8, 70.8) | 36.8 (16.5, 57.5) |
| 12 months | NE (NE, NE) | 27.6 (8.8, 50.6) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Constipation - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 8 (27.6%) | 6 (20.0%) |
| Censored Patients, n (%) | 21 (72.4%) | 24 (80.0%) |
| Median (95% CI), (Months) [a] | 6.93 (1.61, 15.11) | 11.50 (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6251 | |
| HR (95% CI) [c] | 1.310 (0.436, 3.935) | |
| HR P-Value [c] | 0.6298 | |
| Heterogeneity p-value [d] | 0.2364 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.1 (32.6, 80.6) | 63.8 (33.4, 83.2) |
| 12 months | 45.8 (14.9, 72.6) | 31.9 (1.8, 72.4) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 7 (24.1%) | 6 (20.0%) |
| Censored Patients, n (%) | 22 (75.9%) | 24 (80.0%) |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | NE (3.06, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5761 | |
| HR (95% CI) [c] | 1.367 (0.458, 4.084) | |
| HR P-Value [c] | 0.5752 | |
| Heterogeneity p-value [d] | 0.2877 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 57.6 (29.9, 77.8) | 62.3 (34.0, 81.3) |
| 12 months | 57.6 (29.9, 77.8) | 62.3 (34.0, 81.3) |
| 18 months | 57.6 (29.9, 77.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 7 (24.1%) | 10 (33.3%) |
| Censored Patients, n (%) | 22 (75.9%) | 20 (66.7%) |
| Median (95% CI), (Months) [a] | NE (2.07, NE) | 9.92 (1.77, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4992 | |
| HR (95% CI) [c] | 0.727 (0.276, 1.917) | |
| HR P-Value [c] | 0.5199 | |
| Heterogeneity p-value [d] | 0.1072 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.2 (39.5, 83.3) | 53.3 (27.9, 73.3) |
| 12 months | 55.2 (25.8, 77.0) | NE (NE, NE) |
| 18 months | 55.2 (25.8, 77.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 8 (27.6%) | 11 (36.7%) |
| Censored Patients, n (%) | 21 (72.4%) | 19 (63.3%) |
| Median (95% CI), (Months) [a] | 13.83 (2.17, 13.83) | 4.34 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4652 | |
| HR (95% CI) [c] | 0.700 (0.271, 1.807) | |
| HR P-Value [c] | 0.4606 | |
| Heterogeneity p-value [d] | 0.4439 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.5 (24.1, 74.7) | 33.8 (13.0, 56.3) |
| 12 months | 52.5 (24.1, 74.7) | 33.8 (13.0, 56.3) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Fatigue - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 16 (55.2%) | 16 (53.3%) |
| Censored Patients, n (%) | 13 (44.8%) | 14 (46.7%) |
| Median (95% CI), (Months) [a] | 1.58 (1.45, 5.59) | 1.84 (1.58, 3.02) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8910 | |
| HR (95% CI) [c] | 0.960 (0.475, 1.939) | |
| HR P-Value [c] | 0.9093 | |
| Heterogeneity p-value [d] | 0.6200 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 23.2 (7.3, 44.3) | 22.2 (6.9, 42.9) |
| 12 months | 7.7 (0.6, 28.4) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 6 (20.7%) | 6 (20.0%) |
| Censored Patients, n (%) | 23 (79.3%) | 24 (80.0%) |
| Median (95% CI), (Months) [a] | 6.97 (4.60, NE) | 11.50 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3749 | |
| HR (95% CI) [c] | 1.766 (0.493, 6.333) | |
| HR P-Value [c] | 0.3826 | |
| Heterogeneity p-value [d] | 0.5419 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.6 (32.8, 84.3) | 70.8 (38.8, 88.2) |
| 12 months | NE (NE, NE) | 26.5 (1.5, 65.9) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 6 (20.7%) | 12 (40.0%) |
| Censored Patients, n (%) | 23 (79.3%) | 18 (60.0%) |
| Median (95% CI), (Months) [a] | 9.69 (4.47, NE) | 4.34 (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0657 | |
| HR (95% CI) [c] | 0.407 (0.152, 1.092) | |
| HR P-Value [c] | 0.0743 | |
| Heterogeneity p-value [d] | 0.7081 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.2 (42.8, 87.2) | 40.1 (18.1, 61.3) |
| 12 months | 47.4 (9.5, 79.0) | NE (NE, NE) |
| 18 months | 47.4 (9.5, 79.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Pain - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 11 (37.9%) | 13 (43.3%) |
| Censored Patients, n (%) | 18 (62.1%) | 17 (56.7%) |
| Median (95% CI), (Months) [a] | 2.99 (1.48, 9.72) | 1.77 (1.58, 10.35) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8162 | |
| HR (95% CI) [c] | 0.905 (0.399, 2.053) | |
| HR P-Value [c] | 0.8104 | |
| Heterogeneity p-value [d] | 0.5518 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.1 (13.0, 60.1) | 28.7 (9.8, 51.1) |
| 12 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 18 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 12 (41.4%) | 14 (46.7%) |
| Censored Patients, n (%) | 17 (58.6%) | 16 (53.3%) |
| Median (95% CI), (Months) [a] | 2.07 (1.45, 9.69) | 4.17 (1.51, 5.65) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7681 | |
| HR (95% CI) [c] | 0.890 (0.405, 1.953) | |
| HR P-Value [c] | 0.7713 | |
| Heterogeneity p-value [d] | 0.4138 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.7 (24.4, 70.8) | 20.8 (5.6, 42.7) |
| 12 months | 0.0 (NE, NE) | 20.8 (5.6, 42.7) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 10 (34.5%) | 14 (46.7%) |
| Censored Patients, n (%) | 19 (65.5%) | 16 (53.3%) |
| Median (95% CI), (Months) [a] | 2.53 (1.45, 11.83) | 3.48 (1.58, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5419 | |
| HR (95% CI) [c] | 0.774 (0.332, 1.807) | |
| HR P-Value [c] | 0.5544 | |
| Heterogeneity p-value [d] | 0.4846 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.7 (22.9, 71.7) | 21.1 (5.9, 42.5) |
| 12 months | 16.6 (1.0, 49.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 9 (31.0%) | 13 (43.3%) |
| Censored Patients, n (%) | 20 (69.0%) | 17 (56.7%) |
| Median (95% CI), (Months) [a] | 8.34 (1.58, NE) | 2.89 (1.41, 4.40) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1268 | |
| HR (95% CI) [c] | 0.508 (0.208, 1.238) | |
| HR P-Value [c] | 0.1363 | |
| Heterogeneity p-value [d] | 0.9136 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.3 (25.0, 75.1) | 17.0 (3.3, 39.8) |
| 12 months | 20.0 (1.4, 54.6) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 10 (34.5%) | 11 (36.7%) |
| Censored Patients, n (%) | 19 (65.5%) | 19 (63.3%) |
| Median (95% CI), (Months) [a] | 4.60 (2.07, NE) | 4.40 (3.02, 8.02) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7410 | |
| HR (95% CI) [c] | 0.866 (0.363, 2.068) | |
| HR P-Value [c] | 0.7465 | |
| Heterogeneity p-value [d] | 0.4283 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 40.0 (15.5, 63.7) | 29.6 (8.6, 54.8) |
| 12 months | 32.0 (10.3, 56.4) | 0.0 (NE, NE) |
| 18 months | NE (NE, NE) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Insomnia - 10 pts deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 11 (37.9%) | 10 (33.3%) |
| Censored Patients, n (%) | 18 (62.1%) | 20 (66.7%) |
| Median (95% CI), (Months) [a] | 3.19 (1.91, NE) | 7.39 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6438 | |
| HR (95% CI) [c] | 1.225 (0.516, 2.910) | |
| HR P-Value [c] | 0.6450 | |
| Heterogeneity p-value [d] | 0.4860 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.9 (12.2, 55.6) | 51.3 (25.7, 72.1) |
| 12 months | NE (NE, NE) | 30.8 (8.7, 56.7) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Appetite loss - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 26 (41.9%) | 27 (54.0%) |
| Censored Patients, n (%) | 36 (58.1%) | 23 (46.0%) |
| Median (95% CI), (Months) [a] | 6.21 (4.21, NE) | 2.92 (2.07, 4.21) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0074 | |
| HR (95% CI) [c] | 0.484 (0.280, 0.837) | |
| HR P-Value [c] | 0.0094 | |
| Heterogeneity p-value [d] | 0.0678 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 50.7 (34.0, 65.2) | 20.5 (8.2, 36.7) |
| 12 months | 33.4 (17.1, 50.6) | 0.0 (NE, NE) |
| 18 months | 33.4 (17.1, 50.6) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Cognitive Functioning - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 28 (45.2%) | 19 (38.0%) |
| Censored Patients, n (%) | 34 (54.8%) | 31 (62.0%) |
| Median (95% CI), (Months) [a] | 4.90 (2.83, NE) | 3.06 (2.07, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7767 | |
| HR (95% CI) [c] | 0.927 (0.518, 1.661) | |
| HR P-Value [c] | 0.7996 | |
| Heterogeneity p-value [d] | 0.8723 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 41.3 (26.0, 56.0) | 43.5 (25.8, 60.0) |
| 12 months | 35.4 (19.3, 52.0) | 38.7 (21.2, 55.9) |
| 18 months | 35.4 (19.3, 52.0) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Constipation - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 24 (38.7%) | 14 (28.0%) |
| Censored Patients, n (%) | 38 (61.3%) | 36 (72.0%) |
| Median (95% CI), (Months) [a] | 6.97 (2.96, NE) | 14.13 (3.15, 14.13) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9598 | |
| HR (95% CI) [c] | 0.980 (0.504, 1.904) | |
| HR P-Value [c] | 0.9524 | |
| Heterogeneity p-value [d] | 0.2364 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.3 (37.1, 67.1) | 53.4 (32.3, 70.6) |
| 12 months | 43.7 (26.2, 60.1) | 53.4 (32.3, 70.6) |
| 18 months | 36.5 (18.0, 55.3) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Diarhoea - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 23 (37.1%) | 14 (28.0%) |
| Censored Patients, n (%) | 39 (62.9%) | 36 (72.0%) |
| Median (95% CI), (Months) [a] | 7.33 (5.72, 8.41) | 8.87 (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9270 | |
| HR (95% CI) [c] | 1.035 (0.532, 2.013) | |
| HR P-Value [c] | 0.9195 | |
| Heterogeneity p-value [d] | 0.2877 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.0 (48.4, 78.9) | 52.3 (31.9, 69.3) |
| 12 months | 16.8 (4.4, 36.1) | NE (NE, NE) |
| 18 months | 16.8 (4.4, 36.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Dyspnoea - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 19 (30.6%) | 20 (40.0%) |
| Censored Patients, n (%) | 43 (69.4%) | 30 (60.0%) |
| Median (95% CI), (Months) [a] | 19.29 (5.59, NE) | 4.50 (2.79, 8.57) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0085 | |
| HR (95% CI) [c] | 0.428 (0.223, 0.821) | |
| HR P-Value [c] | 0.0106 | |
| Heterogeneity p-value [d] | 0.1072 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.5 (40.7, 72.6) | 37.3 (17.1, 57.6) |
| 12 months | 54.3 (36.1, 69.3) | 14.0 (1.2, 41.9) |
| 18 months | 54.3 (36.1, 69.3) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Emotional Functioning - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 26 (41.9%) | 14 (28.0%) |
| Censored Patients, n (%) | 36 (58.1%) | 36 (72.0%) |
| Median (95% CI), (Months) [a] | 5.95 (4.47, 19.35) | NE (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9105 | |
| HR (95% CI) [c] | 1.042 (0.541, 2.008) | |
| HR P-Value [c] | 0.9013 | |
| Heterogeneity p-value [d] | 0.4439 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.1 (32.2, 64.0) | 51.5 (30.4, 69.1) |
| 12 months | 33.2 (16.0, 51.4) | 51.5 (30.4, 69.1) |
| 18 months | 33.2 (16.0, 51.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Fatigue - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 33 (53.2%) | 27 (54.0%) |
| Censored Patients, n (%) | 29 (46.8%) | 23 (46.0%) |
| Median (95% CI), (Months) [a] | 2.99 (1.71, 4.90) | 2.30 (1.64, 3.15) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1131 | |
| HR (95% CI) [c] | 0.667 (0.399, 1.115) | |
| HR P-Value [c] | 0.1223 | |
| Heterogeneity p-value [d] | 0.6200 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 32.9 (19.5, 46.9) | 21.3 (8.9, 37.1) |
| 12 months | 27.4 (13.6, 43.1) | 0.0 (NE, NE) |
| 18 months | 27.4 (13.6, 43.1) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Financial Problems - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 17 (27.4%) | 13 (26.0%) |
| Censored Patients, n (%) | 45 (72.6%) | 37 (74.0%) |
| Median (95% CI), (Months) [a] | 18.89 (5.62, NE) | 12.48 (2.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2724 | |
| HR (95% CI) [c] | 0.664 (0.318, 1.386) | |
| HR P-Value [c] | 0.2754 | |
| Heterogeneity p-value [d] | 0.5419 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.9 (45.3, 76.2) | 60.7 (39.7, 76.3) |
| 12 months | 58.7 (40.4, 73.1) | 52.0 (28.3, 71.3) |
| 18 months | 58.7 (40.4, 73.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Nausea / Vomiting - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 23 (37.1%) | 23 (46.0%) |
| Censored Patients, n (%) | 39 (62.9%) | 27 (54.0%) |
| Median (95% CI), (Months) [a] | 7.43 (5.59, NE) | 2.10 (1.54, 4.17) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0040 | |
| HR (95% CI) [c] | 0.433 (0.241, 0.779) | |
| HR P-Value [c] | 0.0052 | |
| Heterogeneity p-value [d] | 0.7081 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.5 (40.1, 70.0) | 32.4 (16.5, 49.4) |
| 12 months | 44.4 (27.2, 60.3) | 0.0 (NE, NE) |
| 18 months | 44.4 (27.2, 60.3) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

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Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Pain - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 28 (45.2%) | 22 (44.0%) |
| Censored Patients, n (%) | 34 (54.8%) | 28 (56.0%) |
| Median (95% CI), (Months) [a] | 3.22 (1.58, 5.68) | 2.30 (1.77, 3.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4793 | |
| HR (95% CI) [c] | 0.823 (0.468, 1.445) | |
| HR P-Value [c] | 0.4973 | |
| Heterogeneity p-value [d] | 0.5518 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 30.0 (16.0, 45.4) | 24.8 (10.6, 42.1) |
| 12 months | 30.0 (16.0, 45.4) | NE (NE, NE) |
| 18 months | 30.0 (16.0, 45.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Physical Functioning - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 31 (50.0%) | 24 (48.0%) |
| Censored Patients, n (%) | 31 (50.0%) | 26 (52.0%) |
| Median (95% CI), (Months) [a] | 5.65 (2.86, 13.77) | 4.27 (1.77, 6.08) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0677 | |
| HR (95% CI) [c] | 0.603 (0.348, 1.044) | |
| HR P-Value [c] | 0.0708 | |
| Heterogeneity p-value [d] | 0.4138 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 45.2 (29.8, 59.4) | 35.3 (18.7, 52.5) |
| 12 months | 38.1 (22.9, 53.2) | 0.0 (NE, NE) |
| 18 months | 19.6 (6.1, 38.7) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Global health status / QoL - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 26 (41.9%) | 22 (44.0%) |
| Censored Patients, n (%) | 36 (58.1%) | 28 (56.0%) |
| Median (95% CI), (Months) [a] | 6.05 (2.79, NE) | 2.83 (1.77, 7.06) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1012 | |
| HR (95% CI) [c] | 0.627 (0.354, 1.111) | |
| HR P-Value [c] | 0.1100 | |
| Heterogeneity p-value [d] | 0.4846 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.0 (37.6, 66.3) | 33.1 (16.6, 50.7) |
| 12 months | 41.6 (25.4, 57.1) | 26.5 (10.7, 45.5) |
| 18 months | 41.6 (25.4, 57.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Role Functioning - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 32 (51.6%) | 25 (50.0%) |
| Censored Patients, n (%) | 30 (48.4%) | 25 (50.0%) |
| Median (95% CI), (Months) [a] | 4.21 (1.71, 8.41) | 2.79 (1.77, 4.27) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1516 | |
| HR (95% CI) [c] | 0.681 (0.399, 1.165) | |
| HR P-Value [c] | 0.1609 | |
| Heterogeneity p-value [d] | 0.9136 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 36.6 (22.3, 51.0) | 32.2 (16.6, 48.9) |
| 12 months | 32.0 (17.6, 47.4) | 0.0 (NE, NE) |
| 18 months | 27.5 (13.5, 43.5) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Social Functioning - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 23 (37.1%) | 17 (34.0%) |
| Censored Patients, n (%) | 39 (62.9%) | 33 (66.0%) |
| Median (95% CI), (Months) [a] | 6.05 (2.86, 20.76) | 7.06 (2.10, 12.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4847 | |
| HR (95% CI) [c] | 0.804 (0.425, 1.520) | |
| HR P-Value [c] | 0.5021 | |
| Heterogeneity p-value [d] | 0.4283 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.6 (37.2, 67.5) | 50.2 (30.3, 67.2) |
| 12 months | 49.8 (33.0, 64.4) | 41.9 (20.5, 62.0) |
| 18 months | 49.8 (33.0, 64.4) | 0.0 (NE, NE) |
| 24 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 30 months | 0.0 (NE, NE) | 0.0 (NE, NE) |
| 36 months | 0.0 (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.2a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Insomnia - 10 pts deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 20 (32.3%) | 17 (34.0%) |
| Censored Patients, n (%) | 42 (67.7%) | 33 (66.0%) |
| Median (95% CI), (Months) [a] | 4.90 (2.83, NE) | 4.63 (1.77, 12.48) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4500 | |
| HR (95% CI) [c] | 0.785 (0.410, 1.503) | |
| HR P-Value [c] | 0.4645 | |
| Heterogeneity p-value [d] | 0.4860 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 43.4 (25.6, 59.9) | 45.2 (25.0, 63.5) |
| 12 months | 43.4 (25.6, 59.9) | 22.6 (1.9, 57.2) |
| 18 months | 43.4 (25.6, 59.9) | 0.0 (NE, NE) |
| 24 months | NE (NE, NE) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:02, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 27 (25.7%) | 31 (30.1%) |
| Censored Patients, n (%) | 78 (74.3%) | 72 (69.9%) |
| Median (95% CI), (Months) [a] | 20.17 (11.43, NE) | 6.67 (4.67, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0085 | |
| HR (95% CI) [c] | 0.488 (0.282, 0.843) | |
| HR P-Value [c] | 0.0101 | |
| Heterogeneity p-value [d] | 0.2659 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.0 (59.8, 81.1) | 54.3 (39.9, 66.7) |
| 12 months | 61.0 (47.1, 72.3) | 19.7 (3.9, 44.3) |
| 18 months | 57.8 (43.2, 69.9) | 19.7 (3.9, 44.3) |
| 24 months | 46.2 (23.0, 66.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 27 (25.7%) | 27 (26.2%) |
| Censored Patients, n (%) | 78 (74.3%) | 76 (73.8%) |
| Median (95% CI), (Months) [a] | 17.05 (12.45, NE) | 8.90 (4.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0797 | |
| HR (95% CI) [c] | 0.609 (0.347, 1.067) | |
| HR P-Value [c] | 0.0829 | |
| Heterogeneity p-value [d] | 0.7570 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.6 (62.5, 83.3) | 56.3 (41.5, 68.6) |
| 12 months | 65.4 (51.3, 76.3) | 46.9 (26.1, 65.2) |
| 18 months | 45.1 (26.7, 61.8) | 46.9 (26.1, 65.2) |
| 24 months | 45.1 (26.7, 61.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 23 (21.9%) | 30 (29.1%) |
| Censored Patients, n (%) | 82 (78.1%) | 73 (70.9%) |
| Median (95% CI), (Months) [a] | NE (10.09, NE) | 6.97 (5.19, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0133 | |
| HR (95% CI) [c] | 0.499 (0.284, 0.875) | |
| HR P-Value [c] | 0.0153 | |
| Heterogeneity p-value [d] | 0.4939 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.9 (63.8, 84.4) | 61.2 (47.5, 72.4) |
| 12 months | 63.1 (49.1, 74.3) | 29.6 (8.0, 55.5) |
| 18 months | 63.1 (49.1, 74.3) | 29.6 (8.0, 55.5) |
| 24 months | 63.1 (49.1, 74.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 10 (9.5%) | 13 (12.6%) |
| Censored Patients, n (%) | 95 (90.5%) | 90 (87.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (8.84, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0386 | |
| HR (95% CI) [c] | 0.400 (0.164, 0.974) | |
| HR P-Value [c] | 0.0436 | |
| Heterogeneity p-value [d] | 0.2953 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 92.7 (83.0, 96.9) | 78.4 (63.8, 87.7) |
| 12 months | 78.2 (61.8, 88.1) | 69.7 (46.2, 84.5) |
| 18 months | 78.2 (61.8, 88.1) | 69.7 (46.2, 84.5) |
| 24 months | 78.2 (61.8, 88.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 24 (22.9%) | 24 (23.3%) |
| Censored Patients, n (%) | 81 (77.1%) | 79 (76.7%) |
| Median (95% CI), (Months) [a] | NE (11.93, NE) | 9.17 (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1756 | |
| HR (95% CI) [c] | 0.667 (0.369, 1.206) | |
| HR P-Value [c] | 0.1801 | |
| Heterogeneity p-value [d] | 0.6408 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.8 (61.8, 82.5) | 65.9 (52.1, 76.5) |
| 12 months | 64.0 (49.8, 75.1) | 47.9 (22.9, 69.2) |
| 18 months | 59.7 (44.0, 72.4) | 47.9 (22.9, 69.2) |
| 24 months | 59.7 (44.0, 72.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 20 (19.0%) | 28 (27.2%) |
| Censored Patients, n (%) | 85 (81.0%) | 75 (72.8%) |
| Median (95% CI), (Months) [a] | 20.17 (14.65, NE) | 7.10 (4.83, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0004 | |
| HR (95% CI) [c] | 0.325 (0.171, 0.620) | |
| HR P-Value [c] | 0.0006 | |
| Heterogeneity p-value [d] | 0.0657 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.6 (74.7, 92.0) | 60.7 (46.1, 72.4) |
| 12 months | 73.2 (58.4, 83.5) | 31.1 (10.6, 54.4) |
| 18 months | 61.6 (43.3, 75.5) | 31.1 (10.6, 54.4) |
| 24 months | 36.9 (11.7, 63.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 43 (41.0%) | 44 (42.7%) |
| Censored Patients, n (%) | 62 (59.0%) | 59 (57.3%) |
| Median (95% CI), (Months) [a] | 11.10 (5.82, 14.55) | 4.40 (1.97, 6.24) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0154 | |
| HR (95% CI) [c] | 0.581 (0.372, 0.908) | |
| HR P-Value [c] | 0.0171 | |
| Heterogeneity p-value [d] | 0.0783 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.6 (47.6, 69.7) | 42.8 (29.4, 55.5) |
| 12 months | 41.3 (28.6, 53.7) | 20.8 (8.2, 37.3) |
| 18 months | 35.0 (21.8, 48.5) | 20.8 (8.2, 37.3) |
| 24 months | 26.3 (10.7, 45.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 19 (18.1%) | 22 (21.4%) |
| Censored Patients, n (%) | 86 (81.9%) | 81 (78.6%) |
| Median (95% CI), (Months) [a] | 20.80 (12.48, NE) | 8.84 (6.14, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0063 | |
| HR (95% CI) [c] | 0.410 (0.212, 0.791) | |
| HR P-Value [c] | 0.0079 | |
| Heterogeneity p-value [d] | 0.4500 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.0 (69.5, 89.7) | 69.1 (53.7, 80.3) |
| 12 months | 69.5 (54.3, 80.5) | 31.7 (8.0, 59.4) |
| 18 months | 62.1 (45.1, 75.2) | 31.7 (8.0, 59.4) |
| 24 months | 49.7 (23.9, 71.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 21 (20.0%) | 26 (25.2%) |
| Censored Patients, n (%) | 84 (80.0%) | 77 (74.8%) |
| Median (95% CI), (Months) [a] | NE (14.03, NE) | 11.93 (5.75, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0048 | |
| HR (95% CI) [c] | 0.419 (0.226, 0.778) | |
| HR P-Value [c] | 0.0058 | |
| Heterogeneity p-value [d] | 0.8391 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.7 (74.9, 92.1) | 63.6 (49.4, 74.9) |
| 12 months | 66.8 (51.4, 78.3) | 36.4 (9.0, 65.4) |
| 18 months | 52.1 (32.3, 68.6) | 36.4 (9.0, 65.4) |
| 24 months | 52.1 (32.3, 68.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 31 (29.5%) | 40 (38.8%) |
| Censored Patients, n (%) | 74 (70.5%) | 63 (61.2%) |
| Median (95% CI), (Months) [a] | 12.45 (9.89, NE) | 4.40 (2.96, 6.47) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0007 | |
| HR (95% CI) [c] | 0.435 (0.266, 0.712) | |
| HR P-Value [c] | 0.0009 | |
| Heterogeneity p-value [d] | 0.2711 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.8 (55.1, 77.7) | 37.9 (25.0, 50.8) |
| 12 months | 51.1 (36.6, 63.9) | 22.8 (6.6, 44.6) |
| 18 months | 48.3 (33.6, 61.5) | 22.8 (6.6, 44.6) |
| 24 months | 32.2 (9.0, 58.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 27 (25.7%) | 34 (33.0%) |
| Censored Patients, n (%) | 78 (74.3%) | 69 (67.0%) |
| Median (95% CI), (Months) [a] | 20.17 (14.03, NE) | 7.00 (4.14, 11.93) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0008 | |
| HR (95% CI) [c] | 0.398 (0.229, 0.692) | |
| HR P-Value [c] | 0.0011 | |
| Heterogeneity p-value [d] | 0.4294 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.7 (64.9, 84.9) | 55.0 (41.6, 66.5) |
| 12 months | 66.5 (52.1, 77.4) | 24.2 (5.9, 49.0) |
| 18 months | 51.0 (33.6, 66.0) | 24.2 (5.9, 49.0) |
| 24 months | 30.6 (10.0, 54.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 32 (30.5%) | 38 (36.9%) |
| Censored Patients, n (%) | 73 (69.5%) | 65 (63.1%) |
| Median (95% CI), (Months) [a] | 10.12 (8.48, NE) | 6.24 (3.68, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0006 | |
| HR (95% CI) [c] | 0.429 (0.261, 0.705) | |
| HR P-Value [c] | 0.0008 | |
| Heterogeneity p-value [d] | 0.7396 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.1 (66.1, 86.3) | 51.7 (38.4, 63.5) |
| 12 months | 45.8 (31.9, 58.7) | 18.8 (4.3, 41.2) |
| 18 months | 42.5 (28.4, 56.0) | 18.8 (4.3, 41.2) |
| 24 months | 42.5 (28.4, 56.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 28 (26.7%) | 40 (38.8%) |
| Censored Patients, n (%) | 77 (73.3%) | 63 (61.2%) |
| Median (95% CI), (Months) [a] | 14.26 (12.48, NE) | 4.40 (3.35, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| HR (95% CI) [c] | 0.347 (0.207, 0.583) | |
| HR P-Value [c] | <0.0001 | |
| Heterogeneity p-value [d] | 0.0496 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.5 (65.9, 85.6) | 42.6 (29.3, 55.3) |
| 12 months | 65.3 (50.8, 76.5) | 16.2 (3.8, 36.5) |
| 18 months | 38.8 (21.6, 55.7) | 16.2 (3.8, 36.5) |
| 24 months | 38.8 (21.6, 55.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 28 (26.7%) | 38 (36.9%) |
| Censored Patients, n (%) | 77 (73.3%) | 65 (63.1%) |
| Median (95% CI), (Months) [a] | 20.17 (10.45, 20.83) | 5.68 (2.86, 8.84) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0002 | |
| HR (95% CI) [c] | 0.378 (0.223, 0.640) | |
| HR P-Value [c] | 0.0003 | |
| Heterogeneity p-value [d] | 0.0749 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.1 (63.7, 84.7) | 49.2 (35.8, 61.3) |
| 12 months | 61.2 (46.8, 72.7) | 31.6 (16.5, 48.0) |
| 18 months | 53.3 (37.0, 67.2) | 31.6 (16.5, 48.0) |
| 24 months | 21.3 (4.2, 47.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=105) | Chemotherapy (N=103) |
|---|---|---|
| Patients with event, n (%) | 31 (29.5%) | 26 (25.2%) |
| Censored Patients, n (%) | 74 (70.5%) | 77 (74.8%) |
| Median (95% CI), (Months) [a] | 16.66 (9.59, NE) | 8.90 (6.67, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3090 | |
| HR (95% CI) [c] | 0.754 (0.434, 1.308) | |
| HR P-Value [c] | 0.3148 | |
| Heterogeneity p-value [d] | 0.7553 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.4 (54.6, 77.3) | 70.0 (57.5, 79.5) |
| 12 months | 52.5 (37.9, 65.2) | 37.4 (15.2, 59.9) |
| 18 months | 43.8 (27.6, 58.8) | 37.4 (15.2, 59.9) |
| 24 months | 29.2 (8.1, 54.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 6 (20.7%) | 5 (16.7%) |
| Censored Patients, n (%) | 23 (79.3%) | 25 (83.3%) |
| Median (95% CI), (Months) [a] | 10.18 (3.19, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7111 | |
| HR (95% CI) [c] | 1.257 (0.380, 4.152) | |
| HR P-Value [c] | 0.7076 | |
| Heterogeneity p-value [d] | 0.2659 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.5 (37.3, 85.5) | 70.6 (43.0, 86.6) |
| 12 months | 33.7 (1.7, 74.8) | 70.6 (43.0, 86.6) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 5 (17.2%) | 9 (30.0%) |
| Censored Patients, n (%) | 24 (82.8%) | 21 (70.0%) |
| Median (95% CI), (Months) [a] | 13.83 (13.83, NE) | 7.16 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1211 | |
| HR (95% CI) [c] | 0.406 (0.125, 1.322) | |
| HR P-Value [c] | 0.1346 | |
| Heterogeneity p-value [d] | 0.7570 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 80.4 (55.8, 92.2) | 56.4 (31.2, 75.5) |
| 12 months | 80.4 (55.8, 92.2) | 48.4 (23.3, 69.7) |
| 18 months | 40.2 (1.4, 82.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 4 (13.8%) | 4 (13.3%) |
| Censored Patients, n (%) | 25 (86.2%) | 26 (86.7%) |
| Median (95% CI), (Months) [a] | 15.11 (15.11, NE) | 11.50 (8.97, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6834 | |
| HR (95% CI) [c] | 0.732 (0.163, 3.293) | |
| HR P-Value [c] | 0.6846 | |
| Heterogeneity p-value [d] | 0.4939 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.1 (51.9, 93.5) | 85.7 (53.9, 96.2) |
| 12 months | 81.1 (51.9, 93.5) | 34.3 (1.5, 76.2) |
| 18 months | 40.5 (1.4, 82.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 3 (10.3%) | 2 (6.7%) |
| Censored Patients, n (%) | 26 (89.7%) | 28 (93.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6393 | |
| HR (95% CI) [c] | 1.534 (0.256, 9.194) | |
| HR P-Value [c] | 0.6393 | |
| Heterogeneity p-value [d] | 0.2953 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.4 (58.9, 94.7) | 88.0 (59.4, 96.9) |
| 12 months | 84.4 (58.9, 94.7) | 88.0 (59.4, 96.9) |
| 18 months | 84.4 (58.9, 94.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 4 (13.8%) | 7 (23.3%) |
| Censored Patients, n (%) | 25 (86.2%) | 23 (76.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 10.35 (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4232 | |
| HR (95% CI) [c] | 0.614 (0.179, 2.101) | |
| HR P-Value [c] | 0.4368 | |
| Heterogeneity p-value [d] | 0.6408 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 77.8 (51.0, 91.1) | 65.1 (38.2, 82.6) |
| 12 months | 77.8 (51.0, 91.1) | 48.8 (16.4, 75.3) |
| 18 months | 77.8 (51.0, 91.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 6 (20.7%) | 5 (16.7%) |
| Censored Patients, n (%) | 23 (79.3%) | 25 (83.3%) |
| Median (95% CI), (Months) [a] | NE (3.19, NE) | NE (3.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4921 | |
| HR (95% CI) [c] | 1.522 (0.460, 5.034) | |
| HR P-Value [c] | 0.4911 | |
| Heterogeneity p-value [d] | 0.0657 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.3 (35.9, 84.8) | 76.5 (48.7, 90.5) |
| 12 months | 53.0 (20.7, 77.5) | 63.8 (29.8, 84.6) |
| 18 months | 53.0 (20.7, 77.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 14 (48.3%) | 10 (33.3%) |
| Censored Patients, n (%) | 15 (51.7%) | 20 (66.7%) |
| Median (95% CI), (Months) [a] | 4.30 (1.48, 9.69) | 8.54 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3523 | |
| HR (95% CI) [c] | 1.484 (0.646, 3.413) | |
| HR P-Value [c] | 0.3524 | |
| Heterogeneity p-value [d] | 0.0783 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 38.8 (16.8, 60.4) | 66.2 (39.6, 83.2) |
| 12 months | 19.4 (3.7, 44.3) | 17.7 (1.3, 50.4) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |
| 36 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 4 (13.8%) | 4 (13.3%) |
| Censored Patients, n (%) | 25 (86.2%) | 26 (86.7%) |
| Median (95% CI), (Months) [a] | NE (5.13, NE) | 11.50 (10.35, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8297 | |
| HR (95% CI) [c] | 1.165 (0.286, 4.749) | |
| HR P-Value [c] | 0.8309 | |
| Heterogeneity p-value [d] | 0.4500 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 81.0 (49.7, 93.9) | 86.9 (56.5, 96.6) |
| 12 months | 67.5 (30.2, 87.9) | 46.3 (7.5, 79.6) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 4 (13.8%) | 7 (23.3%) |
| Censored Patients, n (%) | 25 (86.2%) | 23 (76.7%) |
| Median (95% CI), (Months) [a] | NE (9.69, NE) | NE (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2882 | |
| HR (95% CI) [c] | 0.520 (0.152, 1.778) | |
| HR P-Value [c] | 0.2972 | |
| Heterogeneity p-value [d] | 0.8391 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.1 (58.3, 94.6) | 61.6 (35.4, 79.7) |
| 12 months | 63.1 (18.4, 88.2) | NE (NE, NE) |
| 18 months | 63.1 (18.4, 88.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 6 (20.7%) | 6 (20.0%) |
| Censored Patients, n (%) | 23 (79.3%) | 24 (80.0%) |
| Median (95% CI), (Months) [a] | 10.18 (4.27, NE) | 10.35 (3.48, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6926 | |
| HR (95% CI) [c] | 1.271 (0.401, 4.029) | |
| HR P-Value [c] | 0.6834 | |
| Heterogeneity p-value [d] | 0.2711 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.0 (41.5, 86.5) | 76.6 (48.8, 90.5) |
| 12 months | 35.0 (1.7, 76.3) | 45.9 (12.6, 74.7) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 9 (31.0%) | 11 (36.7%) |
| Censored Patients, n (%) | 20 (69.0%) | 19 (63.3%) |
| Median (95% CI), (Months) [a] | 8.34 (2.07, 10.18) | 4.37 (1.51, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7129 | |
| HR (95% CI) [c] | 0.840 (0.346, 2.039) | |
| HR P-Value [c] | 0.7001 | |
| Heterogeneity p-value [d] | 0.4294 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.9 (44.3, 87.5) | 45.9 (22.8, 66.4) |
| 12 months | 16.0 (0.9, 48.8) | 34.4 (11.5, 59.2) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 6 (20.7%) | 9 (30.0%) |
| Censored Patients, n (%) | 23 (79.3%) | 21 (70.0%) |
| Median (95% CI), (Months) [a] | 8.34 (2.53, NE) | 8.54 (1.58, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6740 | |
| HR (95% CI) [c] | 0.798 (0.282, 2.257) | |
| HR P-Value [c] | 0.6708 | |
| Heterogeneity p-value [d] | 0.7396 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.8 (46.9, 90.3) | 55.1 (29.7, 74.6) |
| 12 months | 37.9 (6.2, 71.2) | 44.1 (17.8, 67.8) |
| 18 months | 37.9 (6.2, 71.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 8 (27.6%) | 6 (20.0%) |
| Censored Patients, n (%) | 21 (72.4%) | 24 (80.0%) |
| Median (95% CI), (Months) [a] | 8.34 (1.58, NE) | NE (1.64, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5030 | |
| HR (95% CI) [c] | 1.438 (0.495, 4.177) | |
| HR P-Value [c] | 0.5042 | |
| Heterogeneity p-value [d] | 0.0496 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.2 (32.0, 80.9) | 63.3 (35.8, 81.6) |
| 12 months | 22.9 (1.5, 59.9) | 63.3 (35.8, 81.6) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 6 (20.7%) | 4 (13.3%) |
| Censored Patients, n (%) | 23 (79.3%) | 26 (86.7%) |
| Median (95% CI), (Months) [a] | 10.18 (3.09, NE) | NE (8.02, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3065 | |
| HR (95% CI) [c] | 1.924 (0.537, 6.890) | |
| HR P-Value [c] | 0.3147 | |
| Heterogeneity p-value [d] | 0.0749 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.3 (37.3, 85.3) | 86.2 (55.0, 96.4) |
| 12 months | 33.6 (1.7, 74.6) | 61.5 (24.8, 84.4) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=29) | Chemotherapy (N=30) |
|---|---|---|
| Patients with event, n (%) | 5 (17.2%) | 5 (16.7%) |
| Censored Patients, n (%) | 24 (82.8%) | 25 (83.3%) |
| Median (95% CI), (Months) [a] | NE (4.27, NE) | NE (7.39, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9876 | |
| HR (95% CI) [c] | 1.002 (0.288, 3.491) | |
| HR P-Value [c] | 0.9973 | |
| Heterogeneity p-value [d] | 0.7553 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 75.3 (46.4, 90.0) | 82.4 (54.7, 93.9) |
| 12 months | 64.5 (32.4, 84.3) | 60.0 (26.0, 82.4) |
| 18 months | 64.5 (32.4, 84.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Appetite loss - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 16 (25.8%) | 17 (34.0%) |
| Censored Patients, n (%) | 46 (74.2%) | 33 (66.0%) |
| Median (95% CI), (Months) [a] | NE (6.21, NE) | 9.69 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0372 | |
| HR (95% CI) [c] | 0.485 (0.242, 0.972) | |
| HR P-Value [c] | 0.0413 | |
| Heterogeneity p-value [d] | 0.2659 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.8 (54.0, 82.4) | 54.1 (35.3, 69.5) |
| 12 months | 57.4 (37.5, 73.1) | 18.0 (1.2, 51.7) |
| 18 months | 57.4 (37.5, 73.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Cognitive Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 15 (24.2%) | 15 (30.0%) |
| Censored Patients, n (%) | 47 (75.8%) | 35 (70.0%) |
| Median (95% CI), (Months) [a] | NE (16.53, NE) | 6.08 (2.99, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0529 | |
| HR (95% CI) [c] | 0.488 (0.232, 1.027) | |
| HR P-Value [c] | 0.0587 | |
| Heterogeneity p-value [d] | 0.7570 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.0 (56.6, 84.0) | 53.8 (33.8, 70.2) |
| 12 months | 68.4 (50.3, 81.1) | 48.4 (28.2, 66.0) |
| 18 months | 51.3 (26.5, 71.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Constipation - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 13 (21.0%) | 9 (18.0%) |
| Censored Patients, n (%) | 49 (79.0%) | 41 (82.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 14.13 (14.13, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7631 | |
| HR (95% CI) [c] | 0.878 (0.374, 2.062) | |
| HR P-Value [c] | 0.7649 | |
| Heterogeneity p-value [d] | 0.4939 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.7 (59.6, 84.8) | 73.1 (52.6, 85.9) |
| 12 months | 69.4 (51.2, 81.9) | 73.1 (52.6, 85.9) |
| 18 months | 69.4 (51.2, 81.9) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Diarhoea - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 11 (17.7%) | 6 (12.0%) |
| Censored Patients, n (%) | 51 (82.3%) | 44 (88.0%) |
| Median (95% CI), (Months) [a] | 18.10 (8.34, NE) | NE (8.87, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8019 | |
| HR (95% CI) [c] | 0.877 (0.311, 2.472) | |
| HR P-Value [c] | 0.8041 | |
| Heterogeneity p-value [d] | 0.2953 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 84.2 (67.1, 92.9) | 82.0 (61.8, 92.1) |
| 12 months | 68.4 (45.6, 83.3) | 65.6 (27.5, 87.1) |
| 18 months | 59.9 (34.0, 78.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Dyspnoea - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 7 (11.3%) | 10 (20.0%) |
| Censored Patients, n (%) | 55 (88.7%) | 40 (80.0%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (5.65, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0387 | |
| HR (95% CI) [c] | 0.358 (0.130, 0.989) | |
| HR P-Value [c] | 0.0475 | |
| Heterogeneity p-value [d] | 0.6408 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.8 (74.4, 95.3) | 64.3 (40.5, 80.6) |
| 12 months | 84.5 (67.2, 93.1) | 57.9 (33.6, 76.0) |
| 18 months | 74.0 (44.3, 89.4) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Emotional Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 10 (16.1%) | 4 (8.0%) |
| Censored Patients, n (%) | 52 (83.9%) | 46 (92.0%) |
| Median (95% CI), (Months) [a] | NE (16.85, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5808 | |
| HR (95% CI) [c] | 1.396 (0.430, 4.539) | |
| HR P-Value [c] | 0.5789 | |
| Heterogeneity p-value [d] | 0.0657 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.8 (69.6, 91.7) | 87.7 (70.4, 95.2) |
| 12 months | 78.8 (61.0, 89.2) | 87.7 (70.4, 95.2) |
| 18 months | 69.0 (42.1, 85.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

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Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Fatigue - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 22 (35.5%) | 20 (40.0%) |
| Censored Patients, n (%) | 40 (64.5%) | 30 (60.0%) |
| Median (95% CI), (Months) [a] | 16.53 (4.86, NE) | 3.38 (2.10, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0875 | |
| HR (95% CI) [c] | 0.596 (0.323, 1.102) | |
| HR P-Value [c] | 0.0987 | |
| Heterogeneity p-value [d] | 0.0783 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.8 (38.9, 68.2) | 41.8 (24.6, 58.1) |
| 12 months | 54.8 (38.9, 68.2) | 31.4 (12.0, 53.1) |
| 18 months | 47.0 (27.4, 64.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Financial Problems - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 14 (22.6%) | 10 (20.0%) |
| Censored Patients, n (%) | 48 (77.4%) | 40 (80.0%) |
| Median (95% CI), (Months) [a] | NE (9.76, NE) | NE (4.17, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4759 | |
| HR (95% CI) [c] | 0.743 (0.327, 1.686) | |
| HR P-Value [c] | 0.4767 | |
| Heterogeneity p-value [d] | 0.4500 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.2 (56.1, 84.5) | 67.5 (46.2, 81.9) |
| 12 months | 63.6 (43.3, 78.3) | 59.1 (34.3, 77.1) |
| 18 months | 55.6 (32.5, 73.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Nausea / Vomiting - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 14 (22.6%) | 11 (22.0%) |
| Censored Patients, n (%) | 48 (77.4%) | 39 (78.0%) |
| Median (95% CI), (Months) [a] | NE (7.43, NE) | 11.07 (5.82, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3718 | |
| HR (95% CI) [c] | 0.699 (0.315, 1.547) | |
| HR P-Value [c] | 0.3766 | |
| Heterogeneity p-value [d] | 0.8391 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 73.2 (56.9, 84.2) | 69.7 (47.8, 83.8) |
| 12 months | 65.2 (46.8, 78.6) | 31.0 (1.9, 70.7) |
| 18 months | 65.2 (46.8, 78.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Pain - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 15 (24.2%) | 14 (28.0%) |
| Censored Patients, n (%) | 47 (75.8%) | 36 (72.0%) |
| Median (95% CI), (Months) [a] | 19.15 (5.72, NE) | 11.07 (2.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2691 | |
| HR (95% CI) [c] | 0.658 (0.311, 1.389) | |
| HR P-Value [c] | 0.2722 | |
| Heterogeneity p-value [d] | 0.2711 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.2 (49.2, 78.6) | 55.2 (35.0, 71.4) |
| 12 months | 66.2 (49.2, 78.6) | 27.6 (2.0, 65.3) |
| 18 months | 66.2 (49.2, 78.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Physical Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 20 (32.3%) | 19 (38.0%) |
| Censored Patients, n (%) | 42 (67.7%) | 31 (62.0%) |
| Median (95% CI), (Months) [a] | NE (5.72, NE) | 6.08 (3.38, 9.72) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0694 | |
| HR (95% CI) [c] | 0.559 (0.296, 1.055) | |
| HR P-Value [c] | 0.0727 | |
| Heterogeneity p-value [d] | 0.4294 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.6 (45.4, 74.3) | 50.9 (31.0, 67.6) |
| 12 months | 53.2 (35.3, 68.1) | 23.1 (4.8, 49.3) |
| 18 months | 53.2 (35.3, 68.1) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Global health status / QoL - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 17 (27.4%) | 16 (32.0%) |
| Censored Patients, n (%) | 45 (72.6%) | 34 (68.0%) |
| Median (95% CI), (Months) [a] | NE (7.33, NE) | 7.06 (2.56, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1051 | |
| HR (95% CI) [c] | 0.569 (0.284, 1.141) | |
| HR P-Value [c] | 0.1122 | |
| Heterogeneity p-value [d] | 0.7396 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.9 (53.3, 80.3) | 50.1 (29.9, 67.3) |
| 12 months | 64.9 (48.0, 77.5) | 43.8 (23.5, 62.6) |
| 18 months | 56.8 (35.1, 73.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Role Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 18 (29.0%) | 13 (26.0%) |
| Censored Patients, n (%) | 44 (71.0%) | 37 (74.0%) |
| Median (95% CI), (Months) [a] | NE (5.59, NE) | 9.72 (3.38, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6653 | |
| HR (95% CI) [c] | 0.853 (0.415, 1.751) | |
| HR P-Value [c] | 0.6642 | |
| Heterogeneity p-value [d] | 0.0496 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 62.0 (45.6, 74.8) | 66.2 (47.0, 79.8) |
| 12 months | 62.0 (45.6, 74.8) | 40.1 (9.6, 70.0) |
| 18 months | 56.4 (37.8, 71.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Social Functioning - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 13 (21.0%) | 11 (22.0%) |
| Censored Patients, n (%) | 49 (79.0%) | 39 (78.0%) |
| Median (95% CI), (Months) [a] | 20.76 (15.44, NE) | NE (4.44, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2369 | |
| HR (95% CI) [c] | 0.606 (0.260, 1.417) | |
| HR P-Value [c] | 0.2480 | |
| Heterogeneity p-value [d] | 0.0749 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 78.8 (63.8, 88.2) | 63.7 (41.7, 79.3) |
| 12 months | 72.3 (51.9, 85.1) | 56.7 (33.1, 74.6) |
| 18 months | 63.2 (37.6, 80.7) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 18.3.4a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Insomnia - 10 pts sustained deterioration

| | Cemiplimab (N=62) | Chemotherapy (N=50) |
|---|---|---|
| Patients with event, n (%) | 11 (17.7%) | 10 (20.0%) |
| Censored Patients, n (%) | 51 (82.3%) | 40 (80.0%) |
| Median (95% CI), (Months) [a] | NE (8.25, NE) | 9.72 (9.72, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1476 | |
| HR (95% CI) [c] | 0.522 (0.214, 1.273) | |
| HR P-Value [c] | 0.1530 | |
| Heterogeneity p-value [d] | 0.7553 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.5 (57.8, 87.8) | 72.4 (51.6, 85.4) |
| 12 months | 63.6 (39.7, 80.1) | 24.1 (1.2, 63.4) |
| 18 months | 53.0 (25.8, 74.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |
| 36 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-sub-pdl1.sas (23JAN23:12:16:12, yingyuan.lin)

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65

| | Cemiplimab (N=179) | Chemotherapy (N=153) |
|---|---|---|
| Patients with event, n (%) | 50 (27.9%) | 46 (30.1%) |
| Censored Patients, n (%) | 129 (72.1%) | 107 (69.9%) |
| Median (95% CI), (Months) [a] | NE (13.63, NE) | NE (7.79, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.12323 | |
| HR (95% CI) [c] | 0.788 (0.526, 1.180) | |
| HR P-Value [c] | 0.2473 | |
| Heterogeneity p-value [d] | 0.9524 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.6 (63.2, 78.4) | 64.5 (54.0, 73.2) |
| 12 months | 61.2 (50.2, 70.5) | 56.9 (42.8, 68.7) |
| 18 months | 58.0 (45.7, 68.5) | 56.9 (42.8, 68.7) |
| 24 months | 58.0 (45.7, 68.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

| | Cemiplimab (N=16) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 6 (31.6%) |
| Censored Patients, n (%) | 10 (62.5%) | 13 (68.4%) |
| Median (95% CI), (Months) [a] | 16.10 (5.22, NE) | NE (1.64, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.23146 | |
| HR (95% CI) [c] | 0.622 (0.173, 2.237) | |
| HR P-Value [c] | 0.4669 | |
| Heterogeneity p-value [d] | 0.9524 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.1 (38.4, 88.6) | 64.2 (36.0, 82.5) |
| 12 months | 71.1 (38.4, 88.6) | NE (NE, NE) |
| 18 months | 37.9 (7.0, 70.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

| | Cemiplimab (N=135) | Chemotherapy (N=115) |
|---|---|---|
| Patients with event, n (%) | 30 (22.2%) | 30 (26.1%) |
| Censored Patients, n (%) | 105 (77.8%) | 85 (73.9%) |
| Median (95% CI), (Months) [a] | NE (16.10, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.05585 | |
| HR (95% CI) [c] | 0.661 (0.395, 1.105) | |
| HR P-Value [c] | 0.1144 | |
| Heterogeneity p-value [d] | 0.2196 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 76.8 (67.1, 84.0) | 70.2 (58.9, 78.9) |
| 12 months | 69.9 (57.7, 79.2) | 65.5 (51.0, 76.6) |
| 18 months | 62.1 (46.5, 74.3) | 65.5 (51.0, 76.6) |
| 24 months | 62.1 (46.5, 74.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

| | Cemiplimab (N=60) | Chemotherapy (N=57) |
|---|---|---|
| Patients with event, n (%) | 26 (43.3%) | 22 (38.6%) |
| Censored Patients, n (%) | 34 (56.7%) | 35 (61.4%) |
| Median (95% CI), (Months) [a] | 7.16 (2.23, NE) | 8.38 (4.76, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.47503 | |
| HR (95% CI) [c] | 1.018 (0.573, 1.810) | |
| HR P-Value [c] | 0.9513 | |
| Heterogeneity p-value [d] | 0.2196 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.4 (46.0, 72.1) | 51.1 (31.5, 67.6) |
| 12 months | 40.8 (20.9, 59.9) | 34.0 (8.8, 62.1) |
| 18 months | 27.2 (6.8, 53.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America

| | Cemiplimab (N=22) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 12 (57.1%) |
| Censored Patients, n (%) | 16 (72.7%) | 9 (42.9%) |
| Median (95% CI), (Months) [a] | NE (3.45, NE) | 3.71 (0.82, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.01379 | |
| HR (95% CI) [c] | 0.346 (0.129, 0.927) | |
| HR P-Value [c] | 0.0349 | |
| Heterogeneity p-value [d] | 0.1522 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.1 (46.6, 85.9) | 36.3 (12.2, 61.3) |
| 12 months | 71.1 (46.6, 85.9) | 24.2 (4.7, 51.7) |
| 18 months | 71.1 (46.6, 85.9) | 24.2 (4.7, 51.7) |
| 24 months | 71.1 (46.6, 85.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia

| | Cemiplimab (N=39) | Chemotherapy (N=33) |
|---|---|---|
| Patients with event, n (%) | 17 (43.6%) | 11 (33.3%) |
| Censored Patients, n (%) | 22 (56.4%) | 22 (66.7%) |
| Median (95% CI), (Months) [a] | 8.31 (2.10, NE) | 8.38 (4.76, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.36598 | |
| HR (95% CI) [c] | 1.139 (0.529, 2.452) | |
| HR P-Value [c] | 0.7399 | |
| Heterogeneity p-value [d] | 0.1522 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.5 (46.6, 77.8) | 60.4 (33.9, 79.1) |
| 12 months | 43.6 (21.5, 63.8) | 40.3 (8.9, 71.0) |
| 18 months | 32.7 (10.9, 56.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe

| | Cemiplimab (N=75) | Chemotherapy (N=63) |
|---|---|---|
| Patients with event, n (%) | 15 (20.0%) | 9 (14.3%) |
| Censored Patients, n (%) | 60 (80.0%) | 54 (85.7%) |
| Median (95% CI), (Months) [a] | NE (16.10, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.40411 | |
| HR (95% CI) [c] | 1.110 (0.477, 2.586) | |
| HR P-Value [c] | 0.8085 | |
| Heterogeneity p-value [d] | 0.1522 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 79.8 (66.3, 88.3) | 82.5 (67.8, 90.9) |
| 12 months | 71.7 (54.2, 83.4) | 82.5 (67.8, 90.9) |
| 18 months | 62.7 (38.7, 79.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW

| | Cemiplimab (N=59) | Chemotherapy (N=55) |
|---|---|---|
| Patients with event, n (%) | 18 (30.5%) | 20 (36.4%) |
| Censored Patients, n (%) | 41 (69.5%) | 35 (63.6%) |
| Median (95% CI), (Months) [a] | 13.63 (5.22, NE) | NE (4.86, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.12699 | |
| HR (95% CI) [c] | 0.687 (0.358, 1.316) | |
| HR P-Value [c] | 0.2571 | |
| Heterogeneity p-value [d] | 0.1522 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 66.4 (49.8, 78.6) | 57.9 (40.6, 71.8) |
| 12 months | 59.0 (38.2, 74.9) | 57.9 (40.6, 71.8) |
| 18 months | 44.2 (16.4, 69.2) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

| | Cemiplimab (N=160) | Chemotherapy (N=133) |
|---|---|---|
| Patients with event, n (%) | 44 (27.5%) | 38 (28.6%) |
| Censored Patients, n (%) | 116 (72.5%) | 95 (71.4%) |
| Median (95% CI), (Months) [a] | NE (13.63, NE) | NE (7.79, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.09673 | |
| HR (95% CI) [c] | 0.746 (0.479, 1.162) | |
| HR P-Value [c] | 0.1953 | |
| Heterogeneity p-value [d] | 0.7635 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.9 (63.9, 80.0) | 64.7 (52.8, 74.3) |
| 12 months | 64.0 (52.9, 73.2) | 56.0 (40.2, 69.1) |
| 18 months | 54.8 (40.9, 66.8) | NE (NE, NE) |
| 24 months | 54.8 (40.9, 66.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

| | Cemiplimab (N=35) | Chemotherapy (N=39) |
|---|---|---|
| Patients with event, n (%) | 12 (34.3%) | 14 (35.9%) |
| Censored Patients, n (%) | 23 (65.7%) | 25 (64.1%) |
| Median (95% CI), (Months) [a] | NE (2.17, NE) | NE (2.23, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.40837 | |
| HR (95% CI) [c] | 0.912 (0.421, 1.975) | |
| HR P-Value [c] | 0.8155 | |
| Heterogeneity p-value [d] | 0.7635 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 64.7 (45.1, 78.8) | 62.6 (45.1, 76.0) |
| 12 months | 56.6 (33.6, 74.4) | 62.6 (45.1, 76.0) |
| 18 months | NE (NE, NE) | 62.6 (45.1, 76.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

| | Cemiplimab (N=87) | Chemotherapy (N=76) |
|---|---|---|
| Patients with event, n (%) | 29 (33.3%) | 18 (23.7%) |
| Censored Patients, n (%) | 58 (66.7%) | 58 (76.3%) |
| Median (95% CI), (Months) [a] | 16.10 (8.31, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.43491 | |
| HR (95% CI) [c] | 1.051 (0.575, 1.922) | |
| HR P-Value [c] | 0.8710 | |
| Heterogeneity p-value [d] | 0.1424 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.8 (55.3, 77.5) | 73.8 (61.5, 82.8) |
| 12 months | 51.5 (33.7, 66.8) | 73.8 (61.5, 82.8) |
| 18 months | 38.6 (15.1, 62.0) | NE (NE, NE) |
| 24 months | 38.6 (15.1, 62.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

| | Cemiplimab (N=108) | Chemotherapy (N=96) |
|---|---|---|
| Patients with event, n (%) | 27 (25.0%) | 34 (35.4%) |
| Censored Patients, n (%) | 81 (75.0%) | 62 (64.6%) |
| Median (95% CI), (Months) [a] | NE (13.83, NE) | NE (5.13, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.02984 | |
| HR (95% CI) [c] | 0.615 (0.369, 1.025) | |
| HR P-Value [c] | 0.0619 | |
| Heterogeneity p-value [d] | 0.1424 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.9 (64.2, 82.9) | 59.9 (46.9, 70.7) |
| 12 months | 69.8 (57.2, 79.4) | 52.4 (37.2, 65.5) |
| 18 months | 61.6 (45.5, 74.2) | 52.4 (37.2, 65.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

| | Cemiplimab (N=83) | Chemotherapy (N=64) |
|---|---|---|
| Patients with event, n (%) | 25 (30.1%) | 17 (26.6%) |
| Censored Patients, n (%) | 58 (69.9%) | 47 (73.4%) |
| Median (95% CI), (Months) [a] | NE (13.63, NE) | NE (4.76, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.30242 | |
| HR (95% CI) [c] | 0.846 (0.448, 1.598) | |
| HR P-Value [c] | 0.6061 | |
| Heterogeneity p-value [d] | 0.6747 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.0 (60.0, 81.0) | 62.2 (41.2, 77.5) |
| 12 months | 68.8 (55.3, 78.9) | 53.3 (29.1, 72.5) |
| 18 months | 54.2 (35.5, 69.6) | NE (NE, NE) |
| 24 months | 54.2 (35.5, 69.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

| | Cemiplimab (N=112) | Chemotherapy (N=108) |
|---|---|---|
| Patients with event, n (%) | 31 (27.7%) | 35 (32.4%) |
| Censored Patients, n (%) | 81 (72.3%) | 73 (67.6%) |
| Median (95% CI), (Months) [a] | NE (8.31, NE) | NE (7.79, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.10708 | |
| HR (95% CI) [c] | 0.736 (0.453, 1.196) | |
| HR P-Value [c] | 0.2154 | |
| Heterogeneity p-value [d] | 0.6747 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 70.9 (59.3, 79.8) | 64.0 (52.5, 73.4) |
| 12 months | 55.0 (38.8, 68.5) | 58.7 (43.6, 71.0) |
| 18 months | 55.0 (38.8, 68.5) | 58.7 (43.6, 71.0) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

| | Cemiplimab (N=115) | Chemotherapy (N=94) |
|---|---|---|
| Patients with event, n (%) | 31 (27.0%) | 34 (36.2%) |
| Censored Patients, n (%) | 84 (73.0%) | 60 (63.8%) |
| Median (95% CI), (Months) [a] | NE (11.17, NE) | 8.38 (5.13, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.02139 | |
| HR (95% CI) [c] | 0.604 (0.369, 0.989) | |
| HR P-Value [c] | 0.0450 | |
| Heterogeneity p-value [d] | 0.0996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.1 (63.6, 82.0) | 59.4 (46.4, 70.3) |
| 12 months | 61.4 (47.3, 72.7) | 49.9 (33.4, 64.3) |
| 18 months | 55.8 (39.0, 69.7) | 49.9 (33.4, 64.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

| | Cemiplimab (N=78) | Chemotherapy (N=78) |
|---|---|---|
| Patients with event, n (%) | 25 (32.1%) | 18 (23.1%) |
| Censored Patients, n (%) | 53 (67.9%) | 60 (76.9%) |
| Median (95% CI), (Months) [a] | 13.83 (6.87, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.27416 | |
| HR (95% CI) [c] | 1.205 (0.653, 2.222) | |
| HR P-Value [c] | 0.5505 | |
| Heterogeneity p-value [d] | 0.0996 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 67.0 (53.4, 77.4) | 71.6 (55.9, 82.6) |
| 12 months | 63.8 (49.4, 75.1) | 71.6 (55.9, 82.6) |
| 18 months | 45.6 (22.2, 66.3) | NE (NE, NE) |
| 24 months | 45.6 (22.2, 66.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 11 (42.3%) | 4 (21.1%) |
| Censored Patients, n (%) | 15 (57.7%) | 15 (78.9%) |
| Median (95% CI), (Months) [a] | 11.14 (7.16, NE) | NE (8.38, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.28962 | |
| HR (95% CI) [c] | 1.394 (0.428, 4.536) | |
| HR P-Value [c] | 0.5809 | |
| Heterogeneity p-value [d] | 0.0334 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.2 (50.2, 85.7) | 84.2 (58.7, 94.6) |
| 12 months | 49.6 (23.5, 71.2) | 63.2 (18.5, 88.3) |
| 18 months | 33.1 (7.4, 62.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed

| | Cemiplimab (N=117) | Chemotherapy (N=109) |
|---|---|---|
| Patients with event, n (%) | 31 (26.5%) | 36 (33.0%) |
| Censored Patients, n (%) | 86 (73.5%) | 73 (67.0%) |
| Median (95% CI), (Months) [a] | NE (13.63, NE) | NE (7.79, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.03491 | |
| HR (95% CI) [c] | 0.641 (0.395, 1.041) | |
| HR P-Value [c] | 0.0723 | |
| Heterogeneity p-value [d] | 0.0334 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 72.2 (61.7, 80.3) | 62.4 (50.2, 72.3) |
| 12 months | 65.4 (52.9, 75.3) | 57.6 (42.8, 69.8) |
| 18 months | 61.1 (46.4, 72.9) | 57.6 (42.8, 69.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan

| | Cemiplimab (N=20) | Chemotherapy (N=16) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 7 (43.8%) |
| Censored Patients, n (%) | 17 (85.0%) | 9 (56.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | 4.57 (0.59, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.02968 | |
| HR (95% CI) [c] | 0.293 (0.075, 1.137) | |
| HR P-Value [c] | 0.0760 | |
| Heterogeneity p-value [d] | 0.0334 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.7 (55.1, 94.1) | 37.9 (7.8, 69.2) |
| 12 months | 82.7 (55.1, 94.1) | NE (NE, NE) |
| 18 months | 82.7 (55.1, 94.1) | NE (NE, NE) |
| 24 months | 82.7 (55.1, 94.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine

| | Cemiplimab (N=32) | Chemotherapy (N=28) |
|---|---|---|
| Patients with event, n (%) | 11 (34.4%) | 5 (17.9%) |
| Censored Patients, n (%) | 21 (65.6%) | 23 (82.1%) |
| Median (95% CI), (Months) [a] | 13.83 (5.55, 13.83) | NE (4.76, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.08413 | |
| HR (95% CI) [c] | 2.071 (0.718, 5.972) | |
| HR P-Value [c] | 0.1777 | |
| Heterogeneity p-value [d] | 0.0334 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 61.1 (34.7, 79.5) | 68.1 (32.6, 87.7) |
| 12 months | 61.1 (34.7, 79.5) | 68.1 (32.6, 87.7) |
| 18 months | 0.0 (NE, NE) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65

| | Cemiplimab (N=179) | Chemotherapy (N=153) |
|---|---|---|
| Patients with event, n (%) | 86 (48.0%) | 77 (50.3%) |
| Censored Patients, n (%) | 93 (52.0%) | 76 (49.7%) |
| Median (95% CI), (Months) [a] | 6.93 (4.40, 13.83) | 4.50 (1.87, 11.56) |
| Stratified log-rank test 1-sided p-value [b] | 0.02476 | |
| HR (95% CI) [c] | 0.731 (0.535, 0.999) | |
| HR P-Value [c] | 0.0490 | |
| Heterogeneity p-value [d] | 0.3298 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.4 (43.9, 60.3) | 45.3 (35.9, 54.2) |
| 12 months | 44.6 (35.2, 53.4) | 29.7 (12.4, 49.3) |
| 18 months | 32.7 (21.8, 44.0) | 29.7 (12.4, 49.3) |
| 24 months | 32.7 (21.8, 44.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

| | Cemiplimab (N=16) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 8 (50.0%) | 10 (52.6%) |
| Censored Patients, n (%) | 8 (50.0%) | 9 (47.4%) |
| Median (95% CI), (Months) [a] | 16.10 (1.91, NE) | 1.61 (0.56, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.05392 | |
| HR (95% CI) [c] | 0.419 (0.141, 1.248) | |
| HR P-Value [c] | 0.1183 | |
| Heterogeneity p-value [d] | 0.3298 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (39.5, 85.4) | 46.8 (23.7, 67.0) |
| 12 months | 56.8 (25.9, 78.9) | NE (NE, NE) |
| 18 months | 42.6 (12.8, 70.2) | NE (NE, NE) |
| 24 months | 28.4 (4.9, 59.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

| | Cemiplimab (N=135) | Chemotherapy (N=115) |
|---|---|---|
| Patients with event, n (%) | 62 (45.9%) | 55 (47.8%) |
| Censored Patients, n (%) | 73 (54.1%) | 60 (52.2%) |
| Median (95% CI), (Months) [a] | 11.53 (4.90, 14.36) | 5.03 (1.87, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.01332 | |
| HR (95% CI) [c] | 0.657 (0.453, 0.954) | |
| HR P-Value [c] | 0.0271 | |
| Heterogeneity p-value [d] | 0.9044 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 56.5 (46.5, 65.4) | 49.3 (38.6, 59.2) |
| 12 months | 48.1 (37.1, 58.2) | 32.4 (13.2, 53.3) |
| 18 months | 32.2 (19.9, 45.2) | 32.4 (13.2, 53.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

| | Cemiplimab (N=60) | Chemotherapy (N=57) |
|---|---|---|
| Patients with event, n (%) | 32 (53.3%) | 32 (56.1%) |
| Censored Patients, n (%) | 28 (46.7%) | 25 (43.9%) |
| Median (95% CI), (Months) [a] | 3.45 (1.38, NE) | 2.79 (0.79, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.18753 | |
| HR (95% CI) [c] | 0.799 (0.487, 1.309) | |
| HR P-Value [c] | 0.3729 | |
| Heterogeneity p-value [d] | 0.9044 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.7 (35.2, 60.8) | 35.6 (20.5, 51.0) |
| 12 months | 39.3 (23.9, 54.4) | NE (NE, NE) |
| 18 months | 39.3 (23.9, 54.4) | NE (NE, NE) |
| 24 months | 39.3 (23.9, 54.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America

| | Cemiplimab (N=22) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 12 (54.5%) | 14 (66.7%) |
| Censored Patients, n (%) | 10 (45.5%) | 7 (33.3%) |
| Median (95% CI), (Months) [a] | 5.95 (2.63, NE) | 1.61 (0.66, 5.03) |
| Stratified log-rank test 1-sided p-value [b] | 0.02850 | |
| HR (95% CI) [c] | 0.473 (0.216, 1.038) | |
| HR P-Value [c] | 0.0619 | |
| Heterogeneity p-value [d] | 0.5759 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 47.4 (22.4, 68.9) | 22.9 (5.3, 47.7) |
| 12 months | 35.5 (11.4, 61.1) | 22.9 (5.3, 47.7) |
| 18 months | 23.7 (4.5, 51.3) | 22.9 (5.3, 47.7) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia

| | Cemiplimab (N=39) | Chemotherapy (N=33) |
|---|---|---|
| Patients with event, n (%) | 19 (48.7%) | 14 (42.4%) |
| Censored Patients, n (%) | 20 (51.3%) | 19 (57.6%) |
| Median (95% CI), (Months) [a] | 6.87 (1.38, NE) | NE (0.79, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.39088 | |
| HR (95% CI) [c] | 0.903 (0.448, 1.820) | |
| HR P-Value [c] | 0.7750 | |
| Heterogeneity p-value [d] | 0.5759 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.9 (36.2, 68.8) | 57.0 (38.3, 71.9) |
| 12 months | 42.5 (23.3, 60.4) | 57.0 (38.3, 71.9) |
| 18 months | 42.5 (23.3, 60.4) | NE (NE, NE) |
| 24 months | 42.5 (23.3, 60.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe

| | Cemiplimab (N=75) | Chemotherapy (N=63) |
|---|---|---|
| Patients with event, n (%) | 33 (44.0%) | 23 (36.5%) |
| Censored Patients, n (%) | 42 (56.0%) | 40 (63.5%) |
| Median (95% CI), (Months) [a] | 13.83 (6.80, 16.10) | 11.56 (9.36, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.20222 | |
| HR (95% CI) [c] | 0.785 (0.448, 1.376) | |
| HR P-Value [c] | 0.3986 | |
| Heterogeneity p-value [d] | 0.5759 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 63.5 (50.2, 74.1) | 64.6 (50.8, 75.4) |
| 12 months | 54.7 (39.8, 67.4) | 25.8 (1.8, 63.2) |
| 18 months | 30.1 (13.7, 48.5) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW

| | Cemiplimab (N=59) | Chemotherapy (N=55) |
|---|---|---|
| Patients with event, n (%) | 30 (50.8%) | 36 (65.5%) |
| Censored Patients, n (%) | 29 (49.2%) | 19 (34.5%) |
| Median (95% CI), (Months) [a] | 4.86 (2.17, NE) | 1.68 (0.82, 3.06) |
| Stratified log-rank test 1-sided p-value [b] | 0.02357 | |
| HR (95% CI) [c] | 0.609 (0.373, 0.995) | |
| HR P-Value [c] | 0.0479 | |
| Heterogeneity p-value [d] | 0.5759 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 44.8 (30.2, 58.4) | 29.7 (16.7, 43.8) |
| 12 months | 38.4 (21.9, 54.7) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

| | Cemiplimab (N=160) | Chemotherapy (N=133) |
|---|---|---|
| Patients with event, n (%) | 78 (48.8%) | 67 (50.4%) |
| Censored Patients, n (%) | 82 (51.3%) | 66 (49.6%) |
| Median (95% CI), (Months) [a] | 7.20 (4.80, 14.06) | 4.86 (1.68, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.01183 | |
| HR (95% CI) [c] | 0.679 (0.485, 0.950) | |
| HR P-Value [c] | 0.0238 | |
| Heterogeneity p-value [d] | 0.9212 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.1 (45.1, 62.3) | 46.2 (36.2, 55.7) |
| 12 months | 45.6 (35.8, 54.9) | 26.4 (7.6, 50.3) |
| 18 months | 32.3 (21.2, 43.8) | NE (NE, NE) |
| 24 months | 28.2 (16.6, 41.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

| | Cemiplimab (N=35) | Chemotherapy (N=39) |
|---|---|---|
| Patients with event, n (%) | 16 (45.7%) | 20 (51.3%) |
| Censored Patients, n (%) | 19 (54.3%) | 19 (48.7%) |
| Median (95% CI), (Months) [a] | 6.87 (2.14, NE) | 2.96 (1.41, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.17574 | |
| HR (95% CI) [c] | 0.730 (0.376, 1.417) | |
| HR P-Value [c] | 0.3522 | |
| Heterogeneity p-value [d] | 0.9212 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.2 (34.3, 68.9) | 42.3 (24.2, 59.3) |
| 12 months | 46.5 (26.4, 64.4) | 42.3 (24.2, 59.3) |
| 18 months | 46.5 (26.4, 64.4) | 42.3 (24.2, 59.3) |
| 24 months | 46.5 (26.4, 64.4) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

| | Cemiplimab (N=87) | Chemotherapy (N=76) |
|---|---|---|
| Patients with event, n (%) | 47 (54.0%) | 31 (40.8%) |
| Censored Patients, n (%) | 40 (46.0%) | 45 (59.2%) |
| Median (95% CI), (Months) [a] | 4.86 (3.02, 12.32) | NE (2.04, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.36659 | |
| HR (95% CI) [c] | 0.920 (0.577, 1.466) | |
| HR P-Value [c] | 0.7247 | |
| Heterogeneity p-value [d] | 0.0660 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.7 (36.7, 59.6) | 53.5 (38.7, 66.3) |
| 12 months | 36.7 (23.1, 50.4) | NE (NE, NE) |
| 18 months | NE (NE, NE) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

| | Cemiplimab (N=108) | Chemotherapy (N=96) |
|---|---|---|
| Patients with event, n (%) | 47 (43.5%) | 56 (58.3%) |
| Censored Patients, n (%) | 61 (56.5%) | 40 (41.7%) |
| Median (95% CI), (Months) [a] | 12.19 (5.85, NE) | 2.79 (1.41, 9.36) |
| Stratified log-rank test 1-sided p-value [b] | 0.00161 | |
| HR (95% CI) [c] | 0.554 (0.373, 0.824) | |
| HR P-Value [c] | 0.0036 | |
| Heterogeneity p-value [d] | 0.0660 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 58.4 (47.4, 67.9) | 40.6 (29.9, 51.1) |
| 12 months | 52.2 (40.2, 62.9) | 26.7 (11.0, 45.3) |
| 18 months | 42.5 (28.7, 55.6) | 26.7 (11.0, 45.3) |
| 24 months | 37.8 (23.2, 52.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

| | Cemiplimab (N=83) | Chemotherapy (N=64) |
|---|---|---|
| Patients with event, n (%) | 41 (49.4%) | 27 (42.2%) |
| Censored Patients, n (%) | 42 (50.6%) | 37 (57.8%) |
| Median (95% CI), (Months) [a] | 11.17 (4.27, 16.10) | NE (1.58, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.14868 | |
| HR (95% CI) [c] | 0.765 (0.465, 1.260) | |
| HR P-Value [c] | 0.2923 | |
| Heterogeneity p-value [d] | 0.5992 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.9 (41.5, 64.8) | 51.9 (34.7, 66.5) |
| 12 months | 46.3 (33.1, 58.5) | 51.9 (34.7, 66.5) |
| 18 months | 31.8 (17.7, 46.9) | NE (NE, NE) |
| 24 months | 31.8 (17.7, 46.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

| | Cemiplimab (N=112) | Chemotherapy (N=108) |
|---|---|---|
| Patients with event, n (%) | 53 (47.3%) | 60 (55.6%) |
| Censored Patients, n (%) | 59 (52.7%) | 48 (44.4%) |
| Median (95% CI), (Months) [a] | 7.16 (3.55, 19.02) | 2.96 (1.38, 9.36) |
| Stratified log-rank test 1-sided p-value [b] | 0.01710 | |
| HR (95% CI) [c] | 0.667 (0.457, 0.972) | |
| HR P-Value [c] | 0.0350 | |
| Heterogeneity p-value [d] | 0.5992 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 54.4 (43.7, 64.0) | 41.4 (31.0, 51.5) |
| 12 months | 45.8 (34.0, 56.9) | 16.6 (1.7, 45.3) |
| 18 months | 36.4 (22.0, 51.0) | 16.6 (1.7, 45.3) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

| | Cemiplimab (N=115) | Chemotherapy (N=94) |
|---|---|---|
| Patients with event, n (%) | 54 (47.0%) | 52 (55.3%) |
| Censored Patients, n (%) | 61 (53.0%) | 42 (44.7%) |
| Median (95% CI), (Months) [a] | 11.17 (4.40, 14.36) | 3.06 (1.41, 11.56) |
| Stratified log-rank test 1-sided p-value [b] | 0.00574 | |
| HR (95% CI) [c] | 0.605 (0.409, 0.896) | |
| HR P-Value [c] | 0.0121 | |
| Heterogeneity p-value [d] | 0.3500 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 55.9 (45.1, 65.4) | 41.7 (30.4, 52.6) |
| 12 months | 45.7 (33.6, 56.9) | 16.7 (1.7, 45.6) |
| 18 months | 32.0 (18.5, 46.3) | 16.7 (1.7, 45.6) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

| | Cemiplimab (N=78) | Chemotherapy (N=78) |
|---|---|---|
| Patients with event, n (%) | 40 (51.3%) | 35 (44.9%) |
| Censored Patients, n (%) | 38 (48.7%) | 43 (55.1%) |
| Median (95% CI), (Months) [a] | 5.95 (2.79, 14.06) | NE (1.51, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.30161 | |
| HR (95% CI) [c] | 0.884 (0.558, 1.399) | |
| HR P-Value [c] | 0.5984 | |
| Heterogeneity p-value [d] | 0.3500 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 49.9 (37.4, 61.2) | 53.0 (40.9, 63.7) |
| 12 months | 44.2 (31.0, 56.6) | 53.0 (40.9, 63.7) |
| 18 months | 33.2 (17.4, 49.8) | NE (NE, NE) |
| 24 months | 33.2 (17.4, 49.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 15 (57.7%) | 7 (36.8%) |
| Censored Patients, n (%) | 11 (42.3%) | 12 (63.2%) |
| Median (95% CI), (Months) [a] | 6.93 (2.17, 16.10) | 9.36 (0.56, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.48357 | |
| HR (95% CI) [c] | 1.019 (0.402, 2.583) | |
| HR P-Value [c] | 0.9688 | |
| Heterogeneity p-value [d] | 0.6713 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 59.4 (37.5, 75.9) | 68.4 (42.8, 84.4) |
| 12 months | 41.6 (20.4, 61.7) | NE (NE, NE) |
| 18 months | 22.2 (4.8, 47.3) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed

| | Cemiplimab (N=117) | Chemotherapy (N=109) |
|---|---|---|
| Patients with event, n (%) | 55 (47.0%) | 59 (54.1%) |
| Censored Patients, n (%) | 62 (53.0%) | 50 (45.9%) |
| Median (95% CI), (Months) [a] | 11.17 (4.40, NE) | 2.99 (1.38, 11.56) |
| Stratified log-rank test 1-sided p-value [b] | 0.00894 | |
| HR (95% CI) [c] | 0.638 (0.439, 0.926) | |
| HR P-Value [c] | 0.0182 | |
| Heterogeneity p-value [d] | 0.6713 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 52.7 (42.4, 62.0) | 40.1 (29.2, 50.8) |
| 12 months | 46.2 (34.8, 56.8) | 26.7 (8.2, 49.9) |
| 18 months | 40.0 (27.4, 52.3) | 26.7 (8.2, 49.9) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan

| | Cemiplimab (N=20) | Chemotherapy (N=16) |
|---|---|---|
| Patients with event, n (%) | 11 (55.0%) | 8 (50.0%) |
| Censored Patients, n (%) | 9 (45.0%) | 8 (50.0%) |
| Median (95% CI), (Months) [a] | 7.20 (1.68, 14.06) | 2.07 (0.56, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.13837 | |
| HR (95% CI) [c] | 0.579 (0.215, 1.558) | |
| HR P-Value [c] | 0.2793 | |
| Heterogeneity p-value [d] | 0.6713 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 60.7 (33.9, 79.4) | 44.6 (18.2, 68.3) |
| 12 months | 45.5 (15.3, 71.9) | NE (NE, NE) |
| 18 months | 15.2 (0.9, 47.3) | NE (NE, NE) |
| 24 months | 0.0 (NE, NE) | NE (NE, NE) |
| 30 months | 0.0 (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine

| | Cemiplimab (N=32) | Chemotherapy (N=28) |
|---|---|---|
| Patients with event, n (%) | 13 (40.6%) | 13 (46.4%) |
| Censored Patients, n (%) | 19 (59.4%) | 15 (53.6%) |
| Median (95% CI), (Months) [a] | 4.90 (1.91, NE) | NE (1.41, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.27335 | |
| HR (95% CI) [c] | 0.789 (0.365, 1.705) | |
| HR P-Value [c] | 0.5473 | |
| Heterogeneity p-value [d] | 0.6713 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 48.7 (25.8, 68.3) | 50.2 (29.8, 67.5) |
| 12 months | 48.7 (25.8, 68.3) | 50.2 (29.8, 67.5) |
| 18 months | 48.7 (25.8, 68.3) | NE (NE, NE) |
| 24 months | 48.7 (25.8, 68.3) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65

| | Cemiplimab (N=179) | Chemotherapy (N=153) |
|---|---|---|
| Patients with event, n (%) | 19 (10.6%) | 6 (3.9%) |
| Censored Patients, n (%) | 160 (89.4%) | 147 (96.1%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.05986 | |
| HR (95% CI) [c] | 2.063 (0.813, 5.235) | |
| HR P-Value [c] | 0.1275 | |
| Heterogeneity p-value [d] | 0.1450 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.1 (80.2, 93.0) | 96.3 (91.2, 98.5) |
| 12 months | 83.7 (74.2, 89.9) | 90.6 (70.8, 97.2) |
| 18 months | 75.0 (58.2, 85.8) | 90.6 (70.8, 97.2) |
| 24 months | 75.0 (58.2, 85.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

| | Cemiplimab (N=16) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 1 (6.3%) | 2 (10.5%) |
| Censored Patients, n (%) | 15 (93.8%) | 17 (89.5%) |
| Median (95% CI), (Months) [a] | NE (16.10, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.08753 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9965 | |
| Heterogeneity p-value [d] | 0.1450 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 86.1 (53.3, 96.5) |
| 12 months | 100.0 (100.0, 100.0) | 86.1 (53.3, 96.5) |
| 18 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 24 months | 80.0 (20.4, 96.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

| | Cemiplimab (N=135) | Chemotherapy (N=115) |
|---|---|---|
| Patients with event, n (%) | 12 (8.9%) | 5 (4.3%) |
| Censored Patients, n (%) | 123 (91.1%) | 110 (95.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.34340 | |
| HR (95% CI) [c] | 1.249 (0.424, 3.680) | |
| HR P-Value [c] | 0.6874 | |
| Heterogeneity p-value [d] | 0.6830 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.8 (83.2, 96.1) | 95.6 (88.4, 98.4) |
| 12 months | 88.4 (78.4, 94.0) | 90.0 (70.3, 96.9) |
| 18 months | 74.4 (54.2, 86.7) | 90.0 (70.3, 96.9) |
| 24 months | 74.4 (54.2, 86.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

| | Cemiplimab (N=60) | Chemotherapy (N=57) |
|---|---|---|
| Patients with event, n (%) | 8 (13.3%) | 3 (5.3%) |
| Censored Patients, n (%) | 52 (86.7%) | 54 (94.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.09139 | |
| HR (95% CI) [c] | 2.394 (0.634, 9.038) | |
| HR P-Value [c] | 0.1979 | |
| Heterogeneity p-value [d] | 0.6830 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 82.9 (65.3, 92.1) | 94.0 (82.3, 98.1) |
| 12 months | 77.0 (55.6, 89.0) | 94.0 (82.3, 98.1) |
| 18 months | 77.0 (55.6, 89.0) | NE (NE, NE) |
| 24 months | 77.0 (55.6, 89.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America

| | Cemiplimab (N=22) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 5 (22.7%) | 1 (4.8%) |
| Censored Patients, n (%) | 17 (77.3%) | 20 (95.2%) |
| Median (95% CI), (Months) [a] | NE (5.13, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.06743 | |
| HR (95% CI) [c] | 4.467 (0.521, 38.317) | |
| HR P-Value [c] | 0.1722 | |
| Heterogeneity p-value [d] | 0.4645 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 74.2 (42.8, 90.1) | 92.9 (59.1, 99.0) |
| 12 months | 63.6 (30.7, 84.1) | 92.9 (59.1, 99.0) |
| 18 months | 63.6 (30.7, 84.1) | 92.9 (59.1, 99.0) |
| 24 months | 63.6 (30.7, 84.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia

| | Cemiplimab (N=39) | Chemotherapy (N=33) |
|---|---|---|
| Patients with event, n (%) | 4 (10.3%) | 2 (6.1%) |
| Censored Patients, n (%) | 35 (89.7%) | 31 (93.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.32511 | |
| HR (95% CI) [c] | 1.472 (0.266, 8.138) | |
| HR P-Value [c] | 0.6575 | |
| Heterogeneity p-value [d] | 0.4645 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.8 (76.6, 97.3) | 93.9 (77.9, 98.4) |
| 12 months | 84.7 (60.4, 94.7) | 93.9 (77.9, 98.4) |
| 18 months | 84.7 (60.4, 94.7) | NE (NE, NE) |
| 24 months | 84.7 (60.4, 94.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe

| | Cemiplimab (N=75) | Chemotherapy (N=63) |
|---|---|---|
| Patients with event, n (%) | 6 (8.0%) | 4 (6.3%) |
| Censored Patients, n (%) | 69 (92.0%) | 59 (93.7%) |
| Median (95% CI), (Months) [a] | NE (16.10, NE) | NE (9.10, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.11316 | |
| HR (95% CI) [c] | 0.400 (0.086, 1.849) | |
| HR P-Value [c] | 0.2407 | |
| Heterogeneity p-value [d] | 0.4645 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.6 (80.0, 98.6) | 94.7 (84.4, 98.3) |
| 12 months | 91.4 (75.6, 97.2) | 81.2 (40.0, 95.4) |
| 18 months | 65.2 (33.5, 84.6) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW

| | Cemiplimab (N=59) | Chemotherapy (N=55) |
|---|---|---|
| Patients with event, n (%) | 5 (8.5%) | 1 (1.8%) |
| Censored Patients, n (%) | 54 (91.5%) | 54 (98.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.06759 | |
| HR (95% CI) [c] | 4.460 (0.520, 38.235) | |
| HR P-Value [c] | 0.1726 | |
| Heterogeneity p-value [d] | 0.4645 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.4 (71.5, 94.7) | 97.7 (84.9, 99.7) |
| 12 months | 87.4 (71.5, 94.7) | 97.7 (84.9, 99.7) |
| 18 months | 87.4 (71.5, 94.7) | NE (NE, NE) |
| 24 months | 87.4 (71.5, 94.7) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

| | Cemiplimab (N=160) | Chemotherapy (N=133) |
|---|---|---|
| Patients with event, n (%) | 17 (10.6%) | 5 (3.8%) |
| Censored Patients, n (%) | 143 (89.4%) | 128 (96.2%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.10229 | |
| HR (95% CI) [c] | 1.920 (0.689, 5.349) | |
| HR P-Value [c] | 0.2123 | |
| Heterogeneity p-value [d] | 0.4039 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 88.4 (79.9, 93.4) | 96.2 (89.9, 98.6) |
| 12 months | 85.2 (75.5, 91.2) | 89.8 (67.2, 97.1) |
| 18 months | 73.8 (56.9, 84.9) | NE (NE, NE) |
| 24 months | 73.8 (56.9, 84.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

| | Cemiplimab (N=35) | Chemotherapy (N=39) |
|---|---|---|
| Patients with event, n (%) | 3 (8.6%) | 3 (7.7%) |
| Censored Patients, n (%) | 32 (91.4%) | 36 (92.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.49554 | |
| HR (95% CI) [c] | 1.009 (0.203, 5.024) | |
| HR P-Value [c] | 0.9911 | |
| Heterogeneity p-value [d] | 0.4039 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 93.4 (76.1, 98.3) | 91.1 (74.2, 97.1) |
| 12 months | 84.9 (55.5, 95.6) | 91.1 (74.2, 97.1) |
| 18 months | 84.9 (55.5, 95.6) | 91.1 (74.2, 97.1) |
| 24 months | 84.9 (55.5, 95.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

| | Cemiplimab (N=87) | Chemotherapy (N=76) |
|---|---|---|
| Patients with event, n (%) | 15 (17.2%) | 0 |
| Censored Patients, n (%) | 72 (82.8%) | 76 (100.0%) |
| Median (95% CI), (Months) [a] | NE (16.10, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.00472 | |
| HR (95% CI) [c] | 18890524 (0.000, NE) | |
| HR P-Value [c] | 0.9919 | |
| Heterogeneity p-value [d] | 0.9875 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 83.1 (70.1, 90.8) | 100.0 (100.0, 100.0) |
| 12 months | 74.5 (58.9, 84.9) | 100.0 (100.0, 100.0) |
| 18 months | 52.2 (22.5, 75.2) | NE (NE, NE) |
| 24 months | 52.2 (22.5, 75.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

| | Cemiplimab (N=108) | Chemotherapy (N=96) |
|---|---|---|
| Patients with event, n (%) | 5 (4.6%) | 8 (8.3%) |
| Censored Patients, n (%) | 103 (95.4%) | 88 (91.7%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.09327 | |
| HR (95% CI) [c] | 0.469 (0.149, 1.478) | |
| HR P-Value [c] | 0.1957 | |
| Heterogeneity p-value [d] | 0.9875 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 94.8 (85.9, 98.1) | 91.9 (83.5, 96.1) |
| 12 months | 94.8 (85.9, 98.1) | 86.5 (69.2, 94.4) |
| 18 months | 89.8 (72.1, 96.5) | 86.5 (69.2, 94.4) |
| 24 months | 89.8 (72.1, 96.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

| | Cemiplimab (N=83) | Chemotherapy (N=64) |
|---|---|---|
| Patients with event, n (%) | 12 (14.5%) | 2 (3.1%) |
| Censored Patients, n (%) | 71 (85.5%) | 62 (96.9%) |
| Median (95% CI), (Months) [a] | NE (17.97, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.08858 | |
| HR (95% CI) [c] | 2.766 (0.594, 12.894) | |
| HR P-Value [c] | 0.1951 | |
| Heterogeneity p-value [d] | 0.2920 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.6 (76.3, 93.7) | 96.8 (87.7, 99.2) |
| 12 months | 85.1 (72.6, 92.2) | 96.8 (87.7, 99.2) |
| 18 months | 67.4 (43.9, 82.8) | NE (NE, NE) |
| 24 months | 67.4 (43.9, 82.8) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

| | Cemiplimab (N=112) | Chemotherapy (N=108) |
|---|---|---|
| Patients with event, n (%) | 8 (7.1%) | 6 (5.6%) |
| Censored Patients, n (%) | 104 (92.9%) | 102 (94.4%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.40628 | |
| HR (95% CI) [c] | 1.137 (0.393, 3.288) | |
| HR P-Value [c] | 0.8127 | |
| Heterogeneity p-value [d] | 0.2920 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 90.4 (78.7, 95.8) | 94.1 (86.1, 97.6) |
| 12 months | 84.7 (70.3, 92.5) | 86.9 (63.2, 95.8) |
| 18 months | 84.7 (70.3, 92.5) | 86.9 (63.2, 95.8) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

| | Cemiplimab (N=115) | Chemotherapy (N=94) |
|---|---|---|
| Patients with event, n (%) | 13 (11.3%) | 6 (6.4%) |
| Censored Patients, n (%) | 102 (88.7%) | 88 (93.6%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.26429 | |
| HR (95% CI) [c] | 1.373 (0.510, 3.694) | |
| HR P-Value [c] | 0.5302 | |
| Heterogeneity p-value [d] | 0.5109 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 87.4 (77.2, 93.2) | 93.5 (84.8, 97.3) |
| 12 months | 85.1 (73.9, 91.8) | 86.8 (65.1, 95.5) |
| 18 months | 73.4 (52.1, 86.3) | 86.8 (65.1, 95.5) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

| | Cemiplimab (N=78) | Chemotherapy (N=78) |
|---|---|---|
| Patients with event, n (%) | 7 (9.0%) | 2 (2.6%) |
| Censored Patients, n (%) | 71 (91.0%) | 76 (97.4%) |
| Median (95% CI), (Months) [a] | NE (14.06, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.13420 | |
| HR (95% CI) [c] | 2.403 (0.485, 11.892) | |
| HR P-Value [c] | 0.2827 | |
| Heterogeneity p-value [d] | 0.5109 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 91.8 (78.4, 97.0) | 97.2 (89.4, 99.3) |
| 12 months | 84.3 (66.6, 93.1) | 97.2 (89.4, 99.3) |
| 18 months | 75.9 (50.0, 89.6) | NE (NE, NE) |
| 24 months | 75.9 (50.0, 89.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 4 (15.4%) | 1 (5.3%) |
| Censored Patients, n (%) | 22 (84.6%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | NE (7.59, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.35232 | |
| HR (95% CI) [c] | 1.552 (0.157, 15.333) | |
| HR P-Value [c] | 0.7069 | |
| Heterogeneity p-value [d] | 0.4776 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 95.8 (73.9, 99.4) | 94.7 (68.1, 99.2) |
| 12 months | 79.9 (47.9, 93.4) | 94.7 (68.1, 99.2) |
| 18 months | 53.2 (9.1, 84.8) | NE (NE, NE) |
| 24 months | NE (NE, NE) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed

| | Cemiplimab (N=117) | Chemotherapy (N=109) |
|---|---|---|
| Patients with event, n (%) | 14 (12.0%) | 4 (3.7%) |
| Censored Patients, n (%) | 103 (88.0%) | 105 (96.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.05092 | |
| HR (95% CI) [c] | 2.476 (0.806, 7.604) | |
| HR P-Value [c] | 0.1134 | |
| Heterogeneity p-value [d] | 0.4776 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.3 (75.0, 91.5) | 96.9 (90.5, 99.0) |
| 12 months | 83.3 (72.4, 90.2) | 90.4 (66.7, 97.5) |
| 18 months | 76.4 (56.8, 88.0) | 90.4 (66.7, 97.5) |
| 24 months | 76.4 (56.8, 88.0) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan

| | Cemiplimab (N=20) | Chemotherapy (N=16) |
|---|---|---|
| Patients with event, n (%) | 1 (5.0%) | 1 (6.3%) |
| Censored Patients, n (%) | 19 (95.0%) | 15 (93.8%) |
| Median (95% CI), (Months) [a] | NE (14.06, NE) | NE (3.71, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.18891 | |
| HR (95% CI) [c] | 0.000 (0.000, NE) | |
| HR P-Value [c] | 0.9975 | |
| Heterogeneity p-value [d] | 0.4776 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 88.9 (43.3, 98.4) |
| 12 months | 100.0 (100.0, 100.0) | NE (NE, NE) |
| 18 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 24 months | 75.0 (12.8, 96.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 22.3.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine

| | Cemiplimab (N=32) | Chemotherapy (N=28) |
|---|---|---|
| Patients with event, n (%) | 1 (3.1%) | 2 (7.1%) |
| Censored Patients, n (%) | 31 (96.9%) | 26 (92.9%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Stratified log-rank test 1-sided p-value [b] | 0.23732 | |
| HR (95% CI) [c] | 0.427 (0.039, 4.716) | |
| HR P-Value [c] | 0.4878 | |
| Heterogeneity p-value [d] | 0.4776 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 96.9 (79.8, 99.6) | 91.1 (68.8, 97.7) |
| 12 months | 96.9 (79.8, 99.6) | 91.1 (68.8, 97.7) |
| 18 months | 96.9 (79.8, 99.6) | NE (NE, NE) |
| 24 months | 96.9 (79.8, 99.6) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] One-sided p-value converted from stratified log-rank test two-sided p-value.
[c] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.

Table 23.1.1. Objective Response Rate (CR+PR)
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Responder n(%) | 31 (15.8%) | 13 (7.1%) |
| Non-responder n(%) | 165 (84.2%) | 170 (92.9%) |
| Risk Difference (95% CI) [1] | 7.11 (-0.55, 14.77) | |
| P-value for Risk Difference [1] | 0.0690 | |
| Odds Ratio (95% CI) [1] | 2.33 (1.17, 4.64) | |
| P-value for Odds Ratio [1] | 0.0074 | |
| Peto Odds Ratio (95% CI) [2] | 2.33 (1.24, 4.37) | |
| P-value for Peto Odds Ratio [2] | 0.0082 | |
| Relative Risk (95% CI) [1] | 2.11 (1.15, 3.89) | |
| Reversed Relative Risk(95% CI) [1] | 0.47 (0.26, 0.87) | |
| P-value for Relative Risk [1] | 0.0166 | |

Data cut-off as of Jan 4th, 2021.
[1] Odds ratio using geographic region and histology stratified Cochran-Mantel-Haenszel test. Relative risk and risk difference were derived from logistic regression with treatment as the fixed factor and stratified by geographic region and histology.
[2] Peto OR calculation is based on Yusuf S et al. (Prof Cardiovasc Dis.1985 Mar-Apr; 27(5):335-71) and its P-value is derived using a normal approximation.

Table 24.1.1. Summary of Prior Cancer Systemic Therapy by Setting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Number of patients with any prior cancer-related systemic therapy, n (%) | 196 (100.0%) | 183 (100.0%) | 379 (100.0%) |
| Therapy setting, n (%) | | | |
| Concurrent with radiotherapy | 95 (48.5%) | 103 (56.3%) | 198 (52.2%) |
| Recurrent, persistent, and/or metastatic | 194 (99.0%) | 183 (100.0%) | 377 (99.5%) |
| Adjuvant | 10 (5.1%) | 8 (4.4%) | 18 (4.7%) |
| Neo-adjuvant | 14 (7.1%) | 12 (6.6%) | 26 (6.9%) |
| Other | 0 | 3 (1.6%) | 3 (0.8%) |
| Number of prior lines (any setting), n (%) | | | |
| 1 | 49 (25.0%) | 33 (18.0%) | 82 (21.6%) |
| 2 | 84 (42.9%) | 76 (41.5%) | 160 (42.2%) |
| 3 | 38 (19.4%) | 46 (25.1%) | 84 (22.2%) |
| 4 | 16 (8.2%) | 14 (7.7%) | 30 (7.9%) |
| 5 | 5 (2.6%) | 9 (4.9%) | 14 (3.7%) |
| 6 | 1 (0.5%) | 3 (1.6%) | 4 (1.1%) |
| 7 | 2 (1.0%) | 1 (0.5%) | 3 (0.8%) |
| 8 | 1 (0.5%) | 1 (0.5%) | 2 (0.5%) |

Data cut-off as of Jan 4th, 2021.
*Eleven patients had a PD date as an incomplete date; therefore, they cannot be included into any of the categories above (<=6 or >6 clarify)
AC=adenocarcinoma/adenosquamous histology; Max=maximum; Min=minimum; SCC=squamous cell carcinoma; SD=standard deviation.

Table 24.1.1. Summary of Prior Cancer Systemic Therapy by Setting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Number of prior lines (any setting) | | | |
| n | 196 | 183 | 379 |
| Mean (SD) | 2.3 (1.20) | 2.5 (1.24) | 2.4 (1.22) |
| Median | 2.0 | 2.0 | 2.0 |
| Q1 : Q3 | 1.5 : 3.0 | 2.0 : 3.0 | 2.0 : 3.0 |
| Min : Max | 1 : 8 | 1 : 8 | 1 : 8 |
| Number of prior lines of systemic therapy for recurrent or metastatic disease, n (%) | | | |
| 1 | 117 (59.7%) | 97 (53.0%) | 214 (56.5%) |
| 2 | 46 (23.5%) | 48 (26.2%) | 94 (24.8%) |
| 3 | 17 (8.7%) | 24 (13.1%) | 41 (10.8%) |
| 4 | 9 (4.6%) | 8 (4.4%) | 17 (4.5%) |
| 5 | 3 (1.5%) | 4 (2.2%) | 7 (1.8%) |
| 6 | 0 | 1 (0.5%) | 1 (0.3%) |
| 7 | 2 (1.0%) | 1 (0.5%) | 3 (0.8%) |

Data cut-off as of Jan 4th, 2021.
*Eleven patients had a PD date as an incomplete date; therefore, they cannot be included into any of the categories above (<=6 or >6 clarify)
AC=adenocarcinoma/adenosquamous histology; Max=maximum; Min=minimum; SCC=squamous cell carcinoma; SD=standard deviation.

Table 24.1.1. Summary of Prior Cancer Systemic Therapy by Setting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Number of prior lines of systemic therapy for recurrent or metastatic disease | | | |
| n | 194 | 183 | 377 |
| Mean (SD) | 1.7 (1.08) | 1.8 (1.11) | 1.7 (1.10) |
| Median | 1.0 | 1.0 | 1.0 |
| Q1 : Q3 | 1.0 : 2.0 | 1.0 : 2.0 | 1.0 : 2.0 |
| Min : Max | 1 : 7 | 1 : 7 | 1 : 7 |
| Number of patients with prior bevacizumab, n (%) | 89 (45.4%) | 85 (46.4%) | 174 (45.9%) |
| Number of patients with prior paclitaxel, n (%) | 168 (85.7%) | 169 (92.3%) | 337 (88.9%) |
| Progressed after prior platinum therapy, n (%) | | | |
| <= 6 months | 174 (88.8%) | 165 (90.2%) | 339 (89.4%) |
| > 6 months | 18 (9.2%) | 16 (8.7%) | 34 (9.0%) |
| Missing* | 4 (2.0%) | 2 (1.1%) | 6 (1.6%) |

Data cut-off as of Jan 4th, 2021.
*Eleven patients had a PD date as an incomplete date; therefore, they cannot be included into any of the categories above (<=6 or >6 clarify)
AC=adenocarcinoma/adenosquamous histology; Max=maximum; Min=minimum; SCC=squamous cell carcinoma; SD=standard deviation.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=179) | Chemotherapy (N=153) |
|---|---|---|
| Patients with event, n (%) | 50 (27.9%) | 46 (30.1%) |
| Censored Patients, n (%) | 129 (72.1%) | 107 (69.9%) |
| Median (95% CI), (Months) [a] | NC (13.63, NC) | NC (7.79, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2465 | |
| Hazard Ratio (95% CI) [c] | 0.788 (0.526, 1.180) | |
| HR P-Value [c] | 0.2473 | |
| Heterogeneity p-value [d] | 0.9524 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 71.6 (63.2, 78.4) | 64.5 (54.0, 73.2) |
| 12 months | 61.2 (50.2, 70.5) | 56.9 (42.8, 68.7) |
| 18 months | 58.0 (45.7, 68.5) | 56.9 (42.8, 68.7) |
| 24 months | 58.0 (45.7, 68.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=179) | Chemotherapy (N=153) |
|---|---|---|
| Patients with event, n (%) | 2 (1.1%) | 16 (10.5%) |
| Censored Patients, n (%) | 177 (98.9%) | 137 (89.5%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.096 (0.022, 0.420) | |
| HR P-Value [c] | 0.0018 | |
| Heterogeneity p-value [d] | 0.9931 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.9 (95.5, 99.7) | 88.1 (80.2, 93.0) |
| 12 months | 98.9 (95.5, 99.7) | 85.4 (75.3, 91.6) |
| 18 months | 98.9 (95.5, 99.7) | 85.4 (75.3, 91.6) |
| 24 months | 98.9 (95.5, 99.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=179) | Chemotherapy (N=153) |
|---|---|---|
| Patients with event, n (%) | 1 (0.6%) | 11 (7.2%) |
| Censored Patients, n (%) | 178 (99.4%) | 142 (92.8%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0007 | |
| Hazard Ratio (95% CI) [c] | 0.068 (0.009, 0.532) | |
| HR P-Value [c] | 0.0104 | |
| Heterogeneity p-value [d] | 0.9992 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.4 (96.0, 99.9) | 91.8 (84.3, 95.8) |
| 12 months | 99.4 (96.0, 99.9) | 88.3 (76.2, 94.4) |
| 18 months | 99.4 (96.0, 99.9) | 88.3 (76.2, 94.4) |
| 24 months | 99.4 (96.0, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-ae-socpt-nopdl1.sas (25OCT22:16:05:39, qiuyue.chen1)

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=16) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 6 (37.5%) | 6 (31.6%) |
| Censored Patients, n (%) | 10 (62.5%) | 13 (68.4%) |
| Median (95% CI), (Months) [a] | 16.10 (5.22, NC) | NC (1.64, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4629 | |
| Hazard Ratio (95% CI) [c] | 0.622 (0.173, 2.237) | |
| HR P-Value [c] | 0.4669 | |
| Heterogeneity p-value [d] | 0.9524 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 71.1 (38.4, 88.6) | 64.2 (36.0, 82.5) |
| 12 months | 71.1 (38.4, 88.6) | NC (NC, NC) |
| 18 months | 37.9 (7.0, 70.2) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-ae-socpt-nopdl1.sas (25OCT22:16:05:39, qiuyue.chen1)

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=16) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (5.3%) |
| Censored Patients, n (%) | 16 (100.0%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3017 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 0.9931 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 93.3 (61.3, 99.0) |
| 12 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=16) | Chemotherapy (N=19) |
|---|---|---|
| Censored Patients, n (%) | 16 (100.0%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | NC | |
| Hazard Ratio (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NC | |
| Heterogeneity p-value [d] | 0.9992 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=135) | Chemotherapy (N=115) |
|---|---|---|
| Patients with event, n (%) | 30 (22.2%) | 30 (26.1%) |
| Censored Patients, n (%) | 105 (77.8%) | 85 (73.9%) |
| Median (95% CI), (Months) [a] | NC (16.10, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1117 | |
| Hazard Ratio (95% CI) [c] | 0.661 (0.395, 1.105) | |
| HR P-Value [c] | 0.1144 | |
| Heterogeneity p-value [d] | 0.2196 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 76.8 (67.1, 84.0) | 70.2 (58.9, 78.9) |
| 12 months | 69.9 (57.7, 79.2) | 65.5 (51.0, 76.6) |
| 18 months | 62.1 (46.5, 74.3) | 65.5 (51.0, 76.6) |
| 24 months | 62.1 (46.5, 74.3) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=135) | Chemotherapy (N=115) |
|---|---|---|
| Patients with event, n (%) | 1 (0.7%) | 11 (9.6%) |
| Censored Patients, n (%) | 134 (99.3%) | 104 (90.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0005 | |
| Hazard Ratio (95% CI) [c] | 0.066 (0.008, 0.511) | |
| HR P-Value [c] | 0.0093 | |
| Heterogeneity p-value [d] | 0.6028 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.2 (94.7, 99.9) | 88.9 (79.0, 94.3) |
| 12 months | 99.2 (94.7, 99.9) | 85.6 (72.9, 92.6) |
| 18 months | 99.2 (94.7, 99.9) | 85.6 (72.9, 92.6) |
| 24 months | 99.2 (94.7, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=135) | Chemotherapy (N=115) |
|---|---|---|
| Patients with event, n (%) | 1 (0.7%) | 9 (7.8%) |
| Censored Patients, n (%) | 134 (99.3%) | 106 (92.2%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0019 | |
| Hazard Ratio (95% CI) [c] | 0.078 (0.010, 0.618) | |
| HR P-Value [c] | 0.0157 | |
| Heterogeneity p-value [d] | 0.9941 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.2 (94.7, 99.9) | 90.8 (81.2, 95.7) |
| 12 months | 99.2 (94.7, 99.9) | 86.3 (70.9, 93.9) |
| 18 months | 99.2 (94.7, 99.9) | 86.3 (70.9, 93.9) |
| 24 months | 99.2 (94.7, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=60) | Chemotherapy (N=57) |
|---|---|---|
| Patients with event, n (%) | 26 (43.3%) | 22 (38.6%) |
| Censored Patients, n (%) | 34 (56.7%) | 35 (61.4%) |
| | | |
| Median (95% CI), (Months) [a] | 7.16 (2.23, NC) | 8.38 (4.76, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9501 | |
| Hazard Ratio (95% CI) [c] | 1.018 (0.573, 1.810) | |
| HR P-Value [c] | 0.9513 | |
| Heterogeneity p-value [d] | 0.2196 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 60.4 (46.0, 72.1) | 51.1 (31.5, 67.6) |
| 12 months | 40.8 (20.9, 59.9) | 34.0 (8.8, 62.1) |
| 18 months | 27.2 (6.8, 53.2) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=60) | Chemotherapy (N=57) |
|---|---|---|
| Patients with event, n (%) | 1 (1.7%) | 6 (10.5%) |
| Censored Patients, n (%) | 59 (98.3%) | 51 (89.5%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0404 | |
| Hazard Ratio (95% CI) [c] | 0.148 (0.018, 1.229) | |
| HR P-Value [c] | 0.0769 | |
| Heterogeneity p-value [d] | 0.6028 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.3 (88.8, 99.8) | 88.2 (75.2, 94.6) |
| 12 months | 98.3 (88.8, 99.8) | 88.2 (75.2, 94.6) |
| 18 months | 98.3 (88.8, 99.8) | NC (NC, NC) |
| 24 months | 98.3 (88.8, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=60) | Chemotherapy (N=57) |
|---|---|---|
| Patients with event, n (%) | 0 | 2 (3.5%) |
| Censored Patients, n (%) | 60 (100.0%) | 55 (96.5%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1432 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9964 | |
| Heterogeneity p-value [d] | 0.9941 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 96.5 (86.6, 99.1) |
| 12 months | 100.0 (100.0, 100.0) | 96.5 (86.6, 99.1) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=22) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 6 (27.3%) | 12 (57.1%) |
| Censored Patients, n (%) | 16 (72.7%) | 9 (42.9%) |
| Median (95% CI), (Months) [a] | NC (3.45, NC) | 3.71 (0.82, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0276 | |
| Hazard Ratio (95% CI) [c] | 0.346 (0.129, 0.927) | |
| HR P-Value [c] | 0.0349 | |
| Heterogeneity p-value [d] | 0.1522 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 71.1 (46.6, 85.9) | 36.3 (12.2, 61.3) |
| 12 months | 71.1 (46.6, 85.9) | 24.2 (4.7, 51.7) |
| 18 months | 71.1 (46.6, 85.9) | 24.2 (4.7, 51.7) |
| 24 months | 71.1 (46.6, 85.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=22) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 5 (23.8%) |
| Censored Patients, n (%) | 22 (100.0%) | 16 (76.2%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (5.49, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0135 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9964 | |
| Heterogeneity p-value [d] | 0.9907 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 74.5 (41.9, 90.5) |
| 12 months | 100.0 (100.0, 100.0) | 62.1 (27.2, 84.0) |
| 18 months | 100.0 (100.0, 100.0) | 62.1 (27.2, 84.0) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=22) | Chemotherapy (N=21) |
|---|---|---|
| Patients with event, n (%) | 0 | 3 (14.3%) |
| Censored Patients, n (%) | 22 (100.0%) | 18 (85.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (5.49, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0711 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9972 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 80.4 (47.2, 93.9) |
| 12 months | 100.0 (100.0, 100.0) | 80.4 (47.2, 93.9) |
| 18 months | 100.0 (100.0, 100.0) | 80.4 (47.2, 93.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=39) | Chemotherapy (N=33) |
|---|---|---|
| Patients with event, n (%) | 17 (43.6%) | 11 (33.3%) |
| Censored Patients, n (%) | 22 (56.4%) | 22 (66.7%) |
| | | |
| Median (95% CI), (Months) [a] | 8.31 (2.10, NC) | 8.38 (4.76, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7320 | |
| Hazard Ratio (95% CI) [c] | 1.139 (0.529, 2.452) | |
| HR P-Value [c] | 0.7399 | |
| Heterogeneity p-value [d] | 0.1522 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 64.5 (46.6, 77.8) | 60.4 (33.9, 79.1) |
| 12 months | 43.6 (21.5, 63.8) | 40.3 (8.9, 71.0) |
| 18 months | 32.7 (10.9, 56.8) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=39) | Chemotherapy (N=33) |
|---|---|---|
| Patients with event, n (%) | 1 (2.6%) | 3 (9.1%) |
| Censored Patients, n (%) | 38 (97.4%) | 30 (90.9%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1926 | |
| Hazard Ratio (95% CI) [c] | 0.248 (0.026, 2.397) | |
| HR P-Value [c] | 0.2283 | |
| Heterogeneity p-value [d] | 0.9907 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 97.4 (83.2, 99.6) | 88.0 (65.3, 96.2) |
| 12 months | 97.4 (83.2, 99.6) | 88.0 (65.3, 96.2) |
| 18 months | 97.4 (83.2, 99.6) | NC (NC, NC) |
| 24 months | 97.4 (83.2, 99.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=39) | Chemotherapy (N=33) |
|---|---|---|
| Censored Patients, n (%) | 39 (100.0%) | 33 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | NC | |
| Hazard Ratio (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NC | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=75) | Chemotherapy (N=63) |
|---|---|---|
| Patients with event, n (%) | 15 (20.0%) | 9 (14.3%) |
| Censored Patients, n (%) | 60 (80.0%) | 54 (85.7%) |
| | | |
| Median (95% CI), (Months) [a] | NC (16.10, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8082 | |
| Hazard Ratio (95% CI) [c] | 1.110 (0.477, 2.586) | |
| HR P-Value [c] | 0.8085 | |
| Heterogeneity p-value [d] | 0.1522 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 79.8 (66.3, 88.3) | 82.5 (67.8, 90.9) |
| 12 months | 71.7 (54.2, 83.4) | 82.5 (67.8, 90.9) |
| 18 months | 62.7 (38.7, 79.5) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=75) | Chemotherapy (N=63) |
|---|---|---|
| Patients with event, n (%) | 1 (1.3%) | 5 (7.9%) |
| Censored Patients, n (%) | 74 (98.7%) | 58 (92.1%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0553 | |
| Hazard Ratio (95% CI) [c] | 0.160 (0.019, 1.370) | |
| HR P-Value [c] | 0.0944 | |
| Heterogeneity p-value [d] | 0.9907 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.6 (90.7, 99.8) | 91.3 (80.1, 96.3) |
| 12 months | 98.6 (90.7, 99.8) | 91.3 (80.1, 96.3) |
| 18 months | 98.6 (90.7, 99.8) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=75) | Chemotherapy (N=63) |
|---|---|---|
| Patients with event, n (%) | 1 (1.3%) | 5 (7.9%) |
| Censored Patients, n (%) | 74 (98.7%) | 58 (92.1%) |
| | | |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0553 | |
| Hazard Ratio (95% CI) [c] | 0.160 (0.019, 1.370) | |
| HR P-Value [c] | 0.0944 | |
| Heterogeneity p-value [d] | 1.0000 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.6 (90.7, 99.8) | 91.3 (80.1, 96.3) |
| 12 months | 98.6 (90.7, 99.8) | 91.3 (80.1, 96.3) |
| 18 months | 98.6 (90.7, 99.8) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=59) | Chemotherapy (N=55) |
|---|---|---|
| Patients with event, n (%) | 18 (30.5%) | 20 (36.4%) |
| Censored Patients, n (%) | 41 (69.5%) | 35 (63.6%) |
| Median (95% CI), (Months) [a] | 13.63 (5.22, NC) | NC (4.86, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2540 | |
| Hazard Ratio (95% CI) [c] | 0.687 (0.358, 1.316) | |
| HR P-Value [c] | 0.2571 | |
| Heterogeneity p-value [d] | 0.1522 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 66.4 (49.8, 78.6) | 57.9 (40.6, 71.8) |
| 12 months | 59.0 (38.2, 74.9) | 57.9 (40.6, 71.8) |
| 18 months | 44.2 (16.4, 69.2) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=59) | Chemotherapy (N=55) |
|---|---|---|
| Patients with event, n (%) | 0 | 4 (7.3%) |
| Censored Patients, n (%) | 59 (100.0%) | 51 (92.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0338 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9949 | |
| Heterogeneity p-value [d] | 0.9907 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 92.2 (80.6, 97.0) |
| 12 months | 100.0 (100.0, 100.0) | 92.2 (80.6, 97.0) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=59) | Chemotherapy (N=55) |
|---|---|---|
| Patients with event, n (%) | 0 | 3 (5.5%) |
| Censored Patients, n (%) | 59 (100.0%) | 52 (94.5%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0591 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9956 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 96.1 (85.3, 99.0) |
| 12 months | 100.0 (100.0, 100.0) | 88.1 (59.4, 97.0) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=160) | Chemotherapy (N=133) |
|---|---|---|
| Patients with event, n (%) | 44 (27.5%) | 38 (28.6%) |
| Censored Patients, n (%) | 116 (72.5%) | 95 (71.4%) |
| | | |
| Median (95% CI), (Months) [a] | NC (13.63, NC) | NC (7.79, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1935 | |
| Hazard Ratio (95% CI) [c] | 0.746 (0.479, 1.162) | |
| HR P-Value [c] | 0.1953 | |
| Heterogeneity p-value [d] | 0.7635 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 72.9 (63.9, 80.0) | 64.7 (52.8, 74.3) |
| 12 months | 64.0 (52.9, 73.2) | 56.0 (40.2, 69.1) |
| 18 months | 54.8 (40.9, 66.8) | NC (NC, NC) |
| 24 months | 54.8 (40.9, 66.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=160) | Chemotherapy (N=133) |
|---|---|---|
| Patients with event, n (%) | 0 | 12 (9.0%) |
| Censored Patients, n (%) | 160 (100.0%) | 121 (91.0%) |
| | | |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9913 | |
| Heterogeneity p-value [d] | 0.9903 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 89.5 (80.8, 94.4) |
| 12 months | 100.0 (100.0, 100.0) | 86.5 (75.2, 92.9) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=160) | Chemotherapy (N=133) |
|---|---|---|
| Patients with event, n (%) | 0 | 9 (6.8%) |
| Censored Patients, n (%) | 160 (100.0%) | 124 (93.2%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0004 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9925 | |
| Heterogeneity p-value [d] | 0.9920 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 92.1 (83.6, 96.3) |
| 12 months | 100.0 (100.0, 100.0) | 88.3 (74.8, 94.8) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=35) | Chemotherapy (N=39) |
|---|---|---|
| Patients with event, n (%) | 12 (34.3%) | 14 (35.9%) |
| Censored Patients, n (%) | 23 (65.7%) | 25 (64.1%) |
| | | |
| Median (95% CI), (Months) [a] | NC (2.17, NC) | NC (2.23, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8167 | |
| Hazard Ratio (95% CI) [c] | 0.912 (0.421, 1.975) | |
| HR P-Value [c] | 0.8155 | |
| Heterogeneity p-value [d] | 0.7635 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 64.7 (45.1, 78.8) | 62.6 (45.1, 76.0) |
| 12 months | 56.6 (33.6, 74.4) | 62.6 (45.1, 76.0) |
| 18 months | NC (NC, NC) | 62.6 (45.1, 76.0) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=35) | Chemotherapy (N=39) |
|---|---|---|
| Patients with event, n (%) | 2 (5.7%) | 5 (12.8%) |
| Censored Patients, n (%) | 33 (94.3%) | 34 (87.2%) |
| | | |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3092 | |
| Hazard Ratio (95% CI) [c] | 0.437 (0.085, 2.254) | |
| HR P-Value [c] | 0.3229 | |
| Heterogeneity p-value [d] | 0.9903 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 94.0 (78.2, 98.5) | 86.0 (69.4, 94.0) |
| 12 months | 94.0 (78.2, 98.5) | 86.0 (69.4, 94.0) |
| 18 months | NC (NC, NC) | 86.0 (69.4, 94.0) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=35) | Chemotherapy (N=39) |
|---|---|---|
| Patients with event, n (%) | 1 (2.9%) | 2 (5.1%) |
| Censored Patients, n (%) | 34 (97.1%) | 37 (94.9%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6197 | |
| Hazard Ratio (95% CI) [c] | 0.549 (0.050, 6.060) | |
| HR P-Value [c] | 0.6249 | |
| Heterogeneity p-value [d] | 0.9920 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 97.0 (80.4, 99.6) | 94.7 (80.6, 98.7) |
| 12 months | 97.0 (80.4, 99.6) | 94.7 (80.6, 98.7) |
| 18 months | 97.0 (80.4, 99.6) | 94.7 (80.6, 98.7) |
| 24 months | 97.0 (80.4, 99.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=87) | Chemotherapy (N=76) |
|---|---|---|
| Patients with event, n (%) | 29 (33.3%) | 18 (23.7%) |
| Censored Patients, n (%) | 58 (66.7%) | 58 (76.3%) |
| | | |
| Median (95% CI), (Months) [a] | 16.10 (8.31, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8698 | |
| Hazard Ratio (95% CI) [c] | 1.051 (0.575, 1.922) | |
| HR P-Value [c] | 0.8710 | |
| Heterogeneity p-value [d] | 0.1424 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 67.8 (55.3, 77.5) | 73.8 (61.5, 82.8) |
| 12 months | 51.5 (33.7, 66.8) | 73.8 (61.5, 82.8) |
| 18 months | 38.6 (15.1, 62.0) | NC (NC, NC) |
| 24 months | 38.6 (15.1, 62.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=87) | Chemotherapy (N=76) |
|---|---|---|
| Patients with event, n (%) | 1 (1.1%) | 7 (9.2%) |
| Censored Patients, n (%) | 86 (98.9%) | 69 (90.8%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0144 | |
| Hazard Ratio (95% CI) [c] | 0.114 (0.014, 0.931) | |
| HR P-Value [c] | 0.0426 | |
| Heterogeneity p-value [d] | 0.9111 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.8 (92.0, 99.8) | 90.0 (80.0, 95.1) |
| 12 months | 98.8 (92.0, 99.8) | 90.0 (80.0, 95.1) |
| 18 months | 98.8 (92.0, 99.8) | NC (NC, NC) |
| 24 months | 98.8 (92.0, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=87) | Chemotherapy (N=76) |
|---|---|---|
| Patients with event, n (%) | 1 (1.1%) | 6 (7.9%) |
| Censored Patients, n (%) | 86 (98.9%) | 70 (92.1%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0311 | |
| Hazard Ratio (95% CI) [c] | 0.137 (0.017, 1.140) | |
| HR P-Value [c] | 0.0659 | |
| Heterogeneity p-value [d] | 0.9917 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.8 (92.0, 99.8) | 91.9 (82.8, 96.3) |
| 12 months | 98.8 (92.0, 99.8) | 91.9 (82.8, 96.3) |
| 18 months | 98.8 (92.0, 99.8) | NC (NC, NC) |
| 24 months | 98.8 (92.0, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=108) | Chemotherapy (N=96) |
|---|---|---|
| Patients with event, n (%) | 27 (25.0%) | 34 (35.4%) |
| Censored Patients, n (%) | 81 (75.0%) | 62 (64.6%) |
| | | |
| Median (95% CI), (Months) [a] | NC (13.83, NC) | NC (5.13, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0597 | |
| Hazard Ratio (95% CI) [c] | 0.615 (0.369, 1.025) | |
| HR P-Value [c] | 0.0619 | |
| Heterogeneity p-value [d] | 0.1424 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 74.9 (64.2, 82.9) | 59.9 (46.9, 70.7) |
| 12 months | 69.8 (57.2, 79.4) | 52.4 (37.2, 65.5) |
| 18 months | 61.6 (45.5, 74.2) | 52.4 (37.2, 65.5) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=108) | Chemotherapy (N=96) |
|---|---|---|
| Patients with event, n (%) | 1 (0.9%) | 10 (10.4%) |
| Censored Patients, n (%) | 107 (99.1%) | 86 (89.6%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0028 | |
| Hazard Ratio (95% CI) [c] | 0.085 (0.011, 0.665) | |
| HR P-Value [c] | 0.0188 | |
| Heterogeneity p-value [d] | 0.9111 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.1 (93.6, 99.9) | 88.5 (78.2, 94.1) |
| 12 months | 99.1 (93.6, 99.9) | 85.1 (72.0, 92.4) |
| 18 months | 99.1 (93.6, 99.9) | 85.1 (72.0, 92.4) |
| 24 months | 99.1 (93.6, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=108) | Chemotherapy (N=96) |
|---|---|---|
| Patients with event, n (%) | 0 | 5 (5.2%) |
| Censored Patients, n (%) | 108 (100.0%) | 91 (94.8%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0149 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9943 | |
| Heterogeneity p-value [d] | 0.9917 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 94.1 (83.7, 97.9) |
| 12 months | 100.0 (100.0, 100.0) | 90.3 (75.5, 96.4) |
| 18 months | 100.0 (100.0, 100.0) | 90.3 (75.5, 96.4) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=83) | Chemotherapy (N=64) |
|---|---|---|
| Patients with event, n (%) | 25 (30.1%) | 17 (26.6%) |
| Censored Patients, n (%) | 58 (69.9%) | 47 (73.4%) |
| | | |
| Median (95% CI), (Months) [a] | NC (13.63, NC) | NC (4.76, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6048 | |
| Hazard Ratio (95% CI) [c] | 0.846 (0.448, 1.598) | |
| HR P-Value [c] | 0.6061 | |
| Heterogeneity p-value [d] | 0.6747 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 72.0 (60.0, 81.0) | 62.2 (41.2, 77.5) |
| 12 months | 68.8 (55.3, 78.9) | 53.3 (29.1, 72.5) |
| 18 months | 54.2 (35.5, 69.6) | NC (NC, NC) |
| 24 months | 54.2 (35.5, 69.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=83) | Chemotherapy (N=64) |
|---|---|---|
| Patients with event, n (%) | 1 (1.2%) | 4 (6.3%) |
| Censored Patients, n (%) | 82 (98.8%) | 60 (93.8%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0548 | |
| Hazard Ratio (95% CI) [c] | 0.152 (0.017, 1.379) | |
| HR P-Value [c] | 0.0940 | |
| Heterogeneity p-value [d] | 0.5449 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.8 (91.8, 99.8) | 88.6 (68.6, 96.2) |
| 12 months | 98.8 (91.8, 99.8) | 88.6 (68.6, 96.2) |
| 18 months | 98.8 (91.8, 99.8) | NC (NC, NC) |
| 24 months | 98.8 (91.8, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=83) | Chemotherapy (N=64) |
|---|---|---|
| Patients with event, n (%) | 0 | 2 (3.1%) |
| Censored Patients, n (%) | 83 (100.0%) | 62 (96.9%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0504 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9966 | |
| Heterogeneity p-value [d] | 0.9929 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 92.6 (68.3, 98.5) |
| 12 months | 100.0 (100.0, 100.0) | 92.6 (68.3, 98.5) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=112) | Chemotherapy (N=108) |
|---|---|---|
| Patients with event, n (%) | 31 (27.7%) | 35 (32.4%) |
| Censored Patients, n (%) | 81 (72.3%) | 73 (67.6%) |
| | | |
| Median (95% CI), (Months) [a] | NC (8.31, NC) | NC (7.79, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2142 | |
| Hazard Ratio (95% CI) [c] | 0.736 (0.453, 1.196) | |
| HR P-Value [c] | 0.2154 | |
| Heterogeneity p-value [d] | 0.6747 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 70.9 (59.3, 79.8) | 64.0 (52.5, 73.4) |
| 12 months | 55.0 (38.8, 68.5) | 58.7 (43.6, 71.0) |
| 18 months | 55.0 (38.8, 68.5) | 58.7 (43.6, 71.0) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=112) | Chemotherapy (N=108) |
|---|---|---|
| Patients with event, n (%) | 1 (0.9%) | 13 (12.0%) |
| Censored Patients, n (%) | 111 (99.1%) | 95 (88.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0006 | |
| Hazard Ratio (95% CI) [c] | 0.068 (0.009, 0.519) | |
| HR P-Value [c] | 0.0096 | |
| Heterogeneity p-value [d] | 0.5449 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.1 (93.7, 99.9) | 88.1 (79.9, 93.1) |
| 12 months | 99.1 (93.7, 99.9) | 84.6 (72.7, 91.6) |
| 18 months | 99.1 (93.7, 99.9) | 84.6 (72.7, 91.6) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=112) | Chemotherapy (N=108) |
|---|---|---|
| Patients with event, n (%) | 1 (0.9%) | 9 (8.3%) |
| Censored Patients, n (%) | 111 (99.1%) | 99 (91.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0064 | |
| Hazard Ratio (95% CI) [c] | 0.098 (0.012, 0.774) | |
| HR P-Value [c] | 0.0276 | |
| Heterogeneity p-value [d] | 0.9929 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.1 (93.7, 99.9) | 92.0 (84.5, 95.9) |
| 12 months | 99.1 (93.7, 99.9) | 87.4 (72.7, 94.5) |
| 18 months | 99.1 (93.7, 99.9) | 87.4 (72.7, 94.5) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=115) | Chemotherapy (N=94) |
|---|---|---|
| Patients with event, n (%) | 31 (27.0%) | 34 (36.2%) |
| Censored Patients, n (%) | 84 (73.0%) | 60 (63.8%) |
| | | |
| Median (95% CI), (Months) [a] | NC (11.17, NC) | 8.38 (5.13, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0428 | |
| Hazard Ratio (95% CI) [c] | 0.604 (0.369, 0.989) | |
| HR P-Value [c] | 0.0450 | |
| Heterogeneity p-value [d] | 0.0996 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 74.1 (63.6, 82.0) | 59.4 (46.4, 70.3) |
| 12 months | 61.4 (47.3, 72.7) | 49.9 (33.4, 64.3) |
| 18 months | 55.8 (39.0, 69.7) | 49.9 (33.4, 64.3) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=115) | Chemotherapy (N=94) |
|---|---|---|
| Patients with event, n (%) | 1 (0.9%) | 15 (16.0%) |
| Censored Patients, n (%) | 114 (99.1%) | 79 (84.0%) |
| | | |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.047 (0.006, 0.356) | |
| HR P-Value [c] | 0.0031 | |
| Heterogeneity p-value [d] | 0.1536 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.1 (93.8, 99.9) | 82.1 (70.7, 89.4) |
| 12 months | 99.1 (93.8, 99.9) | 78.4 (64.4, 87.3) |
| 18 months | 99.1 (93.8, 99.9) | 78.4 (64.4, 87.3) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=115) | Chemotherapy (N=94) |
|---|---|---|
| Patients with event, n (%) | 1 (0.9%) | 10 (10.6%) |
| Censored Patients, n (%) | 114 (99.1%) | 84 (89.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0009 | |
| Hazard Ratio (95% CI) [c] | 0.071 (0.009, 0.556) | |
| HR P-Value [c] | 0.0118 | |
| Heterogeneity p-value [d] | 0.9951 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.1 (93.8, 99.9) | 88.2 (77.5, 94.1) |
| 12 months | 99.1 (93.8, 99.9) | 83.6 (67.8, 92.1) |
| 18 months | 99.1 (93.8, 99.9) | 83.6 (67.8, 92.1) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=78) | Chemotherapy (N=78) |
|---|---|---|
| Patients with event, n (%) | 25 (32.1%) | 18 (23.1%) |
| Censored Patients, n (%) | 53 (67.9%) | 60 (76.9%) |
| | | |
| Median (95% CI), (Months) [a] | 13.83 (6.87, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5483 | |
| Hazard Ratio (95% CI) [c] | 1.205 (0.653, 2.222) | |
| HR P-Value [c] | 0.5505 | |
| Heterogeneity p-value [d] | 0.0996 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 67.0 (53.4, 77.4) | 71.6 (55.9, 82.6) |
| 12 months | 63.8 (49.4, 75.1) | 71.6 (55.9, 82.6) |
| 18 months | 45.6 (22.2, 66.3) | NC (NC, NC) |
| 24 months | 45.6 (22.2, 66.3) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=78) | Chemotherapy (N=78) |
|---|---|---|
| Patients with event, n (%) | 1 (1.3%) | 2 (2.6%) |
| Censored Patients, n (%) | 77 (98.7%) | 76 (97.4%) |
| | | |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5583 | |
| Hazard Ratio (95% CI) [c] | 0.495 (0.045, 5.464) | |
| HR P-Value [c] | 0.5664 | |
| Heterogeneity p-value [d] | 0.1536 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.7 (91.2, 99.8) | 97.2 (89.4, 99.3) |
| 12 months | 98.7 (91.2, 99.8) | 97.2 (89.4, 99.3) |
| 18 months | 98.7 (91.2, 99.8) | NC (NC, NC) |
| 24 months | 98.7 (91.2, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=78) | Chemotherapy (N=78) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (1.3%) |
| Censored Patients, n (%) | 78 (100.0%) | 77 (98.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3138 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Heterogeneity p-value [d] | 0.9951 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 98.5 (90.0, 99.8) |
| 12 months | 100.0 (100.0, 100.0) | 98.5 (90.0, 99.8) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 11 (42.3%) | 4 (21.1%) |
| Censored Patients, n (%) | 15 (57.7%) | 15 (78.9%) |
| | | |
| Median (95% CI), (Months) [a] | 11.14 (7.16, NC) | NC (8.38, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5792 | |
| Hazard Ratio (95% CI) [c] | 1.394 (0.428, 4.536) | |
| HR P-Value [c] | 0.5809 | |
| Heterogeneity p-value [d] | 0.0334 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 72.2 (50.2, 85.7) | 84.2 (58.7, 94.6) |
| 12 months | 49.6 (23.5, 71.2) | 63.2 (18.5, 88.3) |
| 18 months | 33.1 (7.4, 62.5) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (5.3%) |
| Censored Patients, n (%) | 26 (100.0%) | 18 (94.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2294 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9984 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 94.4 (66.6, 99.2) |
| 12 months | 100.0 (100.0, 100.0) | 94.4 (66.6, 99.2) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Censored Patients, n (%) | 26 (100.0%) | 19 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | NC | |
| Hazard Ratio (95% CI) [c] | 1.000 (1.000, 1.000) | |
| HR P-Value [c] | NC | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=117) | Chemotherapy (N=109) |
|---|---|---|
| Patients with event, n (%) | 31 (26.5%) | 36 (33.0%) |
| Censored Patients, n (%) | 86 (73.5%) | 73 (67.0%) |
| | | |
| Median (95% CI), (Months) [a] | NC (13.63, NC) | NC (7.79, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0698 | |
| Hazard Ratio (95% CI) [c] | 0.641 (0.395, 1.041) | |
| HR P-Value [c] | 0.0723 | |
| Heterogeneity p-value [d] | 0.0334 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 72.2 (61.7, 80.3) | 62.4 (50.2, 72.3) |
| 12 months | 65.4 (52.9, 75.3) | 57.6 (42.8, 69.8) |
| 18 months | 61.1 (46.4, 72.9) | 57.6 (42.8, 69.8) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=117) | Chemotherapy (N=109) |
|---|---|---|
| Patients with event, n (%) | 0 | 12 (11.0%) |
| Censored Patients, n (%) | 117 (100.0%) | 97 (89.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9912 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 87.5 (77.5, 93.2) |
| 12 months | 100.0 (100.0, 100.0) | 83.9 (70.6, 91.5) |
| 18 months | 100.0 (100.0, 100.0) | 83.9 (70.6, 91.5) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=117) | Chemotherapy (N=109) |
|---|---|---|
| Patients with event, n (%) | 0 | 8 (7.3%) |
| Censored Patients, n (%) | 117 (100.0%) | 101 (92.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0013 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9928 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 91.5 (81.7, 96.2) |
| 12 months | 100.0 (100.0, 100.0) | 86.9 (71.2, 94.4) |
| 18 months | 100.0 (100.0, 100.0) | 86.9 (71.2, 94.4) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=20) | Chemotherapy (N=16) |
|---|---|---|
| Patients with event, n (%) | 3 (15.0%) | 7 (43.8%) |
| Censored Patients, n (%) | 17 (85.0%) | 9 (56.3%) |
| | | |
| Median (95% CI), (Months) [a] | NC (NC, NC) | 4.57 (0.59, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0594 | |
| Hazard Ratio (95% CI) [c] | 0.293 (0.075, 1.137) | |
| HR P-Value [c] | 0.0760 | |
| Heterogeneity p-value [d] | 0.0334 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 82.7 (55.1, 94.1) | 37.9 (7.8, 69.2) |
| 12 months | 82.7 (55.1, 94.1) | NC (NC, NC) |
| 18 months | 82.7 (55.1, 94.1) | NC (NC, NC) |
| 24 months | 82.7 (55.1, 94.1) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=20) | Chemotherapy (N=16) |
|---|---|---|
| Patients with event, n (%) | 0 | 3 (18.8%) |
| Censored Patients, n (%) | 20 (100.0%) | 13 (81.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0453 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9972 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 81.3 (52.5, 93.5) |
| 12 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=20) | Chemotherapy (N=16) |
|---|---|---|
| Patients with event, n (%) | 0 | 3 (18.8%) |
| Censored Patients, n (%) | 20 (100.0%) | 13 (81.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0453 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9972 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 81.3 (52.5, 93.5) |
| 12 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 18 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=32) | Chemotherapy (N=28) |
|---|---|---|
| Patients with event, n (%) | 11 (34.4%) | 5 (17.9%) |
| Censored Patients, n (%) | 21 (65.6%) | 23 (82.1%) |
| | | |
| Median (95% CI), (Months) [a] | 13.83 (5.55, 13.83) | NC (4.76, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1683 | |
| Hazard Ratio (95% CI) [c] | 2.071 (0.718, 5.972) | |
| HR P-Value [c] | 0.1777 | |
| Heterogeneity p-value [d] | 0.0334 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 61.1 (34.7, 79.5) | 68.1 (32.6, 87.7) |
| 12 months | 61.1 (34.7, 79.5) | 68.1 (32.6, 87.7) |
| 18 months | 0.0 (NC, NC) | NC (NC, NC) |
| 24 months | 0.0 (NC, NC) | NC (NC, NC) |
| 30 months | 0.0 (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=32) | Chemotherapy (N=28) |
|---|---|---|
| Patients with event, n (%) | 2 (6.3%) | 1 (3.6%) |
| Censored Patients, n (%) | 30 (93.8%) | 27 (96.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6230 | |
| Hazard Ratio (95% CI) [c] | 1.810 (0.164, 19.966) | |
| HR P-Value [c] | 0.6281 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 93.6 (76.9, 98.4) | 93.8 (63.2, 99.1) |
| 12 months | 93.6 (76.9, 98.4) | 93.8 (63.2, 99.1) |
| 18 months | 93.6 (76.9, 98.4) | NC (NC, NC) |
| 24 months | 93.6 (76.9, 98.4) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-ae-socpt-nopdl1.sas (25OCT22:16:05:39, qiuyue.chen1)

Table 25.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=32) | Chemotherapy (N=28) |
|---|---|---|
| Patients with event, n (%) | 1 (3.1%) | 0 |
| Censored Patients, n (%) | 31 (96.9%) | 28 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3507 | |
| Hazard Ratio (95% CI) [c] | 25961168 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Heterogeneity p-value [d] | 1.0000 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 96.8 (79.2, 99.5) | 100.0 (100.0, 100.0) |
| 12 months | 96.8 (79.2, 99.5) | 100.0 (100.0, 100.0) |
| 18 months | 96.8 (79.2, 99.5) | NC (NC, NC) |
| 24 months | 96.8 (79.2, 99.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
[d] Heterogeneity p-values are based on type 3 test of proportional hazards model with treatment, subgroup, treatment-by-subgroup as fixed factors.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/t-tte-subgroup-ae-socpt-nopdl1.sas (25OCT22:16:05:39, qiuyue.chen1)

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any TEAE

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 173 (88.7%) | 152 (88.4%) |
| Censored Patients, n (%) | 22 (11.3%) | 20 (11.6%) |
| Median (95% CI), (Months) [a] | 0.56 (0.39, 0.72) | 0.23 (0.13, 0.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0009 | |
| Hazard Ratio (95% CI) [c] | 0.685 (0.549, 0.857) | |
| HR P-Value [c] | 0.0009 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 11.8 (7.5, 17.3) | 9.9 (5.5, 16.0) |
| 12 months | 7.3 (3.7, 12.5) | 0.0 (NC, NC) |
| 18 months | 5.8 (2.5, 11.2) | 0.0 (NC, NC) |
| 24 months | NC (NC, NC) | 0.0 (NC, NC) |
| 30 months | NC (NC, NC) | 0.0 (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 57 (29.2%) | 87 (50.6%) |
| Censored Patients, n (%) | 138 (70.8%) | 85 (49.4%) |
| Median (95% CI), (Months) [a] | NC (13.63, NC) | 3.61 (2.04, 11.56) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.391 (0.277, 0.551) | |
| HR P-Value [c] | <0.0001 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 71.4 (63.5, 77.9) | 43.2 (34.1, 52.1) |
| 12 months | 65.0 (55.8, 72.7) | 28.4 (12.0, 47.4) |
| 18 months | 54.5 (41.6, 65.6) | 28.4 (12.0, 47.4) |
| 24 months | 54.5 (41.6, 65.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 47 (24.1%) | 77 (44.8%) |
| Censored Patients, n (%) | 148 (75.9%) | 95 (55.2%) |
| Median (95% CI), (Months) [a] | NC (16.62, NC) | 5.49 (2.99, NC) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.377 (0.260, 0.548) | |
| HR P-Value [c] | <0.0001 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 78.3 (71.2, 83.9) | 49.8 (40.3, 58.5) |
| 12 months | 72.1 (63.4, 79.1) | 32.7 (16.0, 50.5) |
| 18 months | 61.2 (47.8, 72.1) | 32.7 (16.0, 50.5) |
| 24 months | 61.2 (47.8, 72.1) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Neutropenia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 4 (2.1%) | 19 (11.0%) |
| Censored Patients, n (%) | 191 (97.9%) | 153 (89.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0002 | |
| Hazard Ratio (95% CI) [c] | 0.163 (0.055, 0.480) | |
| HR P-Value [c] | 0.0010 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 97.9 (93.3, 99.3) | 87.9 (81.5, 92.1) |
| 12 months | 96.4 (89.8, 98.7) | 87.9 (81.5, 92.1) |
| 18 months | 96.4 (89.8, 98.7) | 87.9 (81.5, 92.1) |
| 24 months | 96.4 (89.8, 98.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Endocrine disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 15 (7.7%) | 1 (0.6%) |
| Censored Patients, n (%) | 180 (92.3%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0020 | |
| Hazard Ratio (95% CI) [c] | 12.140 (1.603, 91.964) | |
| HR P-Value [c] | 0.0157 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 89.4 (82.8, 93.6) | 100.0 (100.0, 100.0) |
| 12 months | 89.4 (82.8, 93.6) | 97.1 (80.9, 99.6) |
| 18 months | 89.4 (82.8, 93.6) | 97.1 (80.9, 99.6) |
| 24 months | 89.4 (82.8, 93.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Endocrine disorders
PT: Hypothyroidism

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 11 (5.6%) | 0 |
| Censored Patients, n (%) | 184 (94.4%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0033 | |
| Hazard Ratio (95% CI) [c] | 23853838 (0.000, NC) | |
| HR P-Value [c] | 0.9918 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 91.6 (85.0, 95.3) | 100.0 (100.0, 100.0) |
| 12 months | 91.6 (85.0, 95.3) | 100.0 (100.0, 100.0) |
| 18 months | 91.6 (85.0, 95.3) | 100.0 (100.0, 100.0) |
| 24 months | 91.6 (85.0, 95.3) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 107 (54.9%) | 110 (64.0%) |
| Censored Patients, n (%) | 88 (45.1%) | 62 (36.0%) |
| Median (95% CI), (Months) [a] | 4.21 (2.10, 7.52) | 0.95 (0.53, 1.87) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0005 | |
| Hazard Ratio (95% CI) [c] | 0.622 (0.474, 0.815) | |
| HR P-Value [c] | 0.0006 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 45.0 (37.1, 52.5) | 30.1 (21.5, 39.0) |
| 12 months | 32.6 (23.8, 41.7) | 19.0 (8.2, 33.3) |
| 18 months | 32.6 (23.8, 41.7) | NC (NC, NC) |
| 24 months | NC (NC, NC) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Abdominal pain

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 18 (9.2%) | 17 (9.9%) |
| Censored Patients, n (%) | 177 (90.8%) | 155 (90.1%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5646 | |
| Hazard Ratio (95% CI) [c] | 0.822 (0.422, 1.600) | |
| HR P-Value [c] | 0.5645 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 90.0 (83.9, 93.8) | 85.5 (76.3, 91.3) |
| 12 months | 86.8 (78.7, 92.0) | 85.5 (76.3, 91.3) |
| 18 months | 86.8 (78.7, 92.0) | 85.5 (76.3, 91.3) |
| 24 months | 86.8 (78.7, 92.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 10 (5.1%) | 8 (4.7%) |
| Censored Patients, n (%) | 185 (94.9%) | 164 (95.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9509 | |
| Hazard Ratio (95% CI) [c] | 0.971 (0.381, 2.471) | |
| HR P-Value [c] | 0.9503 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 94.8 (89.5, 97.5) | 95.3 (90.8, 97.6) |
| 12 months | 92.1 (84.9, 95.9) | 95.3 (90.8, 97.6) |
| 18 months | 92.1 (84.9, 95.9) | 95.3 (90.8, 97.6) |
| 24 months | 92.1 (84.9, 95.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Constipation

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 32 (16.4%) | 36 (20.9%) |
| Censored Patients, n (%) | 163 (83.6%) | 136 (79.1%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1413 | |
| Hazard Ratio (95% CI) [c] | 0.699 (0.433, 1.129) | |
| HR P-Value [c] | 0.1436 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 83.2 (76.4, 88.1) | 70.5 (60.0, 78.7) |
| 12 months | 78.4 (69.5, 84.9) | 70.5 (60.0, 78.7) |
| 18 months | 78.4 (69.5, 84.9) | 70.5 (60.0, 78.7) |
| 24 months | 78.4 (69.5, 84.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Diarrhoea

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 20 (10.3%) | 27 (15.7%) |
| Censored Patients, n (%) | 175 (89.7%) | 145 (84.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0708 | |
| Hazard Ratio (95% CI) [c] | 0.589 (0.330, 1.053) | |
| HR P-Value [c] | 0.0740 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 88.0 (81.5, 92.3) | 83.1 (75.4, 88.5) |
| 12 months | 86.6 (79.5, 91.4) | 77.9 (66.8, 85.7) |
| 18 months | 86.6 (79.5, 91.4) | NC (NC, NC) |
| 24 months | 86.6 (79.5, 91.4) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Nausea

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 42 (21.5%) | 66 (38.4%) |
| Censored Patients, n (%) | 153 (78.5%) | 106 (61.6%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | 7.82 (5.29, NC) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.432 (0.292, 0.640) | |
| HR P-Value [c] | <0.0001 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 77.6 (70.3, 83.3) | 58.6 (49.1, 66.9) |
| 12 months | 72.3 (62.7, 79.9) | 40.7 (23.9, 56.9) |
| 18 months | 72.3 (62.7, 79.9) | 40.7 (23.9, 56.9) |
| 24 months | 72.3 (62.7, 79.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Stomatitis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 5 (2.6%) | 14 (8.1%) |
| Censored Patients, n (%) | 190 (97.4%) | 158 (91.9%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0094 | |
| Hazard Ratio (95% CI) [c] | 0.281 (0.101, 0.781) | |
| HR P-Value [c] | 0.0150 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 96.9 (91.8, 98.9) | 90.6 (83.7, 94.7) |
| 12 months | 95.8 (89.7, 98.3) | 90.6 (83.7, 94.7) |
| 18 months | 95.8 (89.7, 98.3) | 90.6 (83.7, 94.7) |
| 24 months | 95.8 (89.7, 98.3) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Vomiting

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 40 (20.5%) | 41 (23.8%) |
| Censored Patients, n (%) | 155 (79.5%) | 131 (76.2%) |
| Median (95% CI), (Months) [a] | NC (16.89, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0880 | |
| Hazard Ratio (95% CI) [c] | 0.682 (0.438, 1.061) | |
| HR P-Value [c] | 0.0896 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (74.1, 86.7) | 73.3 (64.5, 80.3) |
| 12 months | 67.4 (55.9, 76.5) | 65.6 (51.5, 76.5) |
| 18 months | 62.6 (47.9, 74.2) | 65.6 (51.5, 76.5) |
| 24 months | 62.6 (47.9, 74.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 83 (42.6%) | 90 (52.3%) |
| Censored Patients, n (%) | 112 (57.4%) | 82 (47.7%) |
| Median (95% CI), (Months) [a] | 19.02 (7.59, NC) | 3.68 (2.07, 4.90) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0051 | |
| Hazard Ratio (95% CI) [c] | 0.648 (0.478, 0.880) | |
| HR P-Value [c] | 0.0055 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 58.8 (51.2, 65.7) | 40.2 (30.4, 49.8) |
| 12 months | 52.9 (44.0, 61.1) | 22.3 (9.1, 39.2) |
| 18 months | 52.9 (44.0, 61.1) | NC (NC, NC) |
| 24 months | 35.9 (19.3, 53.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Asthenia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 19 (9.7%) | 27 (15.7%) |
| Censored Patients, n (%) | 176 (90.3%) | 145 (84.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0300 | |
| Hazard Ratio (95% CI) [c] | 0.520 (0.285, 0.948) | |
| HR P-Value [c] | 0.0327 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 89.8 (84.1, 93.5) | 83.7 (76.2, 89.0) |
| 12 months | 89.8 (84.1, 93.5) | 71.7 (54.9, 83.2) |
| 18 months | 89.8 (84.1, 93.5) | 71.7 (54.9, 83.2) |
| 24 months | 80.8 (56.1, 92.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Fatigue

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 35 (17.9%) | 34 (19.8%) |
| Censored Patients, n (%) | 160 (82.1%) | 138 (80.2%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4296 | |
| Hazard Ratio (95% CI) [c] | 0.825 (0.514, 1.326) | |
| HR P-Value [c] | 0.4274 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 81.5 (74.8, 86.5) | 78.1 (69.8, 84.4) |
| 12 months | 78.5 (70.6, 84.5) | 70.3 (55.9, 80.8) |
| 18 months | 78.5 (70.6, 84.5) | NC (NC, NC) |
| 24 months | 78.5 (70.6, 84.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Oedema peripheral

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 13 (6.7%) | 10 (5.8%) |
| Censored Patients, n (%) | 182 (93.3%) | 162 (94.2%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9367 | |
| Hazard Ratio (95% CI) [c] | 1.034 (0.451, 2.368) | |
| HR P-Value [c] | 0.9369 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 92.7 (87.3, 95.9) | 90.6 (81.9, 95.2) |
| 12 months | 91.0 (83.9, 95.0) | 90.6 (81.9, 95.2) |
| 18 months | 91.0 (83.9, 95.0) | 90.6 (81.9, 95.2) |
| 24 months | 91.0 (83.9, 95.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Pyrexia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 22 (11.3%) | 25 (14.5%) |
| Censored Patients, n (%) | 173 (88.7%) | 147 (85.5%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1827 | |
| Hazard Ratio (95% CI) [c] | 0.676 (0.378, 1.210) | |
| HR P-Value [c] | 0.1874 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 89.8 (84.4, 93.4) | 84.1 (77.0, 89.2) |
| 12 months | 85.4 (76.2, 91.2) | 80.8 (70.2, 87.9) |
| 18 months | 83.0 (72.5, 89.8) | 80.8 (70.2, 87.9) |
| 24 months | 83.0 (72.5, 89.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 13 (6.7%) | 3 (1.7%) |
| Censored Patients, n (%) | 182 (93.3%) | 169 (98.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0513 | |
| Hazard Ratio (95% CI) [c] | 3.264 (0.926, 11.502) | |
| HR P-Value [c] | 0.0657 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 92.1 (85.8, 95.6) | 98.2 (94.5, 99.4) |
| 12 months | 88.8 (80.5, 93.7) | 98.2 (94.5, 99.4) |
| 18 months | 88.8 (80.5, 93.7) | 98.2 (94.5, 99.4) |
| 24 months | 88.8 (80.5, 93.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 65 (33.3%) | 55 (32.0%) |
| Censored Patients, n (%) | 130 (66.7%) | 117 (68.0%) |
| Median (95% CI), (Months) [a] | 16.10 (10.45, NC) | NC (7.89, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3998 | |
| Hazard Ratio (95% CI) [c] | 0.855 (0.593, 1.233) | |
| HR P-Value [c] | 0.4024 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 70.8 (63.1, 77.2) | 61.9 (52.2, 70.2) |
| 12 months | 52.1 (40.4, 62.5) | 58.2 (46.5, 68.3) |
| 18 months | 48.1 (34.9, 60.0) | NC (NC, NC) |
| 24 months | 37.4 (21.5, 53.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Urinary tract infection

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 21 (10.8%) | 16 (9.3%) |
| Censored Patients, n (%) | 174 (89.2%) | 156 (90.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | 18.56 (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8258 | |
| Hazard Ratio (95% CI) [c] | 0.928 (0.477, 1.805) | |
| HR P-Value [c] | 0.8250 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 91.9 (86.8, 95.0) | 89.0 (81.6, 93.5) |
| 12 months | 82.2 (71.1, 89.4) | 89.0 (81.6, 93.5) |
| 18 months | 79.4 (66.8, 87.6) | 89.0 (81.6, 93.5) |
| 24 months | 79.4 (66.8, 87.6) | 0.0 (NC, NC) |
| 30 months | NC (NC, NC) | 0.0 (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Injury, poisoning and procedural complications

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 21 (10.8%) | 13 (7.6%) |
| Censored Patients, n (%) | 174 (89.2%) | 159 (92.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5450 | |
| Hazard Ratio (95% CI) [c] | 1.242 (0.616, 2.503) | |
| HR P-Value [c] | 0.5442 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 90.7 (85.4, 94.1) | 89.0 (80.7, 93.9) |
| 12 months | 86.8 (78.1, 92.2) | 89.0 (80.7, 93.9) |
| 18 months | 81.3 (69.2, 89.0) | 89.0 (80.7, 93.9) |
| 24 months | 81.3 (69.2, 89.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 46 (23.6%) | 44 (25.6%) |
| Censored Patients, n (%) | 149 (76.4%) | 128 (74.4%) |
| Median (95% CI), (Months) [a] | NC (14.55, NC) | NC (7.75, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1399 | |
| Hazard Ratio (95% CI) [c] | 0.728 (0.478, 1.111) | |
| HR P-Value [c] | 0.1410 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 76.1 (68.3, 82.1) | 68.2 (57.7, 76.6) |
| 12 months | 70.0 (60.5, 77.7) | 61.6 (47.8, 72.7) |
| 18 months | 61.0 (47.8, 71.8) | NC (NC, NC) |
| 24 months | 61.0 (47.8, 71.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Aspartate aminotransferase increased

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 7 (3.6%) | 11 (6.4%) |
| Censored Patients, n (%) | 188 (96.4%) | 161 (93.6%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1529 | |
| Hazard Ratio (95% CI) [c] | 0.507 (0.196, 1.310) | |
| HR P-Value [c] | 0.1607 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 95.0 (89.5, 97.7) | 92.5 (86.6, 95.8) |
| 12 months | 95.0 (89.5, 97.7) | 92.5 (86.6, 95.8) |
| 18 months | 95.0 (89.5, 97.7) | 92.5 (86.6, 95.8) |
| 24 months | 95.0 (89.5, 97.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Blood alkaline phosphatase increased

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 9 (4.6%) | 10 (5.8%) |
| Censored Patients, n (%) | 186 (95.4%) | 162 (94.2%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2850 | |
| Hazard Ratio (95% CI) [c] | 0.611 (0.245, 1.522) | |
| HR P-Value [c] | 0.2896 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 95.2 (89.8, 97.8) | 91.8 (82.8, 96.2) |
| 12 months | 92.2 (84.3, 96.2) | 83.9 (65.0, 93.1) |
| 18 months | 92.2 (84.3, 96.2) | 83.9 (65.0, 93.1) |
| 24 months | 92.2 (84.3, 96.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Blood creatinine increased

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 12 (6.2%) | 9 (5.2%) |
| Censored Patients, n (%) | 183 (93.8%) | 163 (94.8%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7145 | |
| Hazard Ratio (95% CI) [c] | 0.847 (0.346, 2.072) | |
| HR P-Value [c] | 0.7163 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 94.1 (88.4, 97.0) | 91.5 (82.4, 96.1) |
| 12 months | 92.7 (86.0, 96.2) | 88.3 (75.8, 94.5) |
| 18 months | 86.4 (73.2, 93.4) | 88.3 (75.8, 94.5) |
| 24 months | 86.4 (73.2, 93.4) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Weight decreased

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 10 (5.1%) | 8 (4.7%) |
| Censored Patients, n (%) | 185 (94.9%) | 164 (95.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6460 | |
| Hazard Ratio (95% CI) [c] | 0.800 (0.308, 2.077) | |
| HR P-Value [c] | 0.6471 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 95.6 (90.8, 97.9) | 94.9 (87.9, 97.9) |
| 12 months | 91.5 (82.2, 96.1) | 89.5 (77.0, 95.4) |
| 18 months | 88.4 (76.1, 94.6) | 89.5 (77.0, 95.4) |
| 24 months | 88.4 (76.1, 94.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 58 (29.7%) | 54 (31.4%) |
| Censored Patients, n (%) | 137 (70.3%) | 118 (68.6%) |
| Median (95% CI), (Months) [a] | NC (15.18, NC) | NC (7.10, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2487 | |
| Hazard Ratio (95% CI) [c] | 0.802 (0.551, 1.167) | |
| HR P-Value [c] | 0.2489 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 70.6 (62.9, 77.0) | 66.0 (57.1, 73.5) |
| 12 months | 65.7 (56.9, 73.1) | 57.0 (44.4, 67.8) |
| 18 months | 56.7 (43.9, 67.7) | 57.0 (44.4, 67.8) |
| 24 months | 56.7 (43.9, 67.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 31 (15.9%) | 27 (15.7%) |
| Censored Patients, n (%) | 164 (84.1%) | 145 (84.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6438 | |
| Hazard Ratio (95% CI) [c] | 0.884 (0.525, 1.489) | |
| HR P-Value [c] | 0.6443 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 82.7 (75.5, 87.9) | 82.5 (75.0, 88.0) |
| 12 months | 79.8 (71.6, 85.9) | 79.6 (69.6, 86.6) |
| 18 months | 76.0 (64.3, 84.4) | 79.6 (69.6, 86.6) |
| 24 months | 76.0 (64.3, 84.4) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 2 (1.0%) | 13 (7.6%) |
| Censored Patients, n (%) | 193 (99.0%) | 159 (92.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0007 | |
| Hazard Ratio (95% CI) [c] | 0.116 (0.026, 0.515) | |
| HR P-Value [c] | 0.0047 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.9 (95.8, 99.7) | 92.7 (87.1, 95.9) |
| 12 months | 98.9 (95.8, 99.7) | 86.5 (73.9, 93.3) |
| 18 months | 98.9 (95.8, 99.7) | 86.5 (73.9, 93.3) |
| 24 months | 98.9 (95.8, 99.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Hypoalbuminaemia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 13 (6.7%) | 9 (5.2%) |
| Censored Patients, n (%) | 182 (93.3%) | 163 (94.8%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7382 | |
| Hazard Ratio (95% CI) [c] | 1.156 (0.493, 2.713) | |
| HR P-Value [c] | 0.7387 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 93.5 (88.3, 96.5) | 91.7 (83.2, 96.0) |
| 12 months | 91.1 (84.4, 95.0) | 91.7 (83.2, 96.0) |
| 18 months | 91.1 (84.4, 95.0) | 91.7 (83.2, 96.0) |
| 24 months | 91.1 (84.4, 95.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Hypokalaemia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 13 (6.7%) | 13 (7.6%) |
| Censored Patients, n (%) | 182 (93.3%) | 159 (92.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4267 | |
| Hazard Ratio (95% CI) [c] | 0.730 (0.335, 1.590) | |
| HR P-Value [c] | 0.4283 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 94.2 (89.0, 97.0) | 91.0 (84.8, 94.8) |
| 12 months | 90.3 (82.9, 94.6) | 91.0 (84.8, 94.8) |
| 18 months | 88.0 (78.7, 93.4) | 91.0 (84.8, 94.8) |
| 24 months | 88.0 (78.7, 93.4) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 52 (26.7%) | 44 (25.6%) |
| Censored Patients, n (%) | 143 (73.3%) | 128 (74.4%) |
| Median (95% CI), (Months) [a] | NC (22.47, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6629 | |
| Hazard Ratio (95% CI) [c] | 0.915 (0.609, 1.374) | |
| HR P-Value [c] | 0.6671 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 75.3 (68.1, 81.1) | 69.1 (59.8, 76.6) |
| 12 months | 65.7 (55.7, 74.0) | 65.8 (54.6, 74.8) |
| 18 months | 63.5 (52.8, 72.4) | 65.8 (54.6, 74.8) |
| 24 months | 50.8 (26.0, 71.1) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 17 (8.7%) | 5 (2.9%) |
| Censored Patients, n (%) | 178 (91.3%) | 167 (97.1%) |
| Median (95% CI), (Months) [a] | NC (22.47, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0686 | |
| Hazard Ratio (95% CI) [c] | 2.489 (0.903, 6.864) | |
| HR P-Value [c] | 0.0781 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 92.2 (87.1, 95.3) | 97.0 (92.0, 98.9) |
| 12 months | 90.1 (82.9, 94.4) | 93.7 (81.3, 97.9) |
| 18 months | 86.8 (75.6, 93.1) | 93.7 (81.3, 97.9) |
| 24 months | 75.9 (46.8, 90.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 21 (10.8%) | 16 (9.3%) |
| Censored Patients, n (%) | 174 (89.2%) | 156 (90.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9475 | |
| Hazard Ratio (95% CI) [c] | 0.978 (0.506, 1.890) | |
| HR P-Value [c] | 0.9473 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 88.6 (81.8, 92.9) | 86.8 (78.4, 92.1) |
| 12 months | 84.0 (75.1, 89.9) | 86.8 (78.4, 92.1) |
| 18 months | 79.8 (66.6, 88.2) | 86.8 (78.4, 92.1) |
| 24 months | 79.8 (66.6, 88.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Pain in extremity

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 13 (6.7%) | 5 (2.9%) |
| Censored Patients, n (%) | 182 (93.3%) | 167 (97.1%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1658 | |
| Hazard Ratio (95% CI) [c] | 2.046 (0.728, 5.753) | |
| HR P-Value [c] | 0.1748 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 92.2 (85.9, 95.8) | 96.3 (91.2, 98.5) |
| 12 months | 89.6 (82.0, 94.1) | 96.3 (91.2, 98.5) |
| 18 months | 89.6 (82.0, 94.1) | 96.3 (91.2, 98.5) |
| 24 months | 89.6 (82.0, 94.1) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 31 (15.9%) | 39 (22.7%) |
| Censored Patients, n (%) | 164 (84.1%) | 133 (77.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (8.80, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0173 | |
| Hazard Ratio (95% CI) [c] | 0.562 (0.348, 0.908) | |
| HR P-Value [c] | 0.0187 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 82.8 (75.6, 88.1) | 77.9 (69.9, 84.1) |
| 12 months | 78.8 (70.3, 85.2) | 54.0 (34.6, 70.0) |
| 18 months | 74.2 (60.9, 83.5) | NC (NC, NC) |
| 24 months | 74.2 (60.9, 83.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders
PT: Dizziness

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 10 (5.1%) | 8 (4.7%) |
| Censored Patients, n (%) | 185 (94.9%) | 164 (95.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6908 | |
| Hazard Ratio (95% CI) [c] | 0.823 (0.317, 2.141) | |
| HR P-Value [c] | 0.6903 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 95.8 (90.6, 98.2) | 95.7 (91.3, 98.0) |
| 12 months | 91.7 (83.9, 95.8) | 91.0 (74.9, 96.9) |
| 18 months | 87.3 (73.1, 94.3) | 91.0 (74.9, 96.9) |
| 24 months | 87.3 (73.1, 94.3) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders
PT: Headache

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 16 (8.2%) | 11 (6.4%) |
| Censored Patients, n (%) | 179 (91.8%) | 161 (93.6%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.6444 | |
| Hazard Ratio (95% CI) [c] | 1.199 (0.554, 2.596) | |
| HR P-Value [c] | 0.6444 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 90.9 (85.5, 94.4) | 93.3 (87.1, 96.6) |
| 12 months | 90.9 (85.5, 94.4) | 81.9 (55.2, 93.5) |
| 18 months | 90.9 (85.5, 94.4) | 81.9 (55.2, 93.5) |
| 24 months | 90.9 (85.5, 94.4) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Psychiatric disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 24 (12.3%) | 21 (12.2%) |
| Censored Patients, n (%) | 171 (87.7%) | 151 (87.8%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7078 | |
| Hazard Ratio (95% CI) [c] | 0.894 (0.496, 1.609) | |
| HR P-Value [c] | 0.7082 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 86.2 (79.4, 90.8) | 84.6 (76.1, 90.2) |
| 12 months | 83.5 (75.8, 89.0) | 79.6 (65.1, 88.6) |
| 18 months | 83.5 (75.8, 89.0) | 79.6 (65.1, 88.6) |
| 24 months | 83.5 (75.8, 89.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 30 (15.4%) | 24 (14.0%) |
| Censored Patients, n (%) | 165 (84.6%) | 148 (86.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9062 | |
| Hazard Ratio (95% CI) [c] | 0.968 (0.563, 1.664) | |
| HR P-Value [c] | 0.9060 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 83.4 (76.4, 88.5) | 82.4 (74.0, 88.3) |
| 12 months | 79.8 (70.9, 86.3) | 82.4 (74.0, 88.3) |
| 18 months | 76.9 (65.9, 84.7) | 82.4 (74.0, 88.3) |
| 24 months | 76.9 (65.9, 84.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders
PT: Haematuria

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 10 (5.1%) | 4 (2.3%) |
| Censored Patients, n (%) | 185 (94.9%) | 168 (97.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2121 | |
| Hazard Ratio (95% CI) [c] | 2.062 (0.646, 6.588) | |
| HR P-Value [c] | 0.2220 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 94.8 (90.2, 97.3) | 97.2 (92.6, 99.0) |
| 12 months | 93.5 (87.7, 96.6) | 97.2 (92.6, 99.0) |
| 18 months | 93.5 (87.7, 96.6) | 97.2 (92.6, 99.0) |
| 24 months | 93.5 (87.7, 96.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Reproductive system and breast disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 32 (16.4%) | 23 (13.4%) |
| Censored Patients, n (%) | 163 (83.6%) | 149 (86.6%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | 17.74 (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8622 | |
| Hazard Ratio (95% CI) [c] | 0.952 (0.549, 1.651) | |
| HR P-Value [c] | 0.8620 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 86.6 (80.2, 91.0) | 83.2 (74.6, 89.1) |
| 12 months | 76.0 (65.7, 83.5) | 79.0 (66.2, 87.4) |
| 18 months | 68.9 (54.6, 79.5) | 0.0 (NC, NC) |
| 24 months | 68.9 (54.6, 79.5) | 0.0 (NC, NC) |
| 30 months | NC (NC, NC) | 0.0 (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Reproductive system and breast disorders
PT: Pelvic pain

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 10 (5.1%) | 12 (7.0%) |
| Censored Patients, n (%) | 185 (94.9%) | 160 (93.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | 17.74 (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1073 | |
| Hazard Ratio (95% CI) [c] | 0.491 (0.203, 1.186) | |
| HR P-Value [c] | 0.1138 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 95.4 (90.3, 97.9) | 90.6 (82.2, 95.1) |
| 12 months | 91.9 (83.3, 96.2) | 86.3 (72.2, 93.5) |
| 18 months | 88.7 (76.8, 94.7) | 0.0 (NC, NC) |
| 24 months | 88.7 (76.8, 94.7) | 0.0 (NC, NC) |
| 30 months | NC (NC, NC) | 0.0 (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Reproductive system and breast disorders
PT: Vaginal haemorrhage

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 10 (5.1%) | 6 (3.5%) |
| Censored Patients, n (%) | 185 (94.9%) | 166 (96.5%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8097 | |
| Hazard Ratio (95% CI) [c] | 1.136 (0.403, 3.201) | |
| HR P-Value [c] | 0.8098 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 96.0 (91.9, 98.1) | 93.8 (85.8, 97.4) |
| 12 months | 92.7 (84.8, 96.5) | 93.8 (85.8, 97.4) |
| 18 months | 89.6 (78.2, 95.2) | 93.8 (85.8, 97.4) |
| 24 months | 89.6 (78.2, 95.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 47 (24.1%) | 29 (16.9%) |
| Censored Patients, n (%) | 148 (75.9%) | 143 (83.1%) |
| Median (95% CI), (Months) [a] | NC (22.80, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3919 | |
| Hazard Ratio (95% CI) [c] | 1.227 (0.768, 1.960) | |
| HR P-Value [c] | 0.3916 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 73.9 (65.5, 80.6) | 79.4 (71.3, 85.5) |
| 12 months | 66.7 (56.7, 74.9) | 79.4 (71.3, 85.5) |
| 18 months | 63.0 (50.8, 72.9) | NC (NC, NC) |
| 24 months | 54.0 (33.7, 70.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 17 (8.7%) | 13 (7.6%) |
| Censored Patients, n (%) | 178 (91.3%) | 159 (92.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8582 | |
| Hazard Ratio (95% CI) [c] | 0.935 (0.449, 1.949) | |
| HR P-Value [c] | 0.8586 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 92.2 (86.3, 95.6) | 92.0 (86.2, 95.4) |
| 12 months | 86.2 (77.2, 91.8) | 88.9 (78.6, 94.4) |
| 18 months | 82.6 (70.3, 90.2) | 88.9 (78.6, 94.4) |
| 24 months | 82.6 (70.3, 90.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 23 (11.8%) | 13 (7.6%) |
| Censored Patients, n (%) | 172 (88.2%) | 159 (92.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4370 | |
| Hazard Ratio (95% CI) [c] | 1.314 (0.659, 2.621) | |
| HR P-Value [c] | 0.4376 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 88.7 (82.6, 92.8) | 91.5 (85.2, 95.2) |
| 12 months | 85.7 (78.0, 90.9) | 88.5 (78.3, 94.0) |
| 18 months | 79.5 (66.6, 87.9) | 88.5 (78.3, 94.0) |
| 24 months | 79.5 (66.6, 87.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Skin and subcutaneous tissue disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 36 (18.5%) | 43 (25.0%) |
| Censored Patients, n (%) | 159 (81.5%) | 129 (75.0%) |
| Median (95% CI), (Months) [a] | NC (15.61, NC) | NC (10.15, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0101 | |
| Hazard Ratio (95% CI) [c] | 0.550 (0.346, 0.872) | |
| HR P-Value [c] | 0.0111 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 83.2 (76.8, 88.0) | 72.3 (63.4, 79.4) |
| 12 months | 83.2 (76.8, 88.0) | 64.3 (45.4, 78.1) |
| 18 months | 62.6 (45.4, 75.8) | NC (NC, NC) |
| 24 months | 62.6 (45.4, 75.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Skin and subcutaneous tissue disorders
PT: Rash

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 12 (6.2%) | 14 (8.1%) |
| Censored Patients, n (%) | 183 (93.8%) | 158 (91.9%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1836 | |
| Hazard Ratio (95% CI) [c] | 0.580 (0.258, 1.304) | |
| HR P-Value [c] | 0.1877 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 95.2 (90.9, 97.5) | 91.7 (86.3, 95.0) |
| 12 months | 95.2 (90.9, 97.5) | 91.7 (86.3, 95.0) |
| 18 months | 84.9 (68.6, 93.2) | 91.7 (86.3, 95.0) |
| 24 months | 84.9 (68.6, 93.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Vascular disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 18 (9.2%) | 11 (6.4%) |
| Censored Patients, n (%) | 177 (90.8%) | 161 (93.6%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4931 | |
| Hazard Ratio (95% CI) [c] | 1.301 (0.612, 2.768) | |
| HR P-Value [c] | 0.4944 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 91.3 (85.9, 94.7) | 91.8 (84.6, 95.7) |
| 12 months | 88.2 (80.5, 92.9) | 91.8 (84.6, 95.7) |
| 18 months | 85.6 (75.8, 91.6) | 91.8 (84.6, 95.7) |
| 24 months | 85.6 (75.8, 91.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Table 25.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any treatment-emergent SAE

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 56 (28.7%) | 52 (30.2%) |
| Censored Patients, n (%) | 139 (71.3%) | 120 (69.8%) |
| Median (95% CI), (Months) [a] | NC (13.63, NC) | NC (7.79, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1887 | |
| Hazard Ratio (95% CI) [c] | 0.774 (0.528, 1.135) | |
| HR P-Value [c] | 0.1898 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 71.5 (63.6, 78.1) | 64.2 (54.3, 72.5) |
| 12 months | 62.5 (52.3, 71.1) | 57.4 (44.5, 68.4) |
| 18 months | 53.7 (40.6, 65.1) | 57.4 (44.5, 68.4) |
| 24 months | 53.7 (40.6, 65.1) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 2 (1.0%) | 17 (9.9%) |
| Censored Patients, n (%) | 193 (99.0%) | 155 (90.1%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.093 (0.021, 0.403) | |
| HR P-Value [c] | 0.0015 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.0 (95.9, 99.7) | 88.7 (81.4, 93.2) |
| 12 months | 99.0 (95.9, 99.7) | 86.3 (77.2, 92.0) |
| 18 months | 99.0 (95.9, 99.7) | 86.3 (77.2, 92.0) |
| 24 months | 99.0 (95.9, 99.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 11 (6.4%) |
| Censored Patients, n (%) | 194 (99.5%) | 161 (93.6%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0008 | |
| Hazard Ratio (95% CI) [c] | 0.070 (0.009, 0.544) | |
| HR P-Value [c] | 0.0110 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.3, 99.9) | 92.7 (85.8, 96.3) |
| 12 months | 99.5 (96.3, 99.9) | 89.6 (78.8, 95.0) |
| 18 months | 99.5 (96.3, 99.9) | 89.6 (78.8, 95.0) |
| 24 months | 99.5 (96.3, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 9 (4.6%) | 10 (5.8%) |
| Censored Patients, n (%) | 186 (95.4%) | 162 (94.2%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3707 | |
| Hazard Ratio (95% CI) [c] | 0.662 (0.267, 1.644) | |
| HR P-Value [c] | 0.3739 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 96.5 (92.4, 98.4) | 91.5 (83.8, 95.7) |
| 12 months | 91.3 (82.0, 95.9) | 91.5 (83.8, 95.7) |
| 18 months | 91.3 (82.0, 95.9) | 91.5 (83.8, 95.7) |
| 24 months | 91.3 (82.0, 95.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 22 (11.3%) | 19 (11.0%) |
| Censored Patients, n (%) | 173 (88.7%) | 153 (89.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (12.25, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4572 | |
| Hazard Ratio (95% CI) [c] | 0.788 (0.420, 1.478) | |
| HR P-Value [c] | 0.4583 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 90.8 (85.3, 94.3) | 87.4 (78.8, 92.7) |
| 12 months | 82.5 (72.5, 89.1) | 77.7 (62.8, 87.2) |
| 18 months | 78.1 (64.1, 87.2) | 68.0 (42.8, 83.9) |
| 24 months | 78.1 (64.1, 87.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any TEAE CTCAE Grade >= 3

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 94 (48.2%) | 87 (50.6%) |
| Censored Patients, n (%) | 101 (51.8%) | 85 (49.4%) |
| Median (95% CI), (Months) [a] | 7.16 (4.80, 13.83) | 3.61 (1.87, 11.56) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0165 | |
| Hazard Ratio (95% CI) [c] | 0.694 (0.515, 0.936) | |
| HR P-Value [c] | 0.0165 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 53.9 (45.9, 61.3) | 45.3 (36.5, 53.7) |
| 12 months | 45.5 (36.5, 54.0) | 29.7 (12.5, 49.2) |
| 18 months | 33.2 (22.8, 44.0) | 29.7 (12.5, 49.2) |
| 24 months | 29.5 (18.4, 41.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 24 (12.3%) | 60 (34.9%) |
| Censored Patients, n (%) | 171 (87.7%) | 112 (65.1%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (11.56, NC) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.276 (0.171, 0.445) | |
| HR P-Value [c] | <0.0001 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 86.9 (80.6, 91.3) | 60.3 (50.9, 68.4) |
| 12 months | 85.5 (78.4, 90.4) | 51.7 (33.4, 67.2) |
| 18 months | 83.3 (74.7, 89.2) | 51.7 (33.4, 67.2) |
| 24 months | 83.3 (74.7, 89.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 21 (10.8%) | 51 (29.7%) |
| Censored Patients, n (%) | 174 (89.2%) | 121 (70.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (11.56, NC) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| Hazard Ratio (95% CI) [c] | 0.290 (0.174, 0.486) | |
| HR P-Value [c] | <0.0001 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 88.7 (82.6, 92.8) | 66.6 (57.3, 74.3) |
| 12 months | 87.3 (80.3, 91.9) | 55.4 (36.9, 70.4) |
| 18 months | 85.0 (76.4, 90.7) | 55.4 (36.9, 70.4) |
| 24 months | 85.0 (76.4, 90.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Neutropenia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 11 (6.4%) |
| Censored Patients, n (%) | 194 (99.5%) | 161 (93.6%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0013 | |
| Hazard Ratio (95% CI) [c] | 0.075 (0.010, 0.584) | |
| HR P-Value [c] | 0.0133 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.2, 99.9) | 92.5 (86.7, 95.8) |
| 12 months | 99.5 (96.2, 99.9) | 92.5 (86.7, 95.8) |
| 18 months | 99.5 (96.2, 99.9) | 92.5 (86.7, 95.8) |
| 24 months | 99.5 (96.2, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 17 (8.7%) | 19 (11.0%) |
| Censored Patients, n (%) | 178 (91.3%) | 153 (89.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1179 | |
| Hazard Ratio (95% CI) [c] | 0.587 (0.299, 1.152) | |
| HR P-Value [c] | 0.1218 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 92.1 (86.1, 95.5) | 84.7 (75.8, 90.6) |
| 12 months | 87.0 (77.8, 92.6) | 79.4 (64.0, 88.8) |
| 18 months | 84.0 (72.5, 91.0) | 79.4 (64.0, 88.8) |
| 24 months | 79.4 (63.6, 88.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 15 (7.7%) | 8 (4.7%) |
| Censored Patients, n (%) | 180 (92.3%) | 164 (95.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4999 | |
| Hazard Ratio (95% CI) [c] | 1.351 (0.562, 3.248) | |
| HR P-Value [c] | 0.5011 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 93.4 (88.7, 96.2) | 94.8 (88.6, 97.7) |
| 12 months | 89.8 (81.7, 94.5) | 88.9 (69.3, 96.3) |
| 18 months | 89.8 (81.7, 94.5) | 88.9 (69.3, 96.3) |
| 24 months | 83.4 (64.4, 92.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 10 (5.1%) | 1 (0.6%) |
| Censored Patients, n (%) | 185 (94.9%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0237 | |
| Hazard Ratio (95% CI) [c] | 7.521 (0.961, 58.871) | |
| HR P-Value [c] | 0.0546 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 93.1 (86.9, 96.4) | 99.4 (95.9, 99.9) |
| 12 months | 91.7 (84.7, 95.6) | 99.4 (95.9, 99.9) |
| 18 months | 91.7 (84.7, 95.6) | 99.4 (95.9, 99.9) |
| 24 months | 91.7 (84.7, 95.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 21 (10.8%) | 18 (10.5%) |
| Censored Patients, n (%) | 174 (89.2%) | 154 (89.5%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (12.22, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5762 | |
| Hazard Ratio (95% CI) [c] | 0.832 (0.437, 1.585) | |
| HR P-Value [c] | 0.5767 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 91.3 (86.1, 94.6) | 89.3 (82.3, 93.6) |
| 12 months | 84.7 (75.4, 90.6) | 82.7 (69.5, 90.5) |
| 18 months | 80.6 (67.5, 88.9) | 73.5 (48.6, 87.7) |
| 24 months | 80.6 (67.5, 88.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 17 (8.7%) | 8 (4.7%) |
| Censored Patients, n (%) | 178 (91.3%) | 164 (95.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3768 | |
| Hazard Ratio (95% CI) [c] | 1.468 (0.623, 3.463) | |
| HR P-Value [c] | 0.3802 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 90.7 (84.4, 94.5) | 95.9 (91.5, 98.0) |
| 12 months | 88.5 (80.1, 93.4) | 89.9 (69.6, 96.9) |
| 18 months | 82.5 (69.6, 90.2) | 89.9 (69.6, 96.9) |
| 24 months | 82.5 (69.6, 90.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 12 (6.2%) | 12 (7.0%) |
| Censored Patients, n (%) | 183 (93.8%) | 160 (93.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5535 | |
| Hazard Ratio (95% CI) [c] | 0.785 (0.351, 1.753) | |
| HR P-Value [c] | 0.5542 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 94.1 (89.1, 96.8) | 93.0 (87.6, 96.1) |
| 12 months | 91.3 (84.3, 95.2) | 90.2 (81.1, 95.1) |
| 18 months | 91.3 (84.3, 95.2) | 90.2 (81.1, 95.1) |
| 24 months | 91.3 (84.3, 95.2) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 11 (5.6%) | 4 (2.3%) |
| Censored Patients, n (%) | 184 (94.4%) | 168 (97.7%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1495 | |
| Hazard Ratio (95% CI) [c] | 2.270 (0.722, 7.142) | |
| HR P-Value [c] | 0.1608 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 93.9 (88.8, 96.8) | 97.5 (93.4, 99.1) |
| 12 months | 92.8 (86.9, 96.1) | 97.5 (93.4, 99.1) |
| 18 months | 92.8 (86.9, 96.1) | 97.5 (93.4, 99.1) |
| 24 months | 92.8 (86.9, 96.1) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any TEAE leading to discontinuation

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 20 (10.3%) | 8 (4.7%) |
| Censored Patients, n (%) | 175 (89.7%) | 164 (95.3%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2754 | |
| Hazard Ratio (95% CI) [c] | 1.588 (0.686, 3.676) | |
| HR P-Value [c] | 0.2799 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 89.2 (82.1, 93.7) | 95.0 (89.6, 97.7) |
| 12 months | 85.2 (76.6, 90.9) | 90.0 (73.5, 96.5) |
| 18 months | 74.6 (58.8, 85.1) | 90.0 (73.5, 96.5) |
| 24 months | 74.6 (58.8, 85.1) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 2 (1.2%) |
| Censored Patients, n (%) | 194 (99.5%) | 170 (98.8%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4884 | |
| Hazard Ratio (95% CI) [c] | 0.438 (0.040, 4.833) | |
| HR P-Value [c] | 0.5006 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 98.8 (95.4, 99.7) |
| 12 months | 99.5 (96.4, 99.9) | 98.8 (95.4, 99.7) |
| 18 months | 99.5 (96.4, 99.9) | 98.8 (95.4, 99.7) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 1 (0.6%) |
| Censored Patients, n (%) | 194 (99.5%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9272 | |
| Hazard Ratio (95% CI) [c] | 0.879 (0.055, 14.046) | |
| HR P-Value [c] | 0.9270 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 12 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 18 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3494 | |
| Hazard Ratio (95% CI) [c] | 26086336 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Neutropenia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2870 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2854 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Cardiac disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4181 | |
| Hazard Ratio (95% CI) [c] | 20665332 (0.000, NC) | |
| HR P-Value [c] | 0.9976 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.9 (92.4, 99.8) | 100.0 (100.0, 100.0) |
| 12 months | 98.9 (92.4, 99.8) | 100.0 (100.0, 100.0) |
| 18 months | 98.9 (92.4, 99.8) | 100.0 (100.0, 100.0) |
| 24 months | 98.9 (92.4, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Cardiac disorders
PT: Autoimmune pericarditis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4181 | |
| Hazard Ratio (95% CI) [c] | 20665332 (0.000, NC) | |
| HR P-Value [c] | 0.9976 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.9 (92.4, 99.8) | 100.0 (100.0, 100.0) |
| 12 months | 98.9 (92.4, 99.8) | 100.0 (100.0, 100.0) |
| 18 months | 98.9 (92.4, 99.8) | 100.0 (100.0, 100.0) |
| 24 months | 98.9 (92.4, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Endocrine disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 2 (1.0%) | 0 |
| Censored Patients, n (%) | 193 (99.0%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2244 | |
| Hazard Ratio (95% CI) [c] | 22827526 (0.000, NC) | |
| HR P-Value [c] | 0.9966 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.5 (93.7, 99.6) | 100.0 (100.0, 100.0) |
| 12 months | 98.5 (93.7, 99.6) | 100.0 (100.0, 100.0) |
| 18 months | 98.5 (93.7, 99.6) | 100.0 (100.0, 100.0) |
| 24 months | 98.5 (93.7, 99.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Endocrine disorders
PT: Hypothyroidism

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 2 (1.0%) | 0 |
| Censored Patients, n (%) | 193 (99.0%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2244 | |
| Hazard Ratio (95% CI) [c] | 22827526 (0.000, NC) | |
| HR P-Value [c] | 0.9966 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.5 (93.7, 99.6) | 100.0 (100.0, 100.0) |
| 12 months | 98.5 (93.7, 99.6) | 100.0 (100.0, 100.0) |
| 18 months | 98.5 (93.7, 99.6) | 100.0 (100.0, 100.0) |
| 24 months | 98.5 (93.7, 99.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 2 (1.0%) | 1 (0.6%) |
| Censored Patients, n (%) | 193 (99.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9916 | |
| Hazard Ratio (95% CI) [c] | 0.986 (0.075, 13.018) | |
| HR P-Value [c] | 0.9916 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.3, 99.9) | 98.9 (92.4, 99.8) |
| 12 months | 99.5 (96.3, 99.9) | 98.9 (92.4, 99.8) |
| 18 months | 96.3 (81.0, 99.3) | 98.9 (92.4, 99.8) |
| 24 months | 96.3 (81.0, 99.3) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Colitis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3514 | |
| Hazard Ratio (95% CI) [c] | 25893249 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.3, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.5 (96.3, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.5 (96.3, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.5 (96.3, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Diverticular perforation

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2583 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 98.9 (92.4, 99.8) |
| 12 months | 100.0 (100.0, 100.0) | 98.9 (92.4, 99.8) |
| 18 months | 100.0 (100.0, 100.0) | 98.9 (92.4, 99.8) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Pancreatic mass

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7557 | |
| Hazard Ratio (95% CI) [c] | 3787486 (0.000, NC) | |
| HR P-Value [c] | 0.9981 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 18 months | 96.8 (79.2, 99.5) | 100.0 (100.0, 100.0) |
| 24 months | 96.8 (79.2, 99.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Pancreatitis chronic

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.7557 | |
| Hazard Ratio (95% CI) [c] | 3787486 (0.000, NC) | |
| HR P-Value [c] | 0.9981 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 18 months | 96.8 (79.2, 99.5) | 100.0 (100.0, 100.0) |
| 24 months | 96.8 (79.2, 99.5) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 1 (0.6%) |
| Censored Patients, n (%) | 194 (99.5%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9272 | |
| Hazard Ratio (95% CI) [c] | 0.879 (0.055, 14.046) | |
| HR P-Value [c] | 0.9270 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 12 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 18 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Malaise

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2870 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3494 | |
| Hazard Ratio (95% CI) [c] | 26086336 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 7 (3.6%) | 0 |
| Censored Patients, n (%) | 188 (96.4%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0289 | |
| Hazard Ratio (95% CI) [c] | 21495936 (0.000, NC) | |
| HR P-Value [c] | 0.9936 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 94.7 (88.4, 97.7) | 100.0 (100.0, 100.0) |
| 12 months | 93.4 (86.1, 96.9) | 100.0 (100.0, 100.0) |
| 18 months | 93.4 (86.1, 96.9) | 100.0 (100.0, 100.0) |
| 24 months | 93.4 (86.1, 96.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 3 (1.5%) | 0 |
| Censored Patients, n (%) | 192 (98.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1697 | |
| Hazard Ratio (95% CI) [c] | 20060050 (0.000, NC) | |
| HR P-Value [c] | 0.9959 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 97.0 (91.0, 99.0) | 100.0 (100.0, 100.0) |
| 12 months | 97.0 (91.0, 99.0) | 100.0 (100.0, 100.0) |
| 18 months | 97.0 (91.0, 99.0) | 100.0 (100.0, 100.0) |
| 24 months | 97.0 (91.0, 99.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3494 | |
| Hazard Ratio (95% CI) [c] | 26086336 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders
PT: Hepatitis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4764 | |
| Hazard Ratio (95% CI) [c] | 17486227 (0.000, NC) | |
| HR P-Value [c] | 0.9977 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 98.6 (90.4, 99.8) | 100.0 (100.0, 100.0) |
| 18 months | 98.6 (90.4, 99.8) | 100.0 (100.0, 100.0) |
| 24 months | 98.6 (90.4, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 2 (1.0%) | 0 |
| Censored Patients, n (%) | 193 (99.0%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2253 | |
| Hazard Ratio (95% CI) [c] | 22719660 (0.000, NC) | |
| HR P-Value [c] | 0.9966 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.2 (92.7, 99.6) | 100.0 (100.0, 100.0) |
| 12 months | 98.2 (92.7, 99.6) | 100.0 (100.0, 100.0) |
| 18 months | 98.2 (92.7, 99.6) | 100.0 (100.0, 100.0) |
| 24 months | 98.2 (92.7, 99.6) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 4 (2.1%) | 0 |
| Censored Patients, n (%) | 191 (97.9%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1739 | |
| Hazard Ratio (95% CI) [c] | 19467034 (0.000, NC) | |
| HR P-Value [c] | 0.9958 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.4 (95.9, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 96.5 (88.9, 98.9) | 100.0 (100.0, 100.0) |
| 18 months | 92.3 (76.4, 97.7) | 100.0 (100.0, 100.0) |
| 24 months | 92.3 (76.4, 97.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: COVID-19 pneumonia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8348 | |
| Hazard Ratio (95% CI) [c] | 3497465 (0.000, NC) | |
| HR P-Value [c] | 0.9987 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 18 months | 95.7 (72.9, 99.4) | 100.0 (100.0, 100.0) |
| 24 months | 95.7 (72.9, 99.4) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Gastroenteritis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4931 | |
| Hazard Ratio (95% CI) [c] | 16740184 (0.000, NC) | |
| HR P-Value [c] | 0.9978 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 98.5 (89.7, 99.8) | 100.0 (100.0, 100.0) |
| 18 months | 98.5 (89.7, 99.8) | 100.0 (100.0, 100.0) |
| 24 months | 98.5 (89.7, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Pelvic abscess

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4735 | |
| Hazard Ratio (95% CI) [c] | 17625229 (0.000, NC) | |
| HR P-Value [c] | 0.9977 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 98.6 (90.5, 99.8) | 100.0 (100.0, 100.0) |
| 18 months | 98.6 (90.5, 99.8) | 100.0 (100.0, 100.0) |
| 24 months | 98.6 (90.5, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Peritonitis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3574 | |
| Hazard Ratio (95% CI) [c] | 25328847 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.4 (95.9, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.4 (95.9, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.4 (95.9, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.4 (95.9, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Pneumonia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.5602 | |
| Hazard Ratio (95% CI) [c] | 14288116 (0.000, NC) | |
| HR P-Value [c] | 0.9980 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 98.2 (88.0, 99.7) | 100.0 (100.0, 100.0) |
| 18 months | 98.2 (88.0, 99.7) | 100.0 (100.0, 100.0) |
| 24 months | 98.2 (88.0, 99.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Pyomyositis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.4735 | |
| Hazard Ratio (95% CI) [c] | 17625229 (0.000, NC) | |
| HR P-Value [c] | 0.9977 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 98.6 (90.5, 99.8) | 100.0 (100.0, 100.0) |
| 18 months | 98.6 (90.5, 99.8) | 100.0 (100.0, 100.0) |
| 24 months | 98.6 (90.5, 99.8) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Injury, poisoning and procedural complications

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 1 (0.6%) |
| Censored Patients, n (%) | 194 (99.5%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8826 | |
| Hazard Ratio (95% CI) [c] | 0.812 (0.051, 12.990) | |
| HR P-Value [c] | 0.8828 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.2 (94.7, 99.9) | 99.3 (95.5, 99.9) |
| 12 months | 99.2 (94.7, 99.9) | 99.3 (95.5, 99.9) |
| 18 months | 99.2 (94.7, 99.9) | 99.3 (95.5, 99.9) |
| 24 months | 99.2 (94.7, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2794 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.3 (95.5, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.3 (95.5, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.3 (95.5, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3799 | |
| Hazard Ratio (95% CI) [c] | 23393830 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.2 (94.7, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.2 (94.7, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.2 (94.7, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.2 (94.7, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 2 (1.0%) | 0 |
| Censored Patients, n (%) | 193 (99.0%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1885 | |
| Hazard Ratio (95% CI) [c] | 25793878 (0.000, NC) | |
| HR P-Value [c] | 0.9965 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 98.9 (95.6, 99.7) | 100.0 (100.0, 100.0) |
| 12 months | 98.9 (95.6, 99.7) | 100.0 (100.0, 100.0) |
| 18 months | 98.9 (95.6, 99.7) | 100.0 (100.0, 100.0) |
| 24 months | 98.9 (95.6, 99.7) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Alanine aminotransferase increased

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3570 | |
| Hazard Ratio (95% CI) [c] | 25366230 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.4 (95.8, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.4 (95.8, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.4 (95.8, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.4 (95.8, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Amylase increased

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3508 | |
| Hazard Ratio (95% CI) [c] | 25947785 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Platelet count decreased

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3494 | |
| Hazard Ratio (95% CI) [c] | 26086336 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 1 (0.6%) |
| Censored Patients, n (%) | 194 (99.5%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9257 | |
| Hazard Ratio (95% CI) [c] | 0.876 (0.055, 14.009) | |
| HR P-Value [c] | 0.9256 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 12 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 18 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 1 (0.6%) |
| Censored Patients, n (%) | 194 (99.5%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.9257 | |
| Hazard Ratio (95% CI) [c] | 0.876 (0.055, 14.009) | |
| HR P-Value [c] | 0.9256 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 12 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 18 months | 99.5 (96.4, 99.9) | 99.4 (95.9, 99.9) |
| 24 months | 99.5 (96.4, 99.9) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 1 (0.6%) |
| Censored Patients, n (%) | 194 (99.5%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3474 | |
| Hazard Ratio (95% CI) [c] | 0.200 (0.006, 6.394) | |
| HR P-Value [c] | 0.3626 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.2 (94.2, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.2 (94.2, 99.9) |
| 18 months | 95.0 (69.5, 99.3) | 99.2 (94.2, 99.9) |
| 24 months | 95.0 (69.5, 99.3) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2636 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.2 (94.2, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.2 (94.2, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.2 (94.2, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.8231 | |
| Hazard Ratio (95% CI) [c] | 3532358 (0.000, NC) | |
| HR P-Value [c] | 0.9986 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 18 months | 95.0 (69.5, 99.3) | 100.0 (100.0, 100.0) |
| 24 months | 95.0 (69.5, 99.3) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 2 (1.2%) |
| Censored Patients, n (%) | 195 (100.0%) | 170 (98.8%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1303 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9964 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 98.7 (95.1, 99.7) |
| 12 months | 100.0 (100.0, 100.0) | 98.7 (95.1, 99.7) |
| 18 months | 100.0 (100.0, 100.0) | 98.7 (95.1, 99.7) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders
PT: Neurotoxicity

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2824 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.3 (95.3, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.3 (95.3, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.3 (95.3, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders
PT: Transient ischaemic attack

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2870 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Psychiatric disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0860 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9981 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 94.7 (68.1, 99.2) |
| 18 months | 100.0 (100.0, 100.0) | 94.7 (68.1, 99.2) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Psychiatric disorders
PT: Agoraphobia

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0860 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9981 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 100.0 (100.0, 100.0) |
| 12 months | 100.0 (100.0, 100.0) | 94.7 (68.1, 99.2) |
| 18 months | 100.0 (100.0, 100.0) | 94.7 (68.1, 99.2) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2870 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders
PT: Renal failure

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2870 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 4 (2.1%) | 0 |
| Censored Patients, n (%) | 191 (97.9%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0719 | |
| Hazard Ratio (95% CI) [c] | 24529493 (0.000, NC) | |
| HR P-Value [c] | 0.9951 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 97.3 (92.5, 99.0) | 100.0 (100.0, 100.0) |
| 12 months | 97.3 (92.5, 99.0) | 100.0 (100.0, 100.0) |
| 18 months | 97.3 (92.5, 99.0) | 100.0 (100.0, 100.0) |
| 24 months | 97.3 (92.5, 99.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 4 (2.1%) | 0 |
| Censored Patients, n (%) | 191 (97.9%) | 172 (100.0%) |
| | | |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0719 | |
| Hazard Ratio (95% CI) [c] | 24529493 (0.000, NC) | |
| HR P-Value [c] | 0.9951 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 97.3 (92.5, 99.0) | 100.0 (100.0, 100.0) |
| 12 months | 97.3 (92.5, 99.0) | 100.0 (100.0, 100.0) |
| 18 months | 97.3 (92.5, 99.0) | 100.0 (100.0, 100.0) |
| 24 months | 97.3 (92.5, 99.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Vascular disorders

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2870 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 25.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Vascular disorders
PT: Deep vein thrombosis

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 0 | 1 (0.6%) |
| Censored Patients, n (%) | 195 (100.0%) | 171 (99.4%) |
| Median (95% CI), (Months) [a] | NC (NC, NC) | NC (NC, NC) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2870 | |
| Hazard Ratio (95% CI) [c] | 0.000 (0.000, NC) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 12 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 18 months | 100.0 (100.0, 100.0) | 99.4 (95.9, 99.9) |
| 24 months | 100.0 (100.0, 100.0) | NC (NC, NC) |
| 30 months | NC (NC, NC) | NC (NC, NC) |

Data cut-off as of Jan 4th, 2021.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any TEAE | 637 | 494 | 186 | 14 | 3 | 721 | 487 | 221 | 11 | 1 |
| Number of Patients with Any TEAE | 15 (7.7) | 64 (32.8) | 81 (41.5) | 10 (5.1) | 3 (1.5) | 14 (8.1) | 51 (29.7) | 76 (44.2) | 10 (5.8) | 1 (0.6) |
| Blood and lymphatic system disorders | 6 (3.1) | 27 (13.8) | 24 (12.3) | 0 | 0 | 7 (4.1) | 20 (11.6) | 55 (32.0) | 5 (2.9) | 0 |
| Anaemia | 4 (2.1) | 22 (11.3) | 21 (10.8) | 0 | 0 | 7 (4.1) | 19 (11.0) | 50 (29.1) | 1 (0.6) | 0 |
| Disseminated intravascular coagulation | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Eosinophilia | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Febrile neutropenia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 5 (2.9) | 0 | 0 |
| Hyperchromasia | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Leukopenia | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 5 (2.9) | 1 (0.6) | 0 |
| Lymph node pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lymphopenia | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Neutropenia | 0 | 3 (1.5) | 1 (0.5) | 0 | 0 | 2 (1.2) | 6 (3.5) | 9 (5.2) | 2 (1.2) | 0 |
| Pancytopenia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Thrombocytopenia | 0 | 0 | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 5 (2.9) | 2 (1.2) | 0 |
| Thrombocytosis | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Cardiac disorders | 6 (3.1) | 2 (1.0) | 0 | 1 (0.5) | 0 | 5 (2.9) | 0 | 0 | 0 | 0 |
| Angina pectoris | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Autoimmune pericarditis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Left ventricular dysfunction | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Myocardial ischaemia | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Palpitations | 0 | 0 | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 | 0 |
| Pericardial effusion | 0 | 1 (0.5) | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Sinus tachycardia | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tachycardia | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Ear and labyrinth disorders | 8 (4.1) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Ear discomfort | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ear pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ear pruritus | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Tinnitus | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vertigo | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Endocrine disorders | 2 (1.0) | 12 (6.2) | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Adrenal insufficiency | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hyperthyroidism | 2 (1.0) | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypothyroidism | 1 (0.5) | 9 (4.6) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Thyroiditis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Eye disorders | 4 (2.1) | 1 (0.5) | 0 | 0 | 0 | 7 (4.1) | 2 (1.2) | 0 | 0 | 0 |
| Corneal perforation | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Dry eye | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Eye pruritus | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Eyelid oedema | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Lacrimation increased | 1 (0.5) | 0 | 0 | 0 | 0 | 5 (2.9) | 1 (0.6) | 0 | 0 | 0 |
| Vision blurred | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vitreous floaters | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Gastrointestinal disorders | 39 (20.0) | 51 (26.2) | 17 (8.7) | 0 | 0 | 42 (24.4) | 49 (28.5) | 19 (11.0) | 0 | 0 |
| Abdominal discomfort | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Abdominal distension | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Abdominal pain | 7 (3.6) | 9 (4.6) | 2 (1.0) | 0 | 0 | 6 (3.5) | 10 (5.8) | 1 (0.6) | 0 | 0 |
| Abdominal pain lower | 1 (0.5) | 2 (1.0) | 1 (0.5) | 0 | 0 | 2 (1.2) | 3 (1.7) | 1 (0.6) | 0 | 0 |
| Abdominal pain upper | 8 (4.1) | 2 (1.0) | 0 | 0 | 0 | 5 (2.9) | 3 (1.7) | 0 | 0 | 0 |
| Anal fissure | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Anal fistula | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Anal haemorrhage | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Anal incontinence | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Anal inflammation | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Anal stenosis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Anorectal discomfort | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Aphthous ulcer | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Ascites | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Change of bowel habit | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Colitis | 1 (0.5) | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Constipation | 16 (8.2) | 16 (8.2) | 0 | 0 | 0 | 17 (9.9) | 18 (10.5) | 1 (0.6) | 0 | 0 |
| Diarrhoea | 11 (5.6) | 6 (3.1) | 3 (1.5) | 0 | 0 | 16 (9.3) | 8 (4.7) | 3 (1.7) | 0 | 0 |
| Diverticular perforation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Dry mouth | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Duodenal ulcer | 0 | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dyspepsia | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 4 (2.3) | 0 | 0 | 0 | 0 |
| Dysphagia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Faeces soft | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Flatulence | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Gastric mucosa erythema | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastric ulcer | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastritis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastritis erosive | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastrointestinal oedema | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | 2 (1.0) | 3 (1.5) | 0 | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 |
| Gingival bleeding | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gingival pain | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Glossitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Haematochezia | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 1 (0.6) | 0 | 0 |
| Haemoperitoneum | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Haemorrhoids | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ileus | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Inguinal hernia | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Intestinal obstruction | 0 | 0 | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 1 (0.6) | 0 | 0 |
| Large intestinal obstruction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lip blister | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lip dry | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lip swelling | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Melaena | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Mouth haemorrhage | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Mouth ulceration | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Nausea | 17 (8.7) | 24 (12.3) | 1 (0.5) | 0 | 0 | 35 (20.3) | 26 (15.1) | 5 (2.9) | 0 | 0 |
| Odynophagia | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Oesophageal obstruction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oesophagitis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Oral papule | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pancreatic mass | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pancreatitis chronic | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Proctalgia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Proctitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rectal haemorrhage | 4 (2.1) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Rectal tenesmus | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Salivary hypersecretion | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 | 0 |
| Stomatitis | 2 (1.0) | 3 (1.5) | 0 | 0 | 0 | 8 (4.7) | 4 (2.3) | 2 (1.2) | 0 | 0 |
| Toothache | 3 (1.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Vomiting | 24 (12.3) | 14 (7.2) | 2 (1.0) | 0 | 0 | 24 (14.0) | 11 (6.4) | 6 (3.5) | 0 | 0 |
| General disorders and administration site conditions | 36 (18.5) | 32 (16.4) | 13 (6.7) | 0 | 2 (1.0) | 31 (18.0) | 51 (29.7) | 7 (4.1) | 0 | 1 (0.6) |
| Asthenia | 9 (4.6) | 4 (2.1) | 6 (3.1) | 0 | 0 | 9 (5.2) | 15 (8.7) | 3 (1.7) | 0 | 0 |
| Catheter site thrombosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Chest pain | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Chills | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Death | 0 | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 |
| Discomfort | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Drug intolerance | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Early satiety | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Face oedema | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Fatigue | 15 (7.7) | 18 (9.2) | 2 (1.0) | 0 | 0 | 10 (5.8) | 22 (12.8) | 2 (1.2) | 0 | 0 |
| Feeling cold | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gait disturbance | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Generalised oedema | 0 | 1 (0.5) | 0 | 0 | 0 | 2 (1.2) | 0 | 1 (0.6) | 0 | 0 |
| Hyperpyrexia | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hyperthermia | 2 (1.0) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Influenza like illness | 3 (1.5) | 1 (0.5) | 1 (0.5) | 0 | 0 | 4 (2.3) | 1 (0.6) | 0 | 0 | 0 |
| Localised oedema | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Malaise | 1 (0.5) | 0 | 0 | 0 | 0 | 4 (2.3) | 3 (1.7) | 1 (0.6) | 0 | 0 |
| Mucosal dryness | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Non-cardiac chest pain | 1 (0.5) | 1 (0.5) | 2 (1.0) | 0 | 0 | 1 (0.6) | 4 (2.3) | 0 | 0 | 0 |
| Oedema | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Oedema peripheral | 8 (4.1) | 4 (2.1) | 1 (0.5) | 0 | 0 | 6 (3.5) | 4 (2.3) | 0 | 0 | 0 |
| Pain | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Performance status decreased | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) |
| Puncture site erythema | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Pyrexia | 14 (7.2) | 7 (3.6) | 1 (0.5) | 0 | 0 | 16 (9.3) | 9 (5.2) | 0 | 0 | 0 |
| Sudden death | 0 | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 |
| Swelling | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hepatobiliary disorders | 1 (0.5) | 2 (1.0) | 8 (4.1) | 2 (1.0) | 0 | 2 (1.2) | 0 | 1 (0.6) | 0 | 0 |
| Autoimmune hepatitis | 0 | 1 (0.5) | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cholecystitis acute | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cholestasis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Hepatic function abnormal | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatic pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatic steatosis | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hepatitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatocellular injury | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hepatotoxicity | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypertransaminasaemia | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Immune-mediated hepatitis | 0 | 0 | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Immune system disorders | 2 (1.0) | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Contrast media allergy | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypersensitivity | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Seasonal allergy | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Infections and infestations | 17 (8.7) | 27 (13.8) | 18 (9.2) | 2 (1.0) | 1 (0.5) | 18 (10.5) | 19 (11.0) | 17 (9.9) | 1 (0.6) | 0 |
| Acute sinusitis | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Aspergillus infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Bacteraemia | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Bronchitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| COVID-19 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| COVID-19 pneumonia | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Candida infection | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cellulitis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Clostridium difficile infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Conjunctivitis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Cystitis | 1 (0.5) | 5 (2.6) | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Cytomegalovirus infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device related infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Empyema | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Enterobacter bacteraemia | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Enterobacter infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Fungal infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Fungal skin infection | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastroenteritis | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastroenteritis viral | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Herpes virus infection | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Herpes zoster | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Infection | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Influenza | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Kidney infection | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Lower respiratory tract infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lymphangitis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Nasopharyngitis | 6 (3.1) | 2 (1.0) | 0 | 0 | 0 | 5 (2.9) | 0 | 0 | 0 | 0 |
| Ophthalmic herpes zoster | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oral candidiasis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oral herpes | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pelvic abscess | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Peritonitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pharyngitis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pneumonia | 1 (0.5) | 3 (1.5) | 2 (1.0) | 0 | 1 (0.5) | 1 (0.6) | 0 | 3 (1.7) | 0 | 0 |
| Postoperative wound infection | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pulmonary tuberculosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pyelonephritis | 0 | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Pyelonephritis acute | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pyomyositis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Rash pustular | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Respiratory tract infection | 0 | 0 | 0 | 0 | 0 | 3 (1.7) | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Respiratory tract infection viral | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Rhinitis | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Sepsis | 0 | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 |
| Serratia infection | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Staphylococcal bacteraemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Staphylococcal infection | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Staphylococcal sepsis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Stoma site infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Streptococcal sepsis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 |
| Tonsillitis | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Tonsillitis bacterial | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Tooth abscess | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Toxic shock syndrome streptococcal | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Upper respiratory tract infection | 4 (2.1) | 3 (1.5) | 0 | 0 | 0 | 2 (1.2) | 1 (0.6) | 0 | 0 | 0 |
| Urinary tract infection | 3 (1.5) | 9 (4.6) | 9 (4.6) | 0 | 0 | 4 (2.3) | 7 (4.1) | 5 (2.9) | 0 | 0 |
| Urinary tract infection bacterial | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Urosepsis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vaginal infection | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Viral infection | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Viral rash | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Viral rhinitis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vulvitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vulvovaginitis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 7 (3.6) | 10 (5.1) | 4 (2.1) | 0 | 0 | 5 (2.9) | 4 (2.3) | 4 (2.3) | 0 | 0 |
| Allergic transfusion reaction | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Animal bite | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chillblains | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Contusion | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Cystitis radiation | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device use error | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Fall | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Febrile nonhaemolytic transfusion reaction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Foot fracture | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastrointestinal stoma complication | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Hand fracture | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Infusion related reaction | 3 (1.5) | 3 (1.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Muscle strain | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Overdose | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Peroneal nerve injury | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Procedural pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Skin injury | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Spinal compression fracture | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Spinal fracture | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tooth fracture | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transfusion reaction | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Upper limb fracture | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Urinary tract stoma complication | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vascular access complication | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Investigations | 14 (7.2) | 15 (7.7) | 13 (6.7) | 4 (2.1) | 0 | 14 (8.1) | 22 (12.8) | 7 (4.1) | 1 (0.6) | 0 |
| Alanine aminotransferase increased | 6 (3.1) | 2 (1.0) | 1 (0.5) | 0 | 0 | 4 (2.3) | 3 (1.7) | 2 (1.2) | 0 | 0 |
| Amylase increased | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Aspartate aminotransferase increased | 2 (1.0) | 3 (1.5) | 2 (1.0) | 0 | 0 | 7 (4.1) | 4 (2.3) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | 3 (1.5) | 2 (1.0) | 4 (2.1) | 0 | 0 | 6 (3.5) | 3 (1.7) | 1 (0.6) | 0 | 0 |
| Blood bilirubin increased | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Blood chloride decreased | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Blood creatine phosphokinase MB increased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood creatine phosphokinase increased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Blood creatinine increased | 5 (2.6) | 4 (2.1) | 2 (1.0) | 1 (0.5) | 0 | 3 (1.7) | 6 (3.5) | 0 | 0 | 0 |
| Blood iron decreased | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Blood thyroid stimulating hormone increased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood triglycerides increased | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Blood urea increased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Breath sounds absent | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| C-reactive protein increased | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gamma-glutamyltransferase increased | 4 (2.1) | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Glomerular filtration rate decreased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Haemoglobin decreased | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| International normalised ratio increased | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Lymphocyte count decreased | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Neutrophil count decreased | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 6 (3.5) | 2 (1.2) | 0 | 0 |
| Platelet count decreased | 1 (0.5) | 0 | 0 | 2 (1.0) | 0 | 0 | 1 (0.6) | 1 (0.6) | 1 (0.6) | 0 |
| SARS-CoV-2 test positive | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Thyroid function test abnormal | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transaminases abnormal | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Tri-iodothyronine decreased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Urine output decreased | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Weight decreased | 3 (1.5) | 4 (2.1) | 3 (1.5) | 0 | 0 | 3 (1.7) | 5 (2.9) | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Weight increased | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| White blood cell count decreased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 3 (1.7) | 1 (0.6) | 0 | 0 |
| Metabolism and nutrition disorders | 20 (10.3) | 26 (13.3) | 10 (5.1) | 2 (1.0) | 0 | 25 (14.5) | 17 (9.9) | 9 (5.2) | 3 (1.7) | 0 |
| Decreased appetite | 17 (8.7) | 13 (6.7) | 1 (0.5) | 0 | 0 | 15 (8.7) | 10 (5.8) | 2 (1.2) | 0 | 0 |
| Dehydration | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 | 0 |
| Electrolyte imbalance | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Glucose tolerance impaired | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Hypercalcaemia | 2 (1.0) | 1 (0.5) | 0 | 1 (0.5) | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hyperglycaemia | 1 (0.5) | 0 | 0 | 1 (0.5) | 0 | 7 (4.1) | 3 (1.7) | 3 (1.7) | 0 | 0 |
| Hyperkalaemia | 1 (0.5) | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypernatraemia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypertriglyceridaemia | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hyperuricaemia | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypoalbuminaemia | 1 (0.5) | 9 (4.6) | 3 (1.5) | 0 | 0 | 3 (1.7) | 3 (1.7) | 3 (1.7) | 0 | 0 |
| Hypocalcaemia | 0 | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Hypochloraemia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypokalaemia | 4 (2.1) | 4 (2.1) | 5 (2.6) | 0 | 0 | 7 (4.1) | 0 | 4 (2.3) | 2 (1.2) | 0 |
| Hypomagnesaemia | 5 (2.6) | 1 (0.5) | 0 | 0 | 0 | 5 (2.9) | 1 (0.6) | 0 | 1 (0.6) | 0 |
| Hyponatraemia | 3 (1.5) | 1 (0.5) | 1 (0.5) | 1 (0.5) | 0 | 1 (0.6) | 0 | 1 (0.6) | 0 | 0 |
| Hypophagia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypophosphataemia | 0 | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Hypoproteinaemia | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Iron deficiency | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vitamin D deficiency | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 22 (11.3) | 22 (11.3) | 8 (4.1) | 0 | 0 | 12 (7.0) | 27 (15.7) | 5 (2.9) | 0 | 0 |
| Arthralgia | 13 (6.7) | 3 (1.5) | 1 (0.5) | 0 | 0 | 2 (1.2) | 3 (1.7) | 0 | 0 | 0 |
| Arthritis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Back pain | 11 (5.6) | 7 (3.6) | 3 (1.5) | 0 | 0 | 4 (2.3) | 10 (5.8) | 2 (1.2) | 0 | 0 |
| Bone pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 |
| Bursitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Coccydynia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Fistula | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Flank pain | 3 (1.5) | 2 (1.0) | 0 | 0 | 0 | 2 (1.2) | 1 (0.6) | 0 | 0 | 0 |
| Groin pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Intervertebral disc degeneration | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Joint stiffness | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Muscle spasms | 3 (1.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Muscular weakness | 1 (0.5) | 0 | 1 (0.5) | 0 | 0 | 2 (1.2) | 3 (1.7) | 1 (0.6) | 0 | 0 |
| Musculoskeletal chest pain | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Musculoskeletal pain | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Myalgia | 6 (3.1) | 0 | 0 | 0 | 0 | 2 (1.2) | 7 (4.1) | 0 | 0 | 0 |
| Neck pain | 2 (1.0) | 3 (1.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pain in extremity | 7 (3.6) | 4 (2.1) | 2 (1.0) | 0 | 0 | 2 (1.2) | 1 (0.6) | 2 (1.2) | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Pain in jaw | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pathological fracture | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Polyarthritis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rheumatoid arthritis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Spinal pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Spondylolisthesis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Torticollis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (1.0) | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Cancer pain | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tumour associated fever | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tumour pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Nervous system disorders | 19 (9.7) | 11 (5.6) | 1 (0.5) | 0 | 0 | 29 (16.9) | 8 (4.7) | 2 (1.2) | 0 | 0 |
| Altered state of consciousness | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Balance disorder | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Brain oedema | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cognitive disorder | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Diabetic neuropathy | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dizziness | 8 (4.1) | 2 (1.0) | 0 | 0 | 0 | 7 (4.1) | 1 (0.6) | 0 | 0 | 0 |
| Dysgeusia | 0 | 0 | 0 | 0 | 0 | 4 (2.3) | 0 | 0 | 0 | 0 |
| Extrapyramidal disorder | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Gait spastic | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Headache | 11 (5.6) | 4 (2.1) | 1 (0.5) | 0 | 0 | 8 (4.7) | 3 (1.7) | 0 | 0 | 0 |
| Hypersomnia | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hypoaesthesia | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Lethargy | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Mental impairment | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Migraine | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Neuropathy peripheral | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Neurotoxicity | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 1 (0.6) | 0 | 0 |
| Paraesthesia | 2 (1.0) | 0 | 0 | 0 | 0 | 2 (1.2) | 1 (0.6) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Sciatica | 0 | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Seizure | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Somnolence | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Syncope | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Taste disorder | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Tension headache | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transient ischaemic attack | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Tremor | 1 (0.5) | 0 | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 | 0 |
| Vocal cord paresis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Product issues | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Device occlusion | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Psychiatric disorders | 8 (4.1) | 14 (7.2) | 2 (1.0) | 0 | 0 | 11 (6.4) | 9 (5.2) | 1 (0.6) | 0 | 0 |
| Adjustment disorder with depressed mood | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Affect lability | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Agitation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Agoraphobia | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Anorexia nervosa | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Anxiety | 3 (1.5) | 4 (2.1) | 1 (0.5) | 0 | 0 | 2 (1.2) | 4 (2.3) | 1 (0.6) | 0 | 0 |
| Attention deficit hyperactivity disorder | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Confusional state | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Delirium | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Depressed mood | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Depression | 4 (2.1) | 3 (1.5) | 0 | 0 | 0 | 4 (2.3) | 1 (0.6) | 0 | 0 | 0 |
| Insomnia | 2 (1.0) | 7 (3.6) | 0 | 0 | 0 | 6 (3.5) | 2 (1.2) | 1 (0.6) | 0 | 0 |
| Mental disorder | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Mood disorder due to a general medical condition | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Personality change | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Suicide attempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Renal and urinary disorders | 11 (5.6) | 8 (4.1) | 11 (5.6) | 0 | 0 | 10 (5.8) | 10 (5.8) | 4 (2.3) | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Acute kidney injury | 2 (1.0) | 0 | 2 (1.0) | 0 | 0 | 4 (2.3) | 1 (0.6) | 0 | 0 | 0 |
| Azotaemia | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Chronic kidney disease | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Cystitis haemorrhagic | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dysuria | 5 (2.6) | 3 (1.5) | 0 | 0 | 0 | 2 (1.2) | 2 (1.2) | 0 | 0 | 0 |
| Haematuria | 4 (2.1) | 2 (1.0) | 4 (2.1) | 0 | 0 | 3 (1.7) | 0 | 1 (0.6) | 0 | 0 |
| Hydronephrosis | 1 (0.5) | 0 | 2 (1.0) | 0 | 0 | 1 (0.6) | 0 | 2 (1.2) | 0 | 0 |
| Micturition urgency | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Nephritis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pollakiuria | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Polyuria | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Proteinuria | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Renal artery stenosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Renal colic | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Renal failure | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Renal impairment | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Renal injury | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ureteric obstruction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ureteric stenosis | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Urinary incontinence | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Urinary retention | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Urinary tract obstruction | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Urine flow decreased | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Urogenital fistula | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Reproductive system and breast disorders | 13 (6.7) | 16 (8.2) | 3 (1.5) | 0 | 0 | 9 (5.2) | 10 (5.8) | 4 (2.3) | 0 | 0 |
| Atrophic vulvovaginitis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Breast oedema | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Breast pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Female genital tract fistula | 0 | 2 (1.0) | 1 (0.5) | 0 | 0 | 1 (0.6) | 2 (1.2) | 1 (0.6) | 0 | 0 |
| Genital haemorrhage | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Genital rash | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Metrorrhagia | 1 (0.5) | 1 (0.5) | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Ovarian cyst | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pelvic discomfort | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Pelvic pain | 4 (2.1) | 6 (3.1) | 0 | 0 | 0 | 4 (2.3) | 5 (2.9) | 3 (1.7) | 0 | 0 |
| Perineal pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Uterine pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vaginal discharge | 3 (1.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Vaginal disorder | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Vaginal fistula | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Vaginal haemorrhage | 4 (2.1) | 5 (2.6) | 1 (0.5) | 0 | 0 | 3 (1.7) | 2 (1.2) | 1 (0.6) | 0 | 0 |
| Vaginal obstruction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vaginal odour | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Vulval ulceration | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Vulvovaginal pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Vulvovaginal pruritus | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 20 (10.3) | 22 (11.3) | 5 (2.6) | 0 | 0 | 16 (9.3) | 10 (5.8) | 3 (1.7) | 0 | 0 |
| Asthma | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Bronchospasm | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Cough | 6 (3.1) | 10 (5.1) | 1 (0.5) | 0 | 0 | 5 (2.9) | 7 (4.1) | 1 (0.6) | 0 | 0 |
| Dysphonia | 3 (1.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Dyspnoea | 12 (6.2) | 7 (3.6) | 4 (2.1) | 0 | 0 | 7 (4.1) | 6 (3.5) | 0 | 0 | 0 |
| Dyspnoea exertional | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Epistaxis | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Haemoptysis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hiccups | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hydrothorax | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypoventilation | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Increased upper airway secretion | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Interstitial lung disease | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Laryngeal inflammation | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Nasal congestion | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oropharyngeal pain | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Pleural effusion | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pneumonitis | 0 | 2 (1.0) | 2 (1.0) | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Pneumothorax | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Productive cough | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Pulmonary embolism | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| Respiratory alkalosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Respiratory distress | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Rhinitis allergic | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Rhinorrhoea | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 23 (11.8) | 10 (5.1) | 3 (1.5) | 0 | 0 | 30 (17.4) | 12 (7.0) | 1 (0.6) | 0 | 0 |
| Alopecia | 0 | 0 | 0 | 0 | 0 | 5 (2.9) | 3 (1.7) | 0 | 0 | 0 |
| Blister | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Cold sweat | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Decubitus ulcer | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dermal cyst | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dermatitis | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Dermatitis acneiform | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Dermatitis allergic | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dry skin | 4 (2.1) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Eczema | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Erythema | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Erythema multiforme | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Erythema nodosum | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Nail discolouration | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Onychoclasis | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Papule | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pruritus | 7 (3.6) | 1 (0.5) | 0 | 0 | 0 | 7 (4.1) | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Rash | 8 (4.1) | 2 (1.0) | 2 (1.0) | 0 | 0 | 10 (5.8) | 4 (2.3) | 0 | 0 | 0 |
| Rash erythematous | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Rash maculo-papular | 4 (2.1) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rash papular | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rash pruritic | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Sensitive skin | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin burning sensation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin discolouration | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Skin hyperpigmentation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin hypopigmentation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin irritation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin toxicity | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Stasis dermatitis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Urticaria | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Social circumstances | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Menopause | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Vascular disorders | 5 (2.6) | 11 (5.6) | 2 (1.0) | 0 | 0 | 3 (1.7) | 4 (2.3) | 4 (2.3) | 0 | 0 |
| Arterial haemorrhage | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Brachiocephalic vein thrombosis | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Deep vein thrombosis | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Embolism | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Flushing | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hot flush | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypertension | 0 | 3 (1.5) | 1 (0.5) | 0 | 0 | 2 (1.2) | 1 (0.6) | 0 | 0 | 0 |
| Hypotension | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Hypovolaemic shock | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Jugular vein thrombosis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lymphoedema | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Peripheral vascular disorder | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Thrombophlebitis superficial | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Varicose ulceration | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Venous thrombosis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any Serious TEAE | 2 | 21 | 56 | 9 | 3 | 1 | 25 | 62 | 3 | 1 |
| Number of Patients with Any Serious TEAE | 1 (0.5) | 9 (4.6) | 36 (18.5) | 7 (3.6) | 3 (1.5) | 0 | 10 (5.8) | 38 (22.1) | 3 (1.7) | 1 (0.6) |
| Blood and lymphatic system disorders | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 16 (9.3) | 0 | 0 |
| Anaemia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 10 (5.8) | 0 | 0 |
| Febrile neutropenia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 5 (2.9) | 0 | 0 |
| Neutropenia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Pancytopenia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Thrombocytopenia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Cardiac disorders | 0 | 1 (0.5) | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Autoimmune pericarditis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pericardial effusion | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Endocrine disorders | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypothyroidism | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastrointestinal disorders | 0 | 1 (0.5) | 8 (4.1) | 0 | 0 | 0 | 2 (1.2) | 8 (4.7) | 0 | 0 |
| Abdominal pain | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Colitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Diarrhoea | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| Diverticular perforation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Duodenal ulcer | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Haematochezia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Intestinal obstruction | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Nausea | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oral papule | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rectal haemorrhage | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Stomatitis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Vomiting | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| General disorders and administration site conditions | 0 | 1 (0.5) | 2 (1.0) | 0 | 2 (1.0) | 0 | 4 (2.3) | 0 | 0 | 1 (0.6) |
| Catheter site thrombosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Death | 0 | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 |
| Influenza like illness | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Performance status decreased | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) |
| Pyrexia | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 |
| Sudden death | 0 | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 |
| Hepatobiliary disorders | 0 | 1 (0.5) | 6 (3.1) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Autoimmune hepatitis | 0 | 1 (0.5) | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cholecystitis acute | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Hepatic function abnormal | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Immune-mediated hepatitis | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Immune system disorders | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Contrast media allergy | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Infections and infestations | 0 | 4 (2.1) | 15 (7.7) | 2 (1.0) | 1 (0.5) | 0 | 5 (2.9) | 13 (7.6) | 1 (0.6) | 0 |
| COVID-19 pneumonia | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cellulitis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Clostridium difficile infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device related infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Empyema | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastroenteritis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastroenteritis viral | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Infection | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Kidney infection | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Ophthalmic herpes zoster | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pelvic abscess | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Peritonitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pneumonia | 0 | 0 | 2 (1.0) | 0 | 1 (0.5) | 0 | 0 | 3 (1.7) | 0 | 0 |
| Pyelonephritis | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Pyelonephritis acute | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pyomyositis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Respiratory tract infection | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Sepsis | 0 | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 |
| Staphylococcal bacteraemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Staphylococcal infection | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Staphylococcal sepsis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Stoma site infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Streptococcal sepsis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 |
| Toxic shock syndrome streptococcal | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Urinary tract infection | 0 | 2 (1.0) | 6 (3.1) | 0 | 0 | 0 | 1 (0.6) | 3 (1.7) | 0 | 0 |
| Urinary tract infection bacterial | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Viral rash | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 |
| Cystitis radiation | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device use error | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Overdose | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Spinal compression fracture | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transfusion reaction | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Investigations | 0 | 0 | 0 | 3 (1.5) | 0 | 0 | 2 (1.2) | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Blood creatine phosphokinase MB increased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood creatinine increased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Neutrophil count decreased | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Platelet count decreased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 |
| Hyperglycaemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Hypocalcaemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Hypokalaemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 |
| Hypomagnesaemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 |
| Hyponatraemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 0 | 2 (1.0) | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Arthritis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Muscular weakness | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Pathological fracture | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Spondylolisthesis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tumour associated fever | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Nervous system disorders | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Seizure | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Transient ischaemic attack | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Product issues | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Device occlusion | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Psychiatric disorders | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Anxiety | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Personality change | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Renal and urinary disorders | 0 | 1 (0.5) | 5 (2.6) | 0 | 0 | 1 (0.6) | 3 (1.7) | 2 (1.2) | 0 | 0 |
| Acute kidney injury | 0 | 0 | 2 (1.0) | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Cystitis haemorrhagic | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Haematuria | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Renal failure | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Renal impairment | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Urinary tract obstruction | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Reproductive system and breast disorders | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| Female genital tract fistula | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Pelvic pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Vaginal haemorrhage | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 1 (0.5) | 2 (1.0) | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 |
| Cough | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Dyspnoea | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Haemoptysis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pneumonitis | 0 | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pneumothorax | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pulmonary embolism | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| Vascular disorders | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 |
| Arterial haemorrhage | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Deep vein thrombosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Hypotension | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Hypovolaemic shock | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.4. Number of patients with treatment-emergent adverse events of interest - immune-related AE (Grade 3) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any immune-related AE (Grade 3 or Greater) | 0 | 0 | 25 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of Patients with Any immune-related AE (Grade 3 or Greater) | 0 | 0 | 21 (10.8) | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Endocrine disorders | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypothyroidism | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastrointestinal disorders | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Colitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Diarrhoea | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oral papule | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatobiliary disorders | 0 | 0 | 7 (3.6) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 |
| Autoimmune hepatitis | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatic function abnormal | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatotoxicity | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Immune-mediated hepatitis | 0 | 0 | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.4. Number of patients with treatment-emergent adverse events of interest - immune-related AE (Grade 3) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Investigations | 0 | 0 | 6 (3.1) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Alanine aminotransferase increased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Aspartate aminotransferase increased | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood creatine phosphokinase MB increased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood creatine phosphokinase increased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Glomerular filtration rate decreased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Polyarthritis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pneumonitis | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.4. Number of patients with treatment-emergent adverse events of interest - immune-related AE (Grade 3) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Skin and subcutaneous tissue disorders | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rash | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Skin toxicity | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.5. Number of patients with treatment-emergent adverse events of interest - Infusion-related reactions (Grade >=2) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any Infusion-related reactions (Grade >=2) | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of Patients with Any Infusion-related reactions (Grade >=2) | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Infusion related reaction | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.6. Number of patients with treatment-emergent adverse events of interest - allergic/hypersensitivity reactions (Grade >=2) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any allergic/hypersensitivity reactions (Grade >=2) | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of Patients with Any allergic/hypersensitivity reactions (Grade >=2) | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Laryngeal inflammation | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dermatitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 27.1.1. Patient Disposition
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Randomized but Never Treated, n (%) | 2 (1.0%) | 10 (5.5%) | 12 (3.2%) |
| Treatment ongoing, n (%) | 29 (14.8%) | 3 (1.6%) | 32 (8.4%) |
| Off treatment, n (%) | 165 (84.2%) | 170 (92.9%) | 335 (88.4%) |
| Treatment completed | 7 (3.6%) | 0 | 7 (1.8%) |
| Treatment discontinued | 158 (80.6%) | 170 (92.9%) | 328 (86.5%) |
| Primary reason for treatment discontinuation | | | |
| ADVERSE EVENT | 19 (9.7%) | 8 (4.4%) | 27 (7.1%) |
| DEATH | 11 (5.6%) | 13 (7.1%) | 24 (6.3%) |
| NON-COMPLIANCE WITH STUDY DRUG(S) | 0 | 1 (0.5%) | 1 (0.3%) |
| SUBJECT DECISION | 5 (2.6%) | 4 (2.2%) | 9 (2.4%) |
| DISEASE PROGRESSION | 122 (62.2%) | 138 (75.4%) | 260 (68.6%) |
| WITHDRAWAL OF CONSENT | 1 (0.5%) | 6 (3.3%) | 7 (1.8%) |

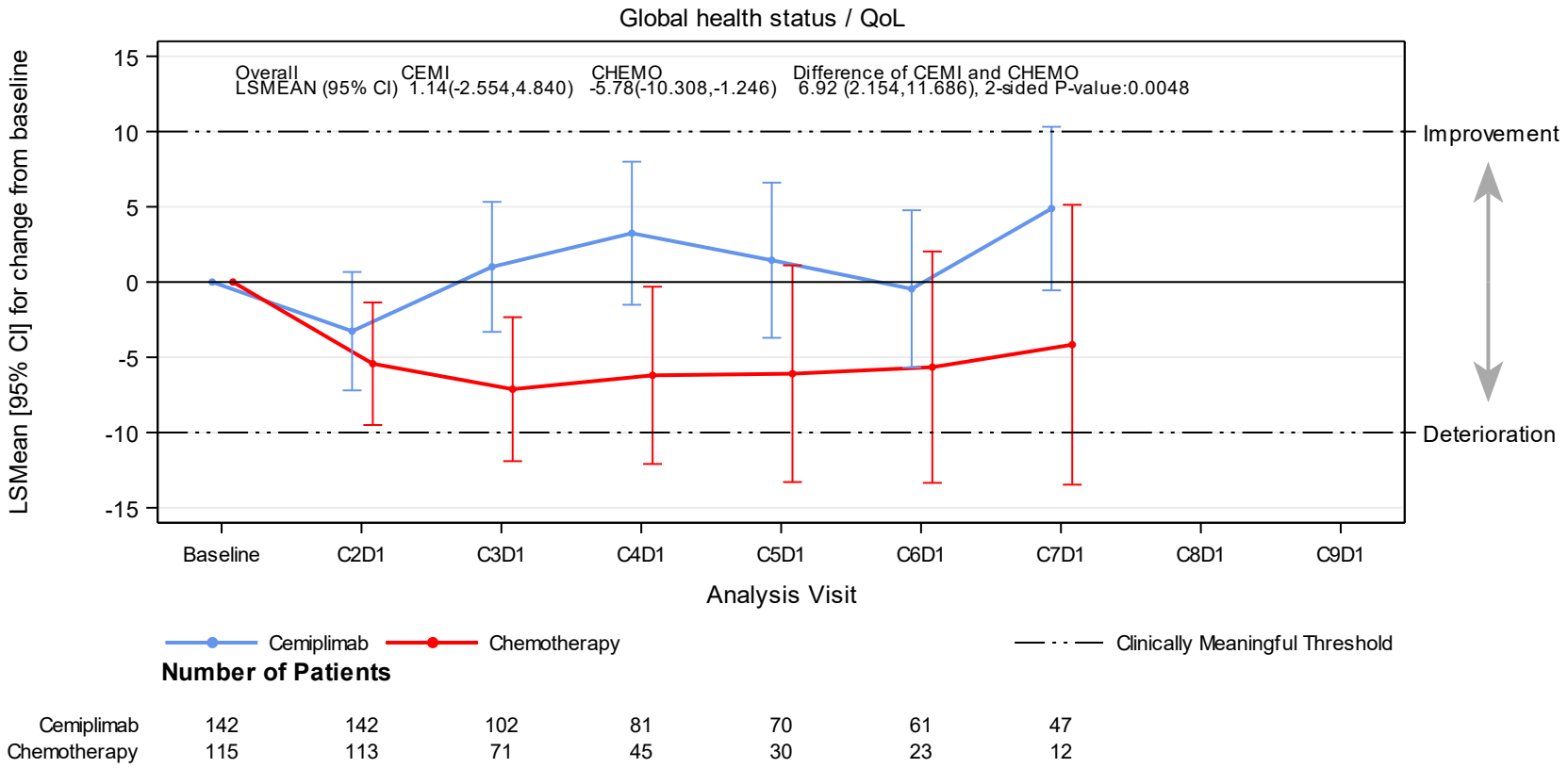
Data cut-off as of Jan 4th, 2021.

Table 27.1.1. Patient Disposition
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Study ongoing, n (%) | 40 (20.4%) | 5 (2.7%) | 45 (11.9%) |
| Off Study, n (%) | 156 (79.6%) | 178 (97.3%) | 334 (88.1%) |
| Study completed | 4 (2.0%) | 0 | 4 (1.1%) |
| Study discontinued | 152 (77.6%) | 178 (97.3%) | 330 (87.1%) |
| Primary reason for study discontinuation | | | |
| ADVERSE EVENT | 7 (3.6%) | 3 (1.6%) | 10 (2.6%) |
| DEATH | 69 (35.2%) | 66 (36.1%) | 135 (35.6%) |
| NON-COMPLIANCE WITH STUDY DRUG(S) | 0 | 1 (0.5%) | 1 (0.3%) |
| SUBJECT DECISION | 15 (7.7%) | 22 (12.0%) | 37 (9.8%) |
| DISEASE PROGRESSION | 56 (28.6%) | 65 (35.5%) | 121 (31.9%) |
| WITHDRAWAL OF CONSENT | 4 (2.0%) | 17 (9.3%) | 21 (5.5%) |
| LOST TO FOLLOW-UP | 1 (0.5%) | 2 (1.1%) | 3 (0.8%) |
| PHYSICIAN DECISION | 0 | 2 (1.1%) | 2 (0.5%) |

Data cut-off as of Jan 4th, 2021.

Figure 1.2.1. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 GHS/QoL
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




**Number of Patients**

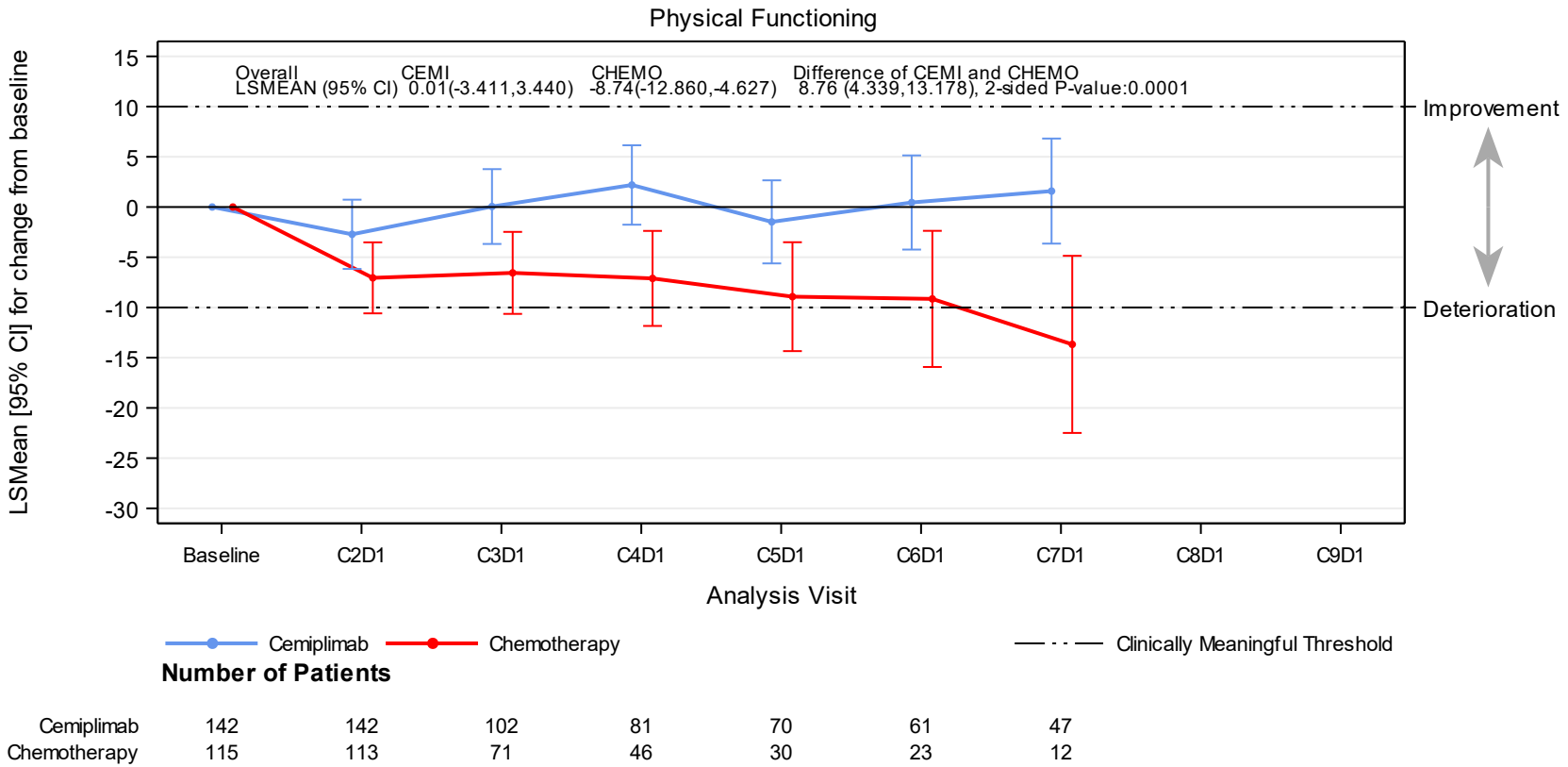
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 45 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:24:55, qiuyue.chen1)

Figure 1.2.2. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Physical Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)



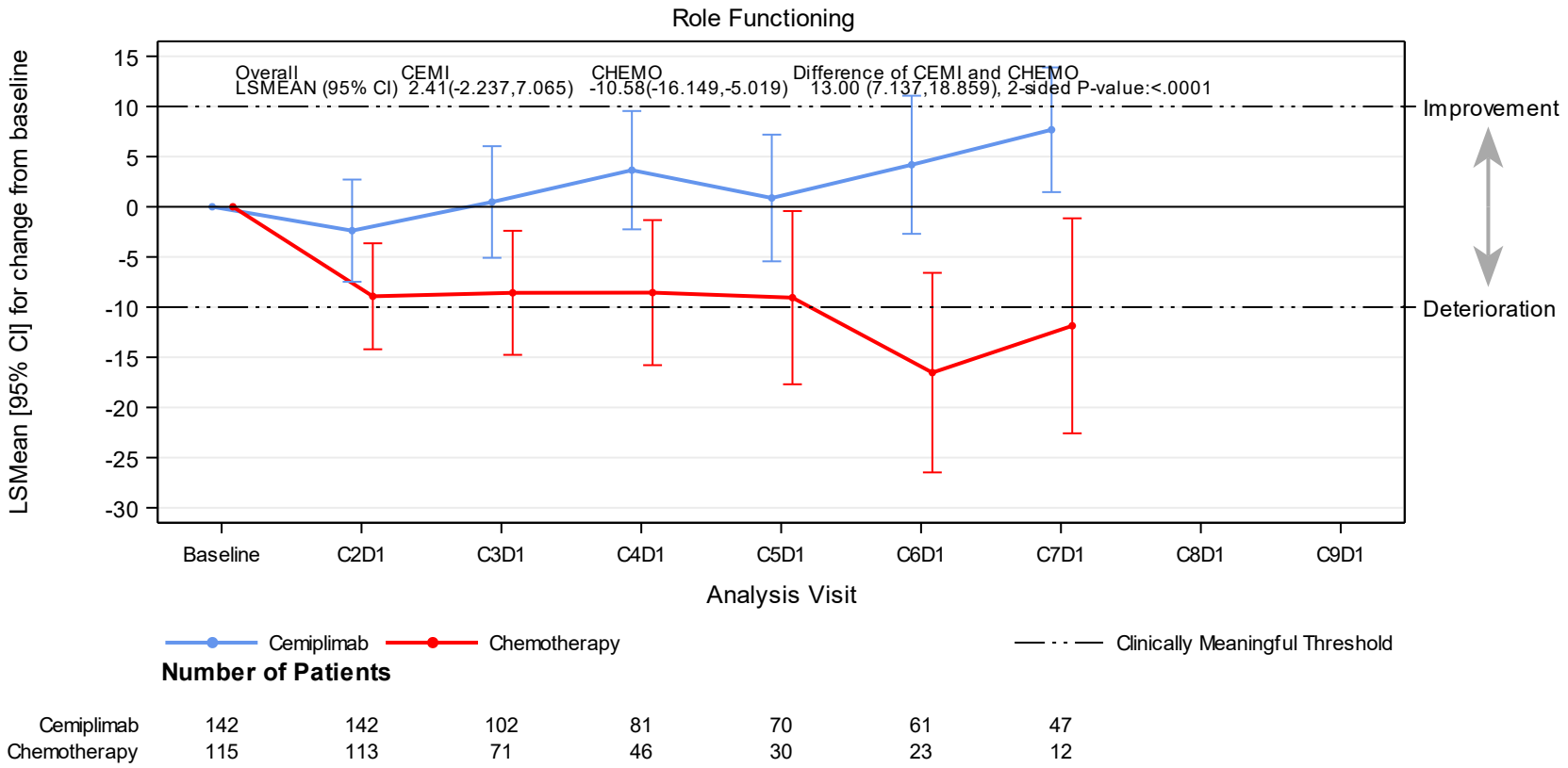

**Number of Patients**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 46 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Figure 1.2.3. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Role Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




**Number of Patients**

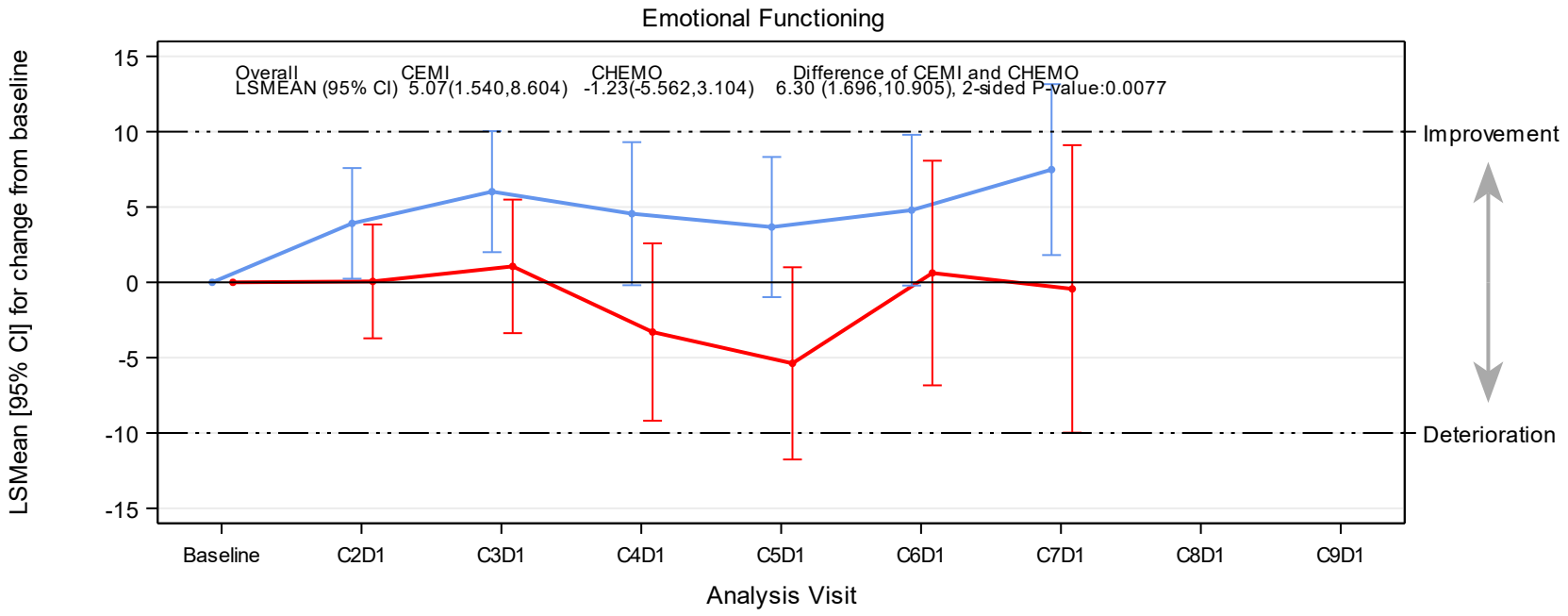
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 46 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:01, qiuyue.chen1)

Figure 1.2.4. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Emotional Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)



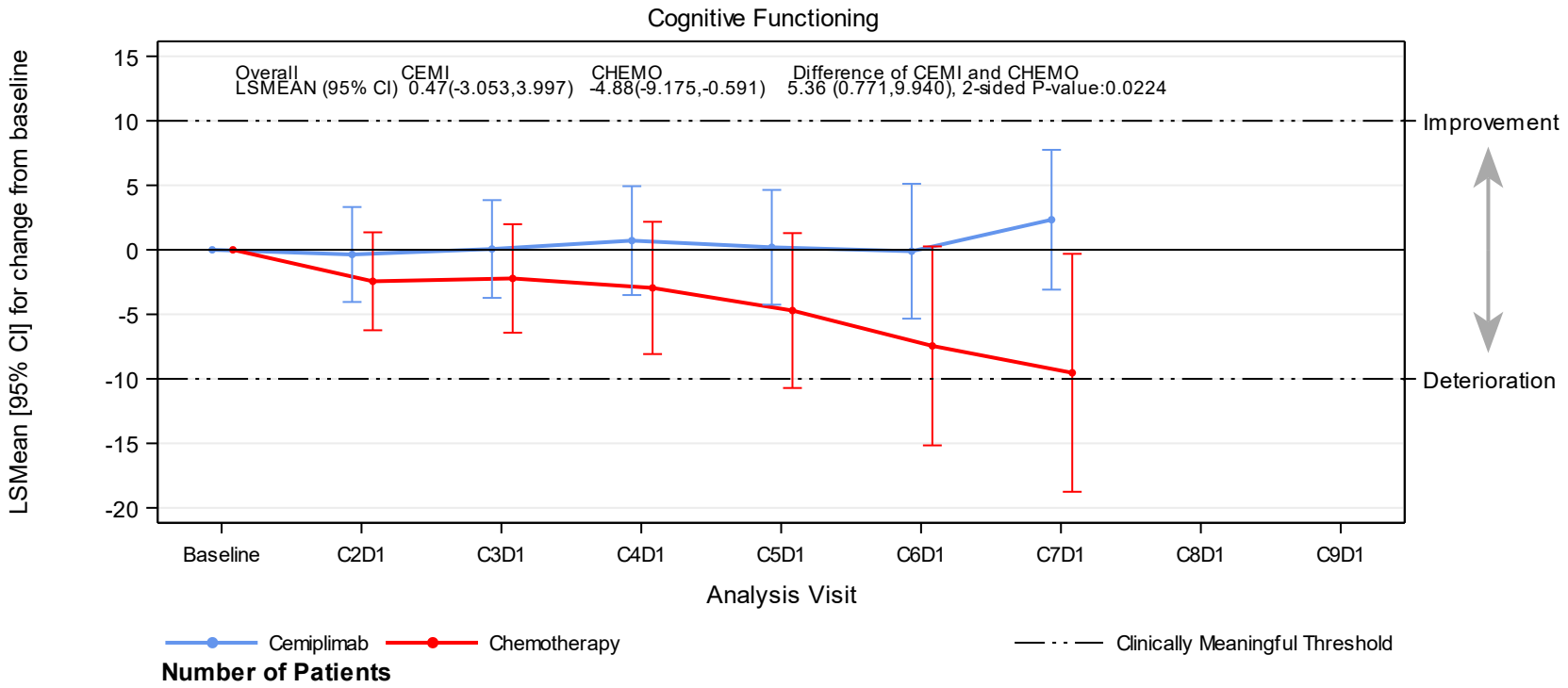

**Number of Patients**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 45 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.
Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:04, qiuyue.chen1)

Figure 1.2.5. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Cognitive Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)



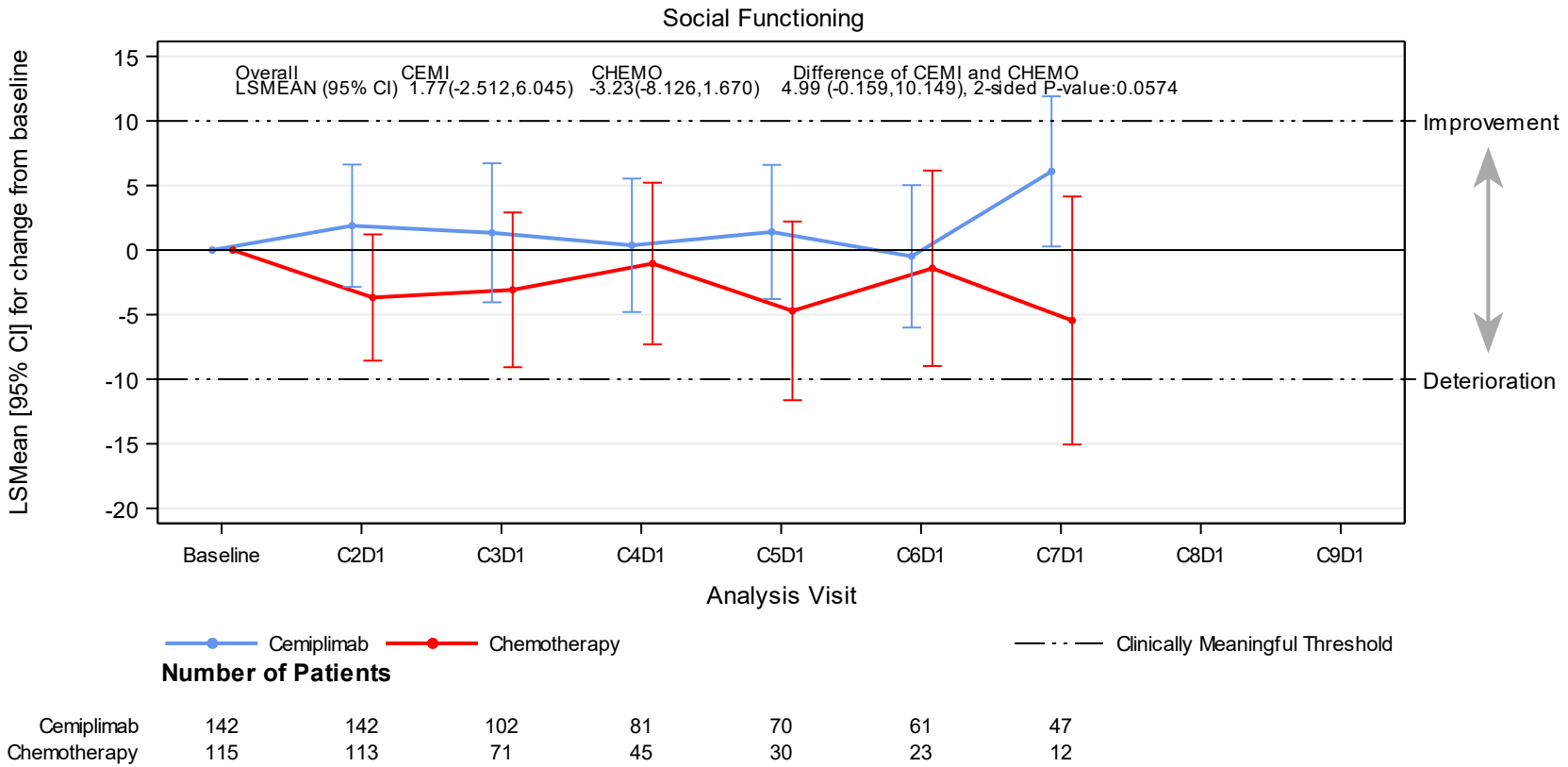

**Number of Patients**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 45 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.
Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:07, qiuyue.chen1)

Figure 1.2.6. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Social Functioning
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)



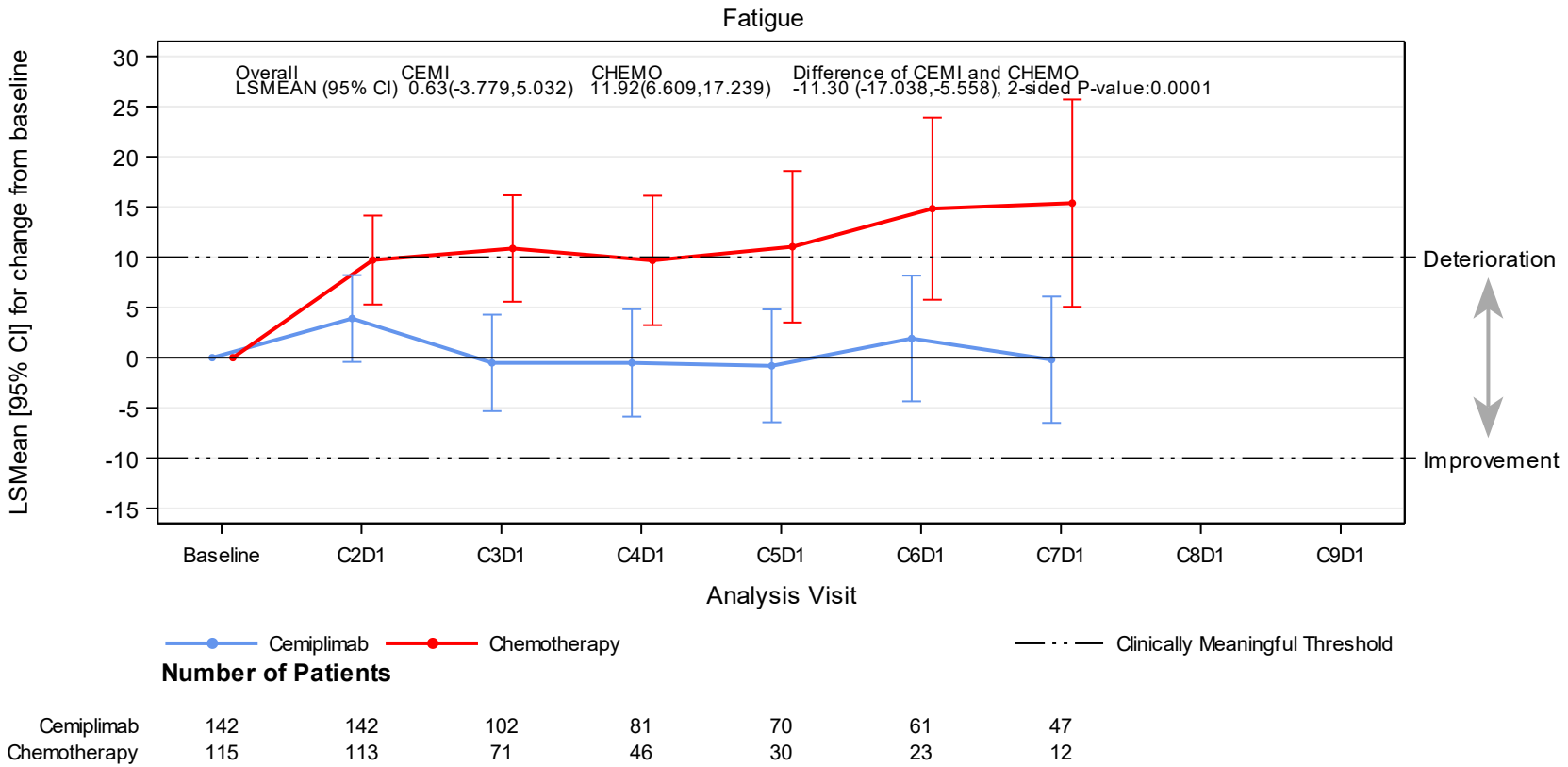

**Number of Patients**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 45 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.
Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:10, qiuyue.chen1)

Figure 1.2.7. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Fatigue
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)



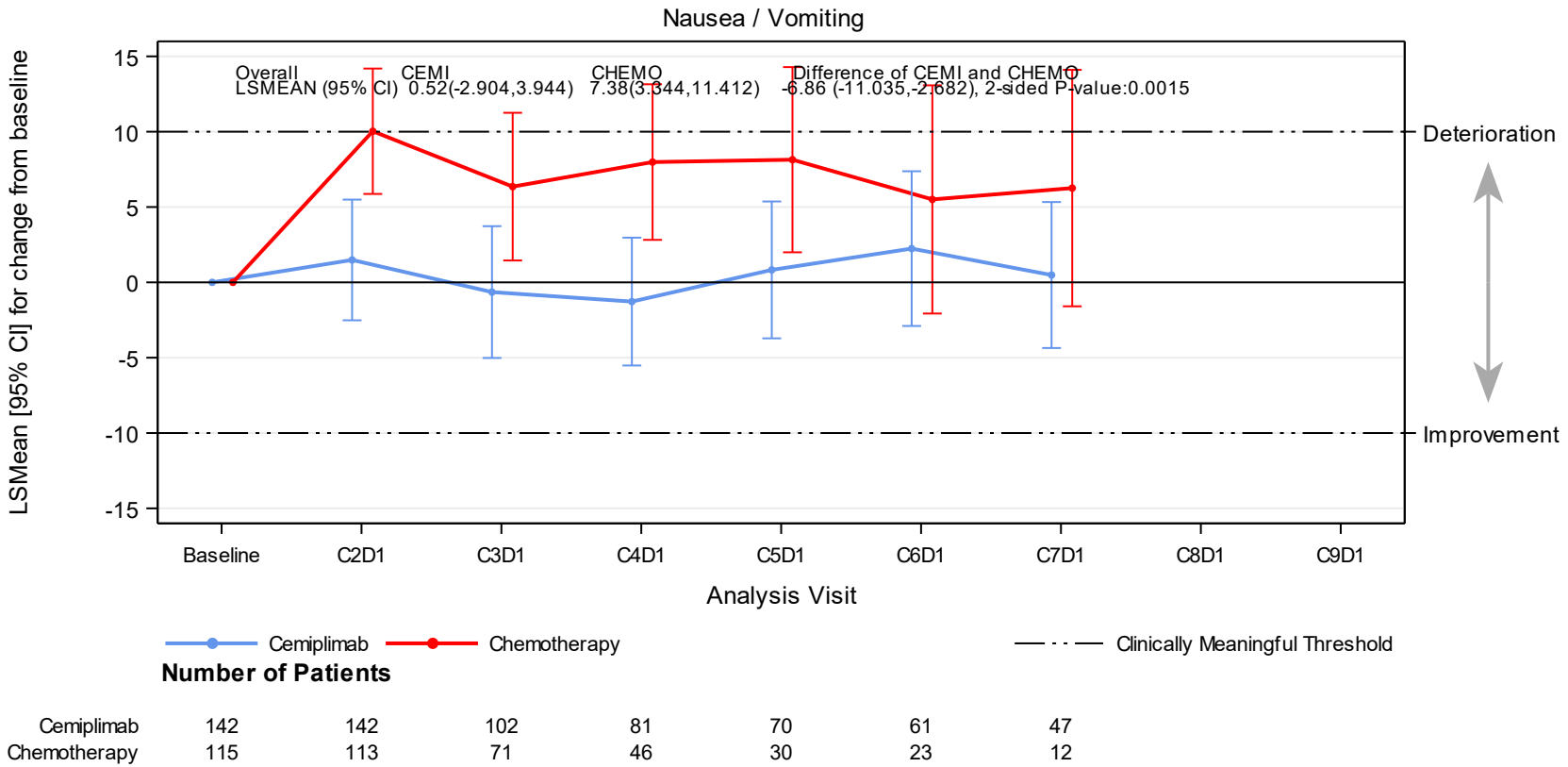

**Number of Patients**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 46 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.
Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:13, qiuyue.chen1)

Figure 1.2.8. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Nausea / Vomiting
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




**Number of Patients**

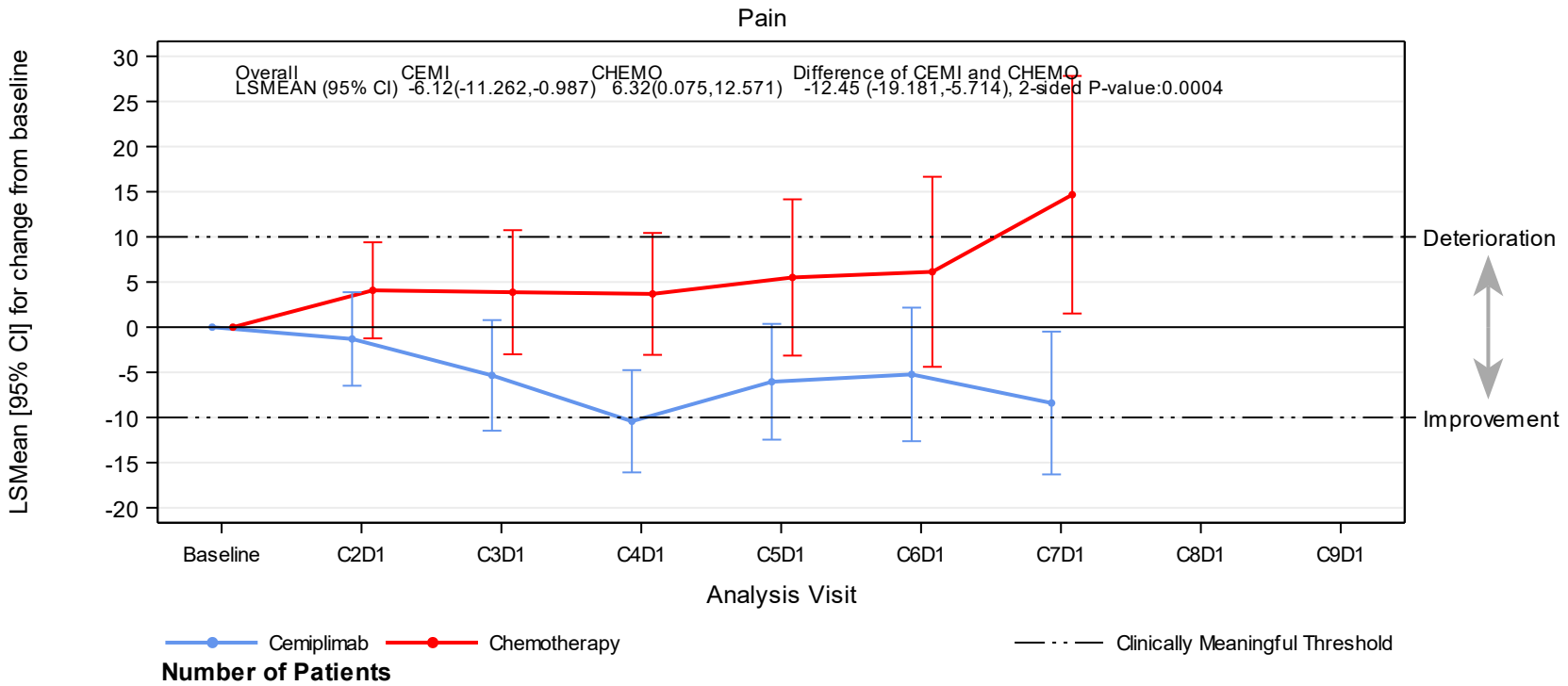
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 46 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:16, qiuyue.chen1)

Figure 1.2.9. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Pain
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




**Number of Patients**

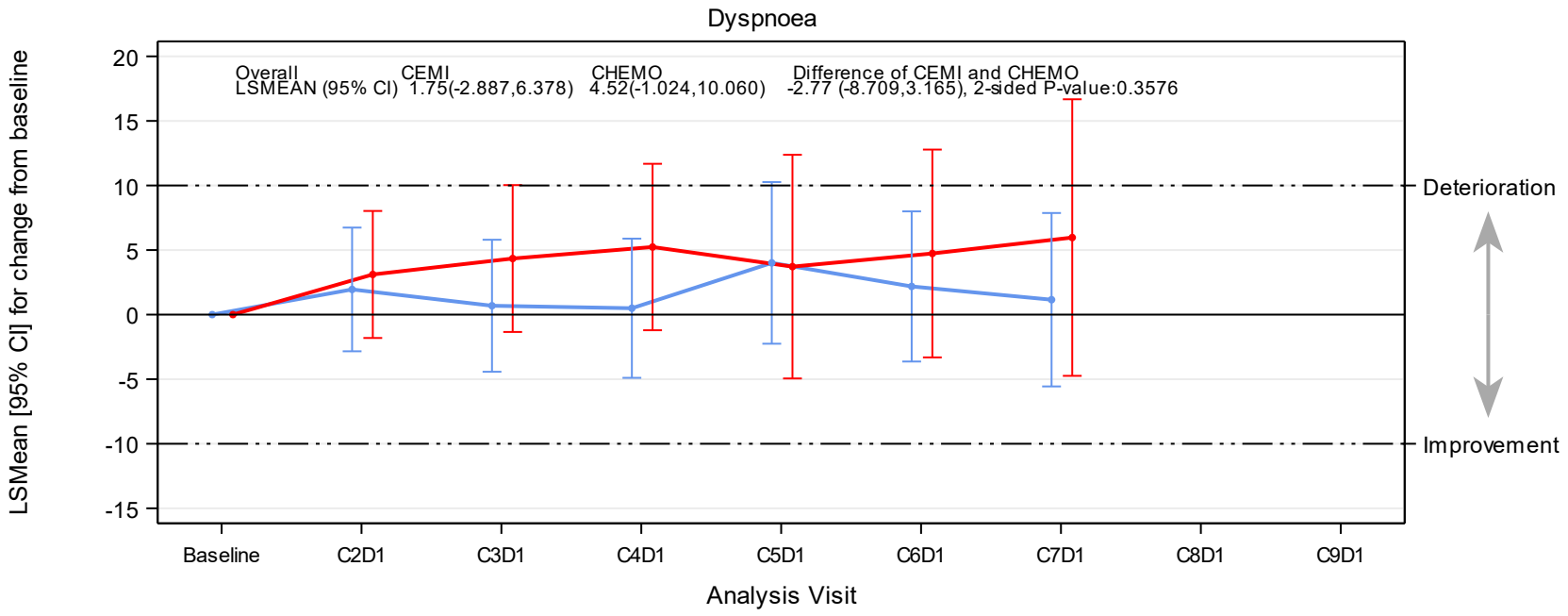
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 46 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:19, qiuyue.chen1)

Figure 1.2.10. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Dyspnoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




**Number of Patients**

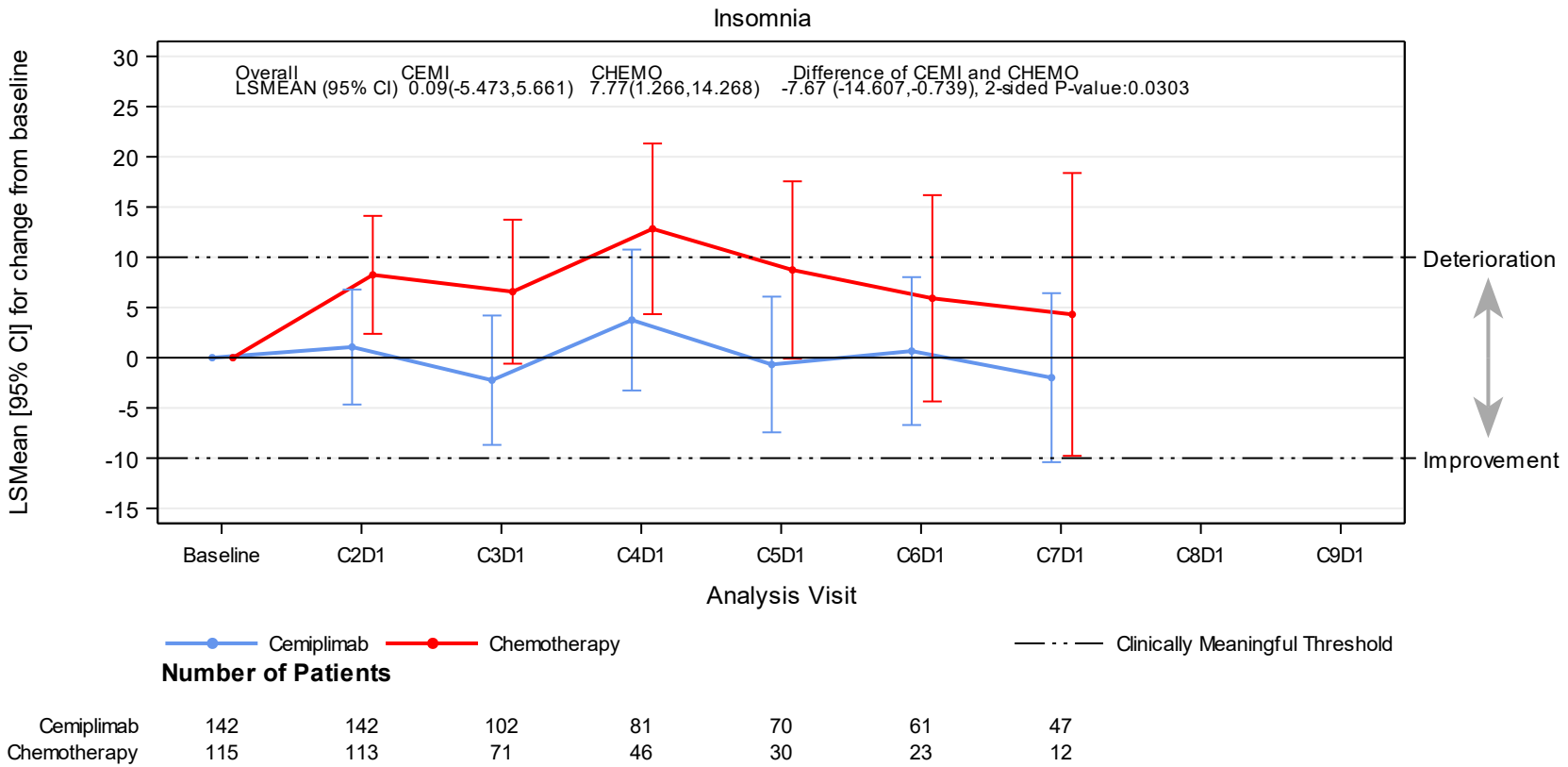
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 141 | 141 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 70 | 46 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:22, qiuyue.chen1)

Figure 1.2.11. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Insomnia
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




**Number of Patients**

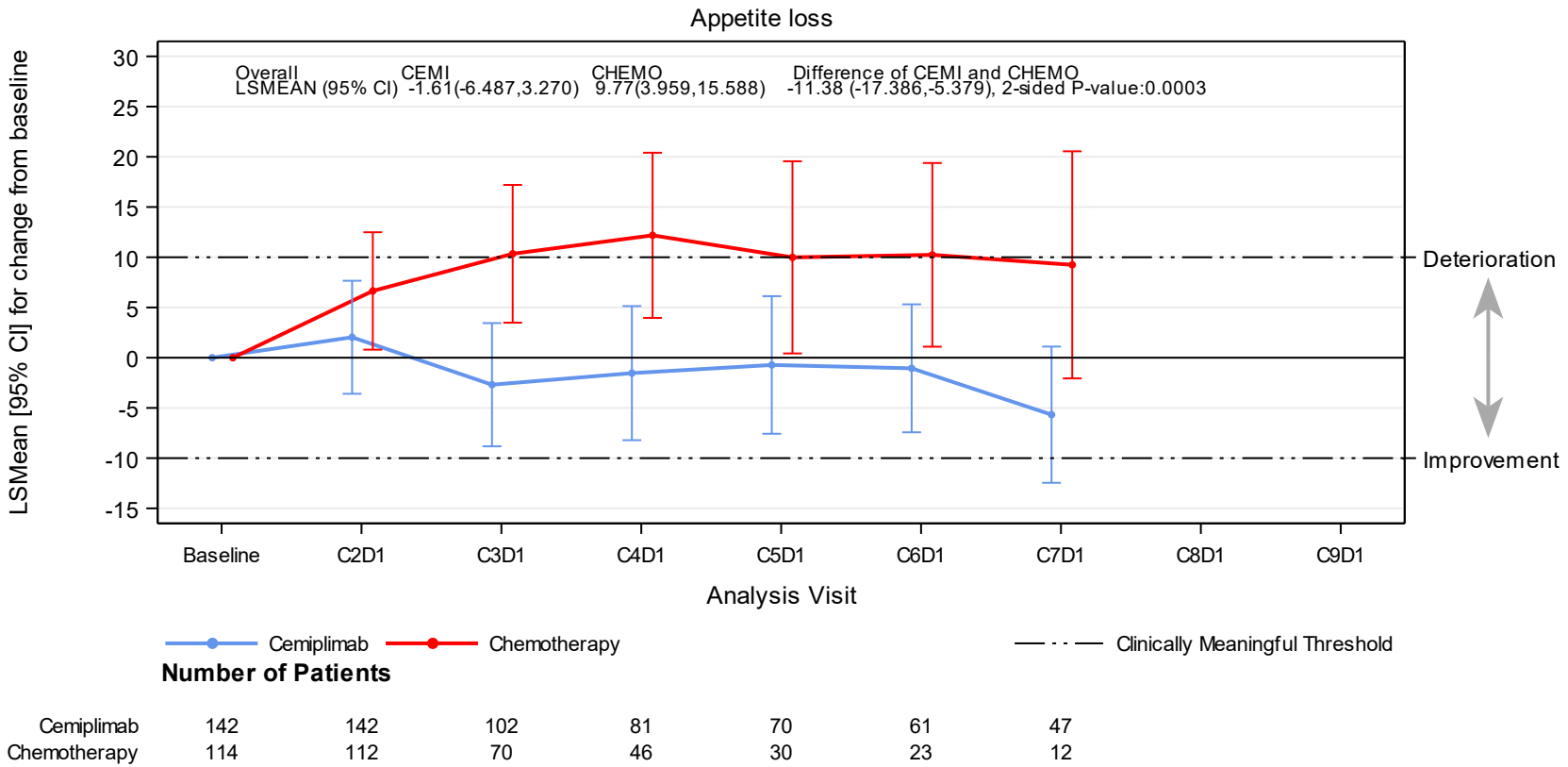
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 46 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:24, qiuyue.chen1)

Figure 1.2.12. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Appetite loss
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)



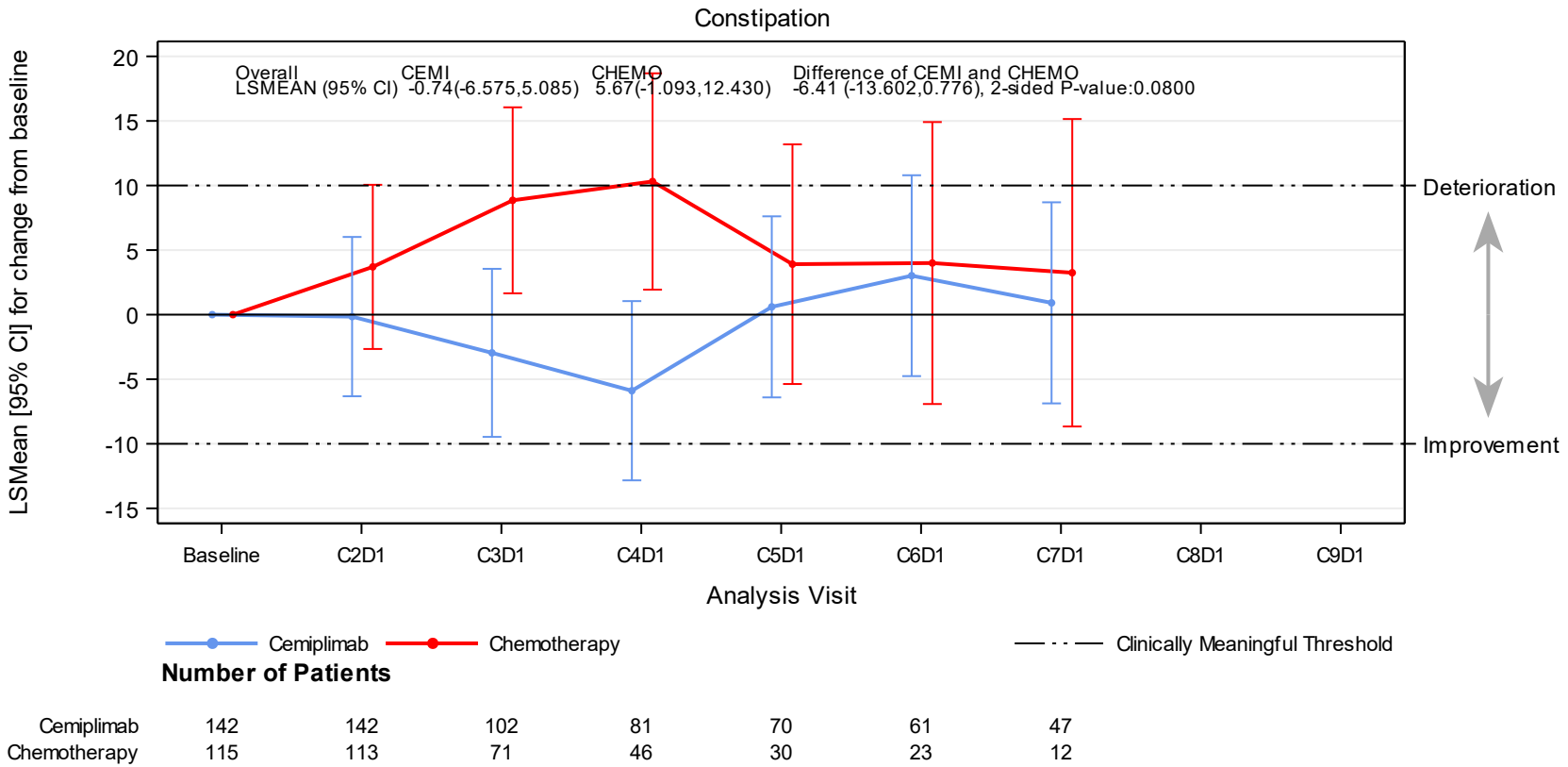

**Number of Patients**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 114 | 112 | 70 | 46 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.
Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:27, qiuyue.chen1)

Figure 1.2.13. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Constipation
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)



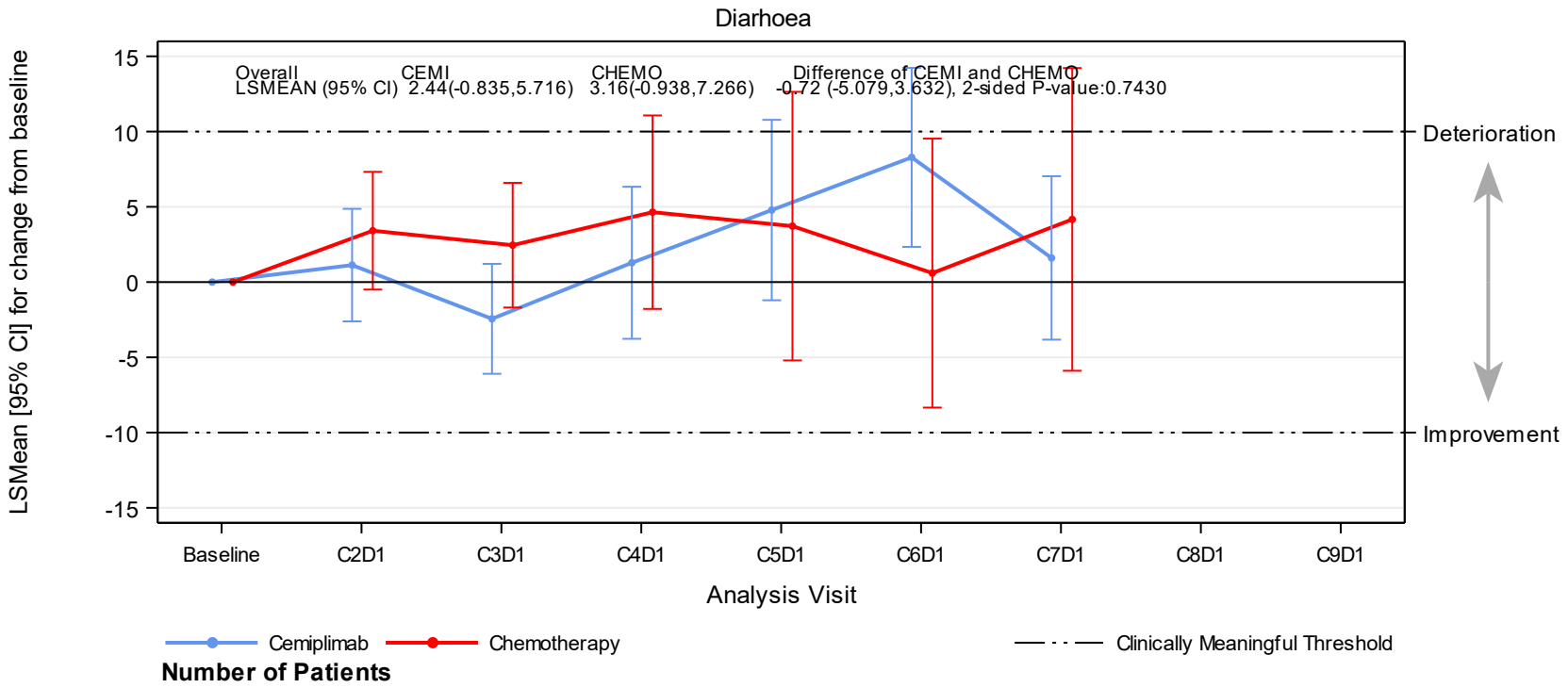

**Number of Patients**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 46 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Figure 1.2.14. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Diarhoea
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




**Number of Patients**

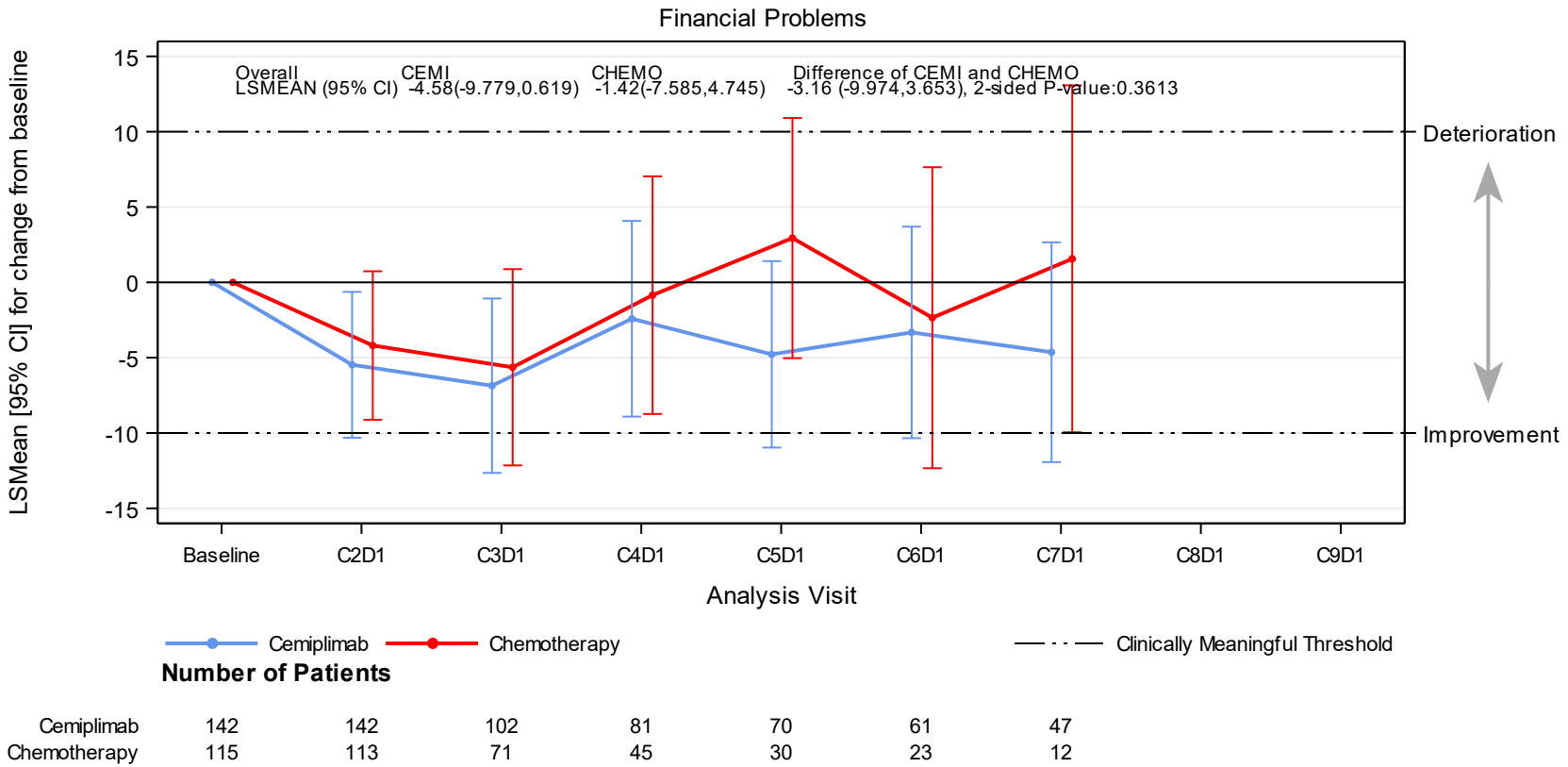
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 45 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:33, qiuyue.chen1)

Figure 1.2.15. Mixed model repeated measures analysis: change from baseline in EORTC QLQ-C30 Financial Problems
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




**Number of Patients**

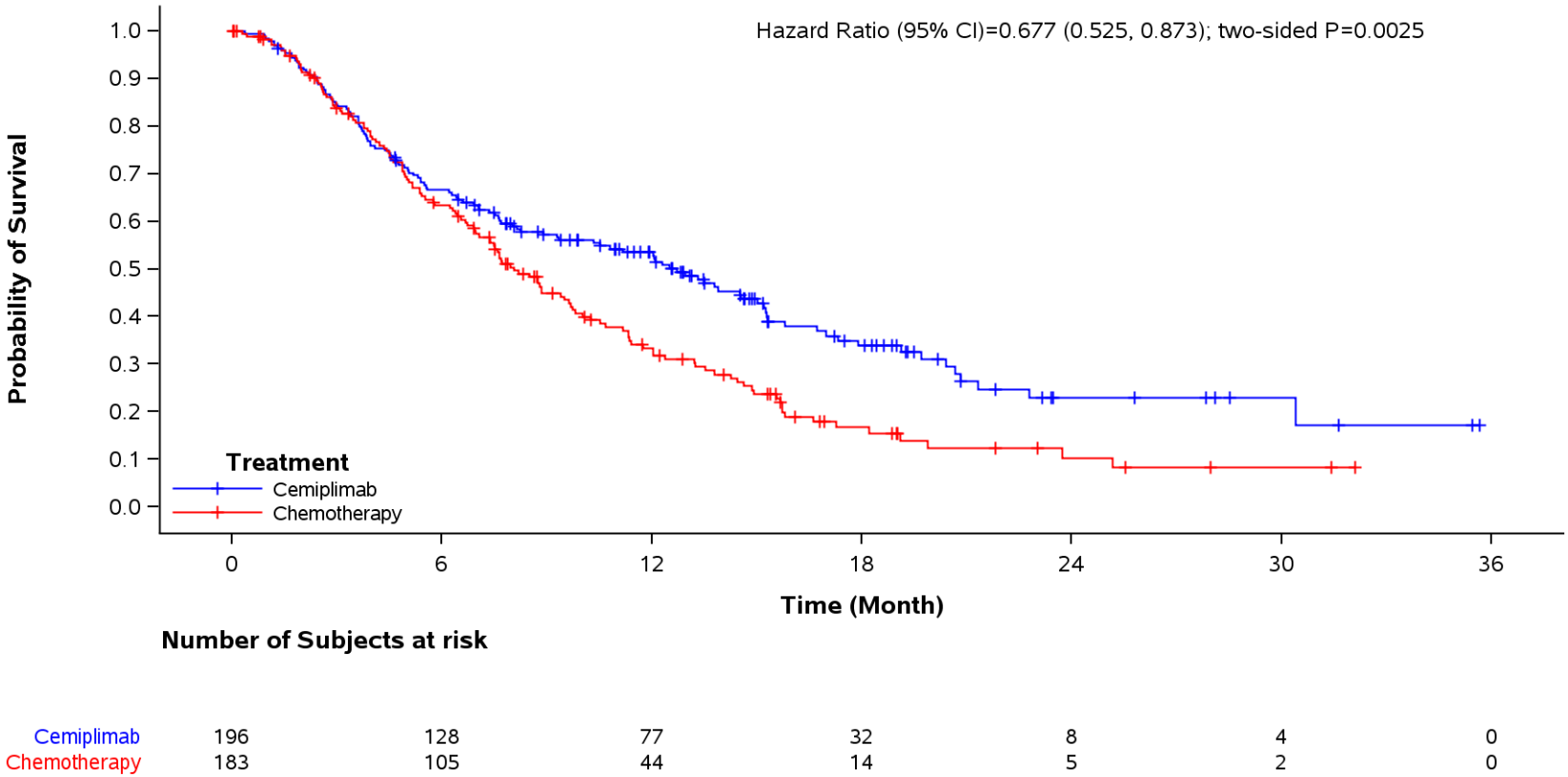
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 142 | 142 | 102 | 81 | 70 | 61 | 47 |
| Chemotherapy | 115 | 113 | 71 | 45 | 30 | 23 | 12 |

Data cut-off as of Jan 4th, 2021.

Note(s): LOCF (Last observation carried forward) method for the last post-baseline available observed value was carried forward to impute missing data for non-monotone missing values only. Repeated measures analysis based on a mixed model for repeated measures: Change= Treatment arm + Time + Baseline PRO Value + Histology + Geographical region + Time* BaselinePRO + Time*Treatment arm.

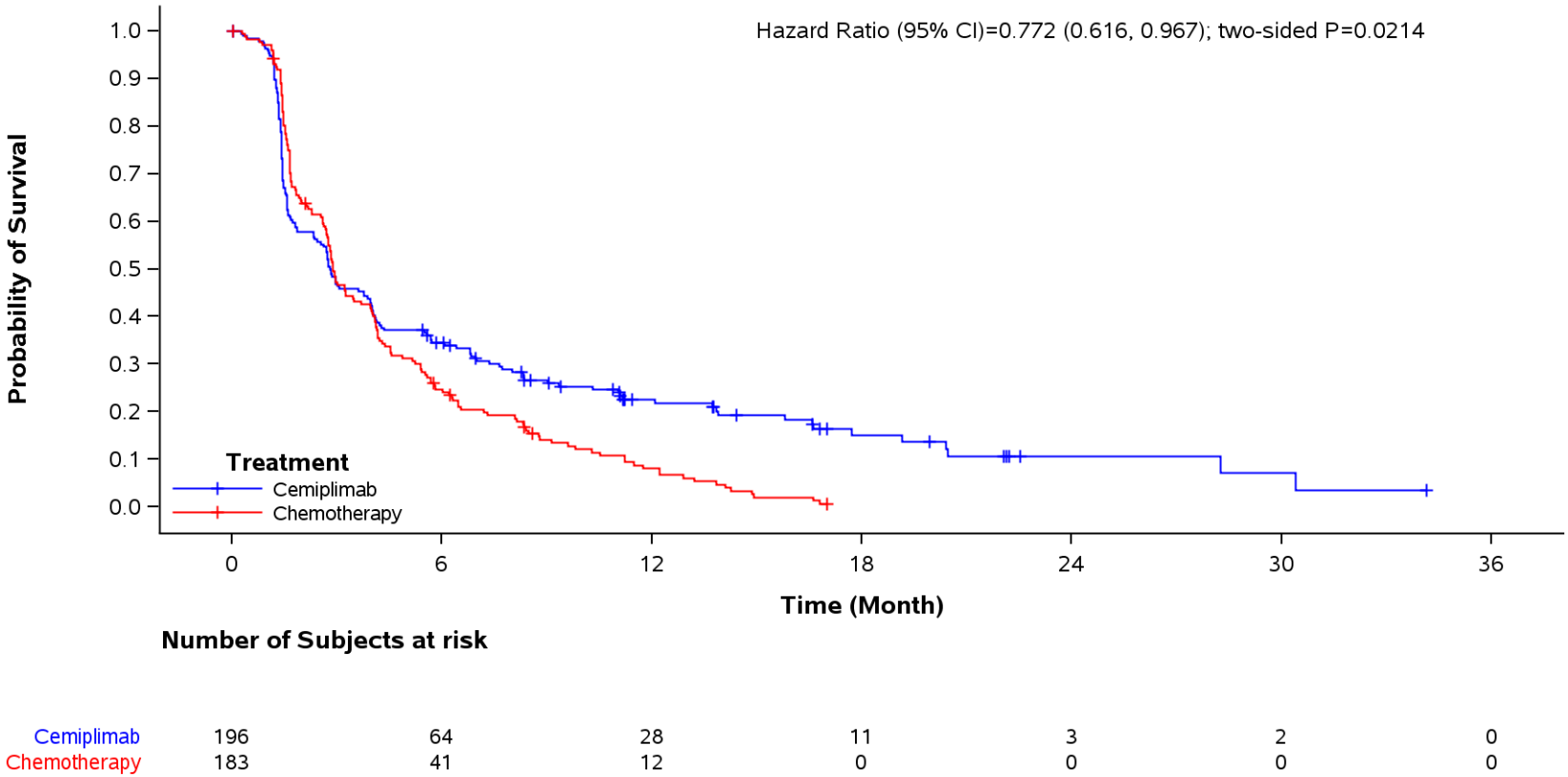
Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-lineplot-mmrm-locf.sas (25OCT22:10:25:35, qiuyue.chen1)

Figure 2.1.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)



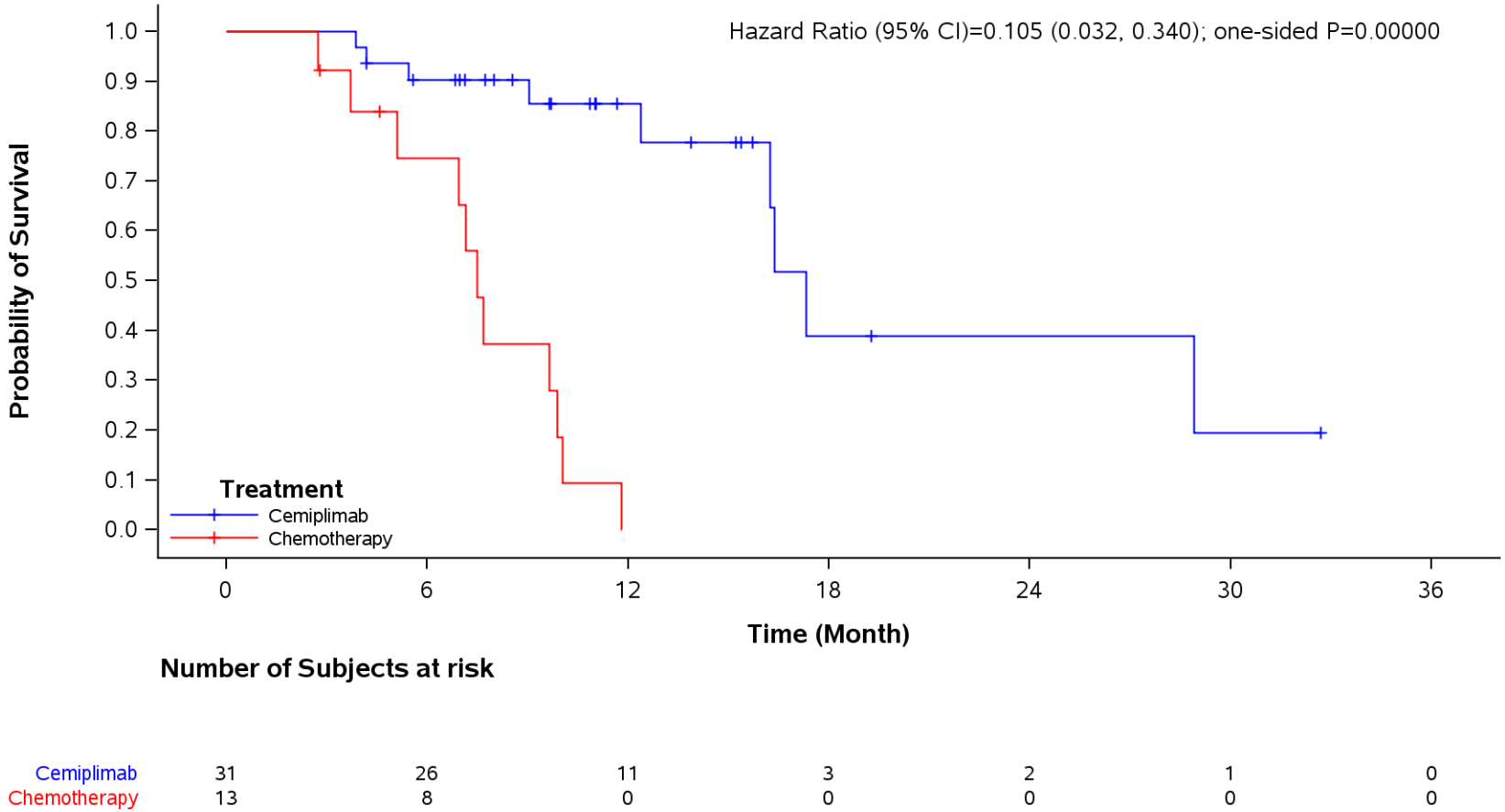

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.3. Kaplan Meier Cumulative Incidence Curve for Estimation of Duration of Response
(Full Analysis Set Exclude Patients Assigned to Gemcitabine - Patients with Confirmed CR or PR)



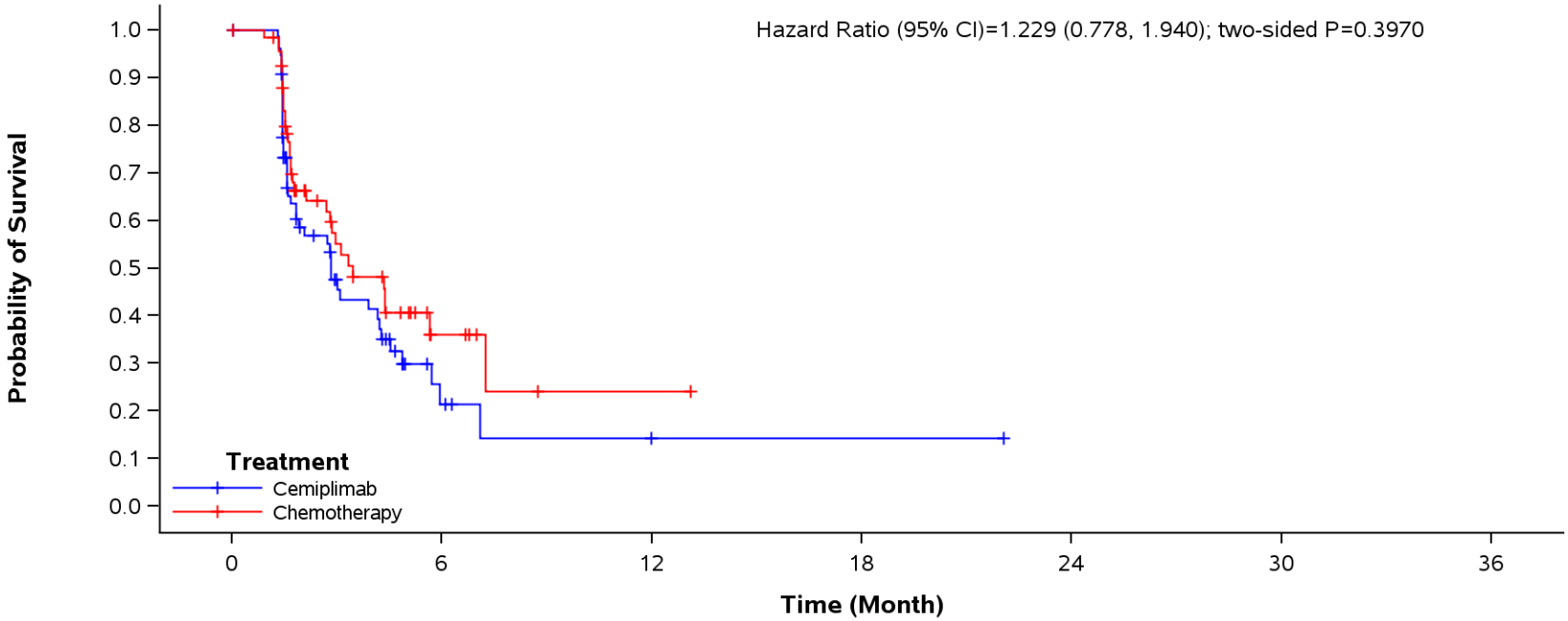

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 26 | 11 | 3 | 2 | 1 | 0 |
| Chemotherapy | 13 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
[a] Based on patients with confirmed CR or PR.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts improvement



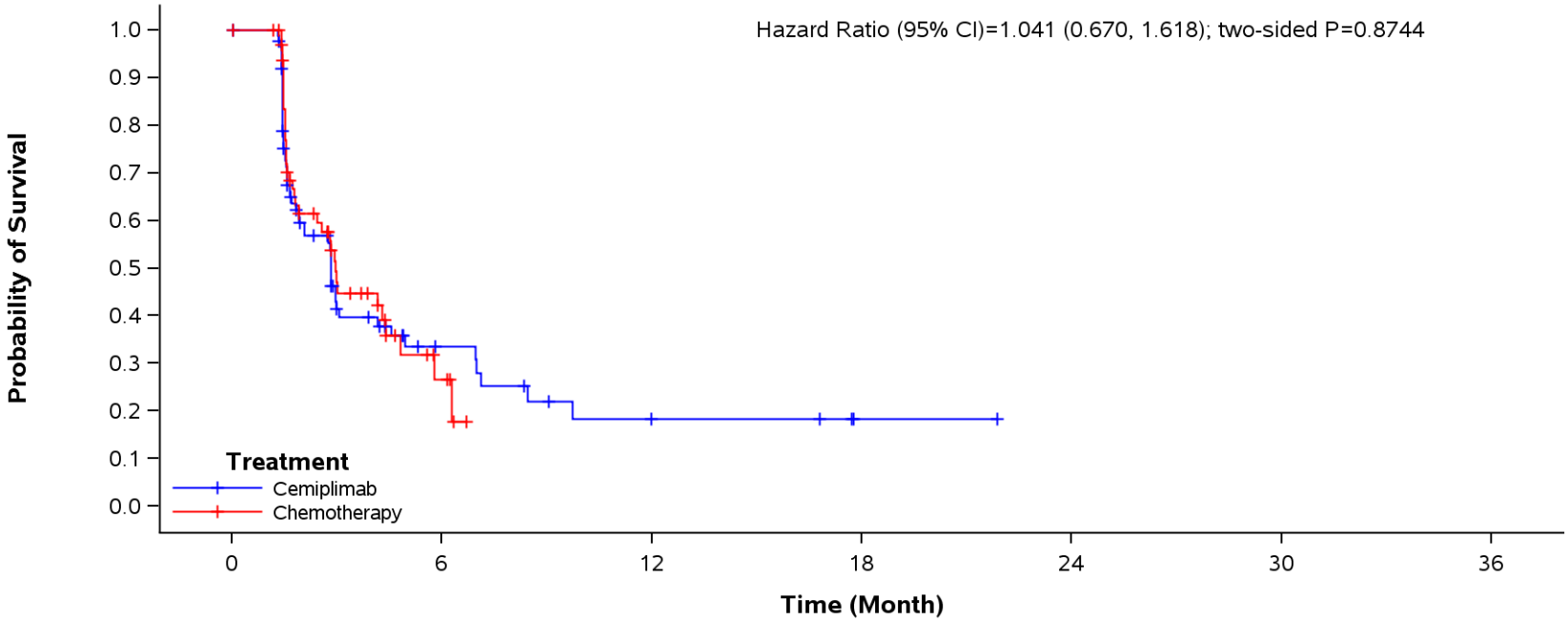

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 183 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts improvement



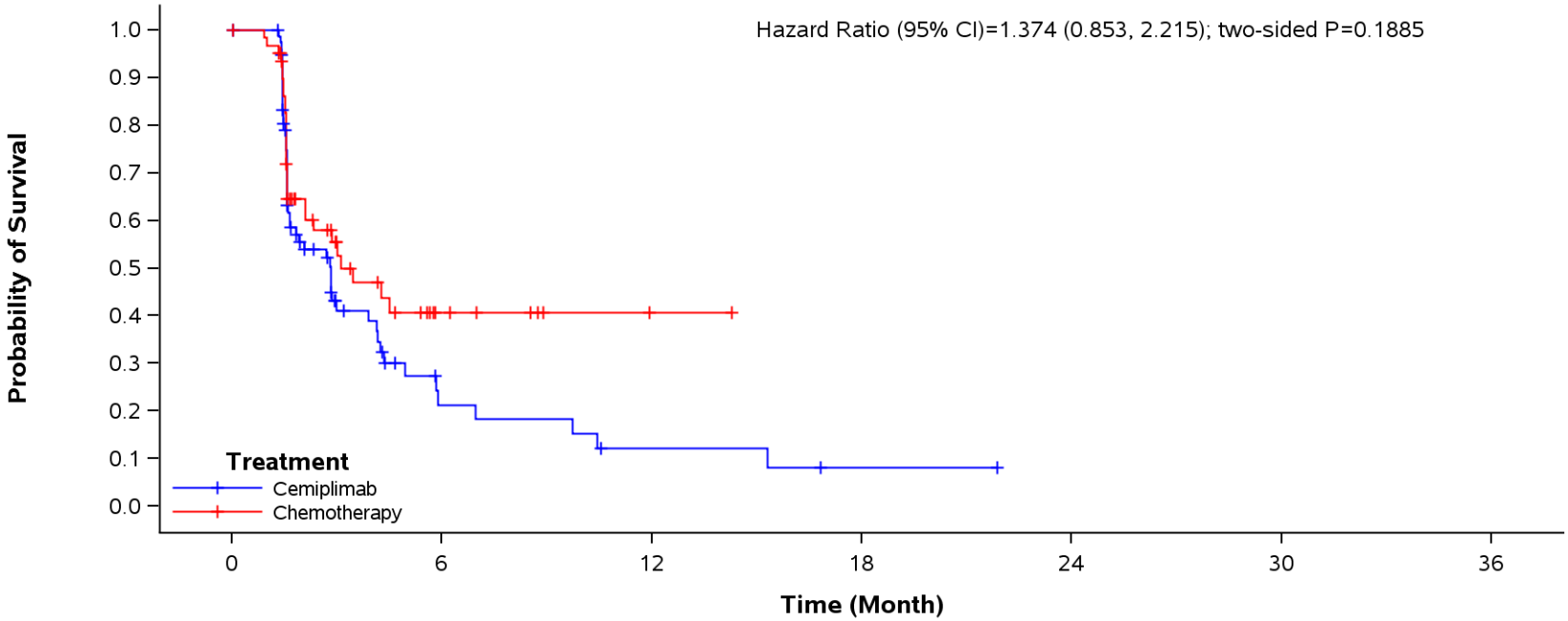

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 12 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 183 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts improvement



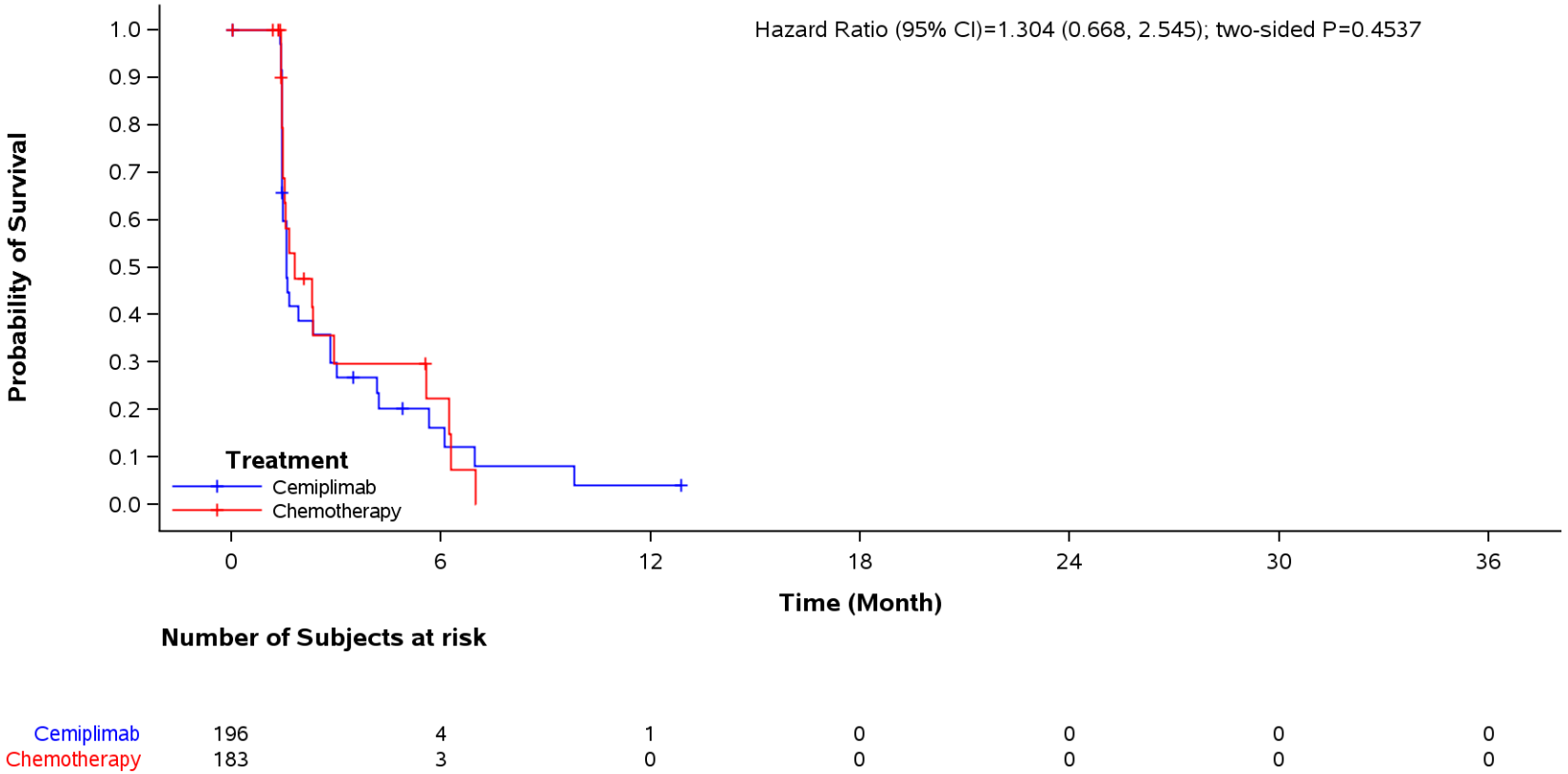

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 7 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 183 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

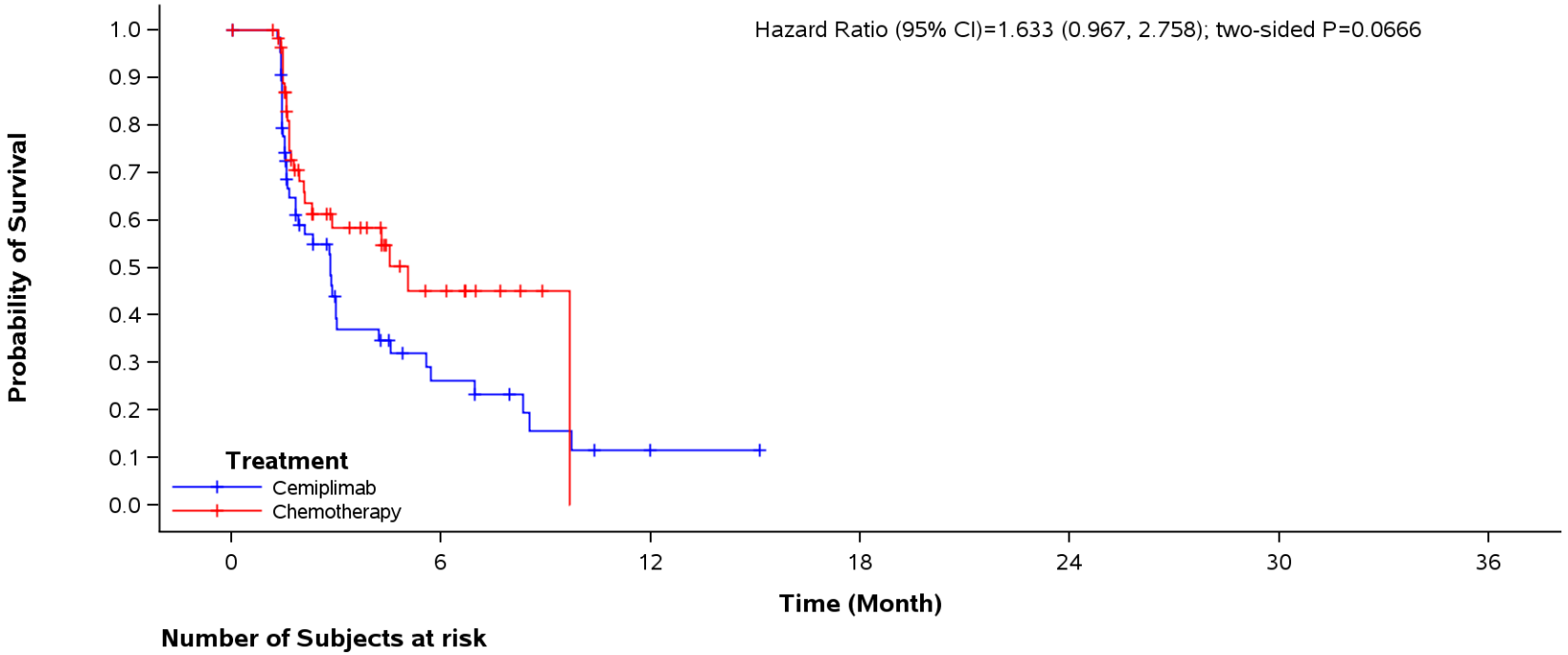
Diarhoea - 10 pts improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts improvement



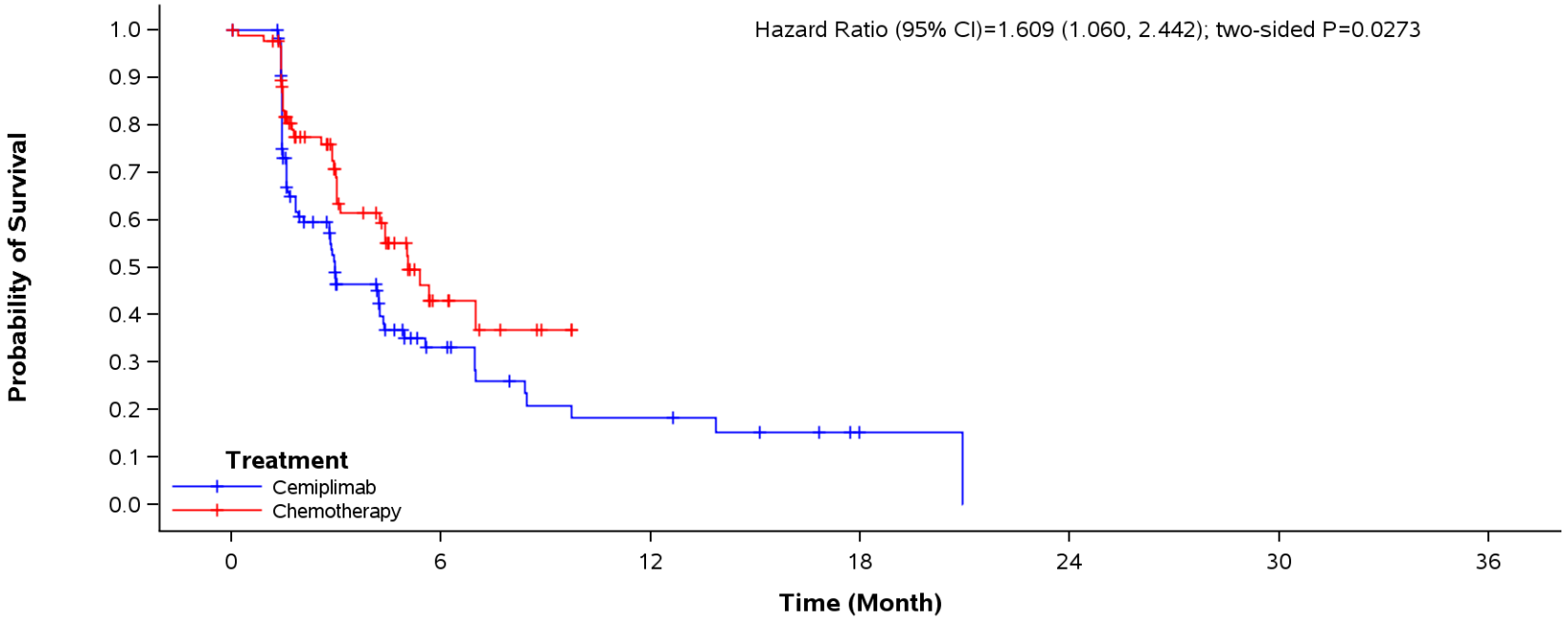

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 9 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 183 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts improvement



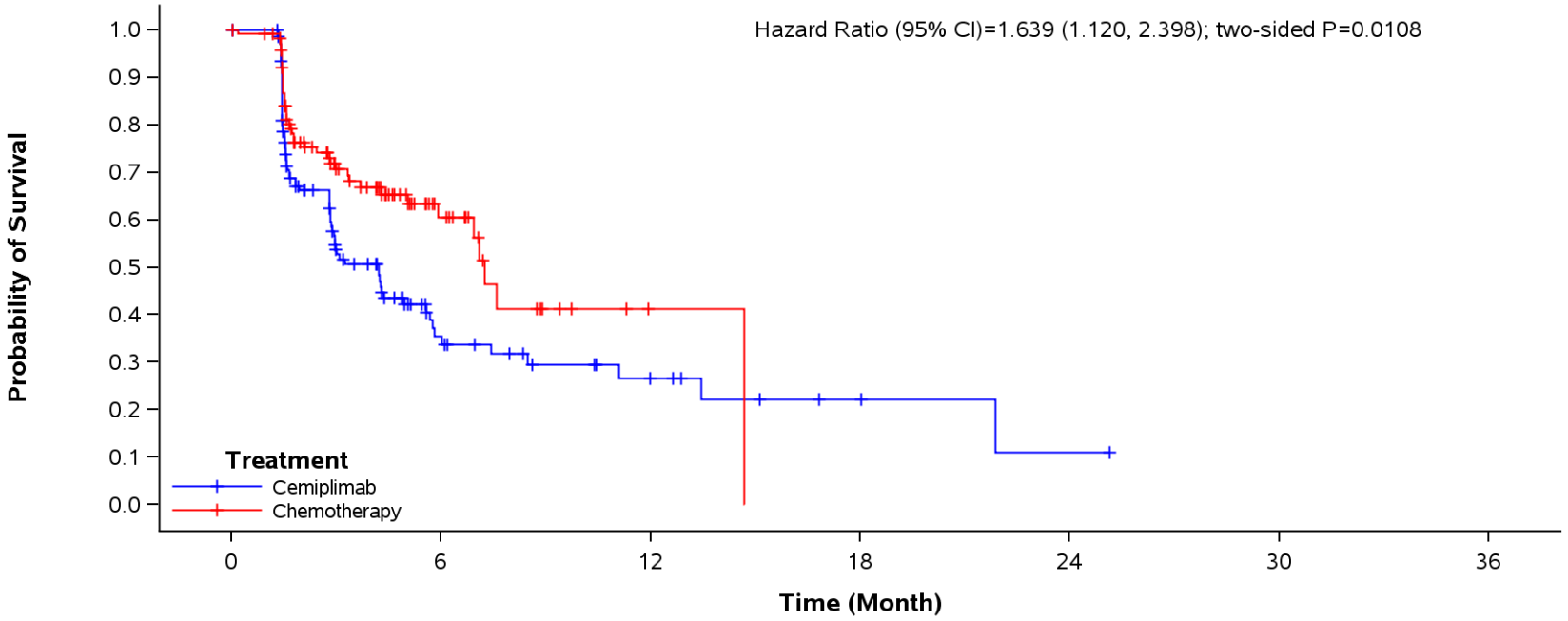

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 16 | 7 | 1 | 0 | 0 | 0 |
| Chemotherapy | 183 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts improvement



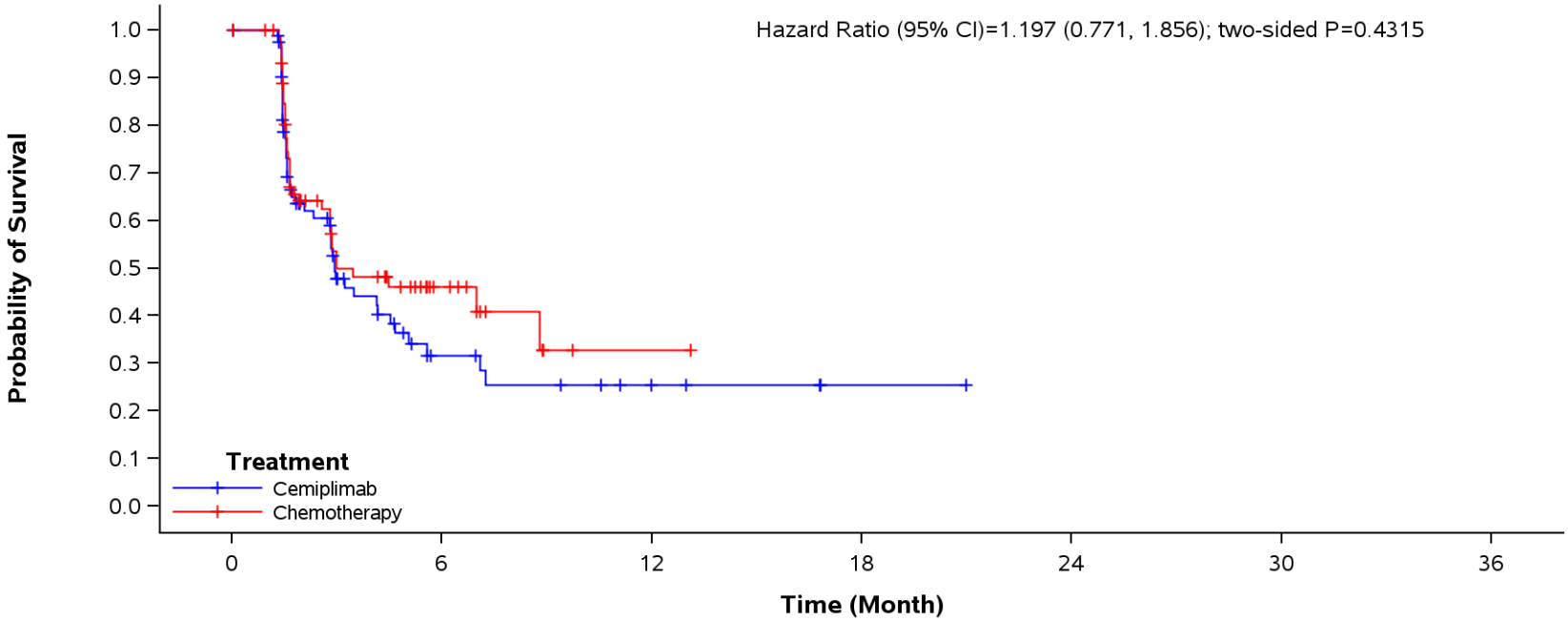

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 21 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 183 | 21 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts improvement



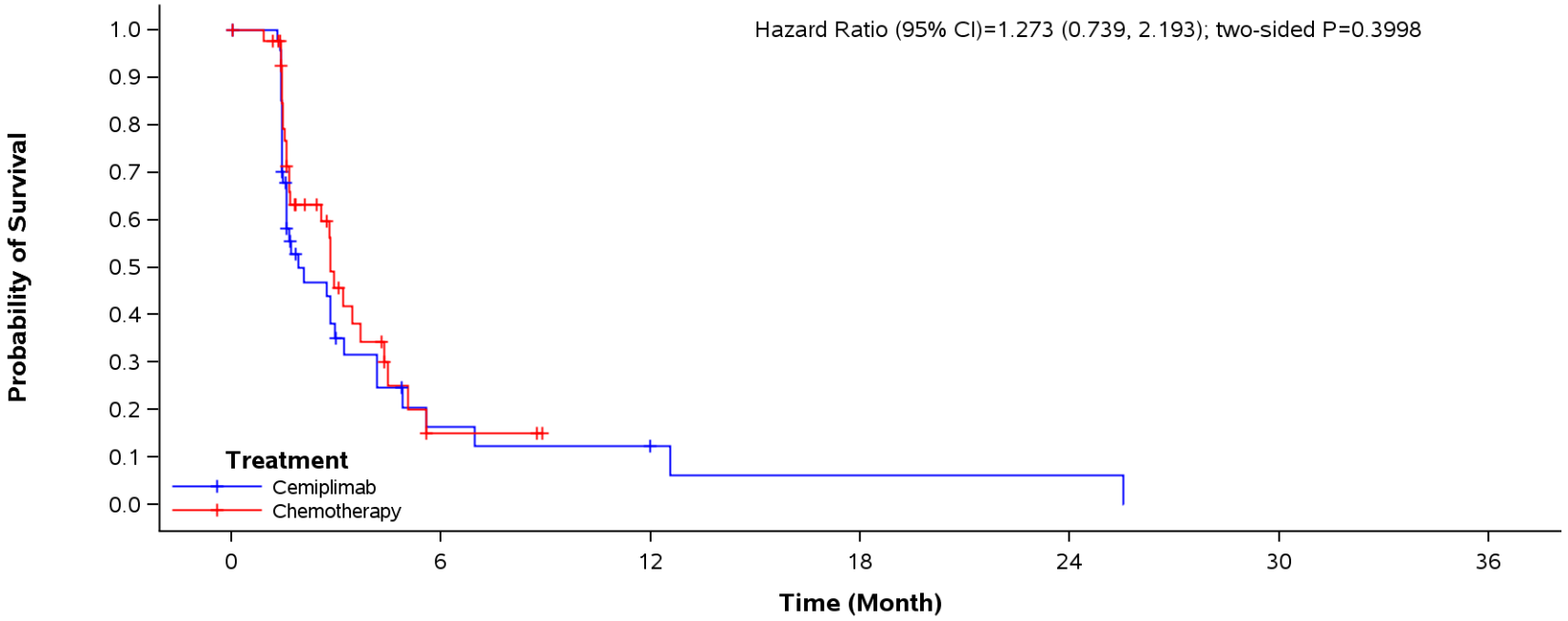

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 11 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 183 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts improvement



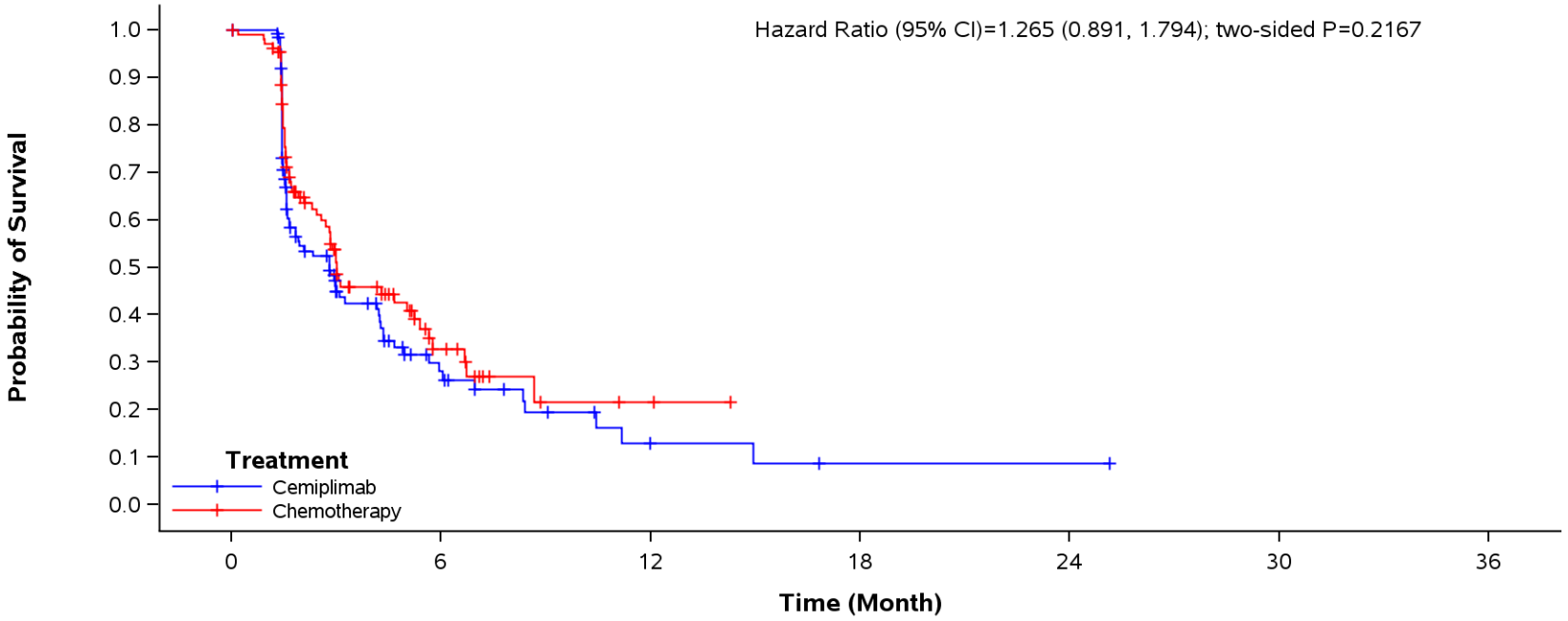

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 4 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 183 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts improvement



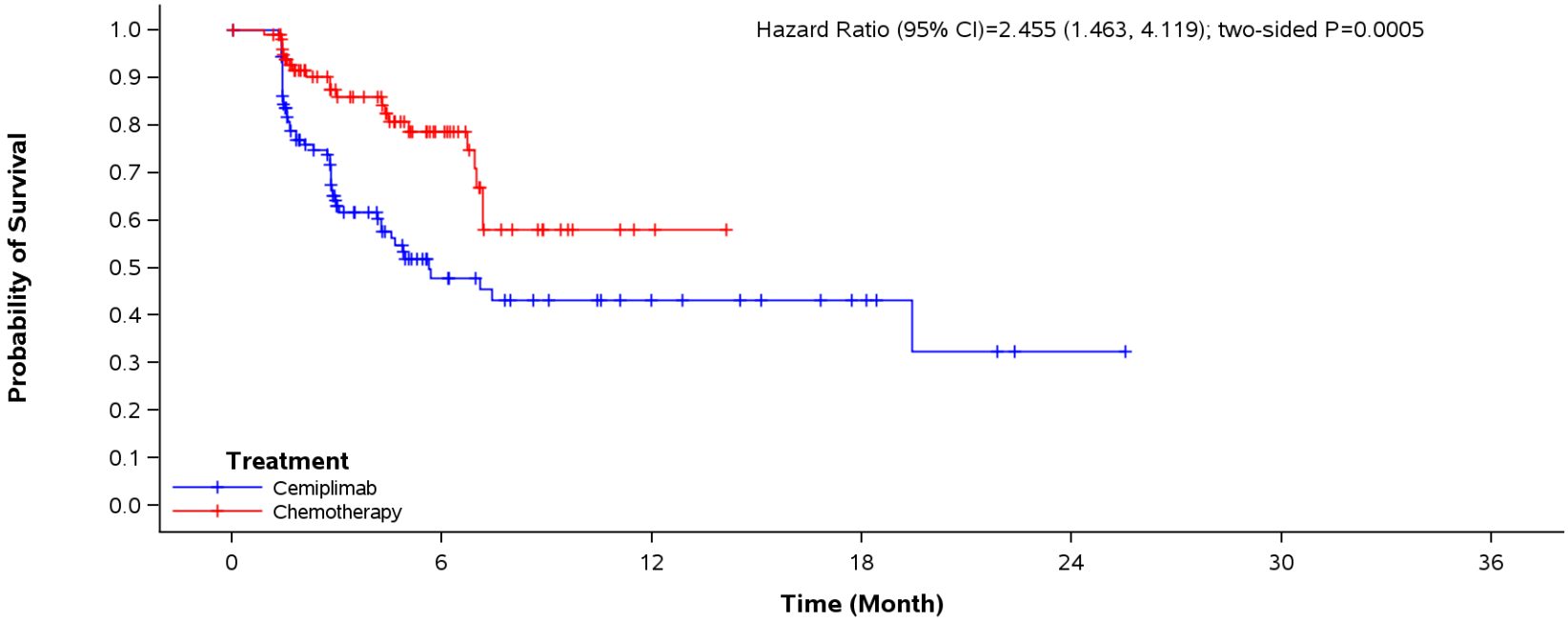

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 16 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 183 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts improvement



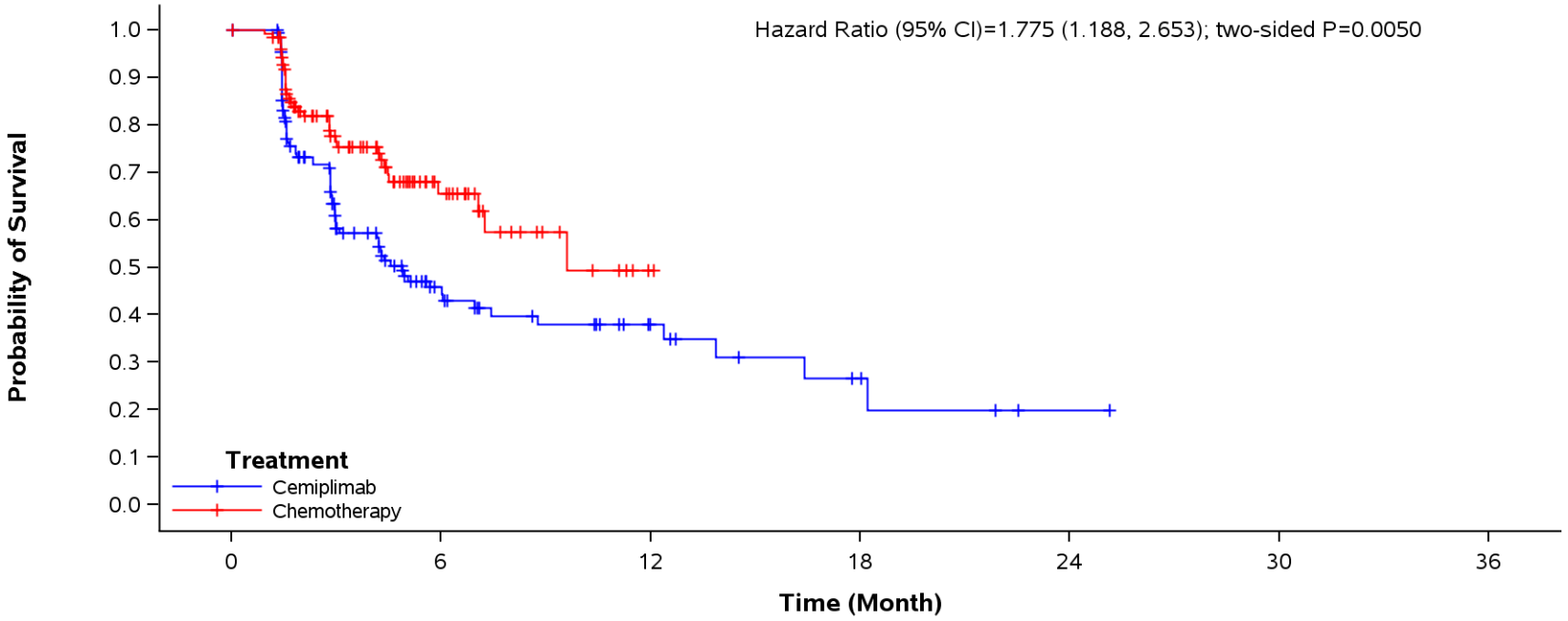

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 24 | 11 | 6 | 1 | 0 | 0 |
| Chemotherapy | 183 | 28 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts improvement



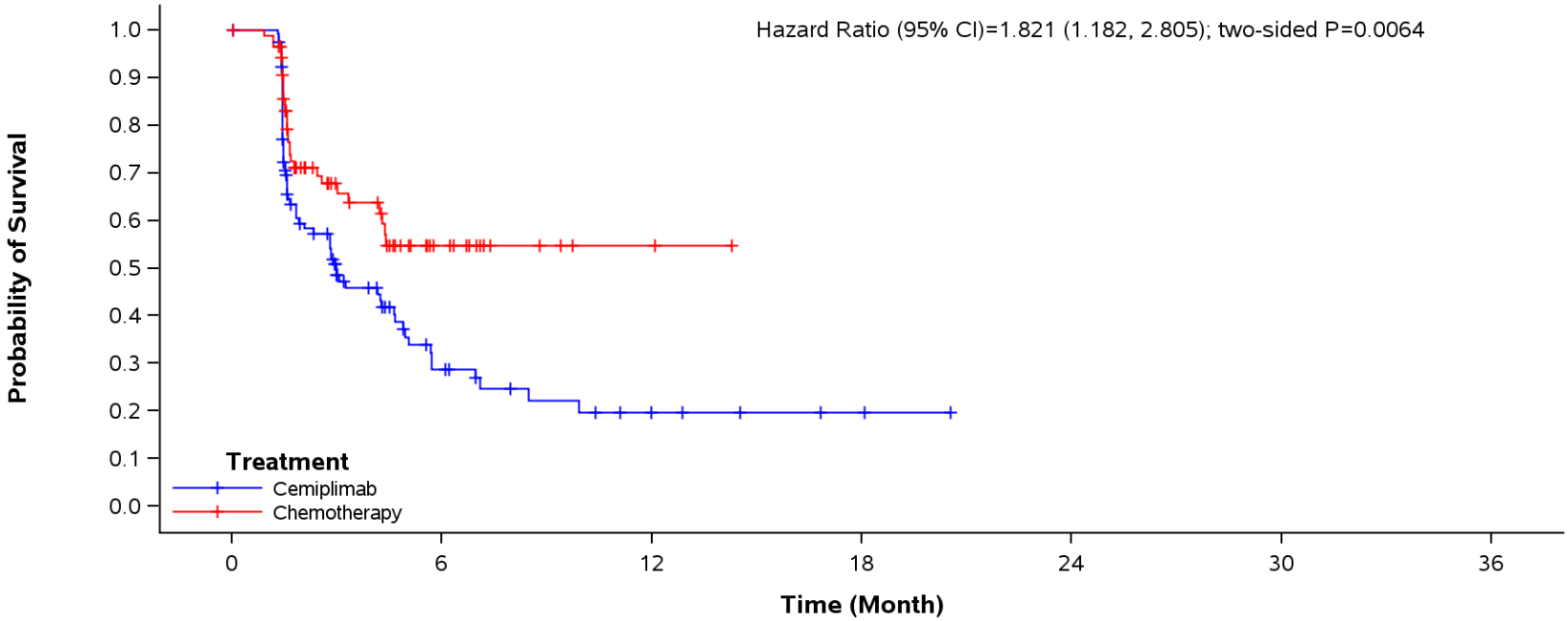

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 33 | 12 | 5 | 1 | 0 | 0 |
| Chemotherapy | 183 | 27 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts improvement



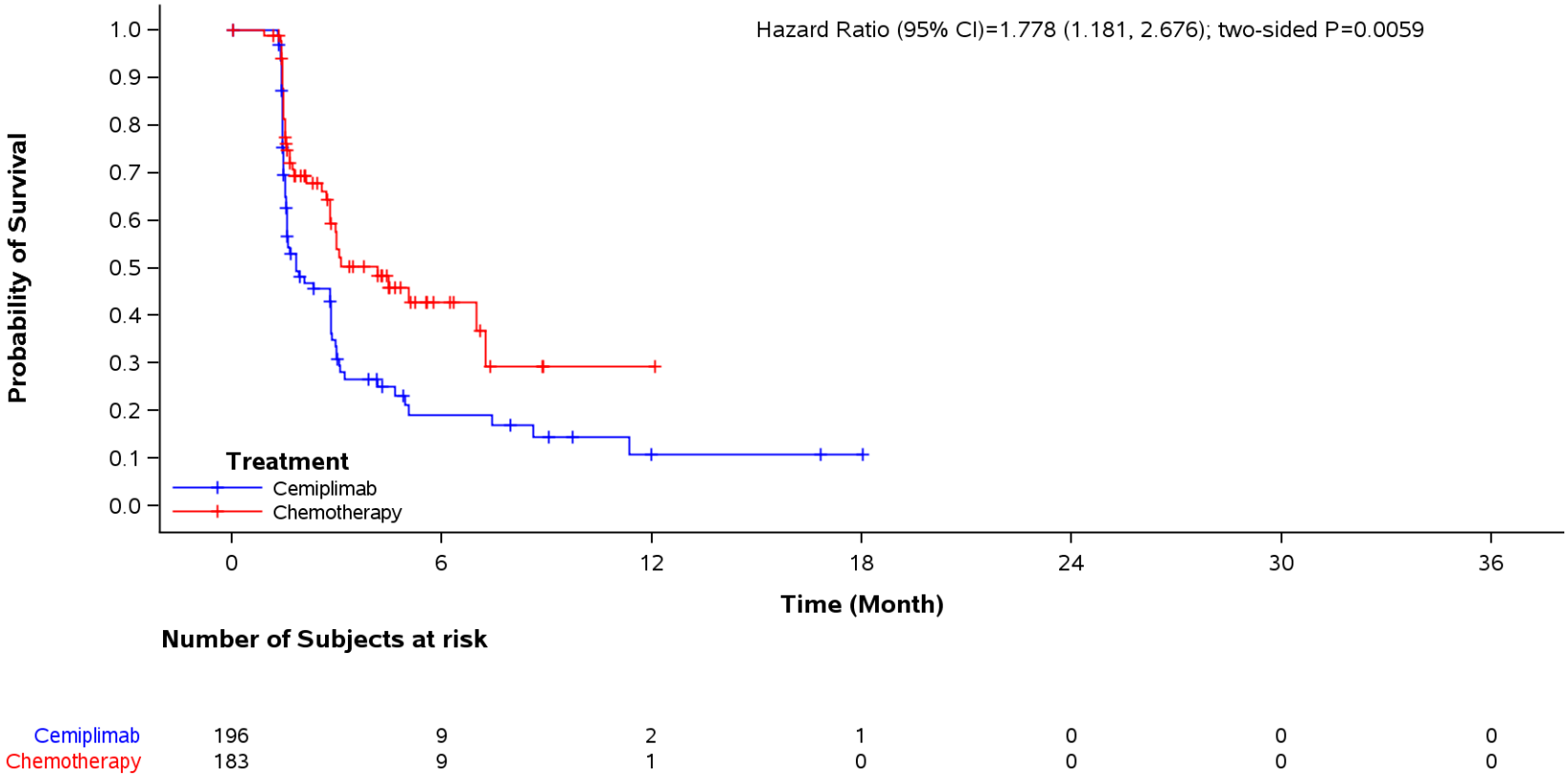

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 17 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 183 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

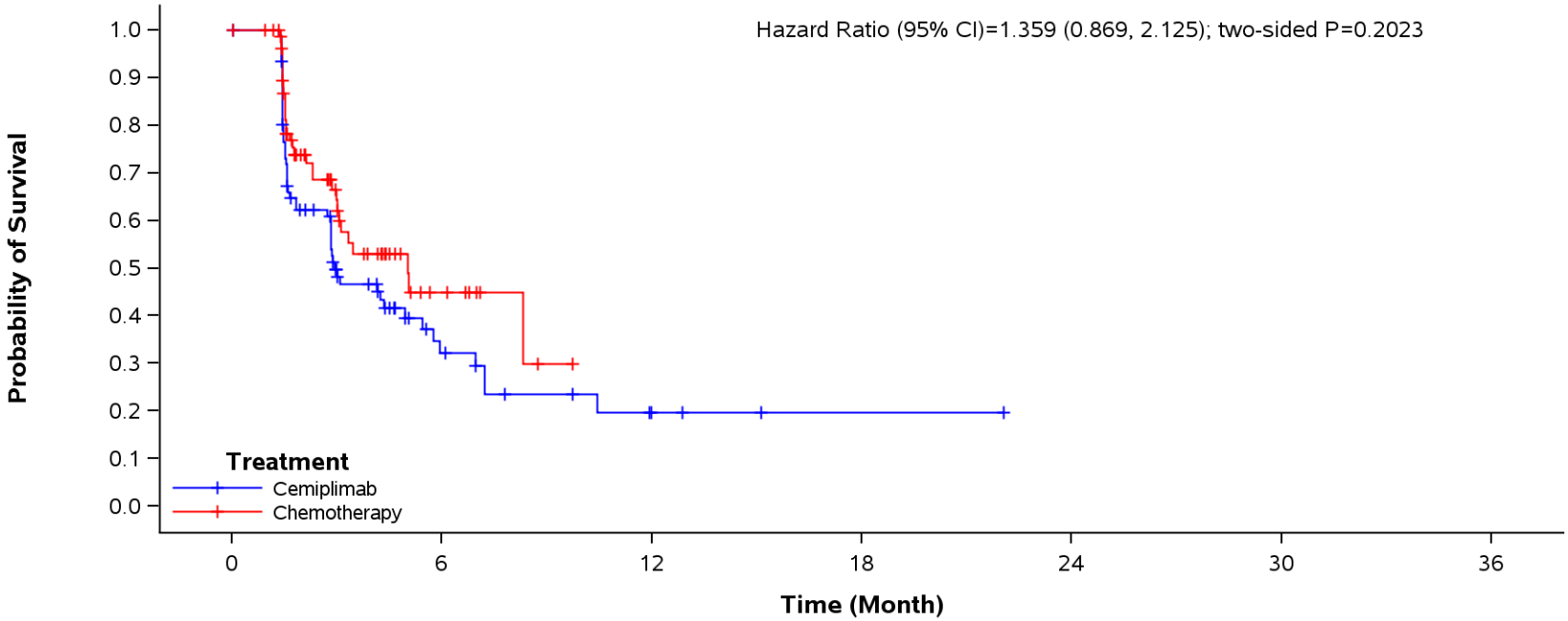
Social Functioning - 10 pts improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.4a. Time to First Improvement with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts improvement



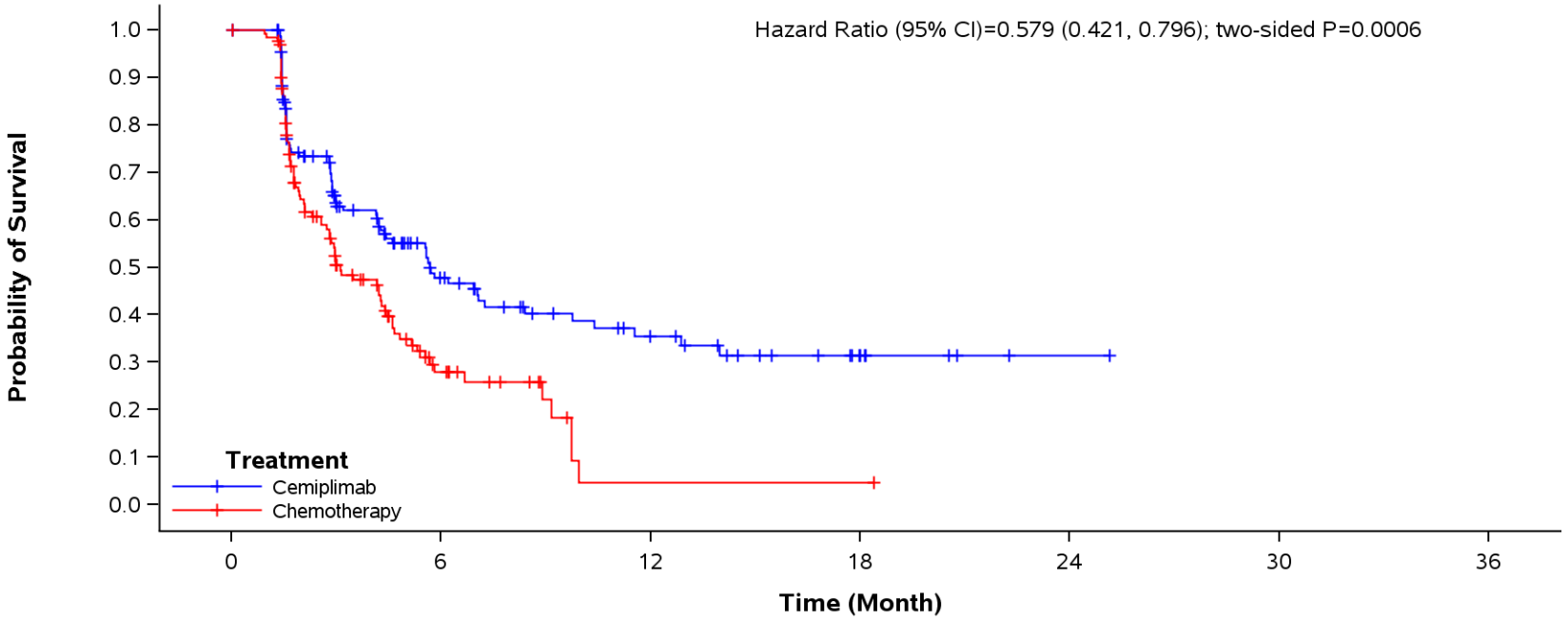

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 13 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 183 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts deterioration



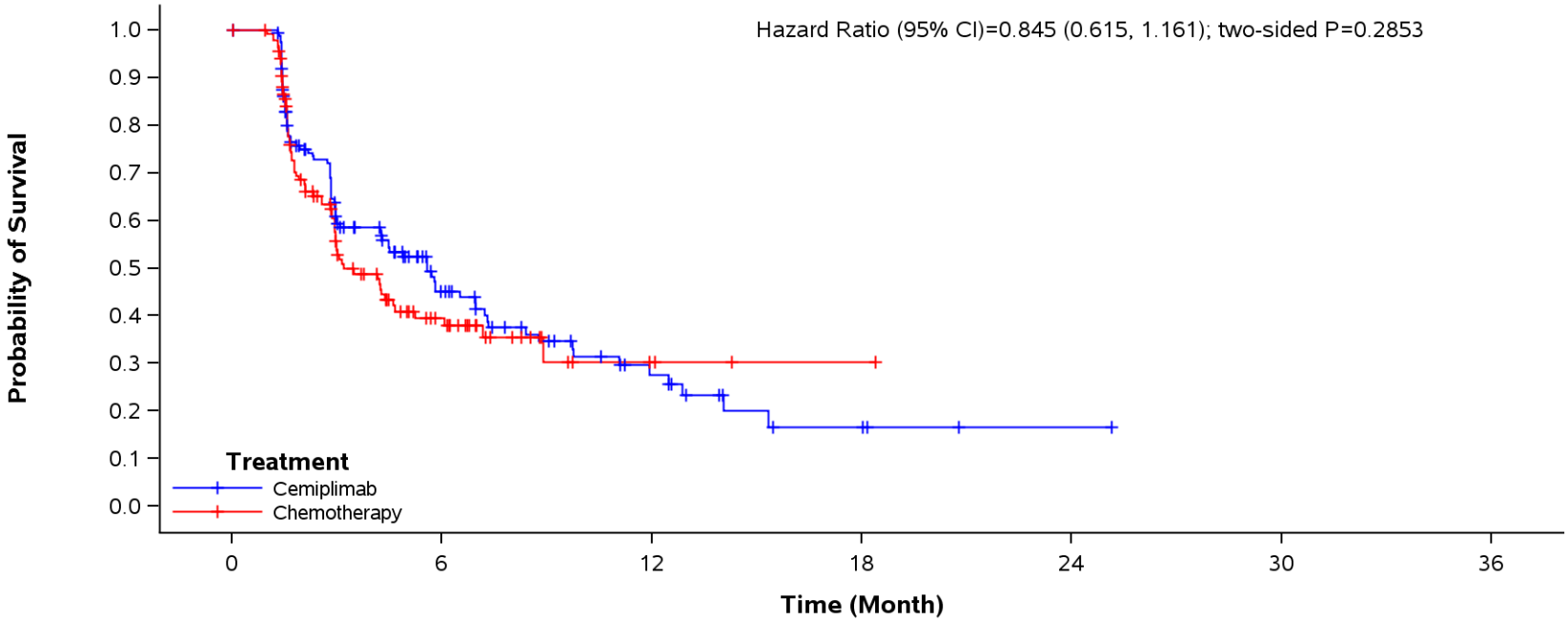

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 43 | 20 | 7 | 1 | 0 | 0 |
| Chemotherapy | 183 | 18 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts deterioration



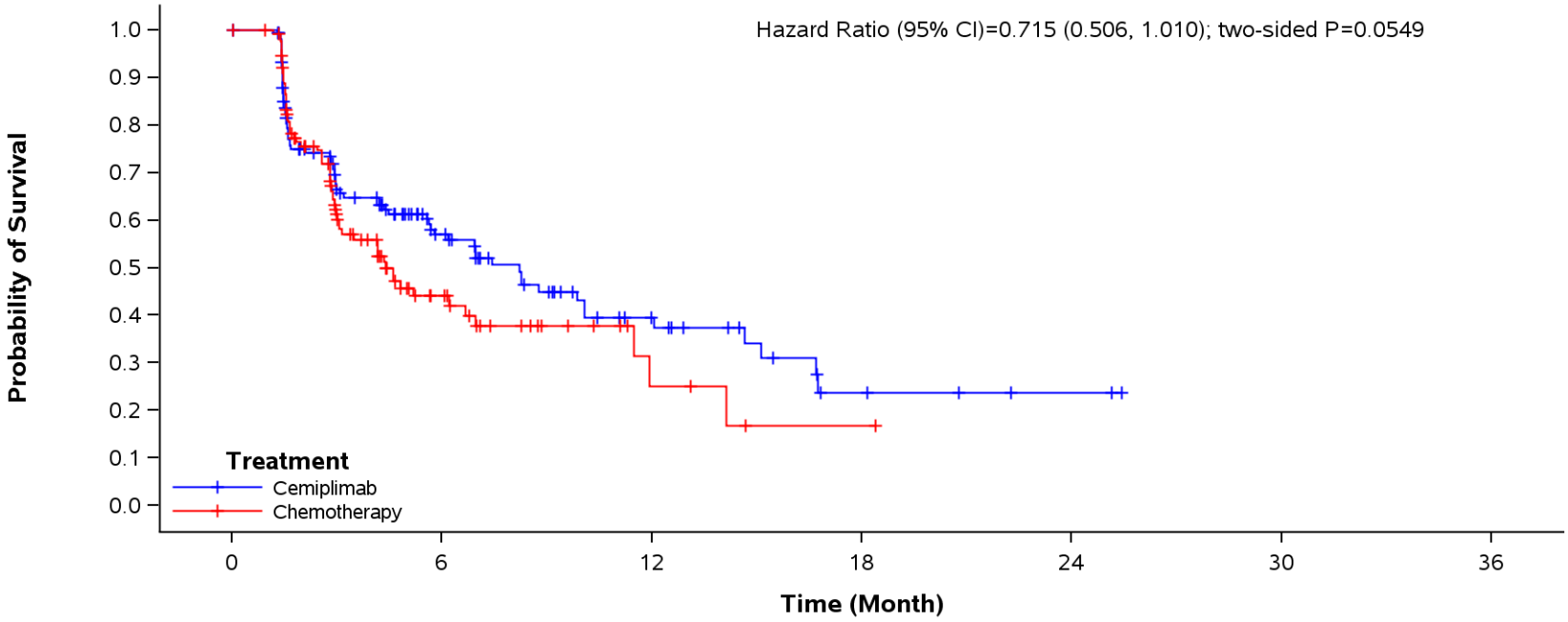

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 41 | 14 | 4 | 1 | 0 | 0 |
| Chemotherapy | 183 | 25 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts deterioration



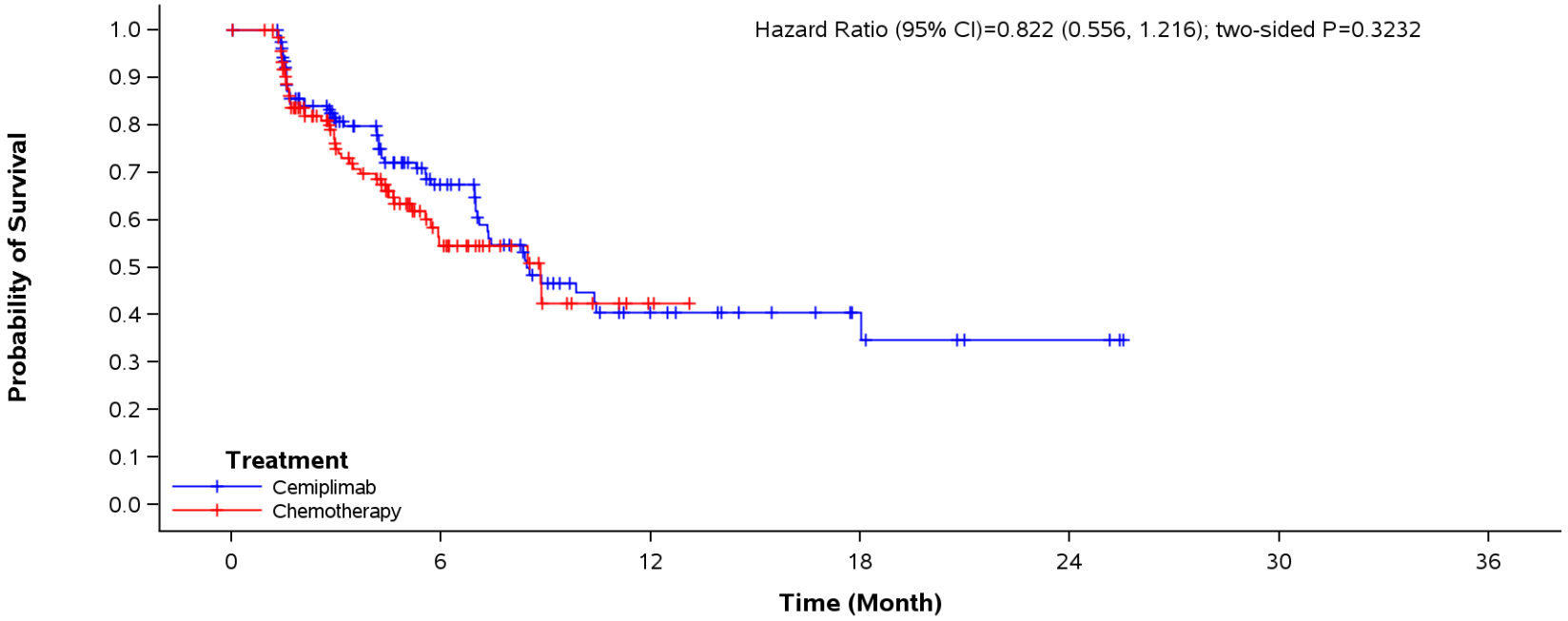

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 49 | 18 | 5 | 2 | 0 | 0 |
| Chemotherapy | 183 | 24 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts deterioration



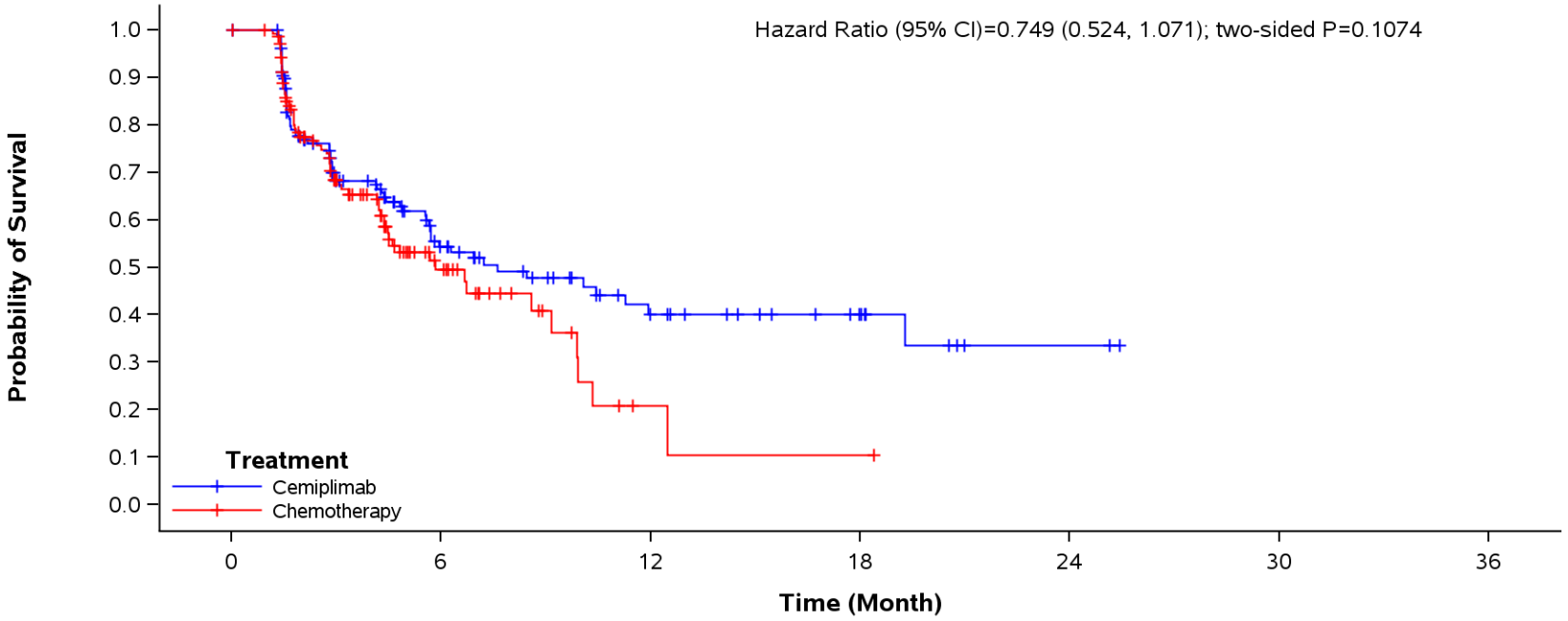

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 54 | 16 | 7 | 3 | 0 | 0 |
| Chemotherapy | 183 | 29 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts deterioration



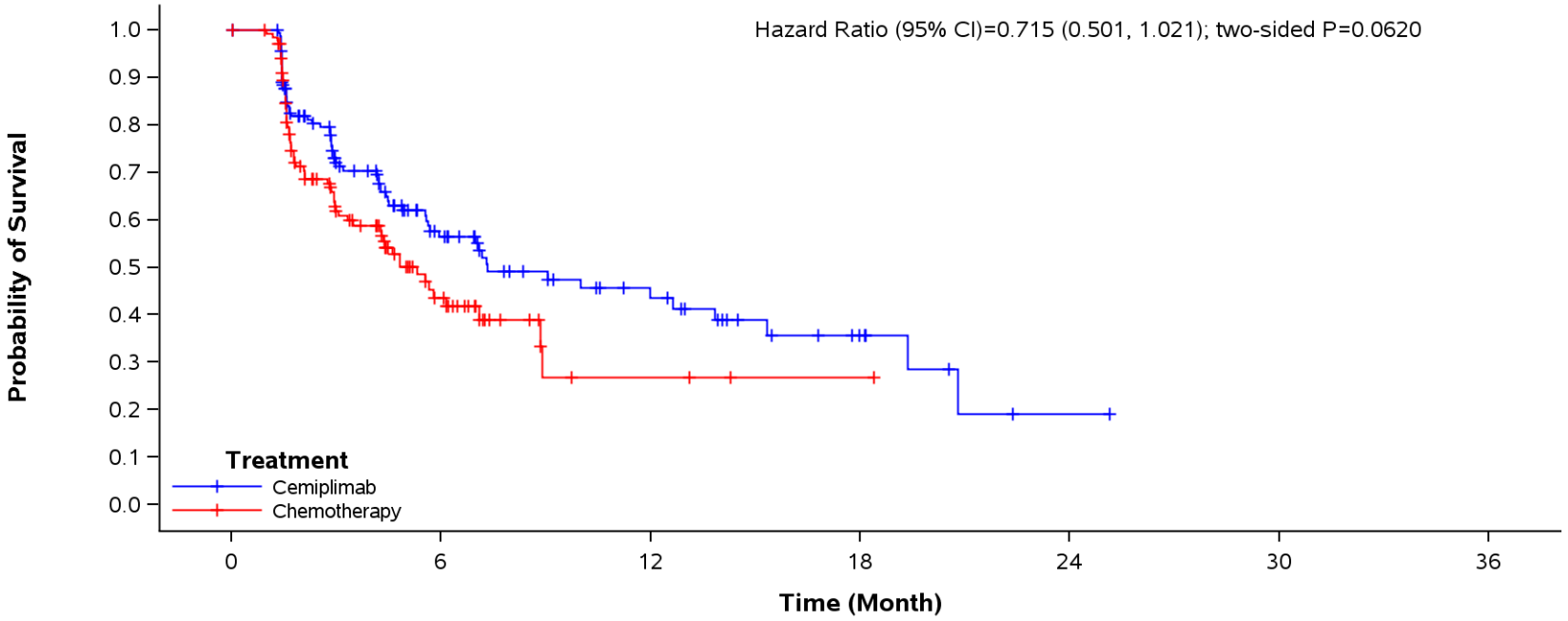

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 47 | 19 | 9 | 2 | 0 | 0 |
| Chemotherapy | 183 | 26 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts deterioration



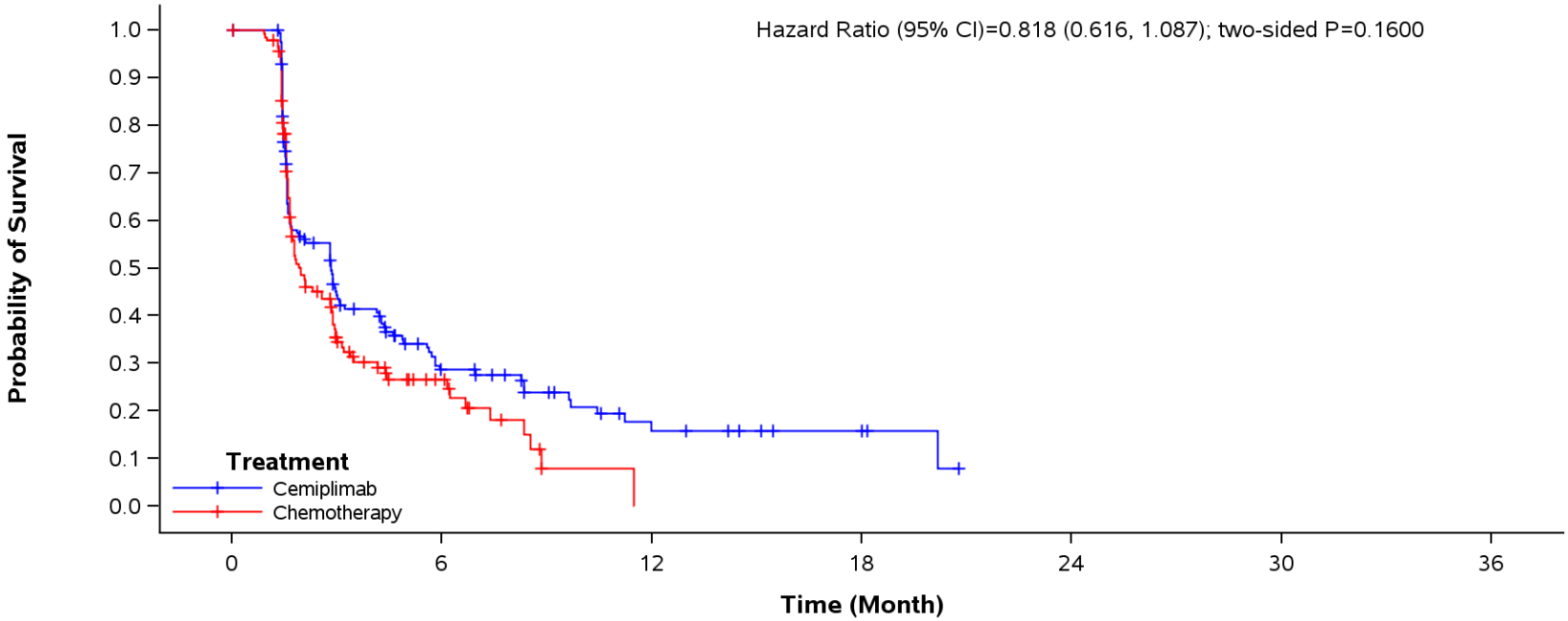

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 49 | 21 | 7 | 1 | 0 | 0 |
| Chemotherapy | 183 | 25 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts deterioration



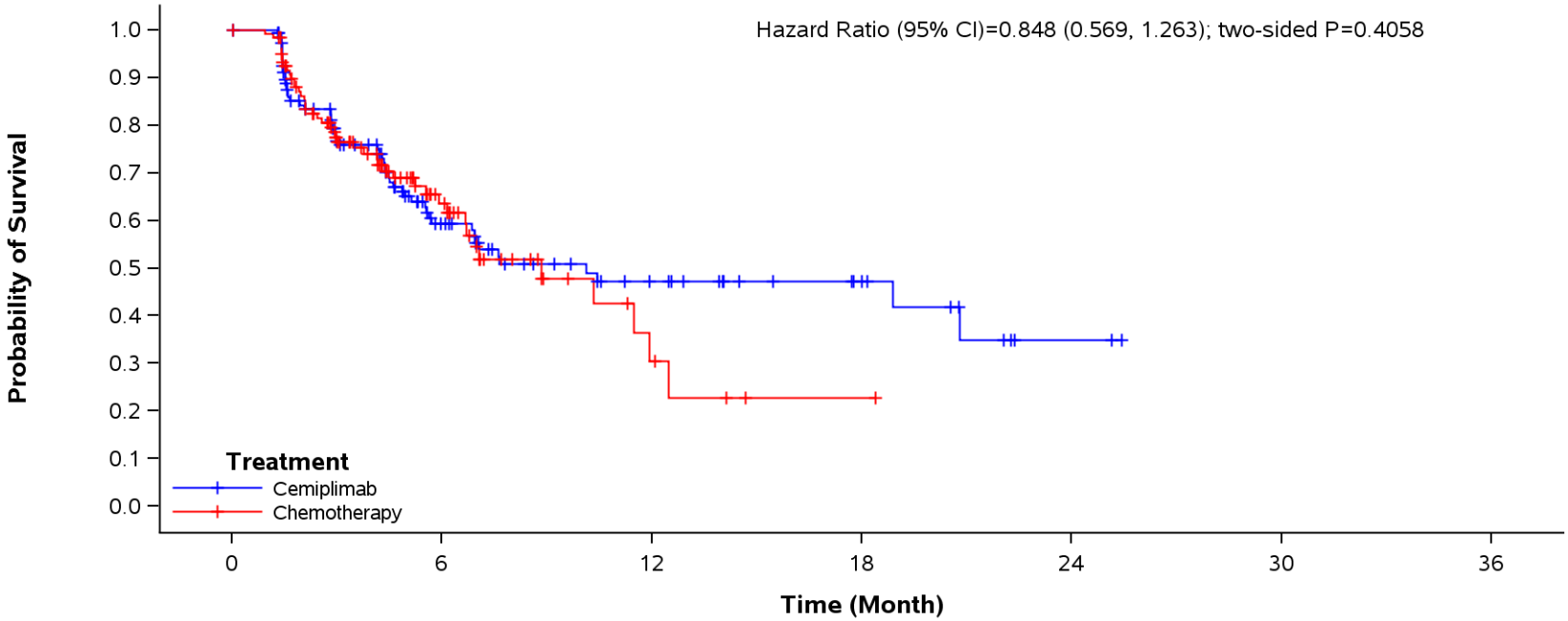

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 30 | 9 | 4 | 0 | 0 | 0 |
| Chemotherapy | 183 | 15 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts deterioration



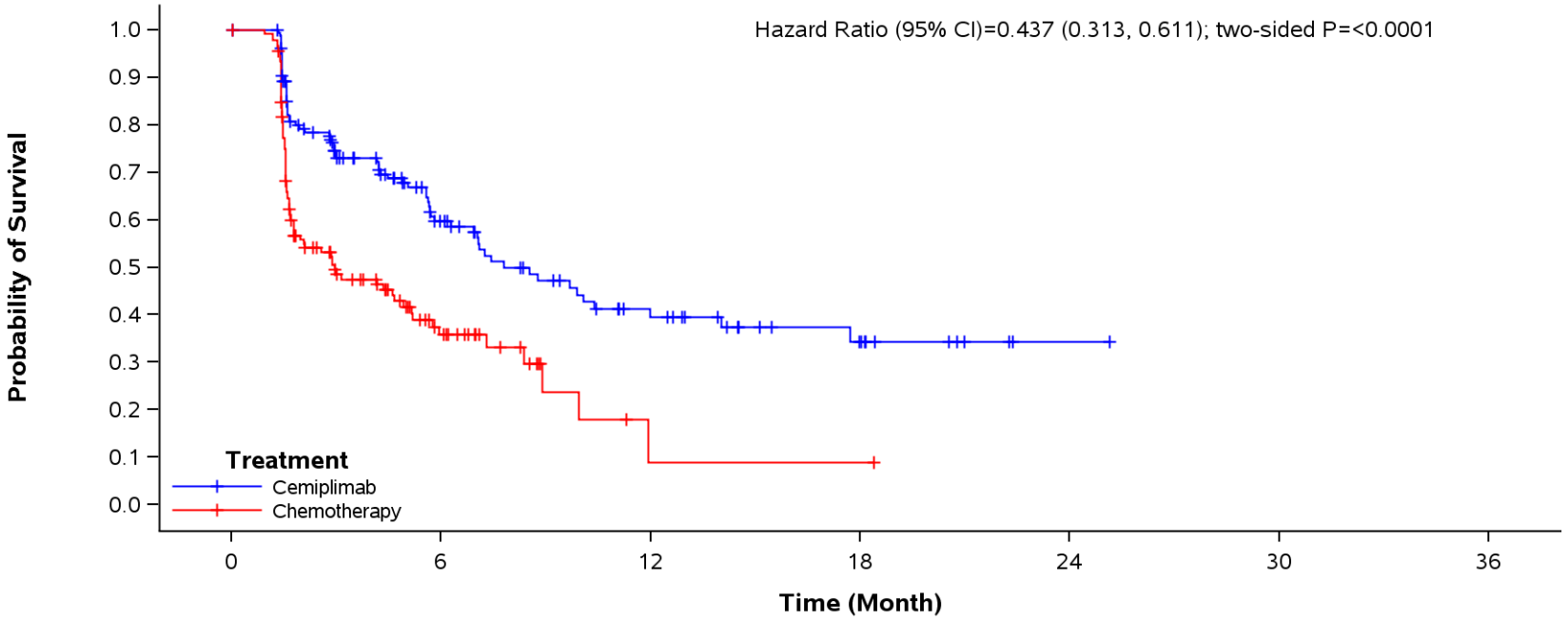

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 48 | 21 | 11 | 2 | 0 | 0 |
| Chemotherapy | 183 | 33 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts deterioration



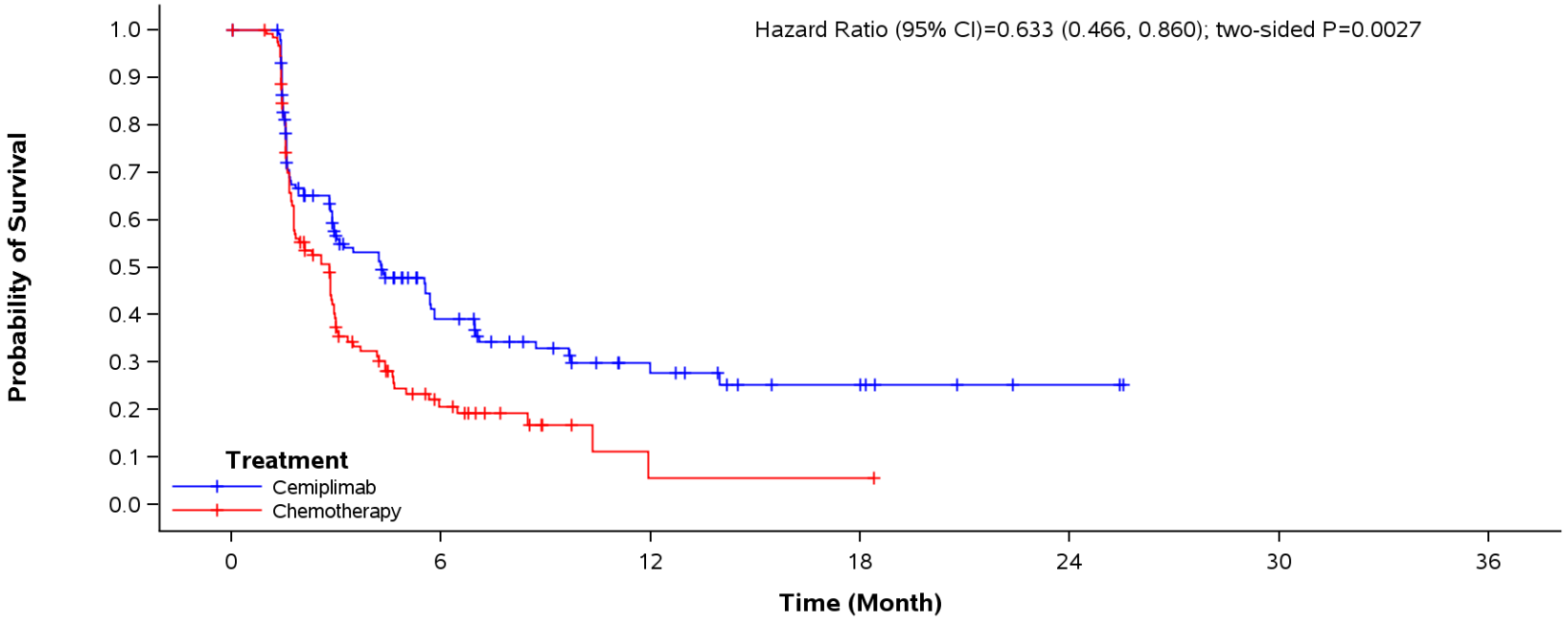

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 56 | 23 | 10 | 1 | 0 | 0 |
| Chemotherapy | 183 | 22 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts deterioration



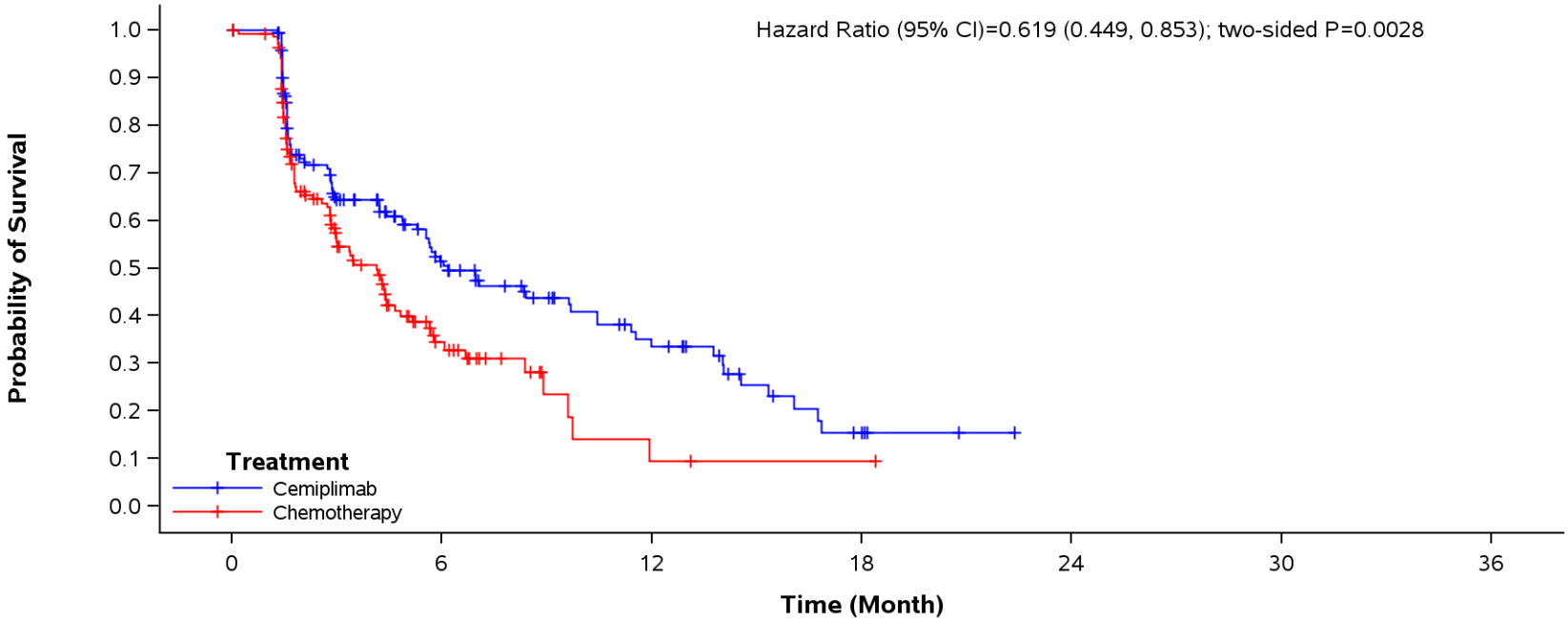

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 36 | 14 | 7 | 2 | 0 | 0 |
| Chemotherapy | 183 | 15 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts deterioration



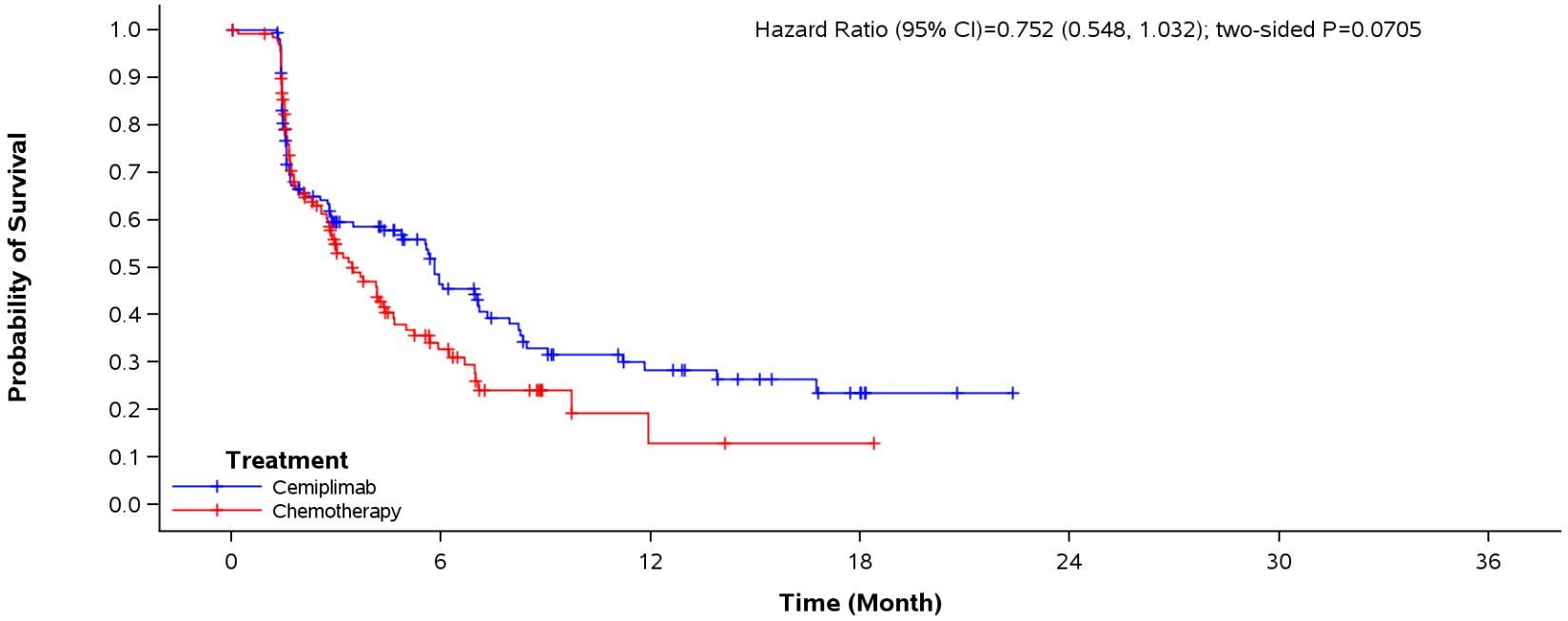

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 52 | 22 | 5 | 0 | 0 | 0 |
| Chemotherapy | 183 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts deterioration



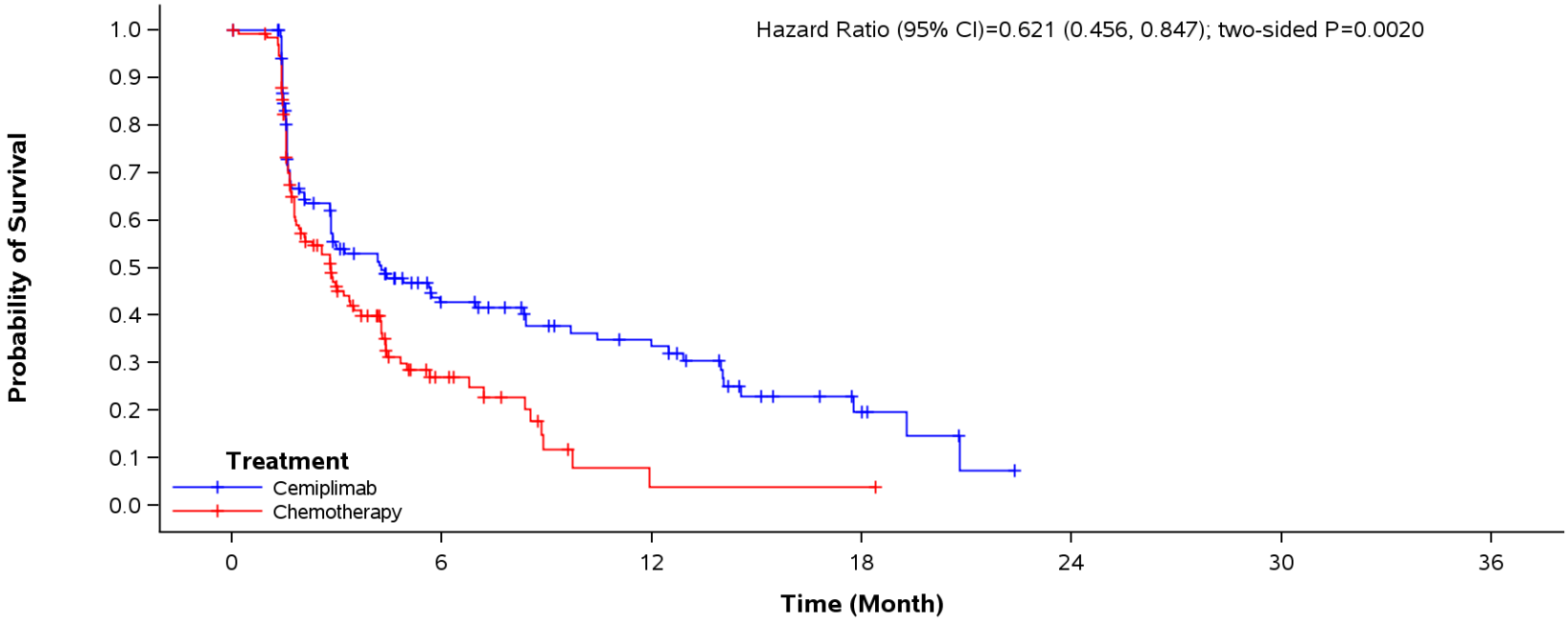

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 44 | 17 | 6 | 0 | 0 | 0 |
| Chemotherapy | 183 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts deterioration



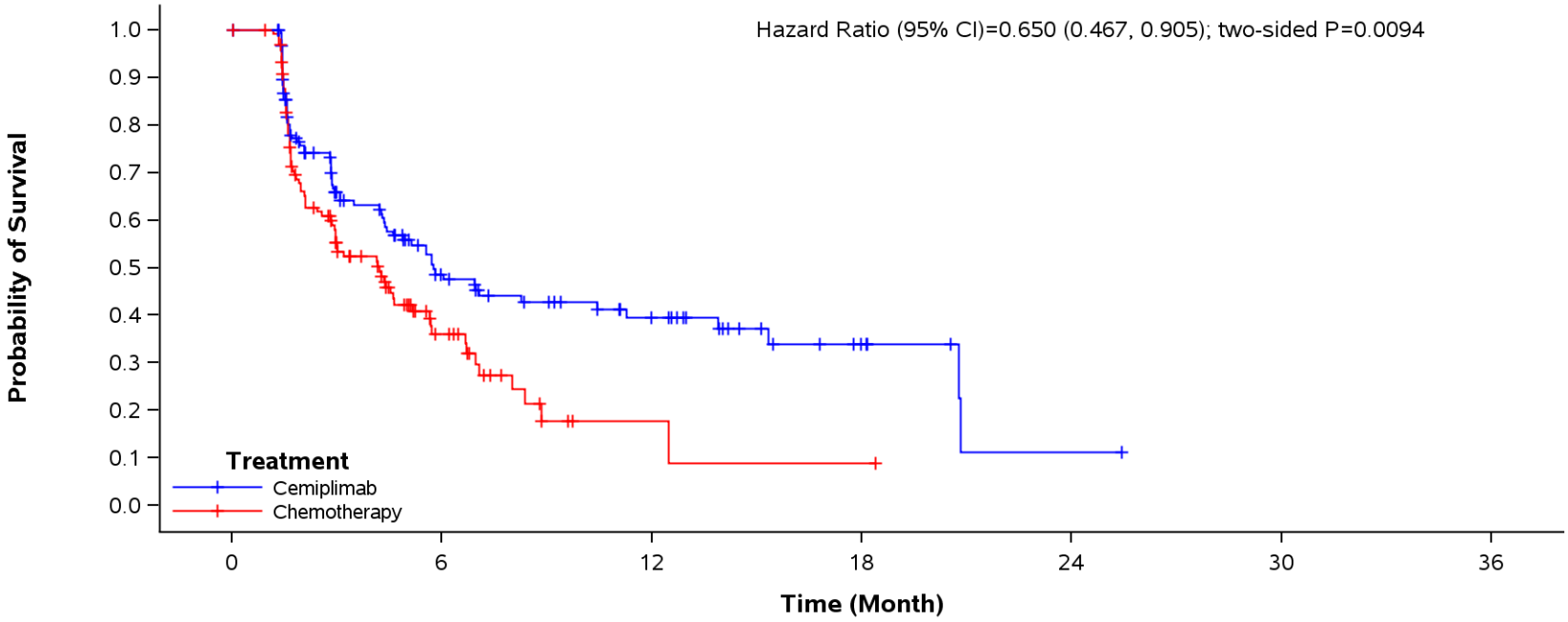

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 40 | 23 | 6 | 0 | 0 | 0 |
| Chemotherapy | 183 | 15 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts deterioration



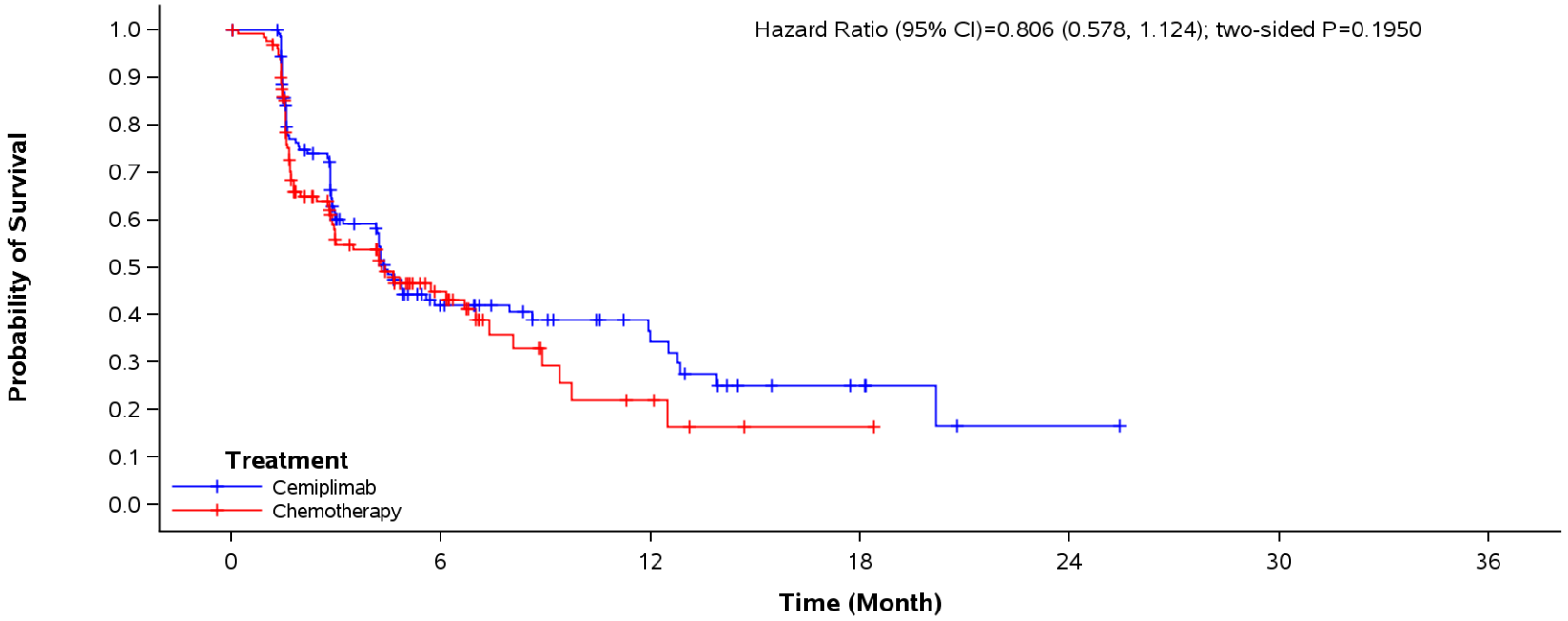

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 45 | 22 | 6 | 1 | 0 | 0 |
| Chemotherapy | 183 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.5a. Time to First Deterioration with C30 10-points Threshold
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts deterioration



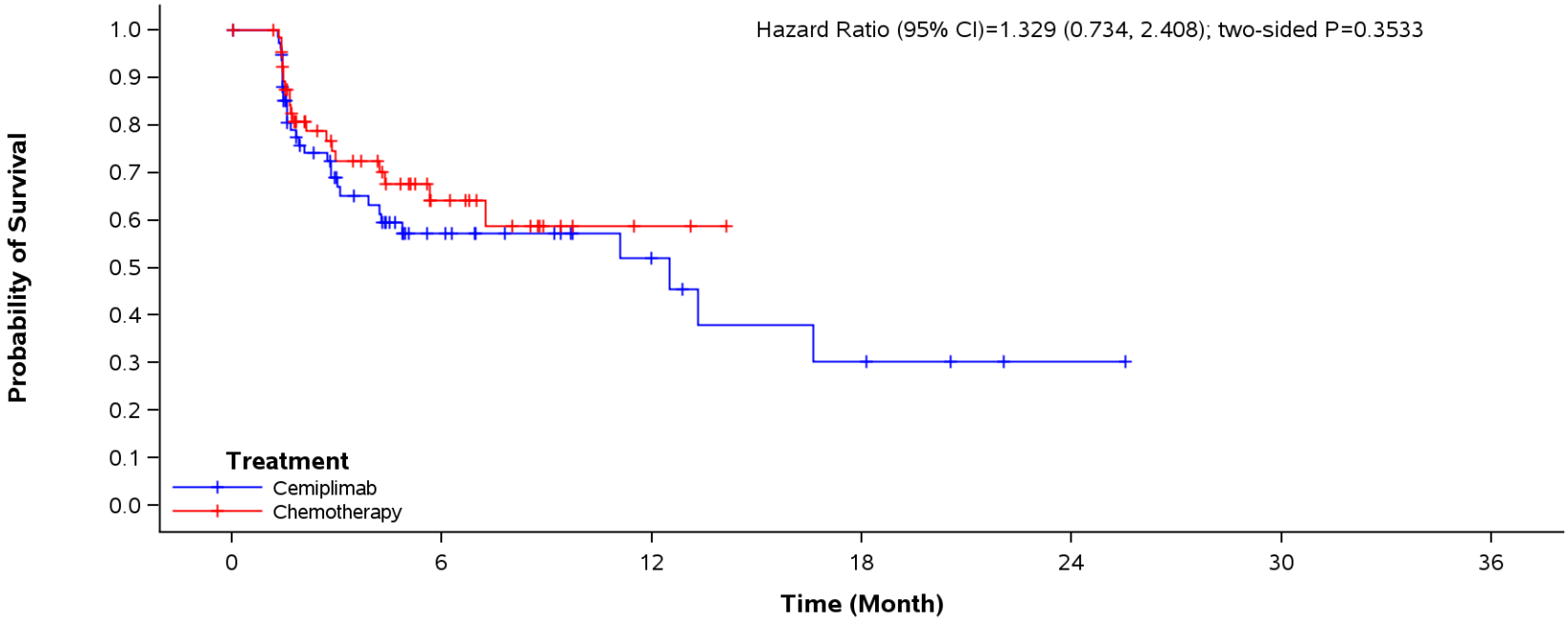

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 34 | 15 | 5 | 1 | 0 | 0 |
| Chemotherapy | 183 | 26 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts sustained improvement



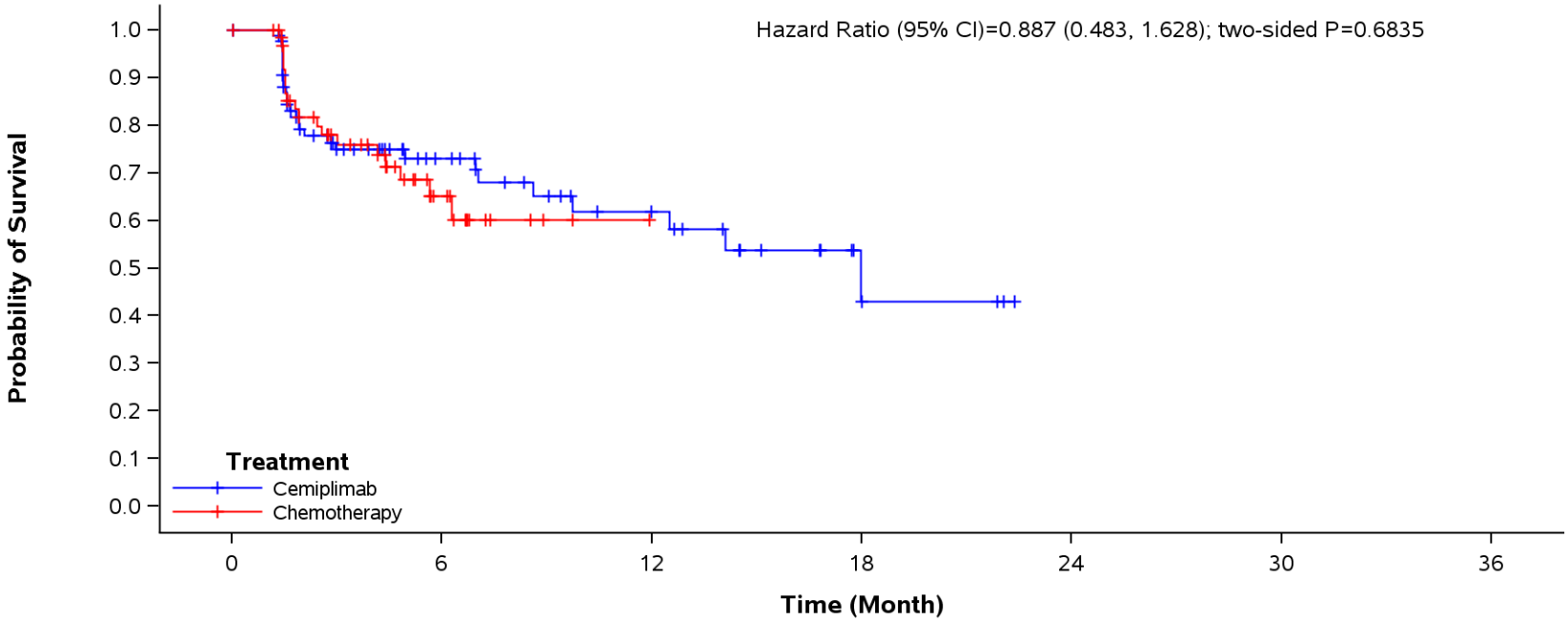

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 20 | 8 | 4 | 1 | 0 | 0 |
| Chemotherapy | 183 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts sustained improvement



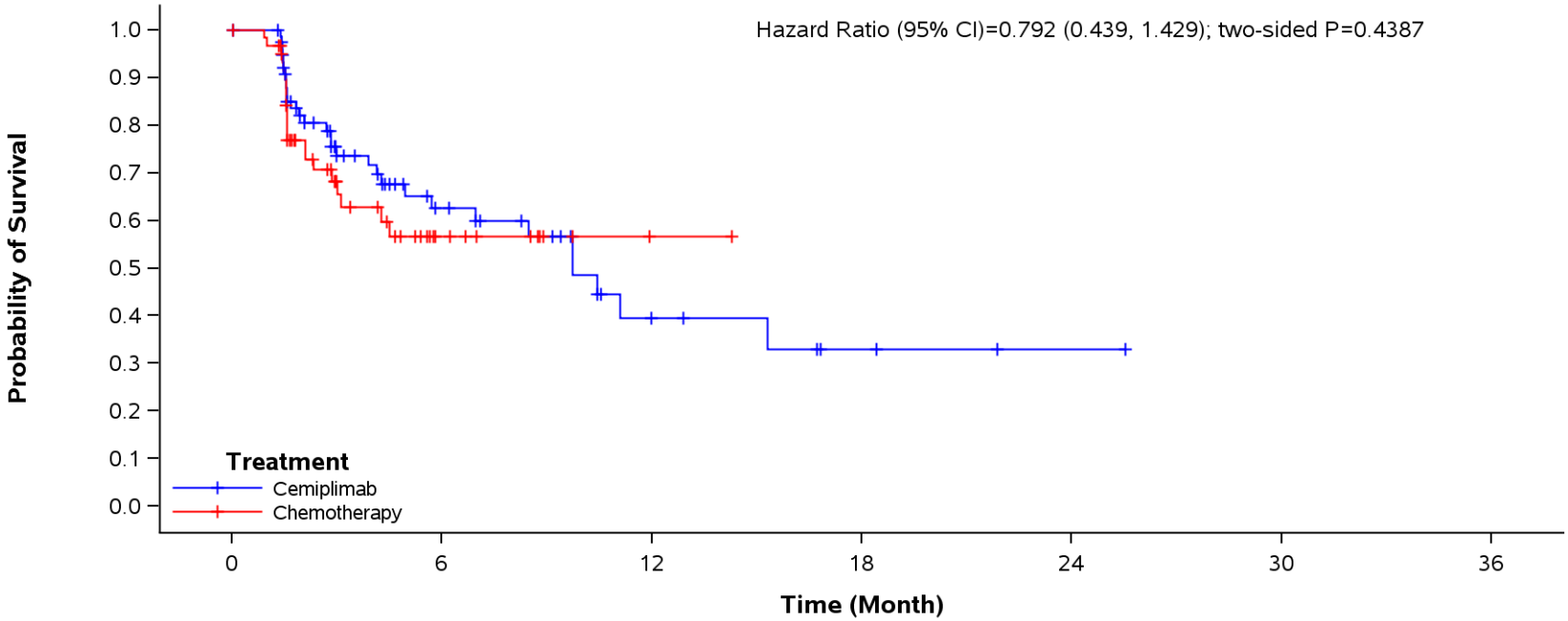

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 34 | 17 | 4 | 0 | 0 | 0 |
| Chemotherapy | 183 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts sustained improvement



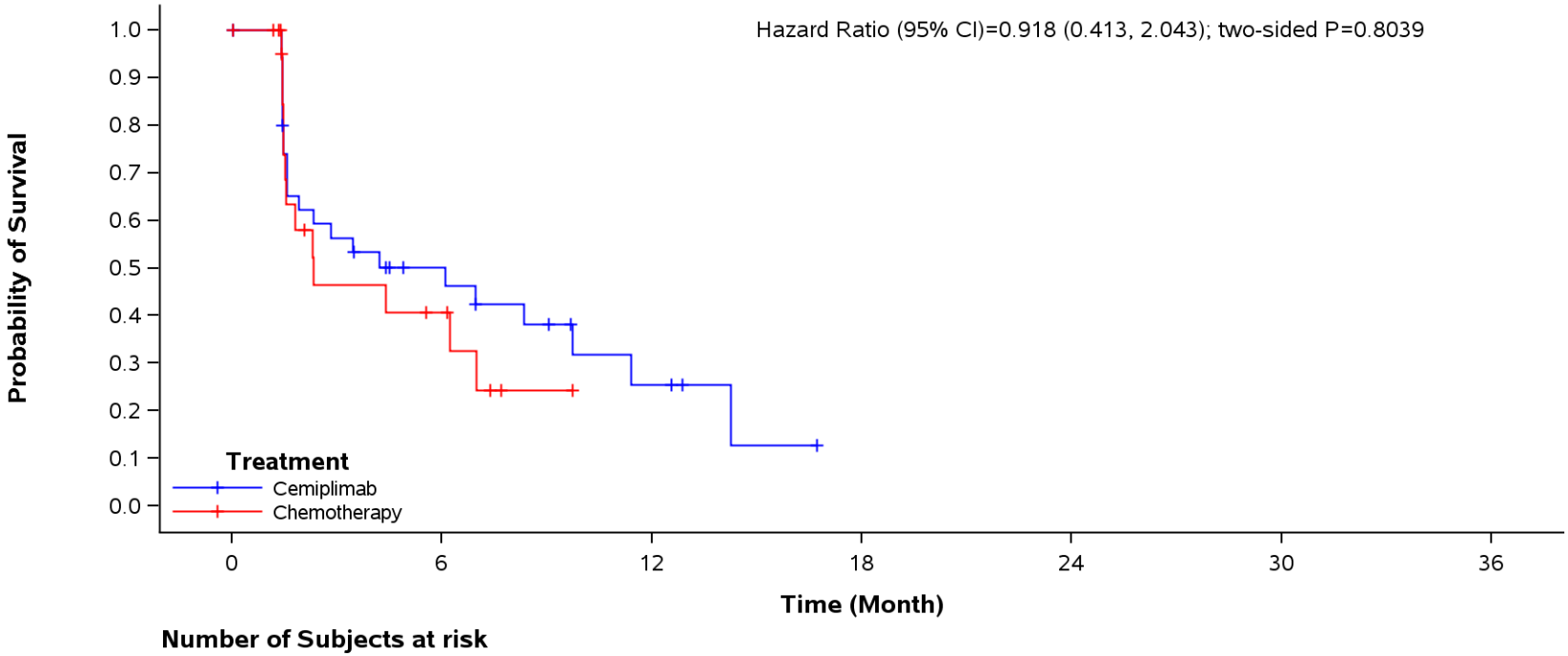

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 24 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 183 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts sustained improvement



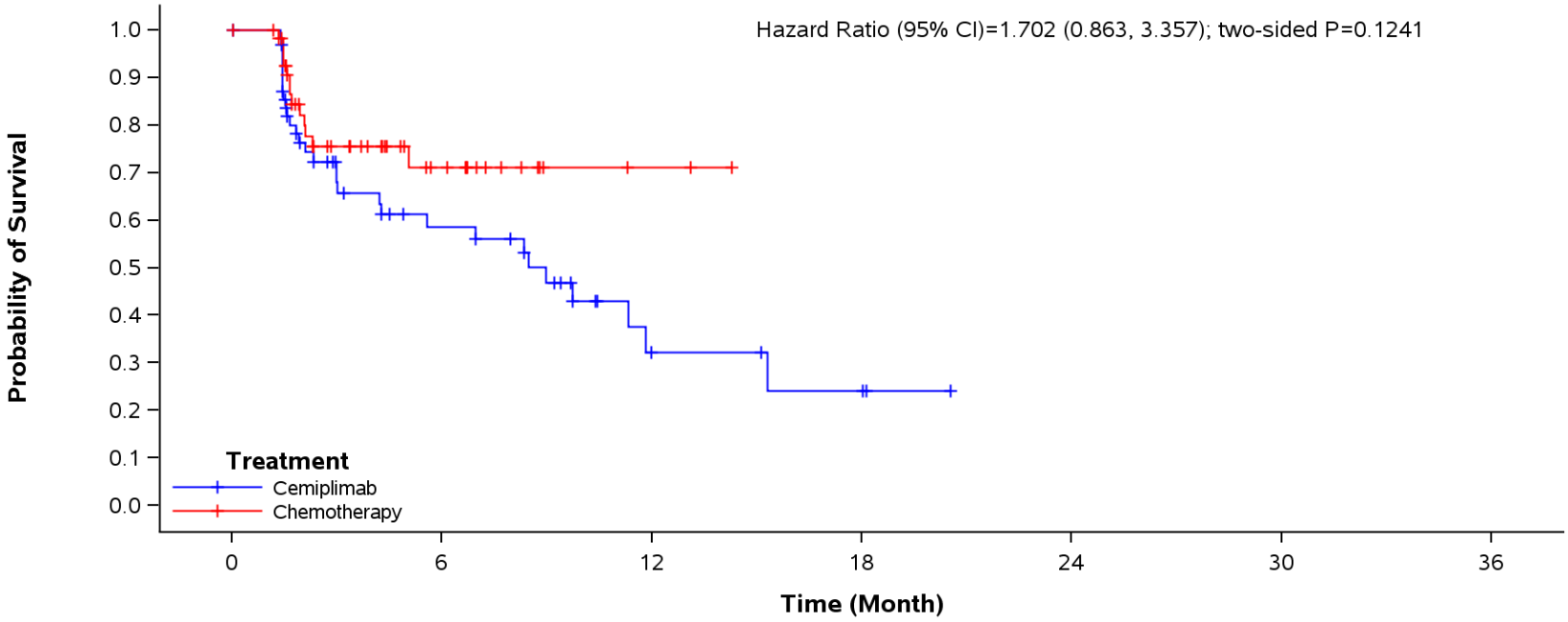

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 13 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 183 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts sustained improvement



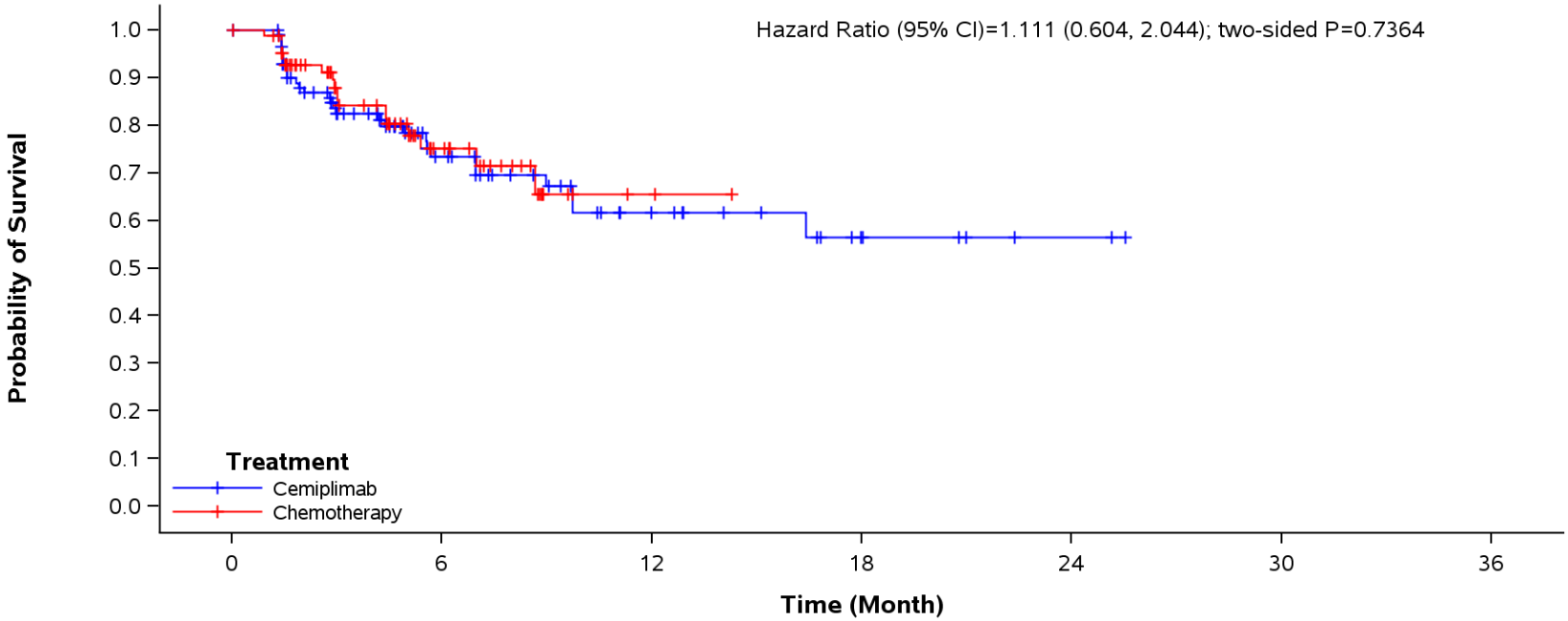

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 23 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 183 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts sustained improvement




**Number of Subjects at risk**

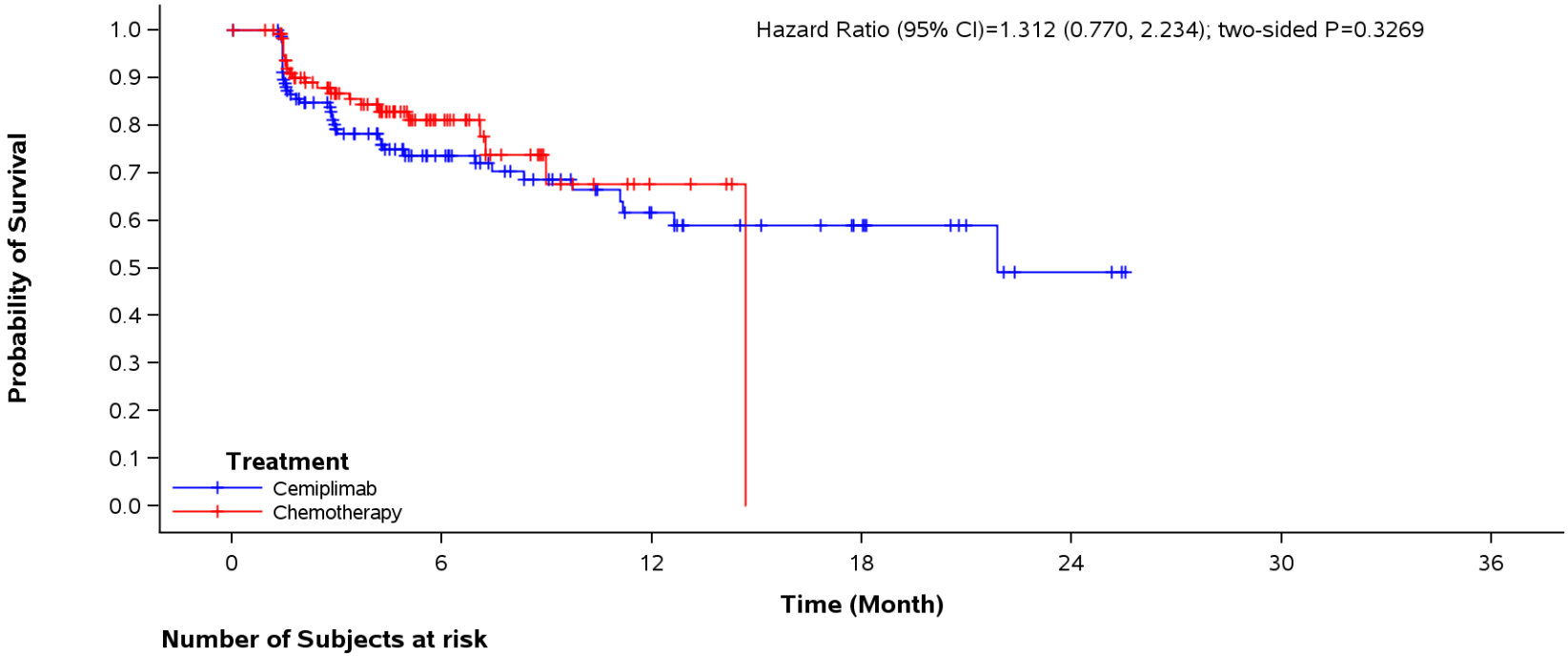
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 43 | 17 | 6 | 2 | 0 | 0 |
| Chemotherapy | 183 | 24 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts sustained improvement



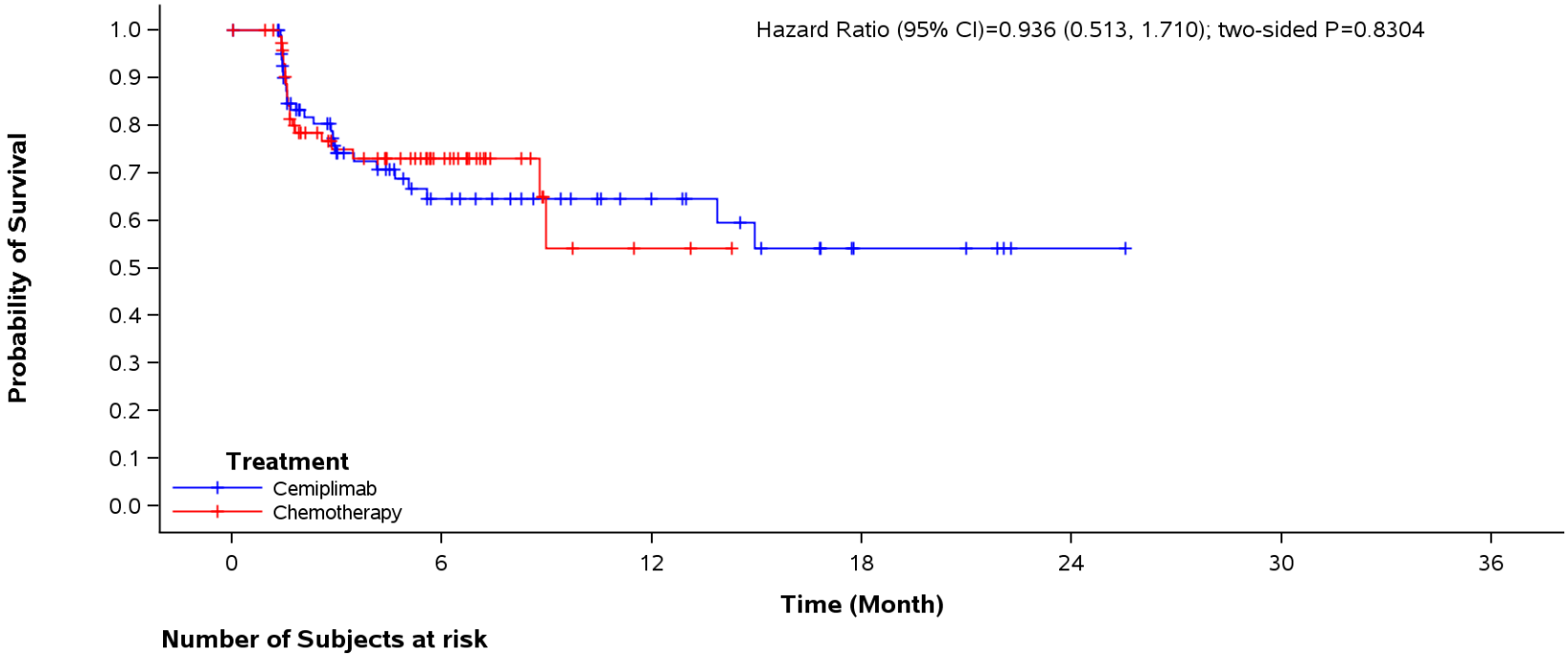

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 52 | 22 | 12 | 3 | 0 | 0 |
| Chemotherapy | 183 | 33 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts sustained improvement



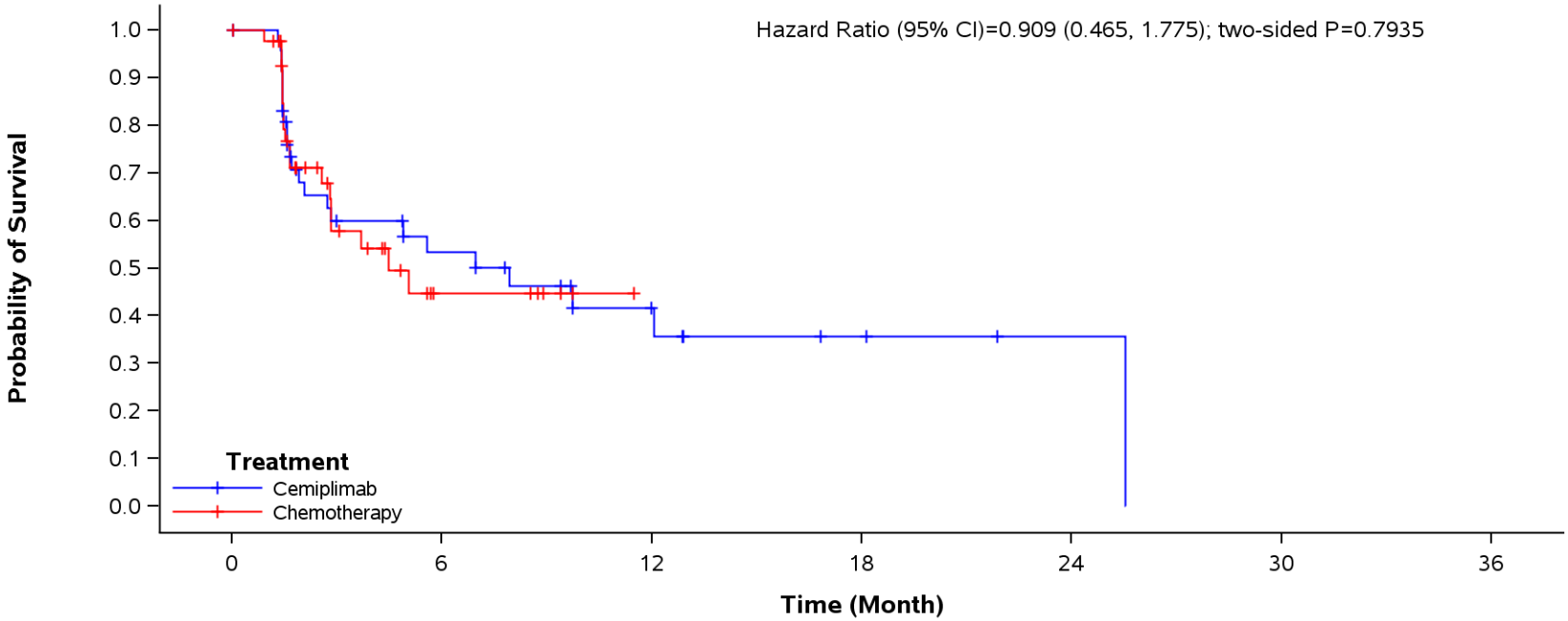

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 28 | 15 | 5 | 1 | 0 | 0 |
| Chemotherapy | 183 | 23 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts sustained improvement



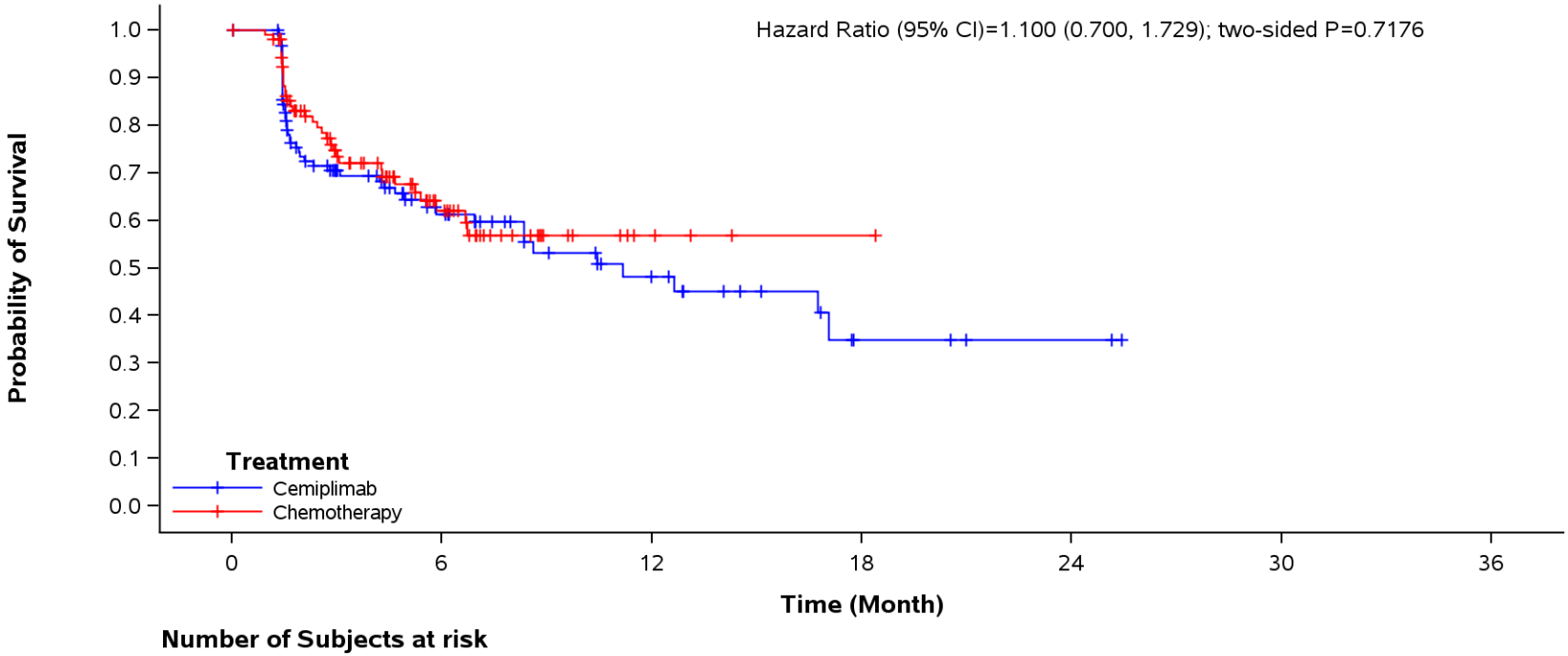

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 16 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 183 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts sustained improvement



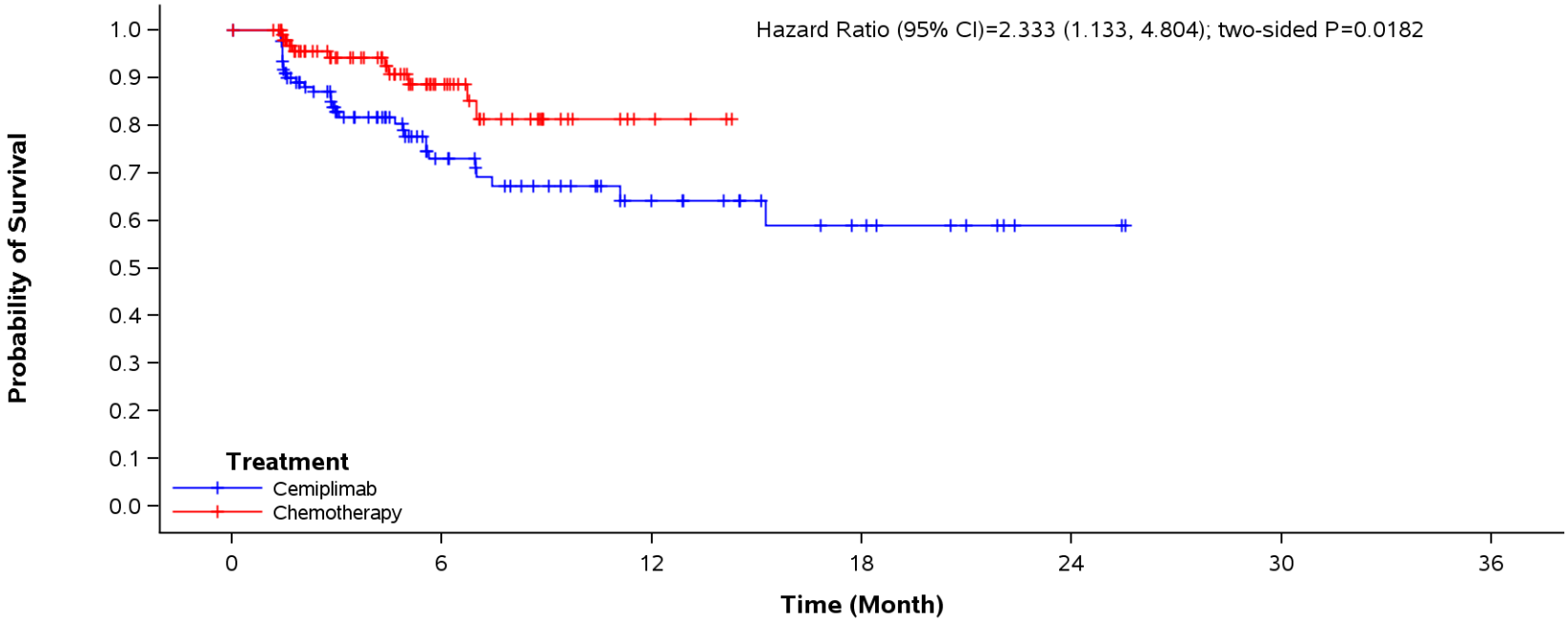

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 40 | 17 | 4 | 2 | 0 | 0 |
| Chemotherapy | 183 | 30 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts sustained improvement



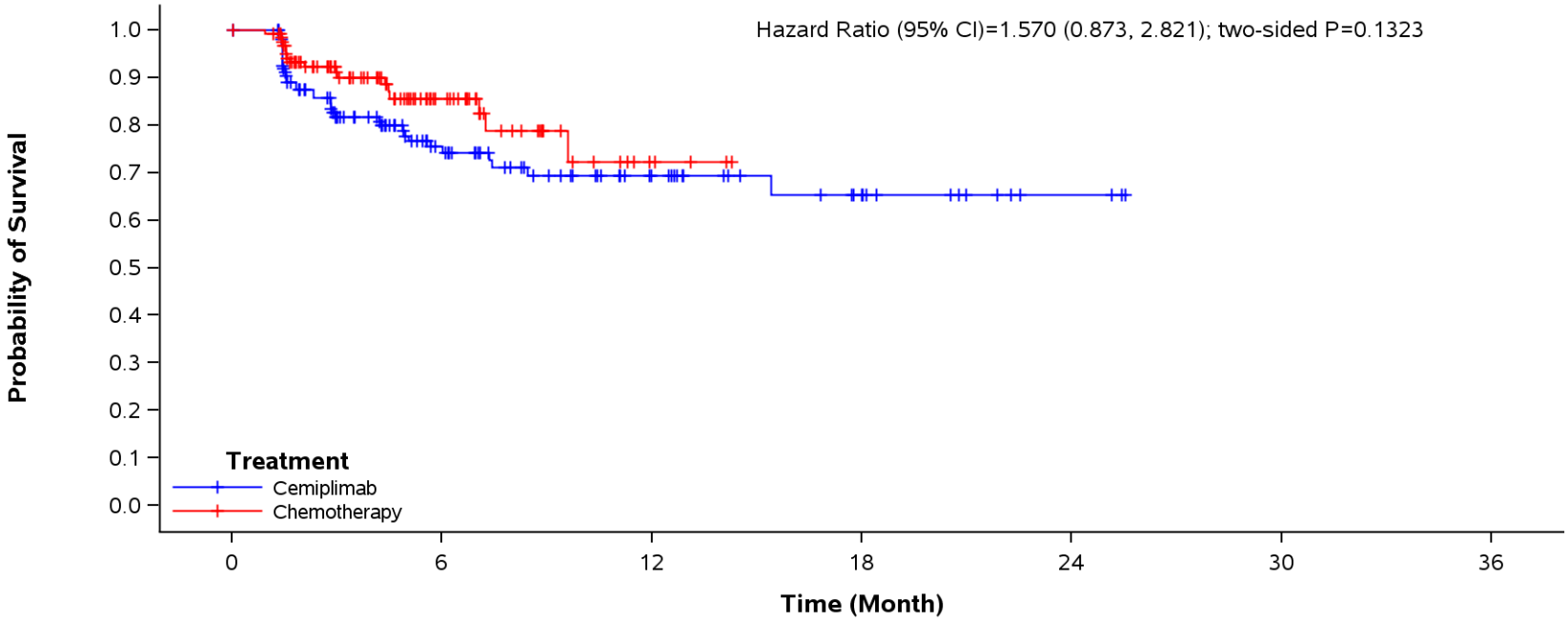

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 43 | 18 | 9 | 2 | 0 | 0 |
| Chemotherapy | 183 | 32 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts sustained improvement




**Number of Subjects at risk**

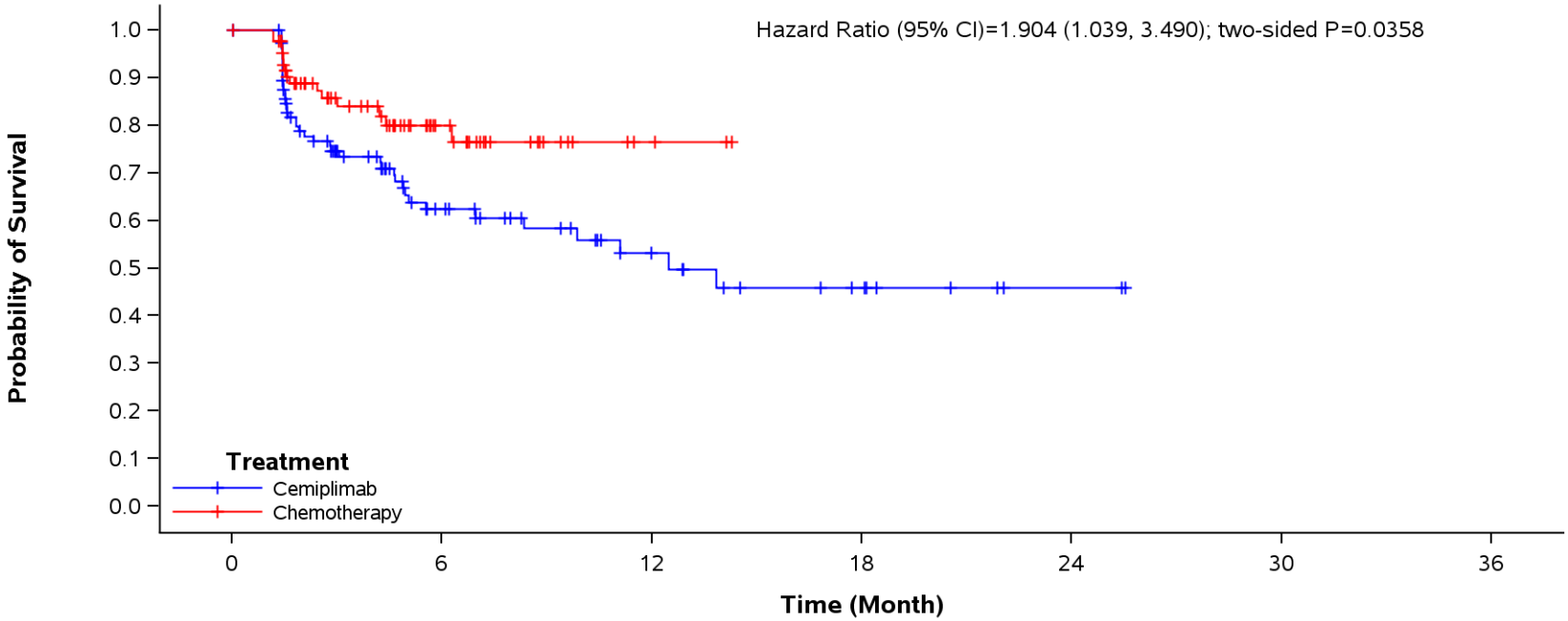
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 60 | 26 | 13 | 3 | 0 | 0 |
| Chemotherapy | 183 | 38 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts sustained improvement



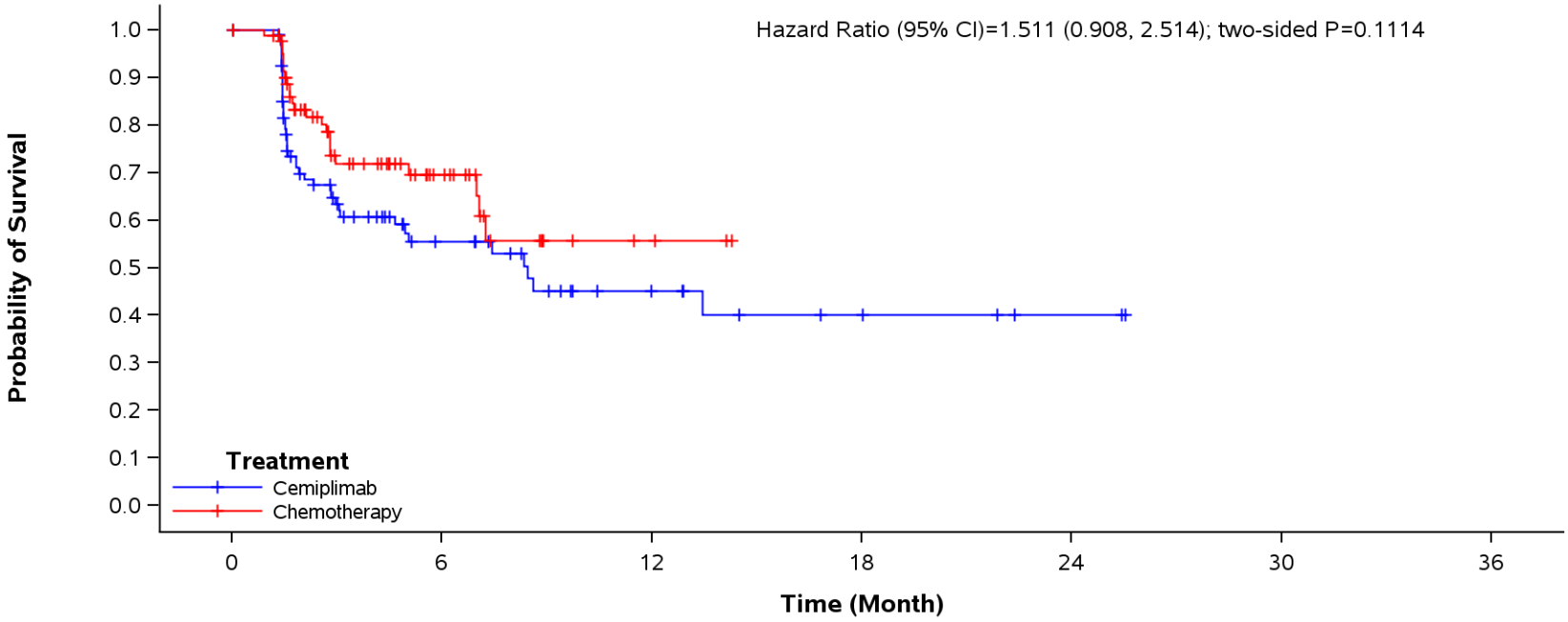

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 38 | 16 | 8 | 2 | 0 | 0 |
| Chemotherapy | 183 | 24 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts sustained improvement



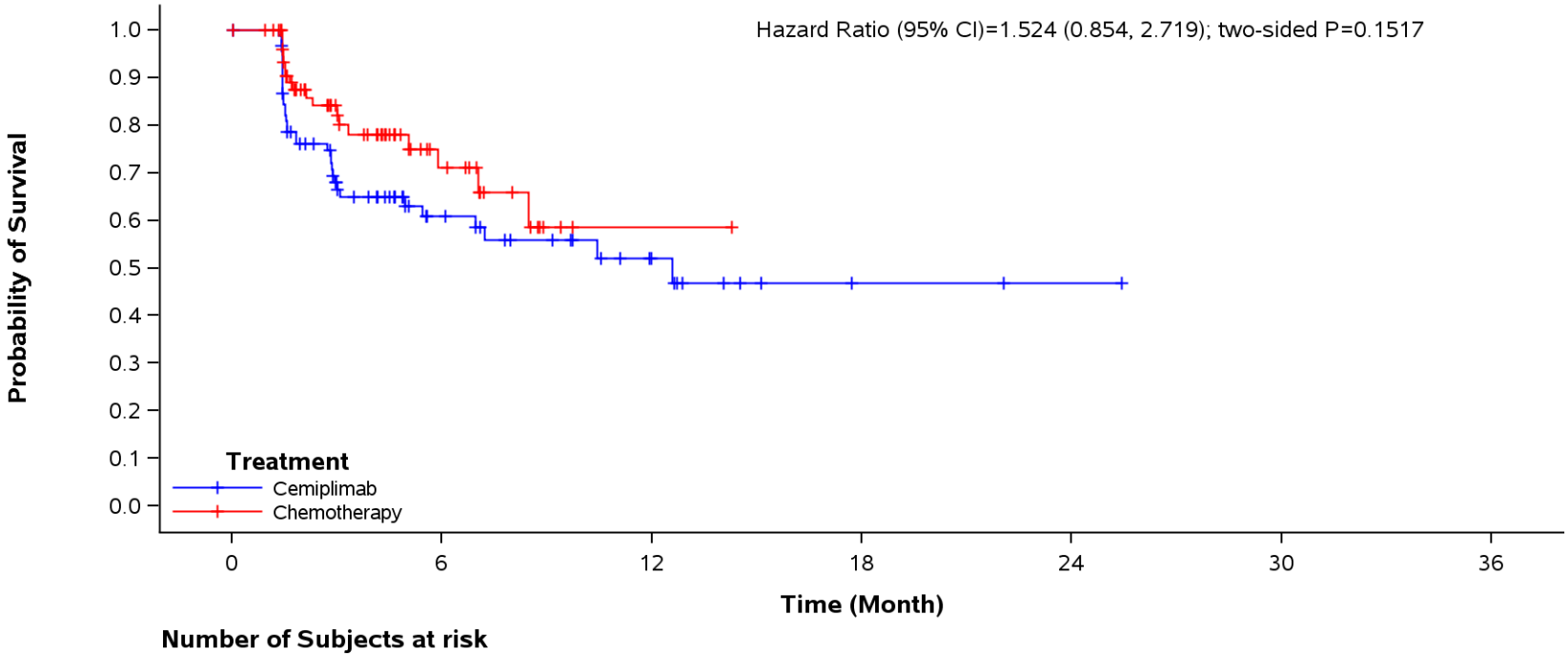

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 28 | 11 | 5 | 2 | 0 | 0 |
| Chemotherapy | 183 | 22 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.6a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts sustained improvement



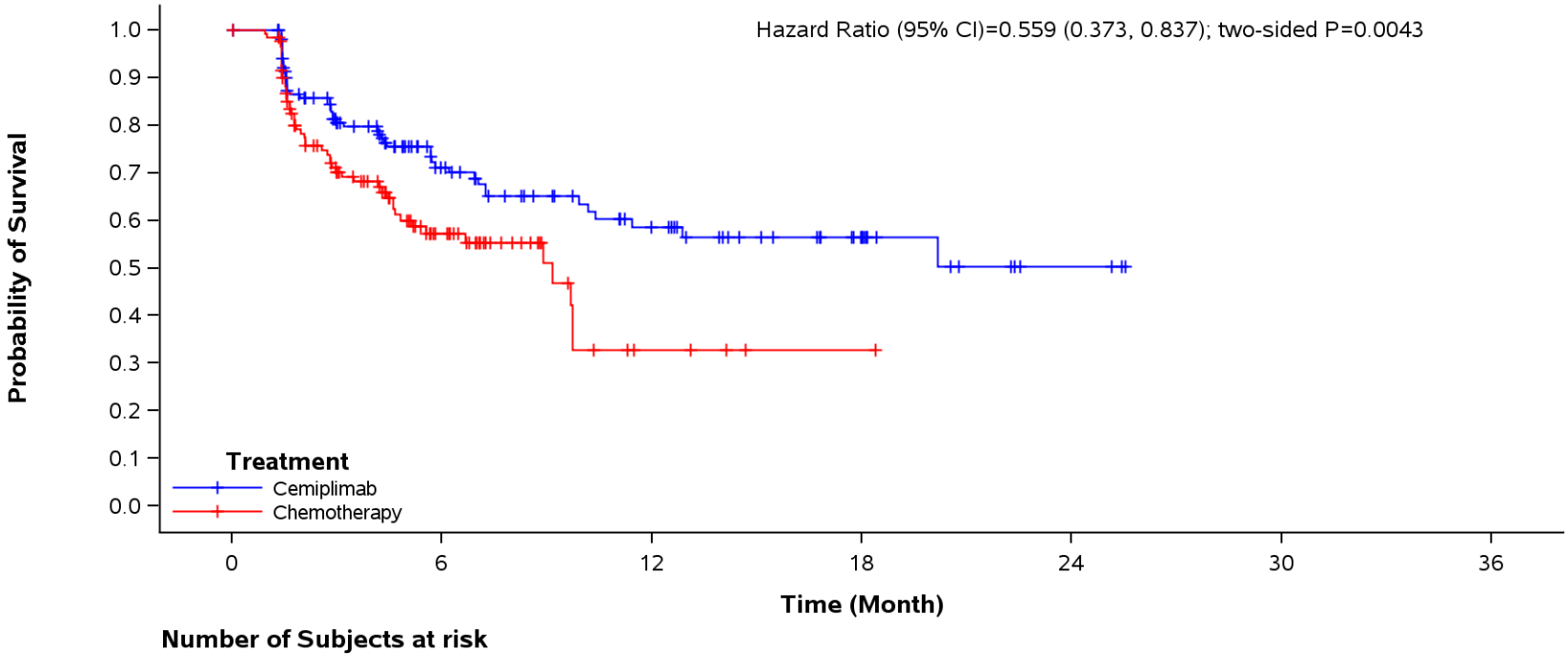

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 27 | 10 | 2 | 1 | 0 | 0 |
| Chemotherapy | 183 | 18 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts sustained deterioration



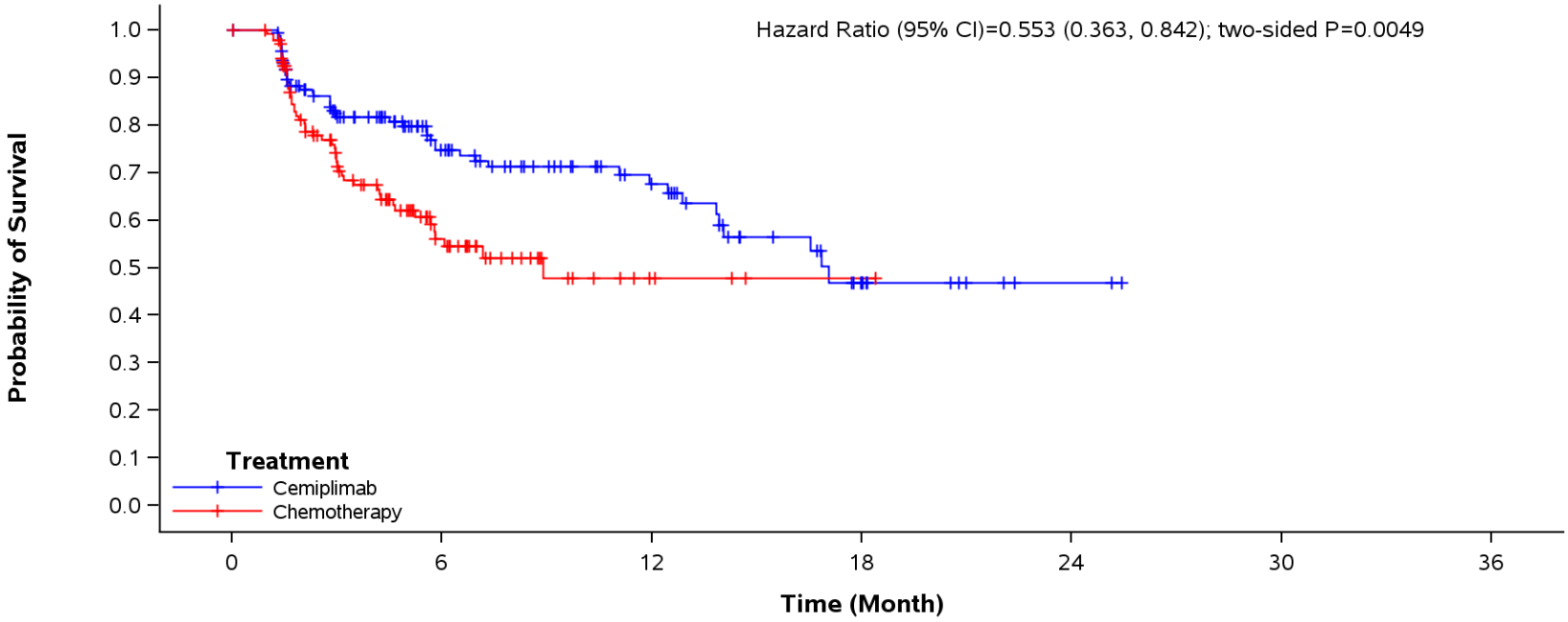

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 64 | 33 | 15 | 3 | 0 | 0 |
| Chemotherapy | 183 | 36 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts sustained deterioration




**Number of Subjects at risk**

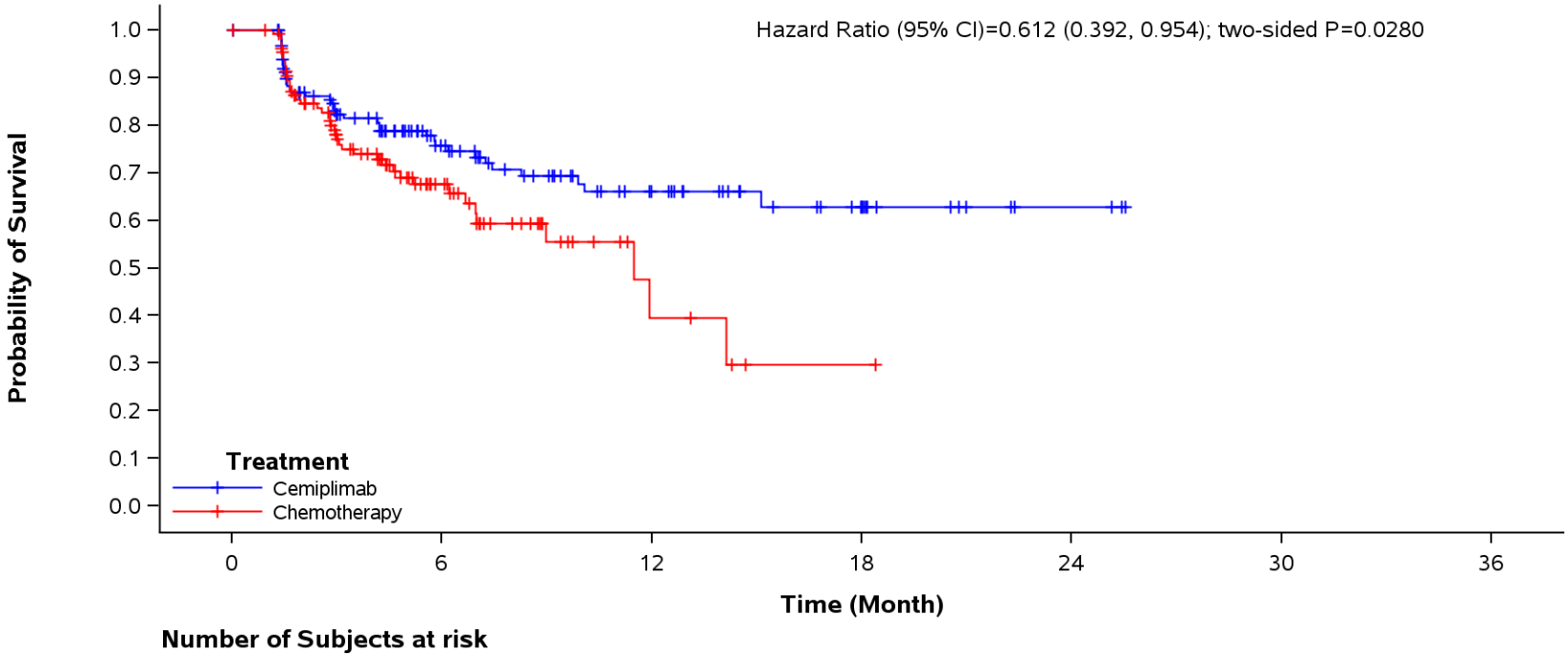
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 71 | 35 | 11 | 2 | 0 | 0 |
| Chemotherapy | 183 | 35 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts sustained deterioration



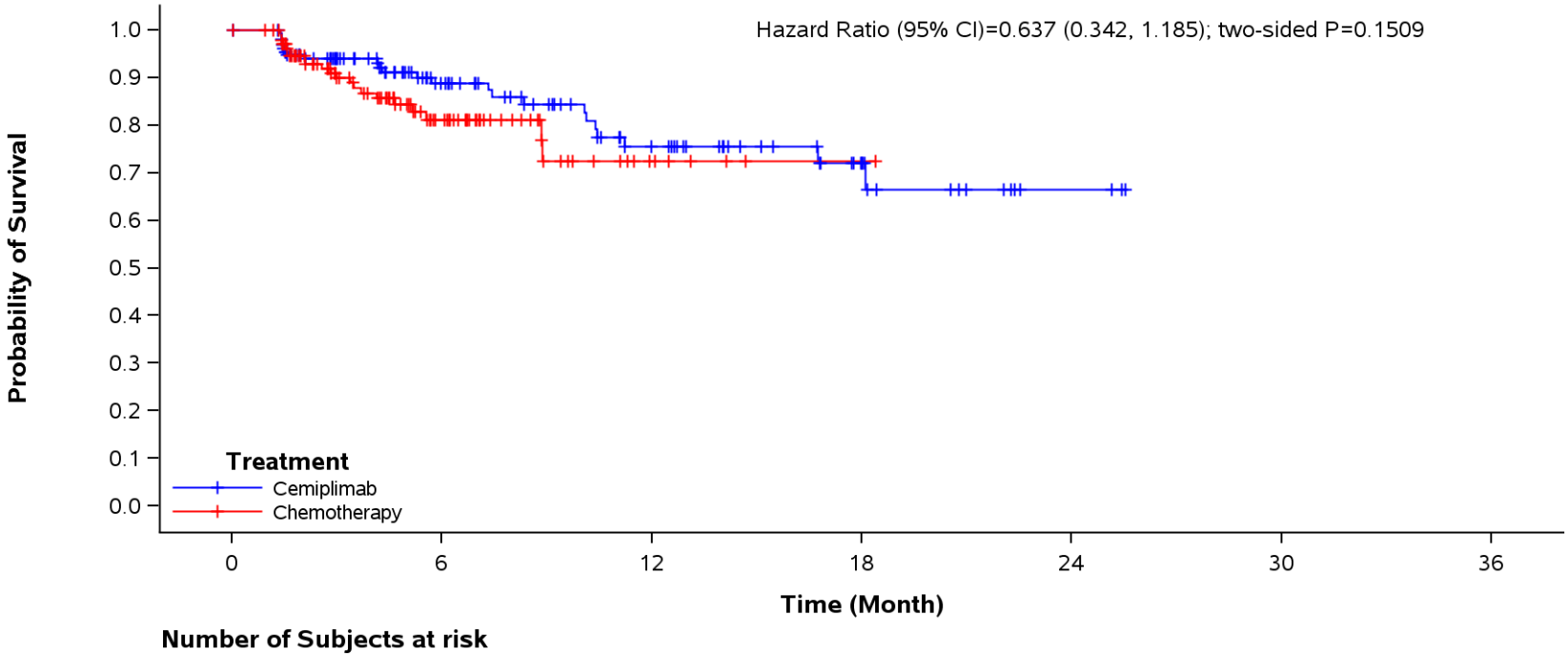

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 67 | 31 | 14 | 3 | 0 | 0 |
| Chemotherapy | 183 | 39 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts sustained deterioration




**Number of Subjects at risk**

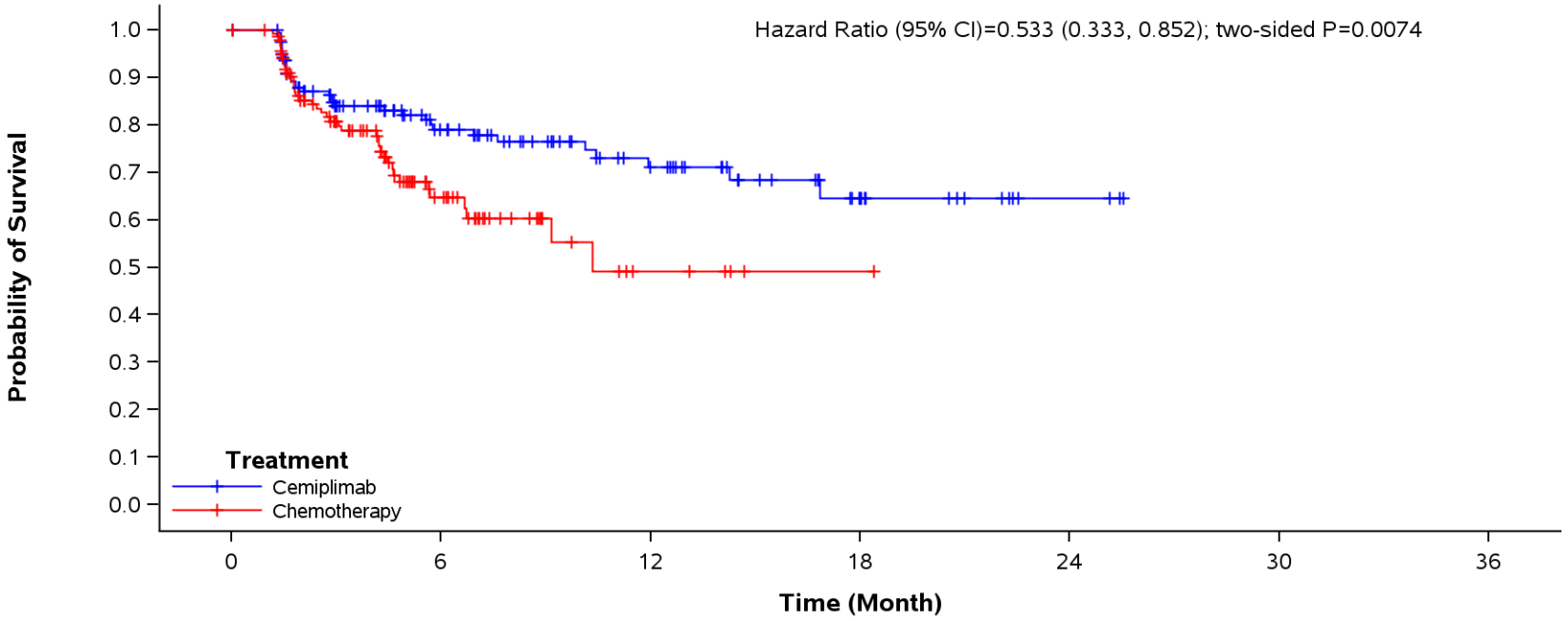
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 73 | 36 | 16 | 3 | 0 | 0 |
| Chemotherapy | 183 | 44 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts sustained deterioration



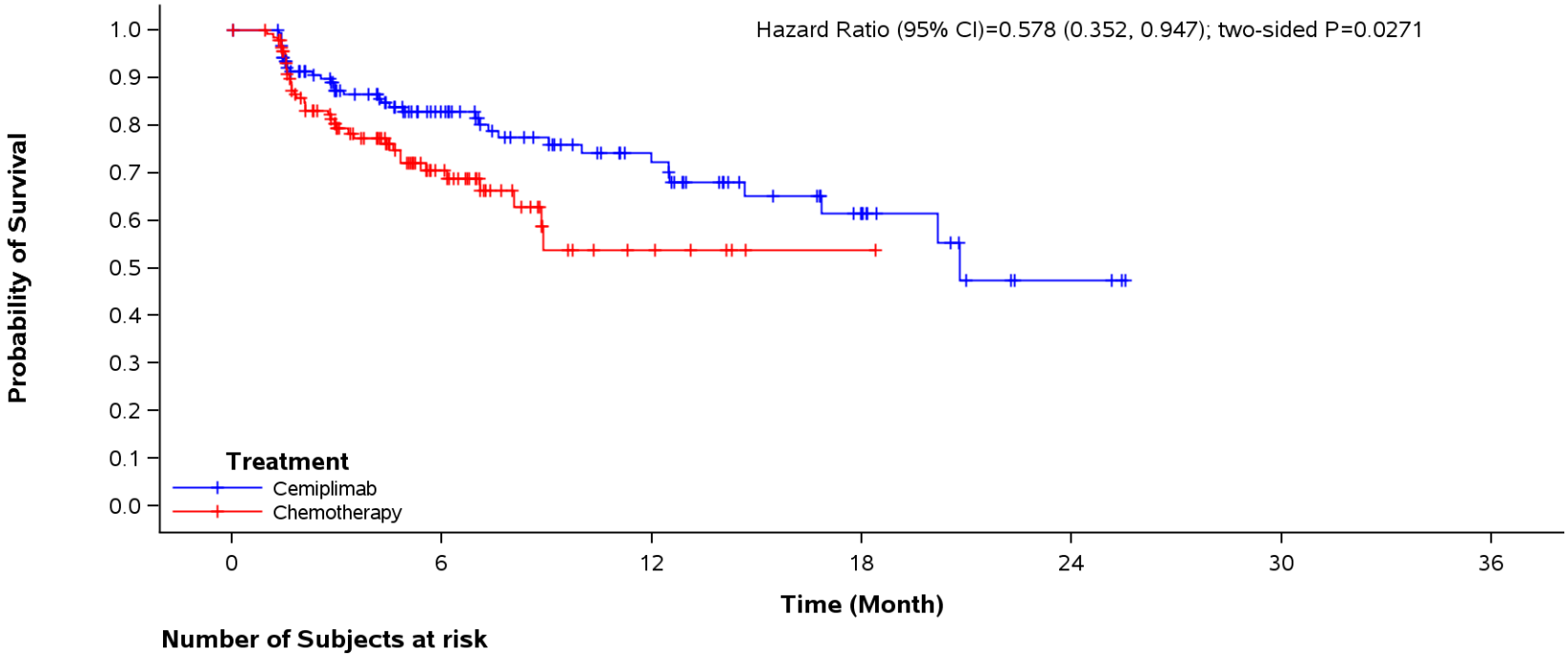

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 71 | 35 | 14 | 3 | 0 | 0 |
| Chemotherapy | 183 | 36 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts sustained deterioration




**Number of Subjects at risk**

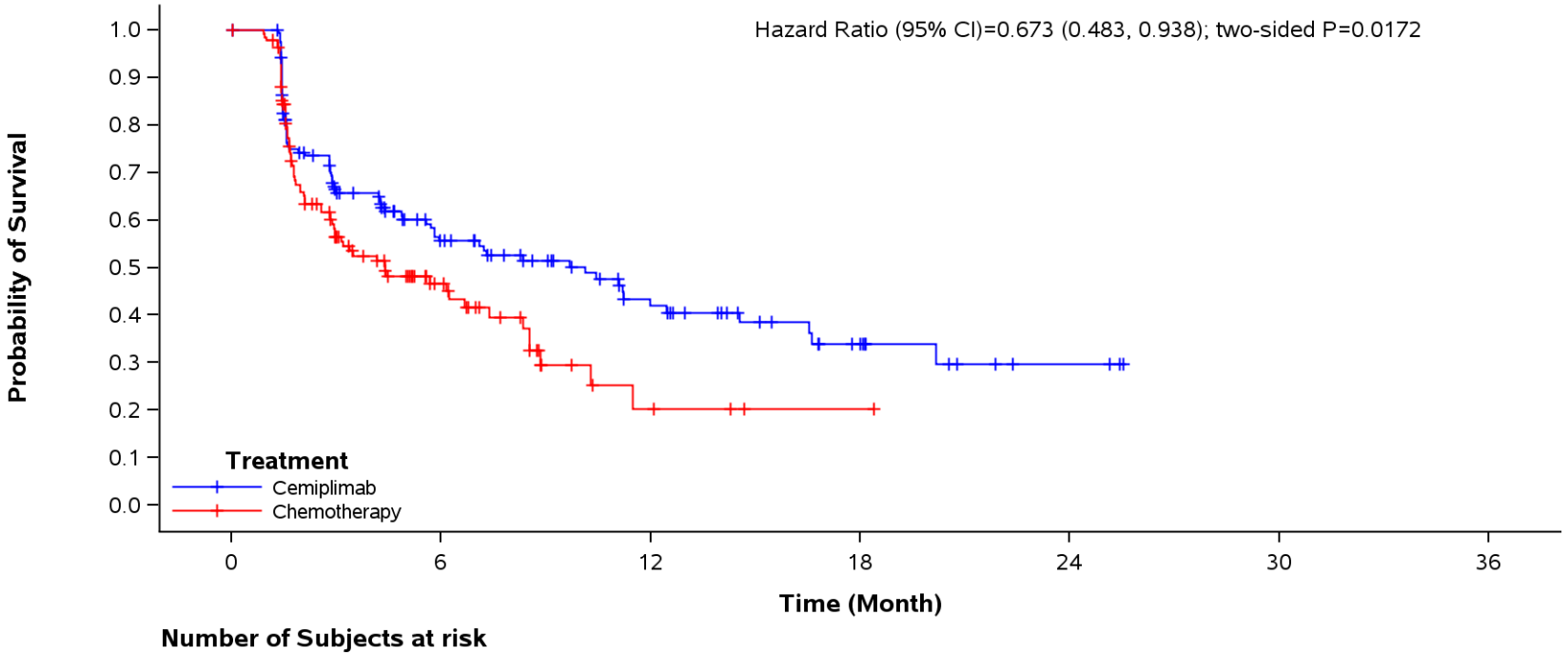
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 73 | 36 | 15 | 3 | 0 | 0 |
| Chemotherapy | 183 | 40 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts sustained deterioration



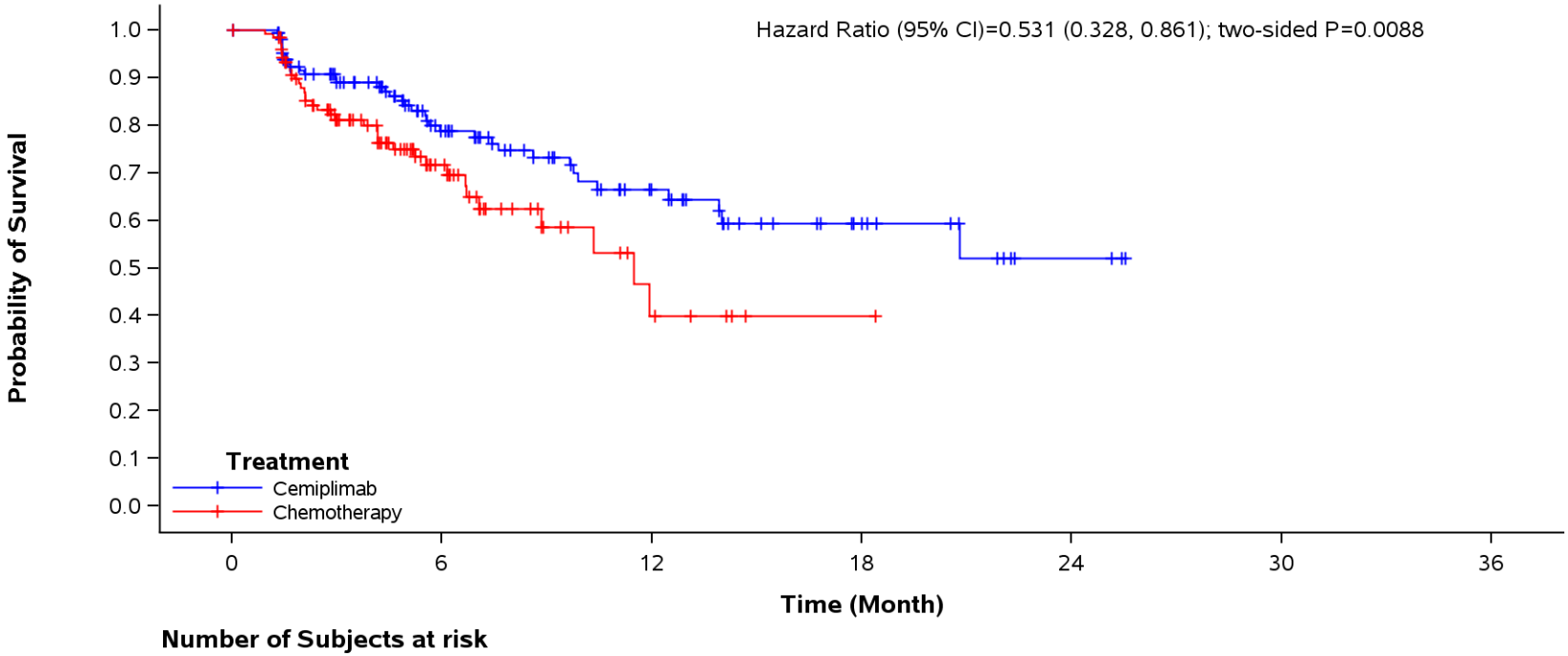

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 61 | 29 | 12 | 3 | 0 | 0 |
| Chemotherapy | 183 | 29 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts sustained deterioration



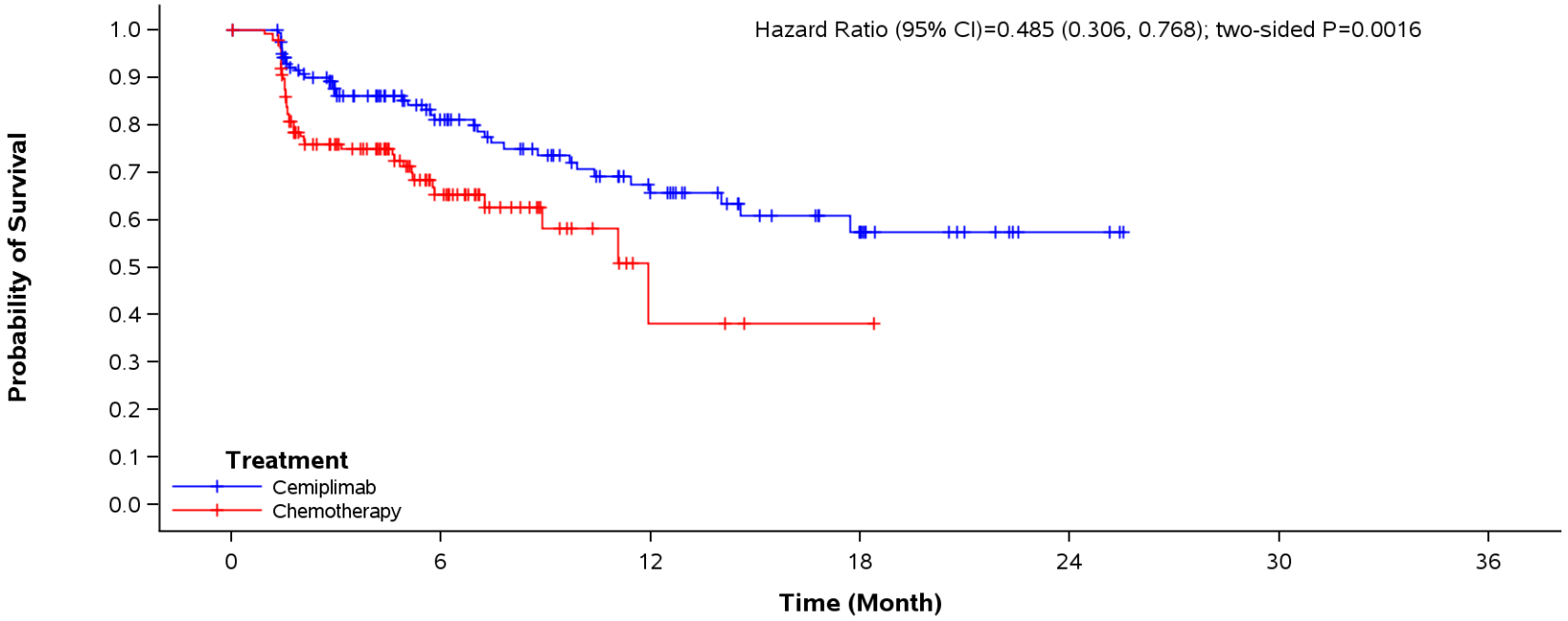

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 68 | 32 | 13 | 3 | 0 | 0 |
| Chemotherapy | 183 | 37 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts sustained deterioration



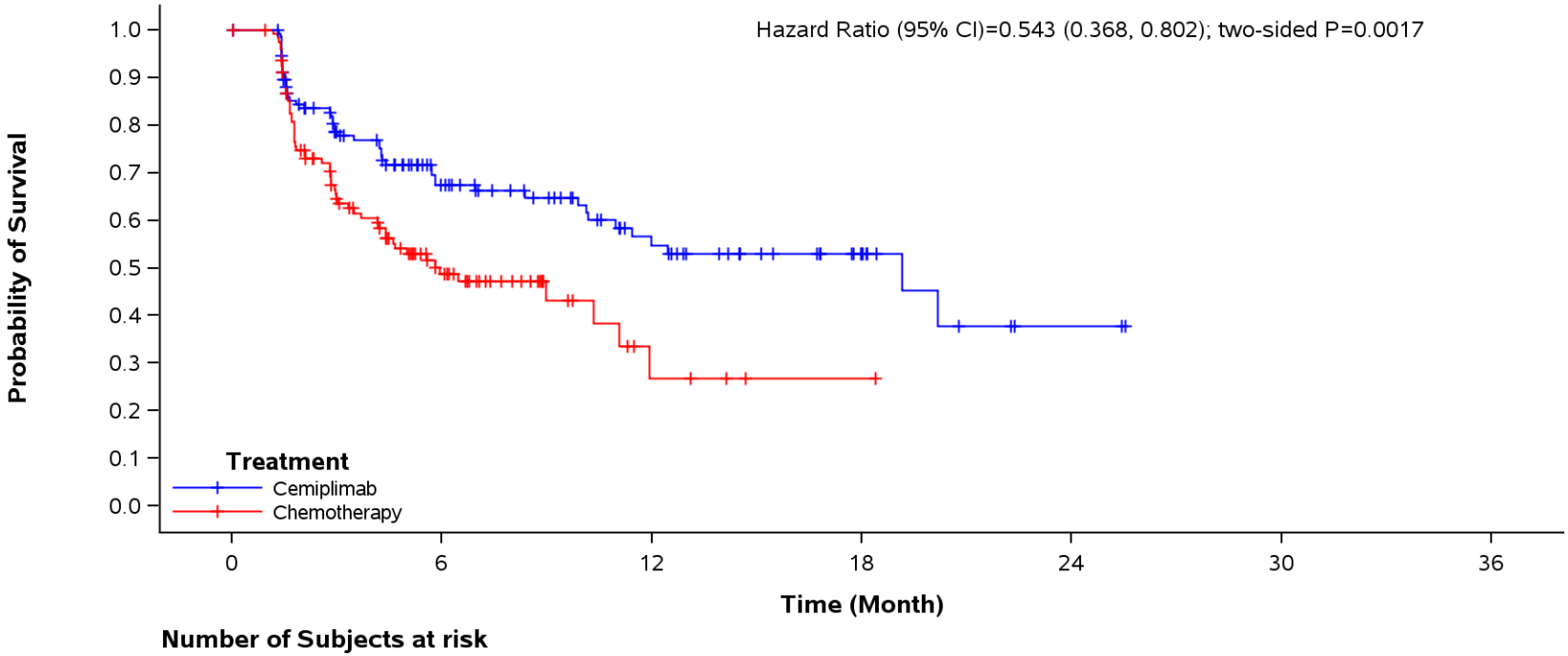

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 76 | 36 | 16 | 3 | 0 | 0 |
| Chemotherapy | 183 | 39 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts sustained deterioration



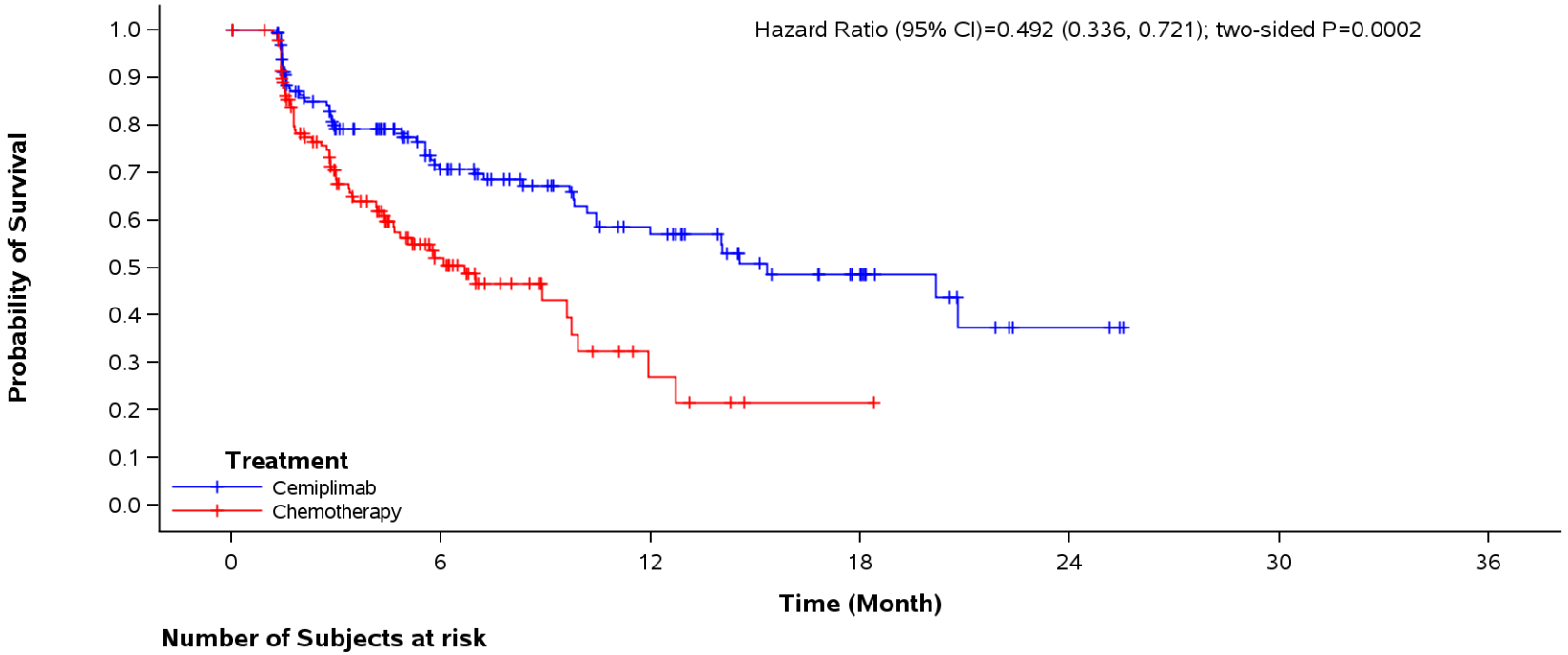

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 62 | 30 | 12 | 2 | 0 | 0 |
| Chemotherapy | 183 | 34 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts sustained deterioration




**Number of Subjects at risk**

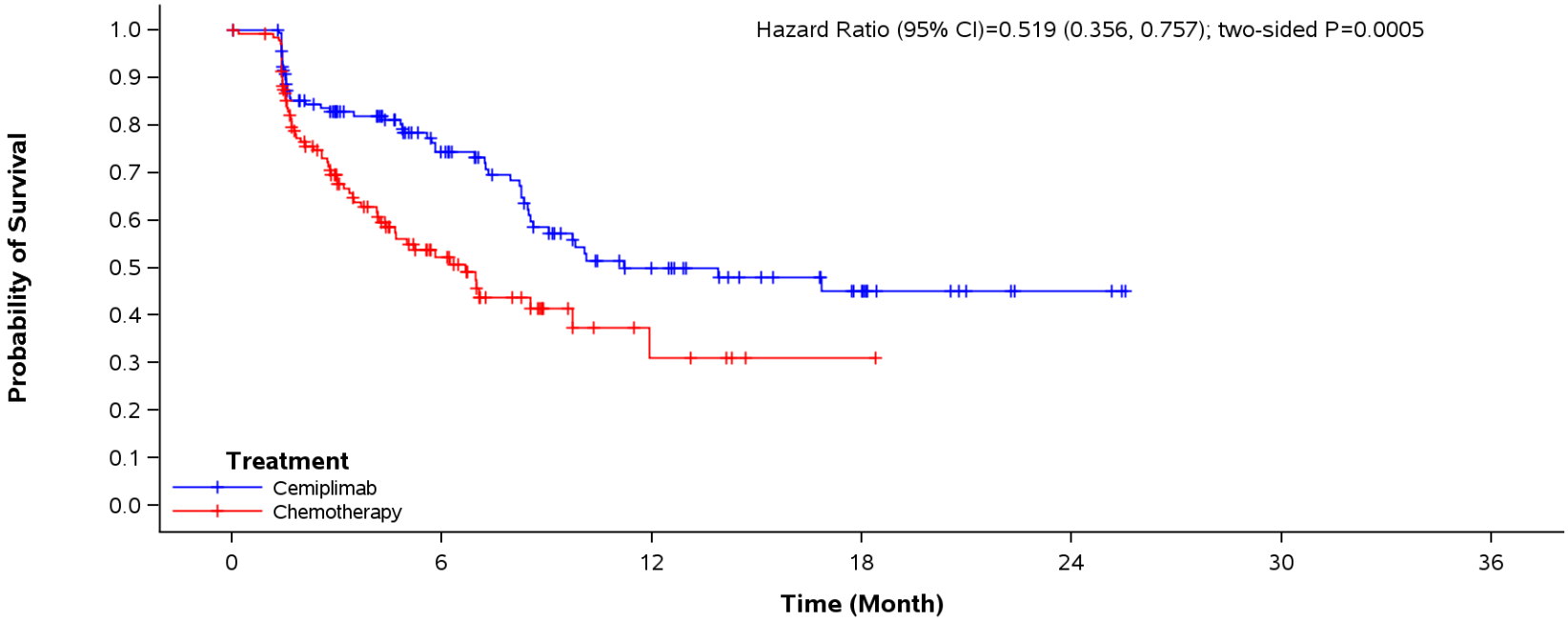
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 71 | 36 | 16 | 3 | 0 | 0 |
| Chemotherapy | 183 | 34 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts sustained deterioration




**Number of Subjects at risk**

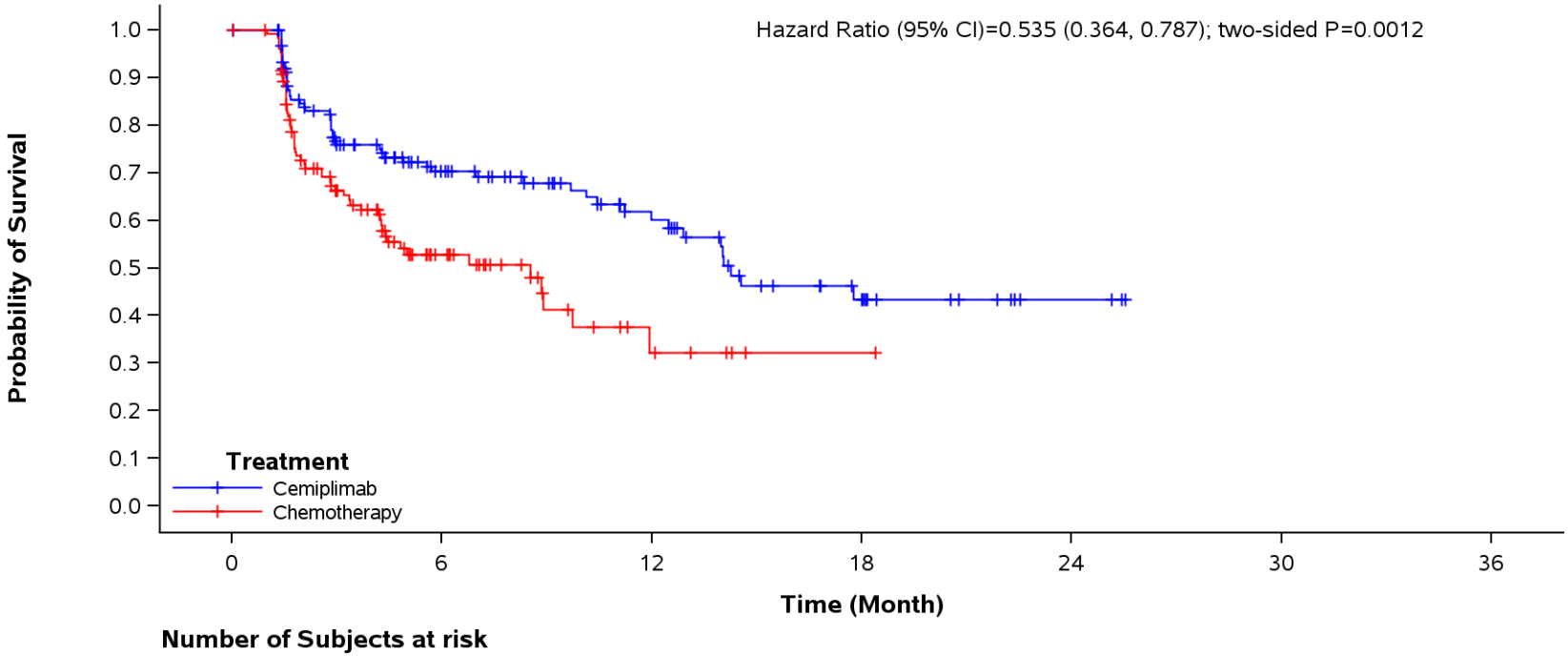
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 72 | 30 | 14 | 3 | 0 | 0 |
| Chemotherapy | 183 | 36 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts sustained deterioration



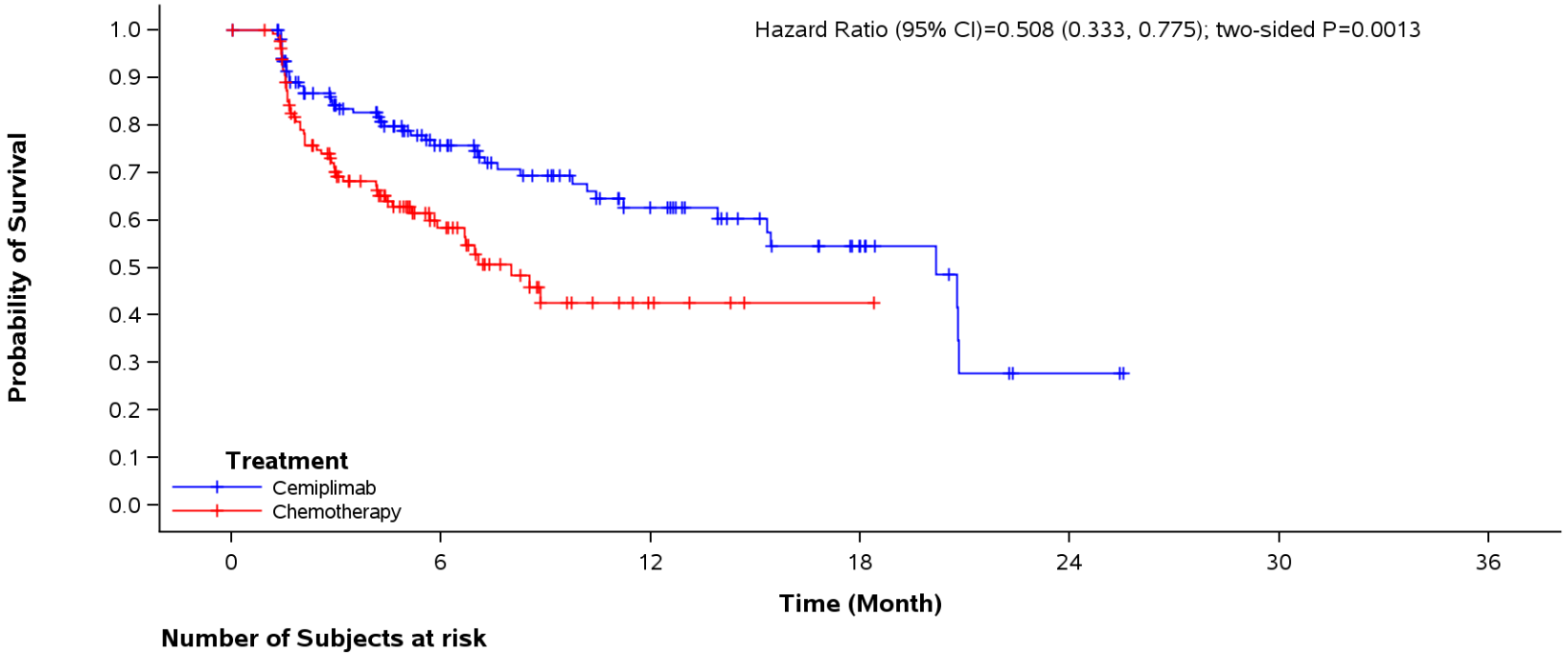

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 66 | 36 | 15 | 3 | 0 | 0 |
| Chemotherapy | 183 | 30 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts sustained deterioration



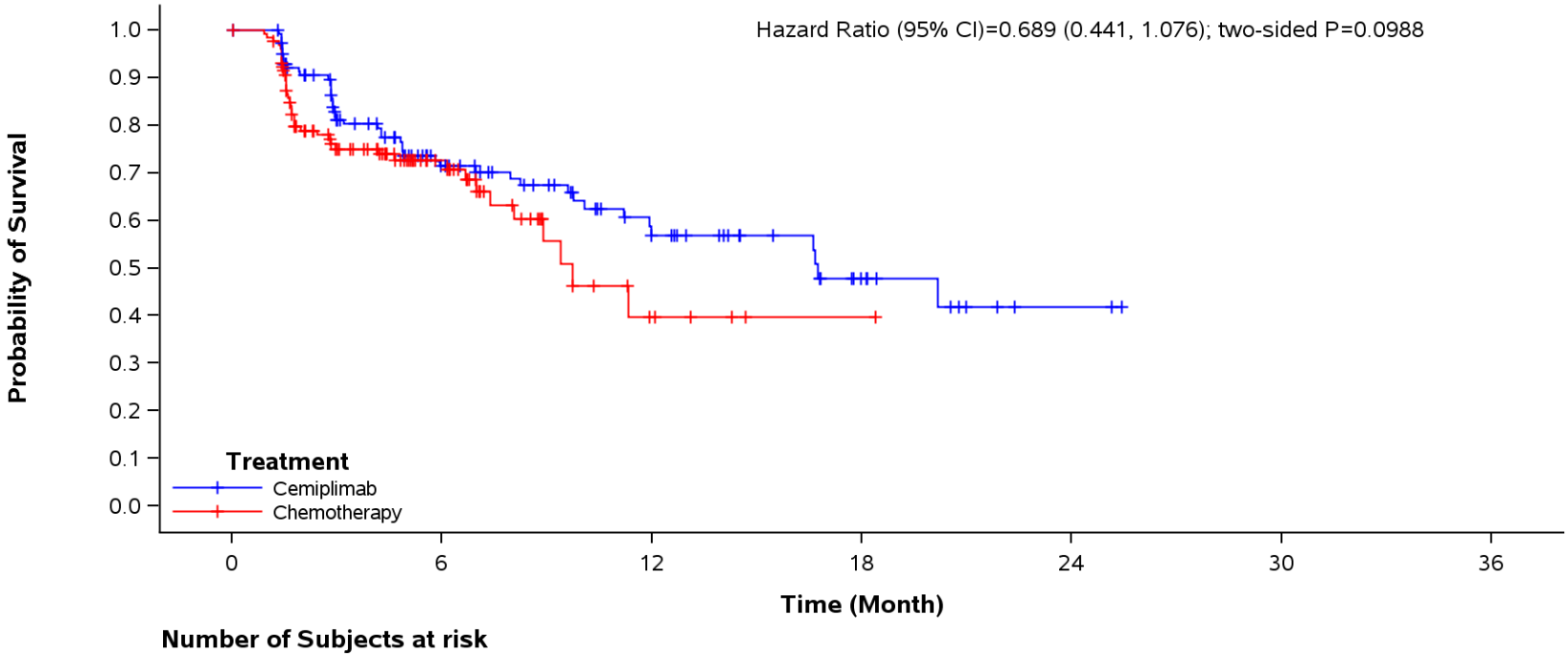

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 68 | 33 | 13 | 2 | 0 | 0 |
| Chemotherapy | 183 | 36 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.7a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts sustained deterioration




**Number of Subjects at risk**

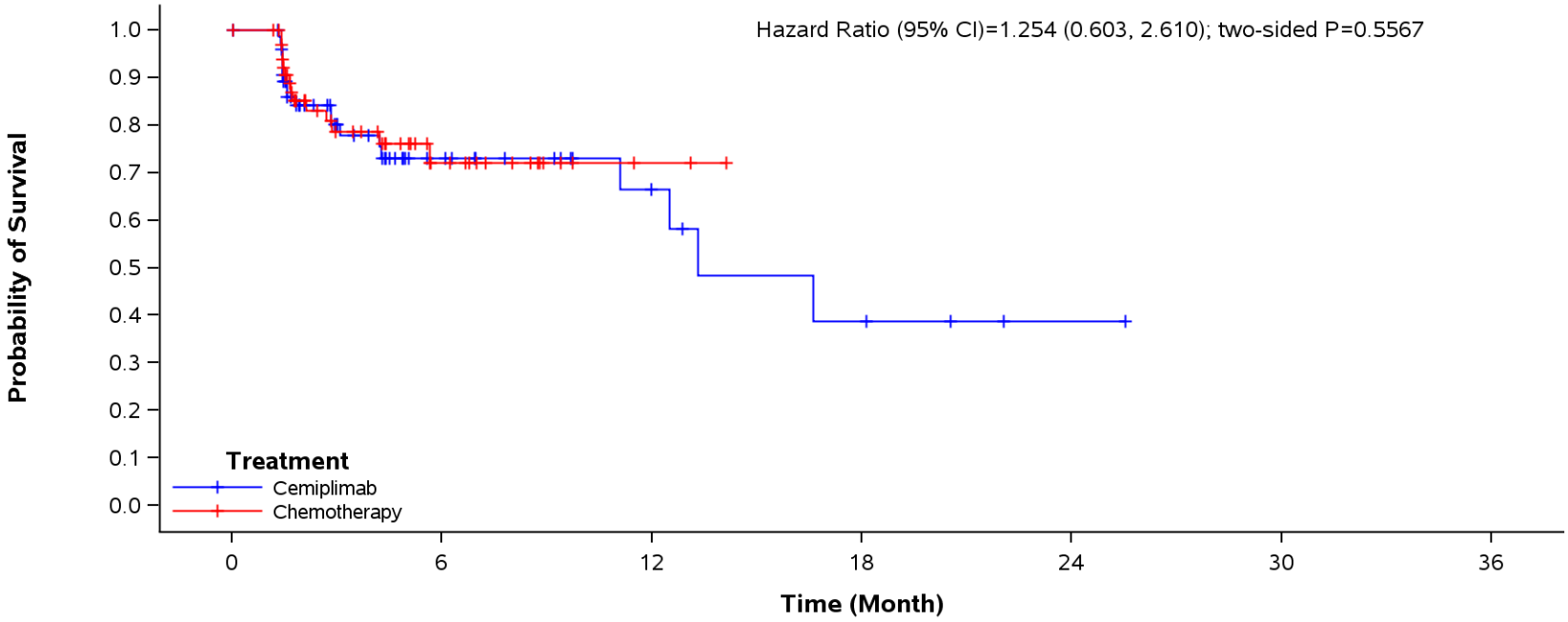
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 63 | 29 | 11 | 2 | 0 | 0 |
| Chemotherapy | 183 | 39 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

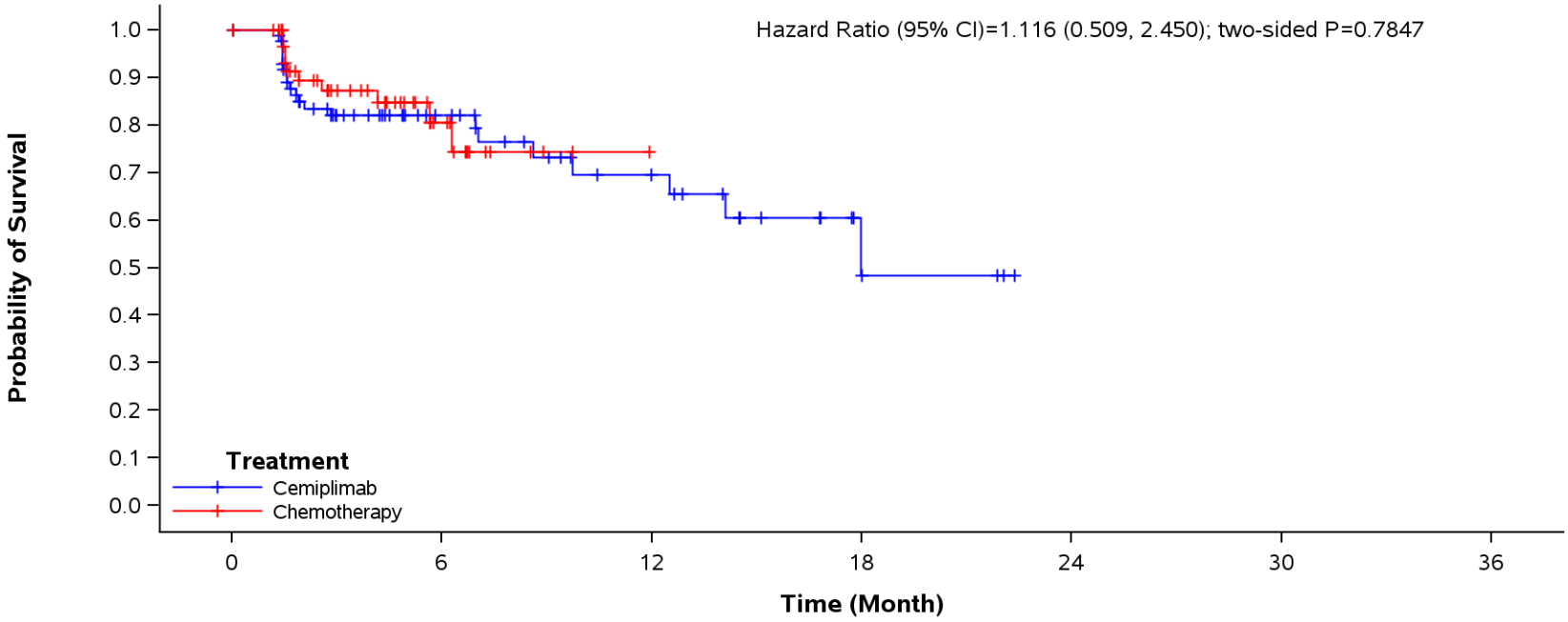
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 20 | 8 | 4 | 1 | 0 | 0 |
| Chemotherapy | 183 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

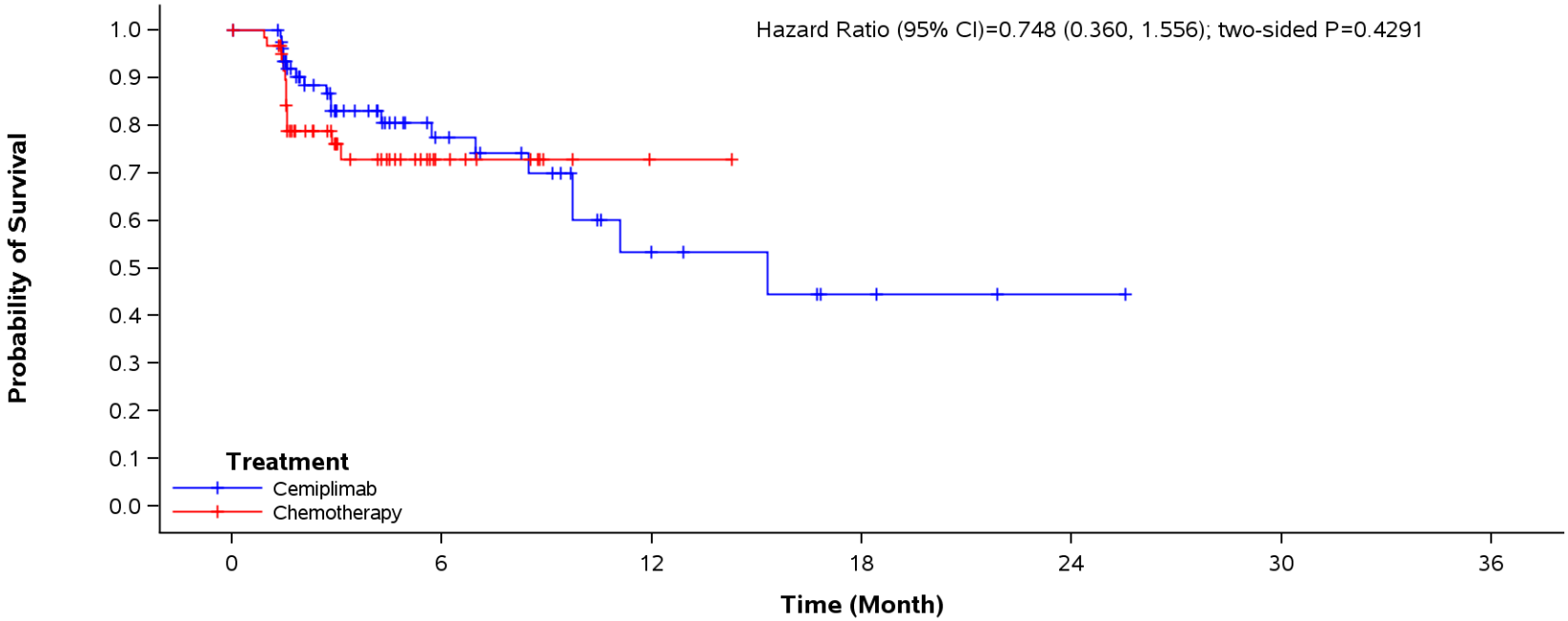
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 34 | 17 | 4 | 0 | 0 | 0 |
| Chemotherapy | 183 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

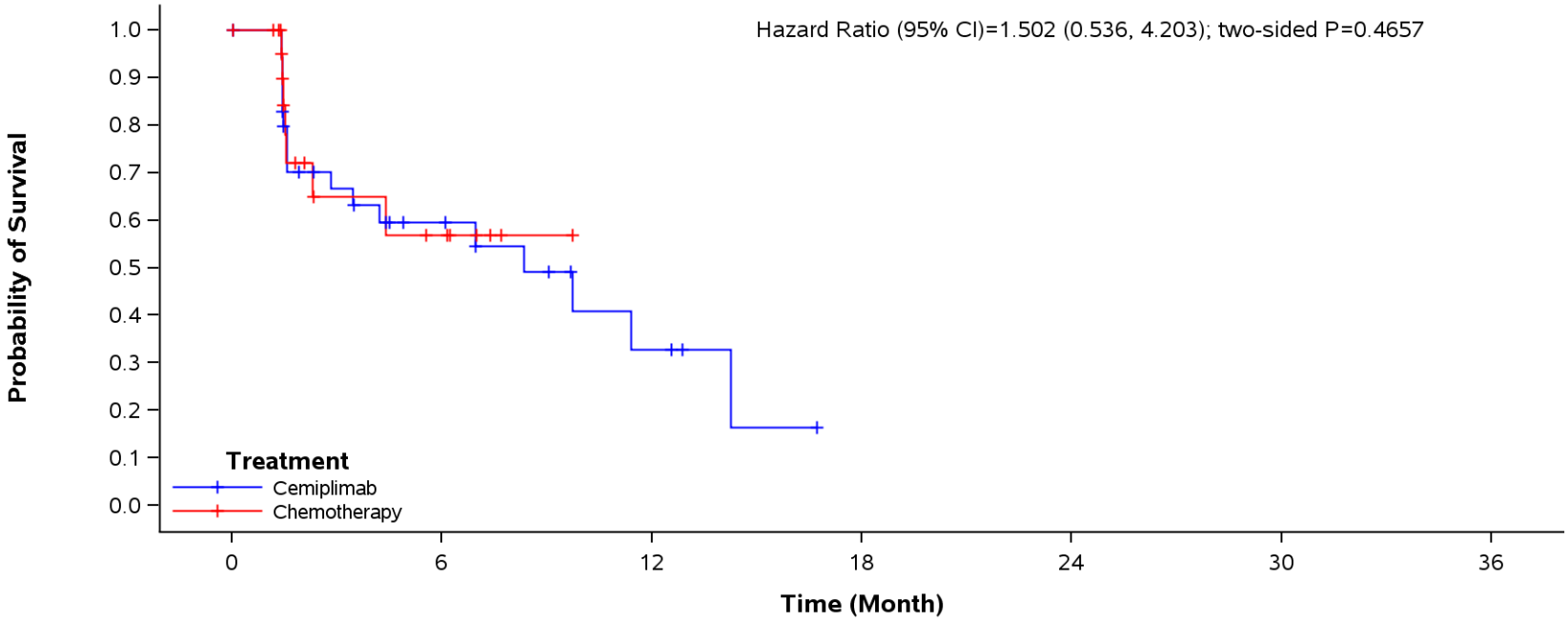
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 24 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 183 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

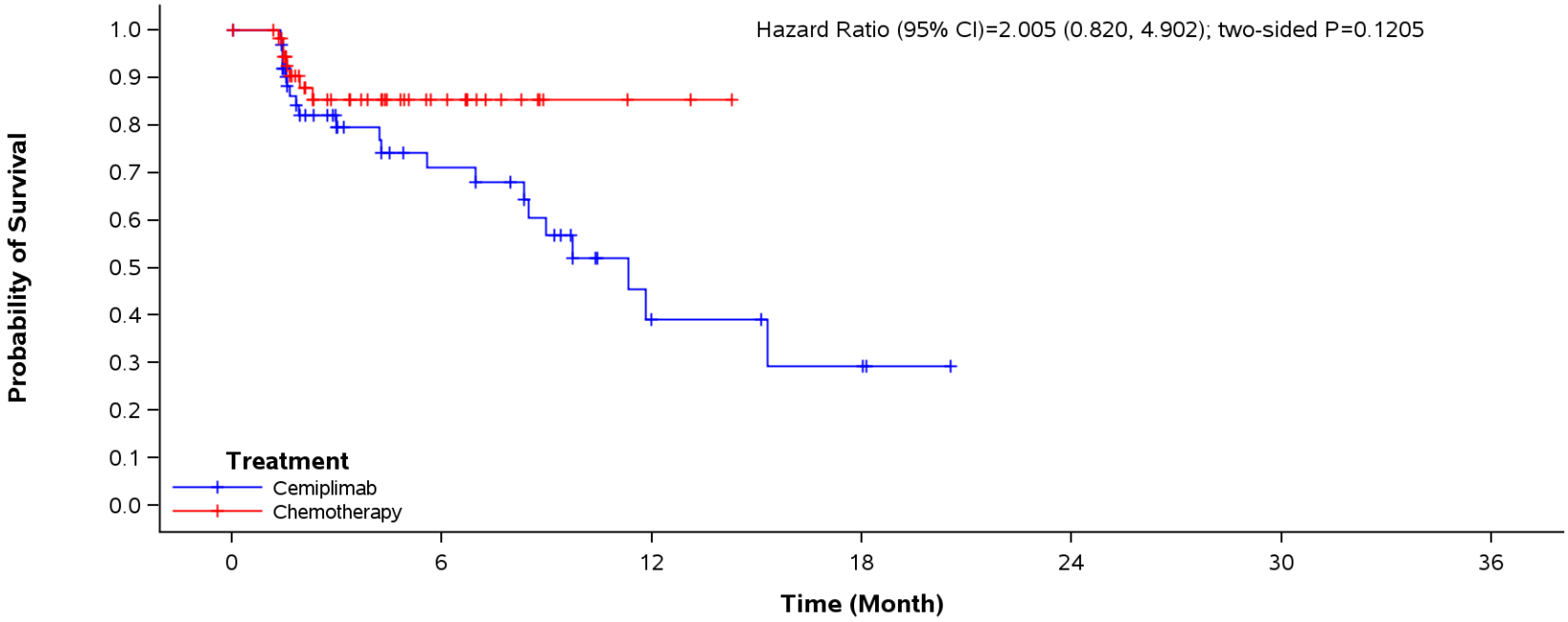
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 13 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 183 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts sensitivity sustained improvement



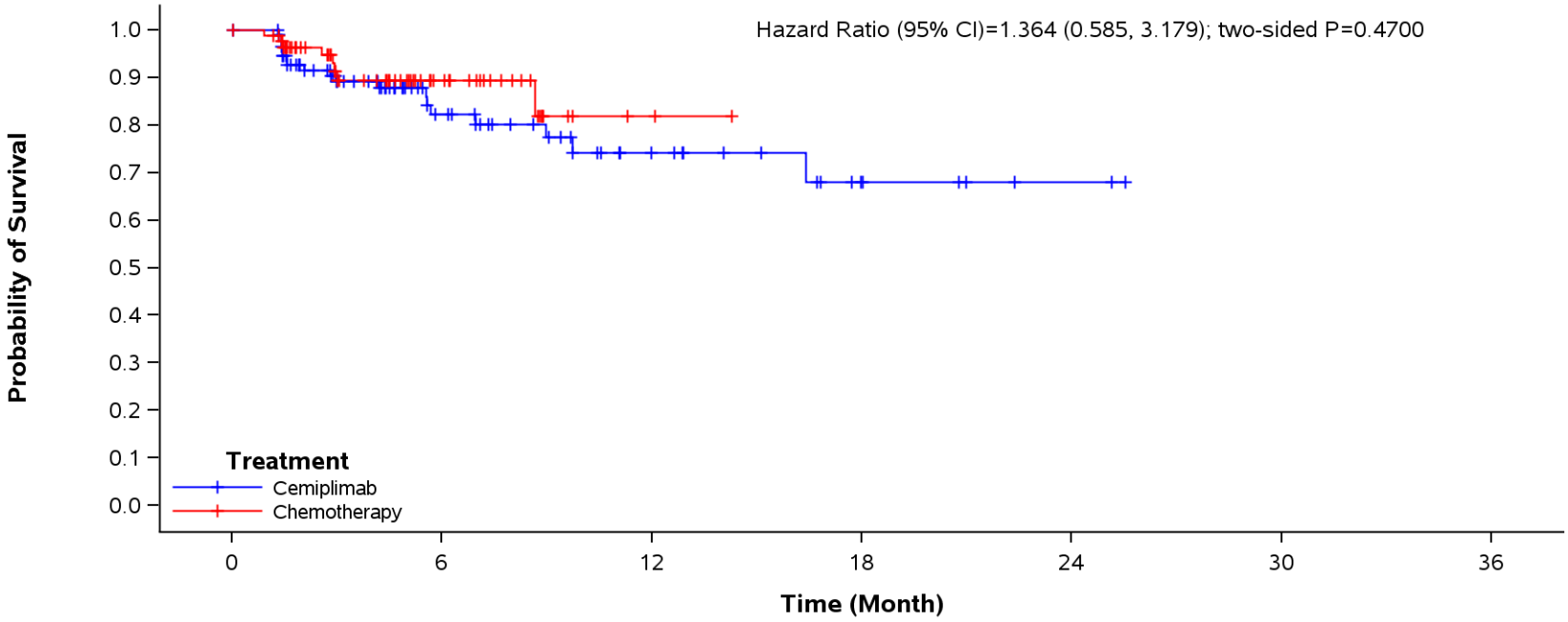

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 23 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 183 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

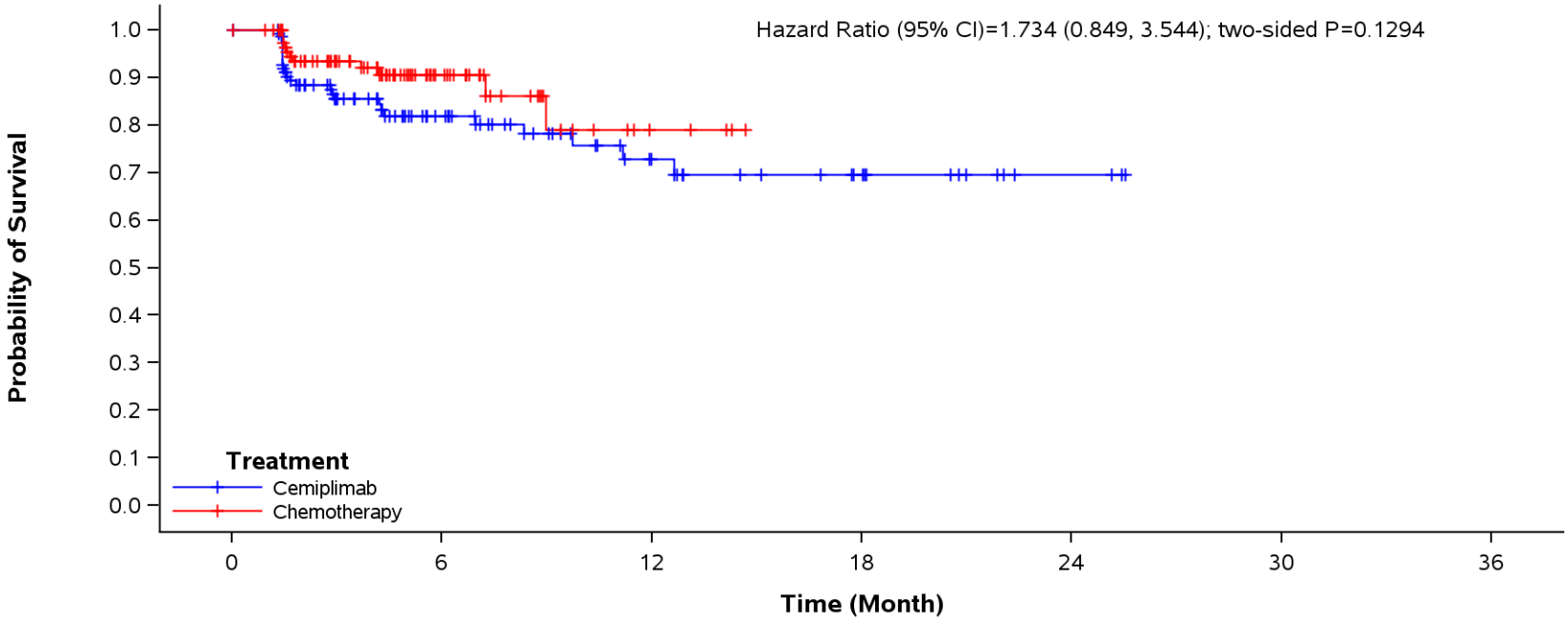
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 43 | 17 | 6 | 2 | 0 | 0 |
| Chemotherapy | 183 | 24 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts sensitivity sustained improvement



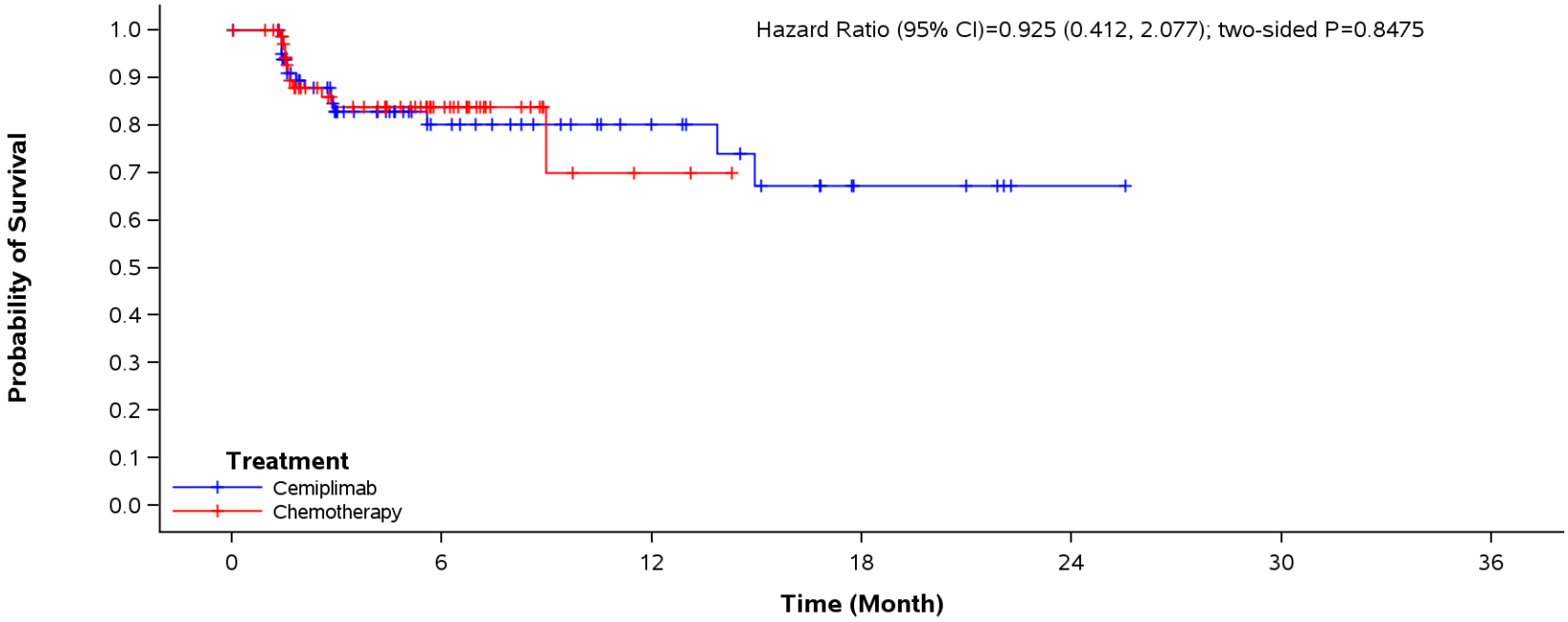

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 52 | 22 | 12 | 3 | 0 | 0 |
| Chemotherapy | 183 | 33 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

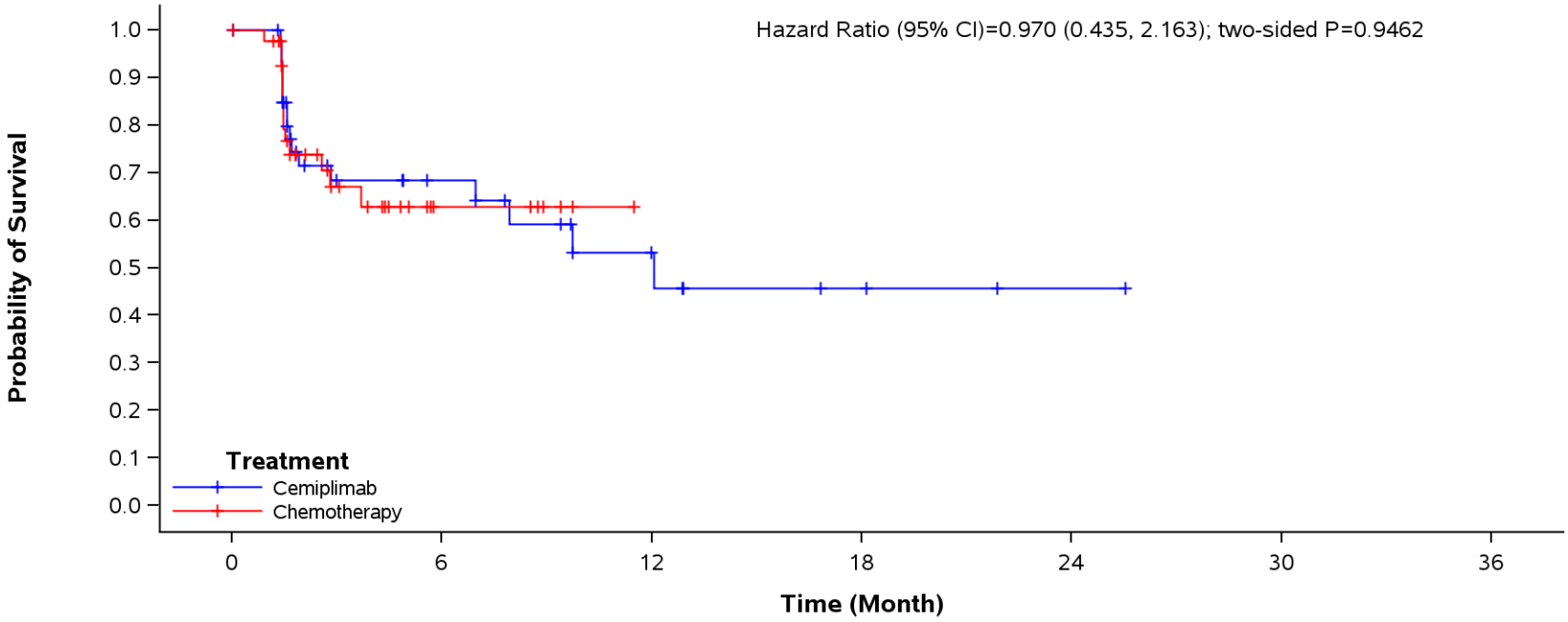
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 28 | 15 | 5 | 1 | 0 | 0 |
| Chemotherapy | 183 | 23 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

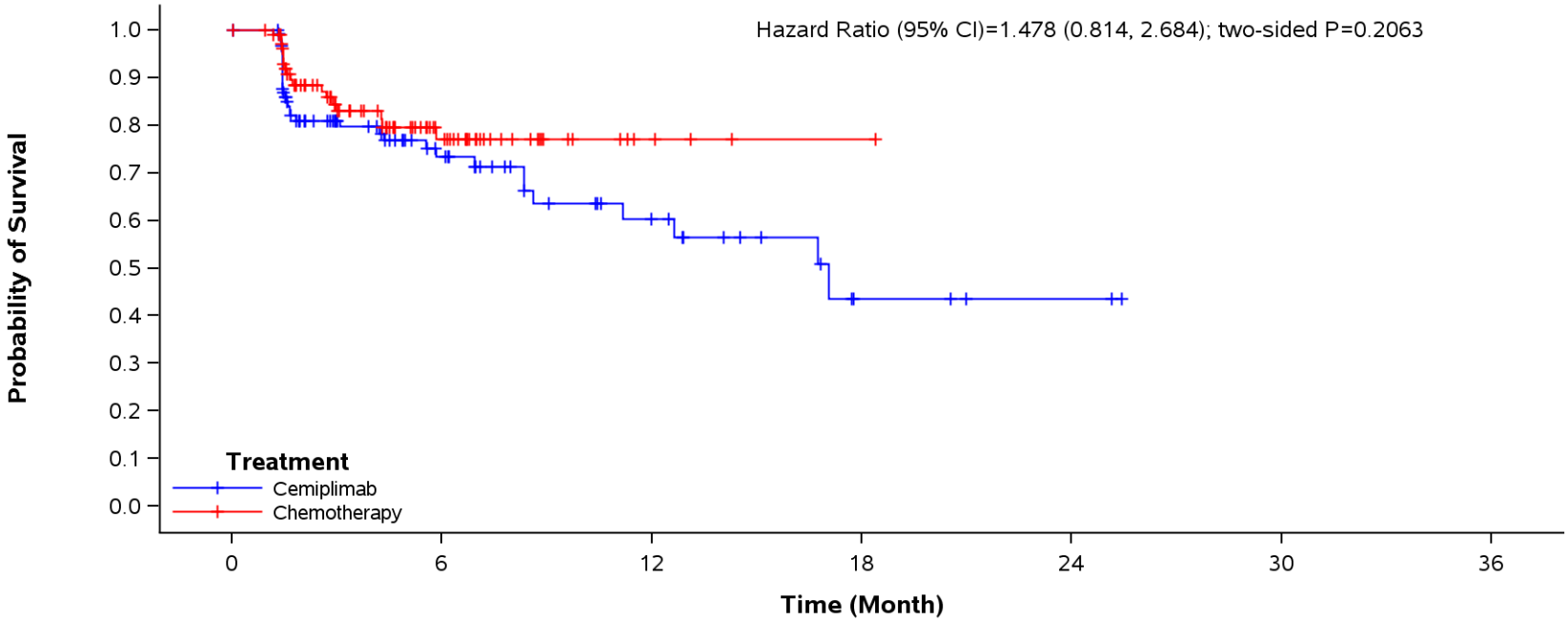
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 16 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 183 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts sensitivity sustained improvement



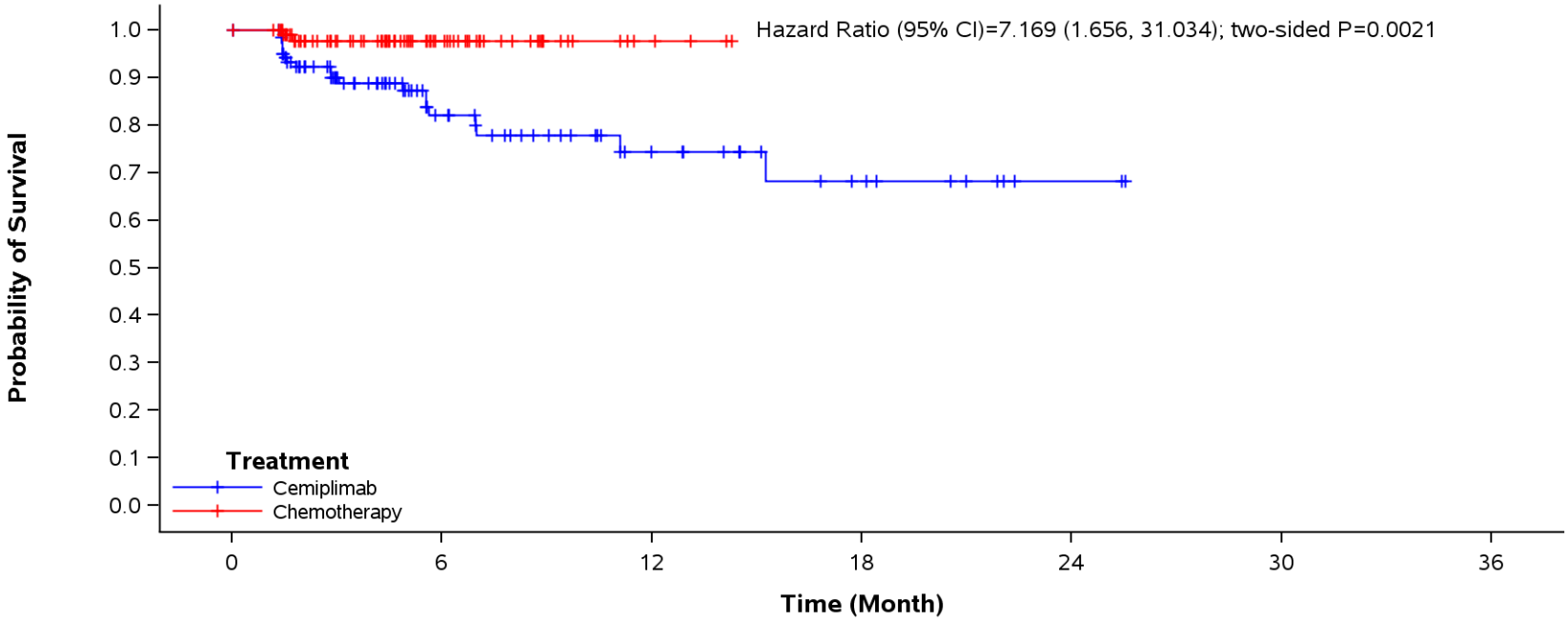

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 40 | 17 | 4 | 2 | 0 | 0 |
| Chemotherapy | 183 | 30 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

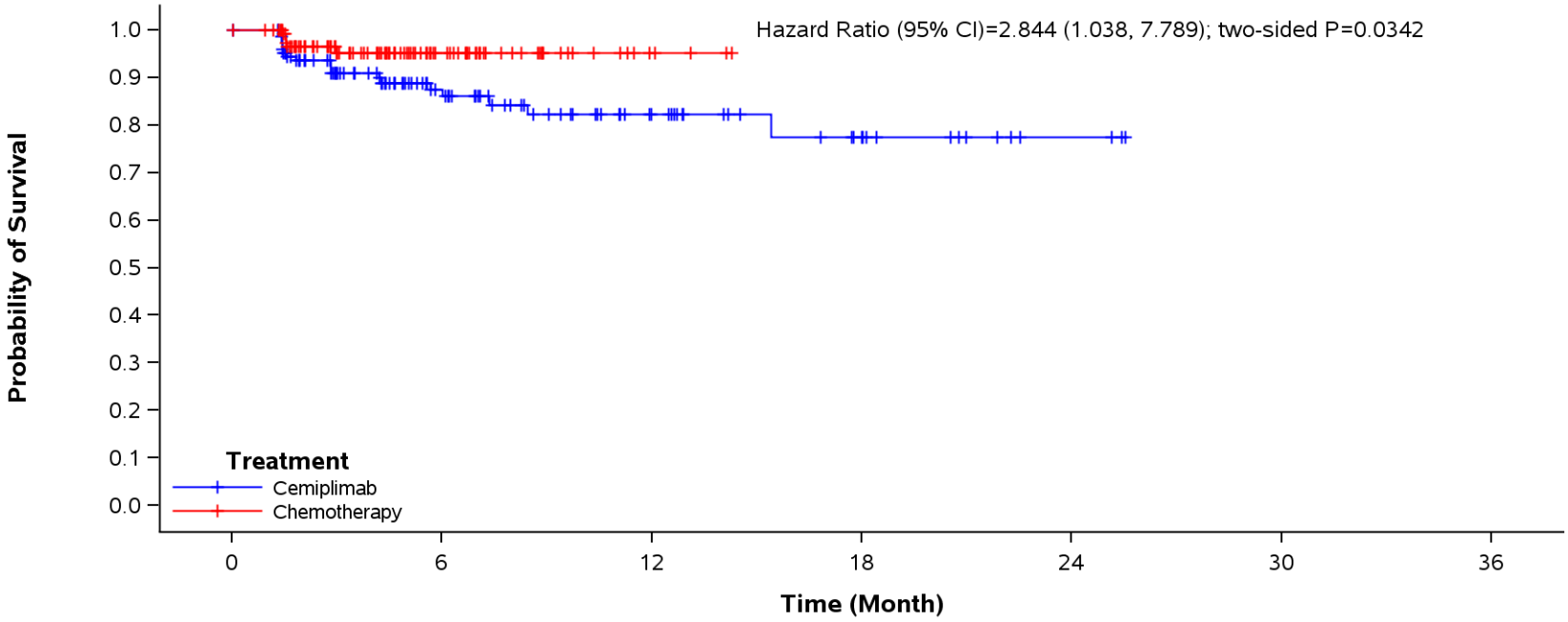
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 43 | 18 | 9 | 2 | 0 | 0 |
| Chemotherapy | 183 | 32 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

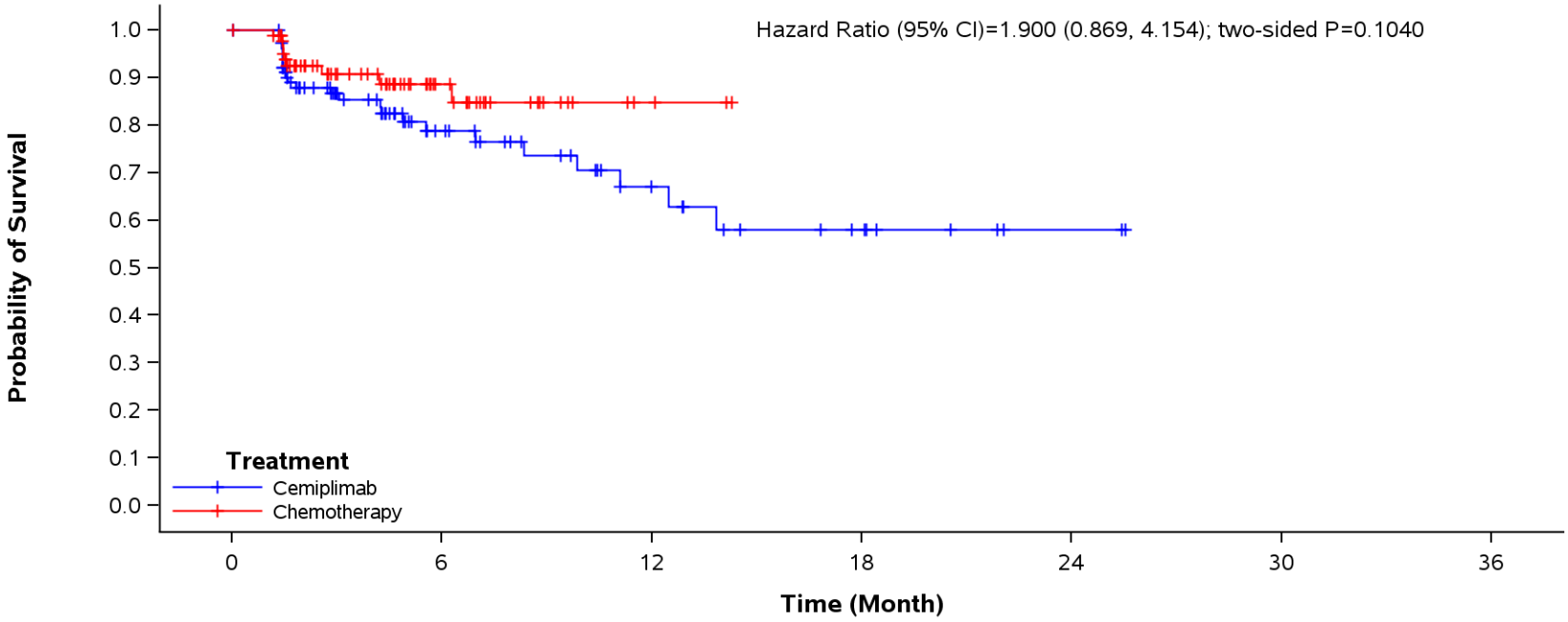
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 60 | 26 | 13 | 3 | 0 | 0 |
| Chemotherapy | 183 | 38 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

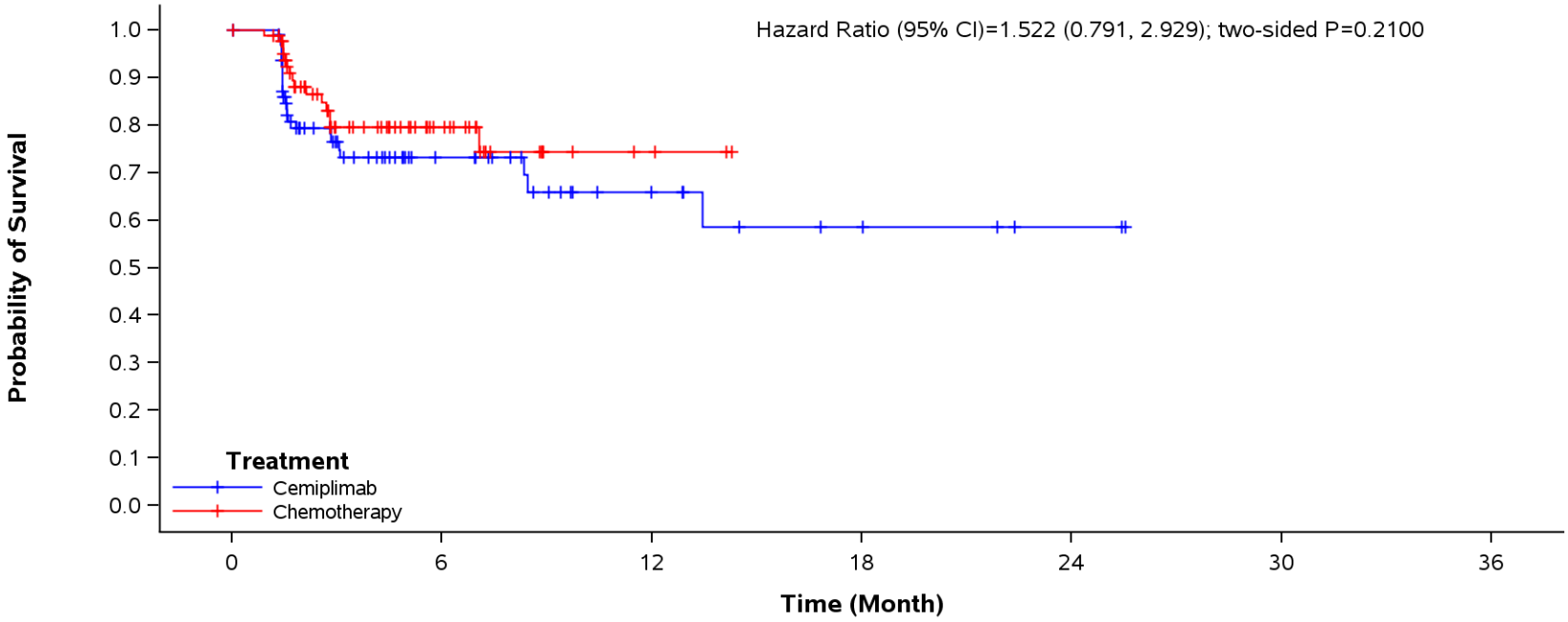
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 38 | 16 | 8 | 2 | 0 | 0 |
| Chemotherapy | 183 | 24 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

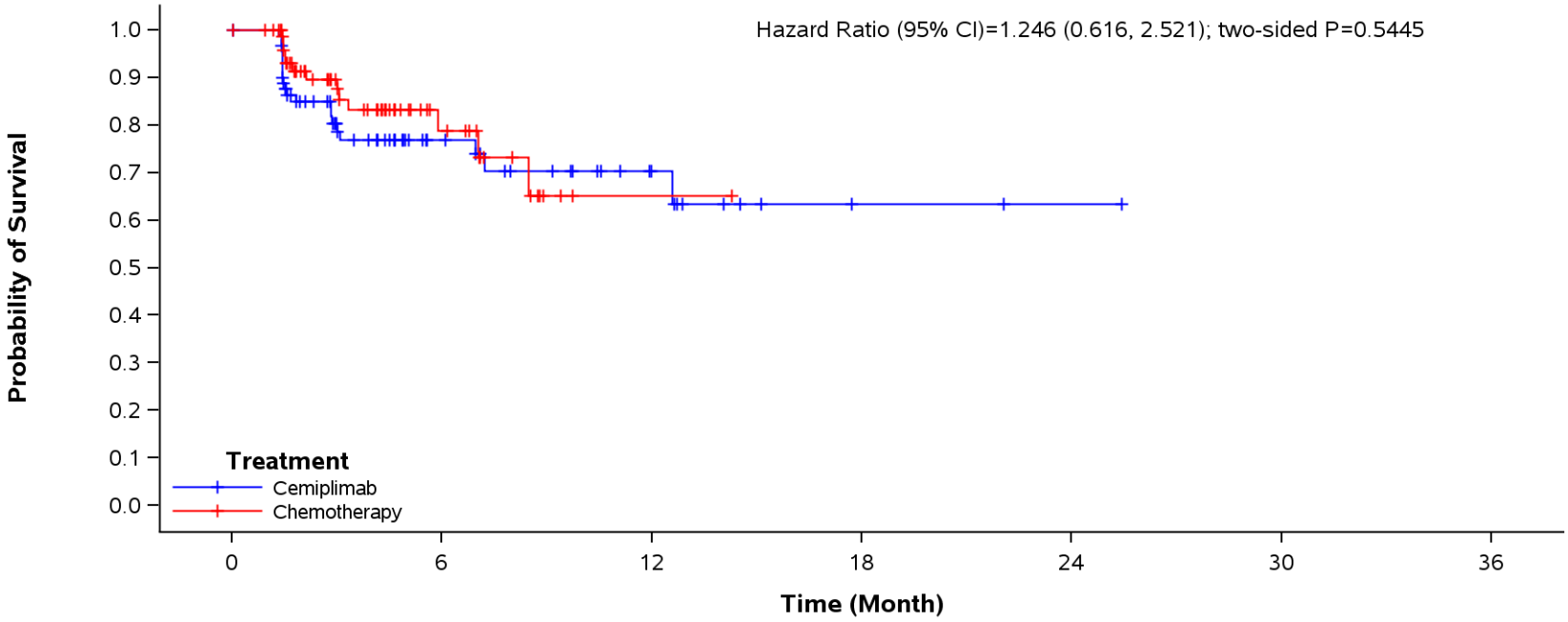
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 28 | 11 | 5 | 2 | 0 | 0 |
| Chemotherapy | 183 | 22 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.8a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

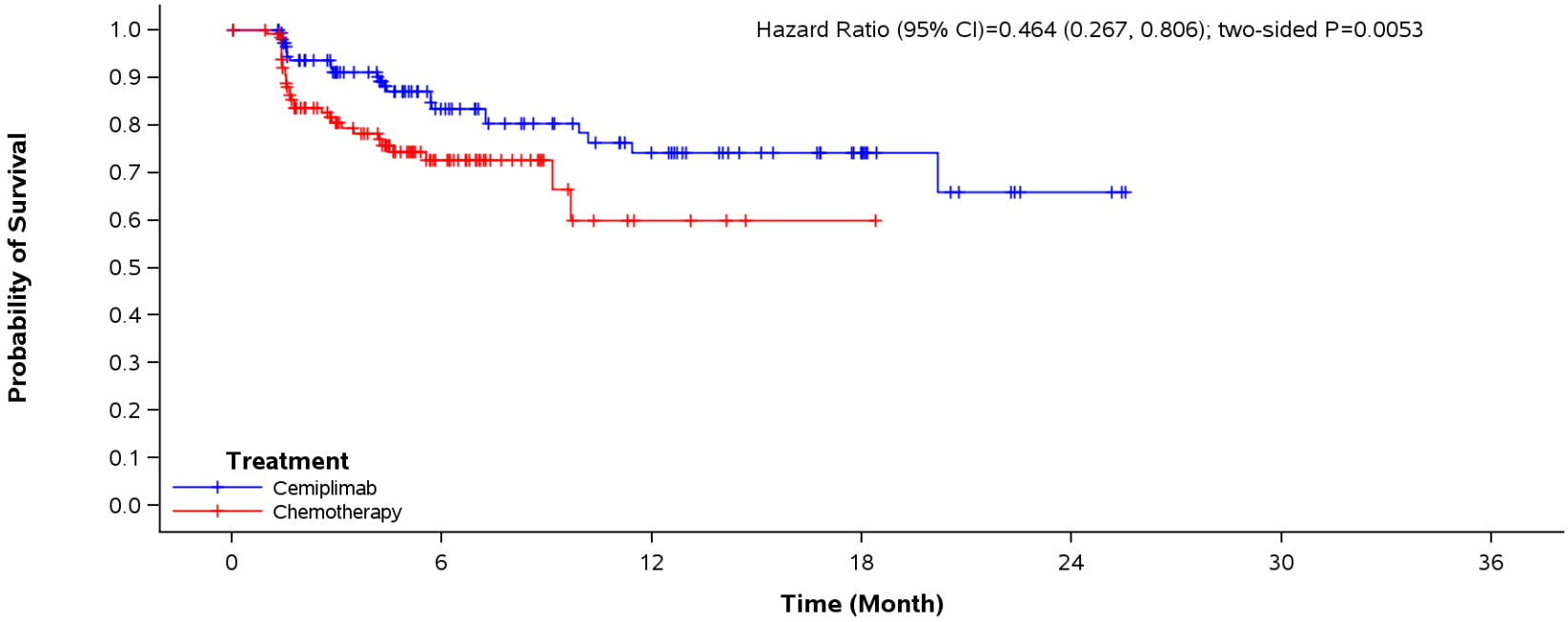
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 27 | 10 | 2 | 1 | 0 | 0 |
| Chemotherapy | 183 | 18 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

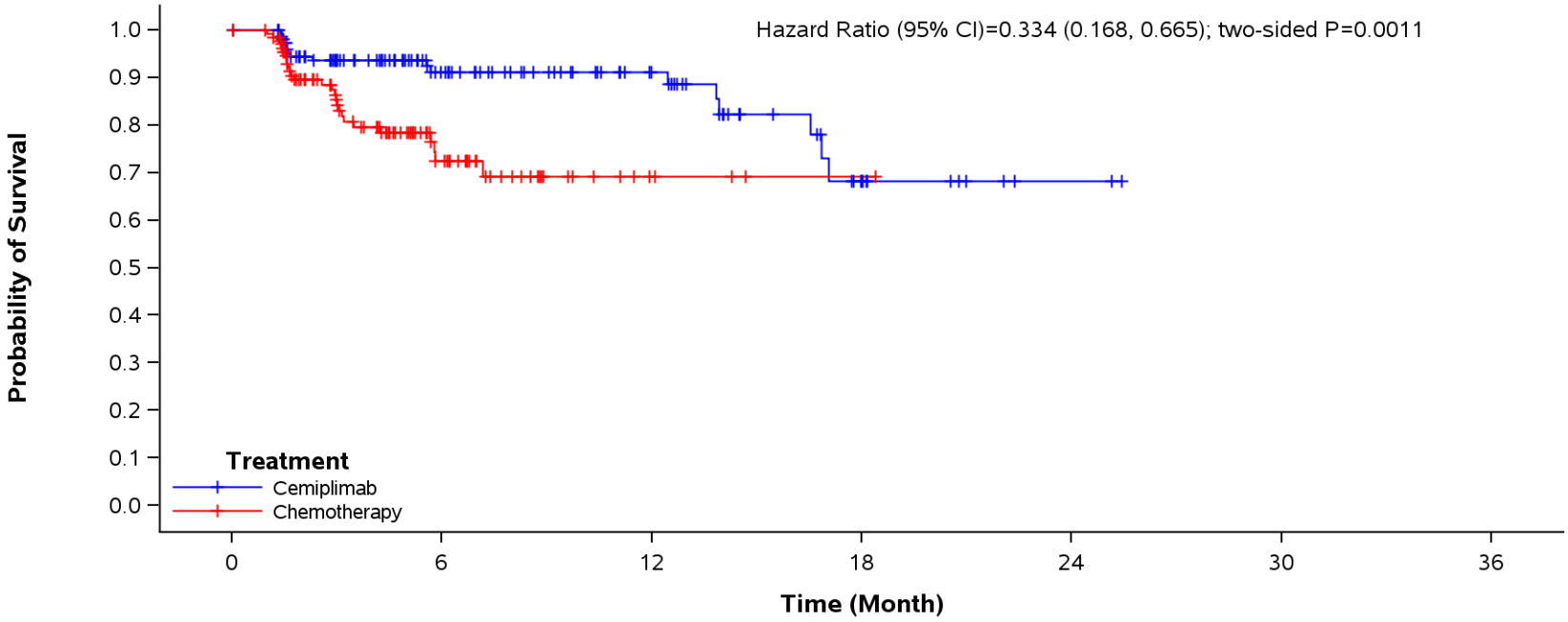
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 64 | 33 | 15 | 3 | 0 | 0 |
| Chemotherapy | 183 | 36 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

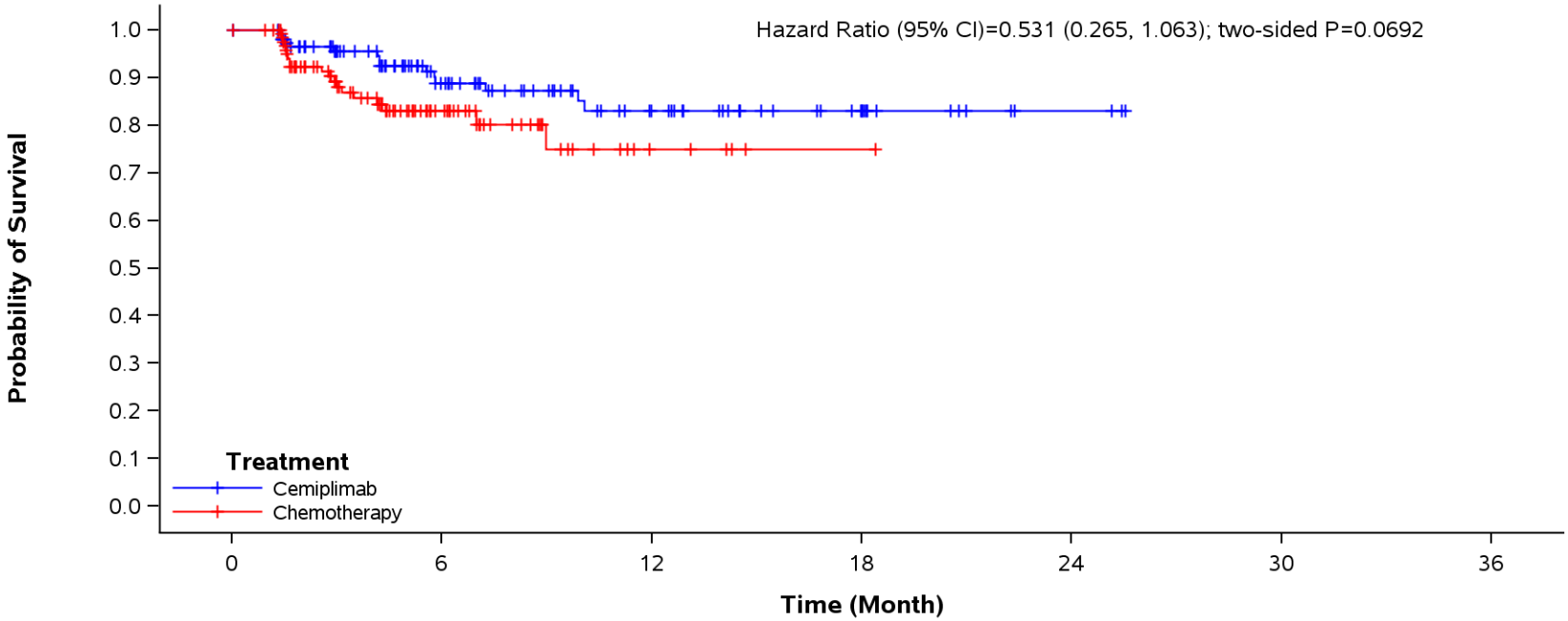
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 71 | 35 | 11 | 2 | 0 | 0 |
| Chemotherapy | 183 | 35 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Constipation - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

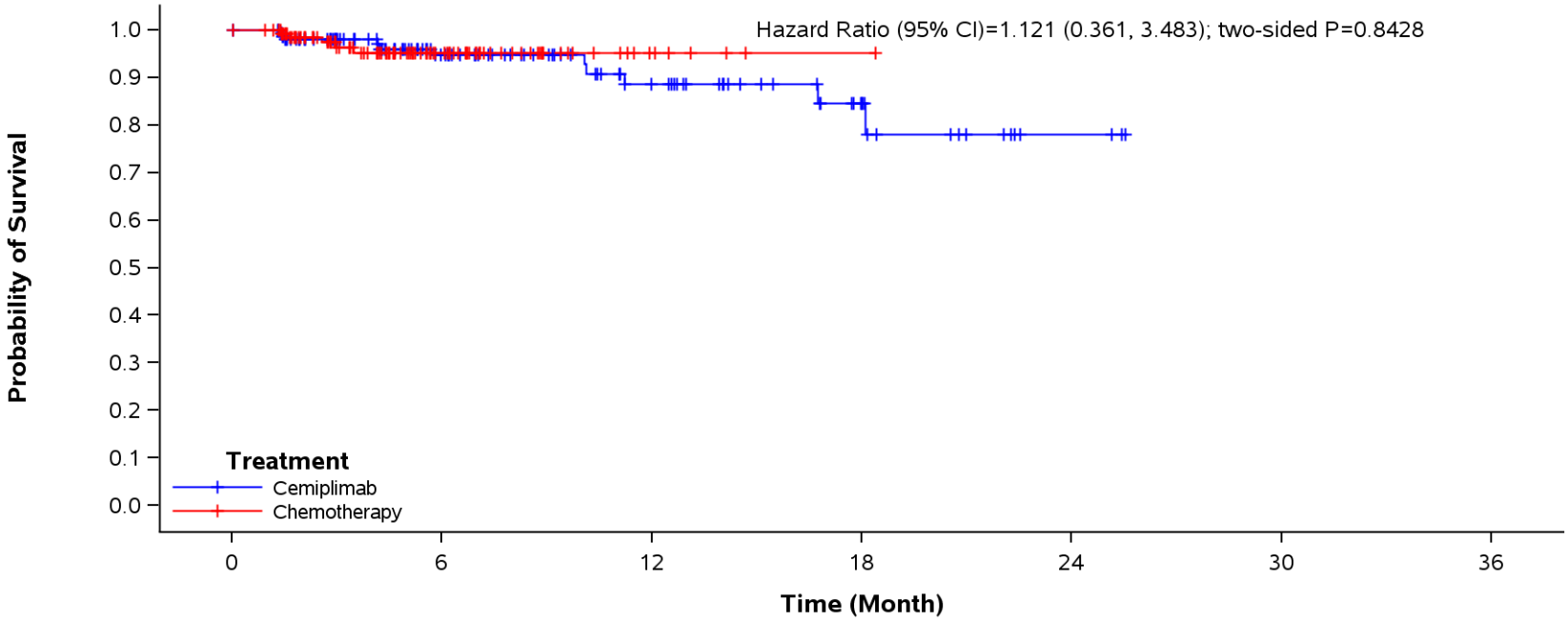
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 67 | 31 | 14 | 3 | 0 | 0 |
| Chemotherapy | 183 | 39 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Diarhoea - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

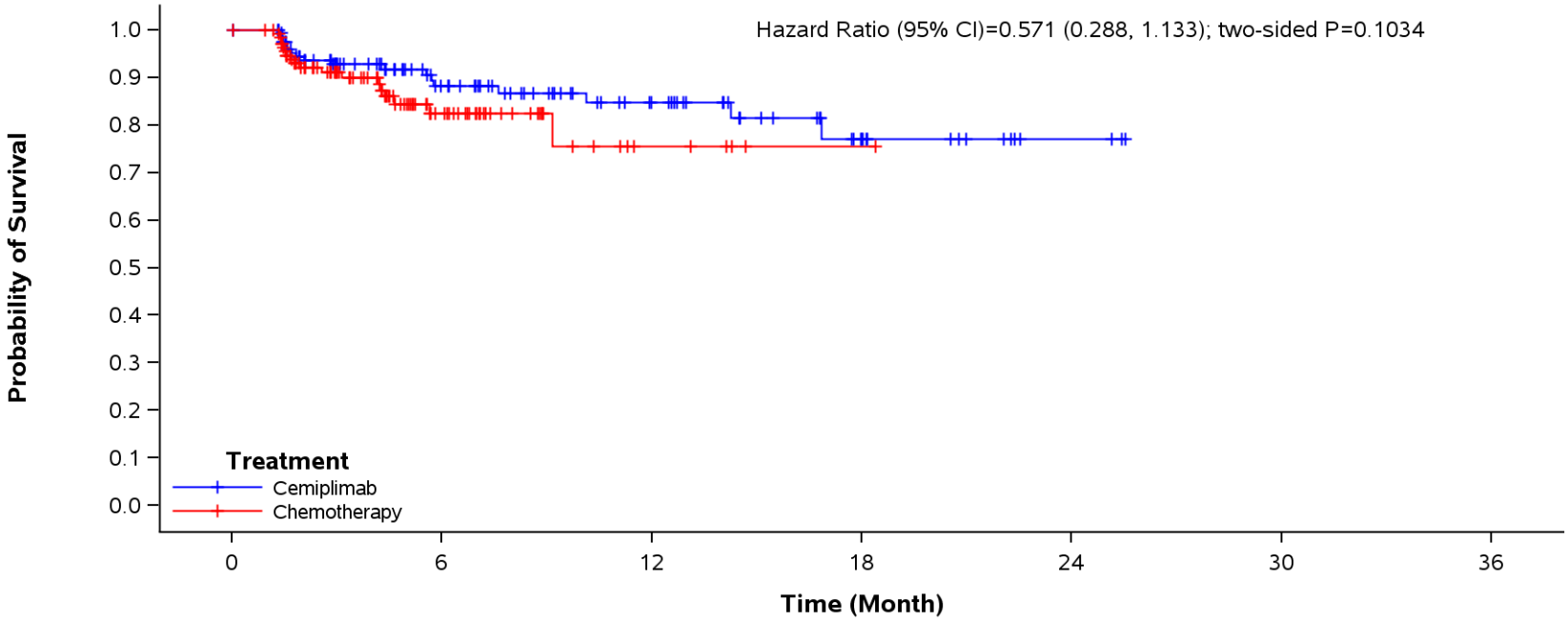
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 73 | 36 | 16 | 3 | 0 | 0 |
| Chemotherapy | 183 | 44 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Dyspnoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

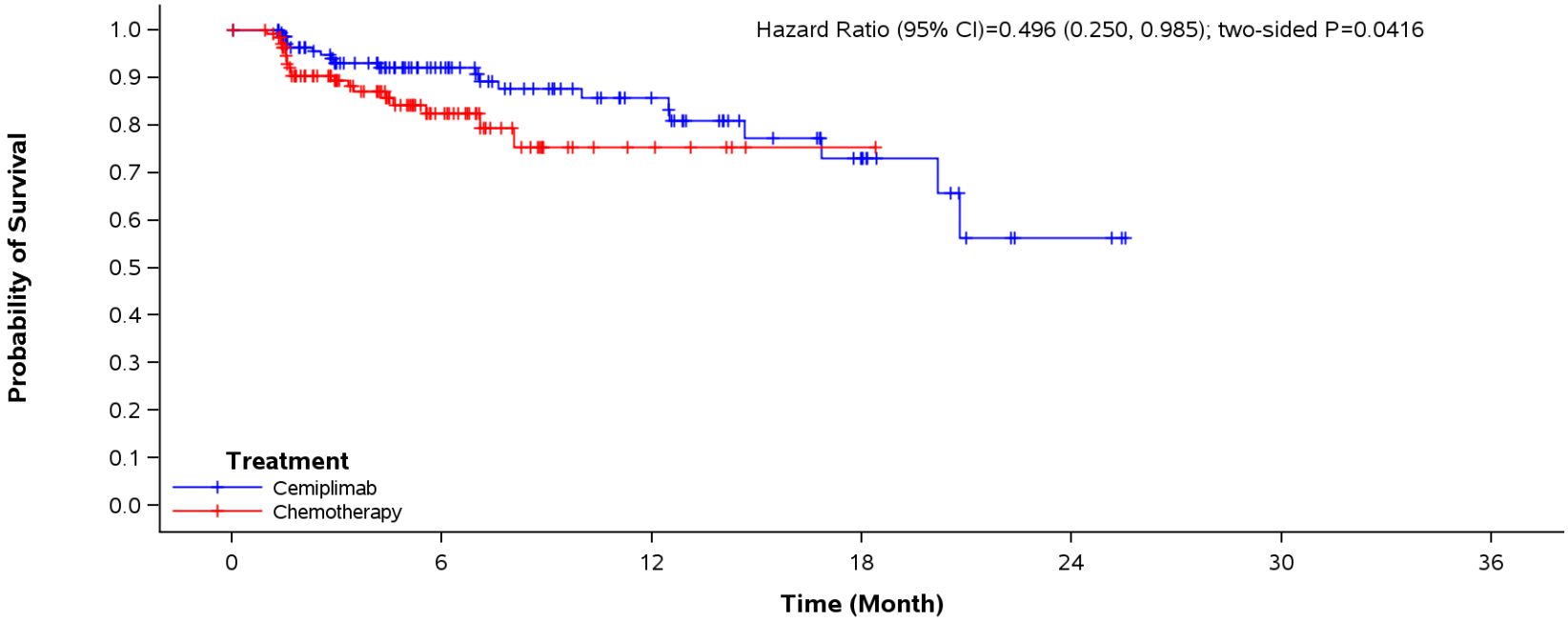
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 71 | 35 | 14 | 3 | 0 | 0 |
| Chemotherapy | 183 | 36 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Emotional Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

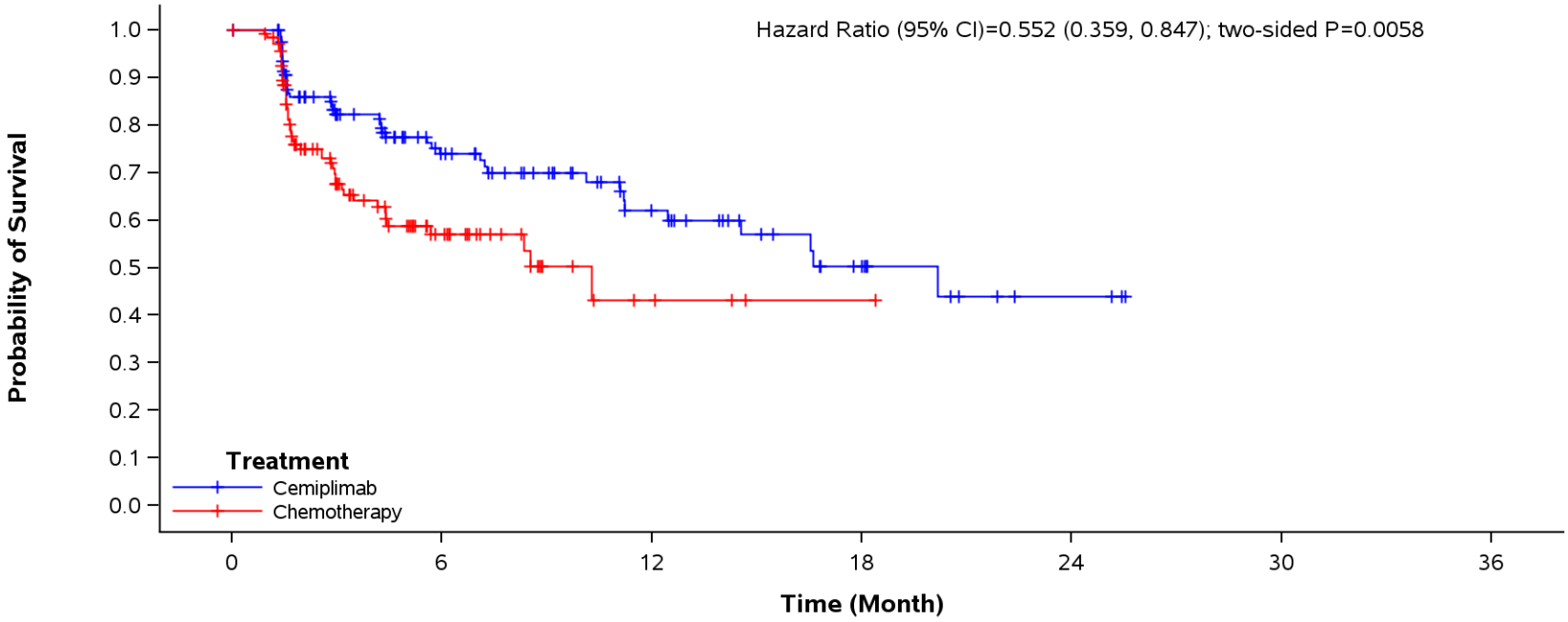
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 73 | 36 | 15 | 3 | 0 | 0 |
| Chemotherapy | 183 | 40 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

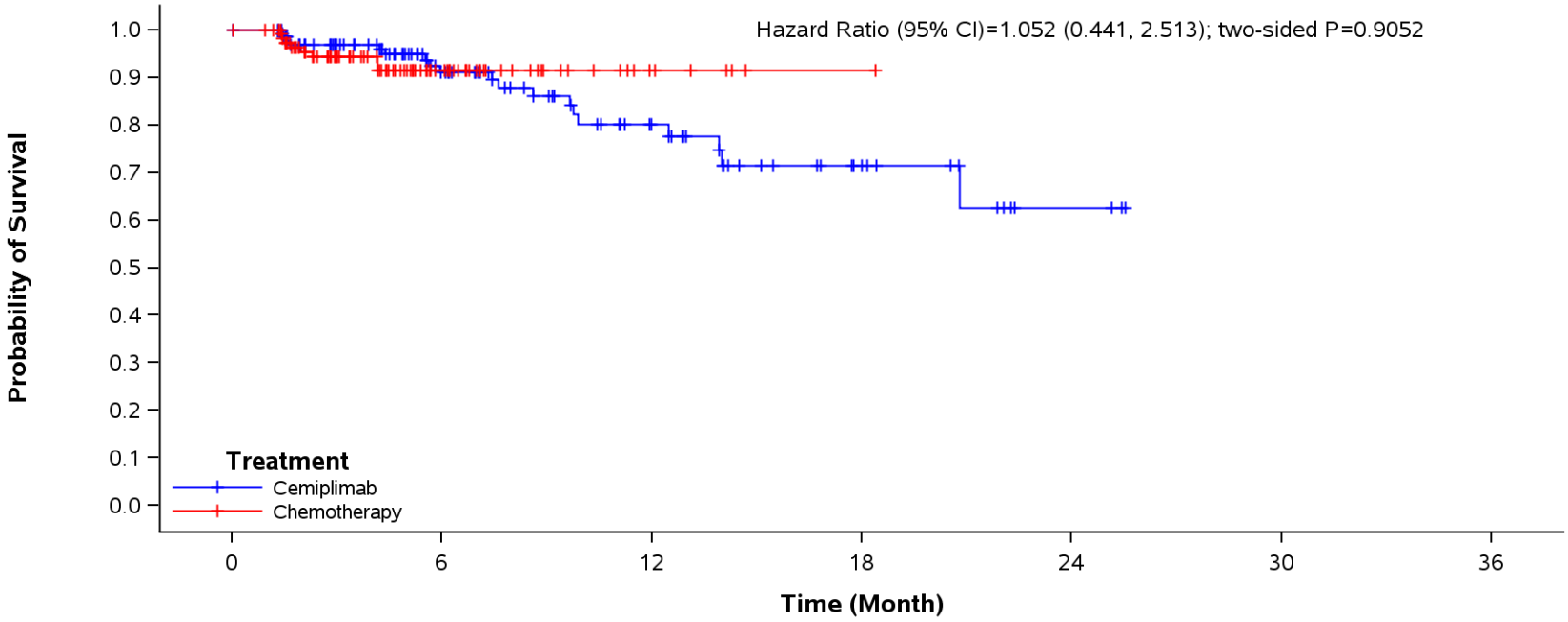
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 61 | 29 | 12 | 3 | 0 | 0 |
| Chemotherapy | 183 | 29 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

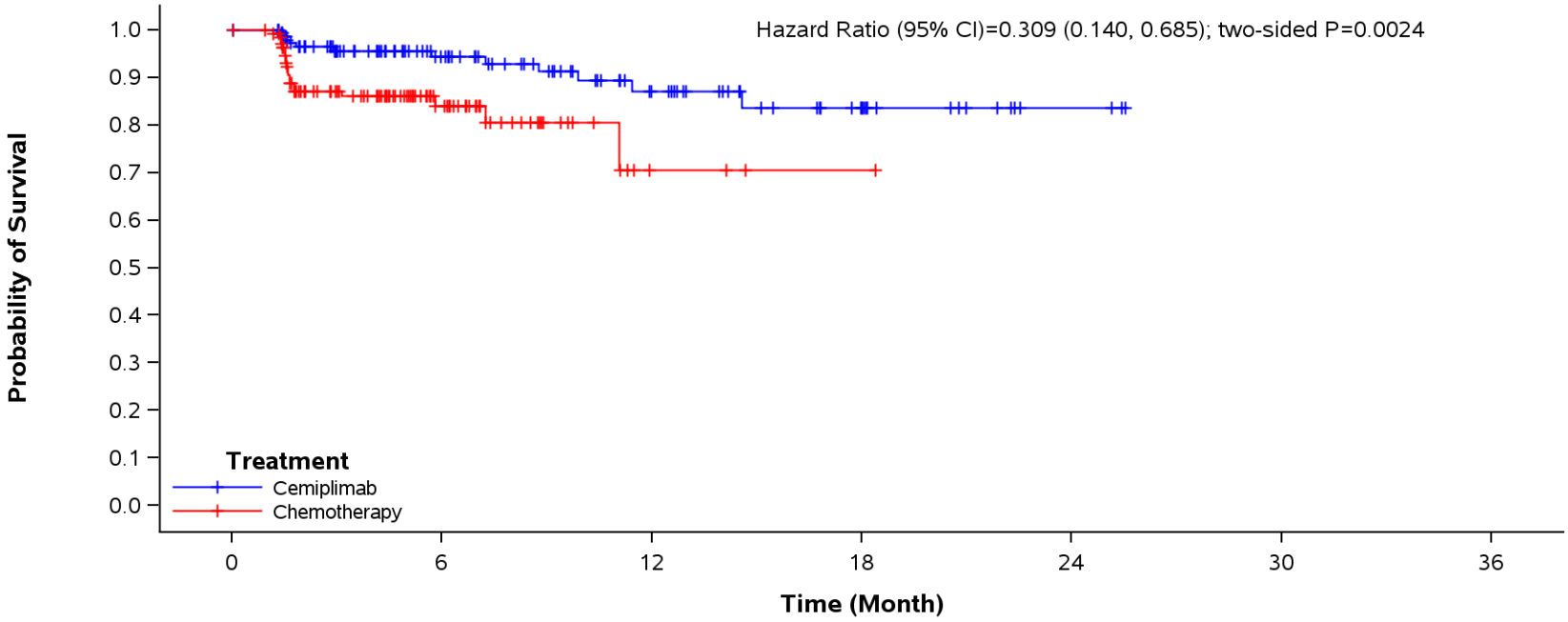
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 68 | 32 | 13 | 3 | 0 | 0 |
| Chemotherapy | 183 | 37 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

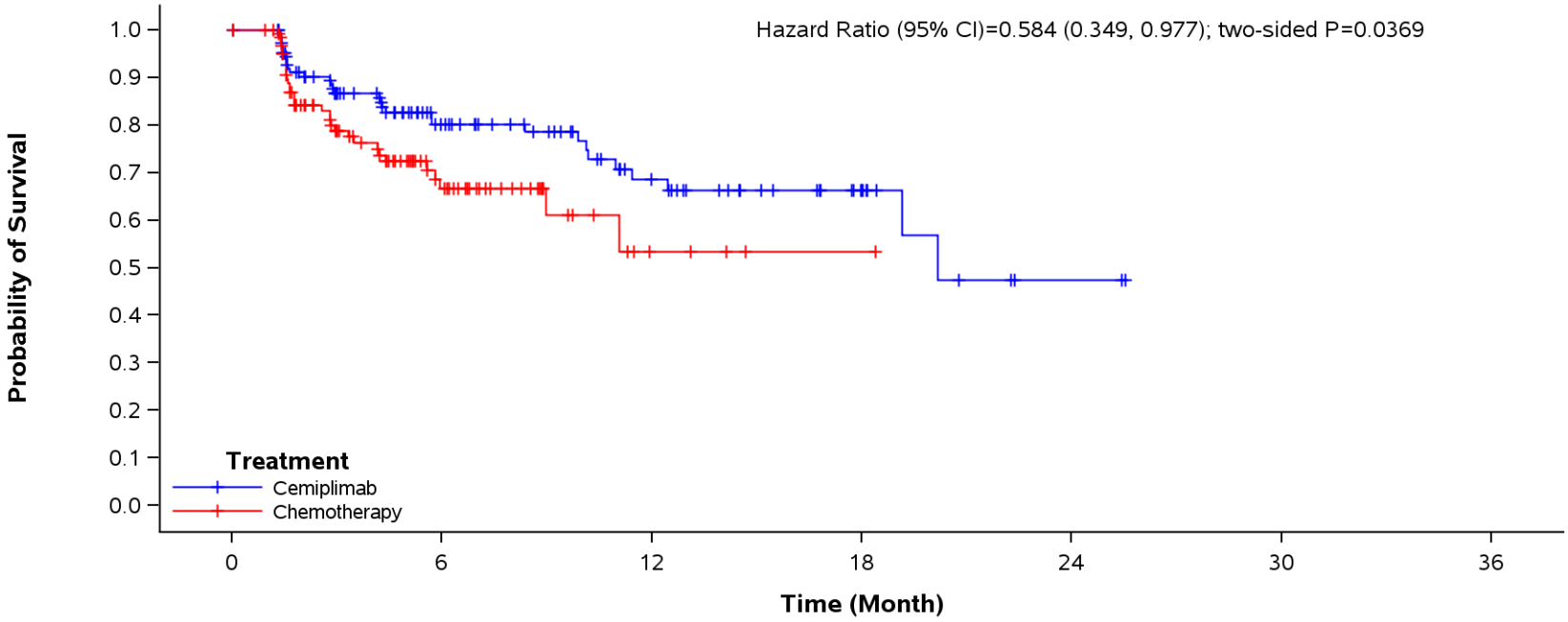
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 76 | 36 | 16 | 3 | 0 | 0 |
| Chemotherapy | 183 | 39 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Pain - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

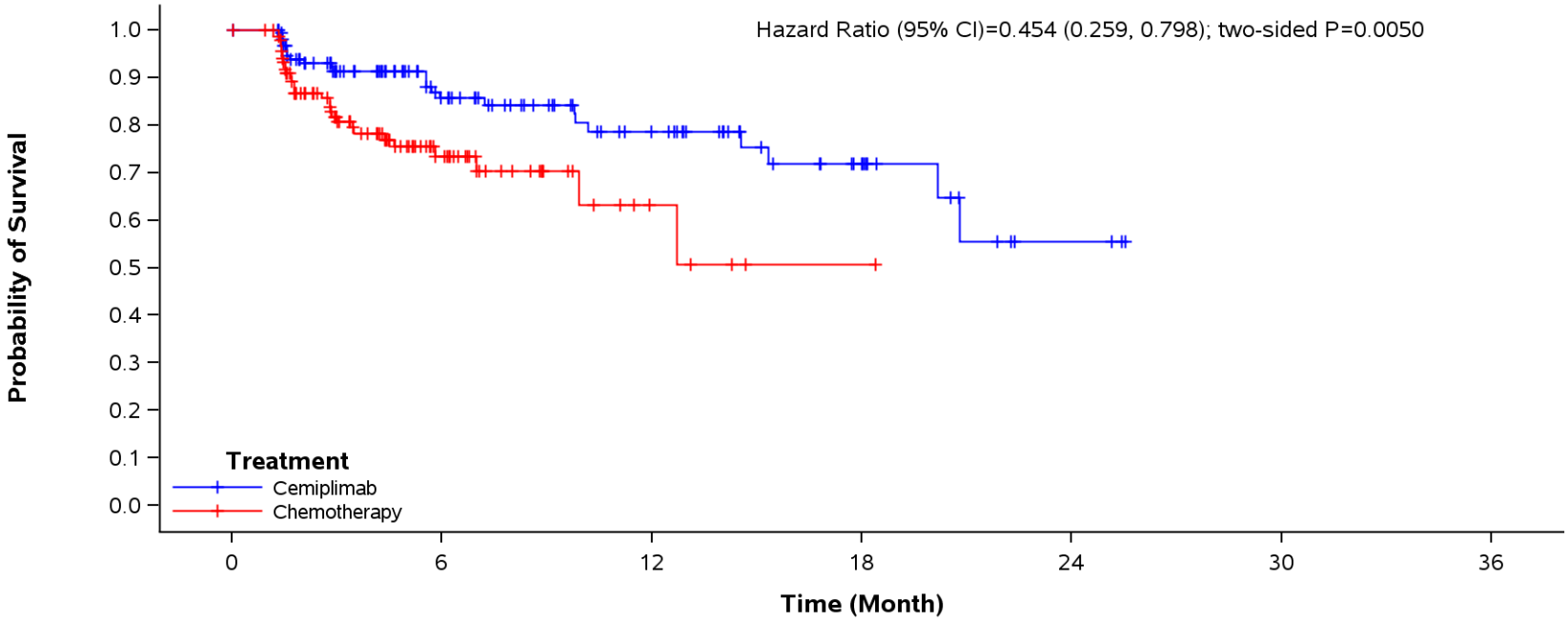
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 62 | 30 | 12 | 2 | 0 | 0 |
| Chemotherapy | 183 | 34 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

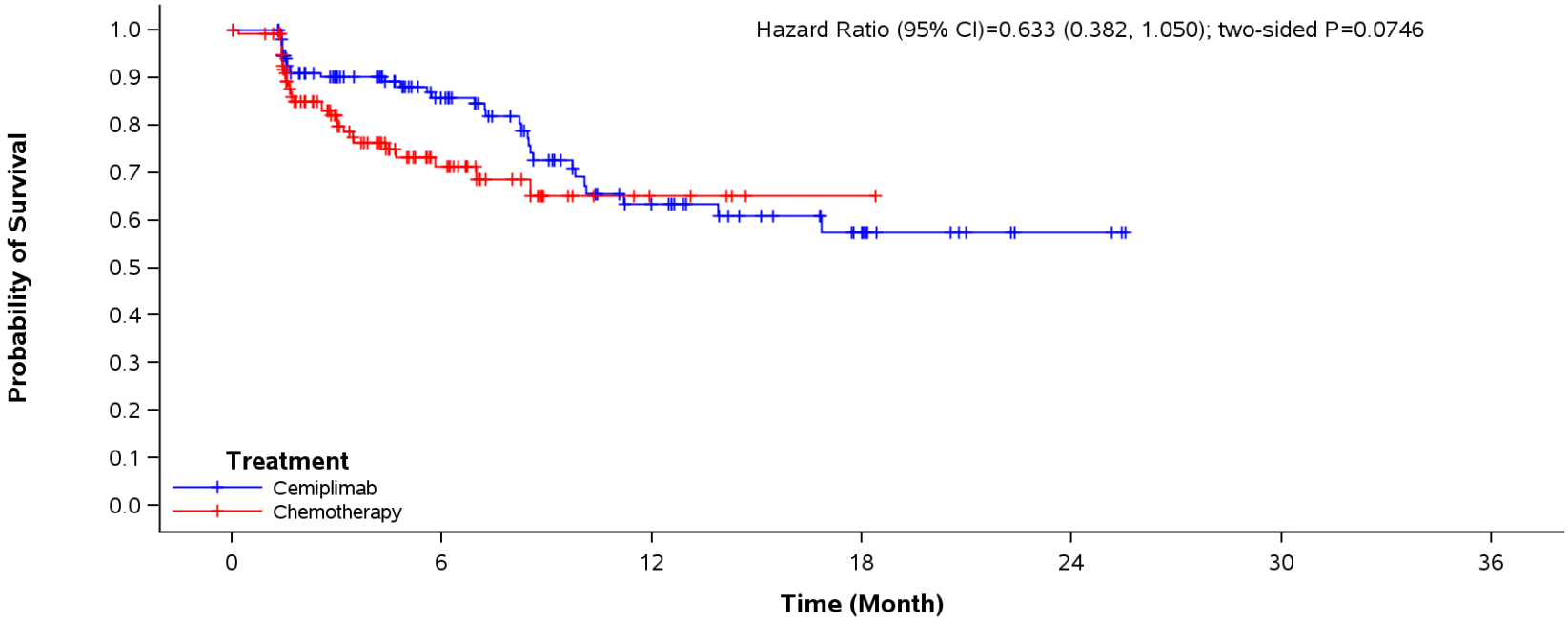
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 71 | 36 | 16 | 3 | 0 | 0 |
| Chemotherapy | 183 | 34 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

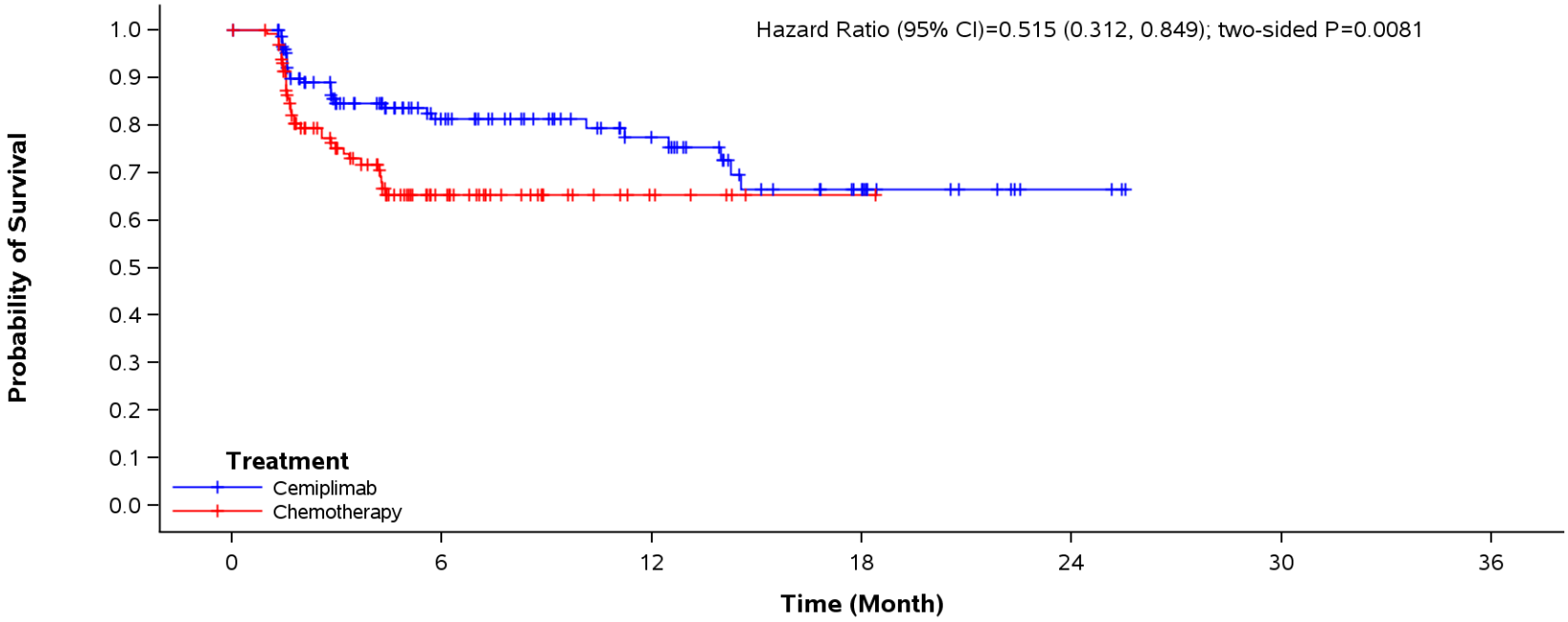
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 72 | 30 | 14 | 3 | 0 | 0 |
| Chemotherapy | 183 | 36 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Role Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

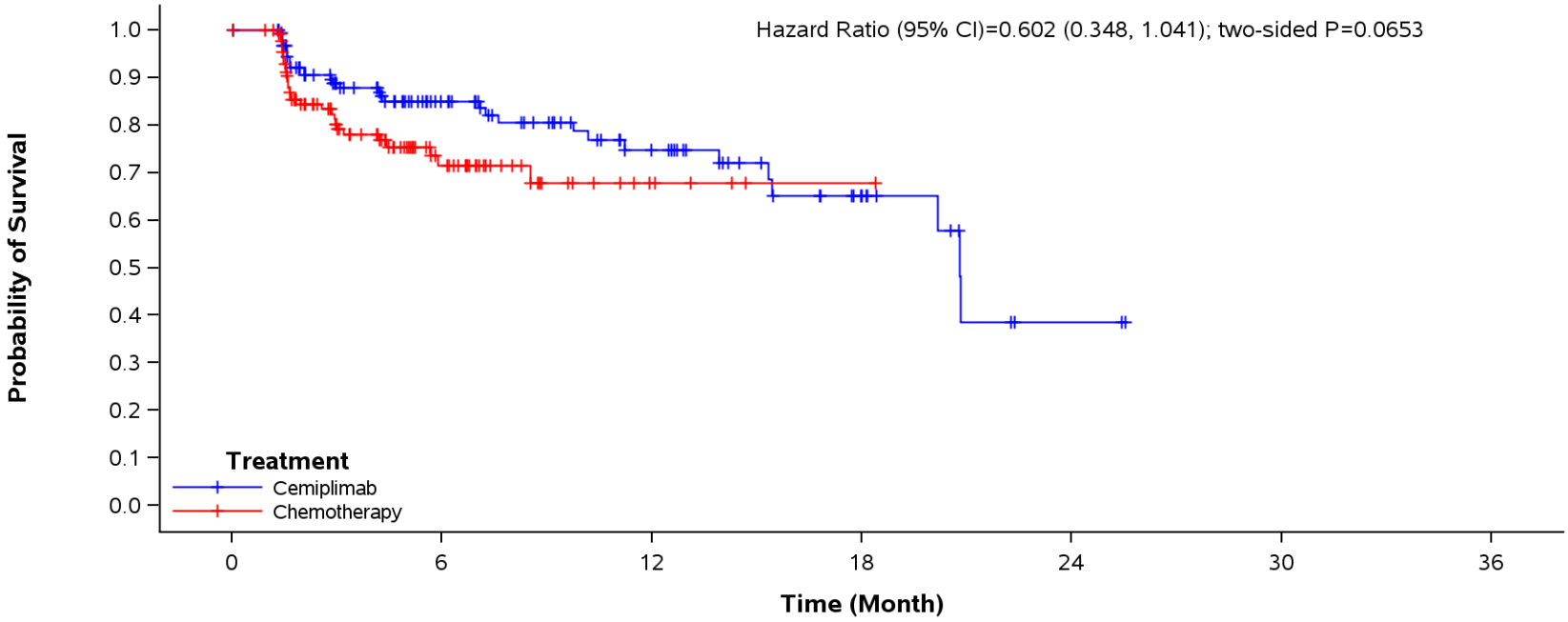
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 66 | 36 | 15 | 3 | 0 | 0 |
| Chemotherapy | 183 | 30 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Social Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

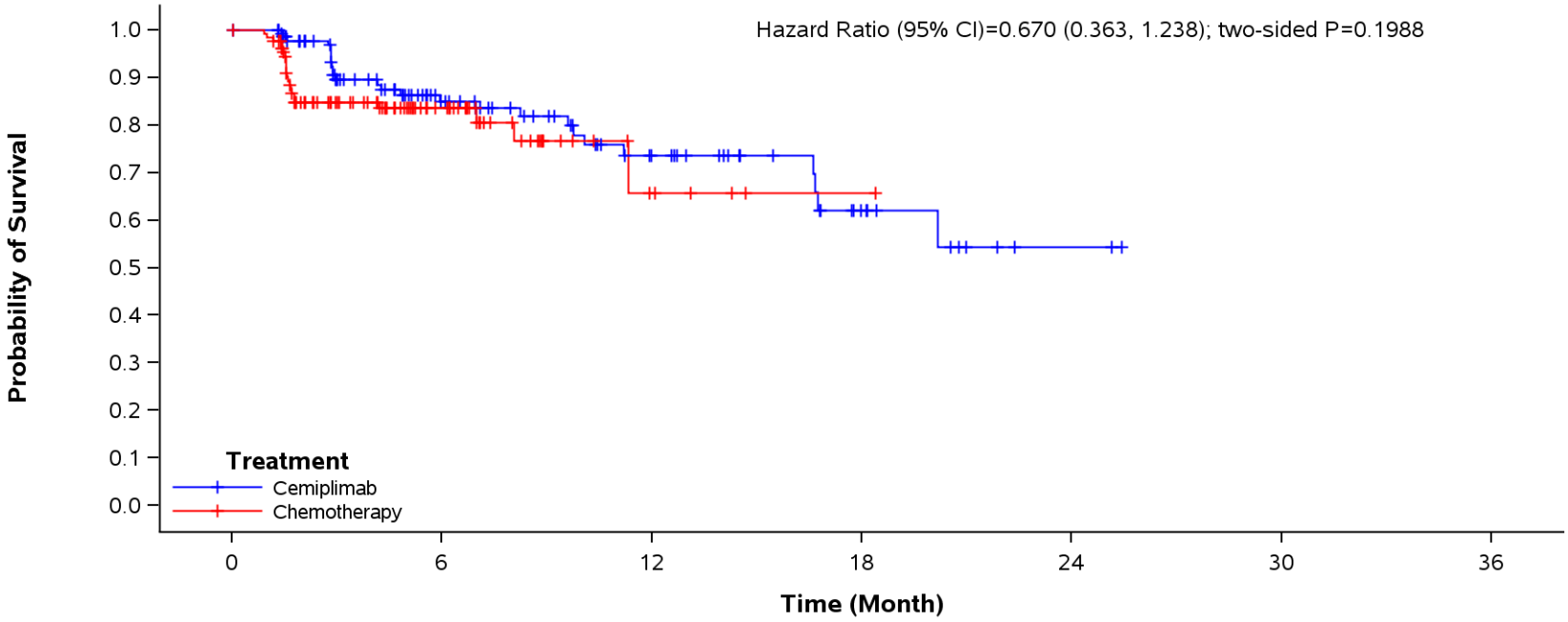
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 68 | 33 | 13 | 2 | 0 | 0 |
| Chemotherapy | 183 | 36 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.1.9a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

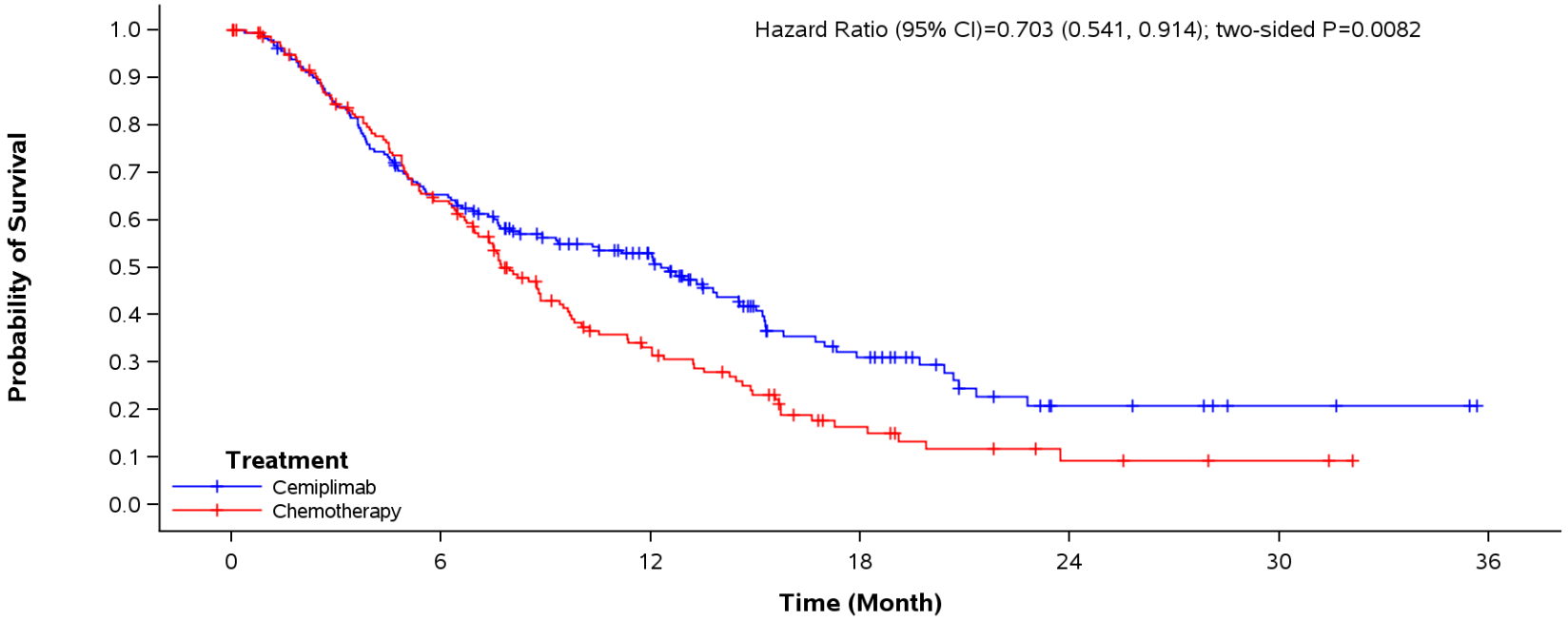
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 196 | 63 | 29 | 11 | 2 | 0 | 0 |
| Chemotherapy | 183 | 39 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



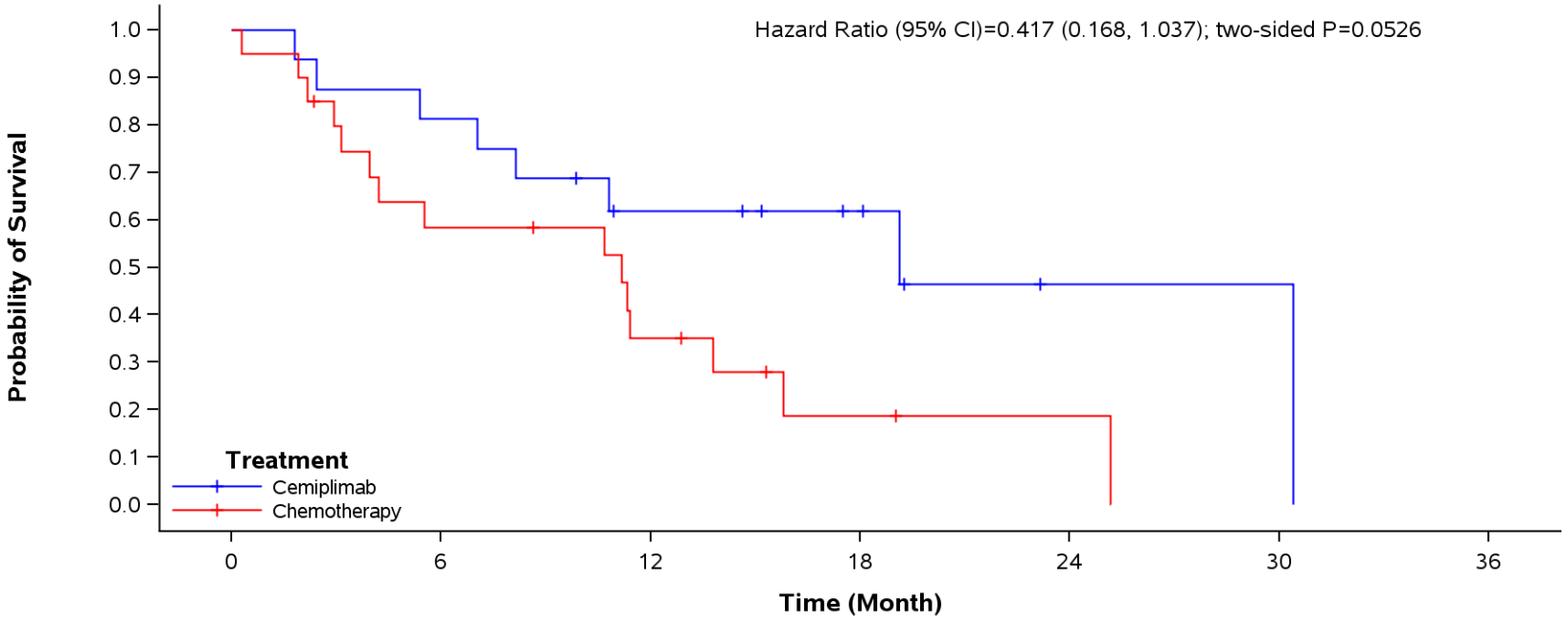

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 115 | 69 | 27 | 7 | 3 | 0 |
| Chemotherapy | 163 | 94 | 38 | 12 | 4 | 2 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



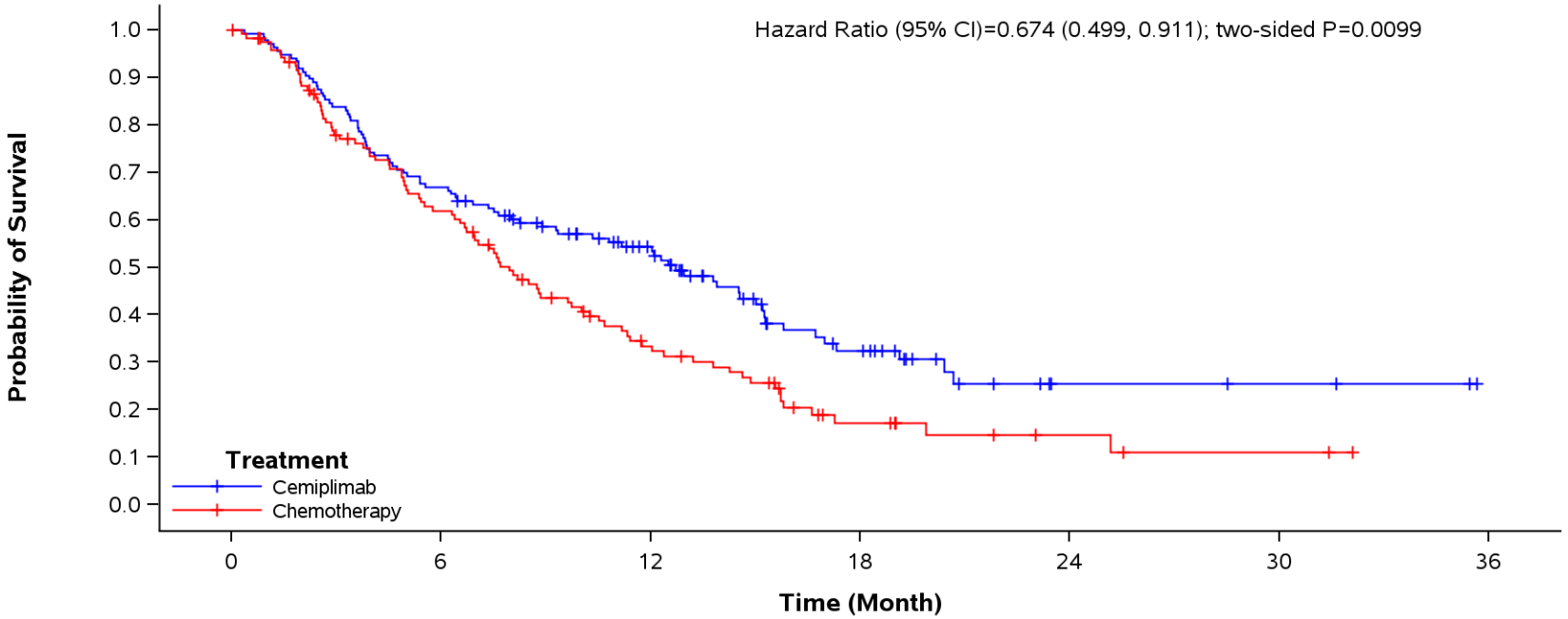

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 13 | 8 | 5 | 1 | 1 | 0 |
| Chemotherapy | 20 | 11 | 6 | 2 | 1 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



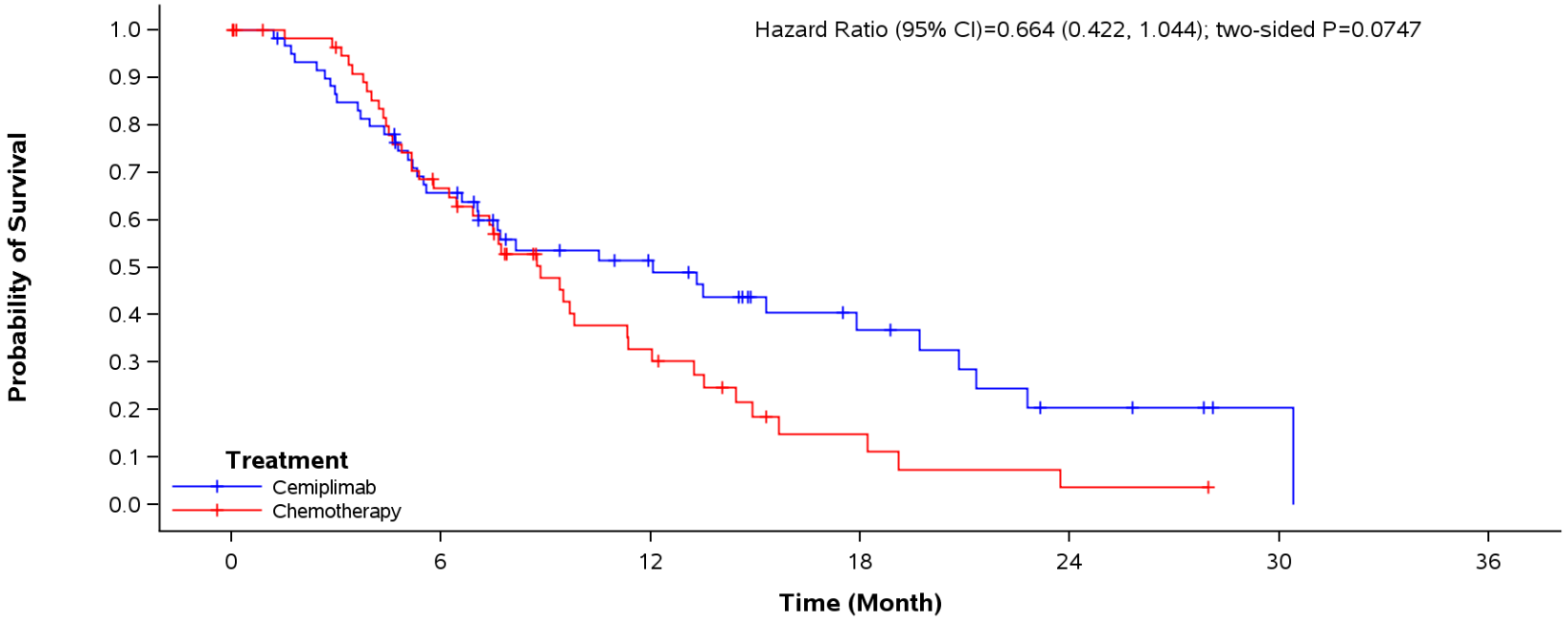

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 91 | 56 | 22 | 4 | 3 | 0 |
| Chemotherapy | 123 | 70 | 31 | 10 | 4 | 2 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



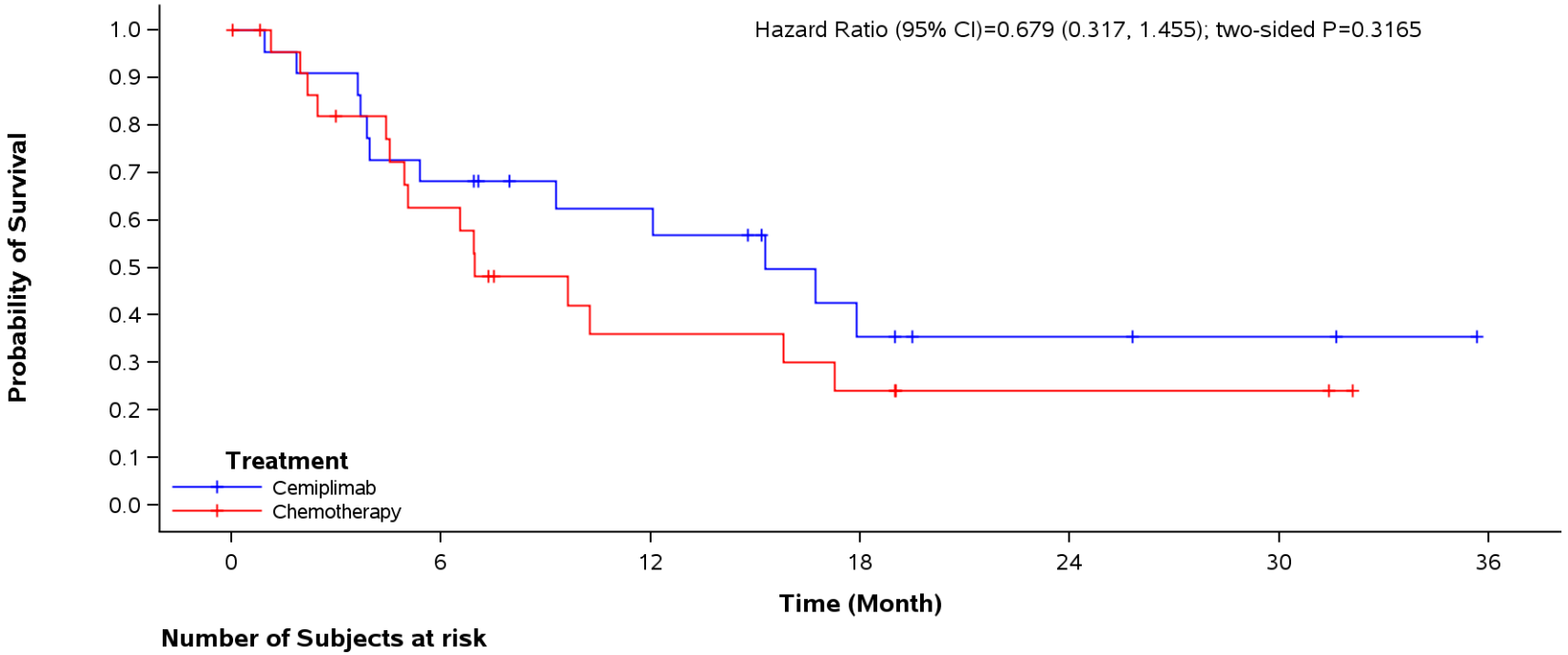

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 37 | 21 | 10 | 4 | 1 | 0 |
| Chemotherapy | 60 | 35 | 13 | 4 | 1 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America



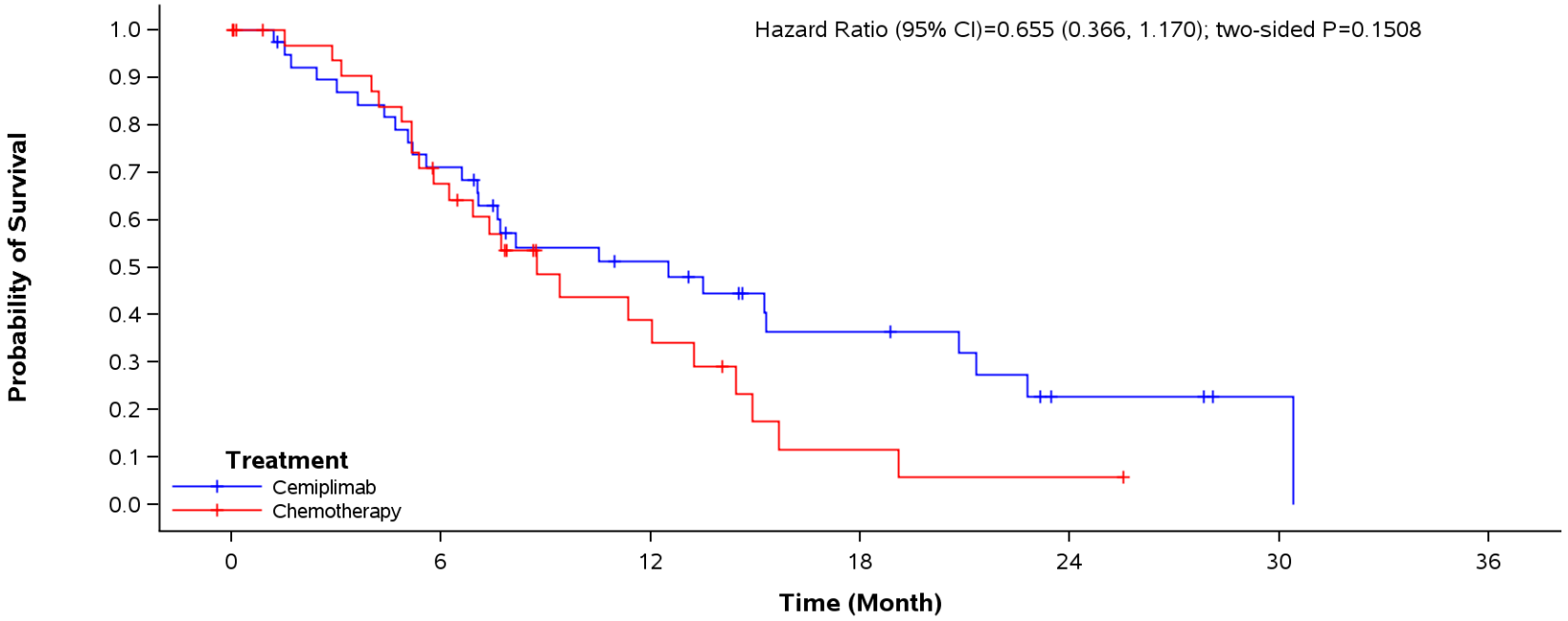

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 15 | 11 | 5 | 3 | 2 | 0 |
| Chemotherapy | 25 | 13 | 6 | 4 | 2 | 2 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia



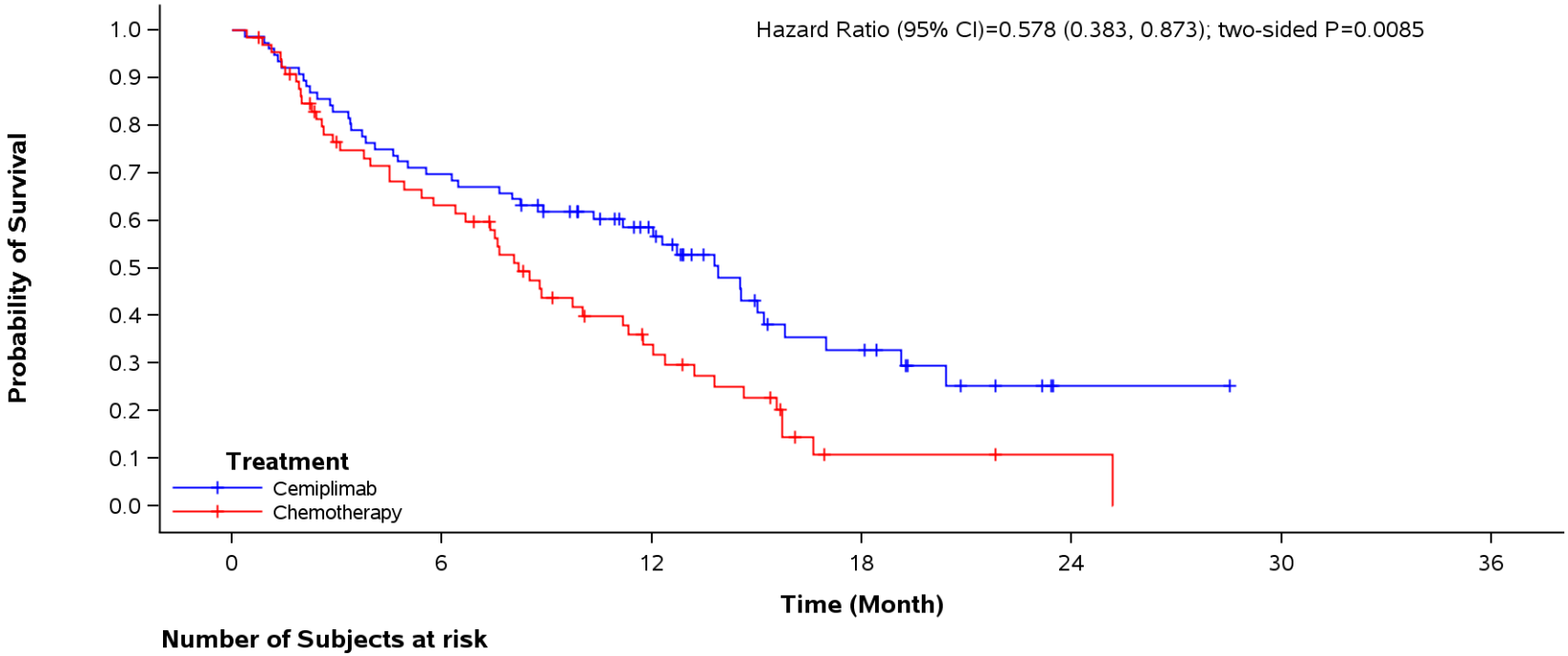

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 27 | 16 | 9 | 3 | 1 | 0 |
| Chemotherapy | 36 | 20 | 8 | 2 | 1 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



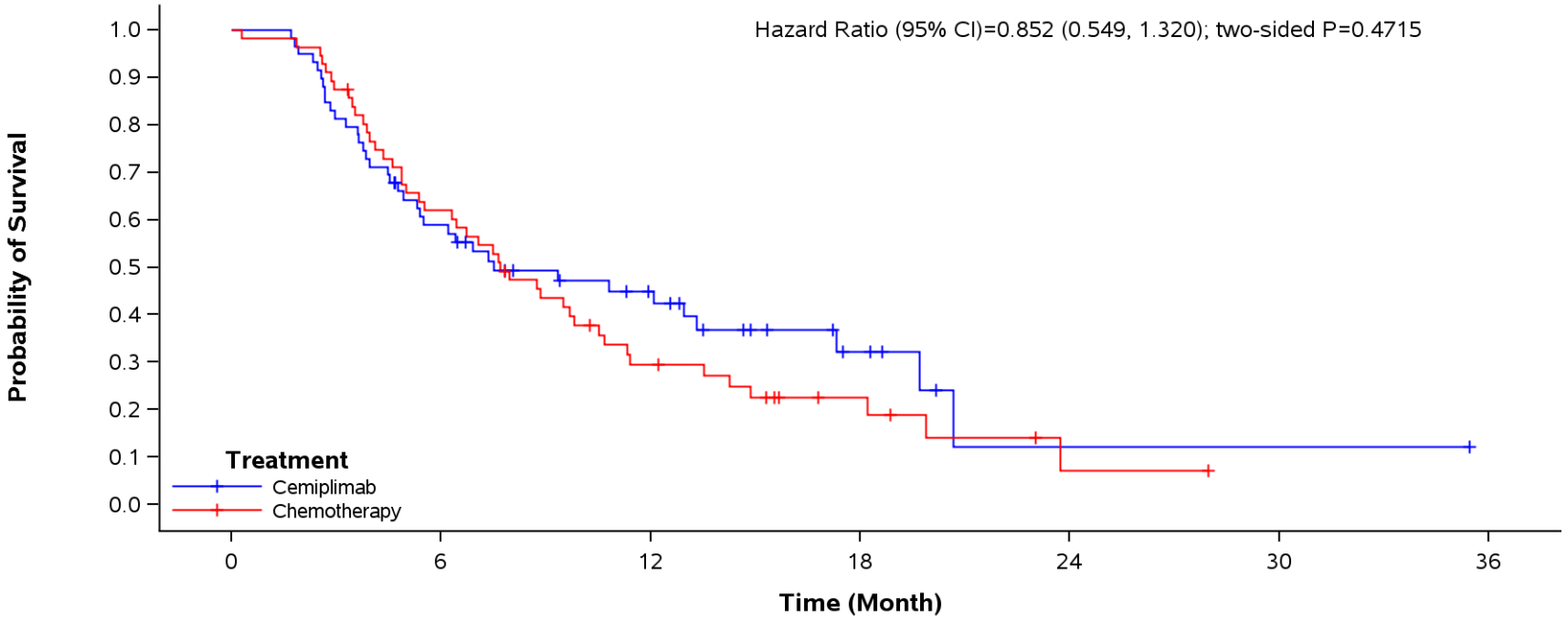

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 53 | 32 | 12 | 1 | 0 | 0 |
| Chemotherapy | 66 | 38 | 16 | 2 | 1 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW



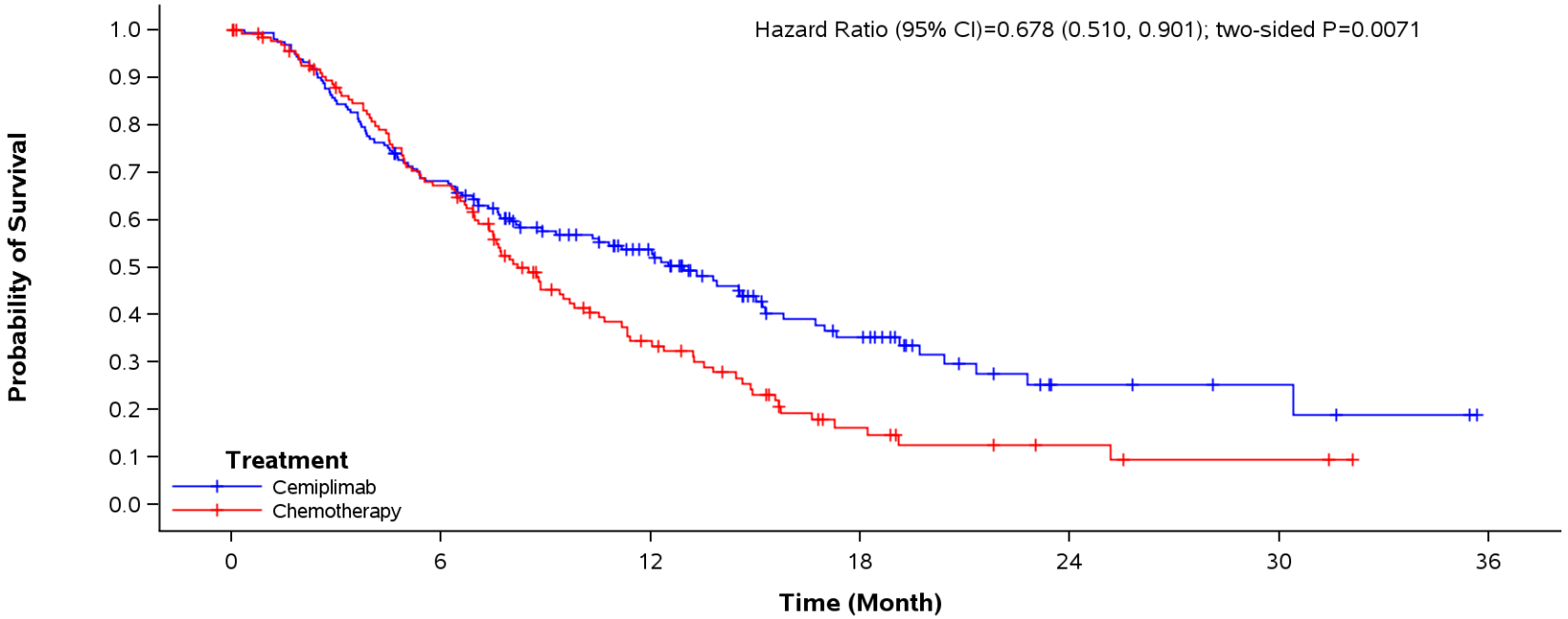

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 33 | 18 | 6 | 1 | 1 | 0 |
| Chemotherapy | 56 | 34 | 14 | 6 | 1 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous



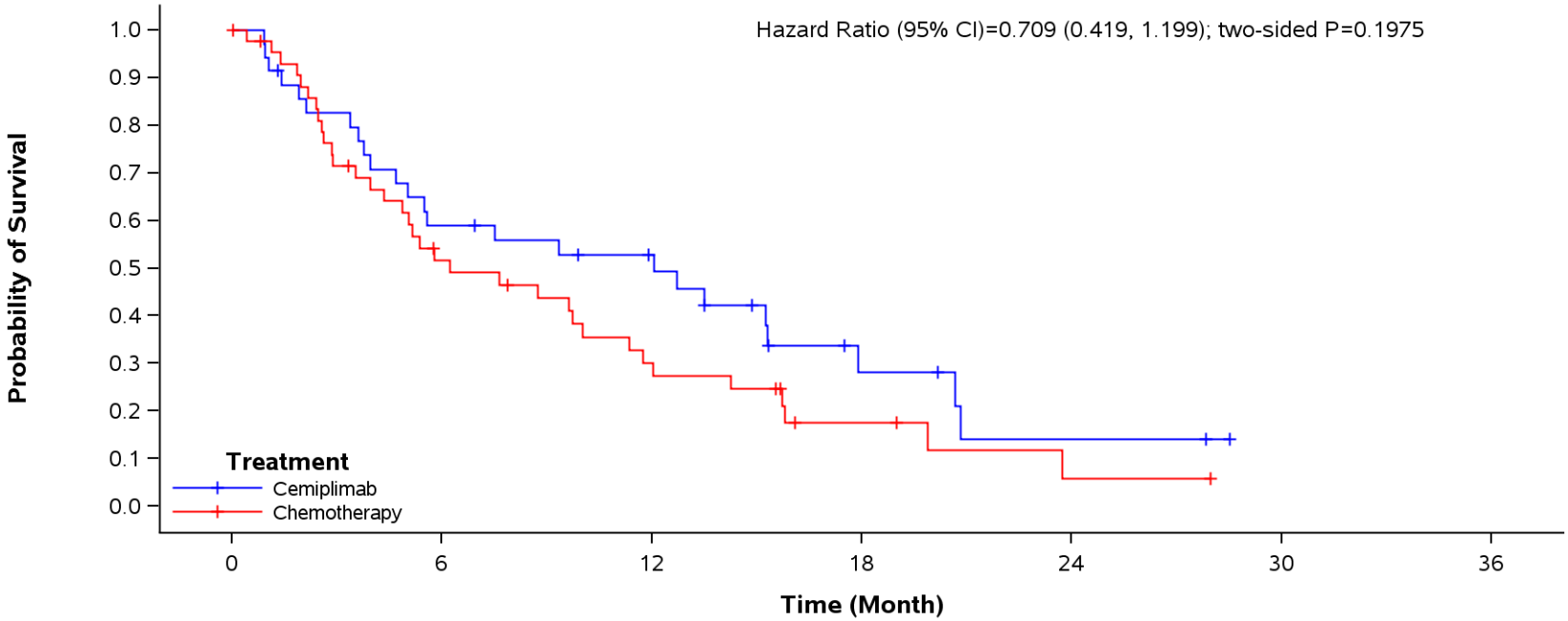

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 108 | 62 | 27 | 6 | 4 | 0 |
| Chemotherapy | 137 | 85 | 33 | 10 | 4 | 2 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



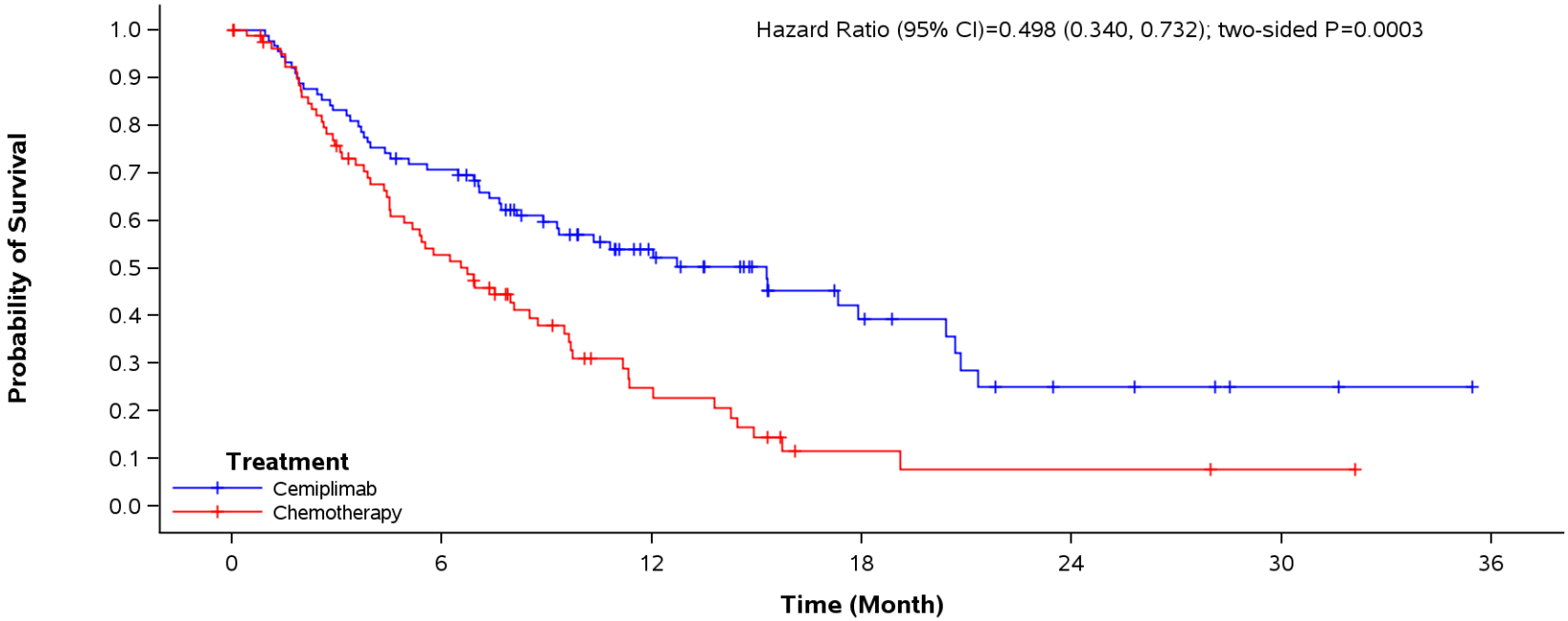

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 20 | 15 | 5 | 2 | 0 | 0 |
| Chemotherapy | 46 | 20 | 11 | 4 | 1 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes



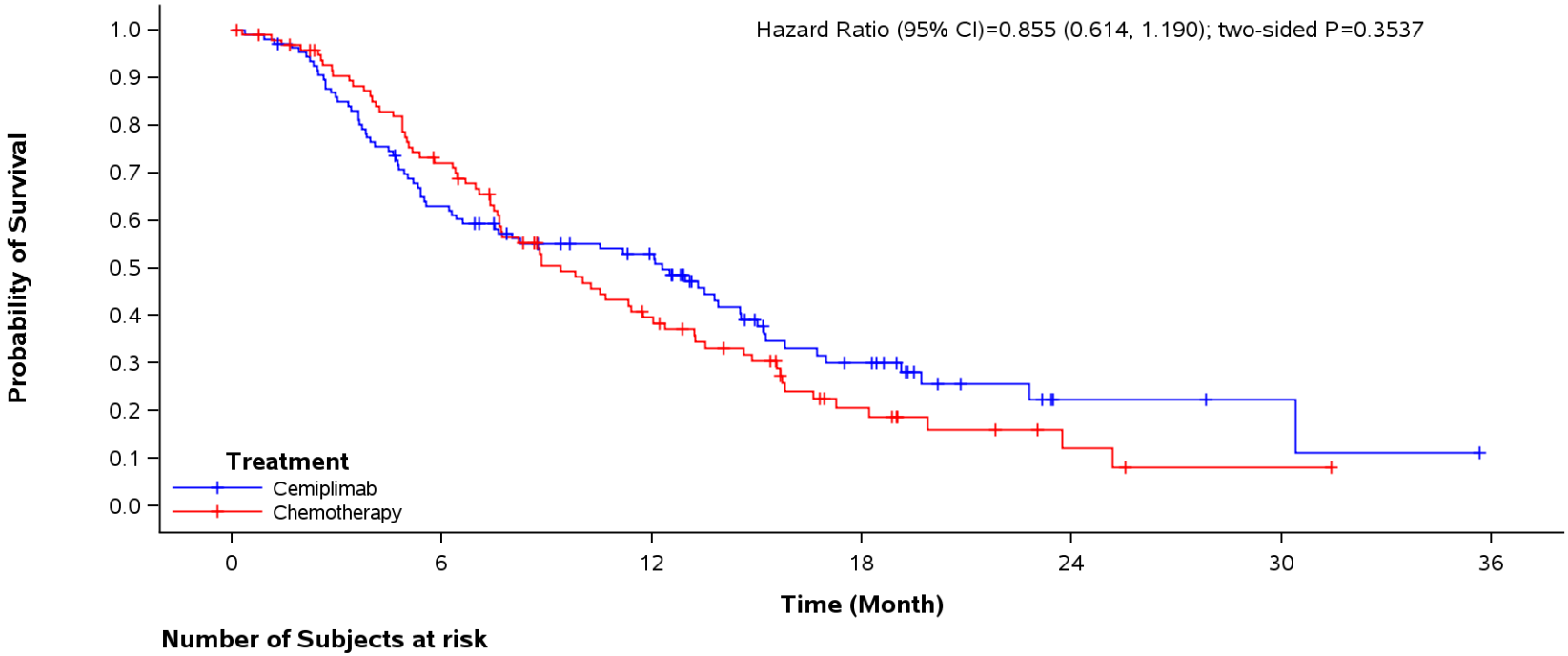

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 62 | 30 | 13 | 5 | 2 | 0 |
| Chemotherapy | 85 | 39 | 12 | 3 | 2 | 1 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No



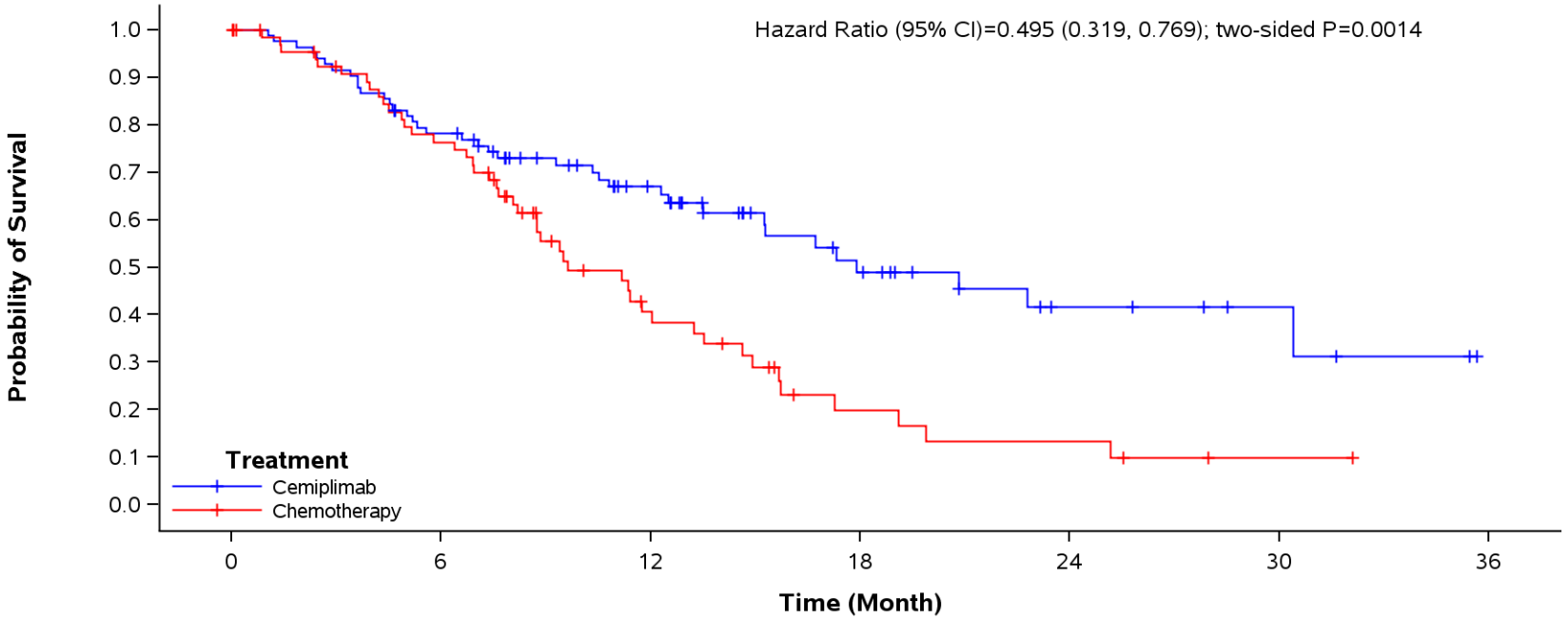

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 66 | 47 | 19 | 3 | 2 | 0 |
| Chemotherapy | 98 | 66 | 32 | 11 | 3 | 1 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0



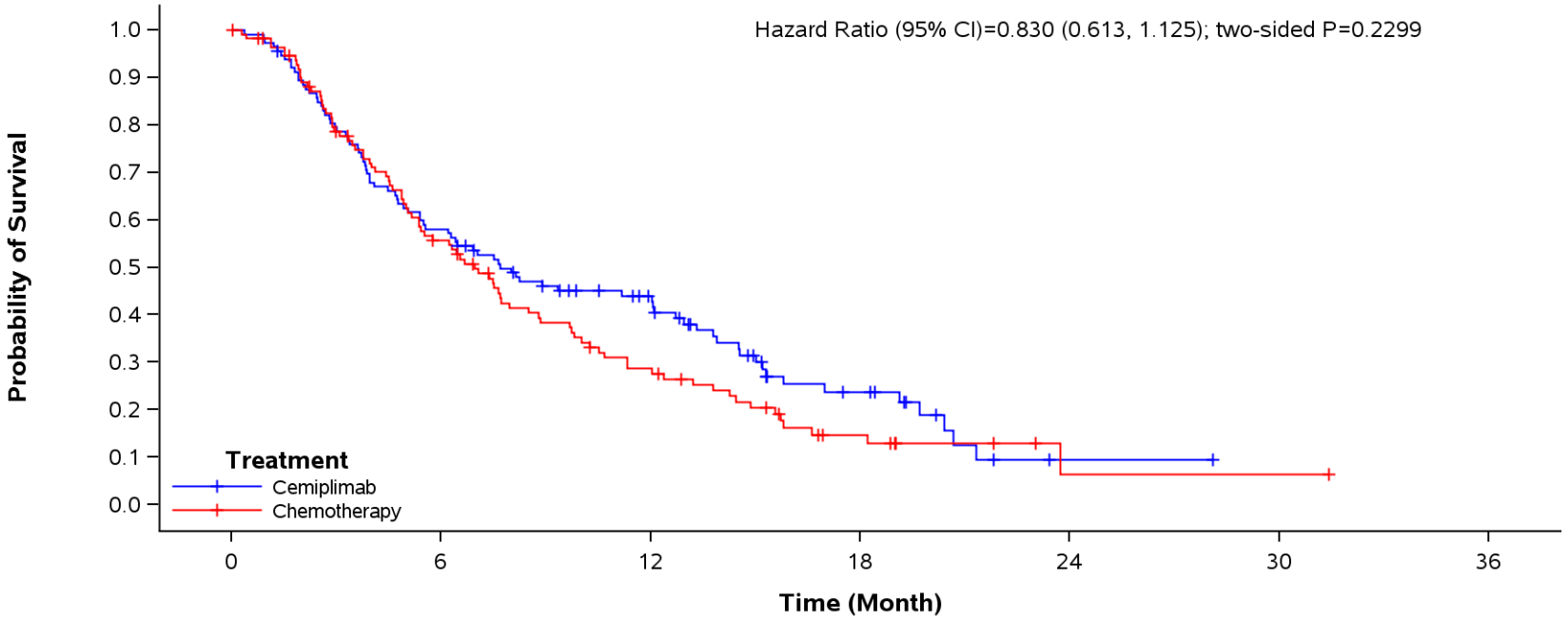

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 63 | 39 | 19 | 7 | 4 | 0 |
| Chemotherapy | 69 | 48 | 18 | 6 | 4 | 1 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1



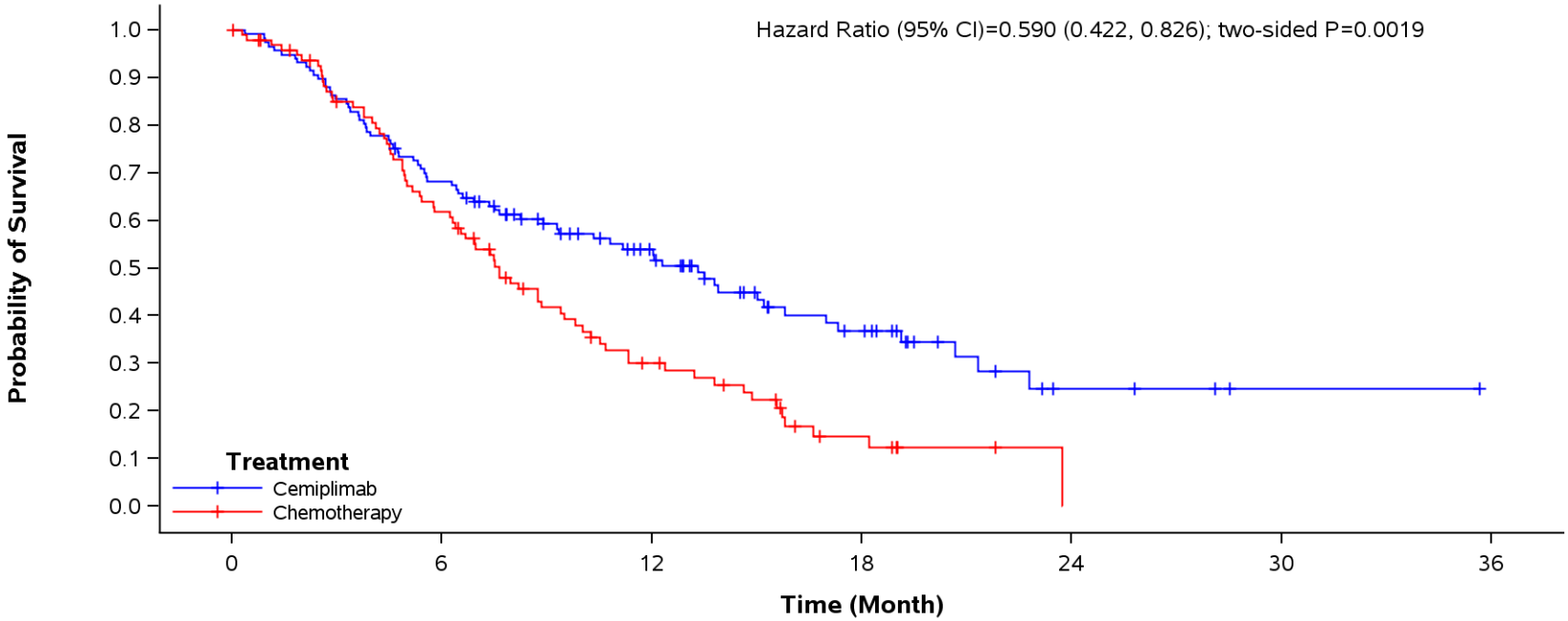

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 65 | 38 | 13 | 1 | 0 | 0 |
| Chemotherapy | 114 | 57 | 26 | 8 | 1 | 1 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line



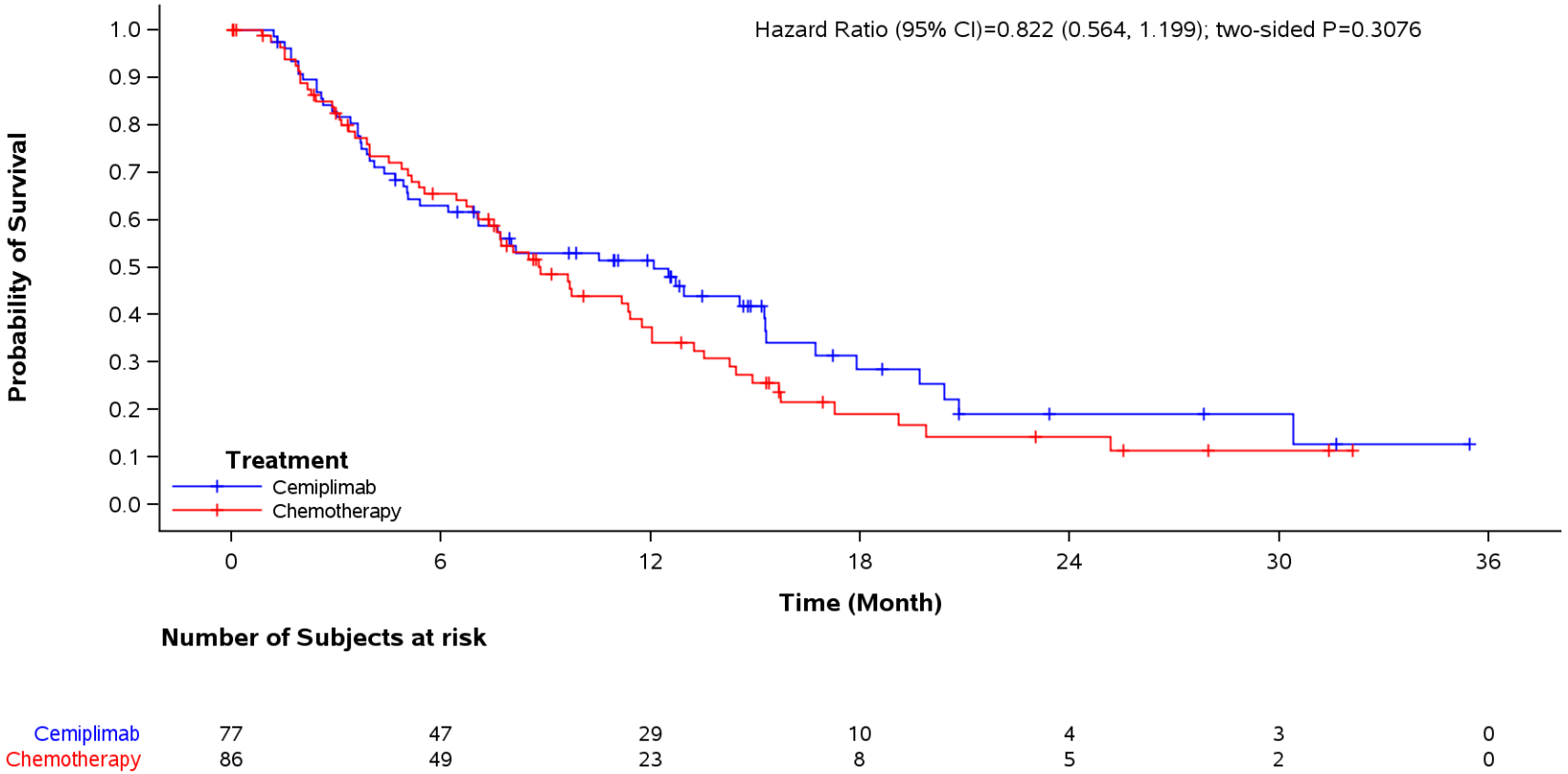

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 79 | 46 | 21 | 4 | 1 | 0 |
| Chemotherapy | 97 | 56 | 21 | 6 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

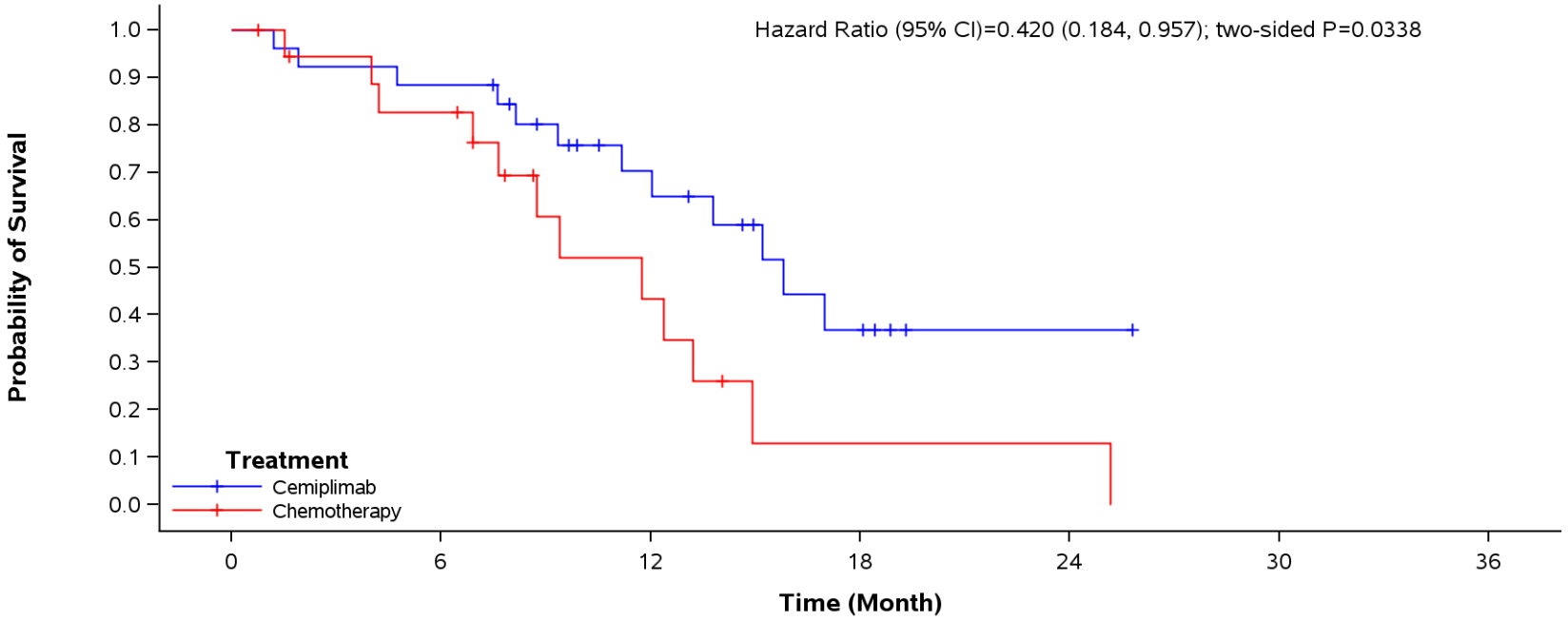
Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



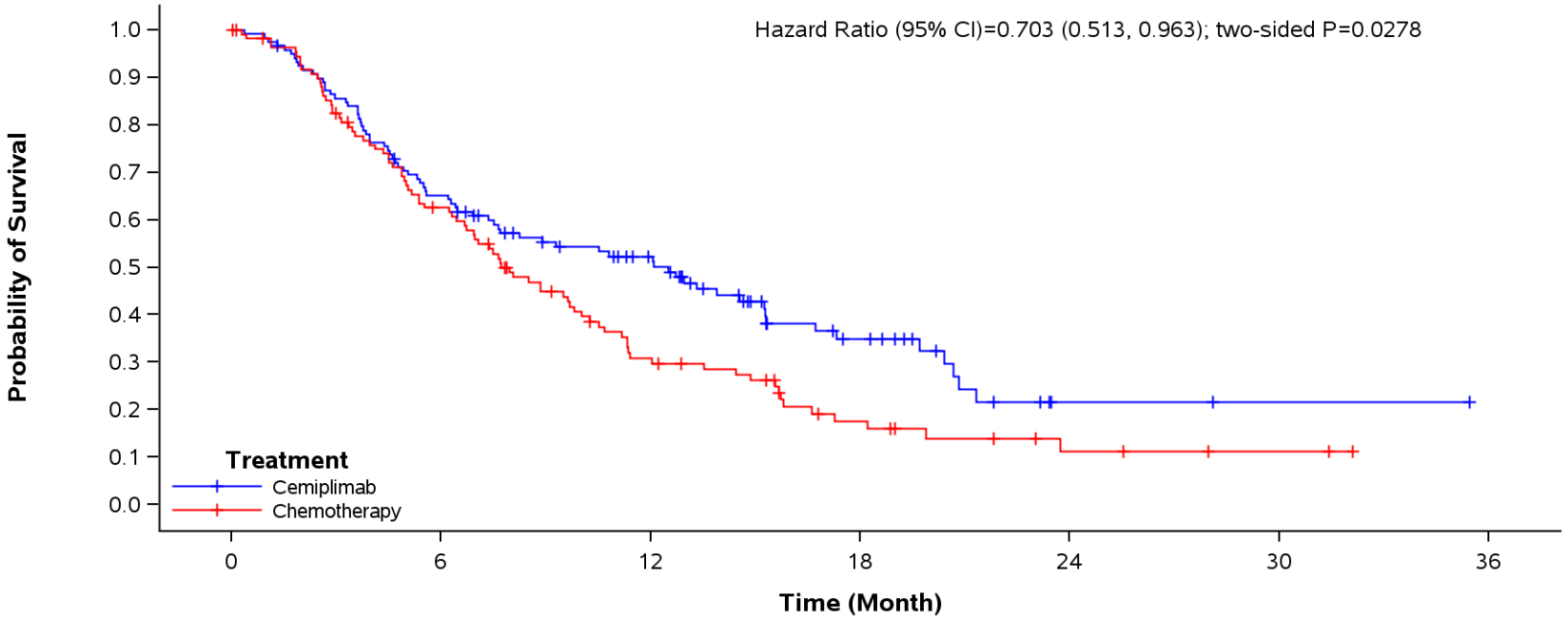

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 23 | 13 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 14 | 5 | 1 | 1 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed



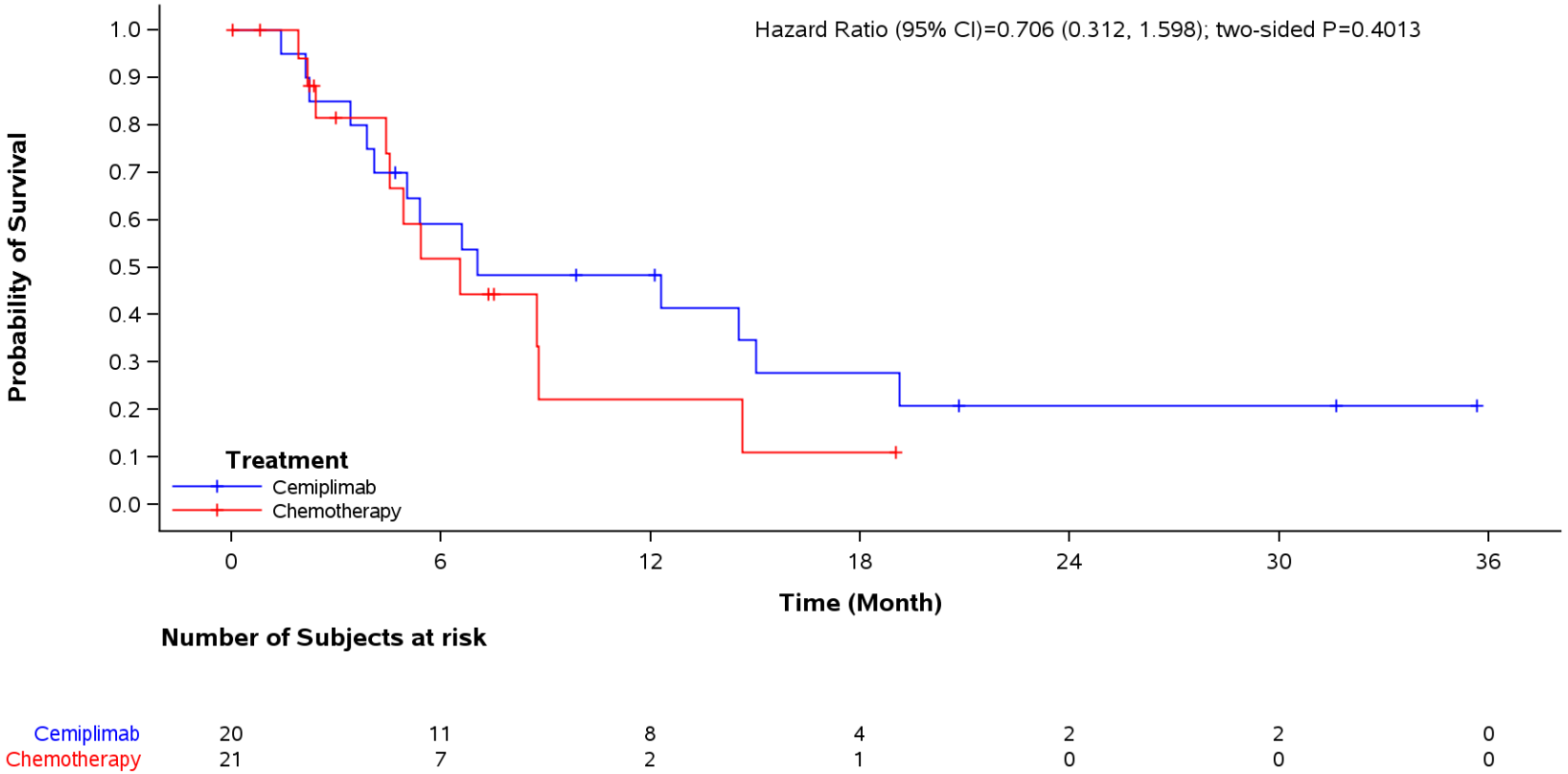

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 76 | 48 | 19 | 2 | 1 | 0 |
| Chemotherapy | 111 | 65 | 28 | 11 | 4 | 2 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan



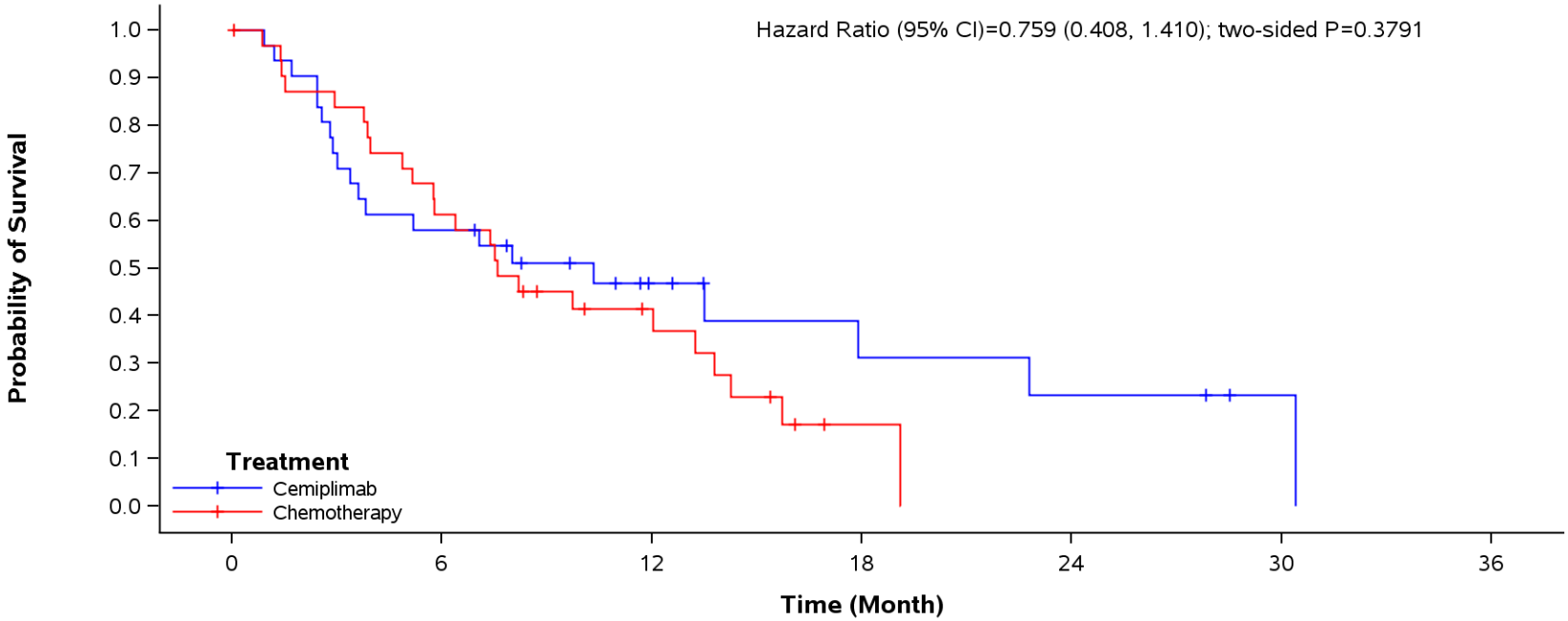

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 11 | 8 | 4 | 2 | 2 | 0 |
| Chemotherapy | 21 | 7 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine



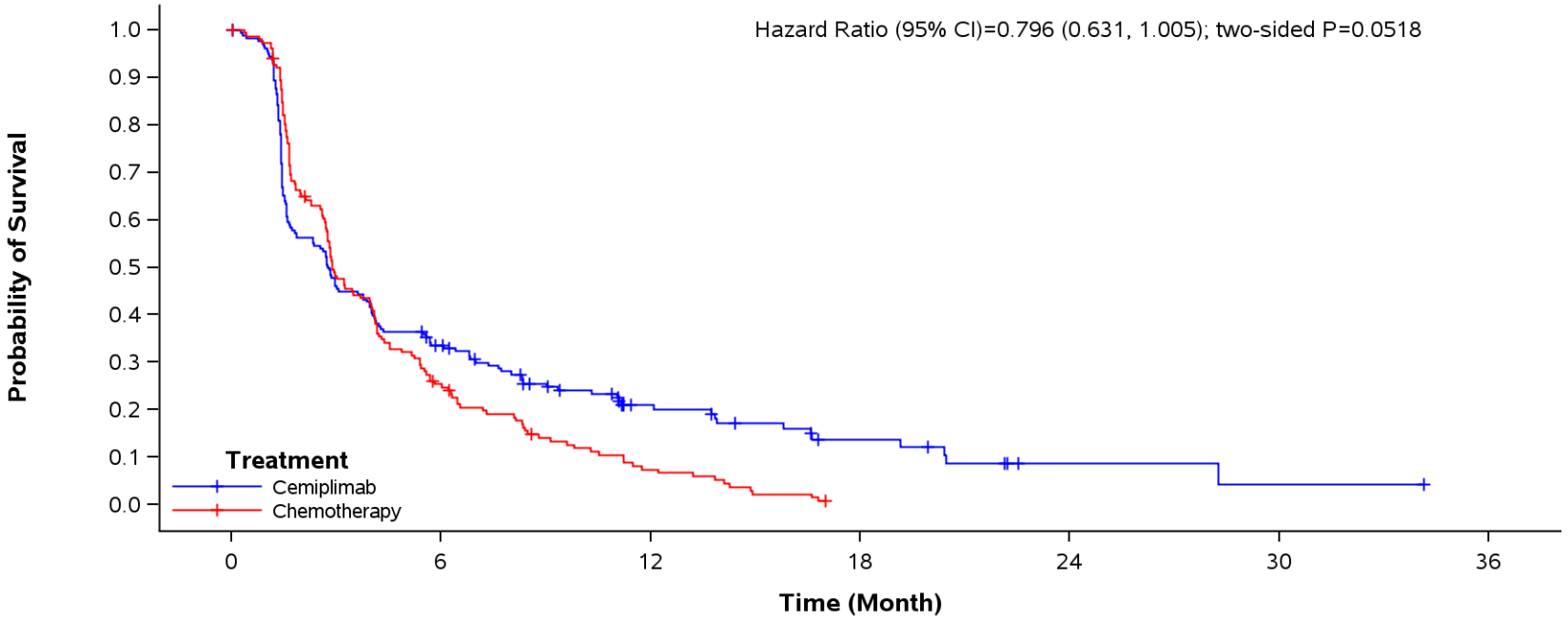

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 18 | 8 | 4 | 3 | 1 | 0 |
| Chemotherapy | 32 | 19 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



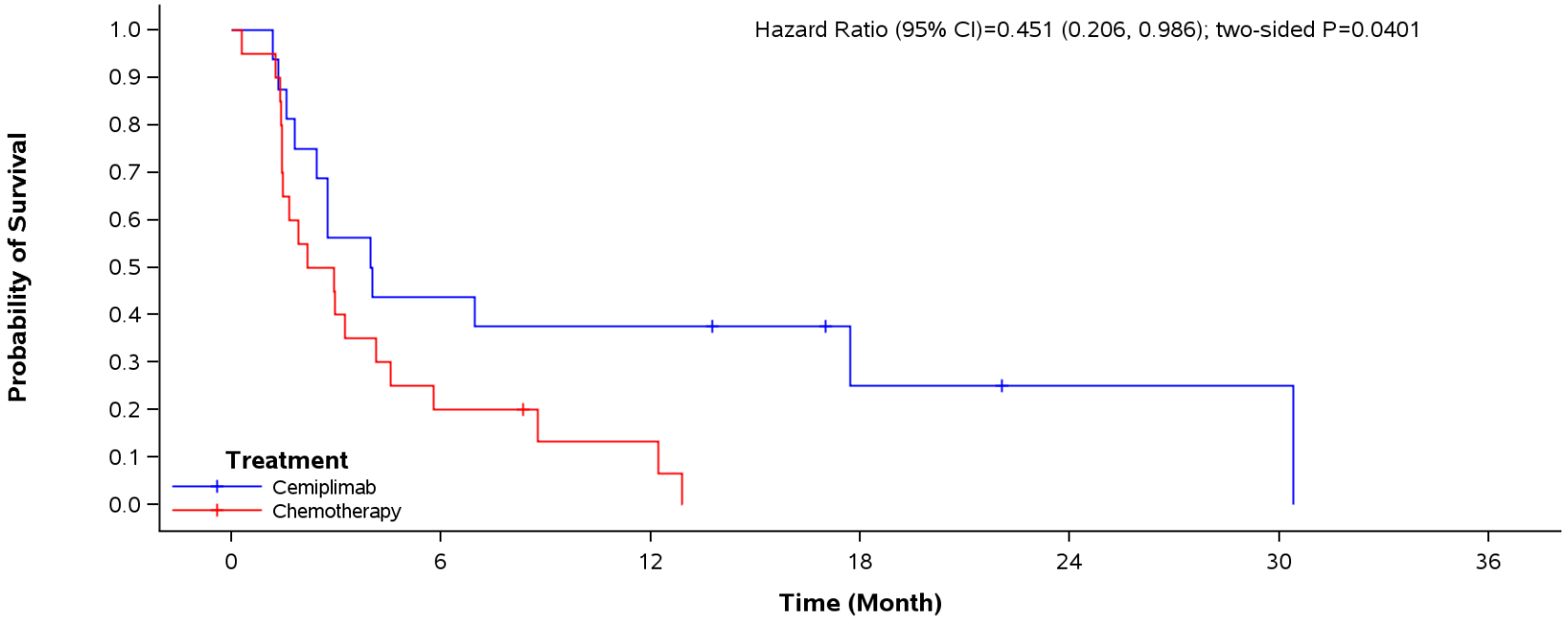

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 57 | 22 | 9 | 2 | 1 | 0 |
| Chemotherapy | 163 | 37 | 10 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



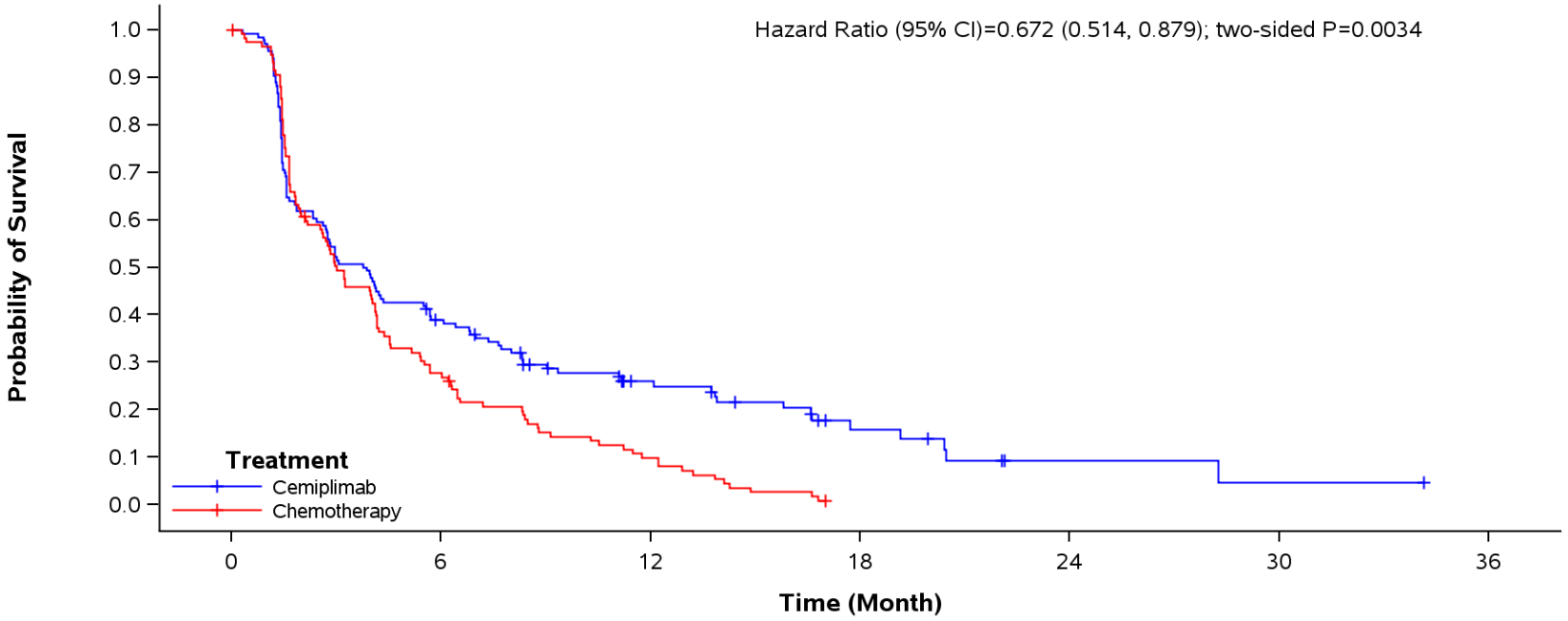

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 6 | 2 | 1 | 1 | 0 |
| Chemotherapy | 20 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



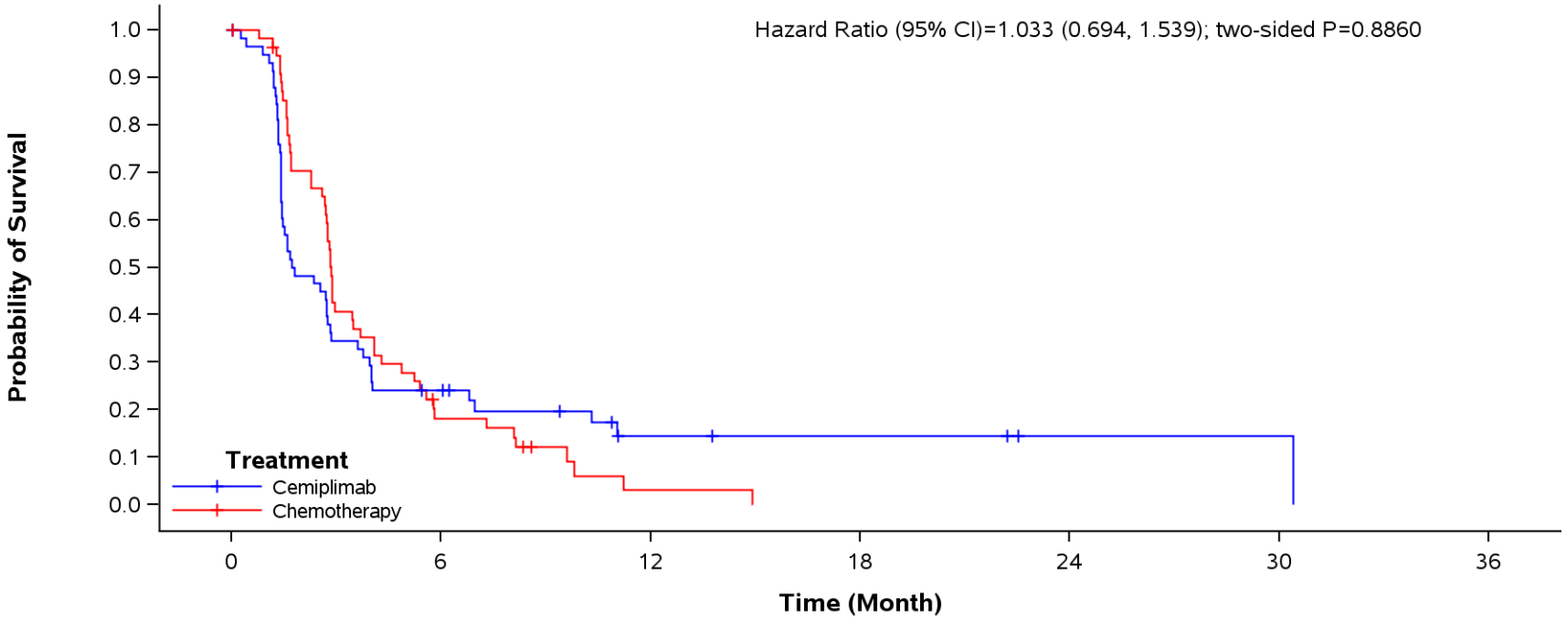

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 51 | 24 | 8 | 2 | 1 | 0 |
| Chemotherapy | 123 | 32 | 11 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



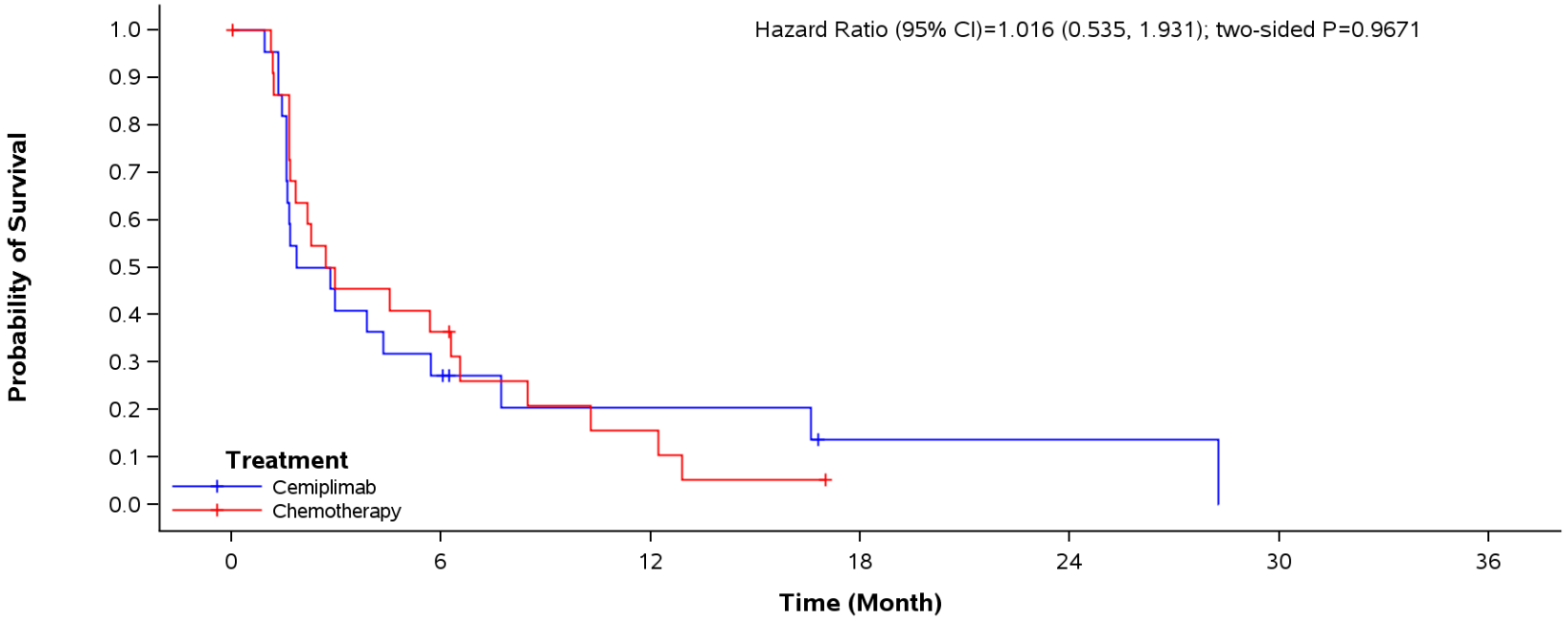

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 4 | 3 | 1 | 1 | 0 |
| Chemotherapy | 60 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America



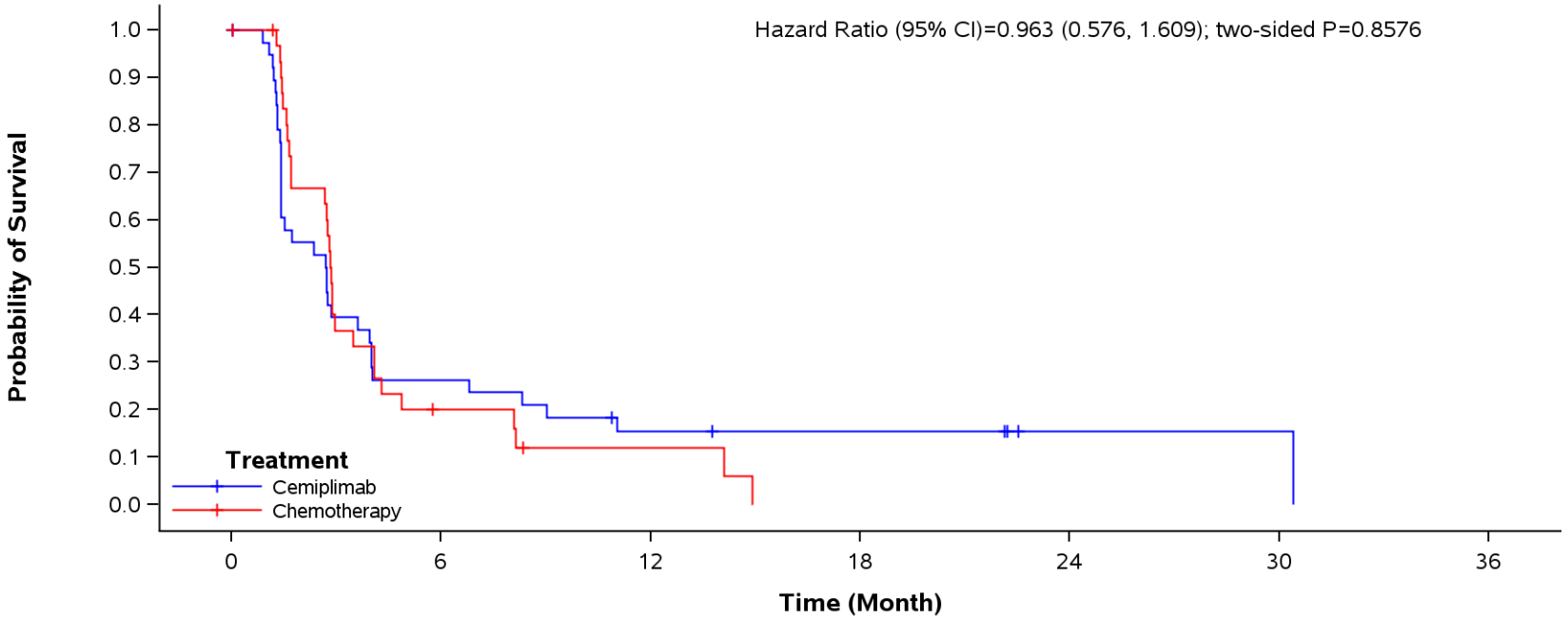

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 25 | 8 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia



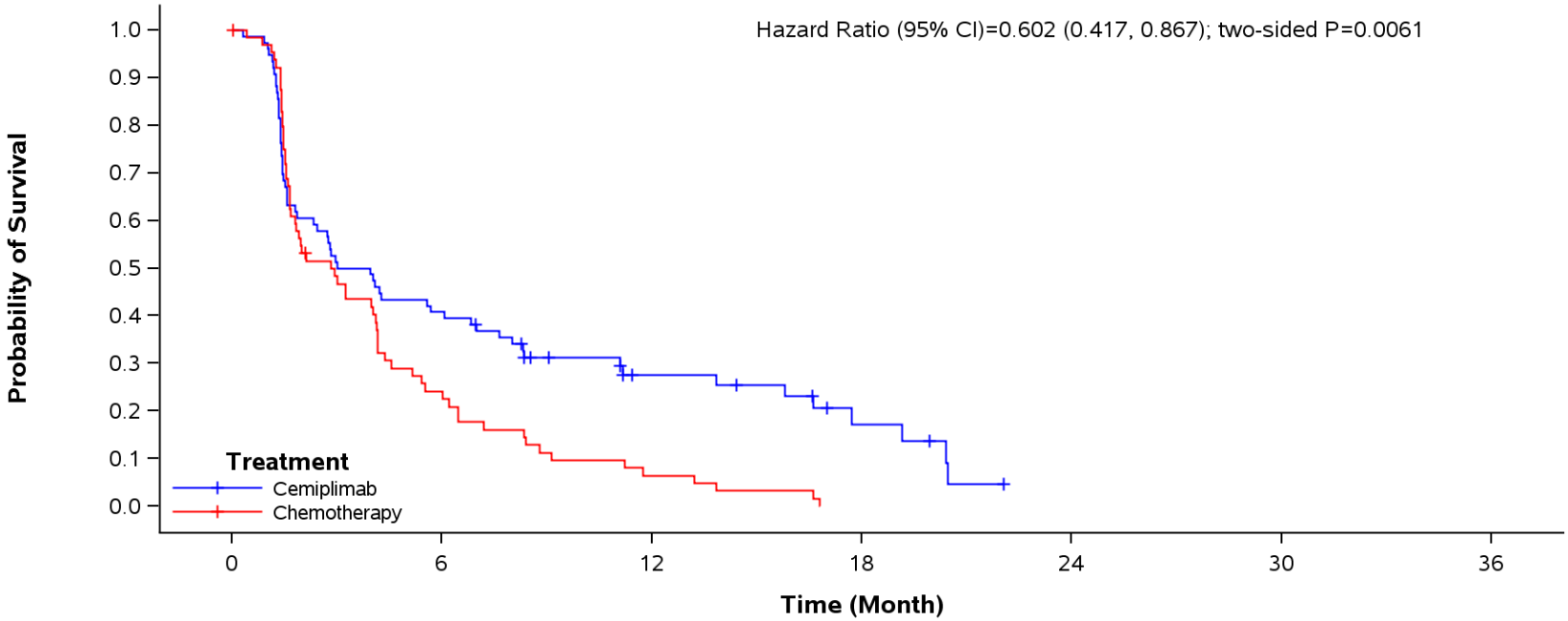

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 5 | 4 | 1 | 1 | 0 |
| Chemotherapy | 36 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



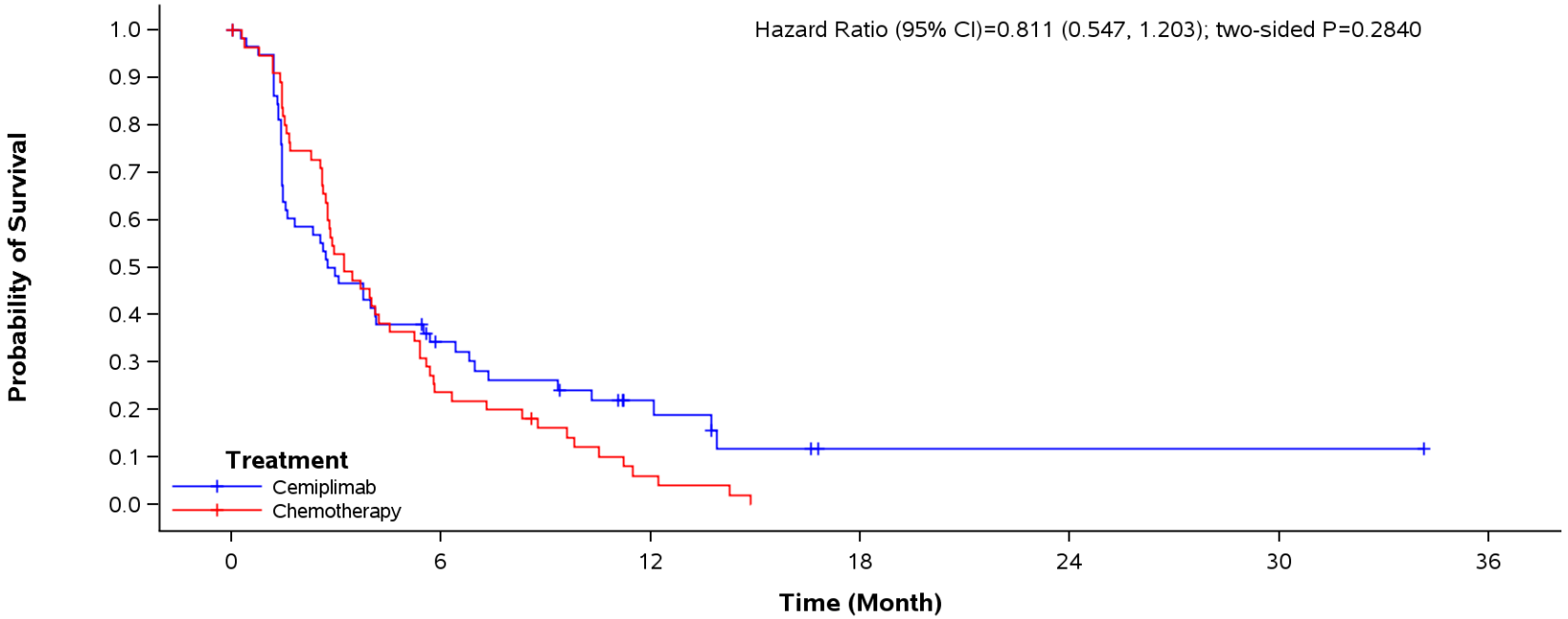

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 13 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW



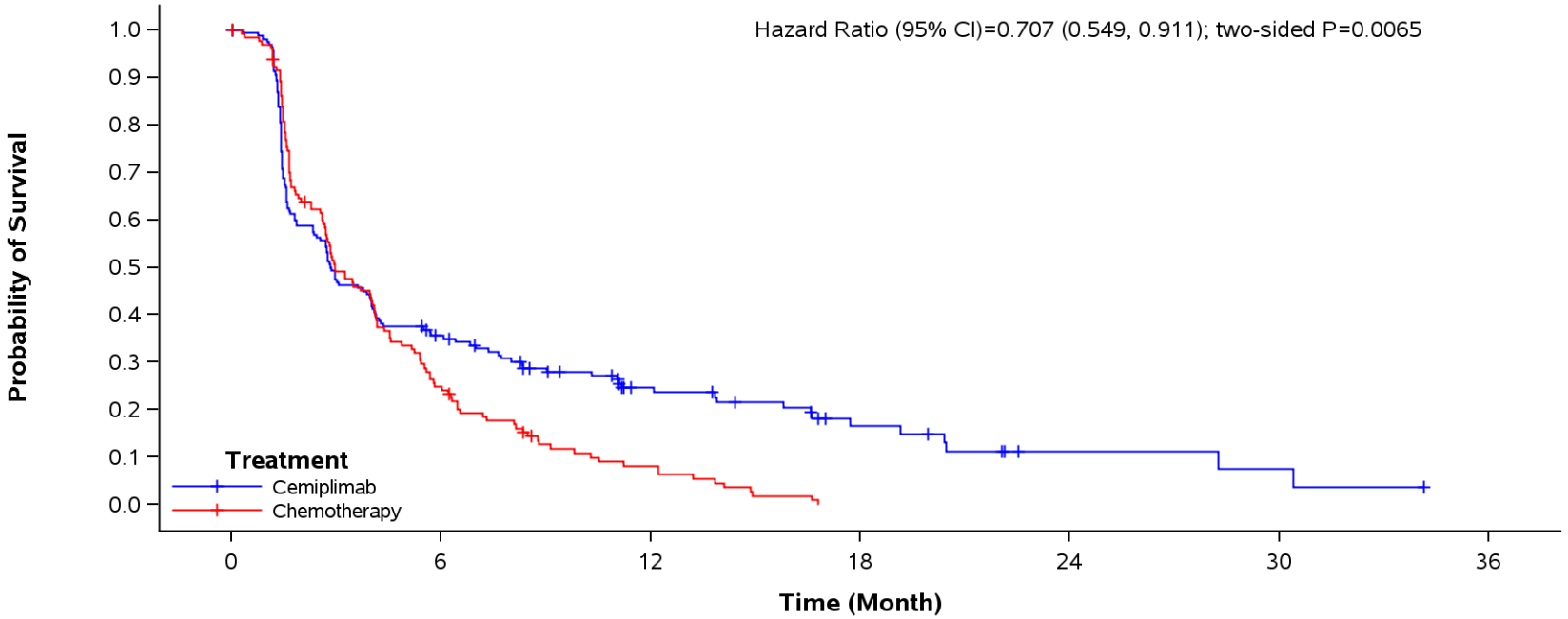

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 17 | 7 | 1 | 1 | 1 | 0 |
| Chemotherapy | 56 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous



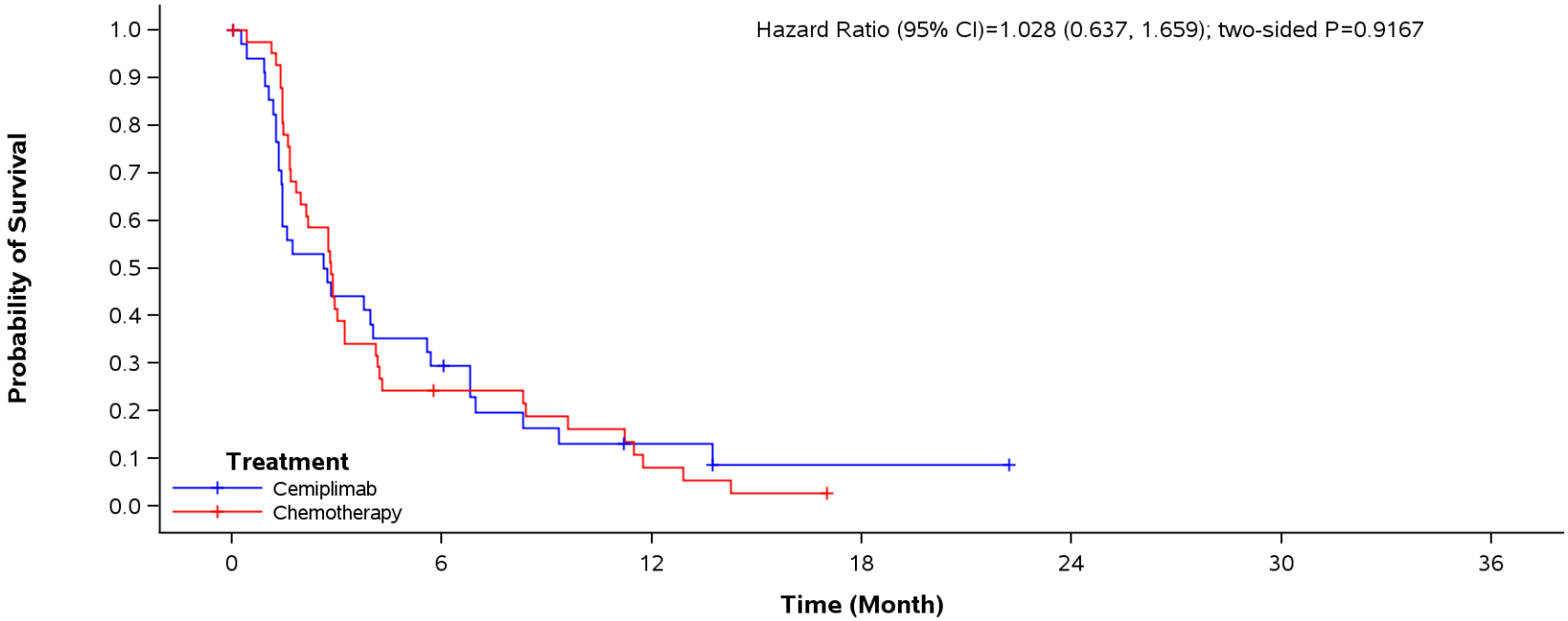

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 54 | 25 | 10 | 3 | 2 | 0 |
| Chemotherapy | 137 | 32 | 9 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



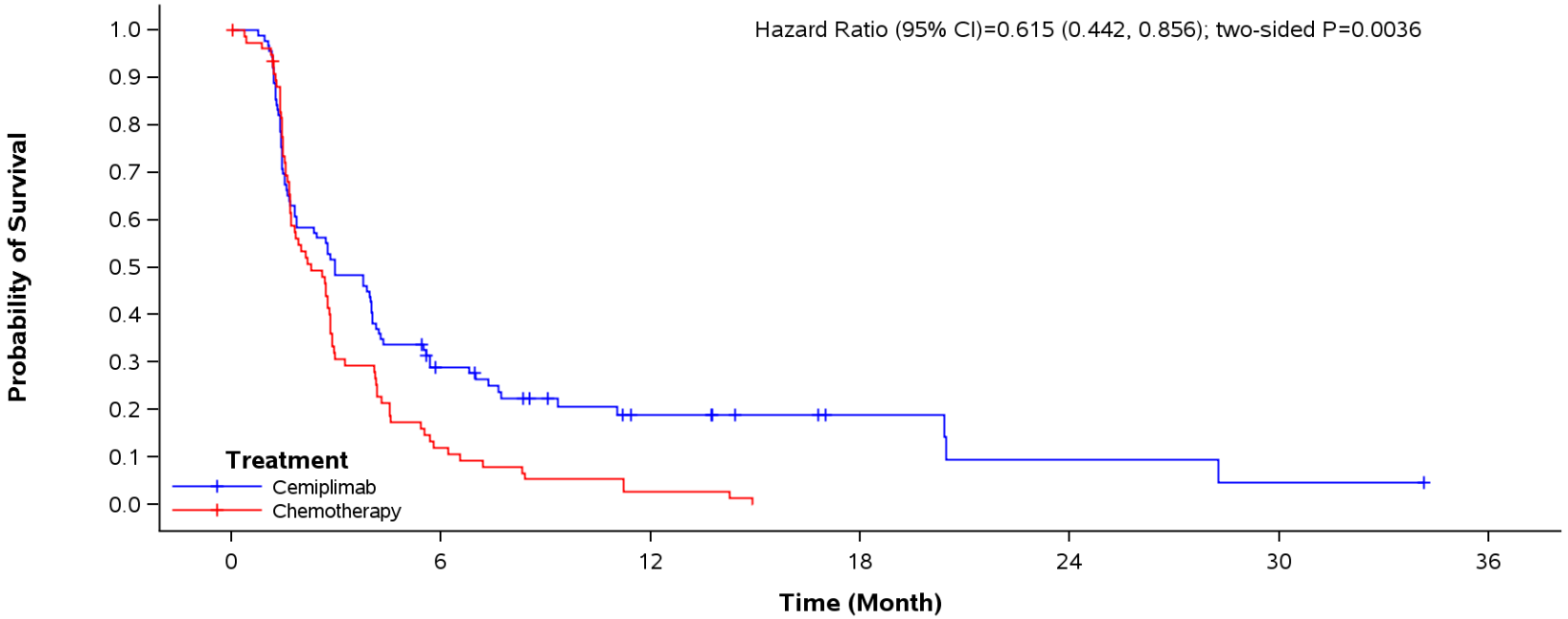

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes



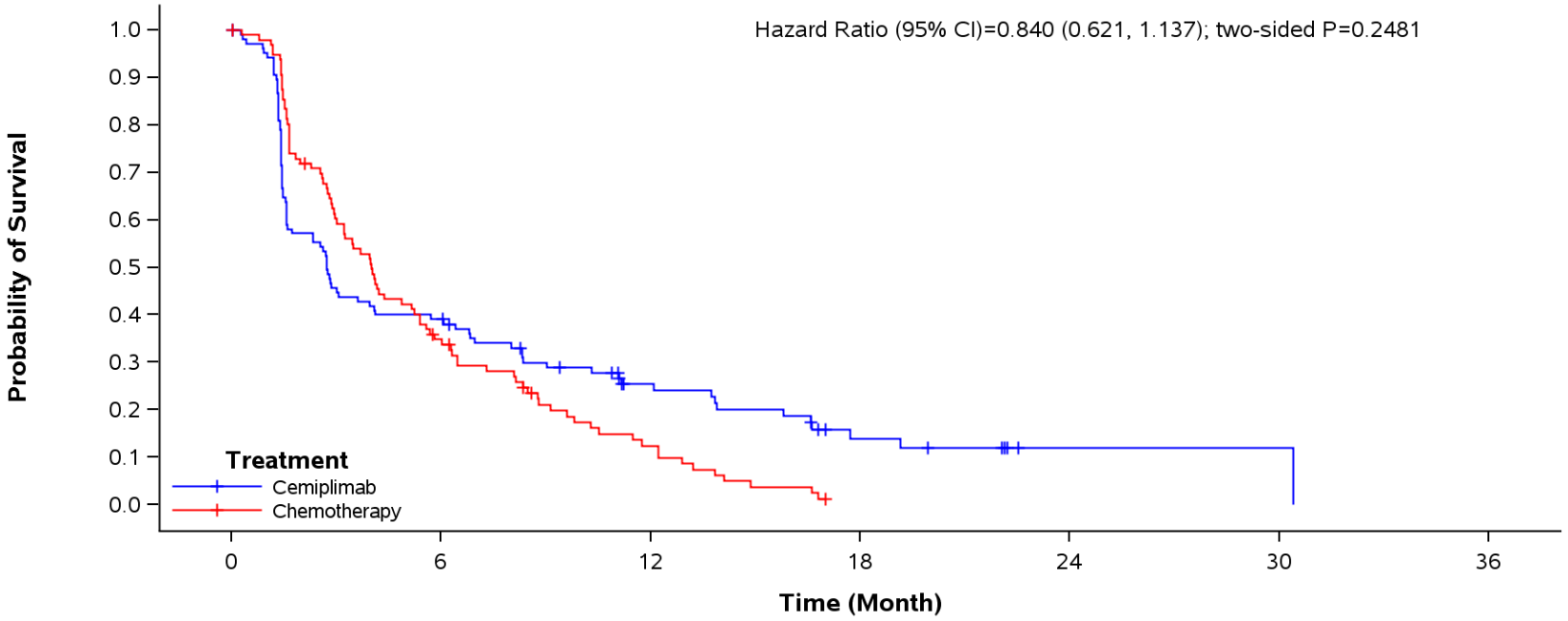

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 23 | 9 | 4 | 2 | 1 | 0 |
| Chemotherapy | 85 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No



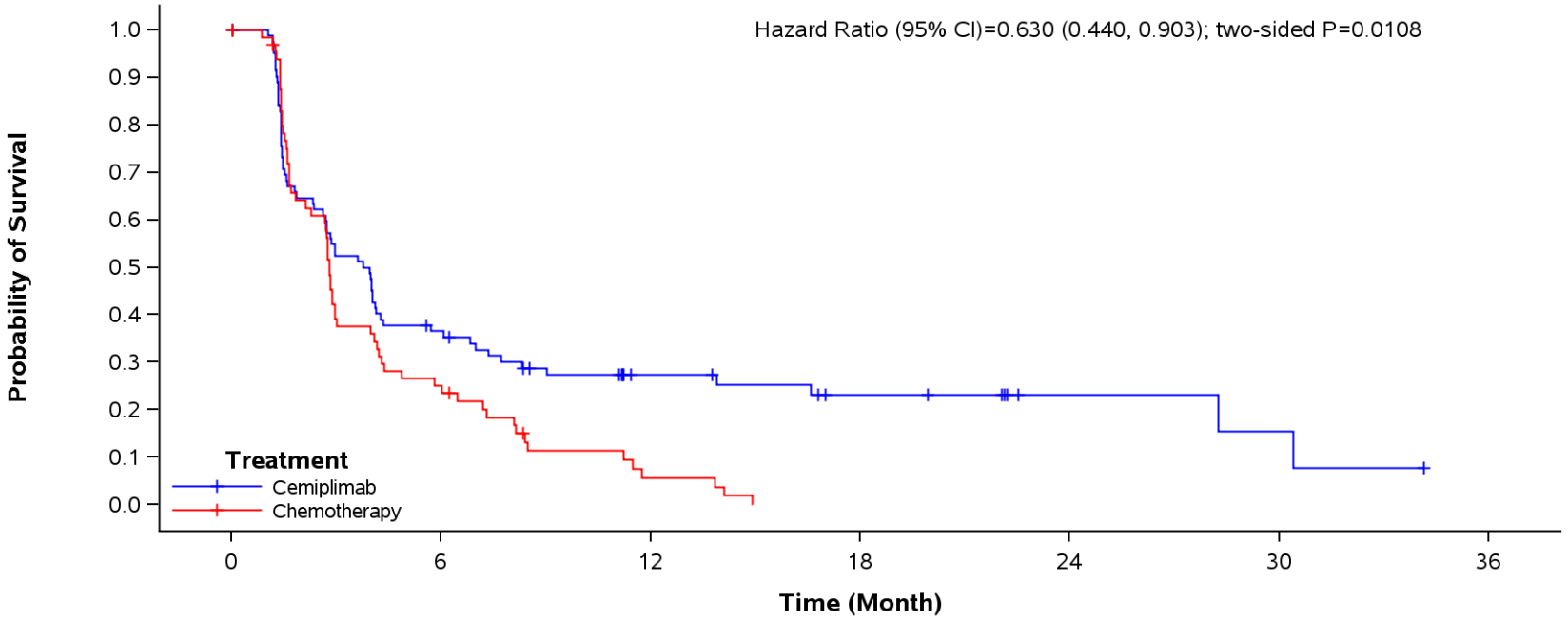

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 41 | 19 | 7 | 1 | 1 | 0 |
| Chemotherapy | 98 | 32 | 10 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0



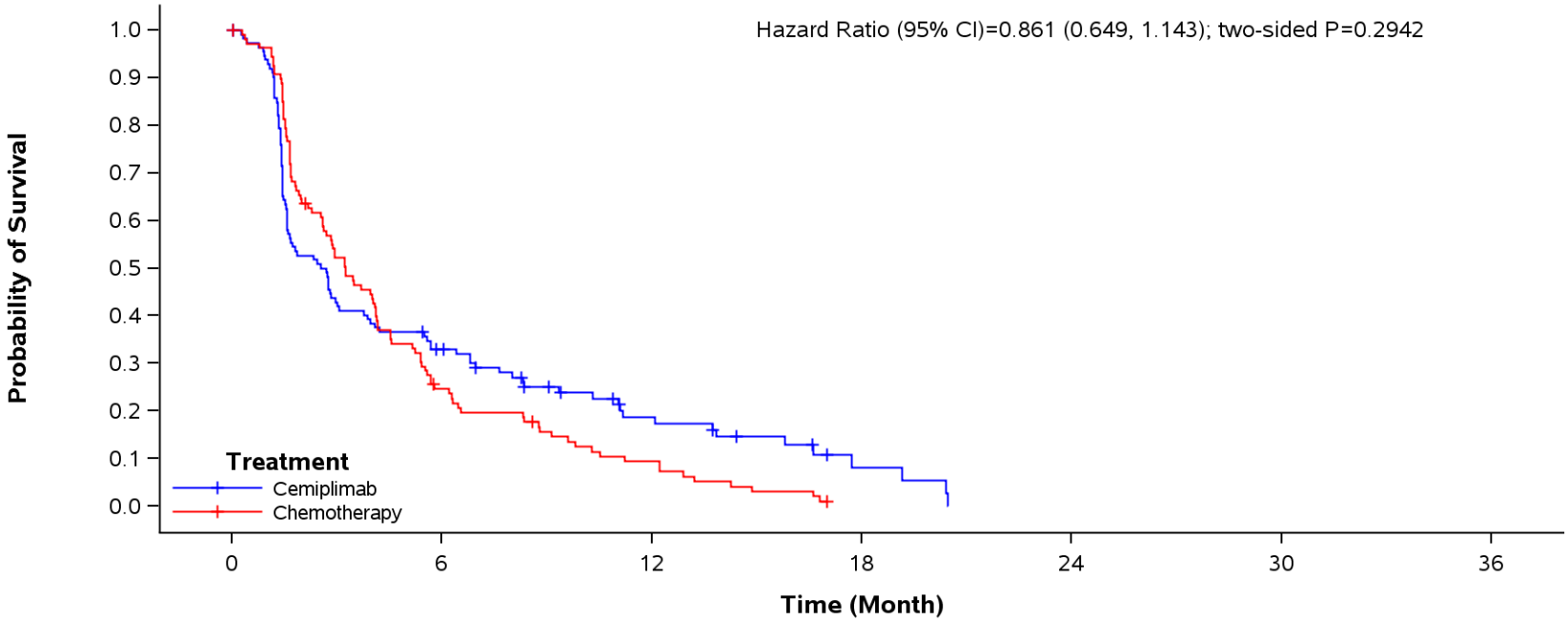

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 29 | 14 | 8 | 3 | 2 | 0 |
| Chemotherapy | 69 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1



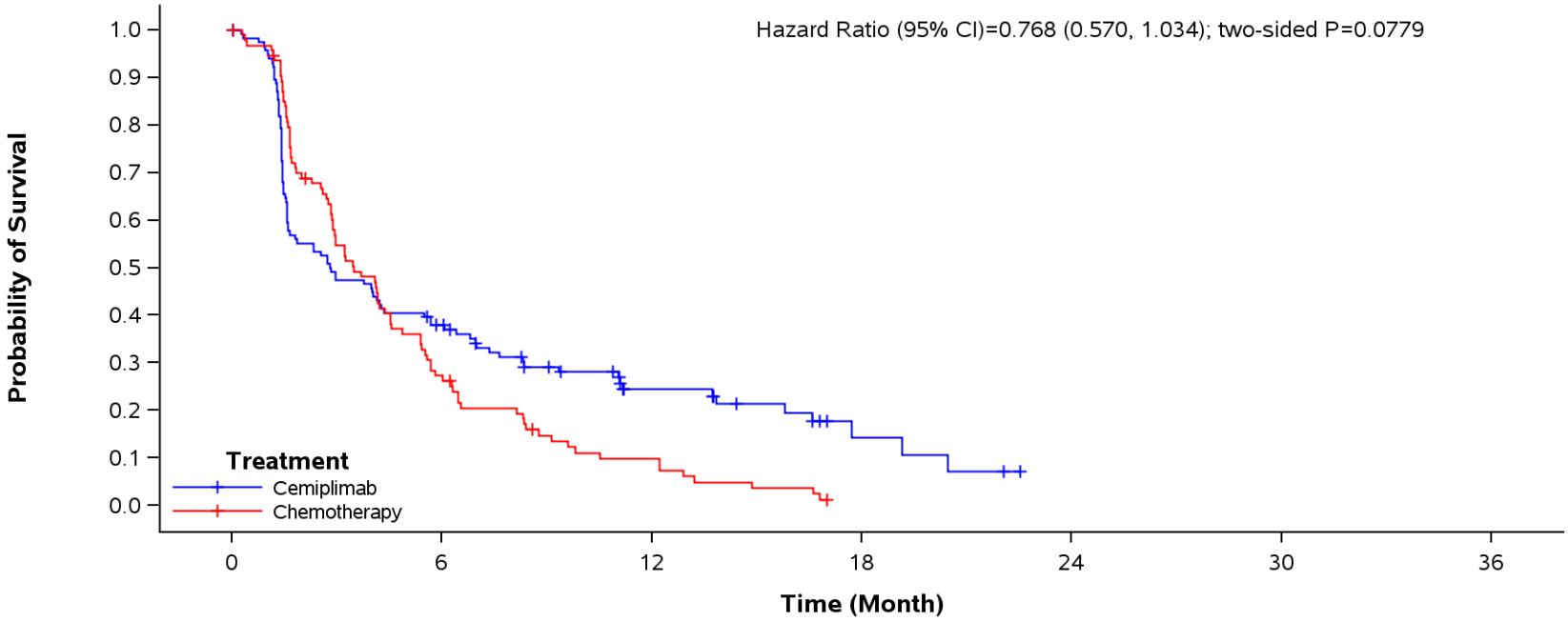

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 35 | 14 | 3 | 0 | 0 | 0 |
| Chemotherapy | 114 | 25 | 9 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line



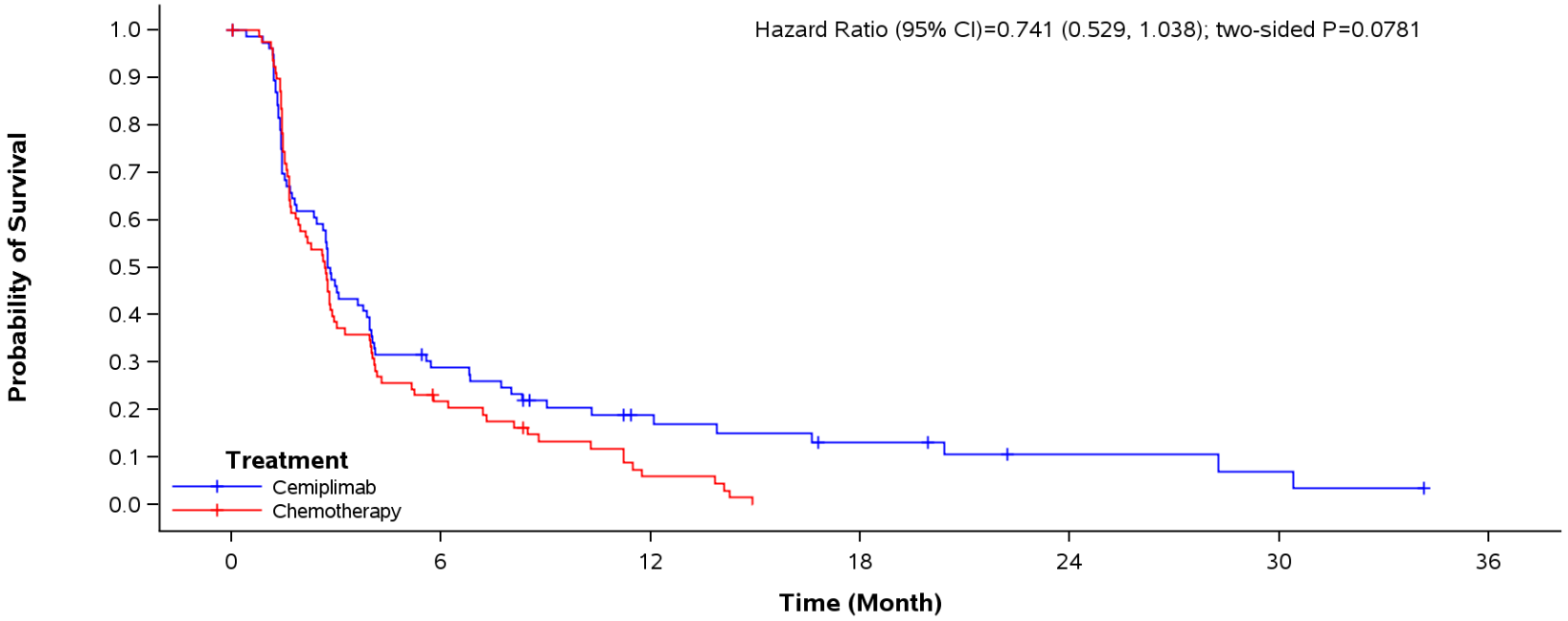

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 42 | 17 | 4 | 0 | 0 | 0 |
| Chemotherapy | 97 | 25 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line



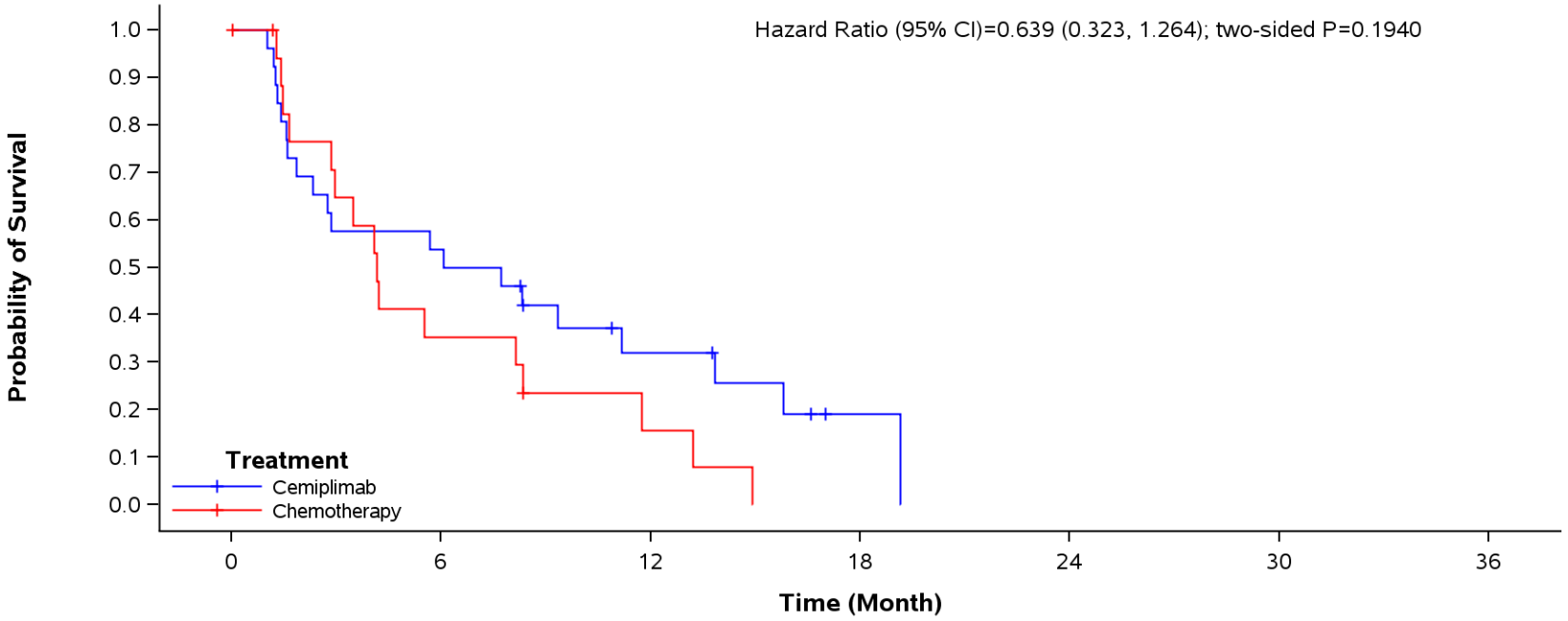

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 21 | 10 | 6 | 3 | 2 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



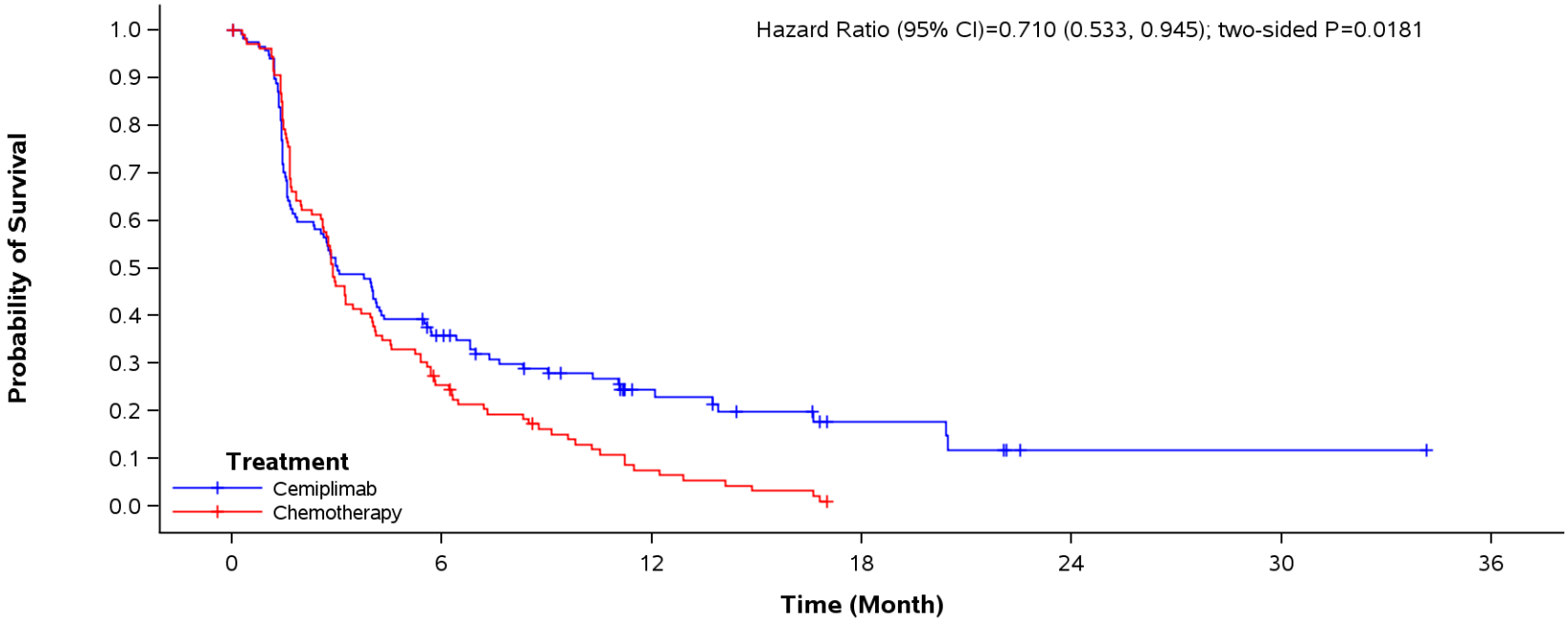

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed



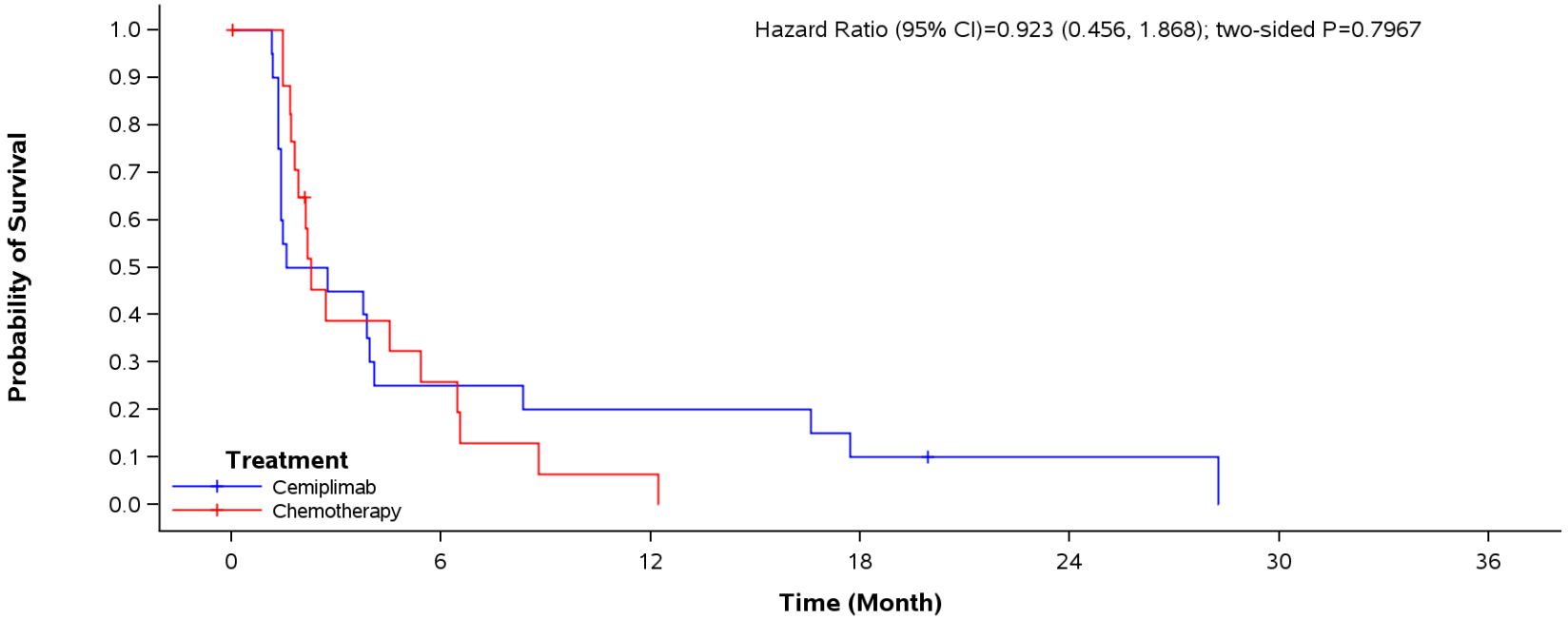

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 39 | 16 | 6 | 1 | 1 | 0 |
| Chemotherapy | 111 | 26 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan



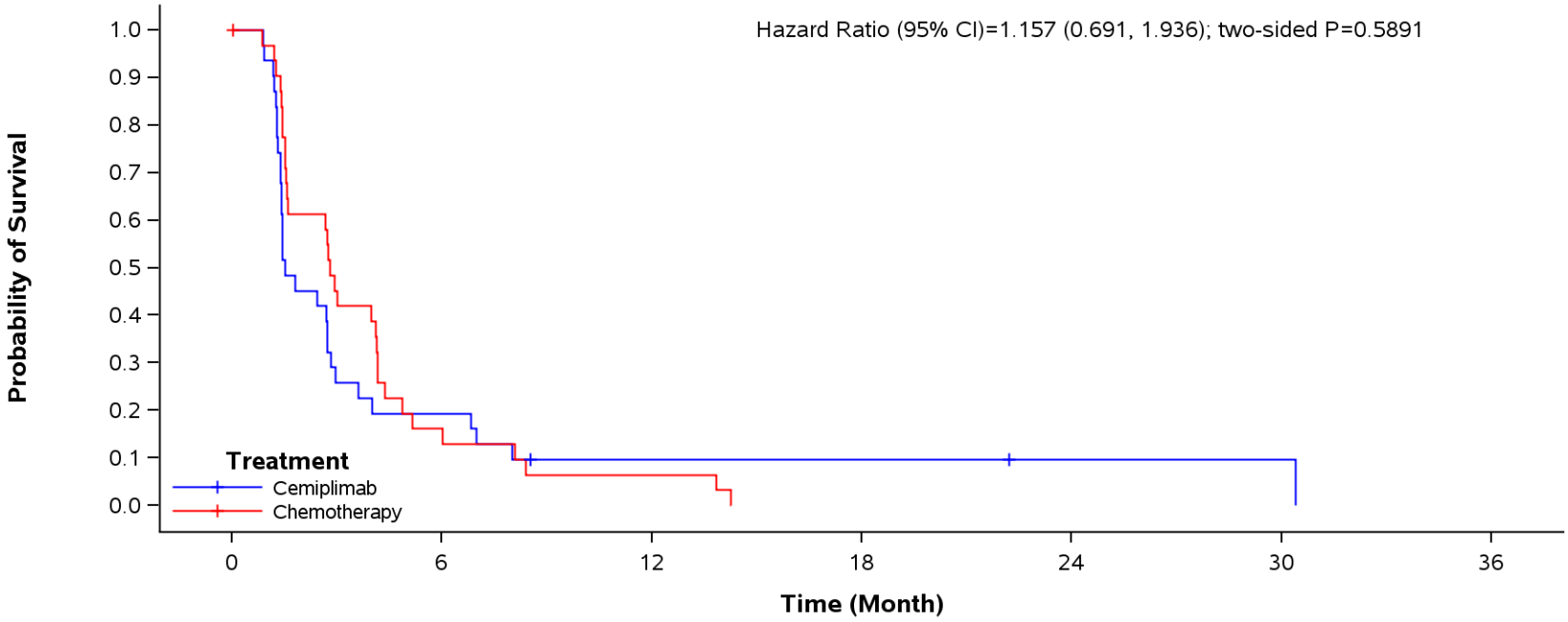

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.2. Kaplan Meier Cumulative Incidence Curve for Progression-free Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine



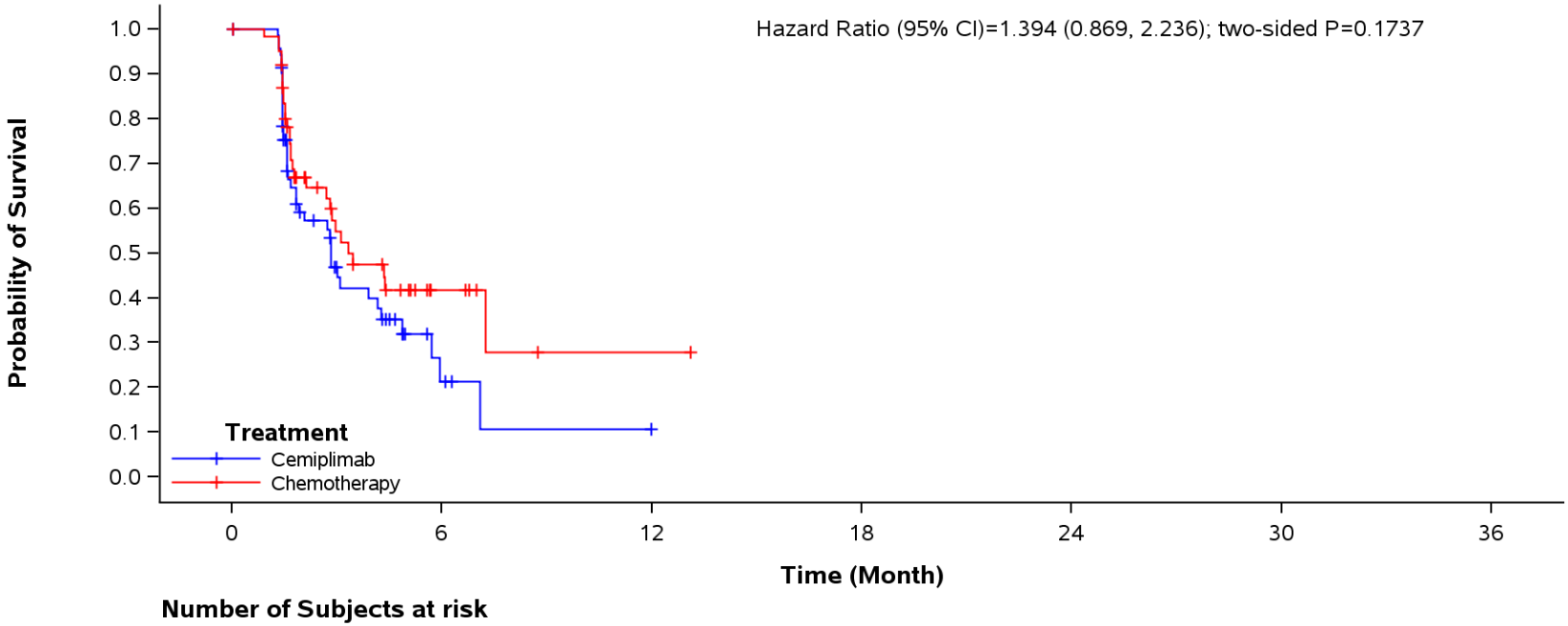

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 2 | 2 | 1 | 1 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts improvement



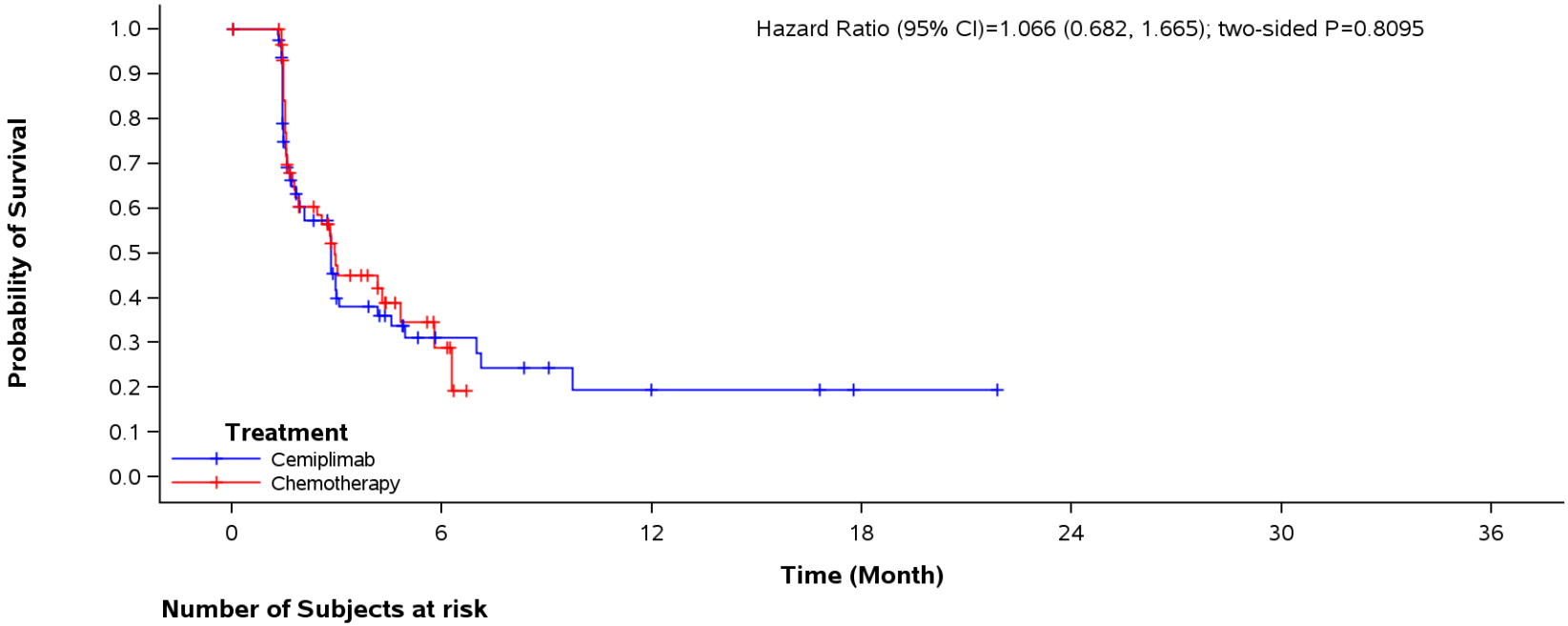

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 163 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts improvement



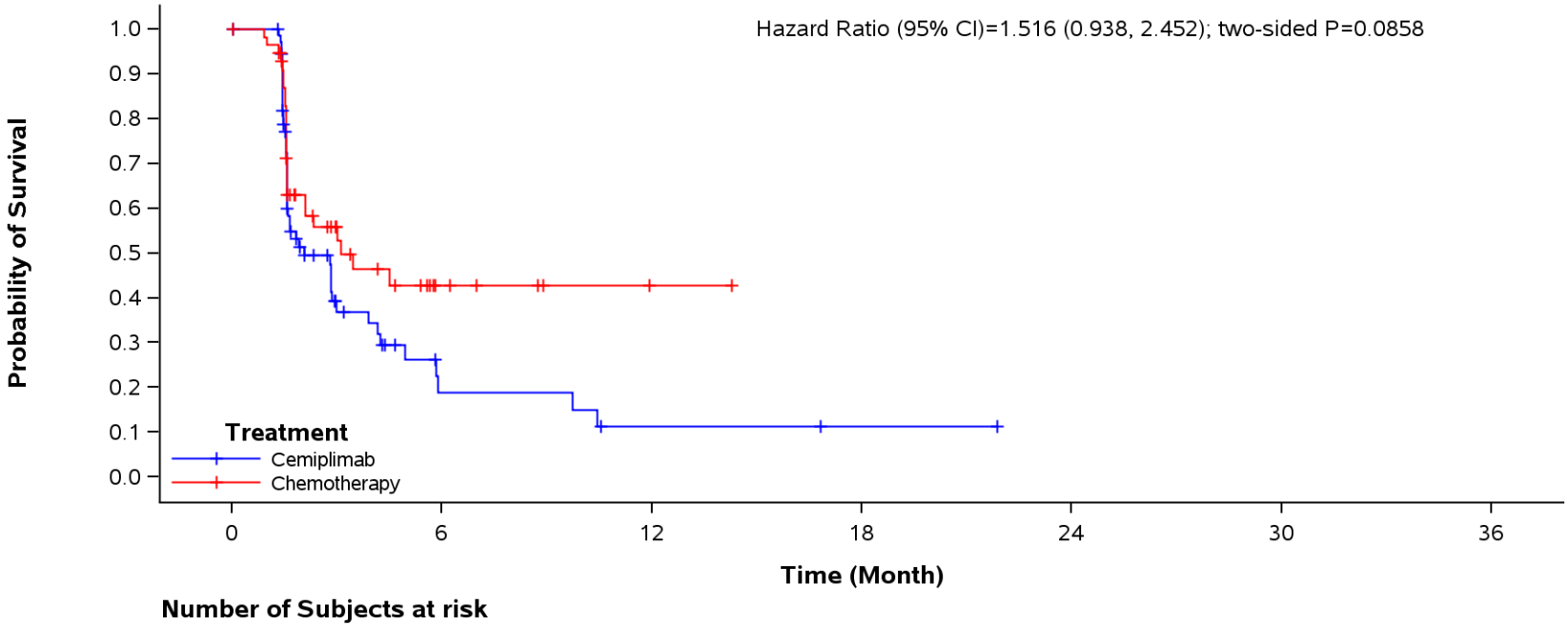

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 9 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 163 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts improvement



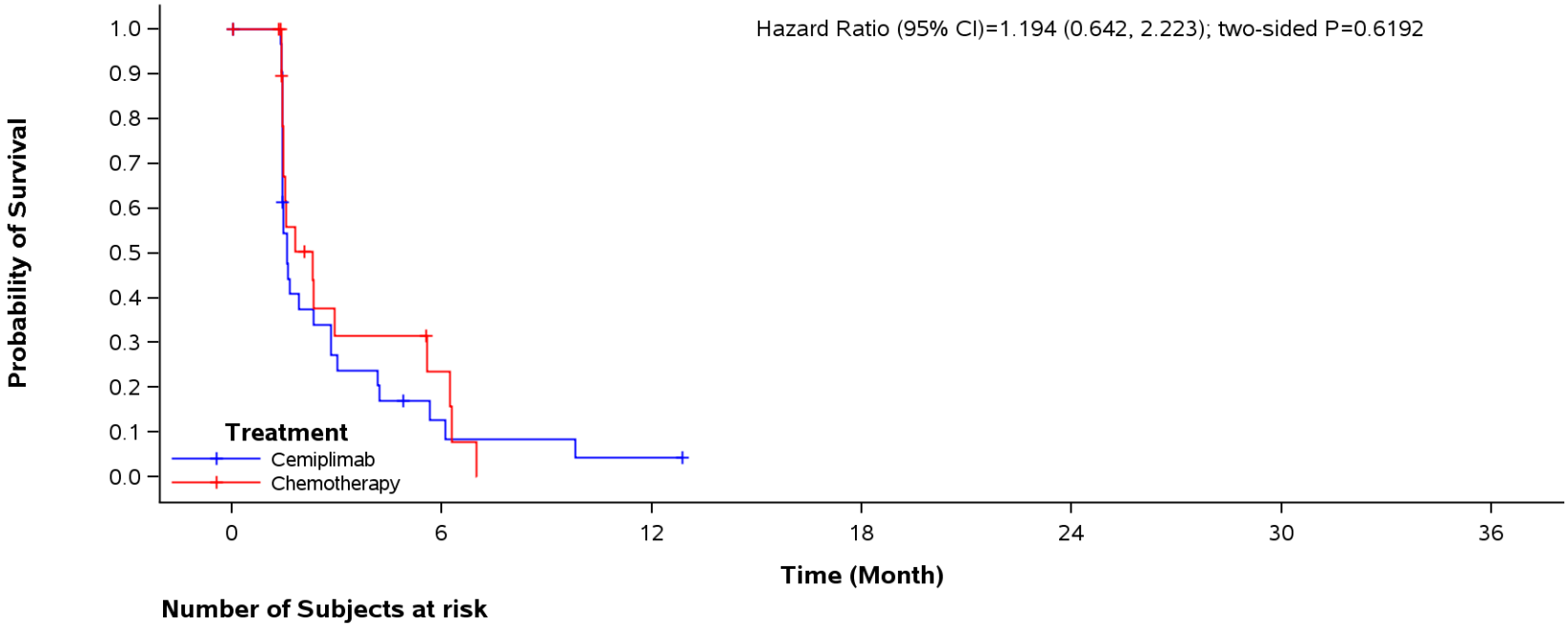

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 5 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 163 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts improvement



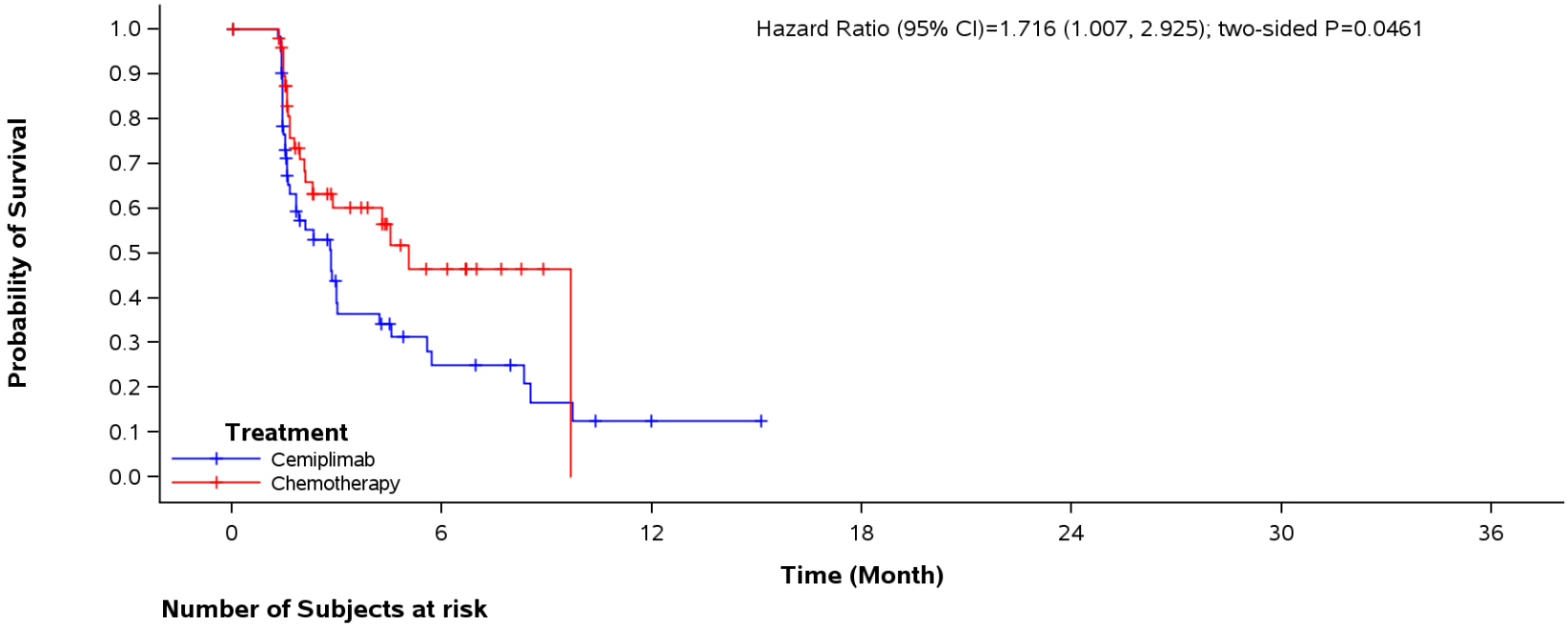

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 163 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts improvement



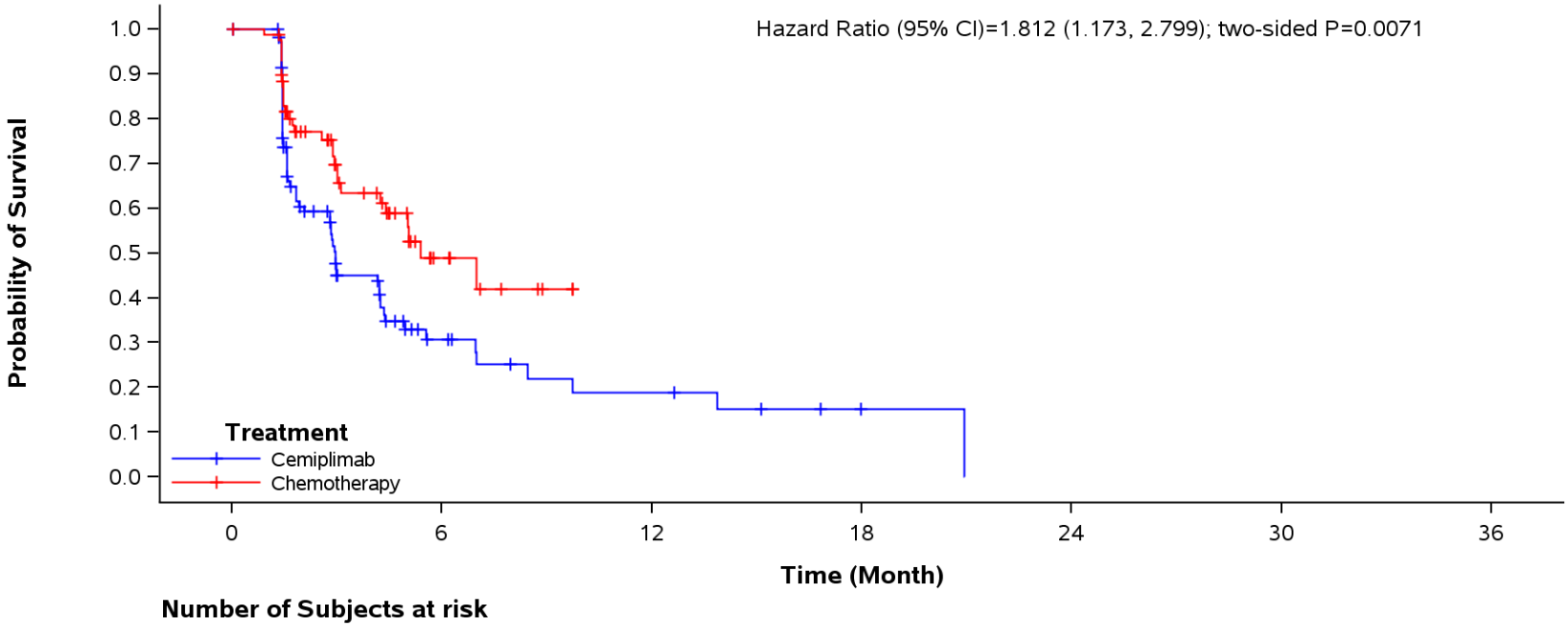

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 8 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 163 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts improvement



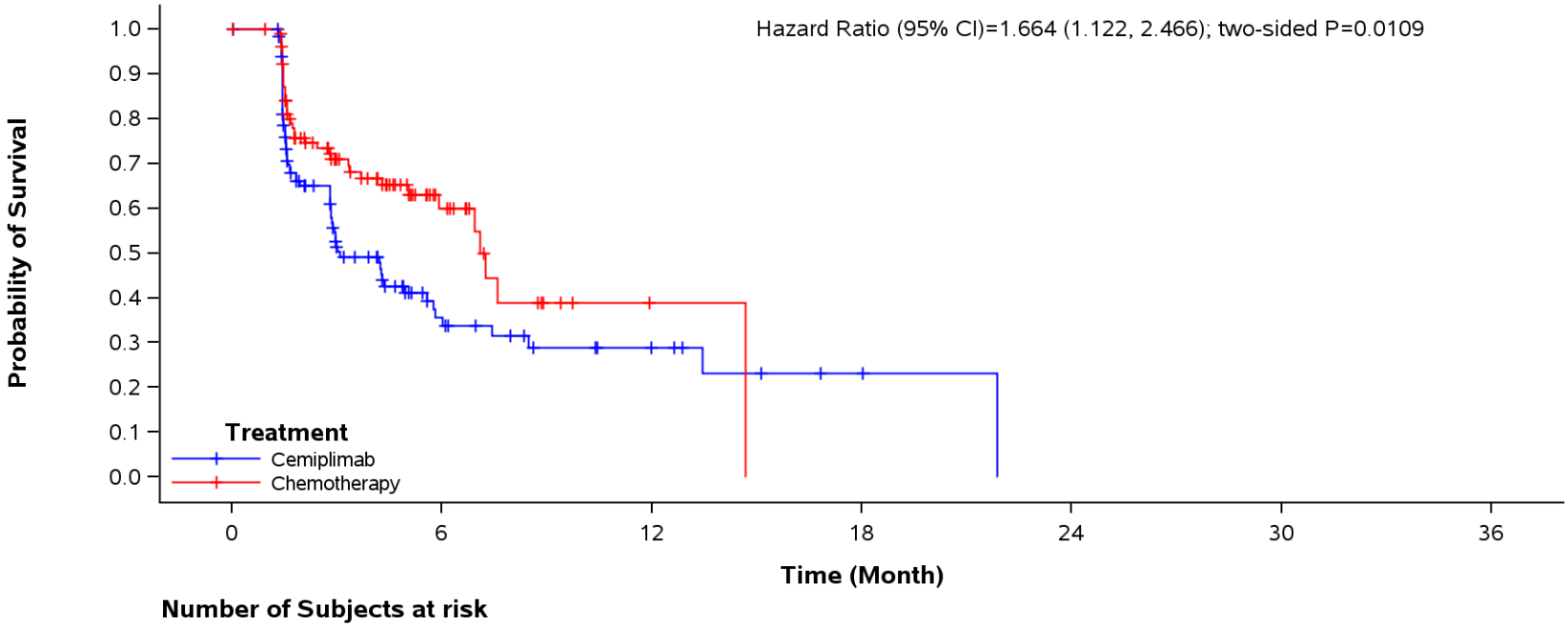

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 13 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 163 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts improvement



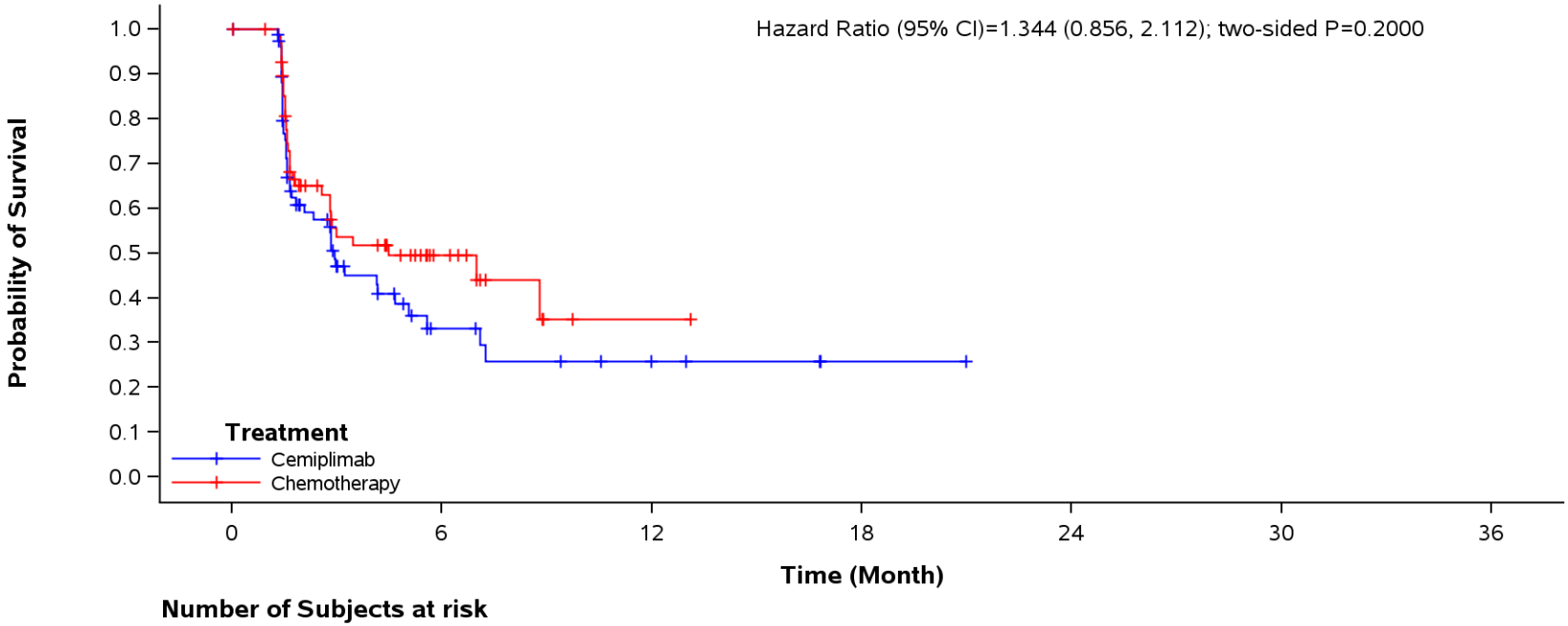

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 19 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 163 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts improvement



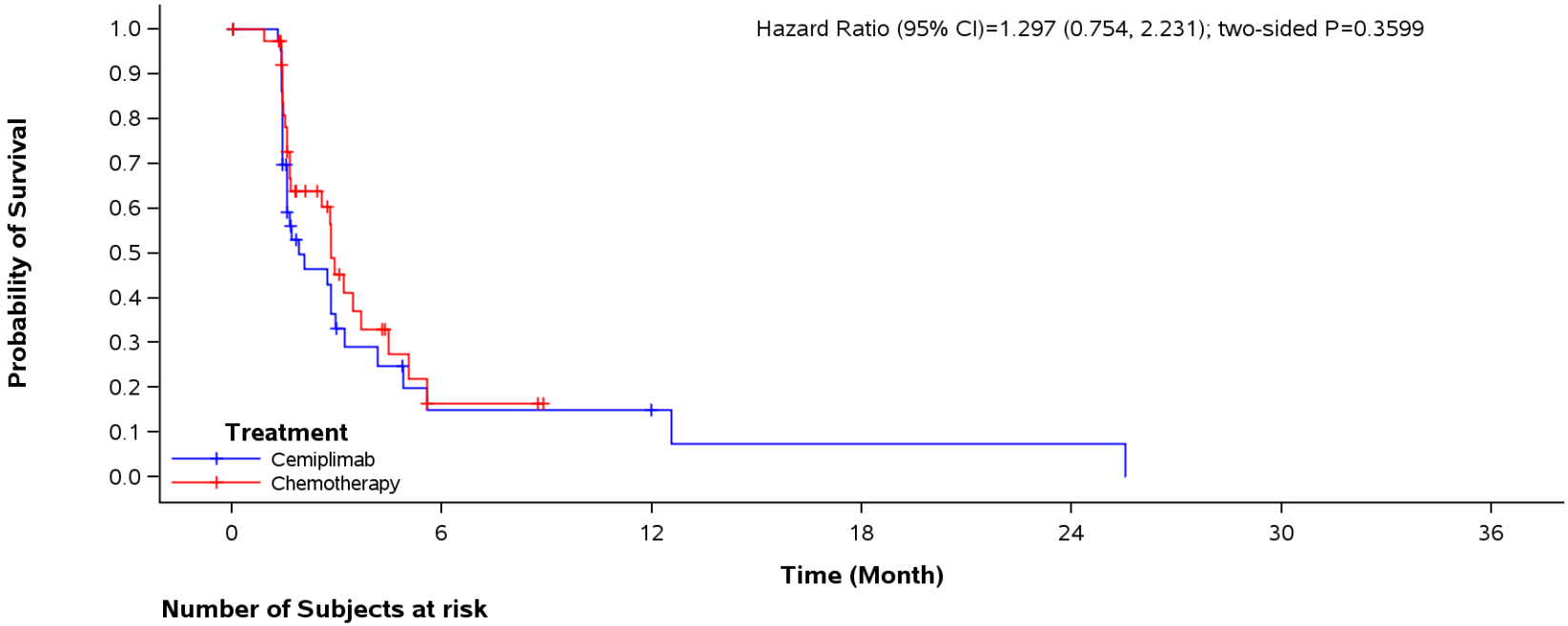

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 10 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 163 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts improvement



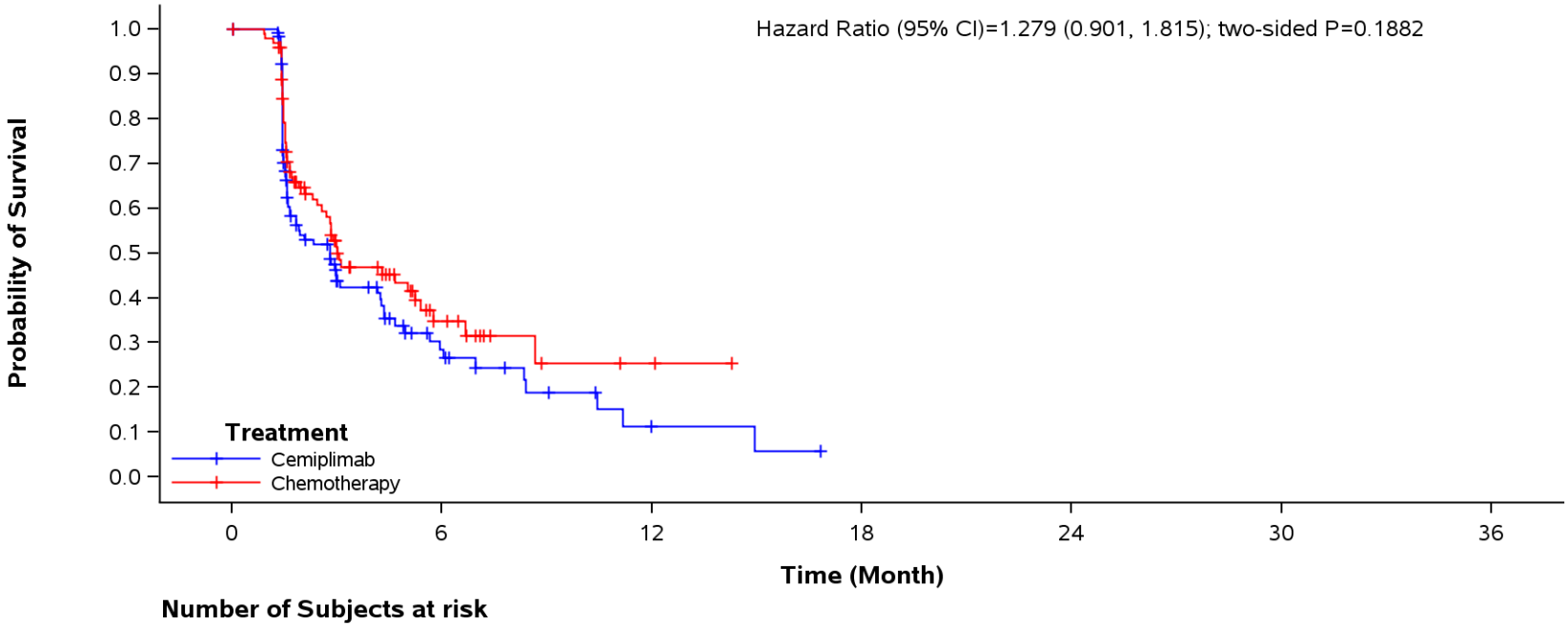

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 163 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts improvement



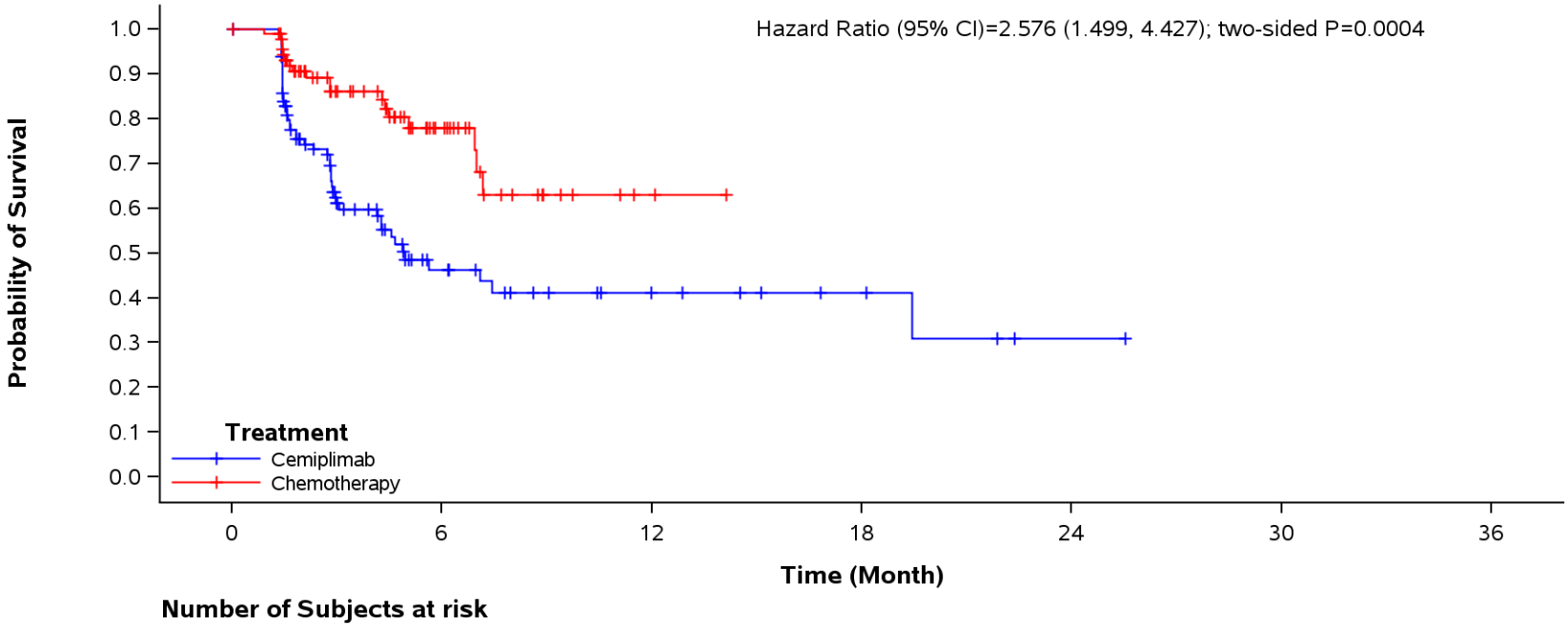

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 15 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 163 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts improvement



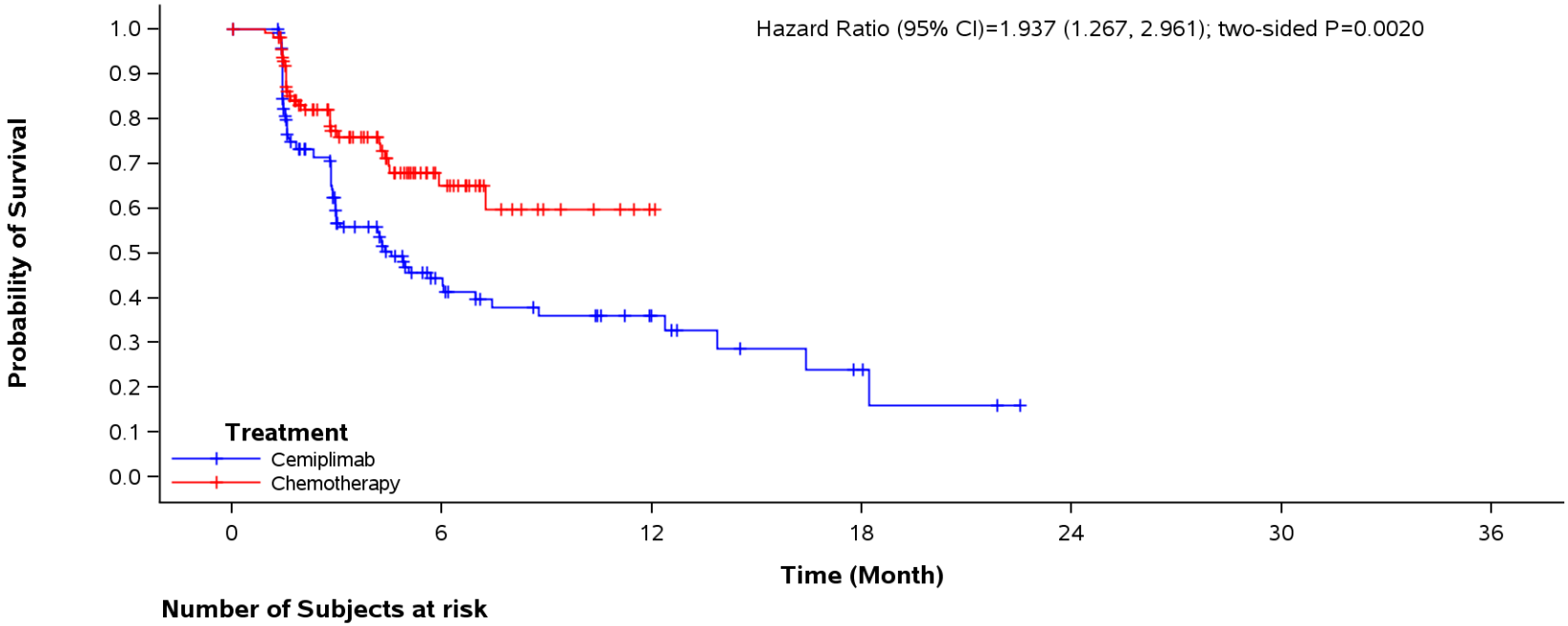

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 21 | 9 | 5 | 1 | 0 | 0 |
| Chemotherapy | 163 | 24 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts improvement



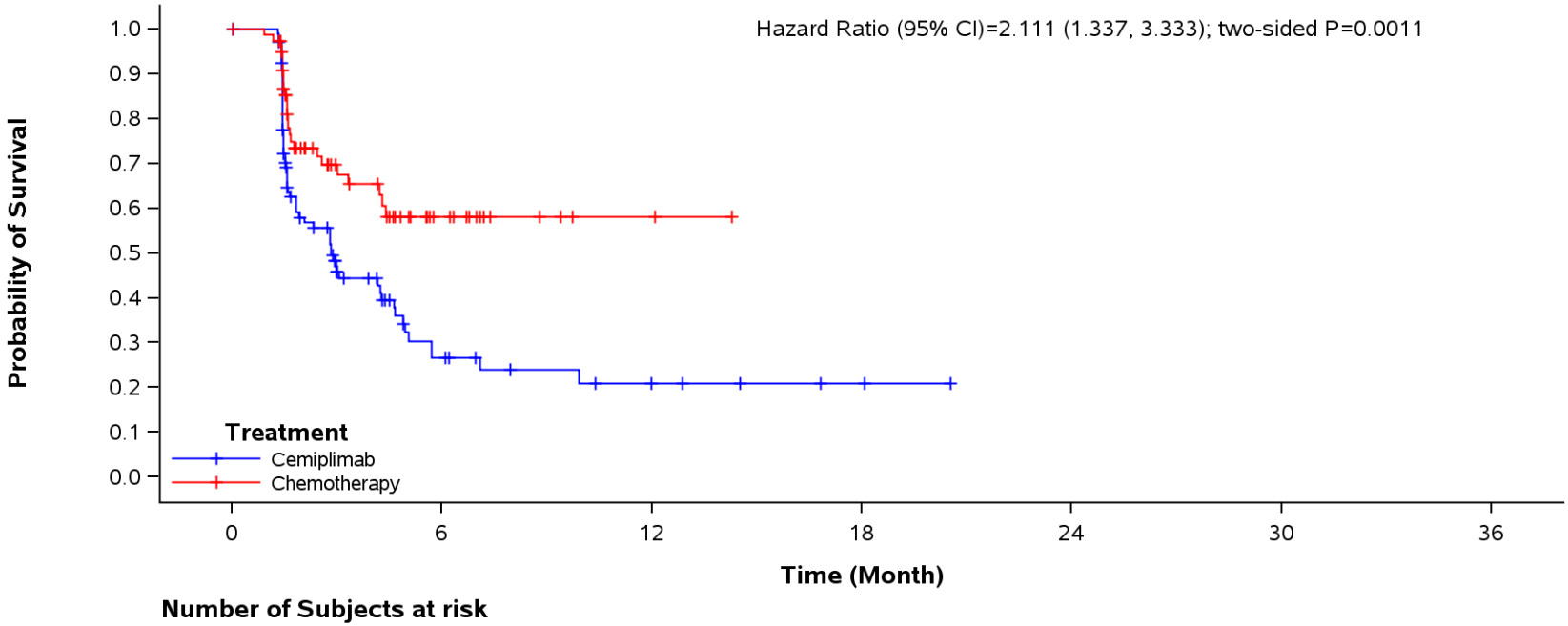

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 30 | 11 | 4 | 0 | 0 | 0 |
| Chemotherapy | 163 | 24 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts improvement



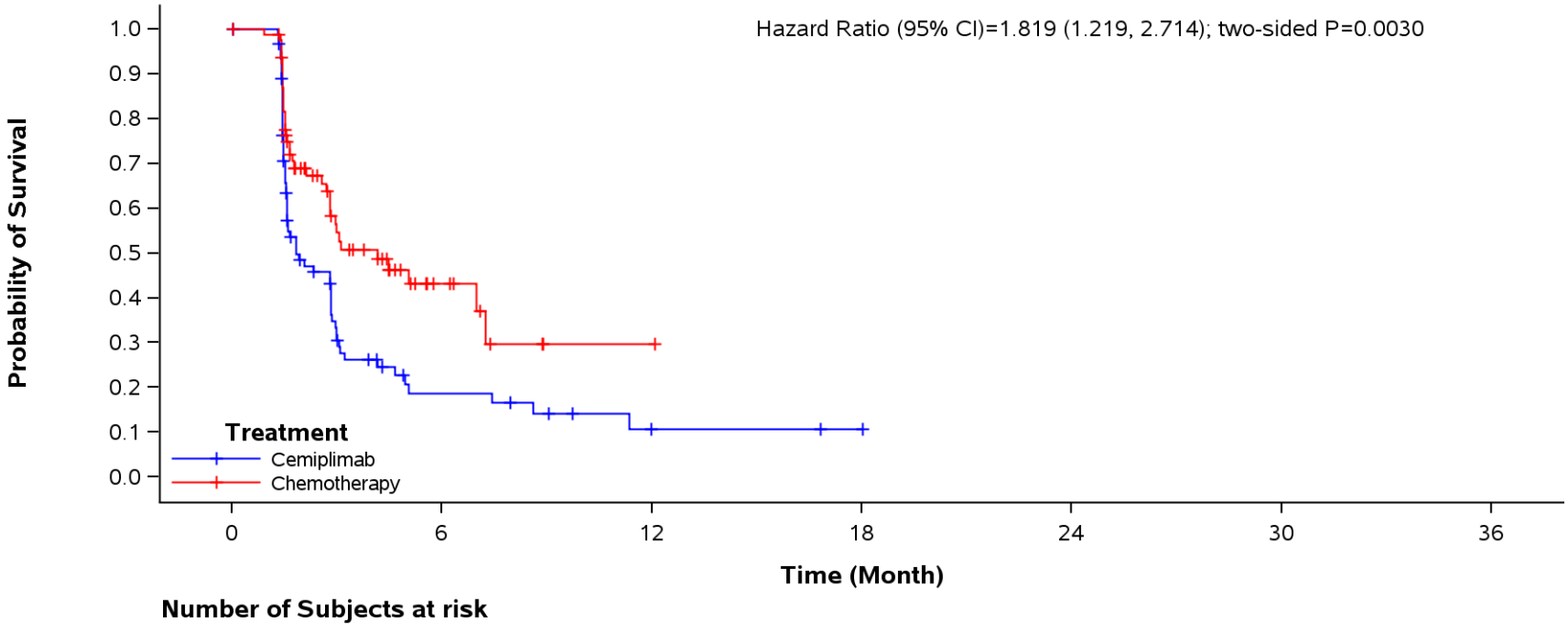

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 14 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 163 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts improvement



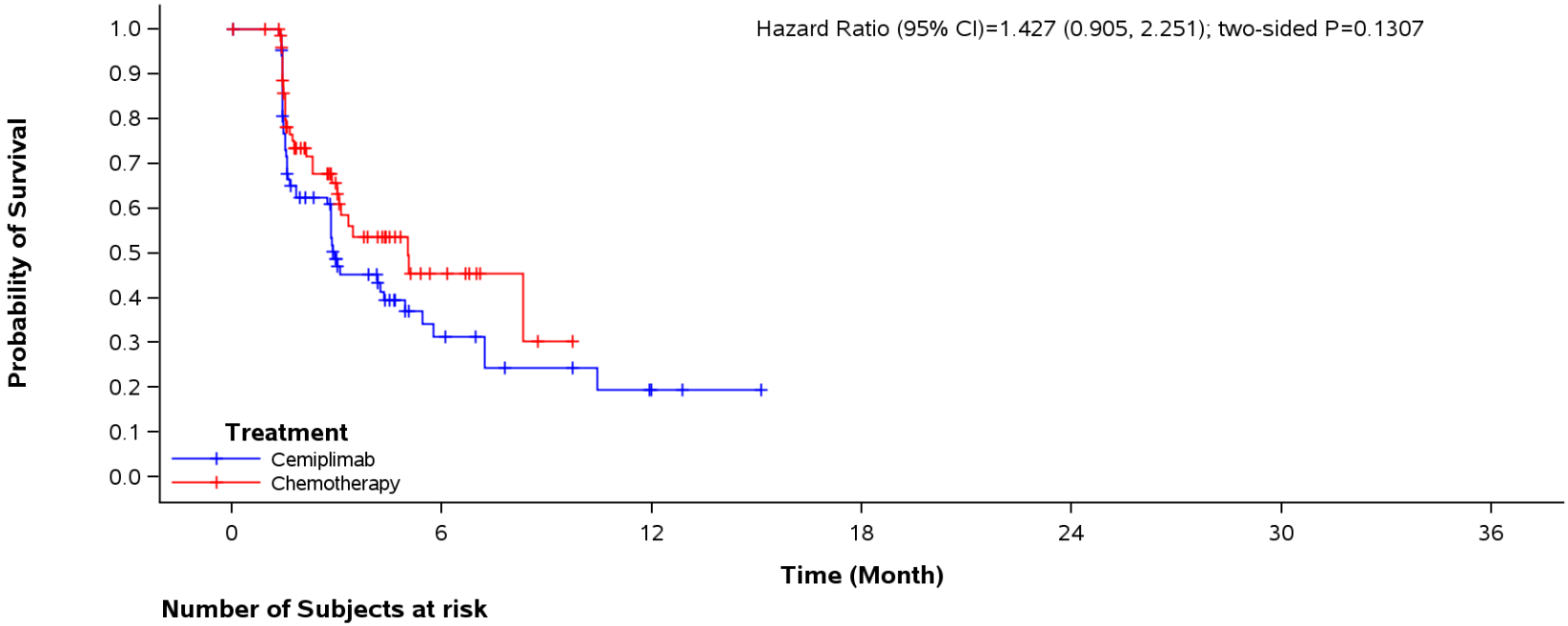

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 9 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 163 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts improvement



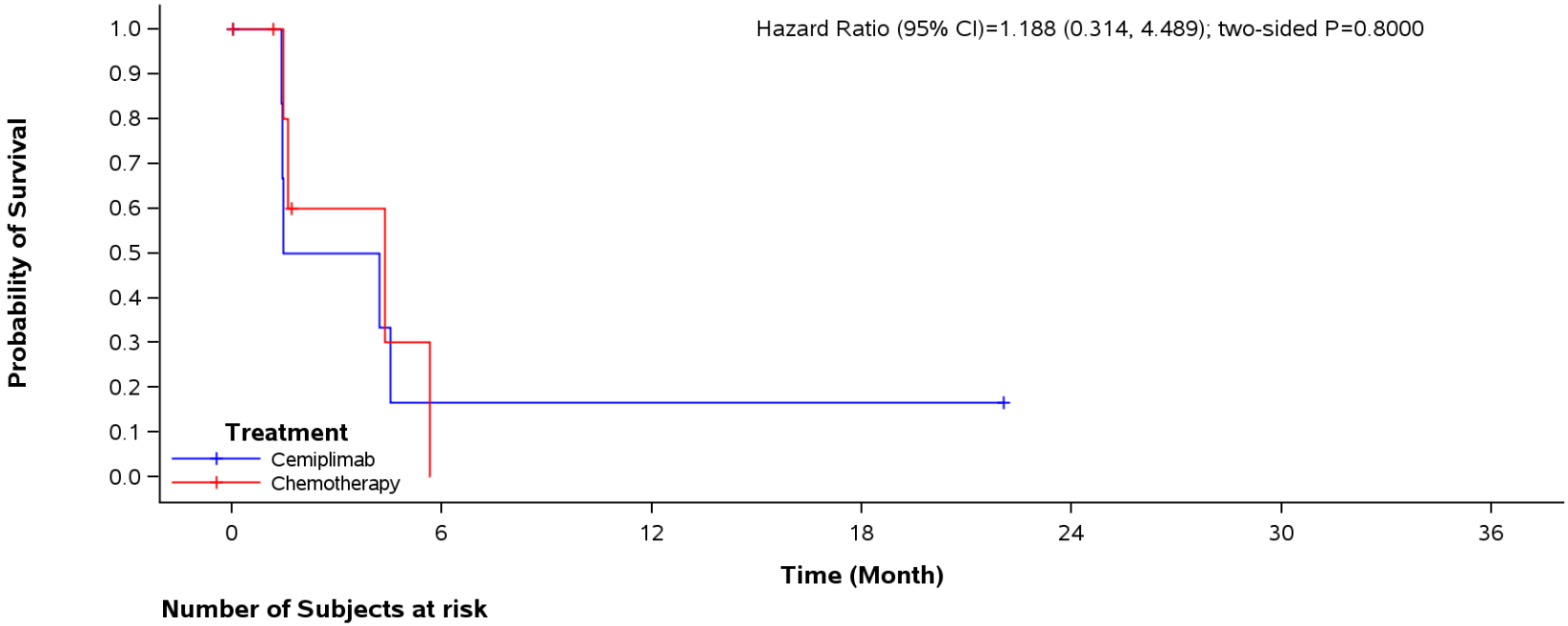

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 11 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 163 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts improvement



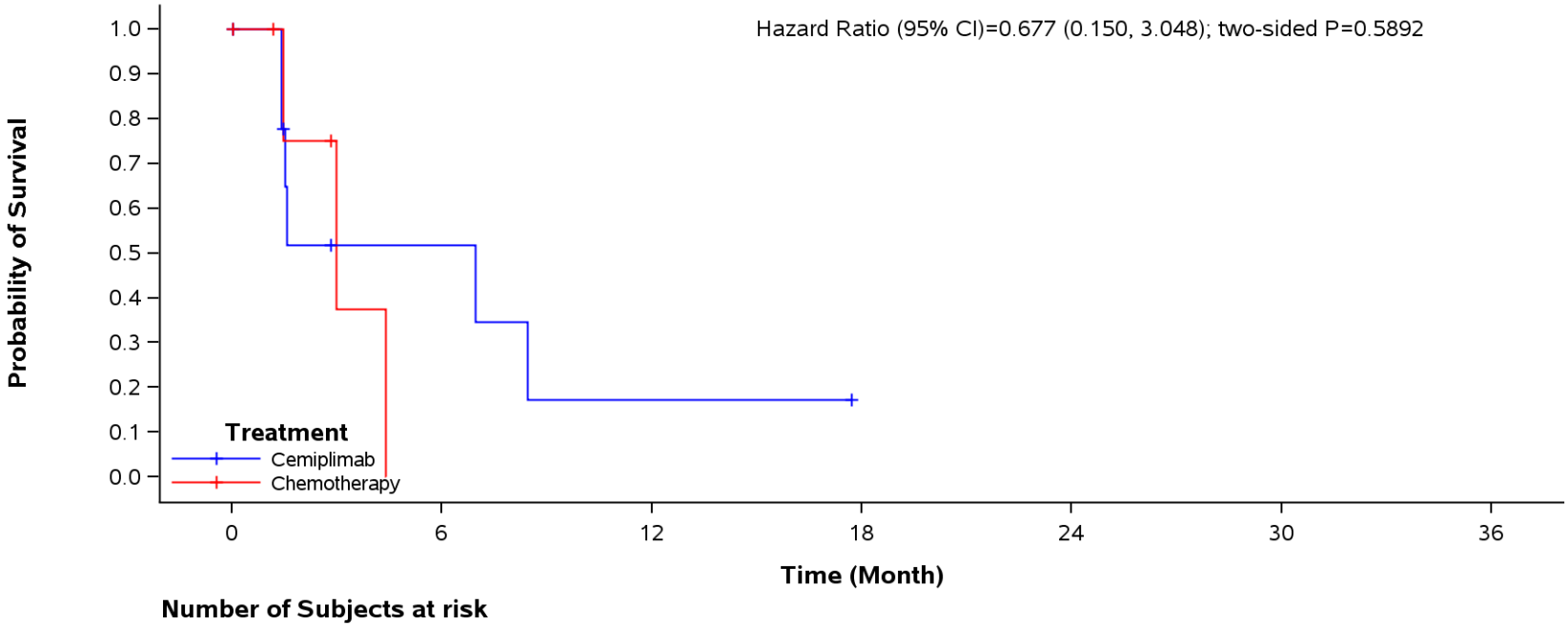

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 1 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts improvement



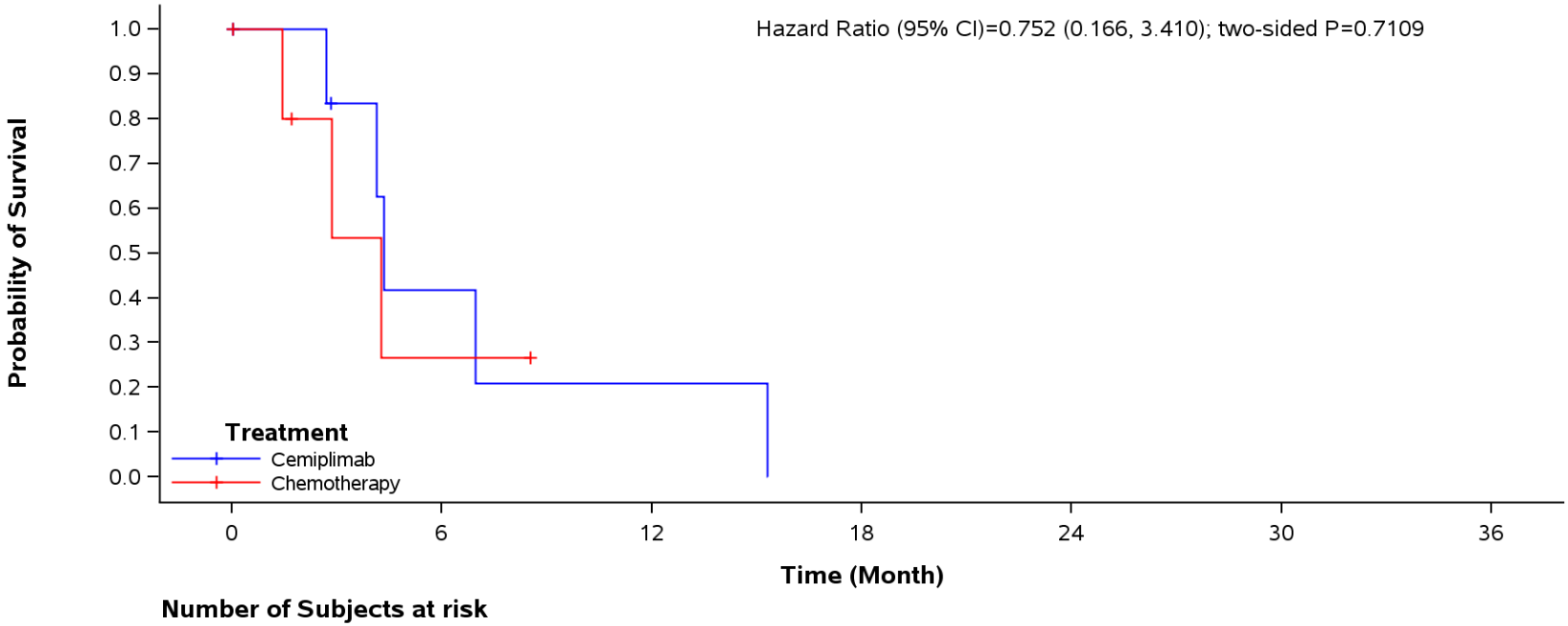

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts improvement



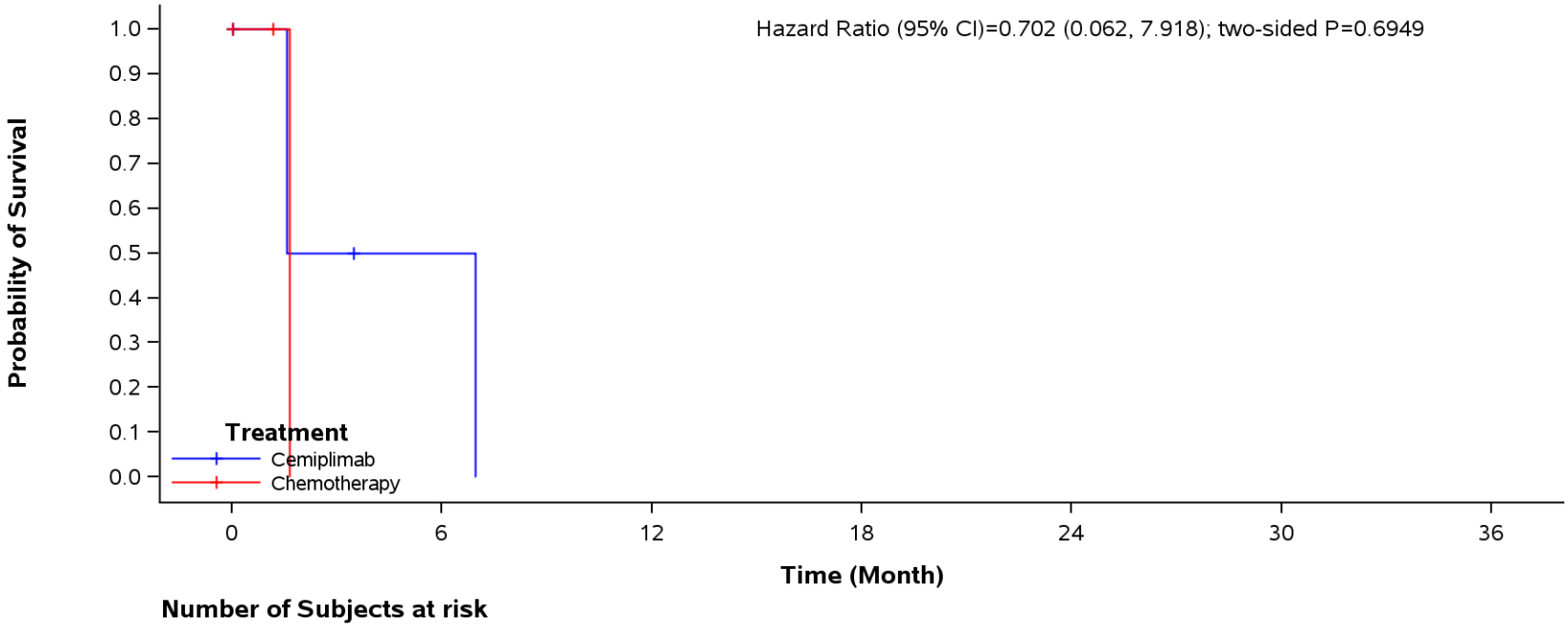

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts improvement



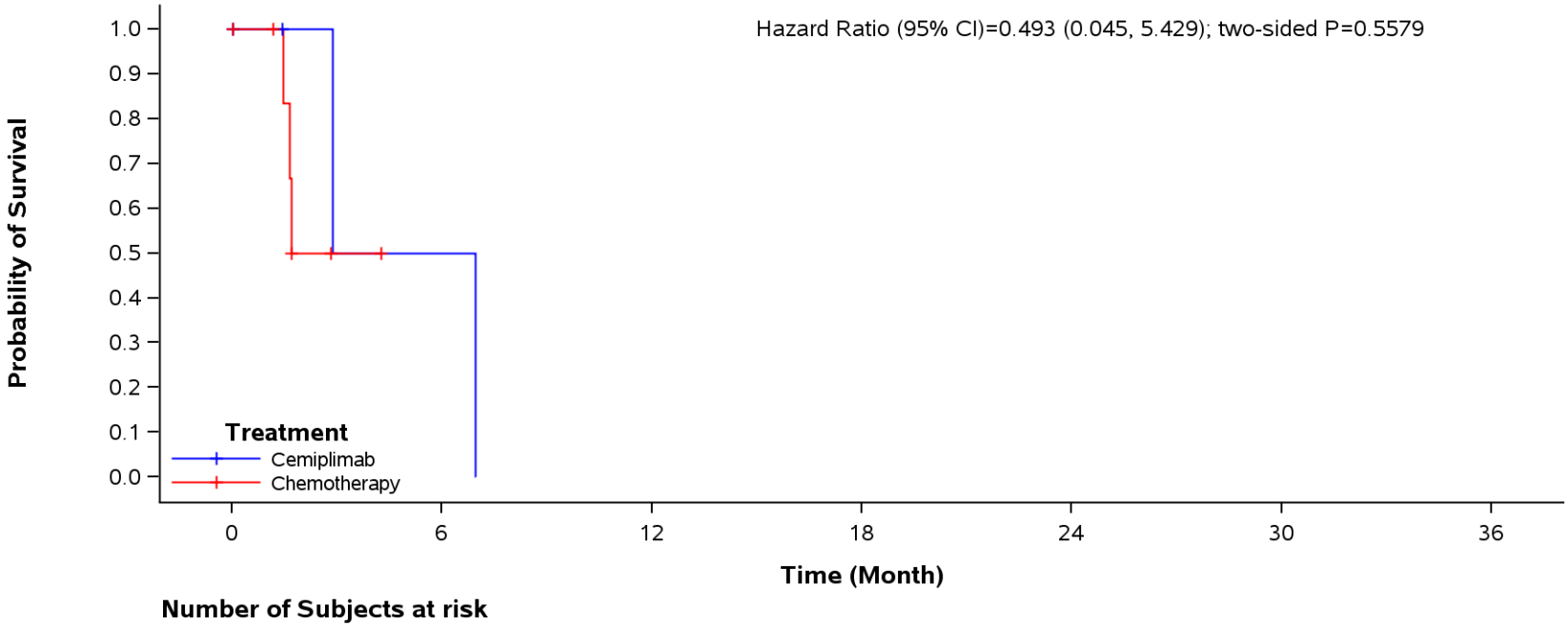

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts improvement



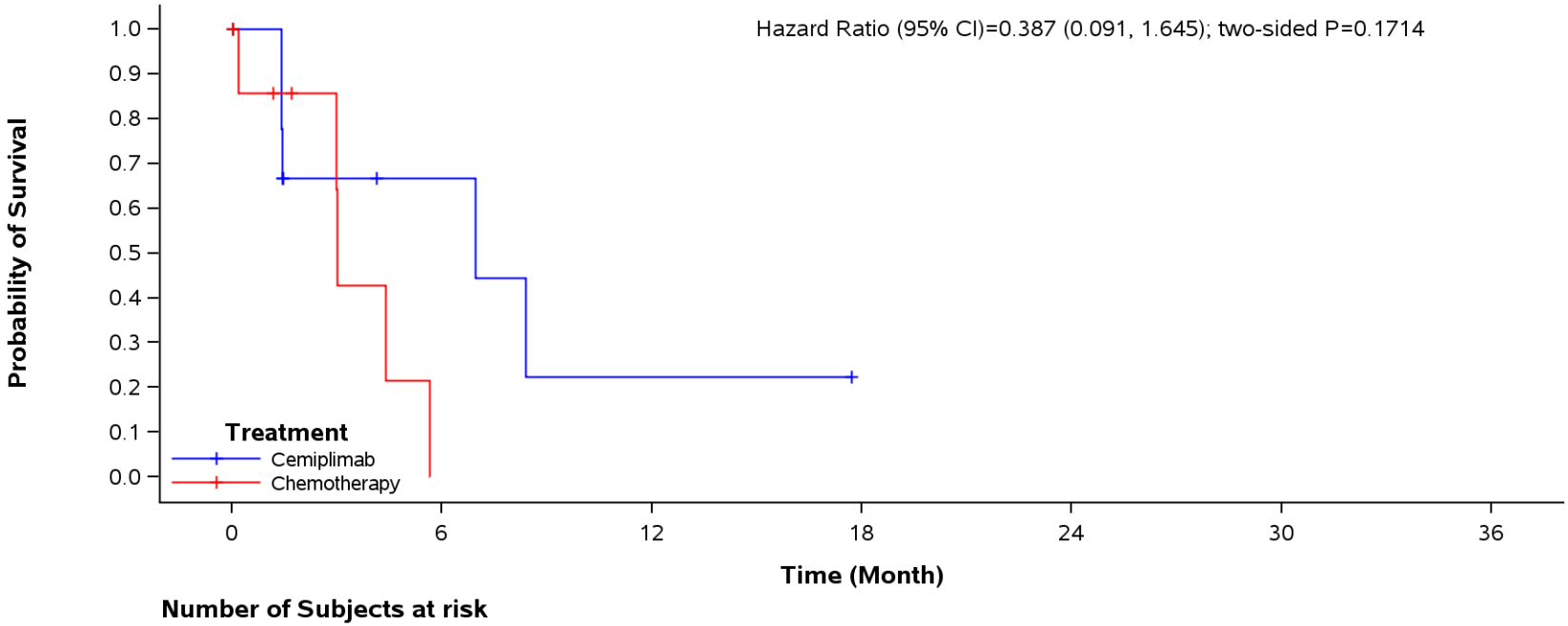

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts improvement



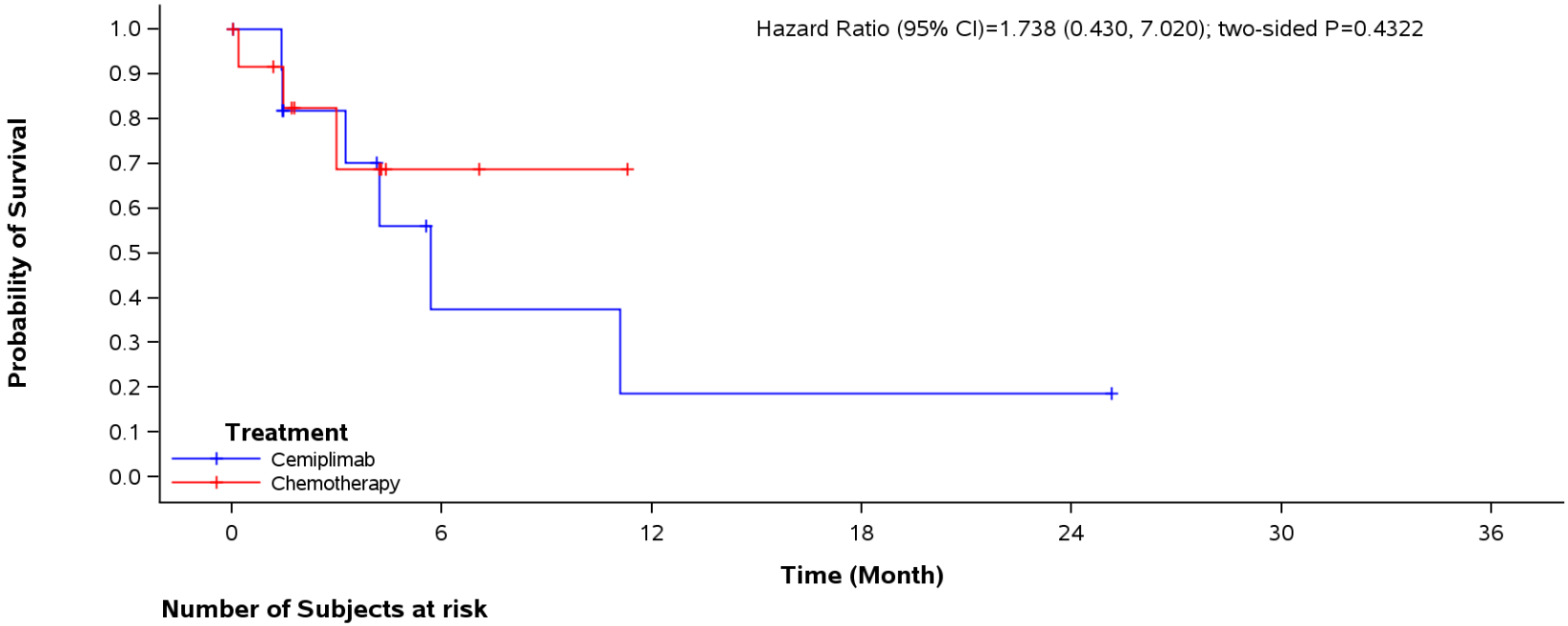

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts improvement



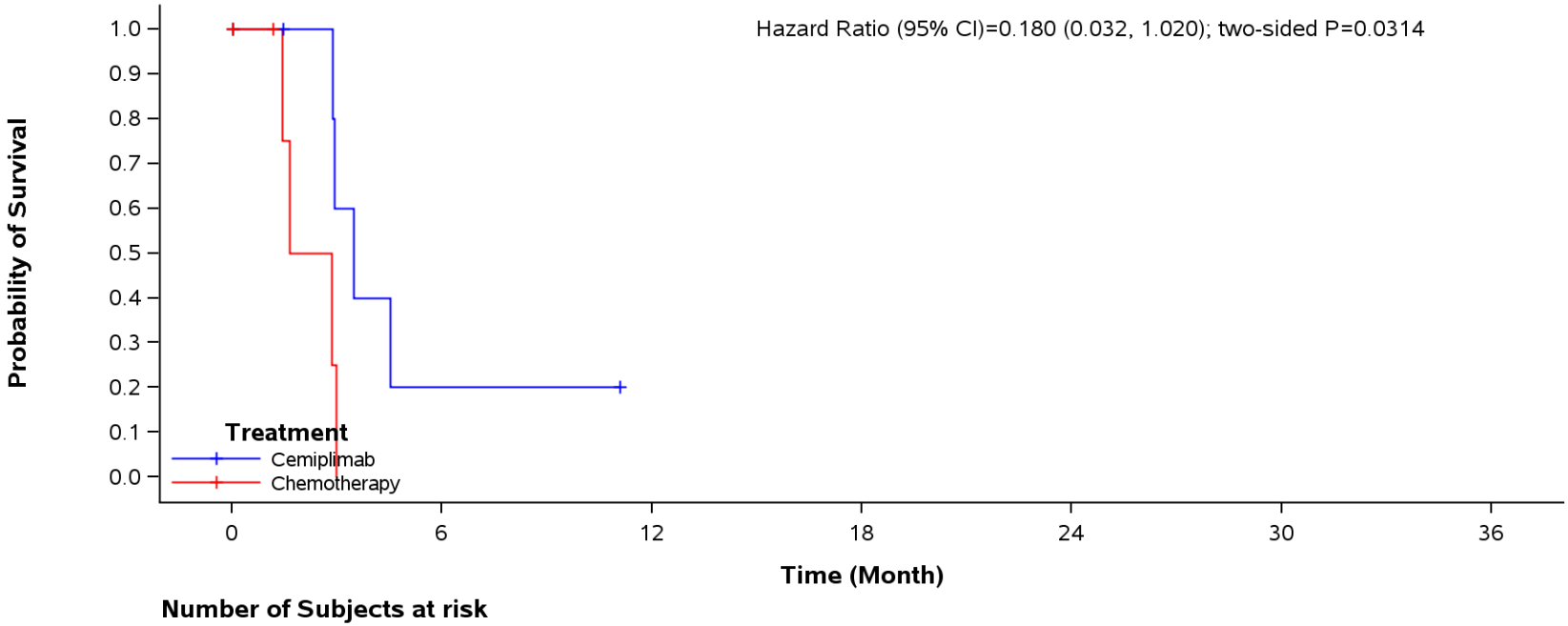

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts improvement



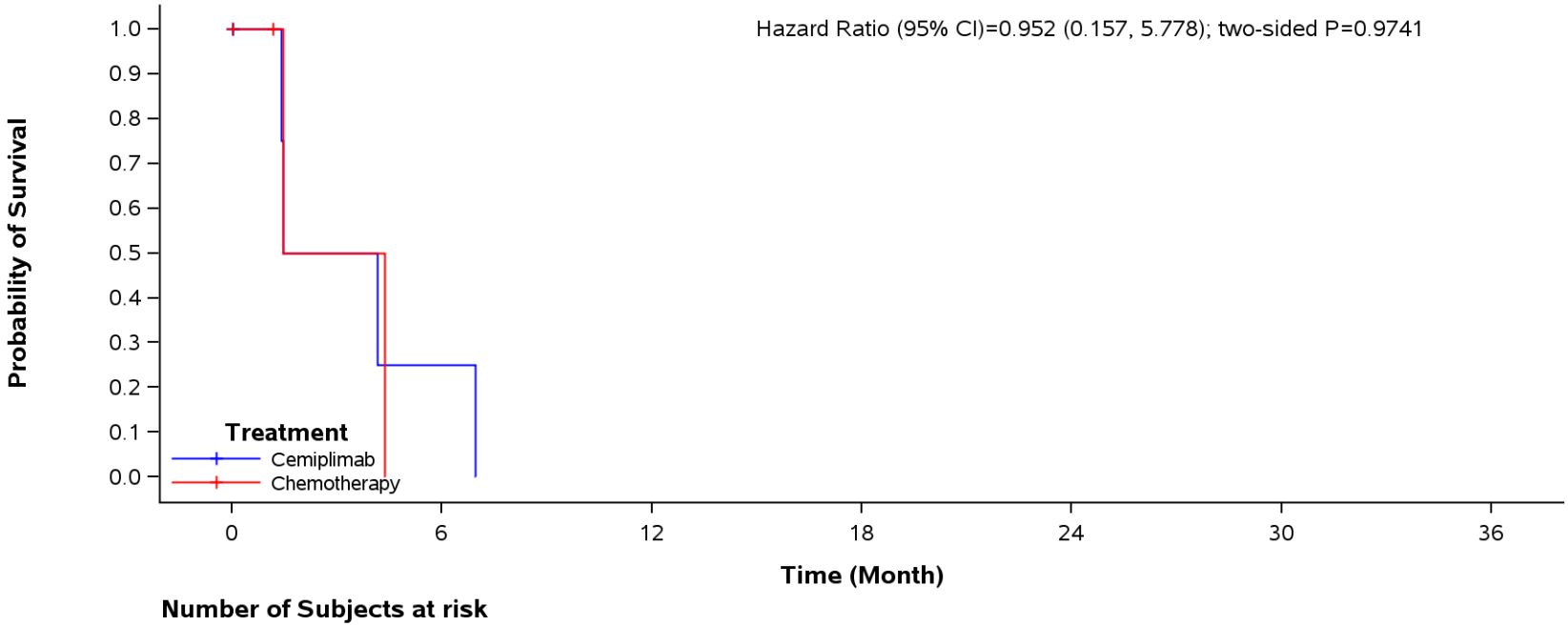

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts improvement



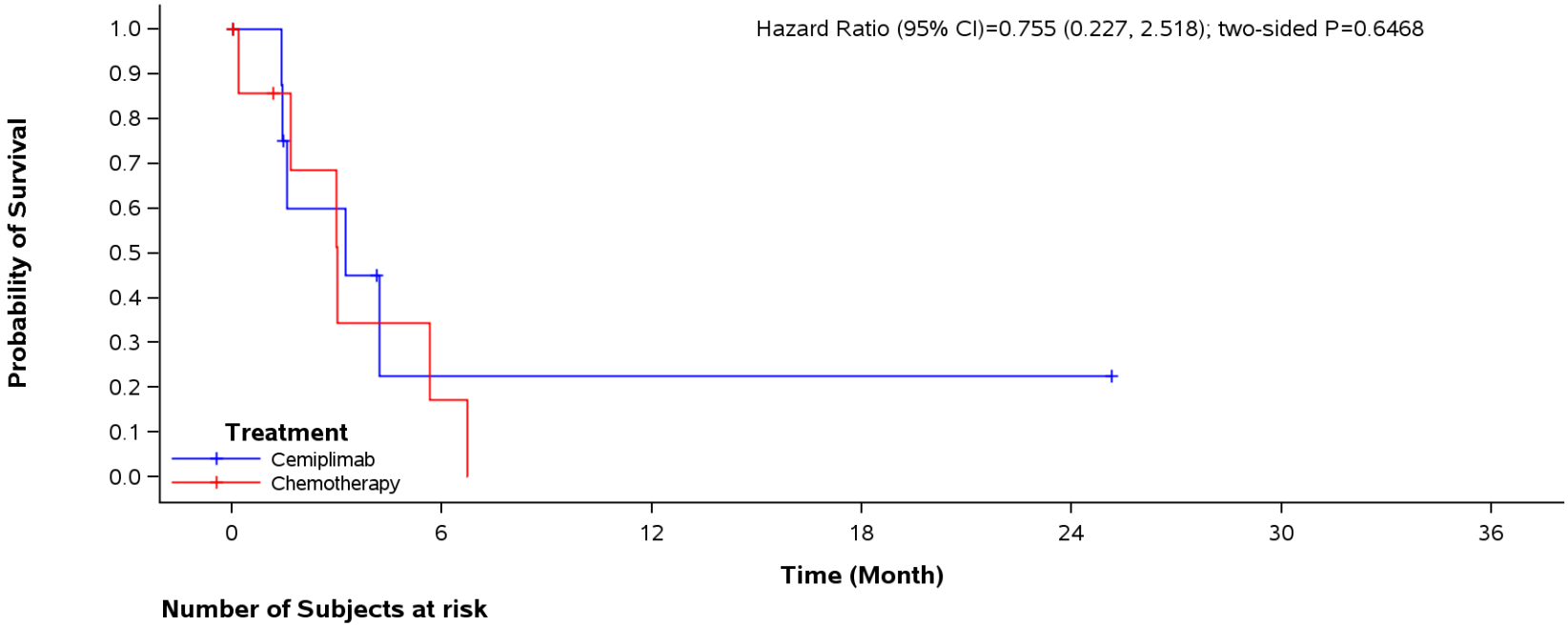

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts improvement



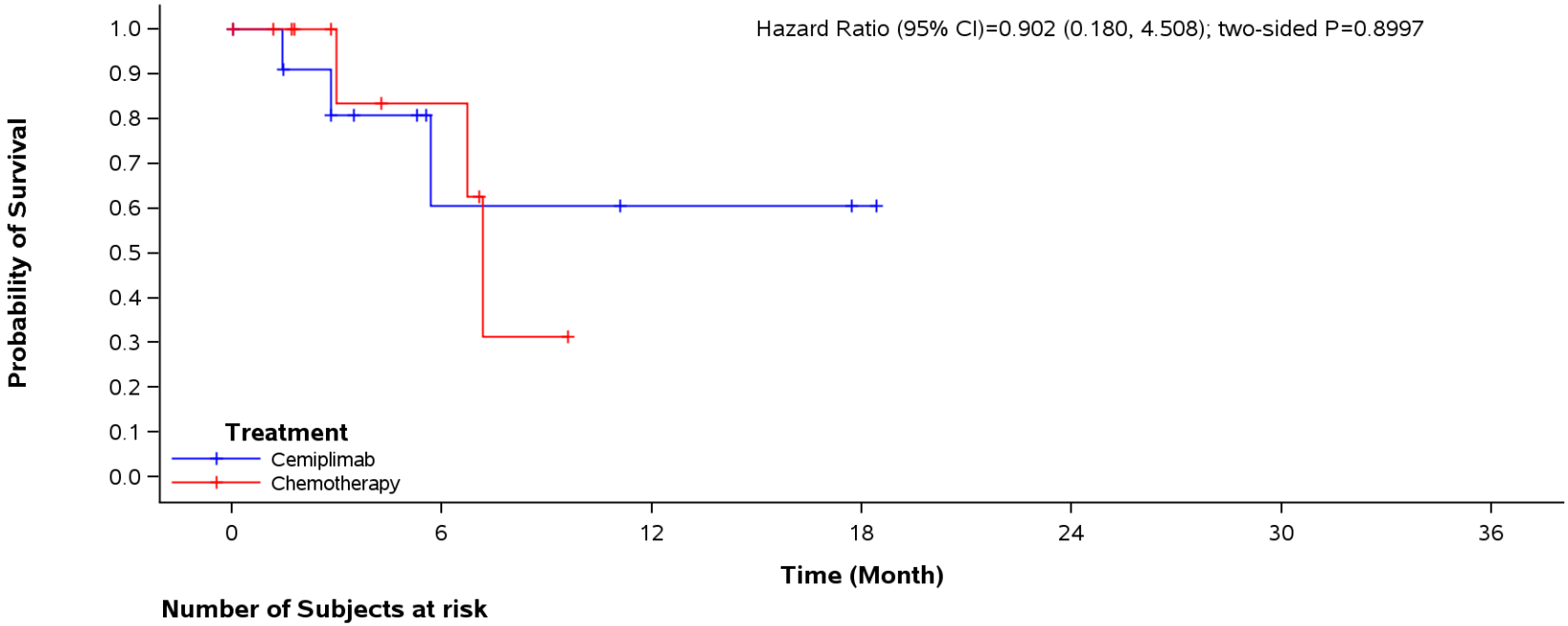

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 1 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts improvement



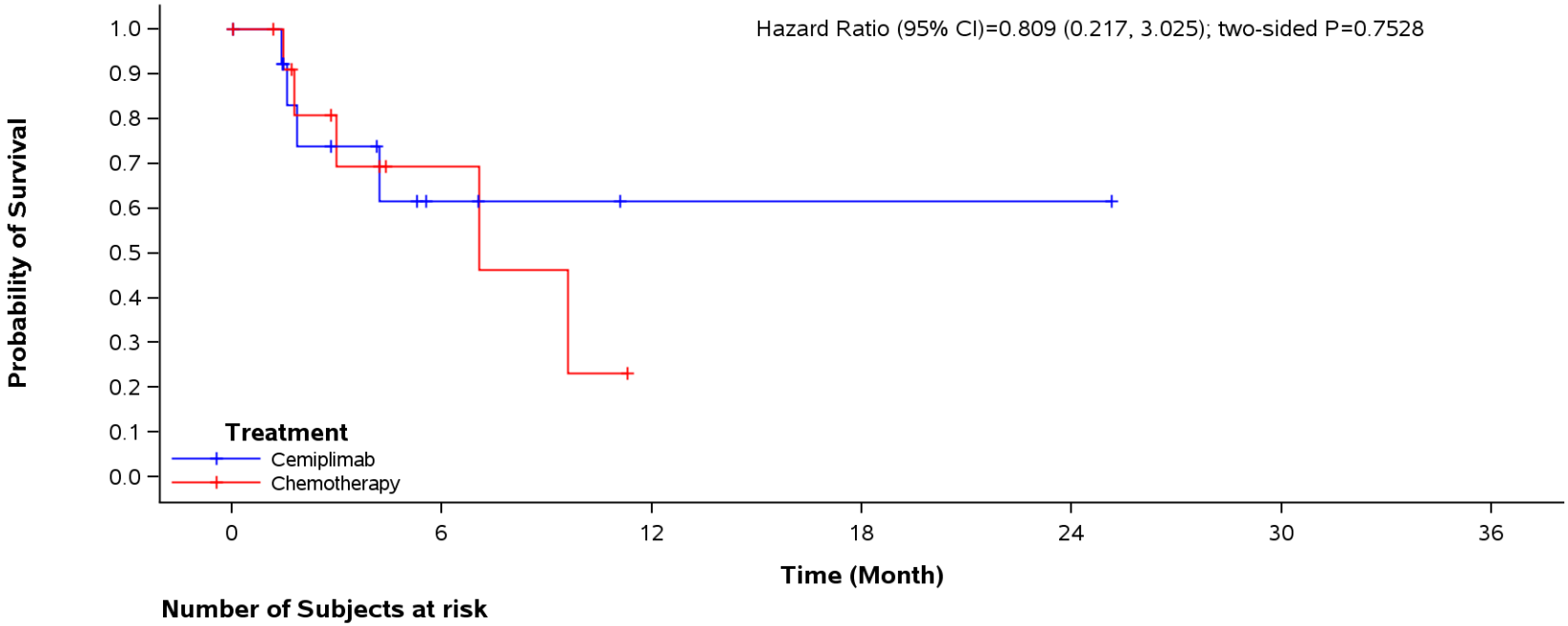

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Global health status / QoL - 10 pts improvement



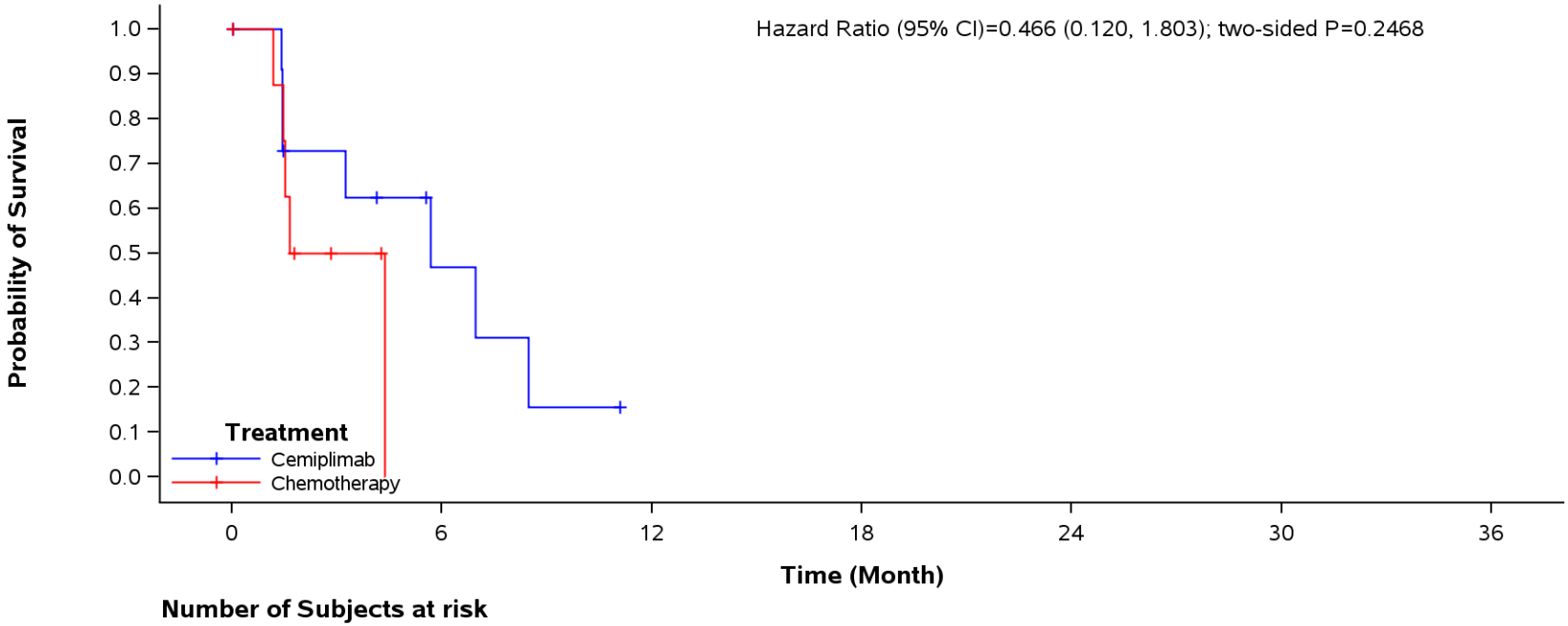

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts improvement



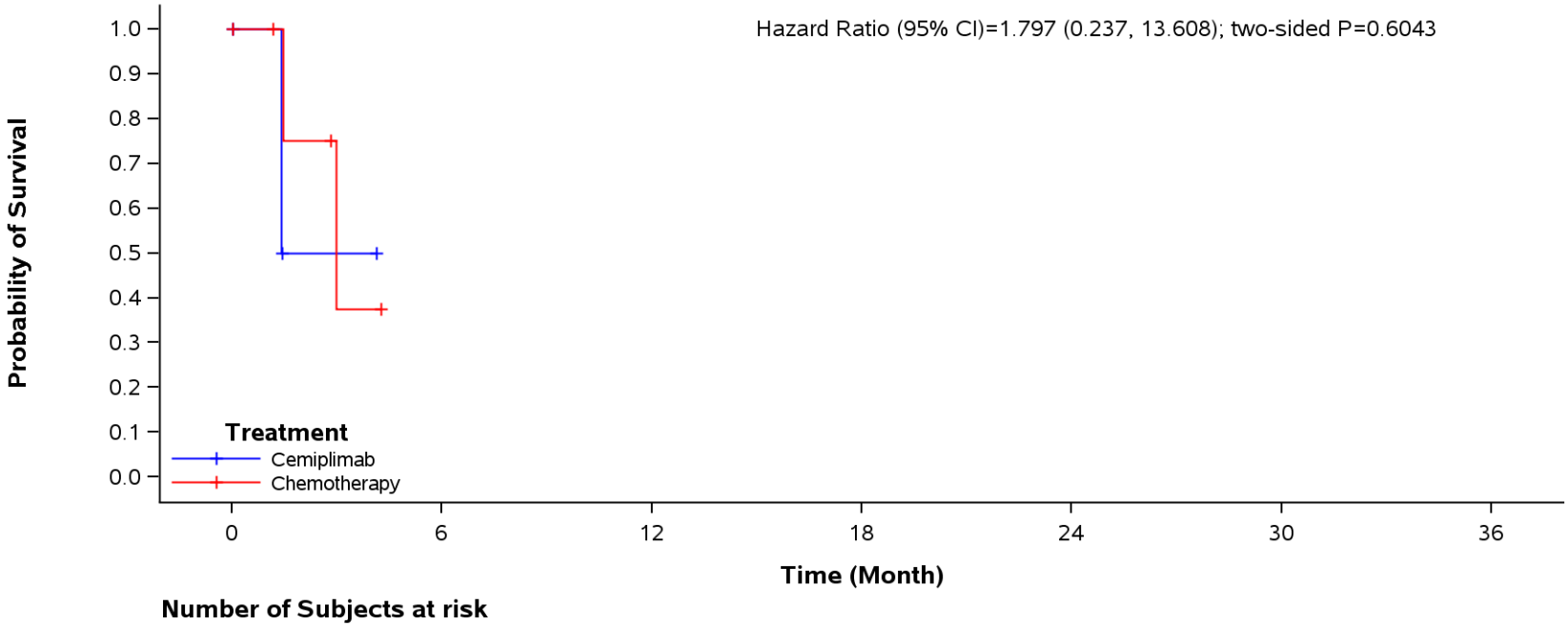

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts improvement



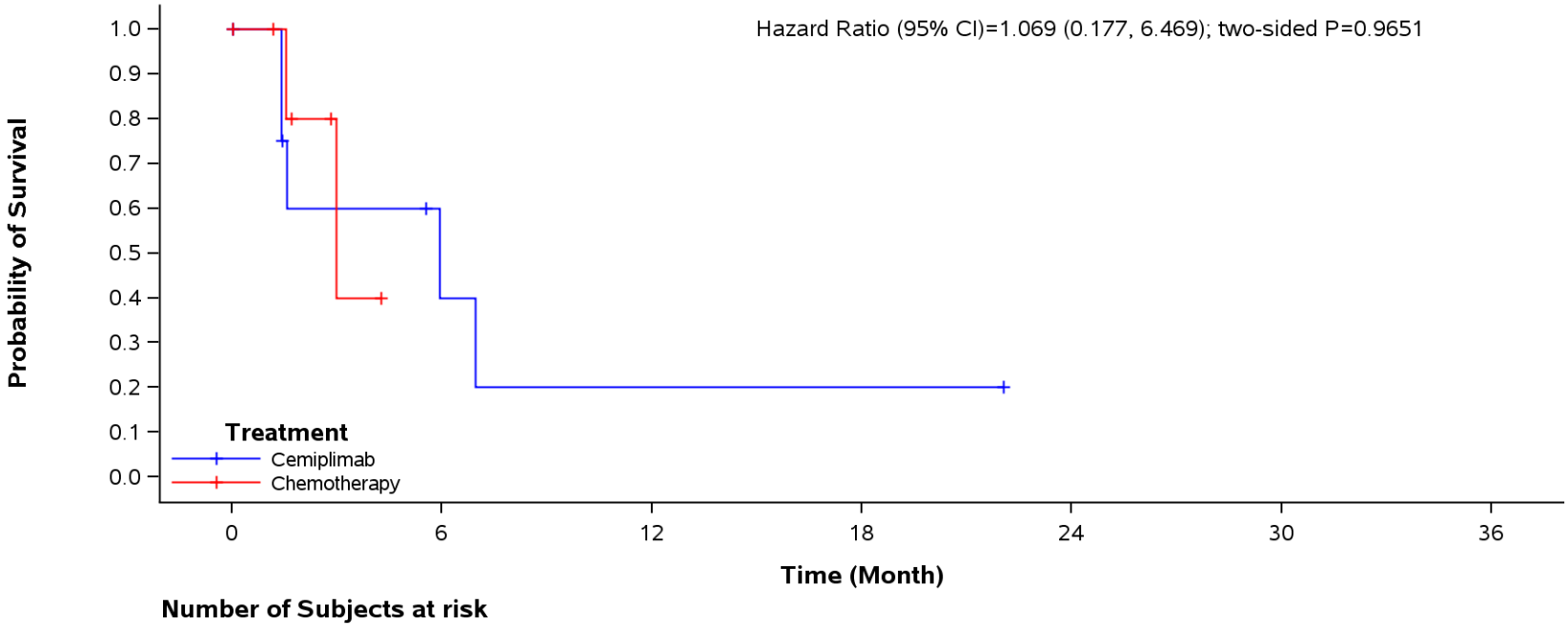

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts improvement



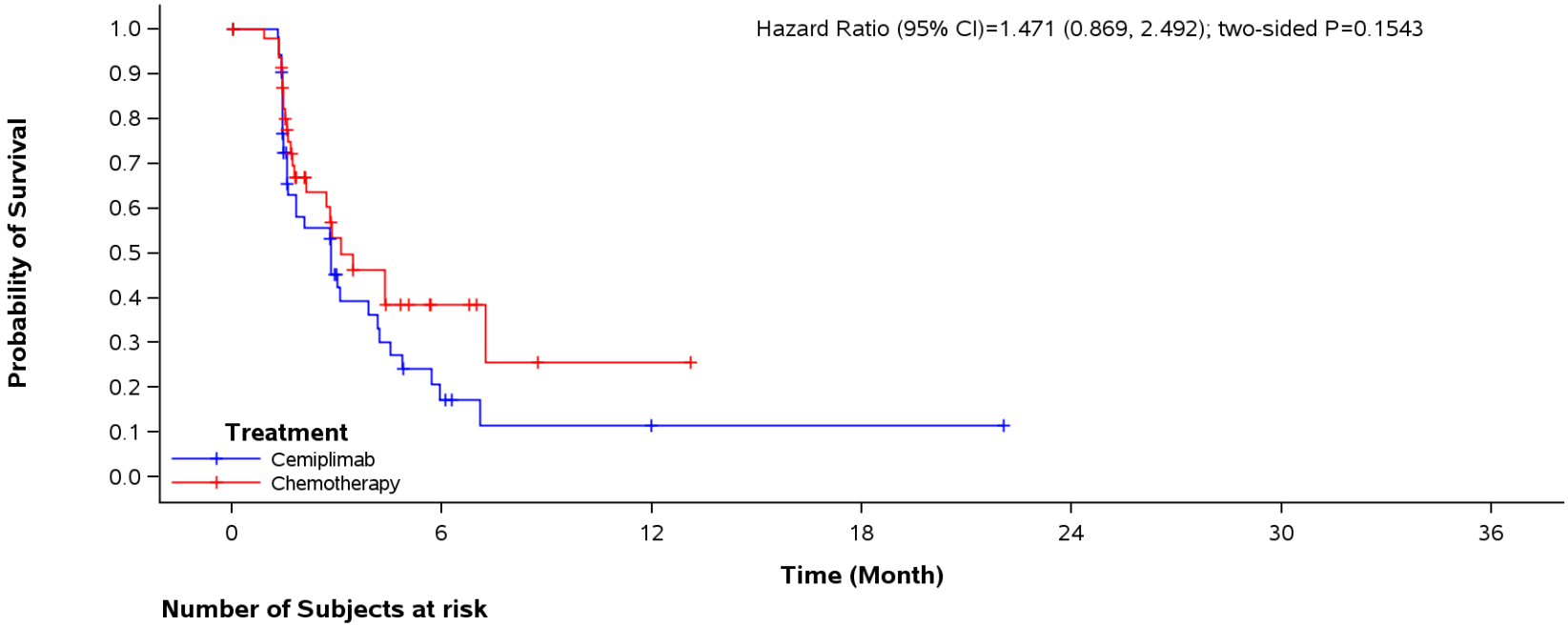

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Appetite loss - 10 pts improvement



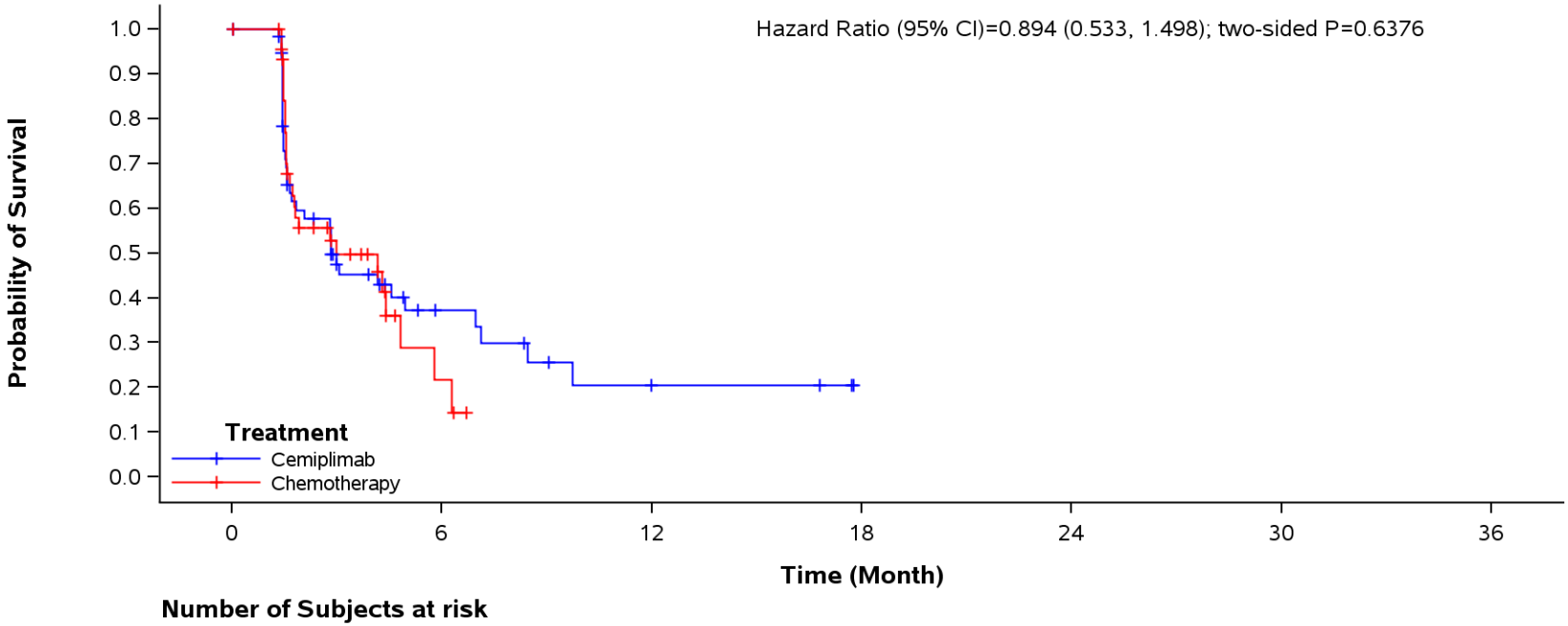

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 123 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Cognitive Functioning - 10 pts improvement



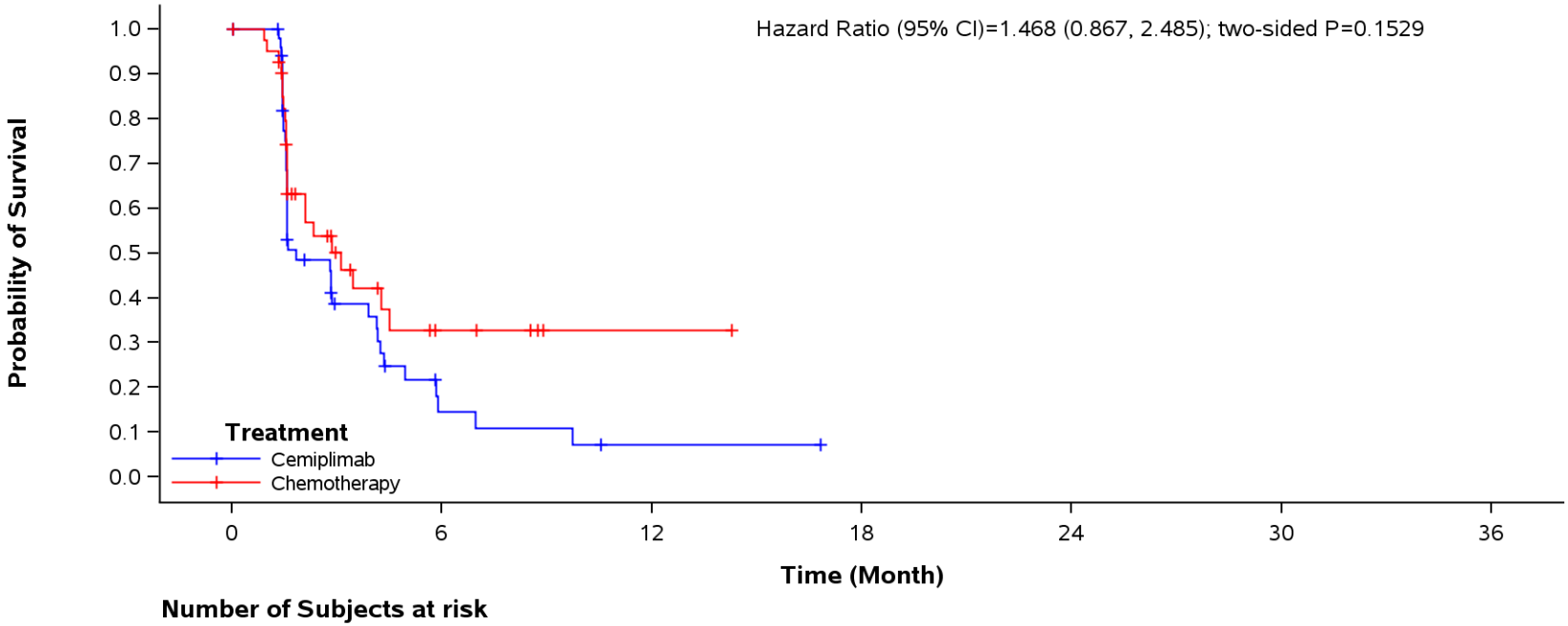

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 10 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 123 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts improvement



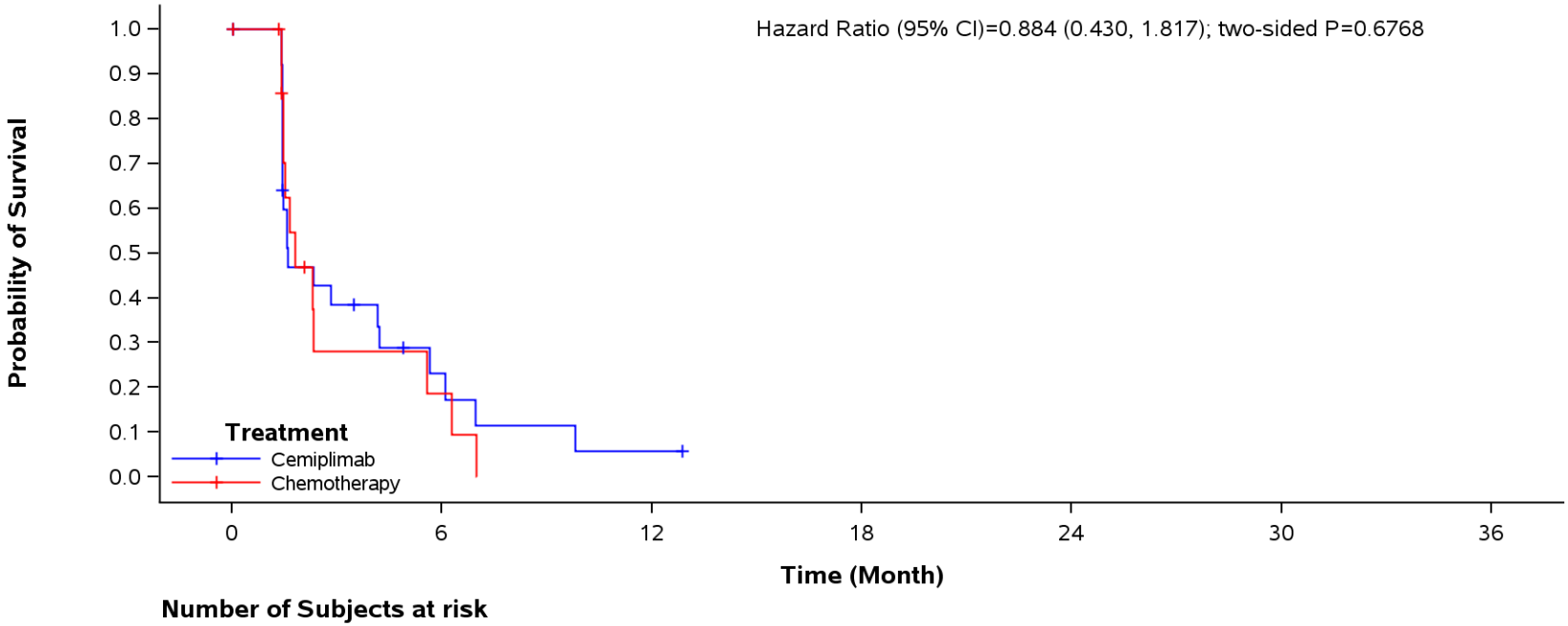

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 123 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts improvement



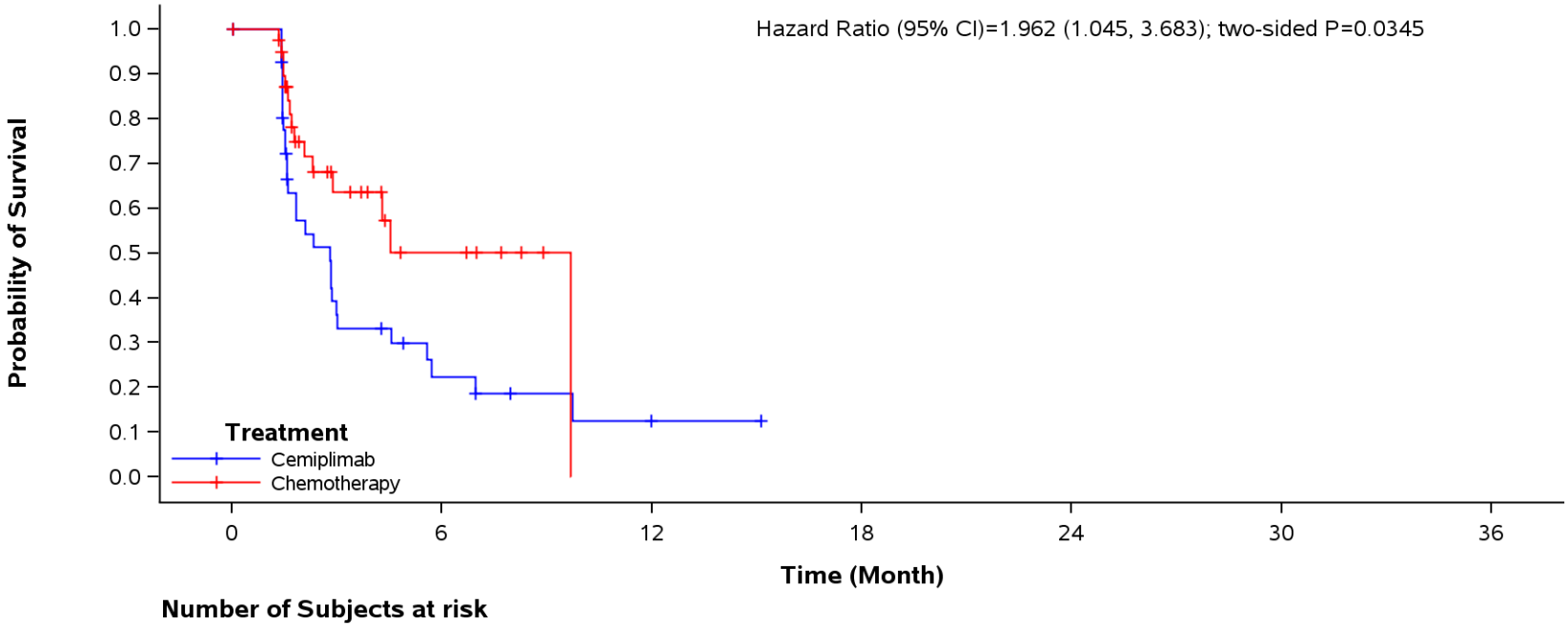

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 123 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts improvement



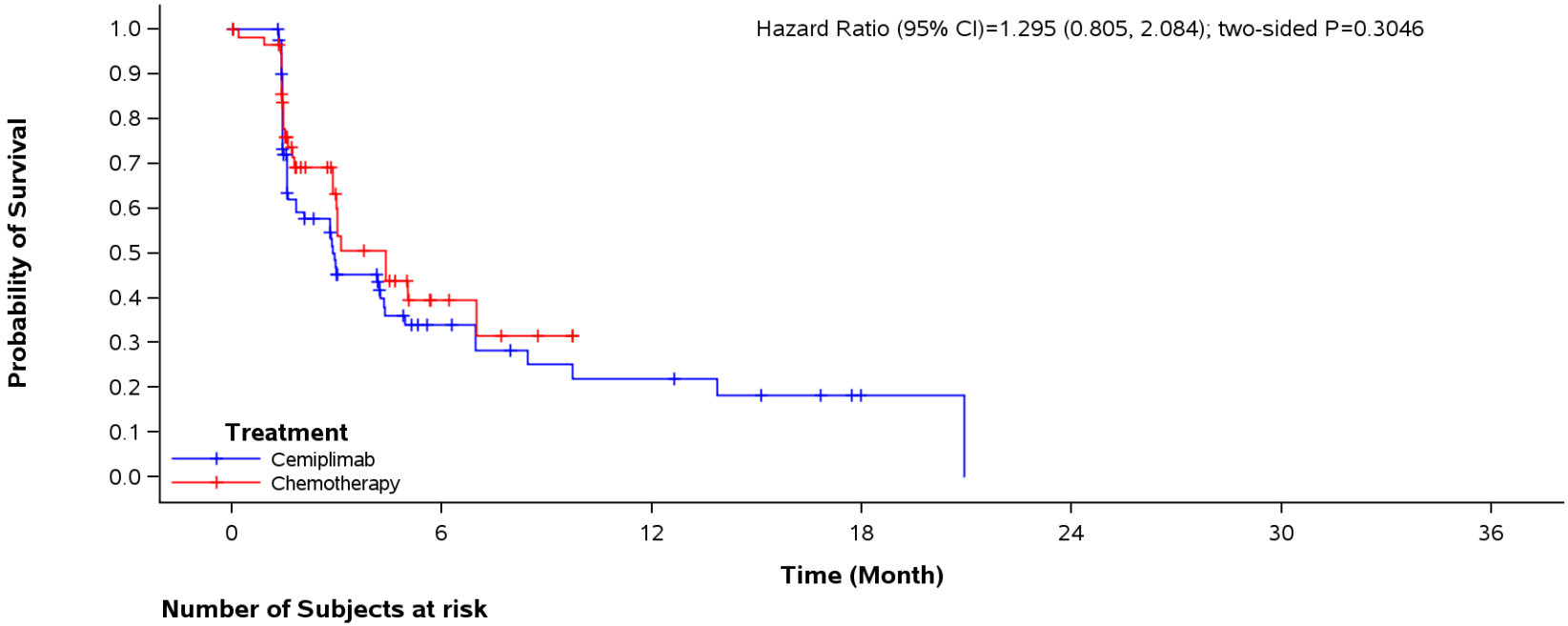

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 123 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts improvement



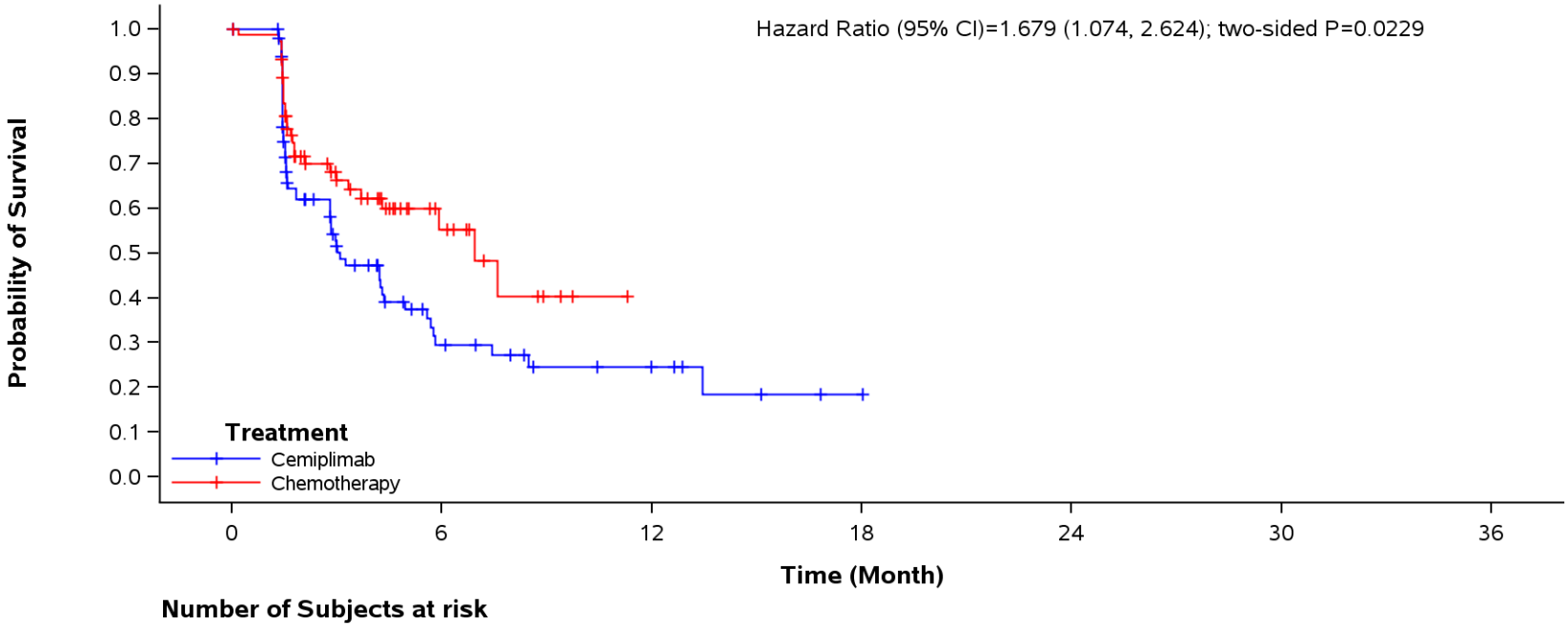

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 13 | 7 | 1 | 0 | 0 | 0 |
| Chemotherapy | 123 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts improvement



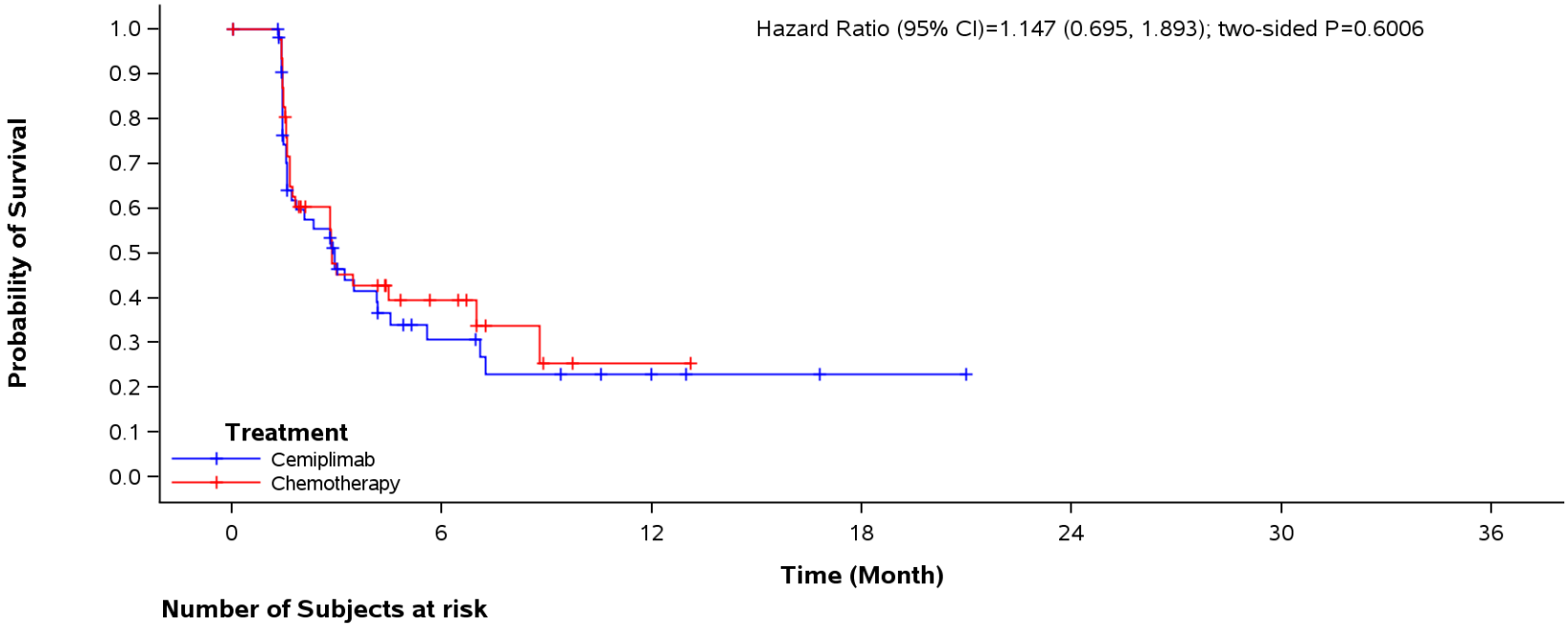

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 15 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 123 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Financial Problems - 10 pts improvement



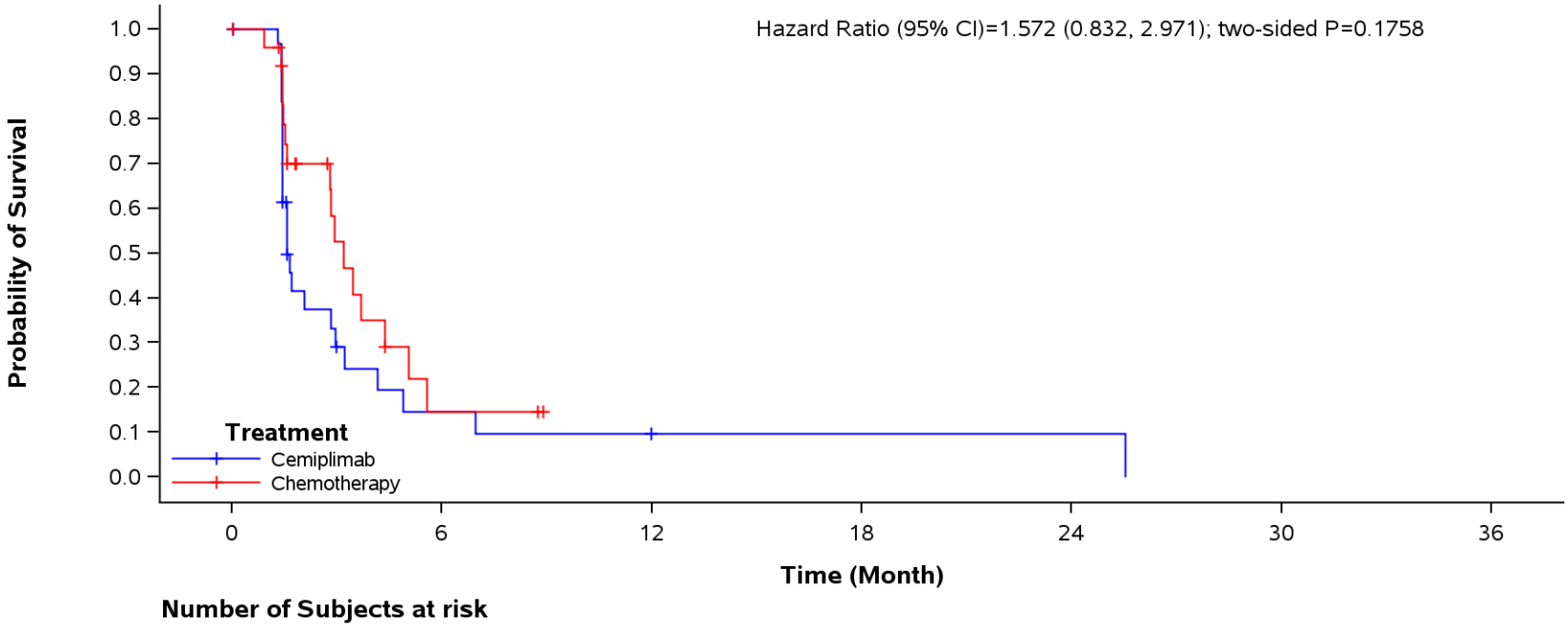

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 9 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 123 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Nausea / Vomiting - 10 pts improvement



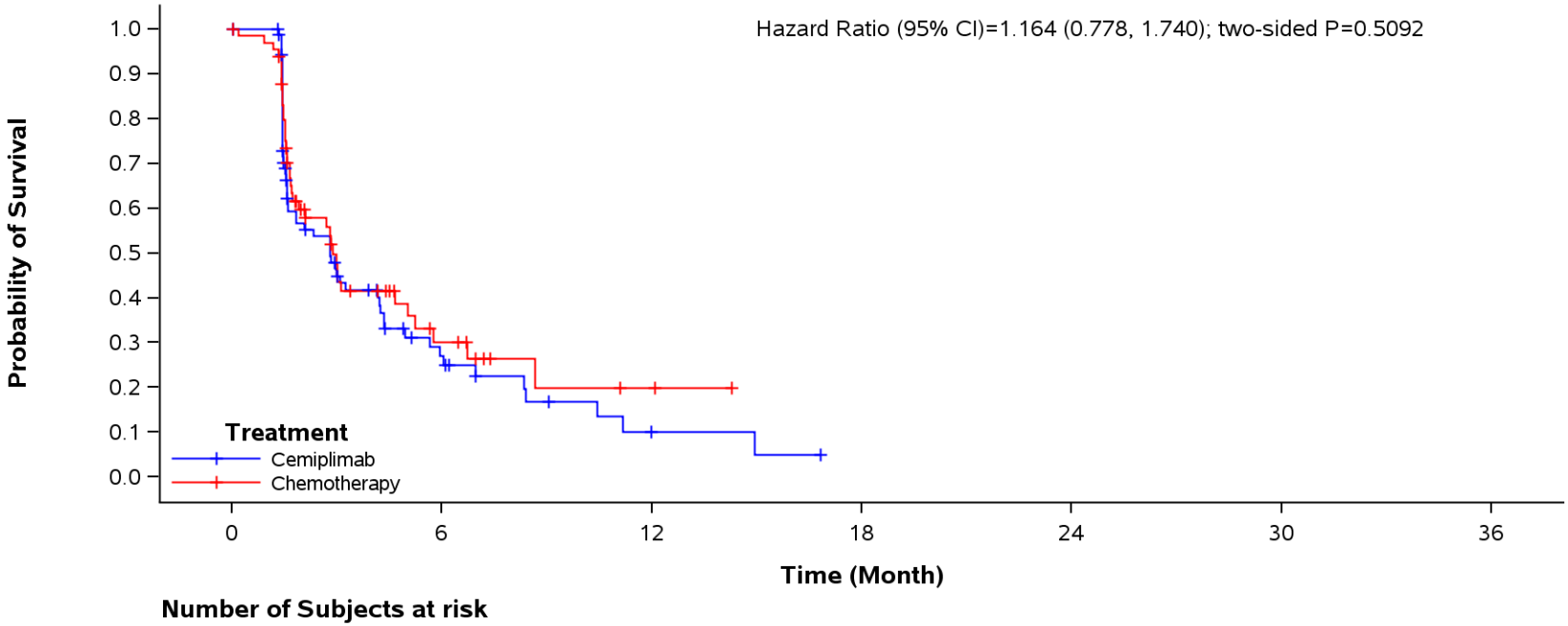

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 123 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts improvement



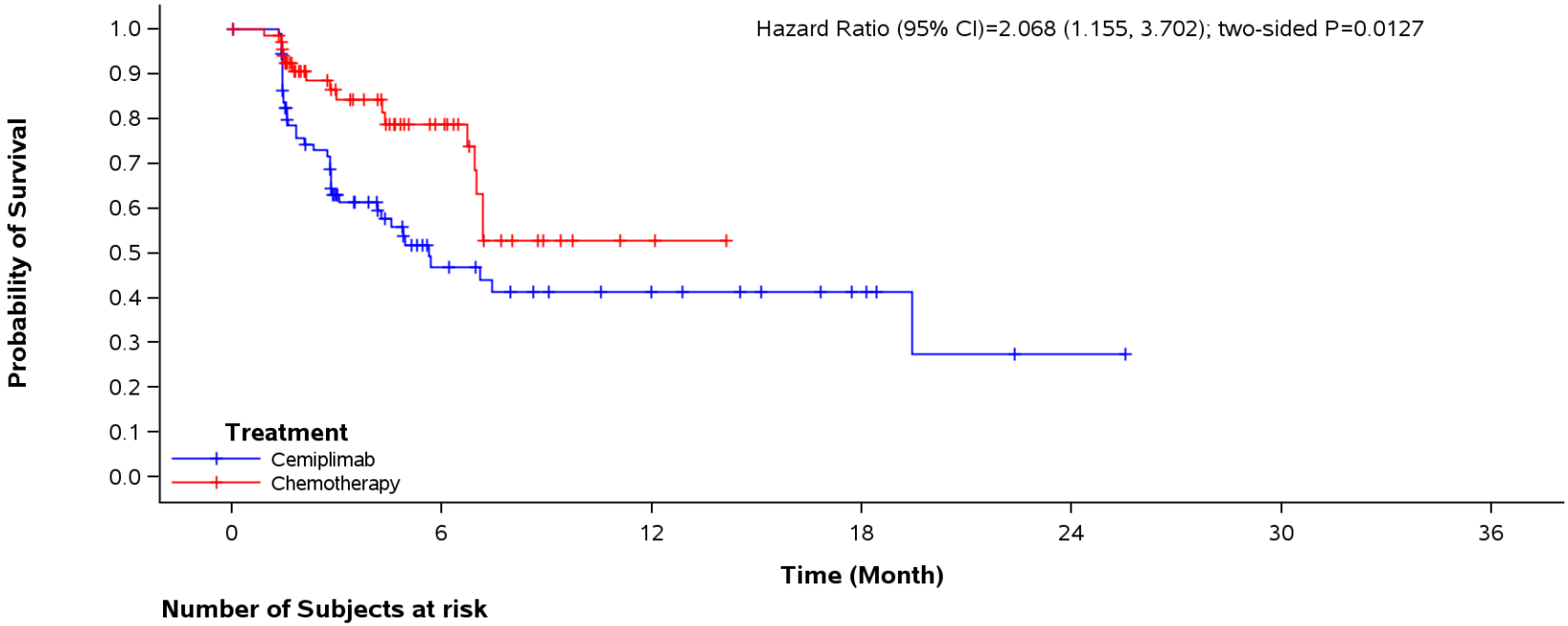

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 13 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 123 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts improvement



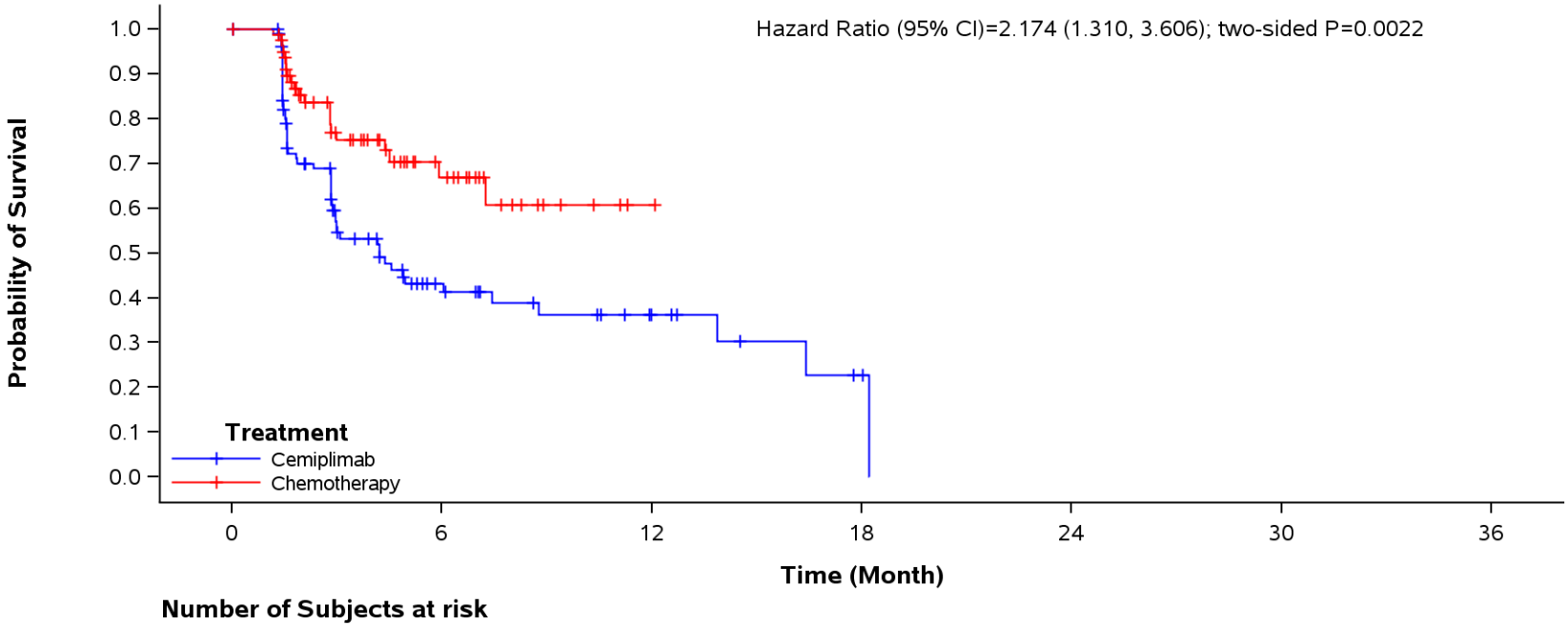

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 19 | 10 | 5 | 1 | 0 | 0 |
| Chemotherapy | 123 | 20 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts improvement



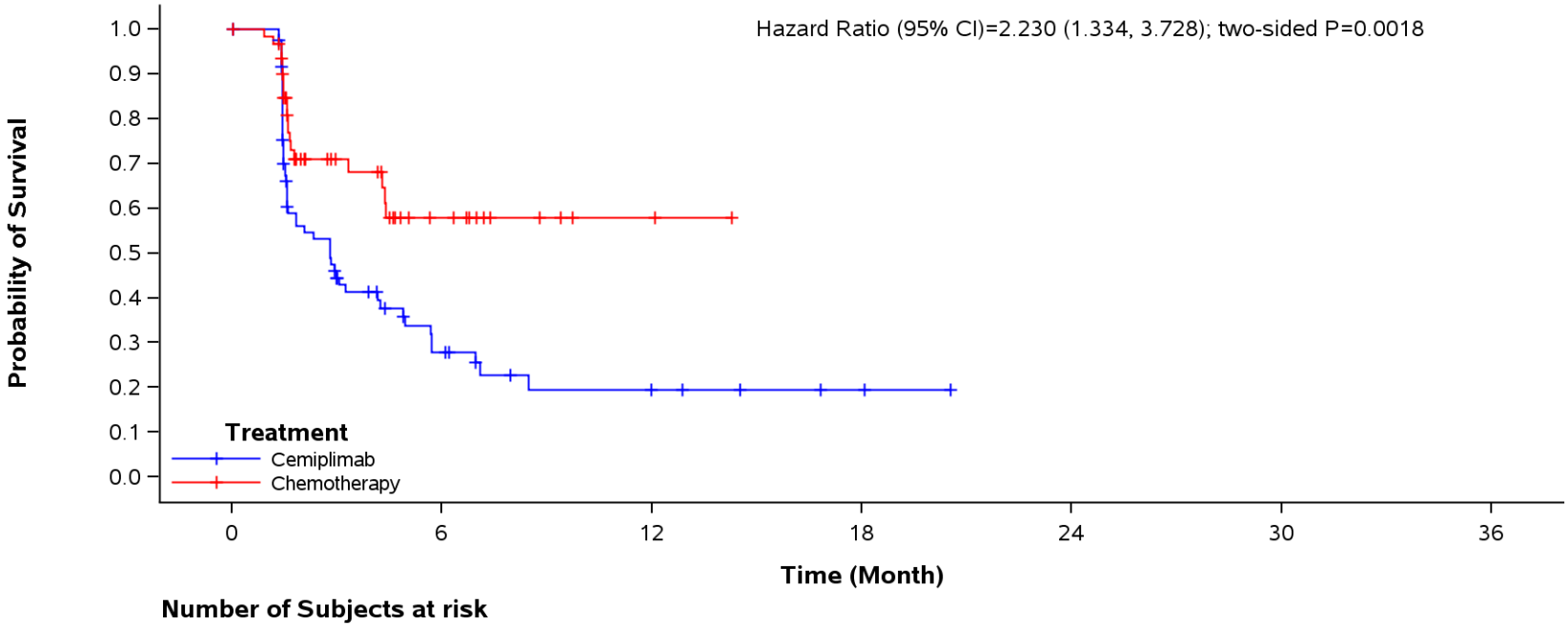

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 23 | 8 | 2 | 0 | 0 | 0 |
| Chemotherapy | 123 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts improvement



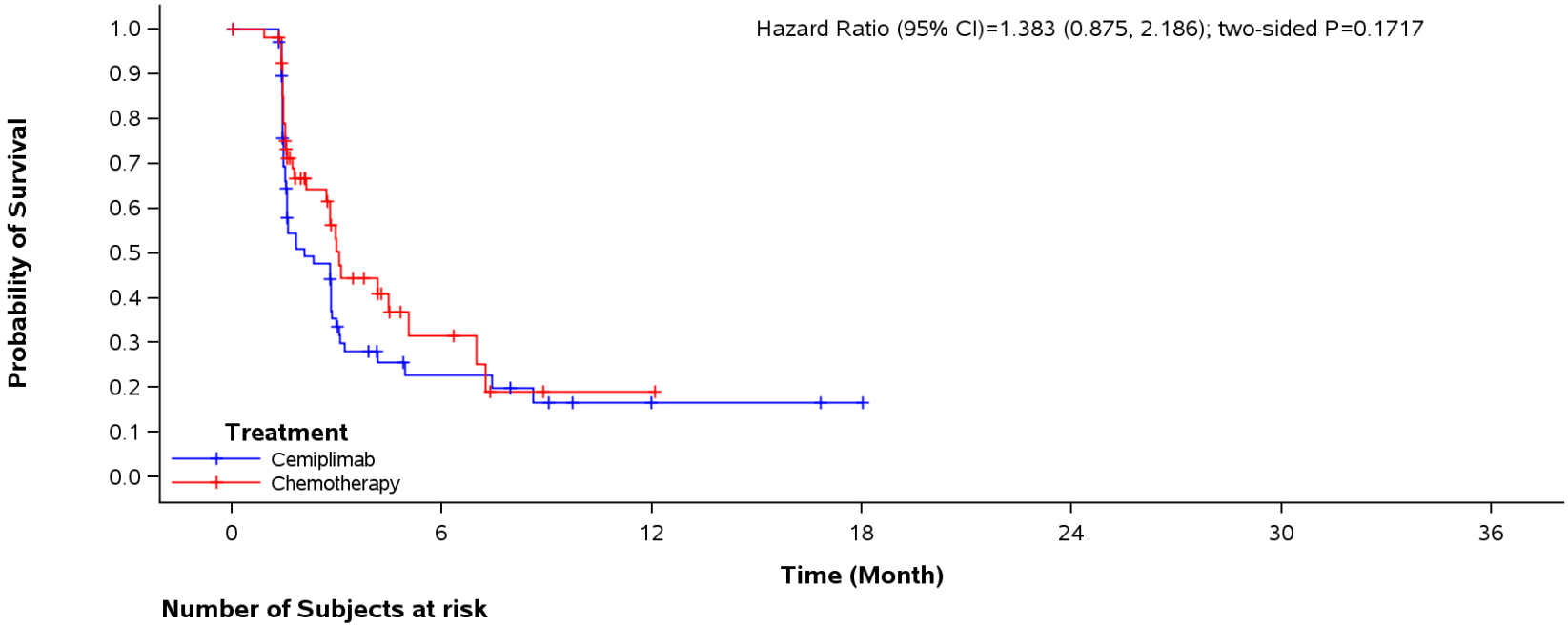

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 14 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 123 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Social Functioning - 10 pts improvement



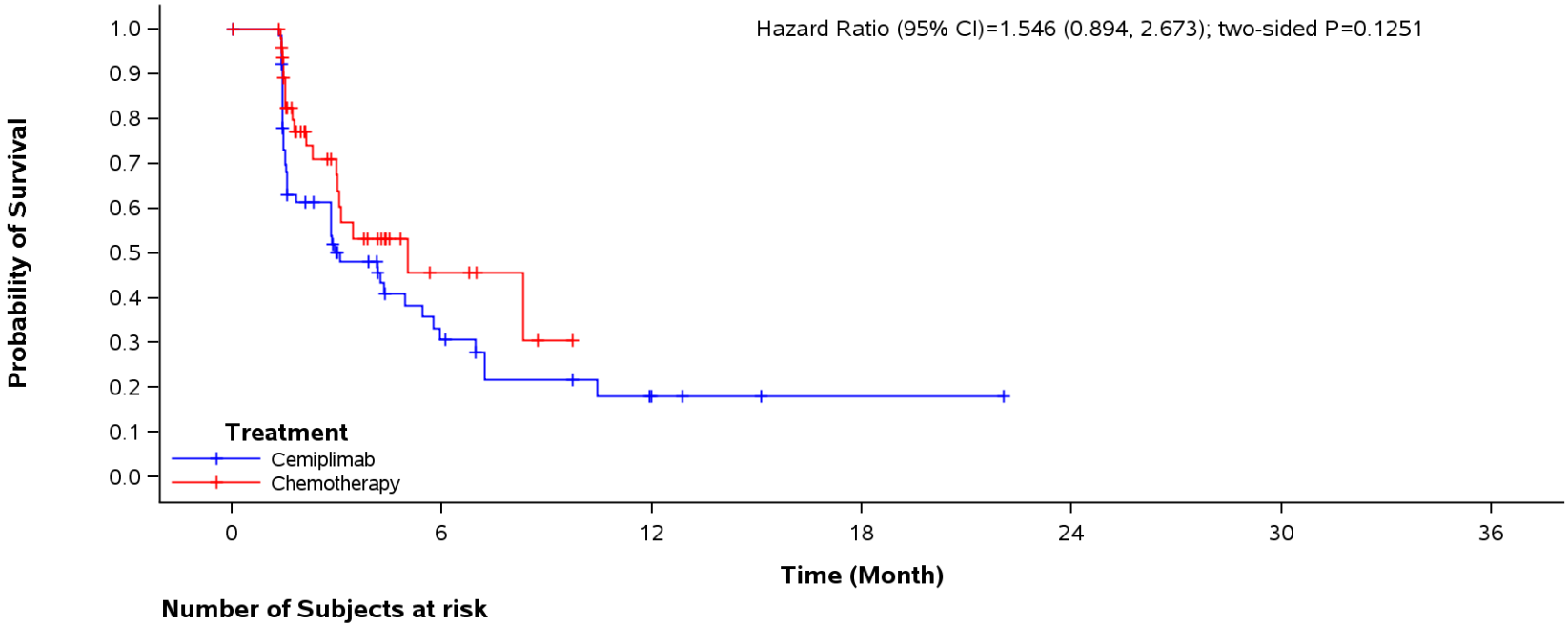

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 123 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts improvement



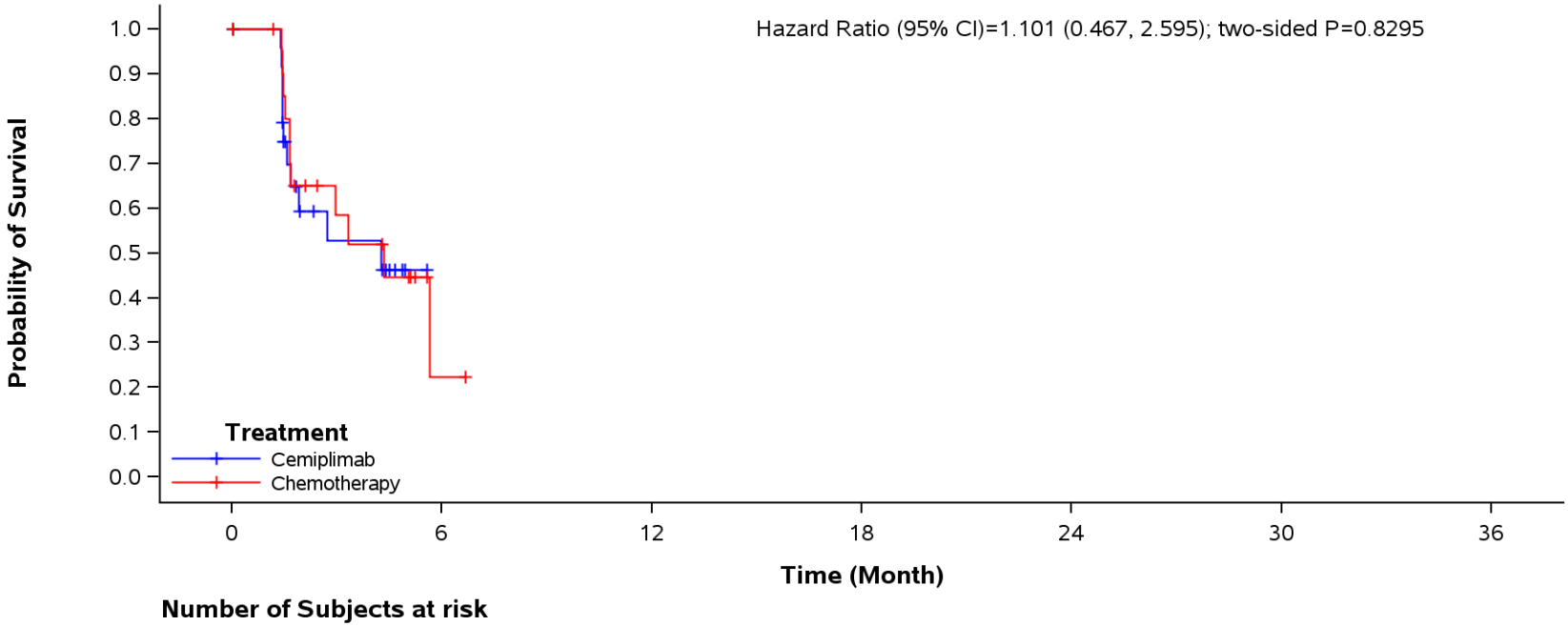

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 12 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 123 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts improvement



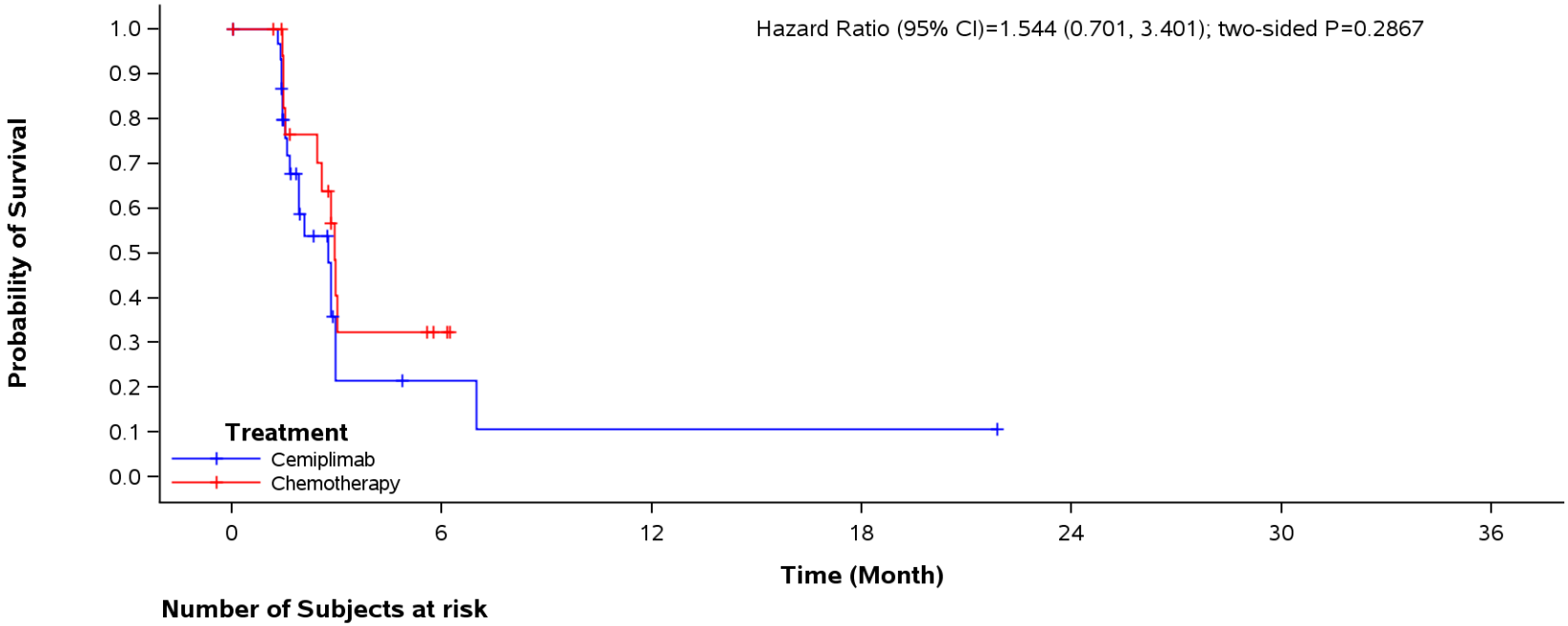

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts improvement



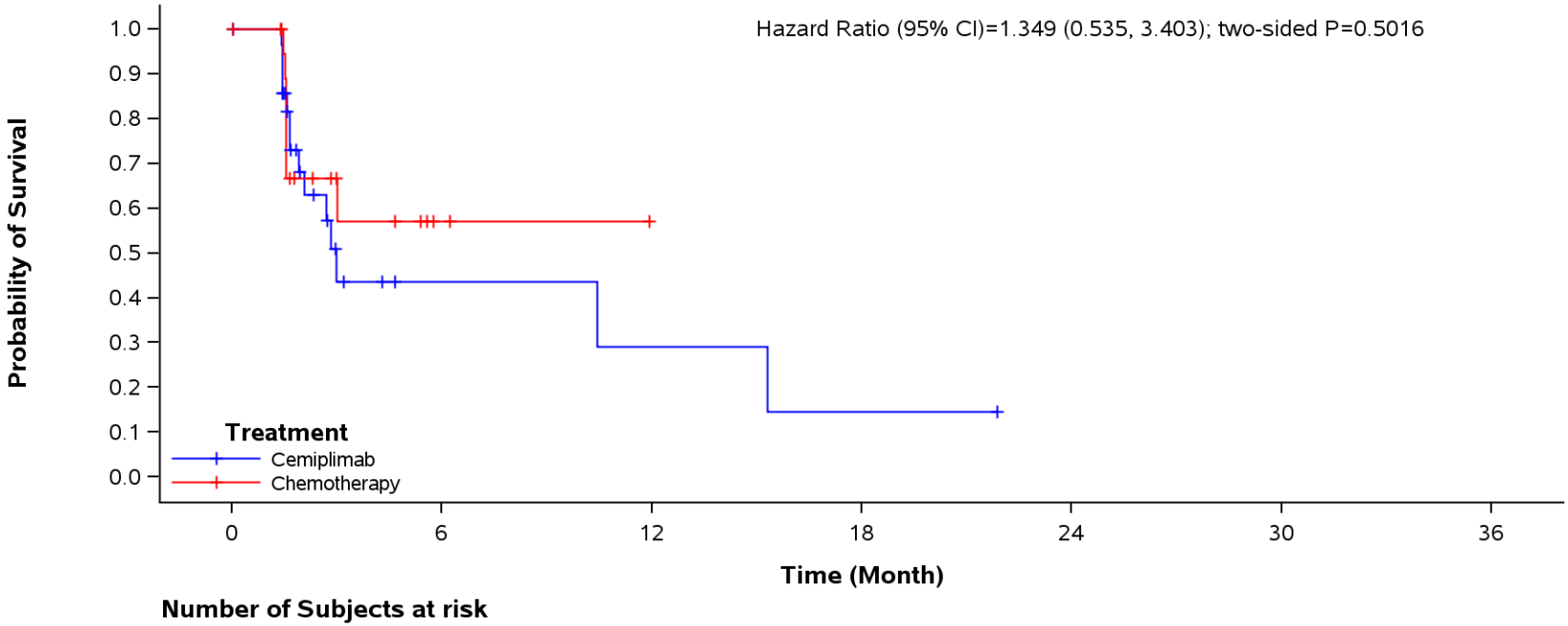

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 2 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts improvement



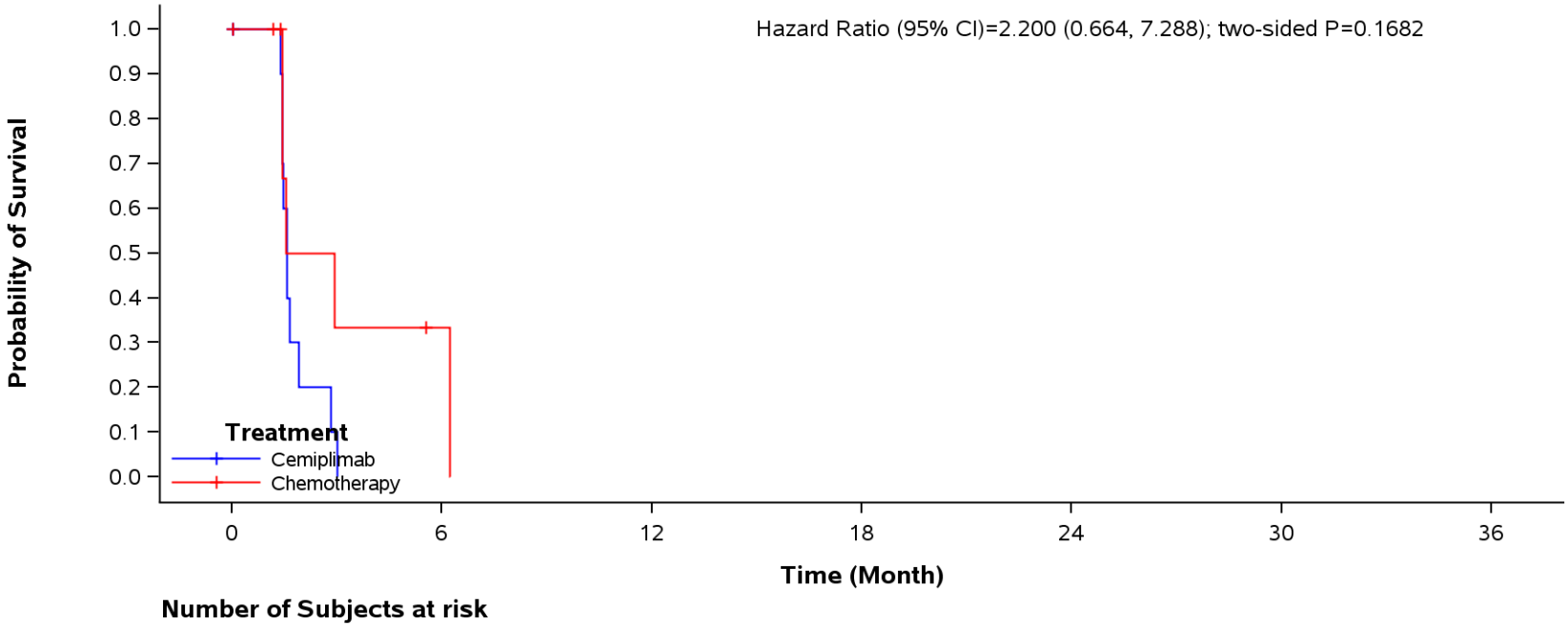

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts improvement



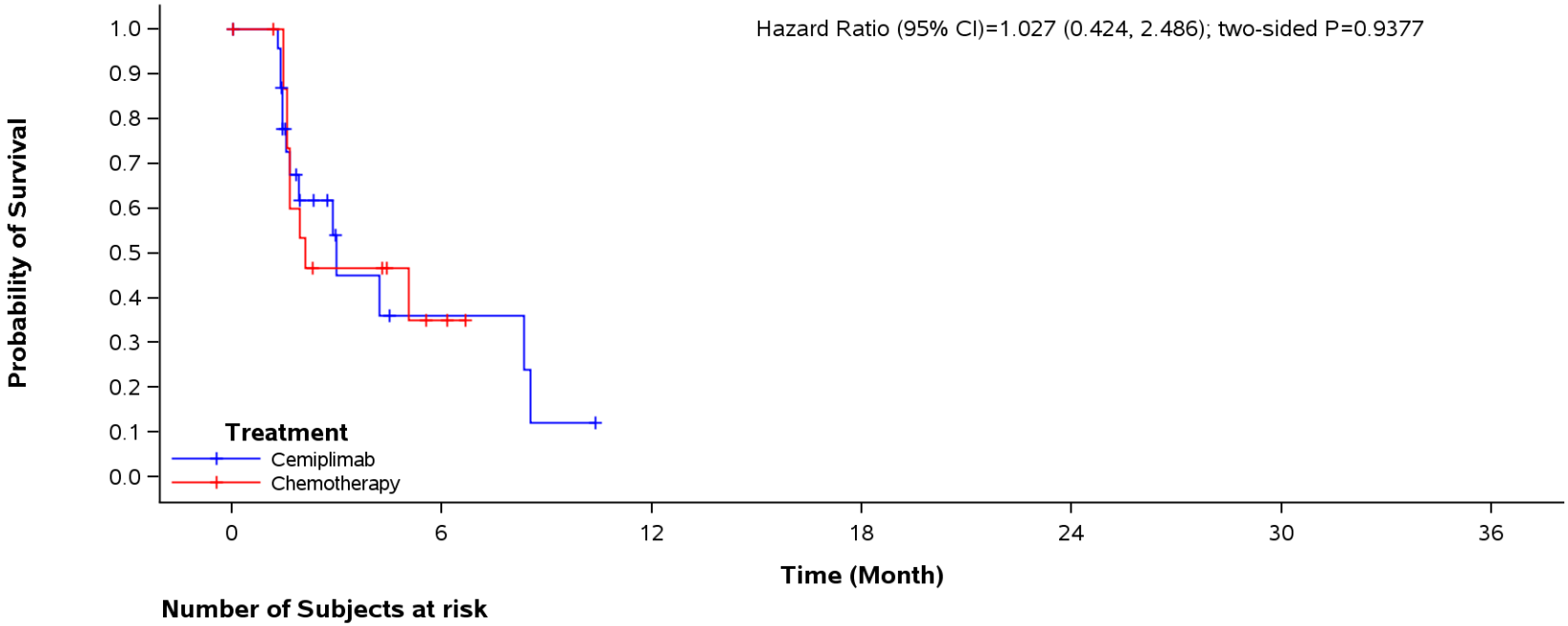

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts improvement



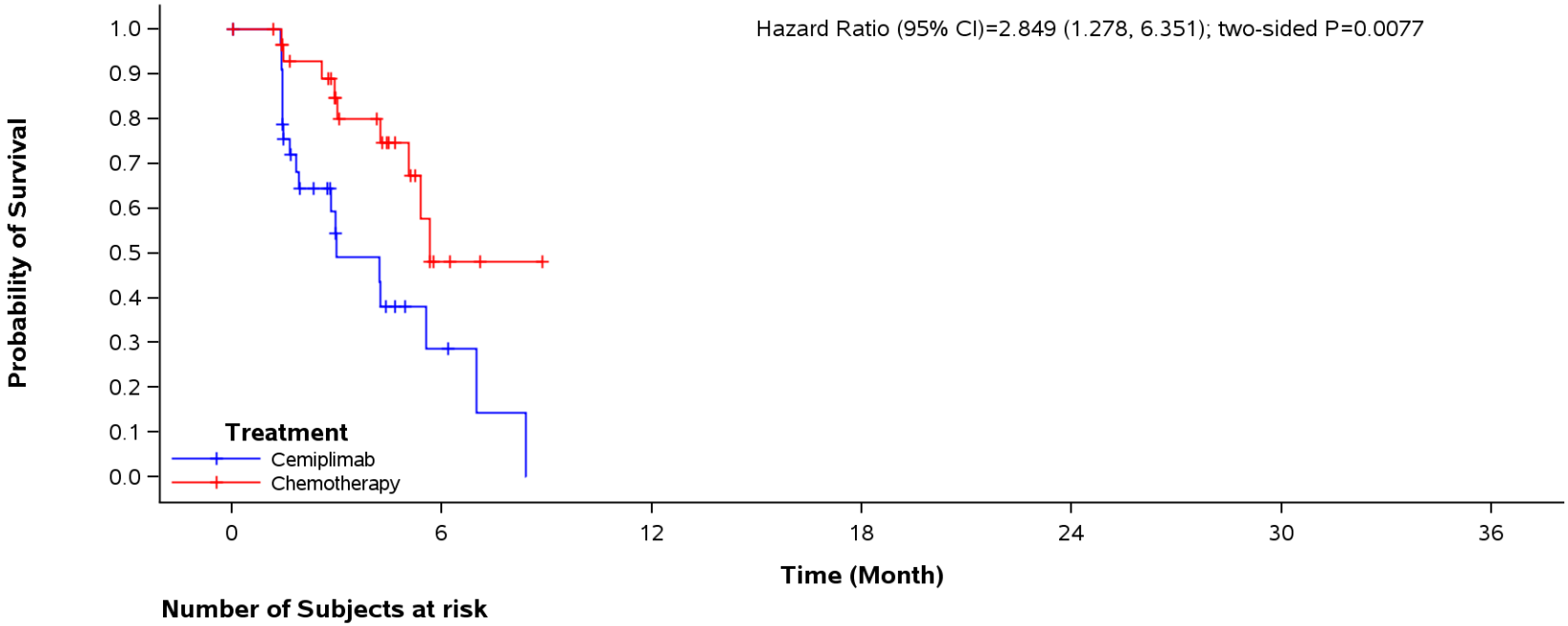

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts improvement



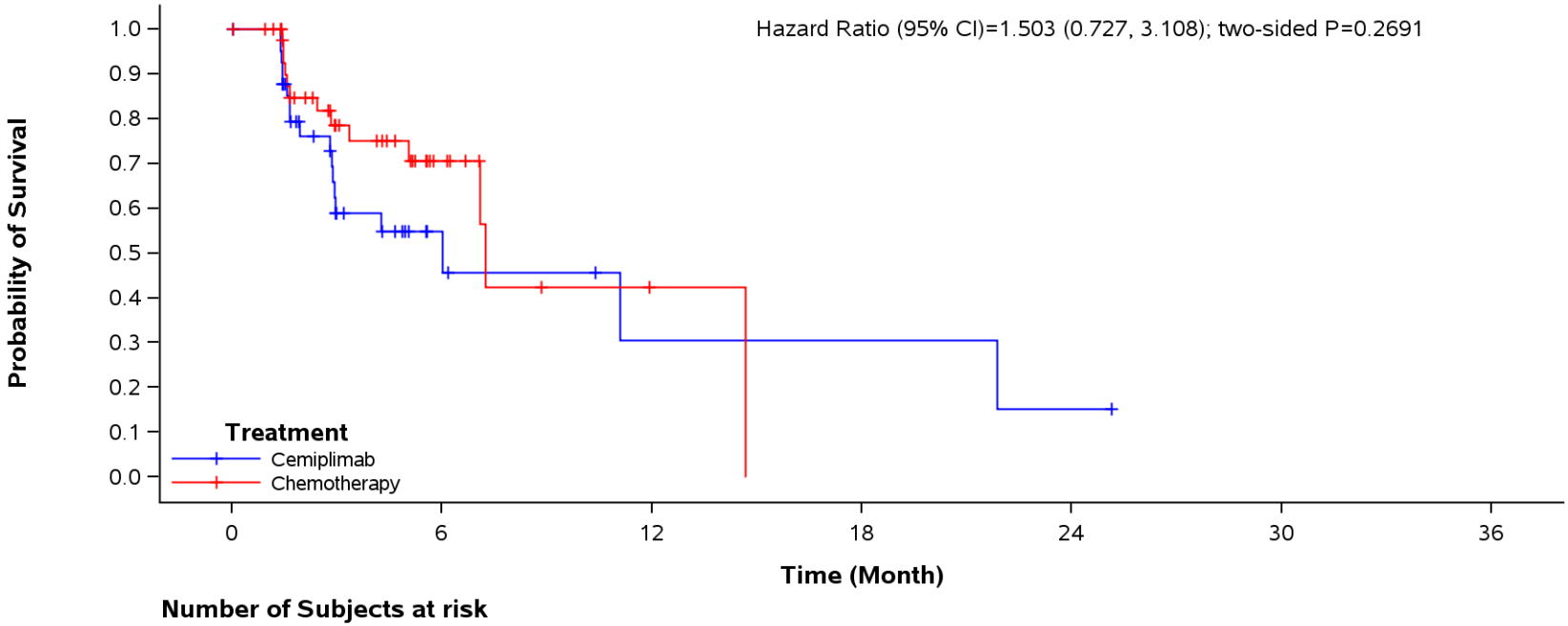

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts improvement



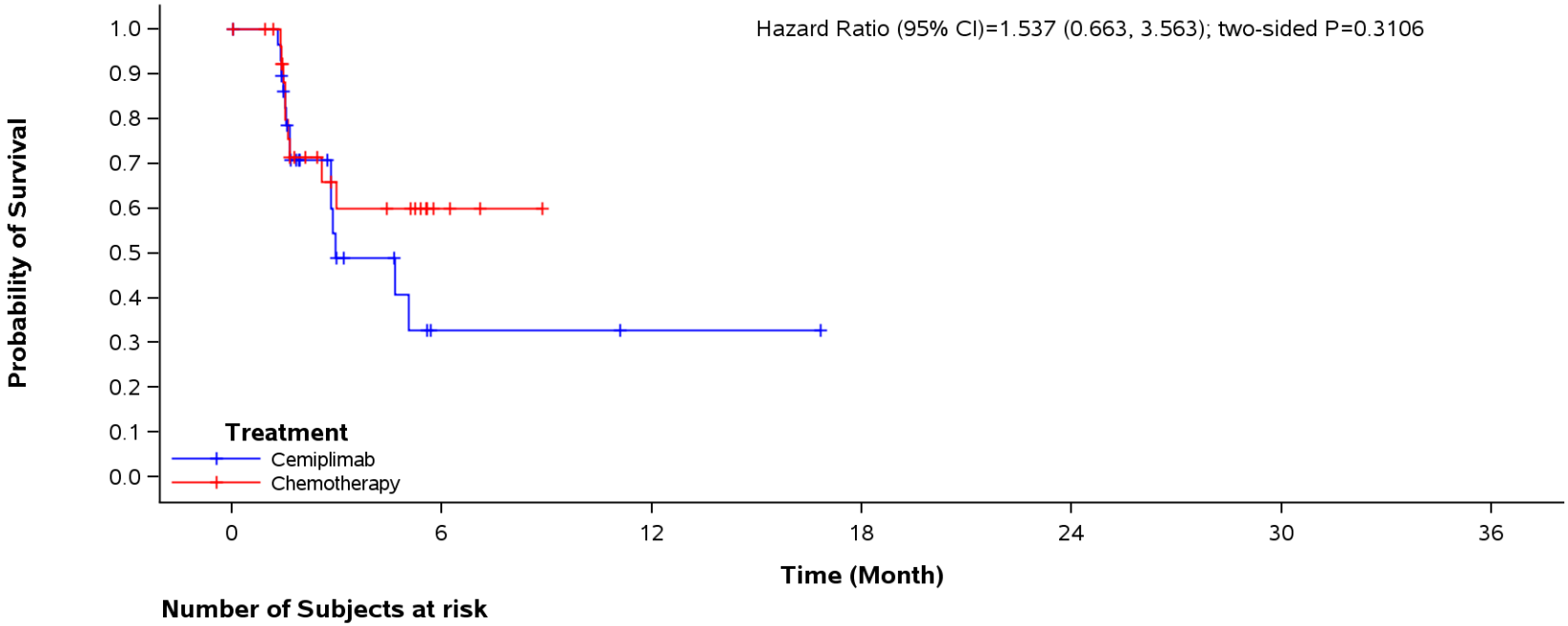

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 6 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts improvement



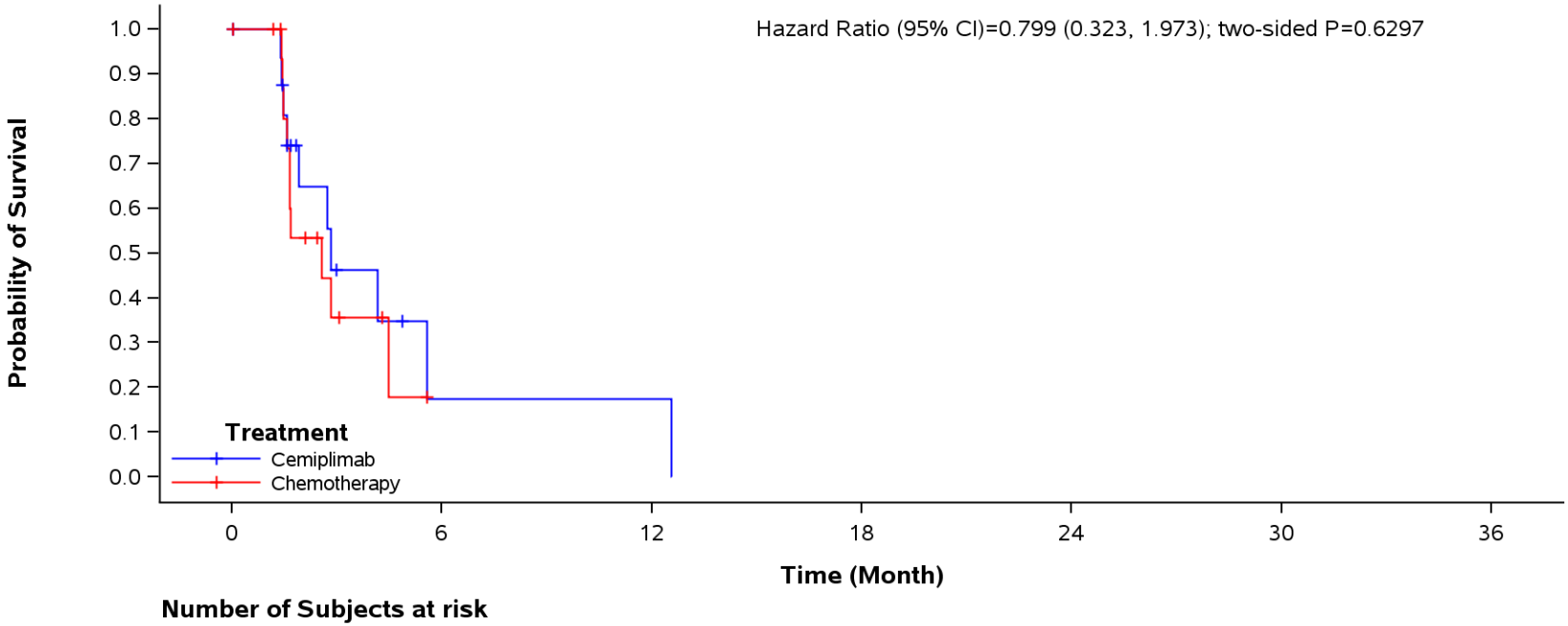

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts improvement



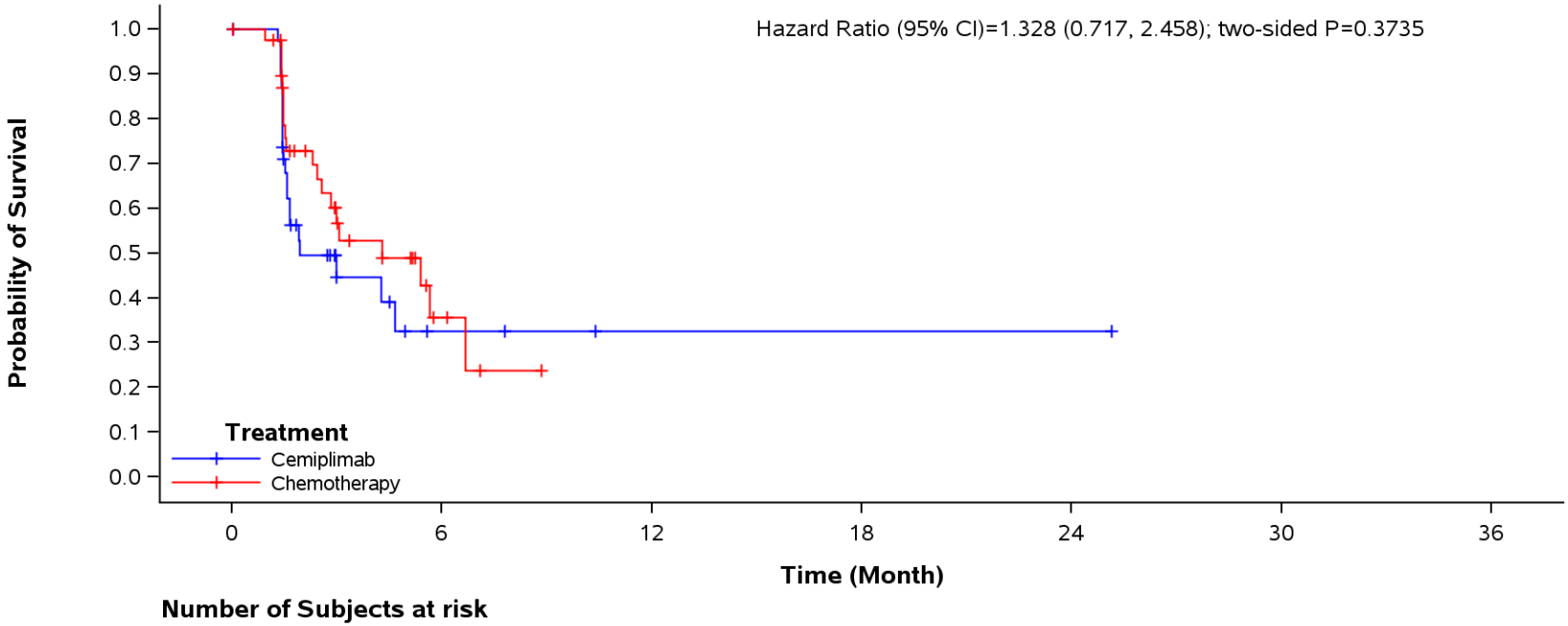

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts improvement



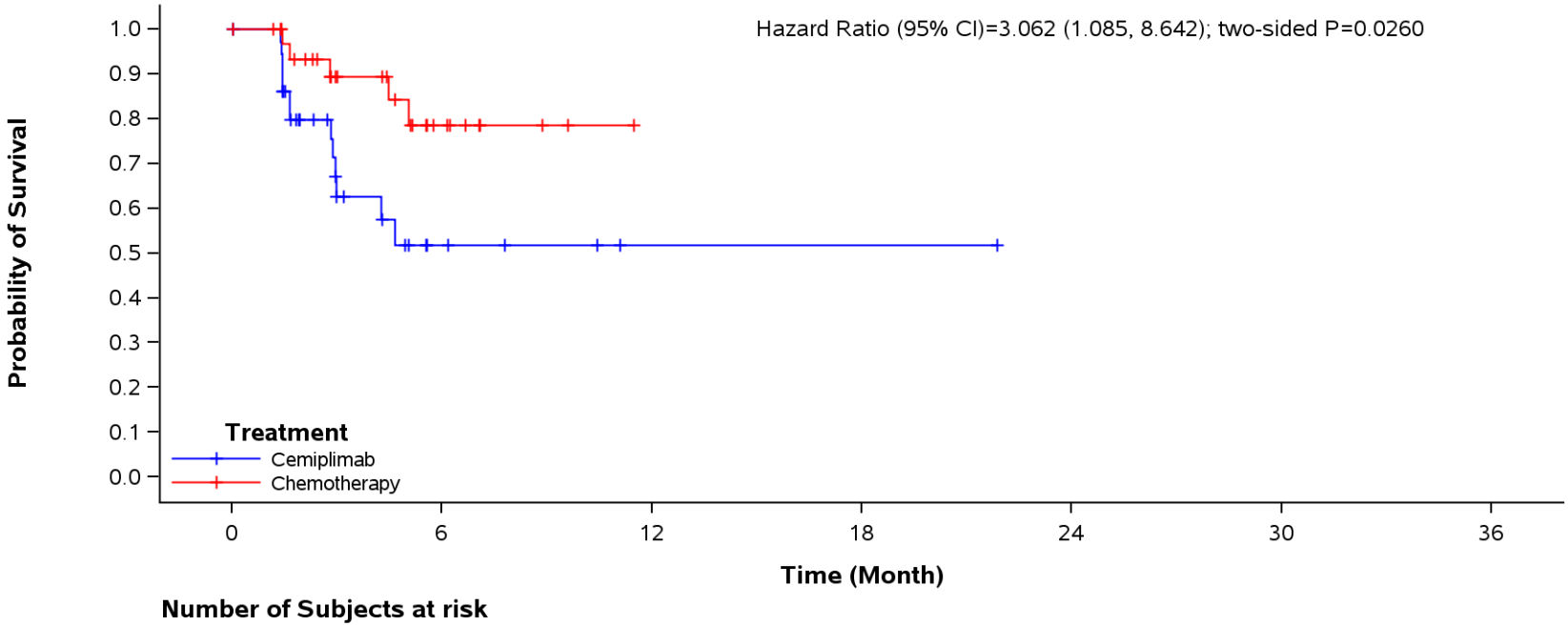

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts improvement



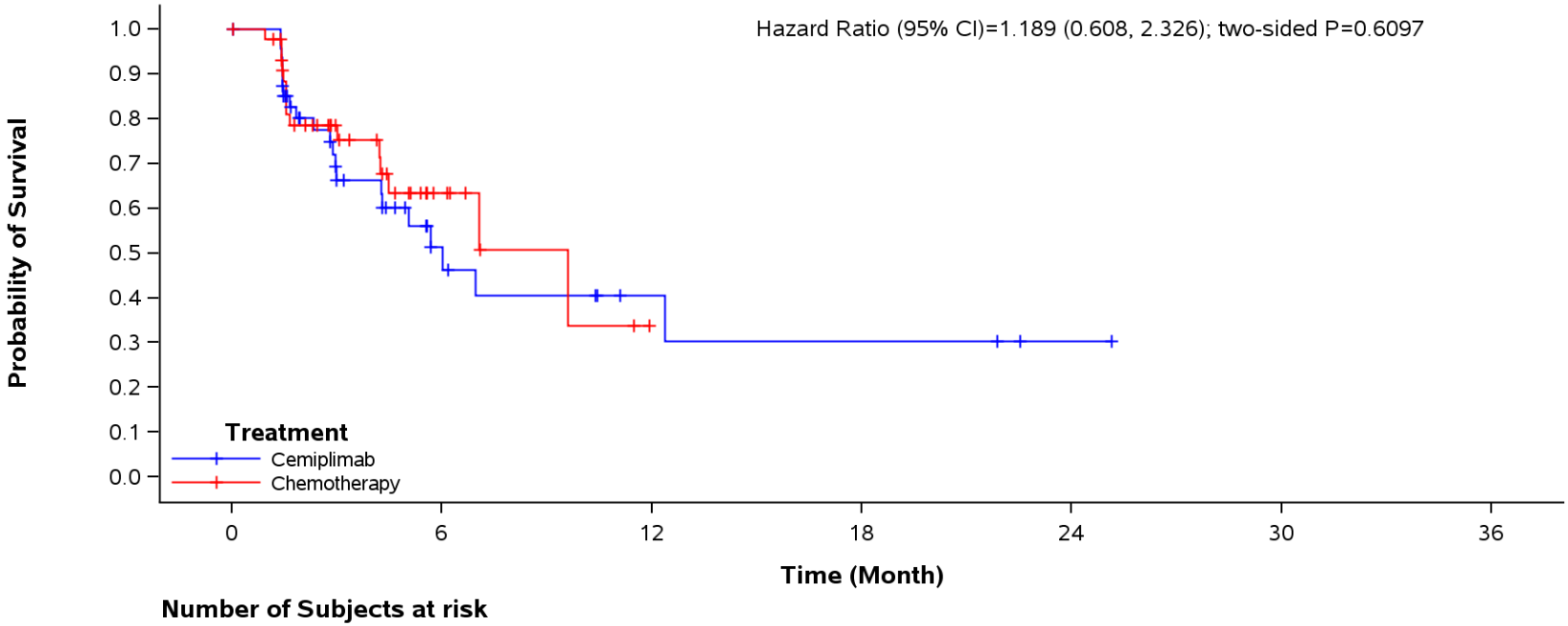

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts improvement



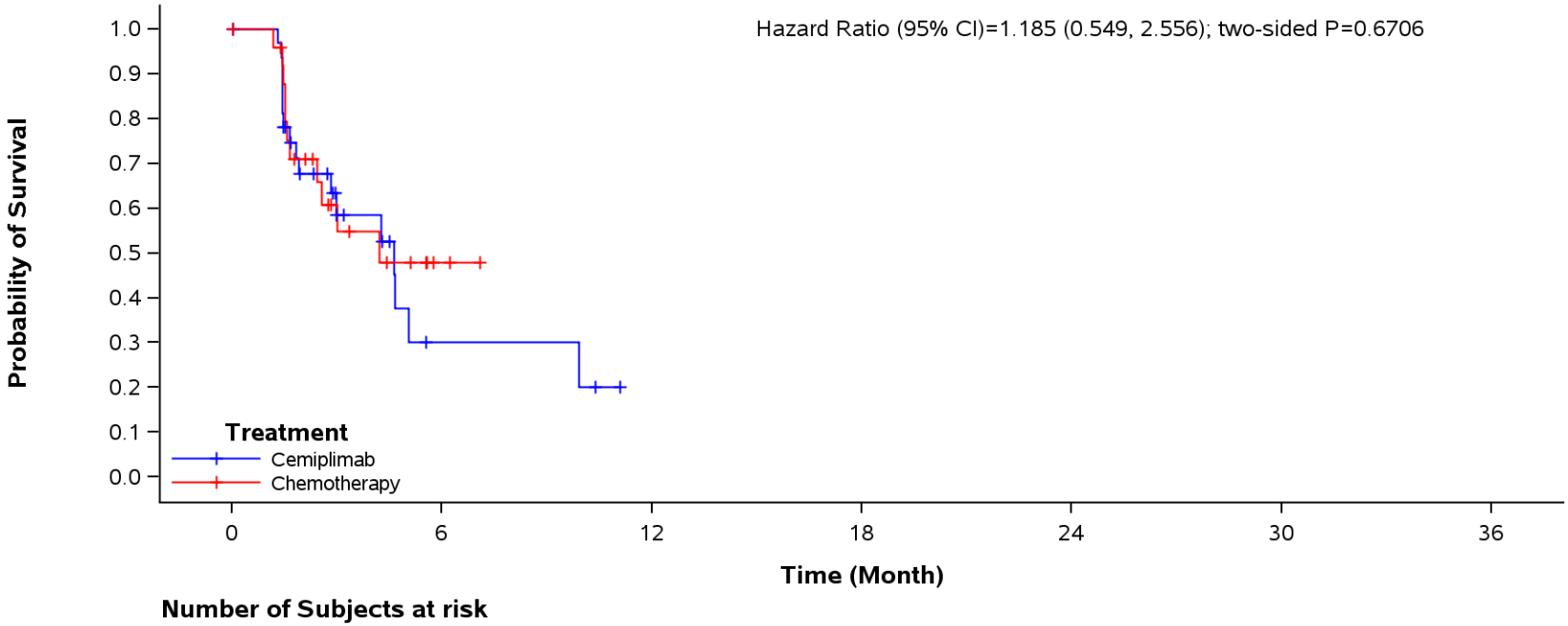

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 10 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 60 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts improvement



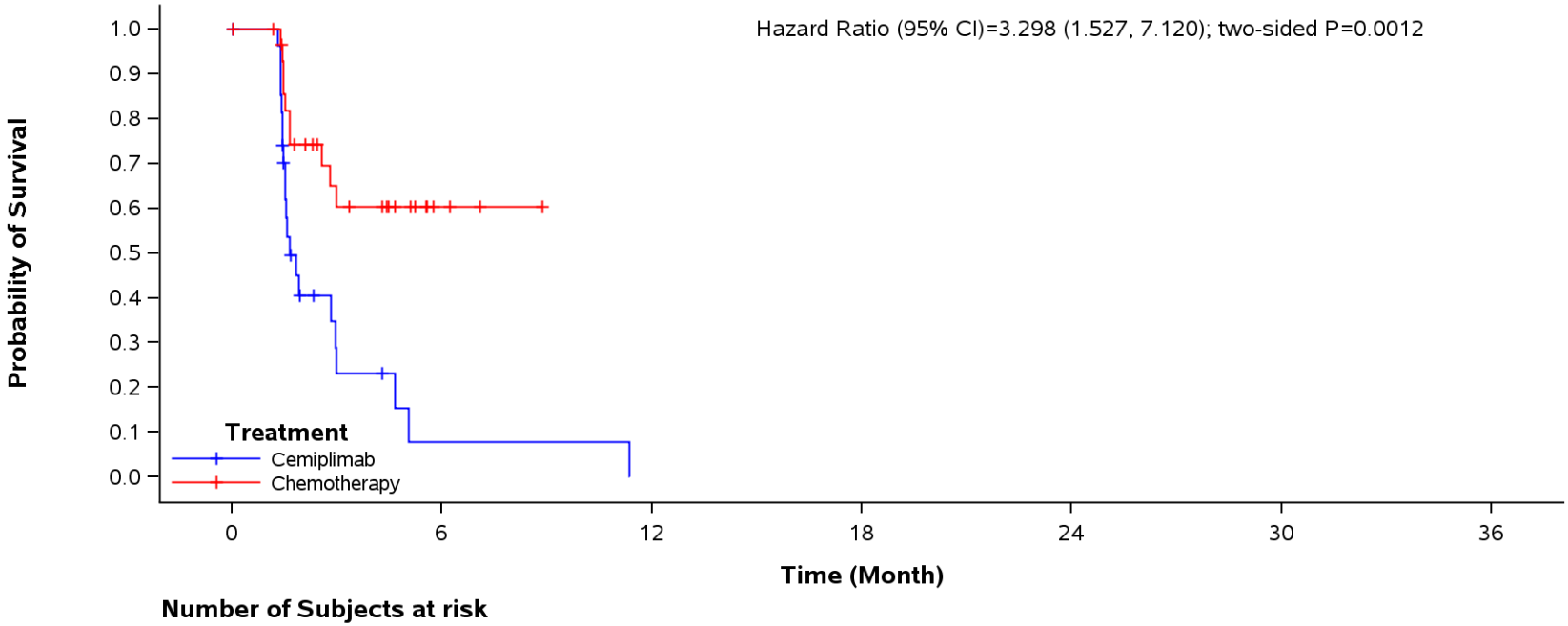

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts improvement



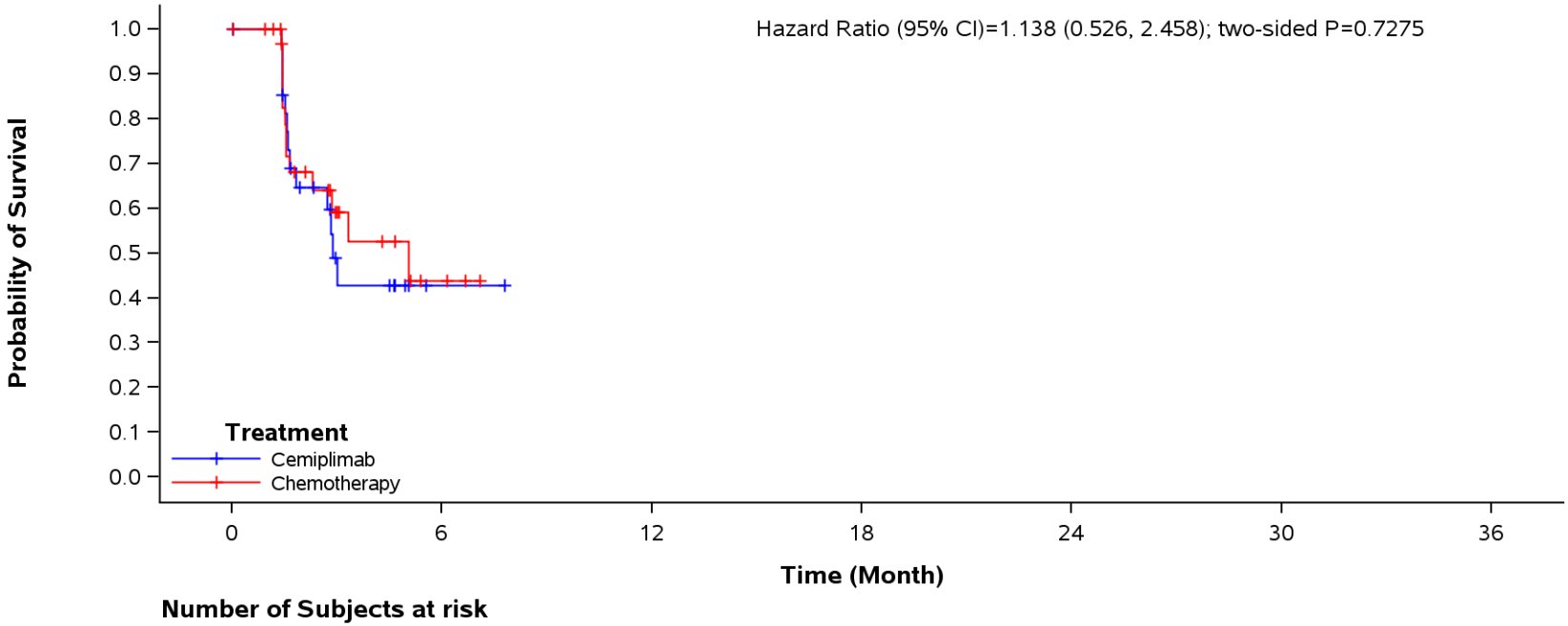

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts improvement



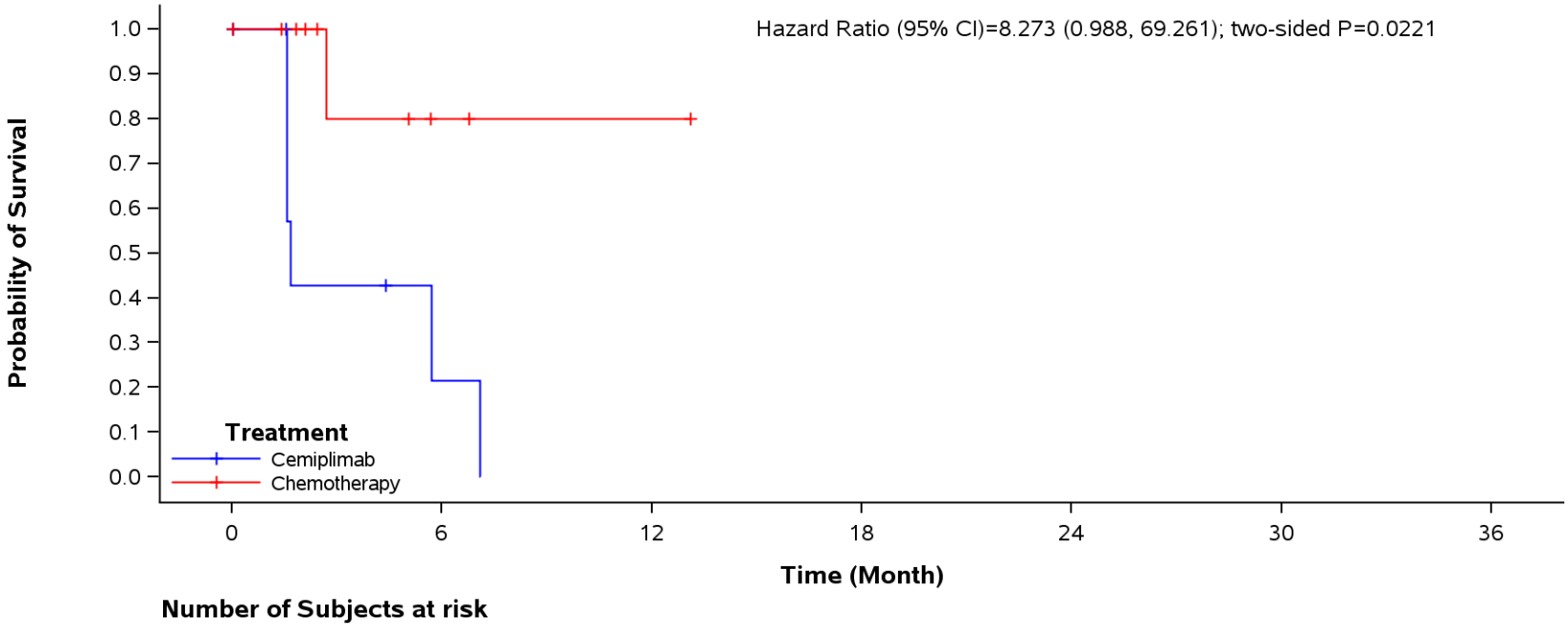

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts improvement



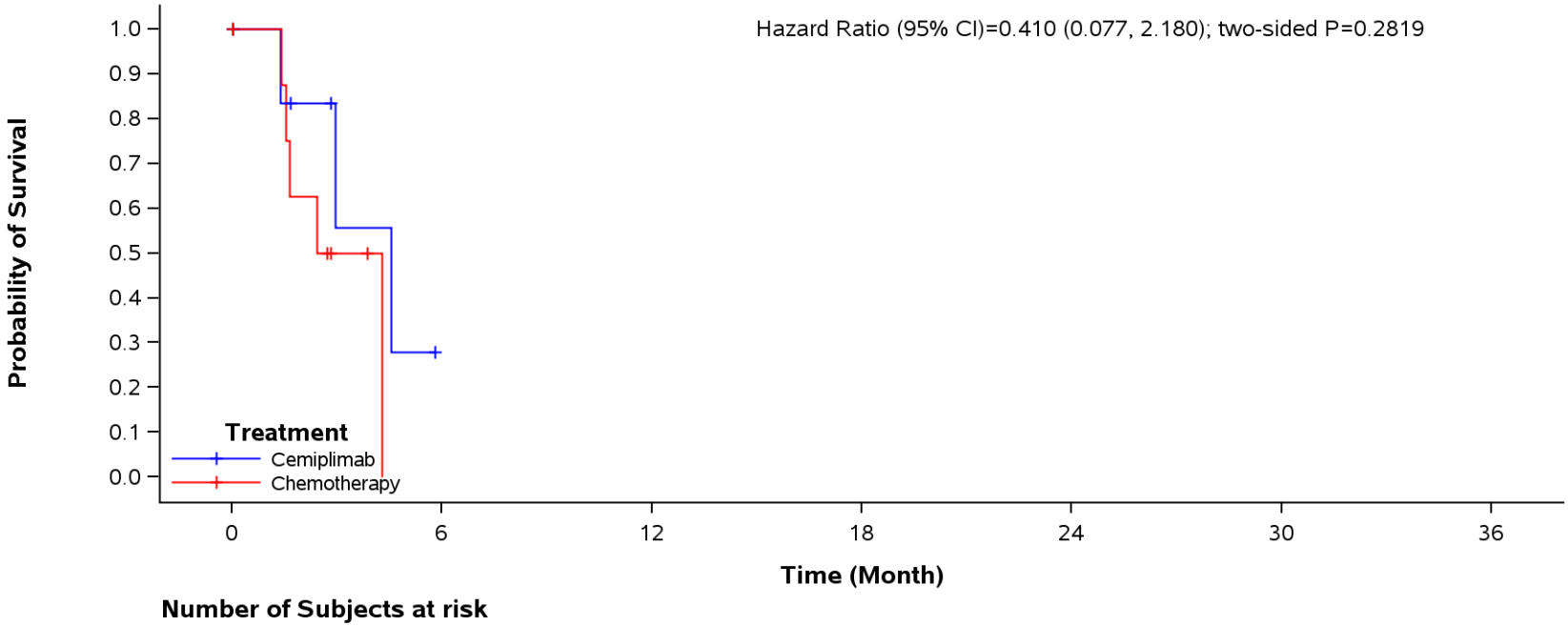

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts improvement



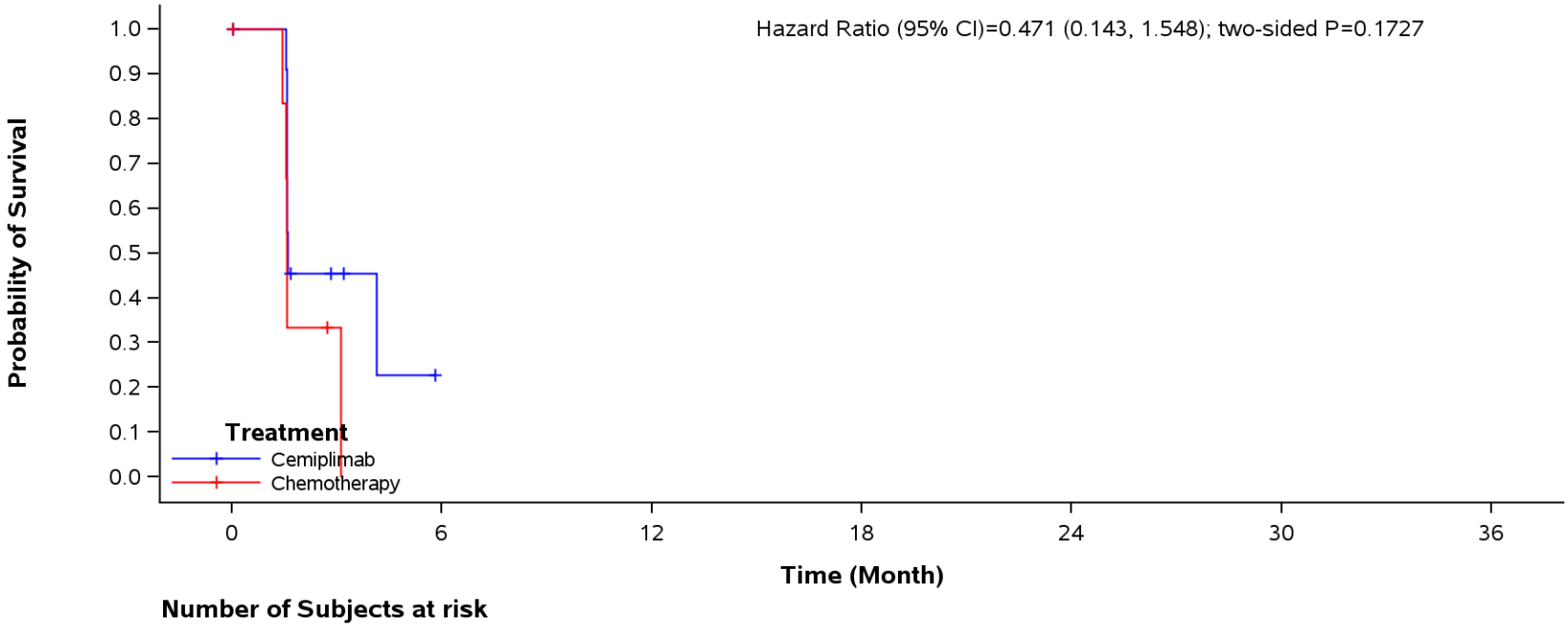

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts improvement



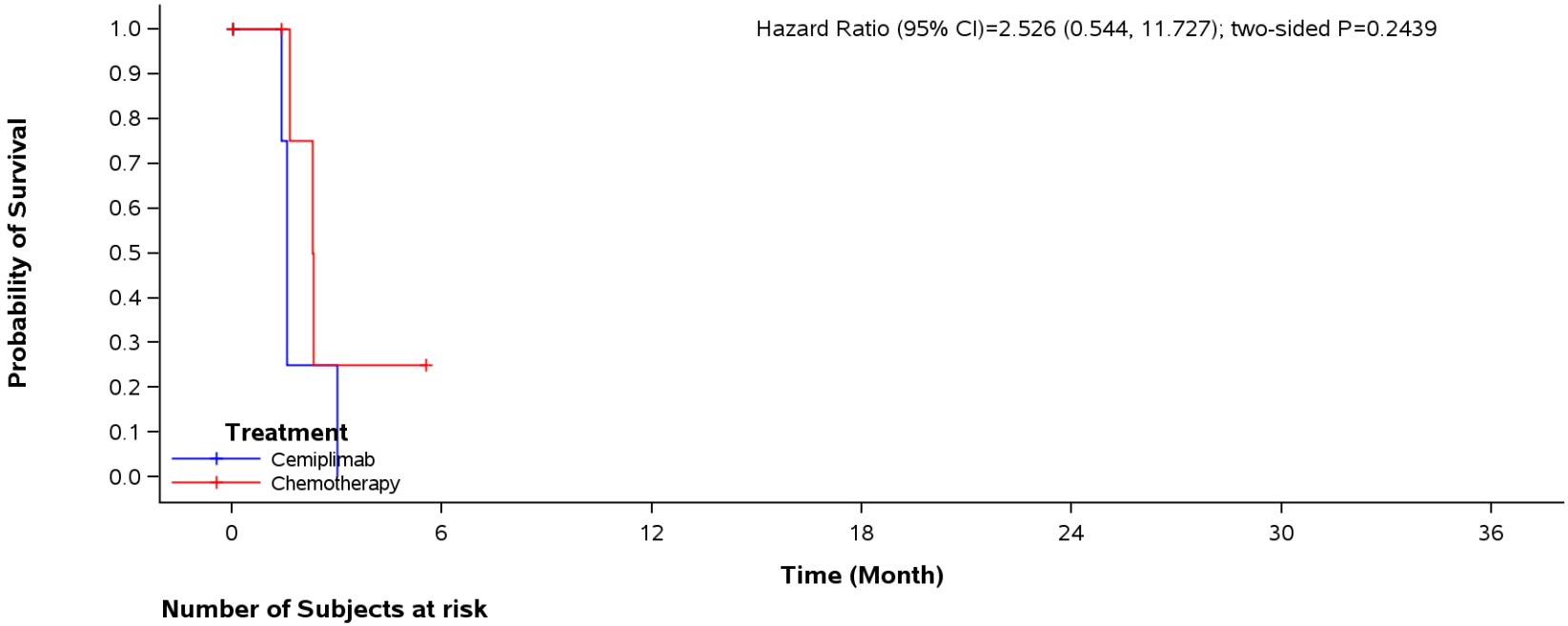

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts improvement



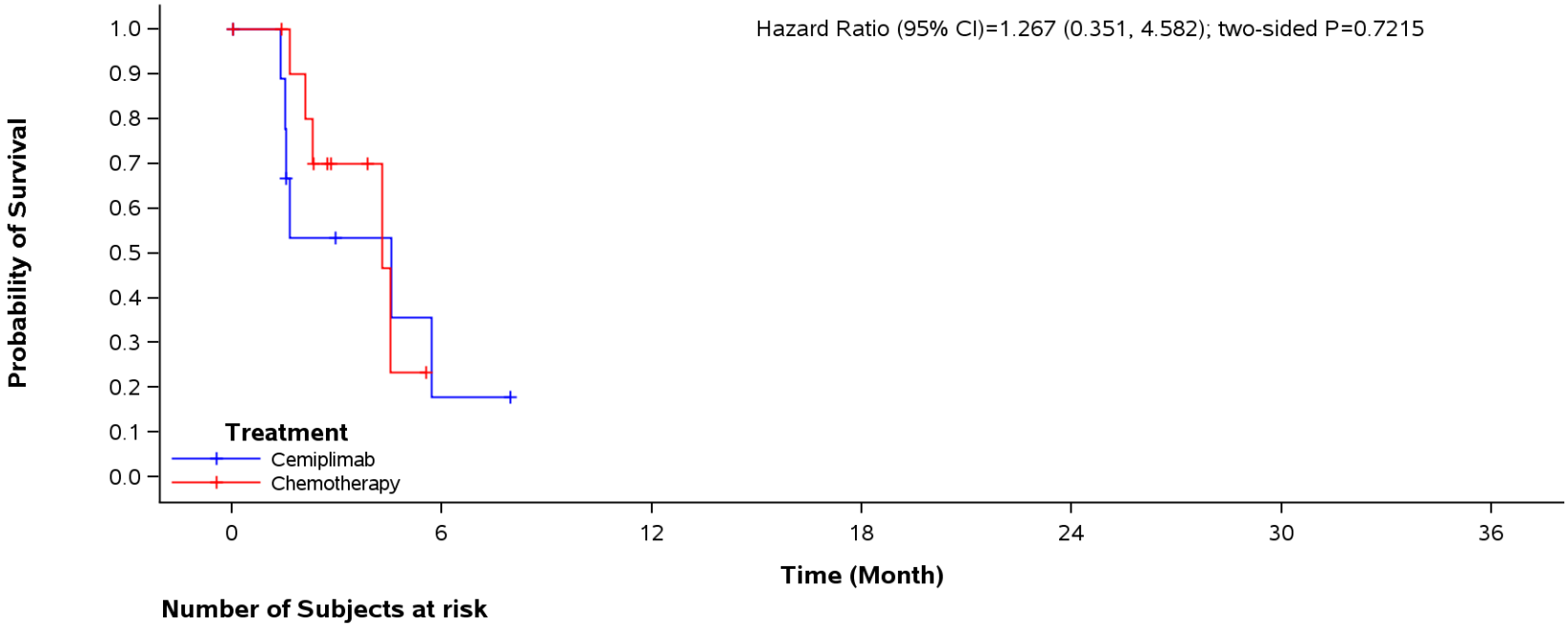

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts improvement



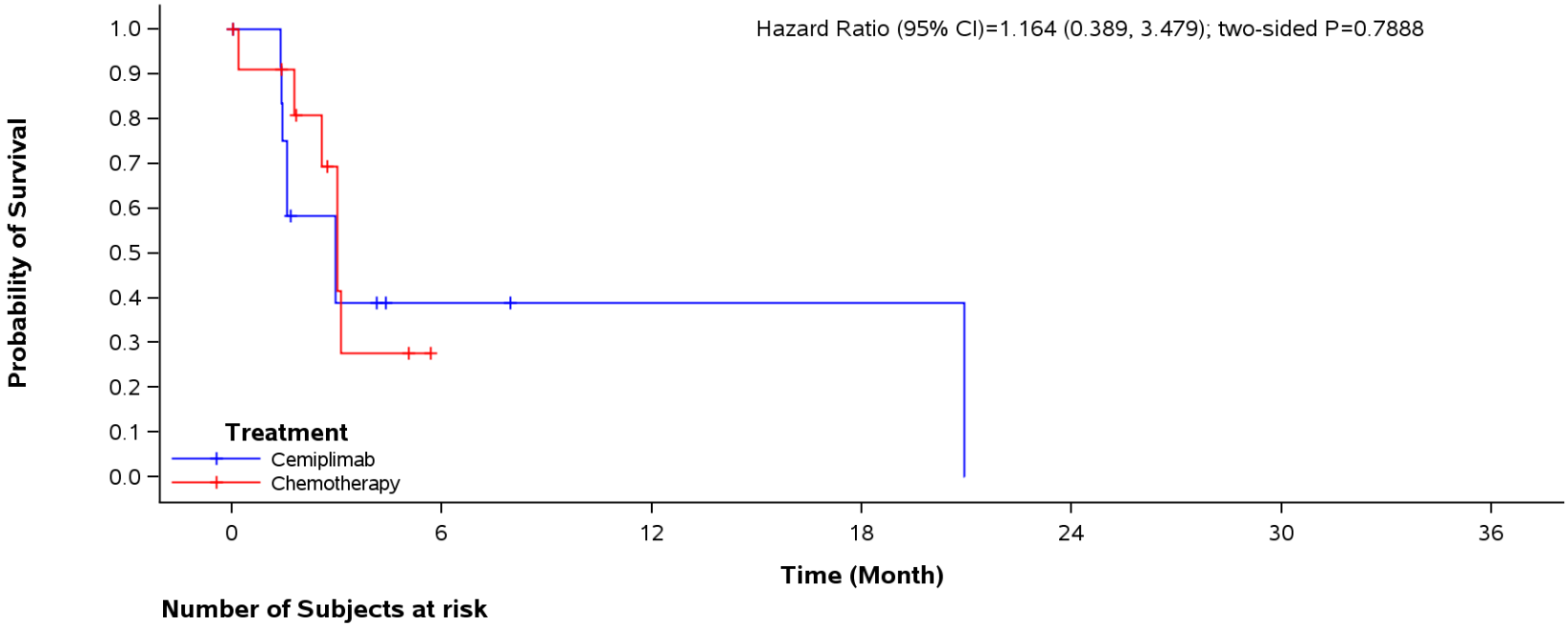

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts improvement



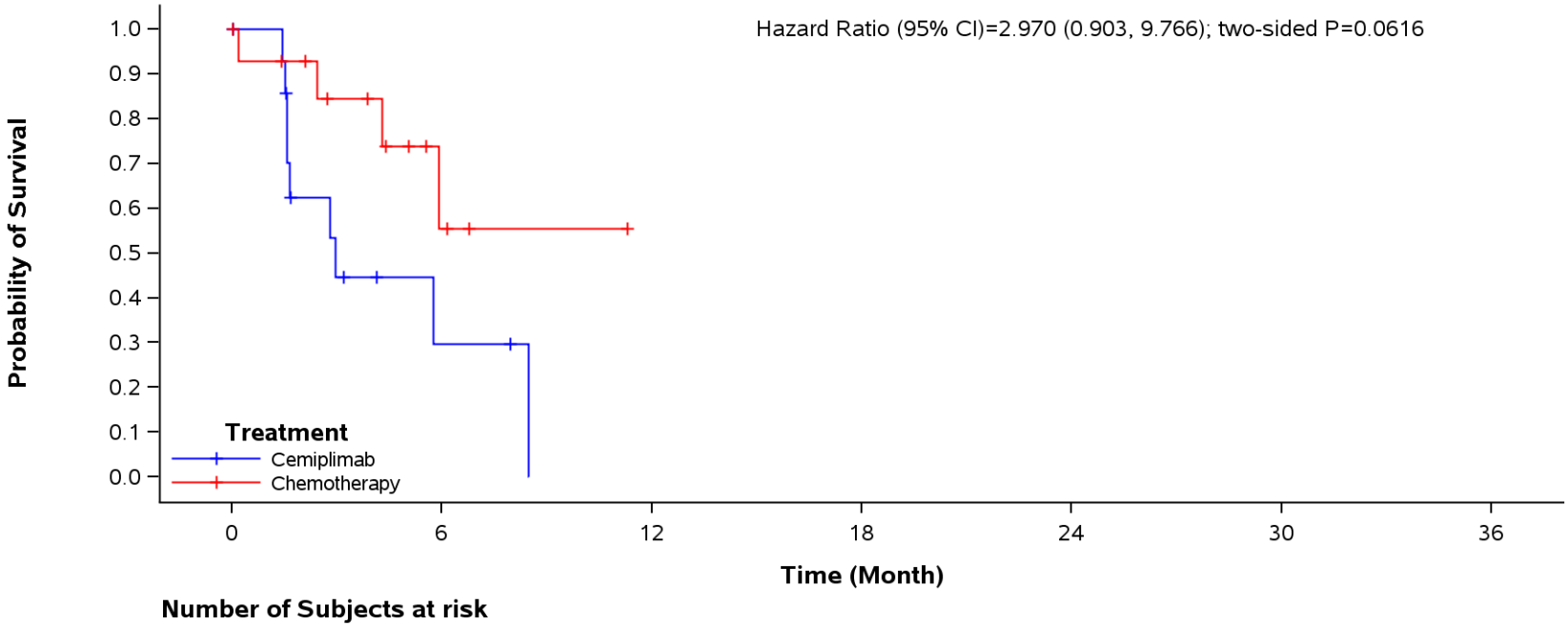

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 2 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts improvement



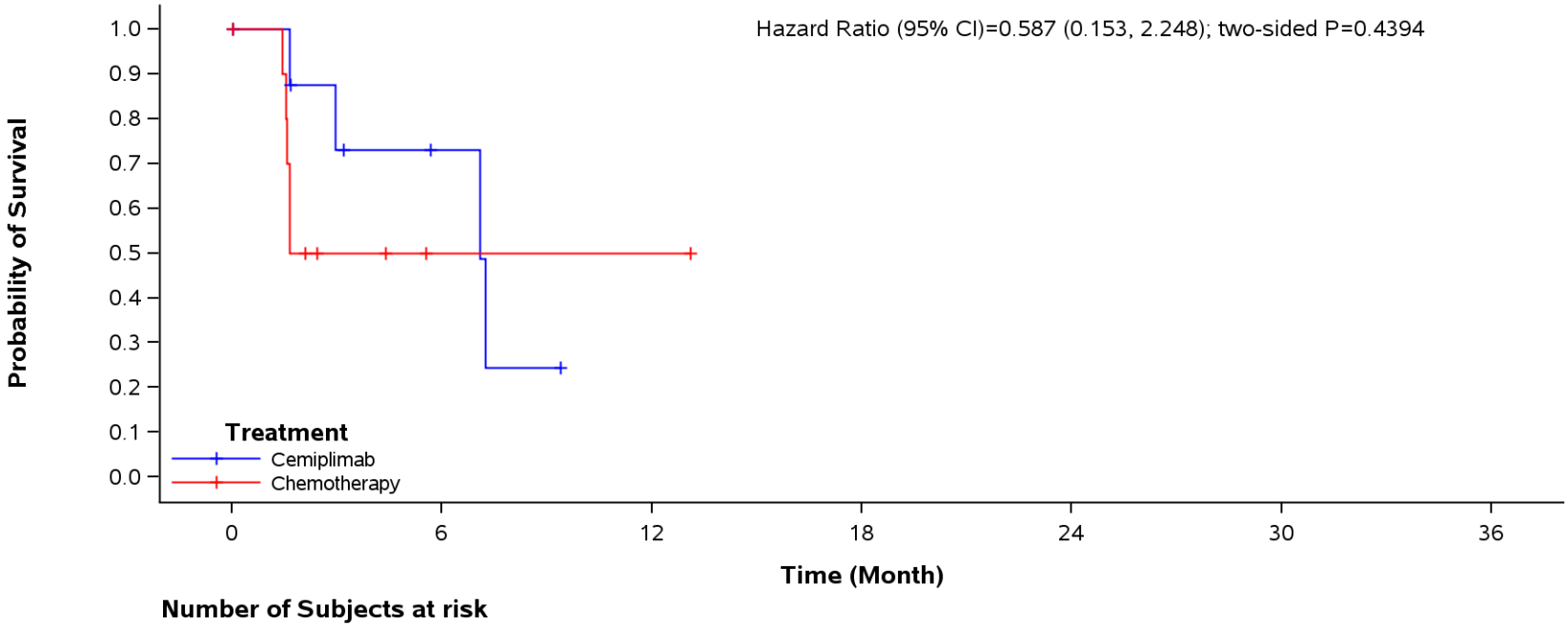

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts improvement



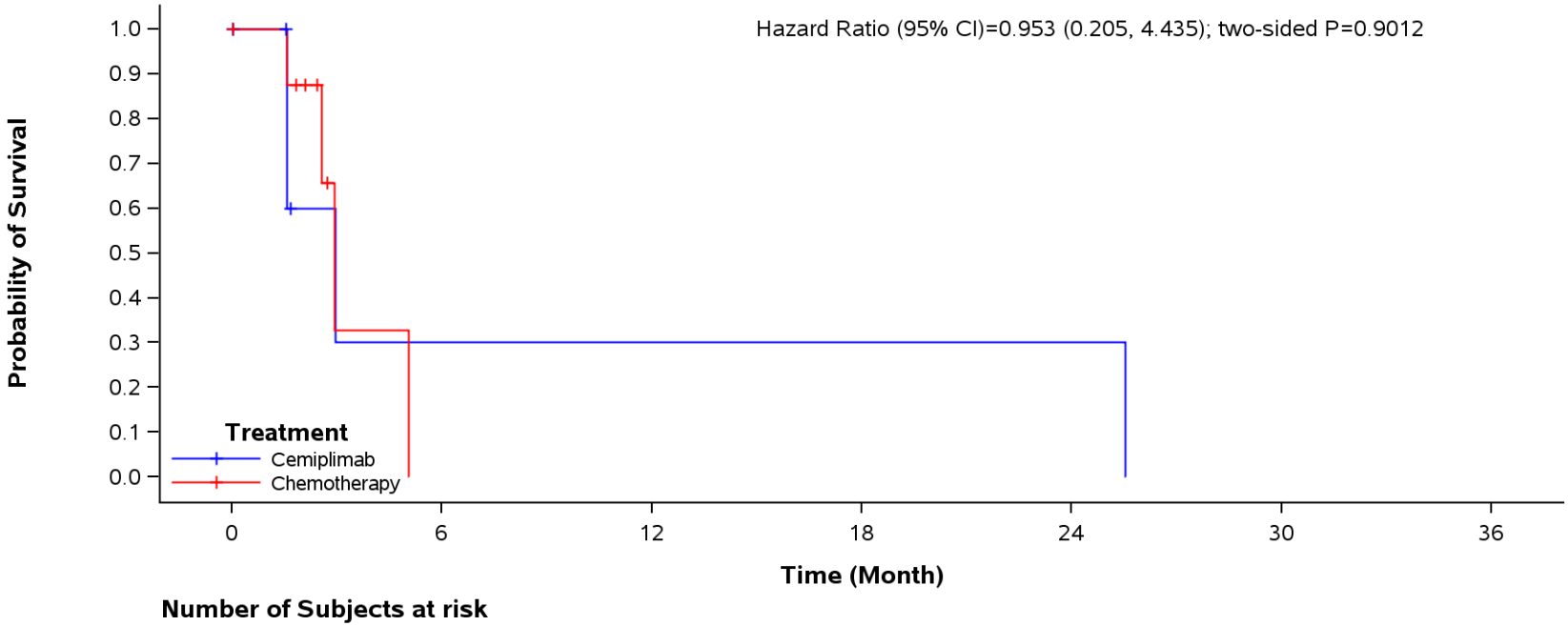

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 1 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts improvement



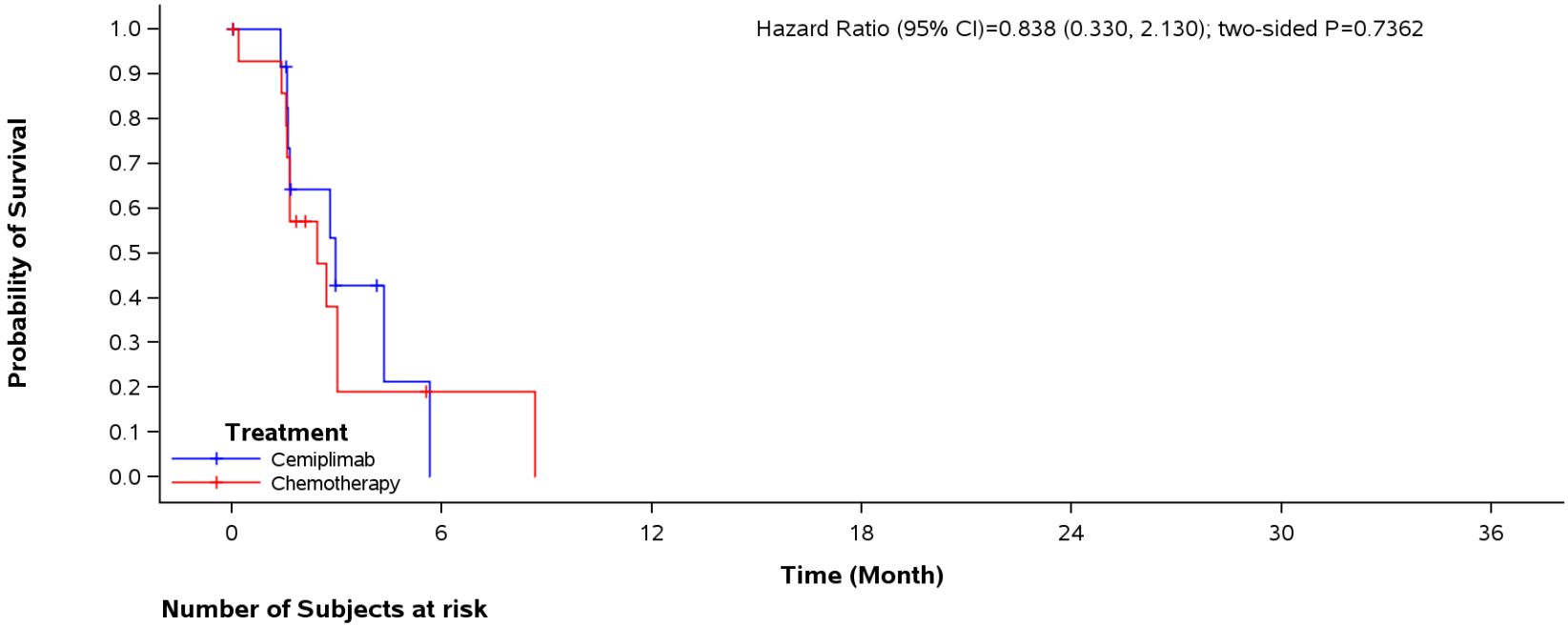

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 1 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts improvement



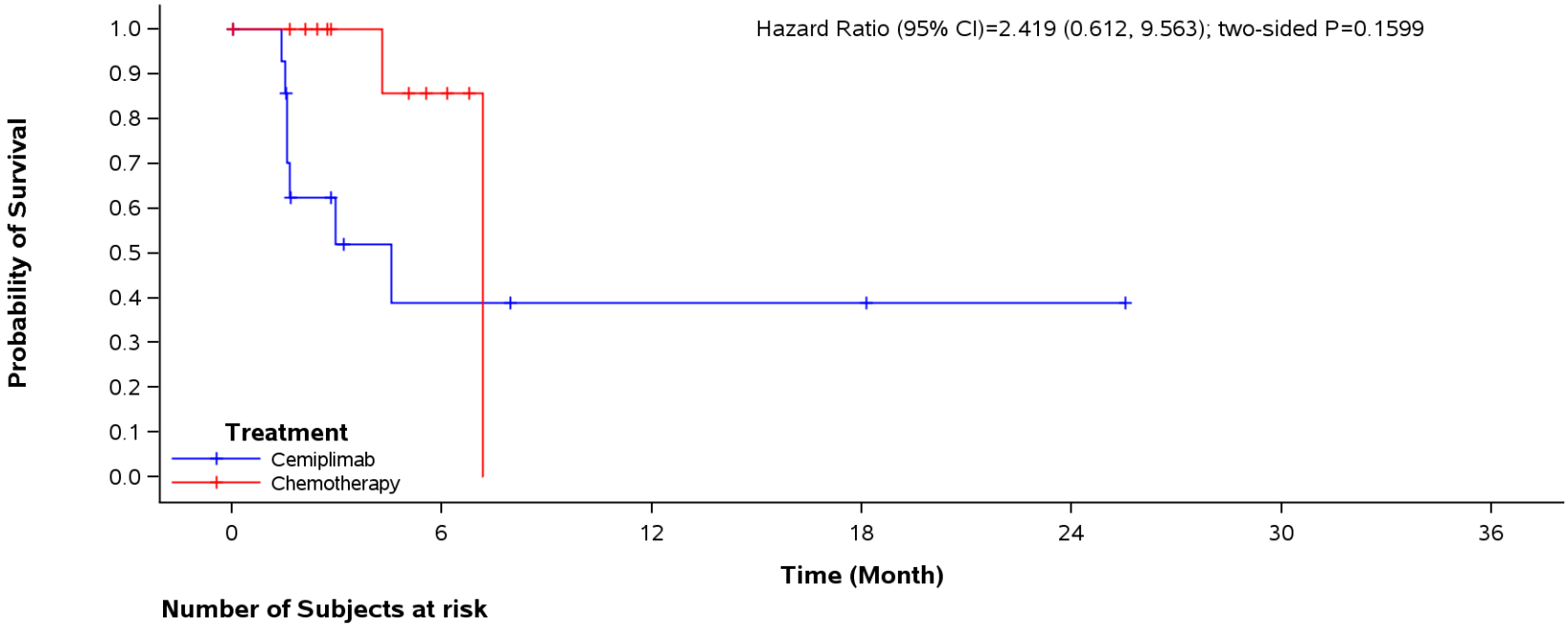

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts improvement



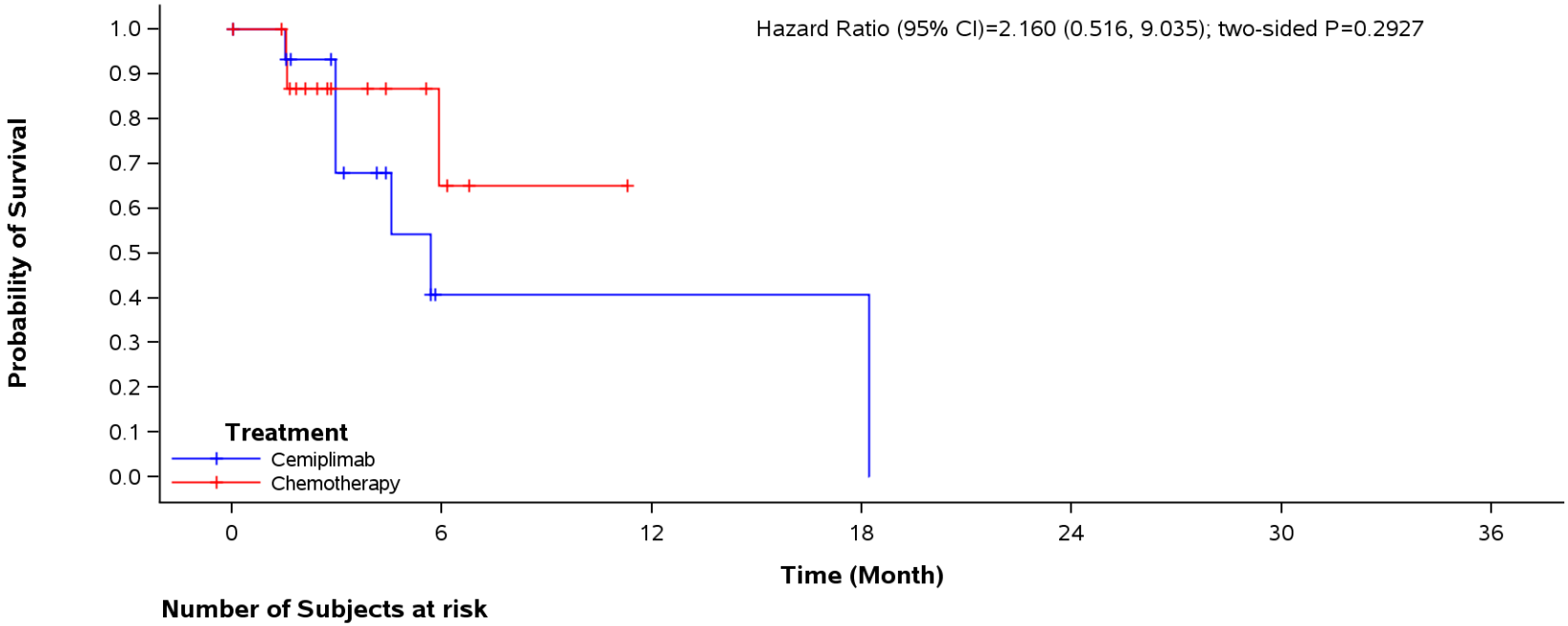

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts improvement



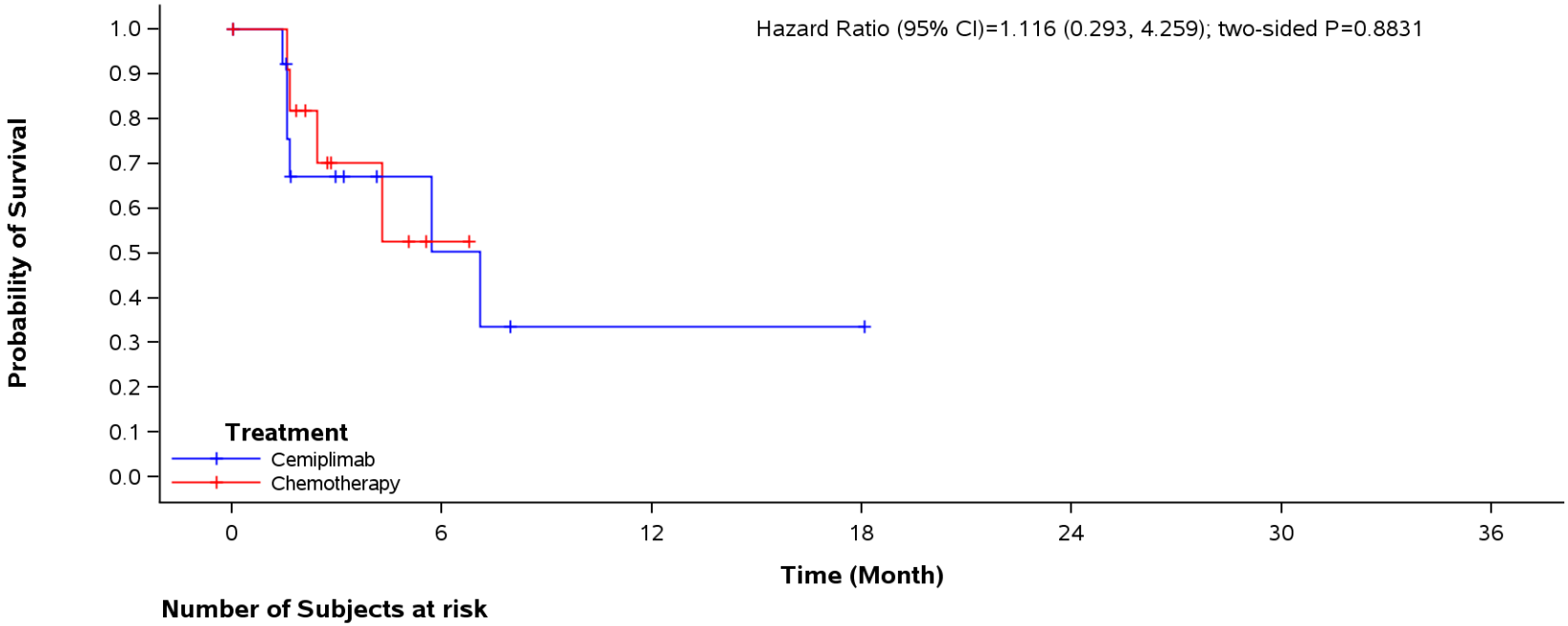

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 1 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts improvement



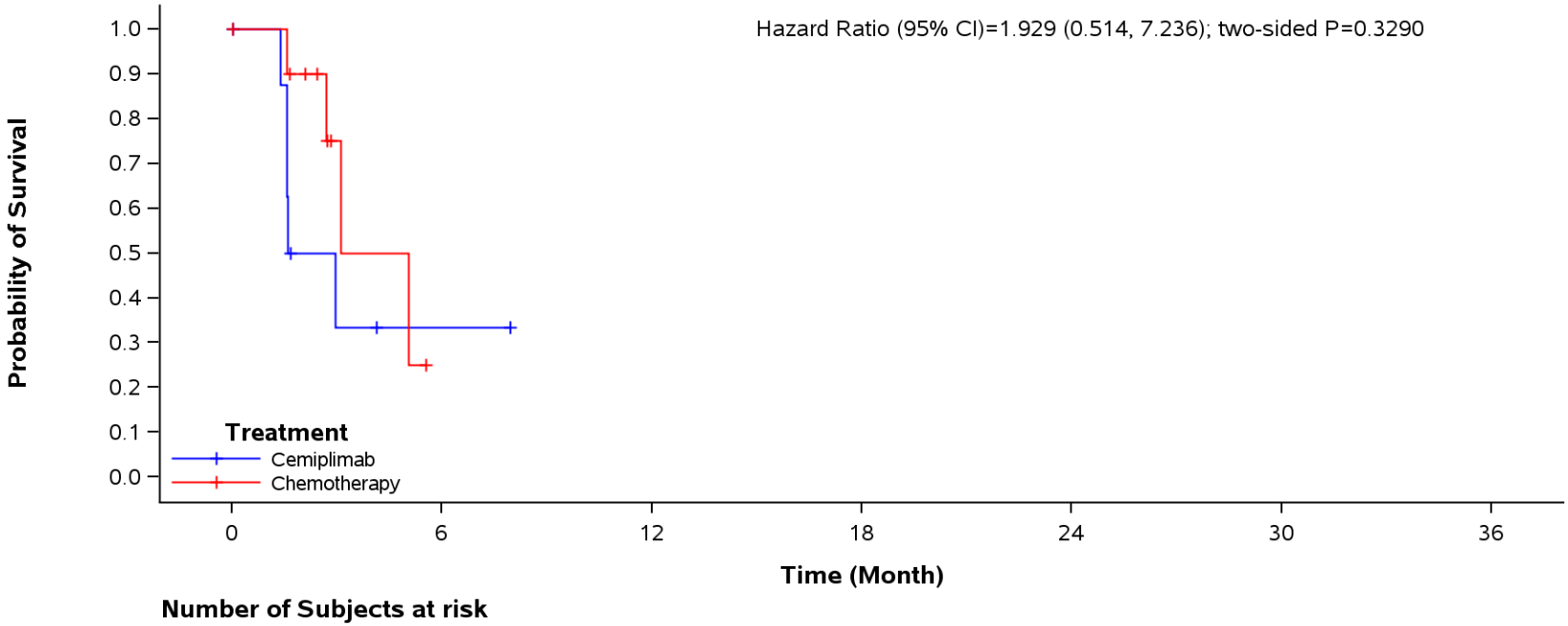

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts improvement



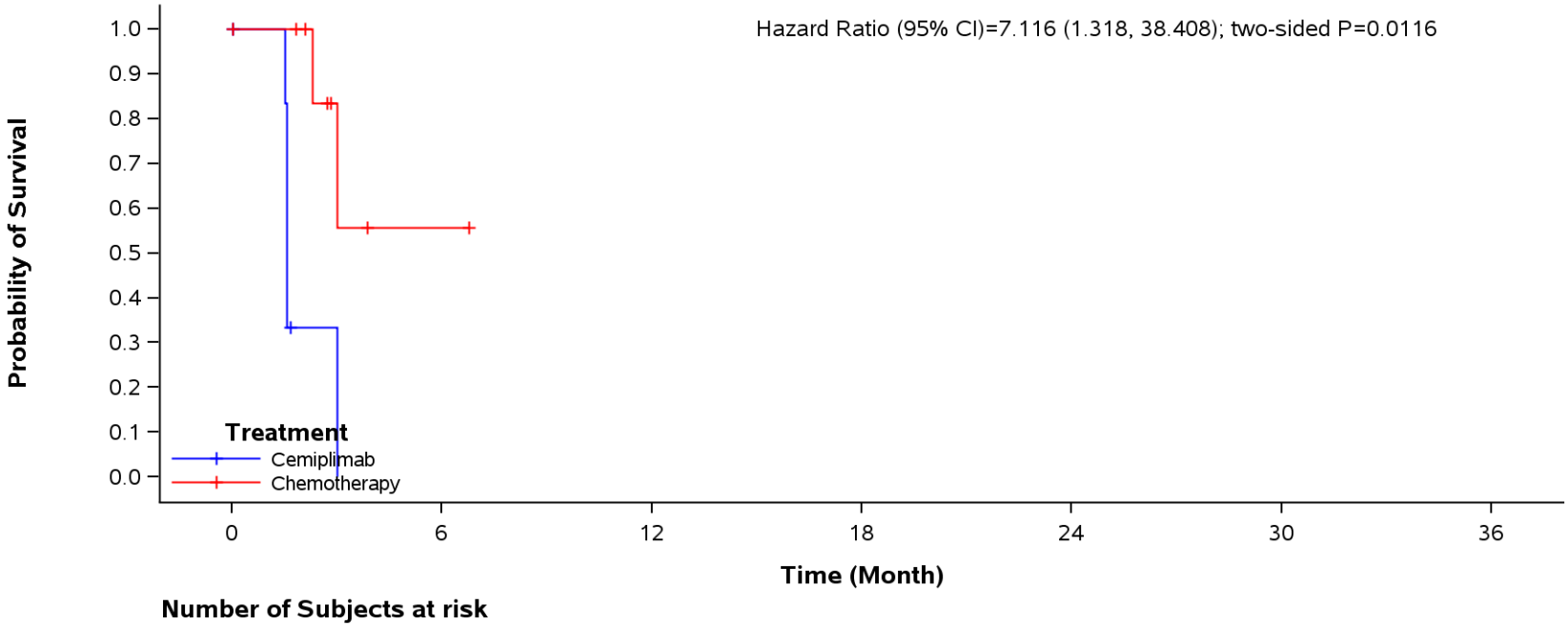

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts improvement



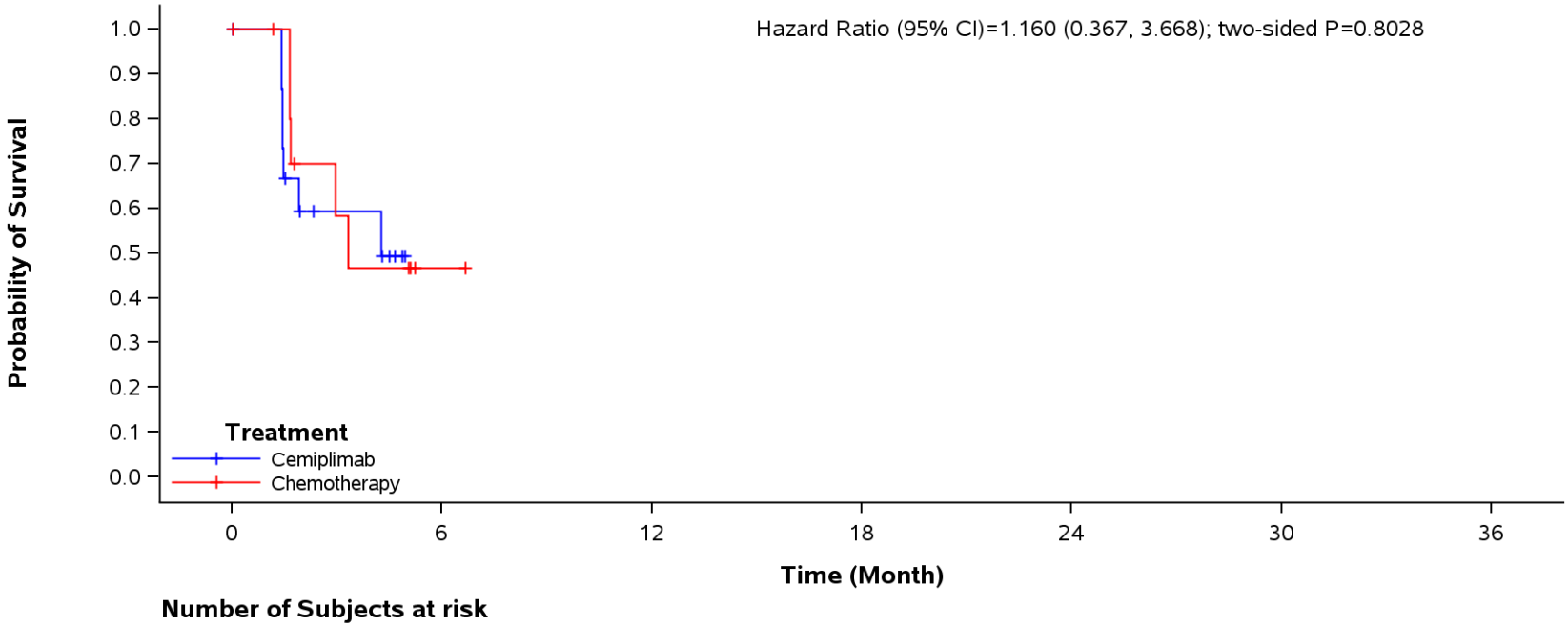

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts improvement



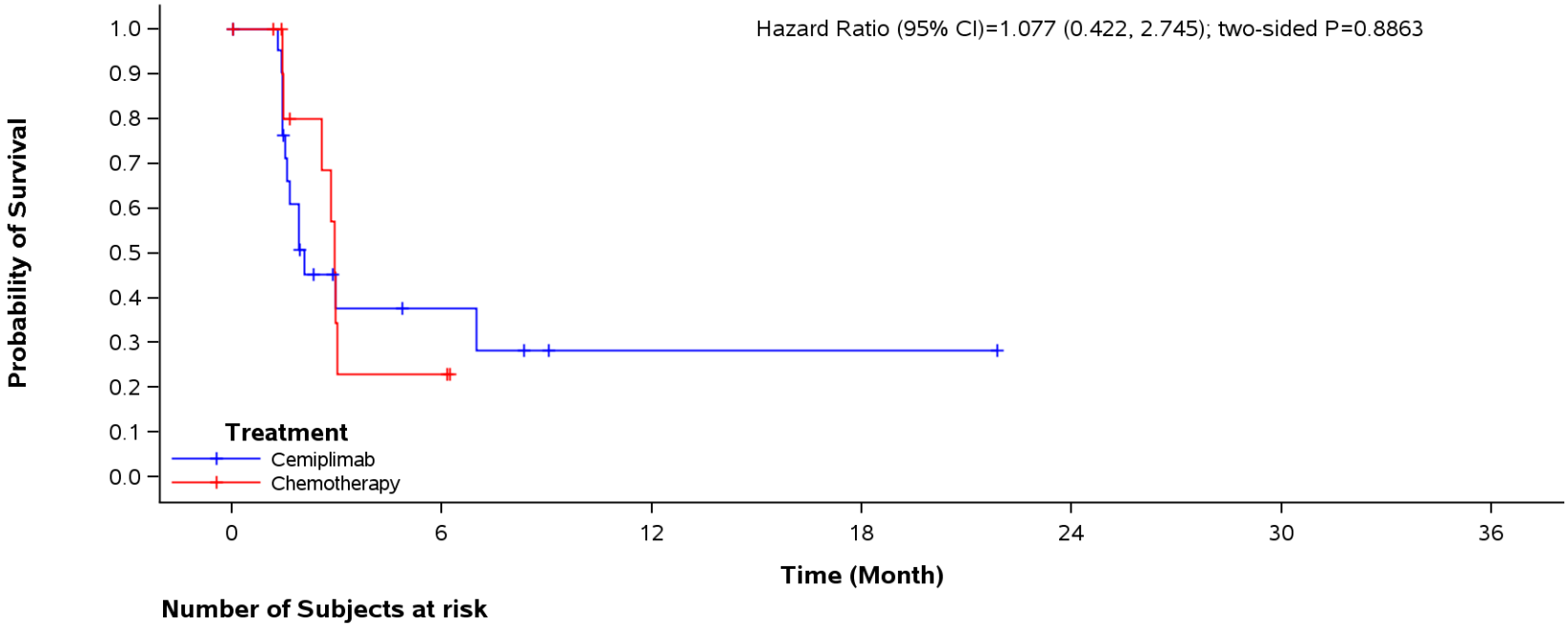

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts improvement



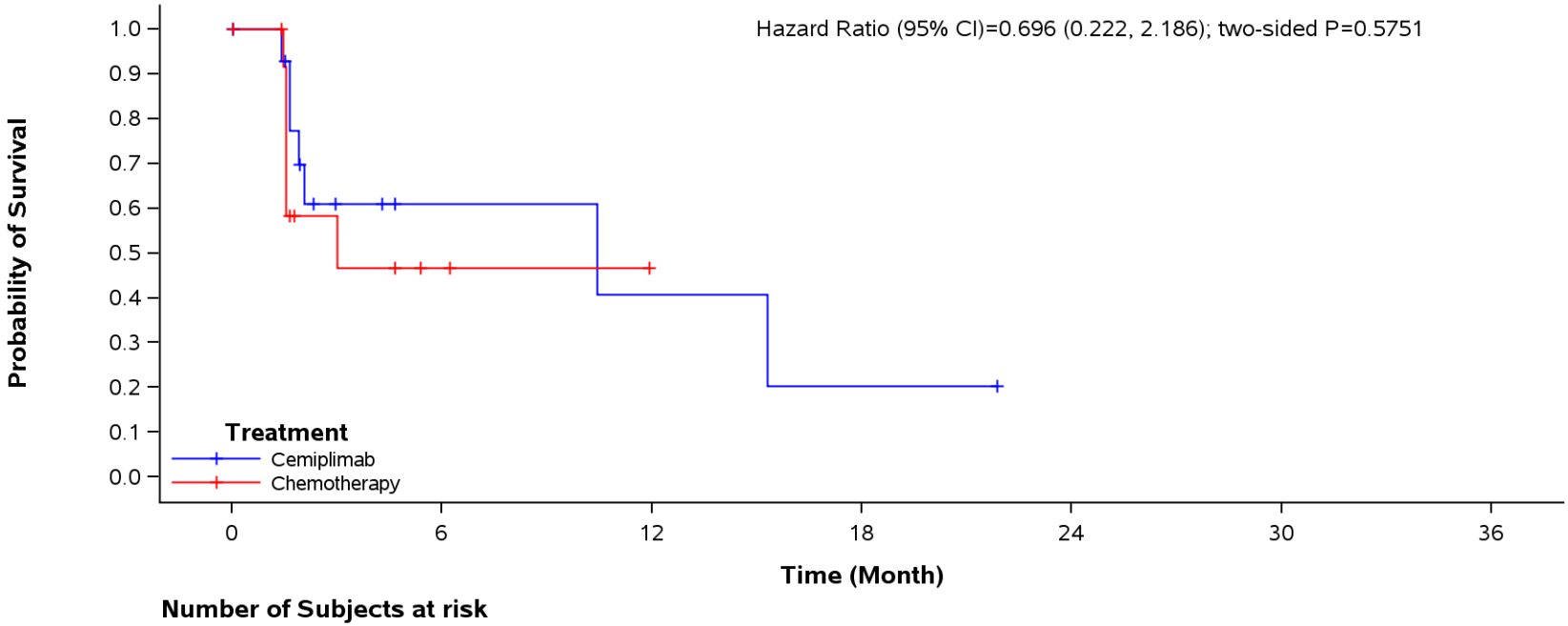

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 4 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts improvement



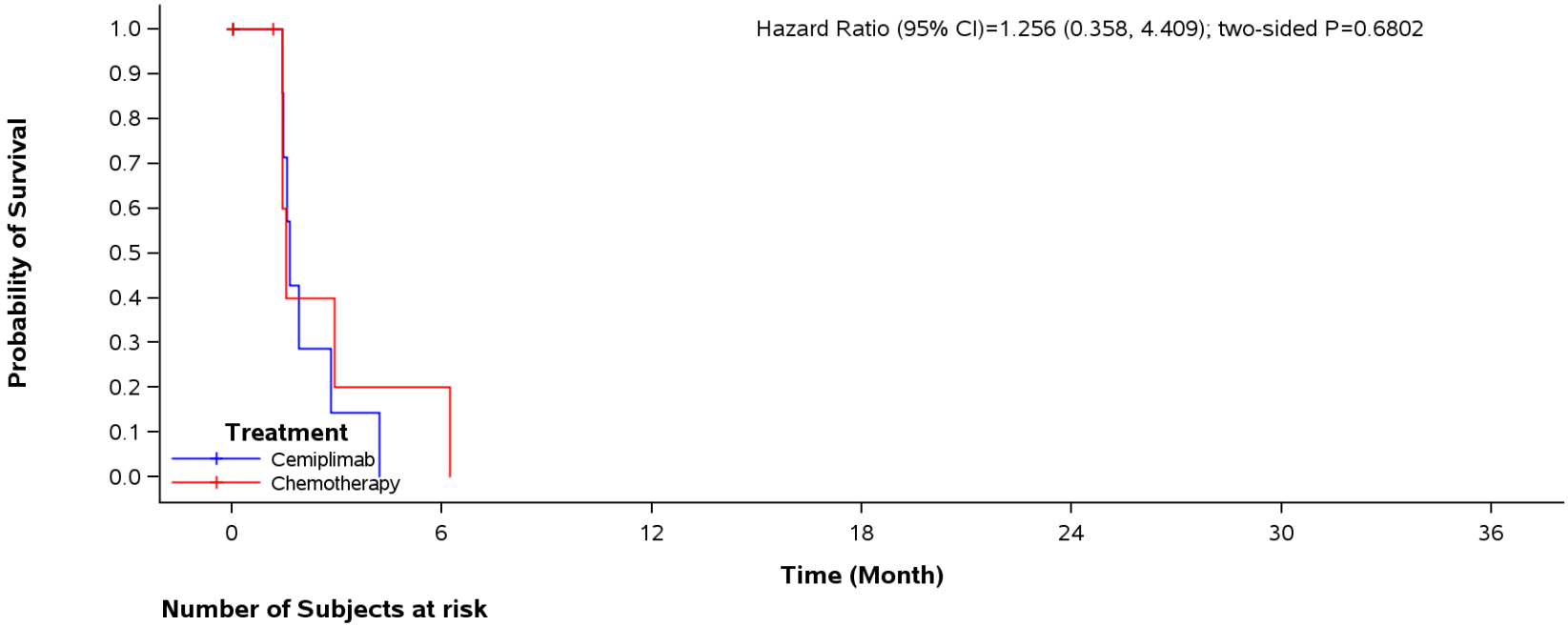

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts improvement



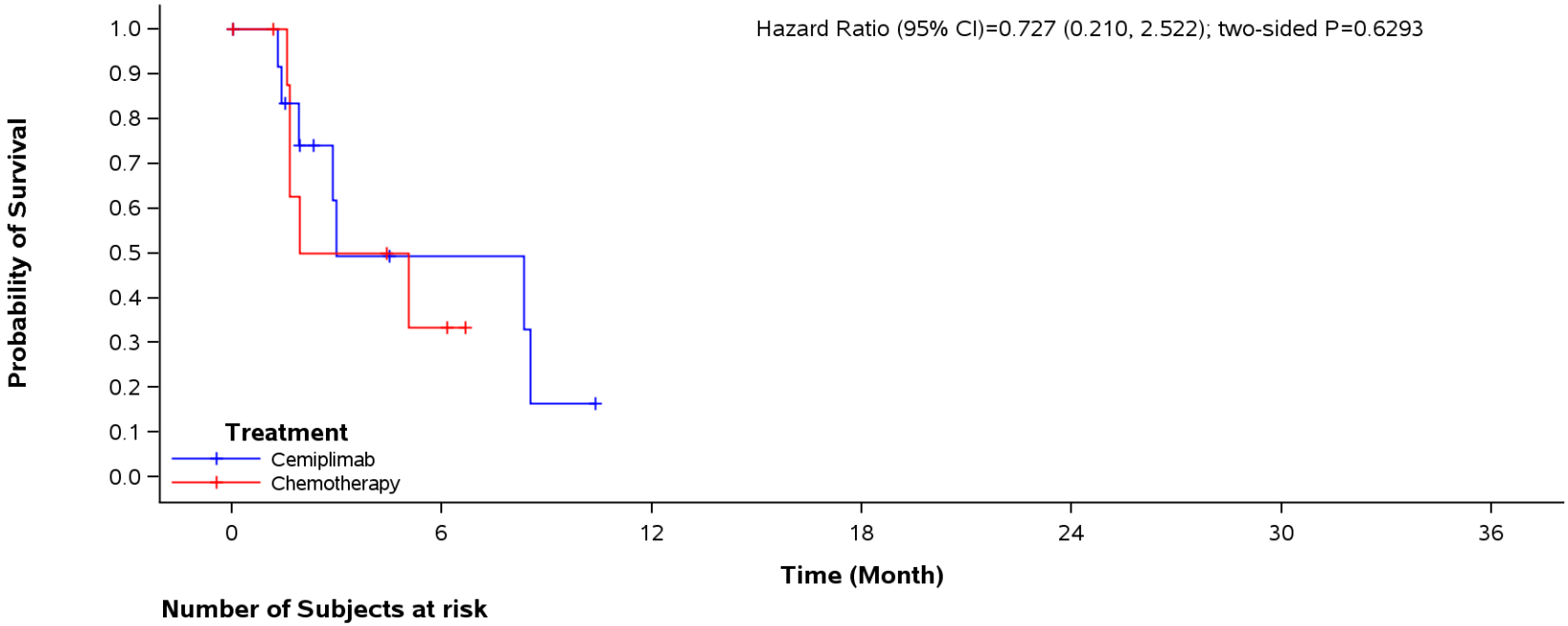

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts improvement



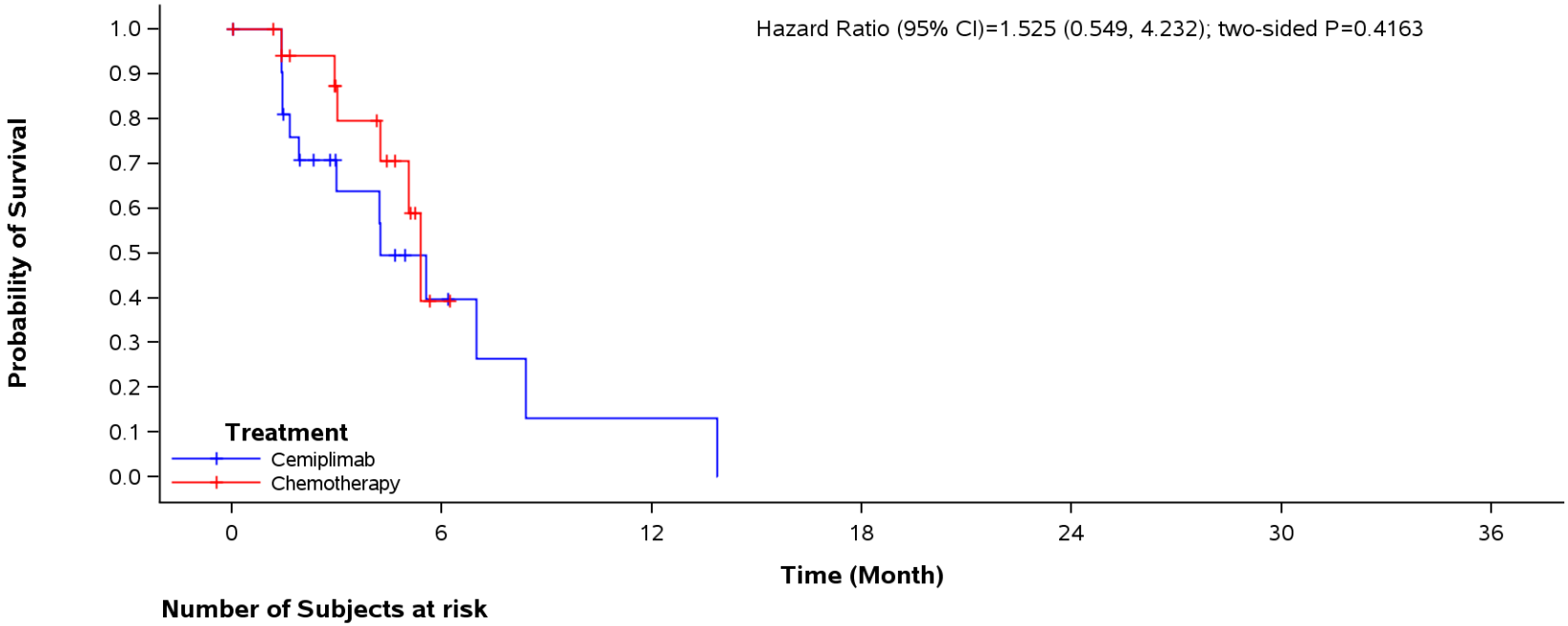

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts improvement



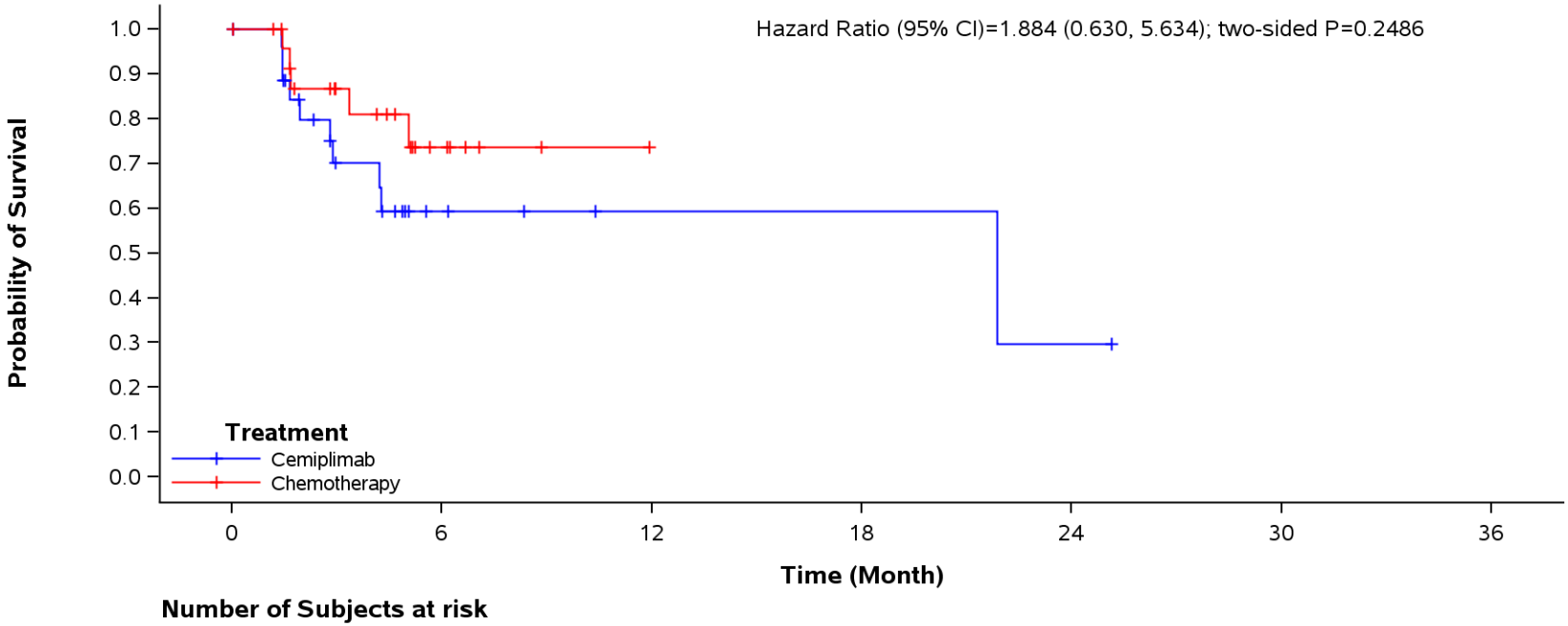

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts improvement



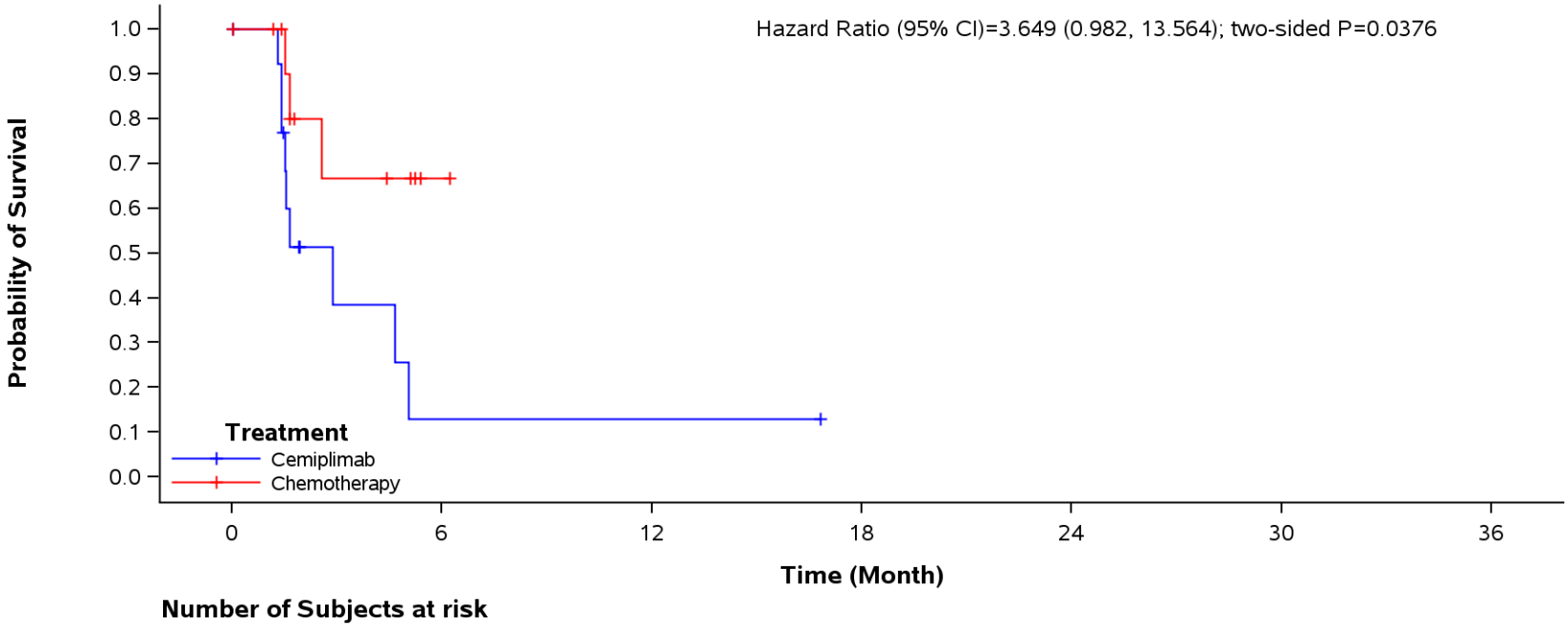

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 5 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 36 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts improvement



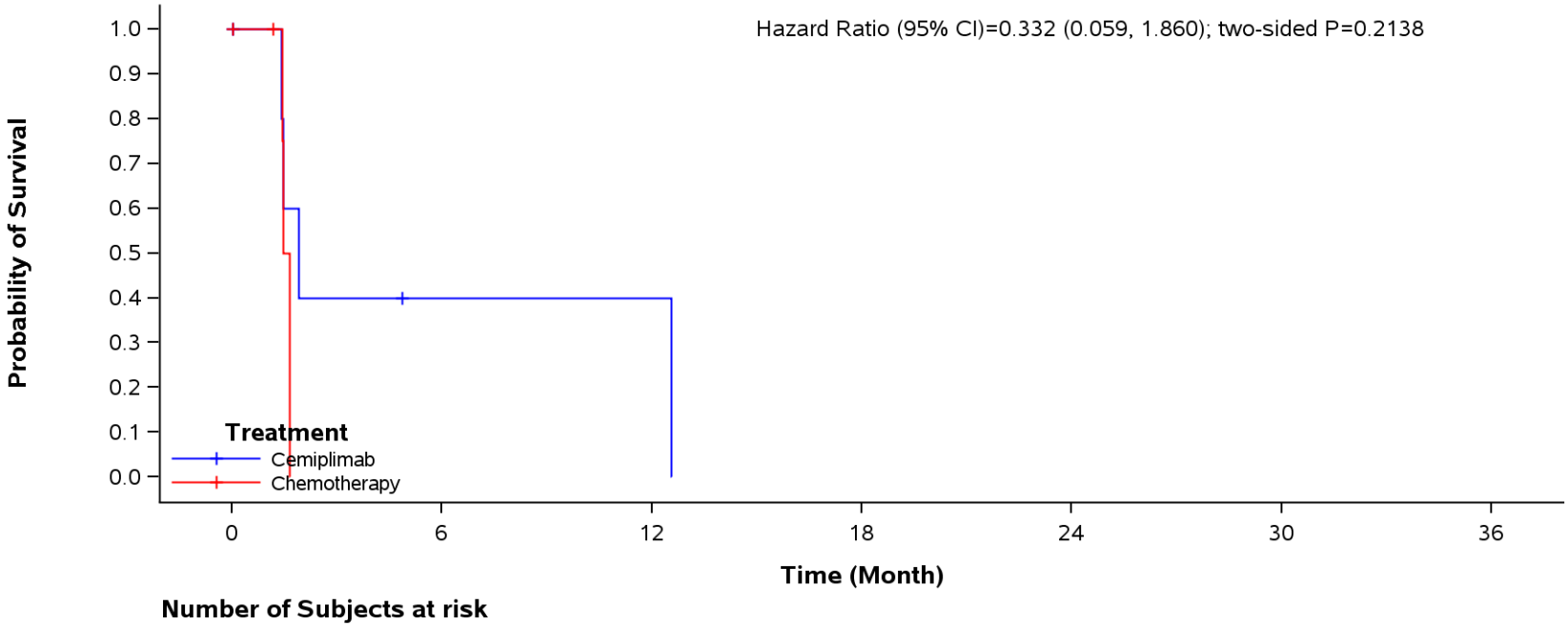

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts improvement



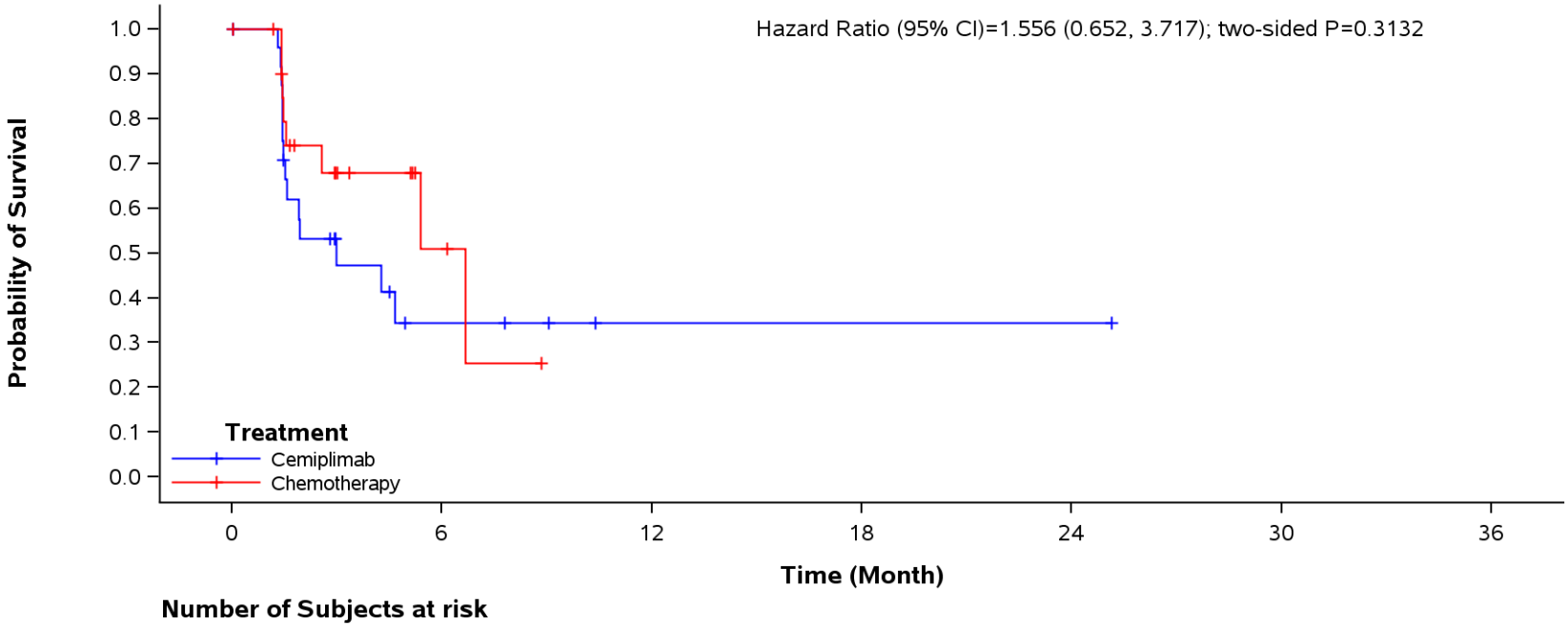

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts improvement



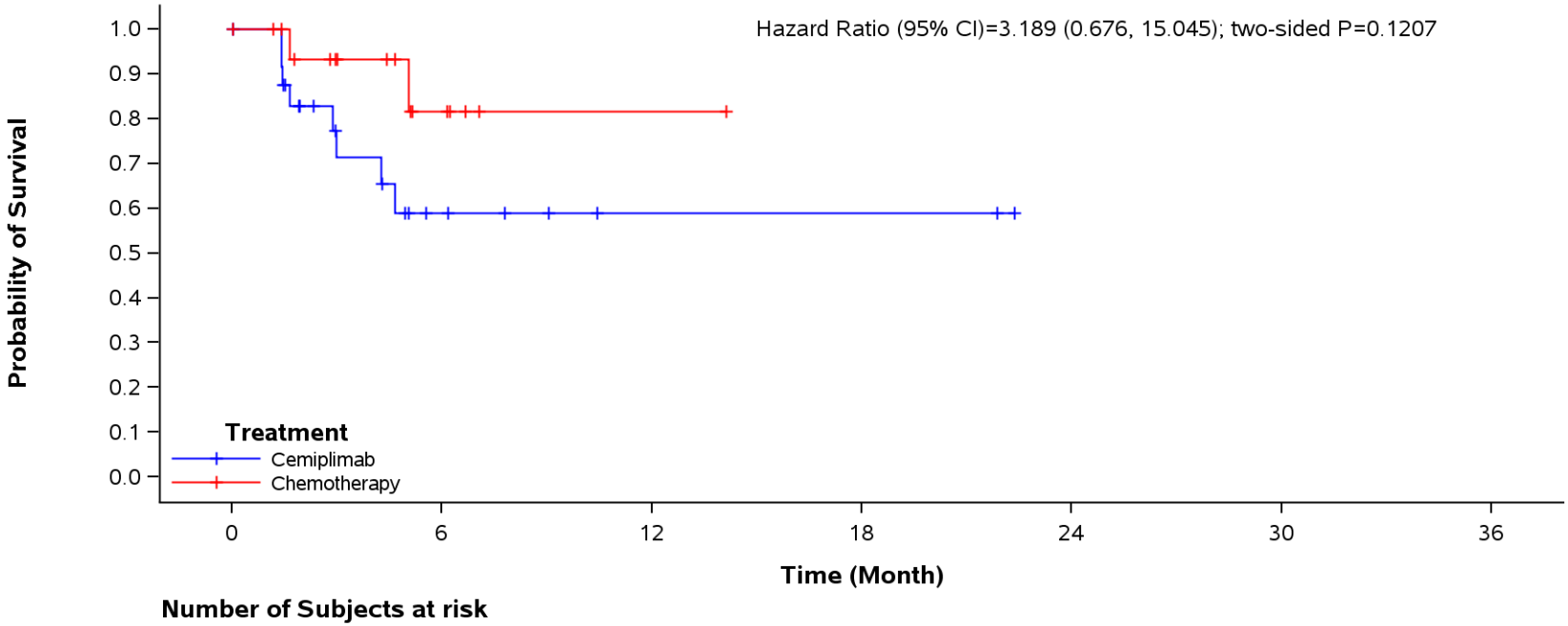

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 4 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts improvement



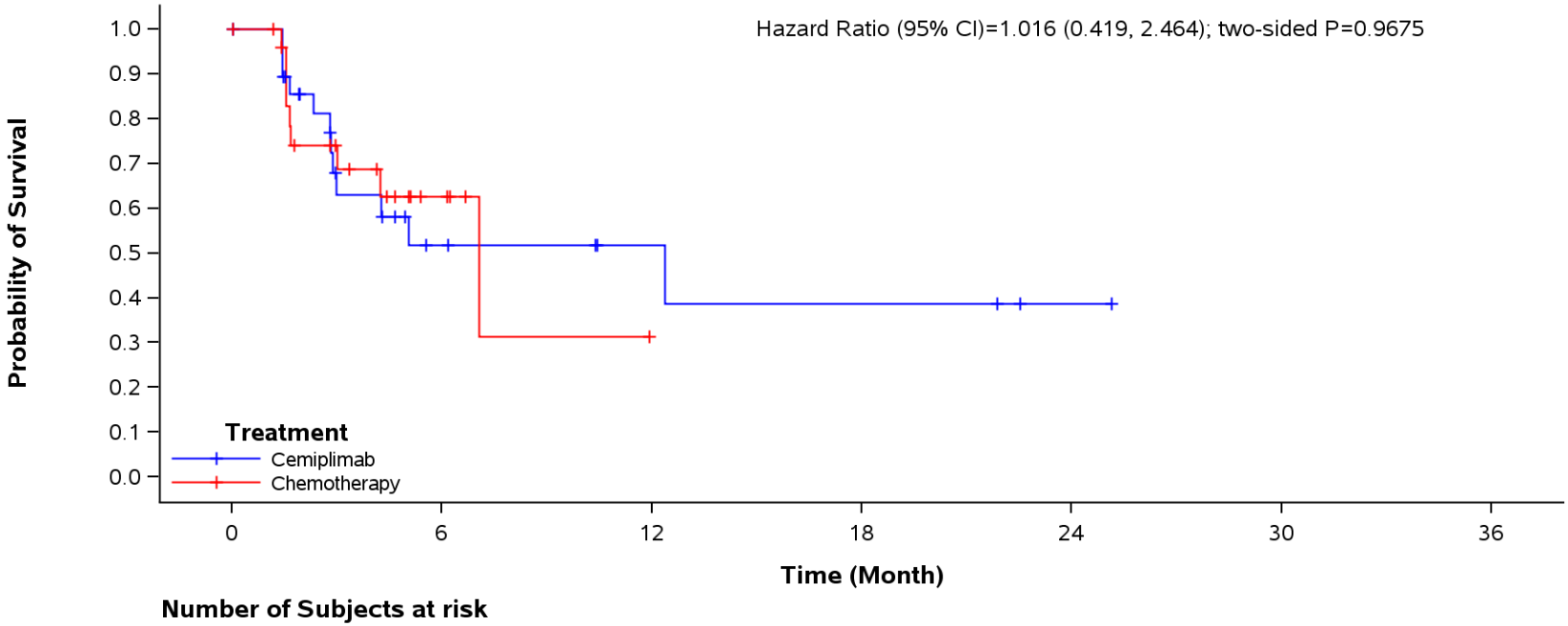

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 6 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Global health status / QoL - 10 pts improvement



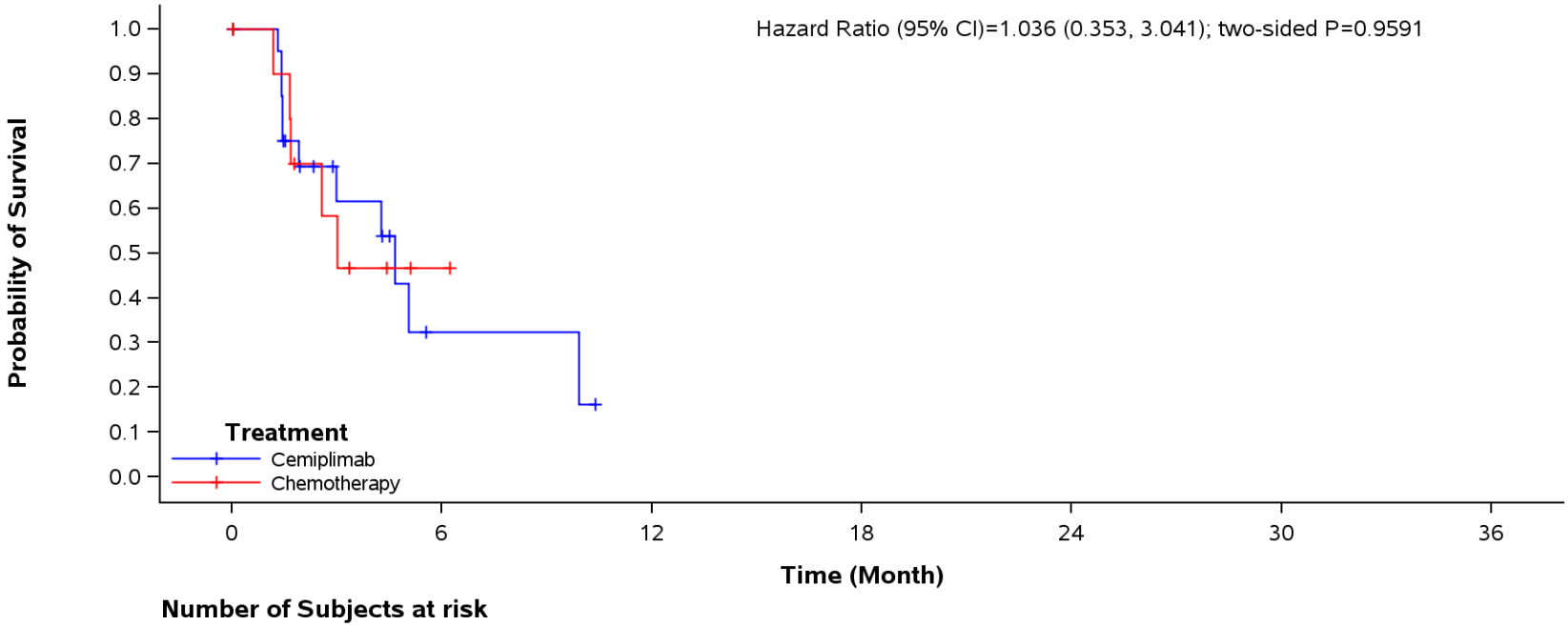

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 7 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts improvement



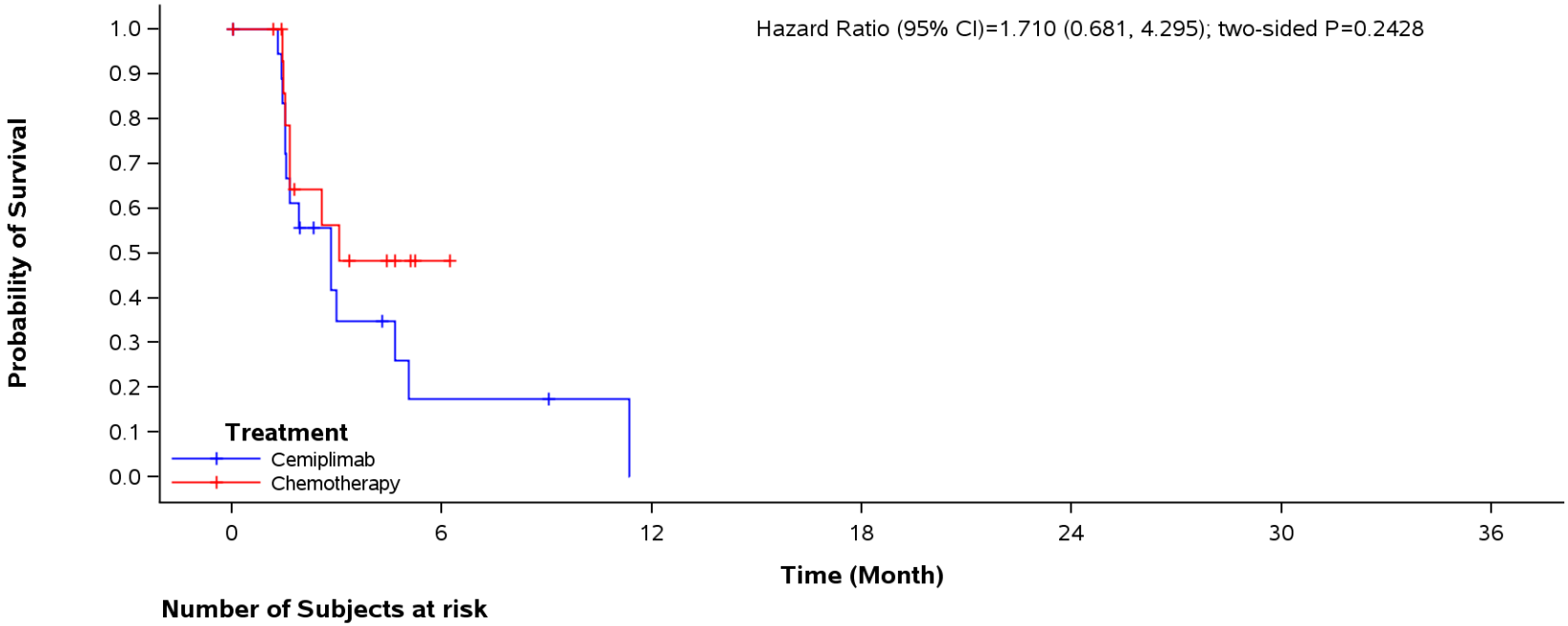

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts improvement



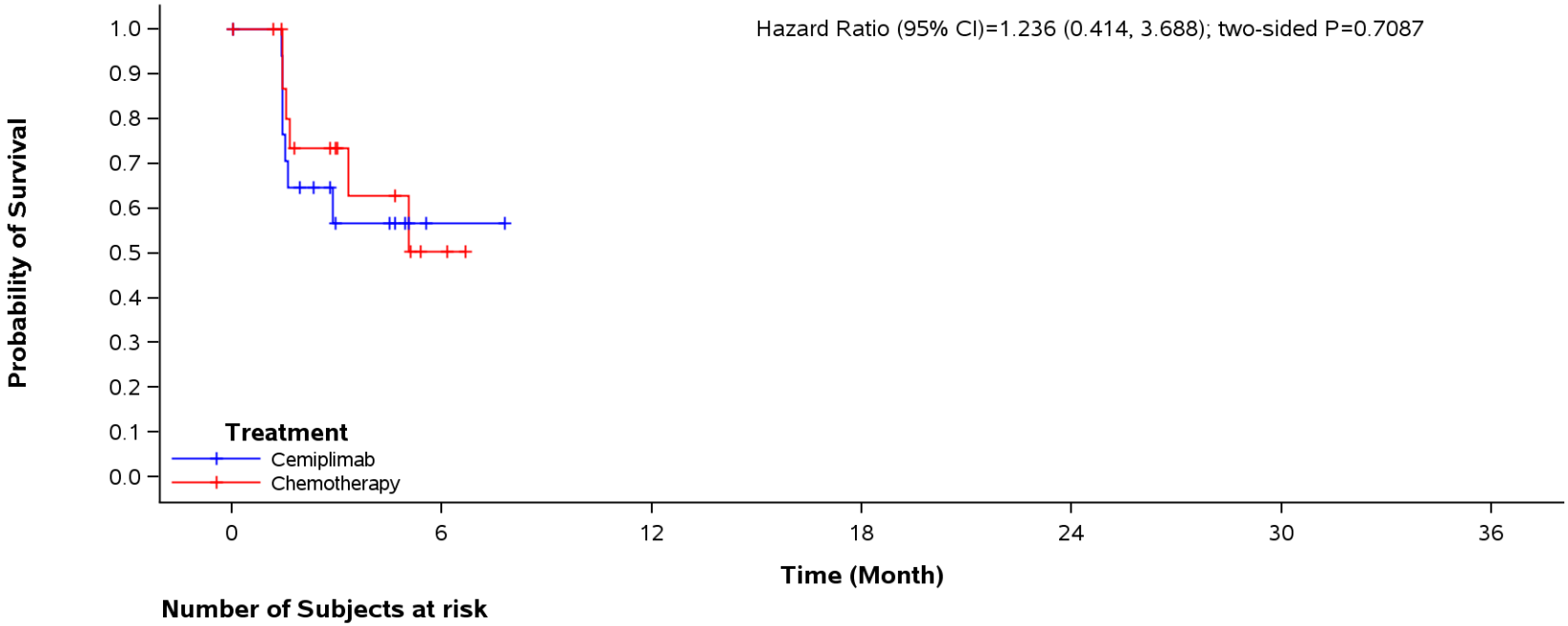

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts improvement



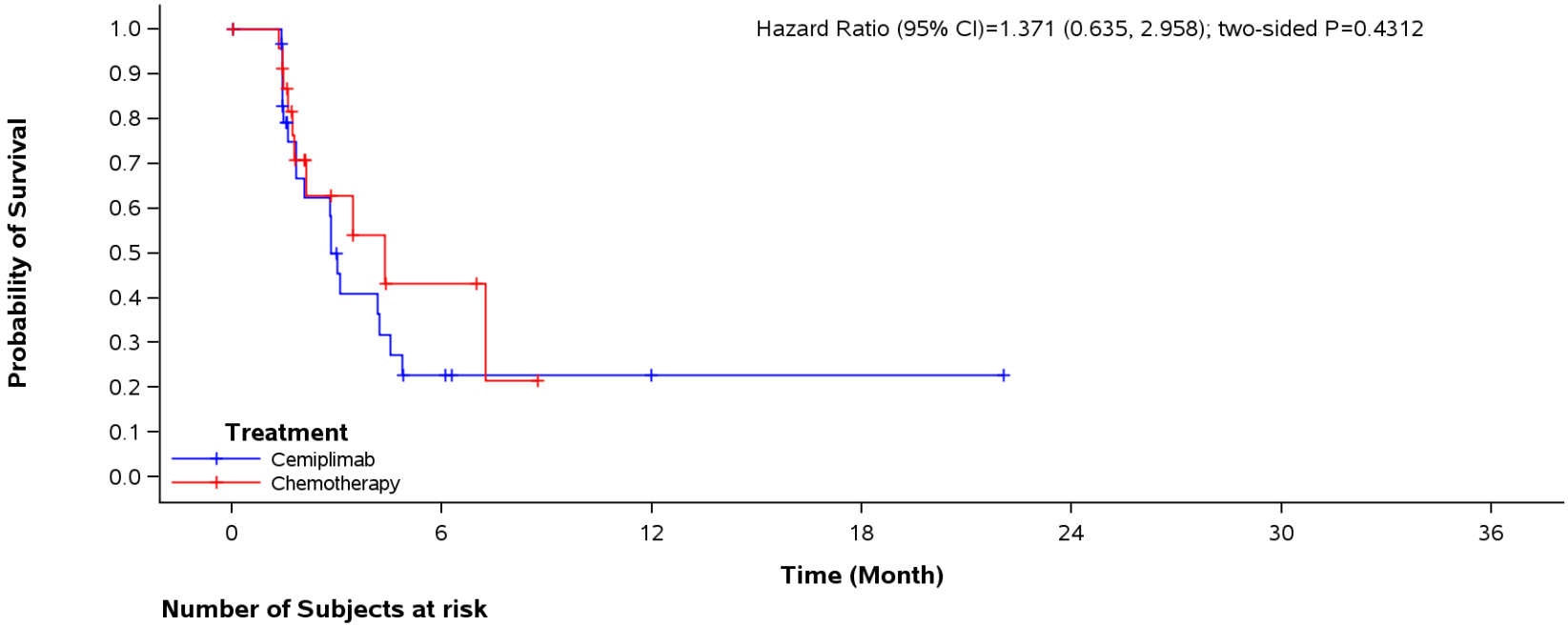

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts improvement



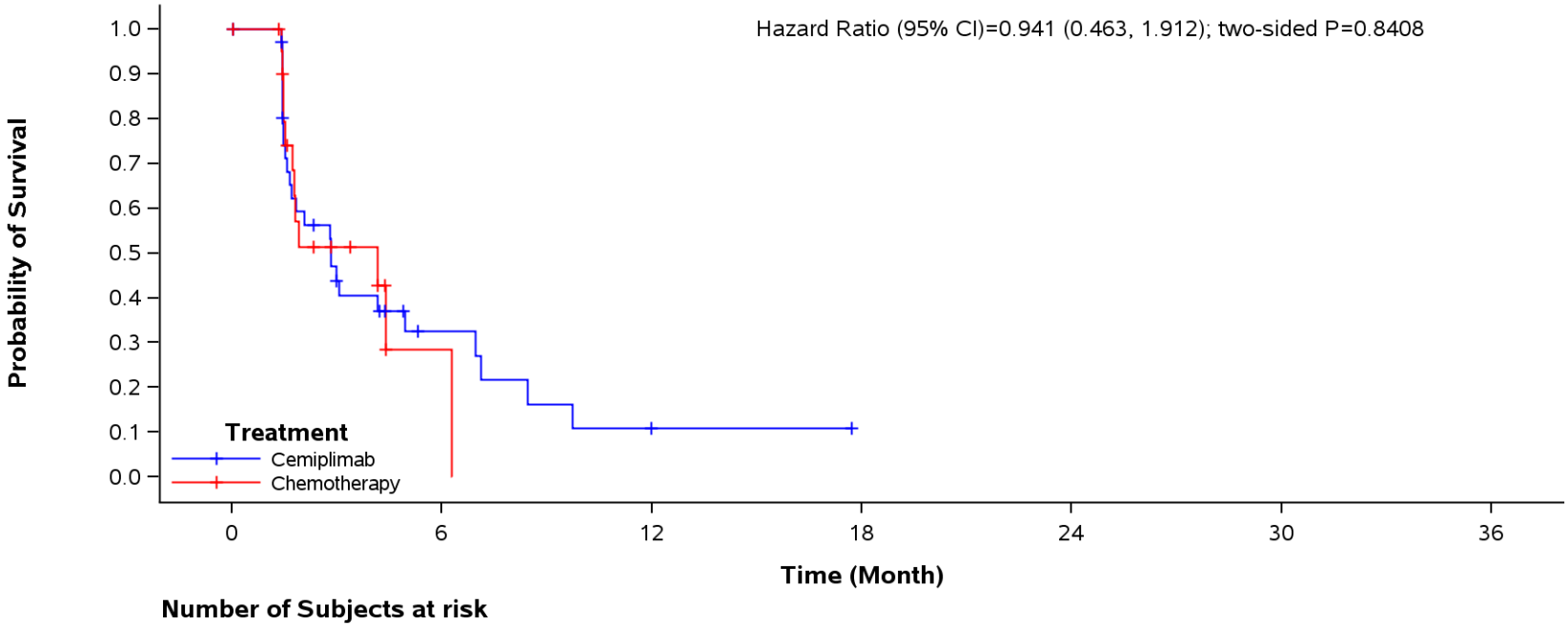

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 4 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts improvement



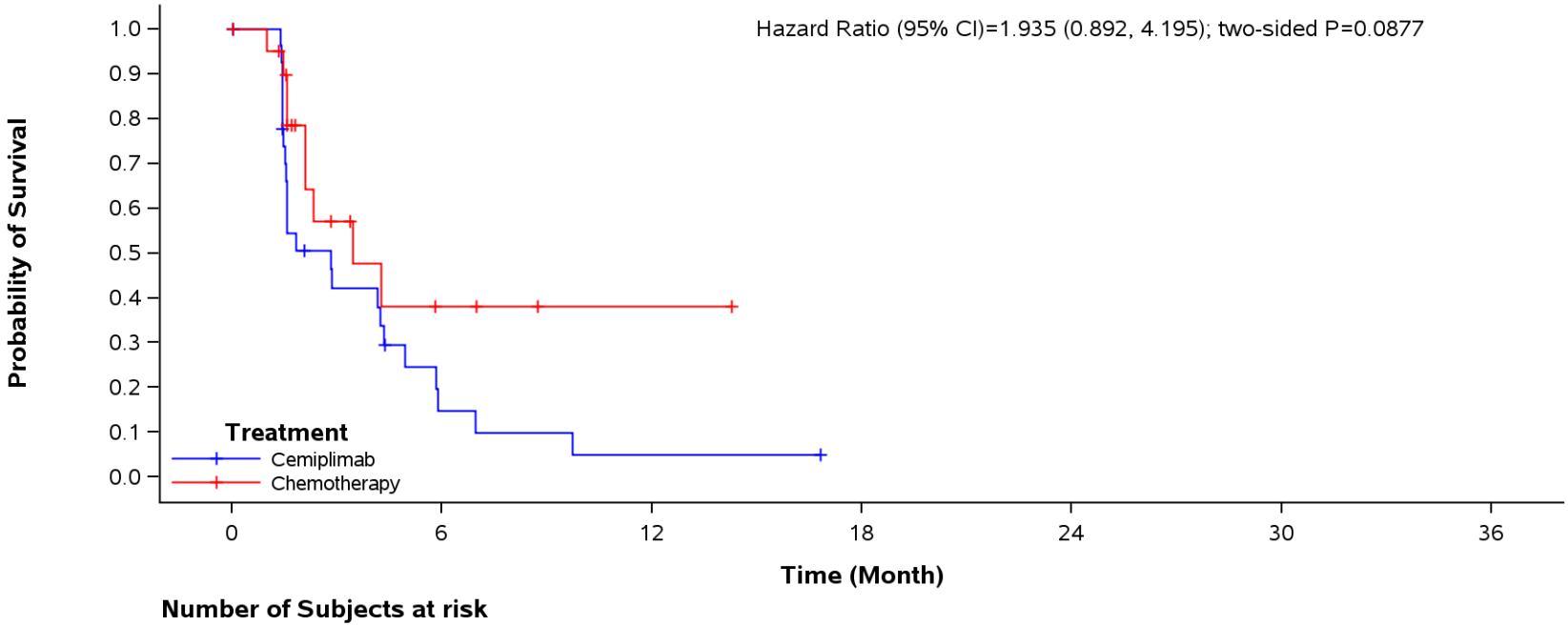

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts improvement



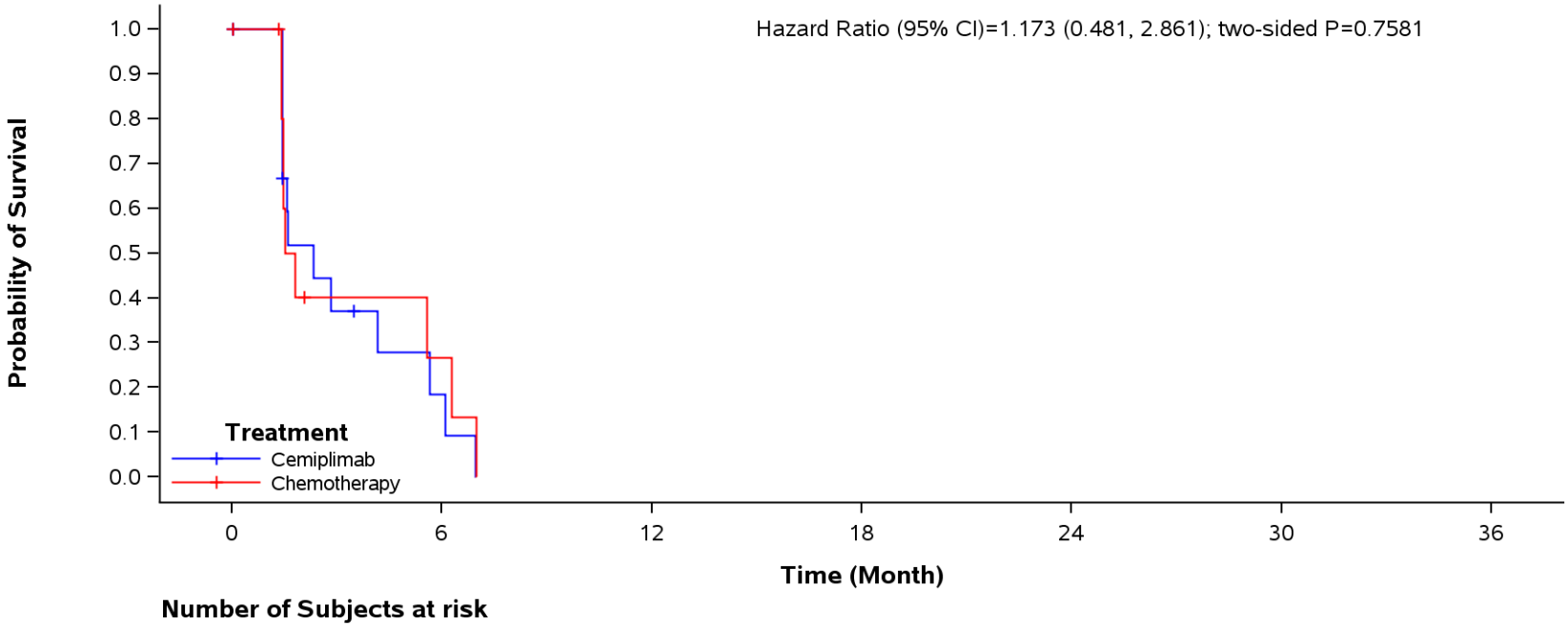

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts improvement



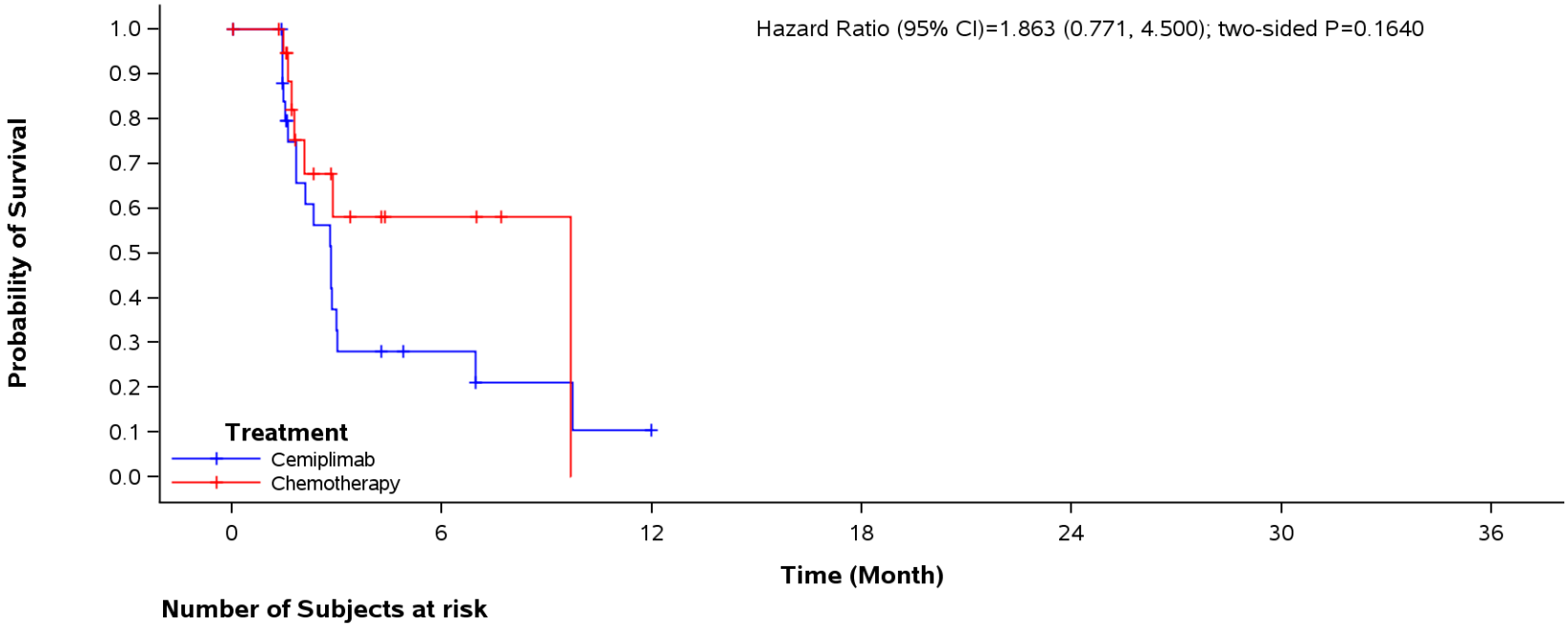

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts improvement



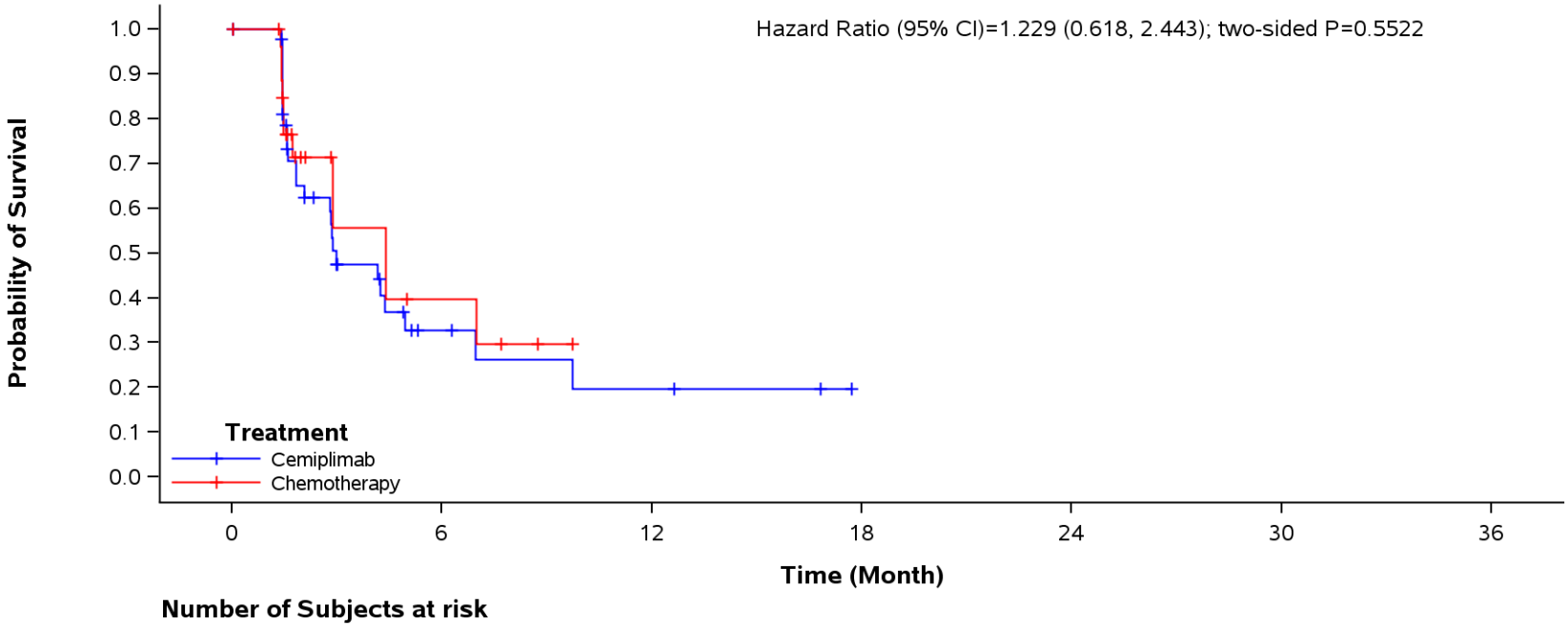

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts improvement



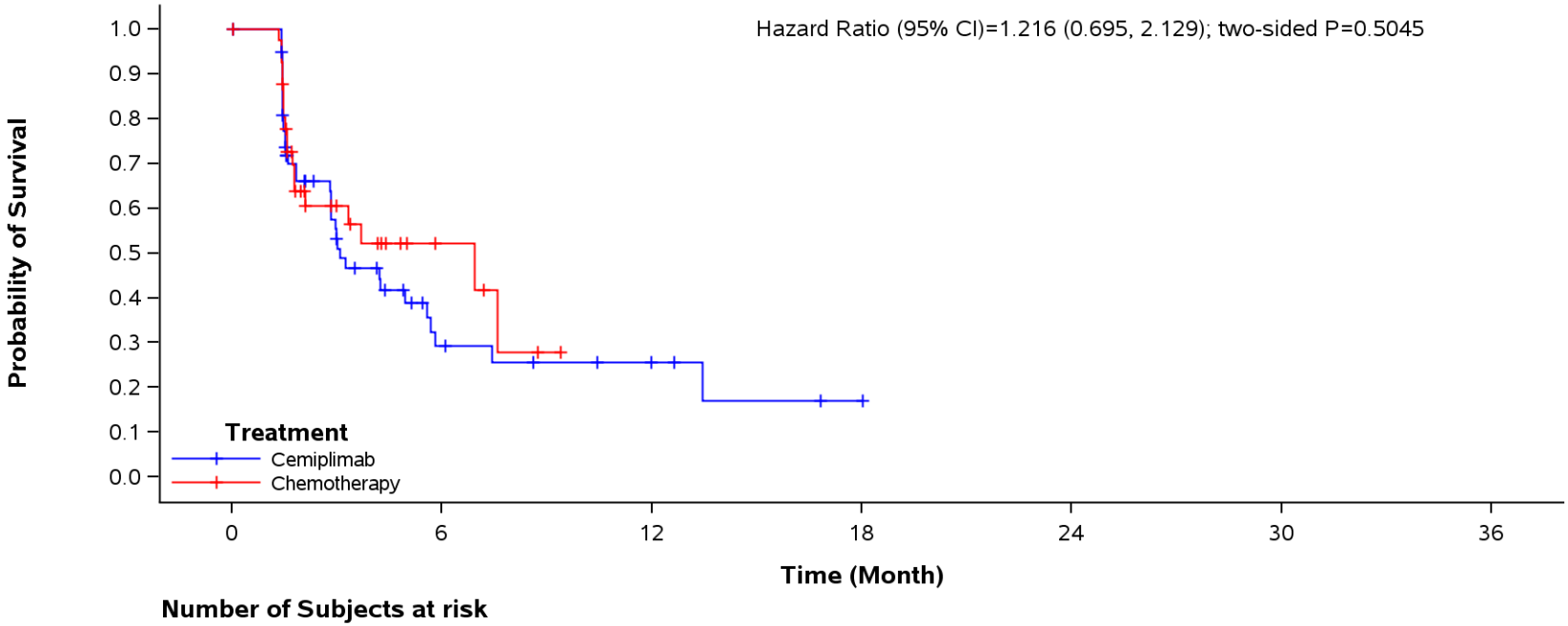

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 6 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts improvement



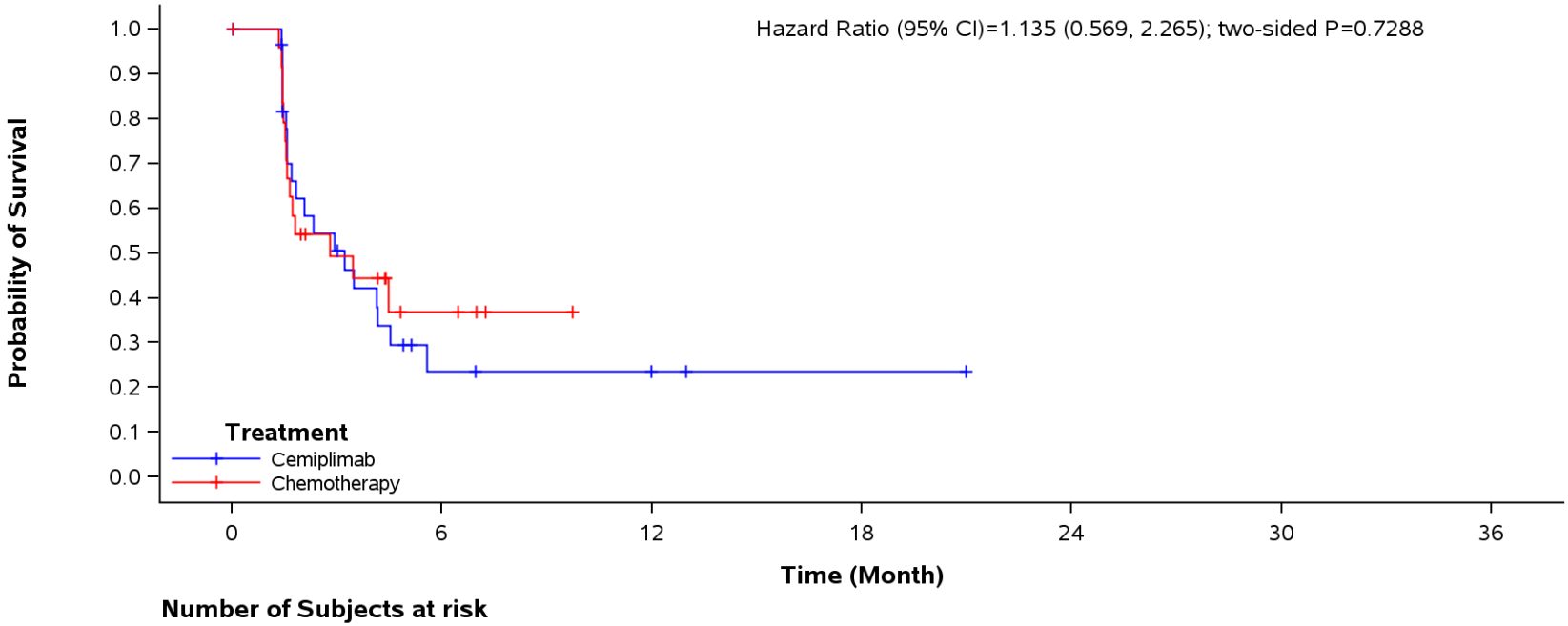

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 9 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts improvement



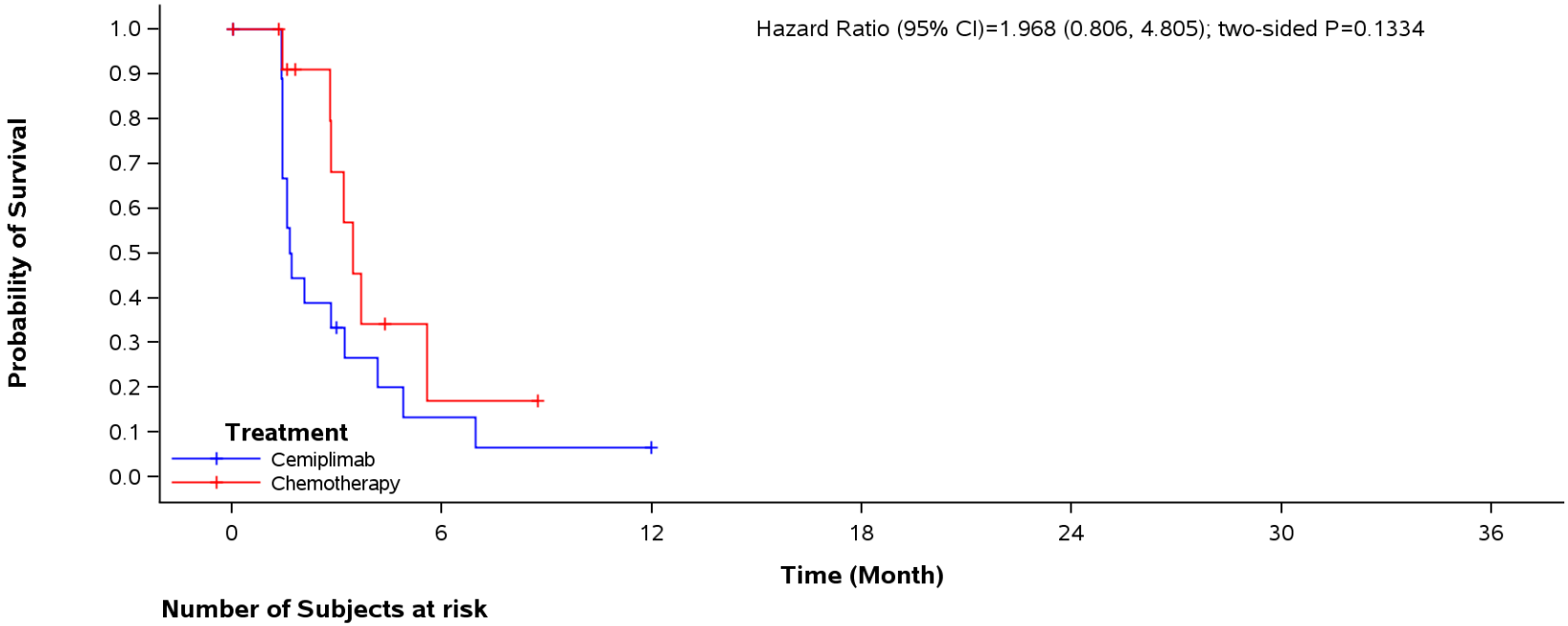

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts improvement



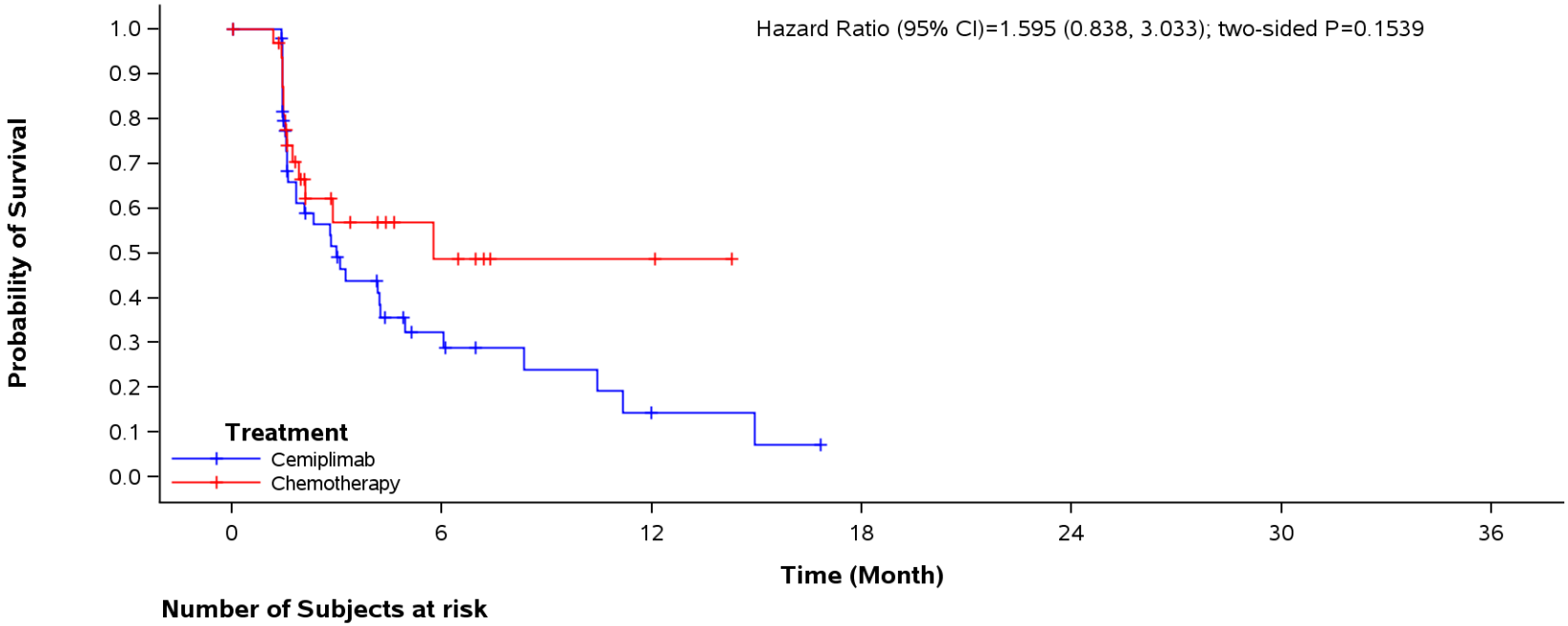

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts improvement



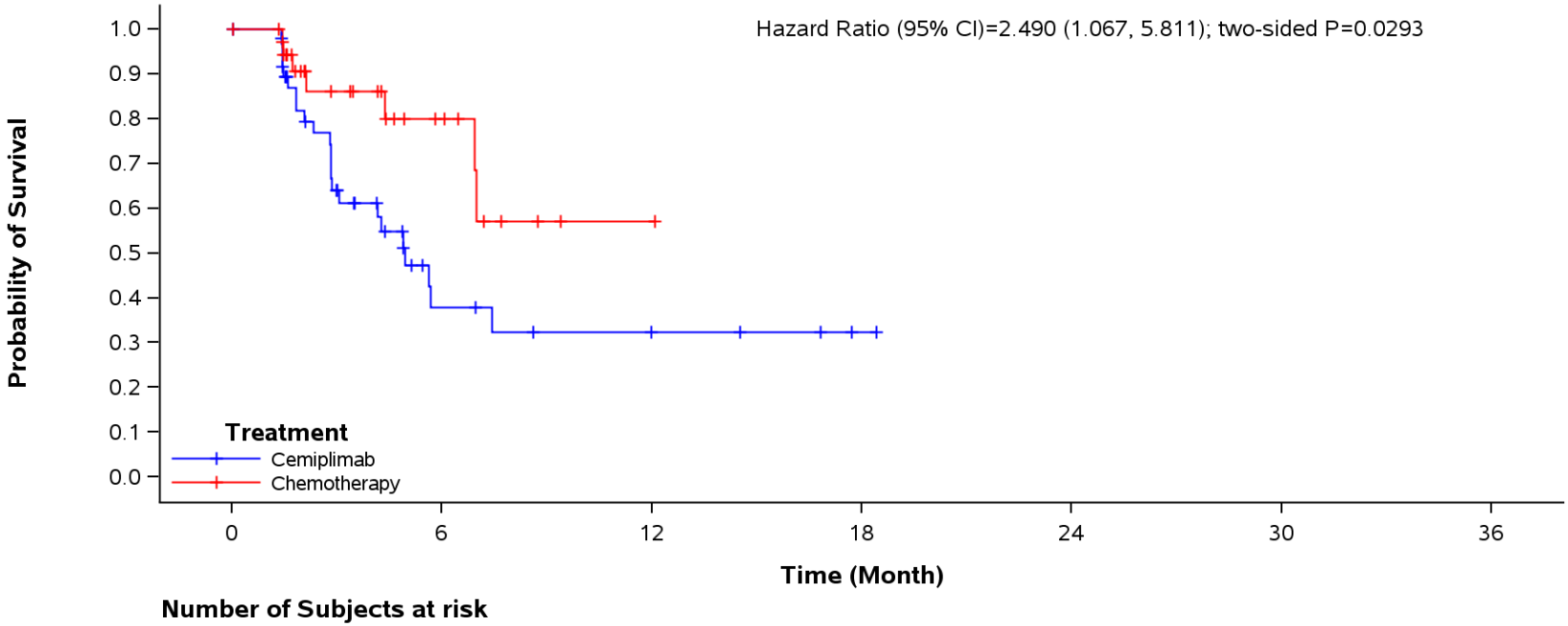

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 9 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts improvement



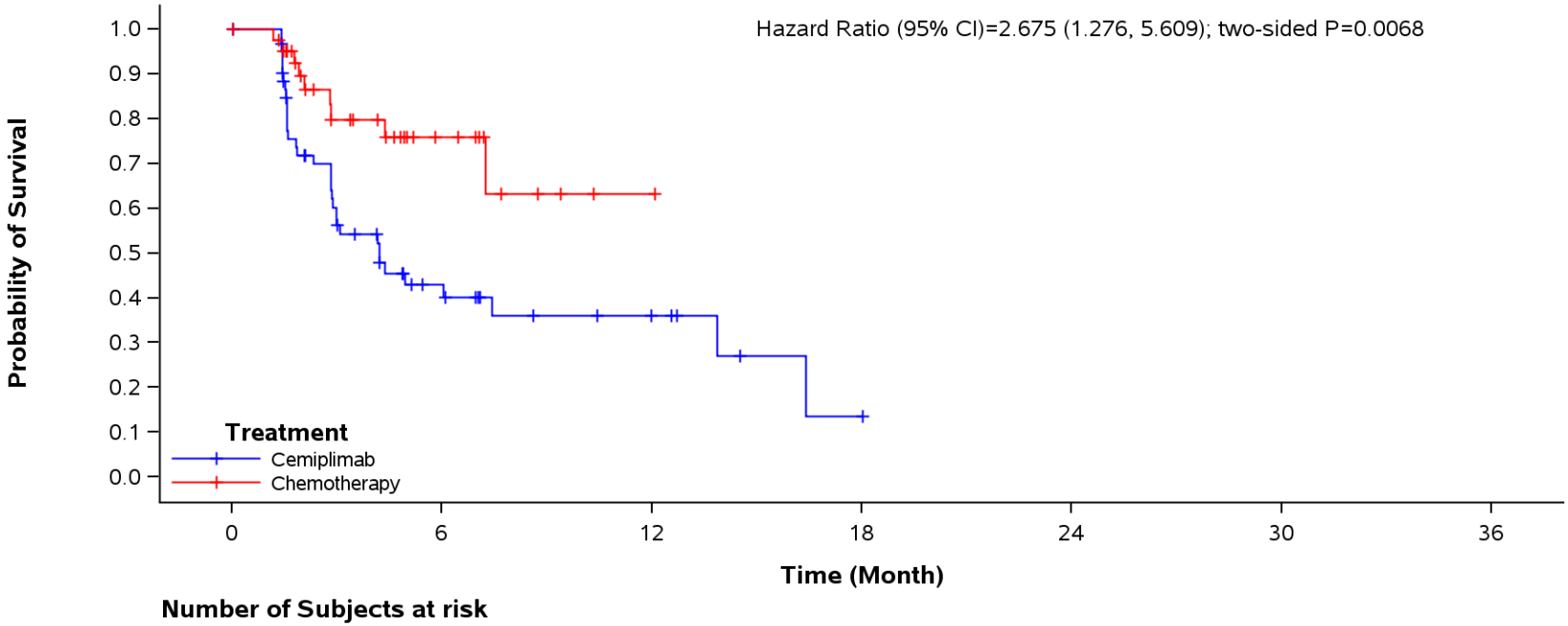

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 8 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts improvement



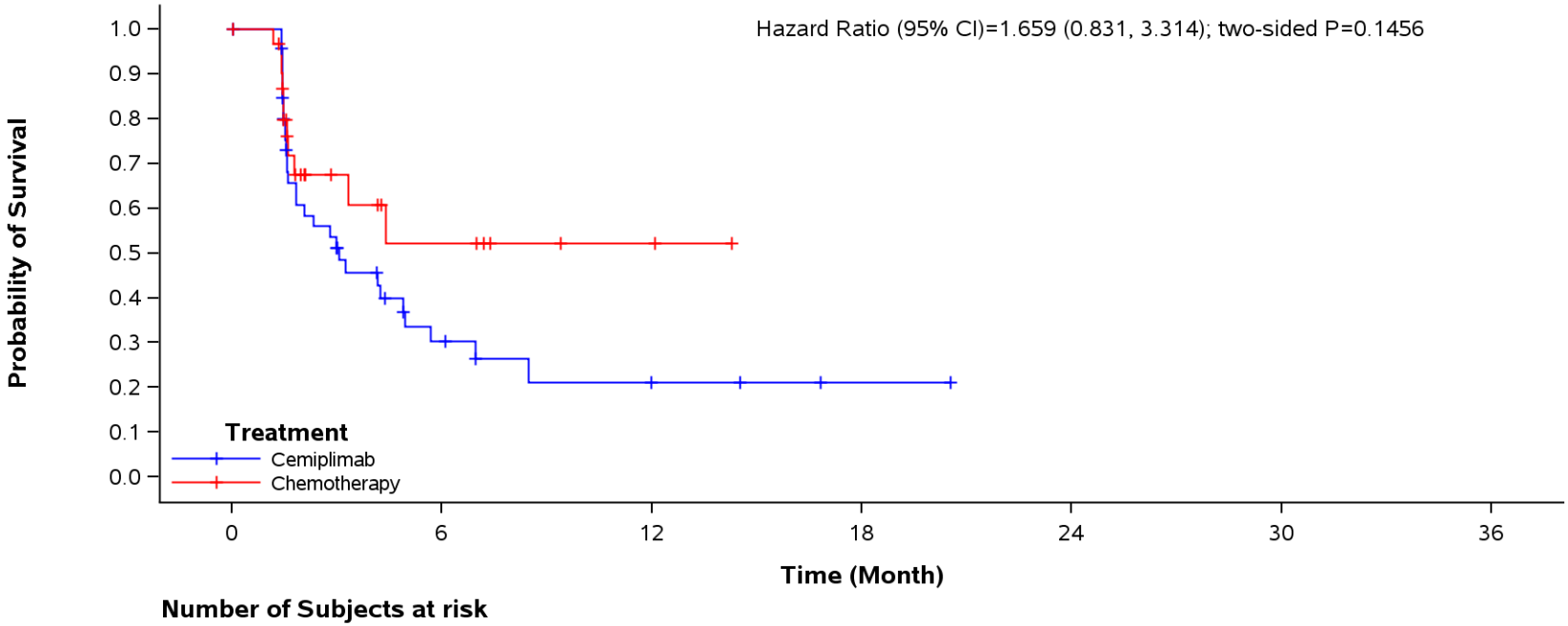

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 15 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts improvement



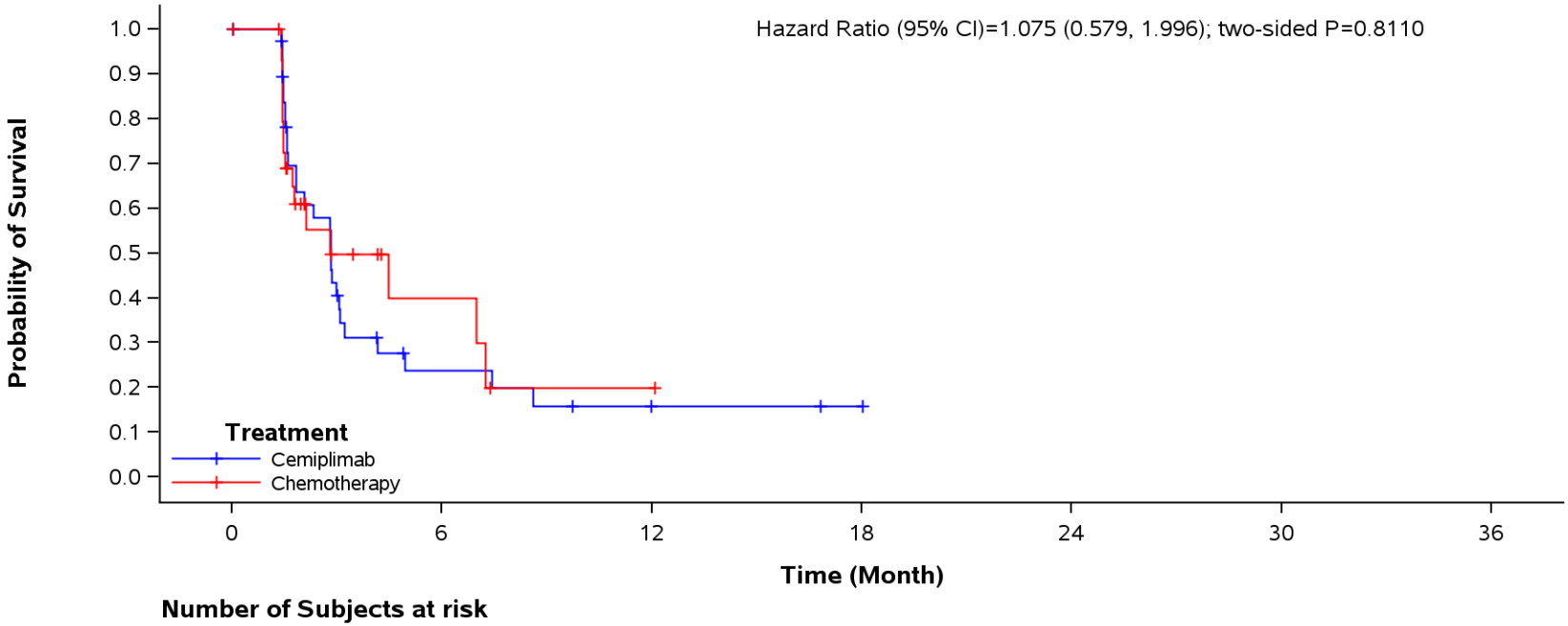

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 9 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts improvement



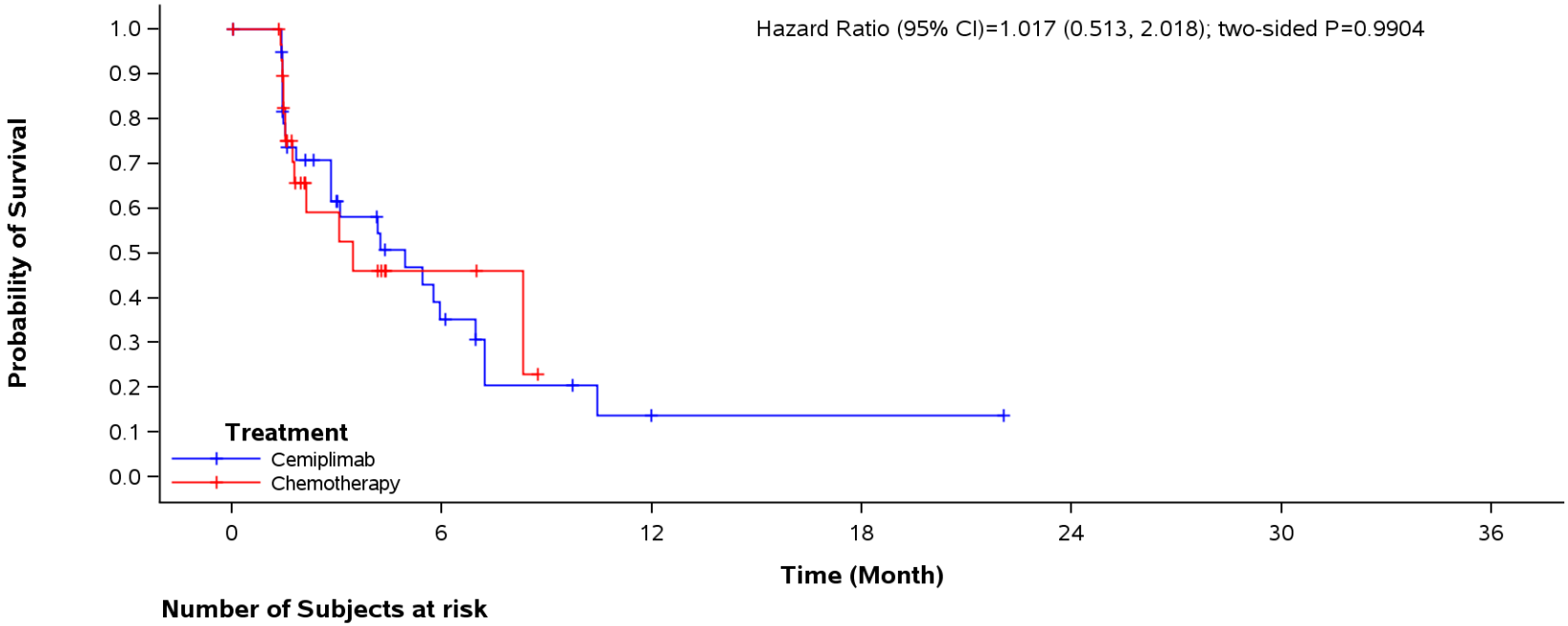

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts improvement



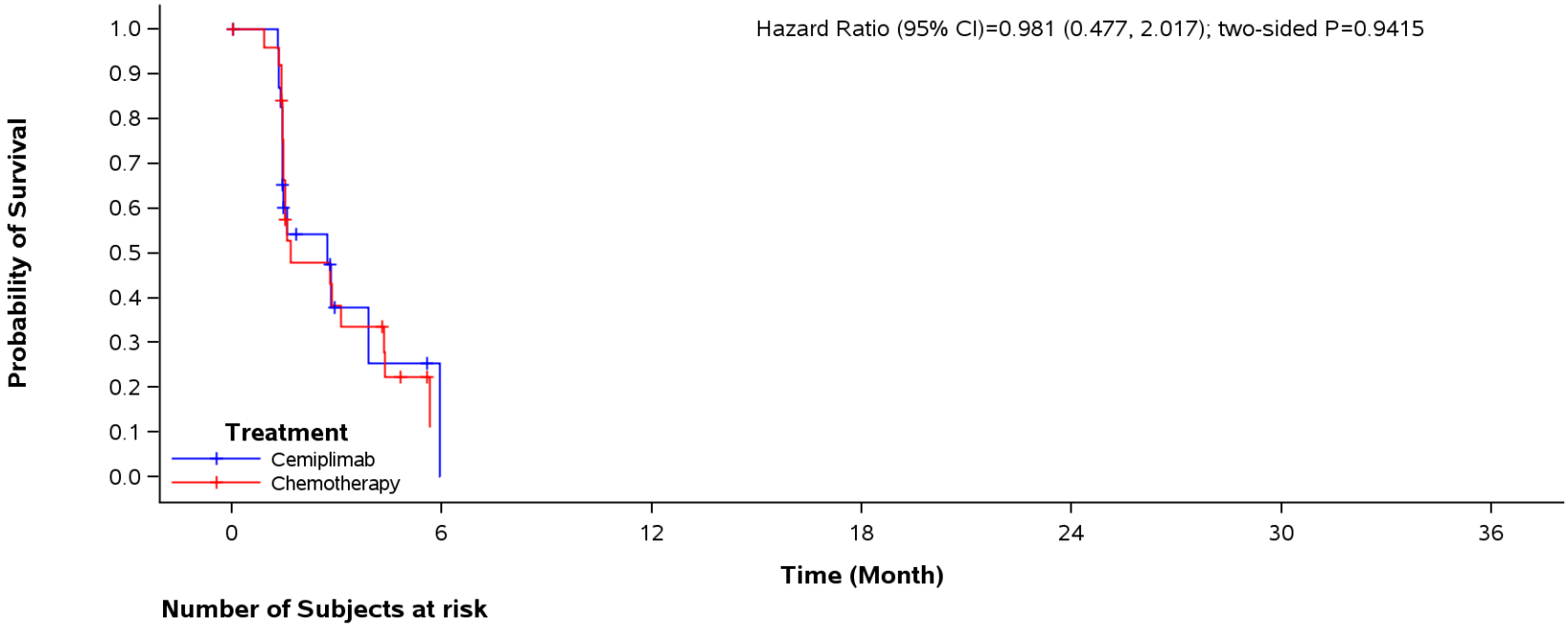

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 9 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts improvement



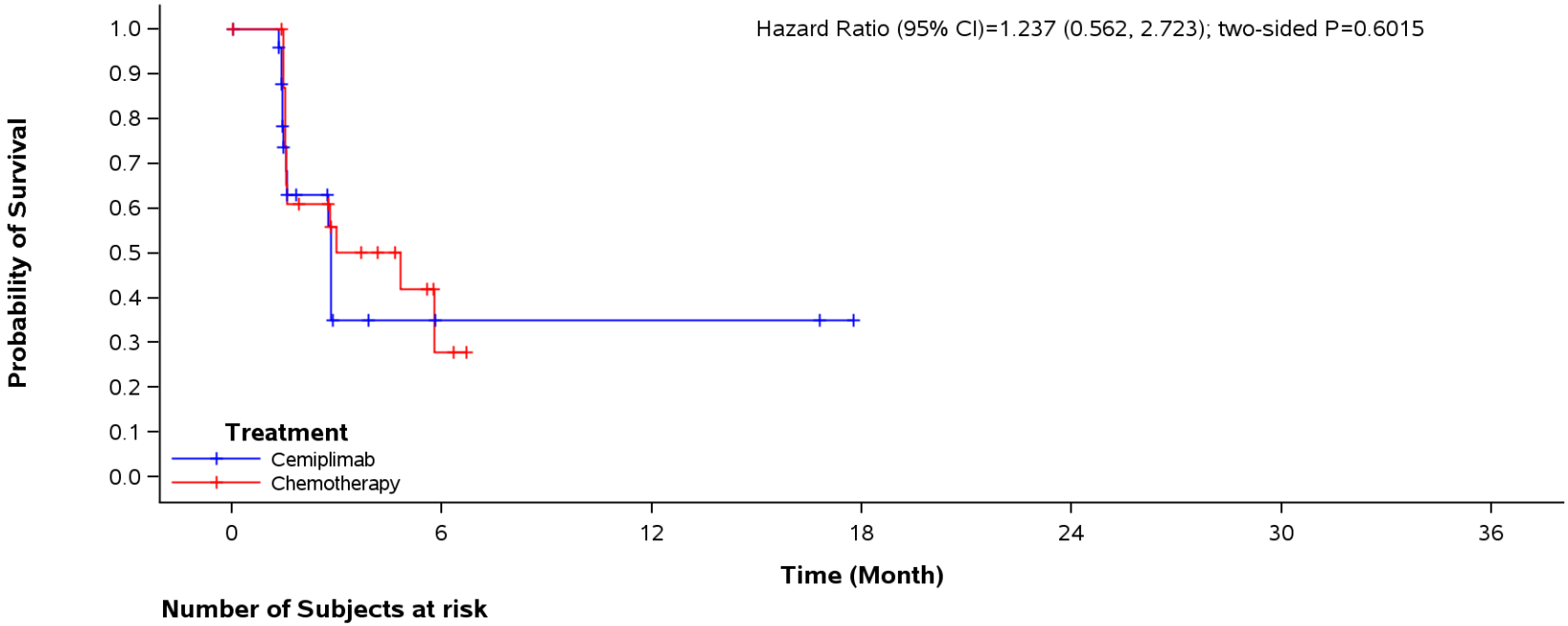

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts improvement



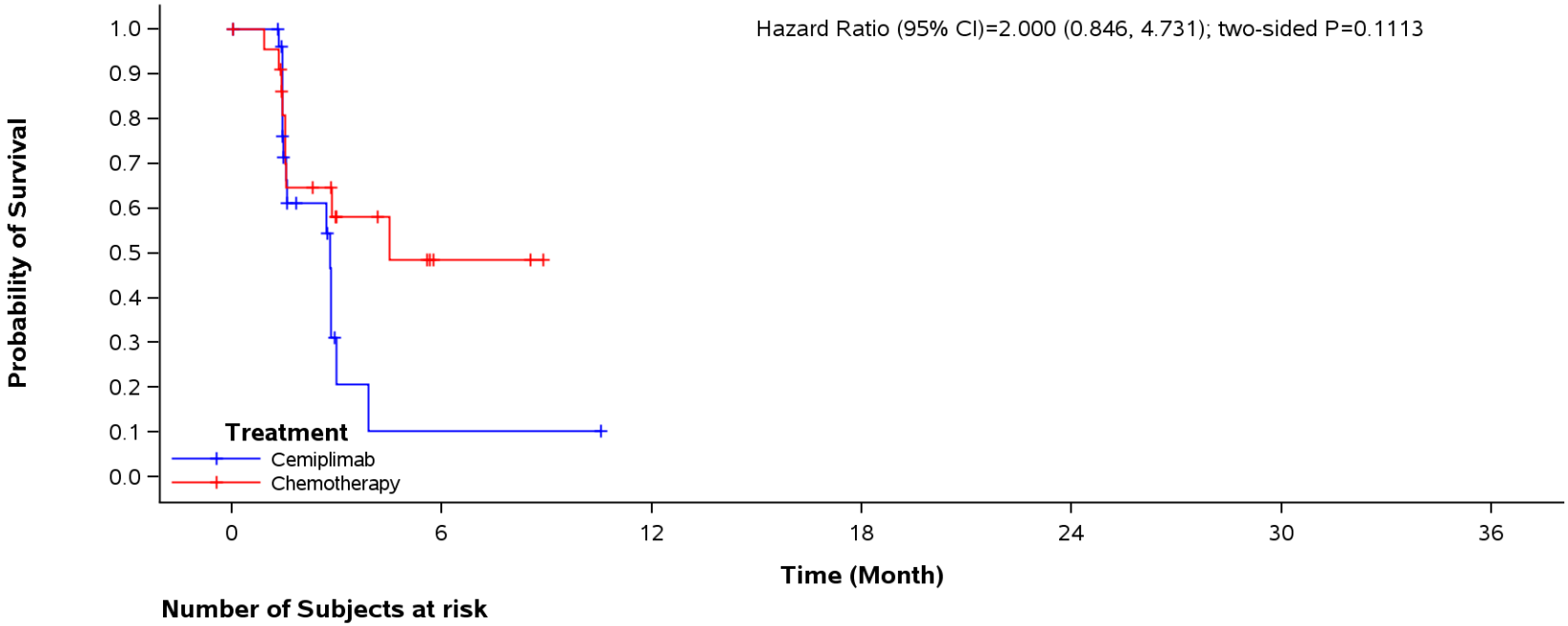

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 2 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts improvement



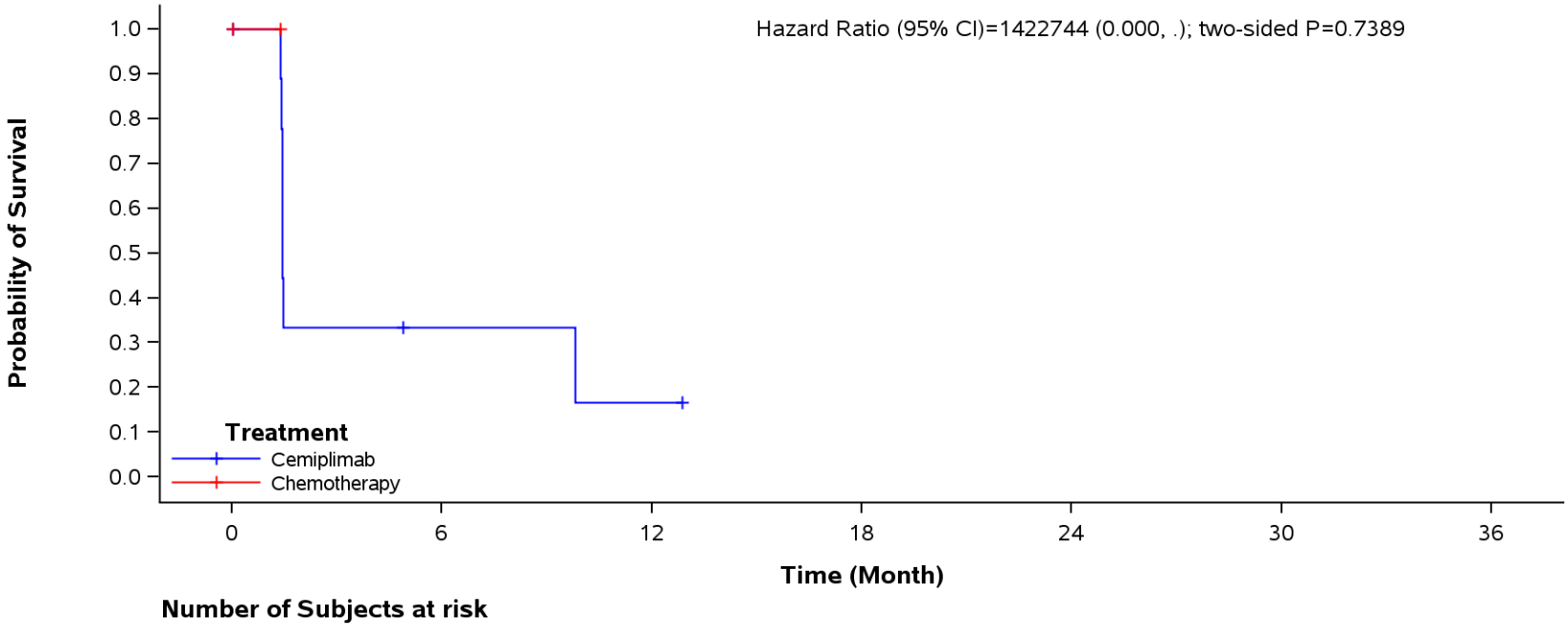

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts improvement



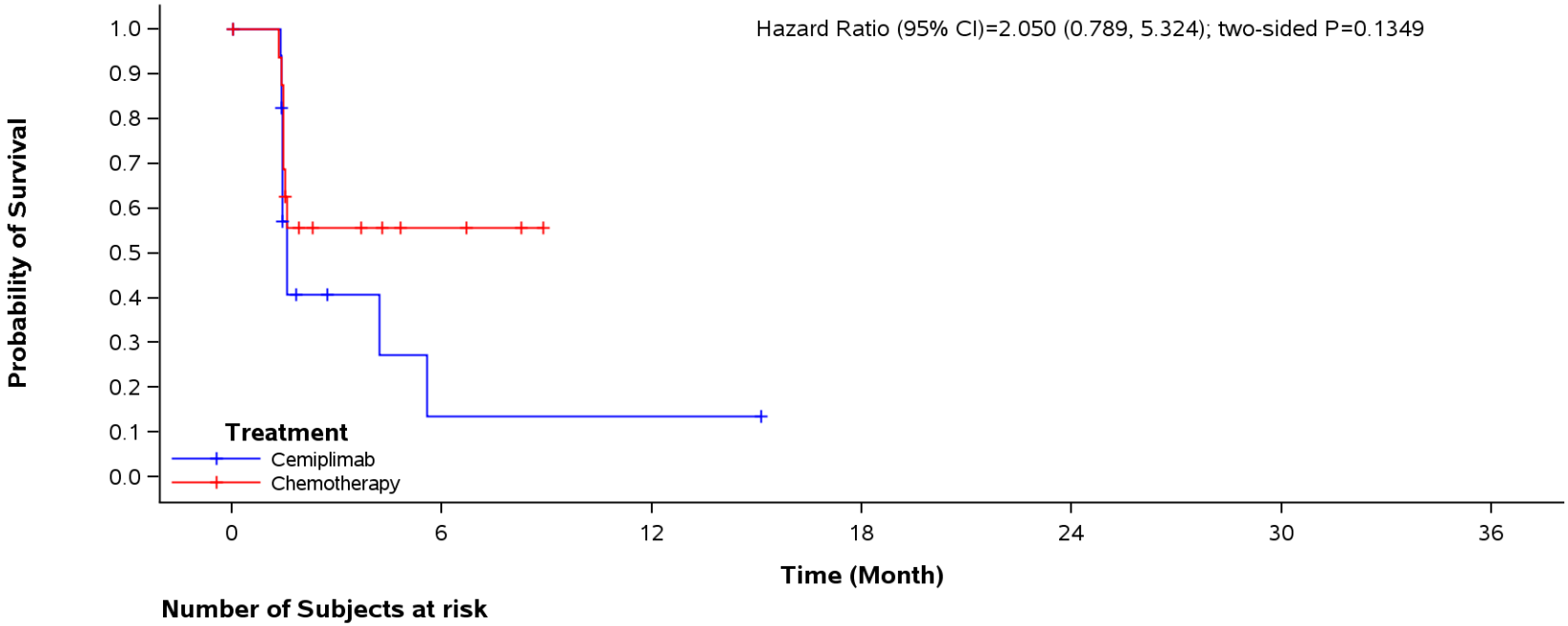

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts improvement



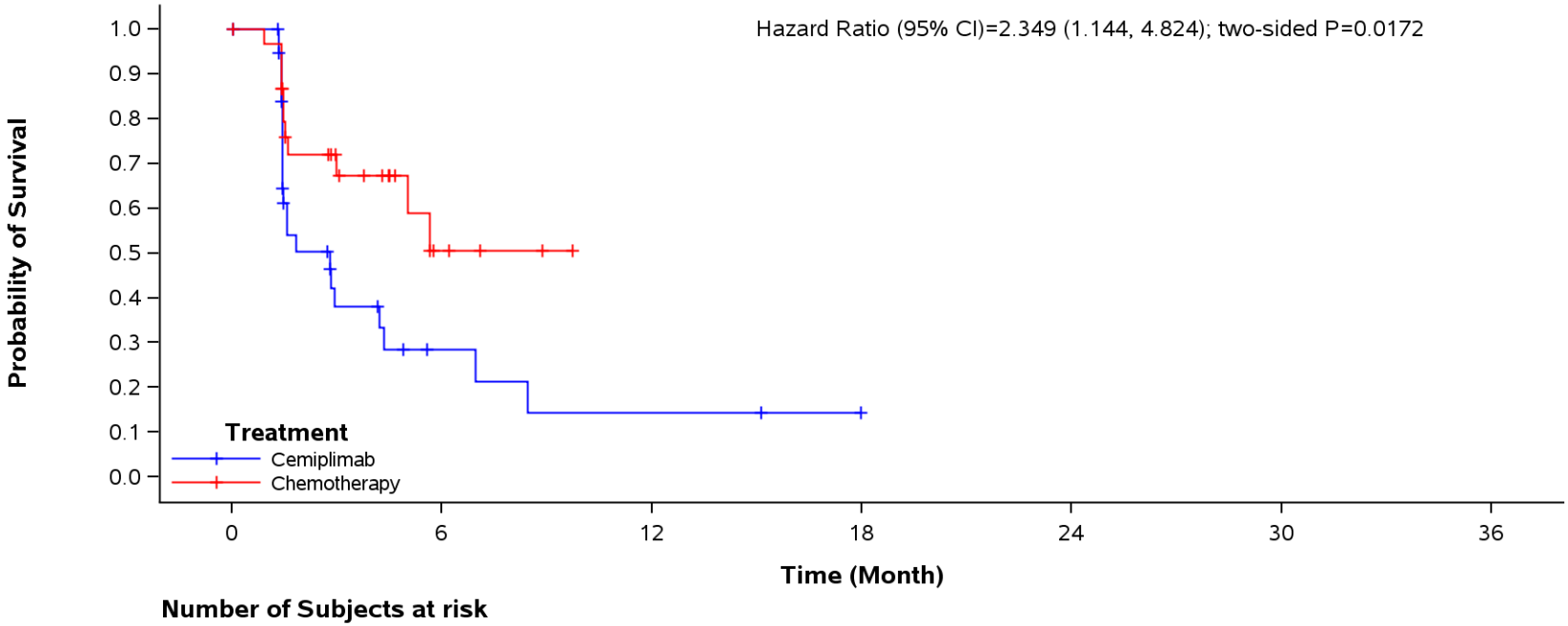

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts improvement



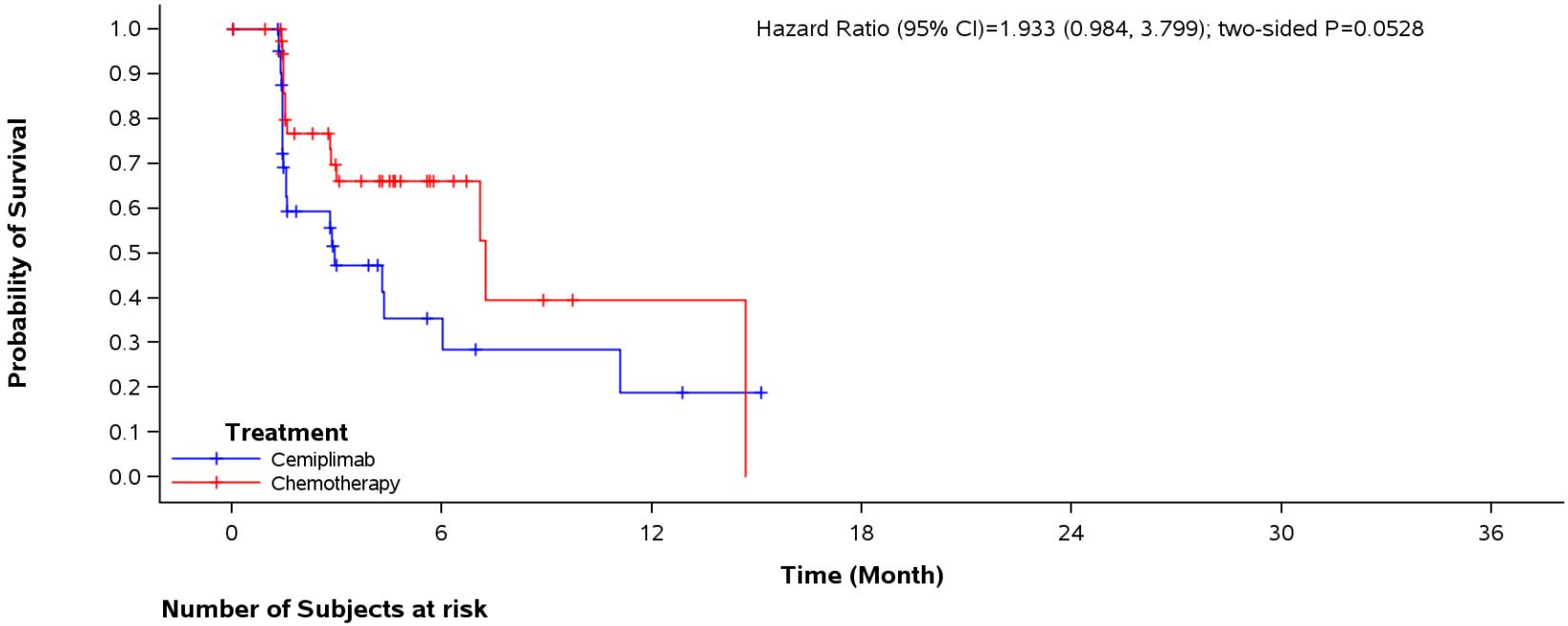

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 4 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts improvement



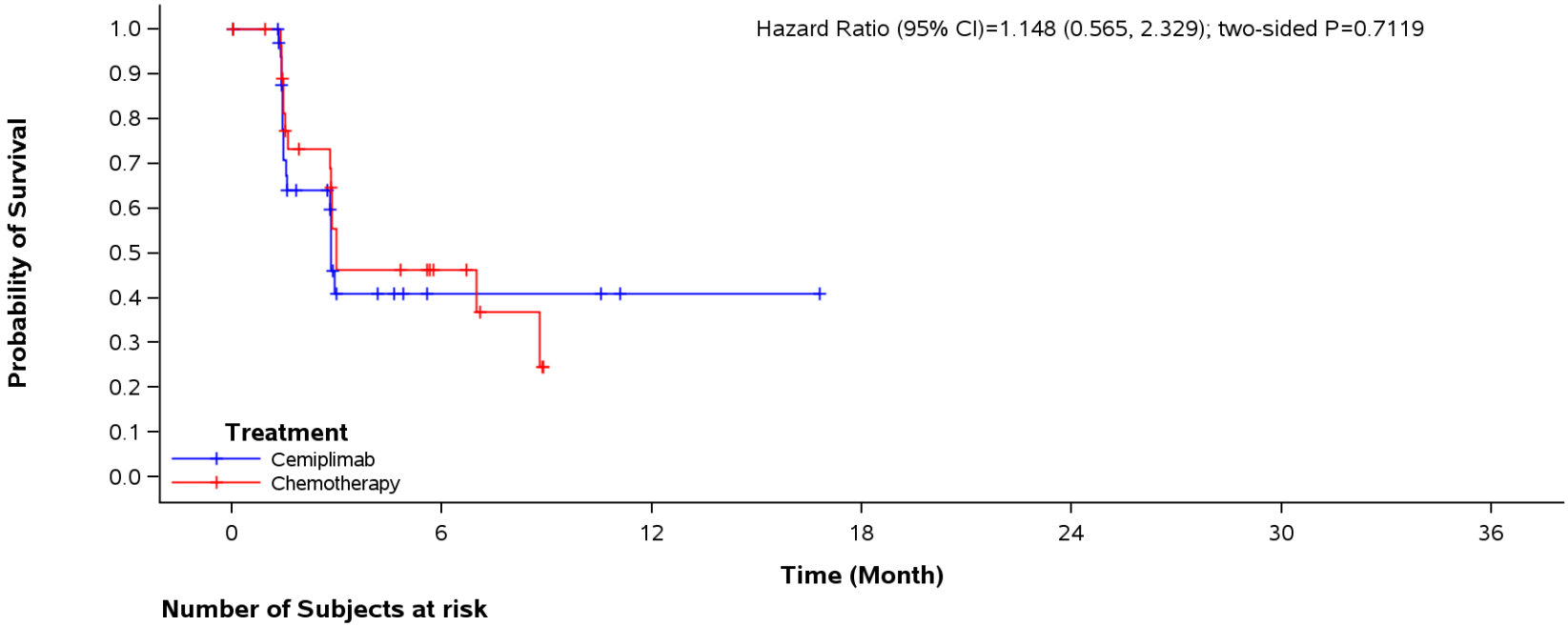

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts improvement



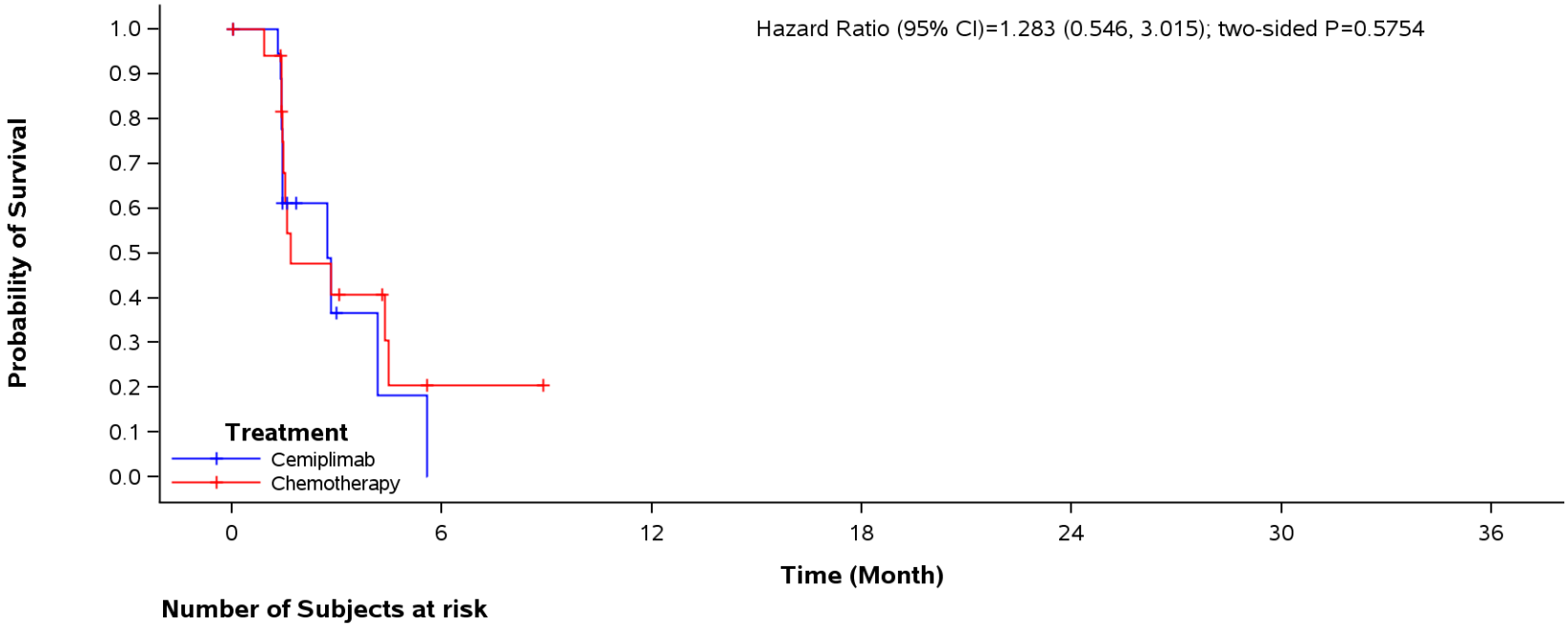

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts improvement



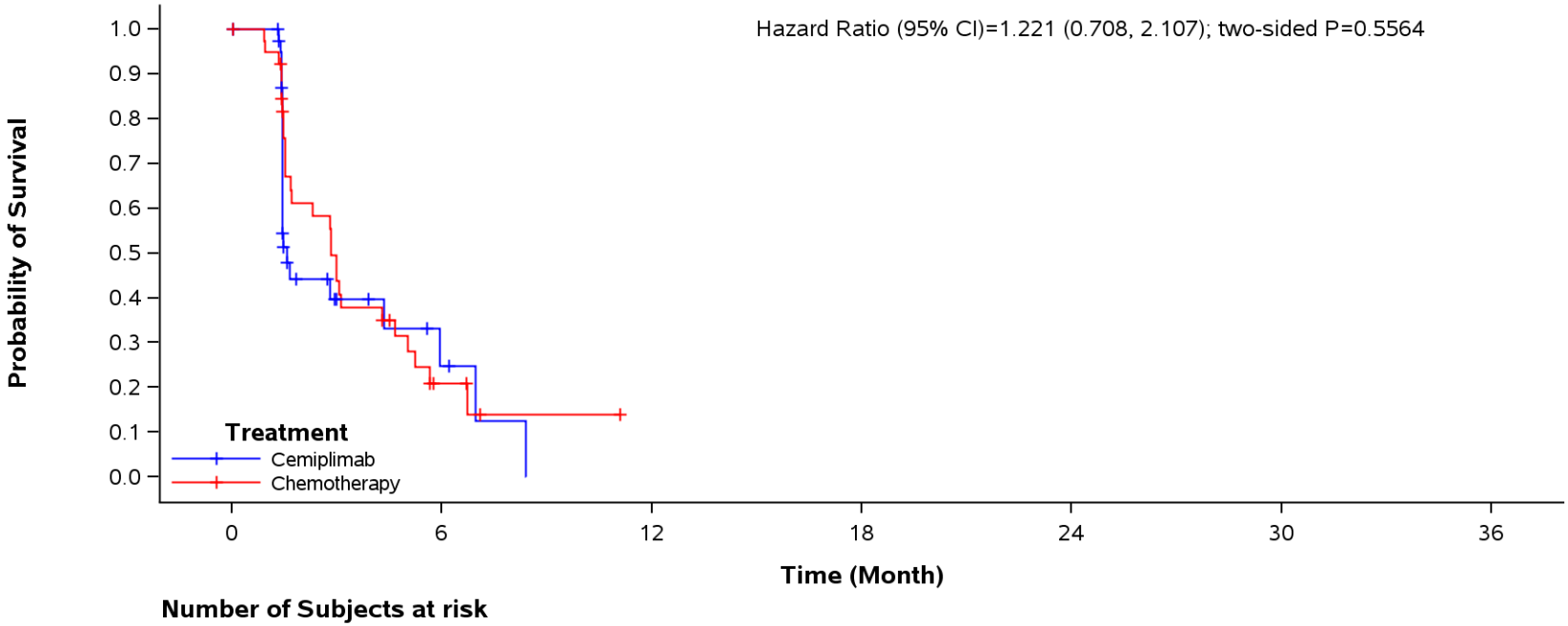

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts improvement




Number of Subjects at risk

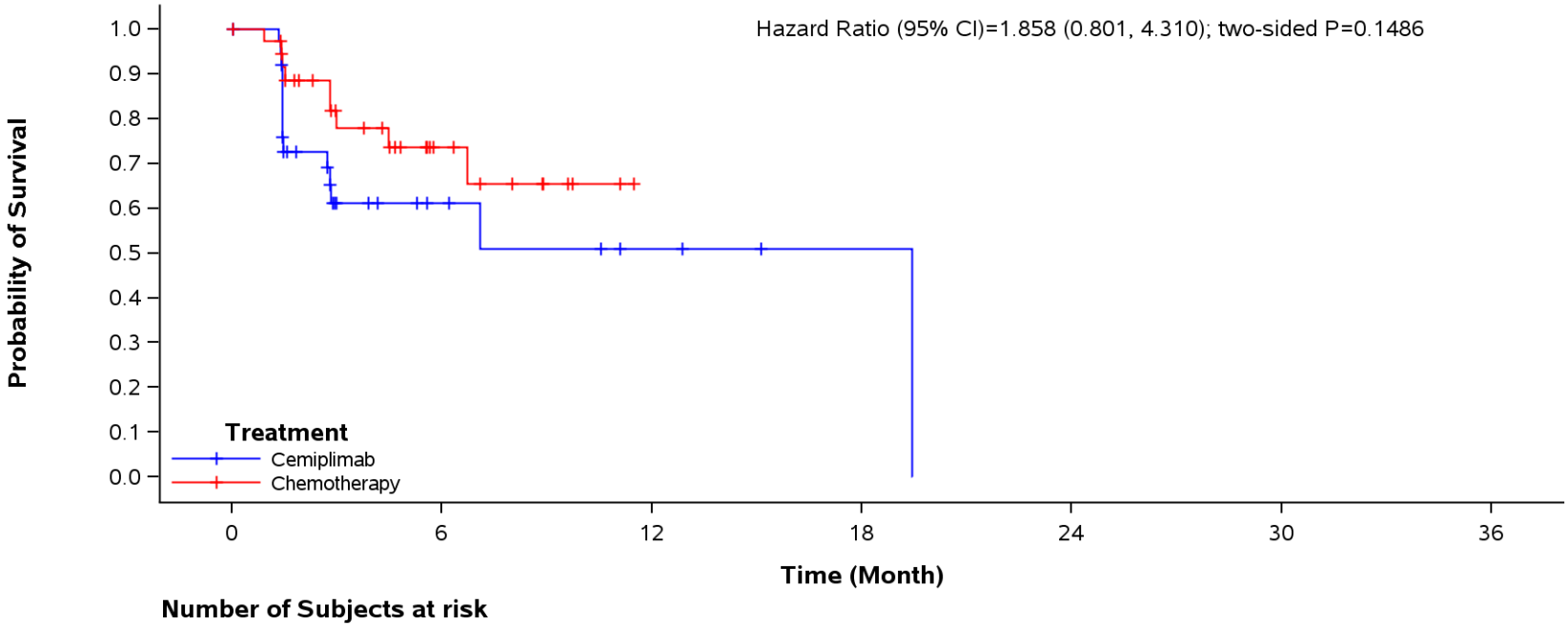
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:15:17, yingyuan.lin)

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts improvement




Number of Subjects at risk

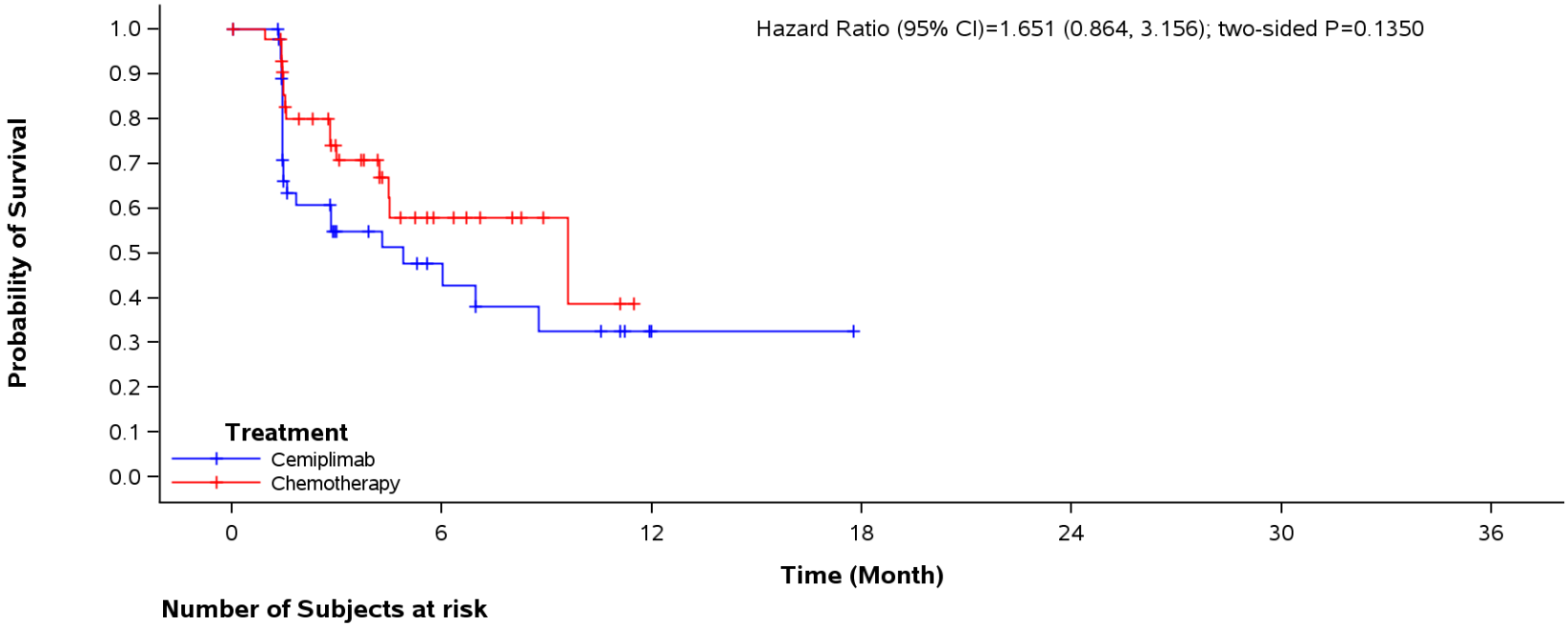
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 7 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 56 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:15:17, yingyuan.lin)

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts improvement



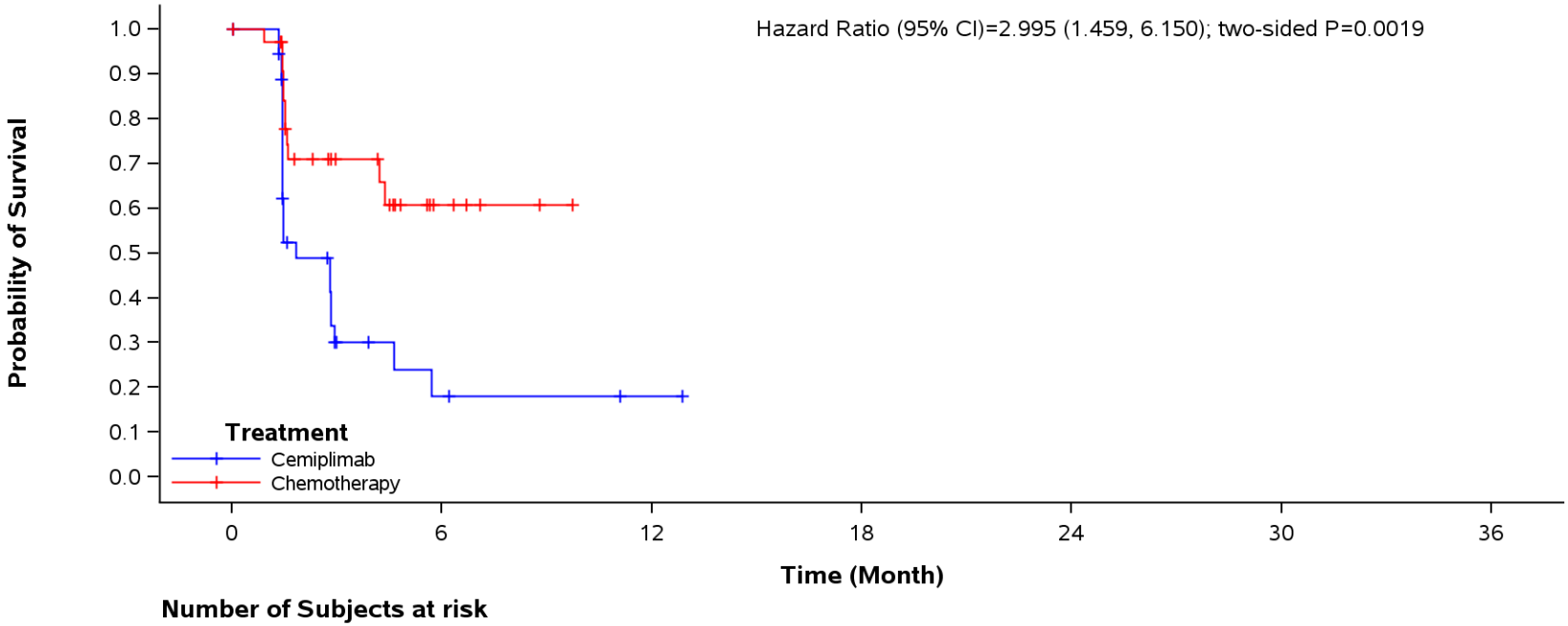

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 10 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts improvement



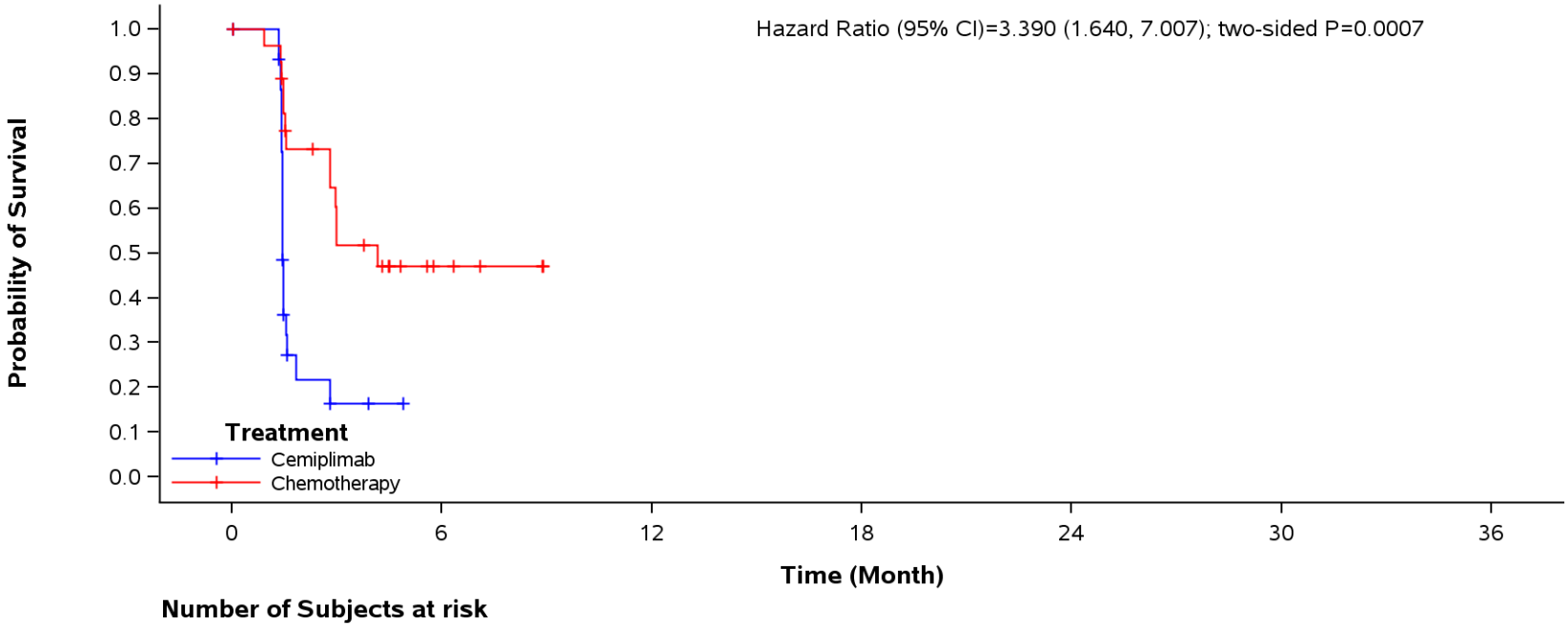

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts improvement



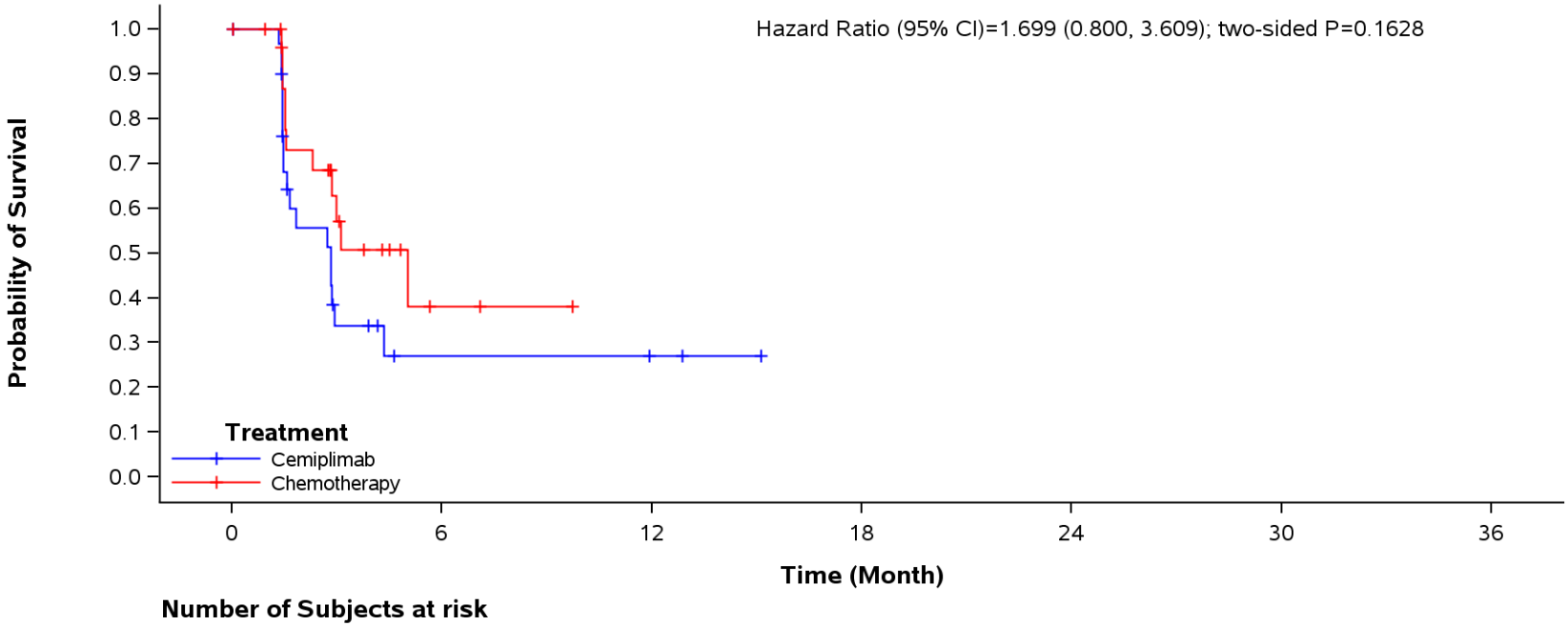

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts improvement



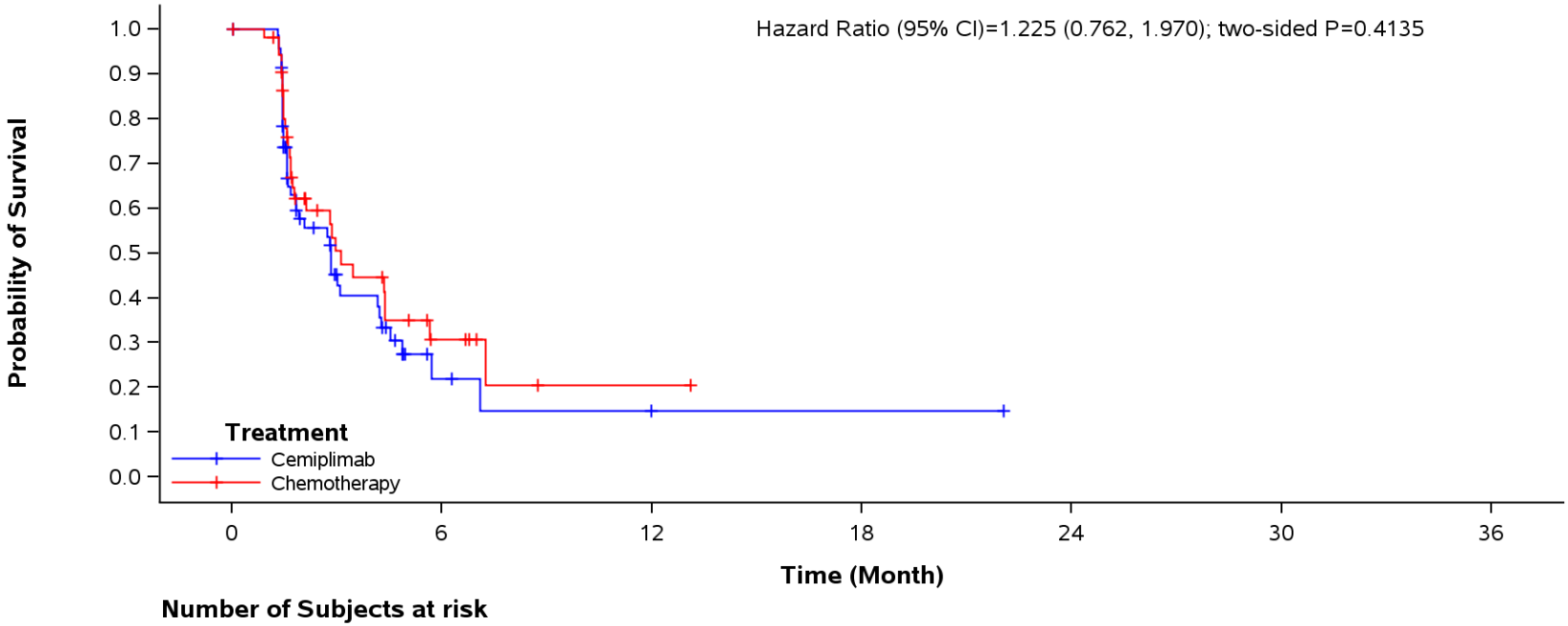

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts improvement



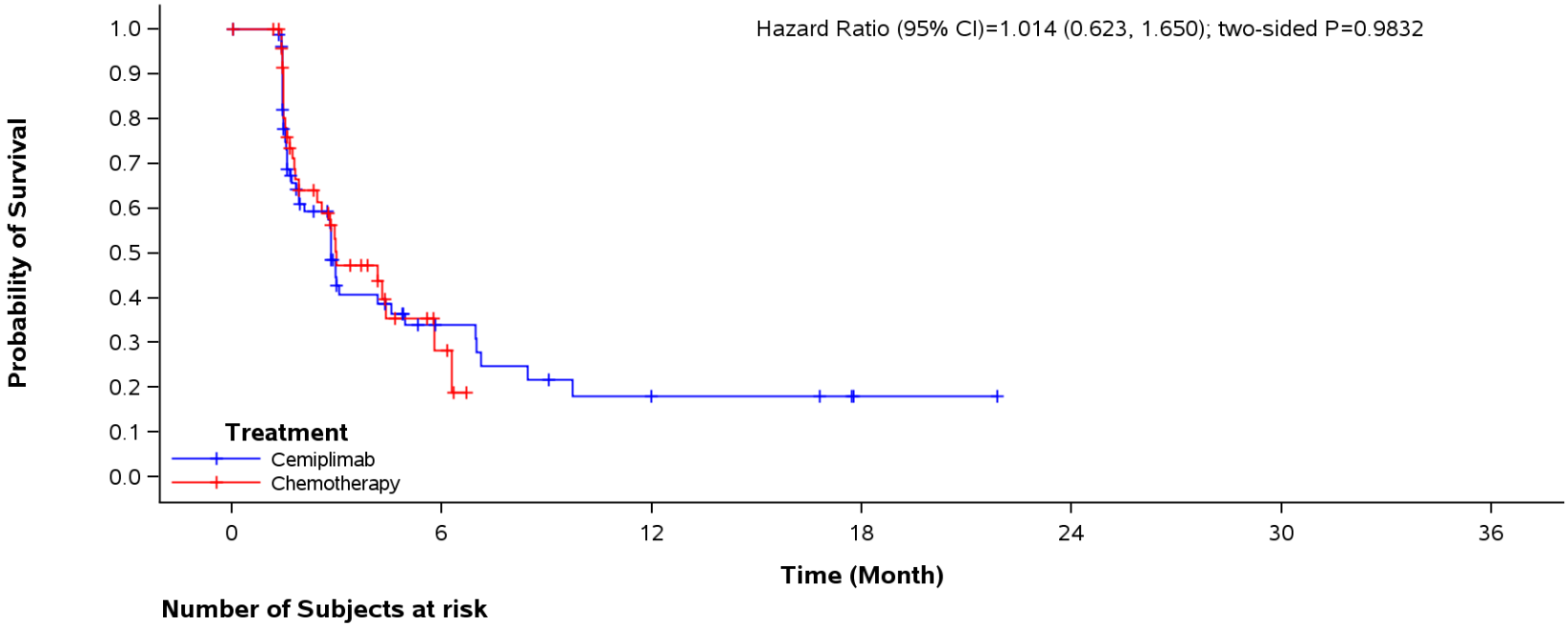

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 4 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 137 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts improvement



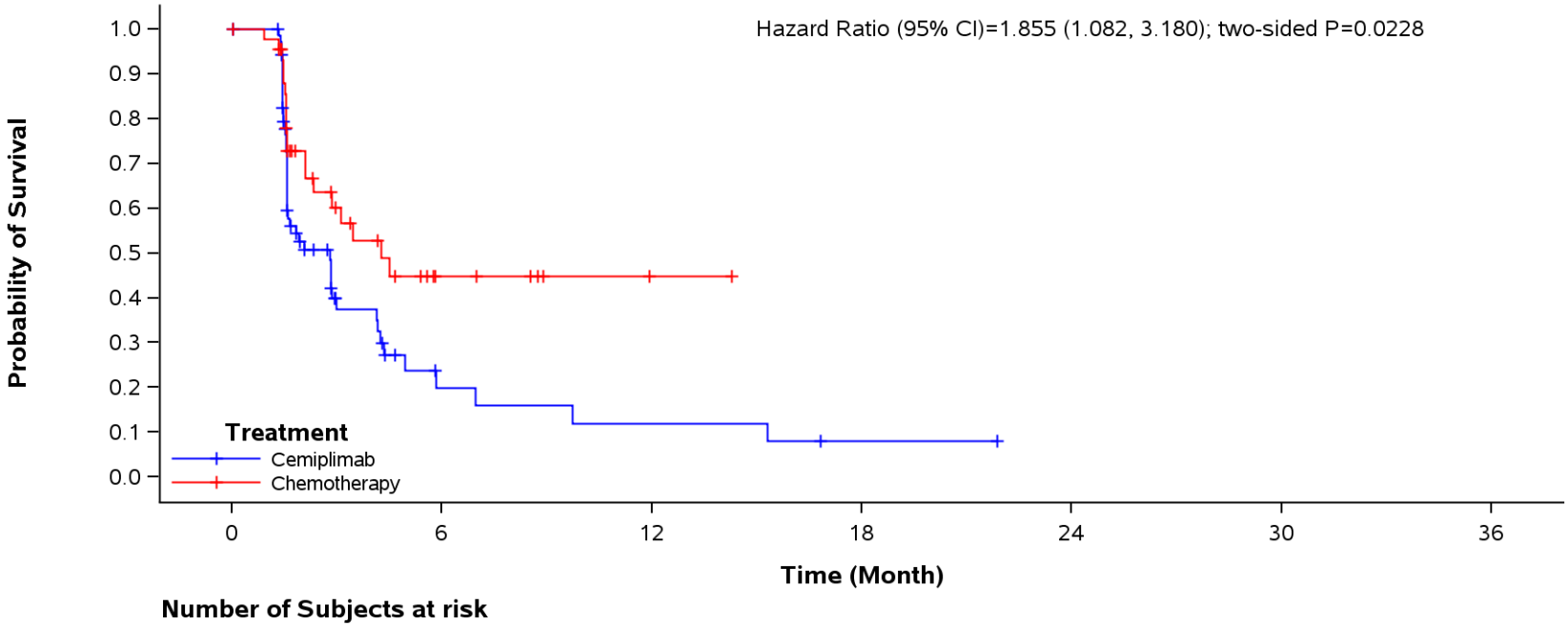

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 11 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 137 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts improvement



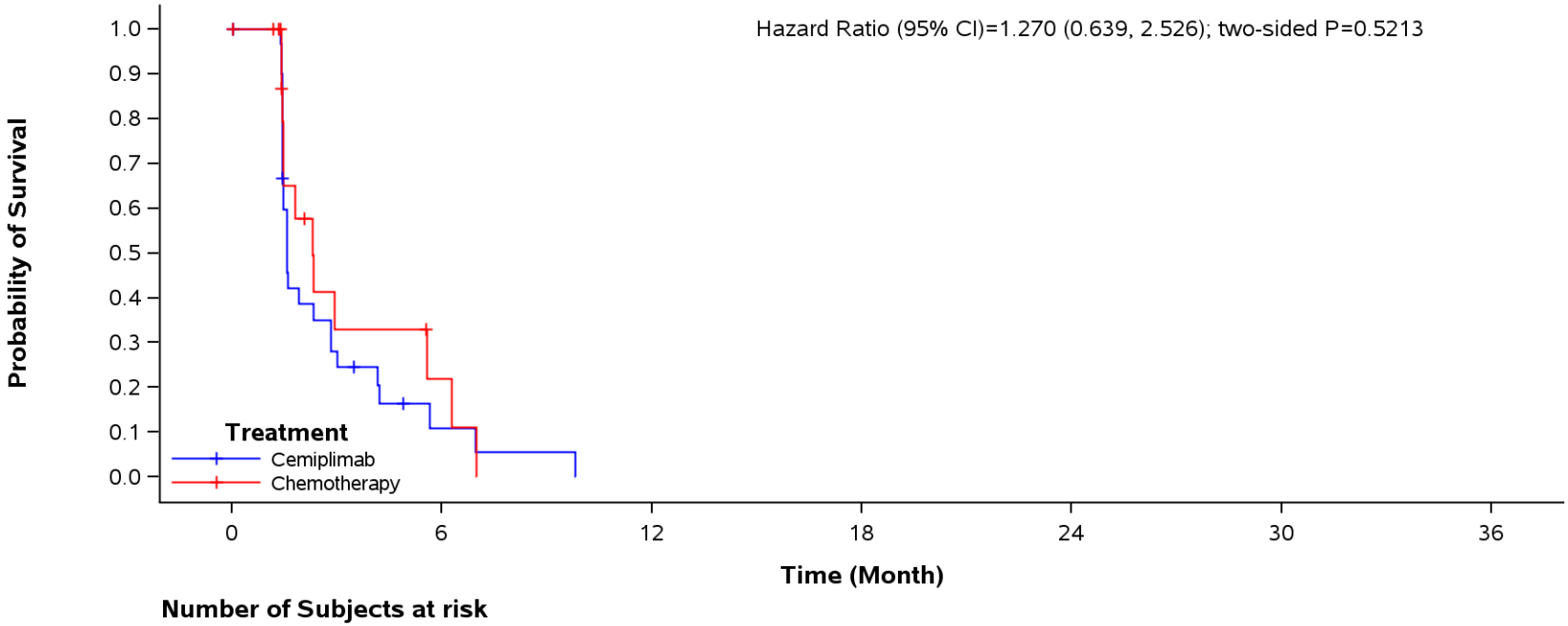

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 137 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts improvement



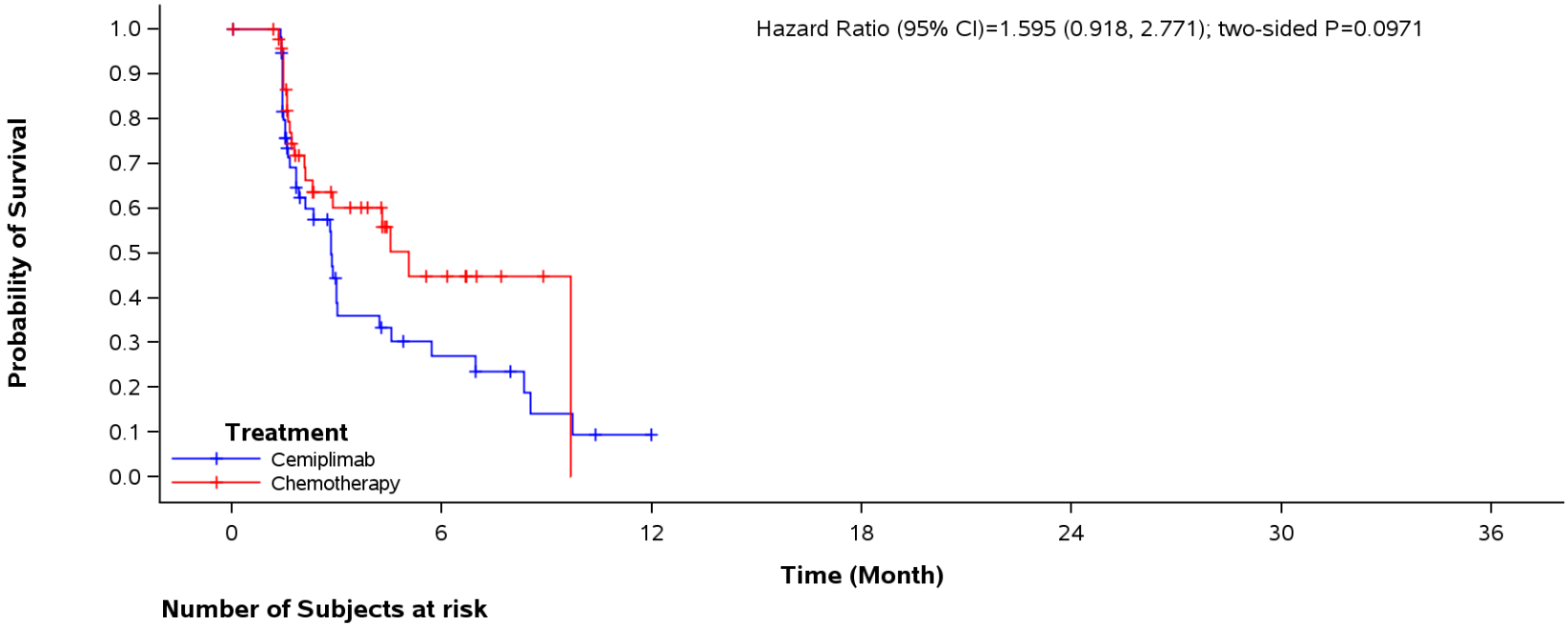

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 137 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts improvement



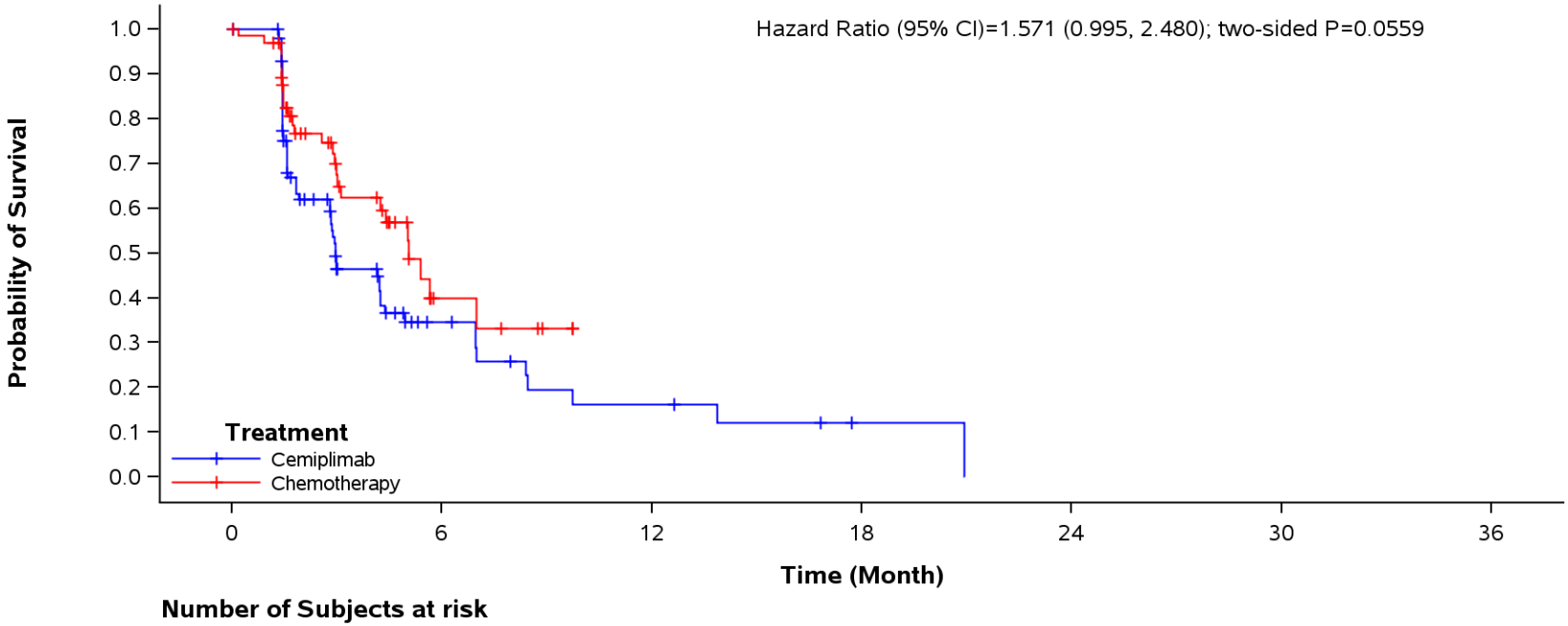

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 8 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 137 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts improvement



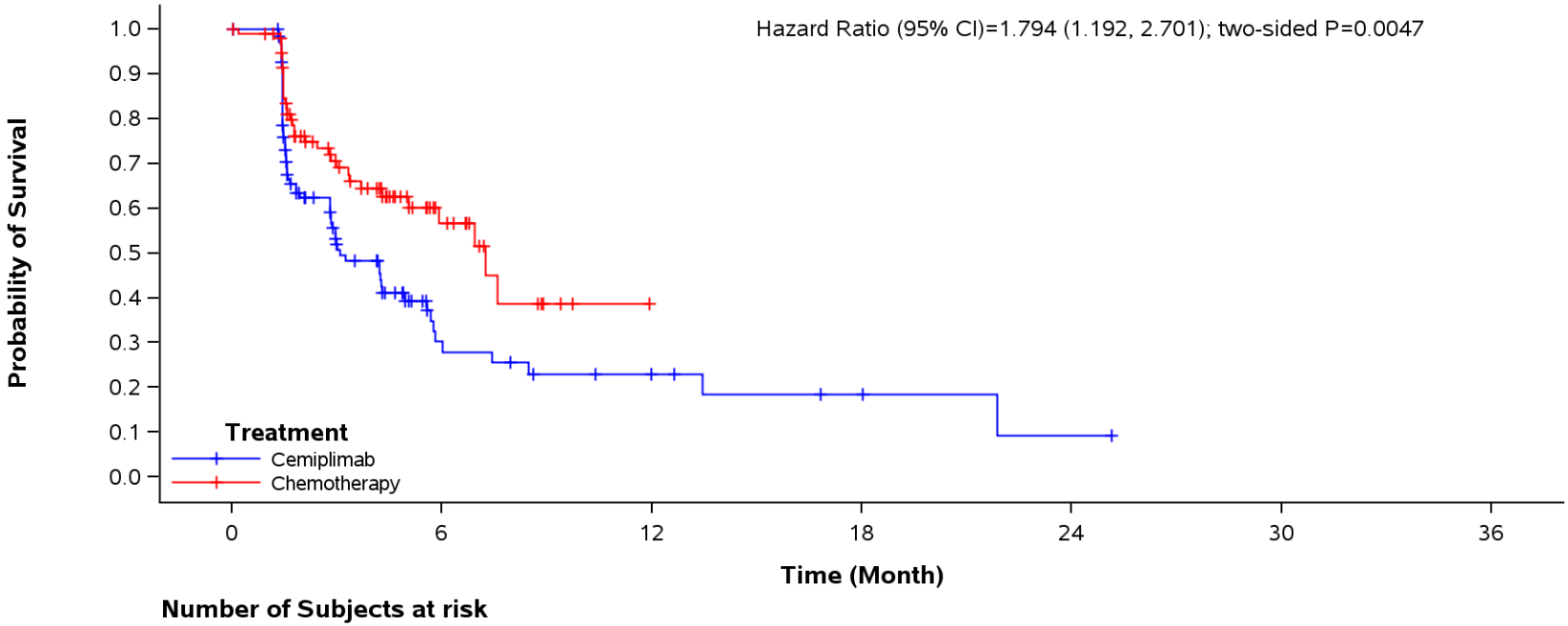

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 13 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 137 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts improvement



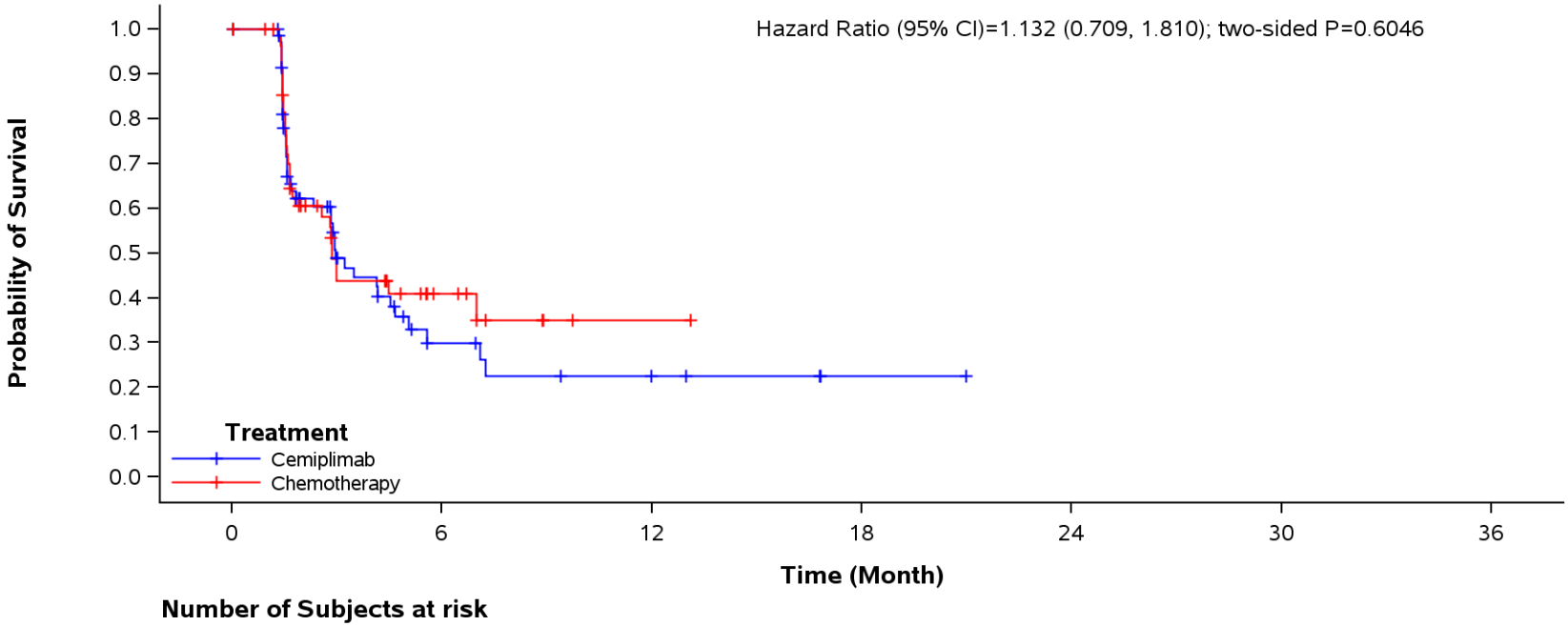

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 13 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 137 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts improvement



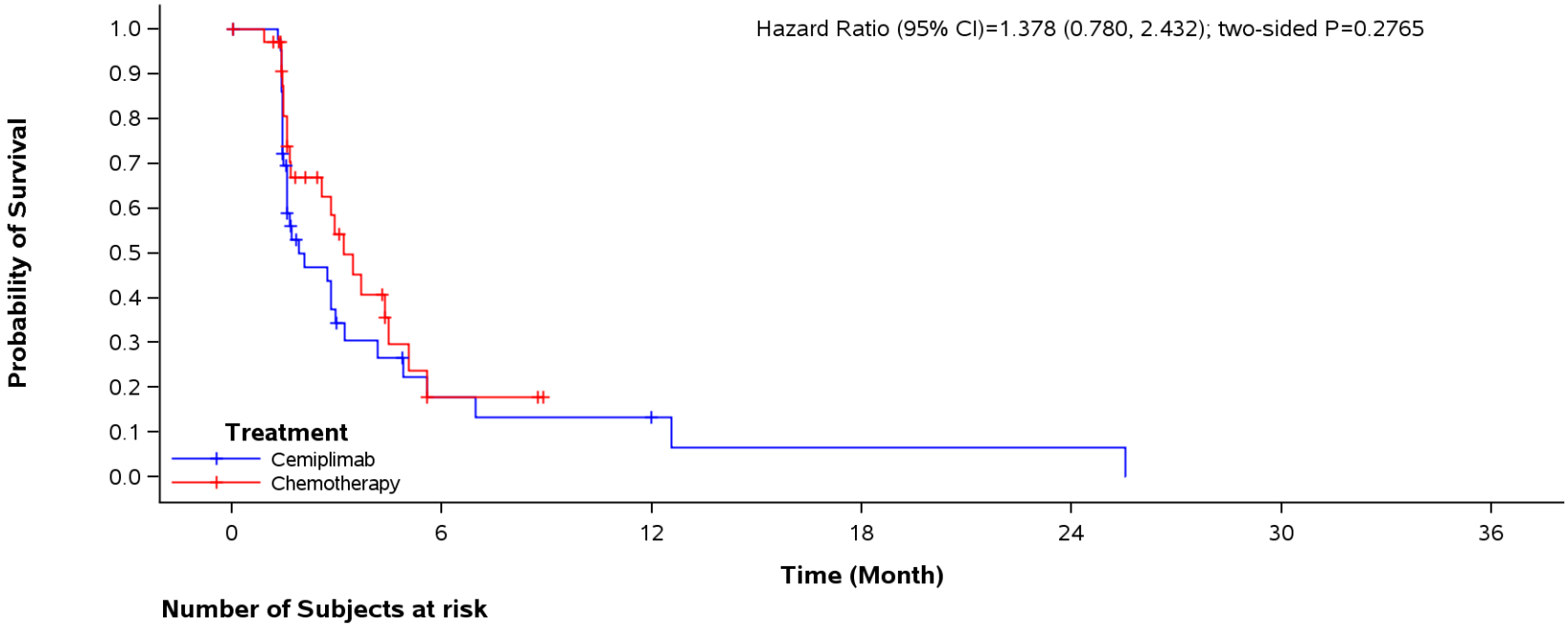

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 9 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 137 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Nausea / Vomiting - 10 pts improvement



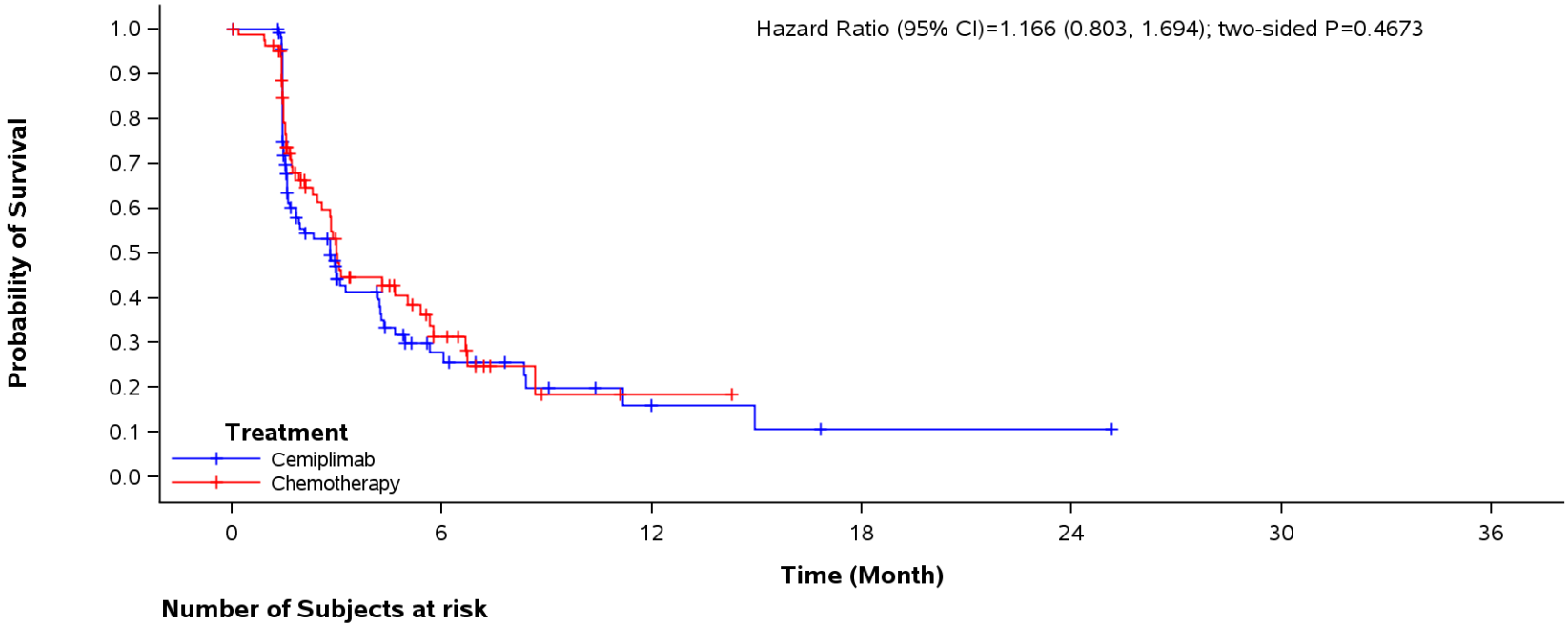

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 4 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 137 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts improvement



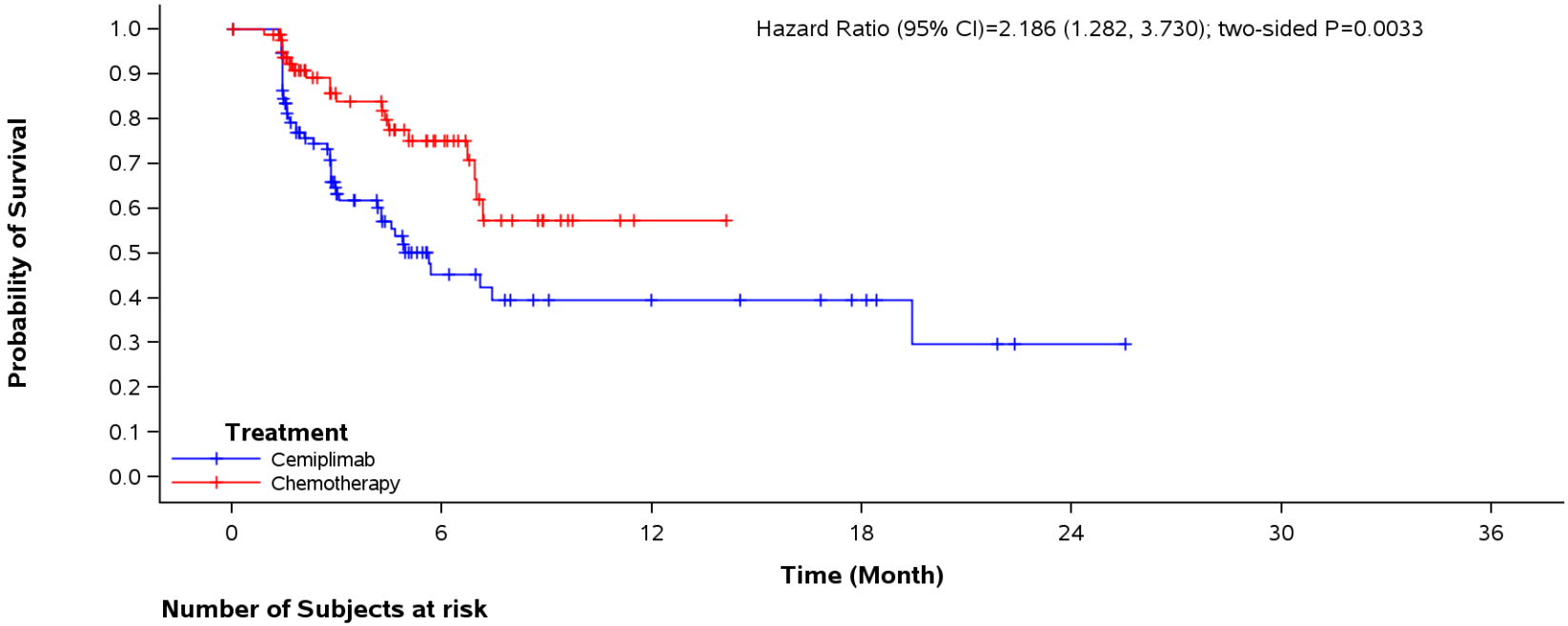

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 13 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 137 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts improvement



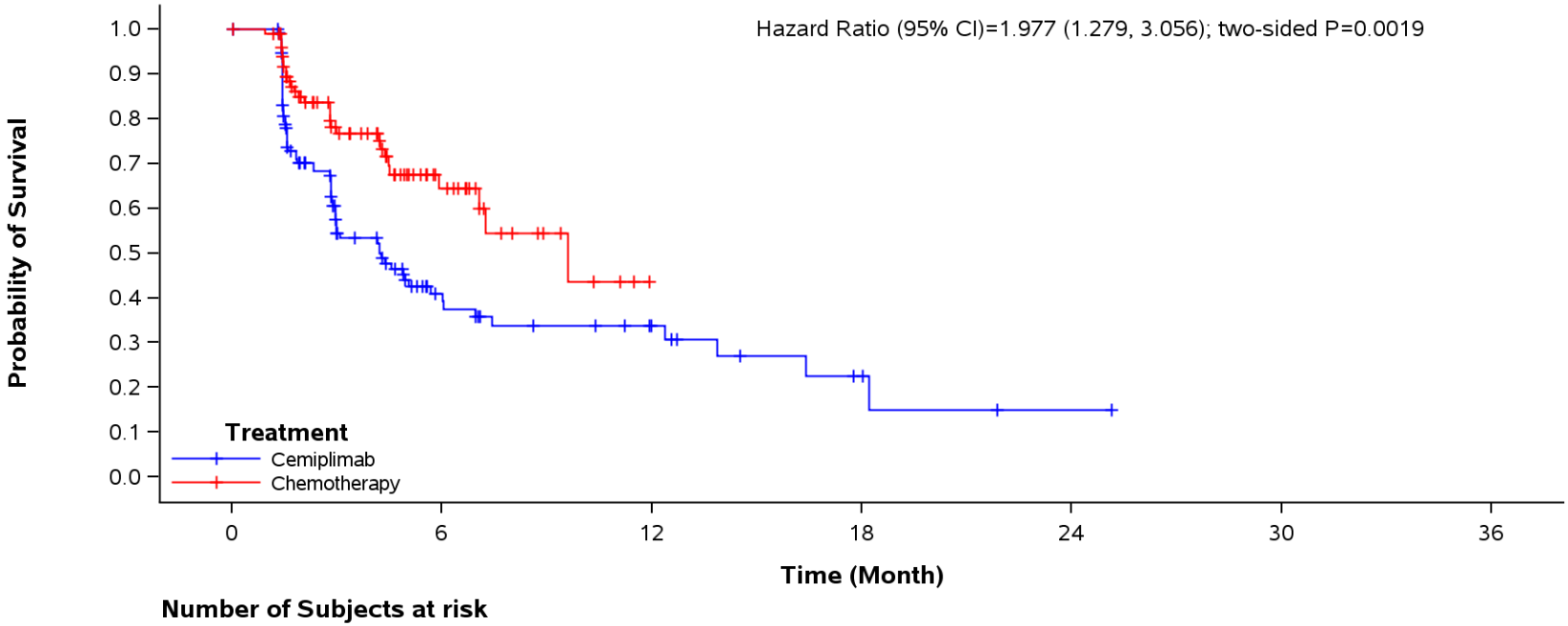

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 18 | 9 | 6 | 1 | 0 | 0 |
| Chemotherapy | 137 | 23 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts improvement



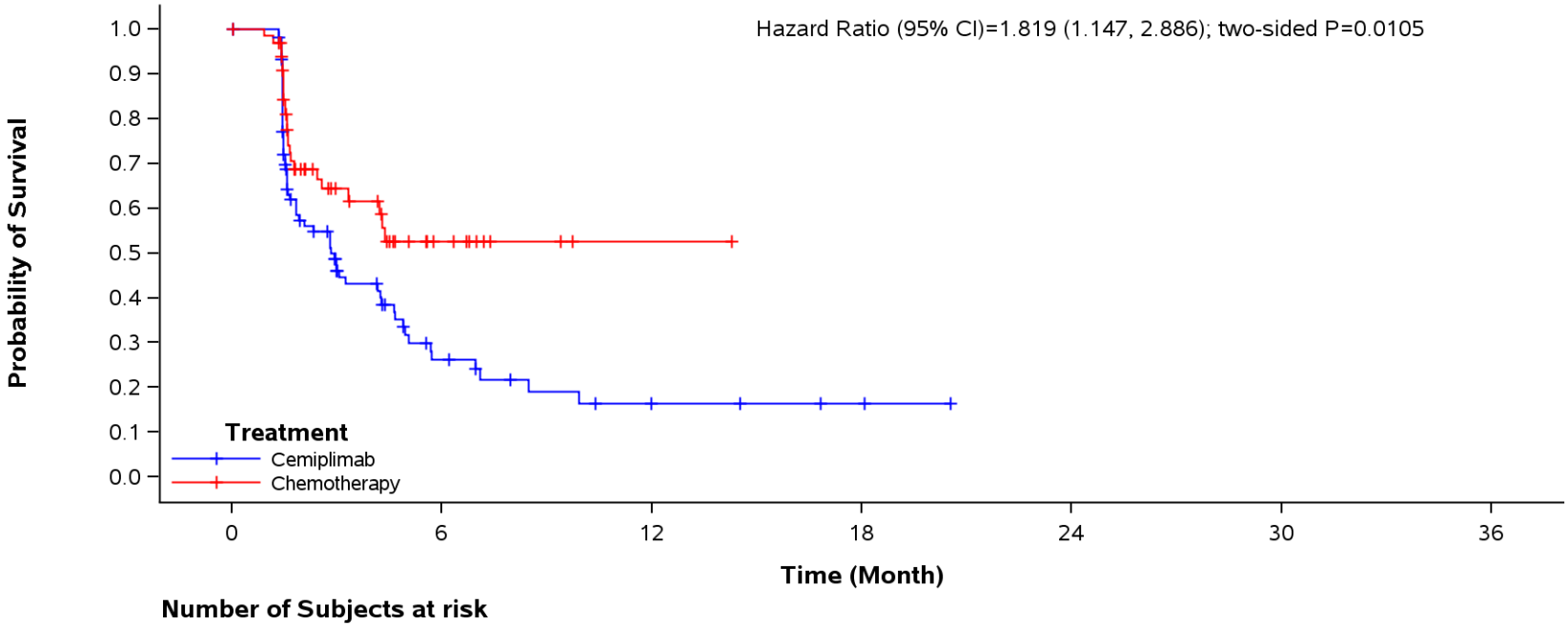

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 24 | 11 | 4 | 1 | 0 | 0 |
| Chemotherapy | 137 | 21 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts improvement



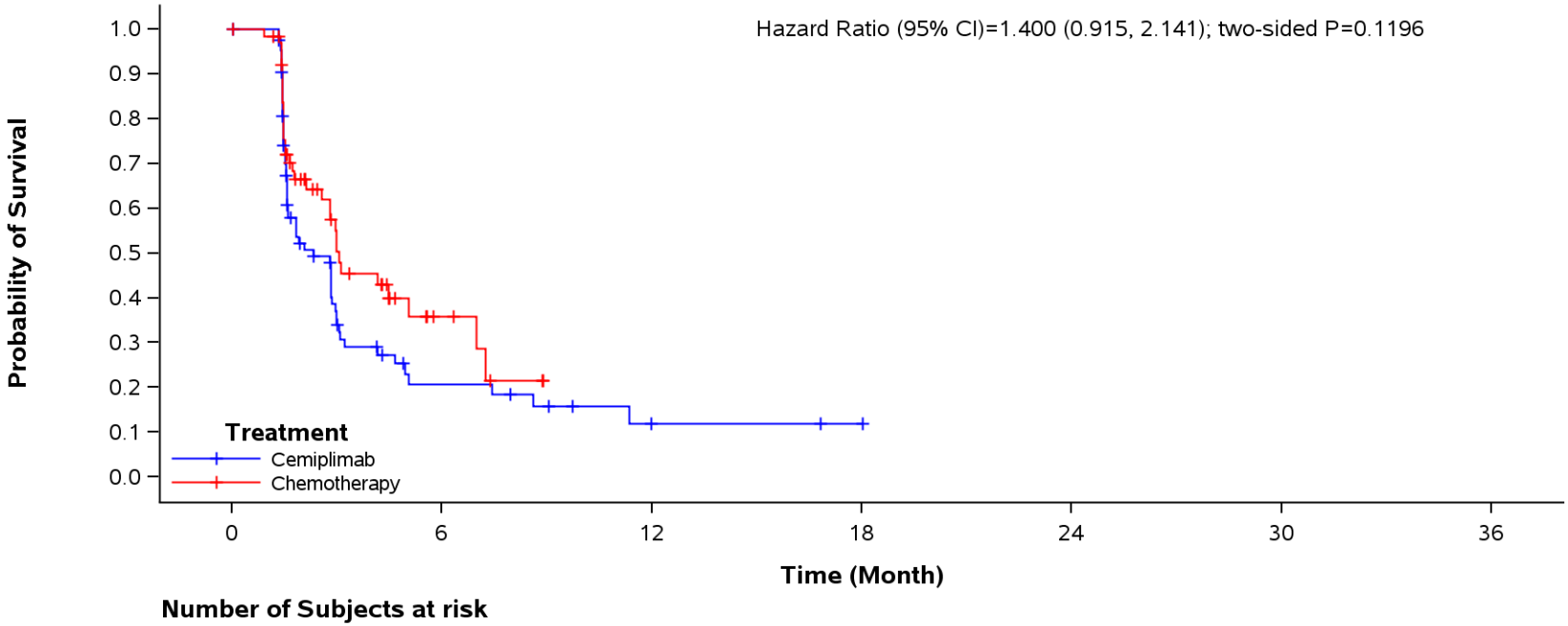

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 14 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 137 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Social Functioning - 10 pts improvement



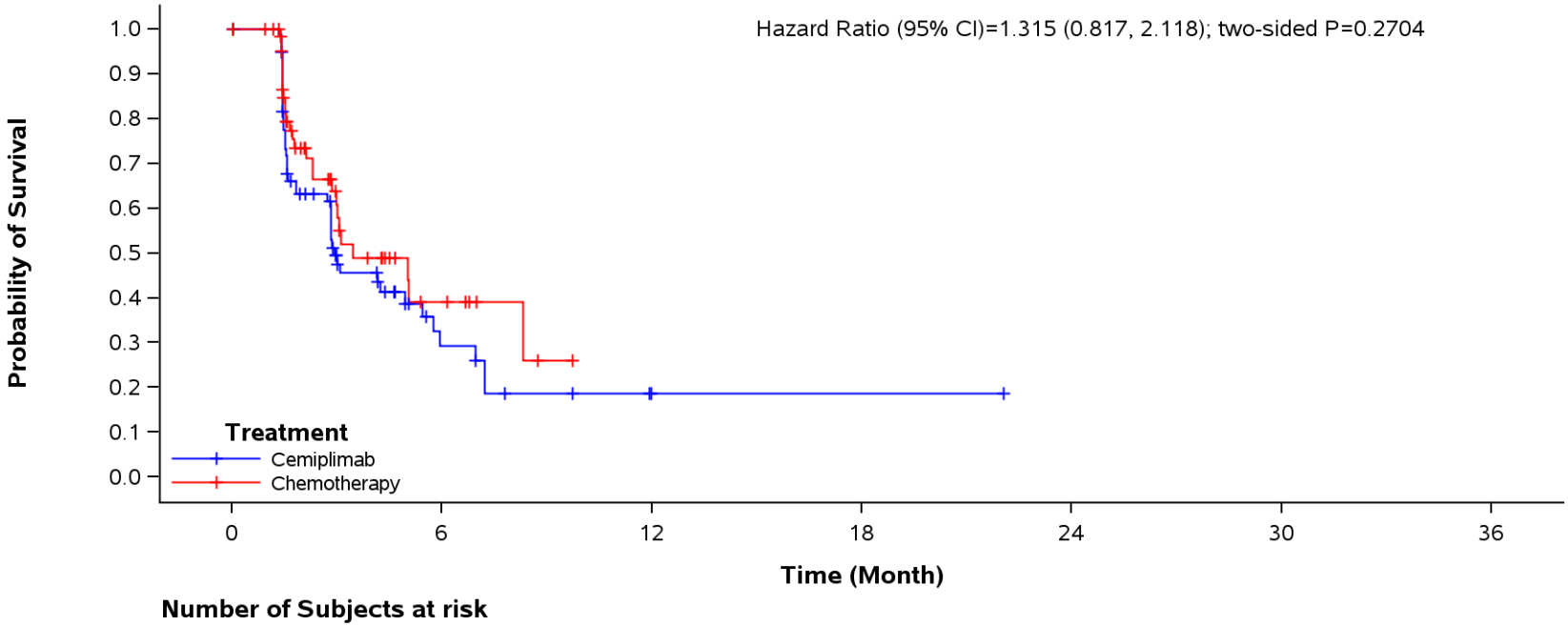

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 9 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 137 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts improvement



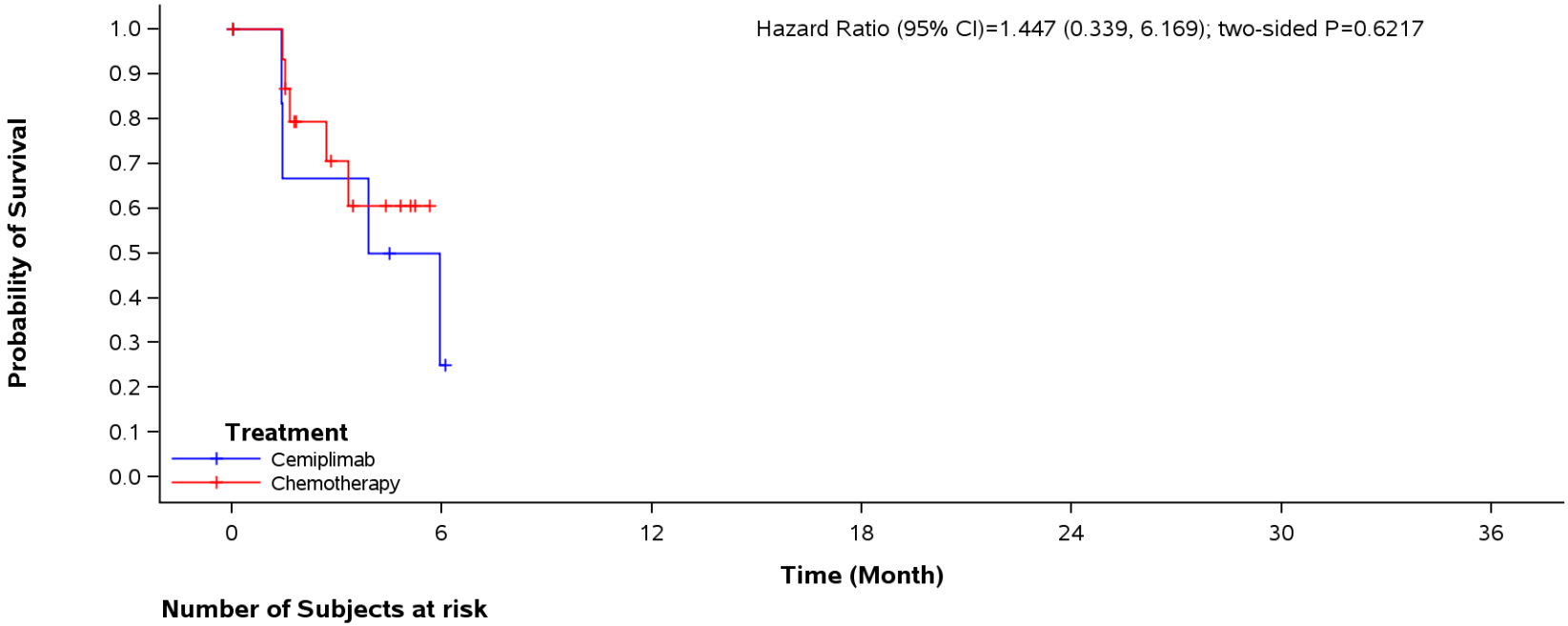

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 9 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 137 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts improvement



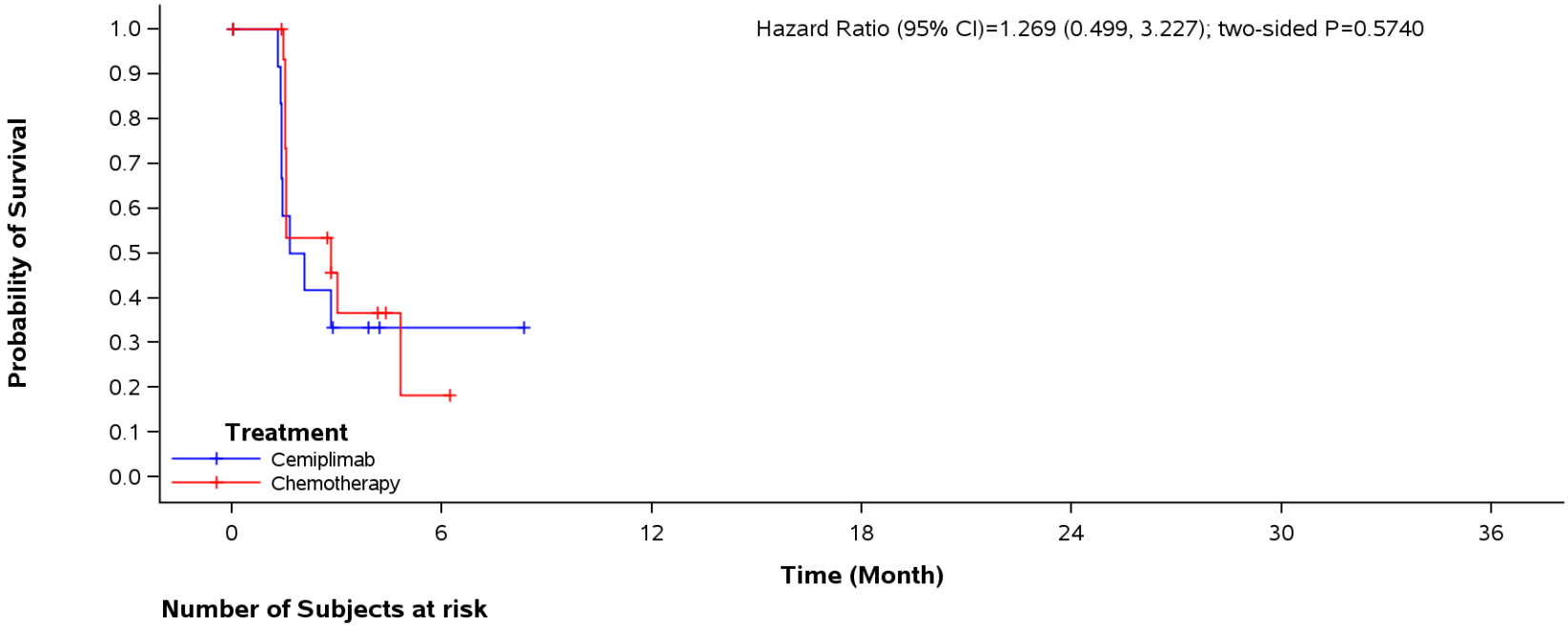

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts improvement



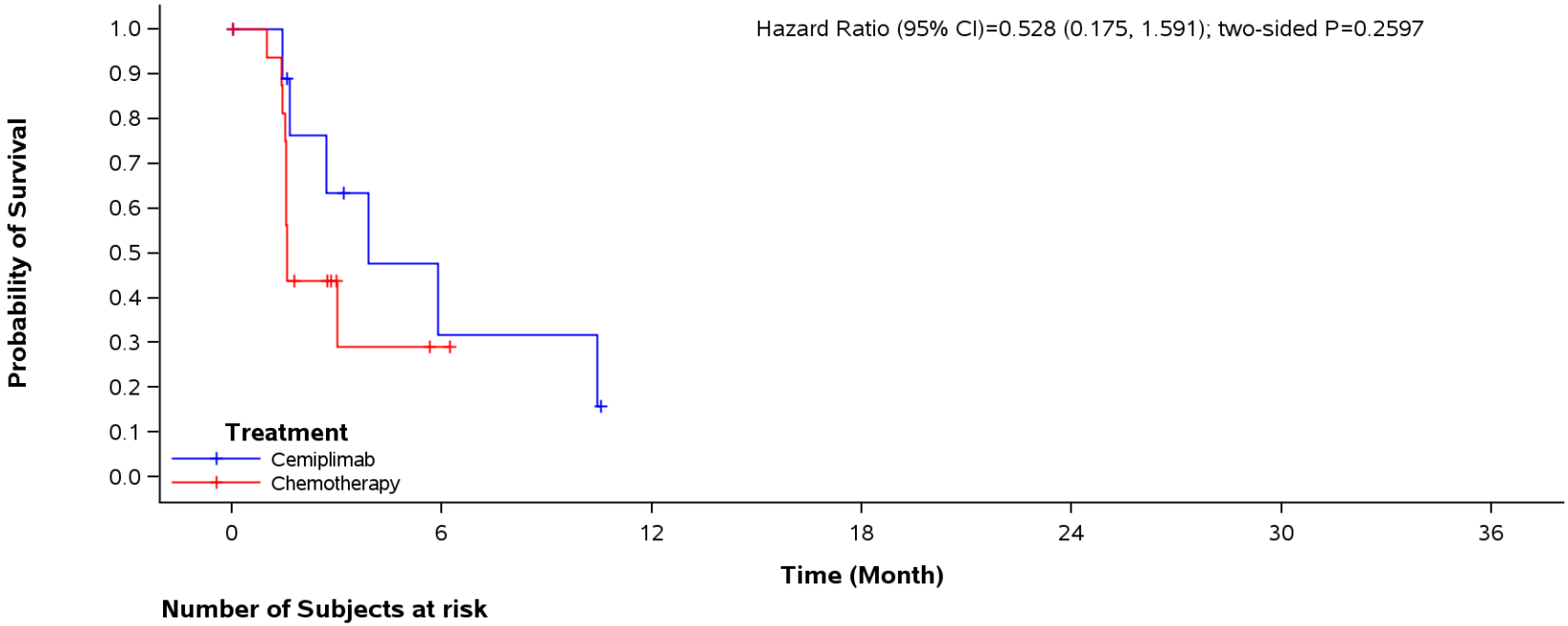

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts improvement



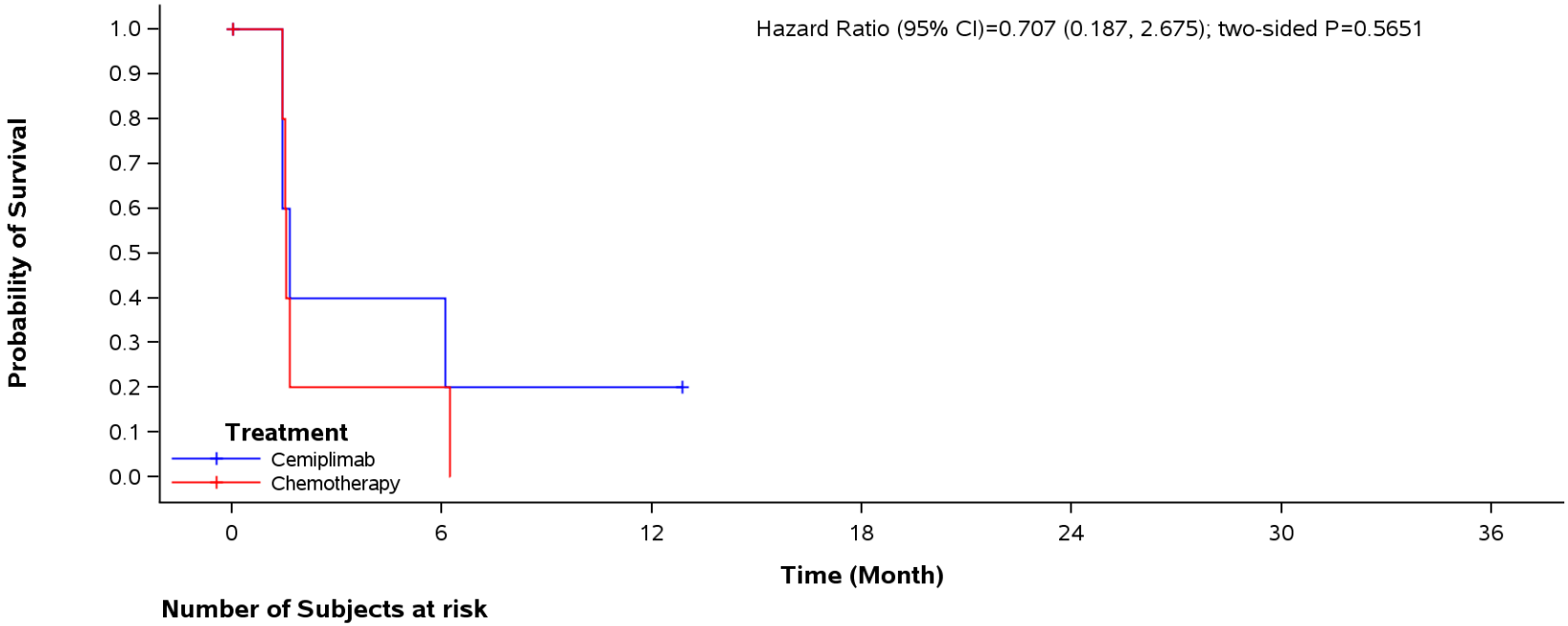

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts improvement



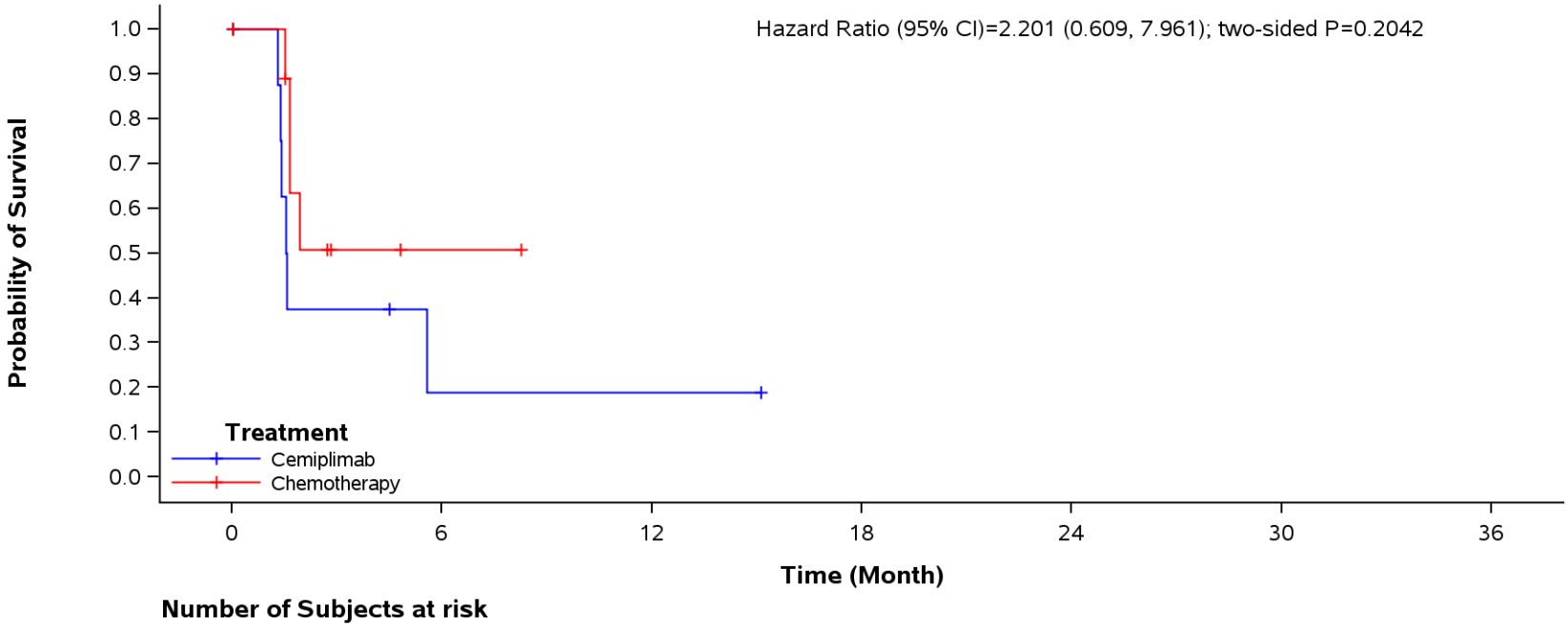

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts improvement




Number of Subjects at risk

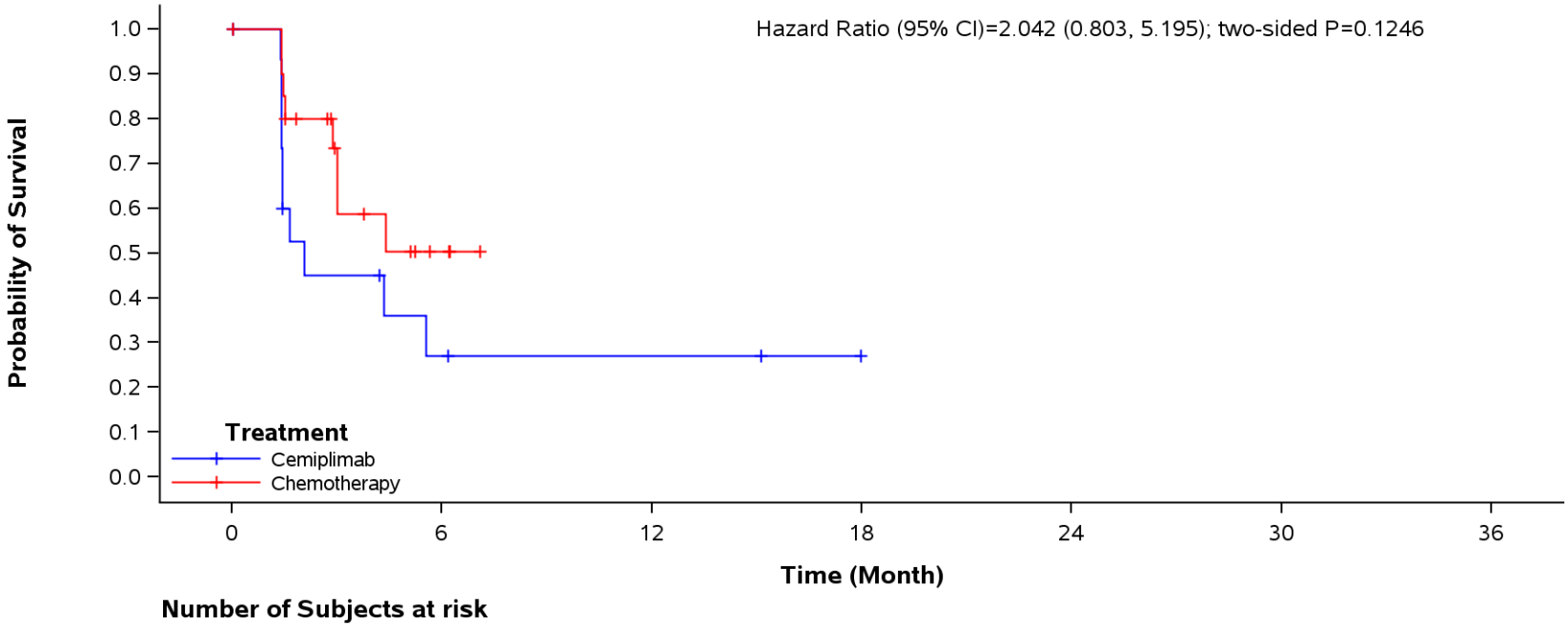
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:15:17, yingyuan.lin)

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts improvement



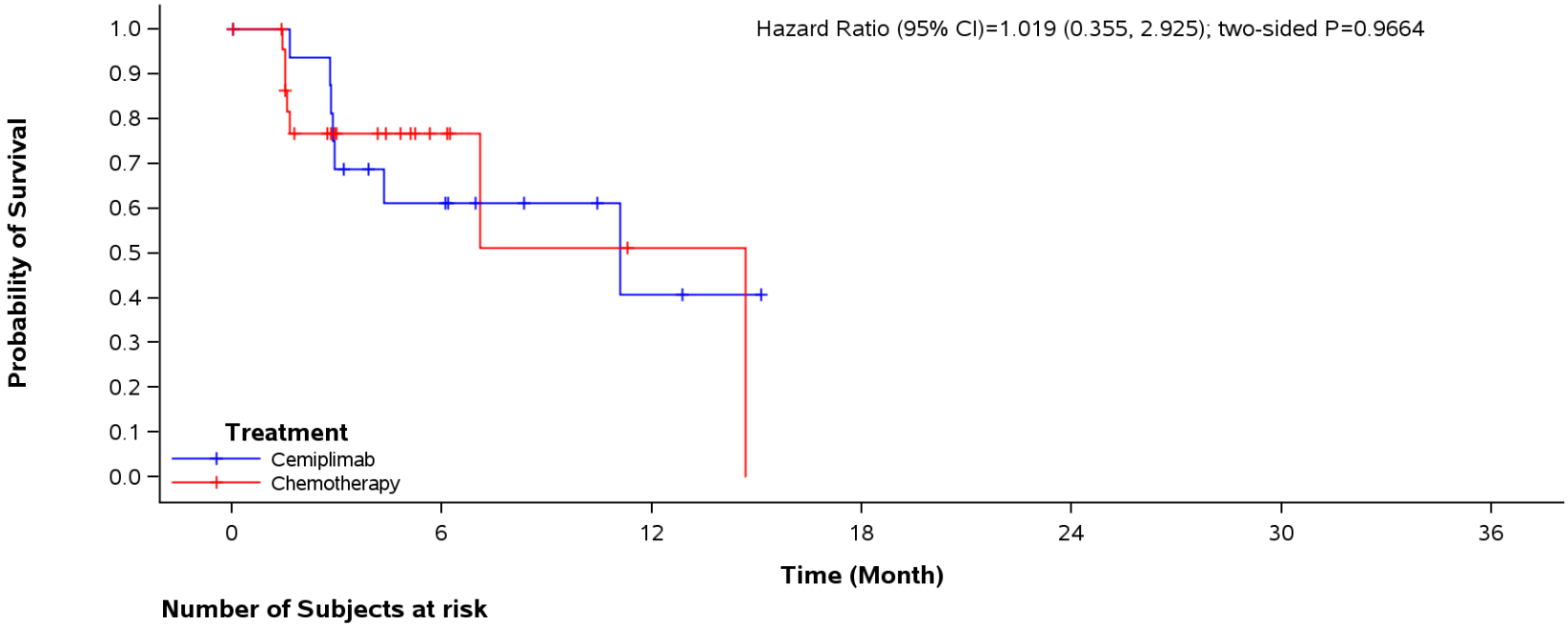

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts improvement



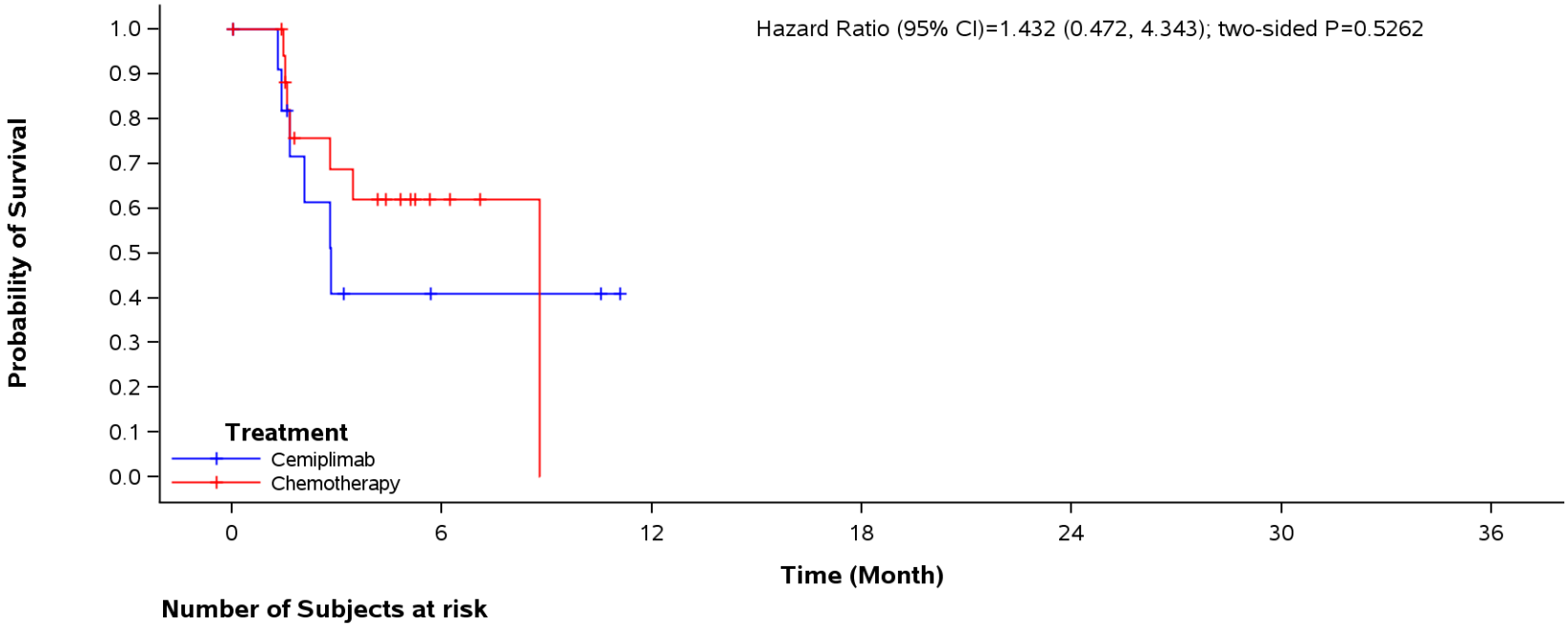

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts improvement



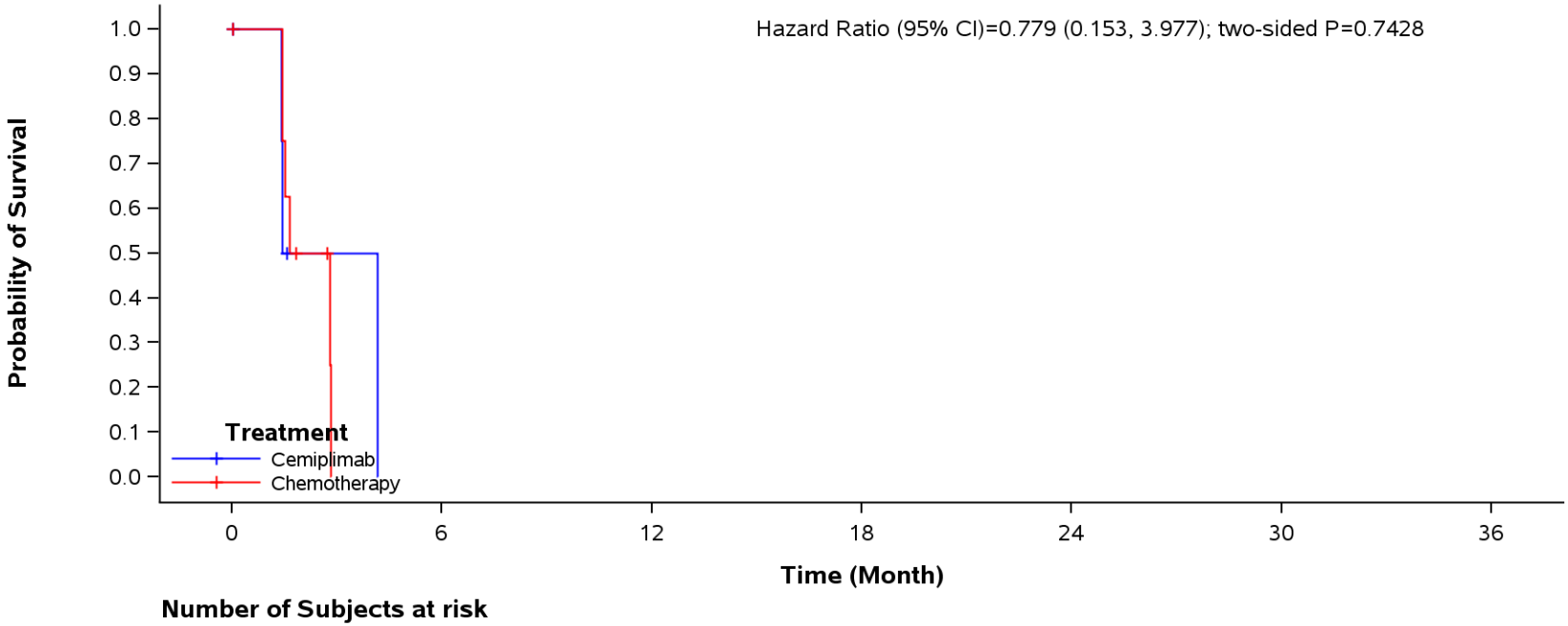

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts improvement



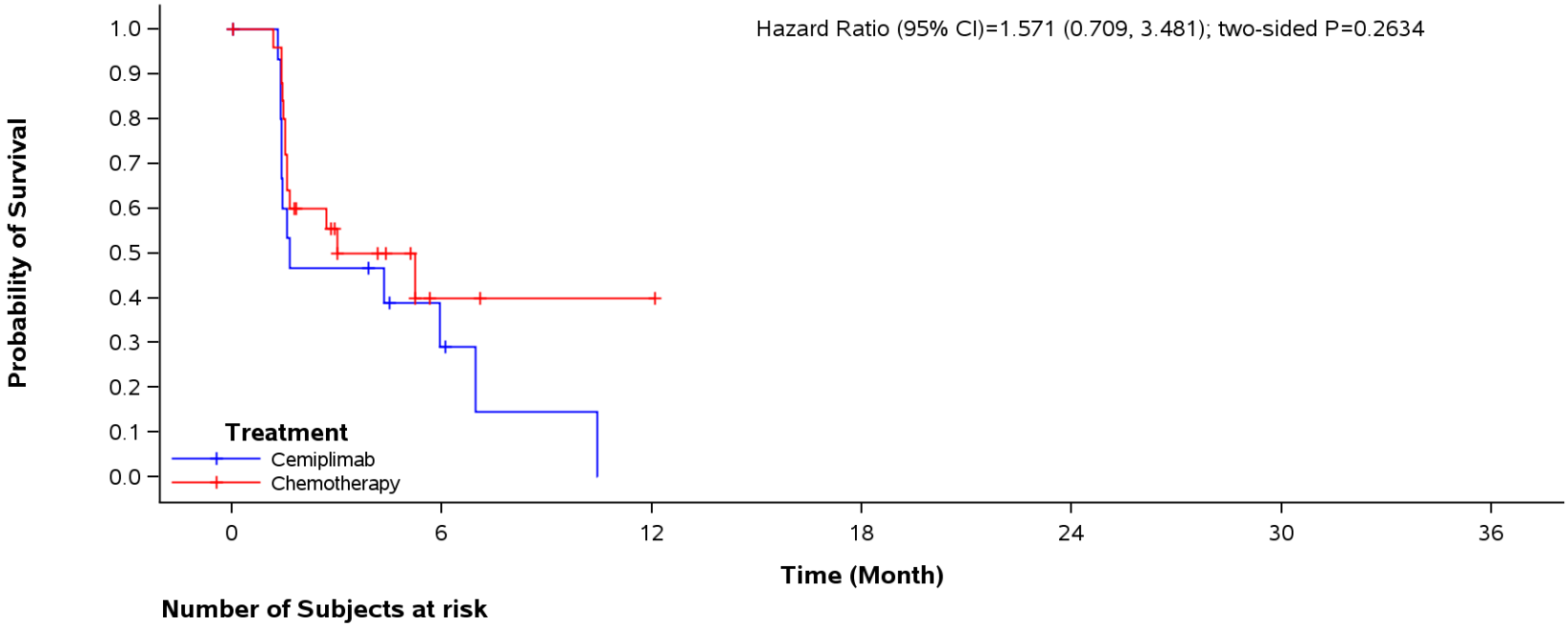

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts improvement



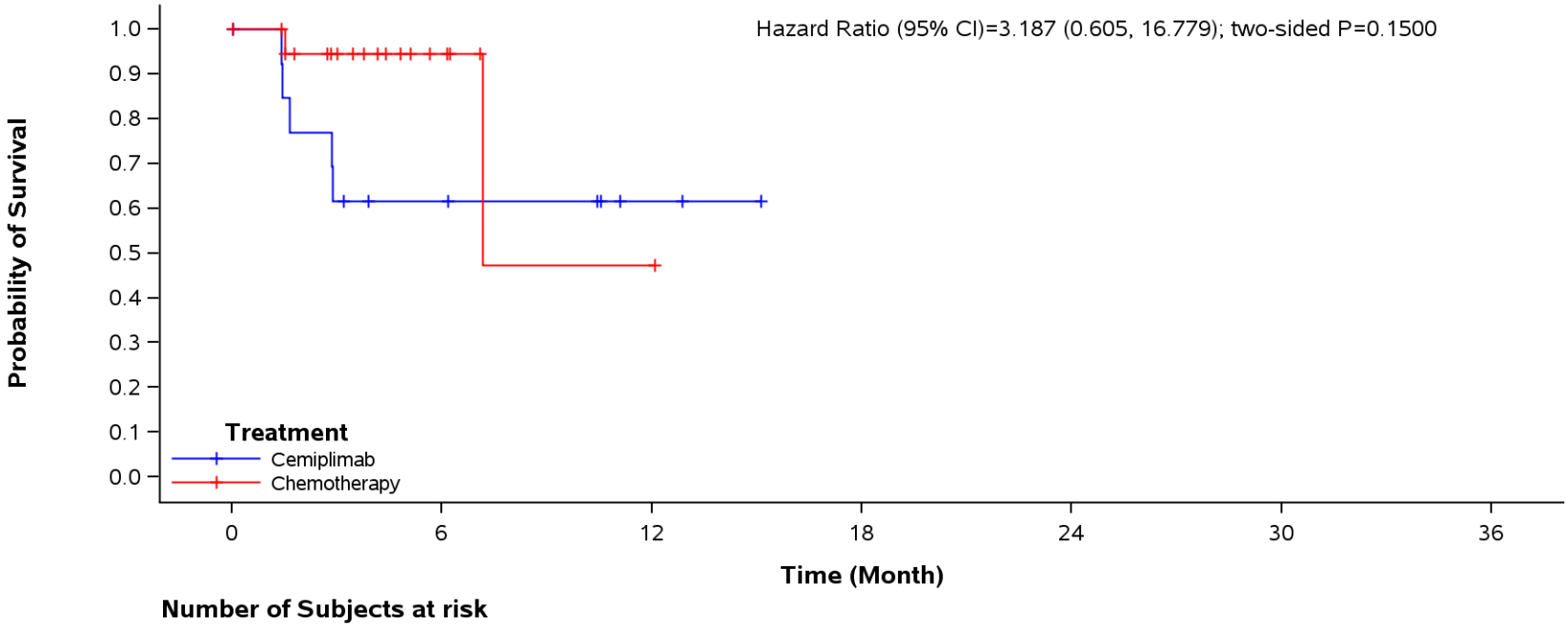

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts improvement



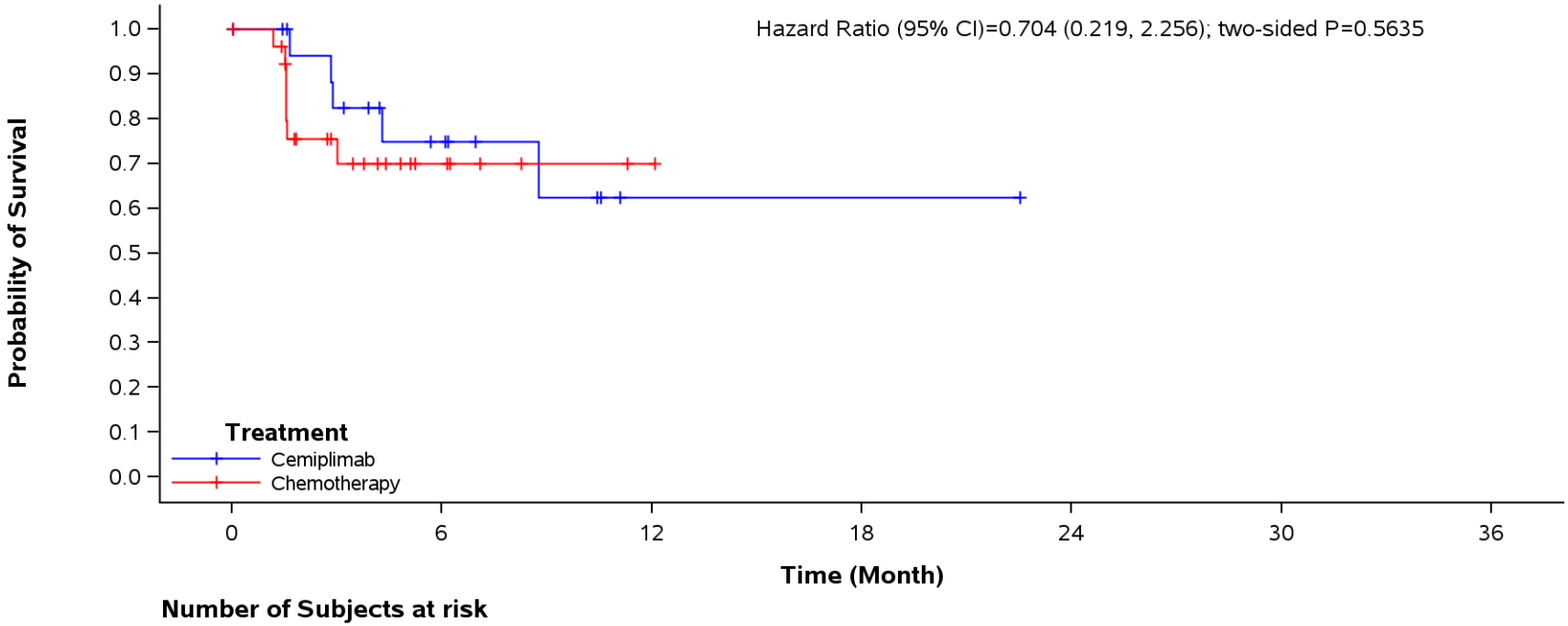

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts improvement



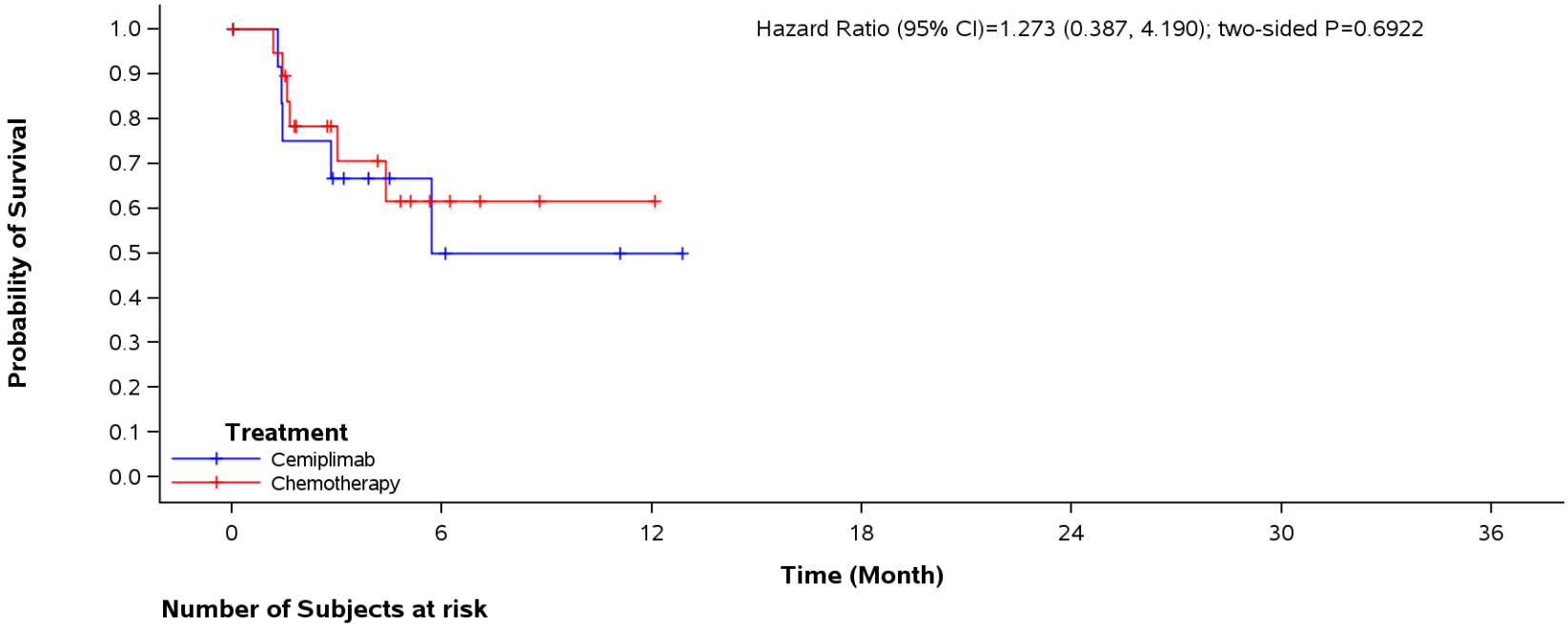

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts improvement



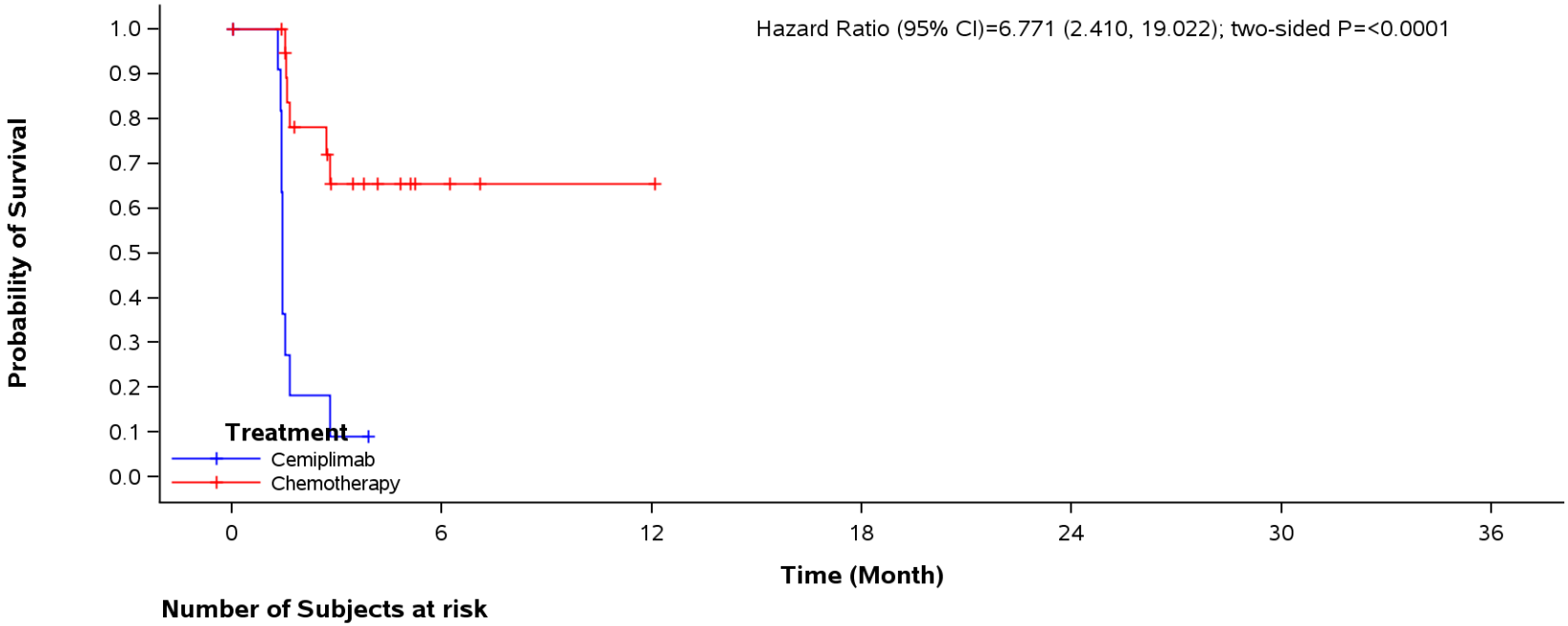

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts improvement



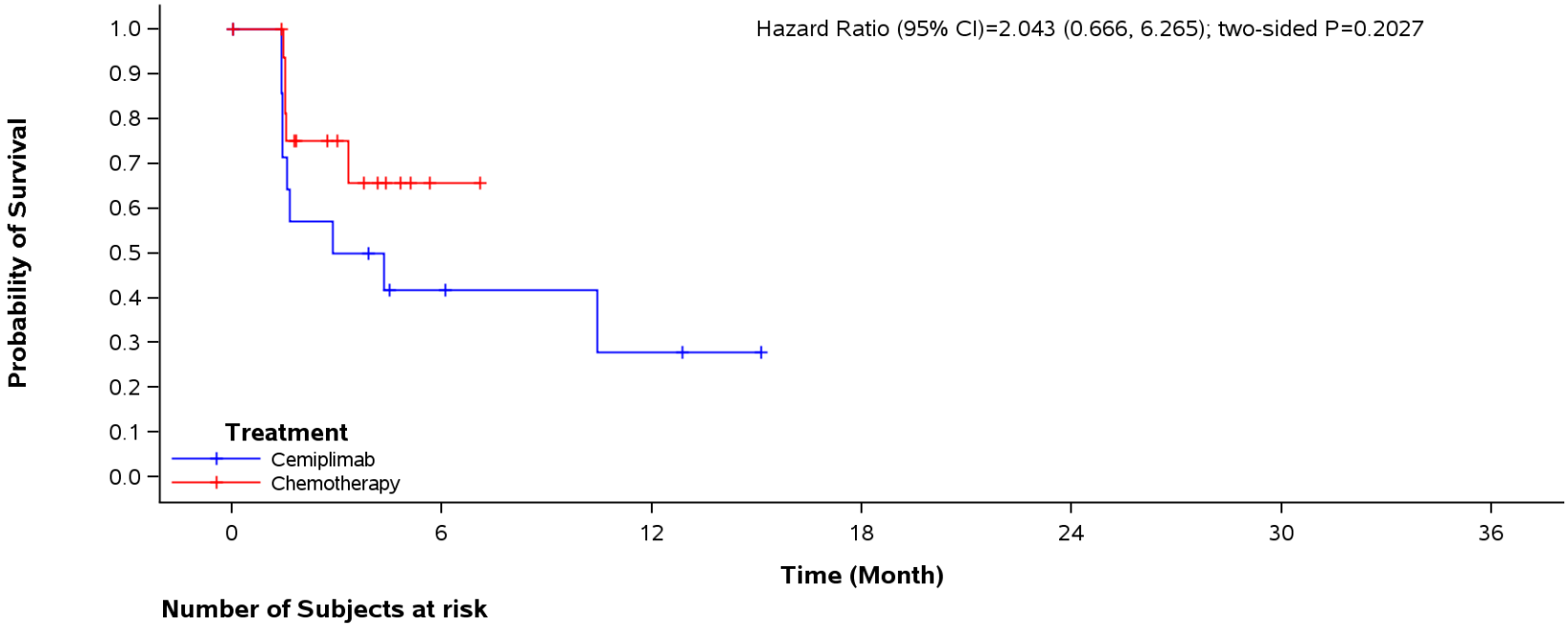

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts improvement



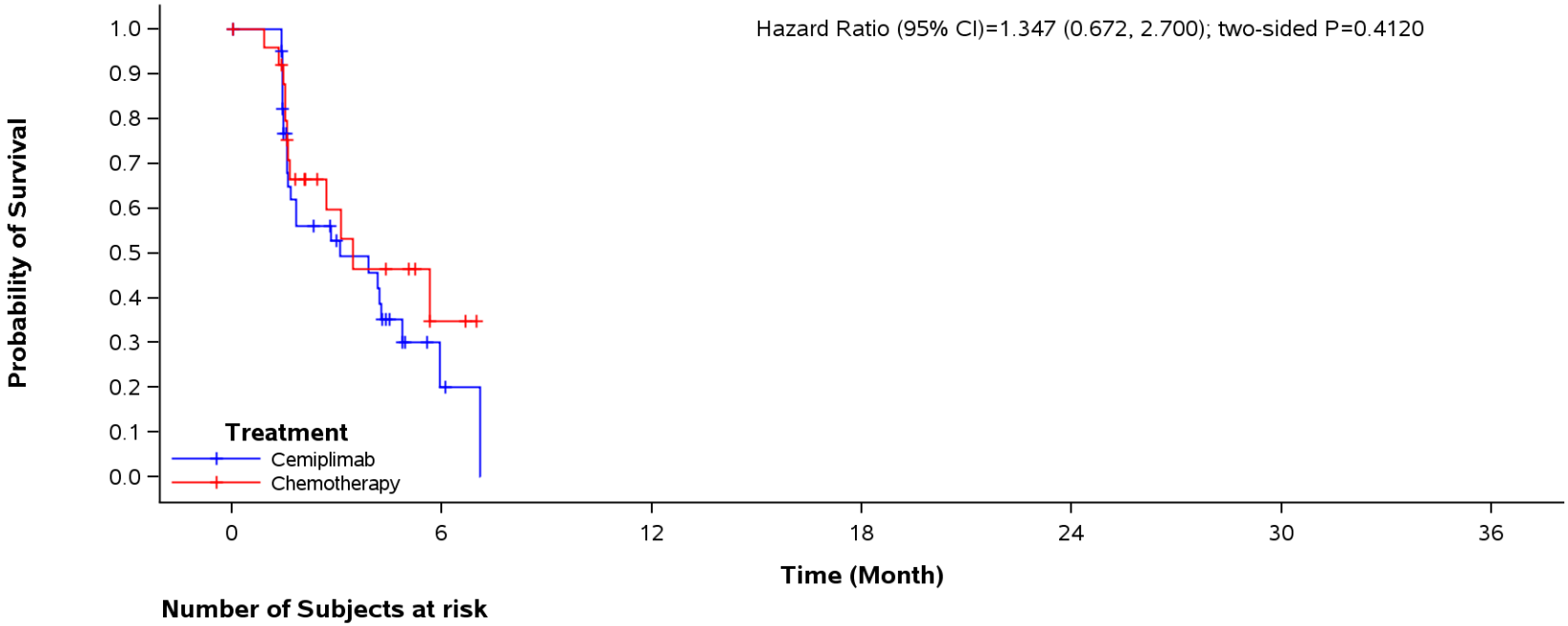

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 4 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts improvement



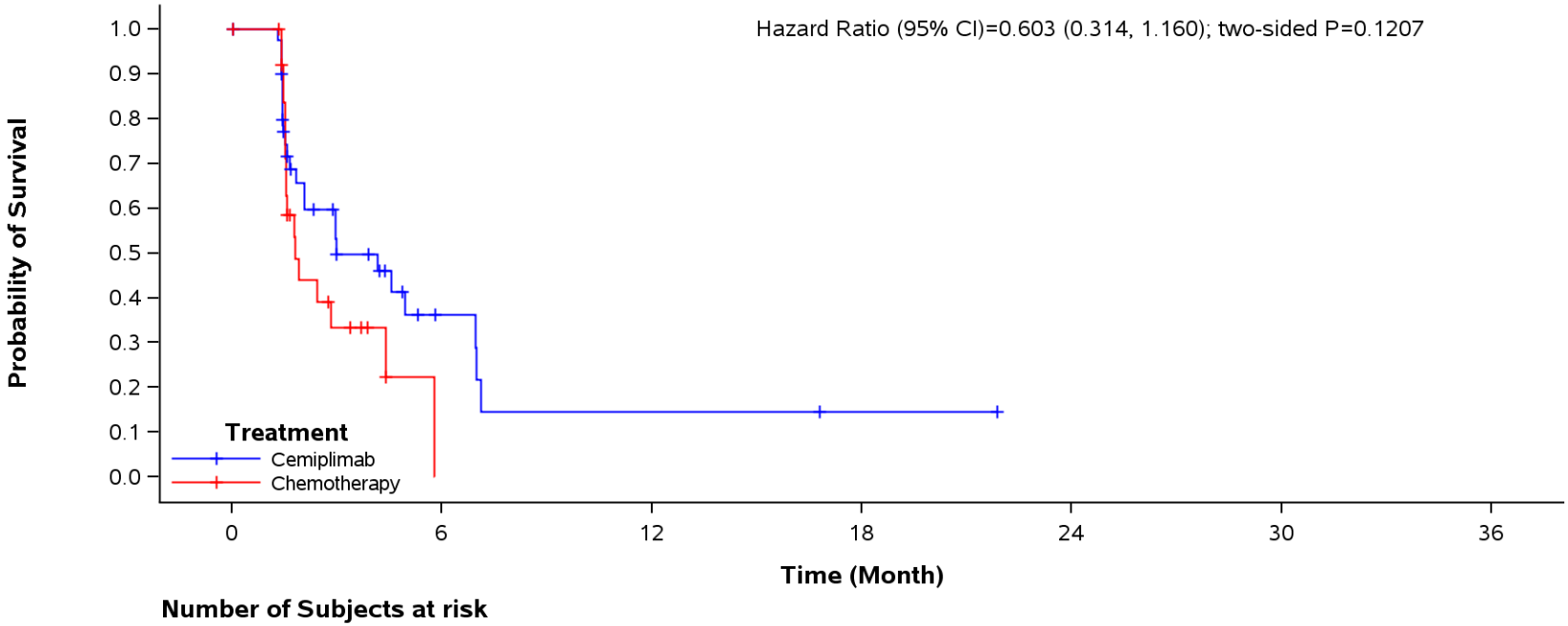

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts improvement



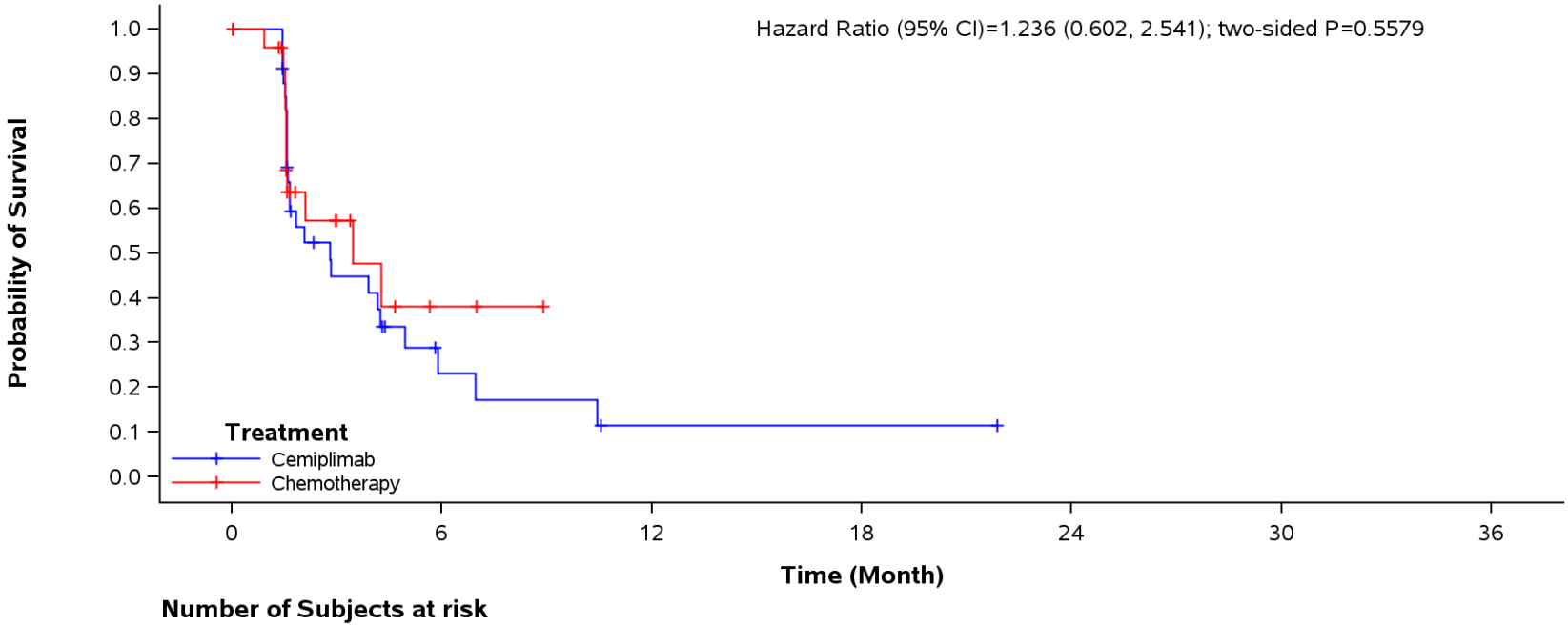

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 5 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts improvement



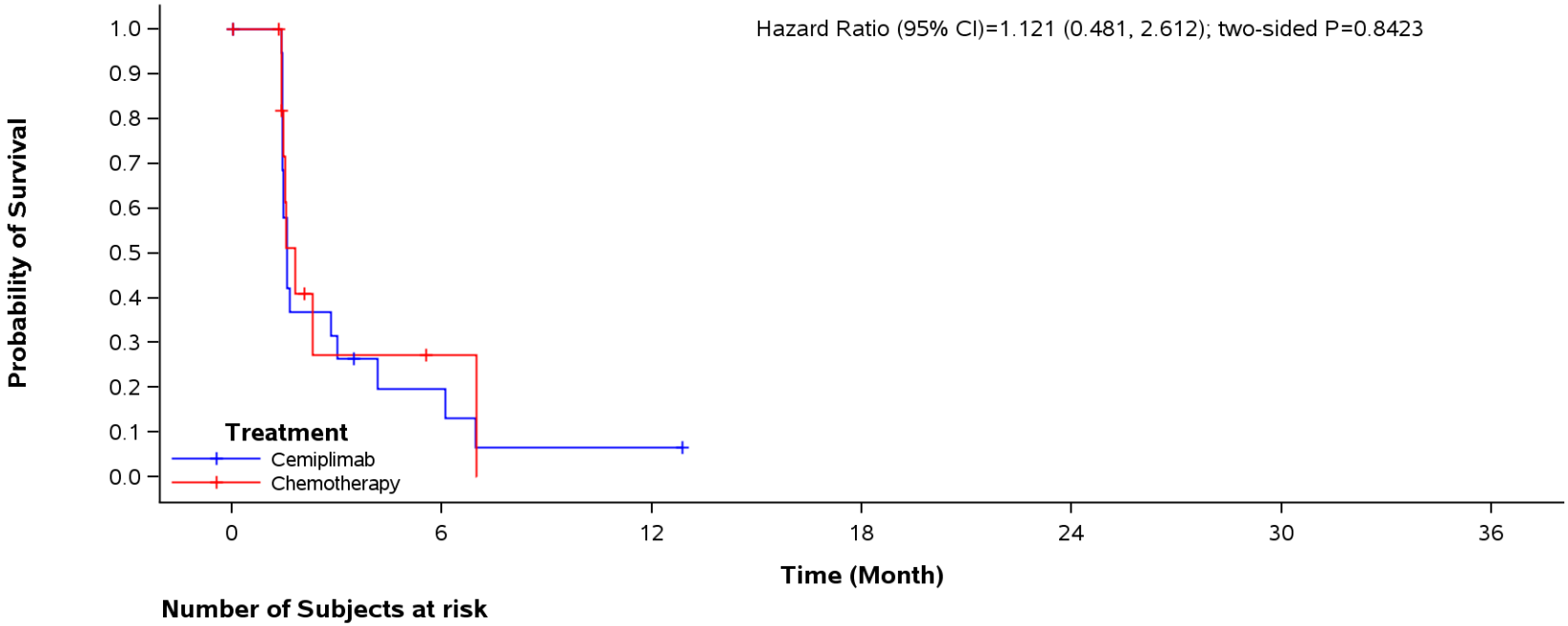

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 4 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts improvement




Number of Subjects at risk

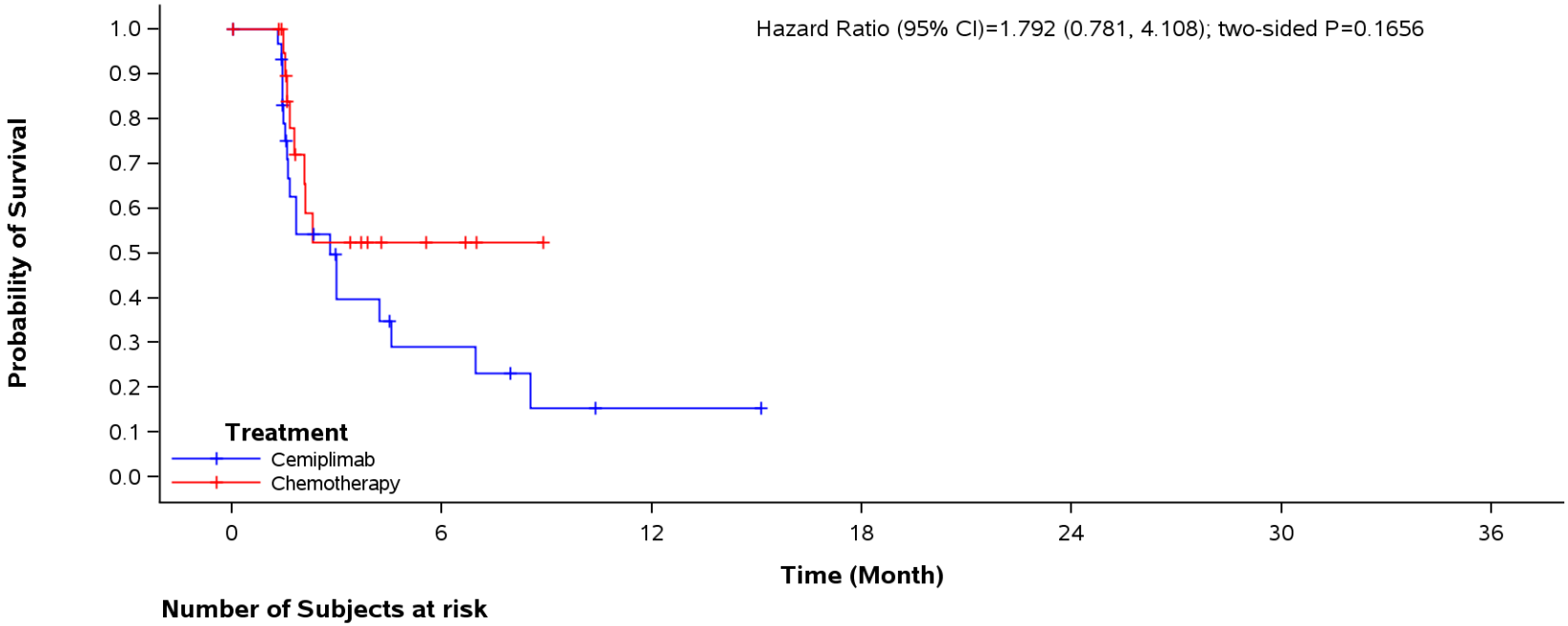
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:15:17, yingyuan.lin)

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts improvement



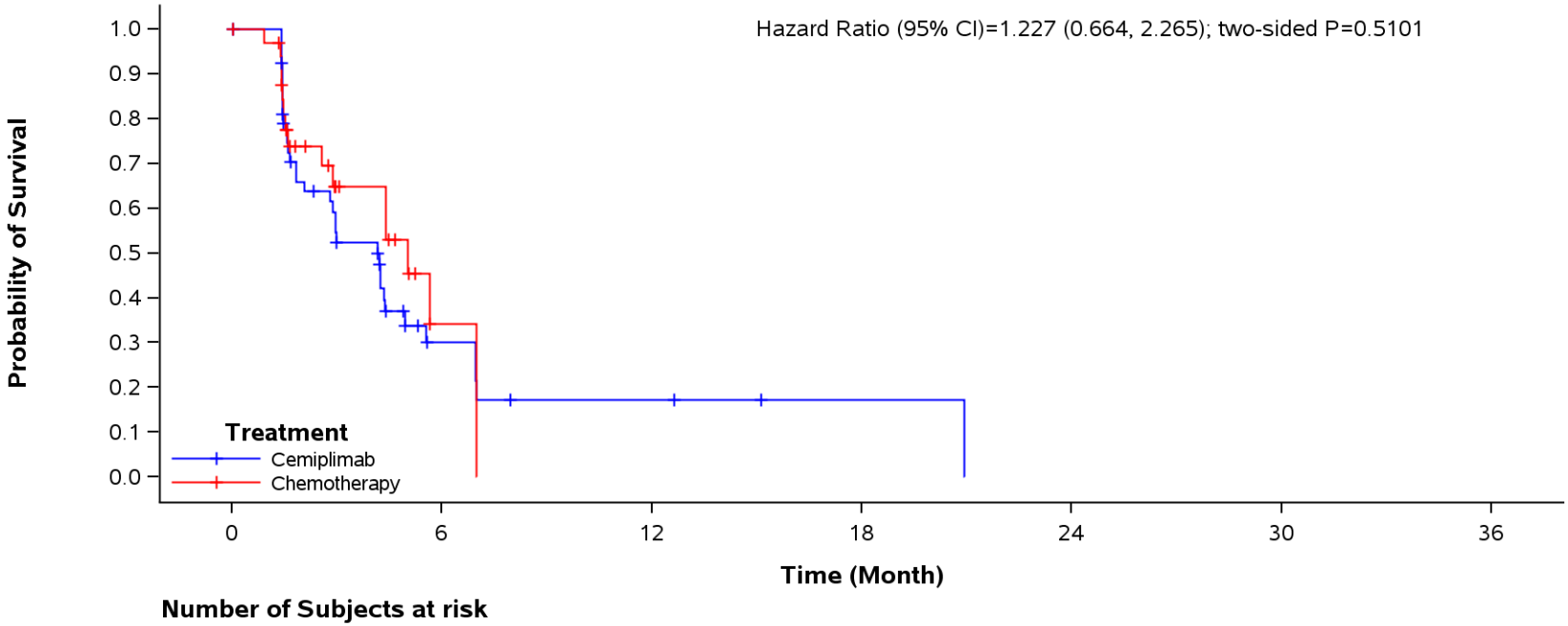

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Emotional Functioning - 10 pts improvement



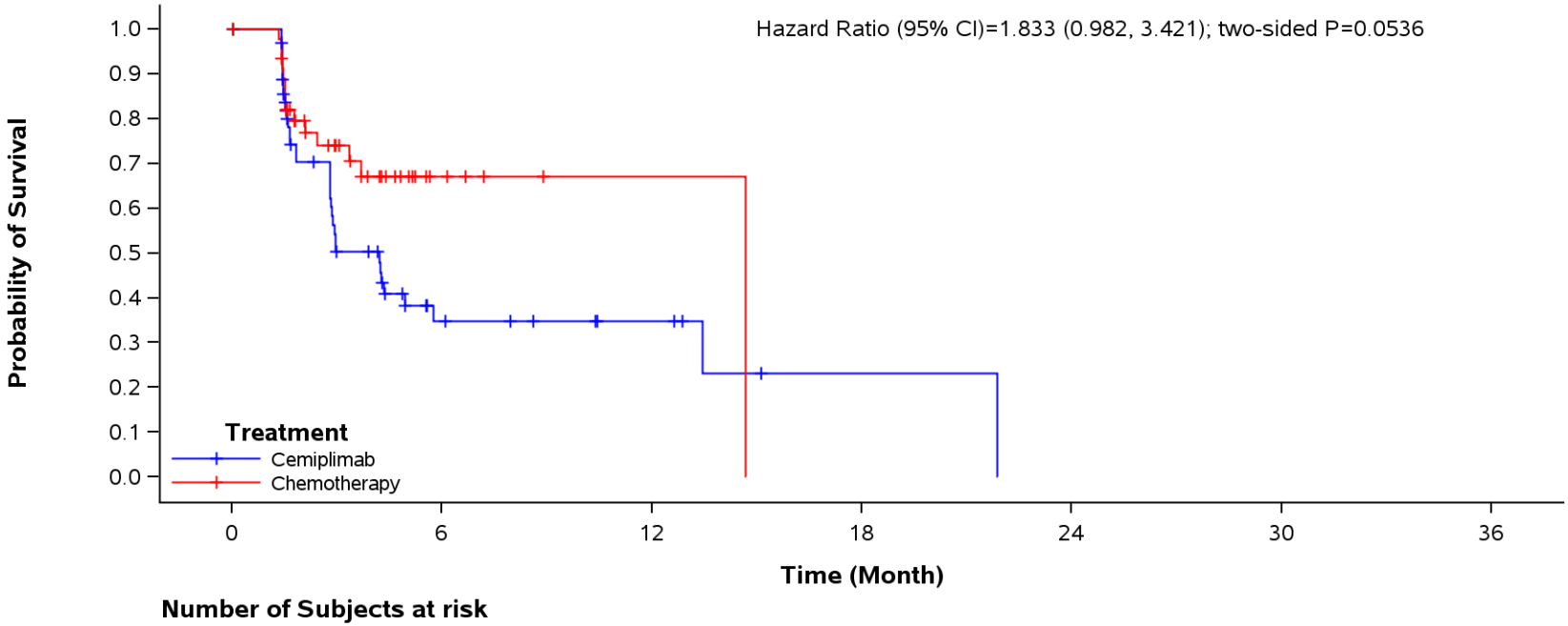

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 7 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts improvement



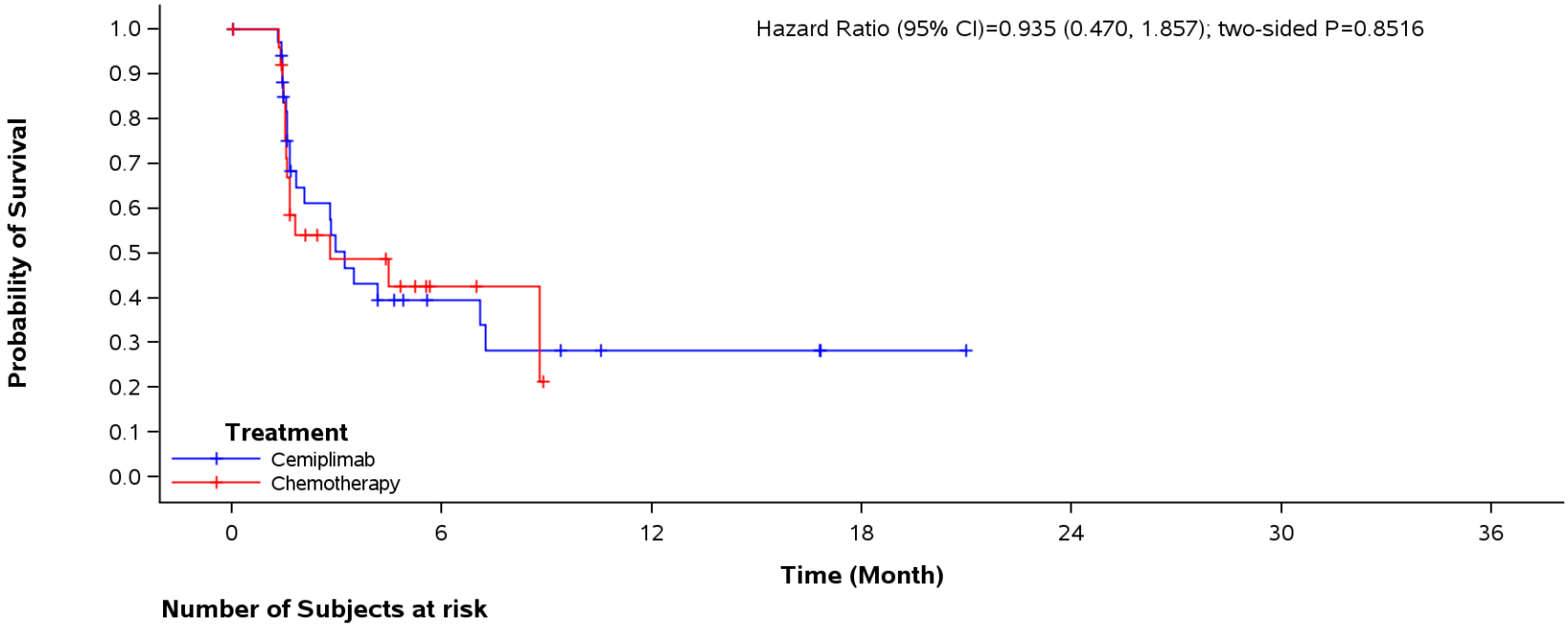

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 10 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts improvement



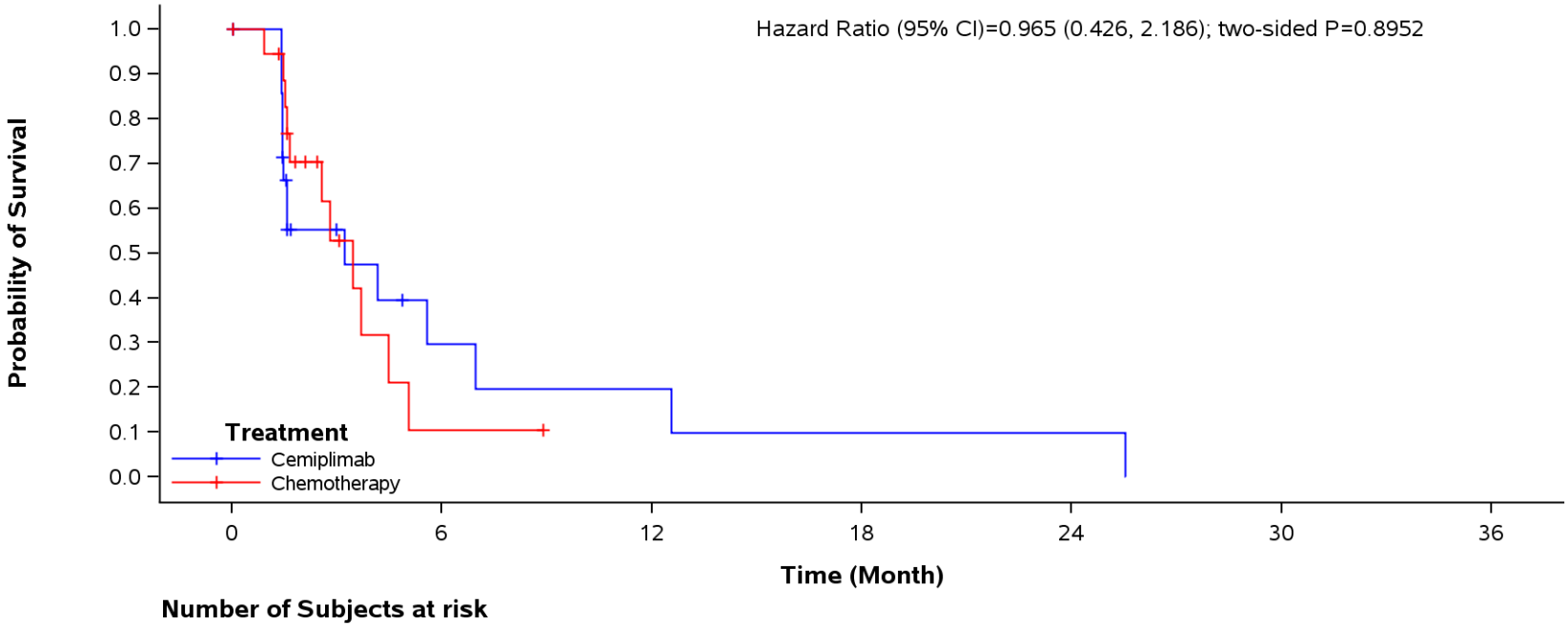

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 7 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts improvement



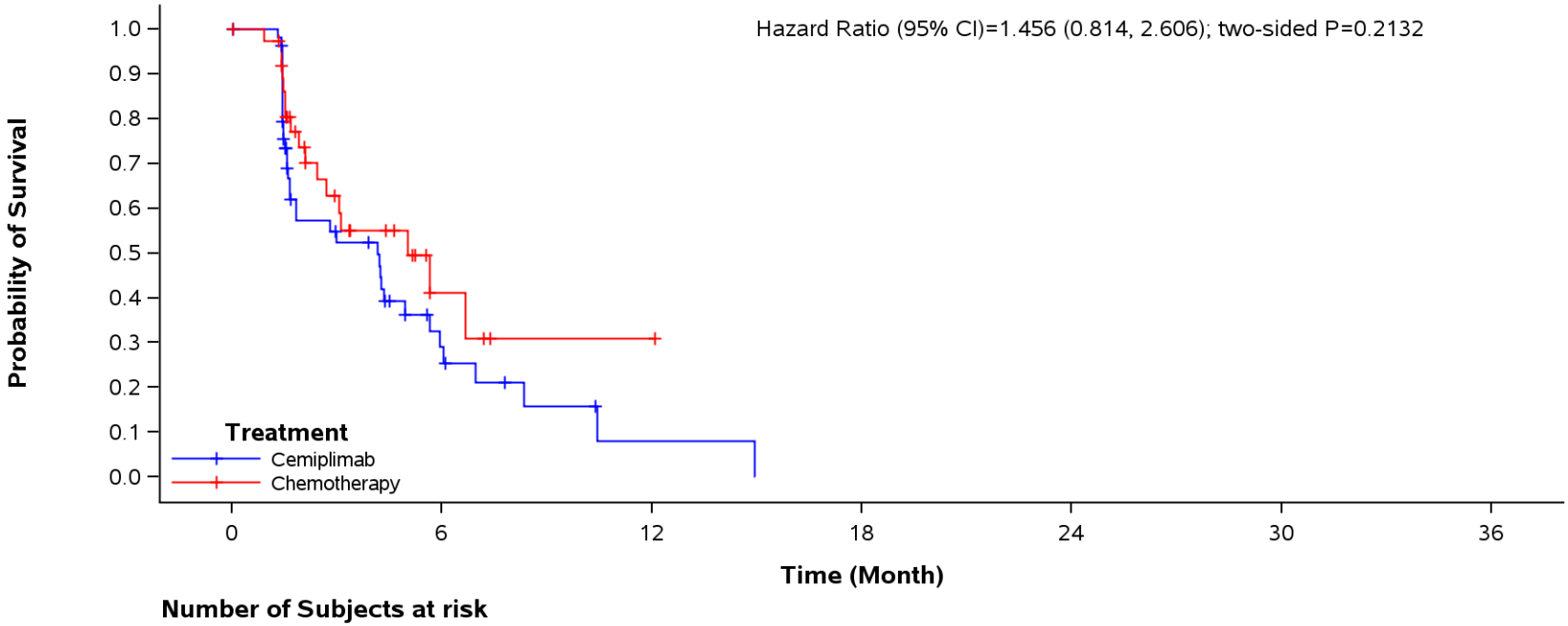

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 85 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts improvement



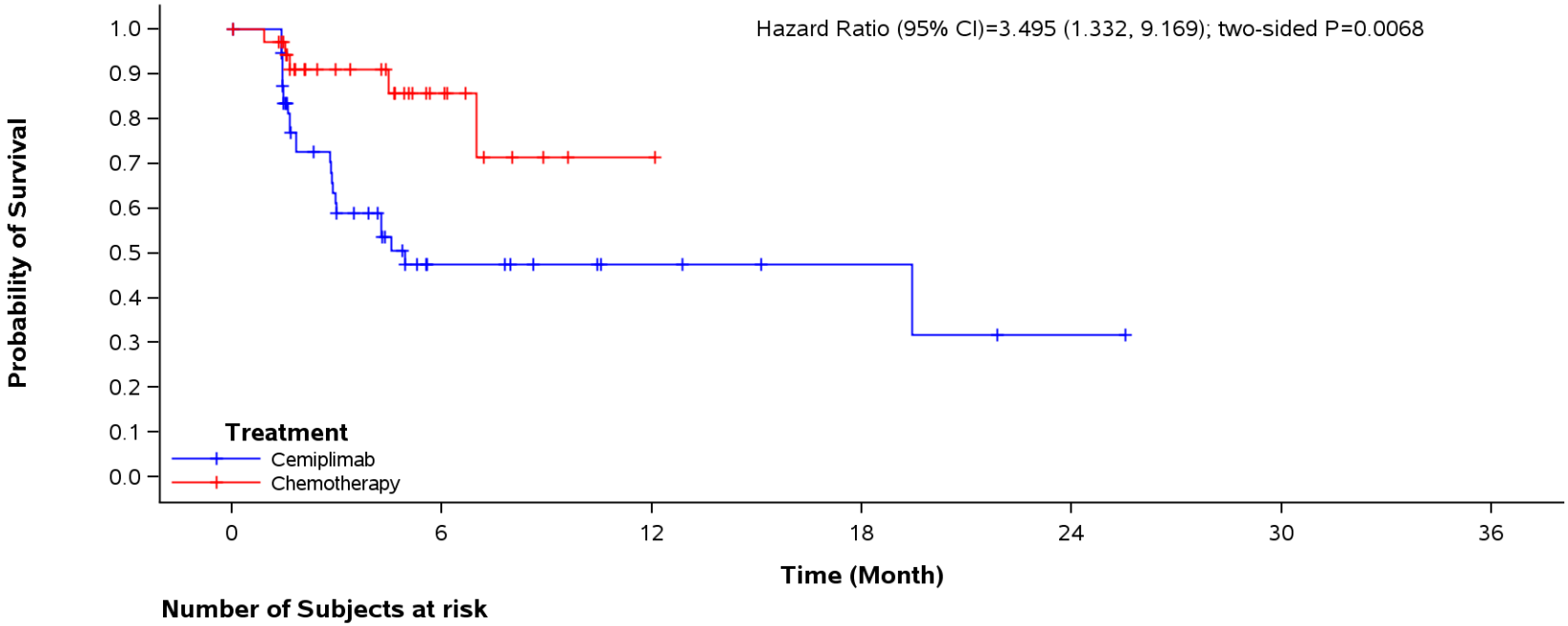

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 8 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Physical Functioning - 10 pts improvement



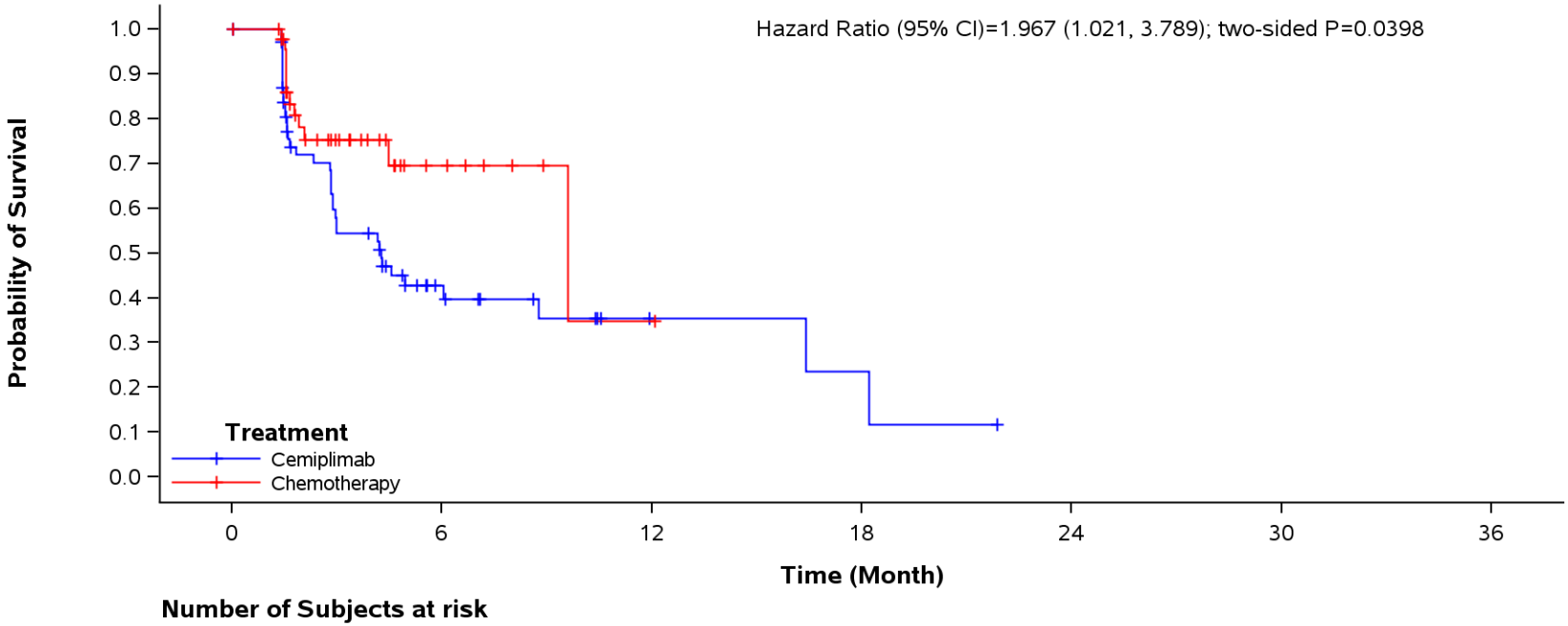

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 10 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 85 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Global health status / QoL - 10 pts improvement



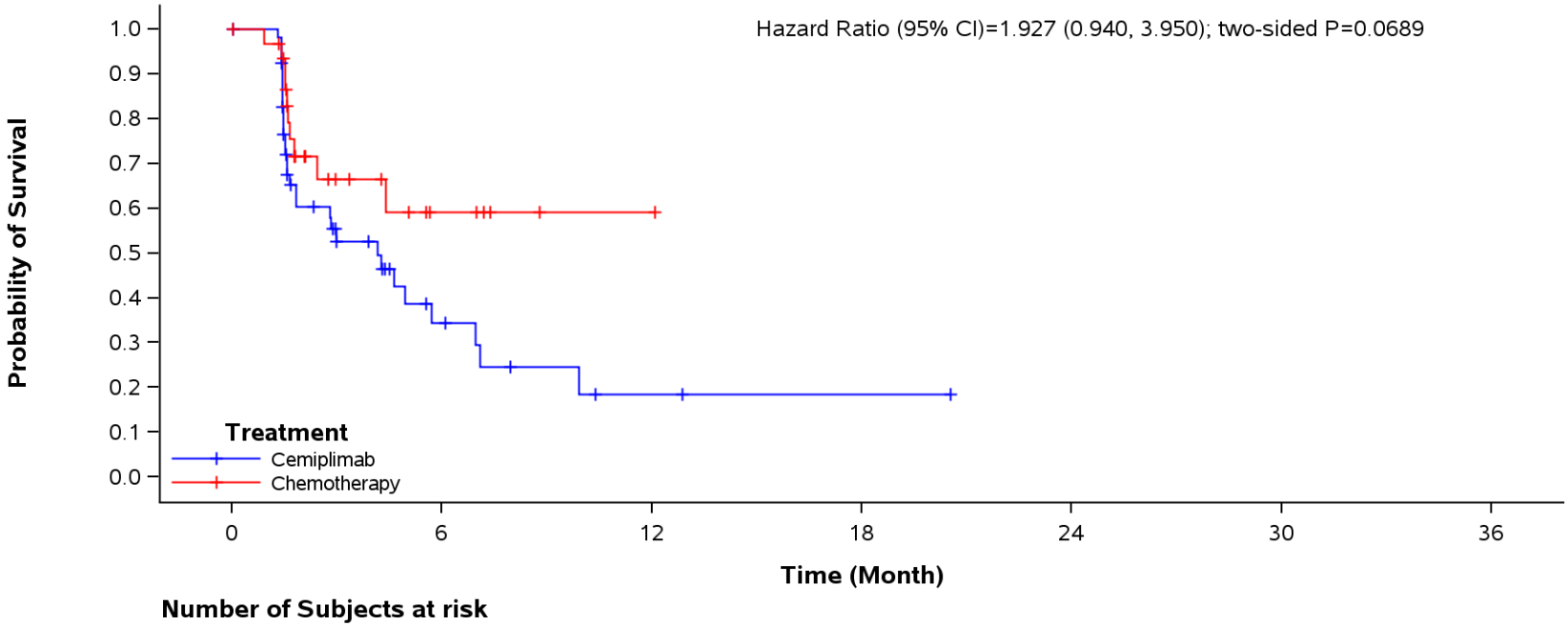

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 14 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 85 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts improvement



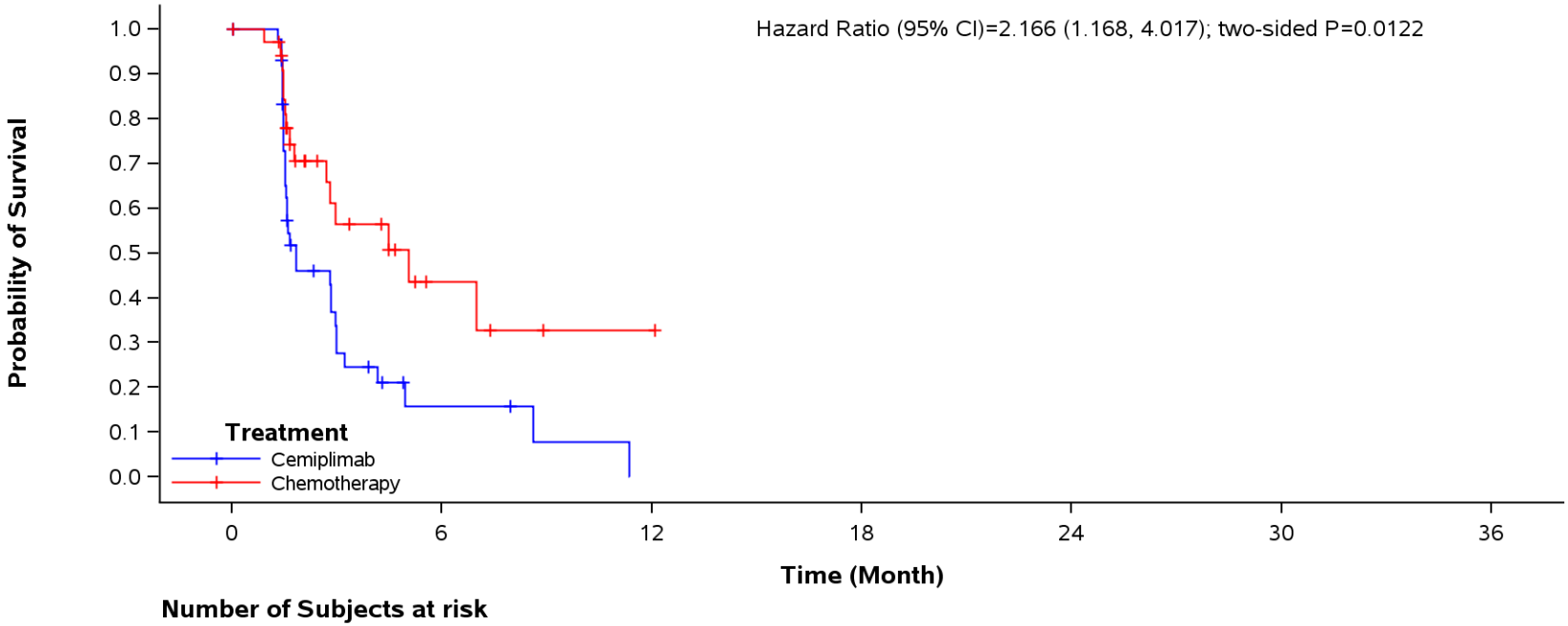

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts improvement



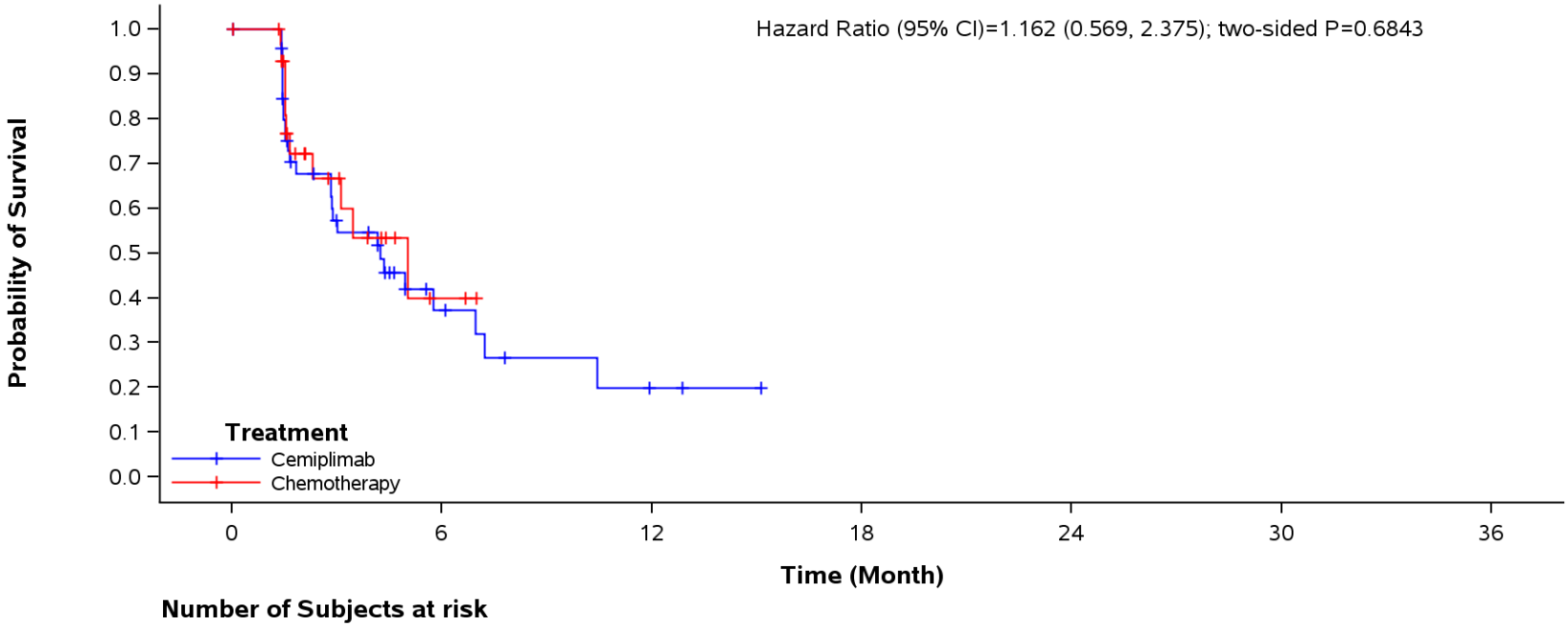

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts improvement



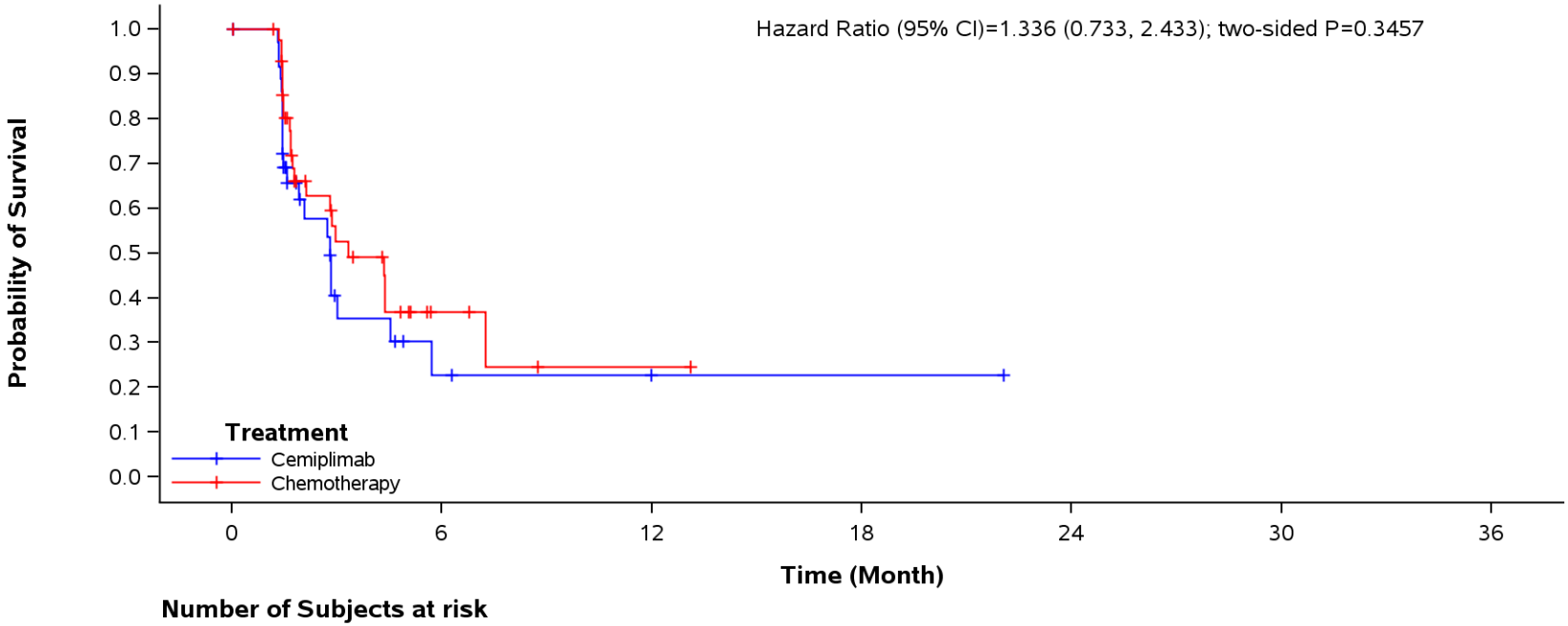

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 8 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts improvement



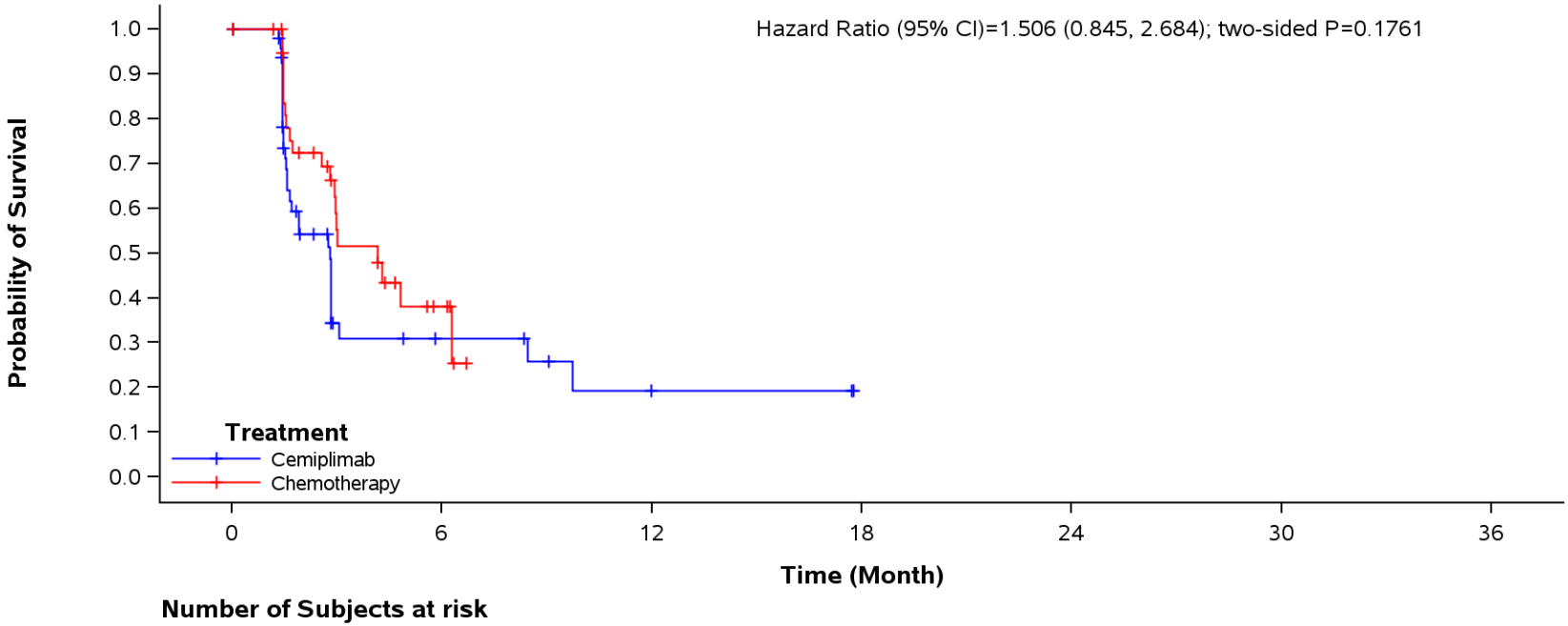

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts improvement



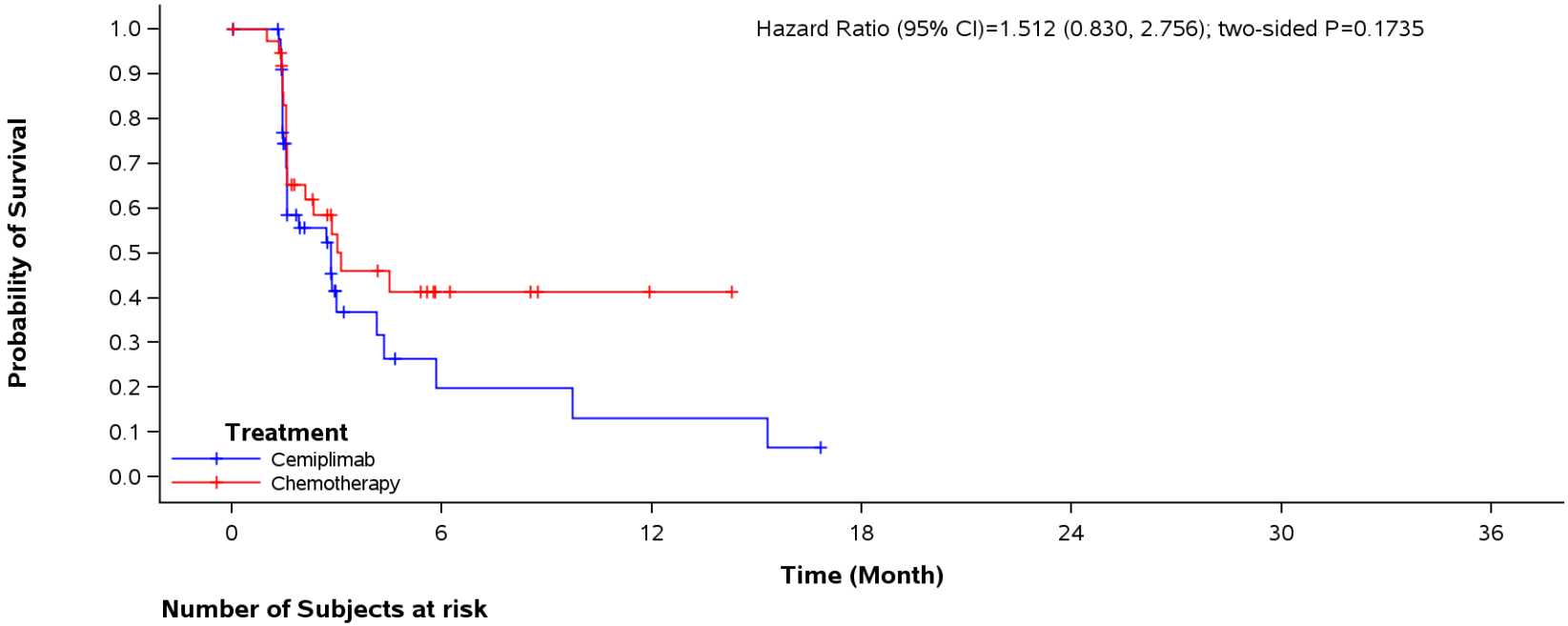

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 7 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 98 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts improvement



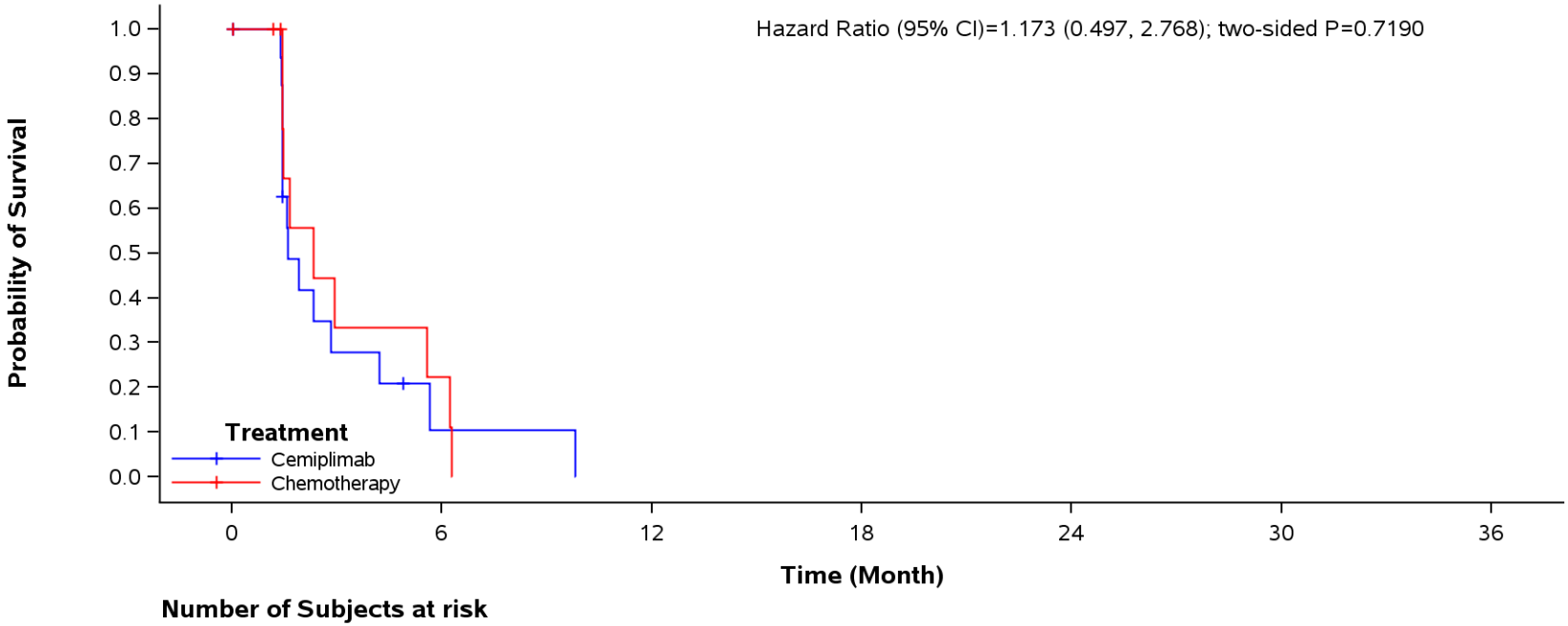

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 98 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts improvement



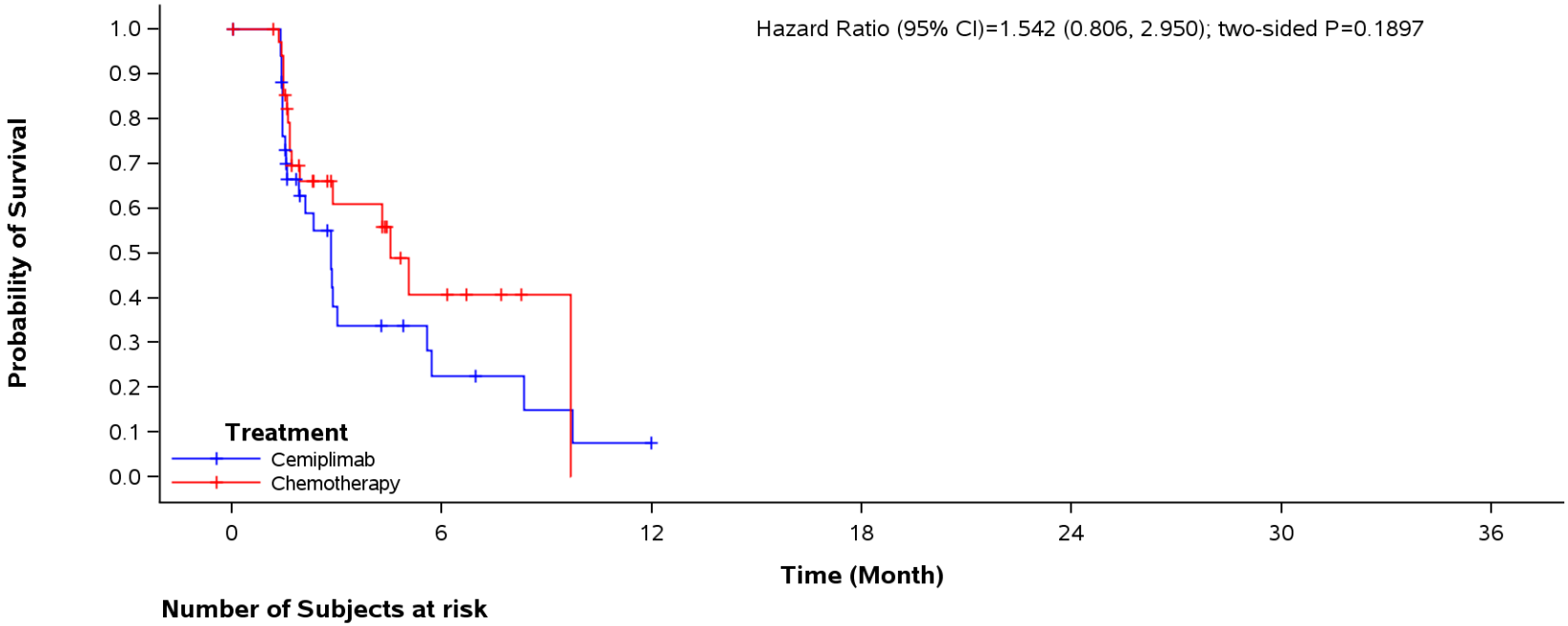

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 98 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Dyspnoea - 10 pts improvement



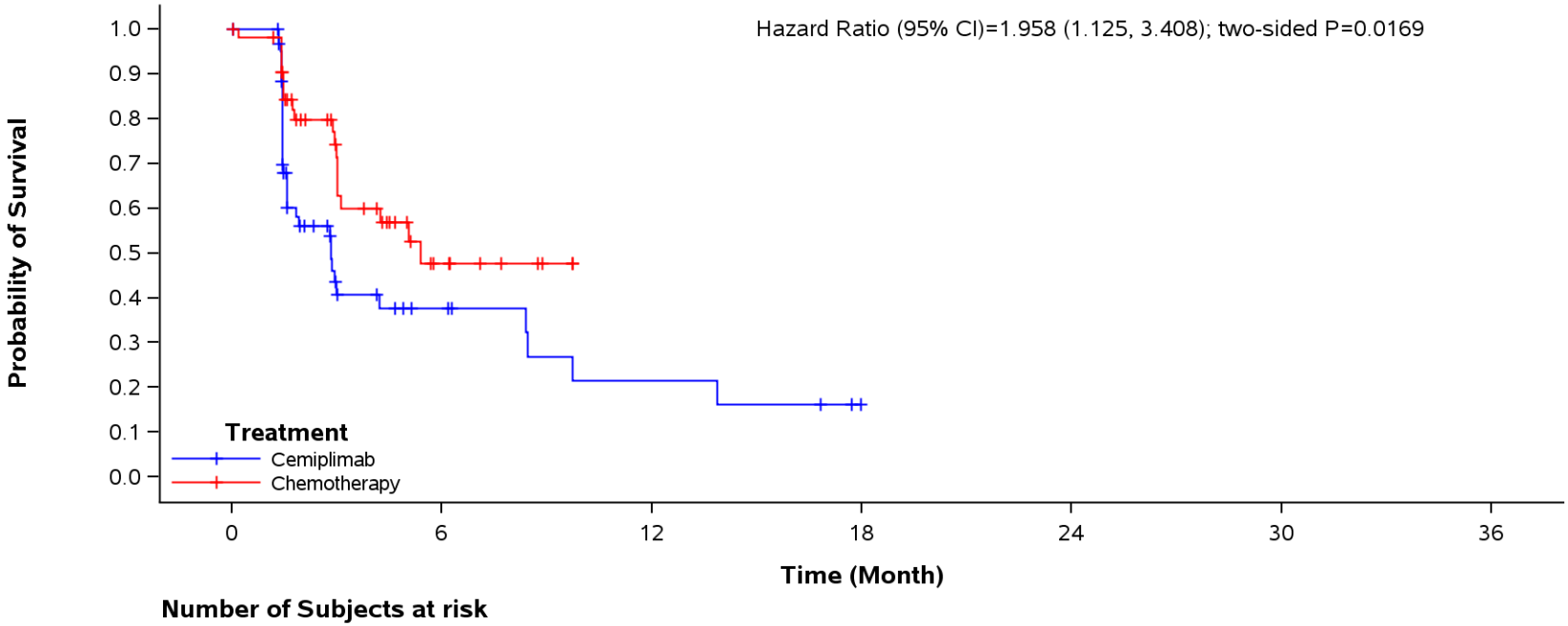

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 98 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Emotional Functioning - 10 pts improvement



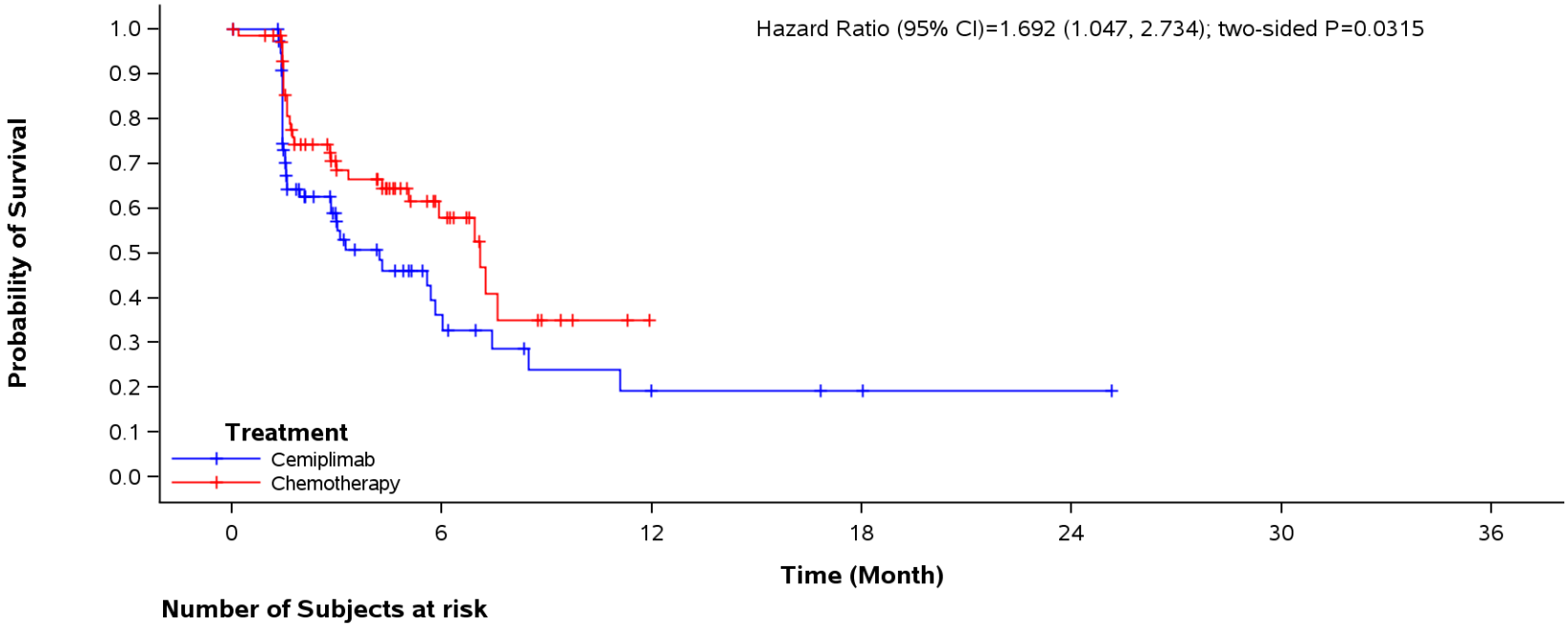

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 9 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 98 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts improvement



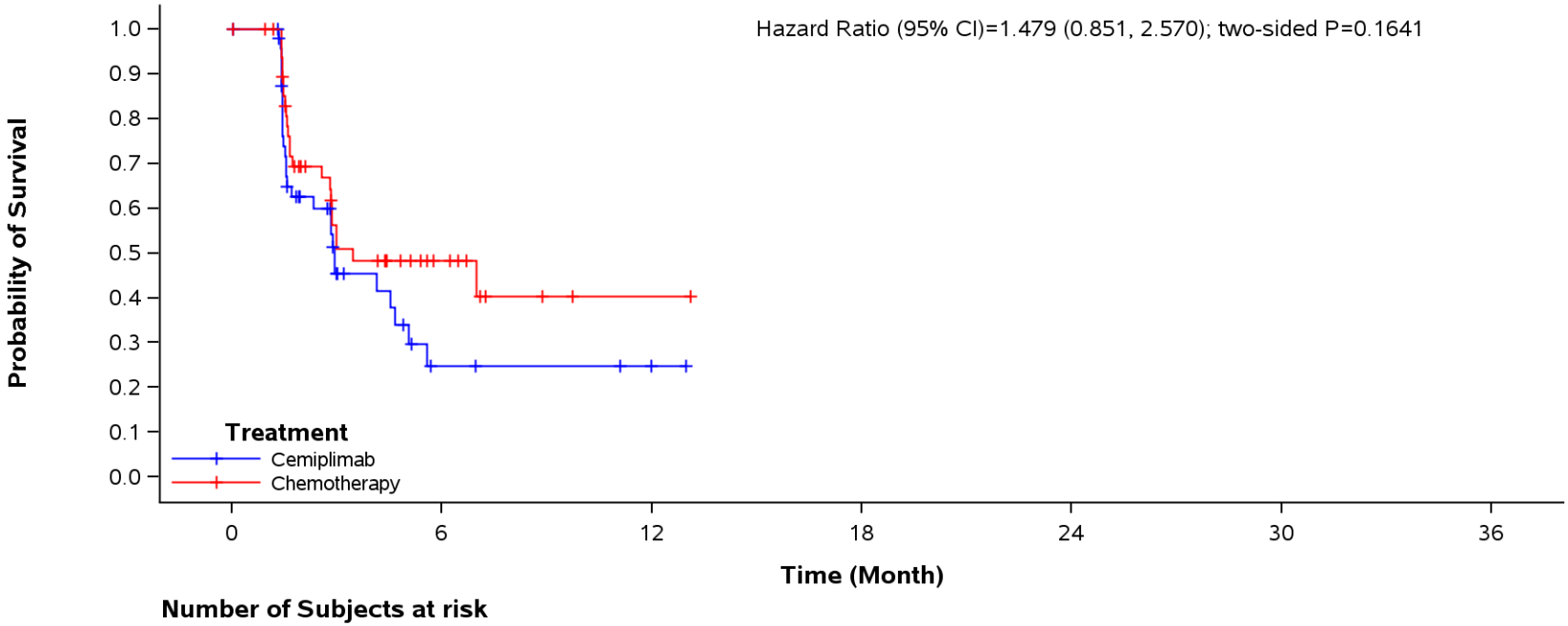

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 11 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 98 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts improvement



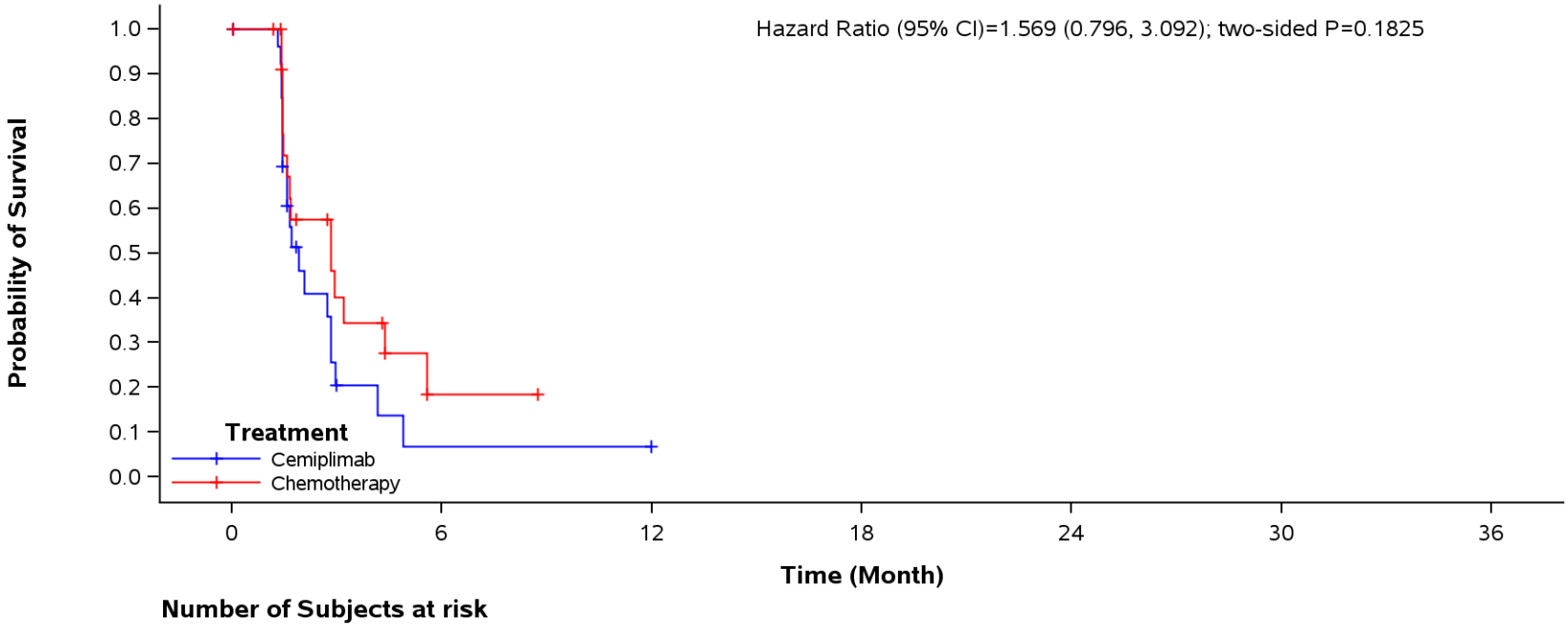

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 98 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts improvement



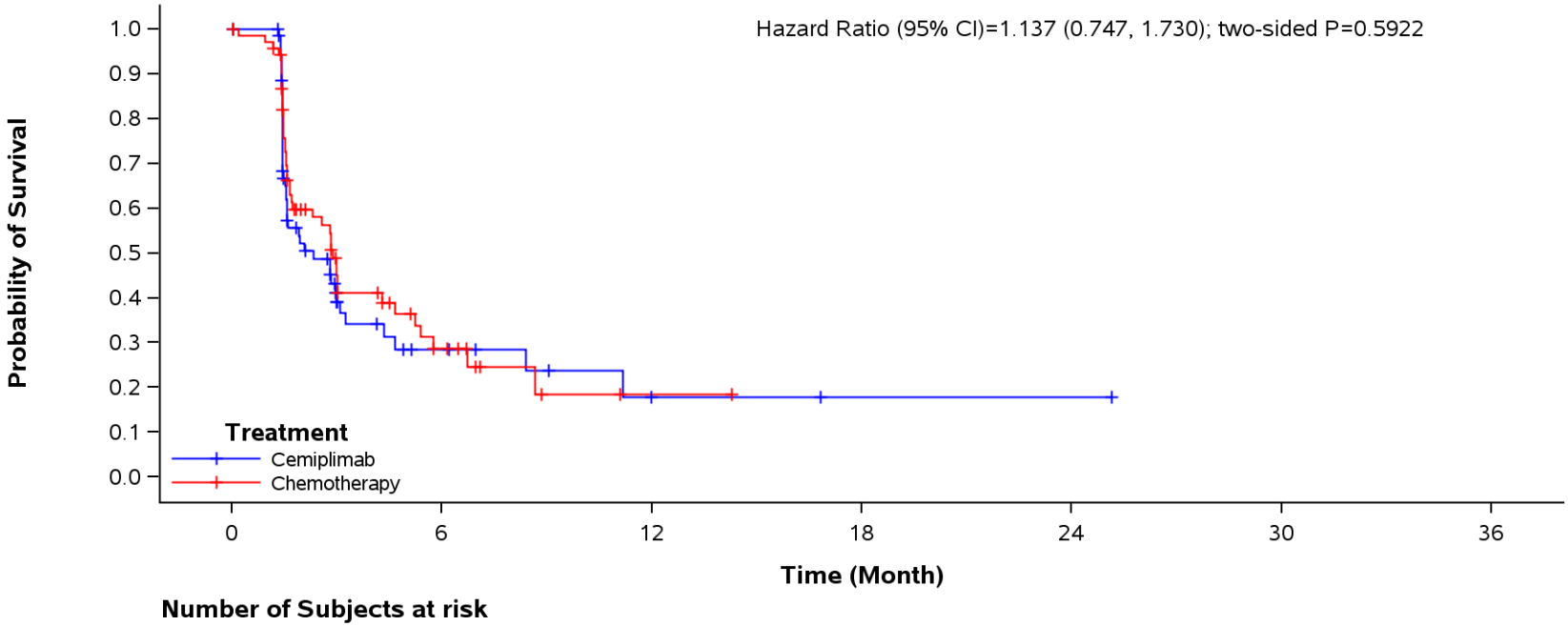

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 98 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts improvement



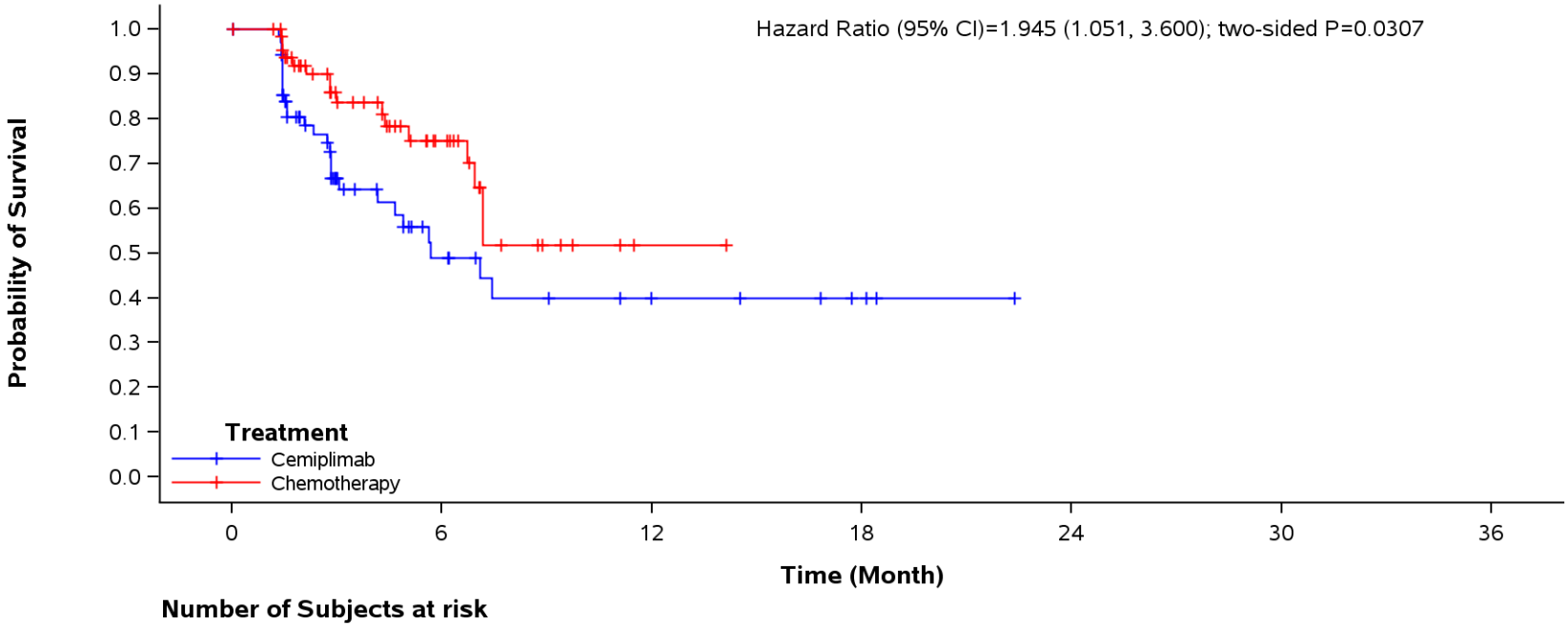

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 8 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 98 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Physical Functioning - 10 pts improvement



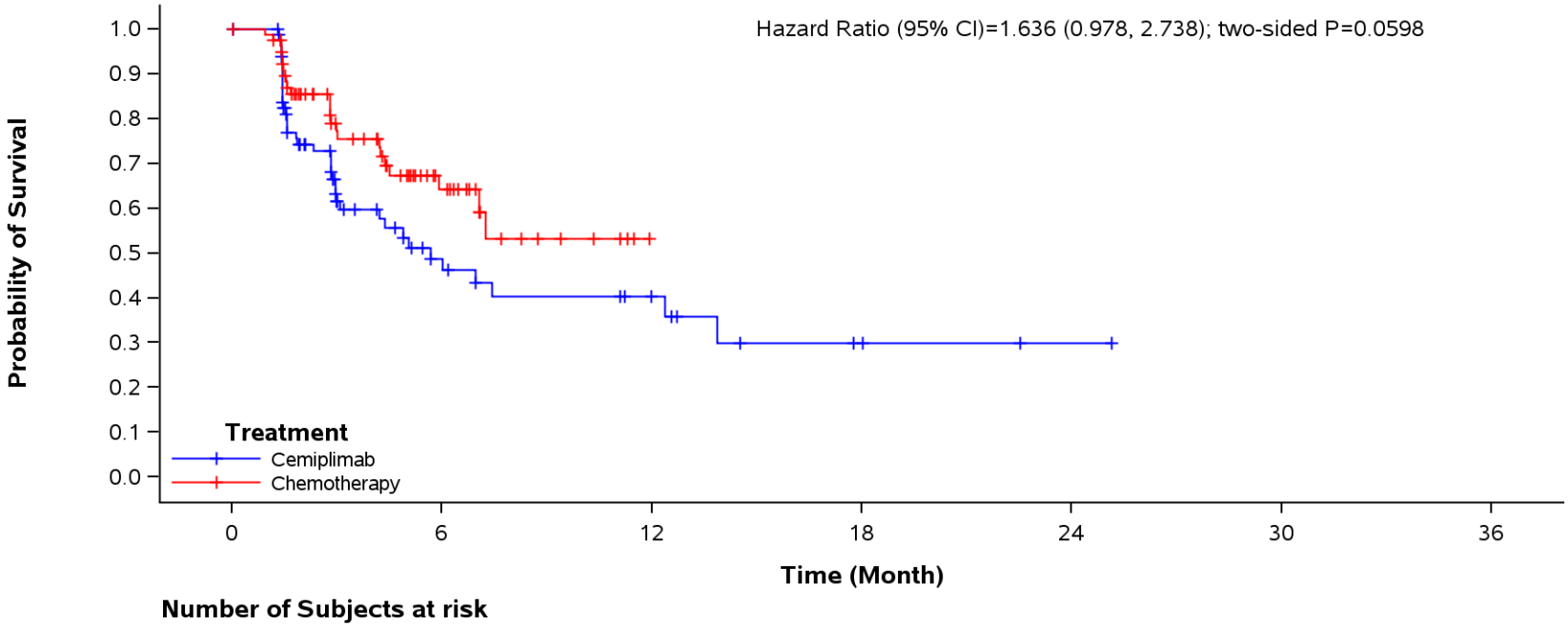

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 14 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 98 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Global health status / QoL - 10 pts improvement



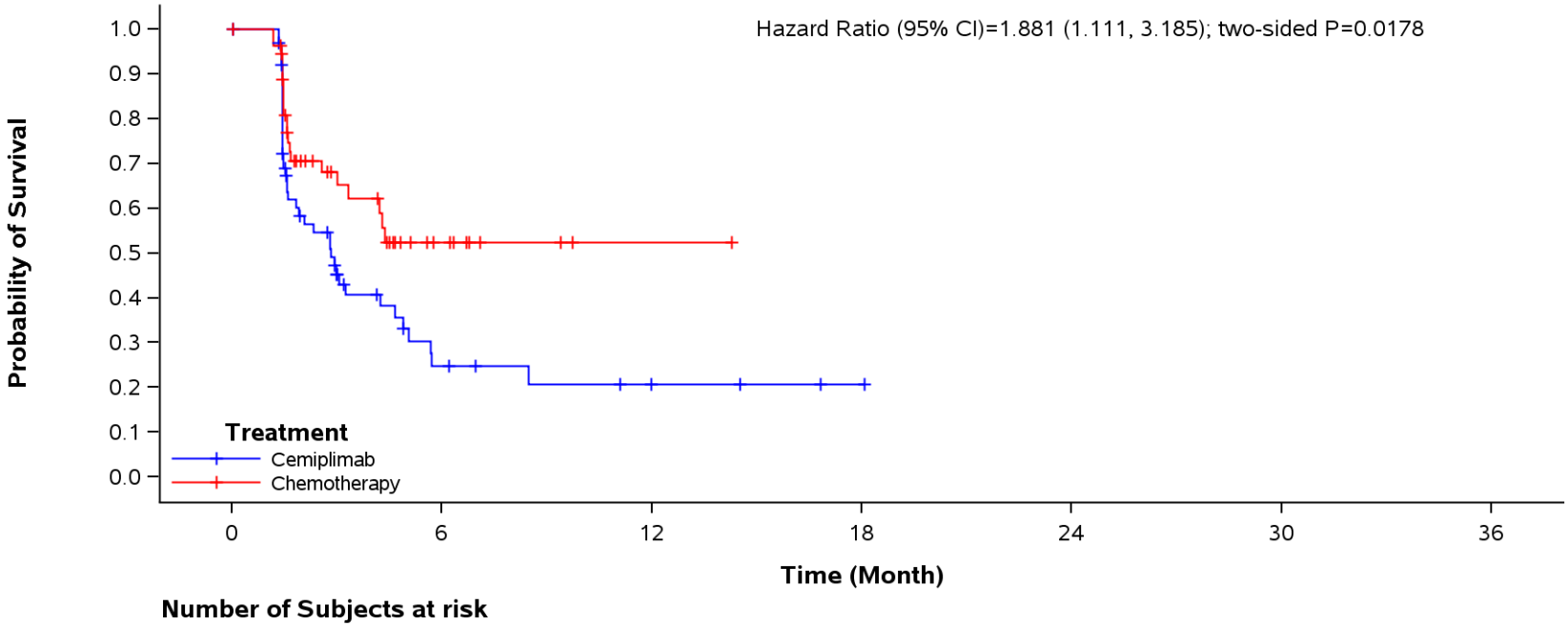

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 19 | 9 | 3 | 1 | 0 | 0 |
| Chemotherapy | 98 | 20 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts improvement



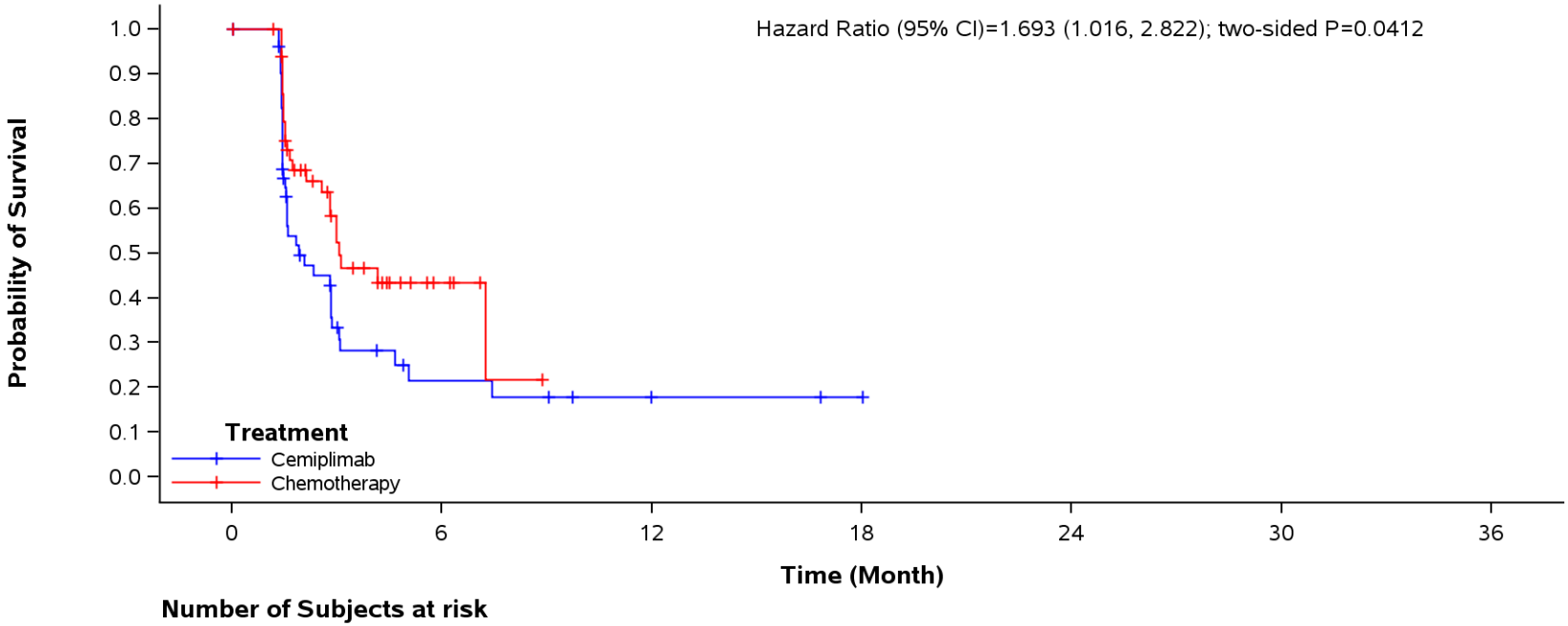

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 9 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts improvement




Number of Subjects at risk

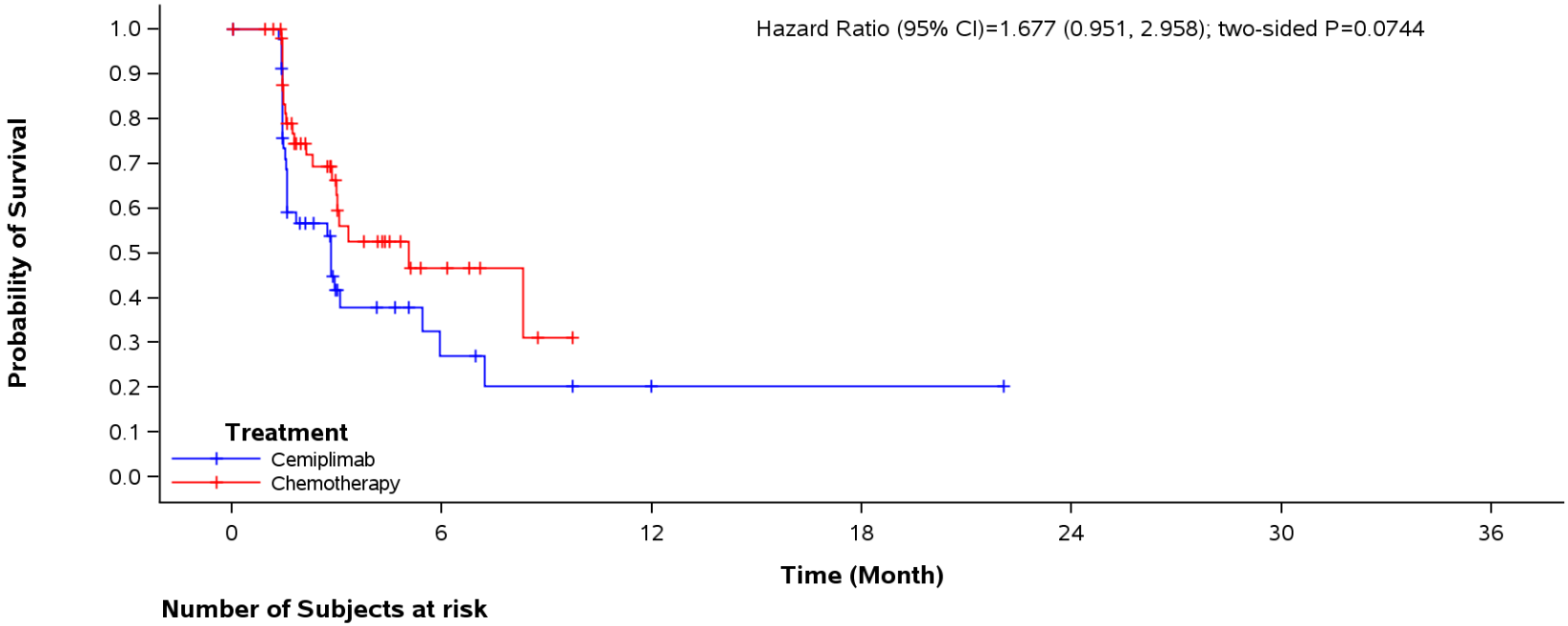
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:15:17, yingyuan.lin)

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts improvement



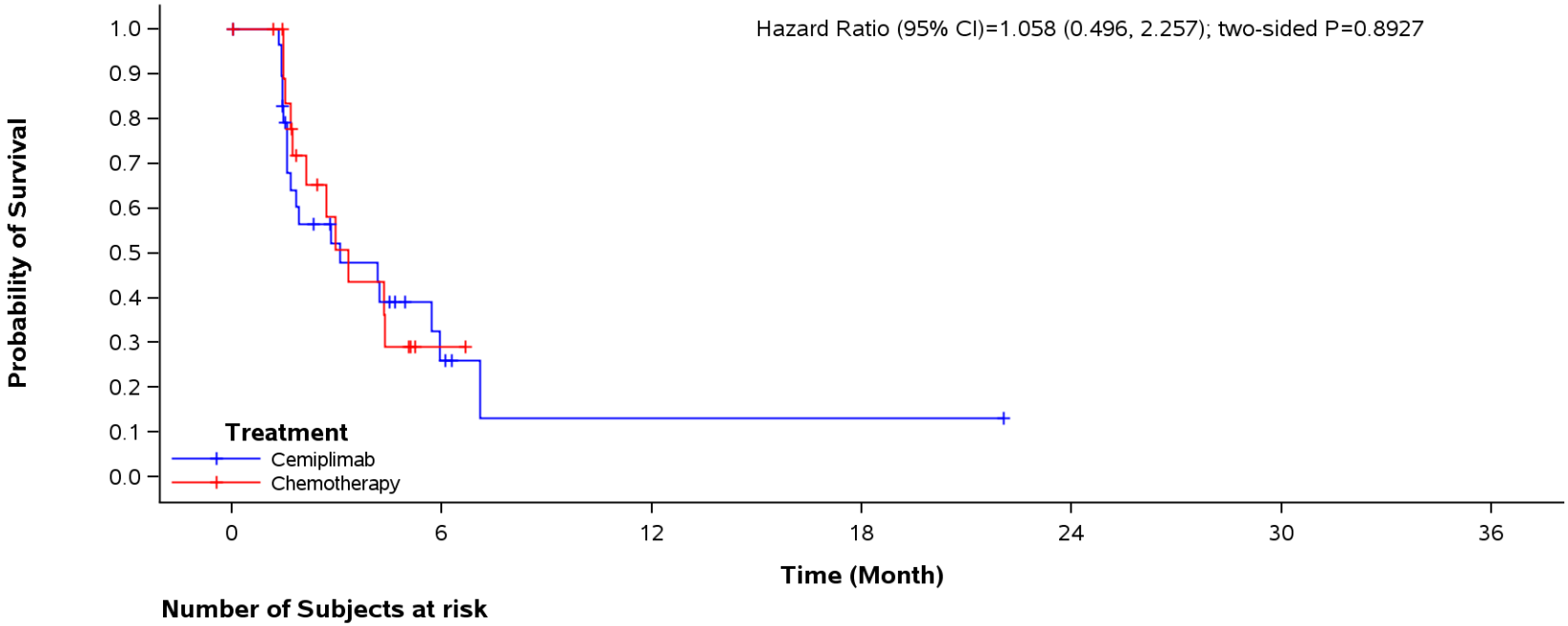

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Appetite loss - 10 pts improvement



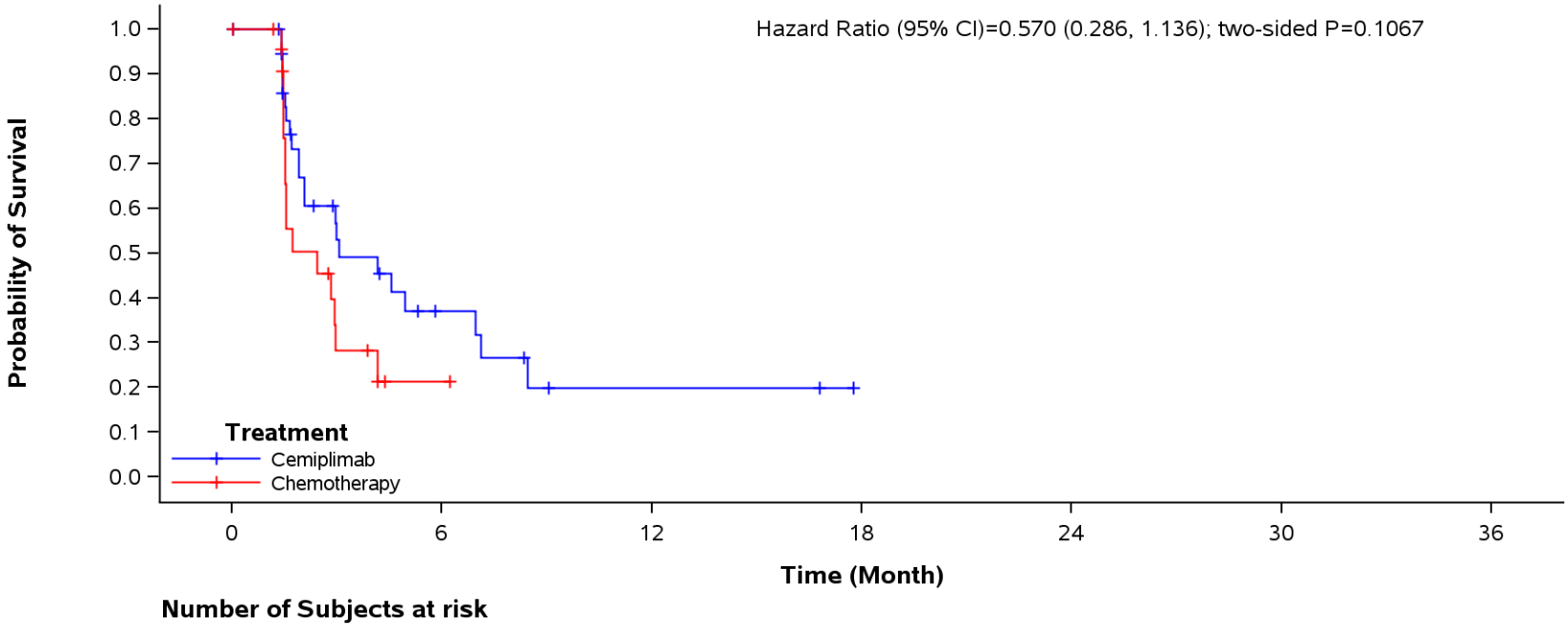

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 4 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 69 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts improvement



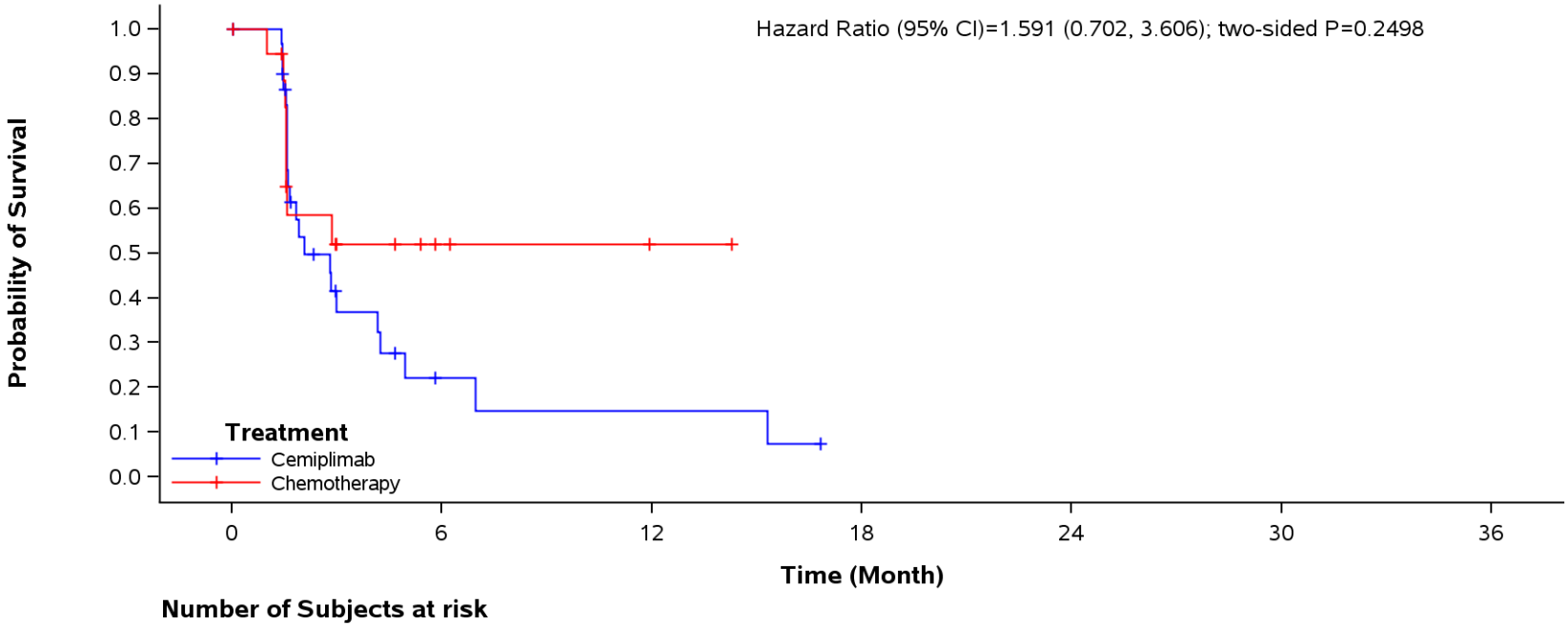

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 7 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 69 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts improvement



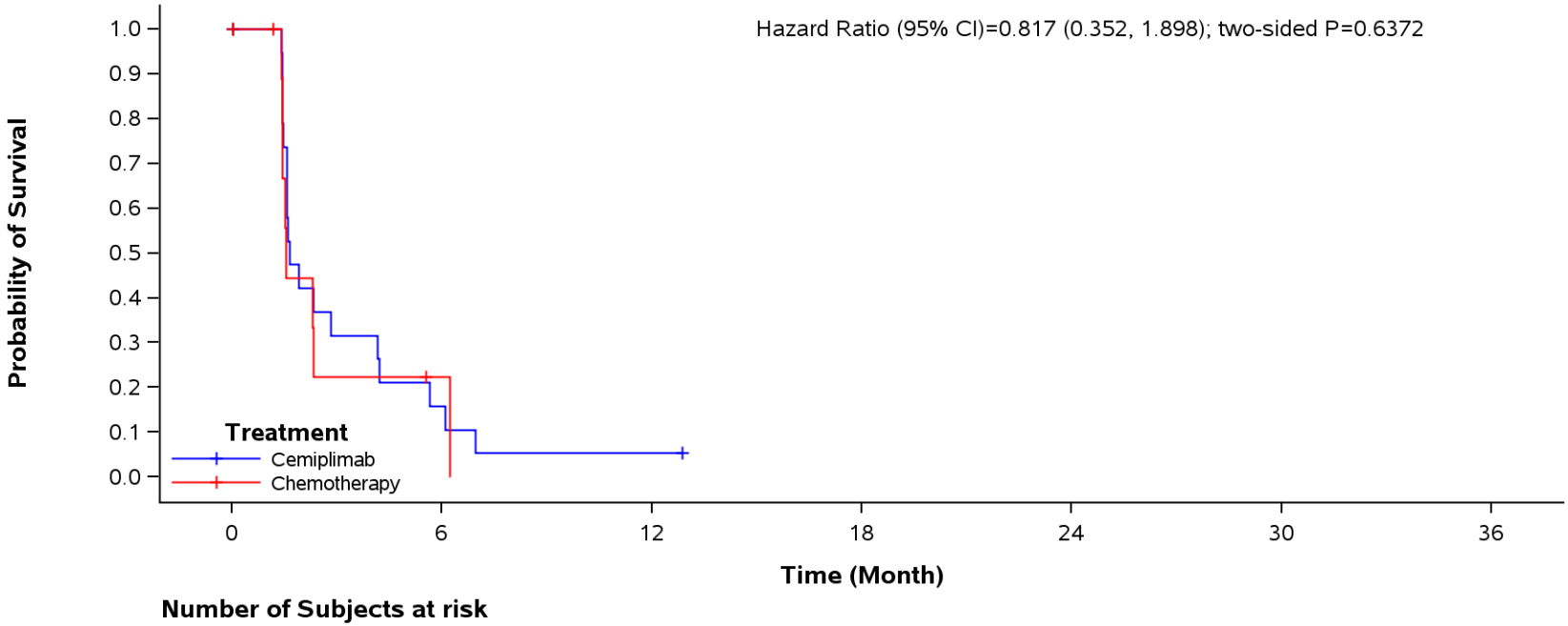

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 69 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Diarhoea - 10 pts improvement



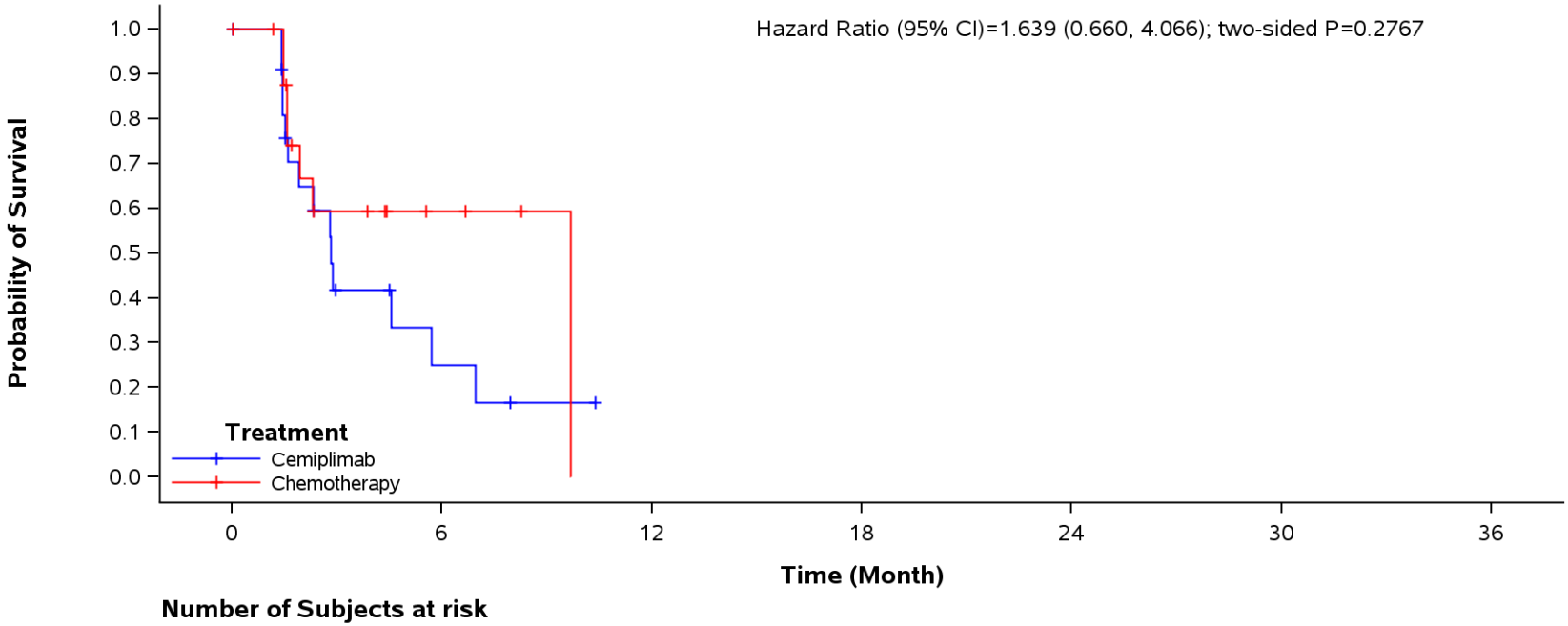

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 69 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Dyspnoea - 10 pts improvement



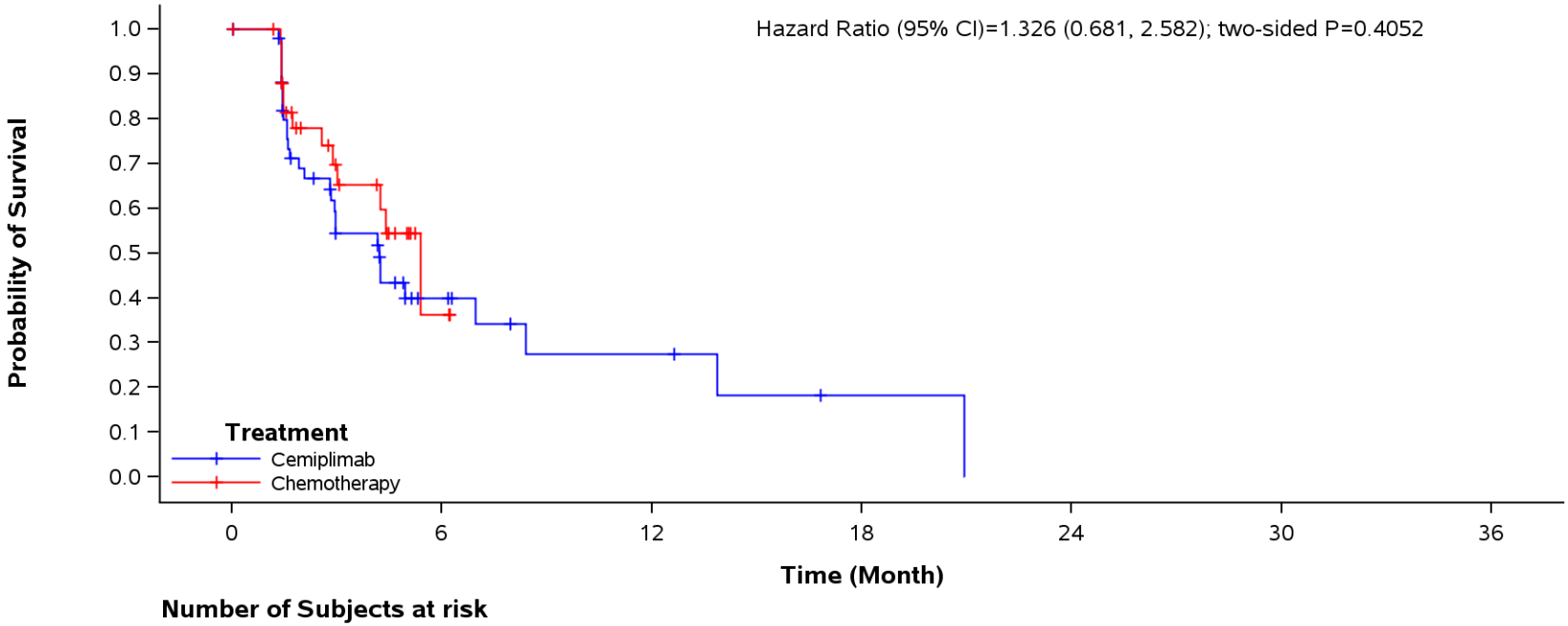

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 69 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Emotional Functioning - 10 pts improvement



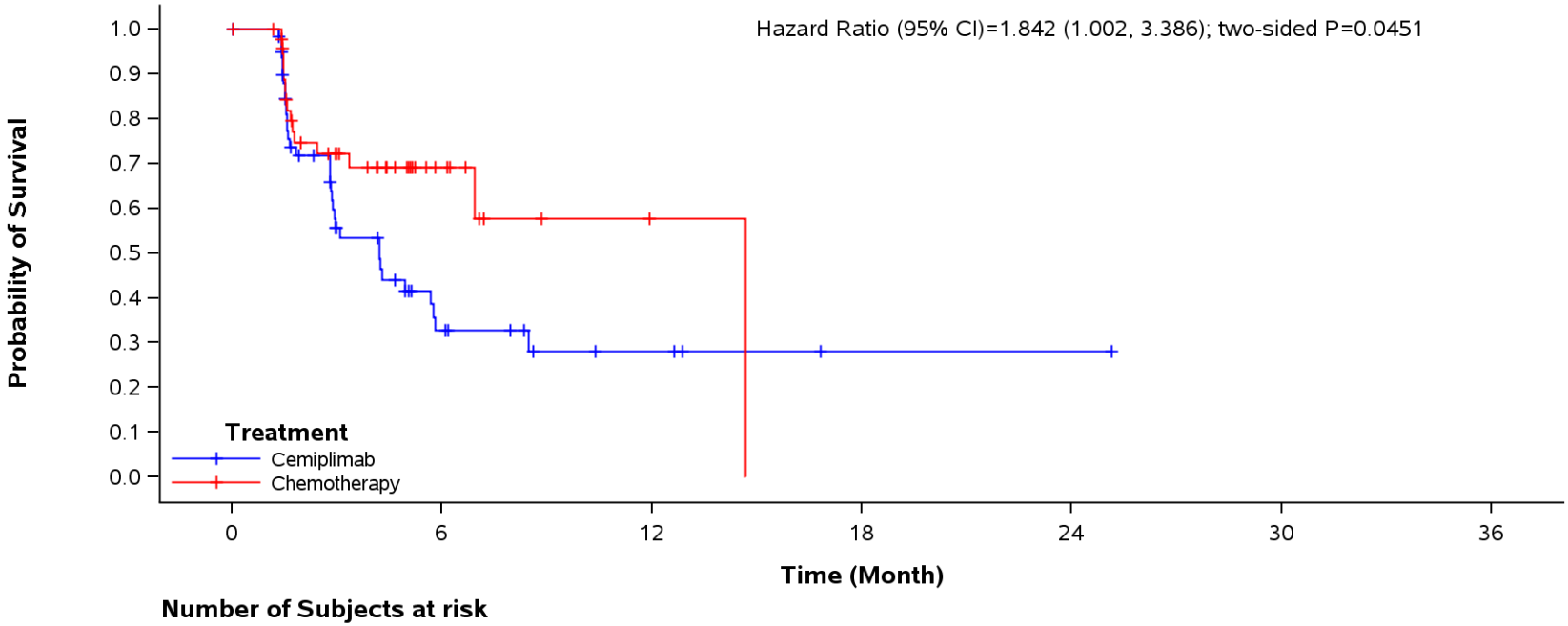

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 9 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 69 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts improvement



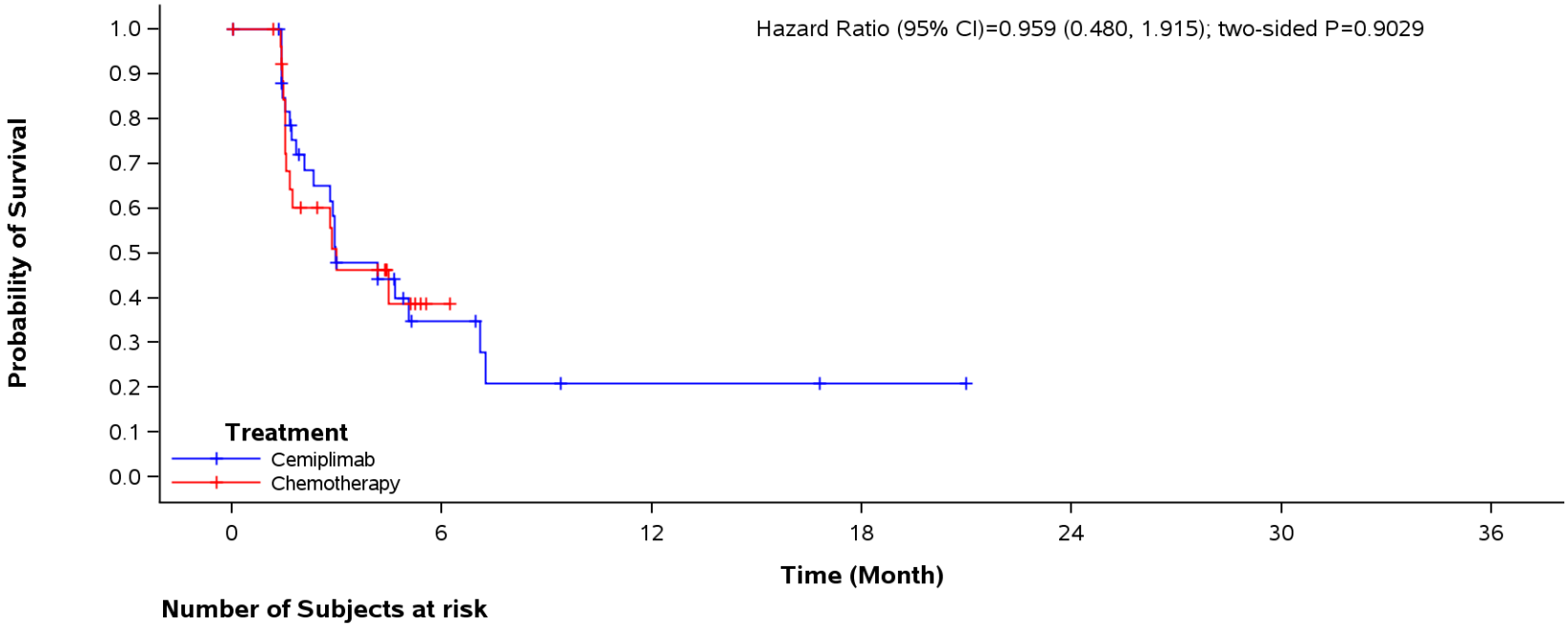

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 11 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 69 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts improvement



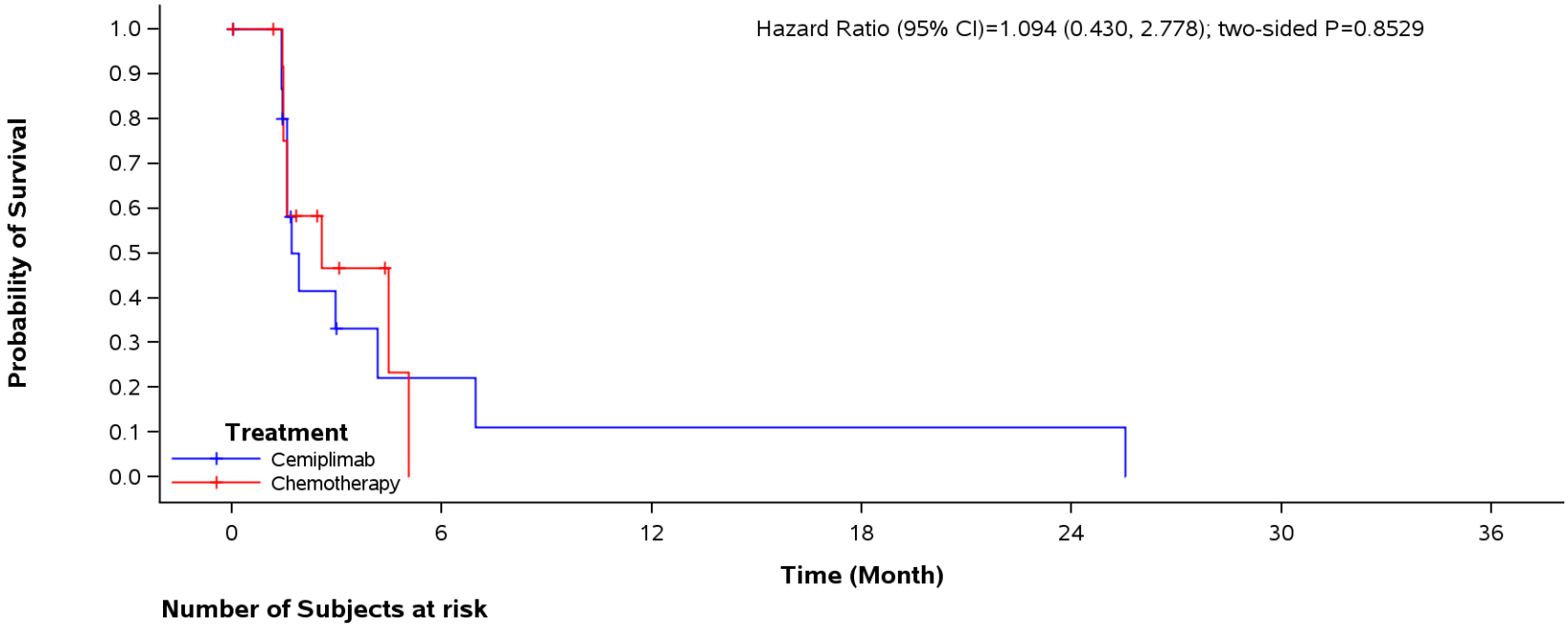

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 69 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts improvement



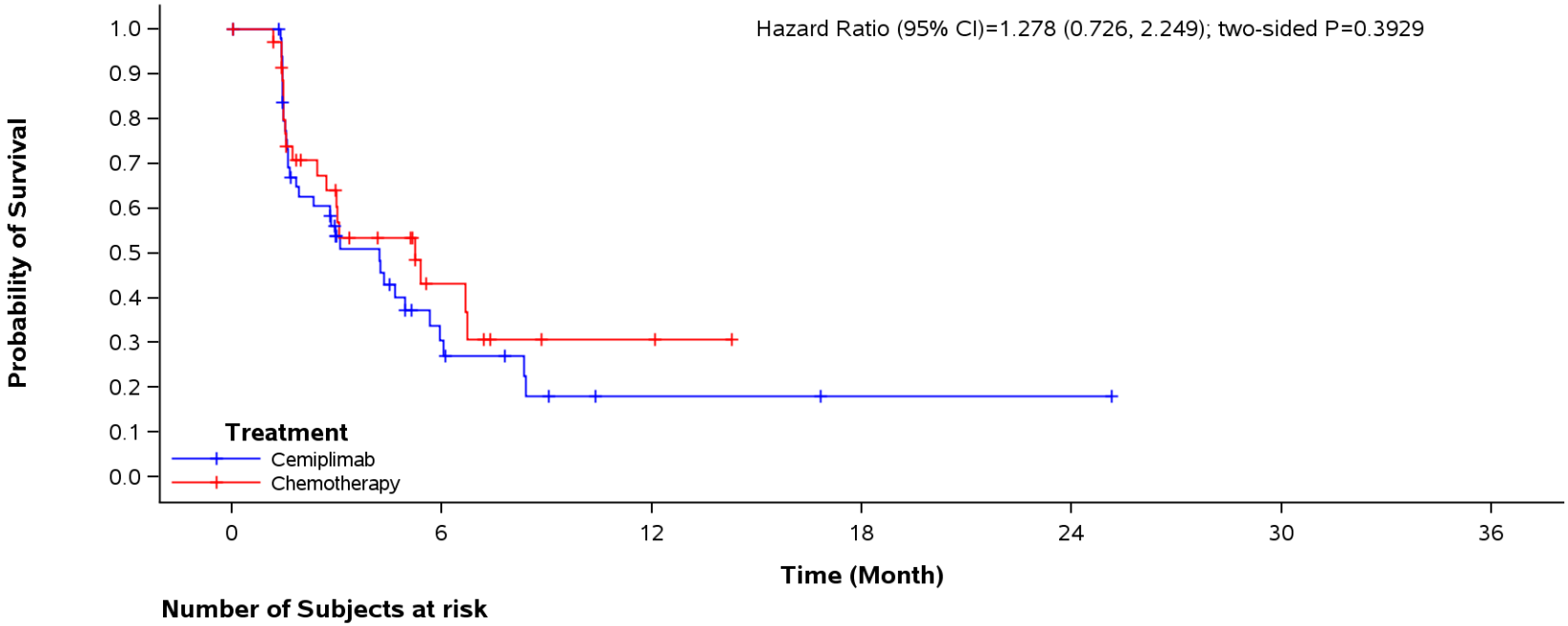

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 2 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 69 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts improvement



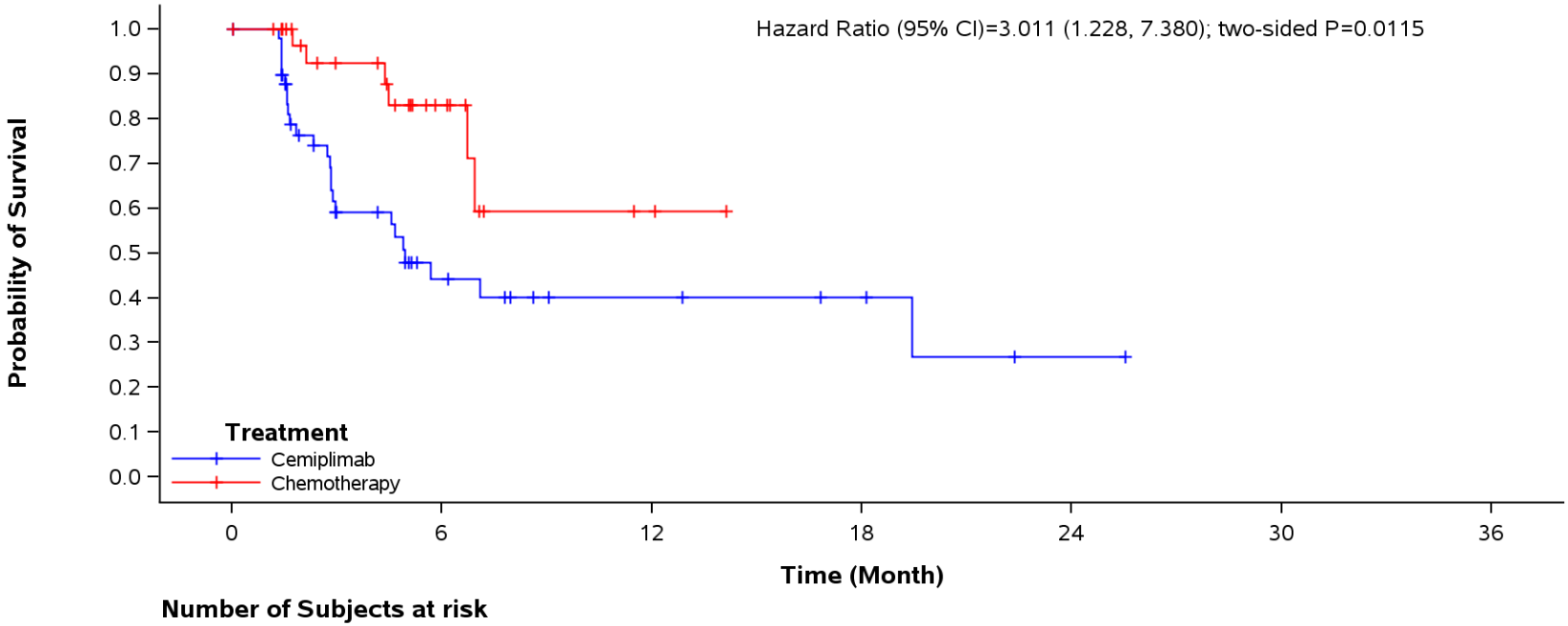

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 9 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 69 | 7 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Physical Functioning - 10 pts improvement



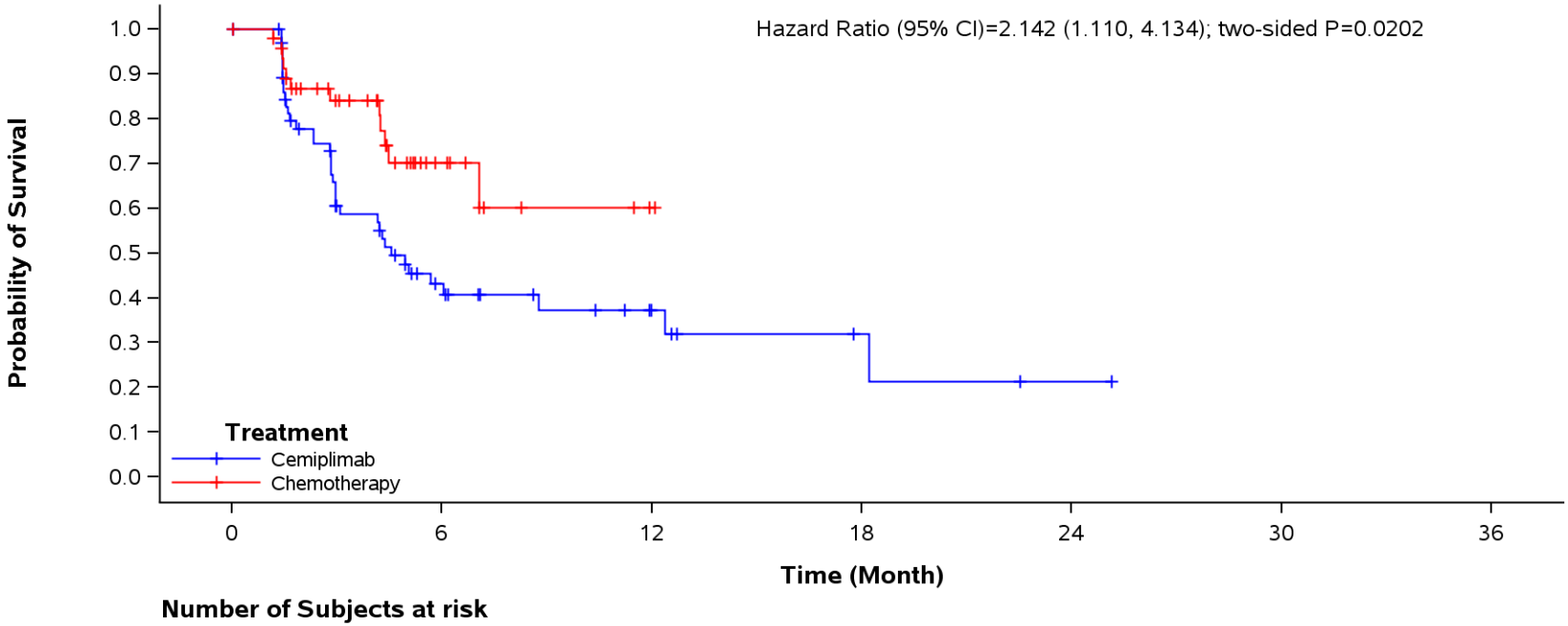

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 12 | 6 | 4 | 1 | 0 | 0 |
| Chemotherapy | 69 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Global health status / QoL - 10 pts improvement



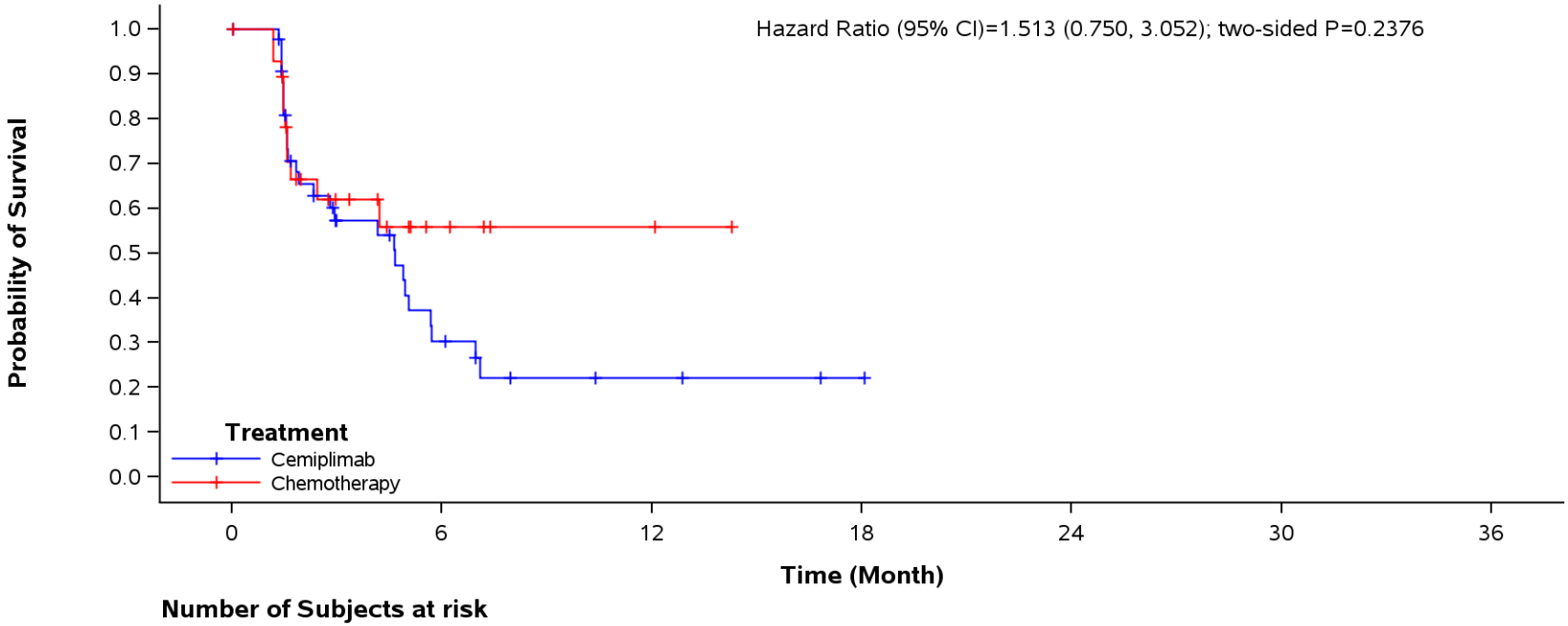

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 18 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 69 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts improvement



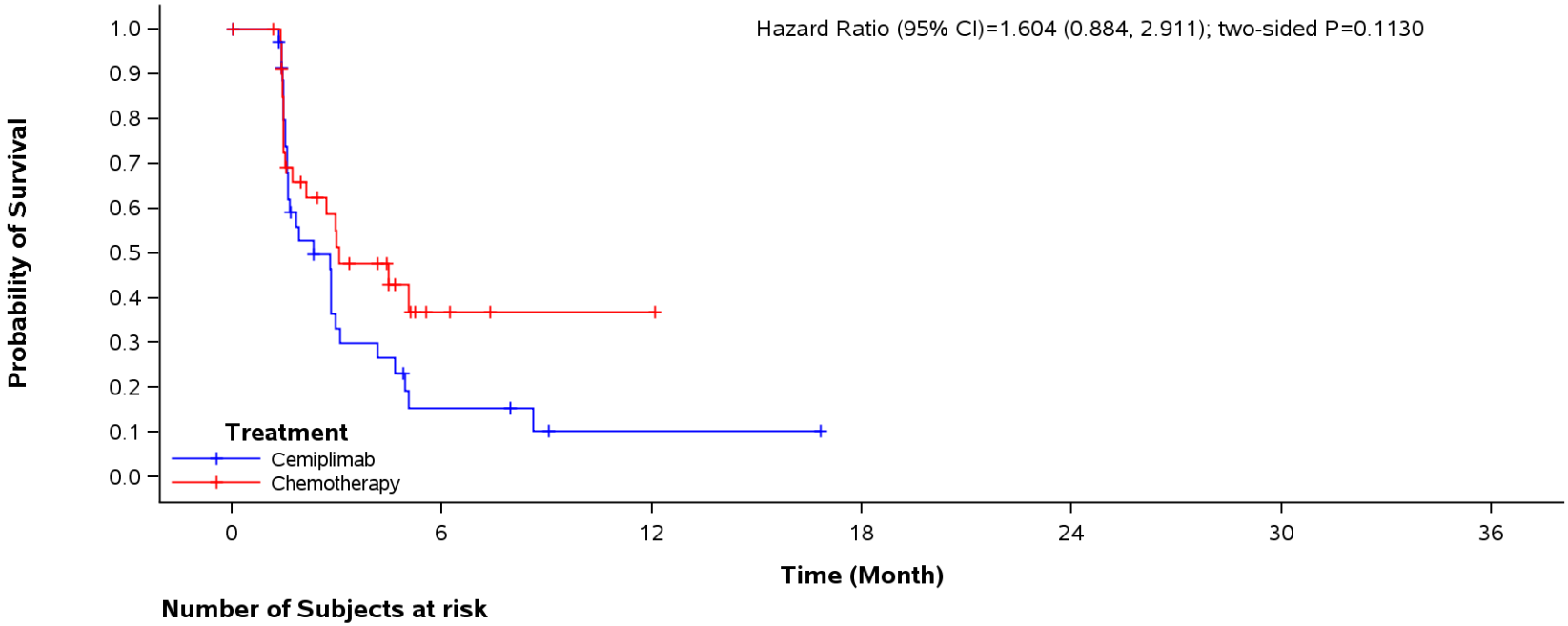

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 9 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 69 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts improvement



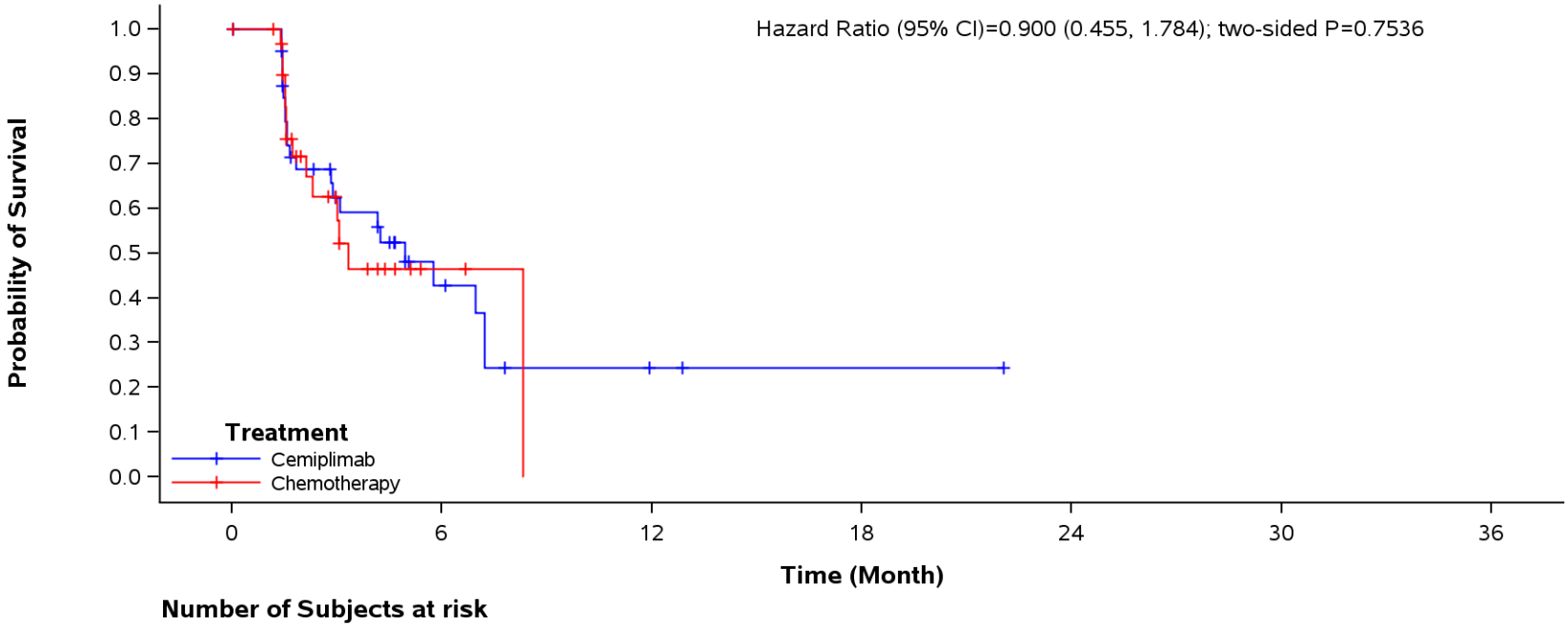

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 69 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts improvement



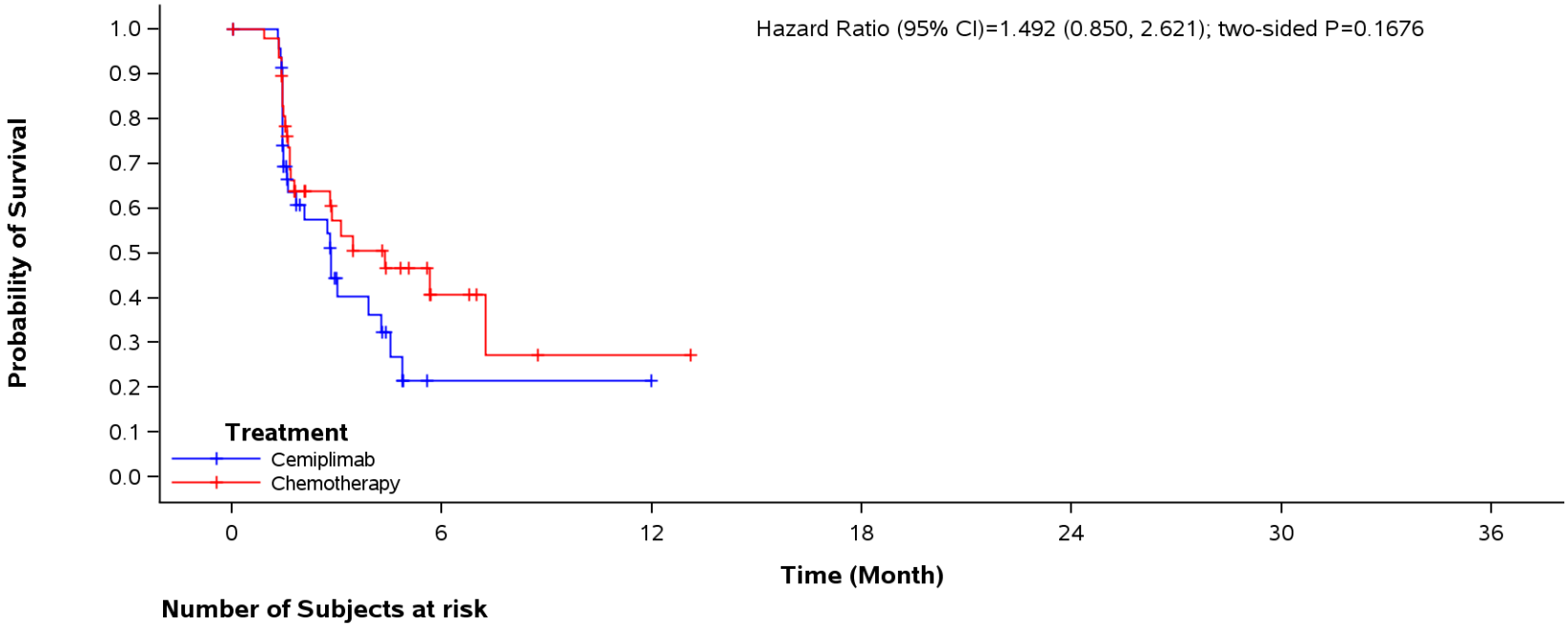

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 69 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts improvement



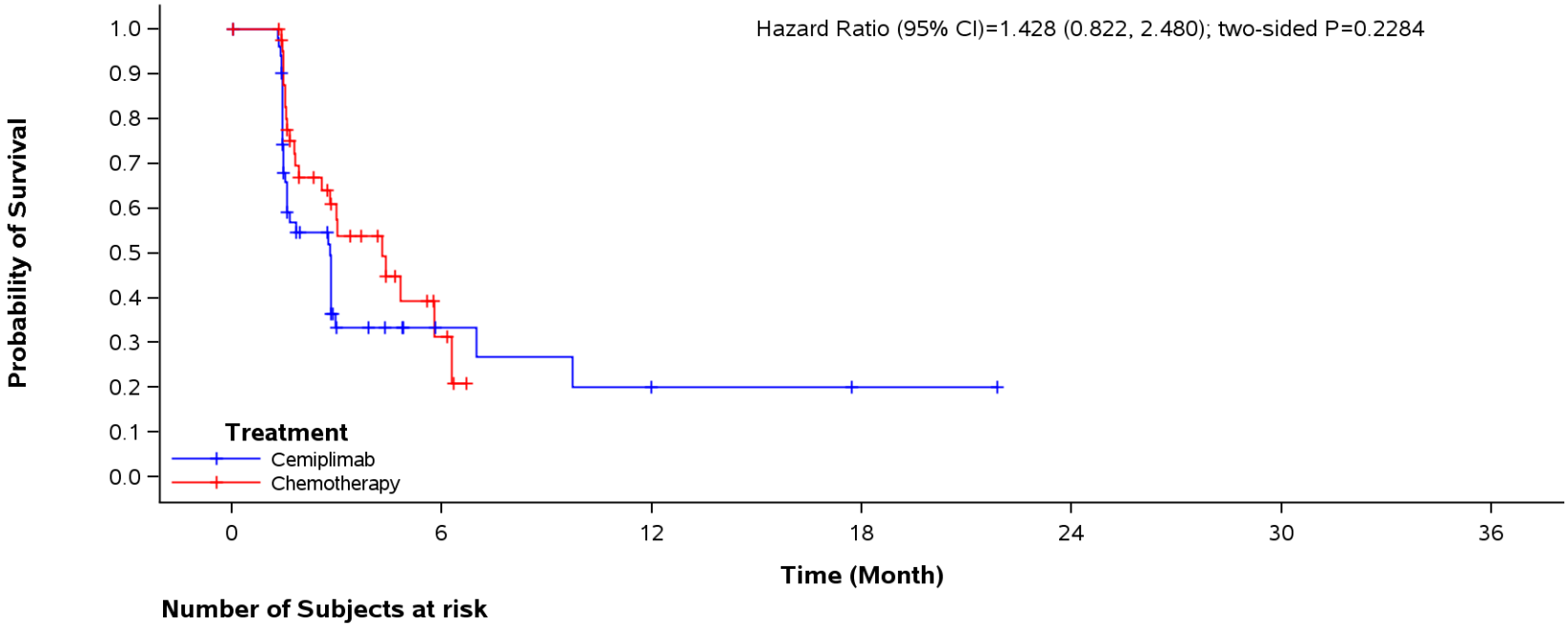

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts improvement



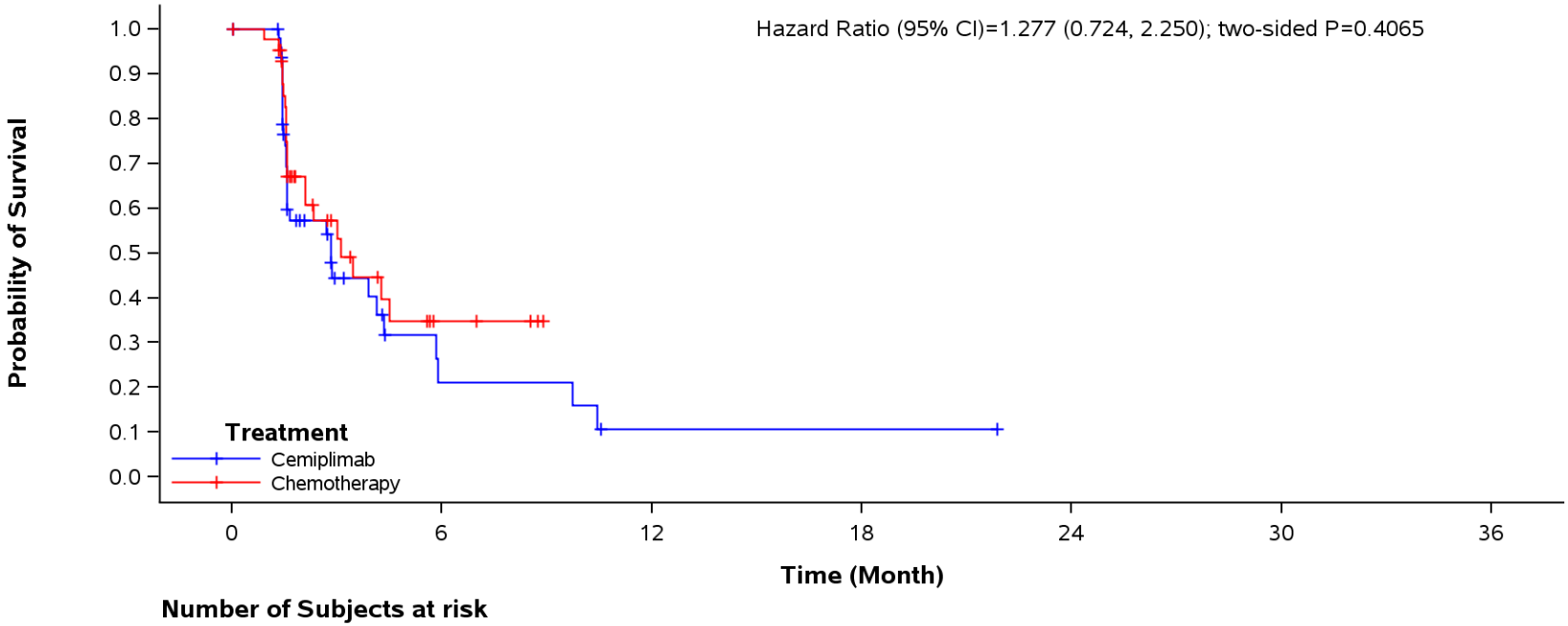

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 5 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts improvement



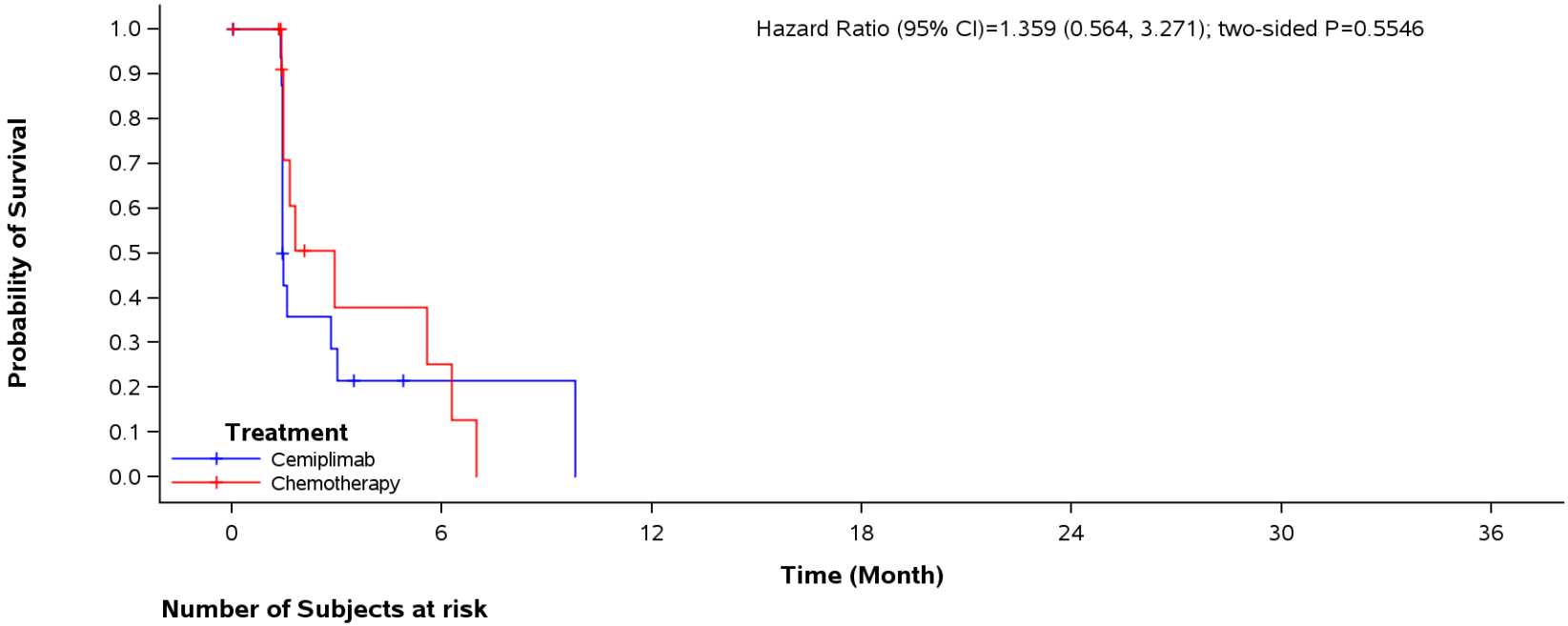

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 4 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts improvement



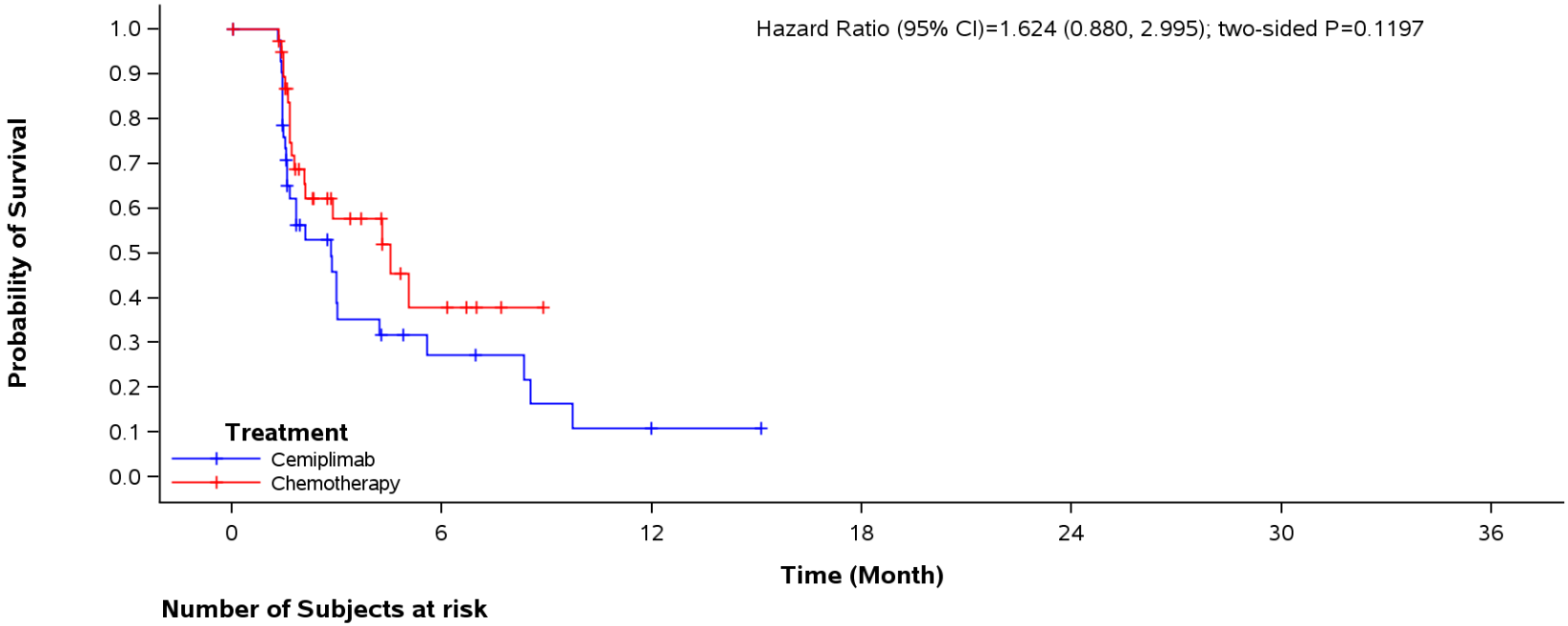

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts improvement



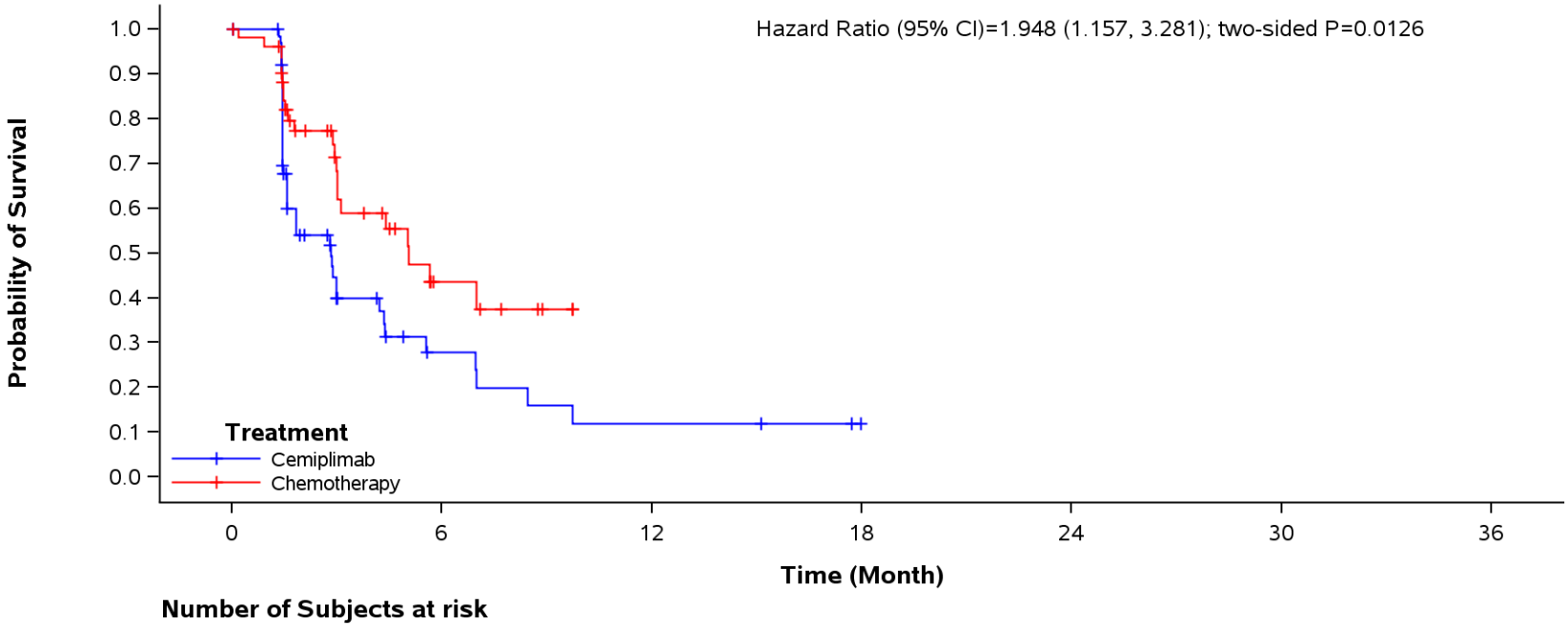

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts improvement



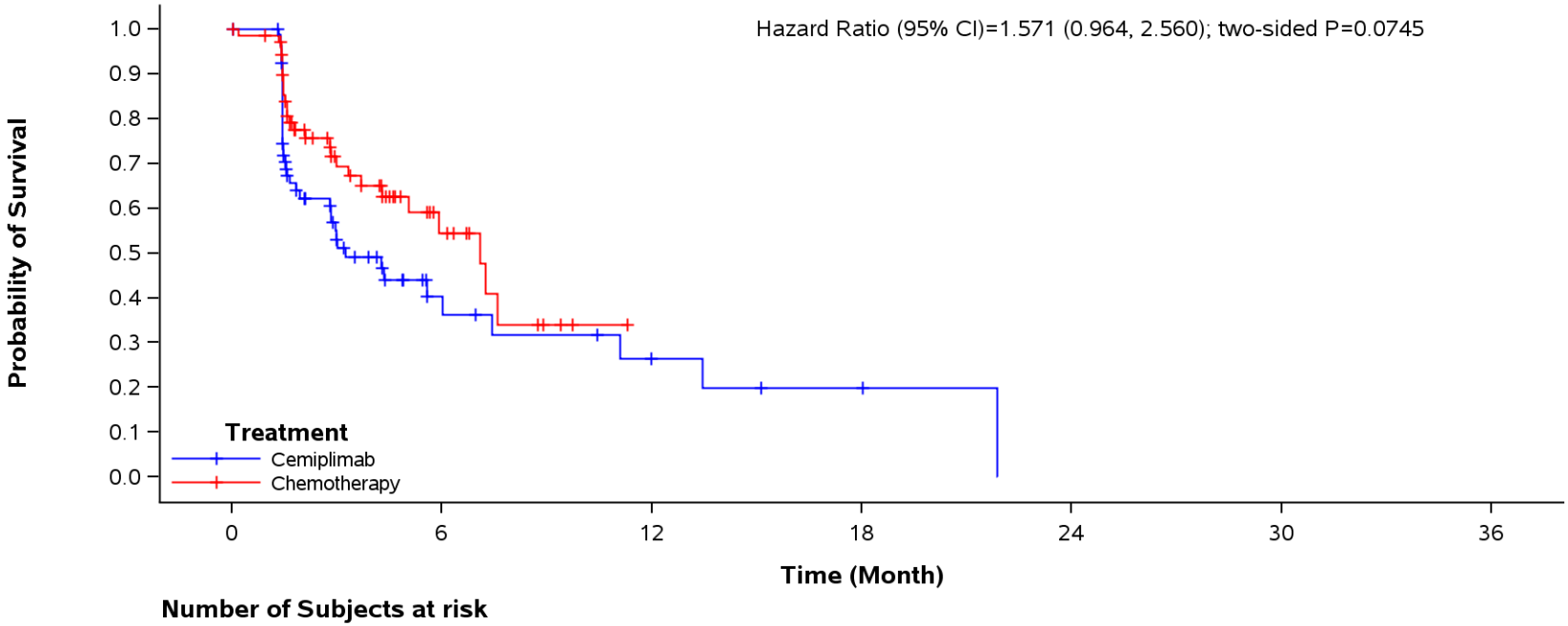

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 7 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts improvement



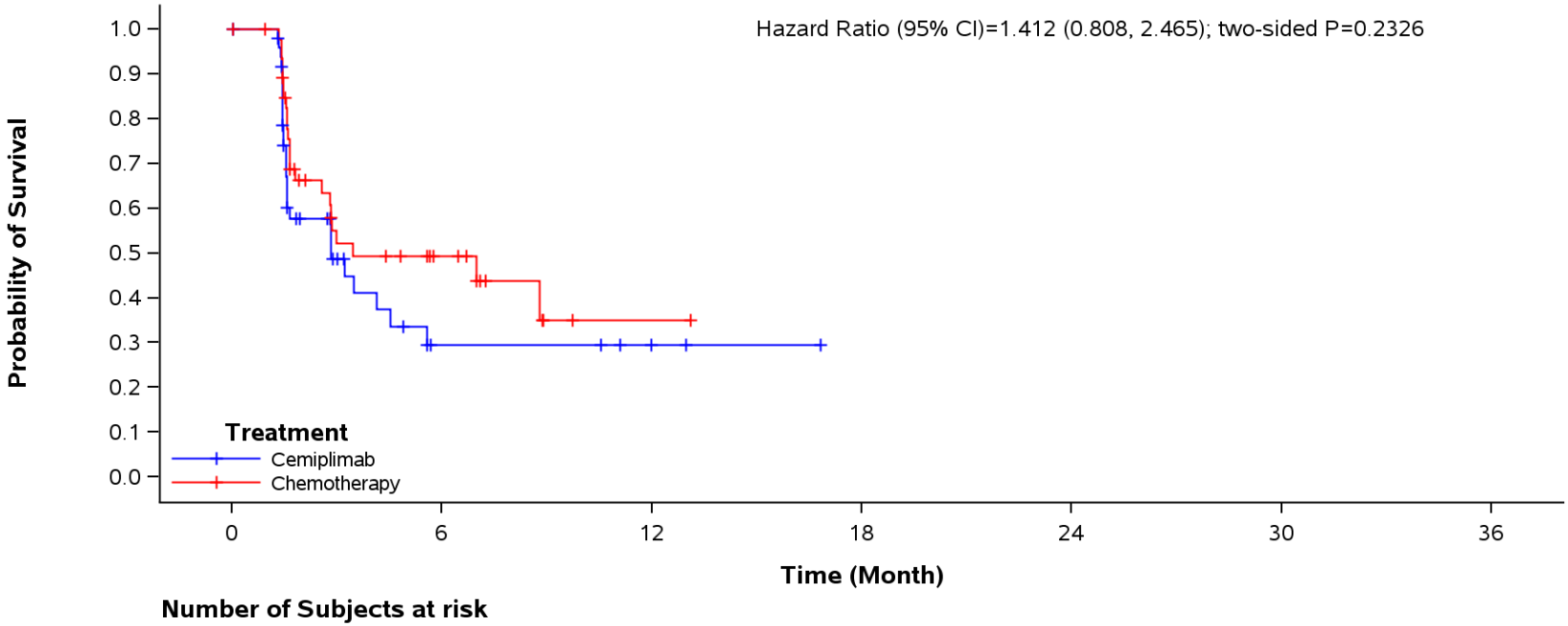

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 10 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts improvement



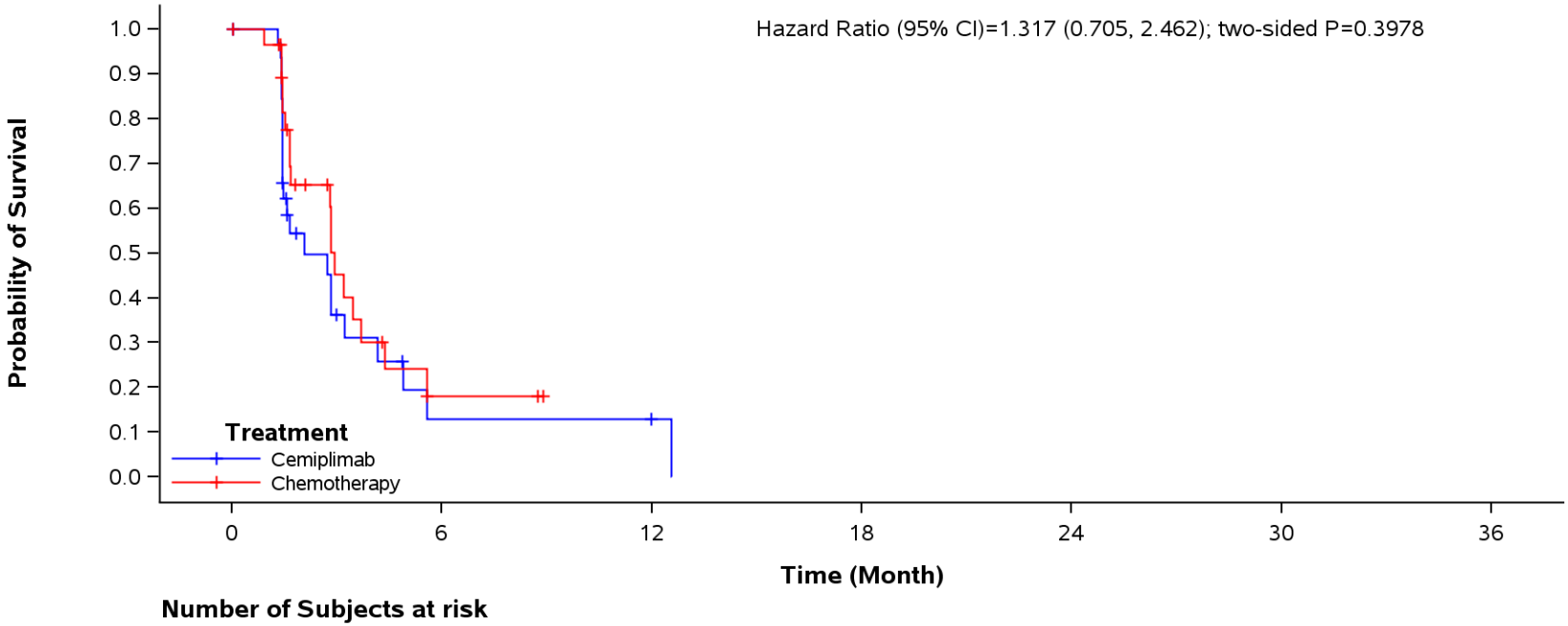

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts improvement



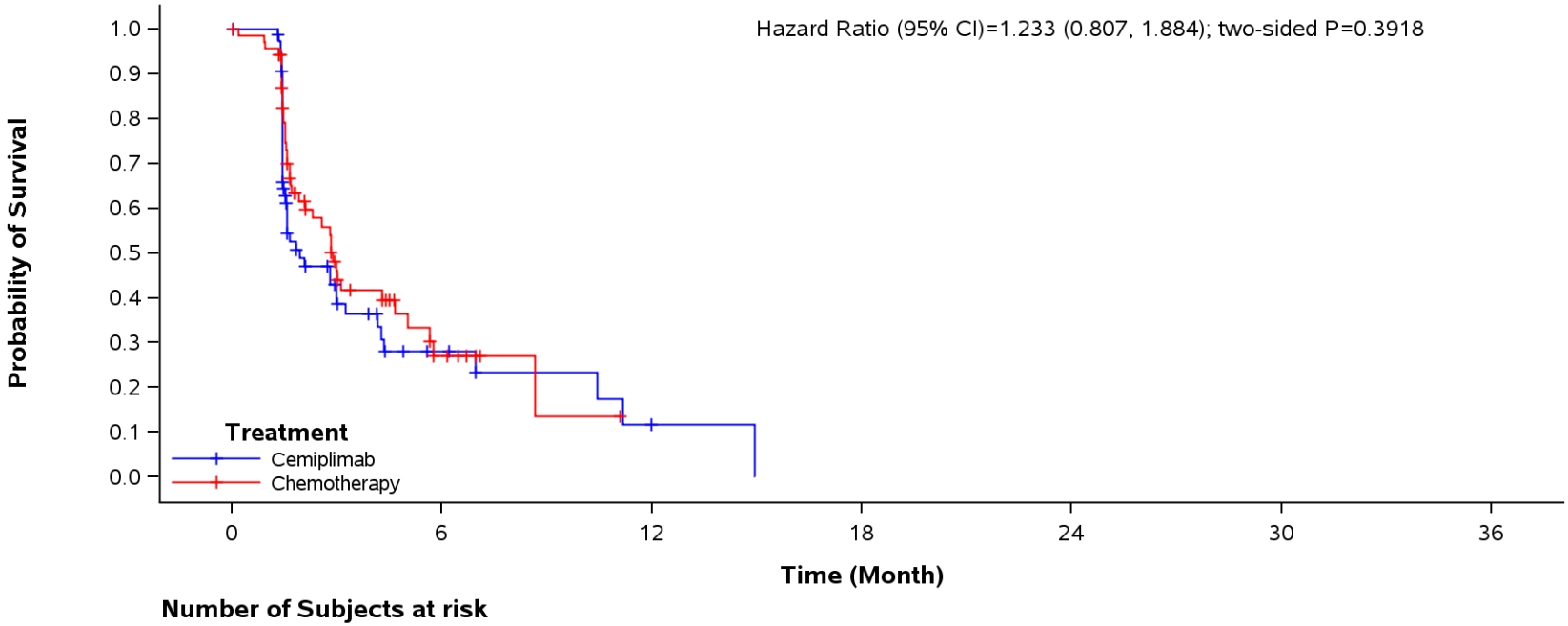

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts improvement



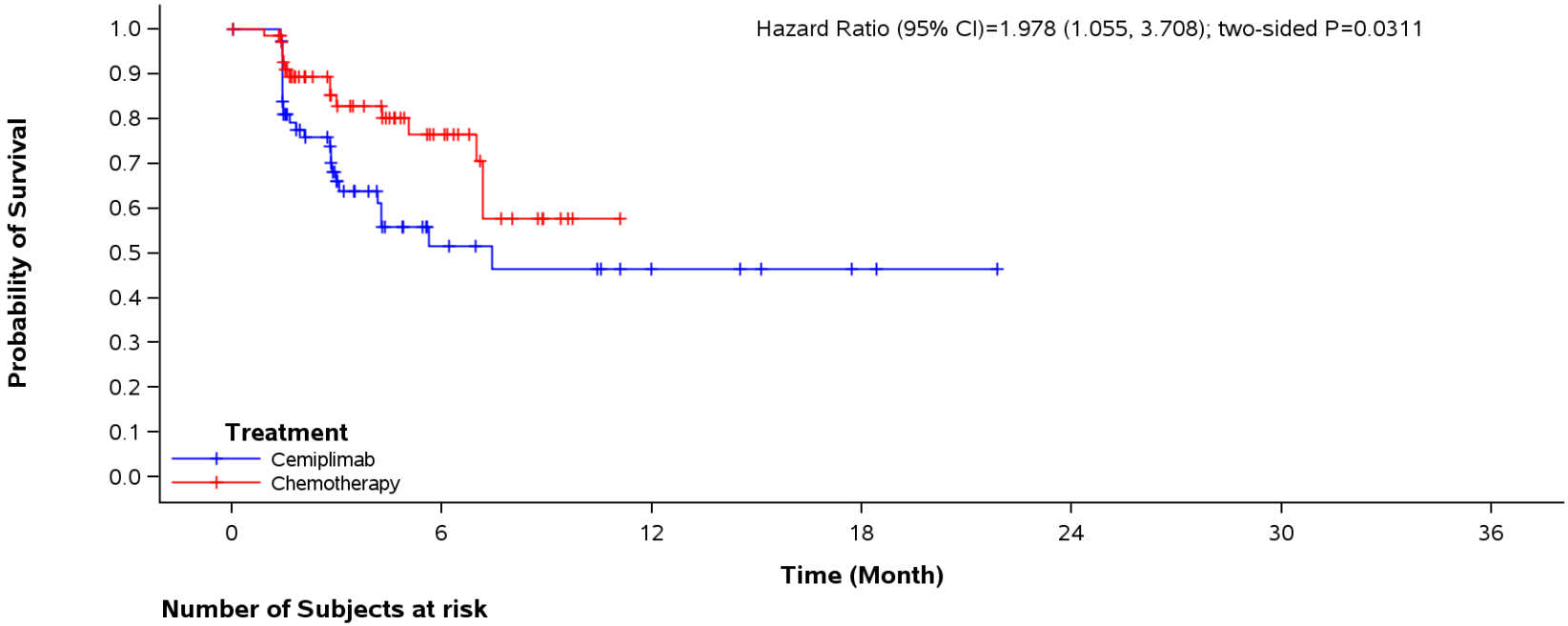

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 7 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts improvement



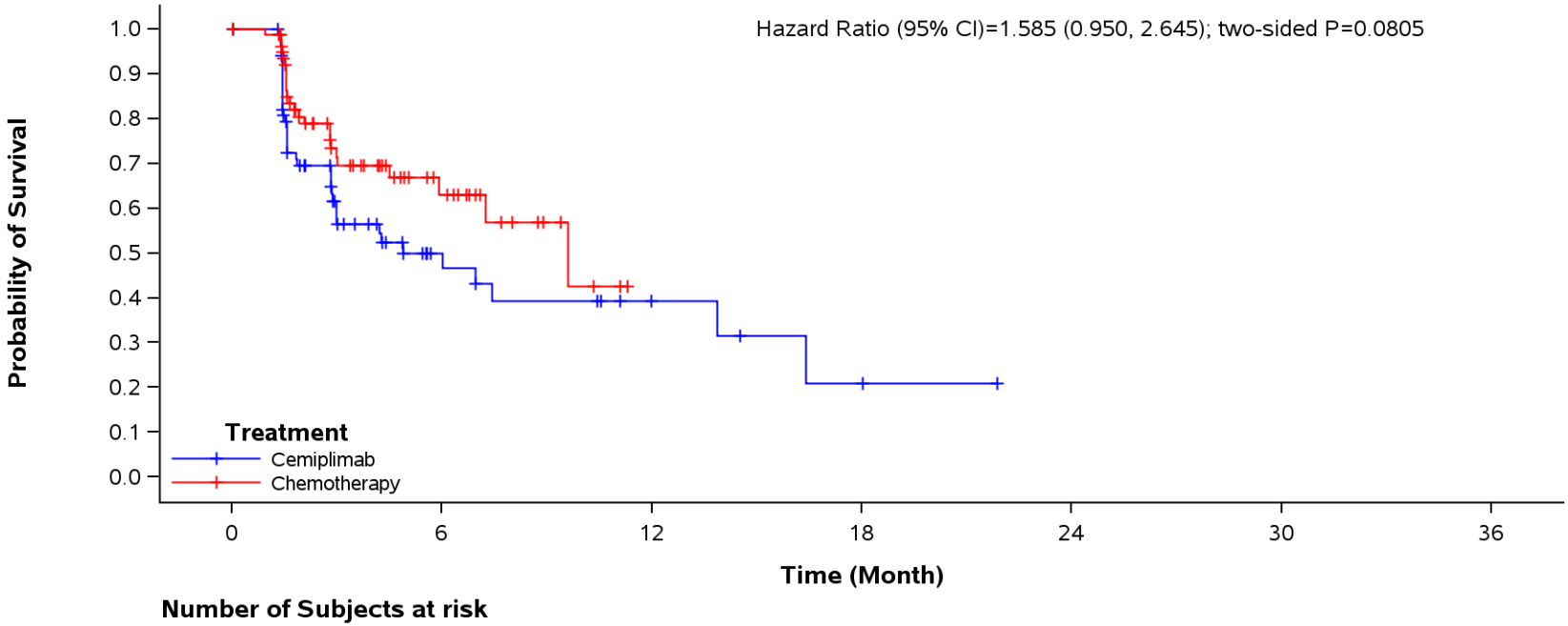

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 12 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 18 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts improvement



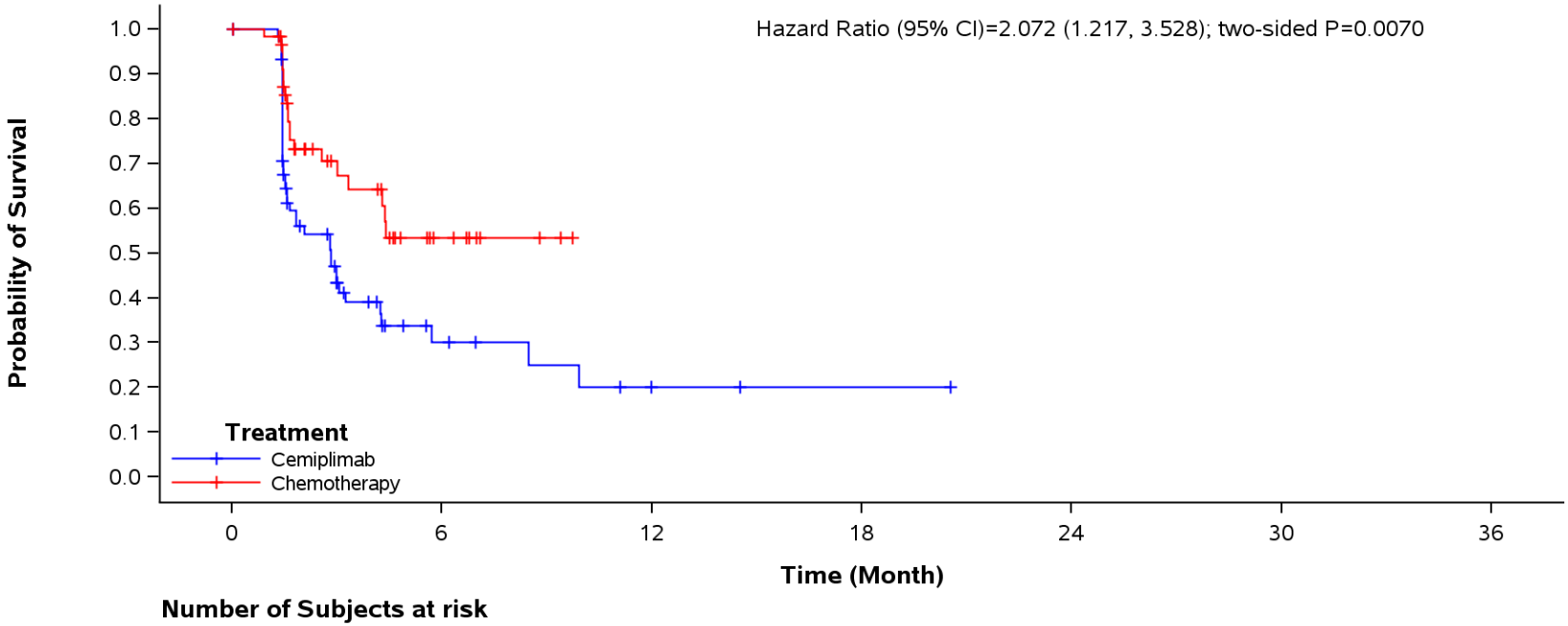

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 15 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 17 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts improvement



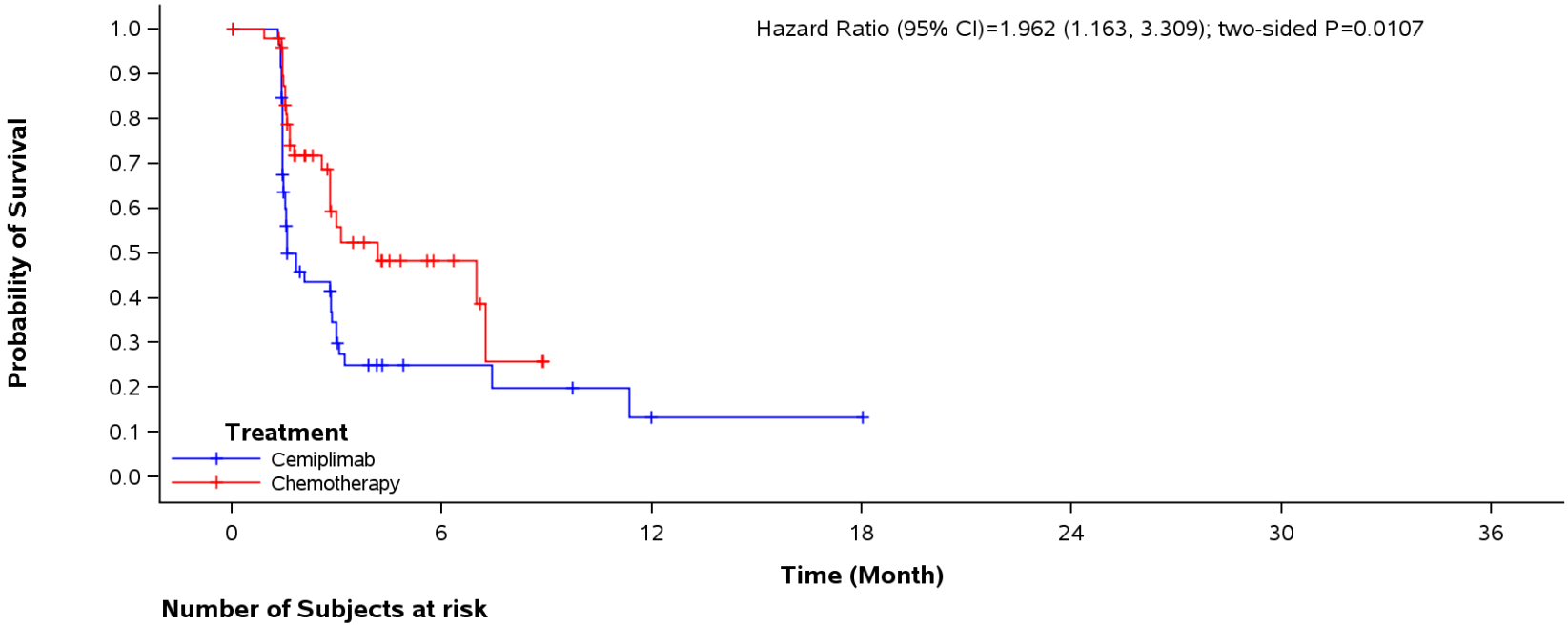

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts improvement



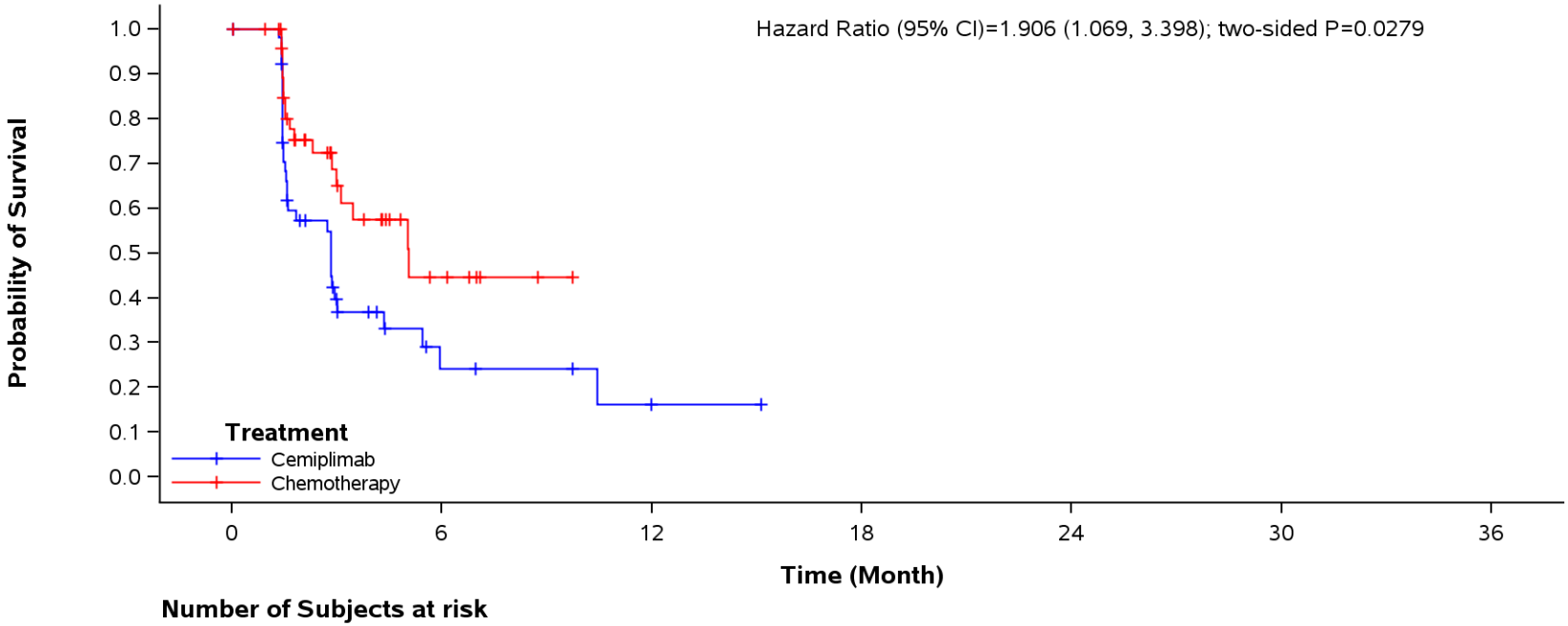

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts improvement



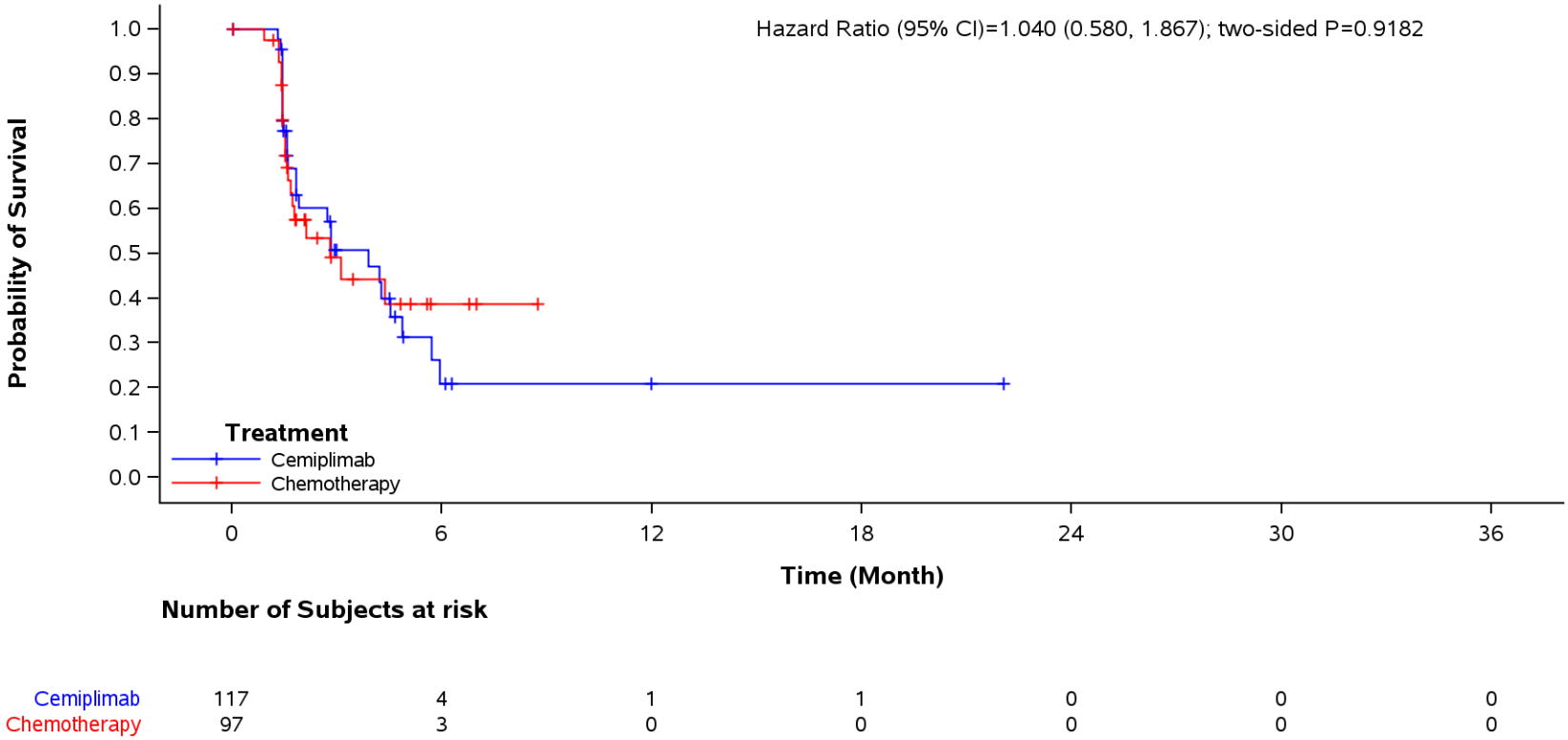

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts improvement



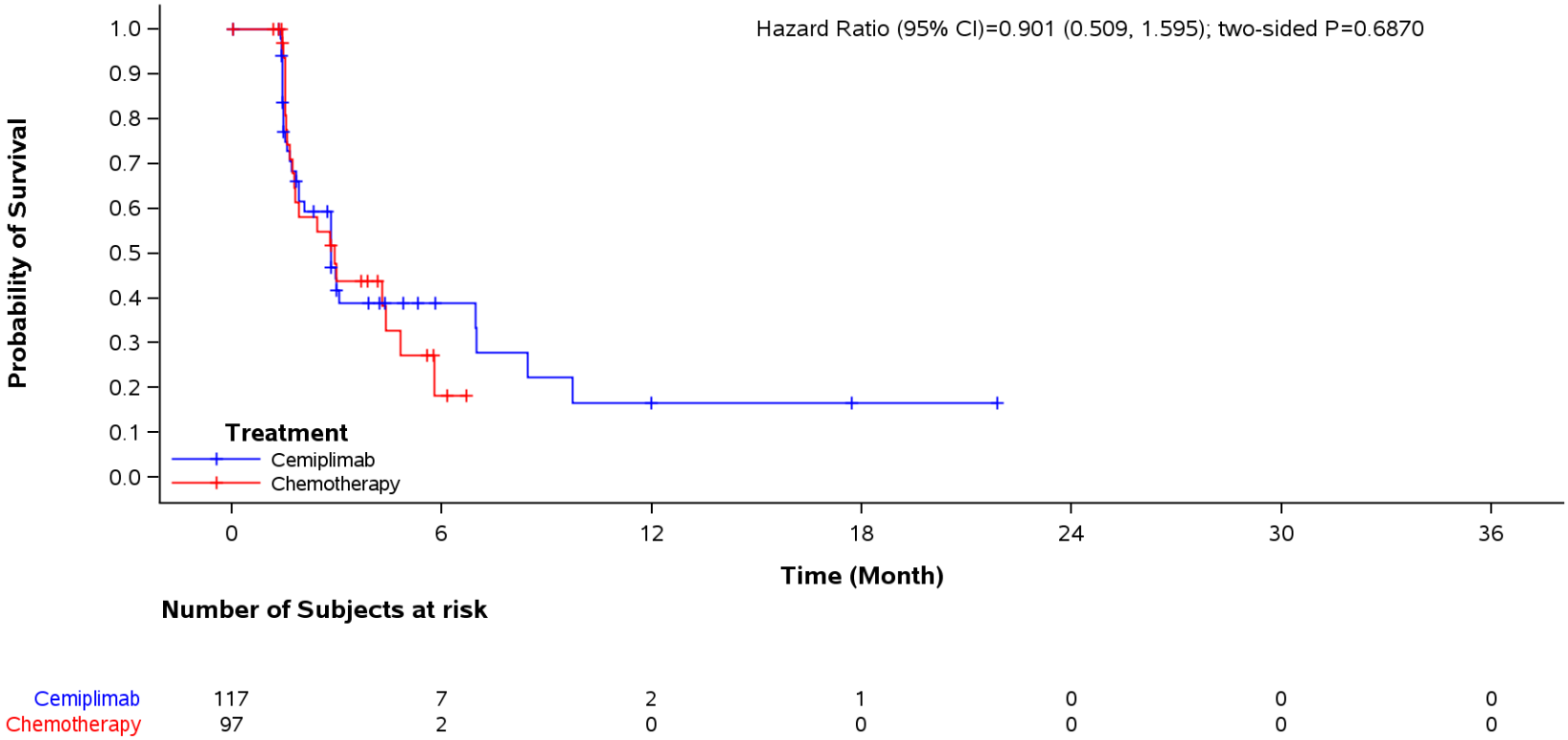

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 4 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 97 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts improvement



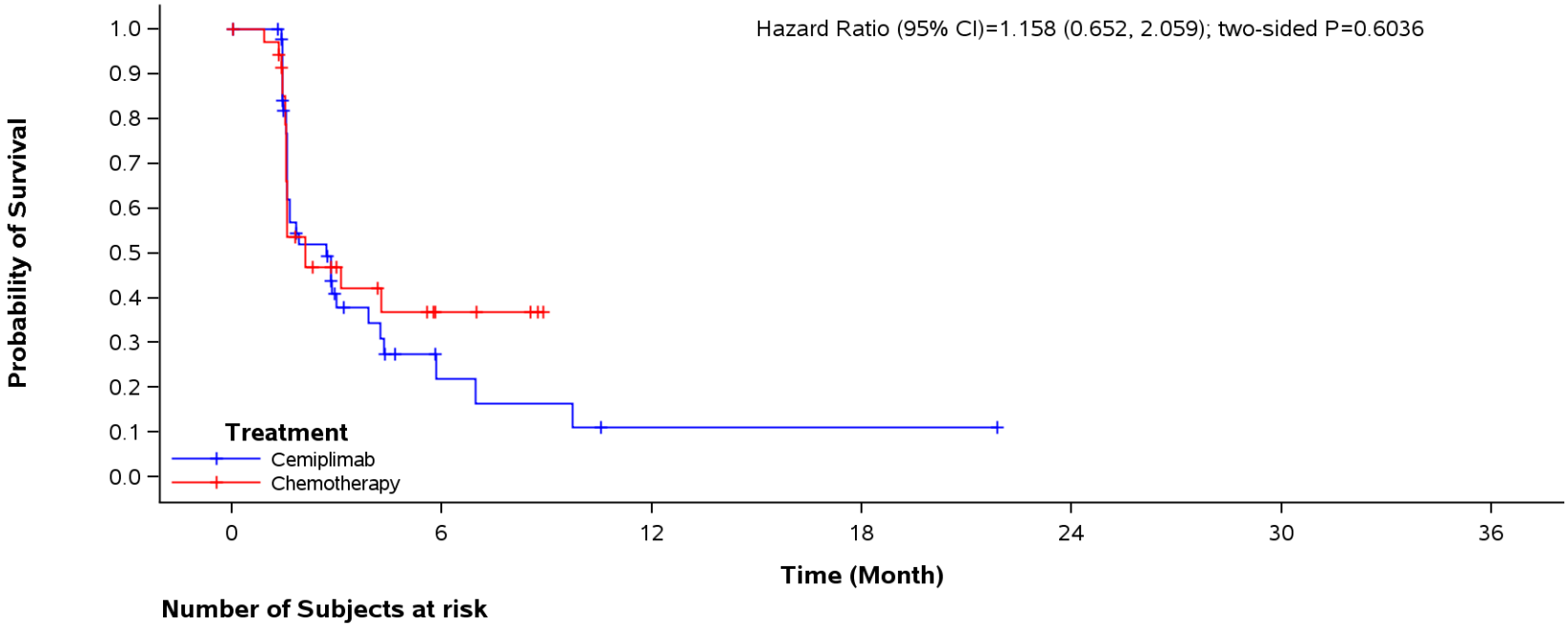

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 97 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts improvement



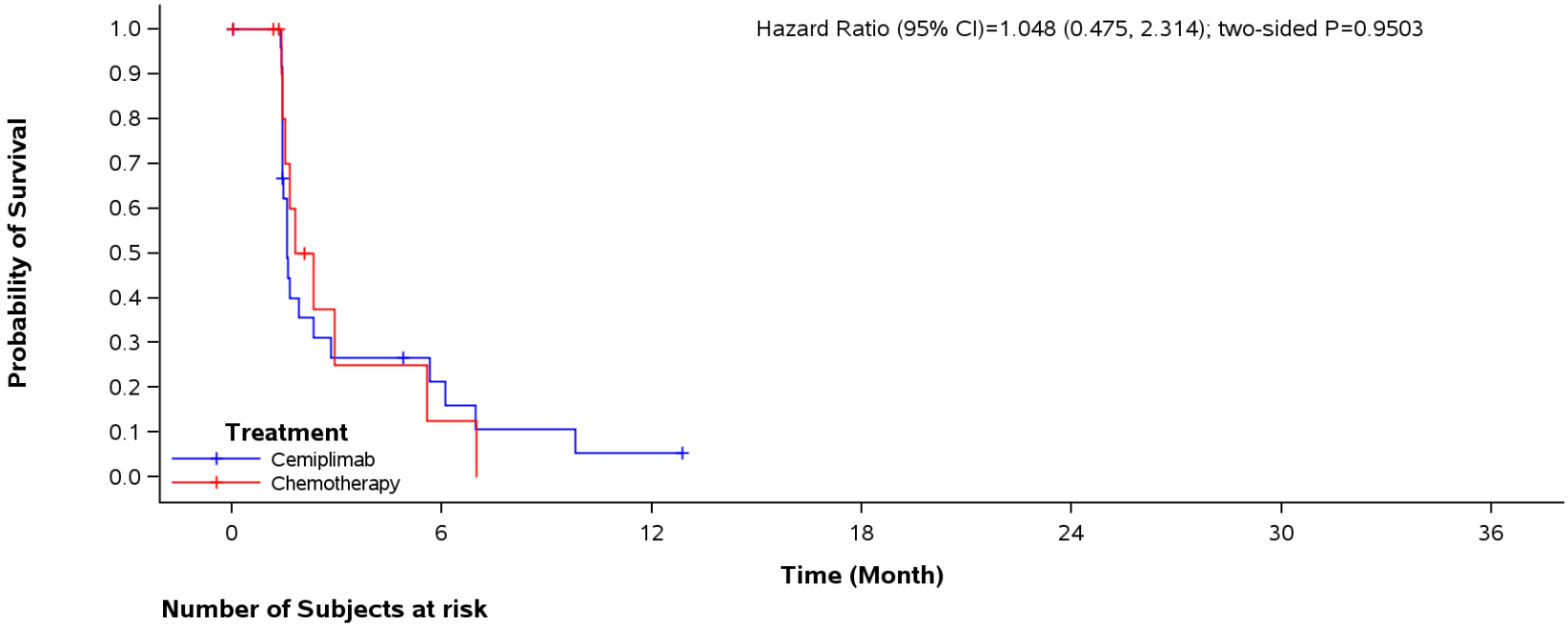

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 4 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 97 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts improvement



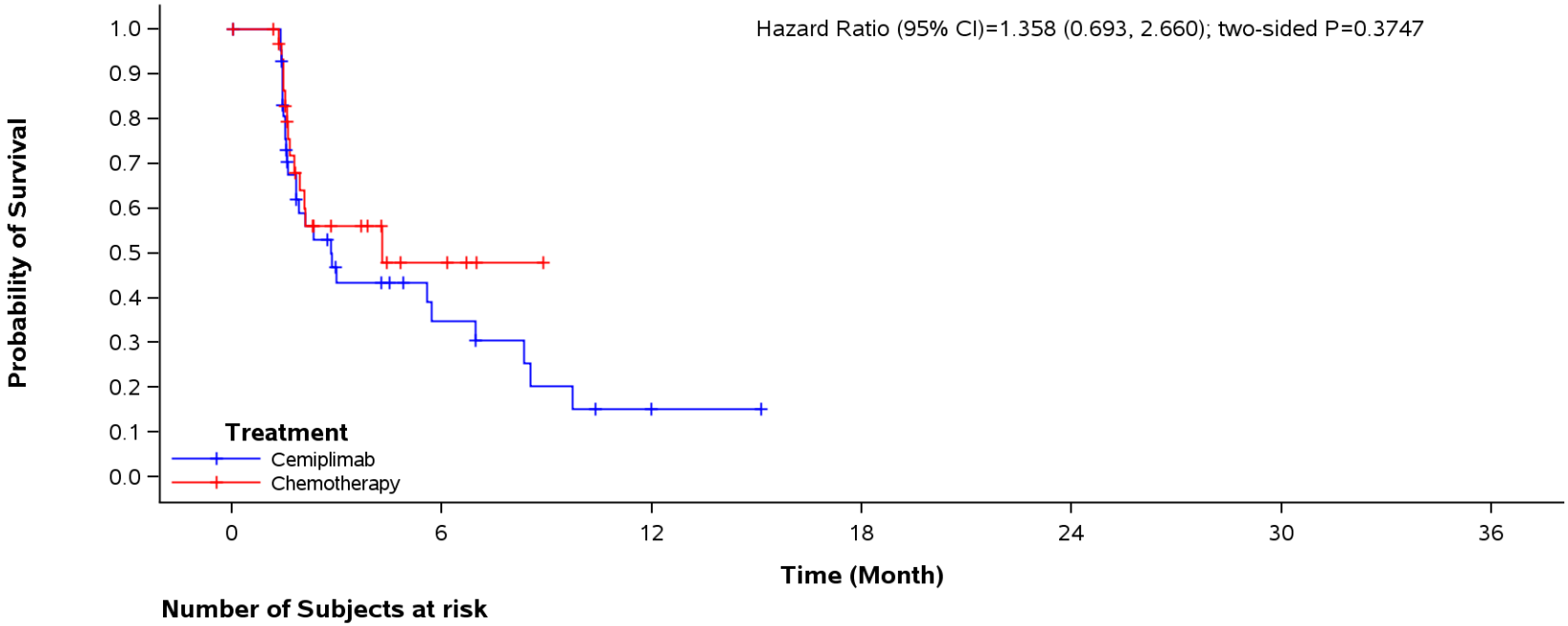

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 97 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts improvement



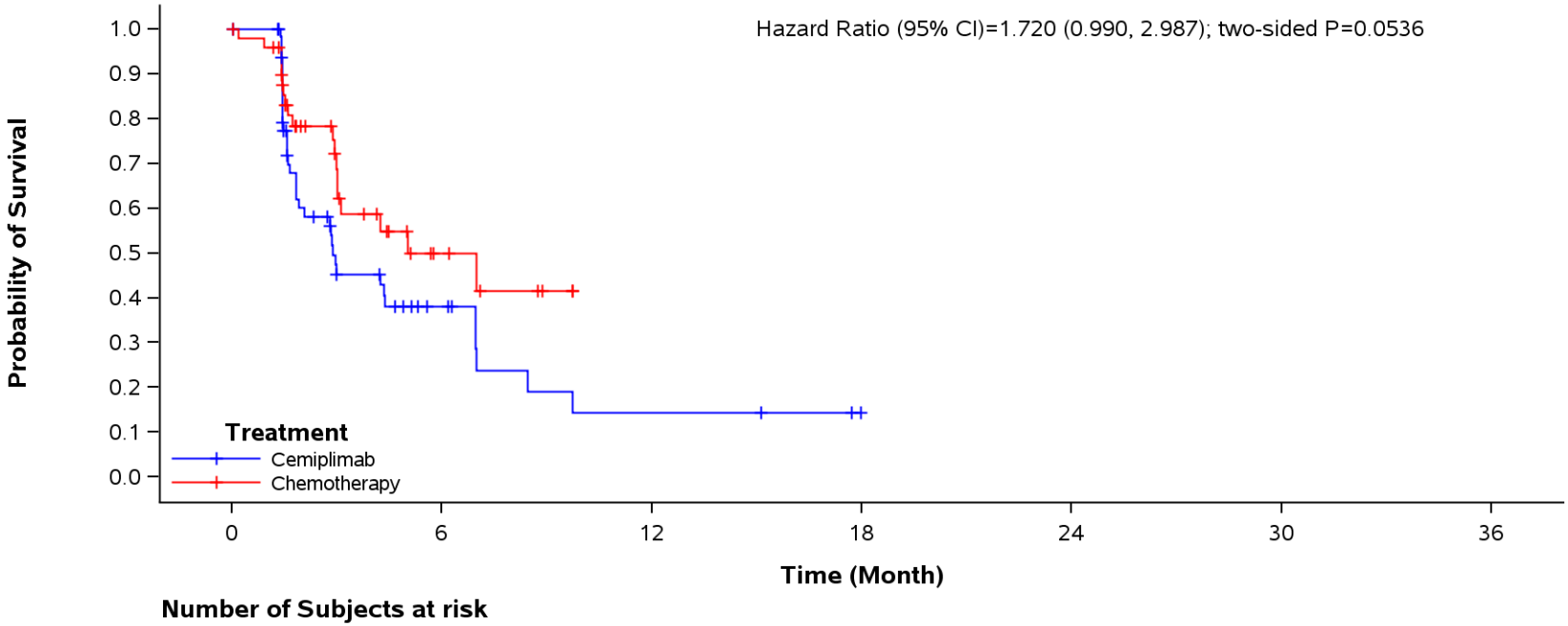

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 8 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 97 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Emotional Functioning - 10 pts improvement



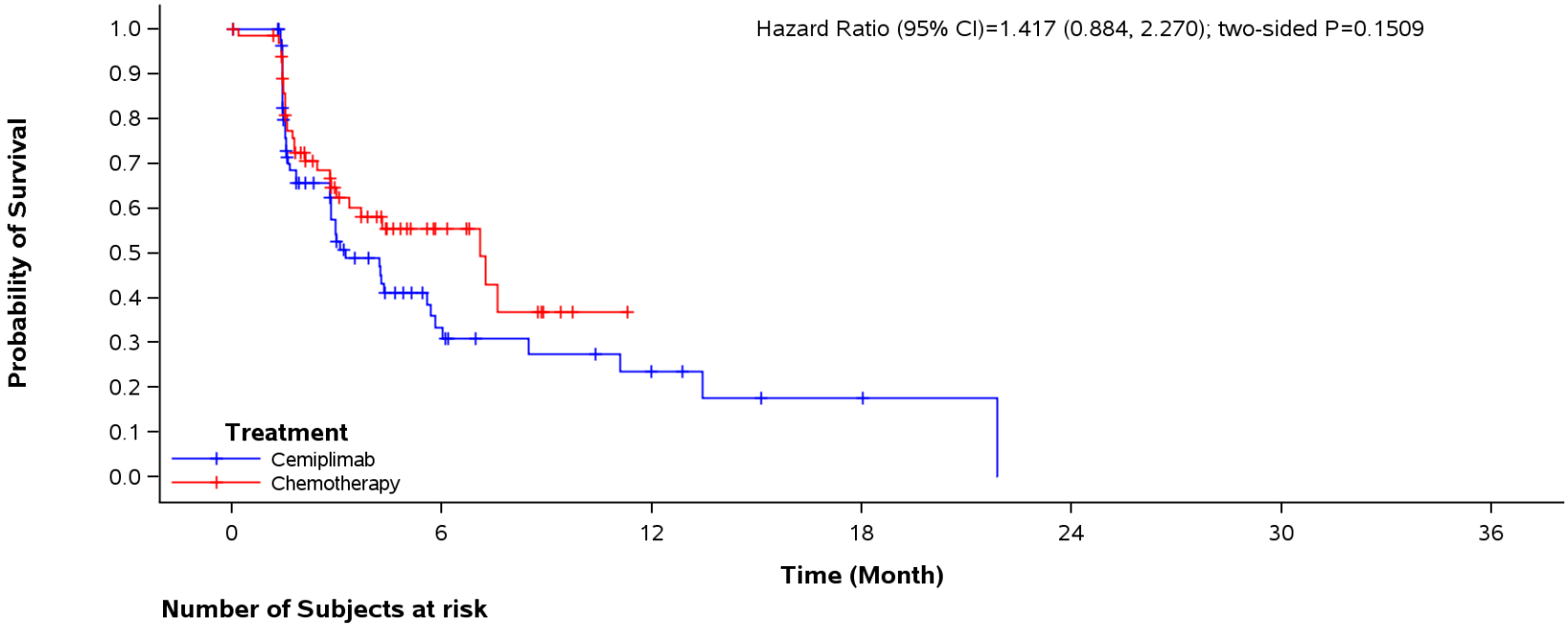

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 10 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 97 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts improvement



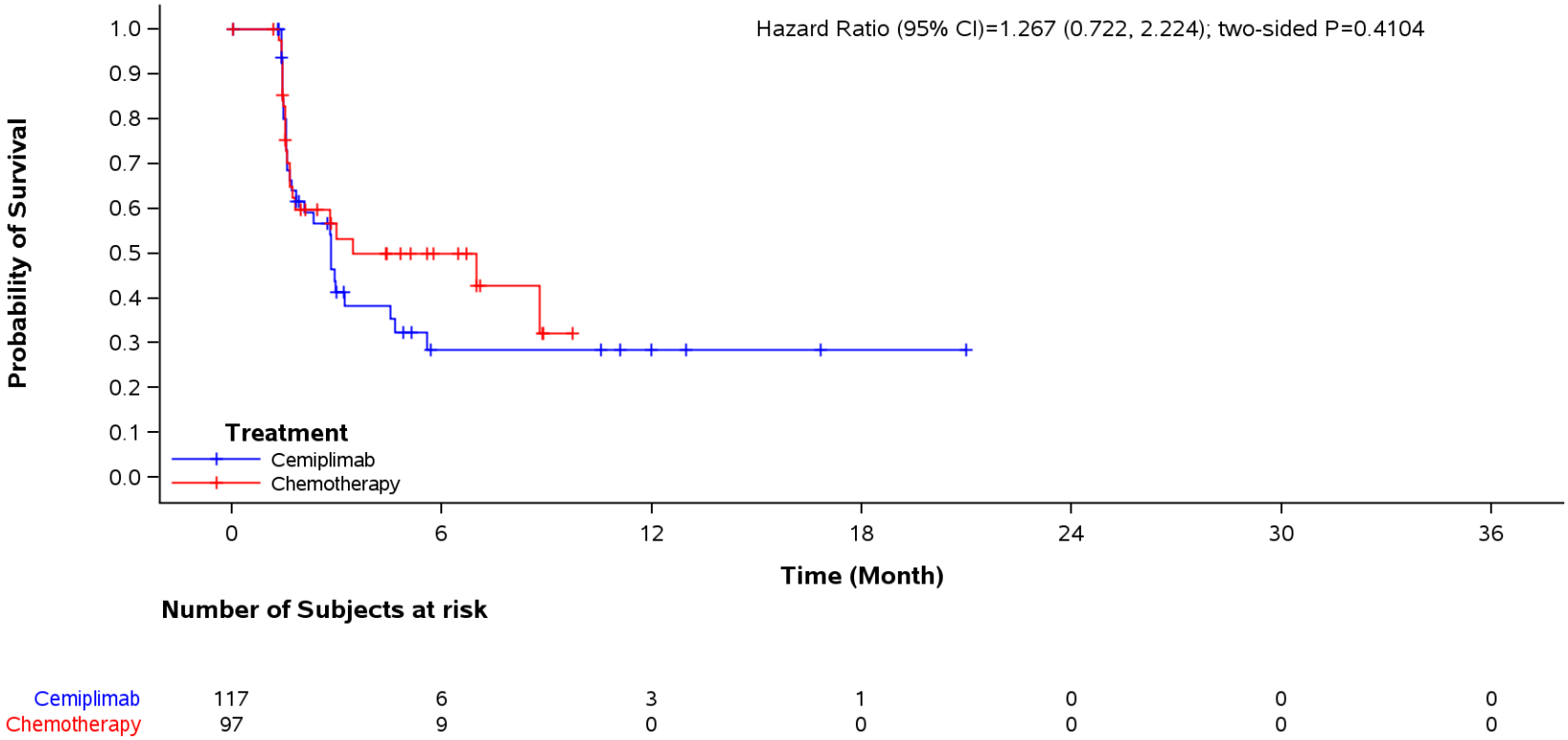

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 13 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts improvement




Number of Subjects at risk

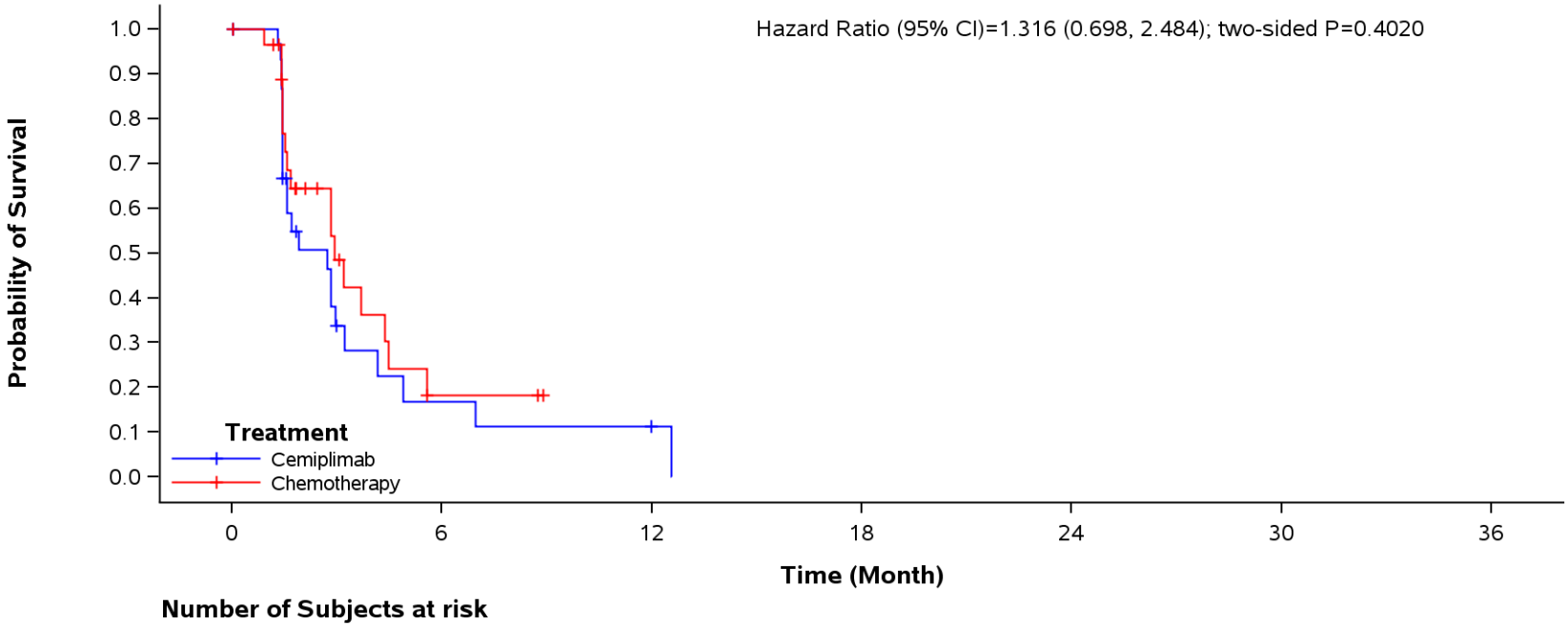
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 6 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 97 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:15:17, yingyuan.lin)

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts improvement



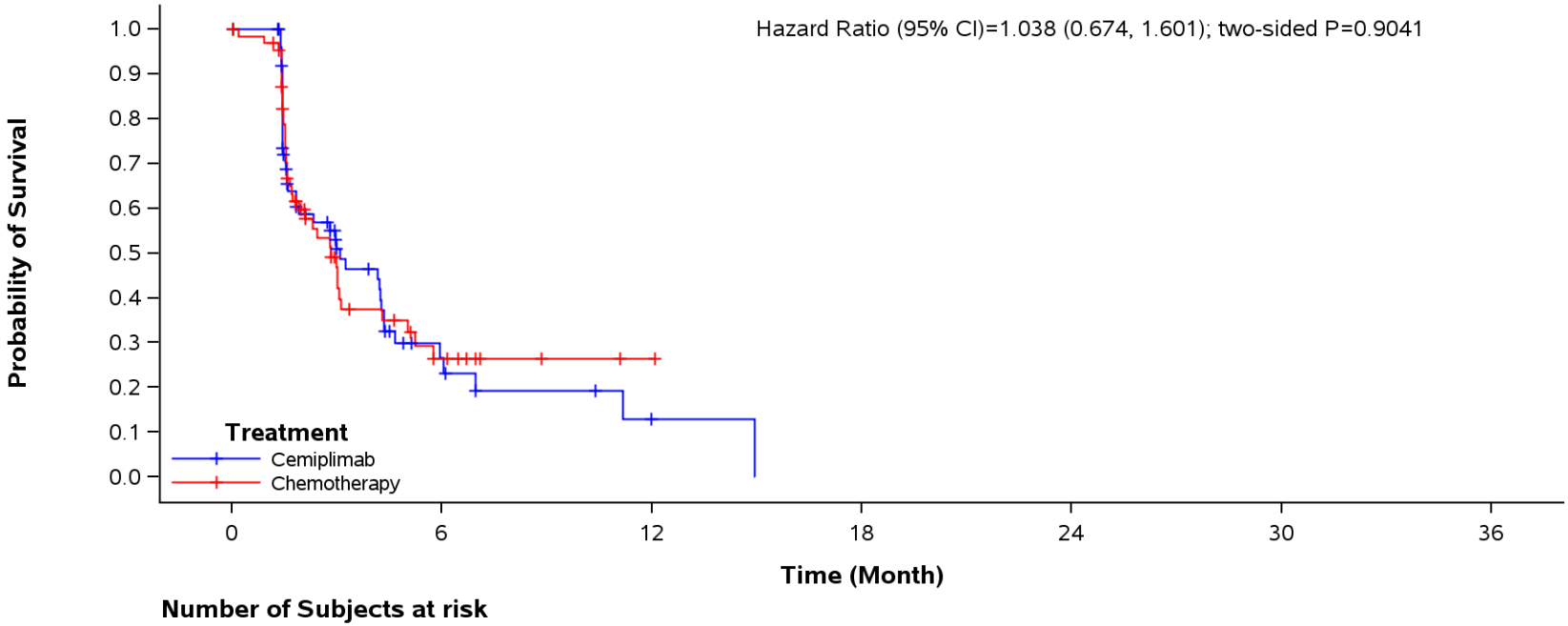

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 97 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Pain - 10 pts improvement



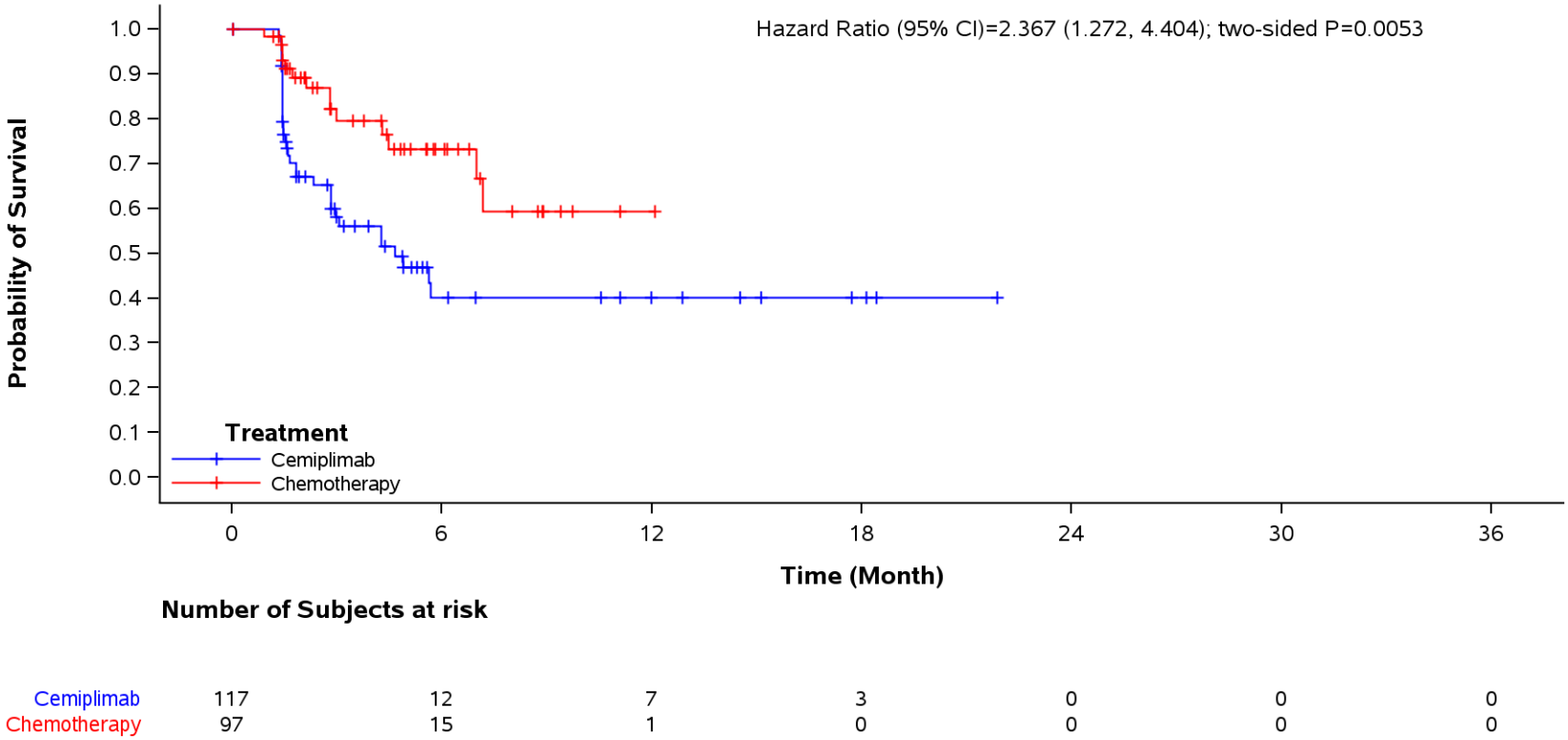

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 8 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 97 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

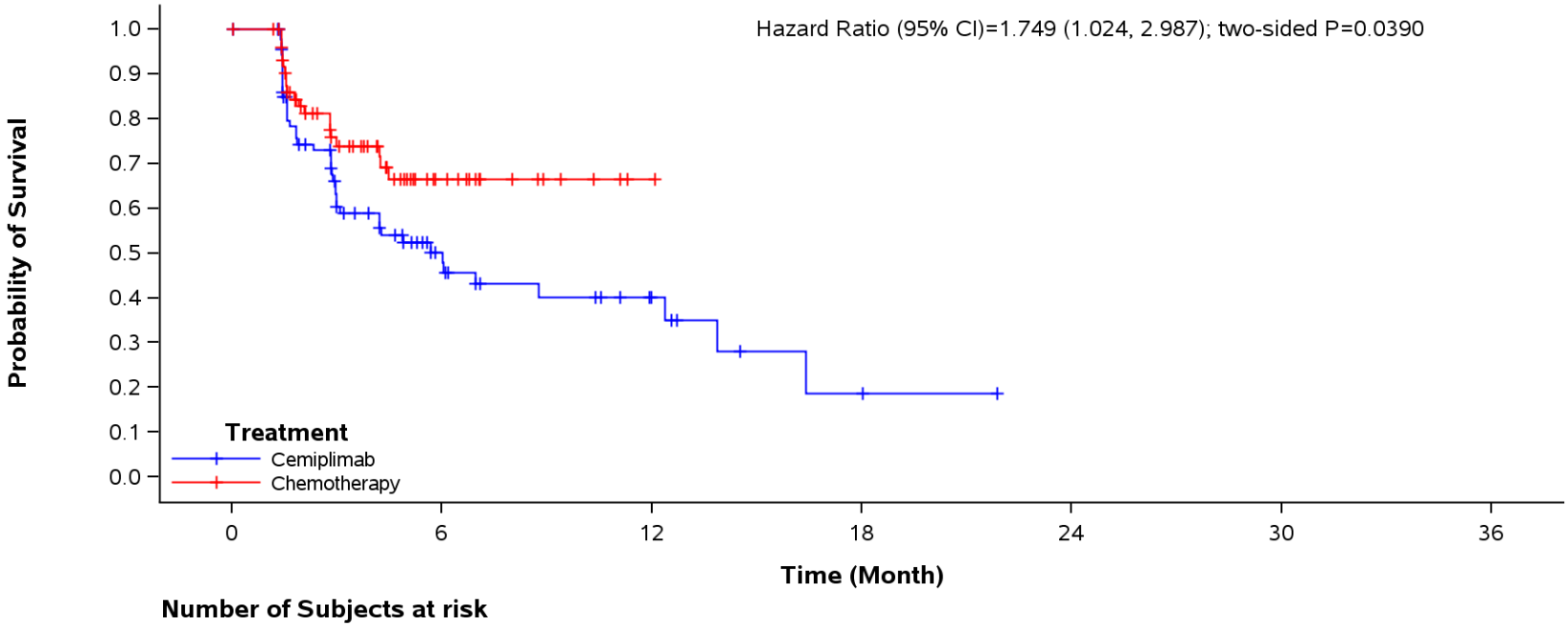
Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Physical Functioning - 10 pts improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts improvement



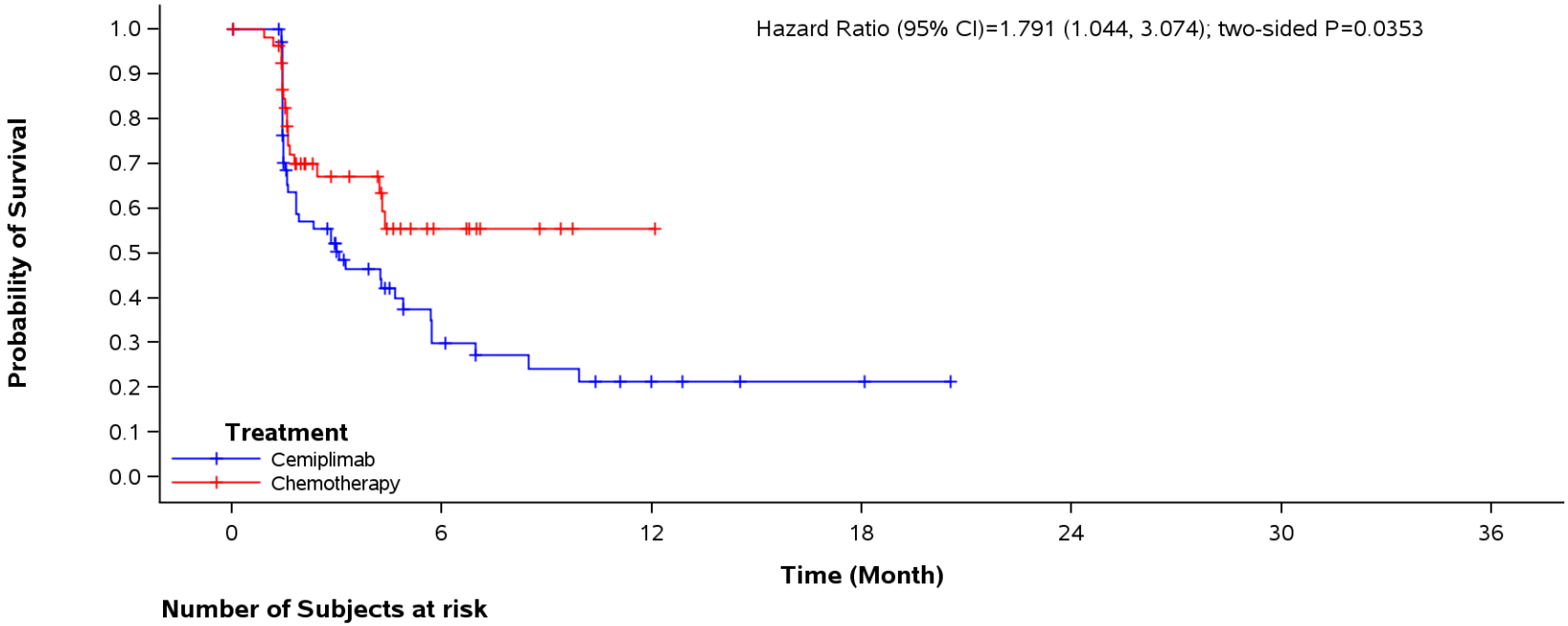

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 22 | 8 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts improvement



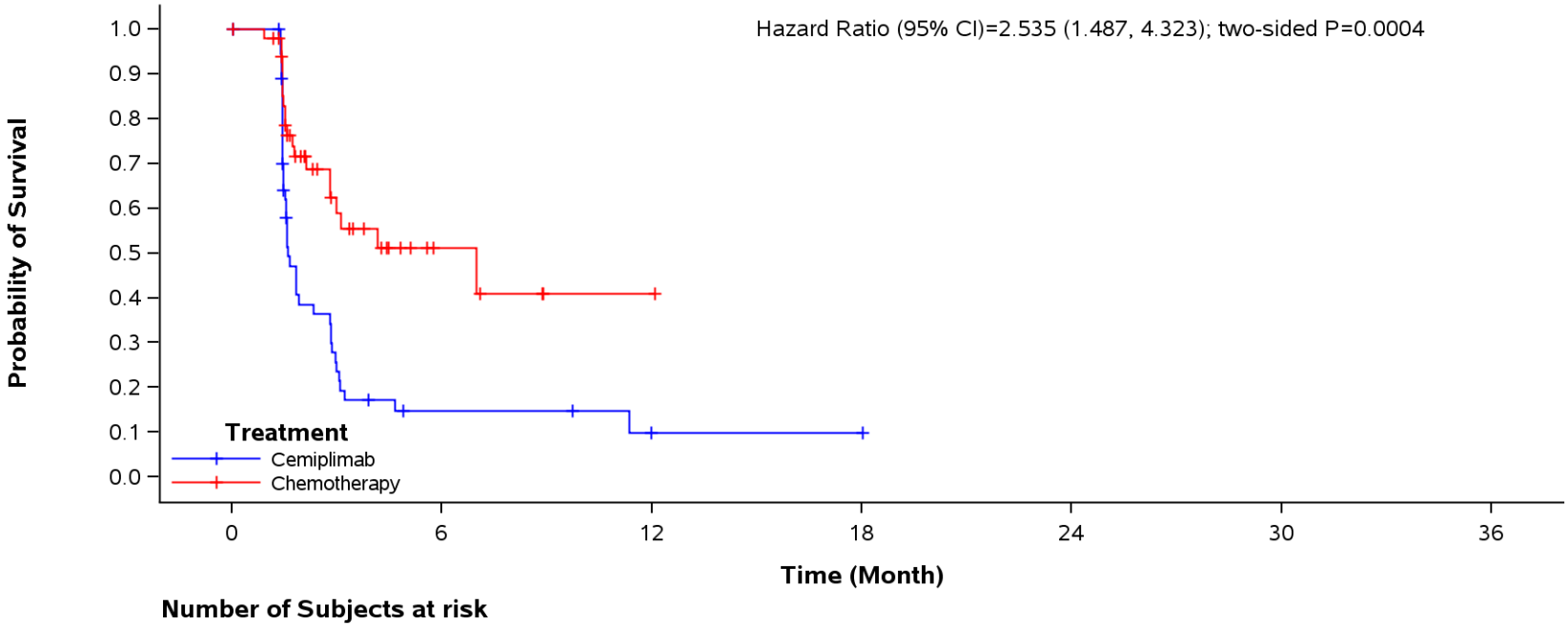

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 12 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts improvement



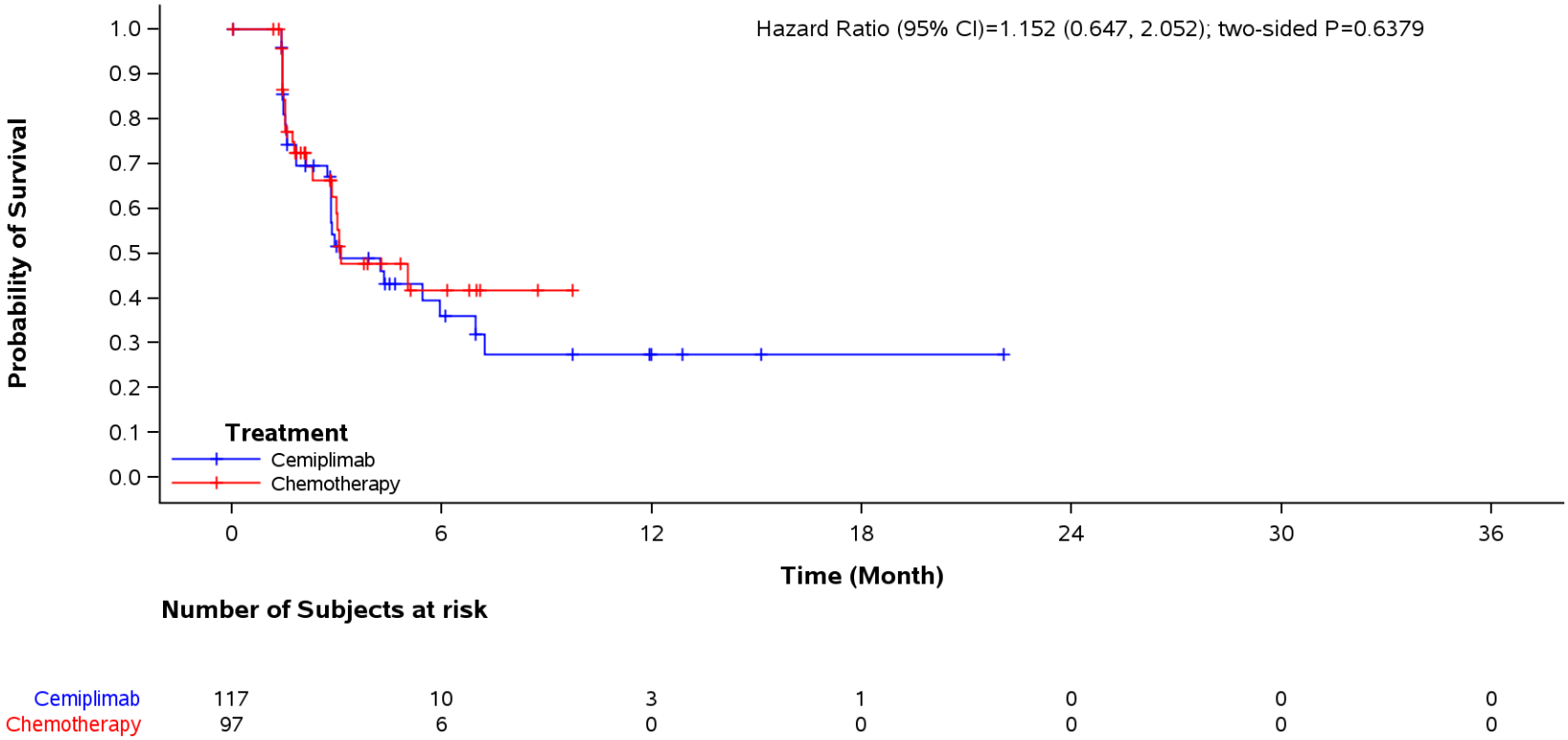

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 4 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 97 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts improvement



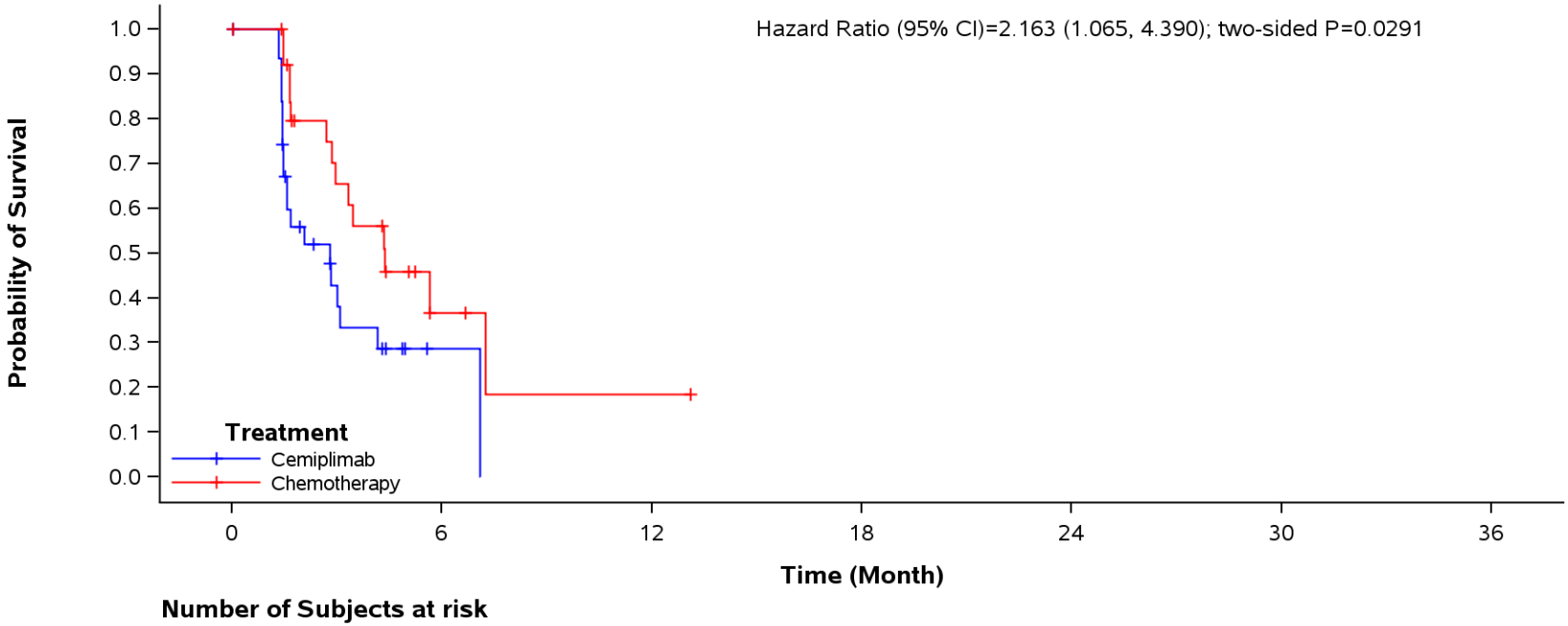

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 10 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 97 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts improvement



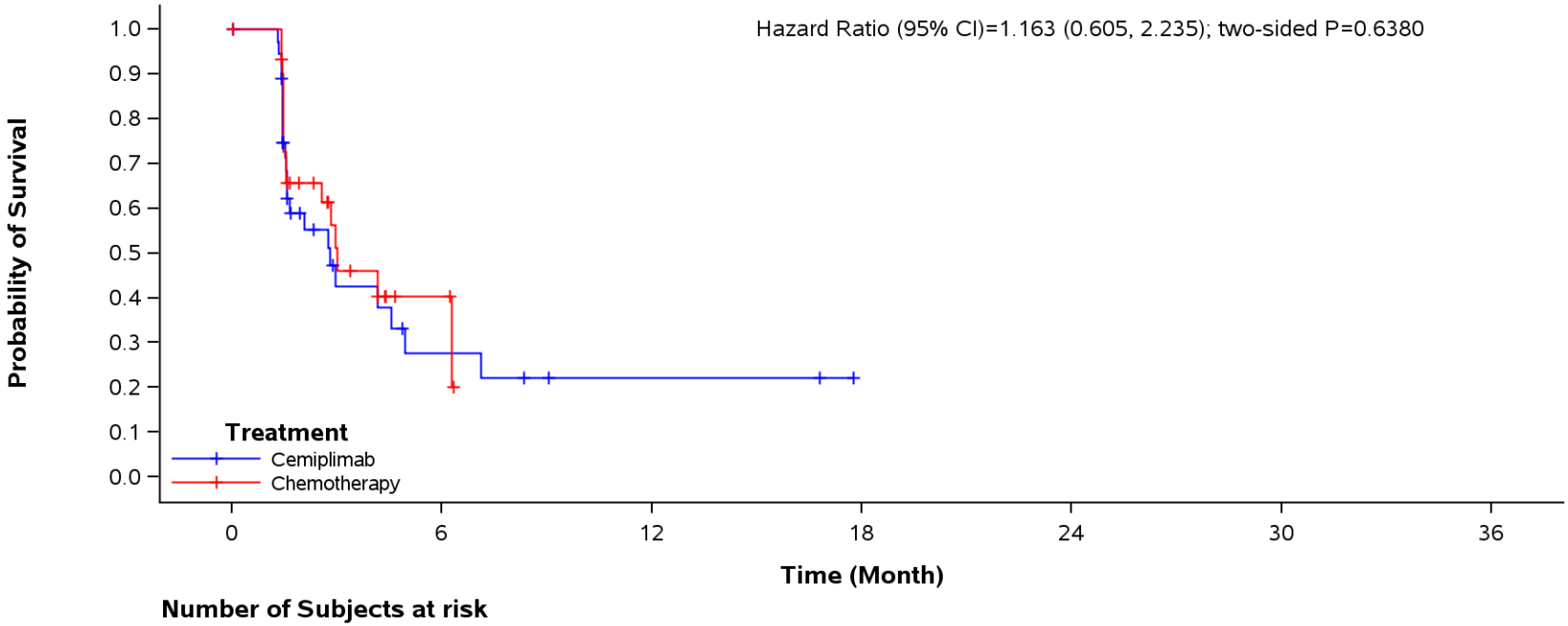

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts improvement



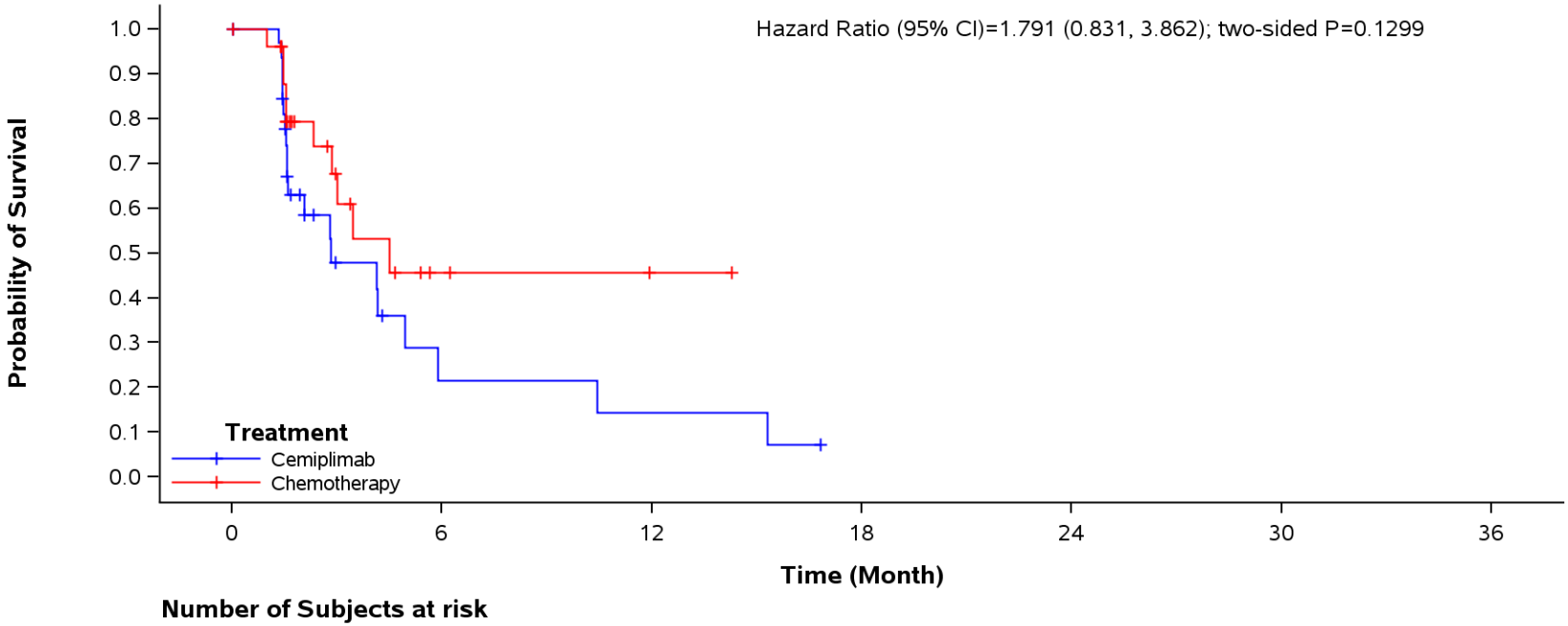

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts improvement



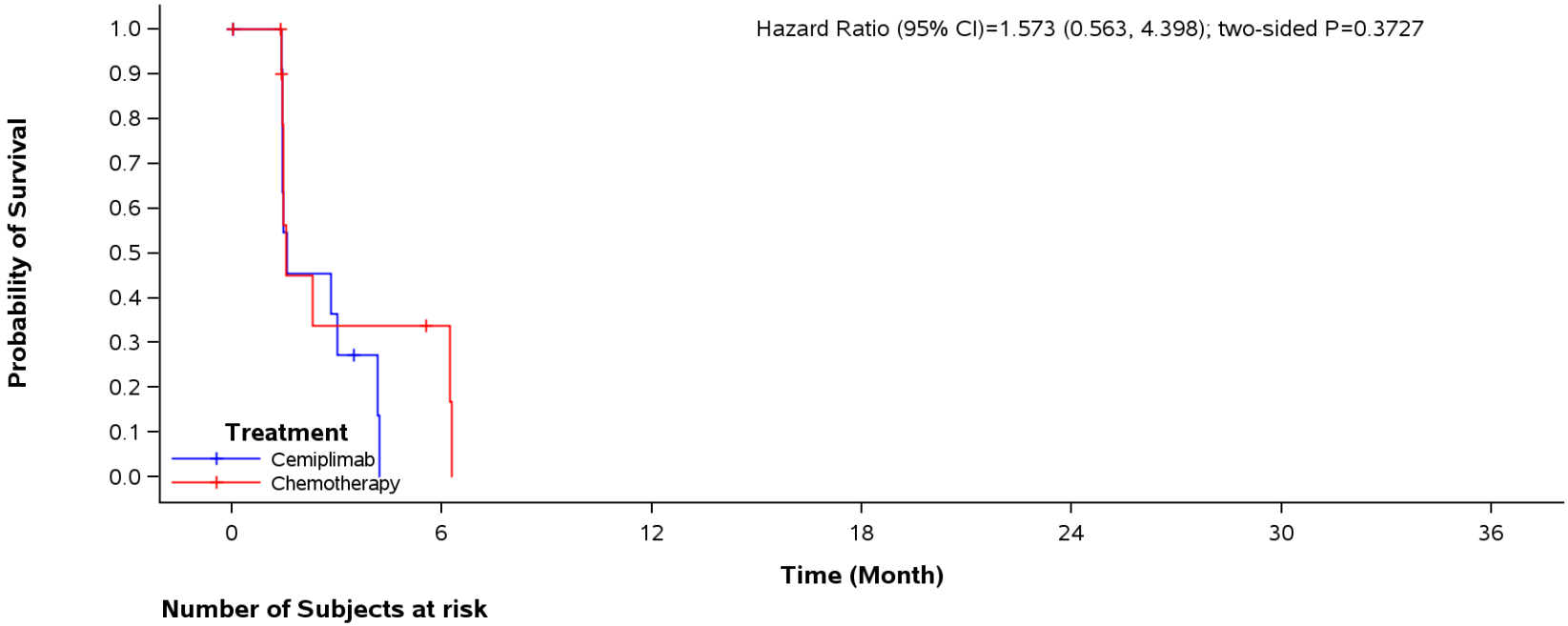

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts improvement



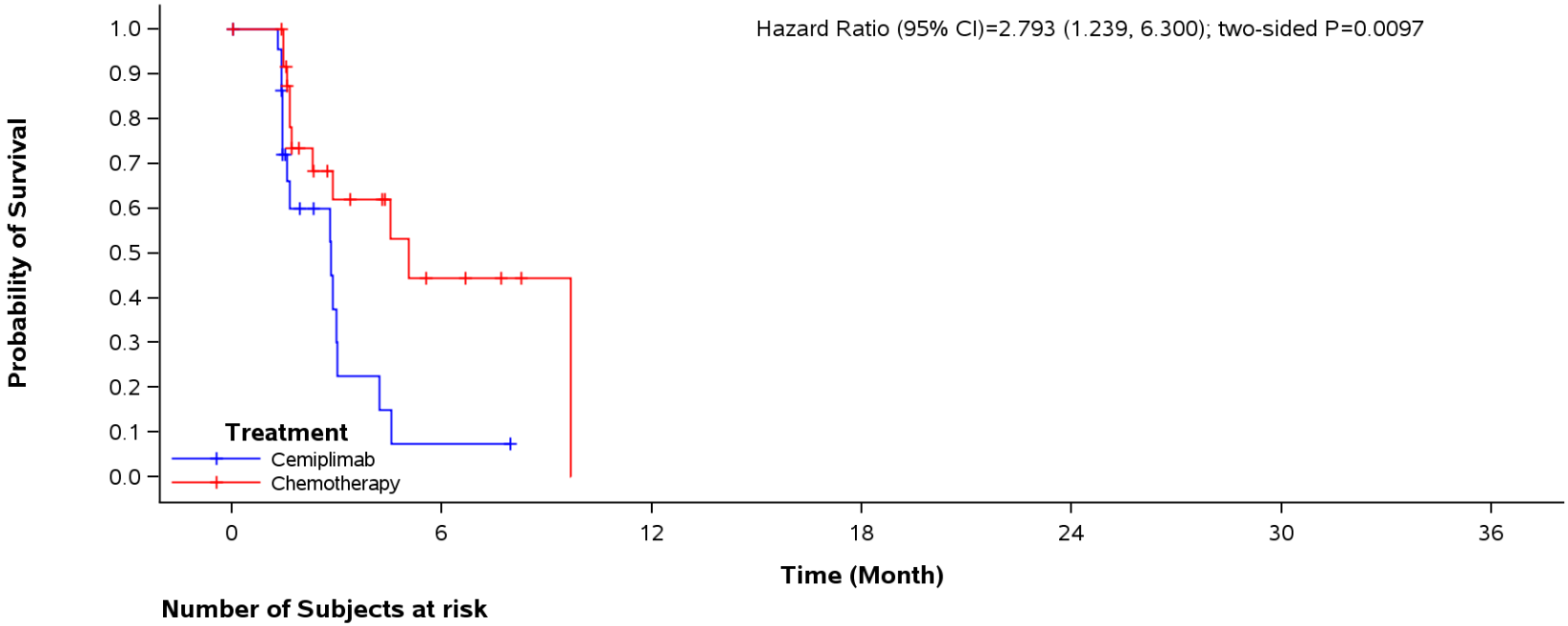

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts improvement



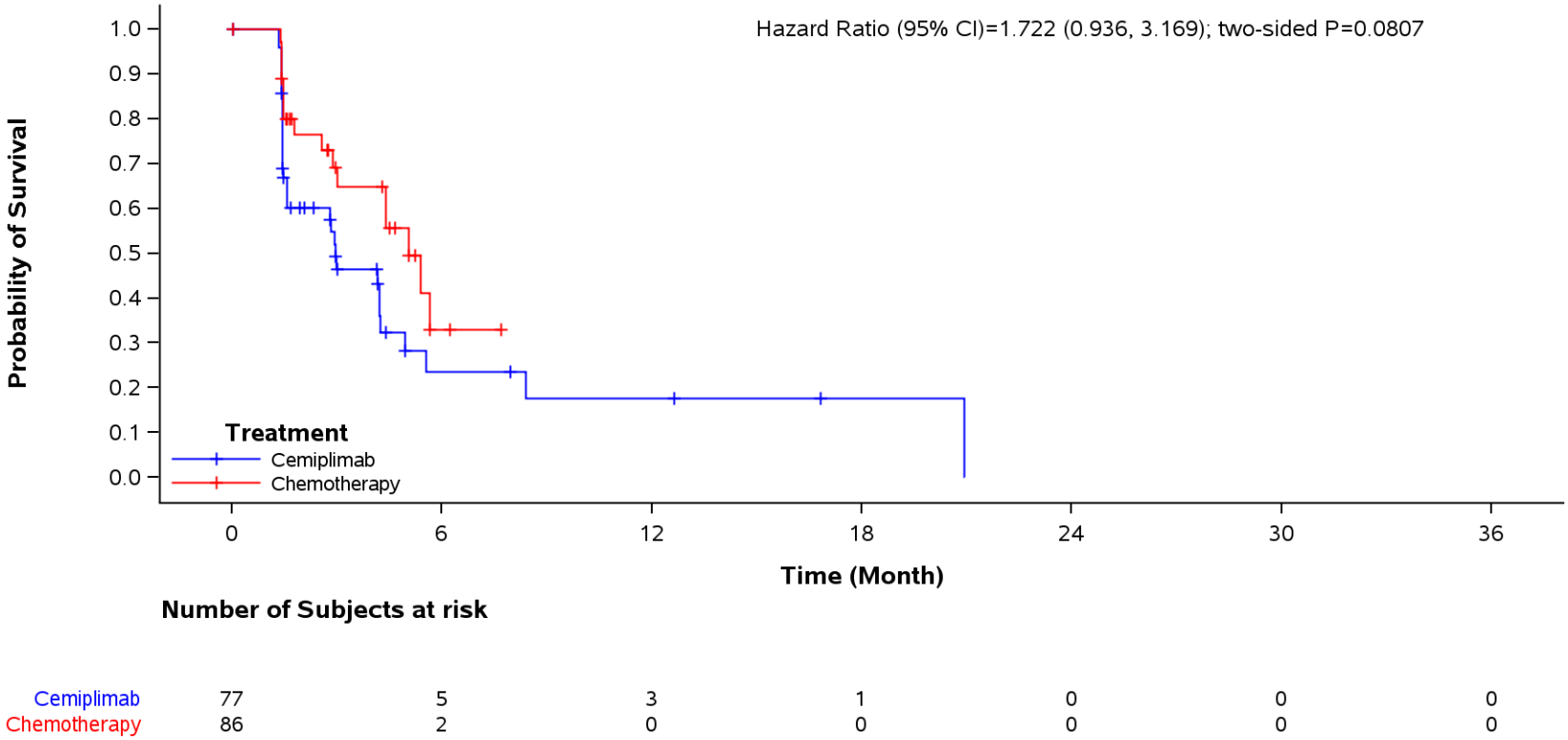

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

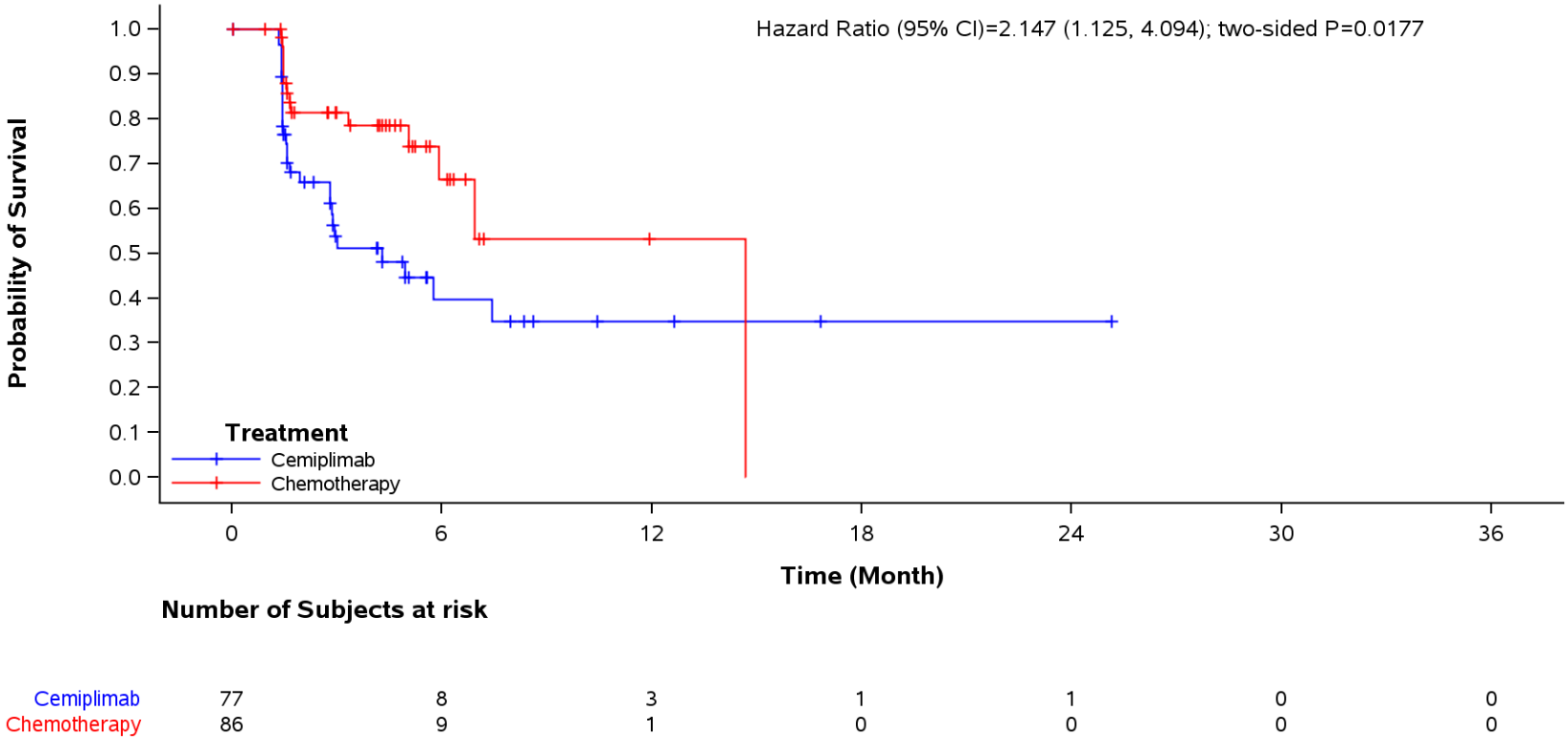
Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

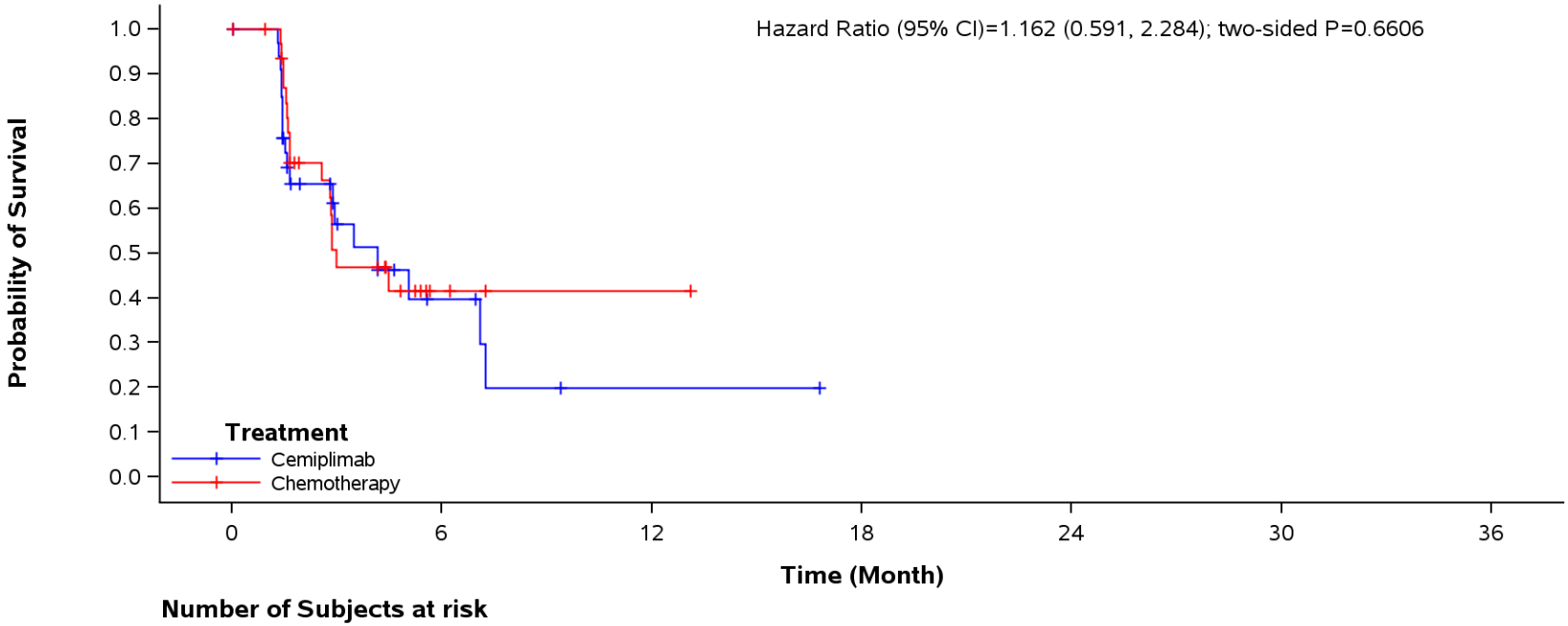
Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts improvement



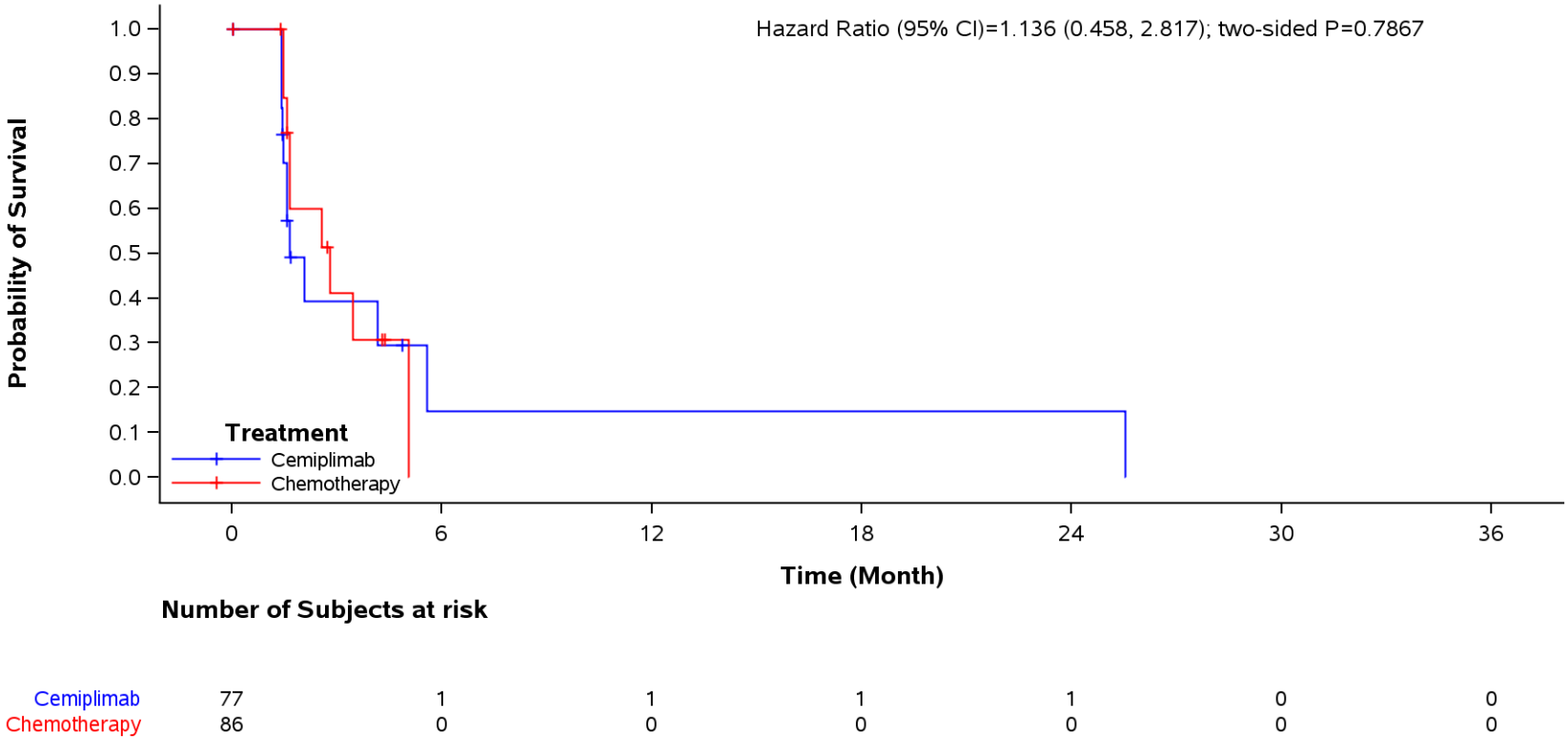

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

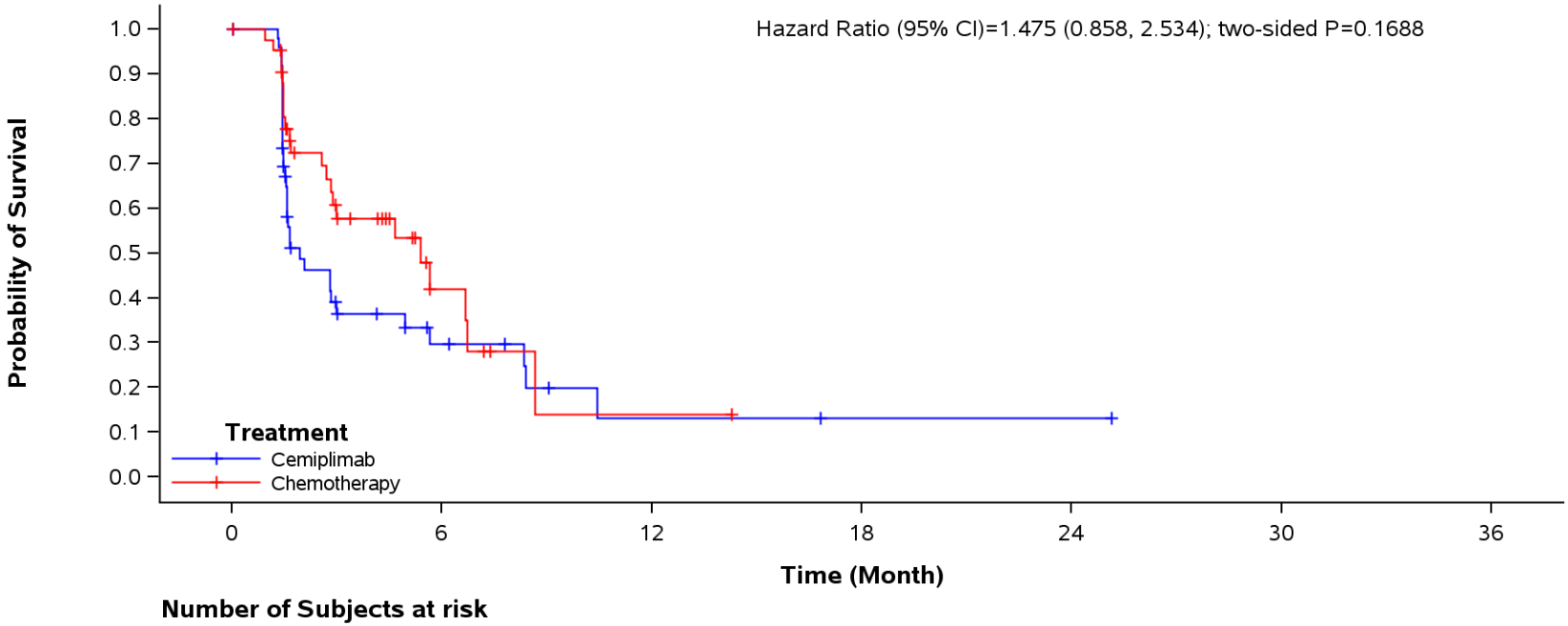
Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts improvement



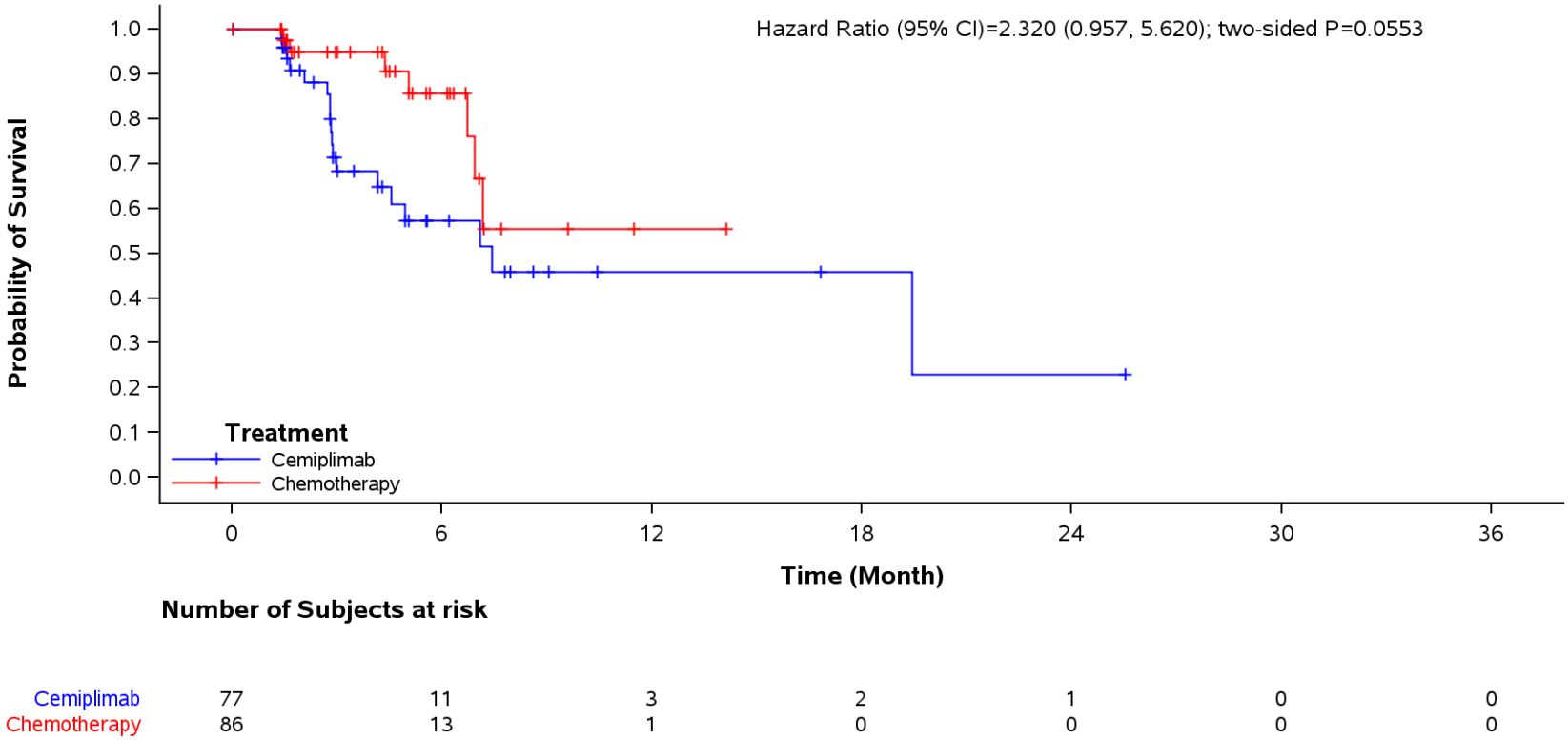

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 8 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 86 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts improvement



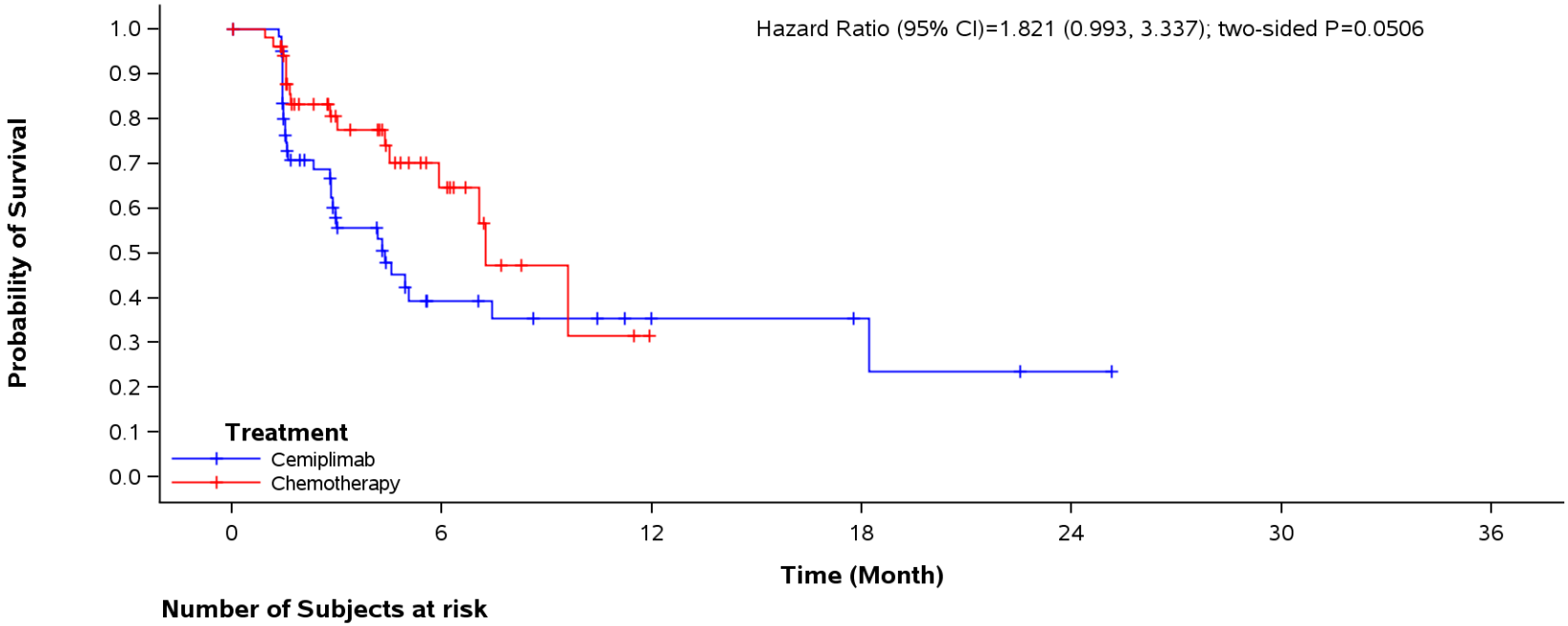

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 11 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 86 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts improvement



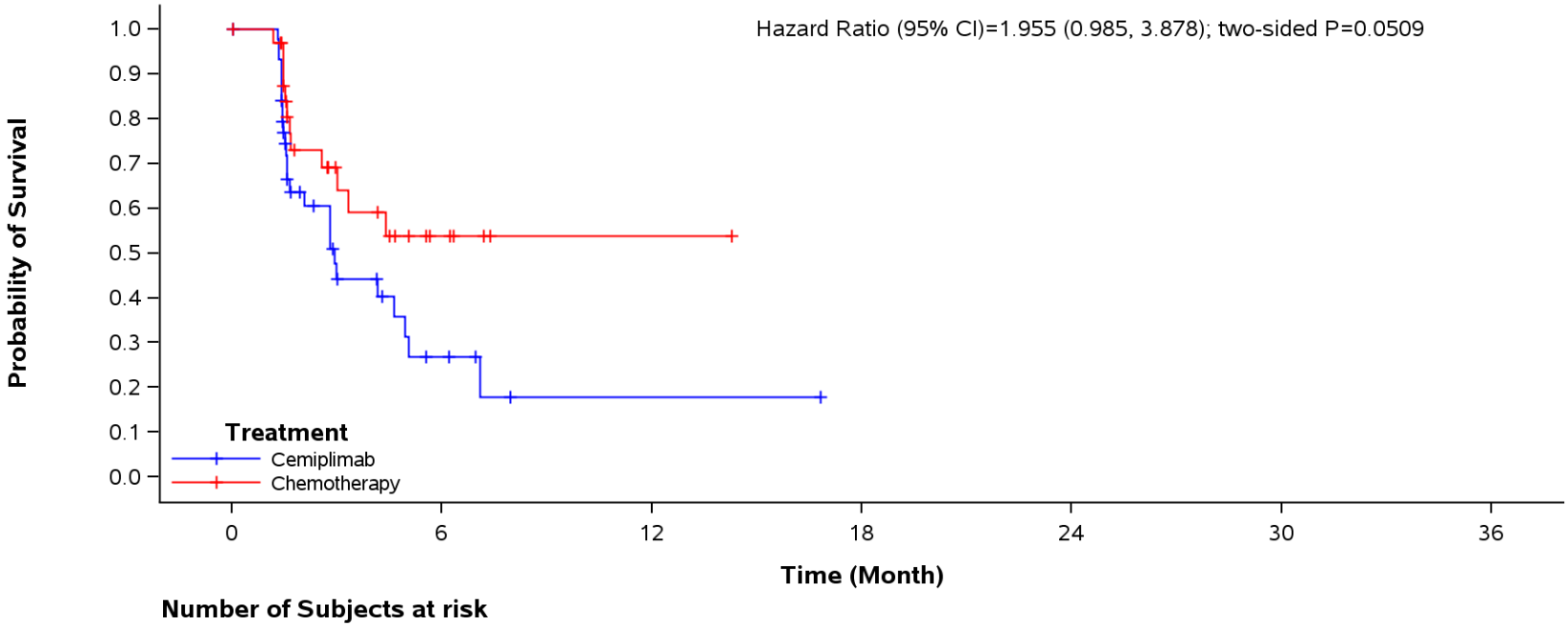

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 11 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 86 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts improvement



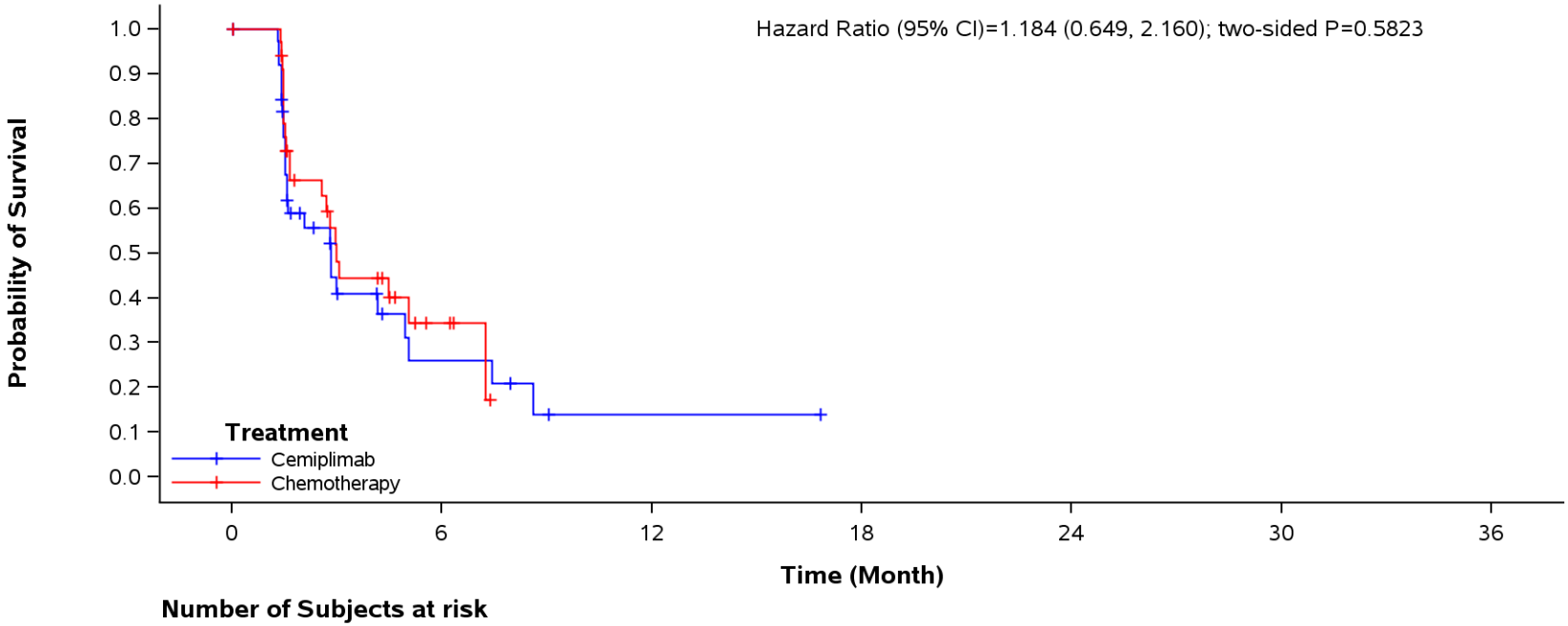

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts improvement




Number of Subjects at risk

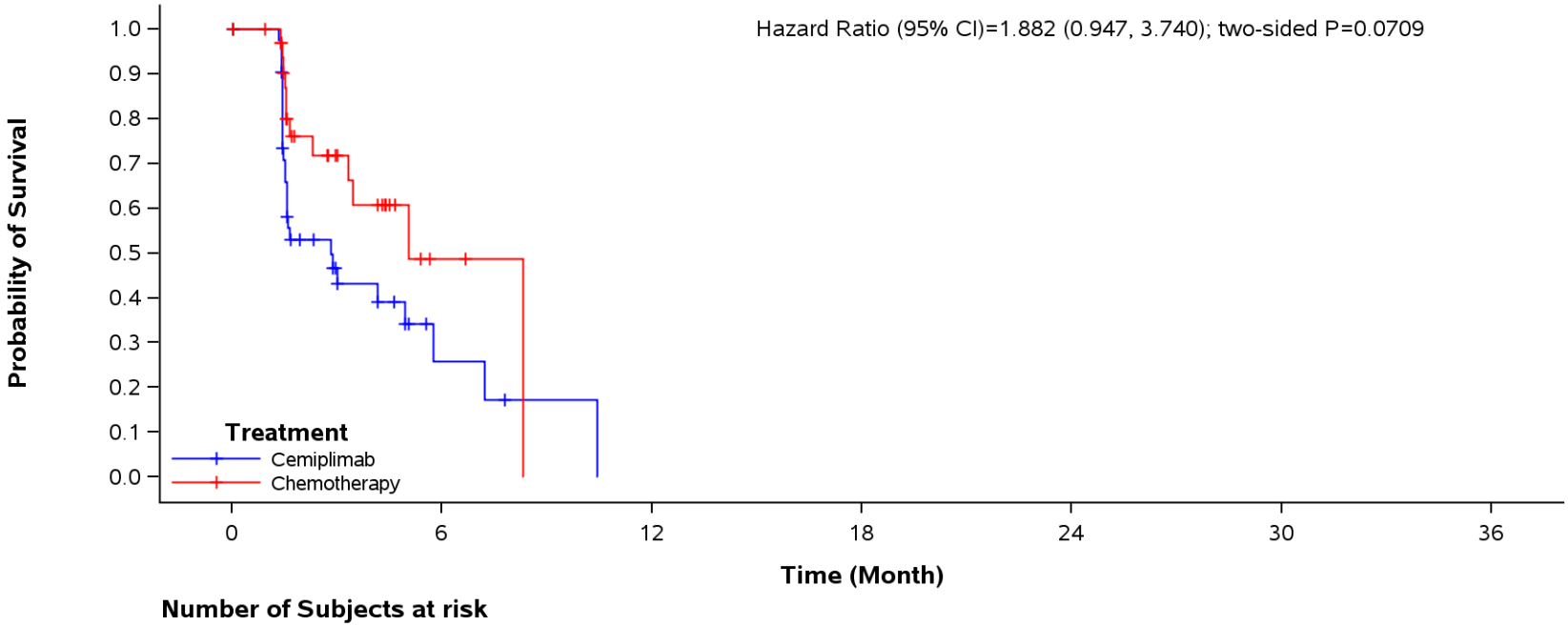
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:15:17, yingyuan.lin)

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts improvement



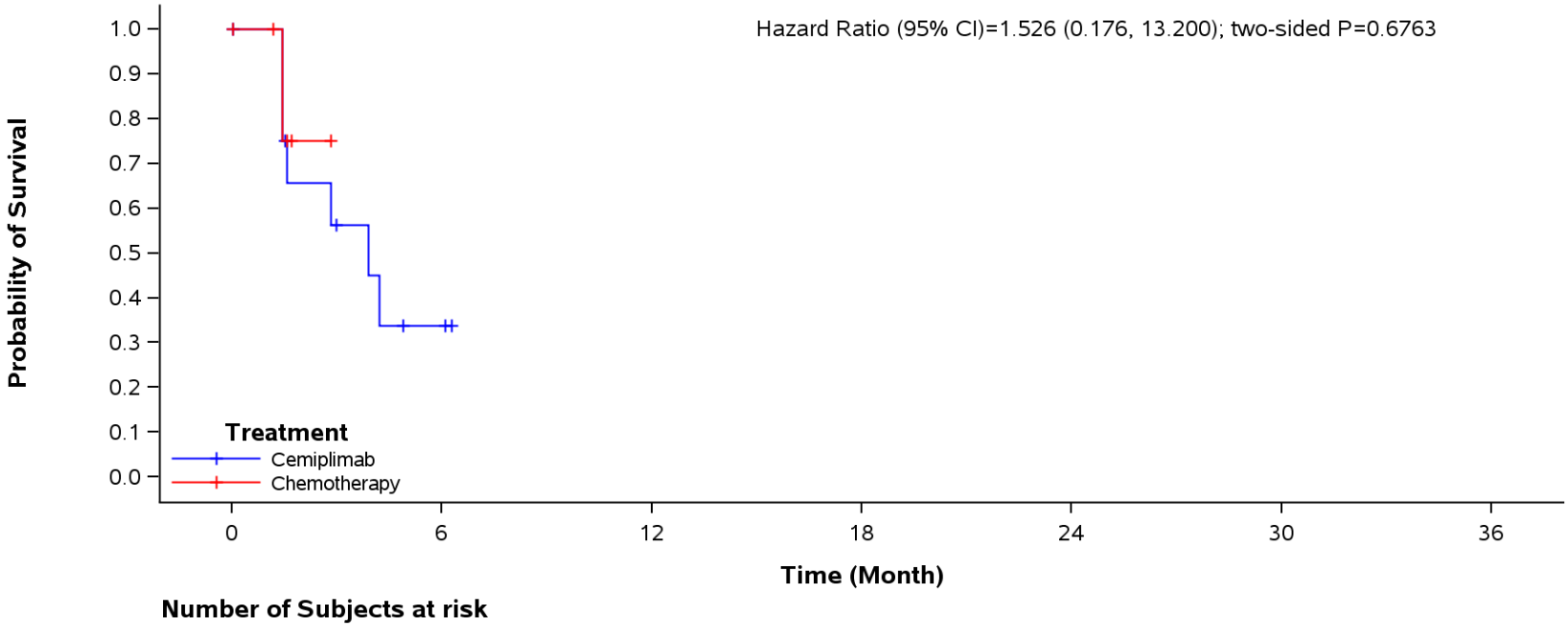

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts improvement



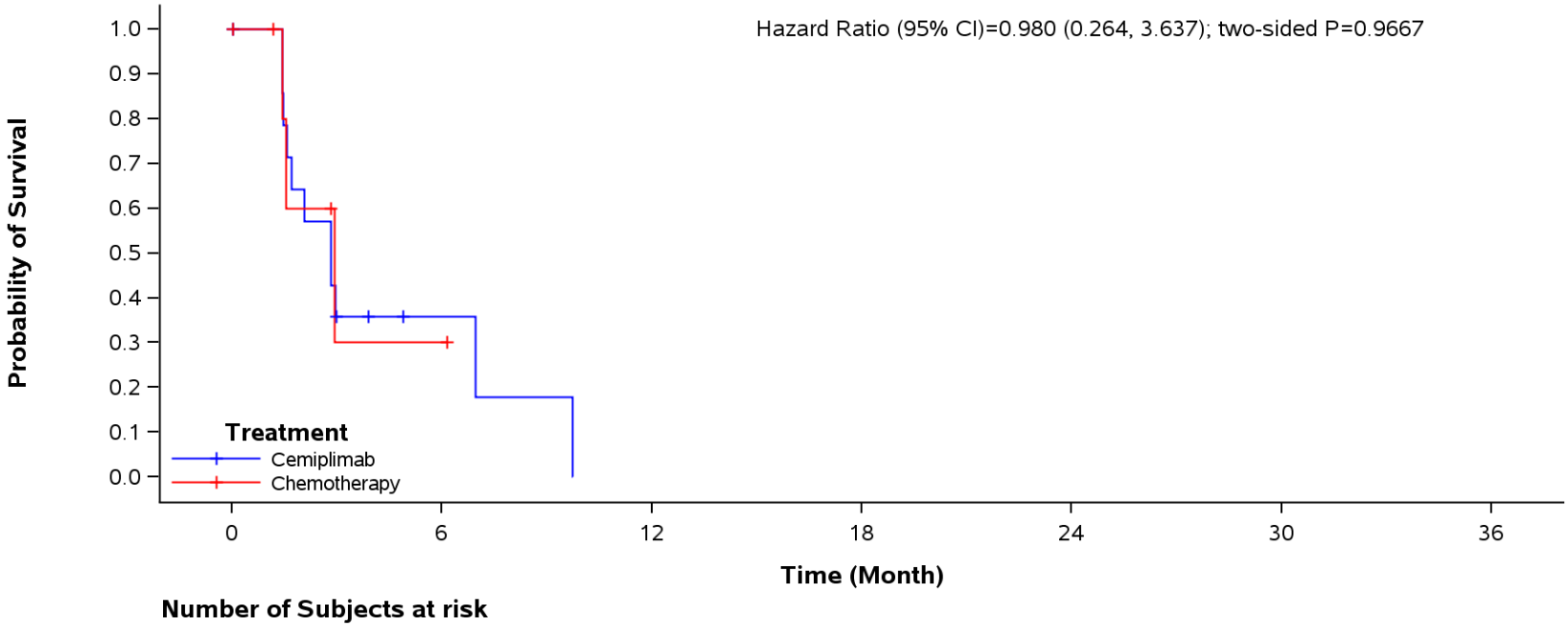

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts improvement



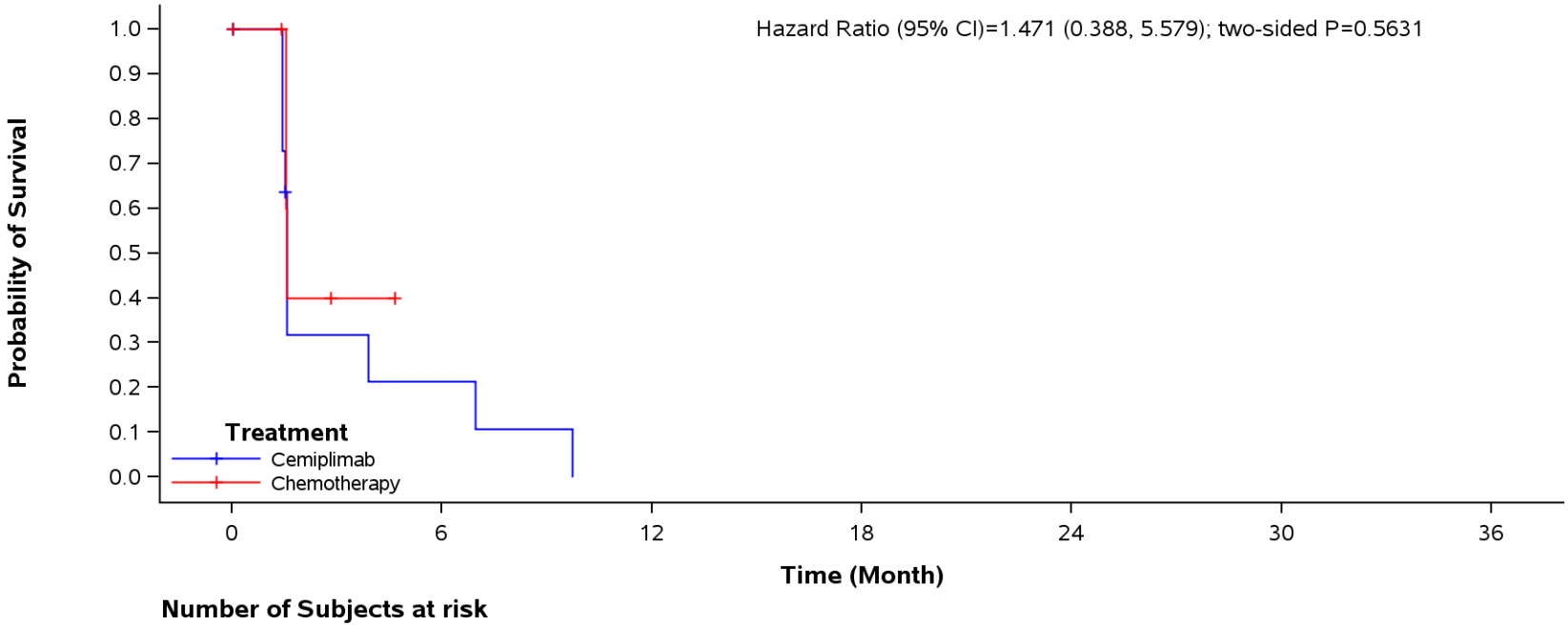

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts improvement



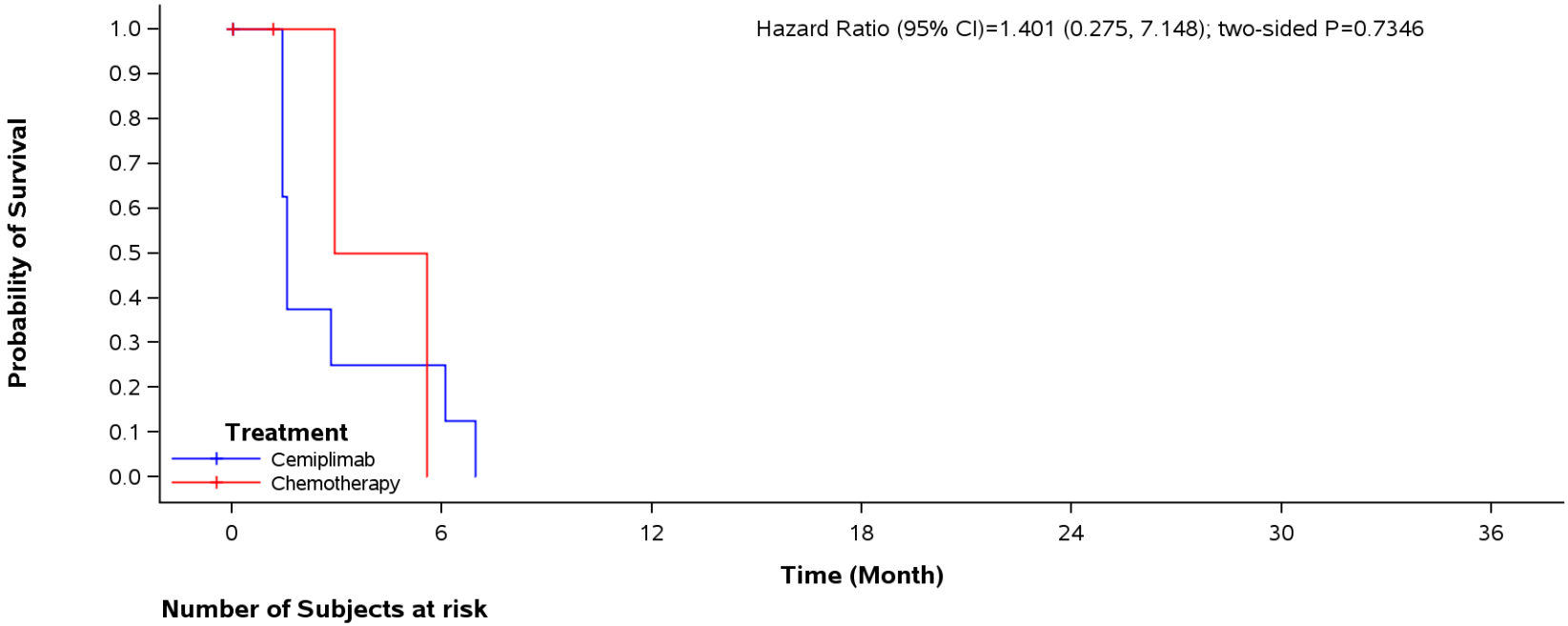

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts improvement



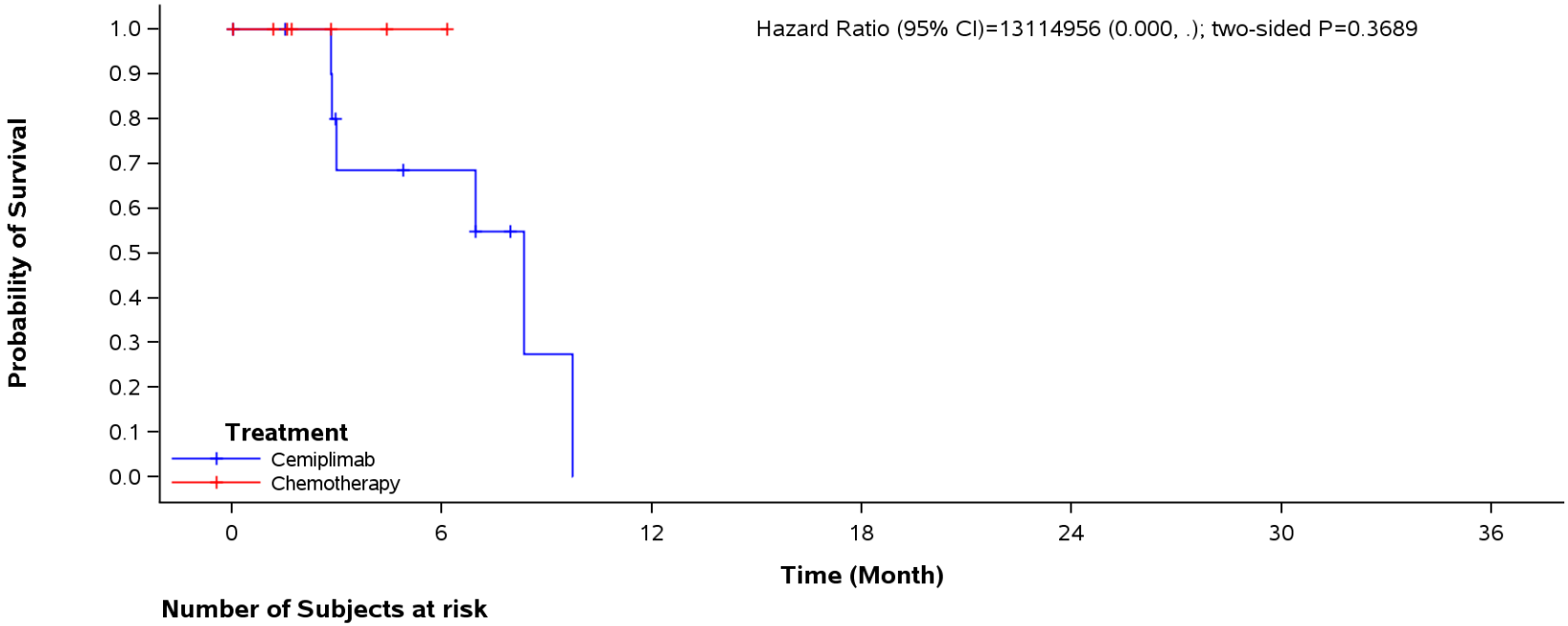

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts improvement



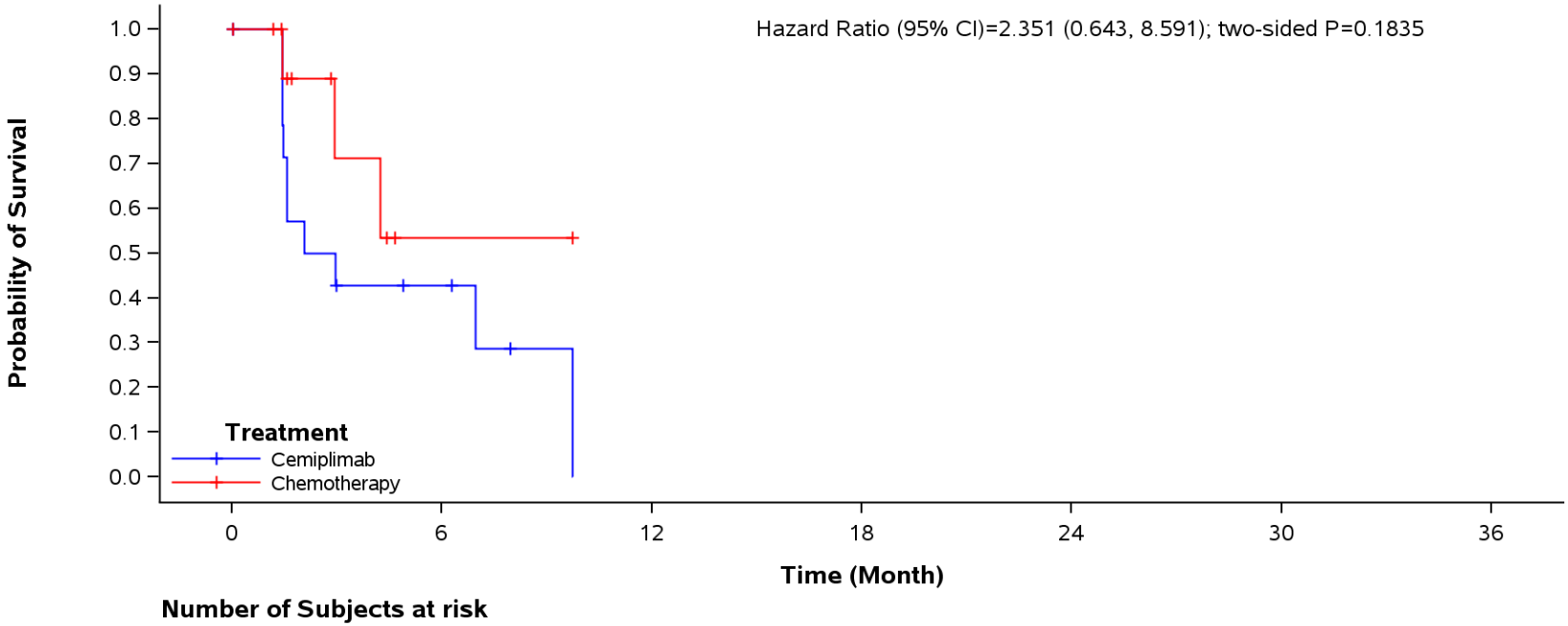

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts improvement



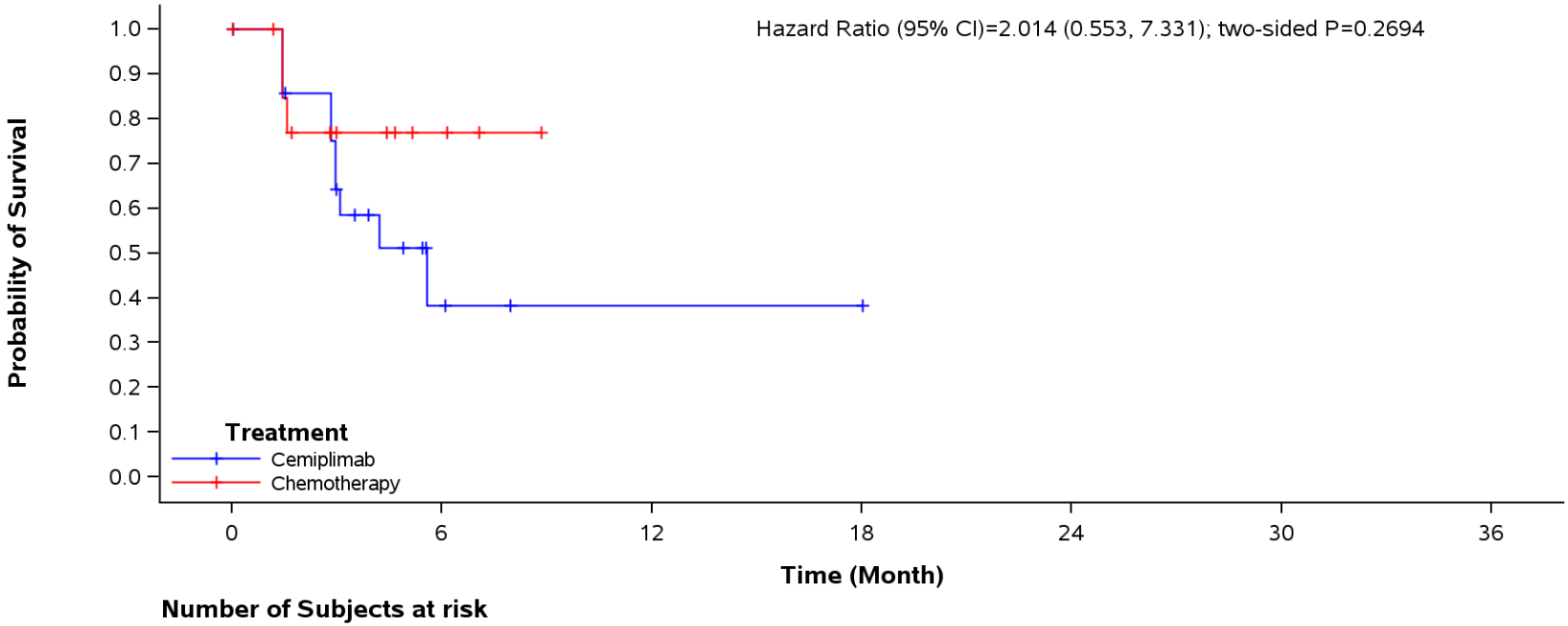

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts improvement



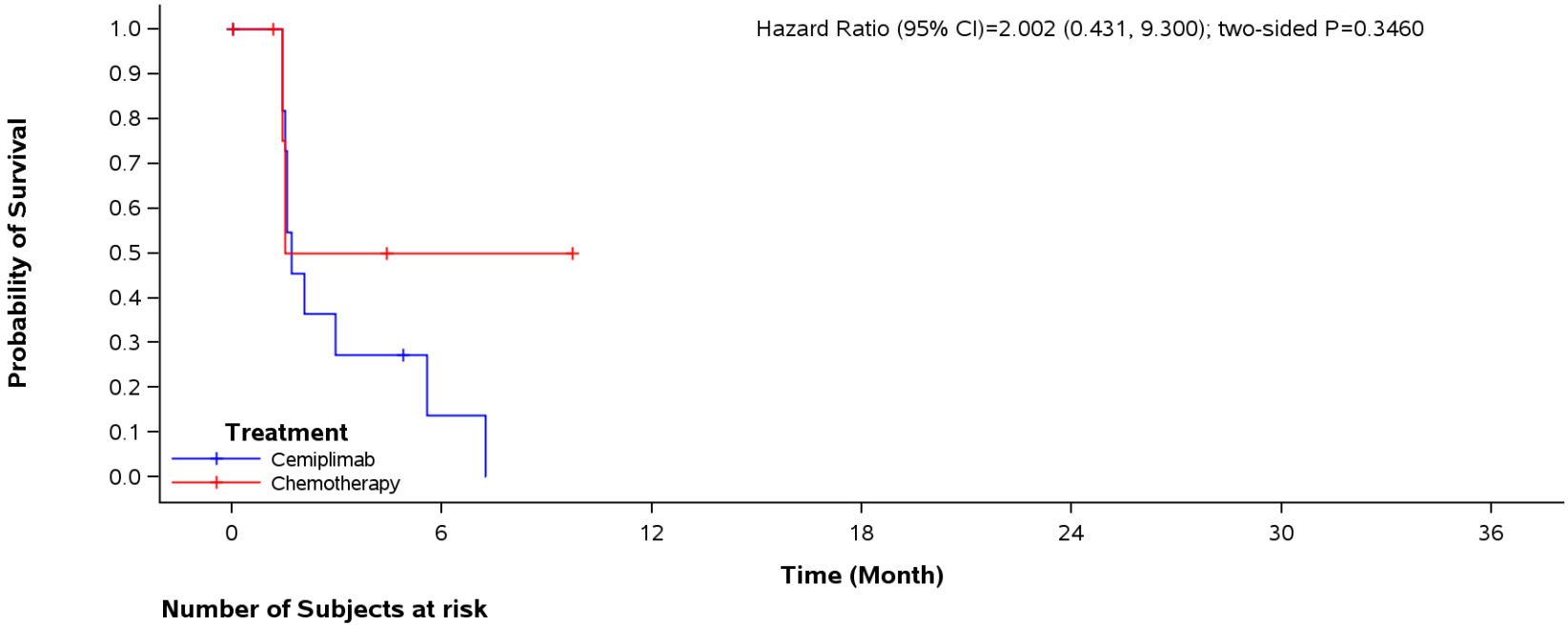

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts improvement



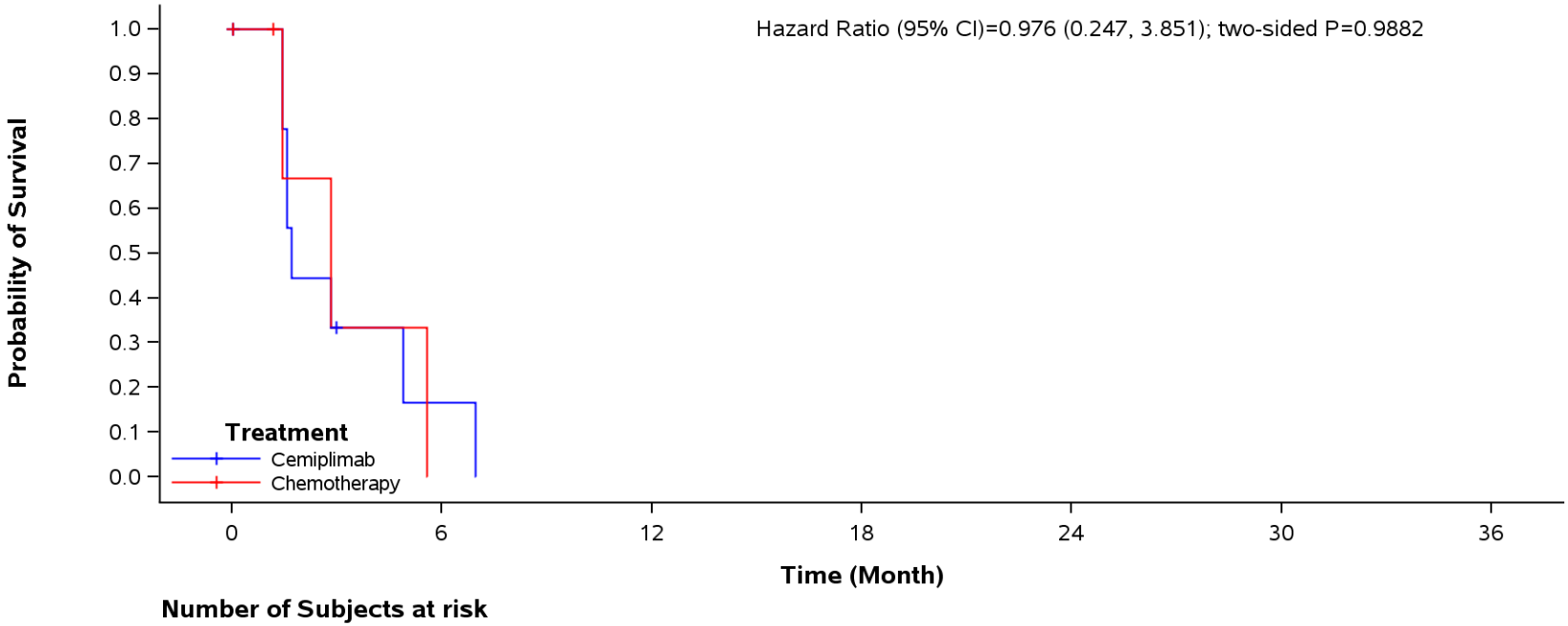

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts improvement



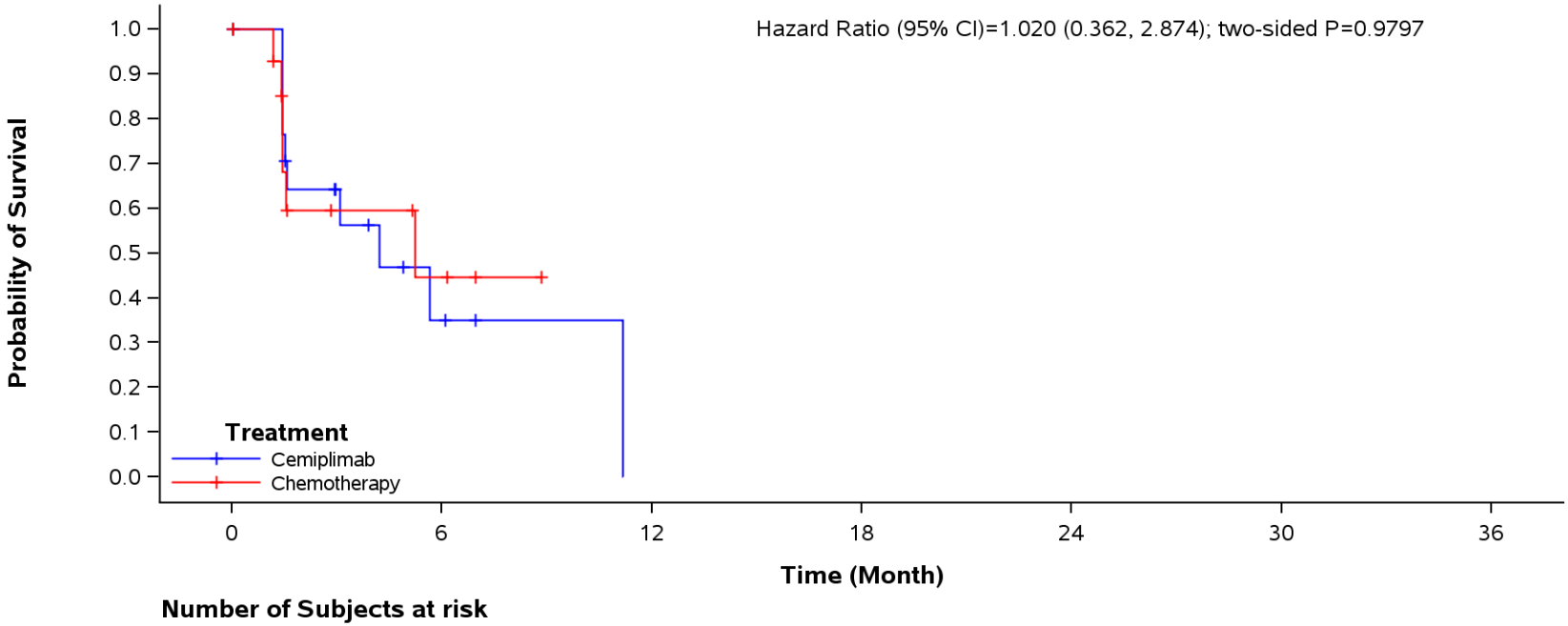

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts improvement



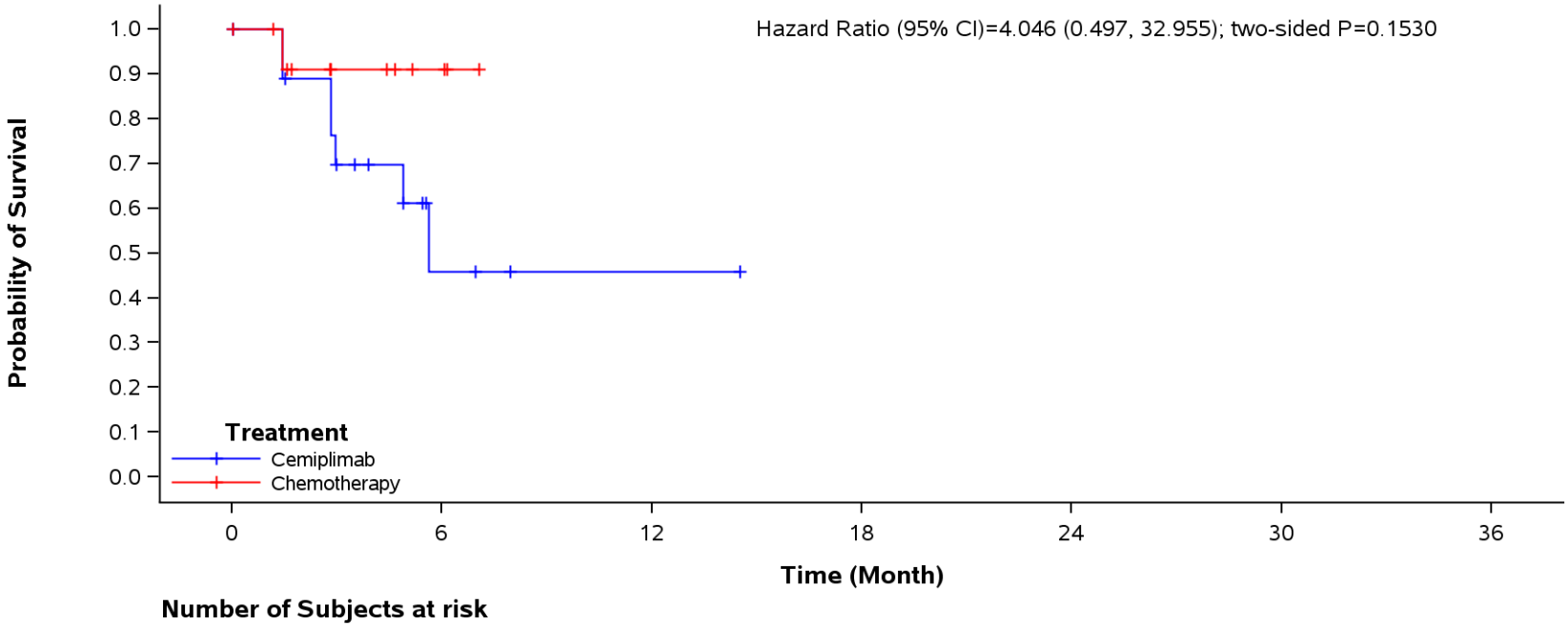

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts improvement



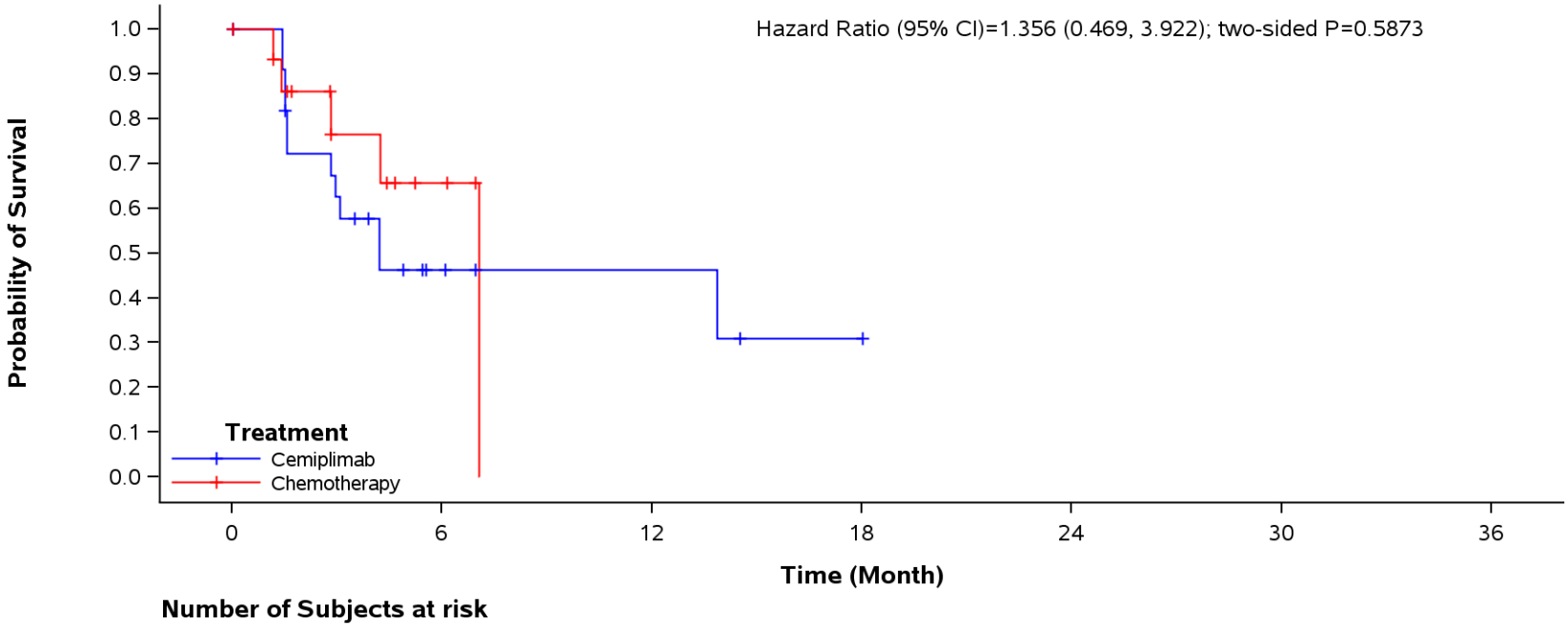

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts improvement



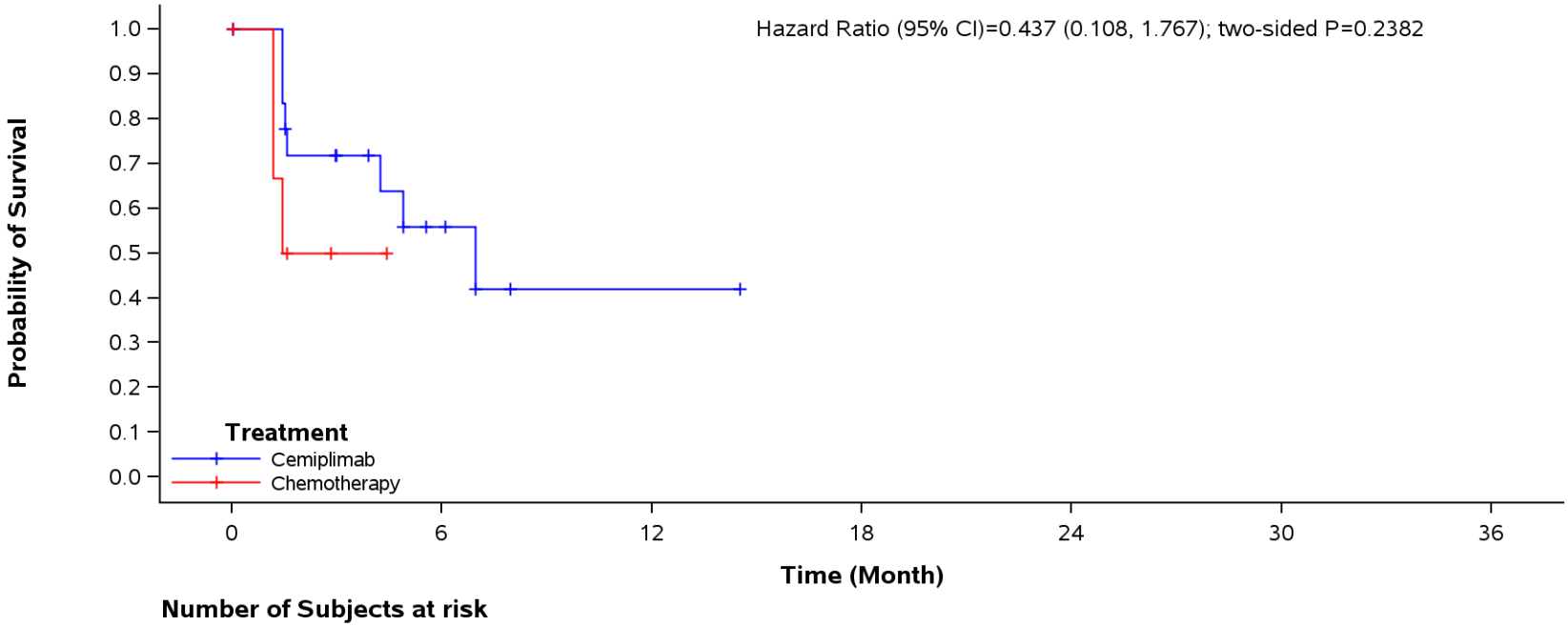

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts improvement



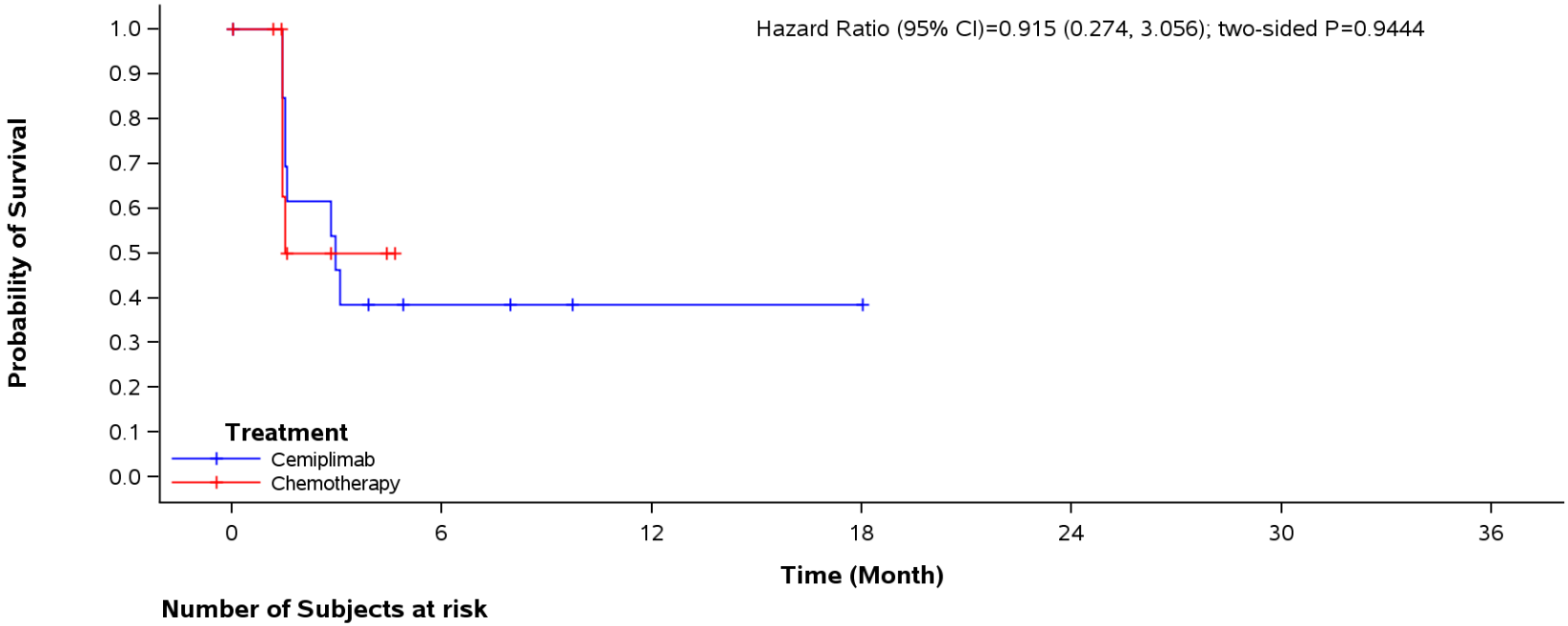

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts improvement



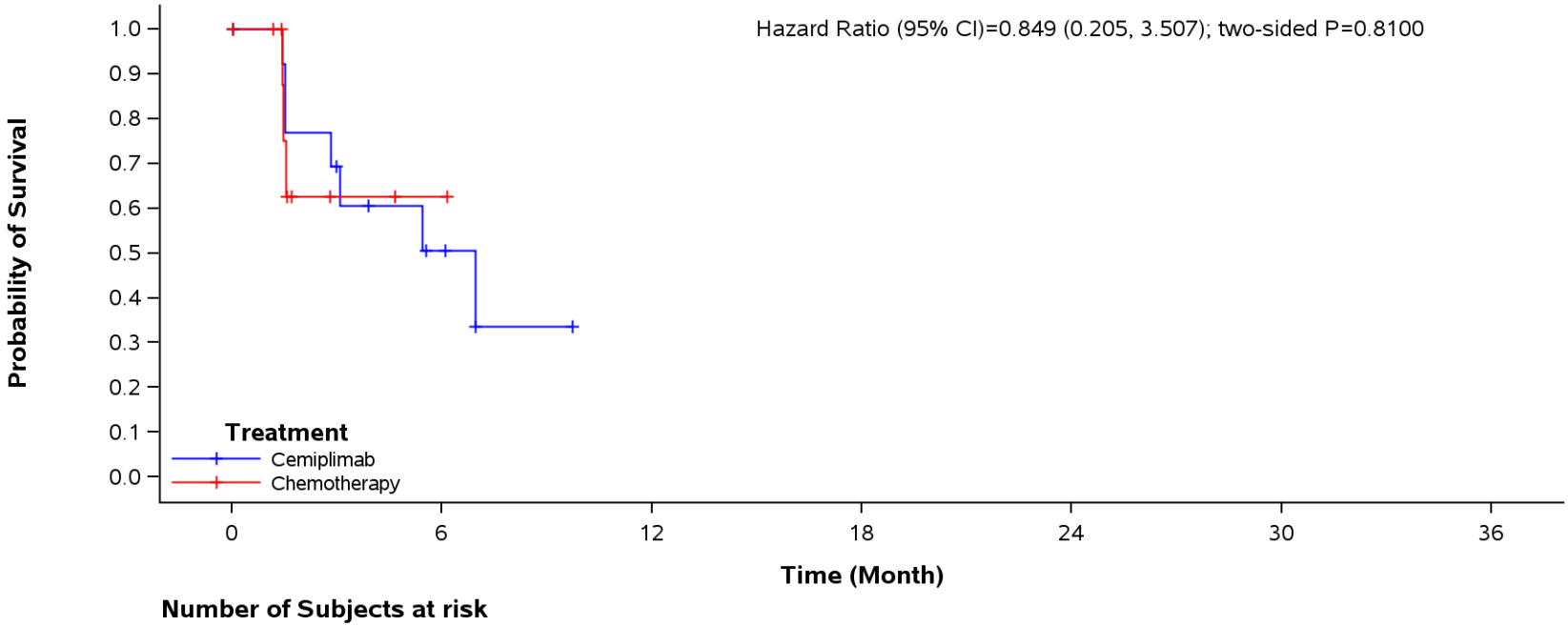

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts improvement



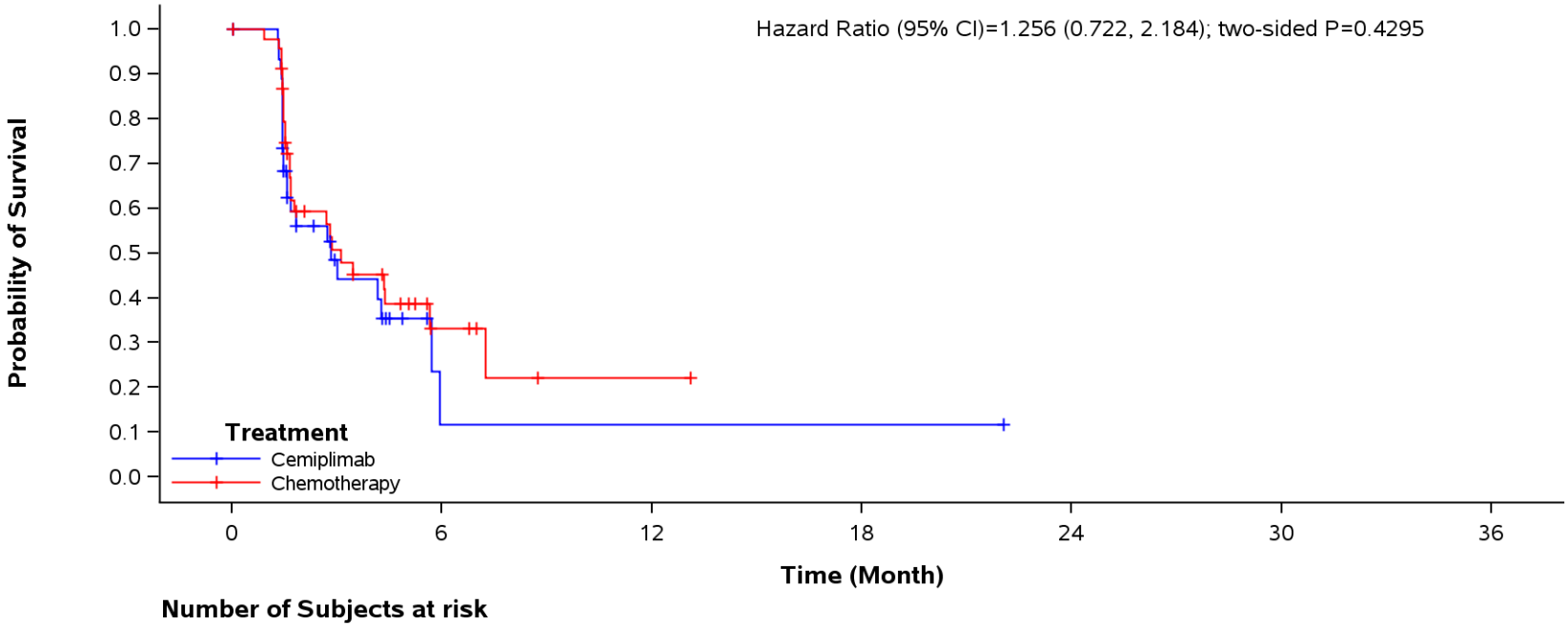

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts improvement



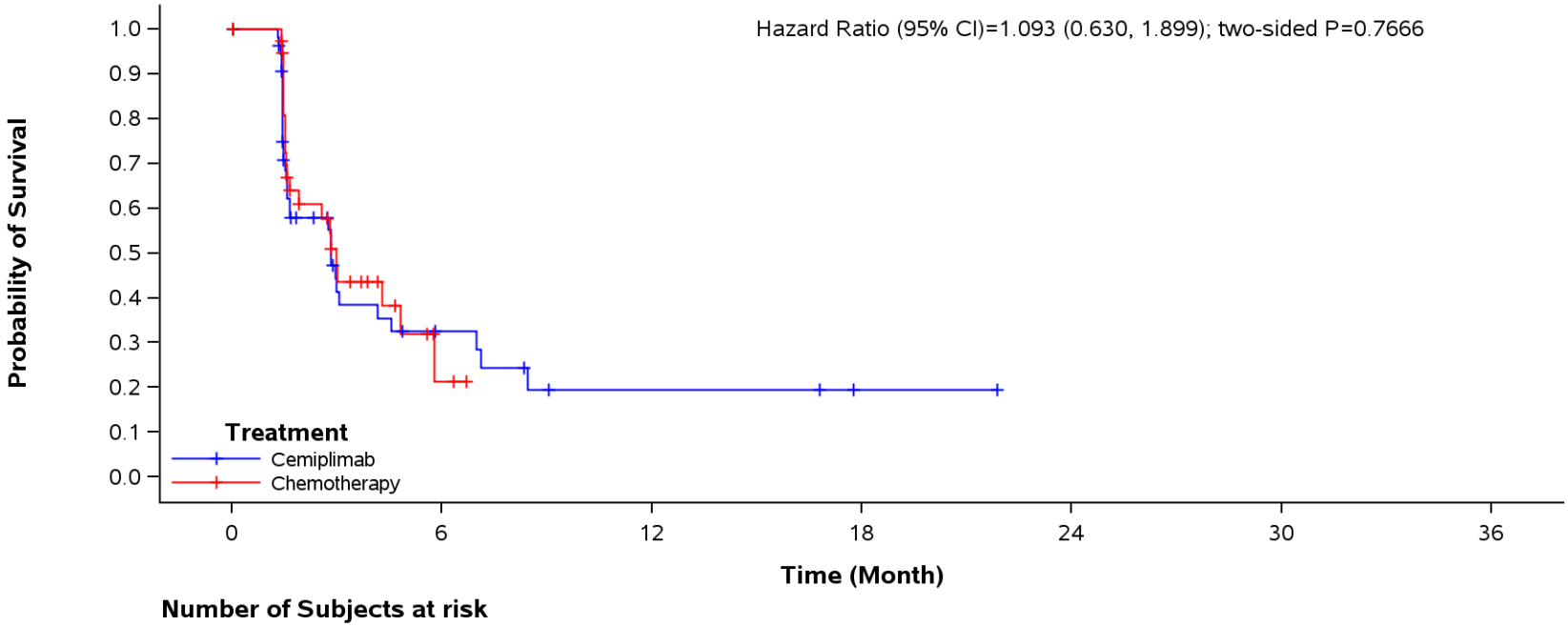

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 1 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 111 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 8 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 111 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

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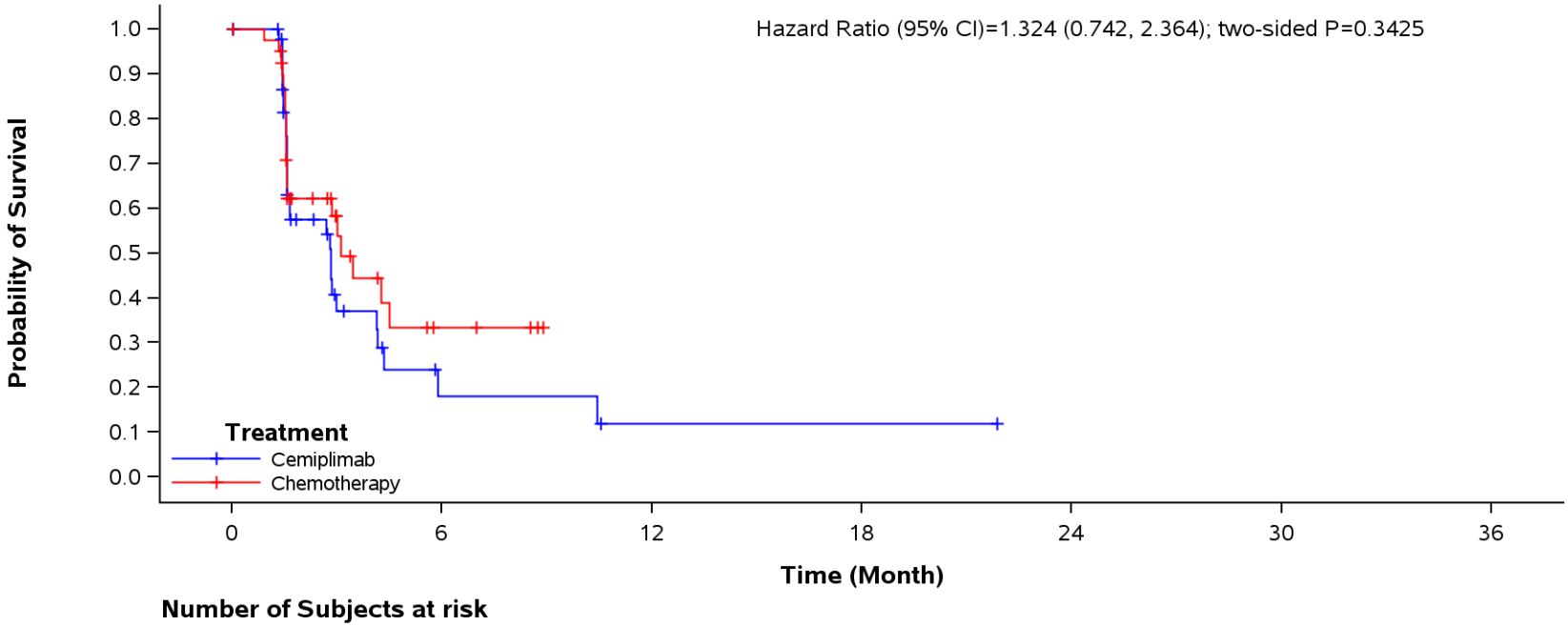
Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts improvement



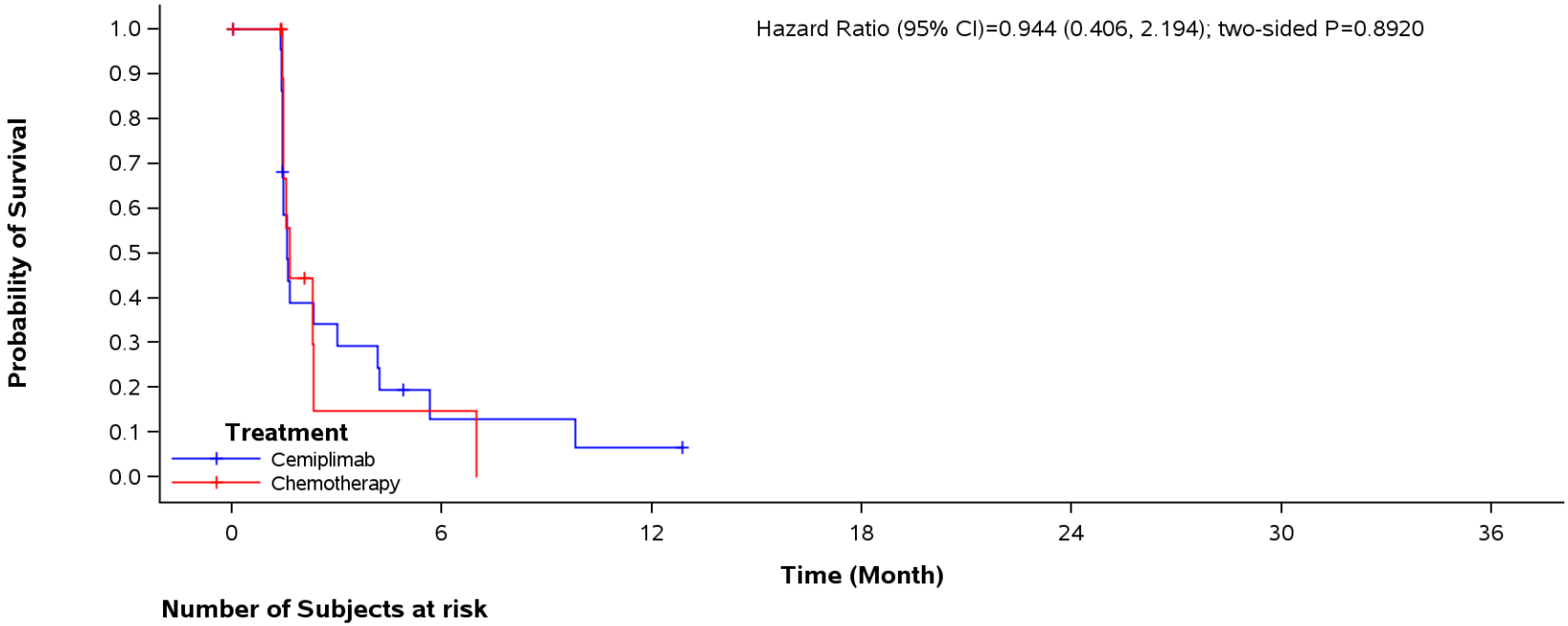

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 111 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts improvement



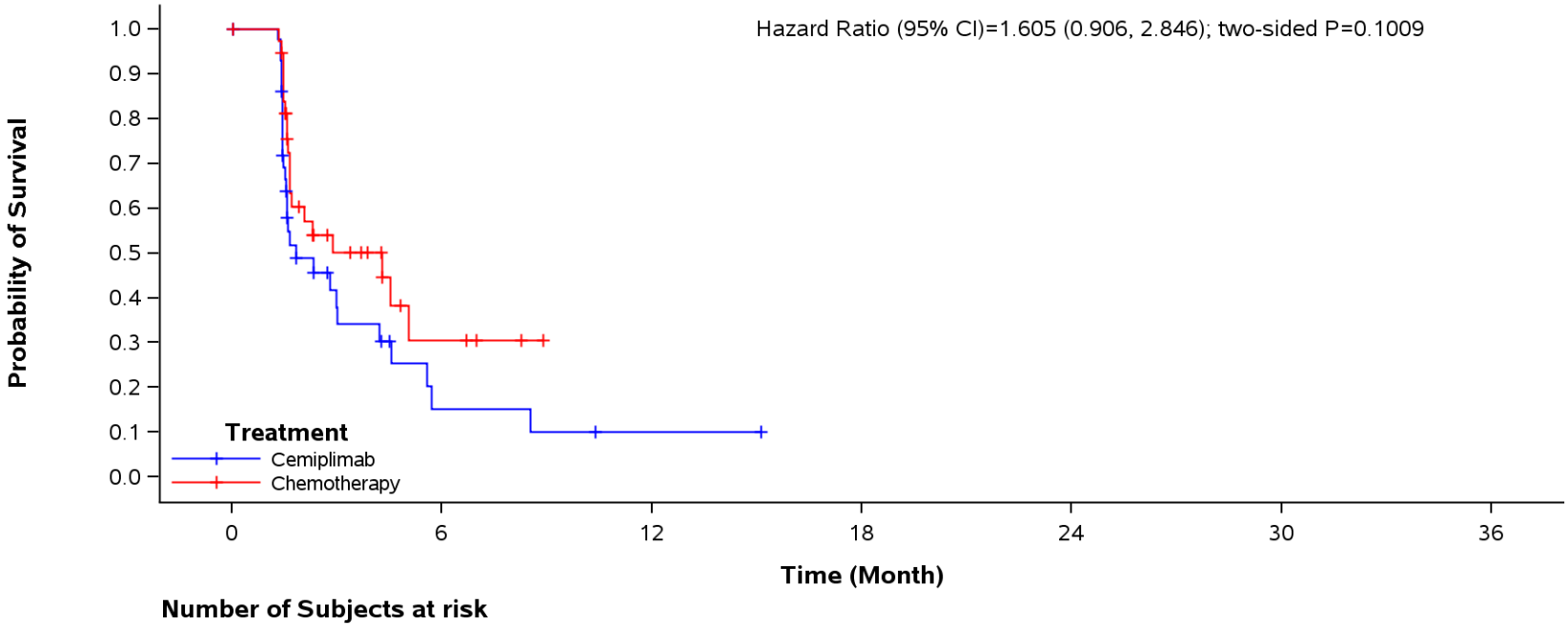

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 111 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts improvement



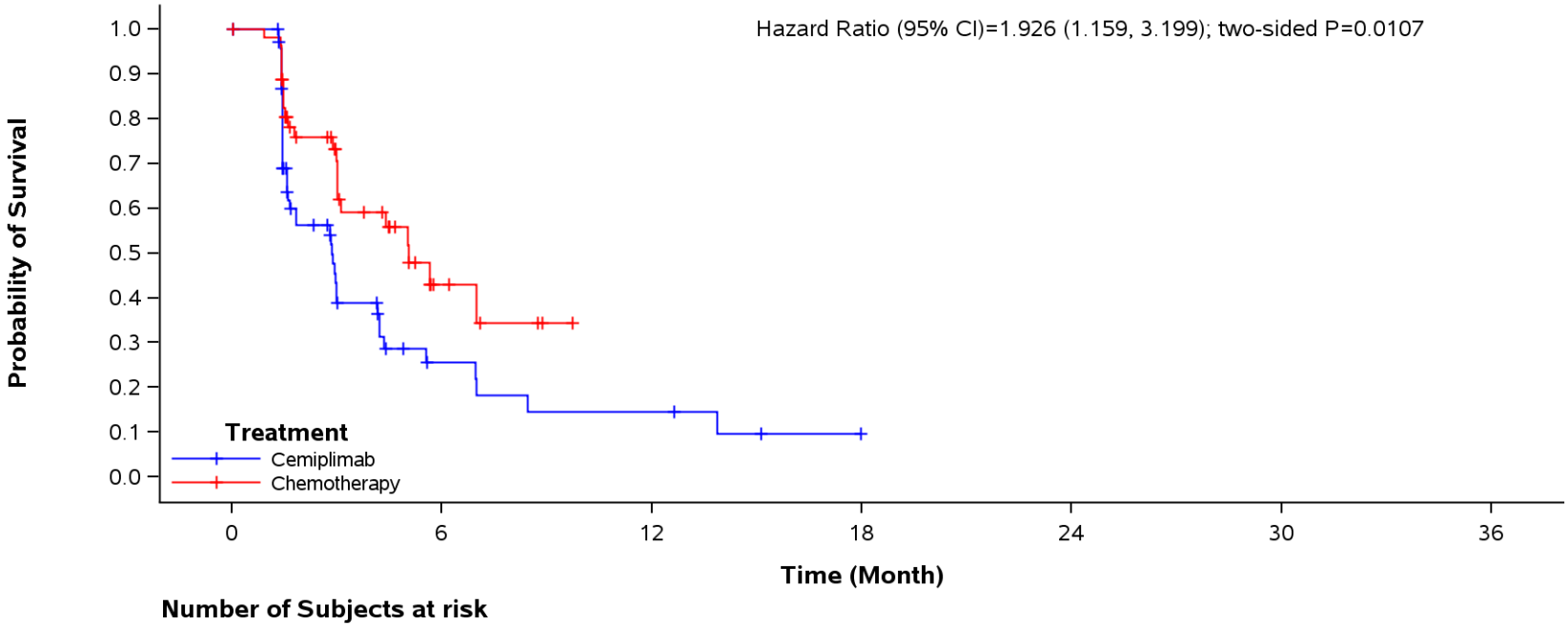

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 111 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts improvement



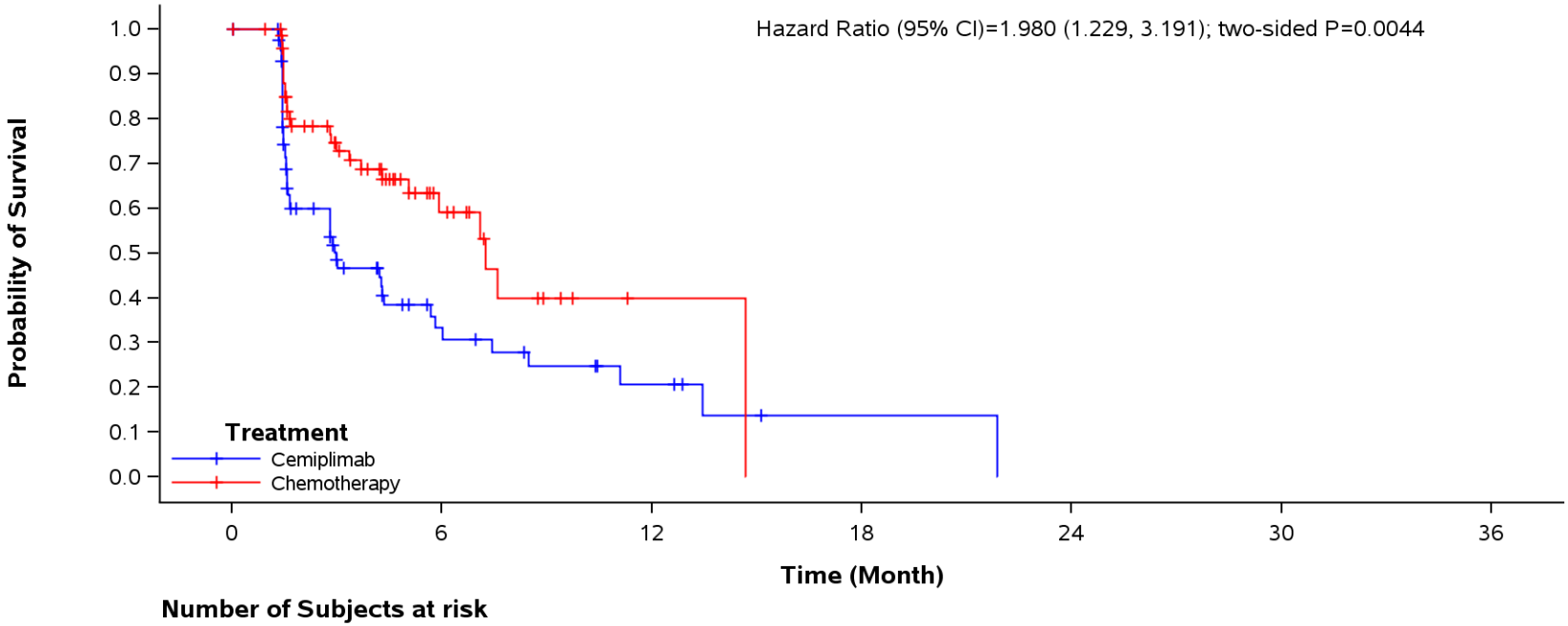

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 7 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 111 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts improvement



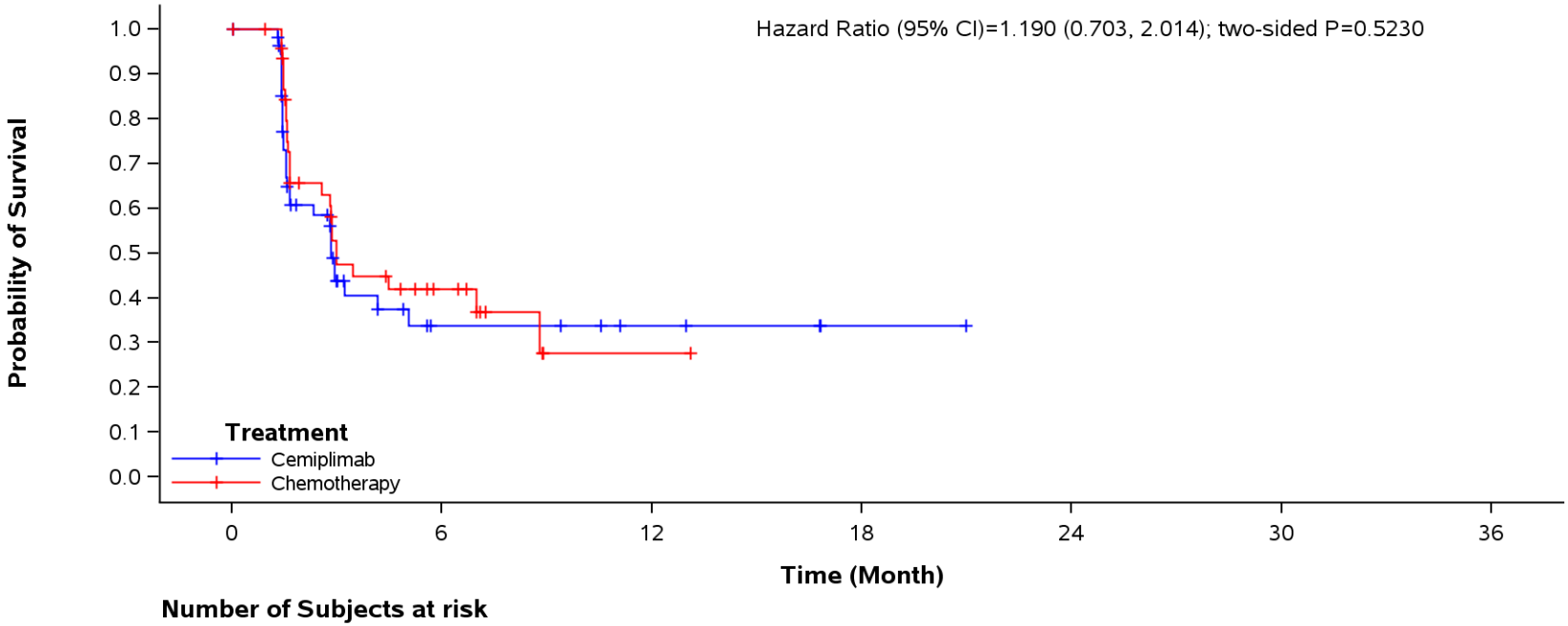

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 13 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 111 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts improvement



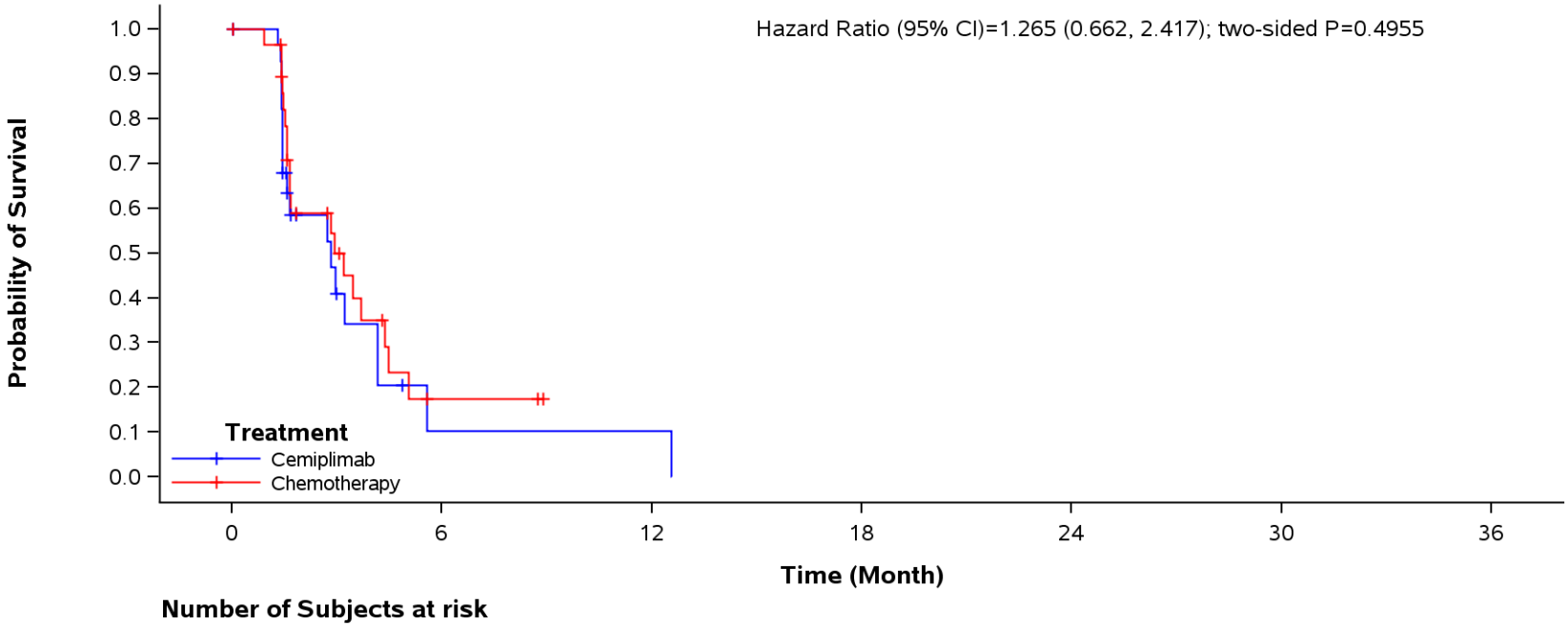

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 7 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 111 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts improvement



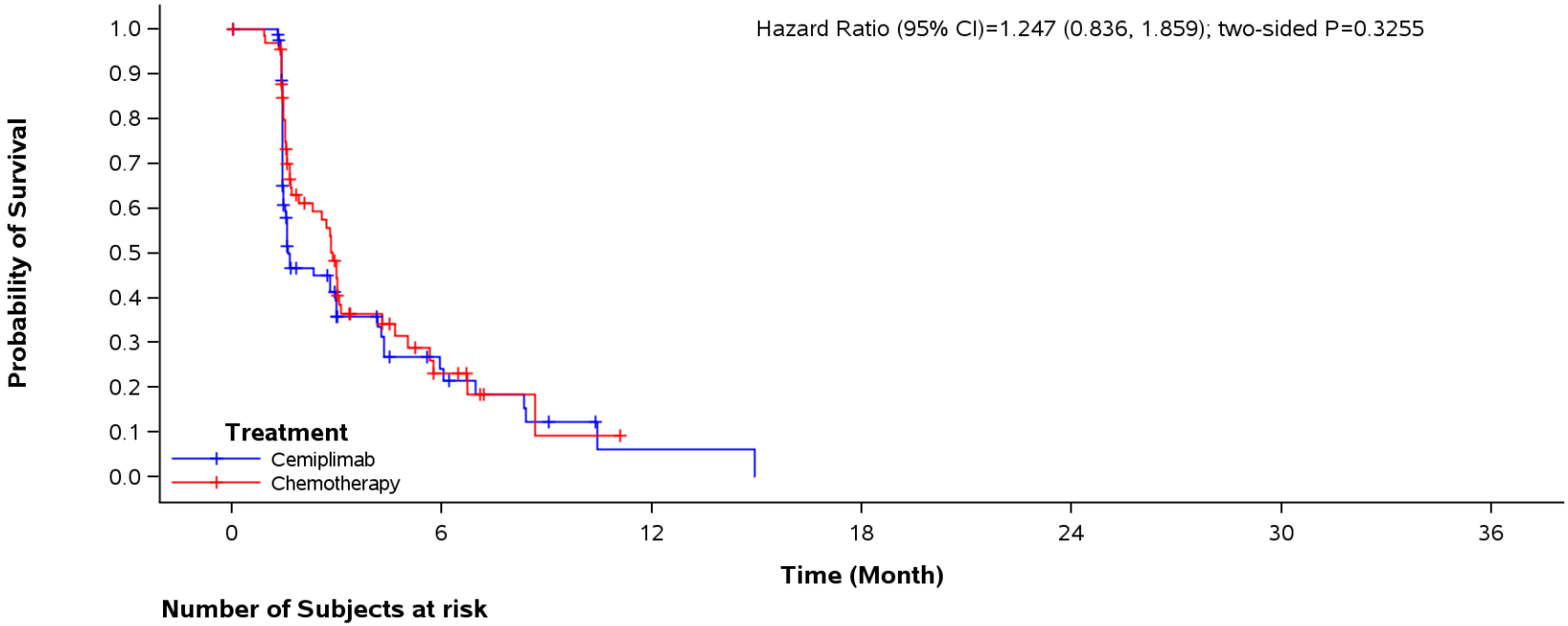

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 111 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts improvement



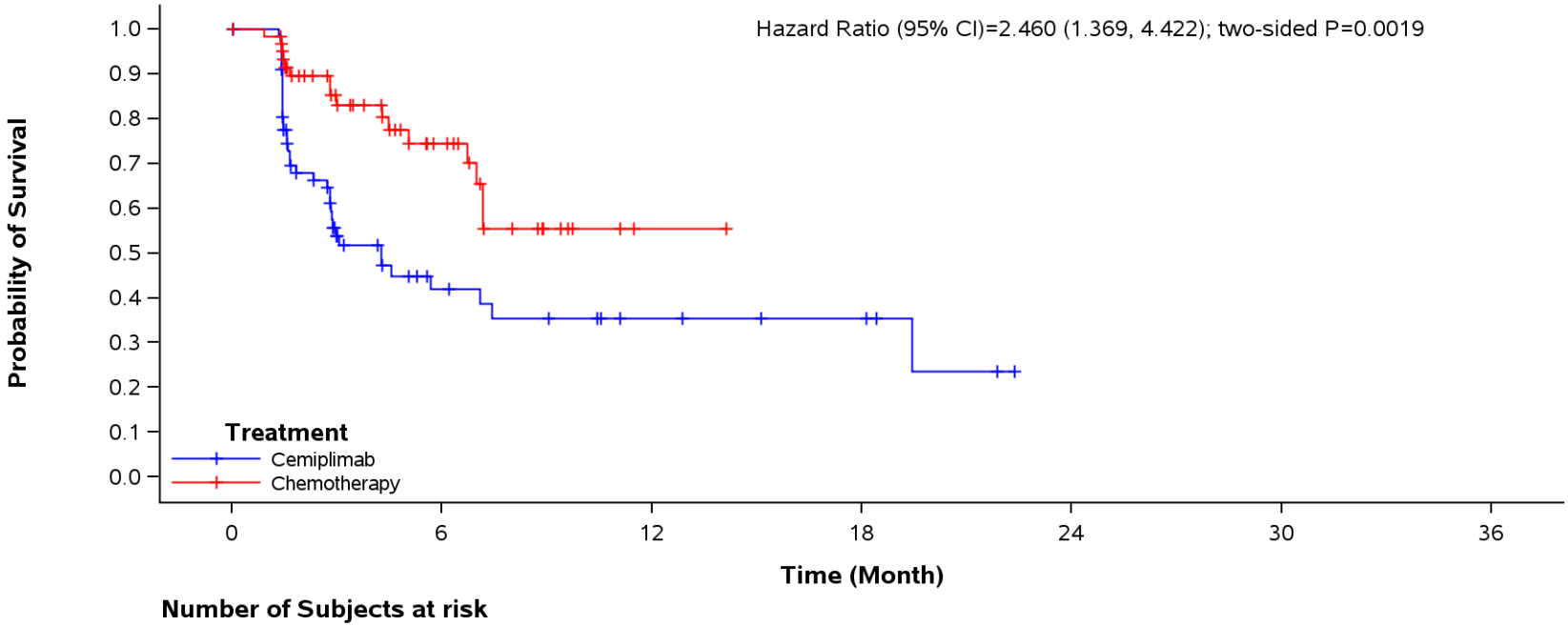

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 9 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 111 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts improvement



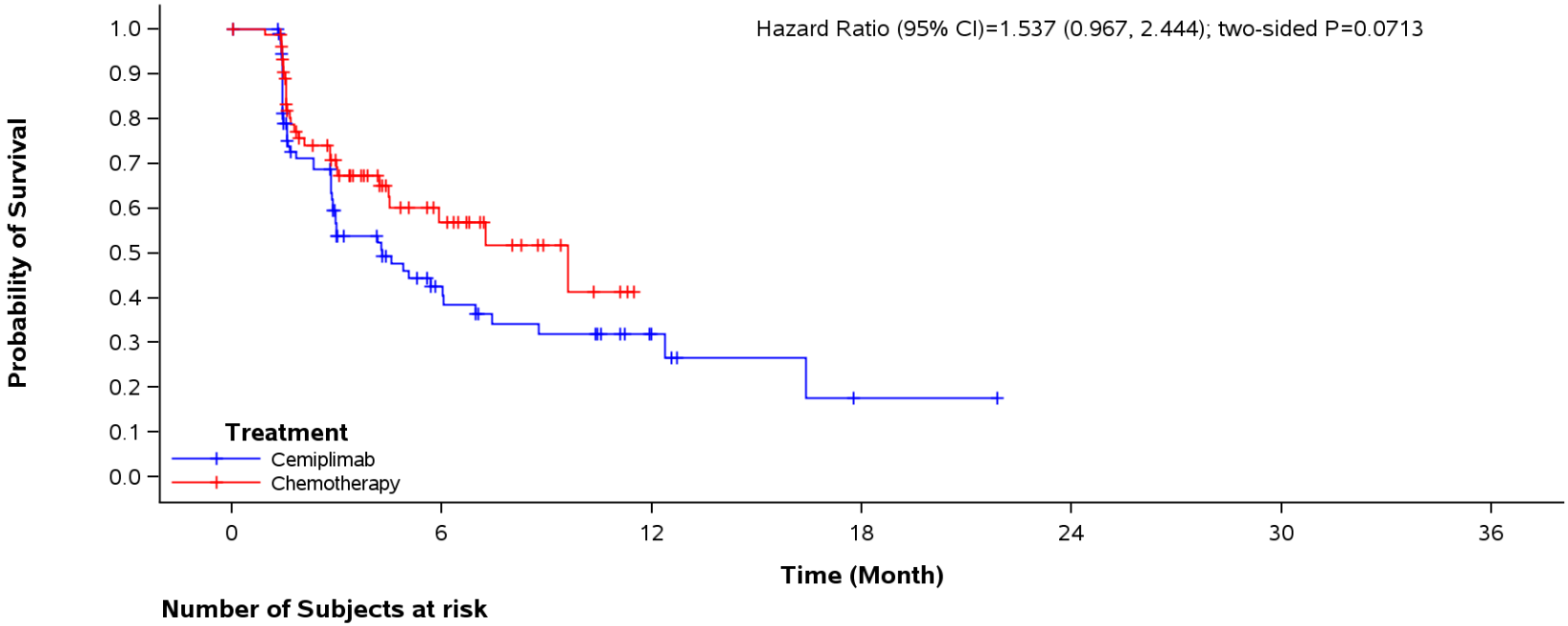

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 14 | 7 | 5 | 0 | 0 | 0 |
| Chemotherapy | 111 | 20 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts improvement



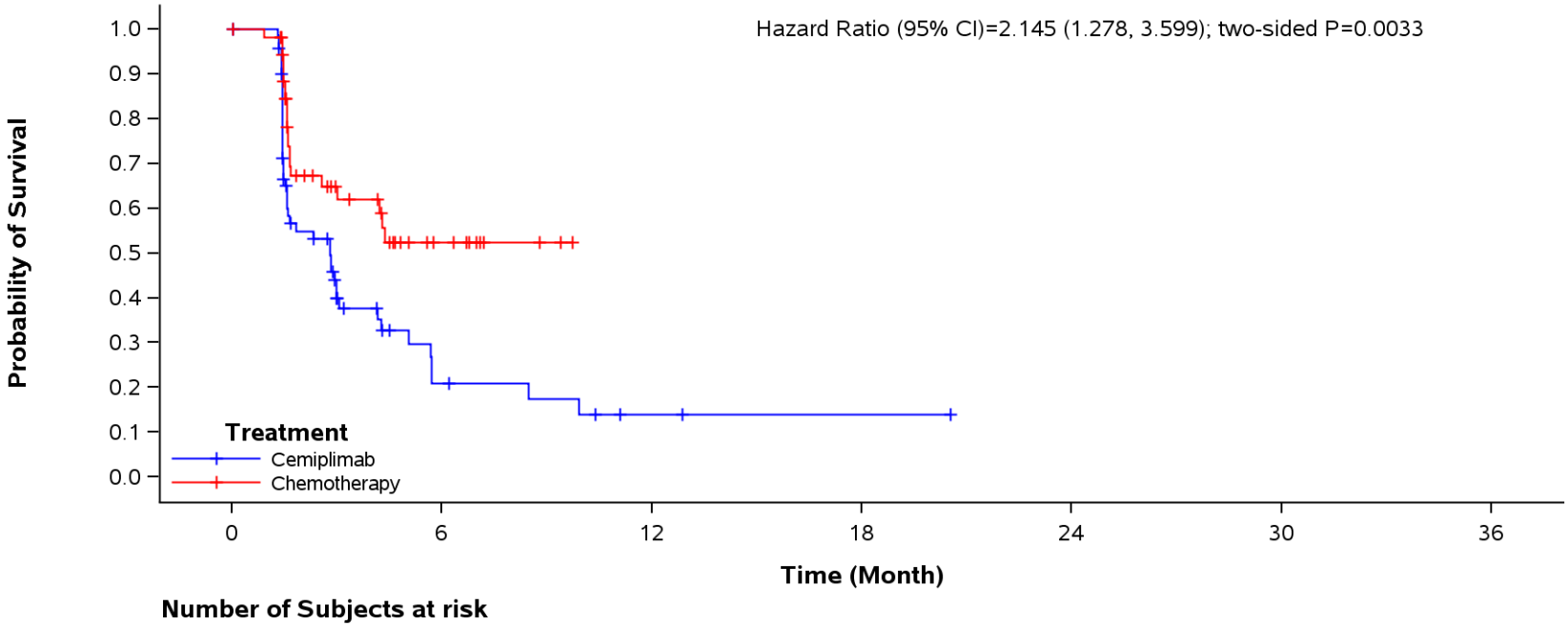

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 21 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 111 | 18 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts improvement




Number of Subjects at risk

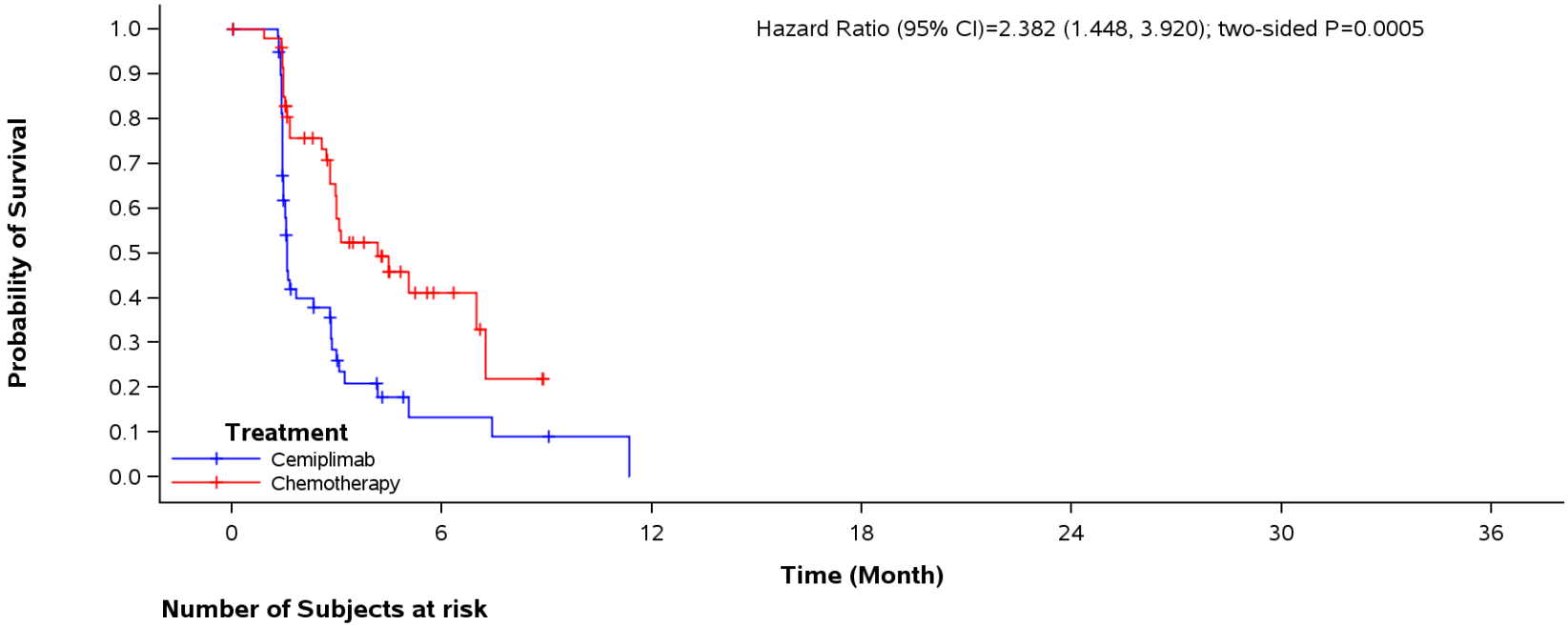
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 111 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:15:17, yingyuan.lin)

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts improvement



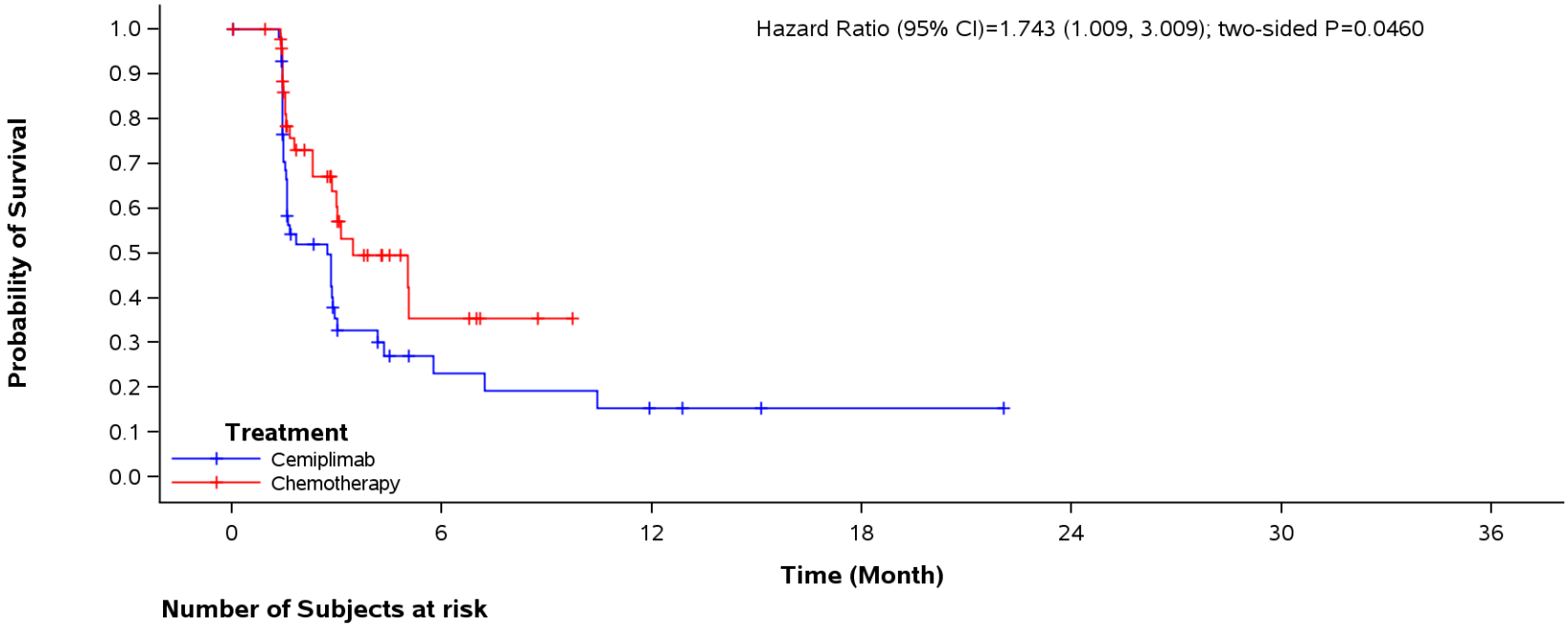

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 111 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts improvement




Number of Subjects at risk

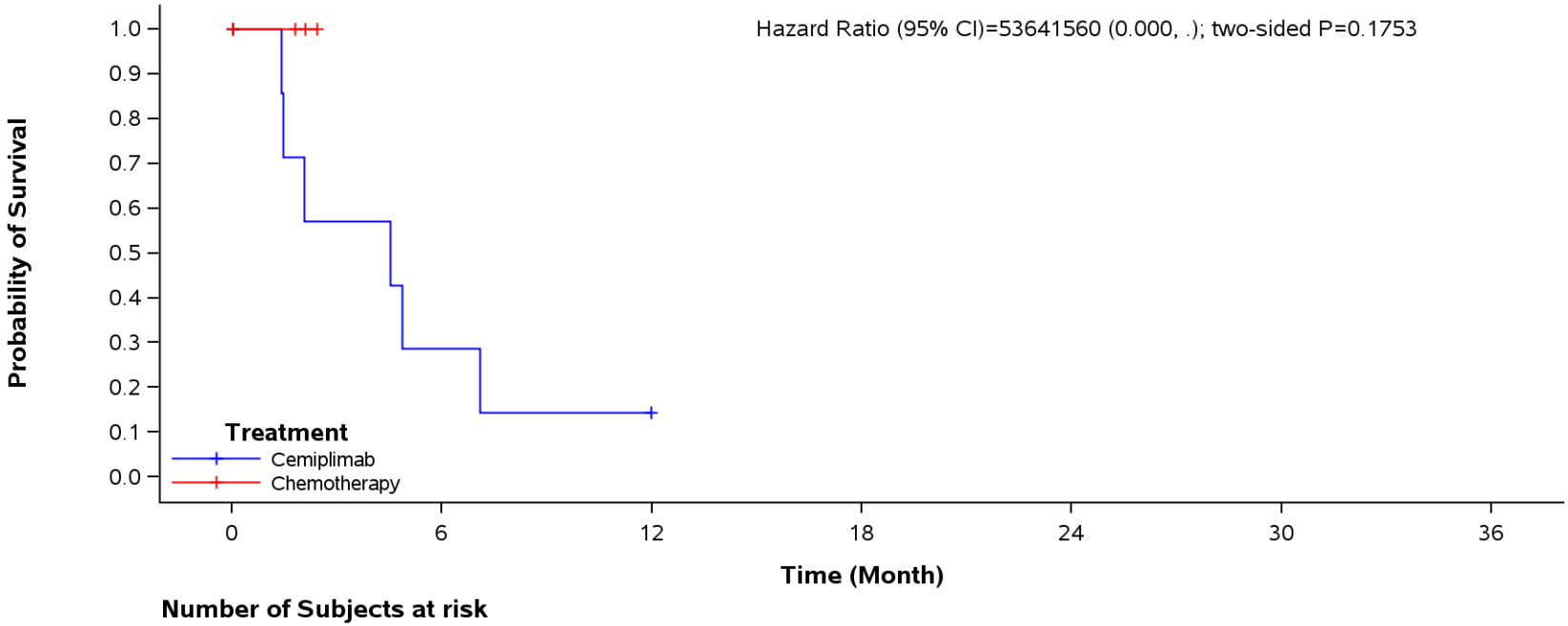
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 6 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 111 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:15:17, yingyuan.lin)

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts improvement



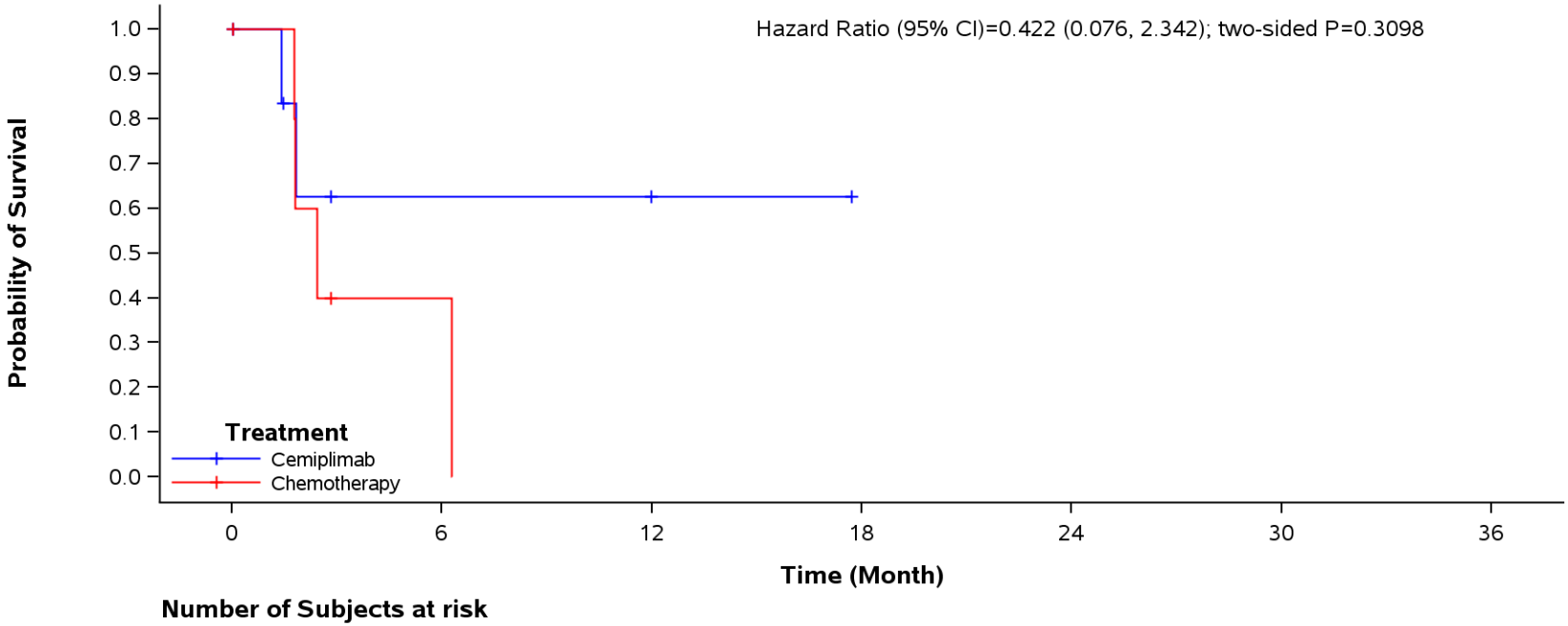

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts improvement



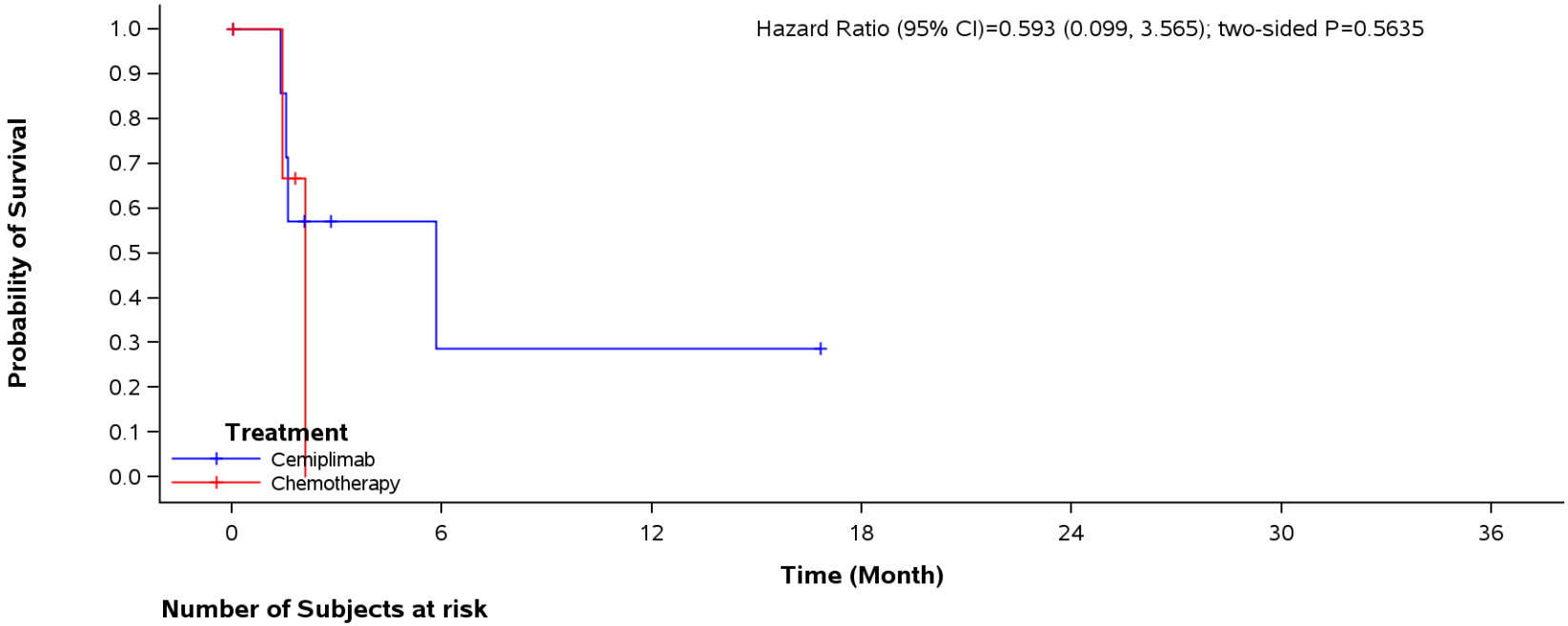

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts improvement



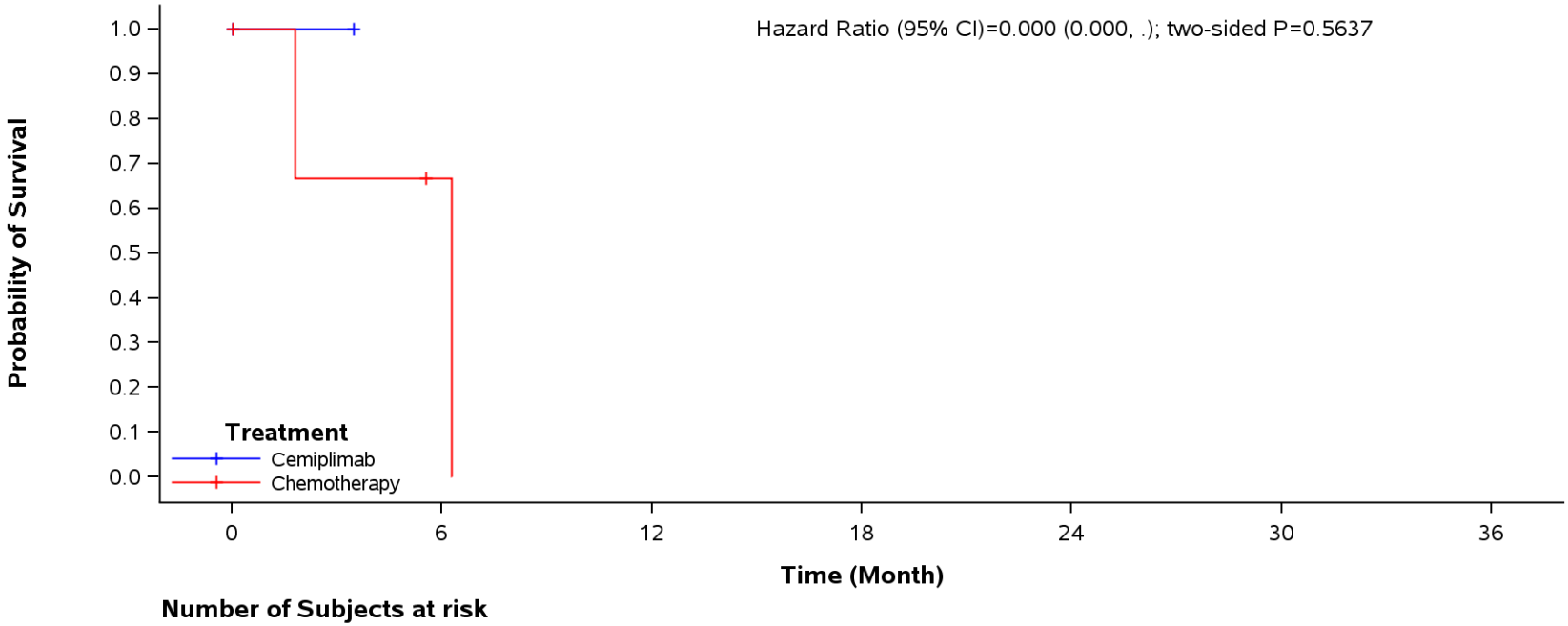

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts improvement



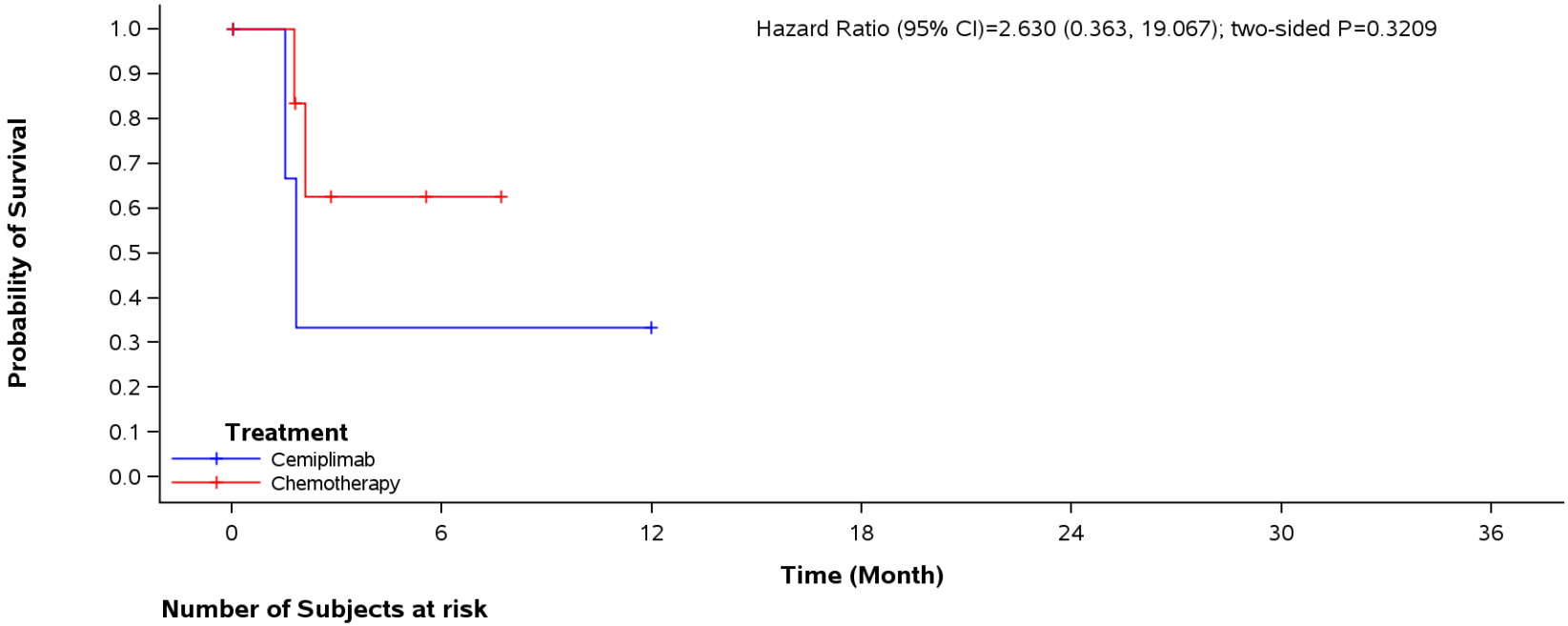

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts improvement



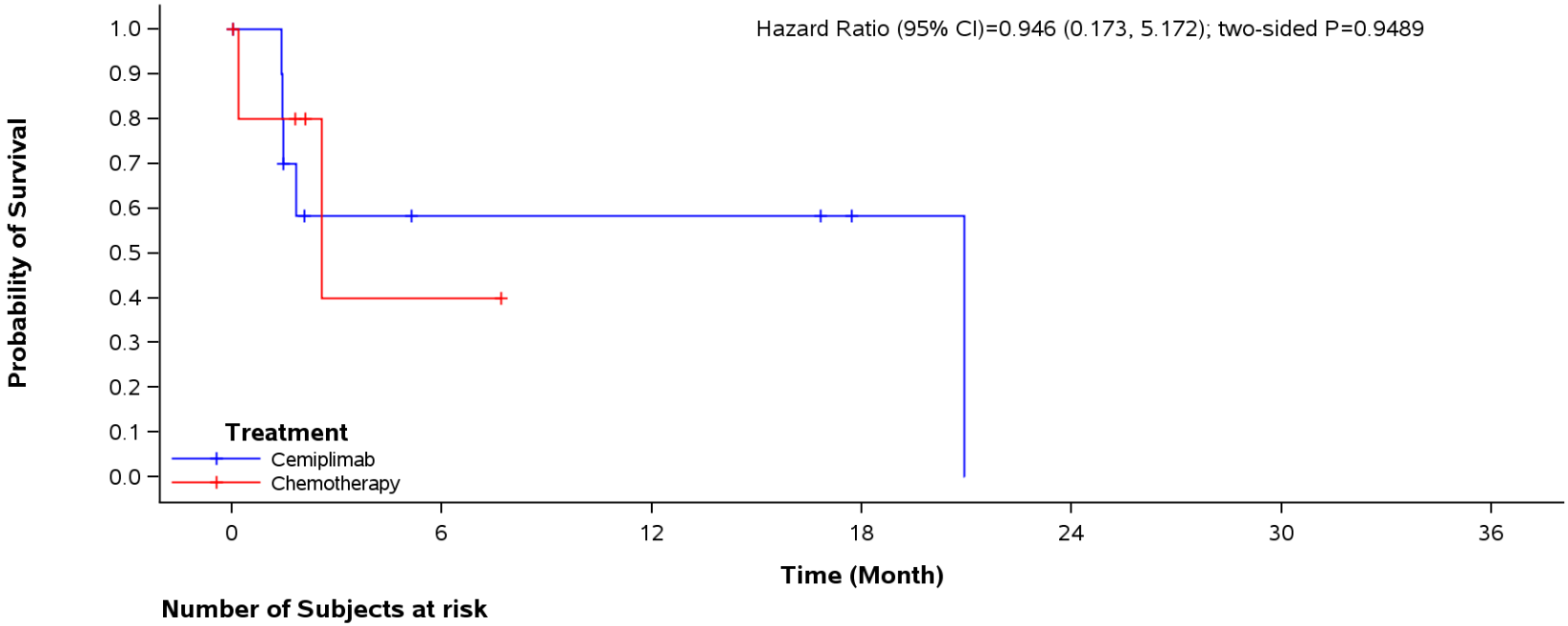

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts improvement



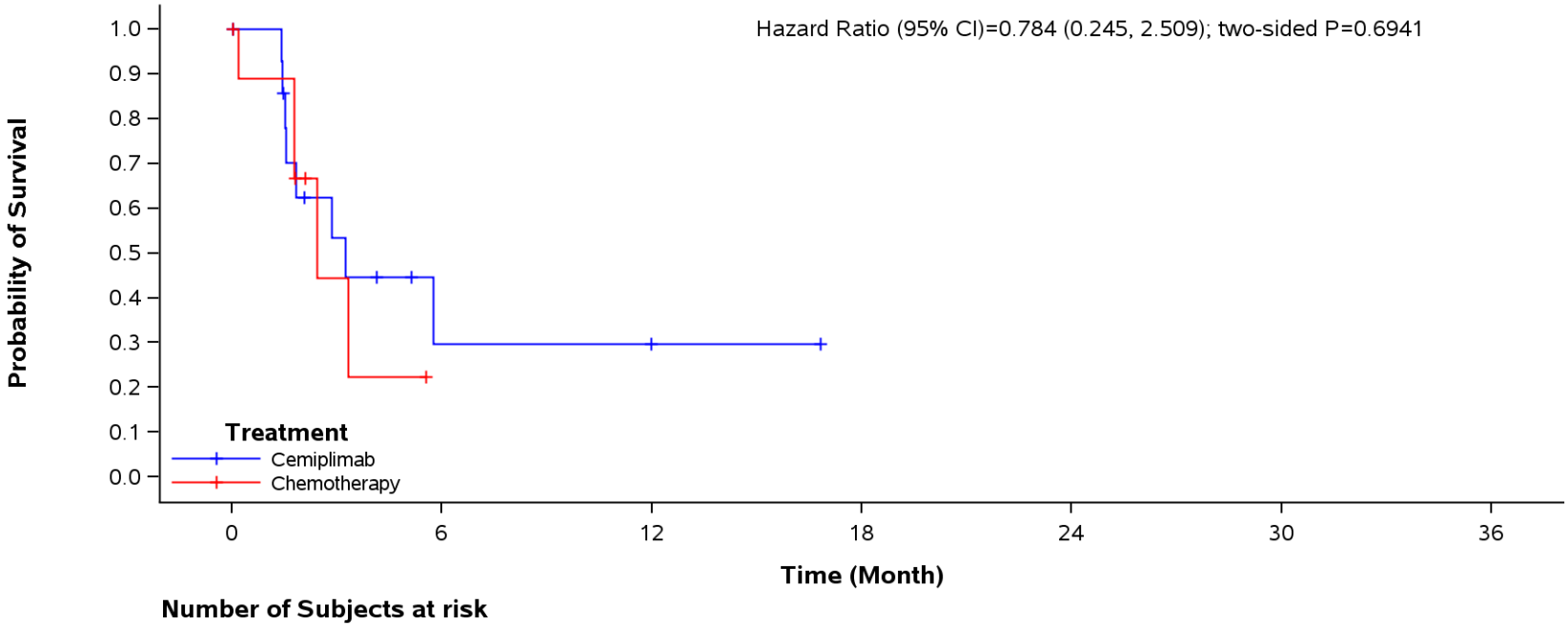

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts improvement



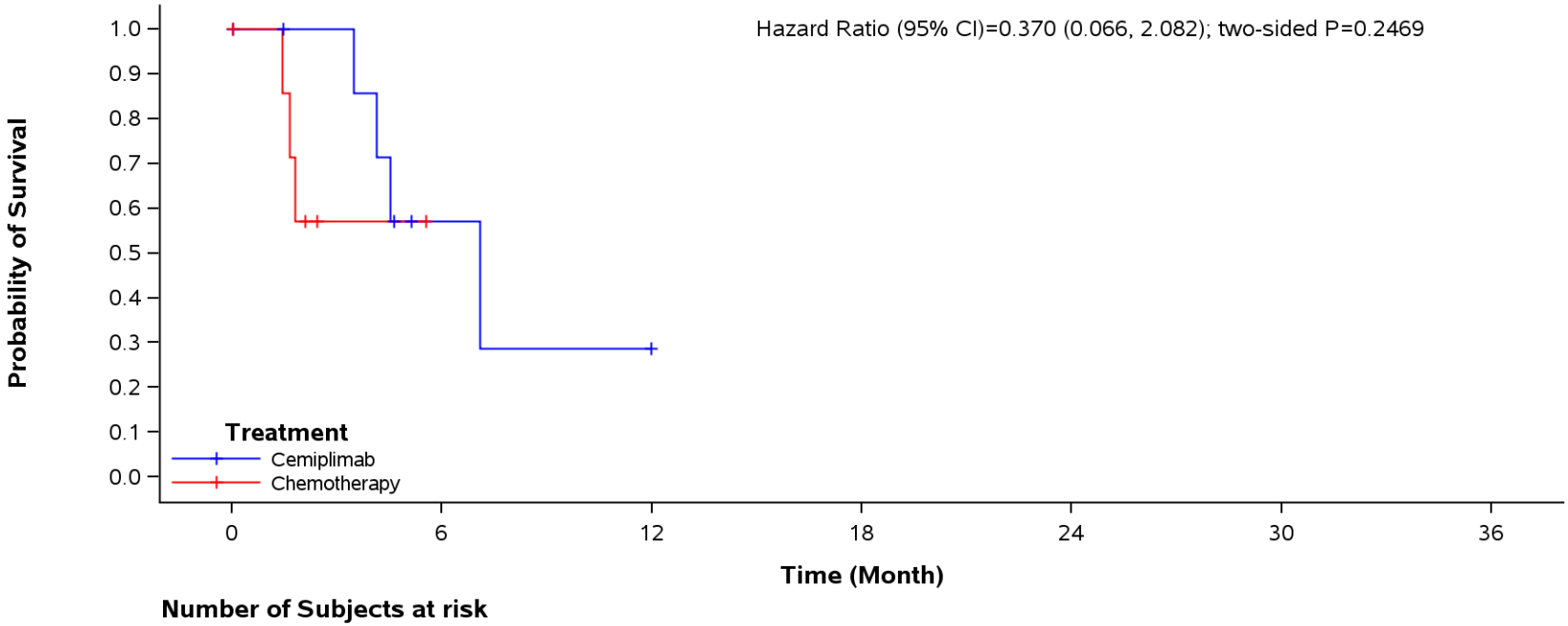

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts improvement



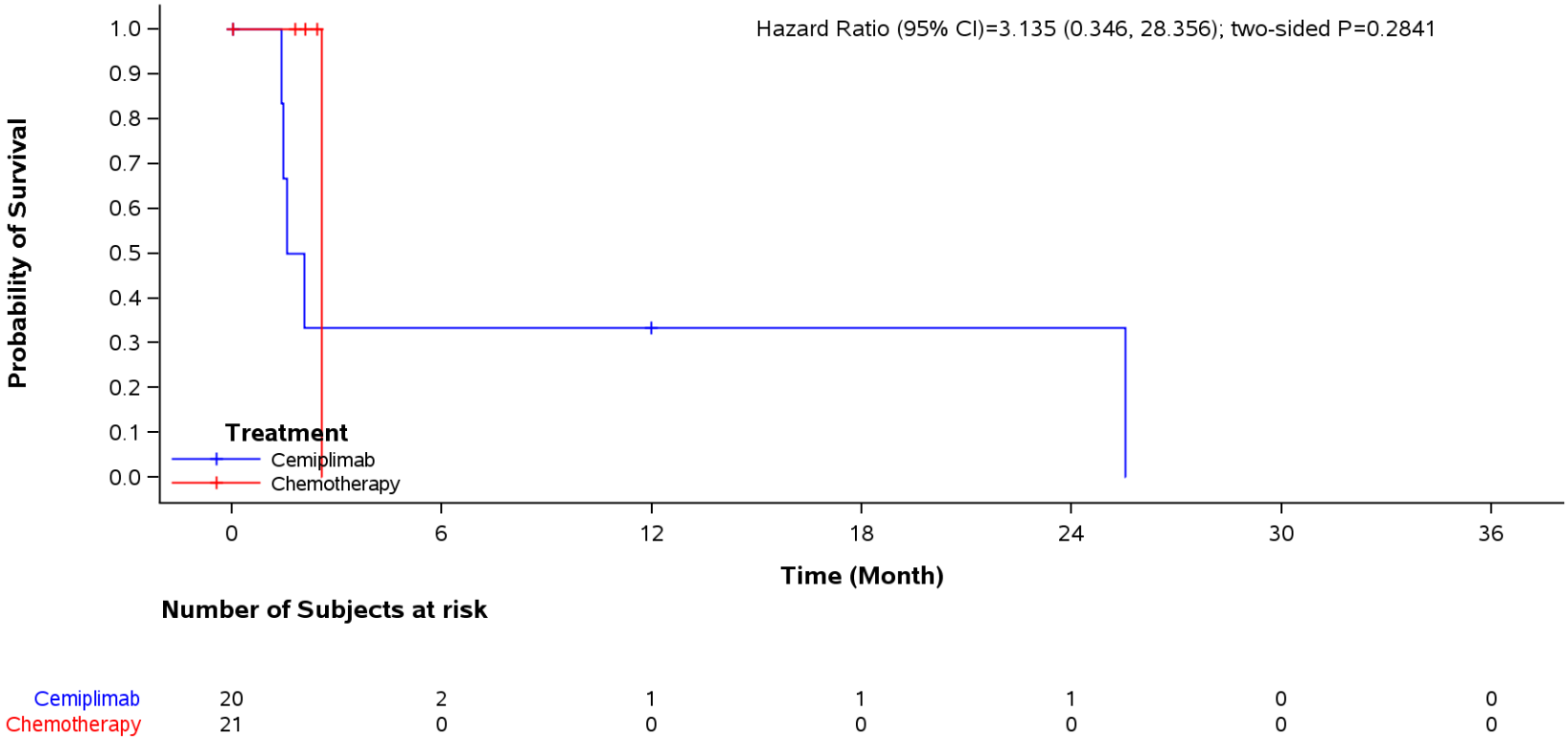

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts improvement



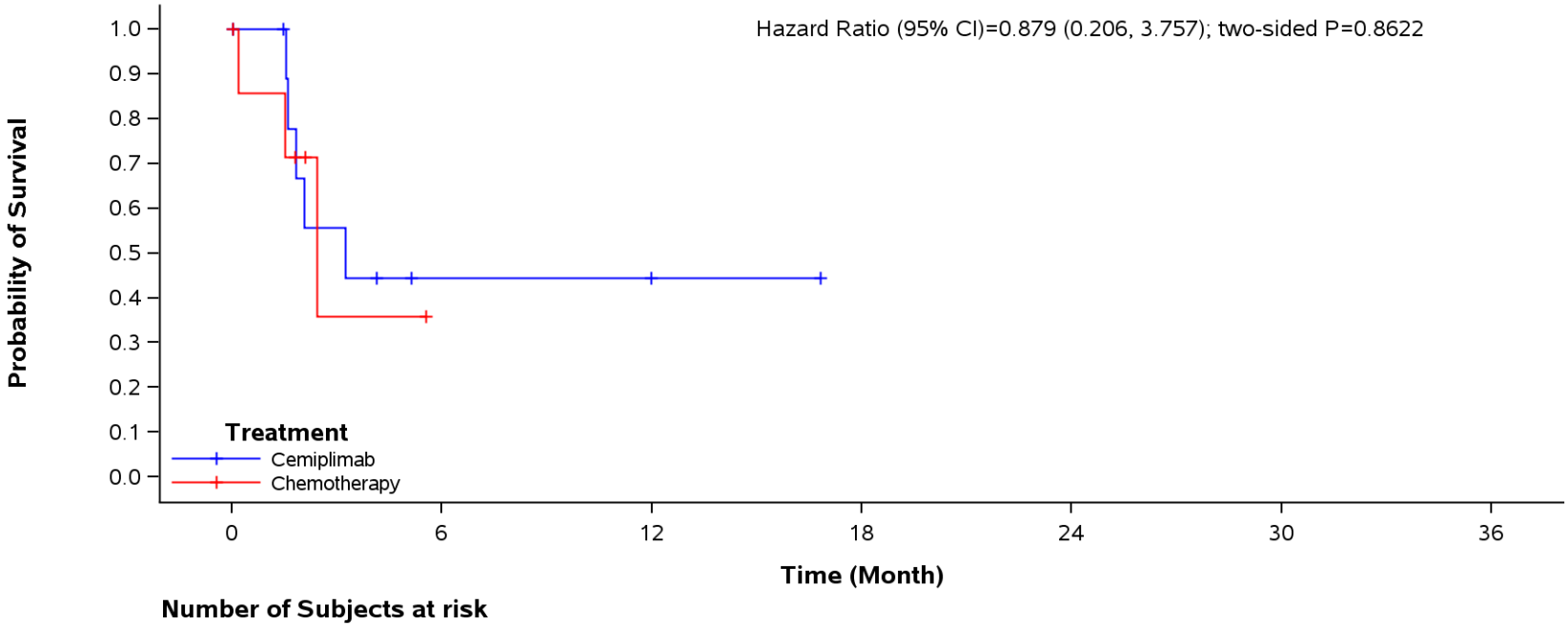

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts improvement



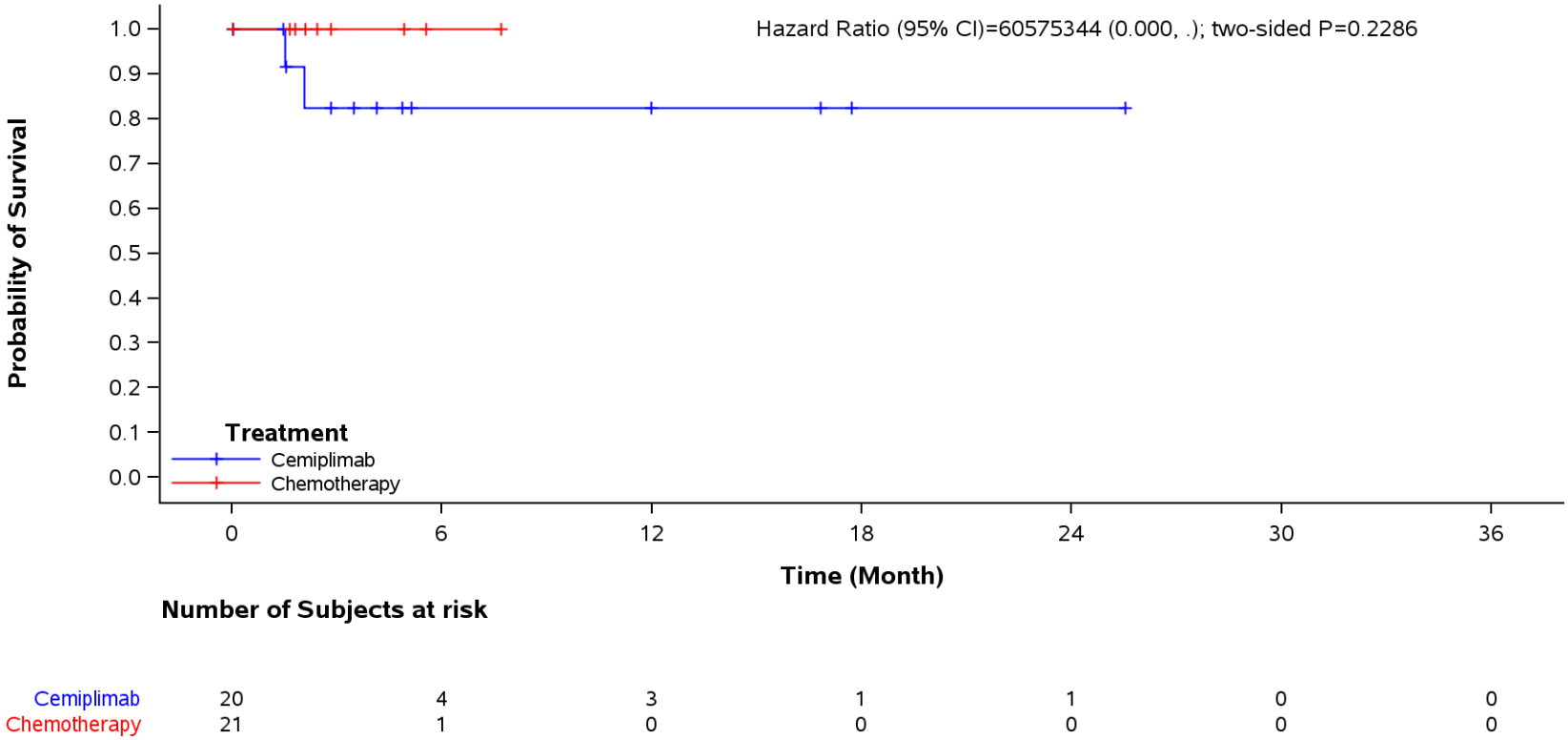

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts improvement



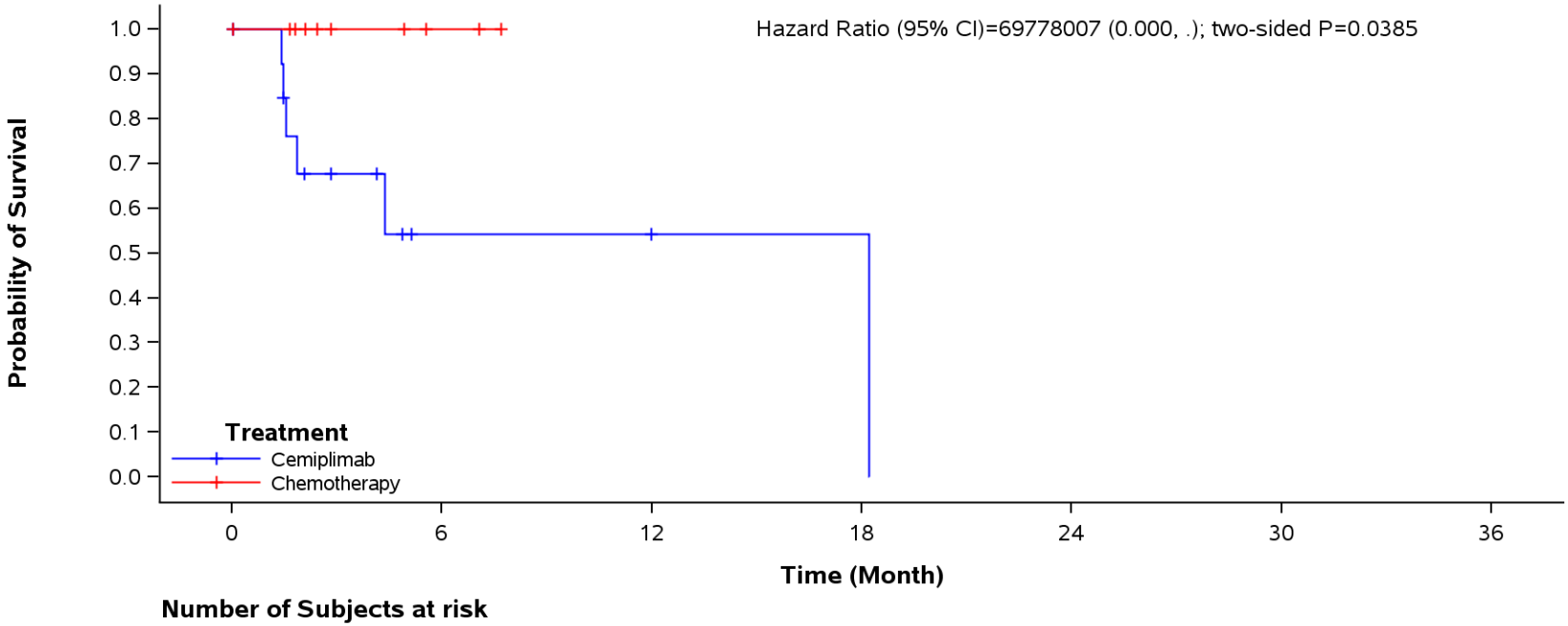

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts improvement



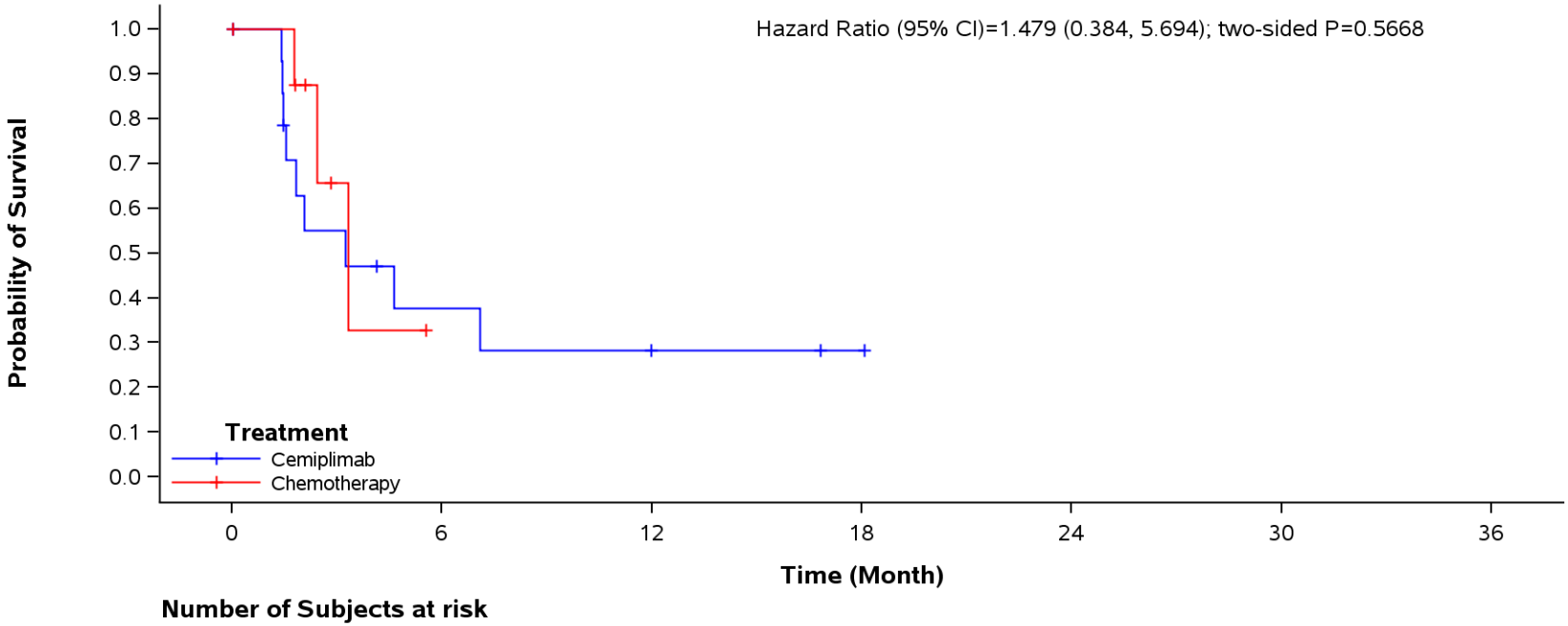

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts improvement



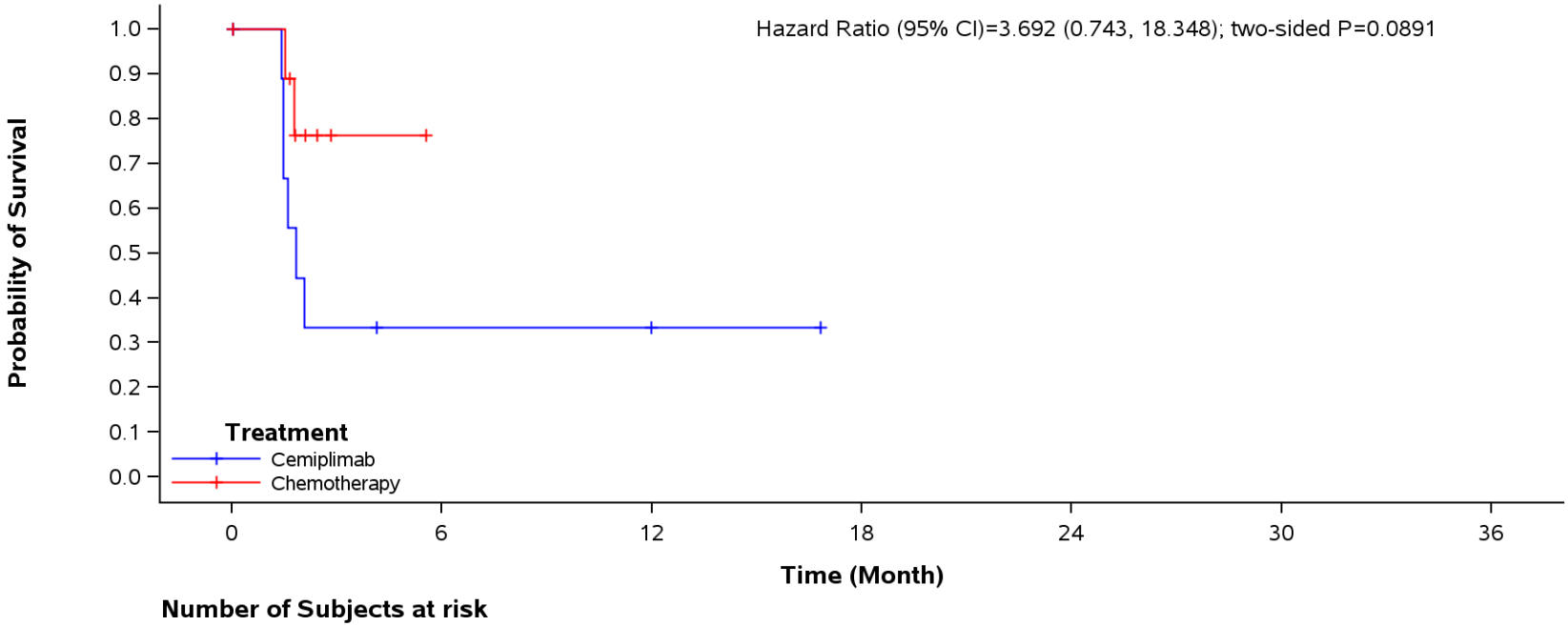

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts improvement



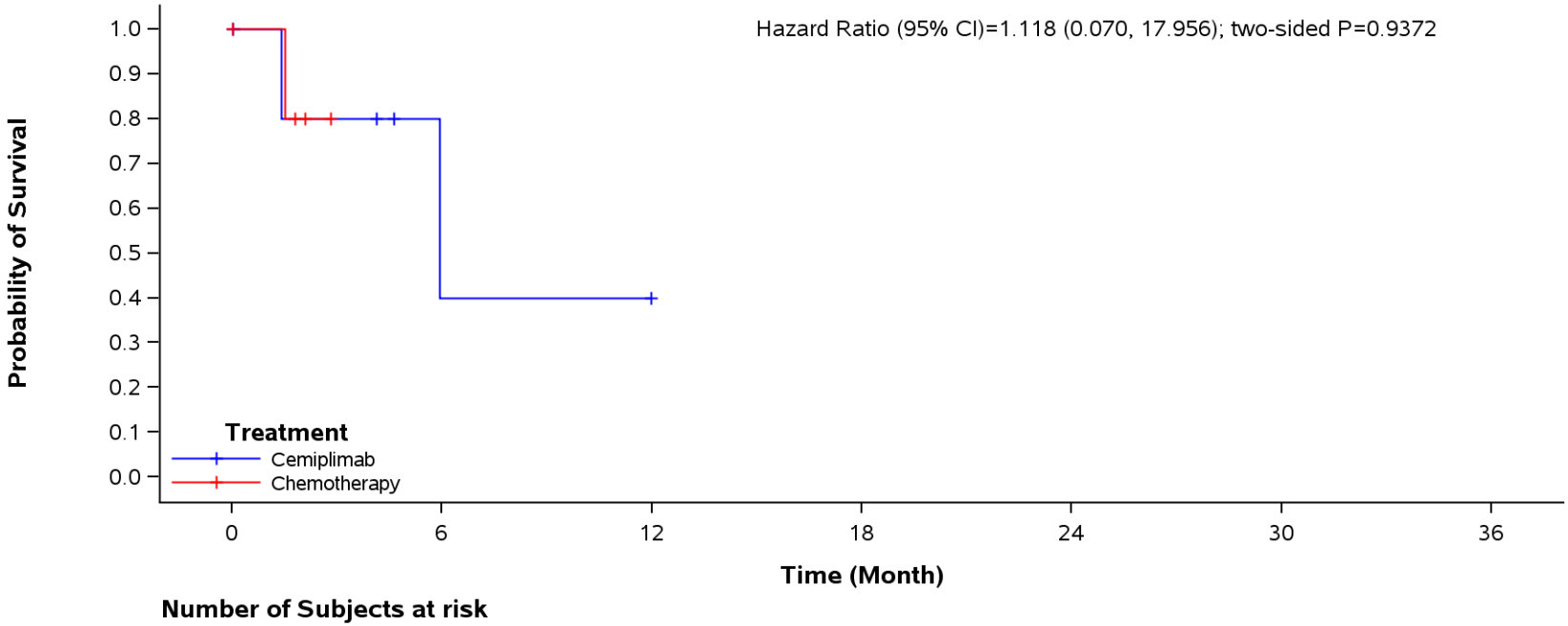

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts improvement



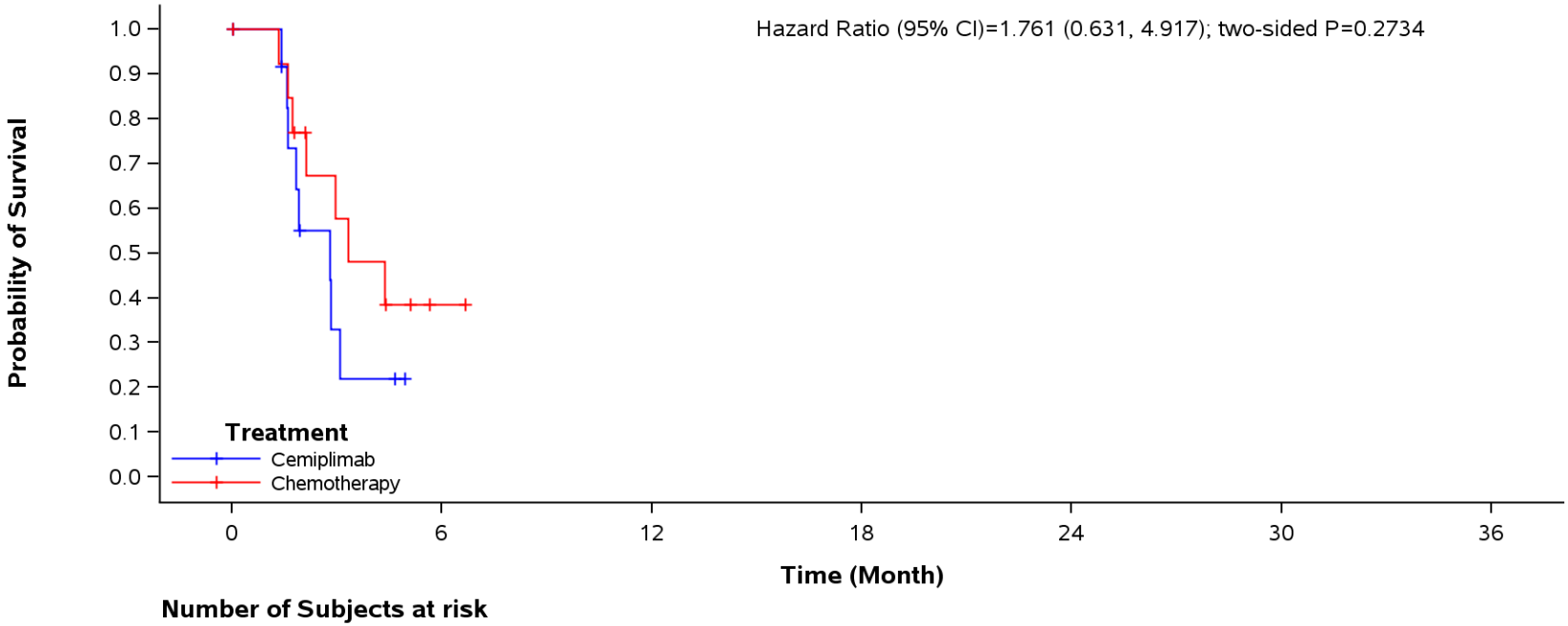

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts improvement



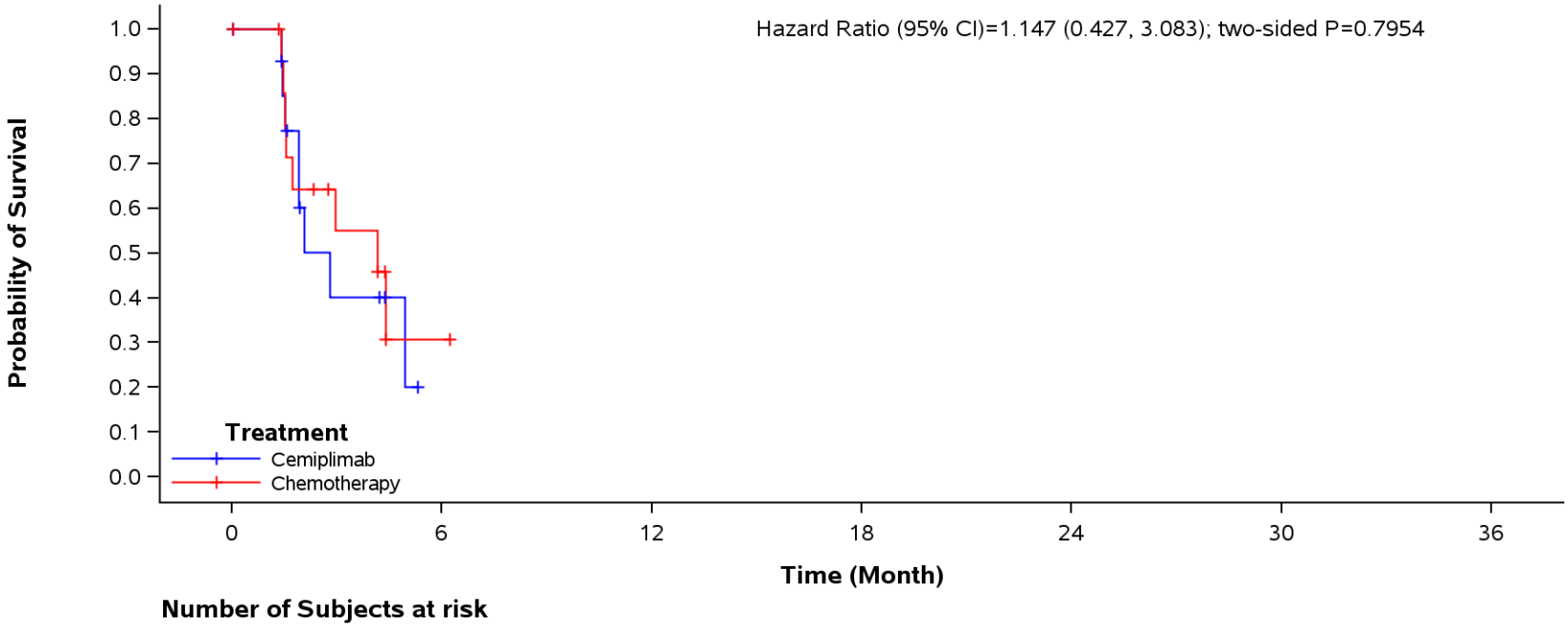

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts improvement



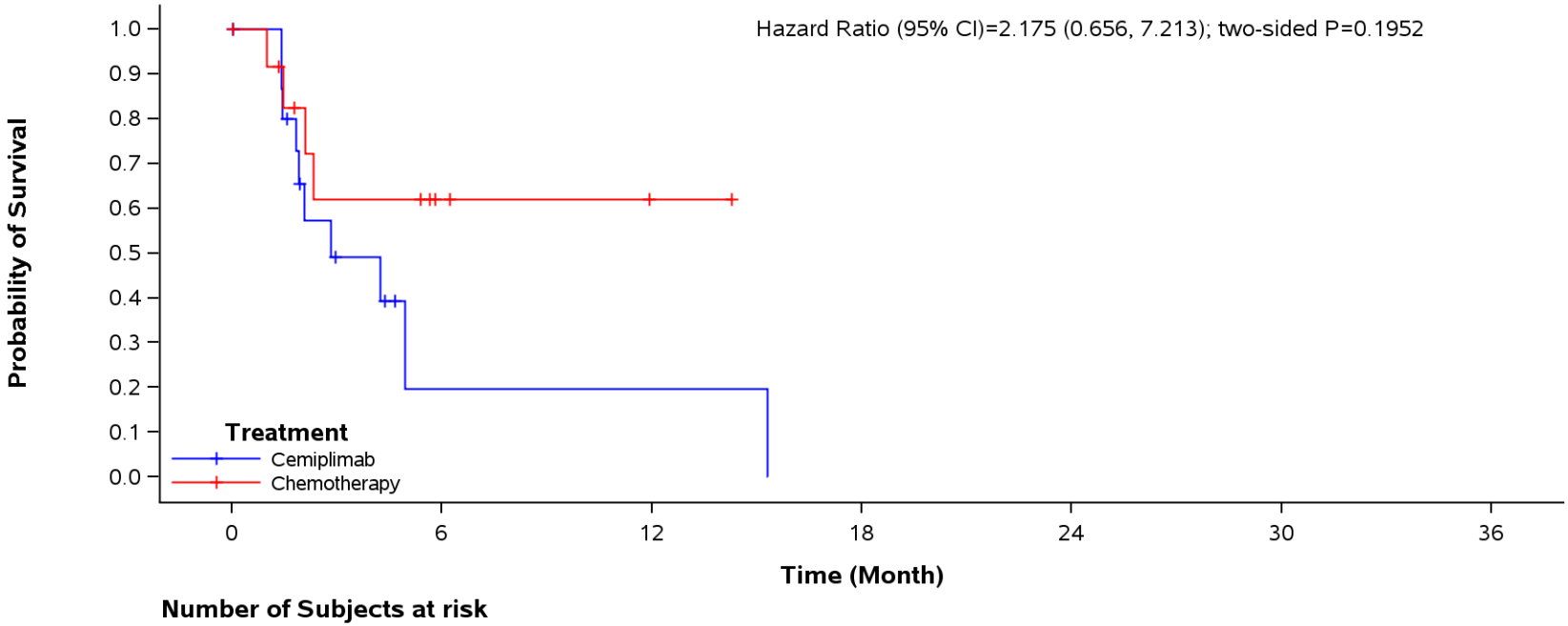

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts improvement



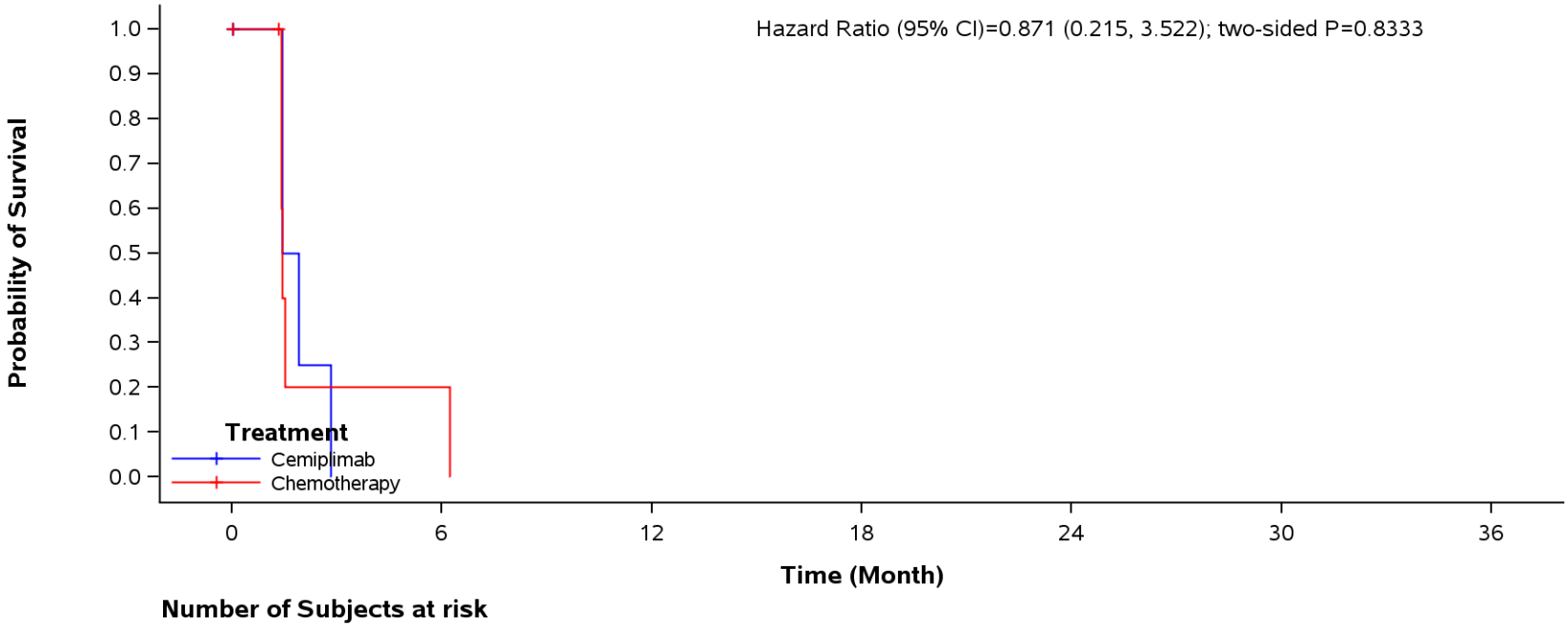

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts improvement



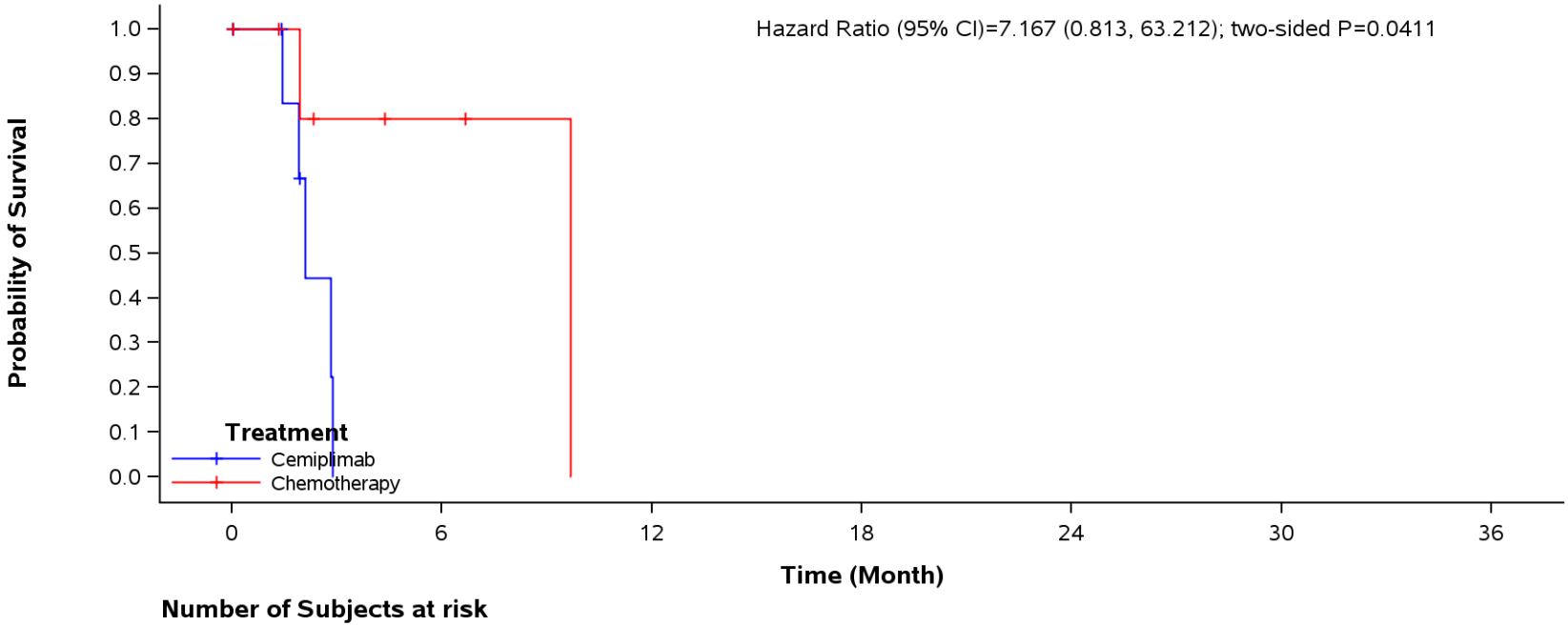

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts improvement



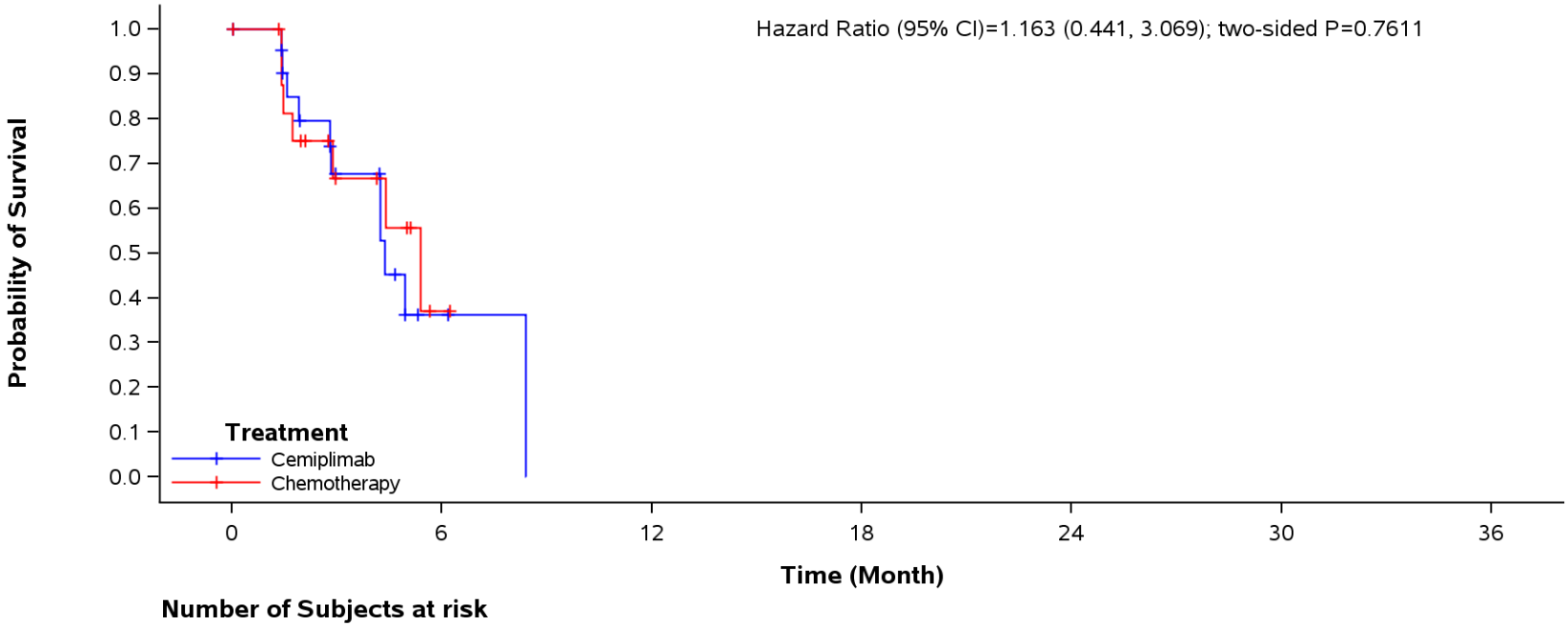

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts improvement



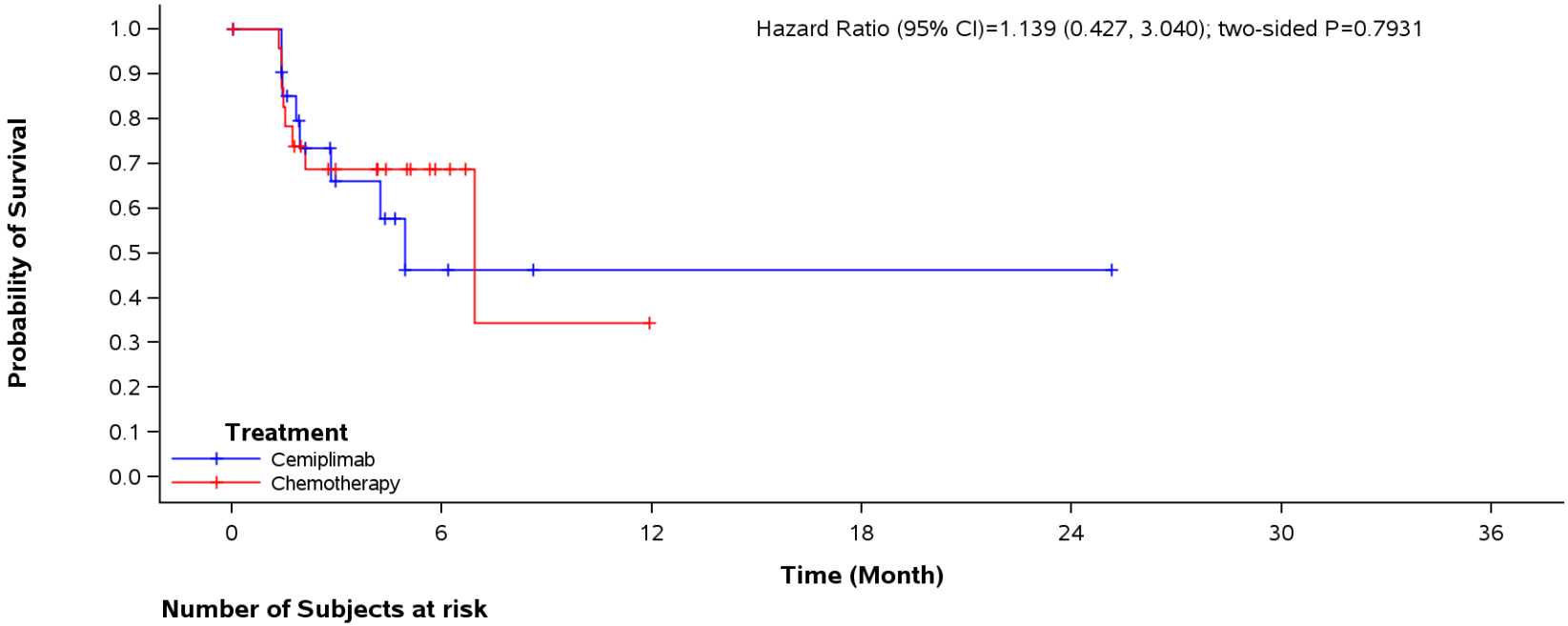

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts improvement



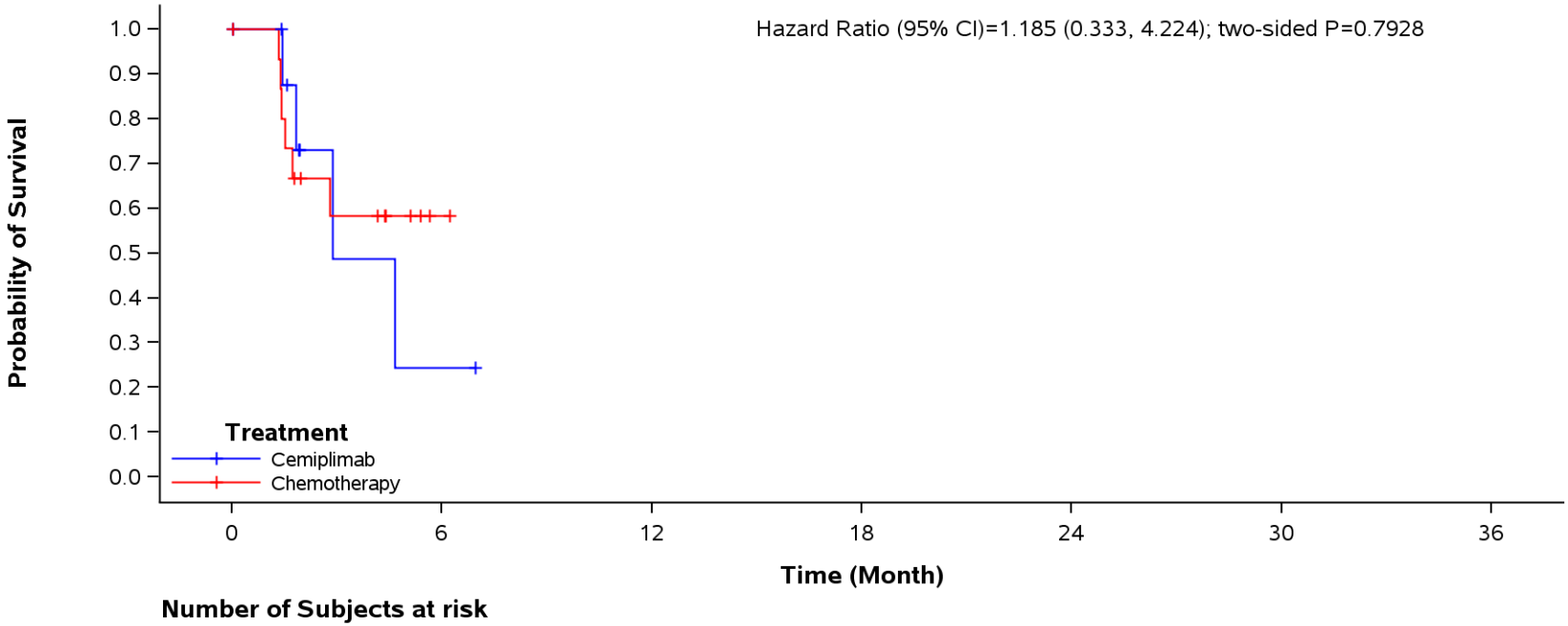

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts improvement



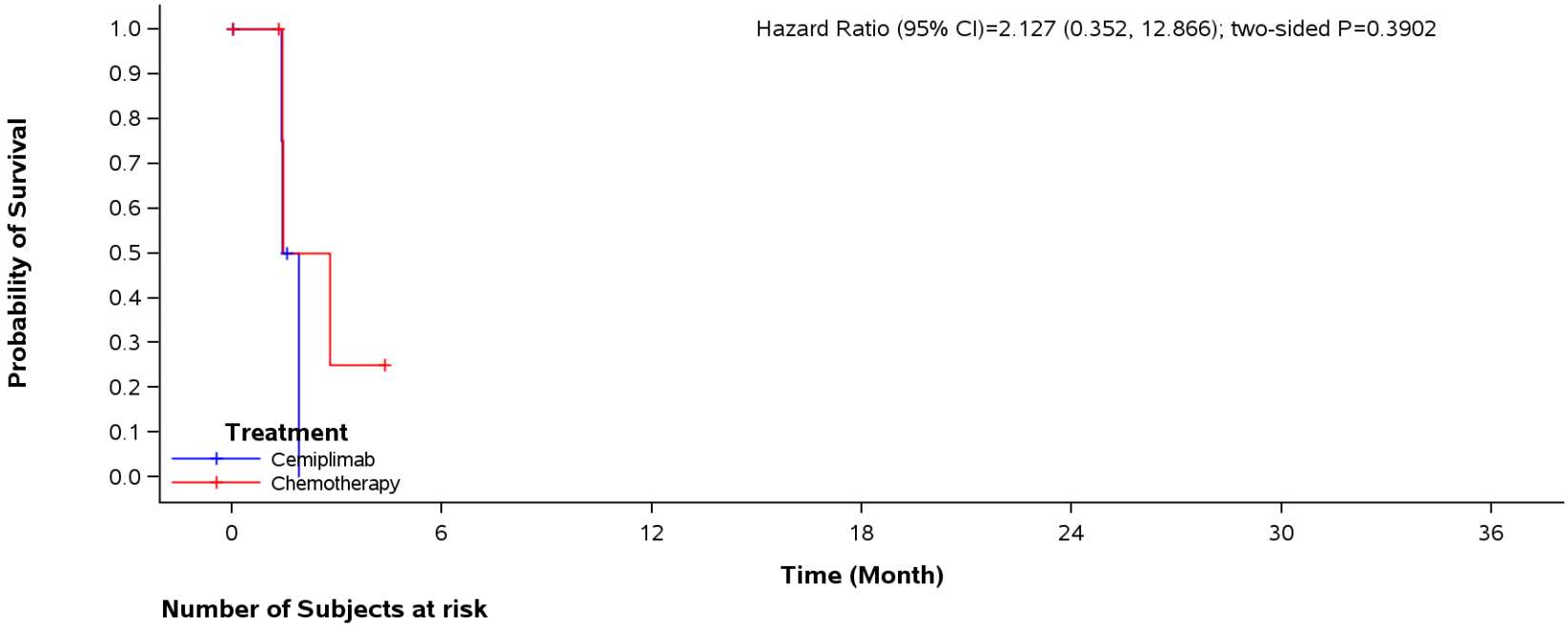

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts improvement



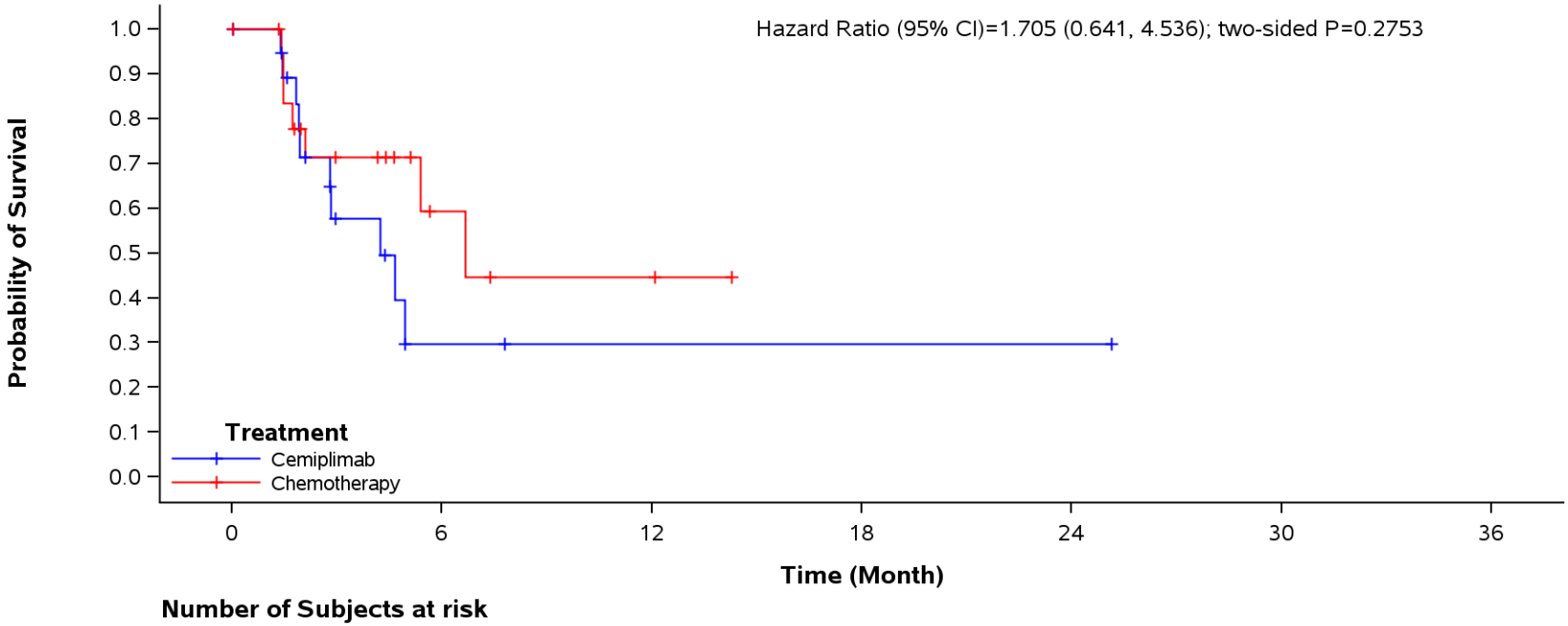

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts improvement



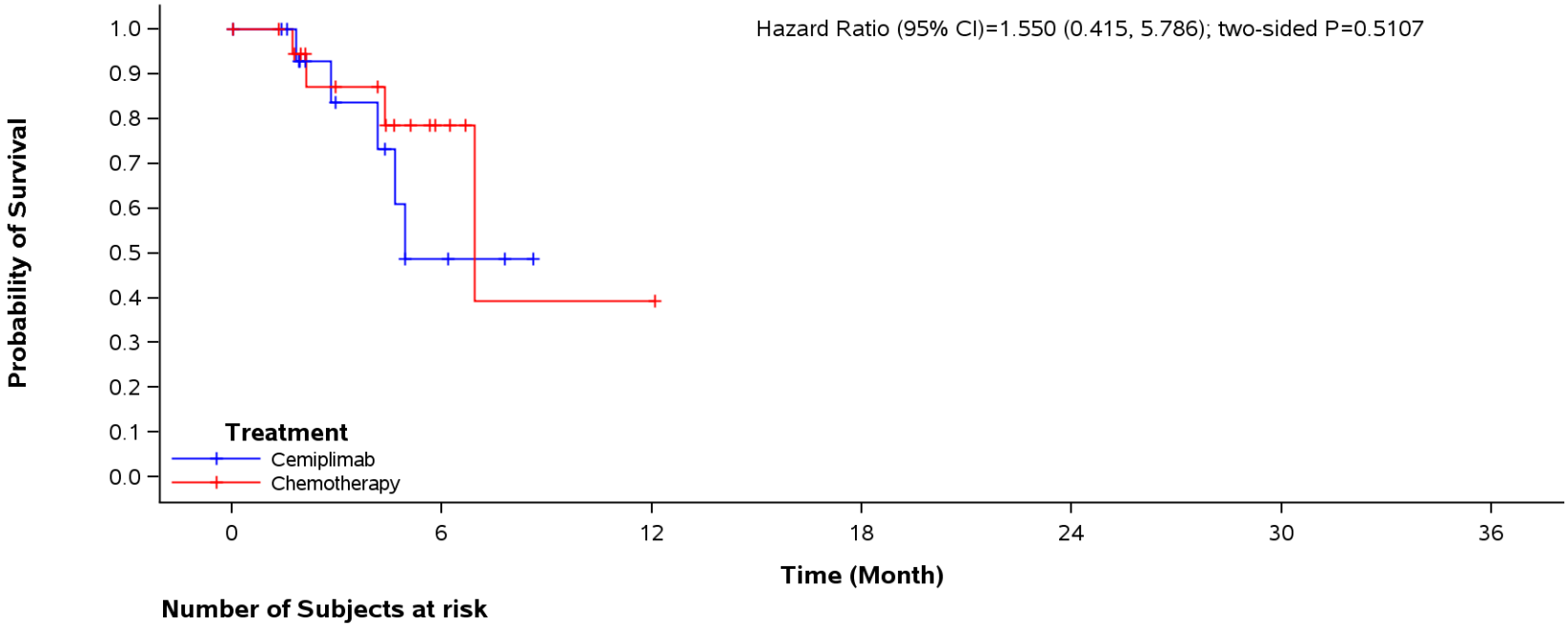

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts improvement



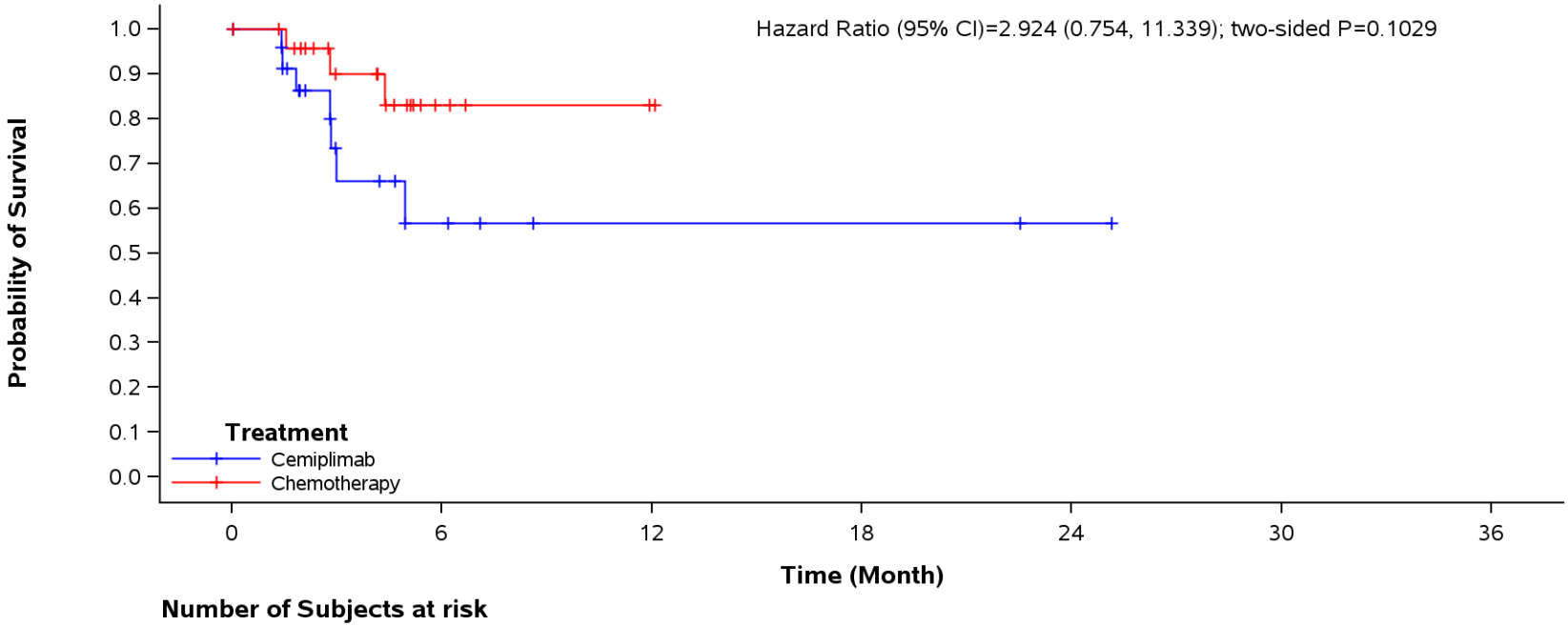

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts improvement



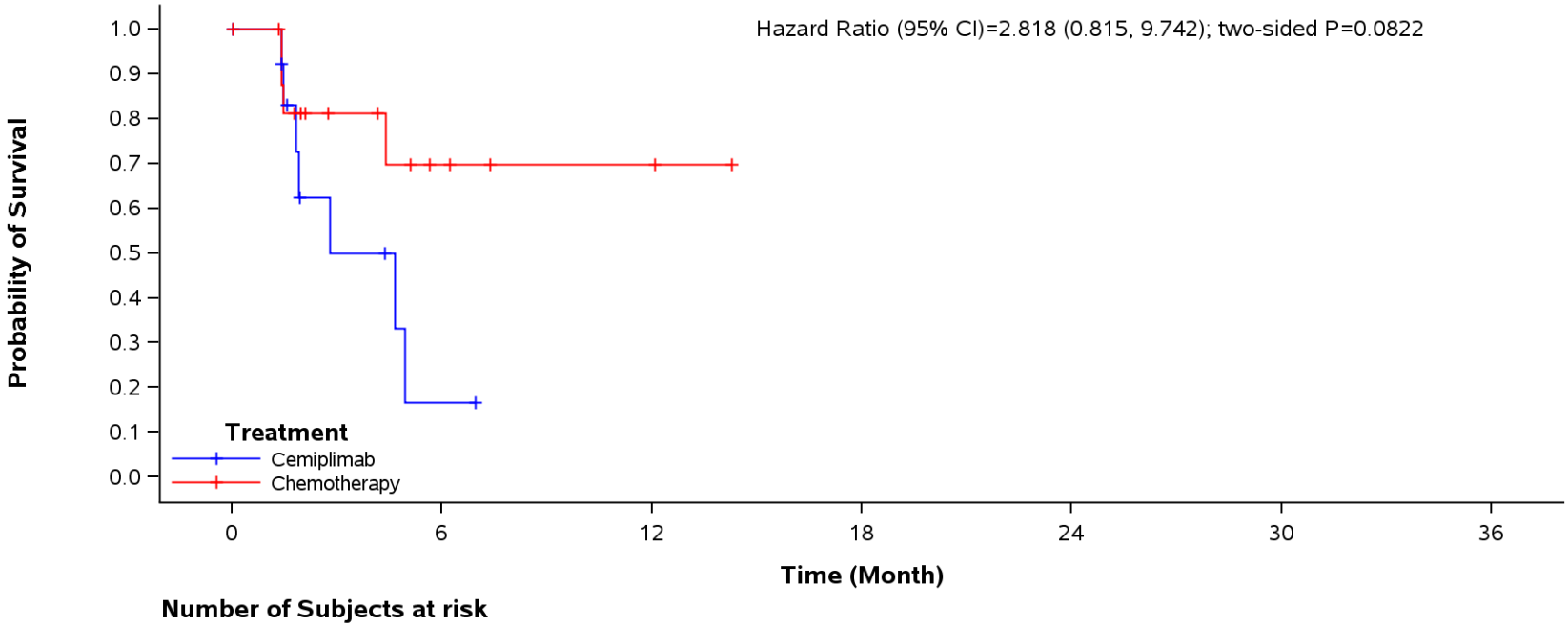

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 5 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts improvement



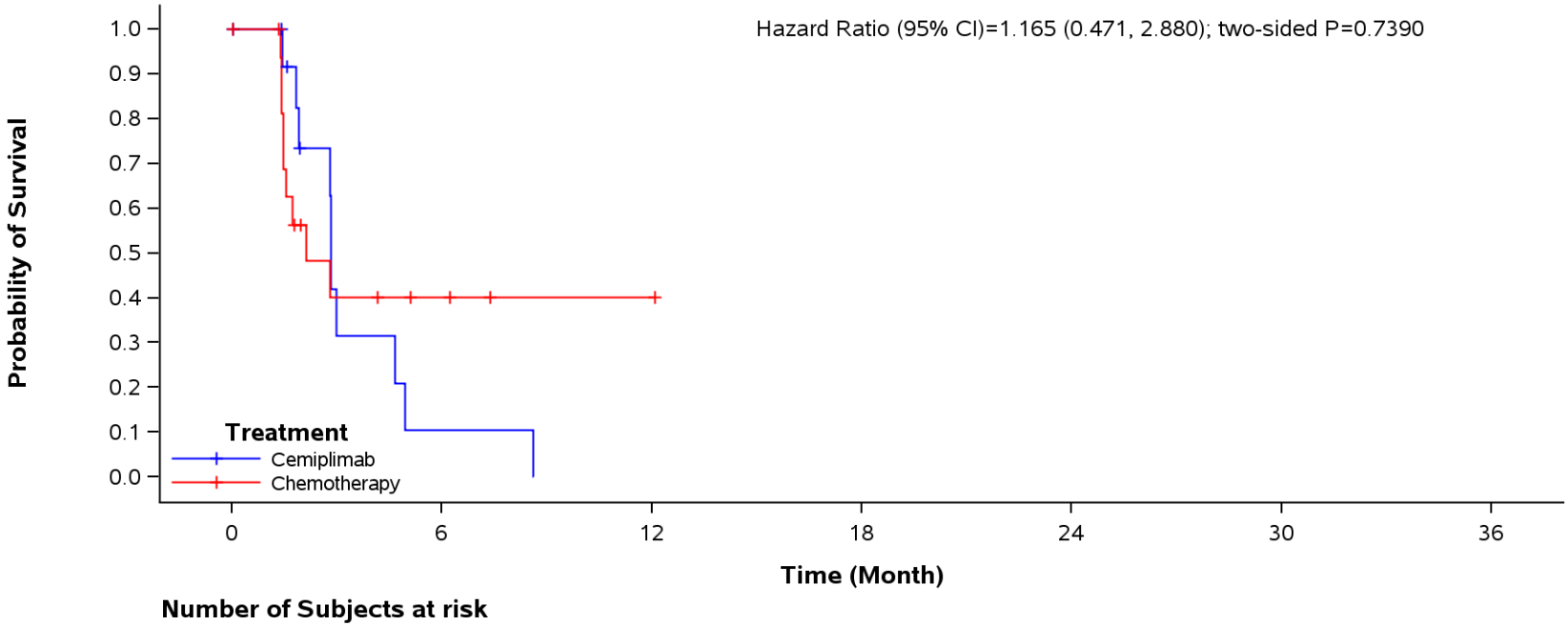

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts improvement



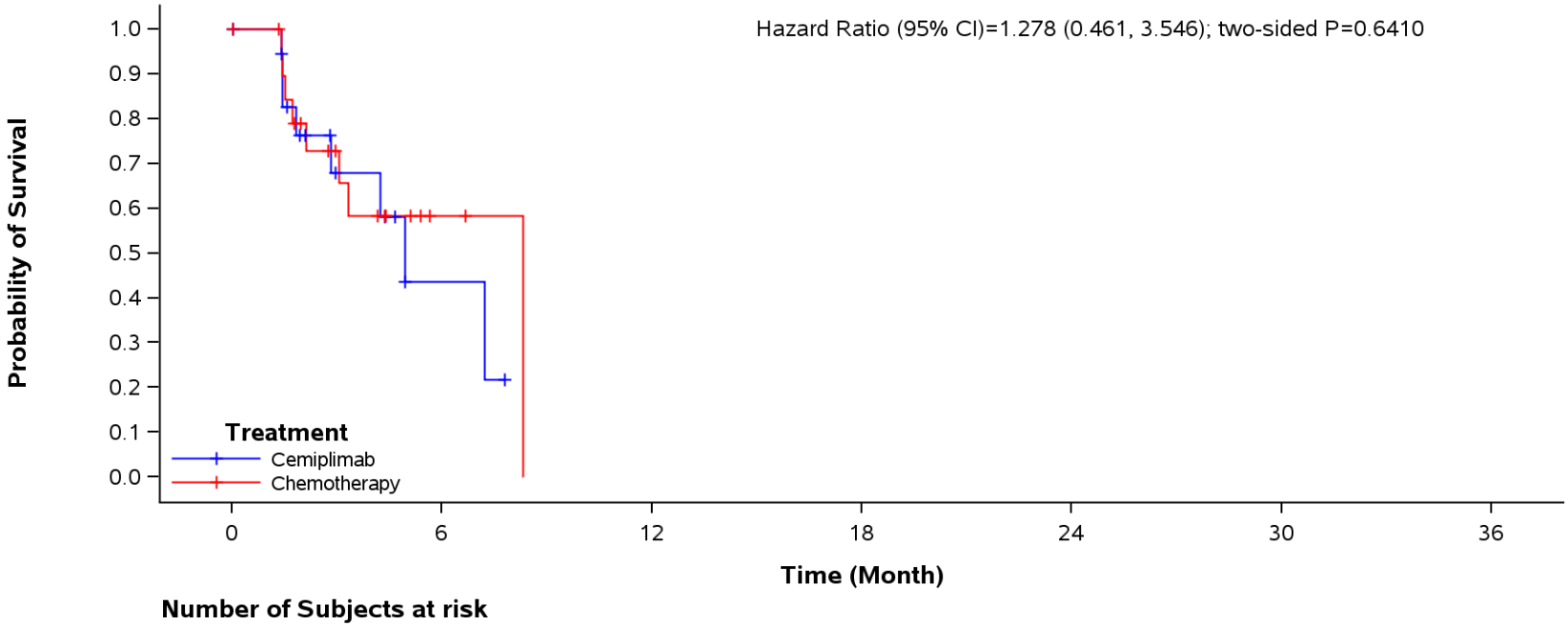

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.3a. Time to First Improvement with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts improvement



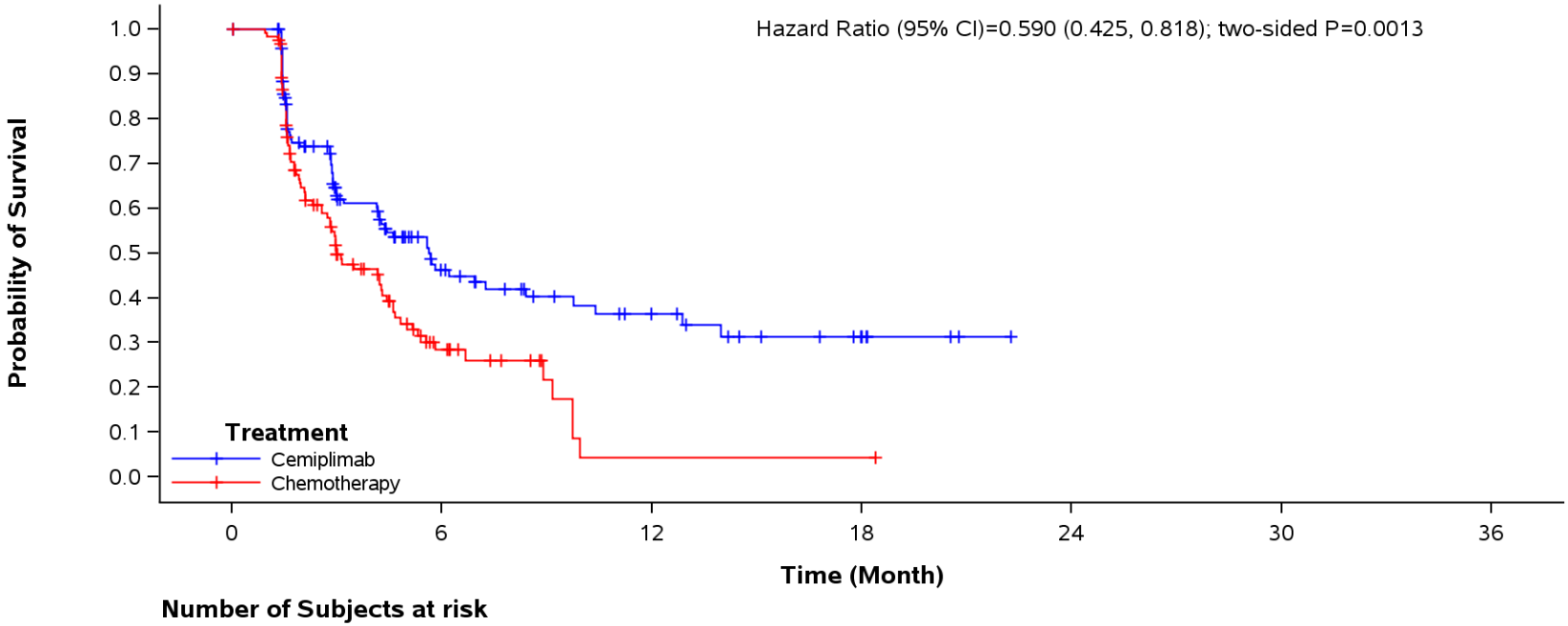

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts deterioration



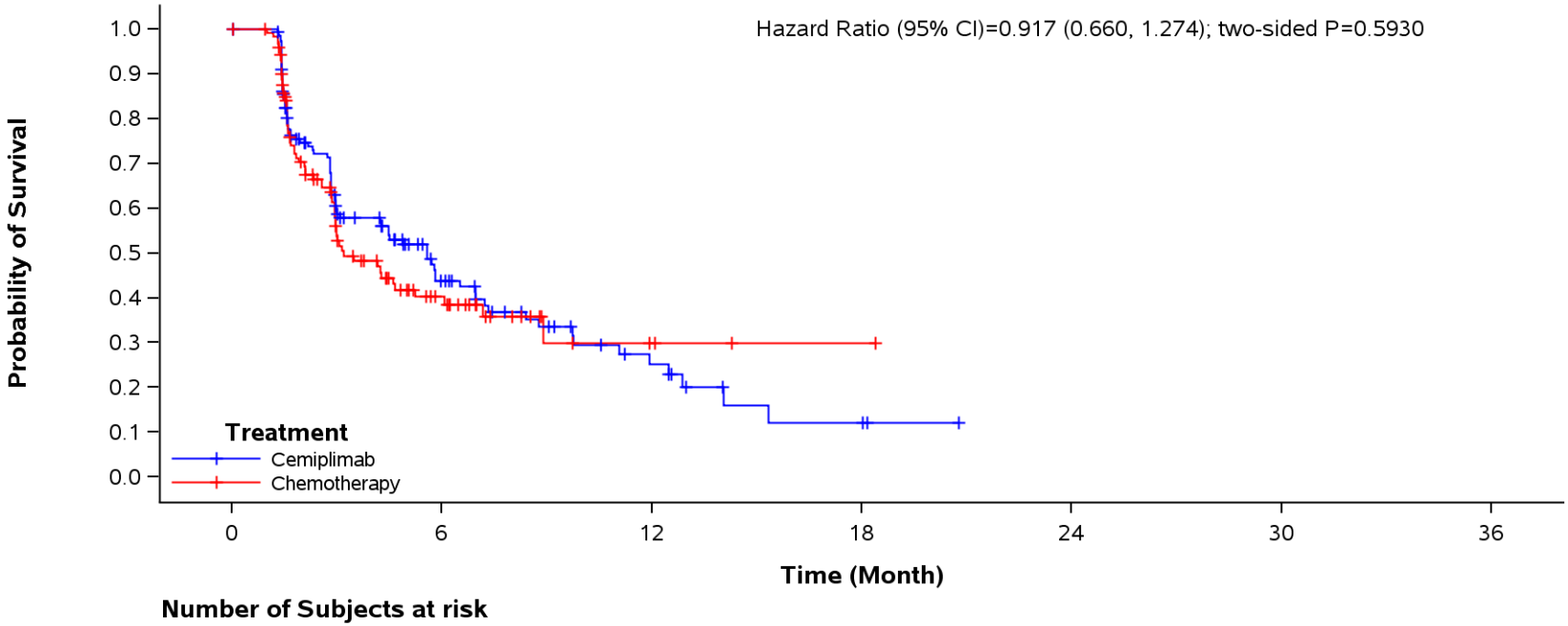

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 36 | 16 | 6 | 0 | 0 | 0 |
| Chemotherapy | 163 | 17 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts deterioration



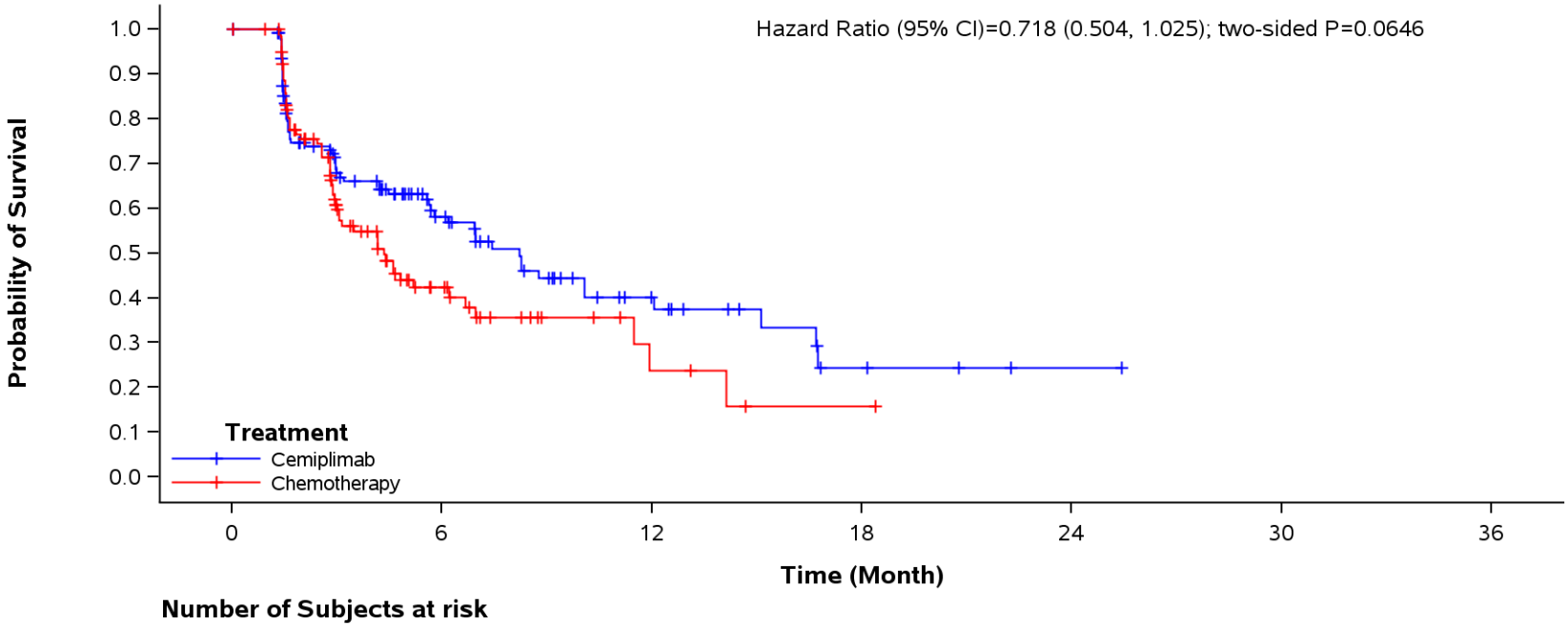

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 36 | 11 | 3 | 0 | 0 | 0 |
| Chemotherapy | 163 | 23 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts deterioration



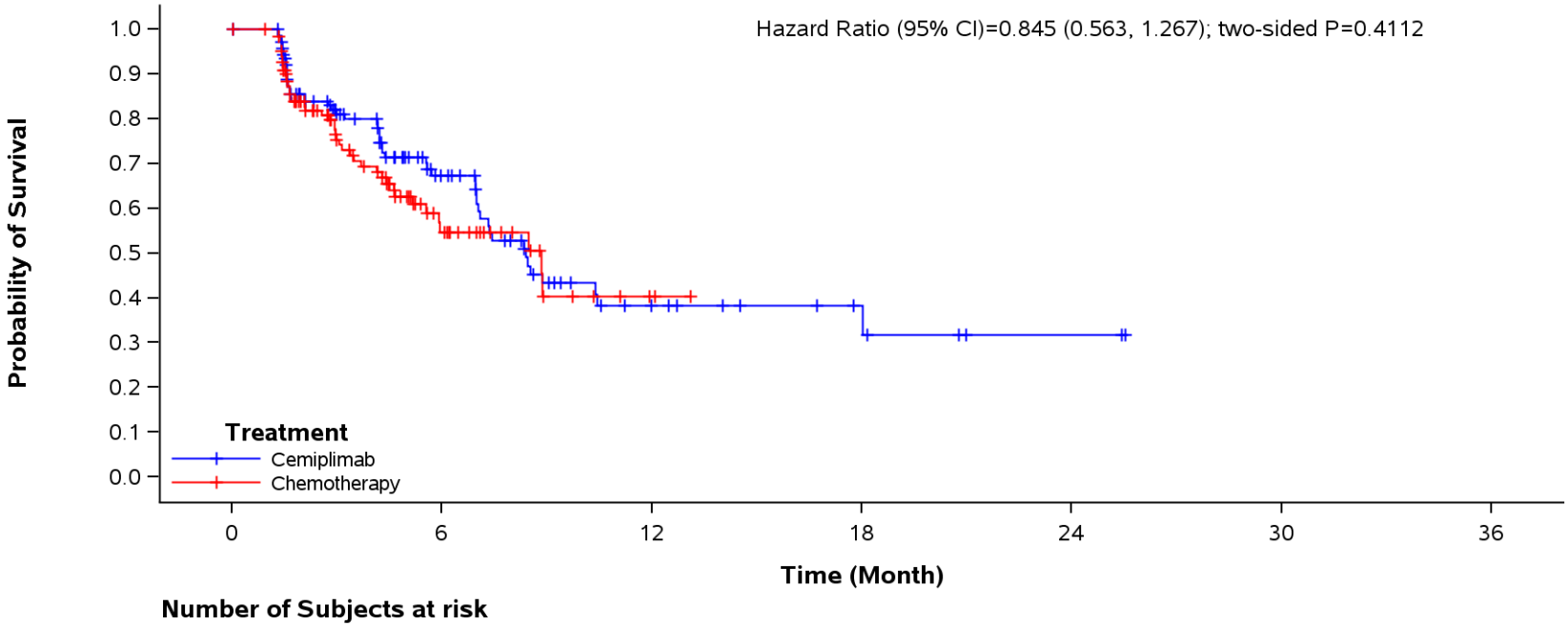

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 44 | 15 | 4 | 1 | 0 | 0 |
| Chemotherapy | 163 | 22 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts deterioration



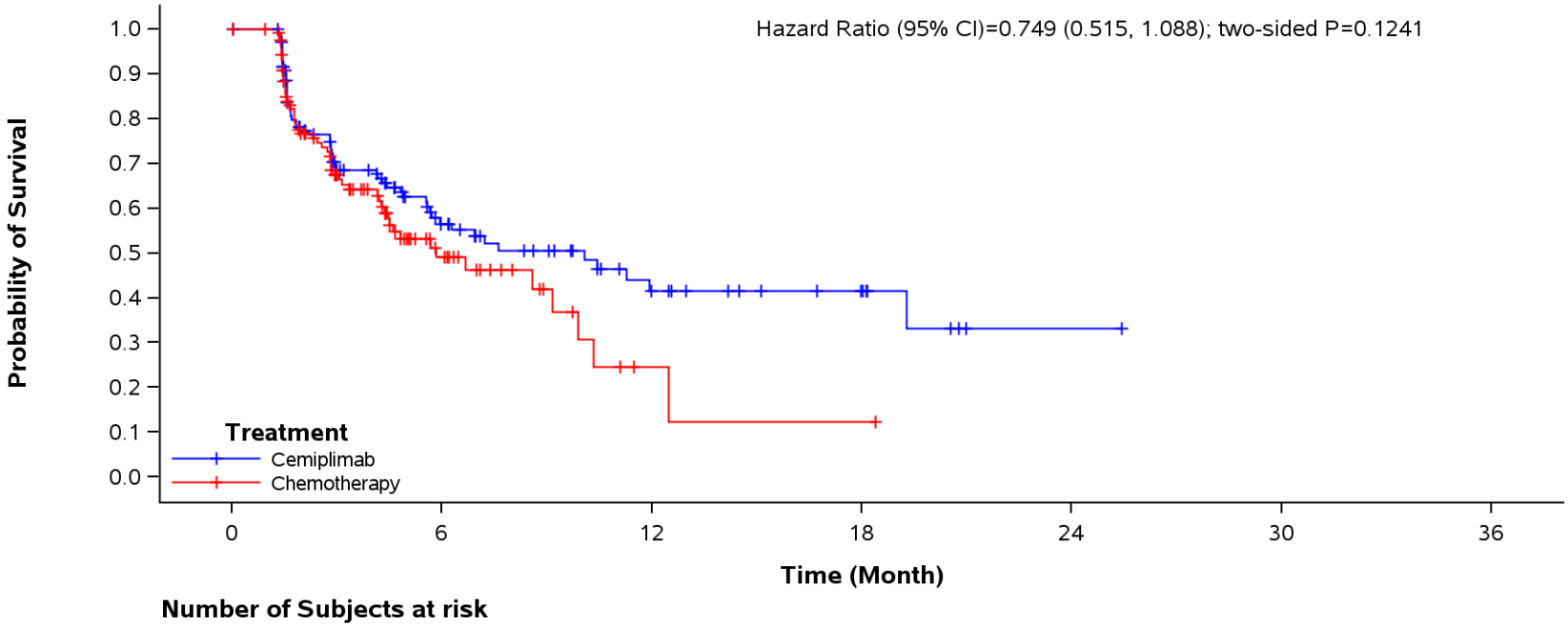

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 47 | 12 | 6 | 2 | 0 | 0 |
| Chemotherapy | 163 | 26 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts deterioration



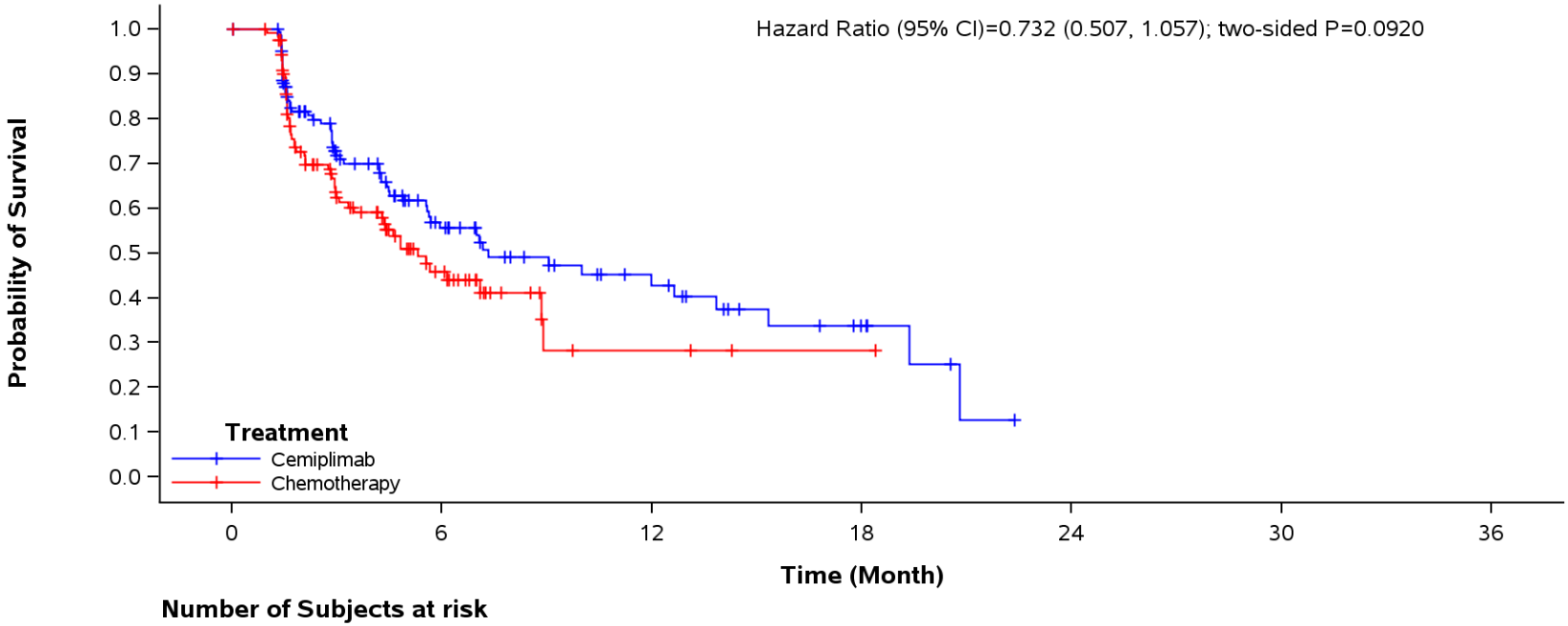

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 43 | 16 | 8 | 1 | 0 | 0 |
| Chemotherapy | 163 | 23 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts deterioration



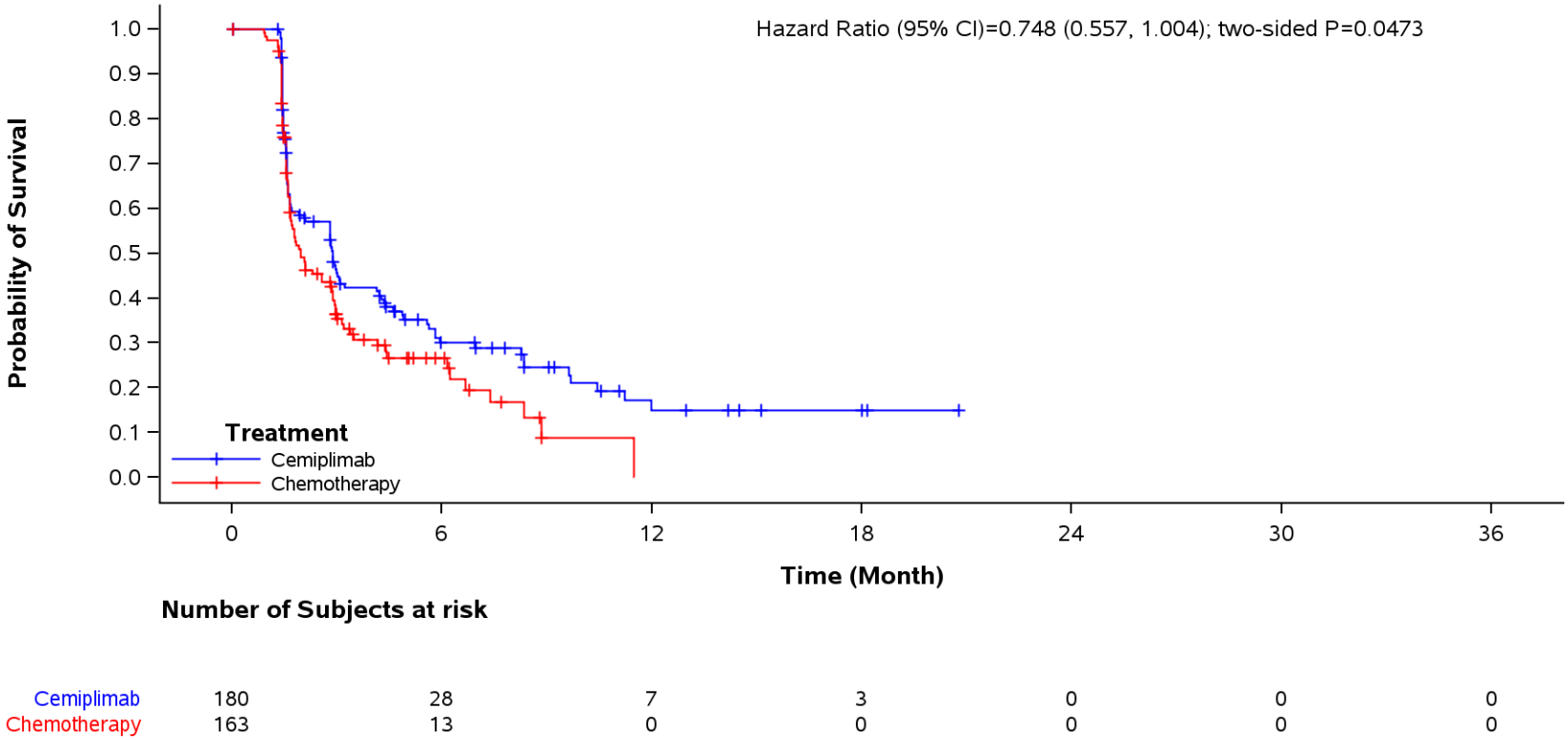

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 44 | 18 | 6 | 0 | 0 | 0 |
| Chemotherapy | 163 | 25 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

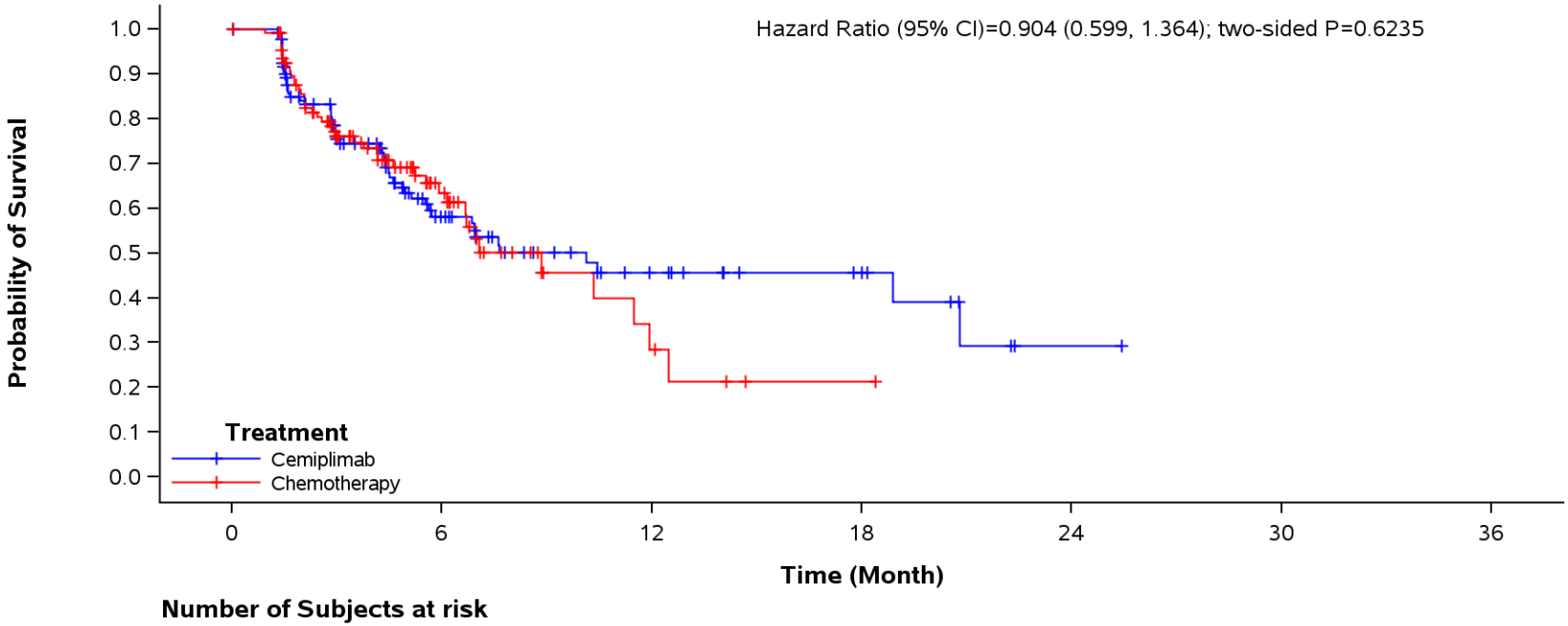
Age Group: <65
Fatigue - 10 pts deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts deterioration



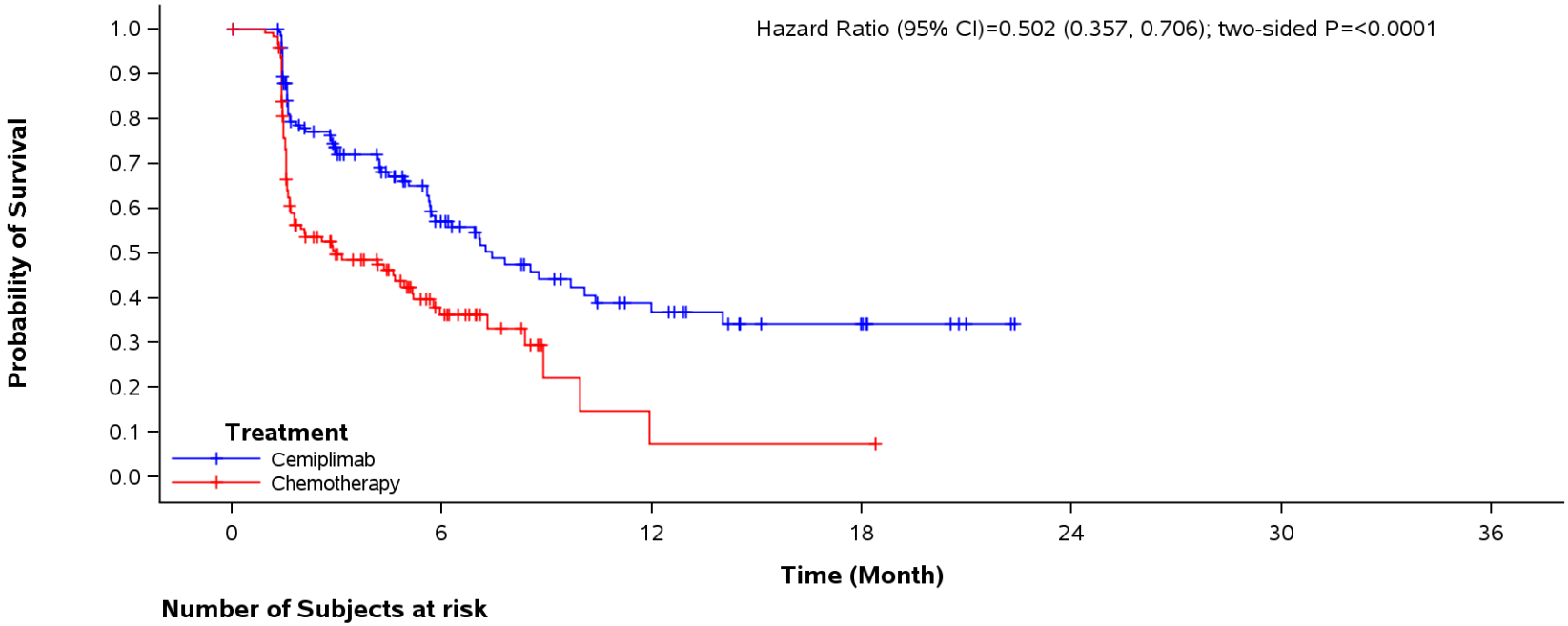

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 41 | 16 | 9 | 1 | 0 | 0 |
| Chemotherapy | 163 | 30 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts deterioration



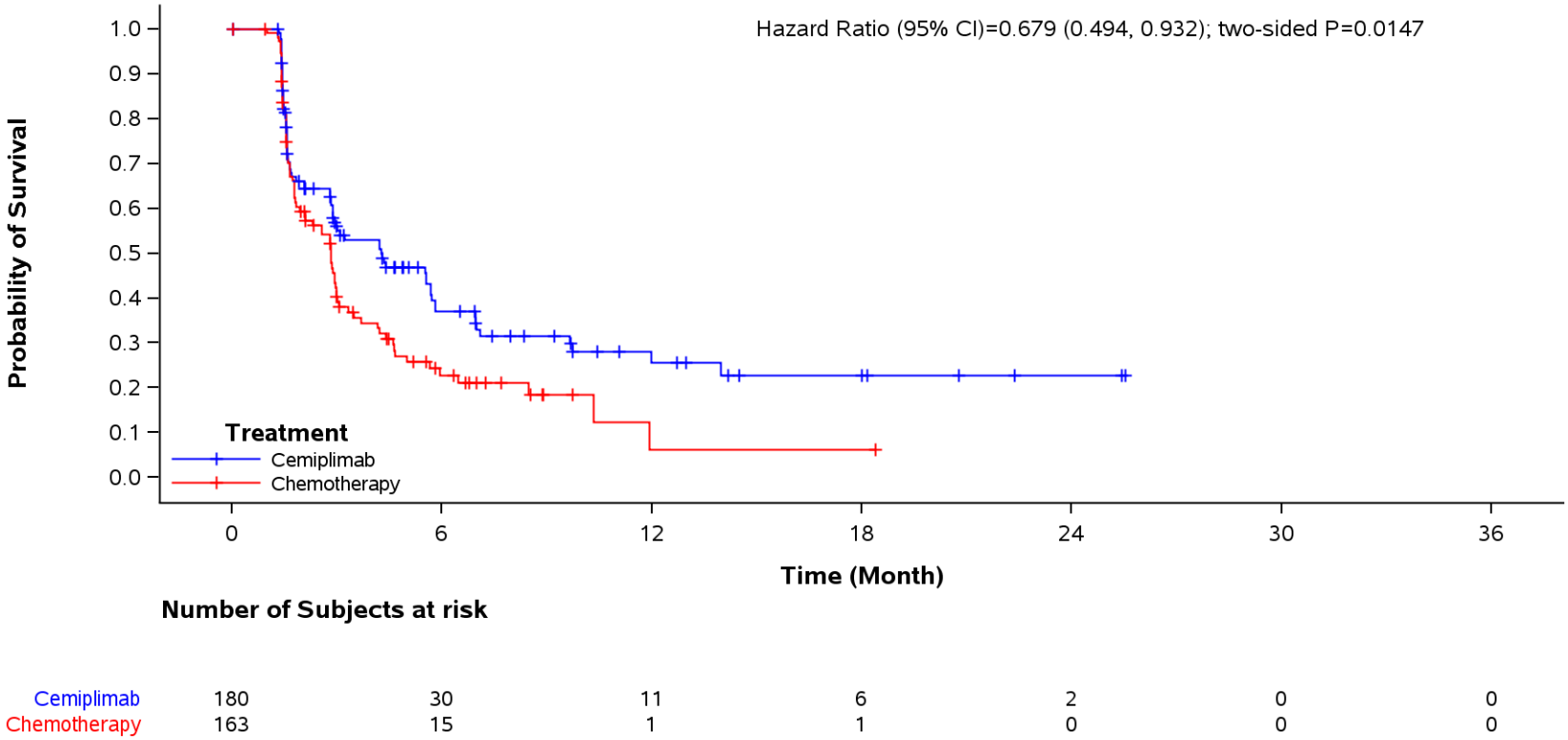

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 48 | 18 | 8 | 0 | 0 | 0 |
| Chemotherapy | 163 | 21 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts deterioration



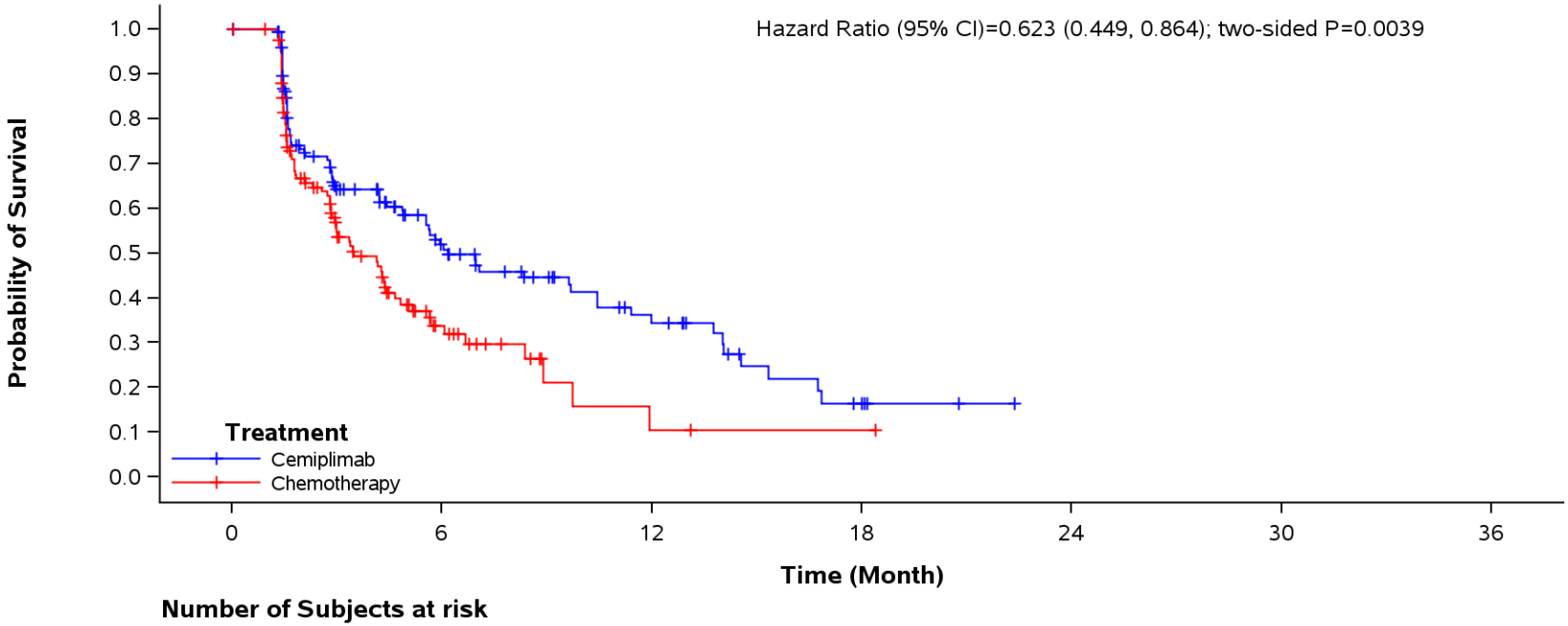

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 30 | 11 | 6 | 2 | 0 | 0 |
| Chemotherapy | 163 | 15 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts deterioration



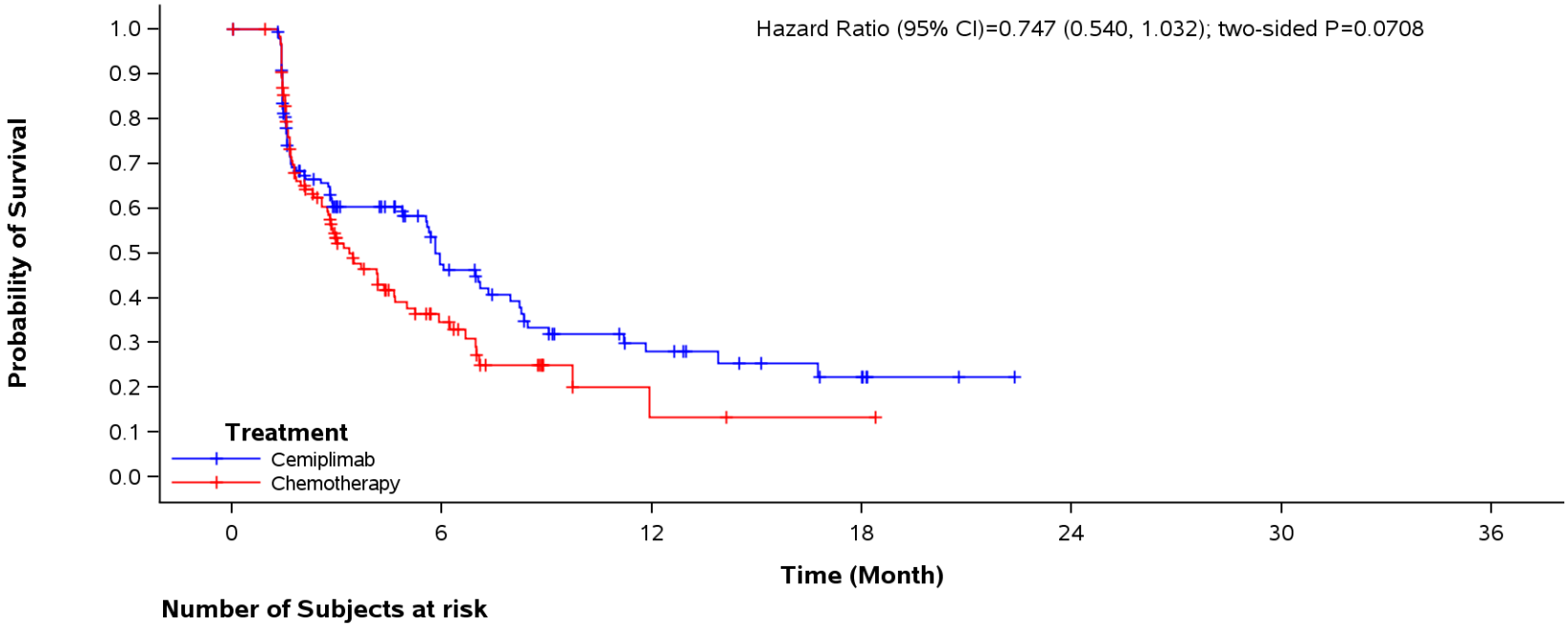

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 46 | 19 | 5 | 0 | 0 | 0 |
| Chemotherapy | 163 | 18 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts deterioration



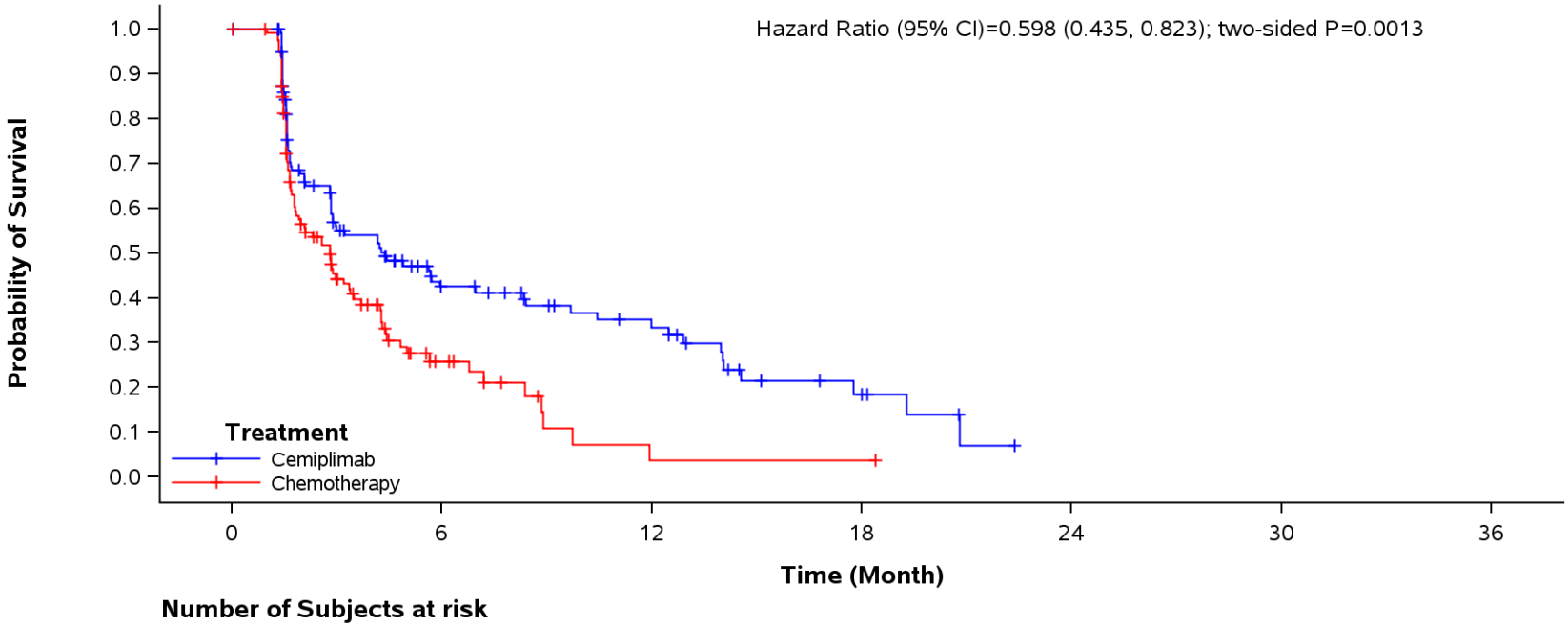

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 39 | 14 | 6 | 0 | 0 | 0 |
| Chemotherapy | 163 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts deterioration



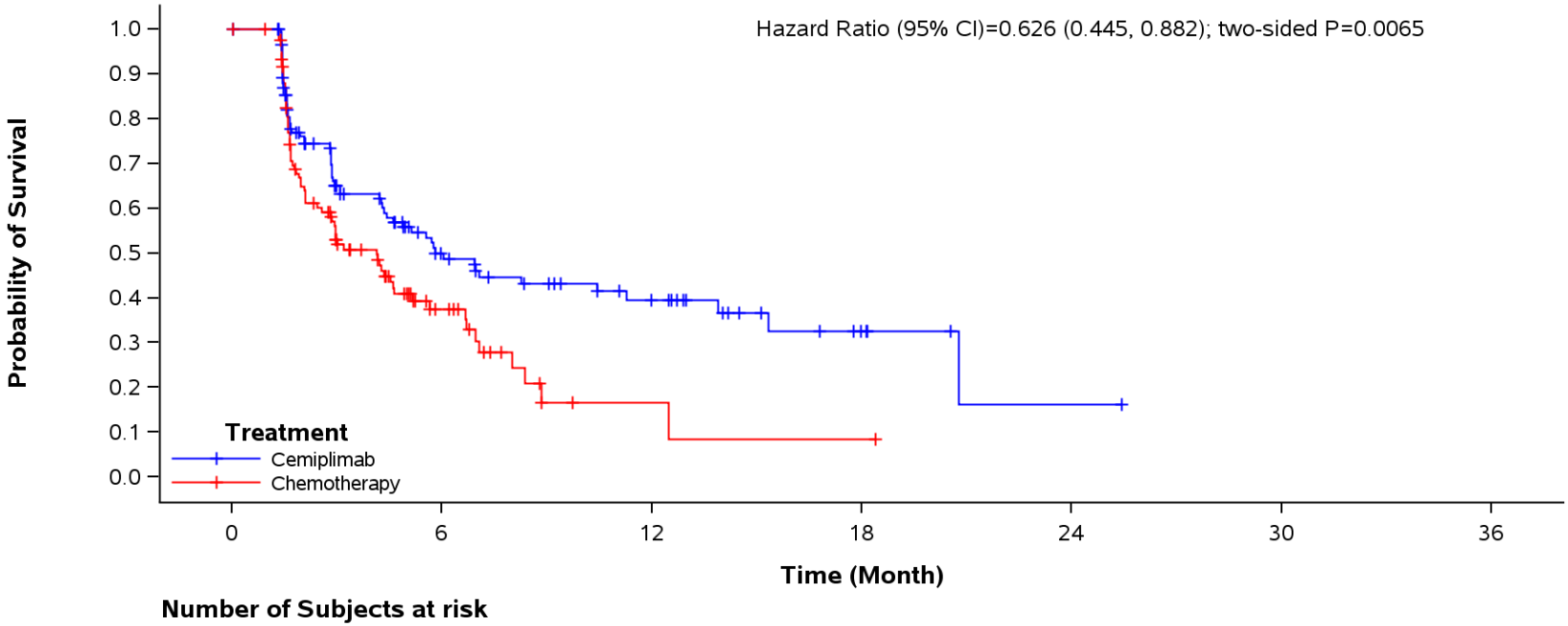

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 35 | 20 | 6 | 0 | 0 | 0 |
| Chemotherapy | 163 | 13 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts deterioration



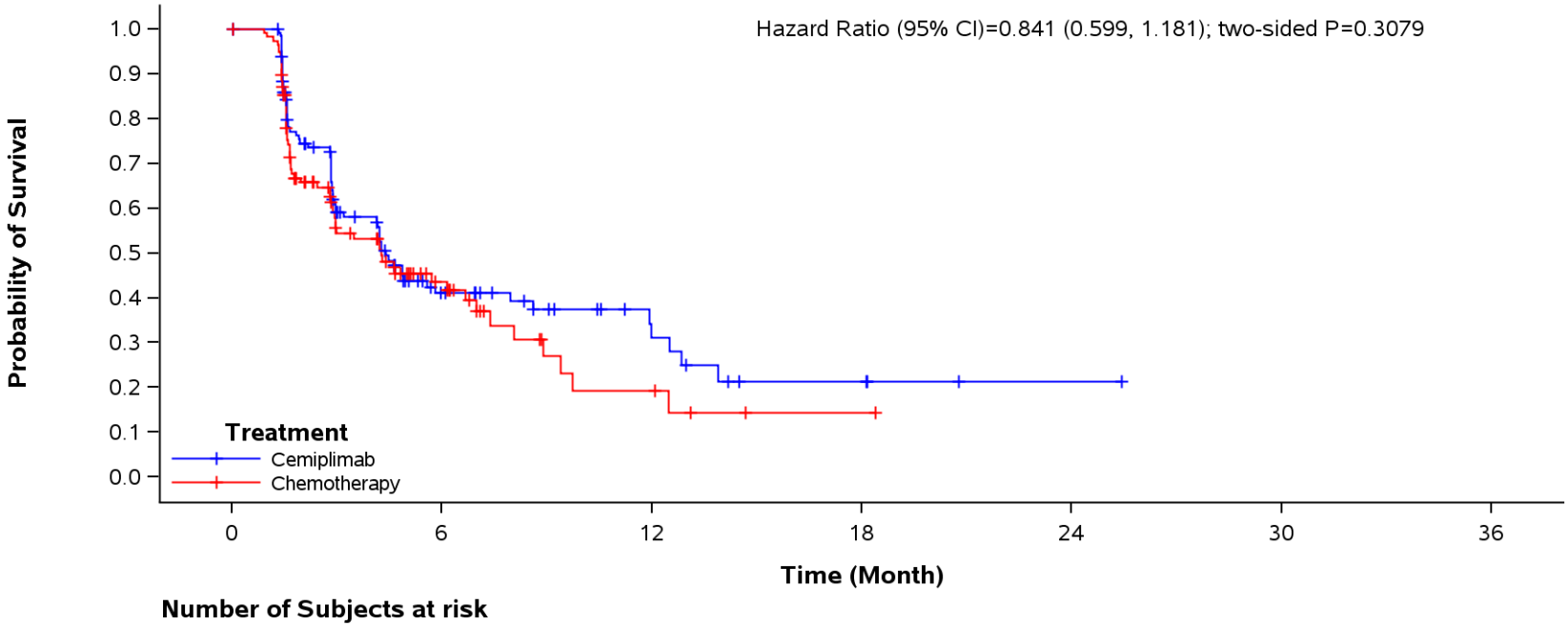

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 40 | 19 | 5 | 1 | 0 | 0 |
| Chemotherapy | 163 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts deterioration



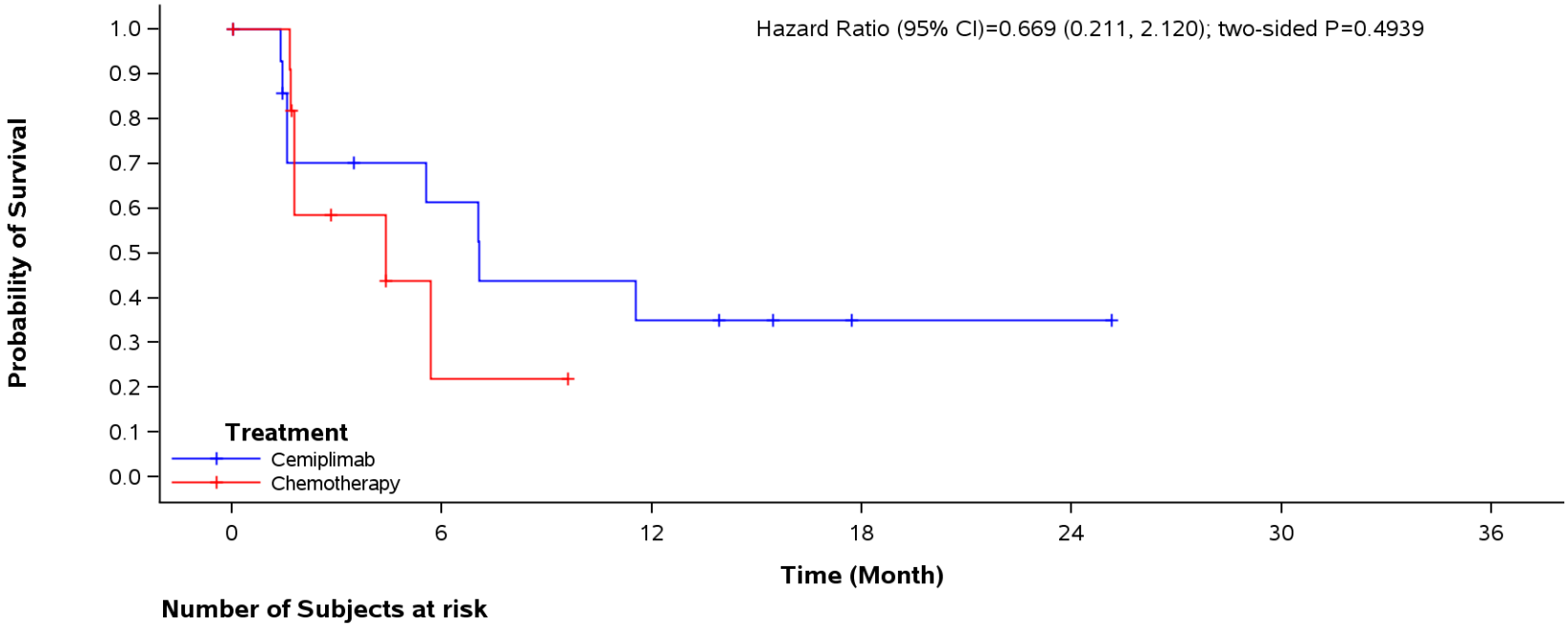

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 29 | 10 | 4 | 1 | 0 | 0 |
| Chemotherapy | 163 | 23 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts deterioration



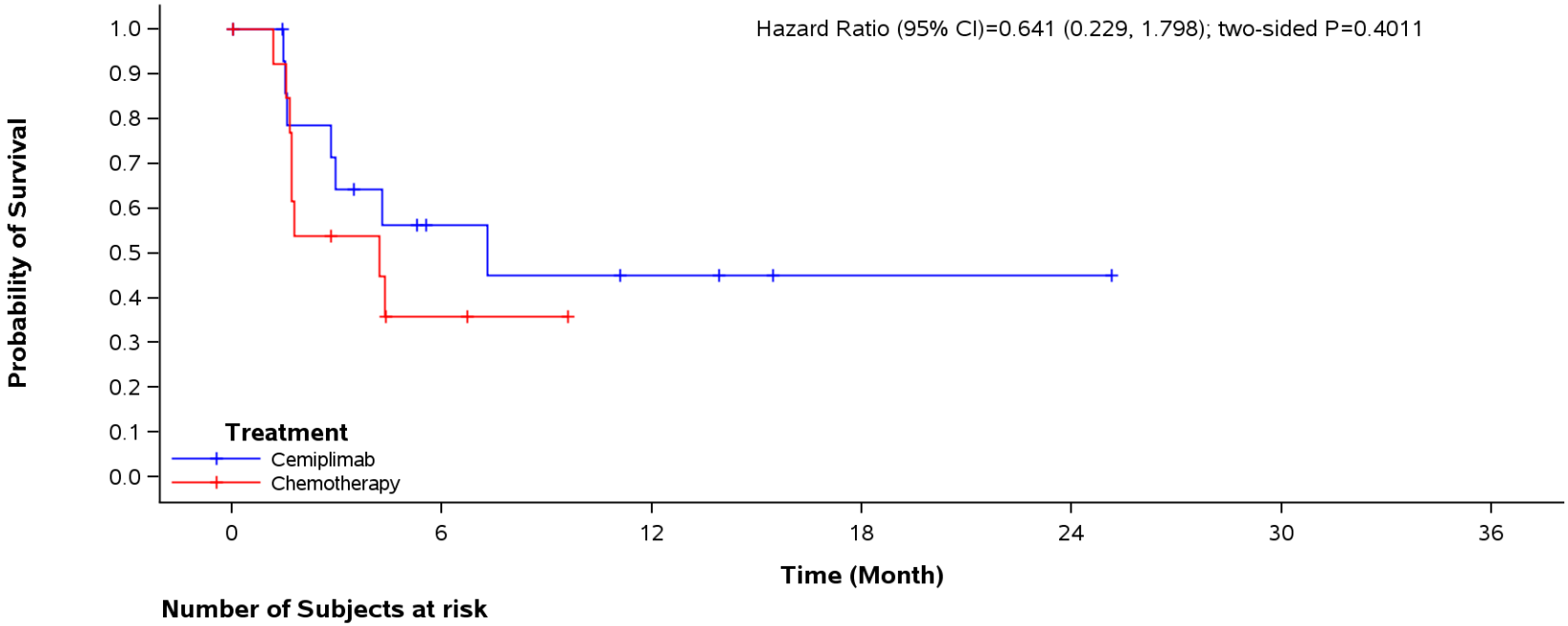

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts deterioration



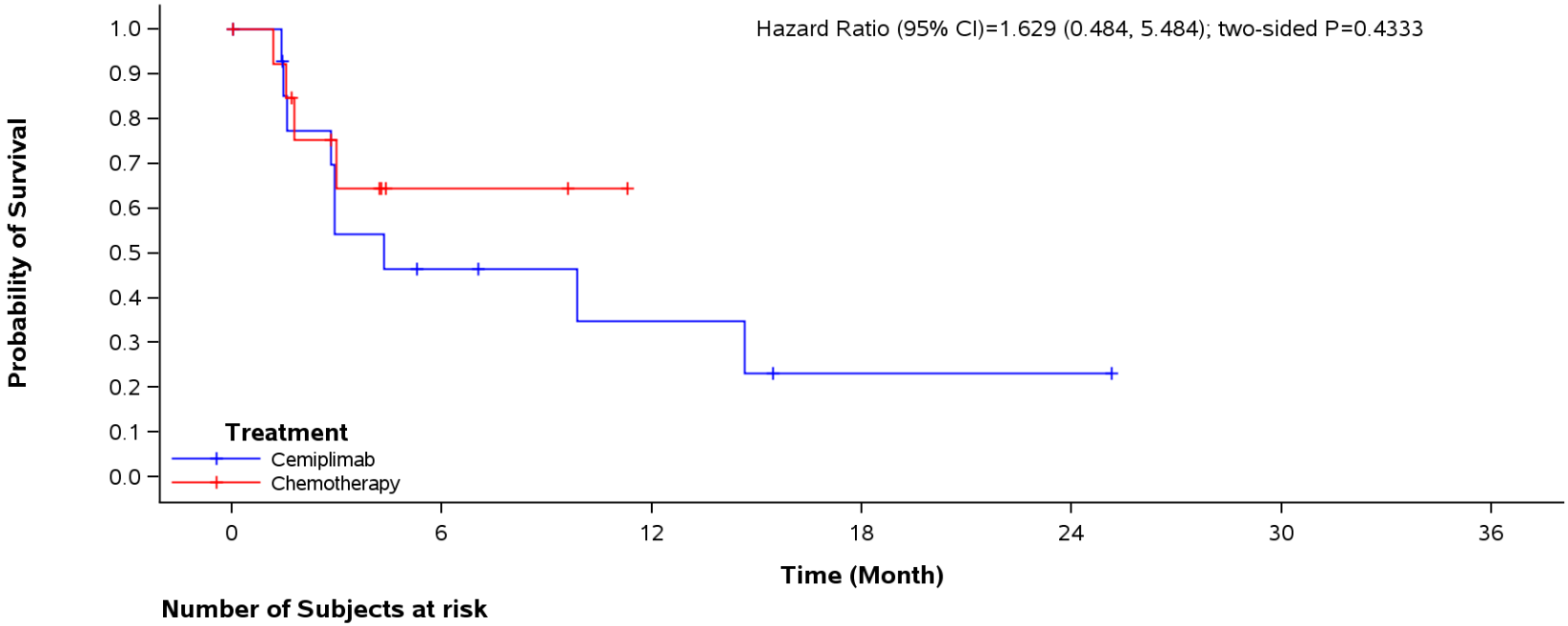

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts deterioration



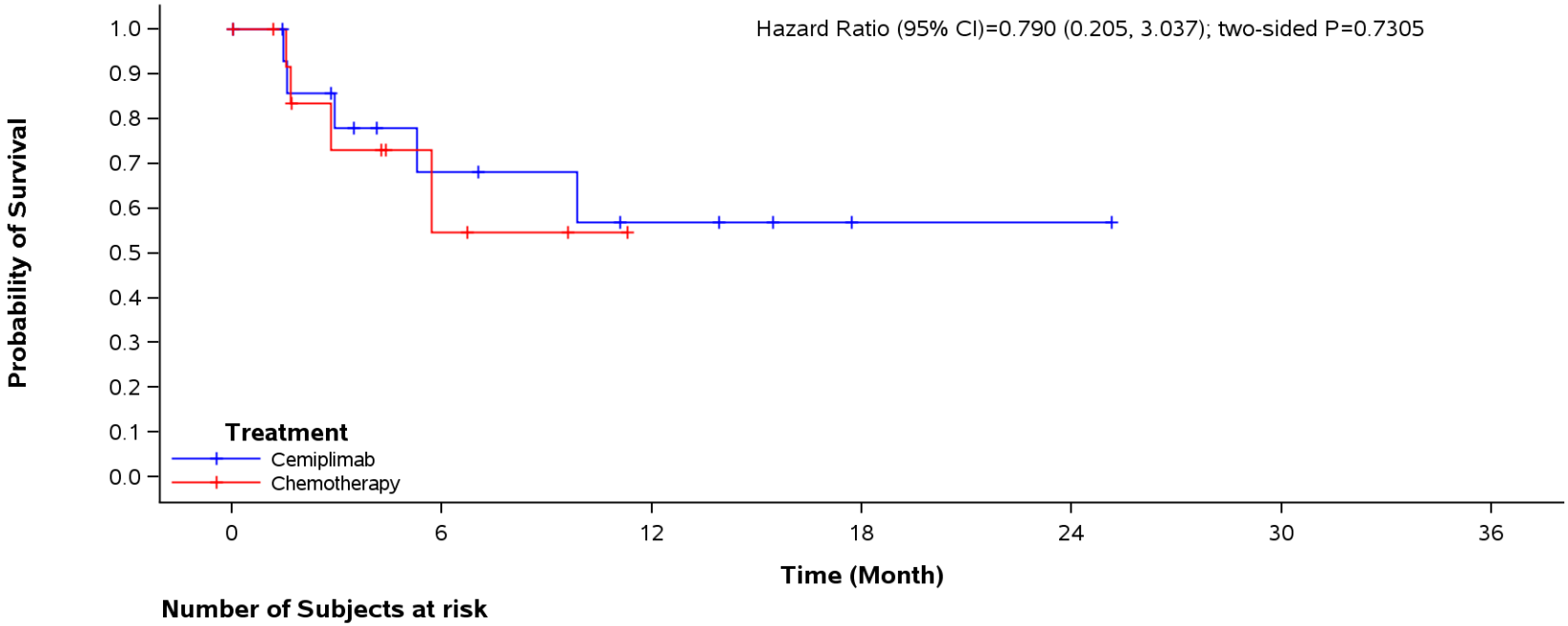

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts deterioration



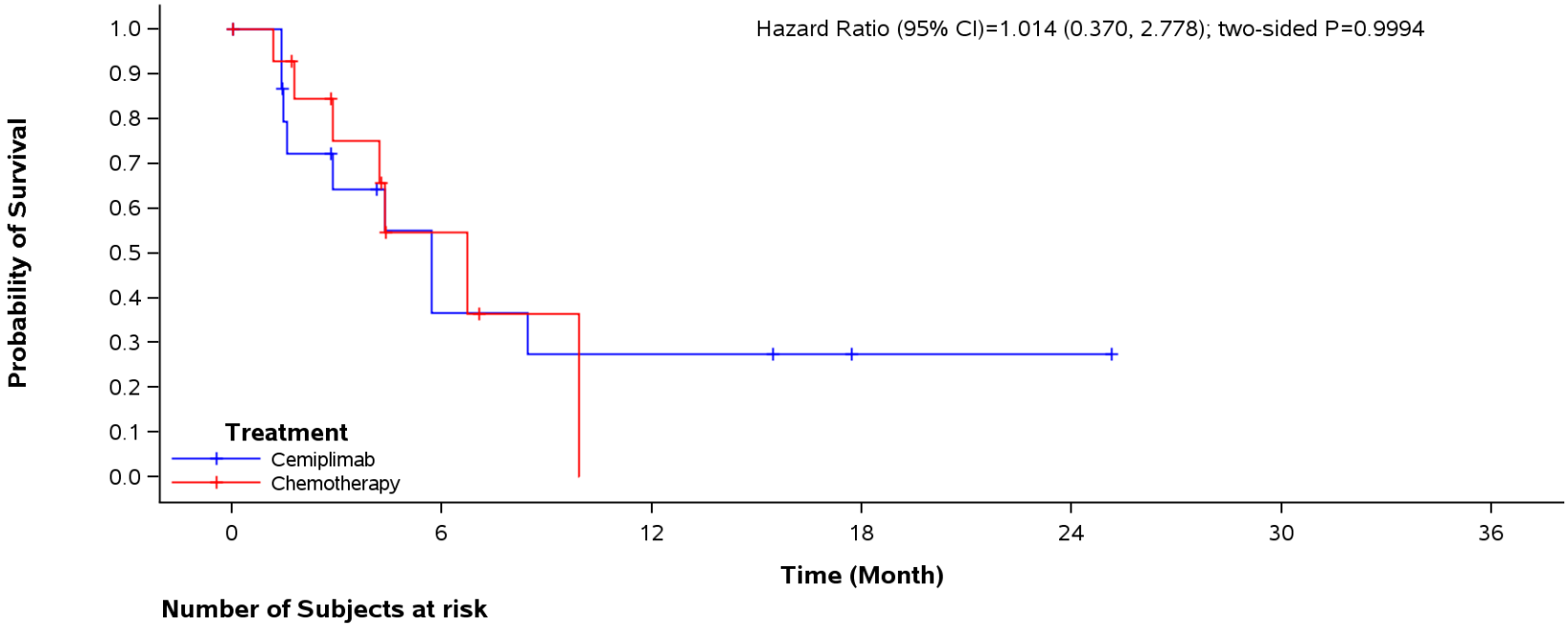

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts deterioration



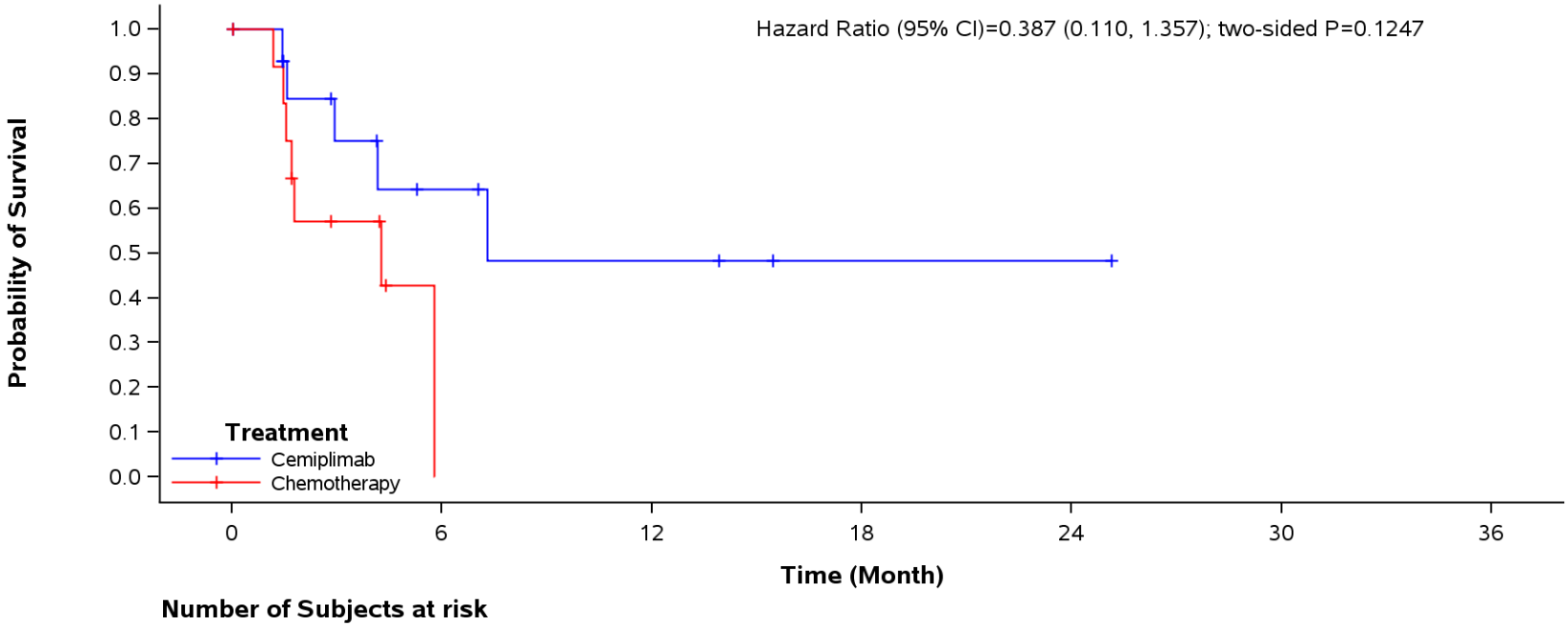

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 4 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts deterioration



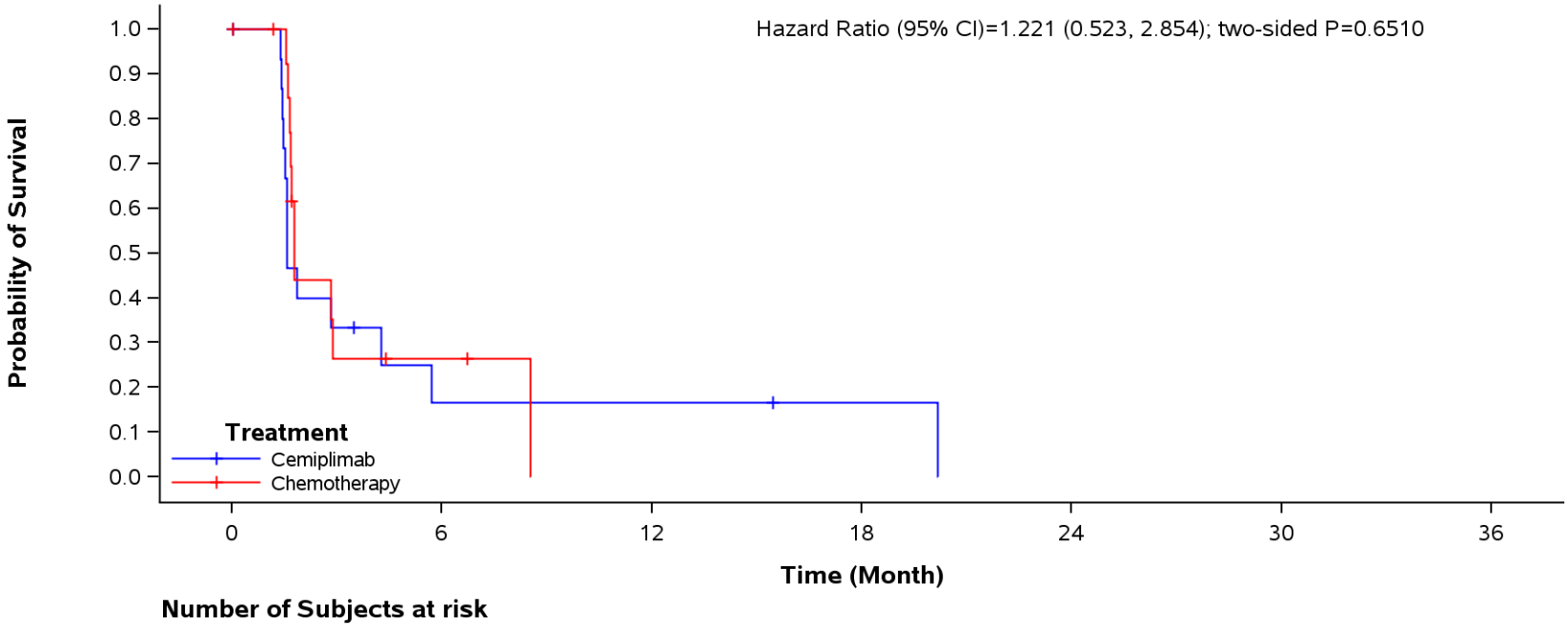

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts deterioration



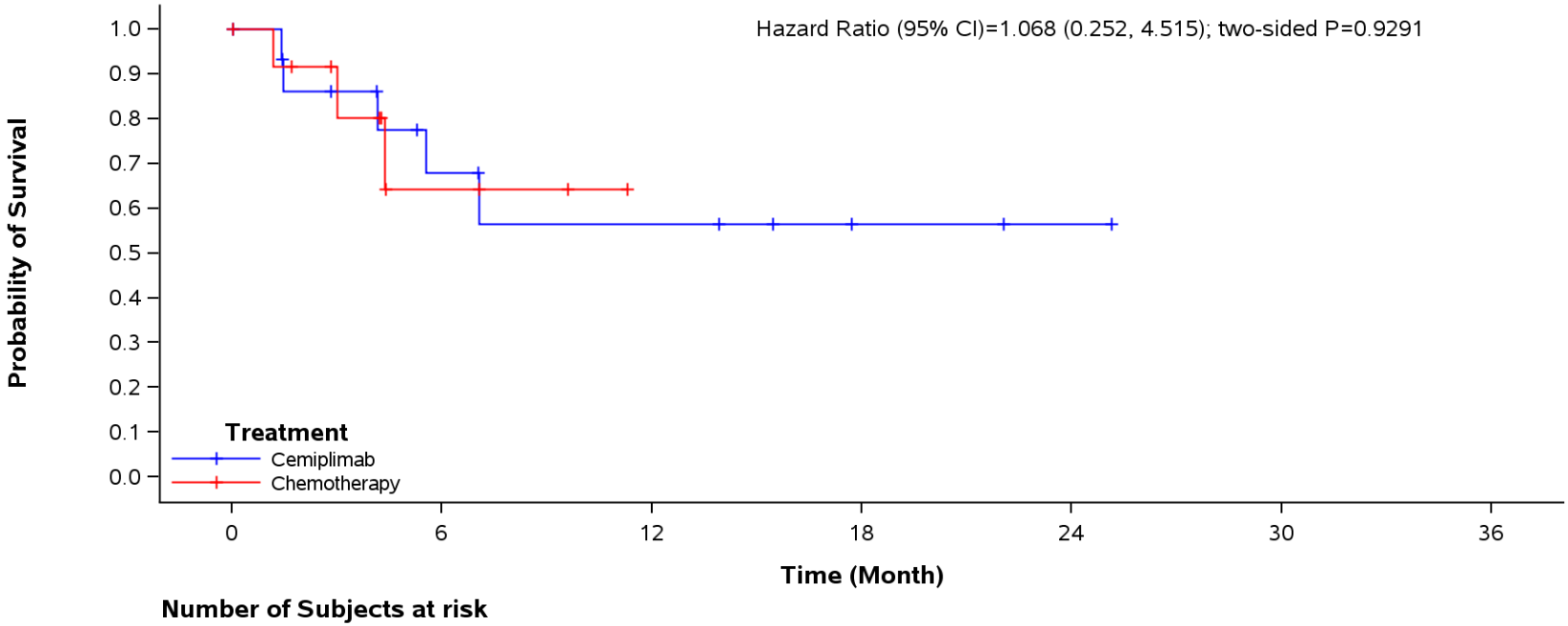

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts deterioration



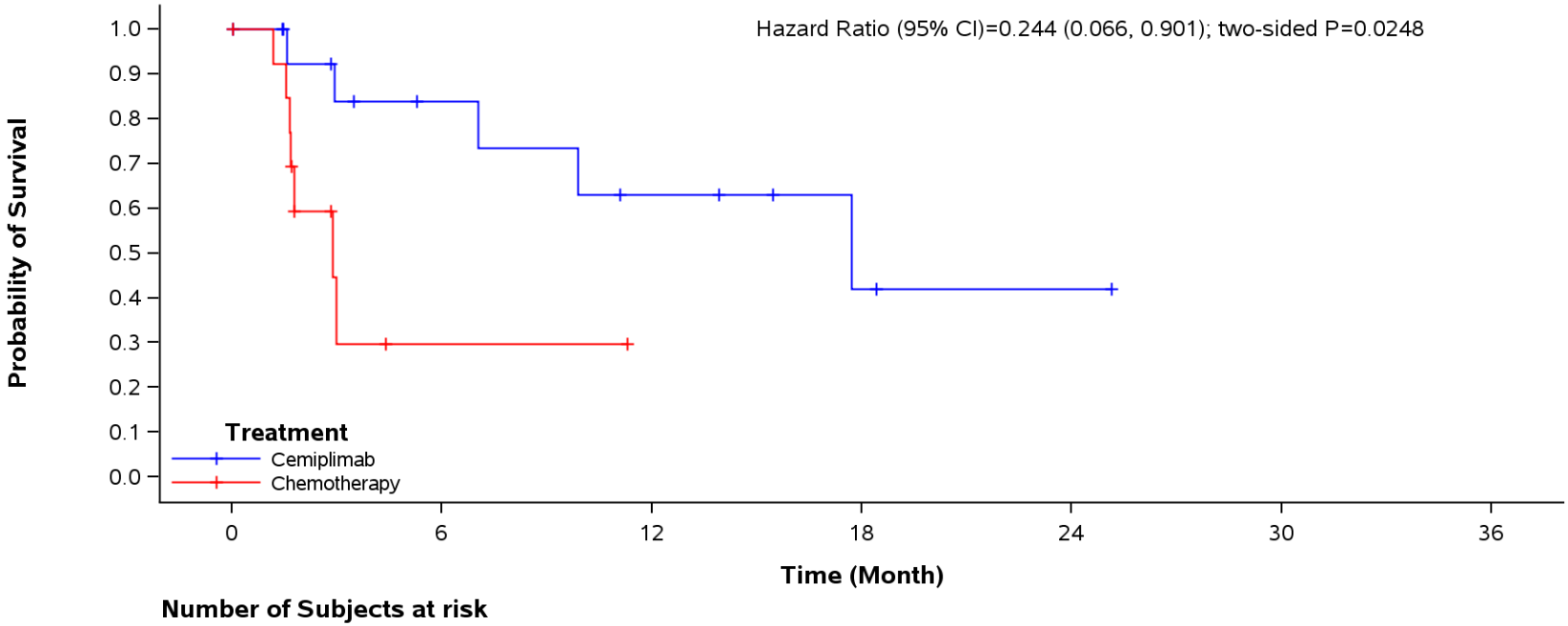

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts deterioration



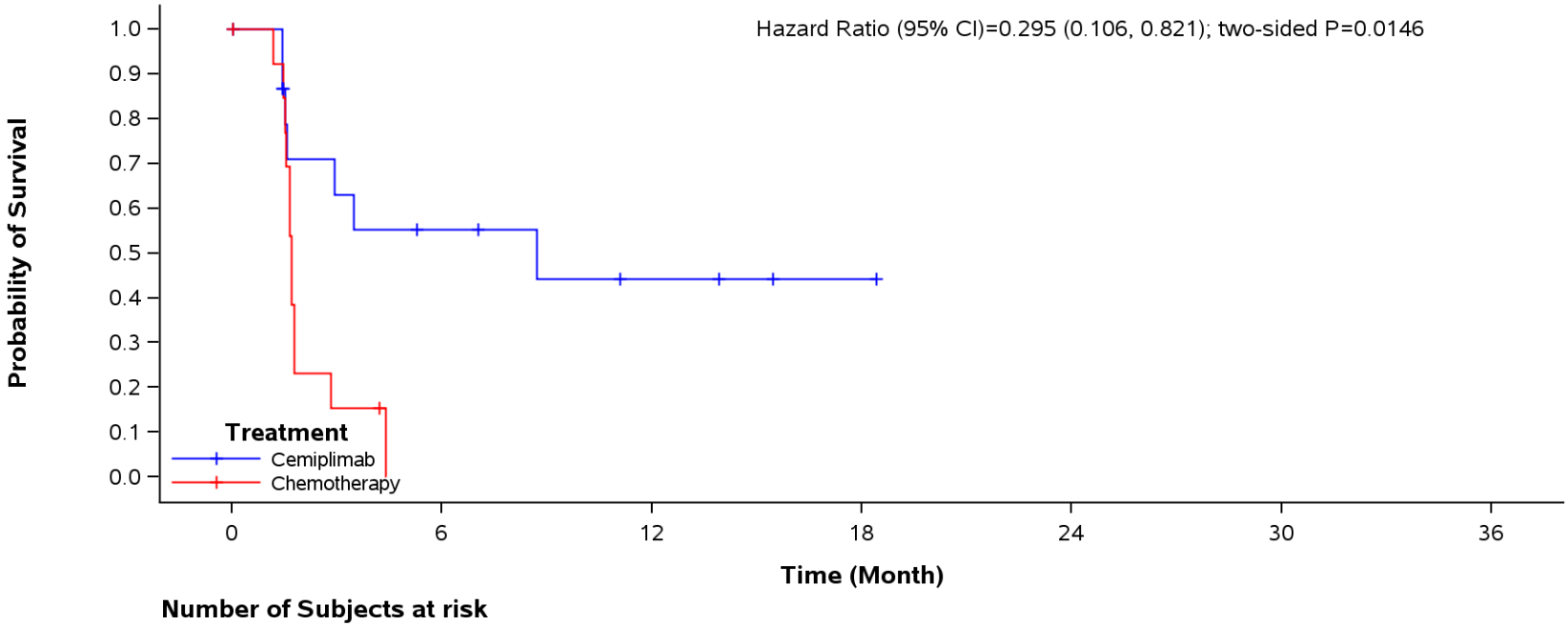

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts deterioration



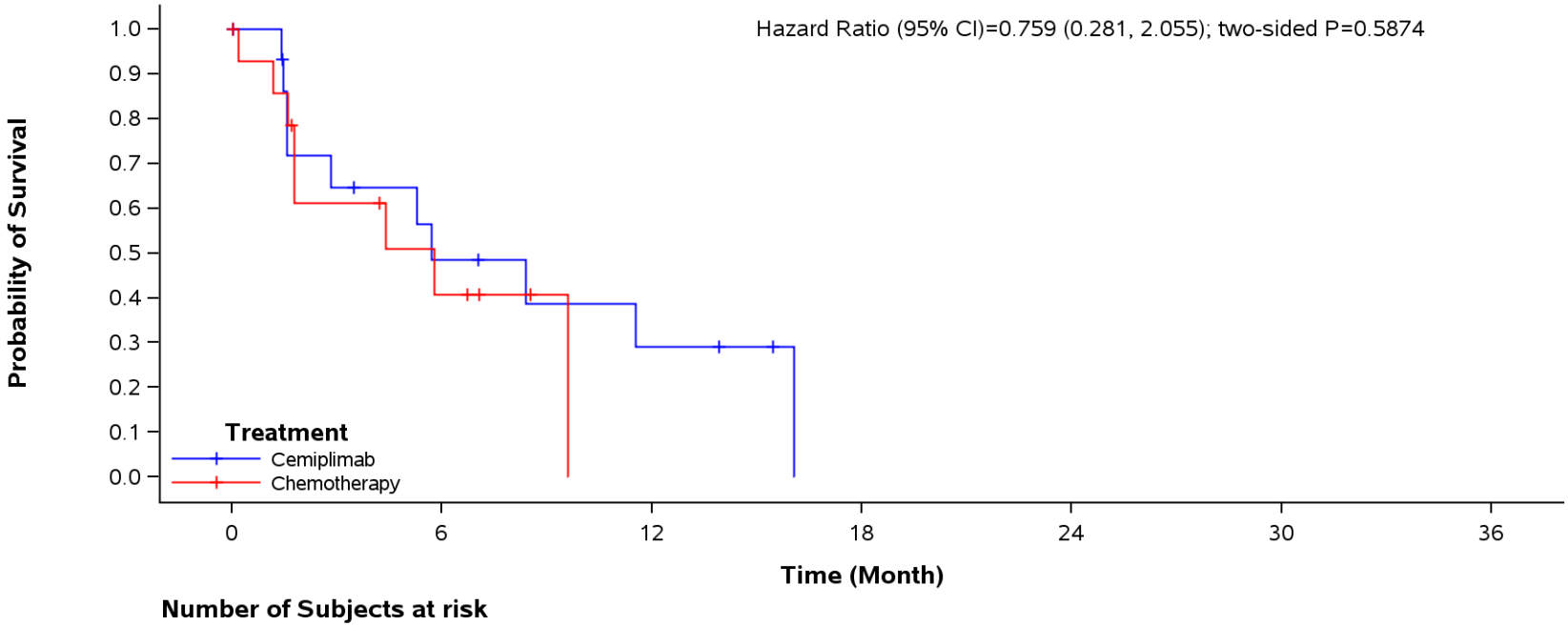

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts deterioration



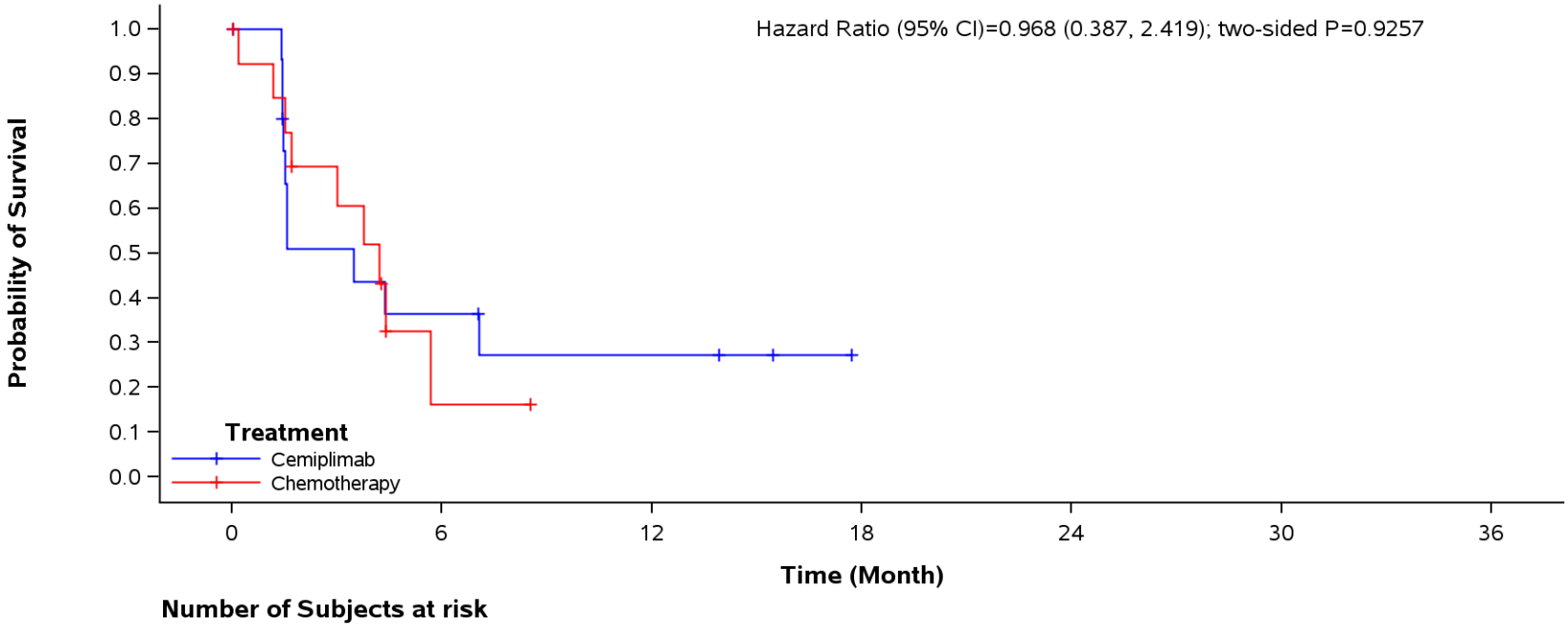

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Global health status / QoL - 10 pts deterioration



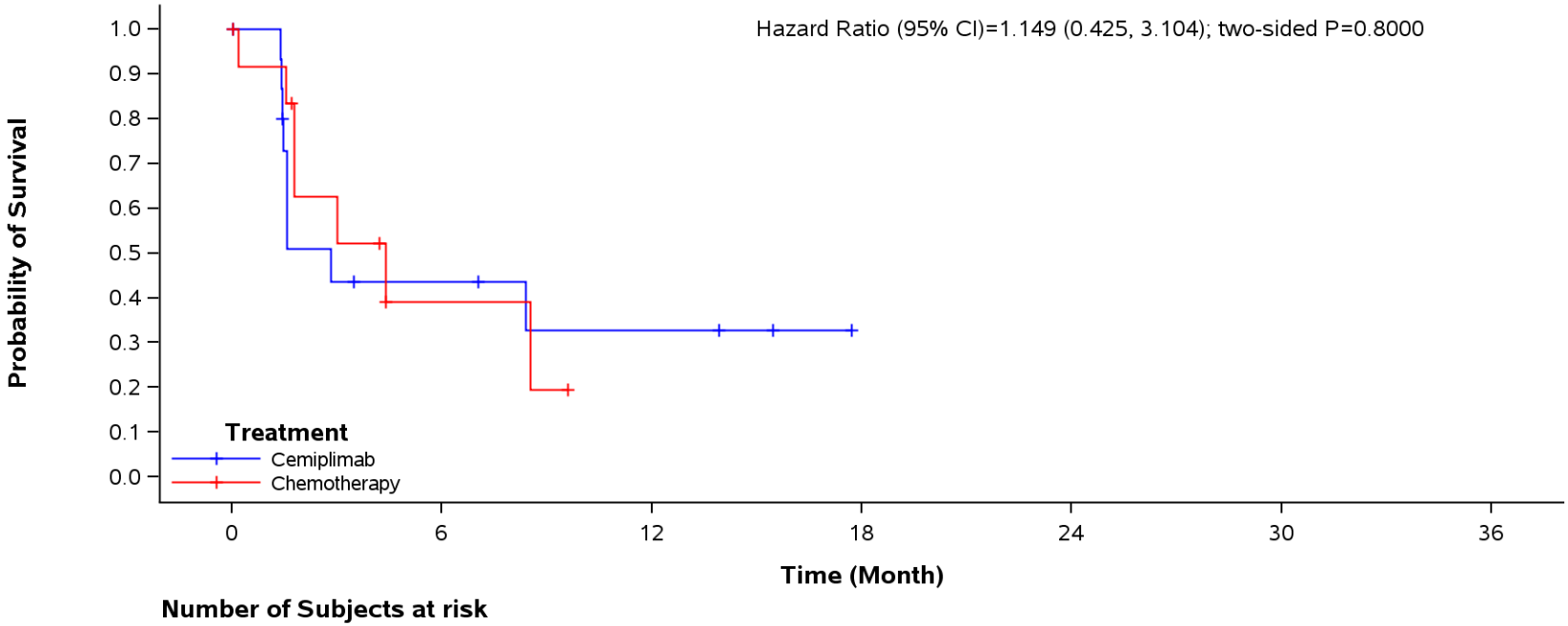

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts deterioration



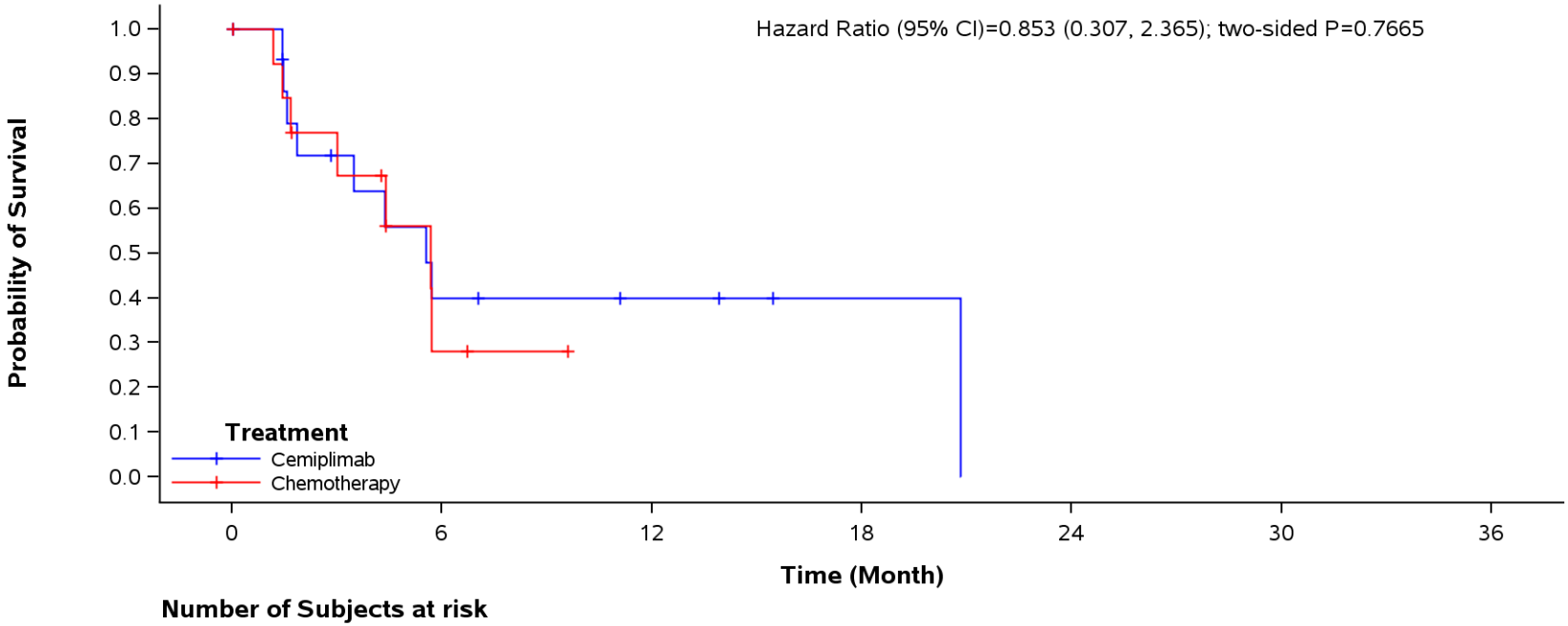

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts deterioration



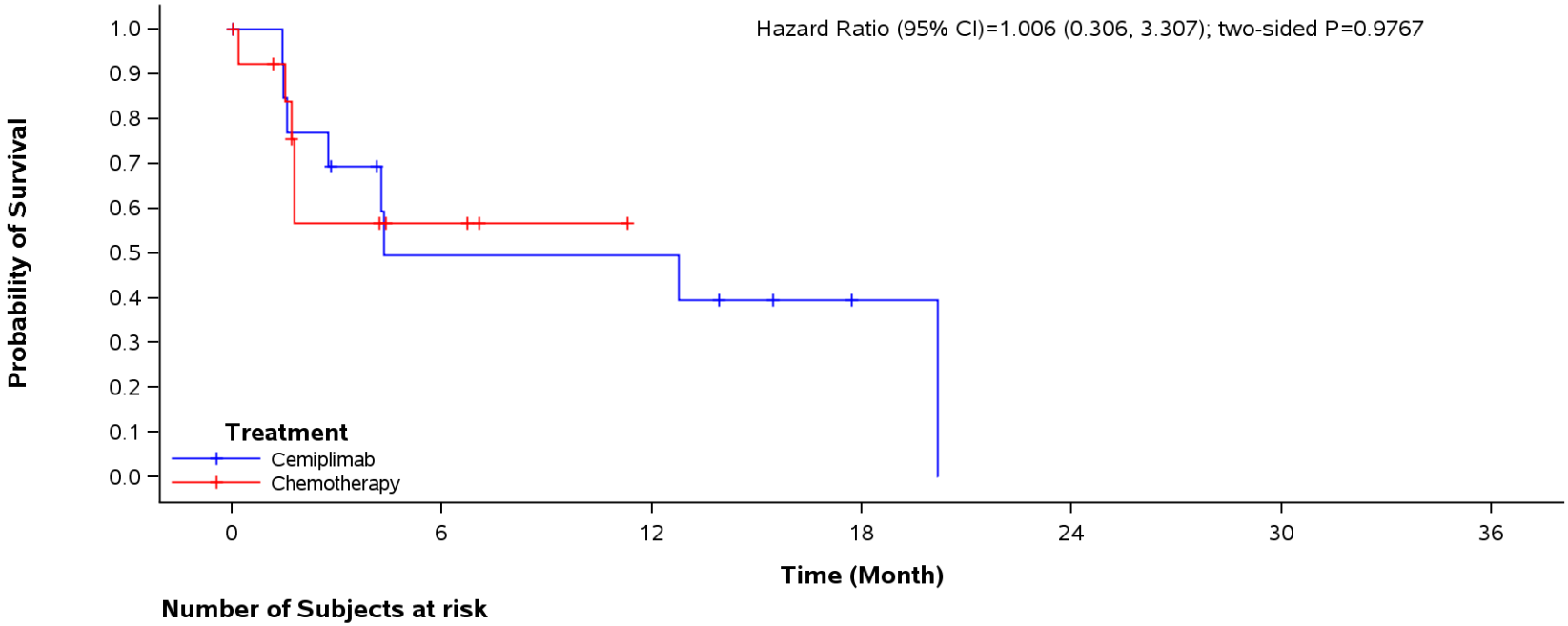

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts deterioration



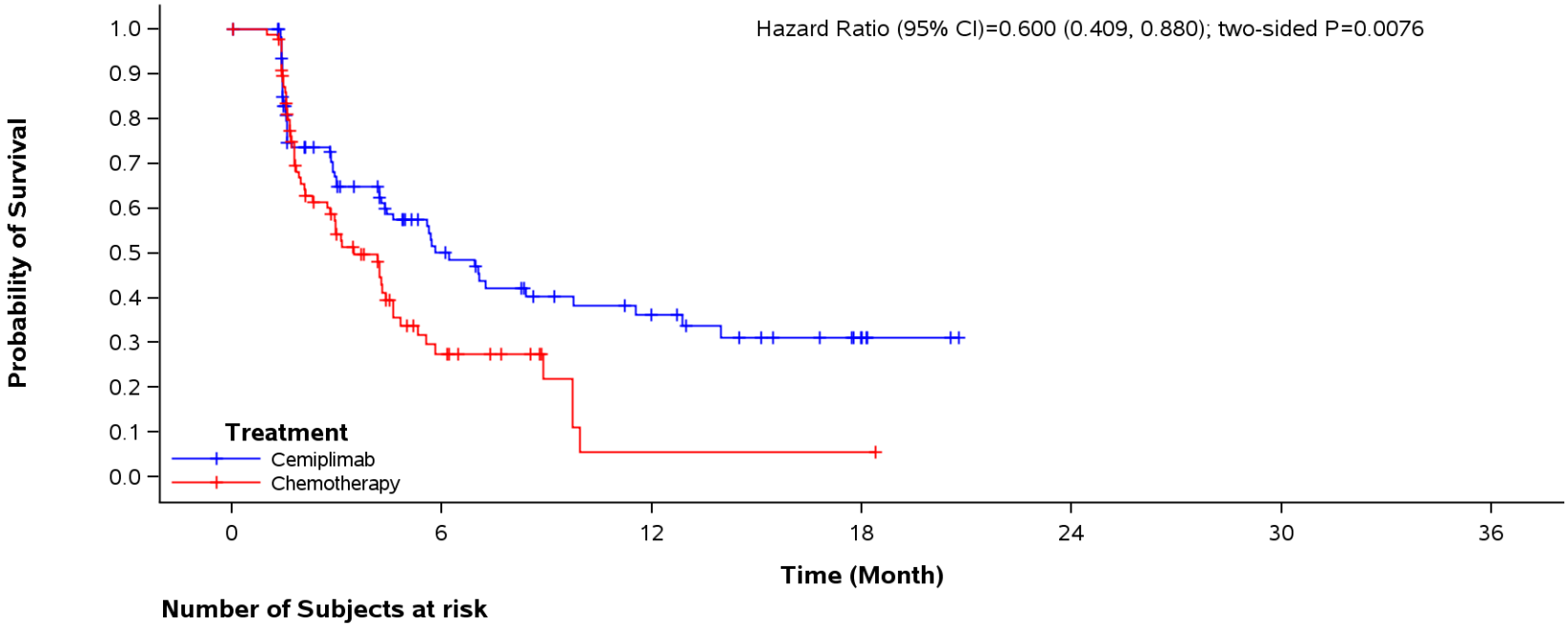

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Appetite loss - 10 pts deterioration



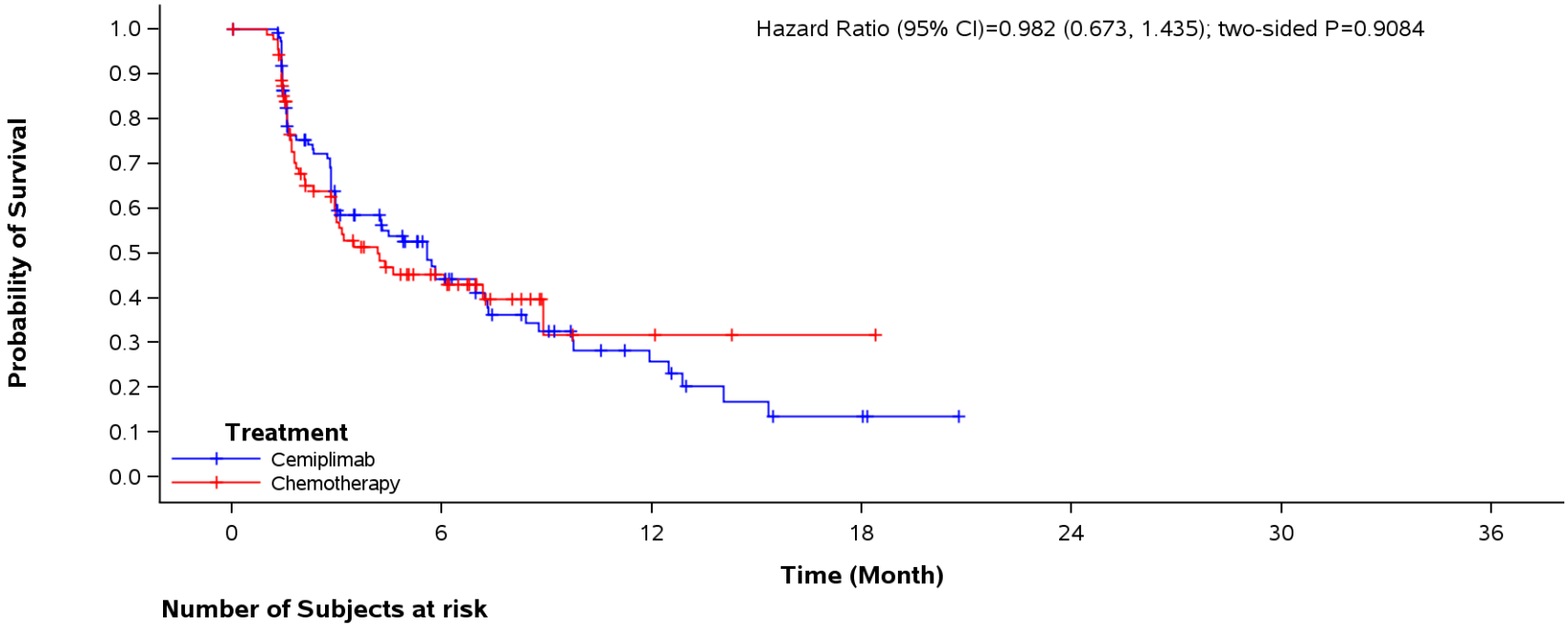

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 34 | 16 | 5 | 0 | 0 | 0 |
| Chemotherapy | 123 | 13 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Cognitive Functioning - 10 pts deterioration



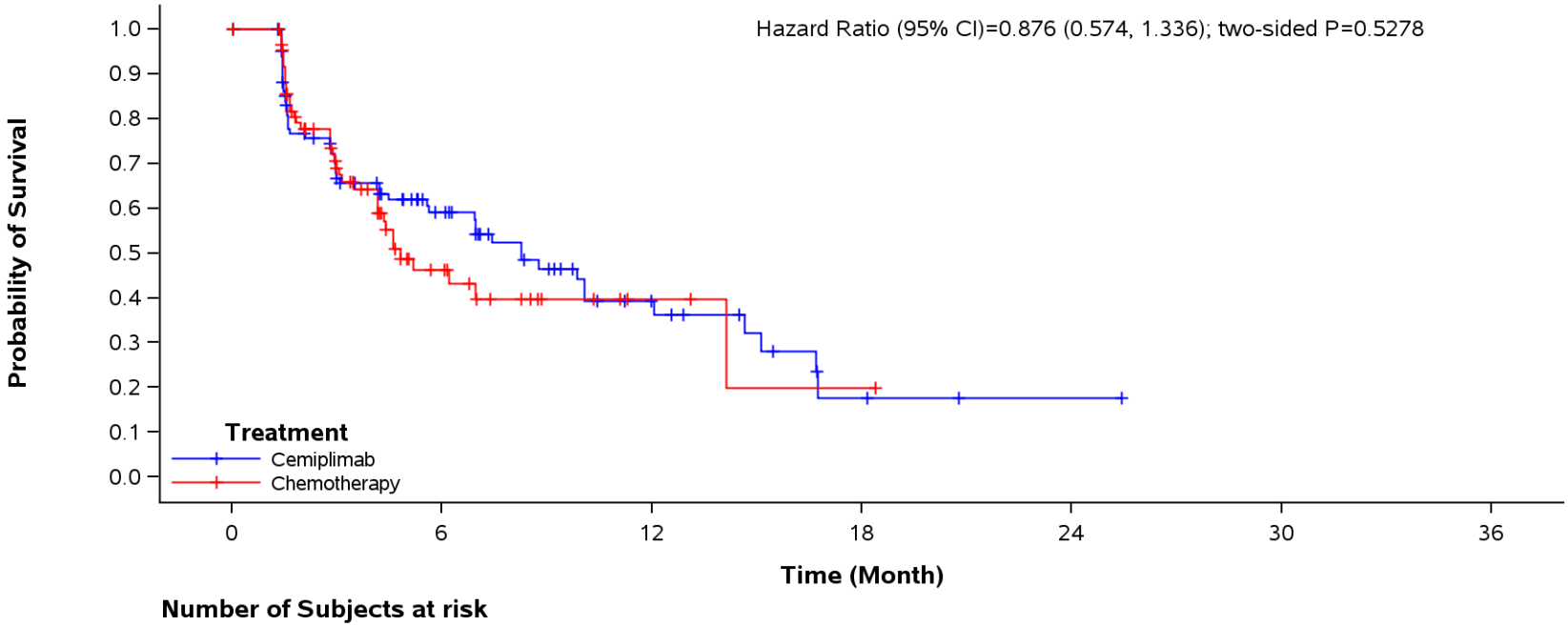

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 32 | 10 | 3 | 0 | 0 | 0 |
| Chemotherapy | 123 | 21 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts deterioration



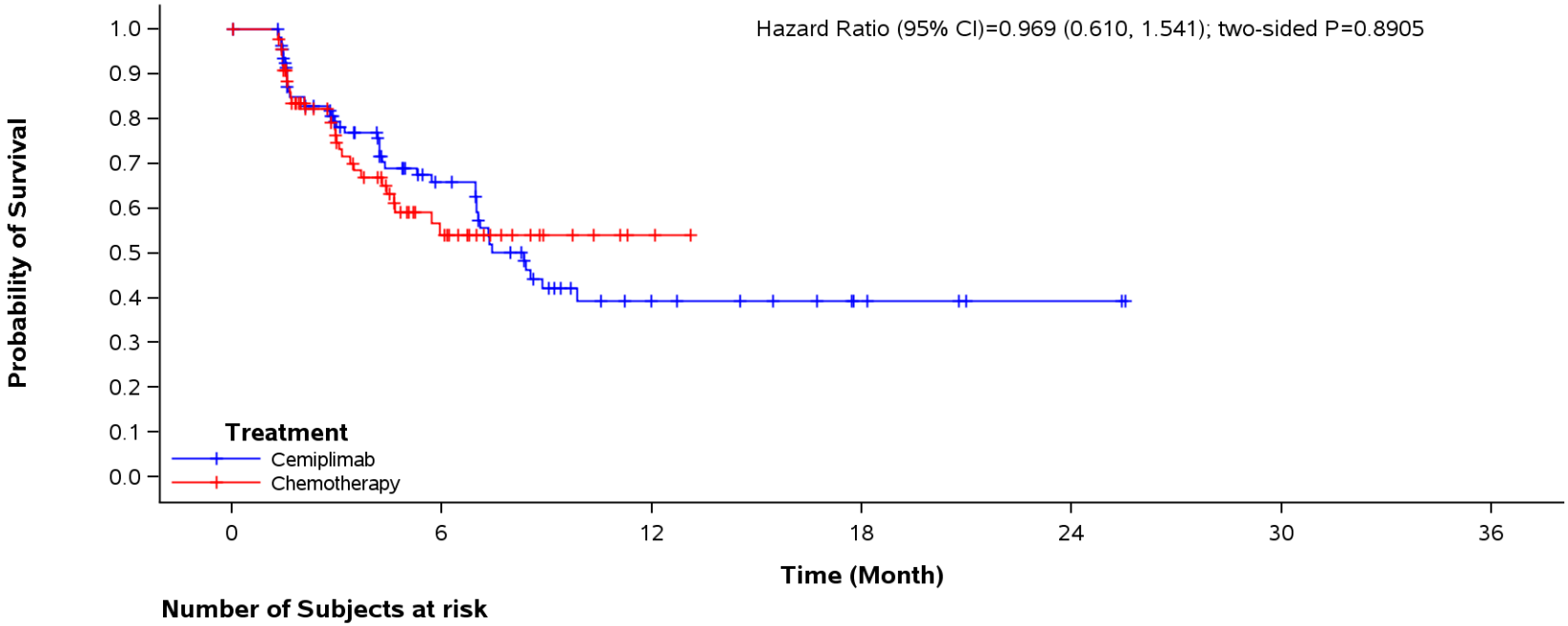

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 39 | 13 | 3 | 1 | 0 | 0 |
| Chemotherapy | 123 | 17 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts deterioration



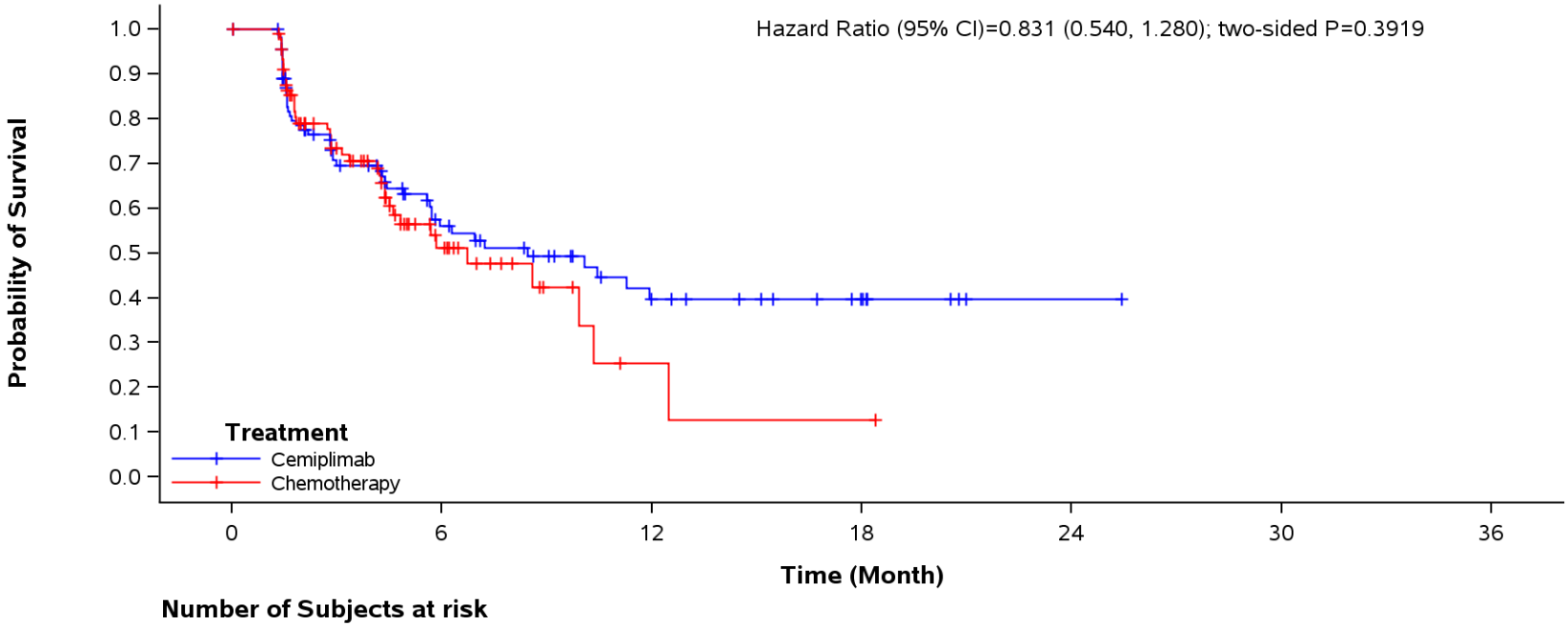

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 41 | 11 | 5 | 2 | 0 | 0 |
| Chemotherapy | 123 | 21 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts deterioration



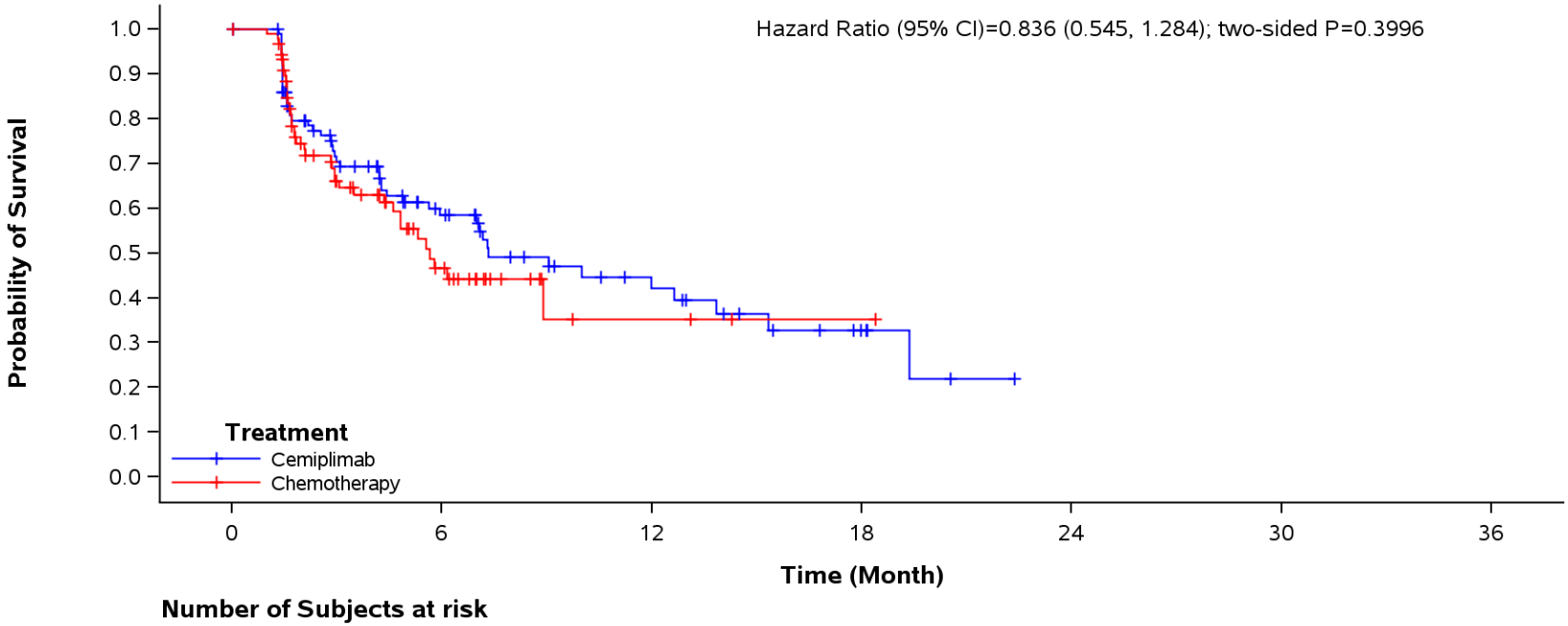

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 37 | 15 | 7 | 1 | 0 | 0 |
| Chemotherapy | 123 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts deterioration



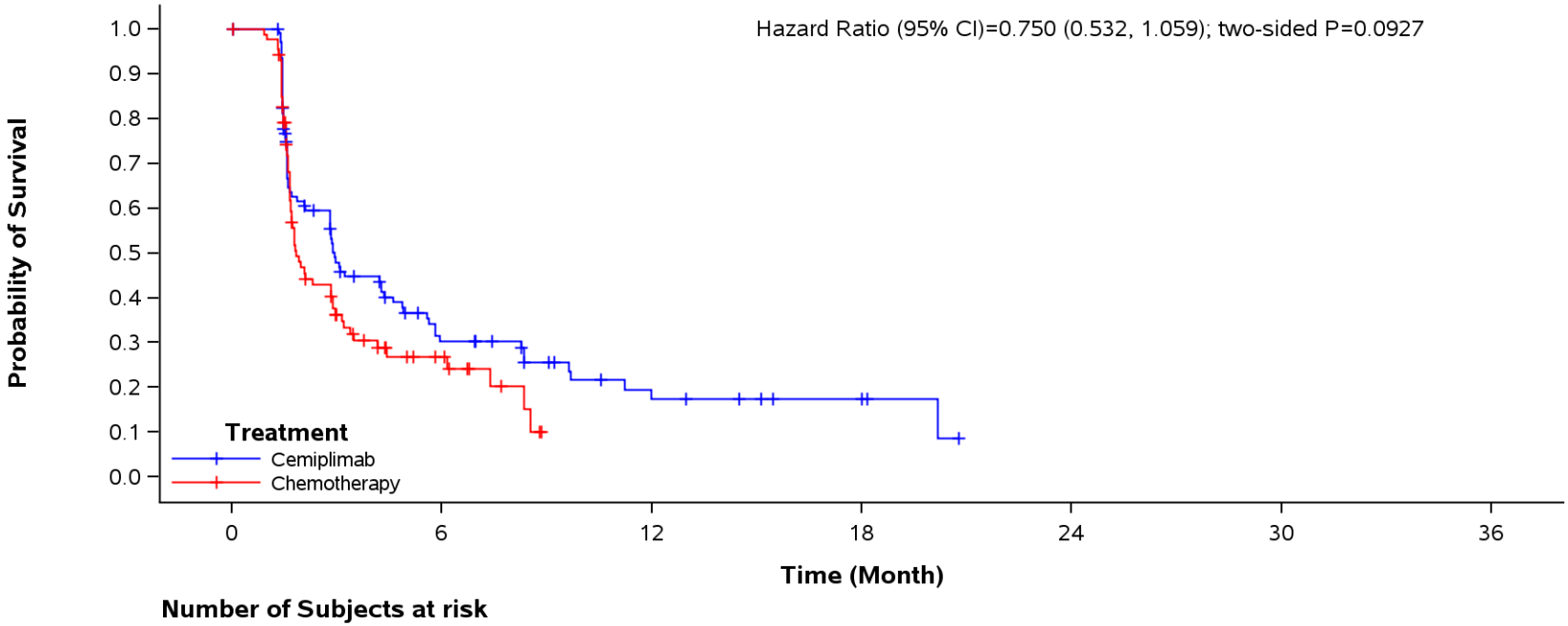

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 39 | 16 | 5 | 0 | 0 | 0 |
| Chemotherapy | 123 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts deterioration



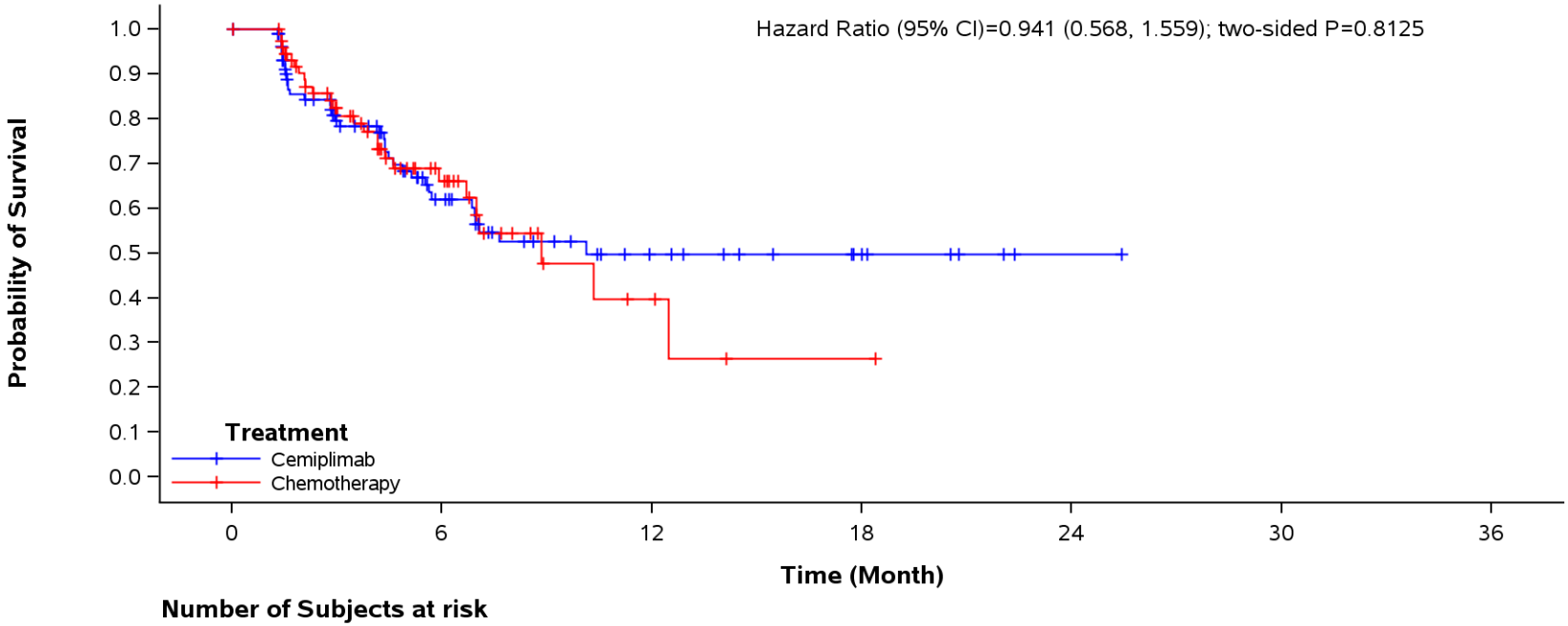

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 24 | 8 | 4 | 0 | 0 | 0 |
| Chemotherapy | 123 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Financial Problems - 10 pts deterioration



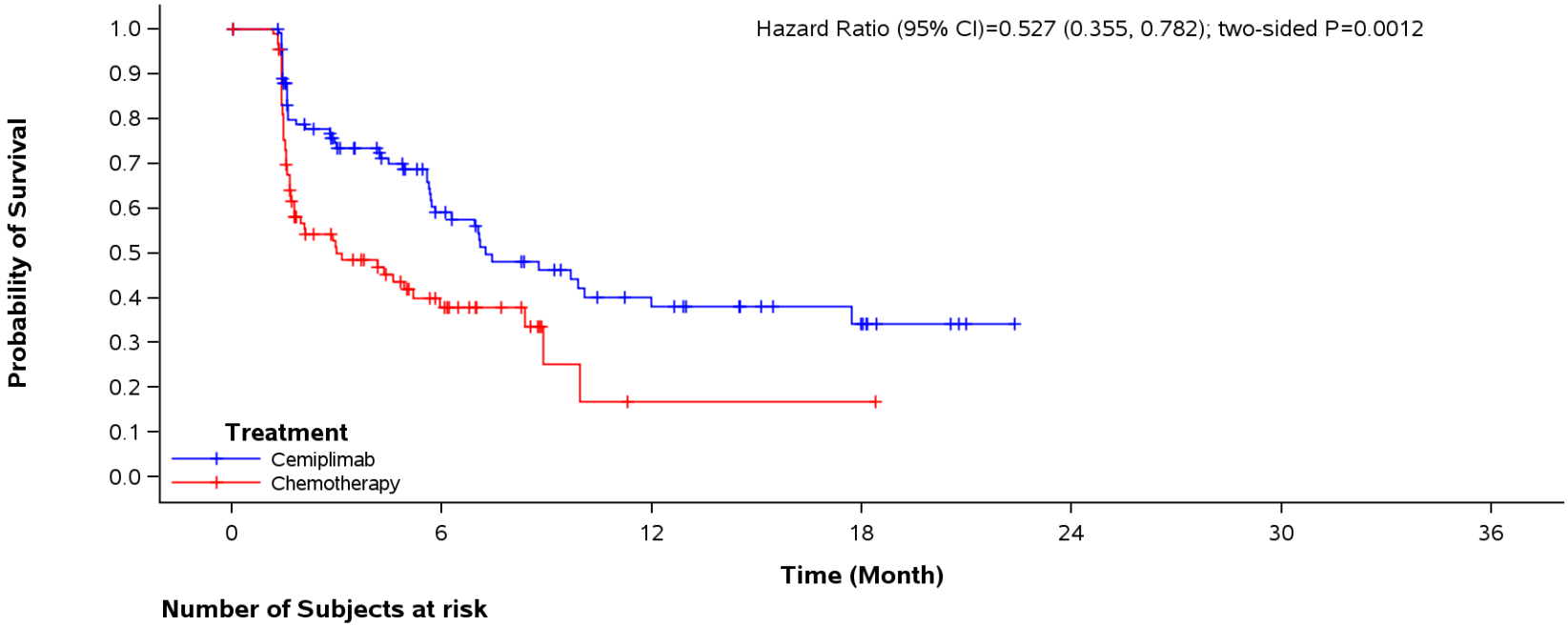

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 37 | 14 | 7 | 1 | 0 | 0 |
| Chemotherapy | 123 | 23 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Nausea / Vomiting - 10 pts deterioration



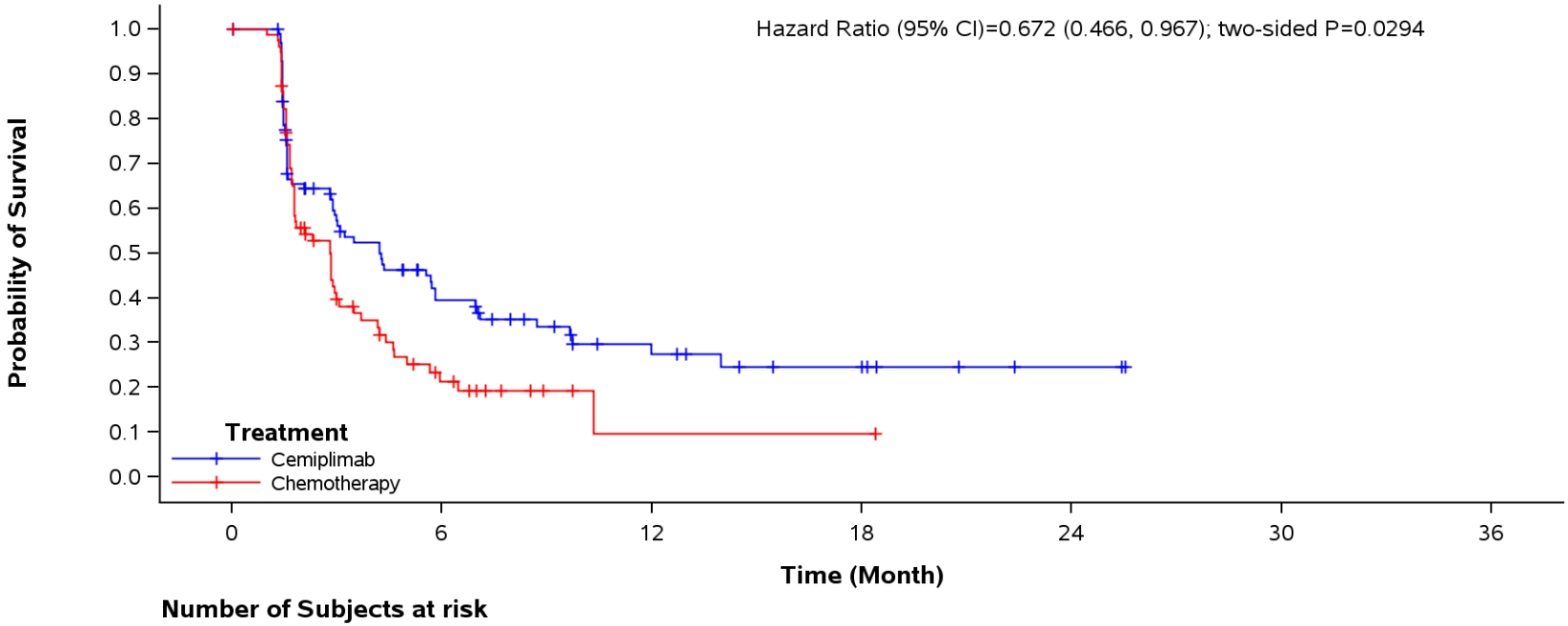

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 42 | 17 | 8 | 0 | 0 | 0 |
| Chemotherapy | 123 | 18 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts deterioration



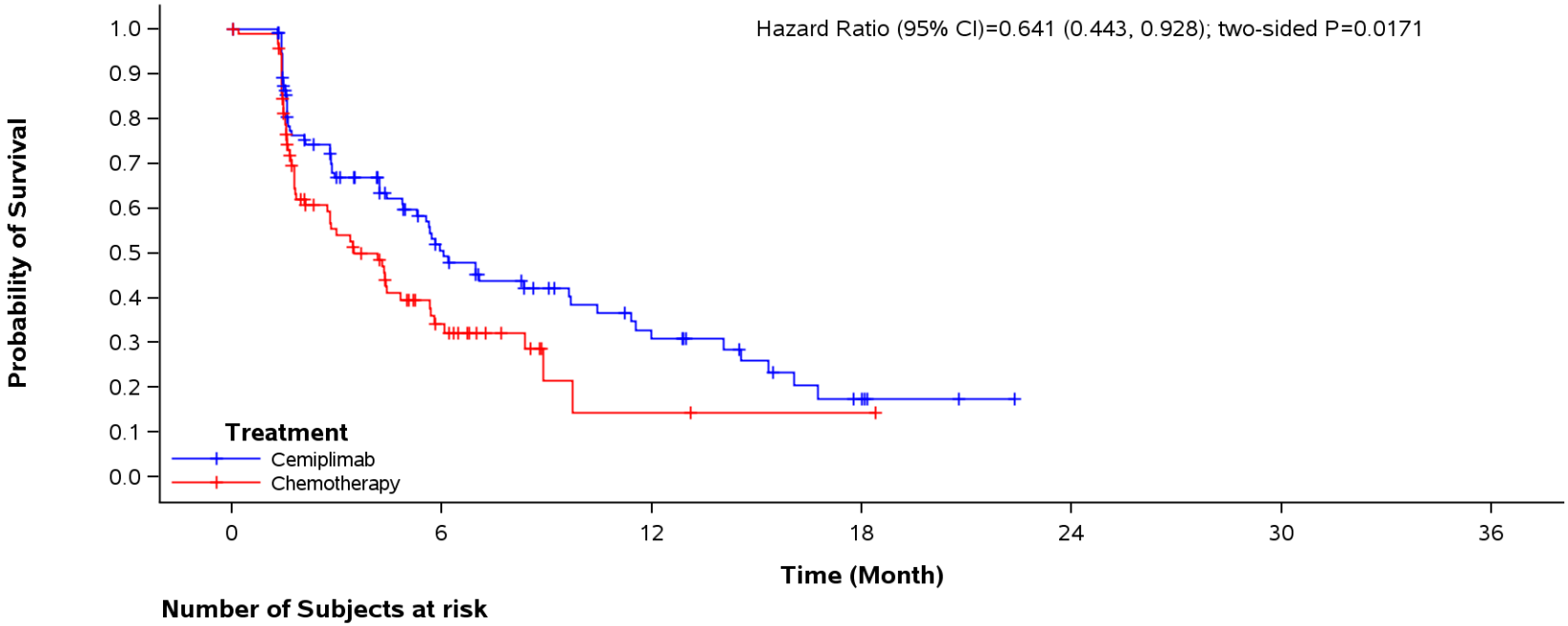

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 29 | 12 | 7 | 2 | 0 | 0 |
| Chemotherapy | 123 | 11 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts deterioration



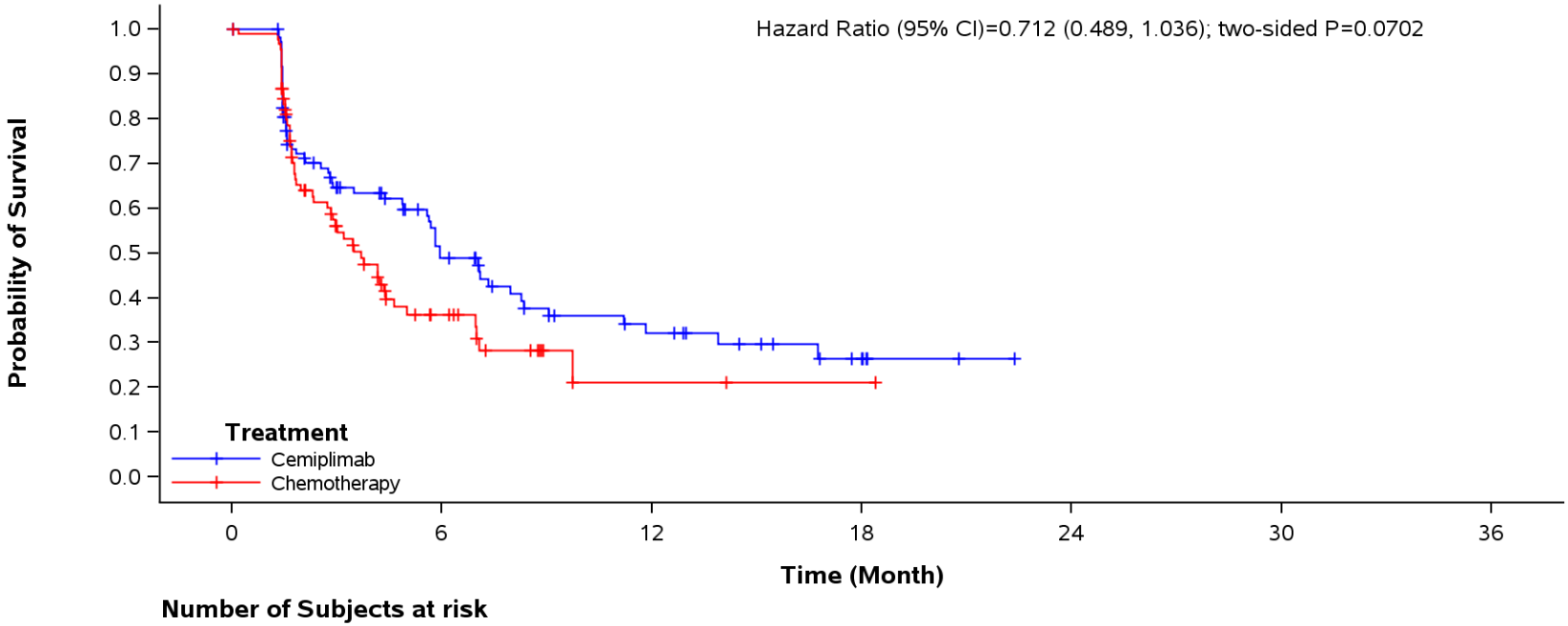

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 38 | 16 | 5 | 0 | 0 | 0 |
| Chemotherapy | 123 | 18 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts deterioration



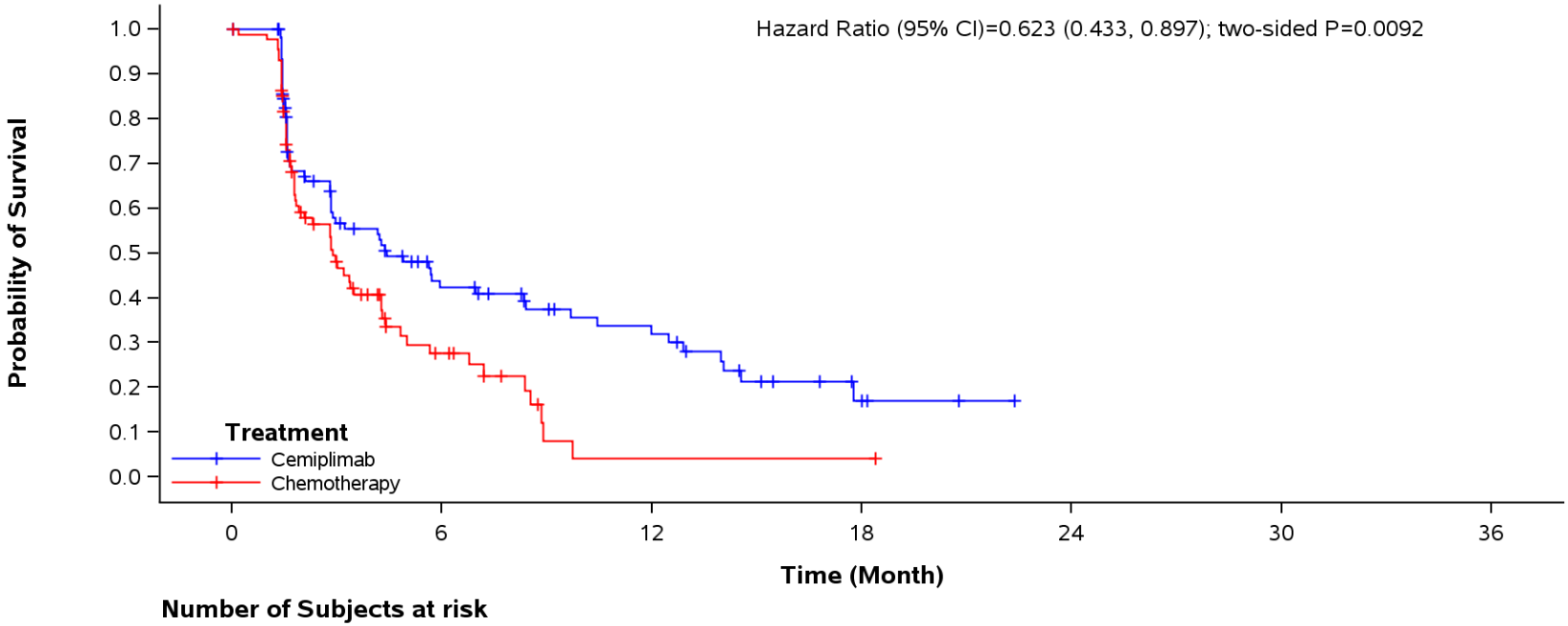

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 36 | 16 | 6 | 0 | 0 | 0 |
| Chemotherapy | 123 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts deterioration



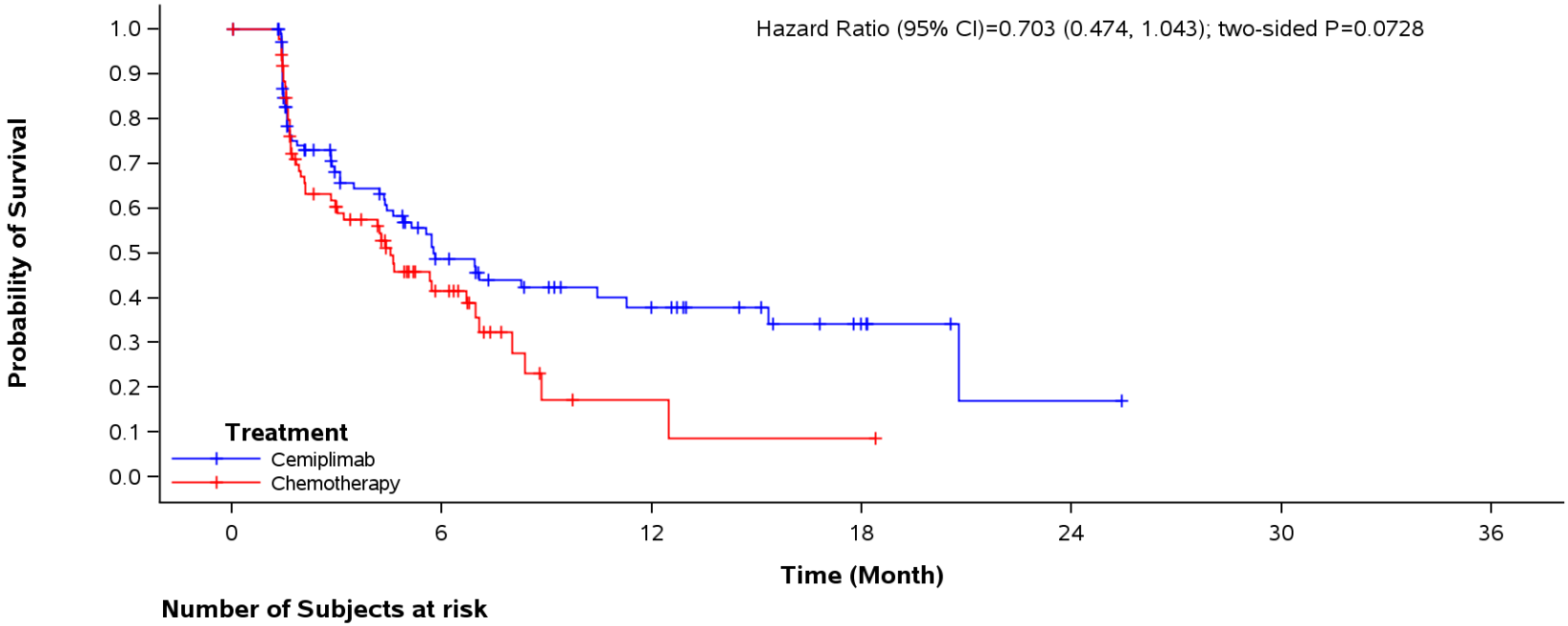

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 30 | 17 | 4 | 0 | 0 | 0 |
| Chemotherapy | 123 | 13 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Social Functioning - 10 pts deterioration



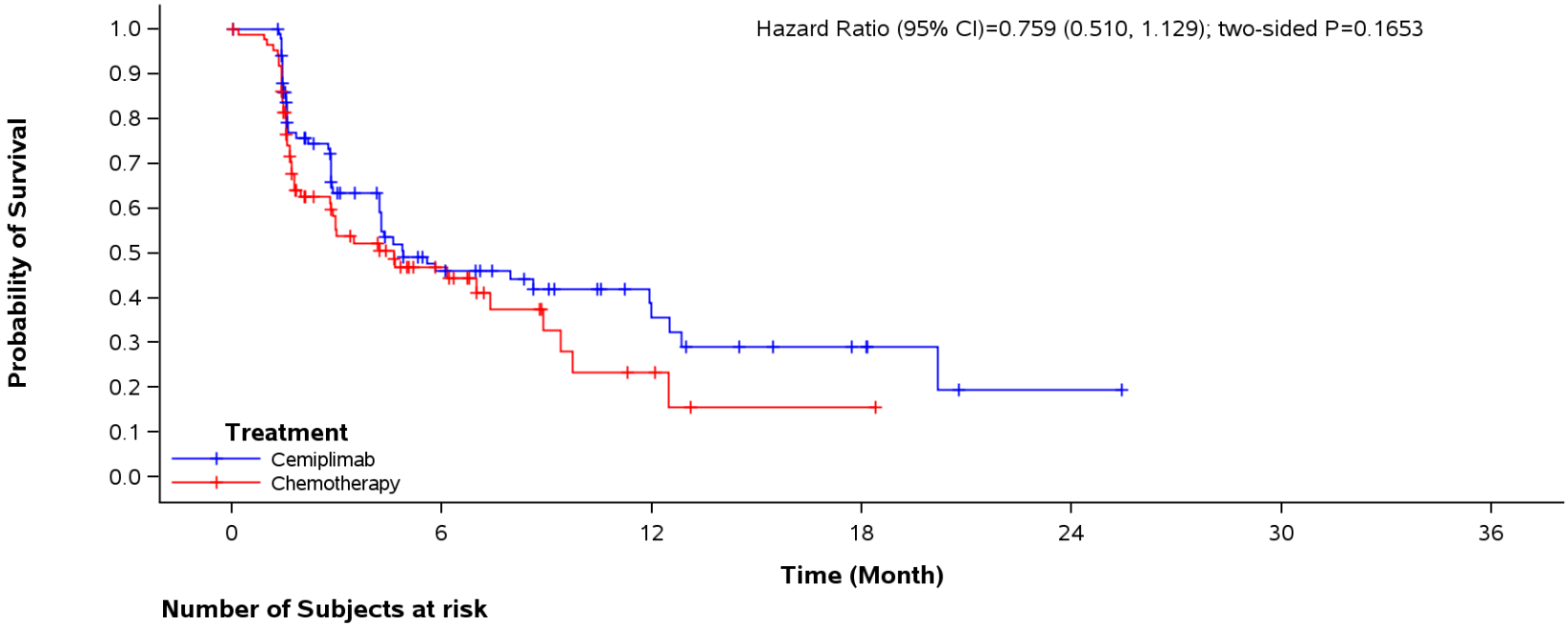

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 34 | 16 | 5 | 1 | 0 | 0 |
| Chemotherapy | 123 | 18 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts deterioration



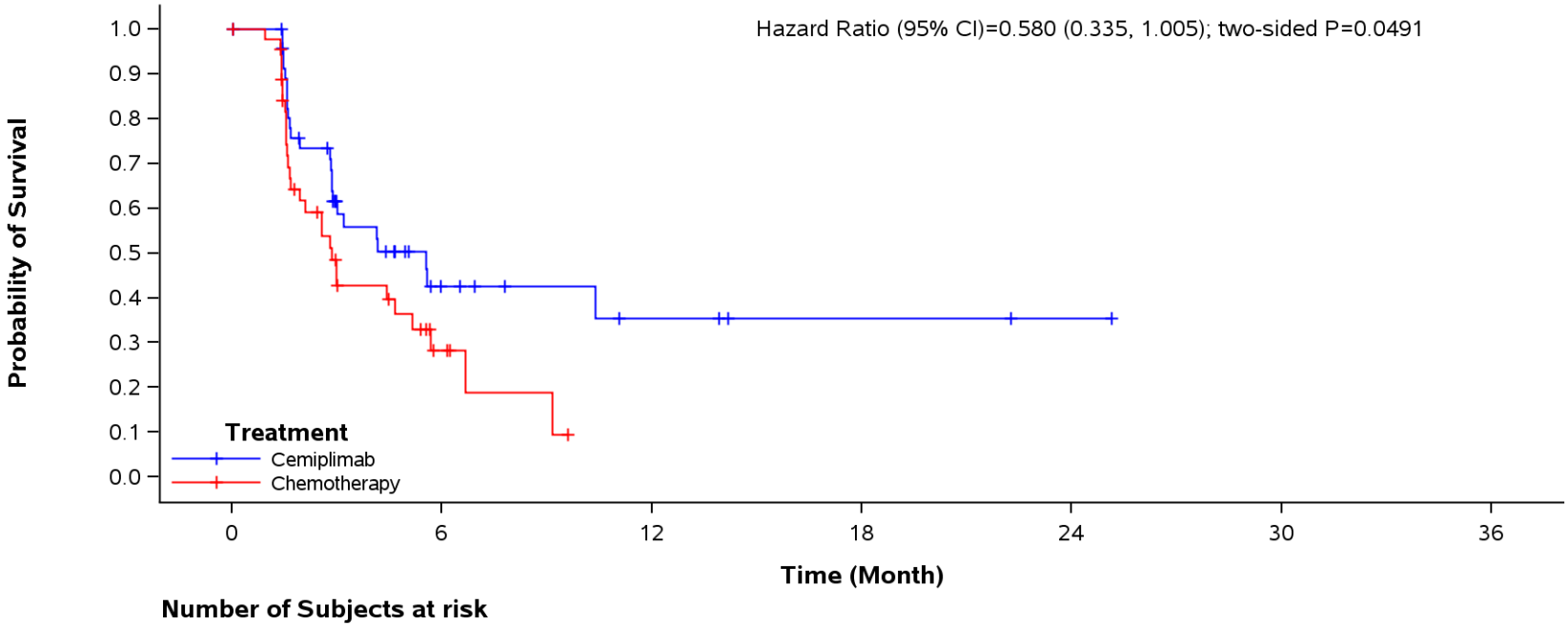

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 29 | 11 | 5 | 1 | 0 | 0 |
| Chemotherapy | 123 | 19 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts deterioration



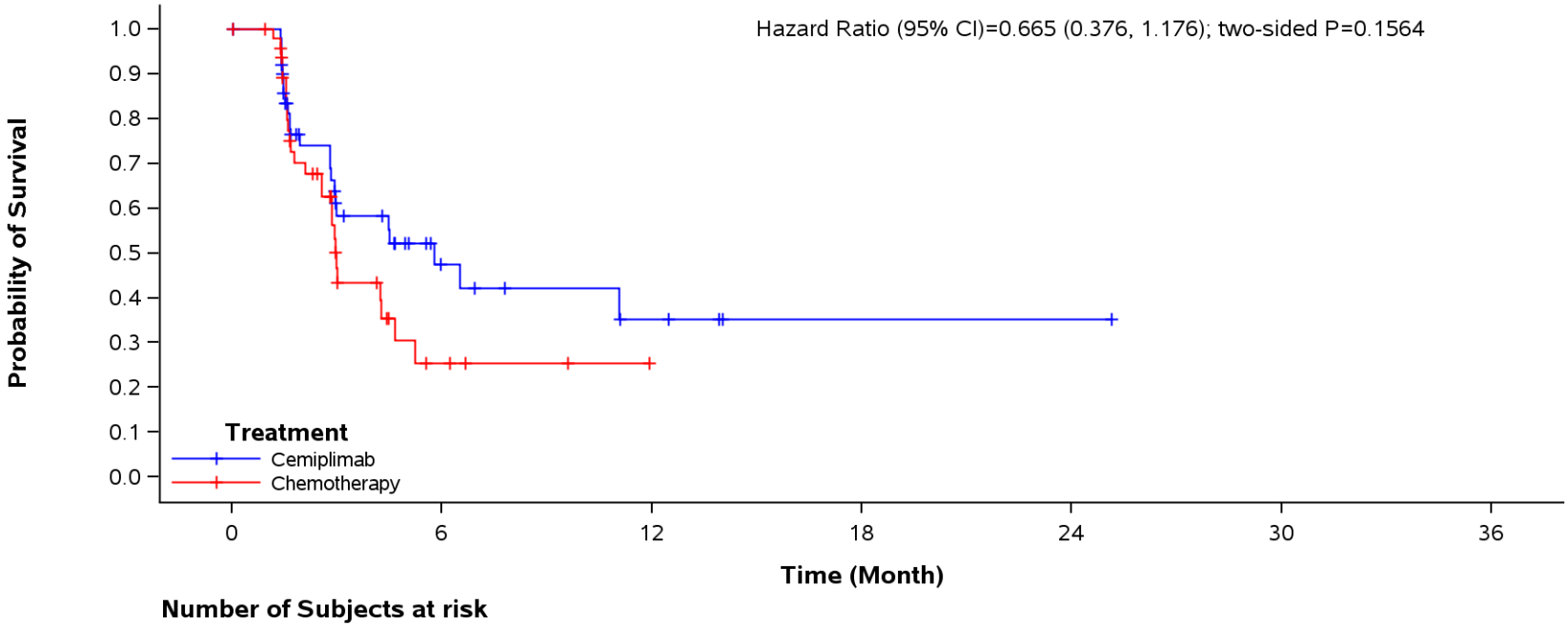

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 9 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts deterioration



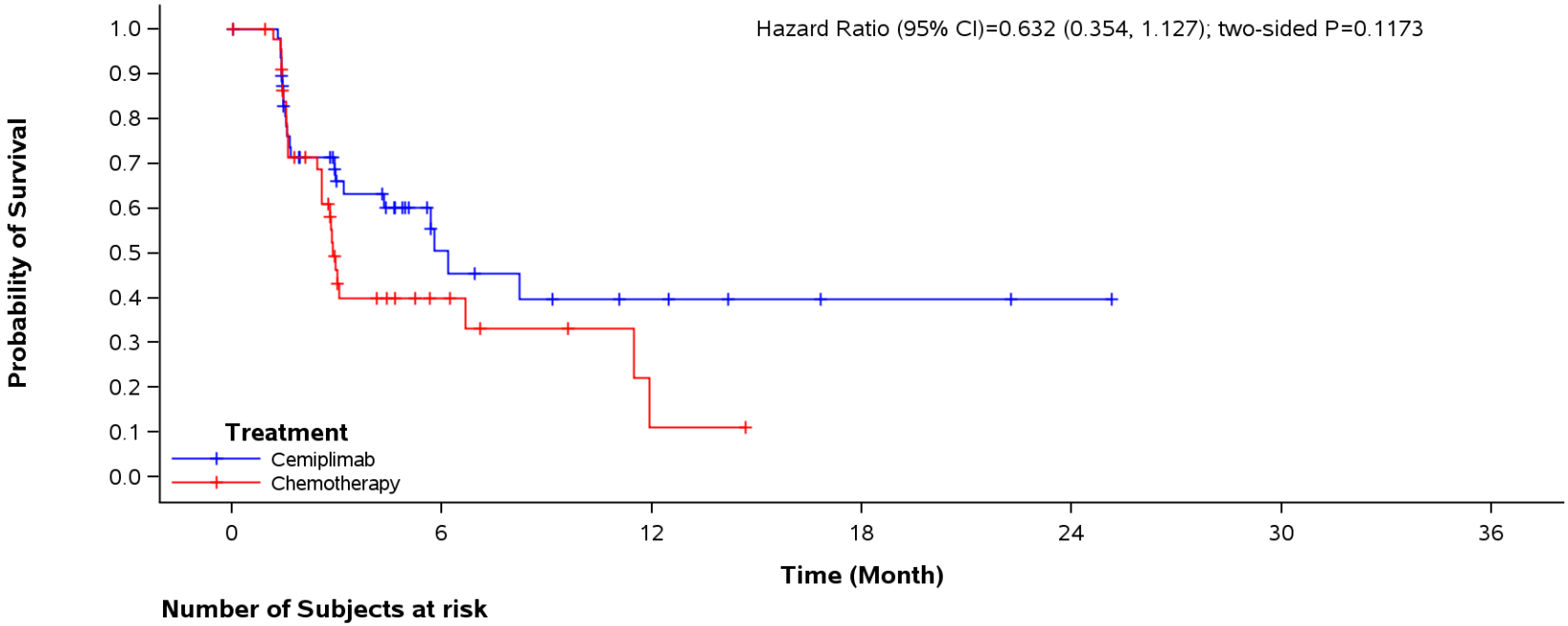

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 9 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts deterioration



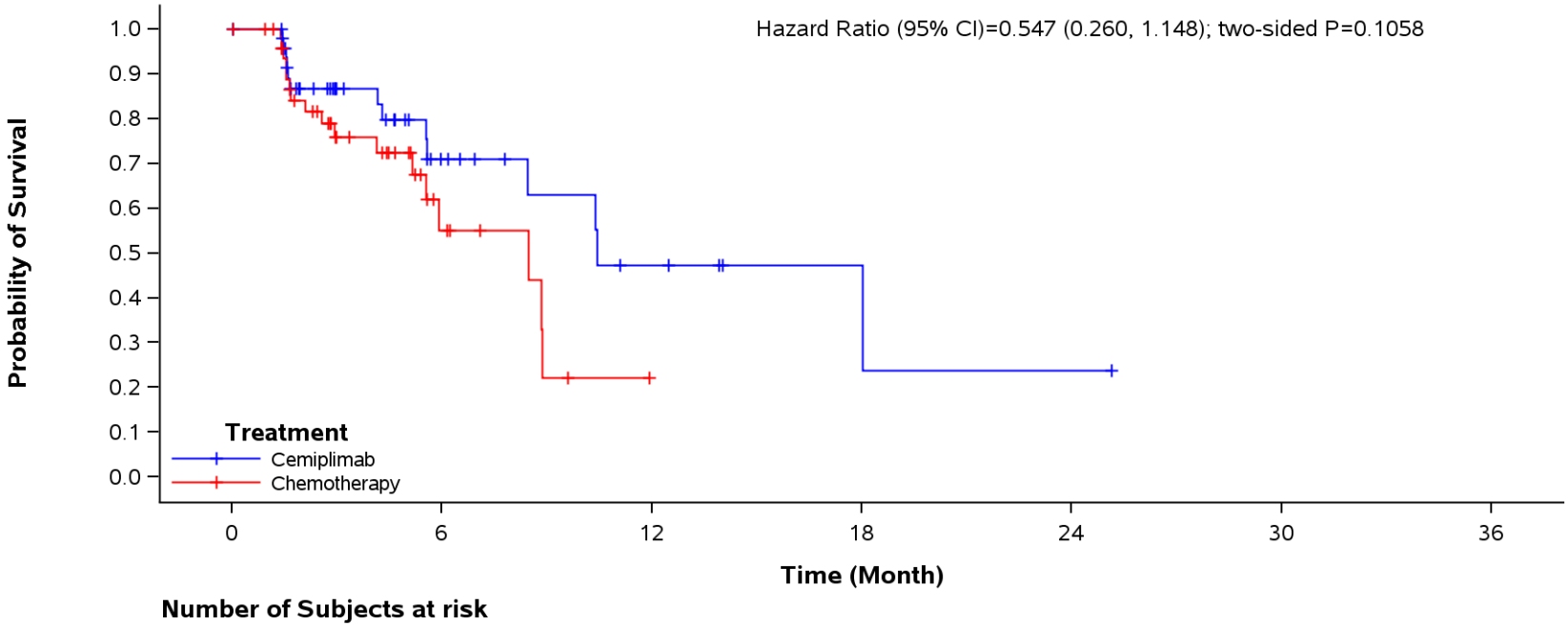

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 10 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts deterioration



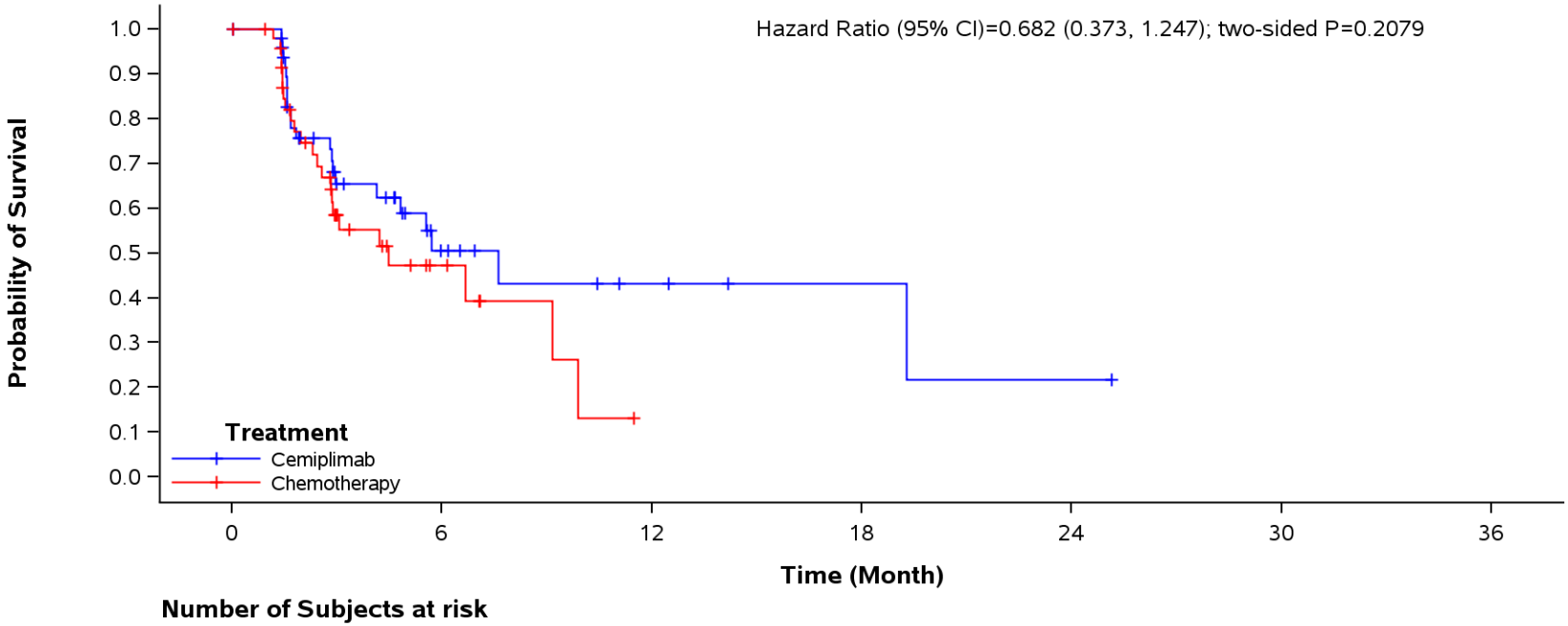

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts deterioration



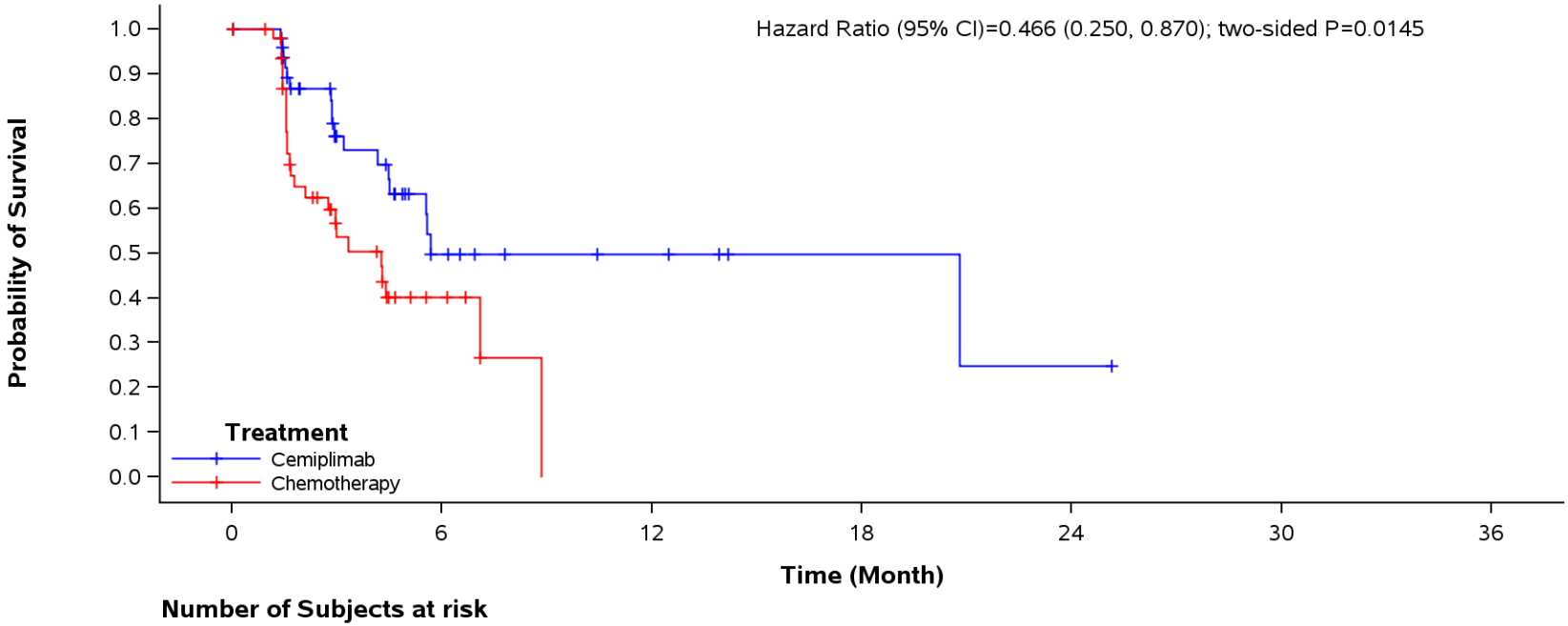

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 10 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts deterioration



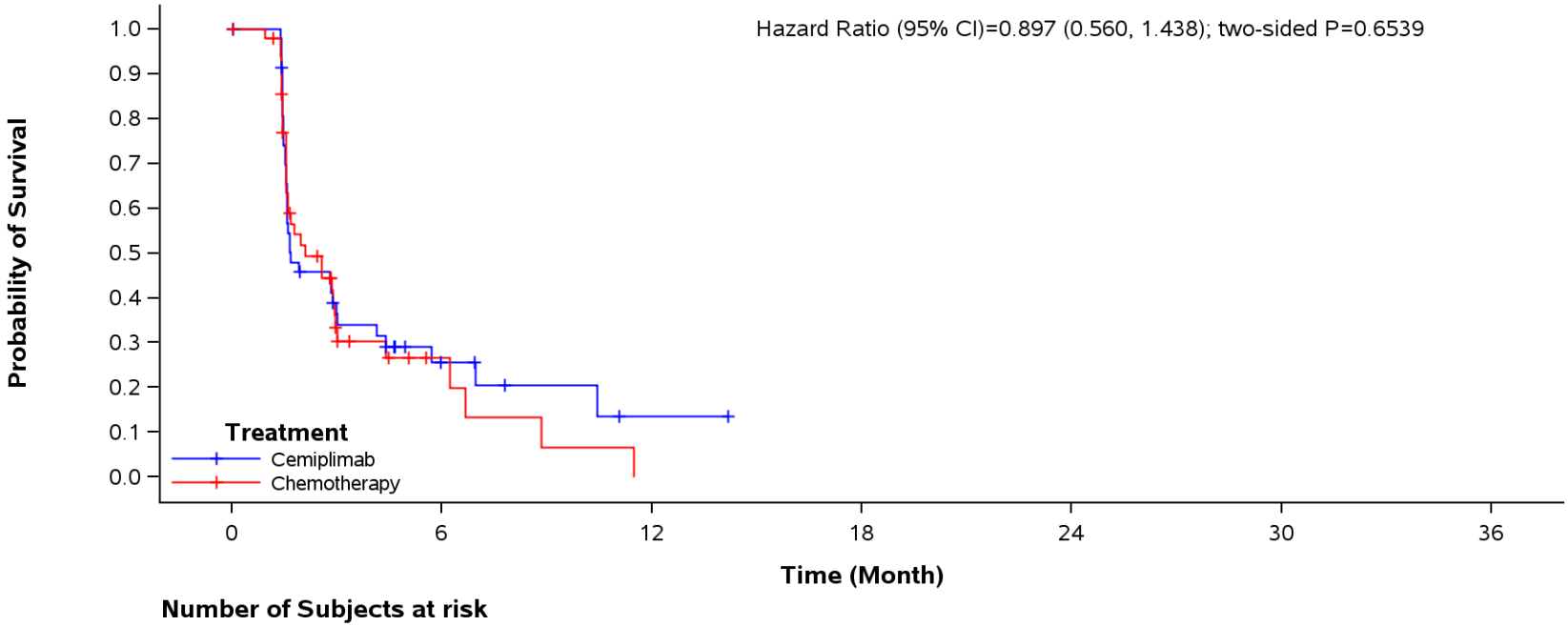

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 10 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts deterioration



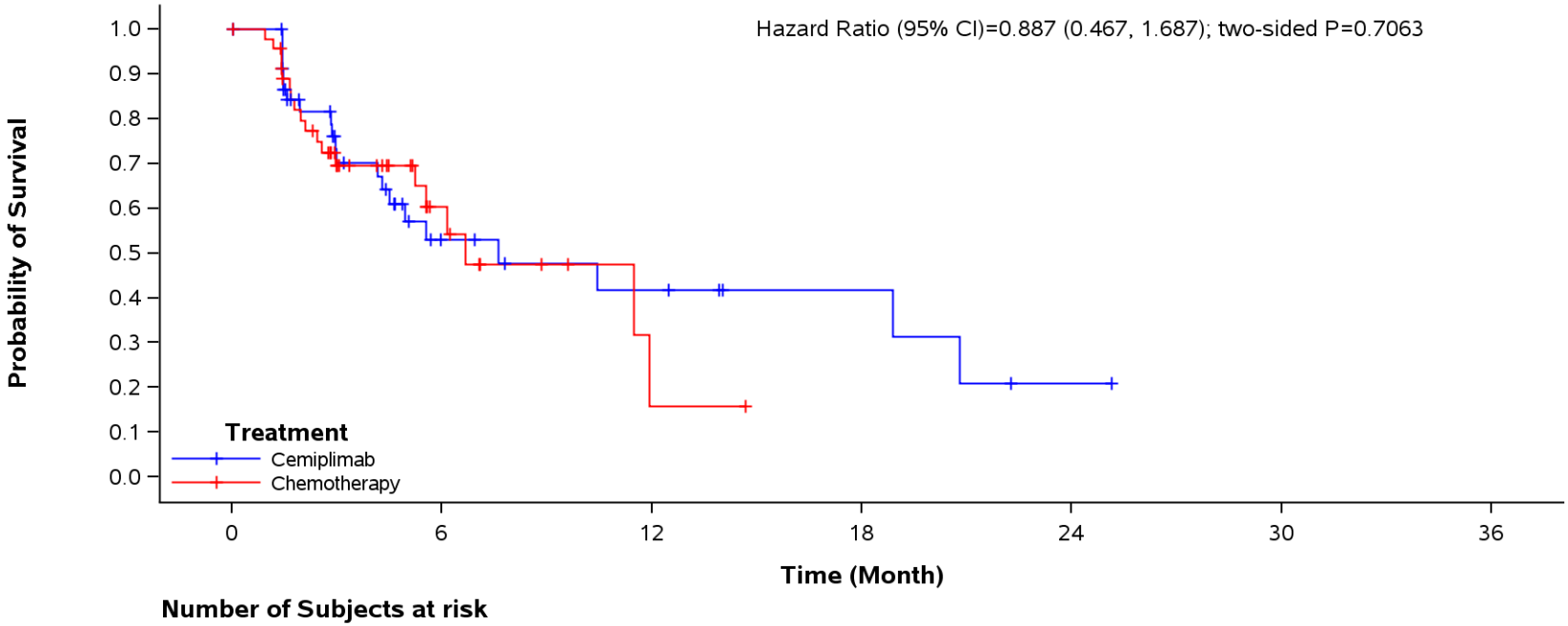

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts deterioration



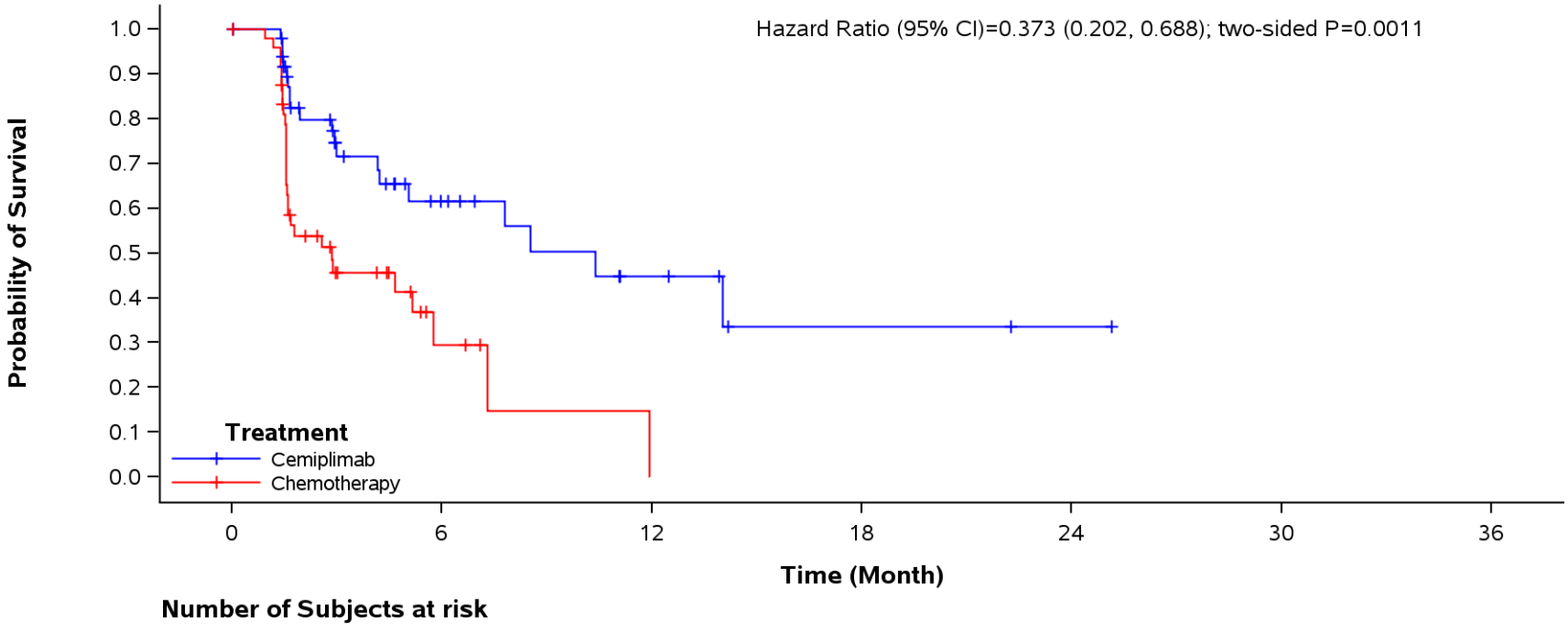

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 11 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts deterioration



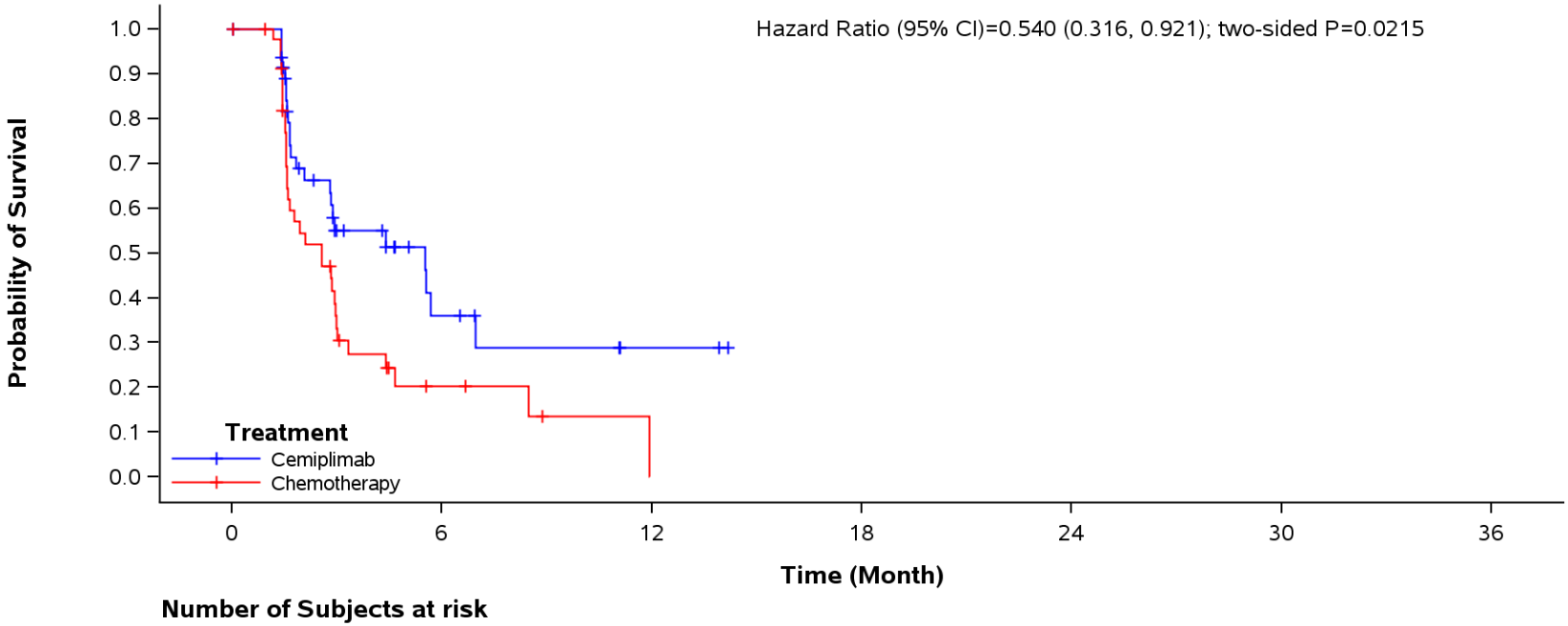

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 14 | 6 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts deterioration



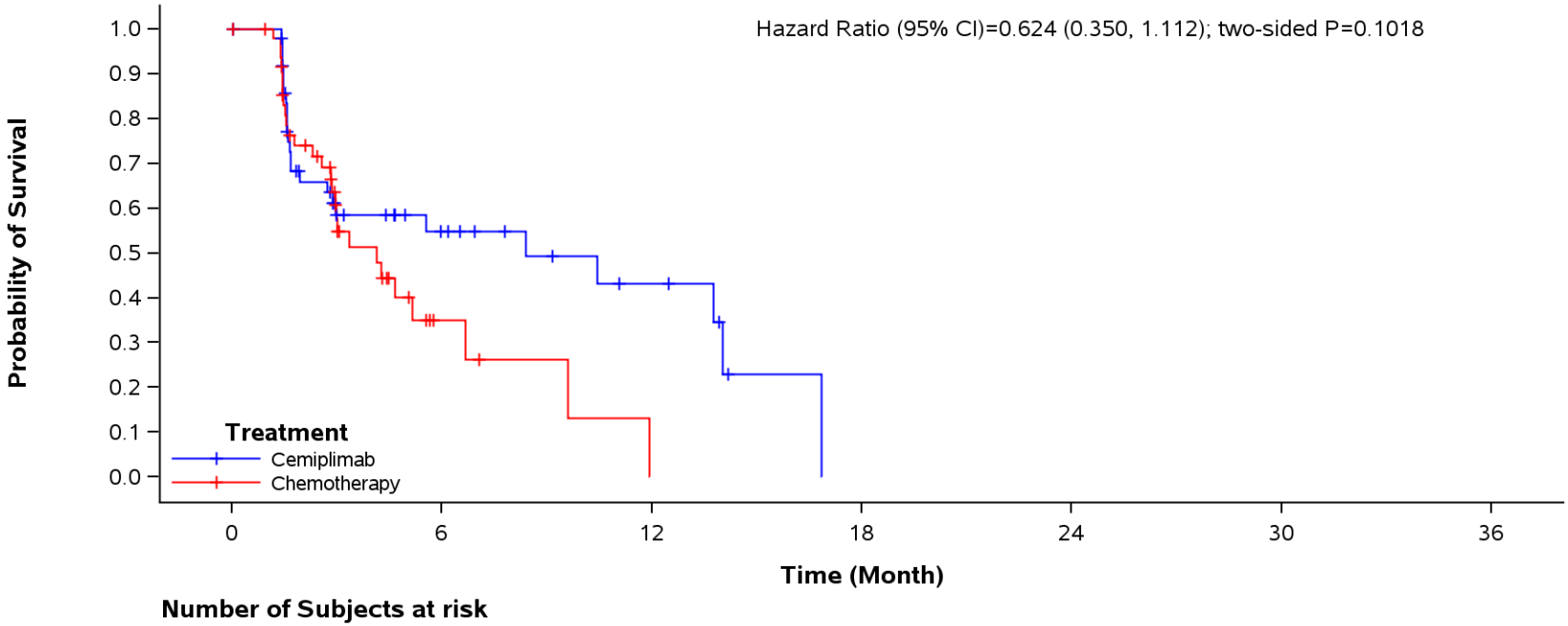

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 7 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts deterioration



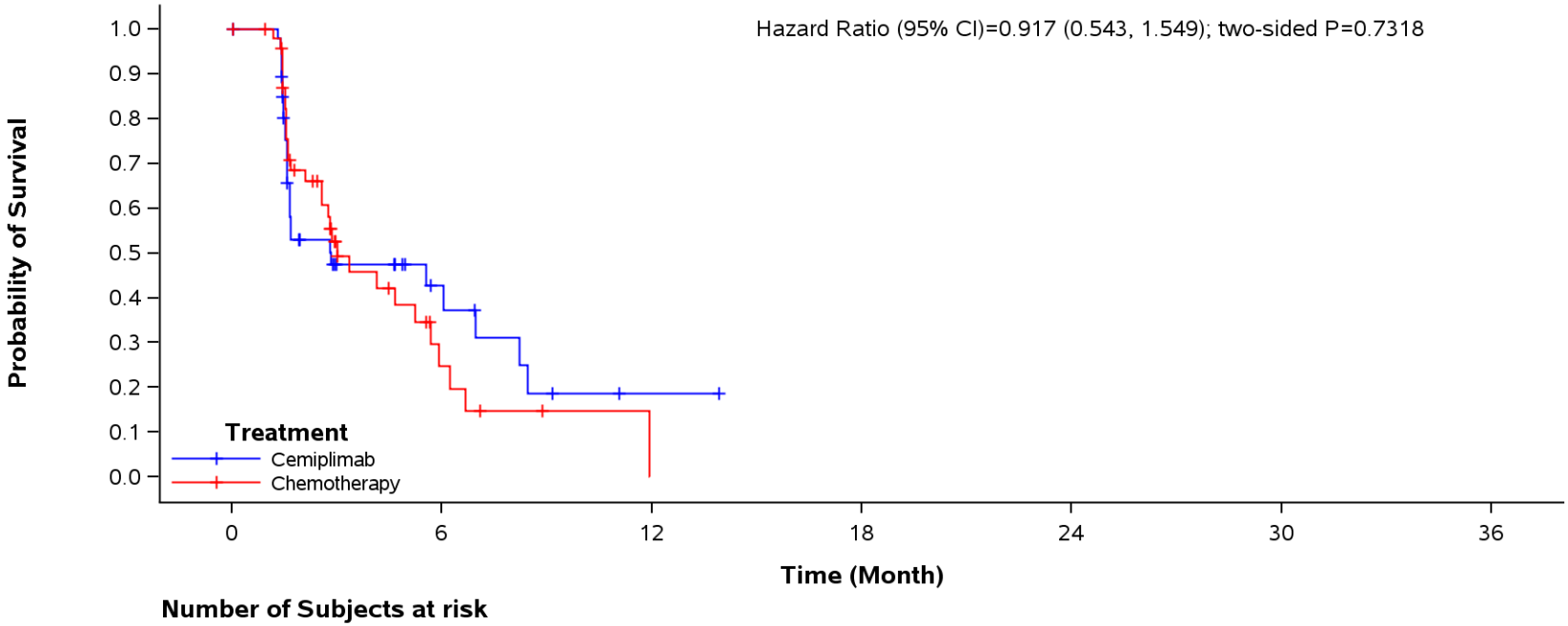

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 14 | 6 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts deterioration



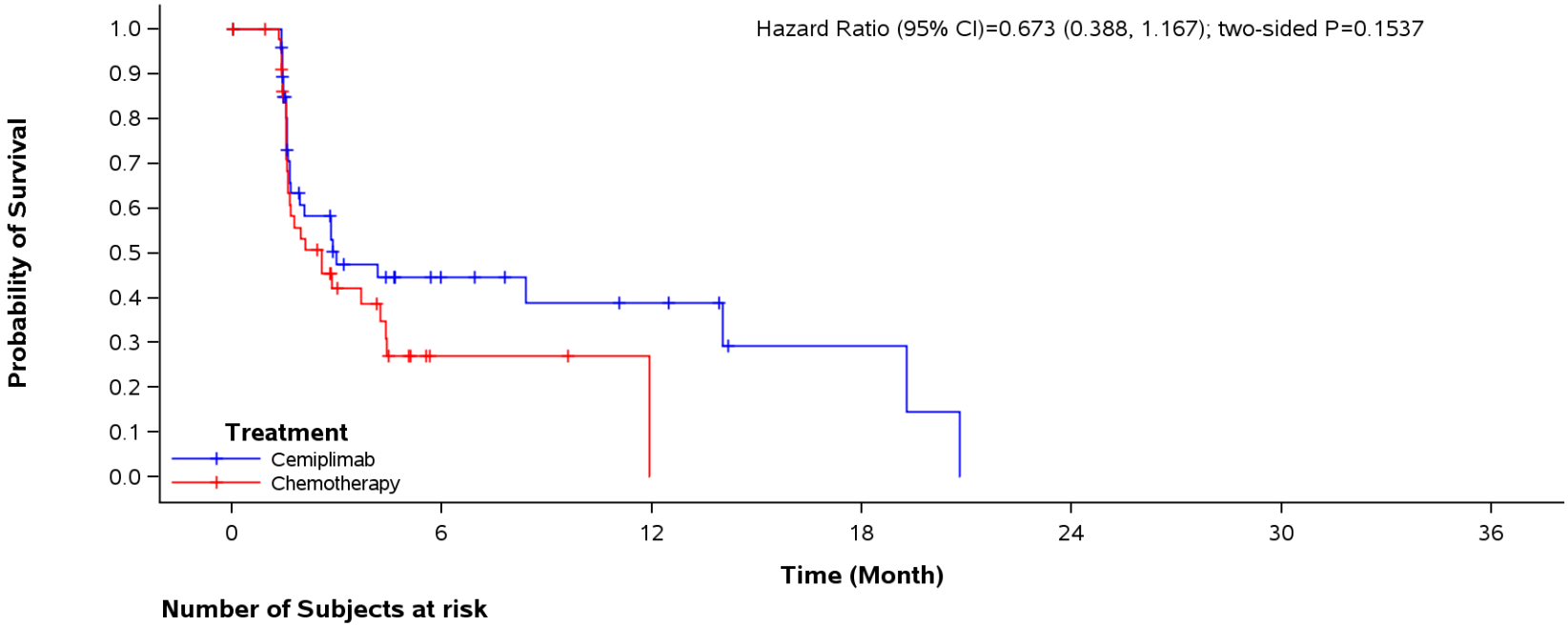

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 8 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts deterioration



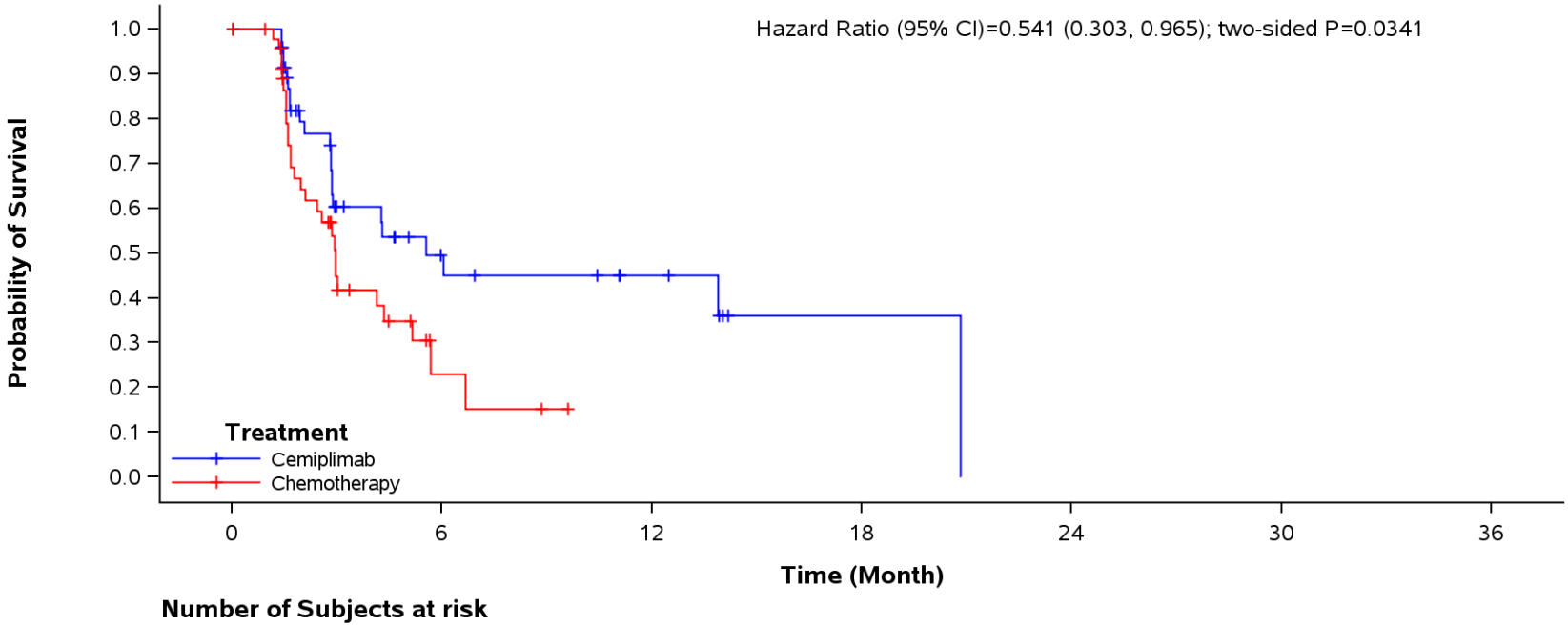

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 10 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 60 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts deterioration



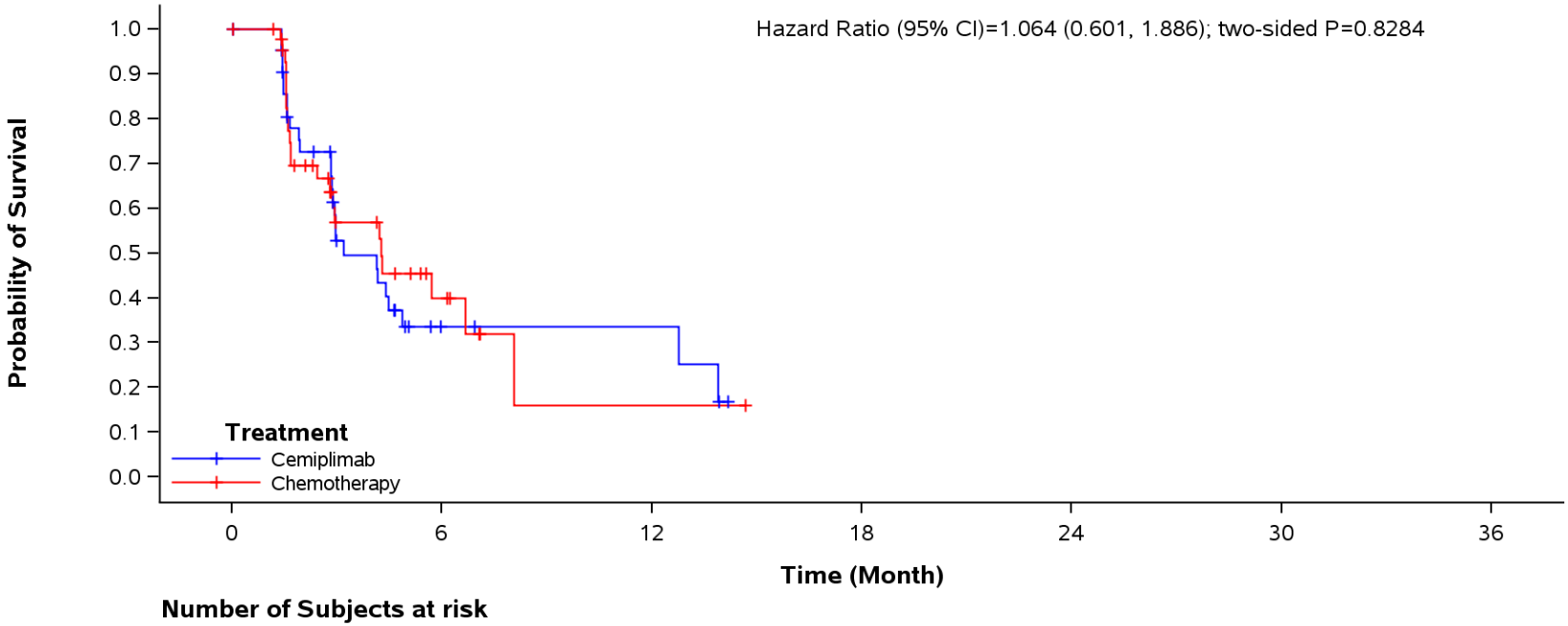

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 11 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts deterioration



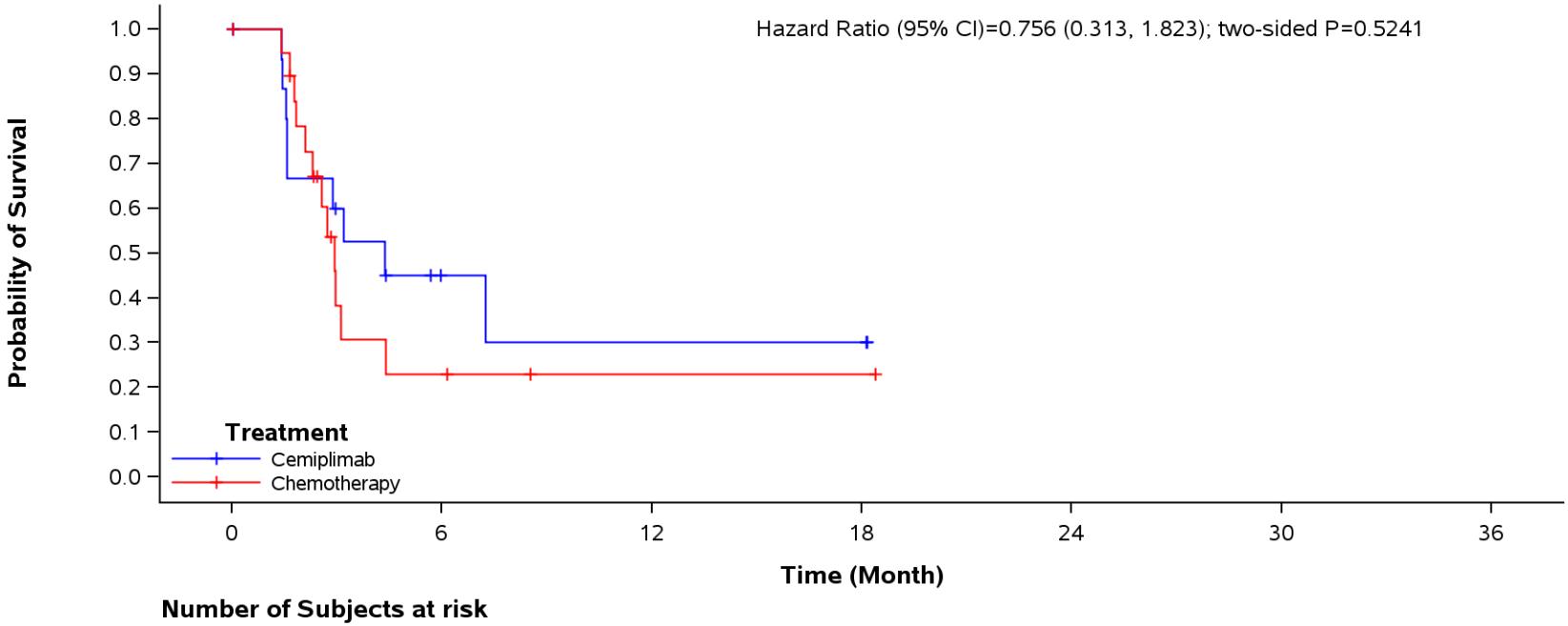

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 5 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts deterioration



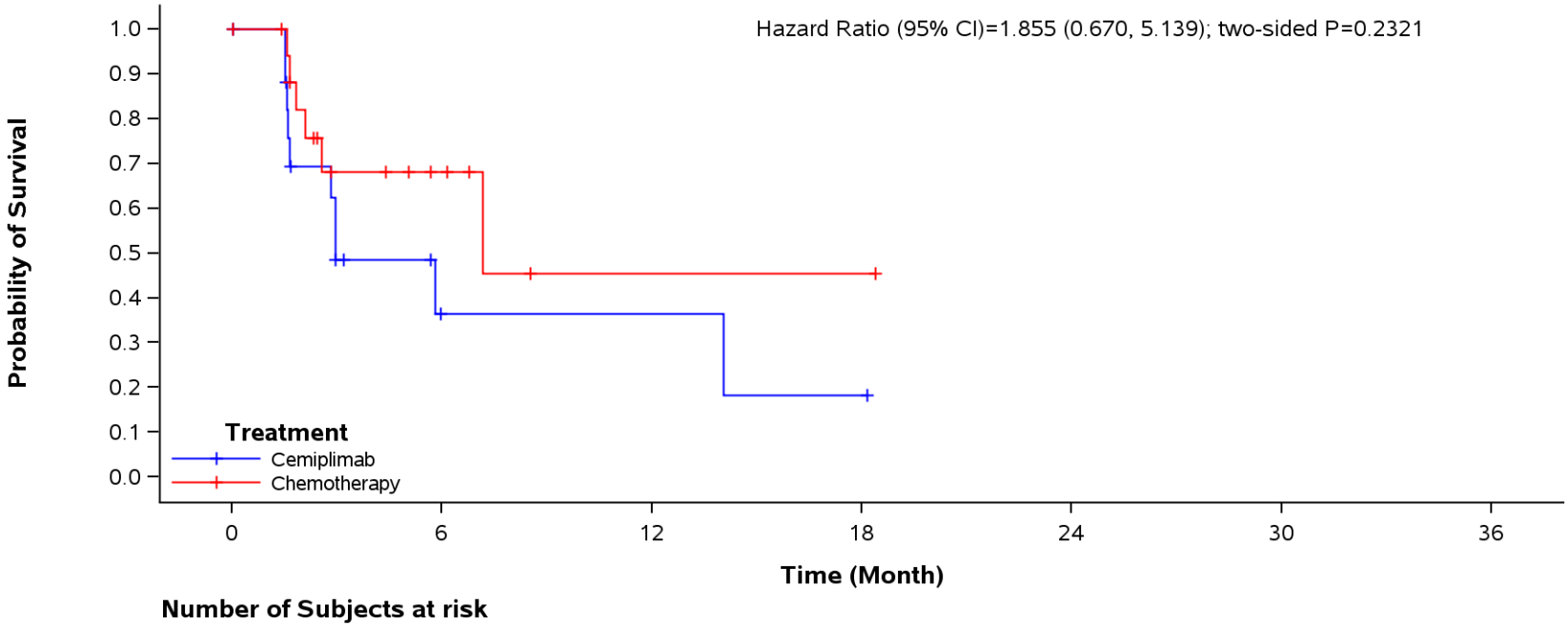

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts deterioration



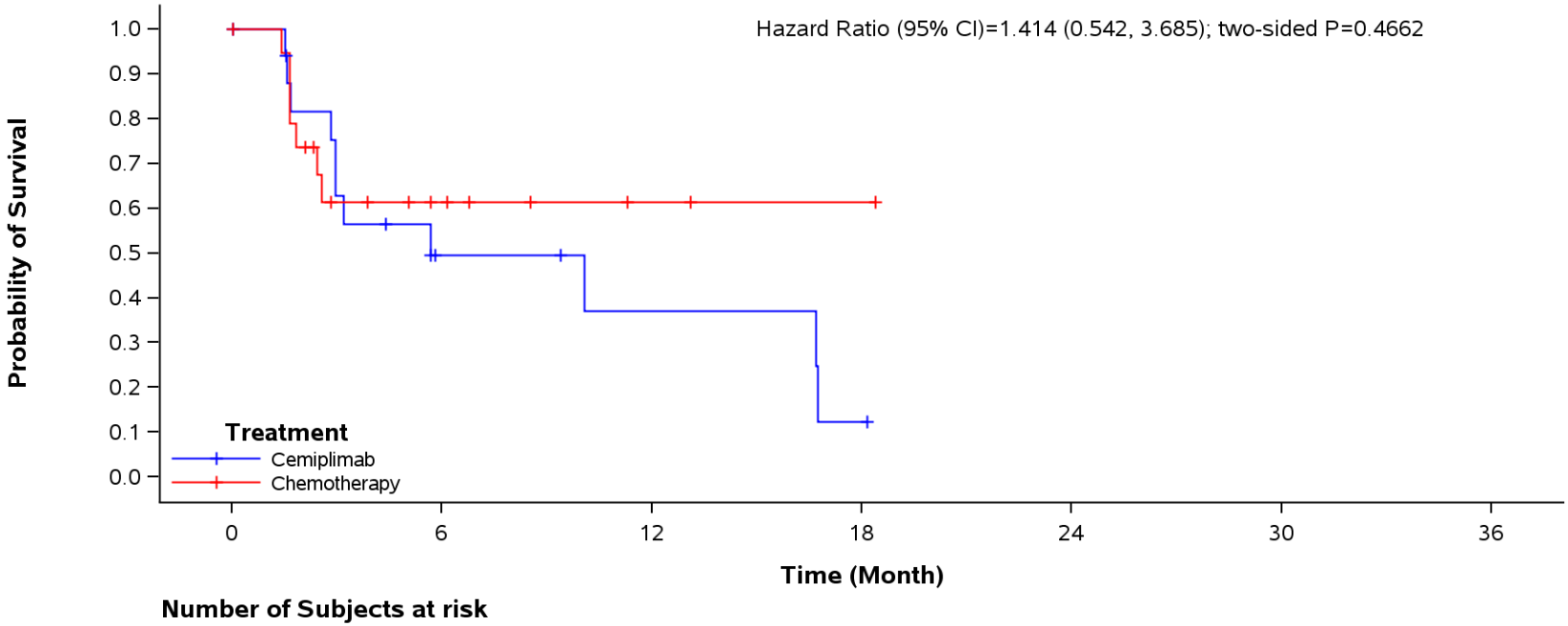

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 2 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts deterioration



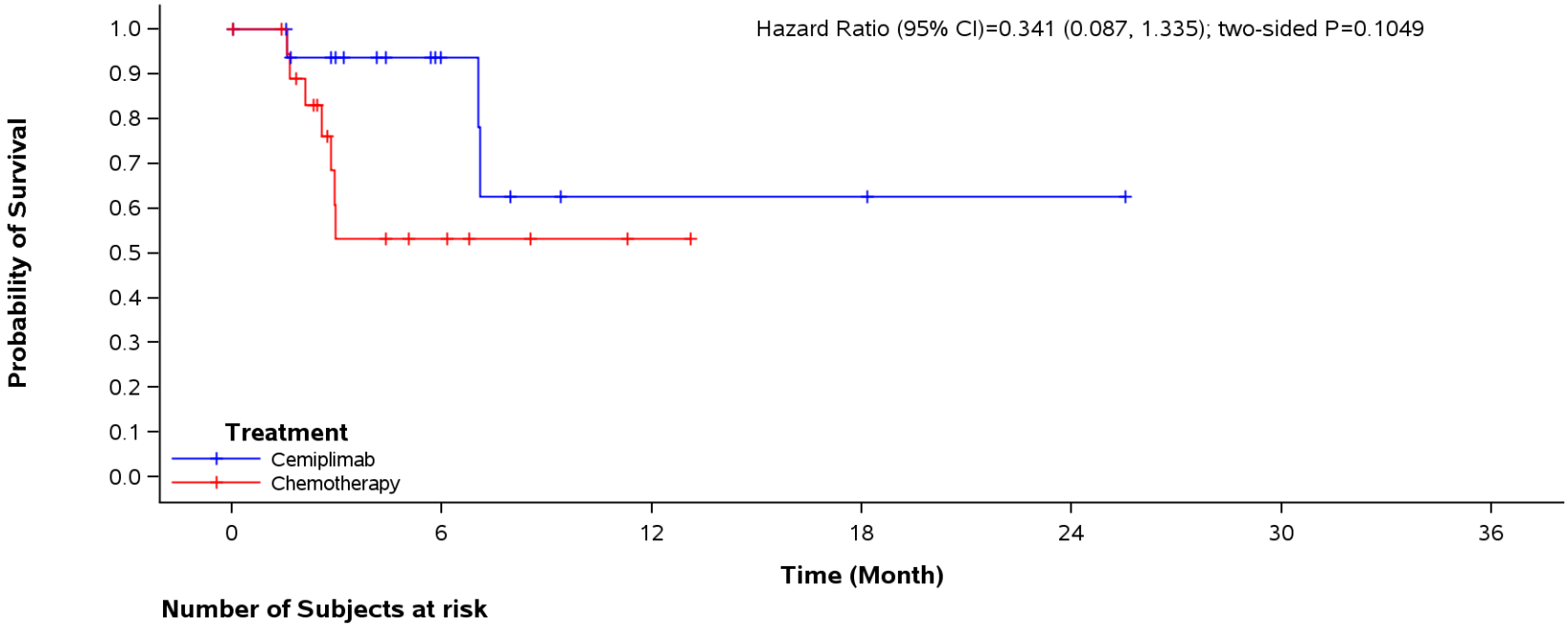

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts deterioration



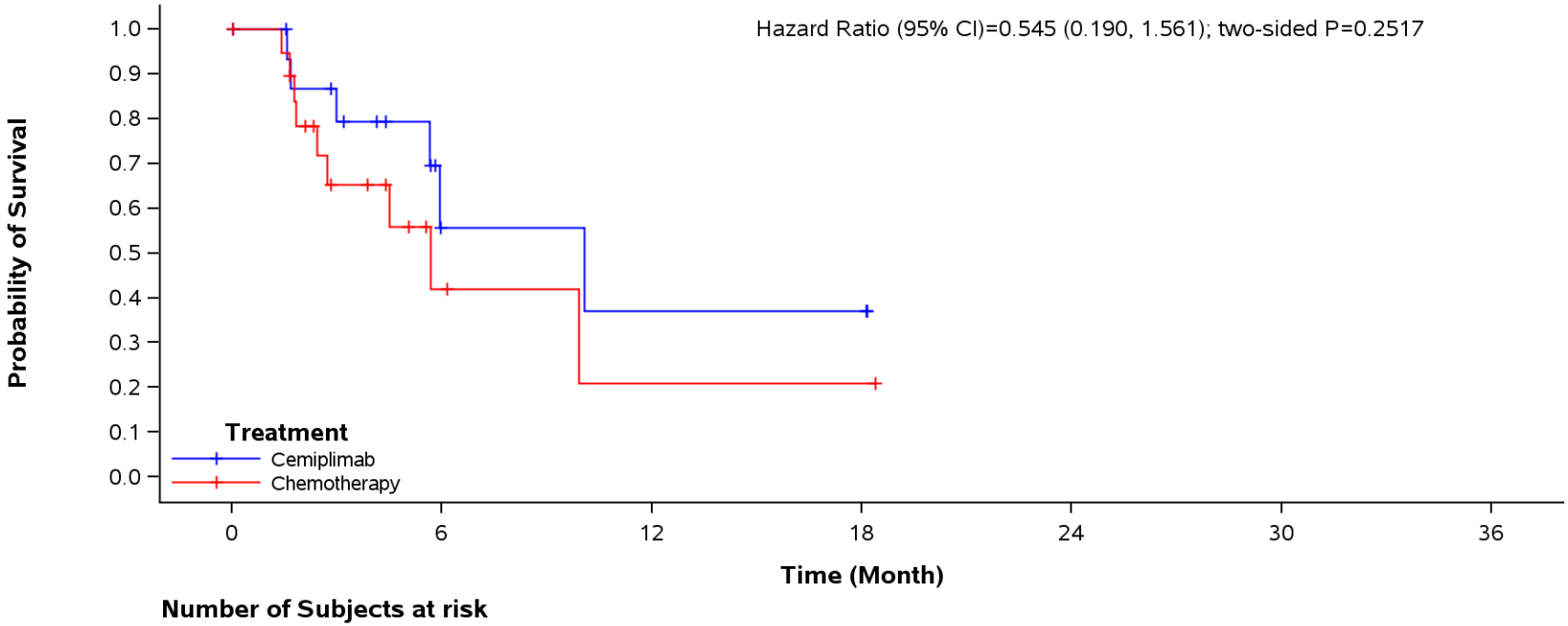

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts deterioration



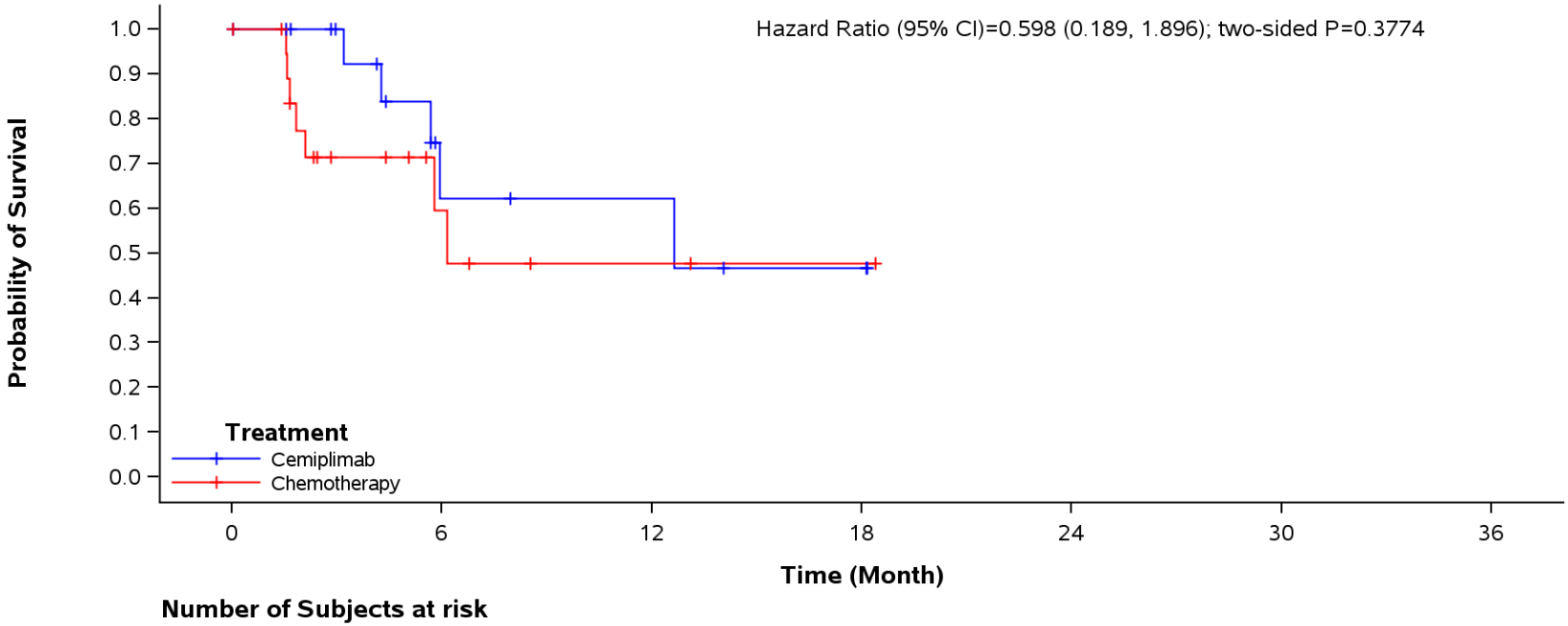

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts deterioration



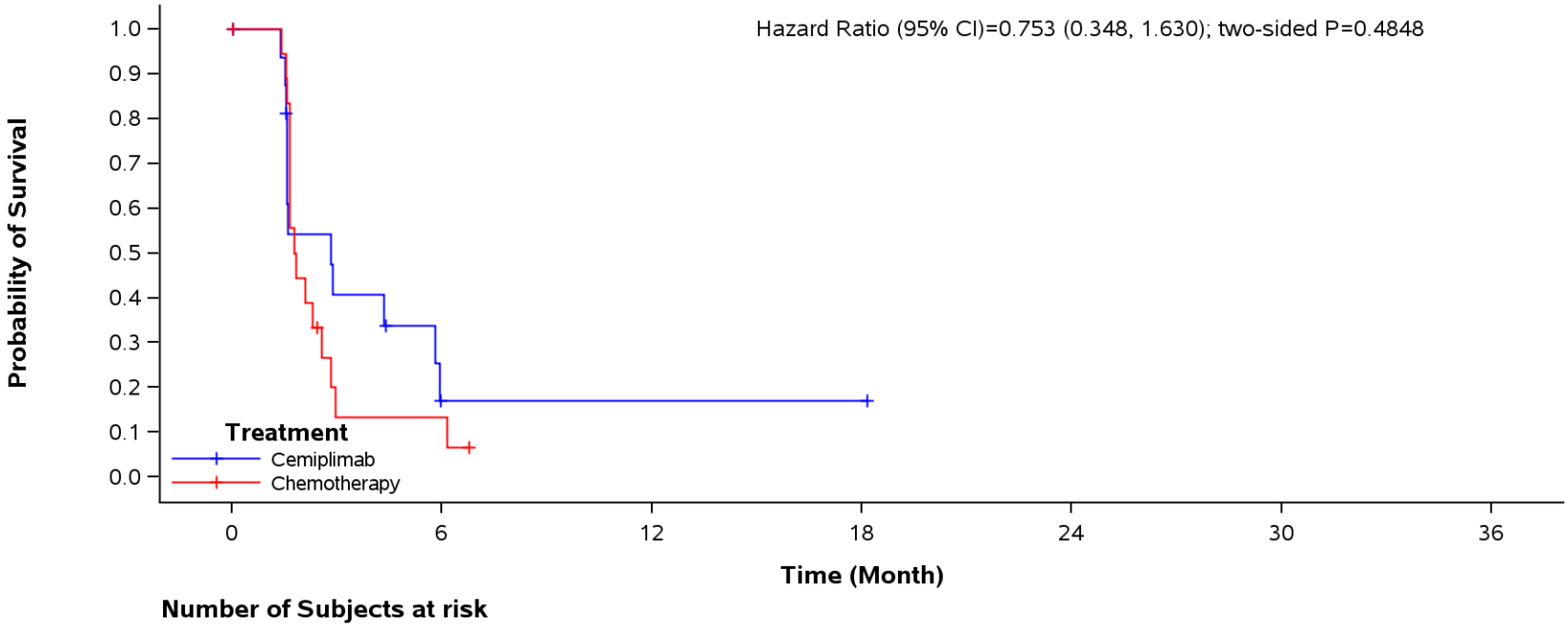

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 5 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts deterioration



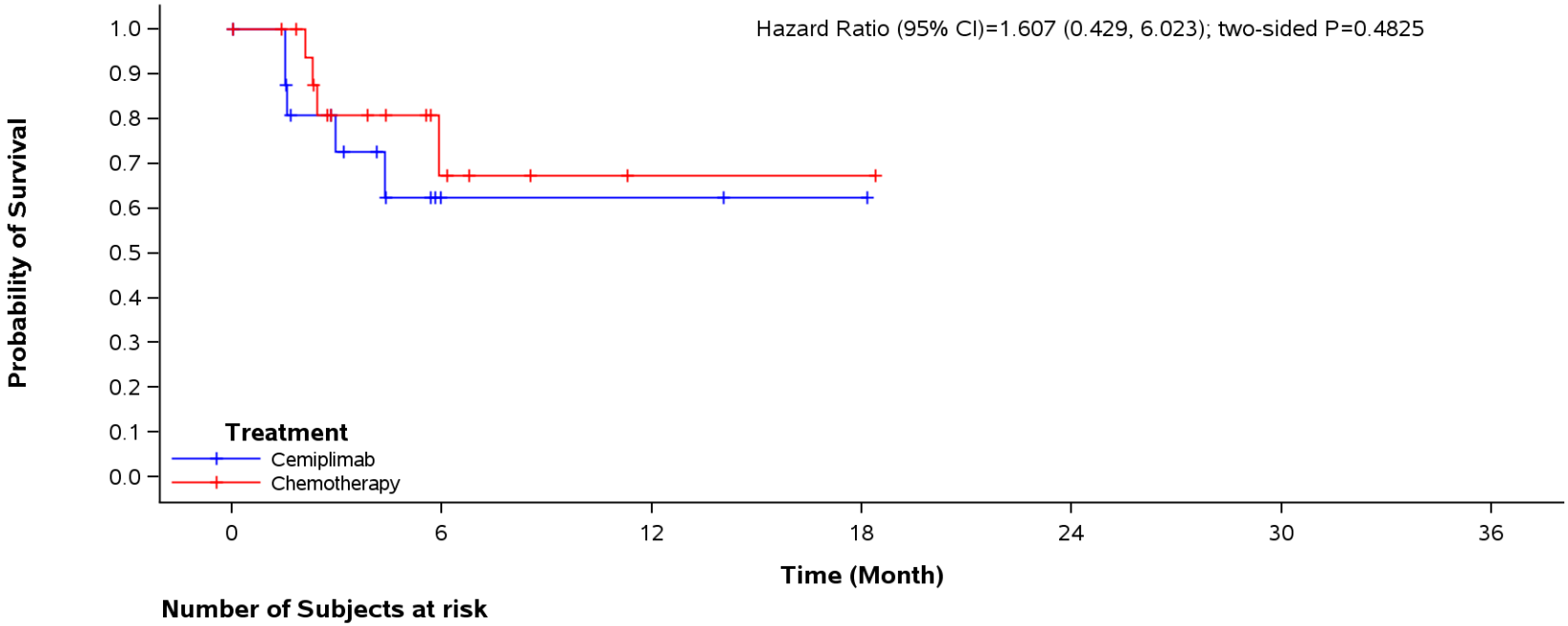

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 1 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts deterioration



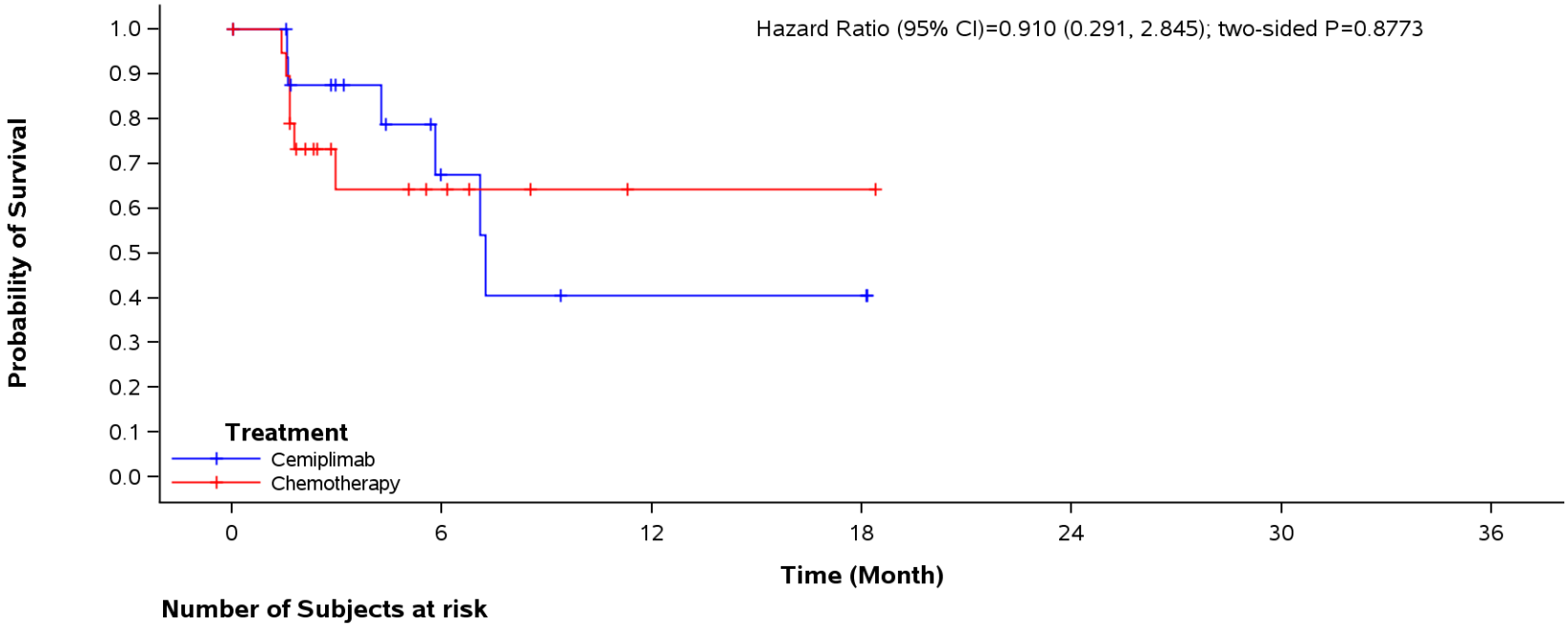

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 2 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts deterioration



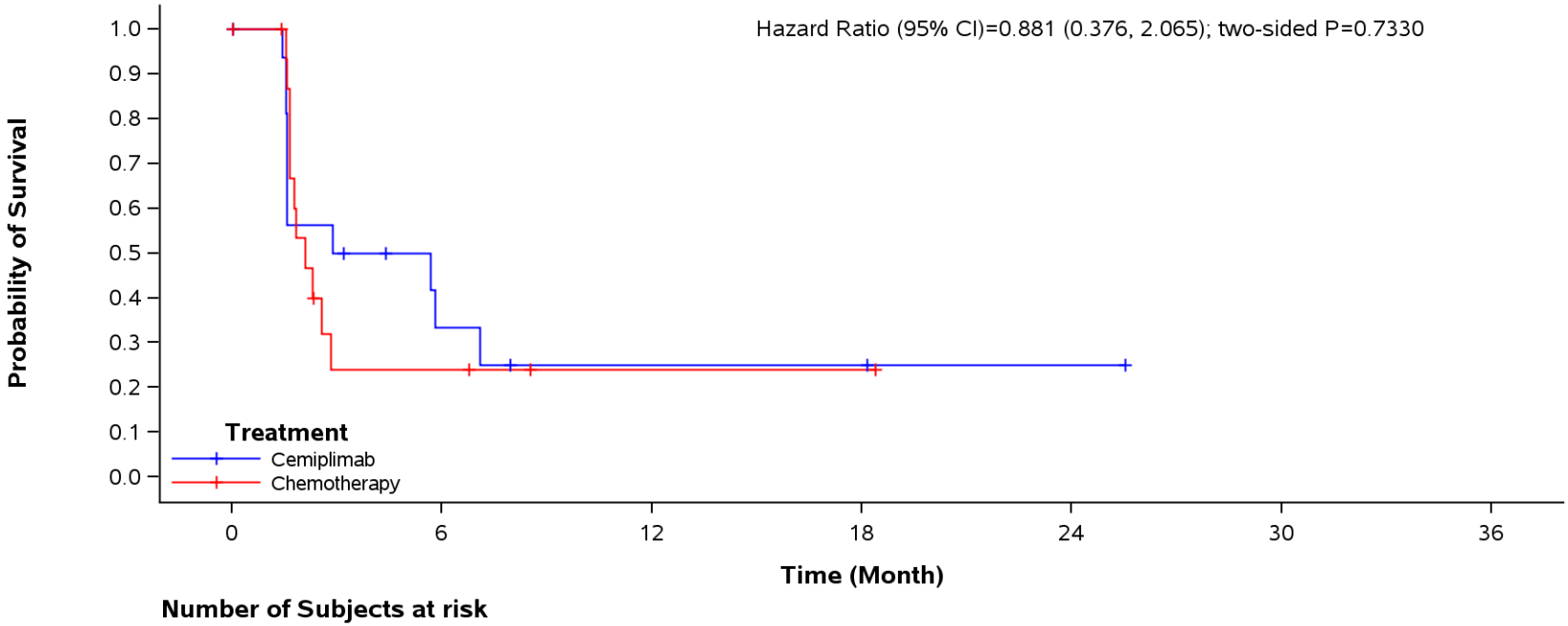

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts deterioration



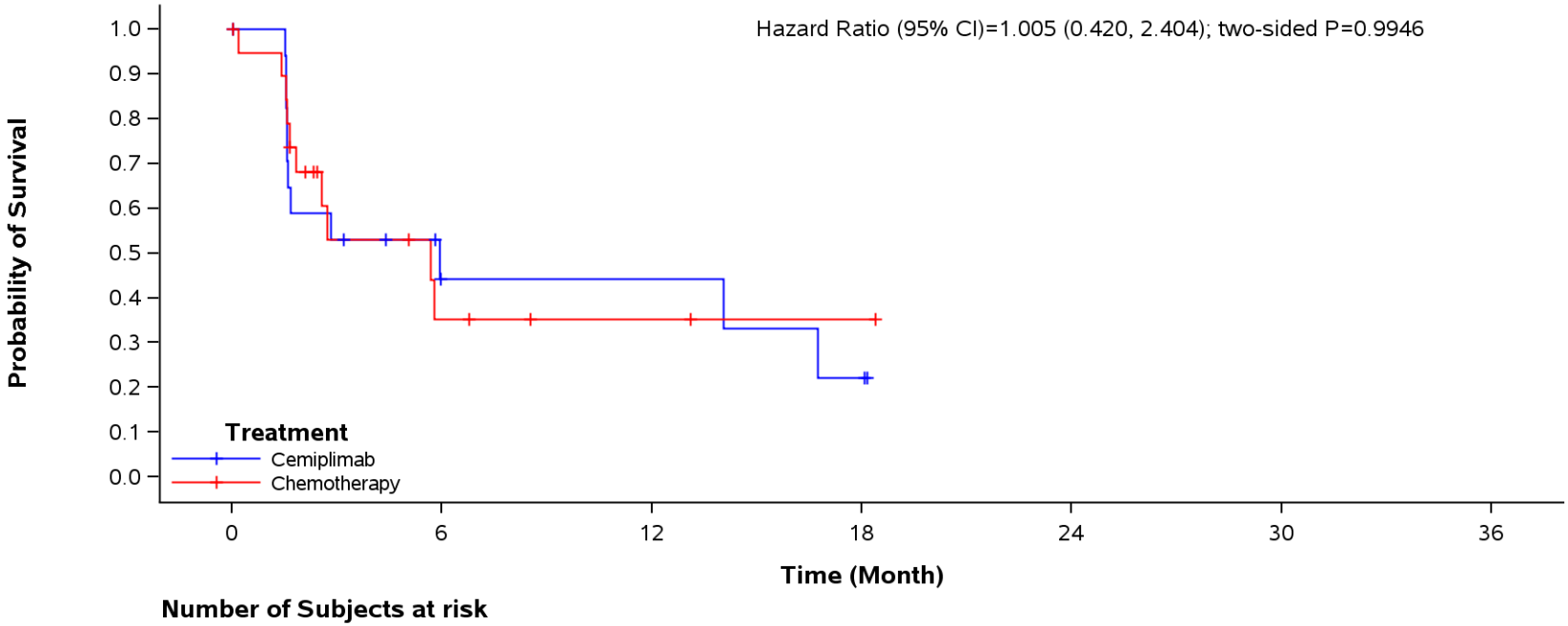

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 4 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts deterioration



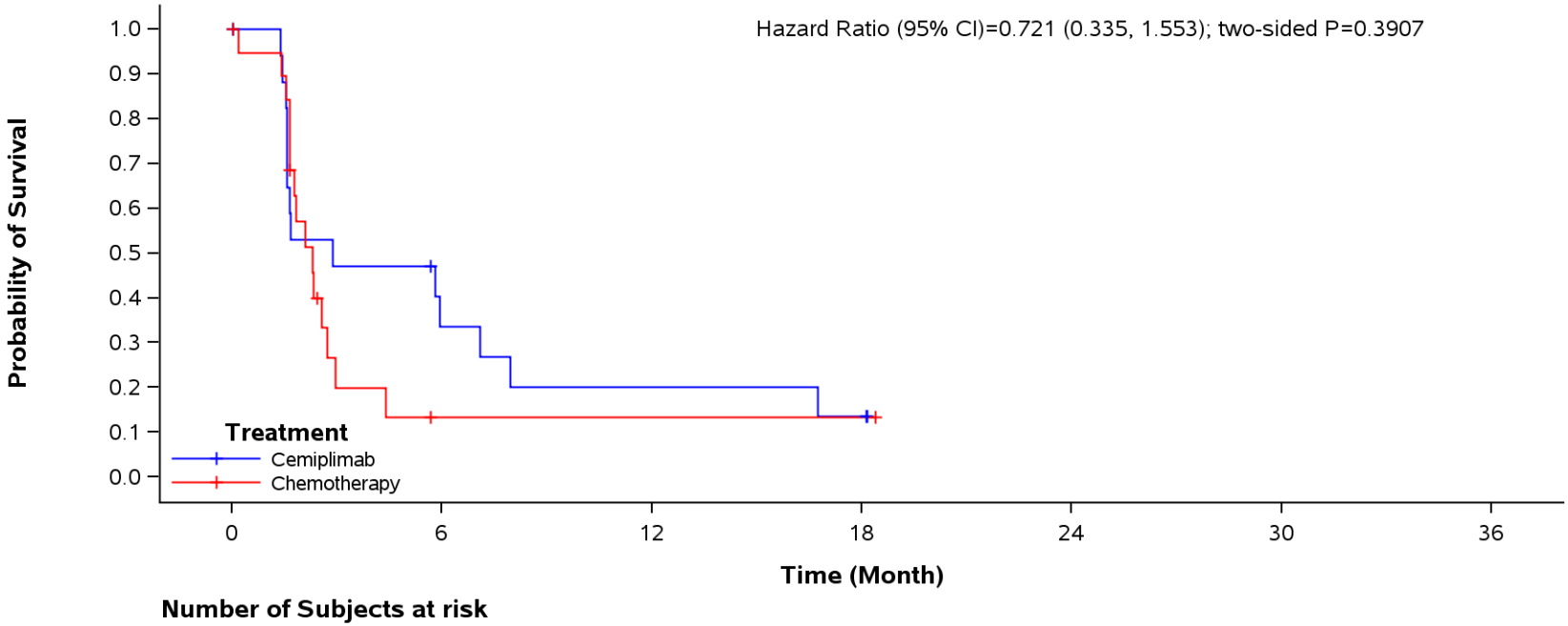

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 4 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 4 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts deterioration



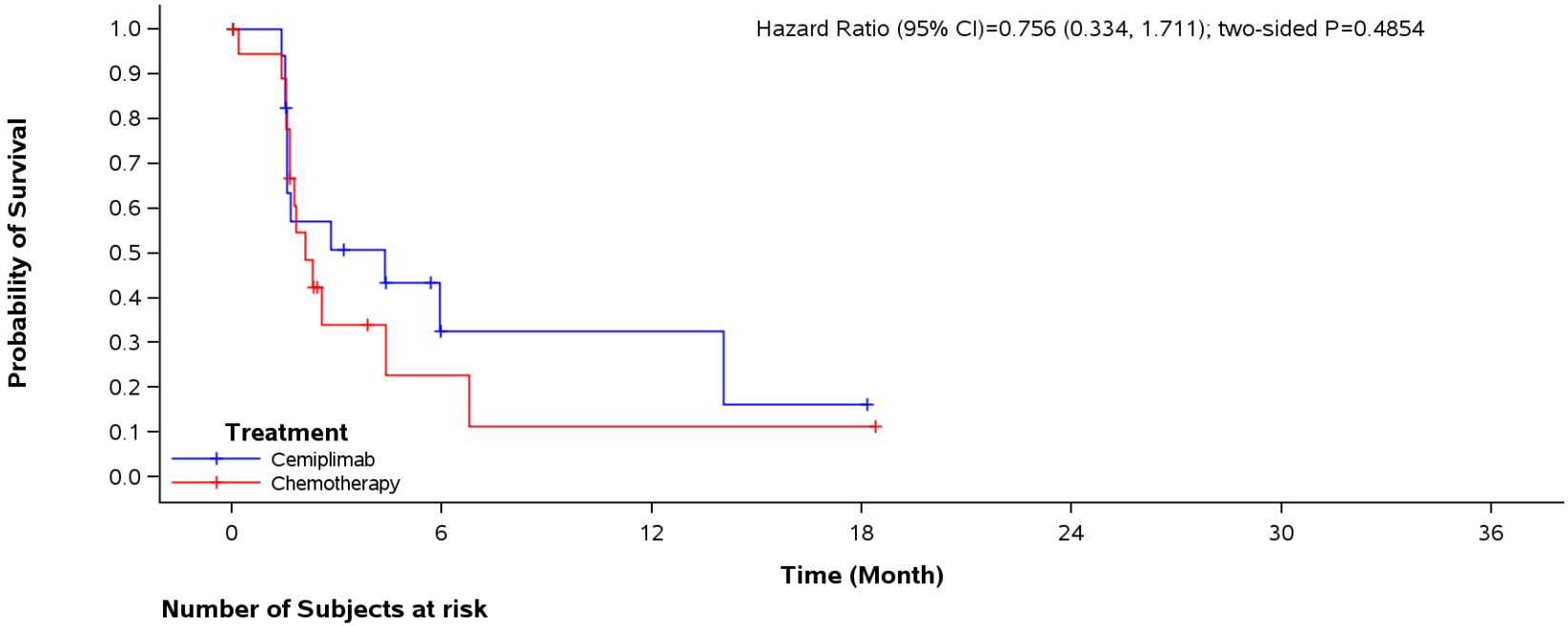

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 1 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts deterioration



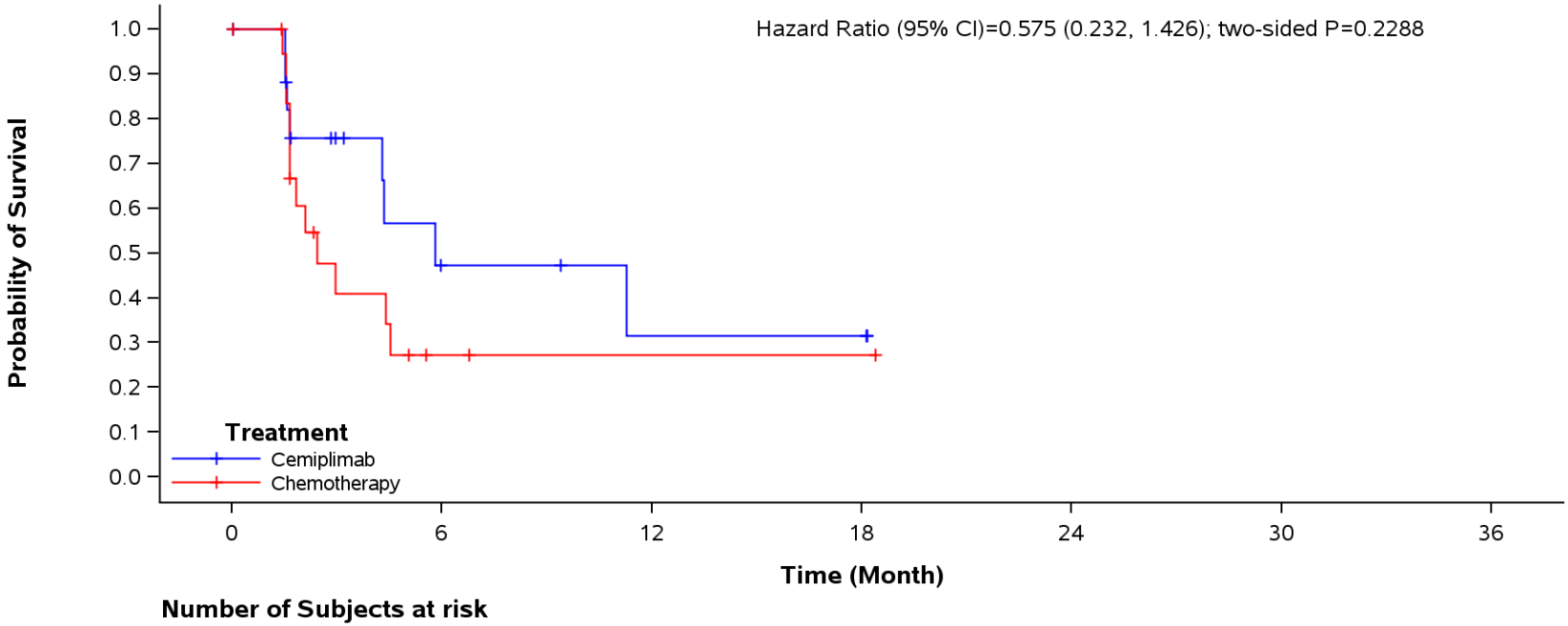

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 2 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts deterioration



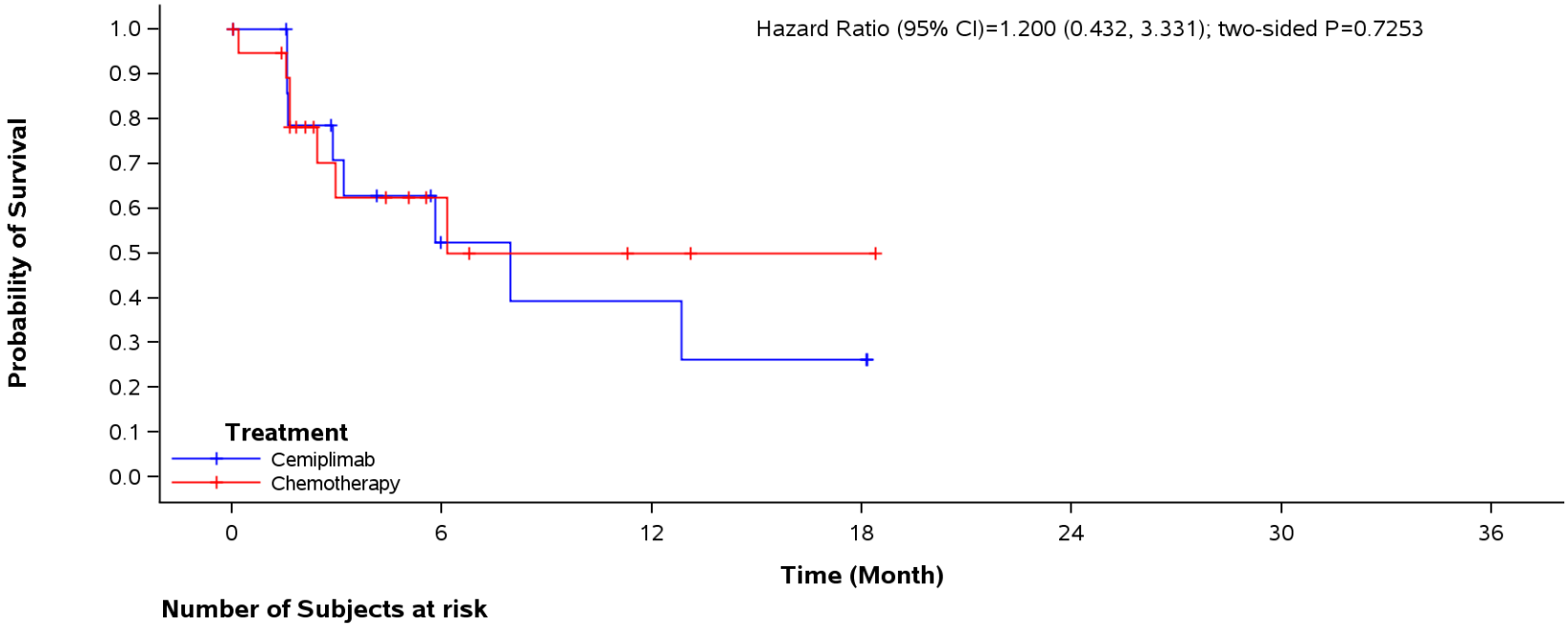

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 4 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts deterioration



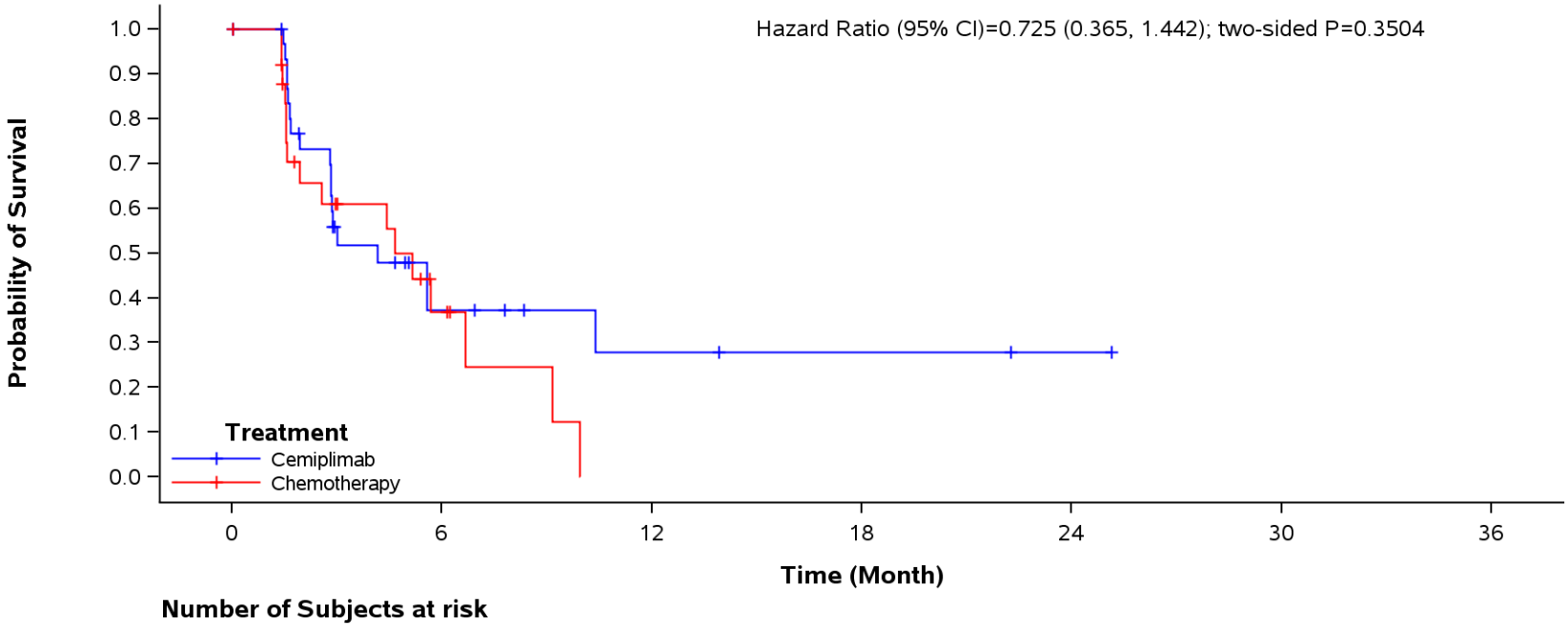

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 4 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 5 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts deterioration



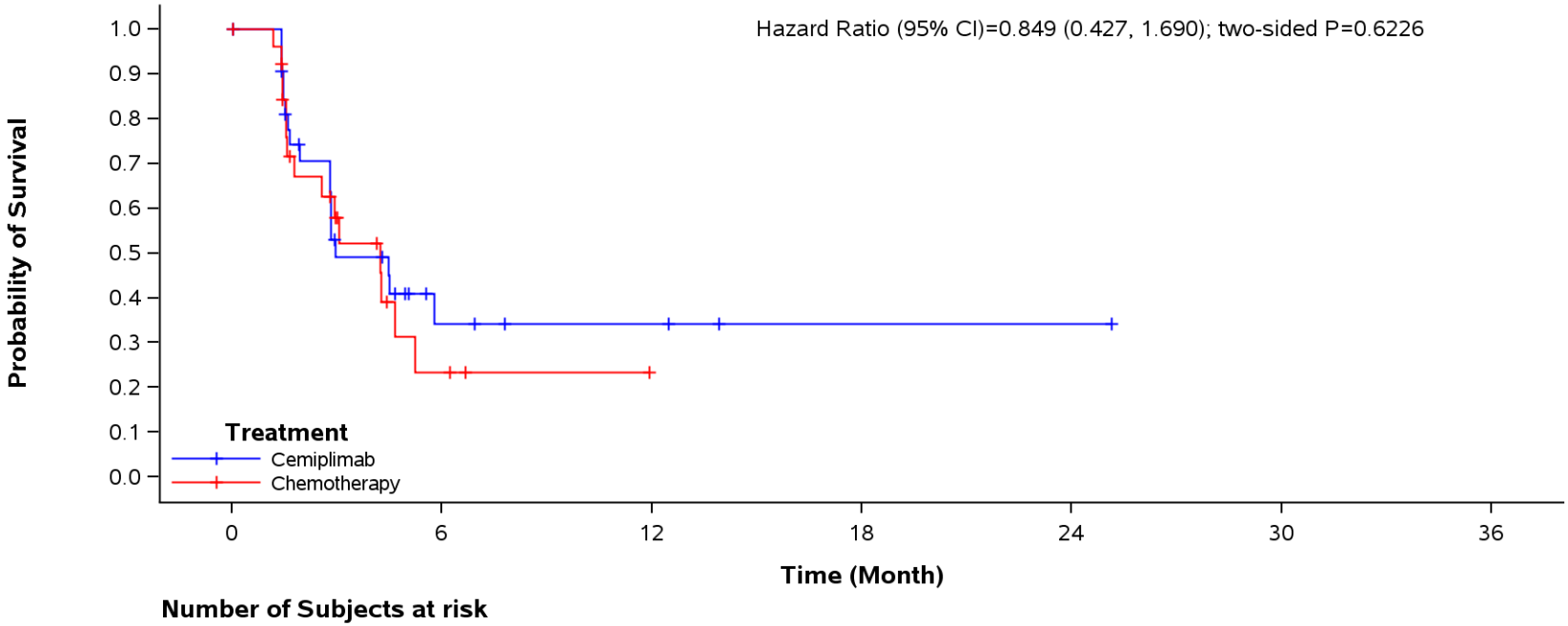

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 7 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 36 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts deterioration



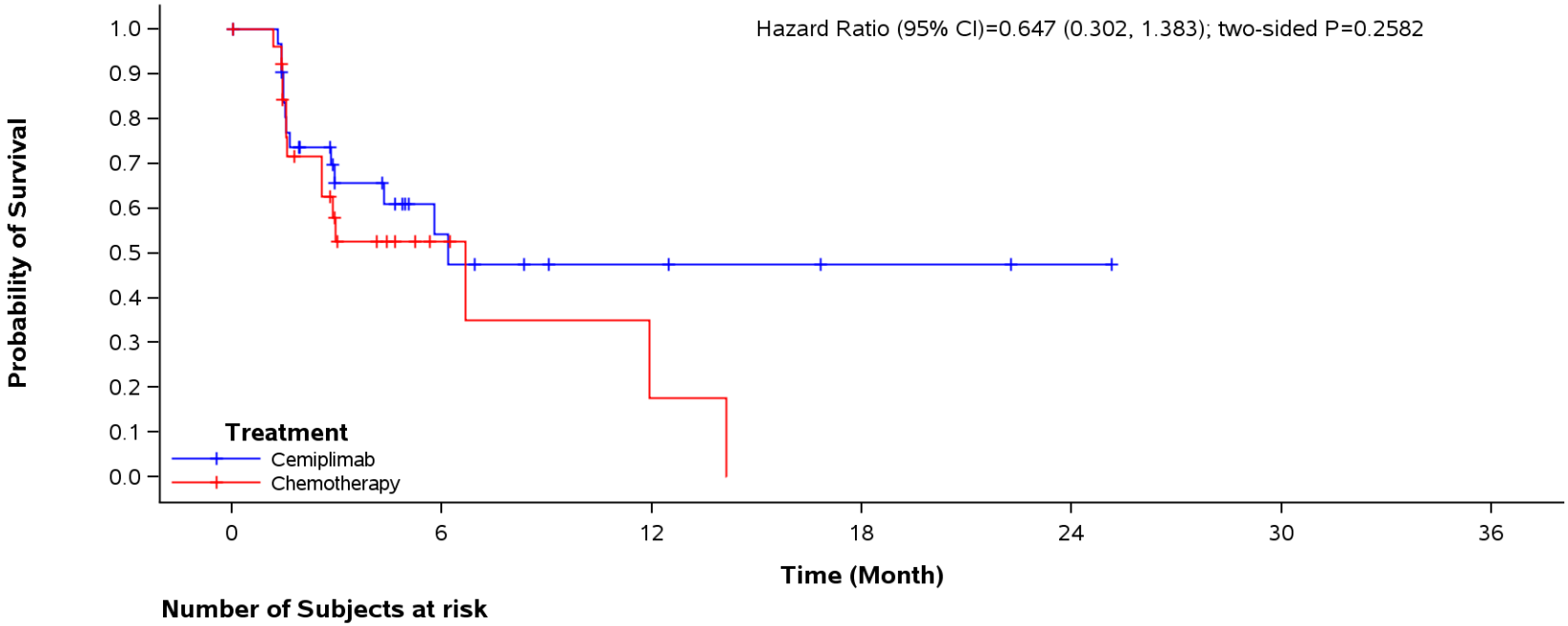

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 5 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts deterioration



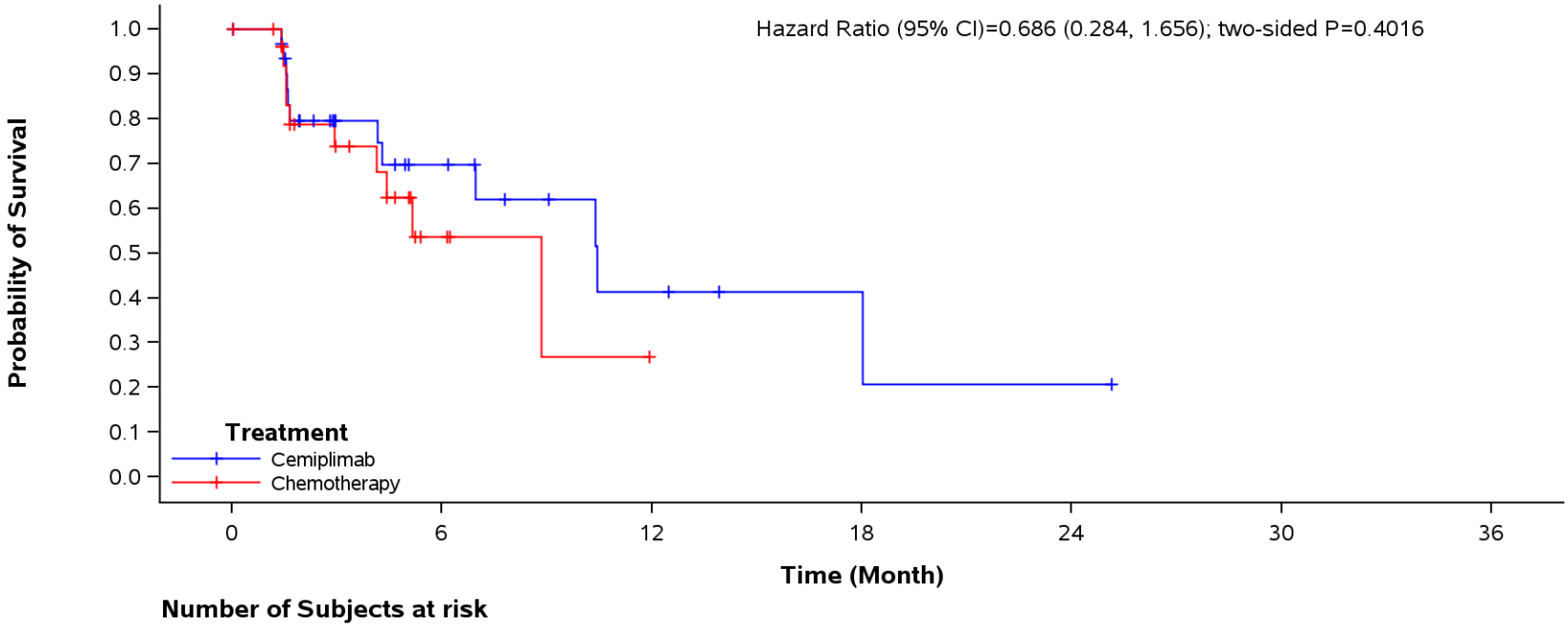

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 8 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 36 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts deterioration



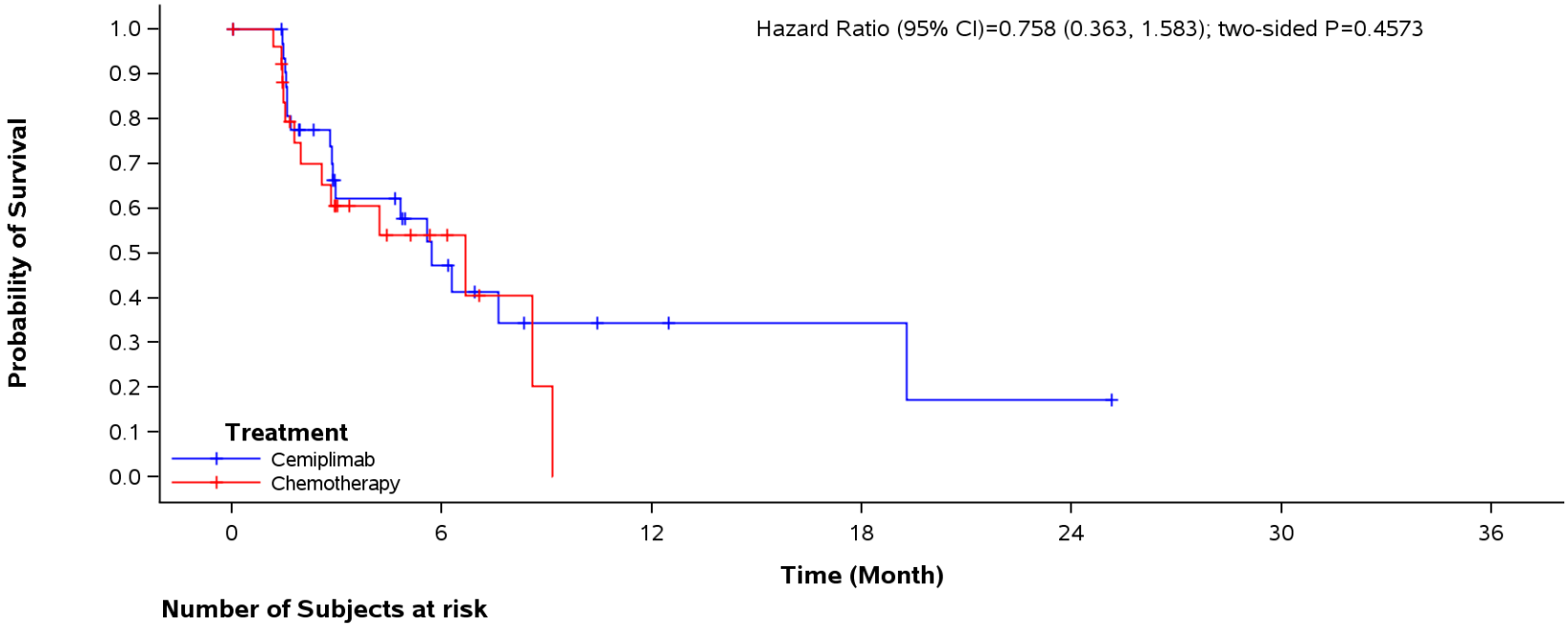

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 11 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 36 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts deterioration



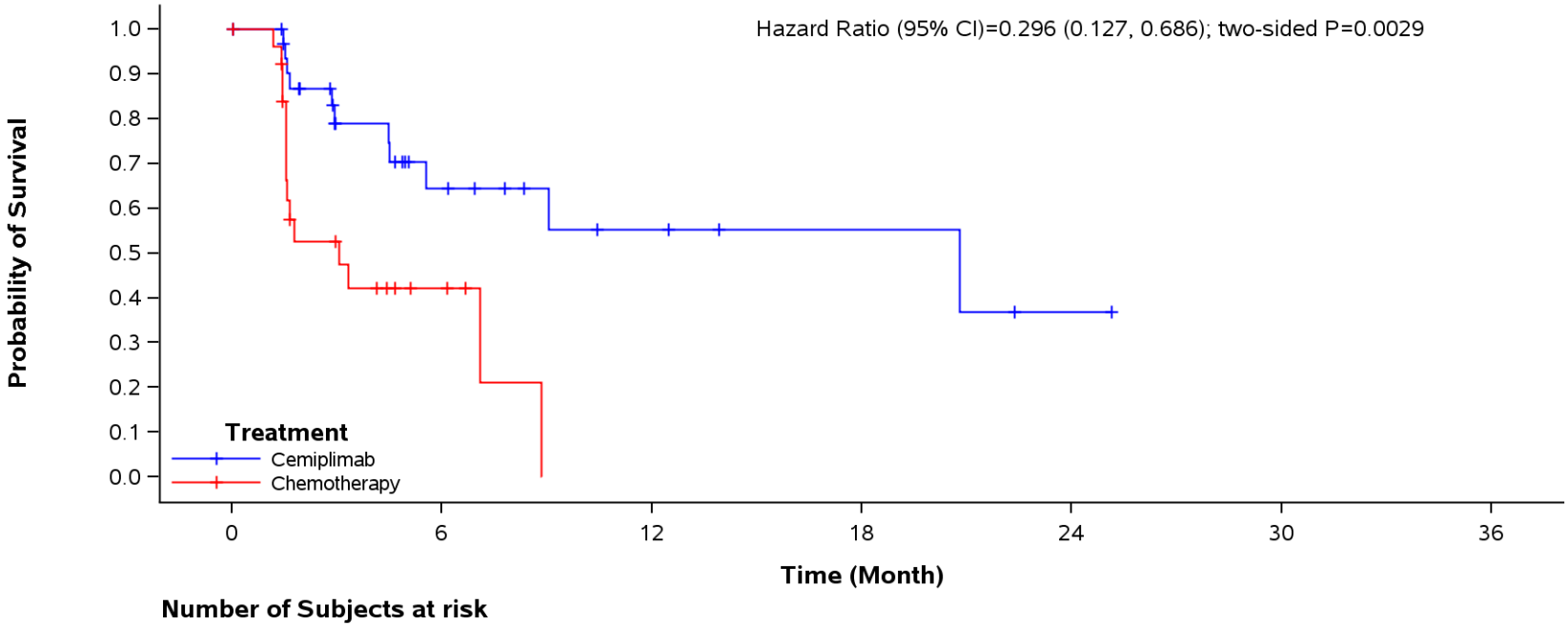

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 36 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts deterioration



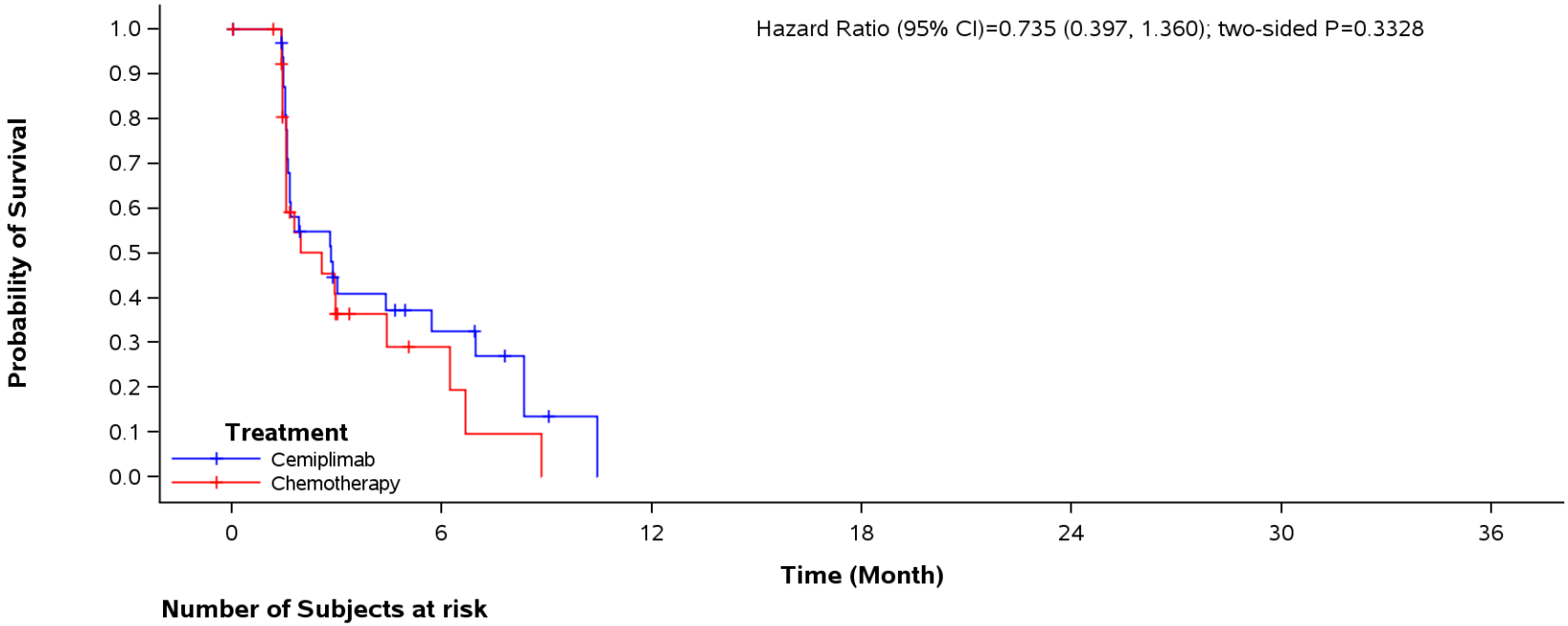

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 11 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts deterioration



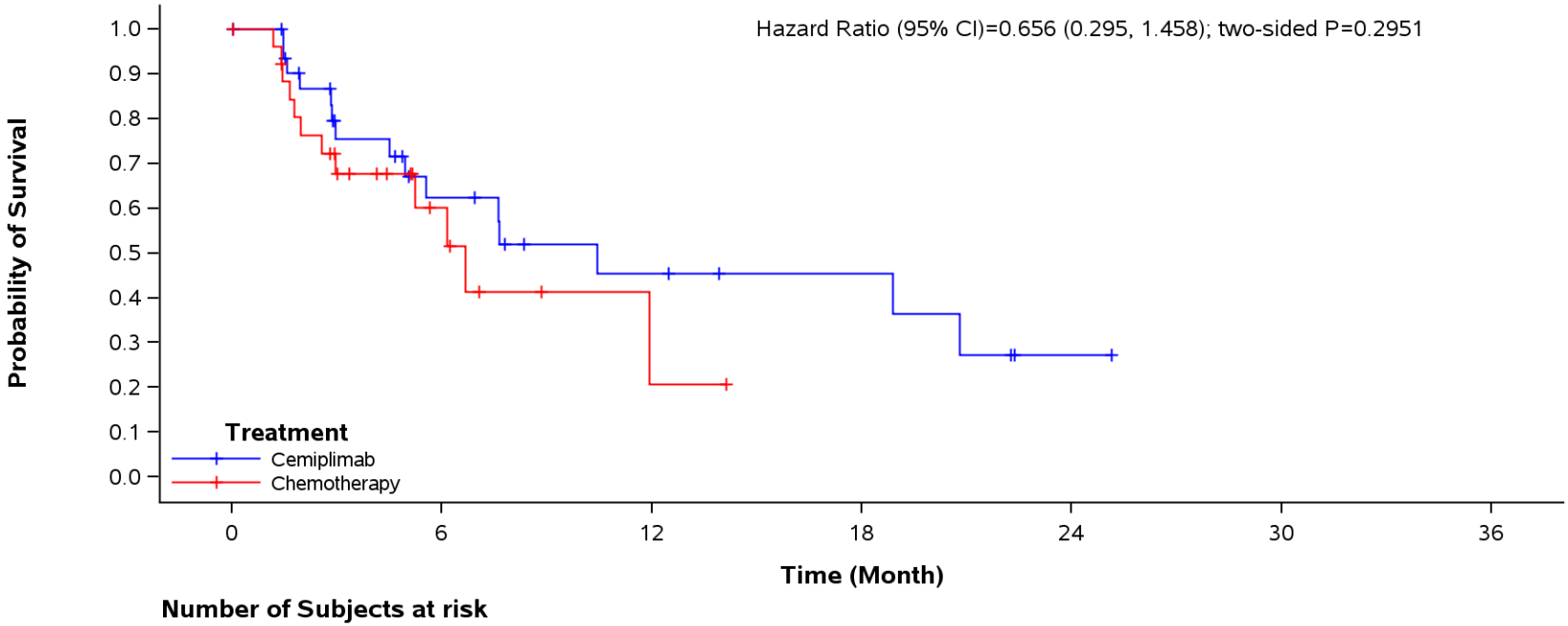

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 7 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts deterioration



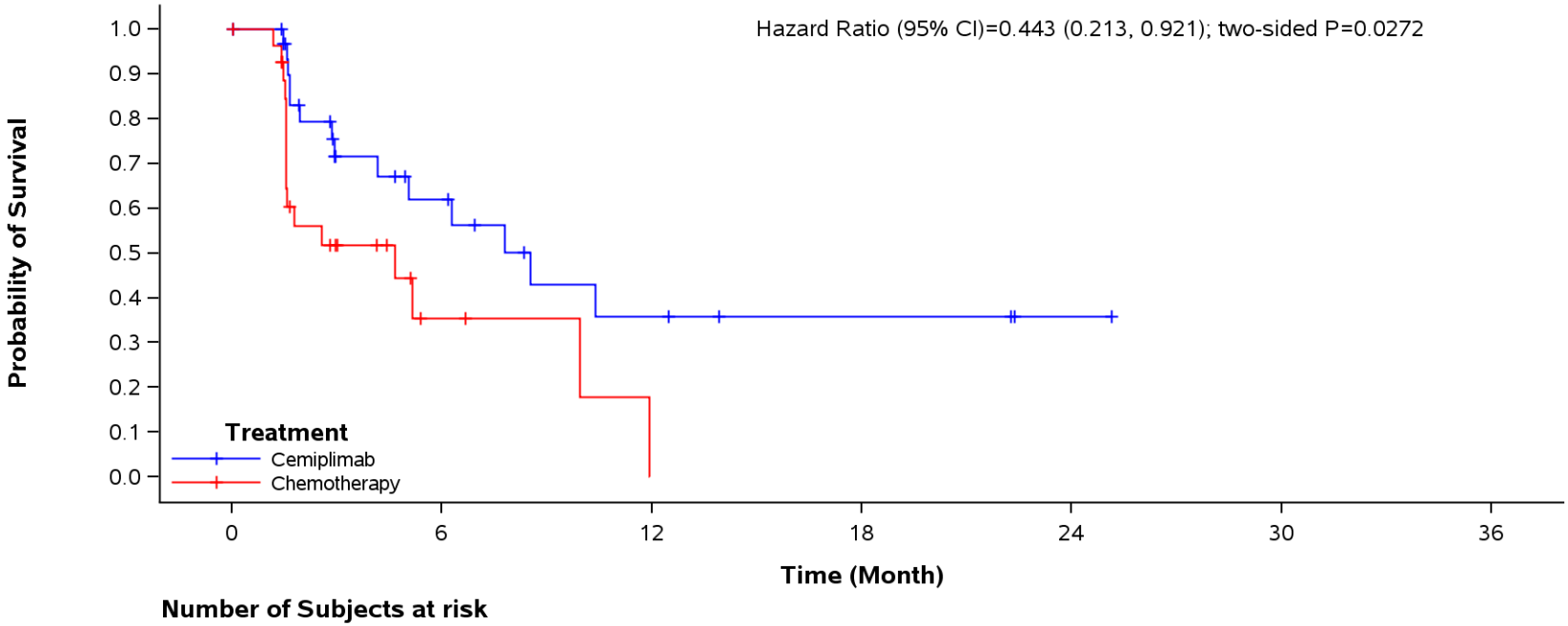

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 7 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts deterioration



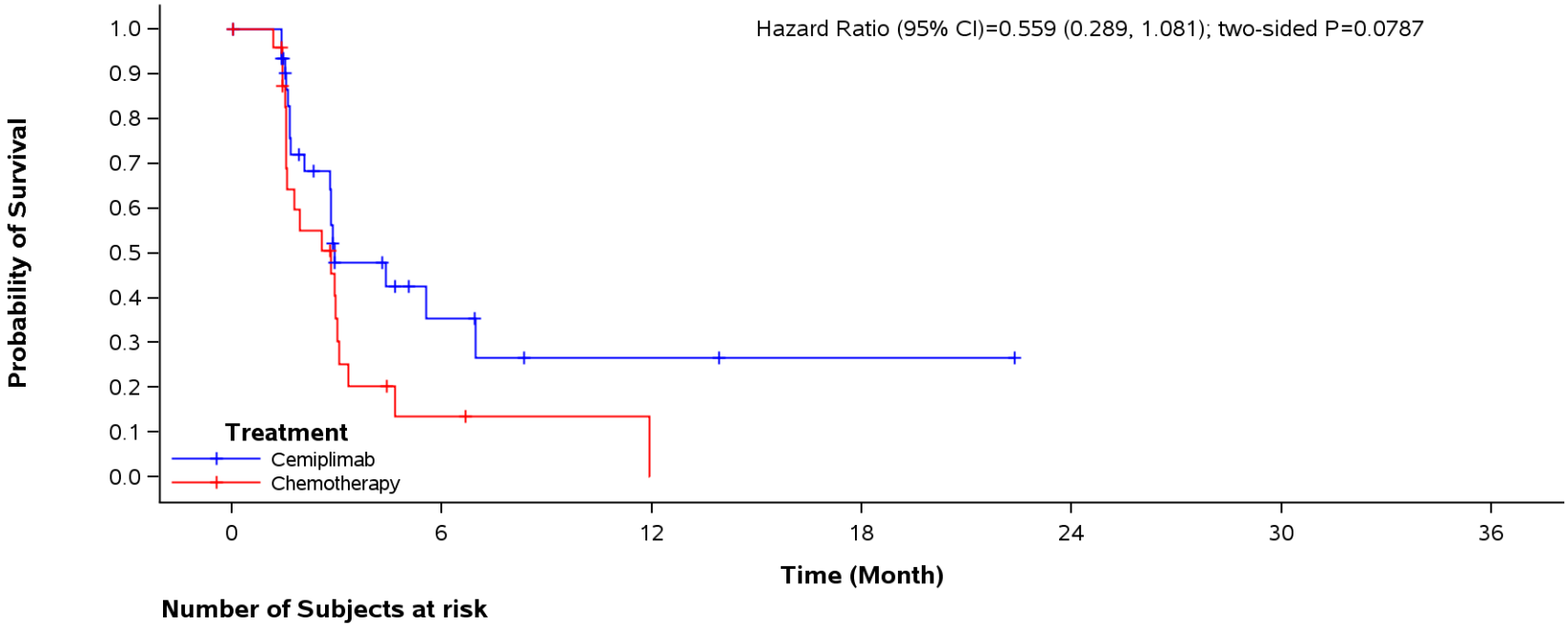

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts deterioration



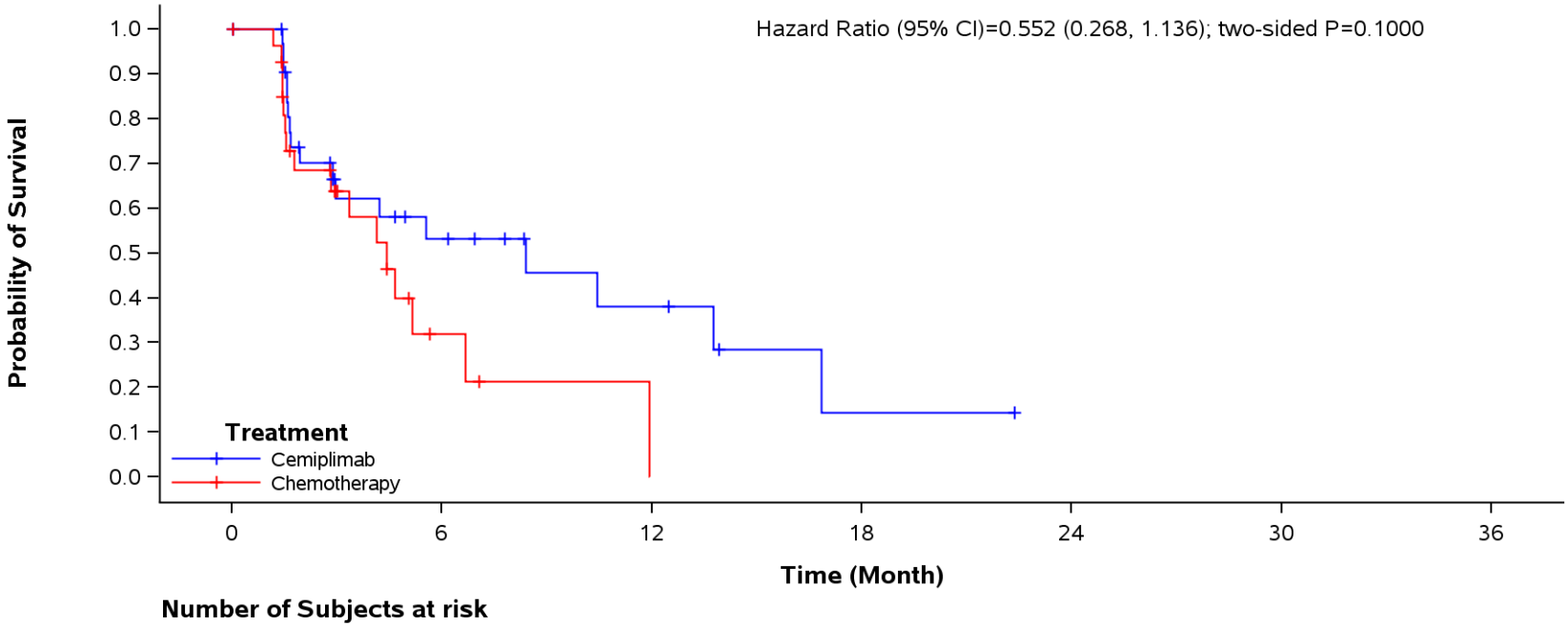

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 5 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts deterioration



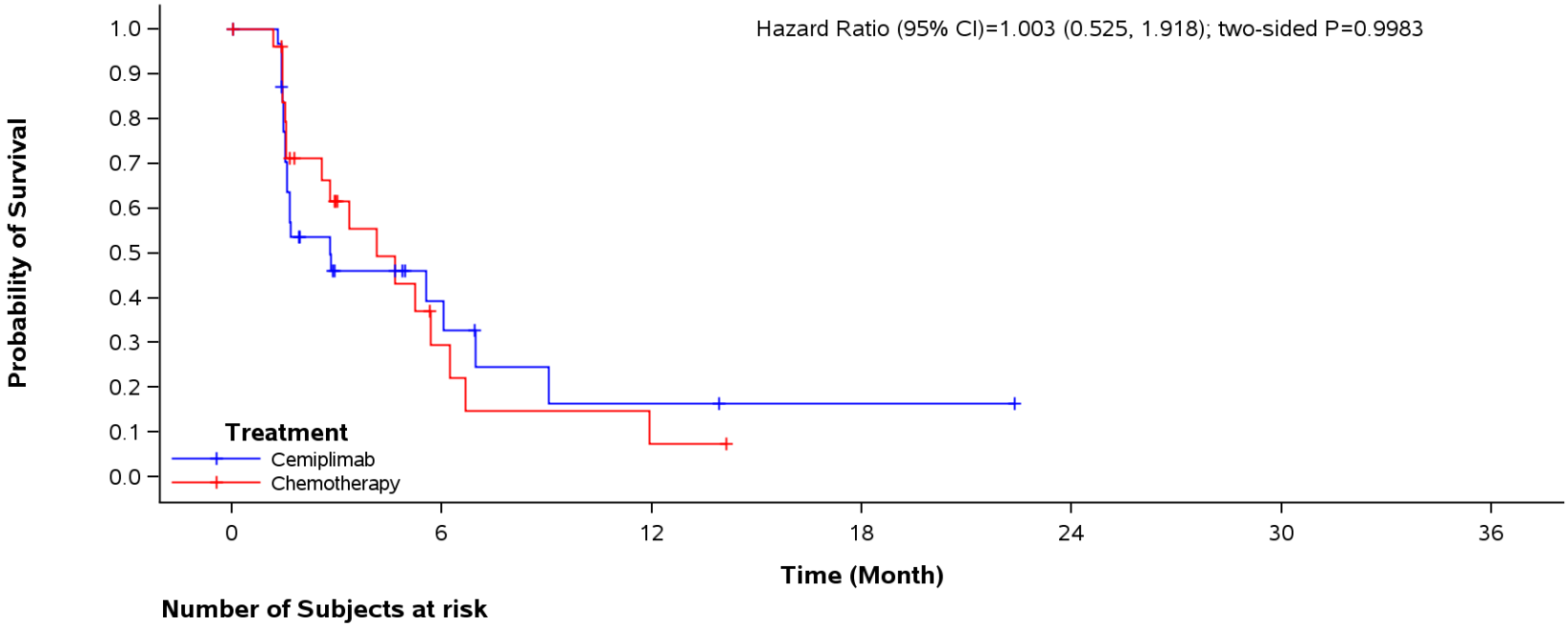

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 11 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Global health status / QoL - 10 pts deterioration



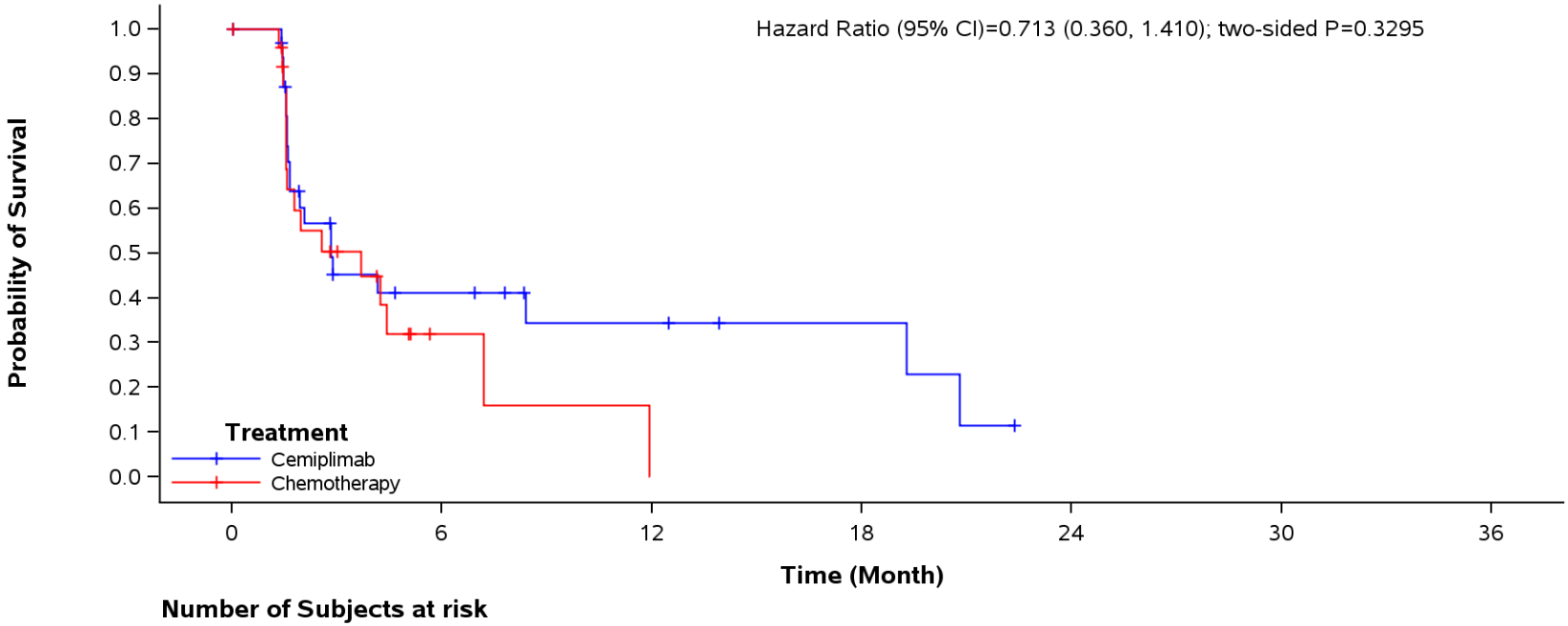

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts deterioration



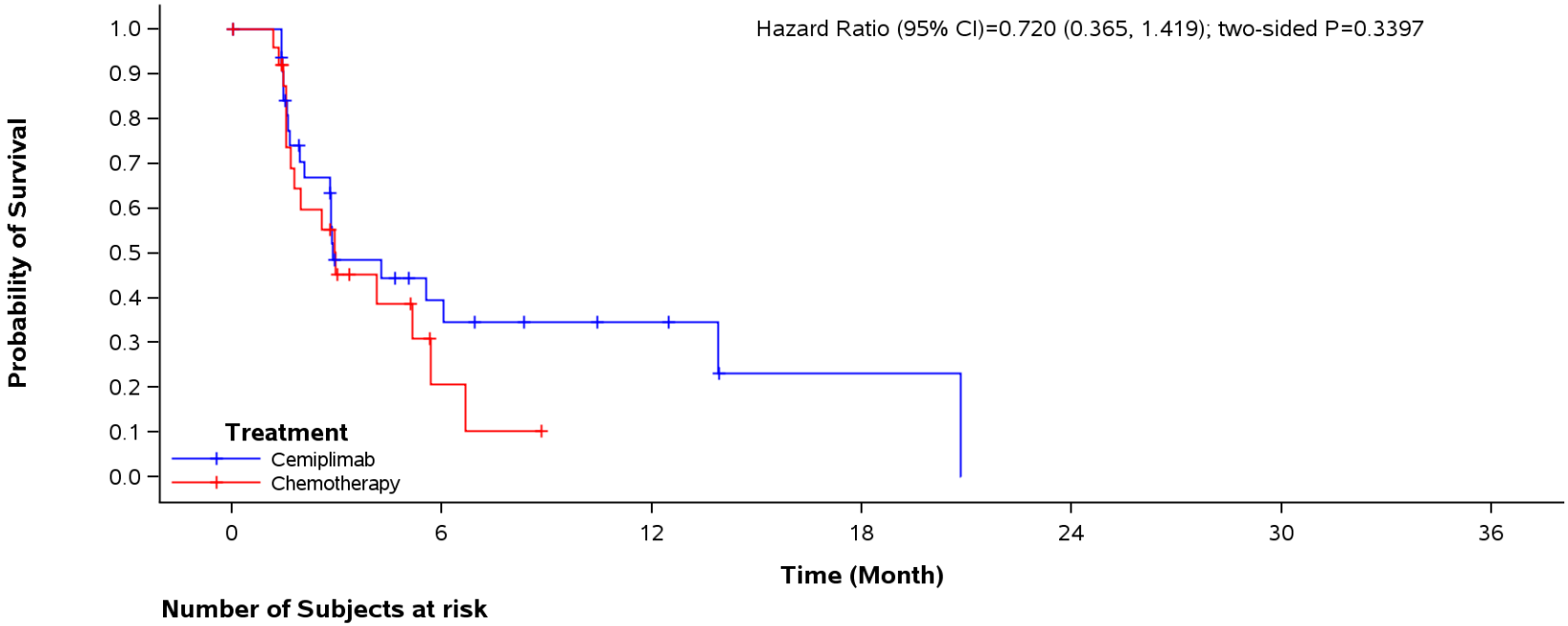

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts deterioration



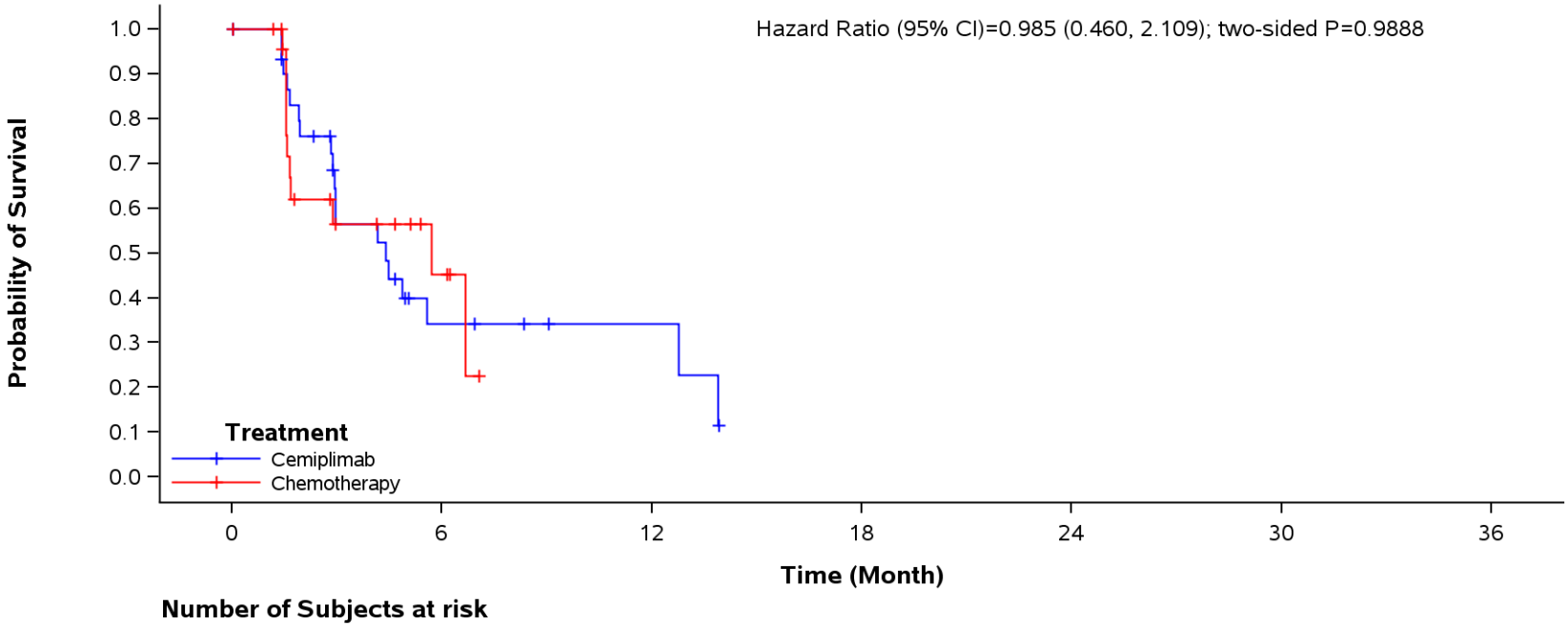

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 8 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts deterioration



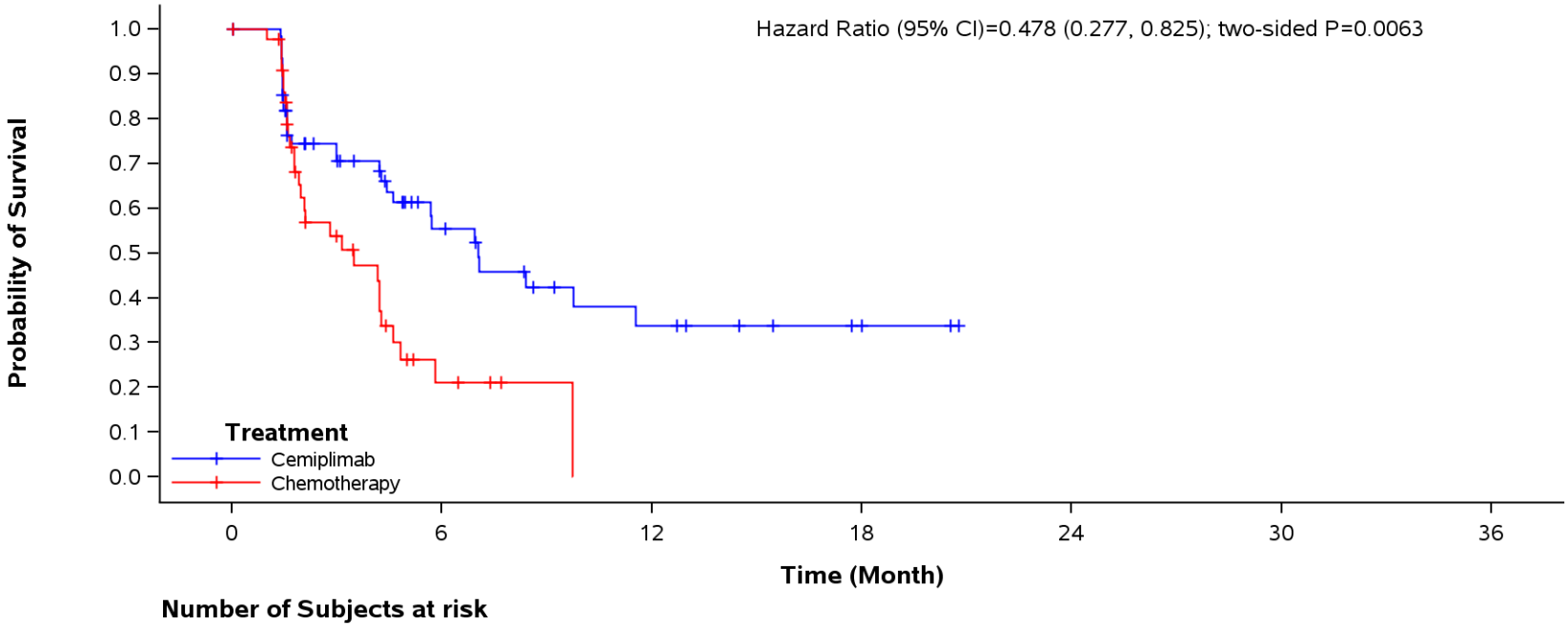

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 6 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts deterioration



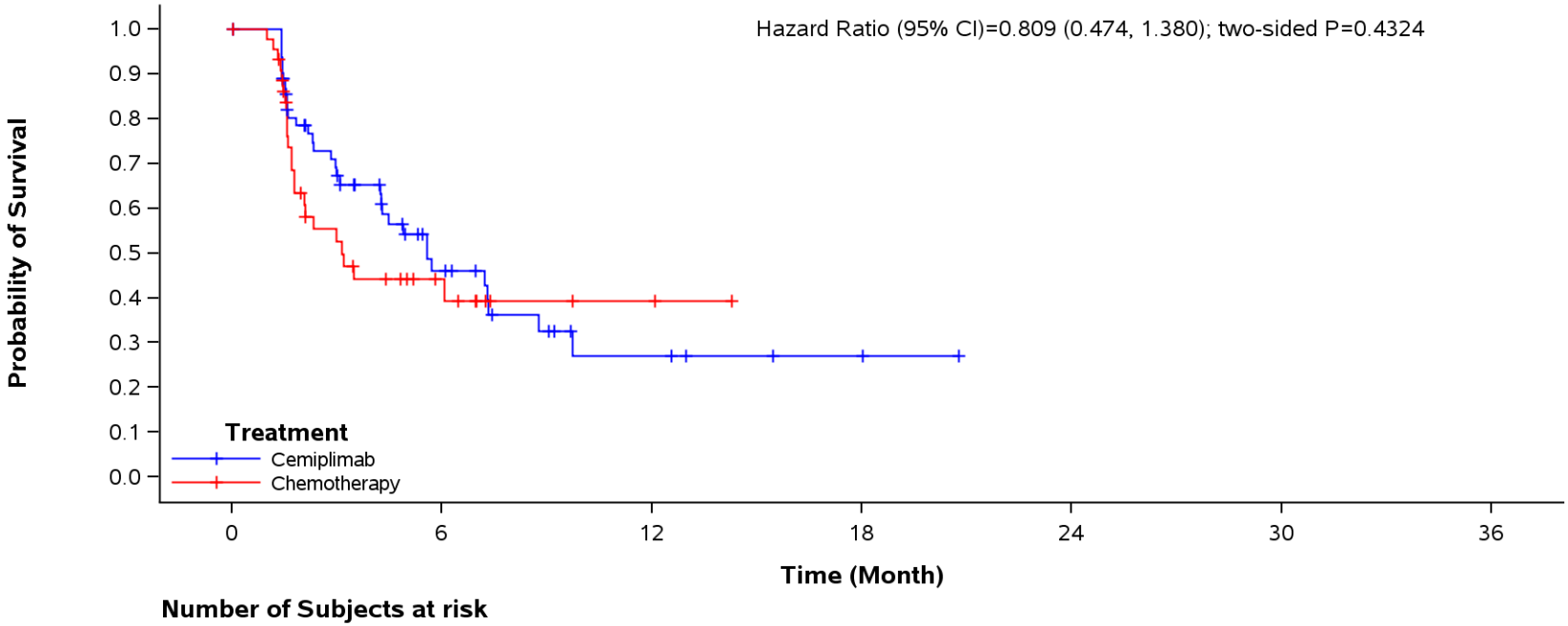

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 19 | 8 | 3 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts deterioration



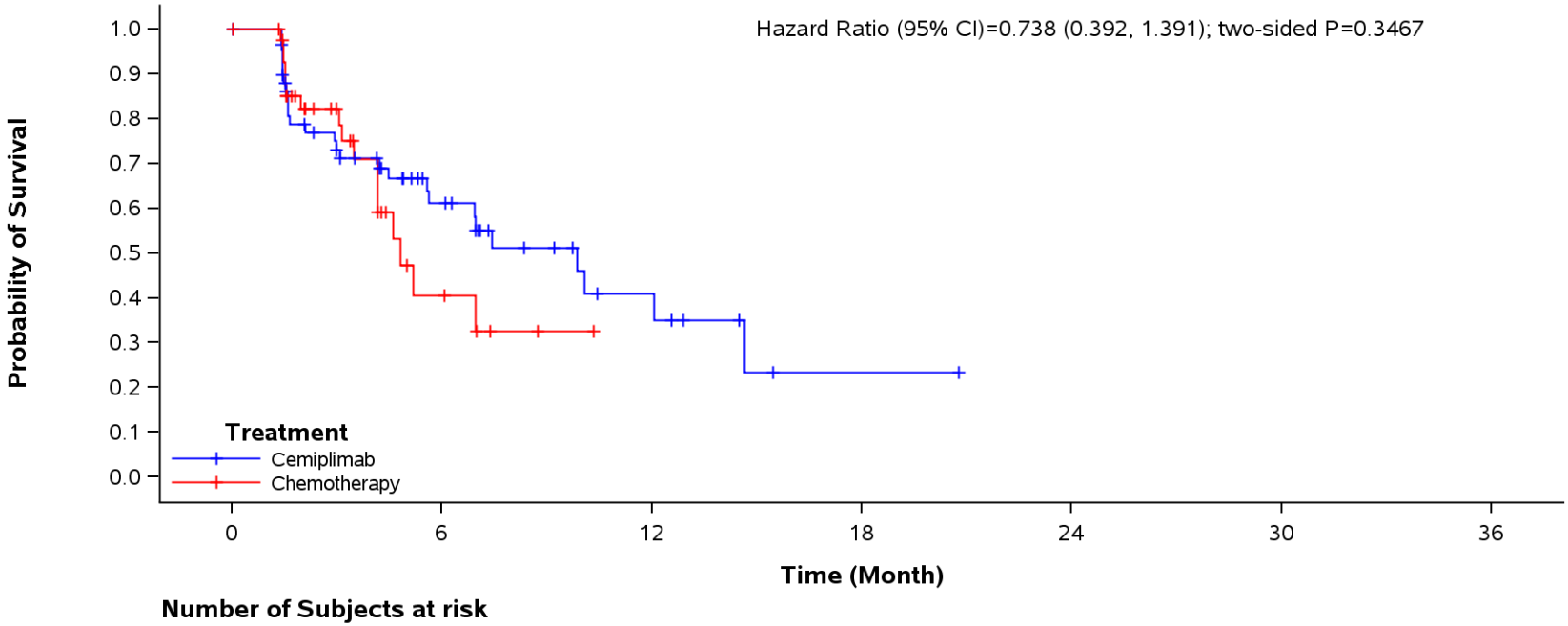

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 17 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts deterioration



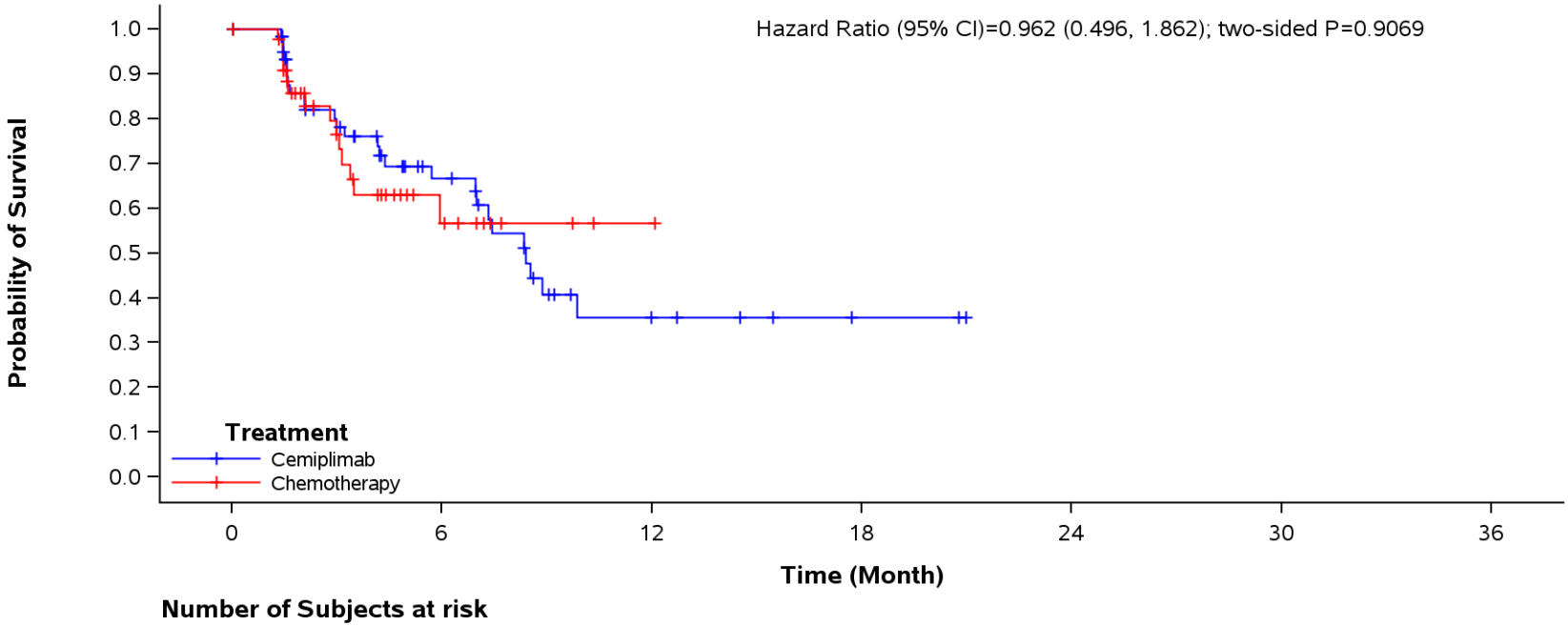

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 22 | 7 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts deterioration



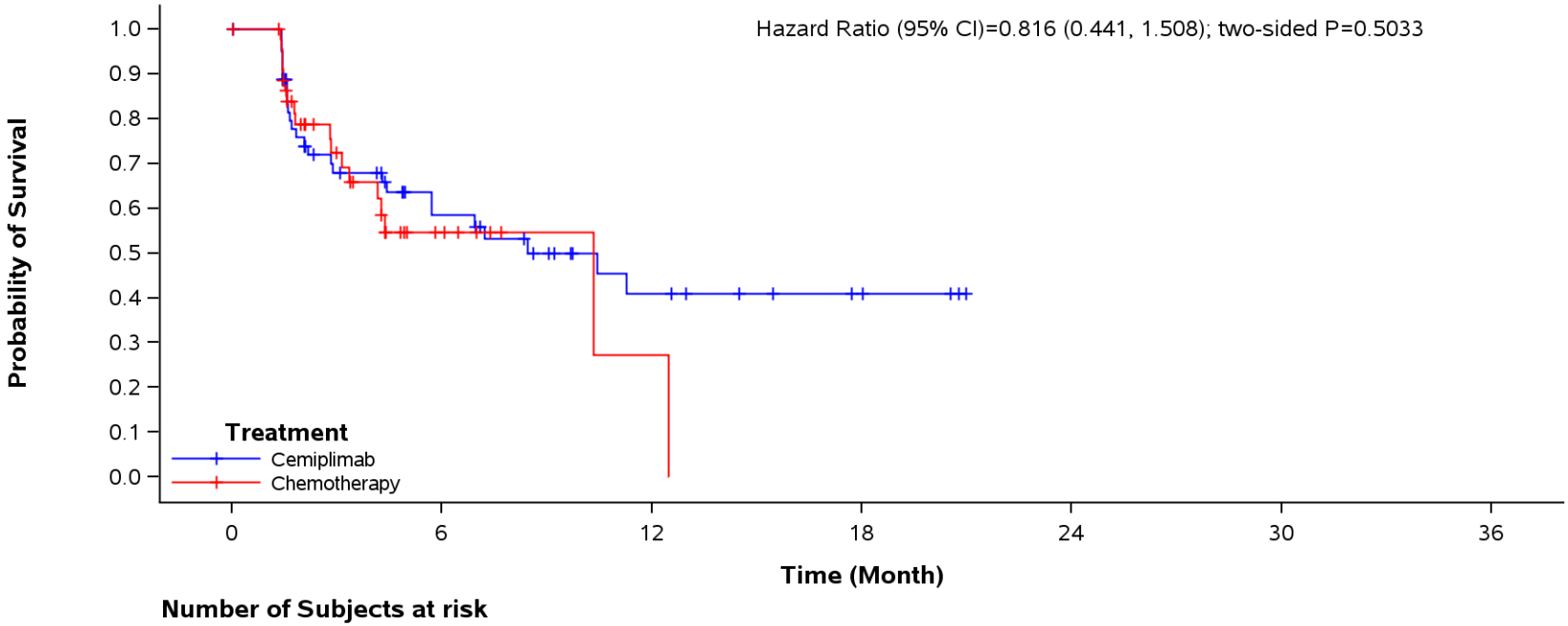

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 24 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts deterioration



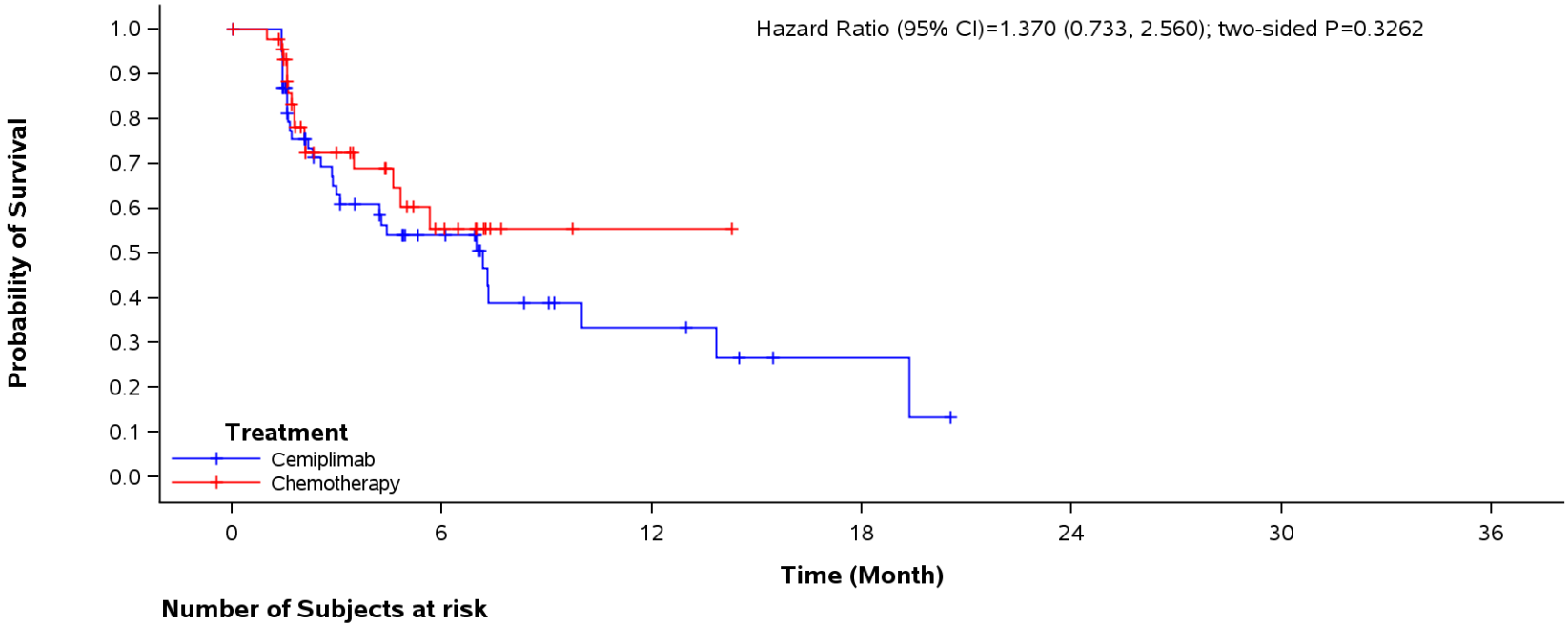

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 23 | 9 | 4 | 0 | 0 | 0 |
| Chemotherapy | 66 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts deterioration



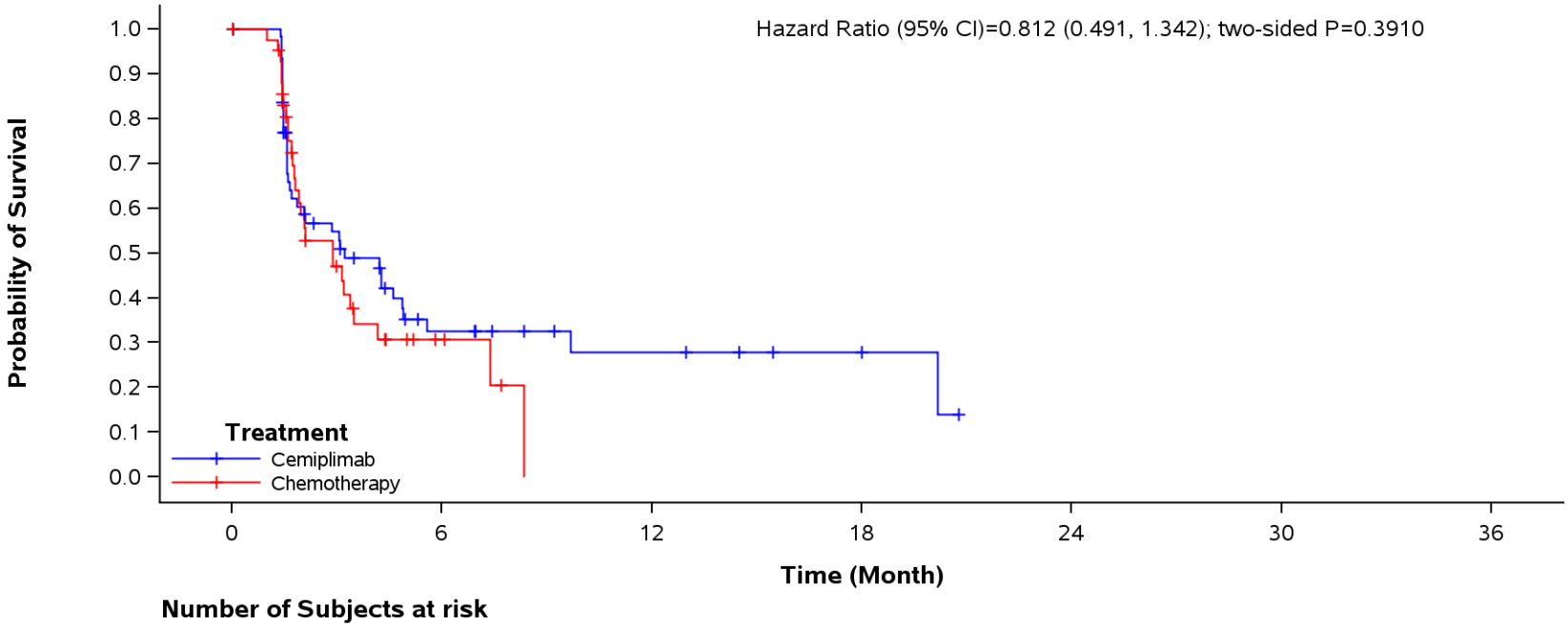

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 19 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts deterioration



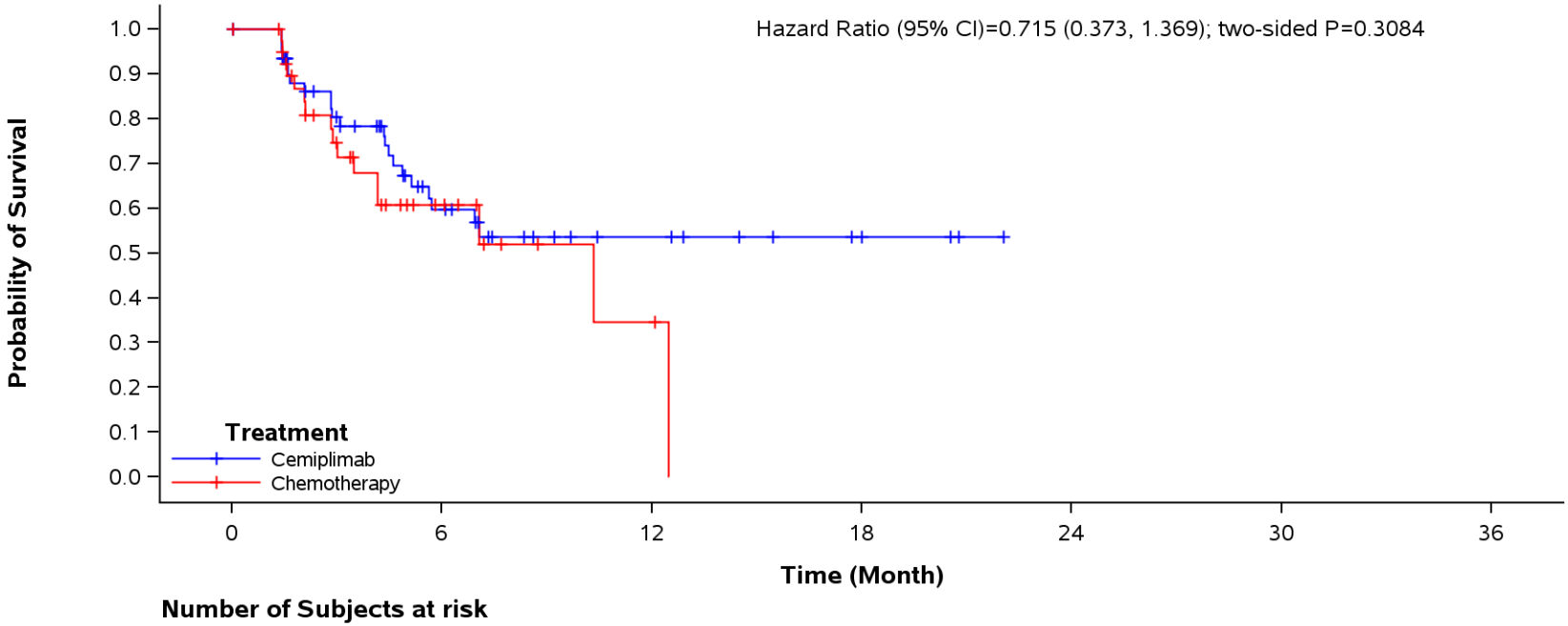

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 12 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts deterioration



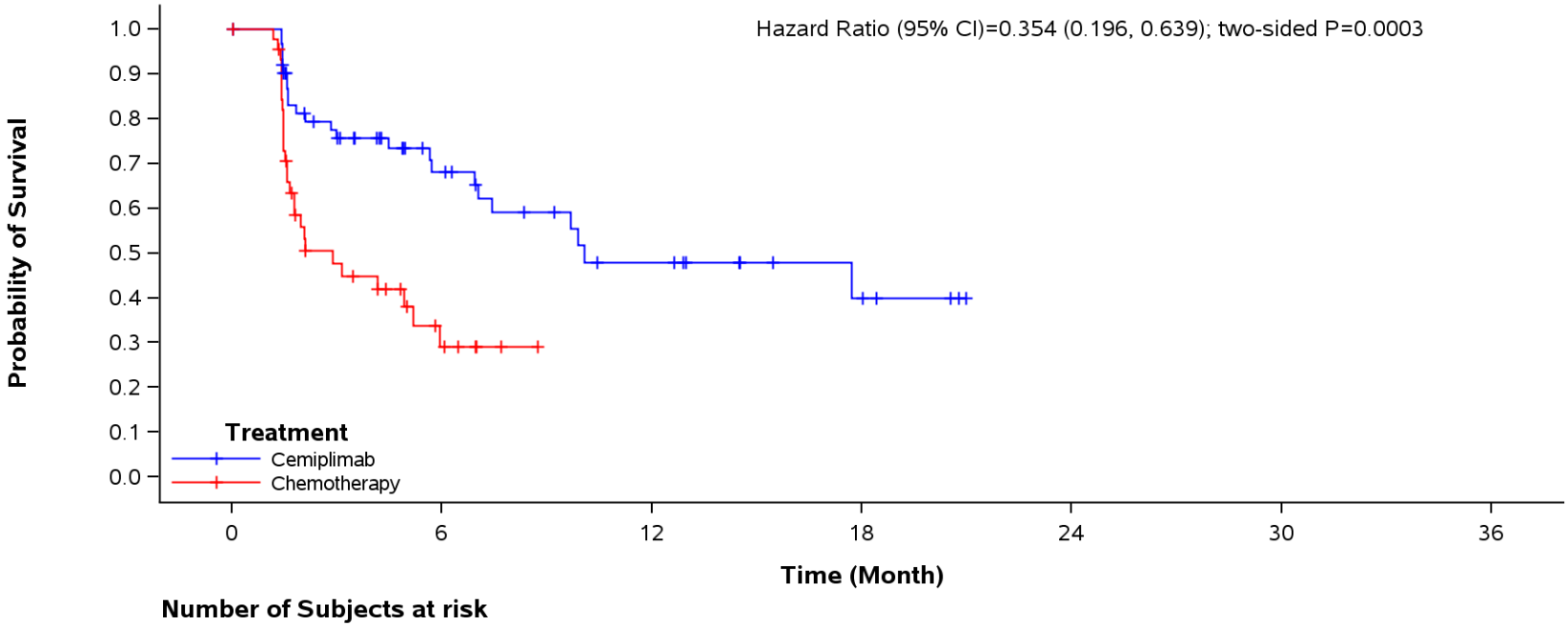

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 23 | 9 | 4 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts deterioration



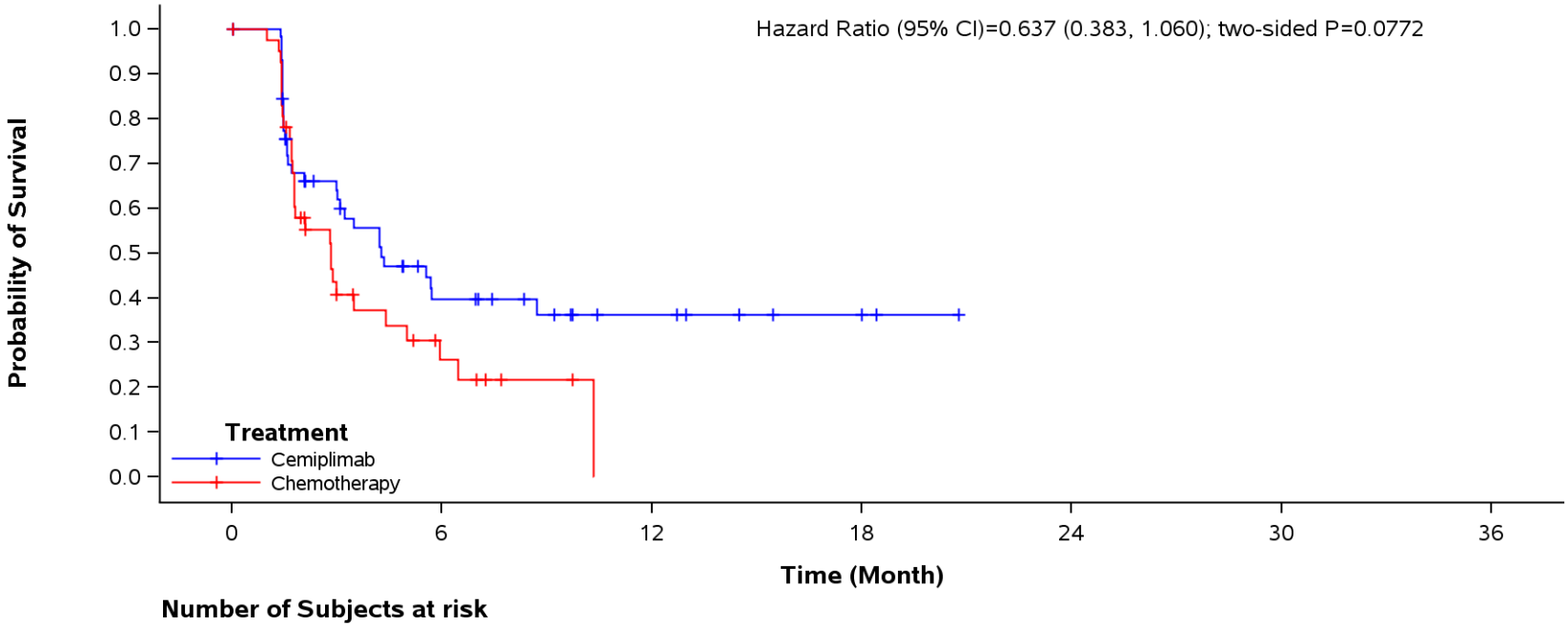

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 26 | 12 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts deterioration




**Number of Subjects at risk**

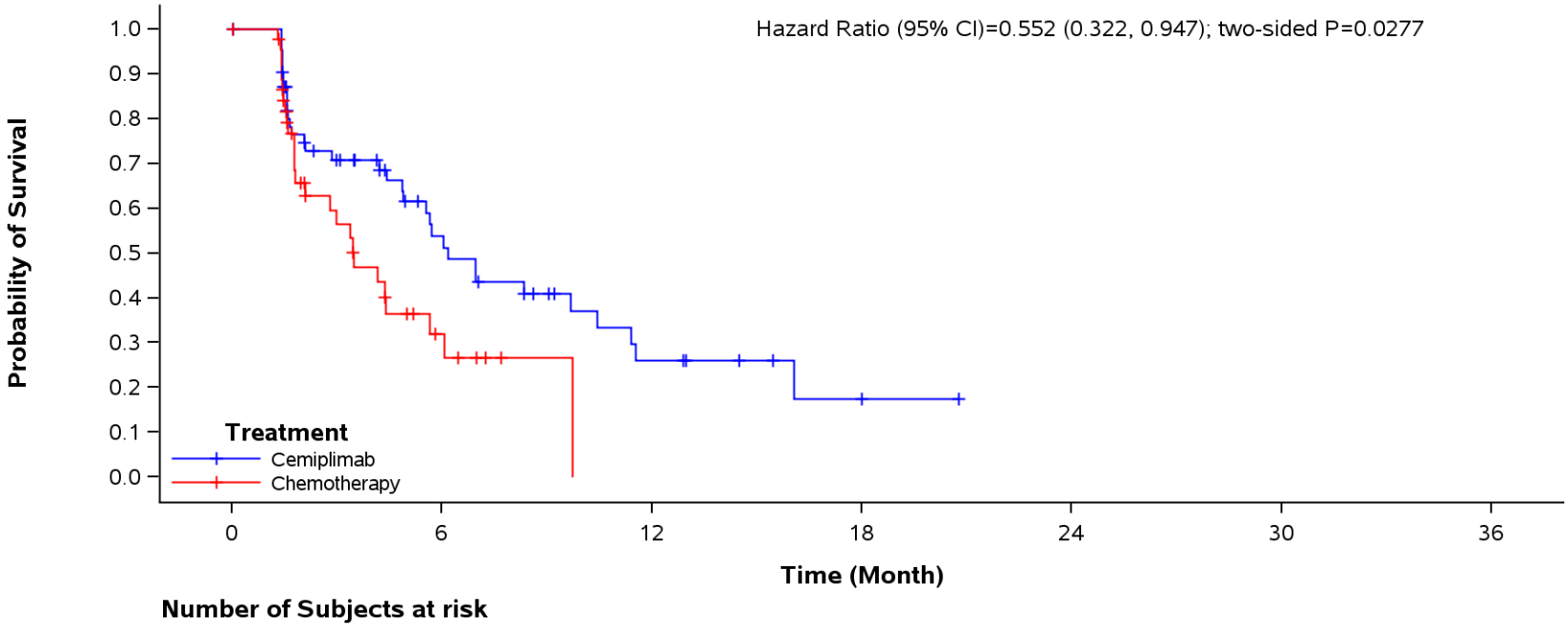
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 16 | 7 | 3 | 0 | 0 | 0 |
| Chemotherapy | 66 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:18:00, yingyuan.lin)

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts deterioration



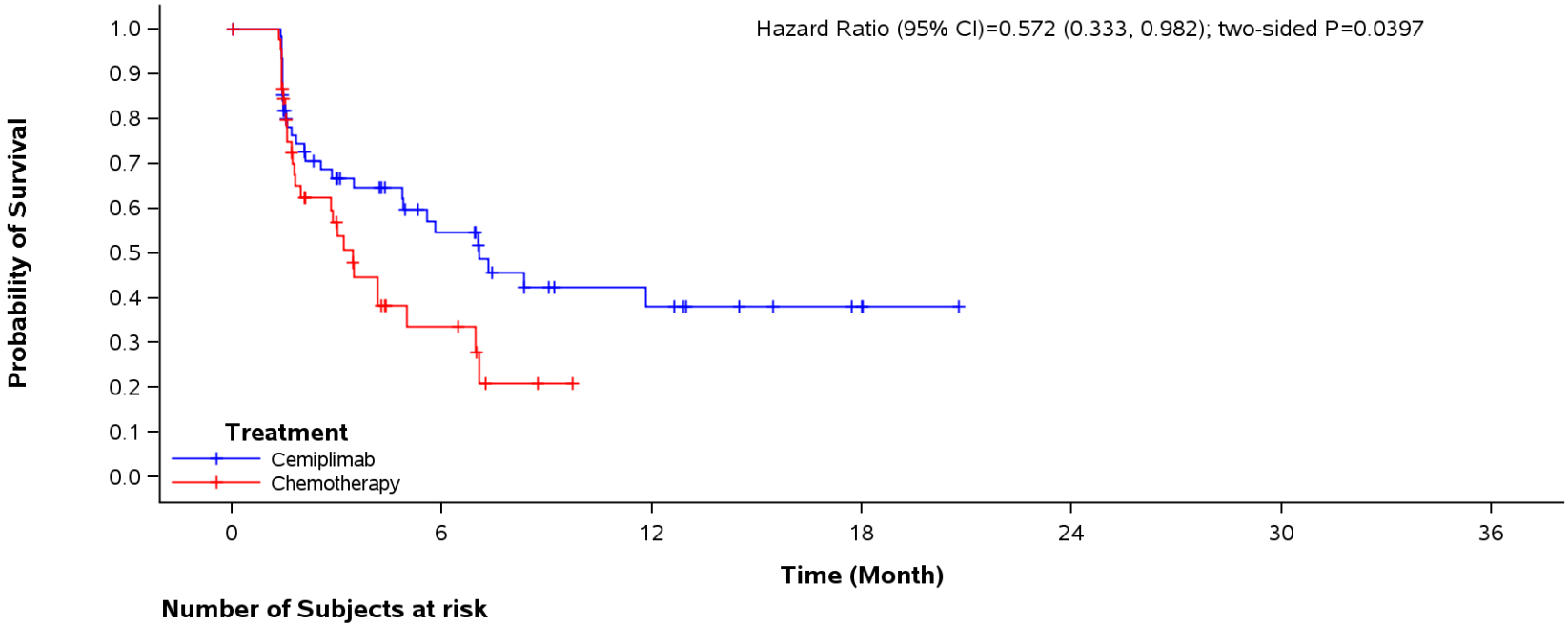

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 21 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts deterioration



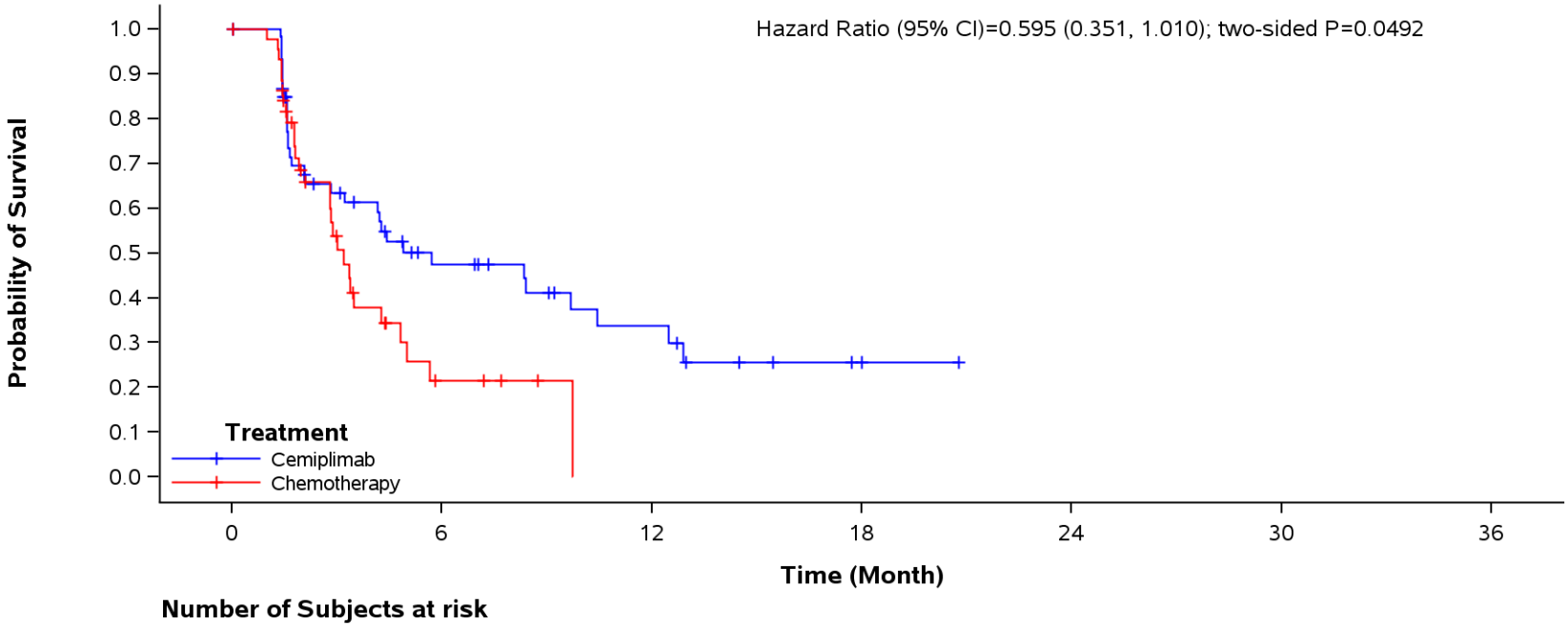

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 21 | 9 | 3 | 0 | 0 | 0 |
| Chemotherapy | 66 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts deterioration



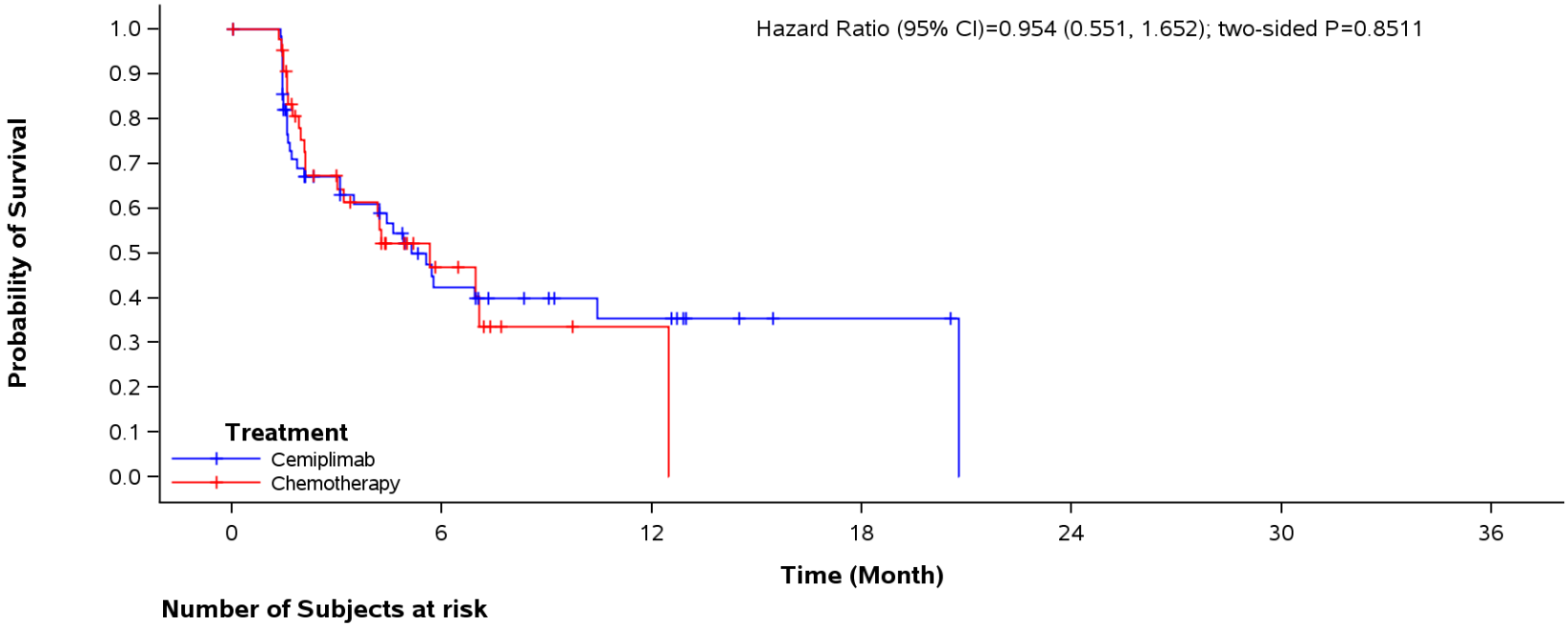

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 18 | 9 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts deterioration



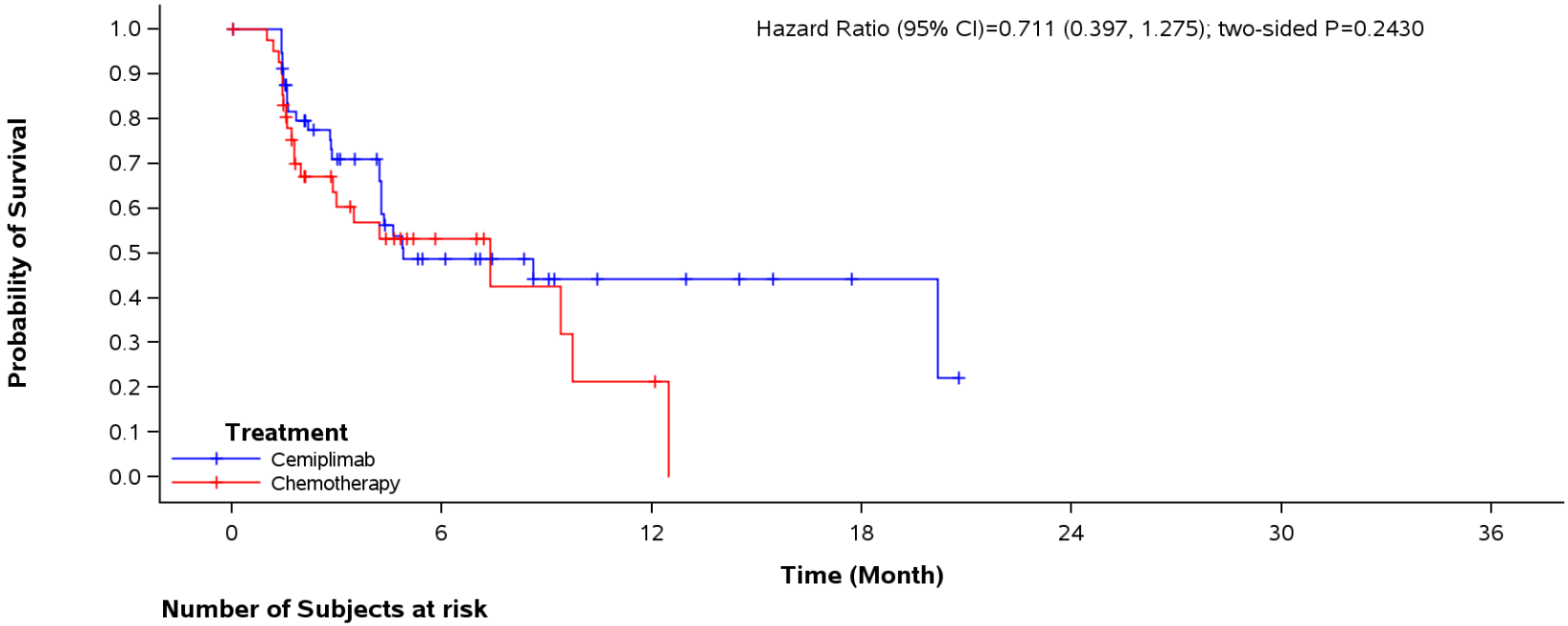

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 17 | 8 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts deterioration



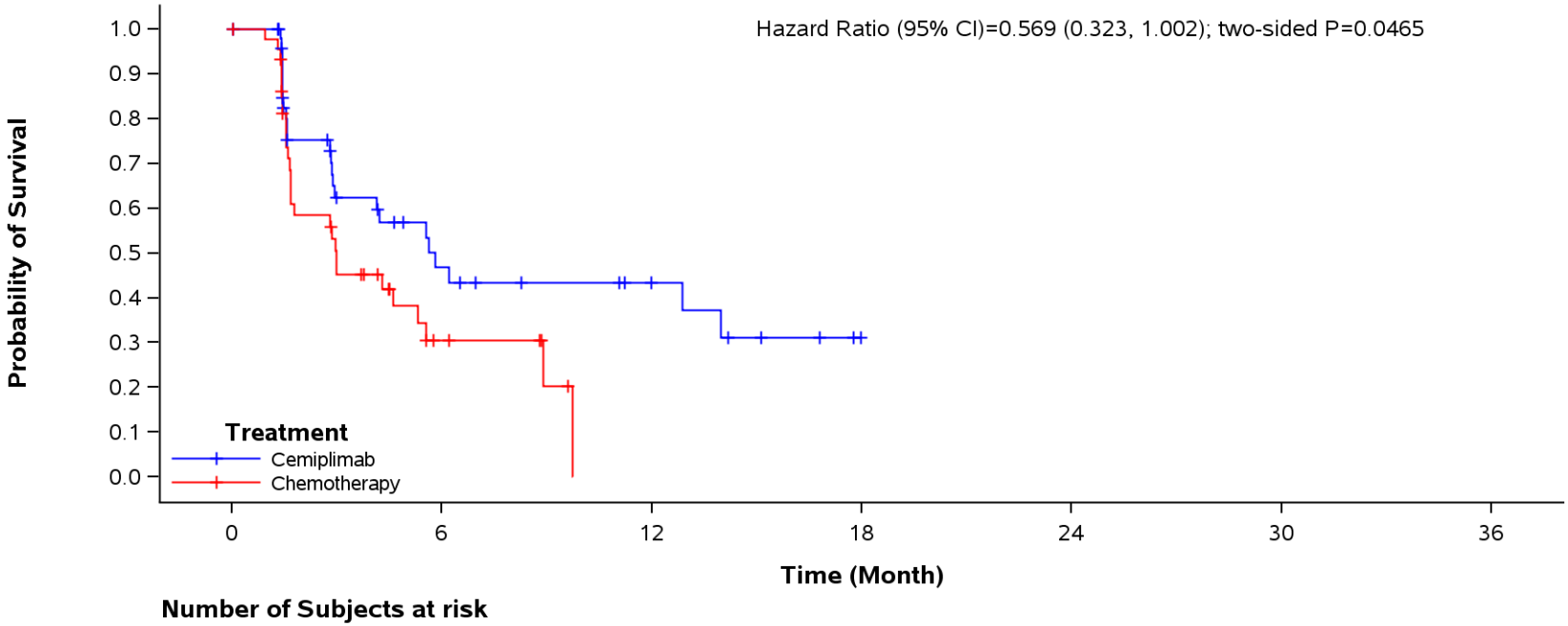

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 17 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 7 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts deterioration



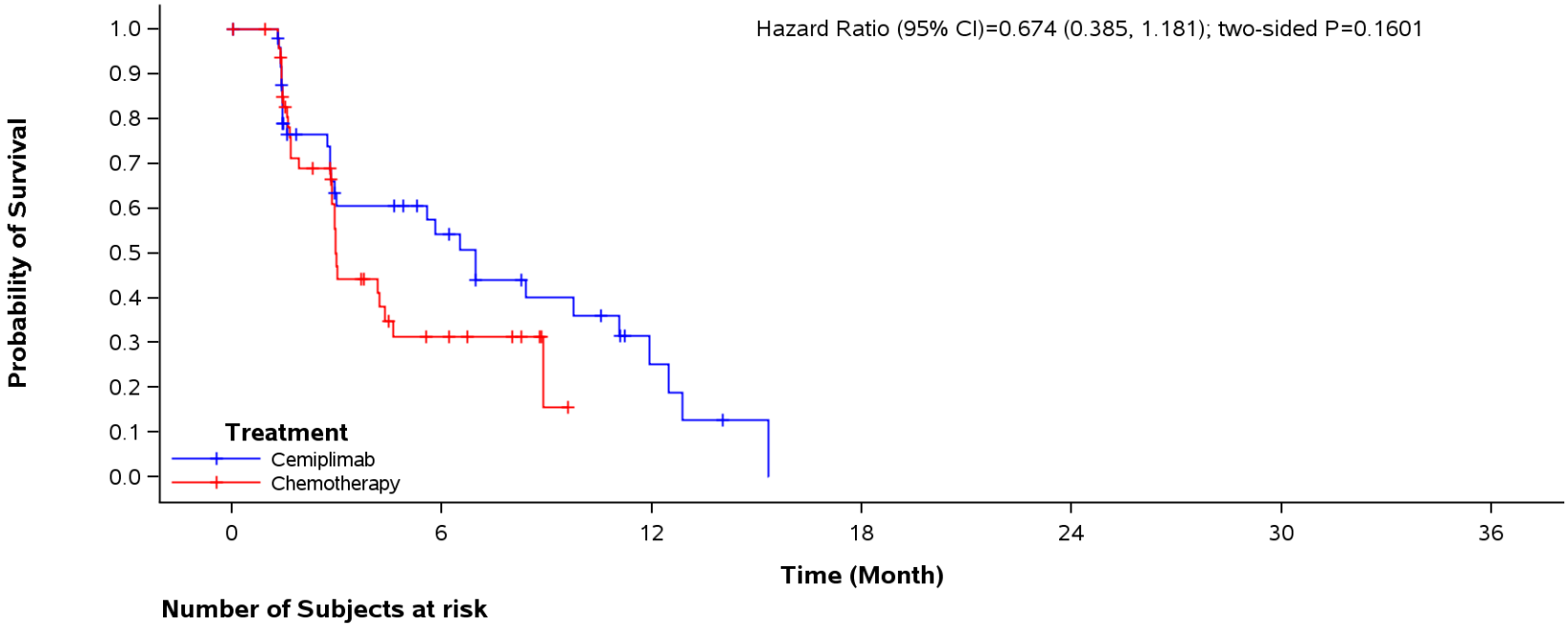

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 14 | 7 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts deterioration



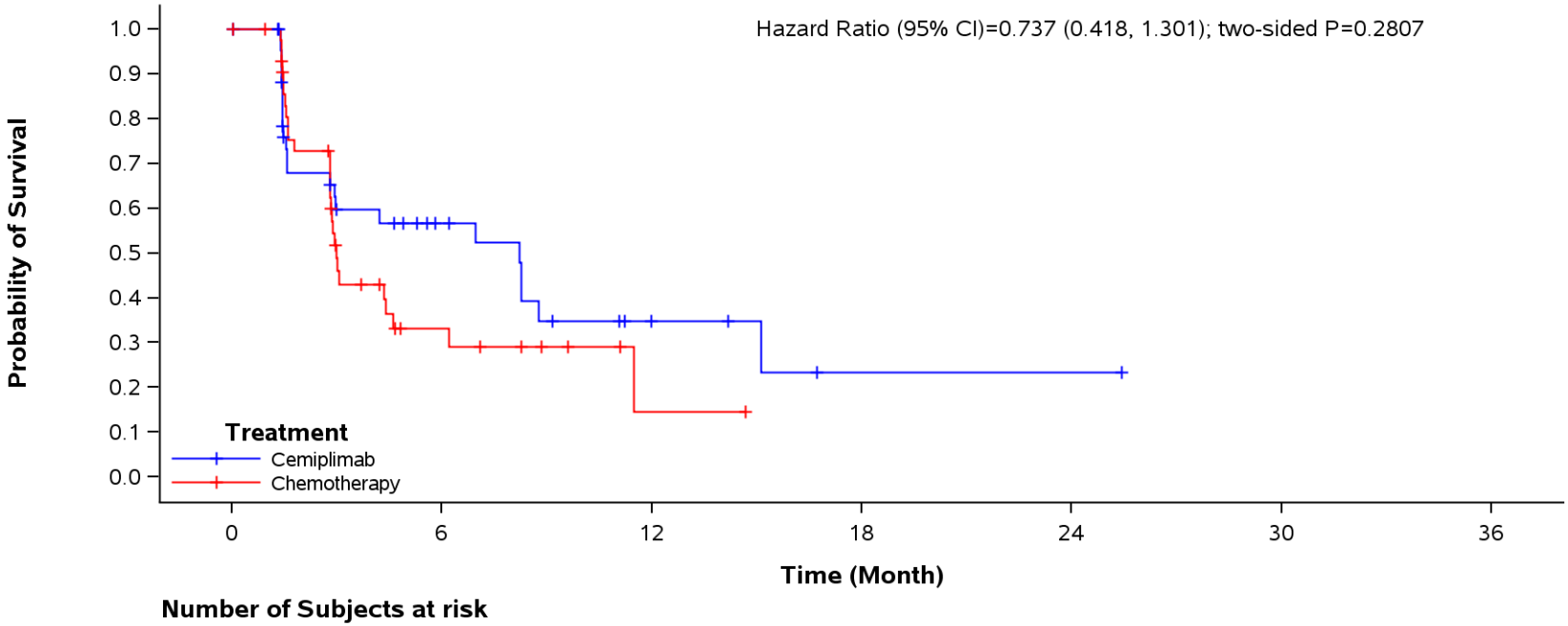

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 17 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts deterioration



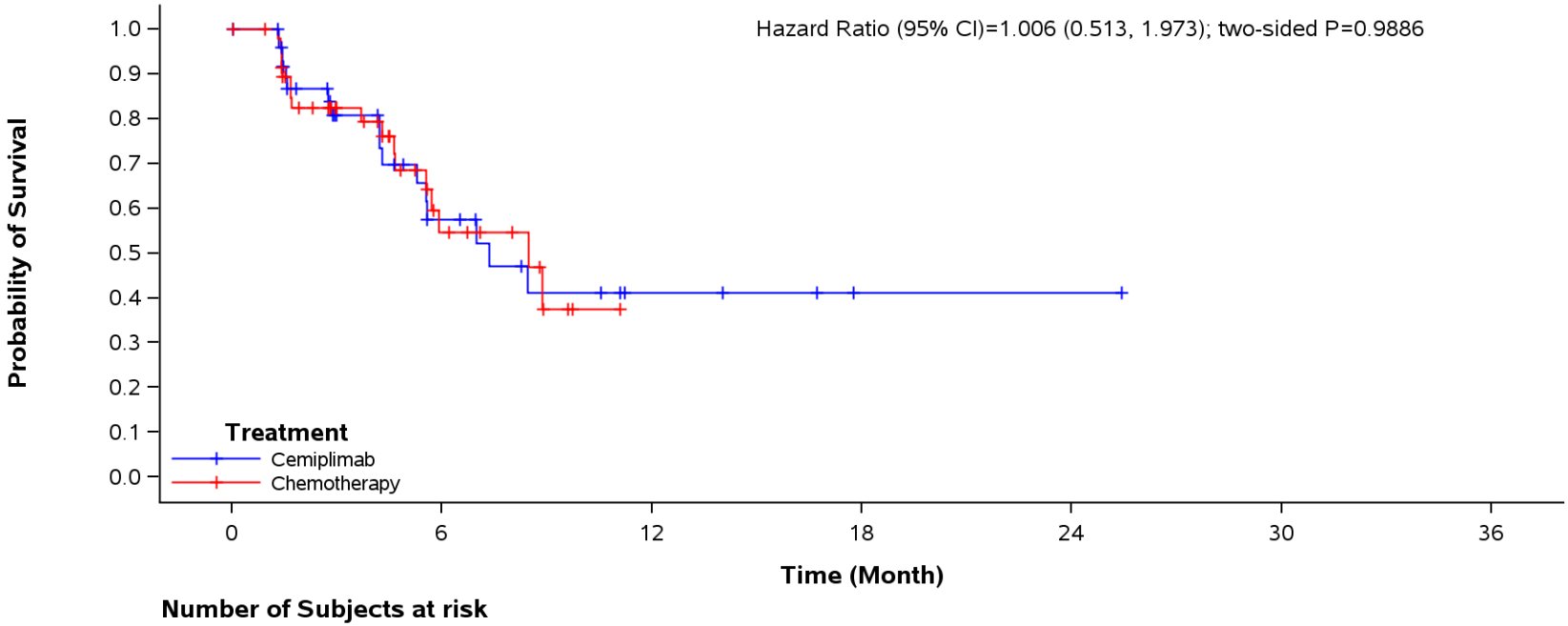

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 14 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts deterioration



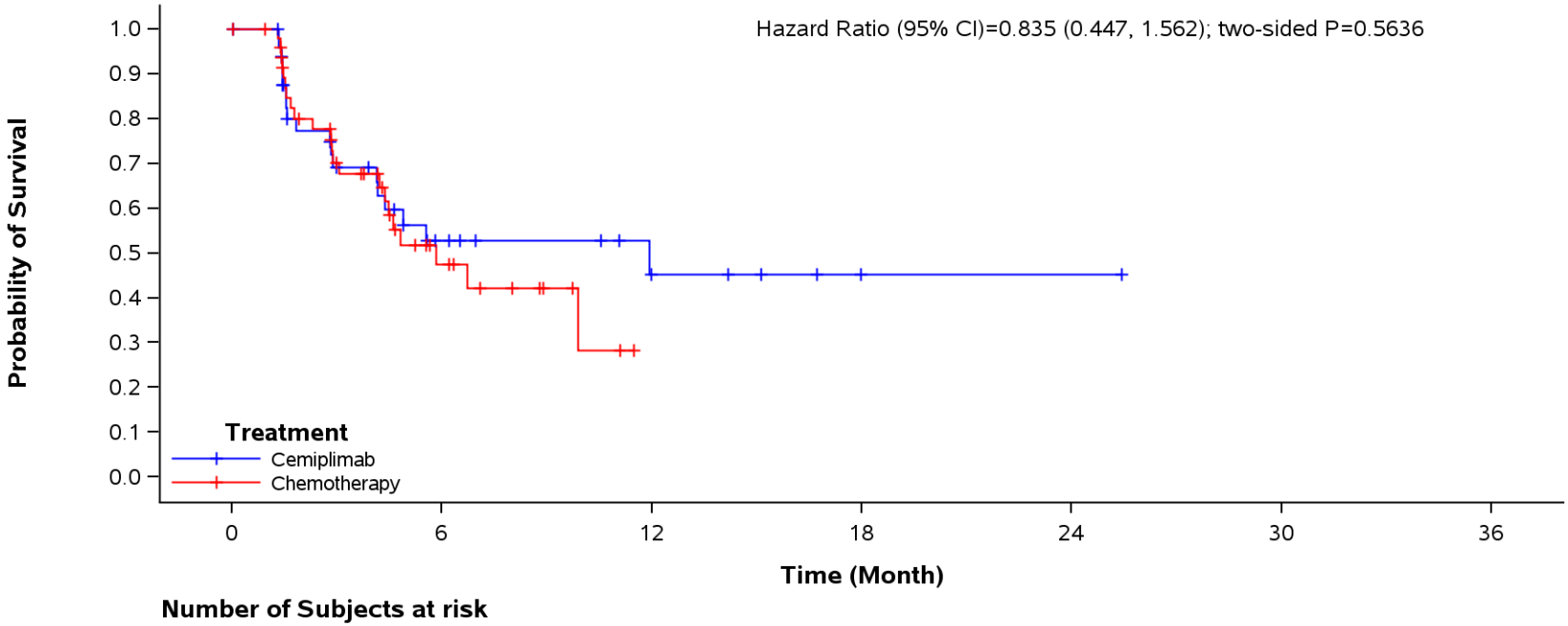

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 13 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts deterioration



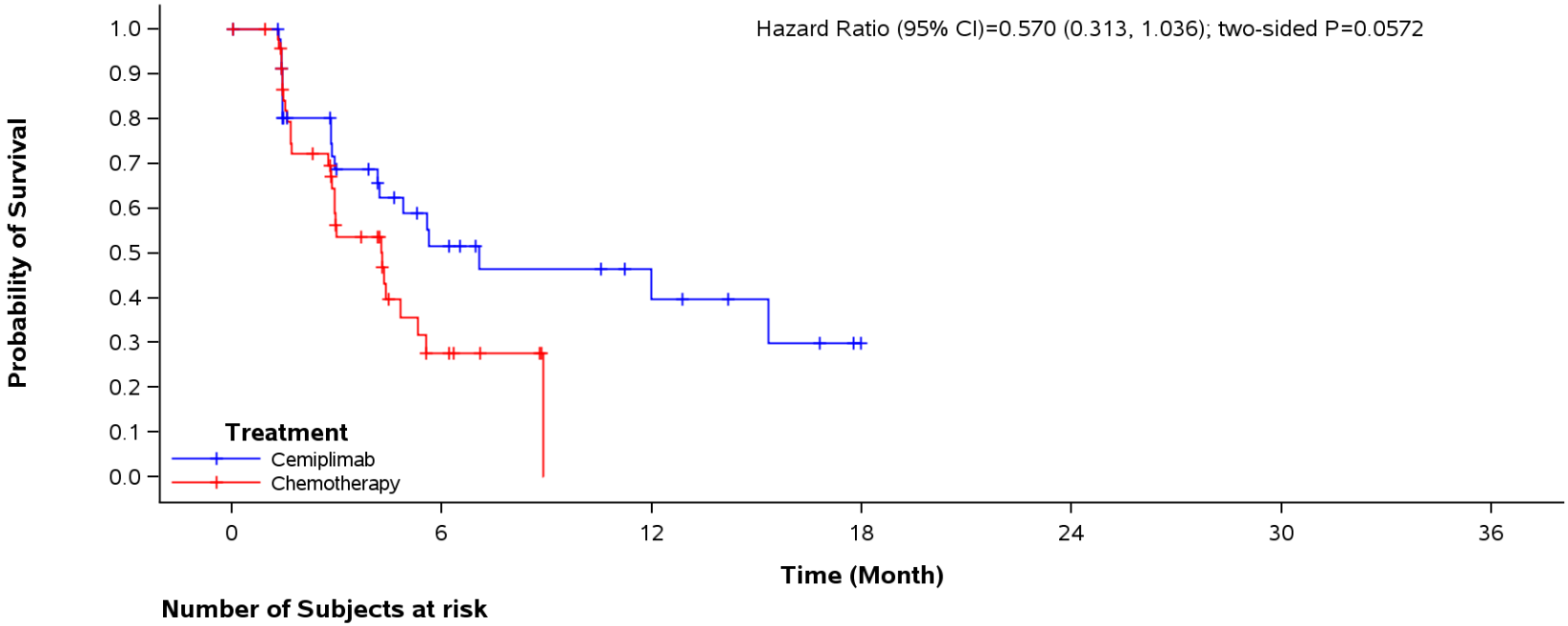

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts deterioration



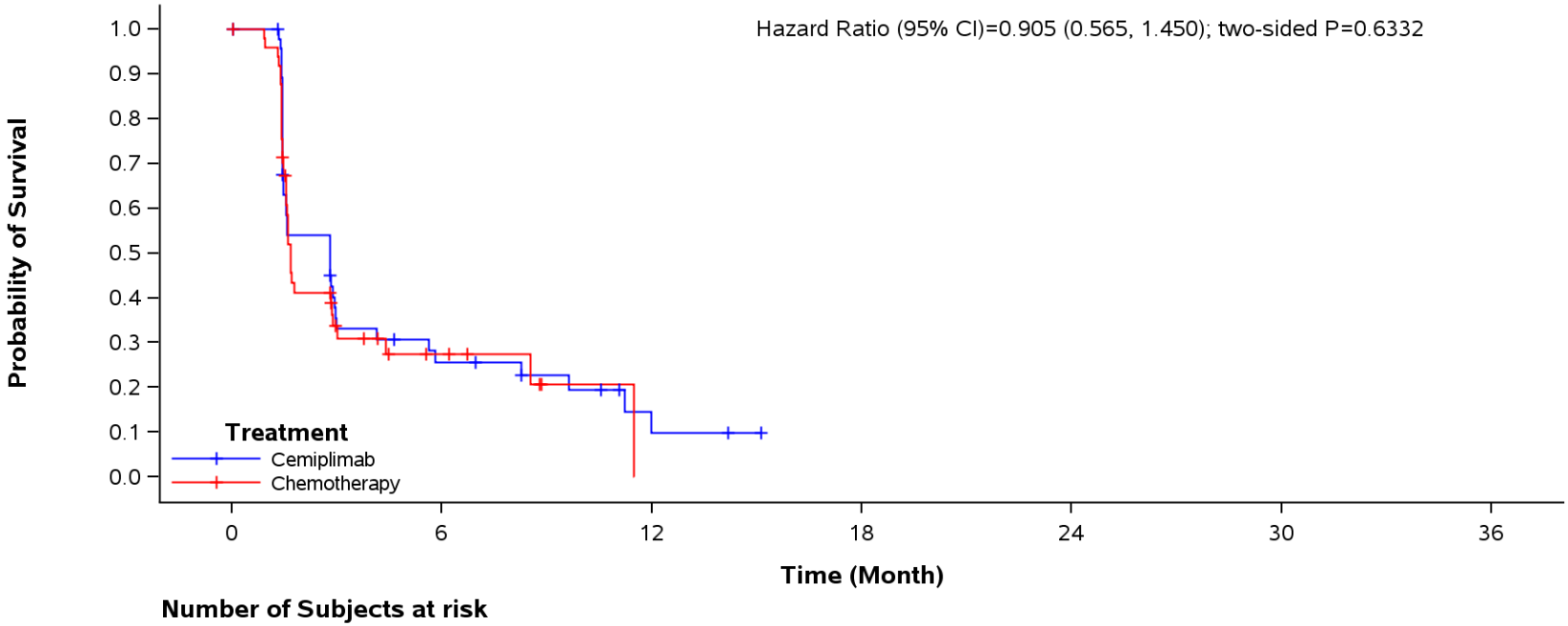

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 14 | 6 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts deterioration



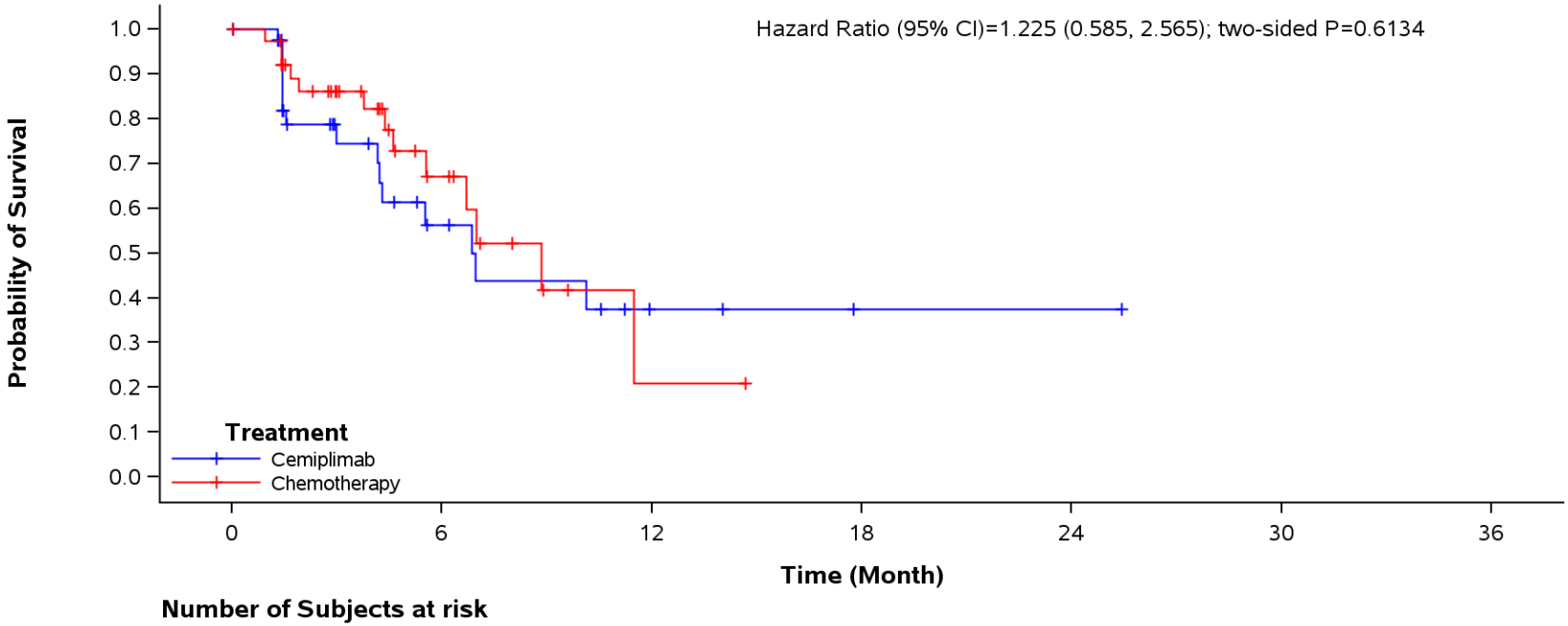

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 10 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts deterioration



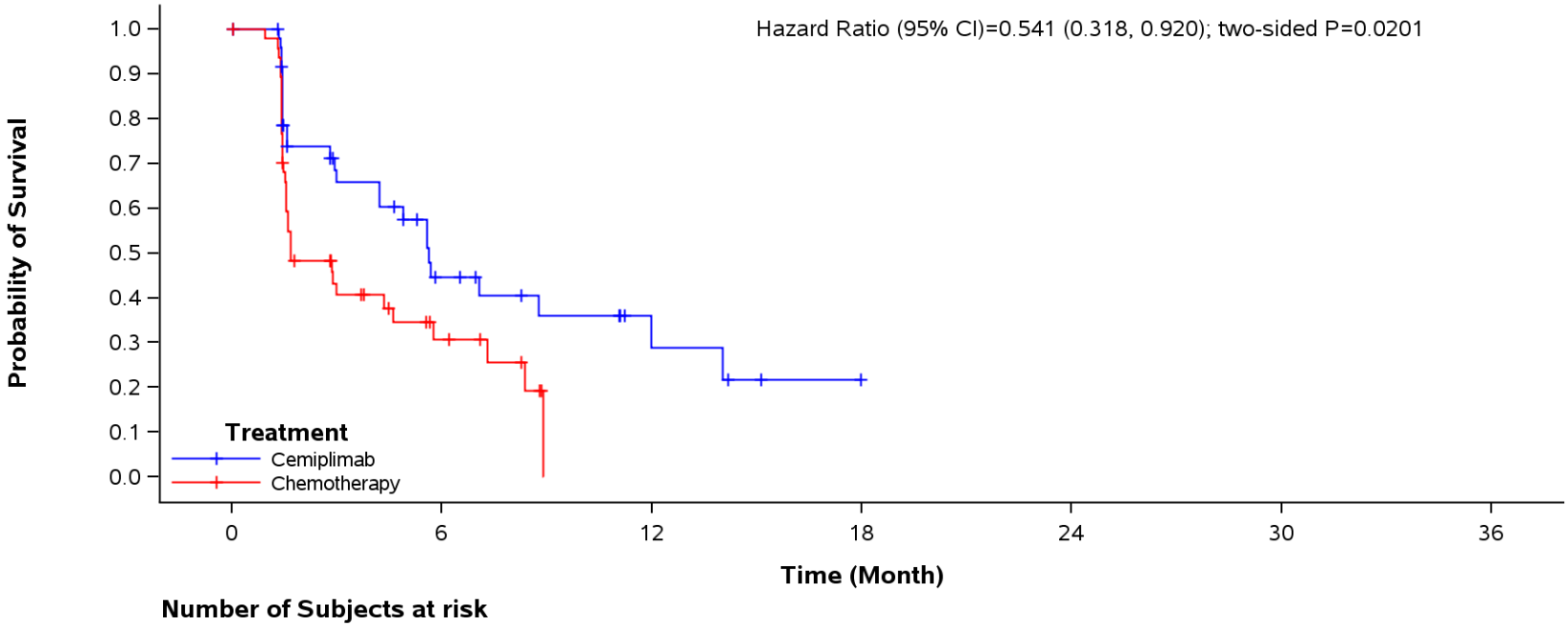

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 10 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts deterioration



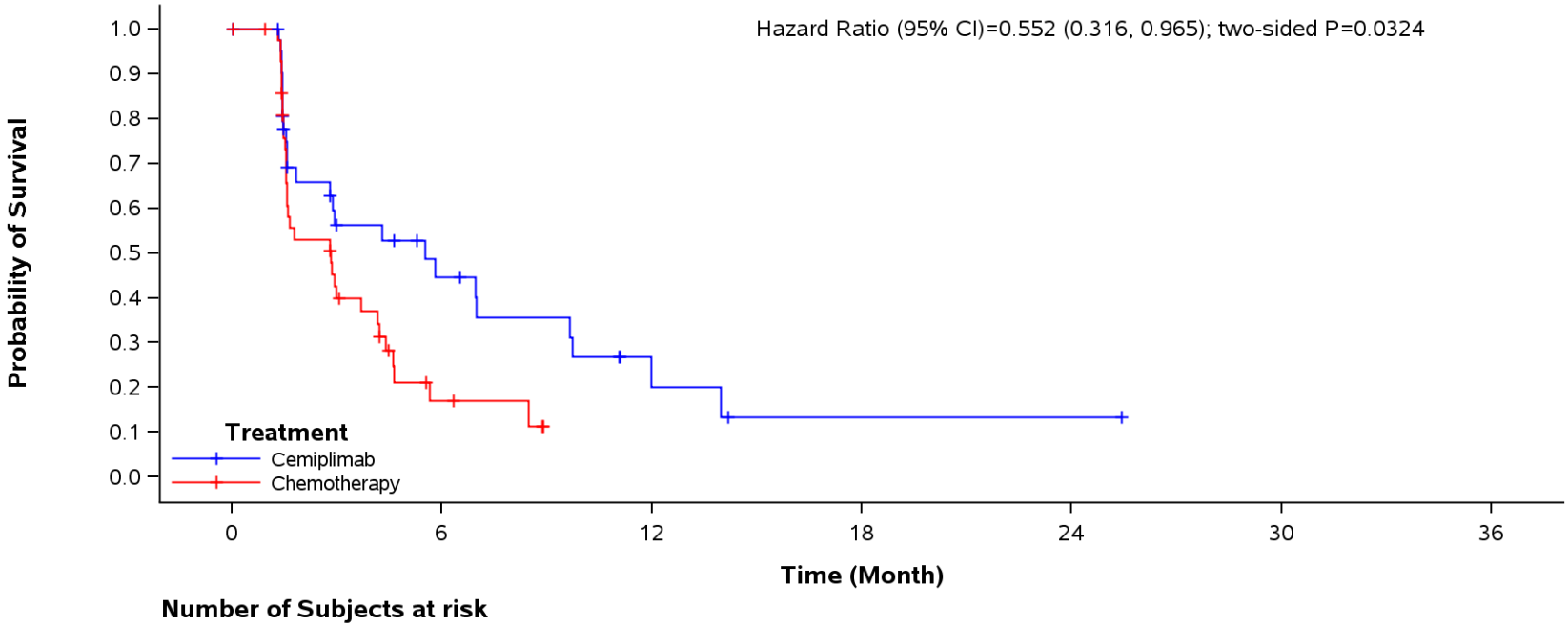

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 13 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts deterioration



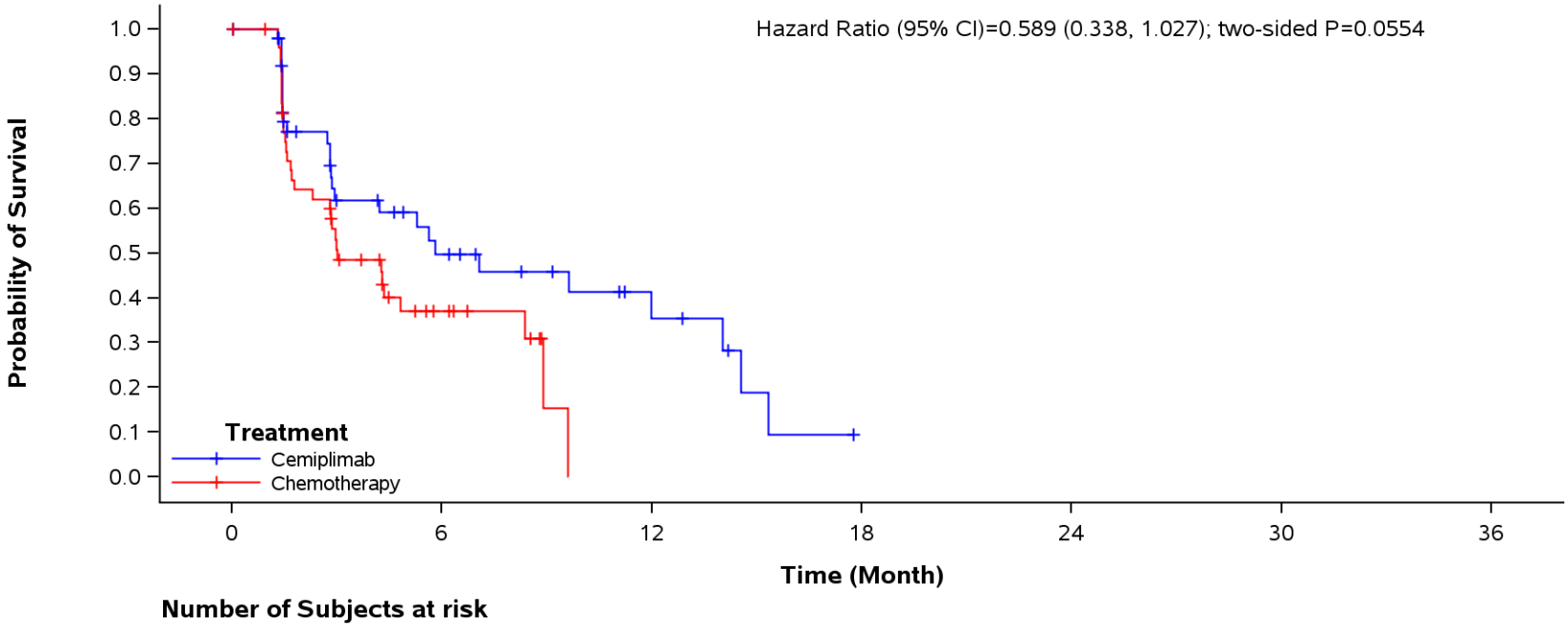

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 11 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts deterioration



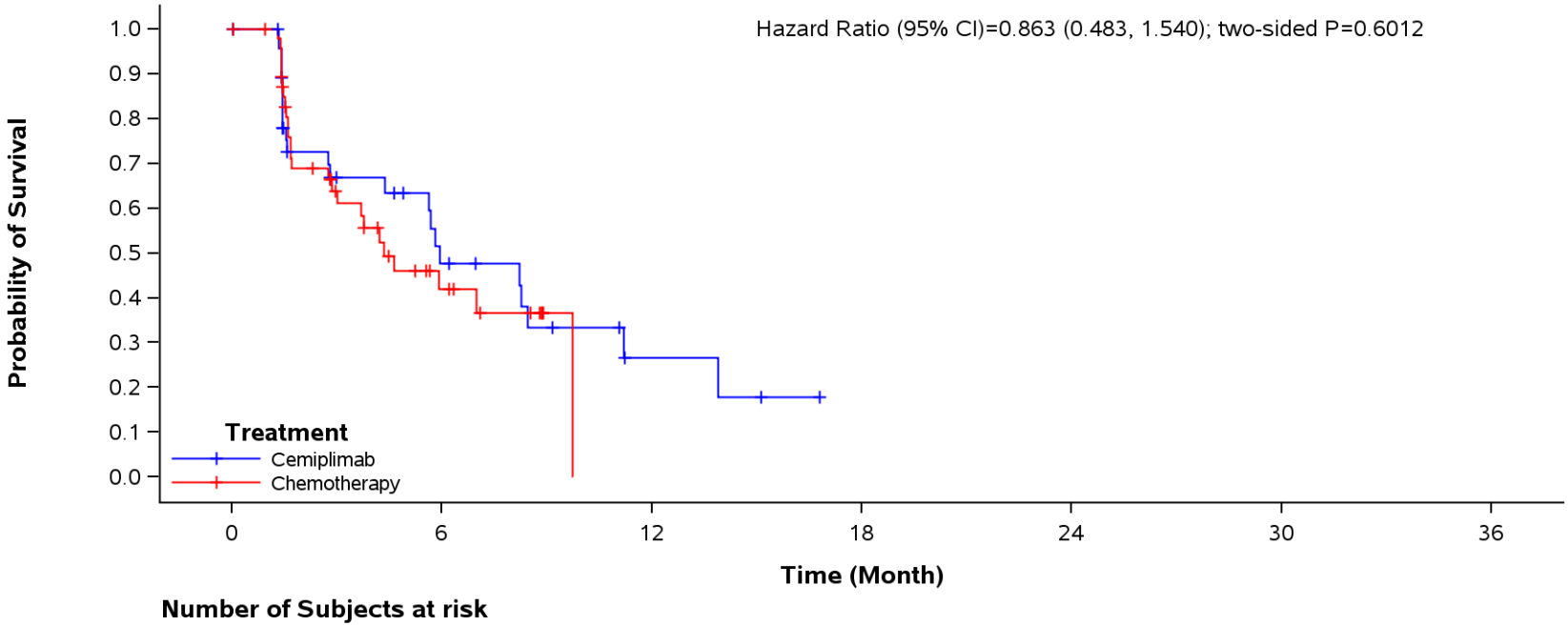

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 16 | 6 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts deterioration



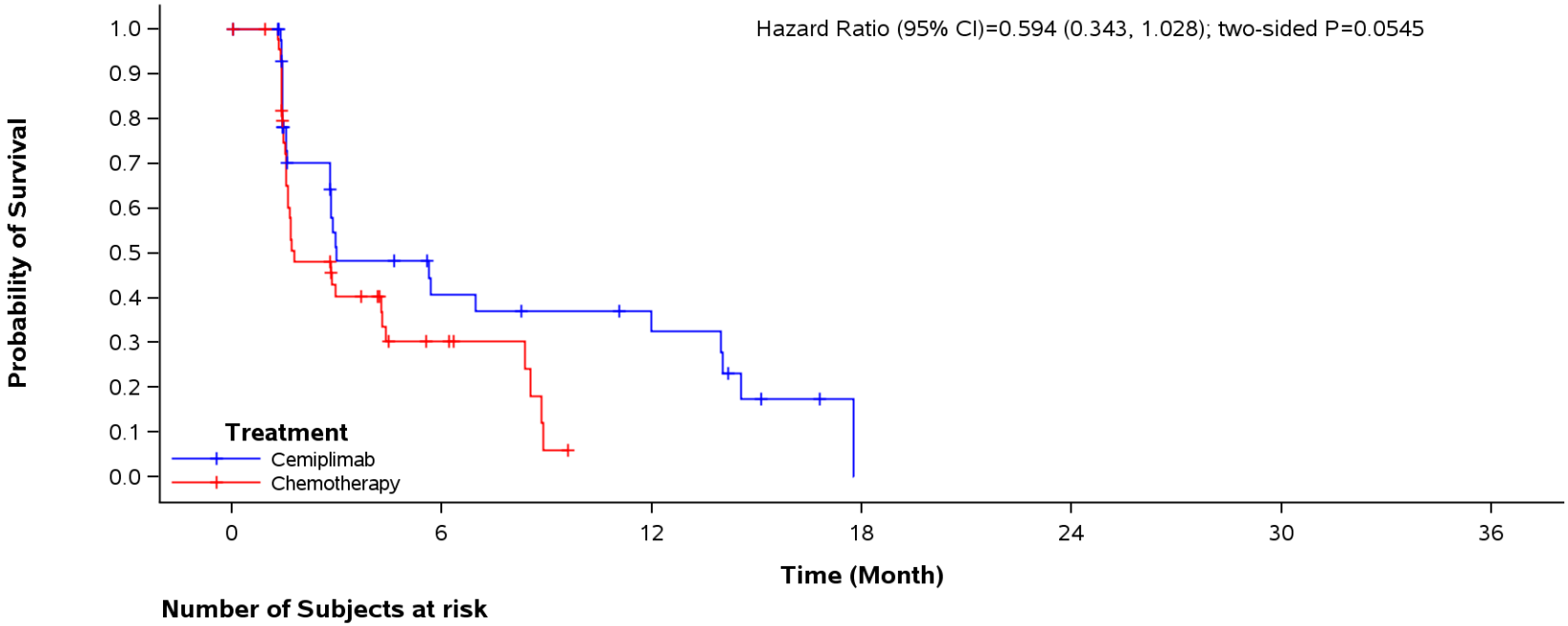

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 12 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts deterioration



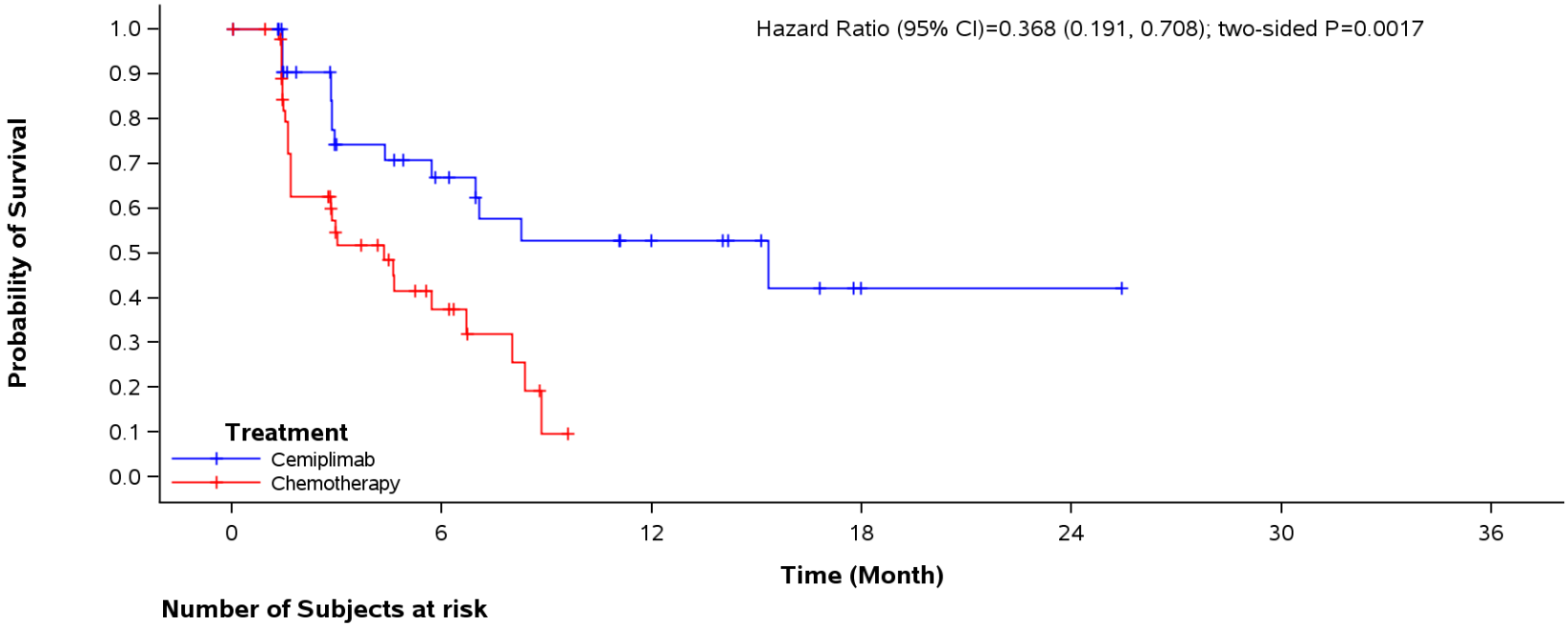

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 11 | 7 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts deterioration



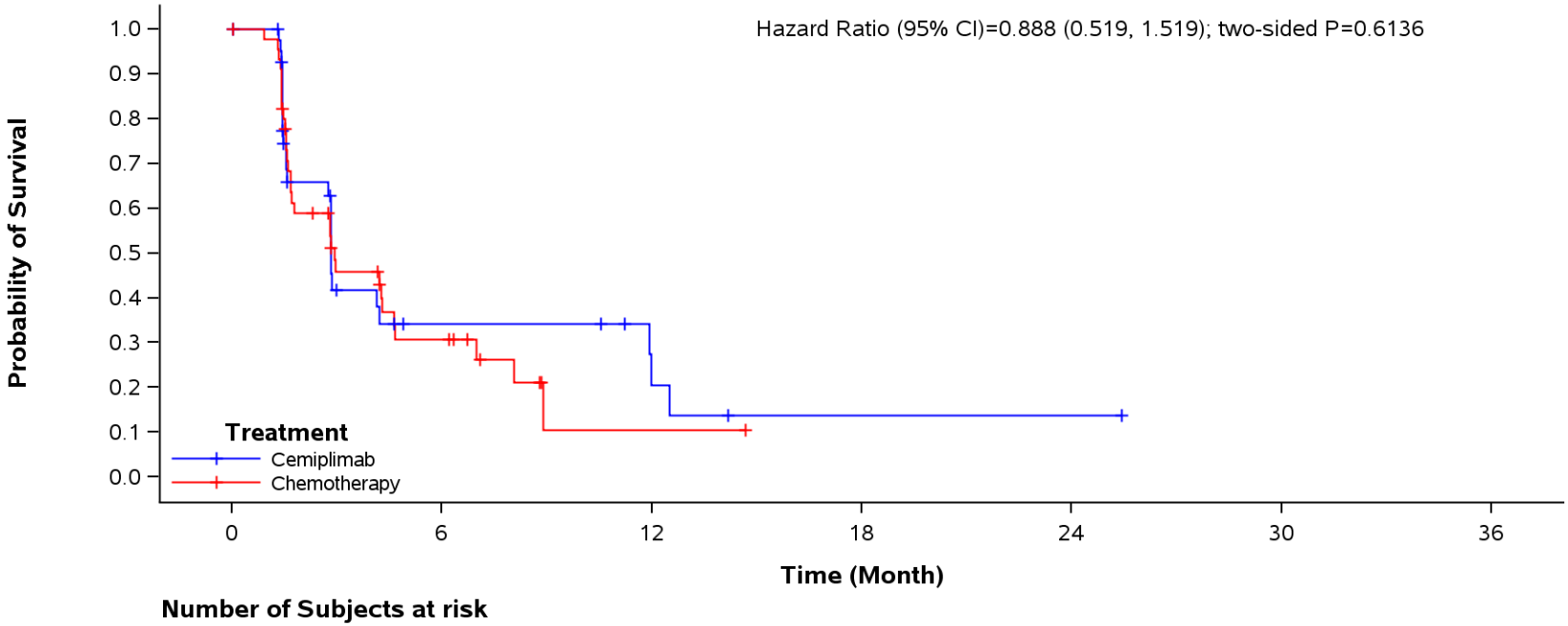

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 16 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts deterioration



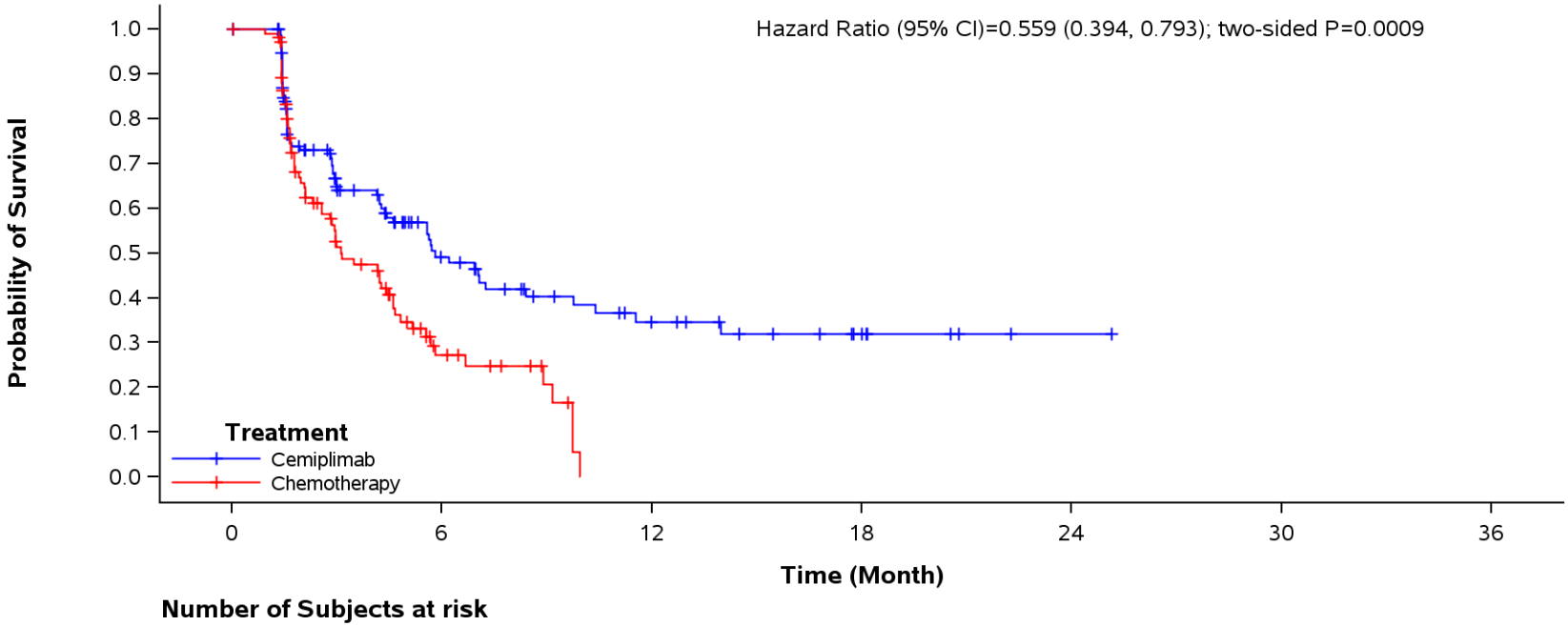

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 7 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts deterioration



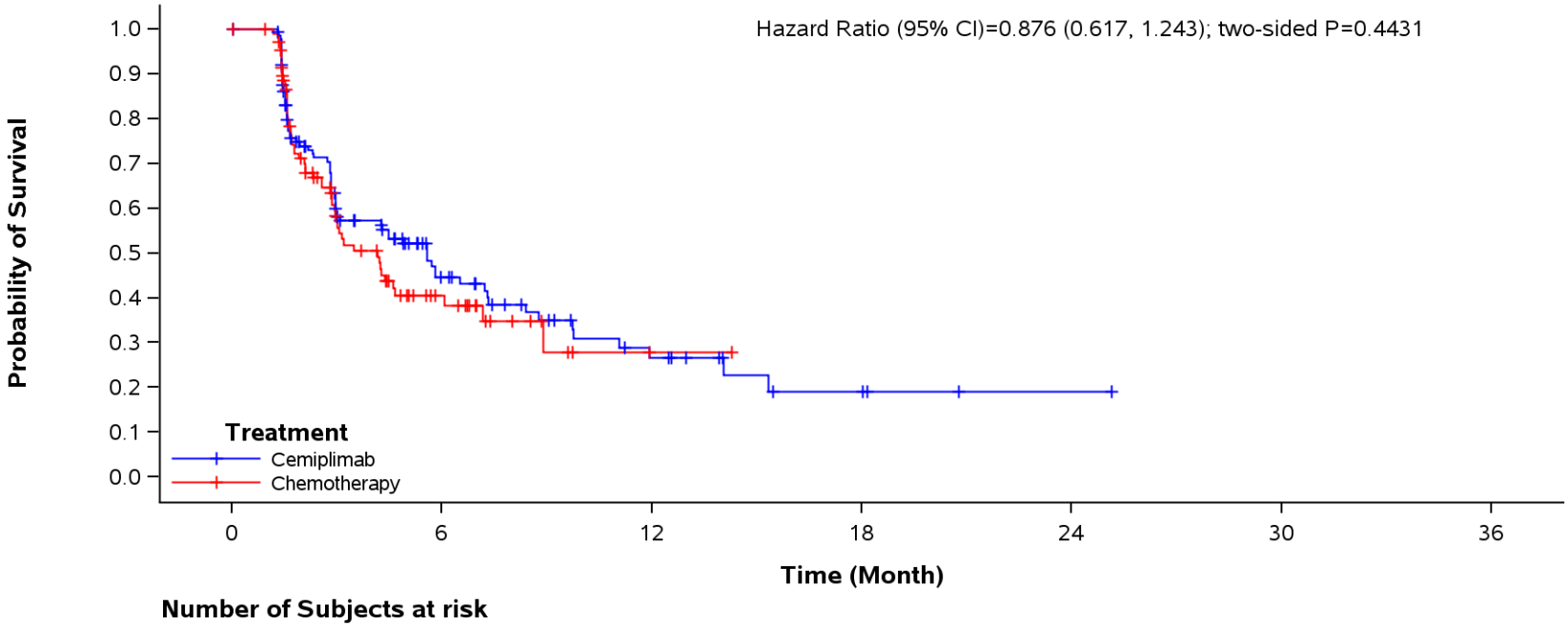

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 37 | 16 | 7 | 1 | 0 | 0 |
| Chemotherapy | 137 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts deterioration



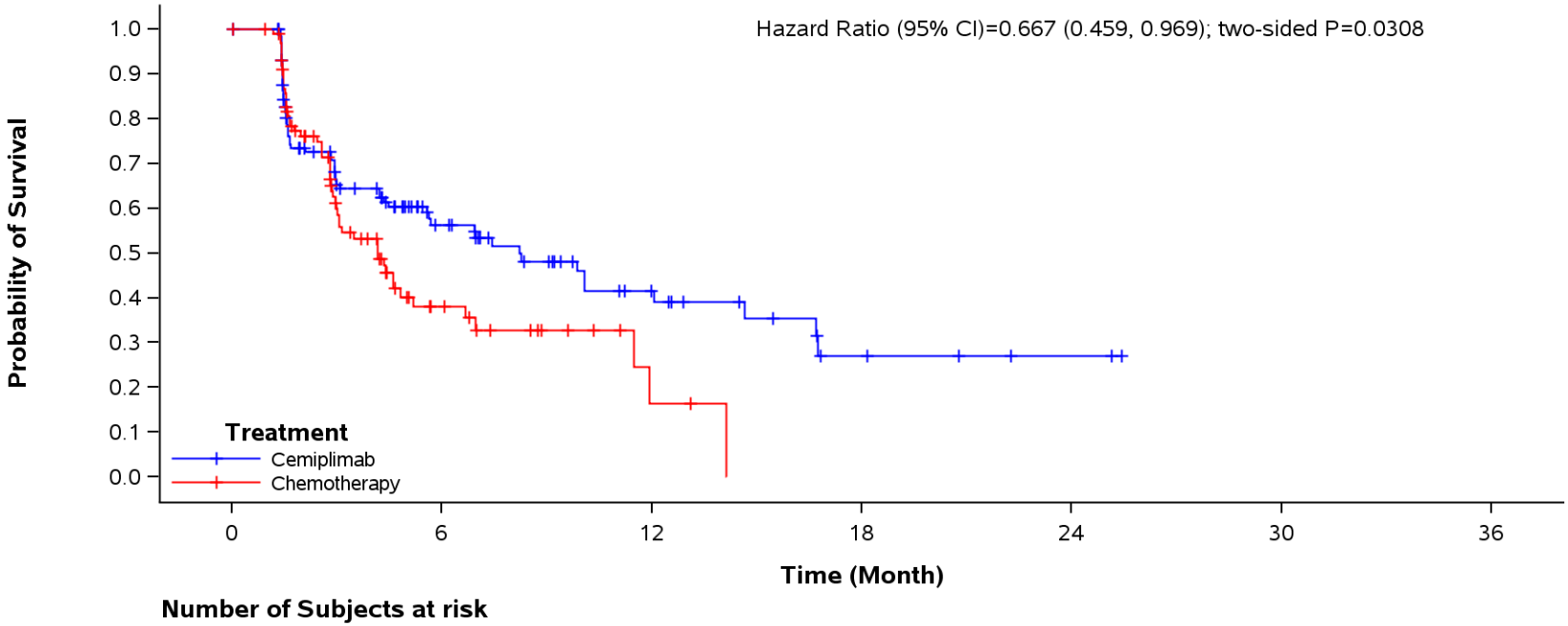

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 34 | 12 | 4 | 1 | 0 | 0 |
| Chemotherapy | 137 | 18 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts deterioration



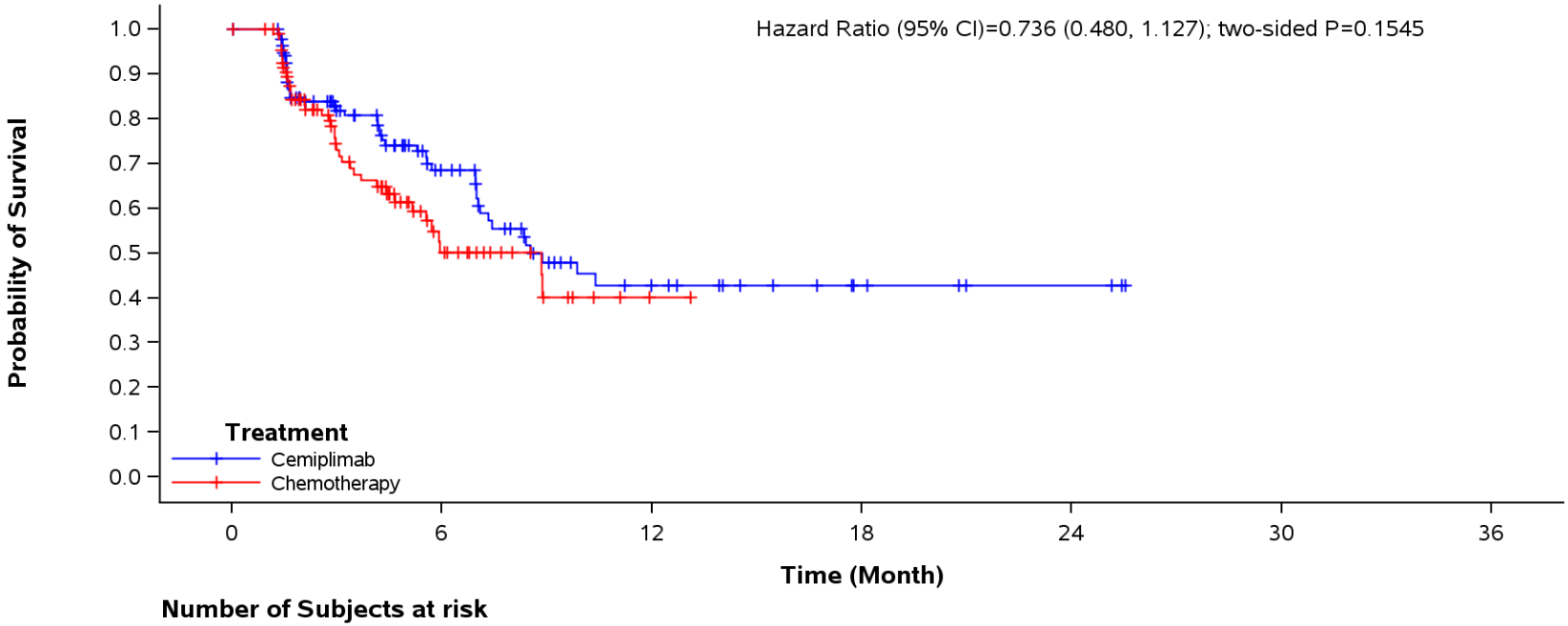

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 40 | 16 | 5 | 2 | 0 | 0 |
| Chemotherapy | 137 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts deterioration



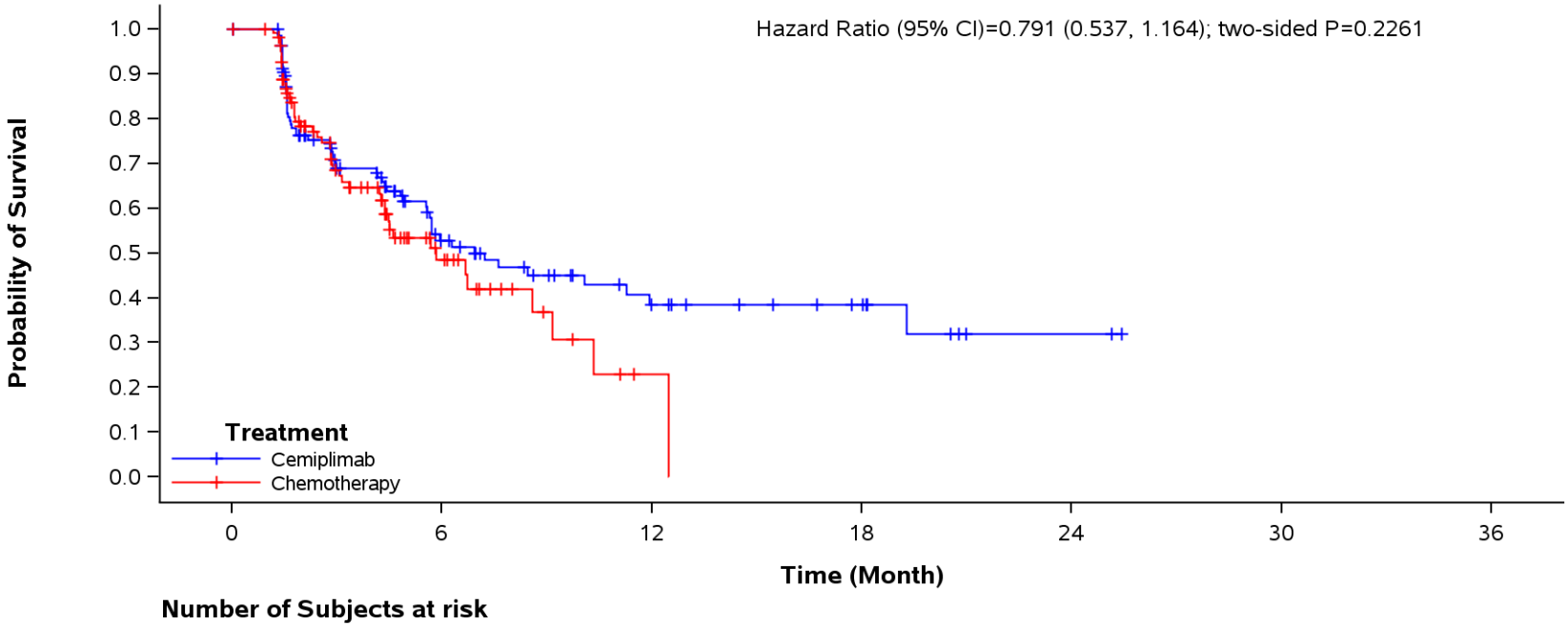

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 47 | 15 | 6 | 3 | 0 | 0 |
| Chemotherapy | 137 | 21 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts deterioration



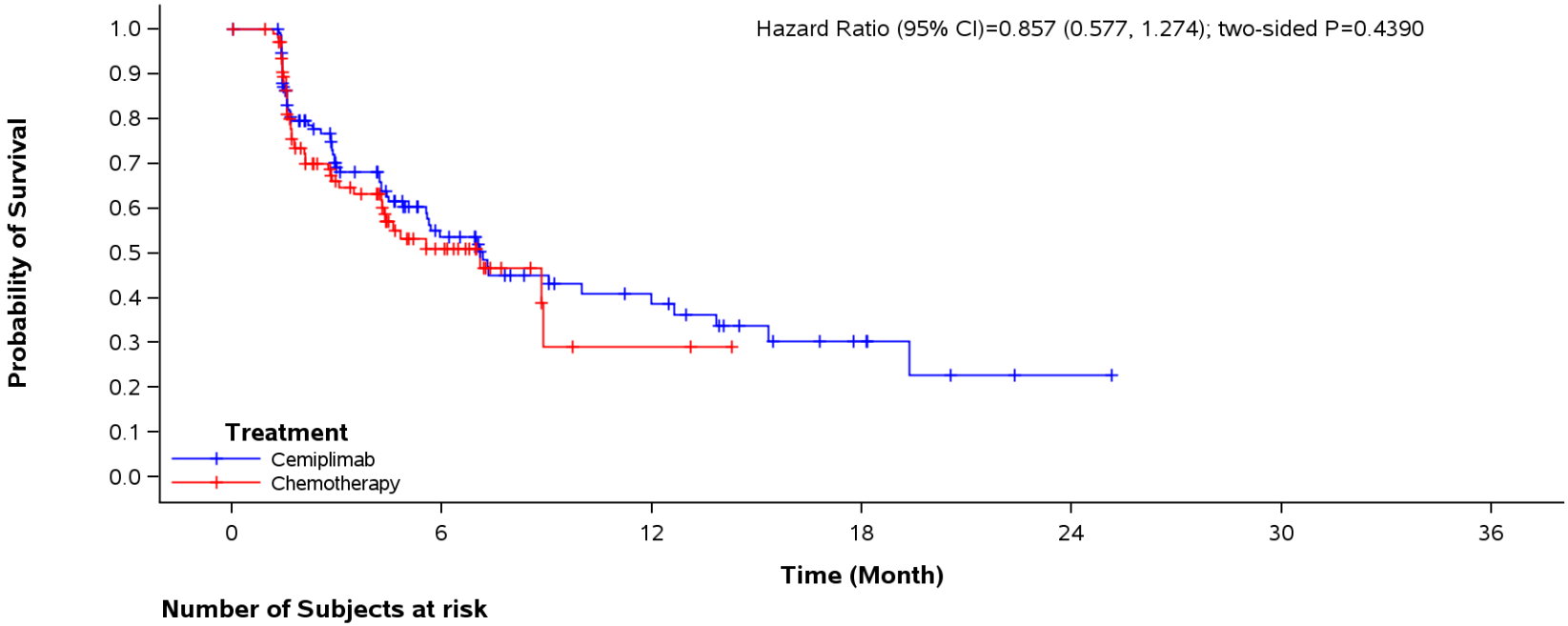

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 39 | 16 | 9 | 2 | 0 | 0 |
| Chemotherapy | 137 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts deterioration



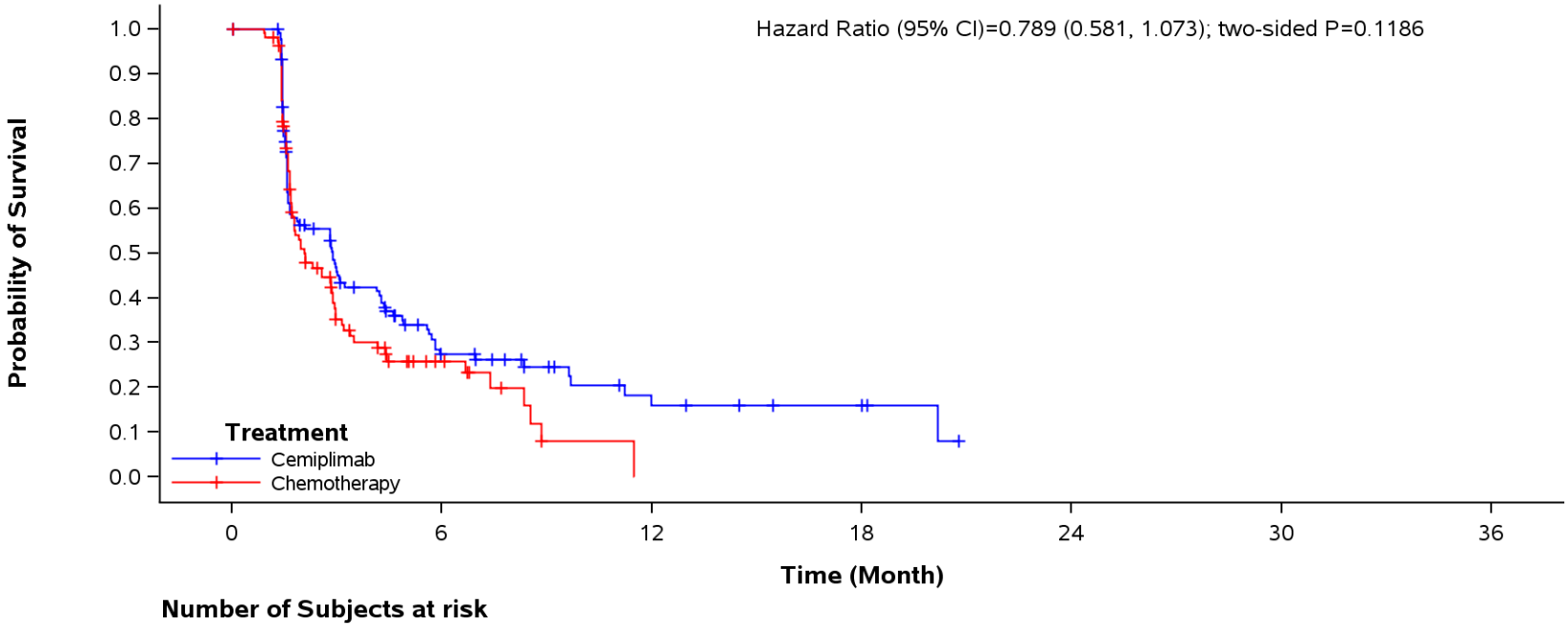

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 39 | 17 | 6 | 1 | 0 | 0 |
| Chemotherapy | 137 | 20 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts deterioration



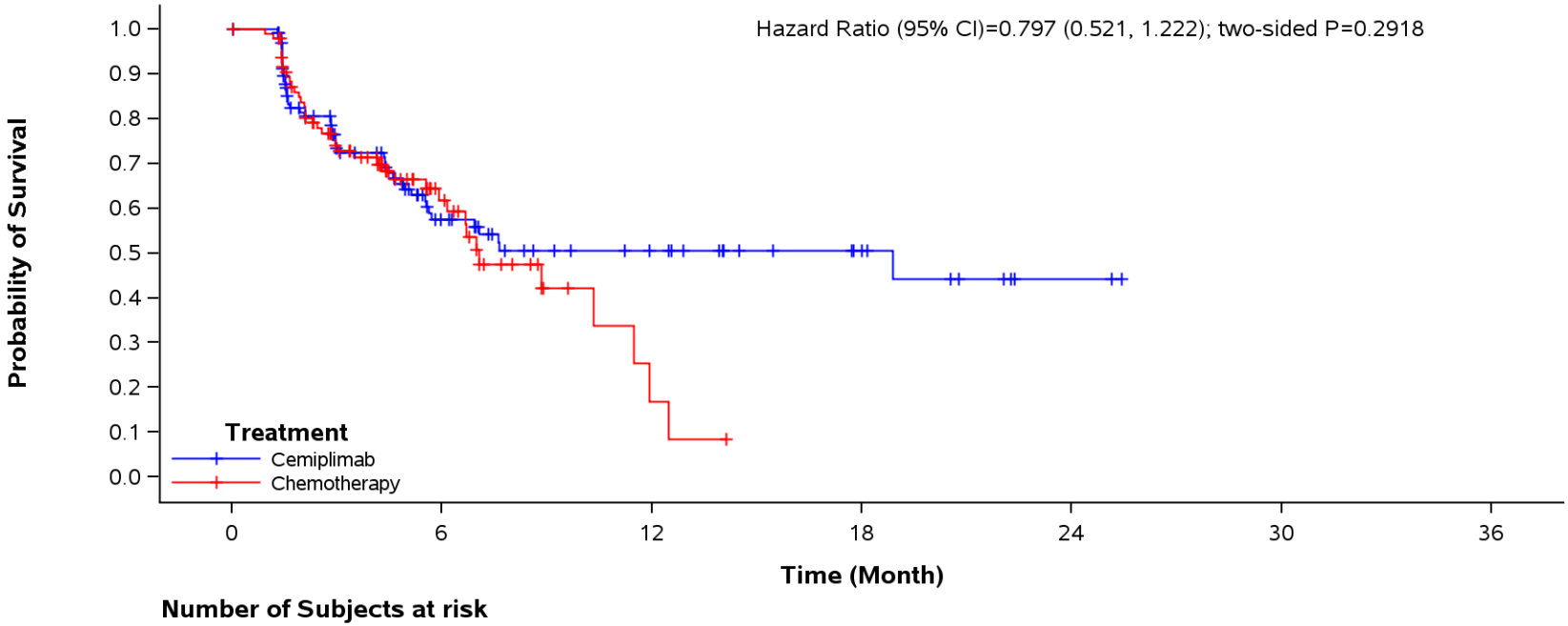

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 24 | 7 | 4 | 0 | 0 | 0 |
| Chemotherapy | 137 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts deterioration



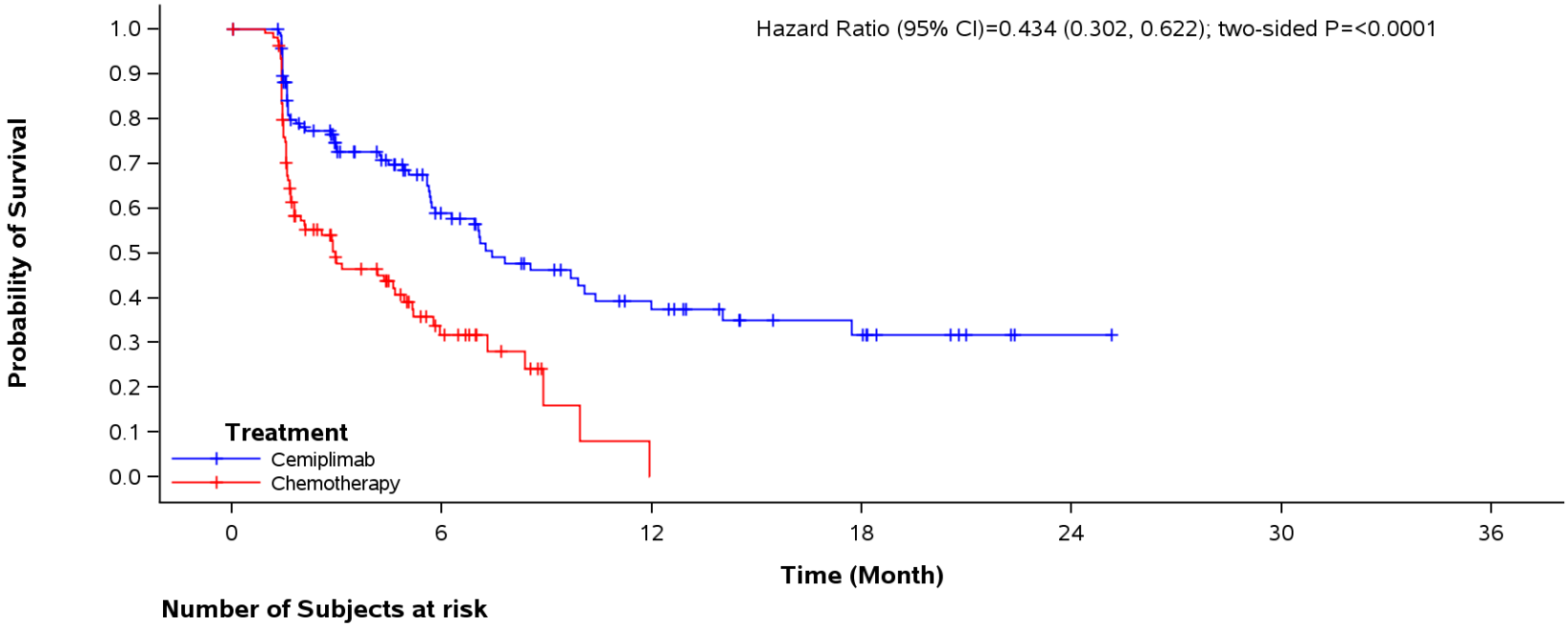

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 39 | 20 | 10 | 2 | 0 | 0 |
| Chemotherapy | 137 | 25 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Nausea / Vomiting - 10 pts deterioration



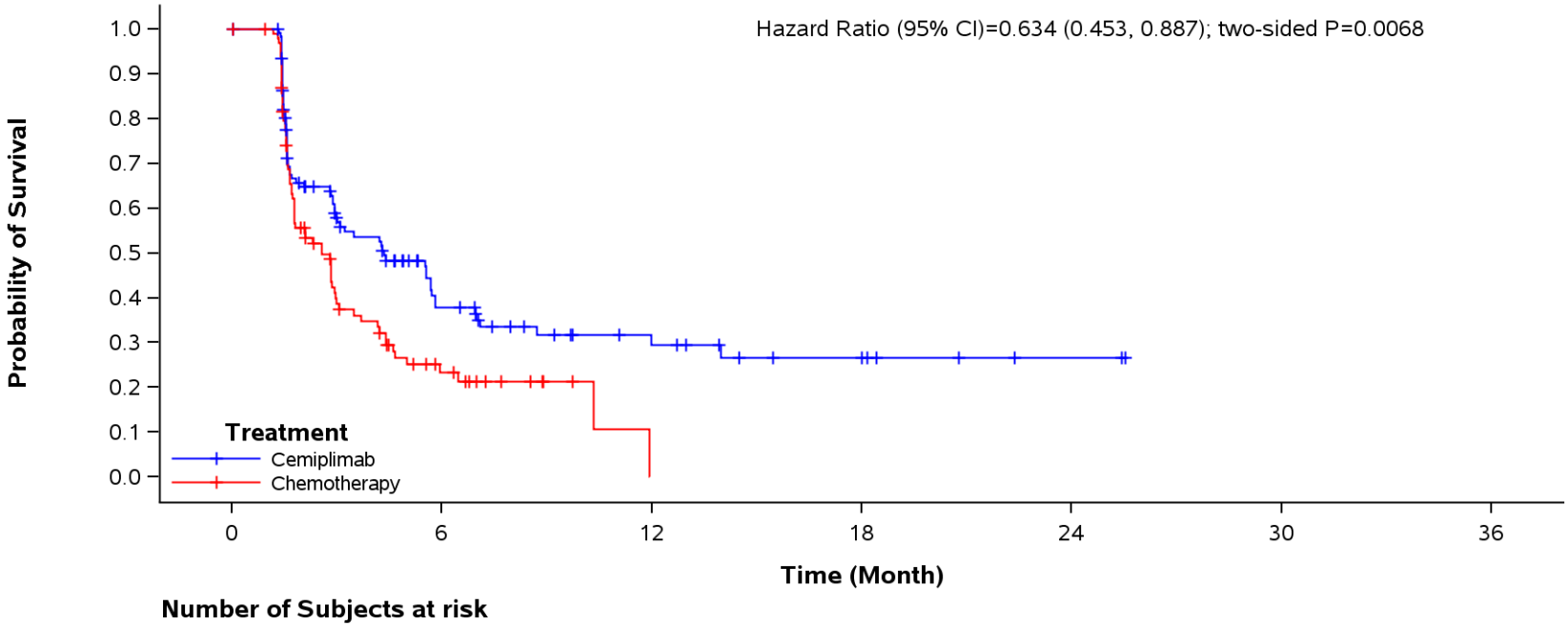

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 47 | 20 | 10 | 1 | 0 | 0 |
| Chemotherapy | 137 | 15 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts deterioration



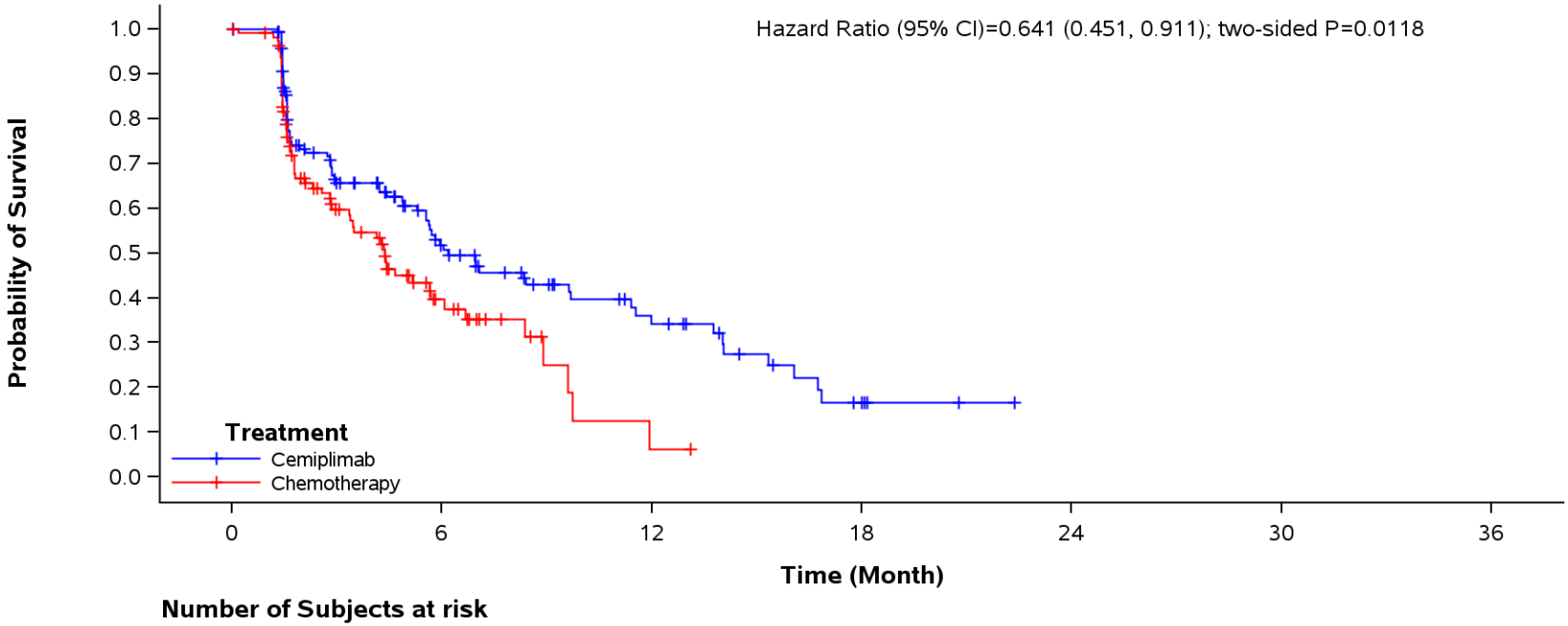

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 29 | 13 | 7 | 2 | 0 | 0 |
| Chemotherapy | 137 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts deterioration



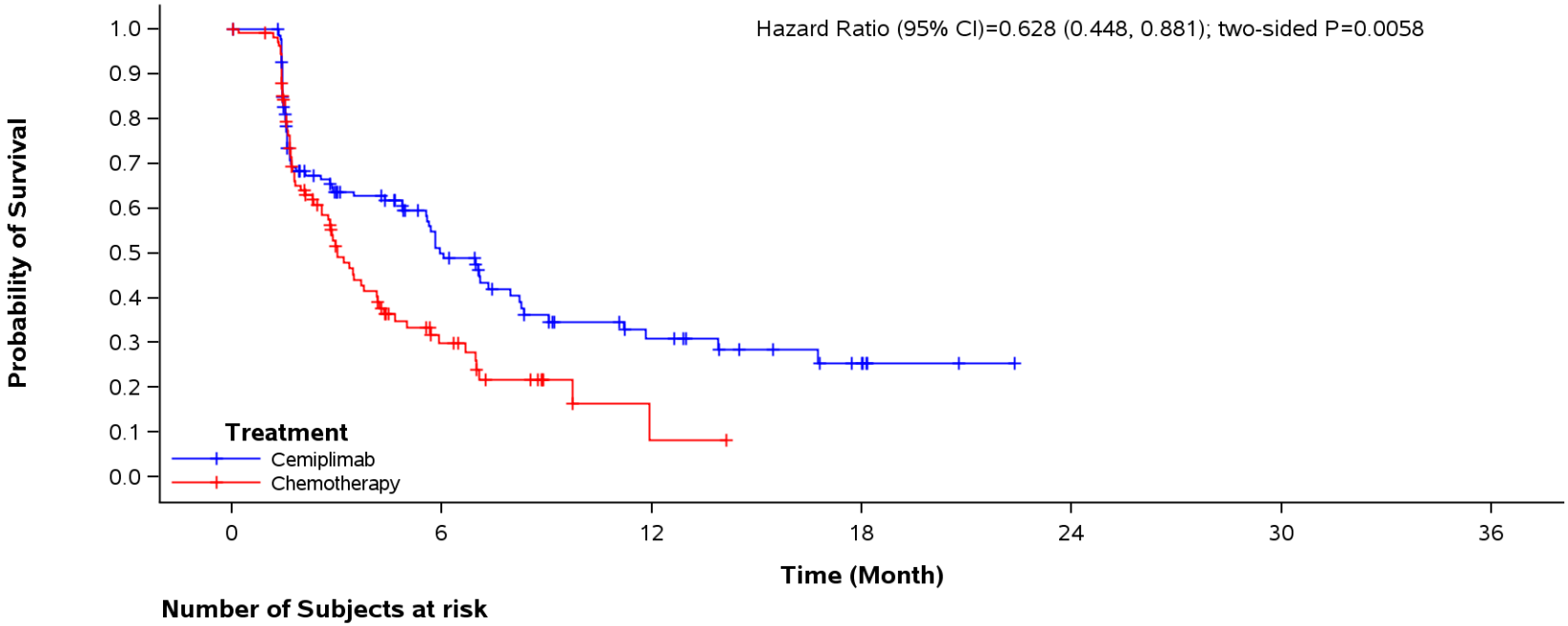

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 45 | 19 | 5 | 0 | 0 | 0 |
| Chemotherapy | 137 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts deterioration



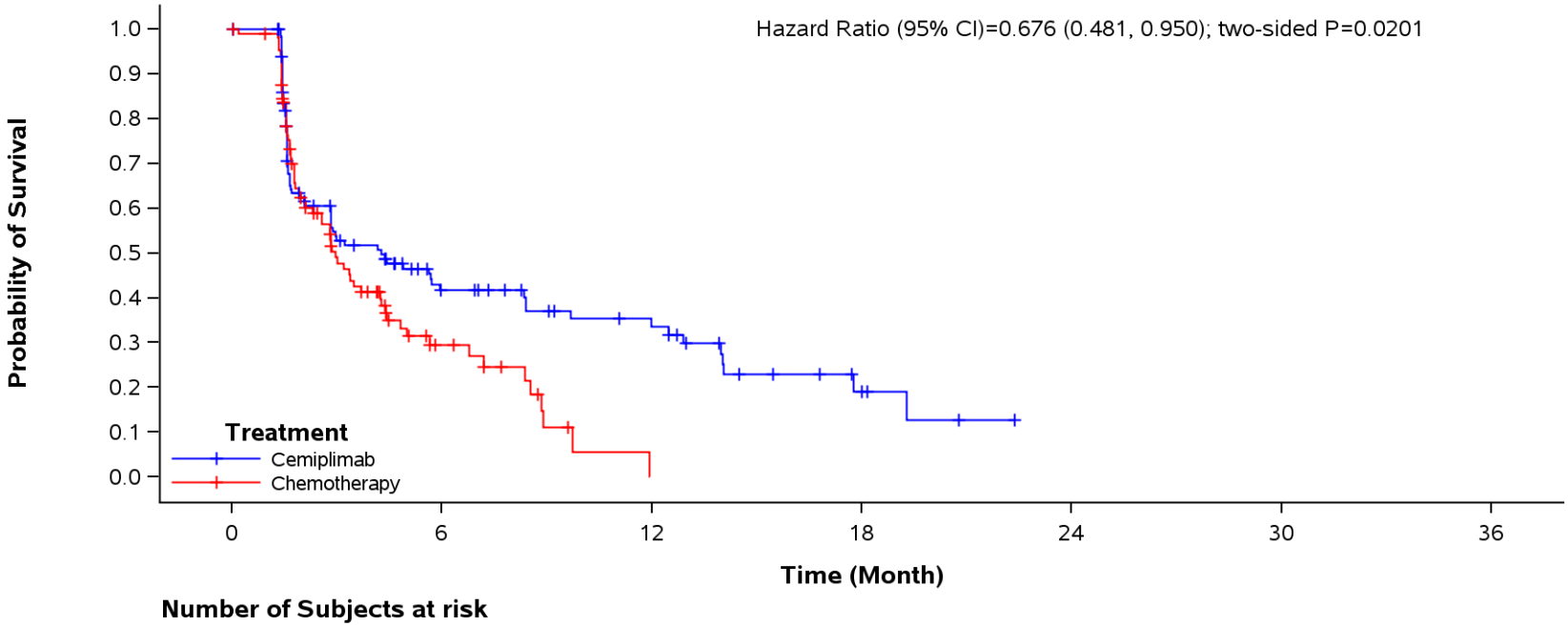

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 42 | 16 | 6 | 0 | 0 | 0 |
| Chemotherapy | 137 | 17 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts deterioration



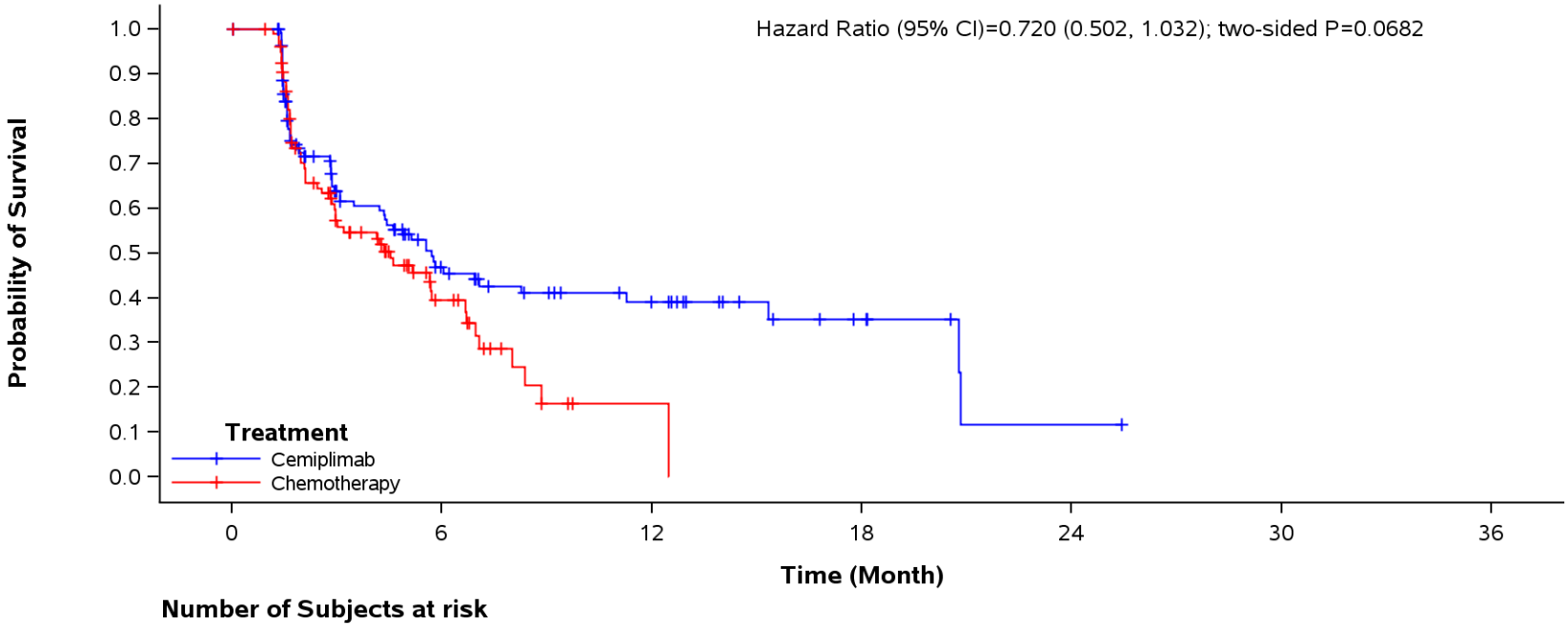

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 33 | 19 | 5 | 0 | 0 | 0 |
| Chemotherapy | 137 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Social Functioning - 10 pts deterioration



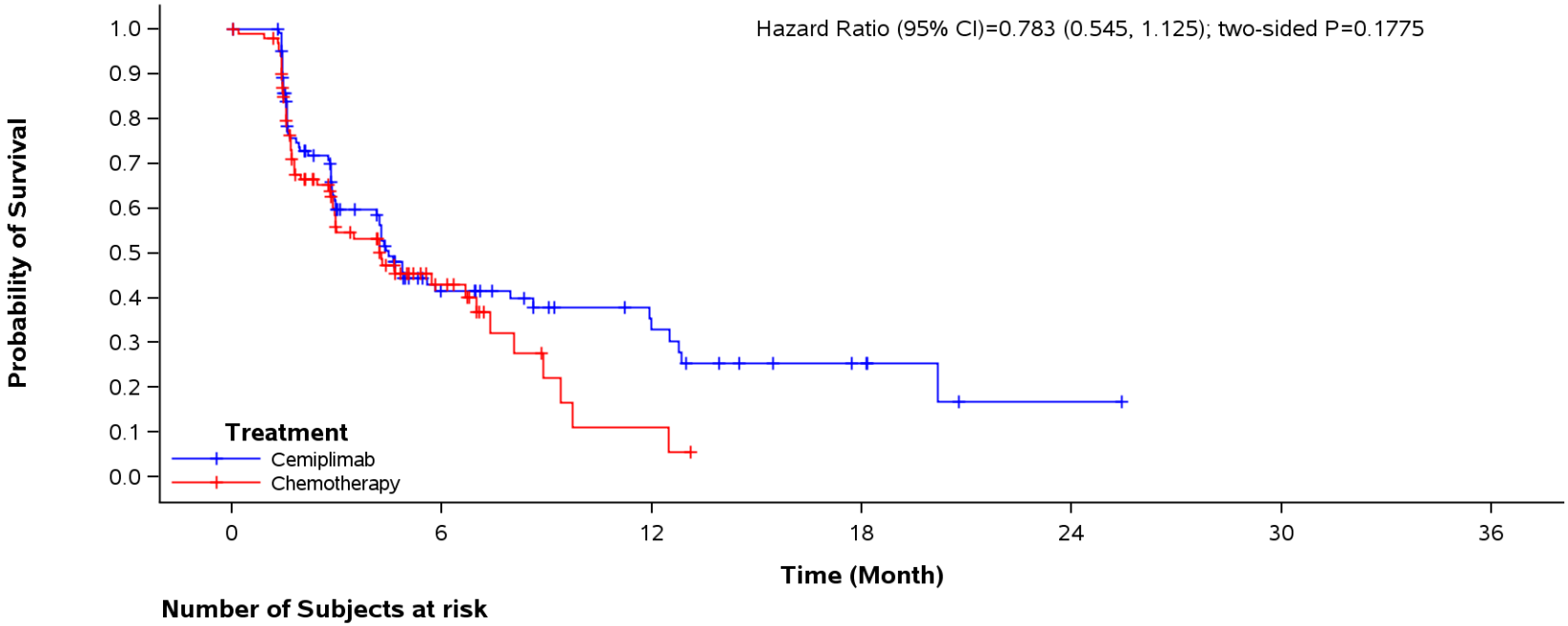

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 36 | 18 | 6 | 1 | 0 | 0 |
| Chemotherapy | 137 | 18 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts deterioration



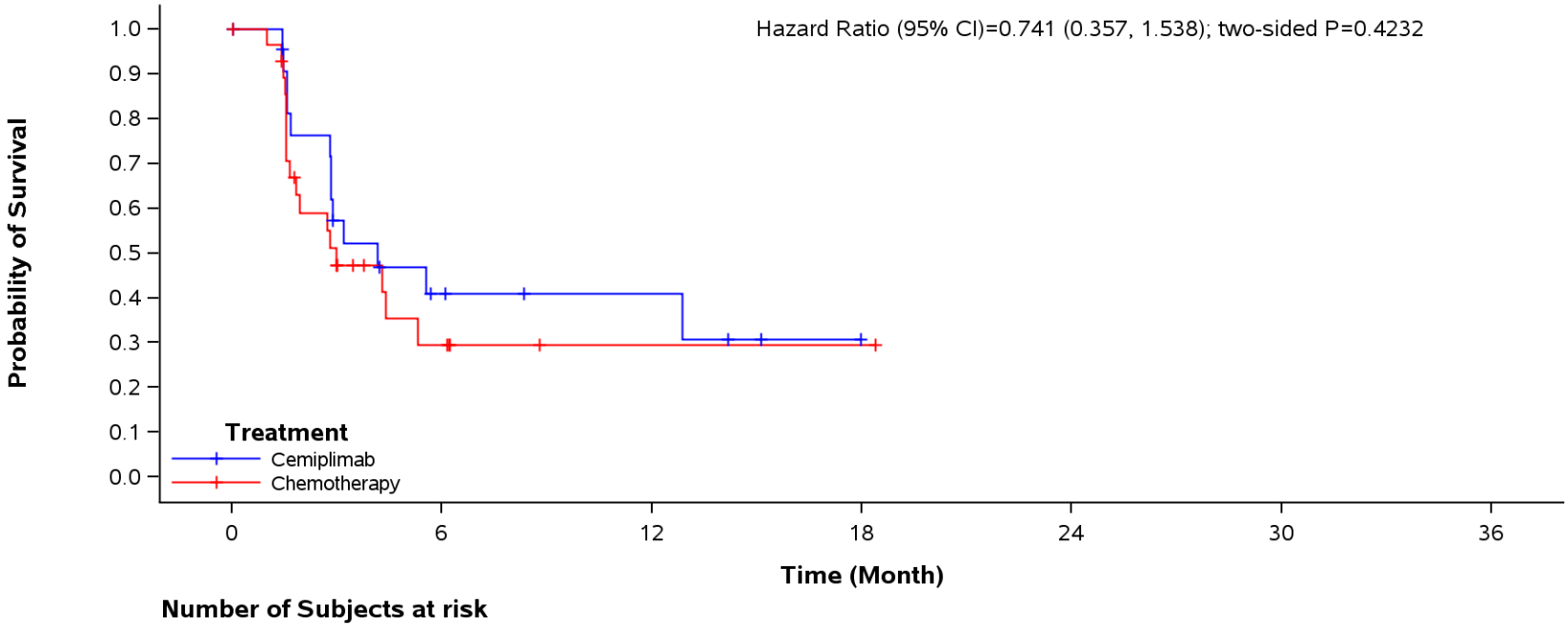

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 28 | 13 | 5 | 1 | 0 | 0 |
| Chemotherapy | 137 | 17 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts deterioration



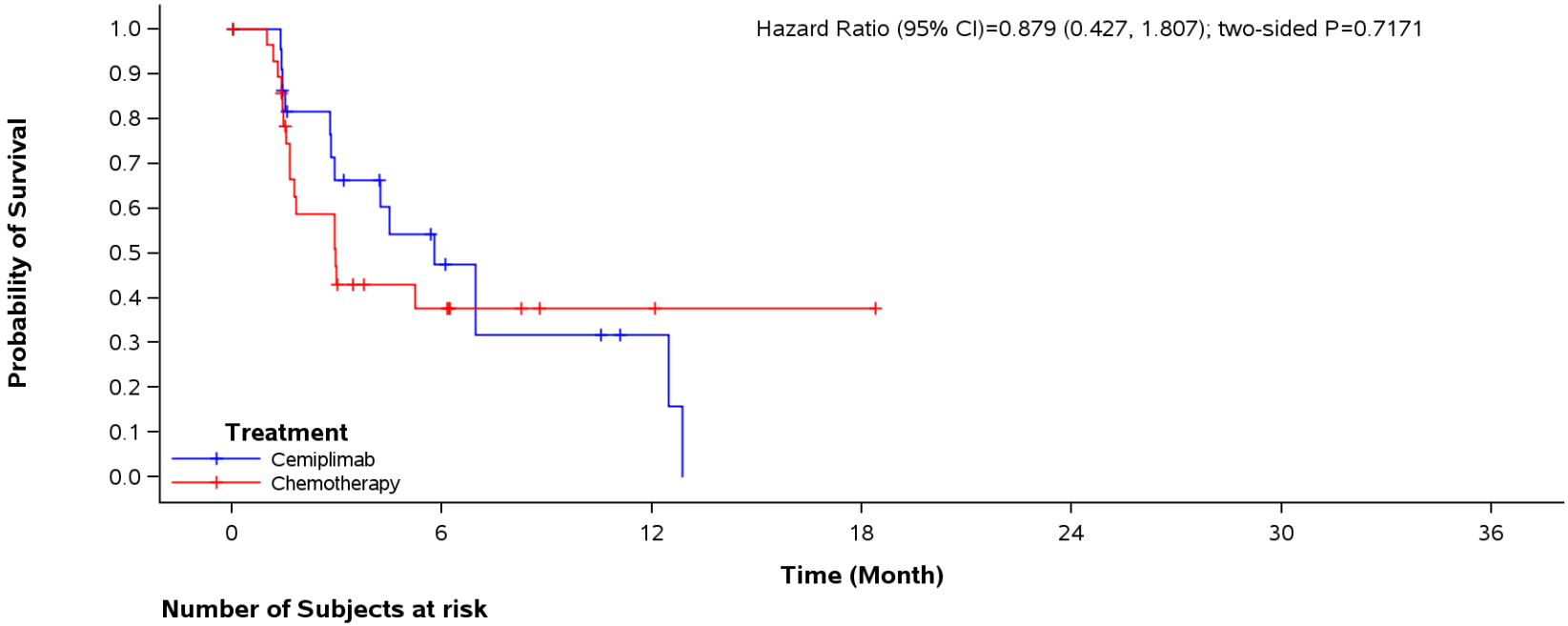

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 6 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts deterioration



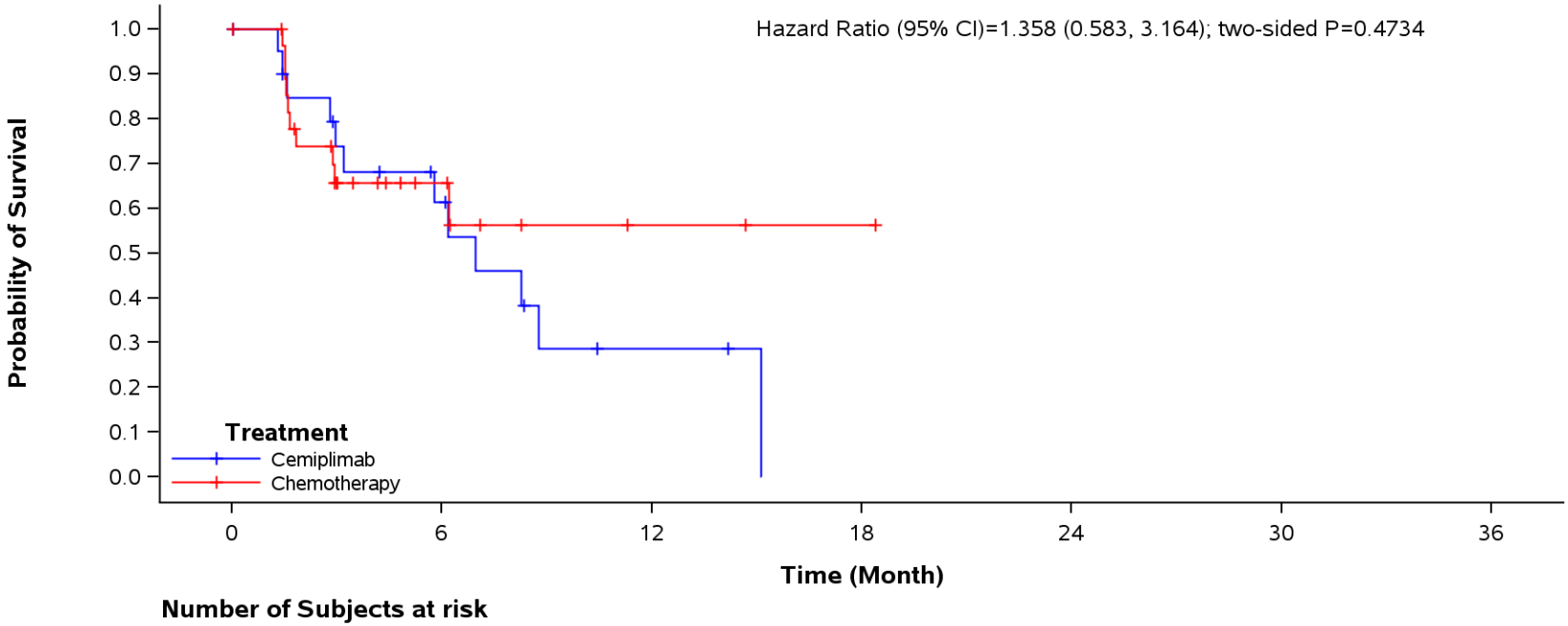

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 7 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts deterioration



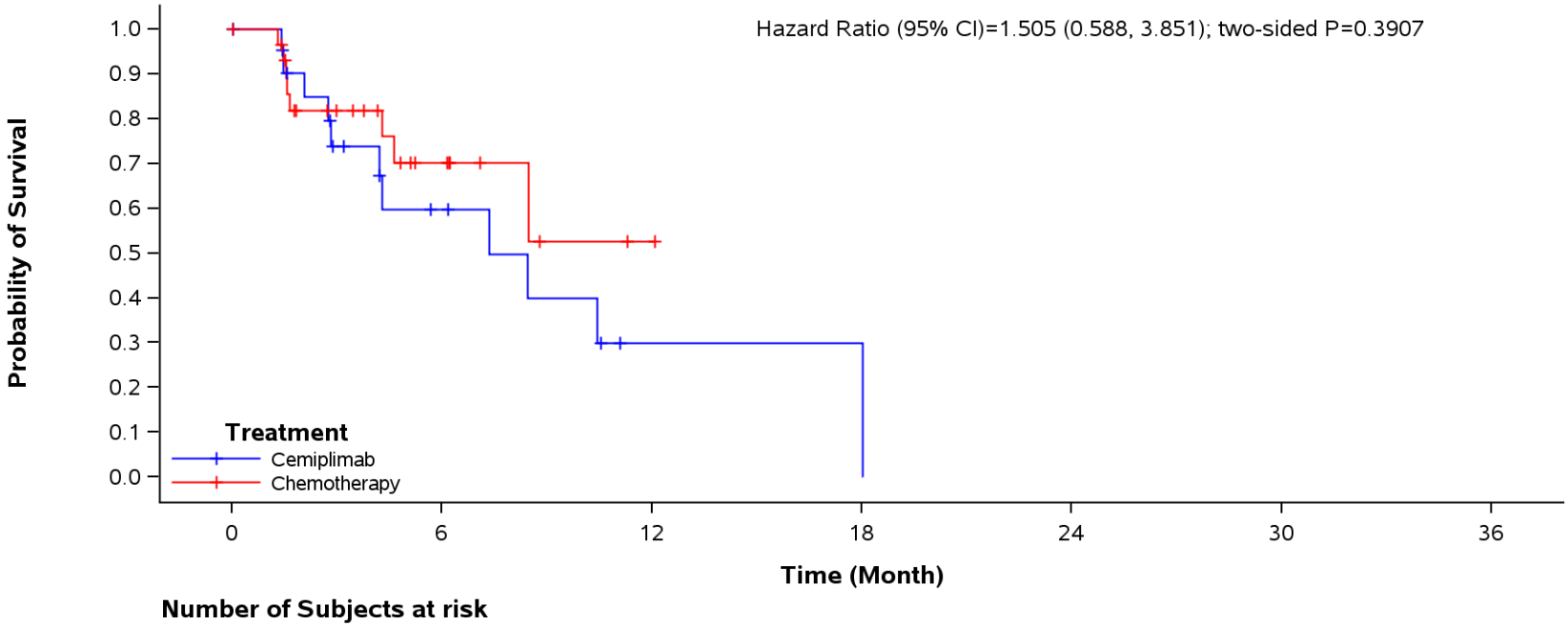

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts deterioration



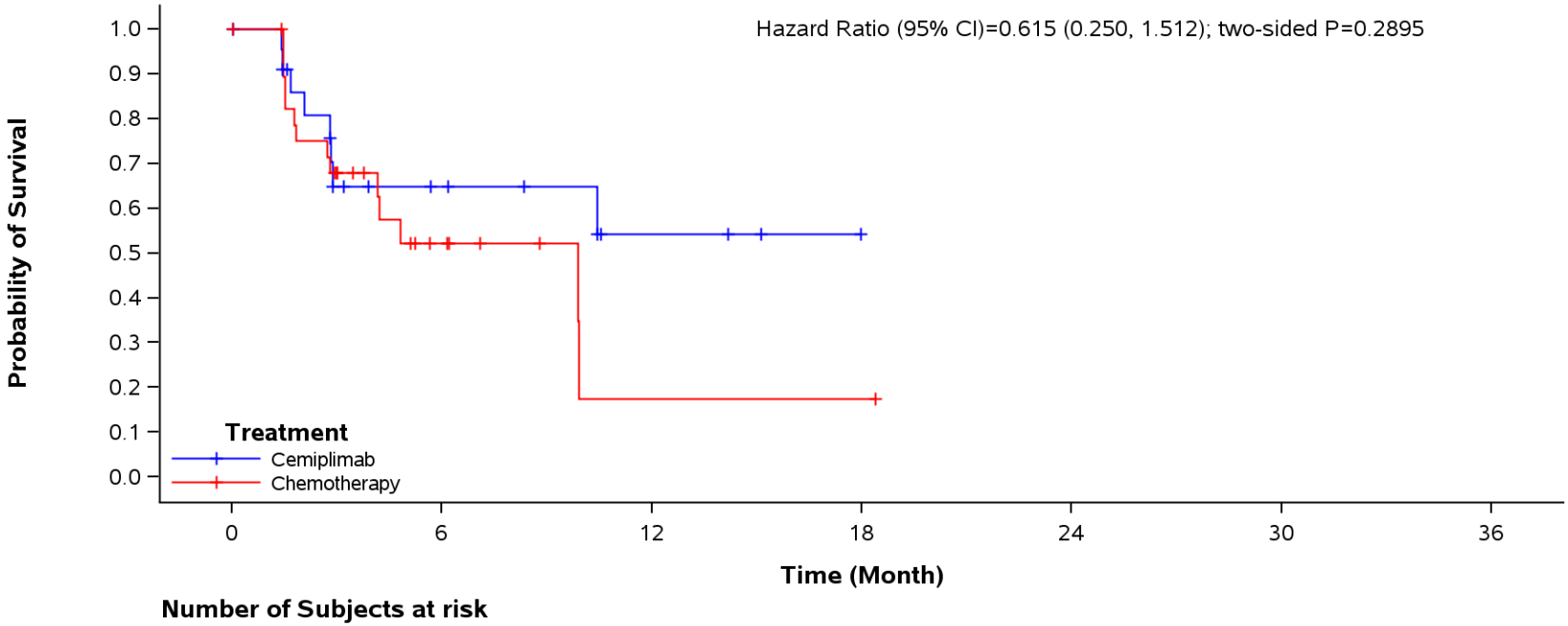

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 7 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts deterioration



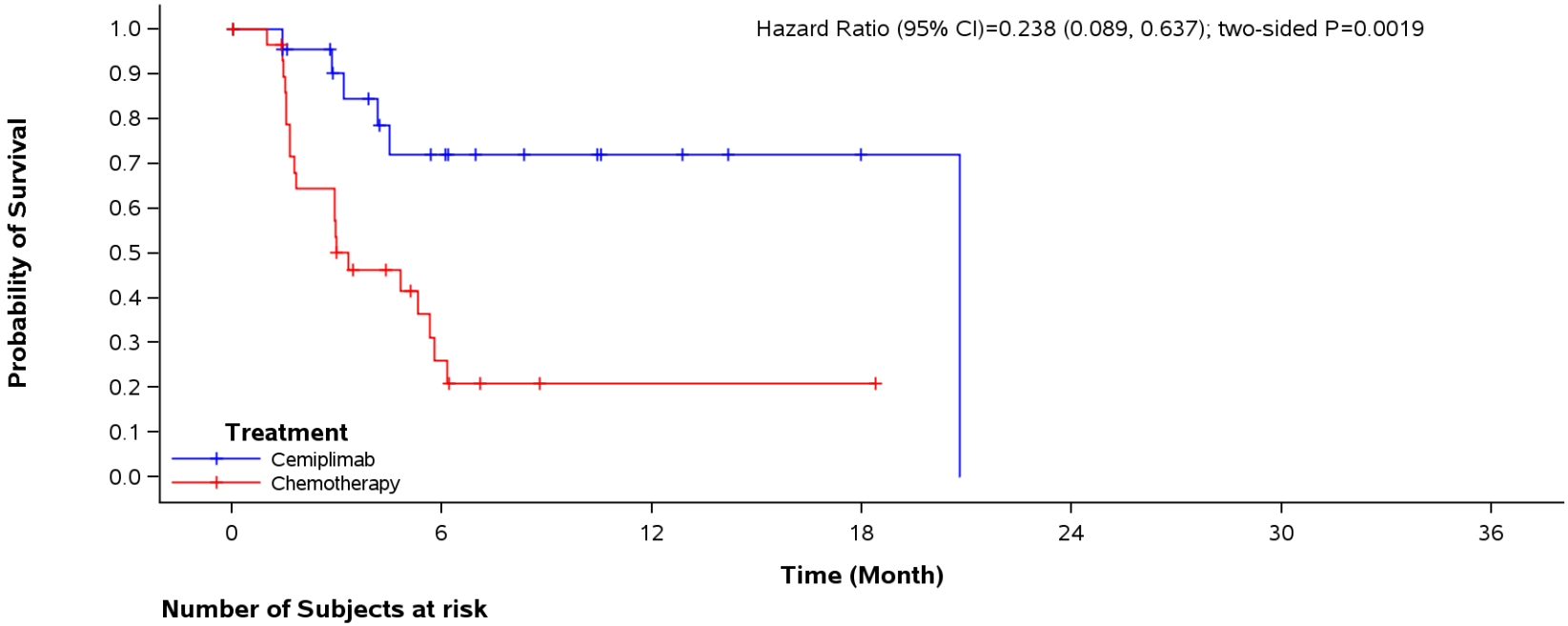

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts deterioration



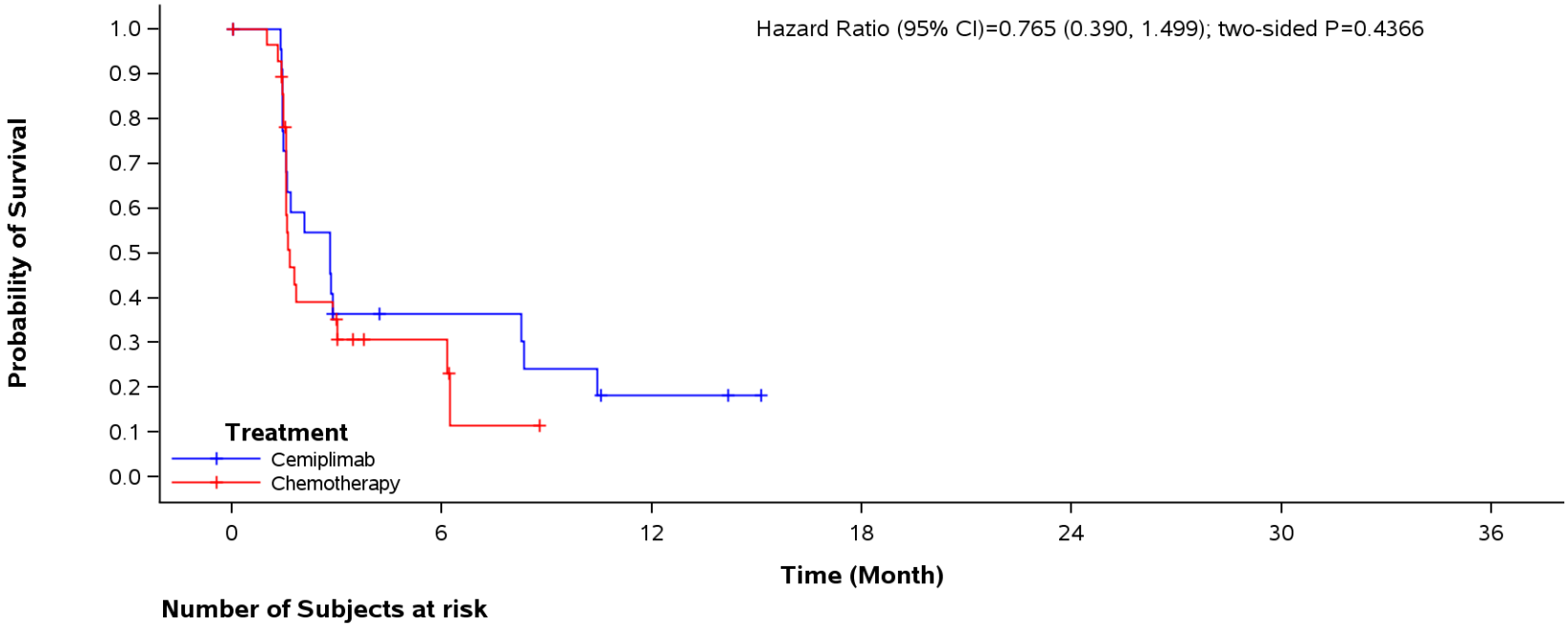

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts deterioration



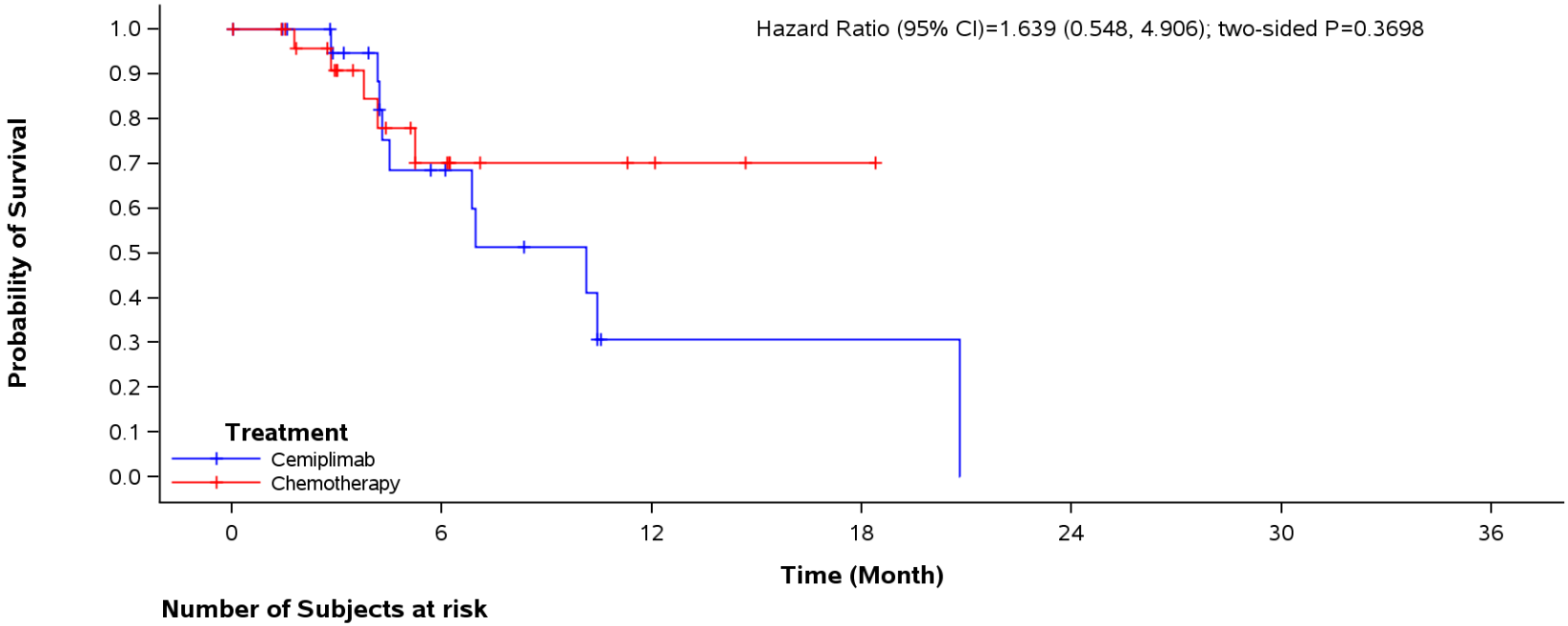

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts deterioration



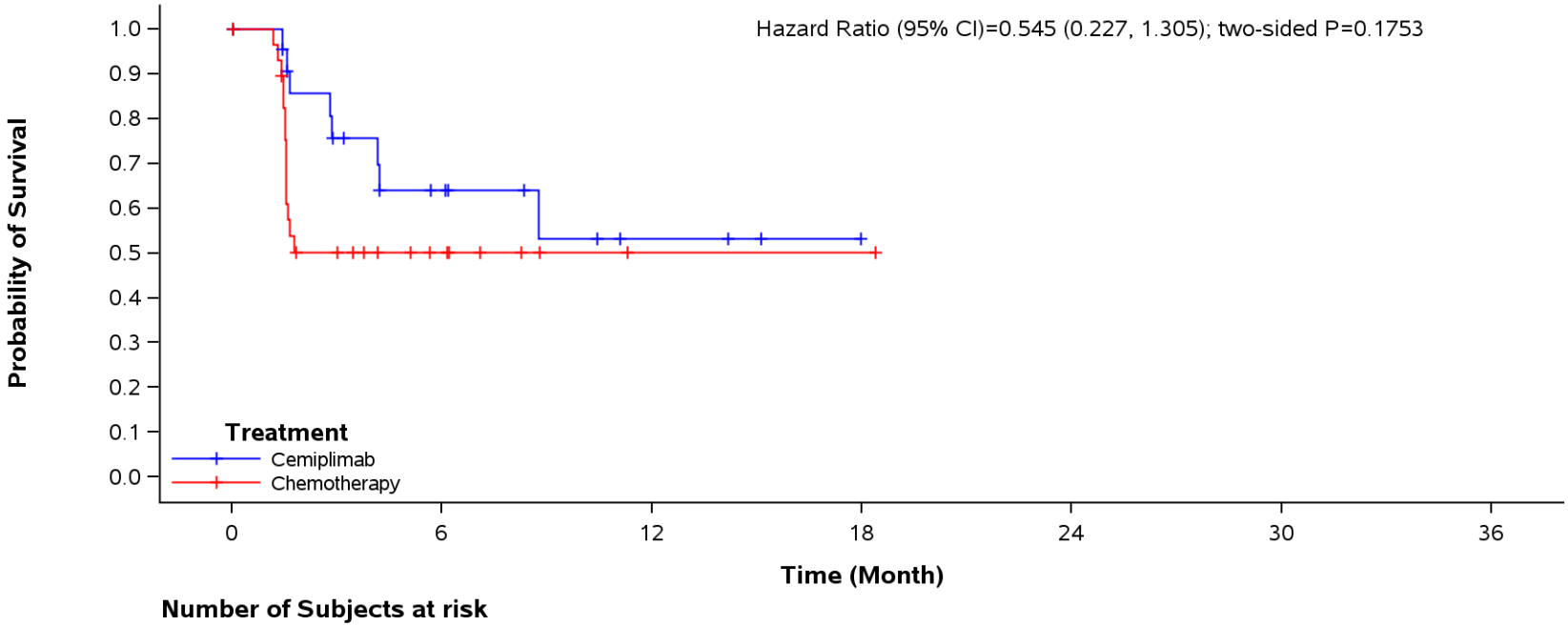

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts deterioration



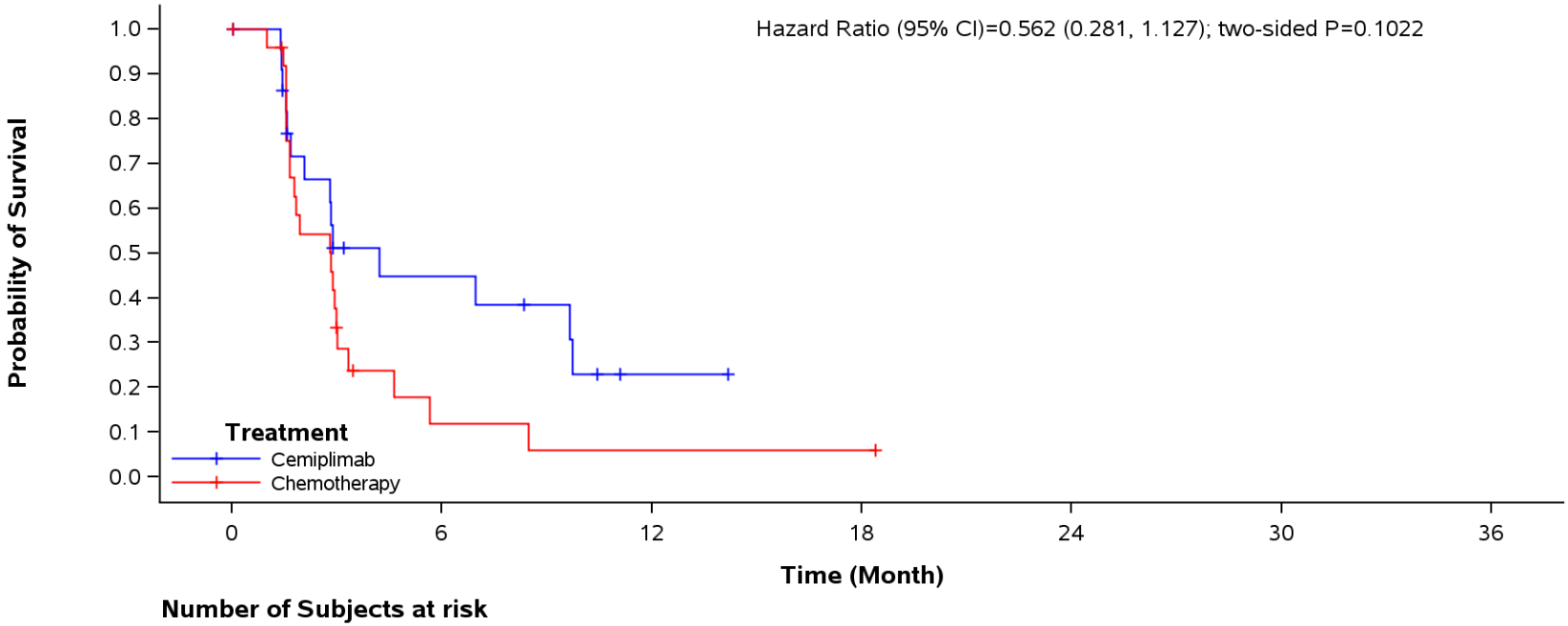

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts deterioration



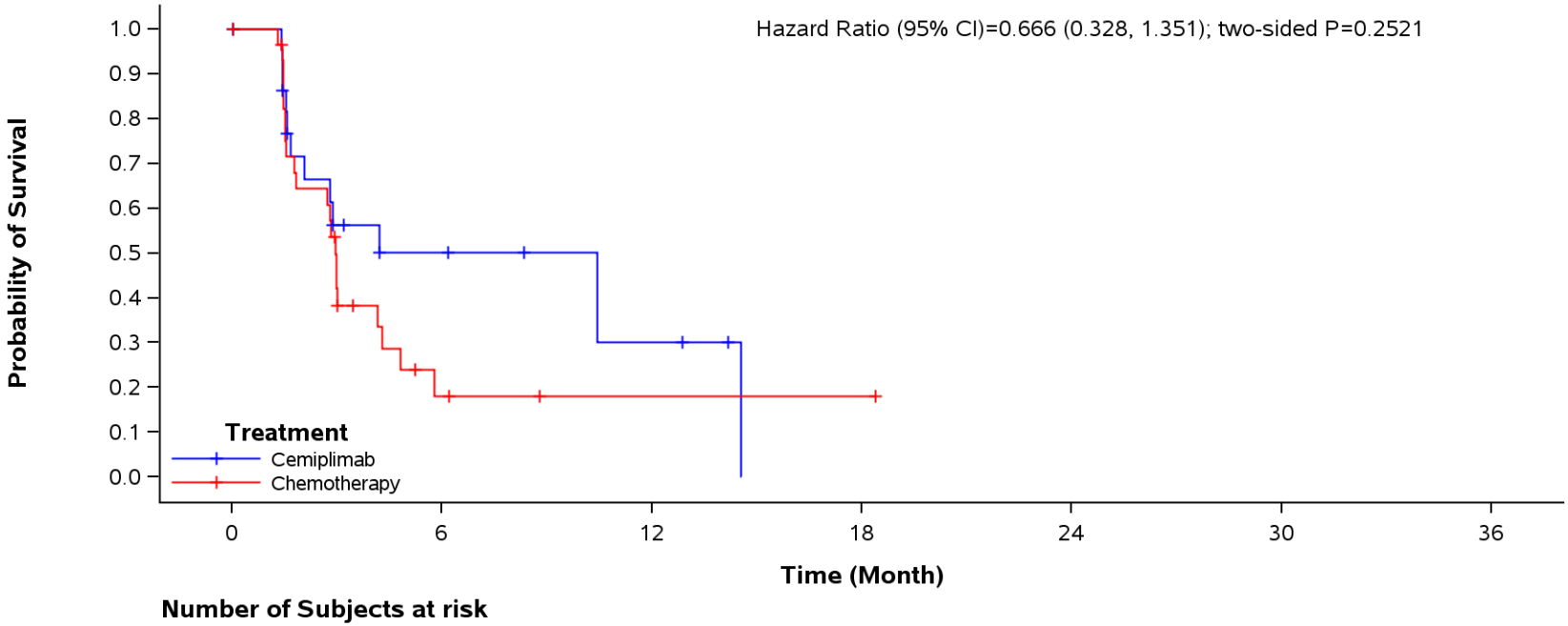

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 7 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts deterioration



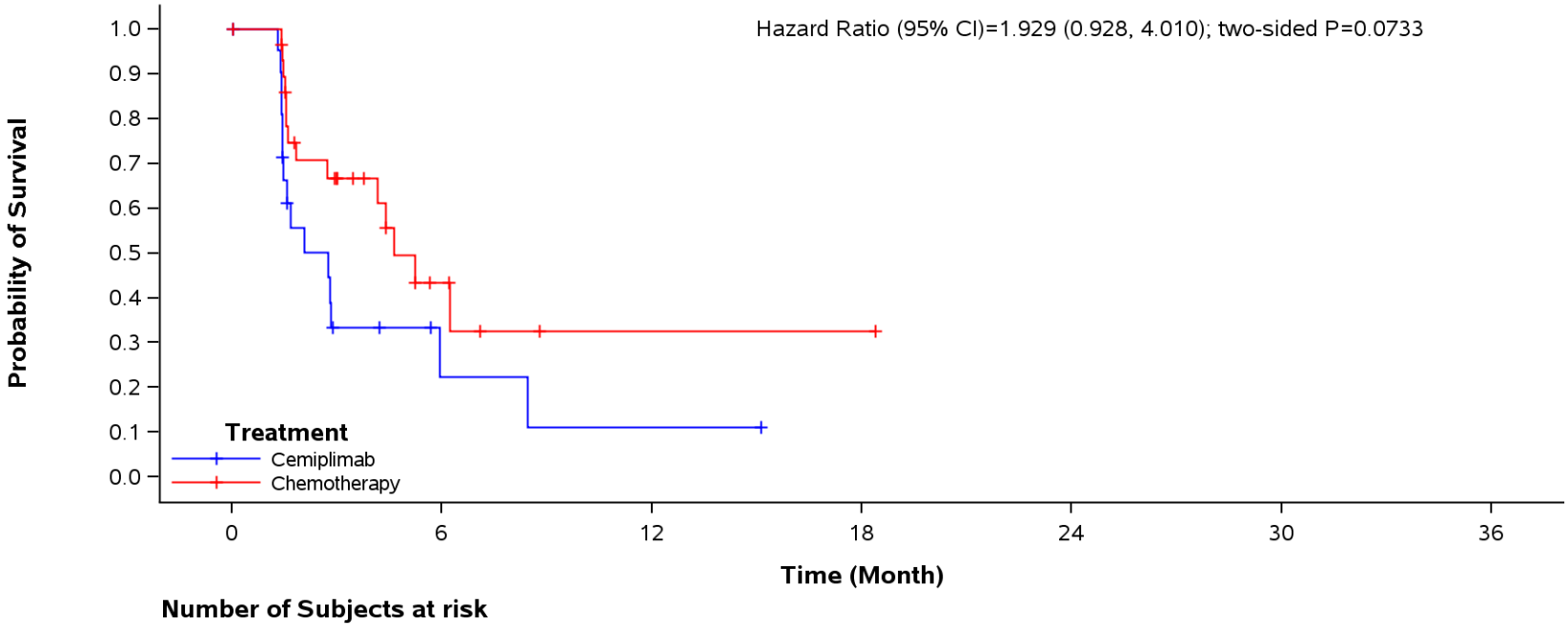

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 7 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts deterioration



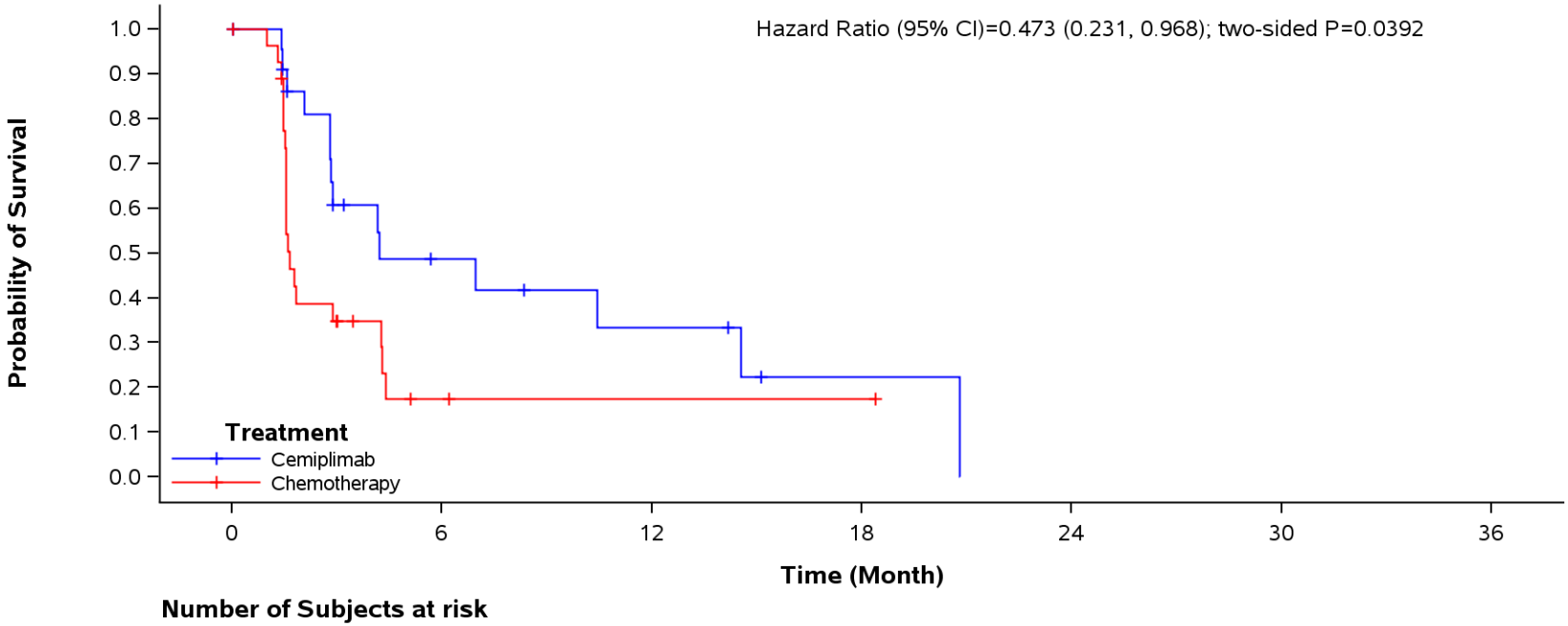

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts deterioration



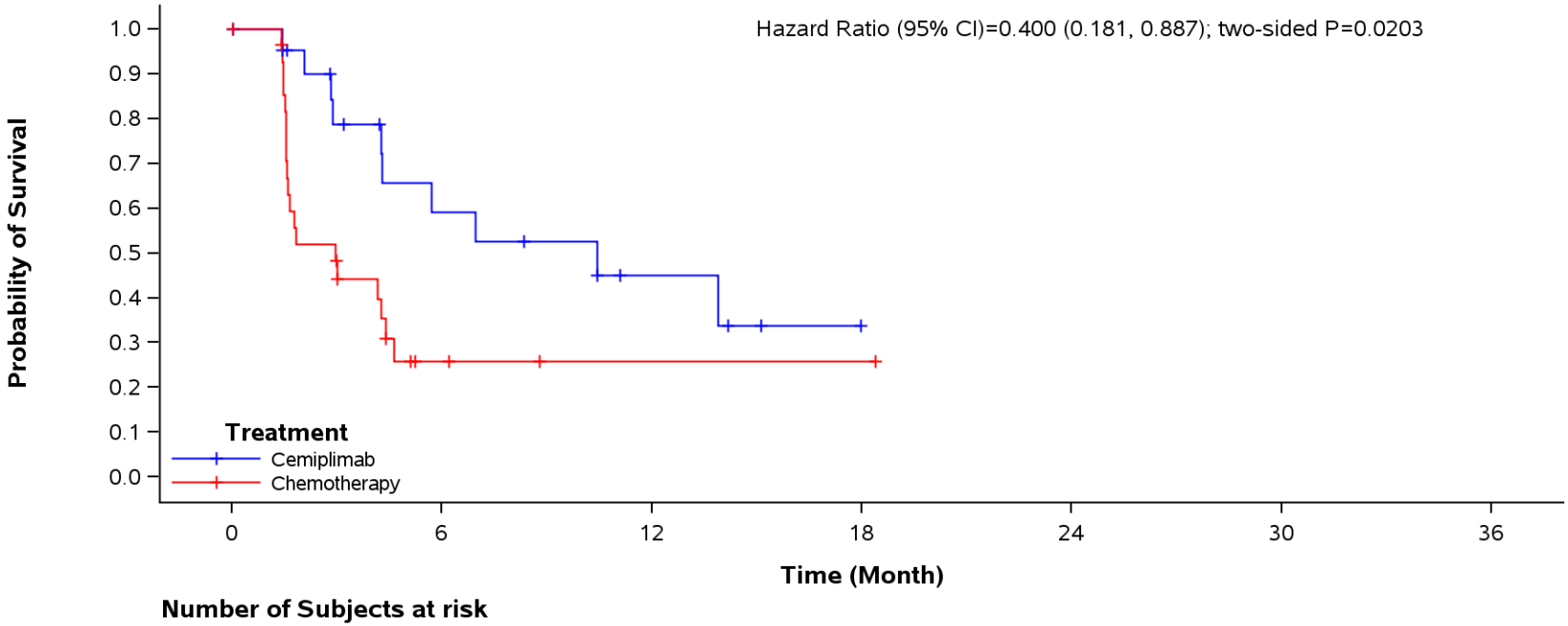

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 7 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts deterioration



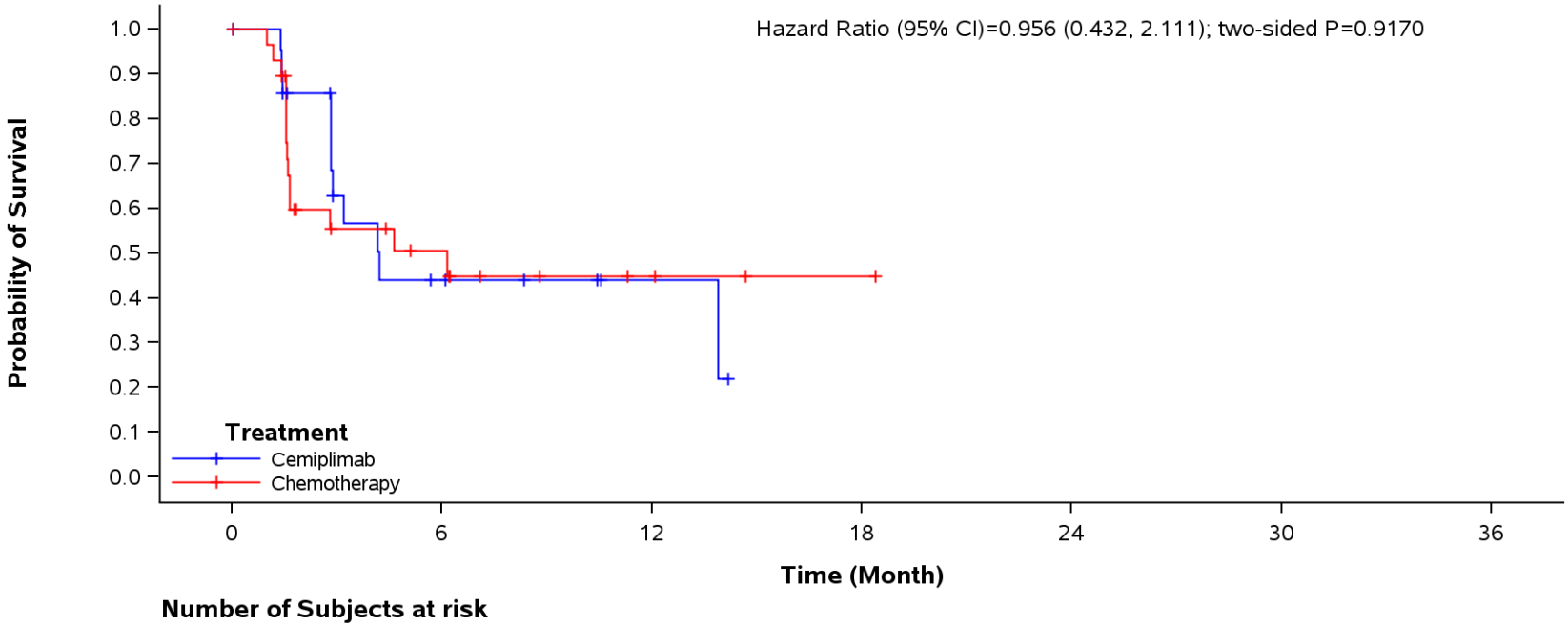

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts deterioration



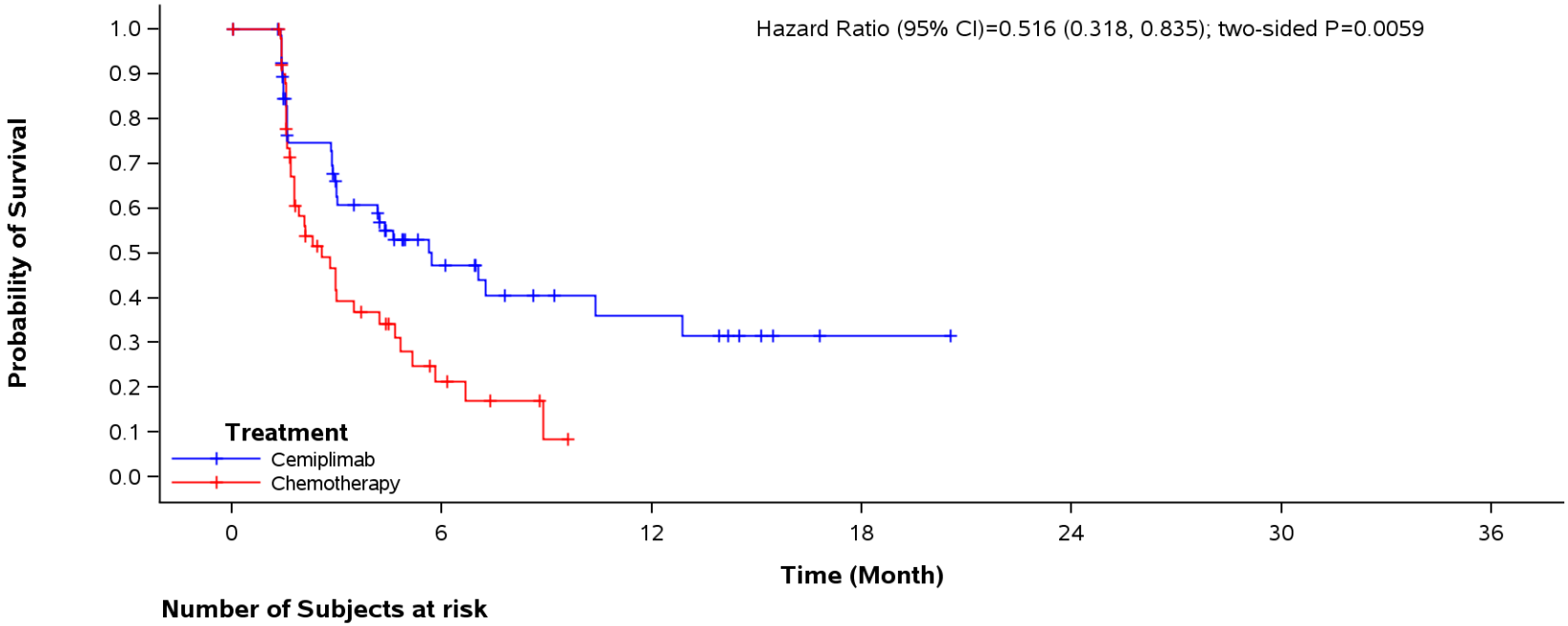

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts deterioration



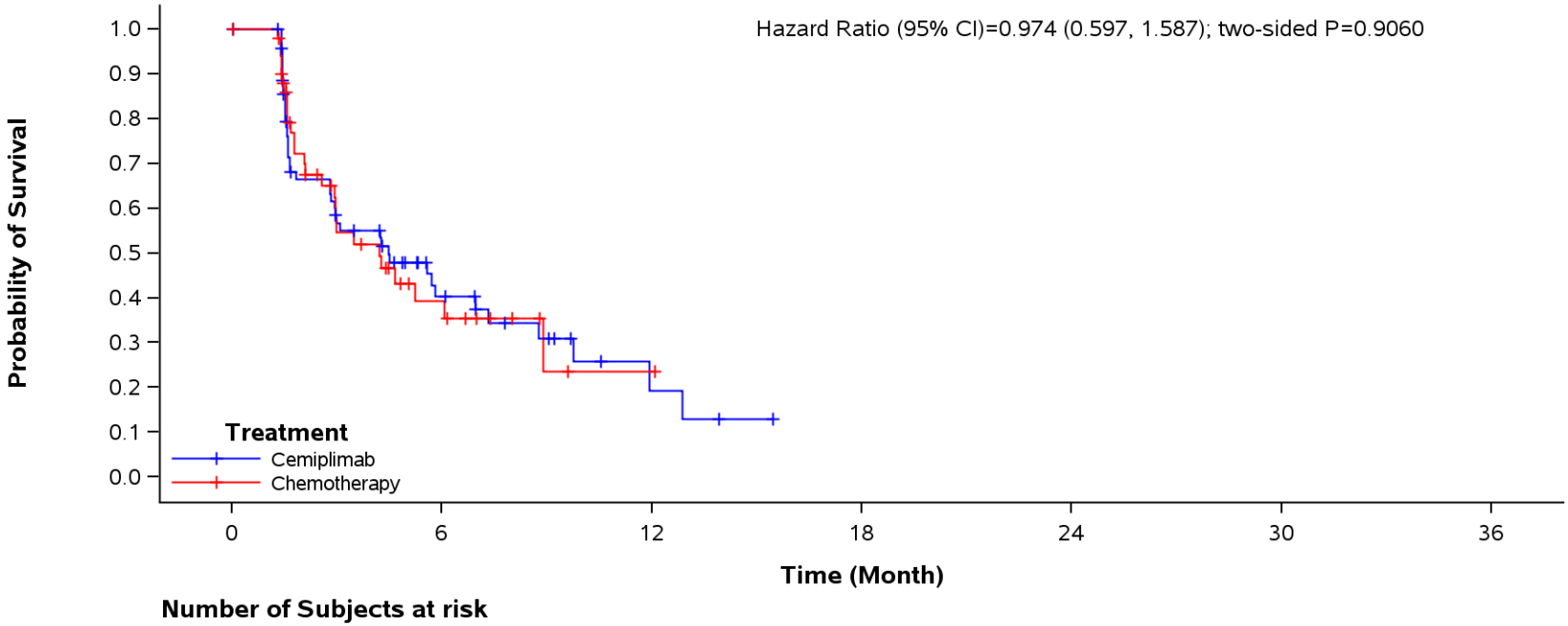

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 17 | 8 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts deterioration



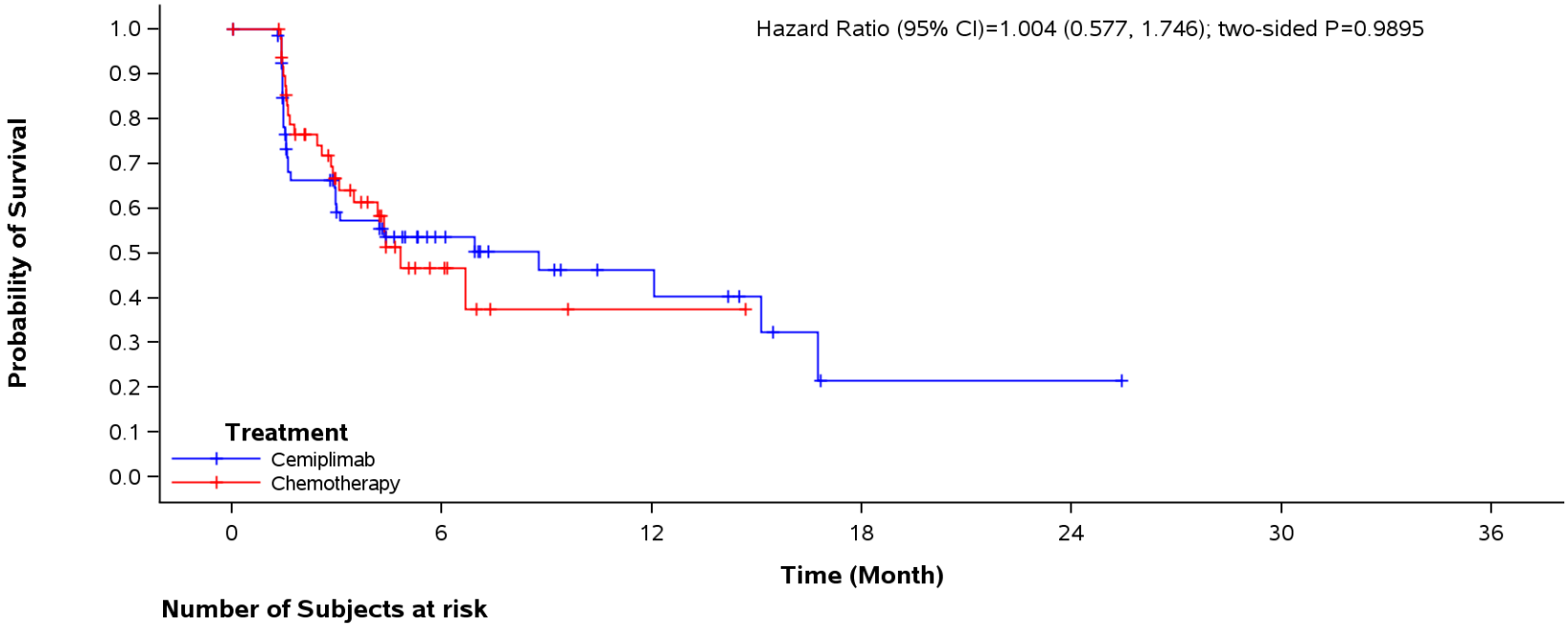

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 16 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts deterioration



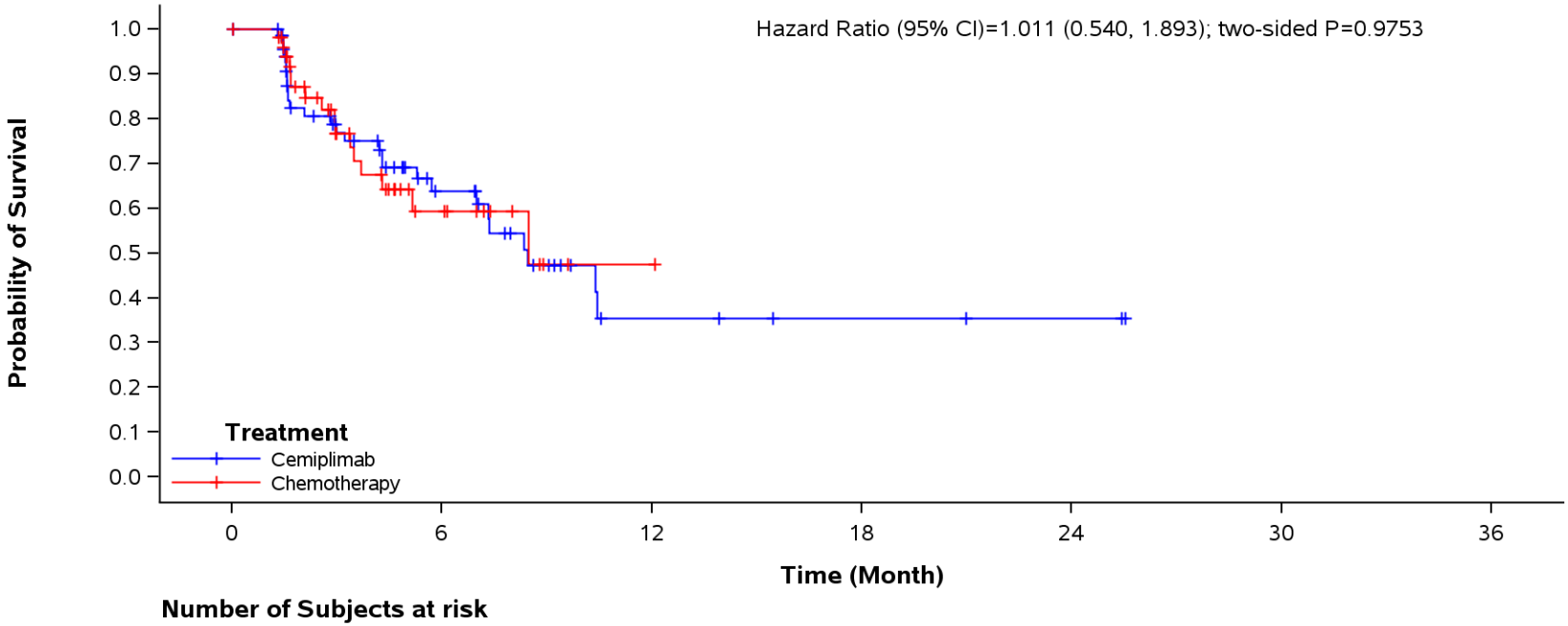

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 18 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 85 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts deterioration



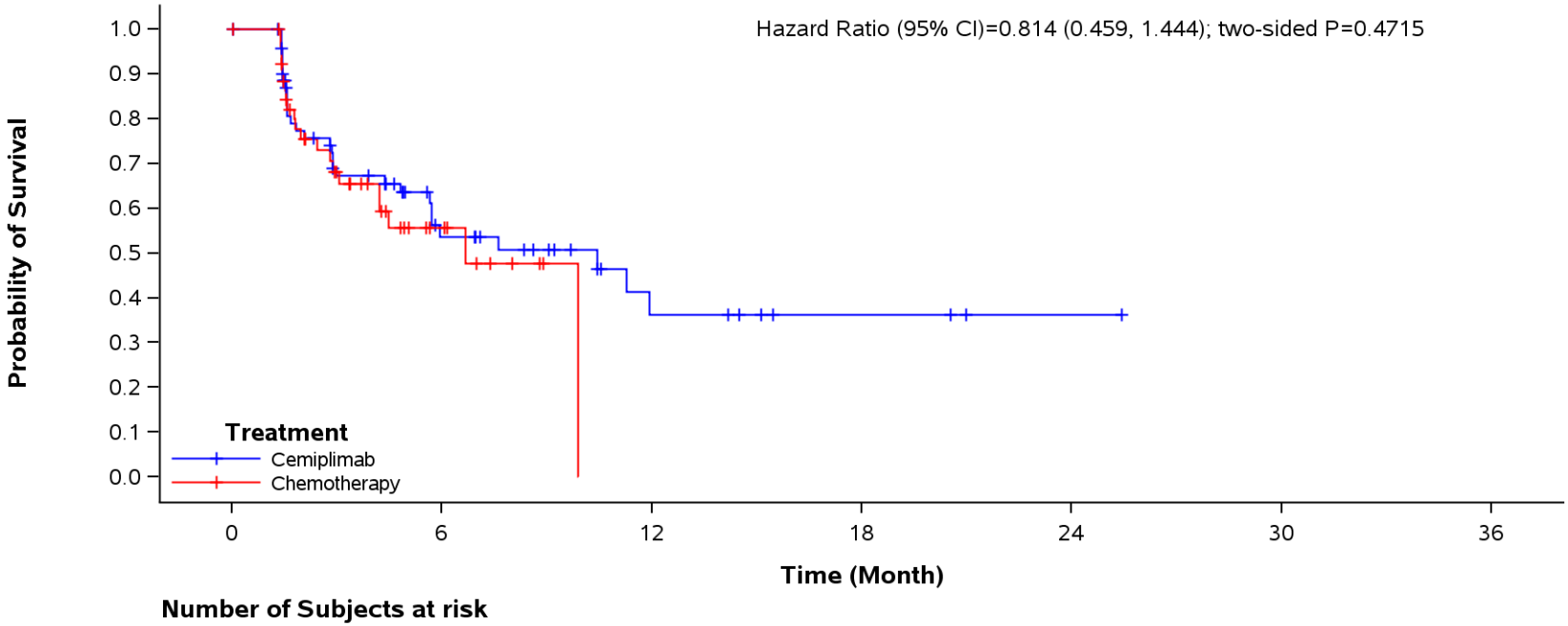

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 23 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 85 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts deterioration



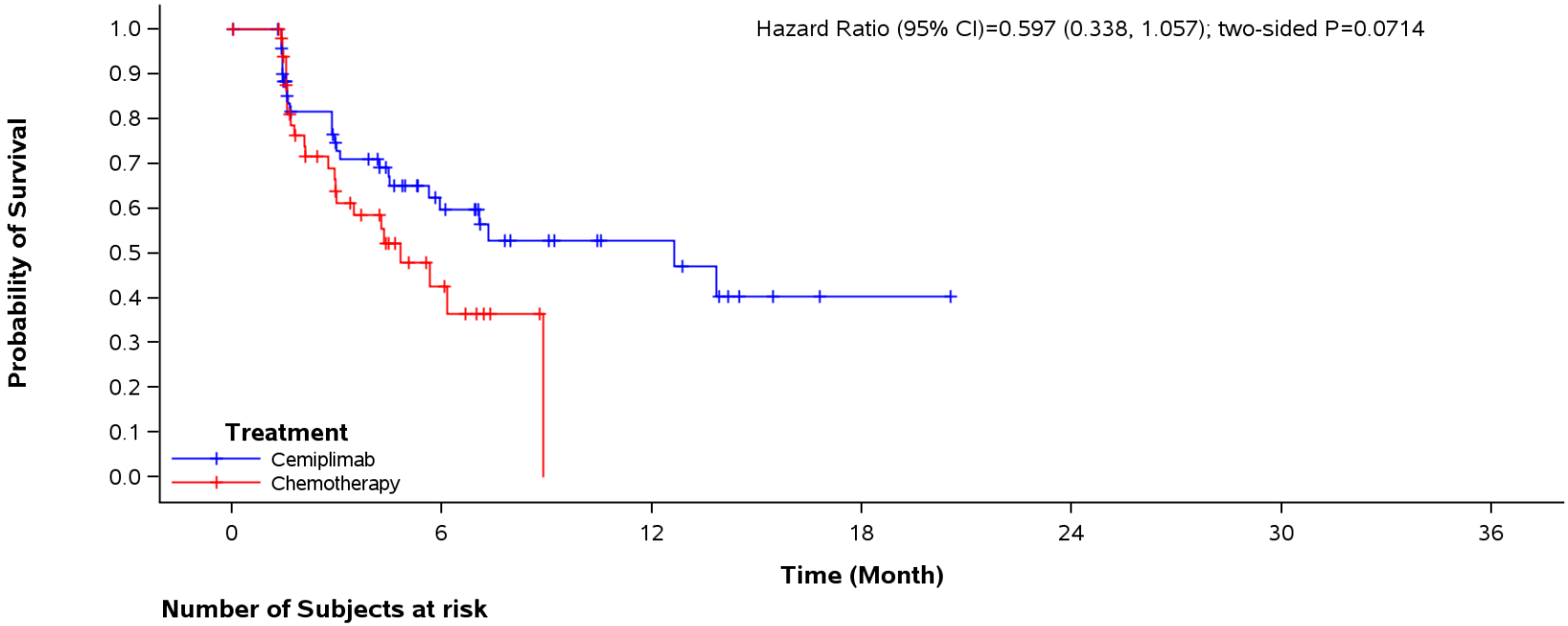

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 21 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 85 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Emotional Functioning - 10 pts deterioration



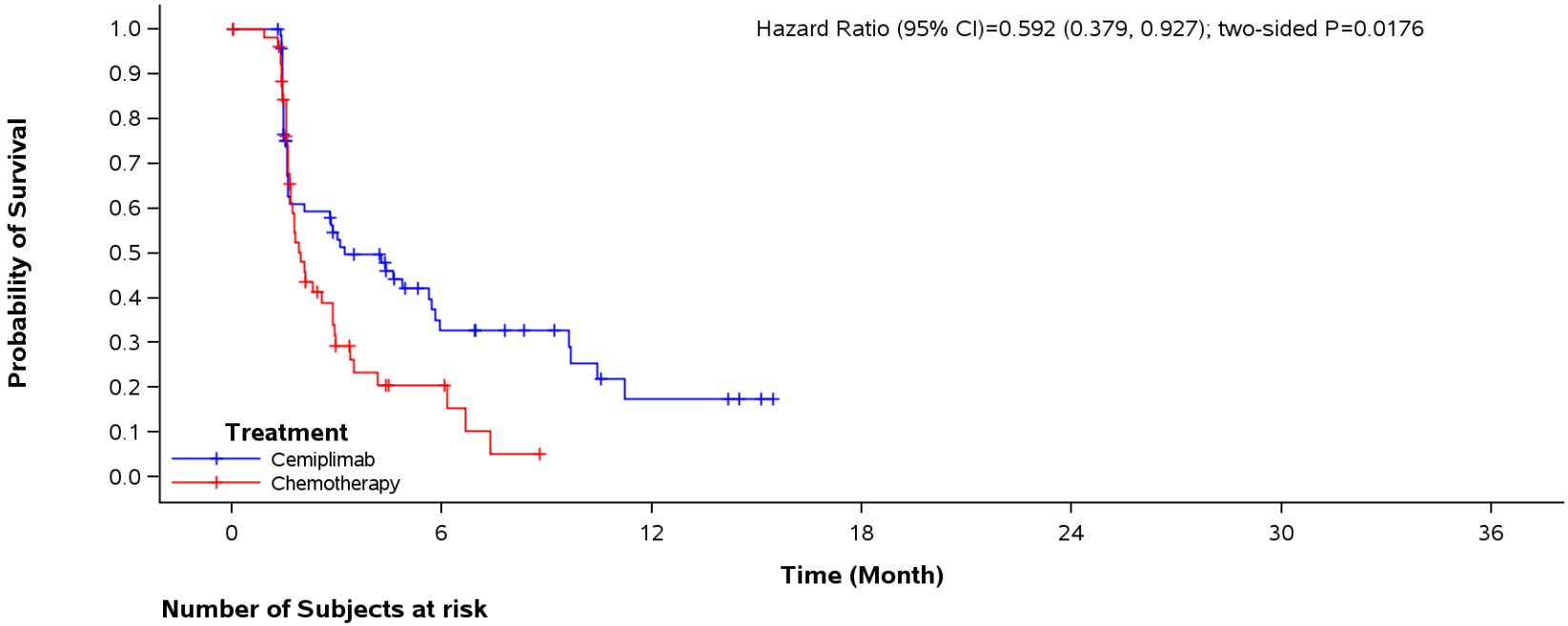

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 22 | 9 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts deterioration



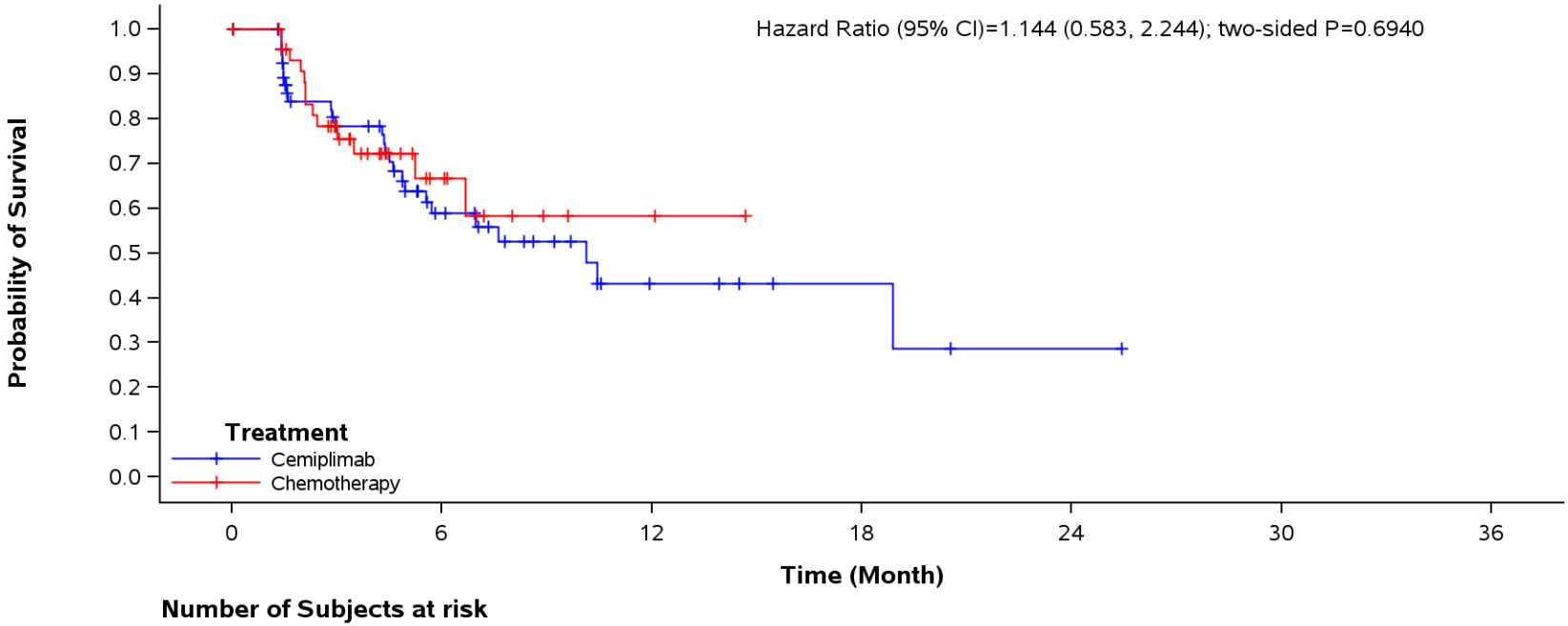

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 14 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts deterioration



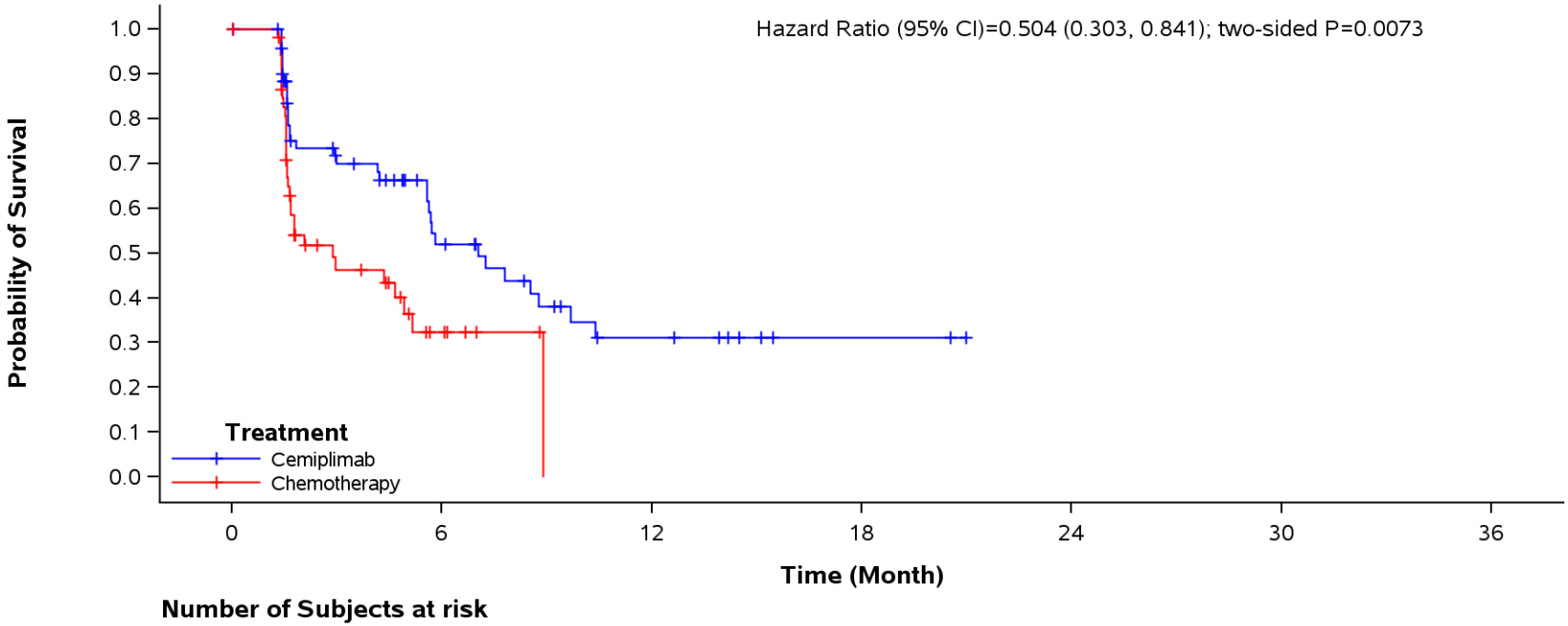

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 22 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 85 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts deterioration



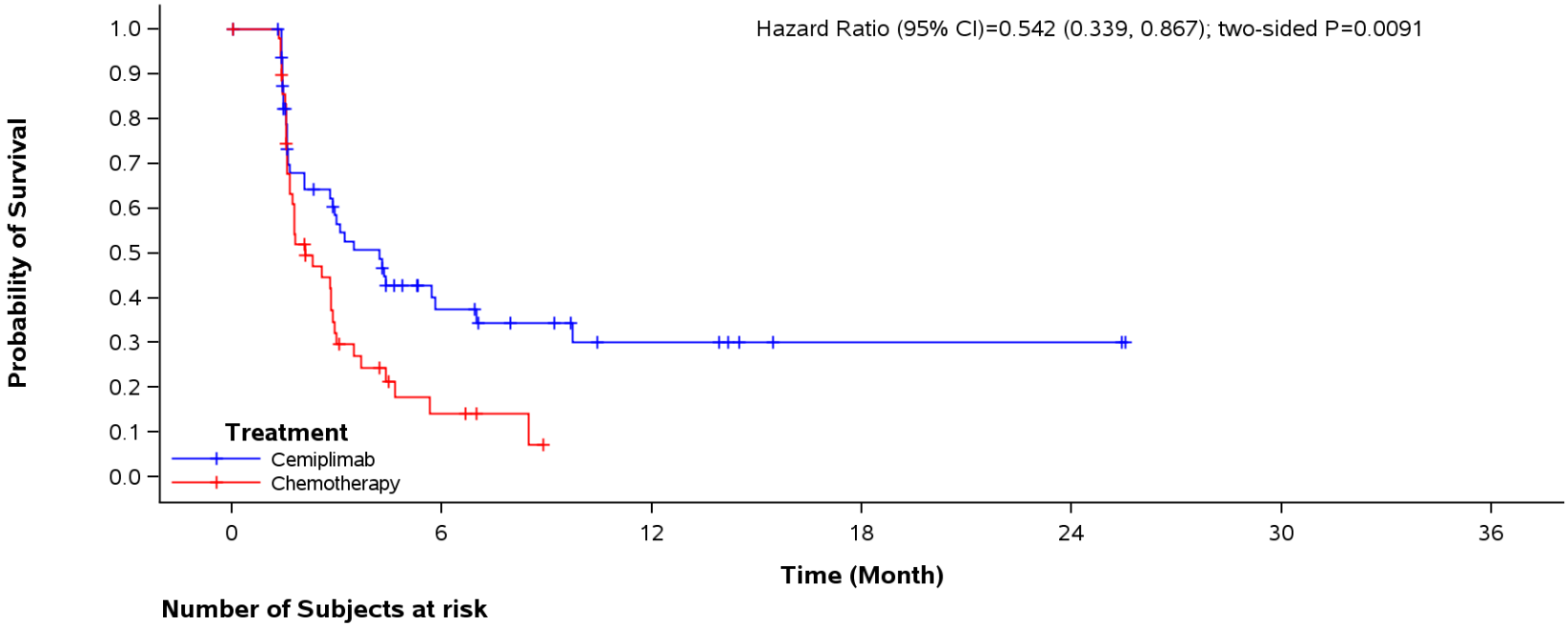

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 22 | 8 | 2 | 0 | 0 | 0 |
| Chemotherapy | 85 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts deterioration



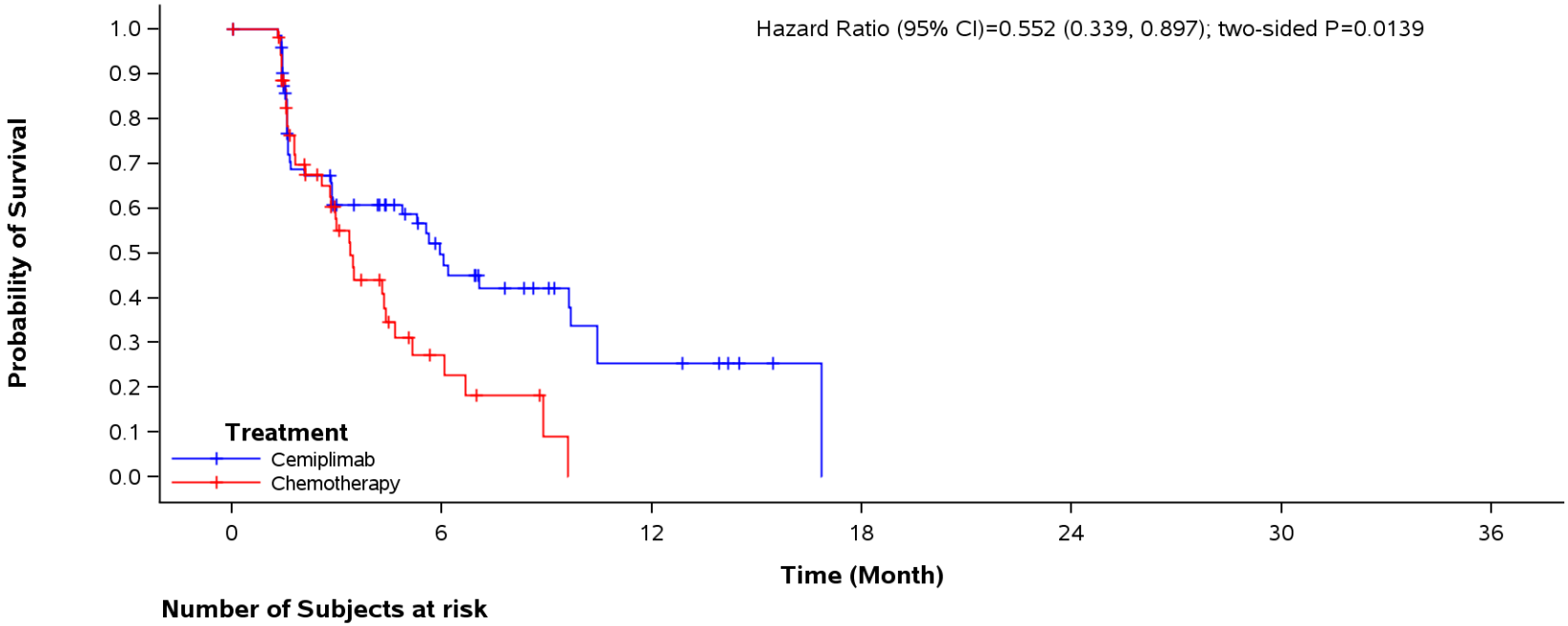

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 14 | 6 | 2 | 2 | 0 | 0 |
| Chemotherapy | 85 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Physical Functioning - 10 pts deterioration



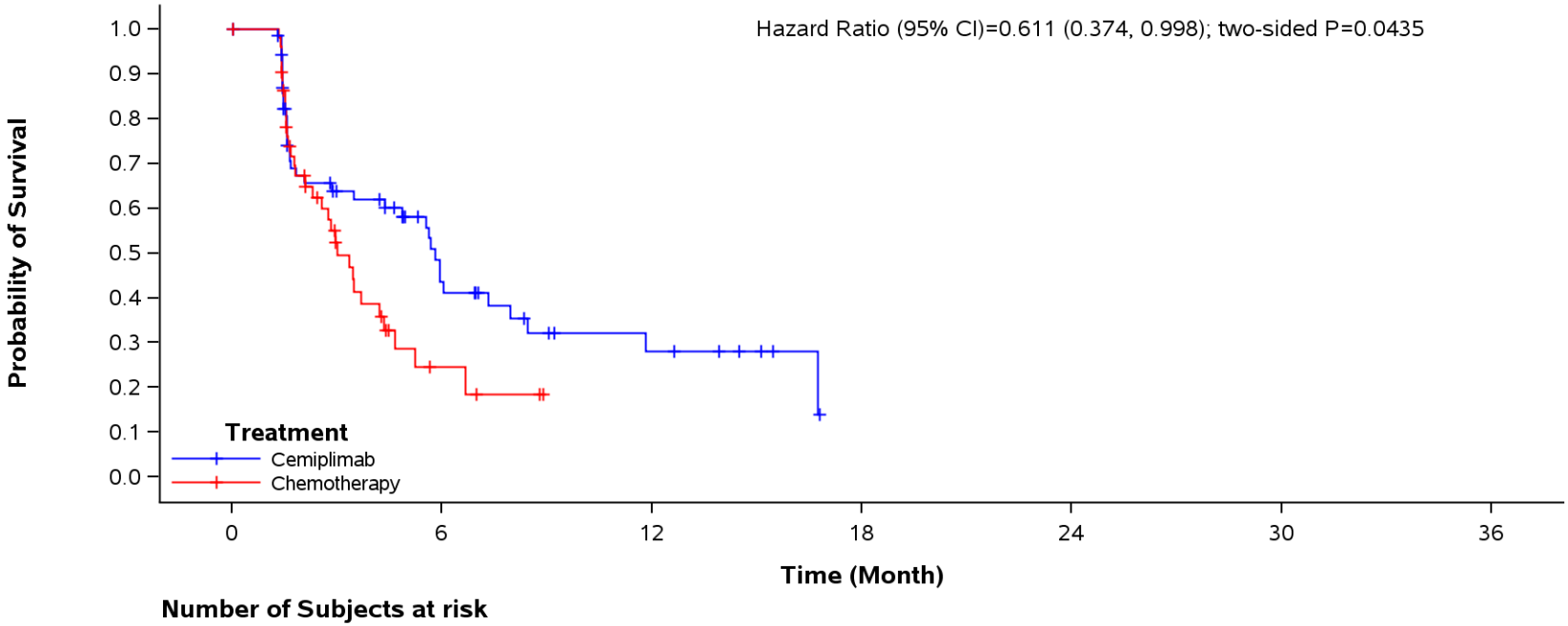

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 21 | 6 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Global health status / QoL - 10 pts deterioration



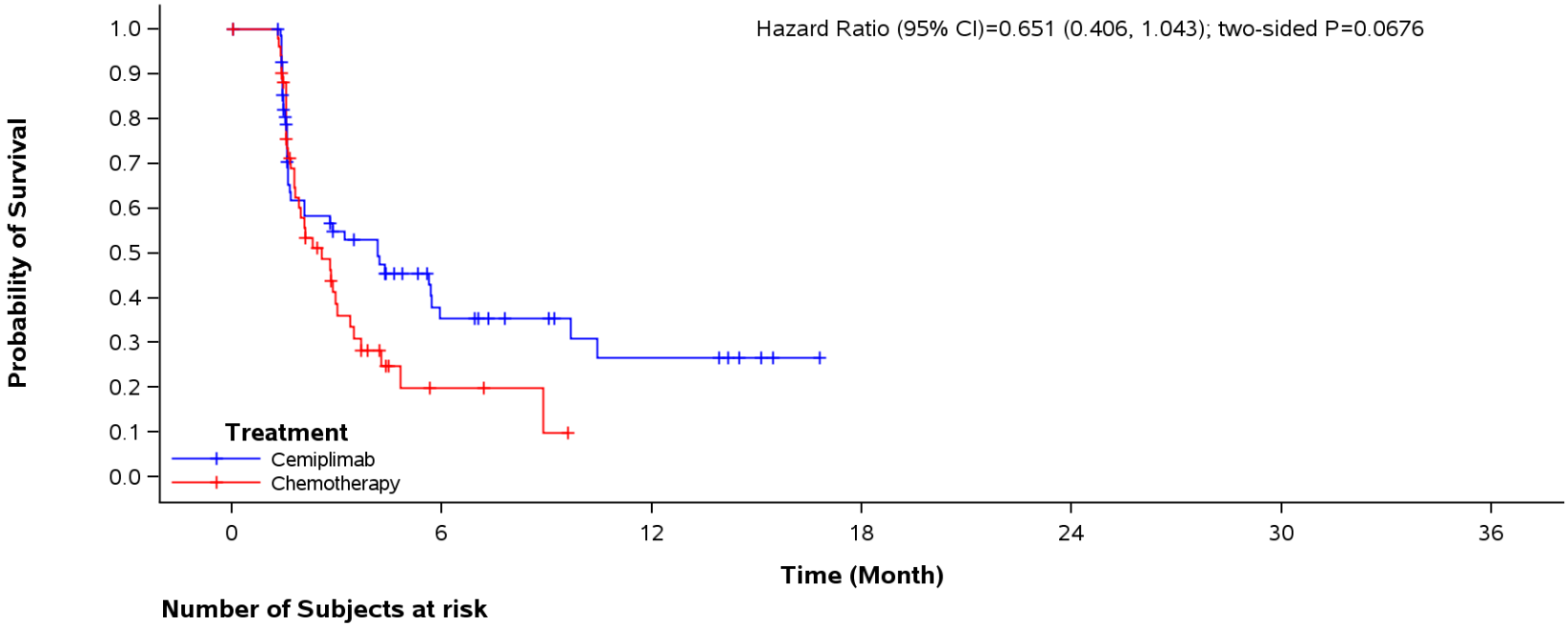

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 18 | 7 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts deterioration



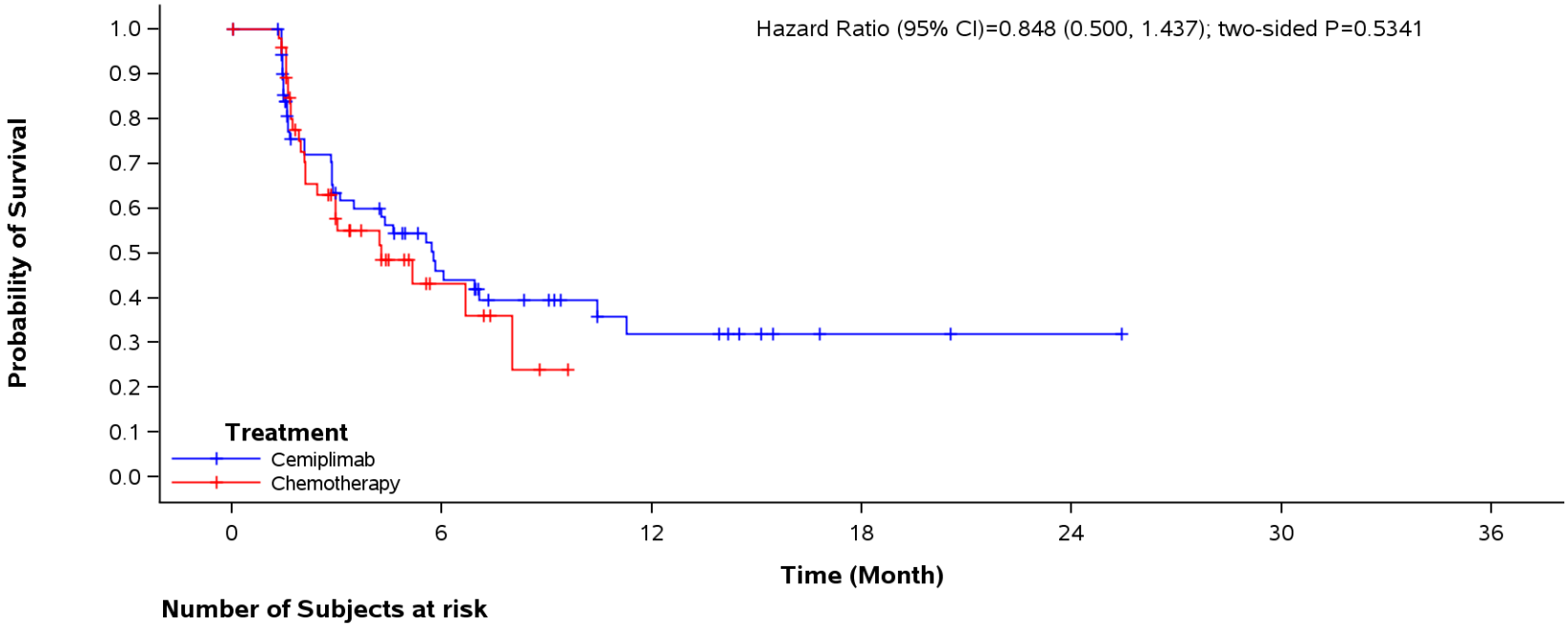

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 14 | 6 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts deterioration



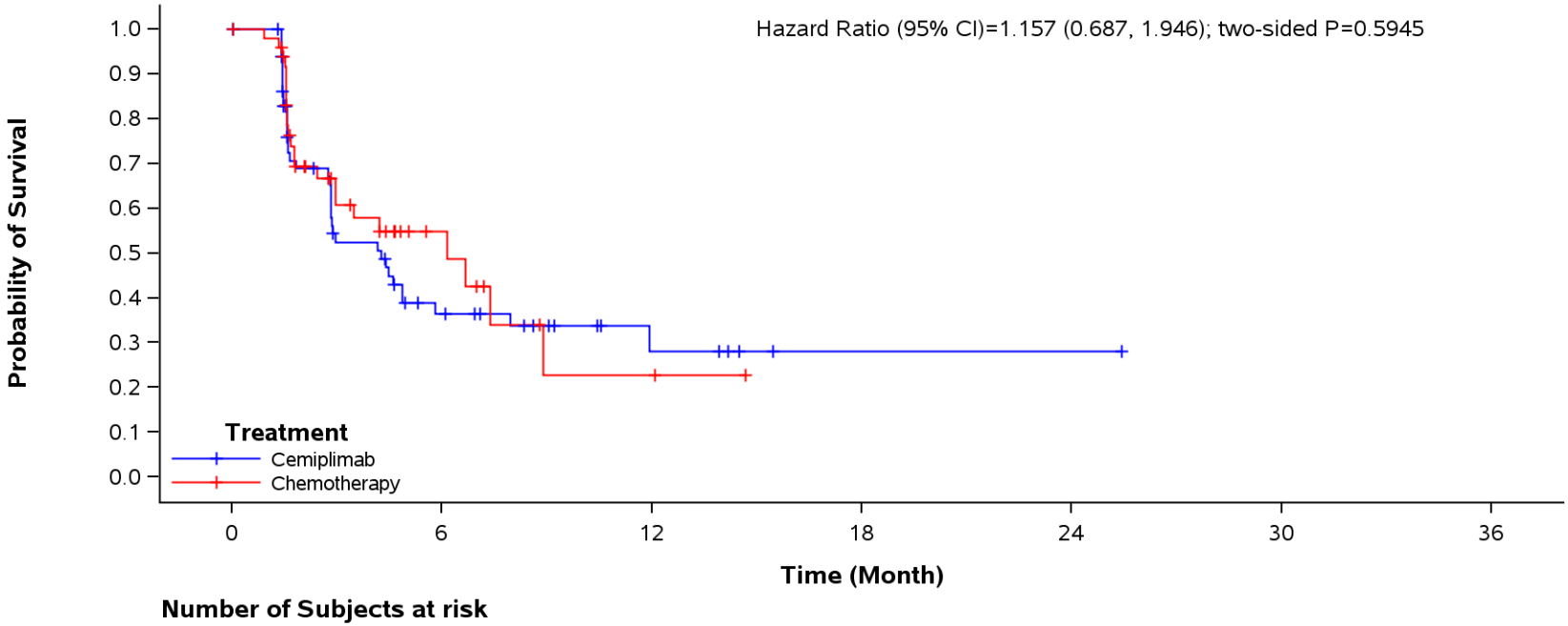

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 22 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 85 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts deterioration



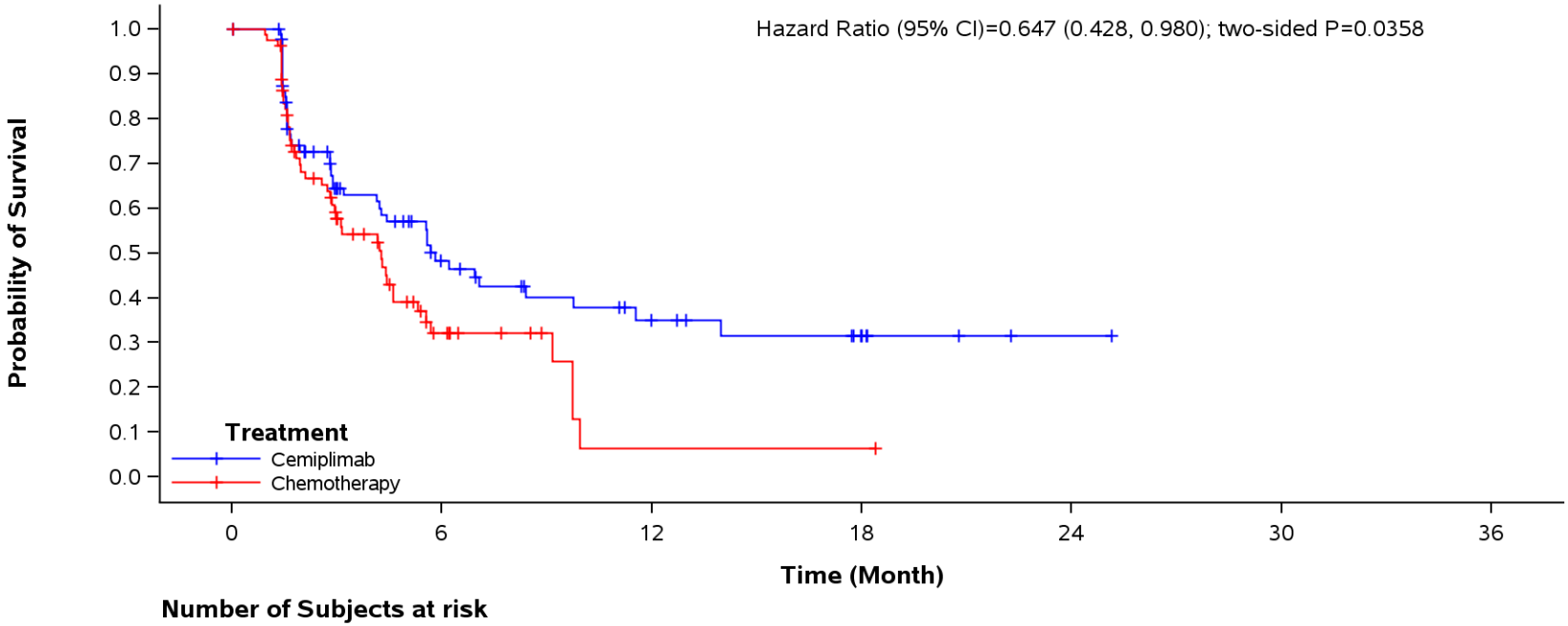

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 16 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 85 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts deterioration



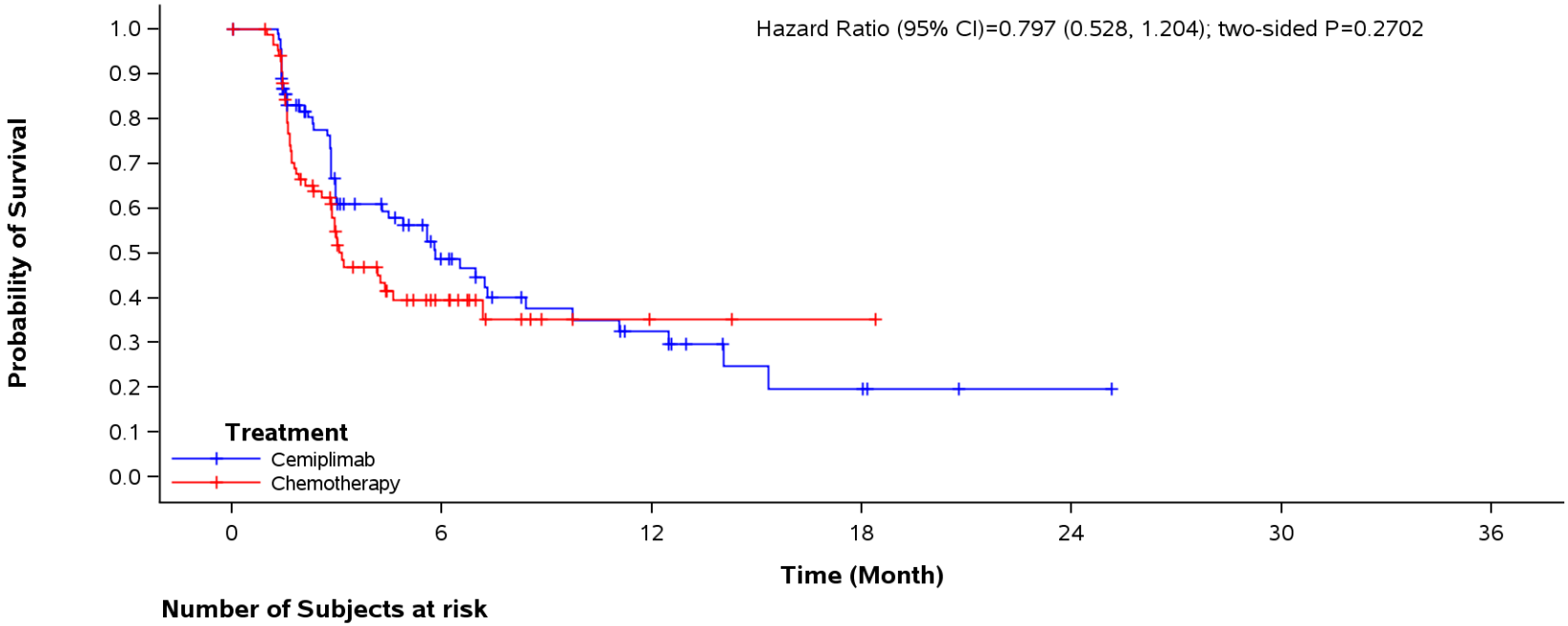

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 26 | 12 | 6 | 1 | 0 | 0 |
| Chemotherapy | 98 | 12 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts deterioration



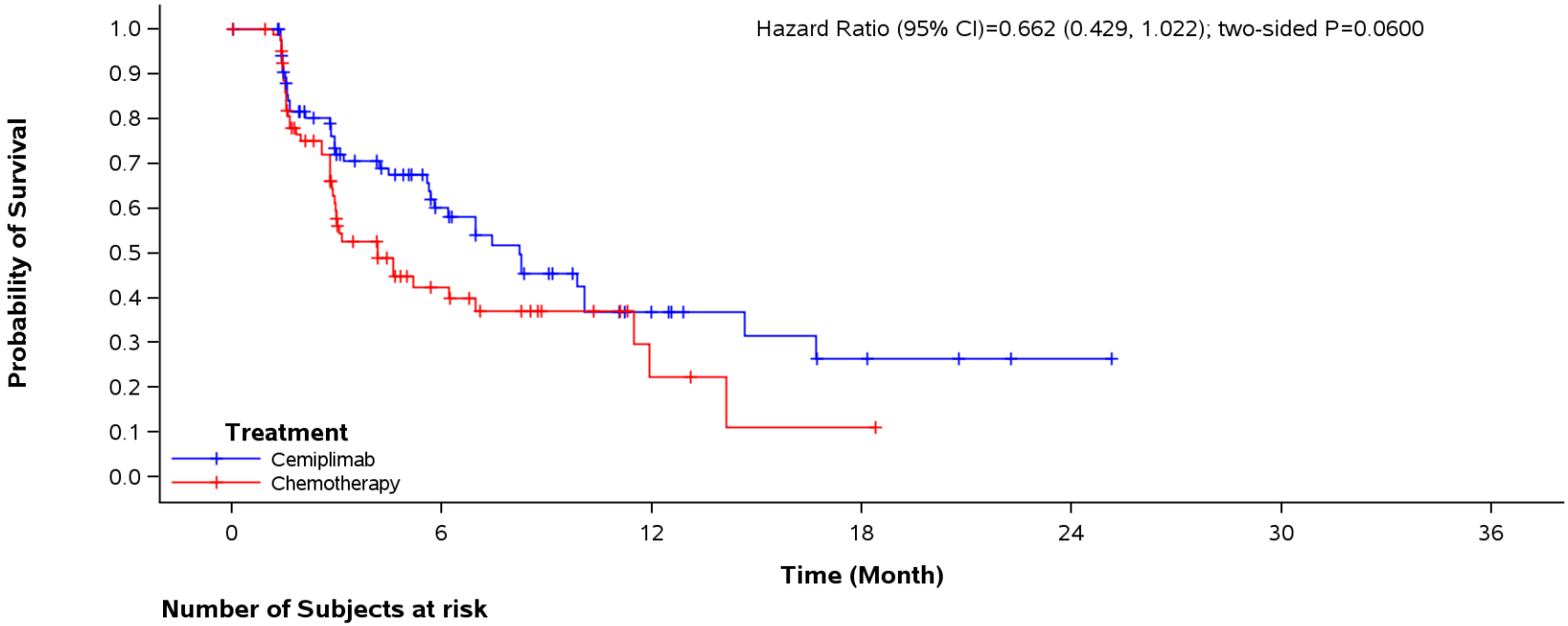

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 25 | 11 | 4 | 1 | 0 | 0 |
| Chemotherapy | 98 | 15 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts deterioration



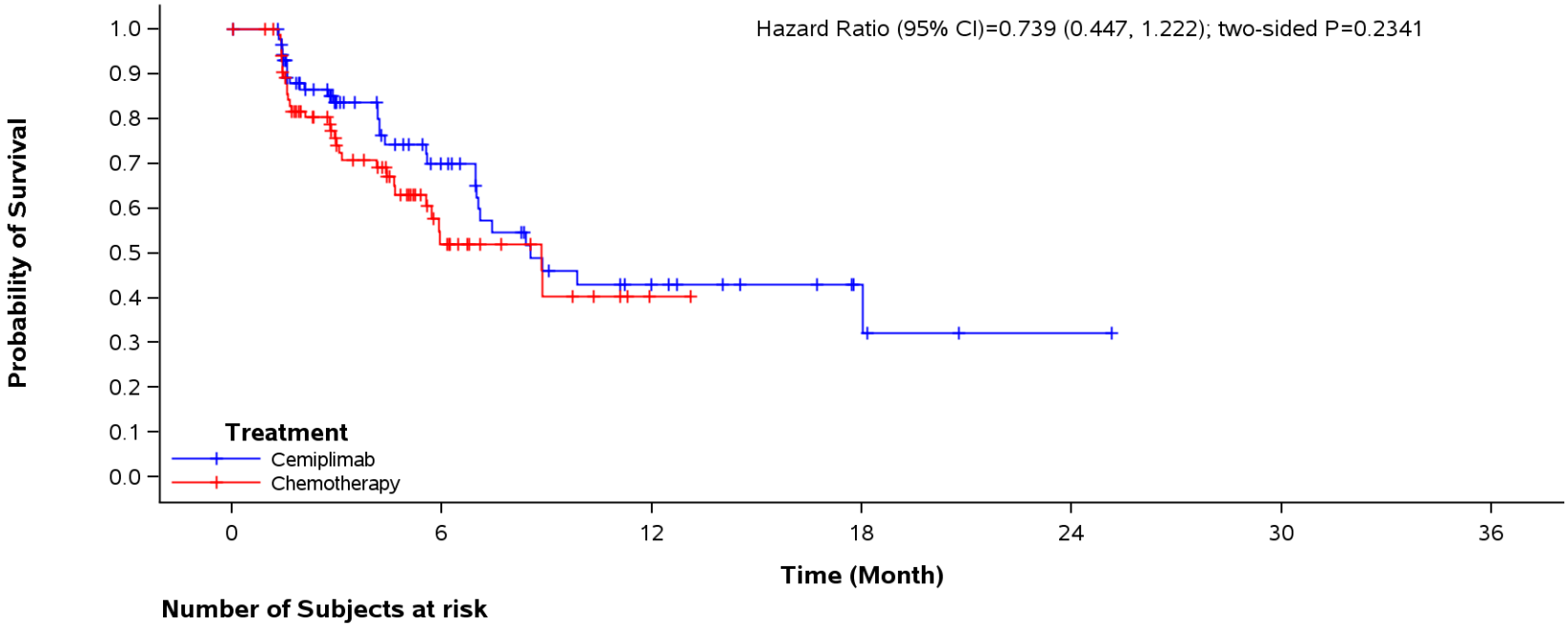

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 31 | 10 | 4 | 1 | 0 | 0 |
| Chemotherapy | 98 | 17 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts deterioration



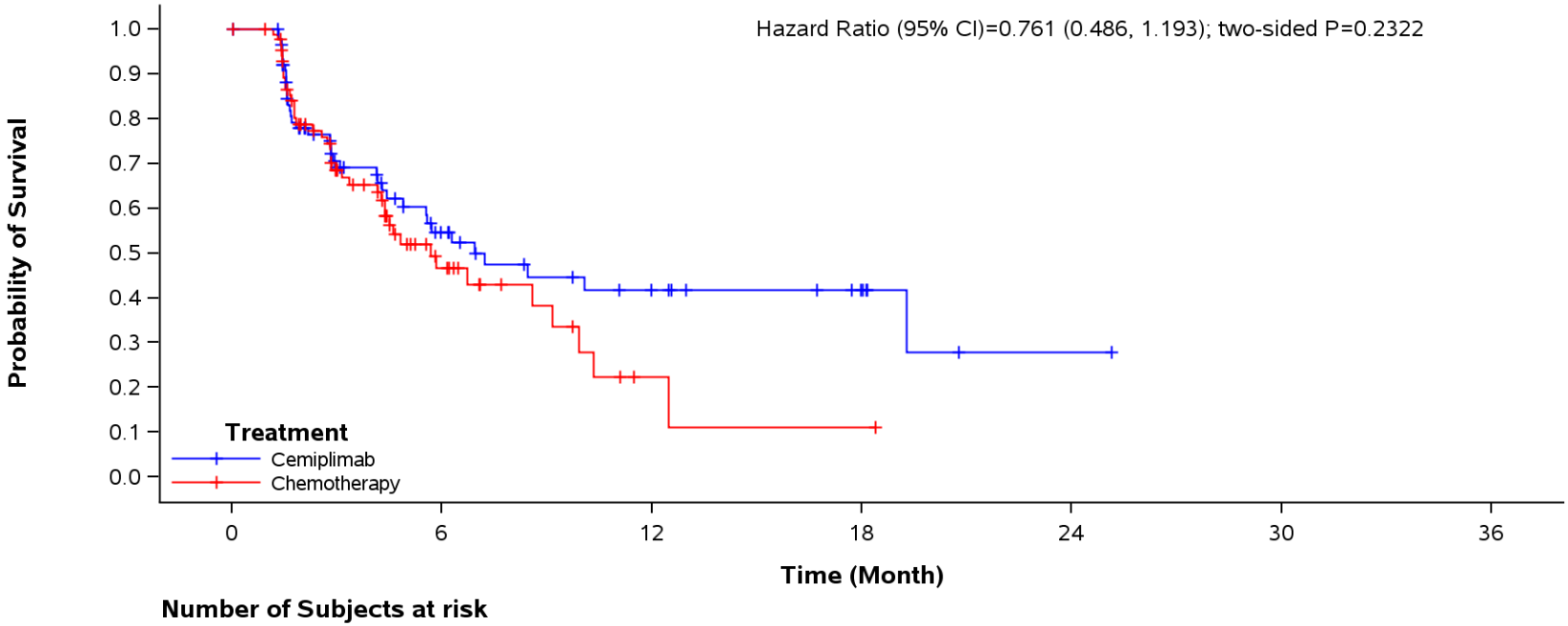

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 31 | 11 | 4 | 1 | 0 | 0 |
| Chemotherapy | 98 | 18 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Dyspnoea - 10 pts deterioration



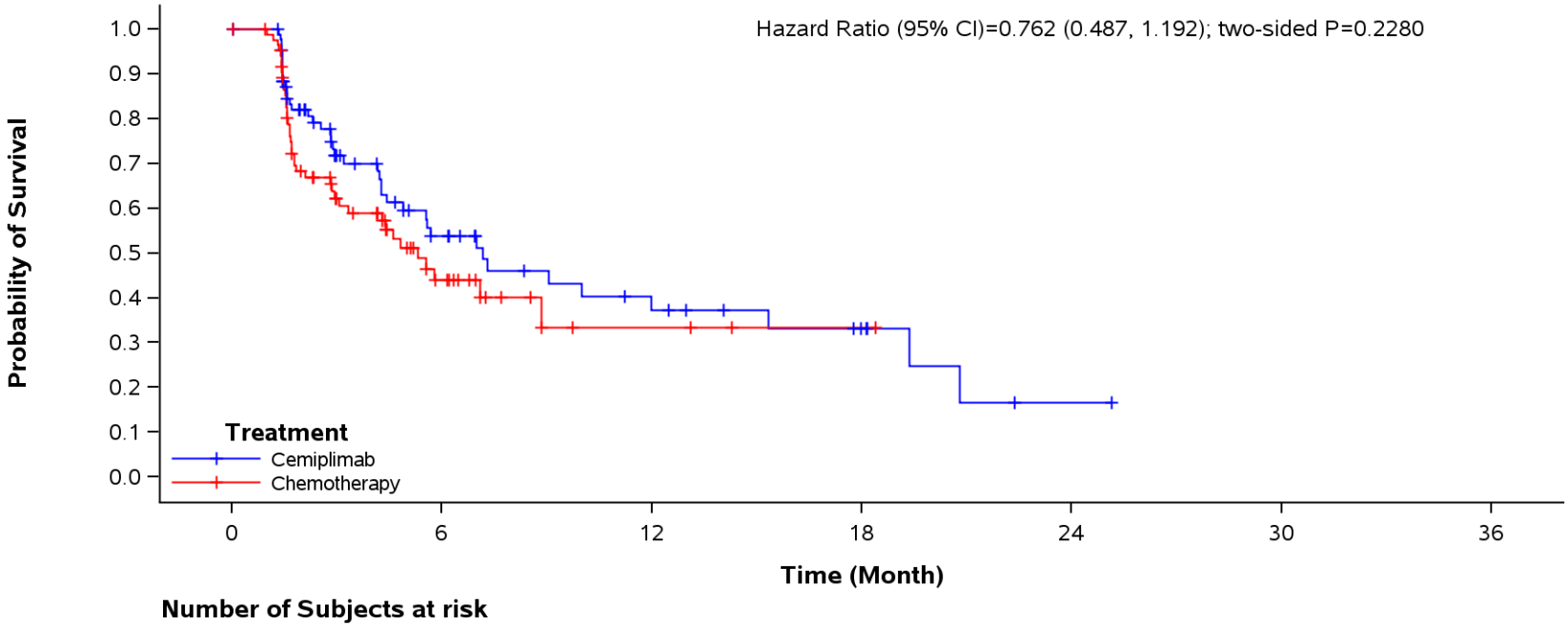

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 26 | 12 | 6 | 1 | 0 | 0 |
| Chemotherapy | 98 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Emotional Functioning - 10 pts deterioration



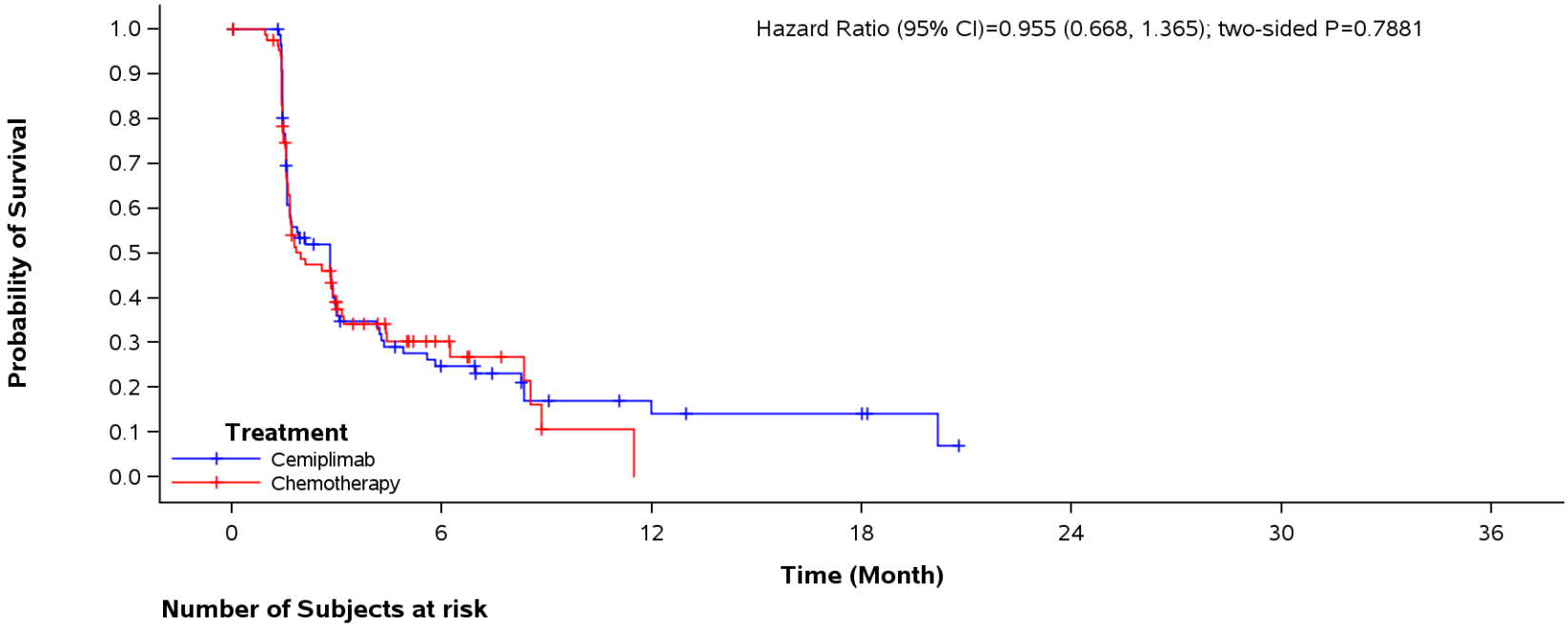

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 27 | 12 | 6 | 1 | 0 | 0 |
| Chemotherapy | 98 | 17 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts deterioration



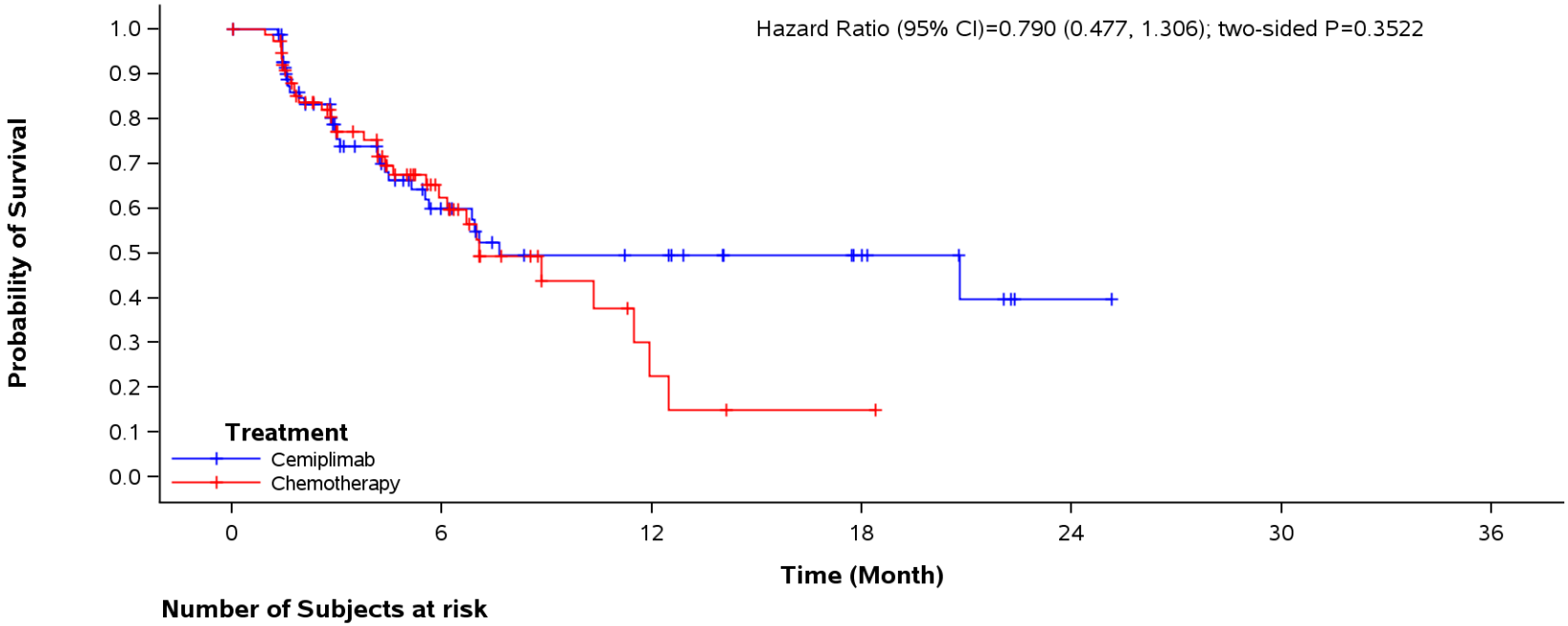

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 16 | 5 | 4 | 0 | 0 | 0 |
| Chemotherapy | 98 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts deterioration



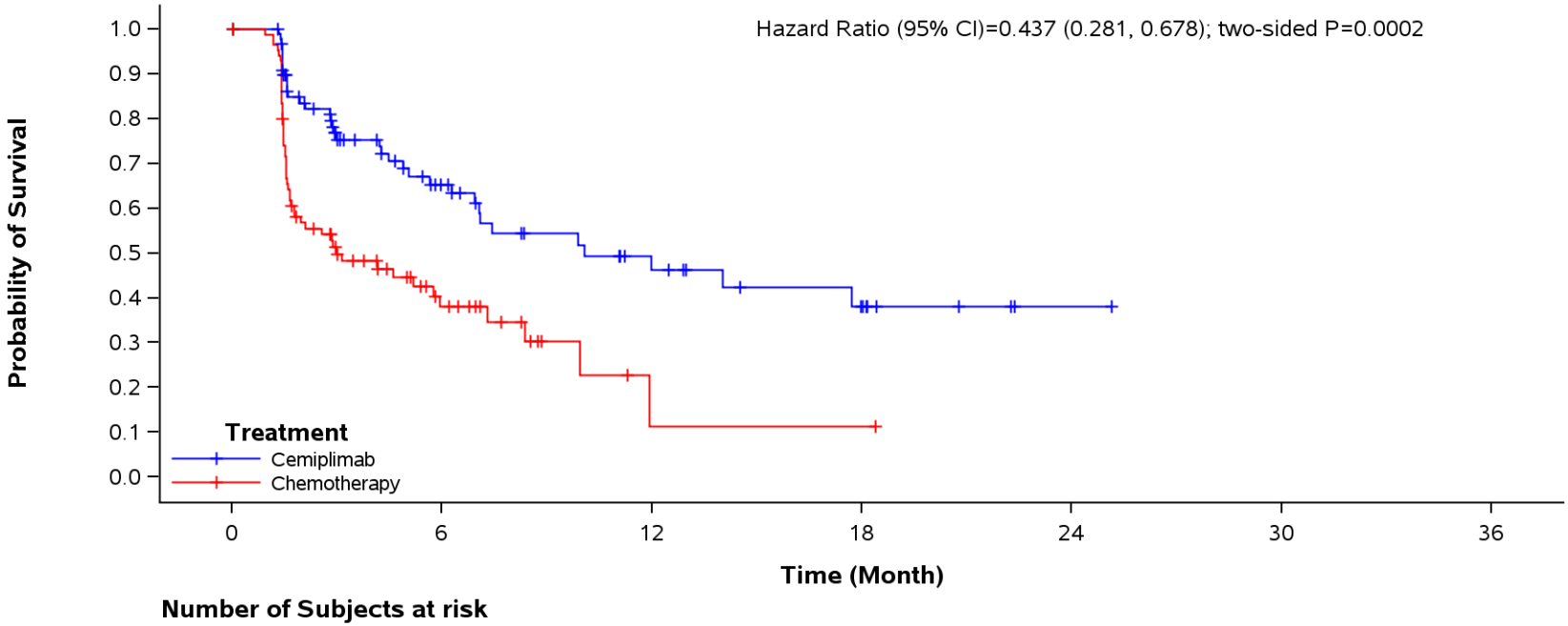

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 26 | 15 | 8 | 1 | 0 | 0 |
| Chemotherapy | 98 | 23 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts deterioration



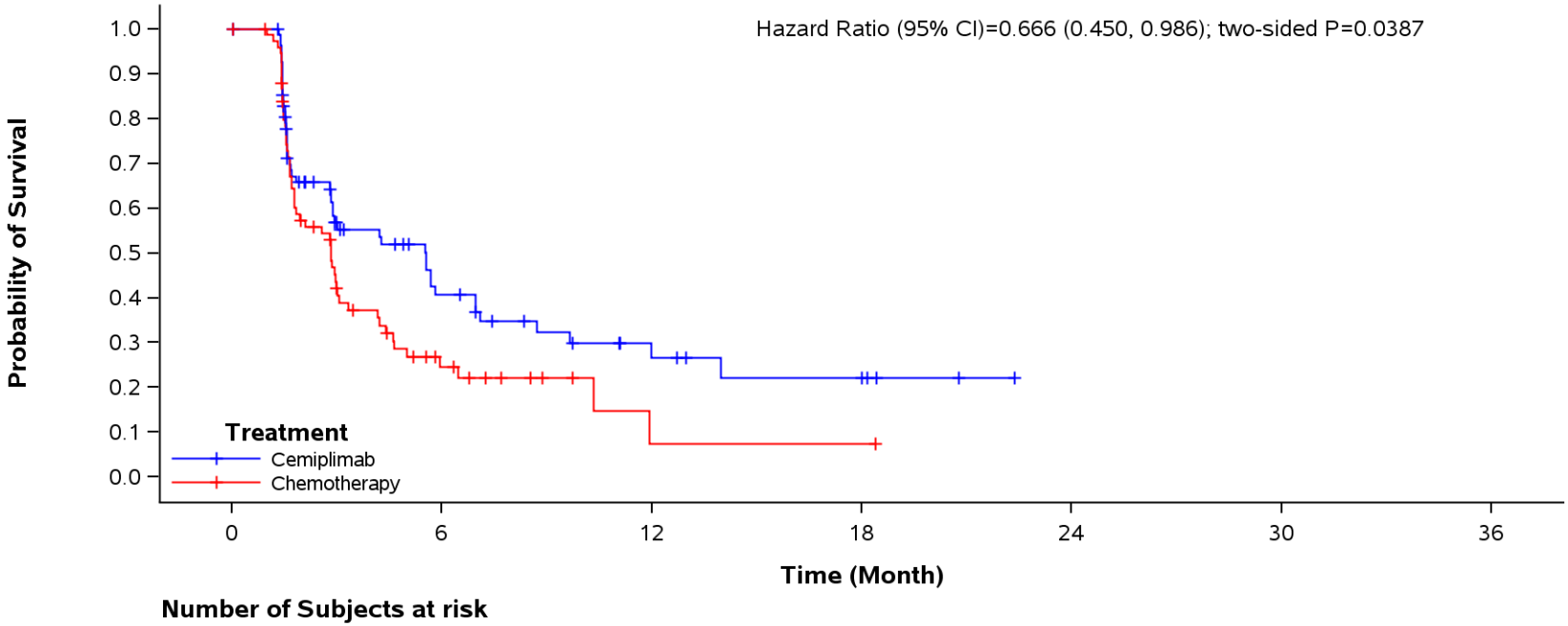

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 34 | 15 | 8 | 1 | 0 | 0 |
| Chemotherapy | 98 | 16 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts deterioration



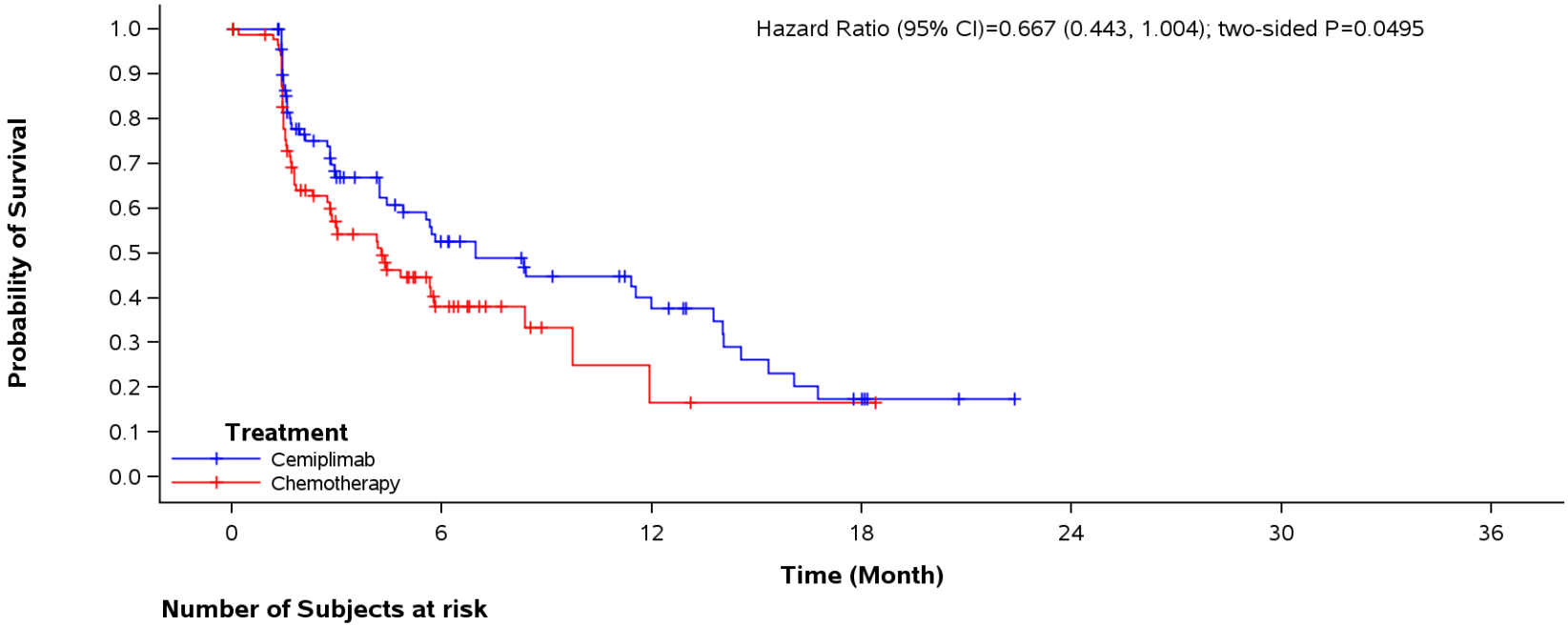

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 22 | 8 | 5 | 0 | 0 | 0 |
| Chemotherapy | 98 | 11 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Physical Functioning - 10 pts deterioration



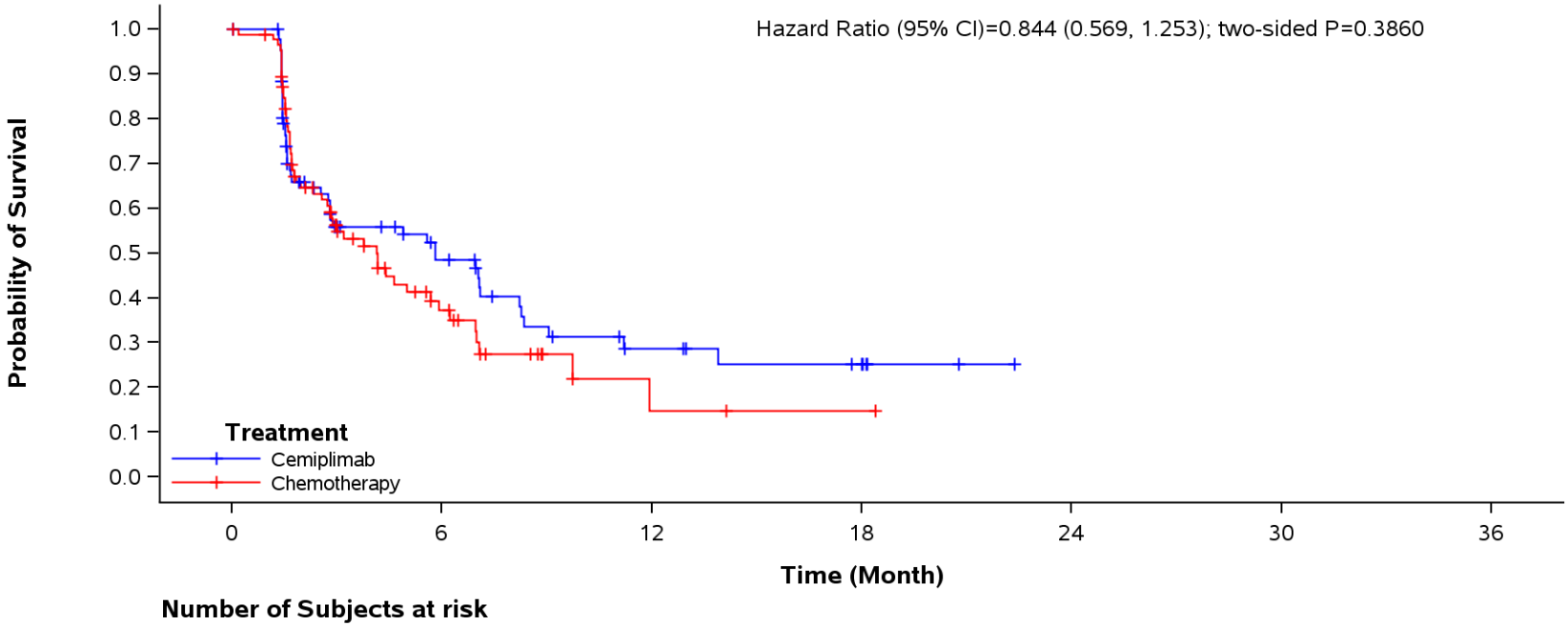

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 31 | 16 | 5 | 0 | 0 | 0 |
| Chemotherapy | 98 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Global health status / QoL - 10 pts deterioration



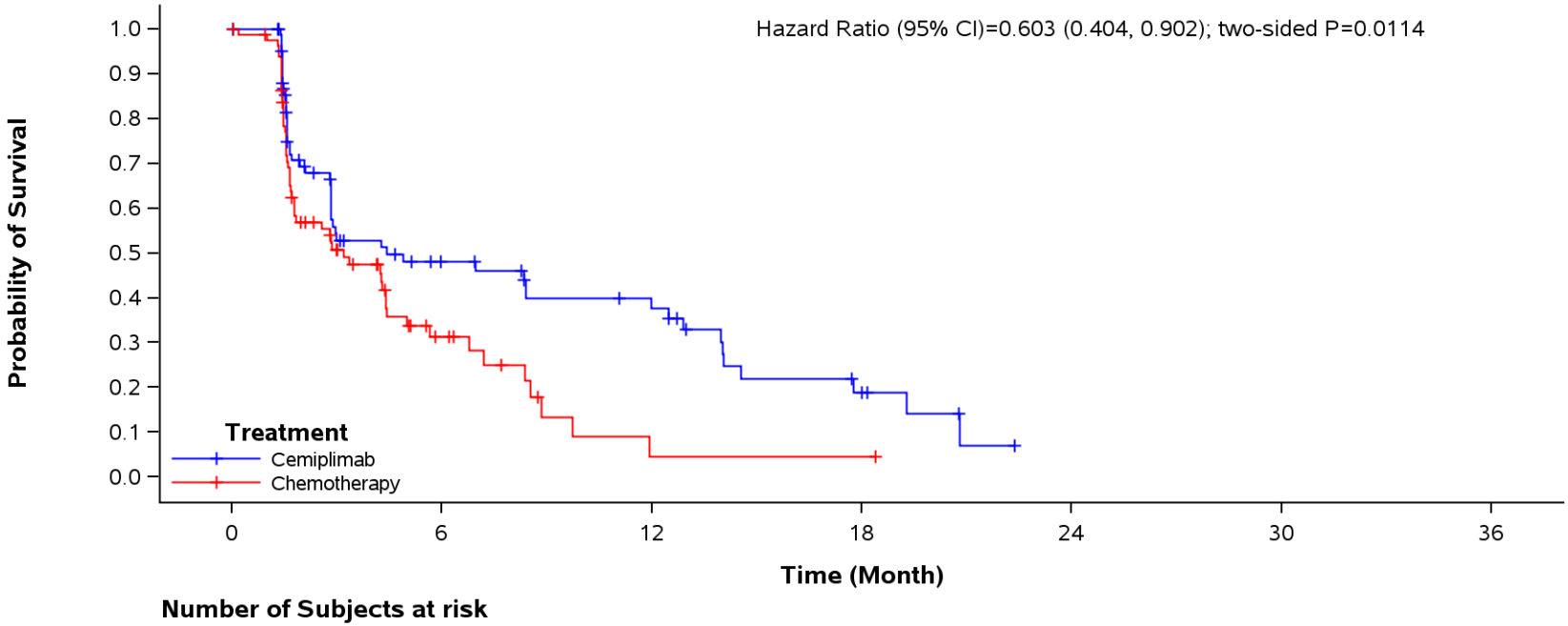

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 26 | 10 | 6 | 0 | 0 | 0 |
| Chemotherapy | 98 | 18 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts deterioration



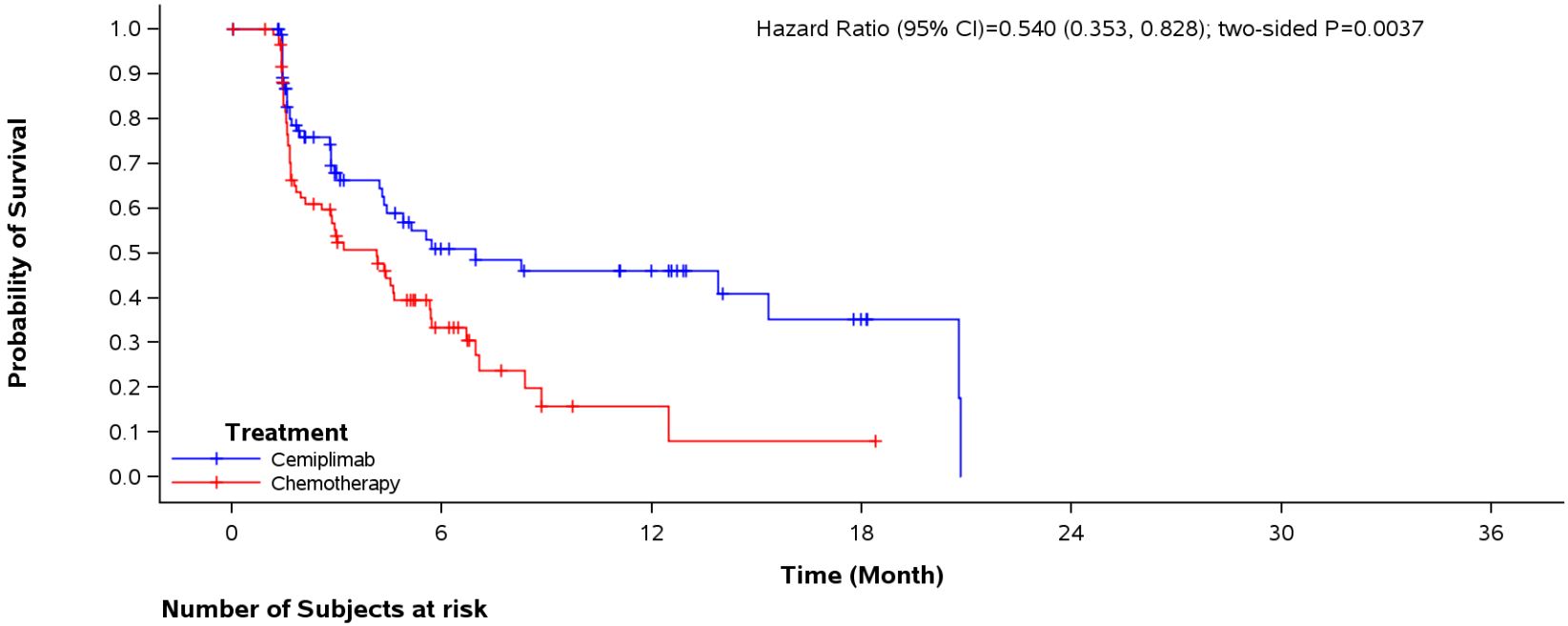

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 26 | 17 | 6 | 0 | 0 | 0 |
| Chemotherapy | 98 | 12 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts deterioration



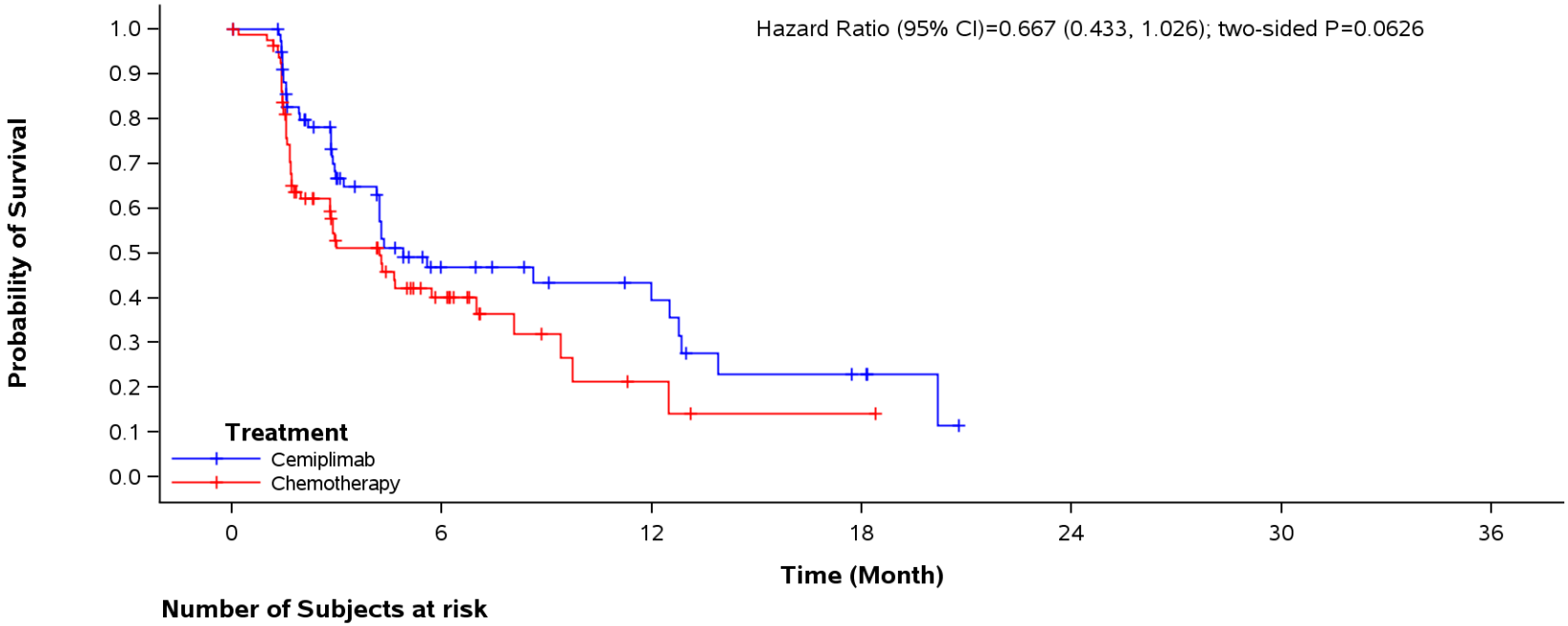

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 23 | 14 | 4 | 0 | 0 | 0 |
| Chemotherapy | 98 | 15 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts deterioration



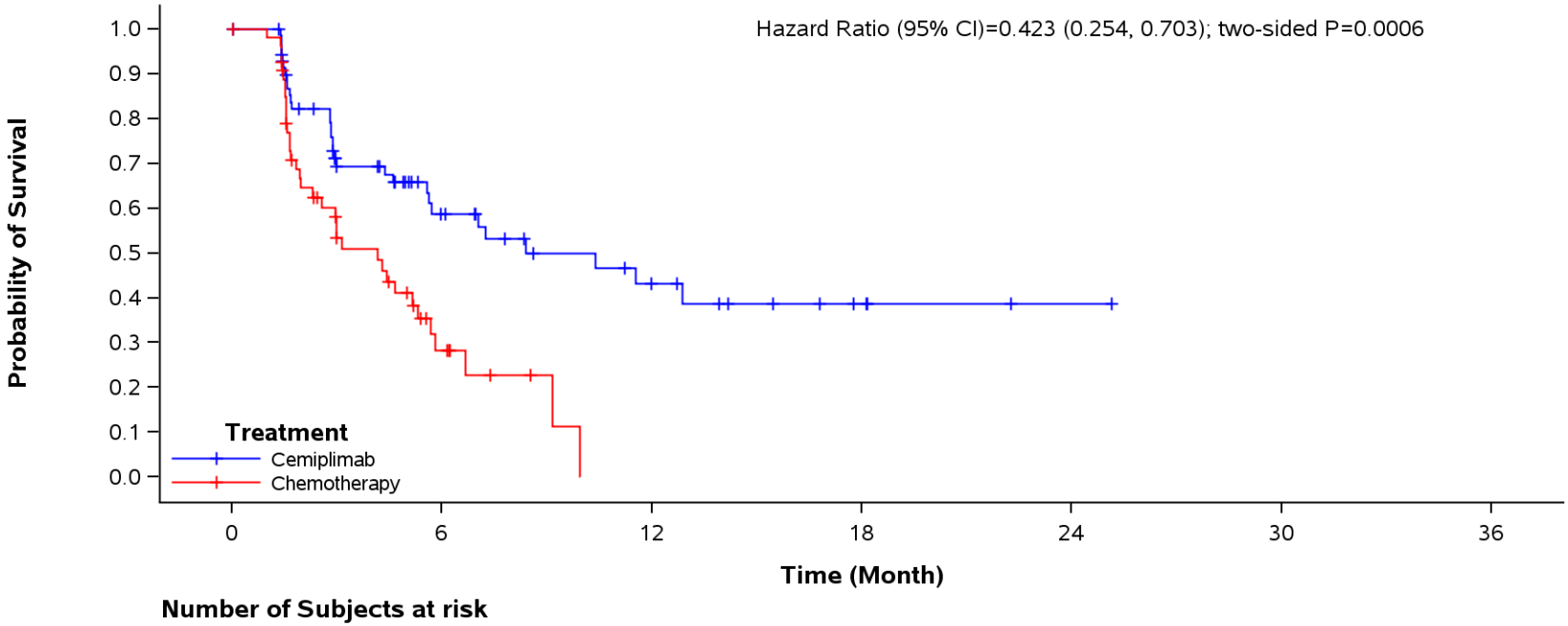

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 18 | 10 | 4 | 0 | 0 | 0 |
| Chemotherapy | 98 | 17 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Appetite loss - 10 pts deterioration



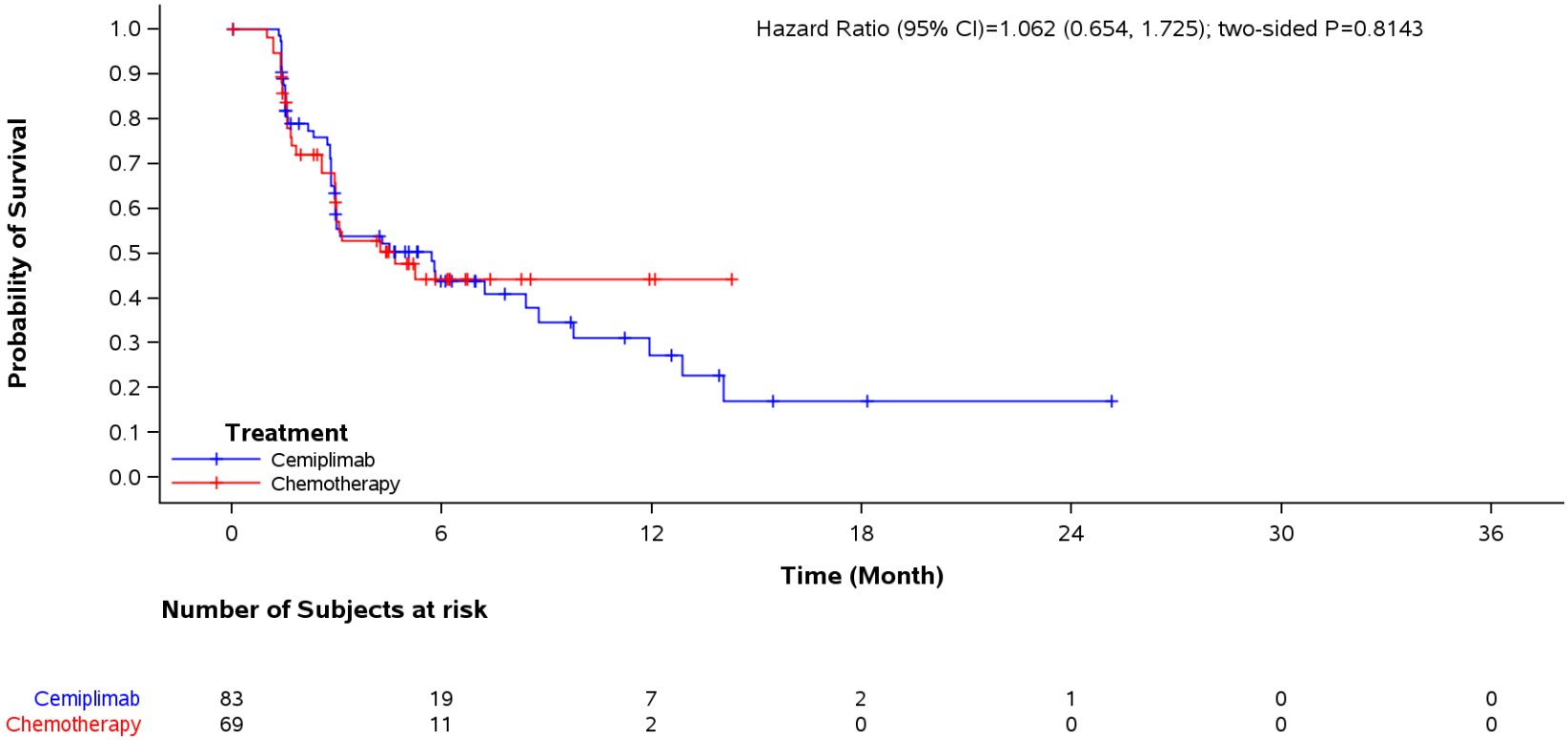

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 24 | 11 | 4 | 1 | 0 | 0 |
| Chemotherapy | 69 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts deterioration



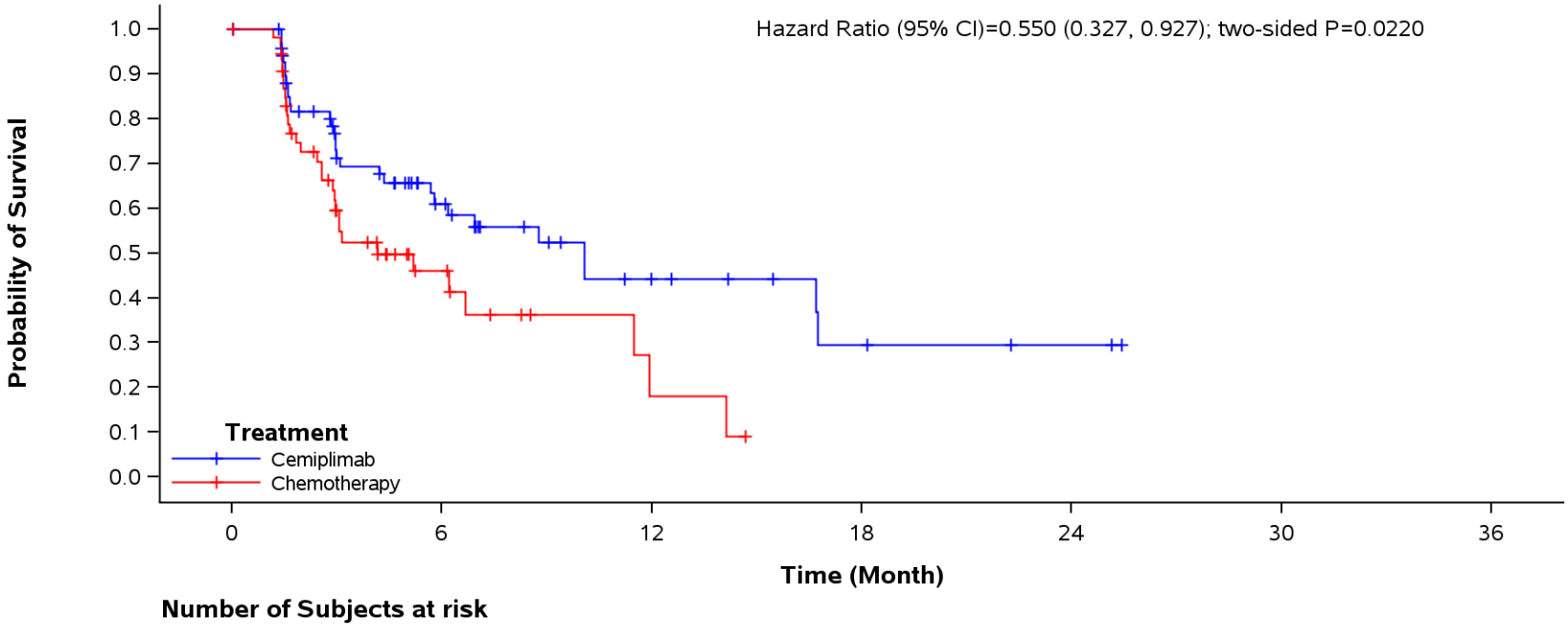

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 19 | 7 | 2 | 1 | 0 | 0 |
| Chemotherapy | 69 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts deterioration



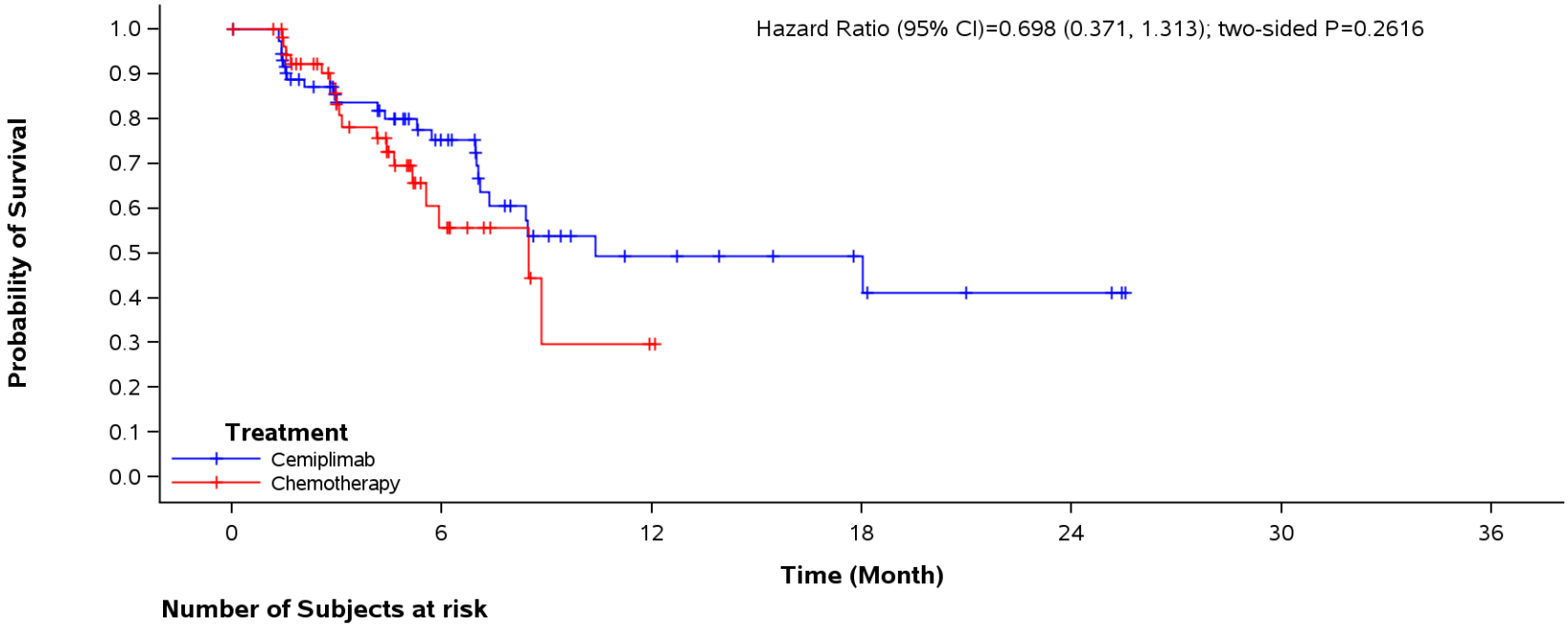

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 25 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 69 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Diarhoea - 10 pts deterioration



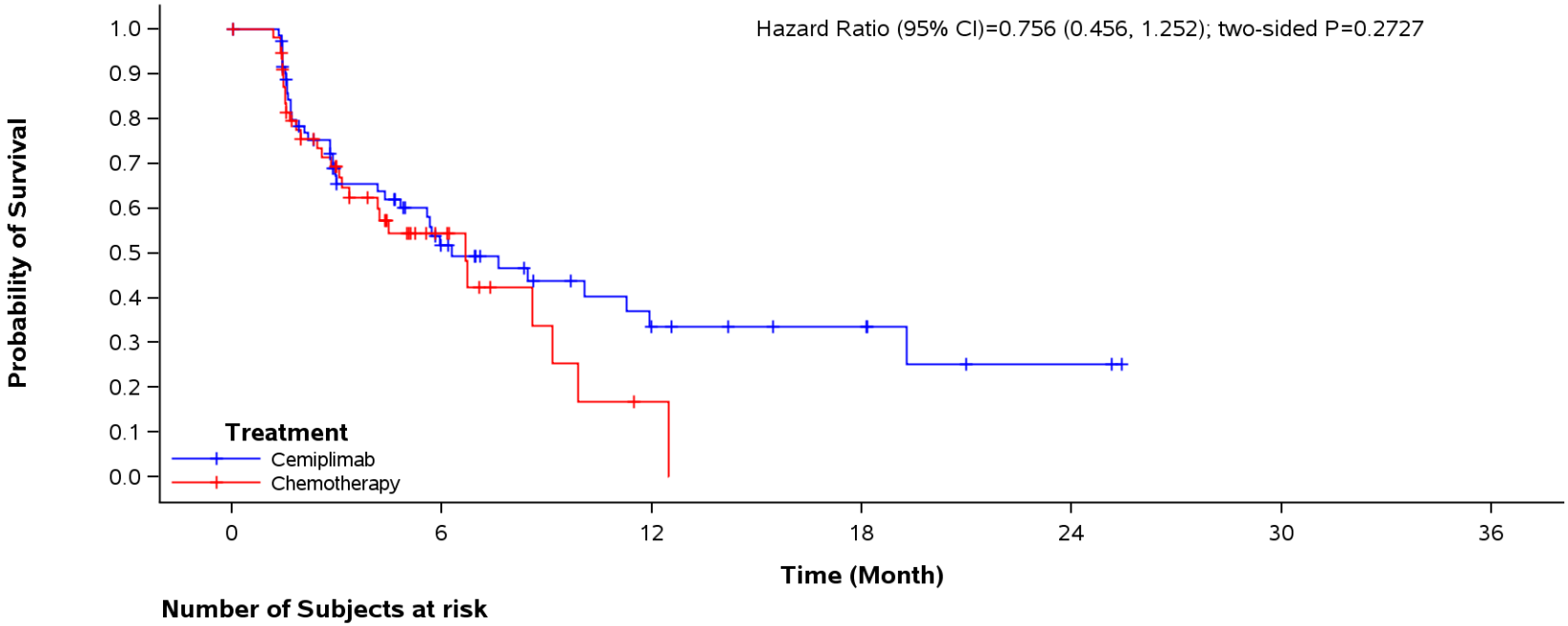

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 30 | 10 | 6 | 3 | 0 | 0 |
| Chemotherapy | 69 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Dyspnoea - 10 pts deterioration



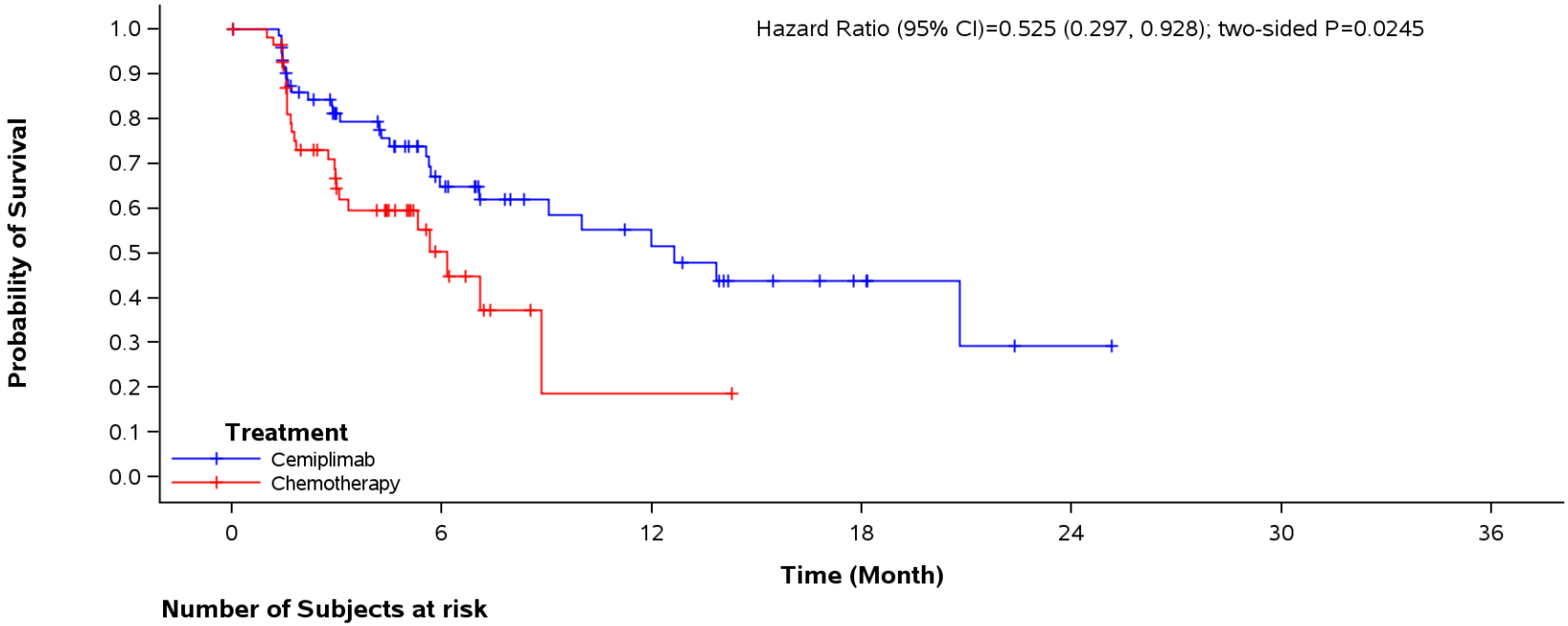

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 23 | 9 | 6 | 2 | 0 | 0 |
| Chemotherapy | 69 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Emotional Functioning - 10 pts deterioration



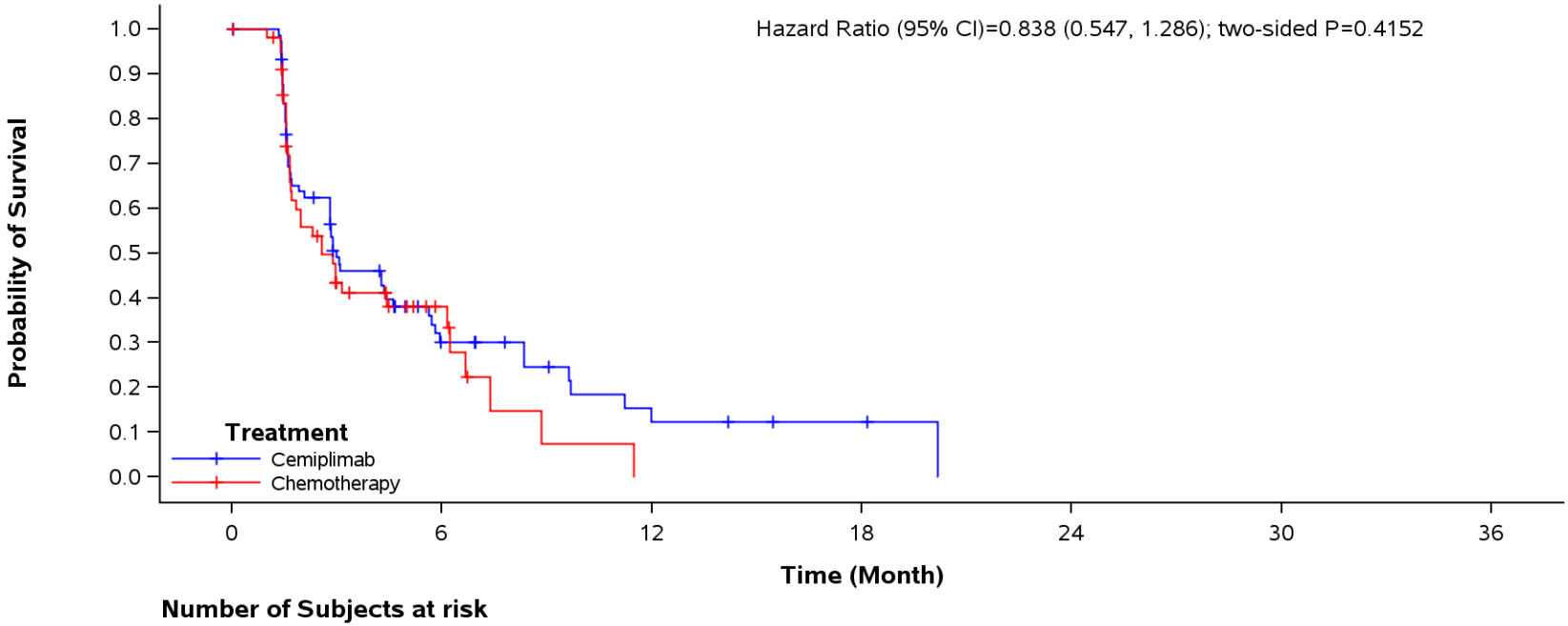

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 28 | 14 | 5 | 1 | 0 | 0 |
| Chemotherapy | 69 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts deterioration



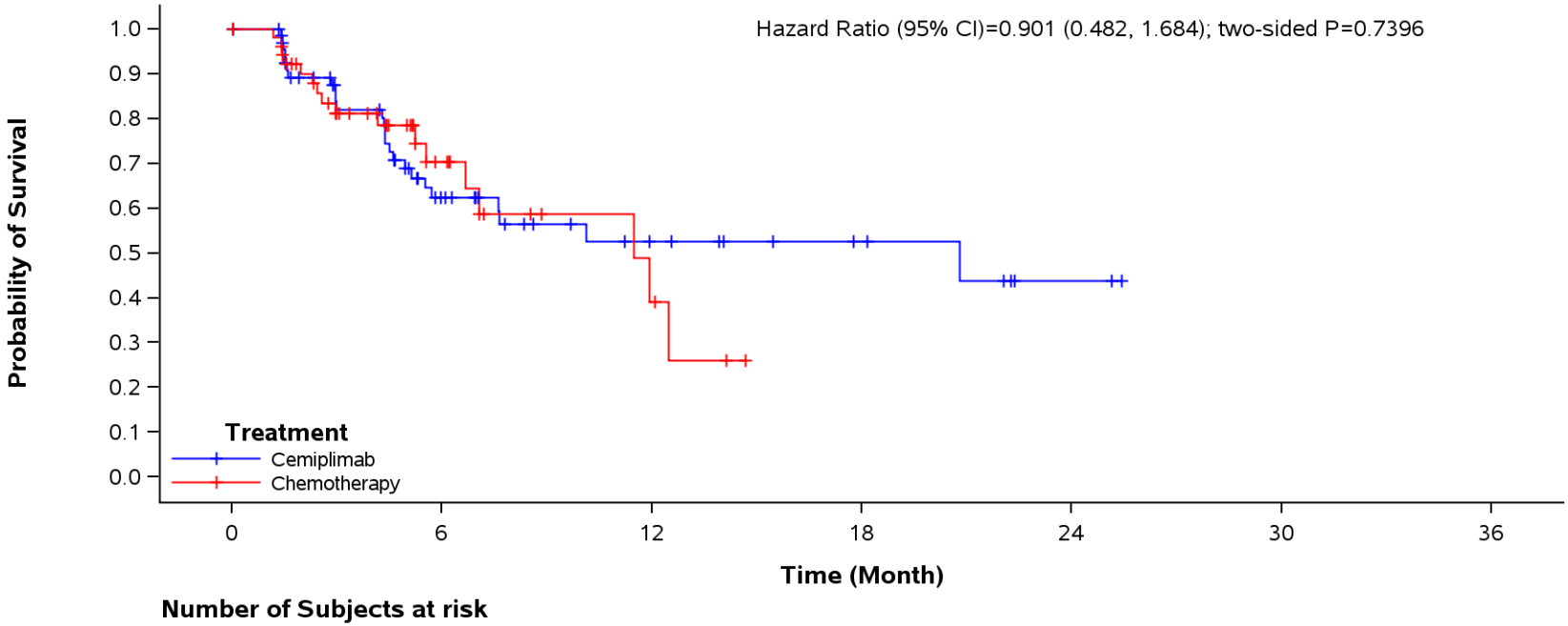

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 14 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 69 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts deterioration



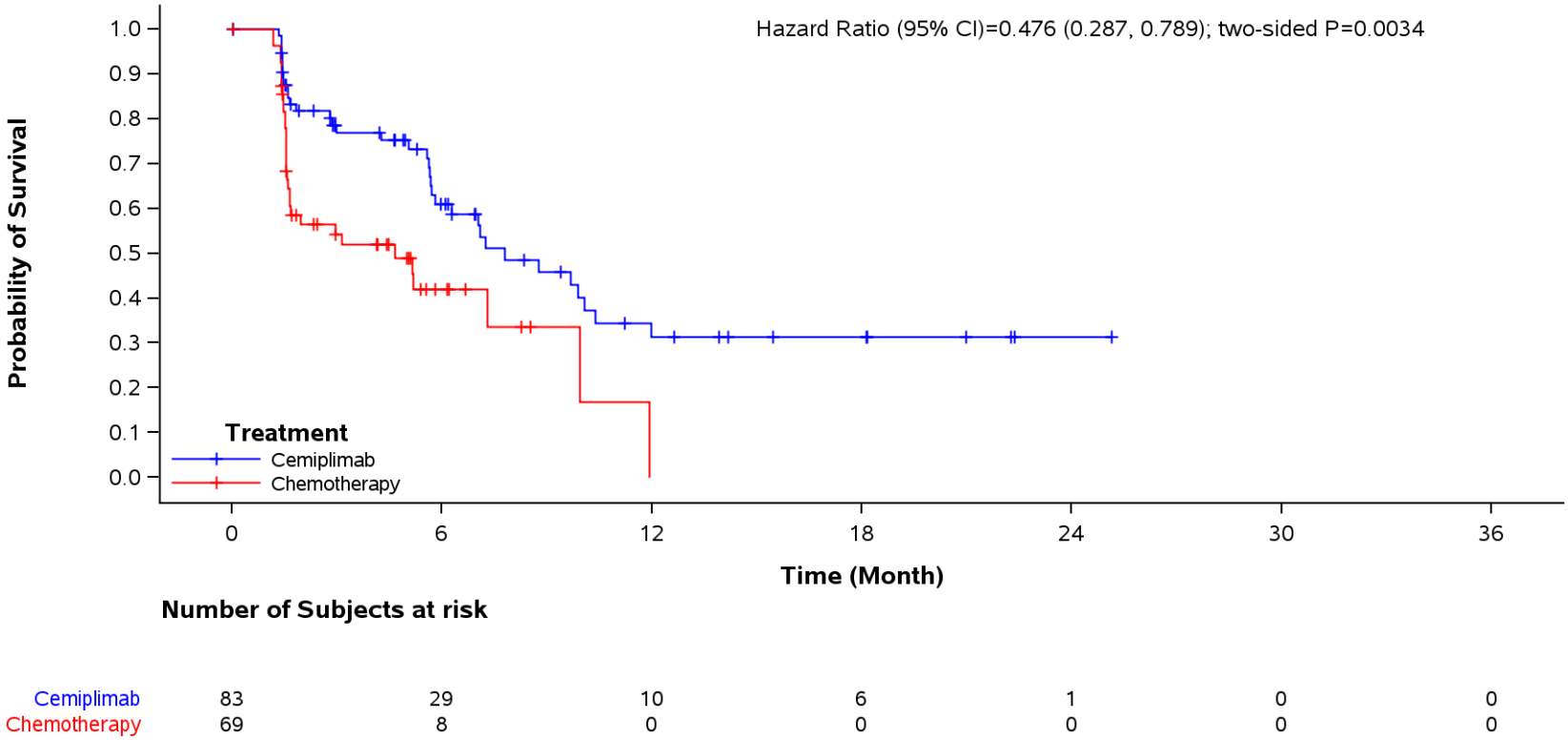

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 26 | 12 | 7 | 2 | 0 | 0 |
| Chemotherapy | 69 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts deterioration



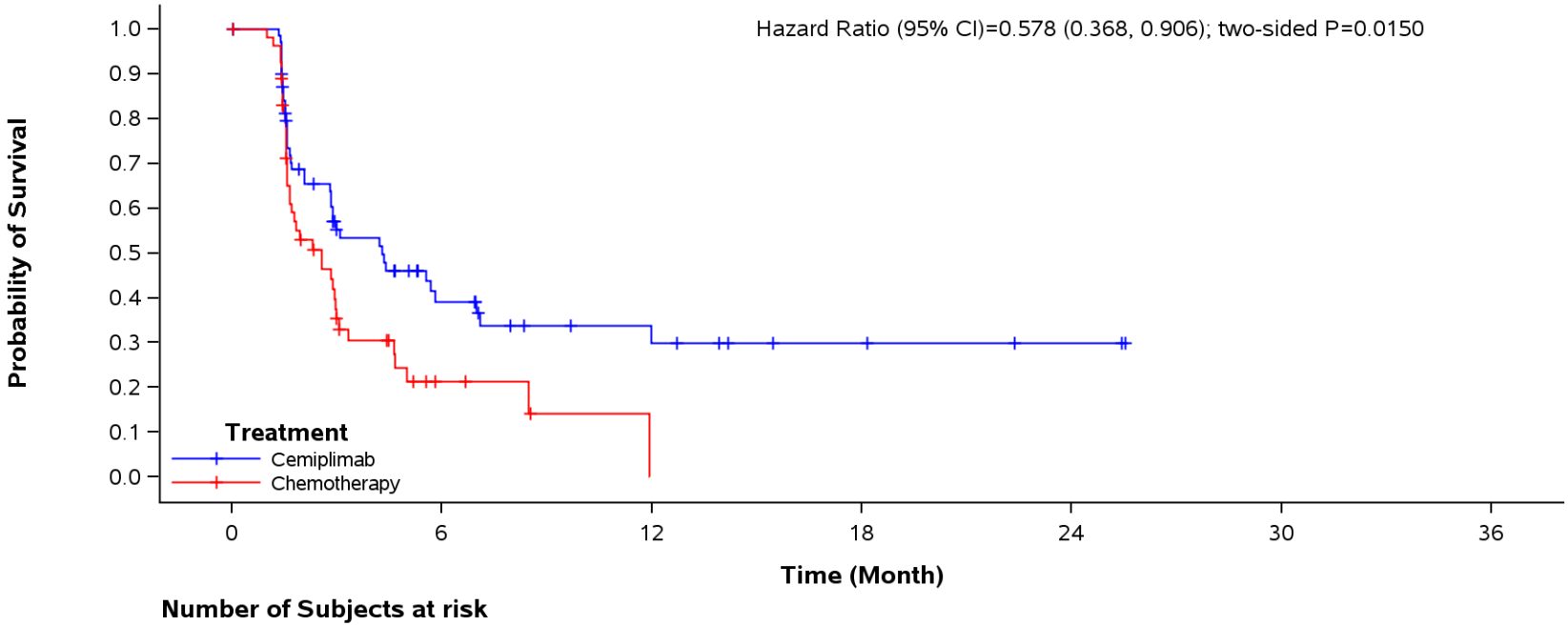

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 29 | 10 | 6 | 1 | 0 | 0 |
| Chemotherapy | 69 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts deterioration



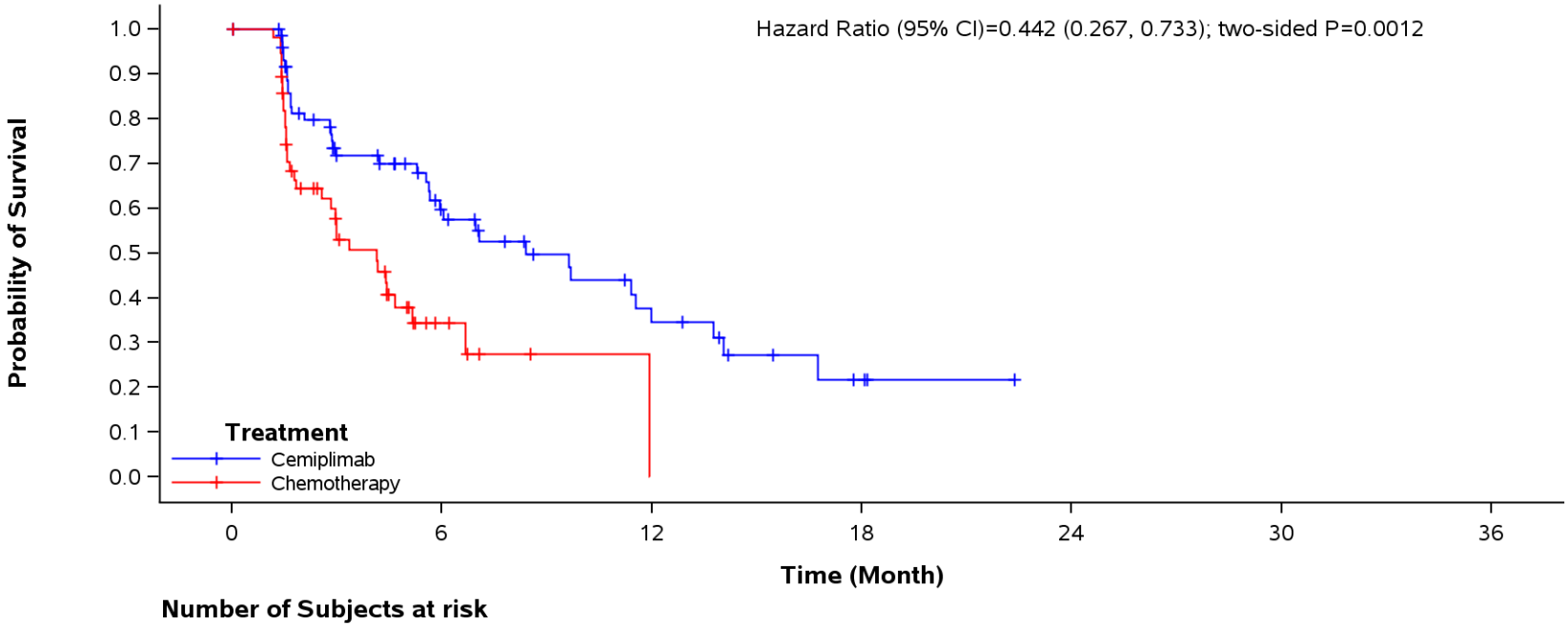

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 17 | 8 | 4 | 2 | 0 | 0 |
| Chemotherapy | 69 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Physical Functioning - 10 pts deterioration



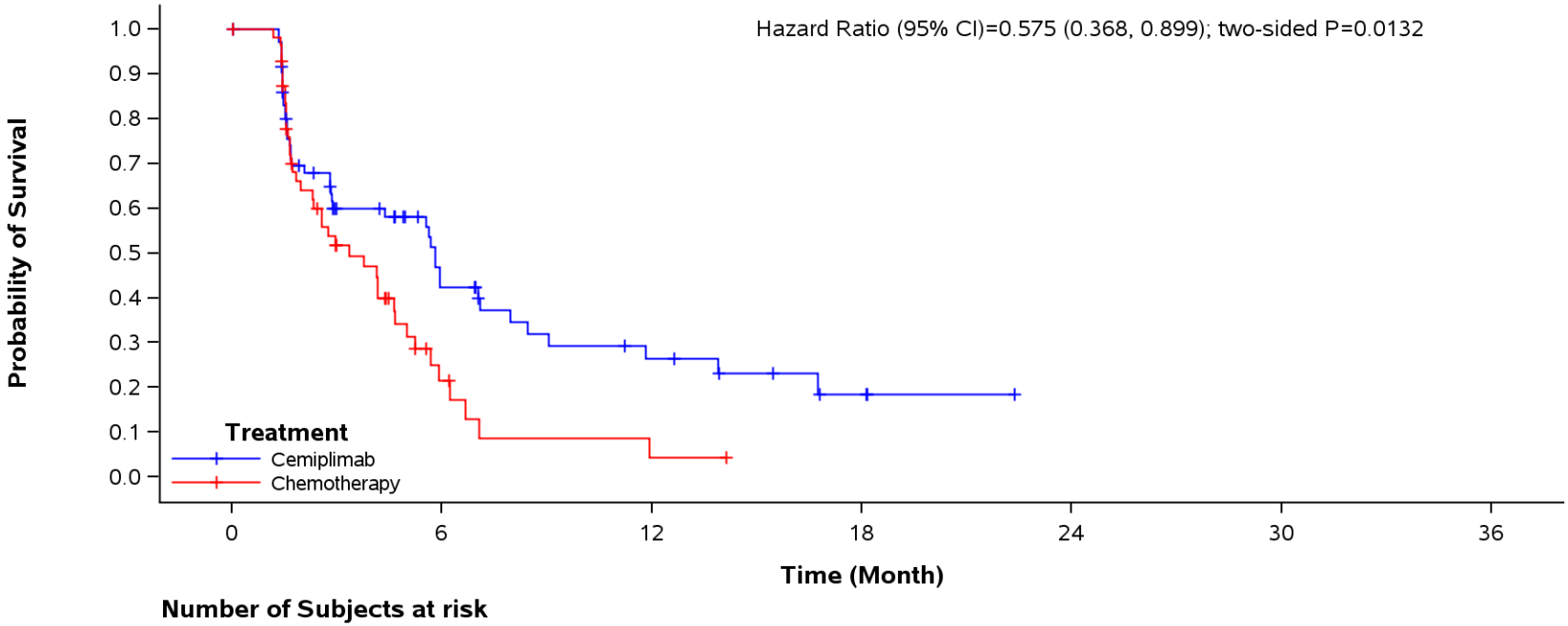

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 27 | 11 | 3 | 0 | 0 | 0 |
| Chemotherapy | 69 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Global health status / QoL - 10 pts deterioration



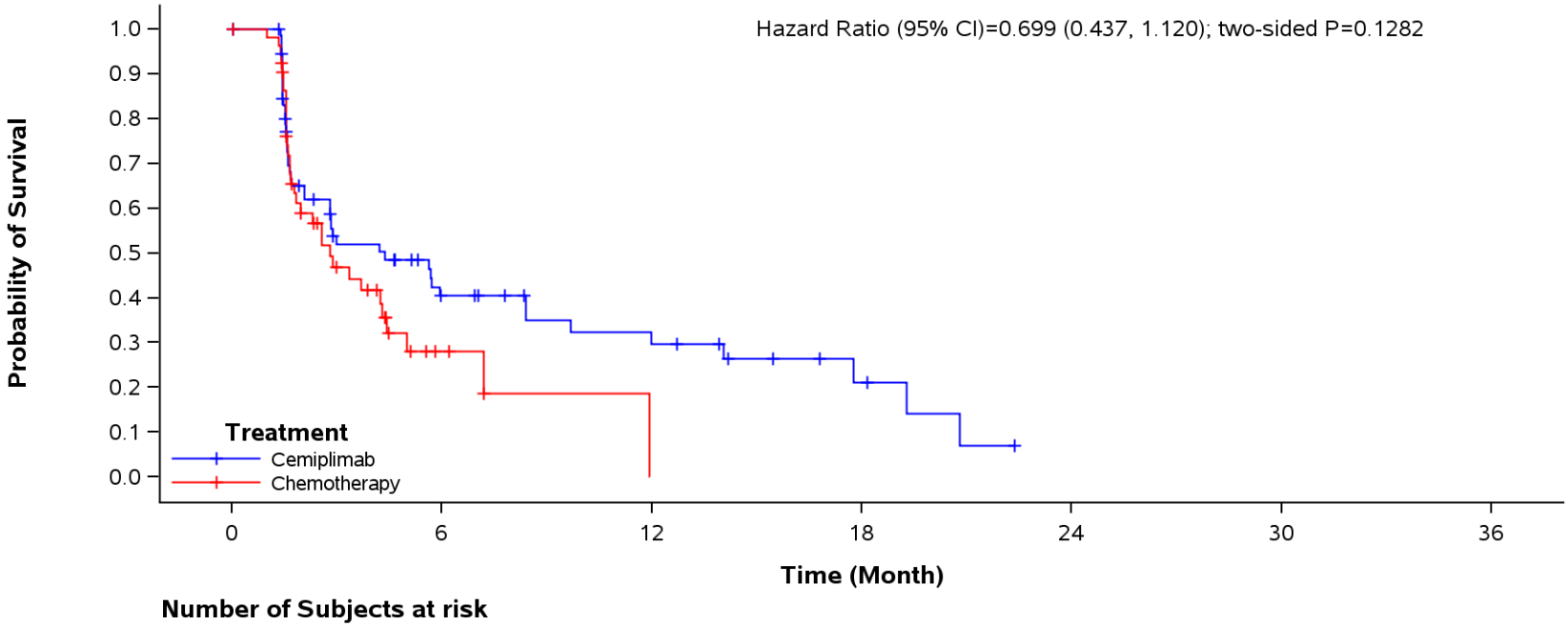

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 19 | 9 | 3 | 0 | 0 | 0 |
| Chemotherapy | 69 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts deterioration



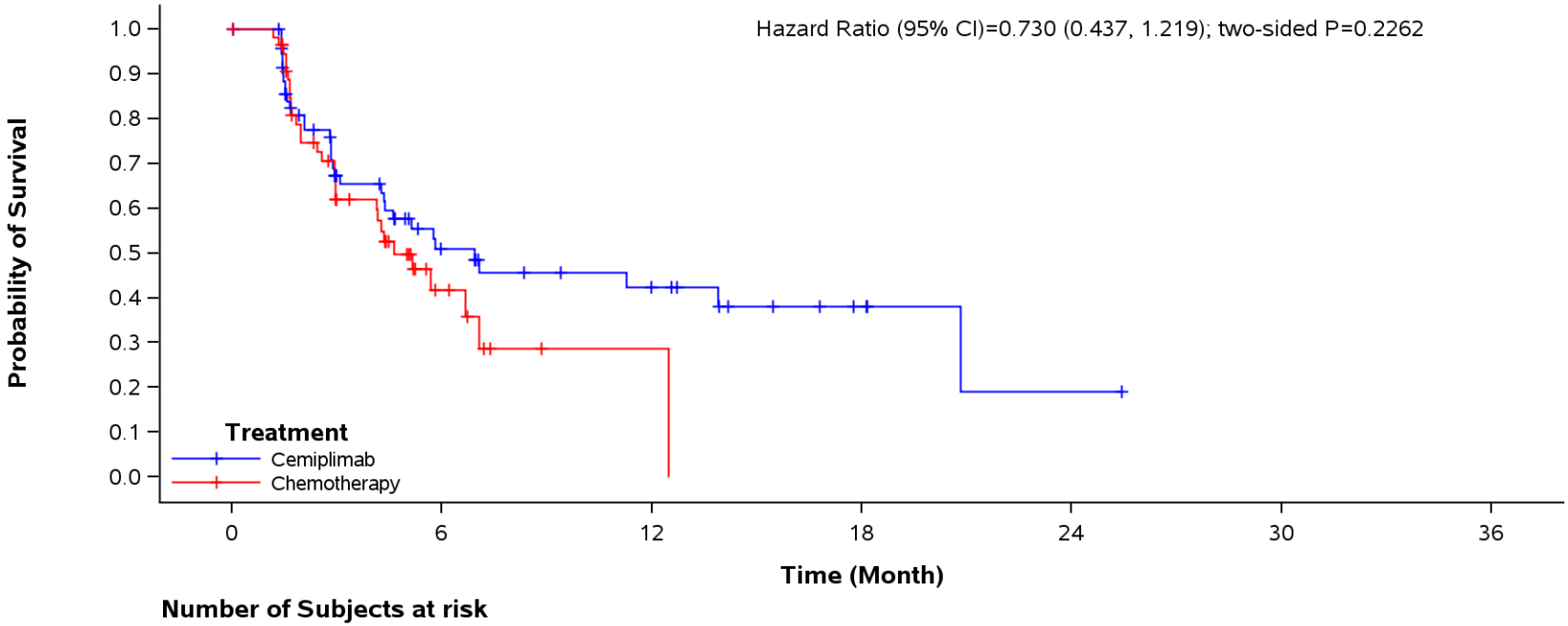

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 19 | 11 | 4 | 0 | 0 | 0 |
| Chemotherapy | 69 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts deterioration



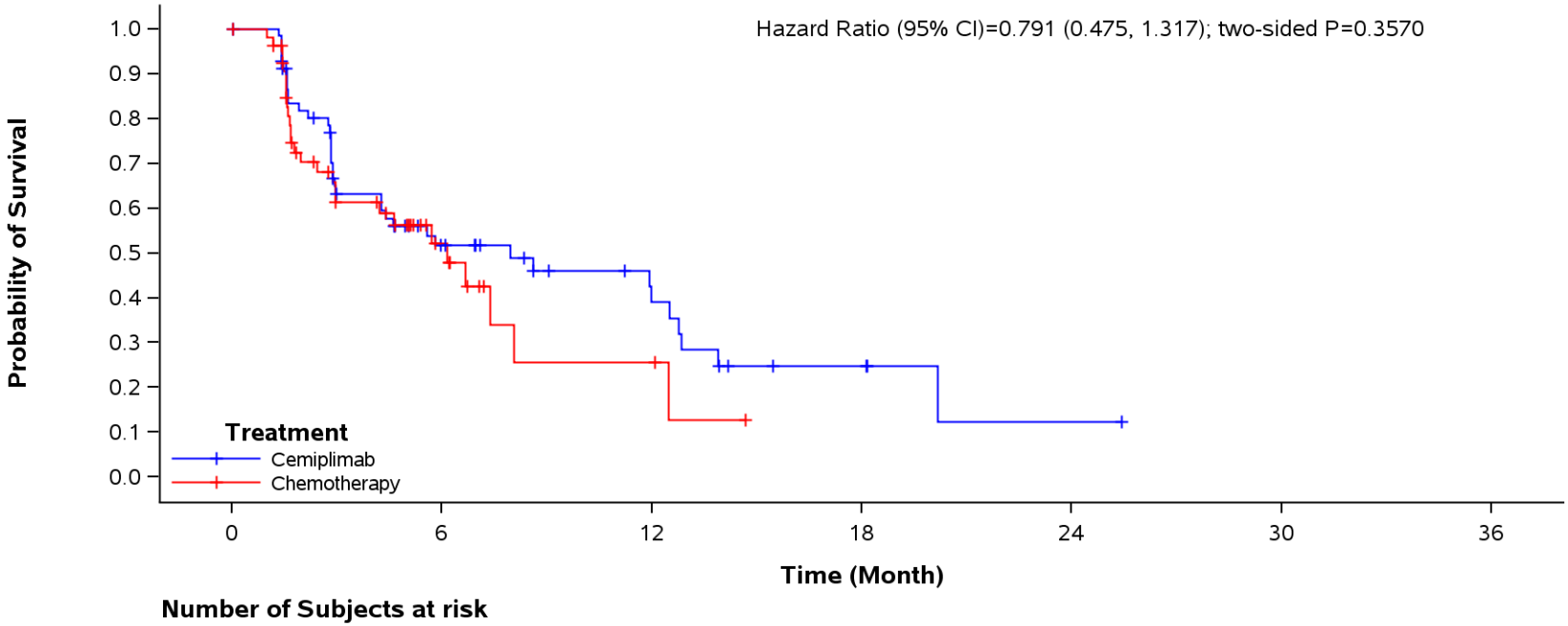

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 21 | 12 | 4 | 1 | 0 | 0 |
| Chemotherapy | 69 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts deterioration



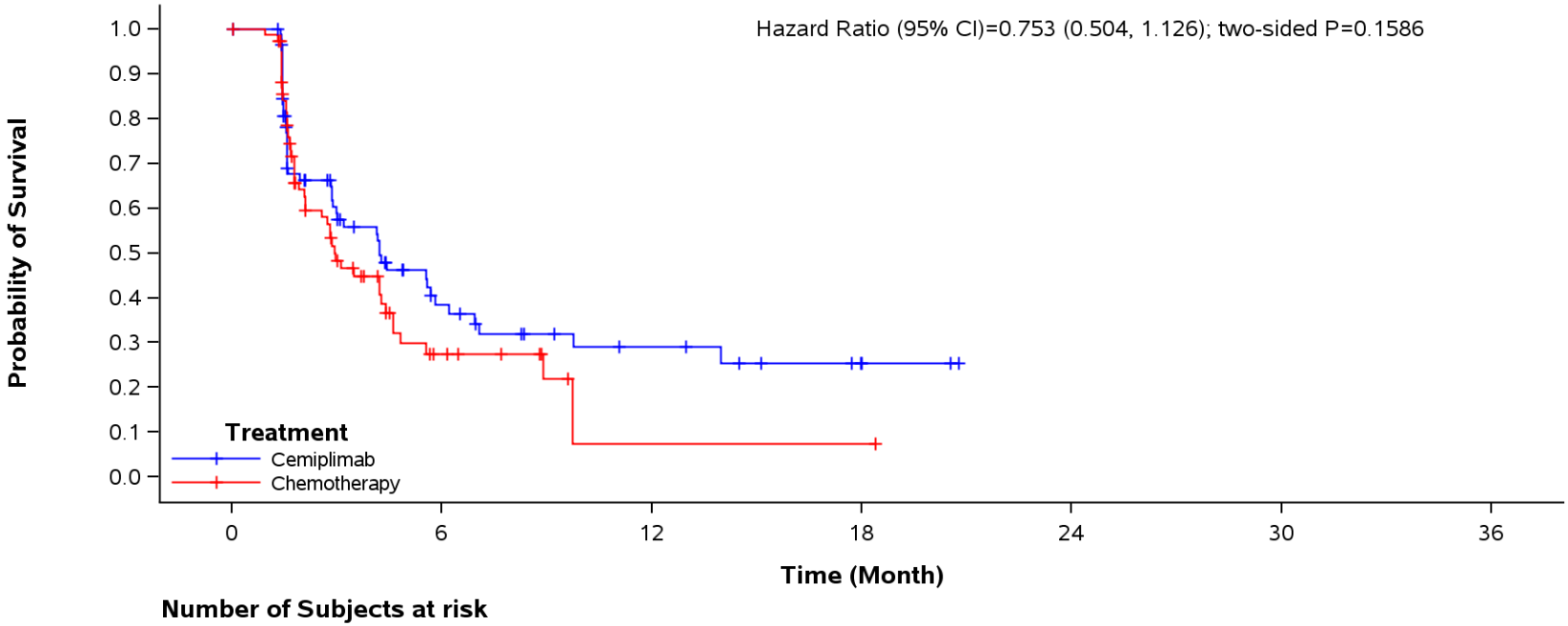

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 23 | 11 | 4 | 1 | 0 | 0 |
| Chemotherapy | 69 | 12 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts deterioration



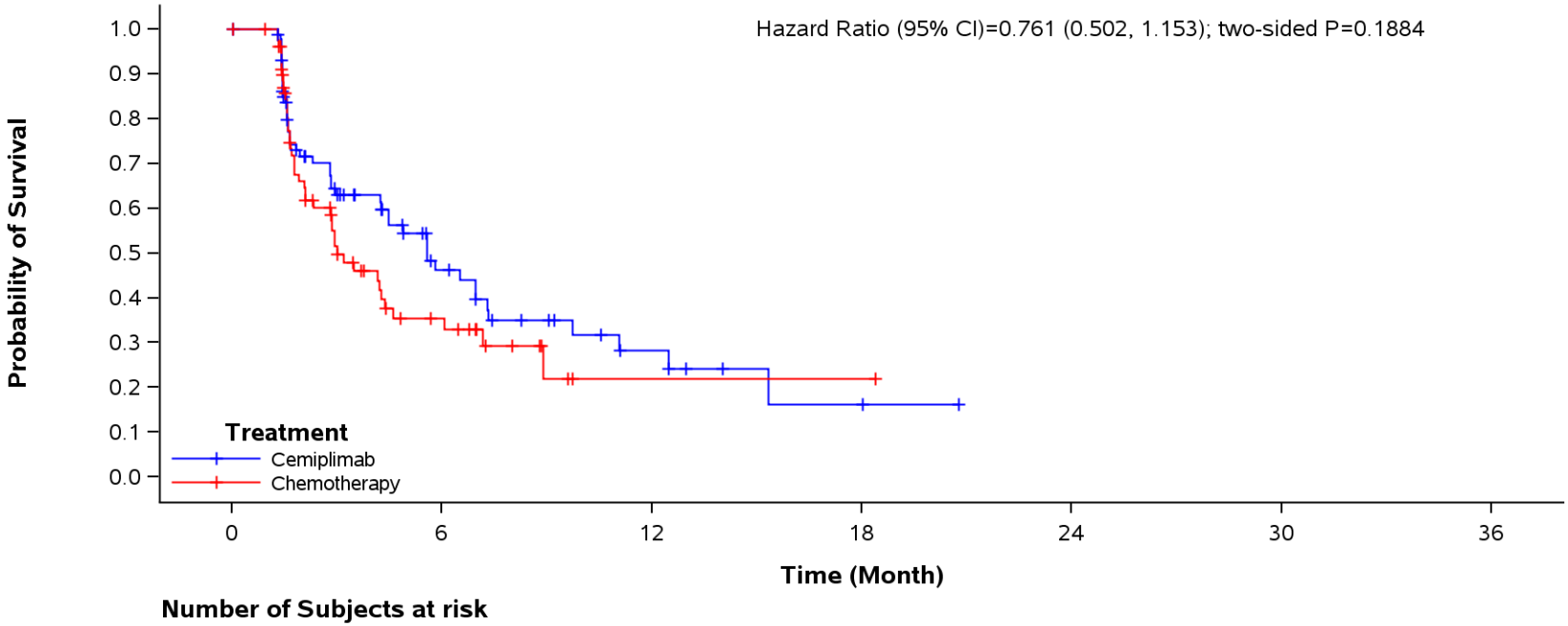

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 19 | 9 | 3 | 0 | 0 | 0 |
| Chemotherapy | 114 | 10 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts deterioration



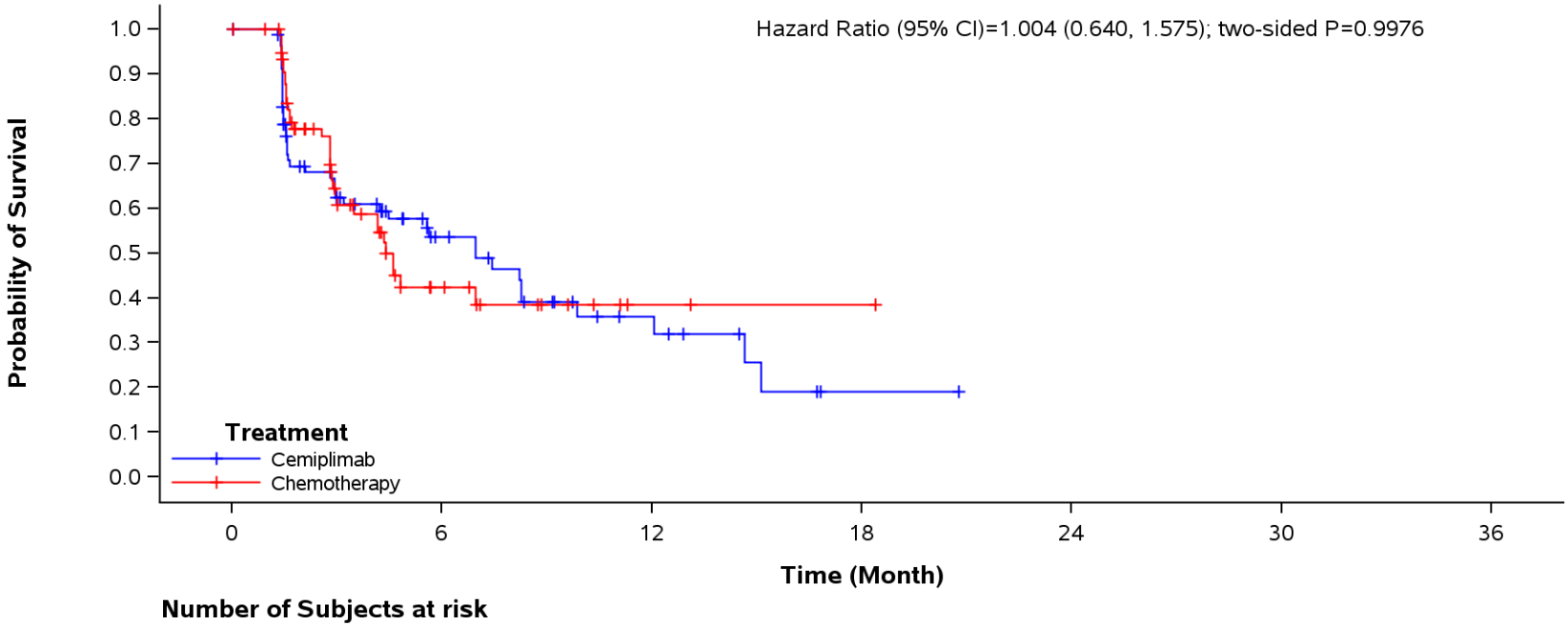

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 22 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 14 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts deterioration



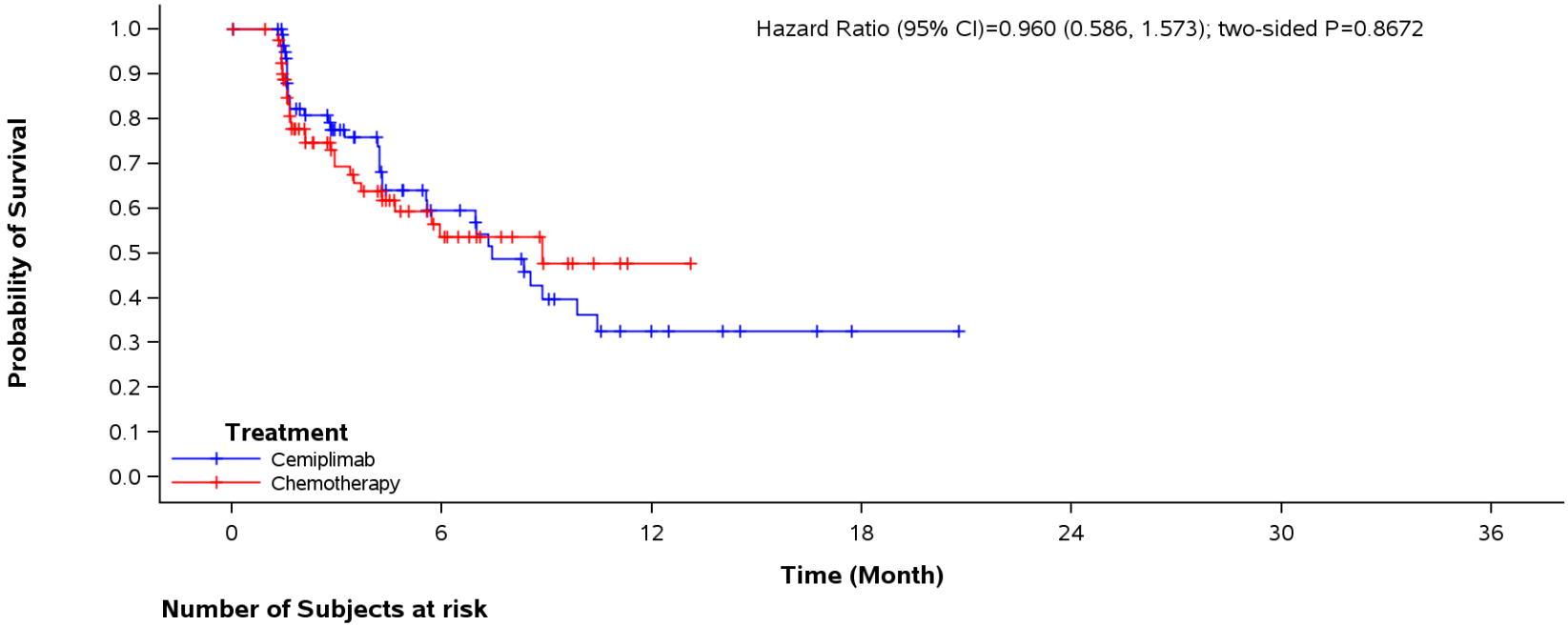

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 24 | 9 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 13 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts deterioration



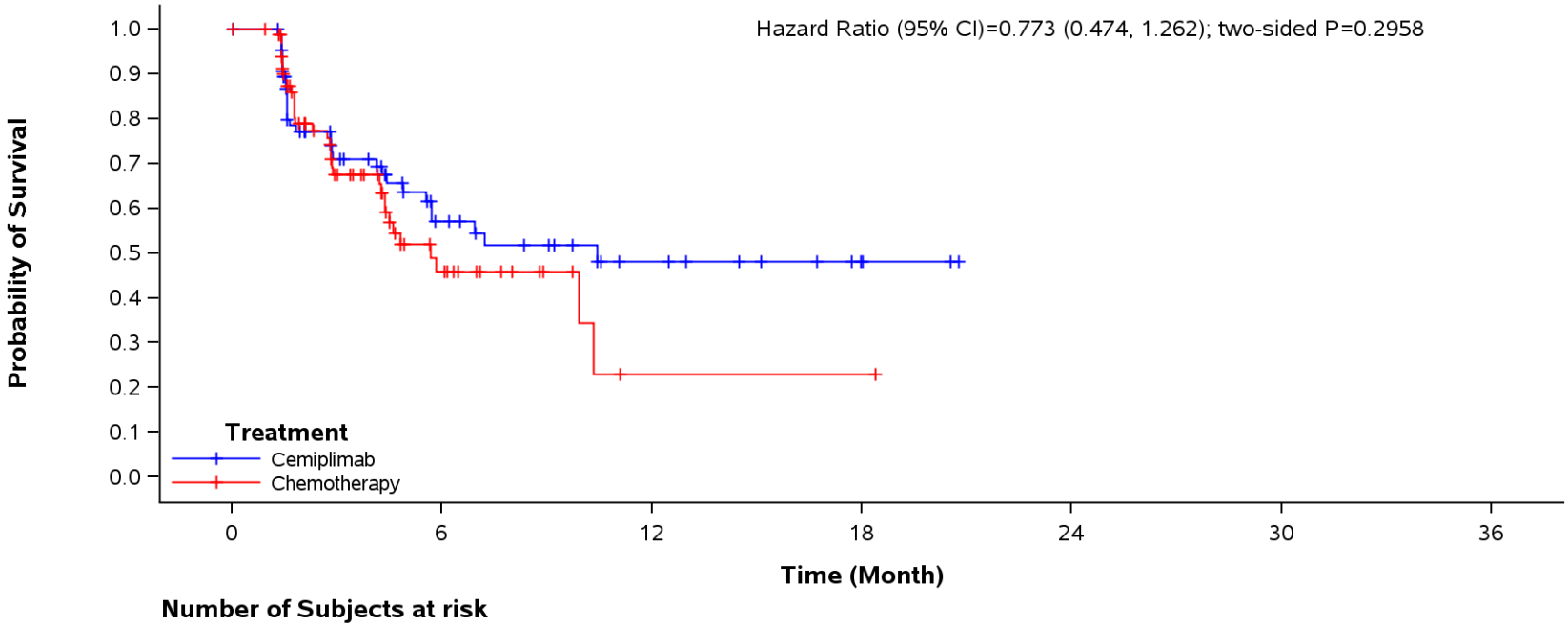

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 24 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 18 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts deterioration



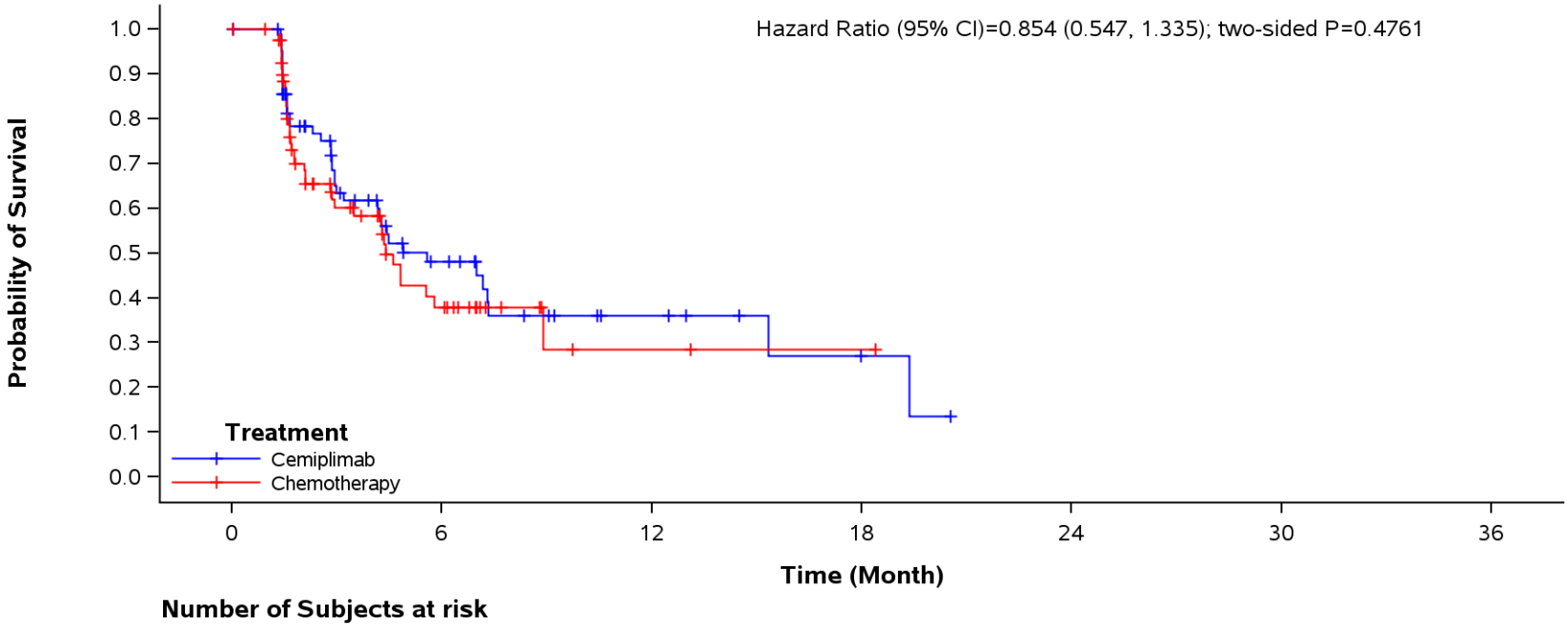

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 24 | 10 | 3 | 0 | 0 | 0 |
| Chemotherapy | 114 | 15 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts deterioration



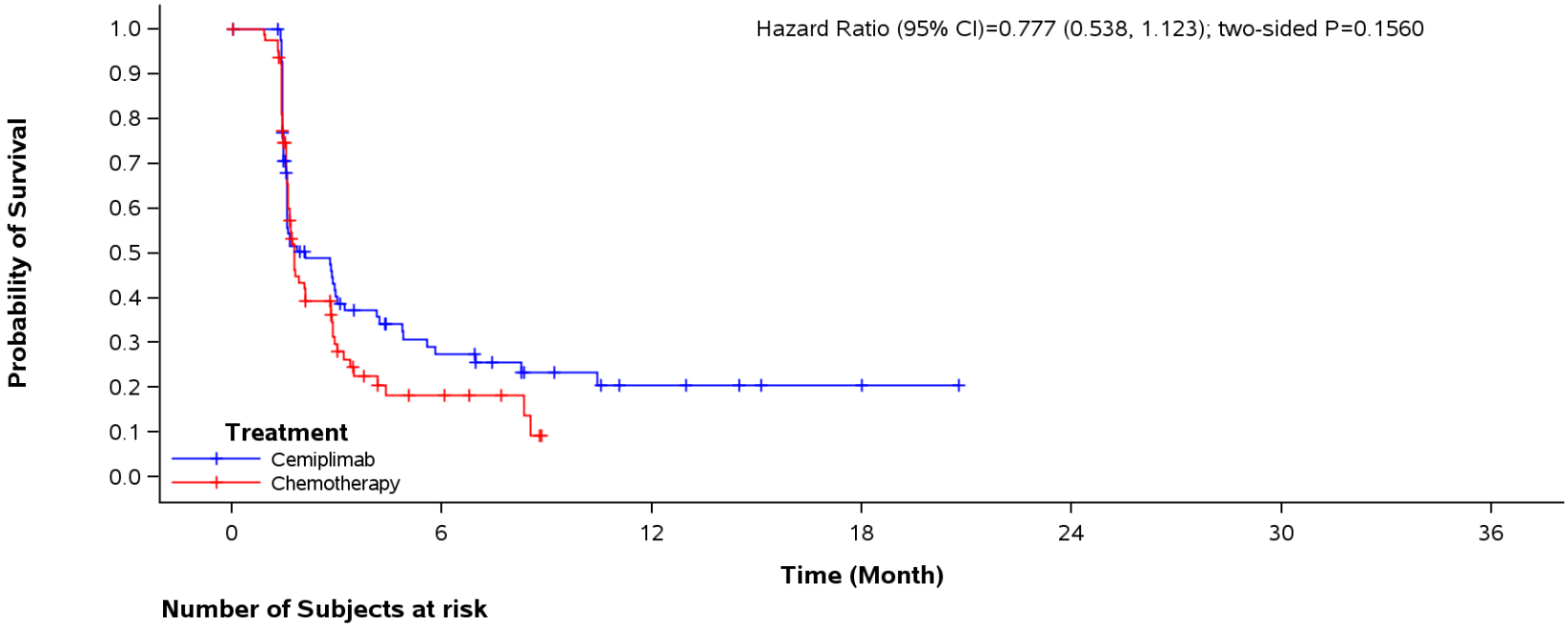

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 21 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts deterioration



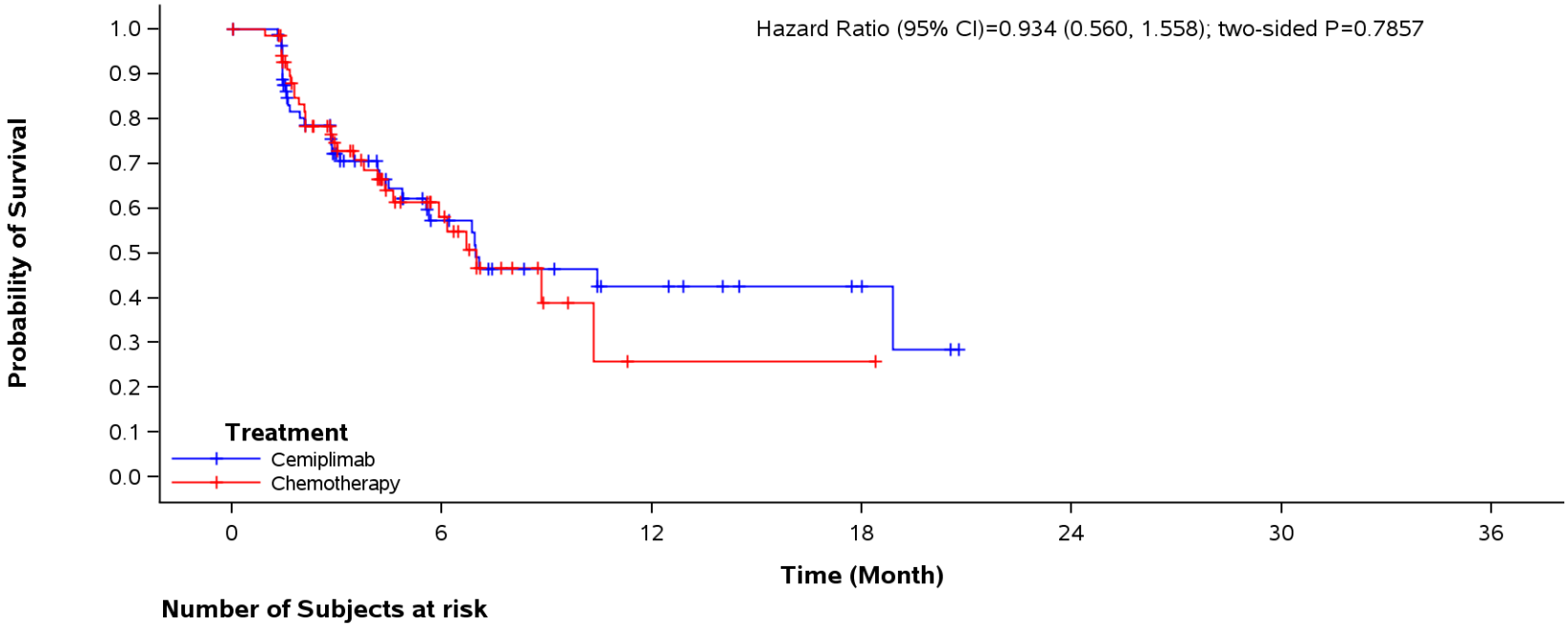

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 16 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts deterioration



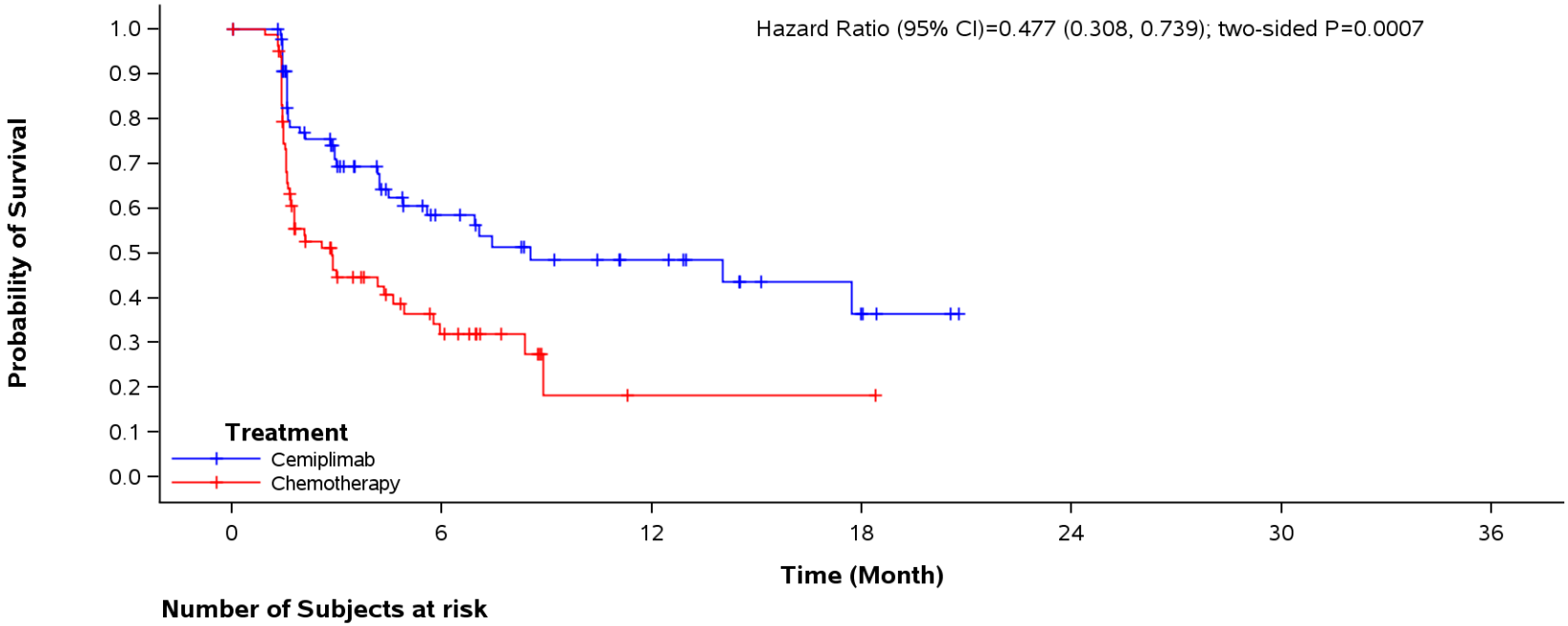

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 22 | 9 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 18 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts deterioration



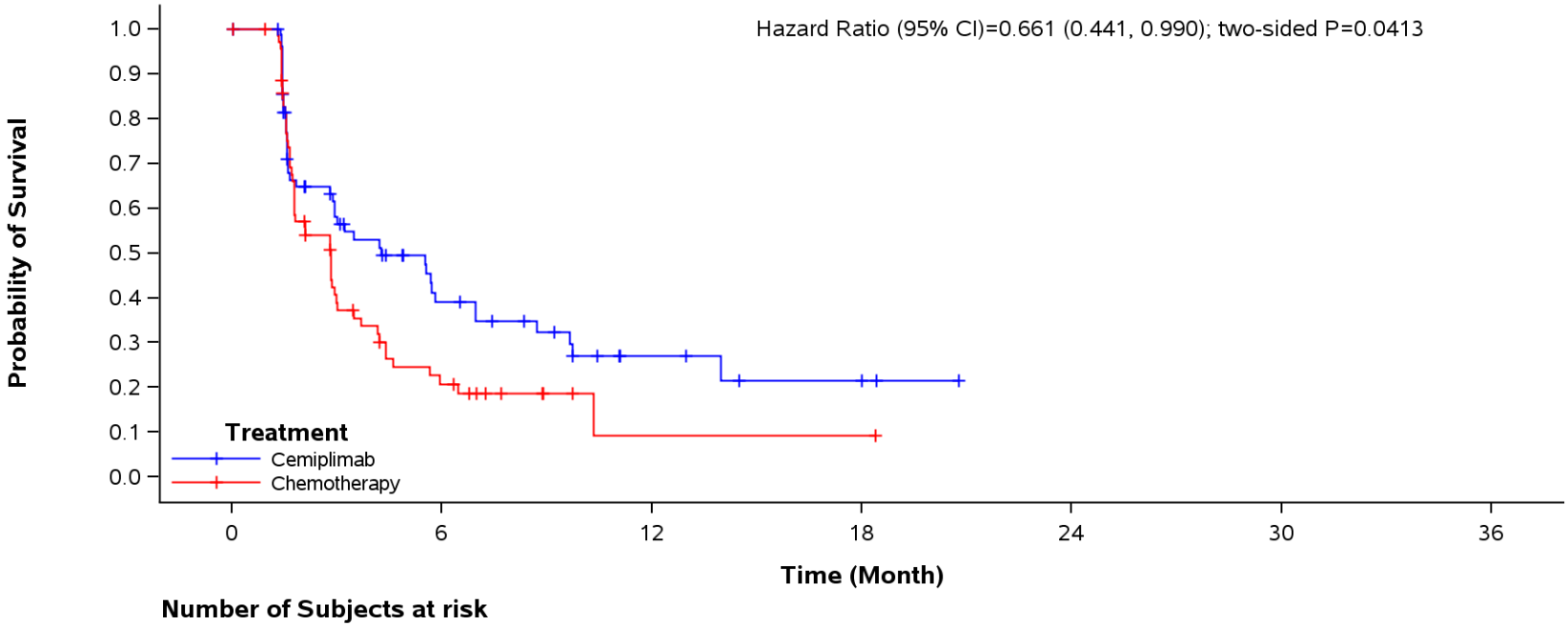

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 27 | 13 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 14 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts deterioration



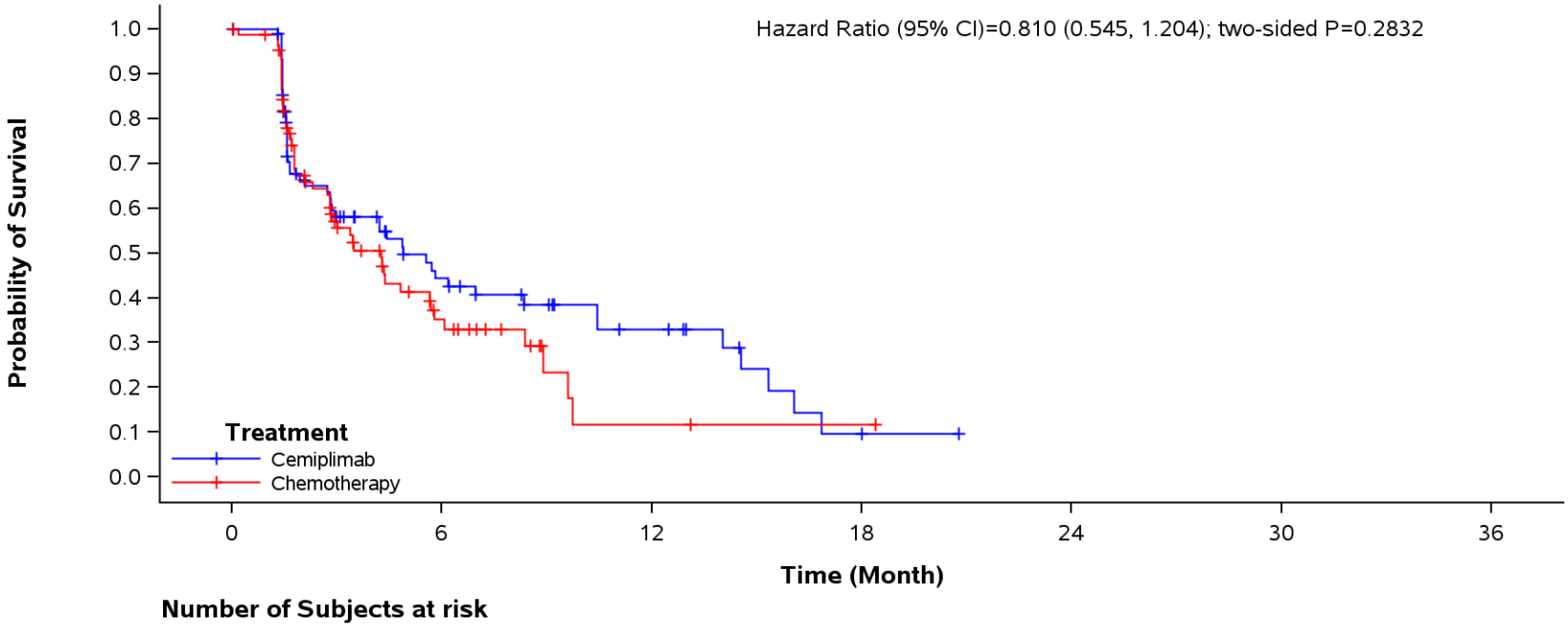

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 19 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 114 | 11 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts deterioration



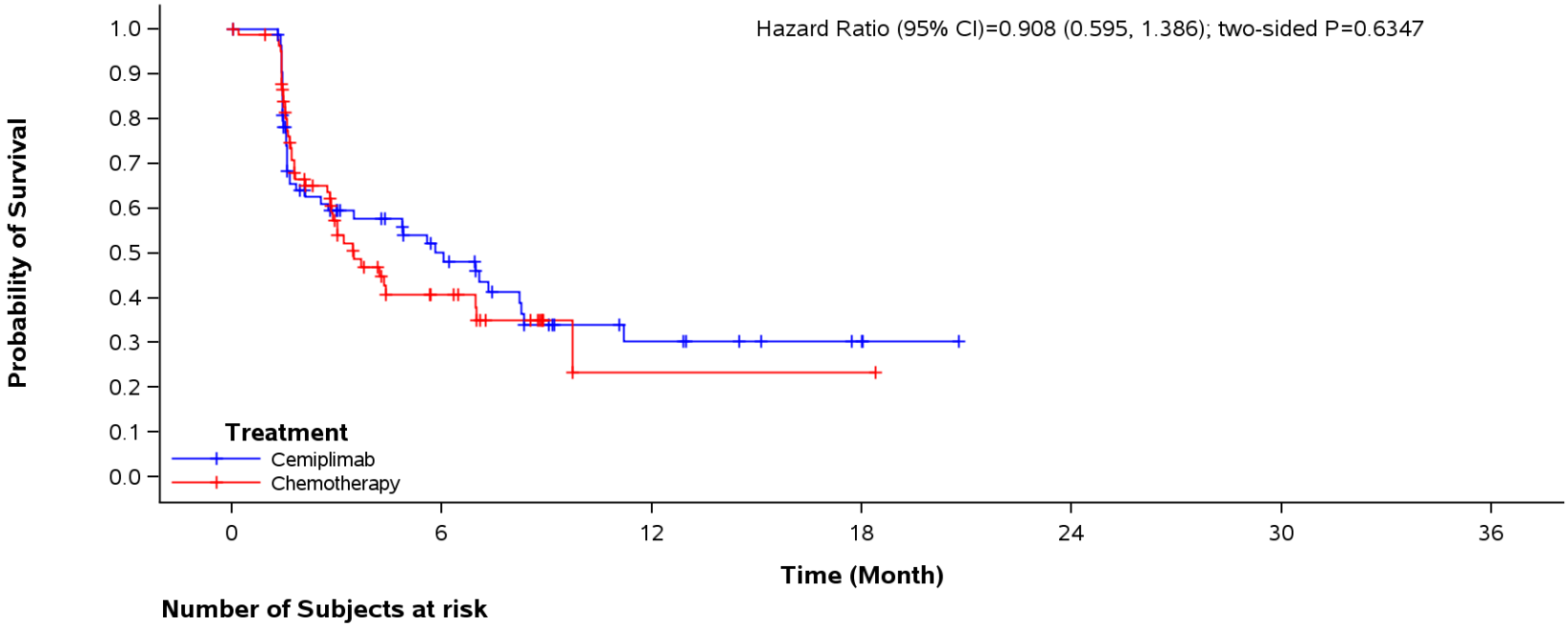

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 25 | 11 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts deterioration



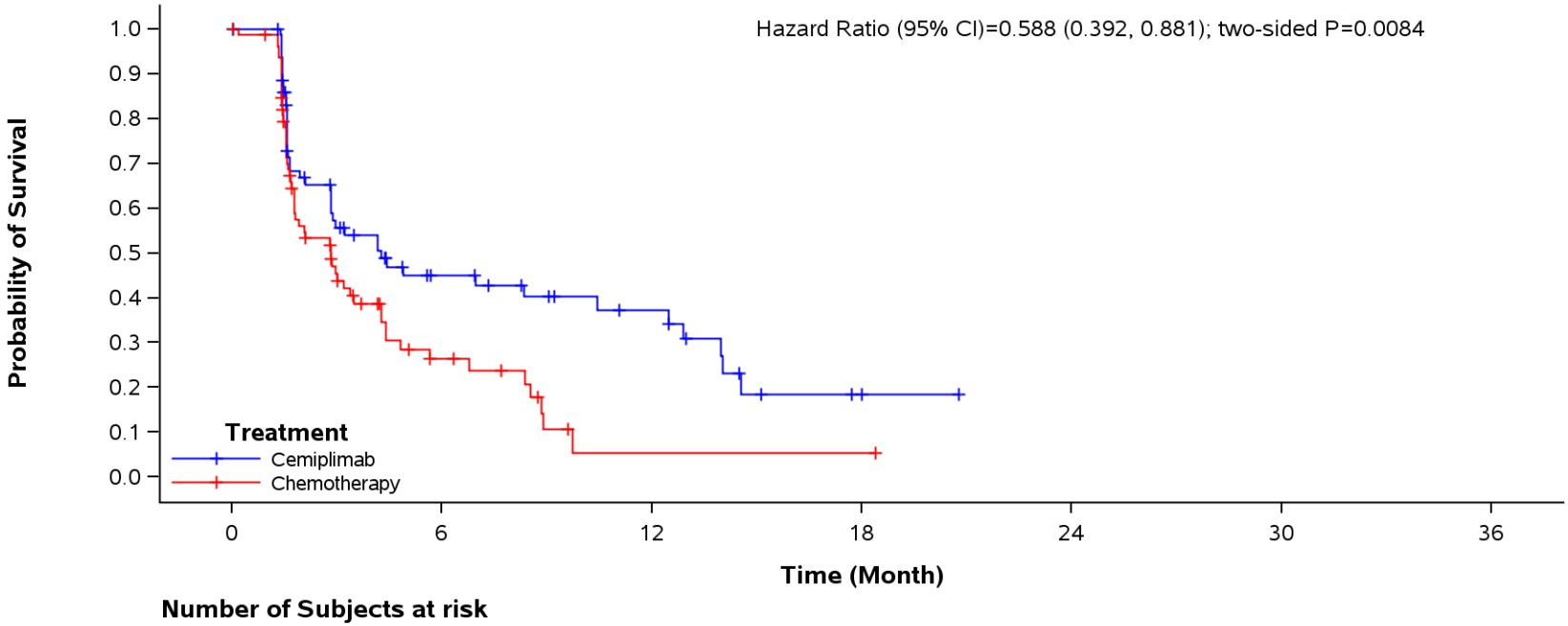

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 25 | 8 | 3 | 0 | 0 | 0 |
| Chemotherapy | 114 | 16 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts deterioration



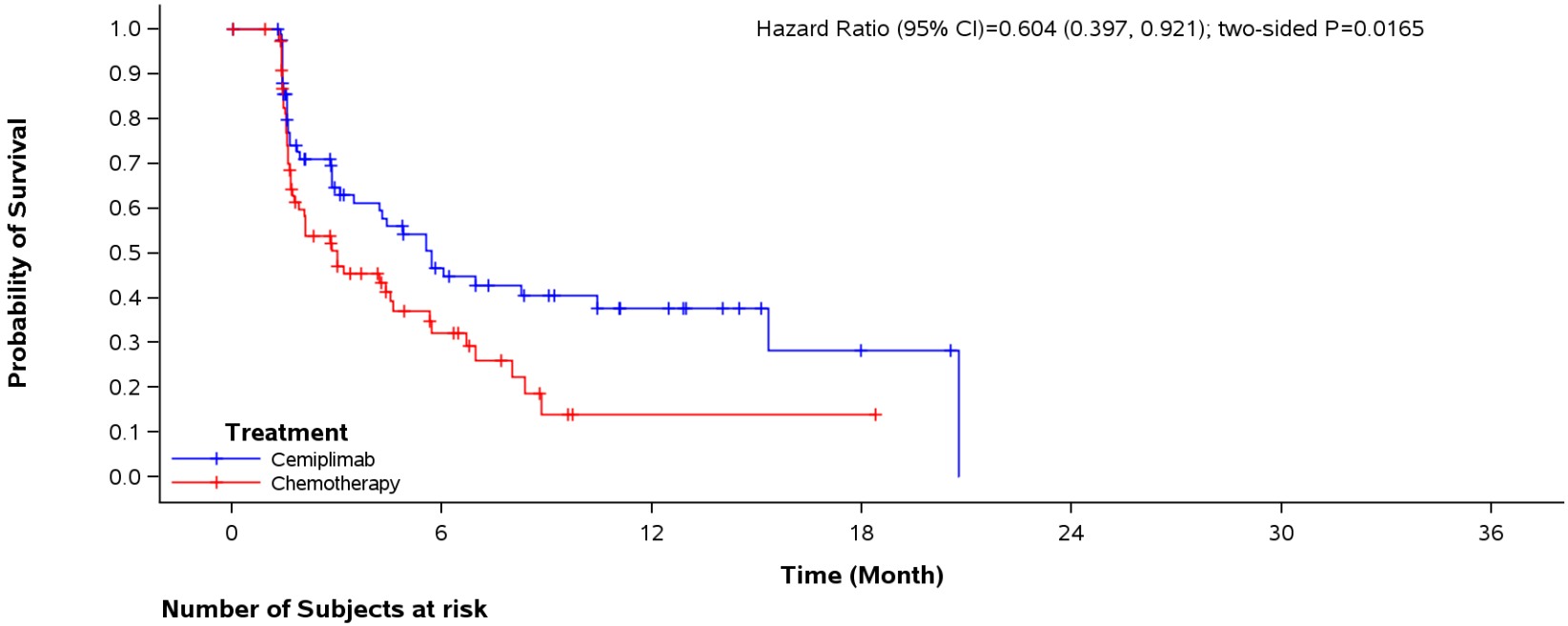

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 21 | 12 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 11 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts deterioration



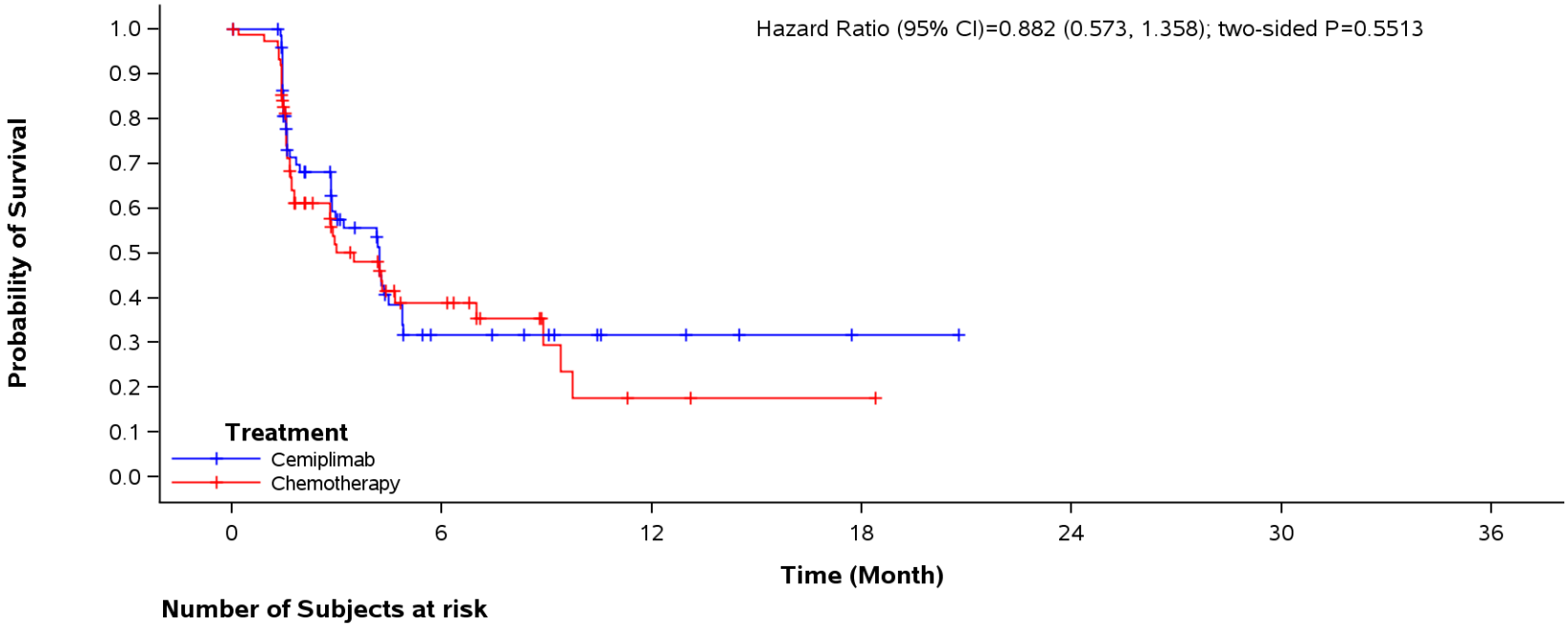

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 24 | 10 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 13 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts deterioration



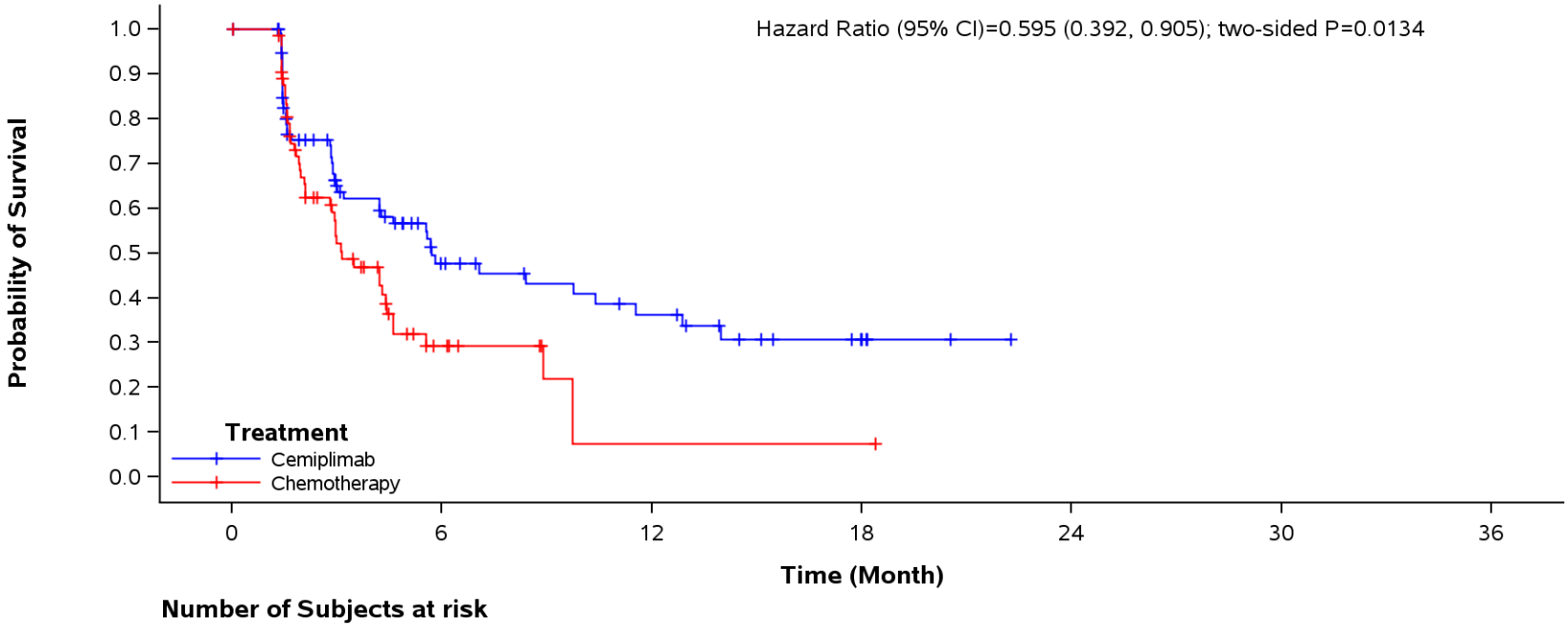

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 11 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 14 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts deterioration



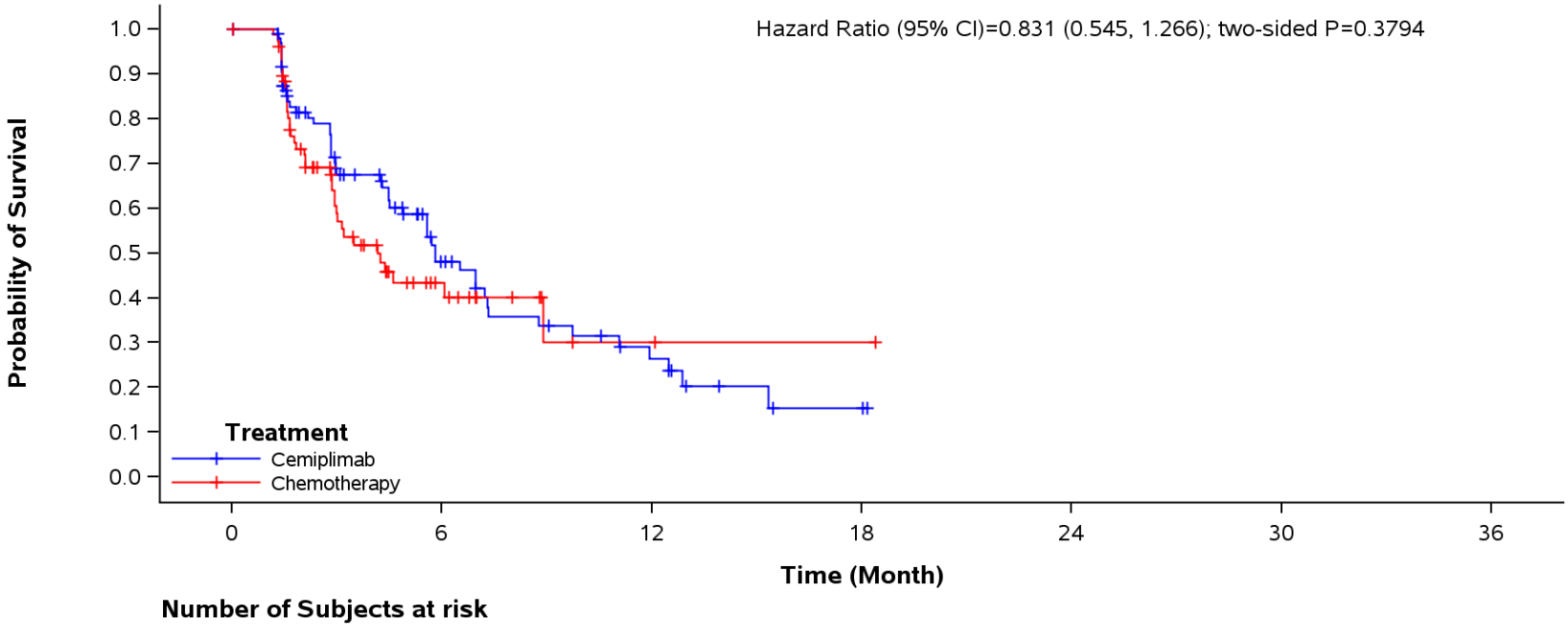

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 25 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 97 | 9 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts deterioration



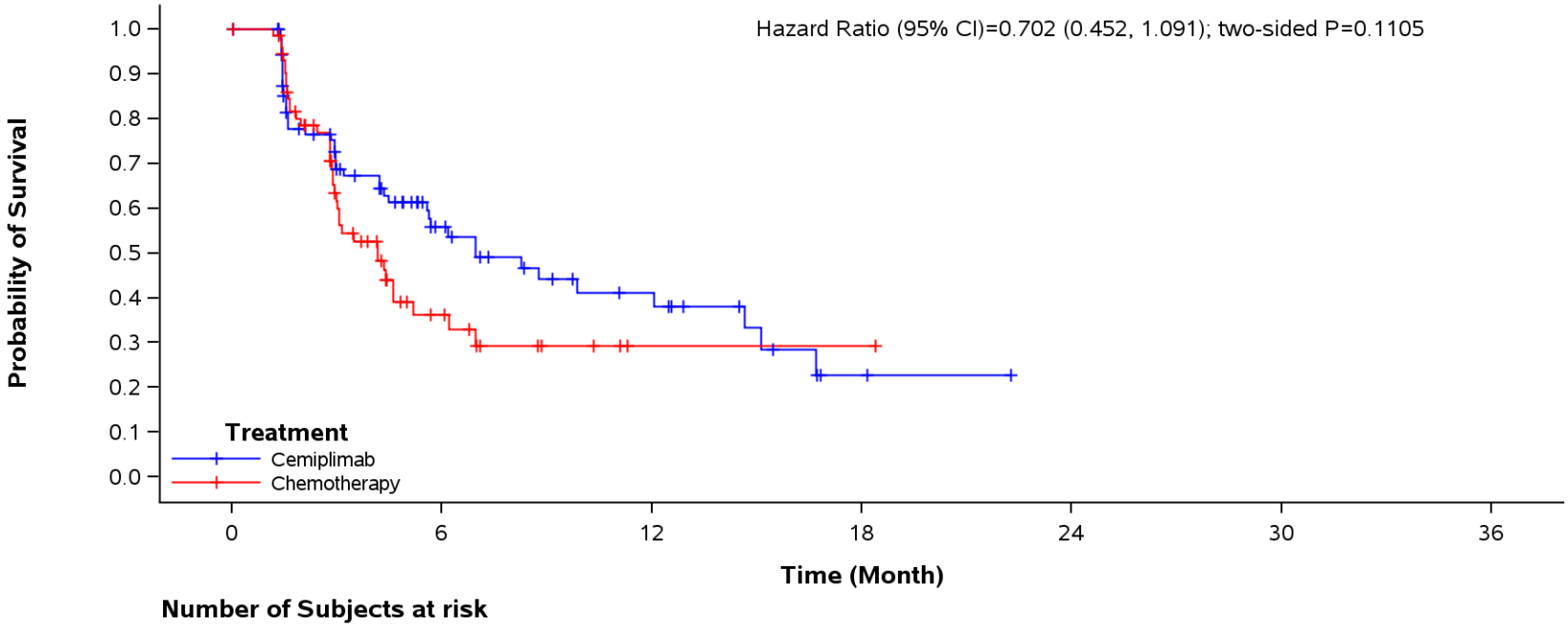

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 26 | 10 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts deterioration



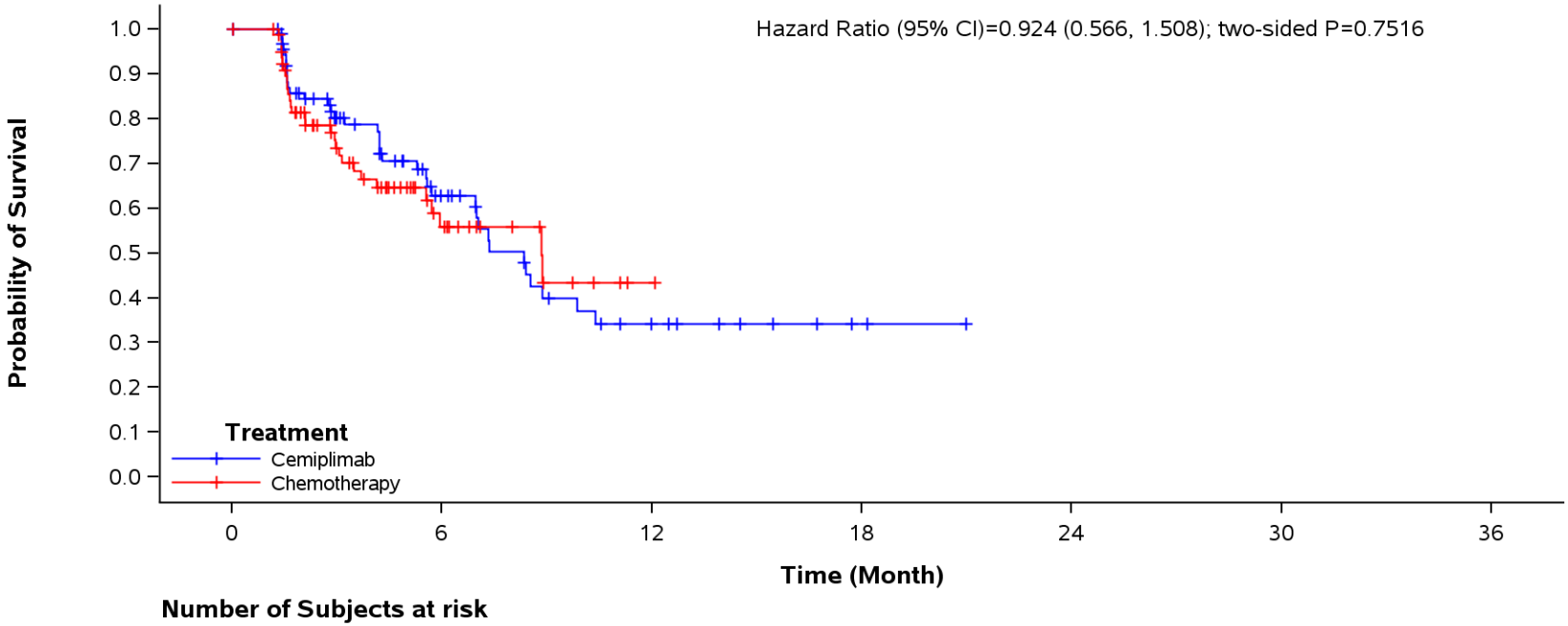

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 27 | 13 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 12 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts deterioration



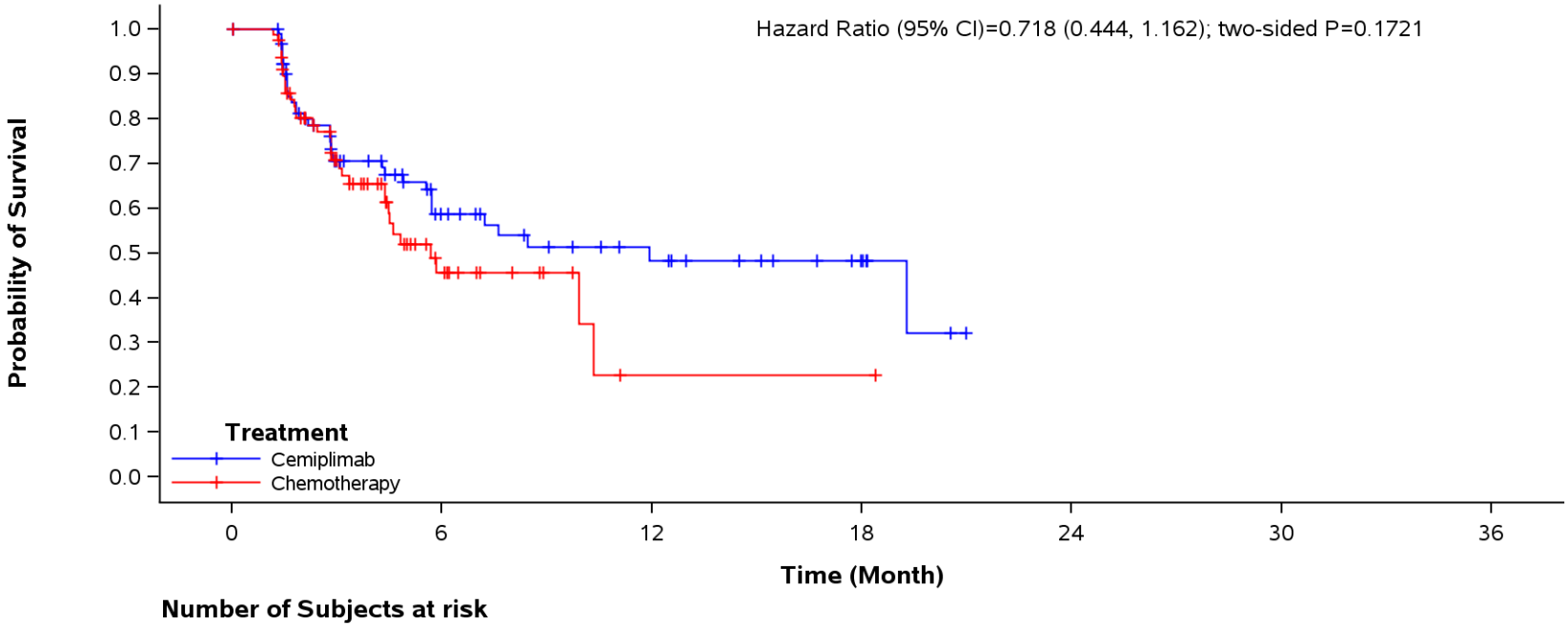

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 29 | 9 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 18 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts deterioration



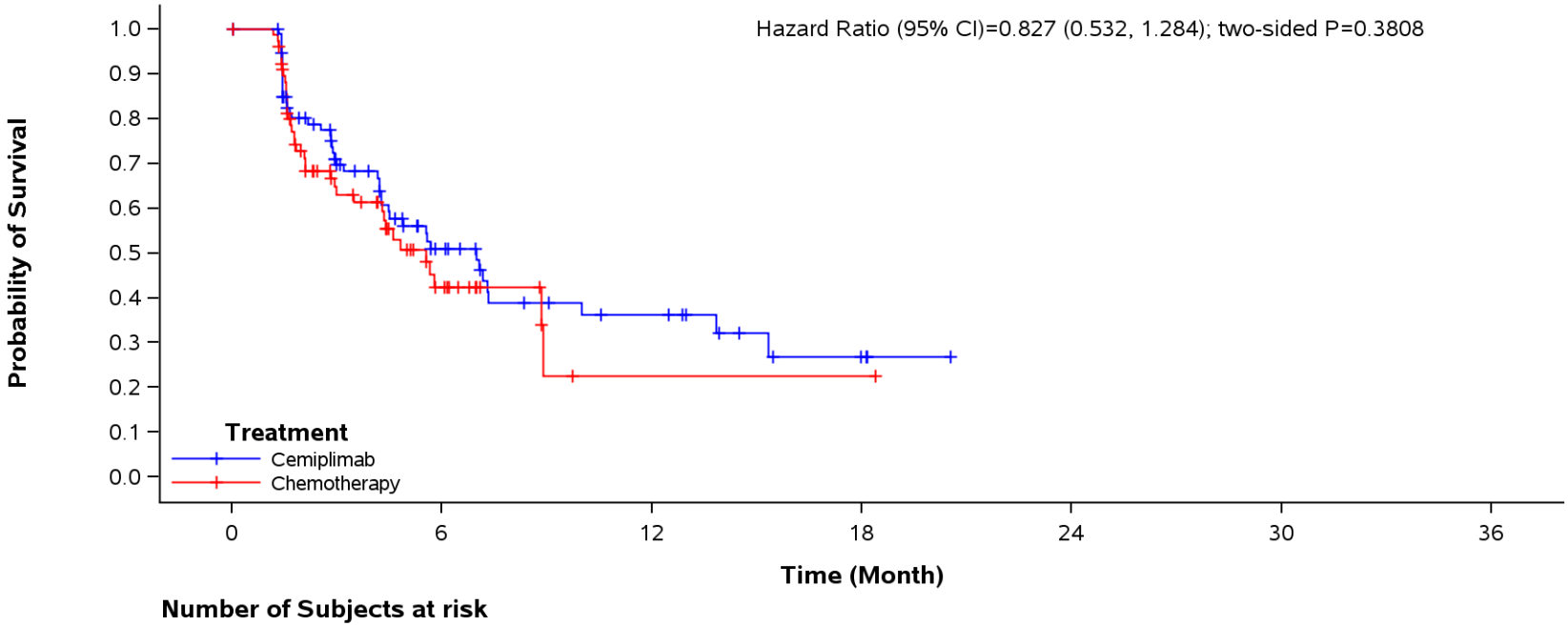

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 29 | 15 | 6 | 0 | 0 | 0 |
| Chemotherapy | 97 | 14 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Emotional Functioning - 10 pts deterioration



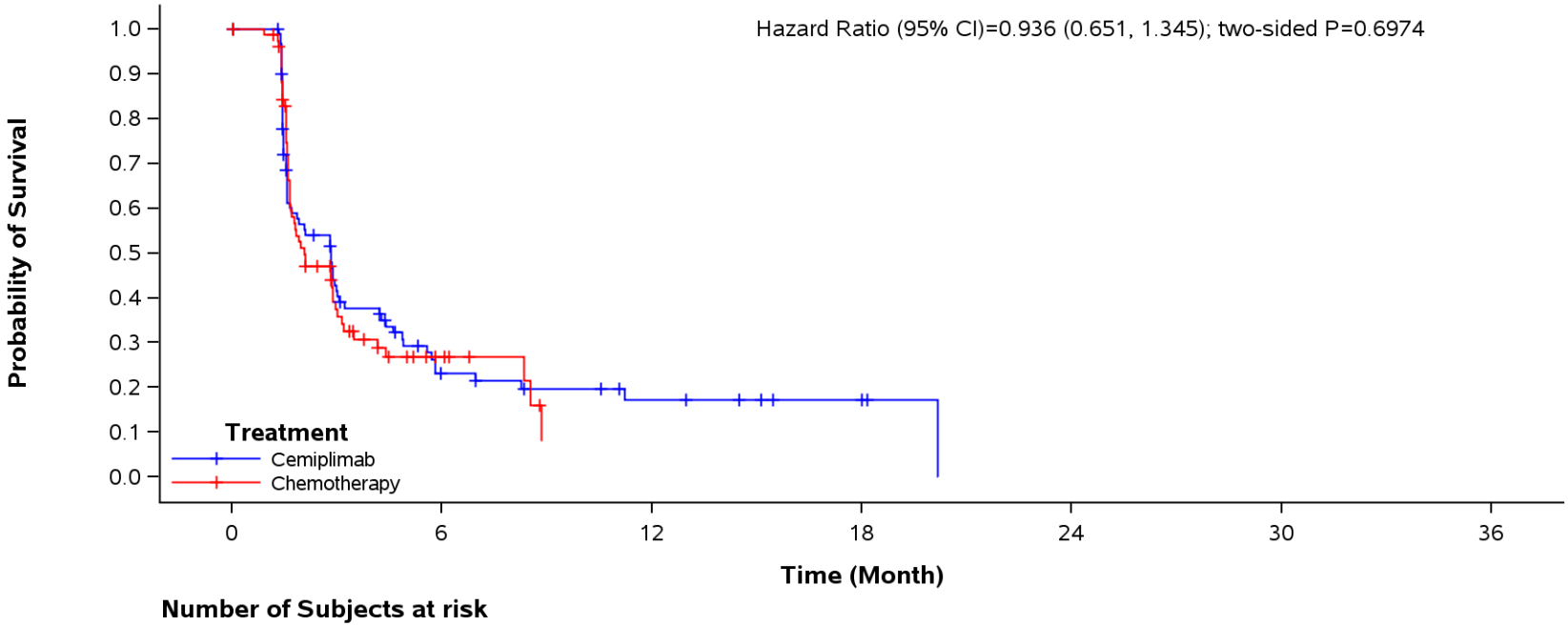

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 27 | 12 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 14 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts deterioration



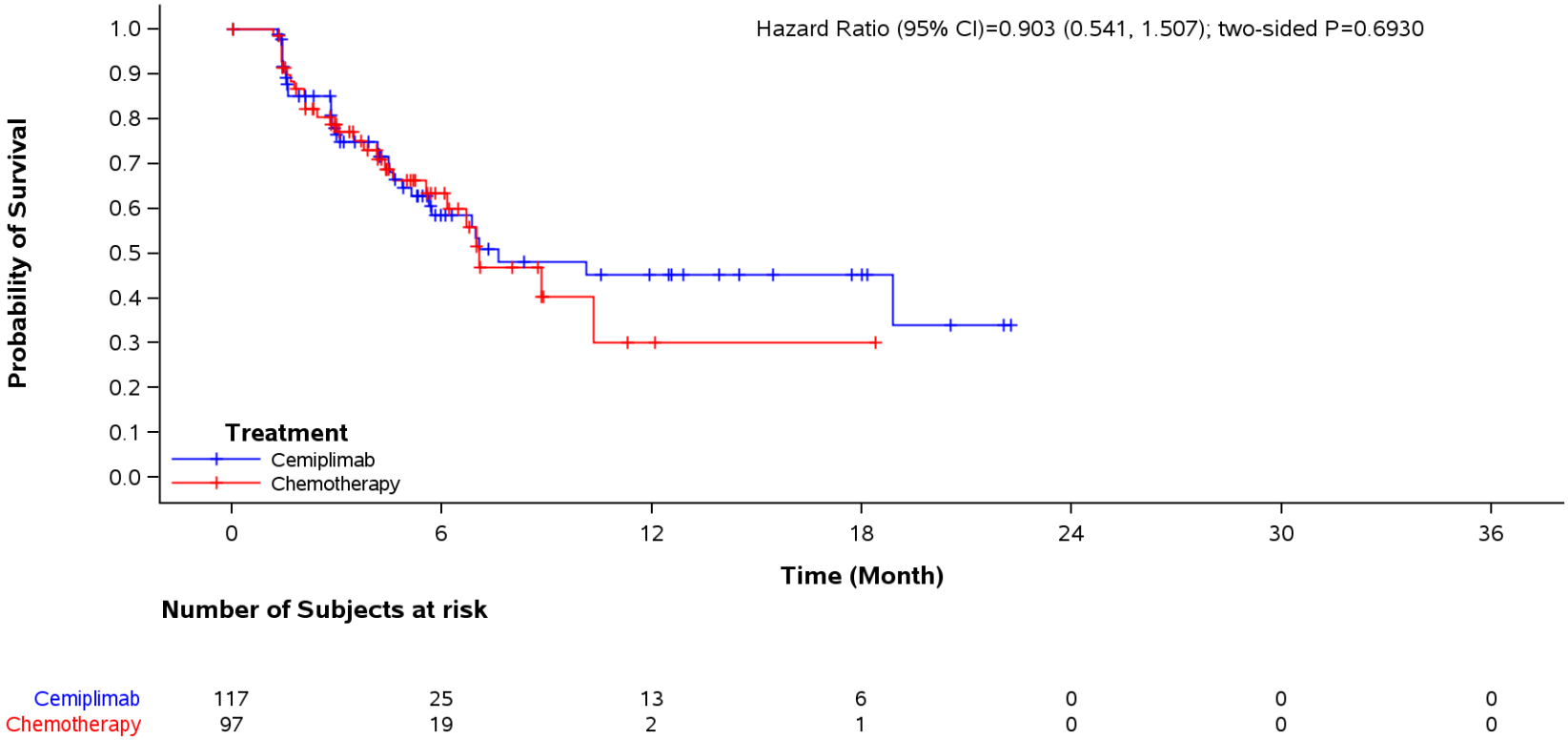

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 14 | 7 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts deterioration




Number of Subjects at risk

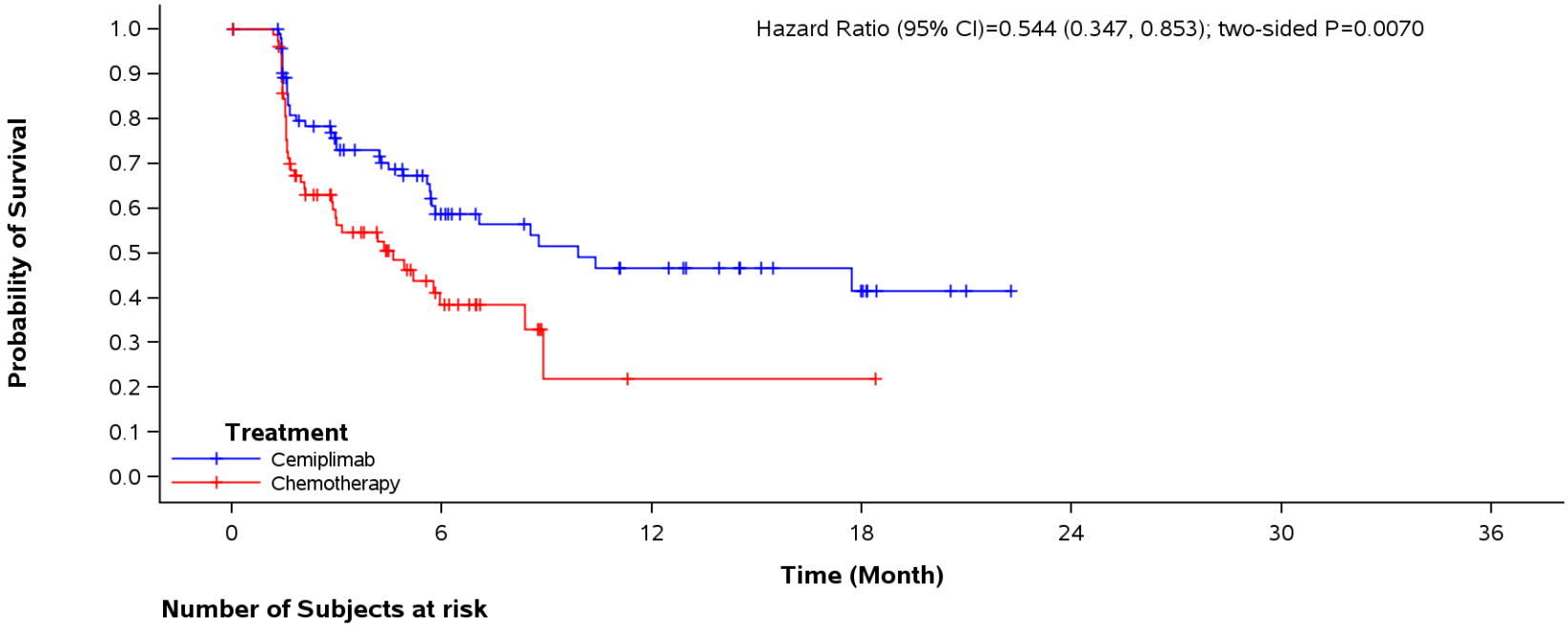
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 25 | 13 | 6 | 0 | 0 | 0 |
| Chemotherapy | 97 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:18:00, yingyuan.lin)

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts deterioration



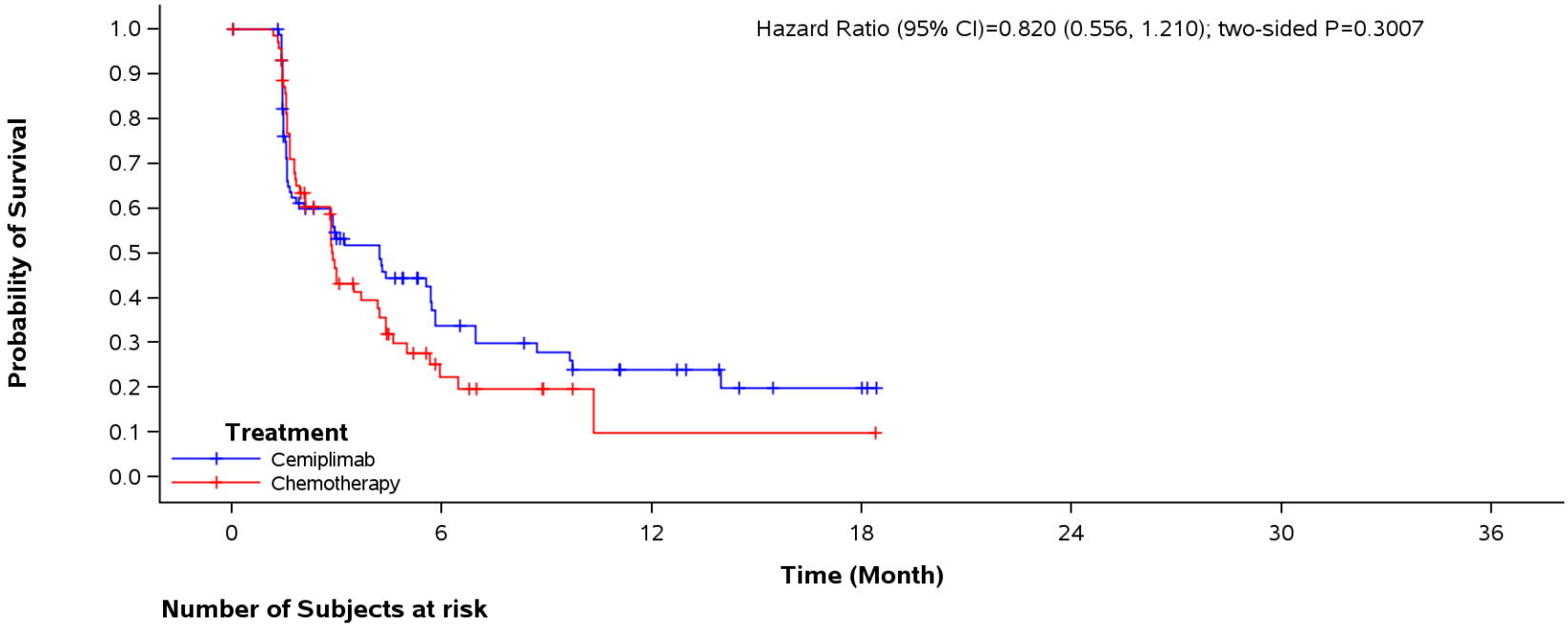

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 32 | 17 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 14 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Pain - 10 pts deterioration



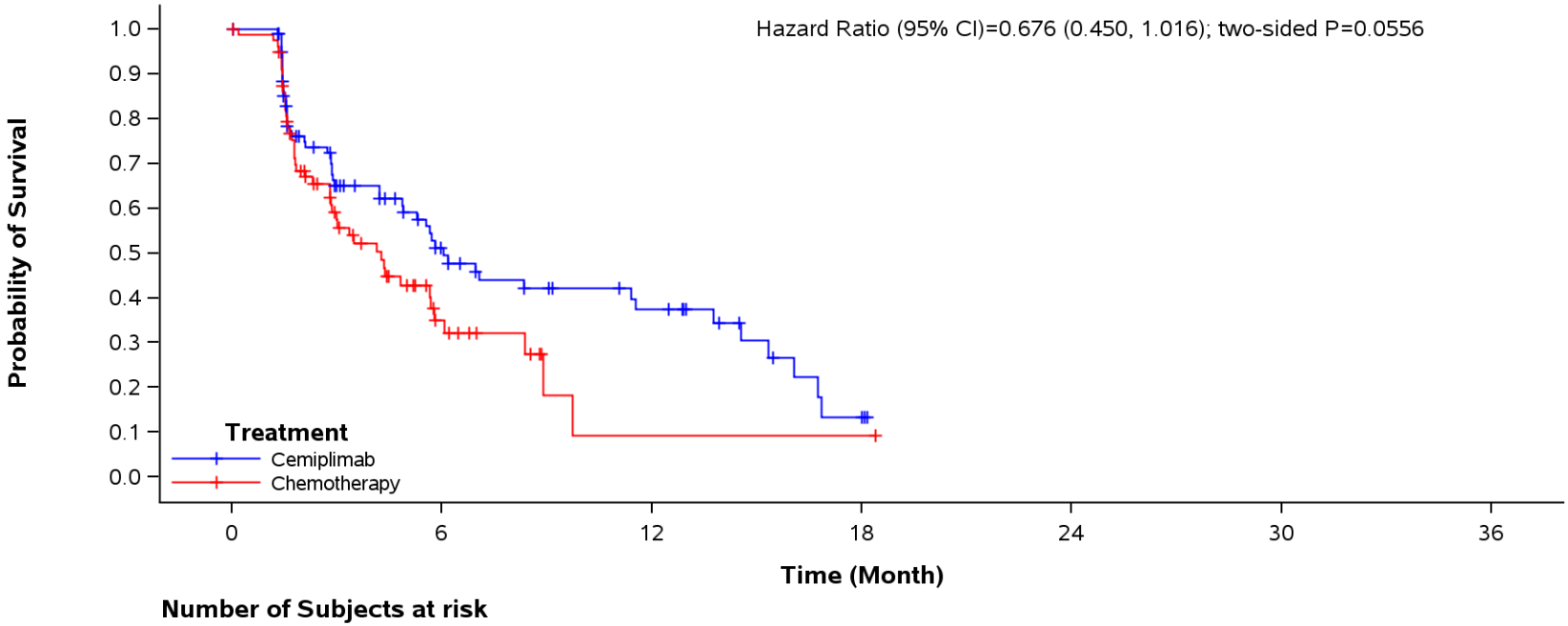

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 19 | 9 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 8 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Physical Functioning - 10 pts deterioration



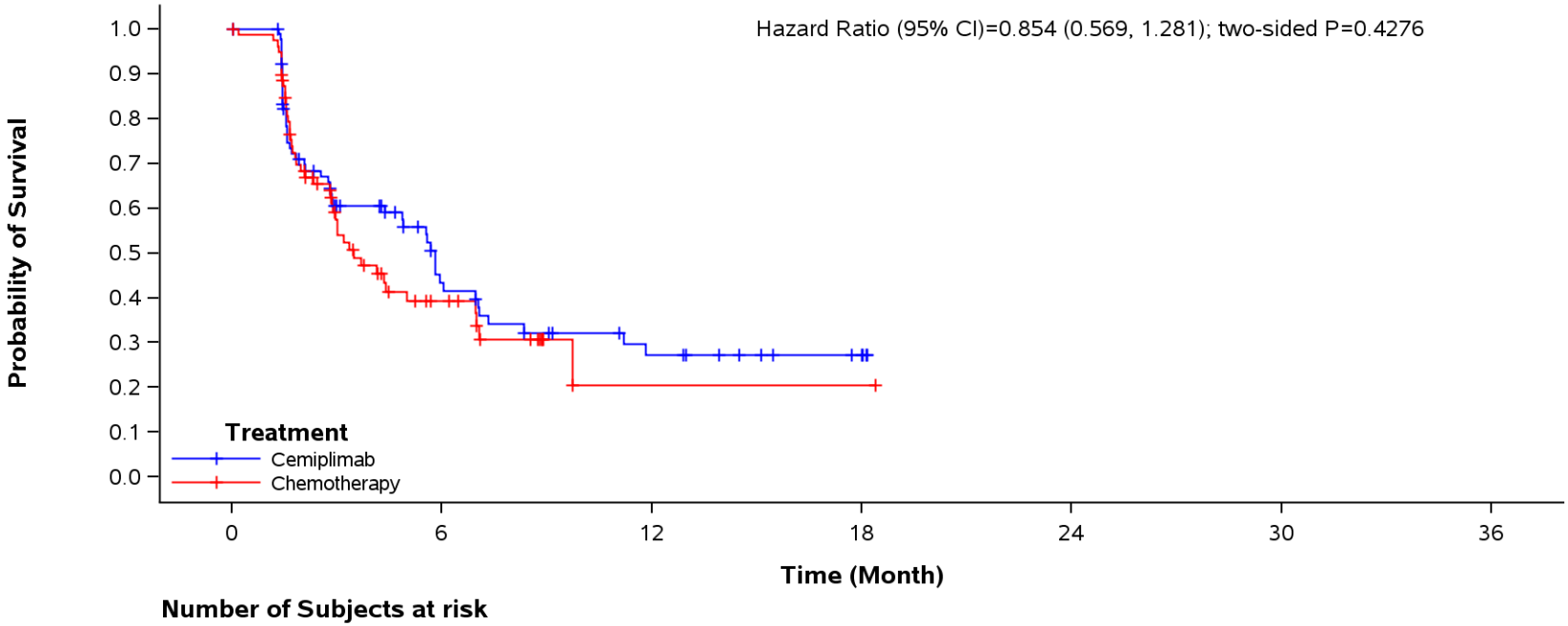

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 30 | 16 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 12 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts deterioration



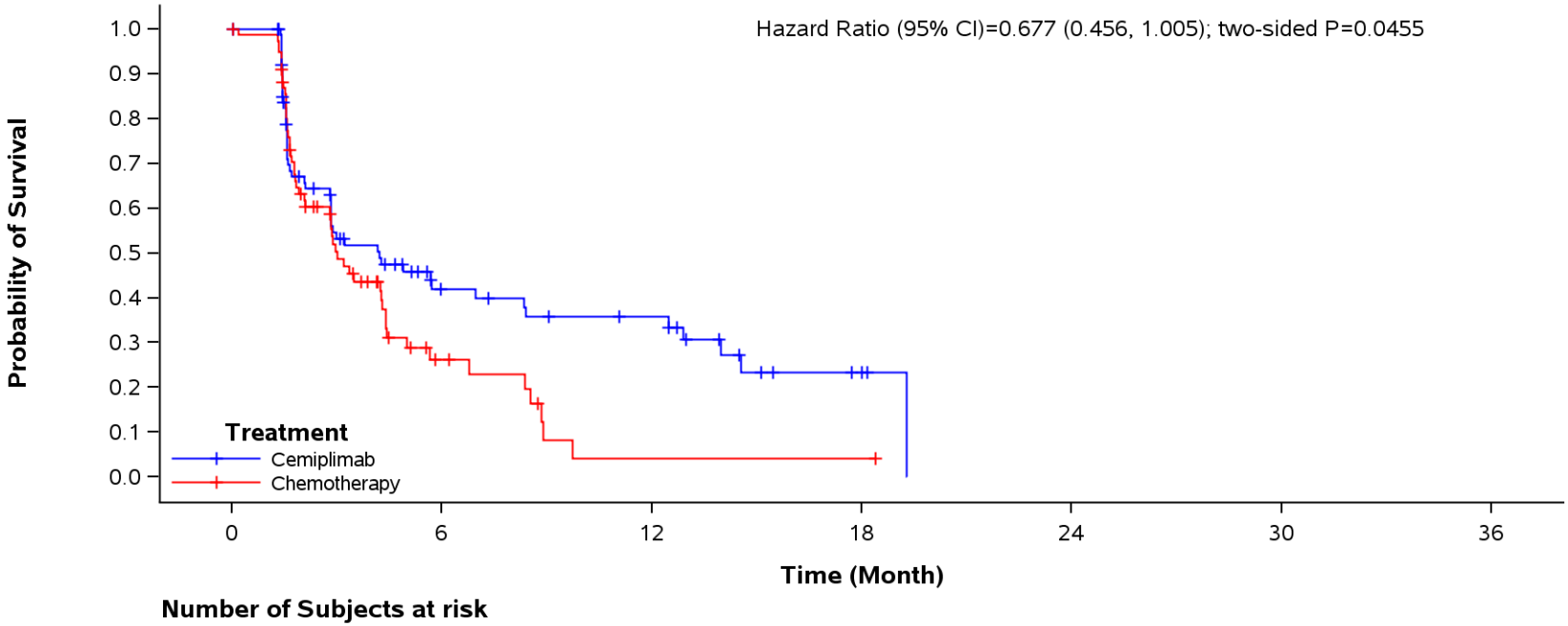

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 24 | 11 | 4 | 0 | 0 | 0 |
| Chemotherapy | 97 | 16 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts deterioration



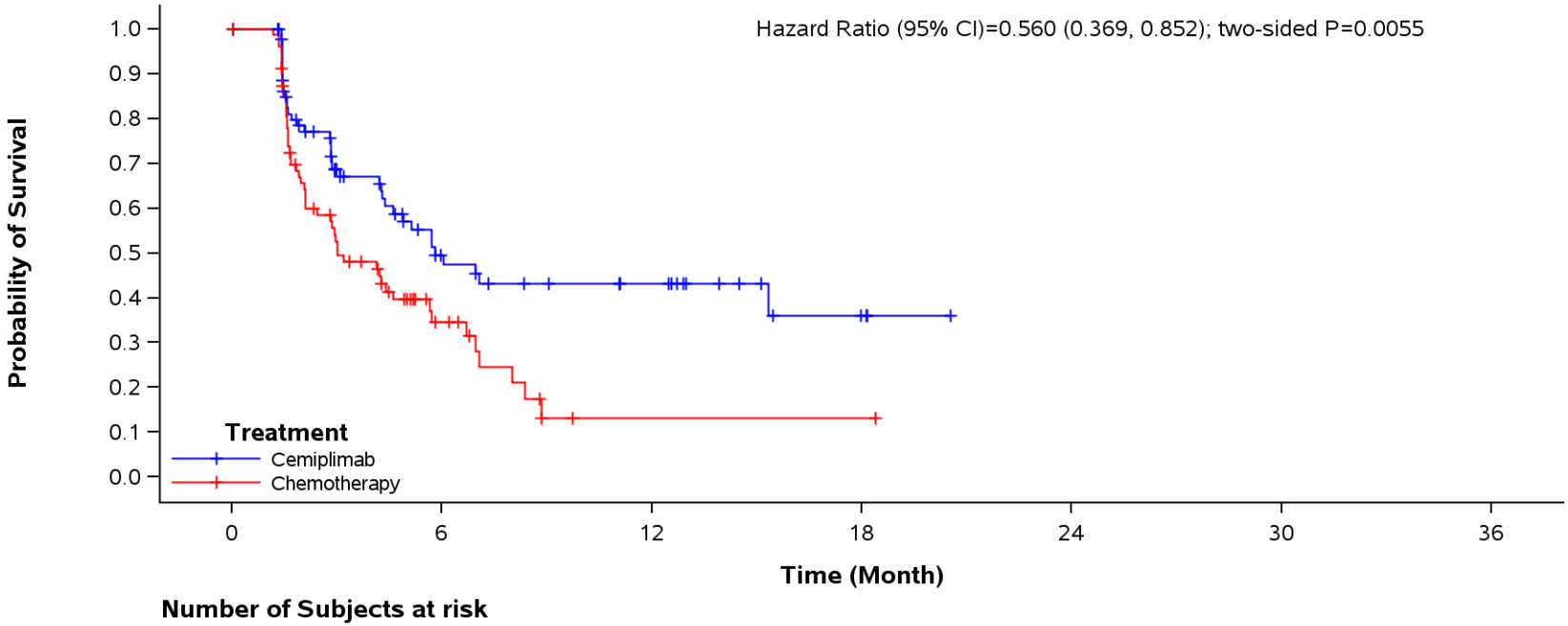

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 21 | 15 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 9 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts deterioration



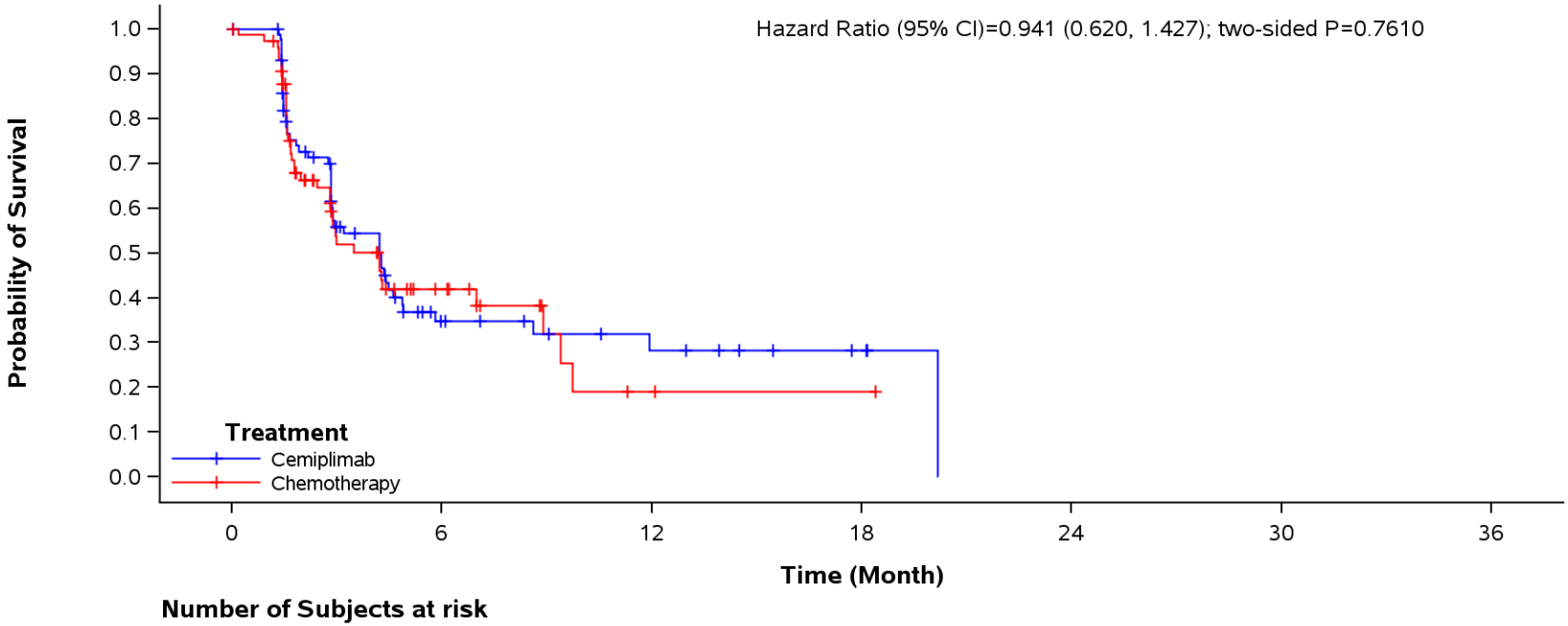

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 24 | 14 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts deterioration



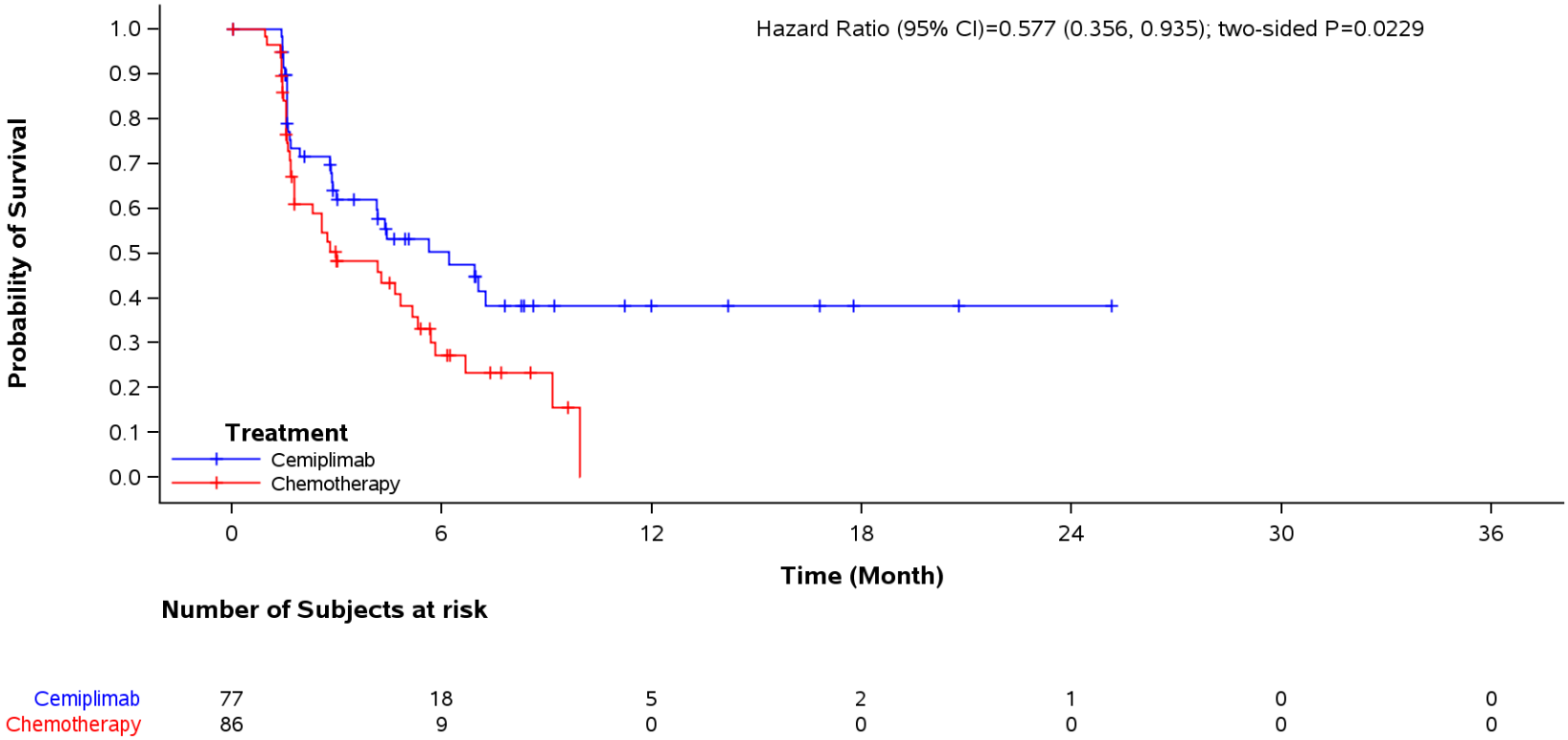

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 16 | 8 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 14 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts deterioration



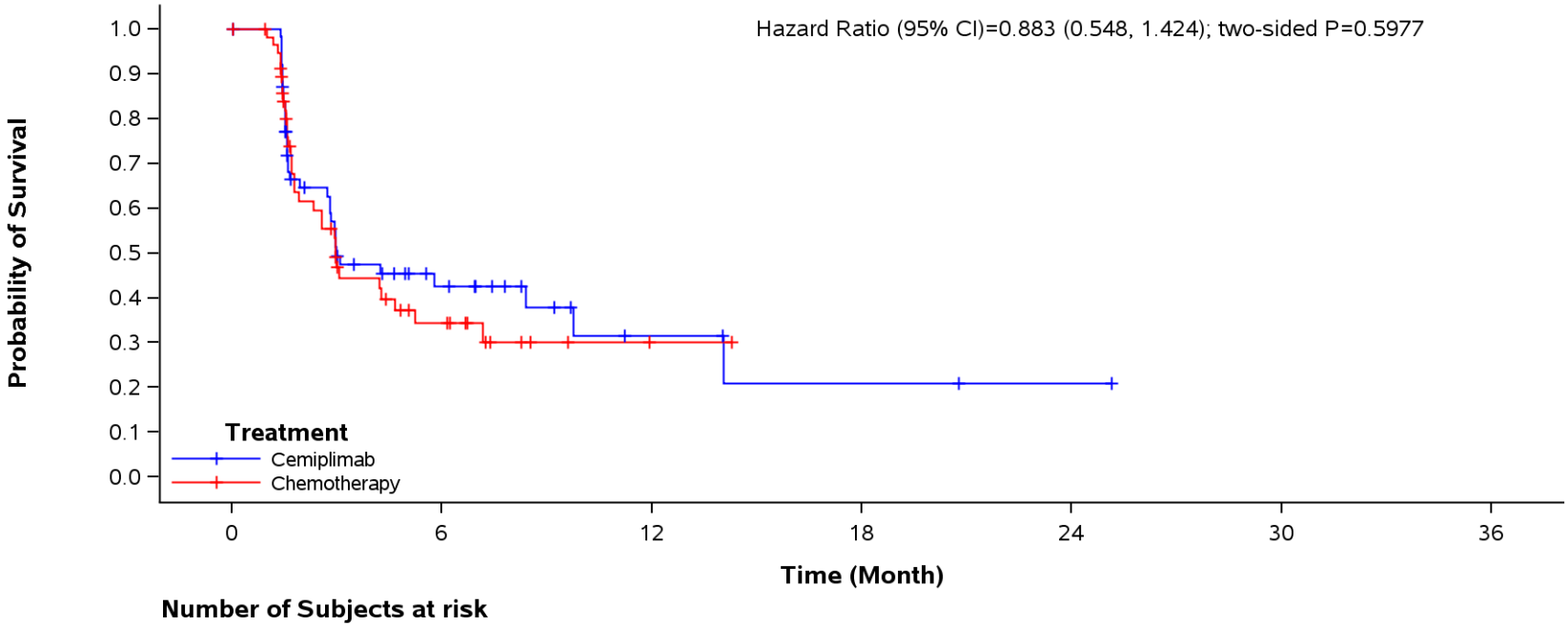

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 18 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 86 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts deterioration



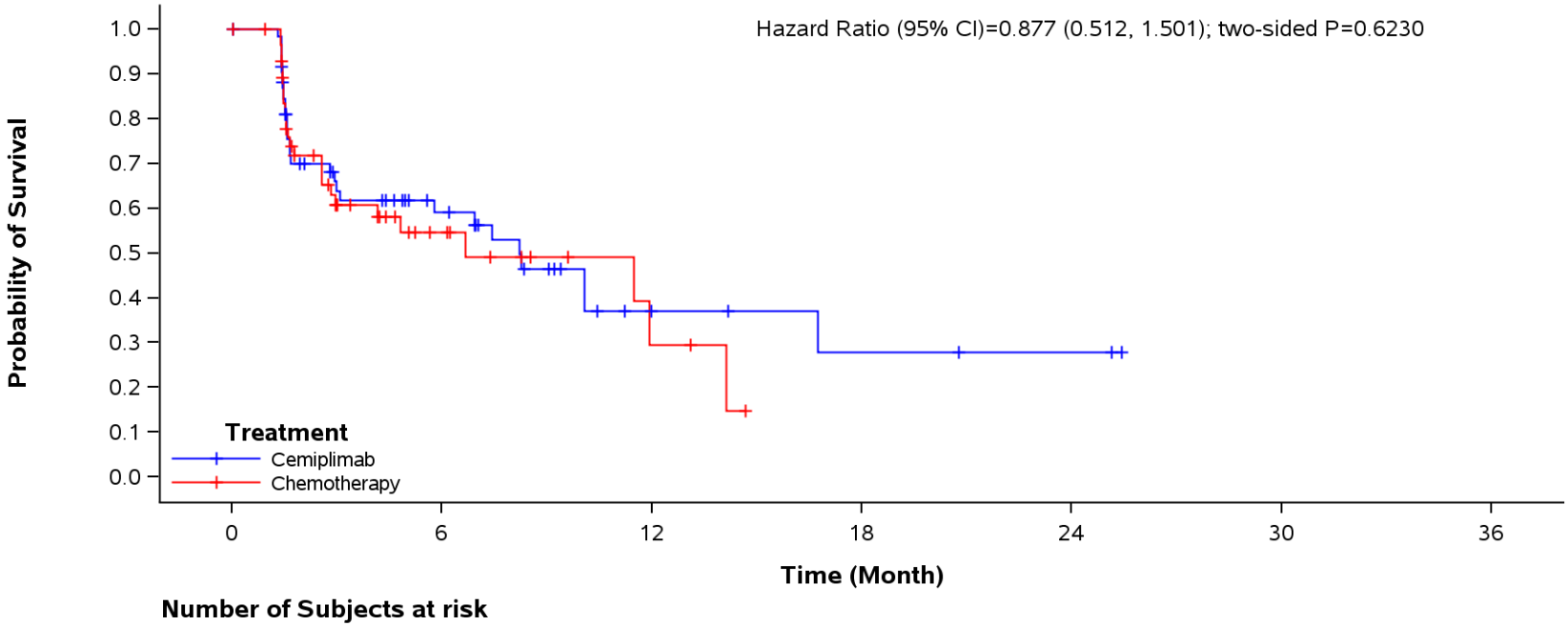

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 15 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 86 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts deterioration



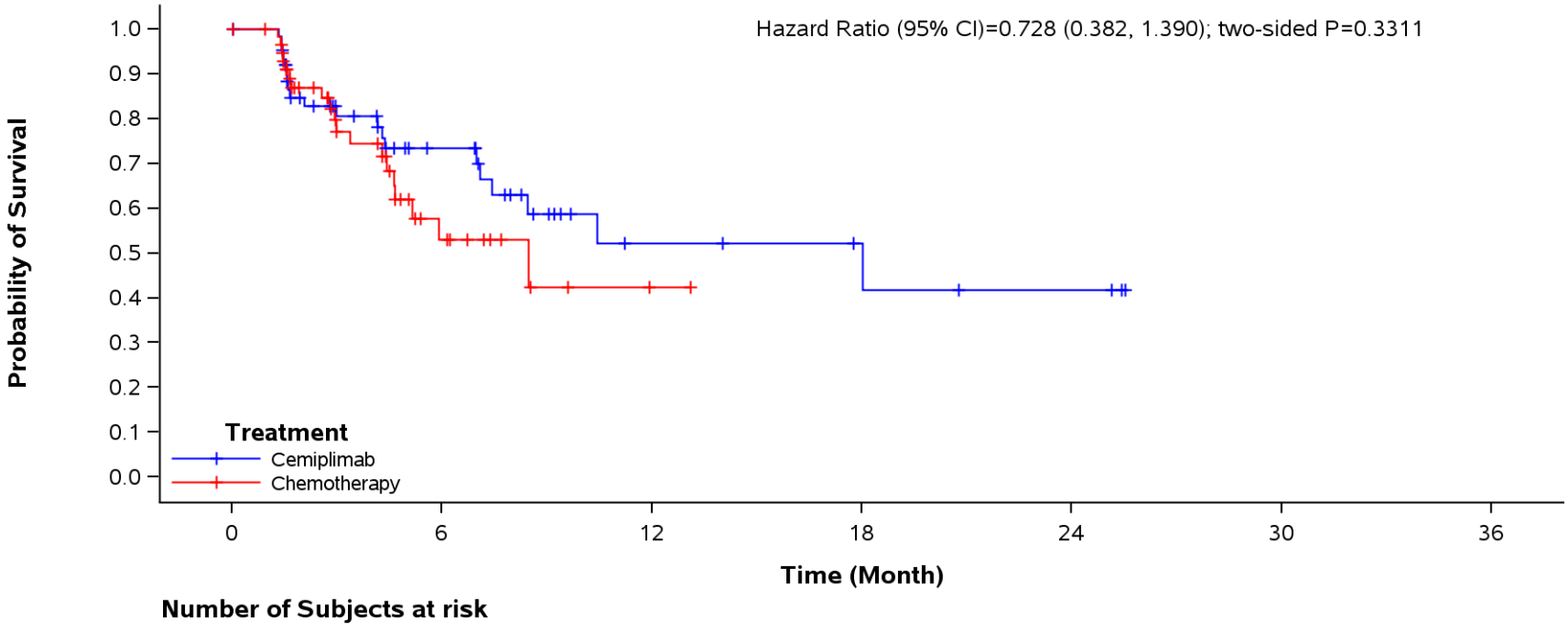

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 22 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 12 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts deterioration



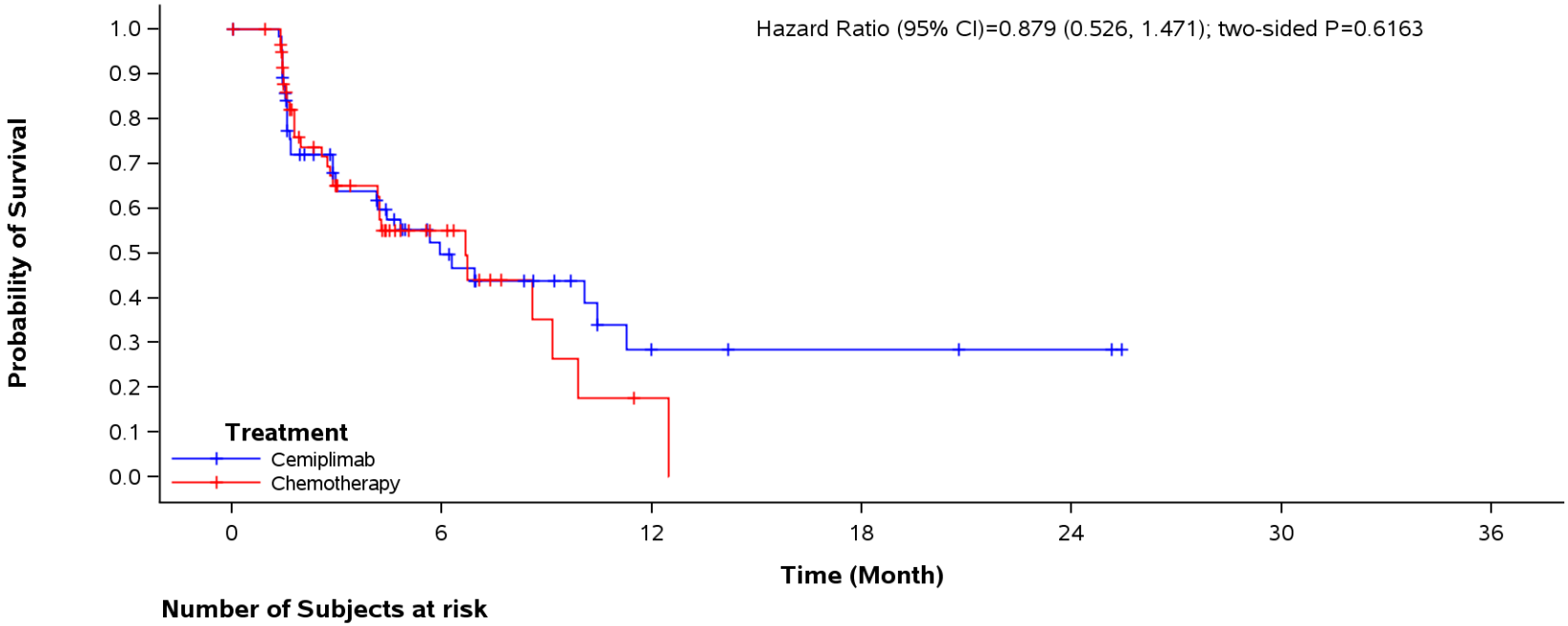

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 24 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts deterioration



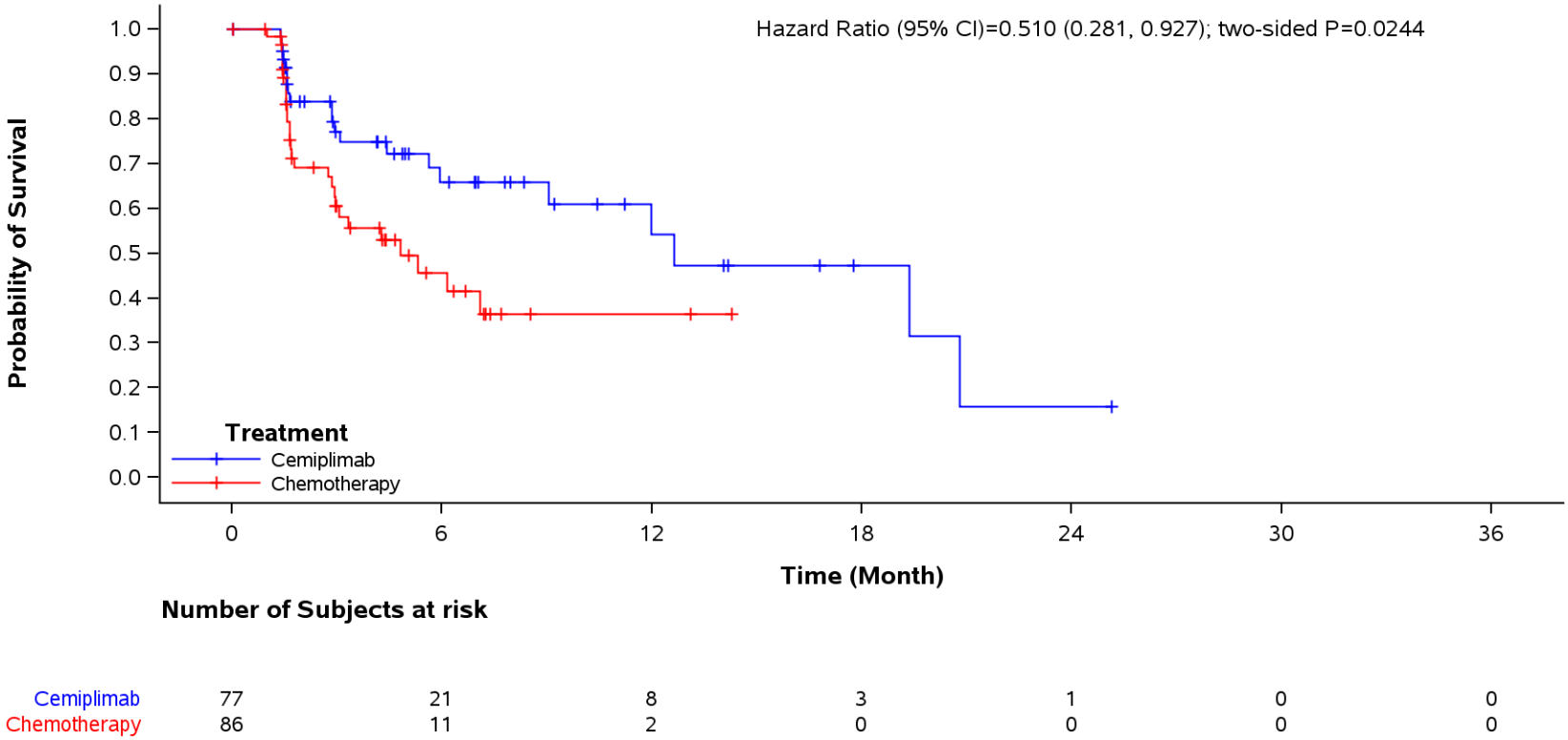

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 18 | 4 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts deterioration



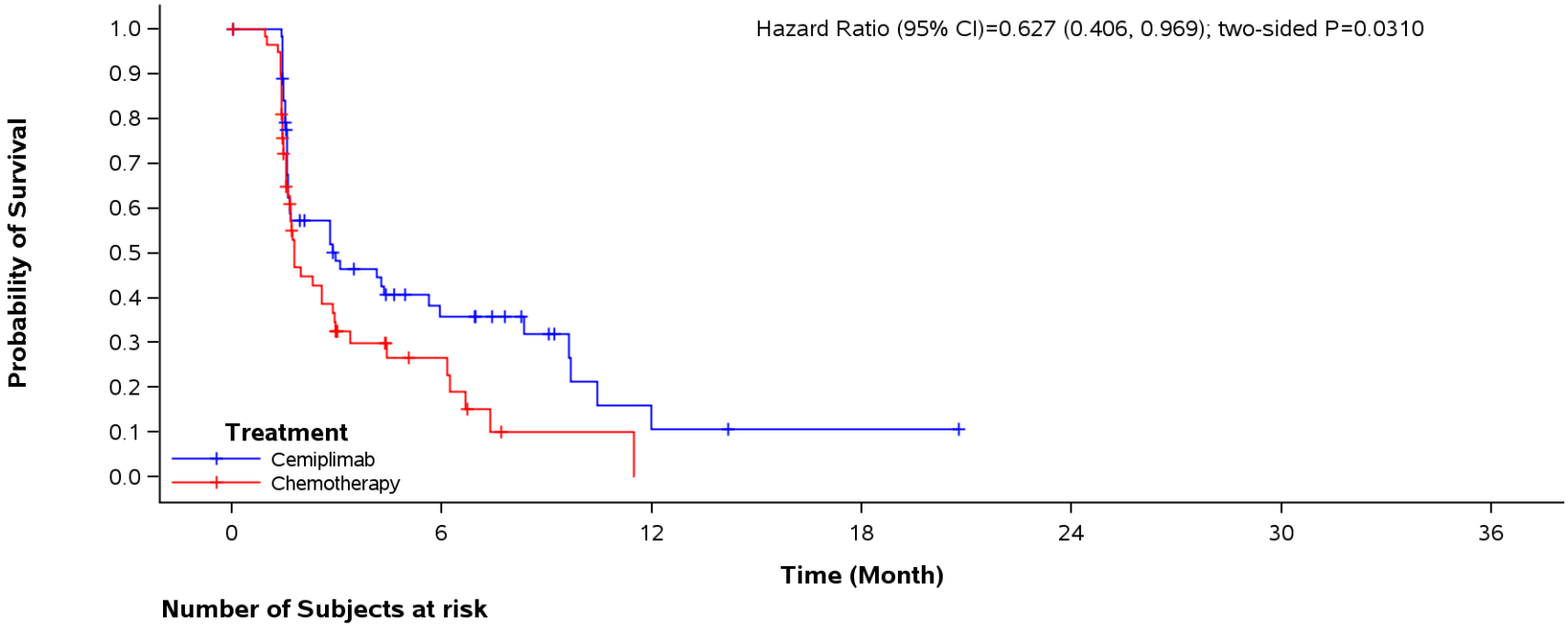

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 21 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 86 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts deterioration



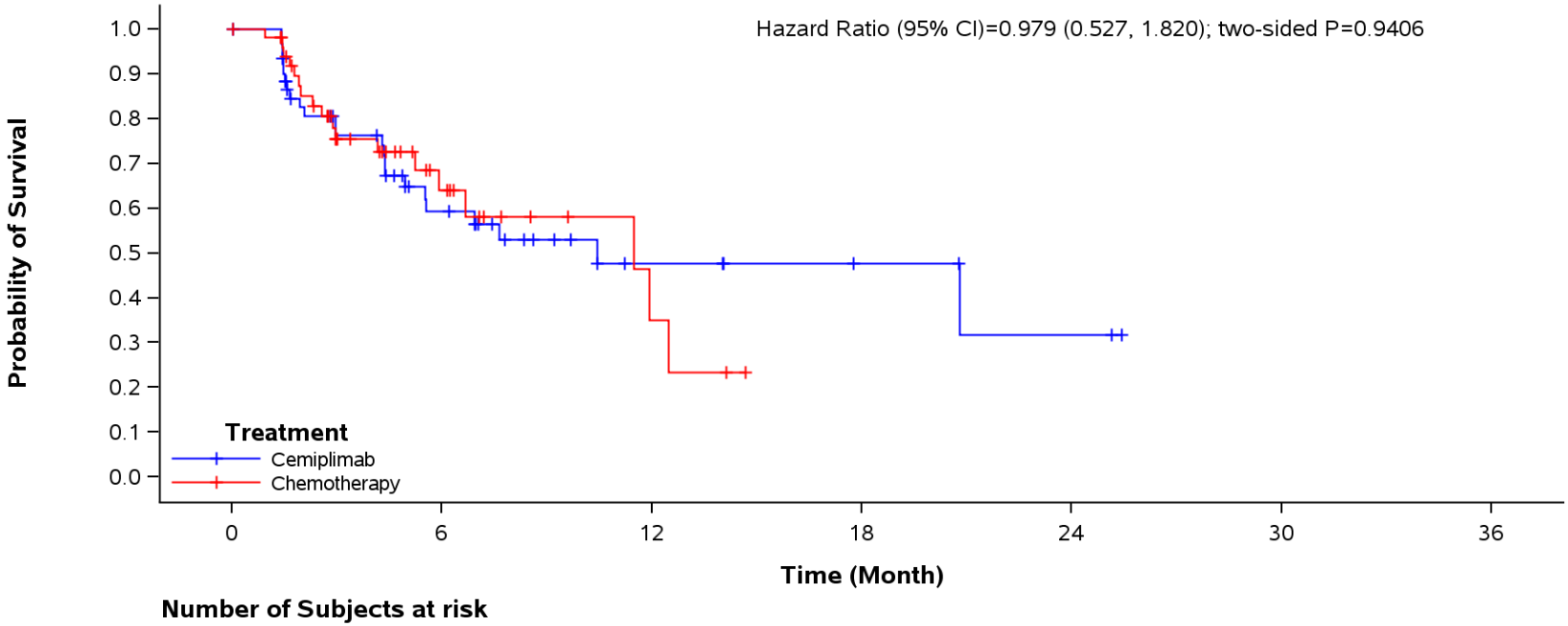

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 15 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 86 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts deterioration



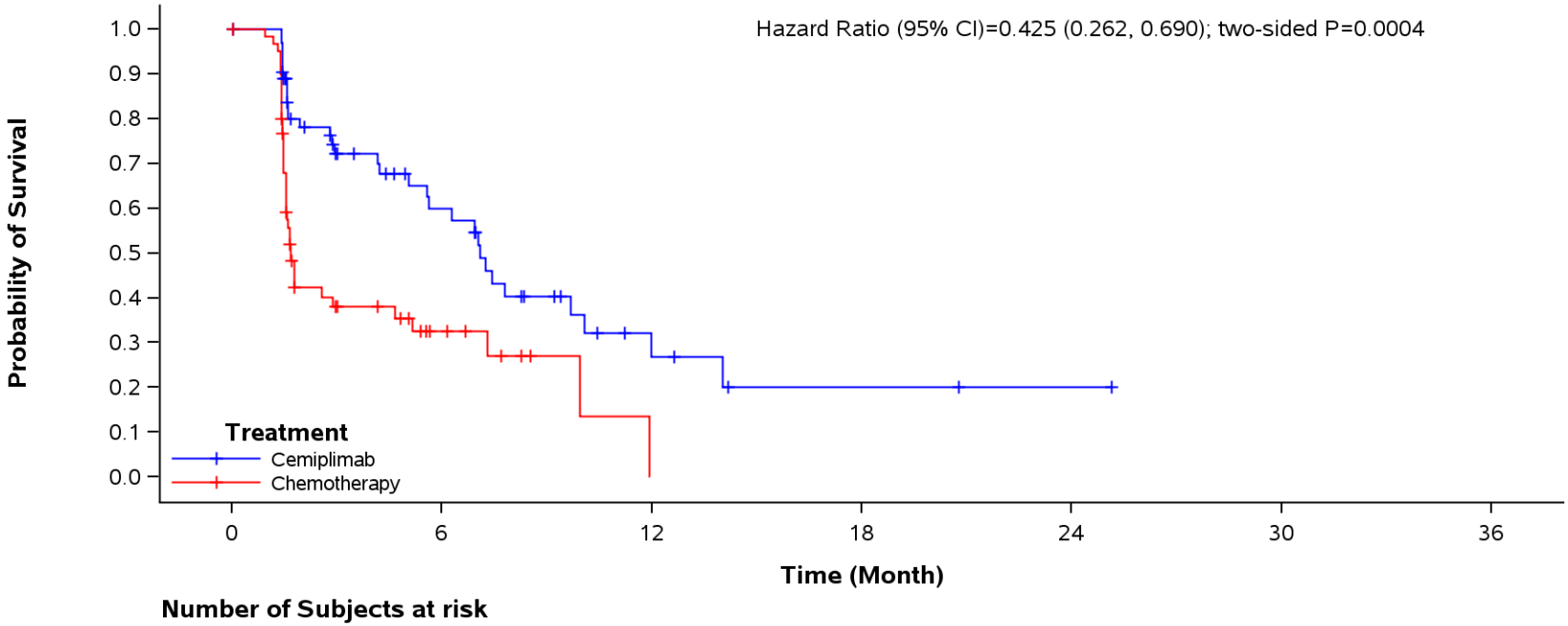

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 22 | 7 | 4 | 2 | 0 | 0 |
| Chemotherapy | 86 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts deterioration



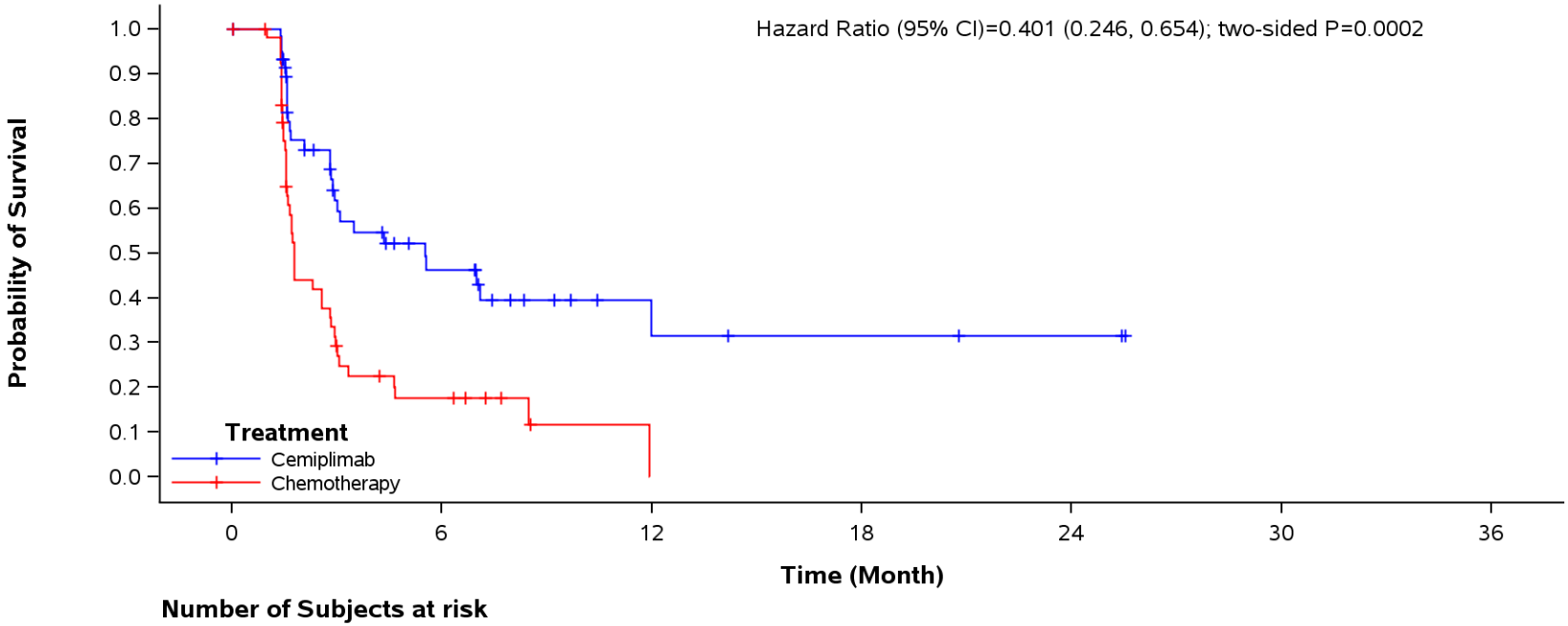

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 23 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 86 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts deterioration



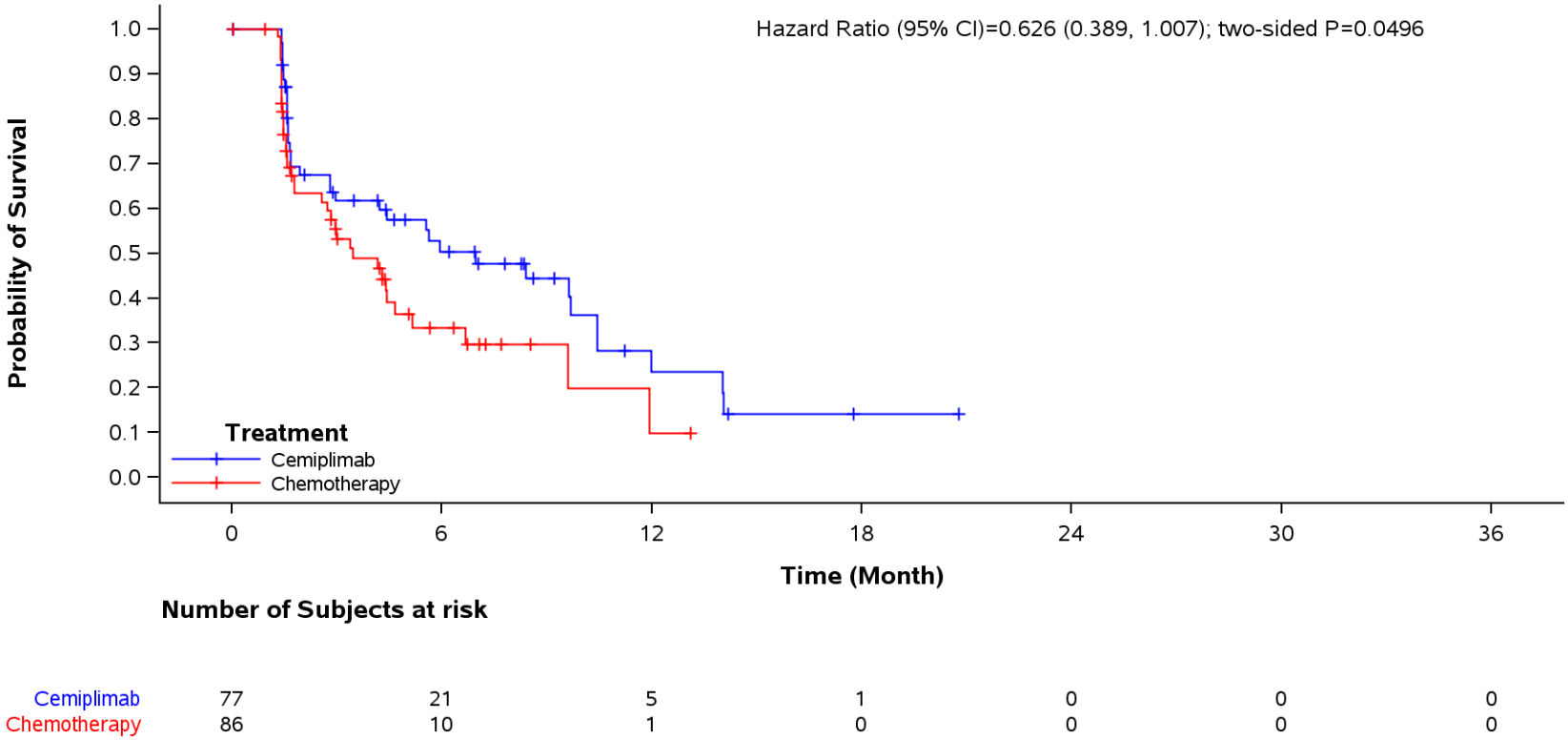

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 16 | 4 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

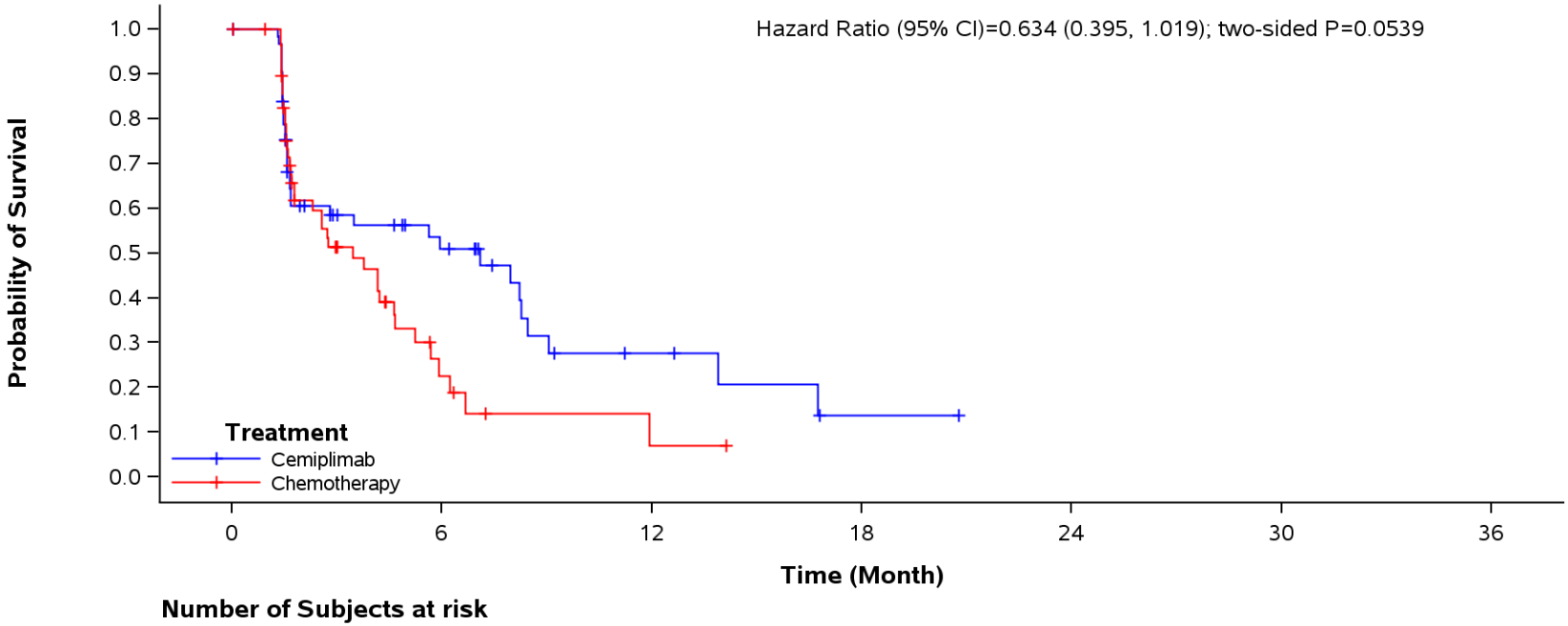
Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts deterioration



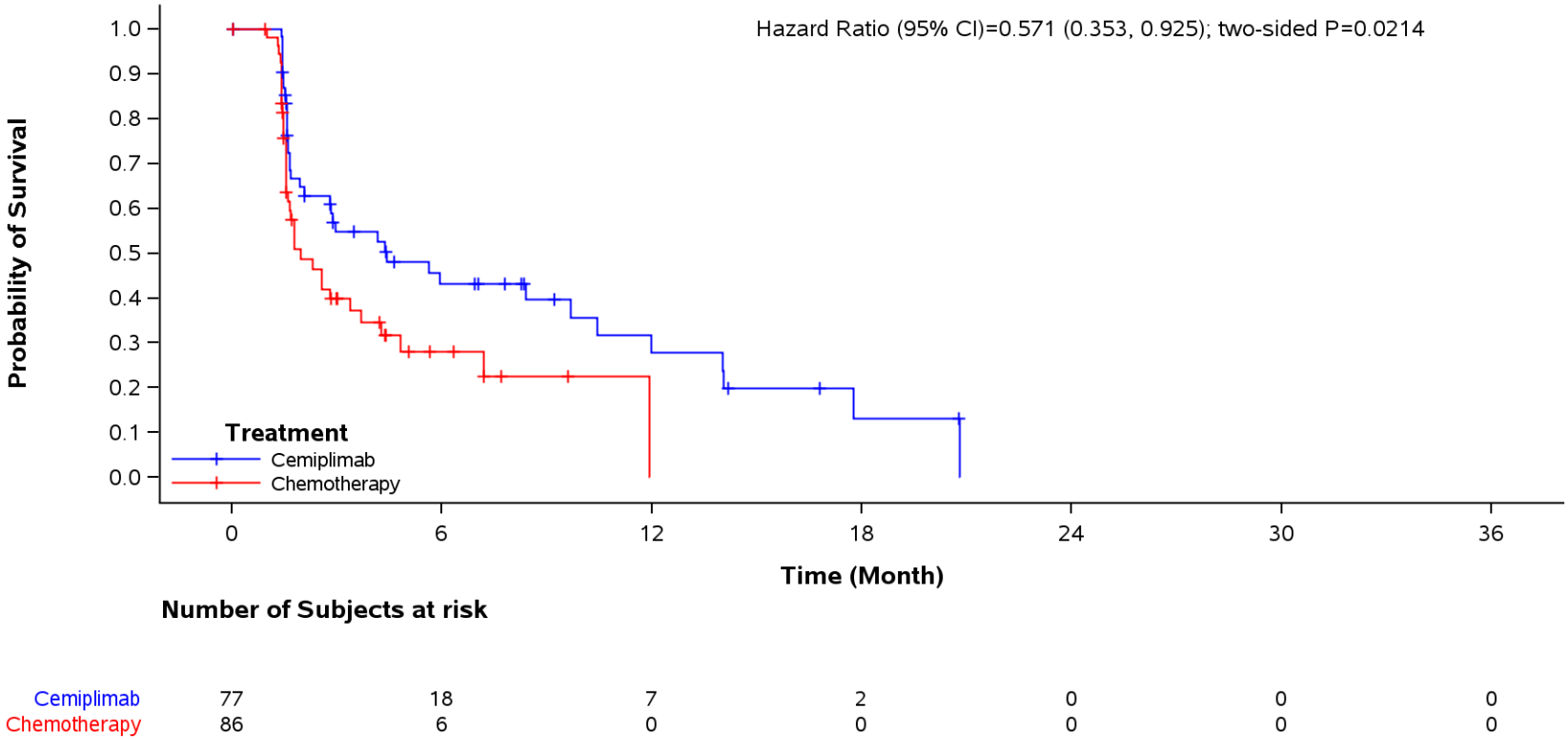

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 19 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 86 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts deterioration



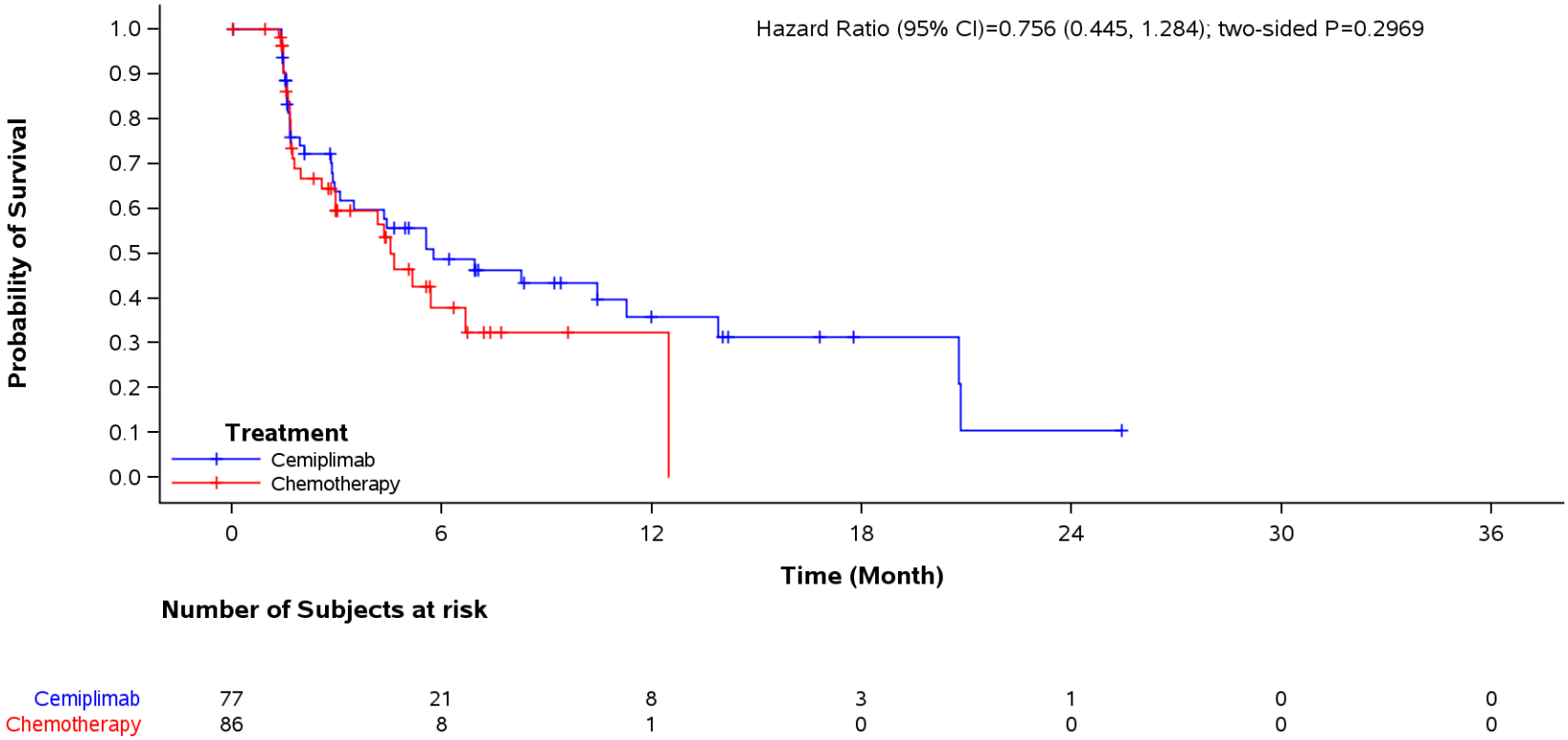

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 18 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 86 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

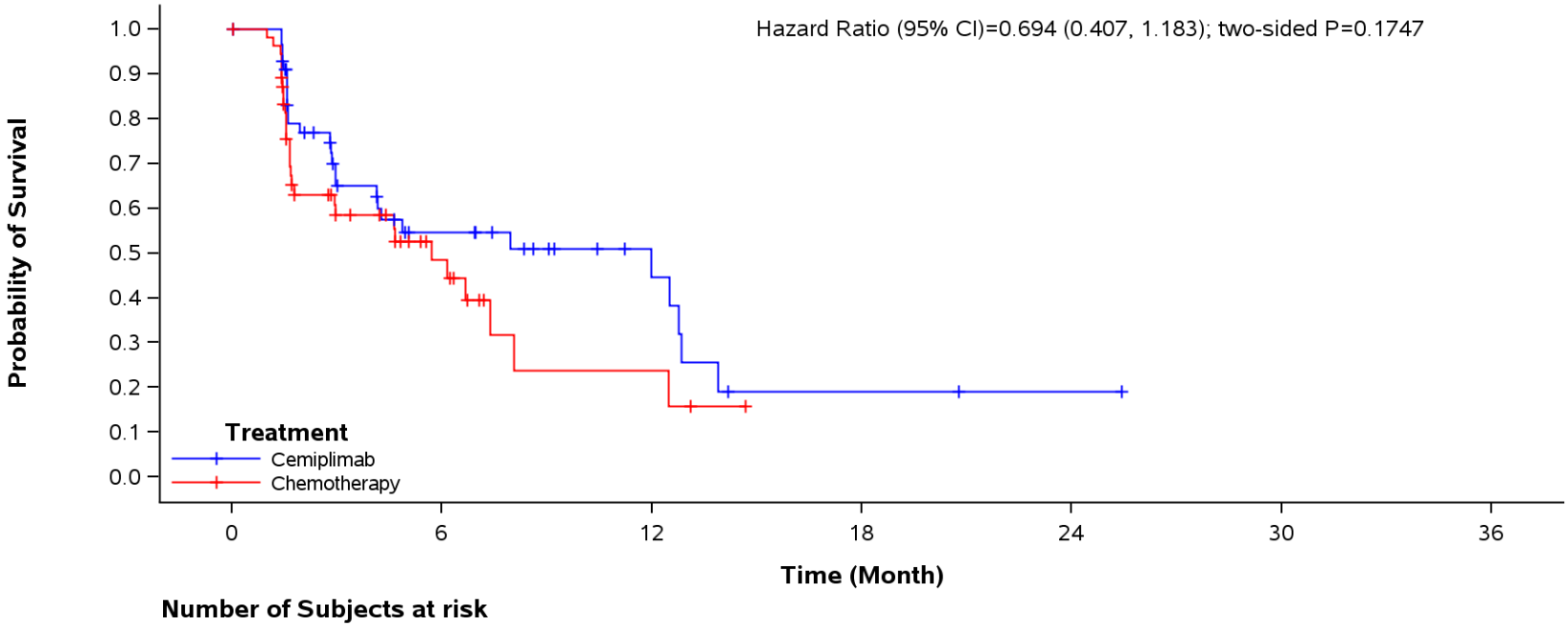
Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts deterioration



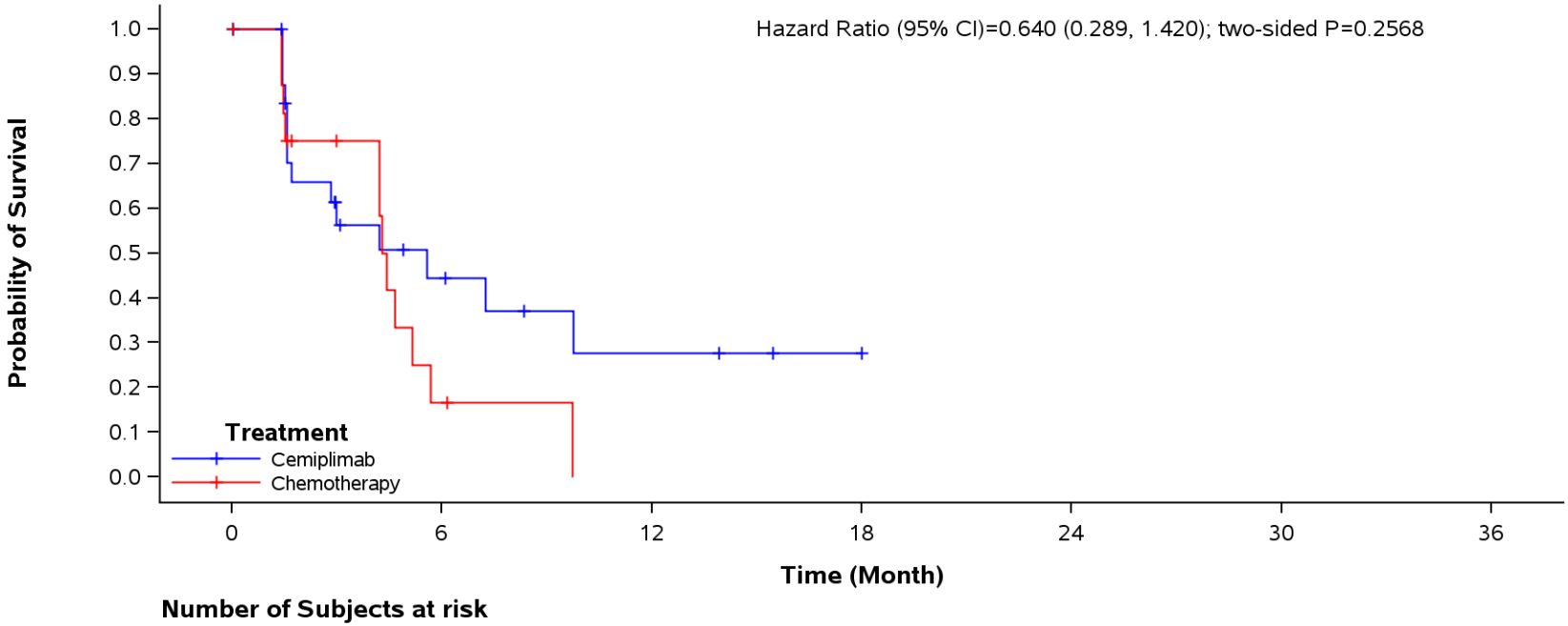

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 18 | 7 | 2 | 1 | 0 | 0 |
| Chemotherapy | 86 | 12 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts deterioration



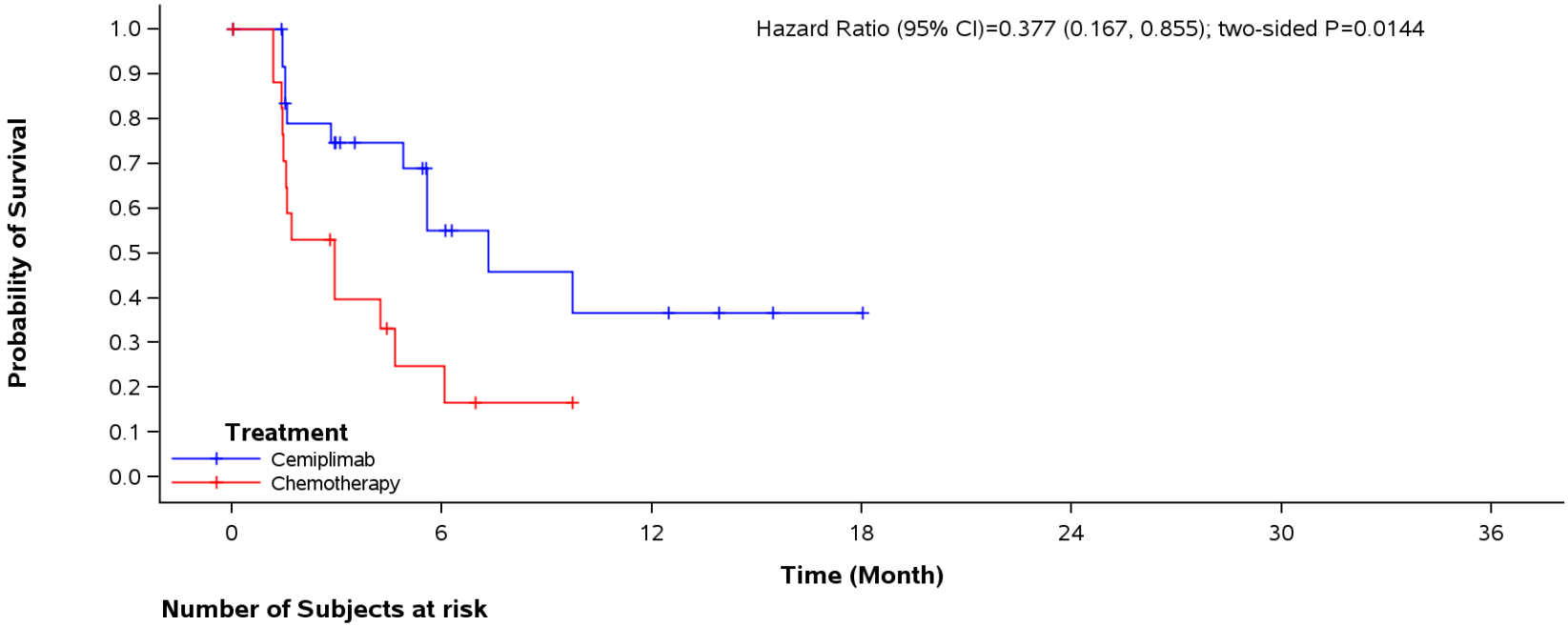

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 7 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts deterioration



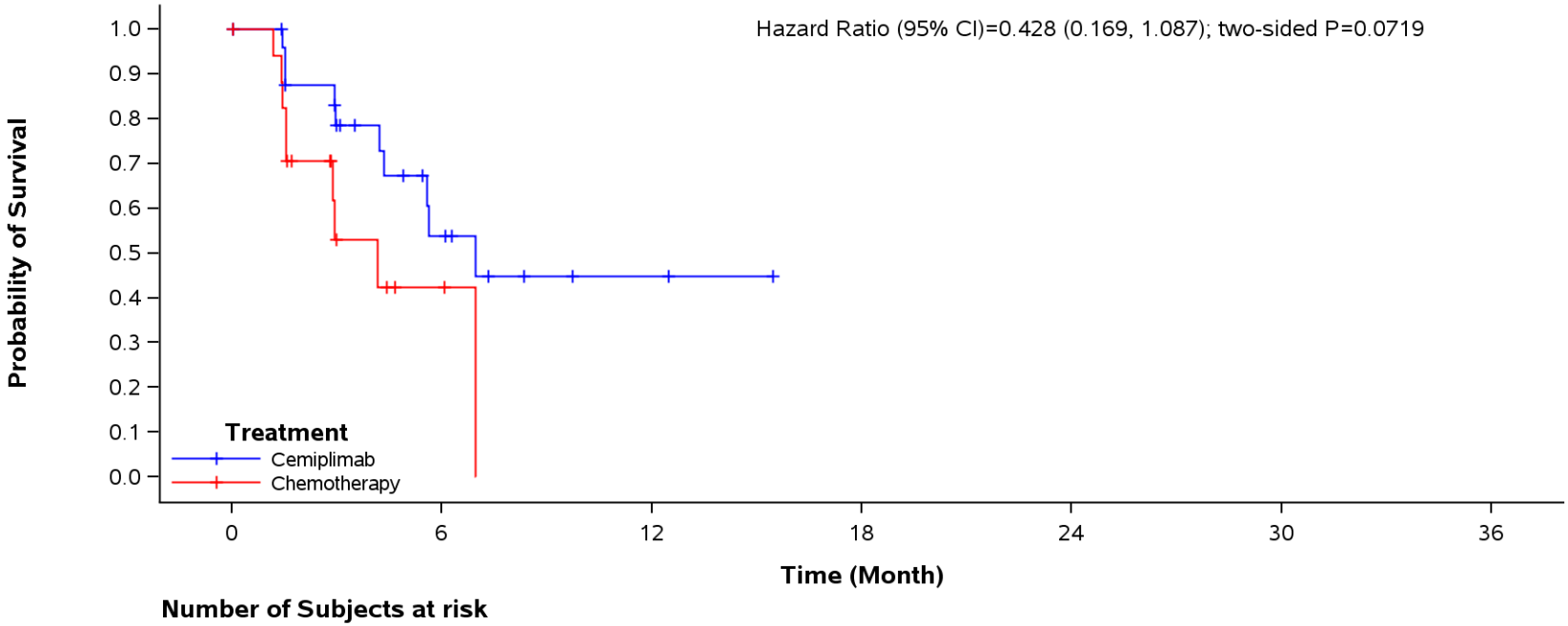

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 8 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts deterioration



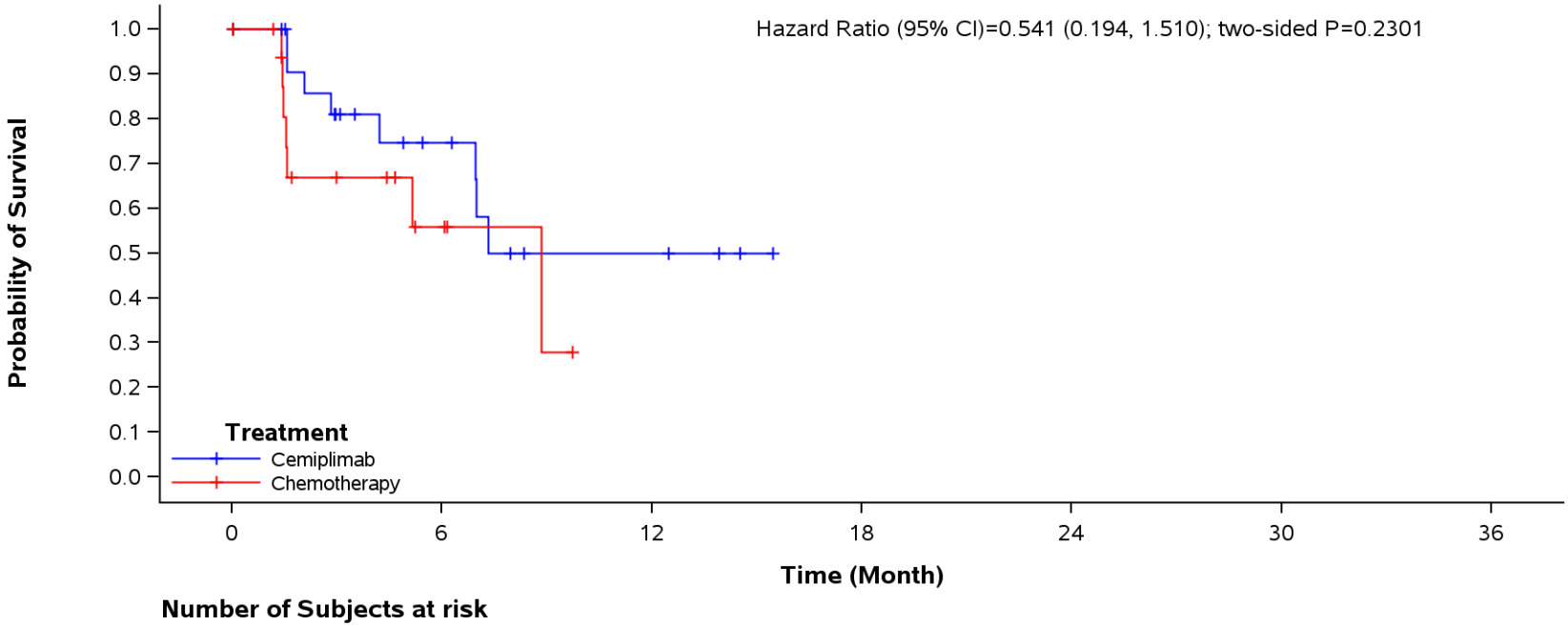

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 8 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts deterioration



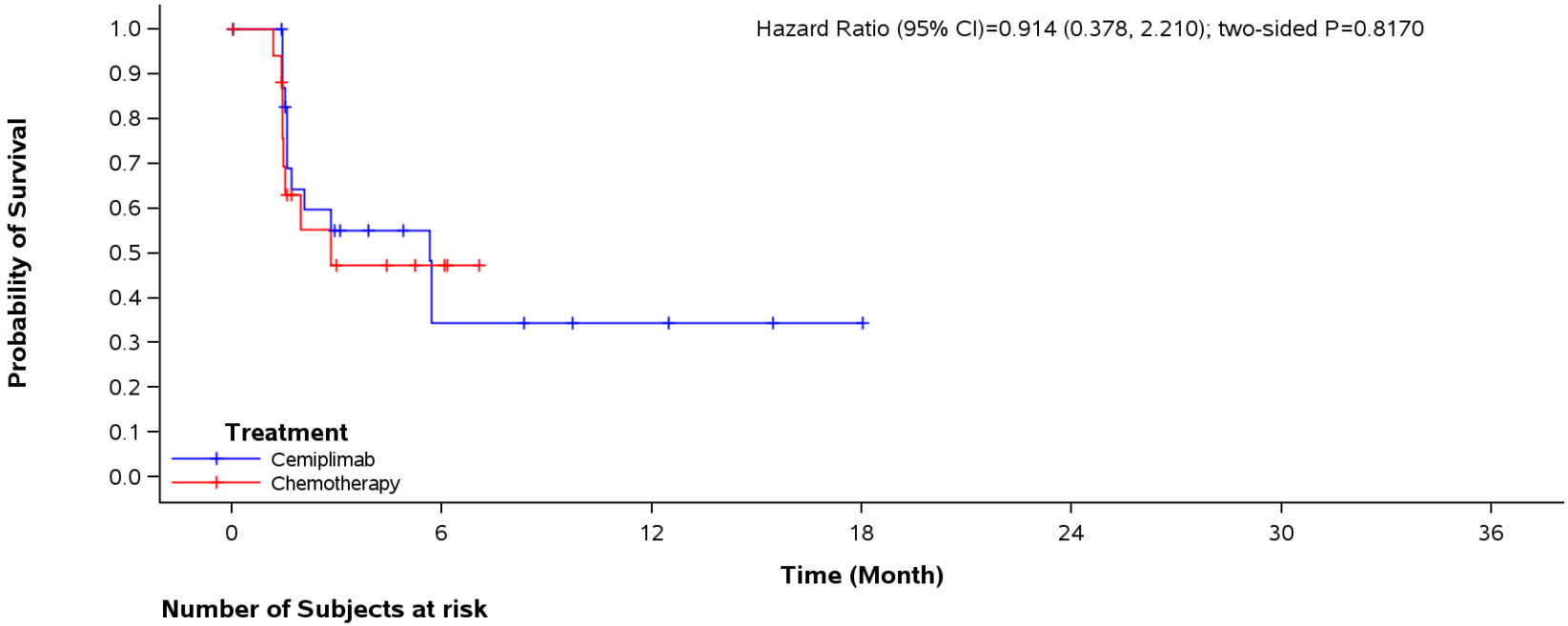

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 10 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts deterioration



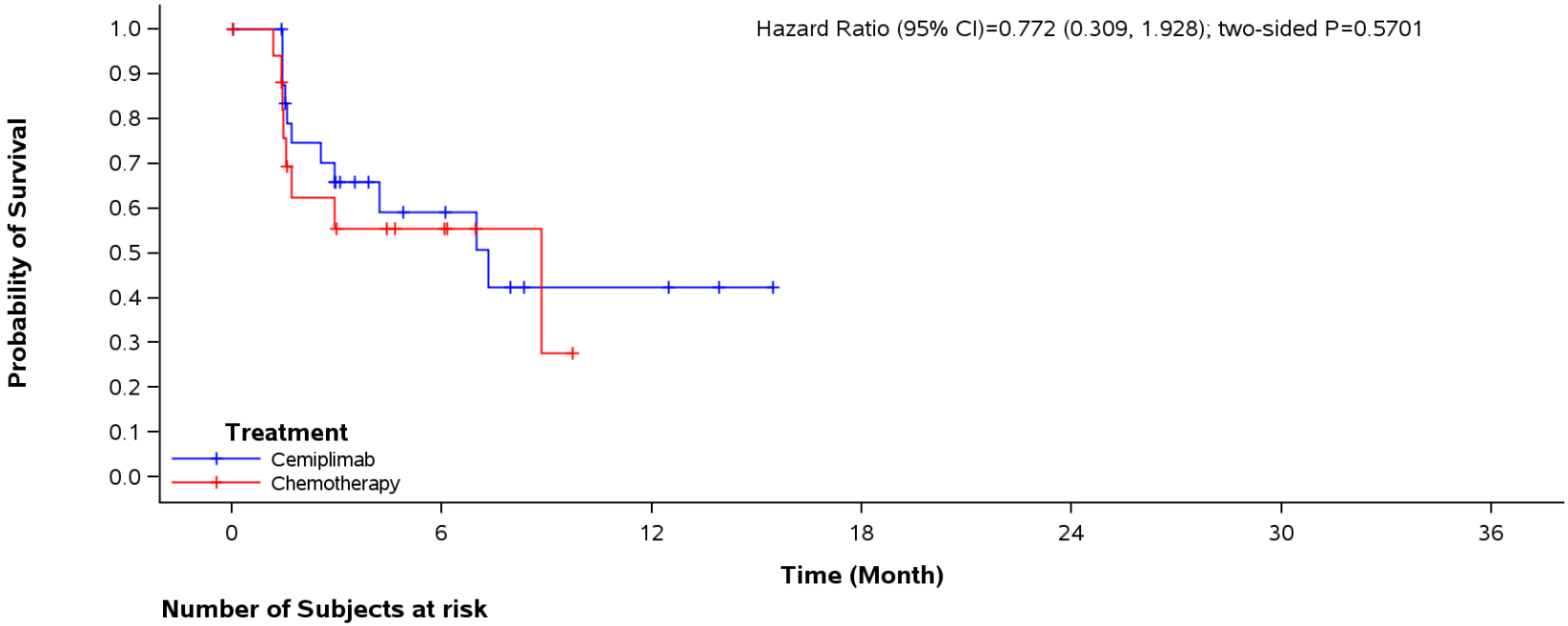

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts deterioration



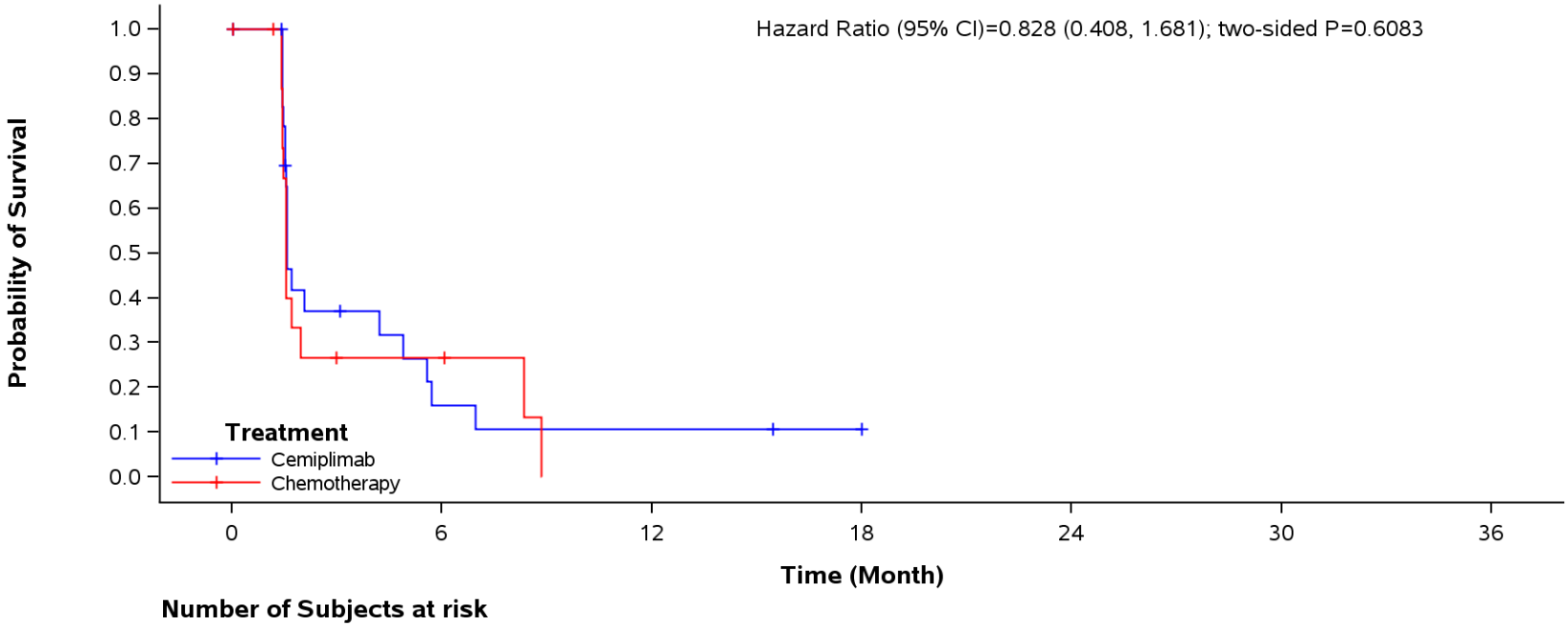

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts deterioration



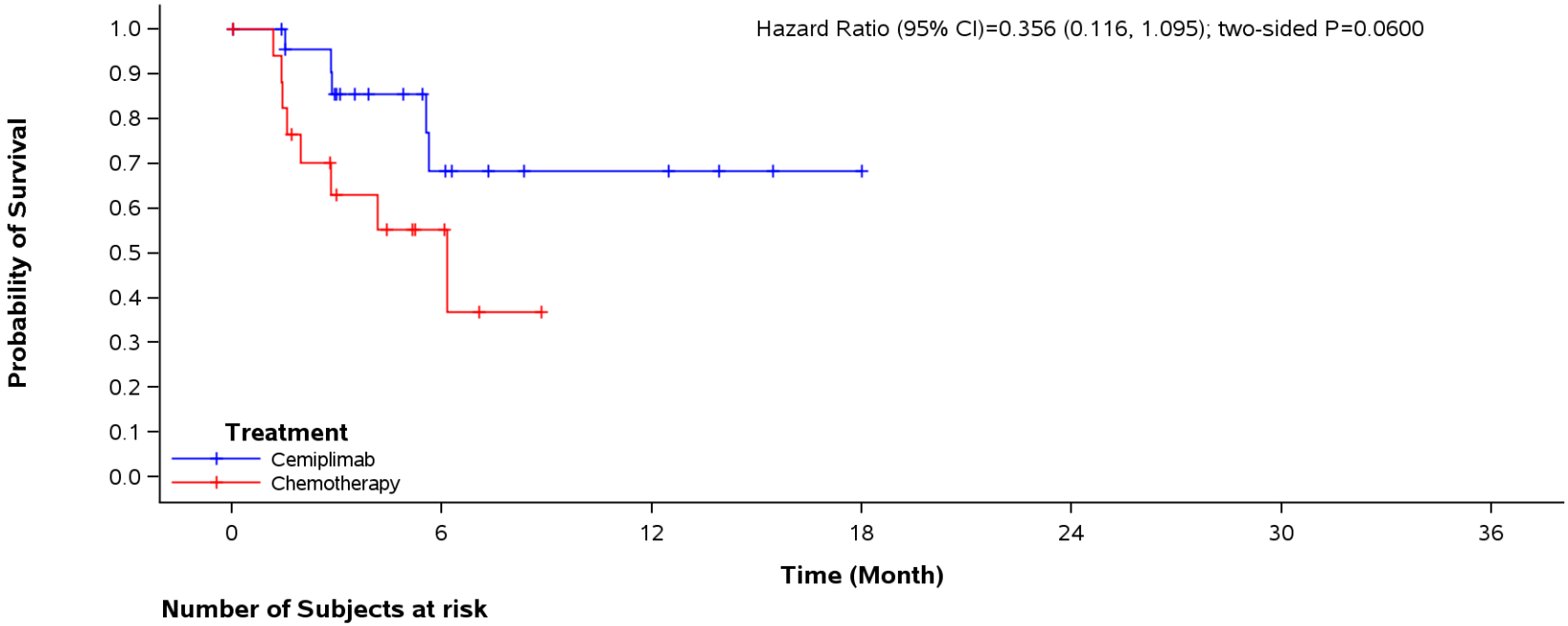

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts deterioration




**Number of Subjects at risk**

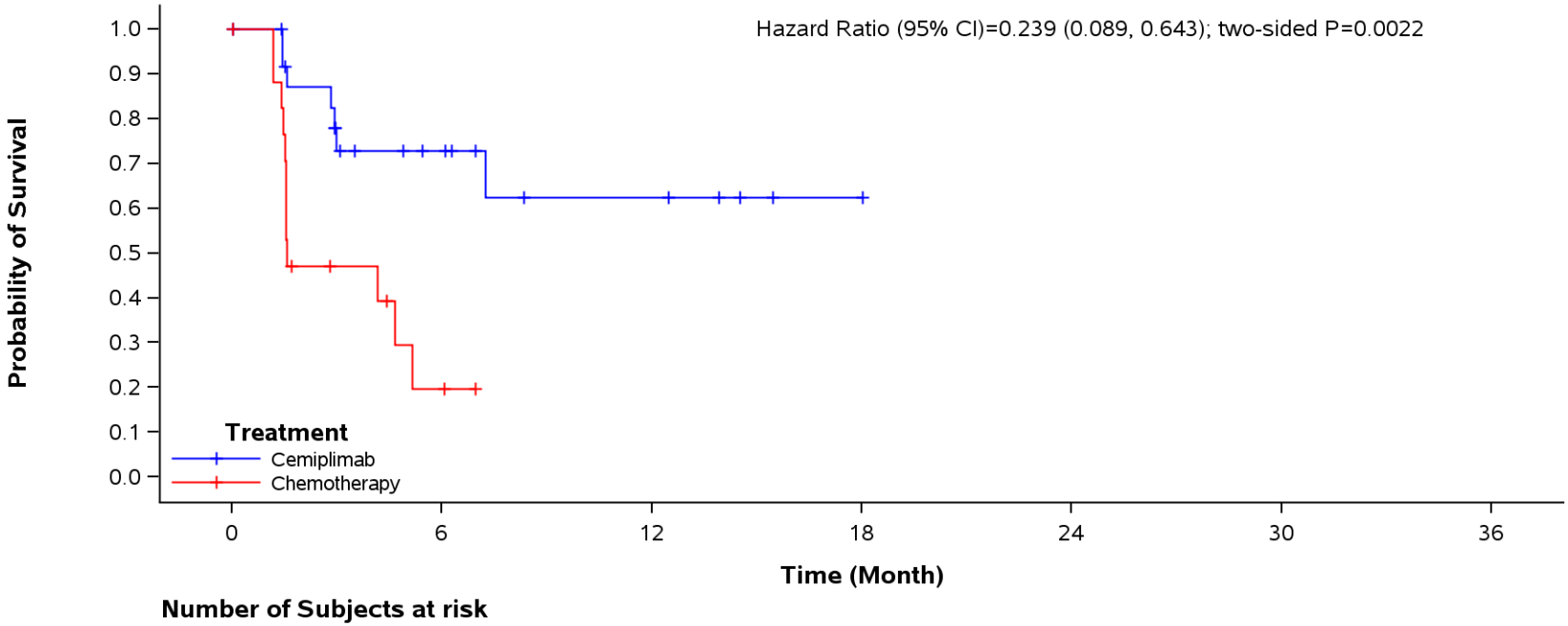
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 8 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:18:00, yingyuan.lin)

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts deterioration



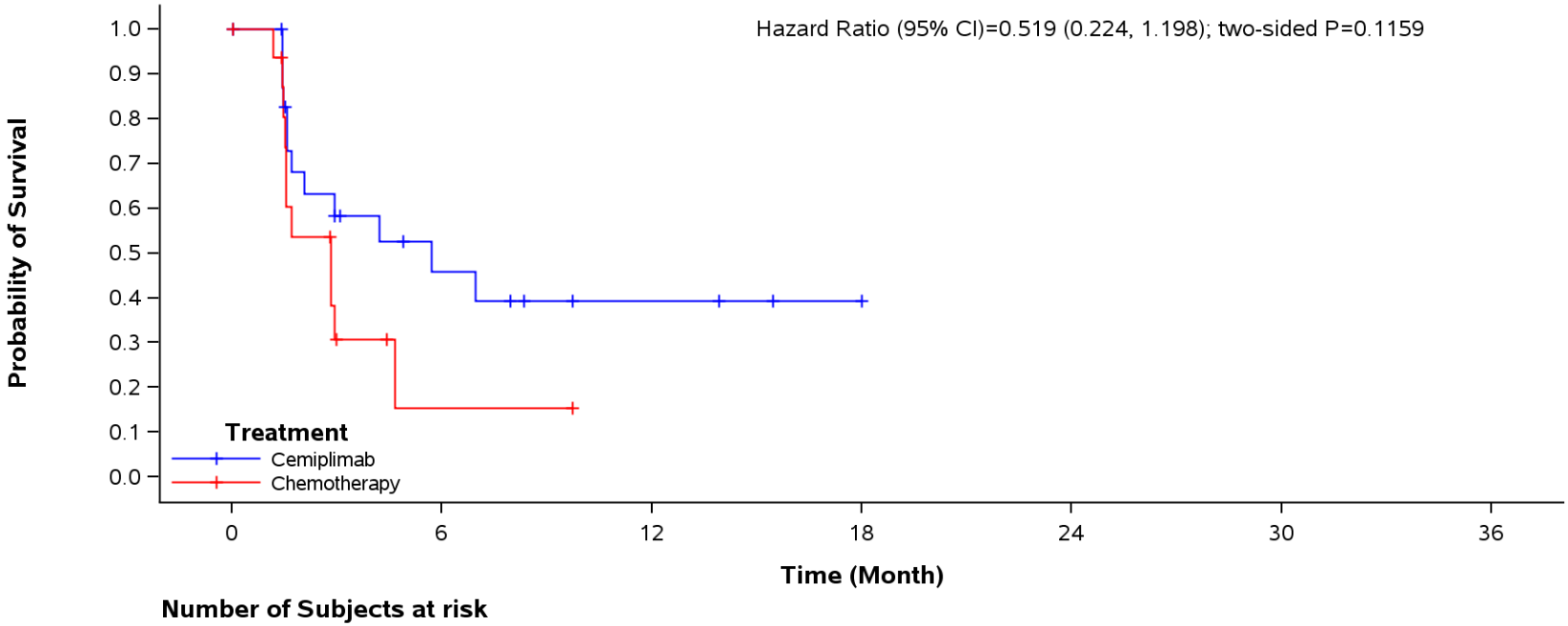

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 10 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts deterioration



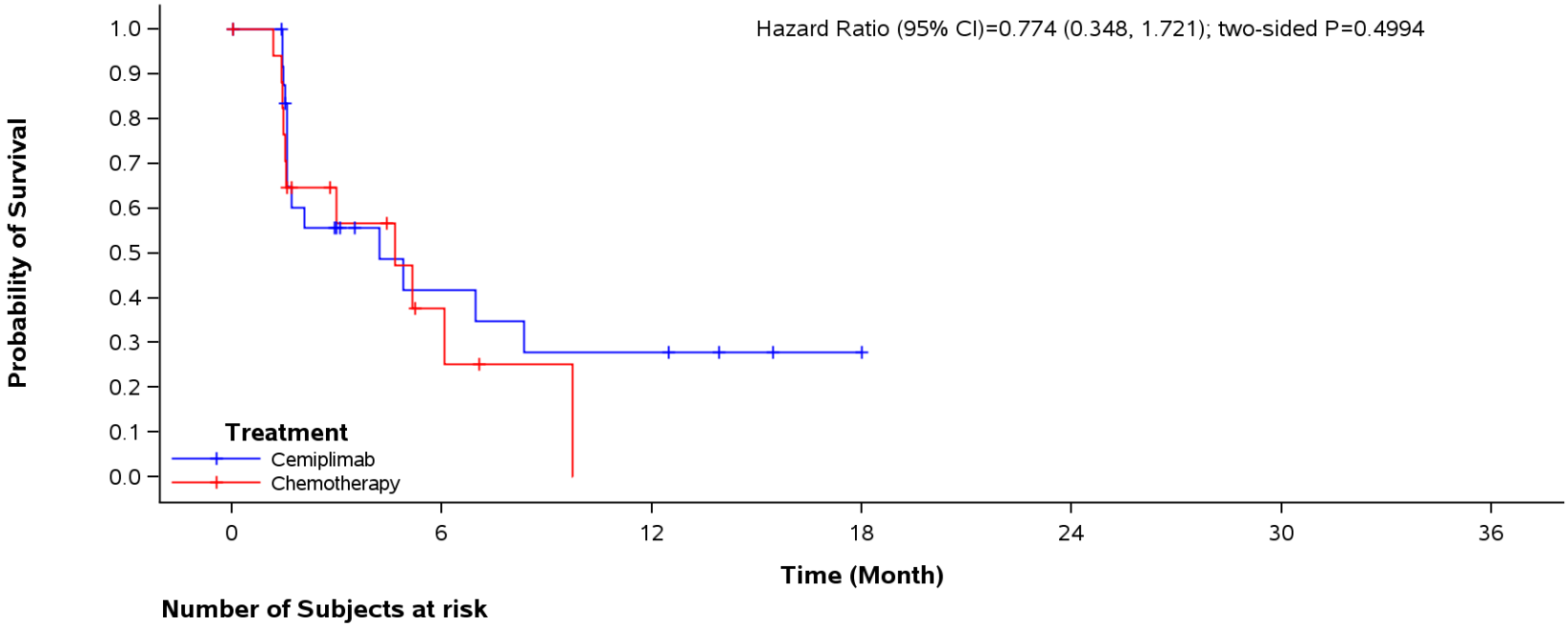

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 7 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts deterioration



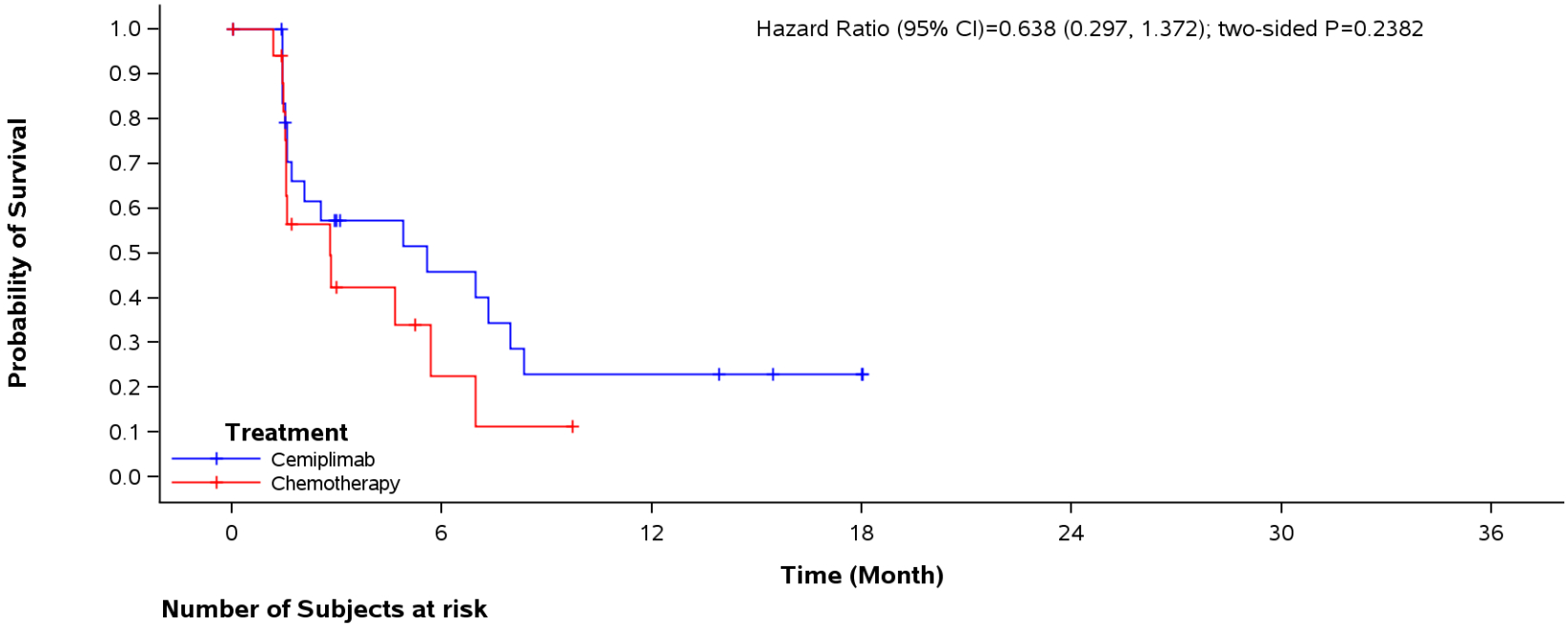

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts deterioration



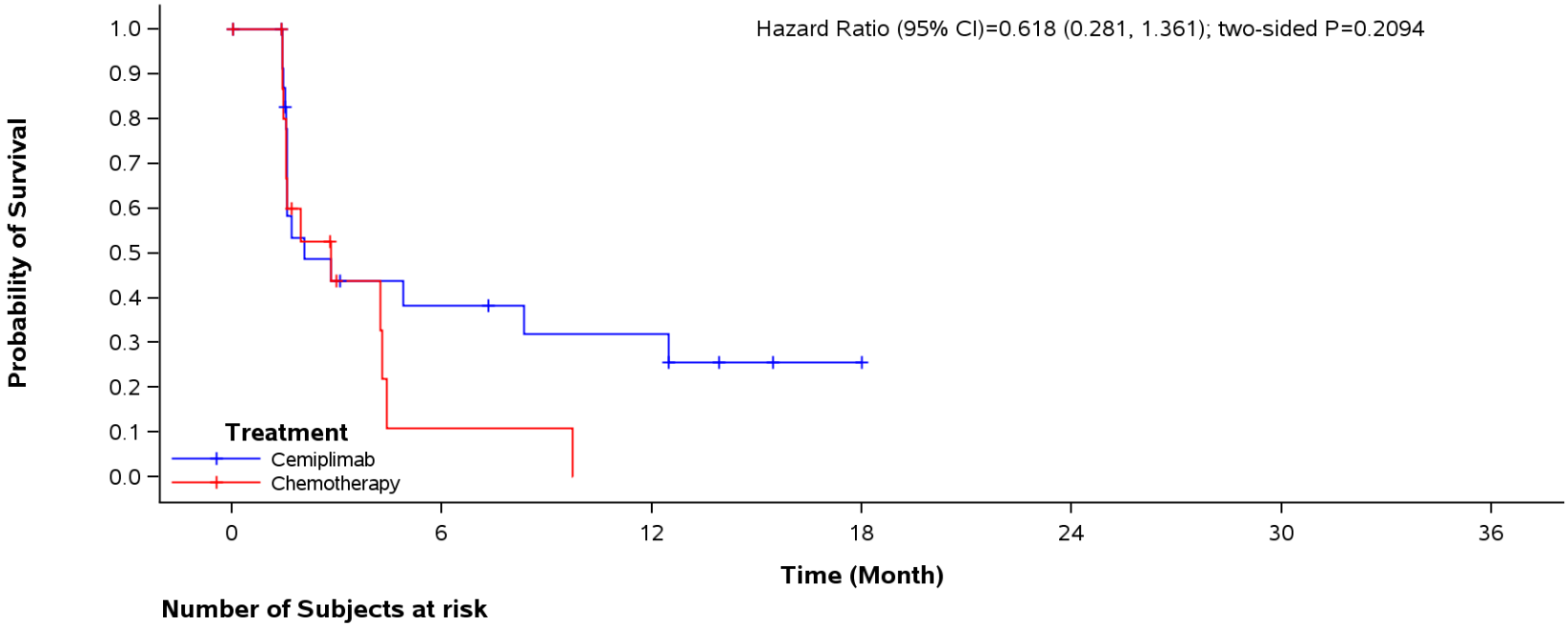

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 8 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts deterioration



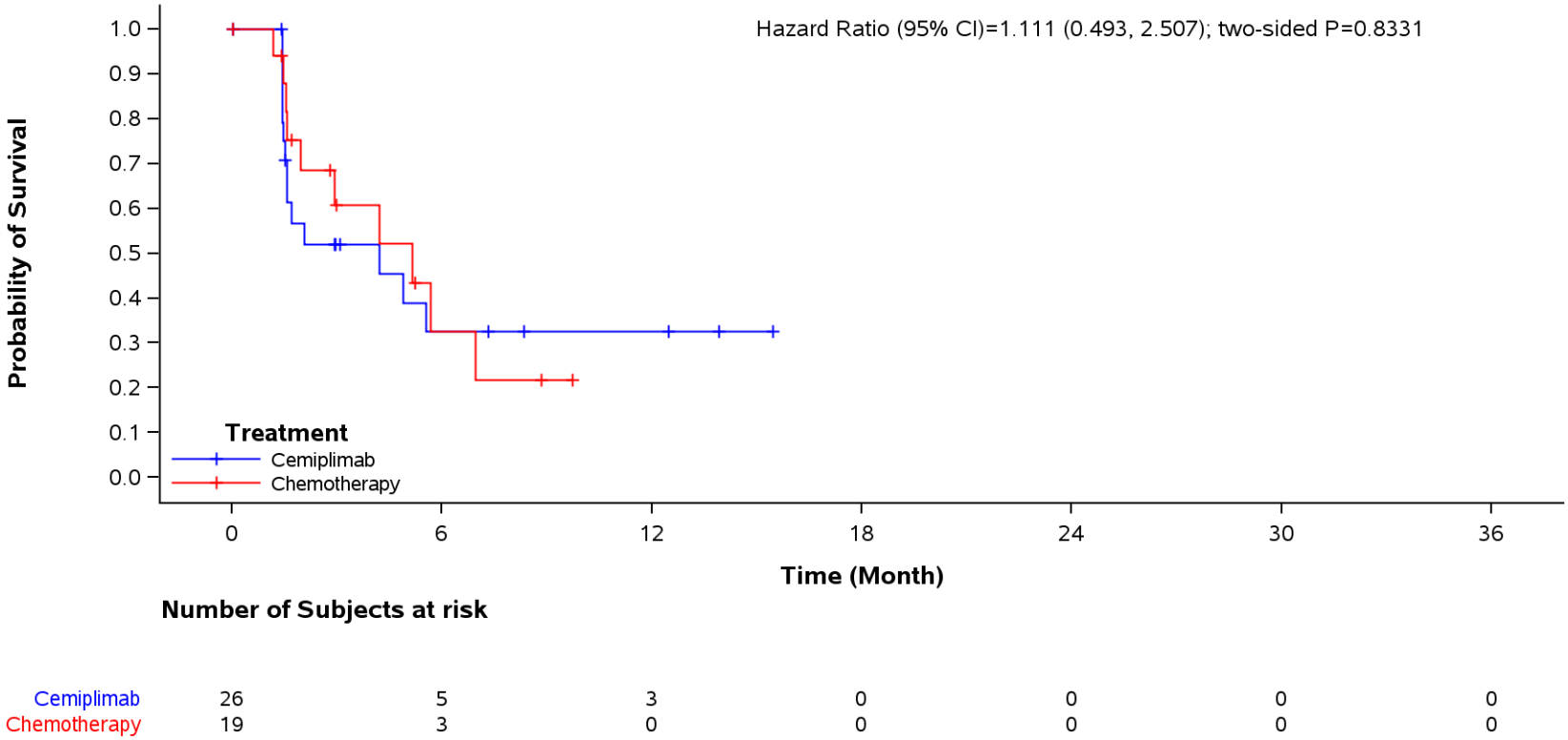

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 7 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

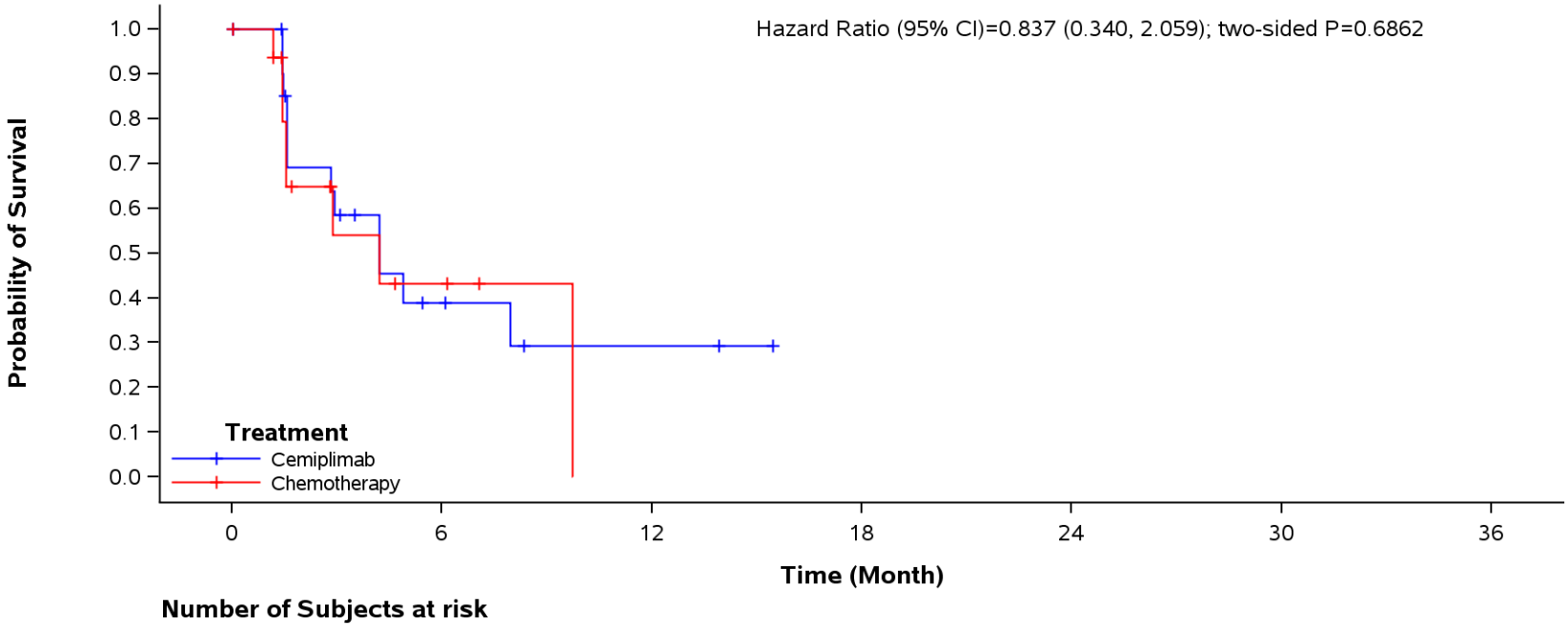
Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts deterioration



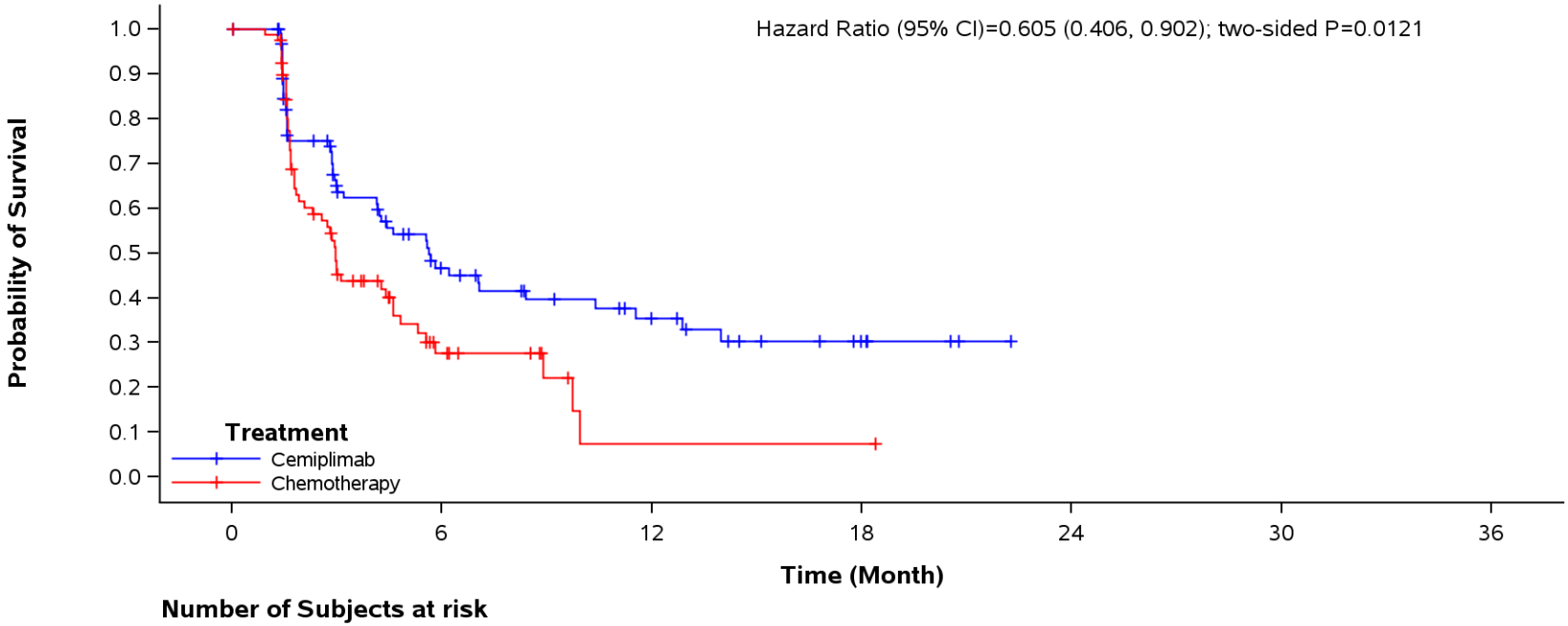

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts deterioration



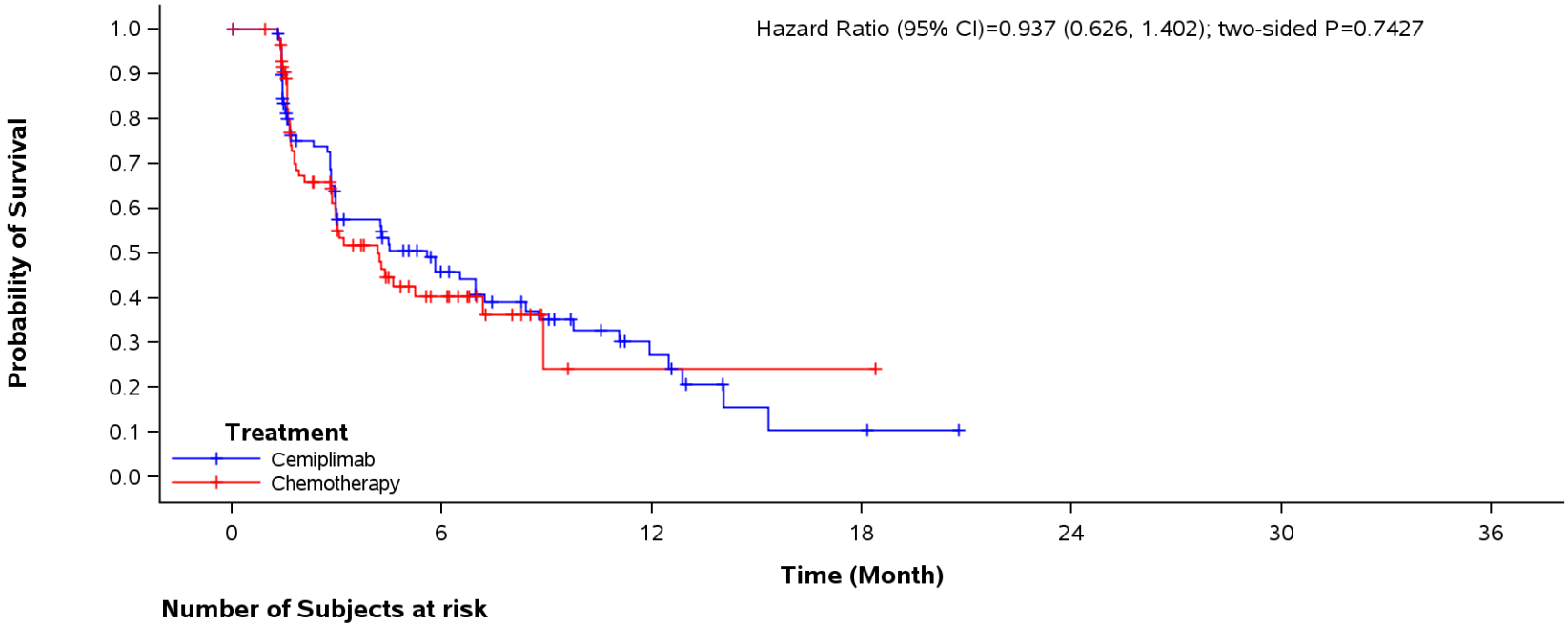

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 29 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 111 | 11 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts deterioration



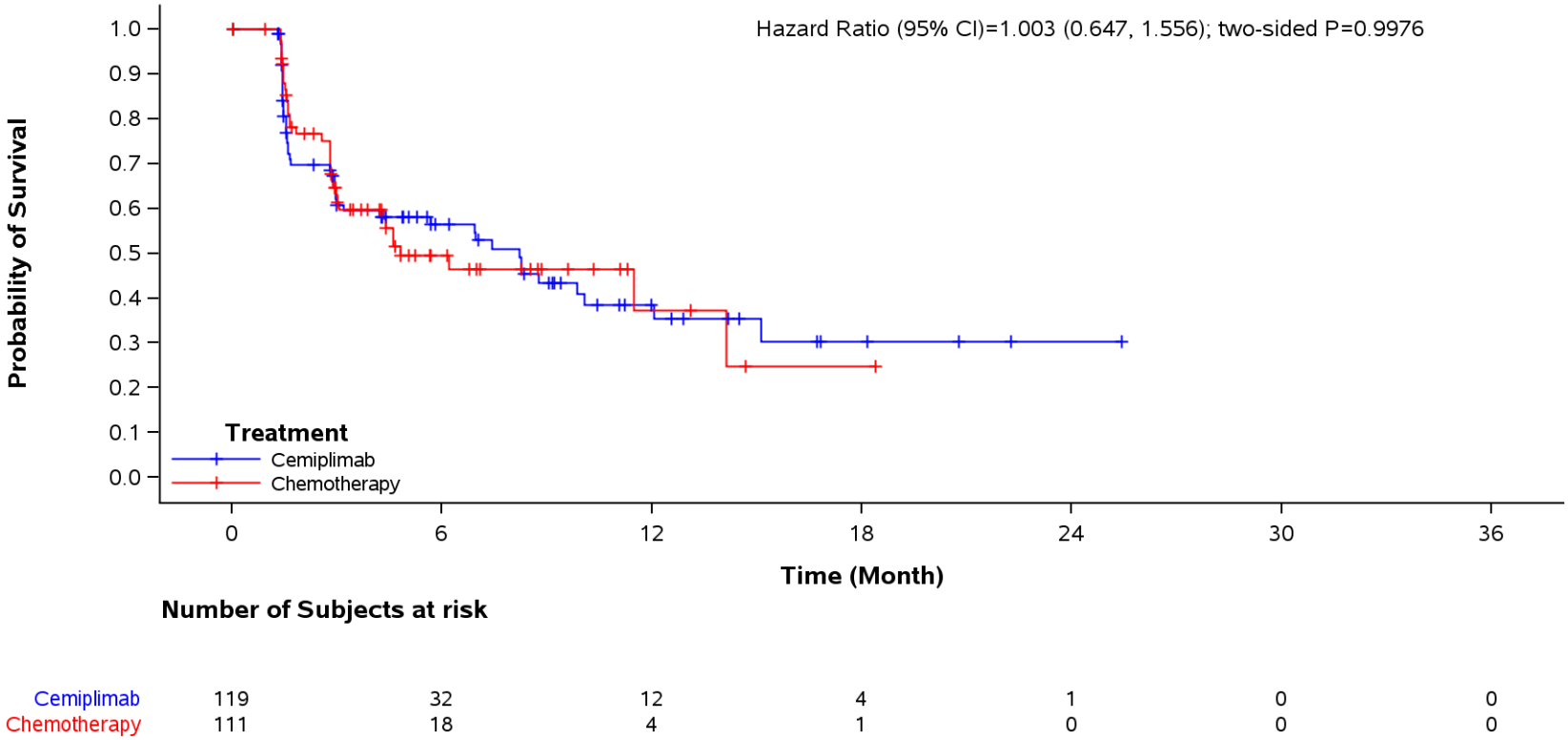

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 28 | 9 | 2 | 0 | 0 | 0 |
| Chemotherapy | 111 | 16 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts deterioration



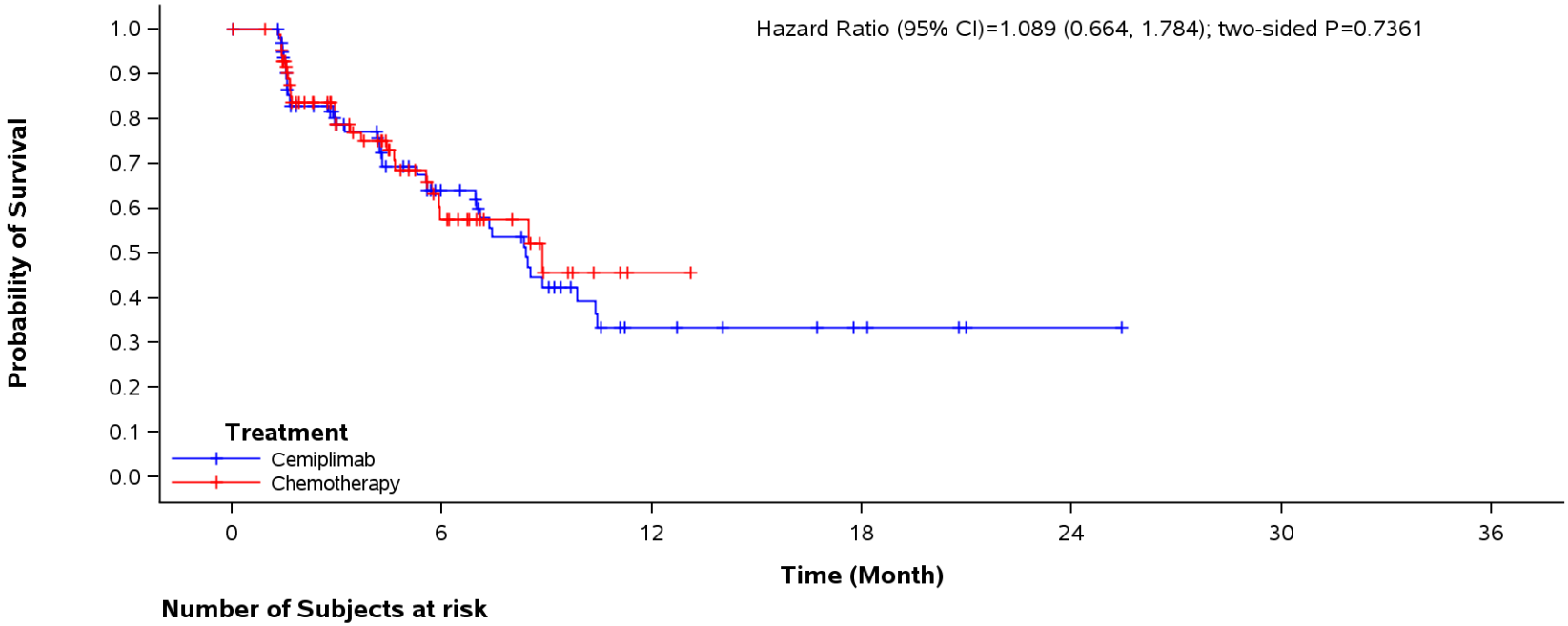

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 32 | 12 | 4 | 1 | 0 | 0 |
| Chemotherapy | 111 | 18 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts deterioration



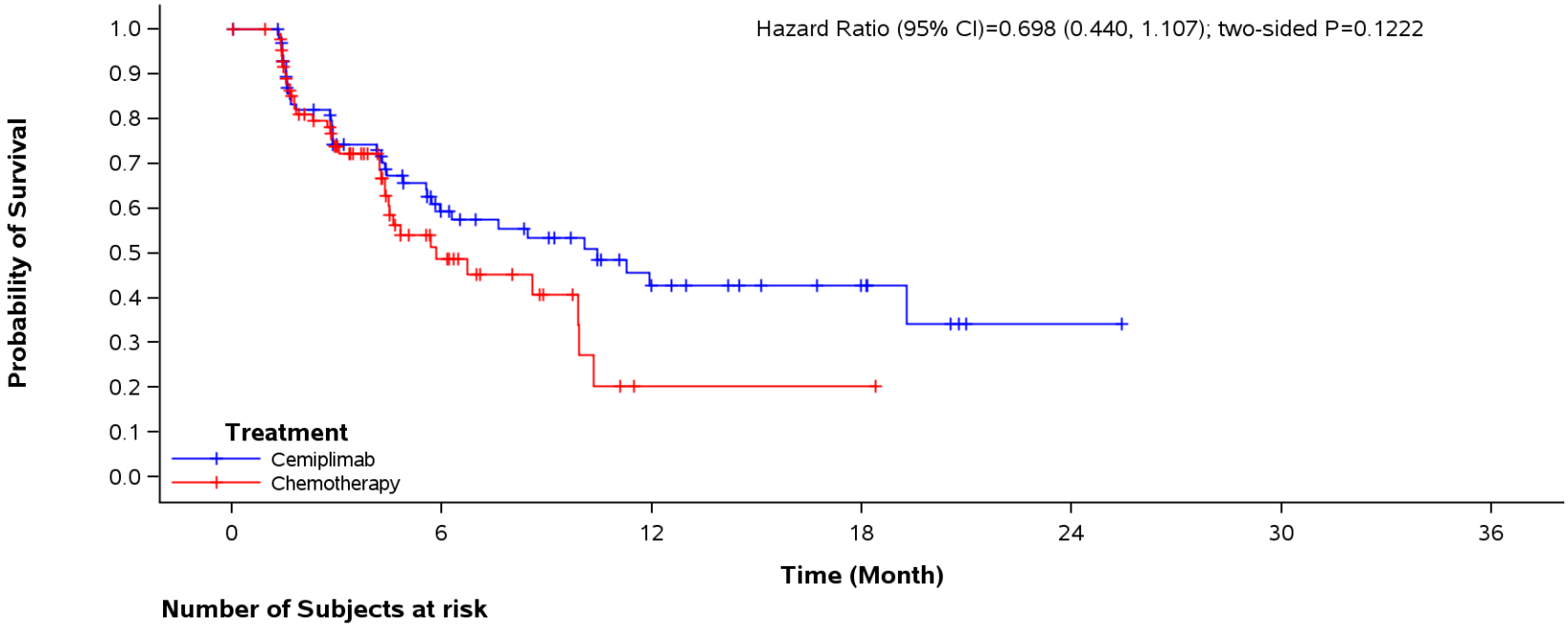

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 33 | 8 | 4 | 1 | 0 | 0 |
| Chemotherapy | 111 | 20 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts deterioration



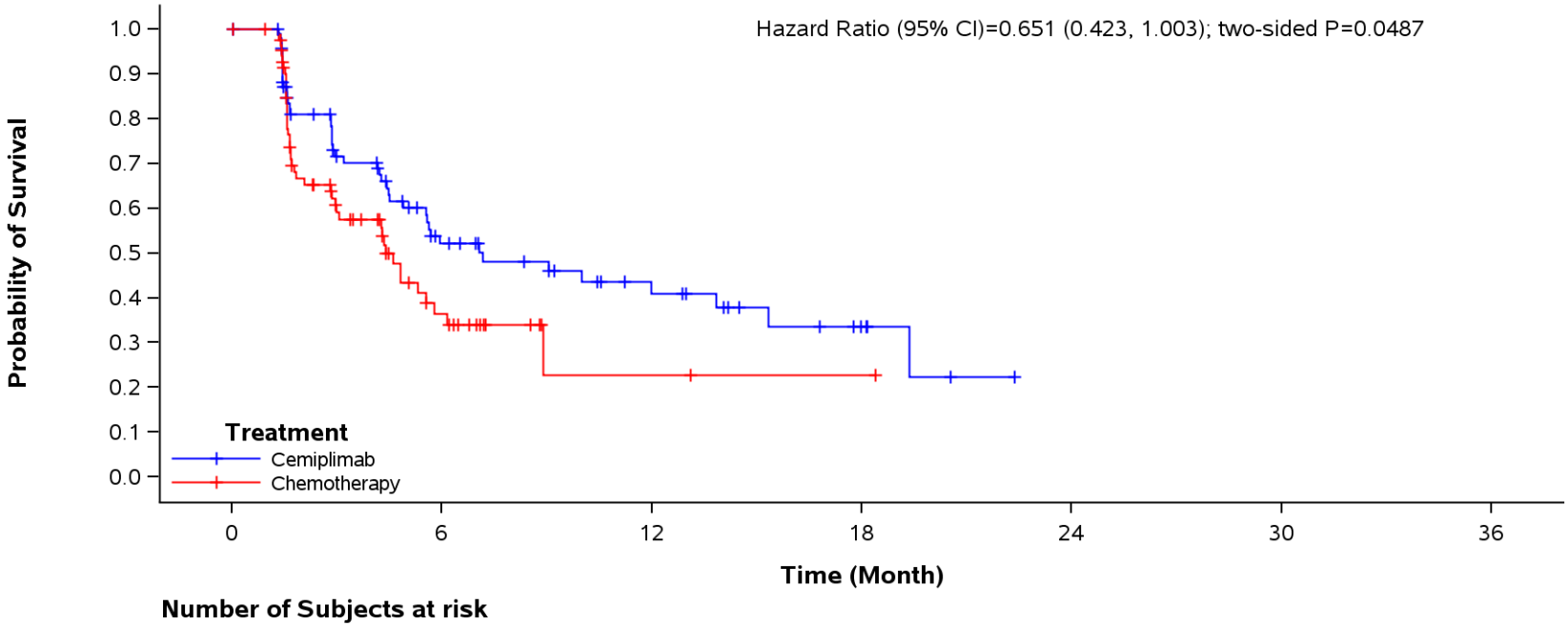

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 33 | 14 | 7 | 1 | 0 | 0 |
| Chemotherapy | 111 | 18 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts deterioration



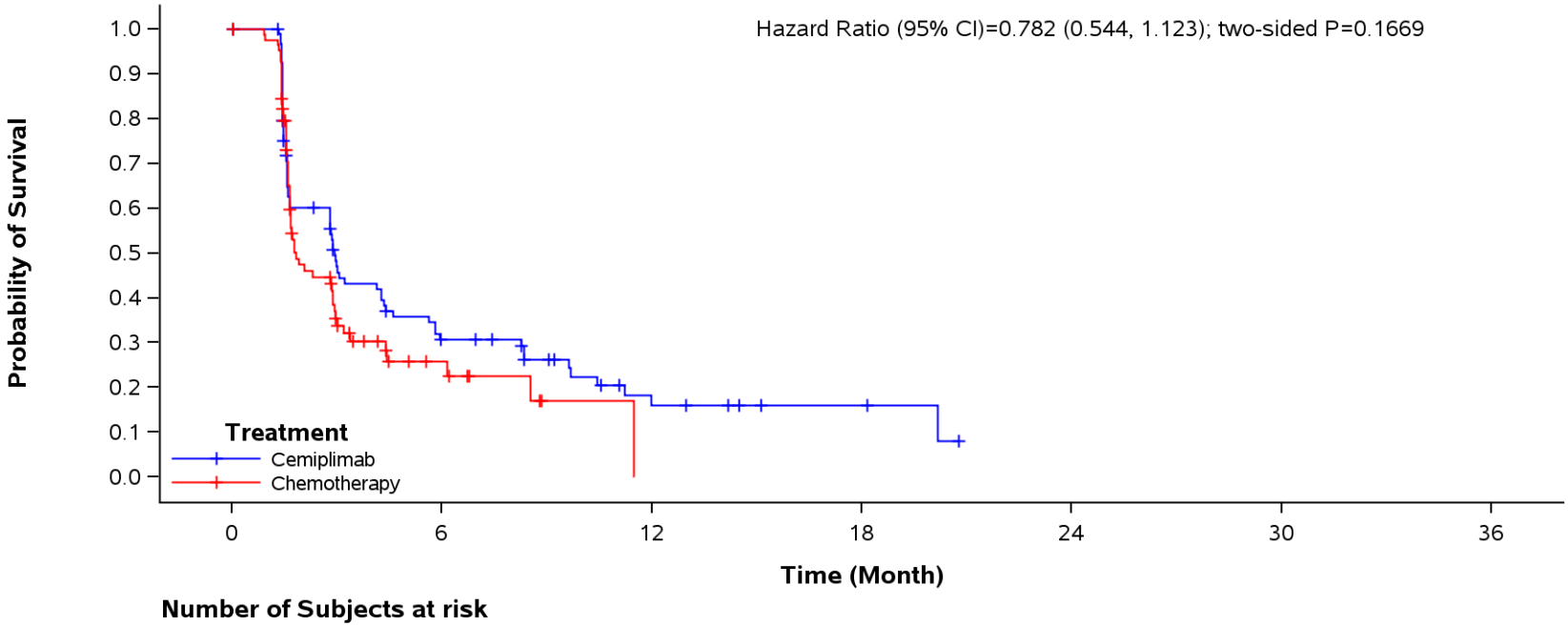

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 31 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 111 | 15 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts deterioration



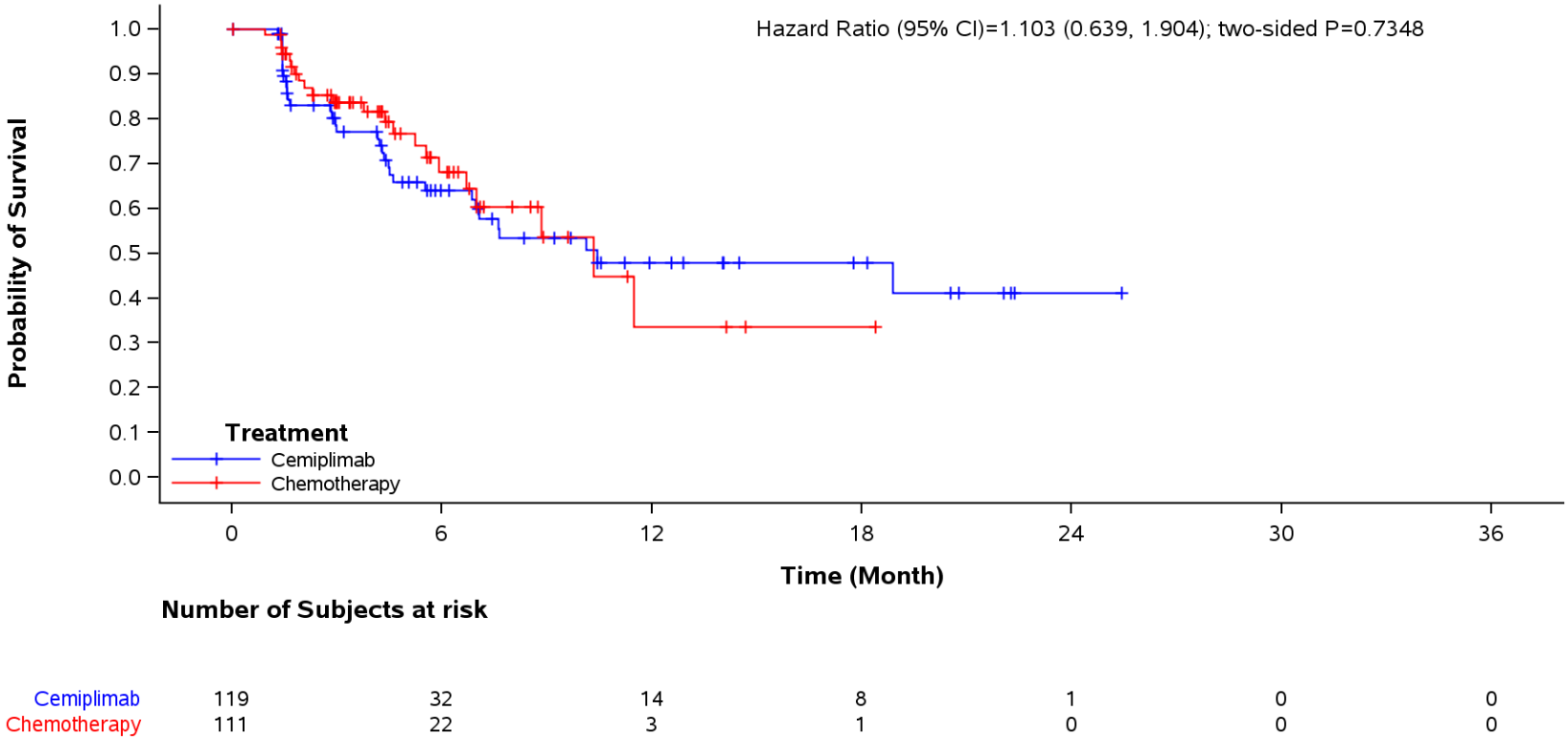

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 23 | 7 | 3 | 0 | 0 | 0 |
| Chemotherapy | 111 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts deterioration



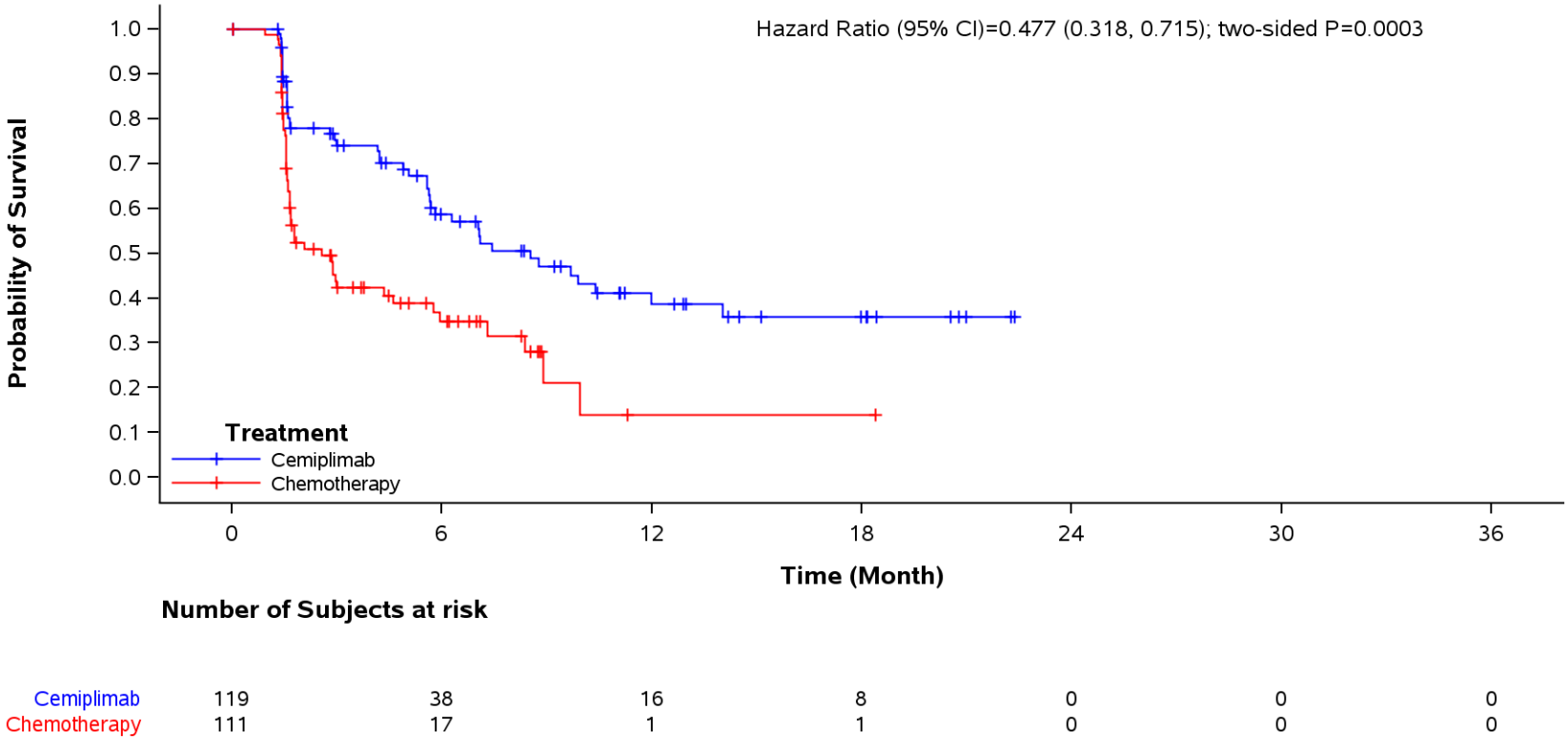

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 32 | 14 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 22 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts deterioration



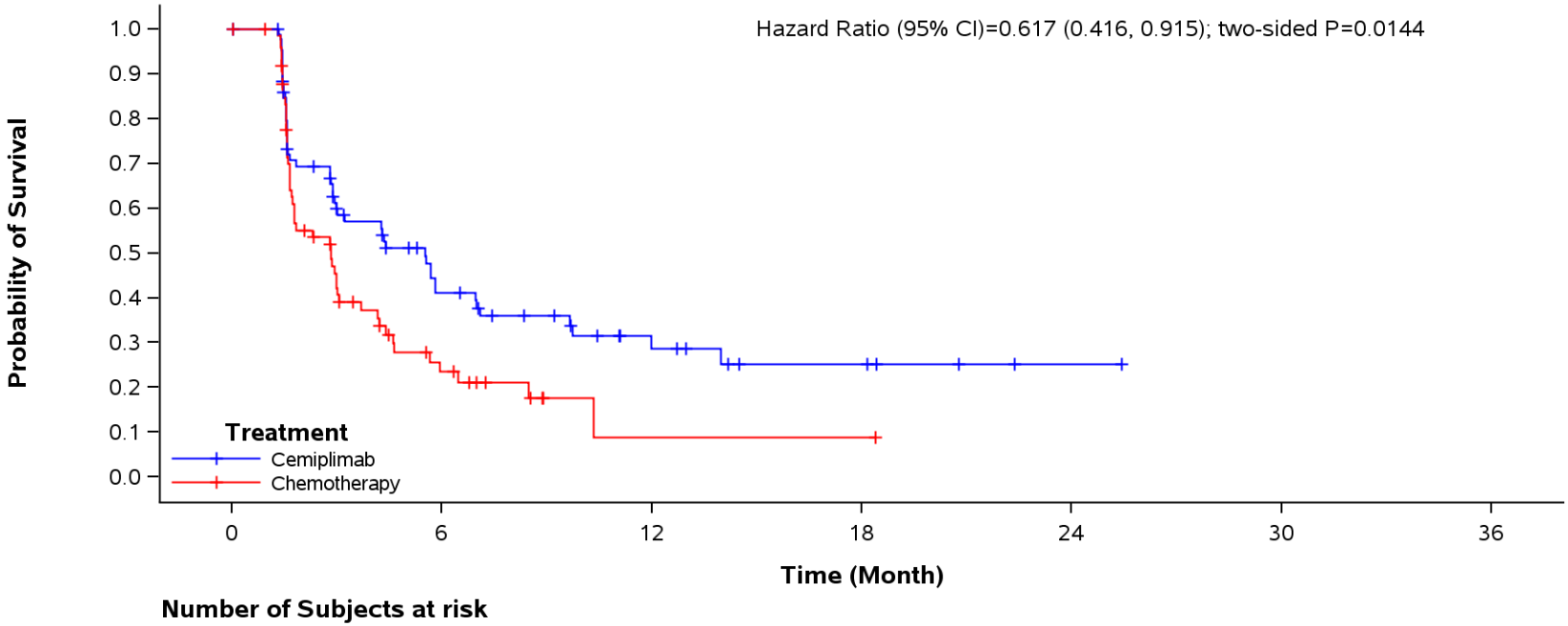

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 38 | 16 | 8 | 0 | 0 | 0 |
| Chemotherapy | 111 | 17 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts deterioration



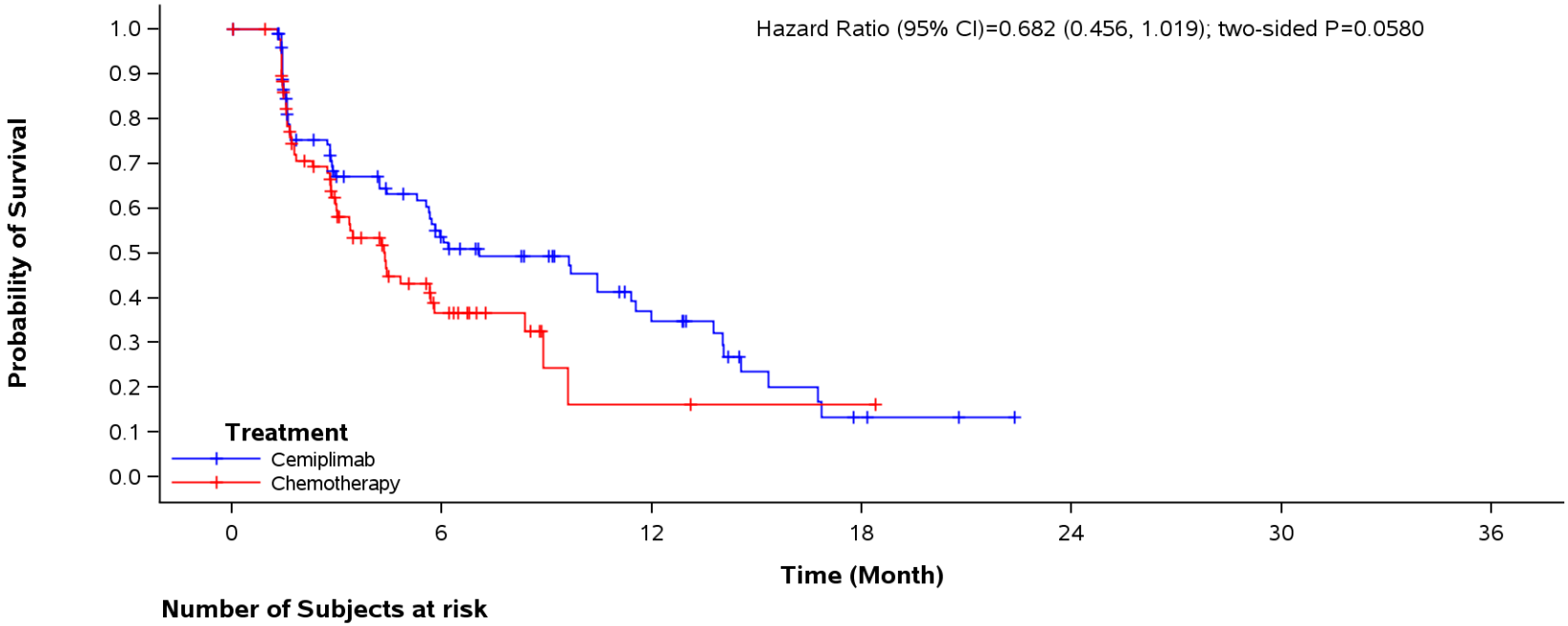

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 25 | 10 | 5 | 1 | 0 | 0 |
| Chemotherapy | 111 | 11 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts deterioration



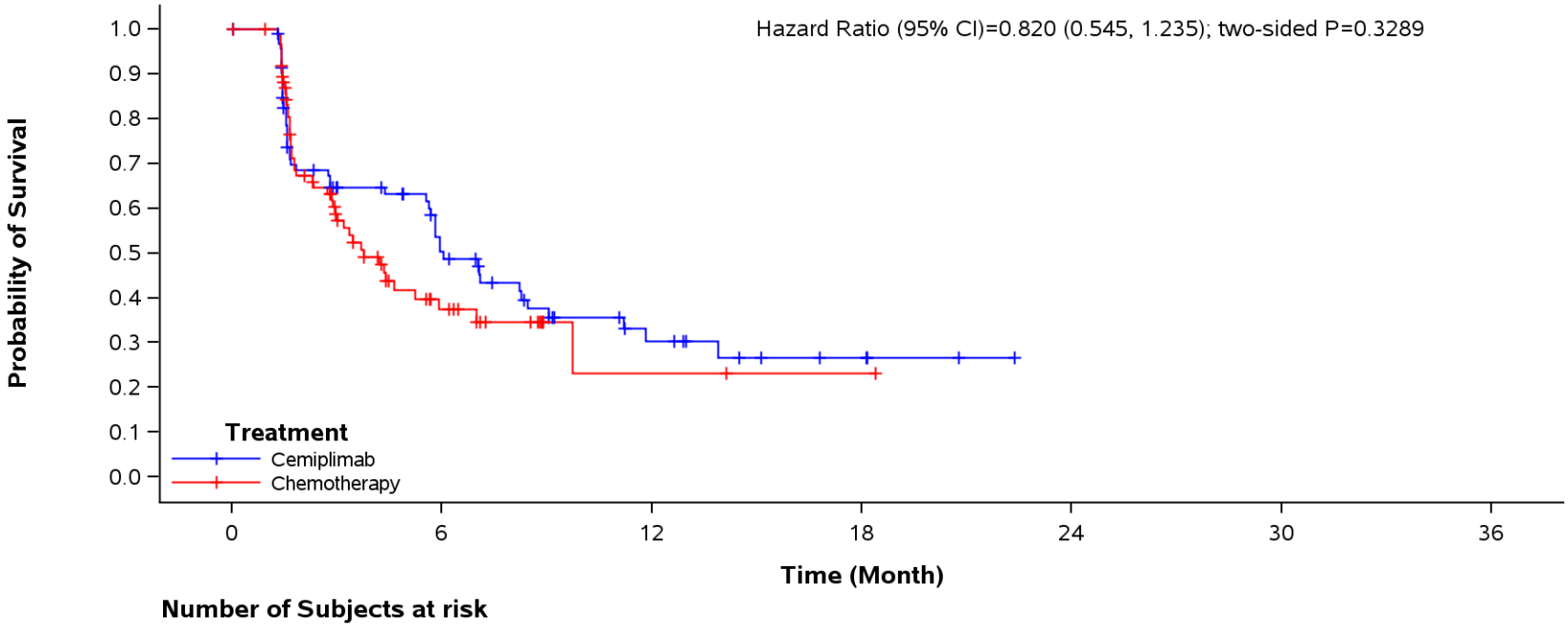

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 38 | 16 | 3 | 0 | 0 | 0 |
| Chemotherapy | 111 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts deterioration



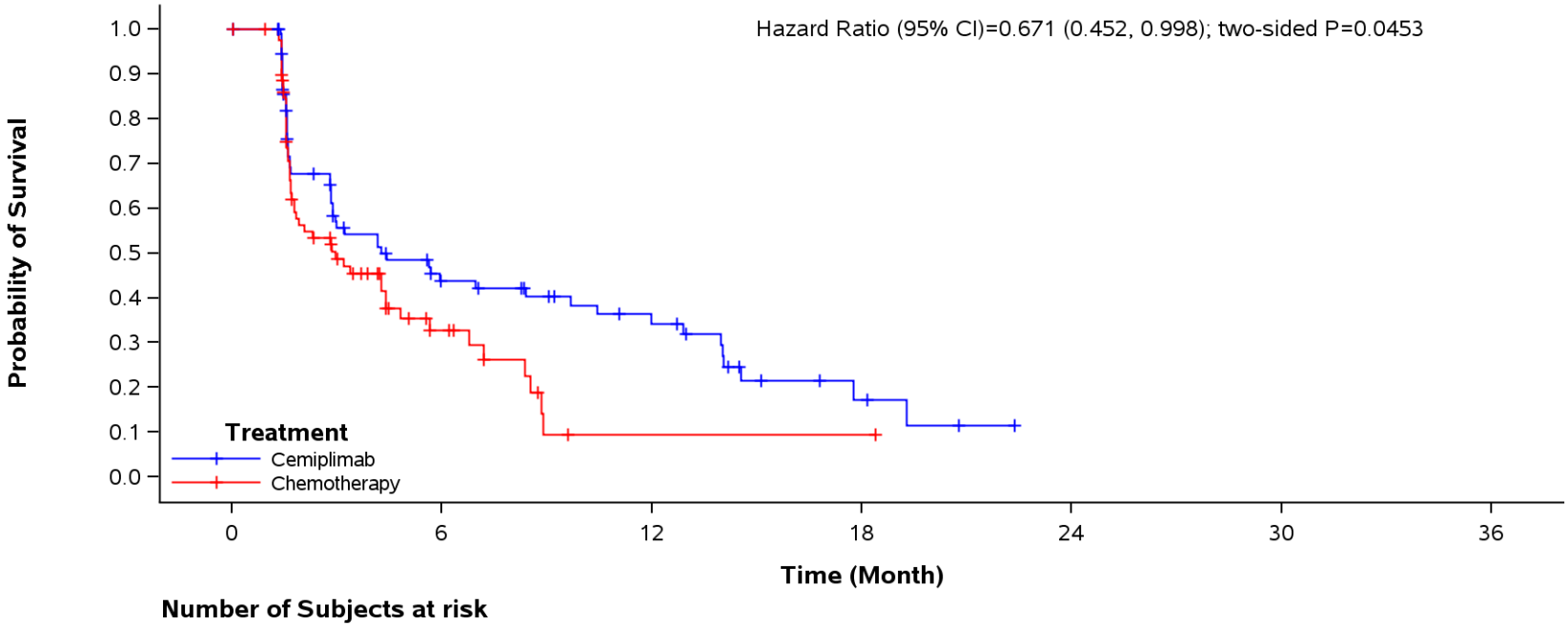

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 31 | 11 | 4 | 0 | 0 | 0 |
| Chemotherapy | 111 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts deterioration



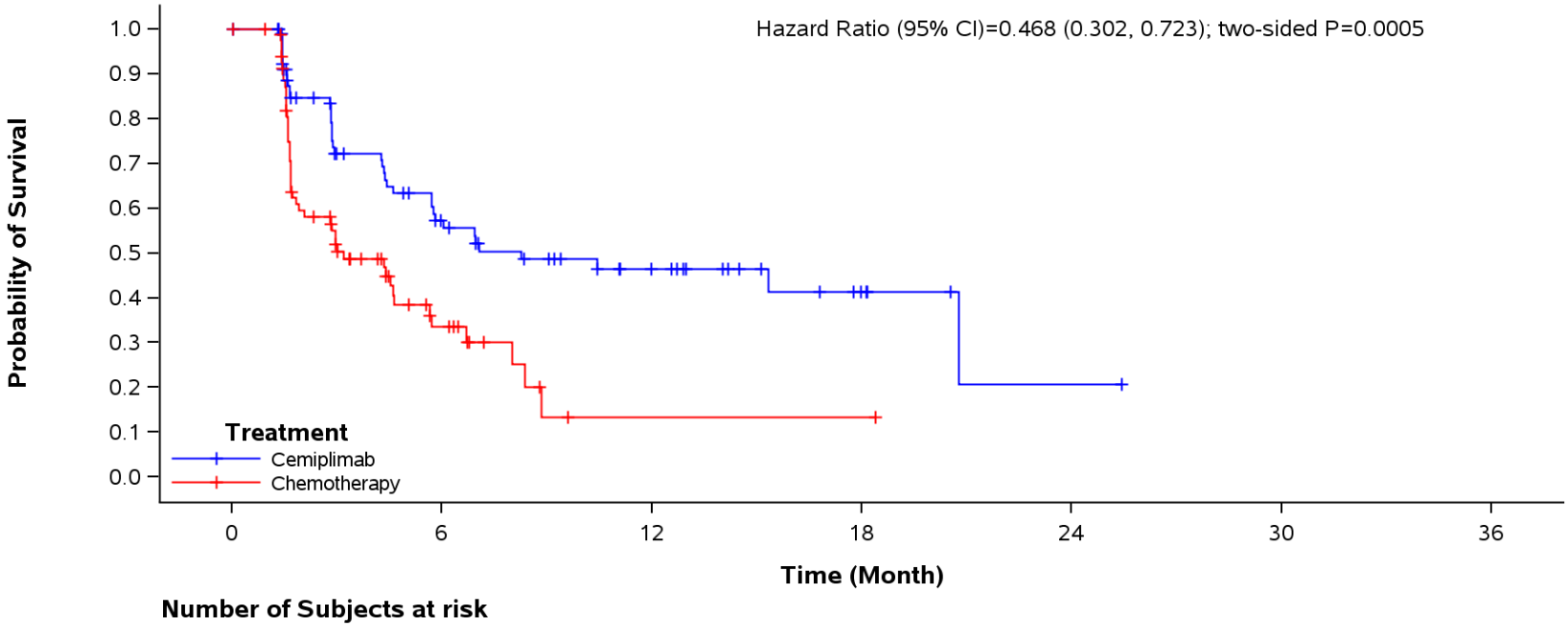

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 27 | 16 | 4 | 0 | 0 | 0 |
| Chemotherapy | 111 | 12 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts deterioration



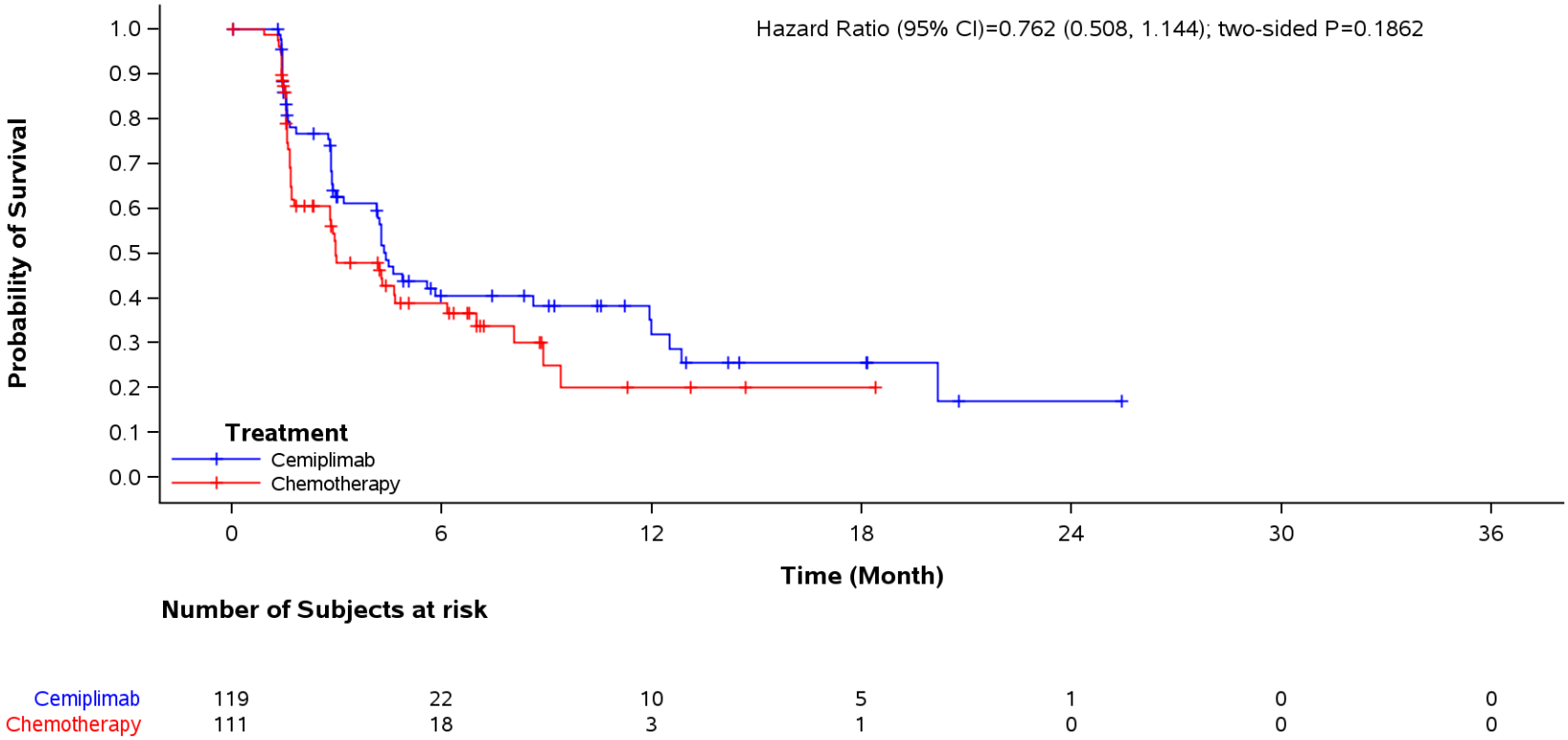

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 35 | 17 | 5 | 1 | 0 | 0 |
| Chemotherapy | 111 | 13 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts deterioration



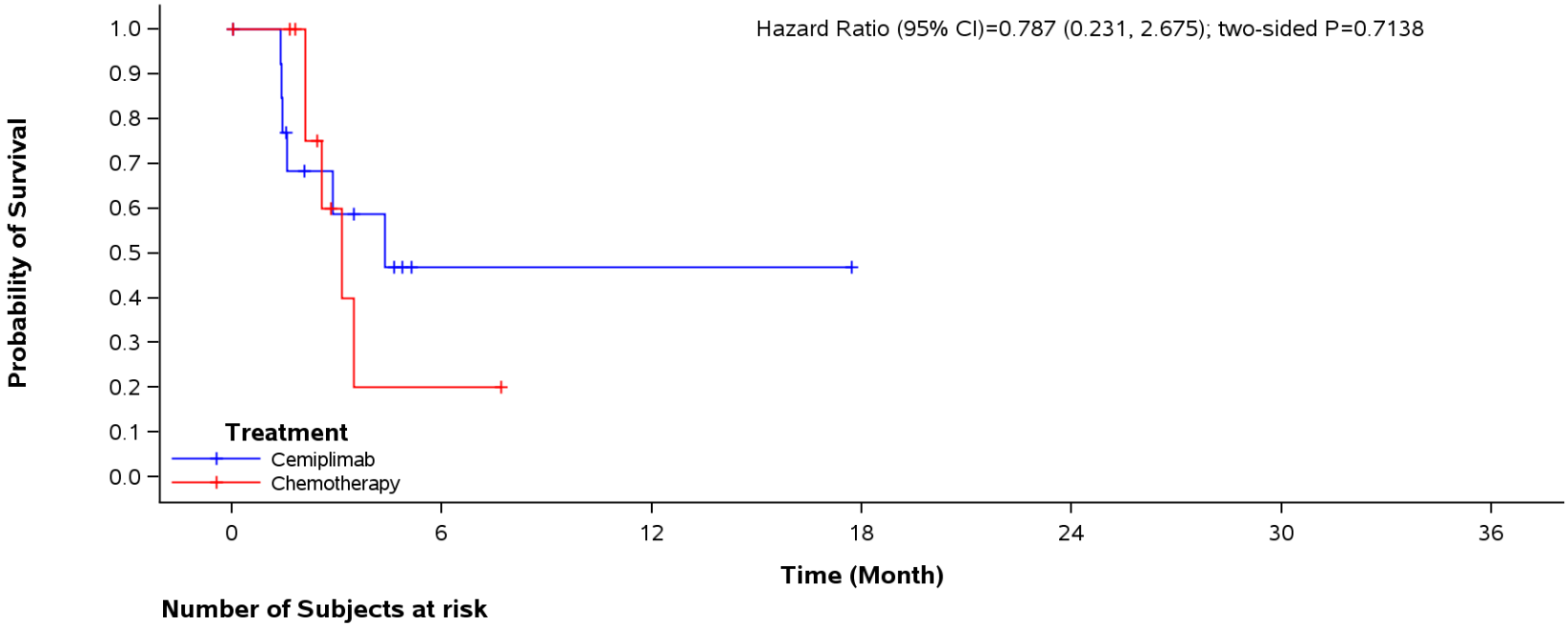

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 22 | 10 | 5 | 1 | 0 | 0 |
| Chemotherapy | 111 | 18 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts deterioration



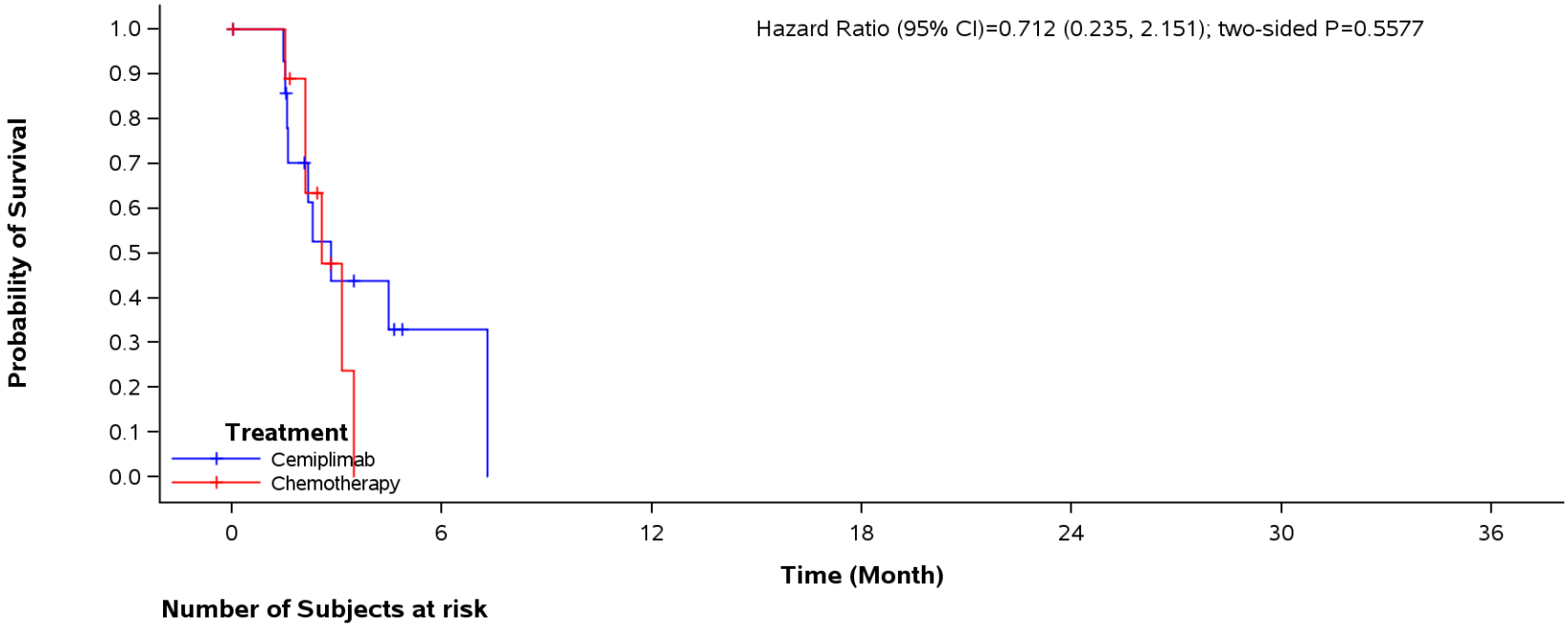

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts deterioration



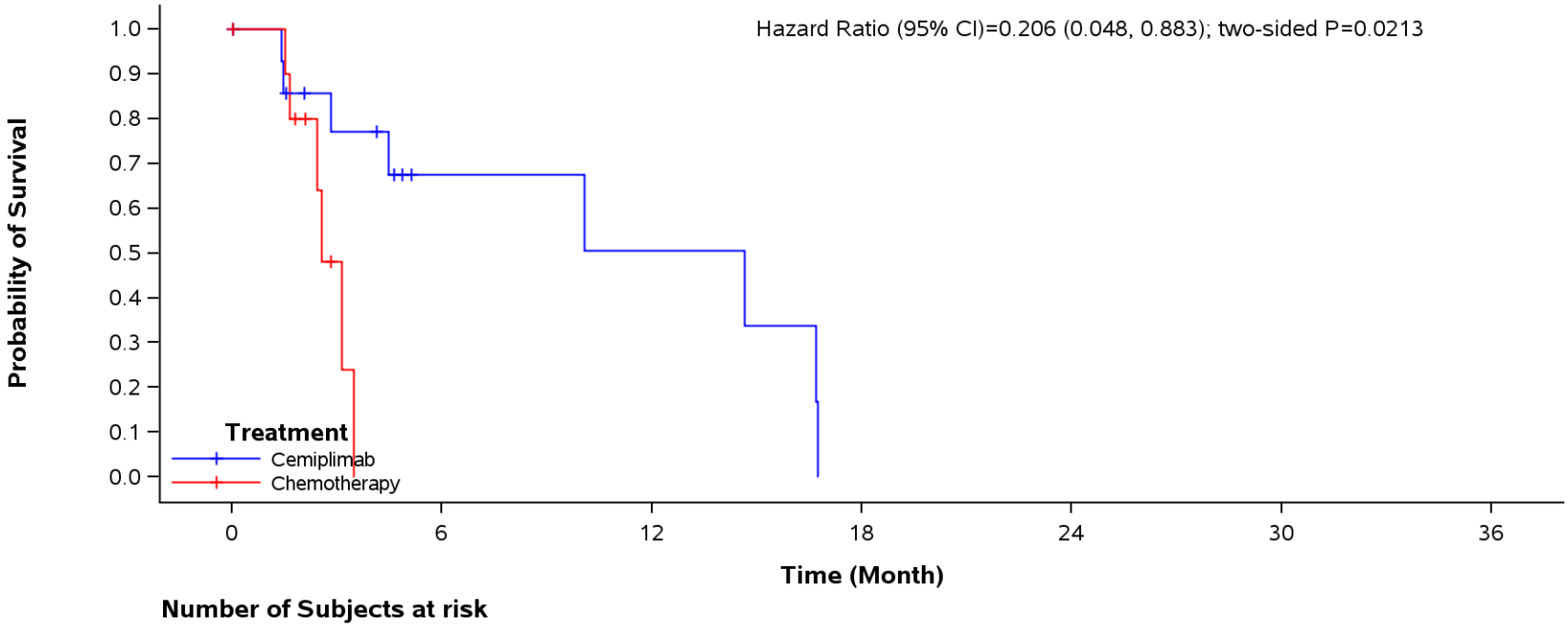

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts deterioration



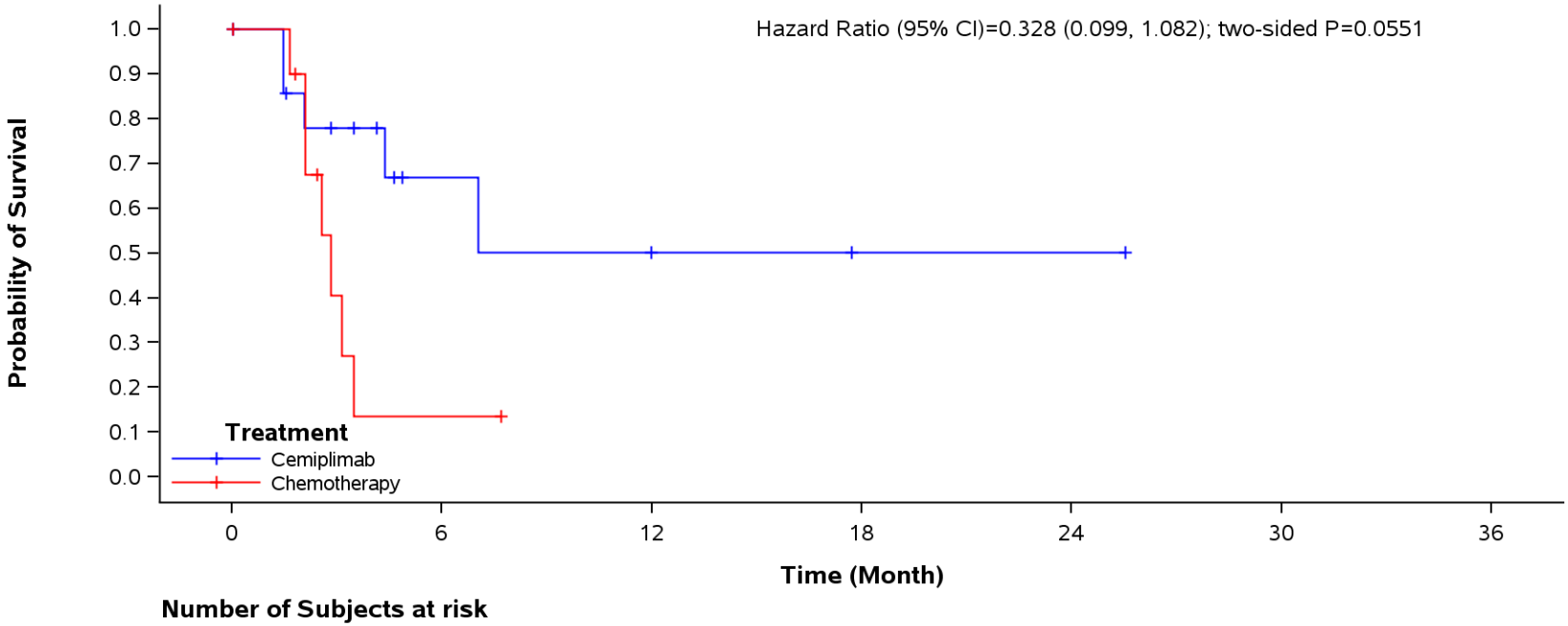

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts deterioration



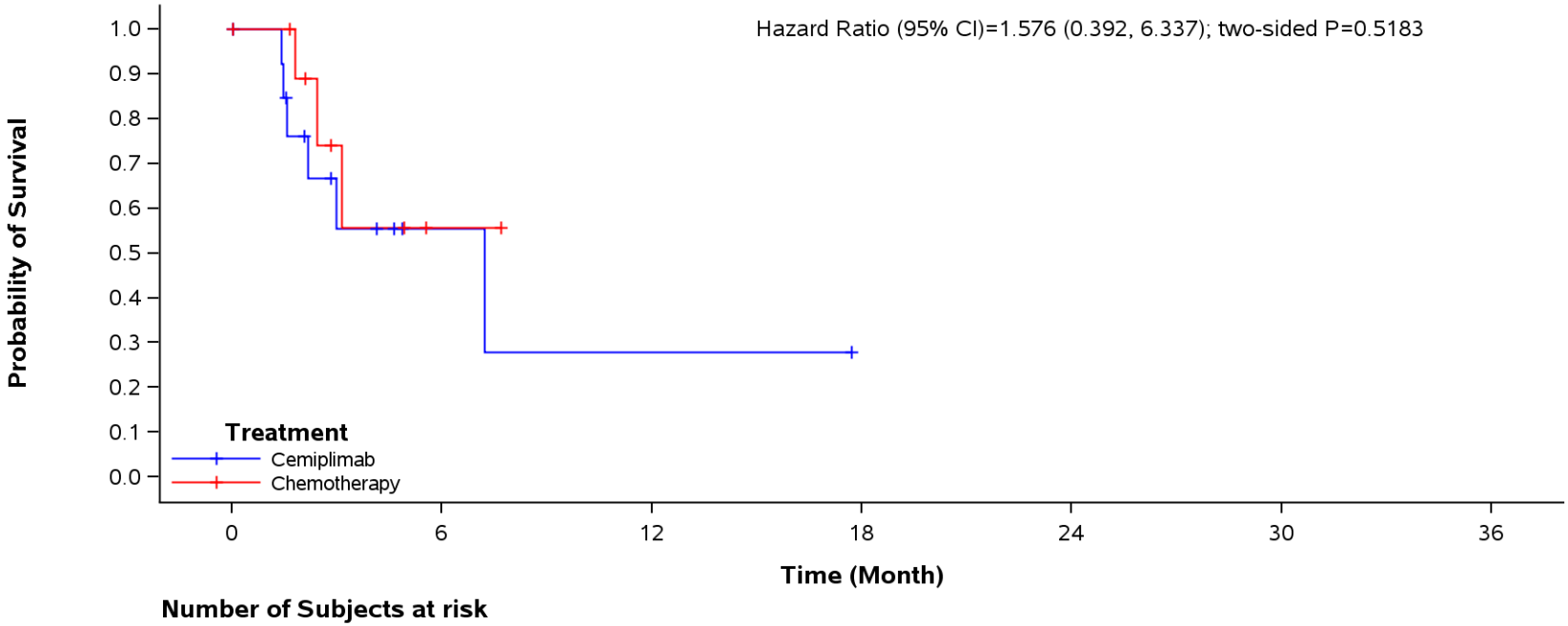

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts deterioration



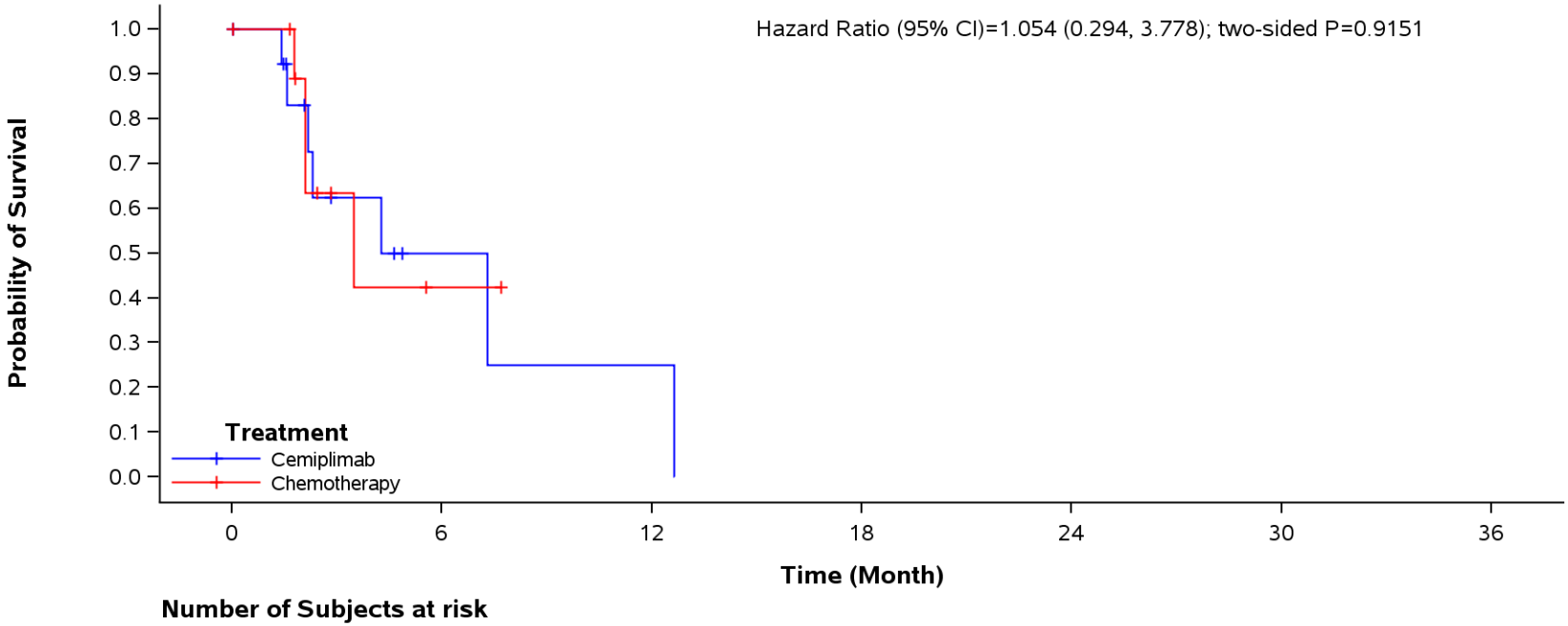

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts deterioration



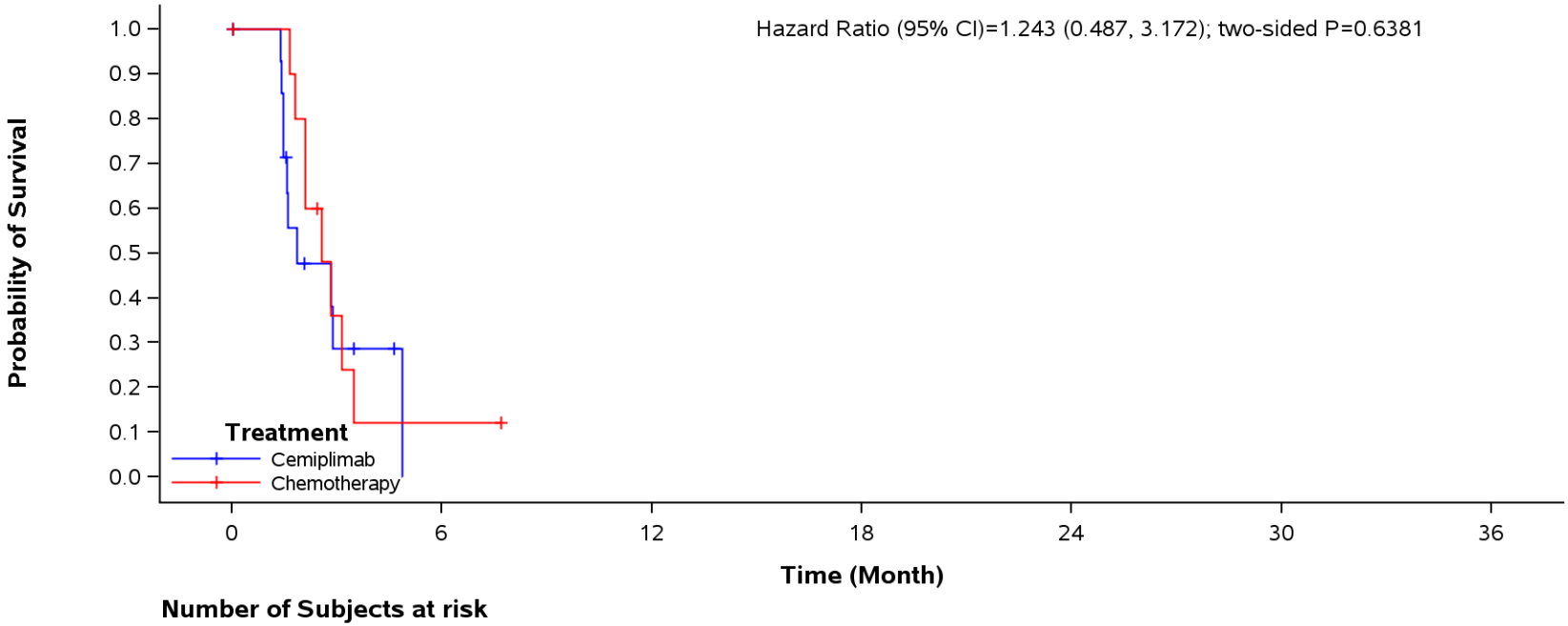

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts deterioration



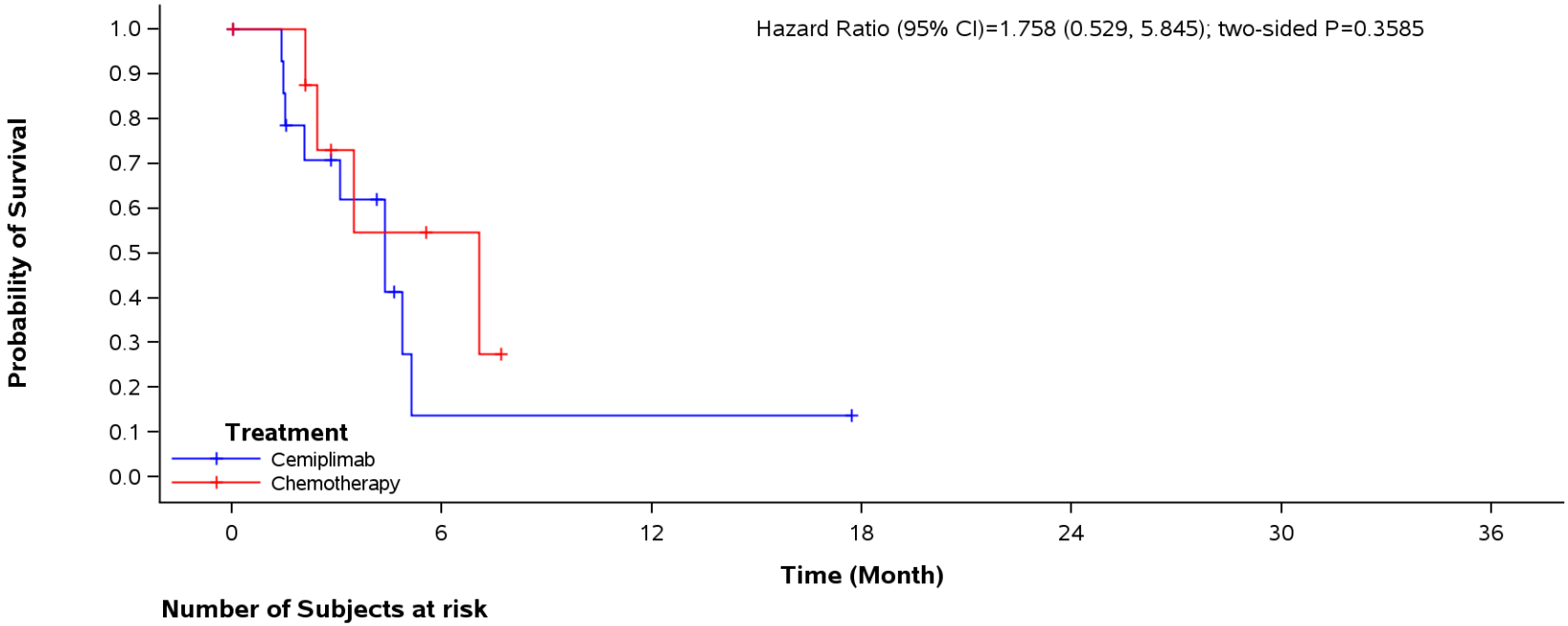

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts deterioration



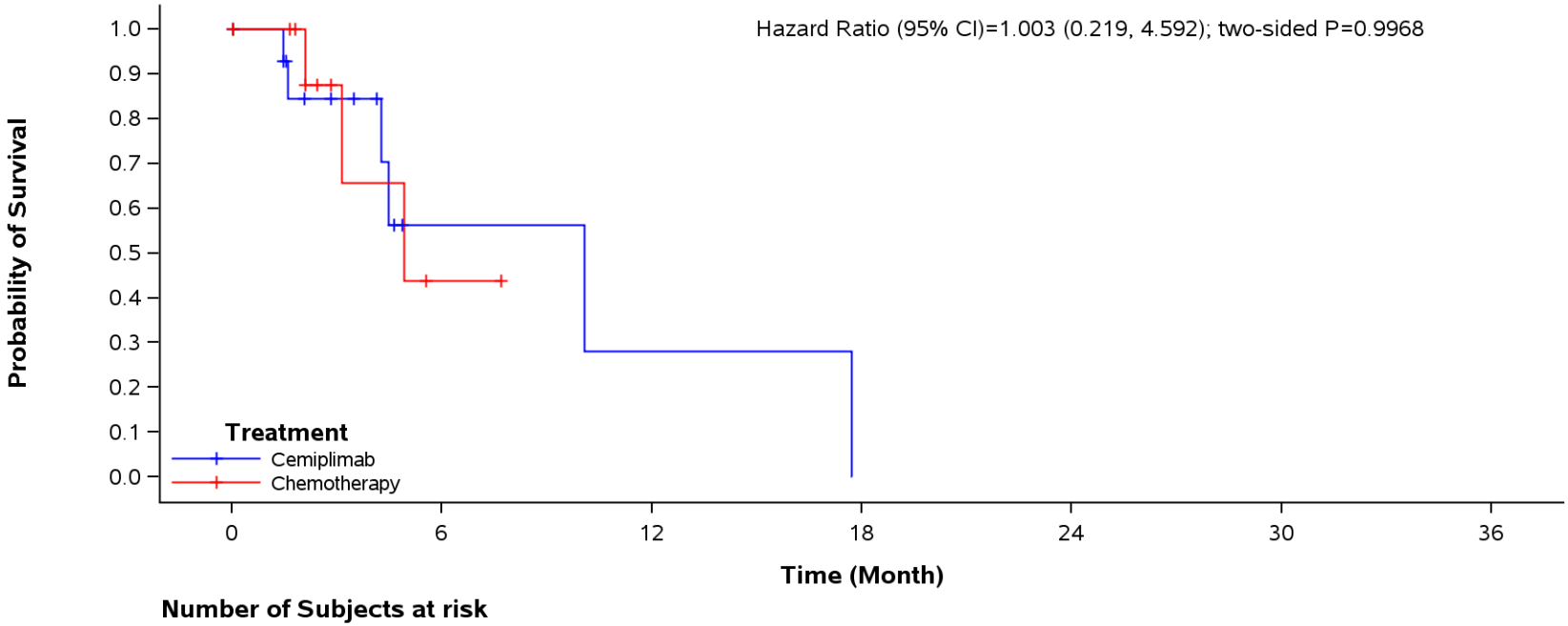

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts deterioration



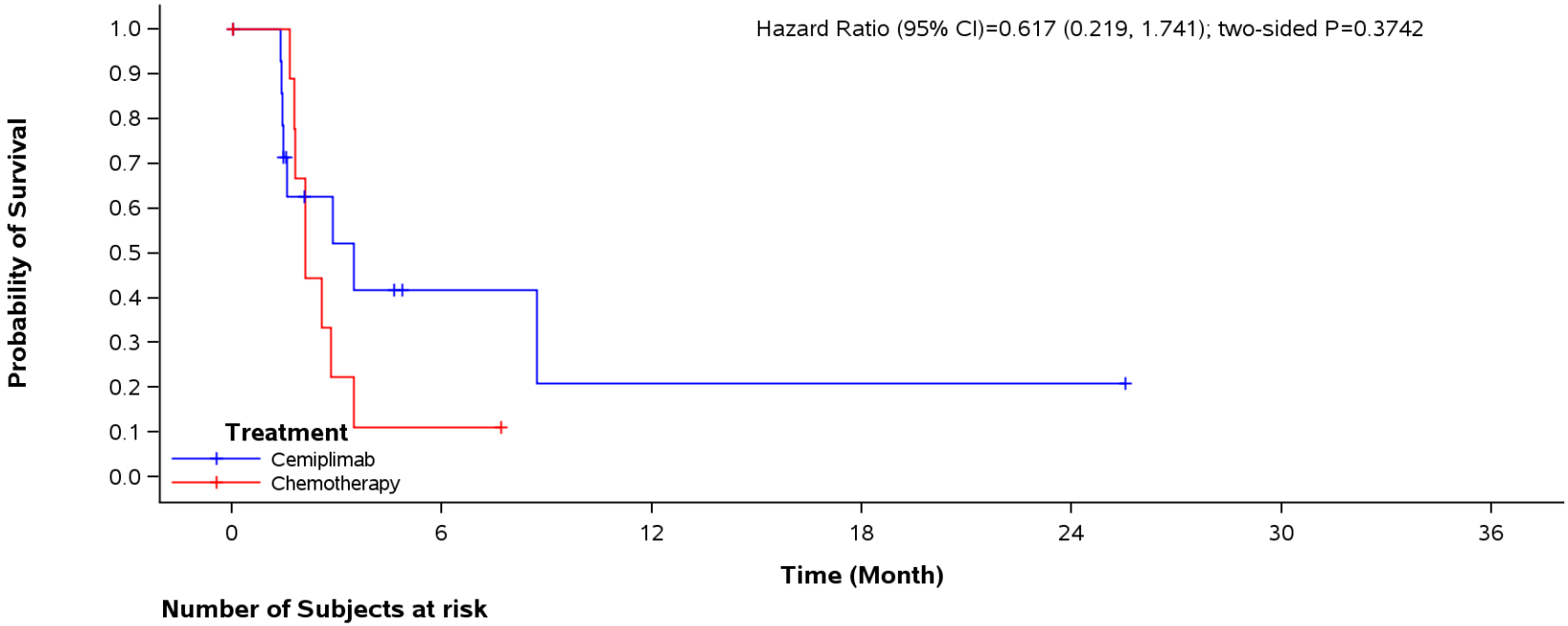

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts deterioration



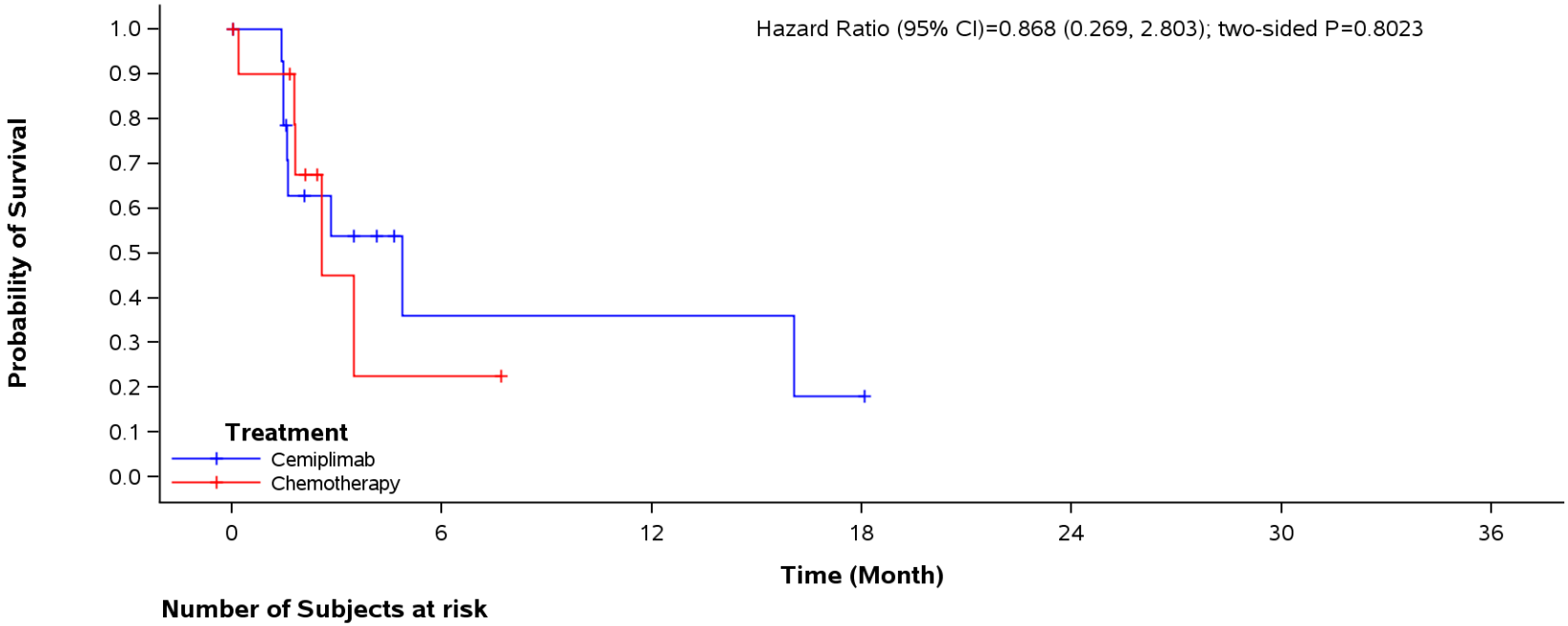

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts deterioration



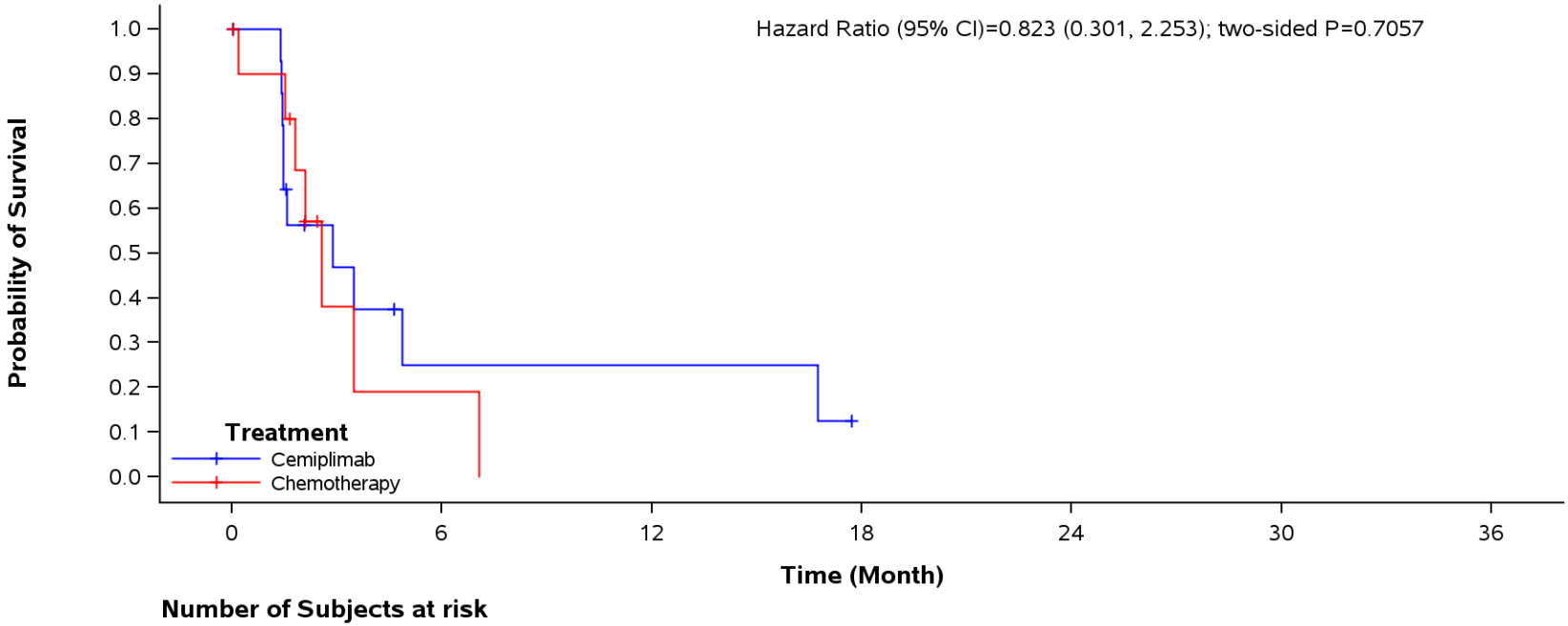

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts deterioration



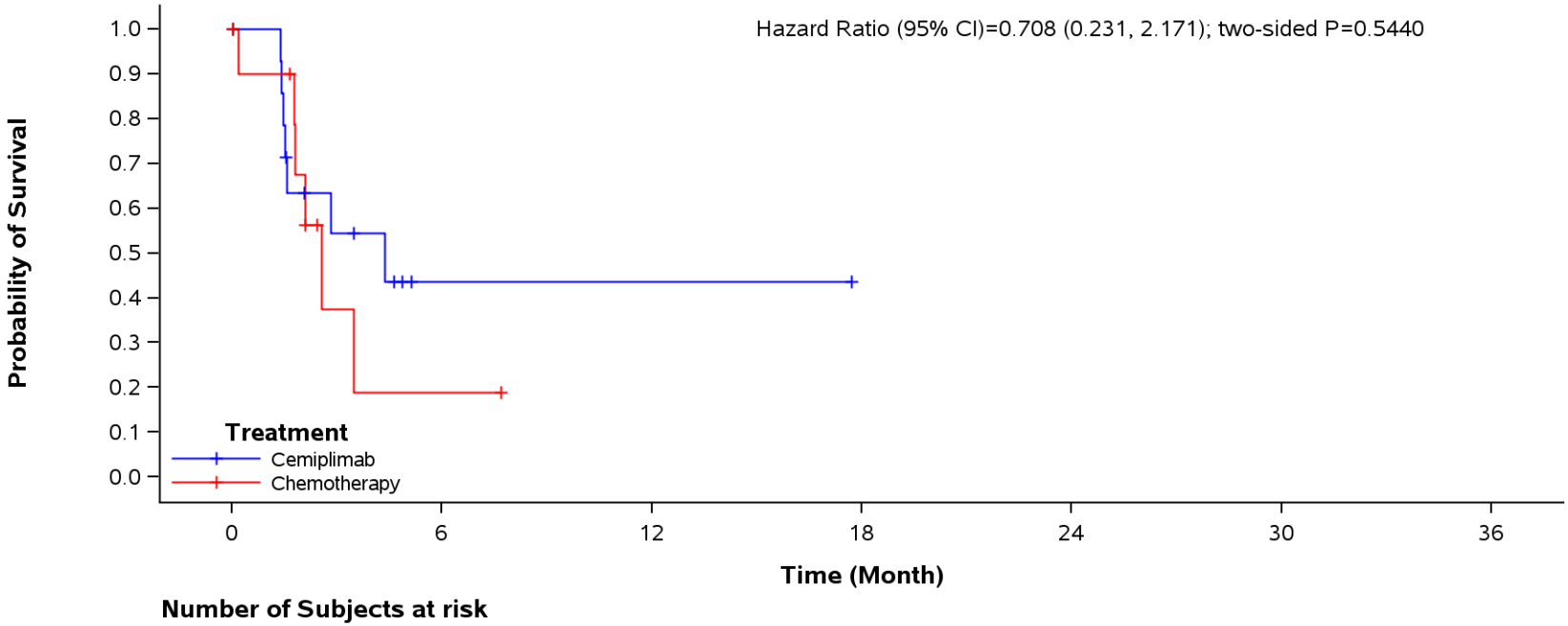

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts deterioration



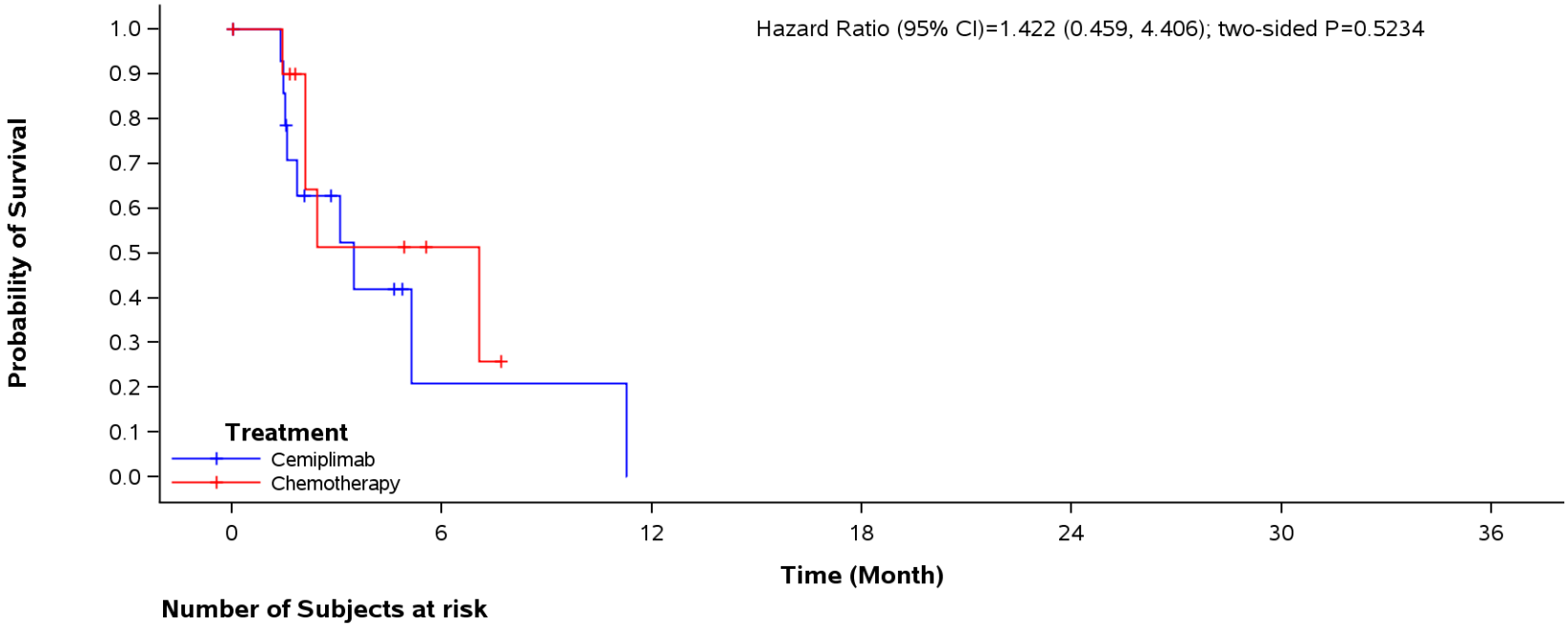

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts deterioration



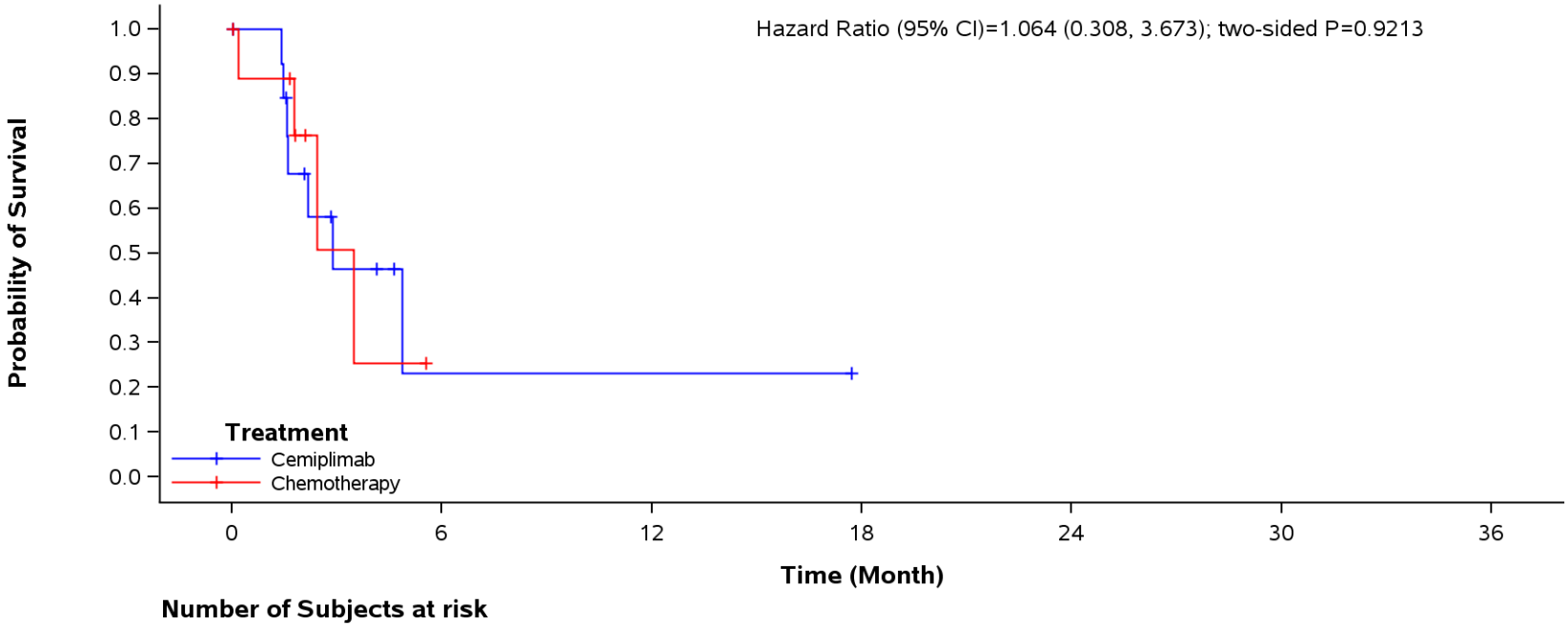

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts deterioration



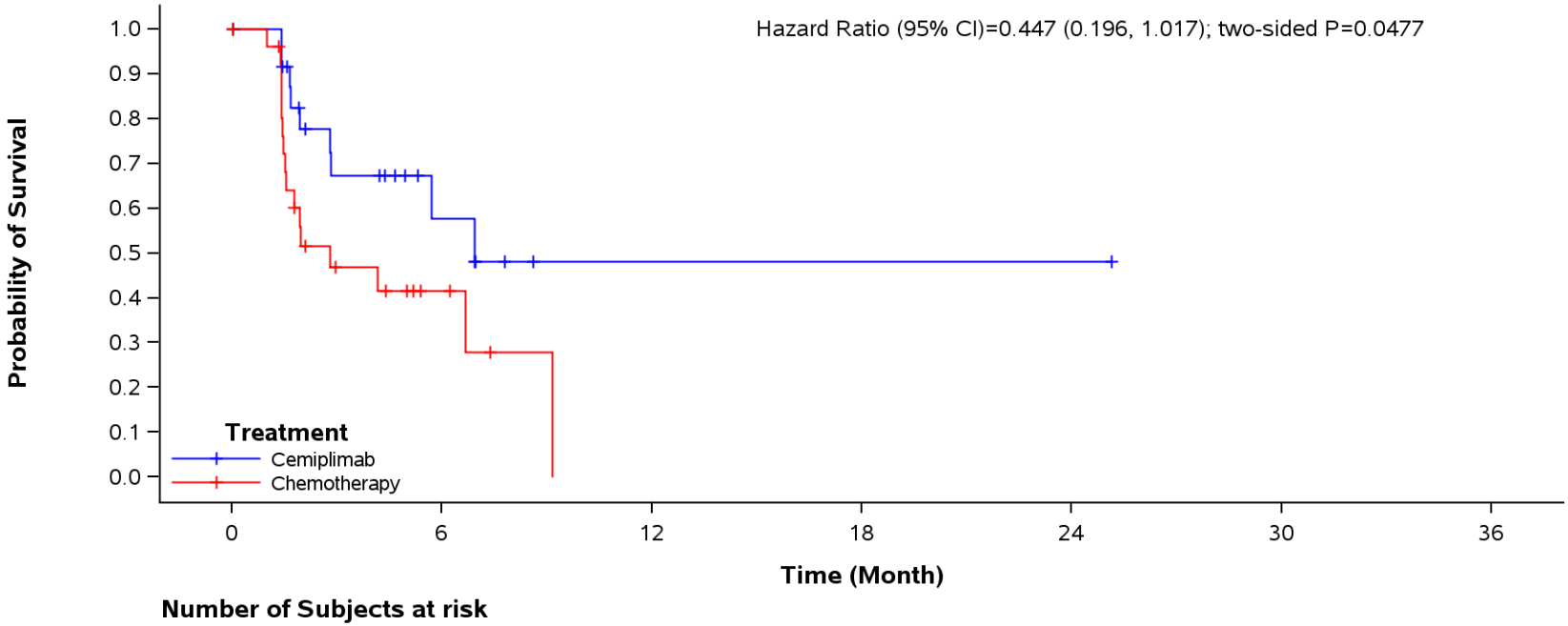

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts deterioration



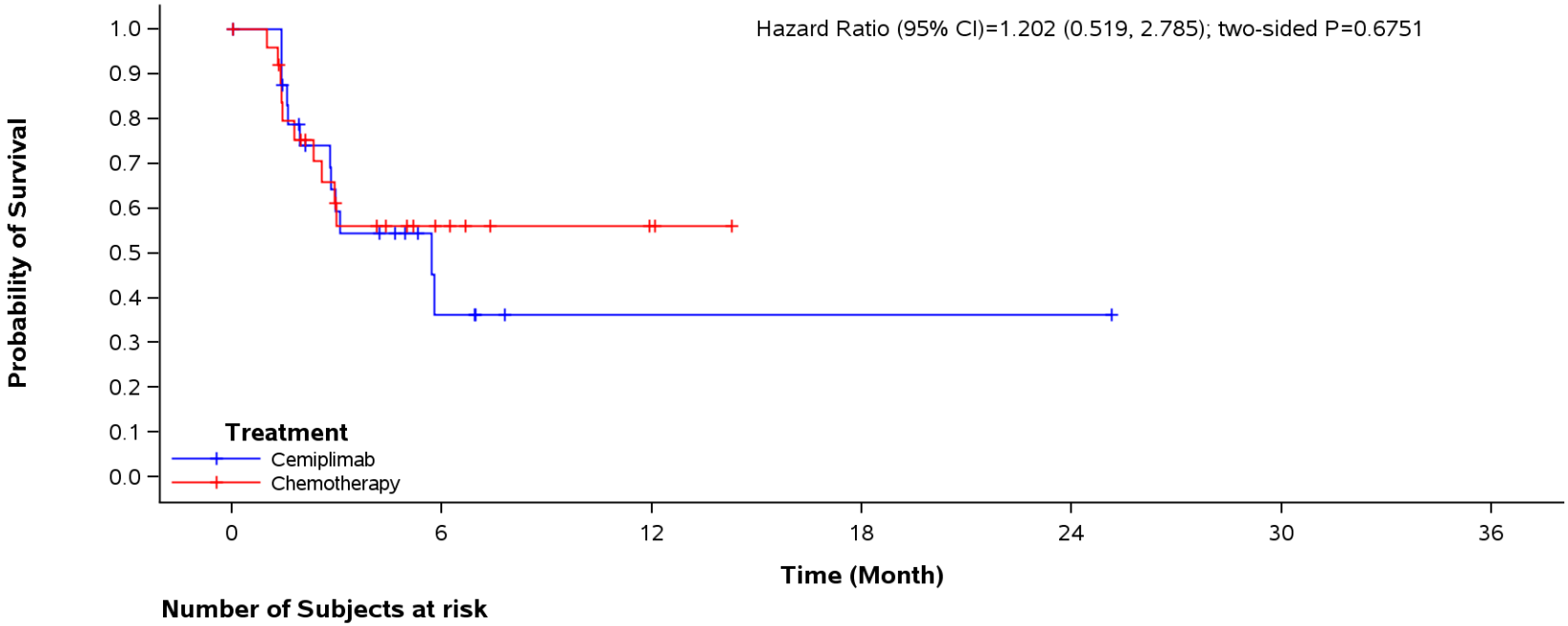

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts deterioration



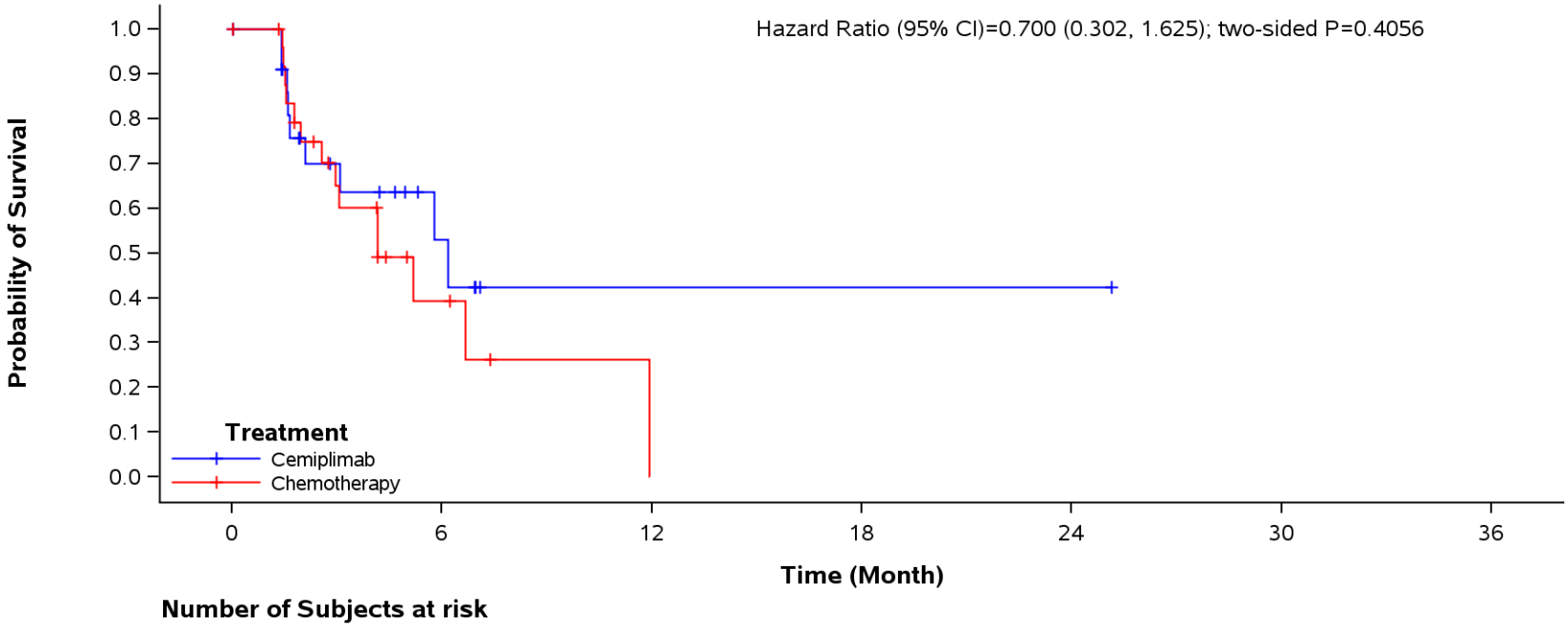

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 4 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts deterioration



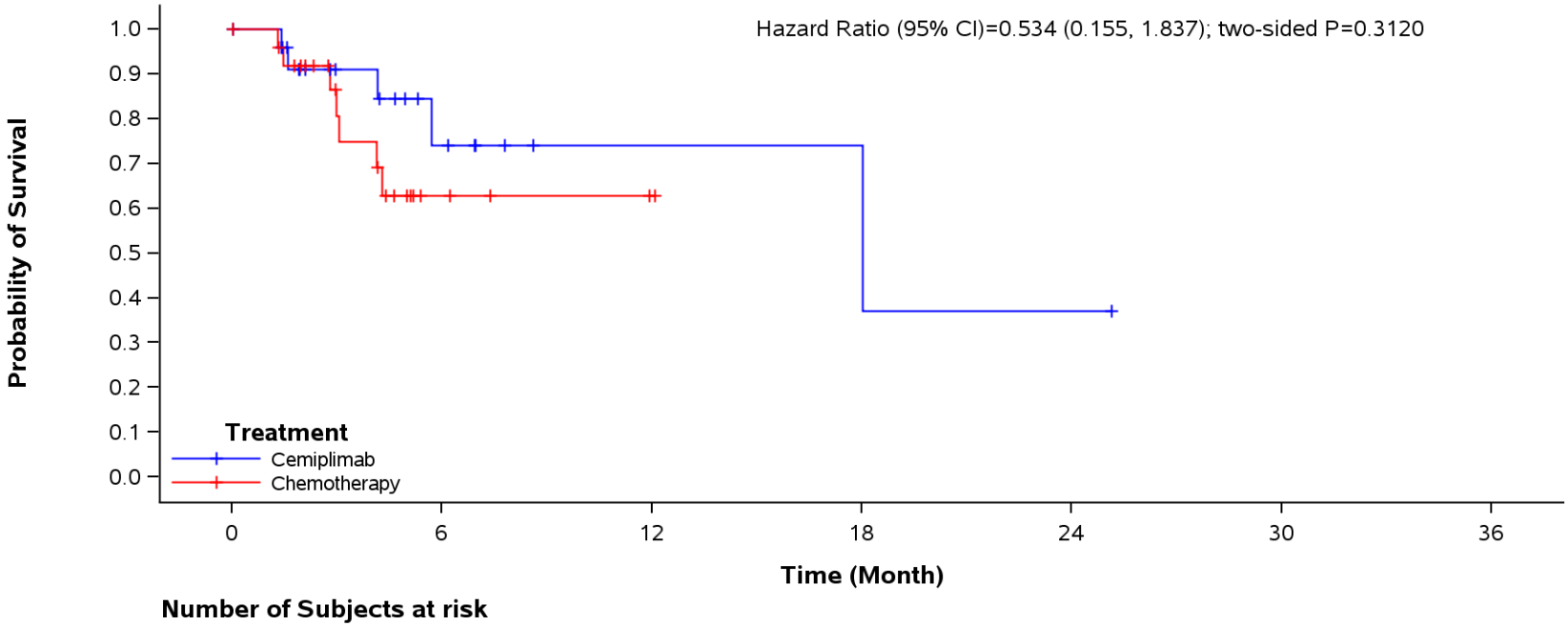

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 5 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts deterioration



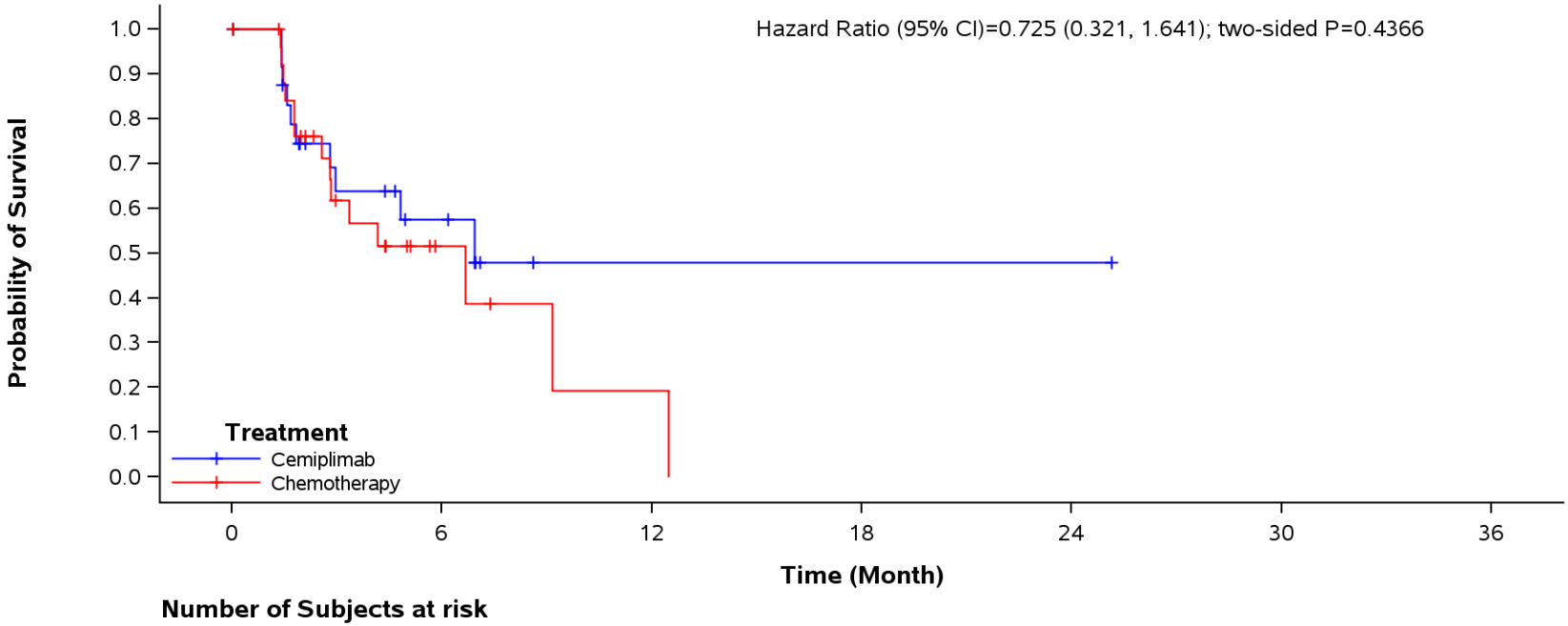

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts deterioration



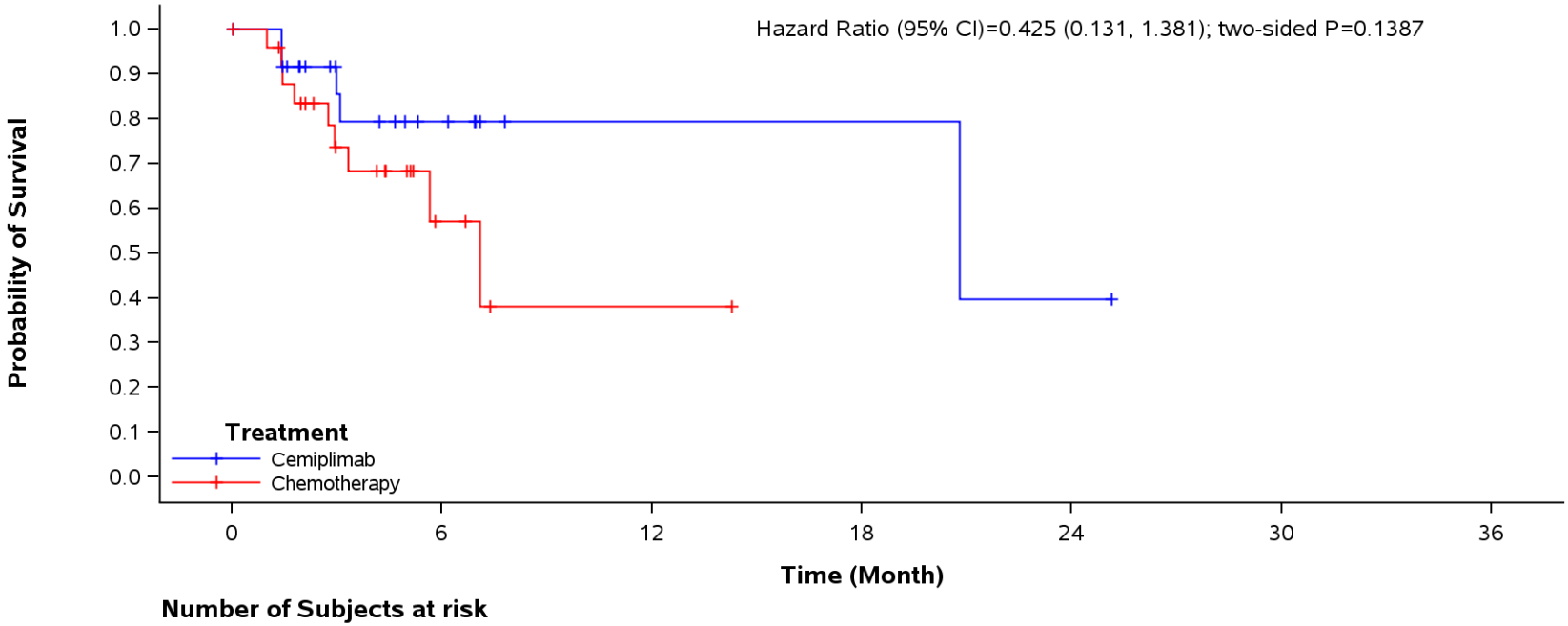

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts deterioration



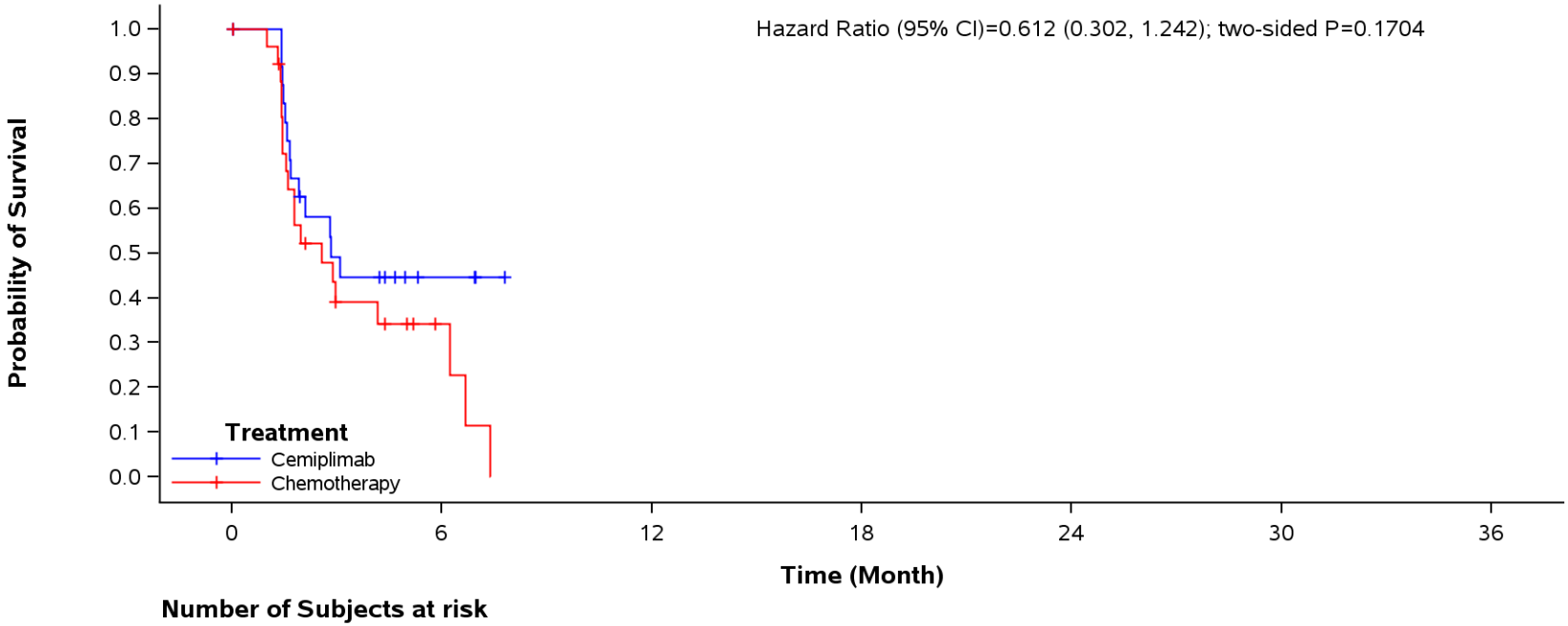

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 8 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts deterioration



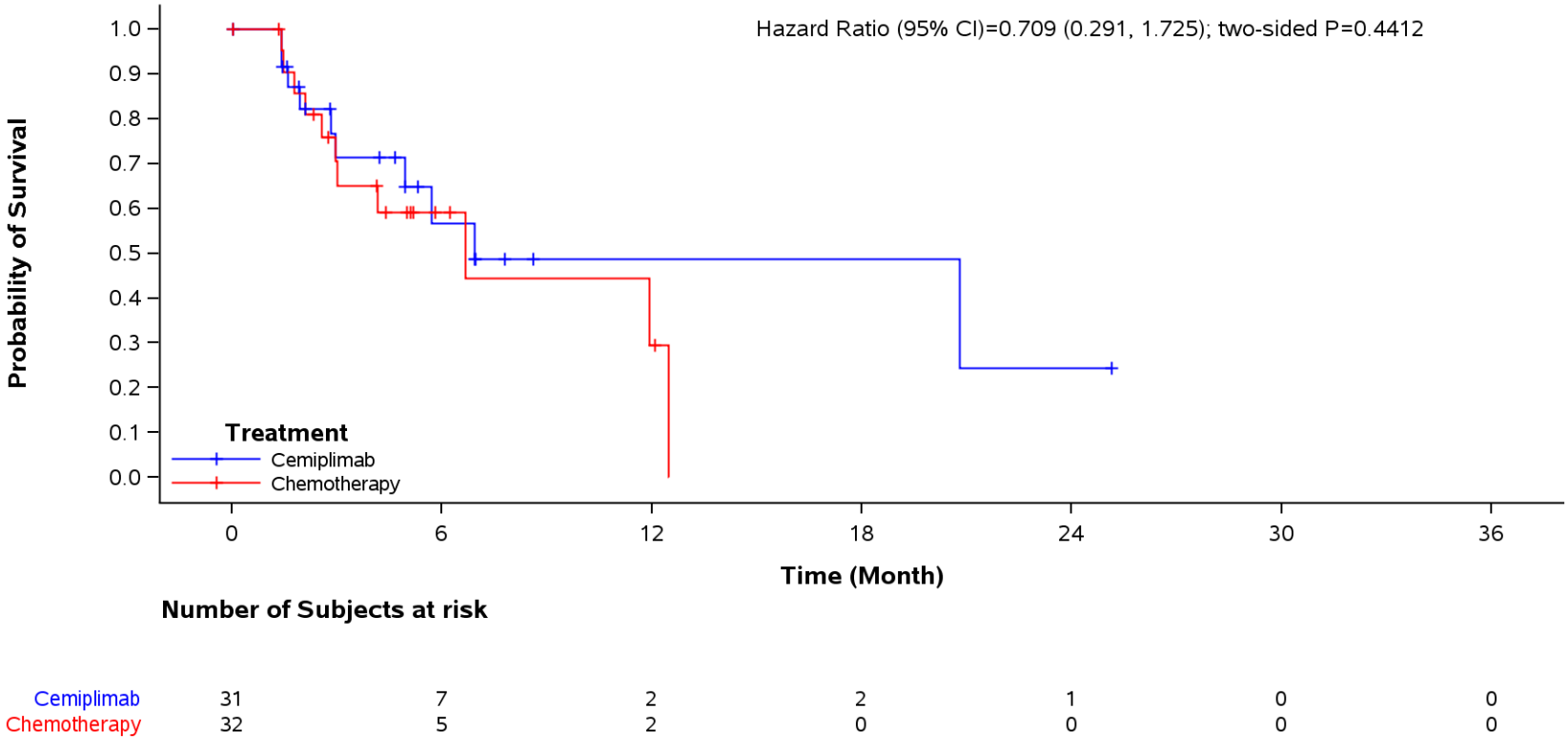

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts deterioration



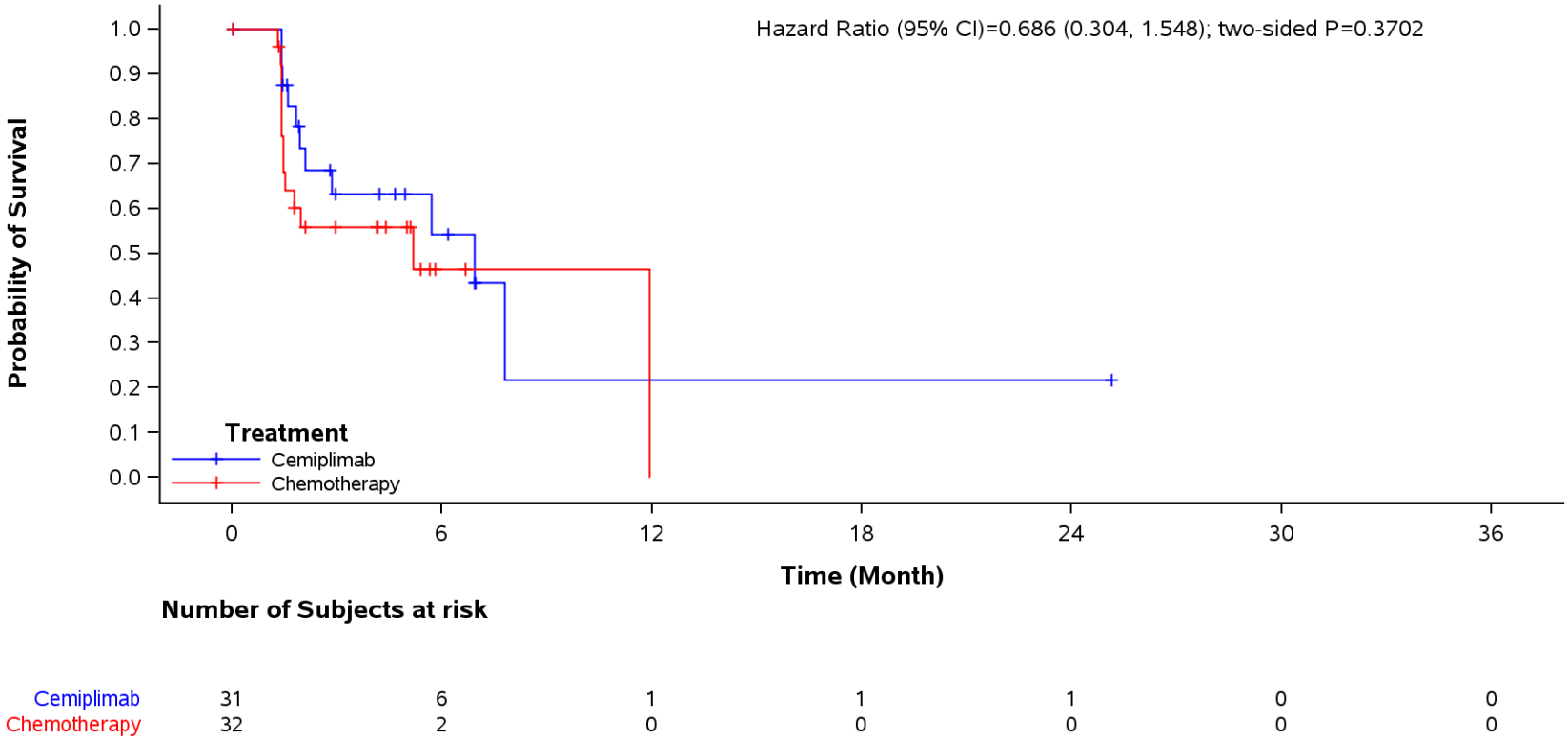

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts deterioration



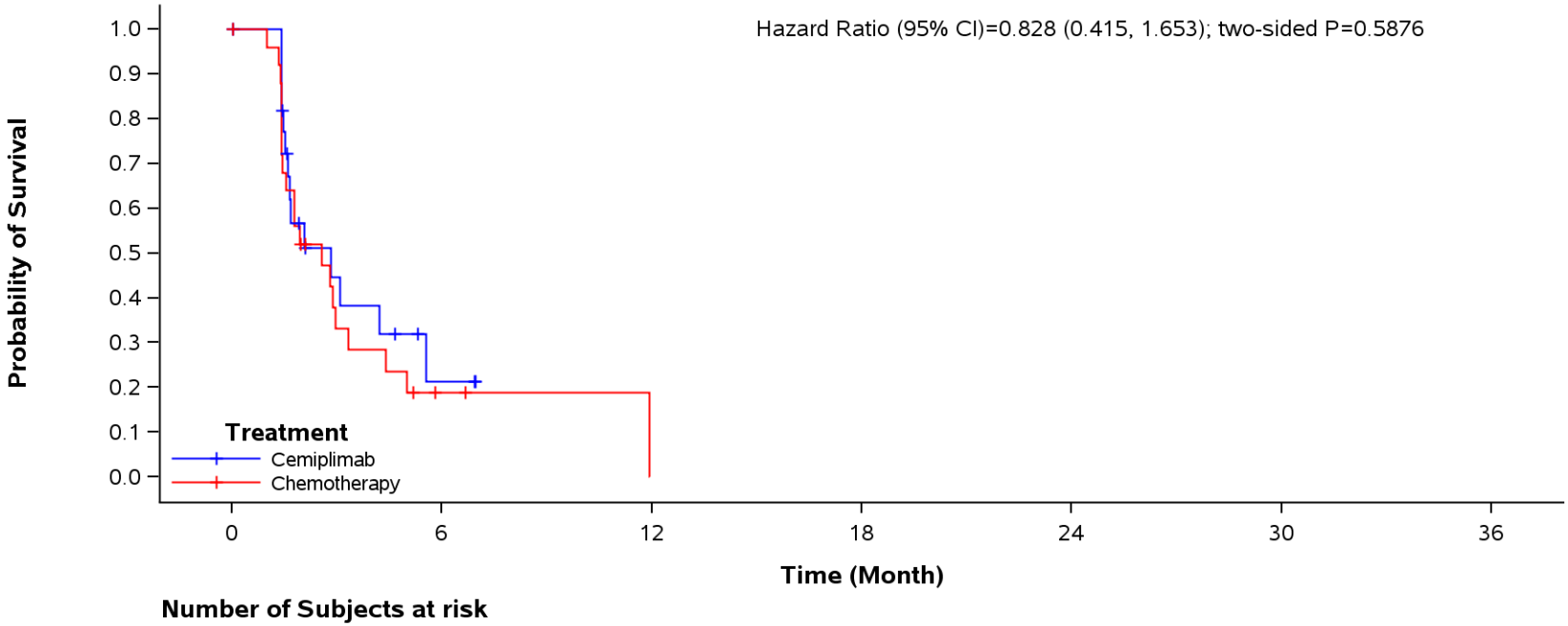

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts deterioration



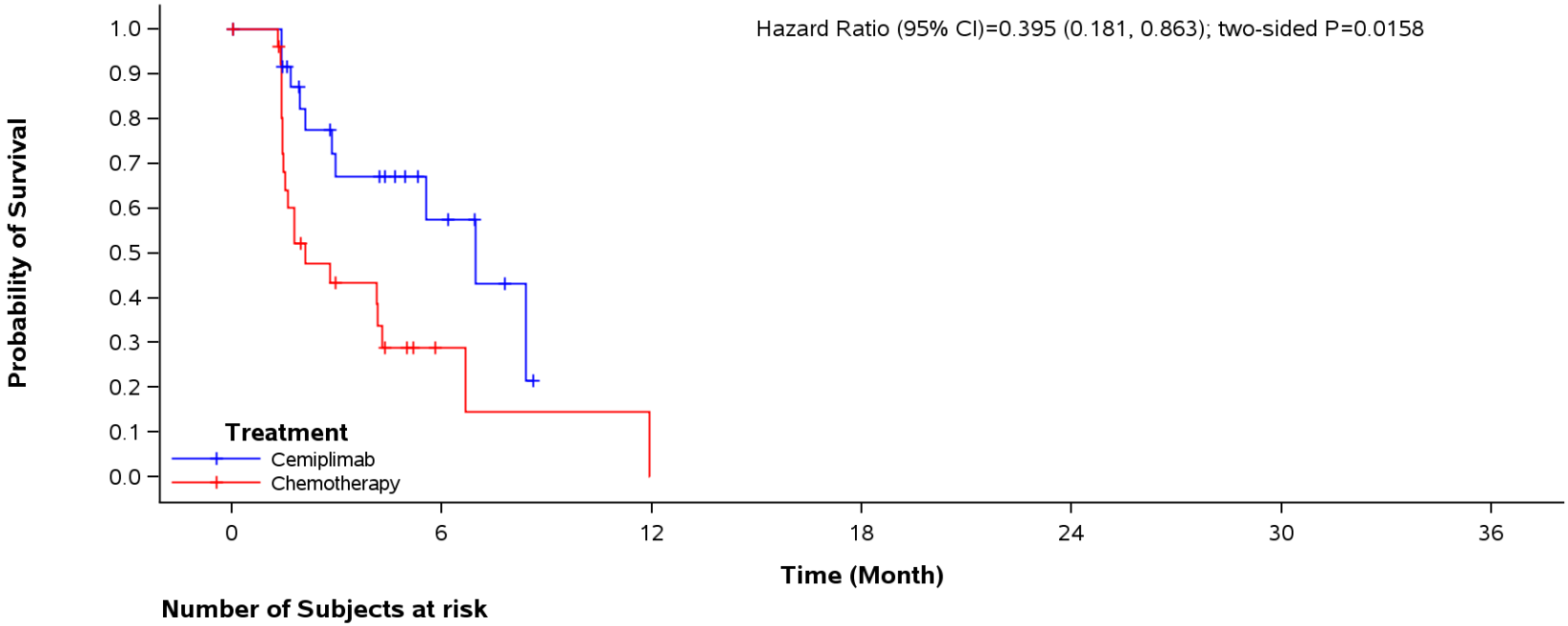

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts deterioration



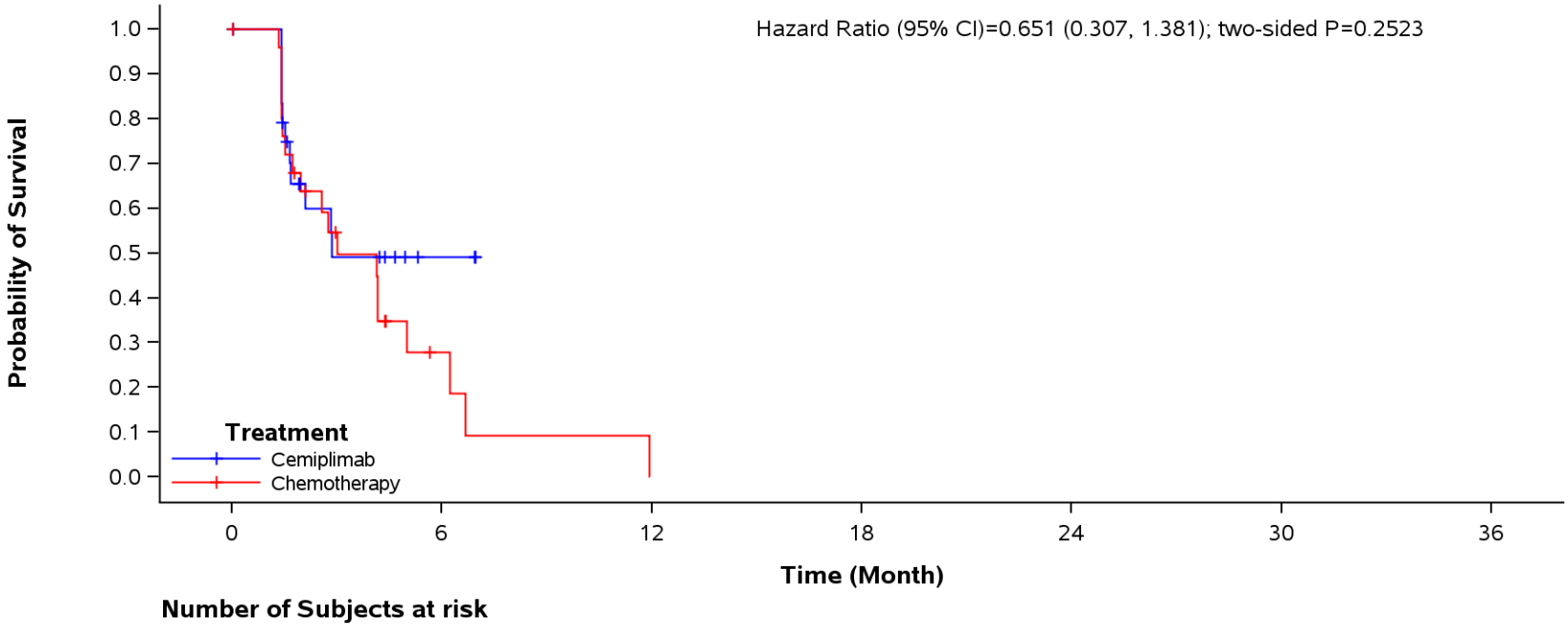

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts deterioration



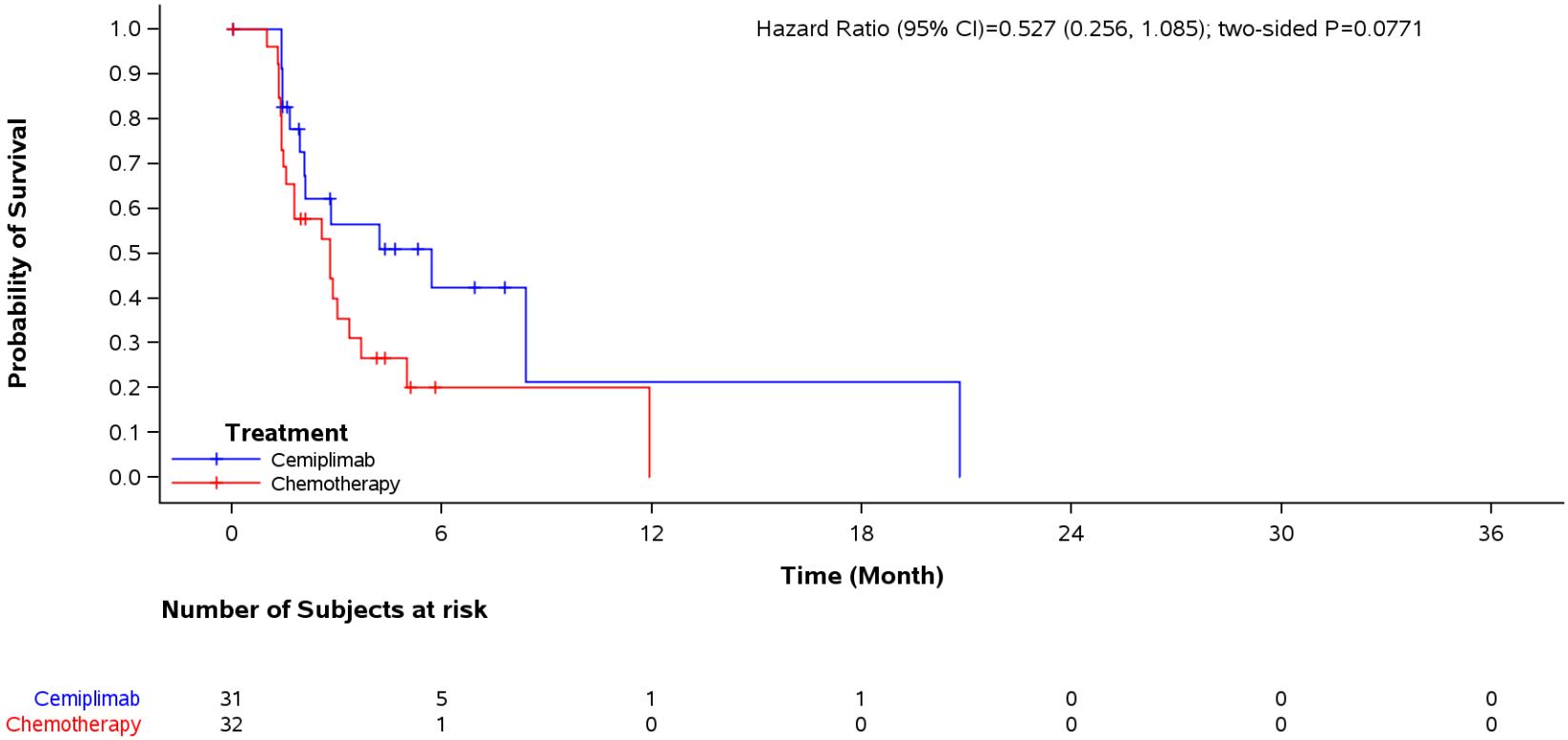

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts deterioration



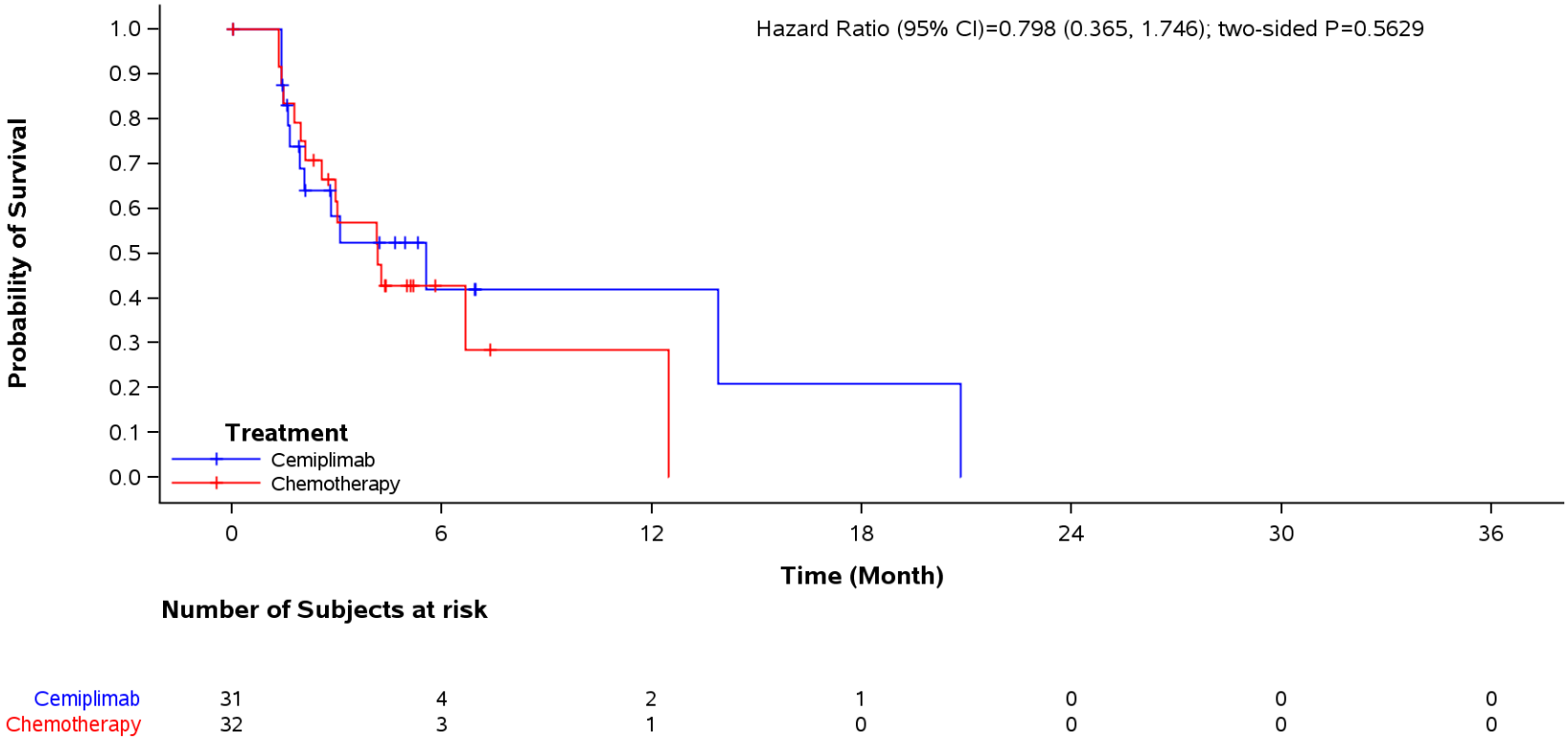

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 32 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts deterioration



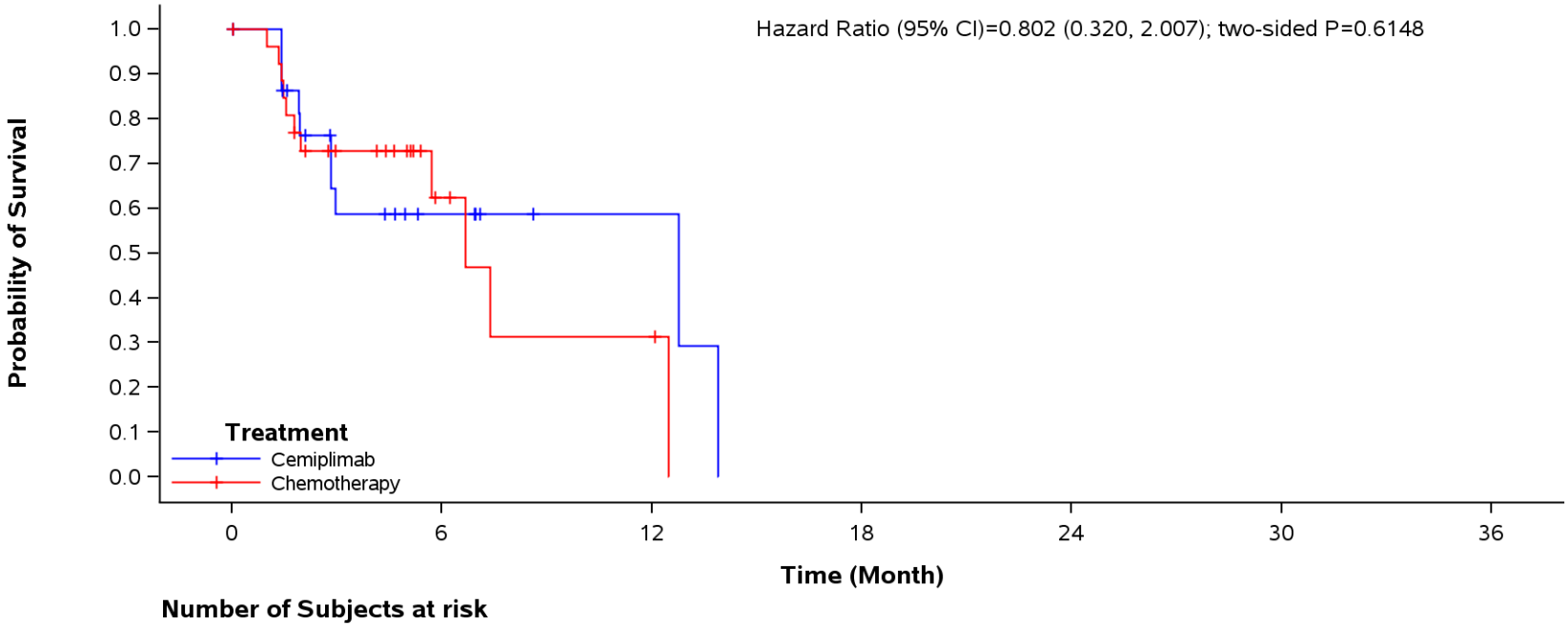

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 32 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts deterioration



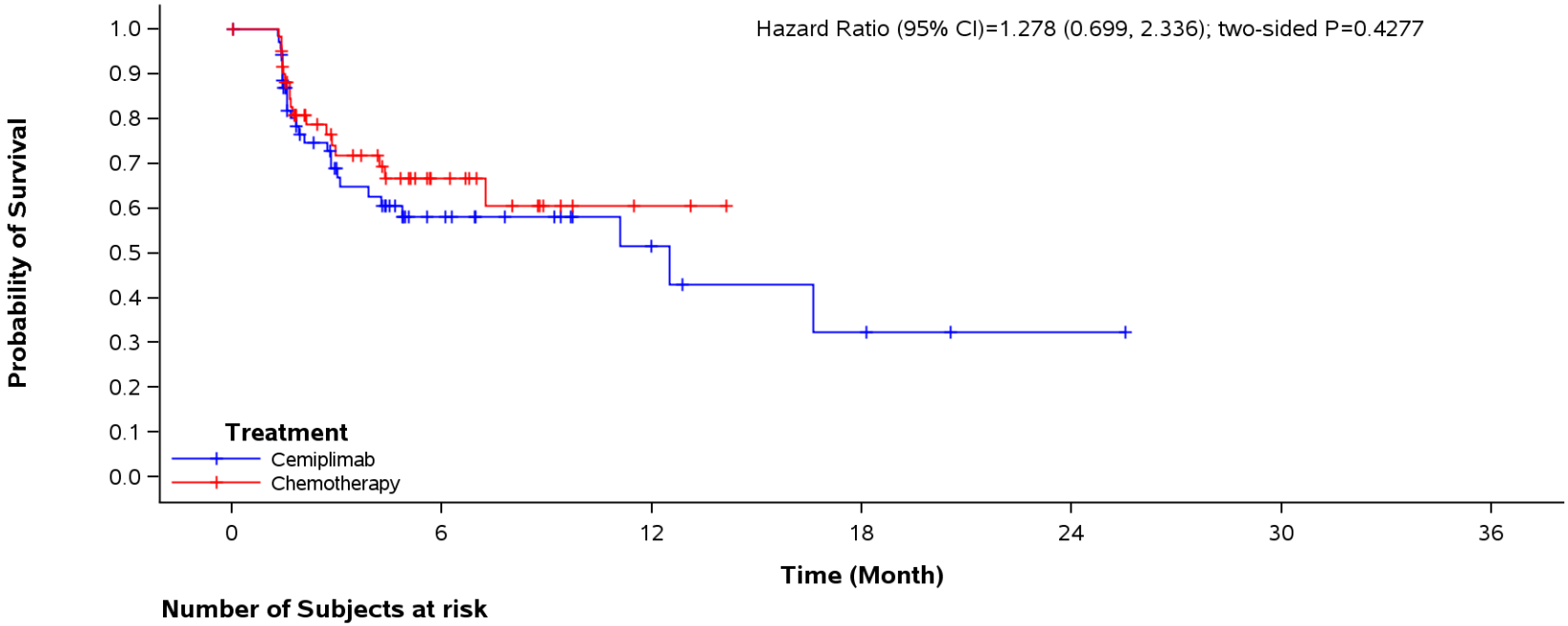

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts sustained improvement



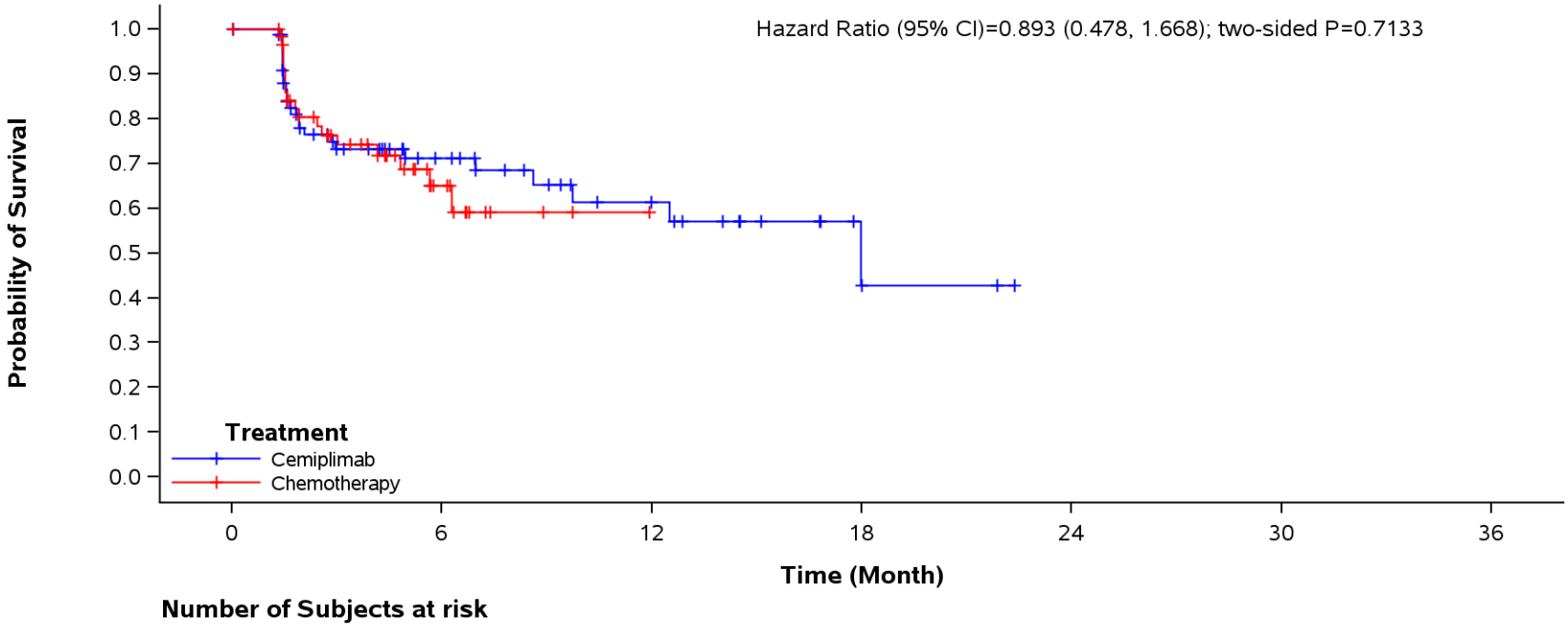

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 18 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 163 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts sustained improvement



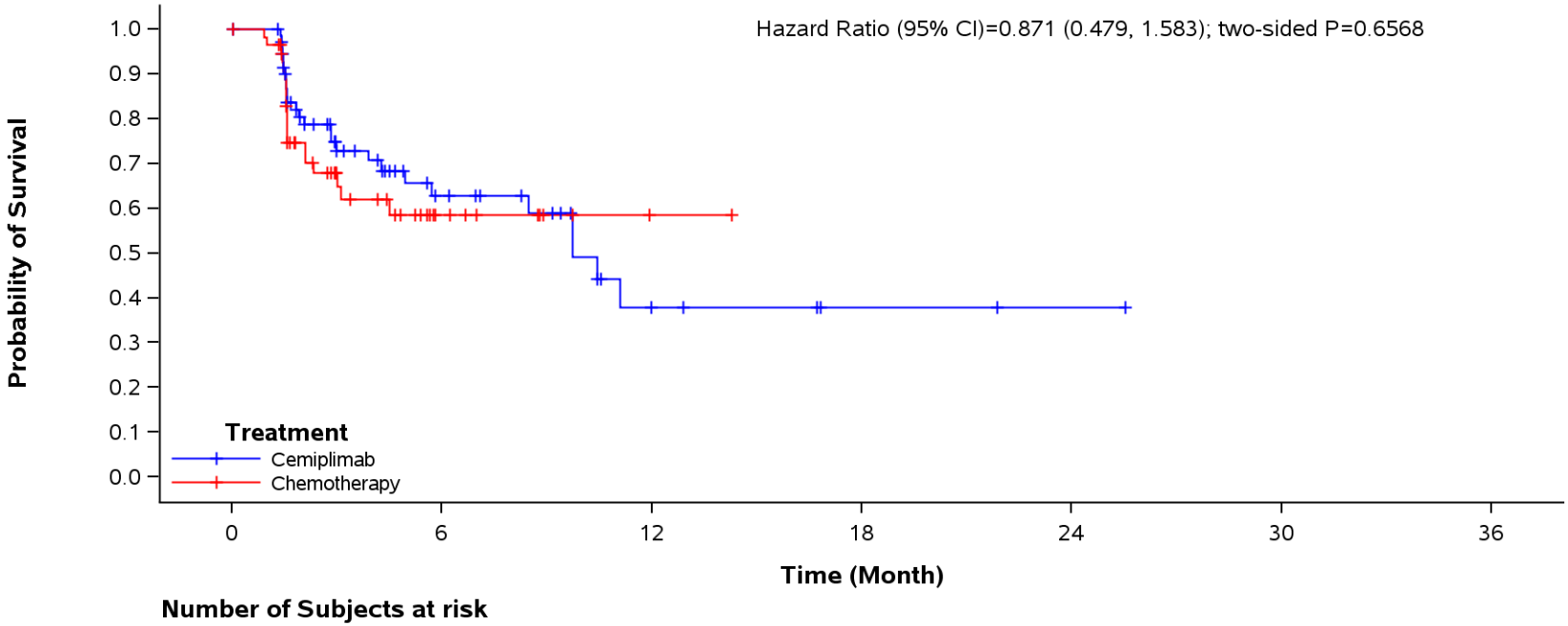

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 30 | 14 | 3 | 0 | 0 | 0 |
| Chemotherapy | 163 | 14 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts sustained improvement



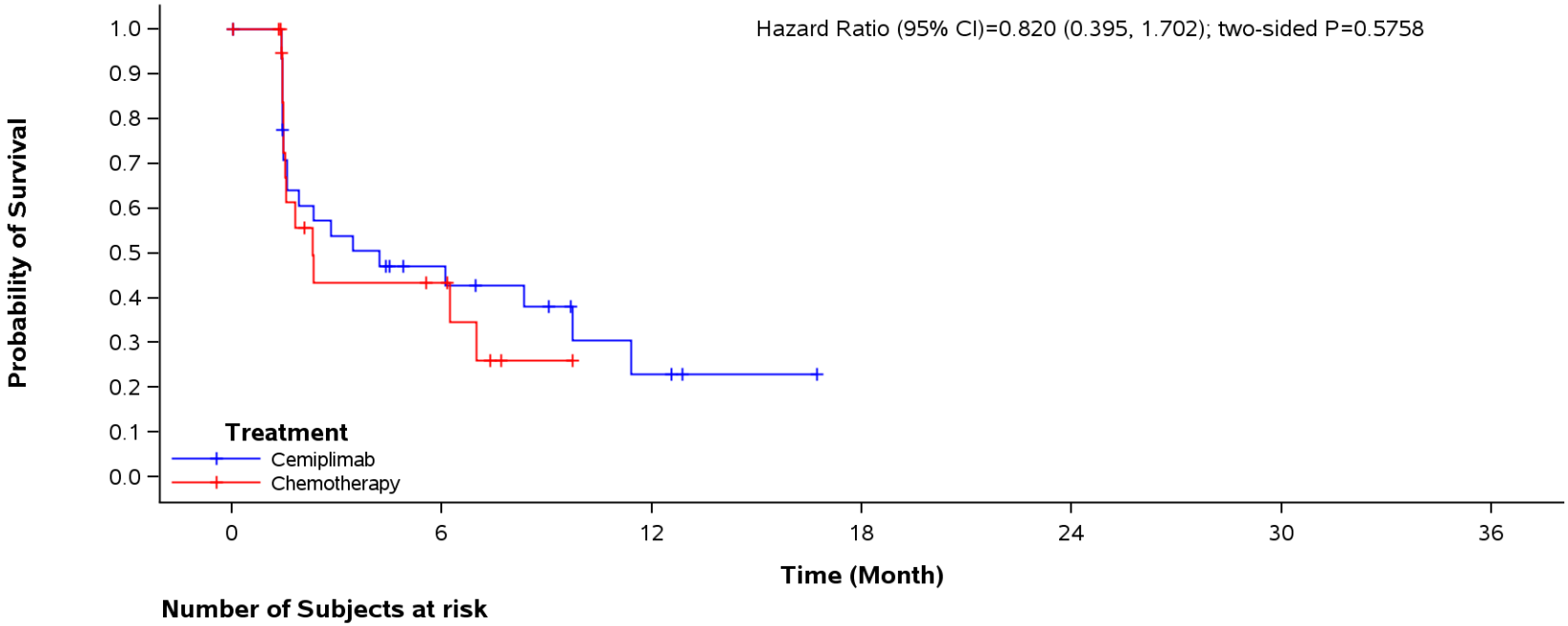

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 21 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 163 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts sustained improvement



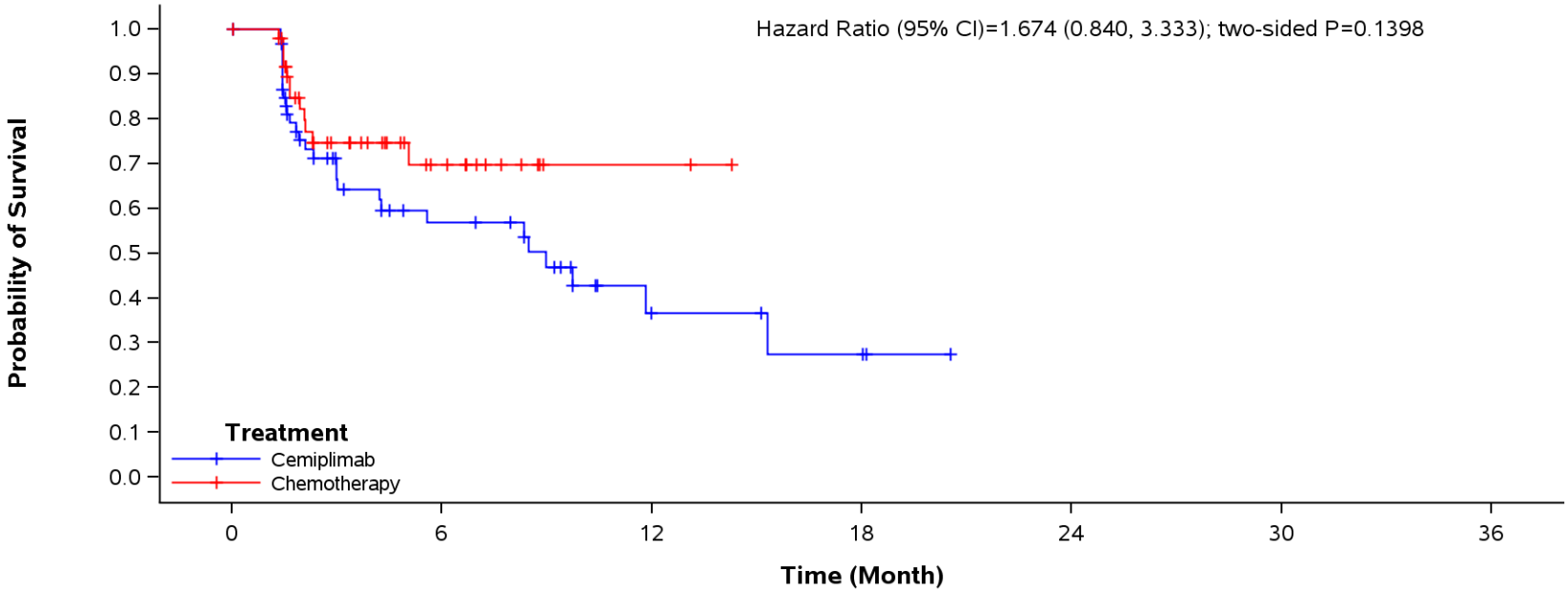

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 11 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 163 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts sustained improvement



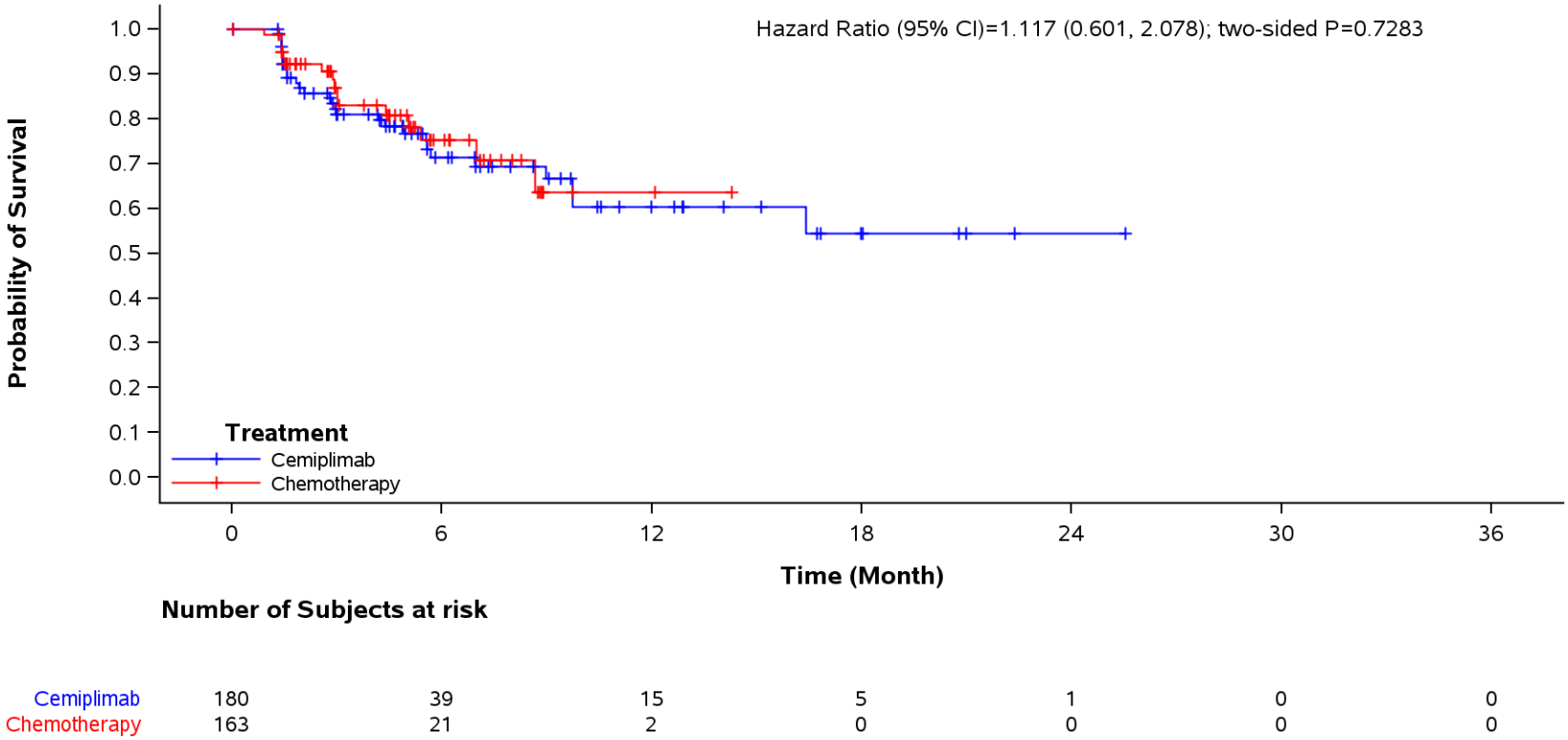

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 21 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 163 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

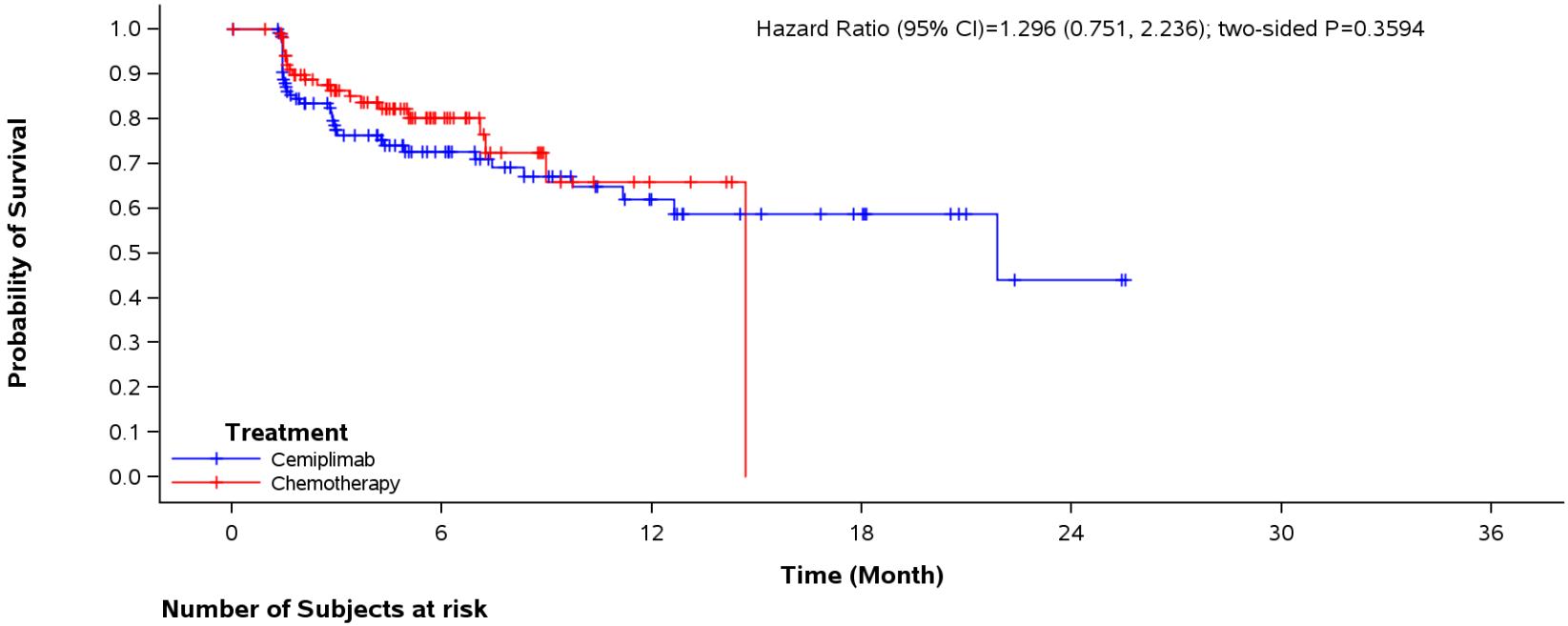
Age Group: <65
Emotional Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts sustained improvement



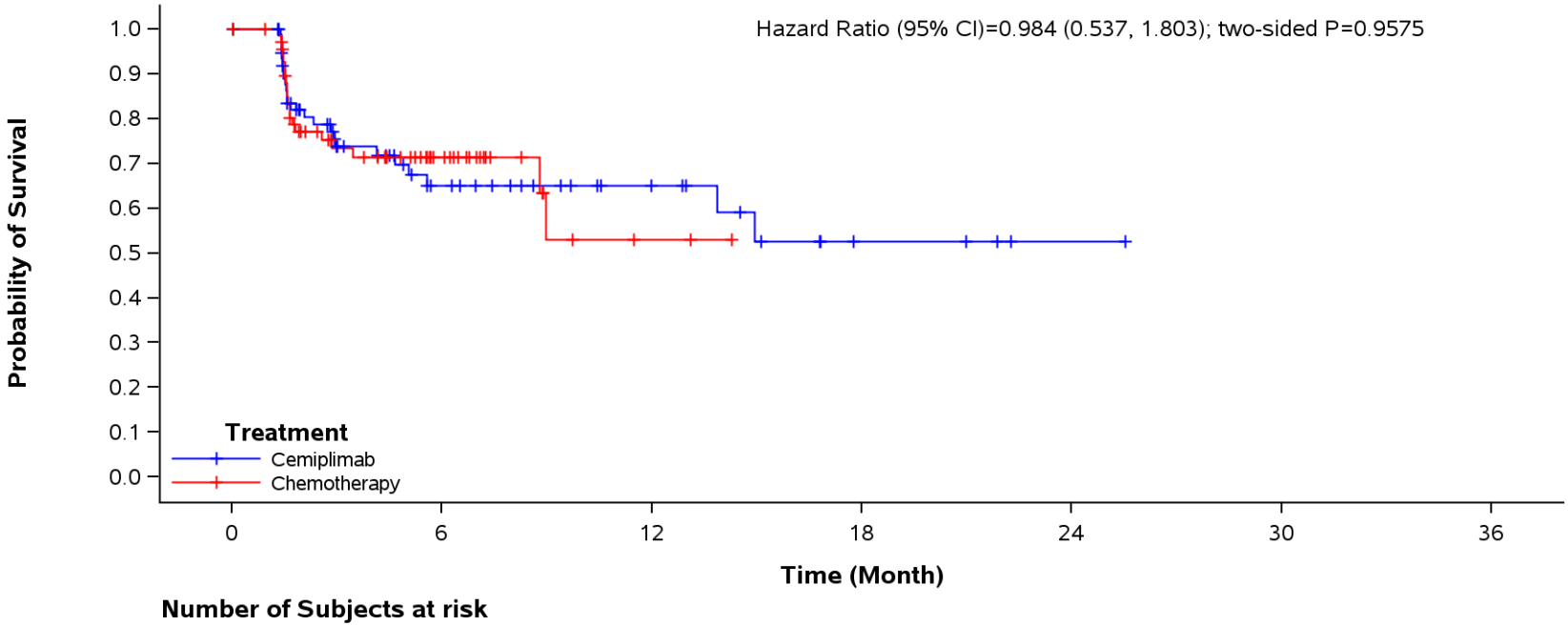

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 48 | 19 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 30 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts sustained improvement



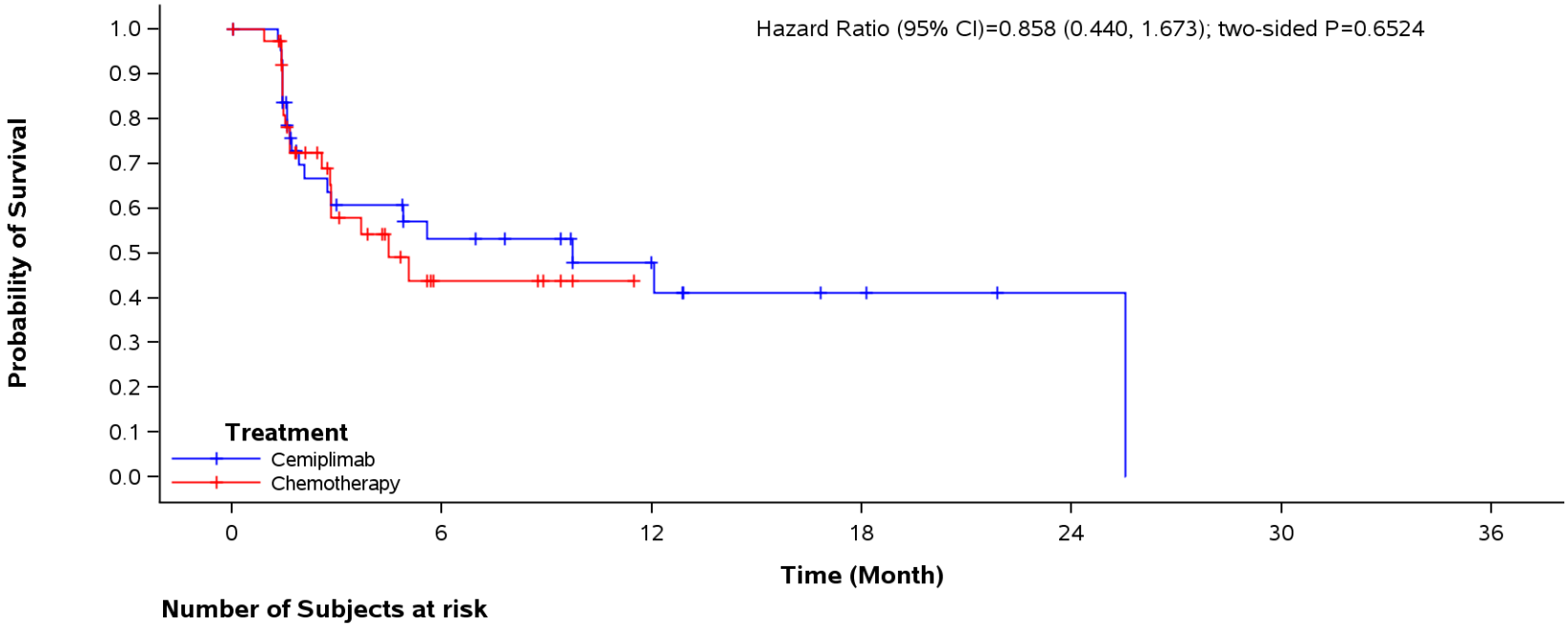

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 25 | 13 | 4 | 1 | 0 | 0 |
| Chemotherapy | 163 | 21 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts sustained improvement



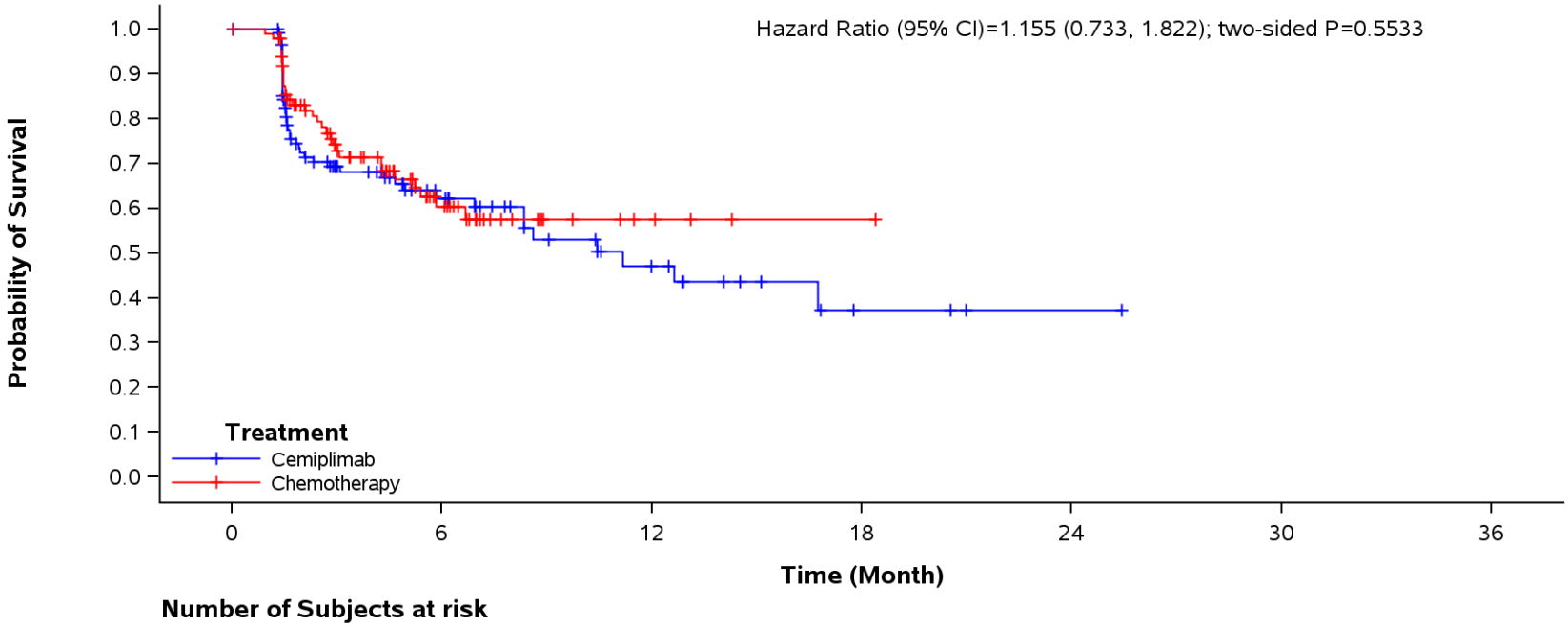

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 14 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 163 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts sustained improvement



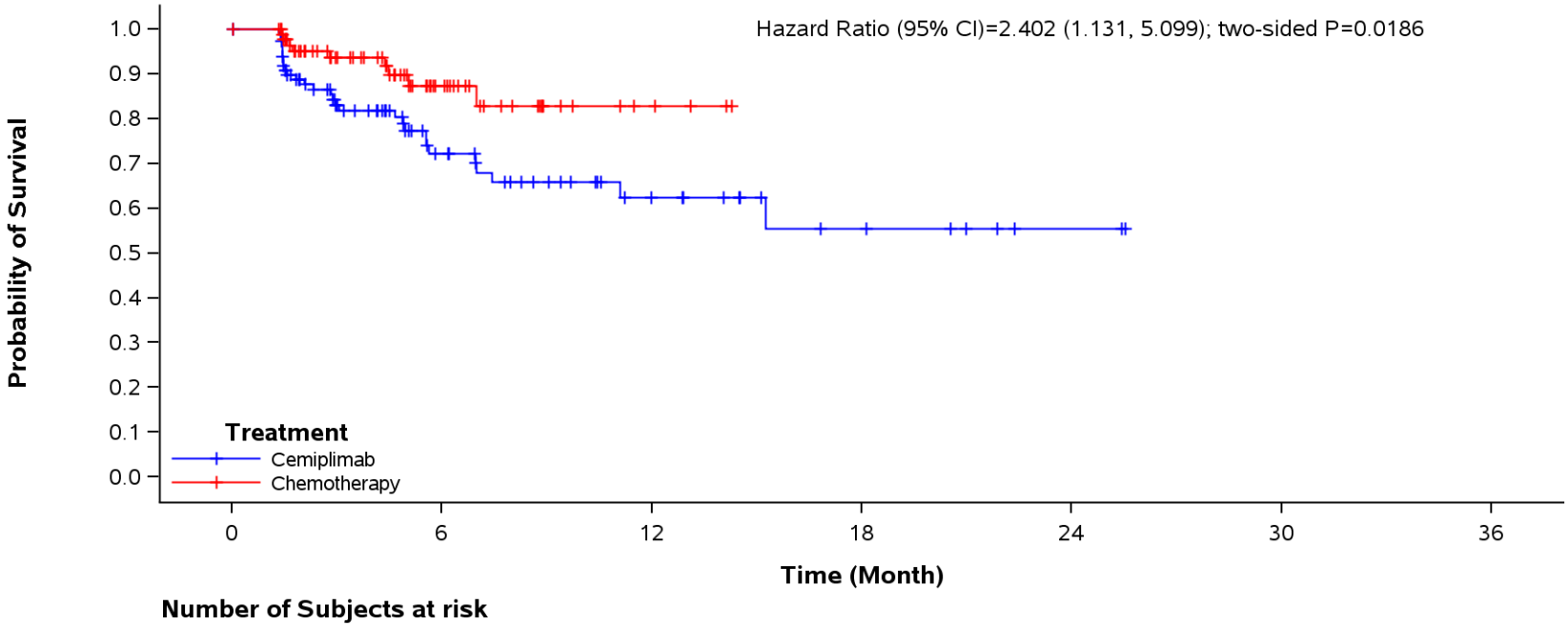

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 37 | 14 | 3 | 1 | 0 | 0 |
| Chemotherapy | 163 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts sustained improvement



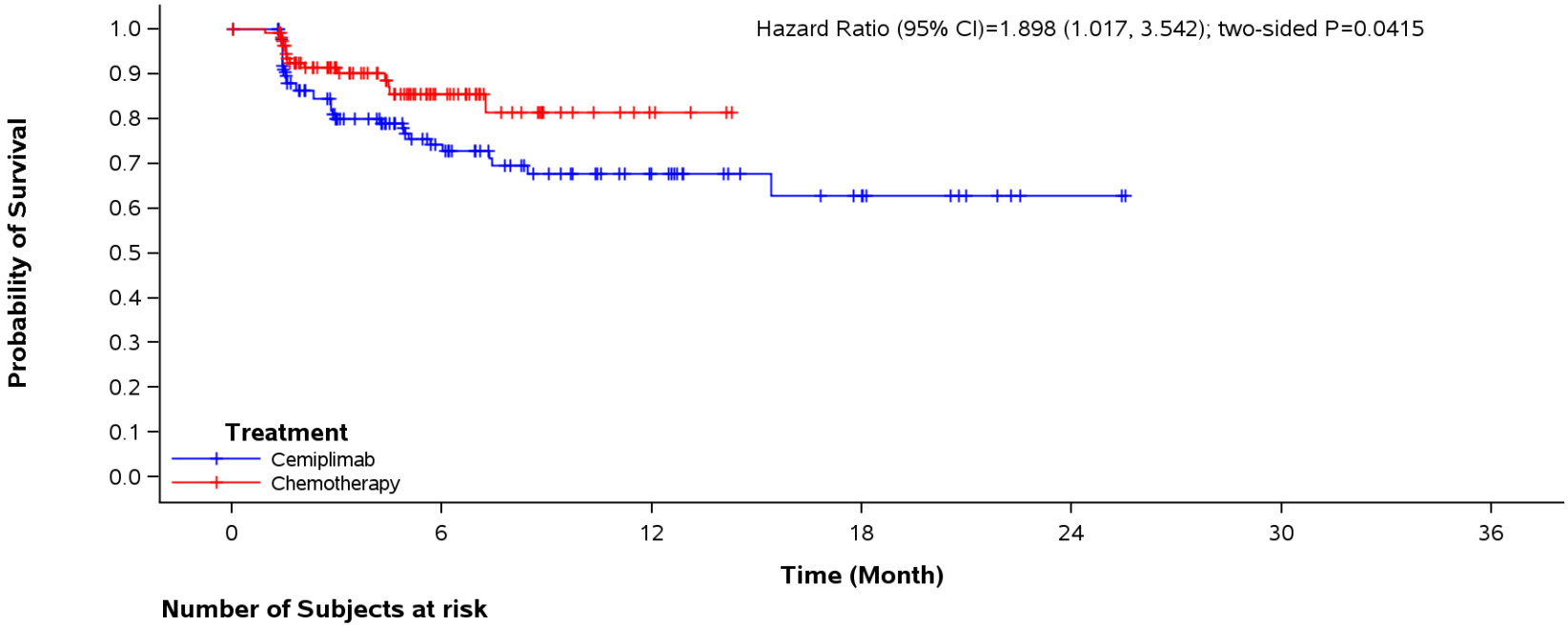

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 39 | 15 | 7 | 2 | 0 | 0 |
| Chemotherapy | 163 | 27 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts sustained improvement



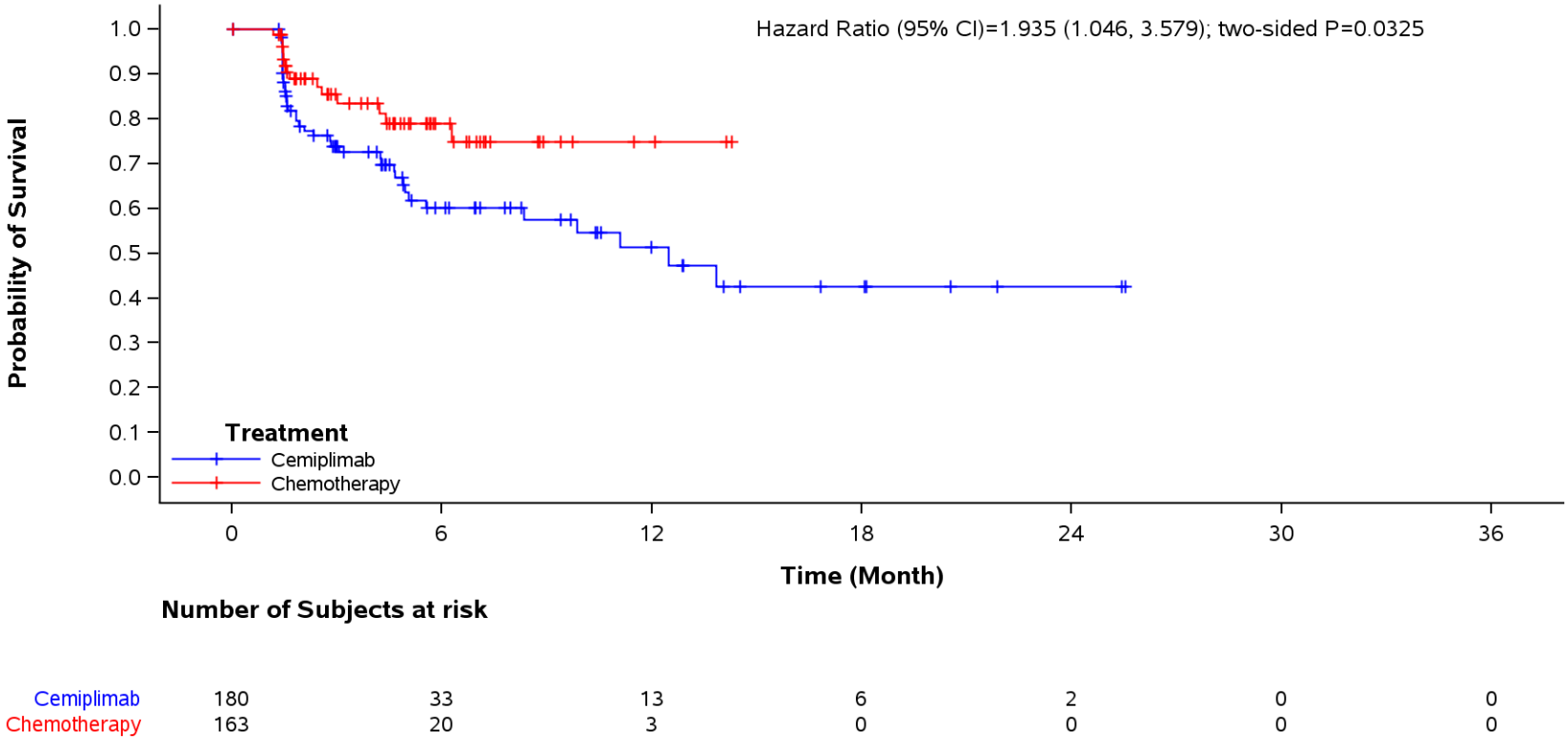

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 55 | 23 | 11 | 2 | 0 | 0 |
| Chemotherapy | 163 | 34 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts sustained improvement



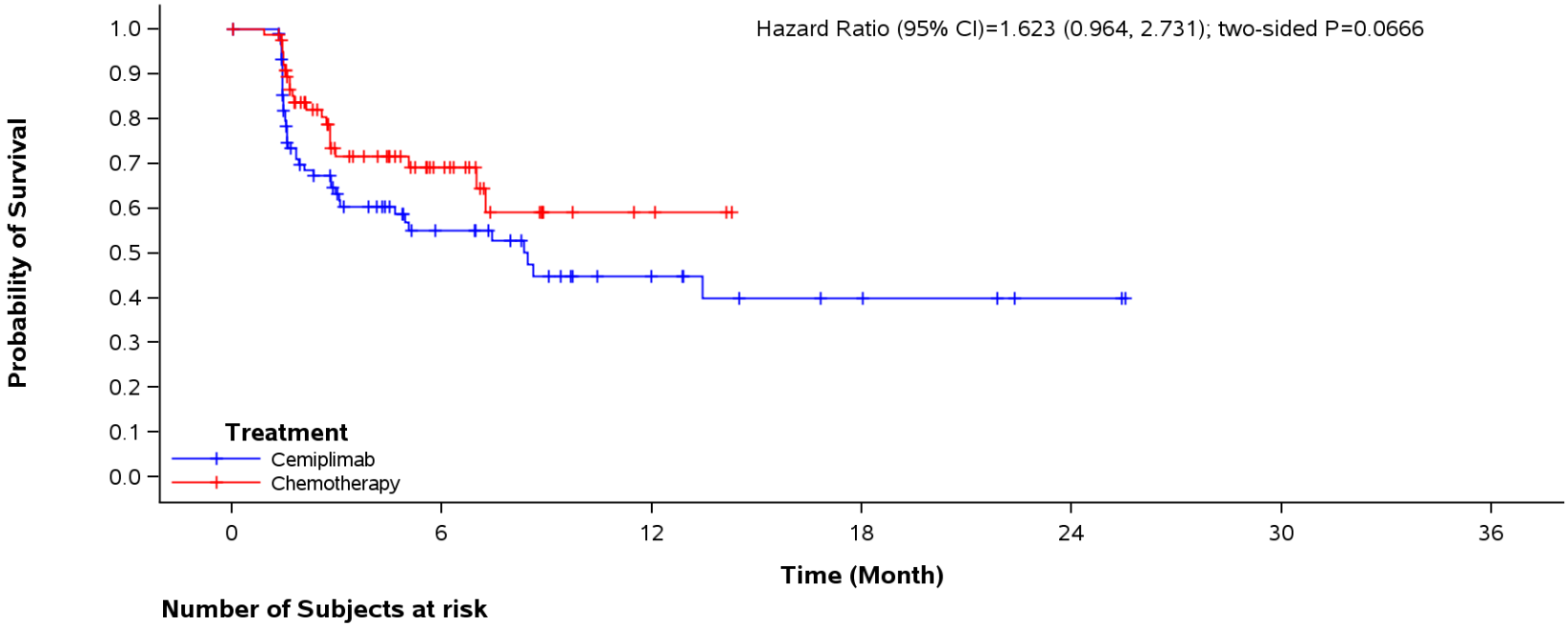

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 33 | 13 | 6 | 2 | 0 | 0 |
| Chemotherapy | 163 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts sustained improvement



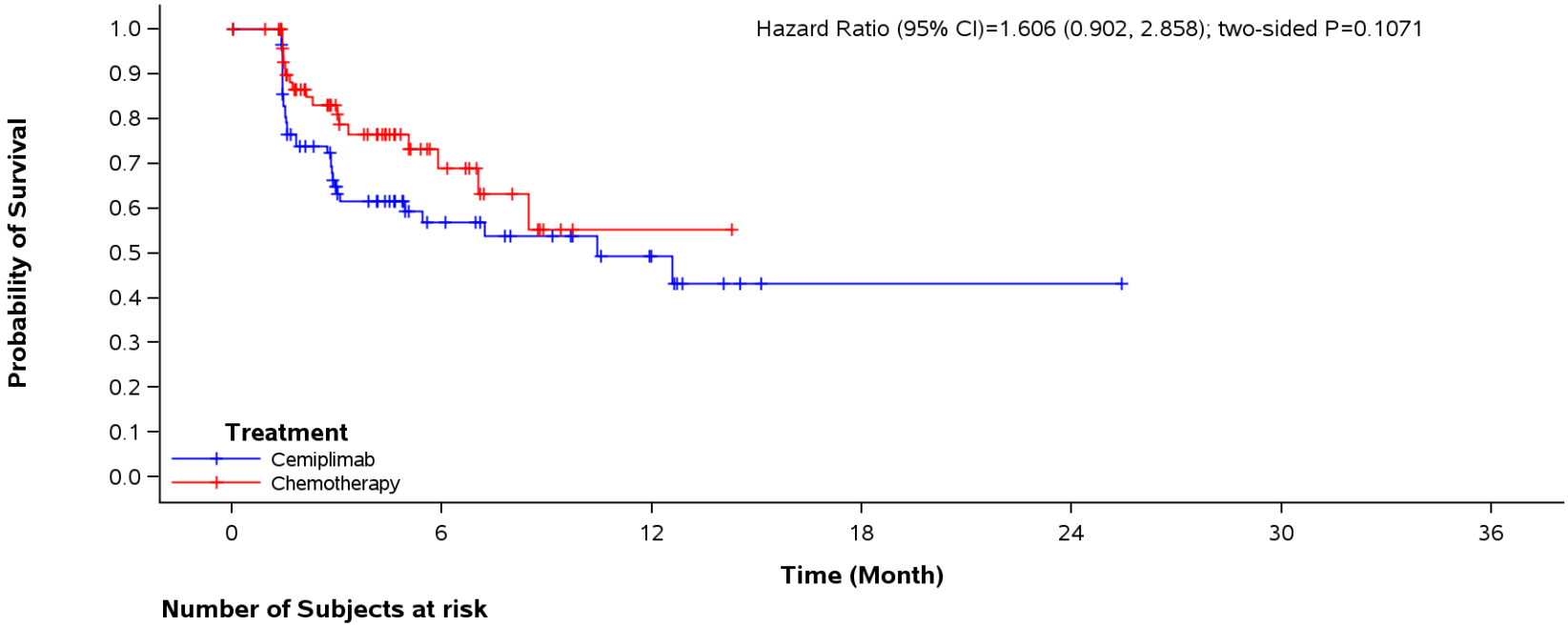

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 28 | 11 | 5 | 2 | 0 | 0 |
| Chemotherapy | 163 | 21 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts sustained improvement



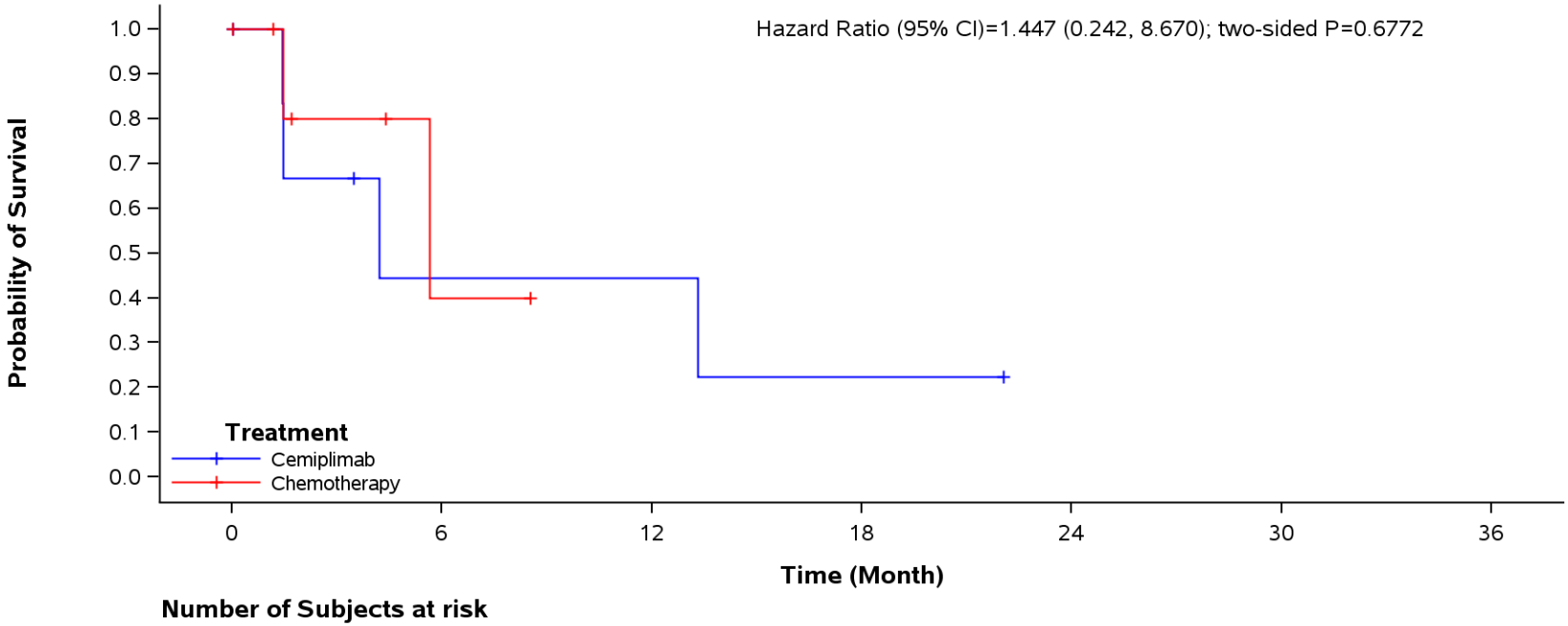

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 23 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 163 | 16 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts sustained improvement



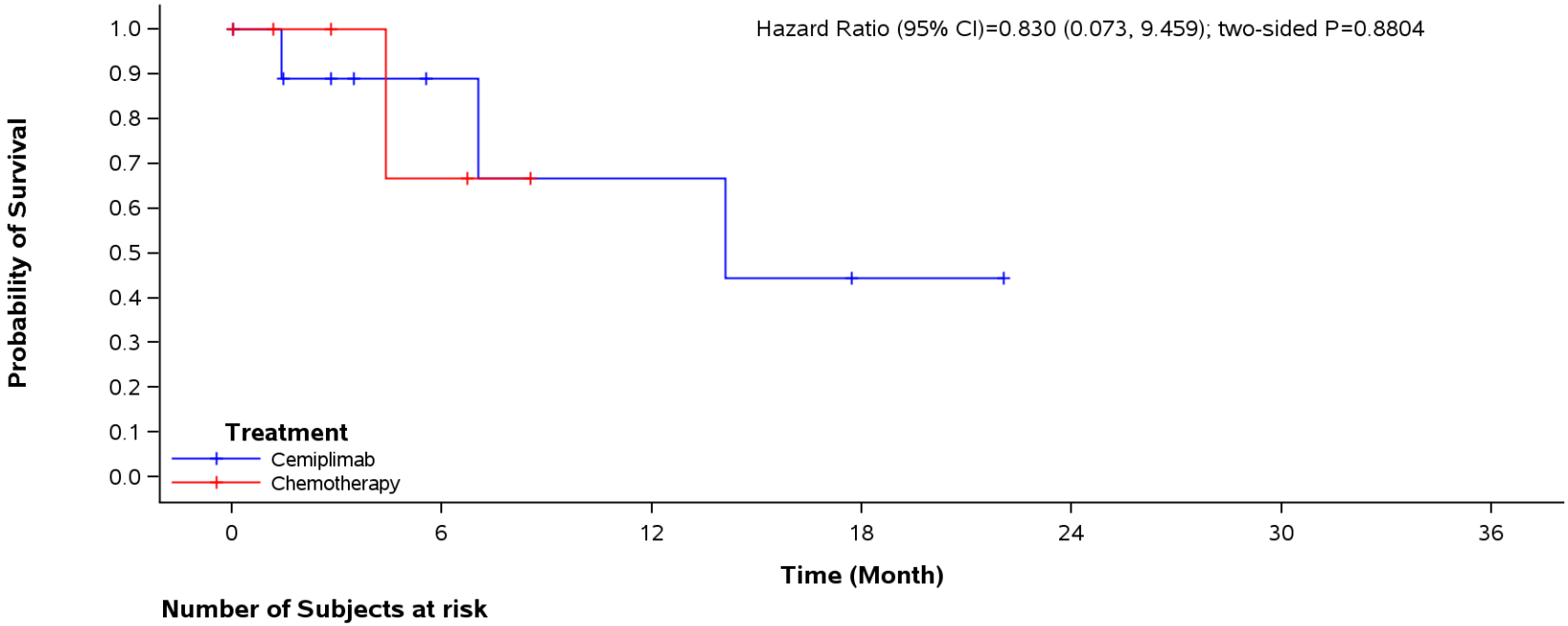

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts sustained improvement



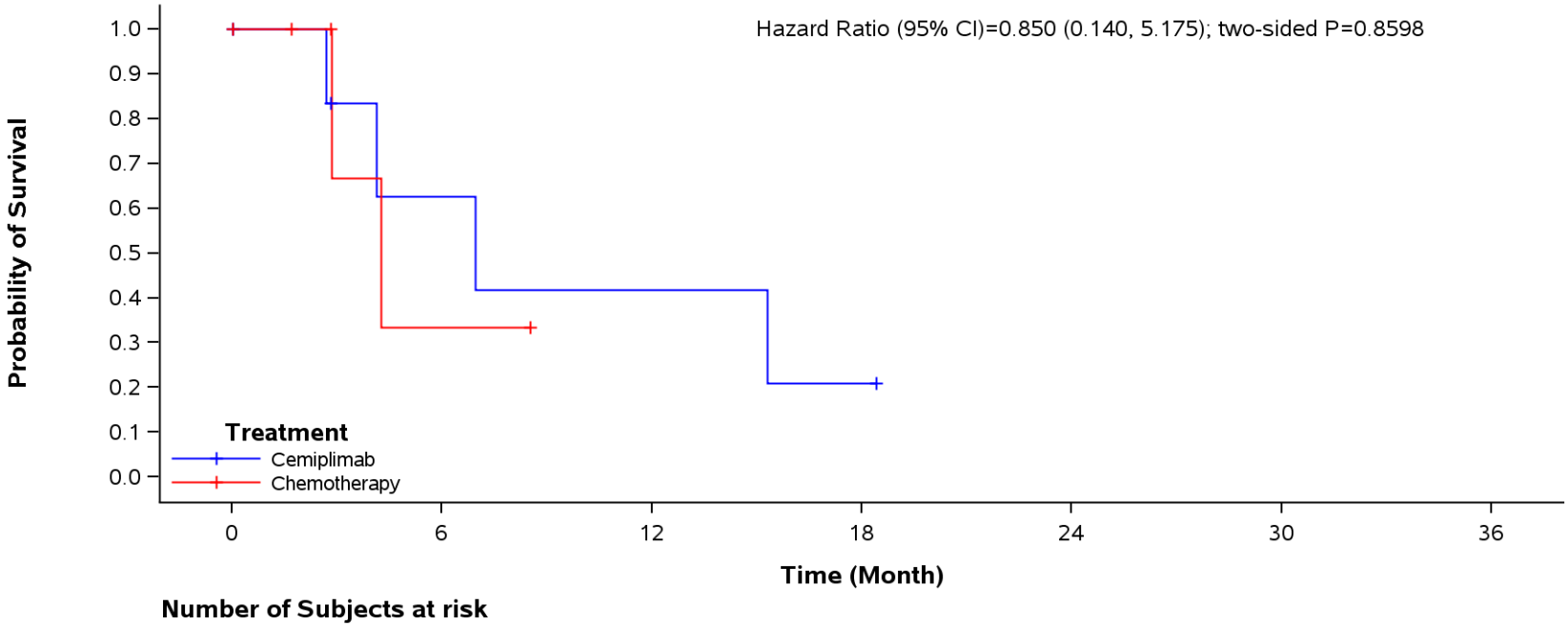

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 4 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts sustained improvement



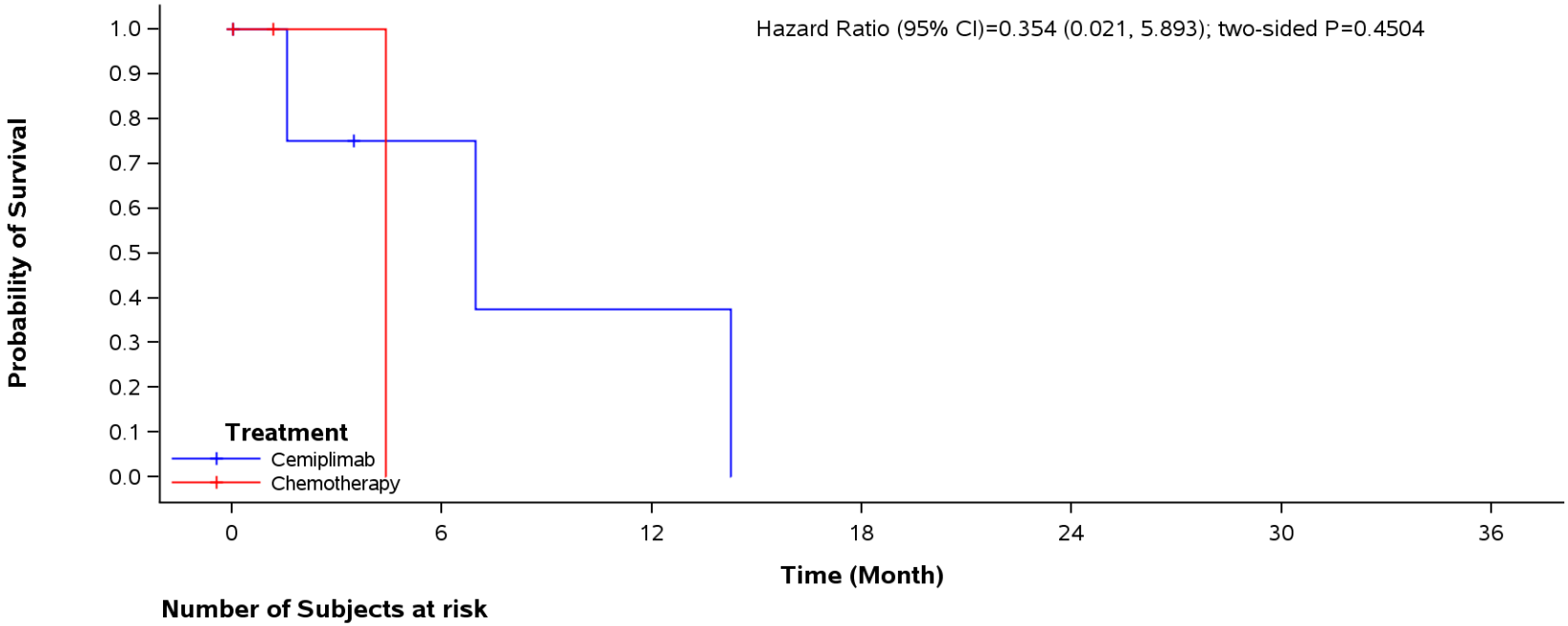

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts sustained improvement



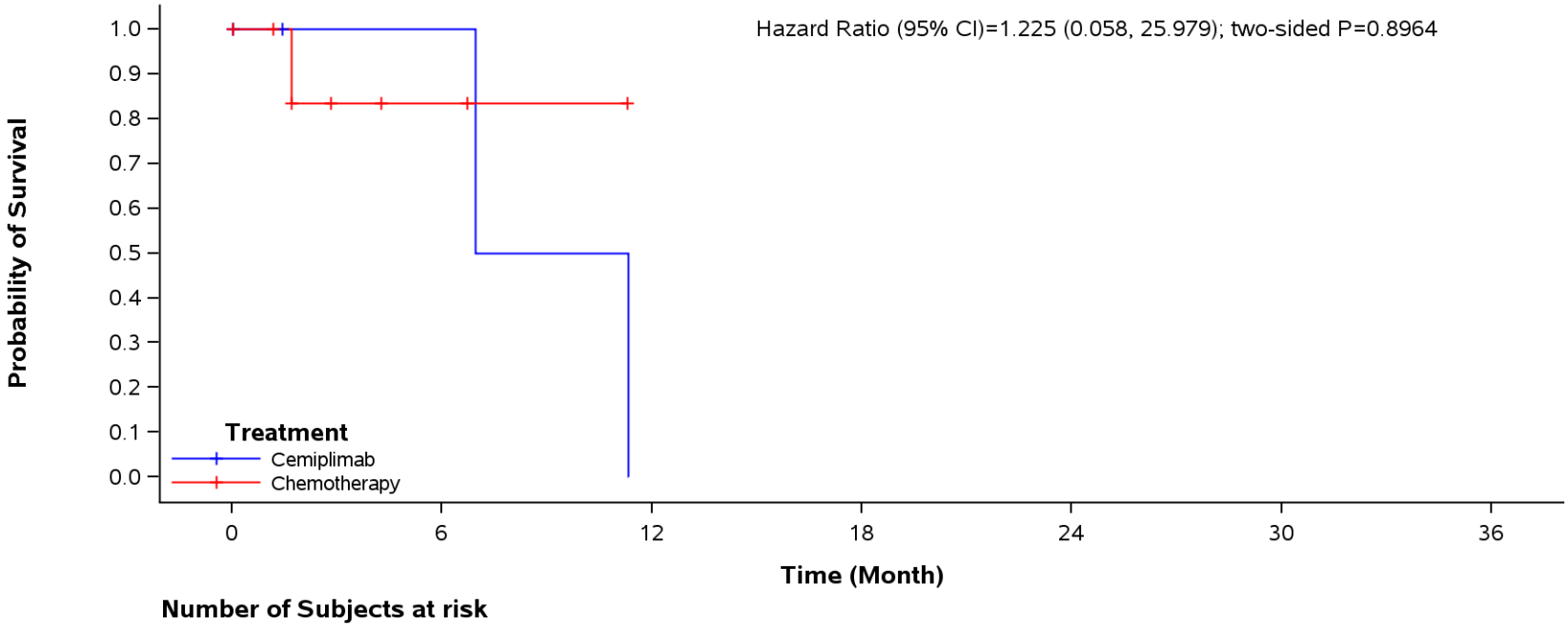

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts sustained improvement



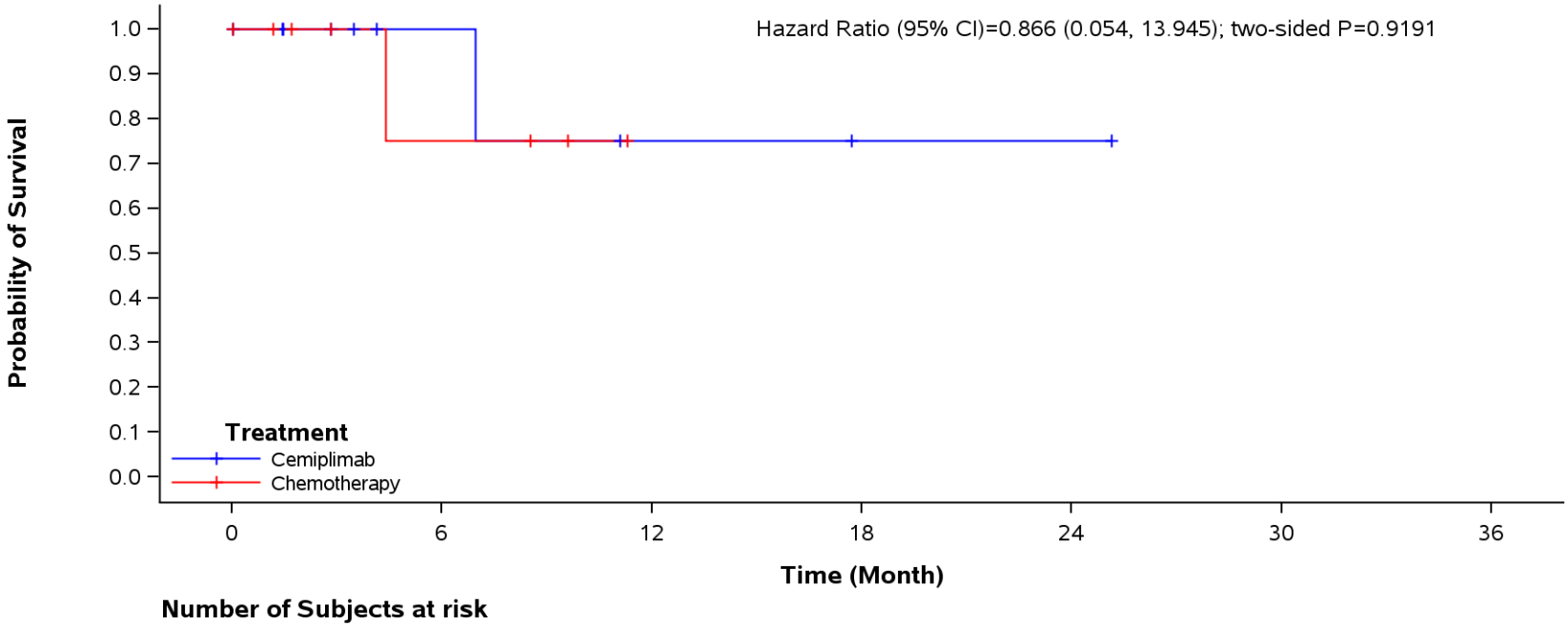

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts sustained improvement



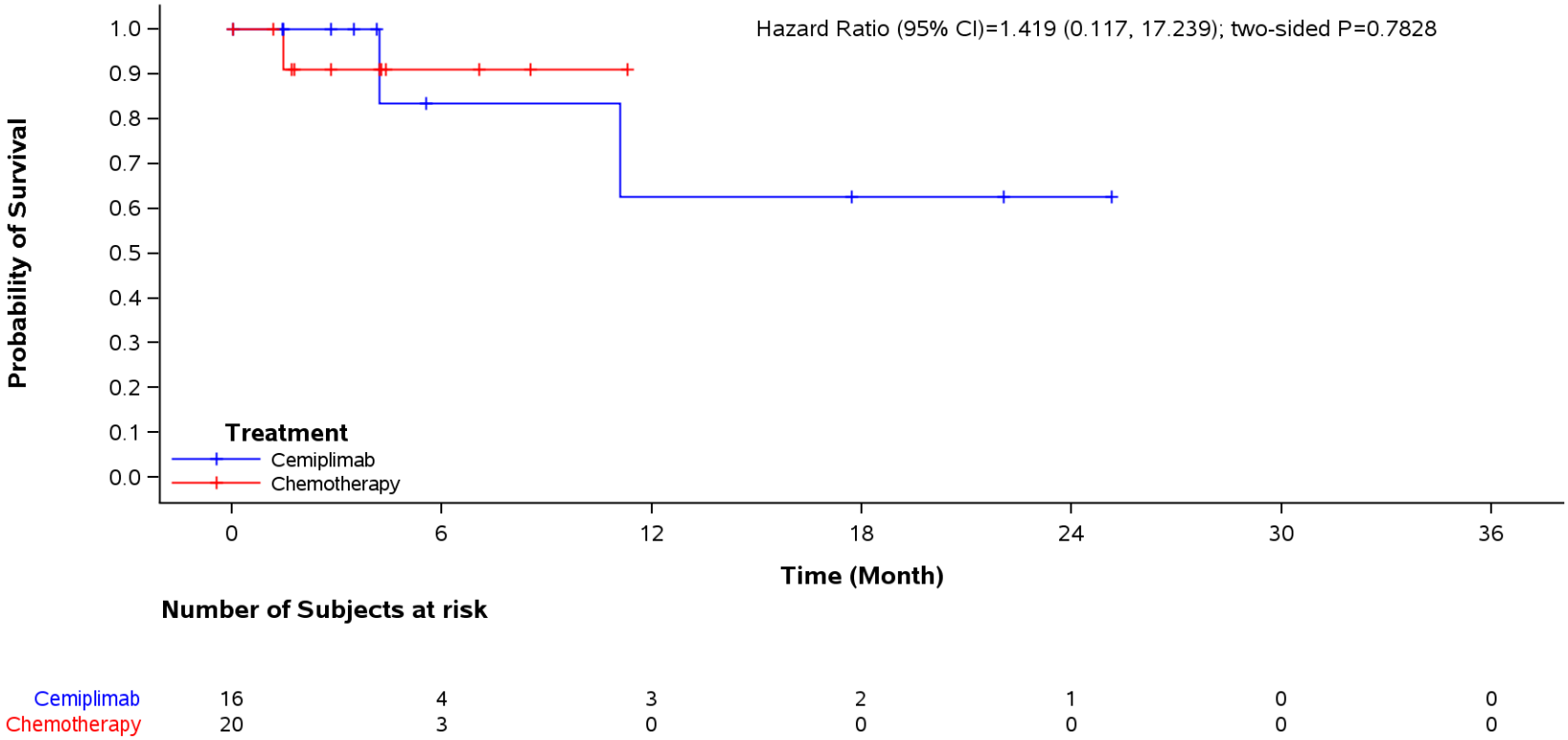

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 4 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

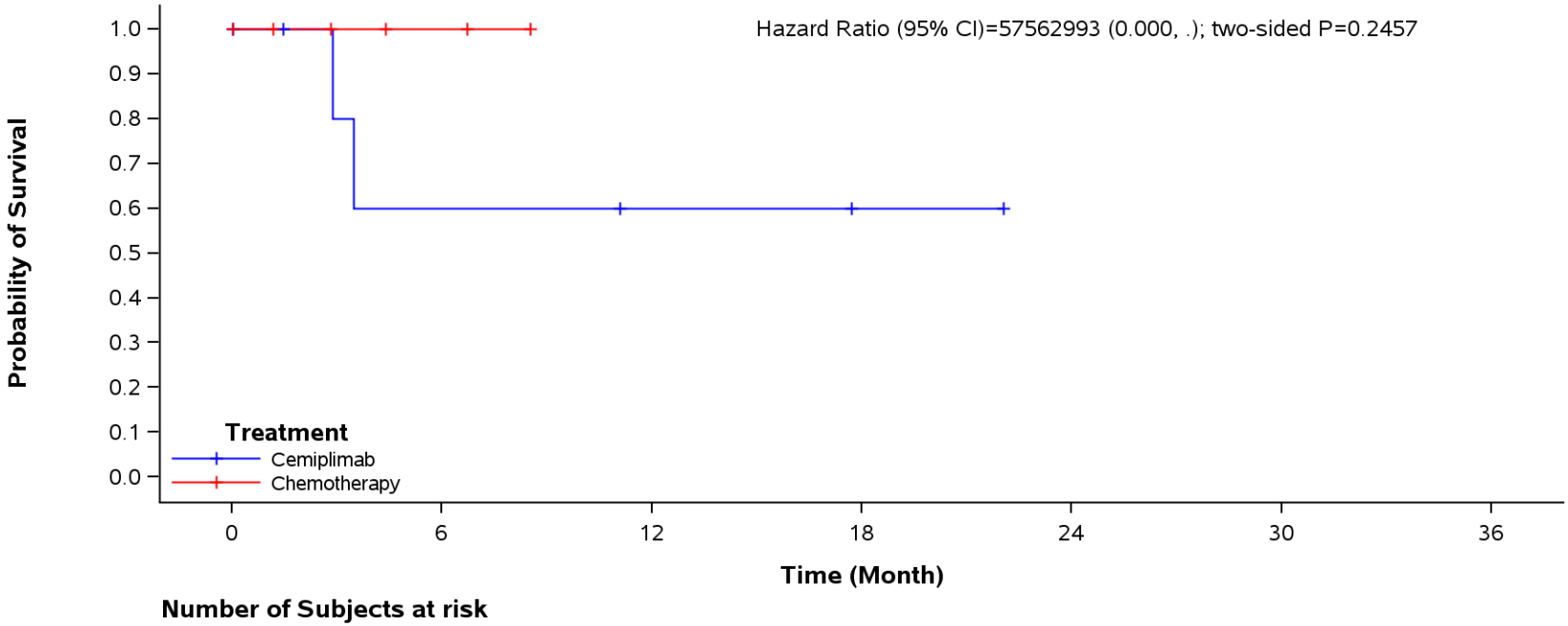
Age Group: >=65
Fatigue - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts sustained improvement



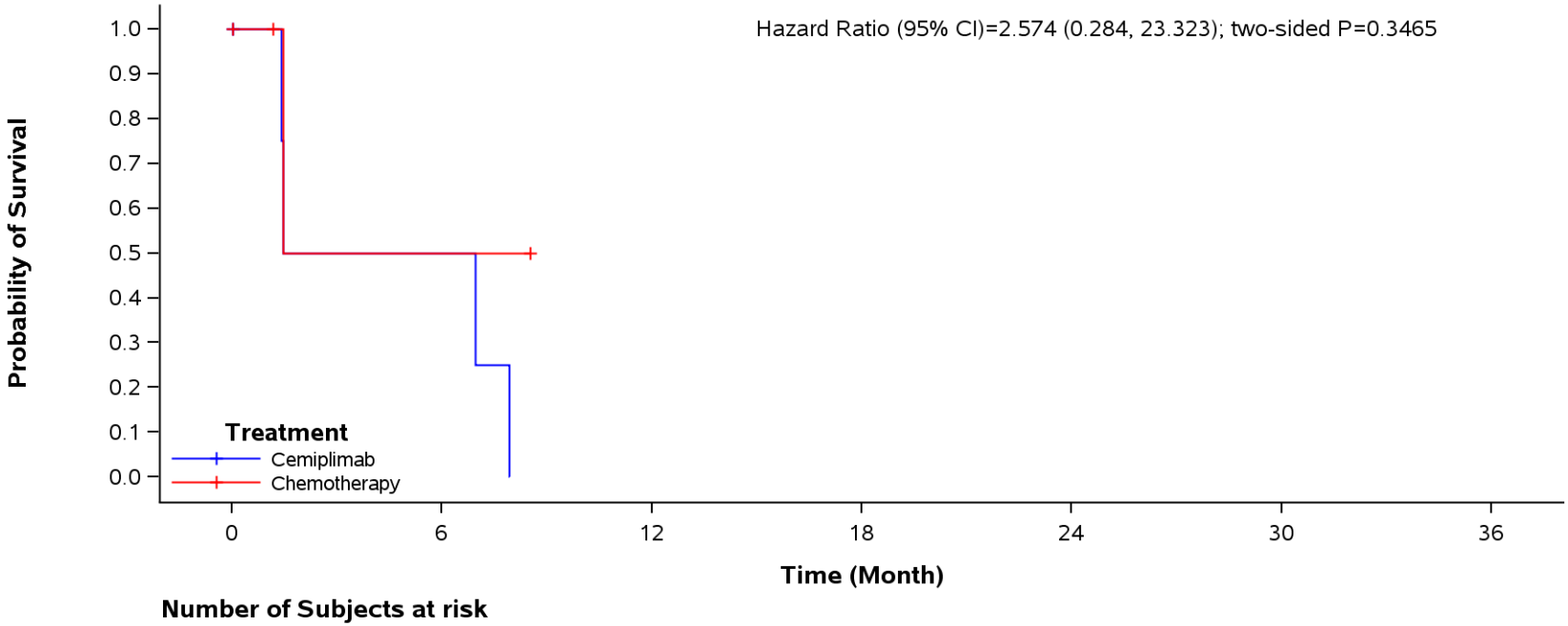

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts sustained improvement



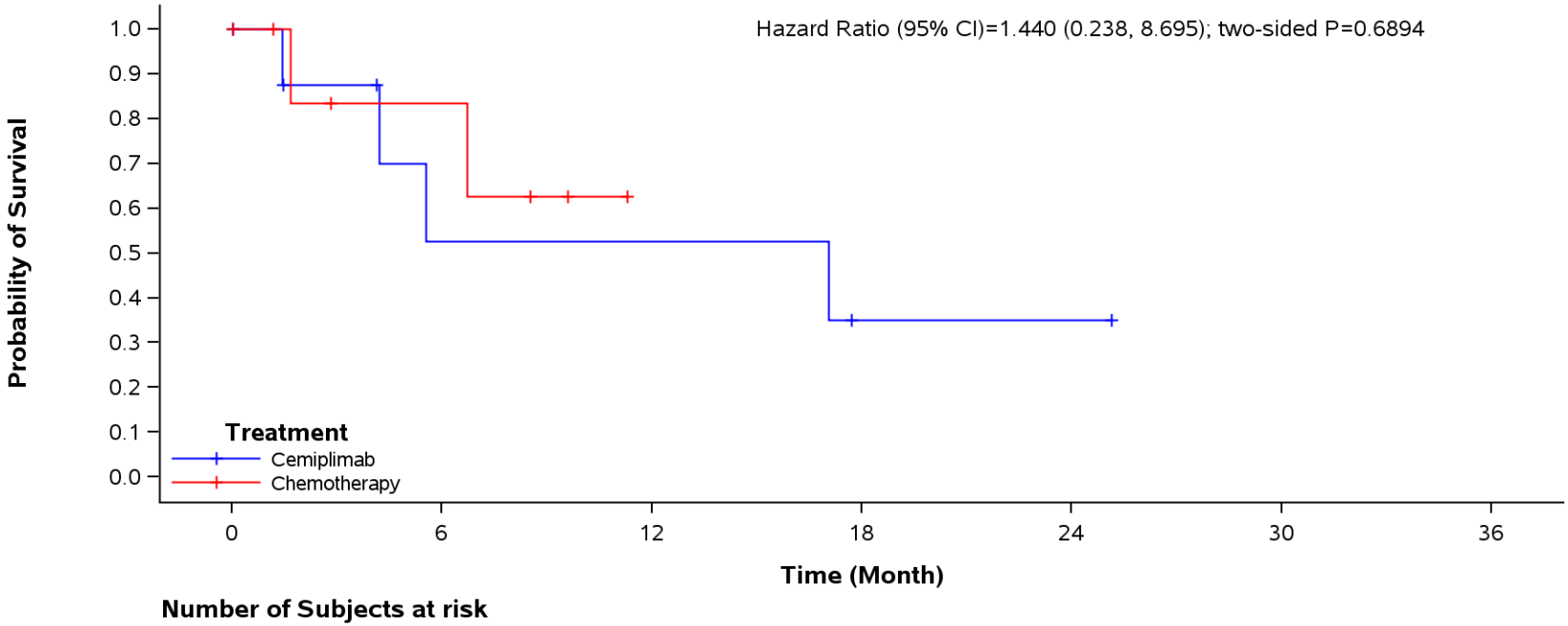

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts sustained improvement



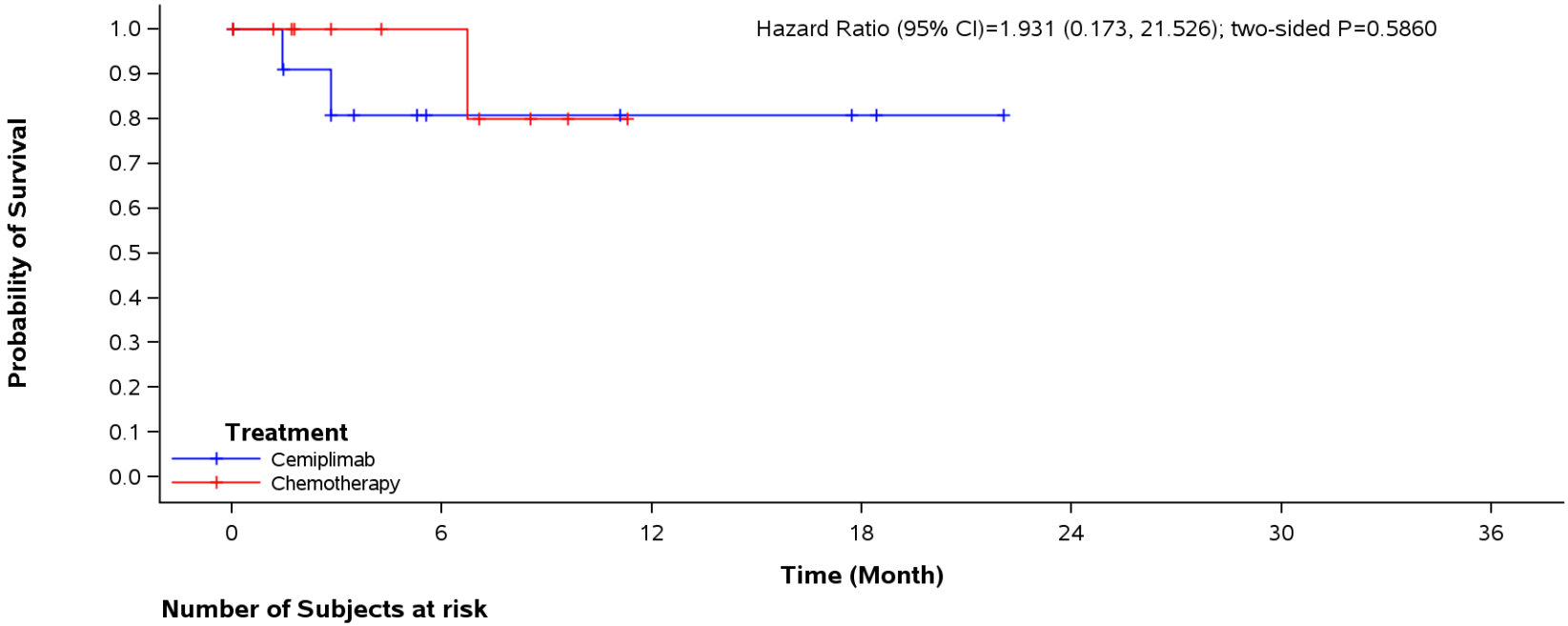

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts sustained improvement



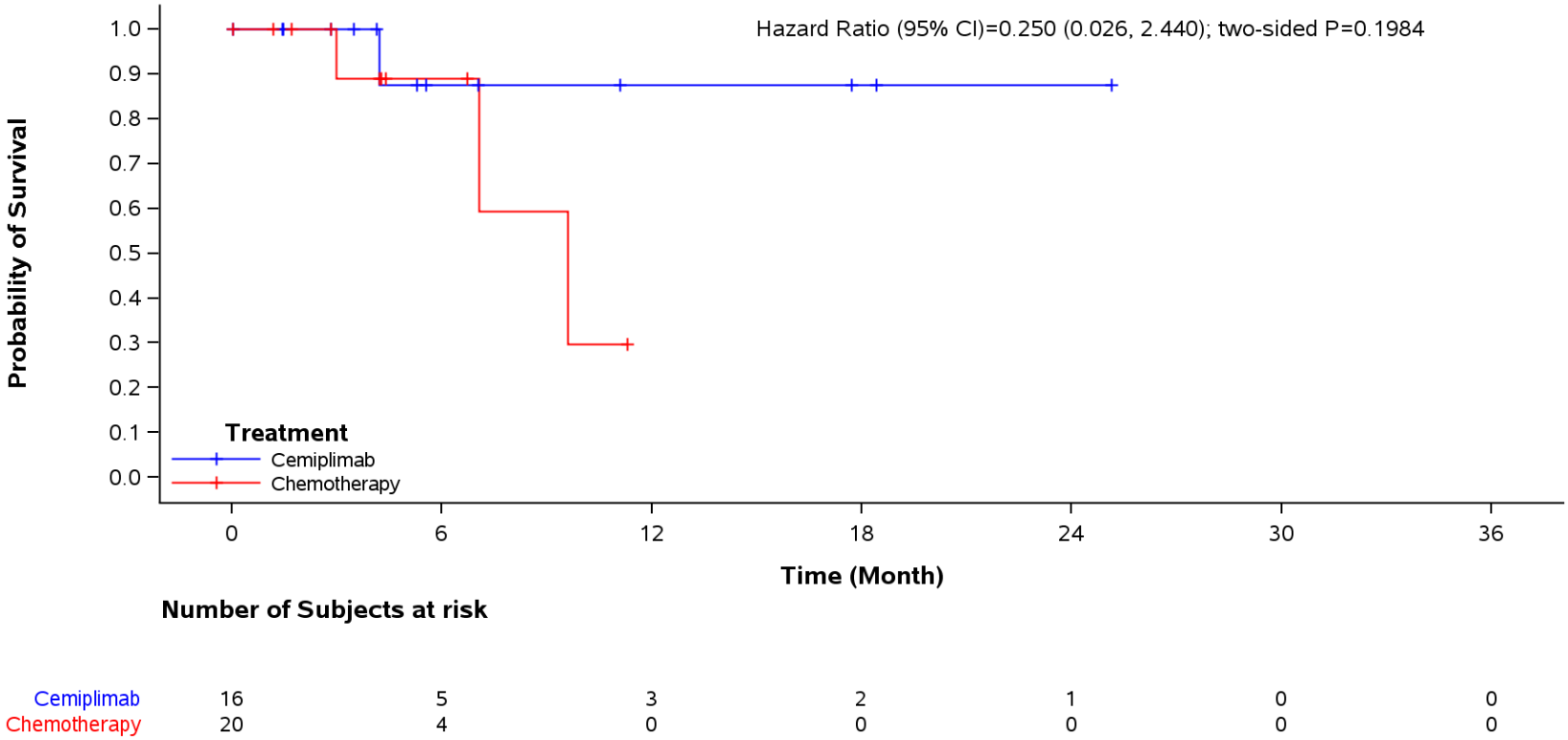

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 4 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 20 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

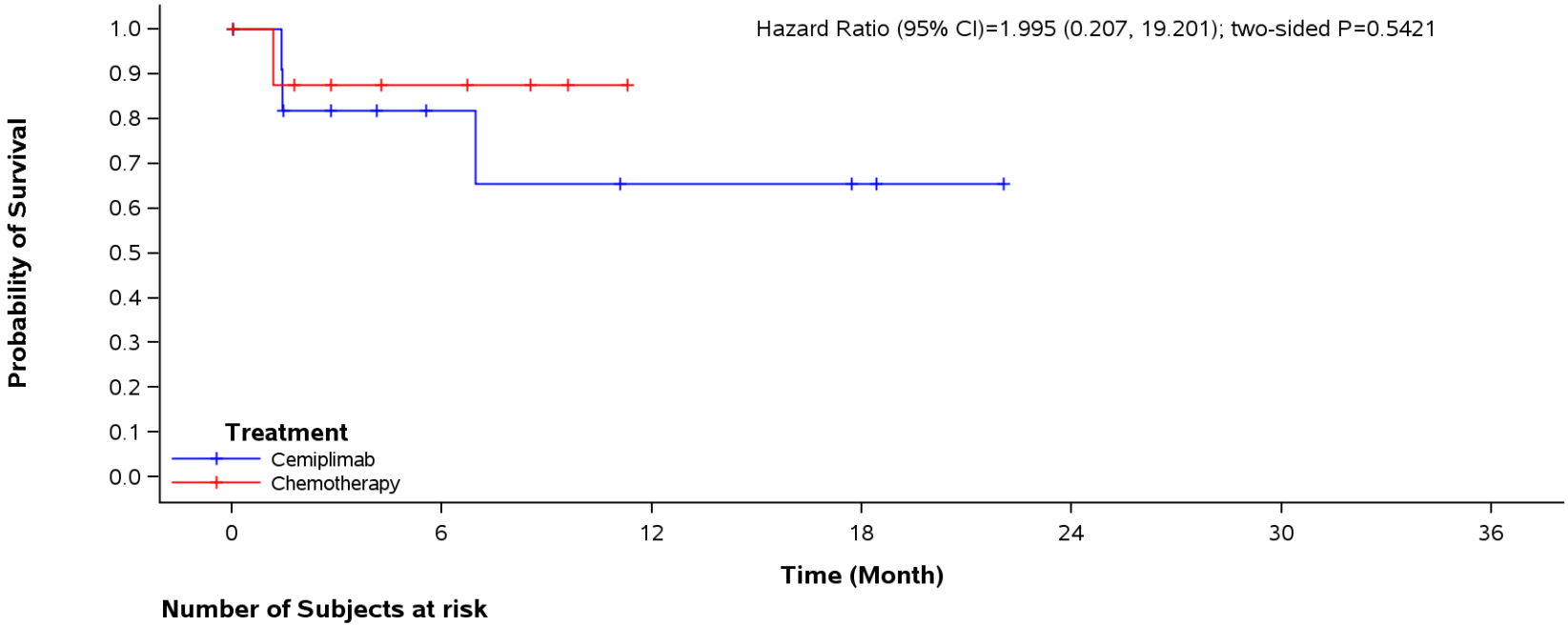
Age Group: >=65
Global health status / QoL - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts sustained improvement



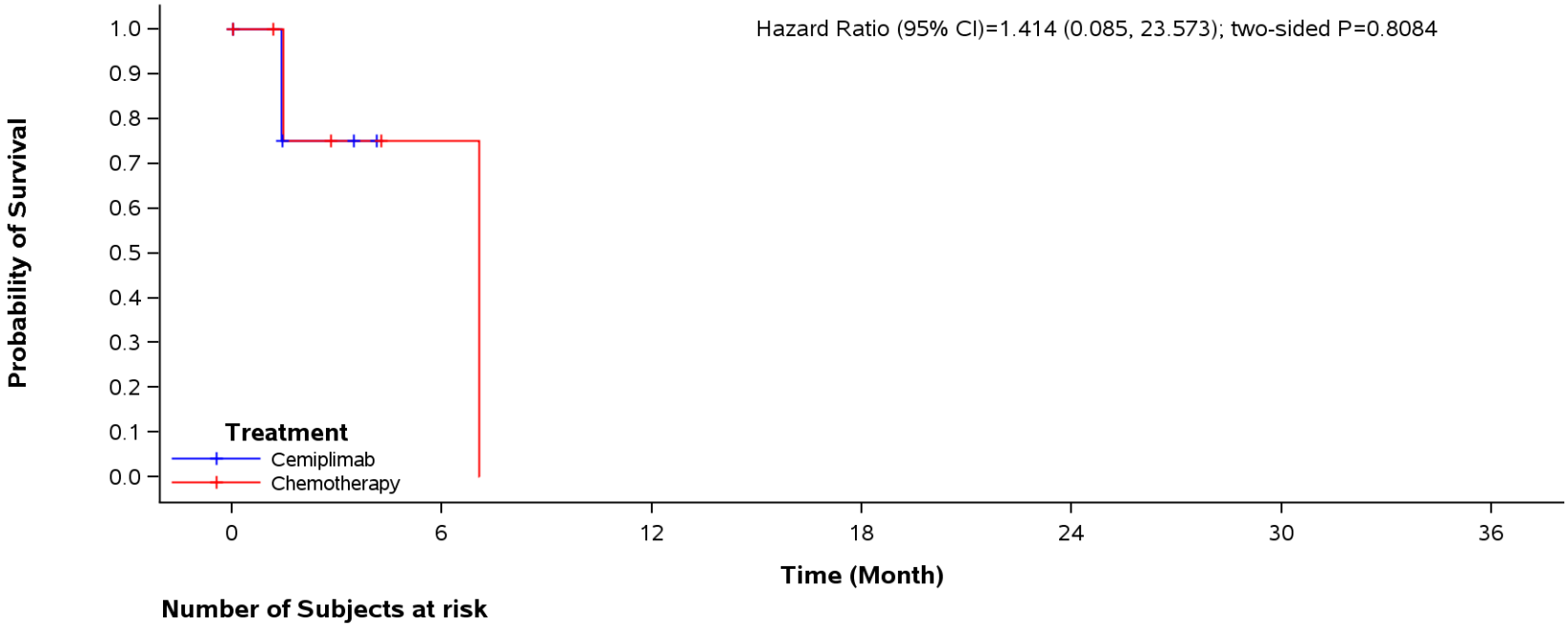

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts sustained improvement



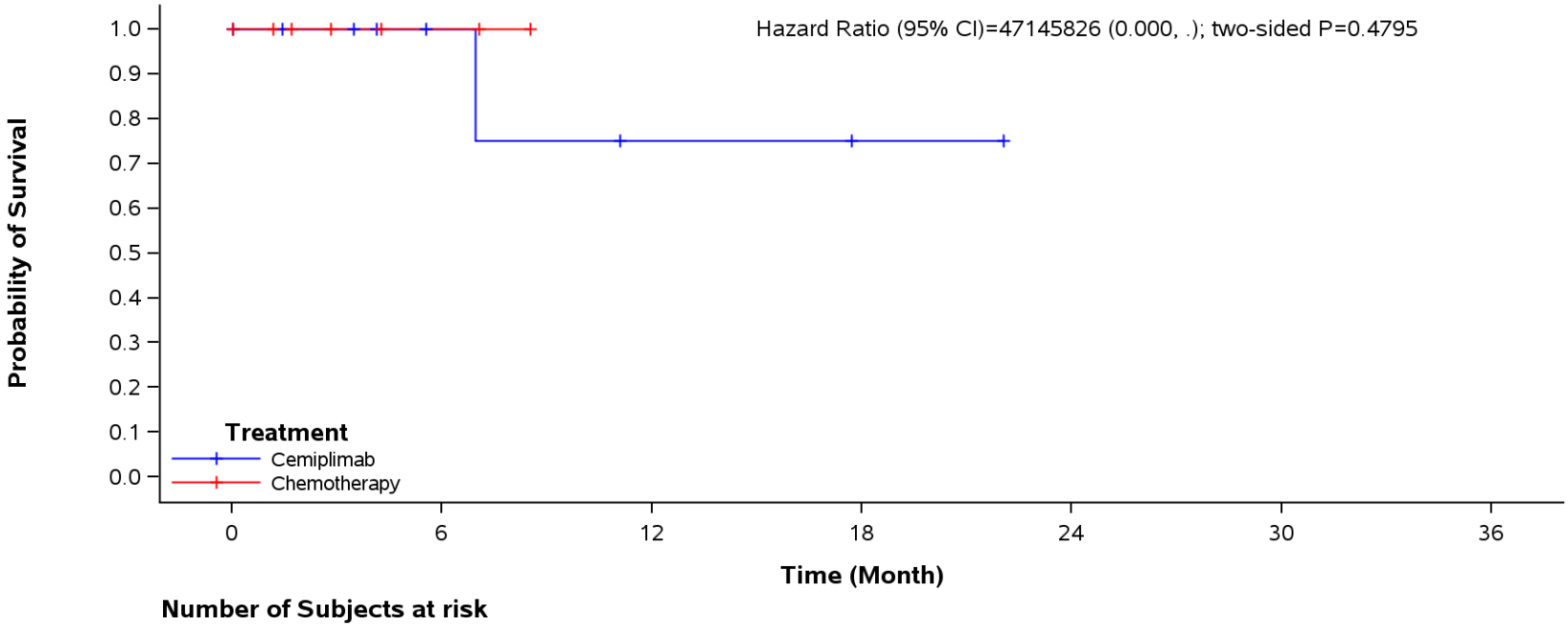

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts sustained improvement



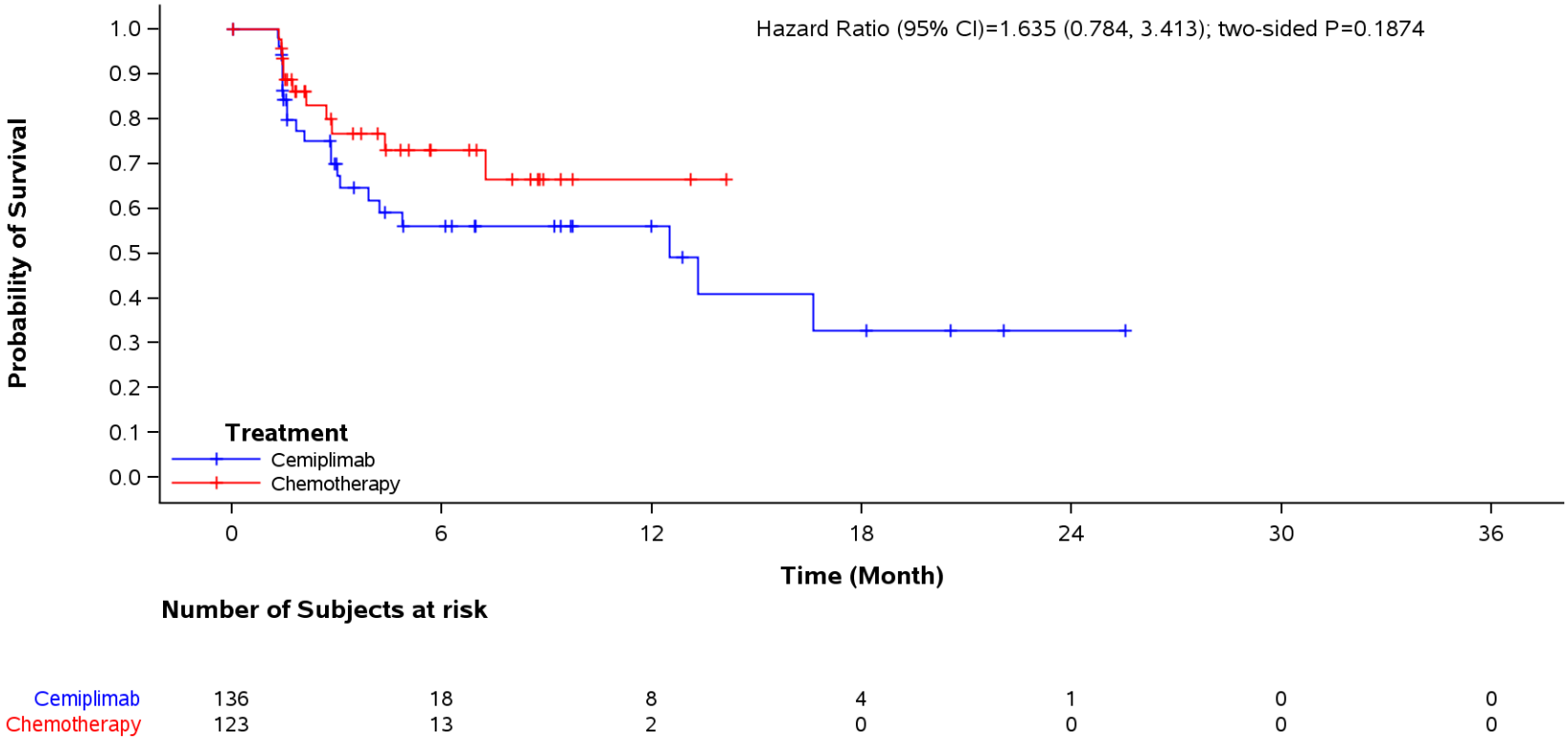

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Appetite loss - 10 pts sustained improvement



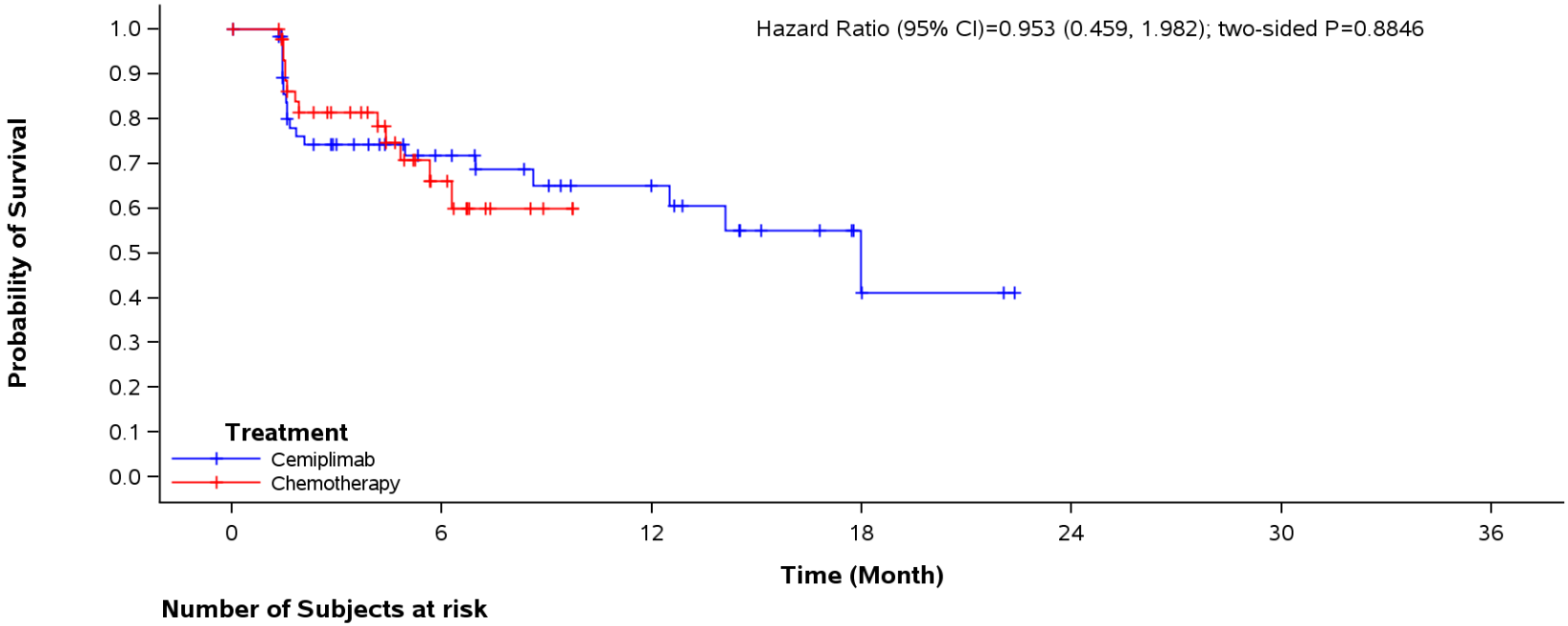

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 18 | 8 | 4 | 1 | 0 | 0 |
| Chemotherapy | 123 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Cognitive Functioning - 10 pts sustained improvement



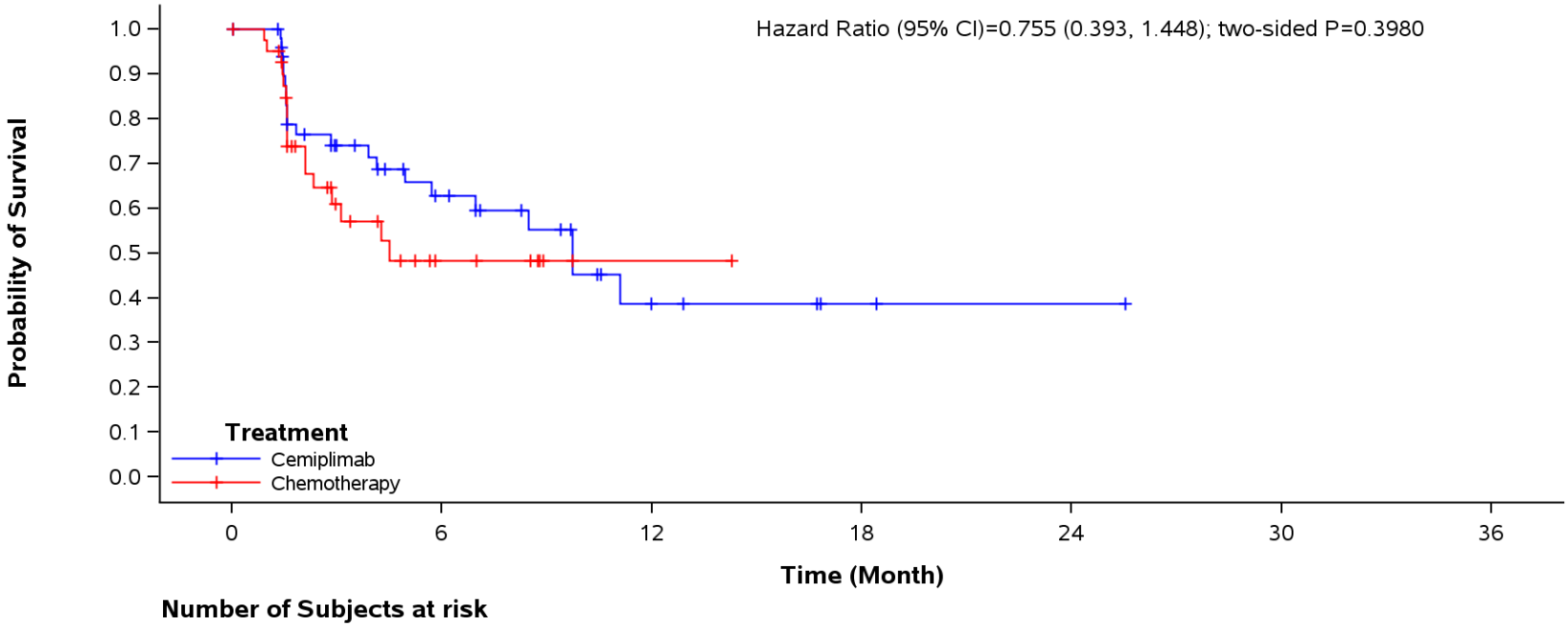

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 26 | 14 | 3 | 0 | 0 | 0 |
| Chemotherapy | 123 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts sustained improvement



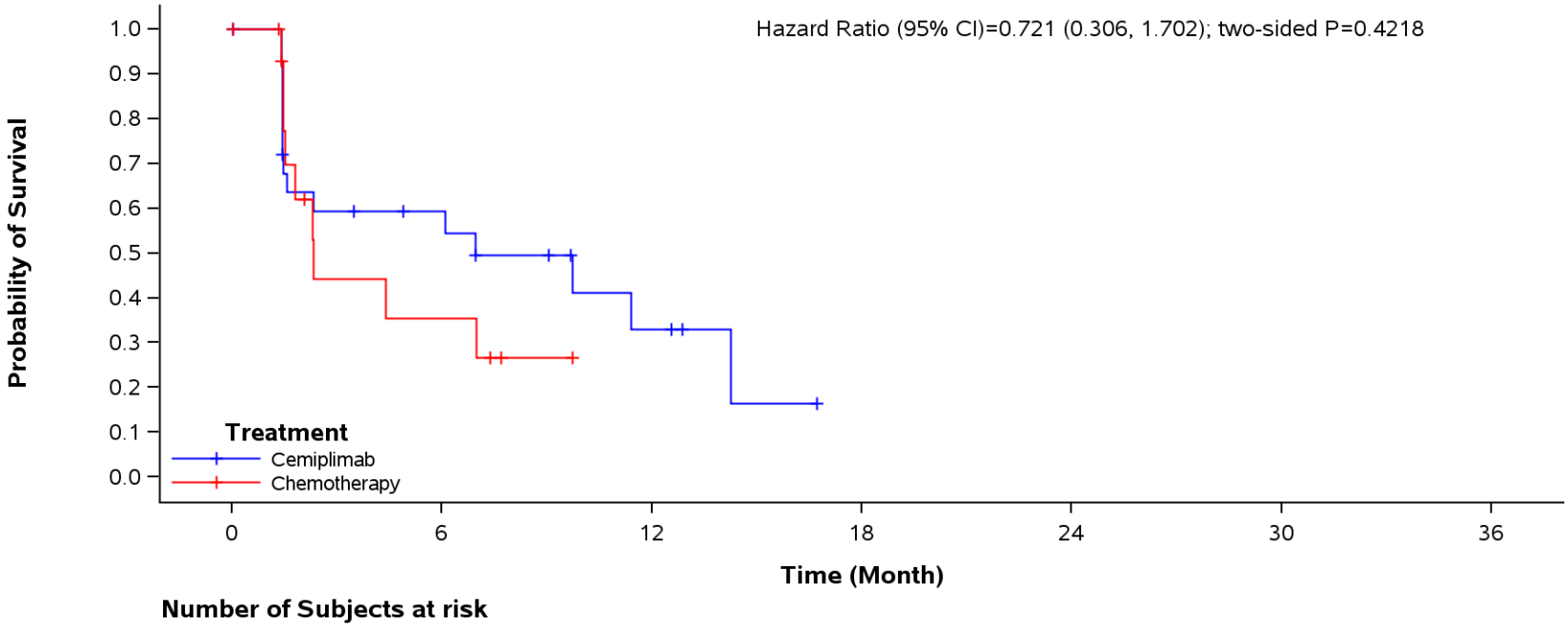

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 20 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 123 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts sustained improvement



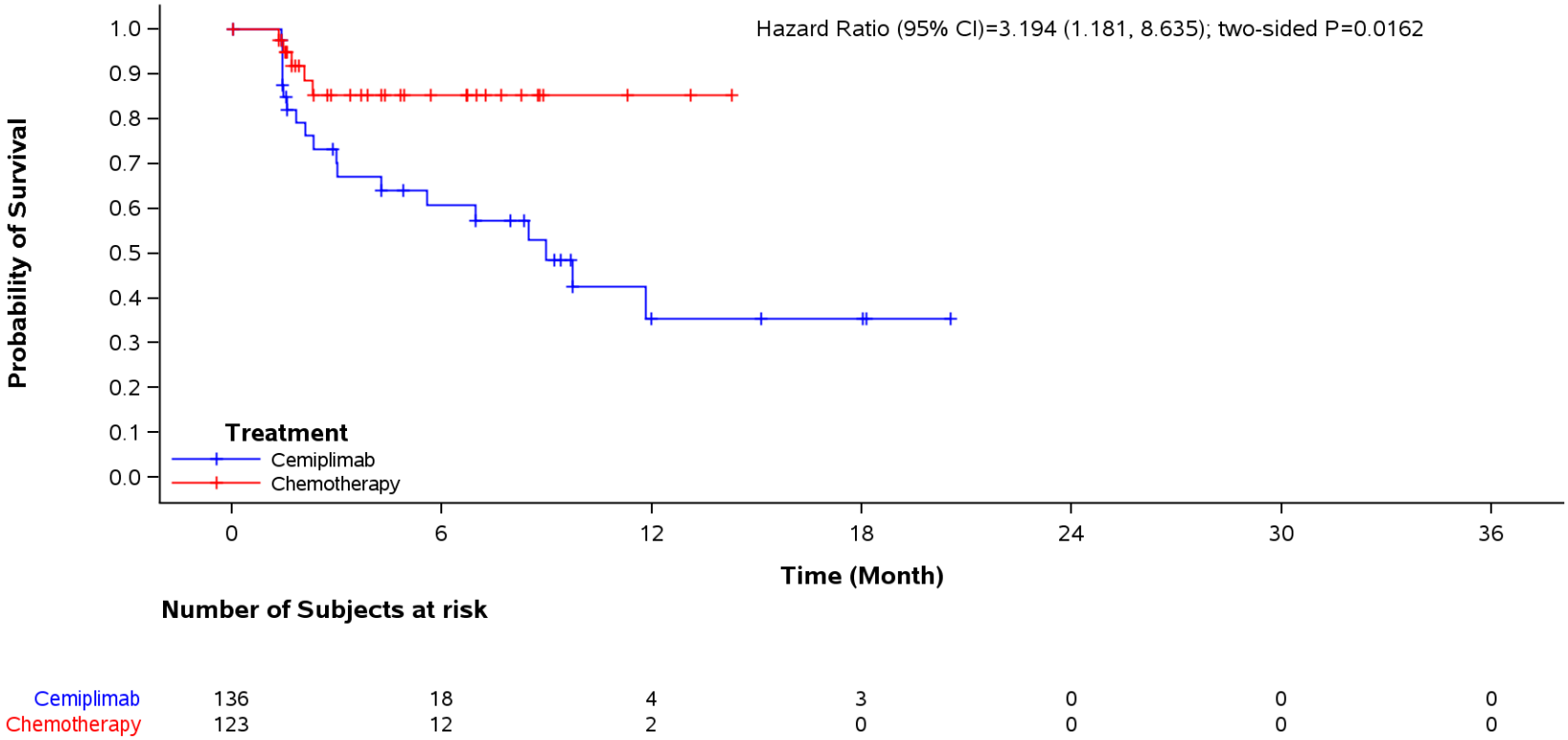

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 12 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 123 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts sustained improvement



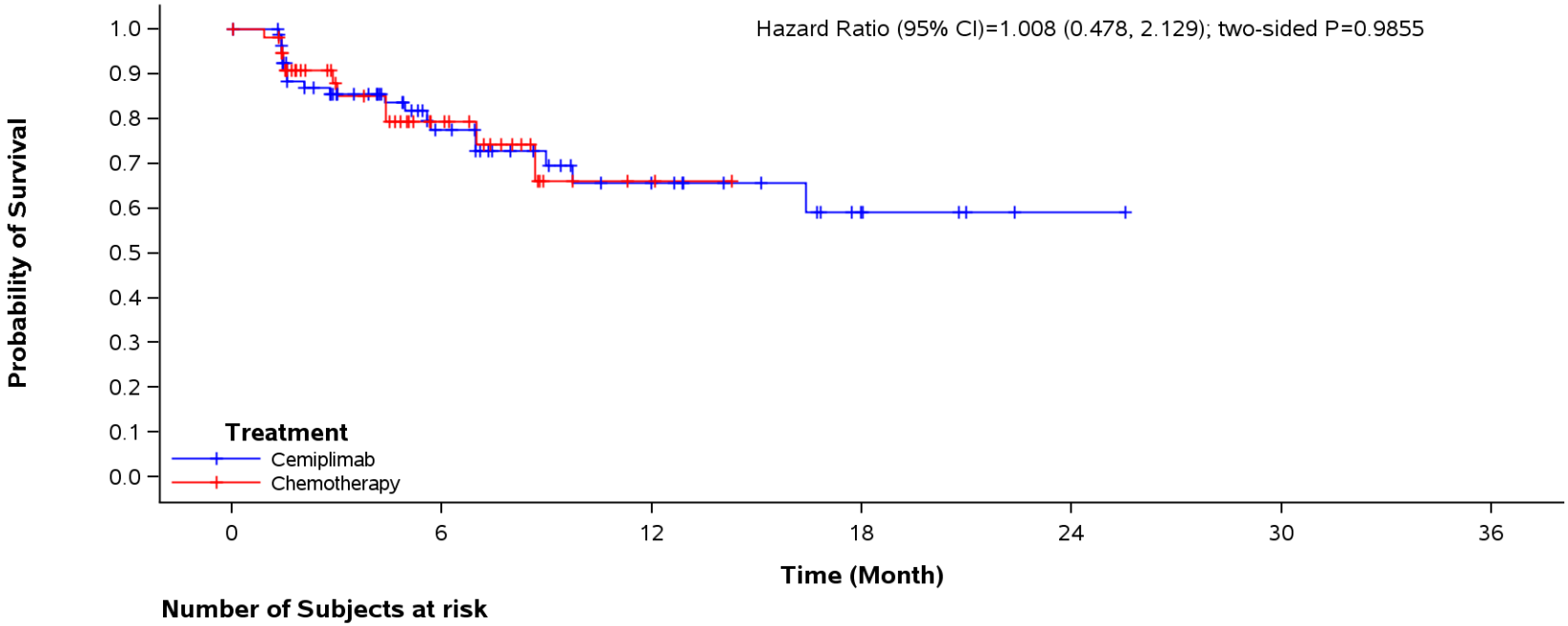

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 18 | 4 | 3 | 0 | 0 | 0 |
| Chemotherapy | 123 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts sustained improvement



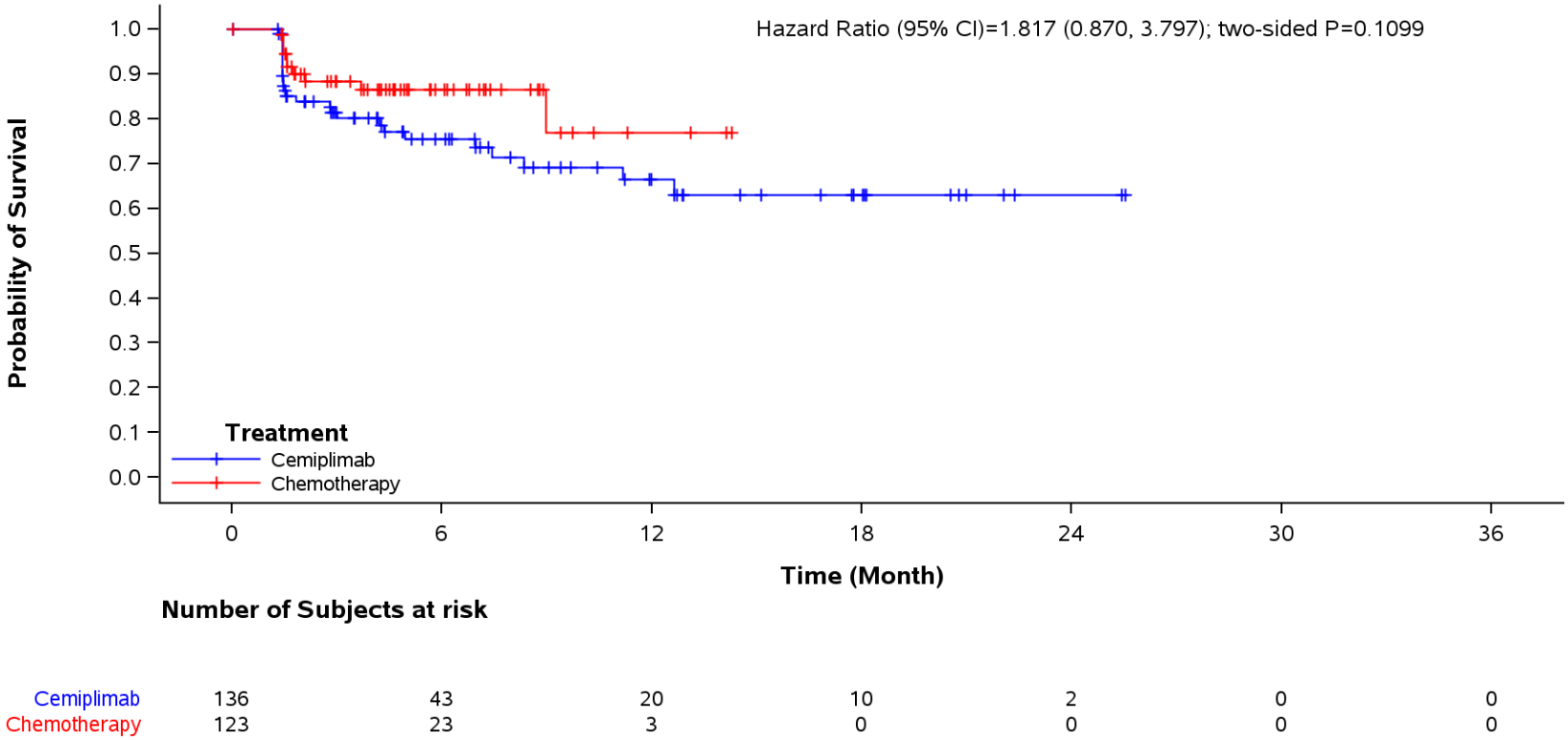

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 35 | 15 | 5 | 1 | 0 | 0 |
| Chemotherapy | 123 | 19 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

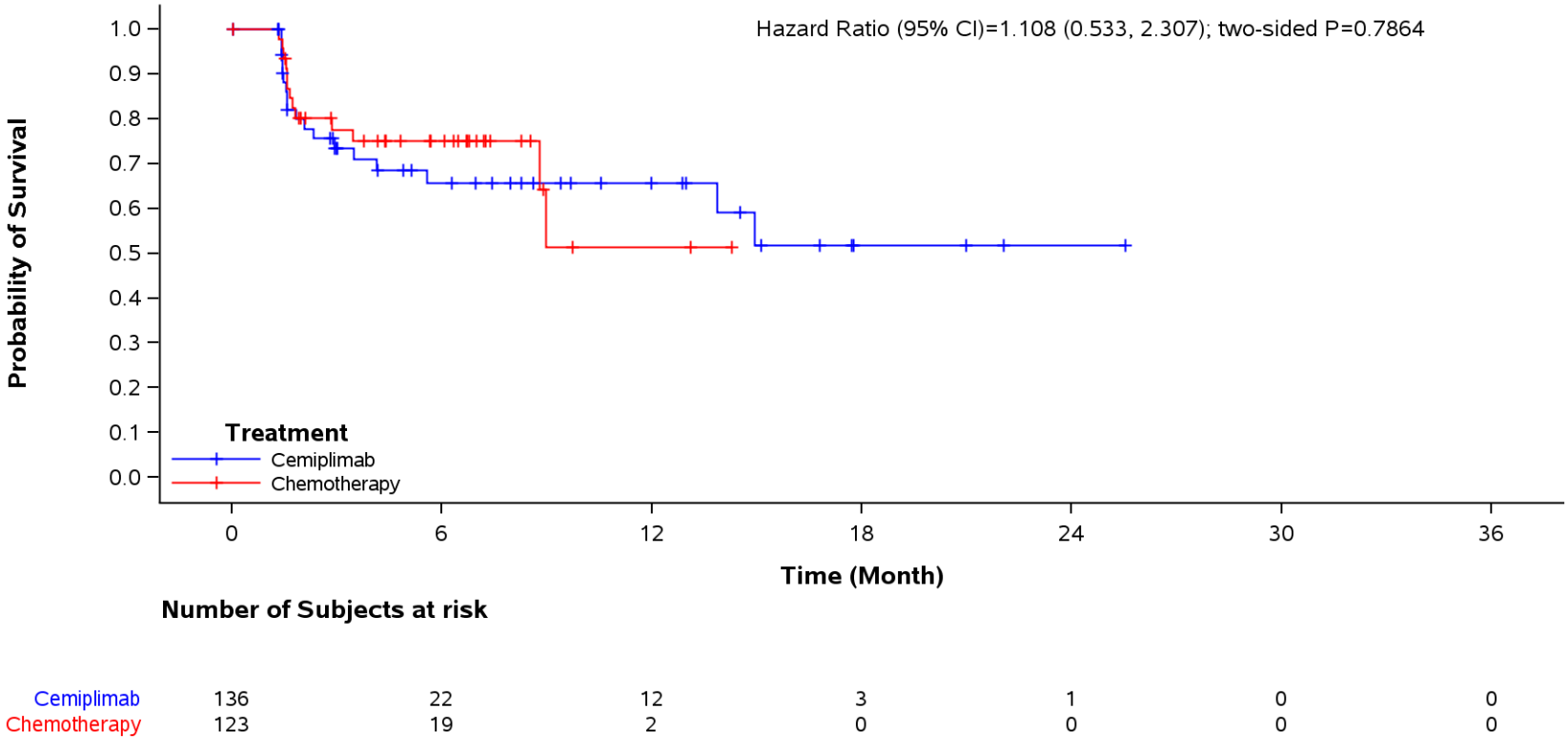
Race: White
Fatigue - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

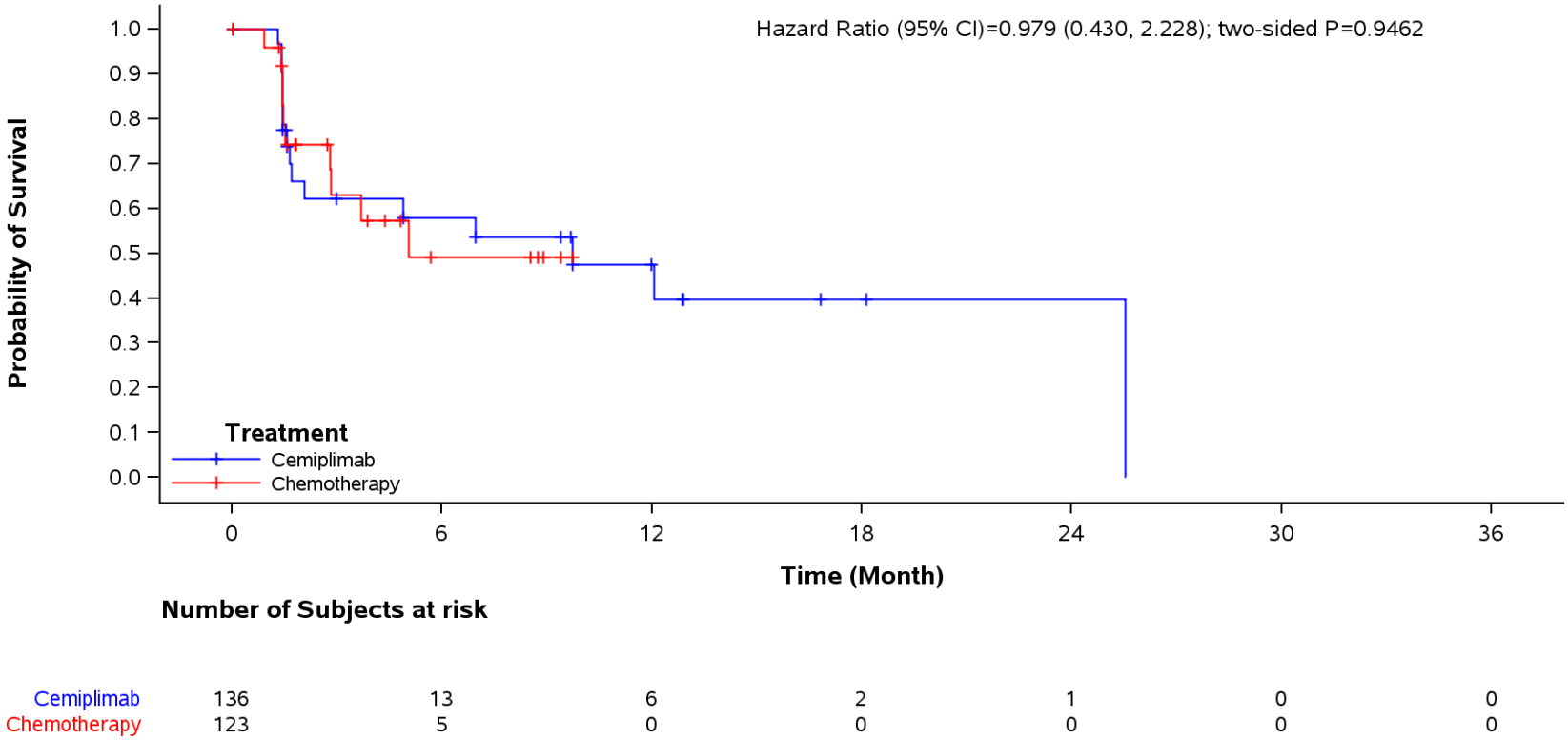
Race: White
Financial Problems - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

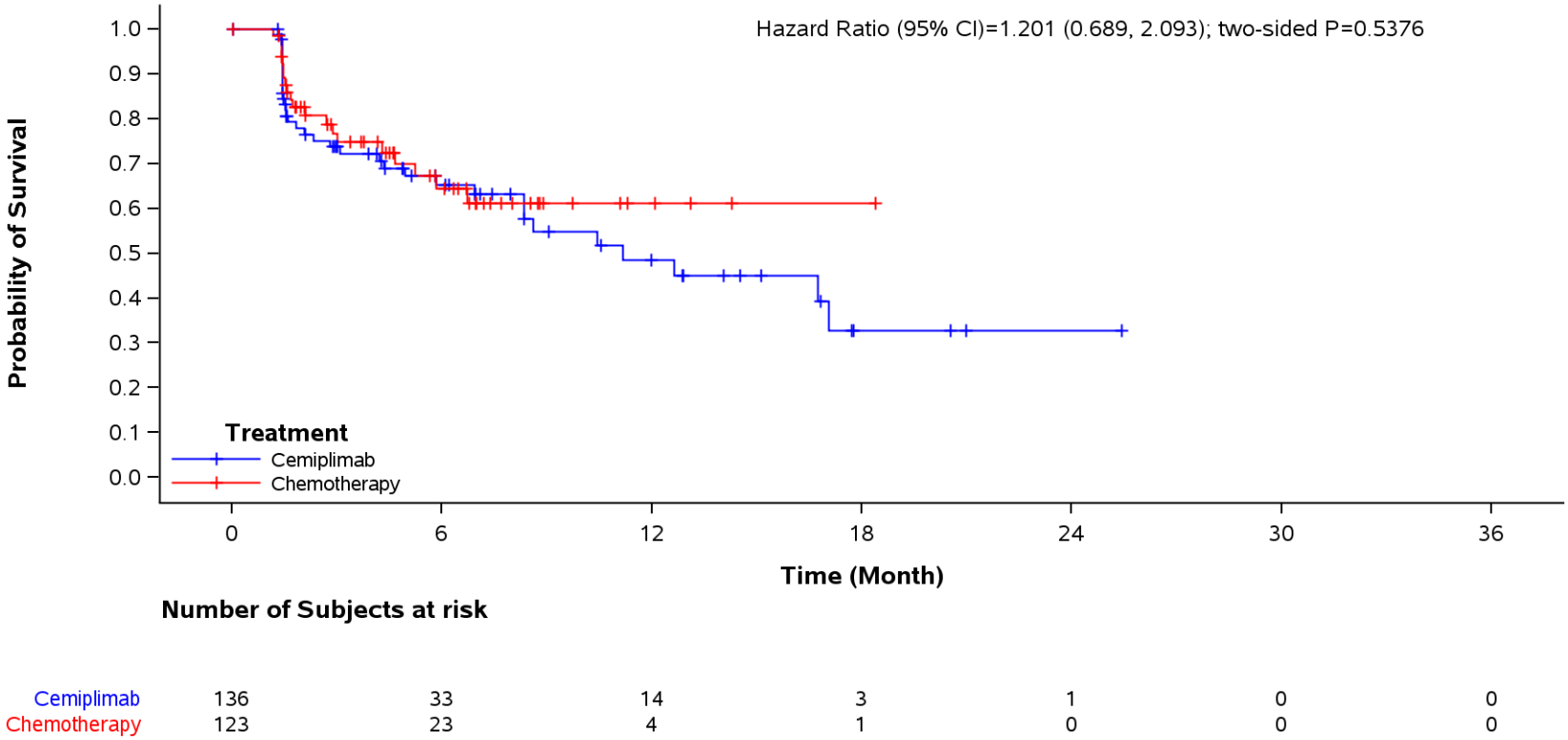
Race: White
Nausea / Vomiting - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts sustained improvement



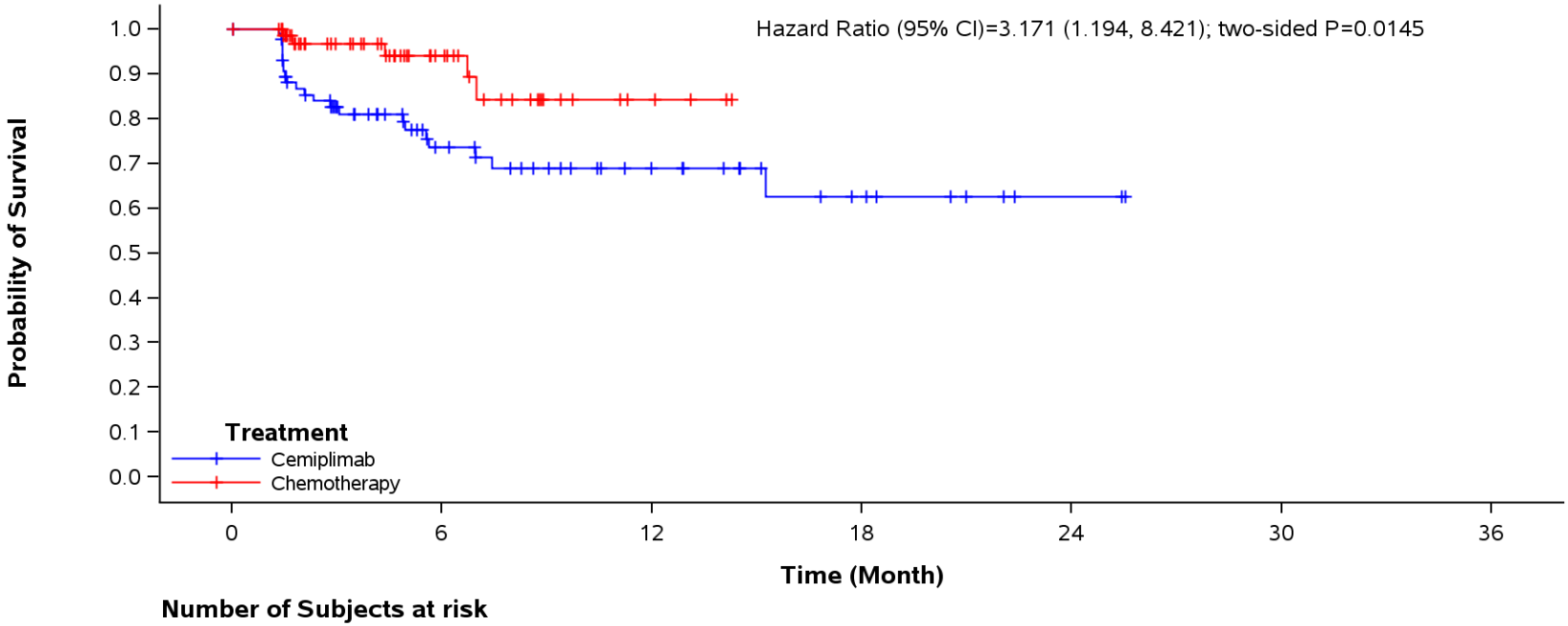

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 33 | 14 | 3 | 1 | 0 | 0 |
| Chemotherapy | 123 | 23 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts sustained improvement



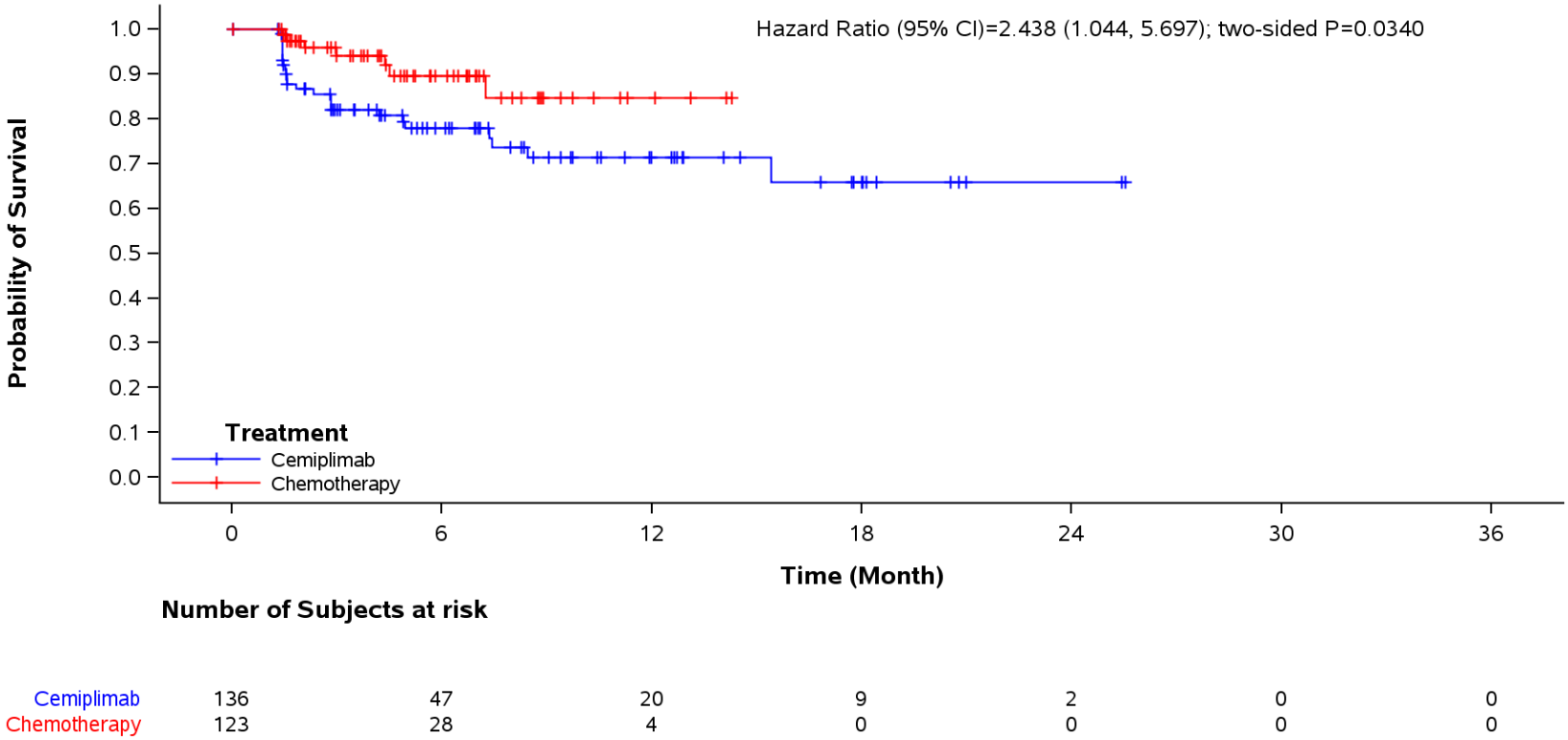

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 35 | 17 | 8 | 2 | 0 | 0 |
| Chemotherapy | 123 | 24 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts sustained improvement



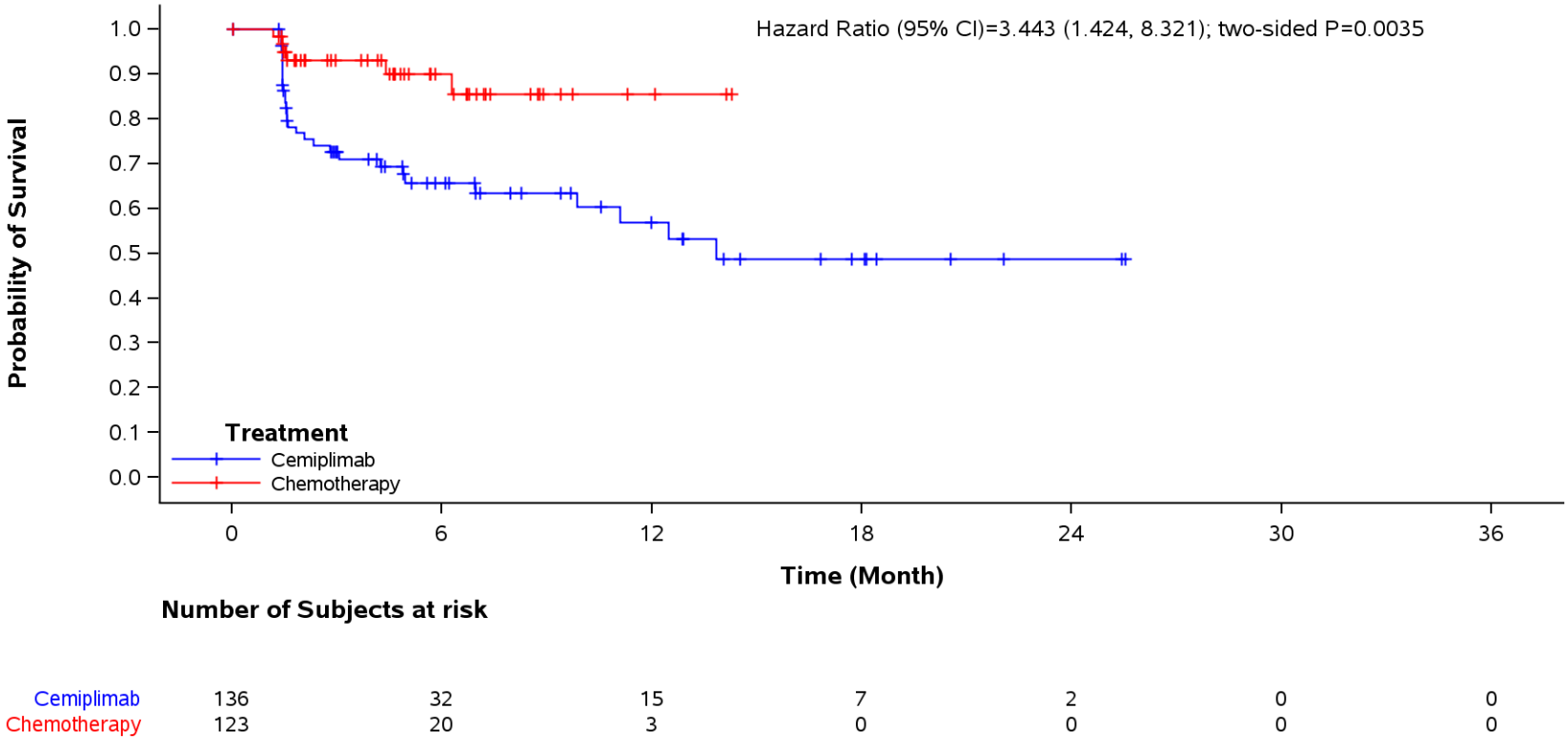

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 47 | 20 | 9 | 2 | 0 | 0 |
| Chemotherapy | 123 | 28 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts sustained improvement



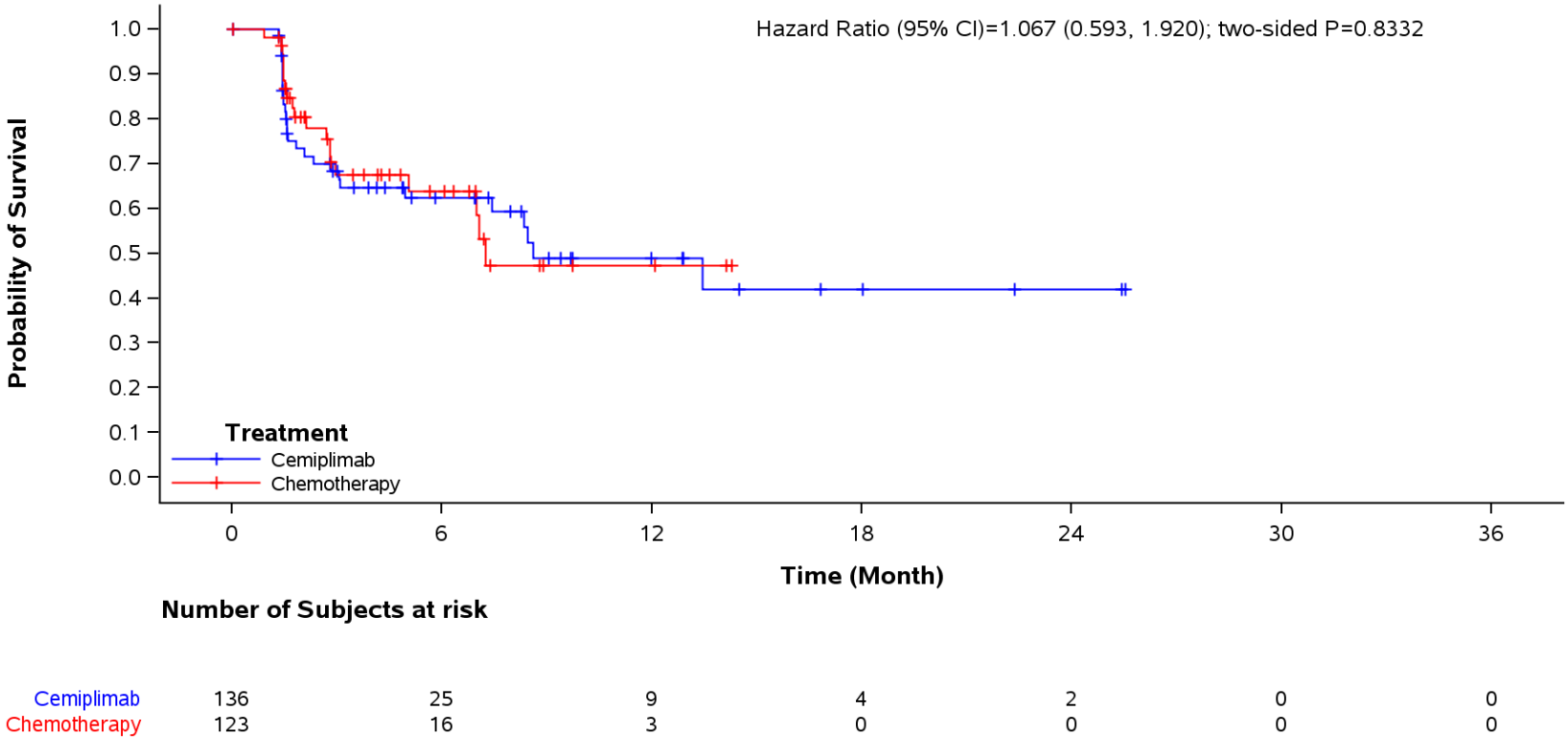

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 32 | 15 | 7 | 2 | 0 | 0 |
| Chemotherapy | 123 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

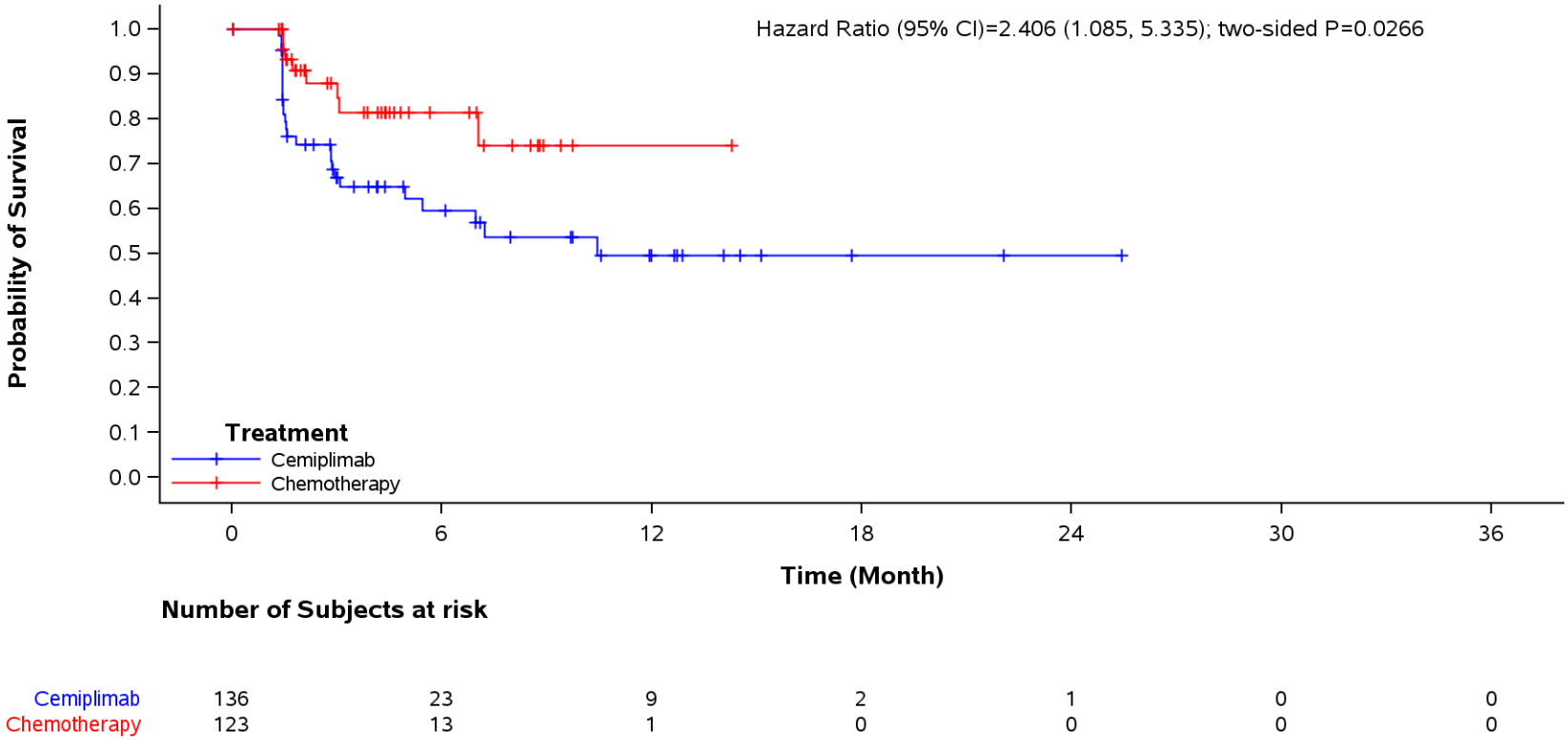
Race: White
Social Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts sustained improvement



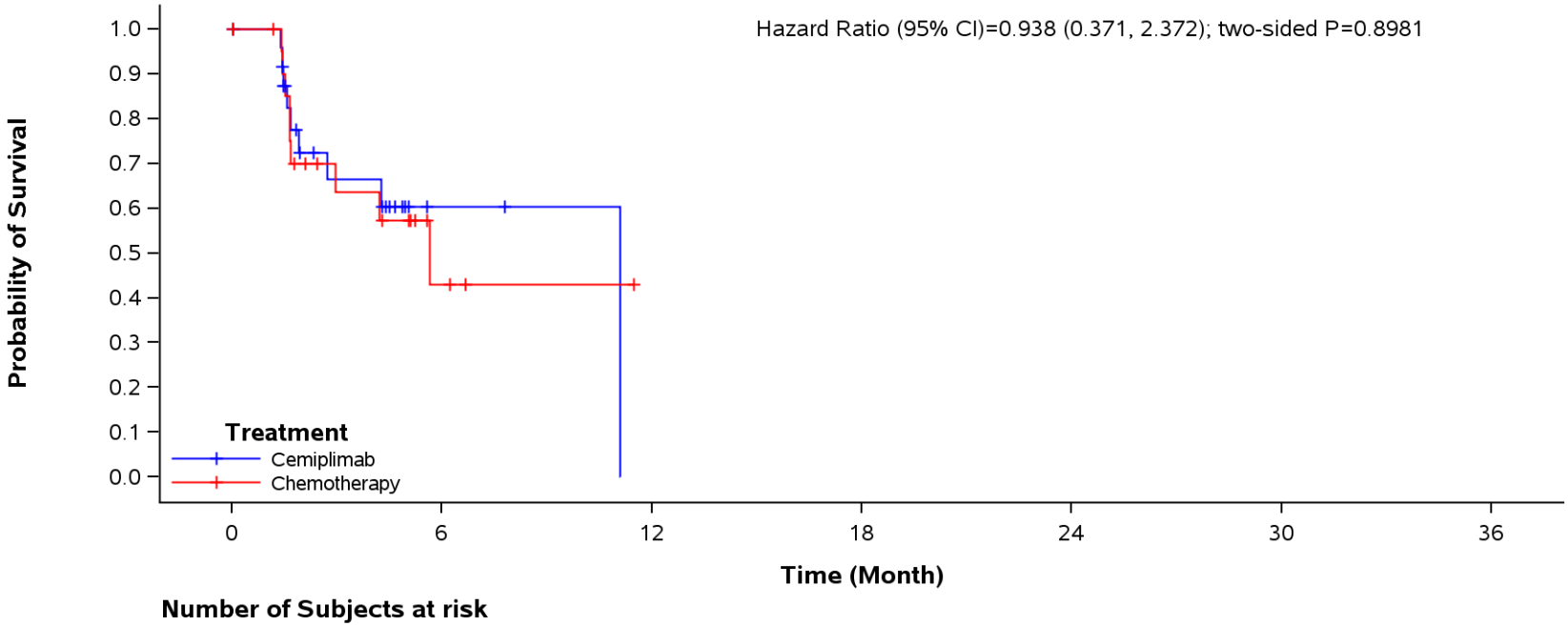

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 23 | 9 | 2 | 1 | 0 | 0 |
| Chemotherapy | 123 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts sustained improvement



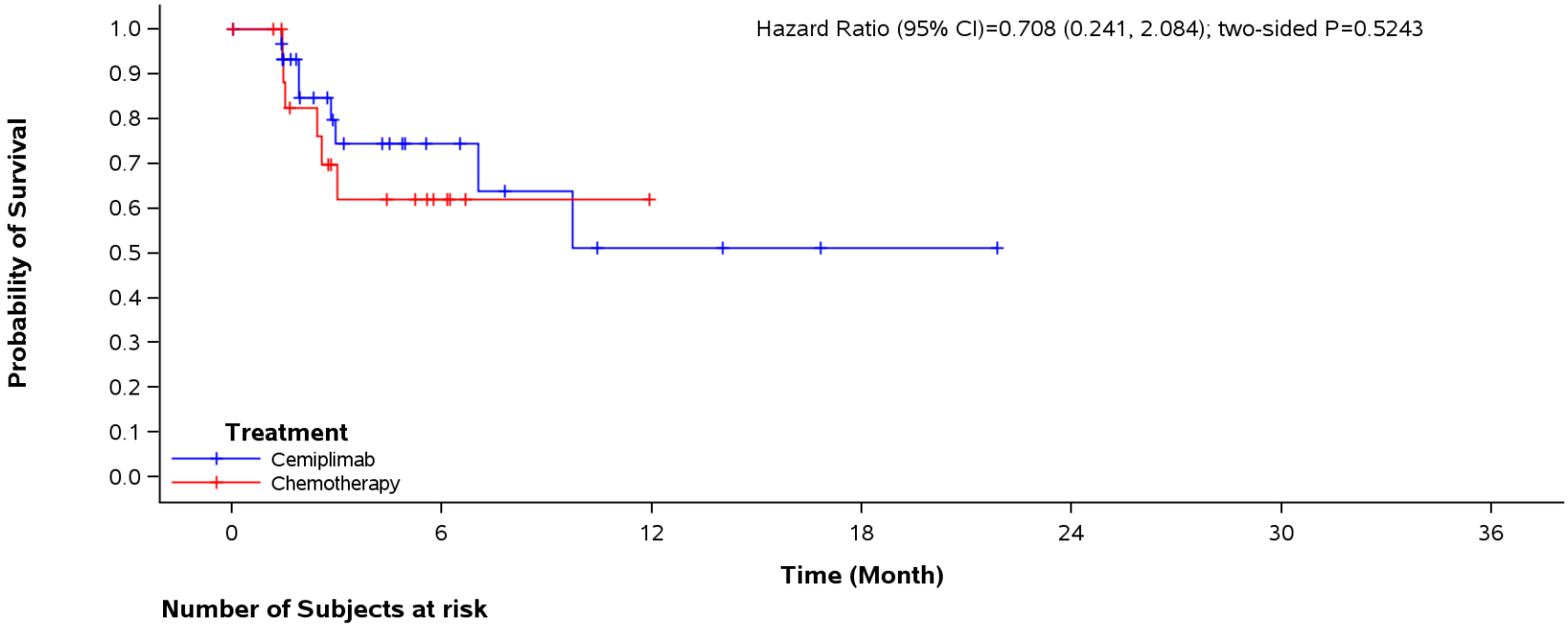

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts sustained improvement



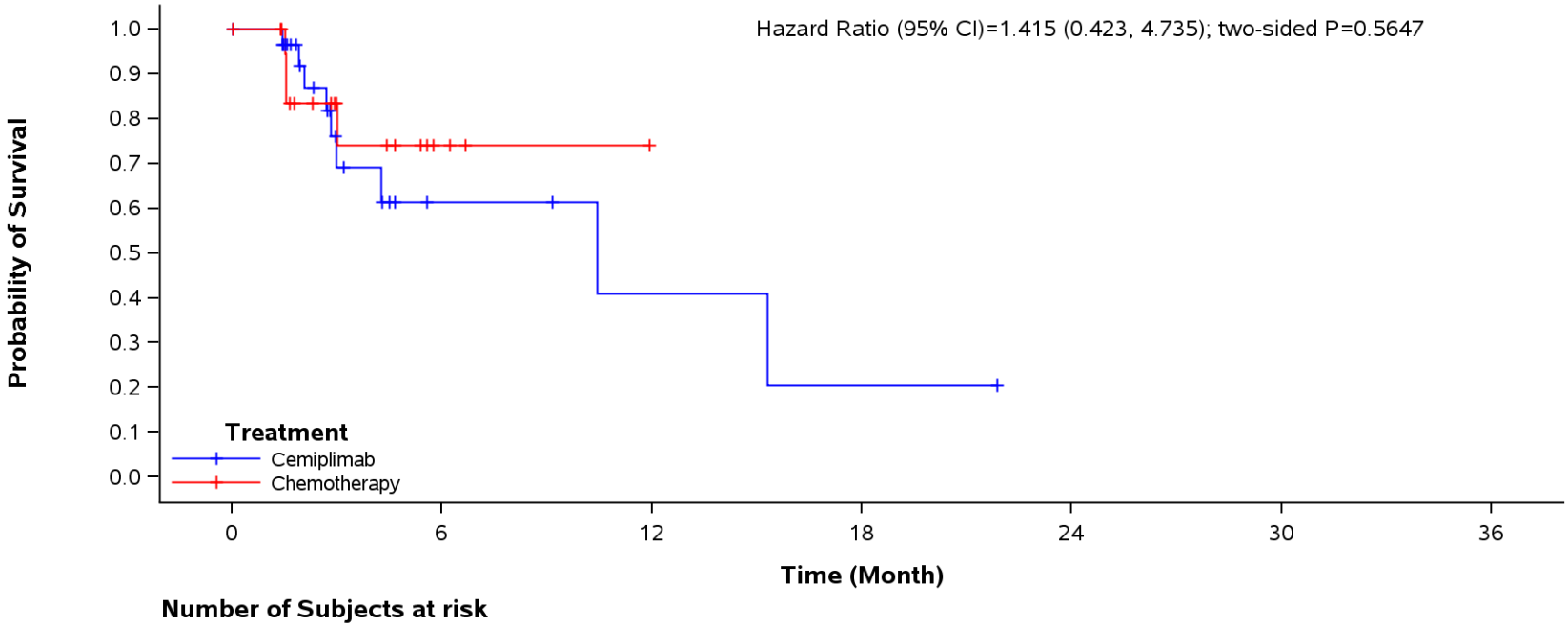

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 8 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts sustained improvement



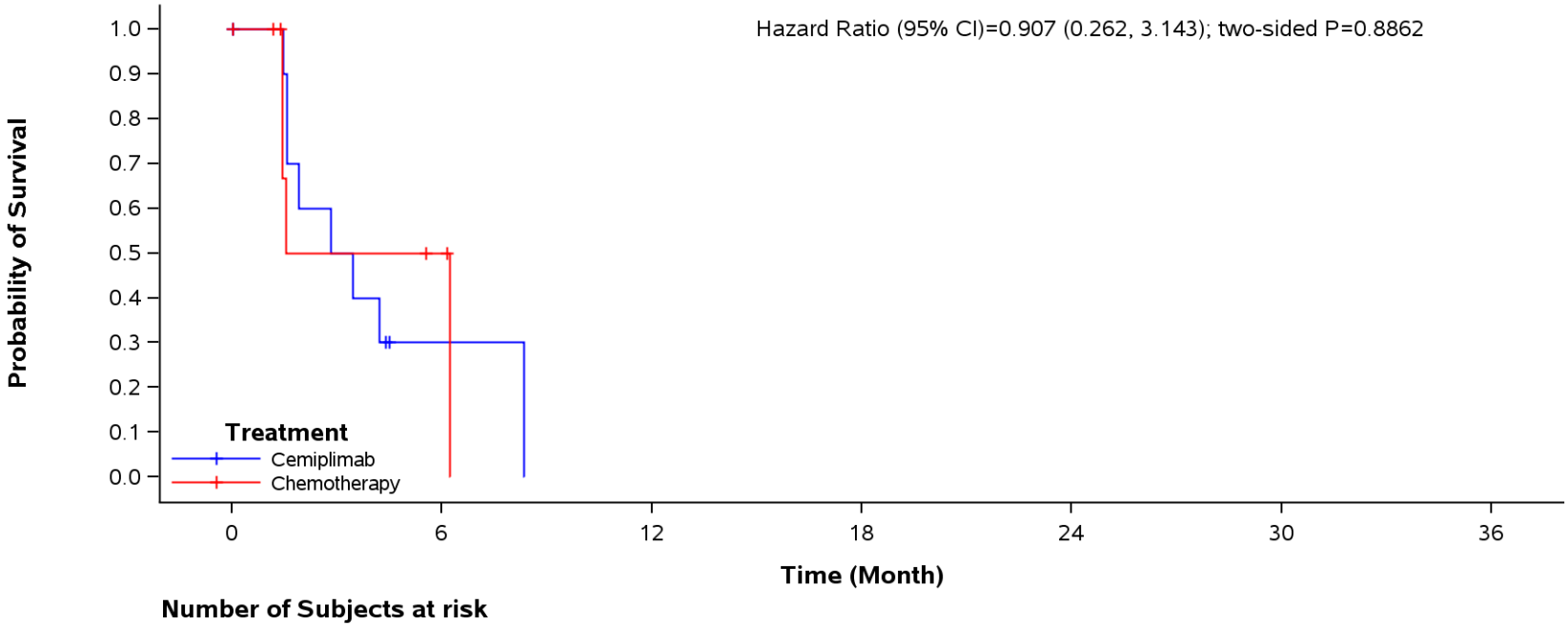

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts sustained improvement



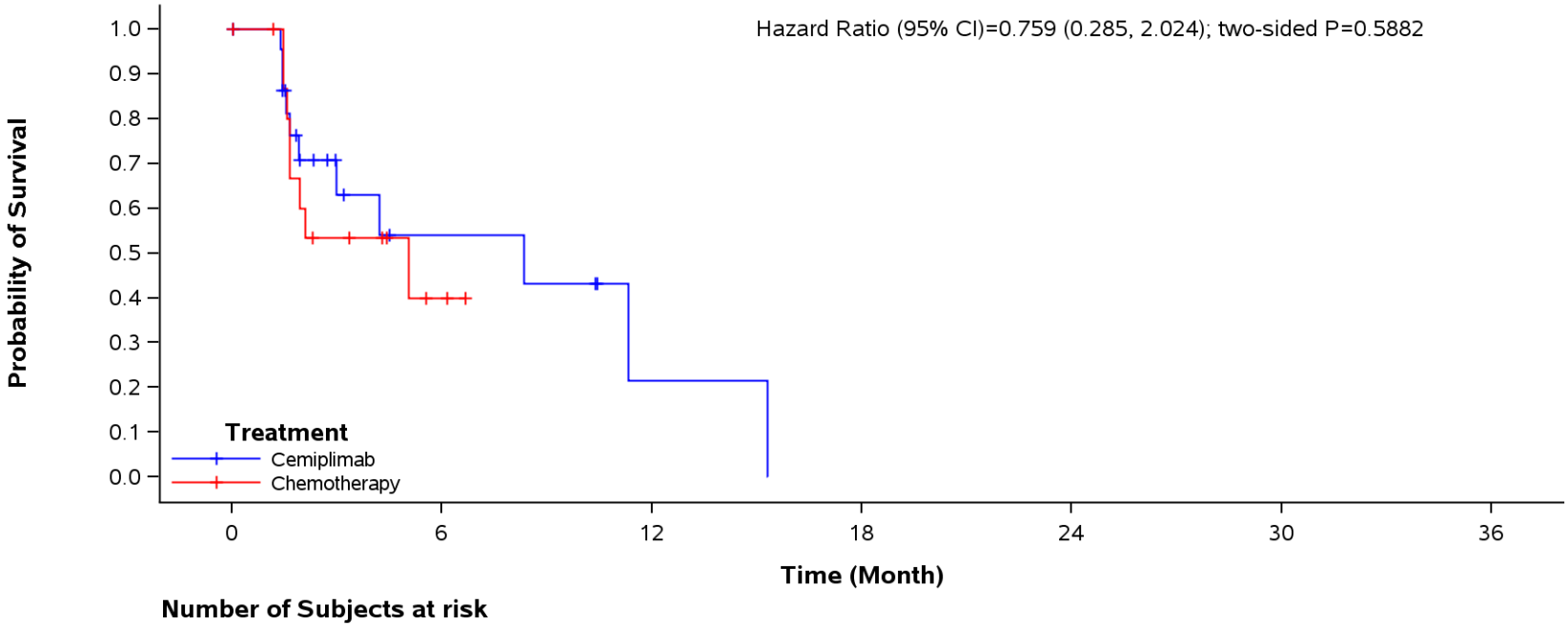

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts sustained improvement



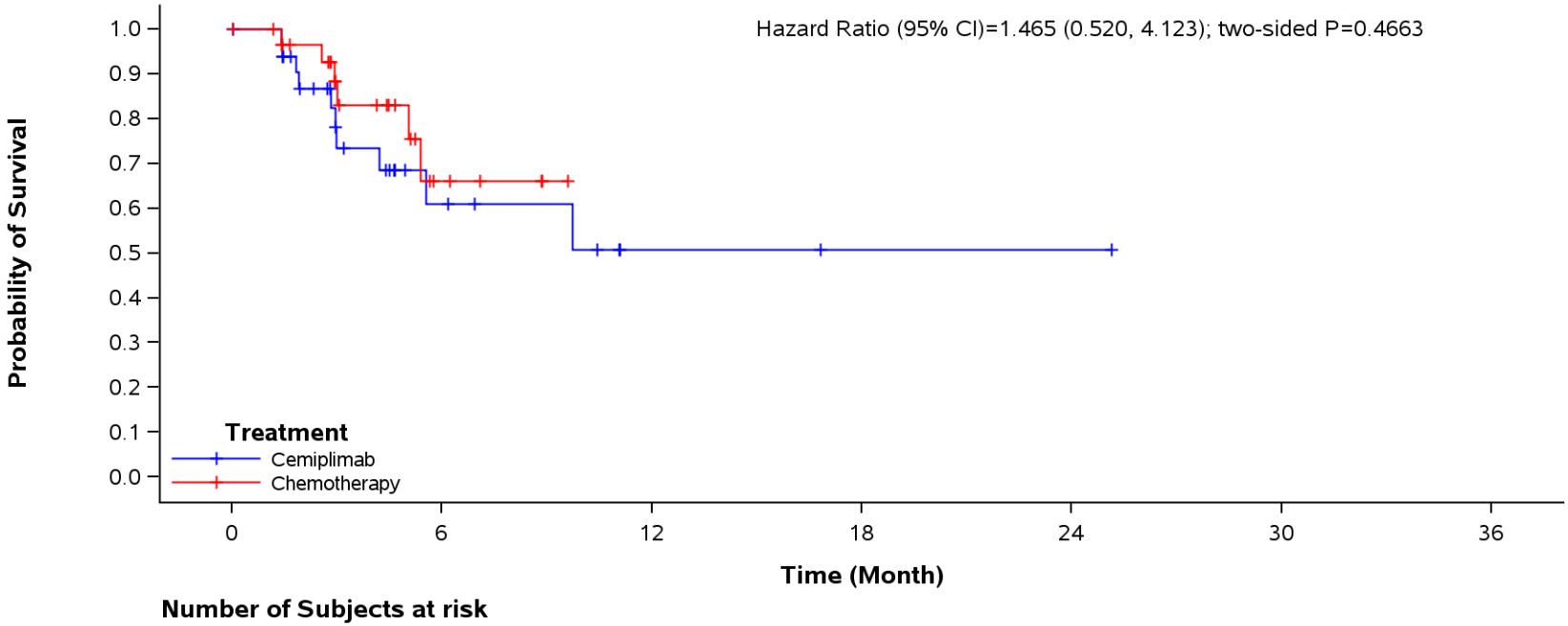

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts sustained improvement



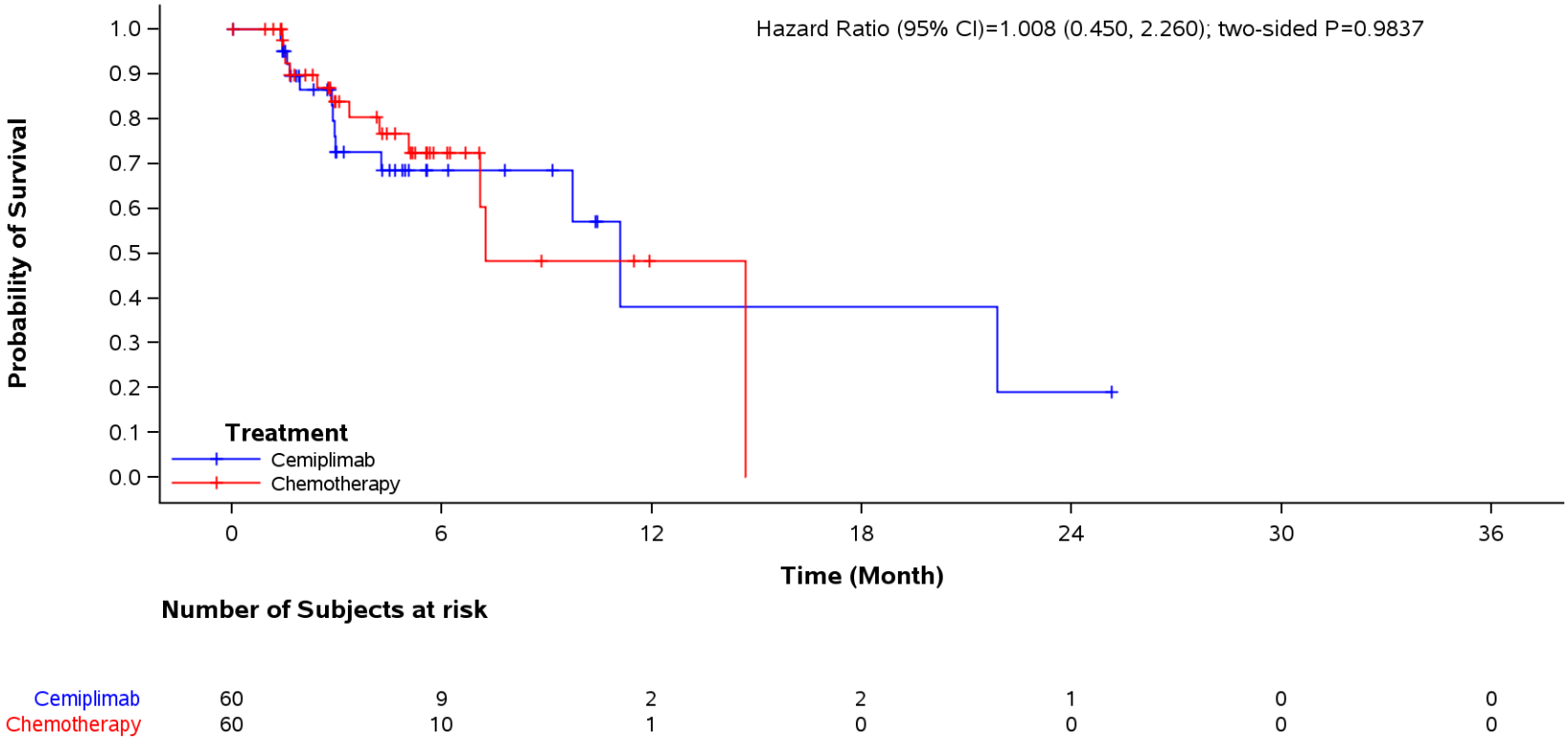

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 8 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 60 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts sustained improvement



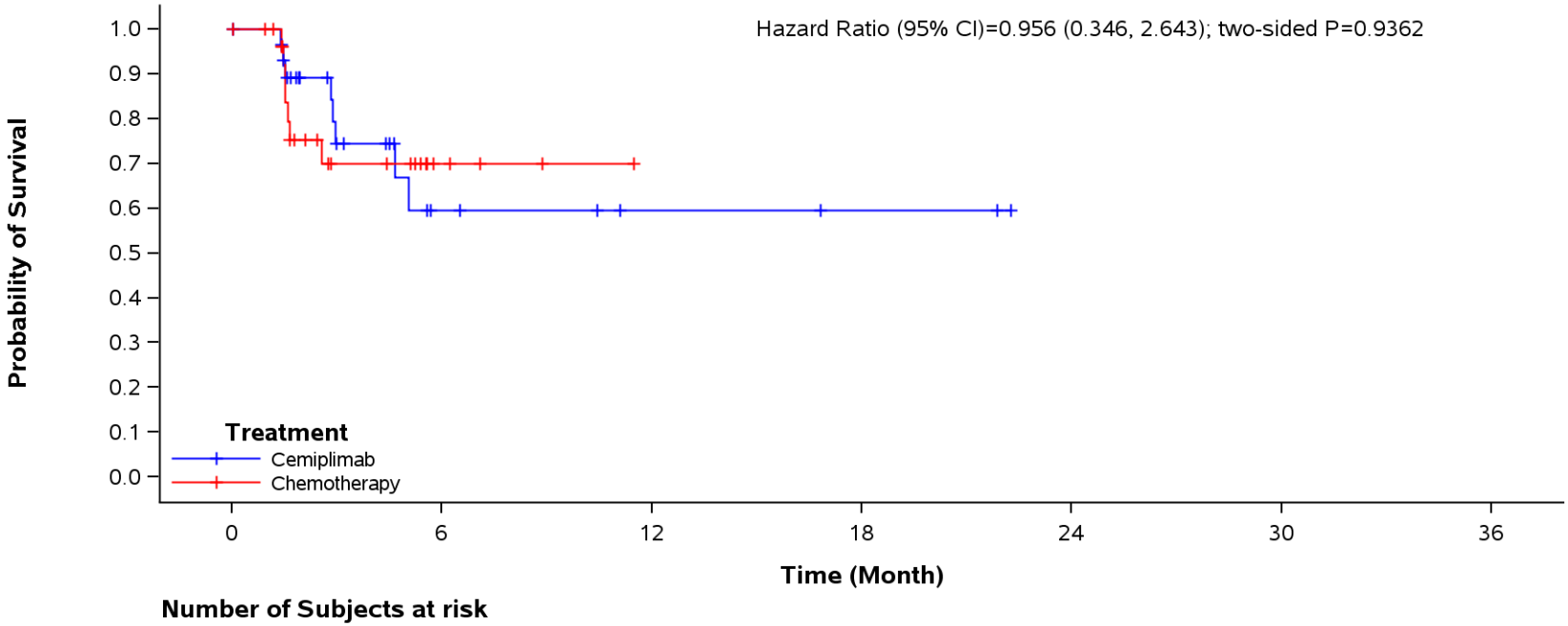

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 9 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts sustained improvement



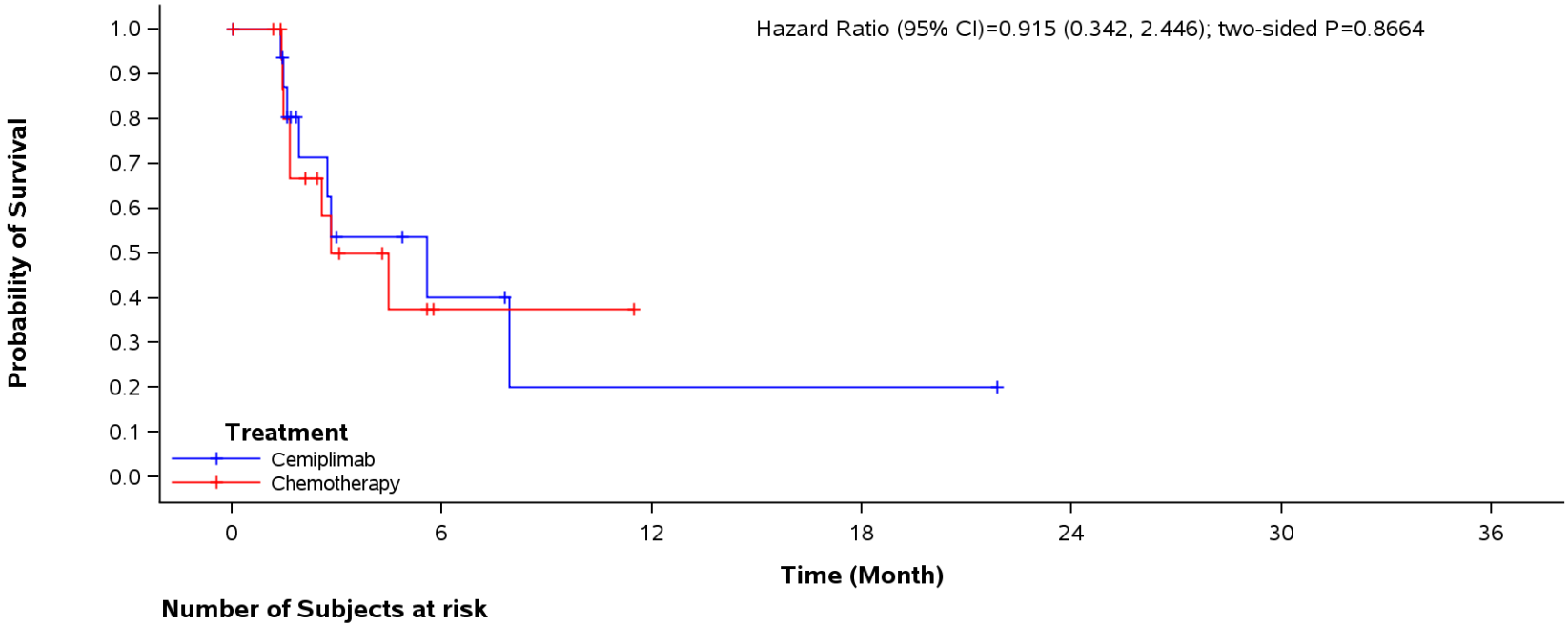

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 6 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts sustained improvement



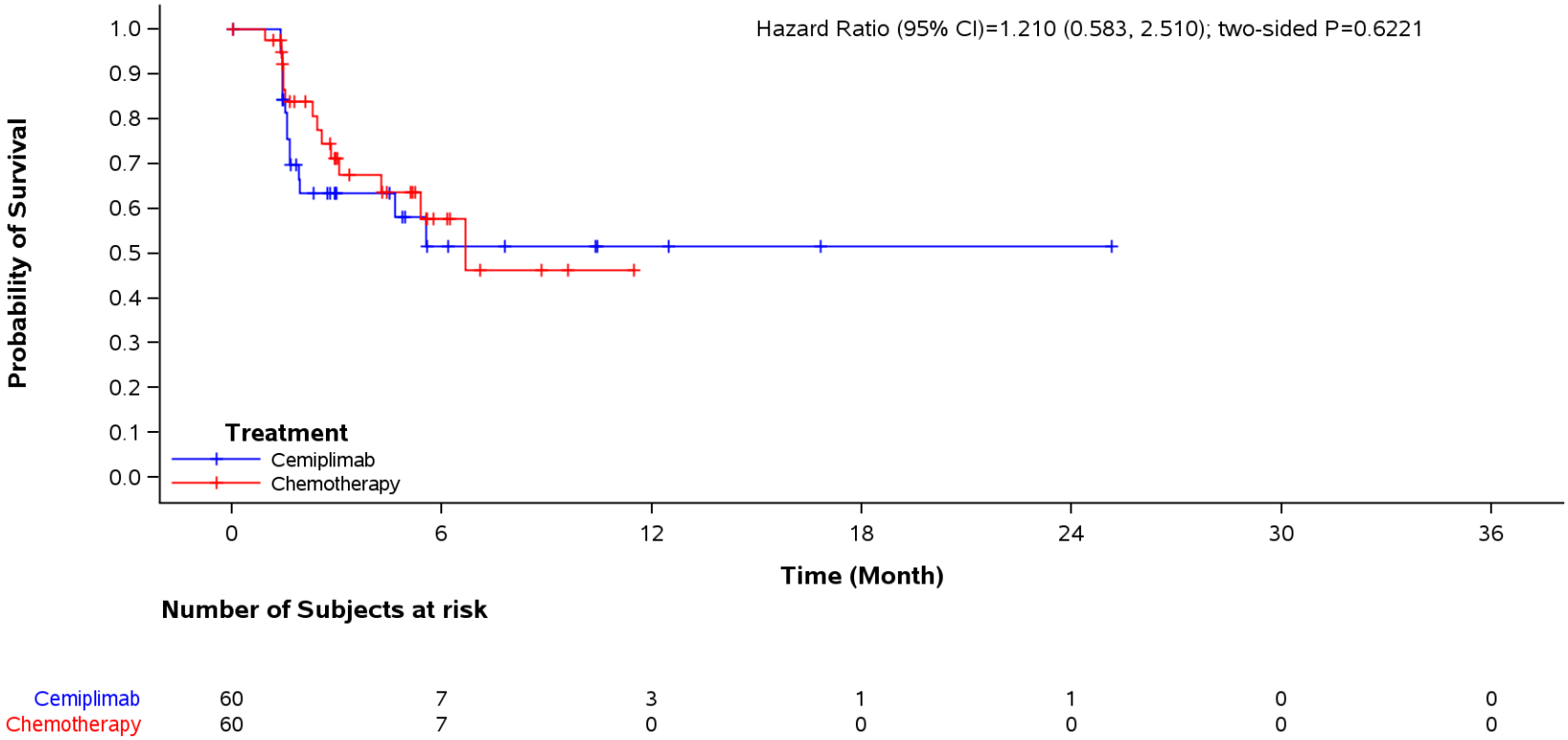

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts sustained improvement



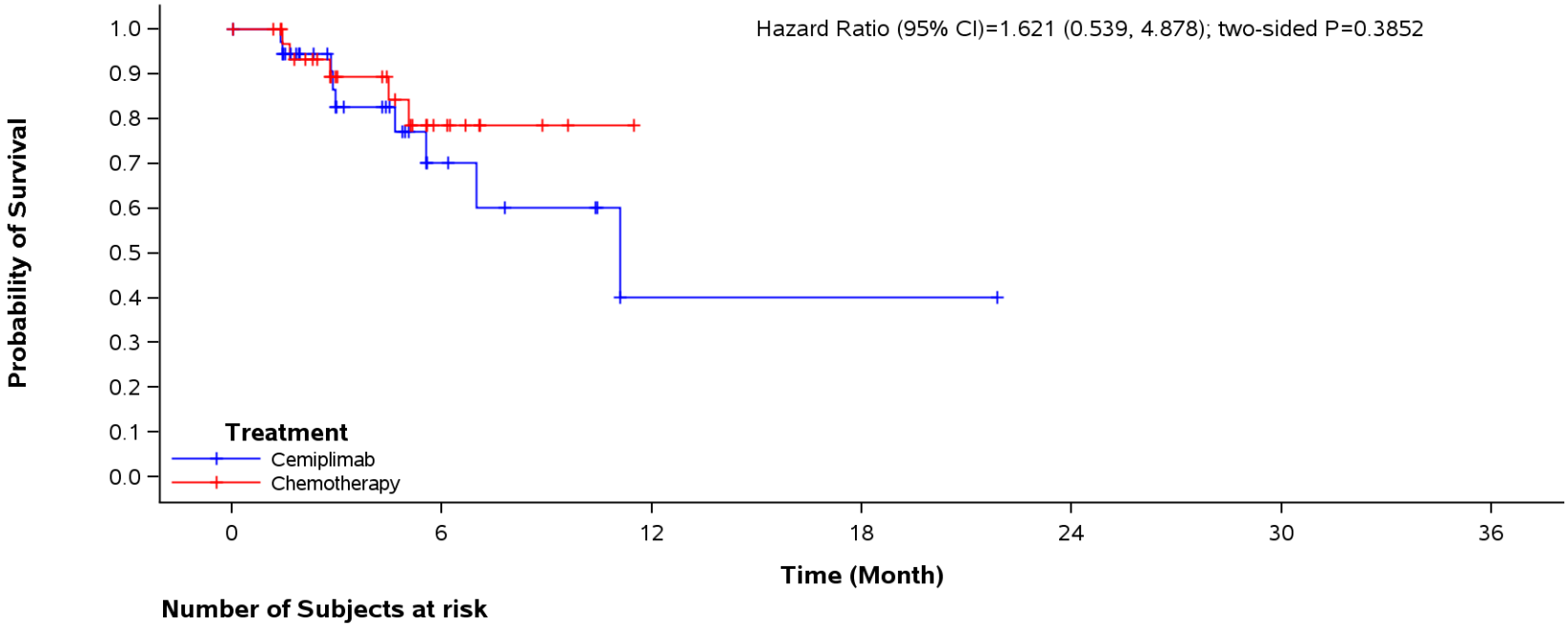

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 7 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 60 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts sustained improvement



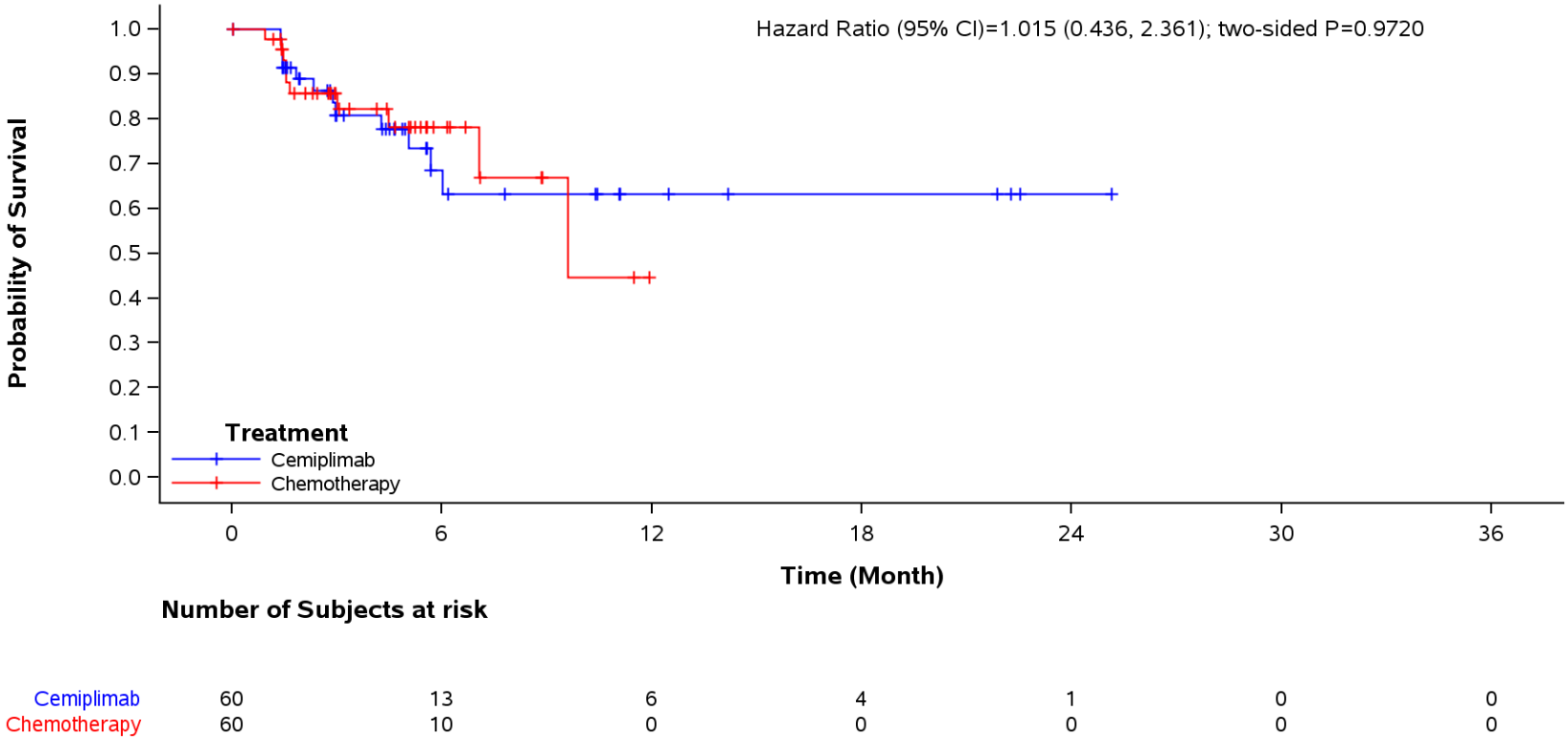

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 8 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts sustained improvement



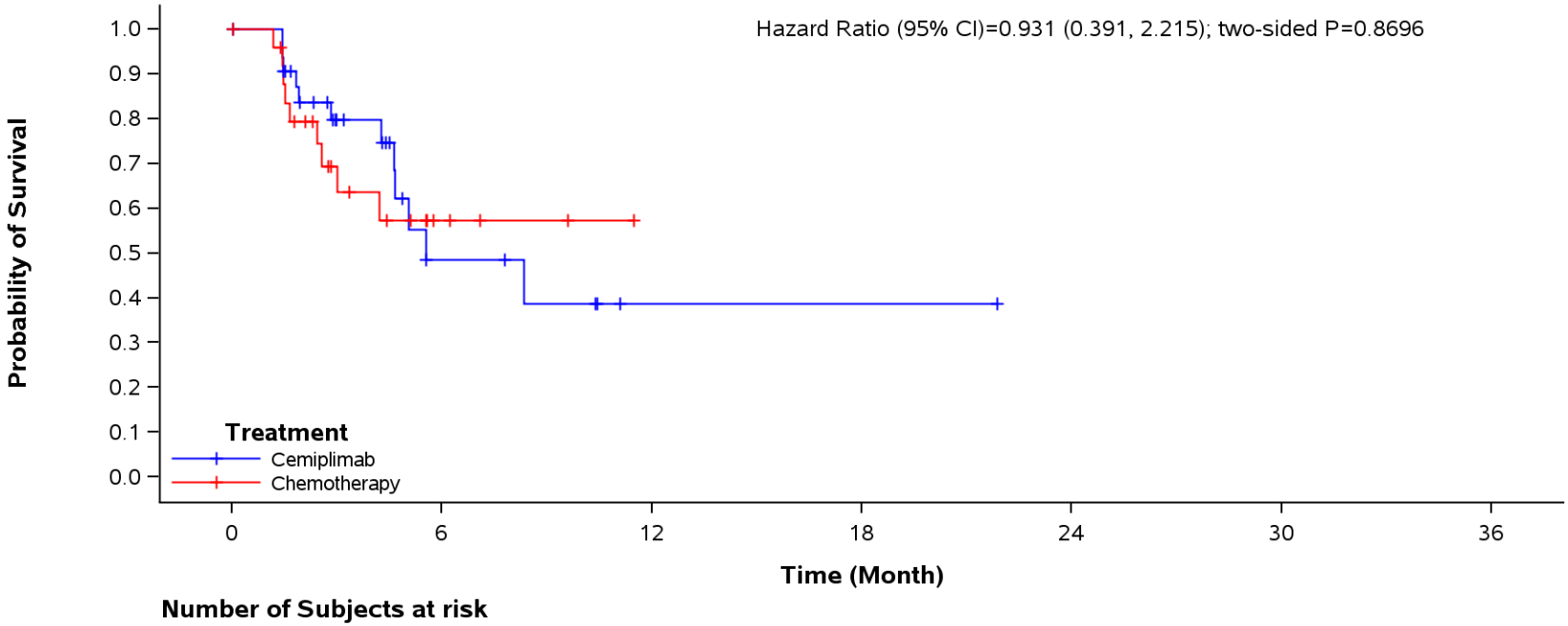

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 6 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts sustained improvement



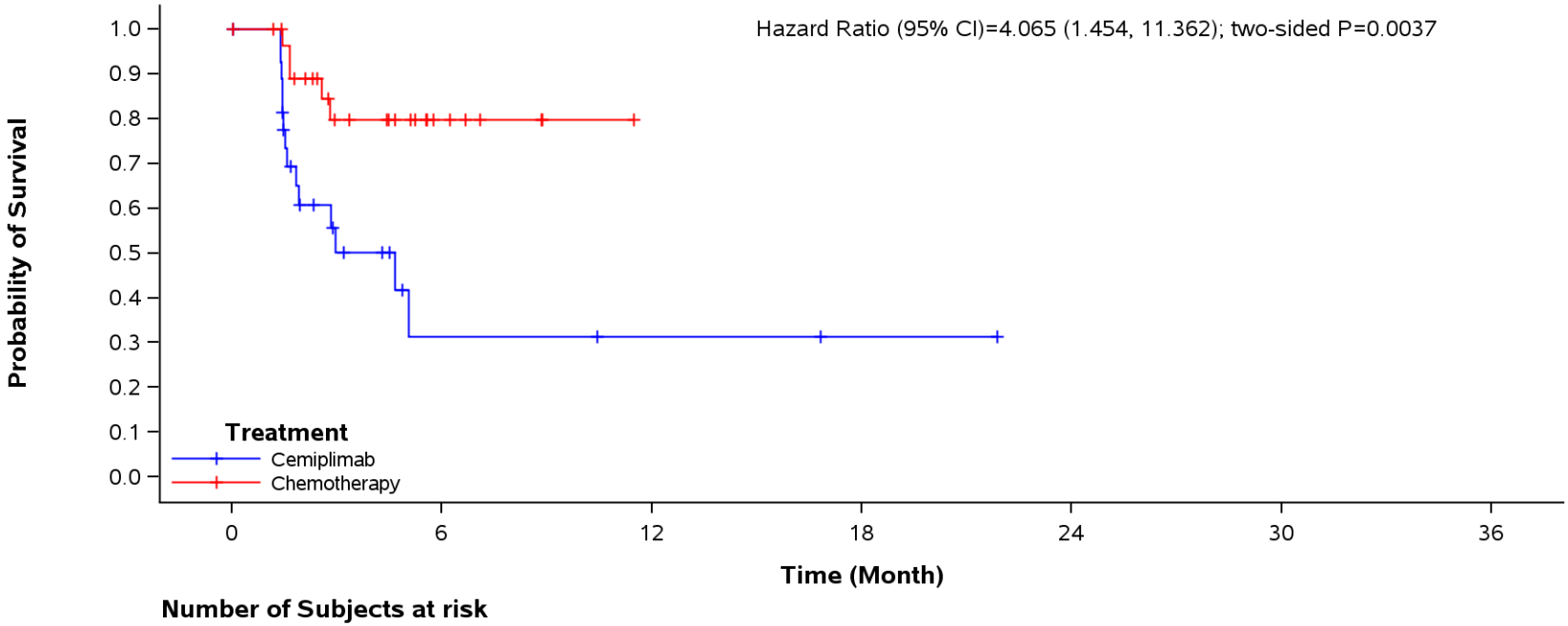

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 6 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts sustained improvement



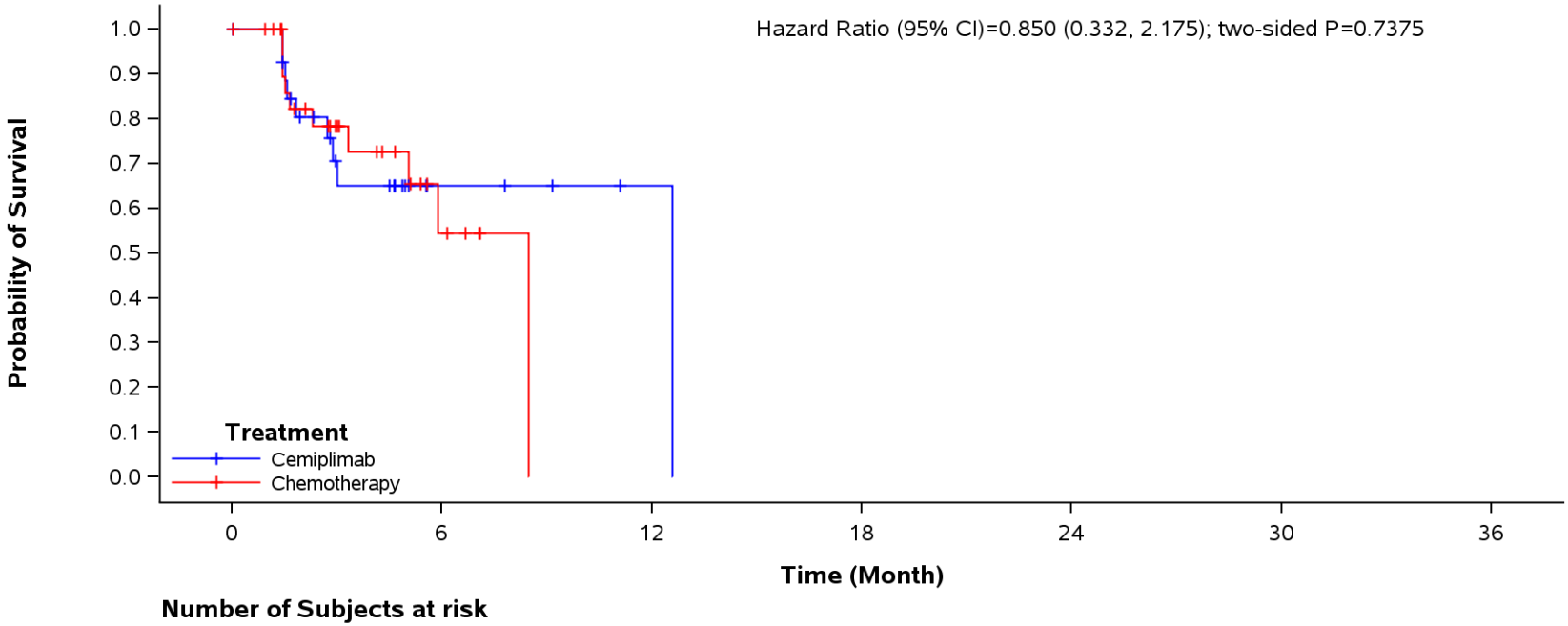

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts sustained improvement



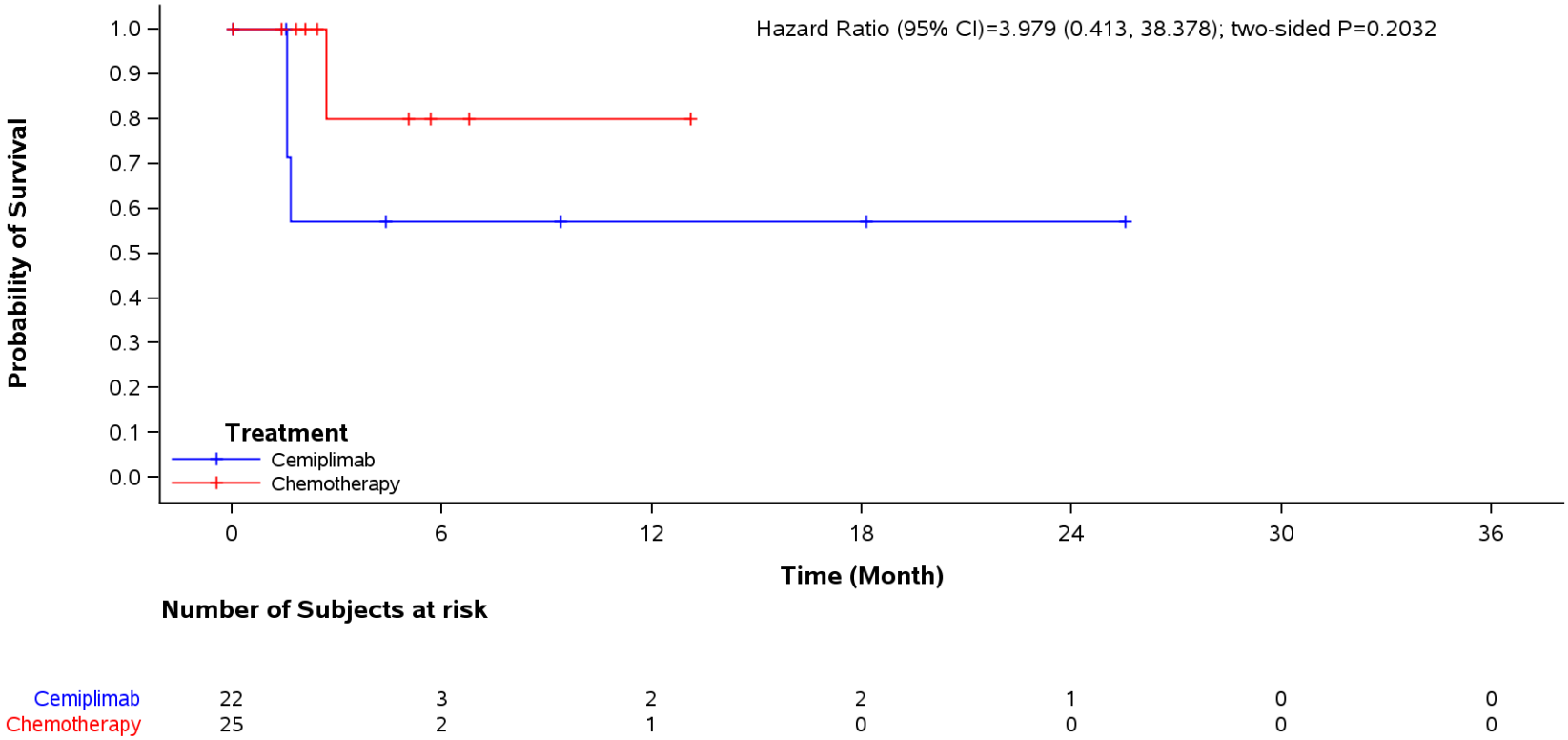

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

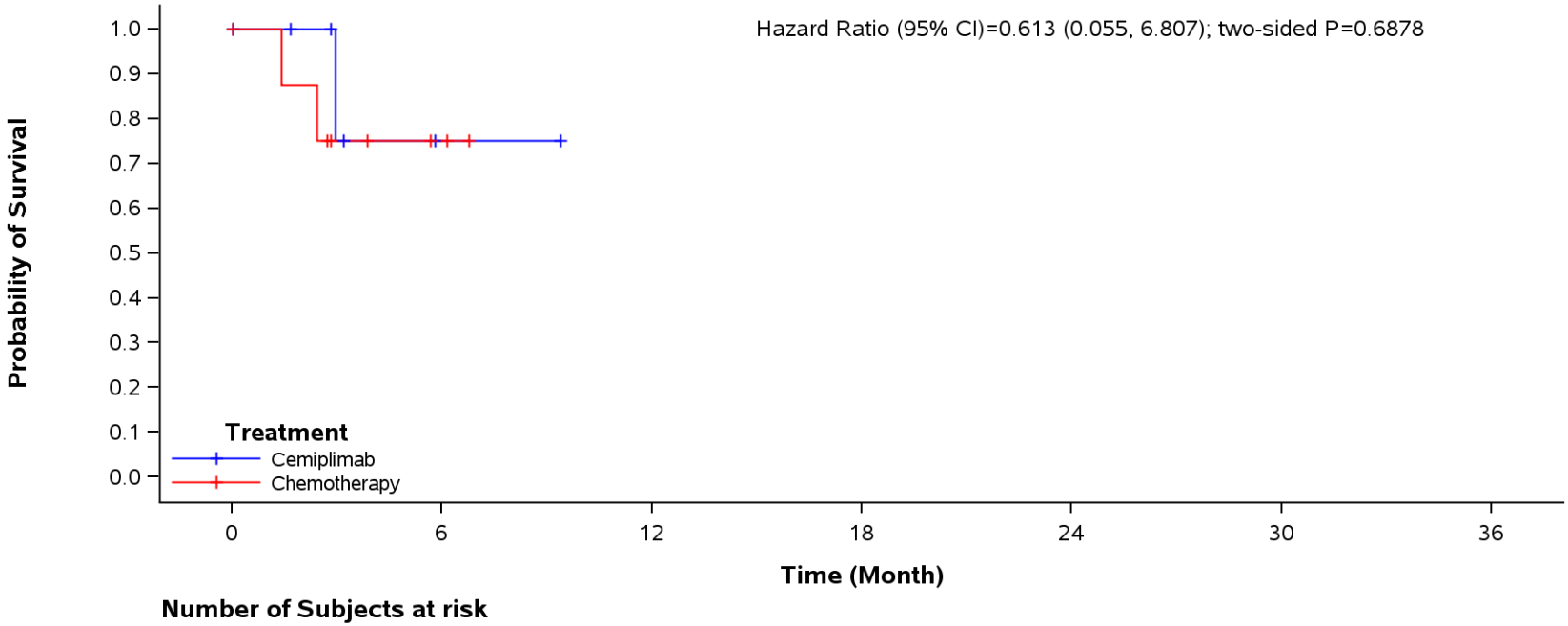
Geographic region: North America
Appetite loss - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts sustained improvement



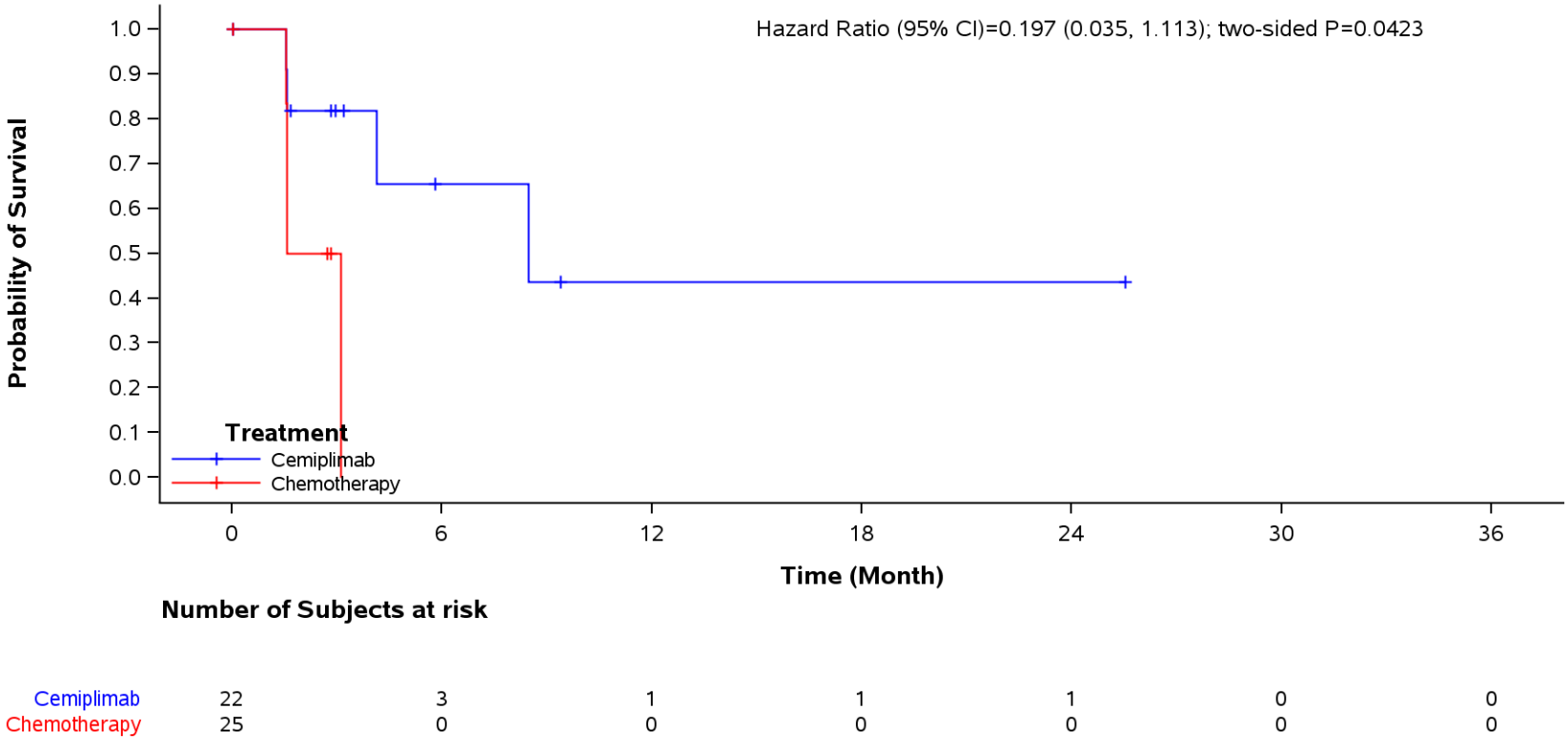

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

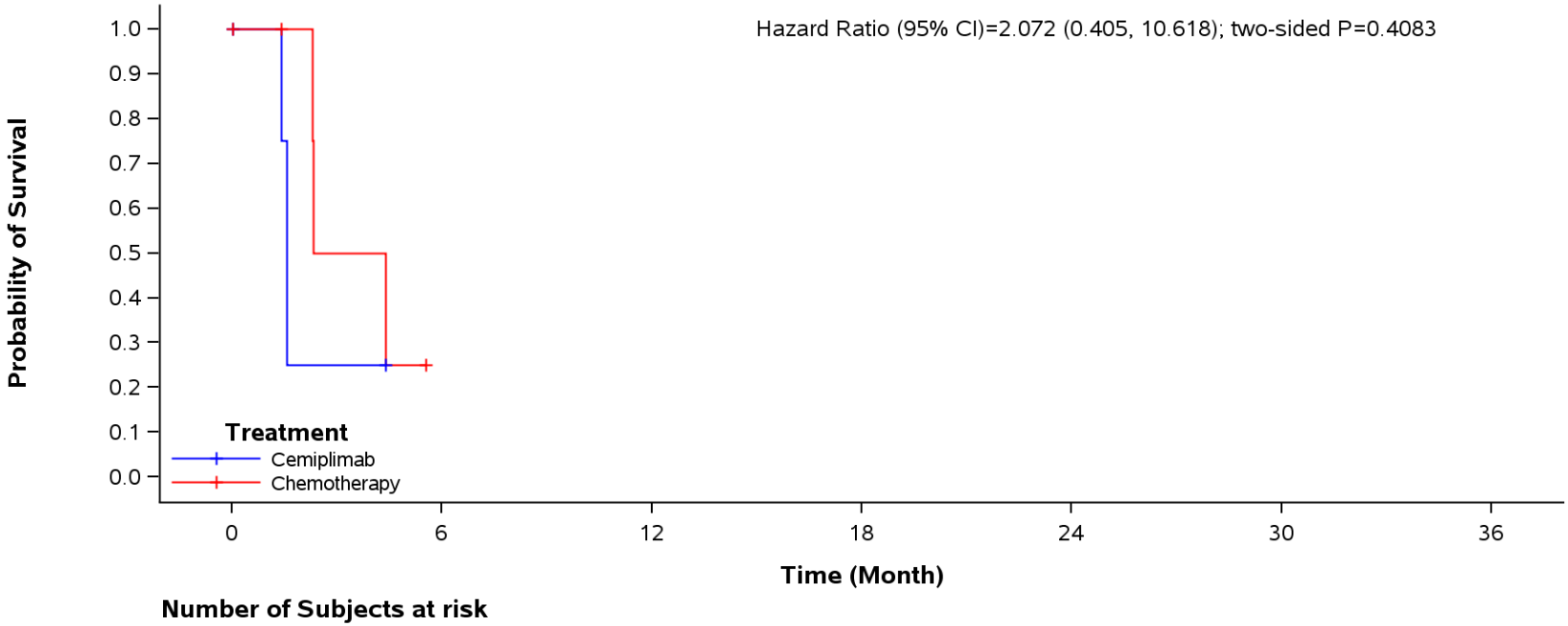
Geographic region: North America
Constipation - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts sustained improvement



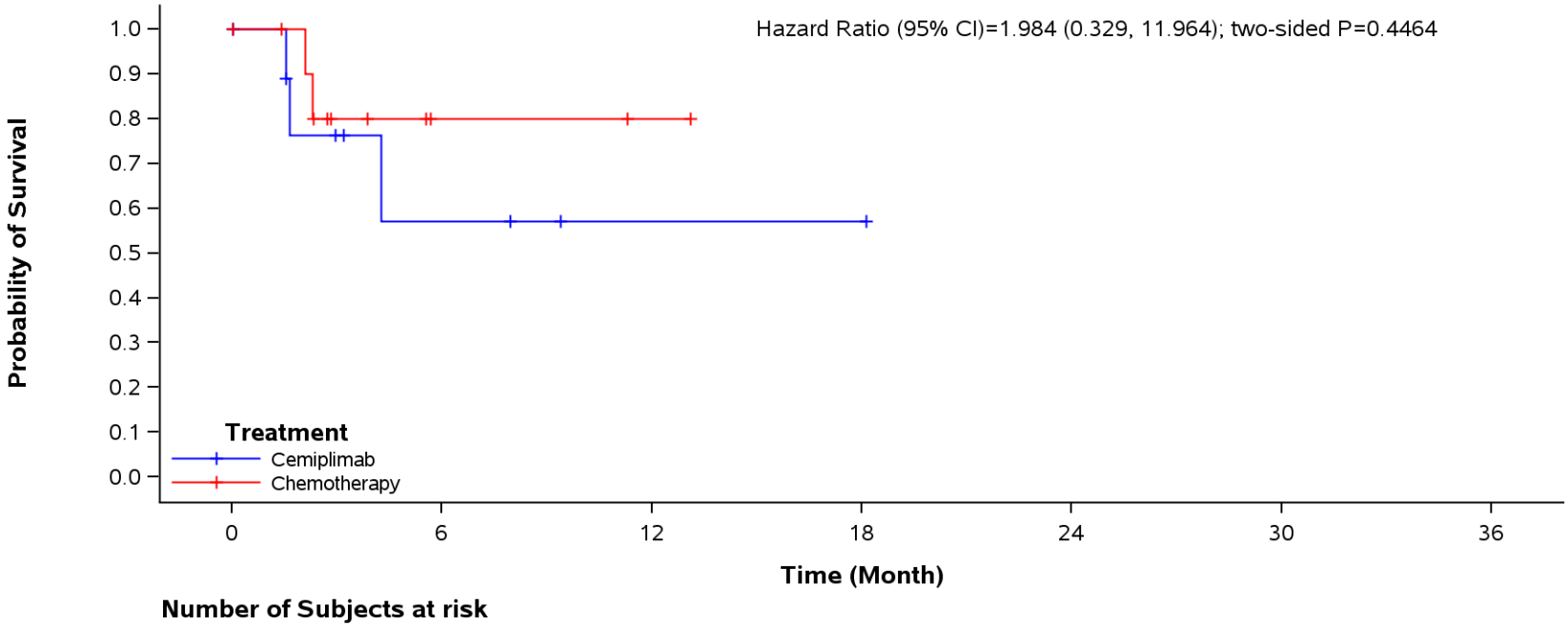

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts sustained improvement



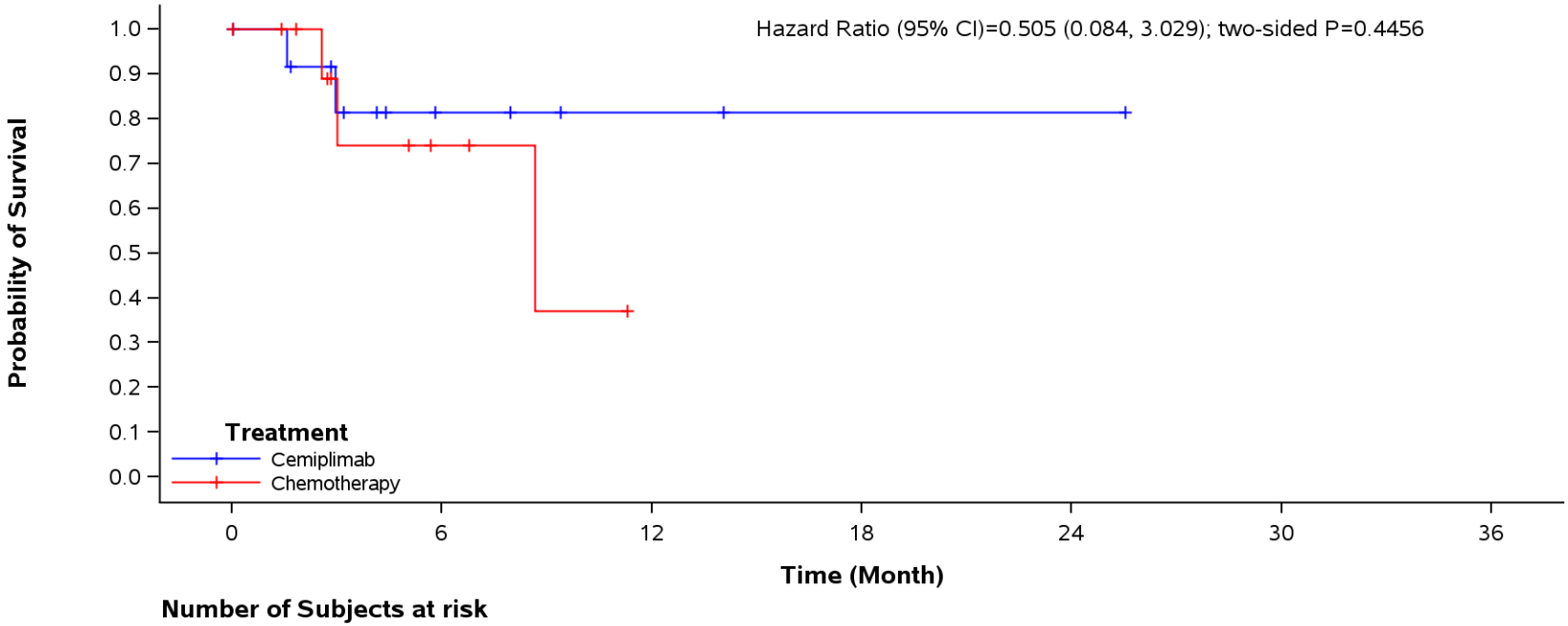

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts sustained improvement



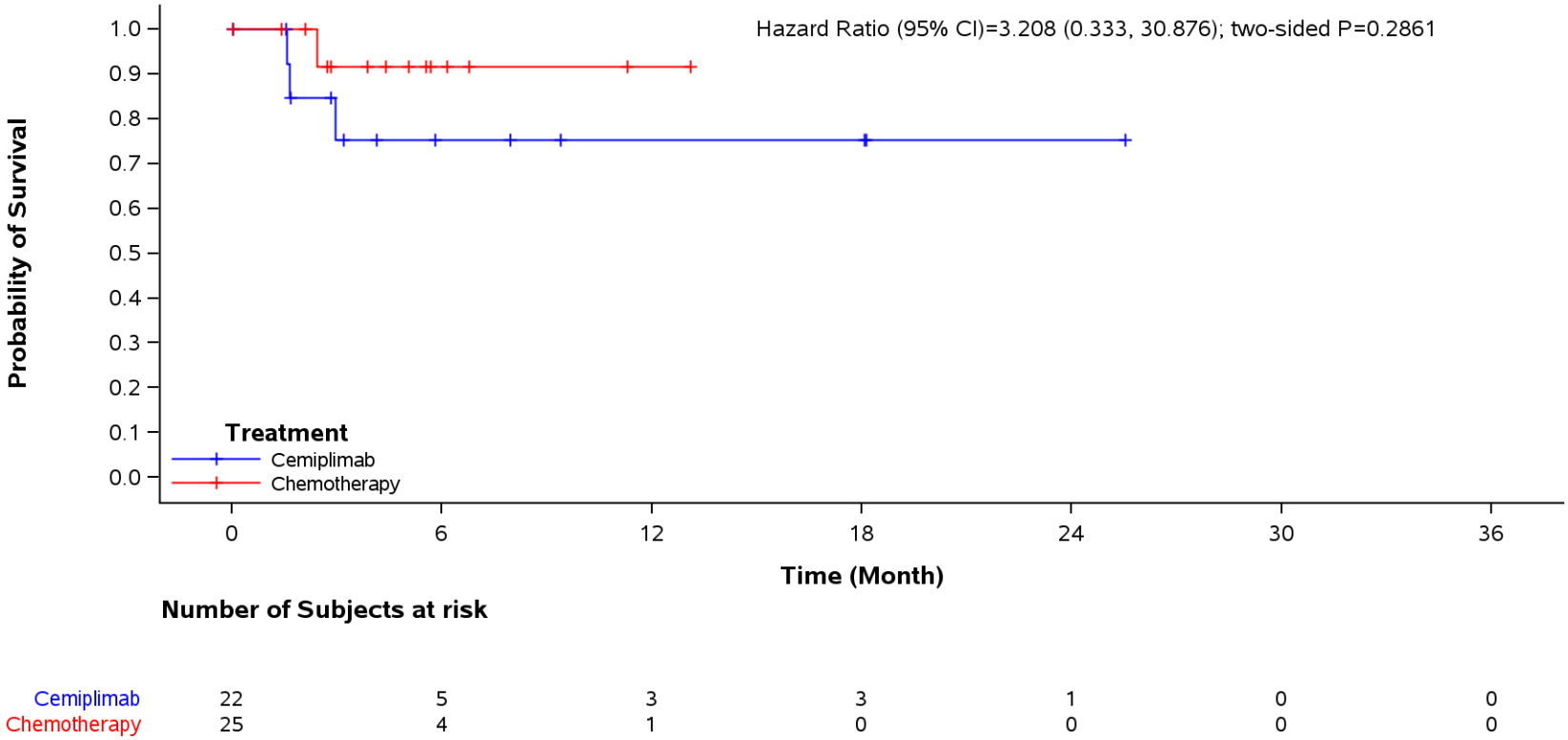

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 4 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 25 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

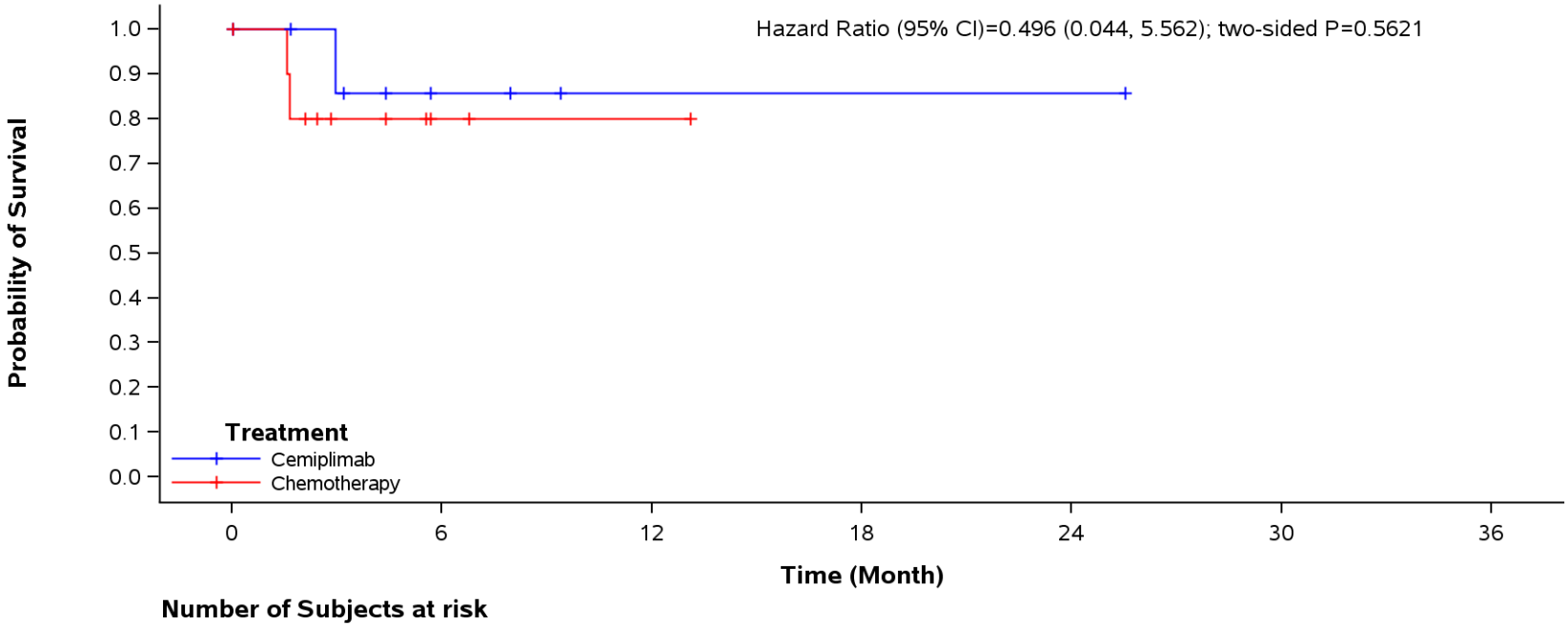
Geographic region: North America
Fatigue - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts sustained improvement



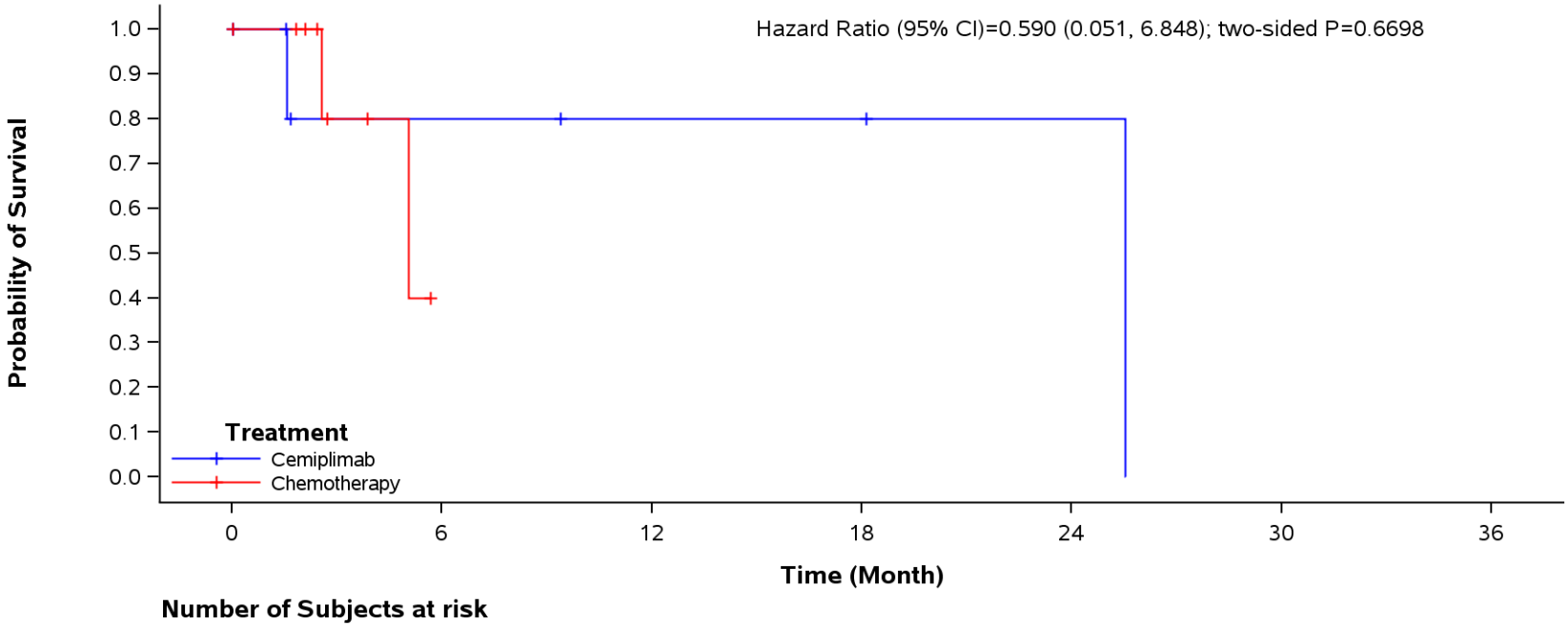

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 25 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts sustained improvement



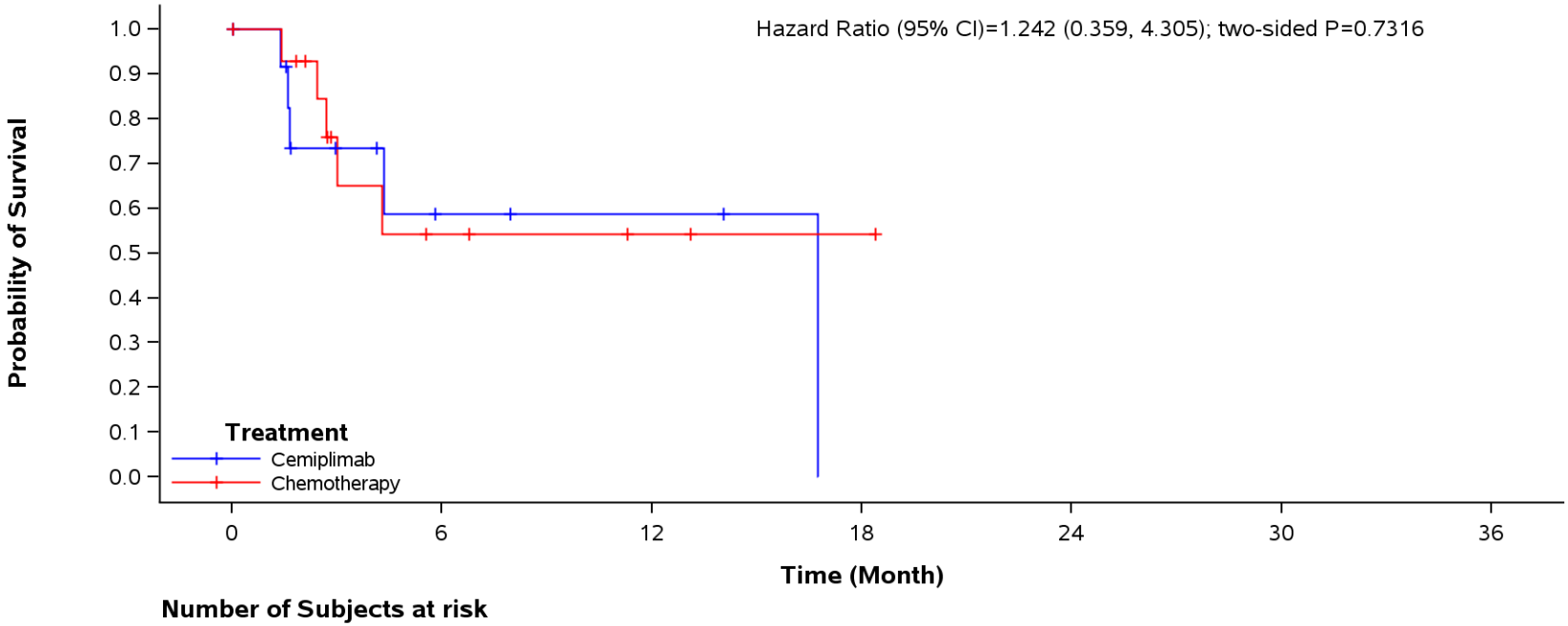

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts sustained improvement



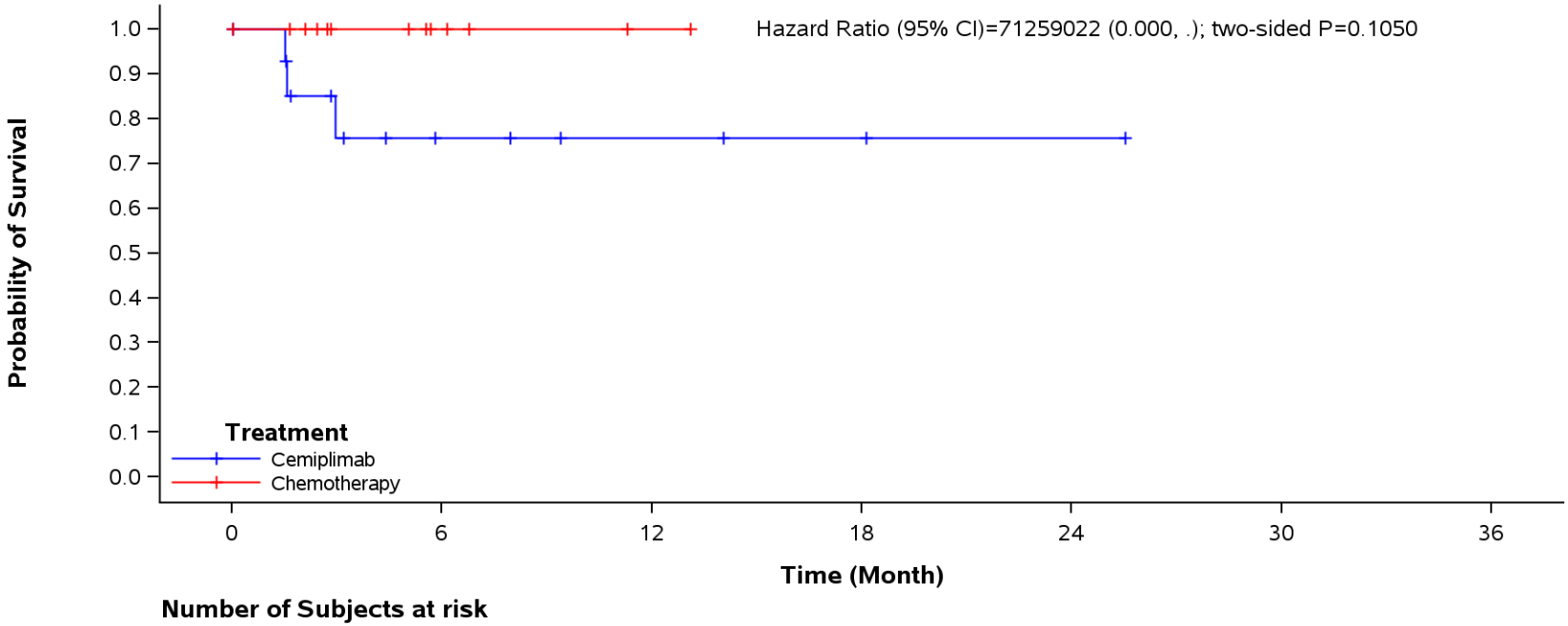

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 4 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts sustained improvement



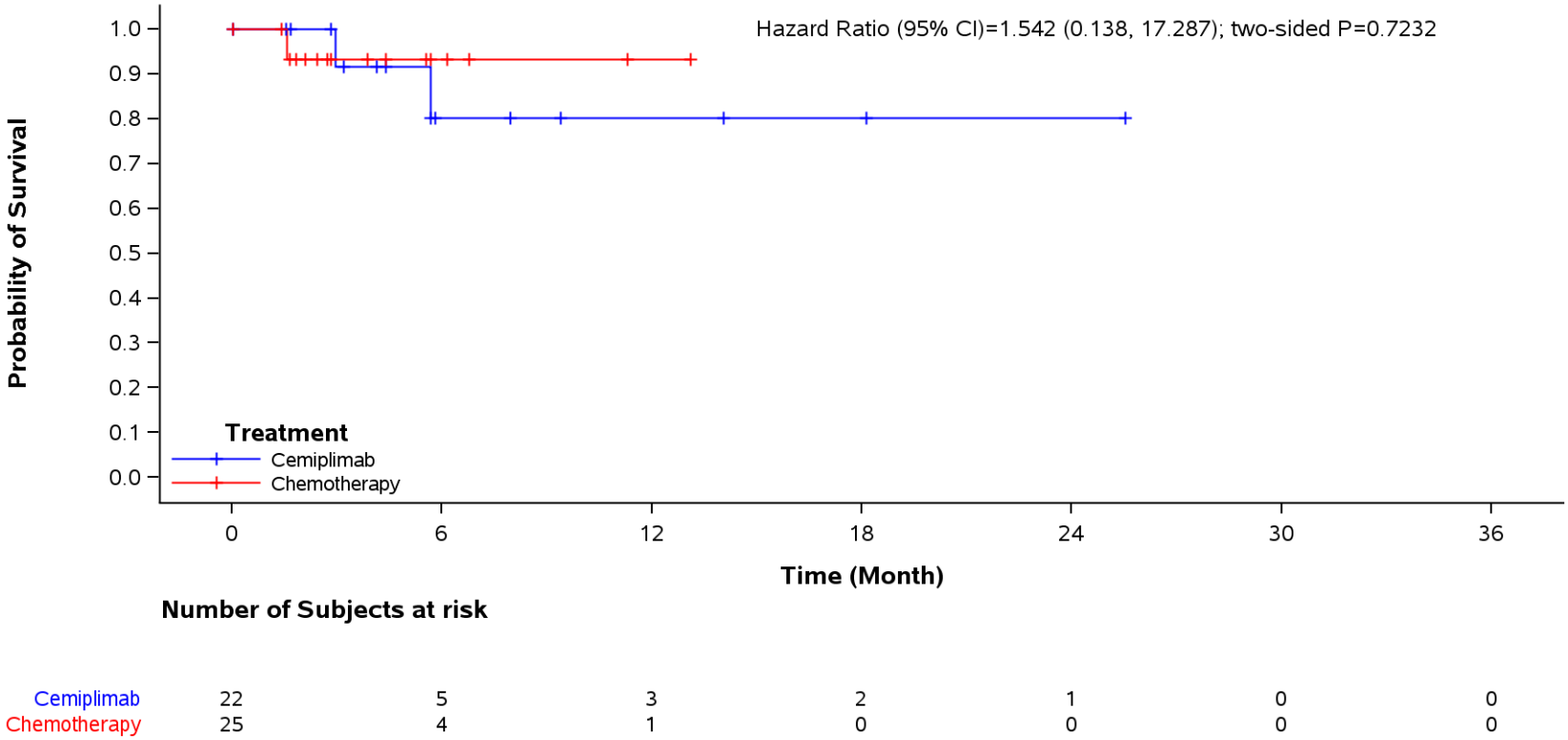

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts sustained improvement



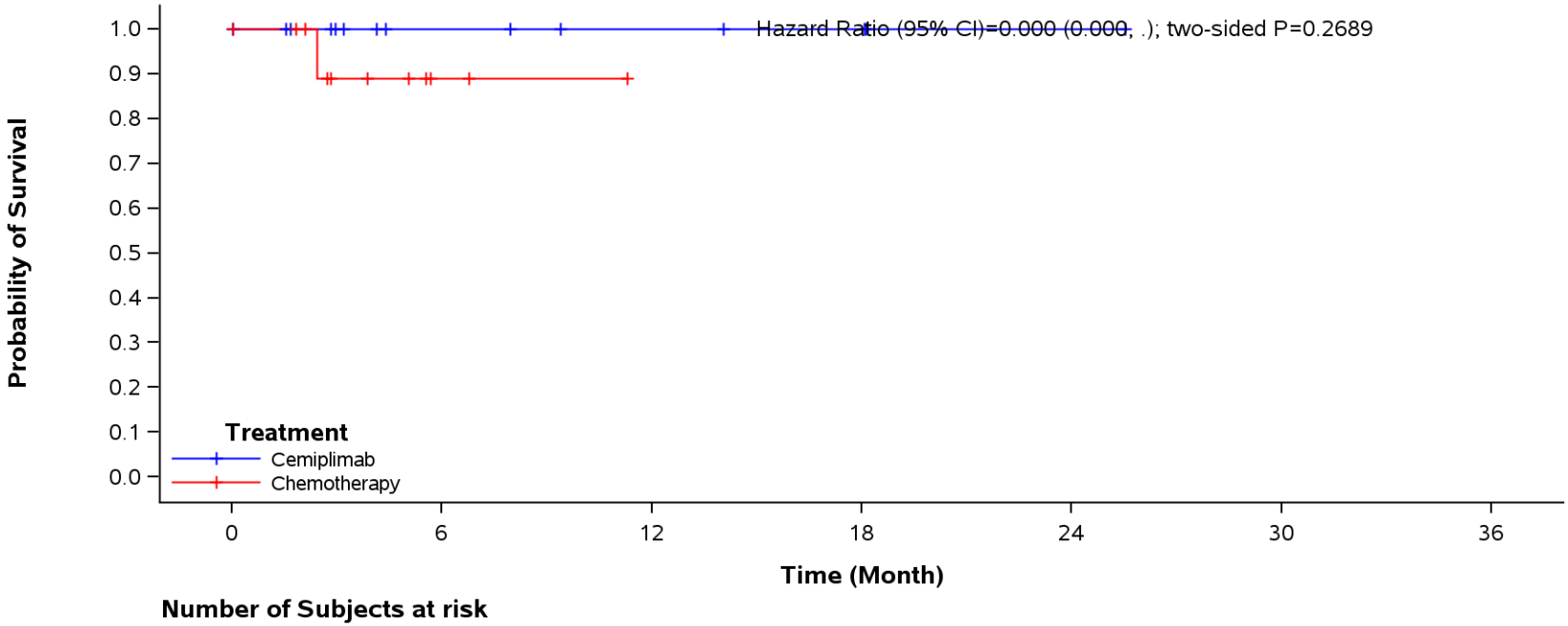

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts sustained improvement



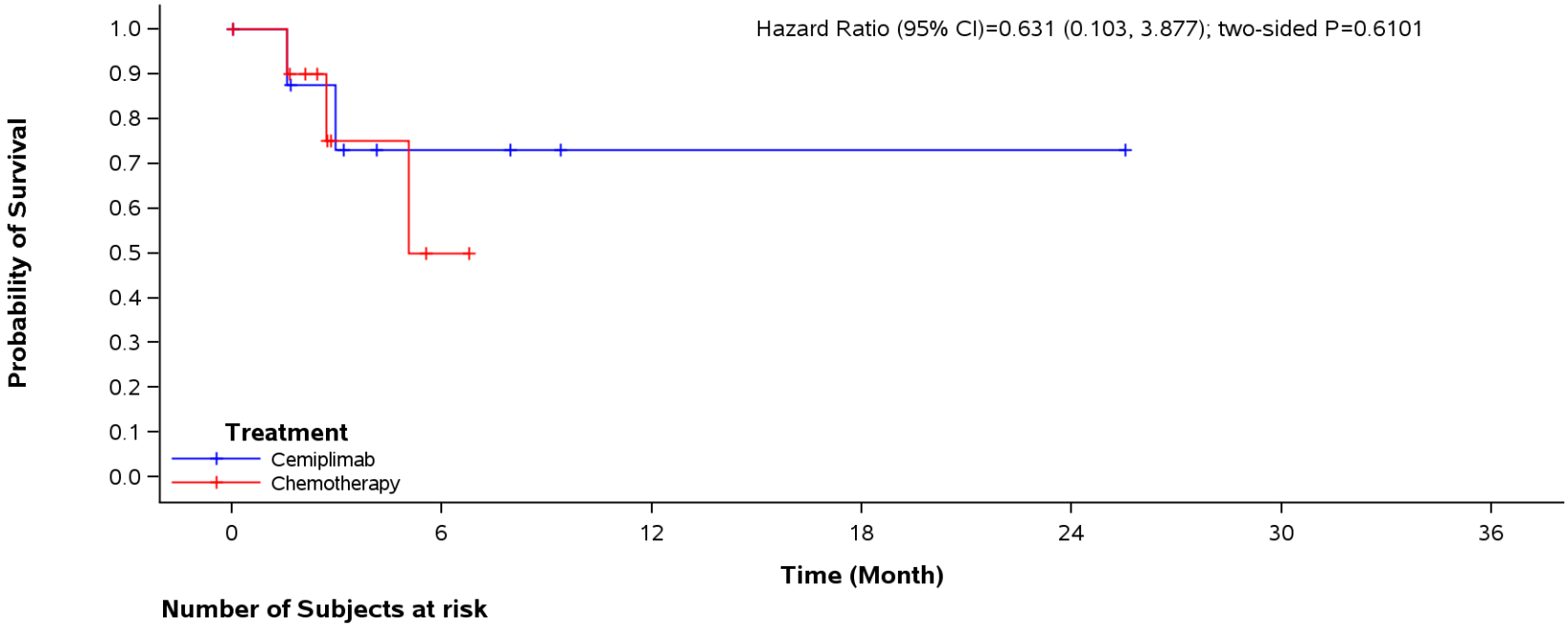

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts sustained improvement



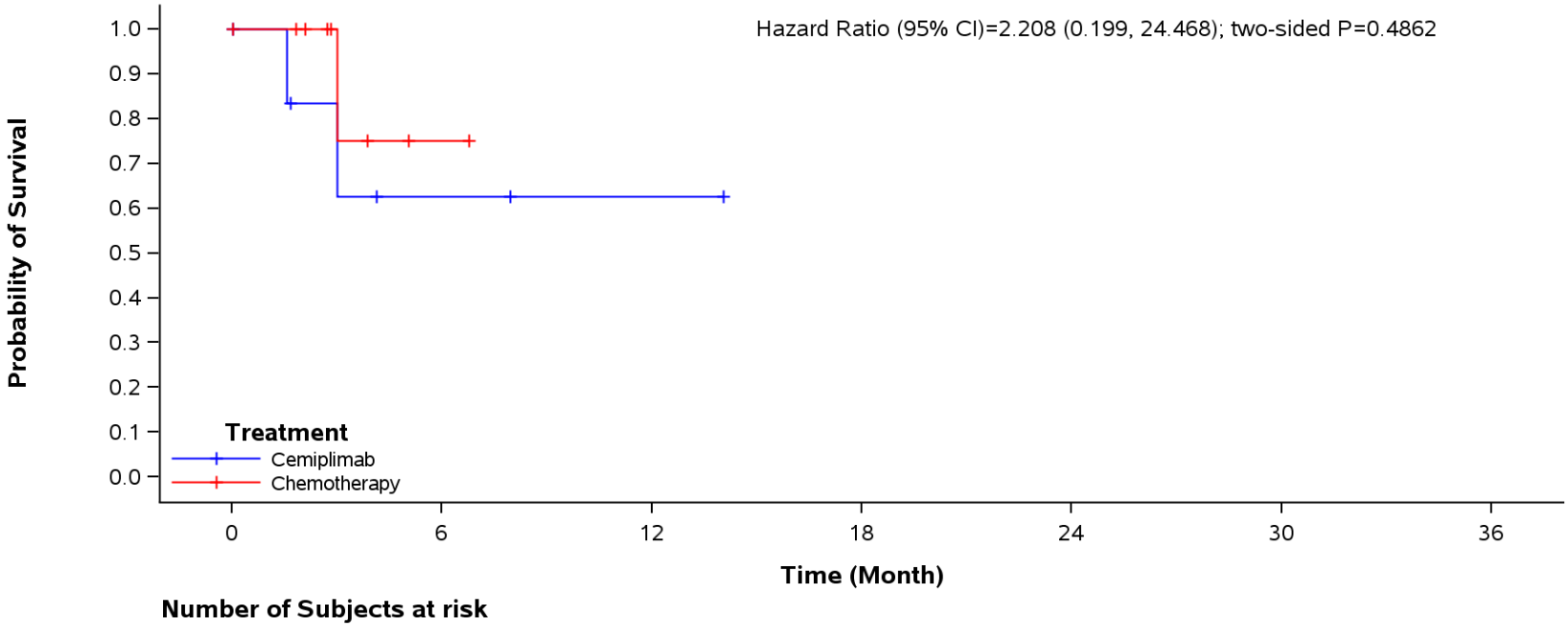

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 25 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts sustained improvement



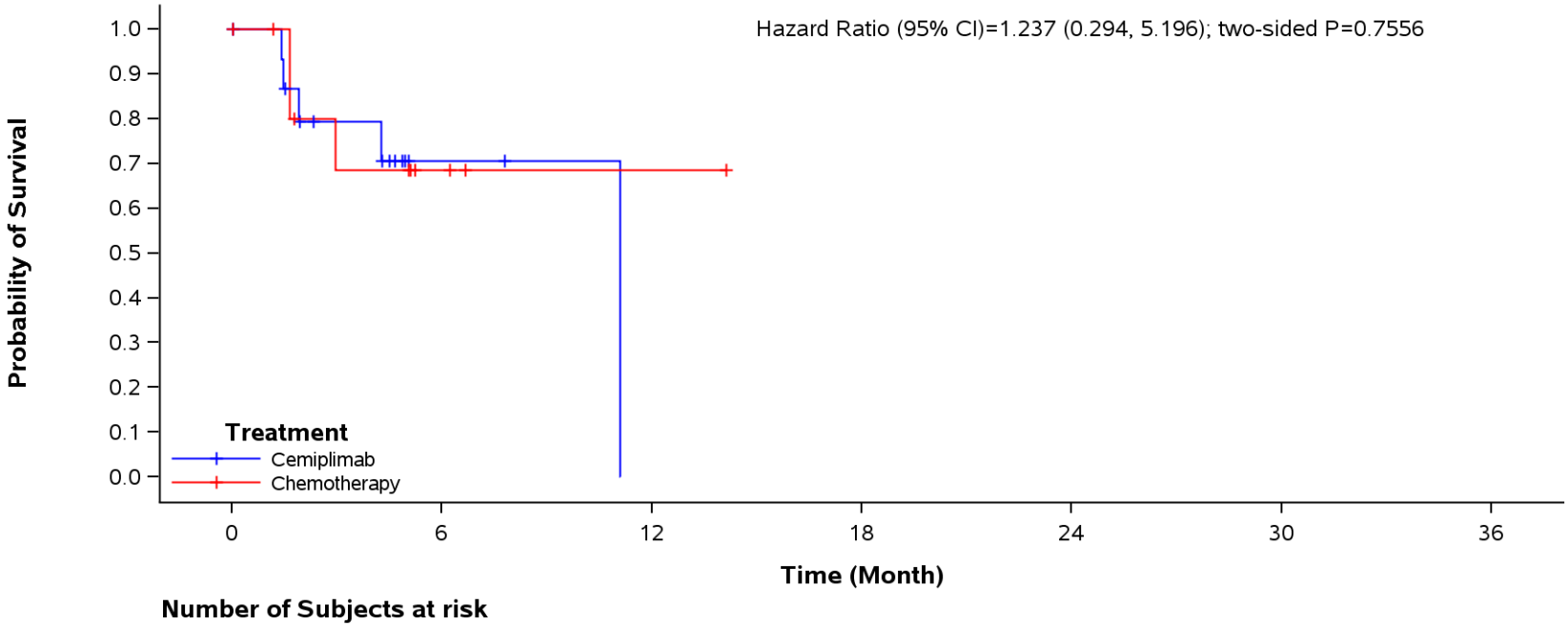

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts sustained improvement



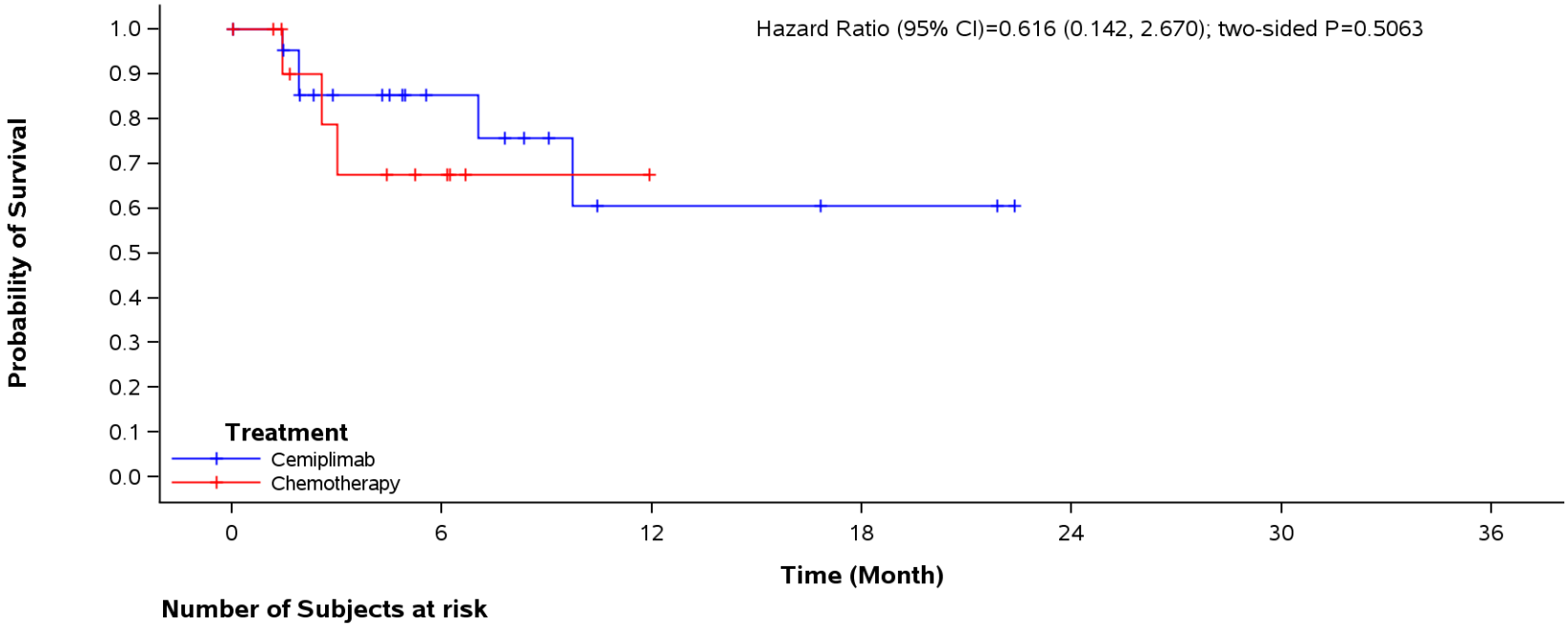

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts sustained improvement



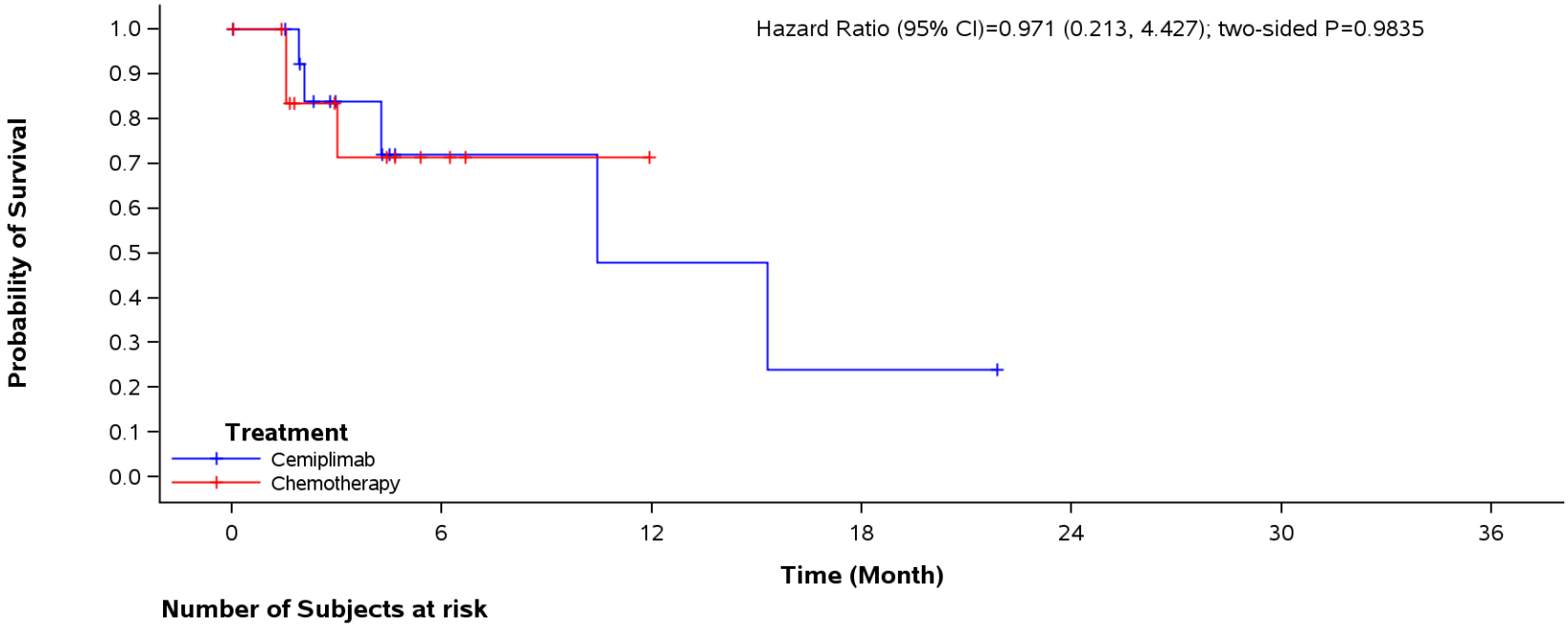

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts sustained improvement



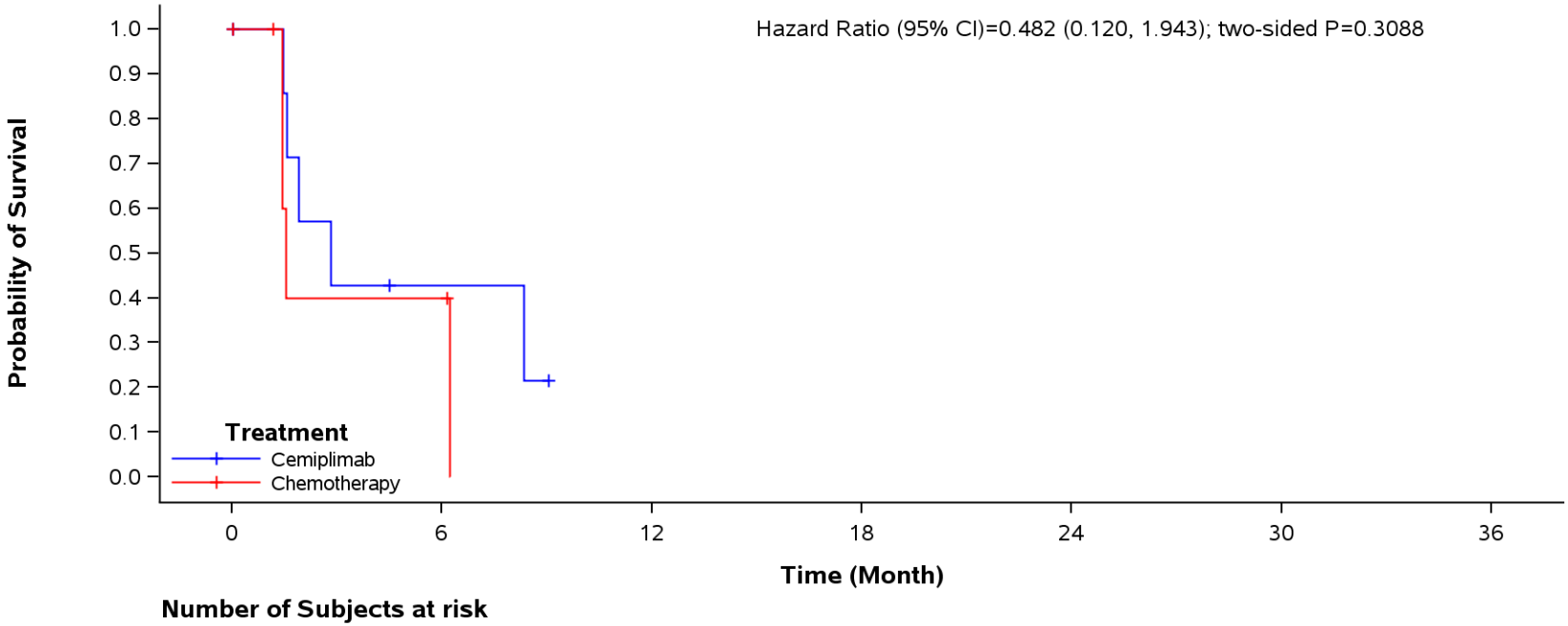

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts sustained improvement



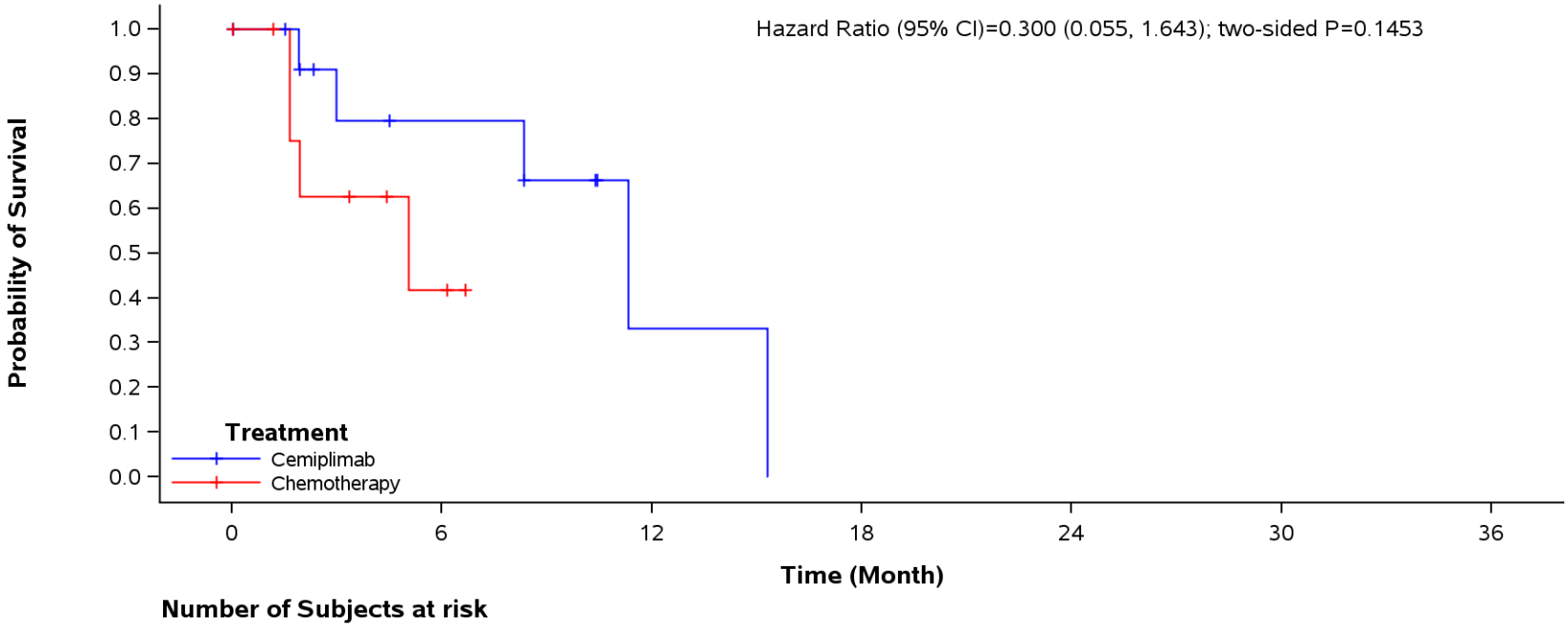

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts sustained improvement



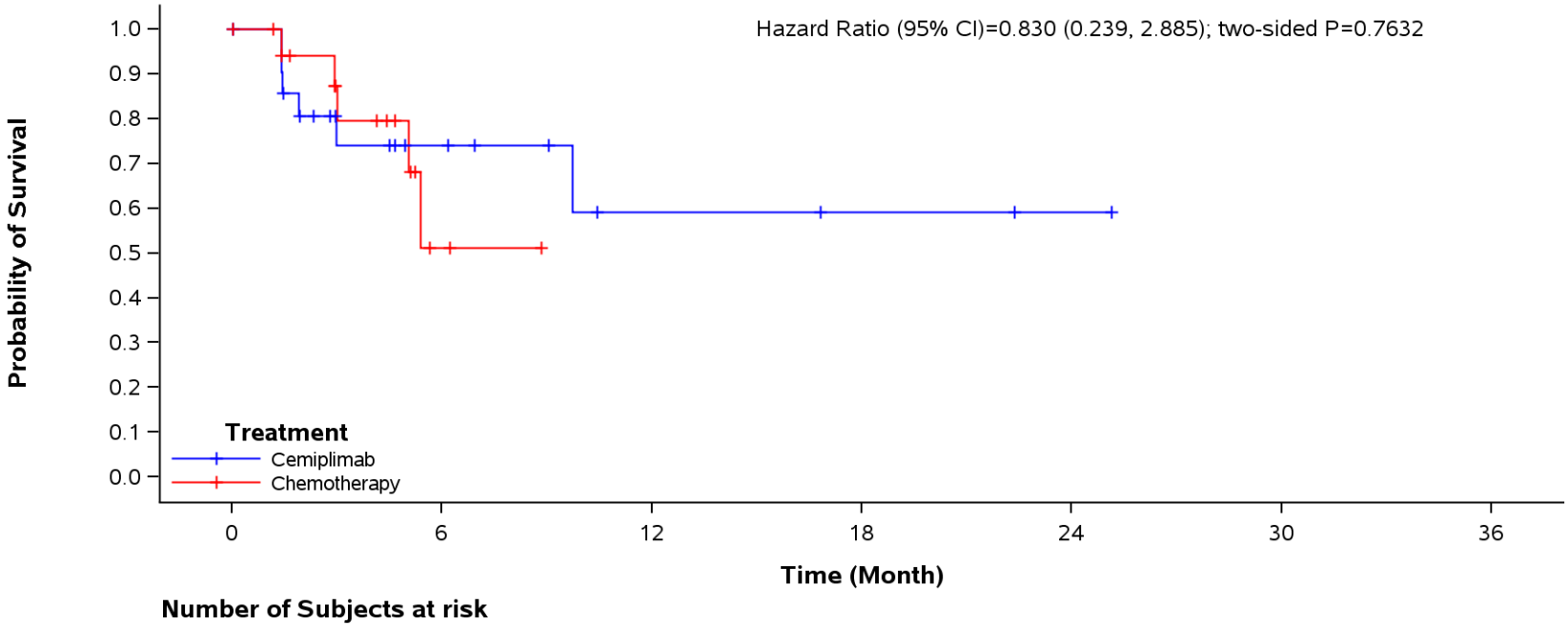

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts sustained improvement



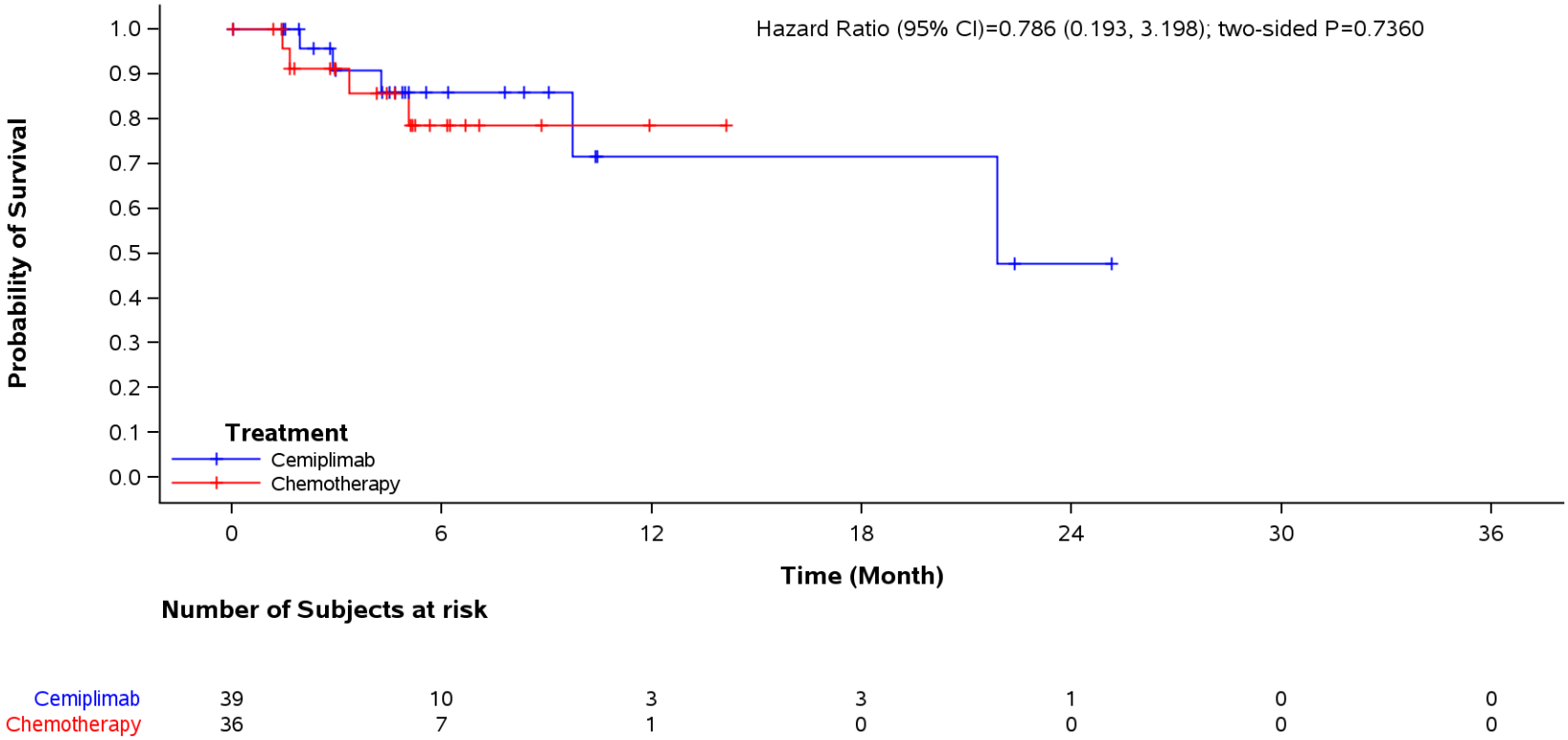

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 8 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts sustained improvement



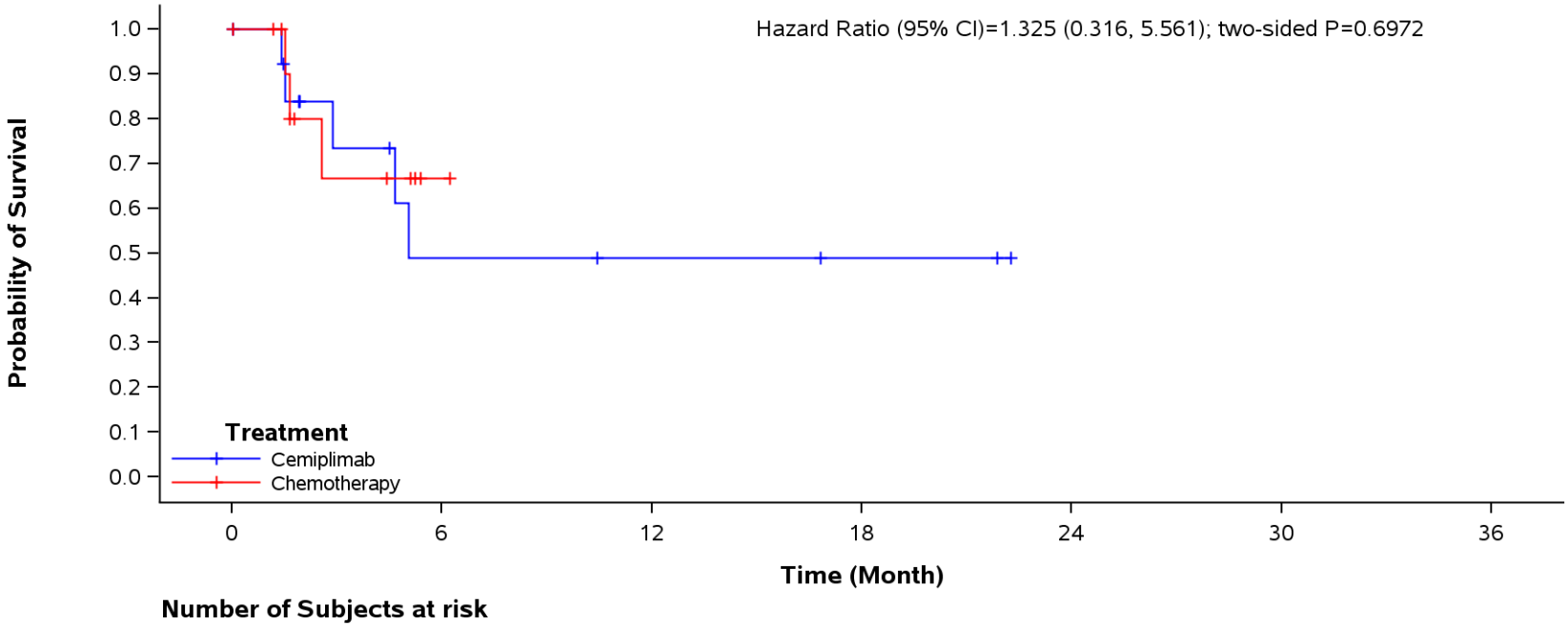

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 3 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts sustained improvement



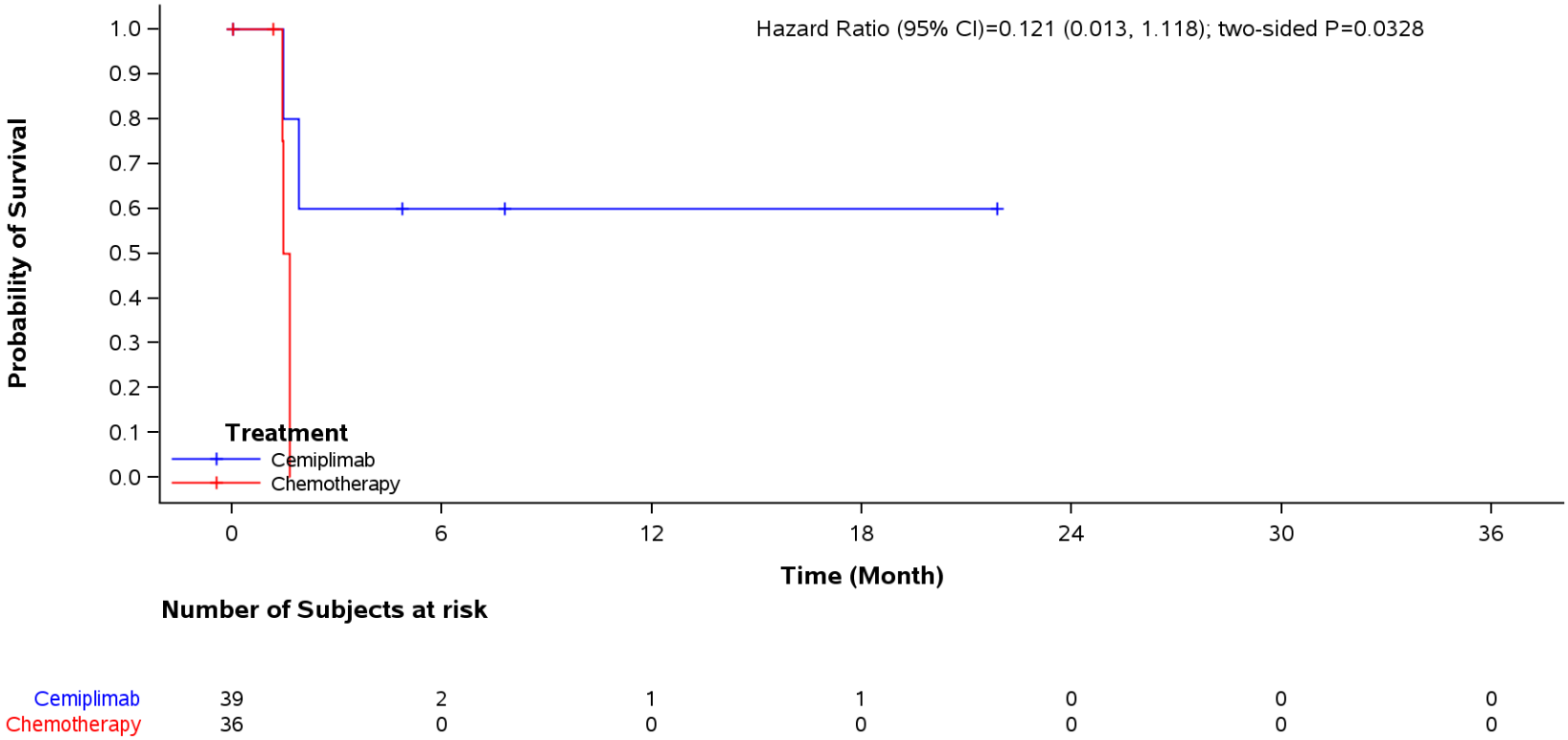

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 4 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

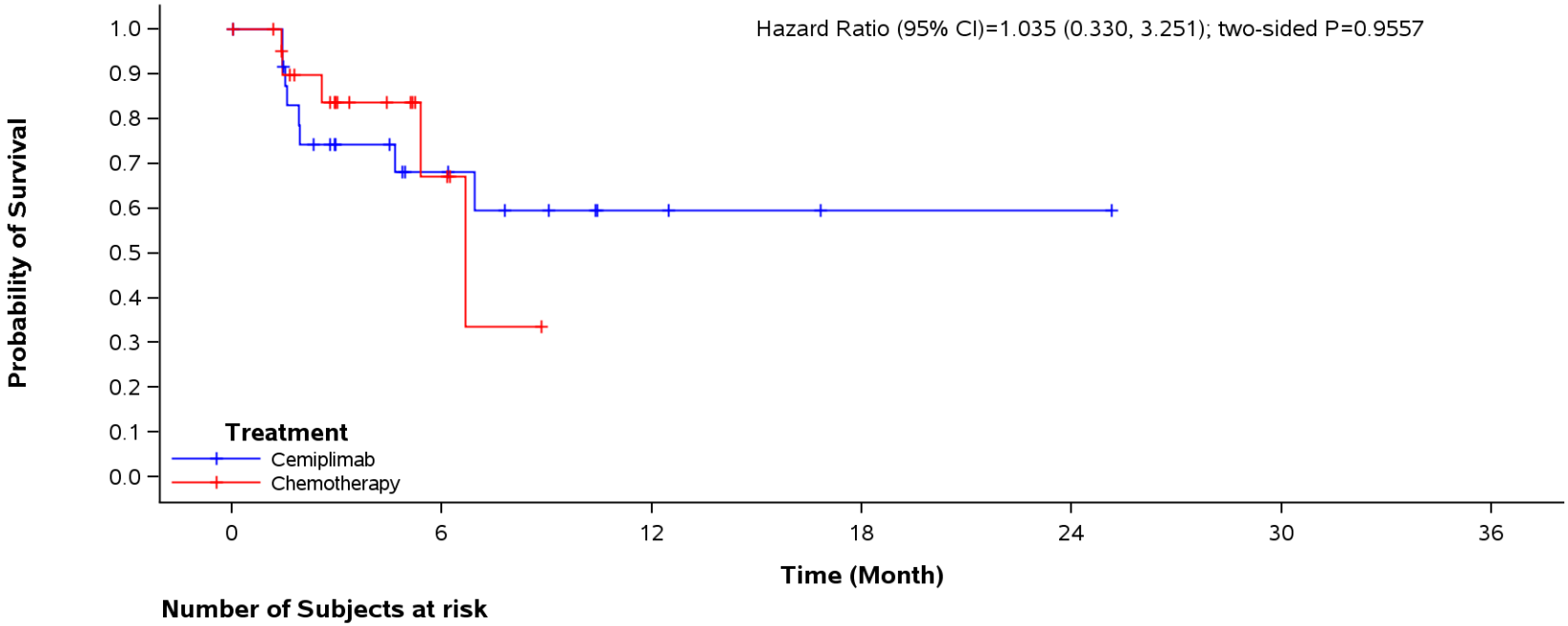
Geographic region: Asia
Nausea / Vomiting - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts sustained improvement




Number of Subjects at risk

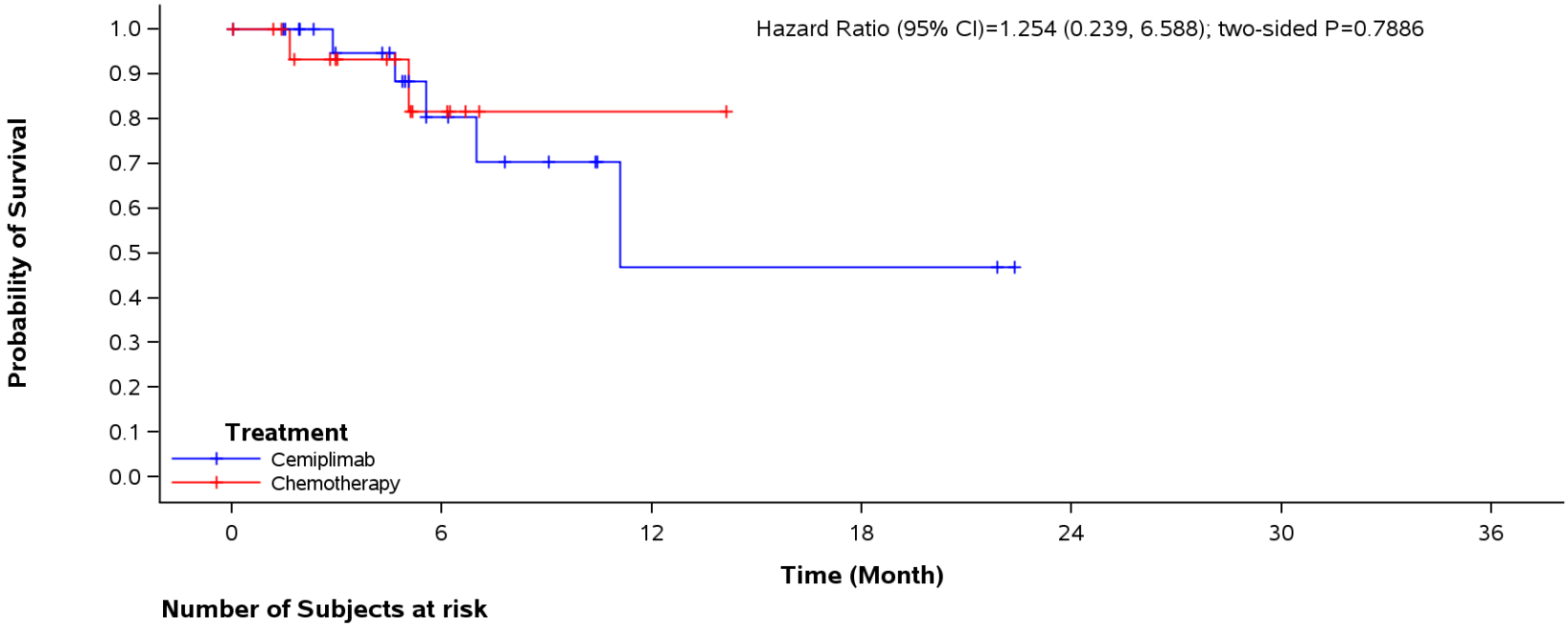
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 36 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:20:32, yingyuan.lin)

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts sustained improvement



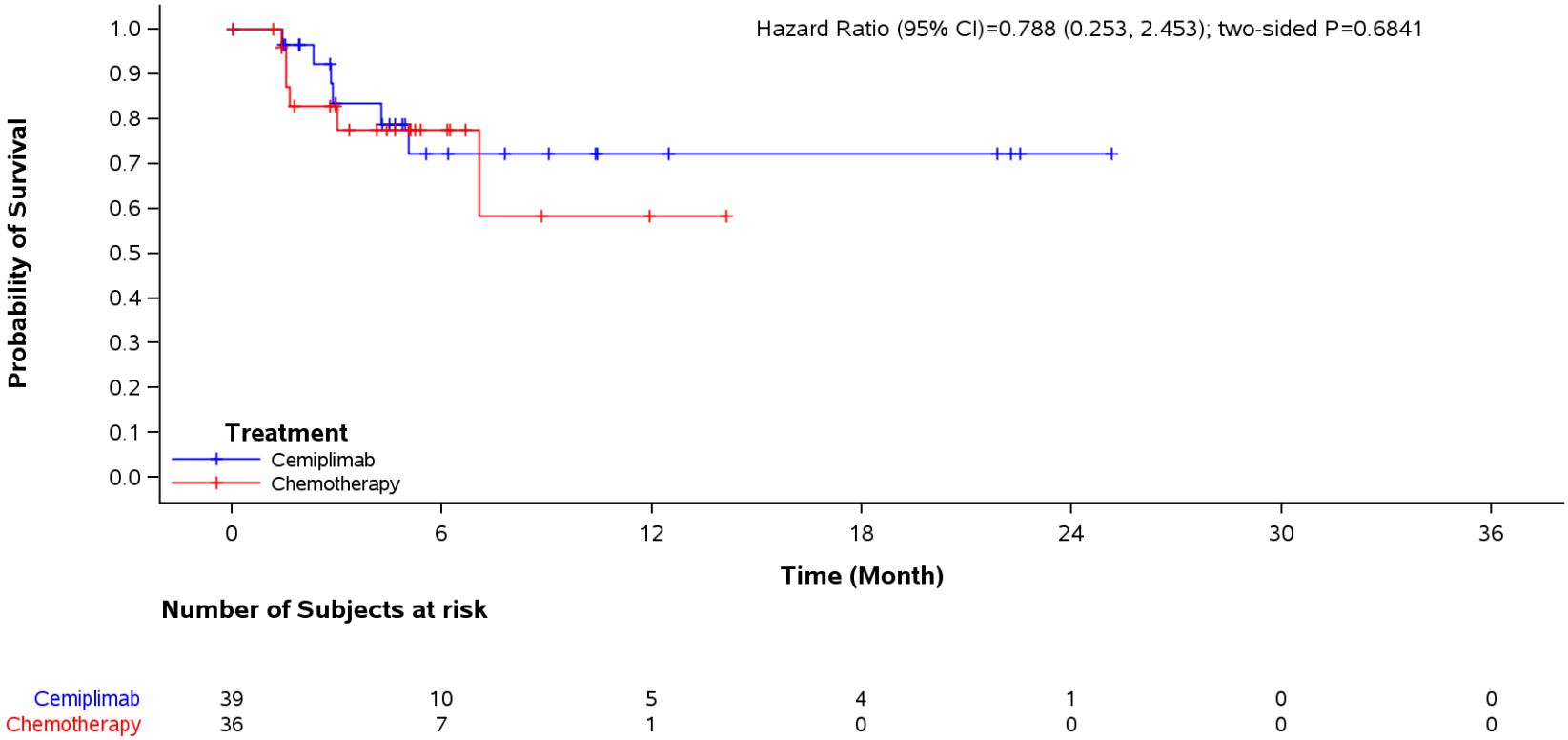

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

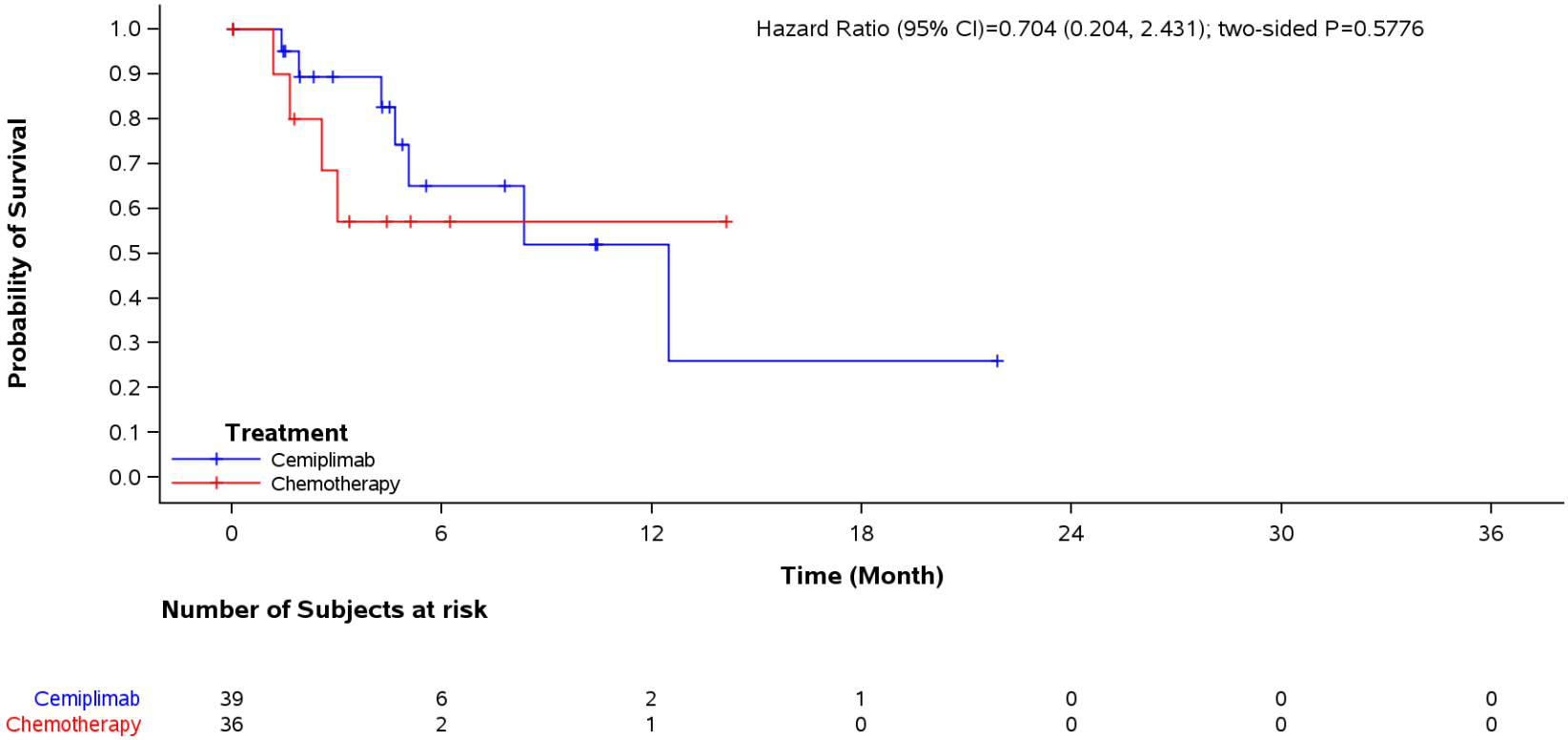
Geographic region: Asia
Global health status / QoL - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts sustained improvement



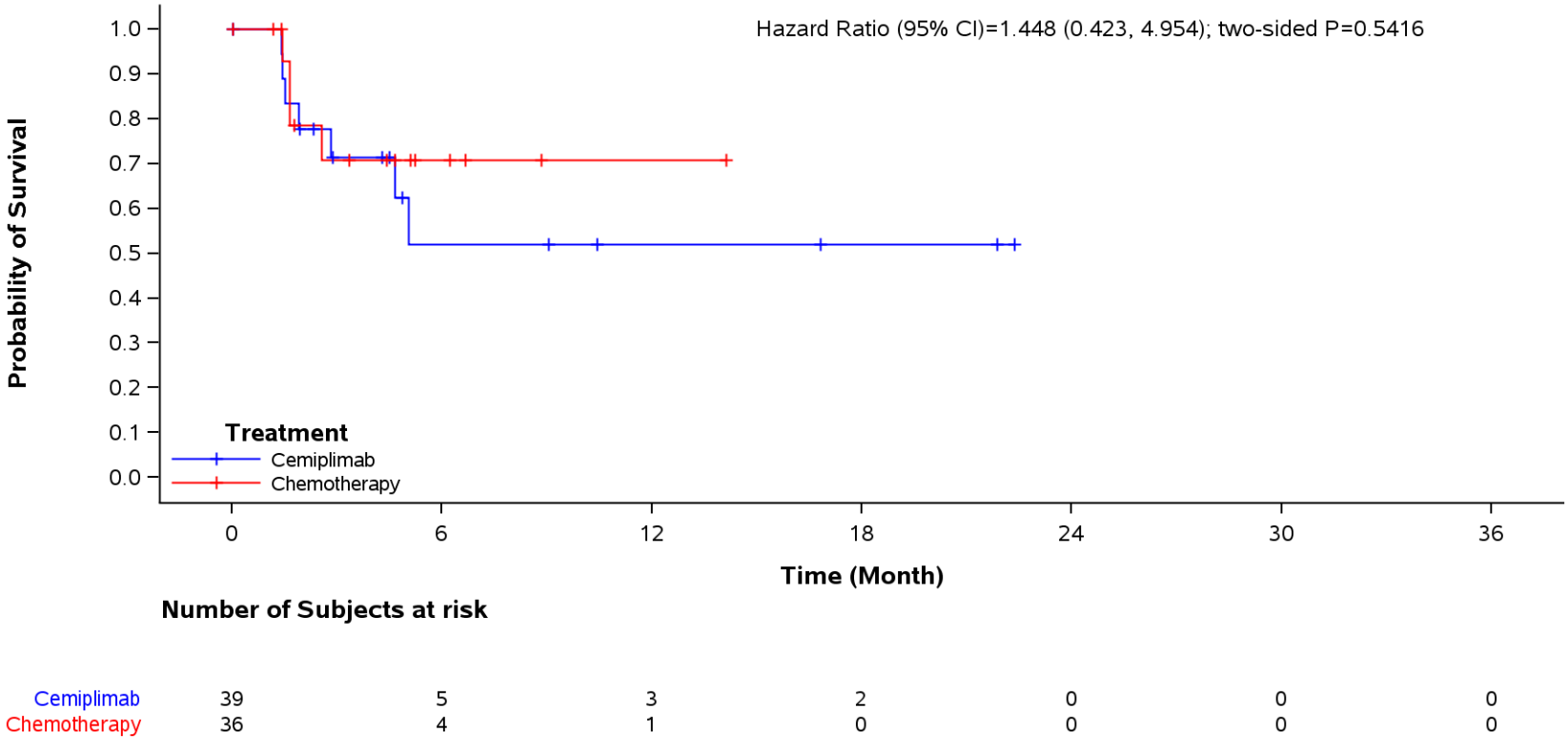

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts sustained improvement



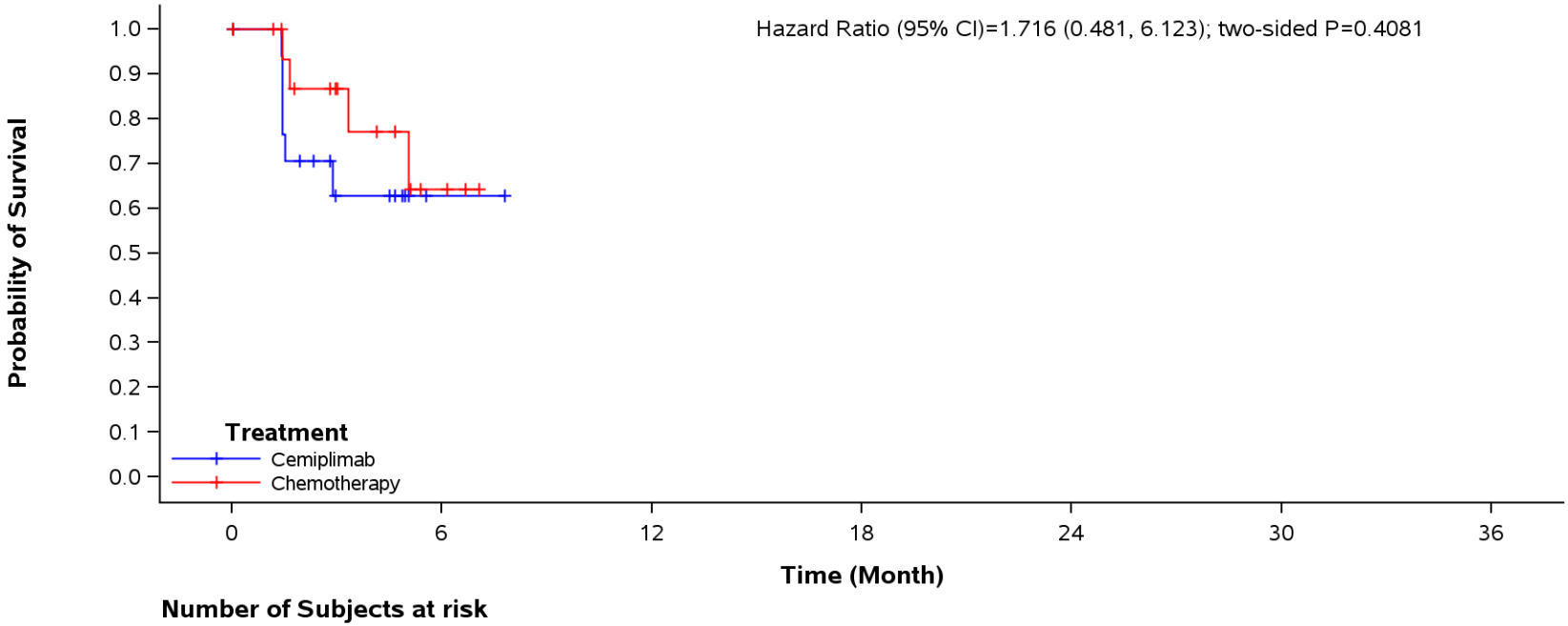

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 5 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts sustained improvement



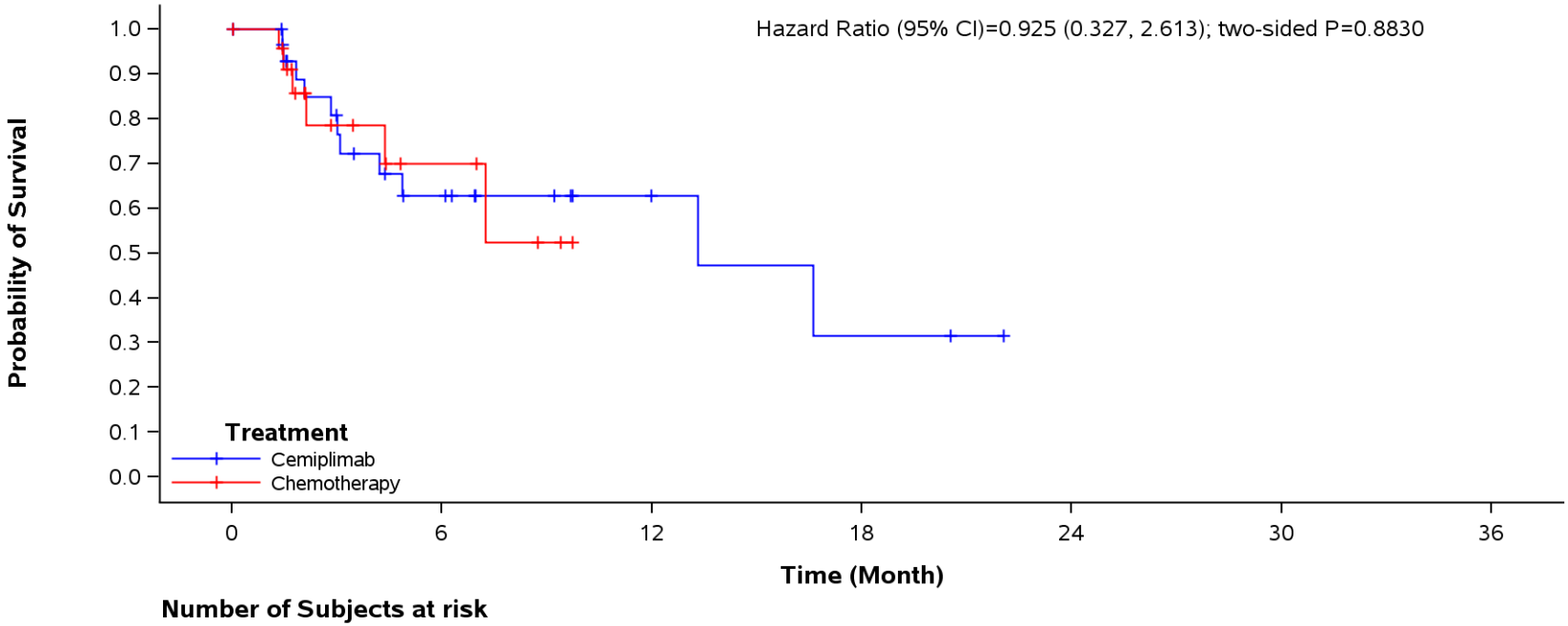

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts sustained improvement



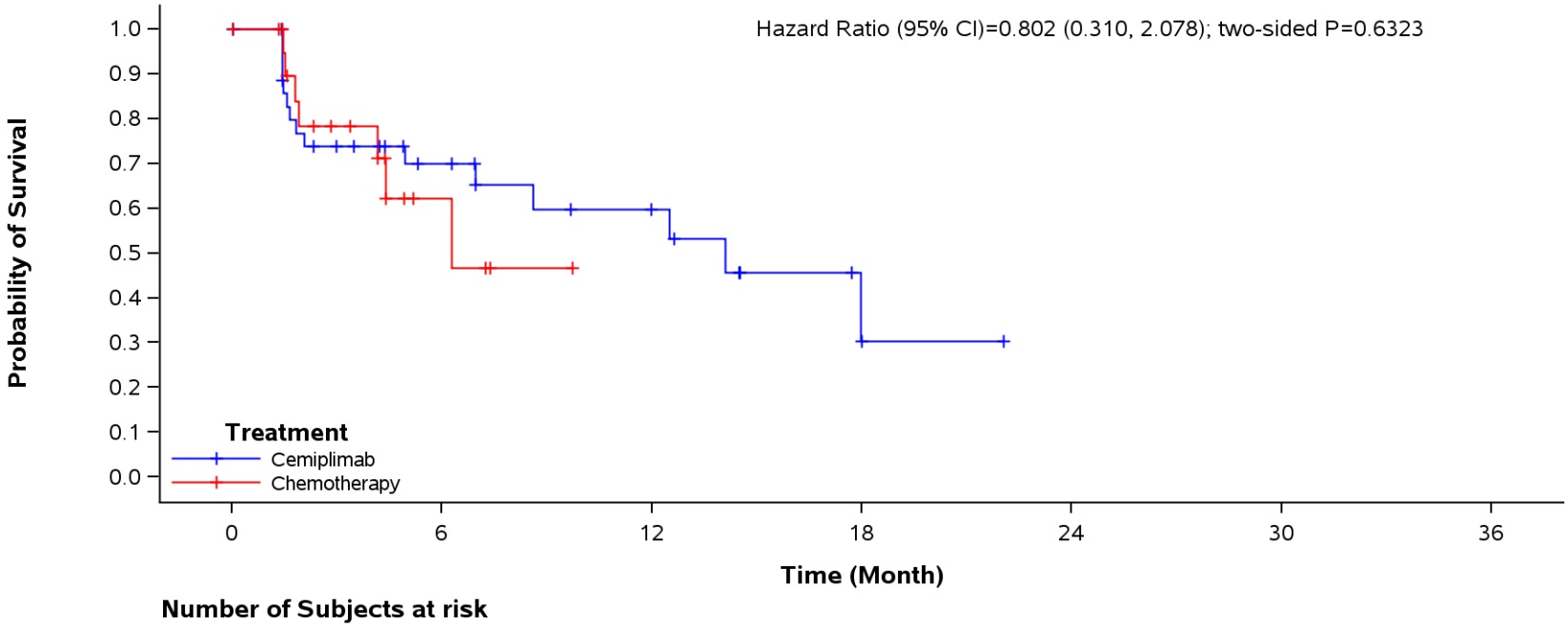

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 12 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts sustained improvement



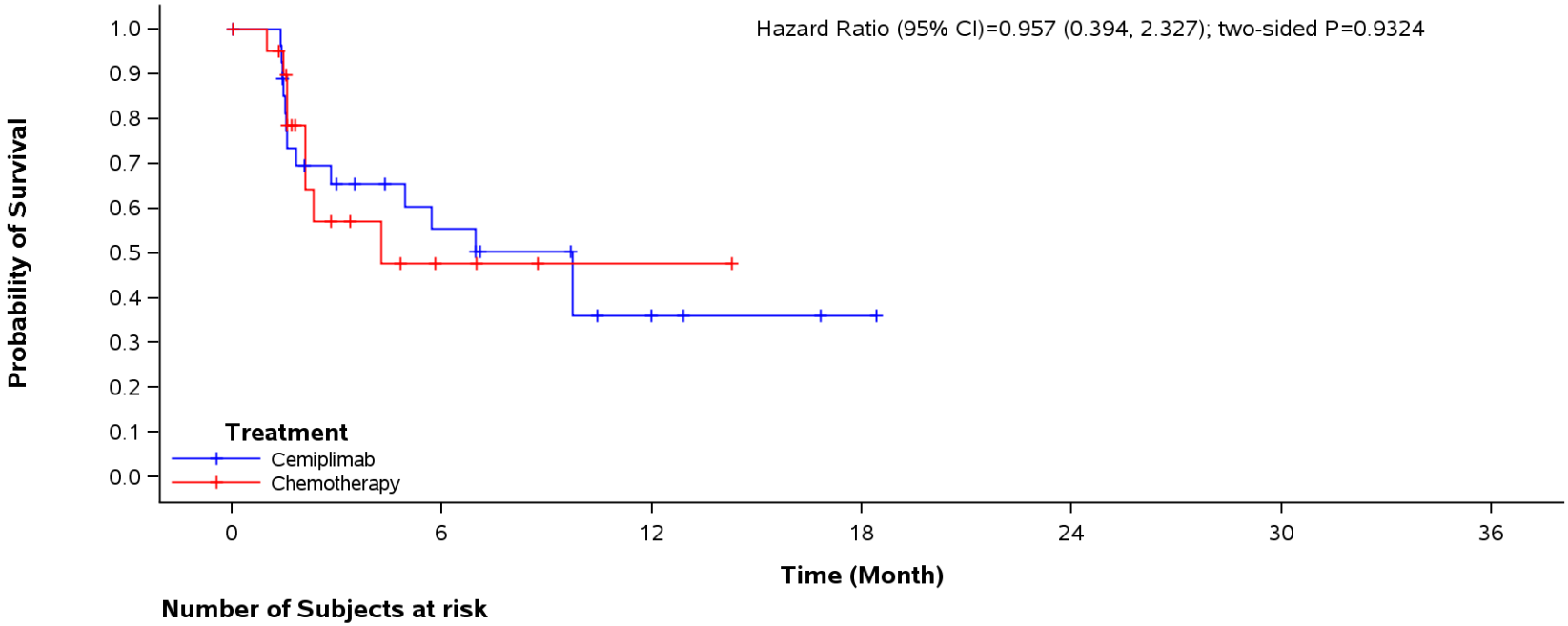

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 17 | 9 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts sustained improvement



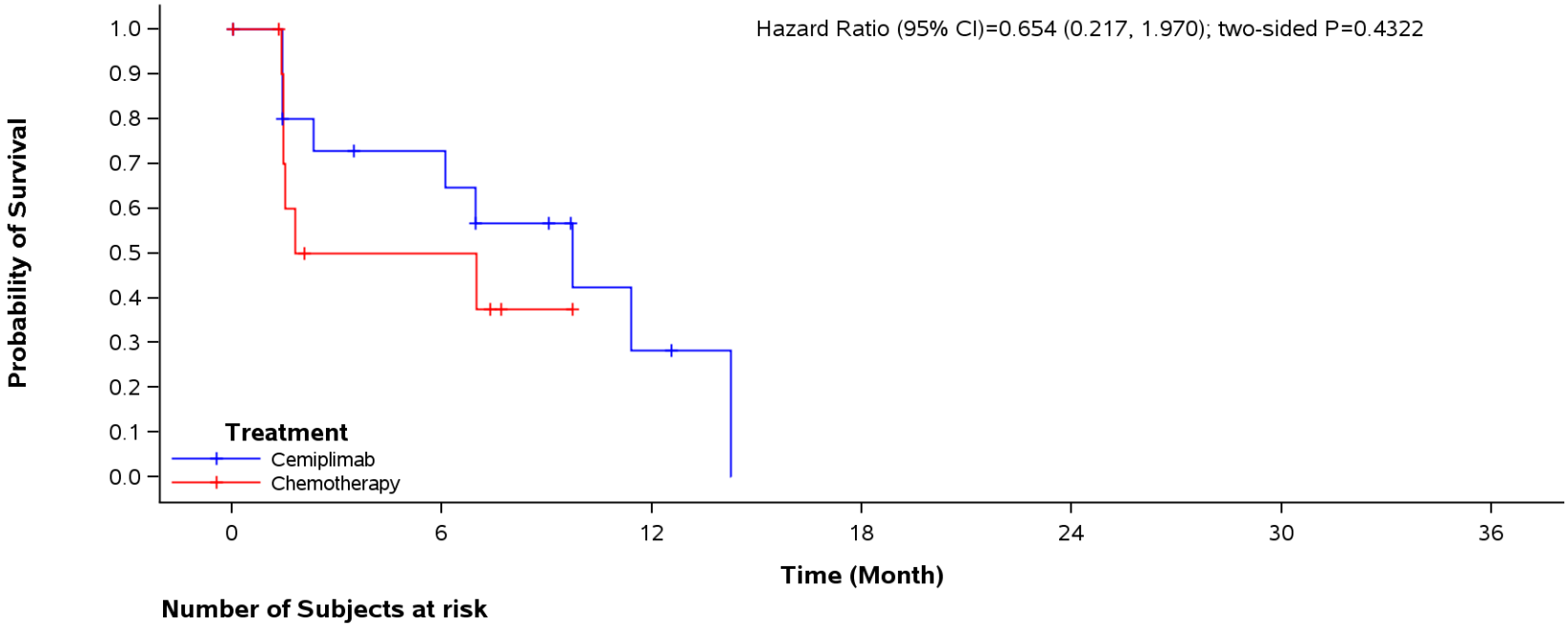

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 11 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts sustained improvement



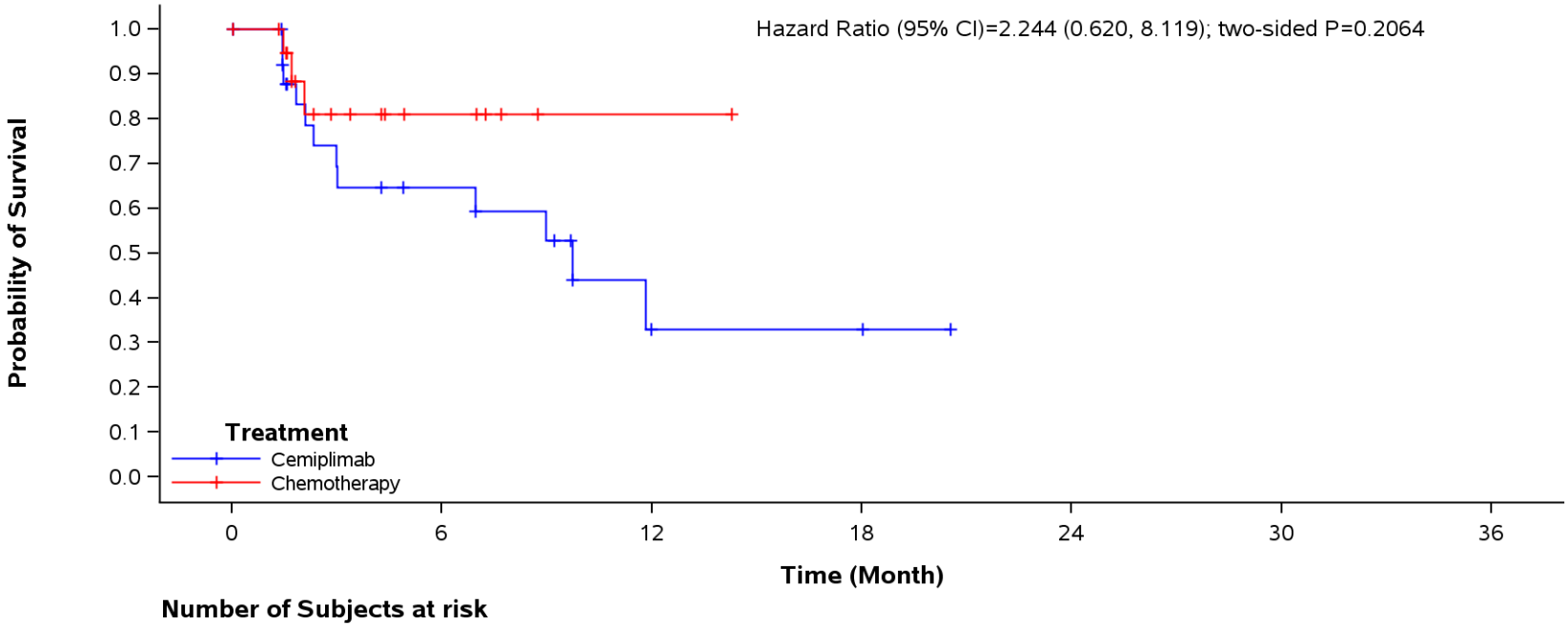

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 9 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts sustained improvement



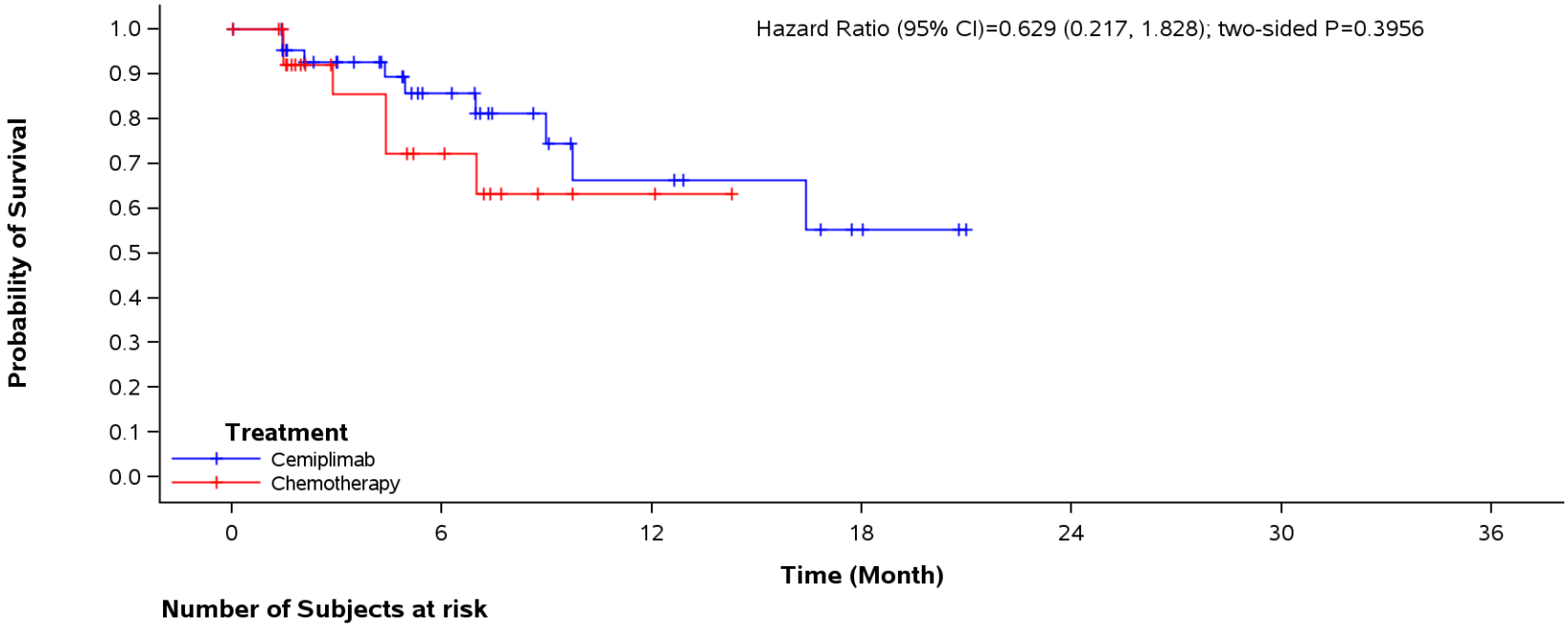

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 12 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts sustained improvement



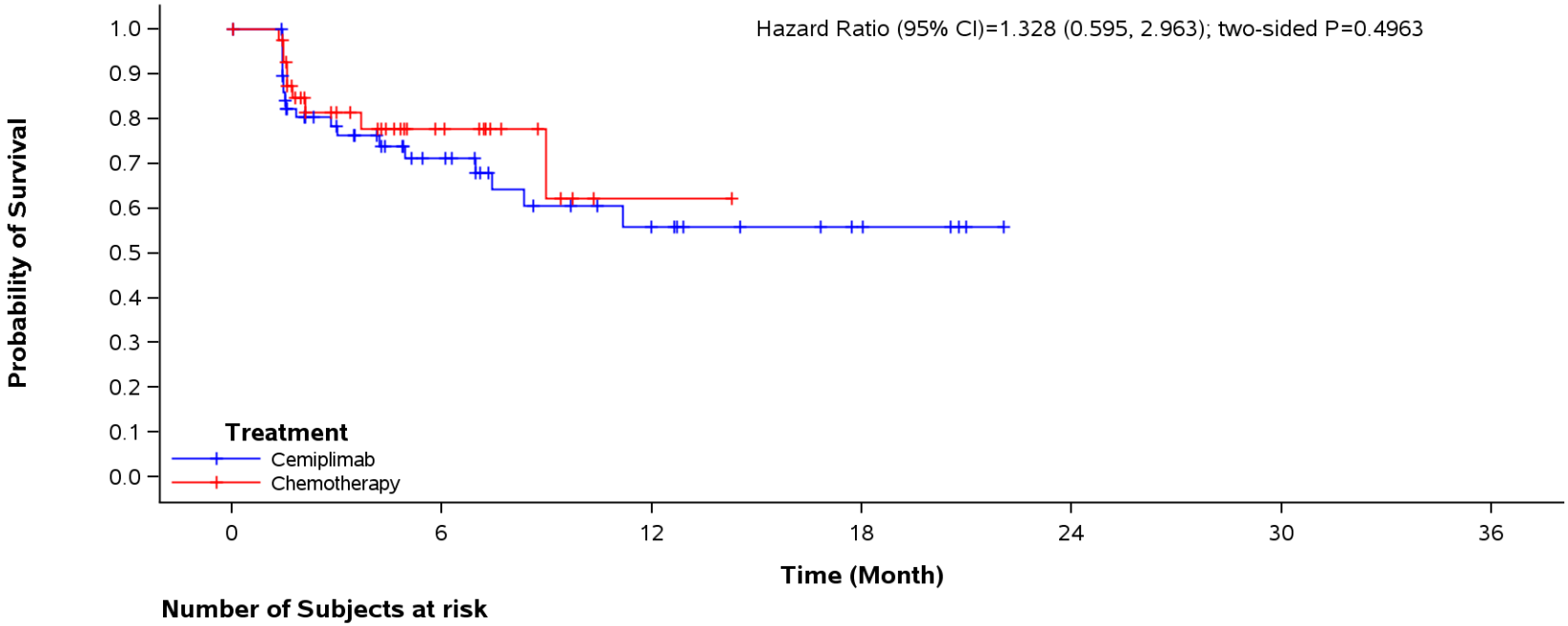

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 21 | 8 | 3 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts sustained improvement



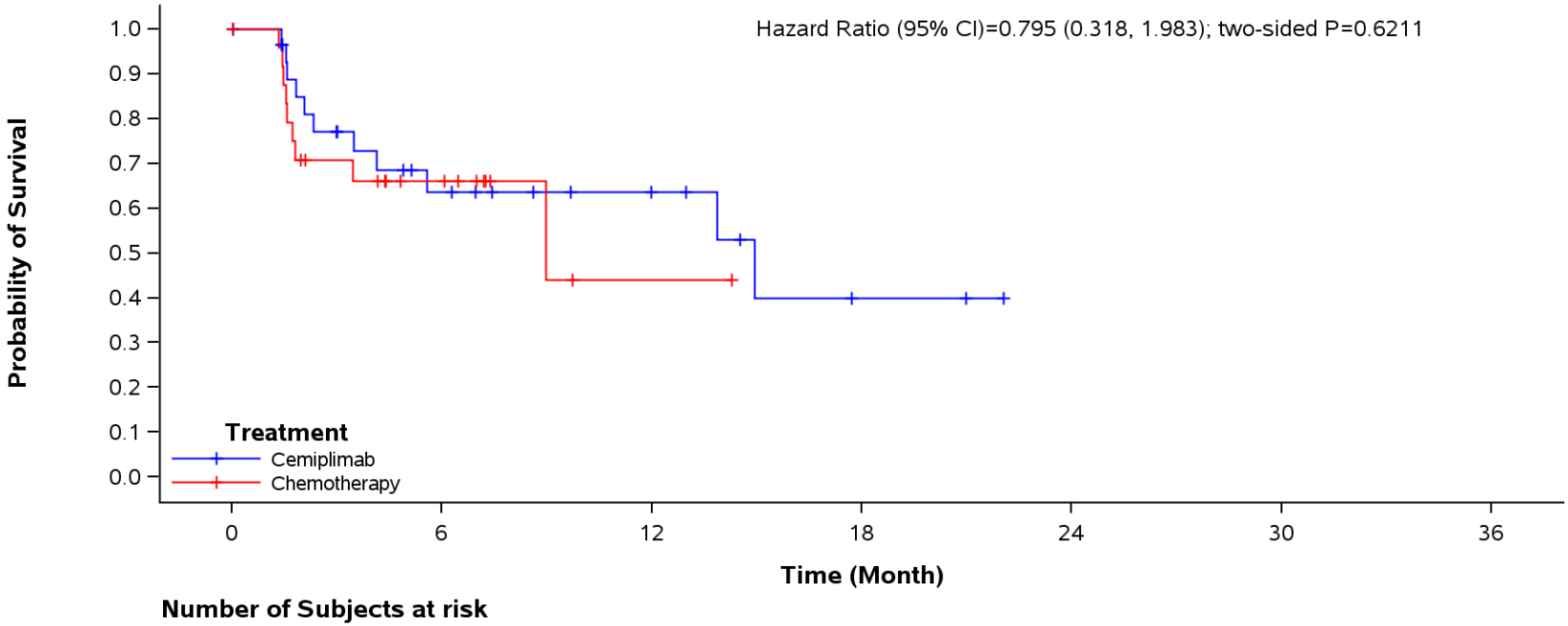

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 25 | 11 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts sustained improvement



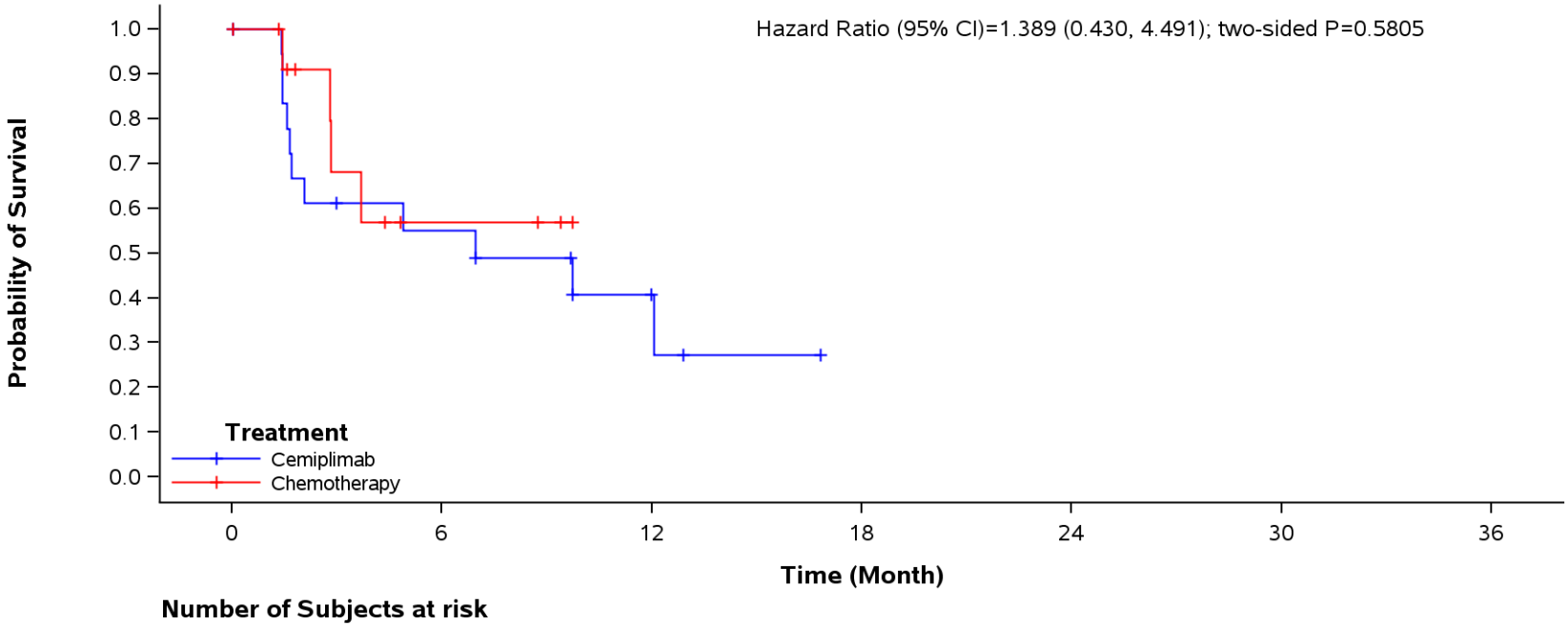

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 13 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts sustained improvement



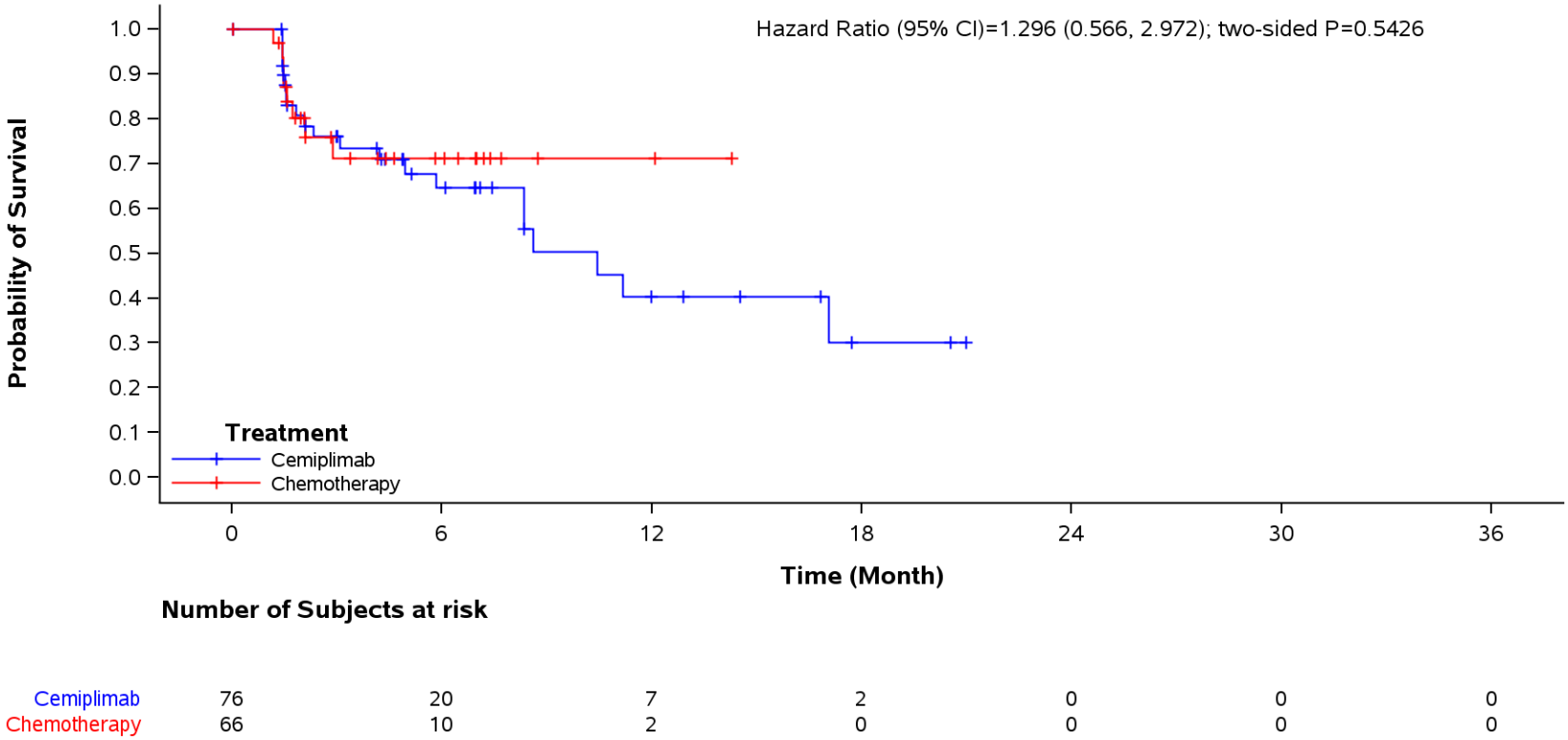

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 9 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts sustained improvement



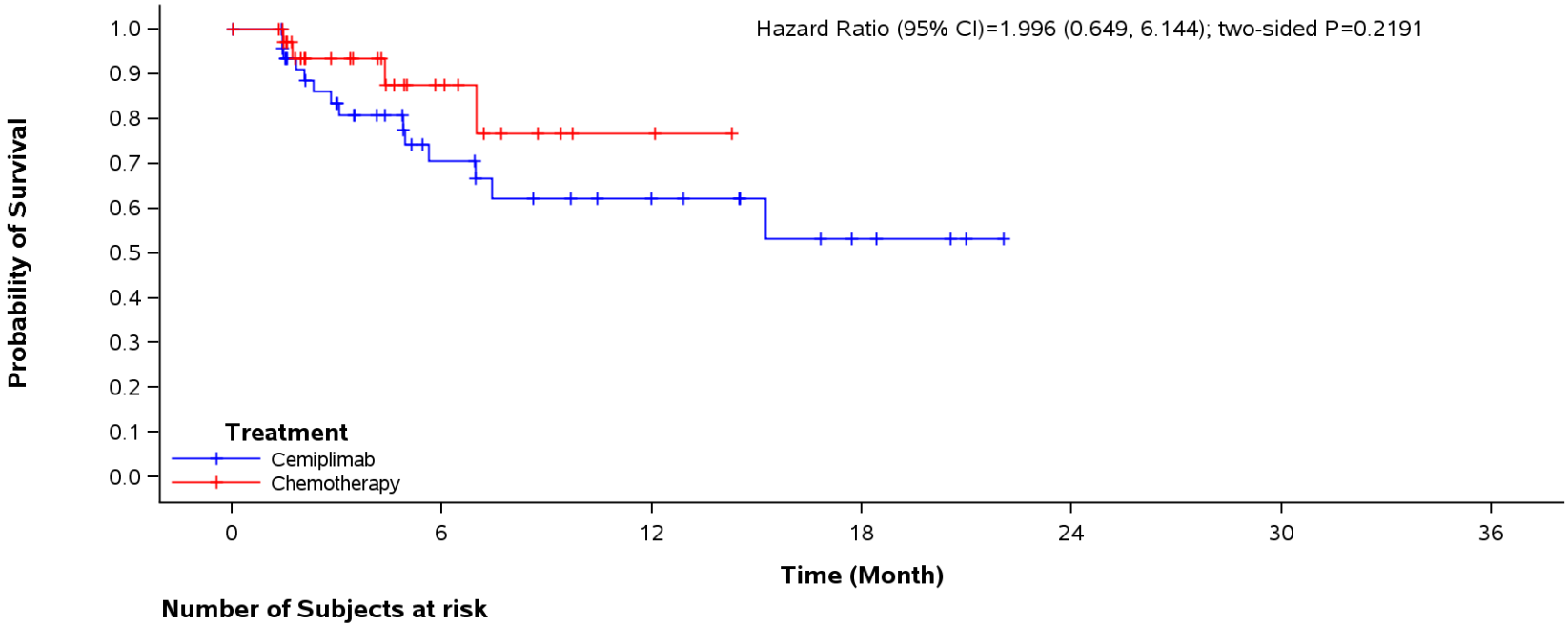

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 20 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts sustained improvement



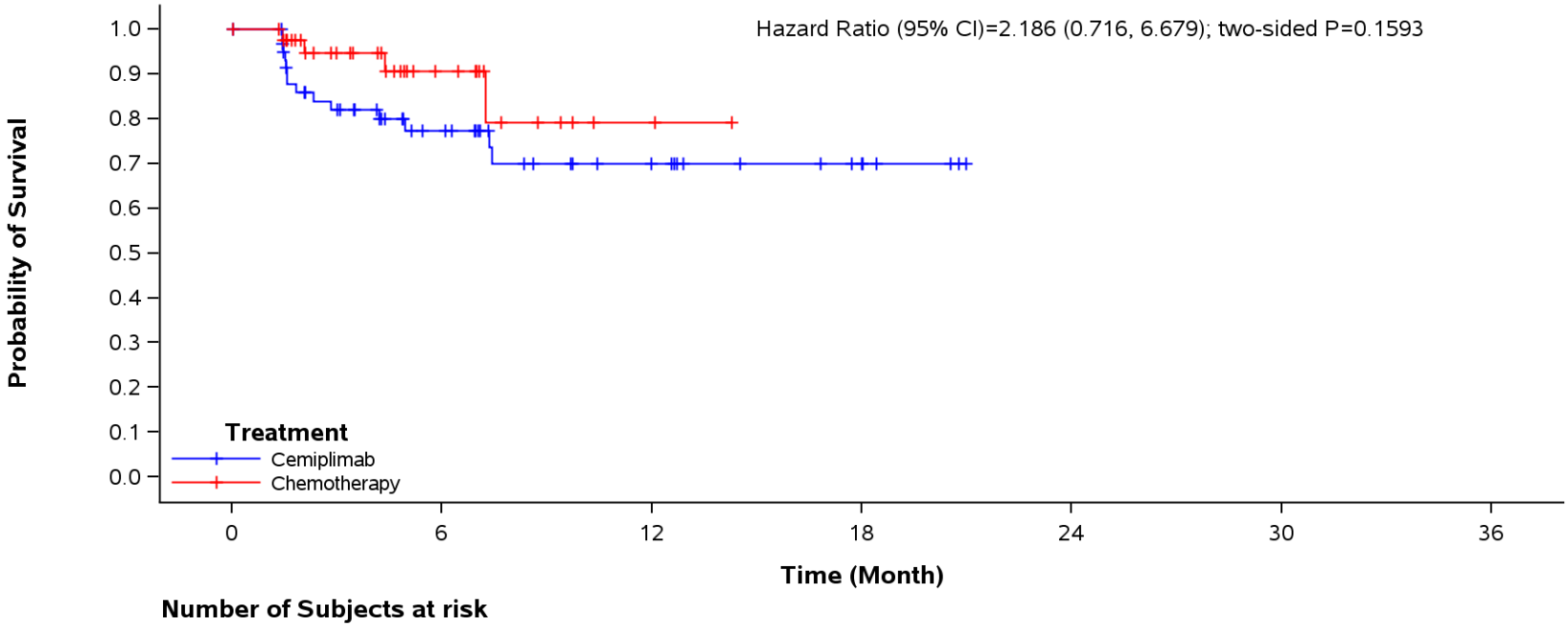

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 19 | 10 | 4 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts sustained improvement



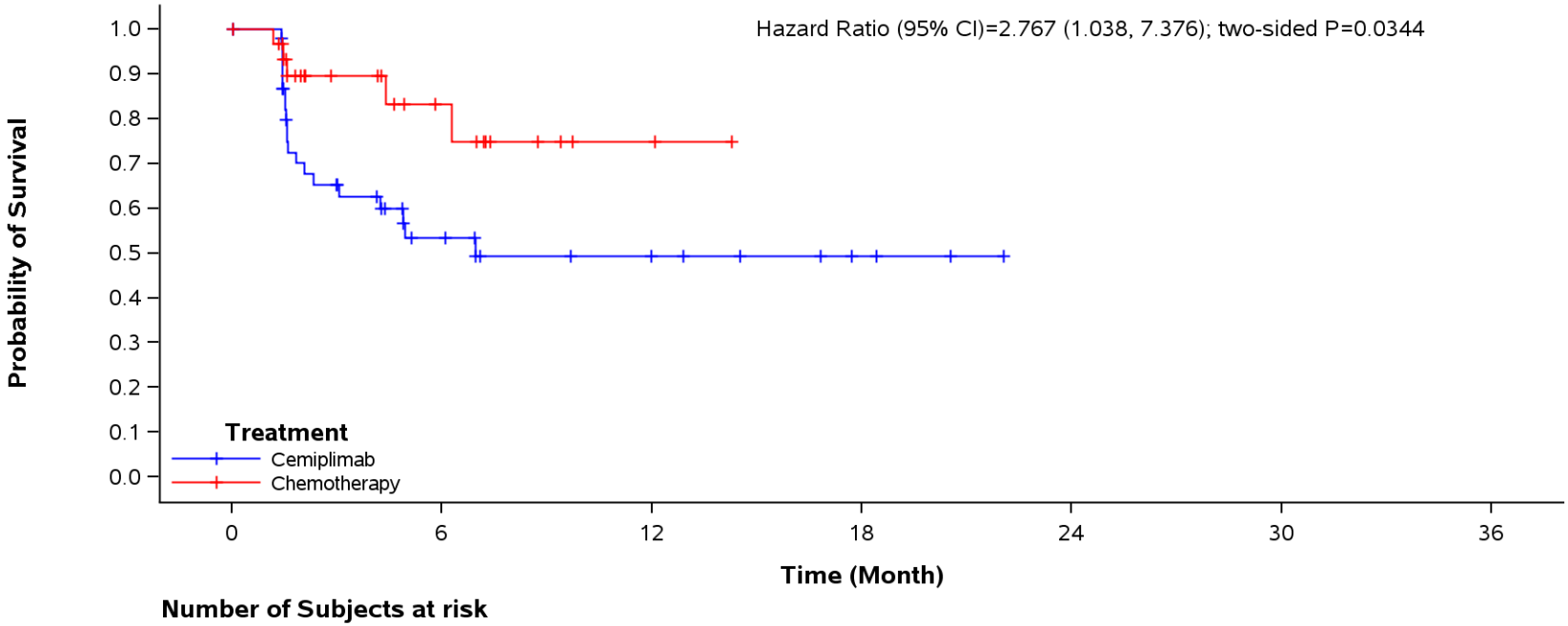

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 29 | 13 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts sustained improvement



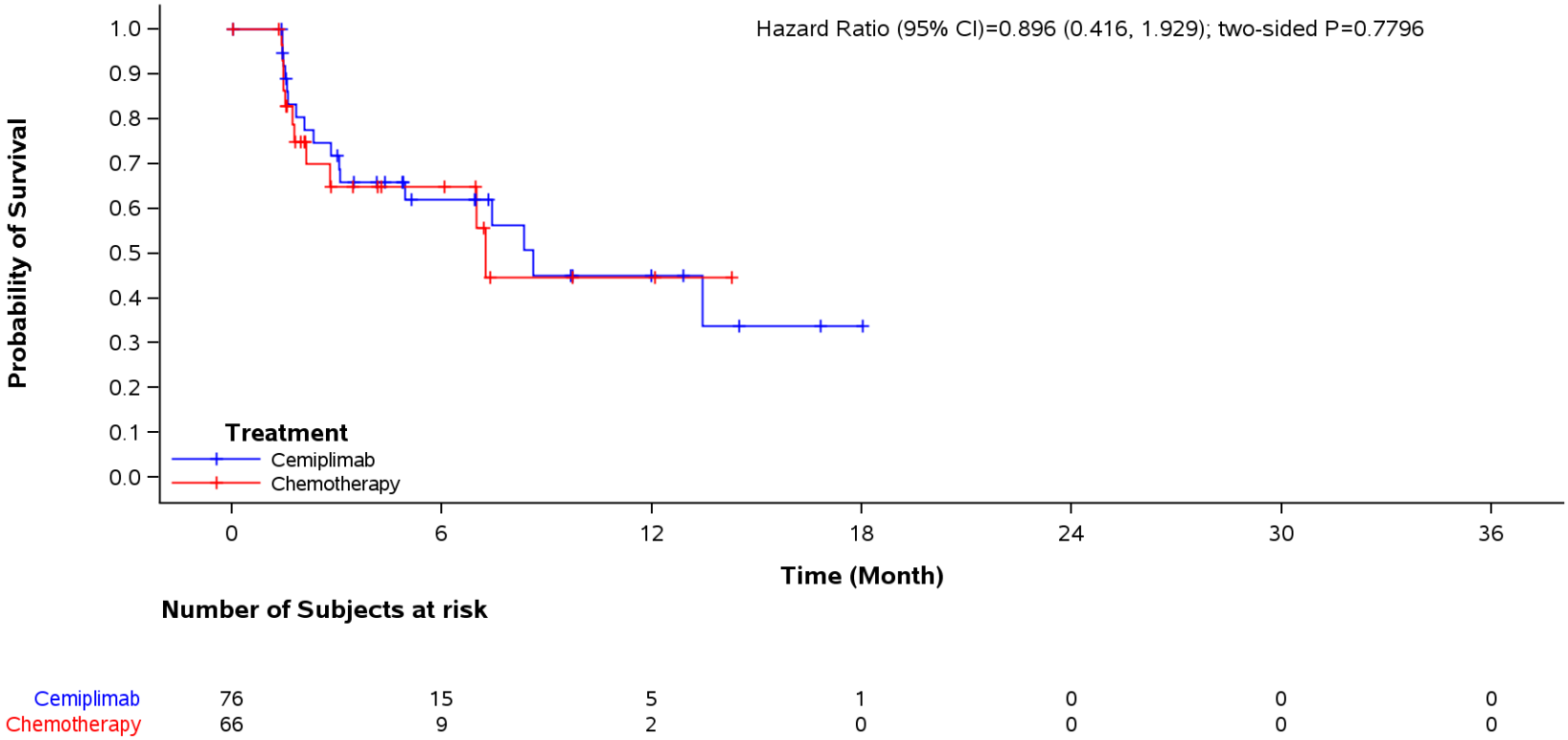

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 15 | 7 | 3 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts sustained improvement



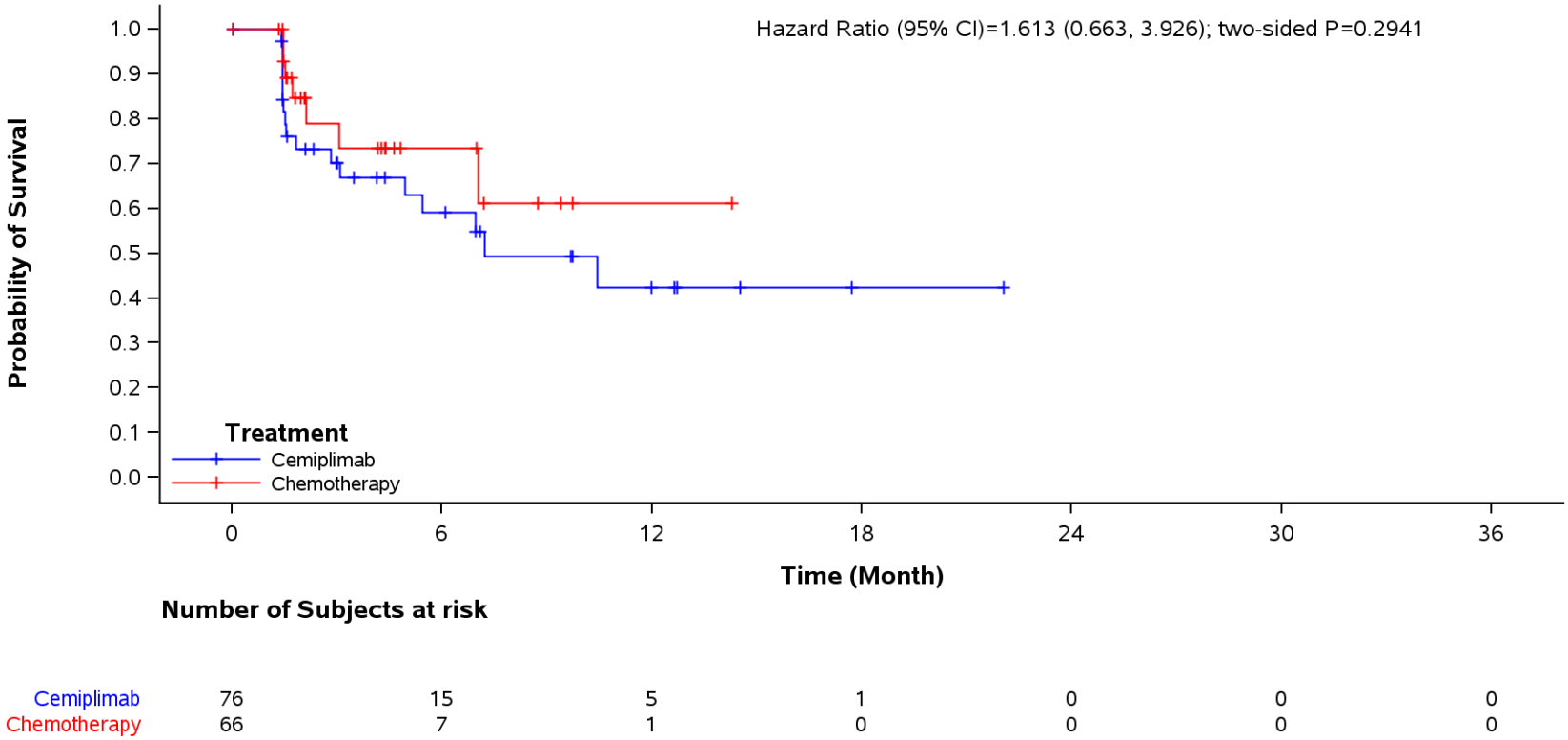

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 15 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts sustained improvement



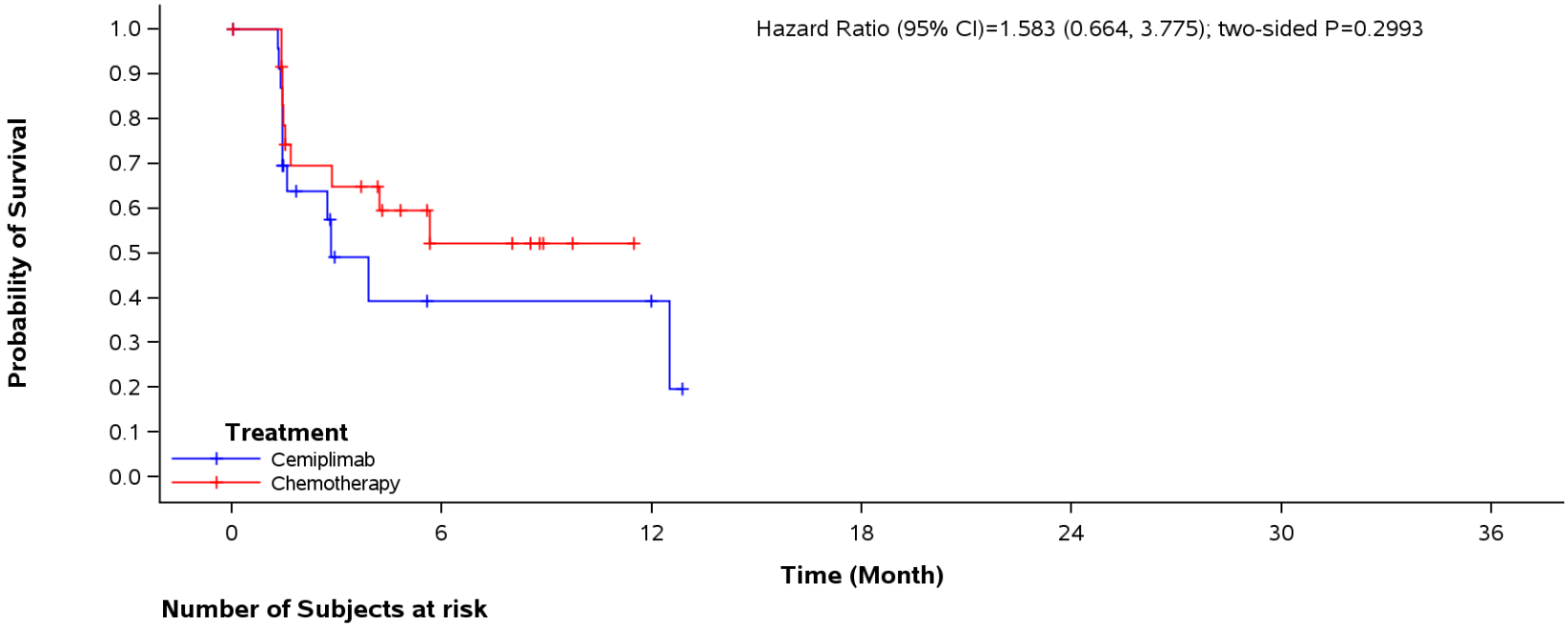

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 15 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts sustained improvement



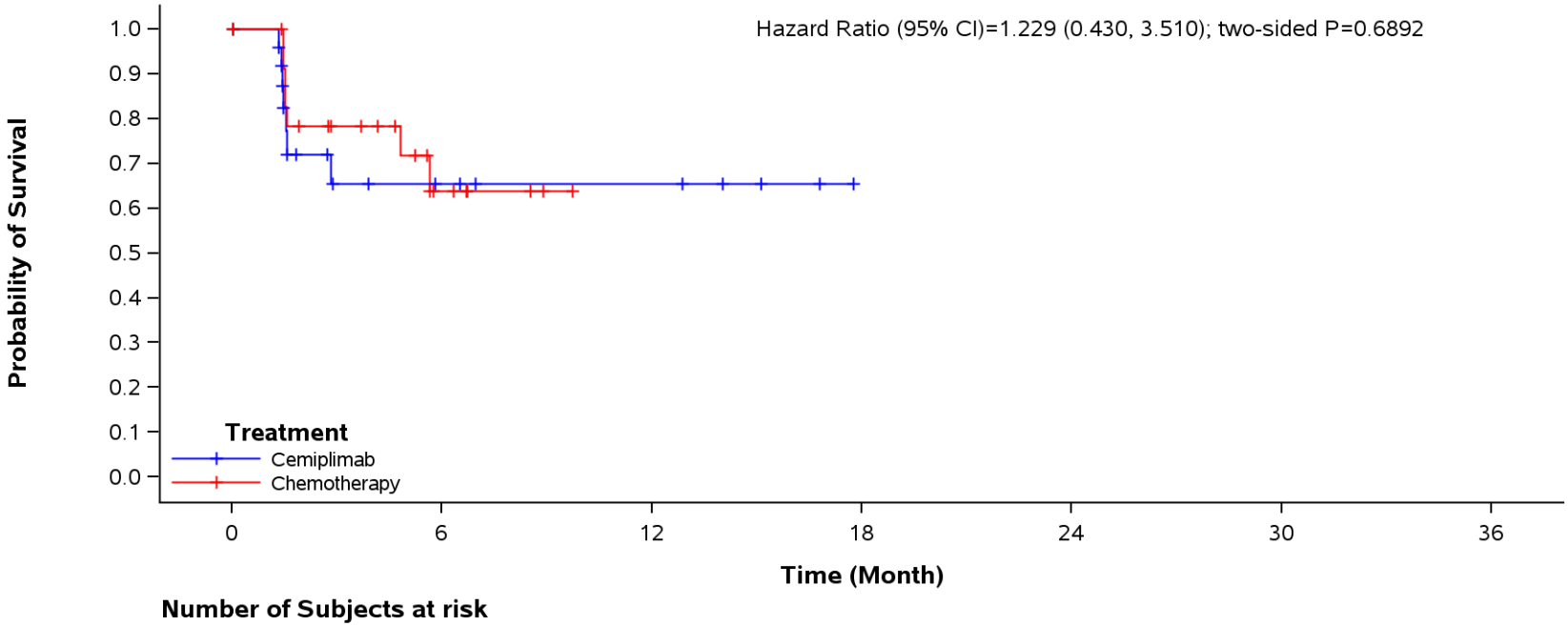

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts sustained improvement



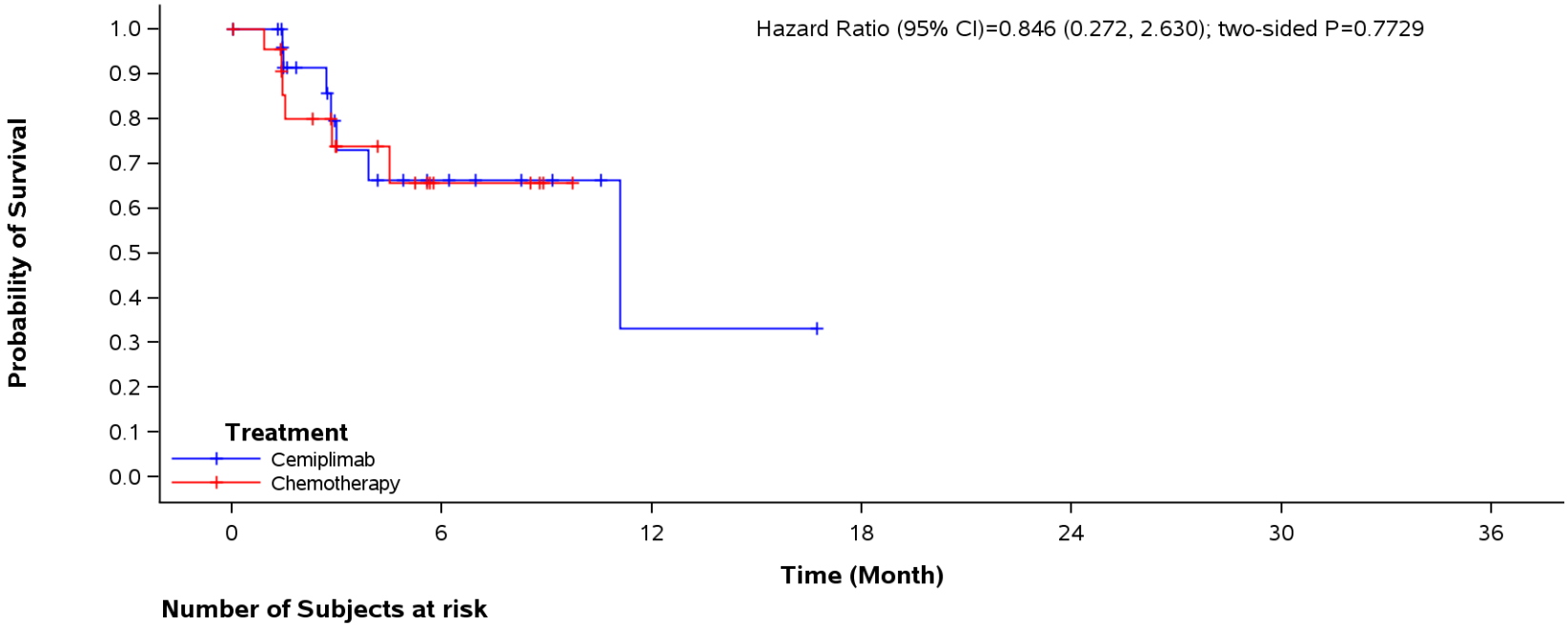

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 7 | 5 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts sustained improvement



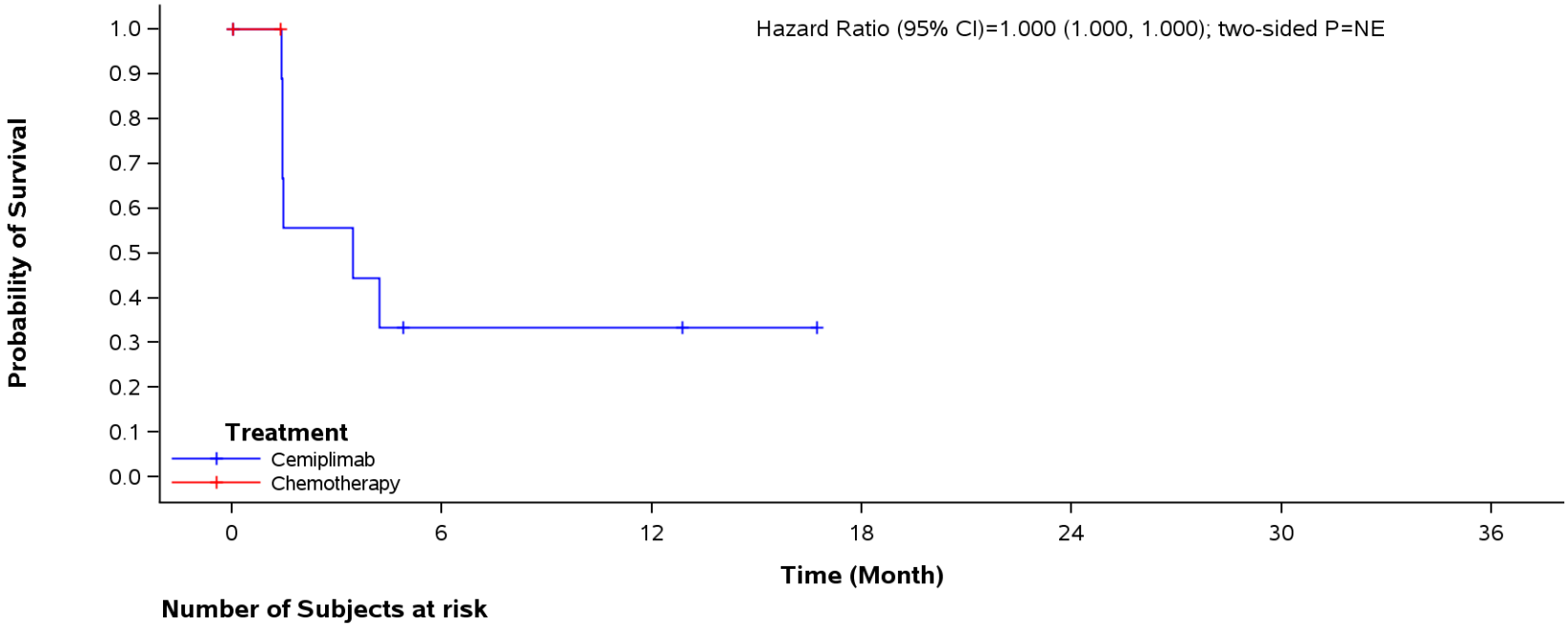

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 7 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts sustained improvement



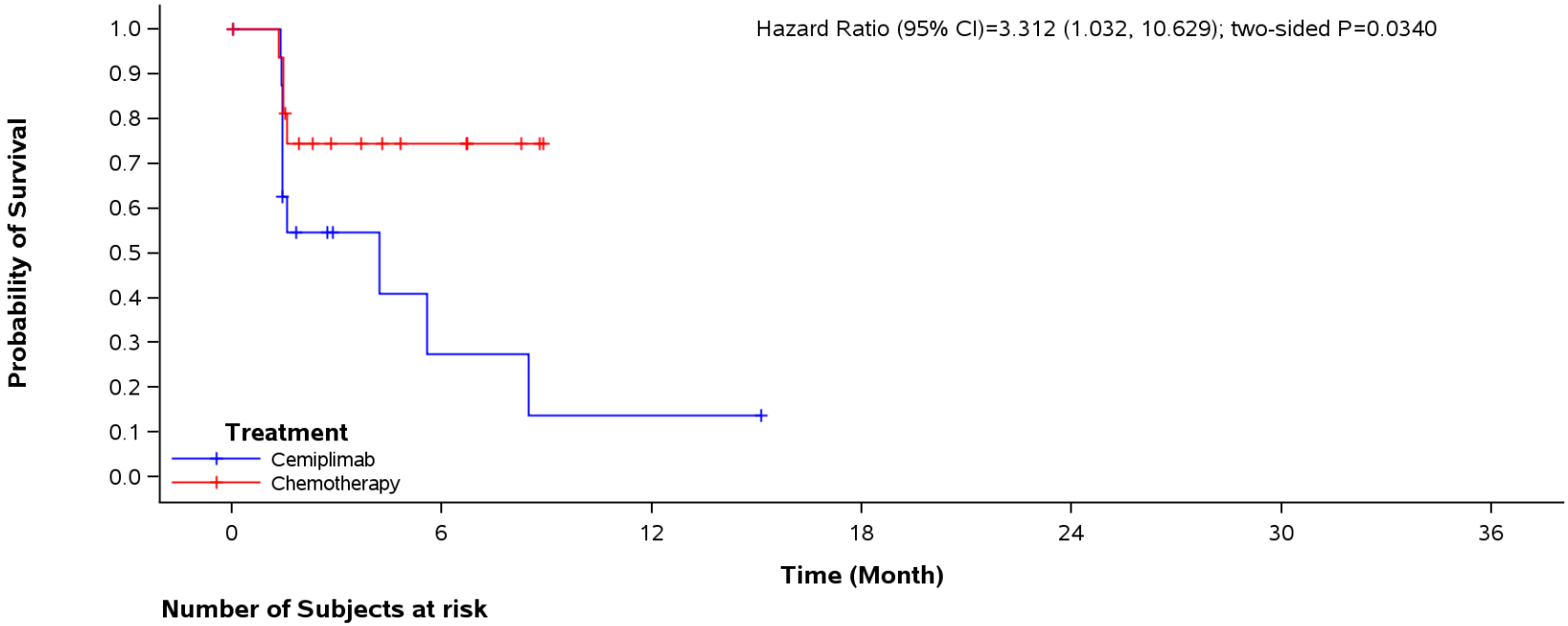

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 2 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts sustained improvement



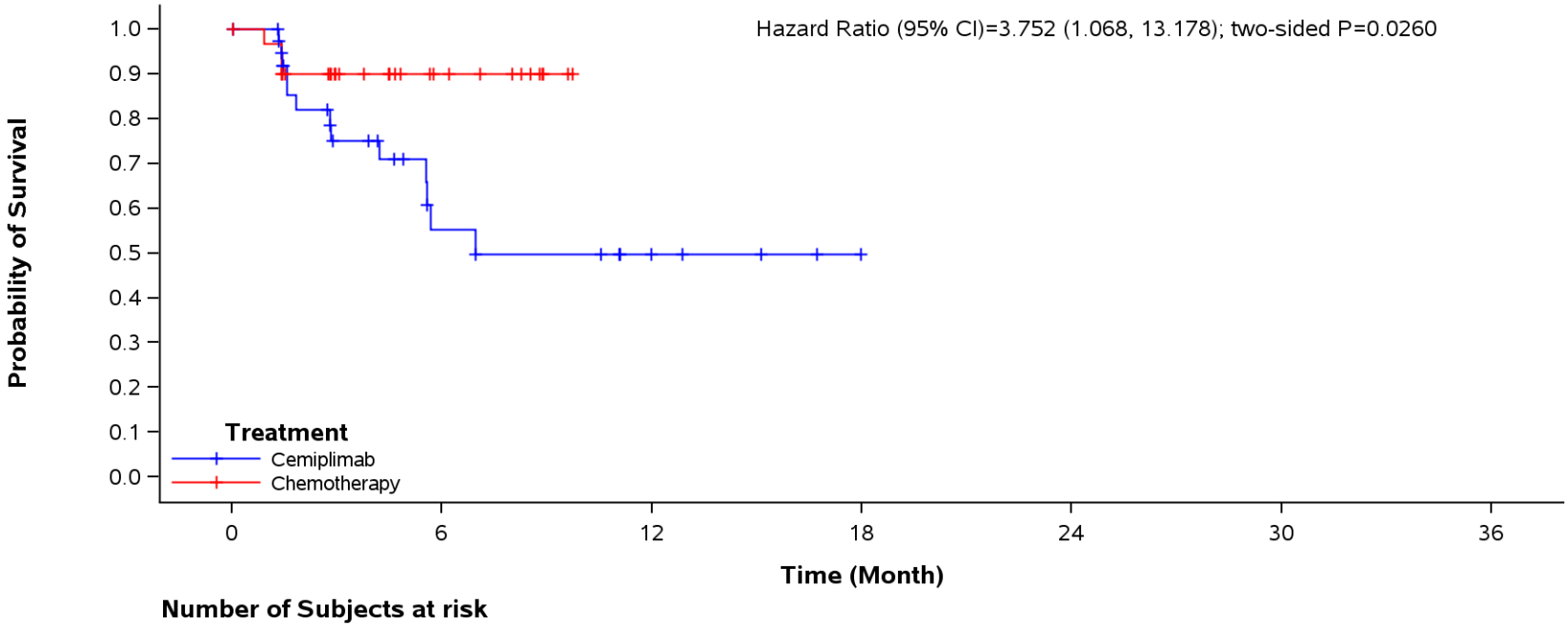

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts sustained improvement



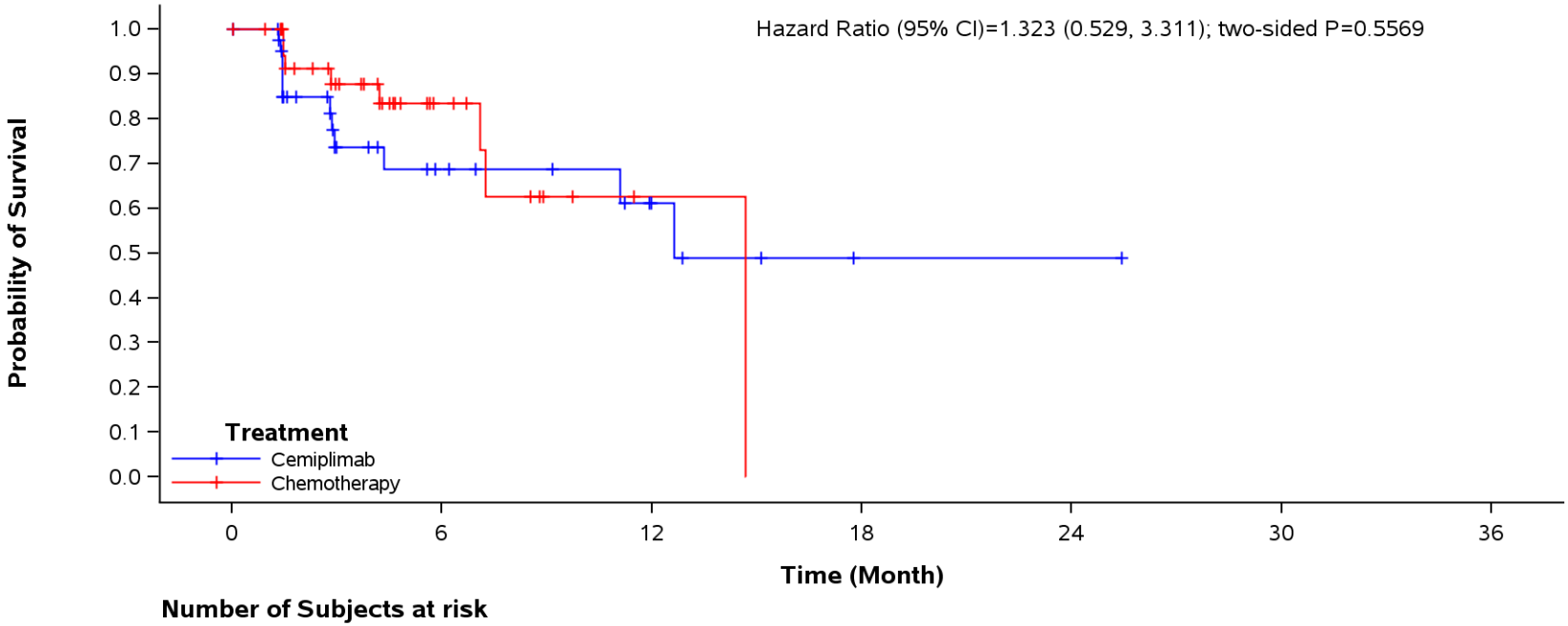

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 10 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts sustained improvement



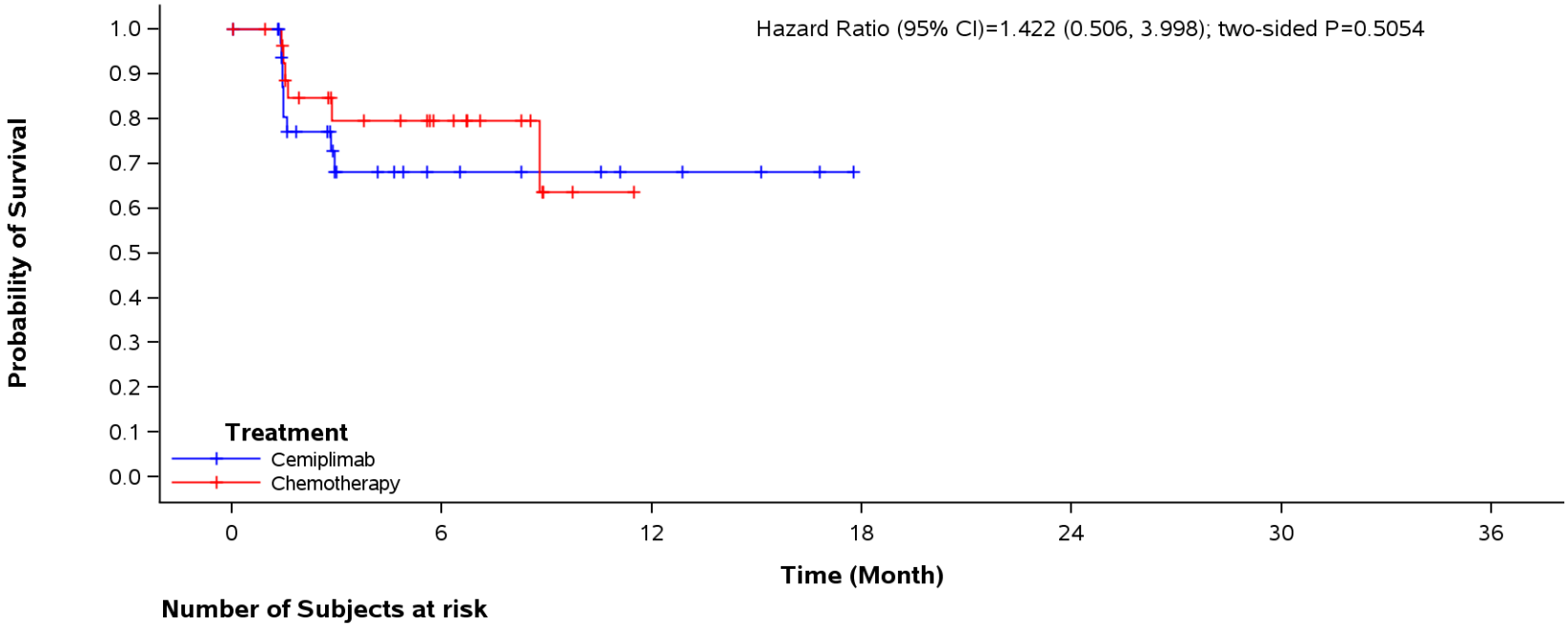

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts sustained improvement



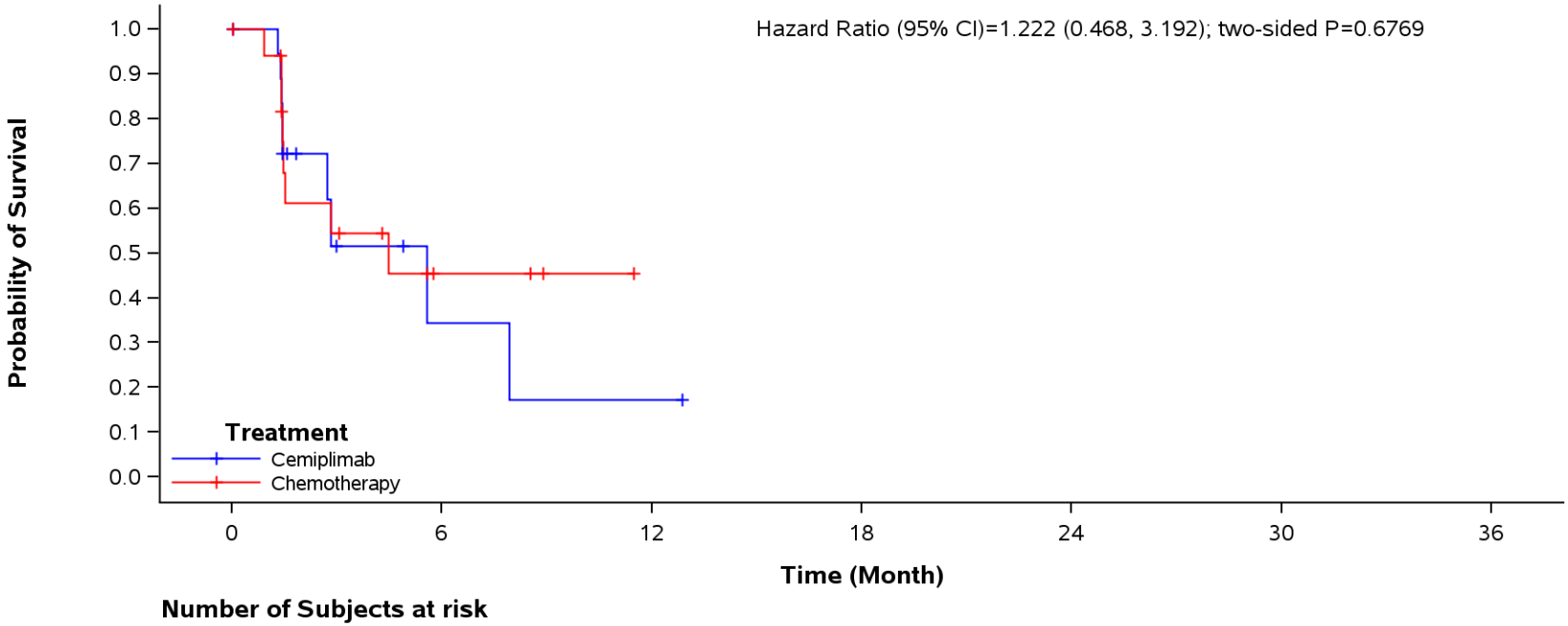

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 8 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts sustained improvement



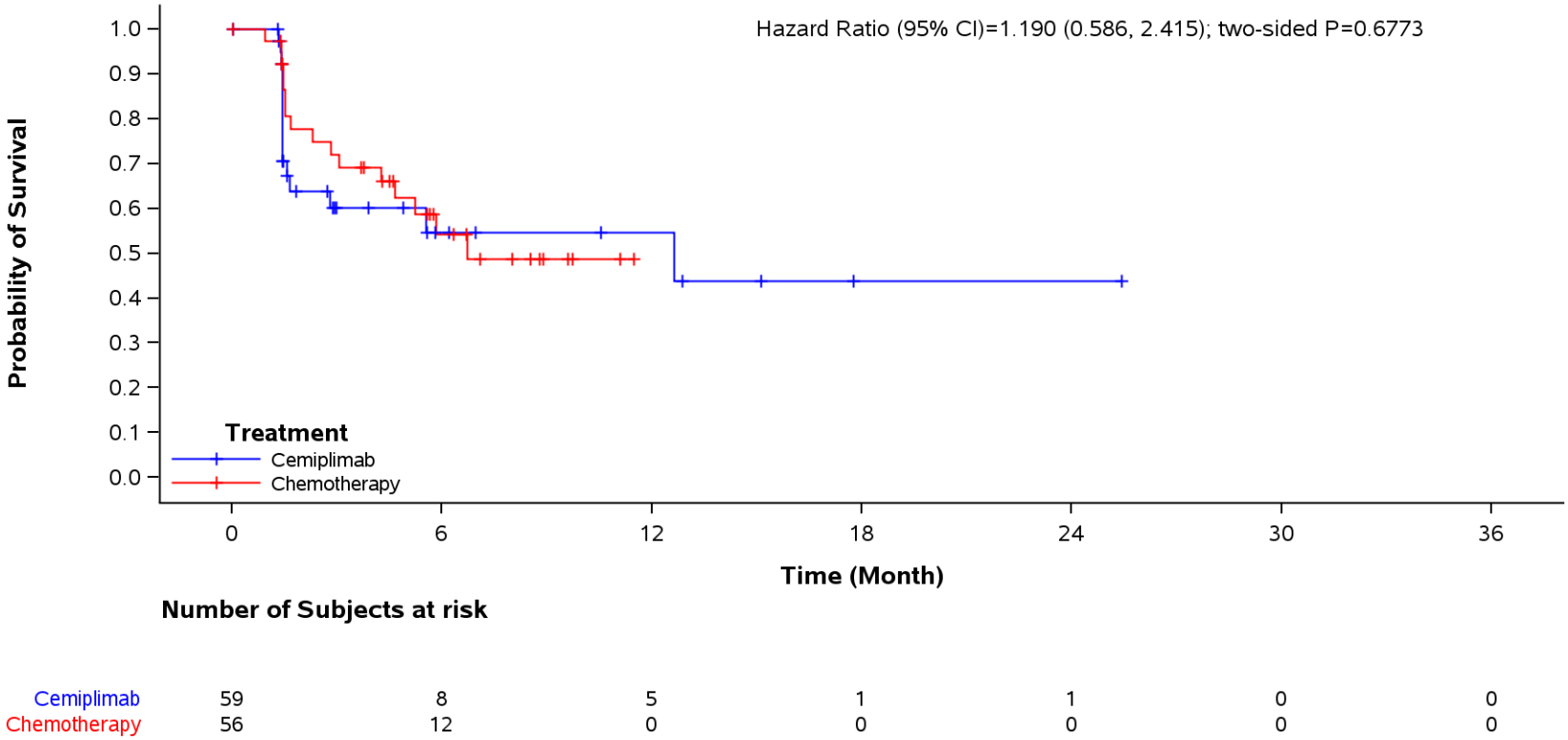

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts sustained improvement



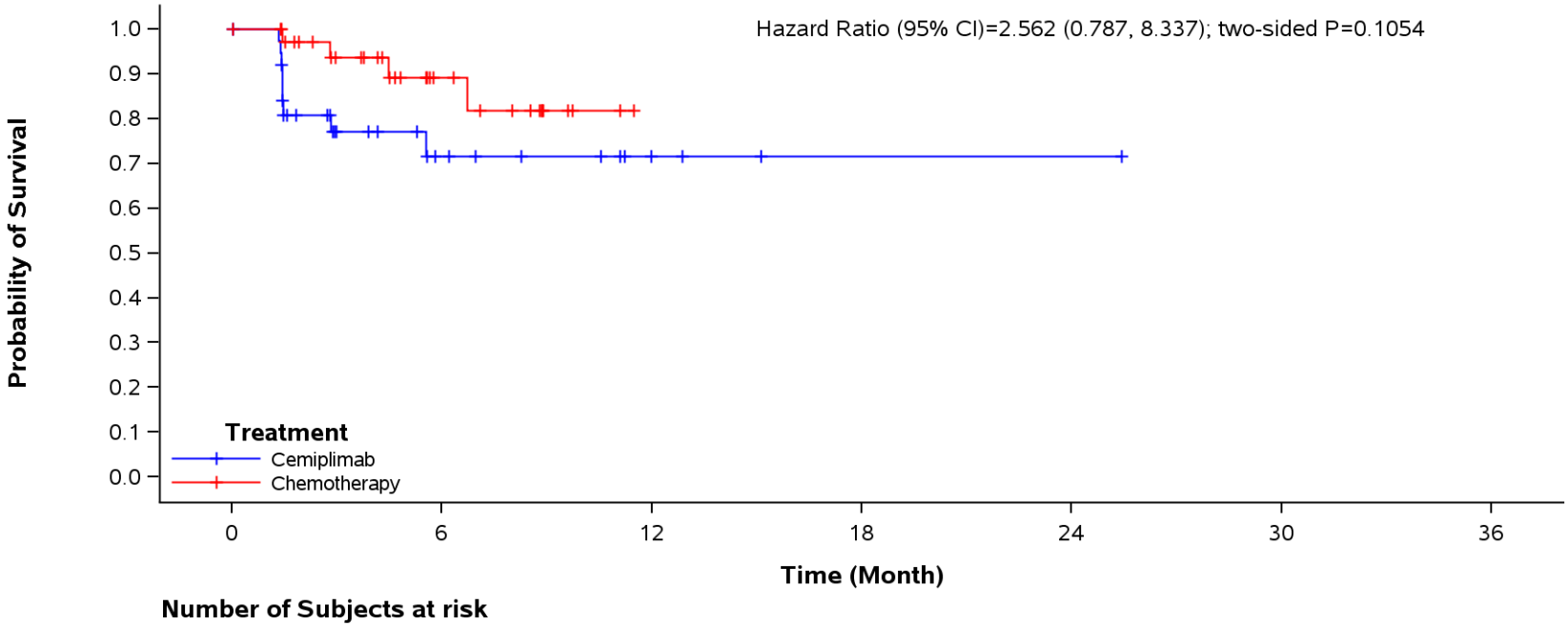

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 8 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts sustained improvement



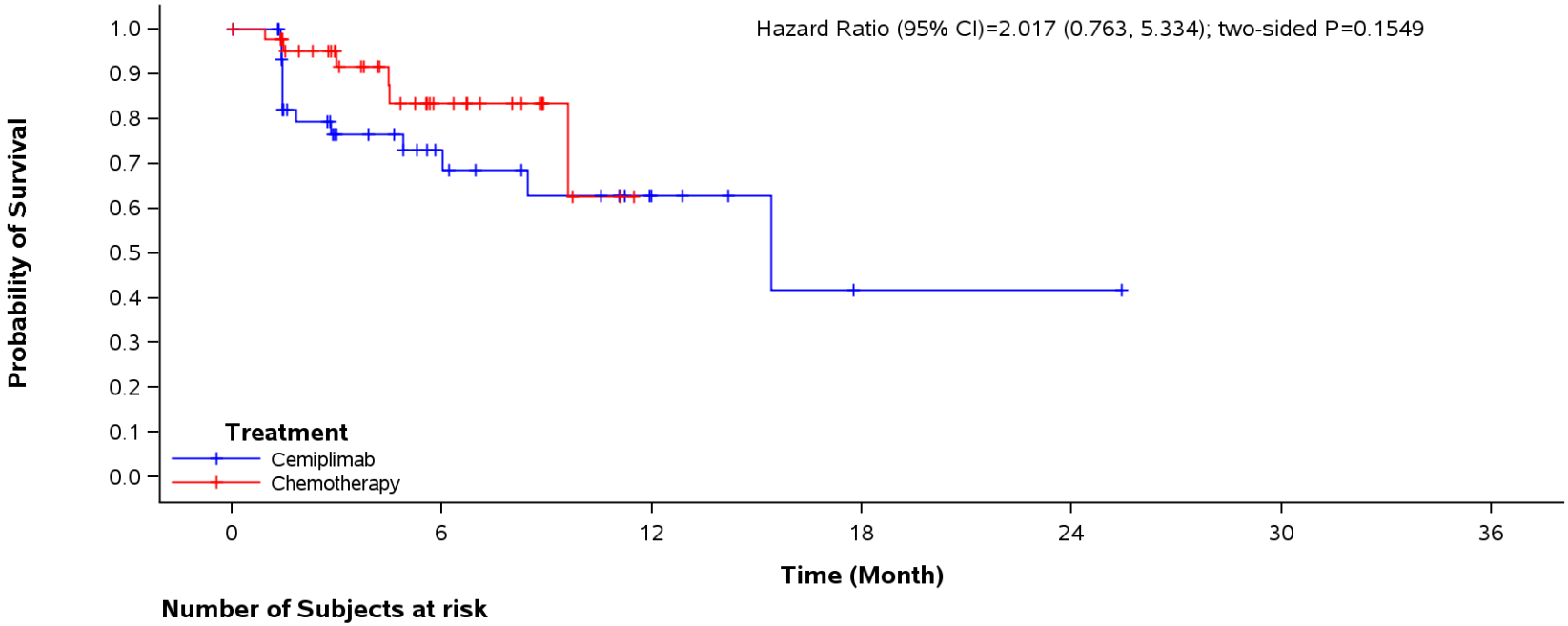

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 10 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts sustained improvement



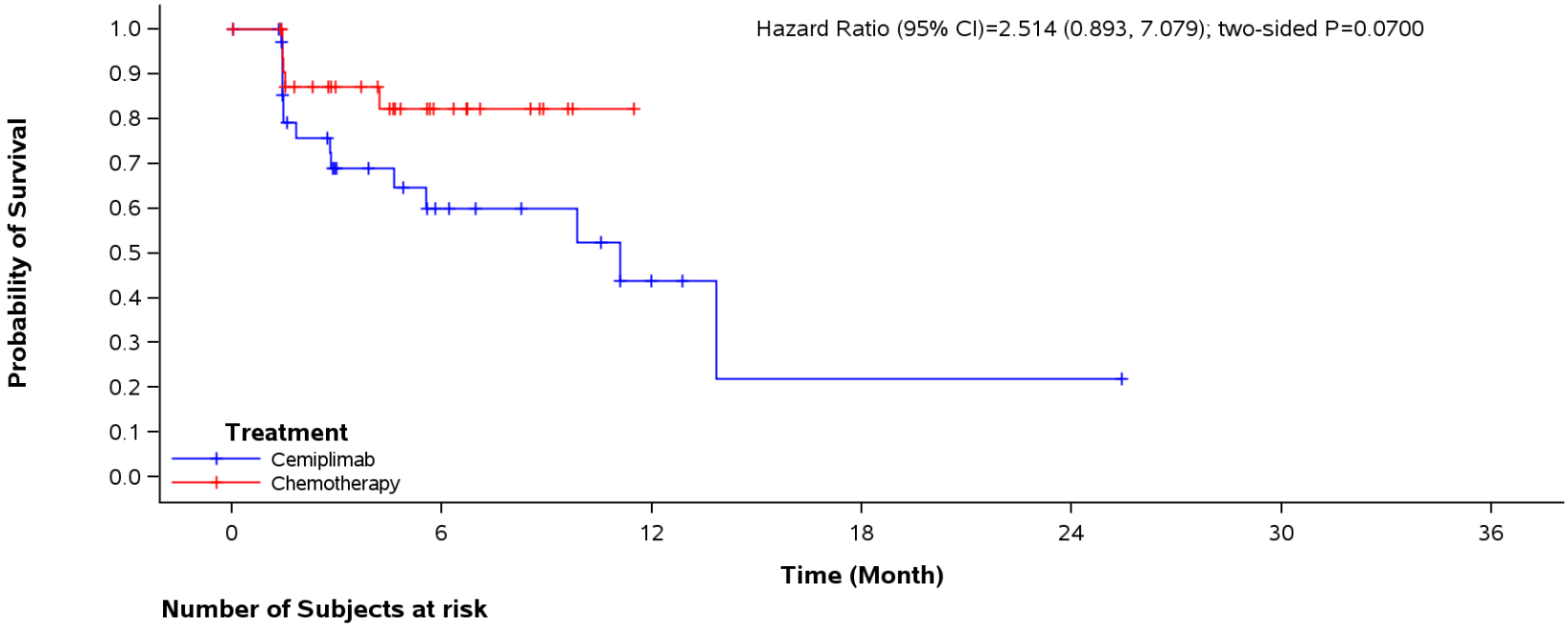

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 16 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts sustained improvement



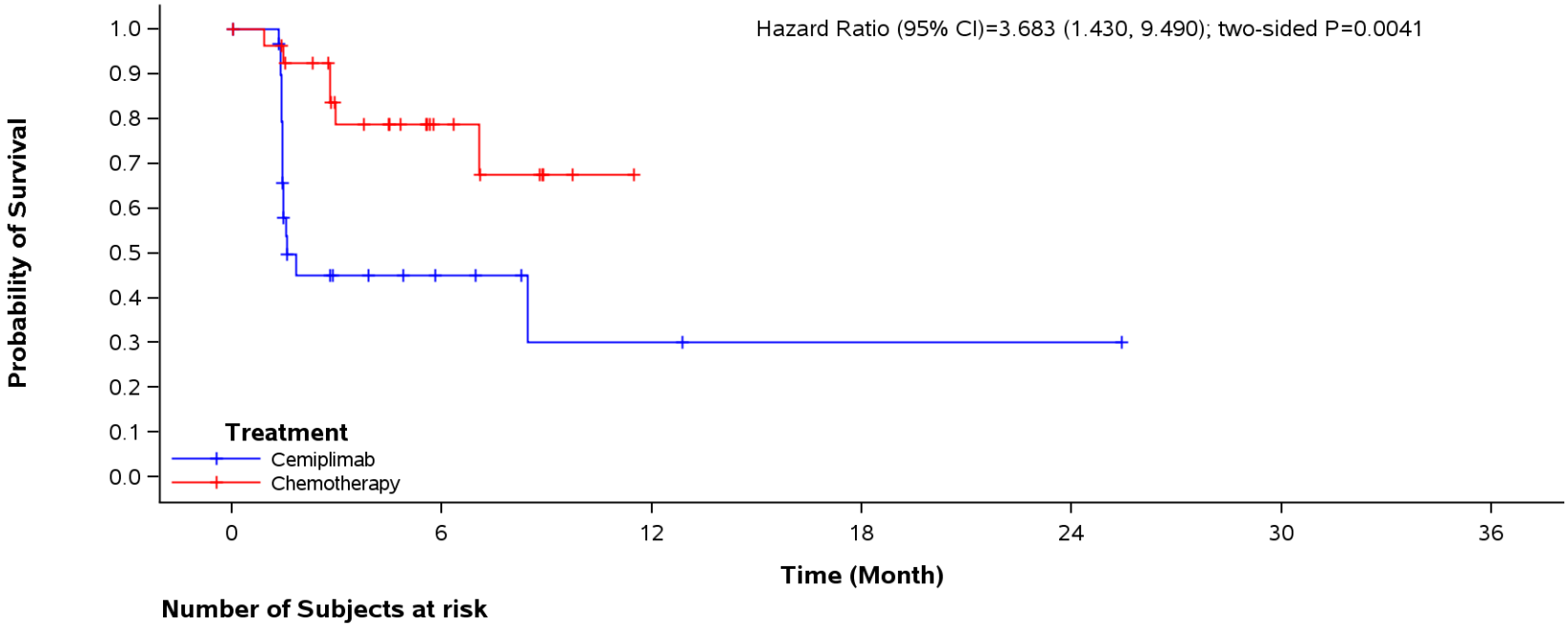

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 11 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts sustained improvement



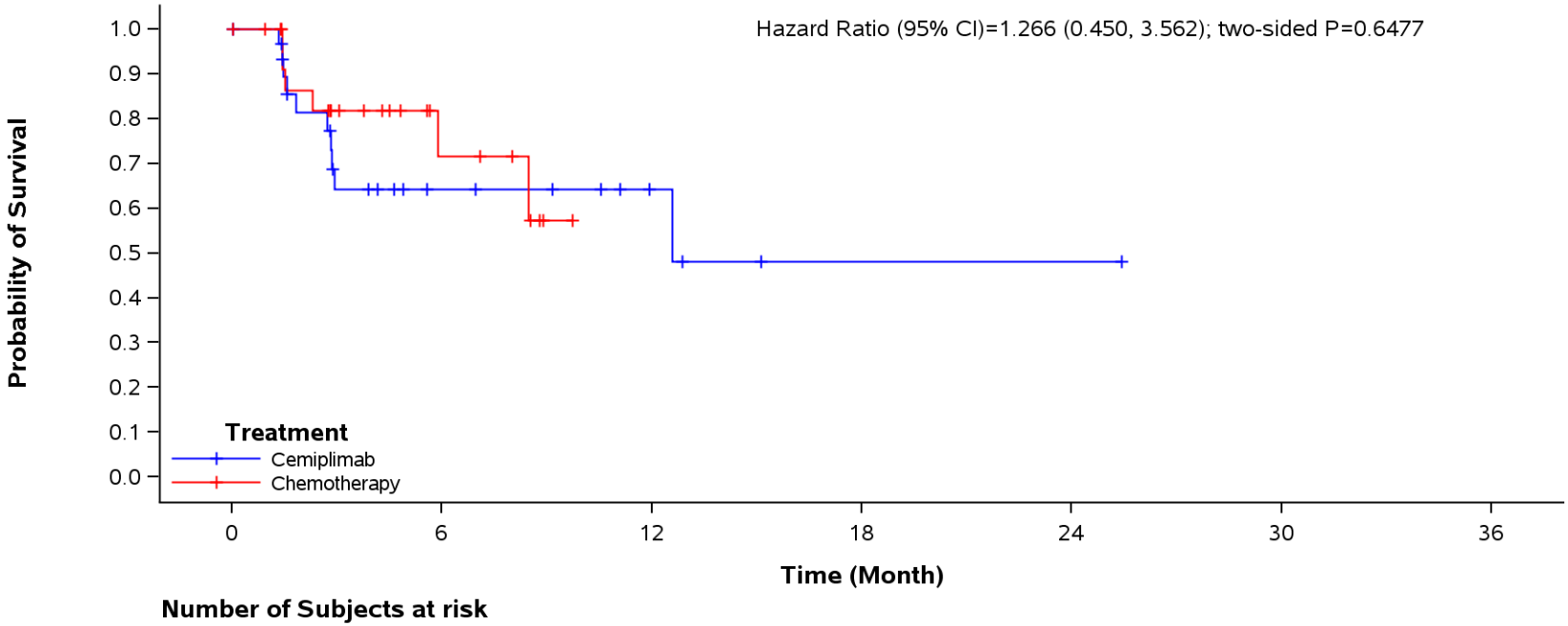

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 5 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts sustained improvement



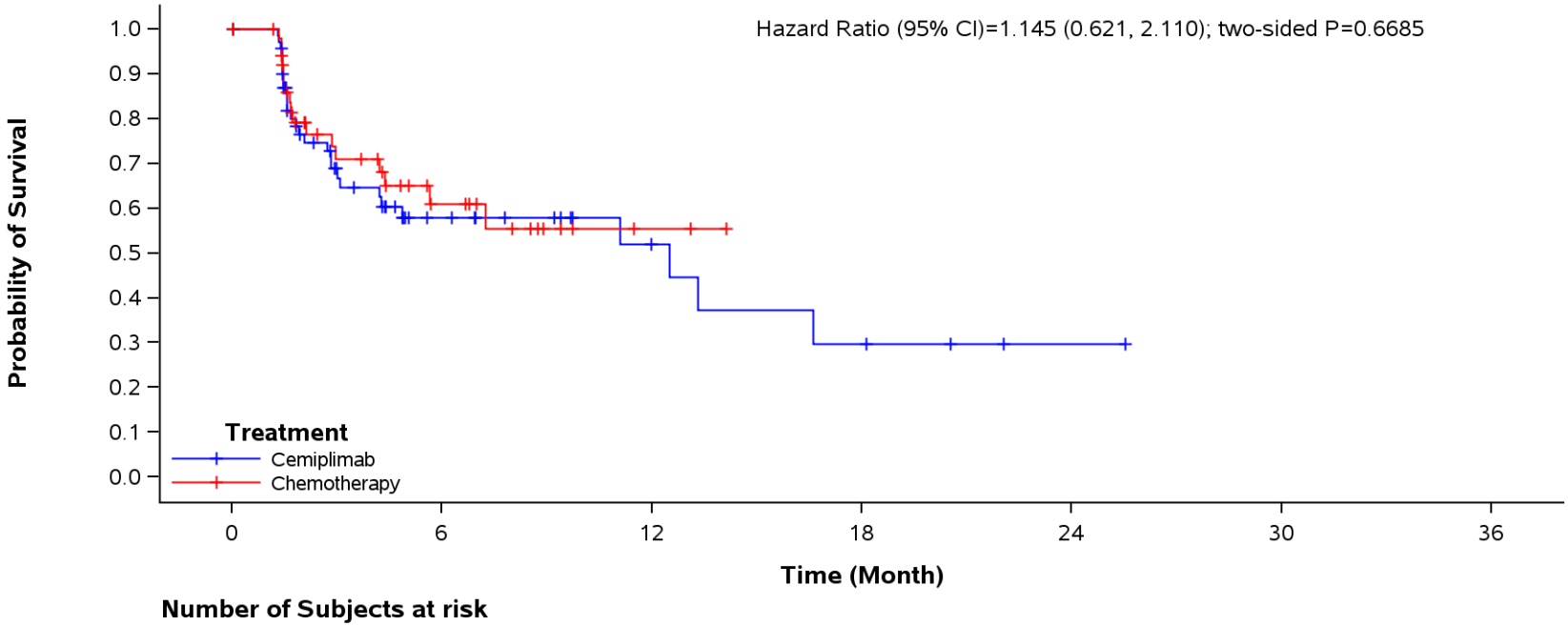

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 9 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts sustained improvement



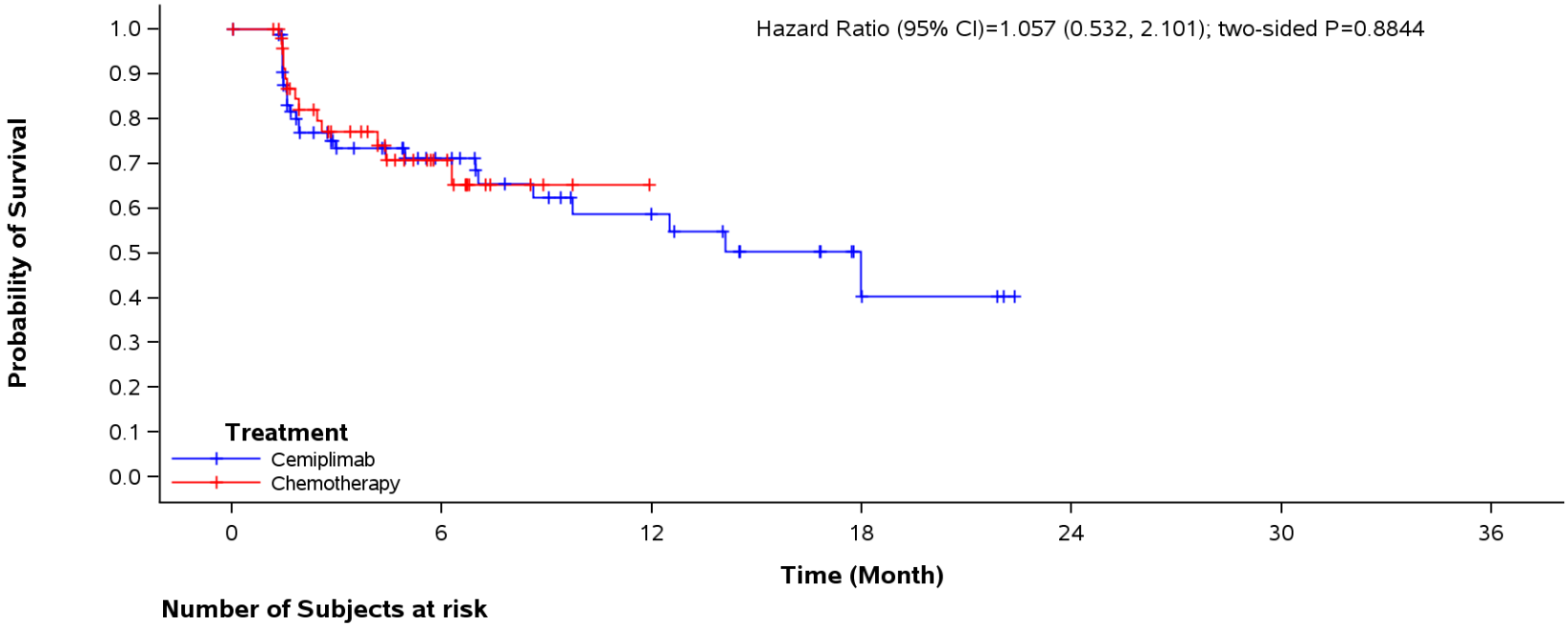

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 18 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 137 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts sustained improvement



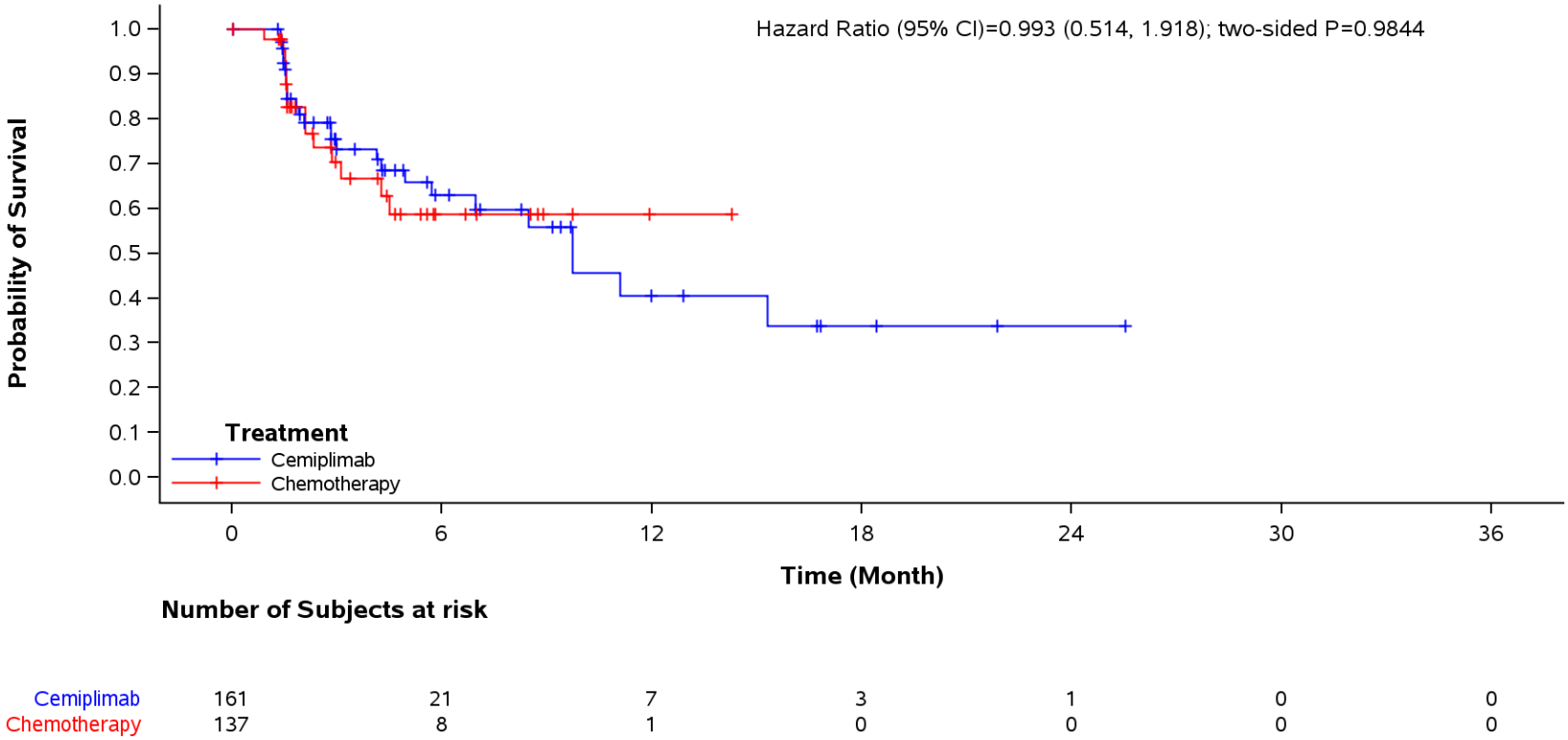

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 29 | 15 | 4 | 0 | 0 | 0 |
| Chemotherapy | 137 | 14 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts sustained improvement



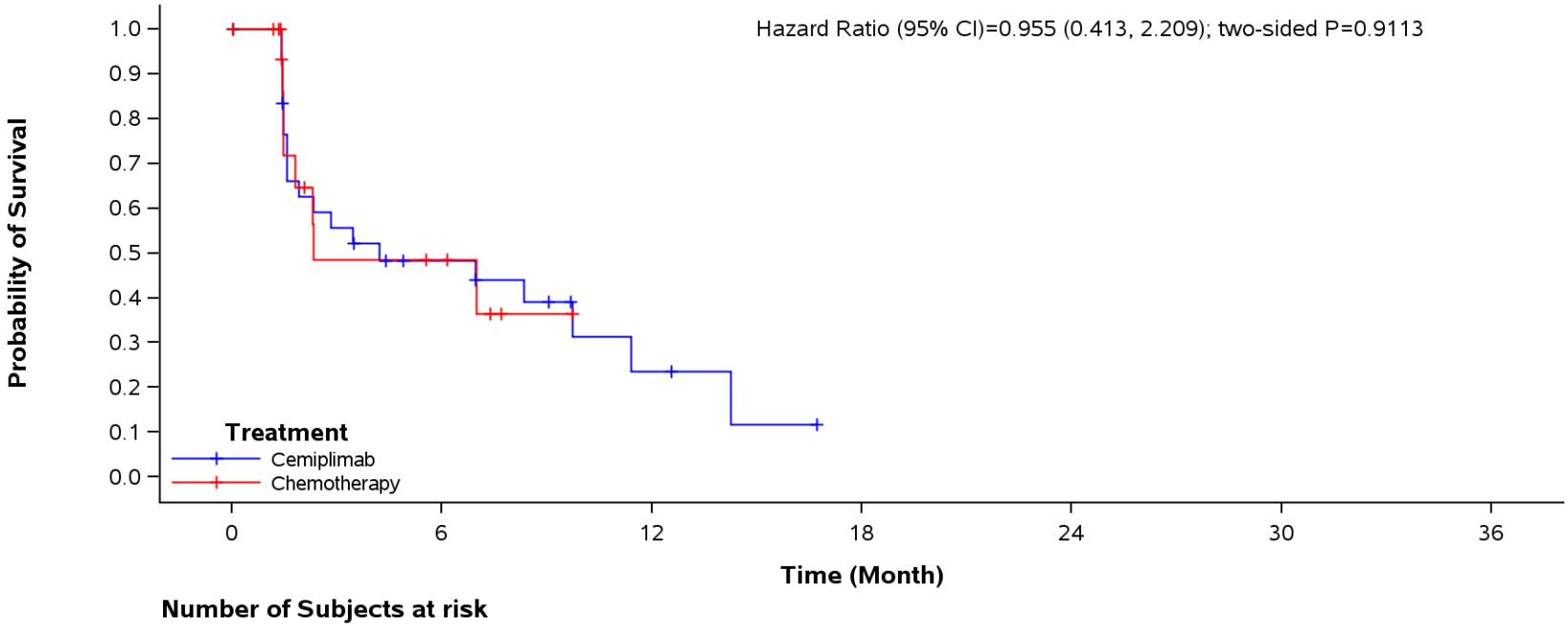

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 21 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 137 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts sustained improvement



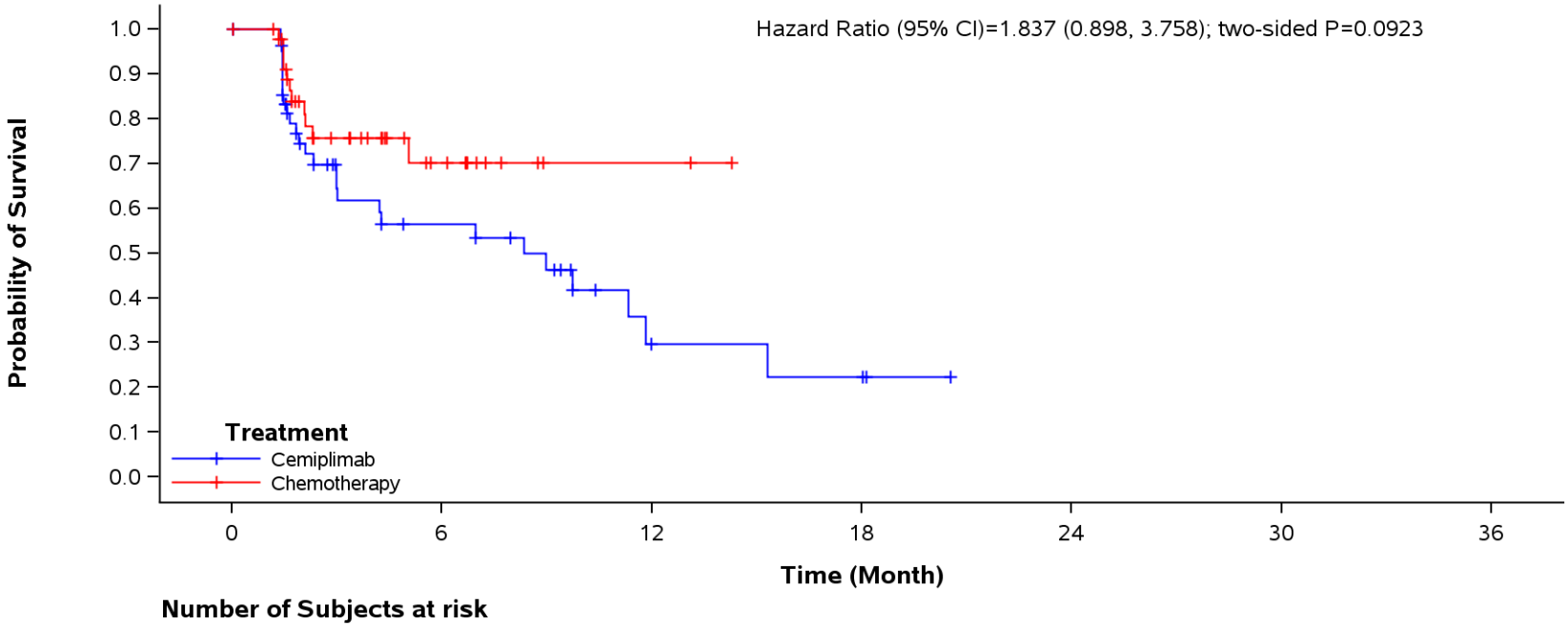

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 11 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 137 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts sustained improvement



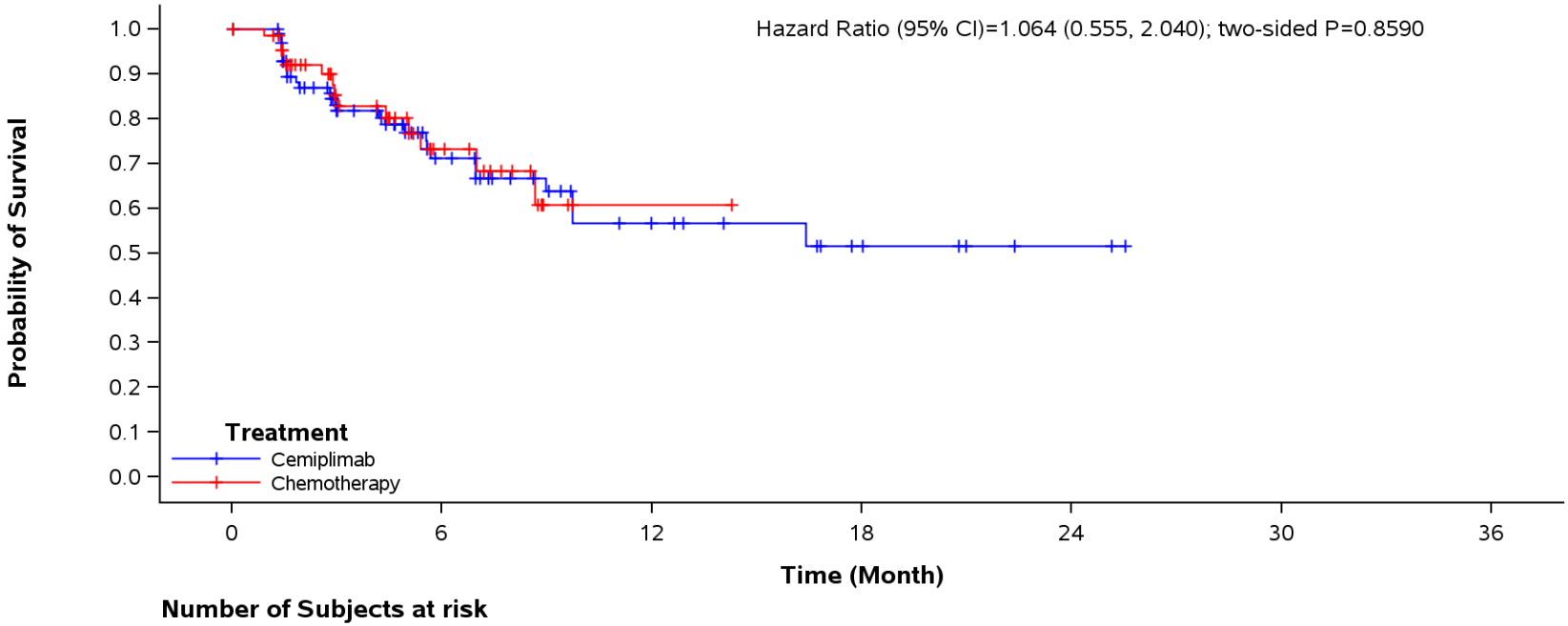

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 19 | 4 | 3 | 0 | 0 | 0 |
| Chemotherapy | 137 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts sustained improvement



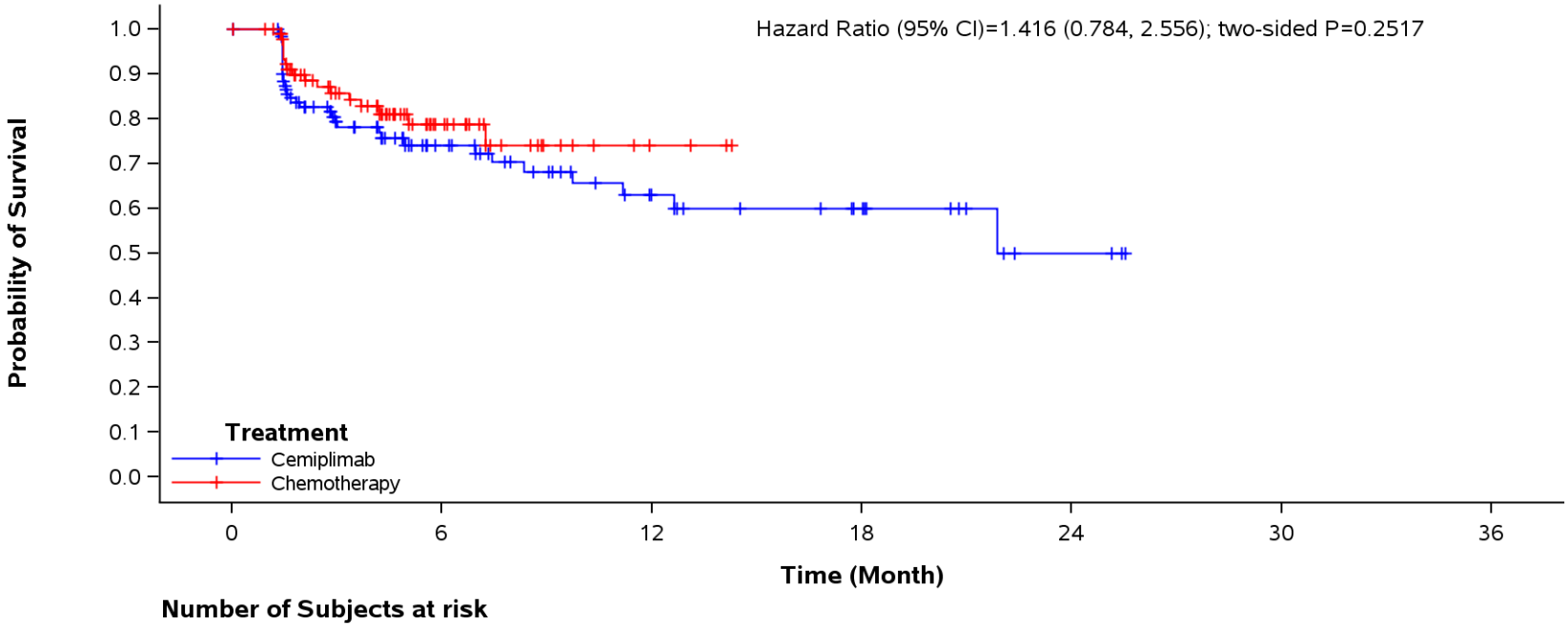

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 35 | 14 | 6 | 2 | 0 | 0 |
| Chemotherapy | 137 | 17 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts sustained improvement



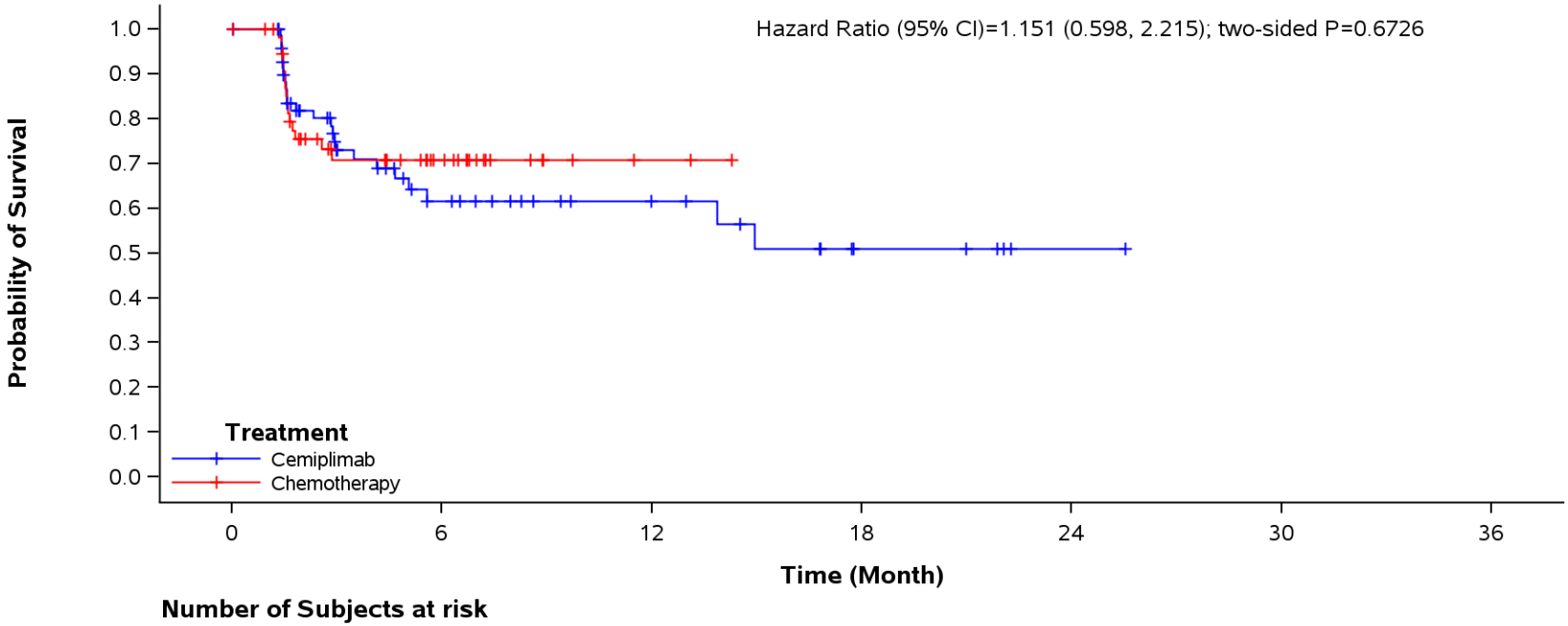

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 43 | 20 | 12 | 3 | 0 | 0 |
| Chemotherapy | 137 | 26 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts sustained improvement



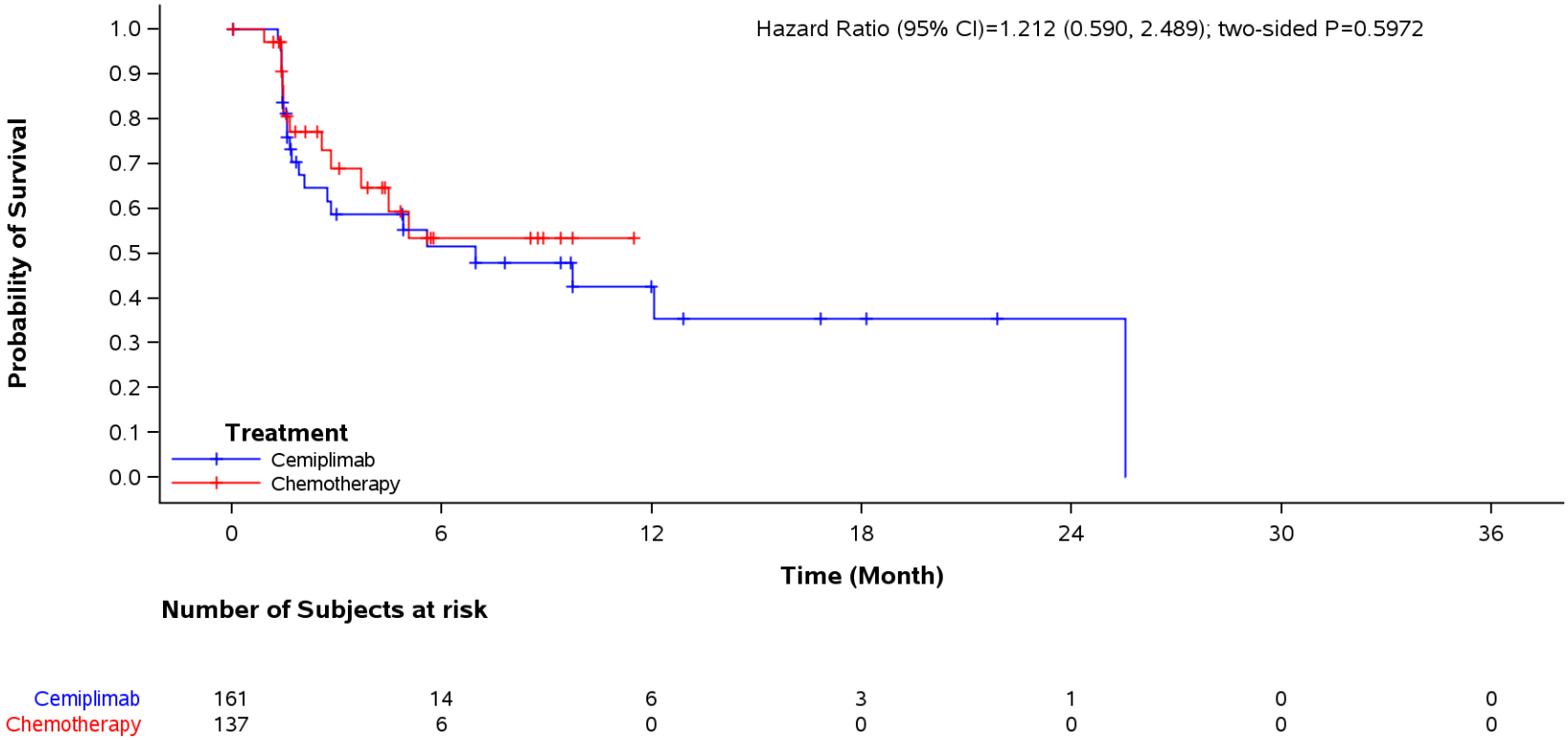

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 23 | 13 | 5 | 1 | 0 | 0 |
| Chemotherapy | 137 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

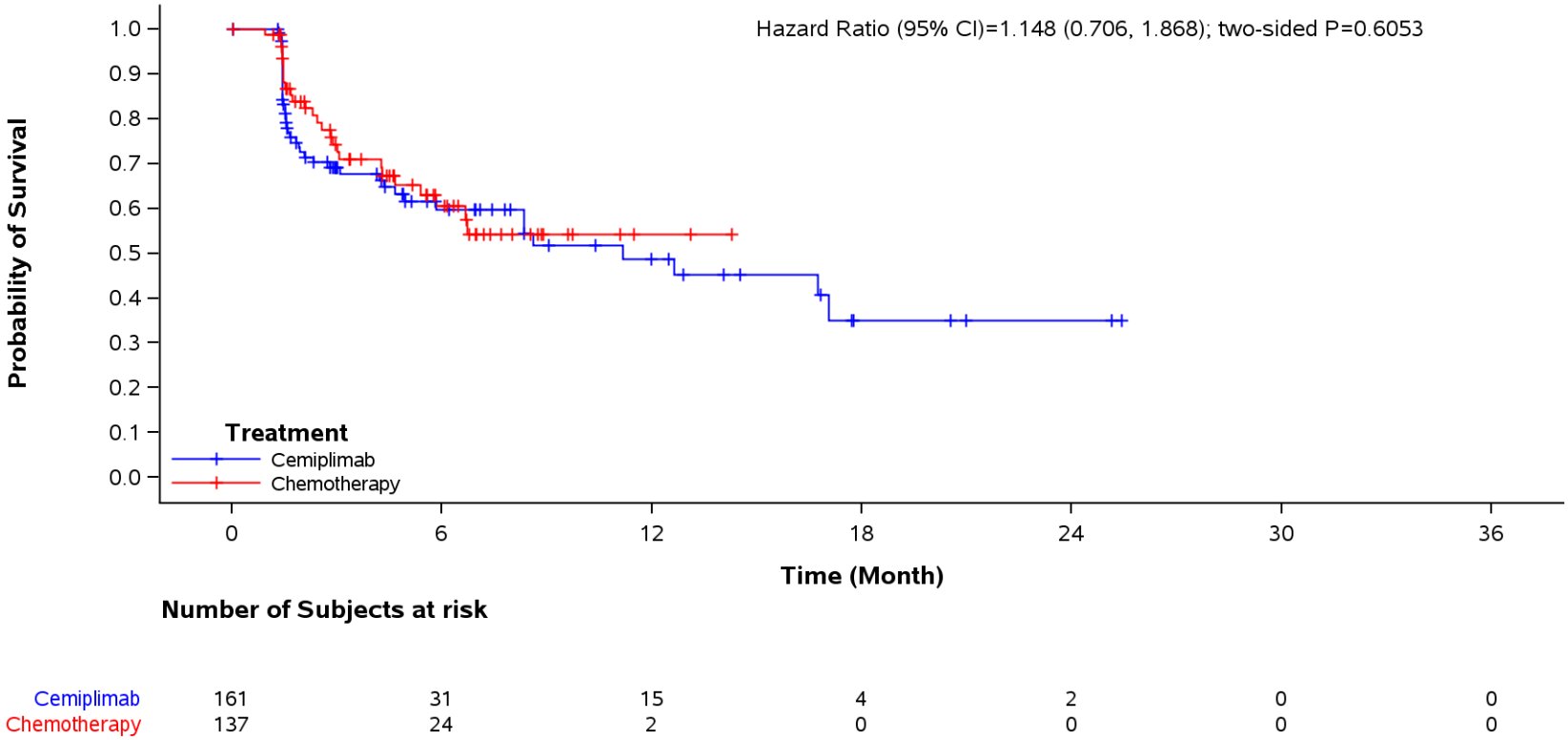
Histology: Squamous
Nausea / Vomiting - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

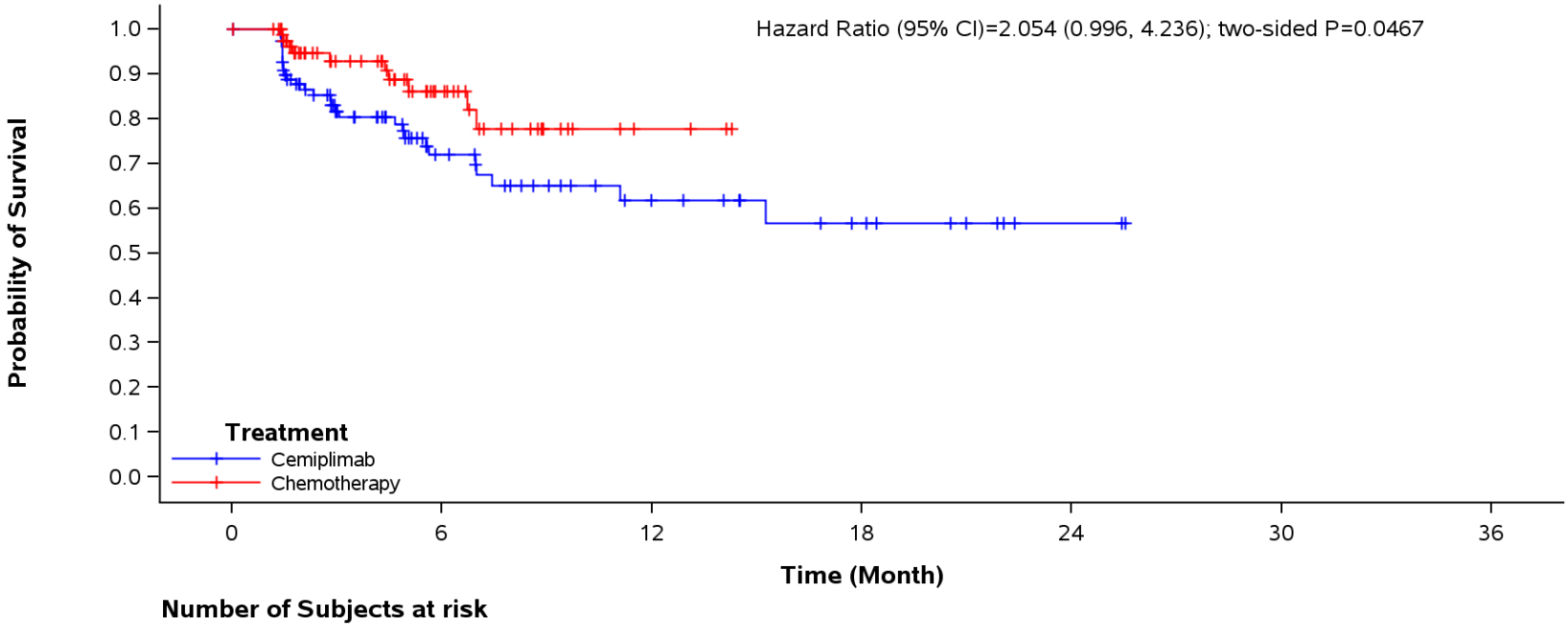
Histology: Squamous
Pain - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts sustained improvement



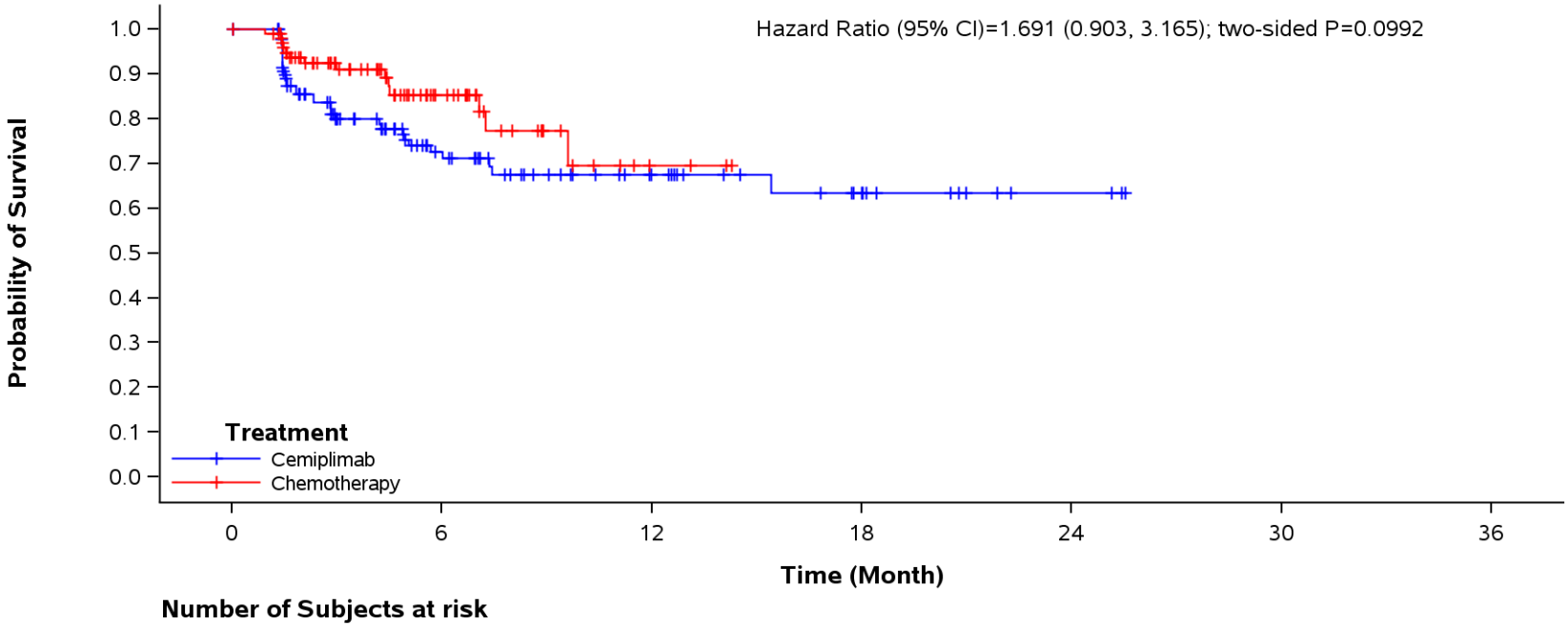

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 35 | 16 | 9 | 2 | 0 | 0 |
| Chemotherapy | 137 | 26 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts sustained improvement



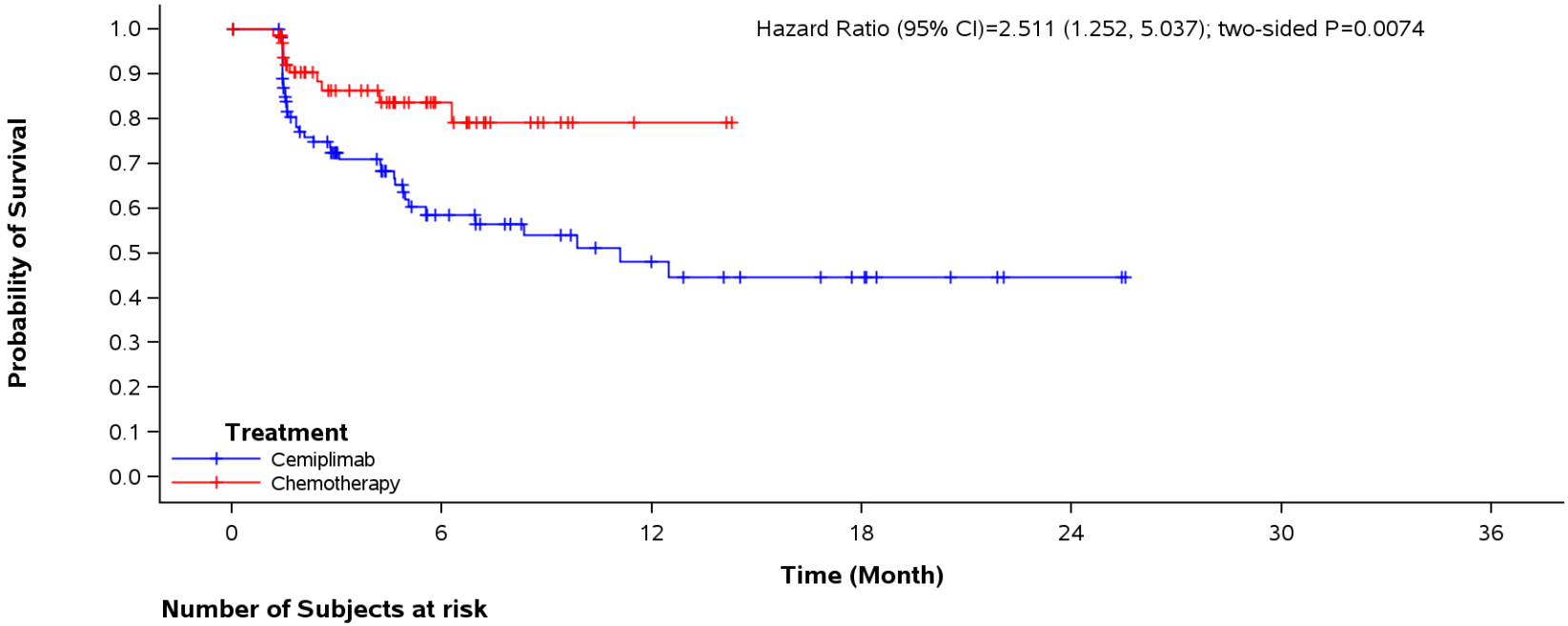

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 49 | 23 | 12 | 3 | 0 | 0 |
| Chemotherapy | 137 | 31 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts sustained improvement



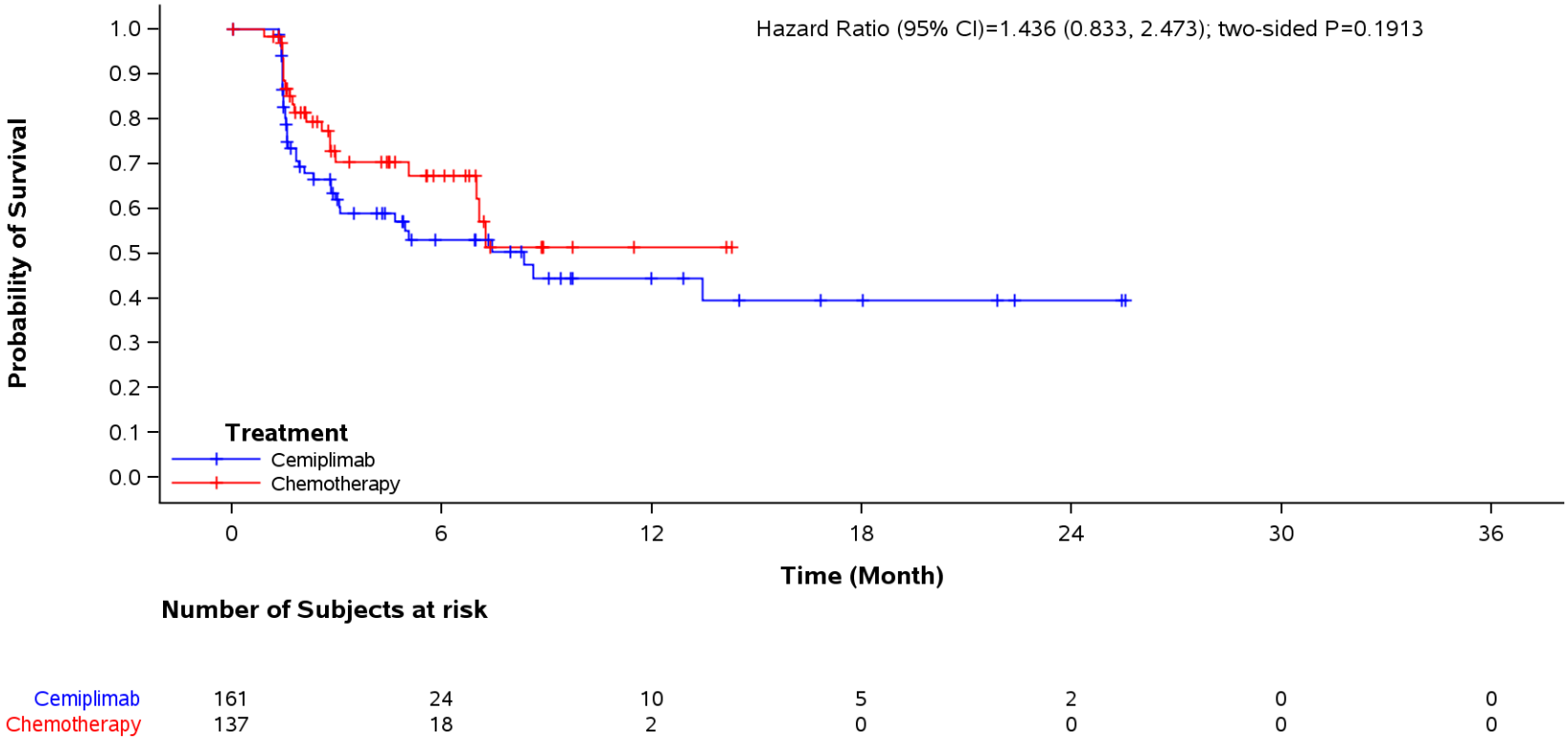

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 31 | 14 | 8 | 2 | 0 | 0 |
| Chemotherapy | 137 | 19 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

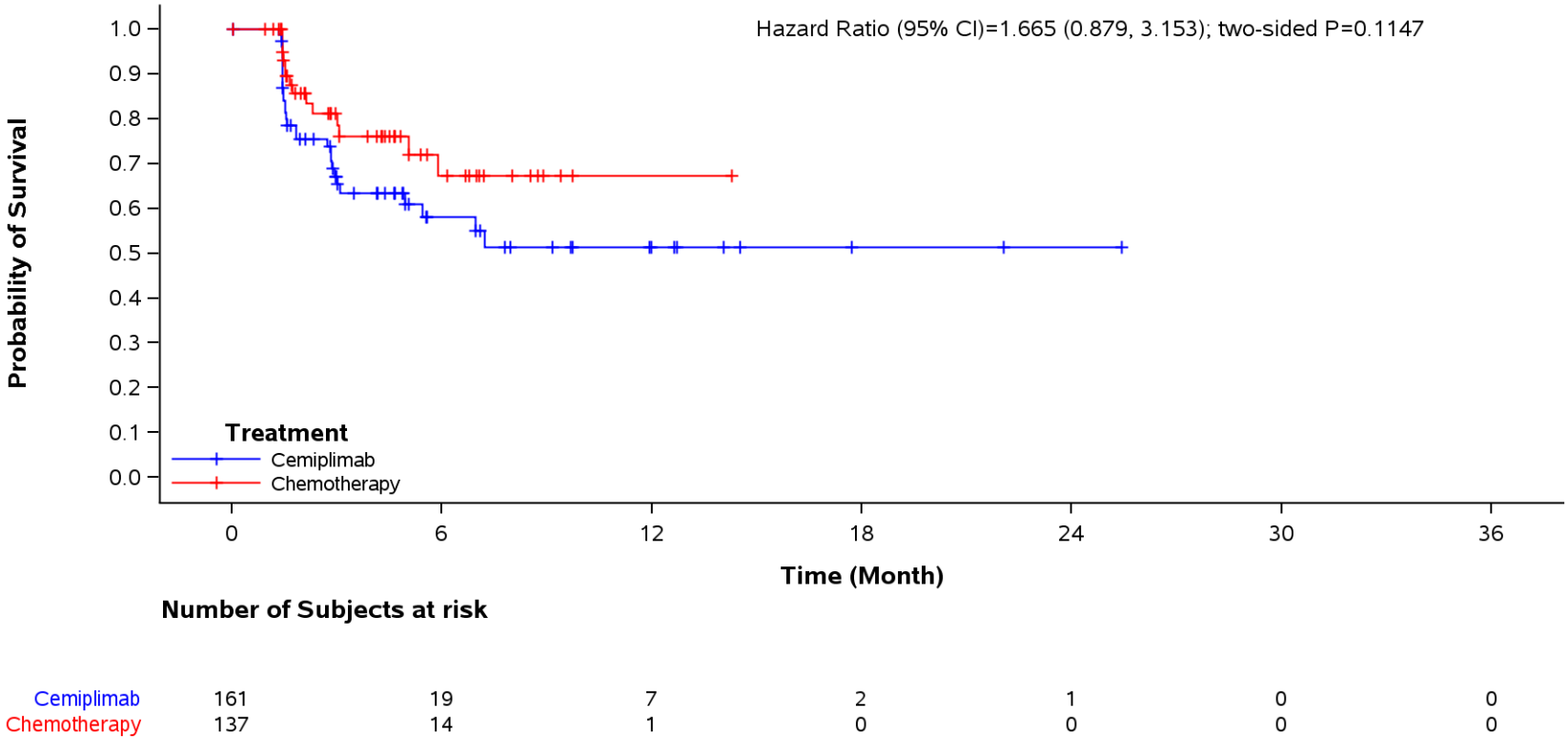
Histology: Squamous
Social Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts sustained improvement



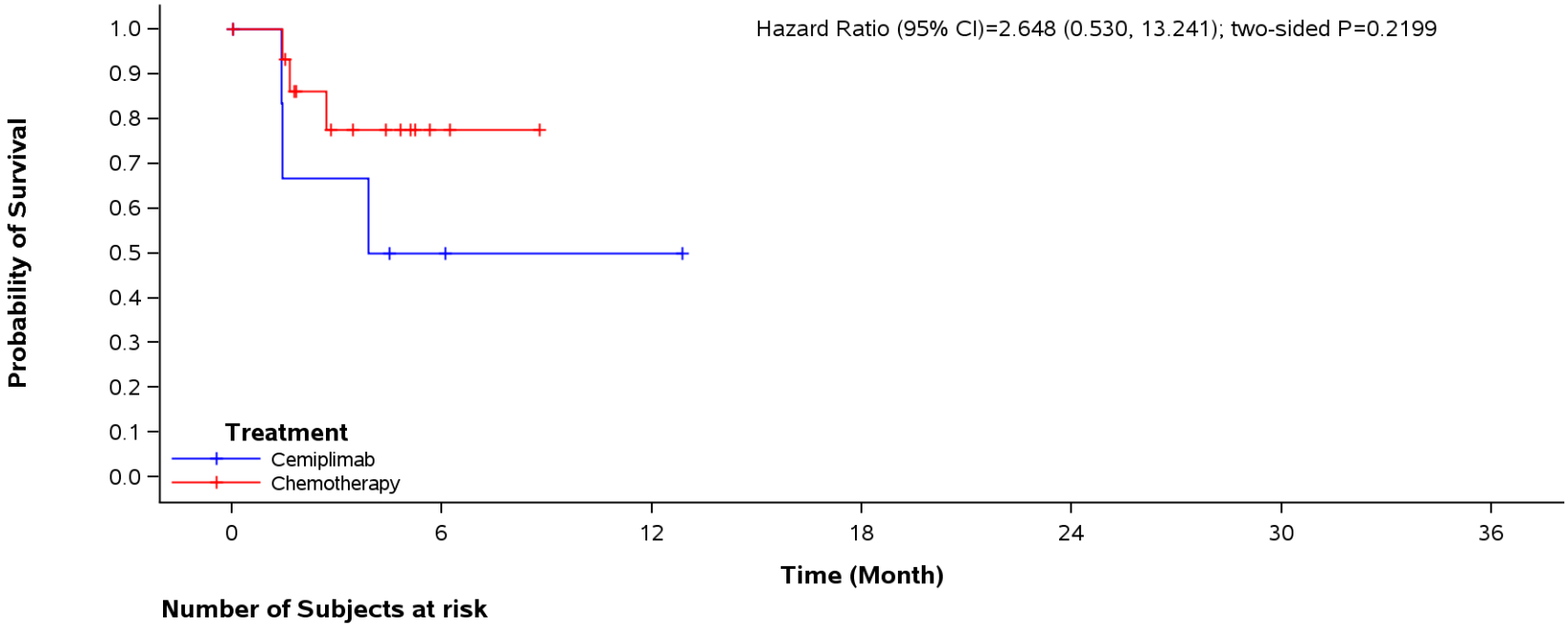

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 19 | 7 | 2 | 1 | 0 | 0 |
| Chemotherapy | 137 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts sustained improvement



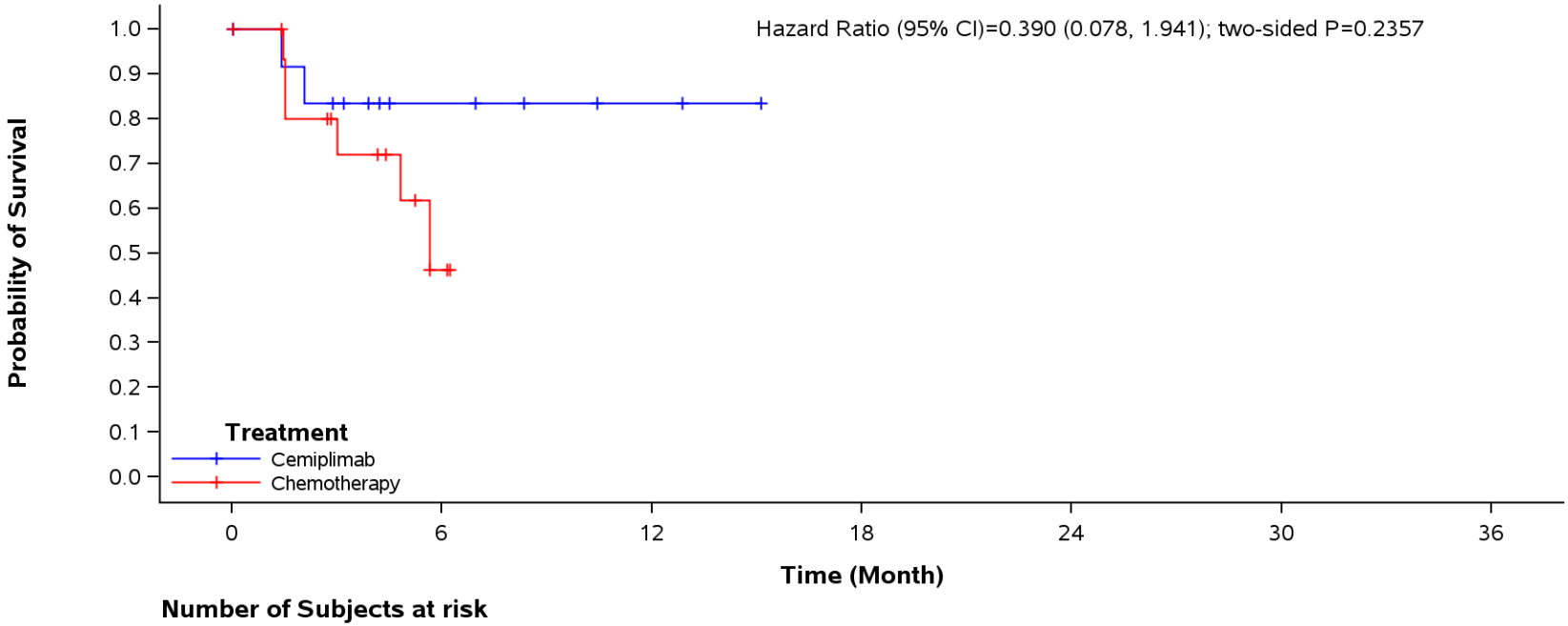

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts sustained improvement



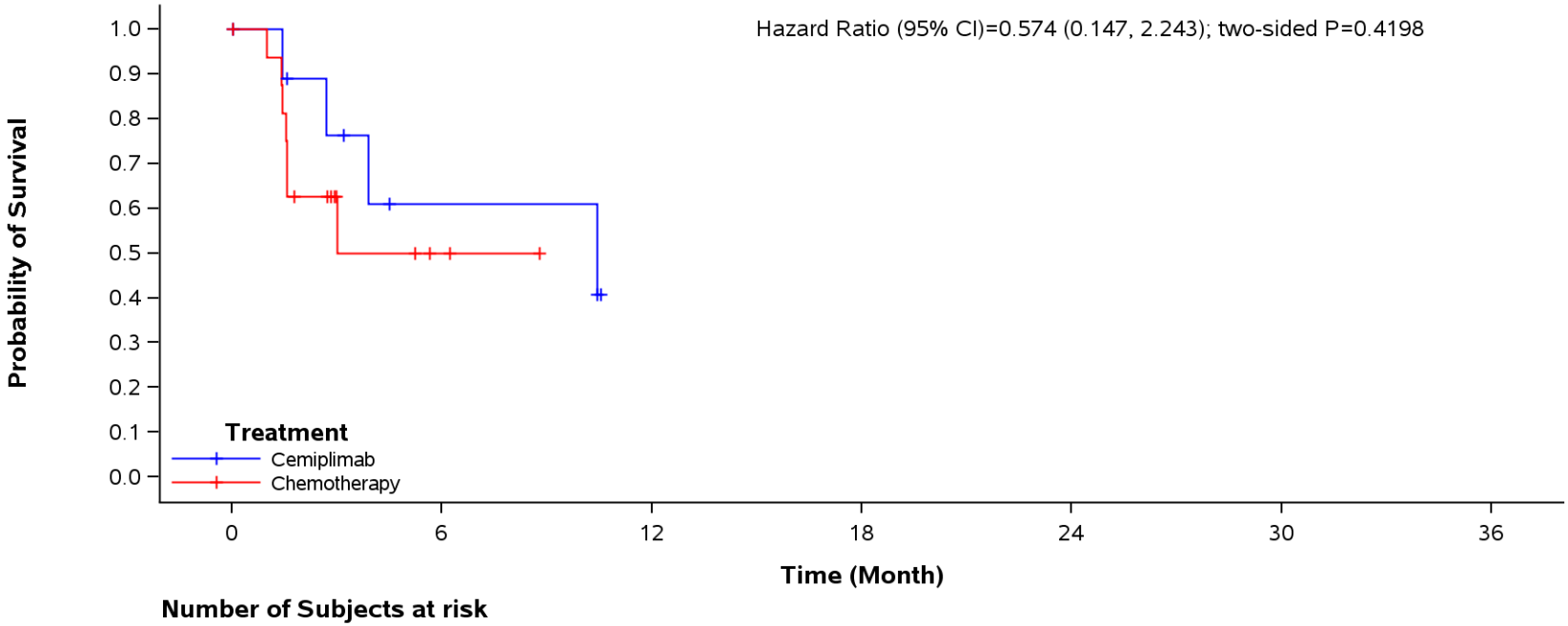

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts sustained improvement



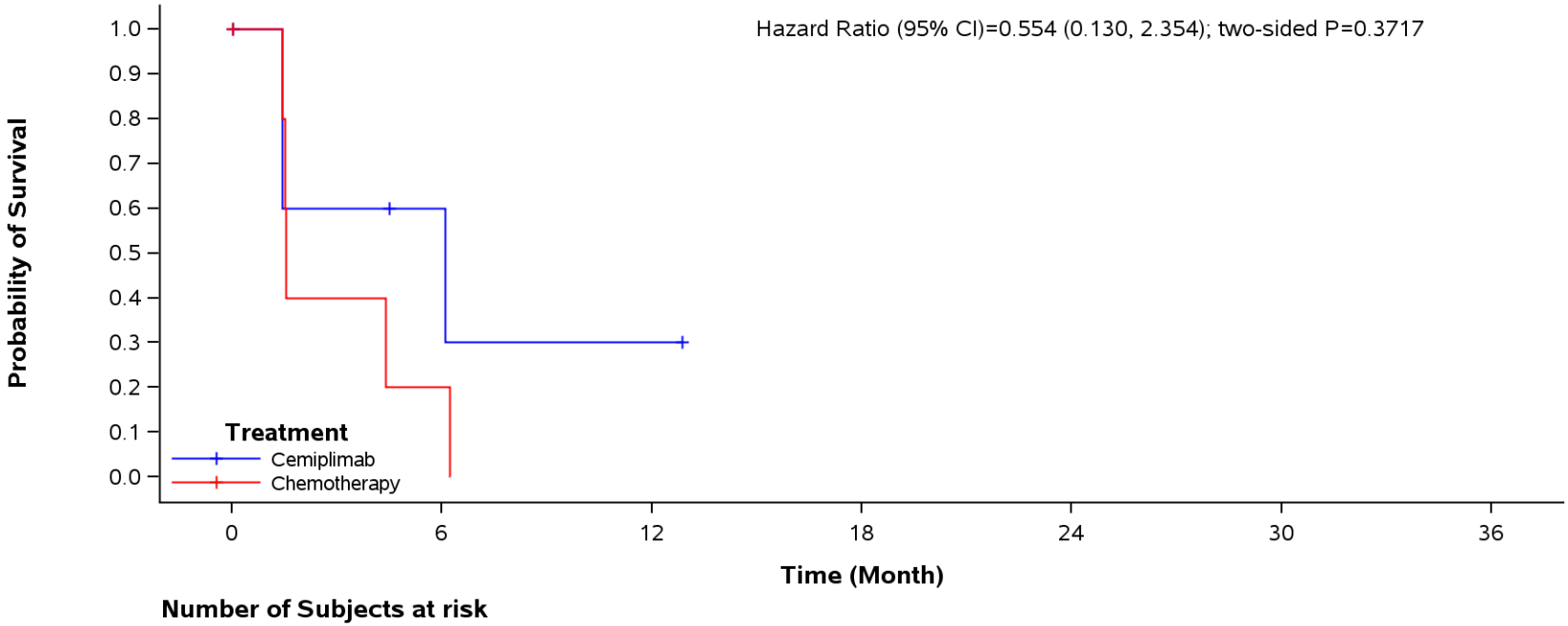

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts sustained improvement



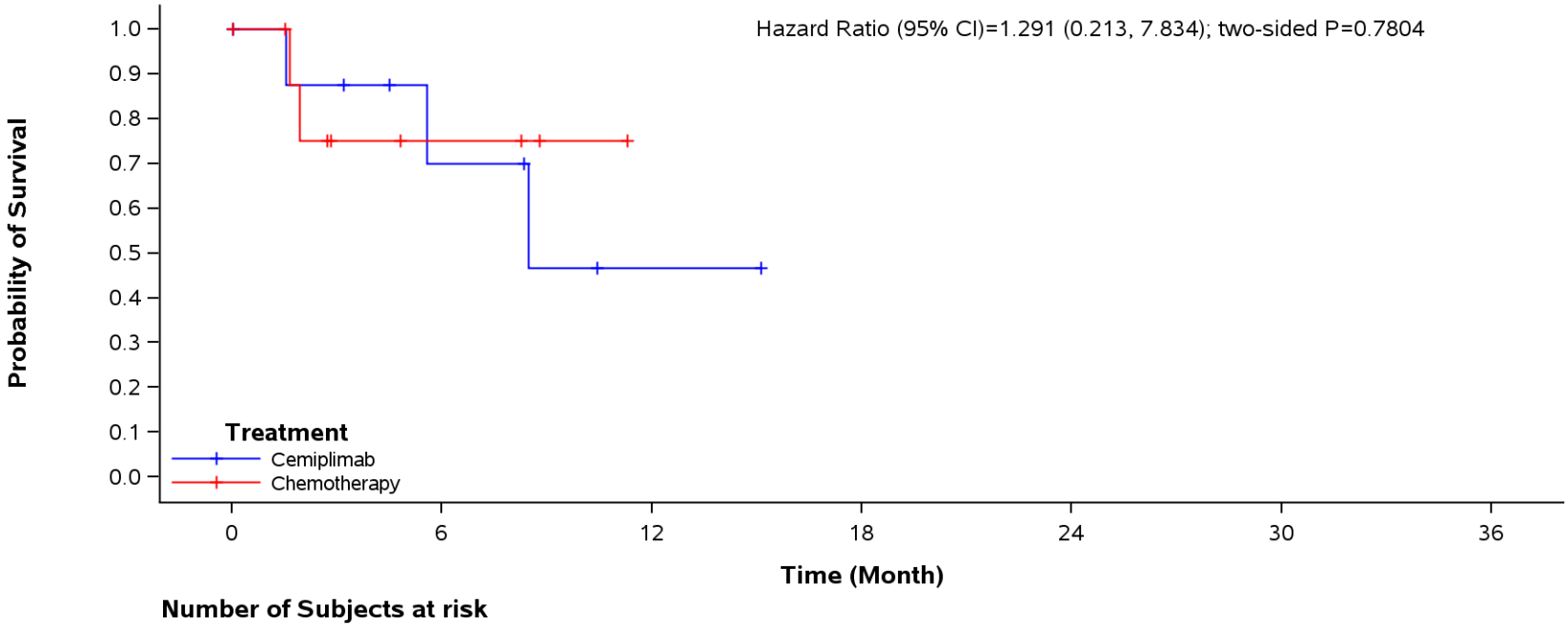

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts sustained improvement



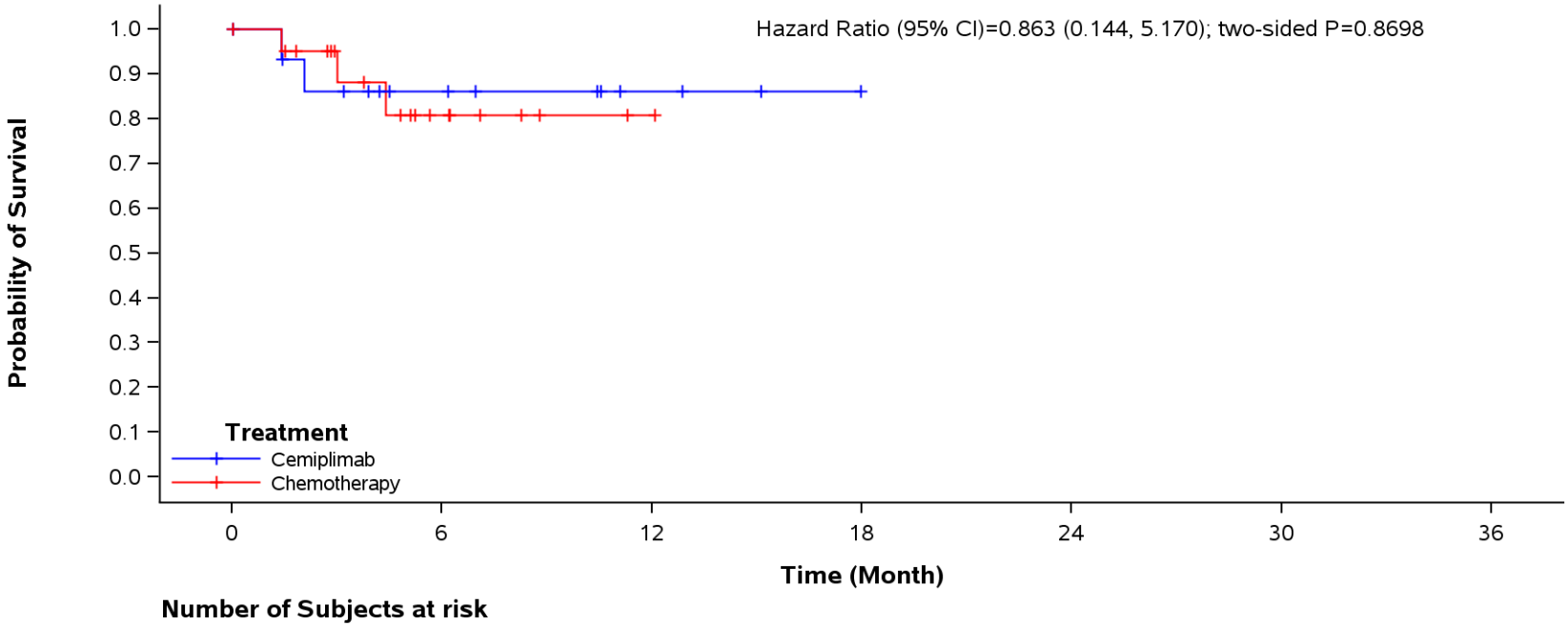

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts sustained improvement



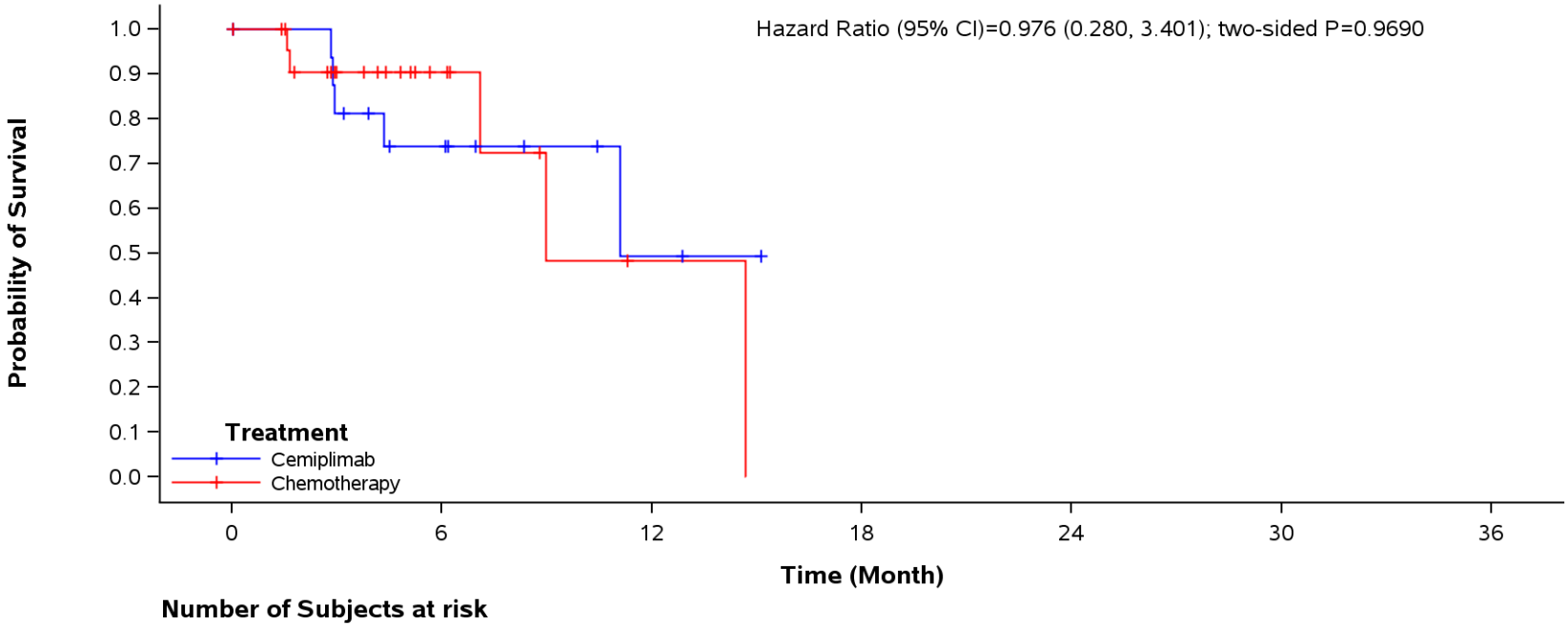

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts sustained improvement



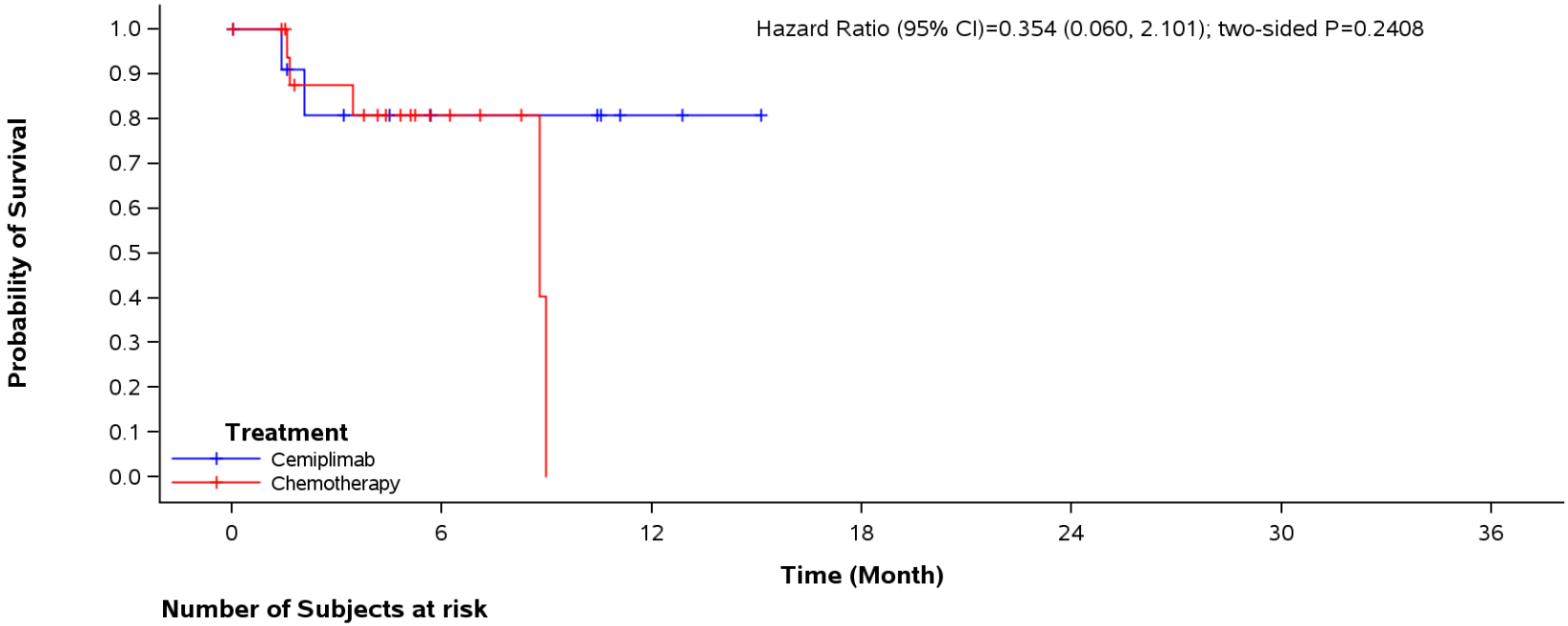

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts sustained improvement



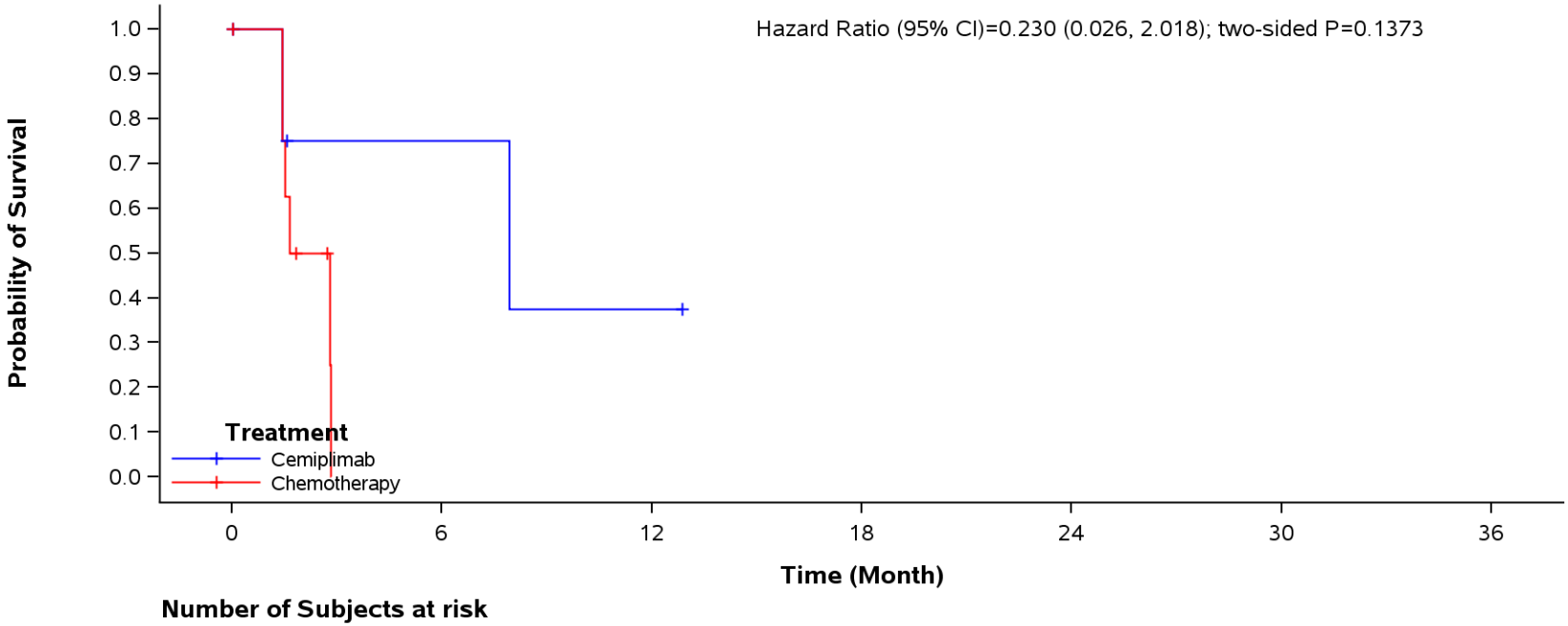

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts sustained improvement



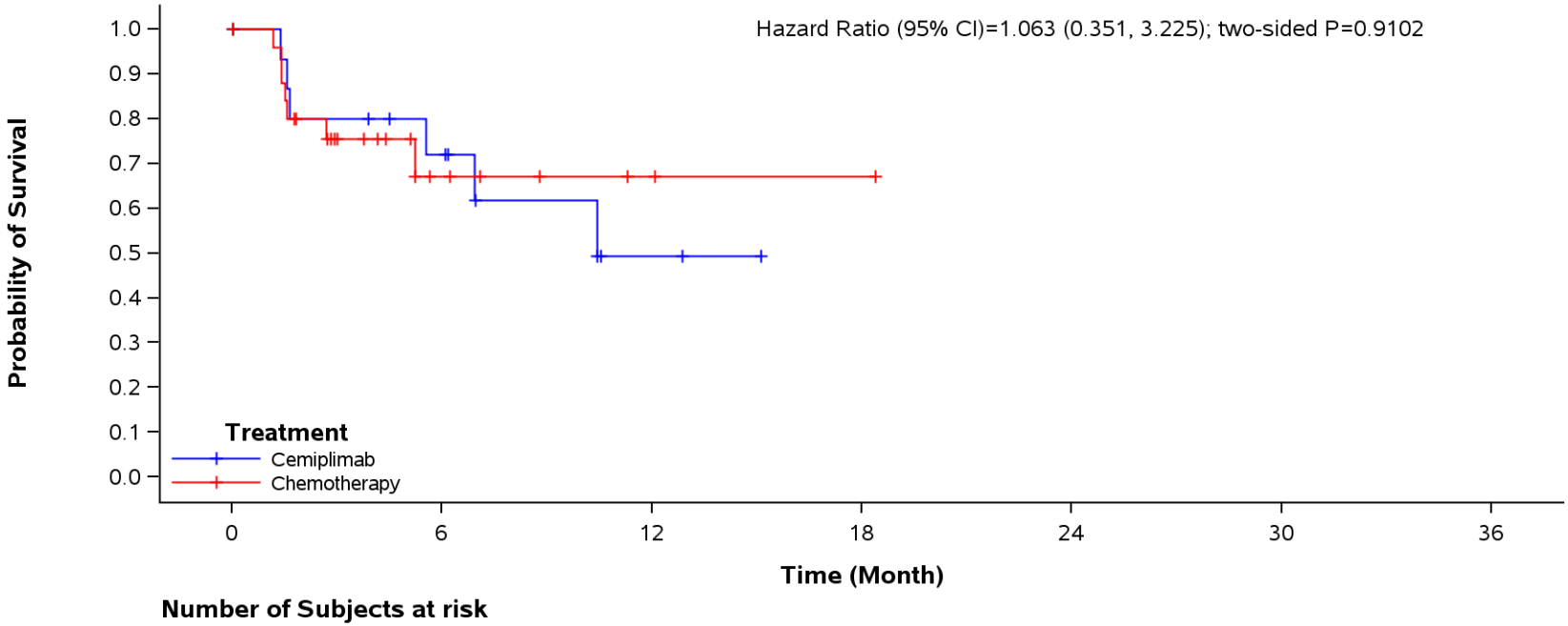

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts sustained improvement



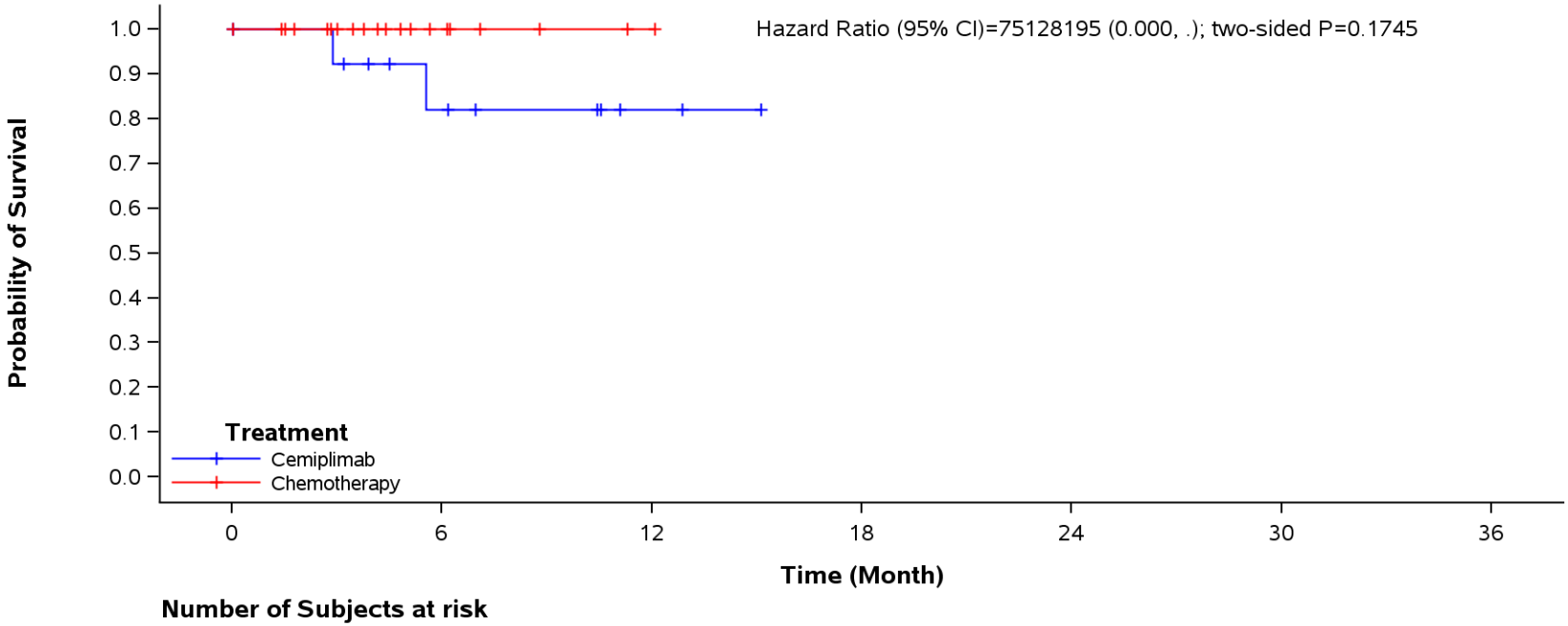

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts sustained improvement



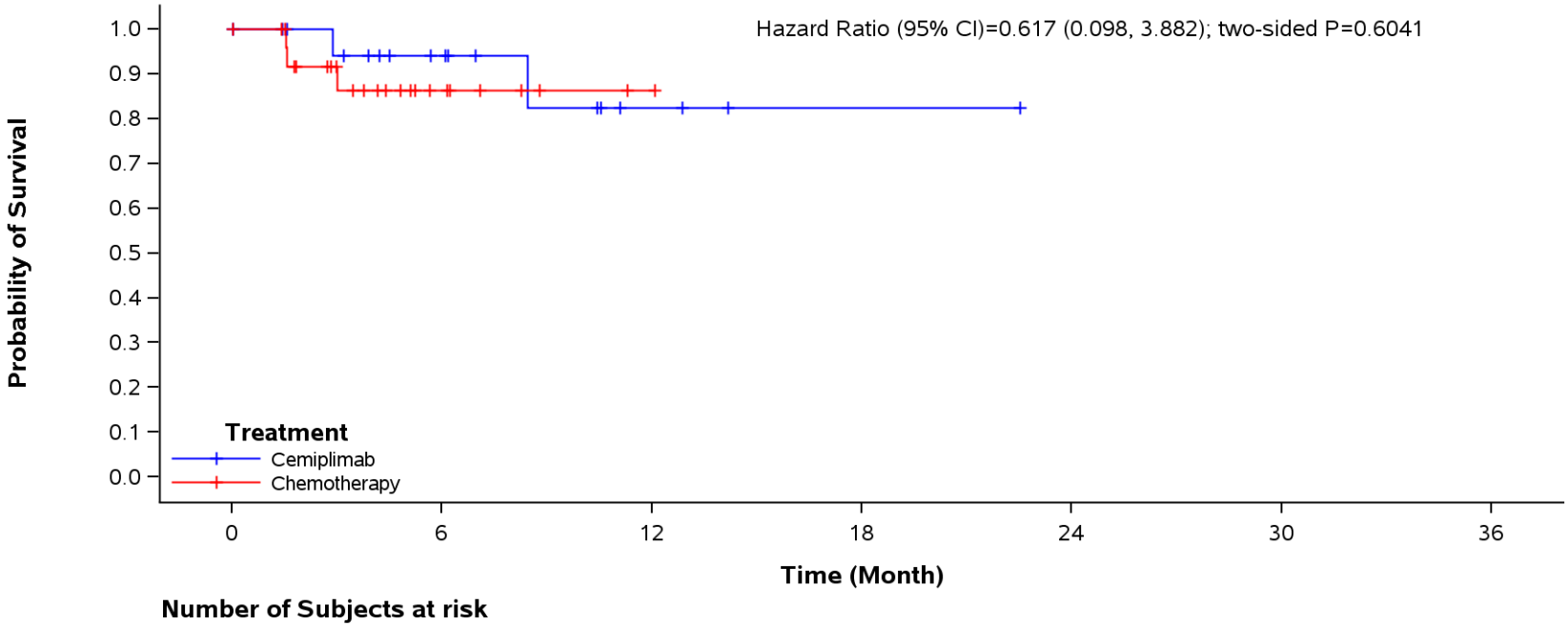

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts sustained improvement



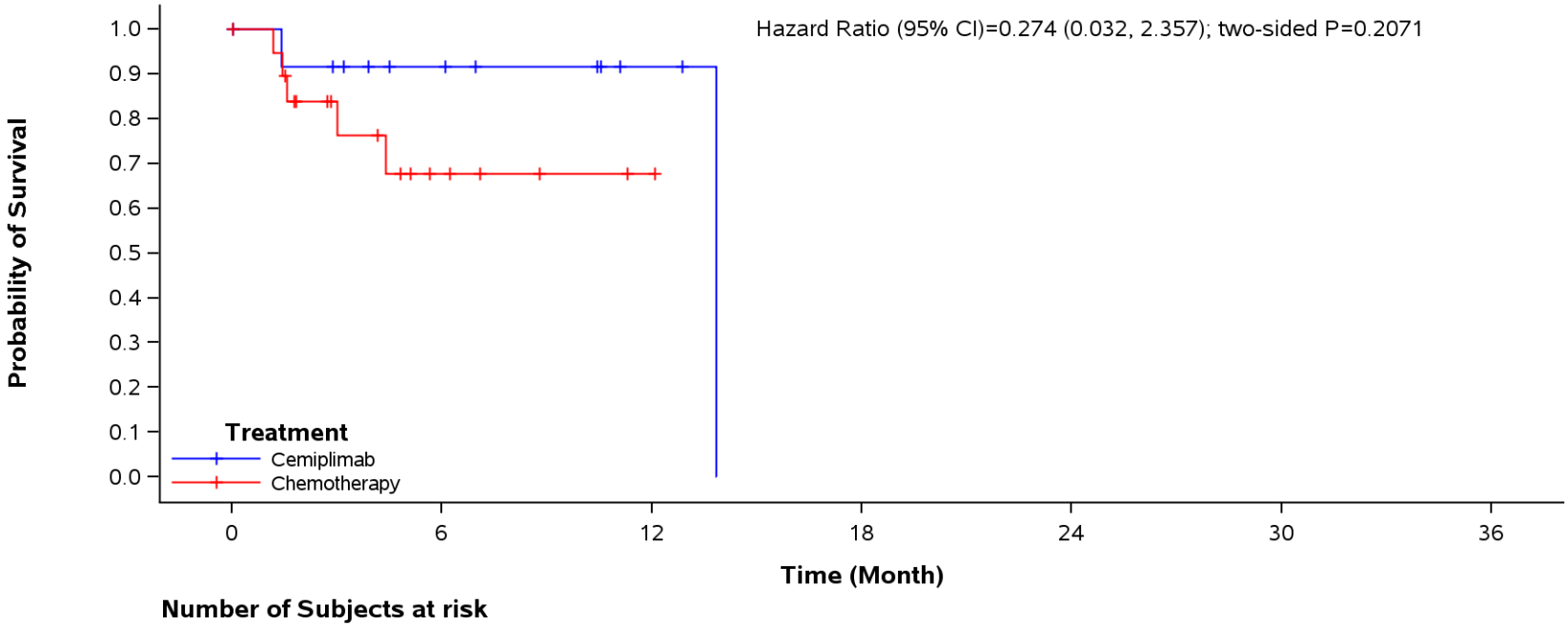

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts sustained improvement



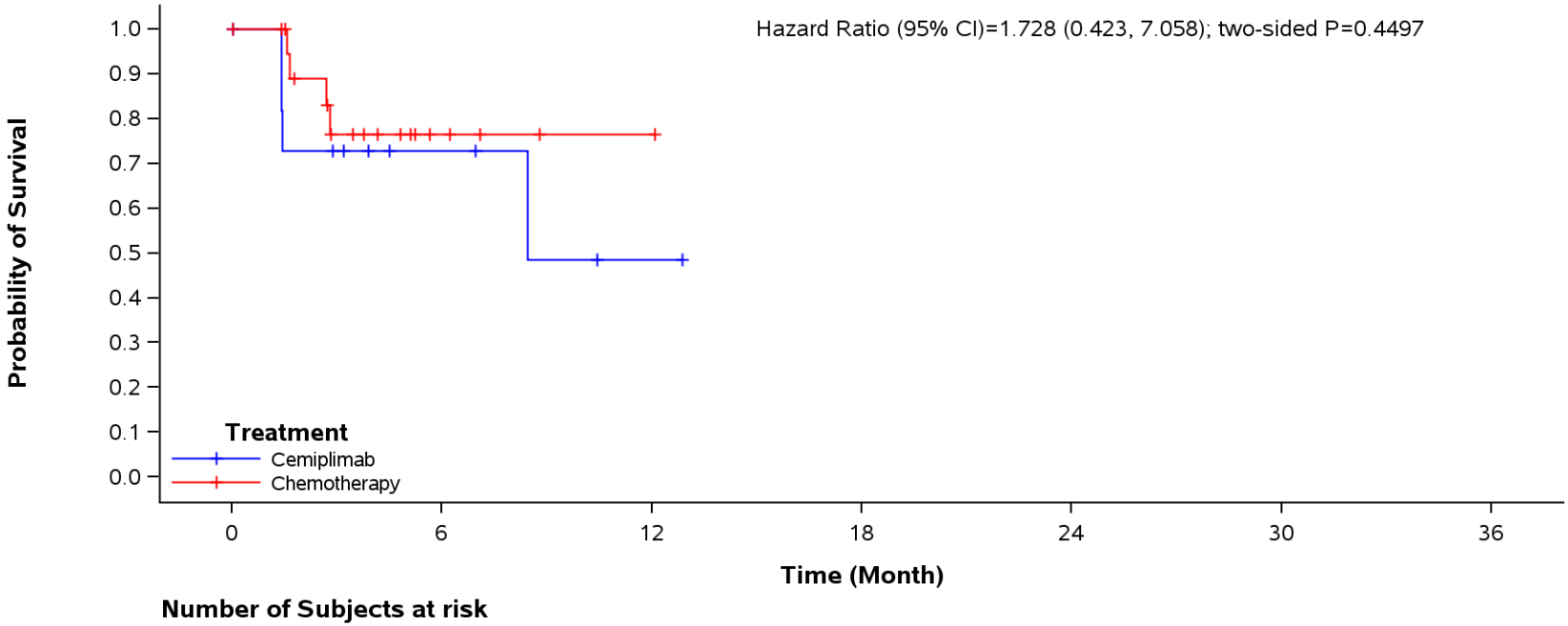

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 7 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts sustained improvement



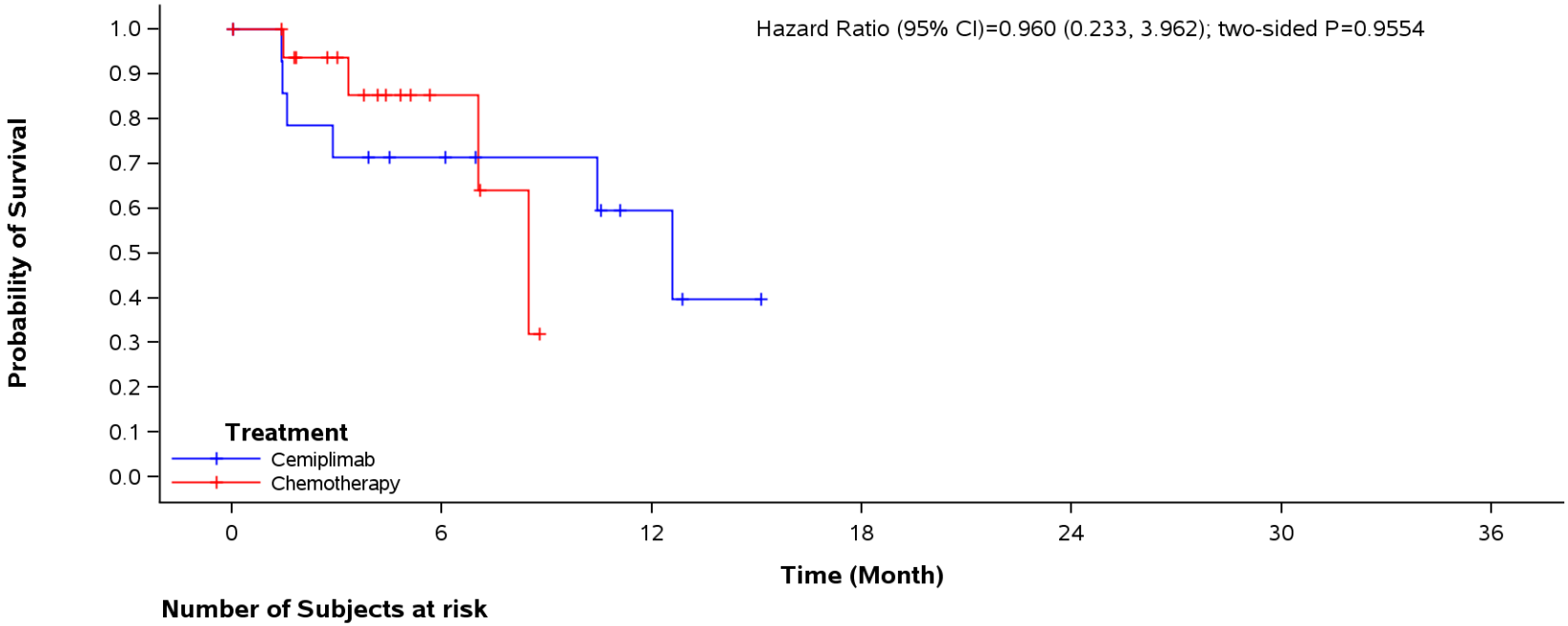

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts sustained improvement



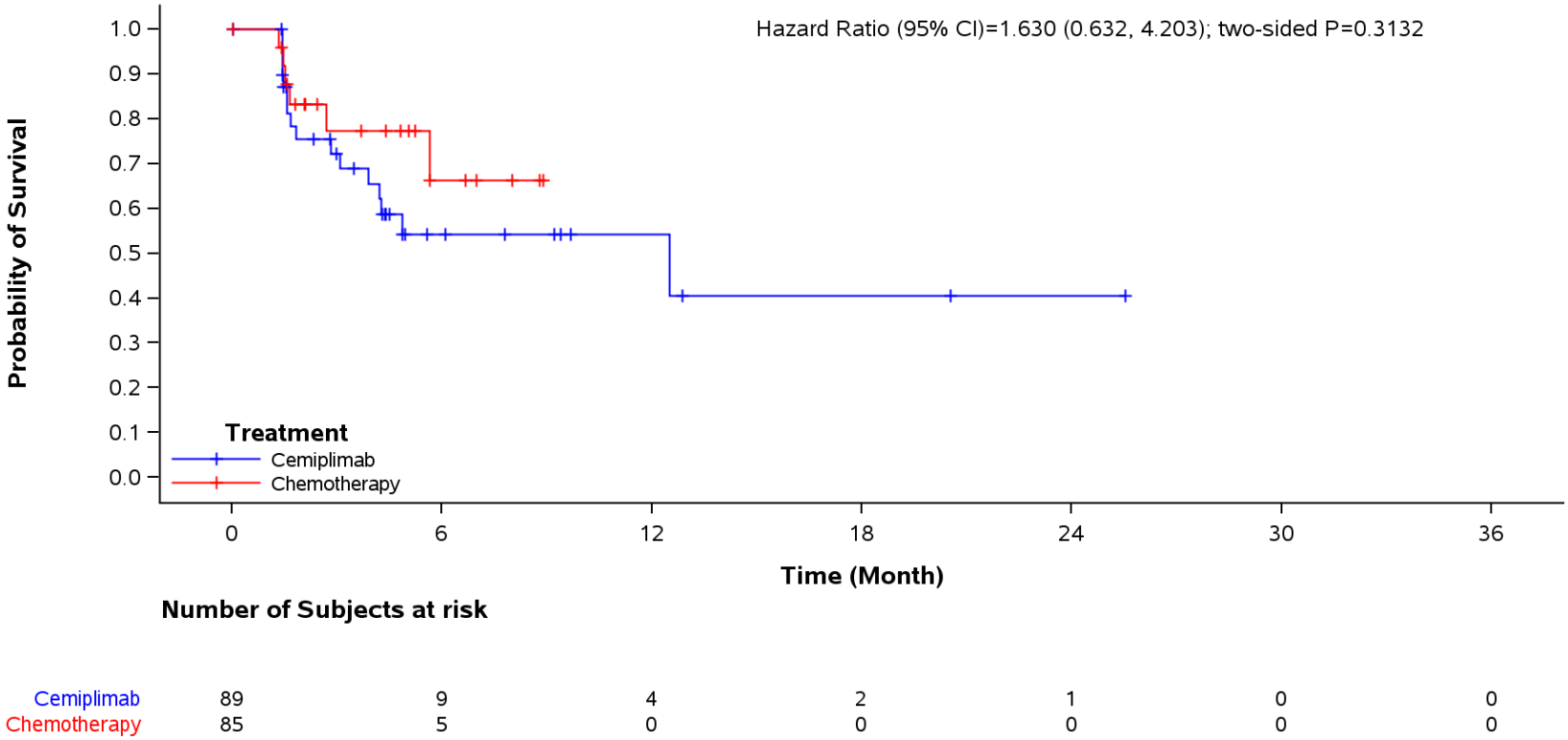

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts sustained improvement



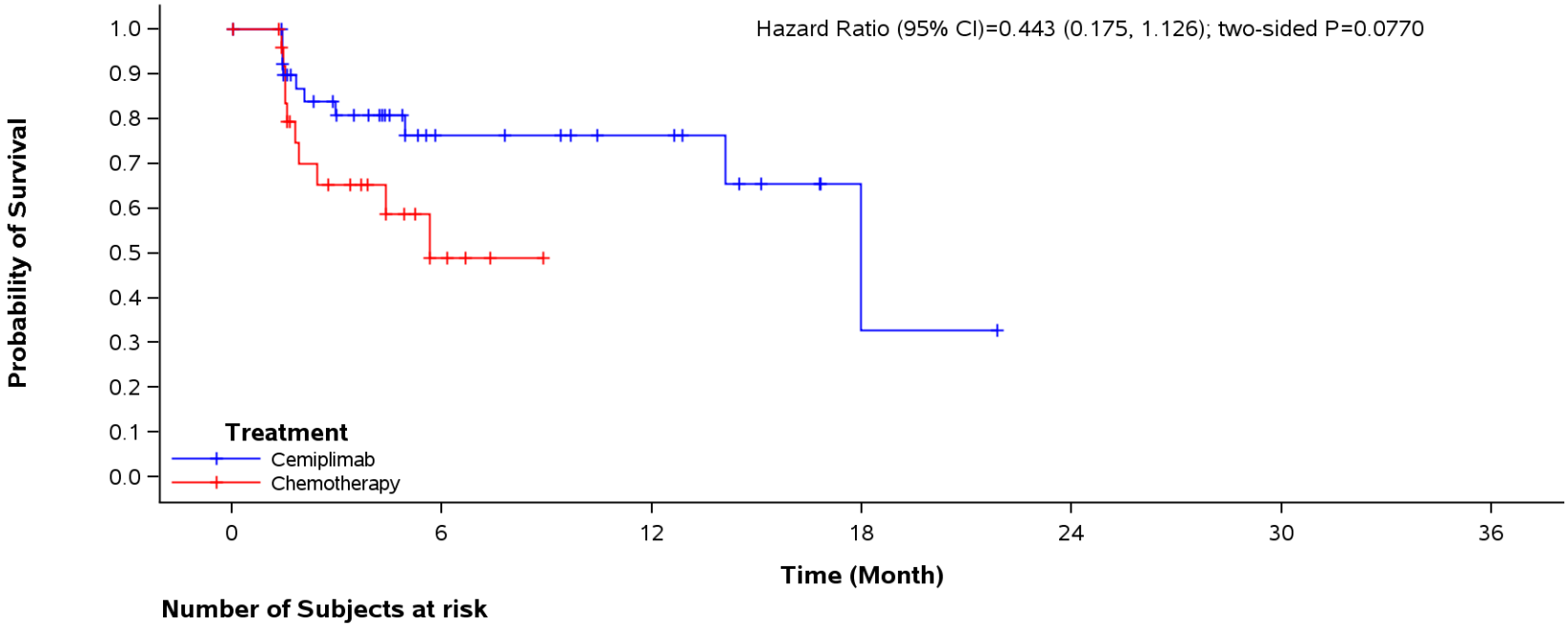

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 9 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 85 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts sustained improvement



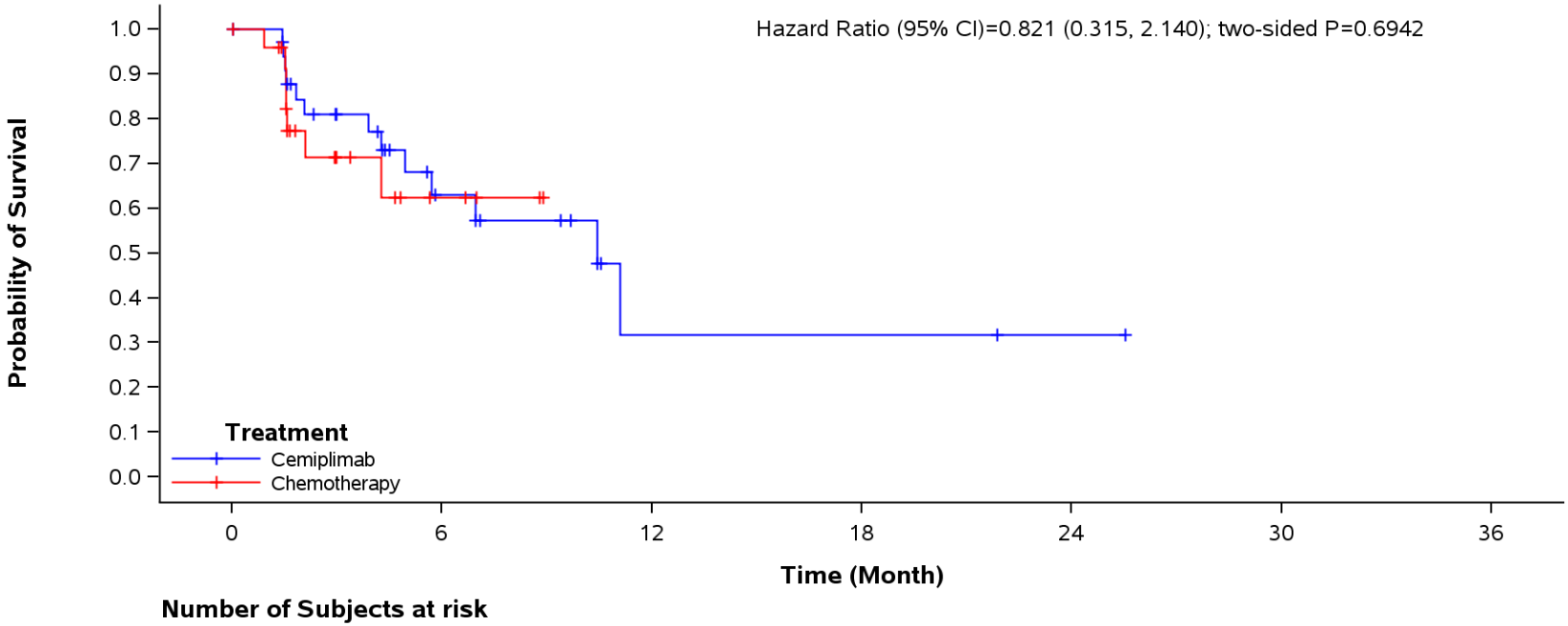

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 13 | 9 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts sustained improvement



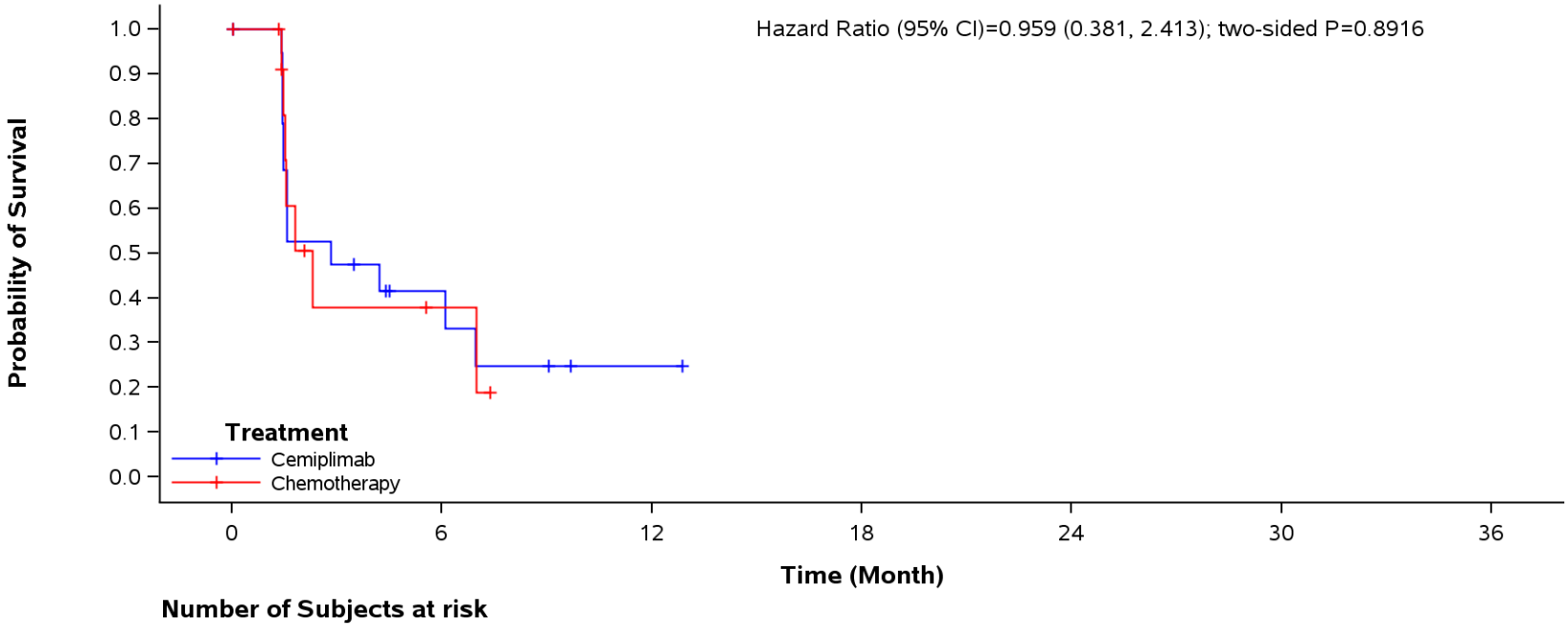

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 11 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 85 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts sustained improvement



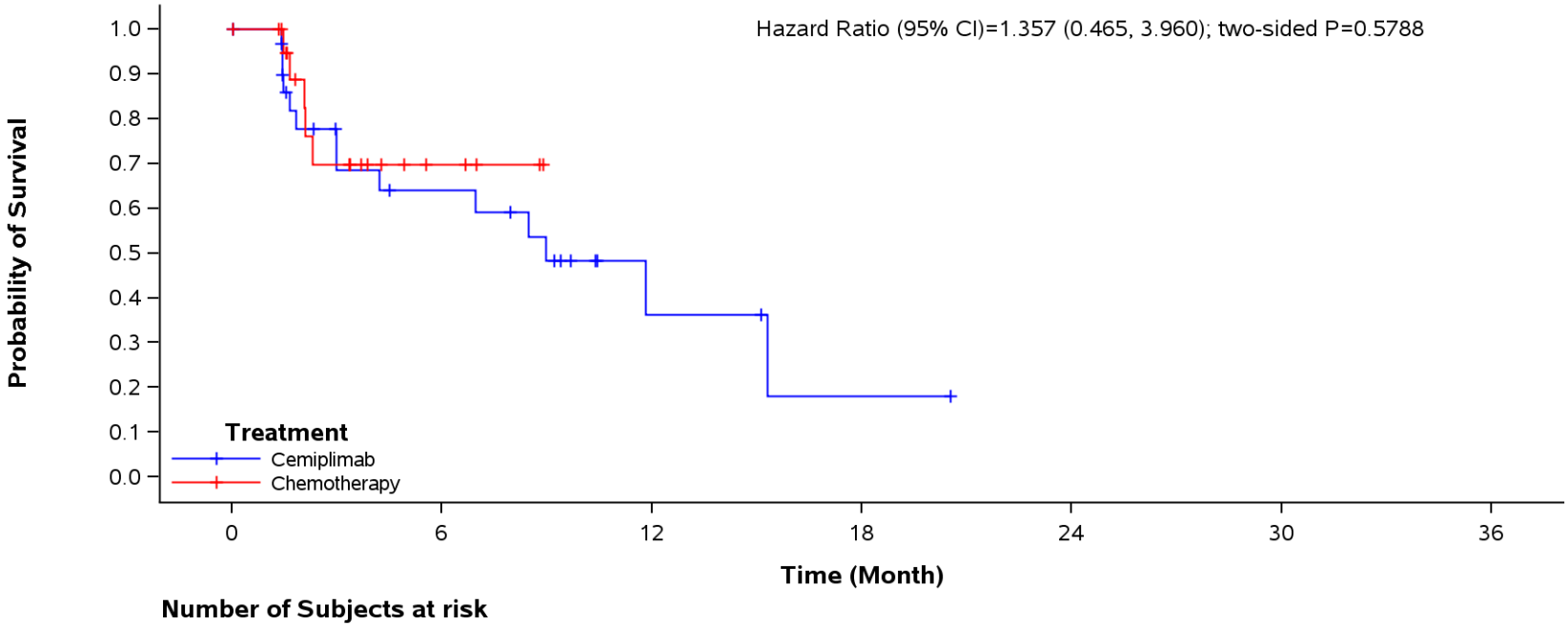

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts sustained improvement



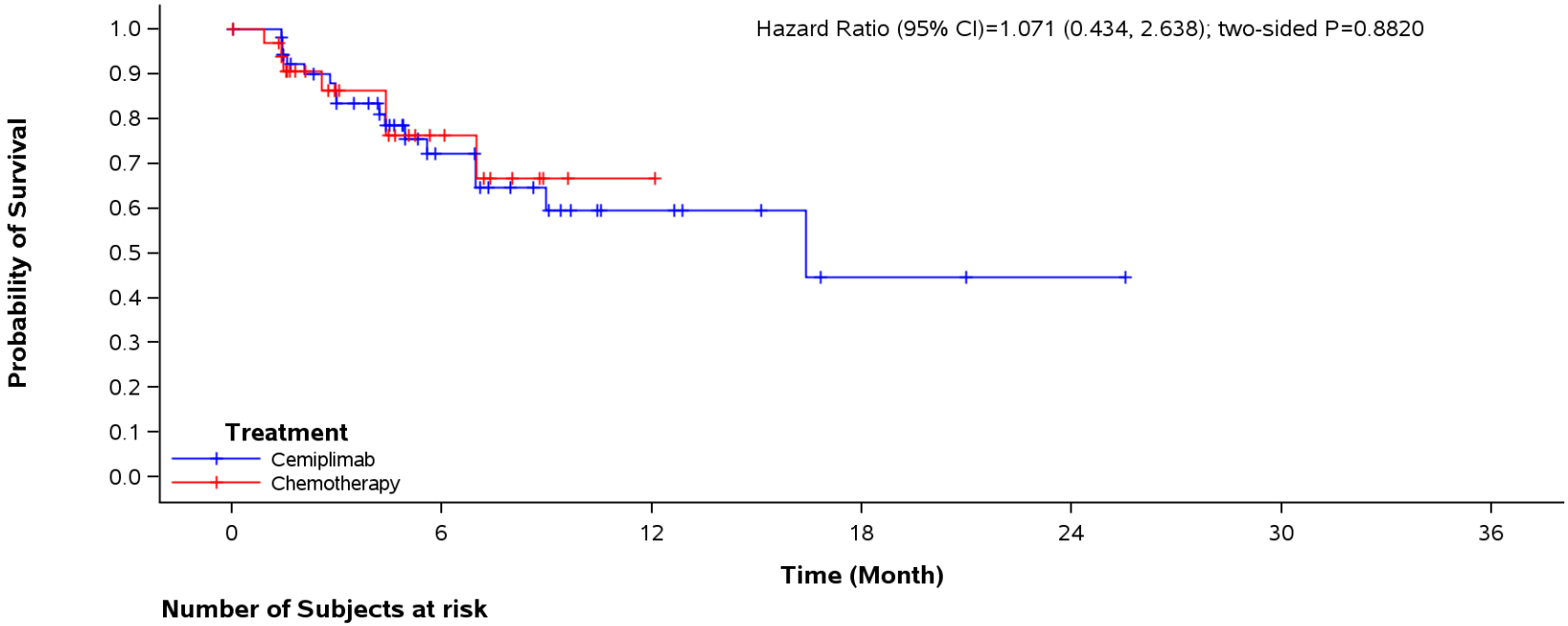

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 13 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Emotional Functioning - 10 pts sustained improvement



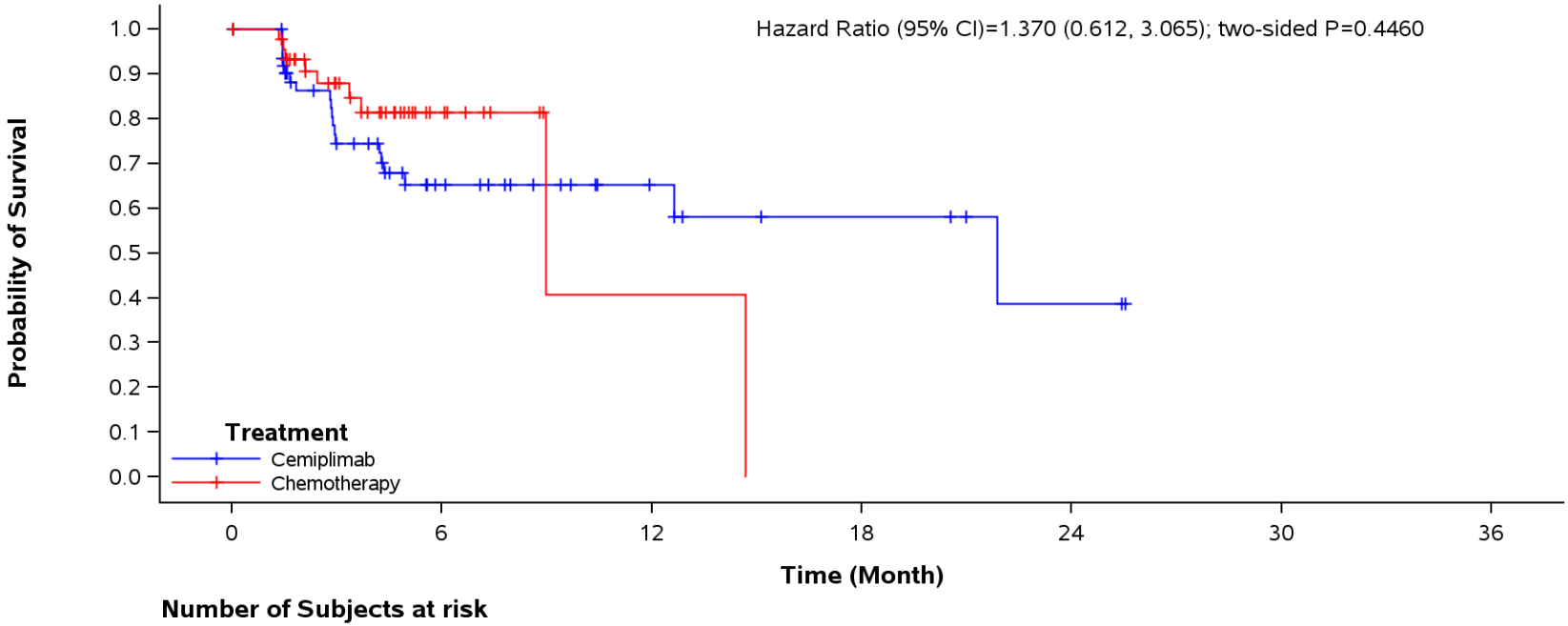

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 20 | 7 | 2 | 1 | 0 | 0 |
| Chemotherapy | 85 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts sustained improvement



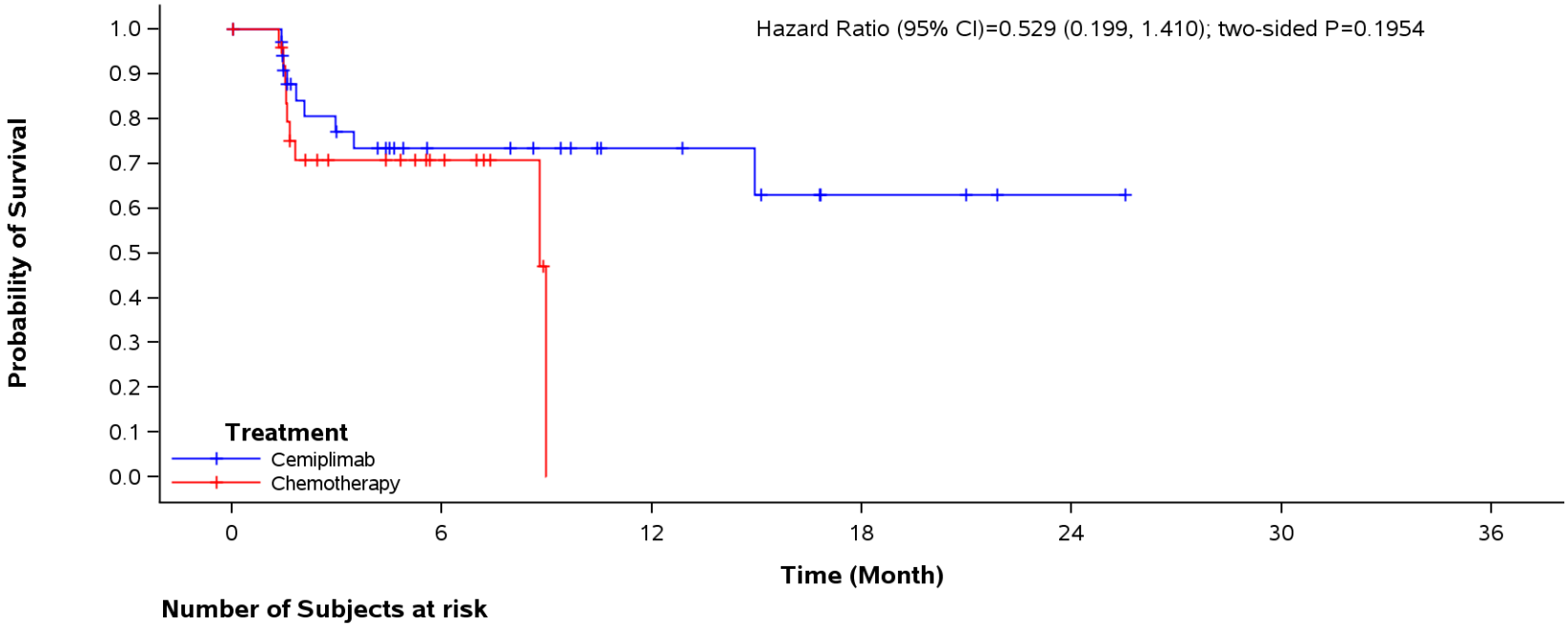

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 21 | 9 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts sustained improvement



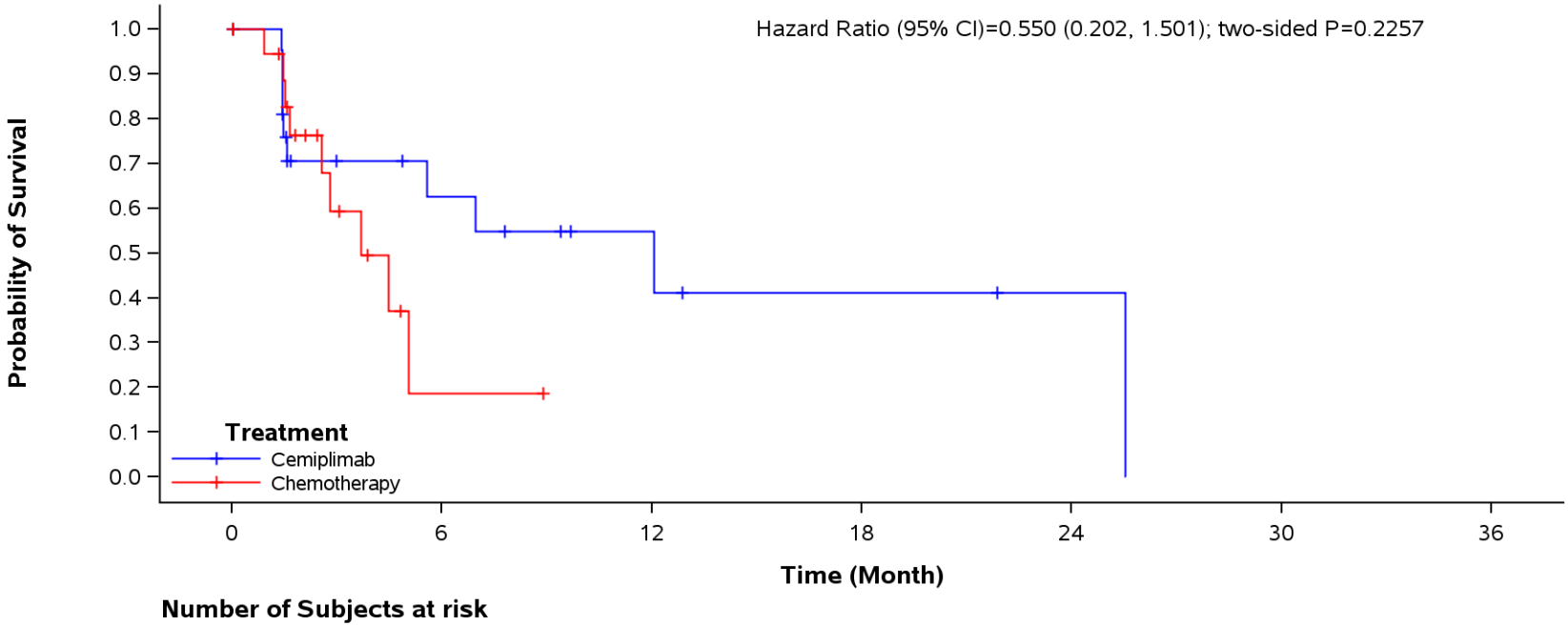

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 14 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 85 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts sustained improvement



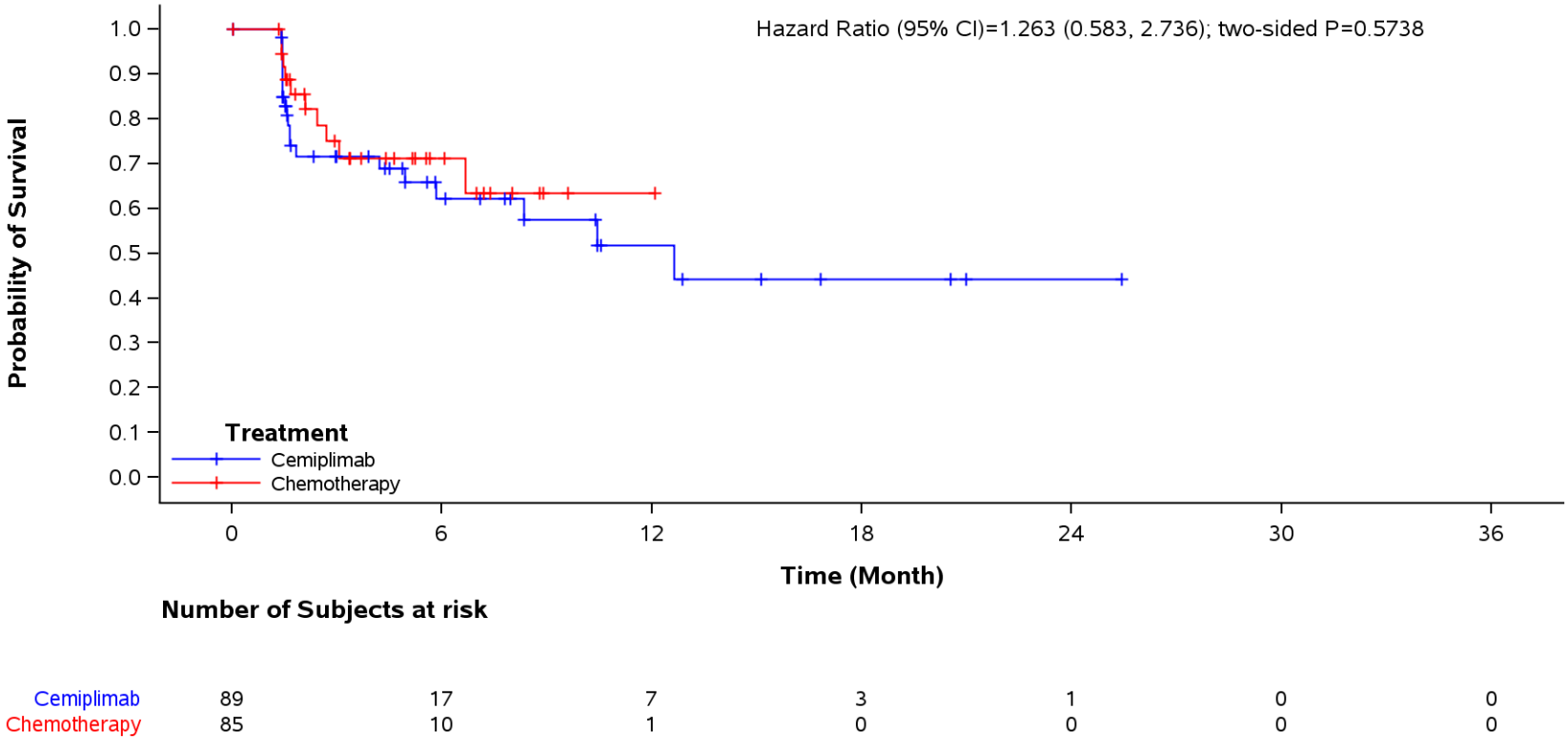

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 8 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 85 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts sustained improvement



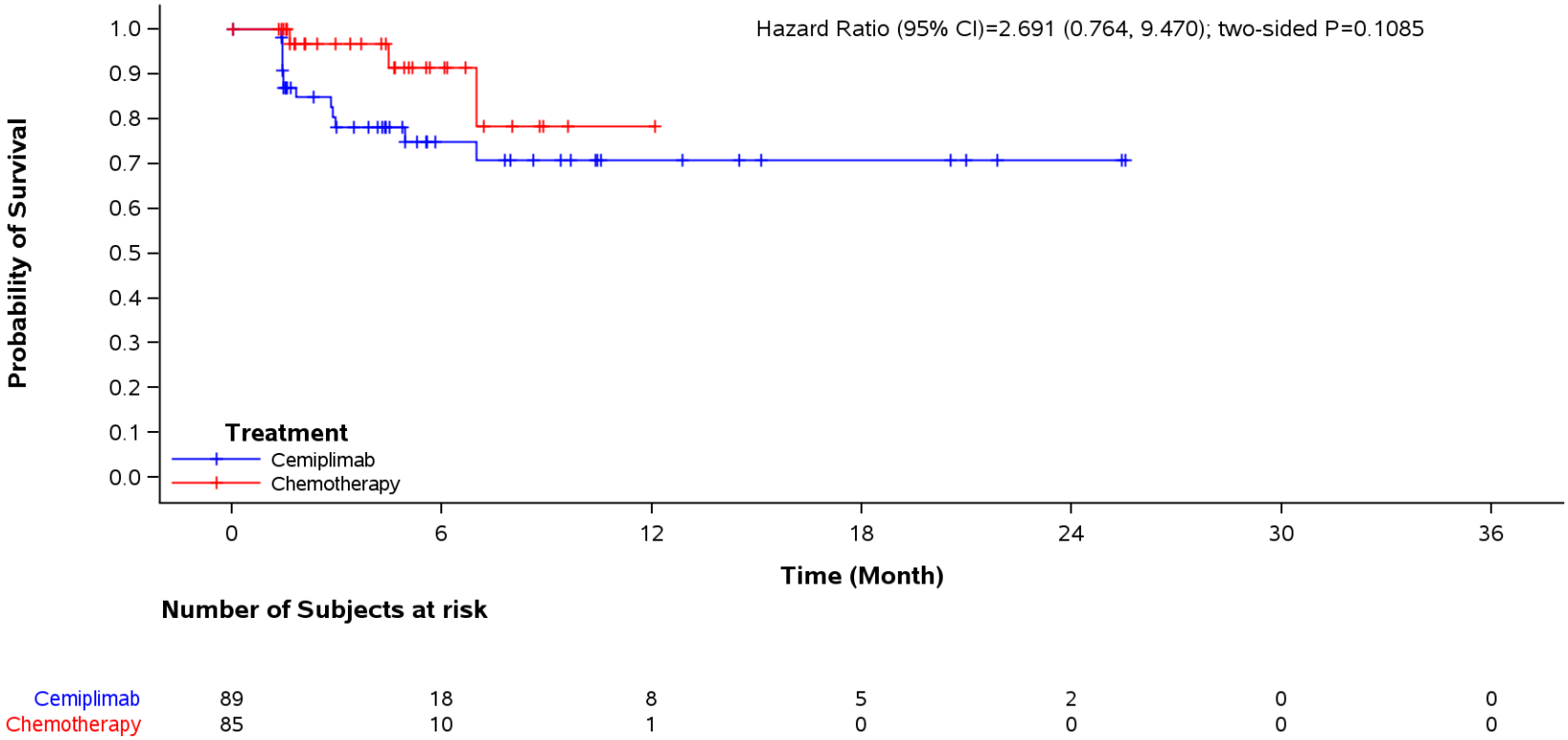

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 17 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Physical Functioning - 10 pts sustained improvement



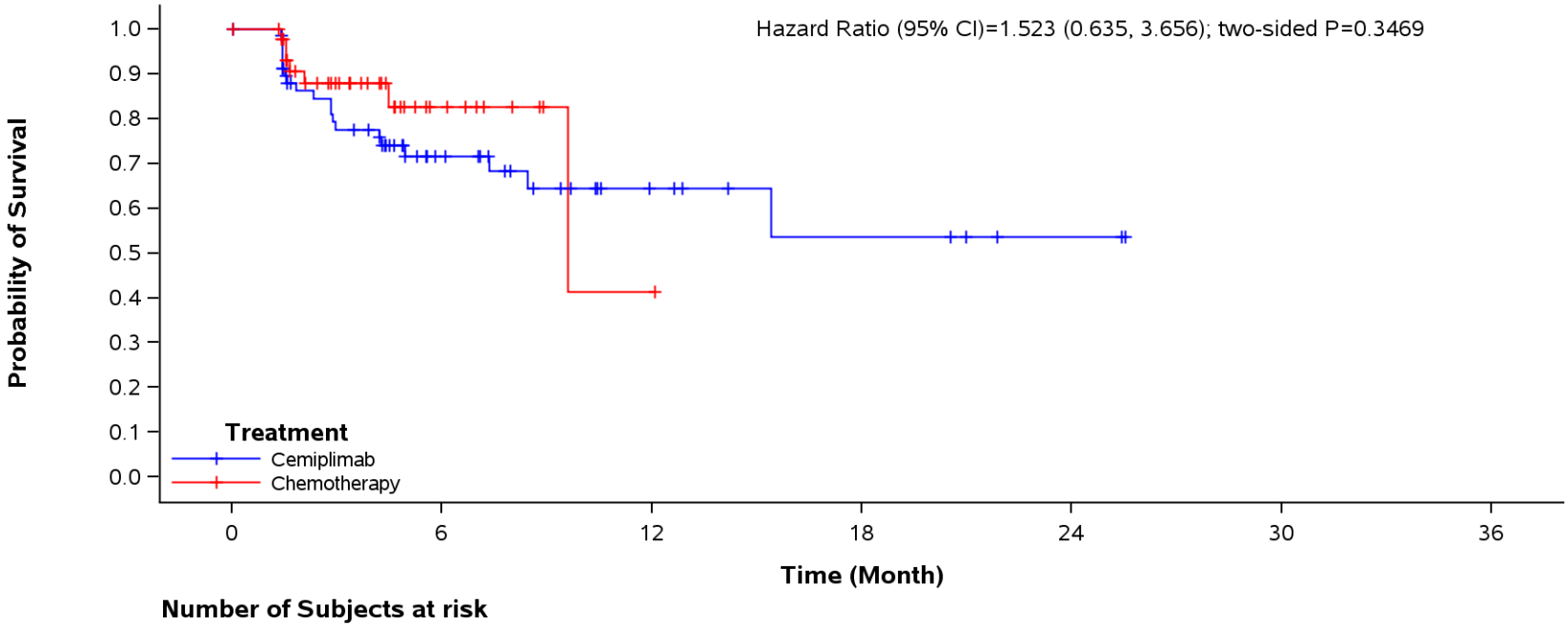

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 18 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Global health status / QoL - 10 pts sustained improvement



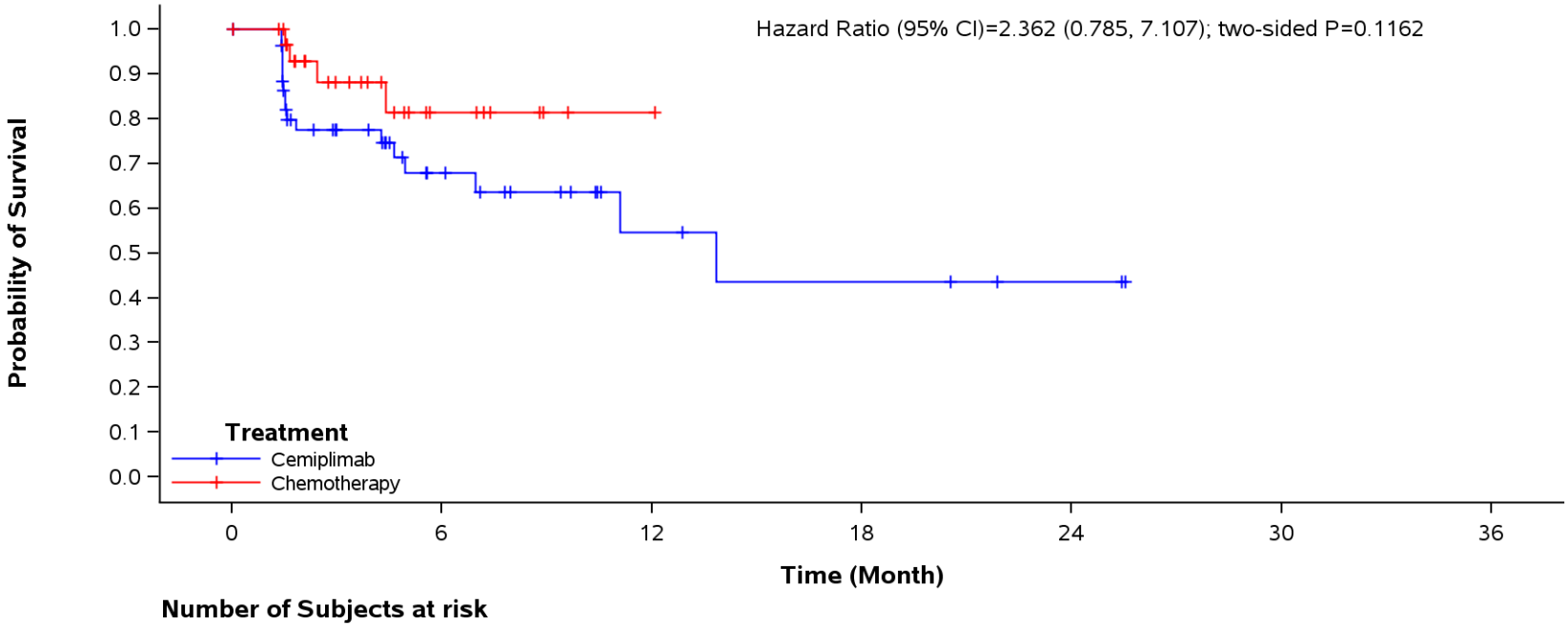

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 25 | 9 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts sustained improvement



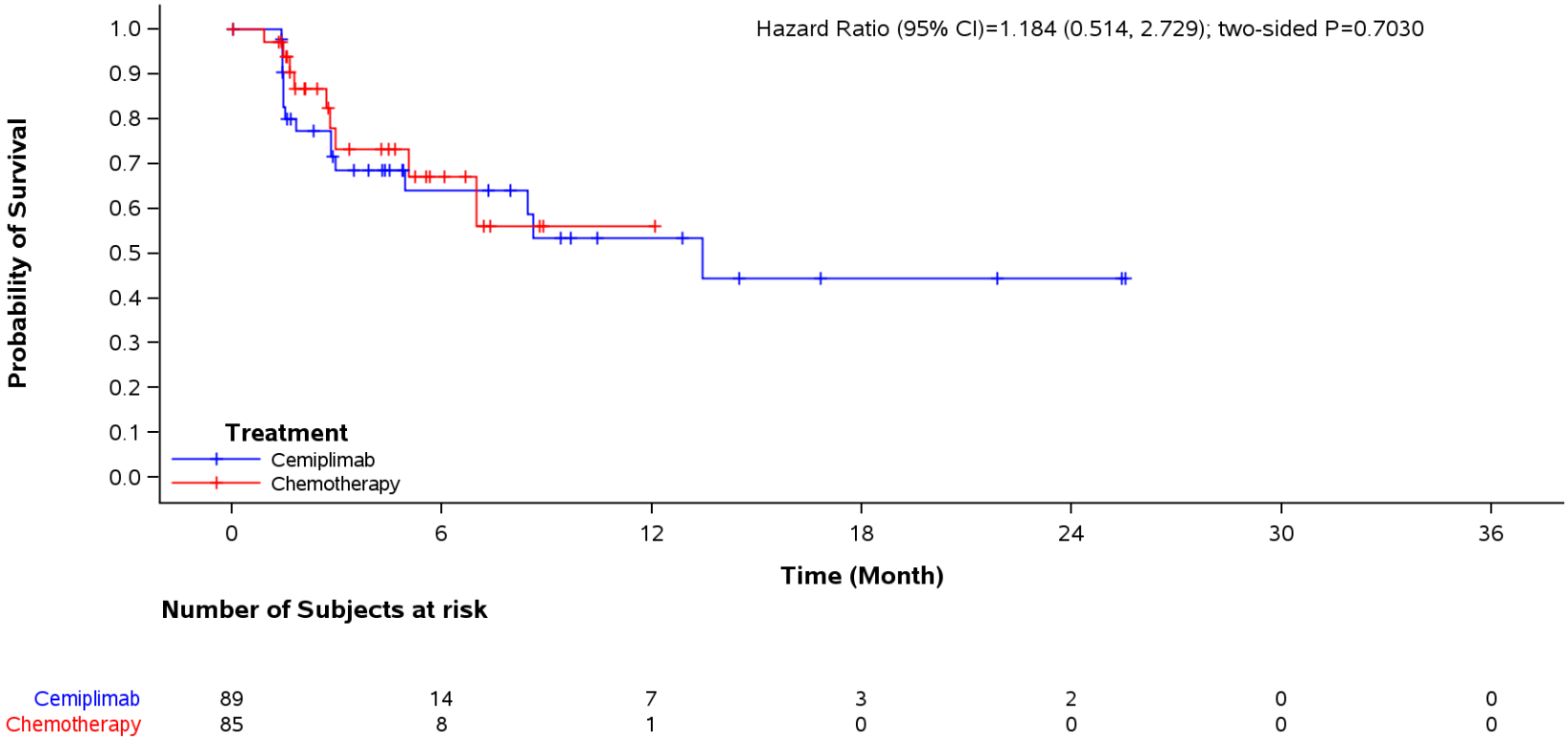

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 17 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts sustained improvement



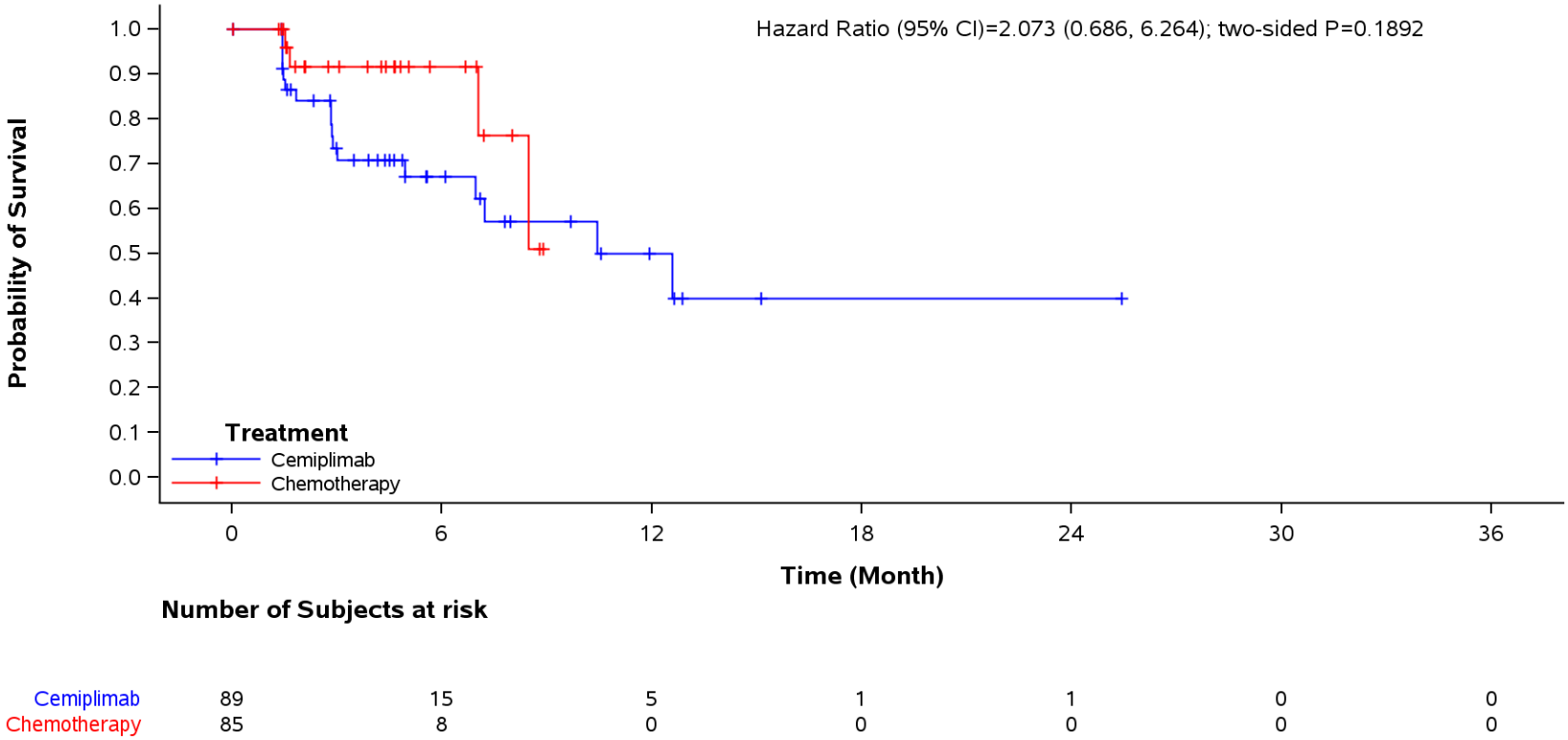

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 14 | 7 | 3 | 2 | 0 | 0 |
| Chemotherapy | 85 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts sustained improvement



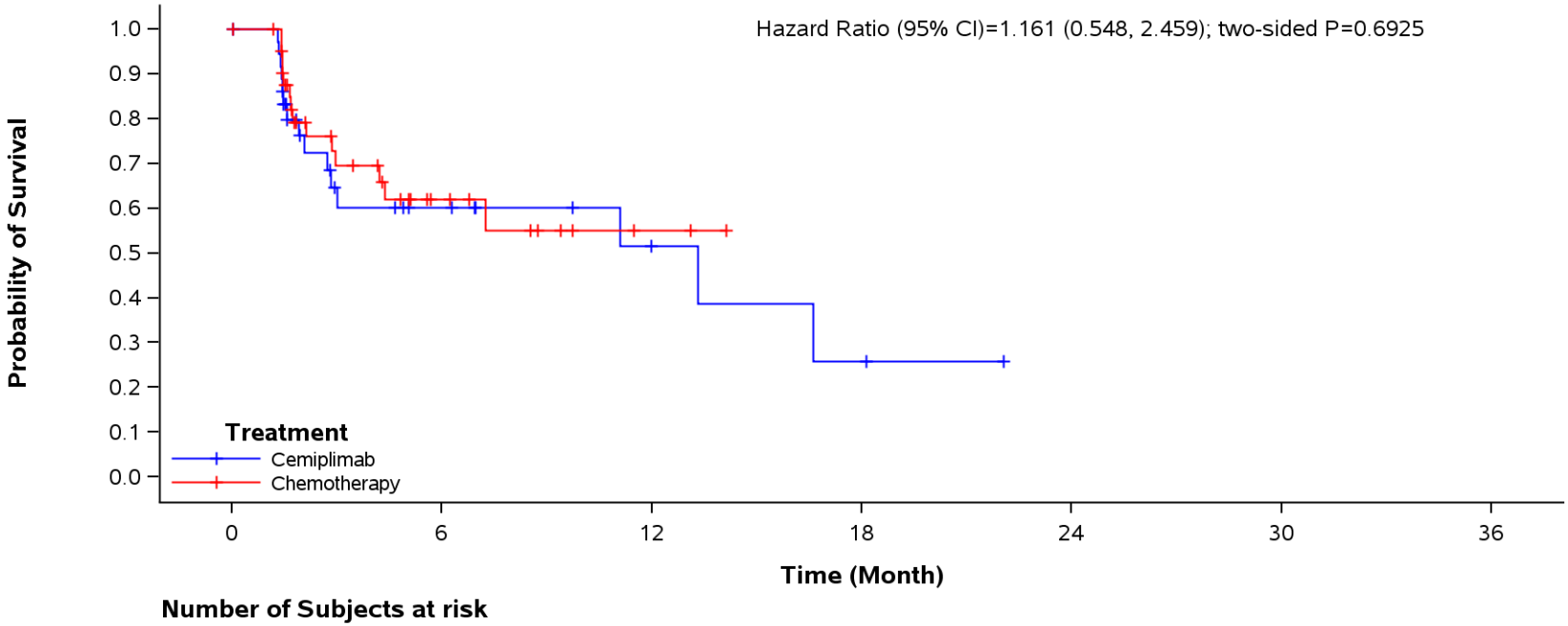

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 15 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 85 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts sustained improvement



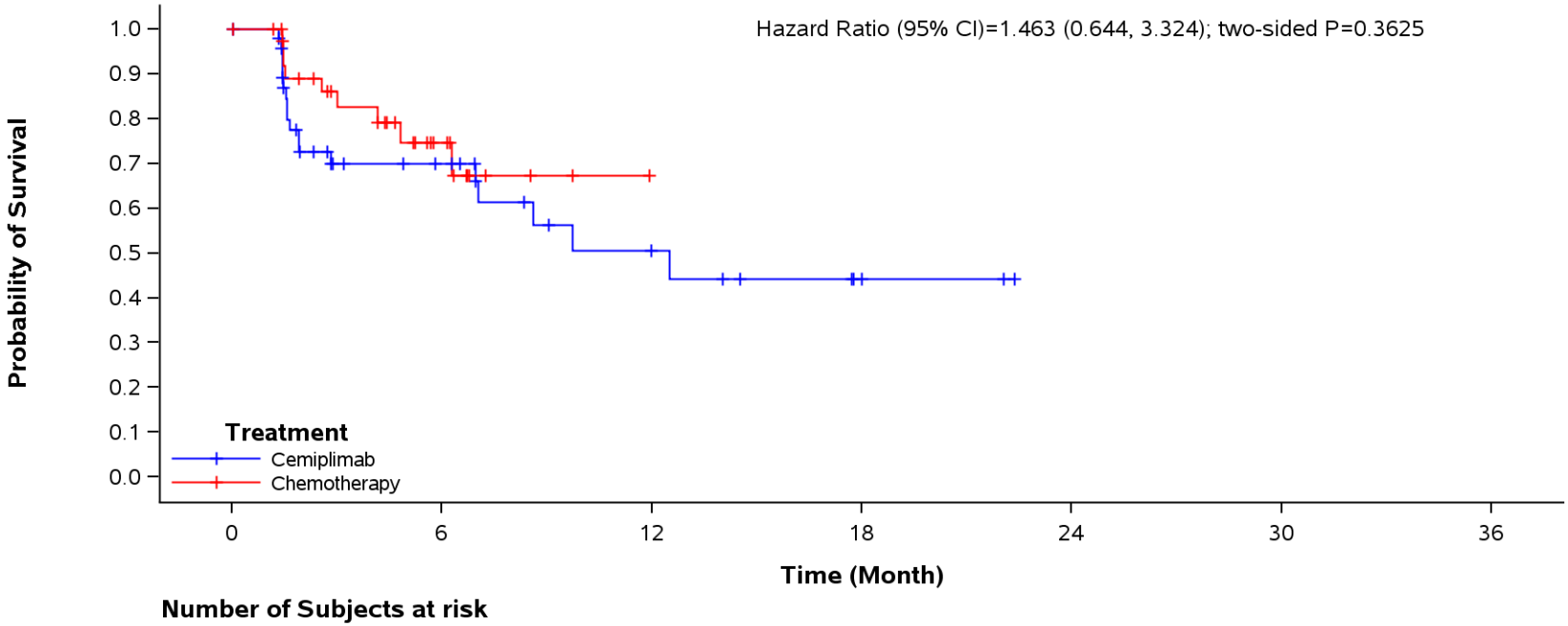

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 11 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 98 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts sustained improvement



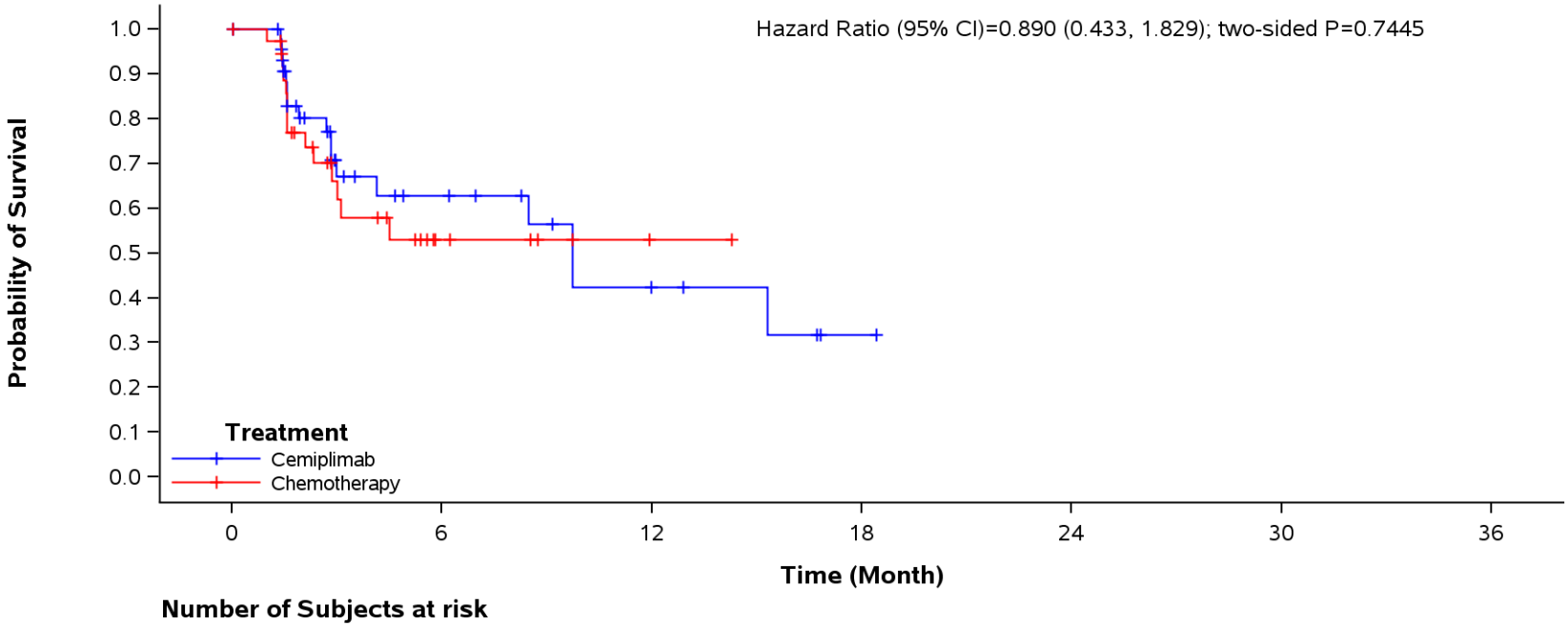

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 21 | 8 | 3 | 0 | 0 | 0 |
| Chemotherapy | 98 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts sustained improvement



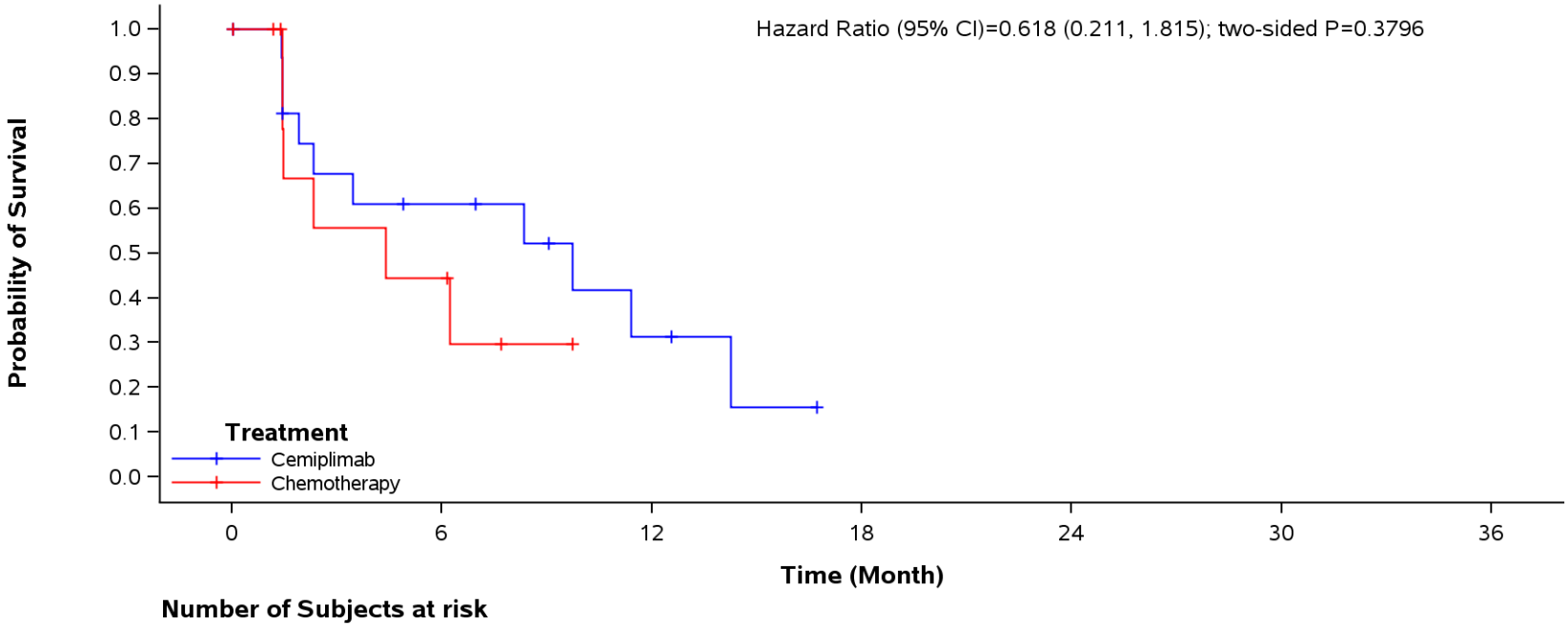

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 13 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts sustained improvement



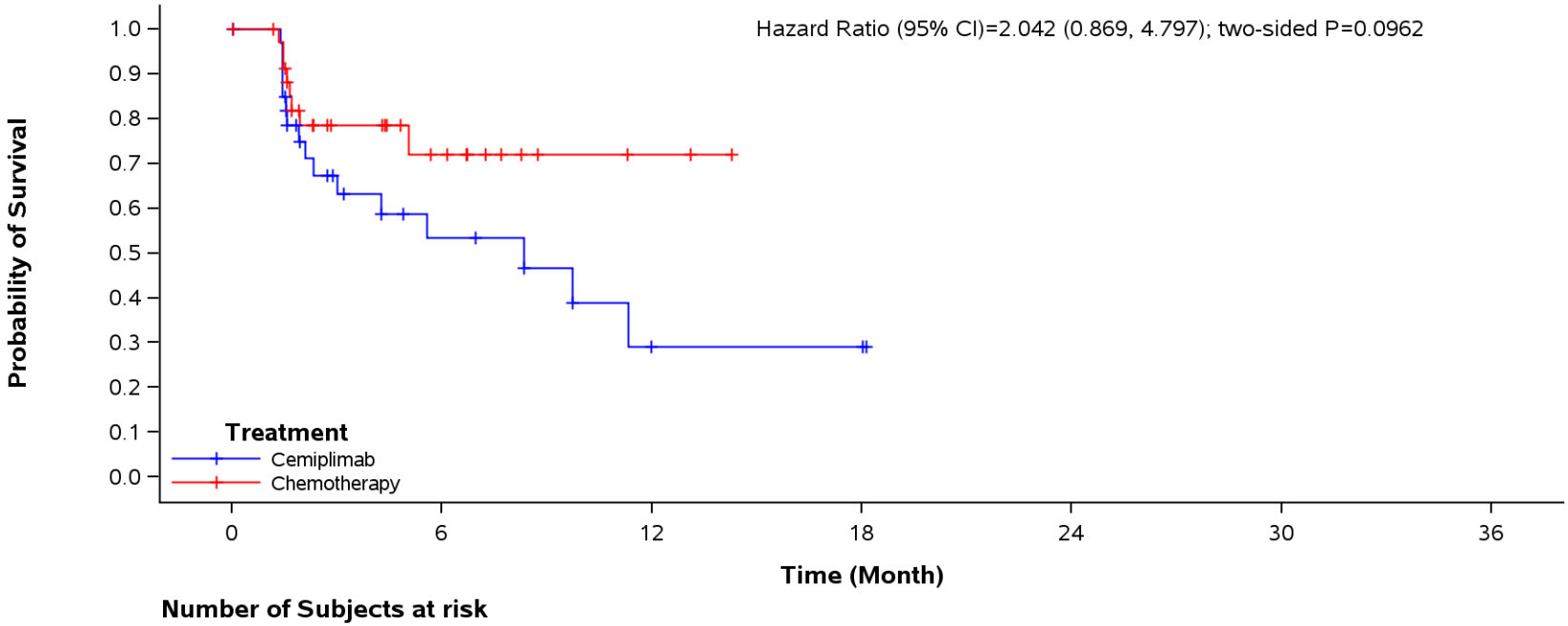

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 98 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Dyspnoea - 10 pts sustained improvement




Number of Subjects at risk

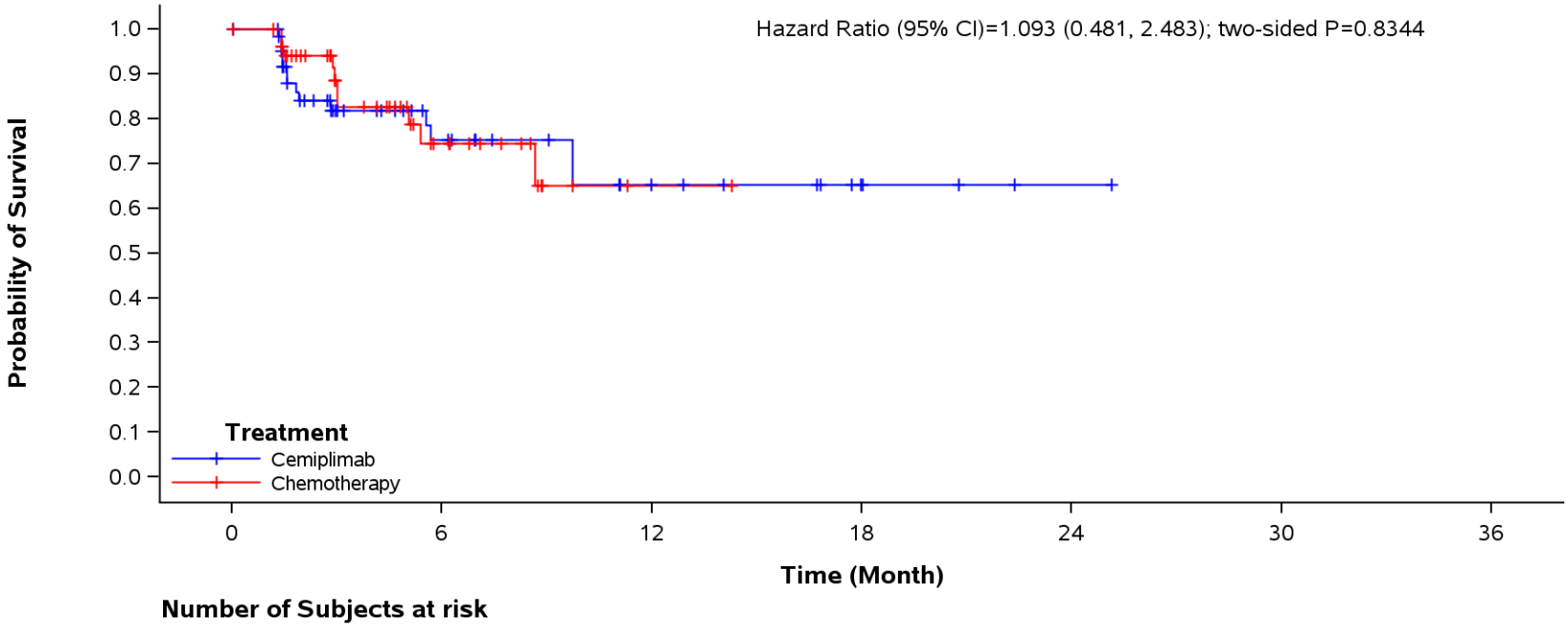
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 10 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 98 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:20:32, yingyuan.lin)

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Emotional Functioning - 10 pts sustained improvement



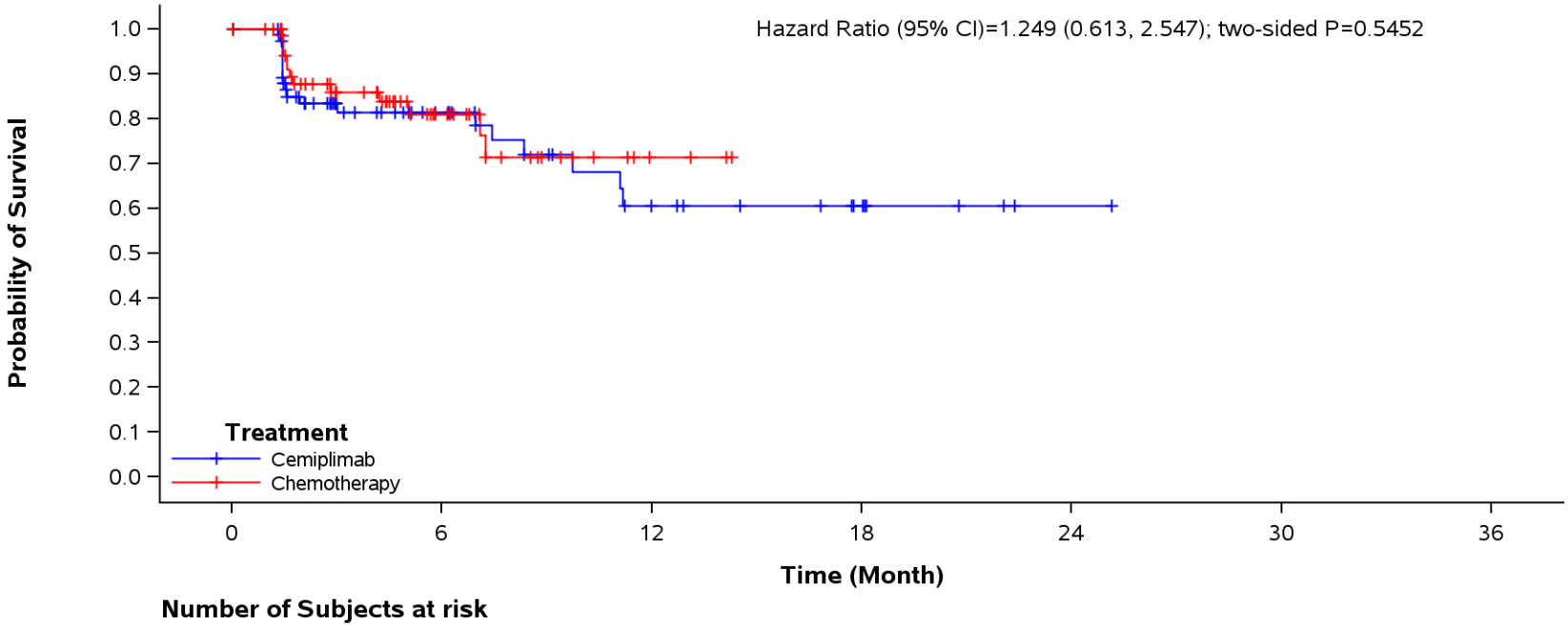

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 23 | 10 | 4 | 1 | 0 | 0 |
| Chemotherapy | 98 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts sustained improvement



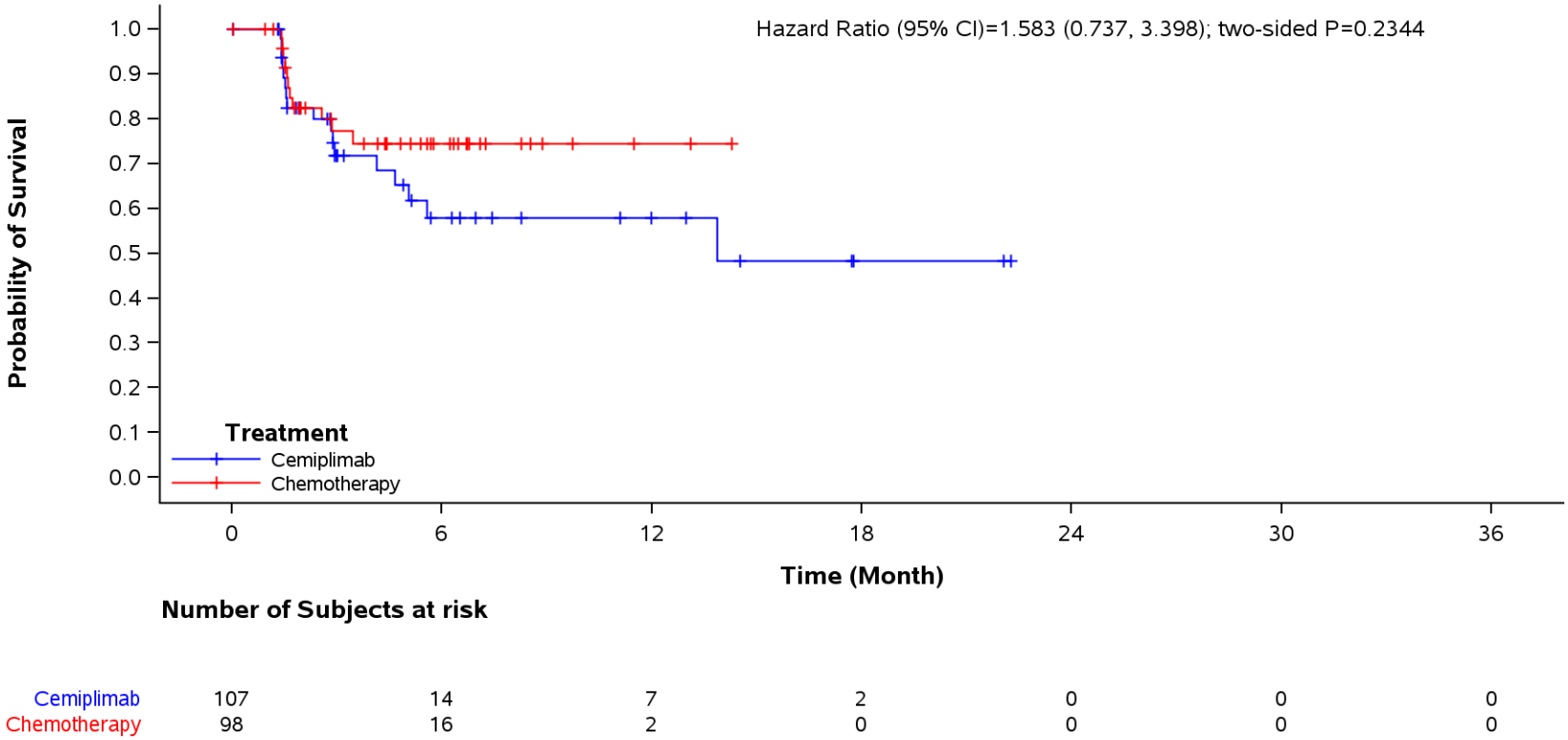

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 31 | 13 | 7 | 1 | 0 | 0 |
| Chemotherapy | 98 | 24 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

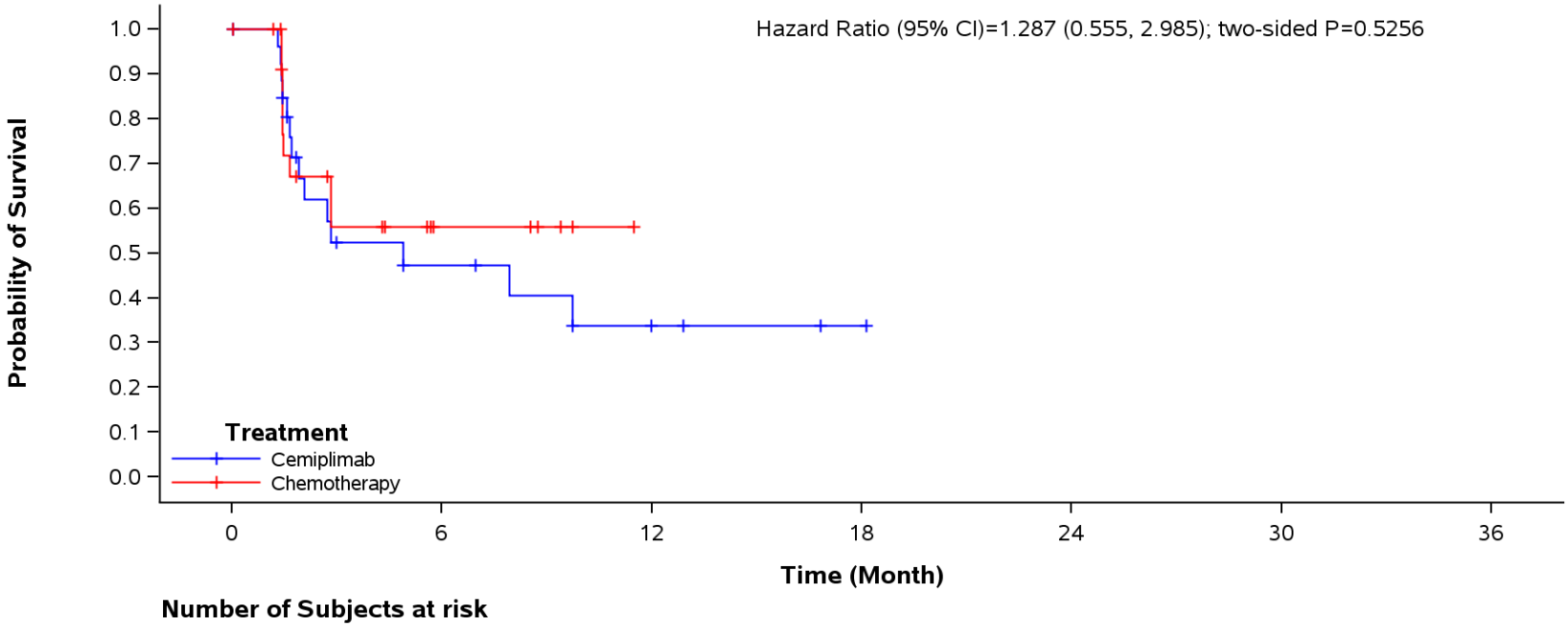
Prior Bevacizumab use: No
Financial Problems - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts sustained improvement



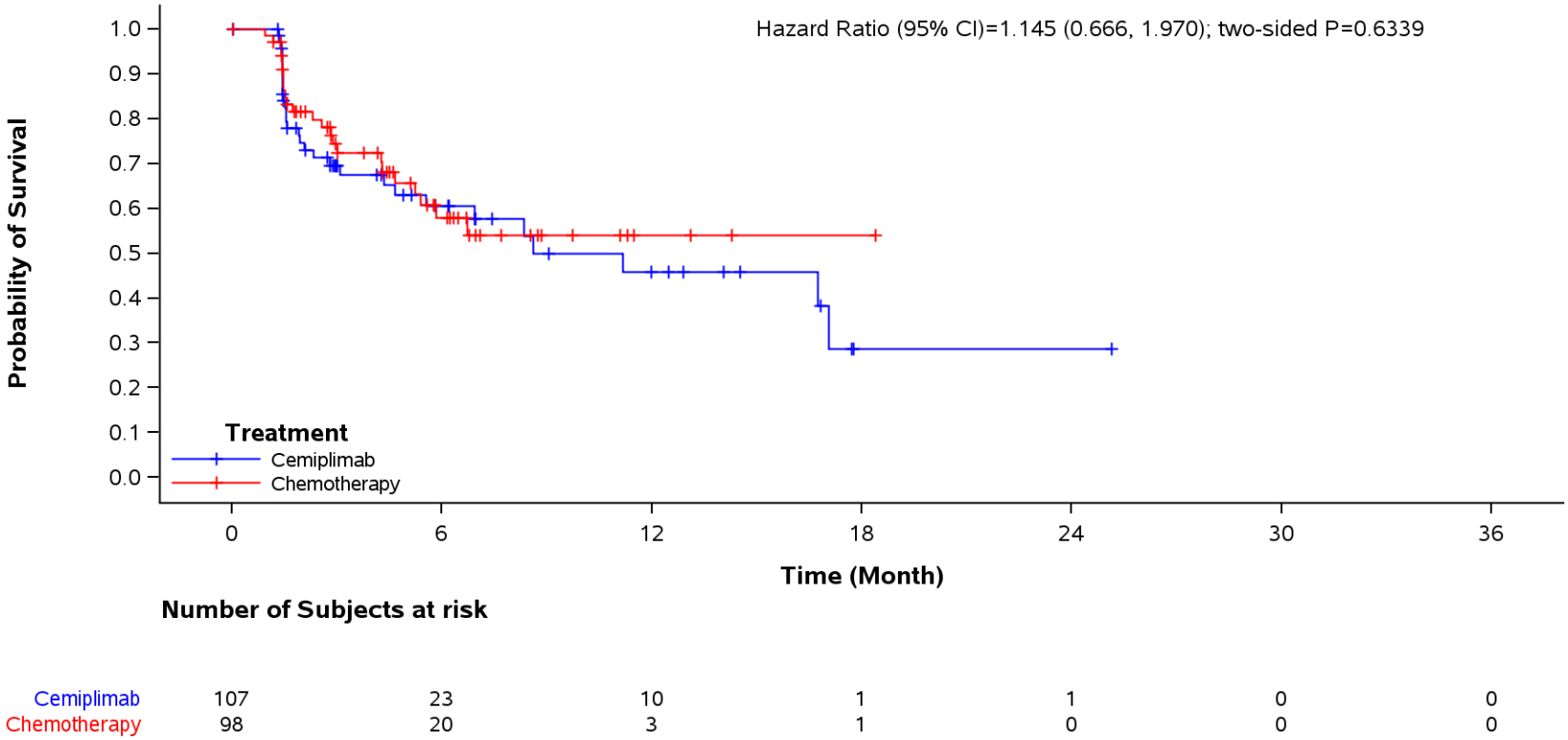

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 8 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts sustained improvement



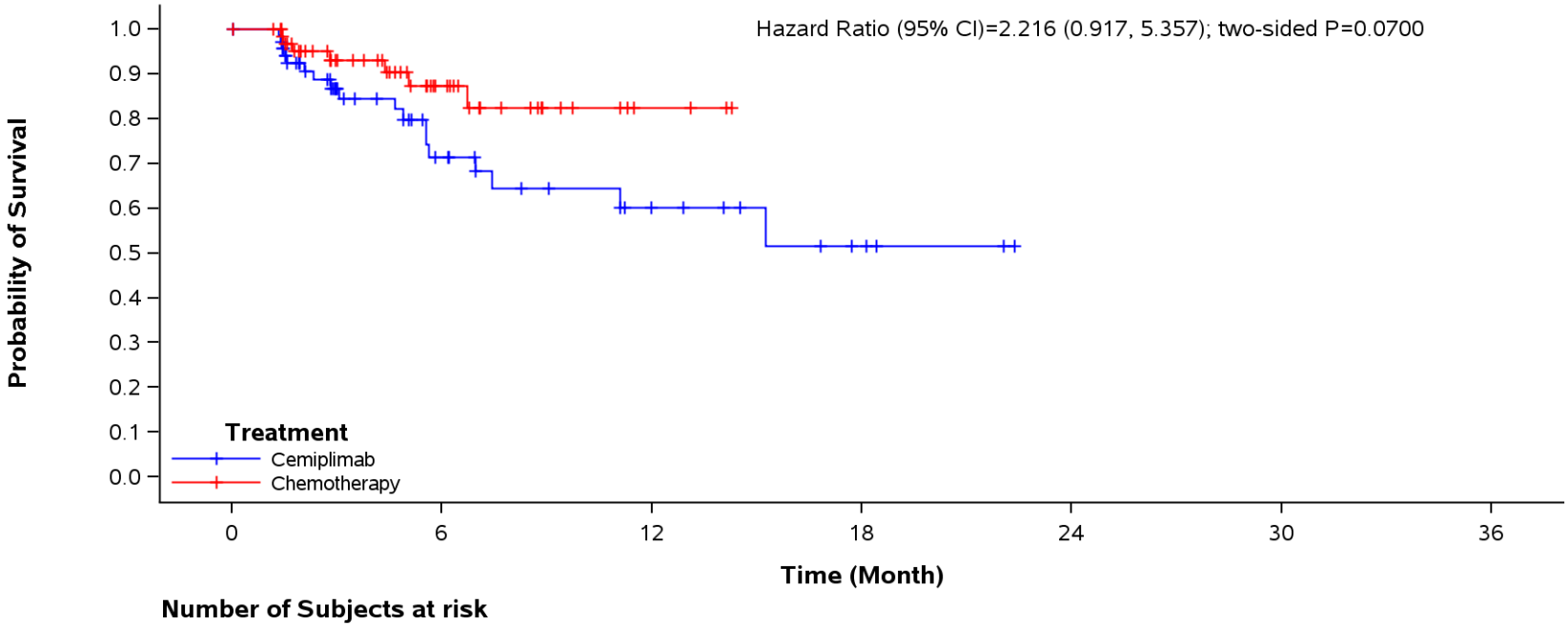

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 23 | 10 | 1 | 1 | 0 | 0 |
| Chemotherapy | 98 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Physical Functioning - 10 pts sustained improvement



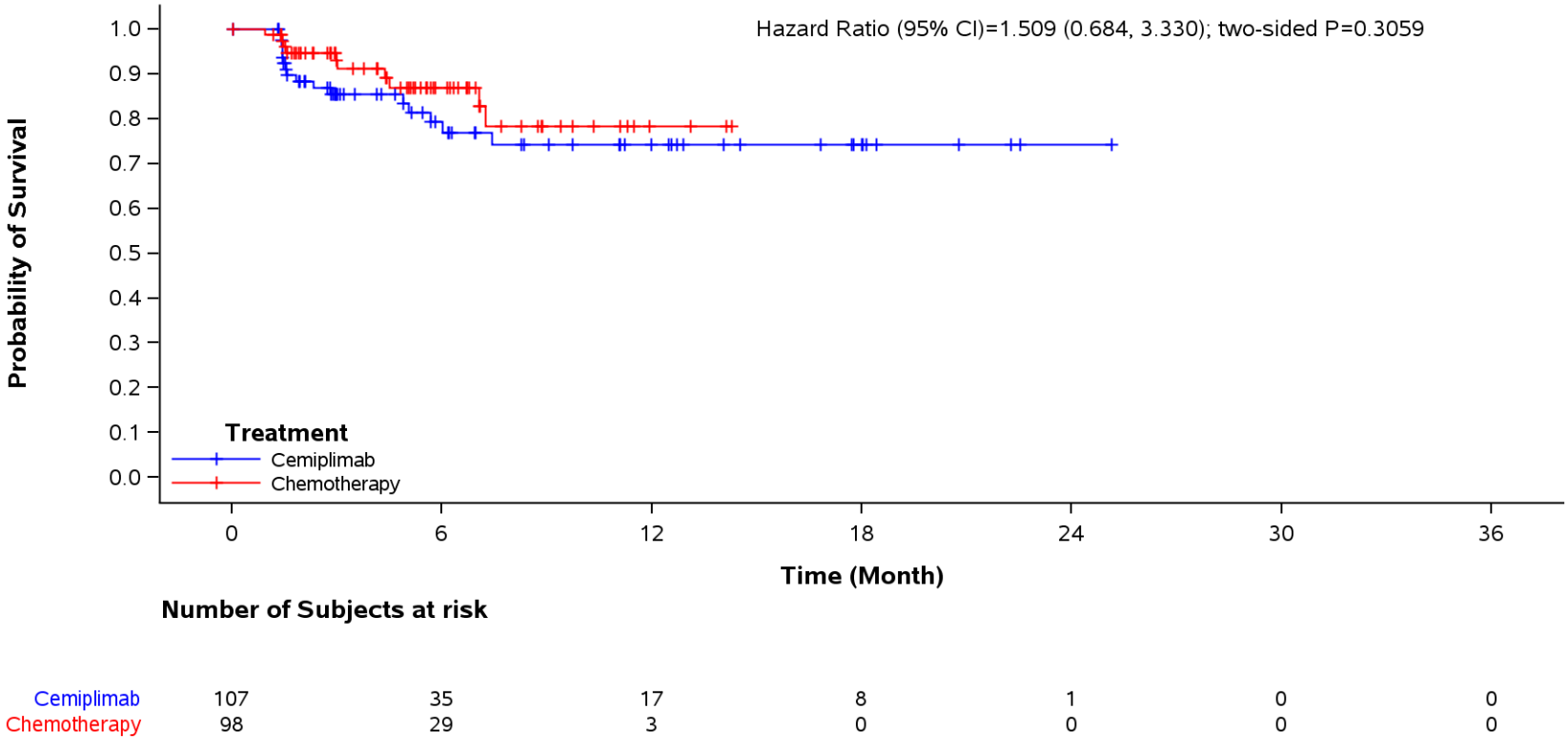

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 25 | 10 | 4 | 0 | 0 | 0 |
| Chemotherapy | 98 | 22 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Global health status / QoL - 10 pts sustained improvement



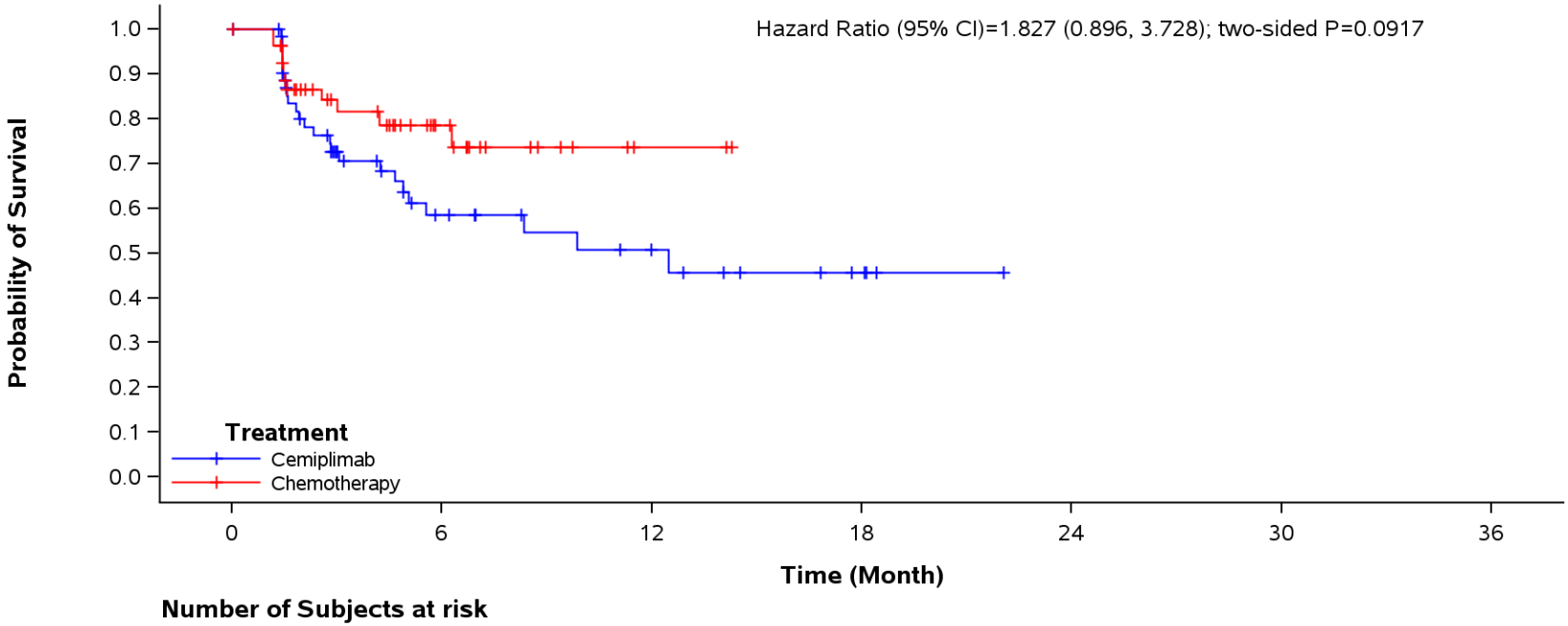

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 35 | 17 | 8 | 1 | 0 | 0 |
| Chemotherapy | 98 | 29 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts sustained improvement



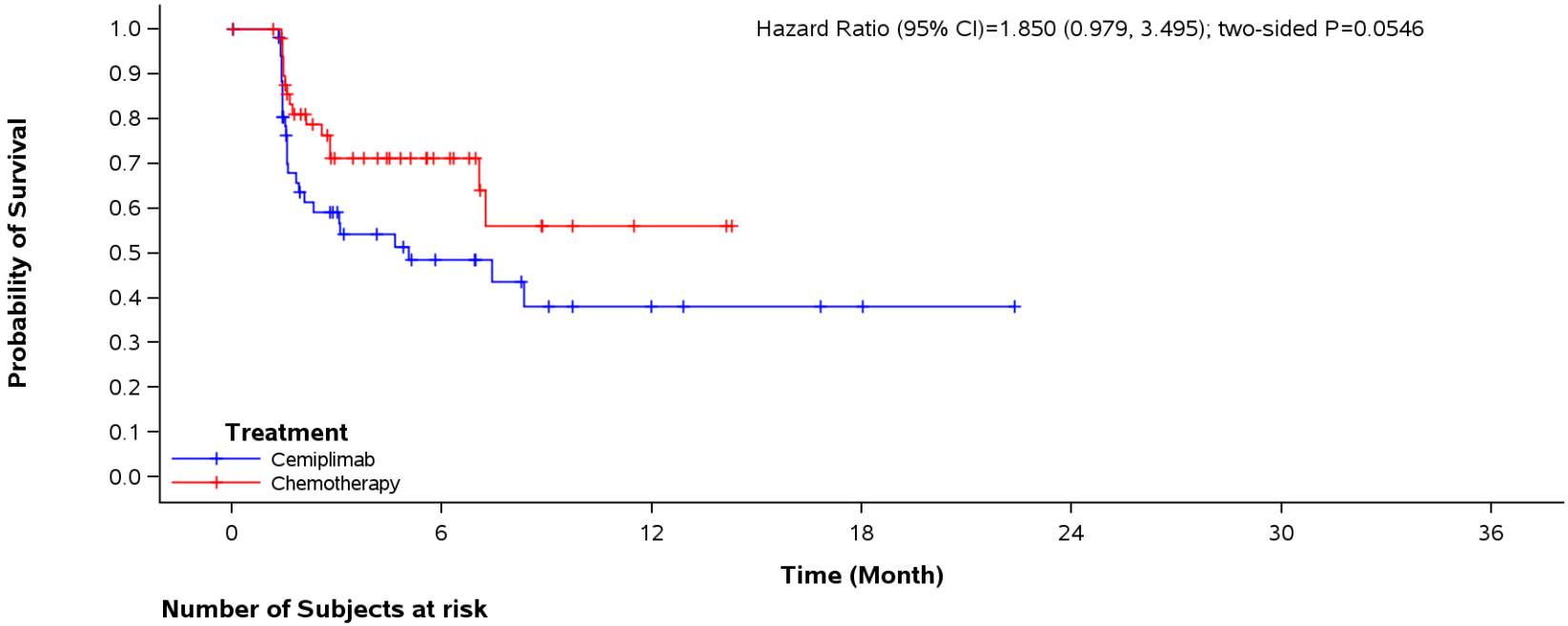

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 21 | 10 | 4 | 0 | 0 | 0 |
| Chemotherapy | 98 | 17 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts sustained improvement



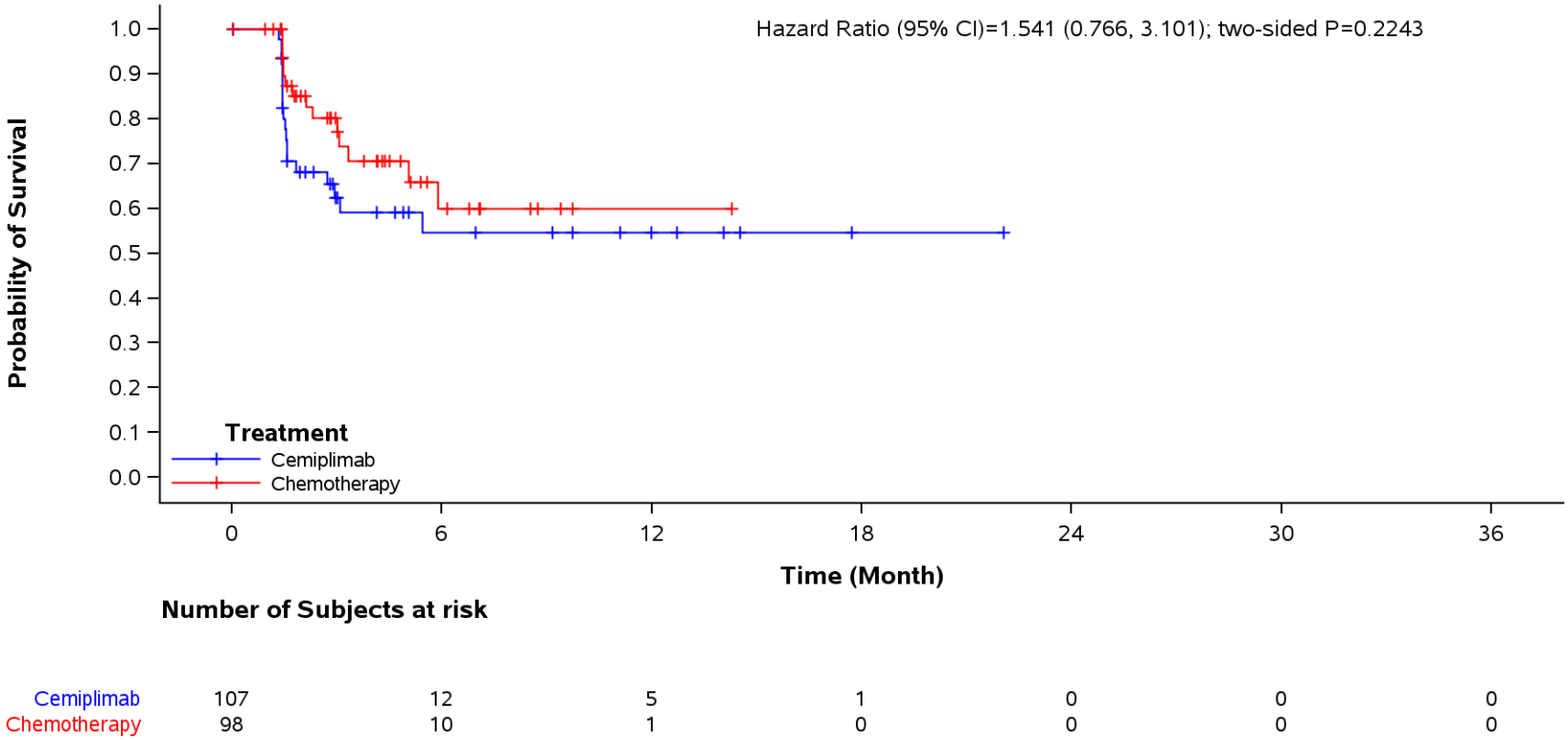

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 14 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 98 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts sustained improvement



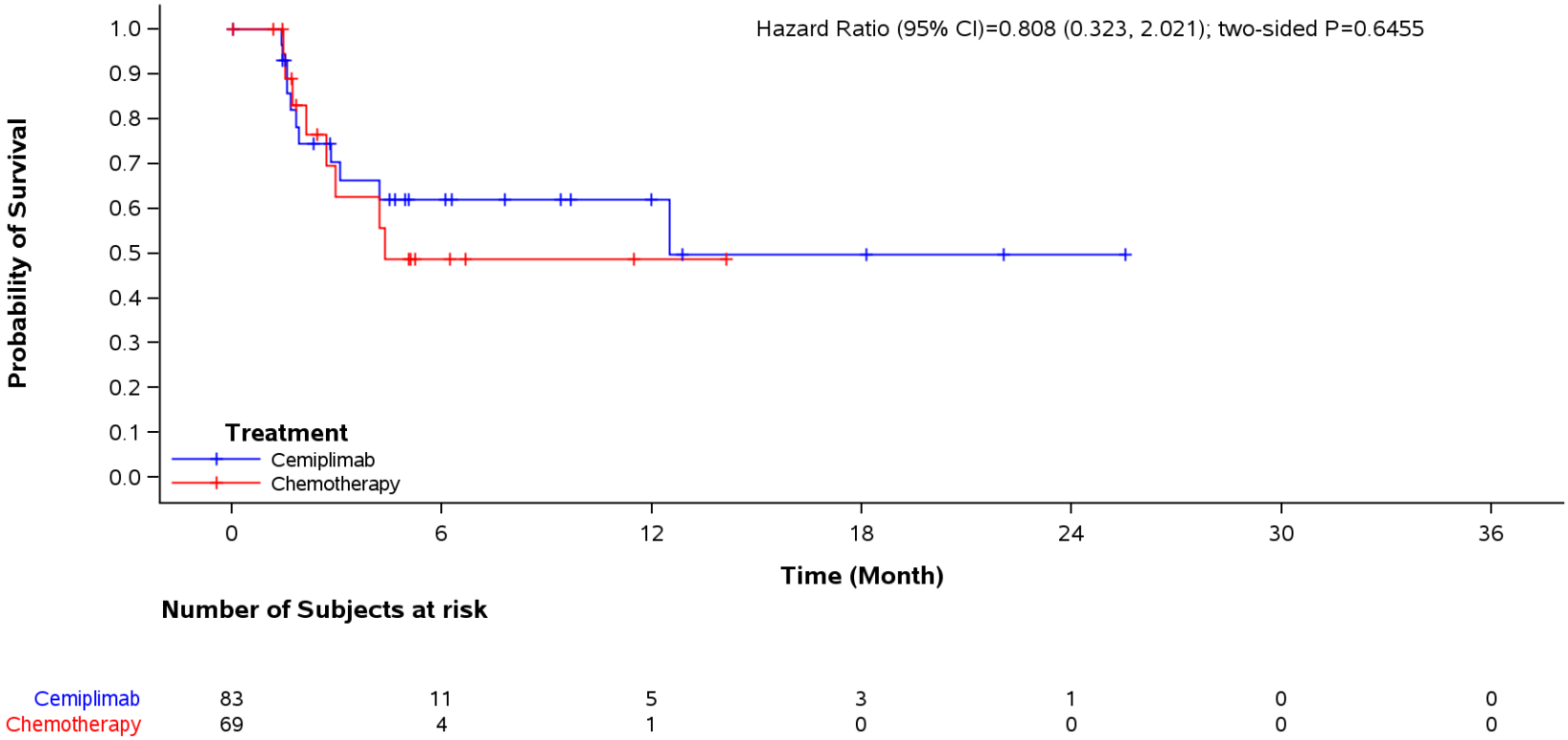

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 12 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Appetite loss - 10 pts sustained improvement



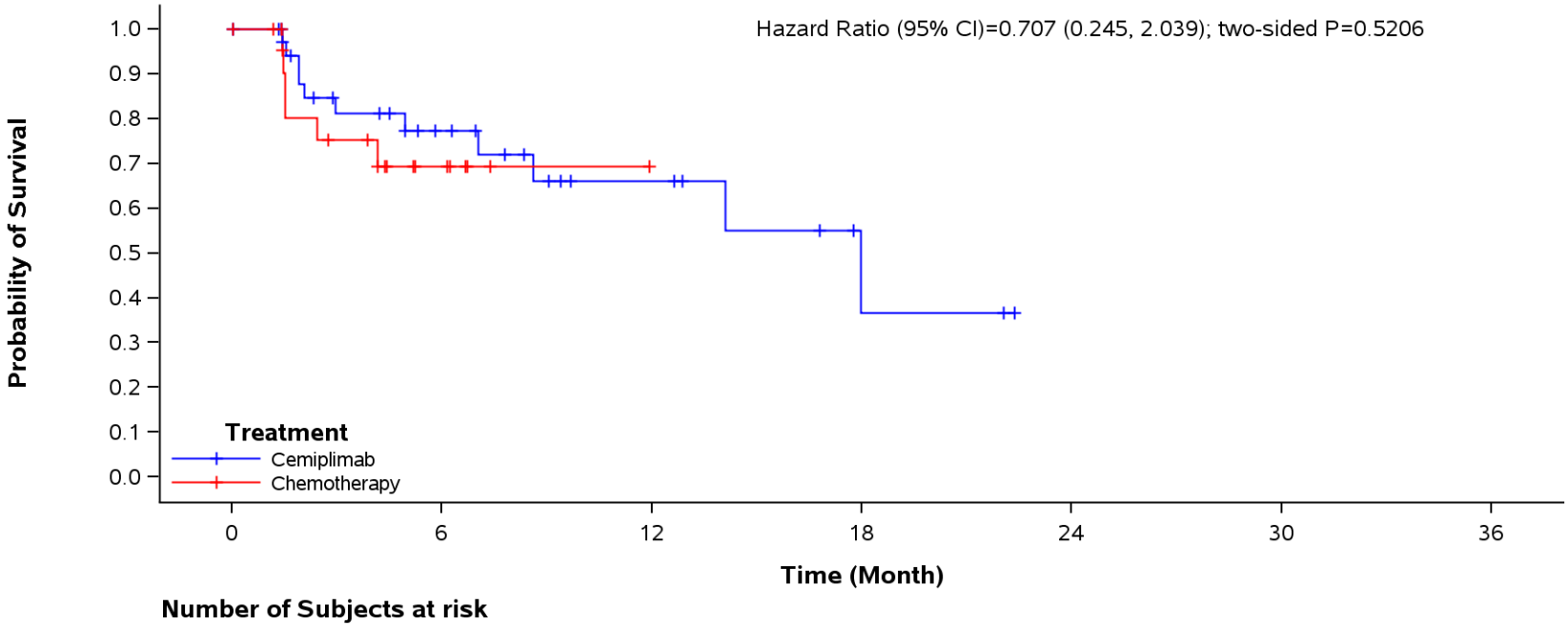

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 11 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 69 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts sustained improvement



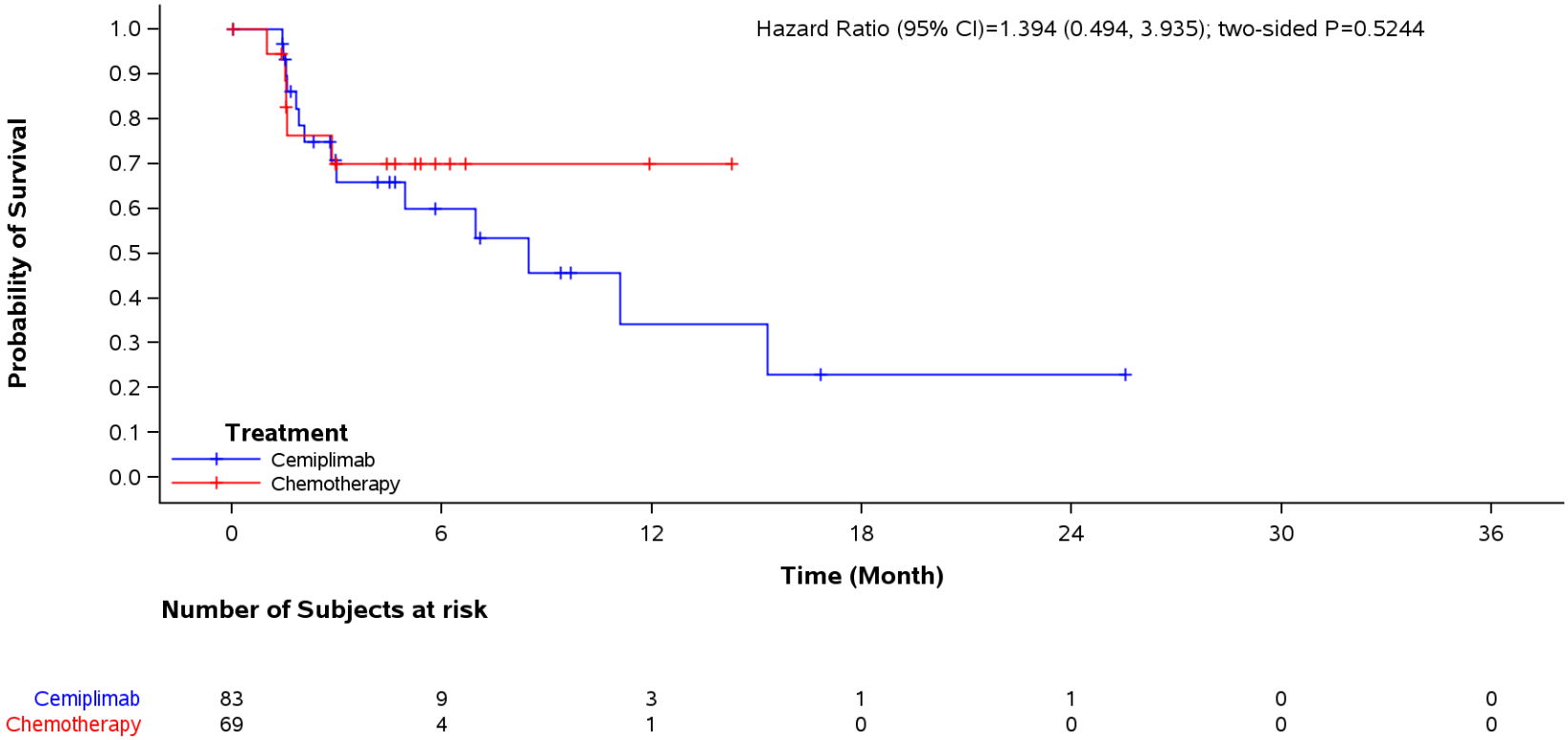

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 17 | 8 | 2 | 0 | 0 | 0 |
| Chemotherapy | 69 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts sustained improvement



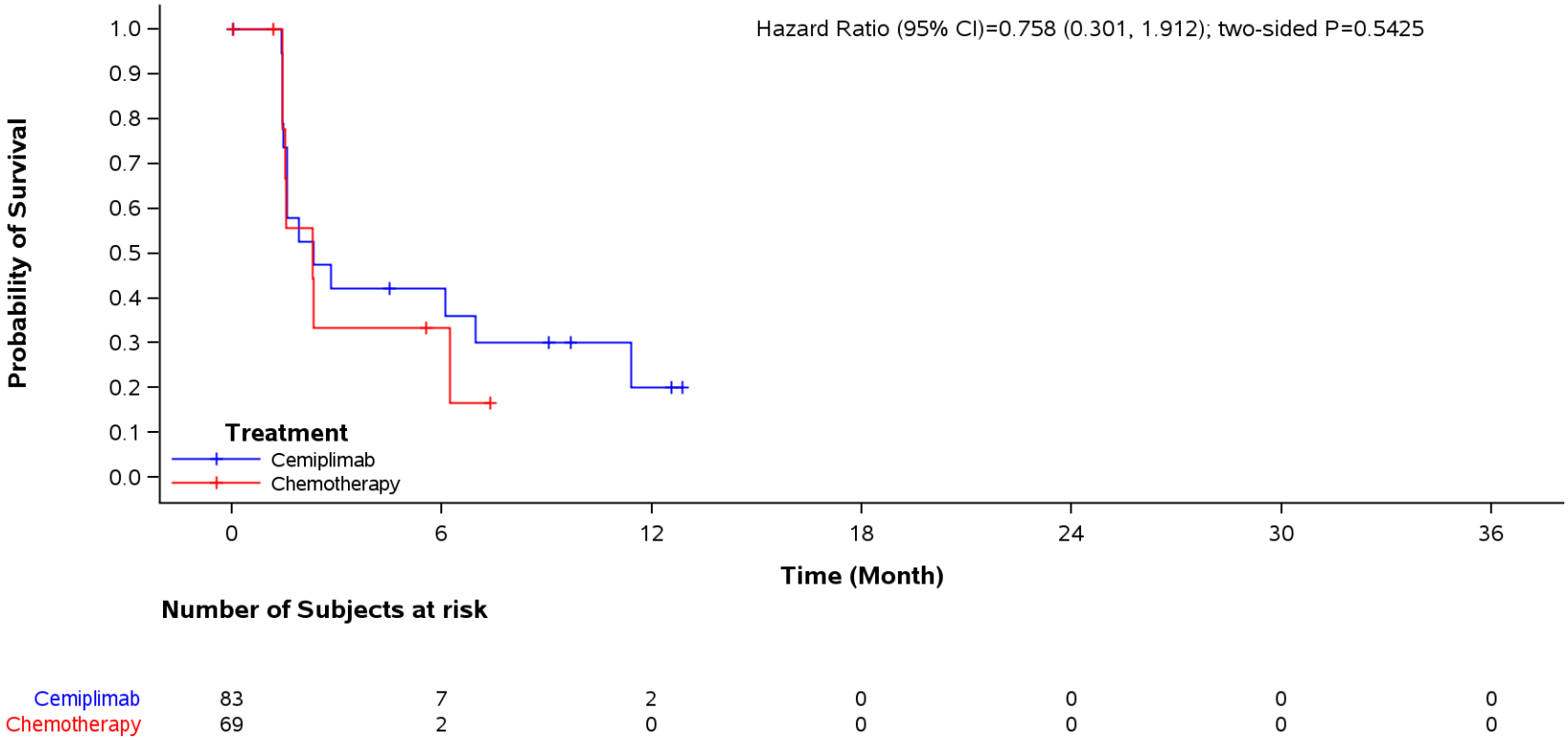

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 9 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 69 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

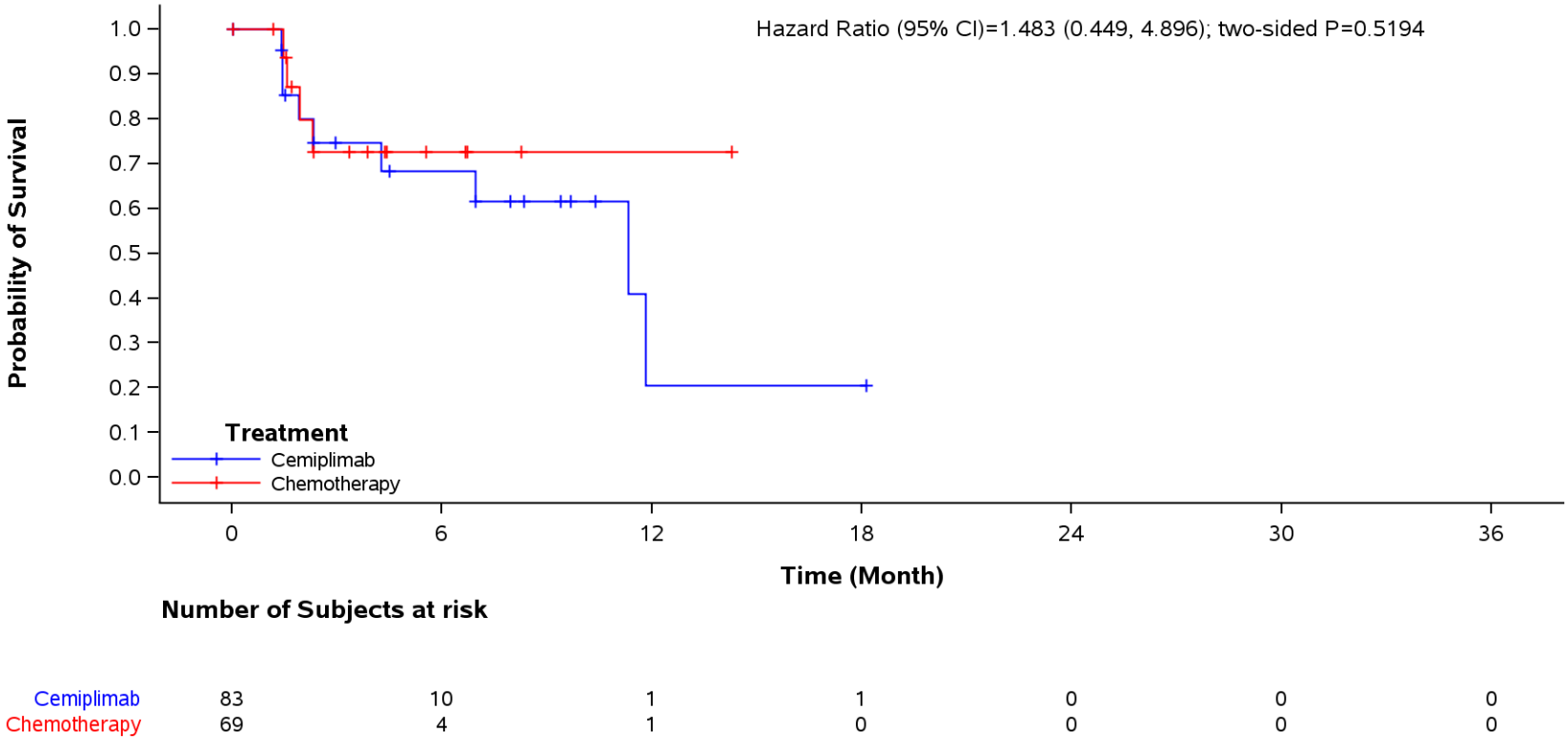
Baseline ECOG Status: 0
Diarhoea - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Dyspnoea - 10 pts sustained improvement



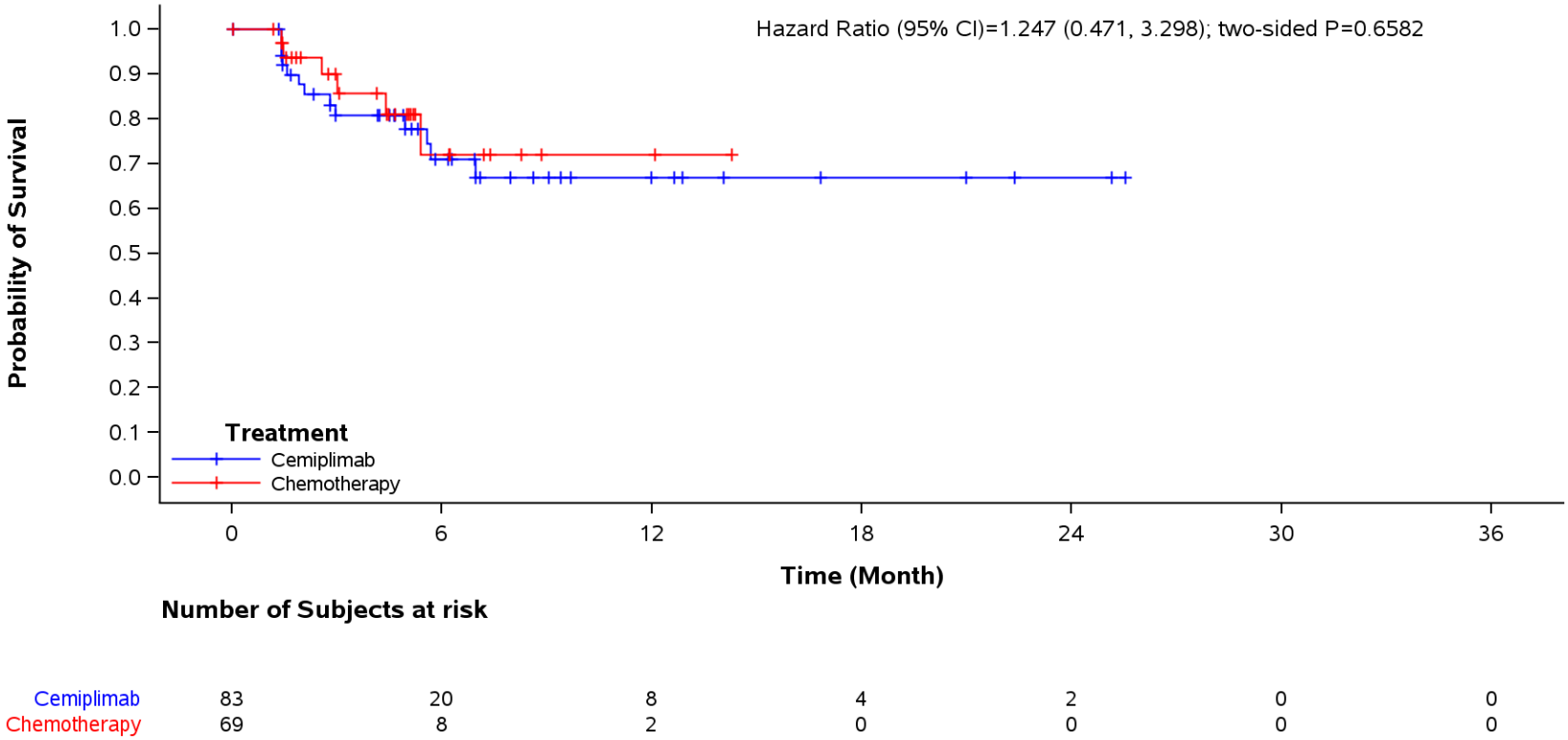

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 10 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 69 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Emotional Functioning - 10 pts sustained improvement



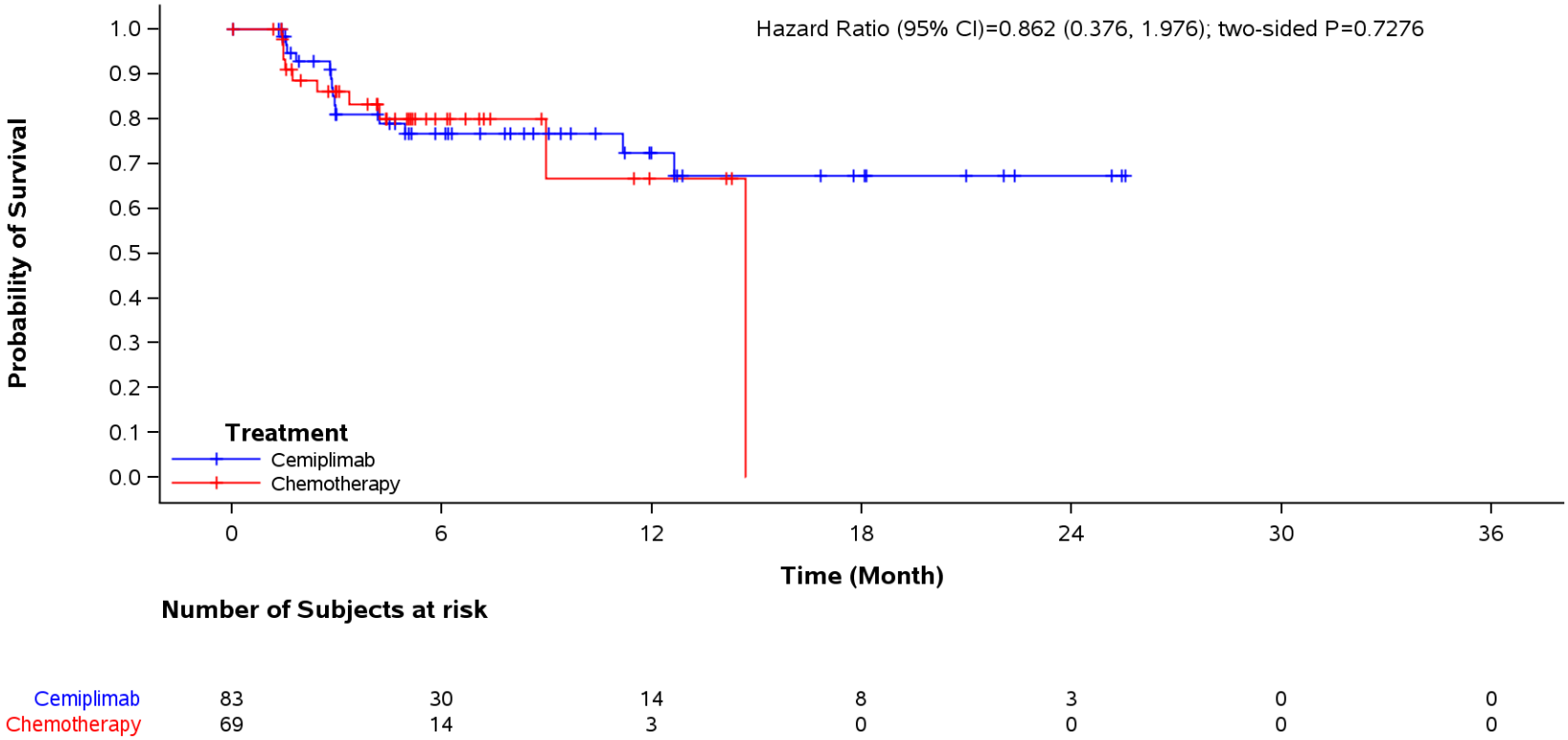

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 20 | 8 | 4 | 2 | 0 | 0 |
| Chemotherapy | 69 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts sustained improvement



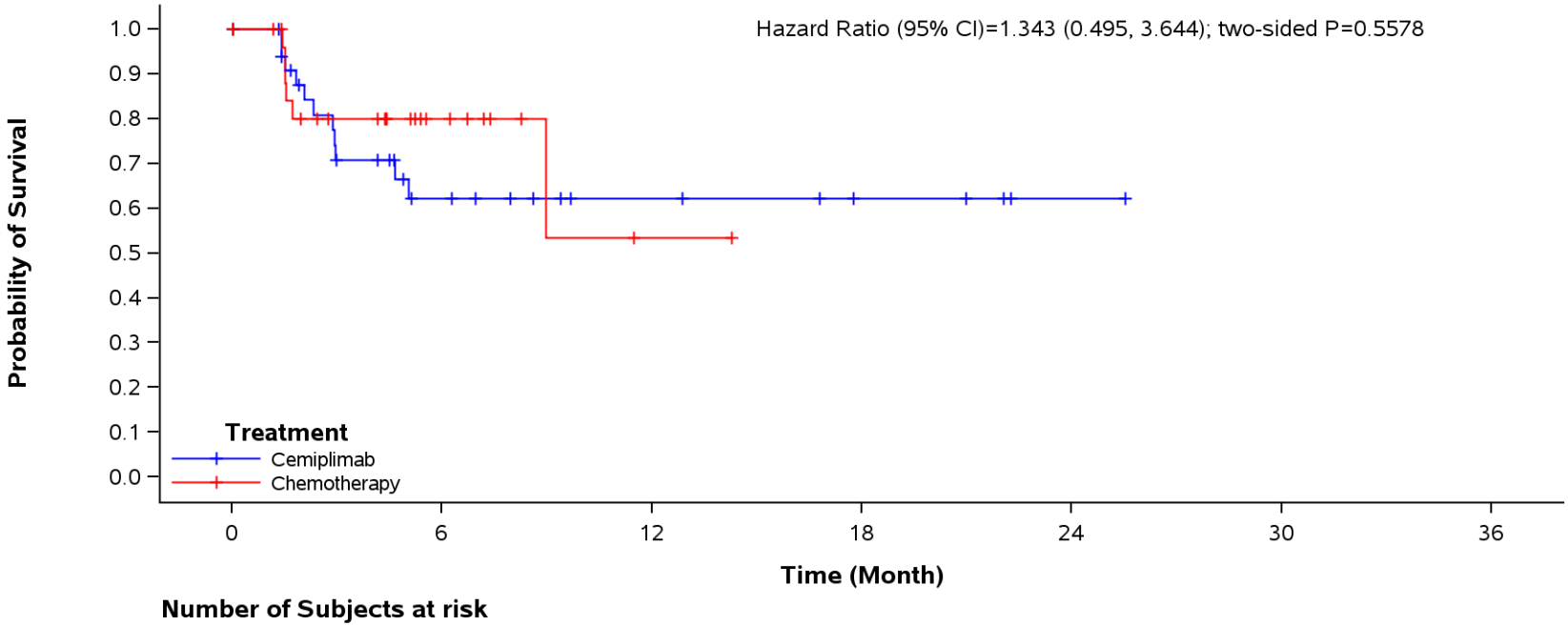

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 30 | 14 | 8 | 3 | 0 | 0 |
| Chemotherapy | 69 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts sustained improvement



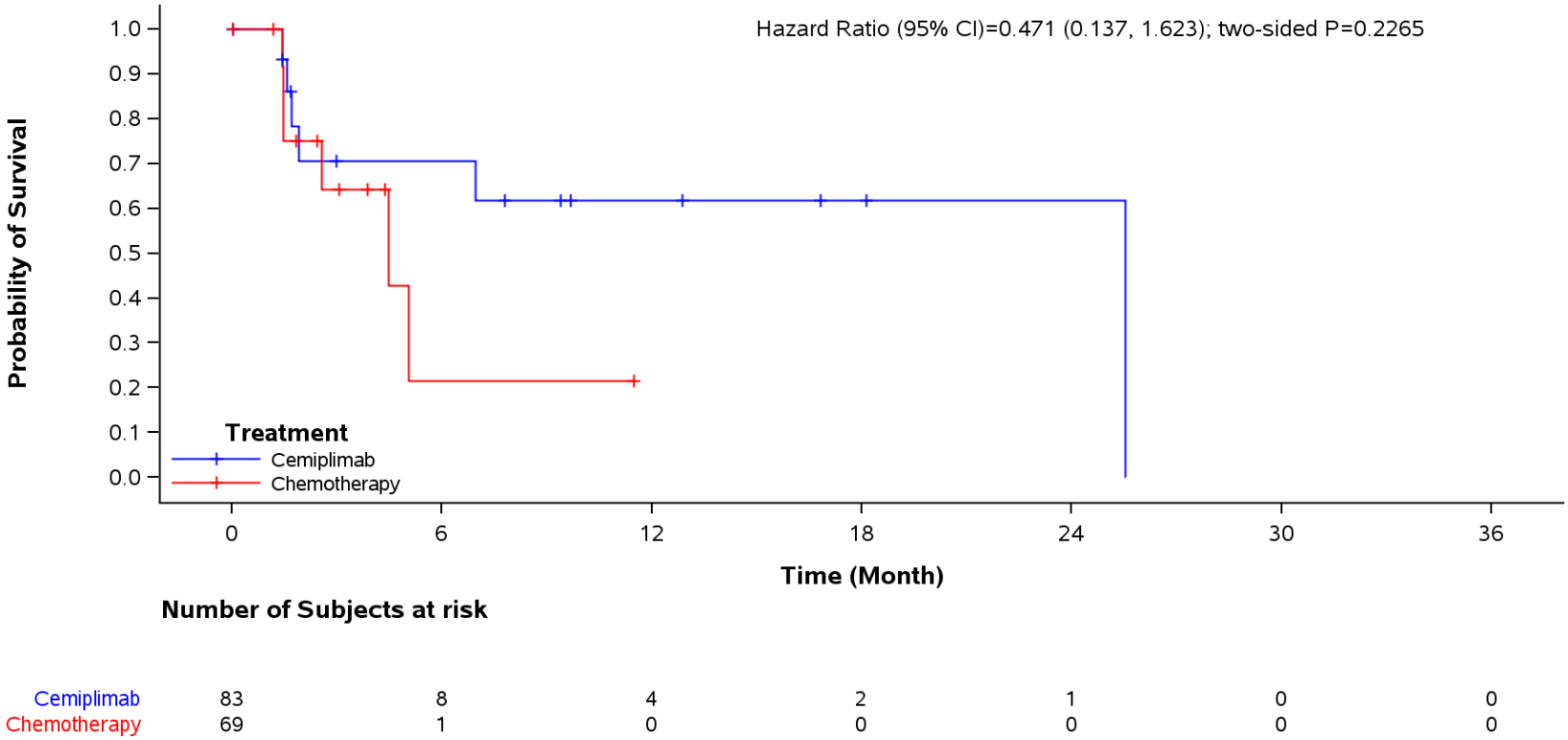

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 13 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 69 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts sustained improvement



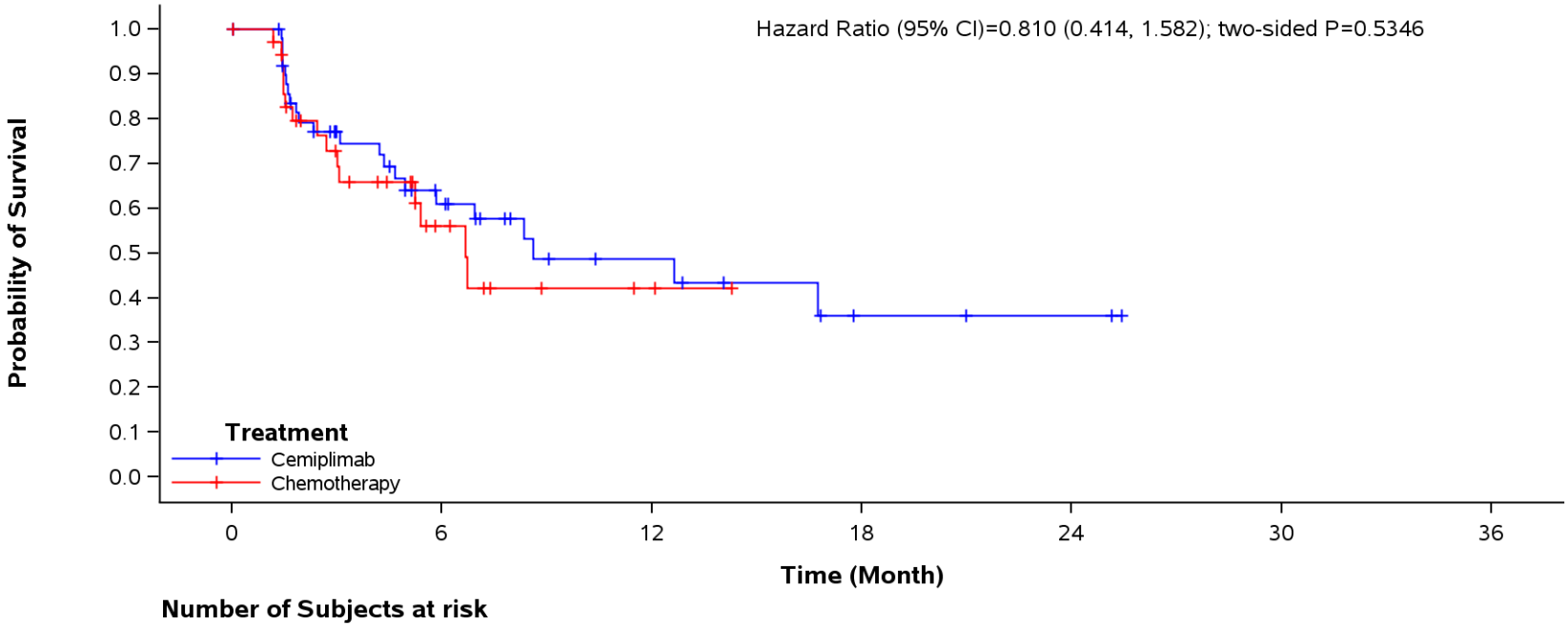

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 8 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 69 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts sustained improvement



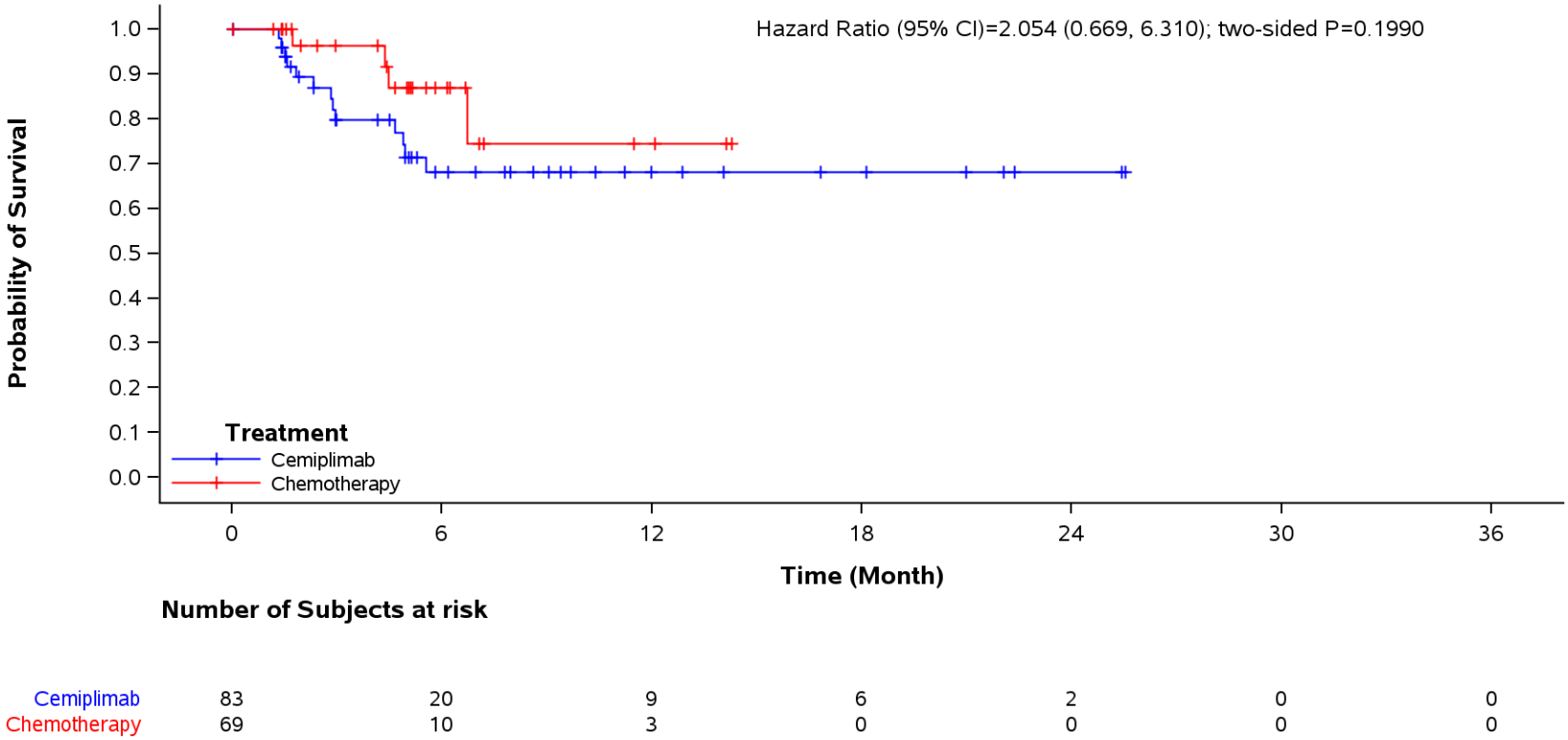

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 20 | 9 | 3 | 2 | 0 | 0 |
| Chemotherapy | 69 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Physical Functioning - 10 pts sustained improvement



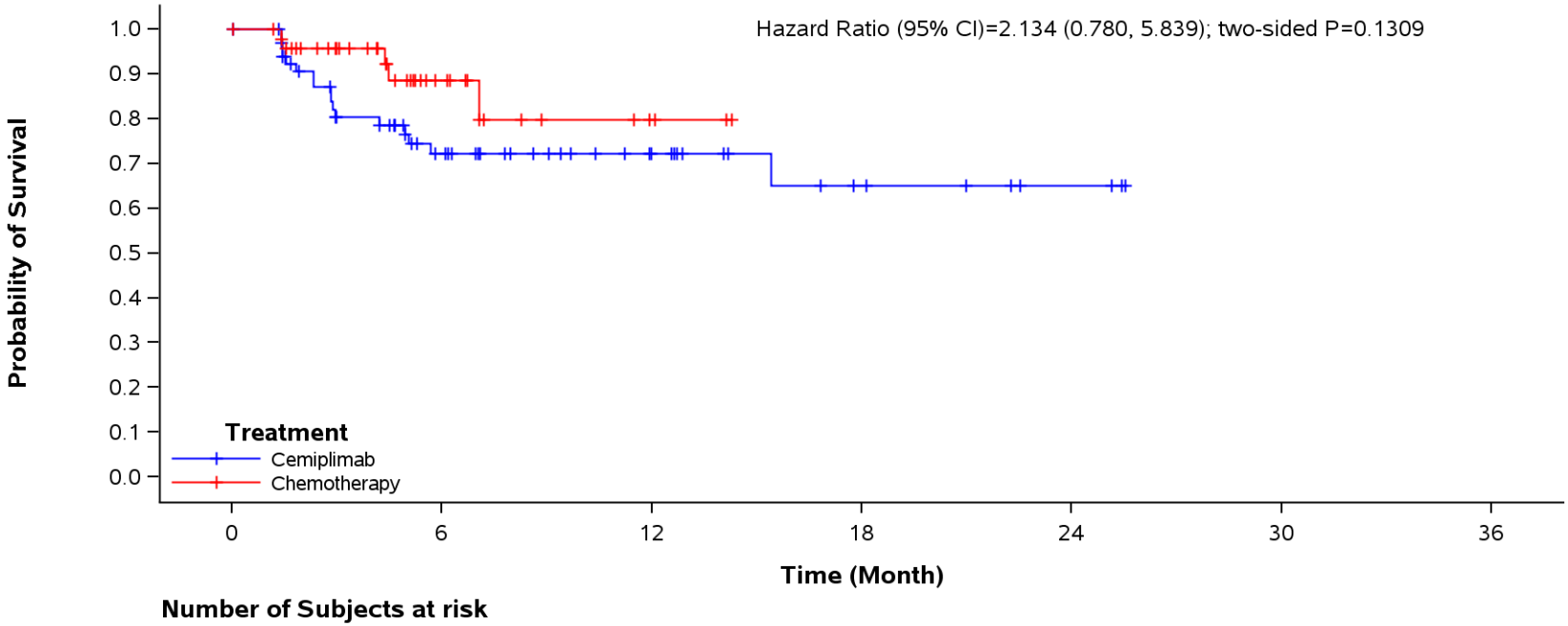

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 20 | 9 | 6 | 2 | 0 | 0 |
| Chemotherapy | 69 | 10 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Global health status / QoL - 10 pts sustained improvement



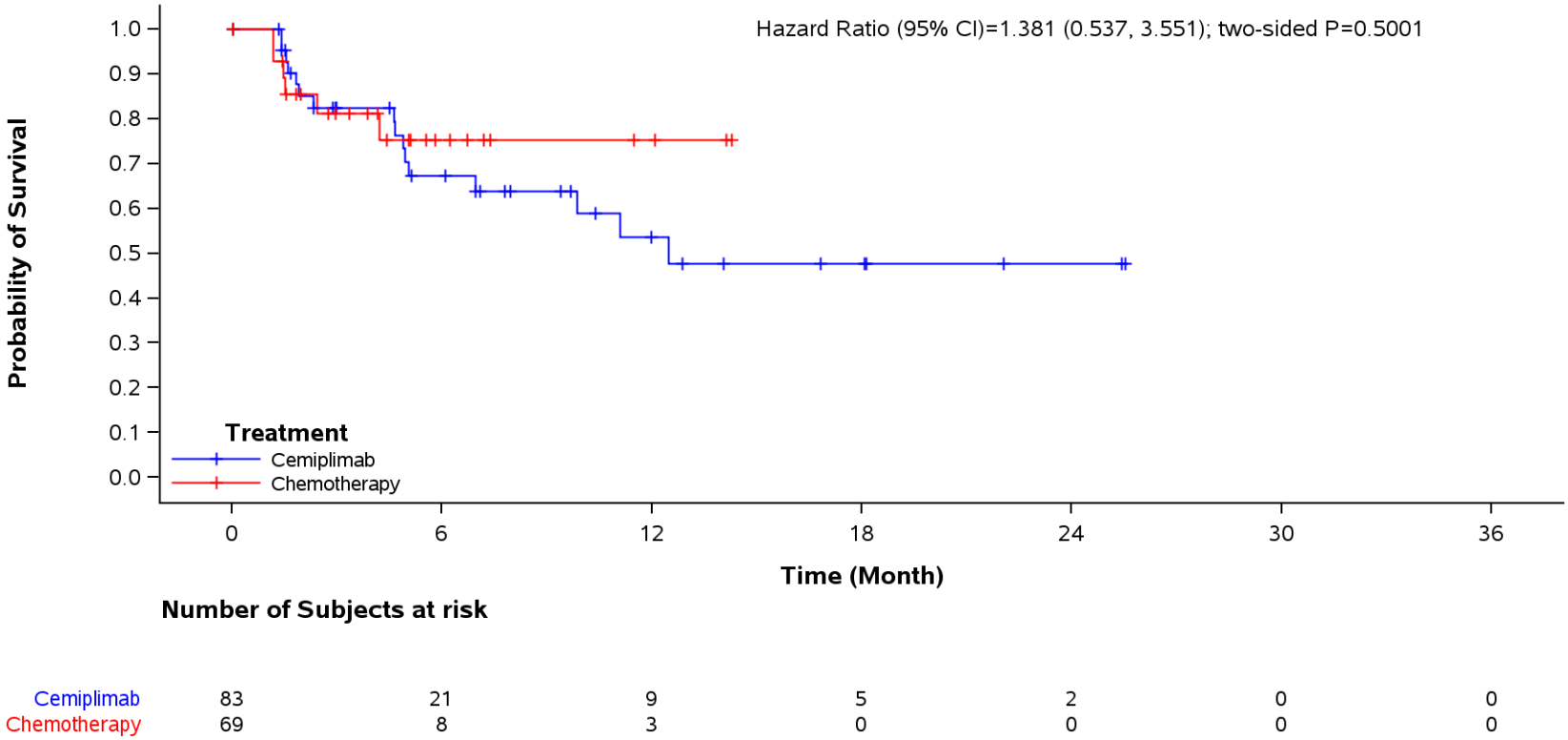

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 32 | 16 | 7 | 3 | 0 | 0 |
| Chemotherapy | 69 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts sustained improvement



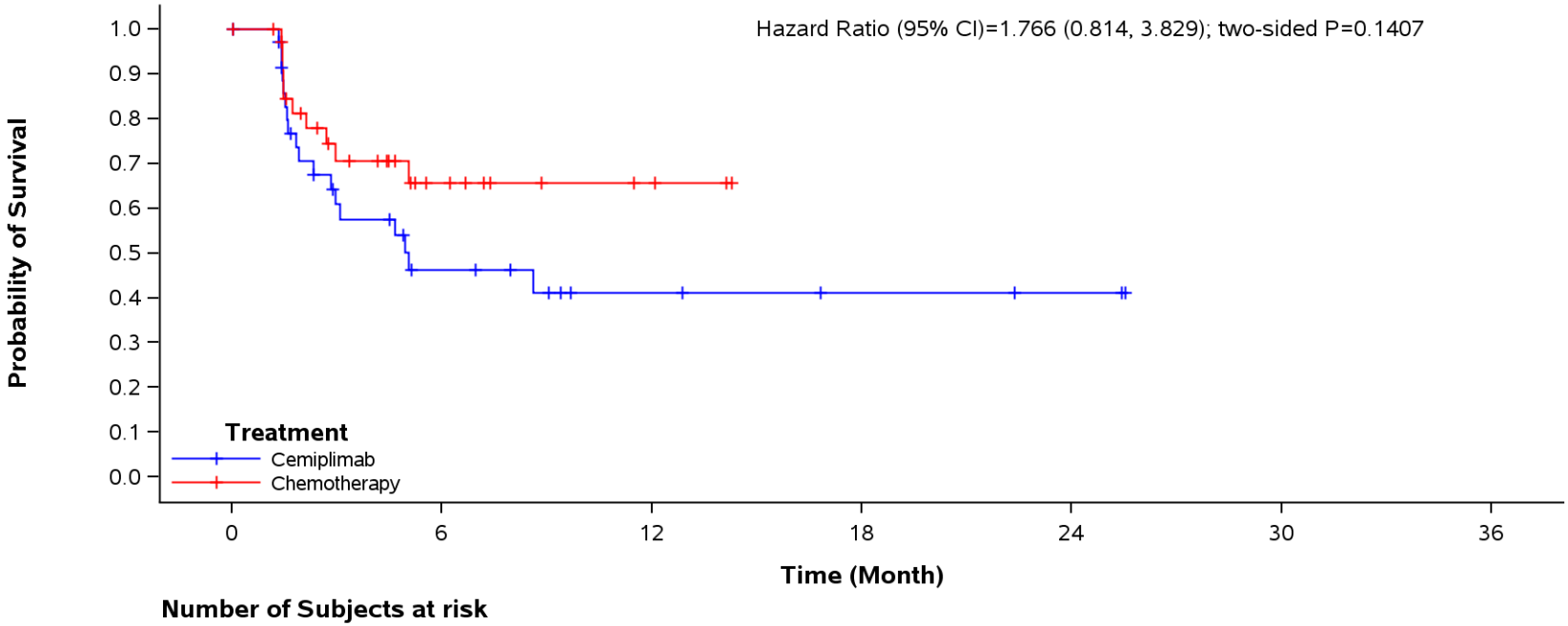

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 21 | 9 | 5 | 2 | 0 | 0 |
| Chemotherapy | 69 | 8 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts sustained improvement



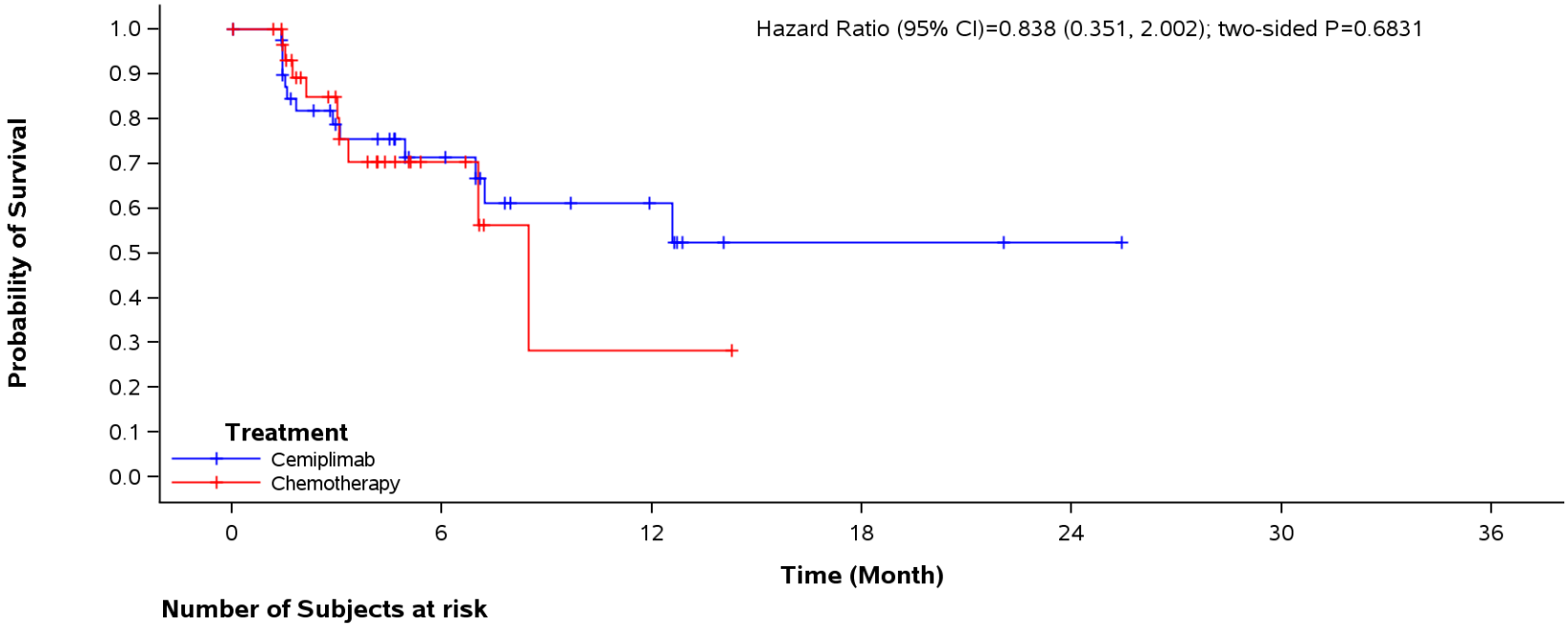

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 11 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 69 | 9 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts sustained improvement



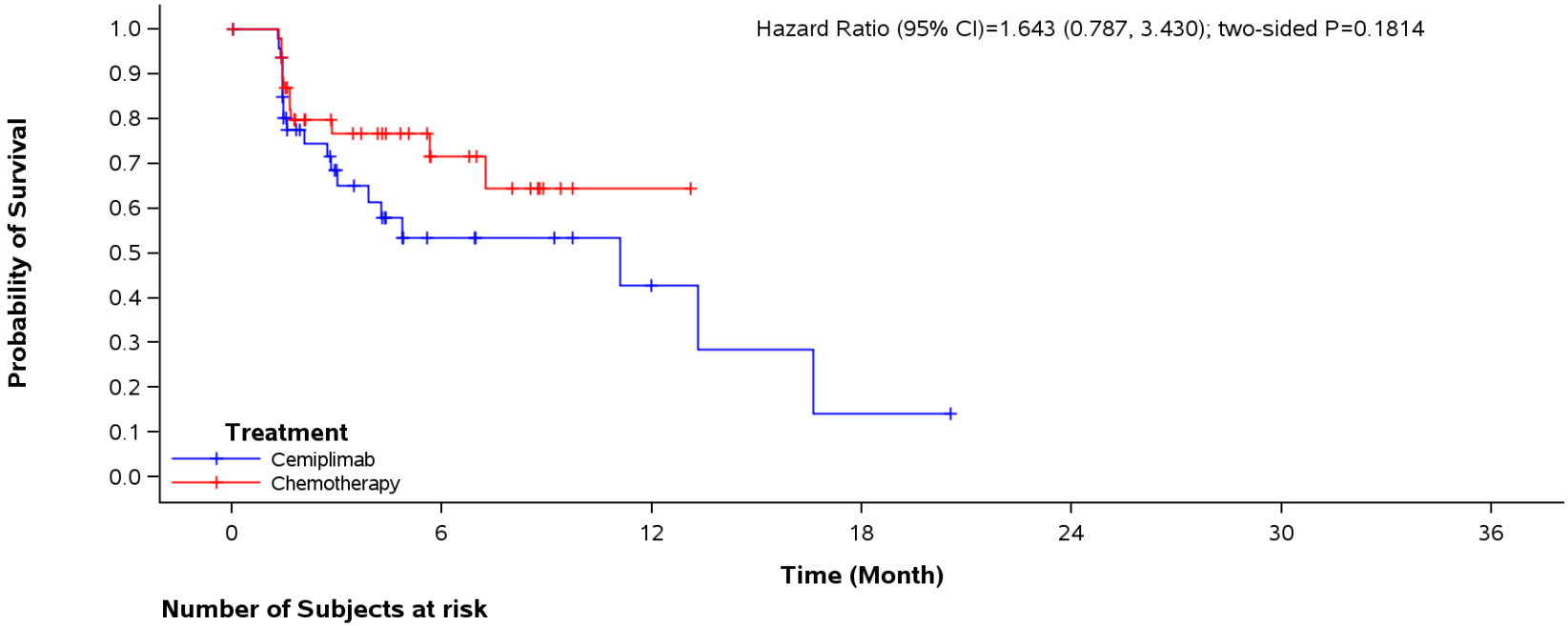

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 16 | 7 | 2 | 1 | 0 | 0 |
| Chemotherapy | 69 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts sustained improvement



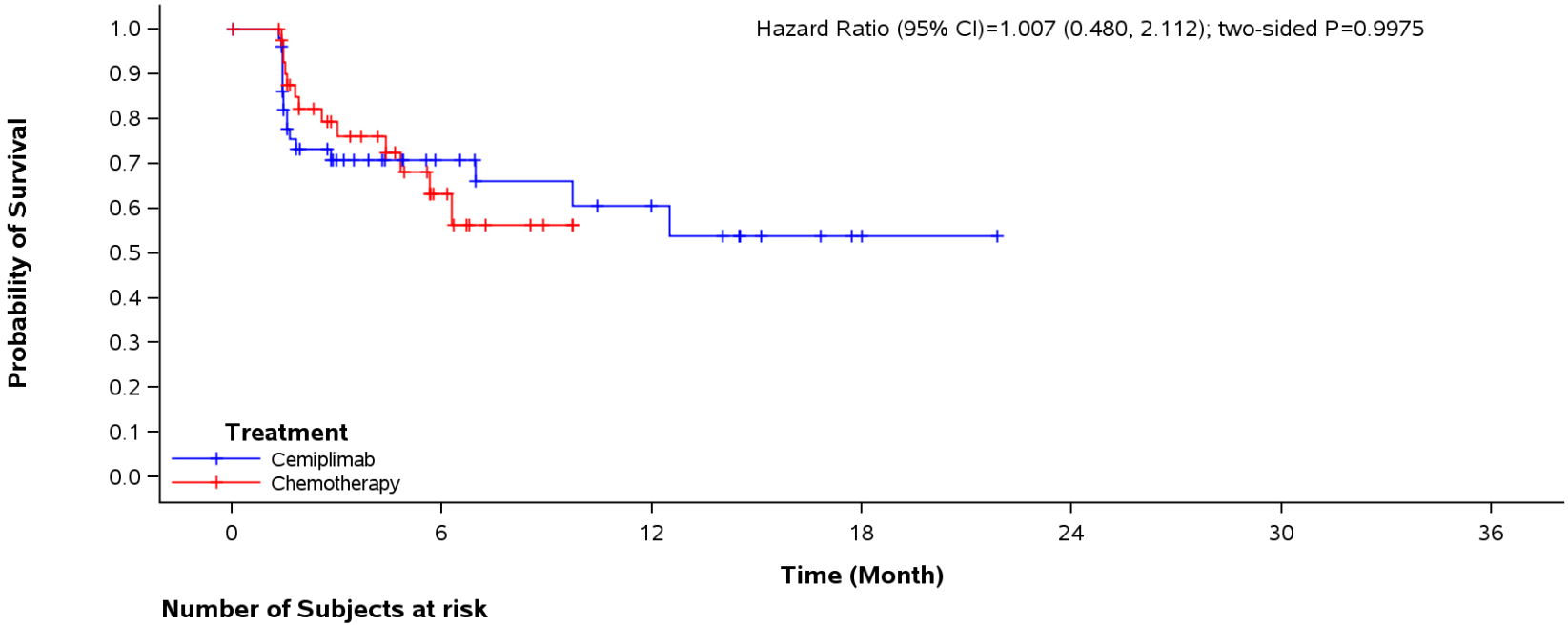

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 9 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts sustained improvement



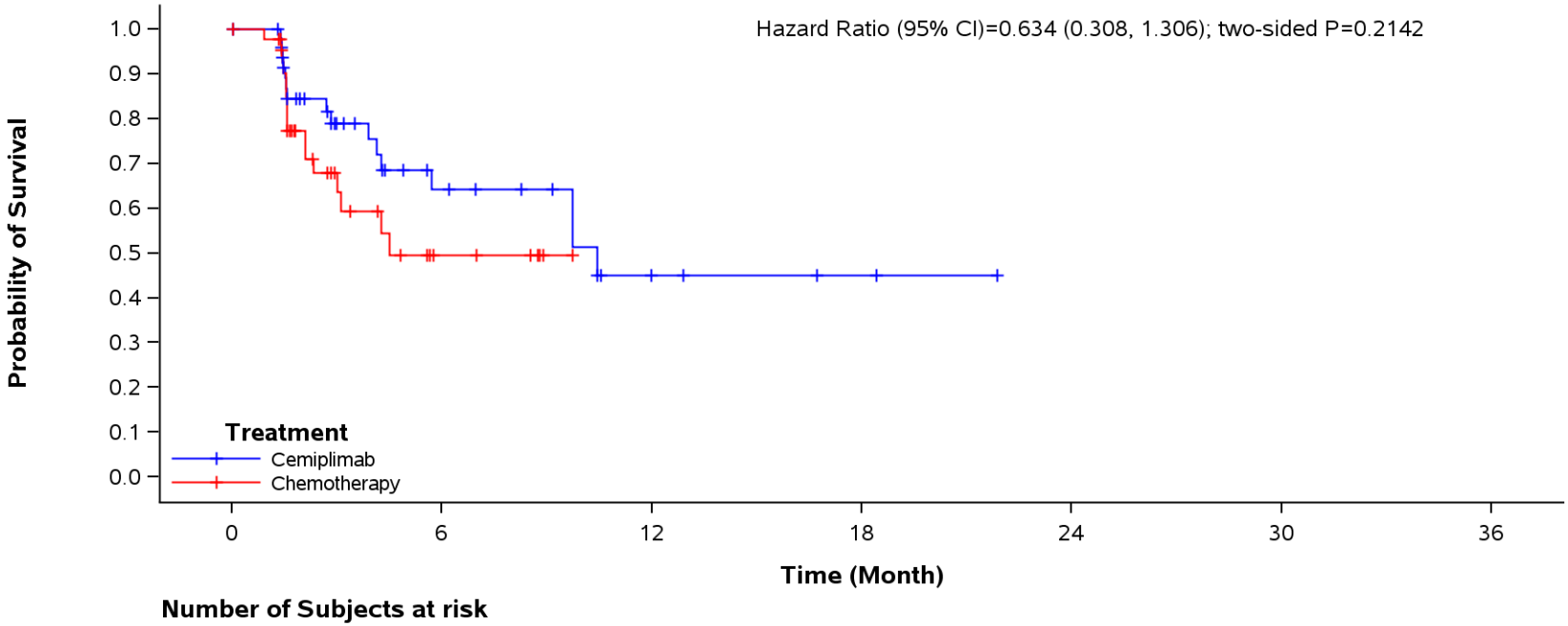

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 17 | 9 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts sustained improvement



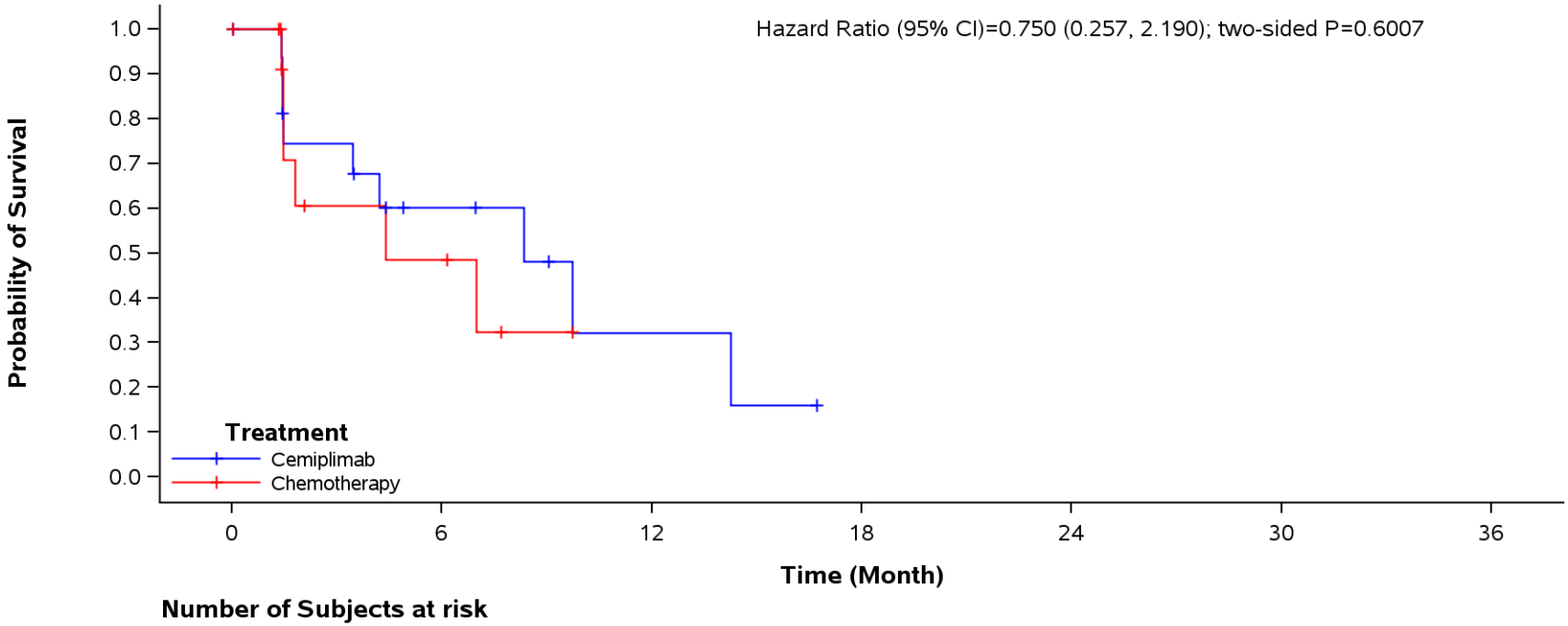

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 15 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts sustained improvement



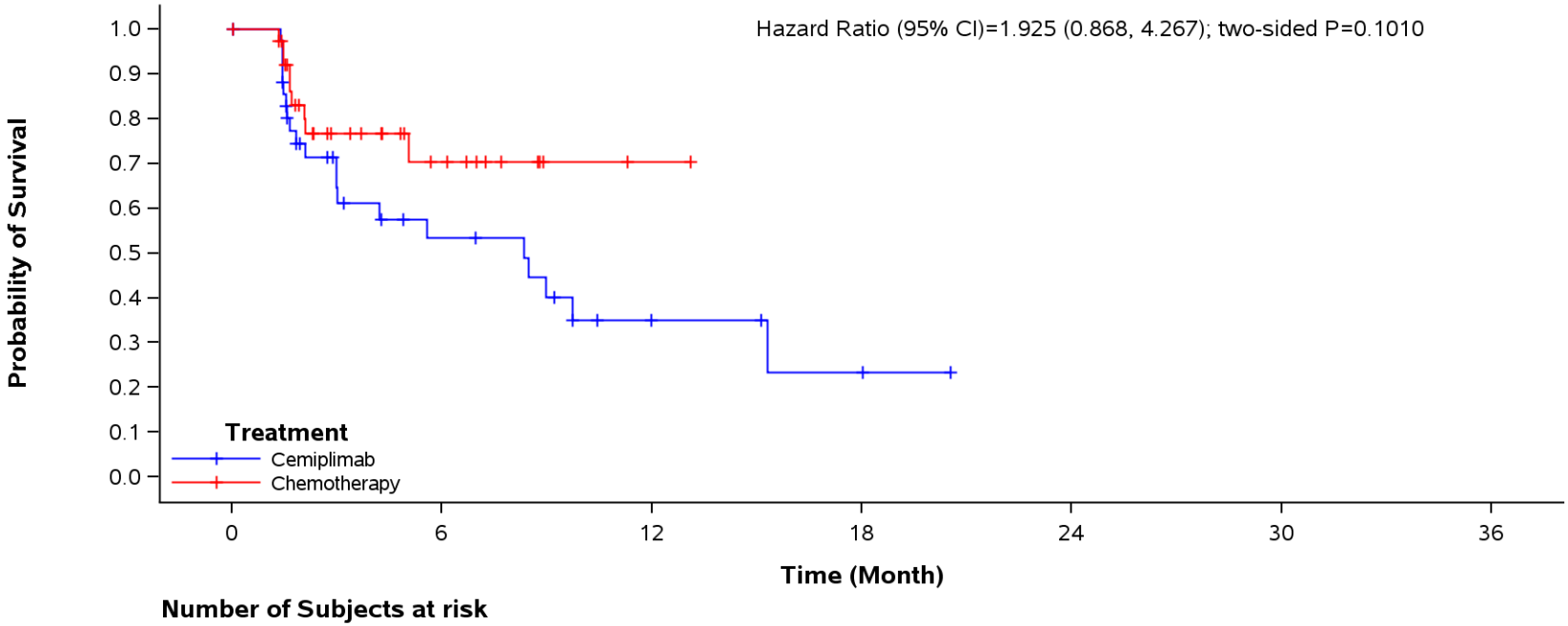

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts sustained improvement



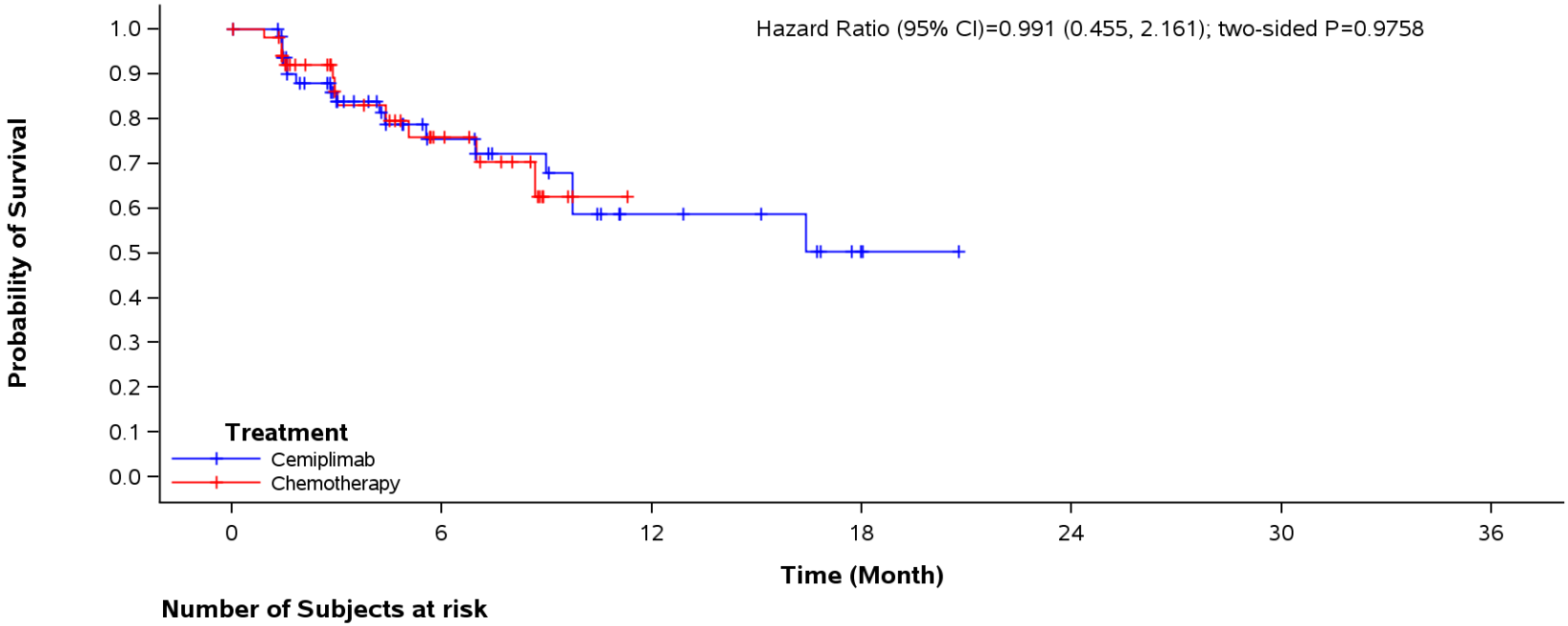

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 13 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts sustained improvement



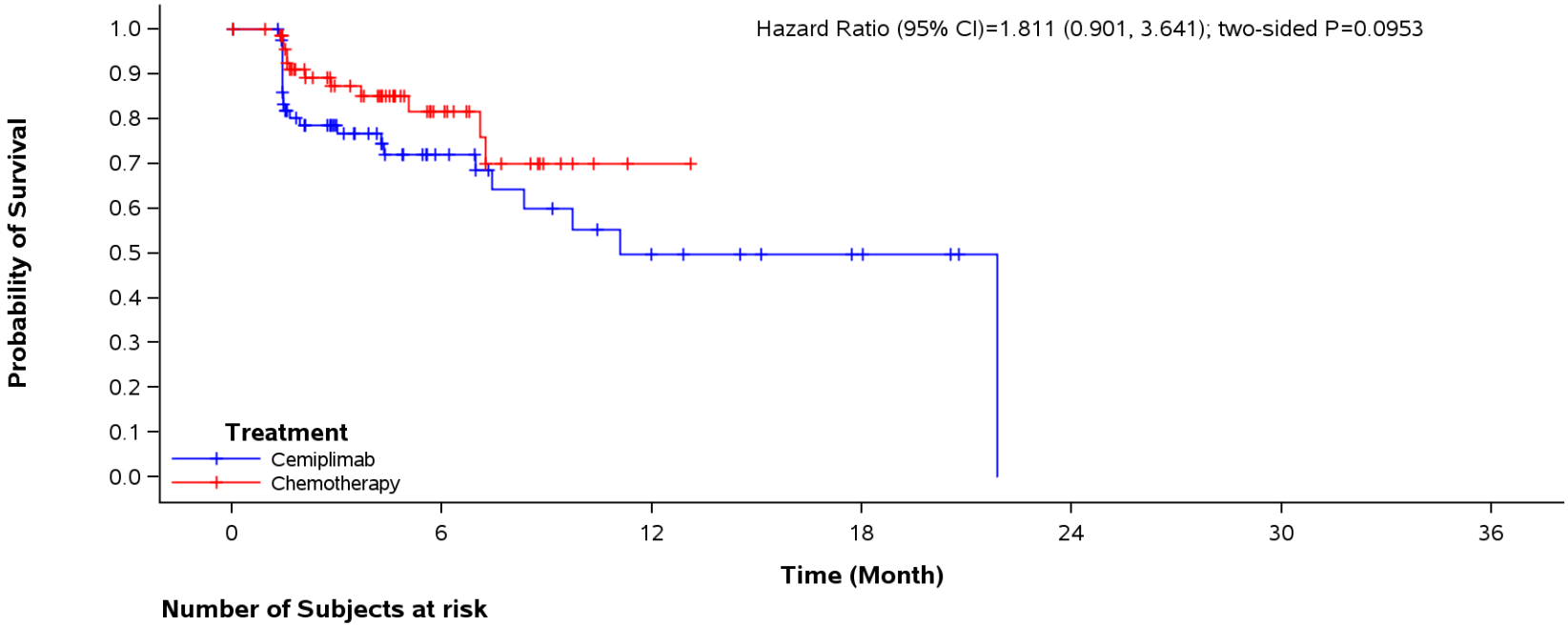

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 23 | 9 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts sustained improvement



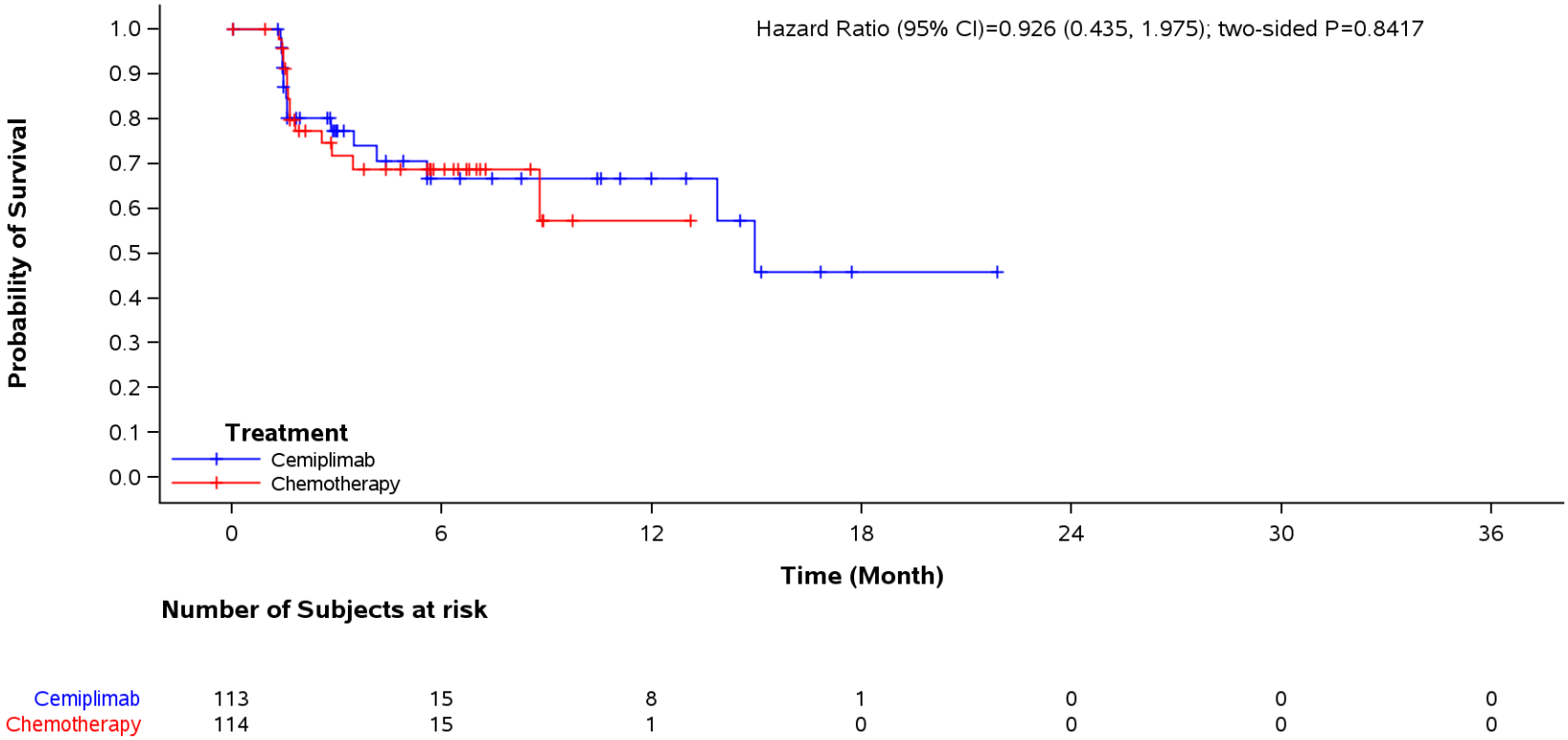

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 22 | 8 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts sustained improvement



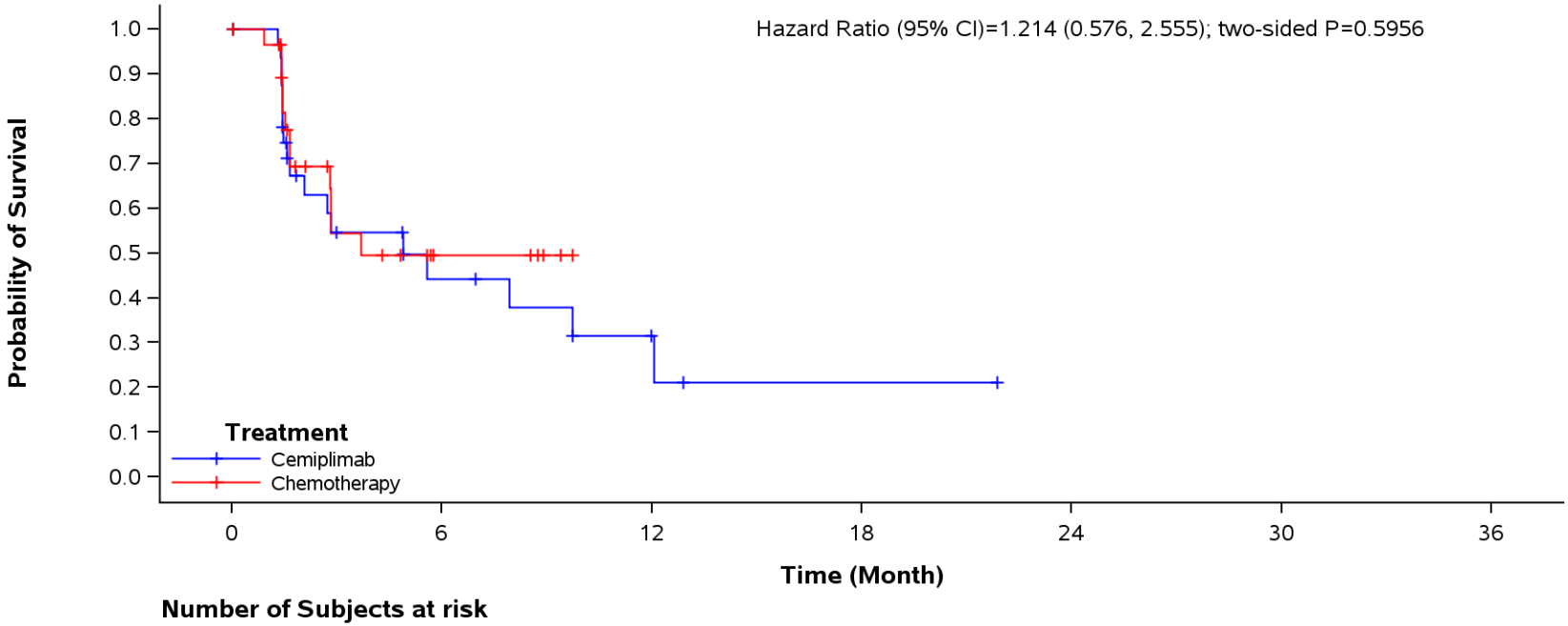

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 15 | 8 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts sustained improvement



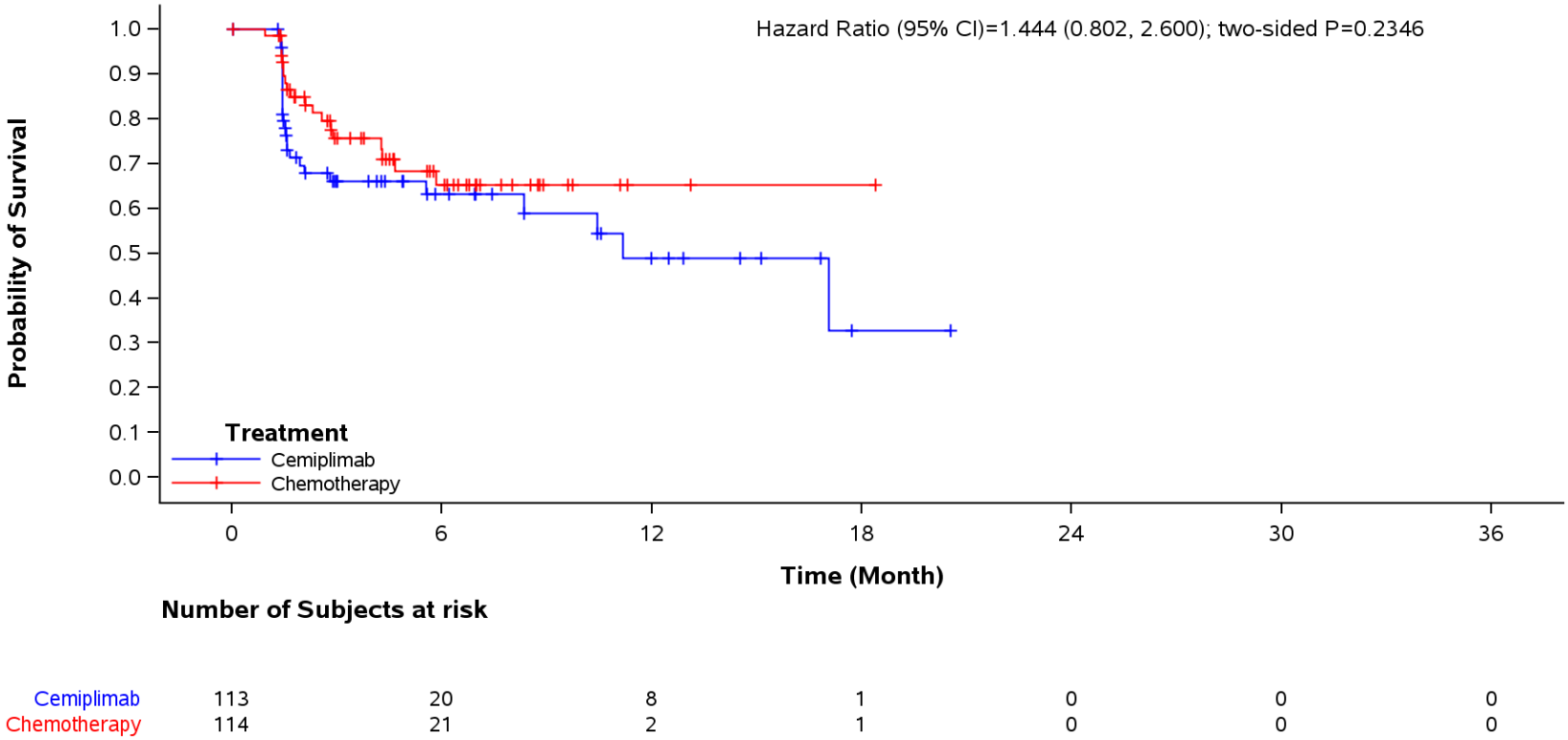

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 8 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts sustained improvement



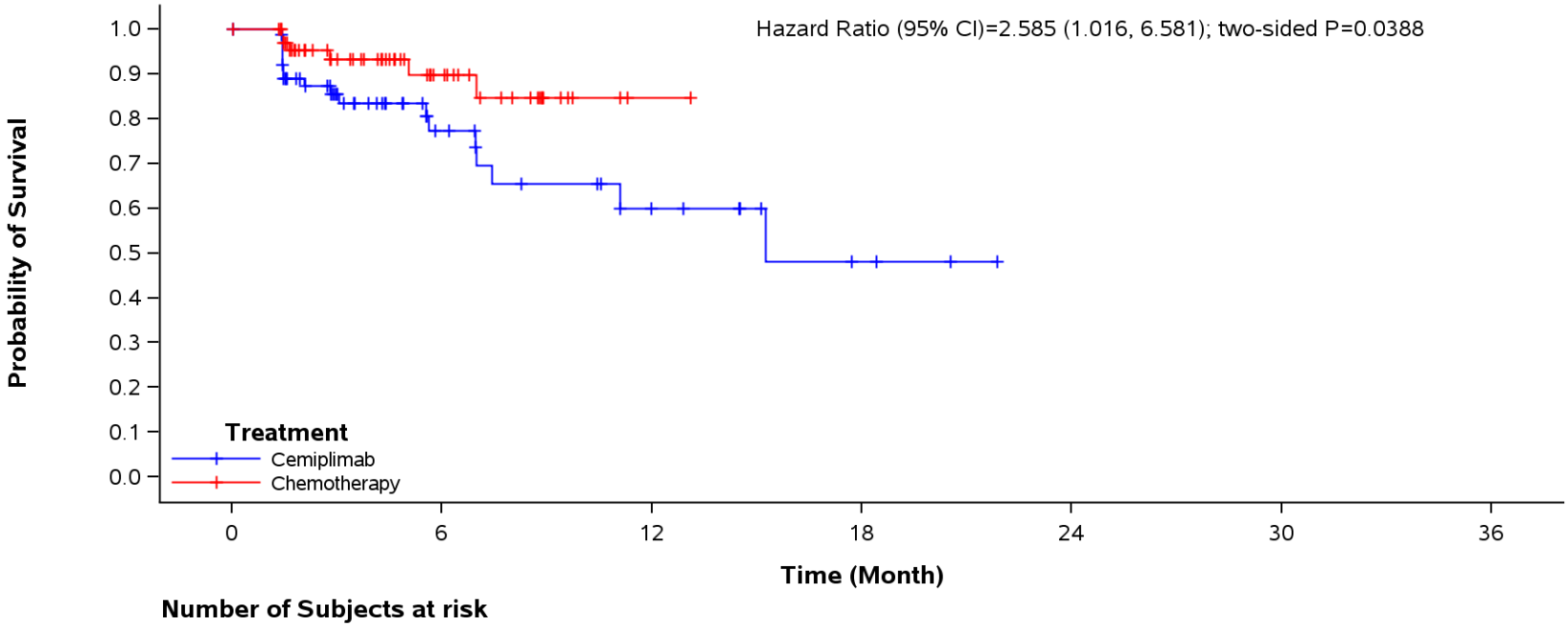

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 20 | 8 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts sustained improvement



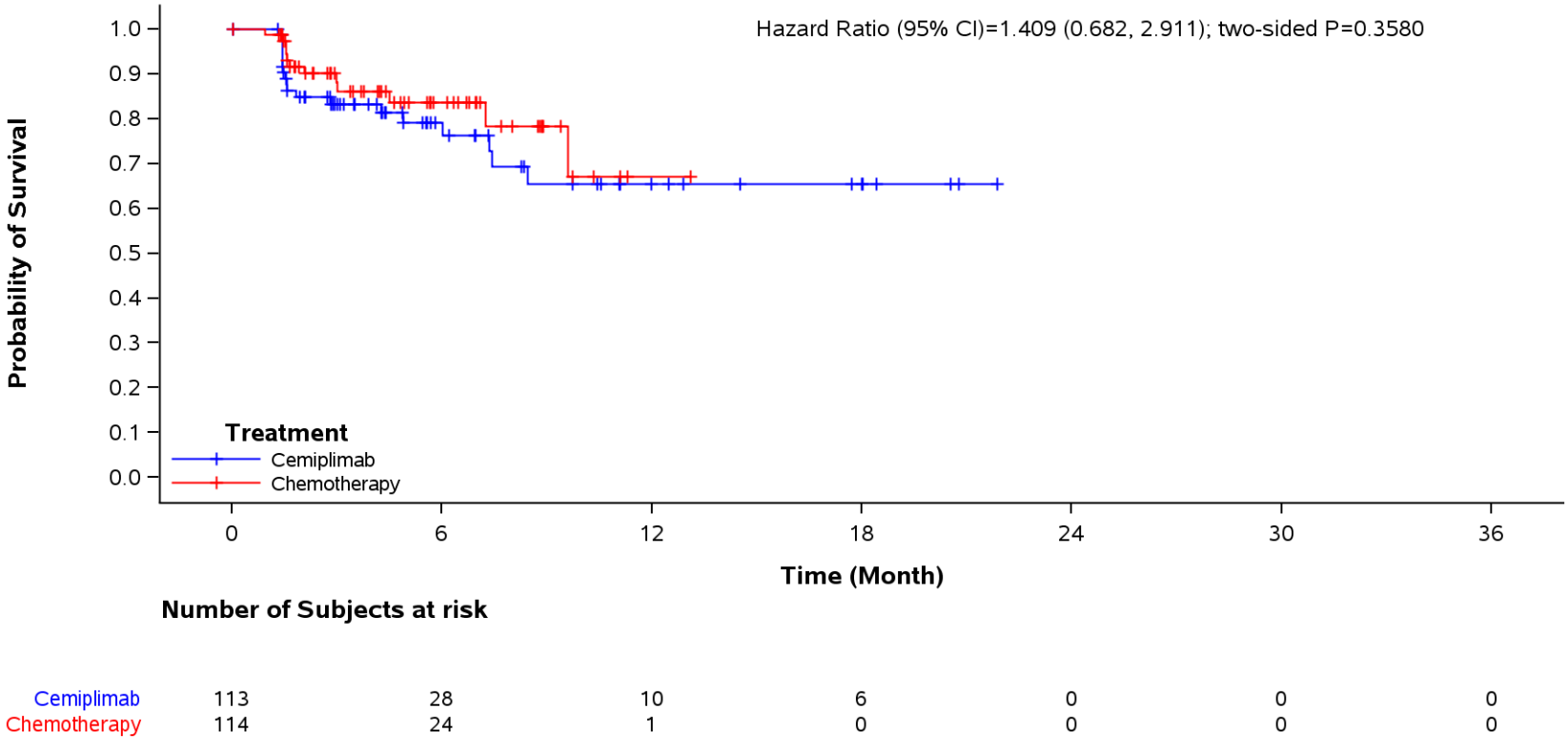

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 23 | 9 | 3 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts sustained improvement



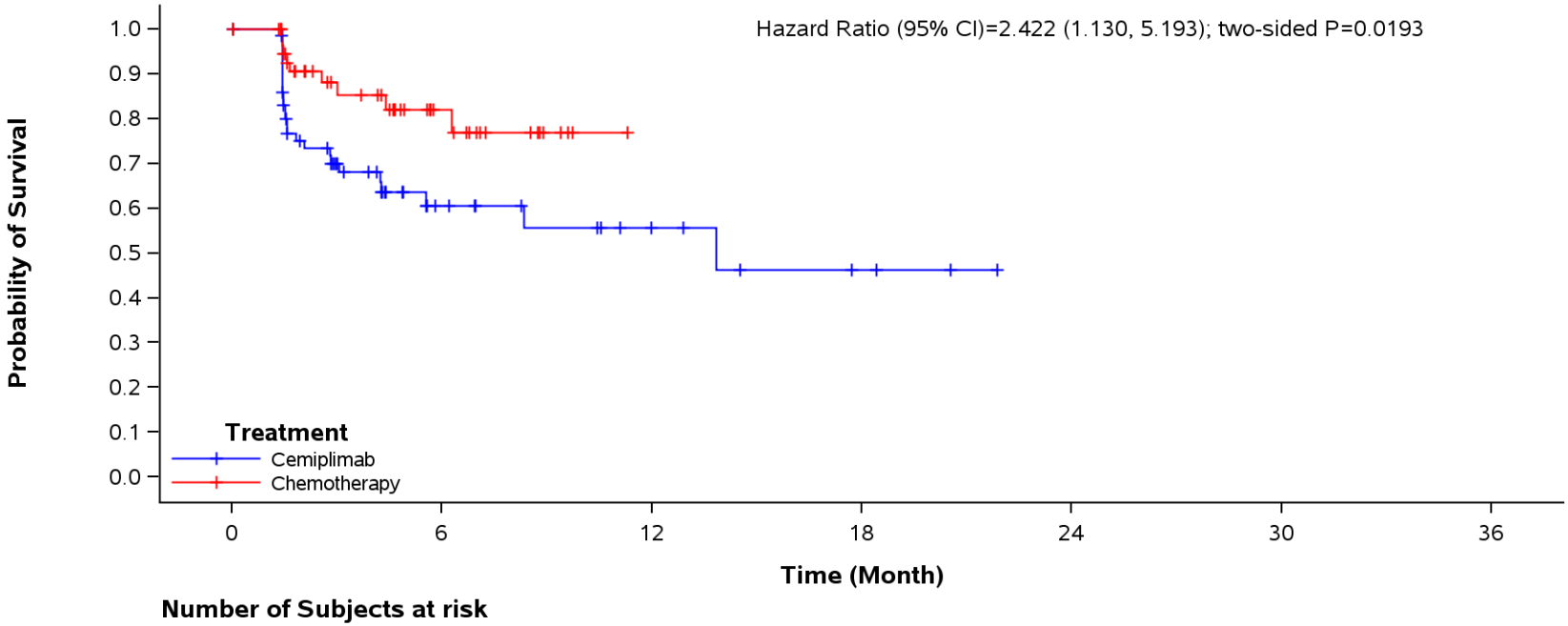

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 28 | 10 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 24 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts sustained improvement



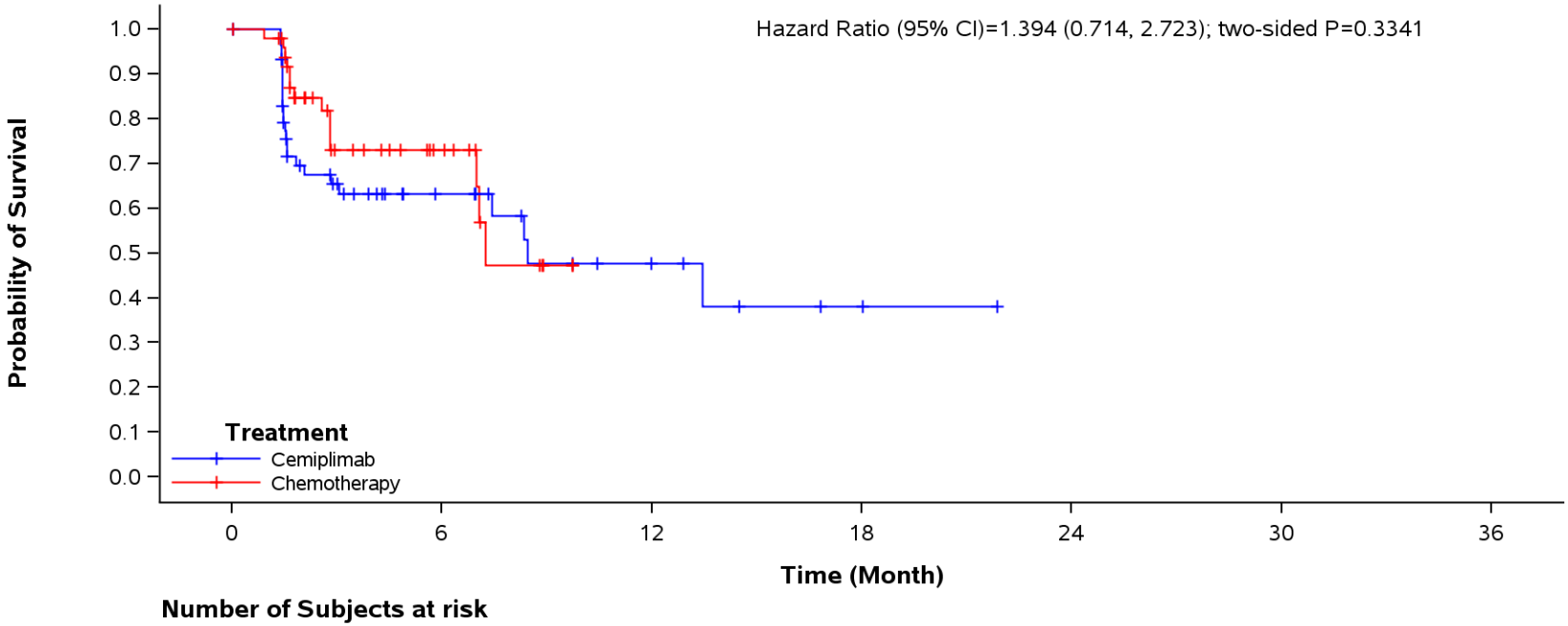

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 17 | 7 | 3 | 0 | 0 | 0 |
| Chemotherapy | 114 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts sustained improvement



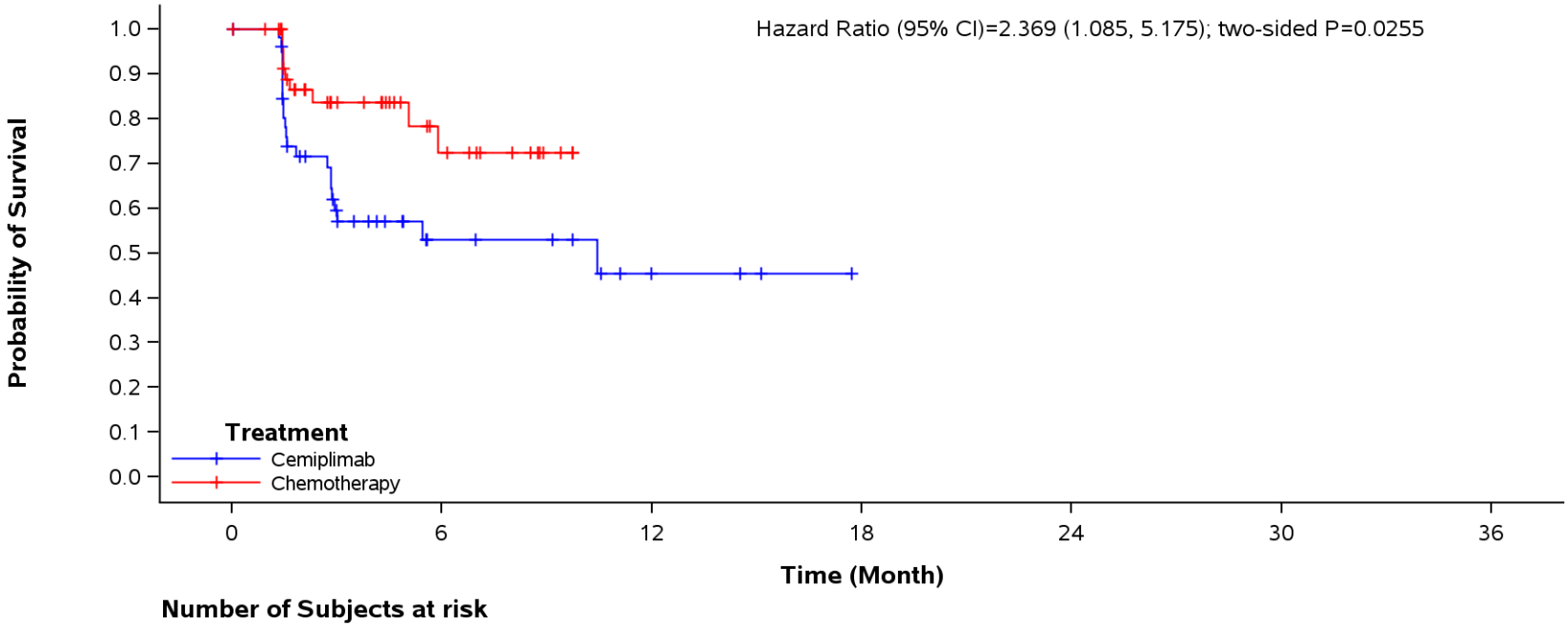

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 17 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts sustained improvement



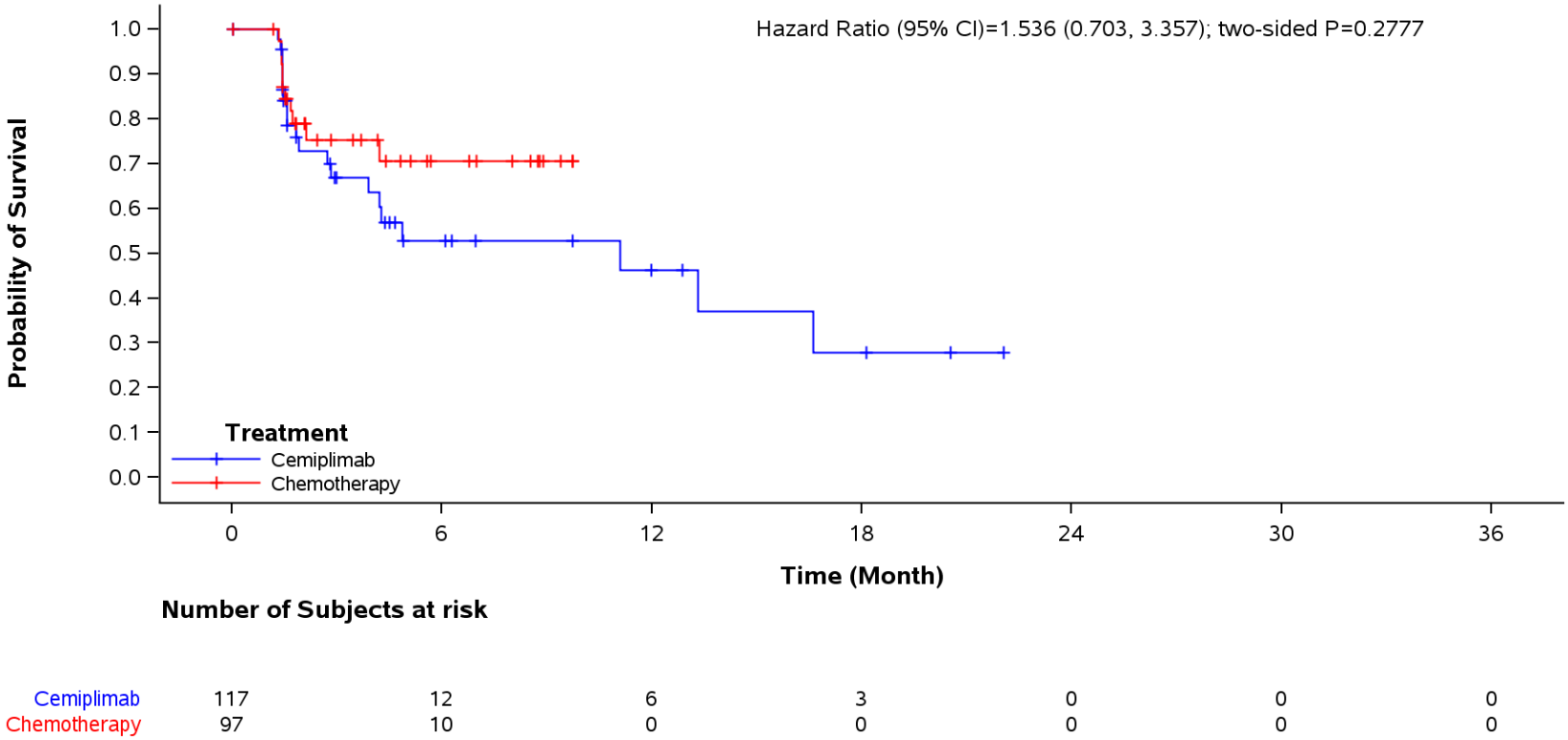

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 11 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

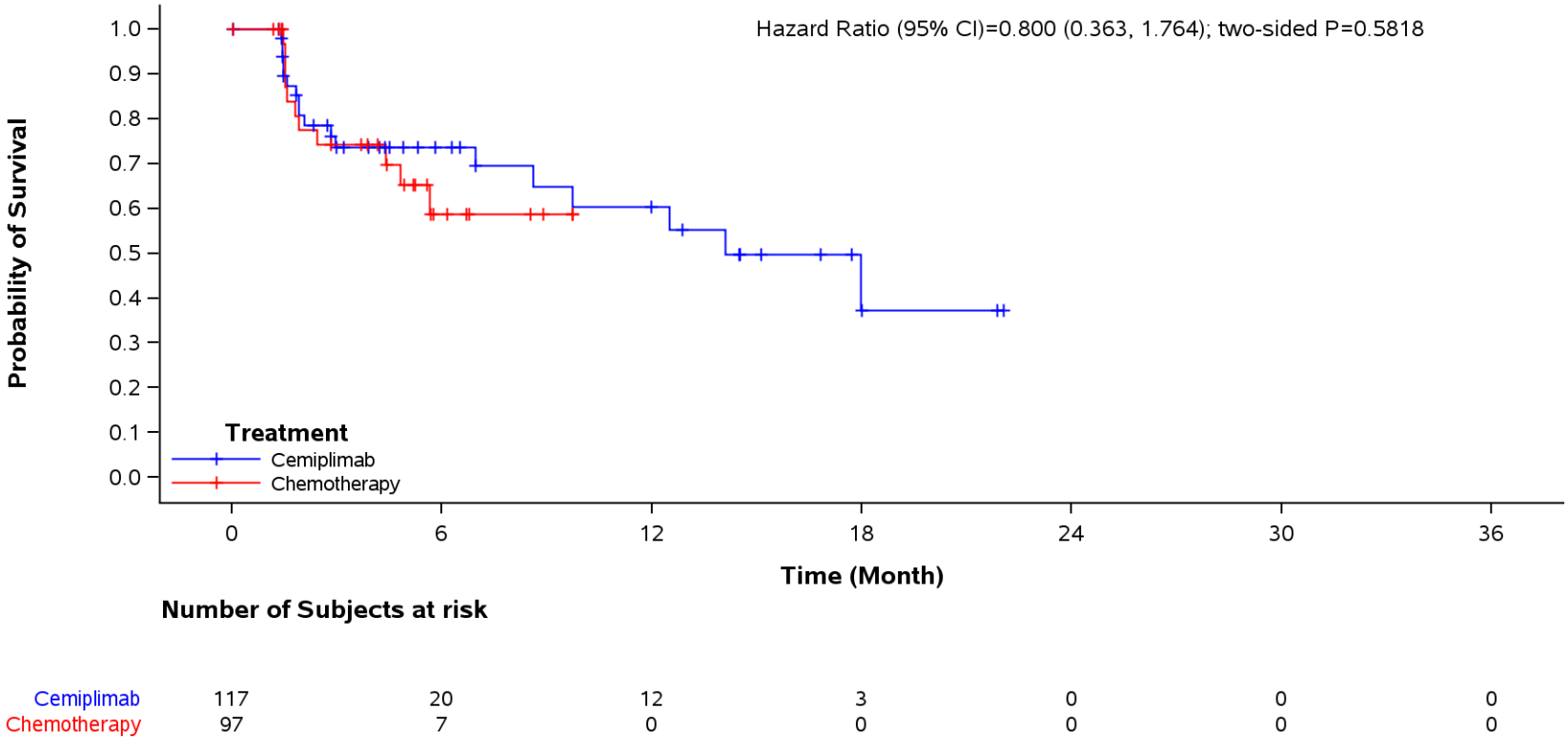
Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

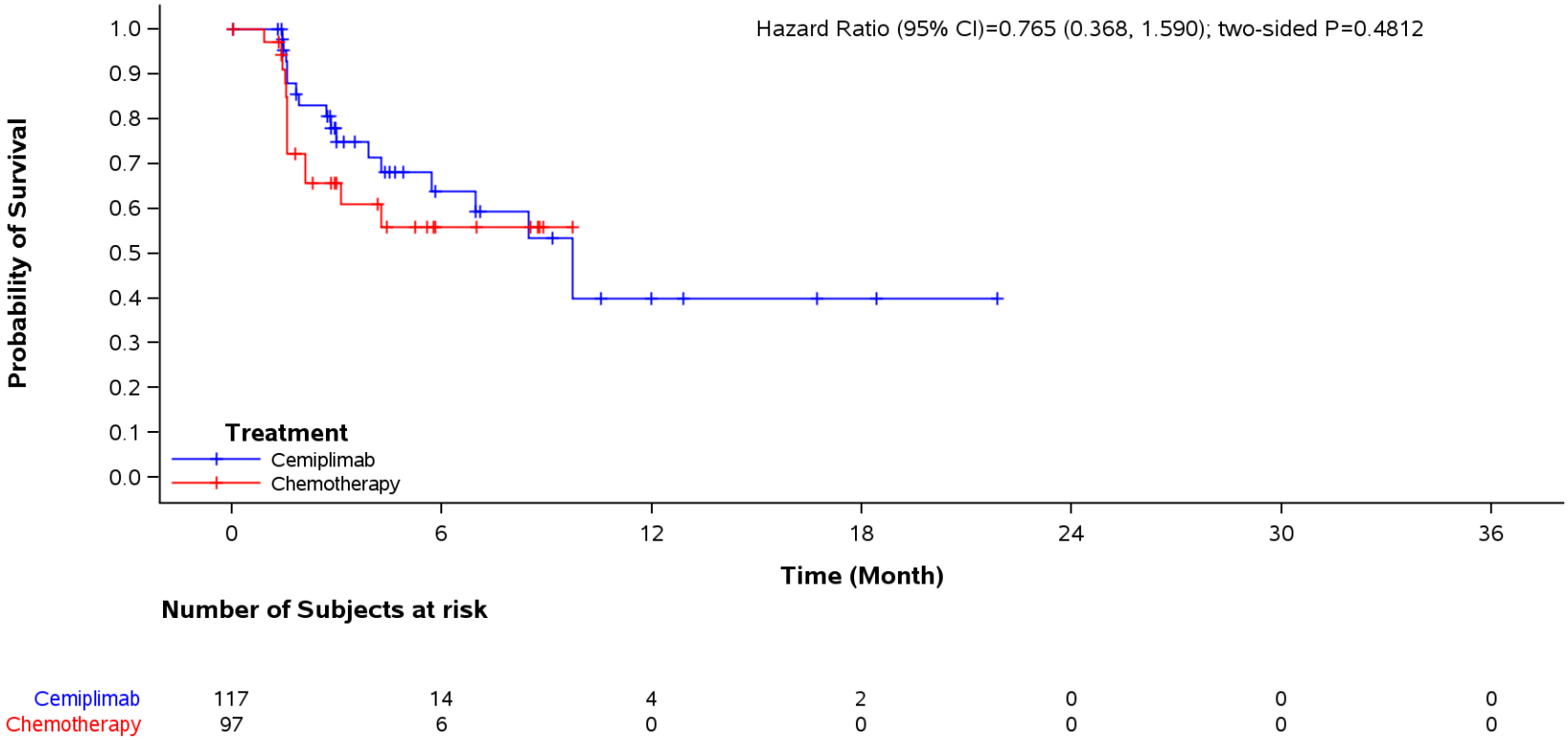
Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts sustained improvement



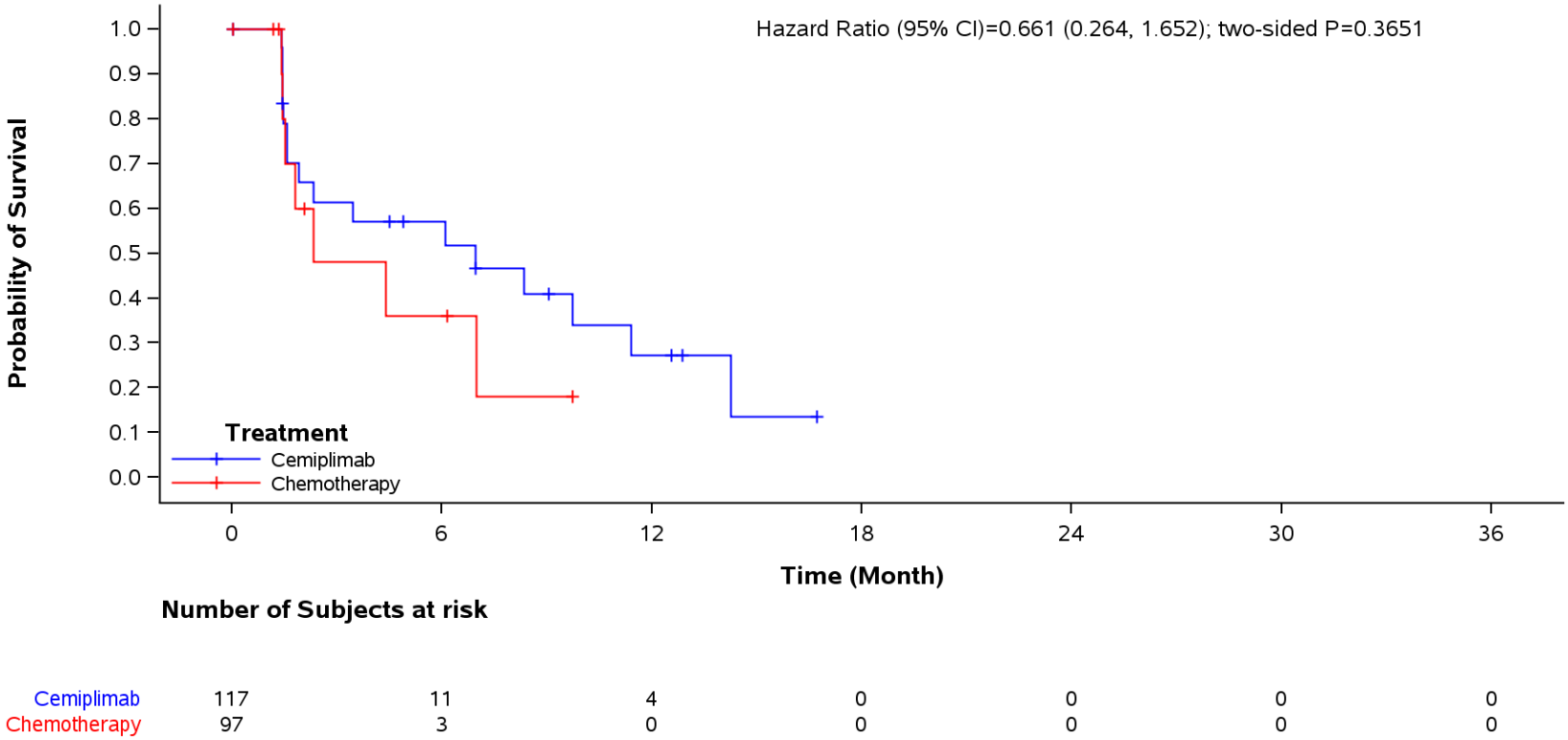

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 14 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

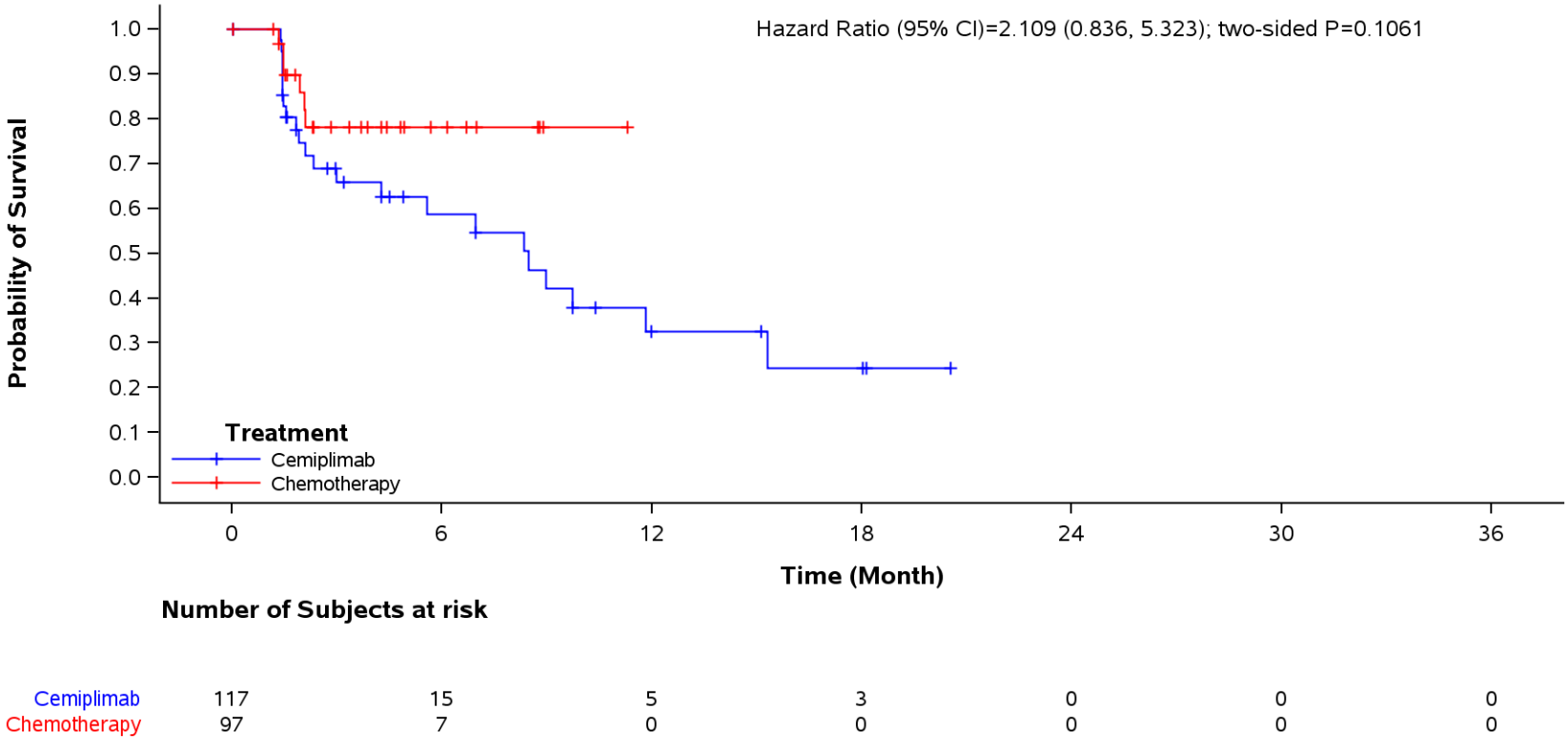
Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

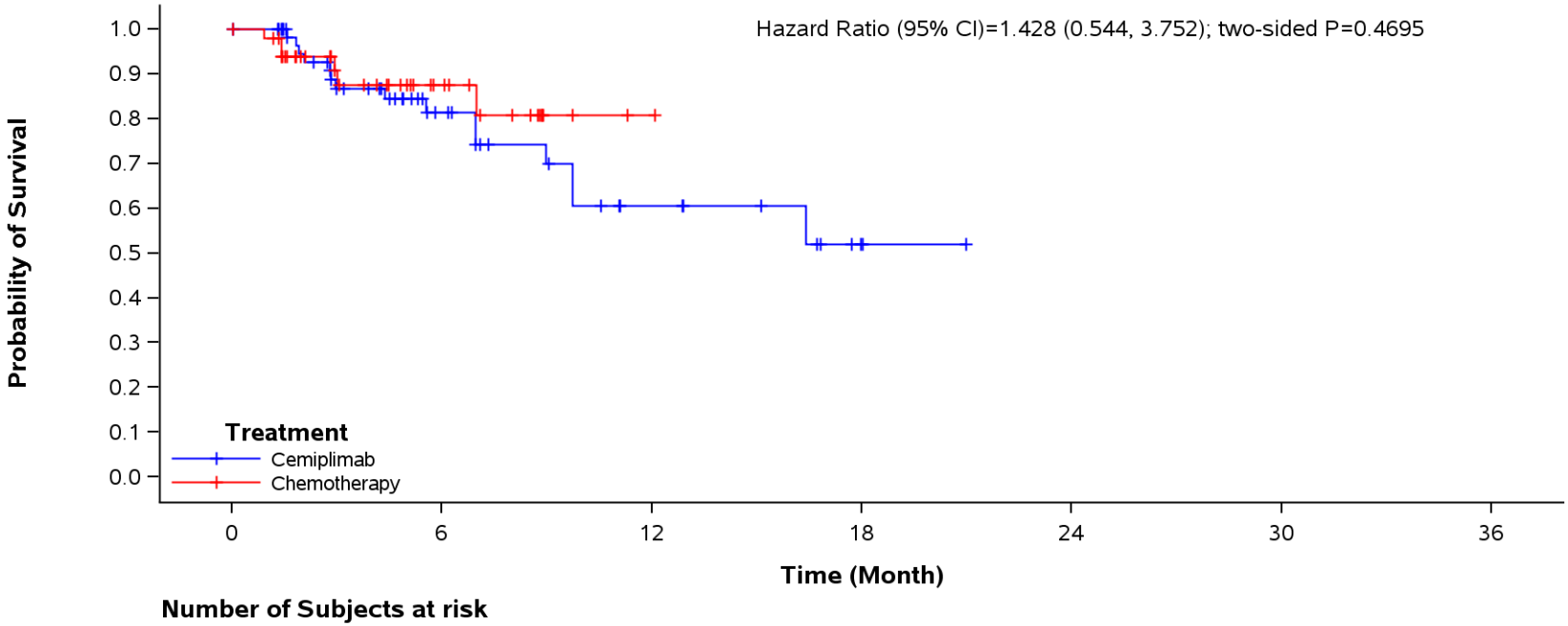
Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Emotional Functioning - 10 pts sustained improvement



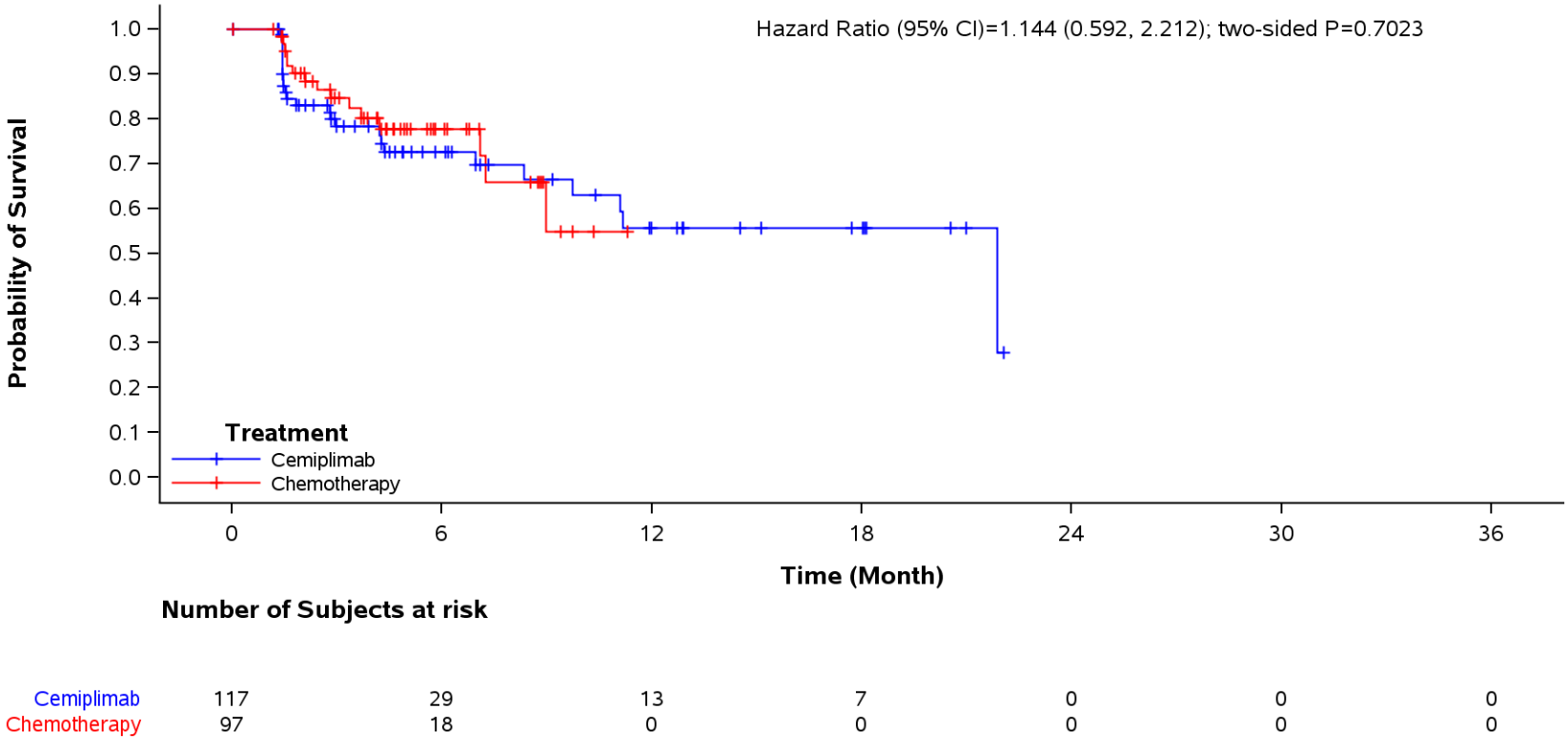

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 25 | 10 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 16 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

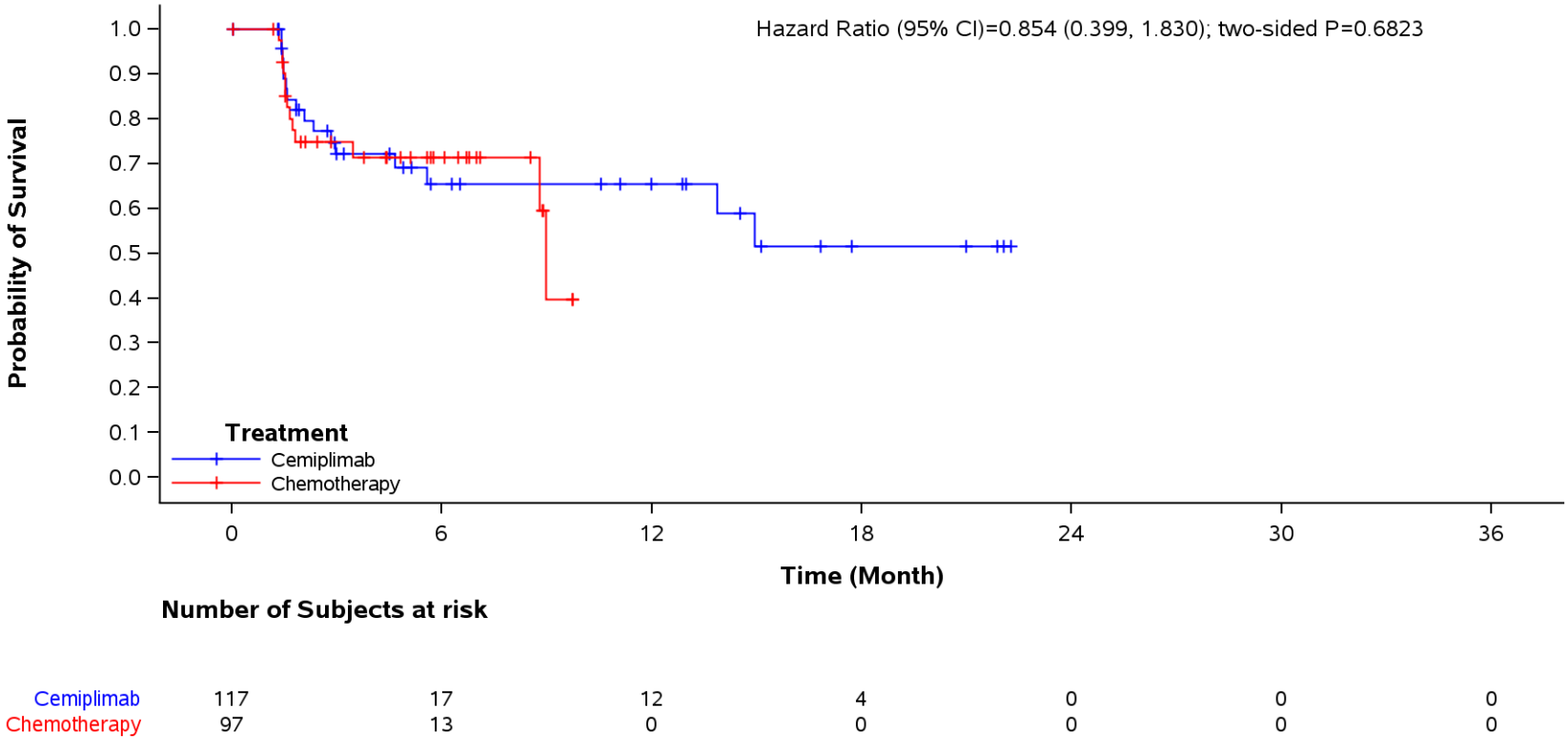
Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts sustained improvement



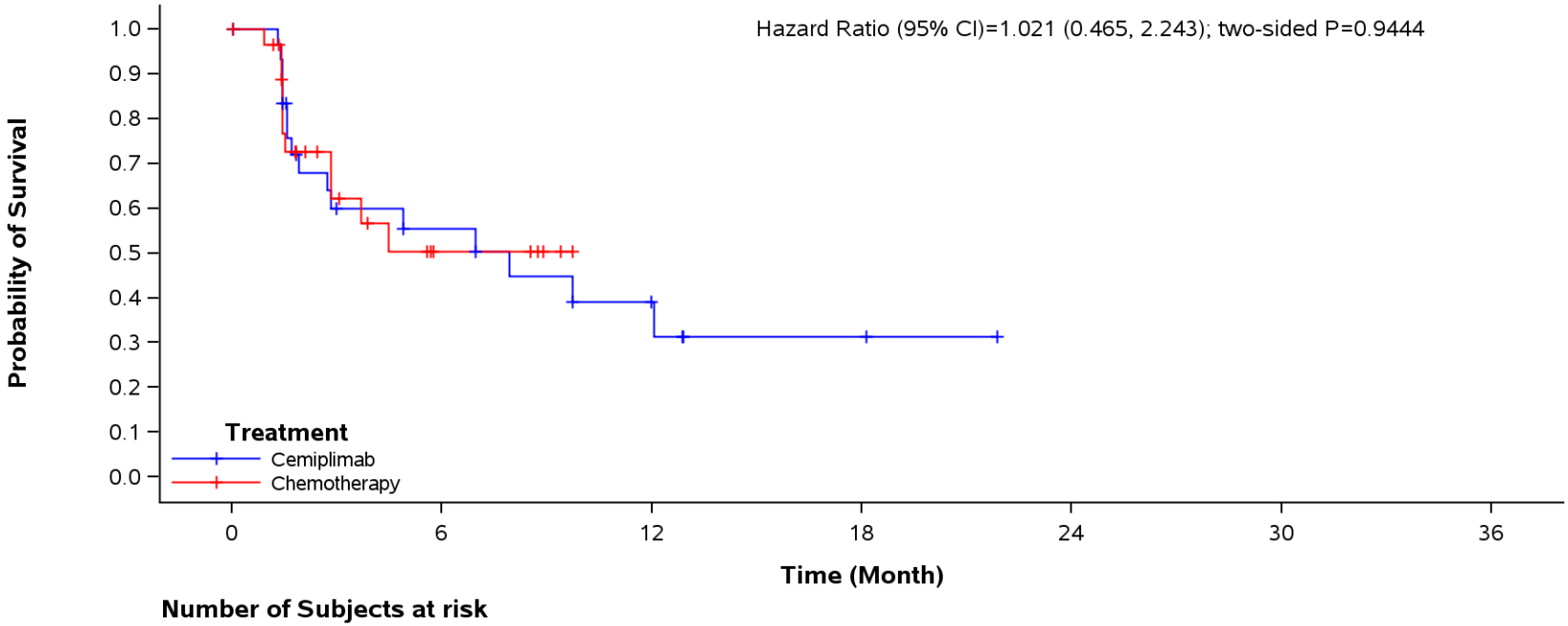

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 17 | 12 | 4 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts sustained improvement



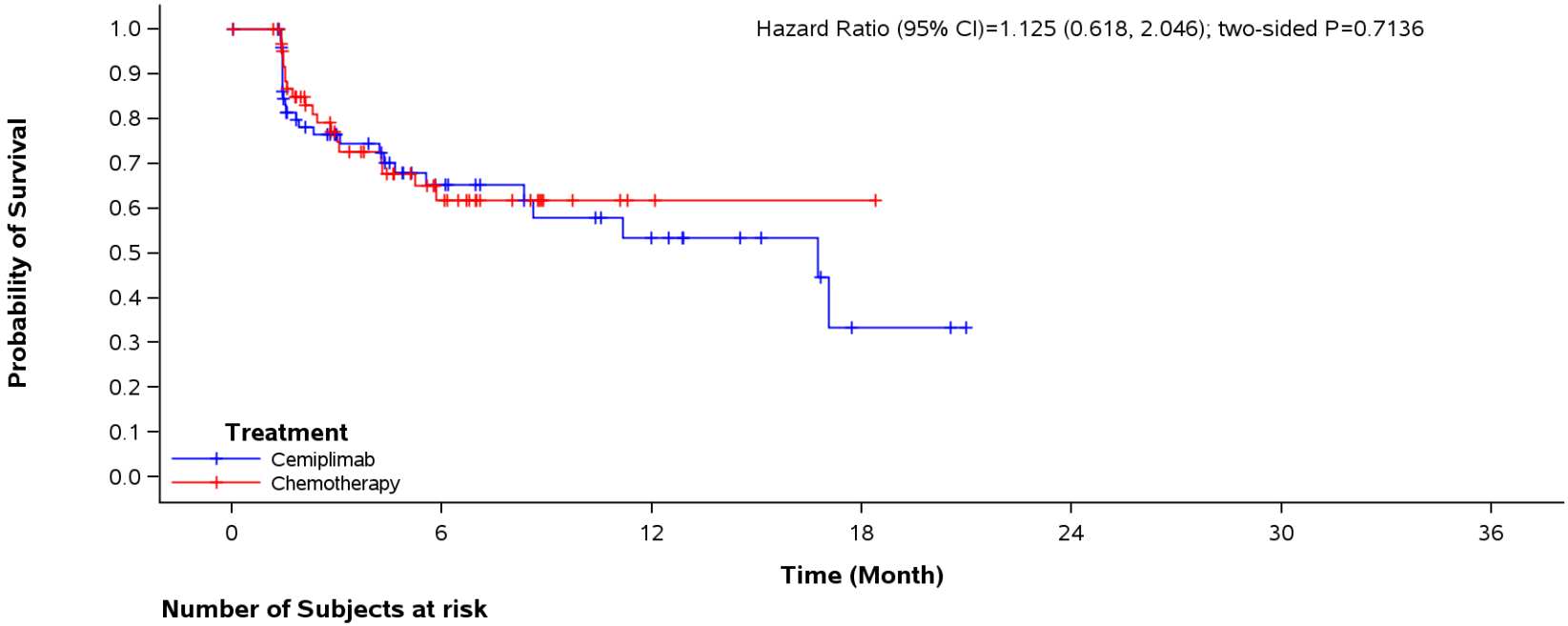

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 11 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Pain - 10 pts sustained improvement



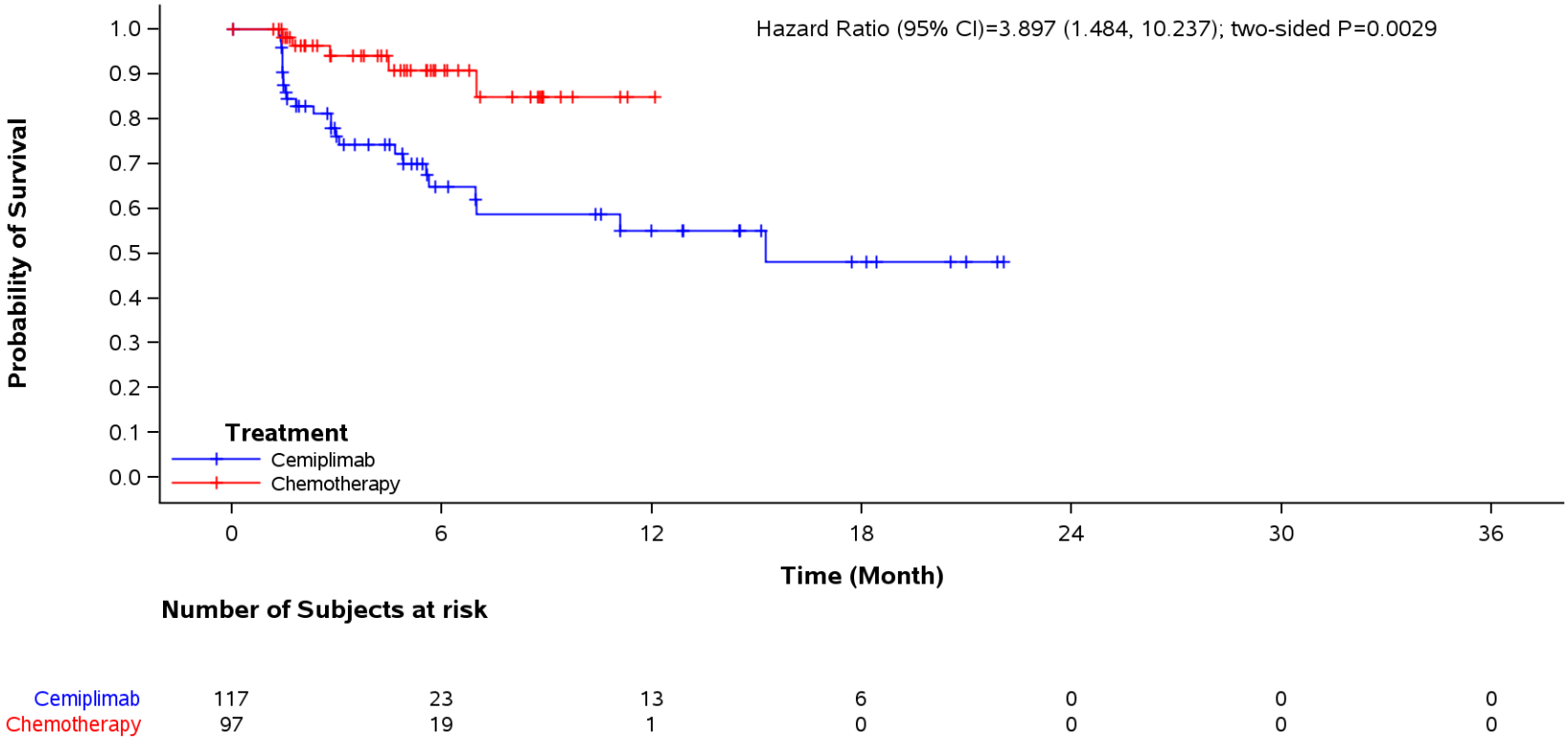

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 23 | 11 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

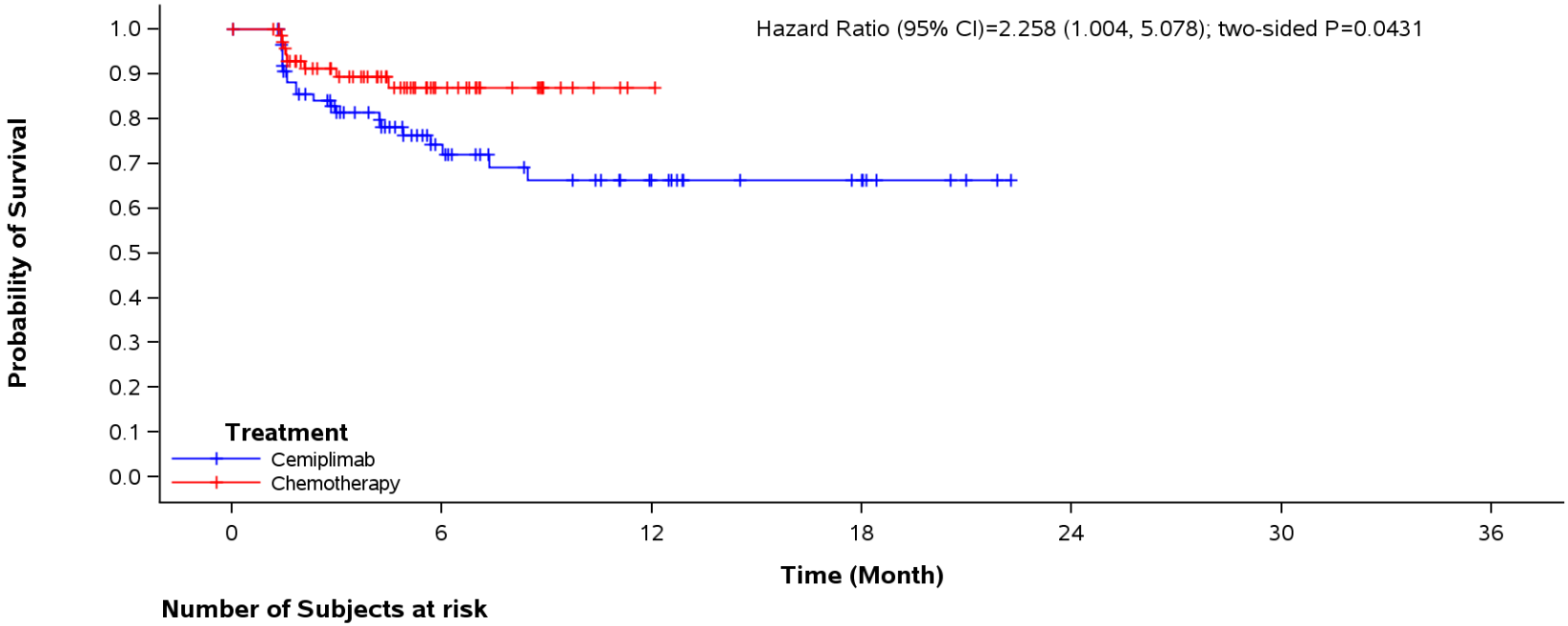
Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Physical Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts sustained improvement



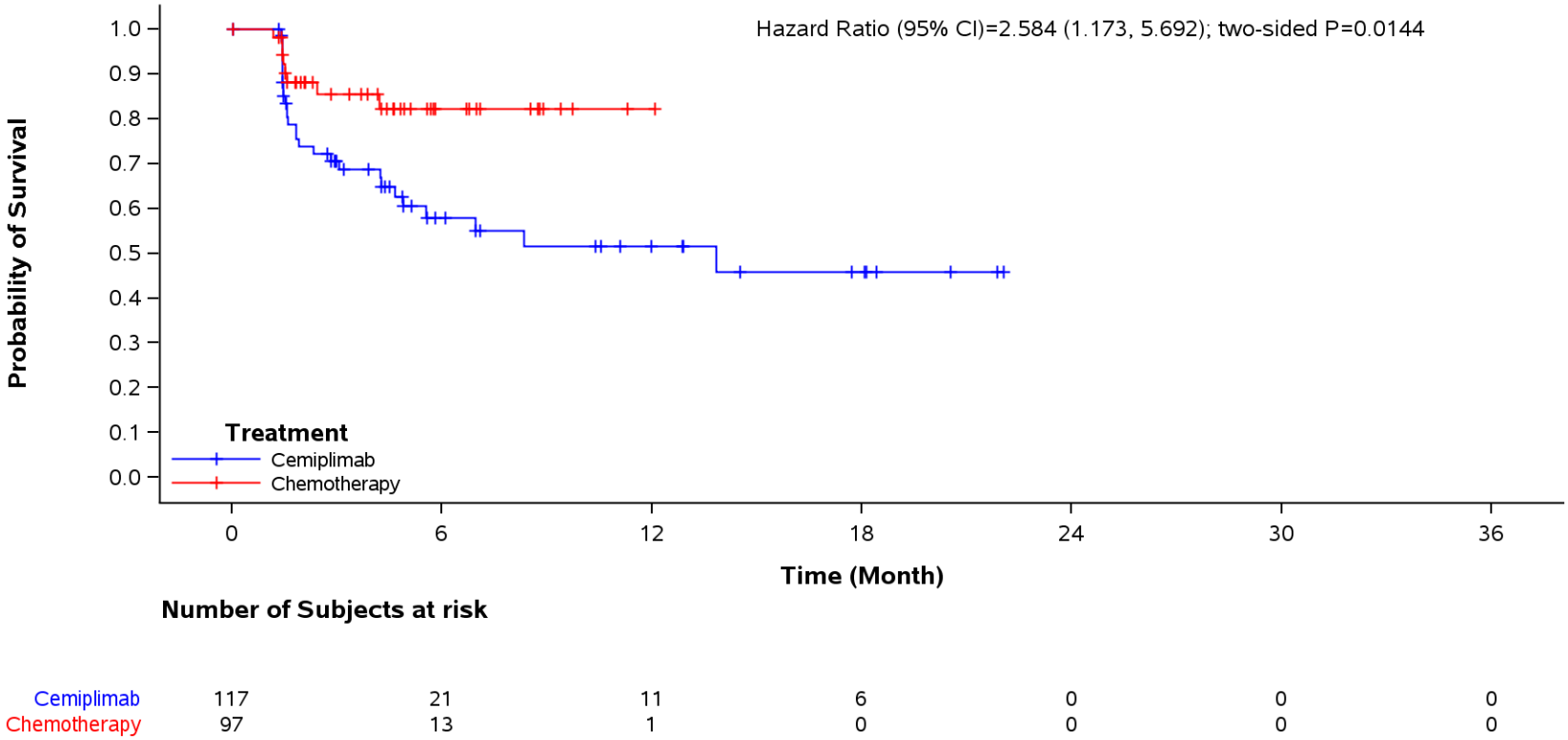

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 33 | 15 | 8 | 0 | 0 | 0 |
| Chemotherapy | 97 | 22 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts sustained improvement



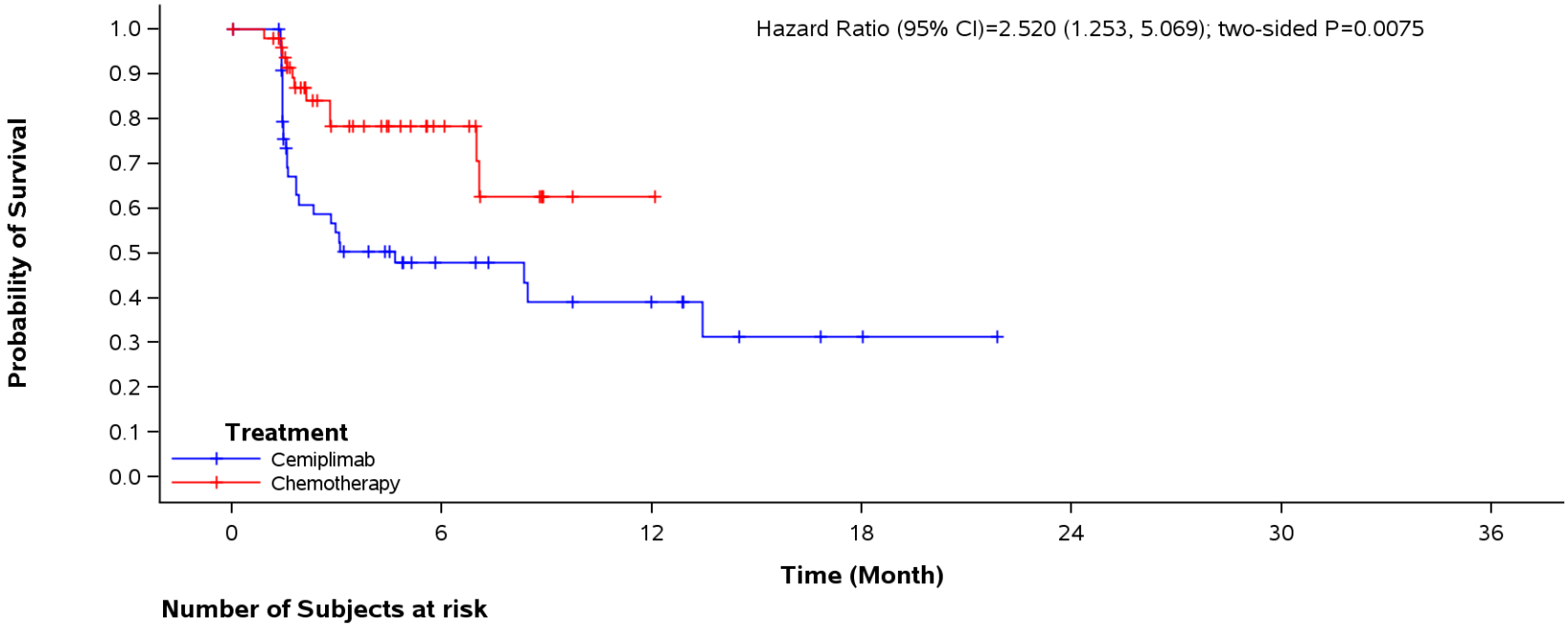

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 21 | 11 | 6 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts sustained improvement



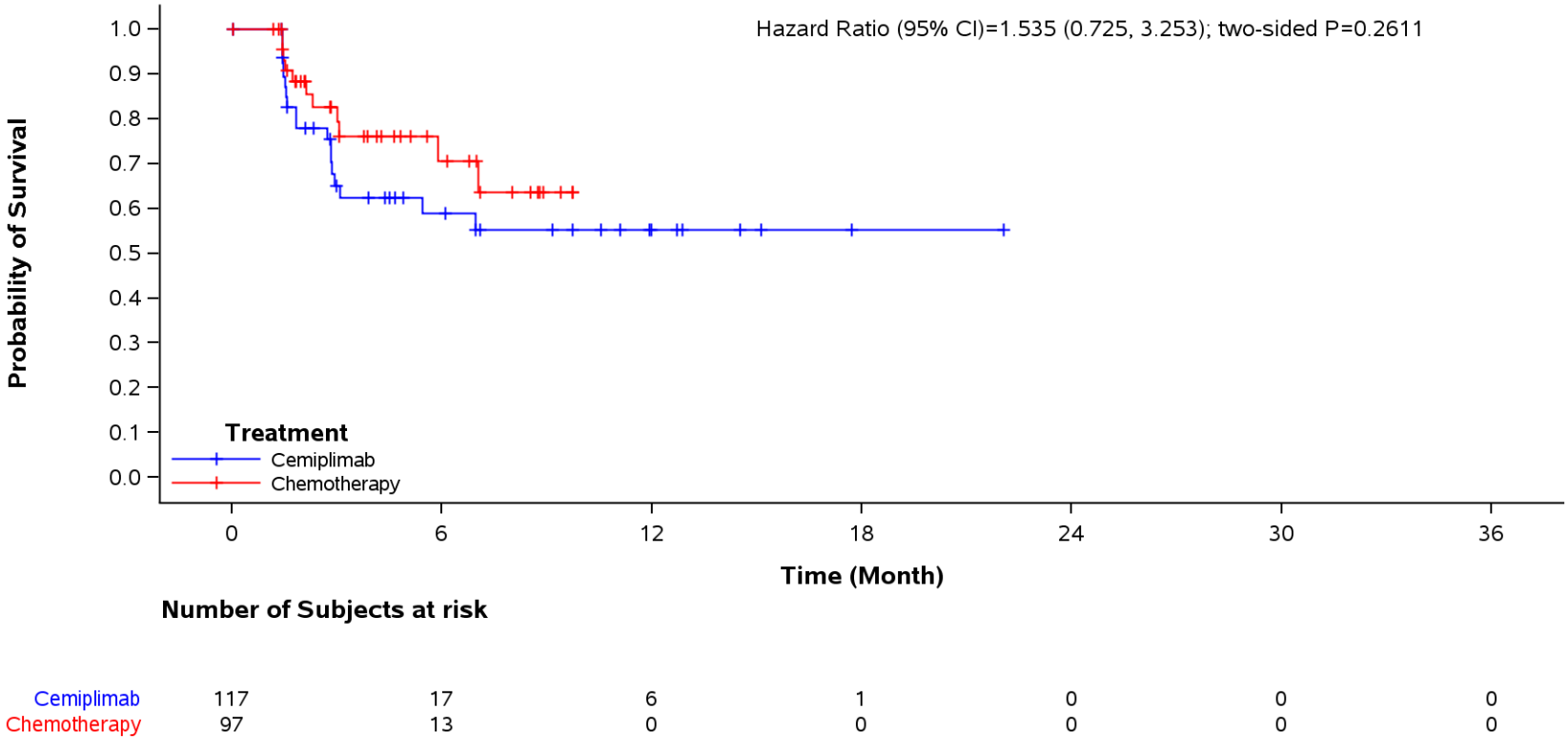

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 14 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts sustained improvement



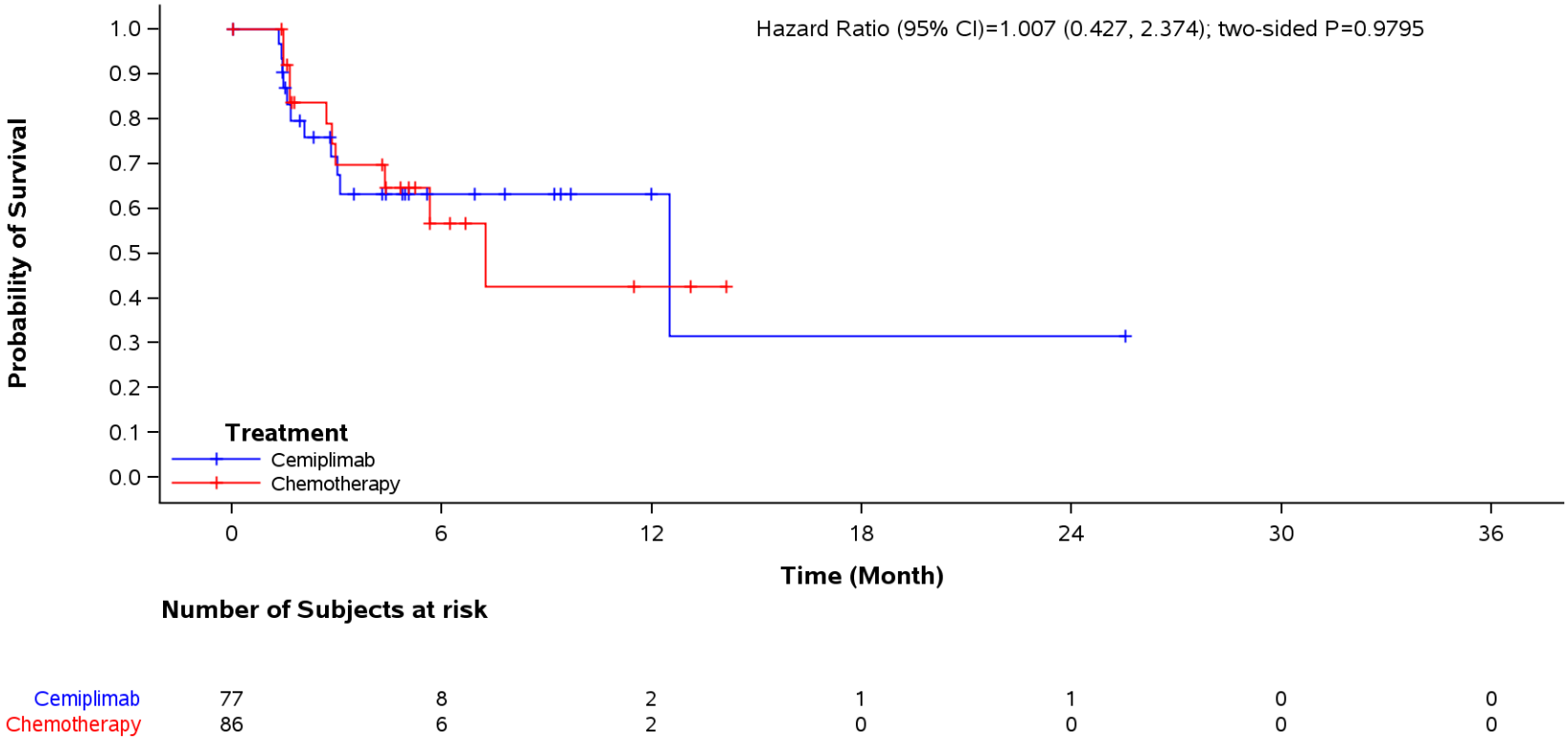

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 17 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

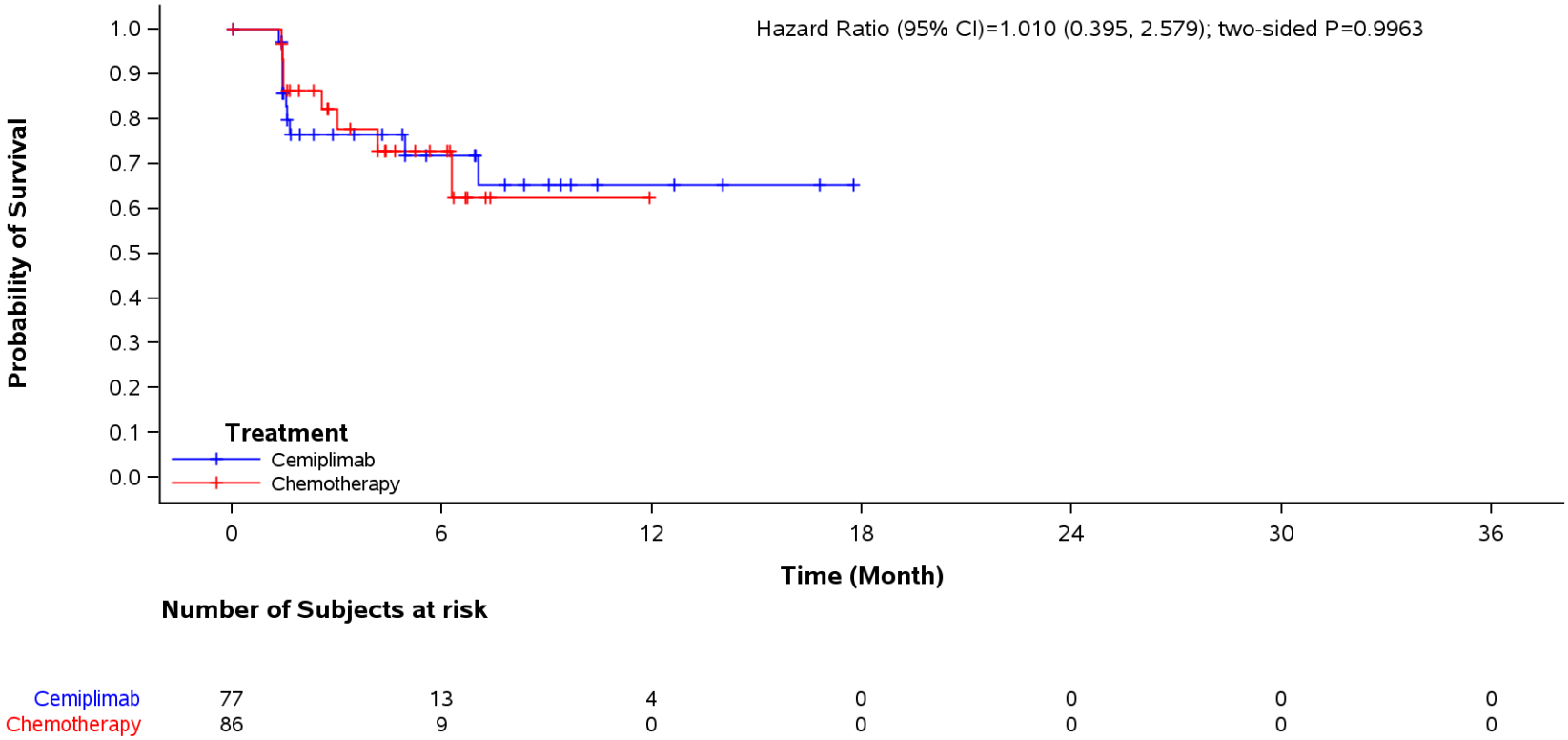
Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

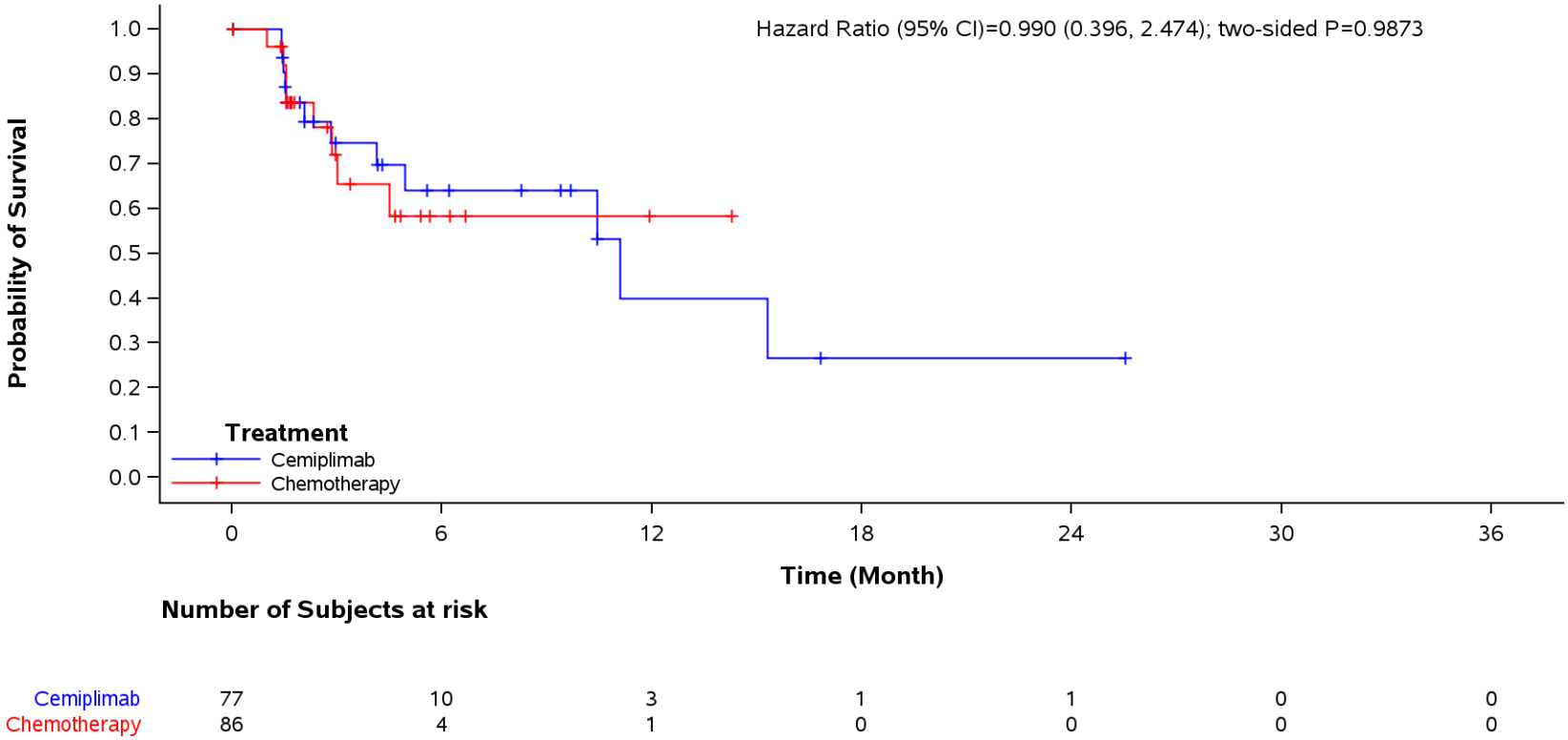
Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts sustained improvement

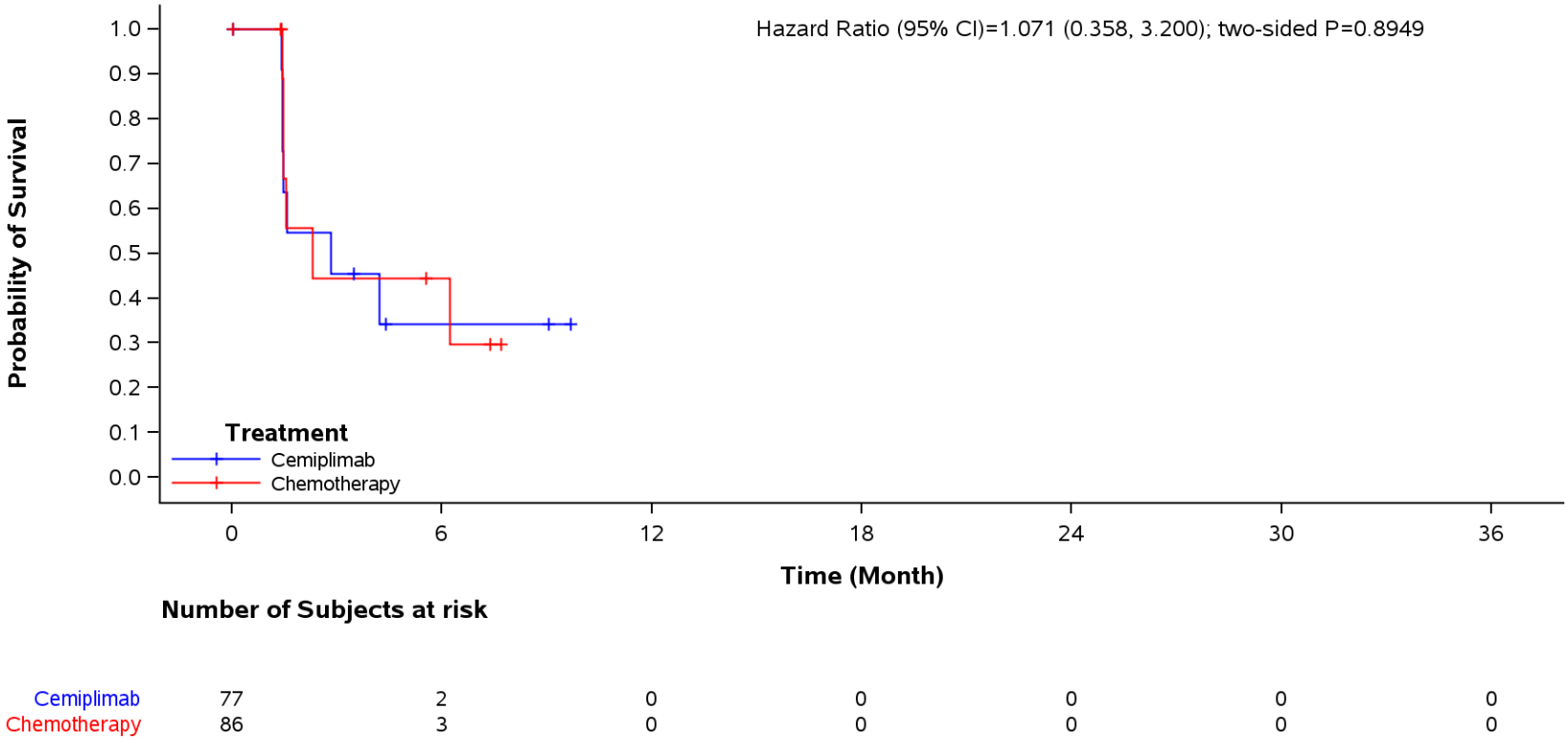



Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

Diarhoea - 10 pts sustained improvement

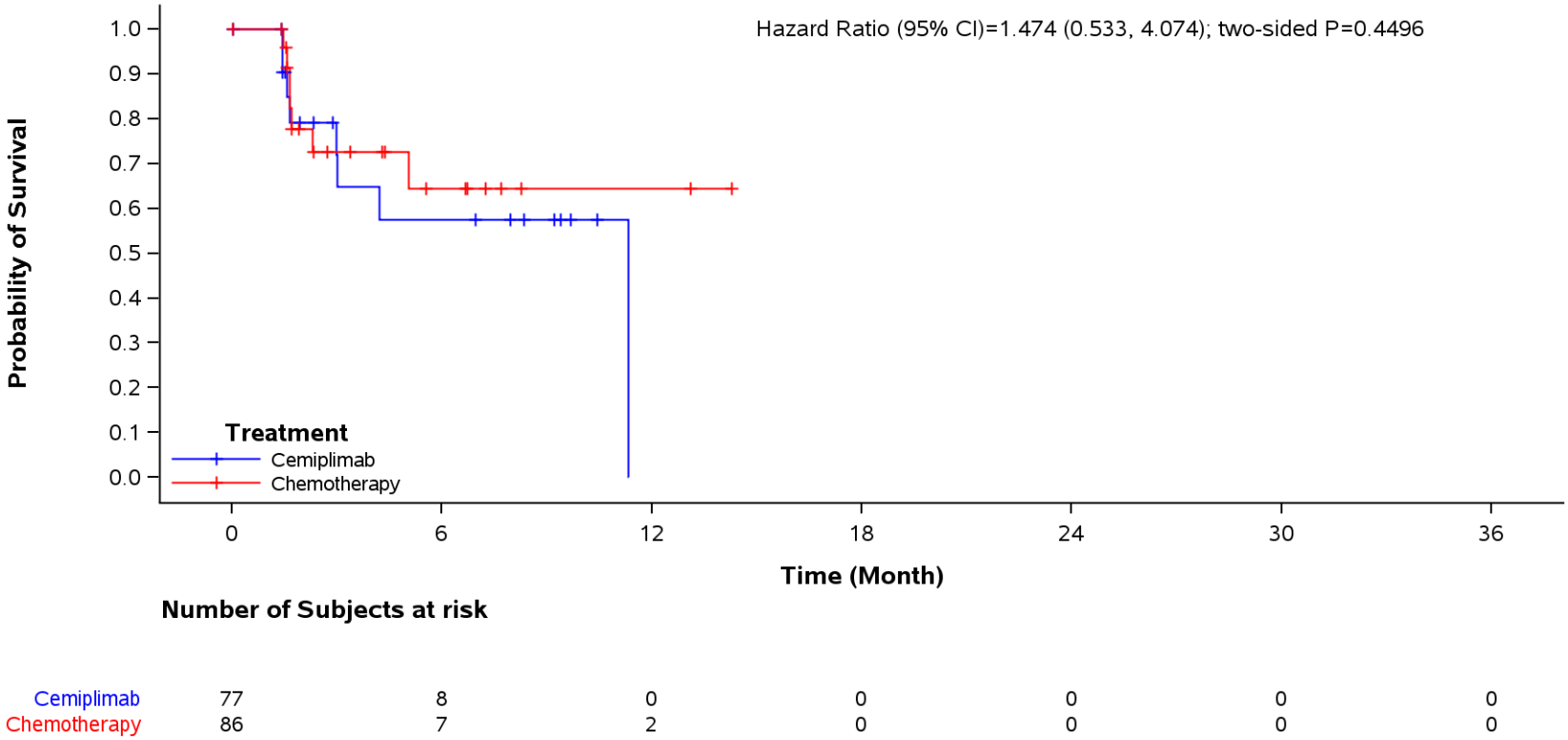



Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts sustained improvement



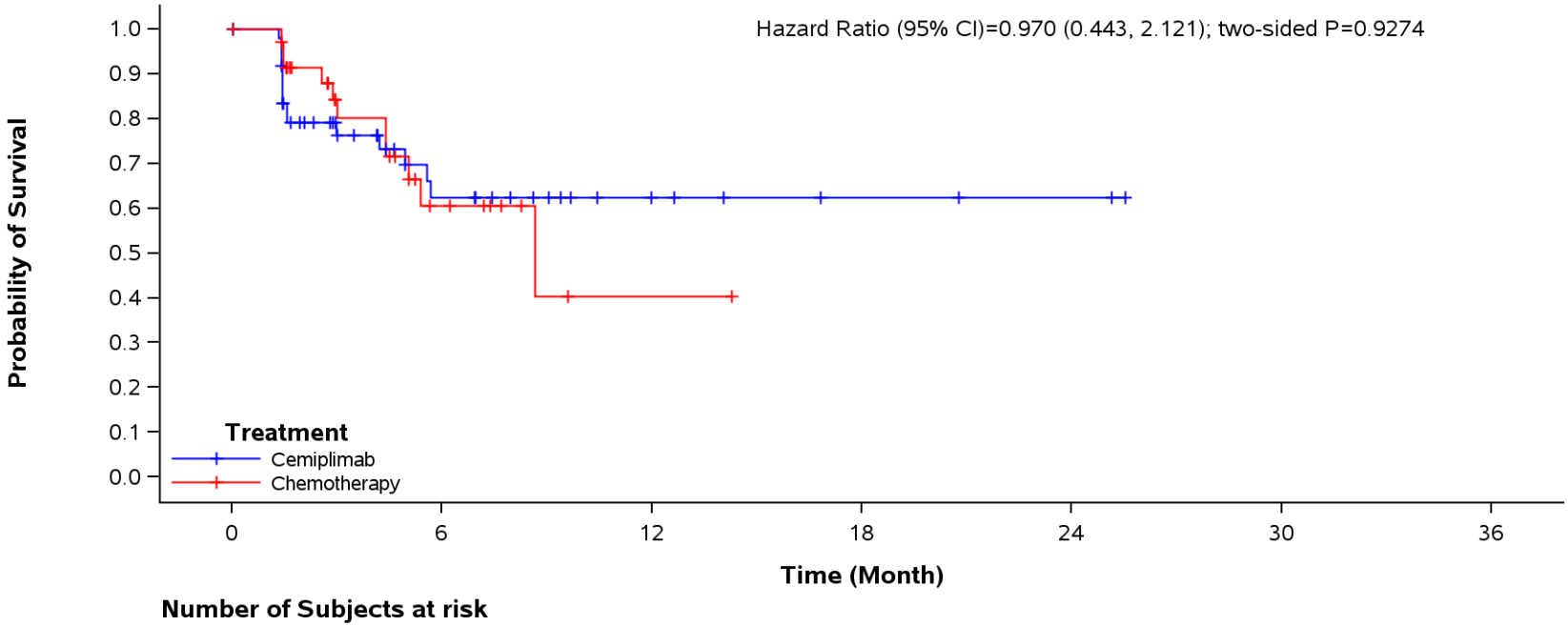

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 8 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 7 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts sustained improvement



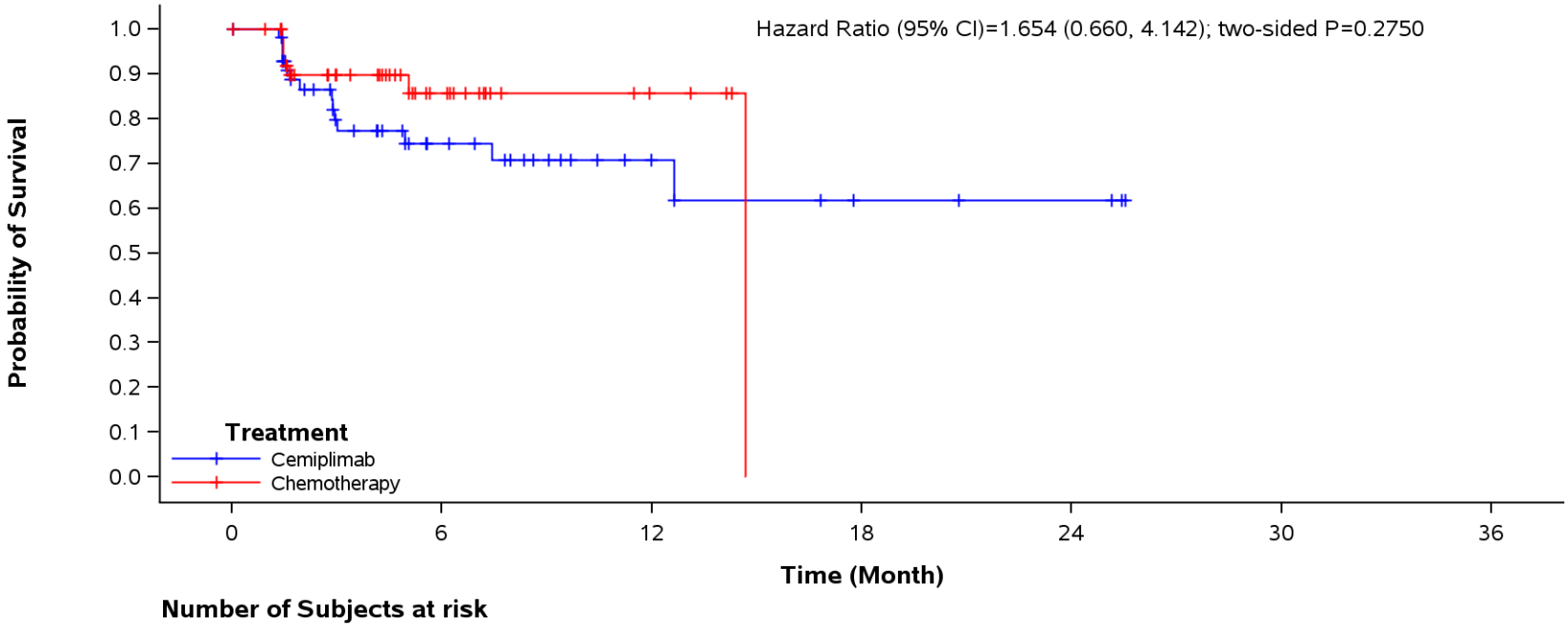

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 17 | 6 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts sustained improvement



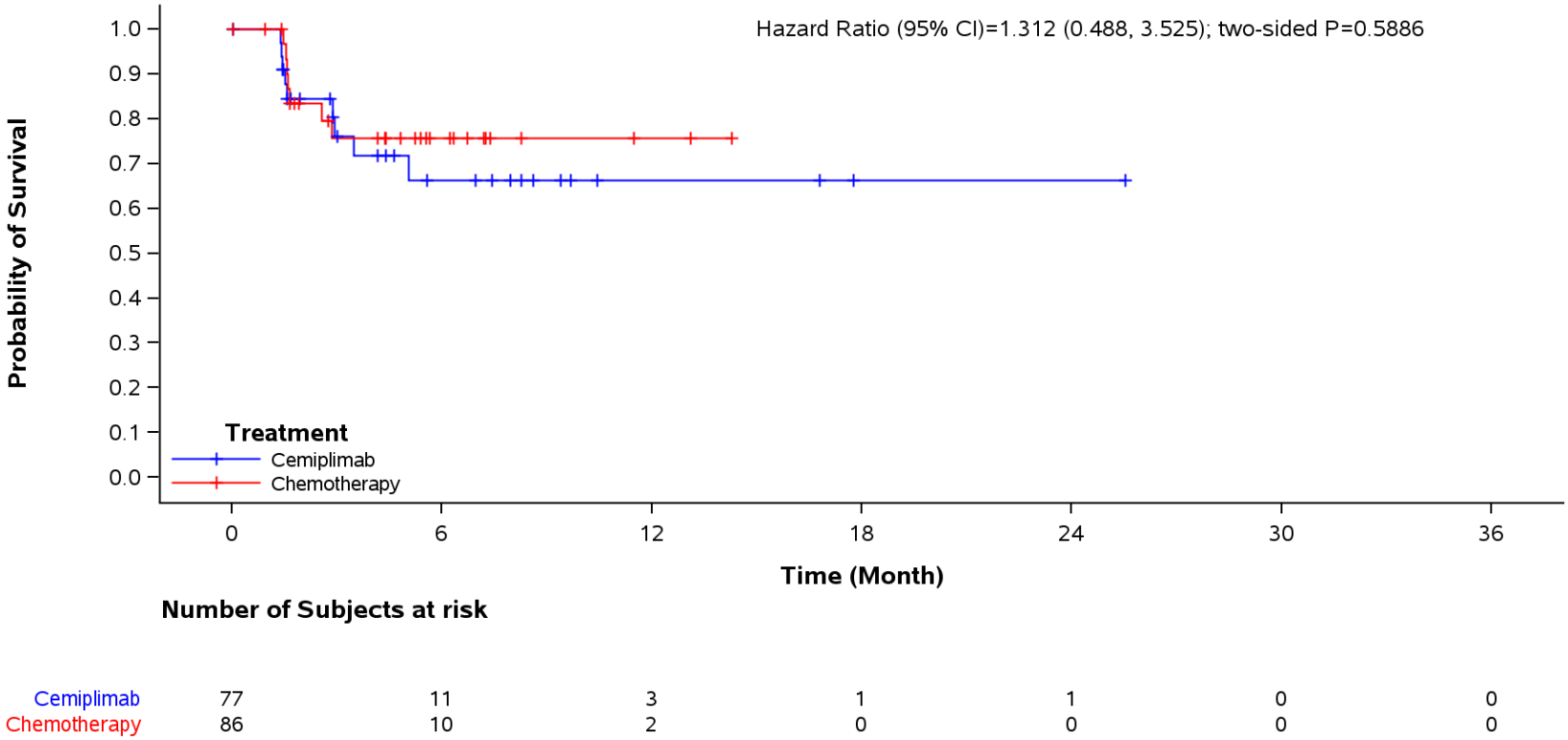

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 22 | 8 | 4 | 3 | 0 | 0 |
| Chemotherapy | 86 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts sustained improvement



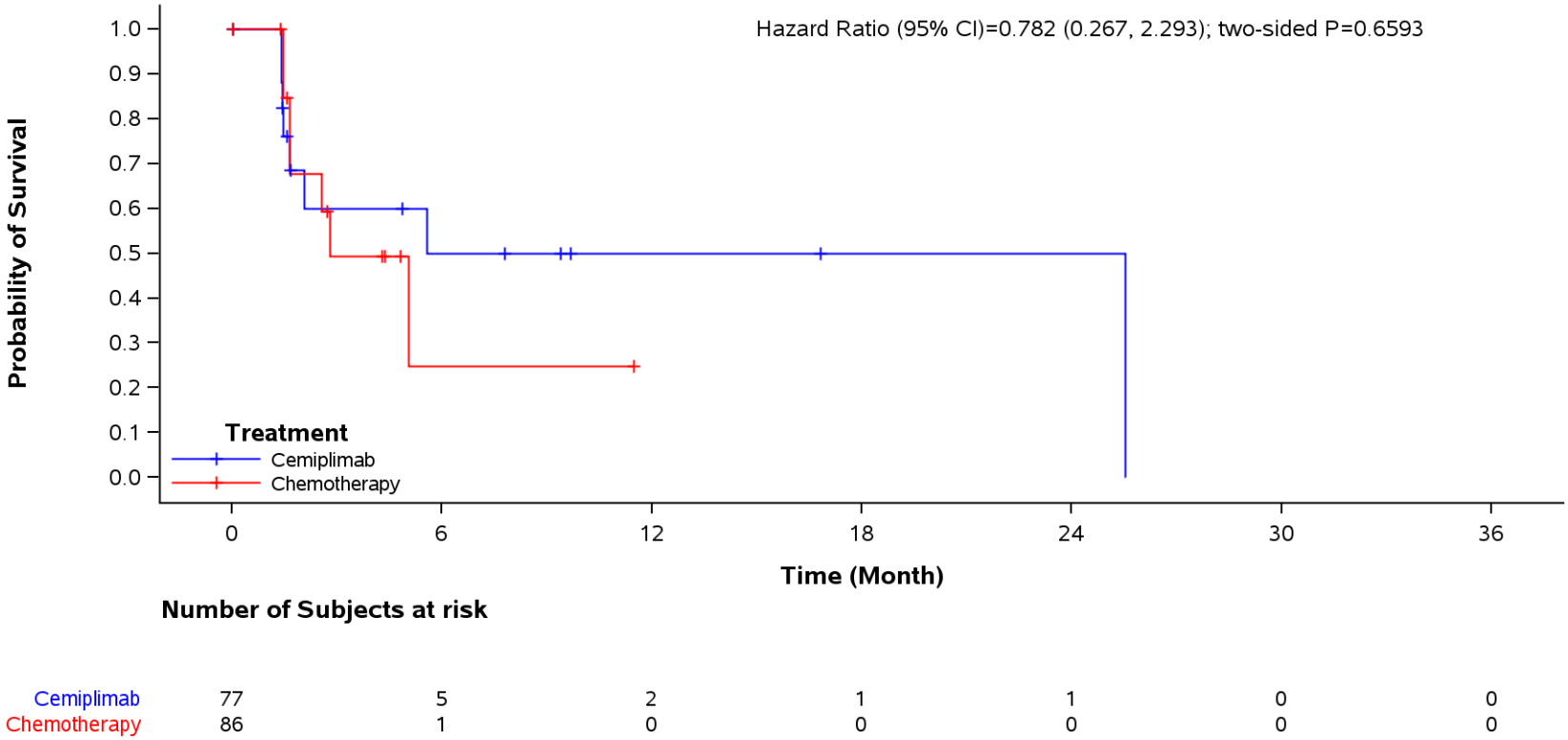

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 11 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 86 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts sustained improvement



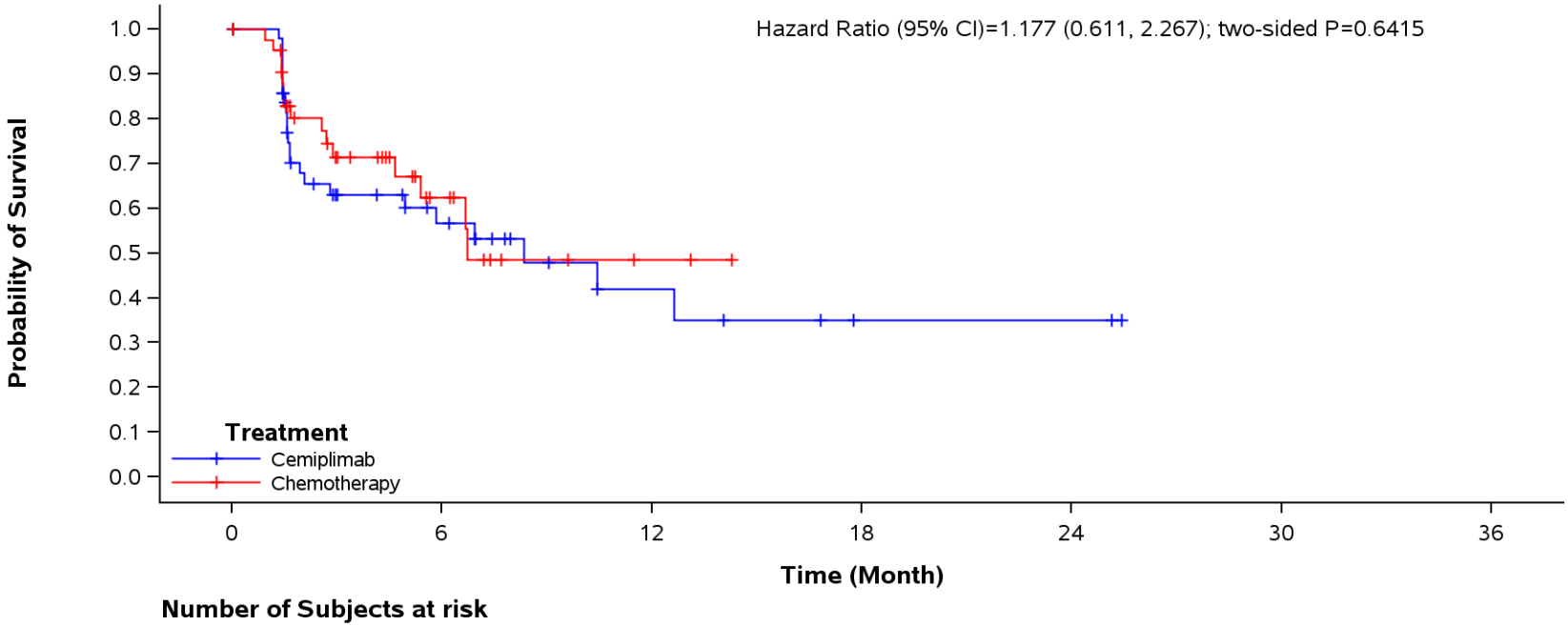

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 5 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 86 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts sustained improvement



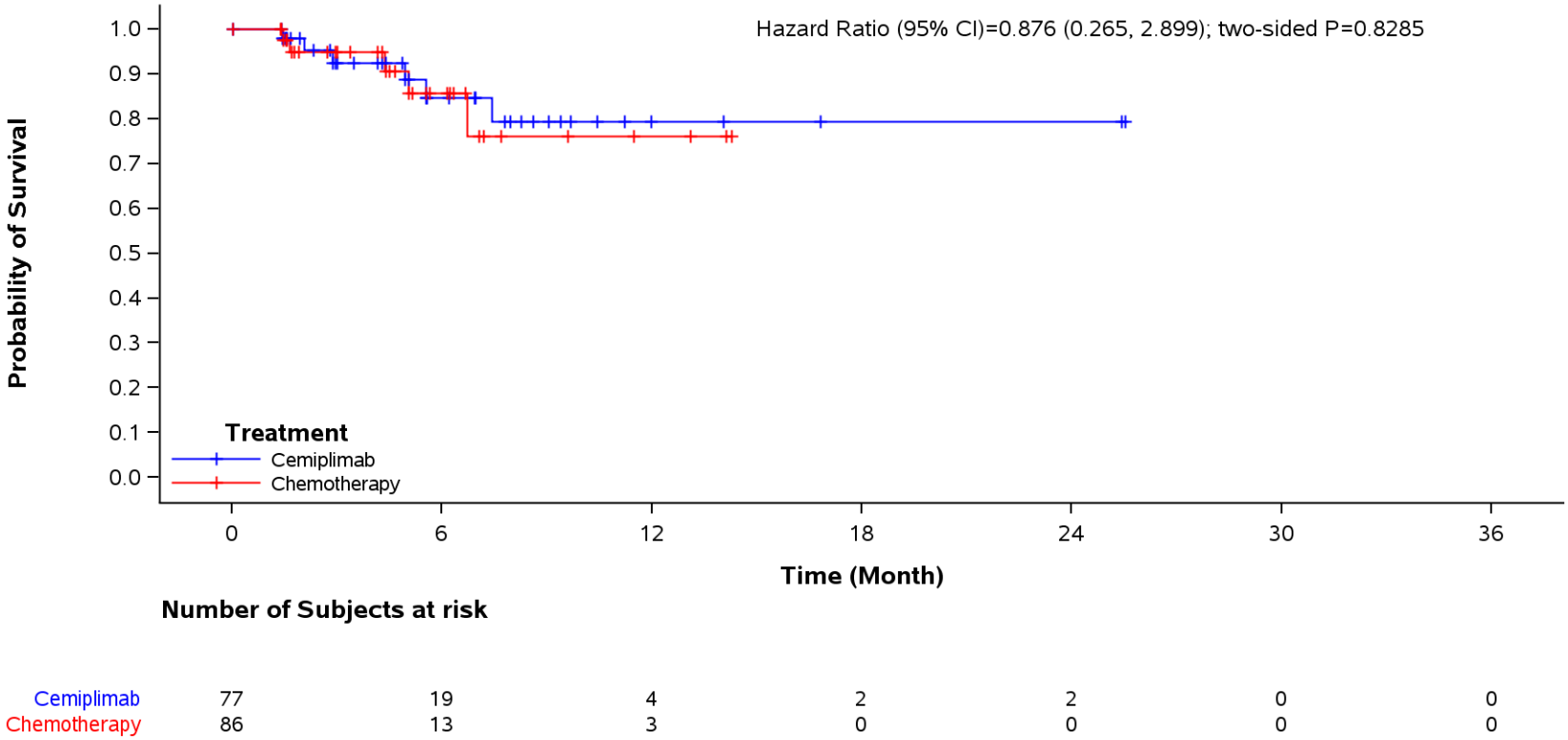

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 17 | 6 | 2 | 2 | 0 | 0 |
| Chemotherapy | 86 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts sustained improvement



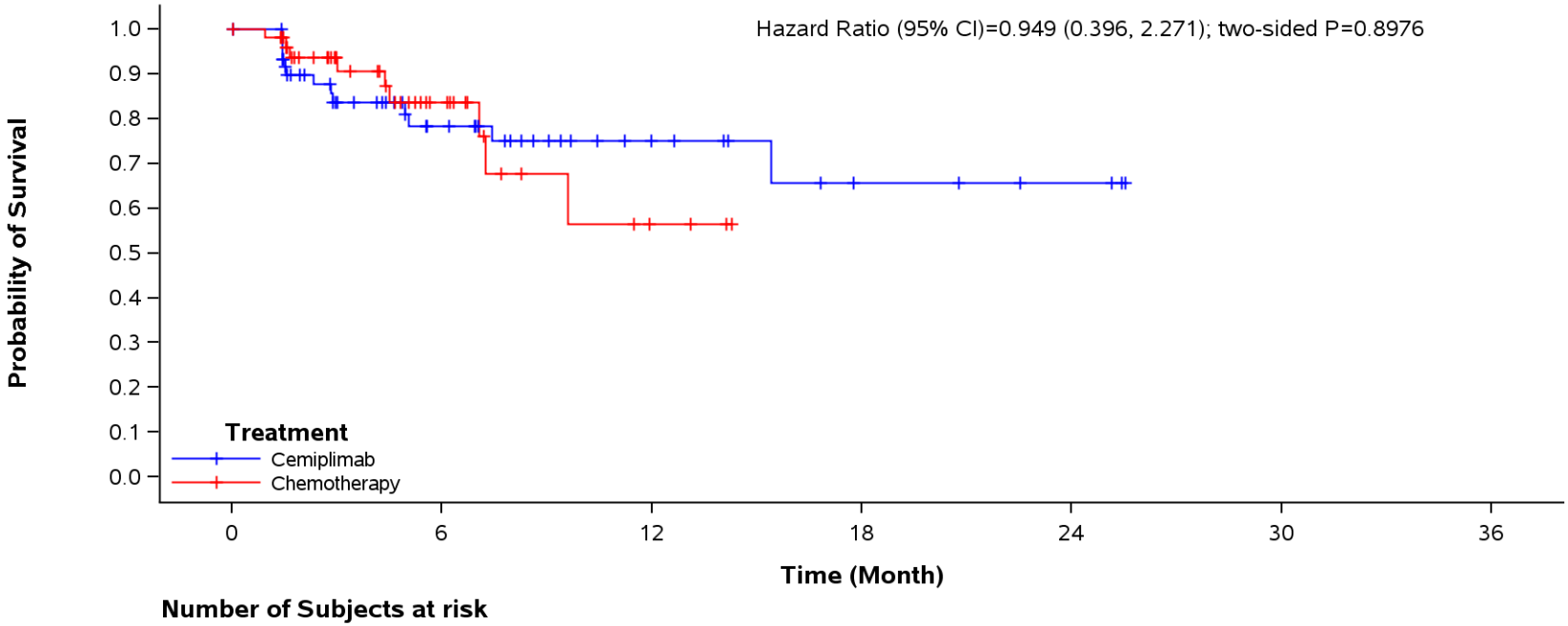

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 19 | 4 | 2 | 2 | 0 | 0 |
| Chemotherapy | 86 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts sustained improvement



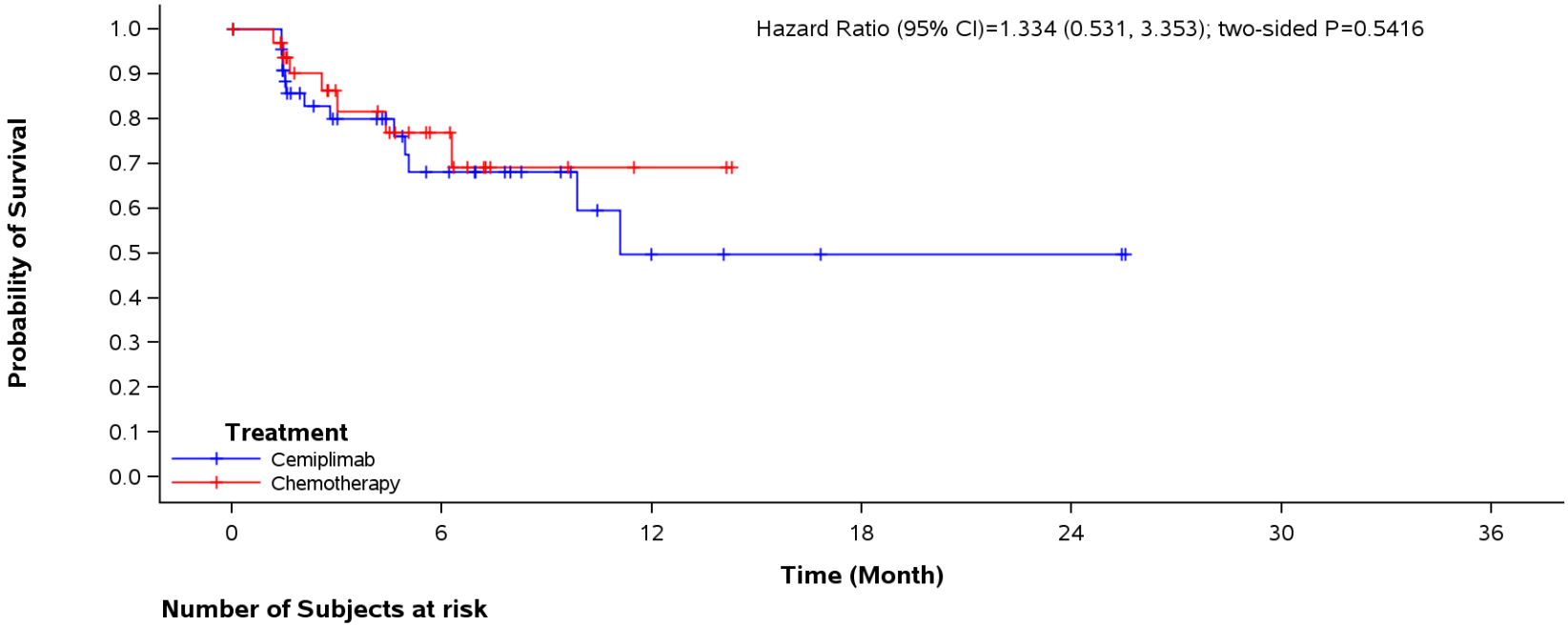

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 27 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts sustained improvement



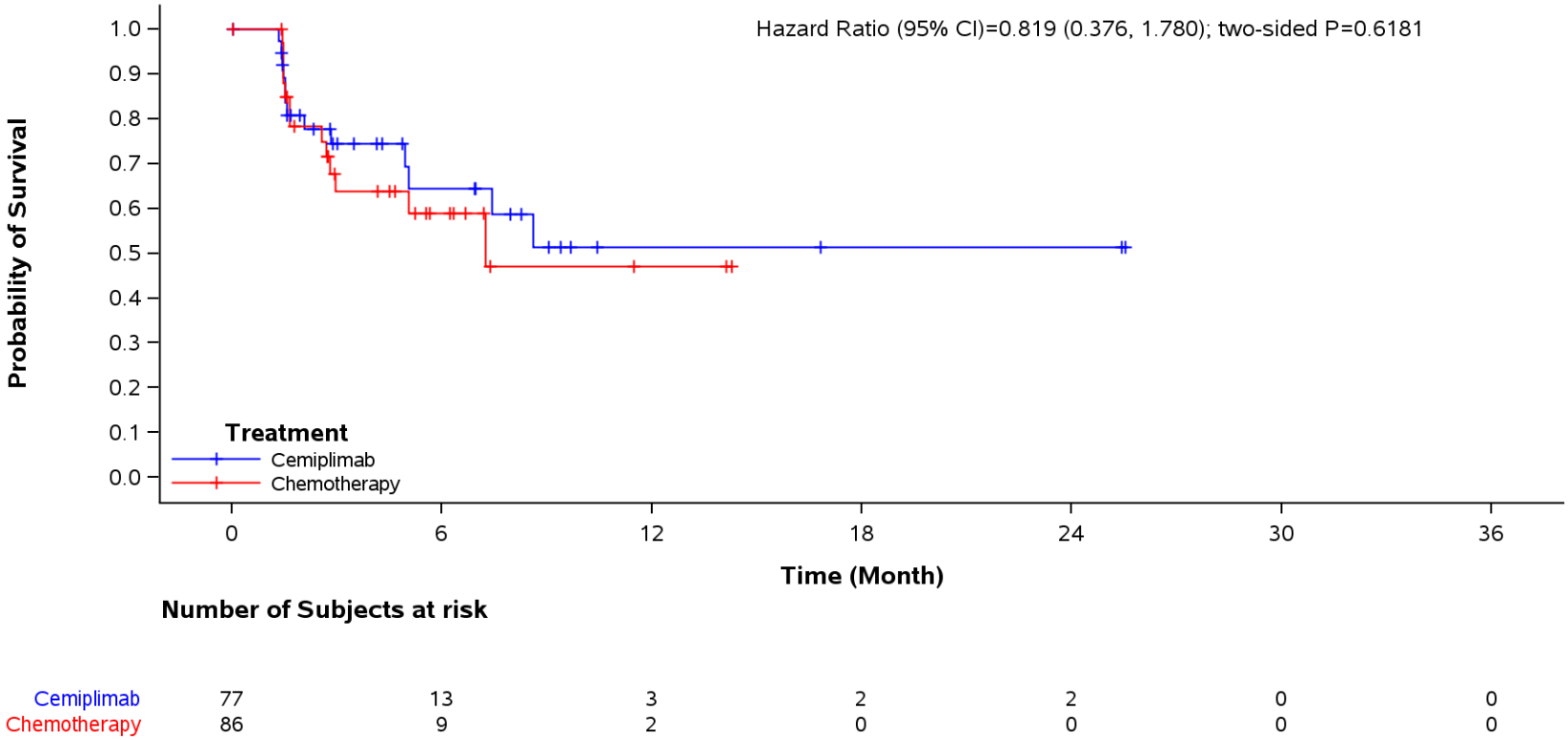

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 16 | 4 | 2 | 2 | 0 | 0 |
| Chemotherapy | 86 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

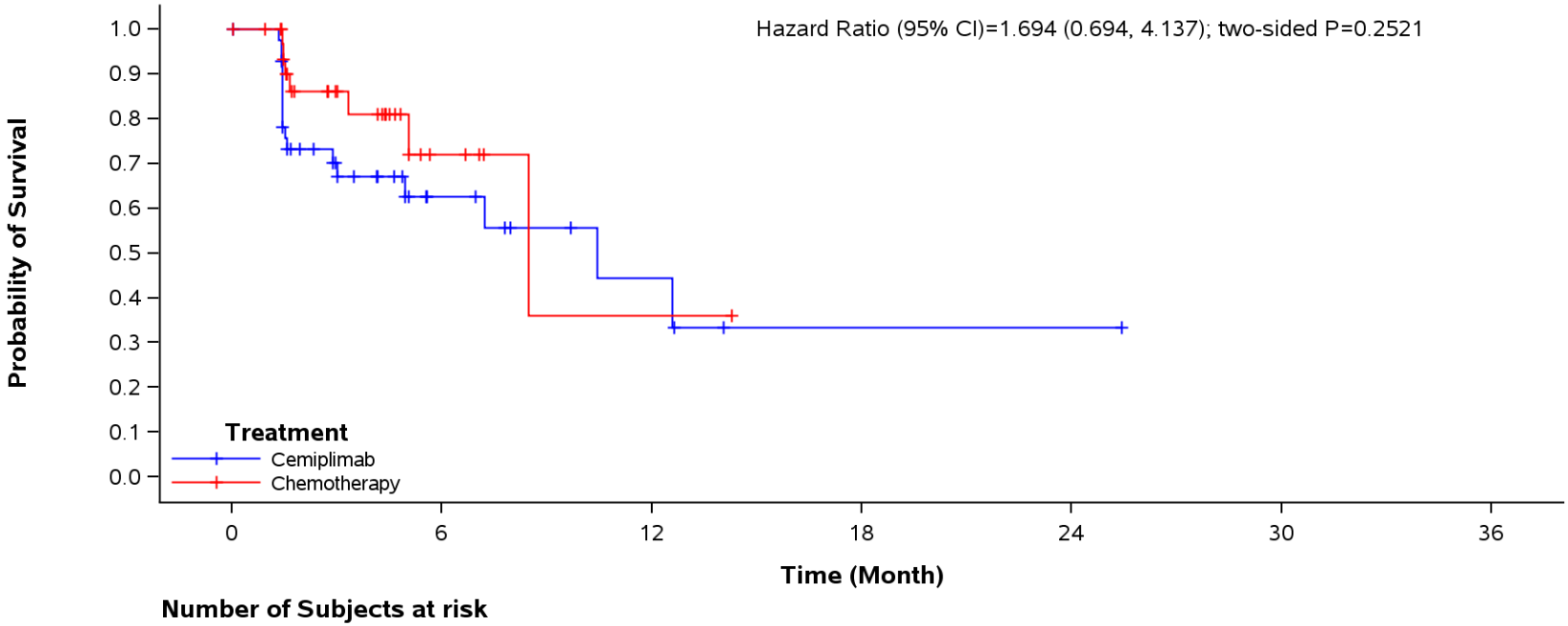
Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts sustained improvement



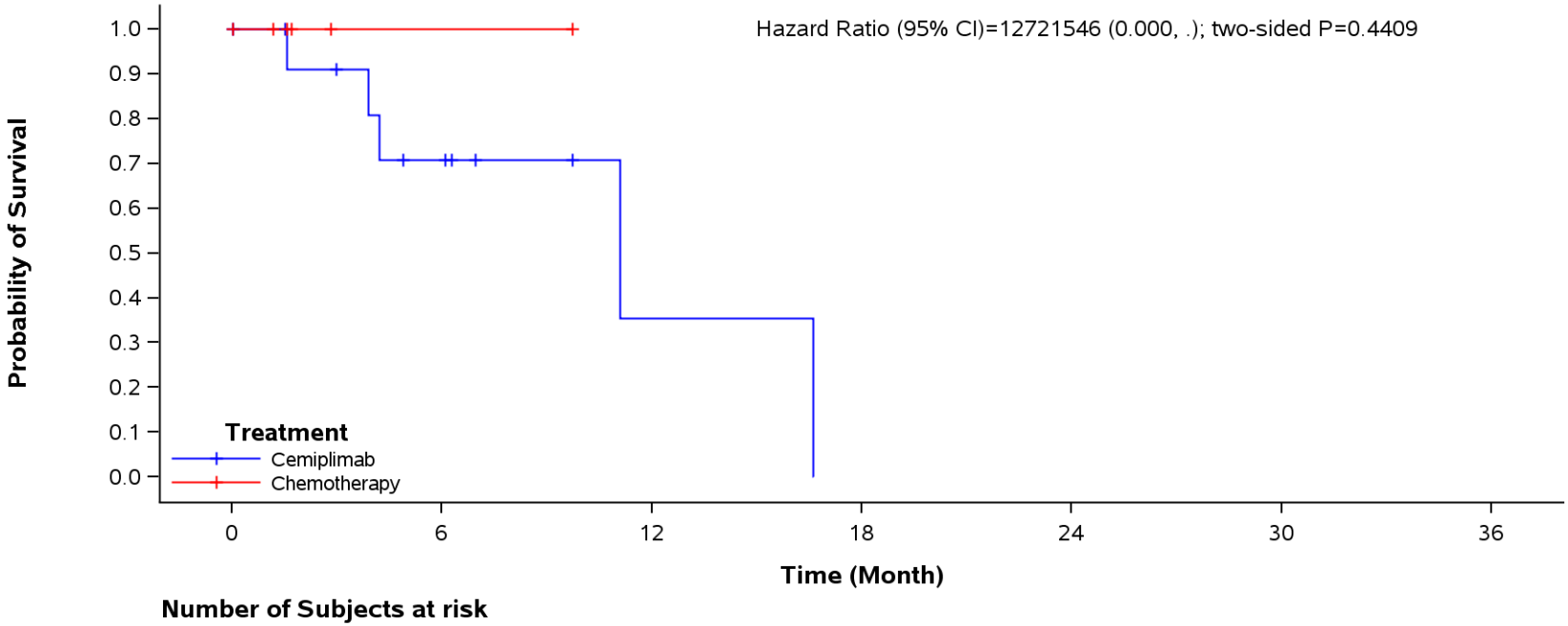

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 10 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 86 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts sustained improvement



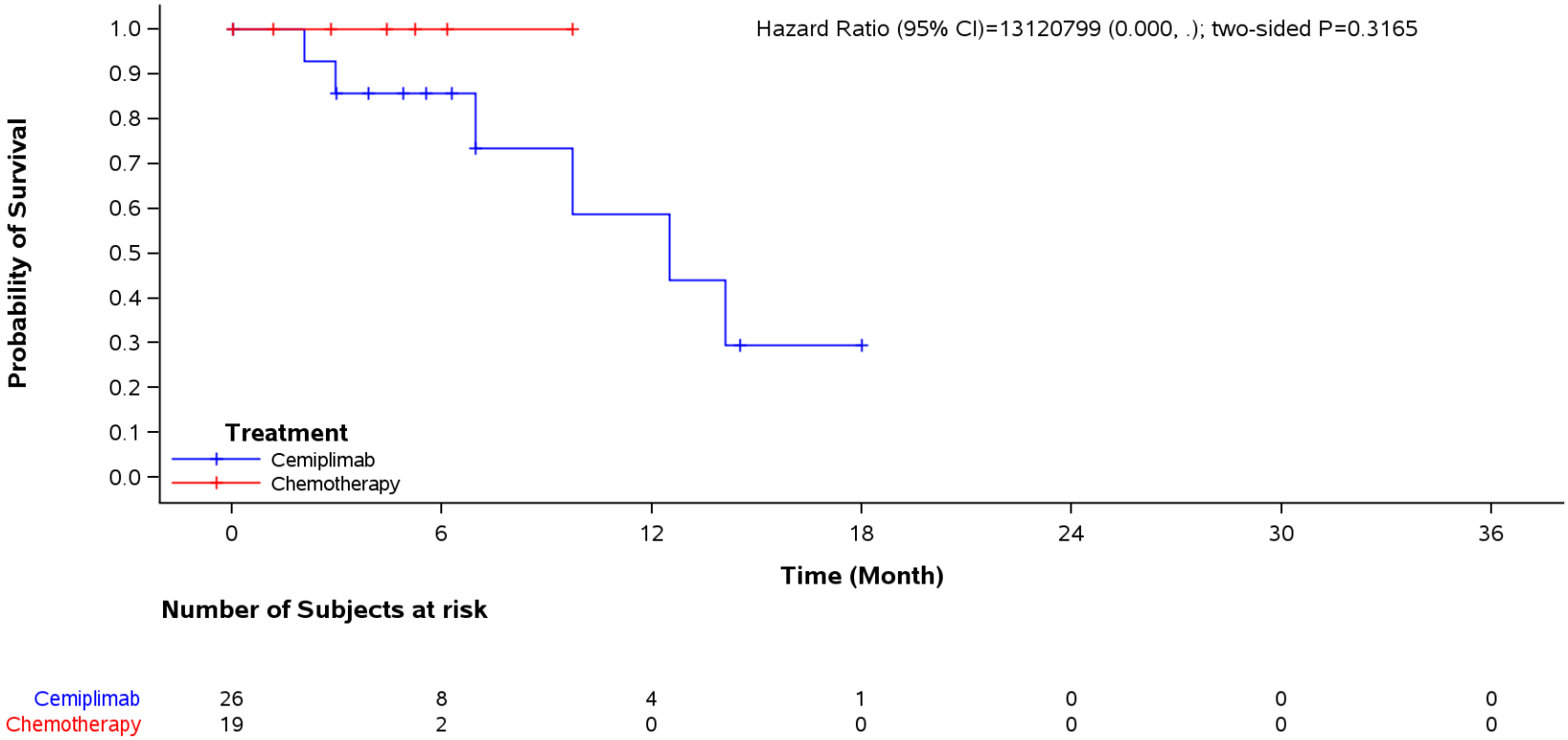

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

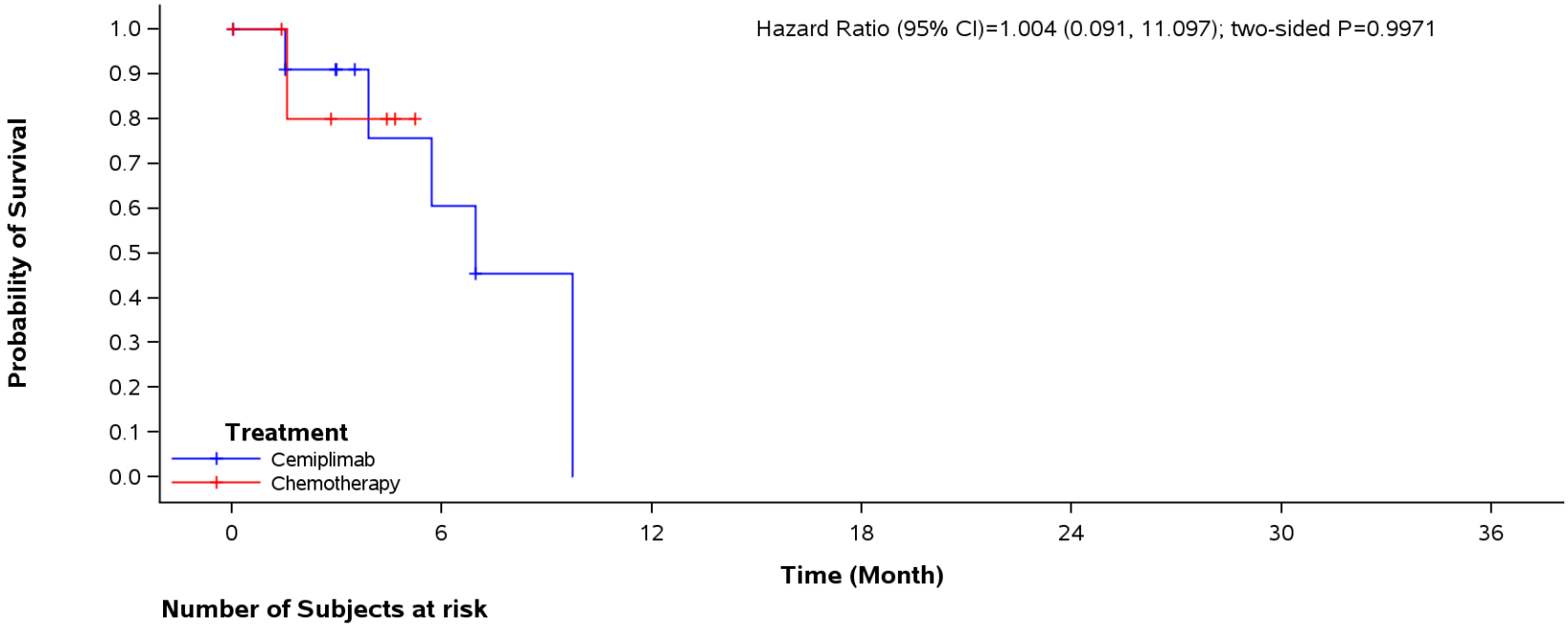
Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts sustained improvement



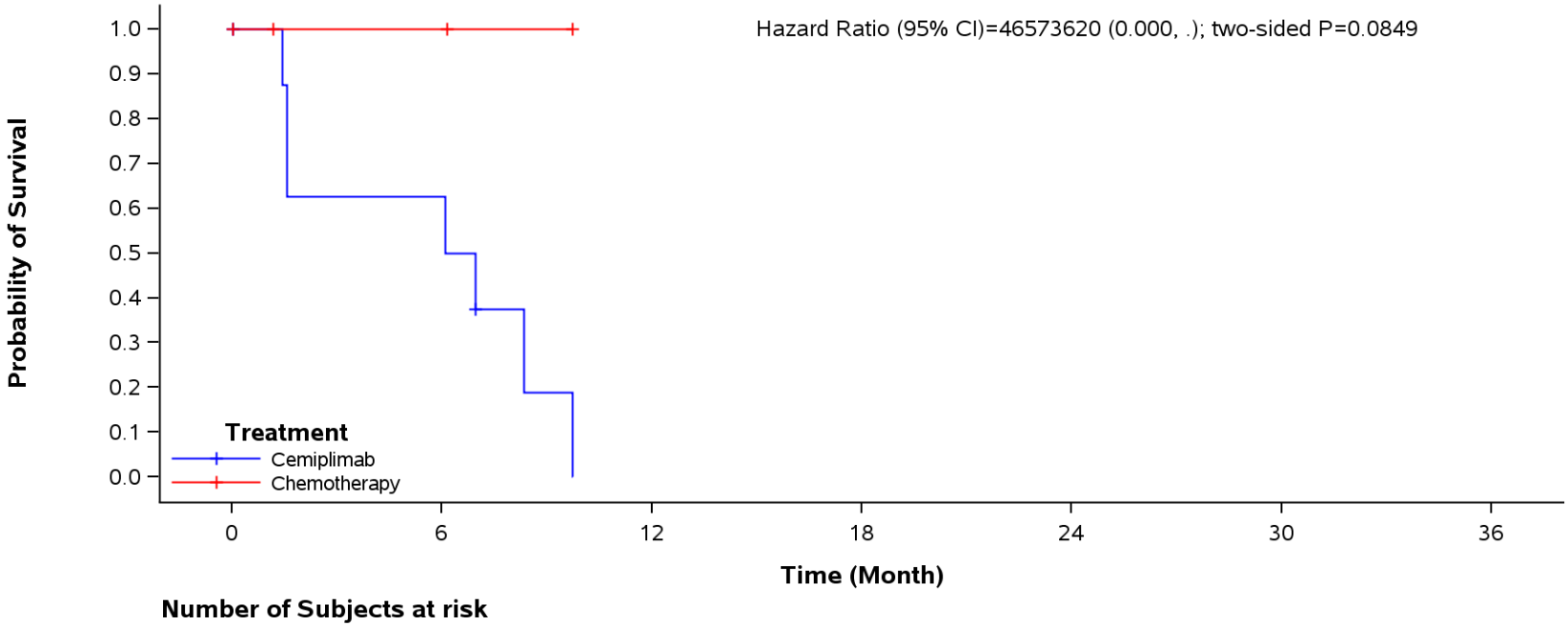

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

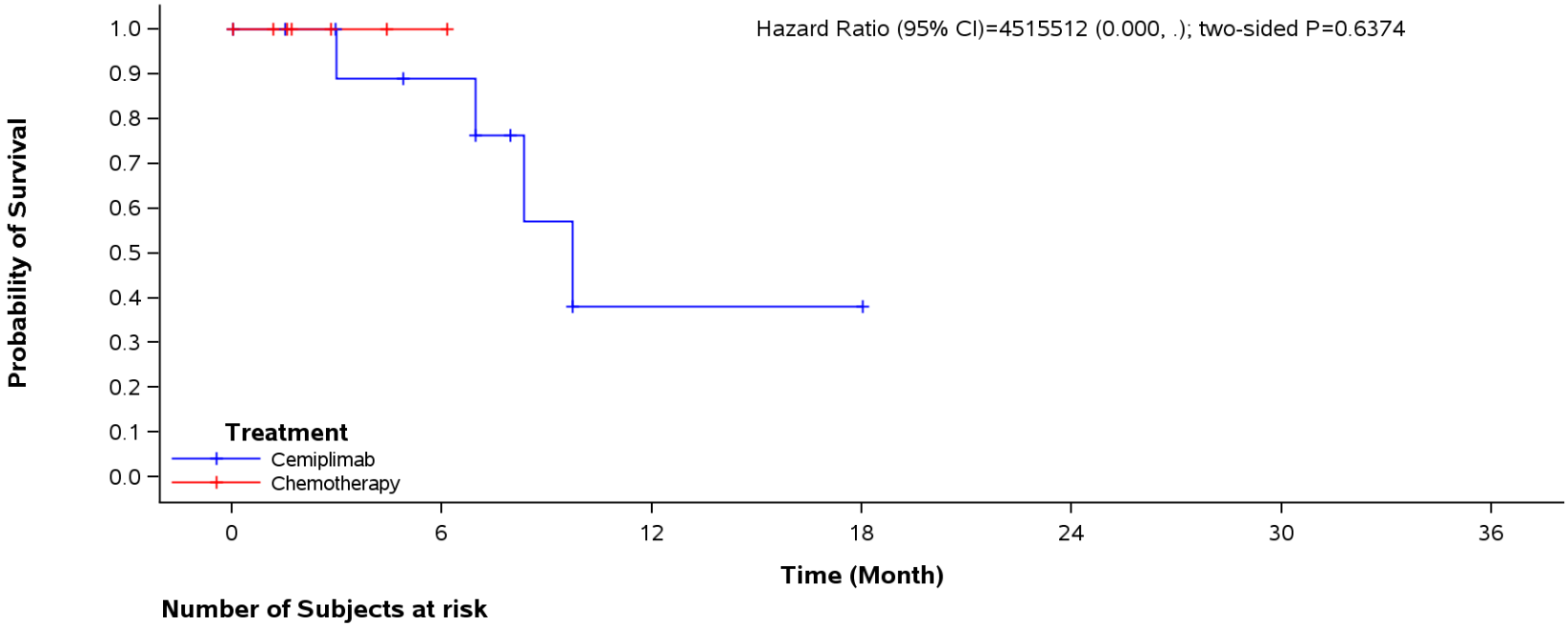
Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts sustained improvement



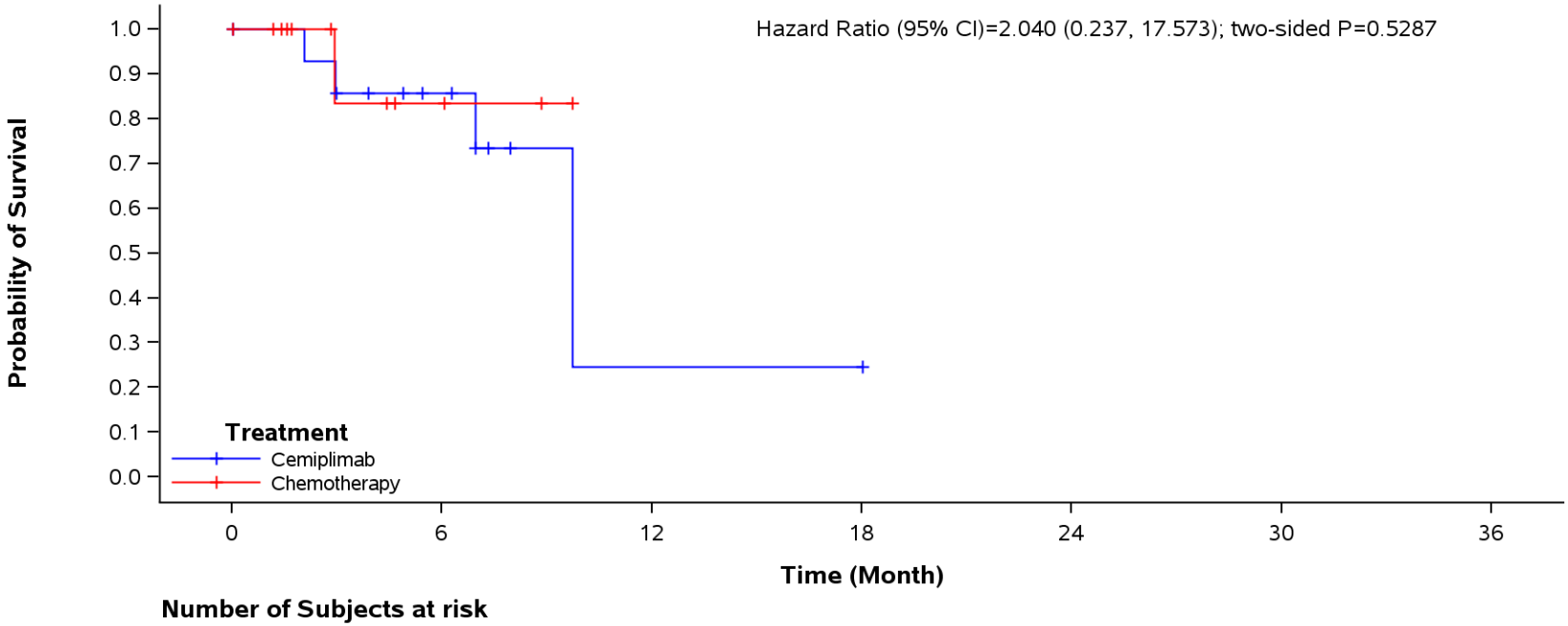

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 7 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts sustained improvement



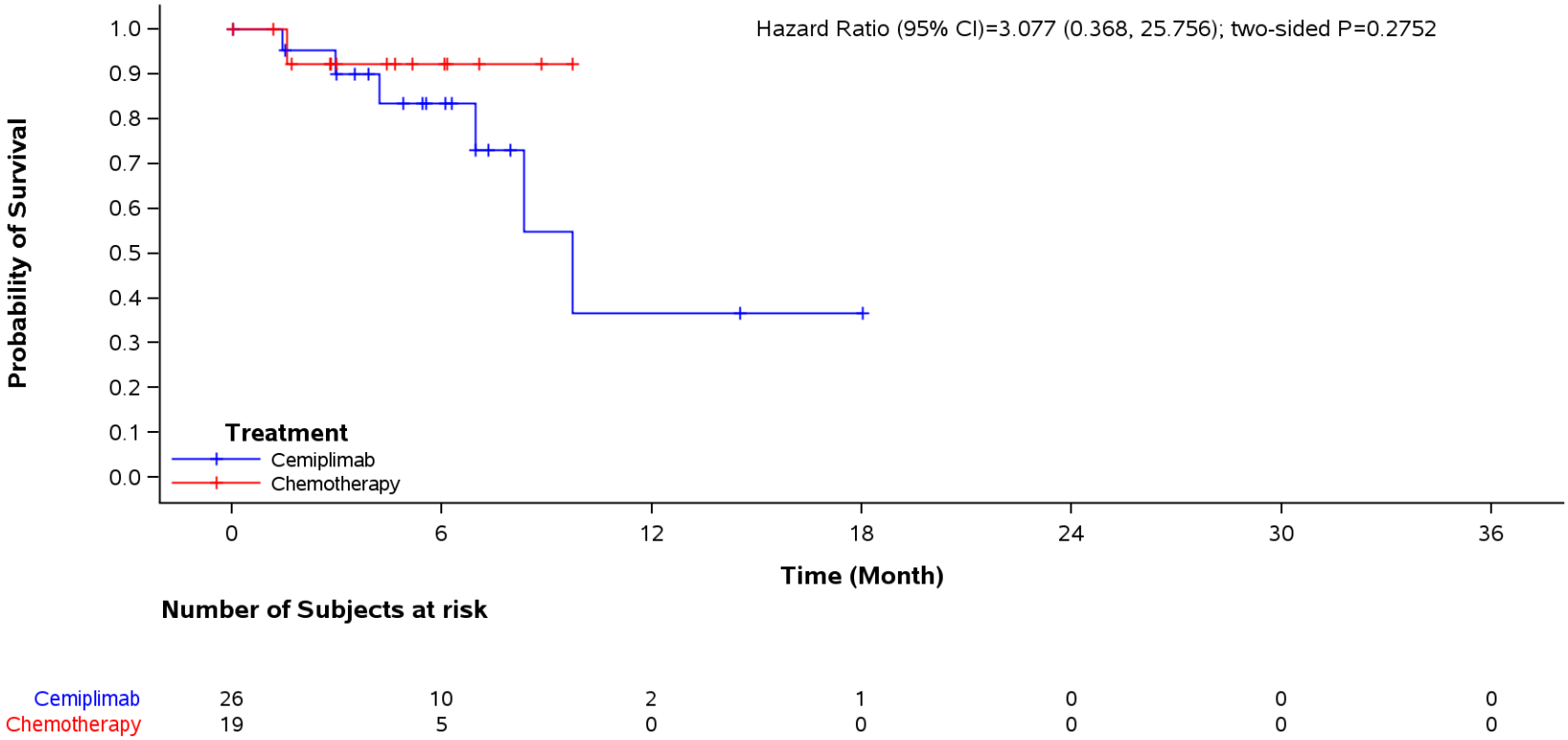

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 8 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

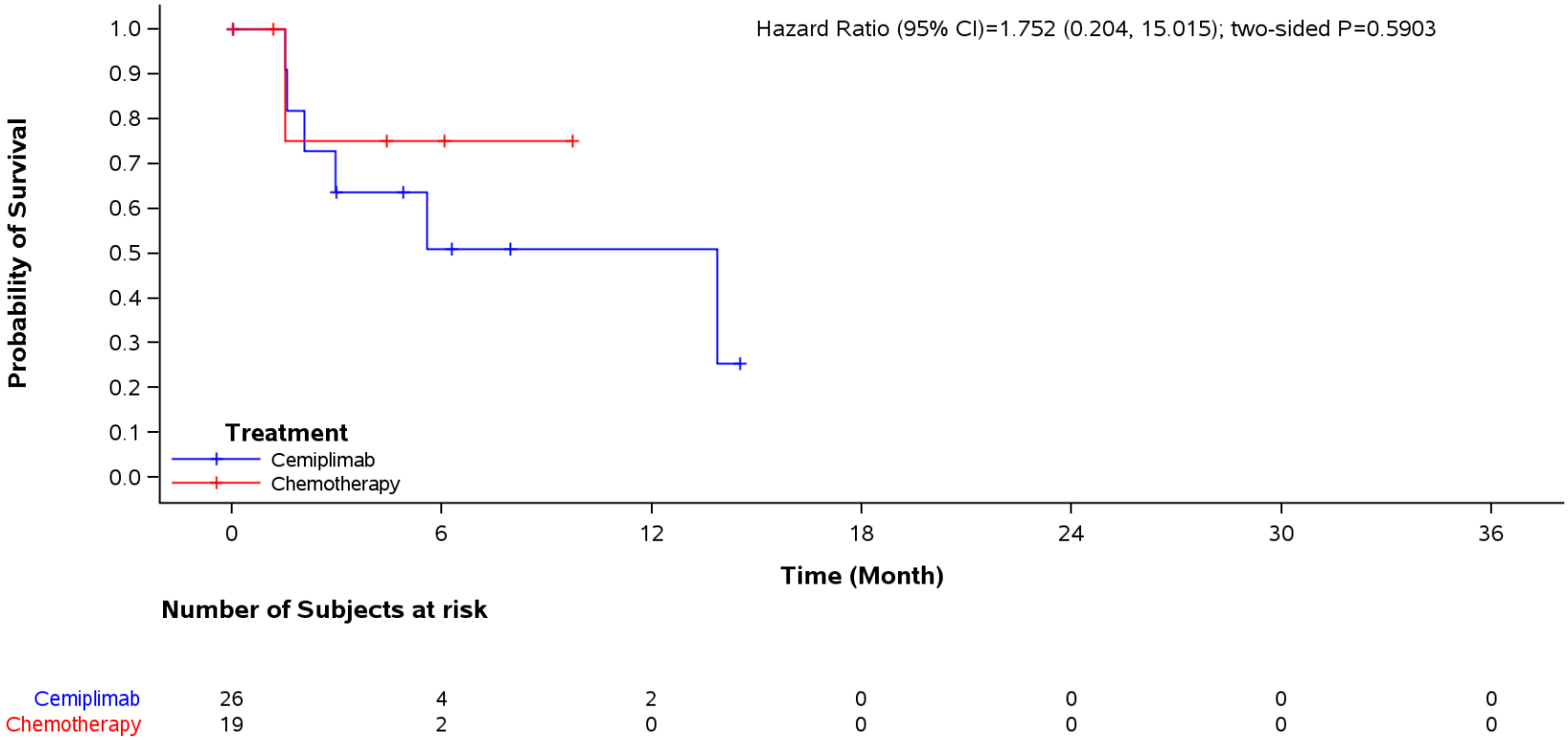
Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

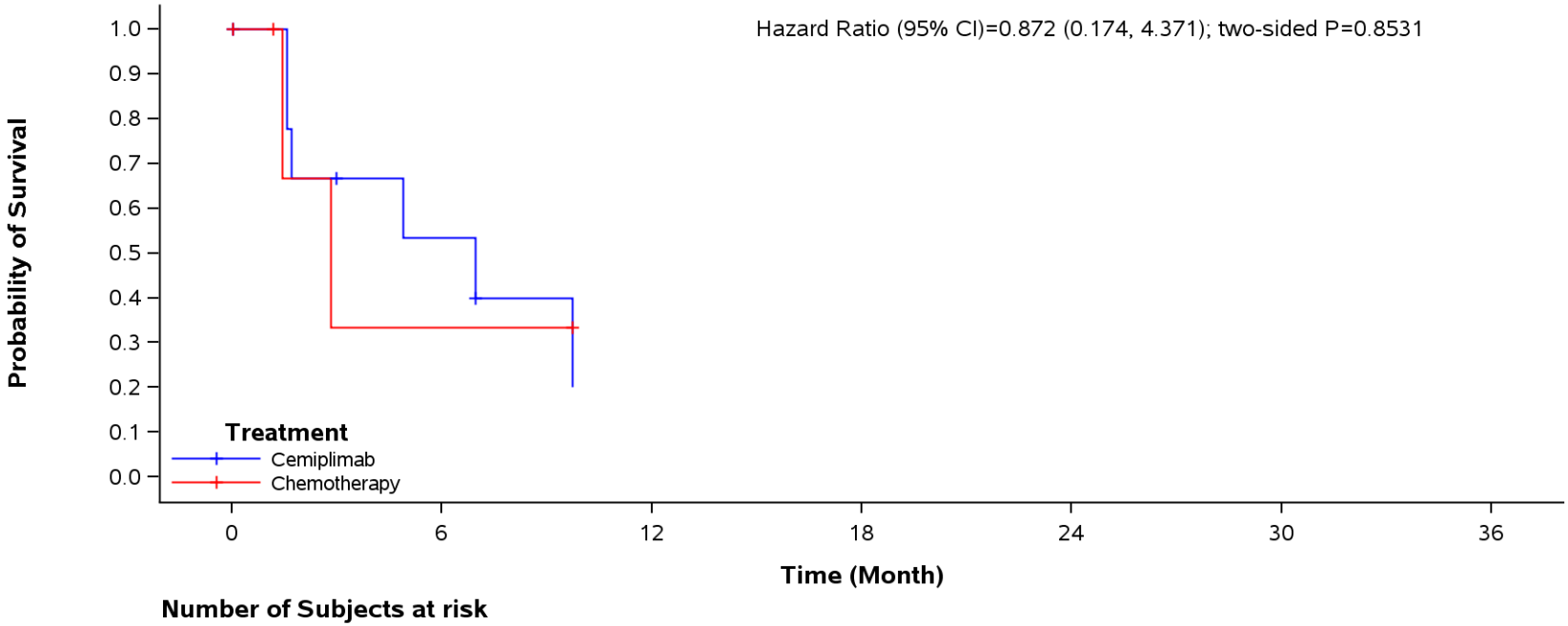
Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts sustained improvement



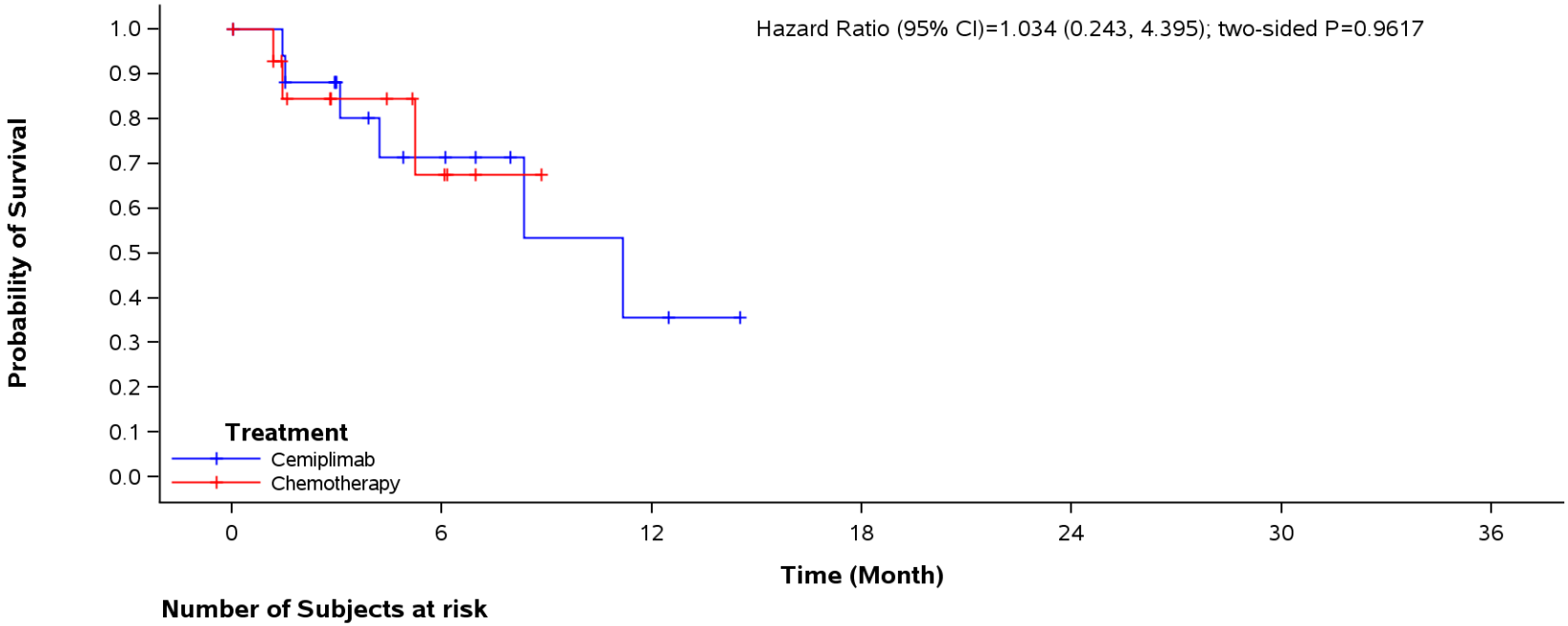

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts sustained improvement



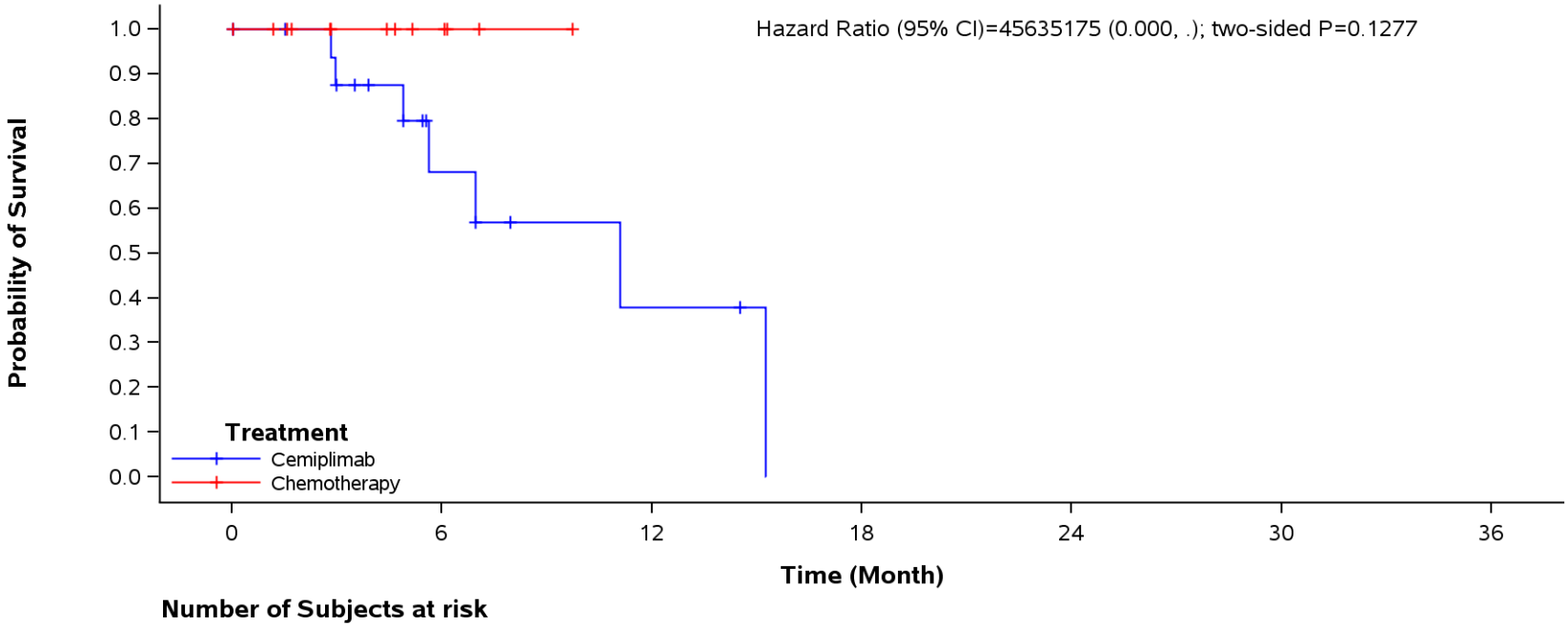

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 7 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts sustained improvement



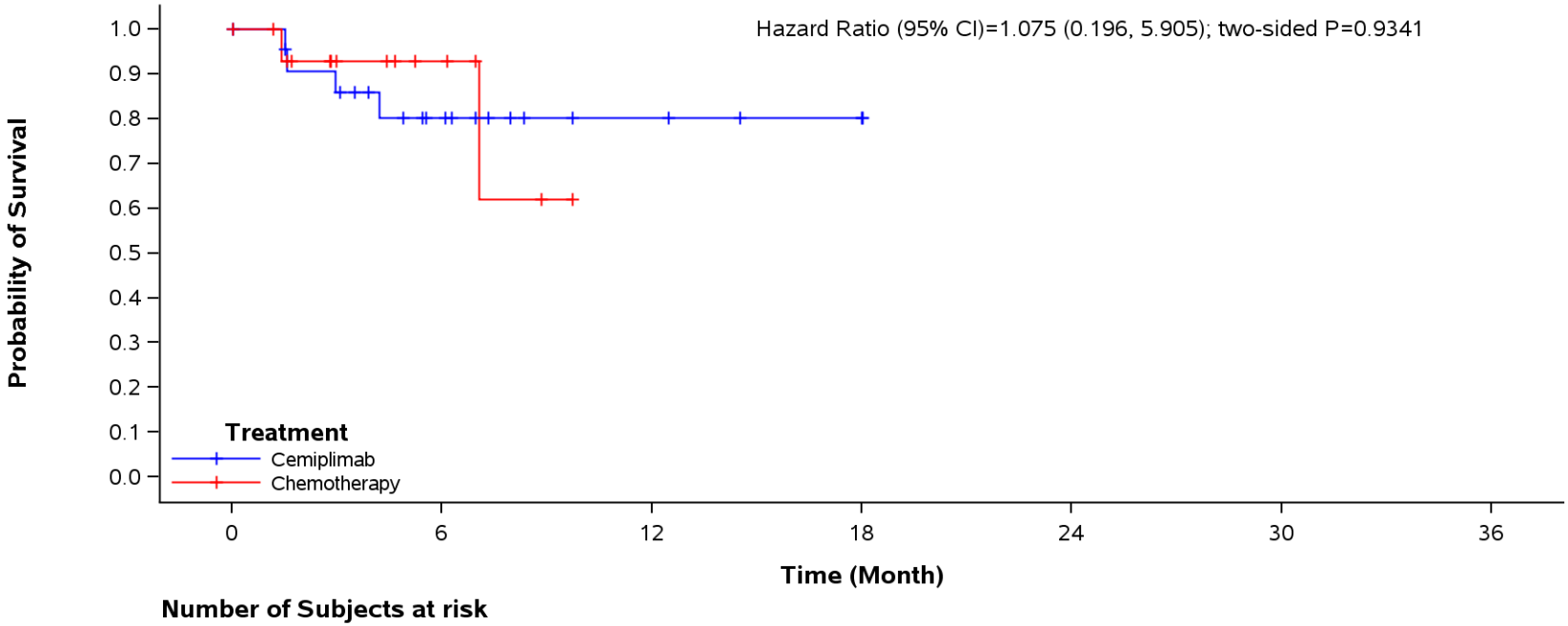

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts sustained improvement



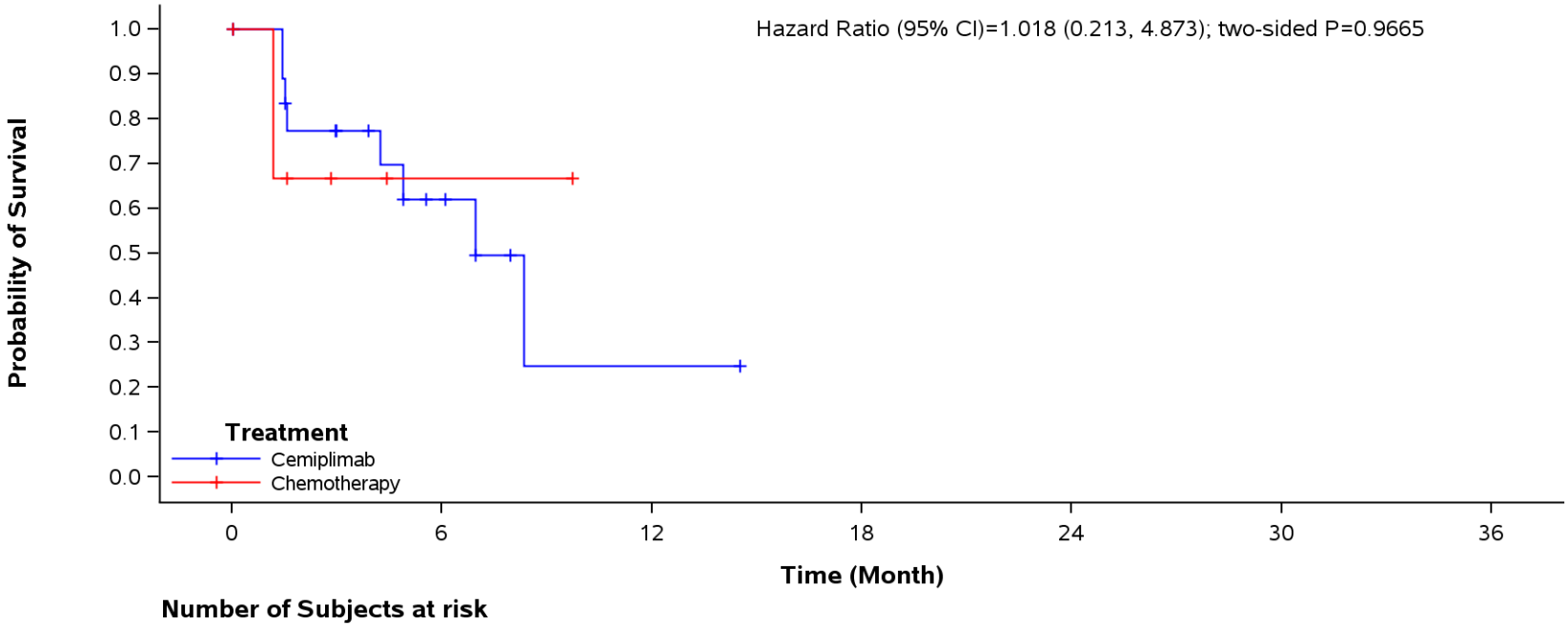

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts sustained improvement



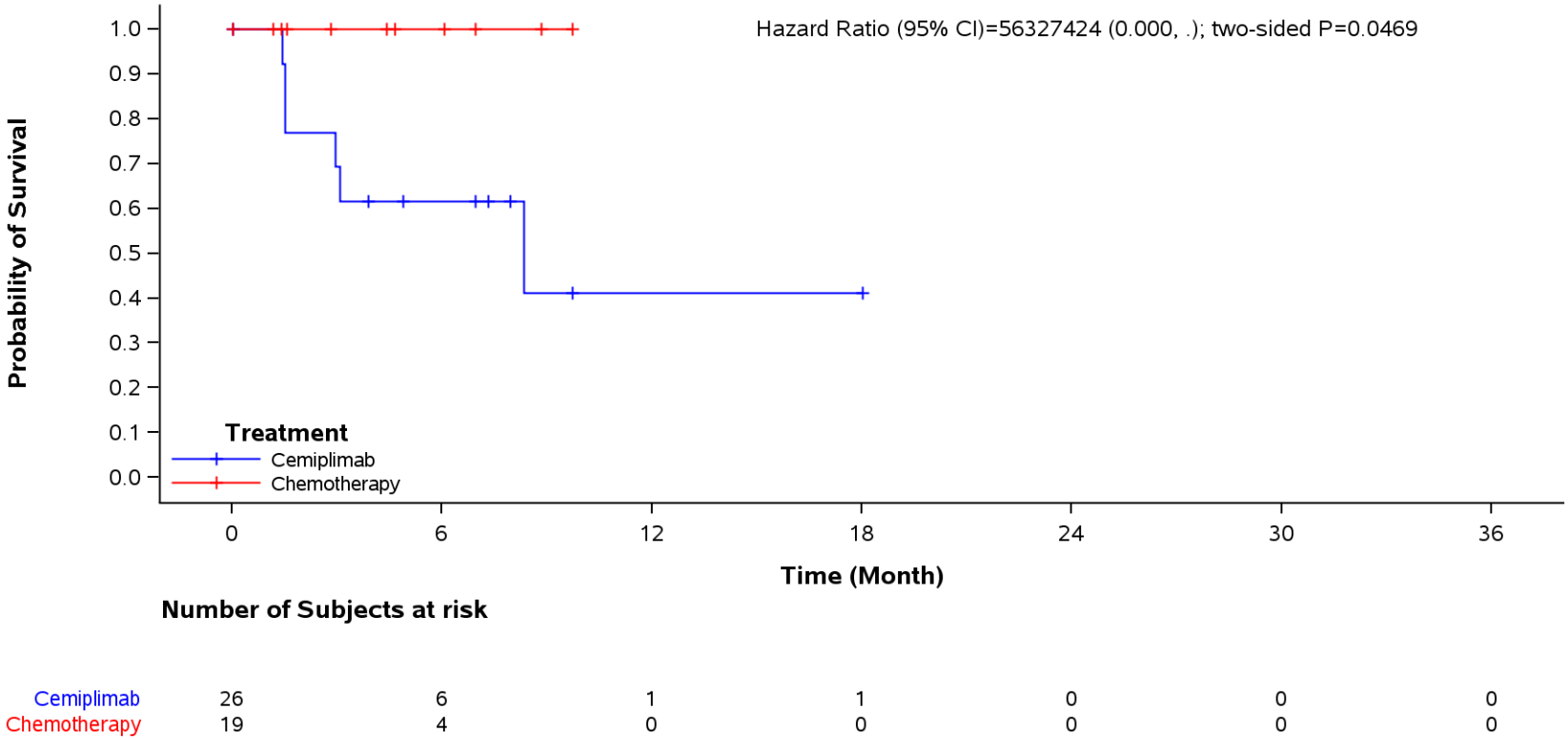

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

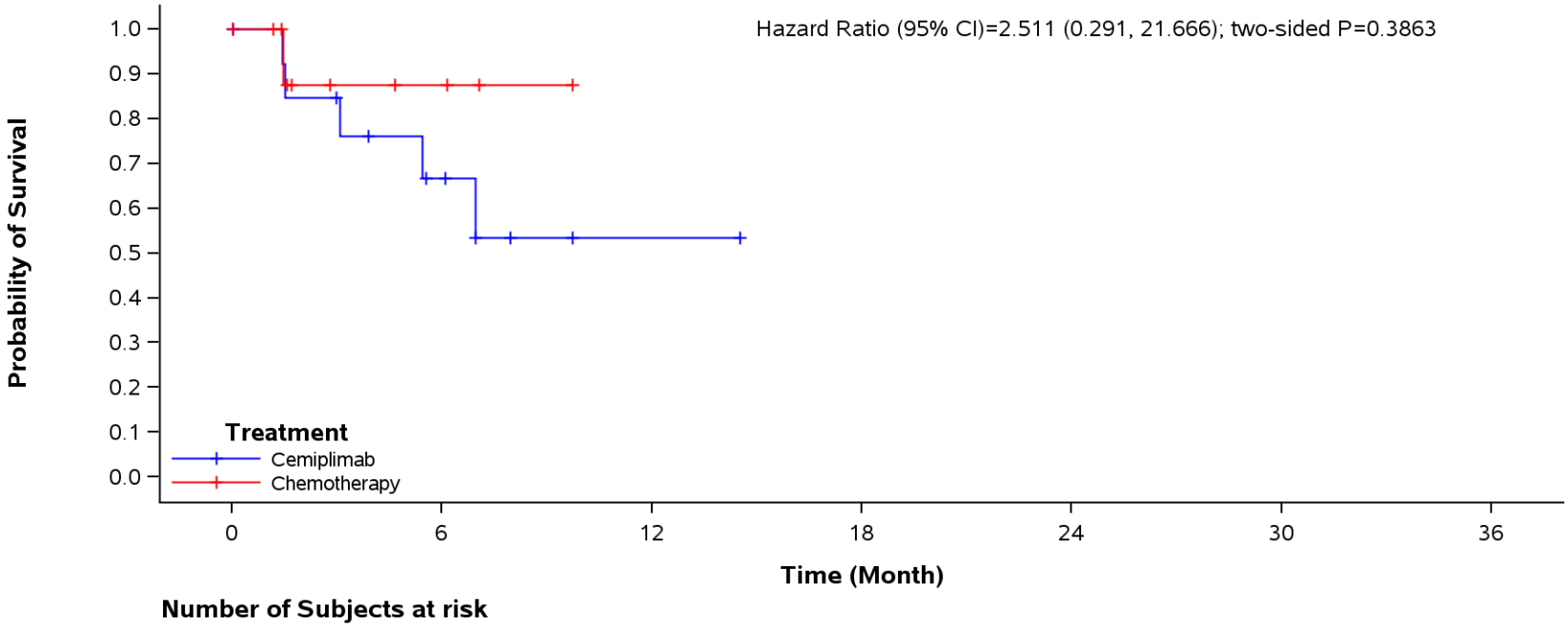
Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts sustained improvement



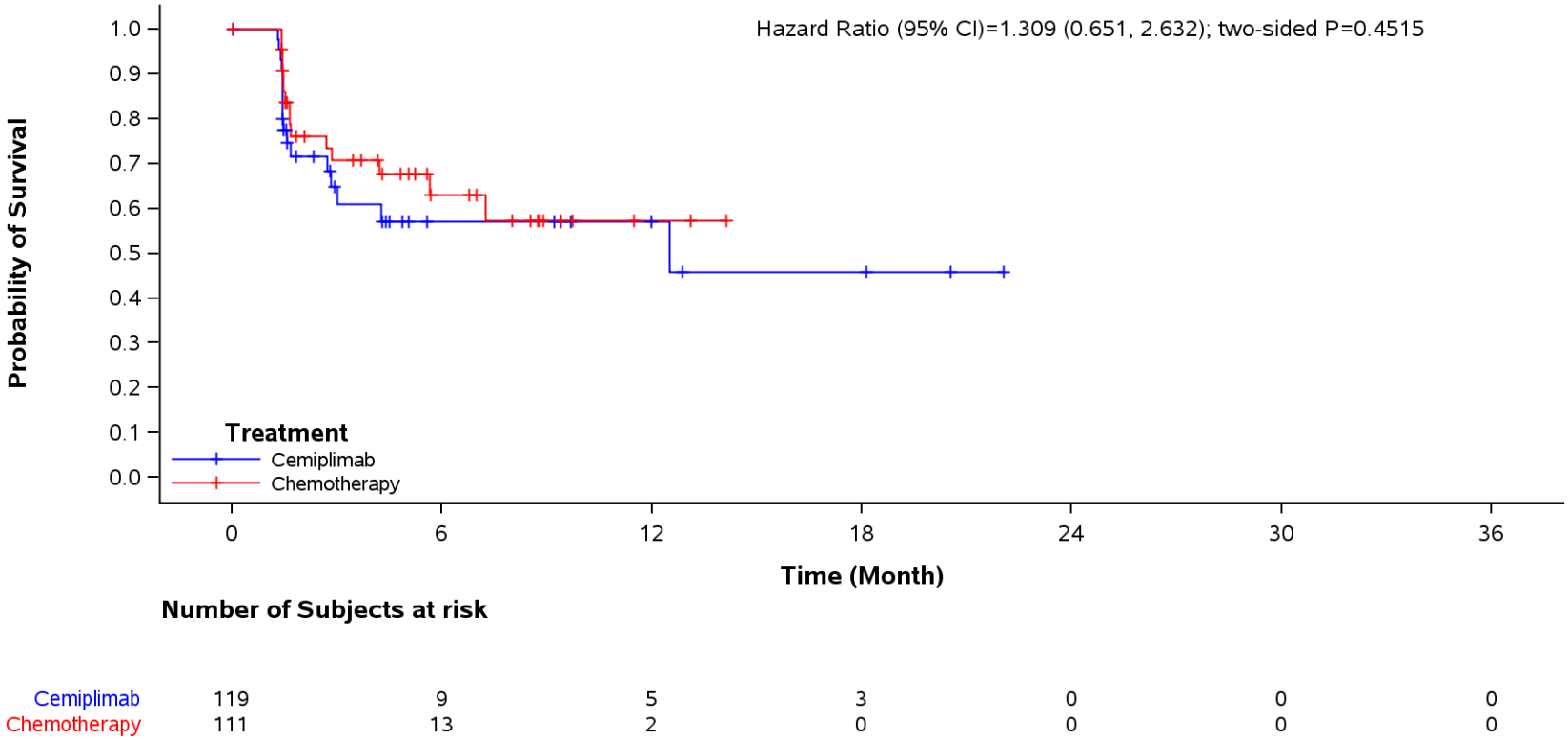

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts sustained improvement



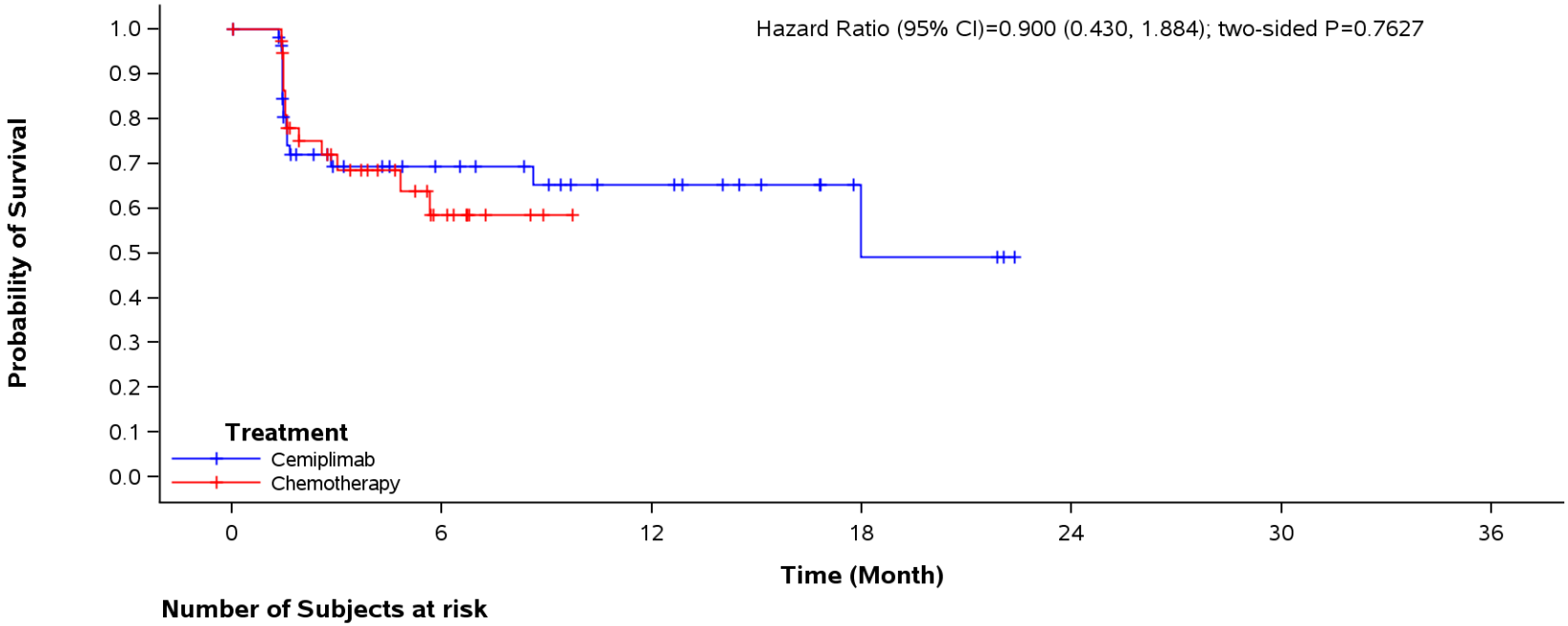

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 9 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 111 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts sustained improvement



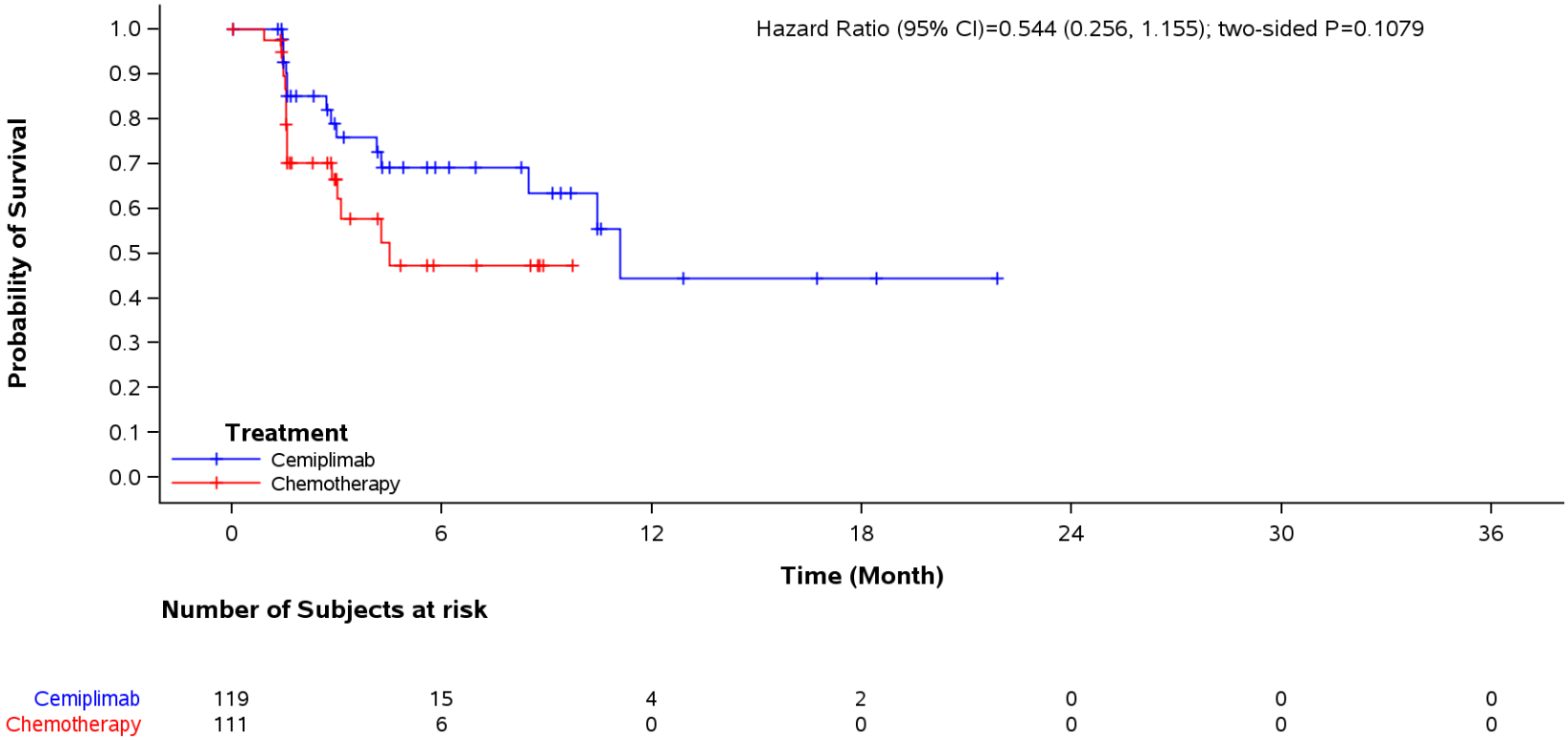

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 20 | 12 | 3 | 0 | 0 | 0 |
| Chemotherapy | 111 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts sustained improvement



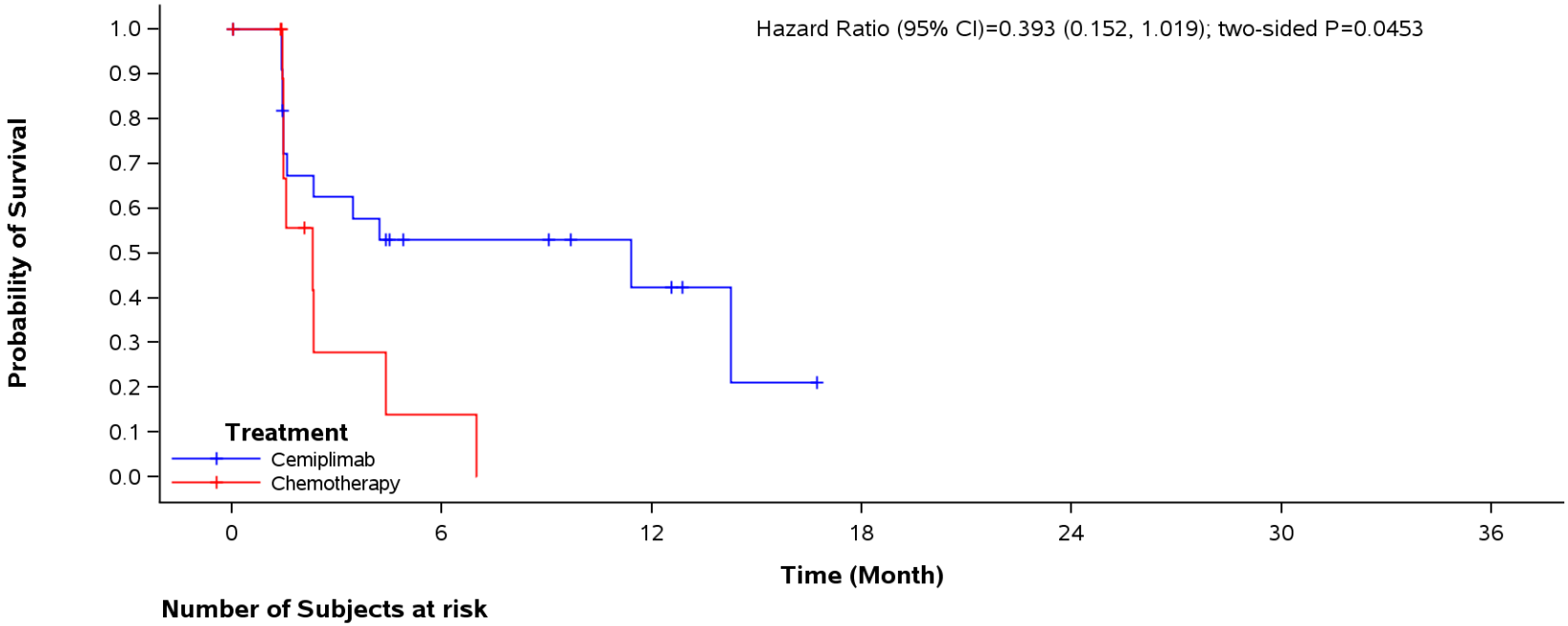

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 15 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 111 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts sustained improvement



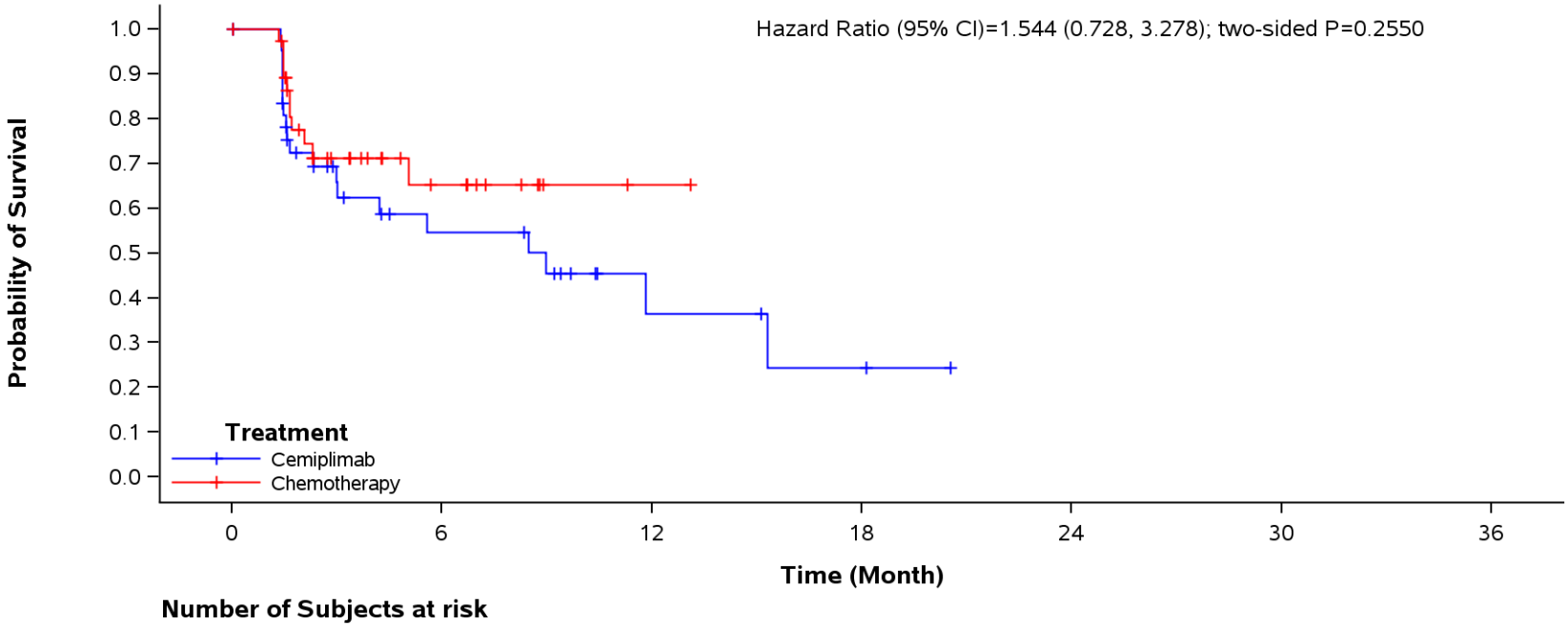

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 8 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 111 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts sustained improvement



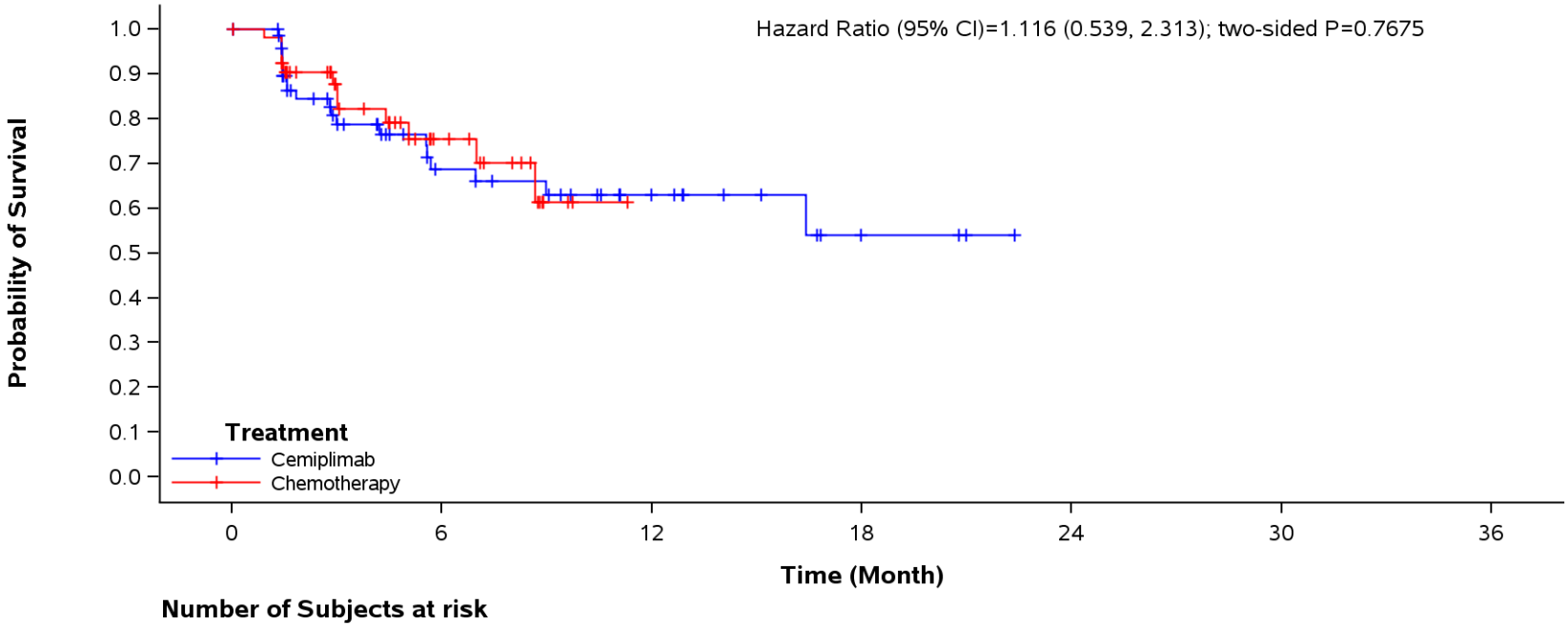

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 13 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 111 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts sustained improvement



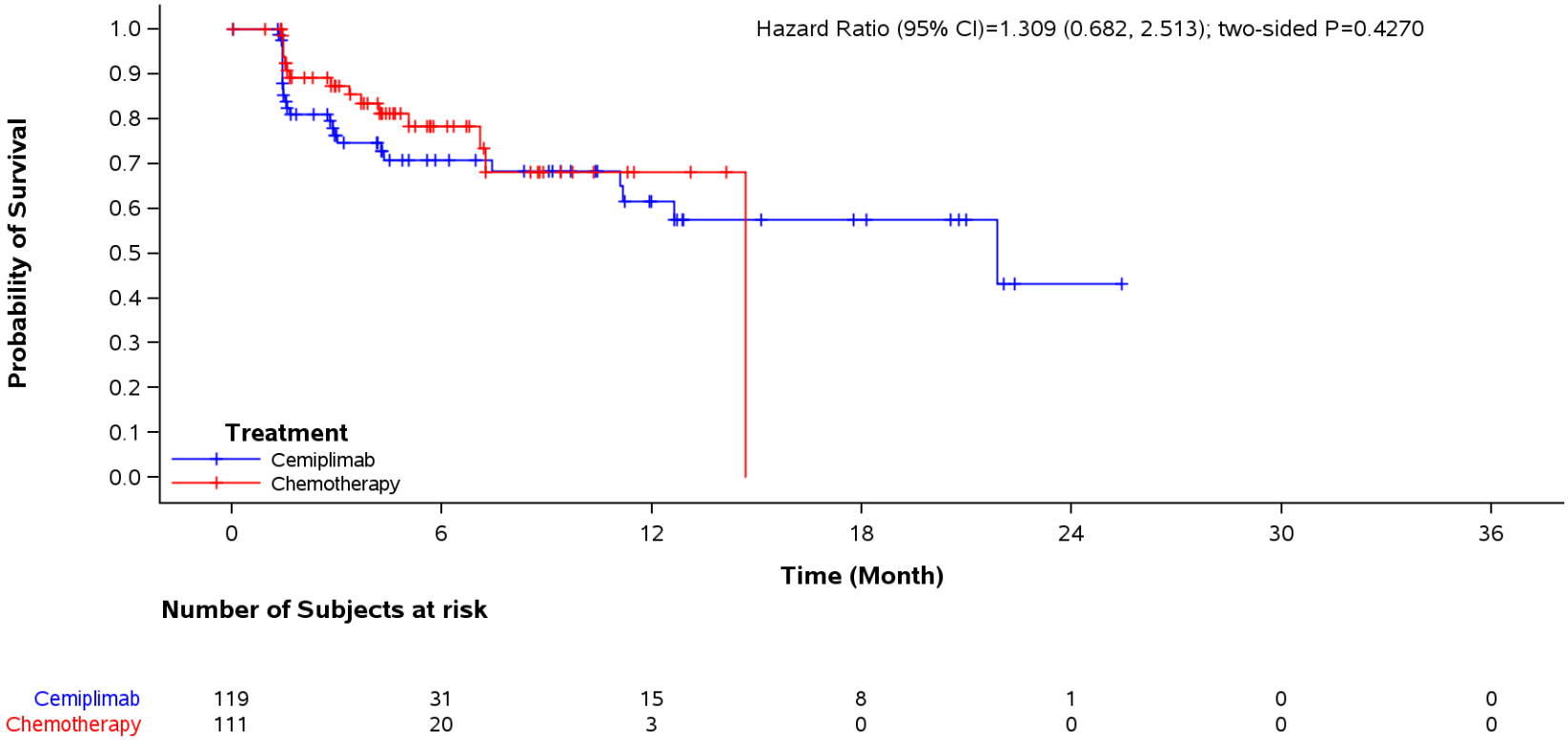

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 25 | 12 | 3 | 0 | 0 | 0 |
| Chemotherapy | 111 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts sustained improvement



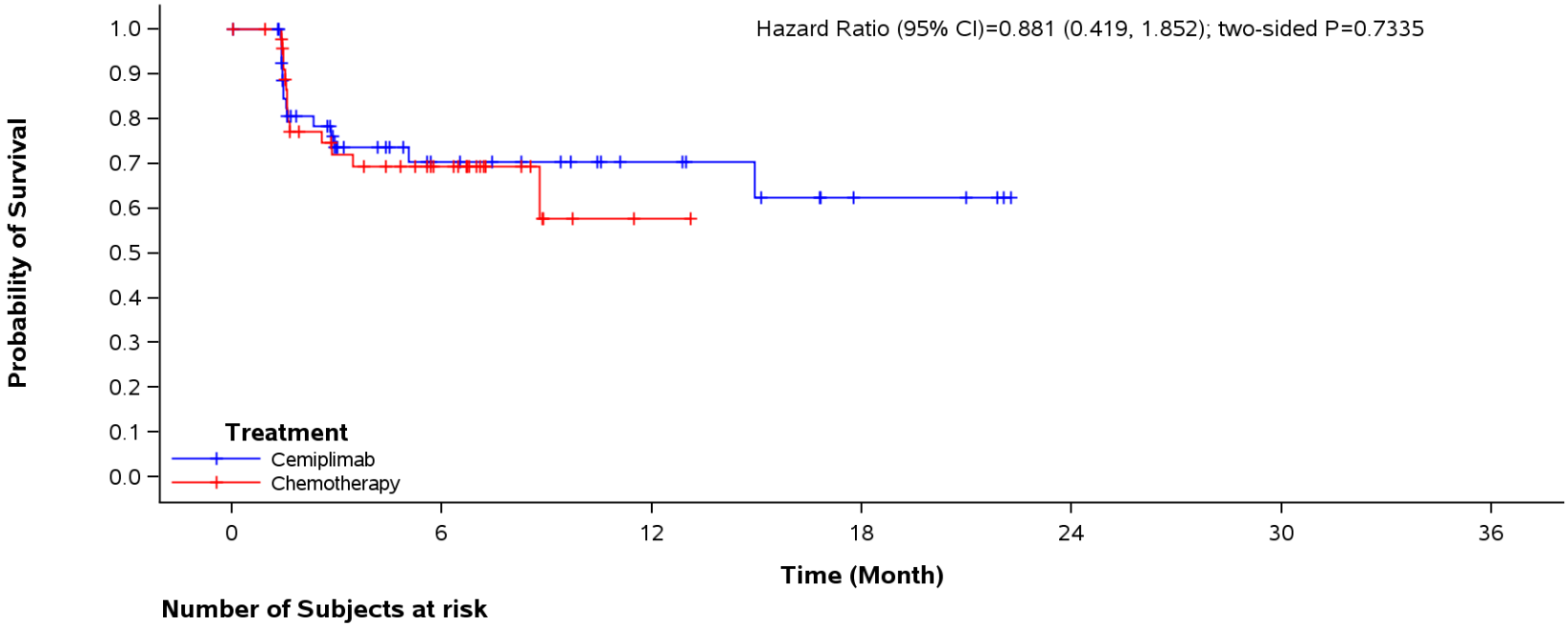

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 31 | 15 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts sustained improvement



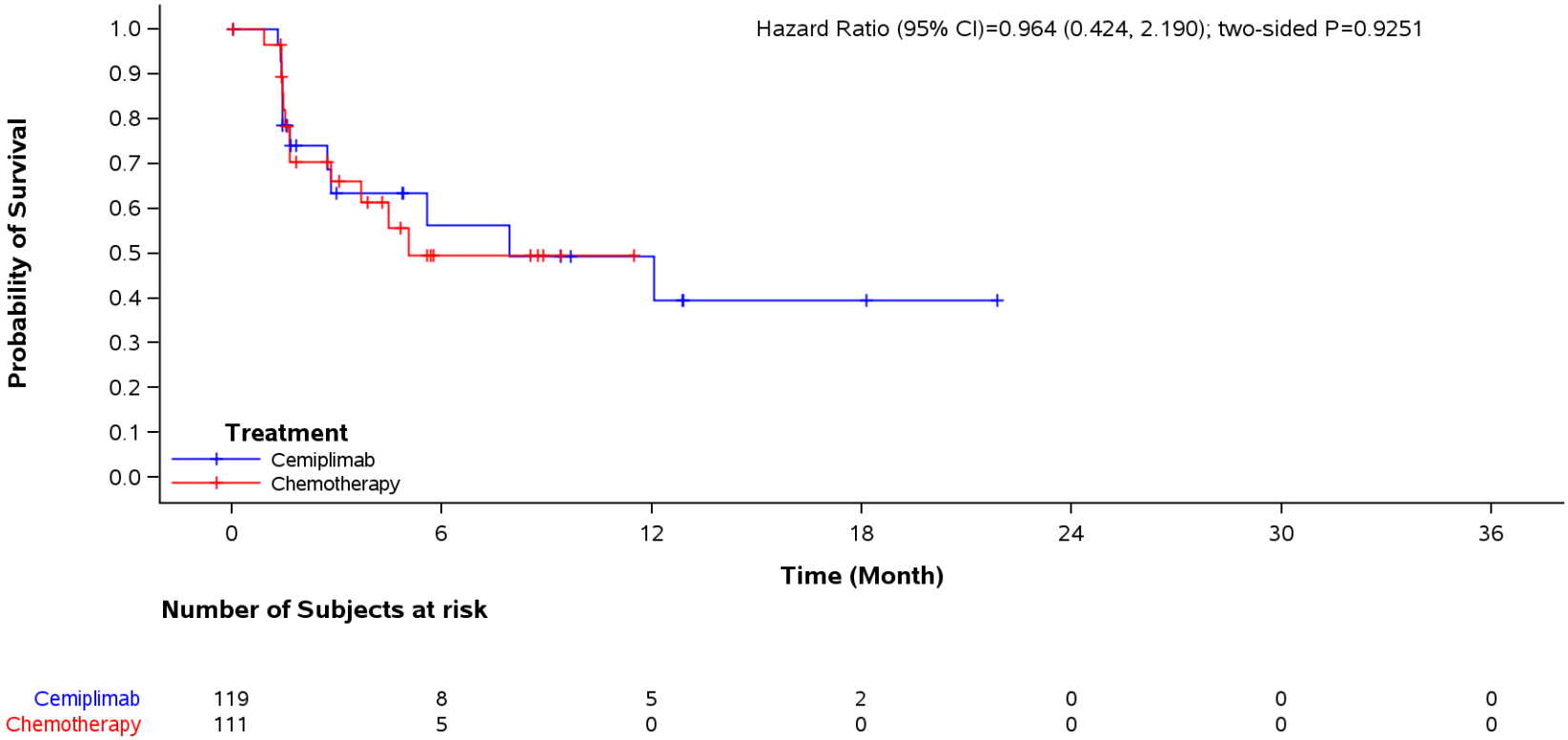

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 19 | 11 | 4 | 0 | 0 | 0 |
| Chemotherapy | 111 | 17 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

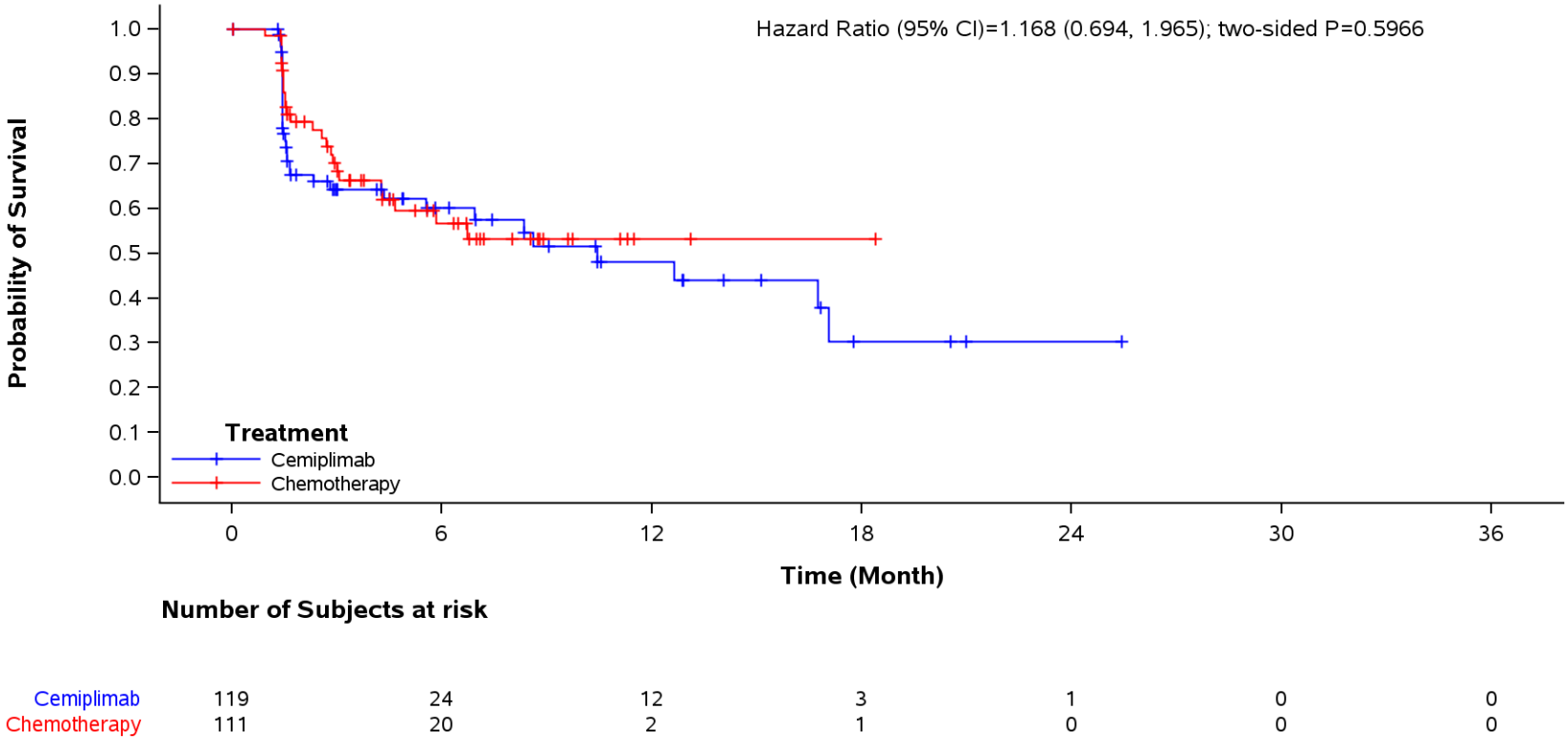
Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts sustained improvement



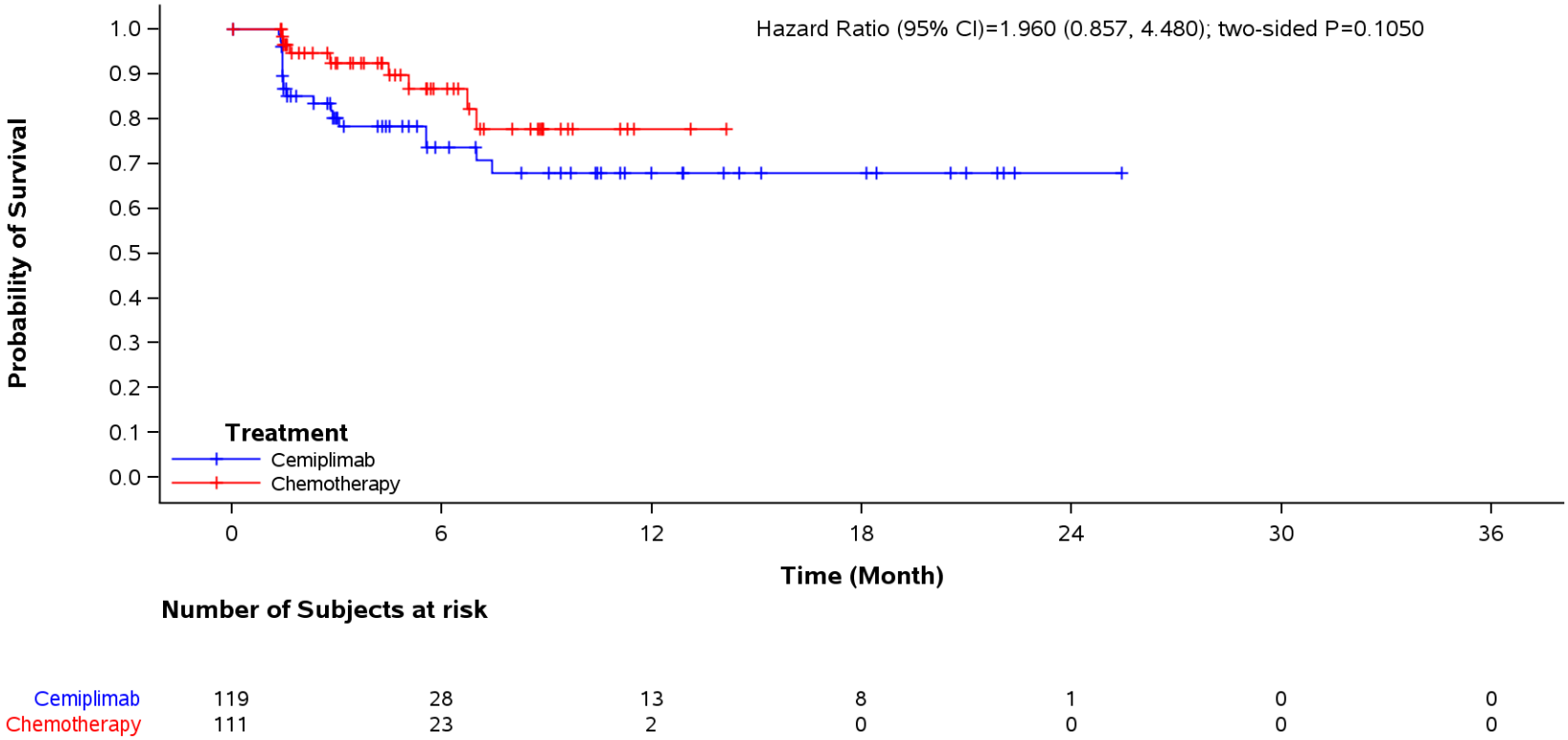

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 24 | 12 | 3 | 1 | 0 | 0 |
| Chemotherapy | 111 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts sustained improvement



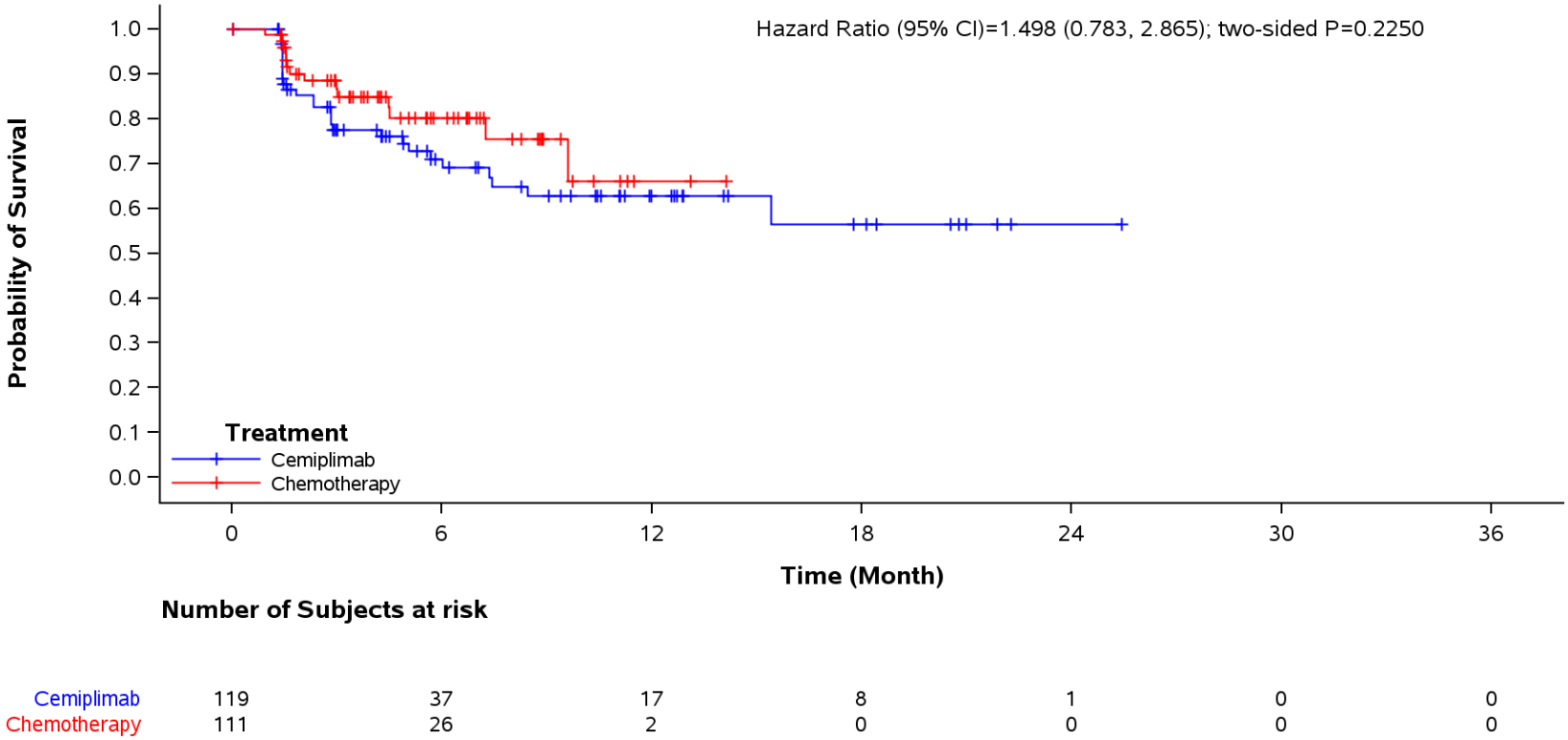

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 28 | 13 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 23 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts sustained improvement



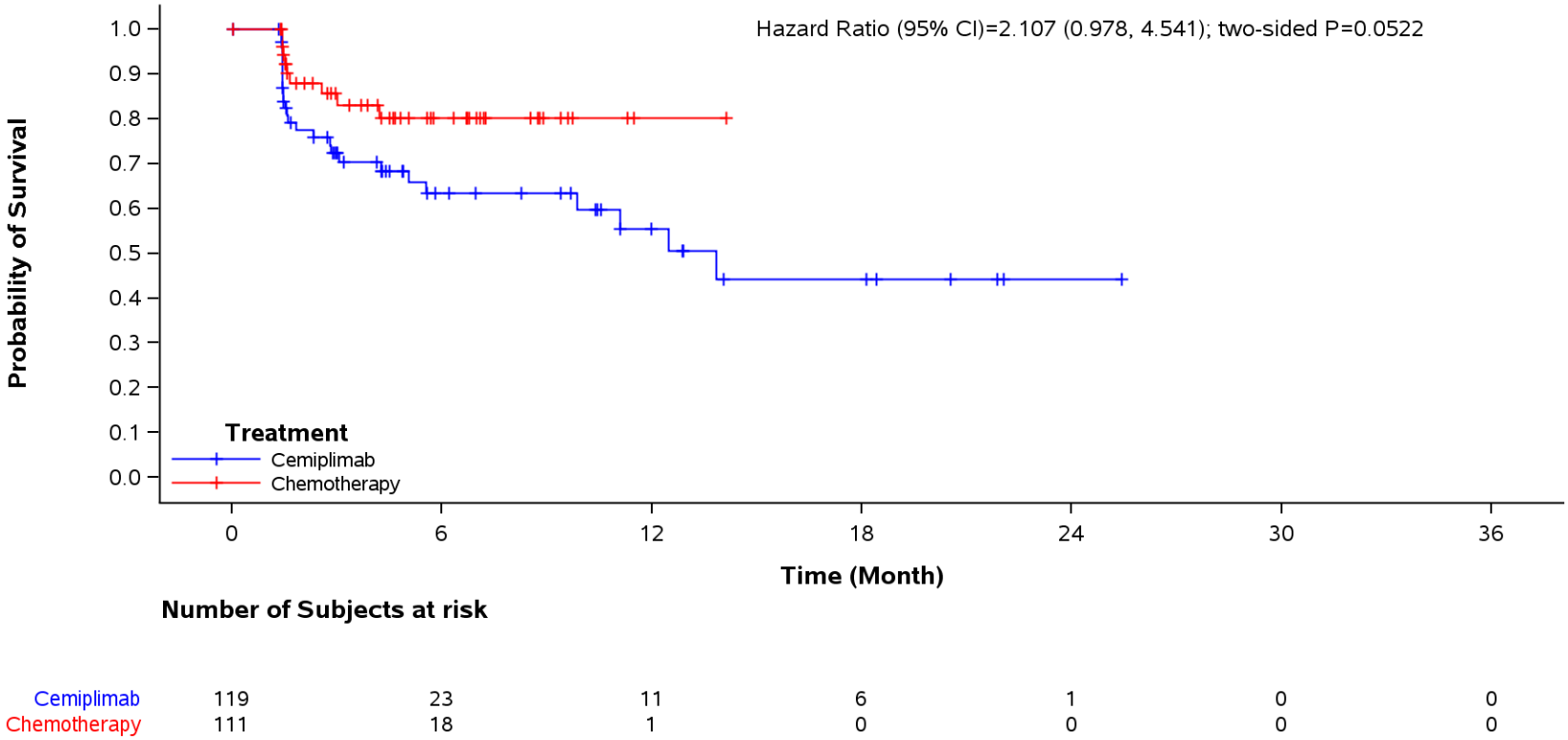

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 37 | 17 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts sustained improvement



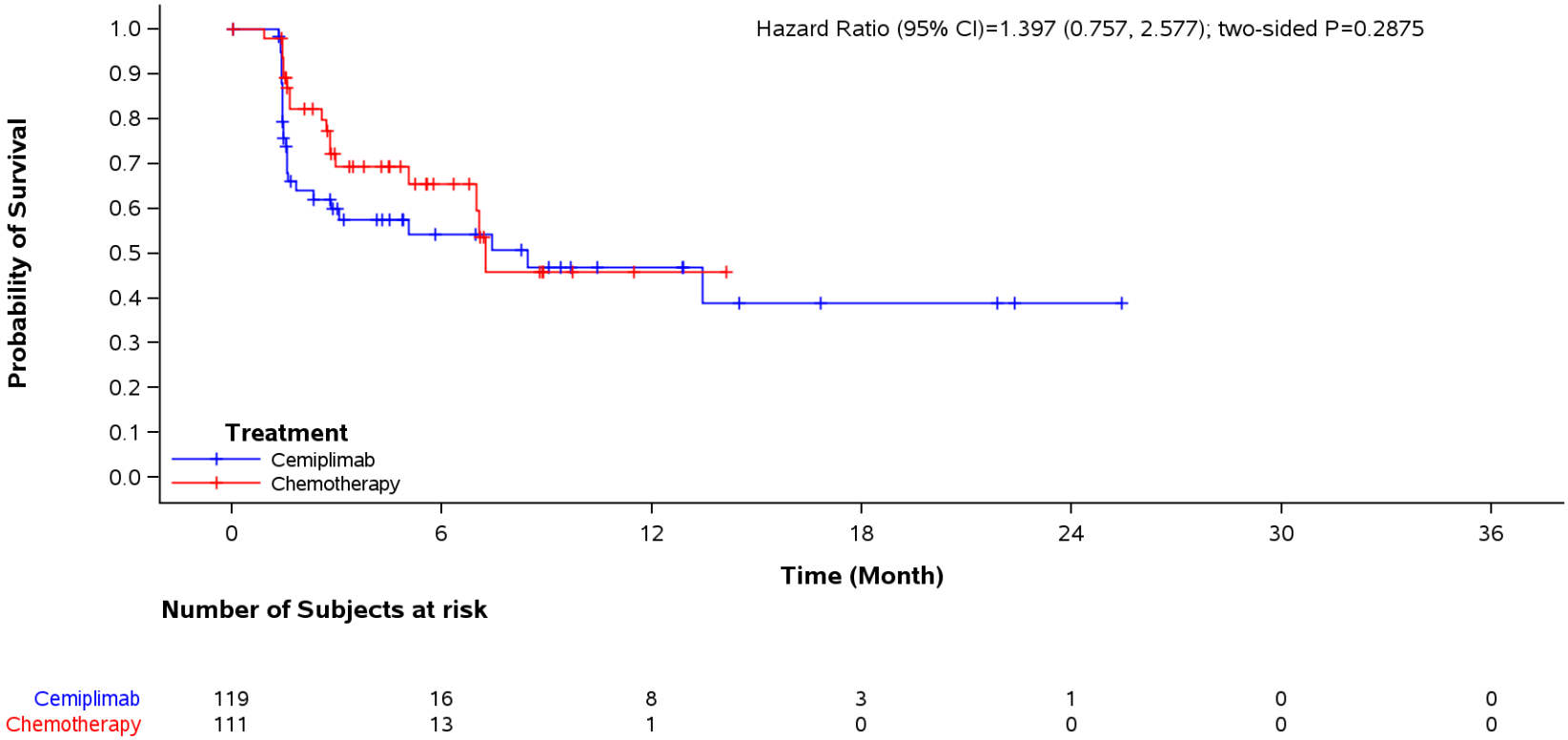

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 23 | 11 | 6 | 1 | 0 | 0 |
| Chemotherapy | 111 | 18 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts sustained improvement



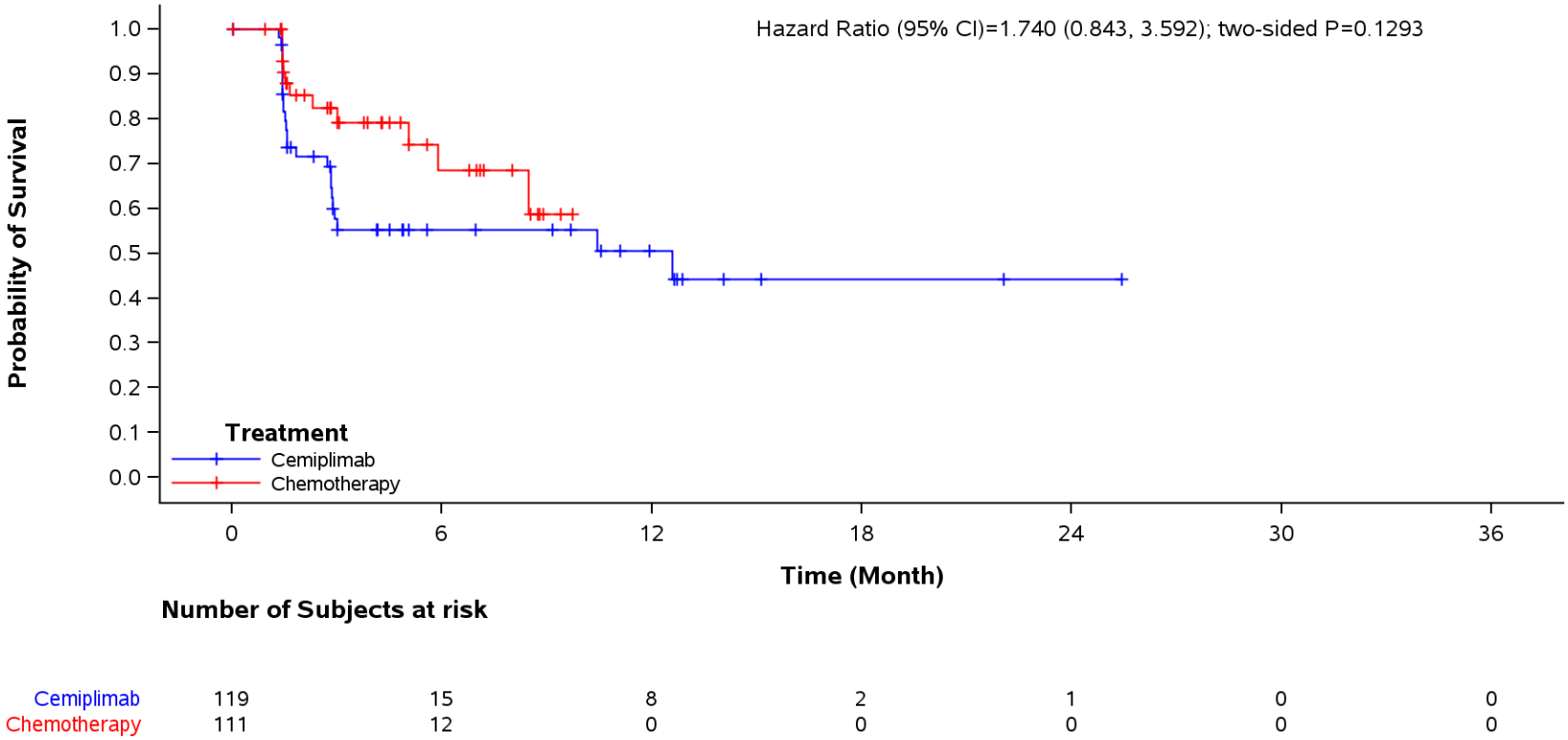

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 16 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 111 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts sustained improvement



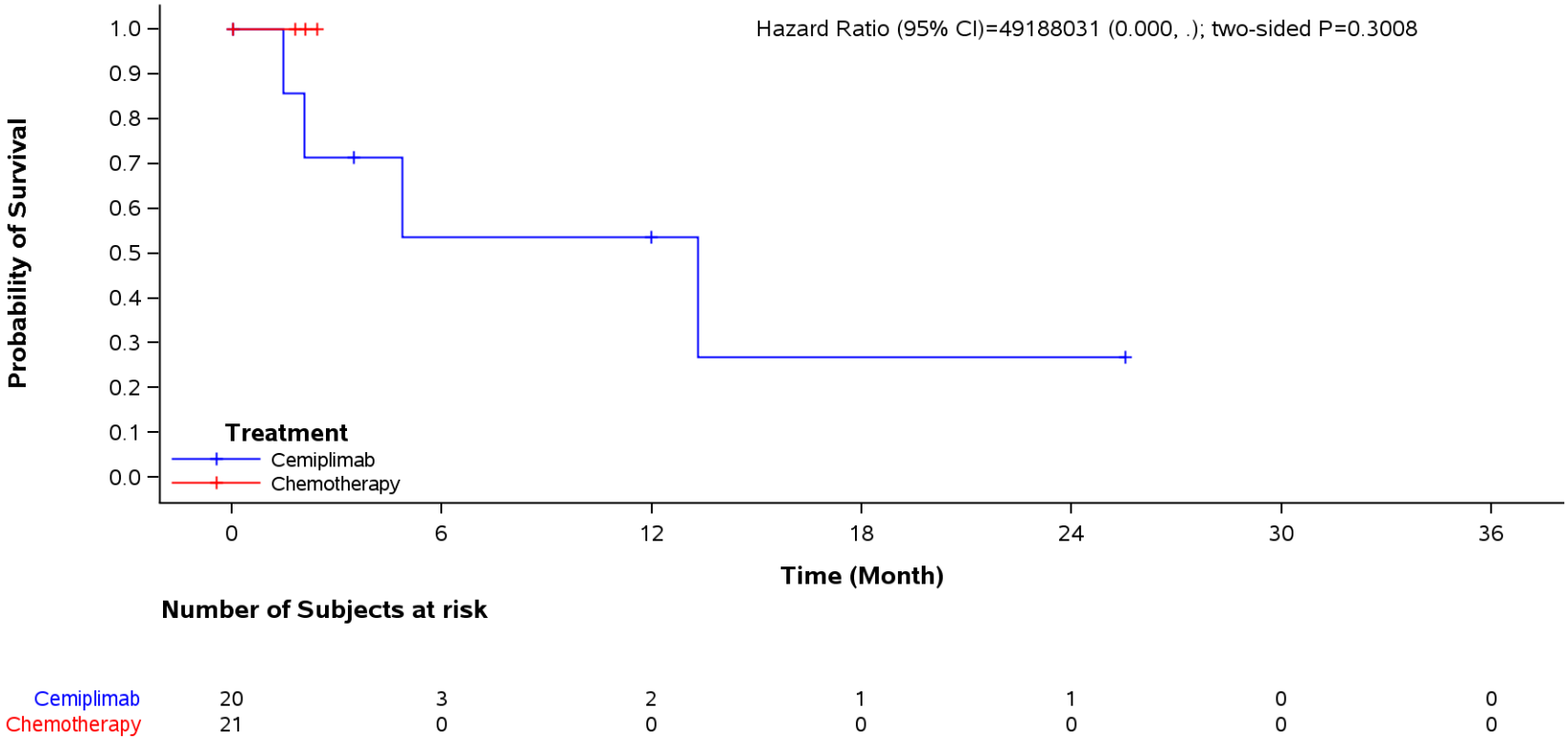

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 15 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 111 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

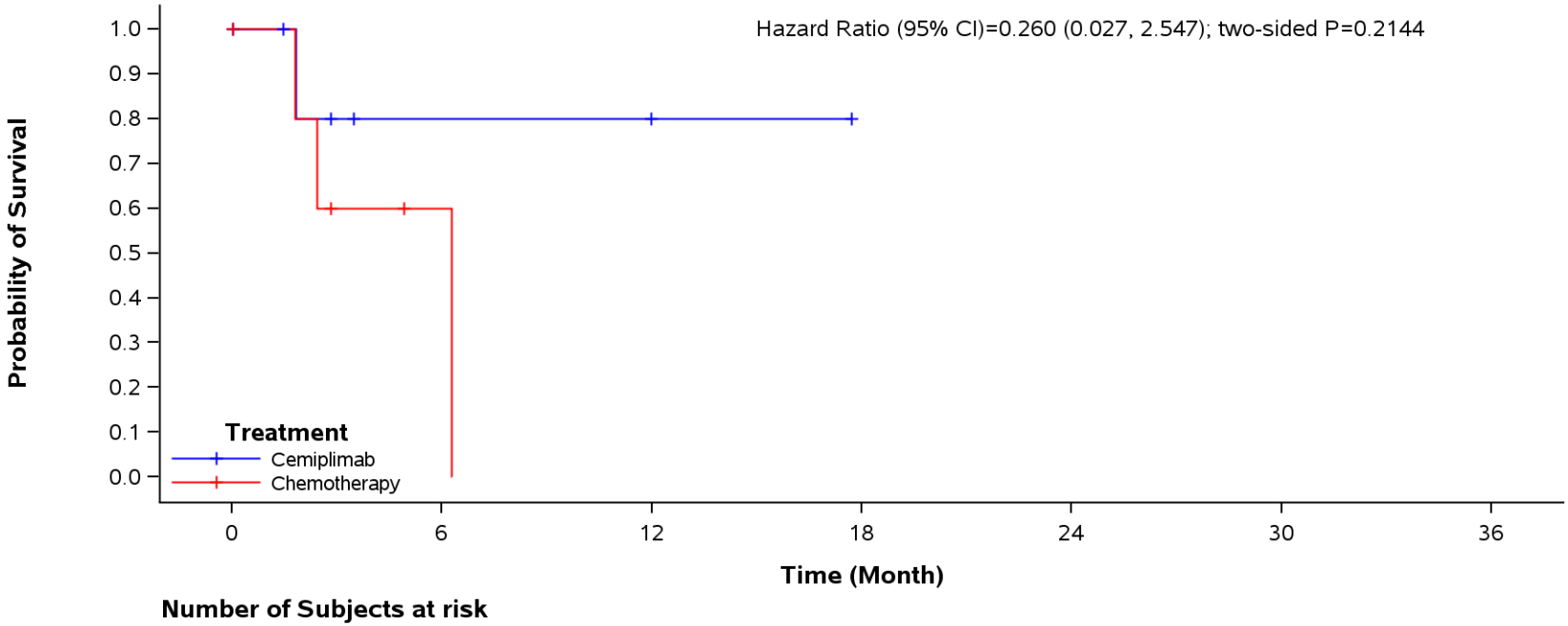
Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts sustained improvement



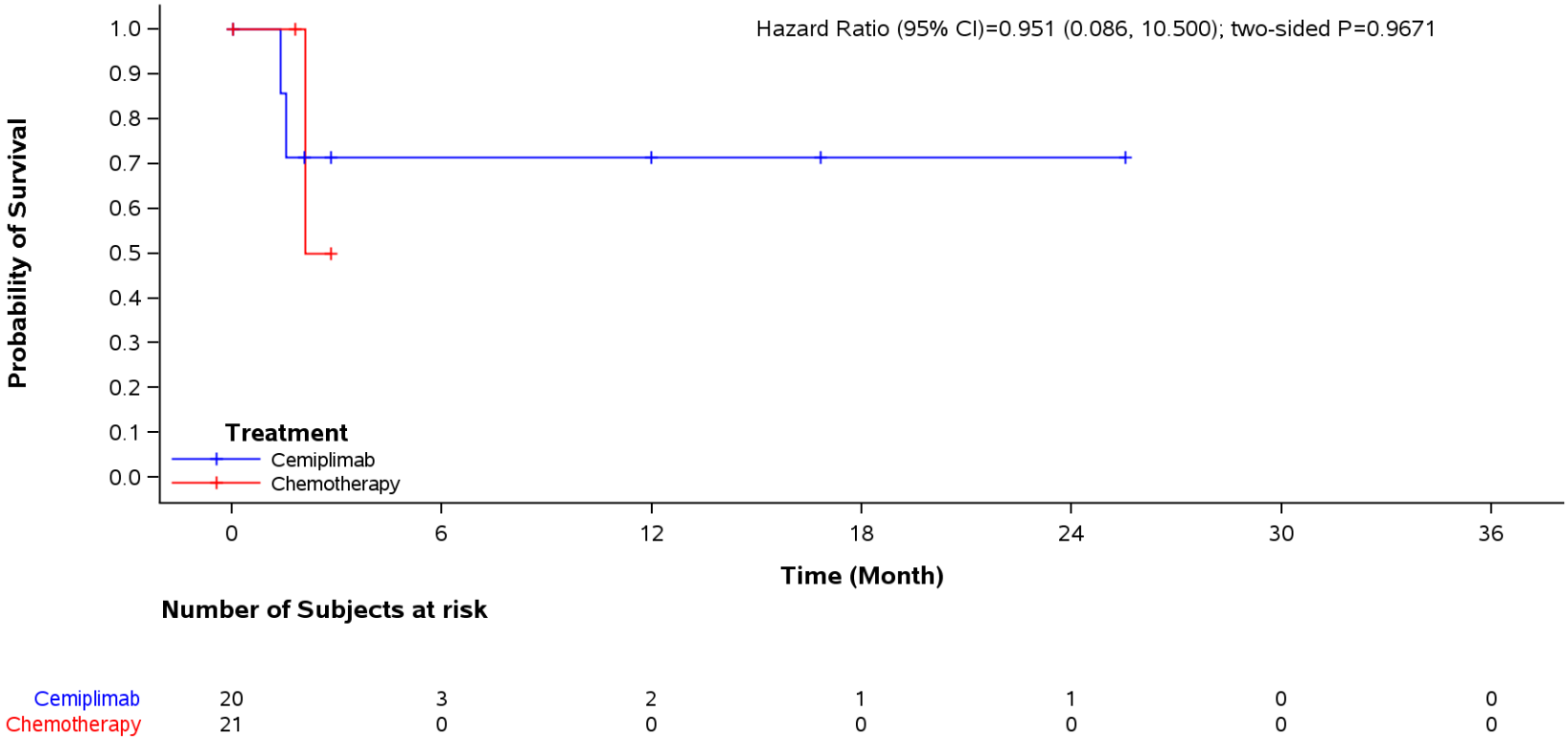

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts sustained improvement



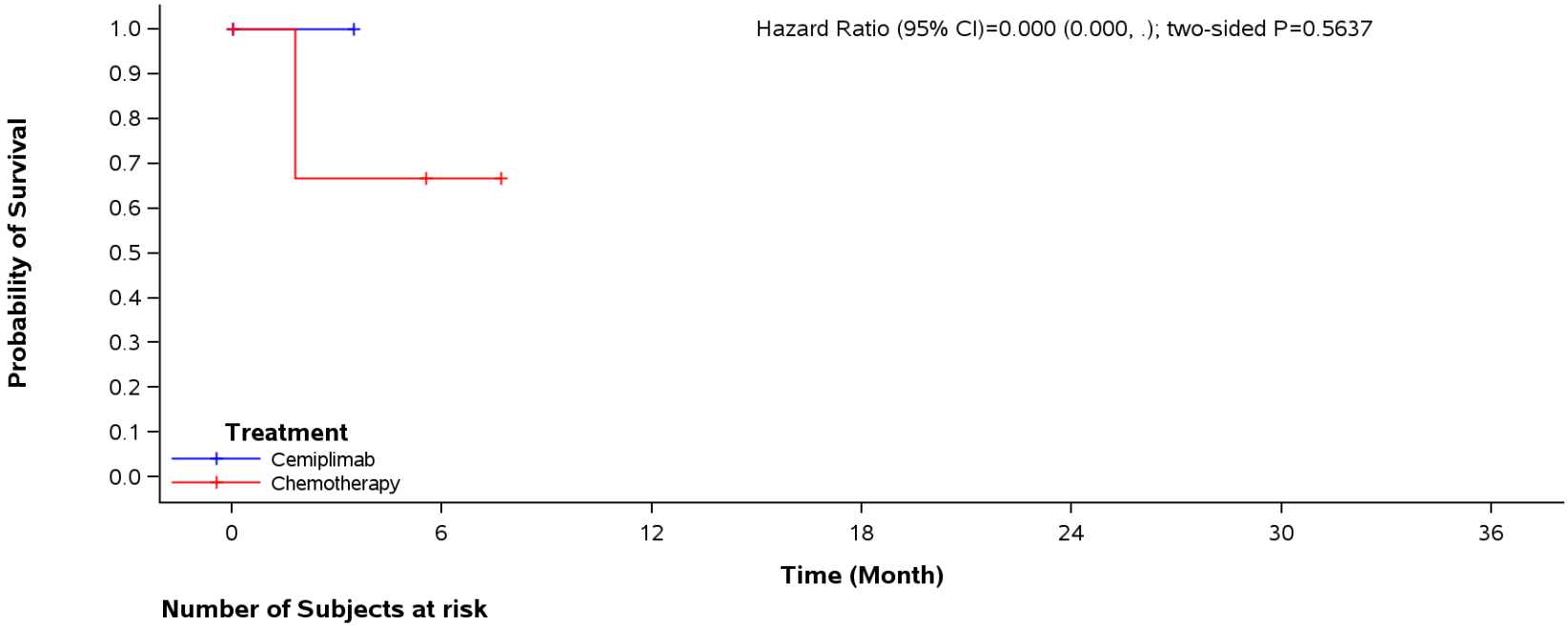

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts sustained improvement



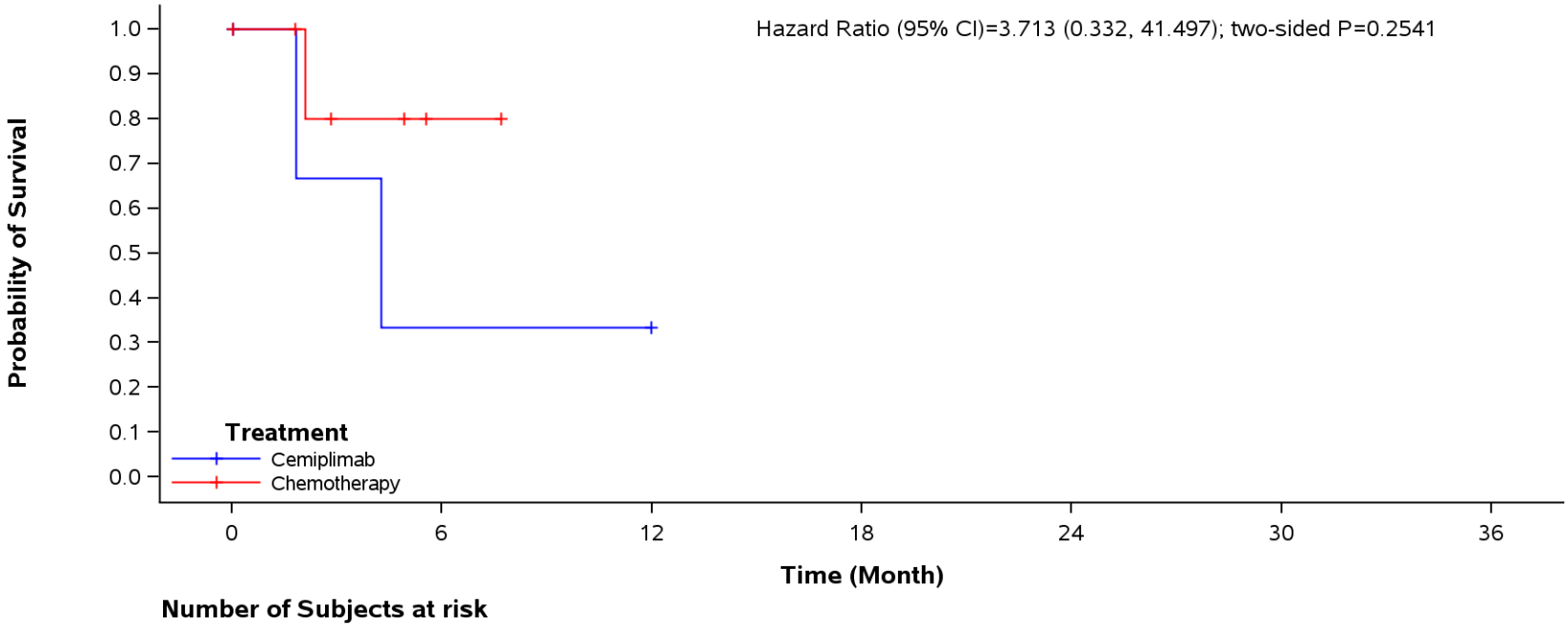

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts sustained improvement



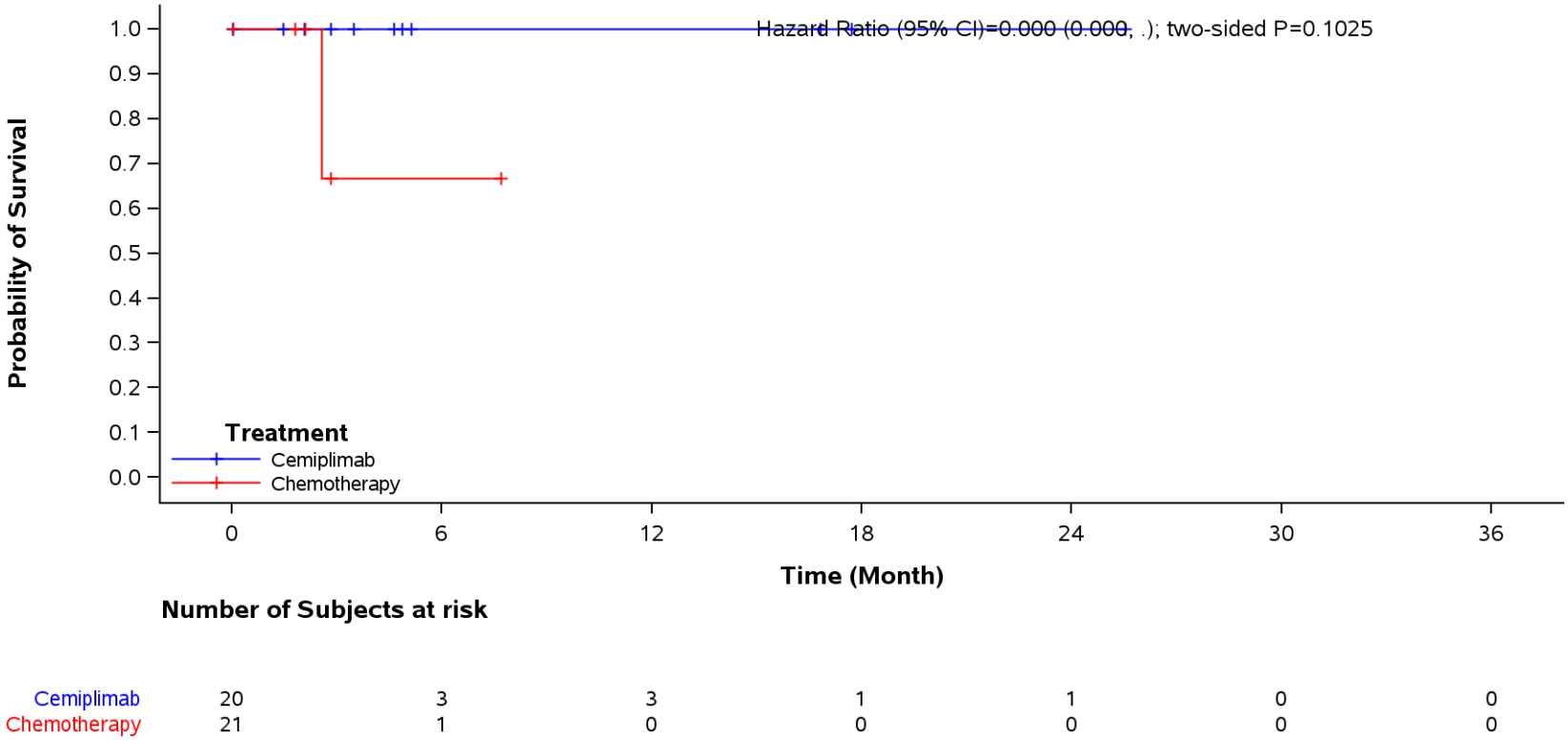

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

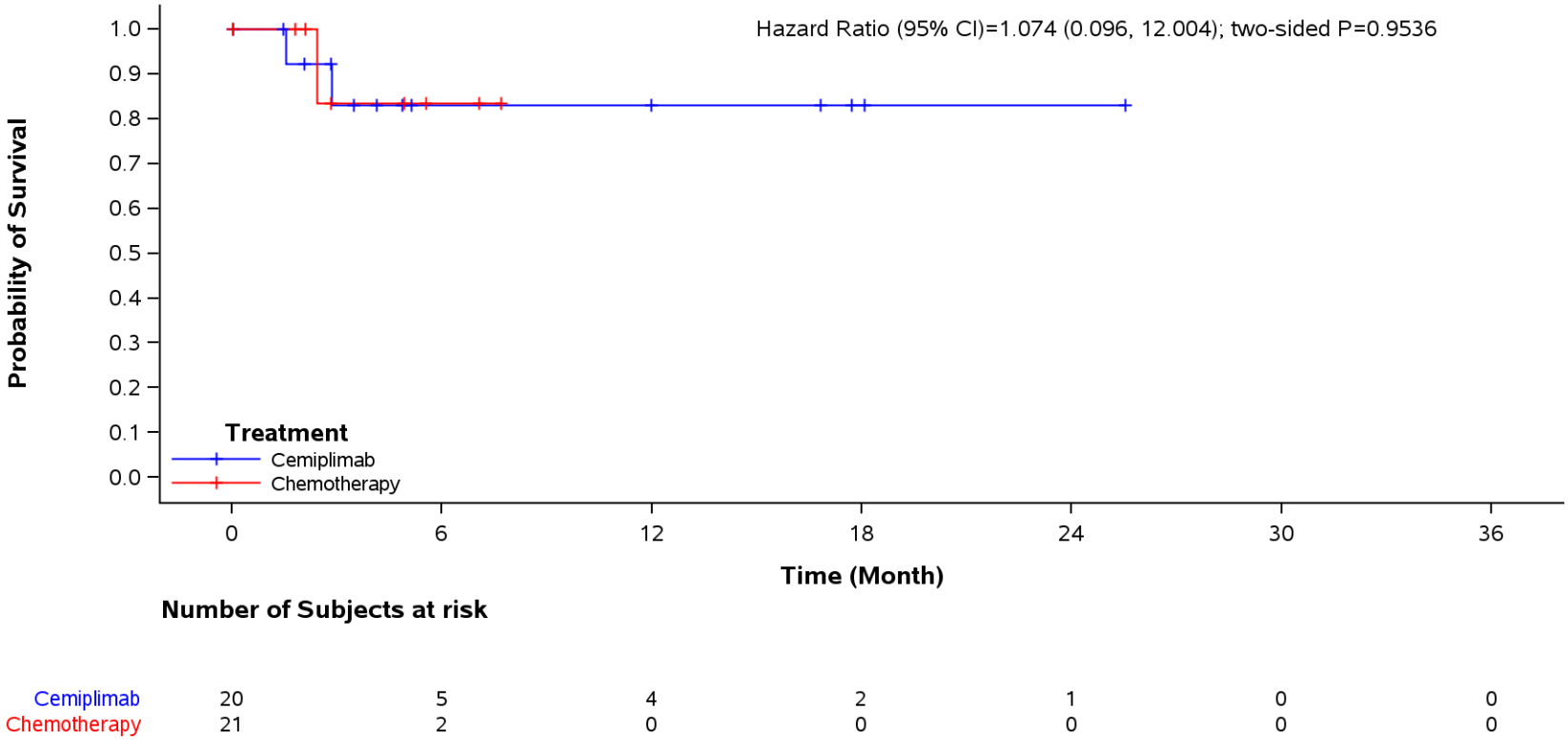
Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts sustained improvement



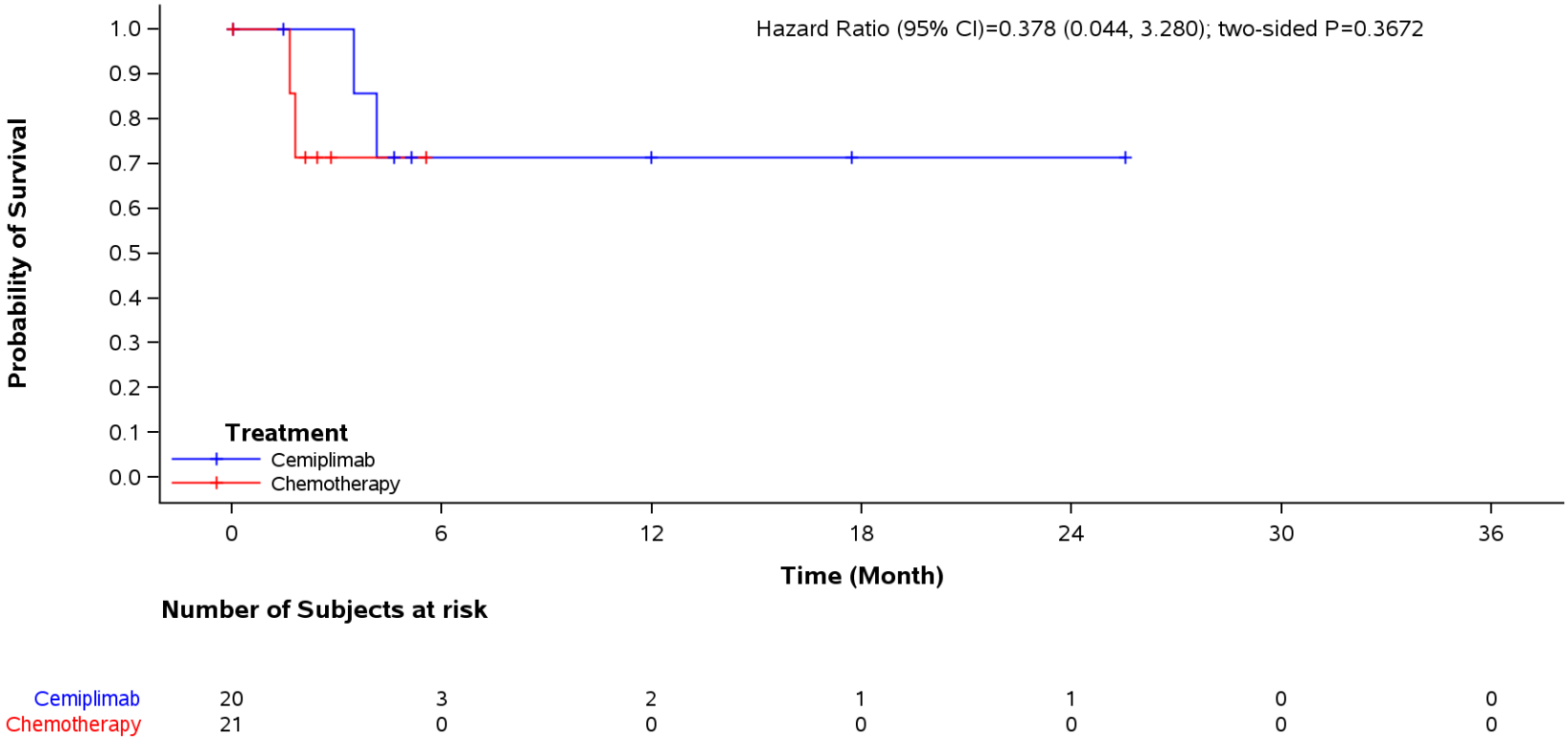

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

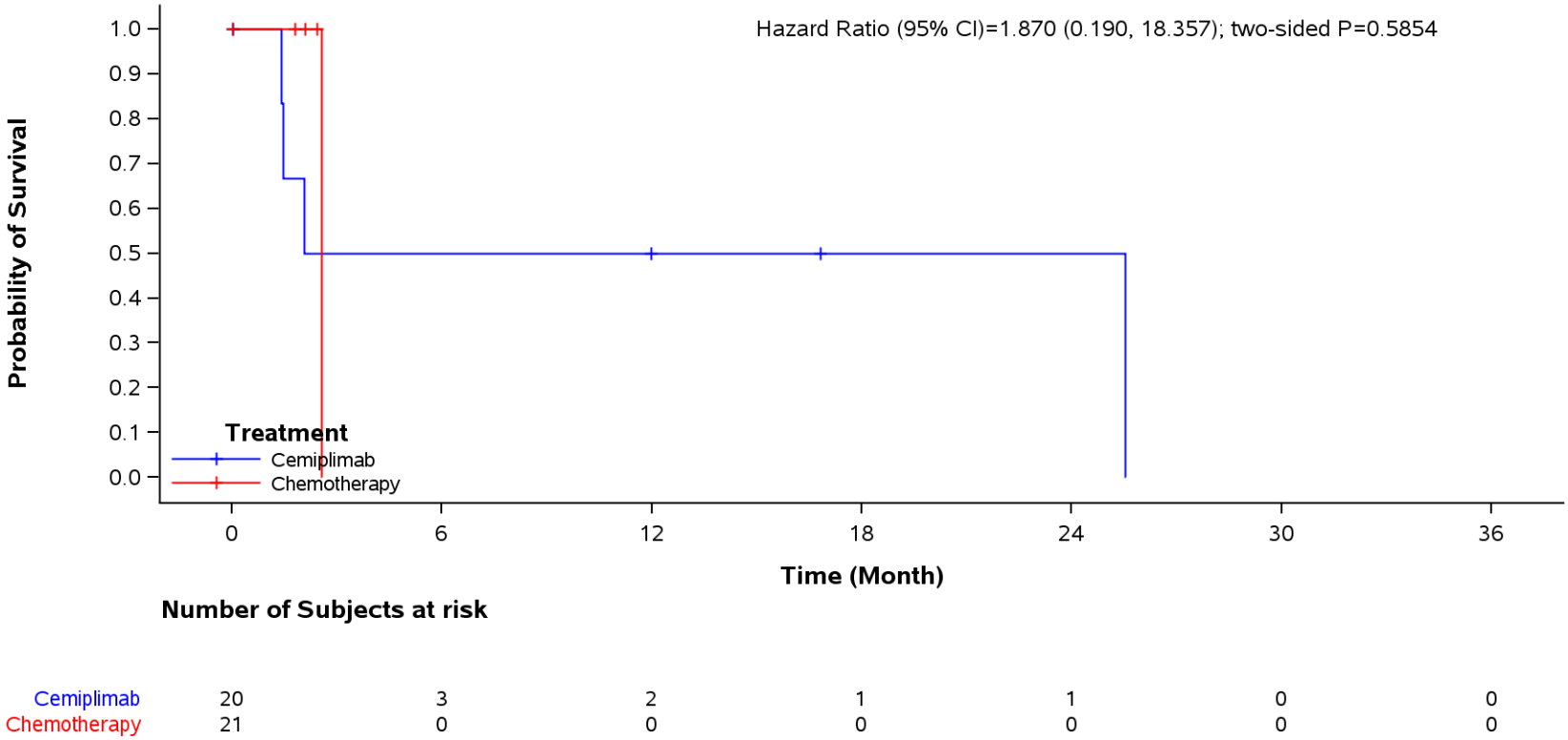
Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

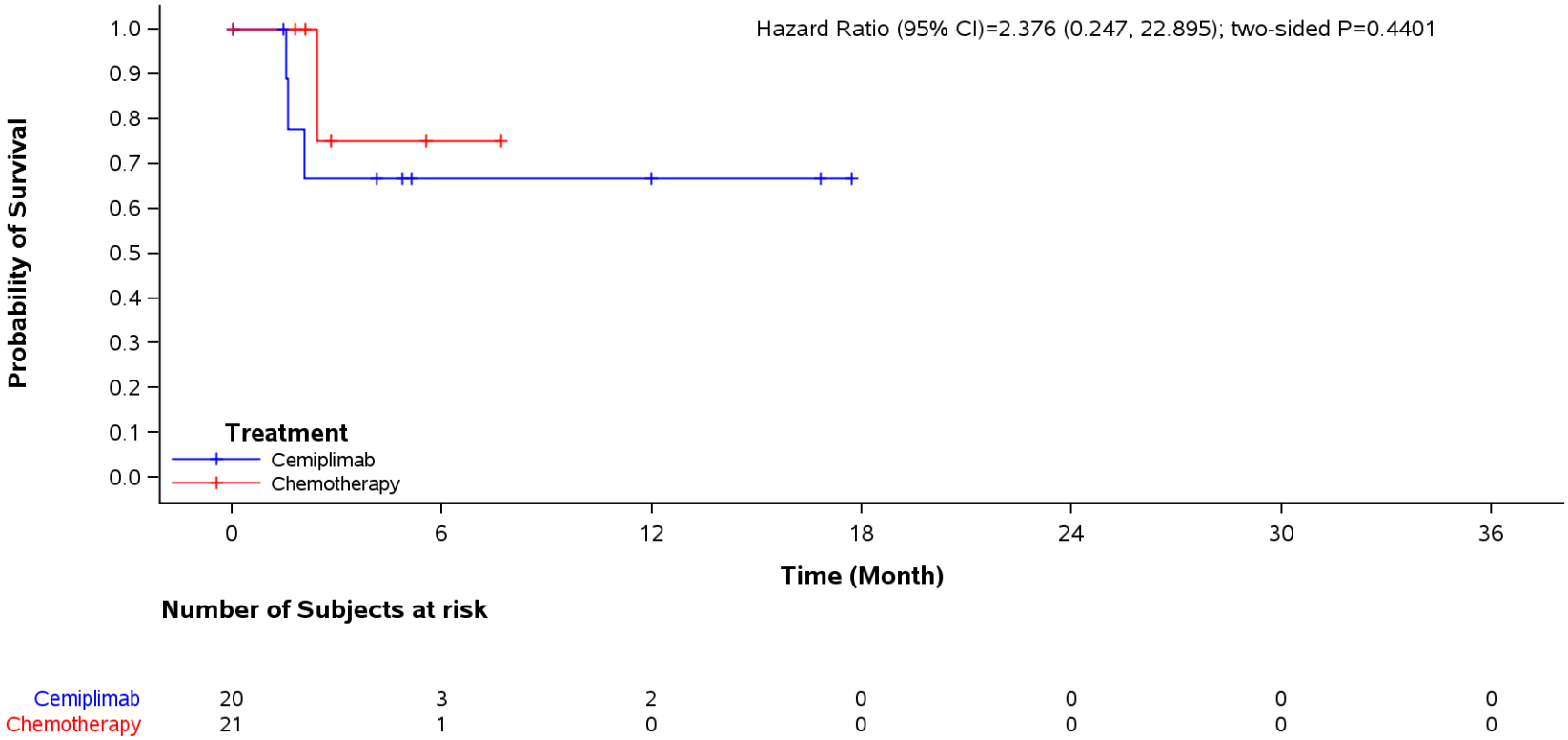
Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts sustained improvement



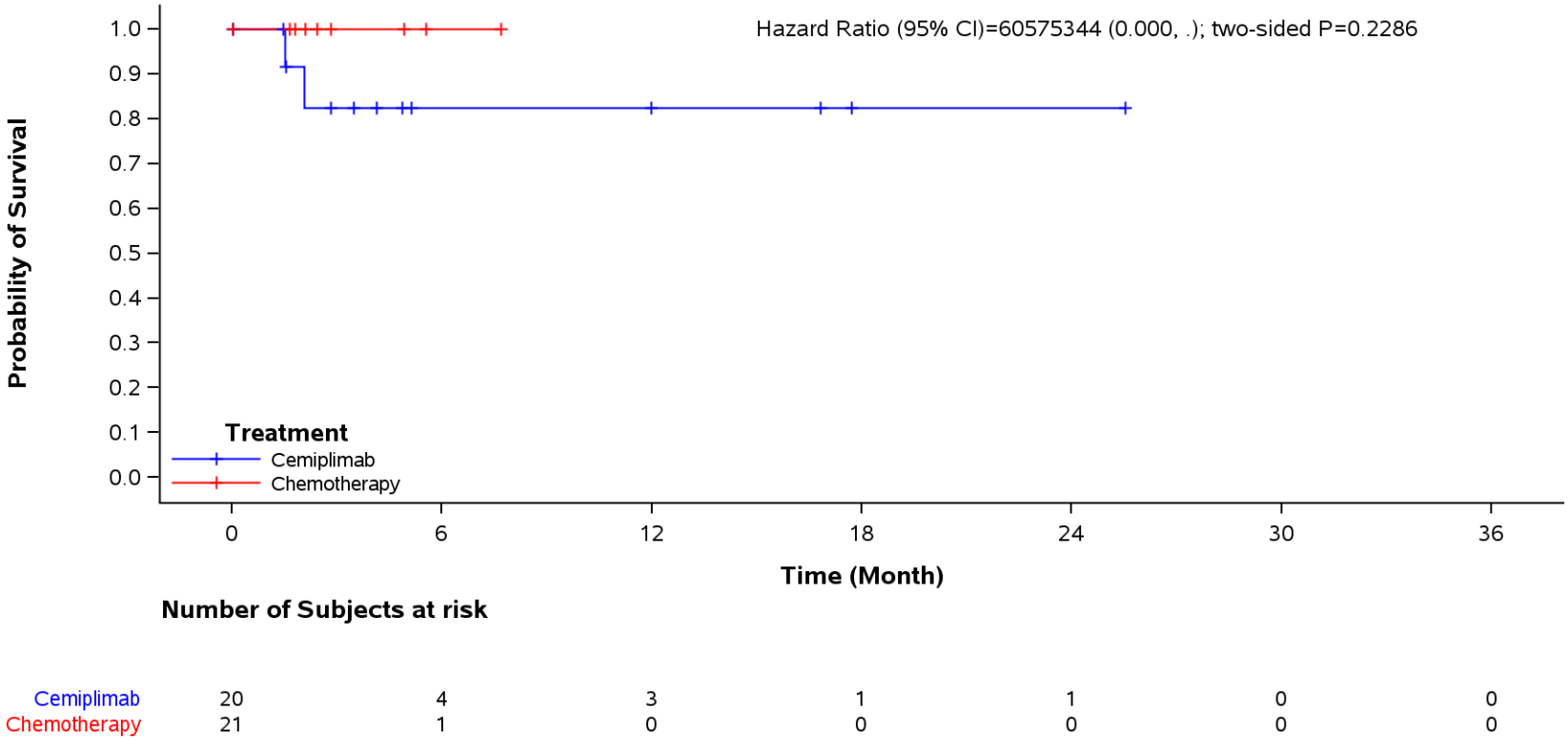

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

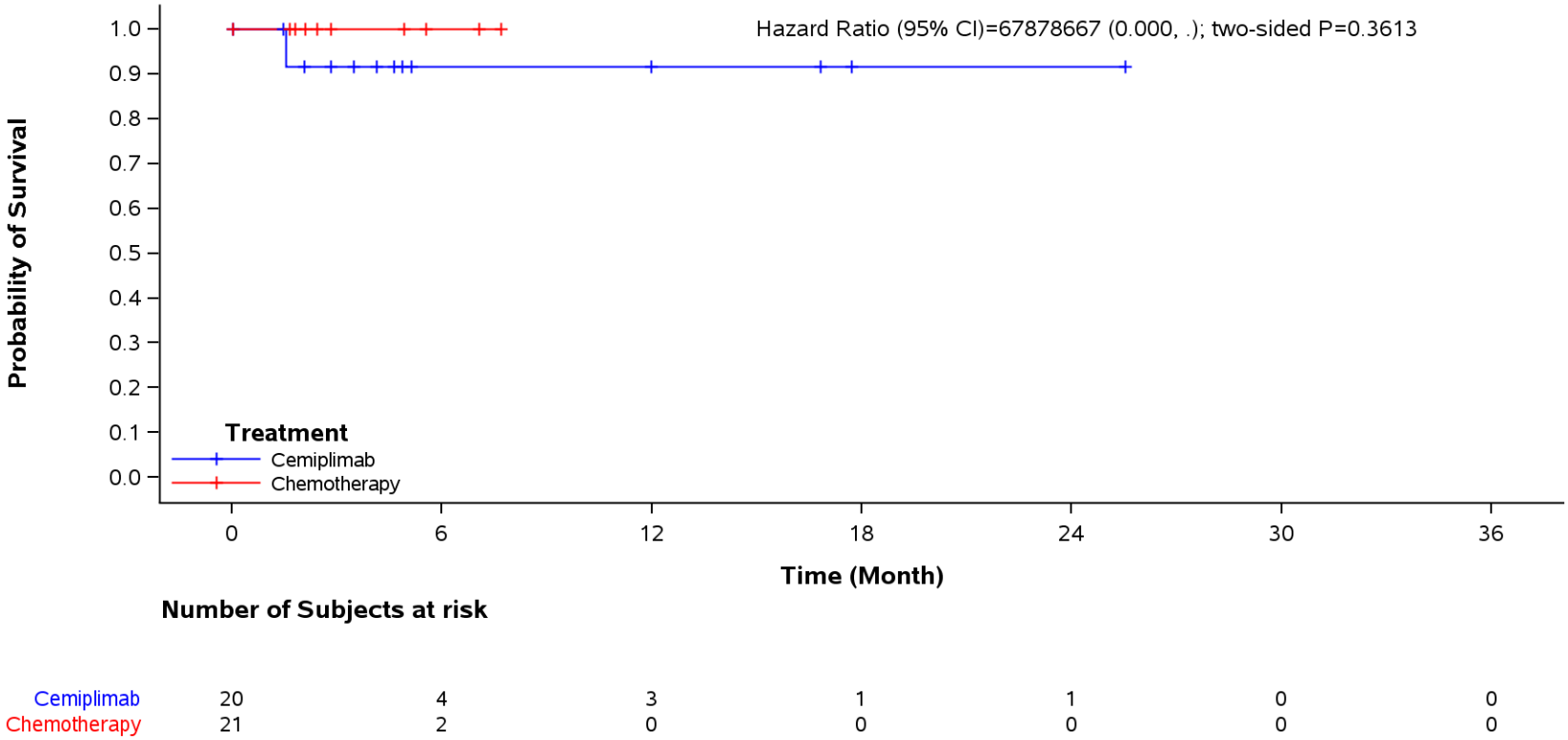
Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

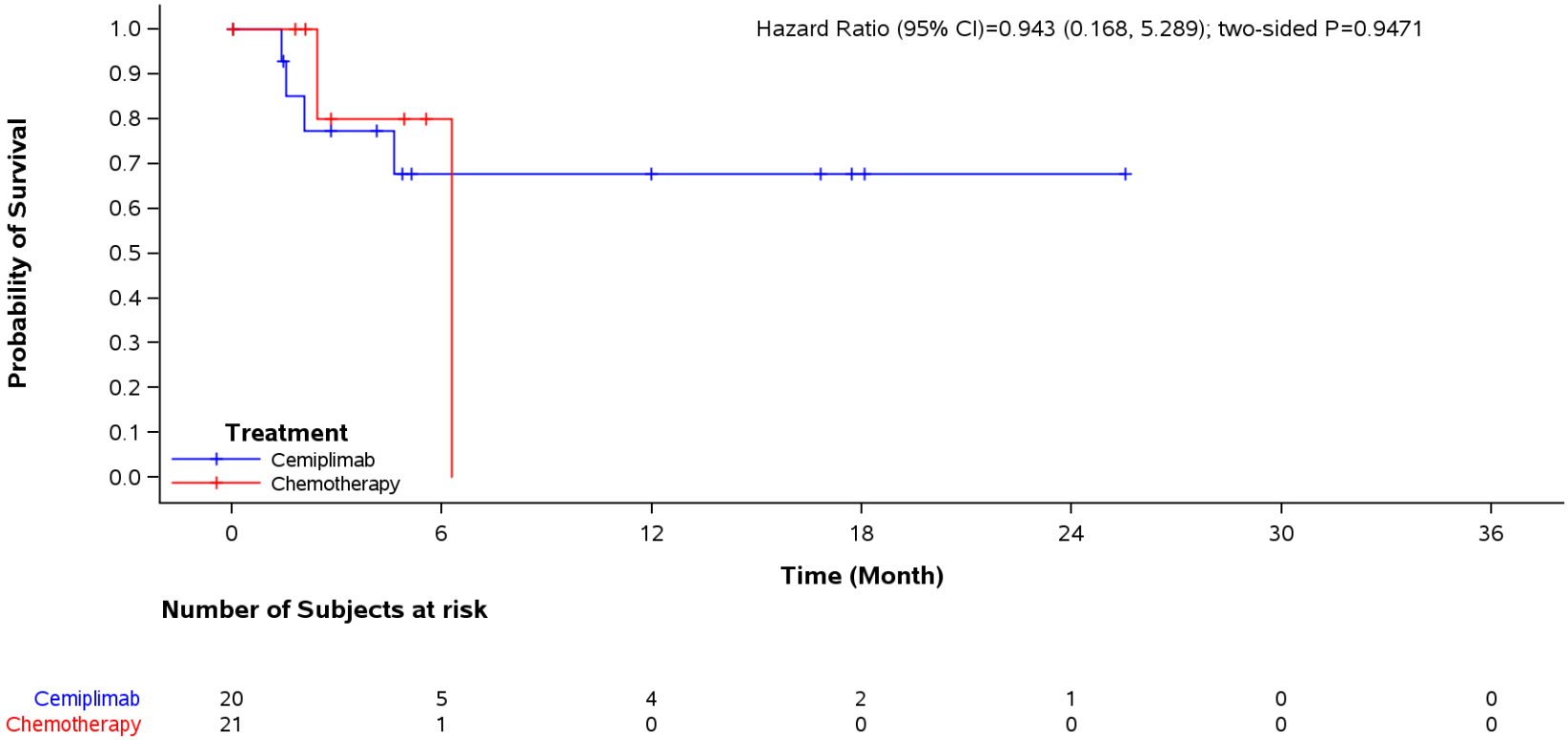
Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts sustained improvement



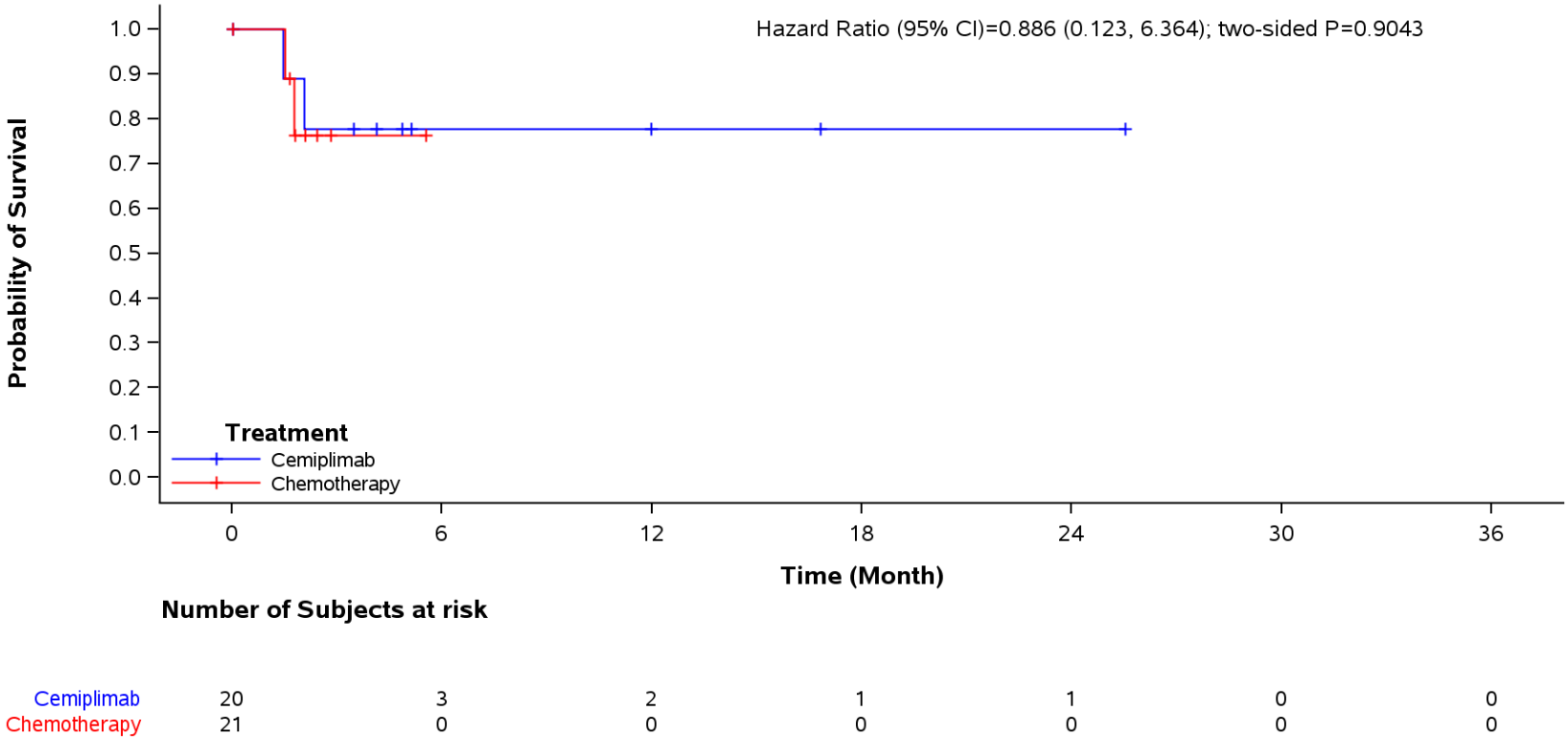

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts sustained improvement



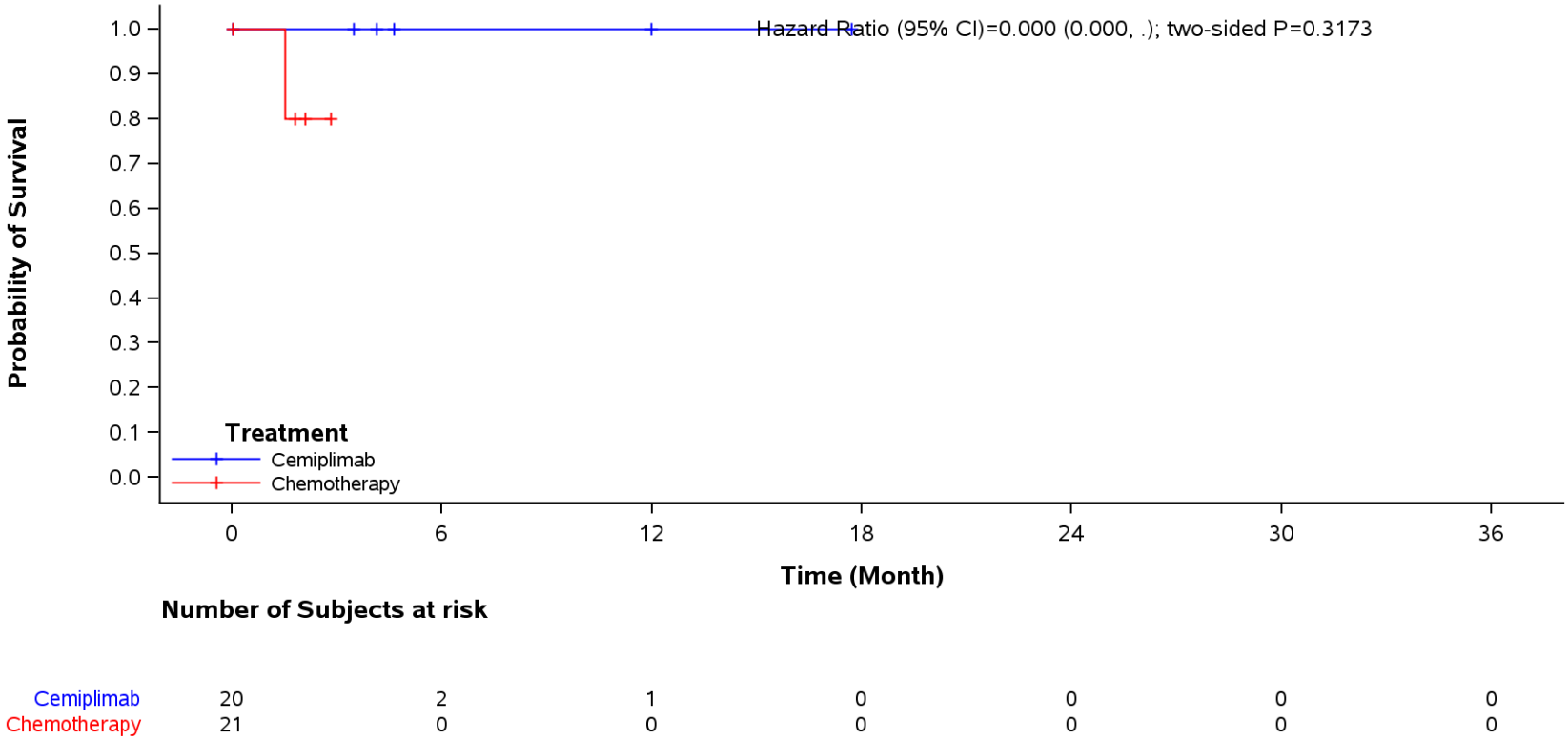

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

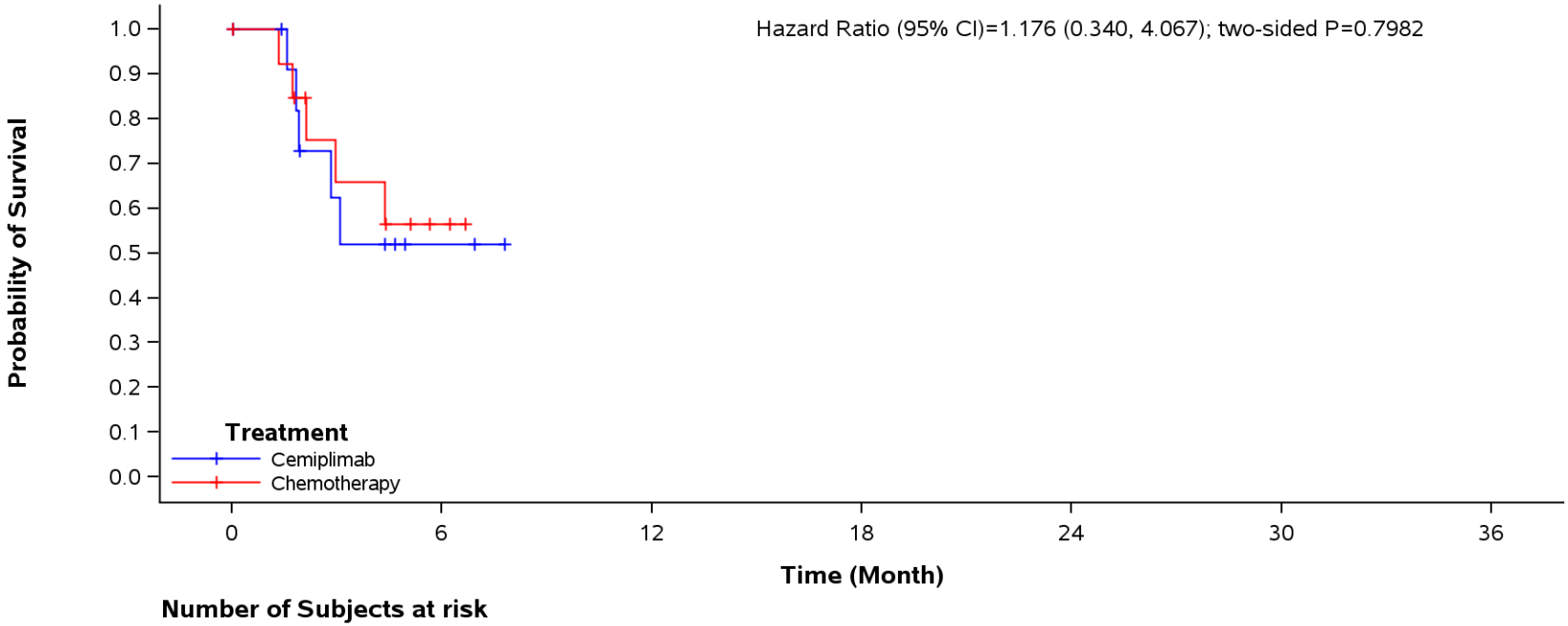
Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts sustained improvement



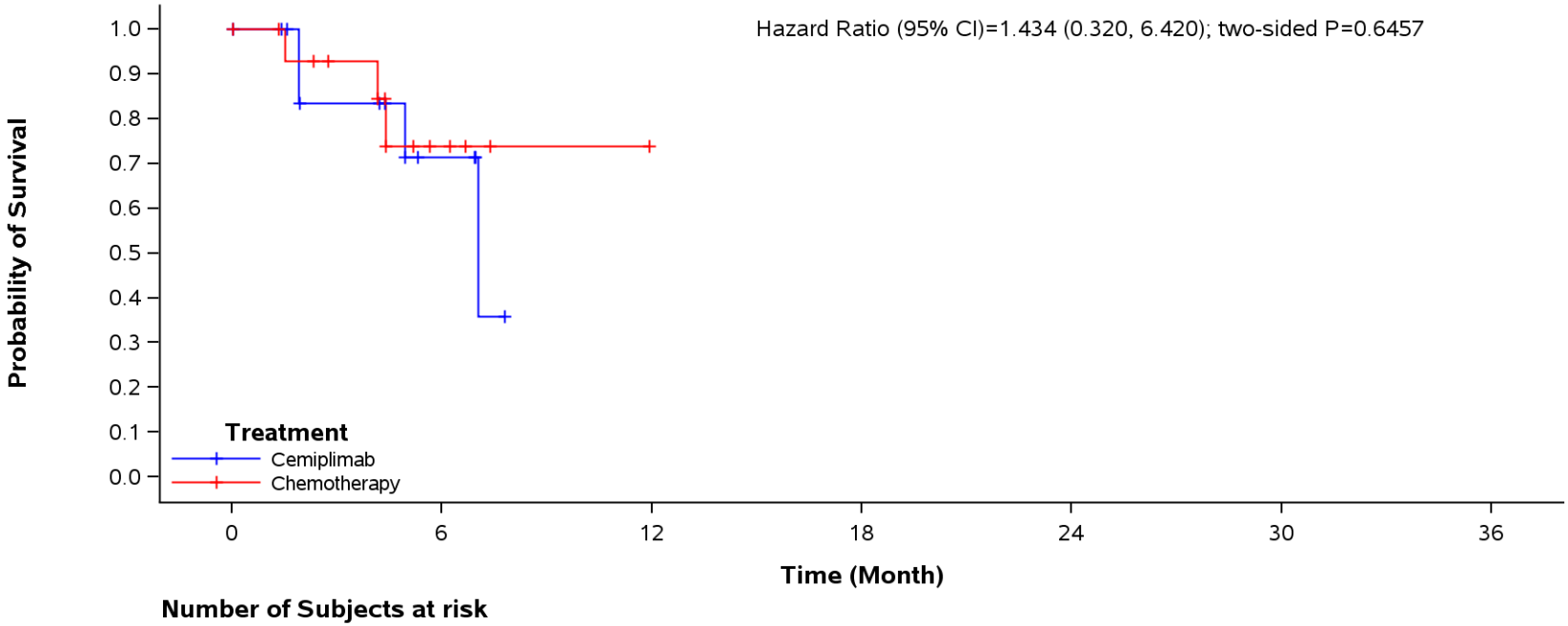

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts sustained improvement



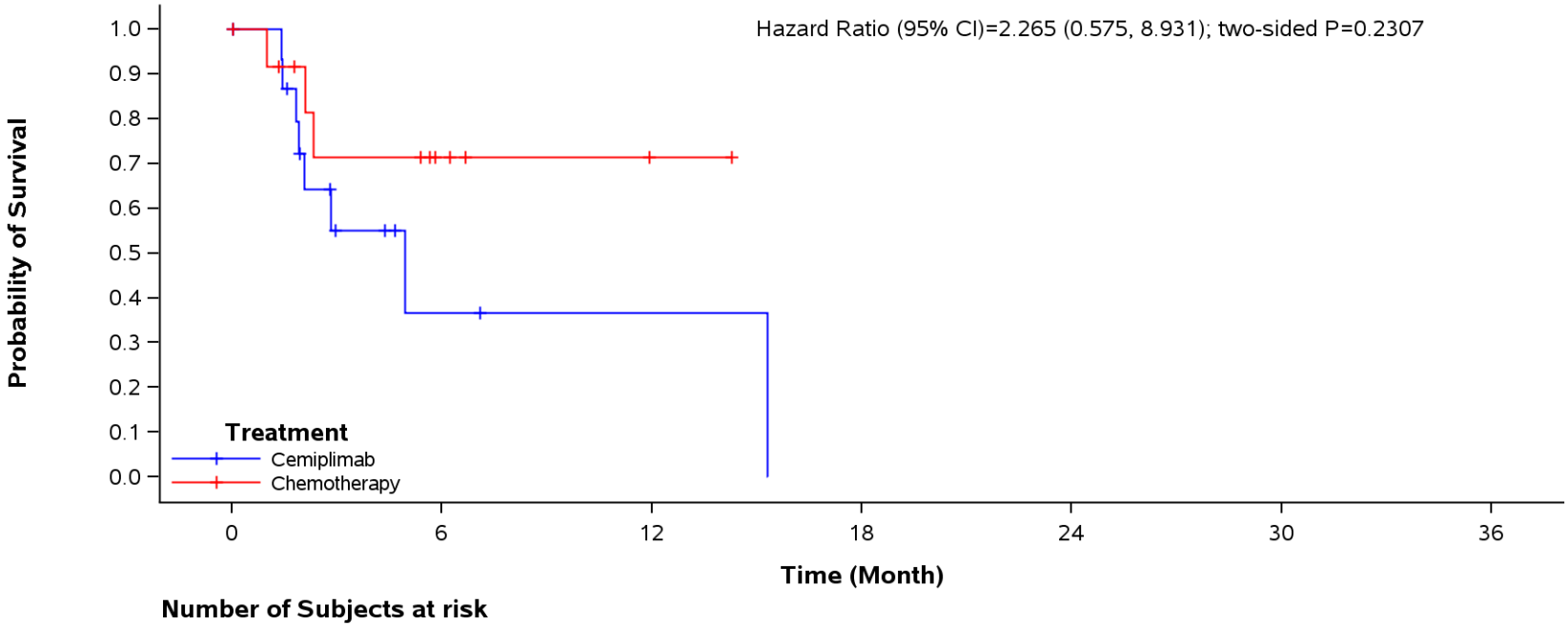

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts sustained improvement



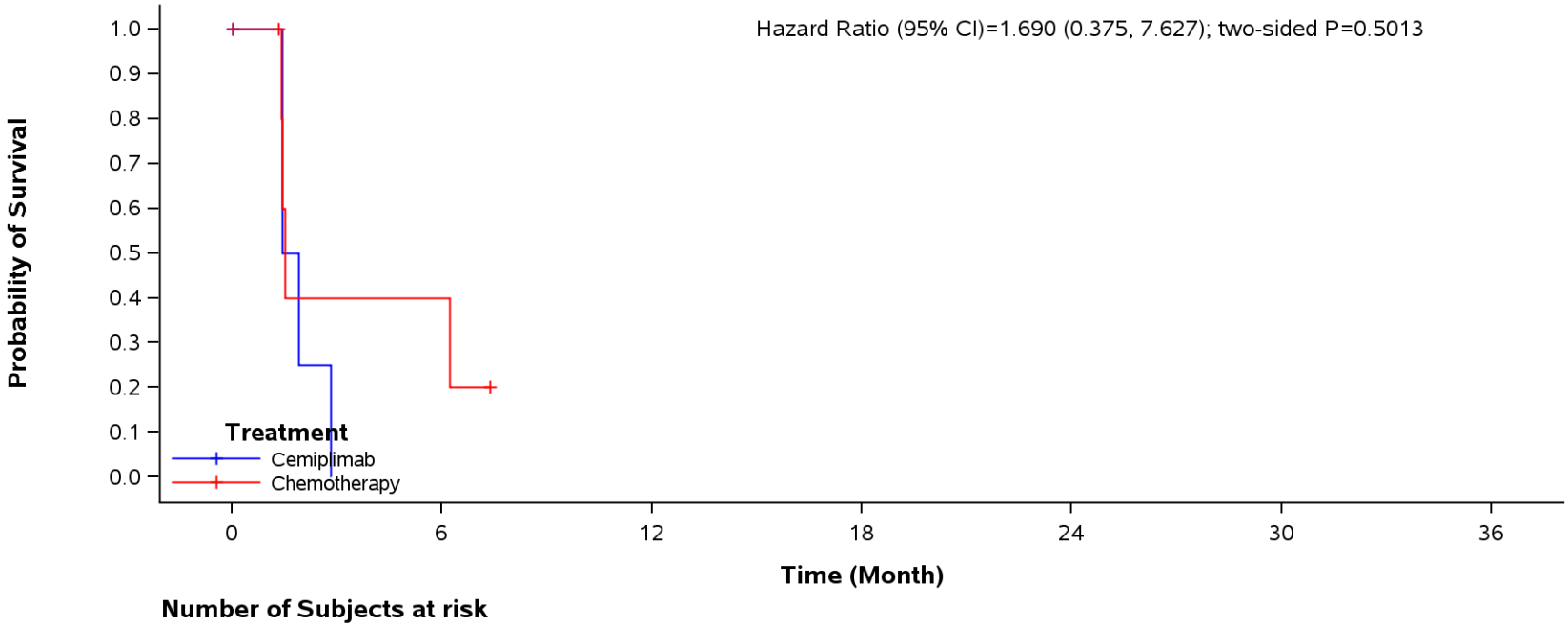

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts sustained improvement



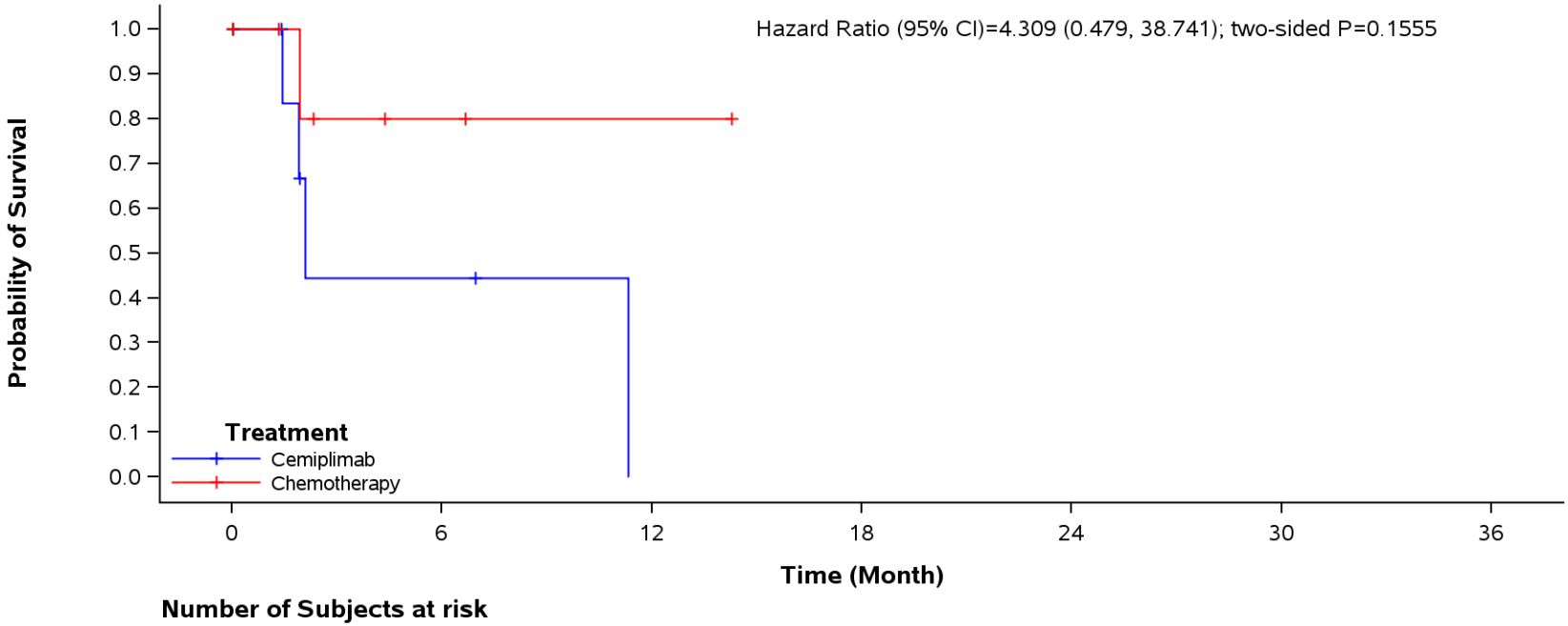

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts sustained improvement



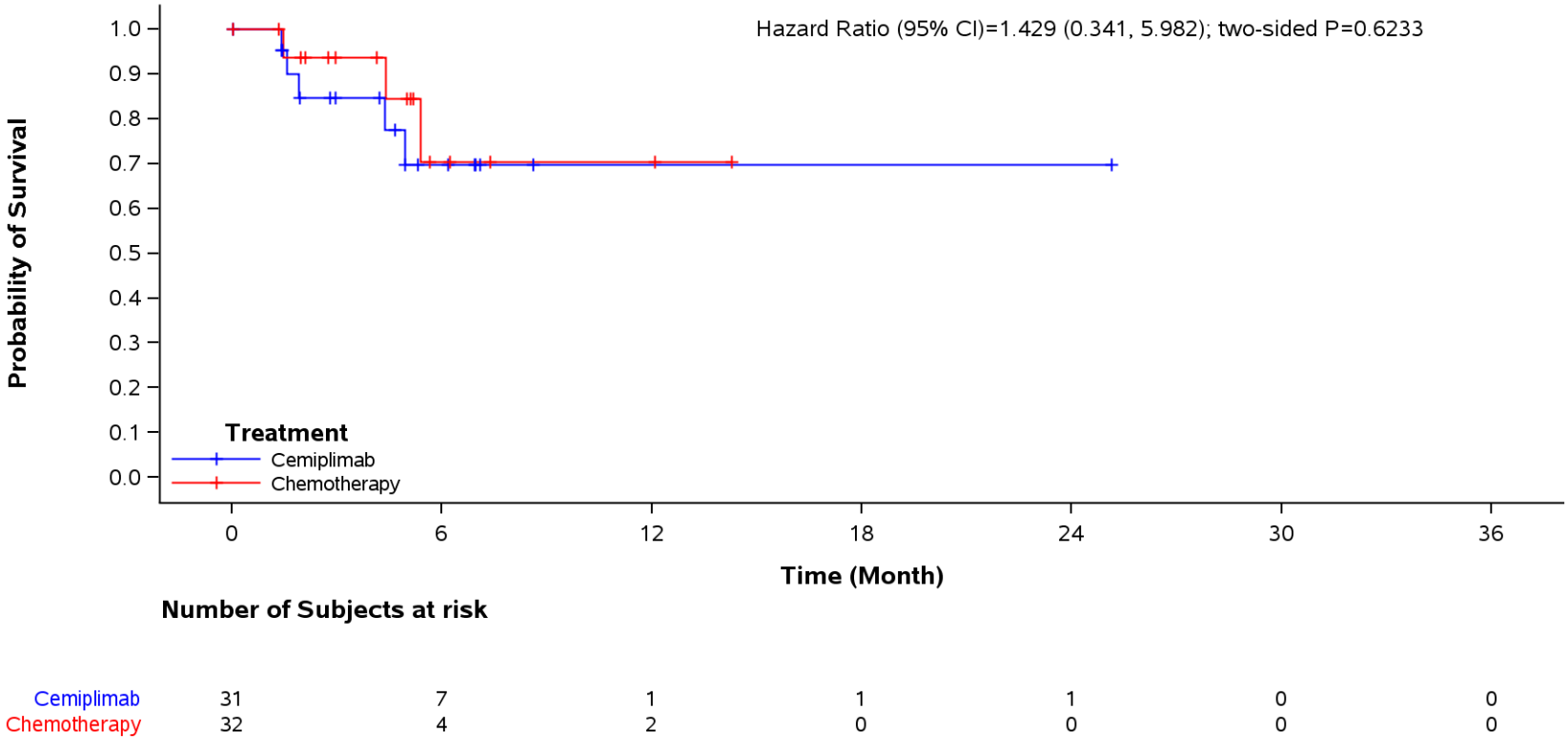

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts sustained improvement



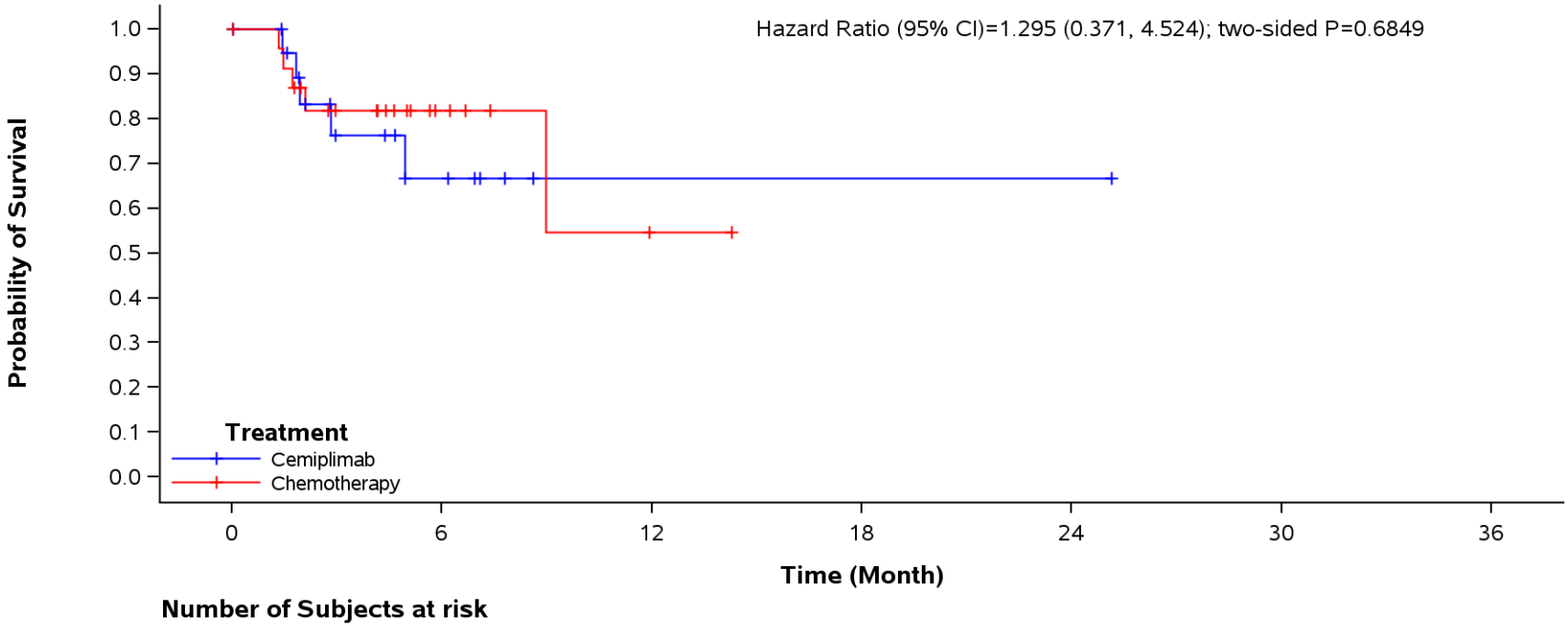

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts sustained improvement



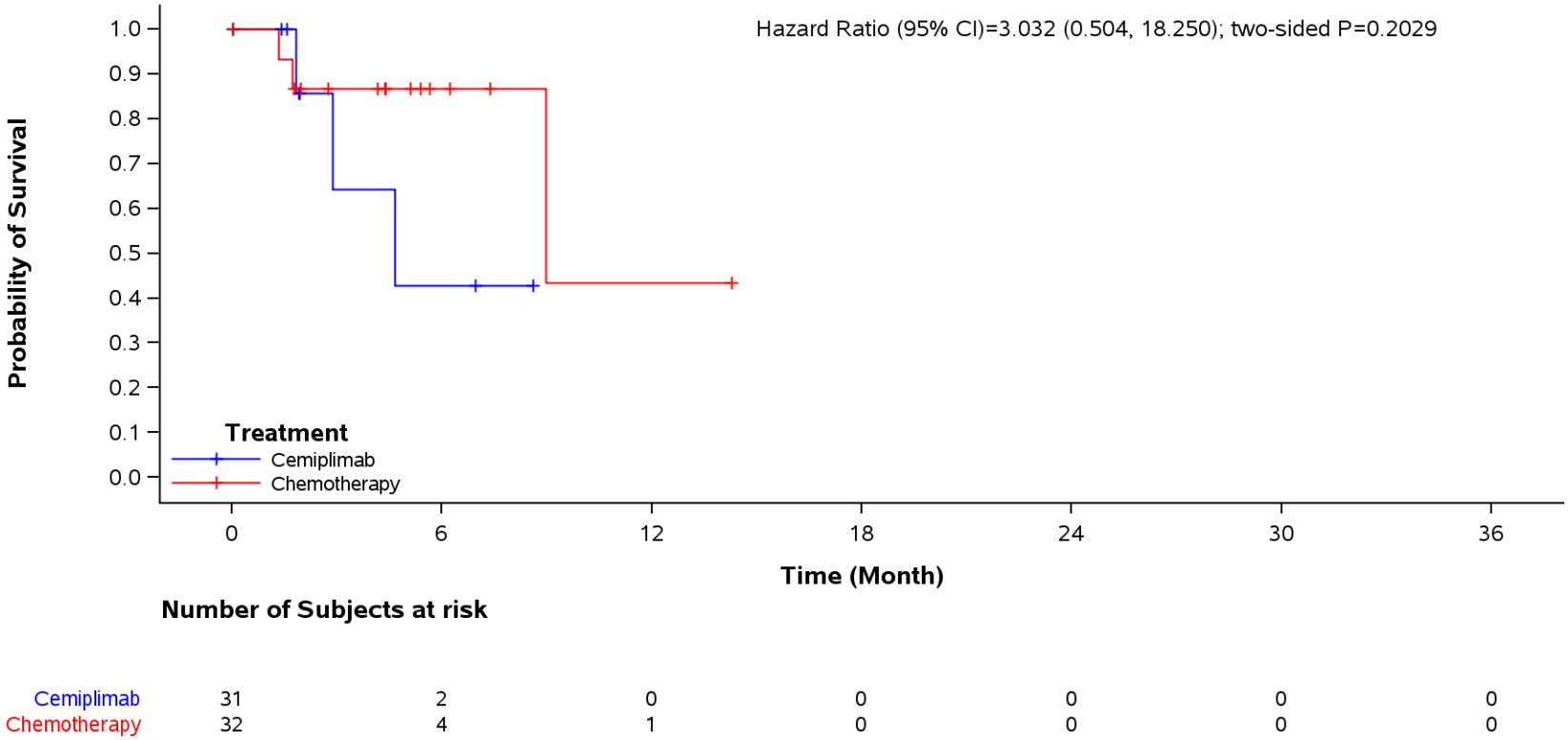

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

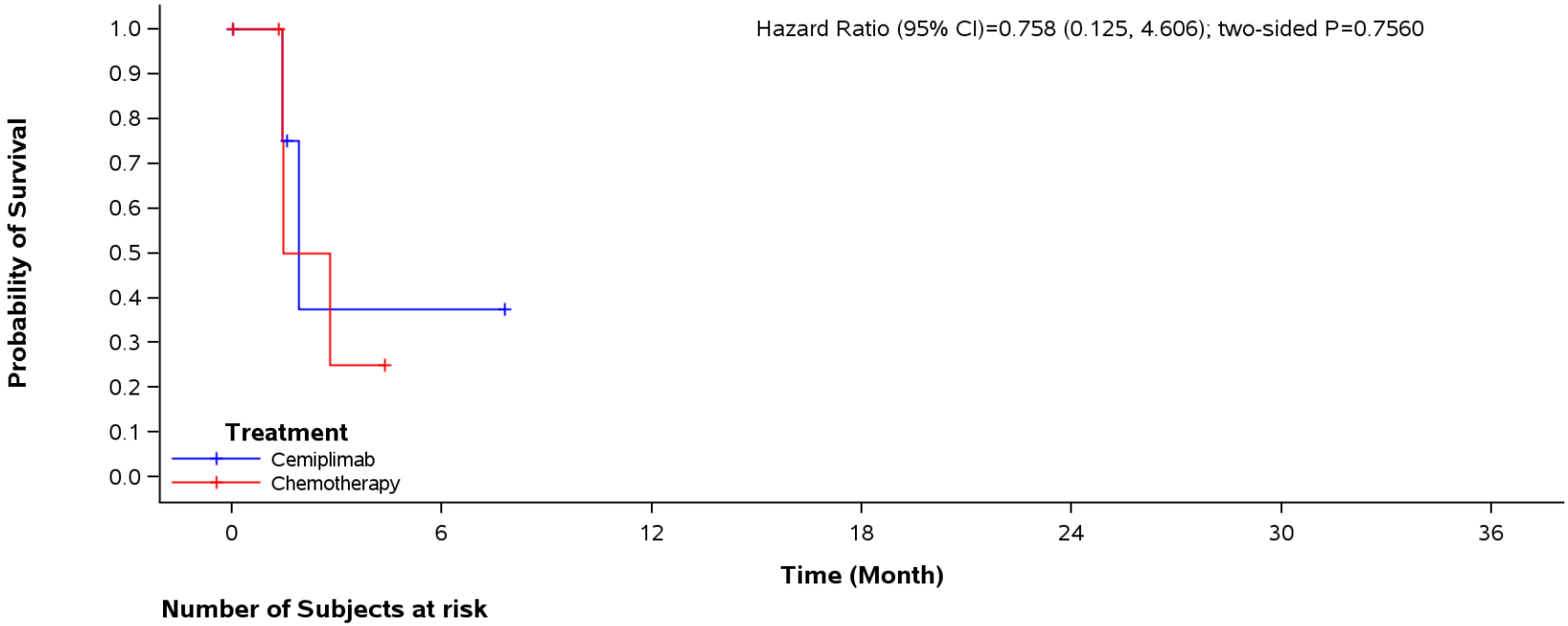
Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts sustained improvement



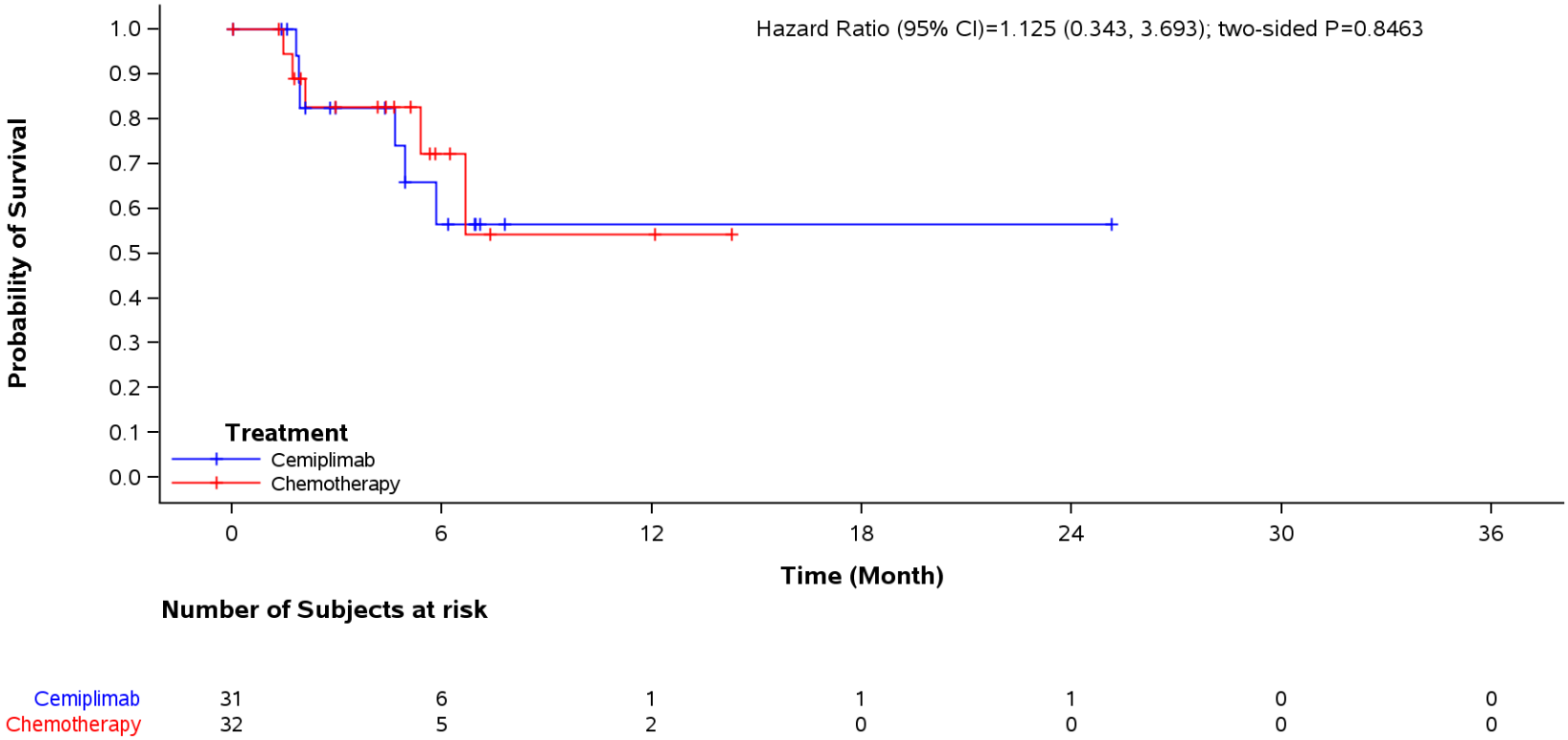

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

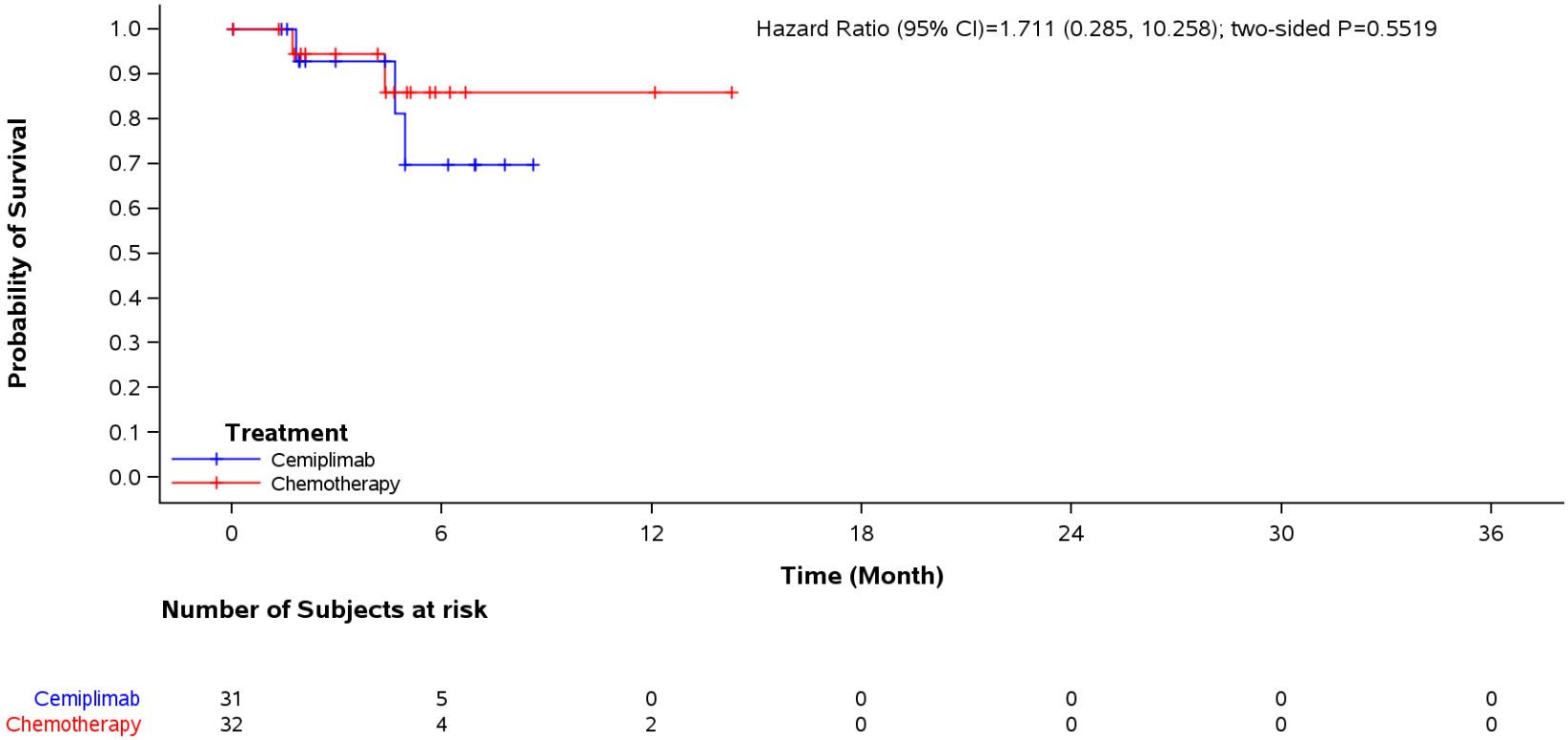
Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts sustained improvement



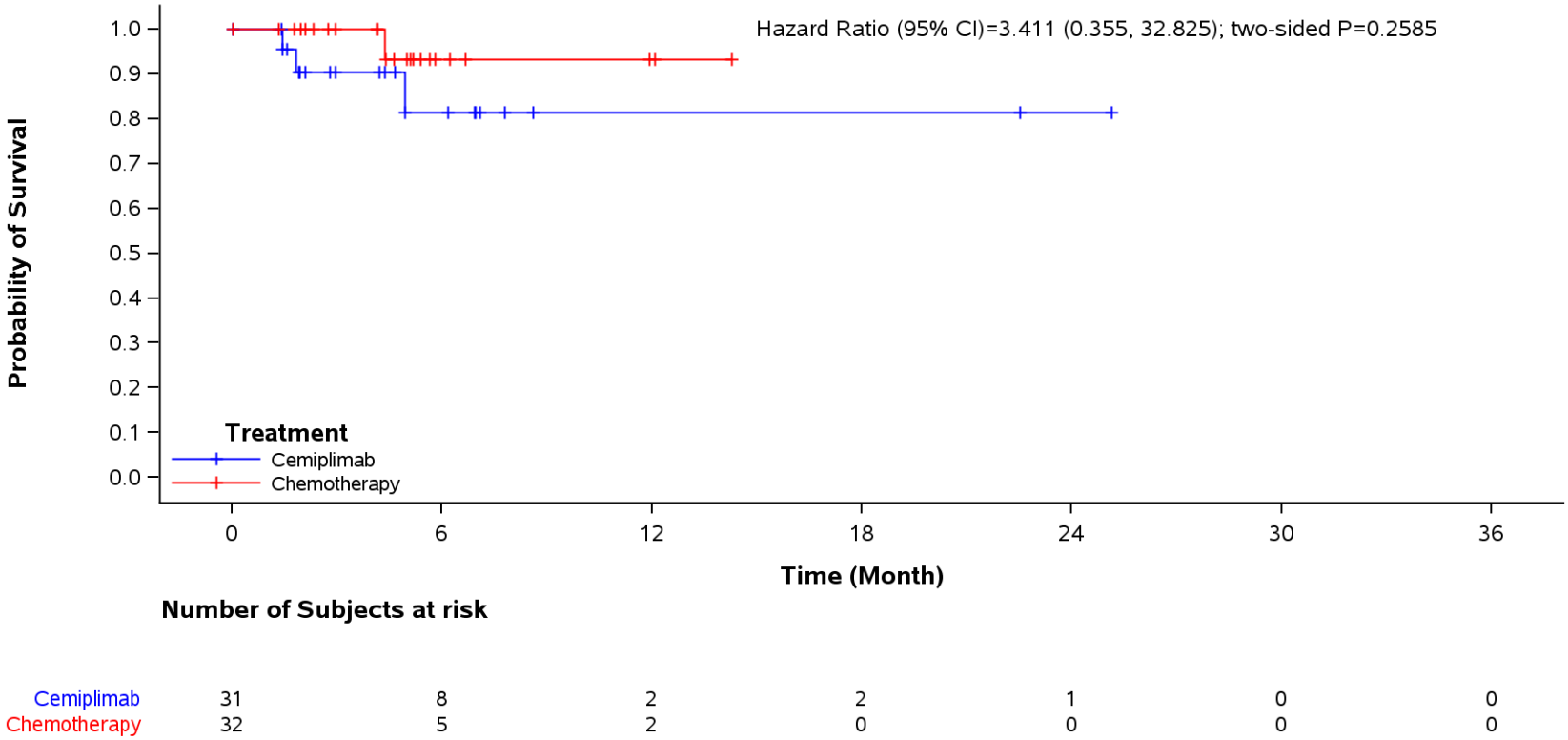

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

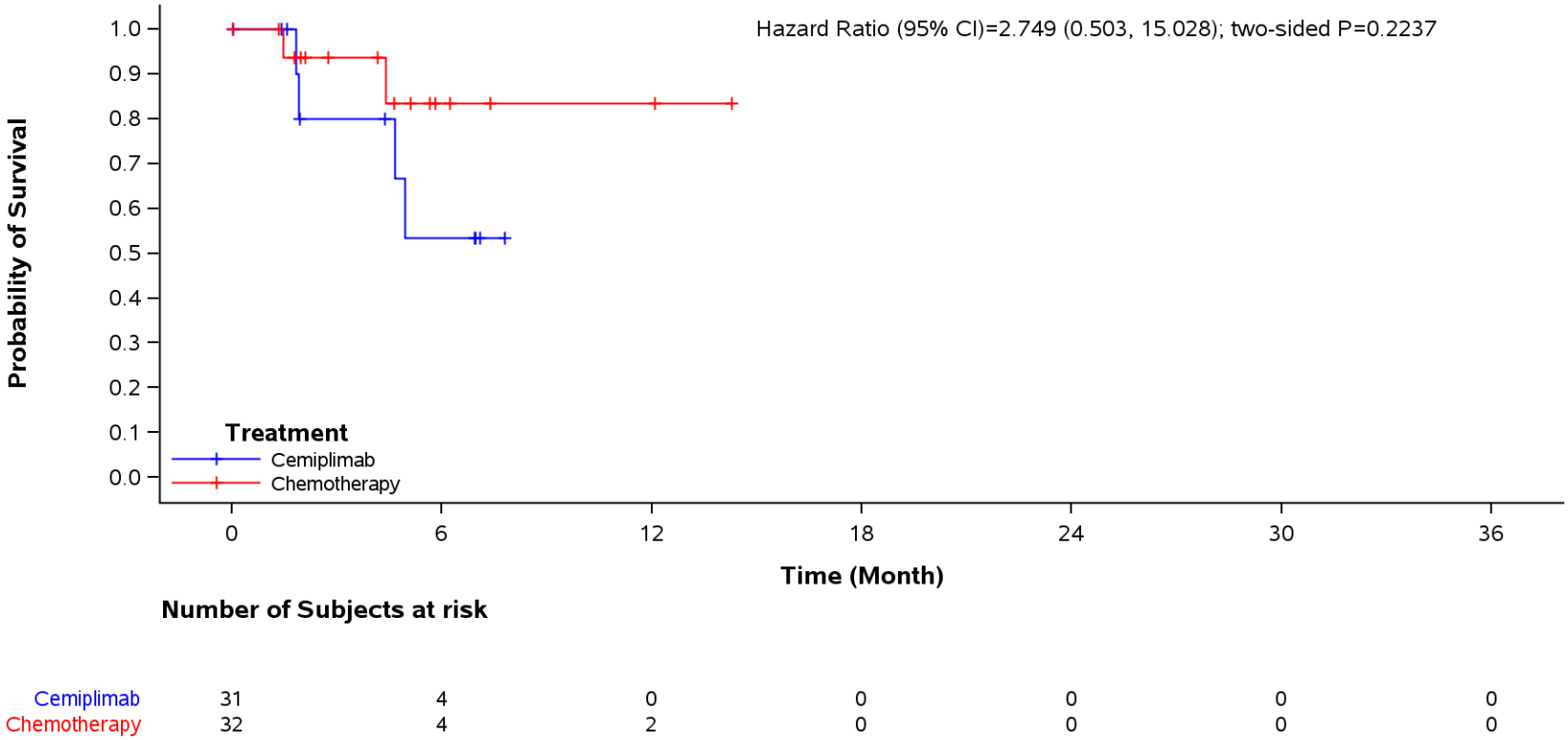
Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

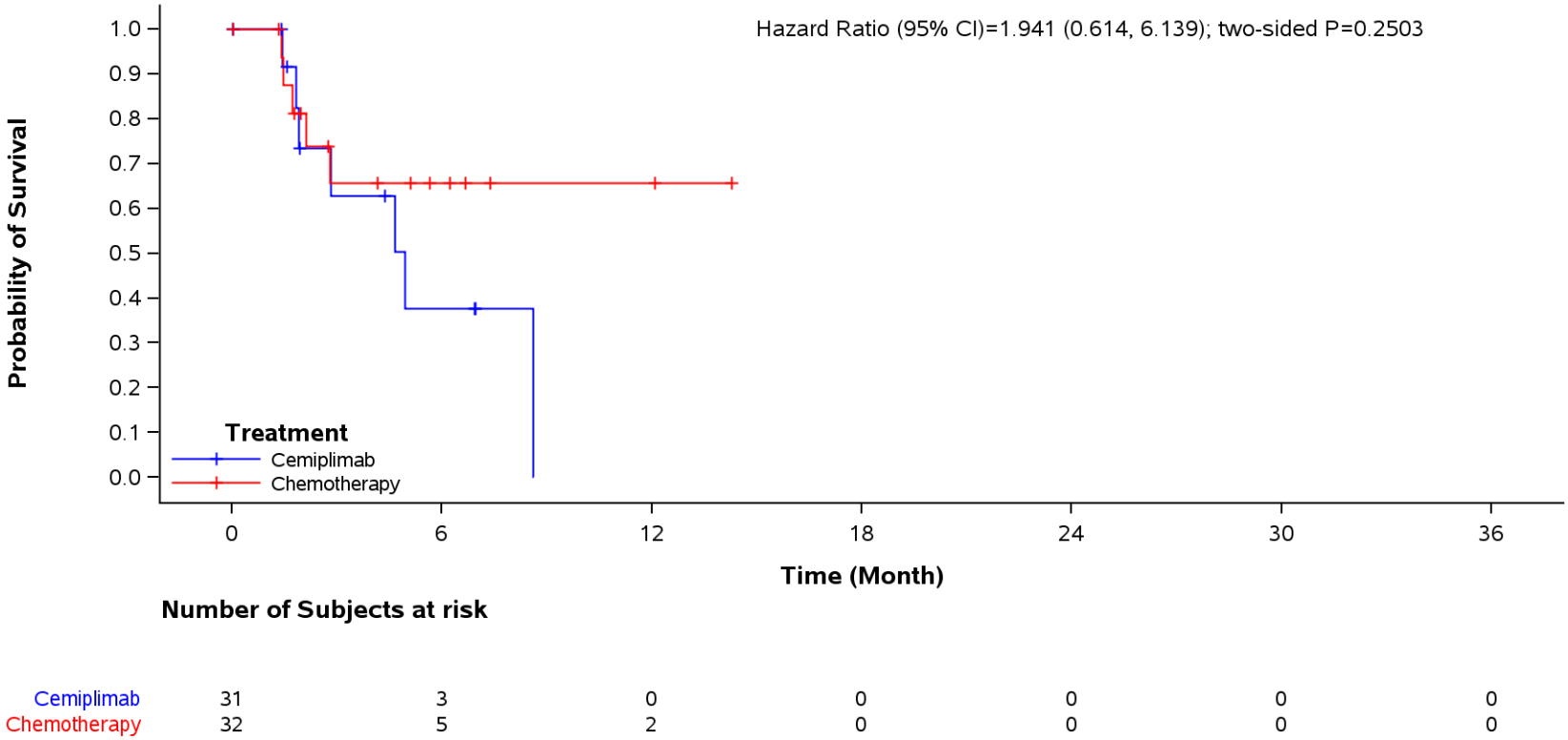
Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

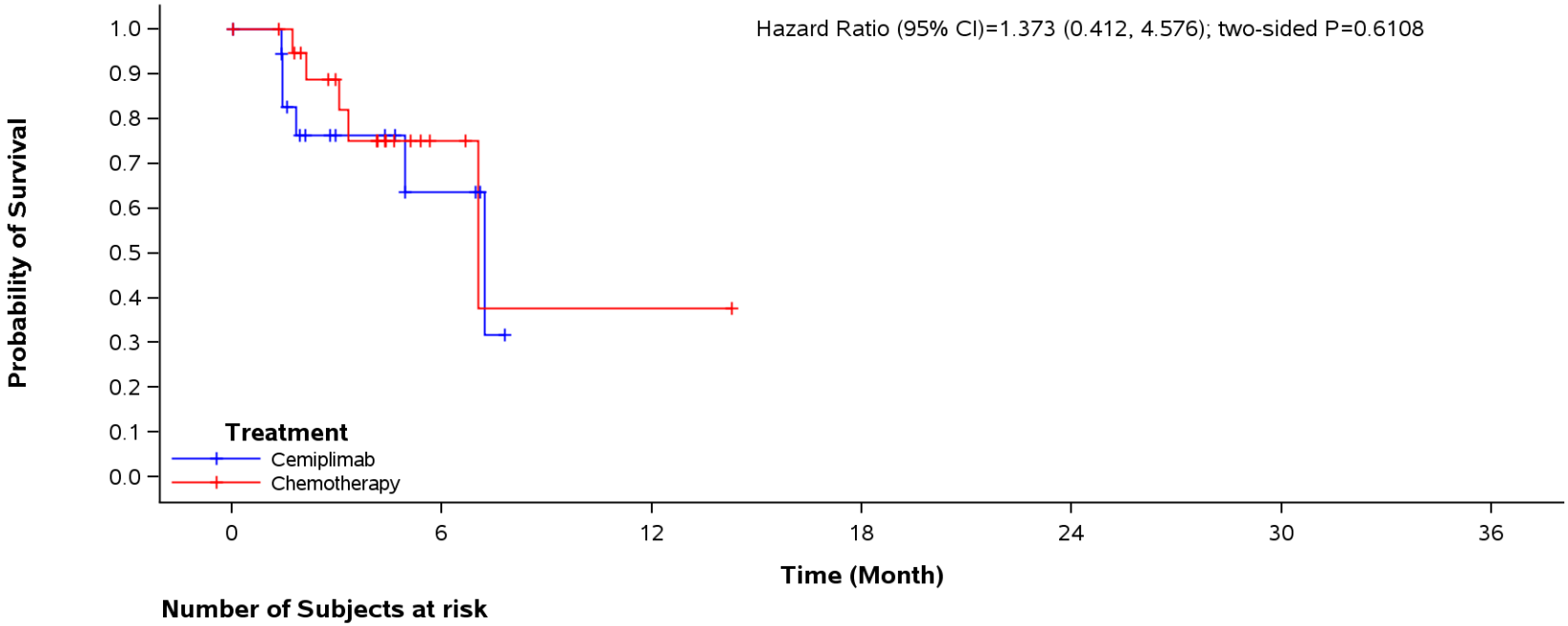
Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts sustained improvement



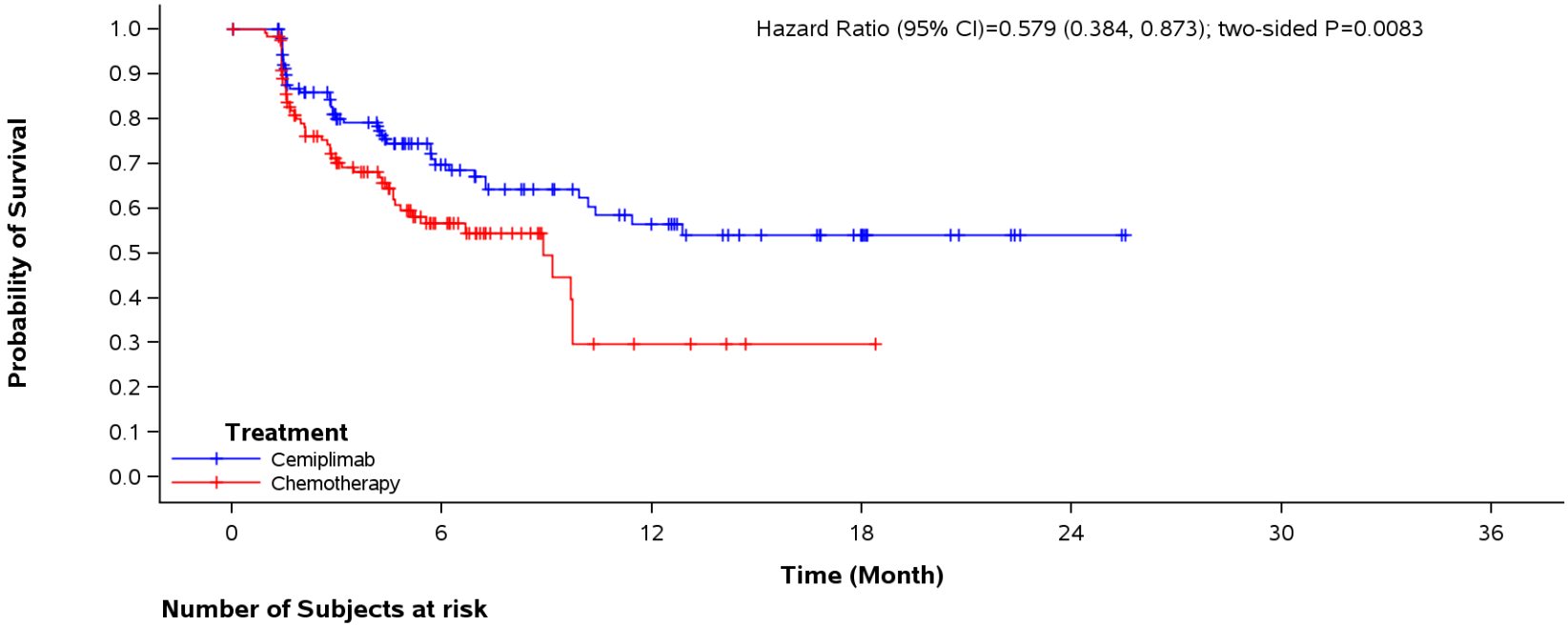

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts sustained deterioration



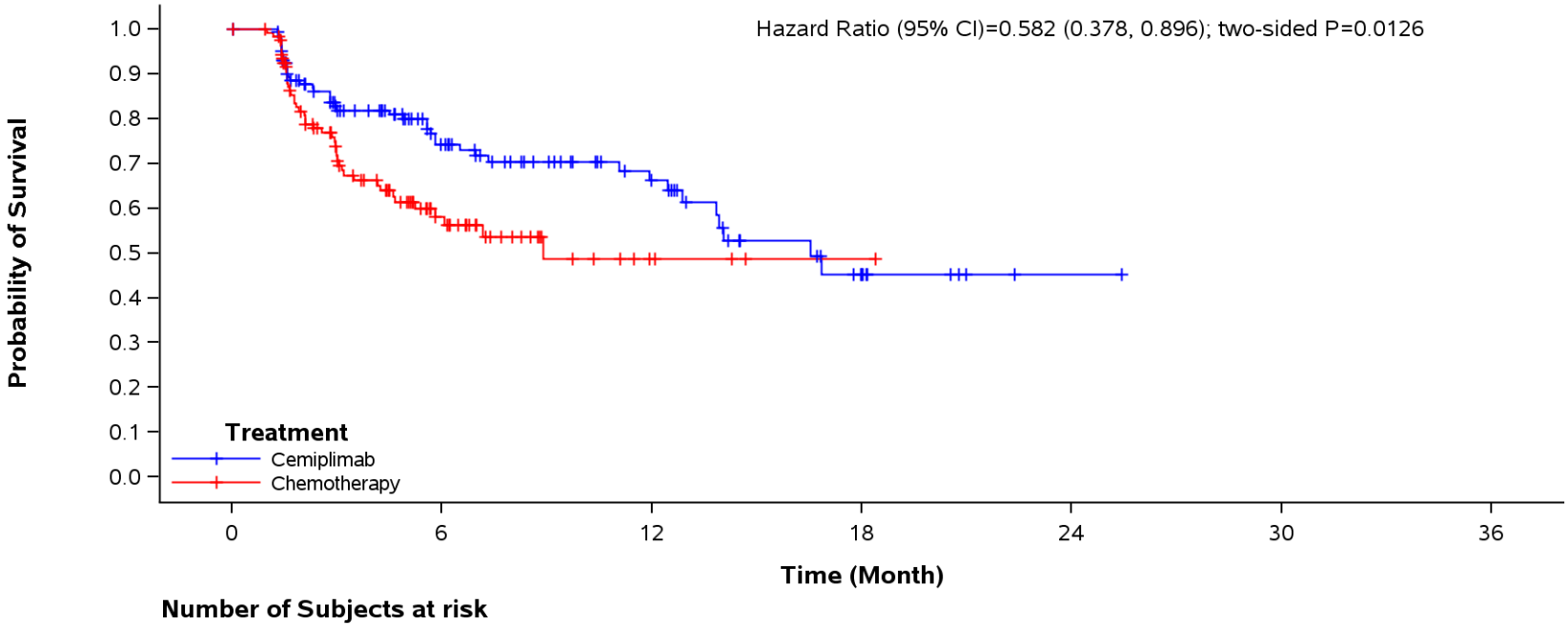

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 56 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 33 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts sustained deterioration



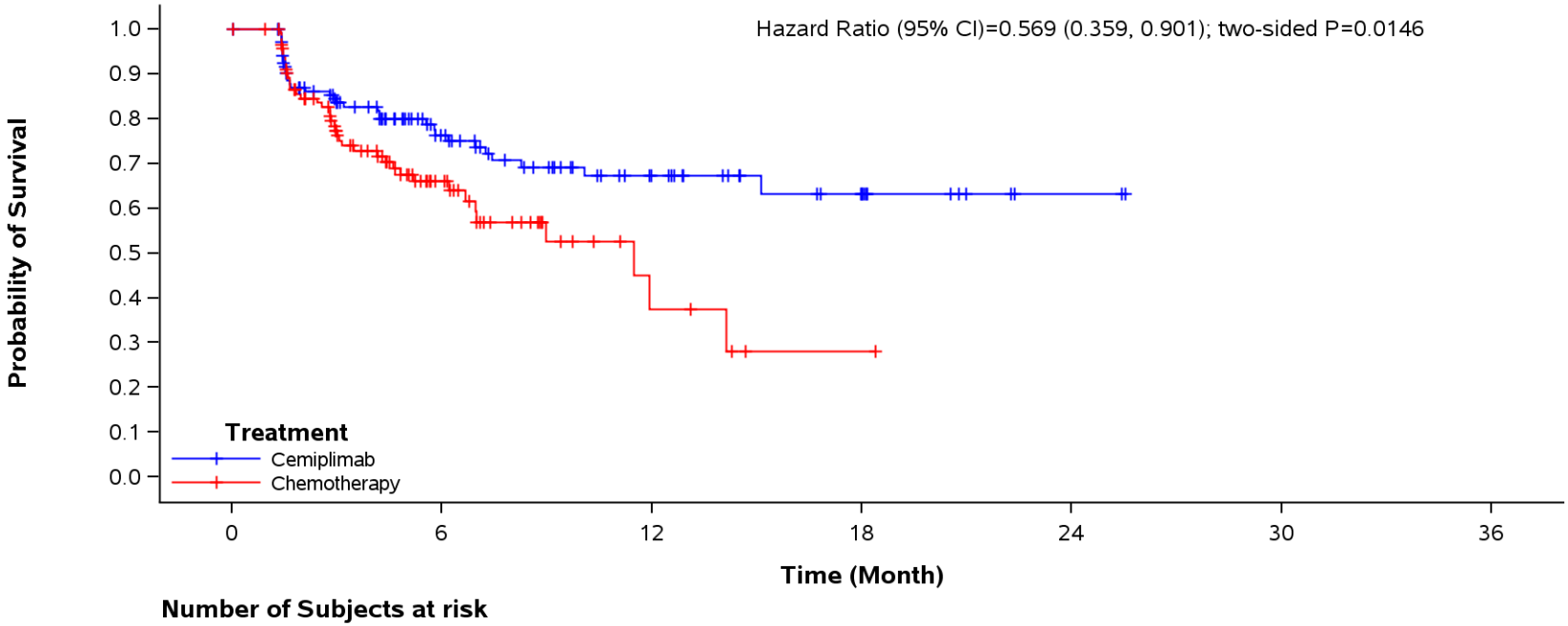

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 64 | 29 | 9 | 1 | 0 | 0 |
| Chemotherapy | 163 | 32 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts sustained deterioration



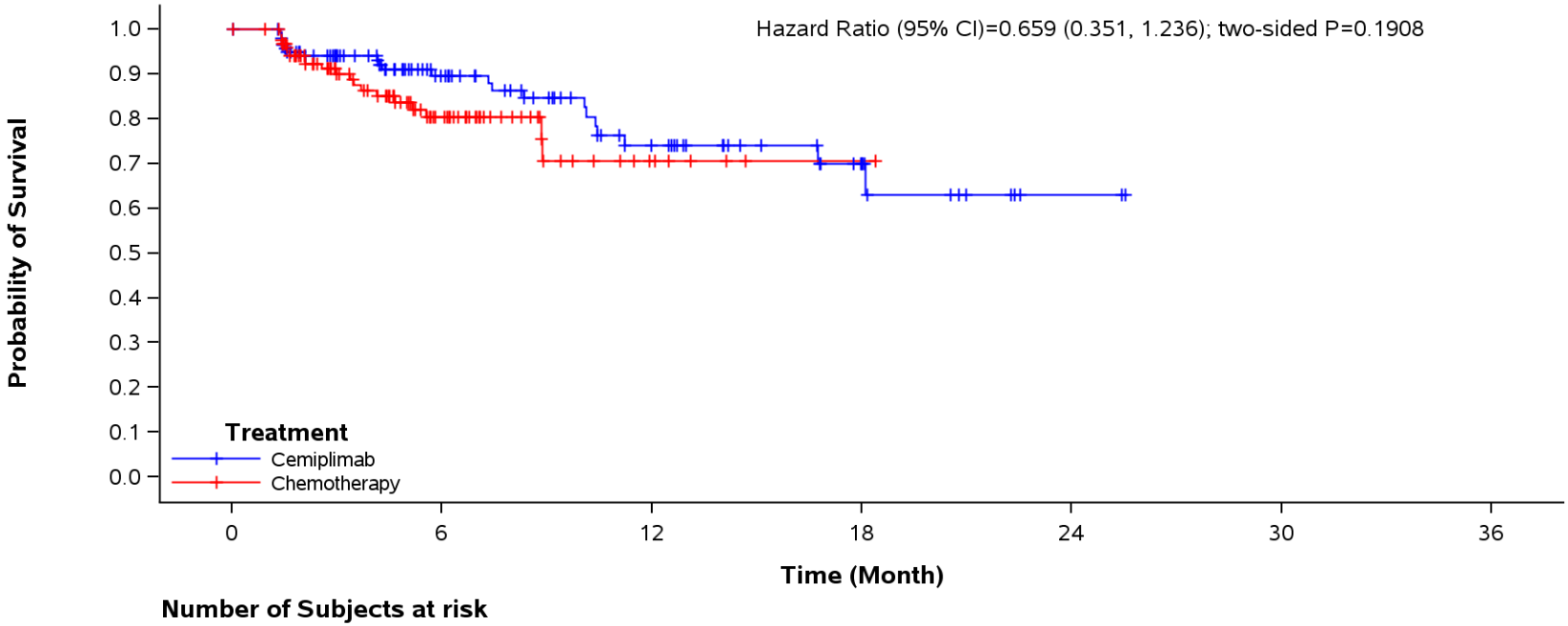

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 60 | 26 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 35 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts sustained deterioration



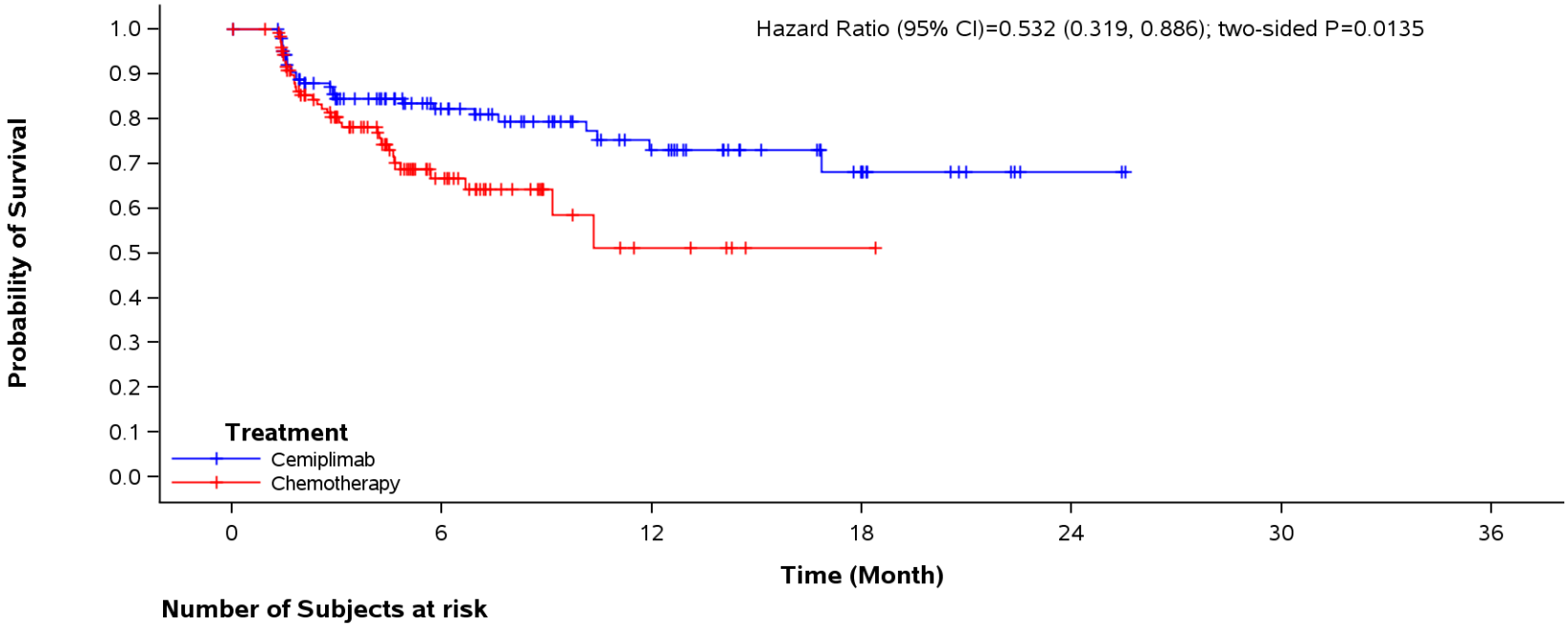

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 65 | 30 | 13 | 2 | 0 | 0 |
| Chemotherapy | 163 | 39 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts sustained deterioration



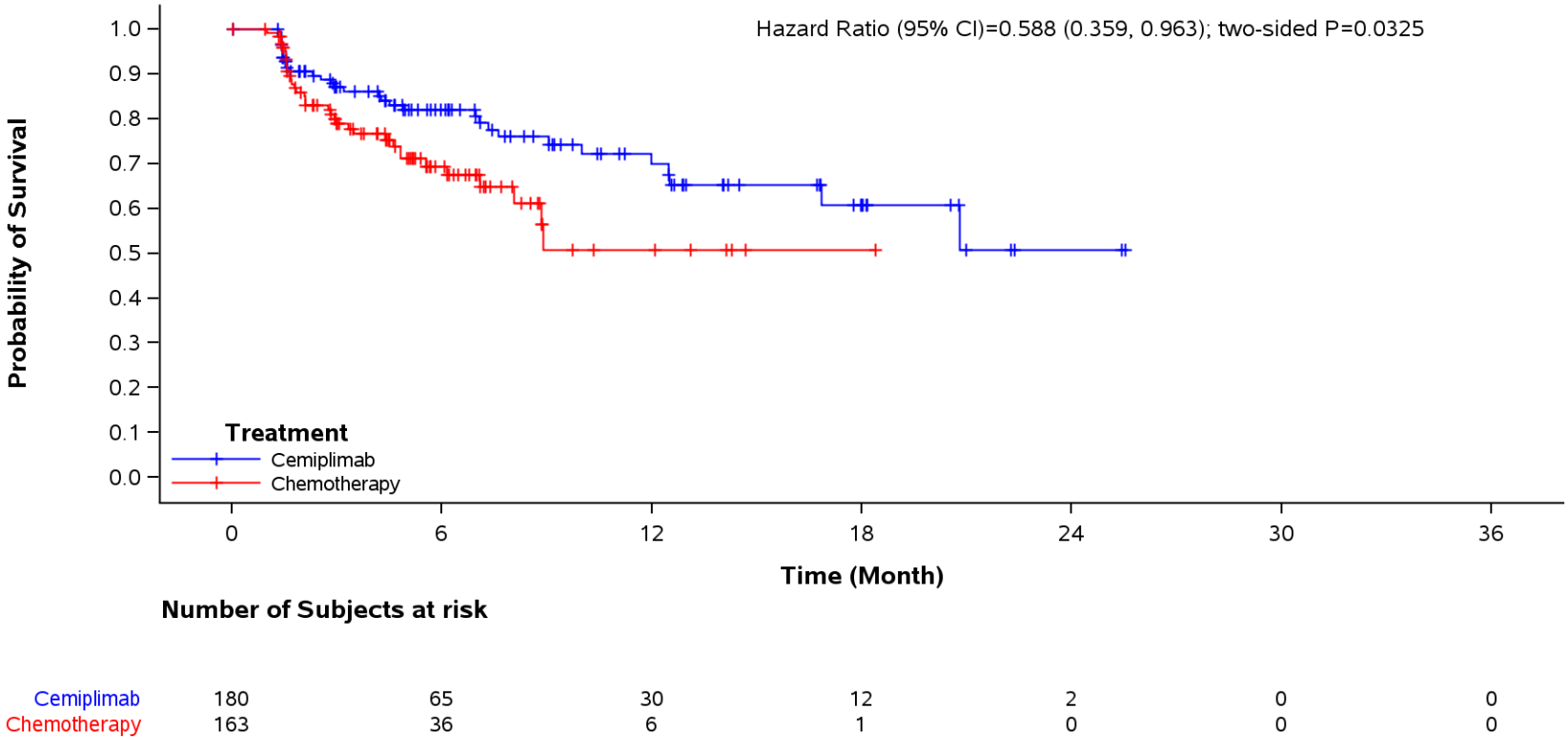

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 65 | 30 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 33 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts sustained deterioration



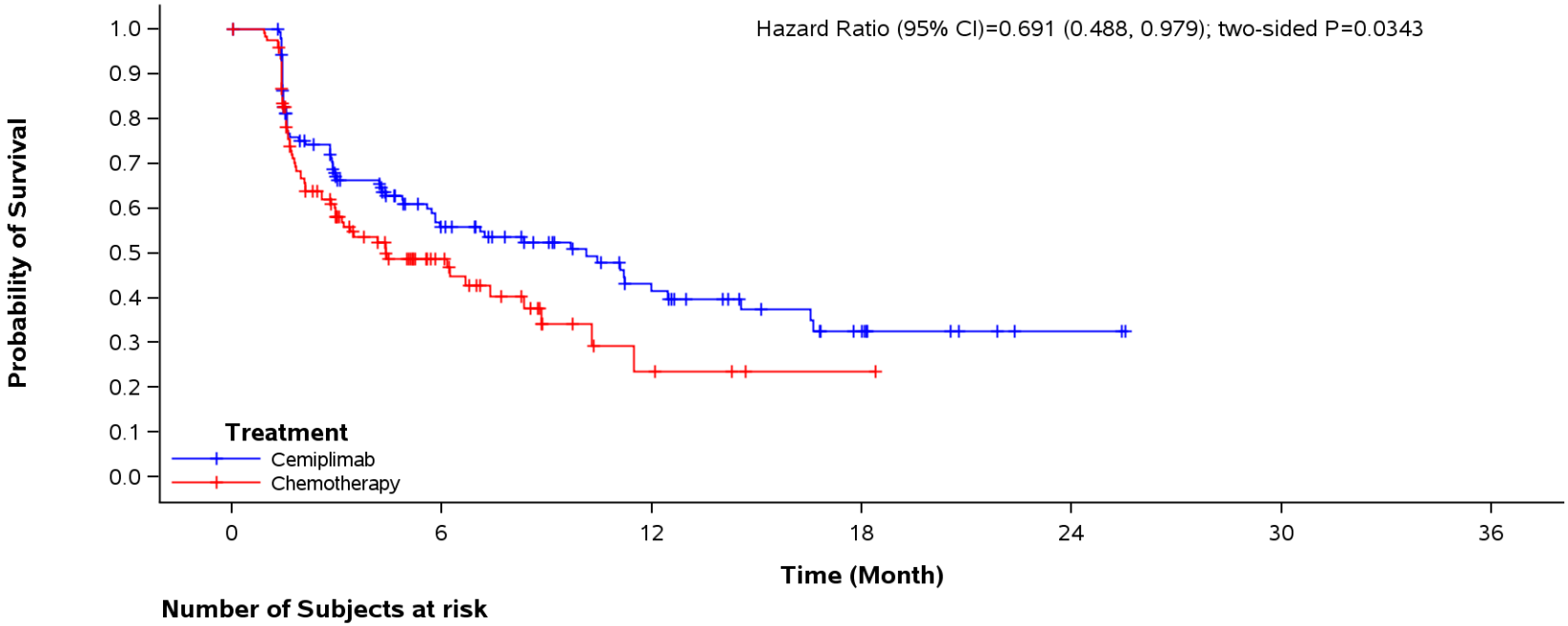

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 65 | 30 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 36 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts sustained deterioration



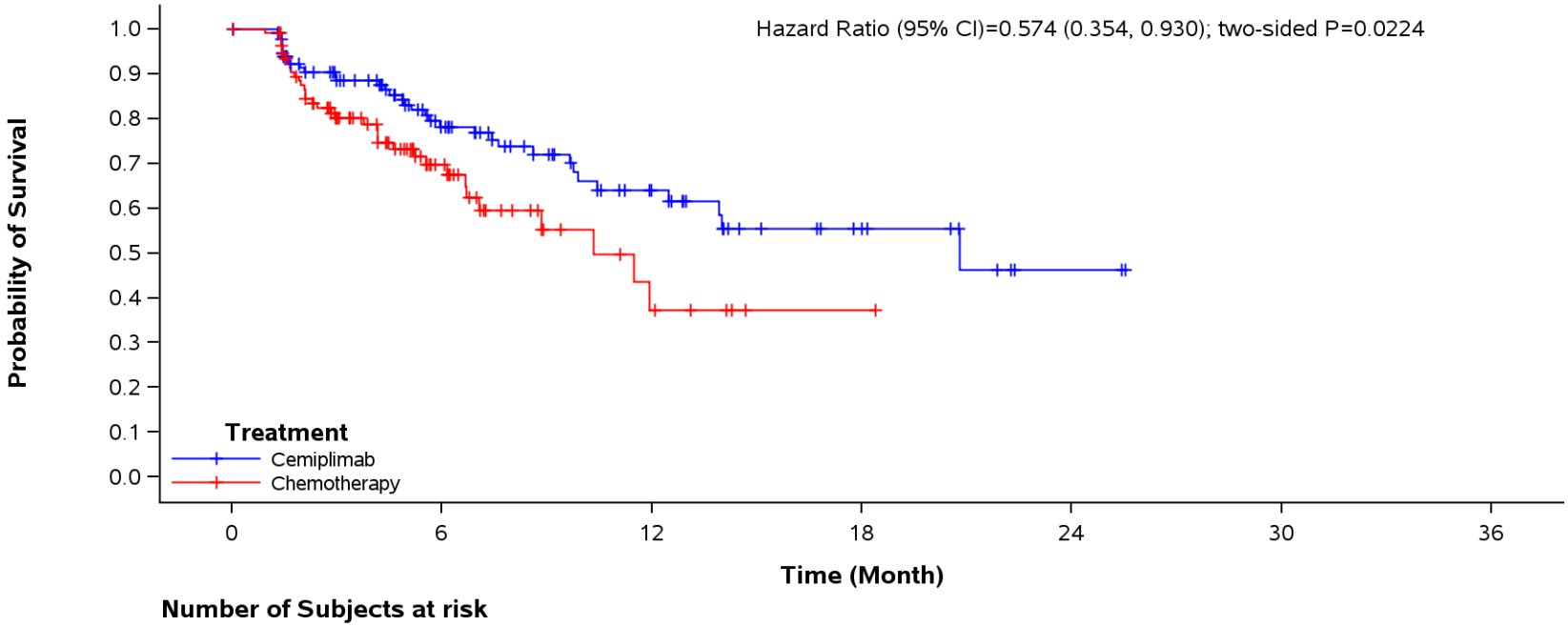

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 55 | 25 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts sustained deterioration



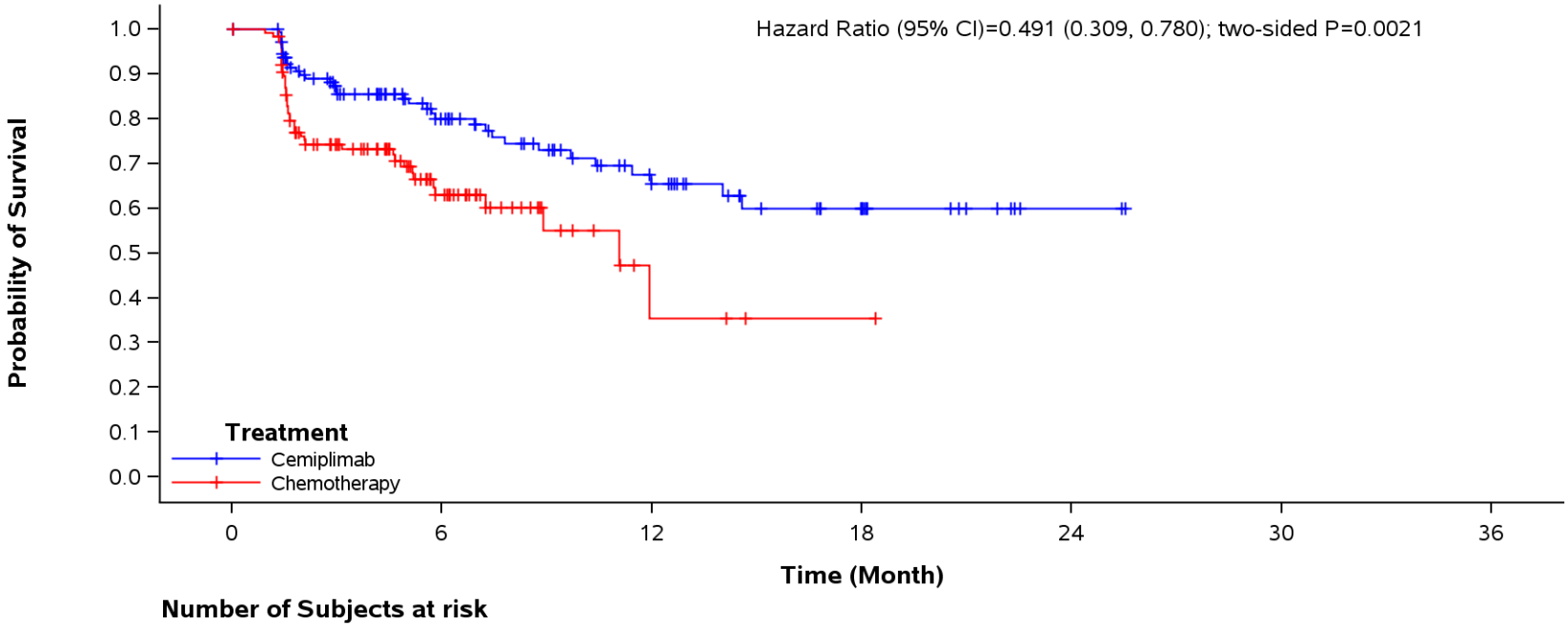

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 60 | 26 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts sustained deterioration



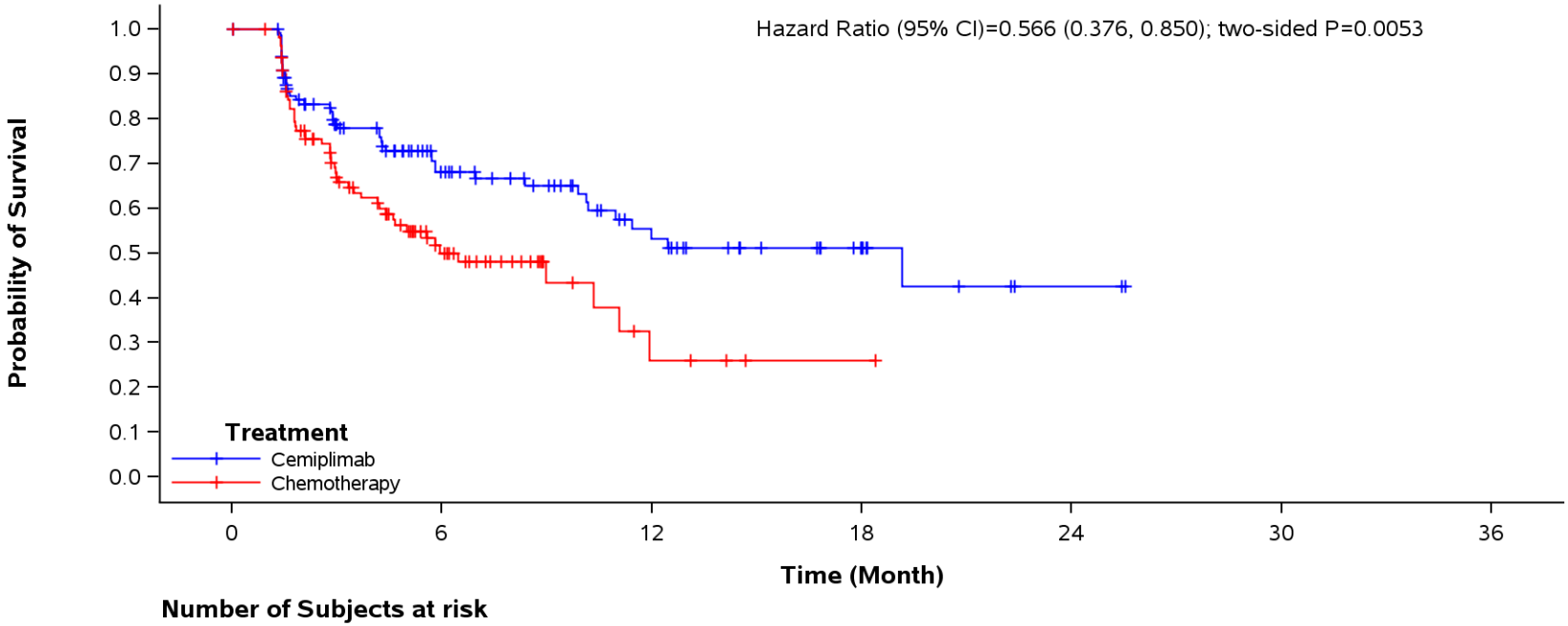

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 68 | 31 | 14 | 2 | 0 | 0 |
| Chemotherapy | 163 | 35 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts sustained deterioration



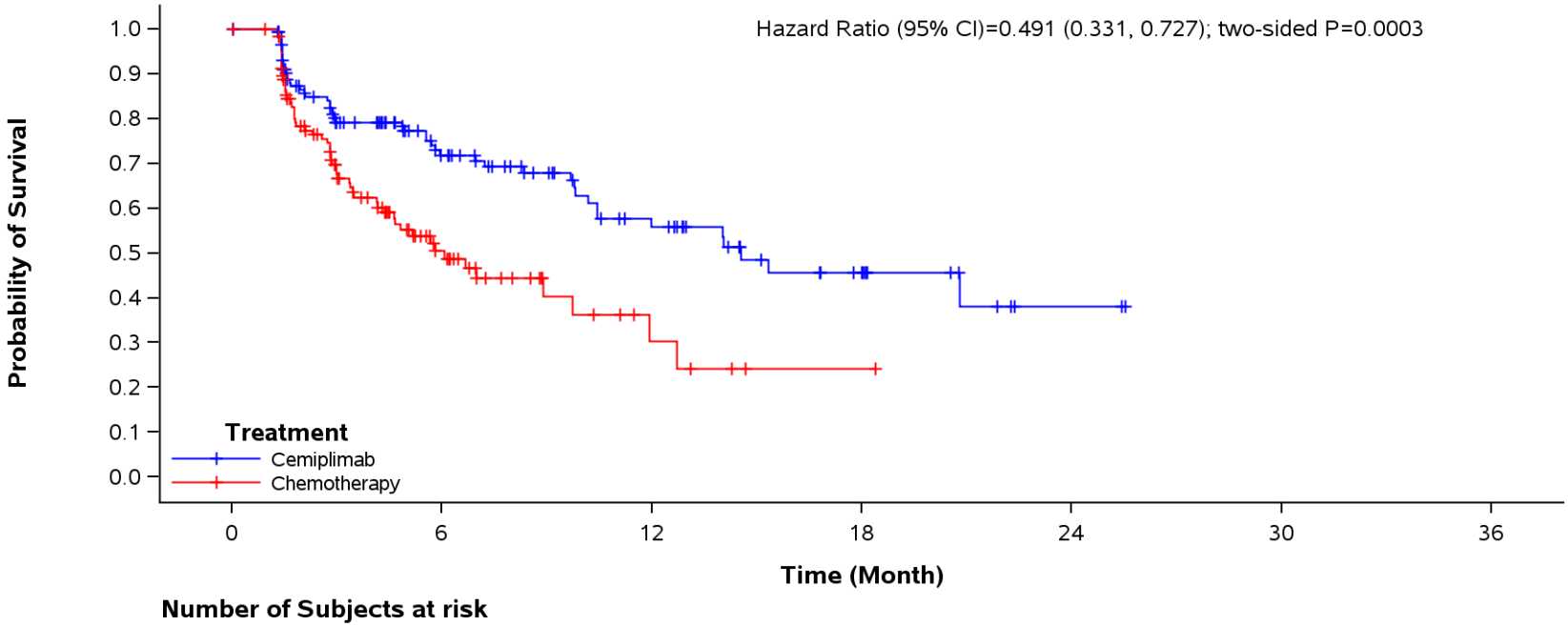

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 55 | 25 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 30 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts sustained deterioration



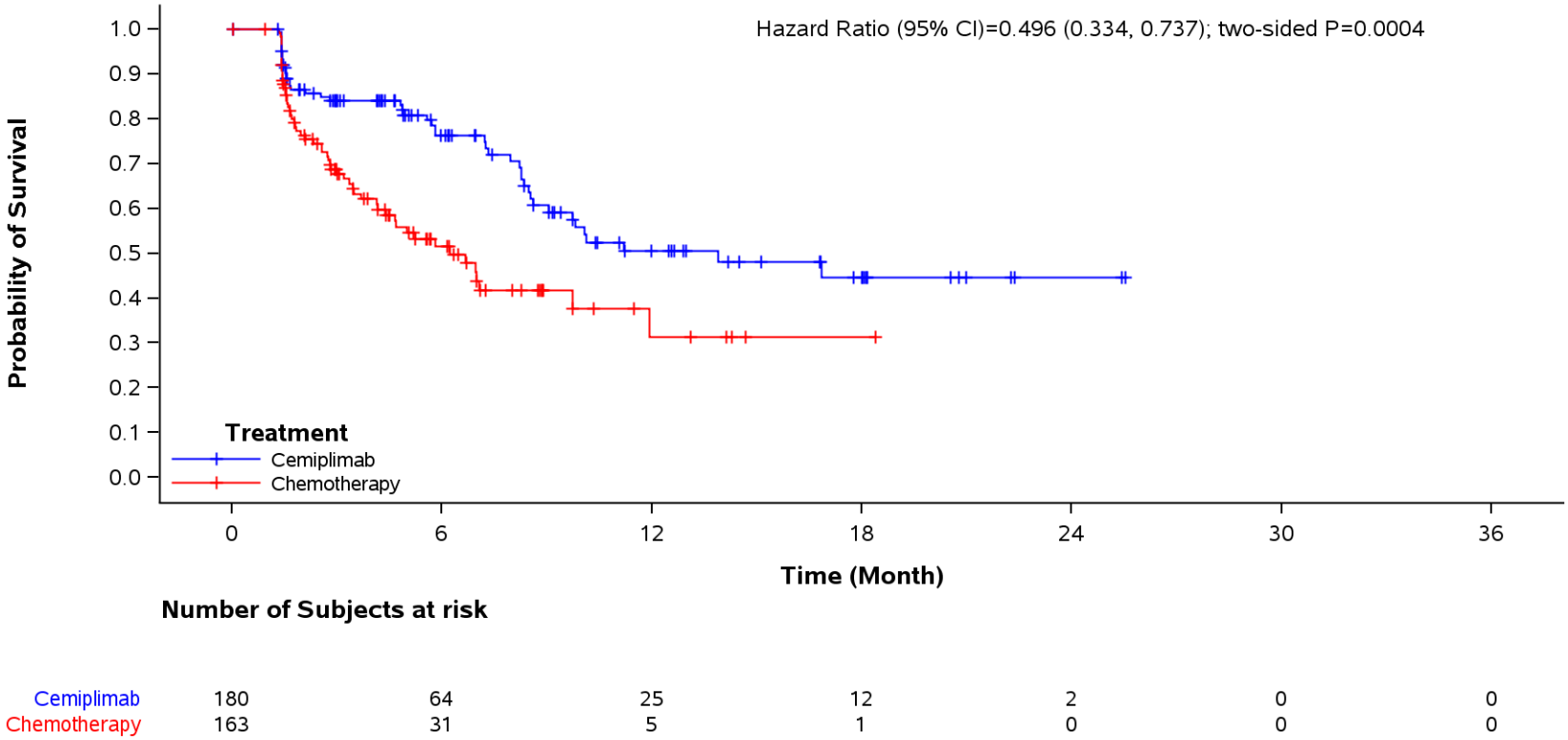

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 64 | 30 | 13 | 2 | 0 | 0 |
| Chemotherapy | 163 | 29 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Global health status / QoL - 10 pts sustained deterioration



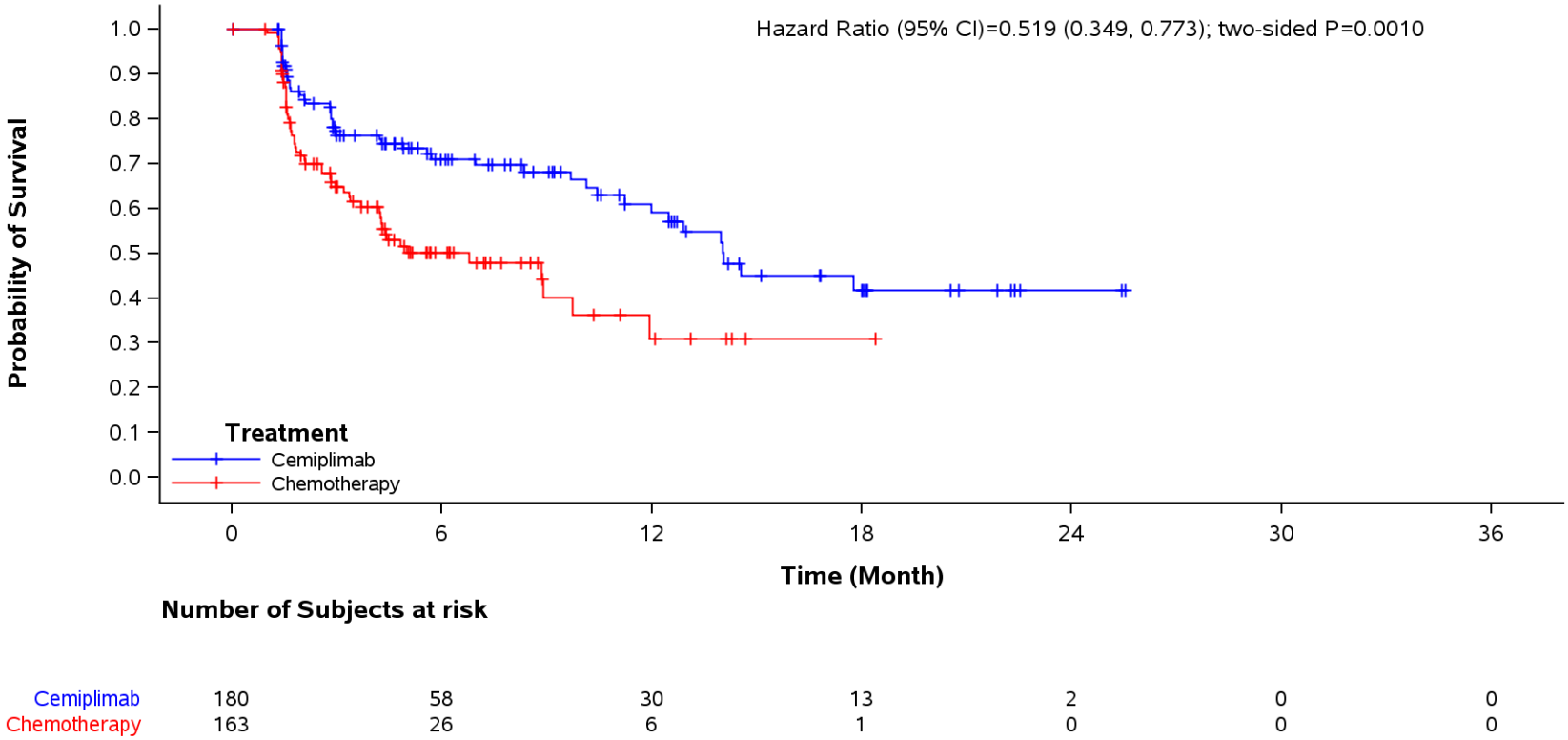

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 64 | 25 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 31 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts sustained deterioration



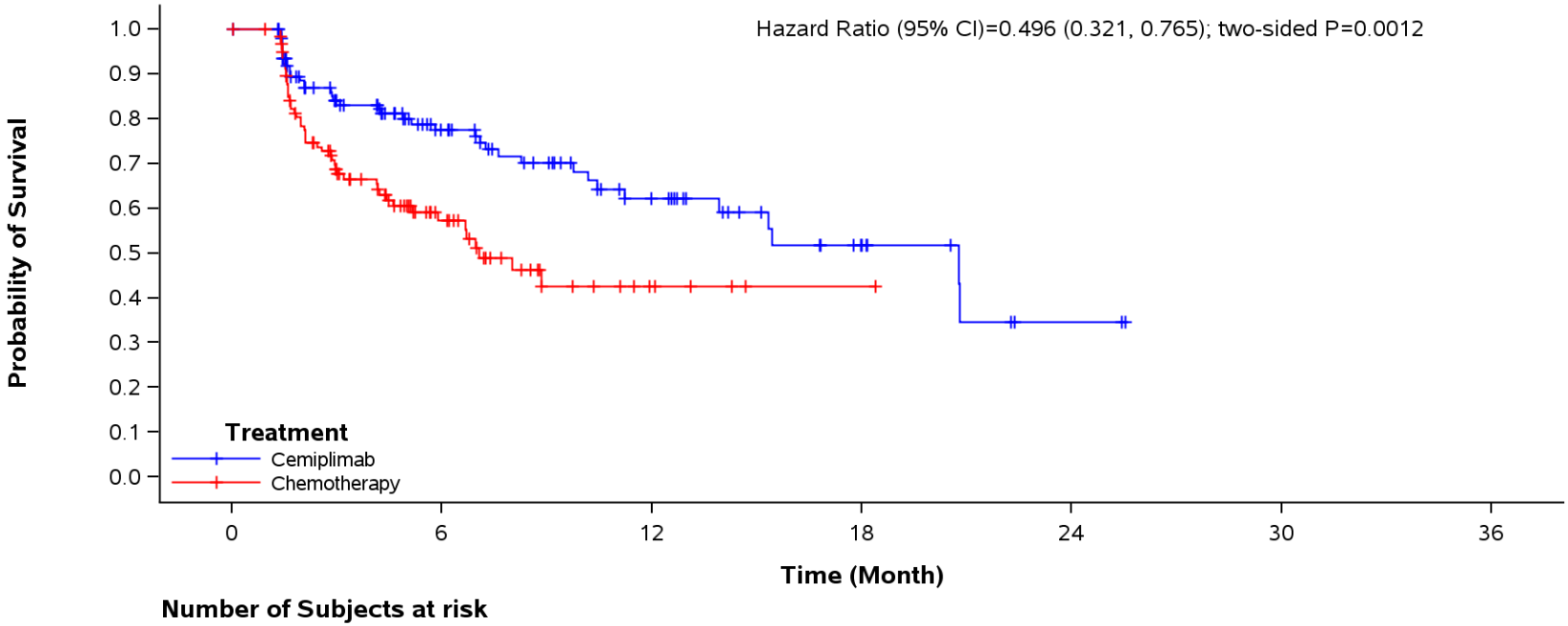

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 58 | 30 | 13 | 2 | 0 | 0 |
| Chemotherapy | 163 | 26 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts sustained deterioration



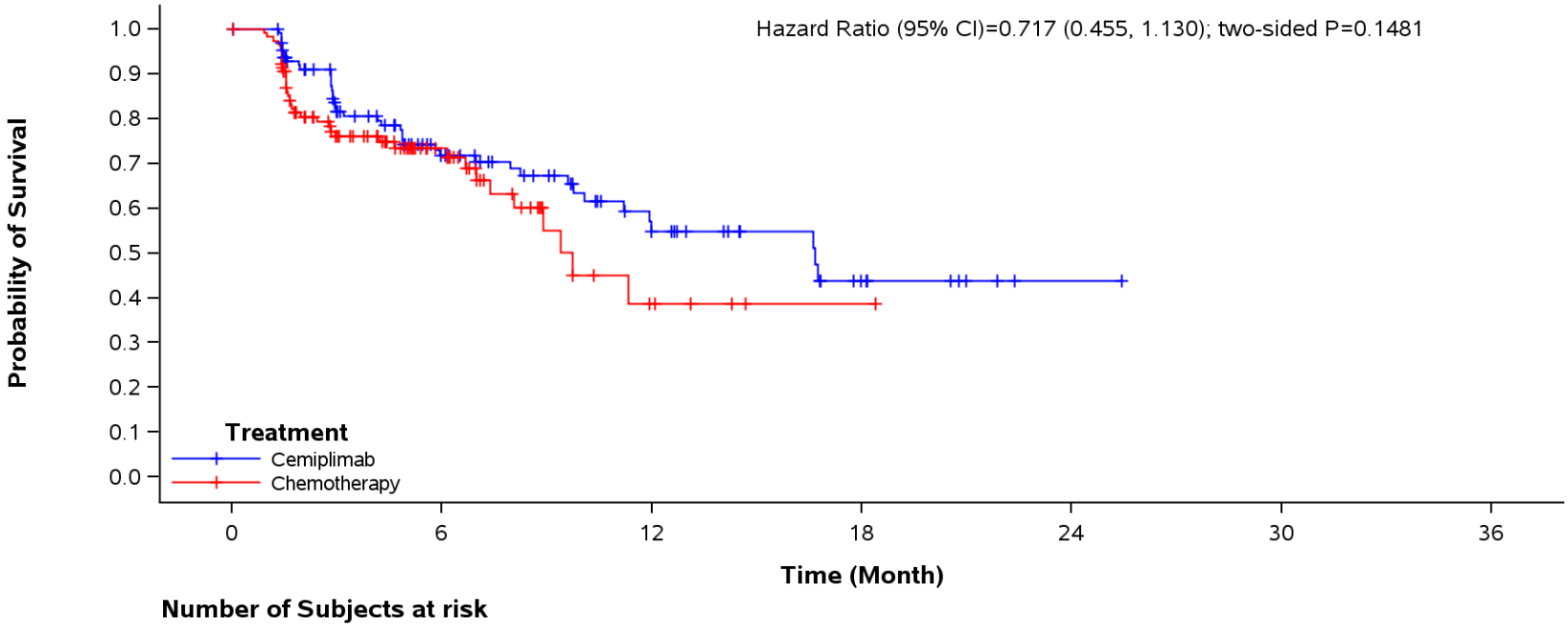

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 60 | 27 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 32 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts sustained deterioration



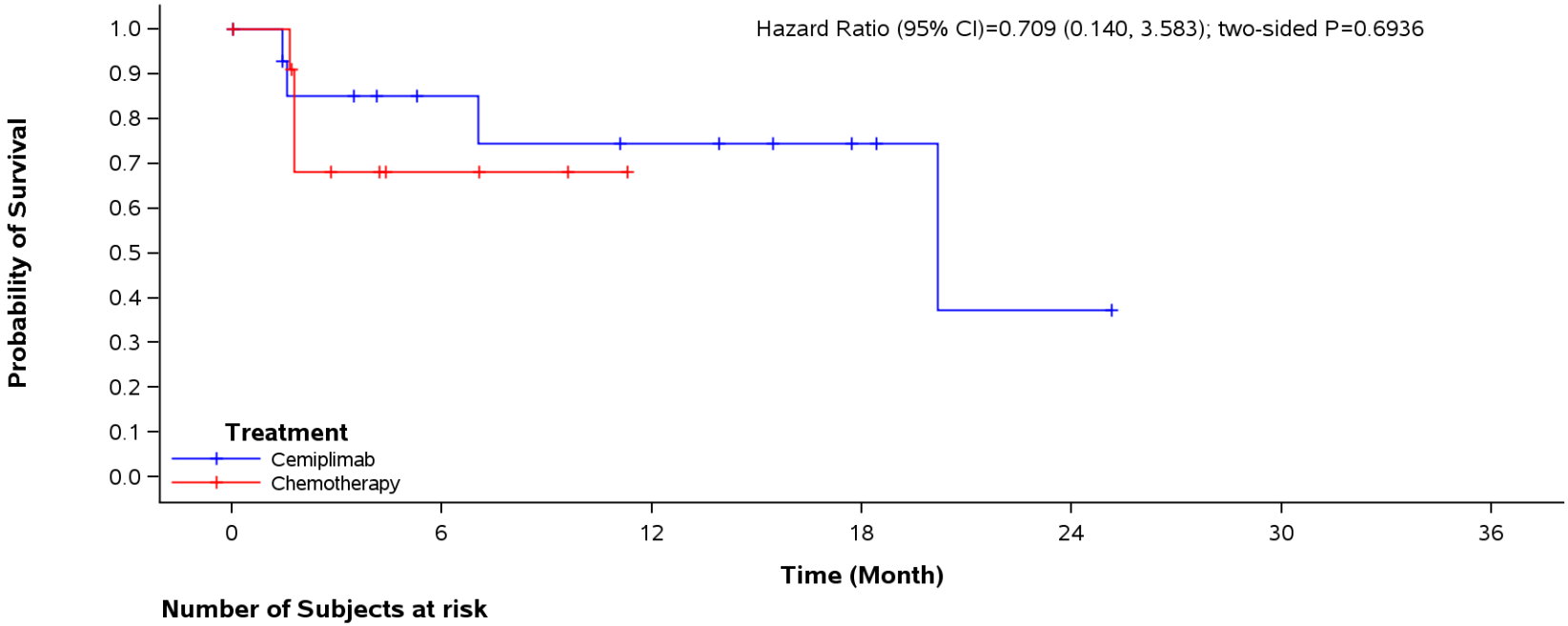

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 57 | 23 | 8 | 1 | 0 | 0 |
| Chemotherapy | 163 | 36 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts sustained deterioration



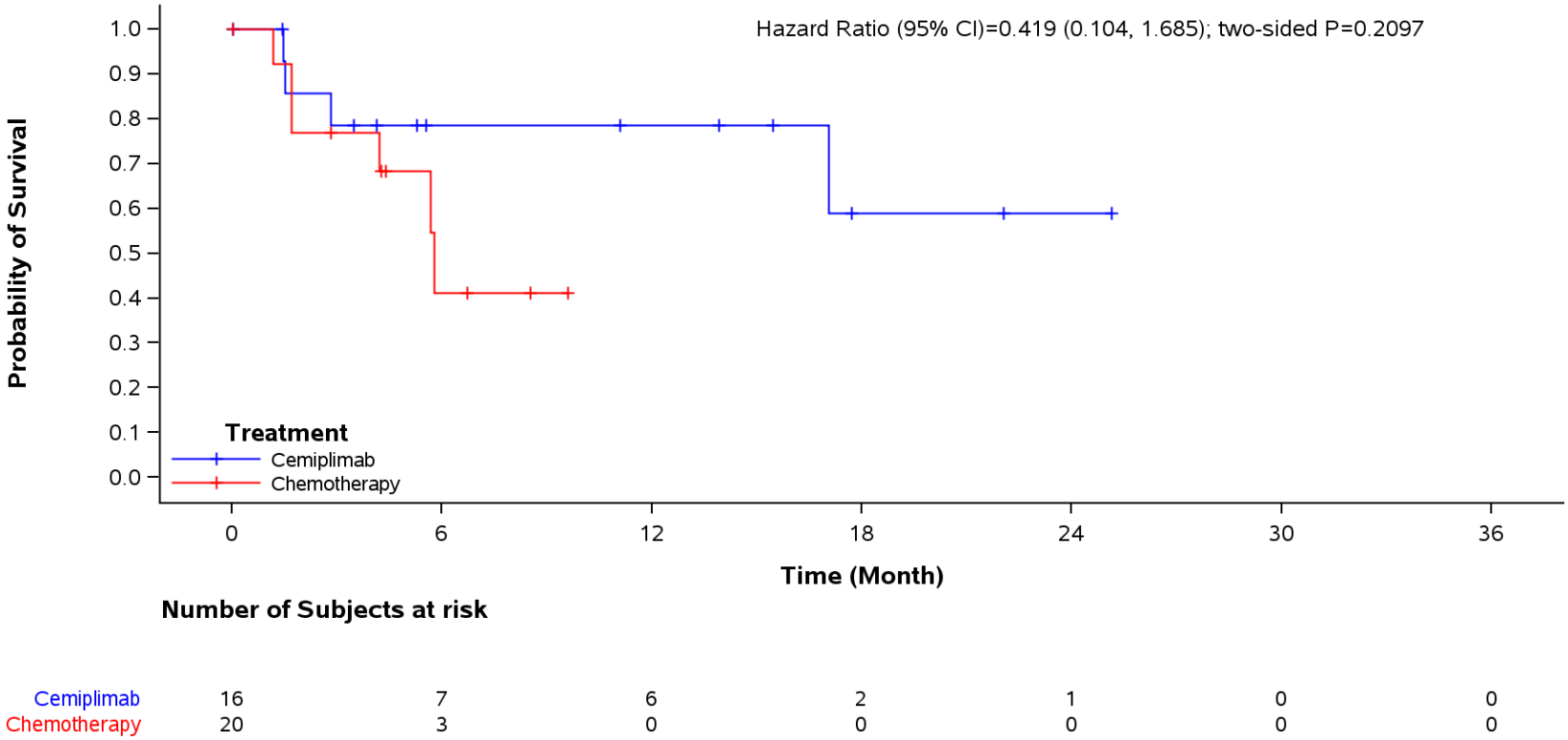

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts sustained deterioration



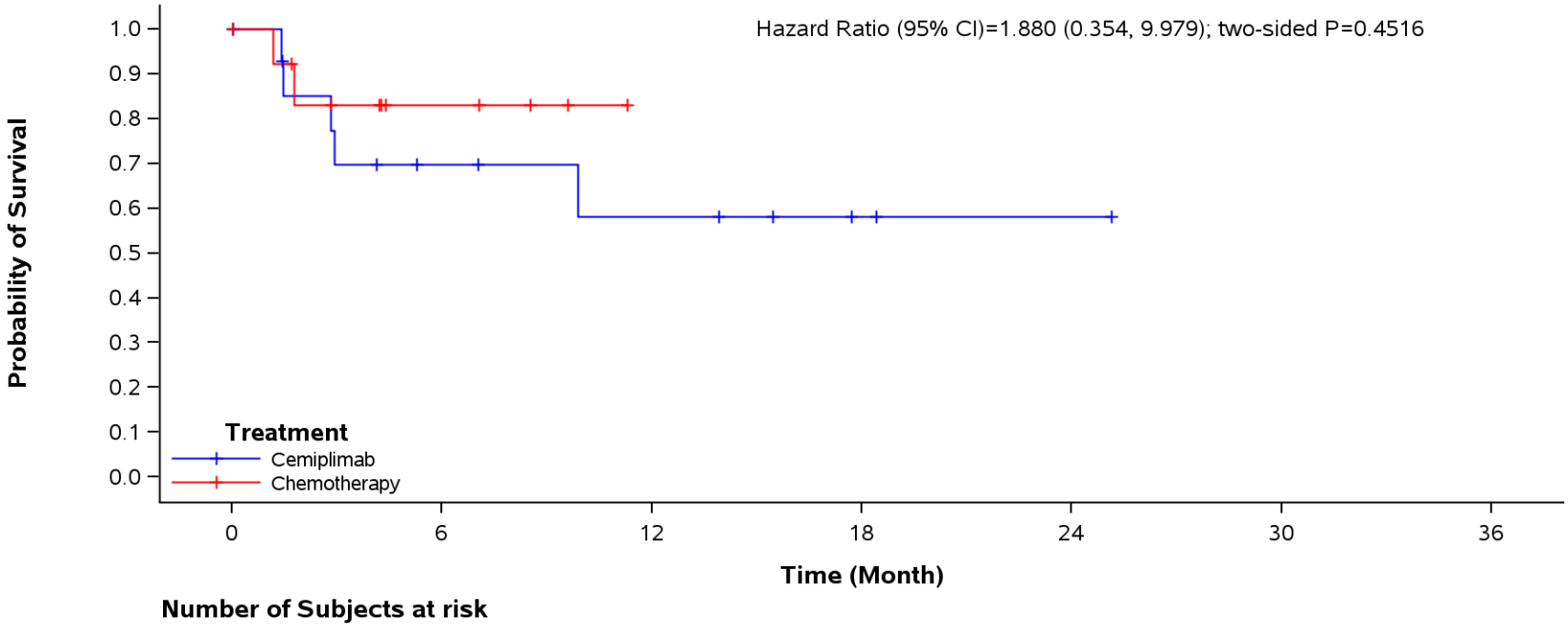

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 6 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts sustained deterioration



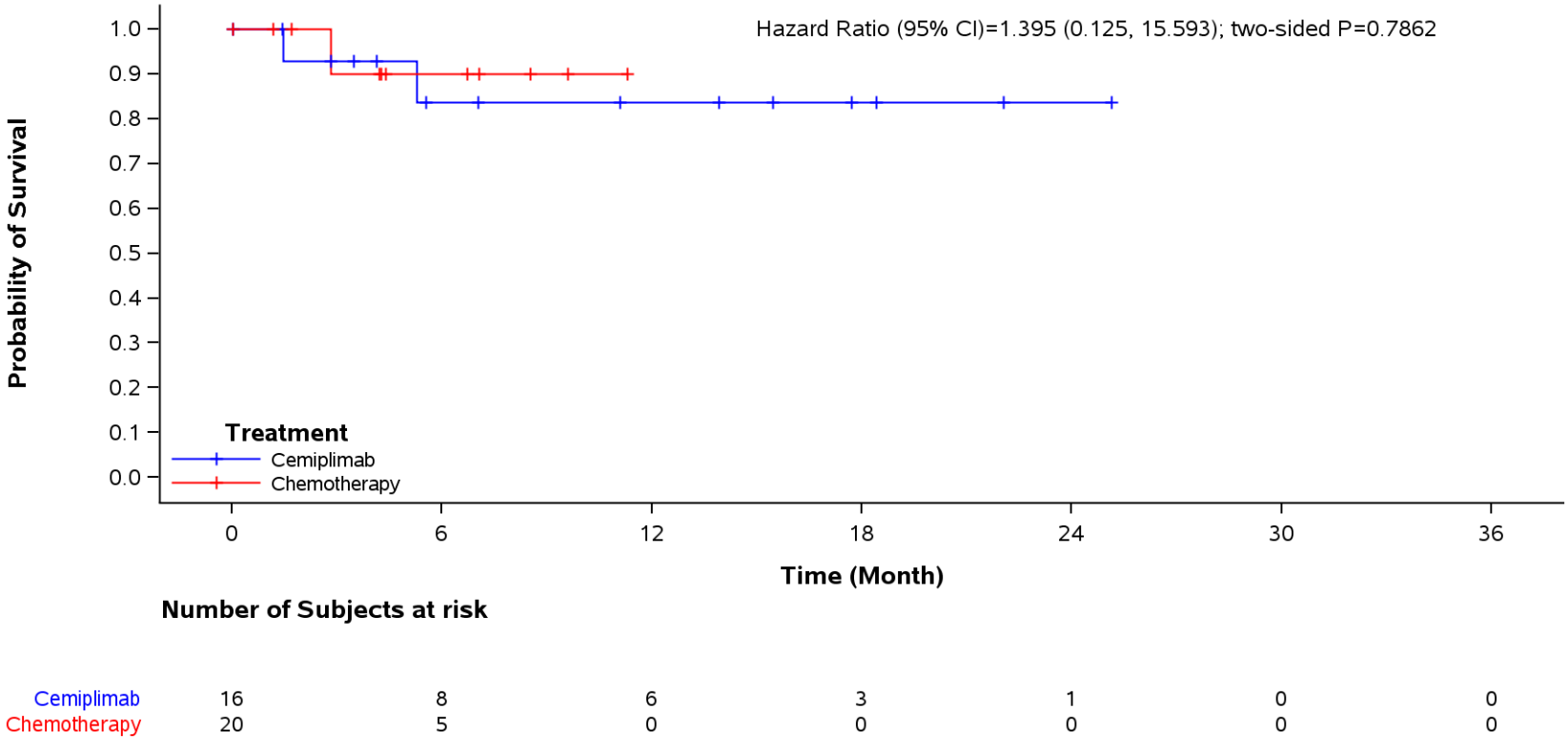

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts sustained deterioration



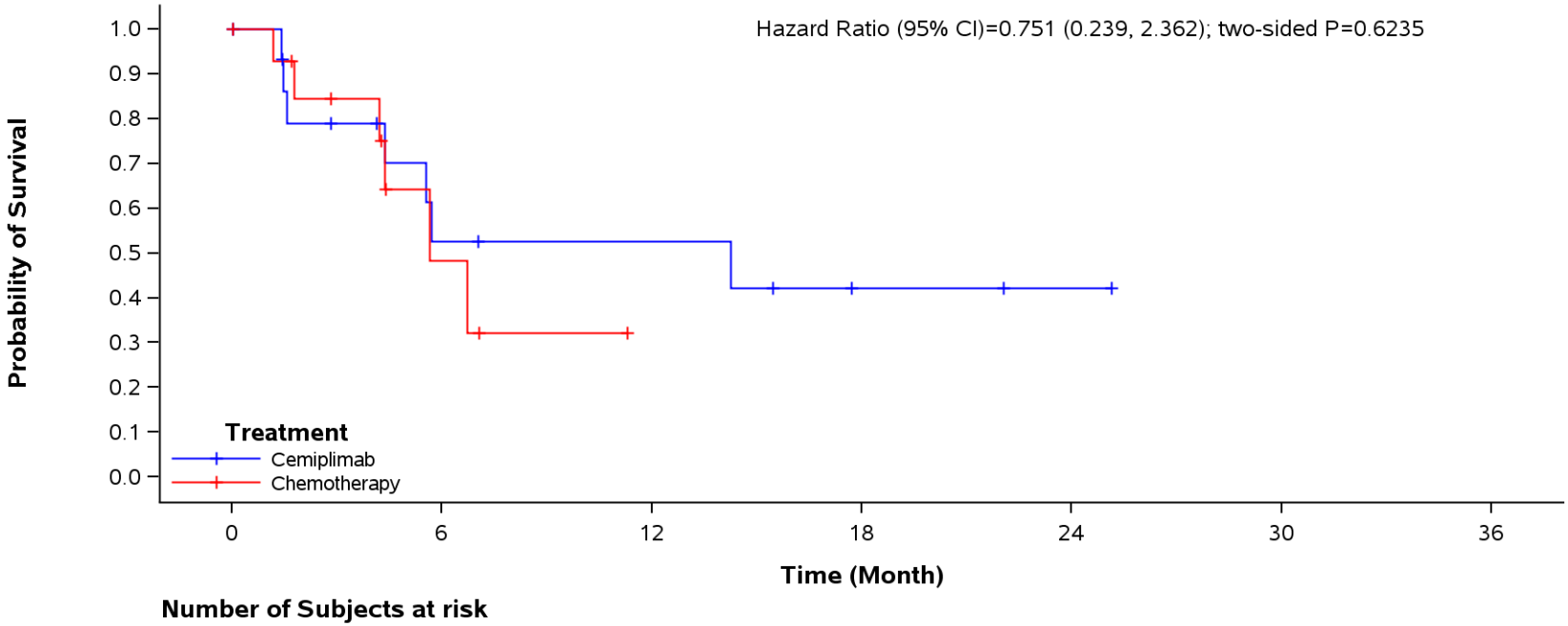

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts sustained deterioration




Number of Subjects at risk

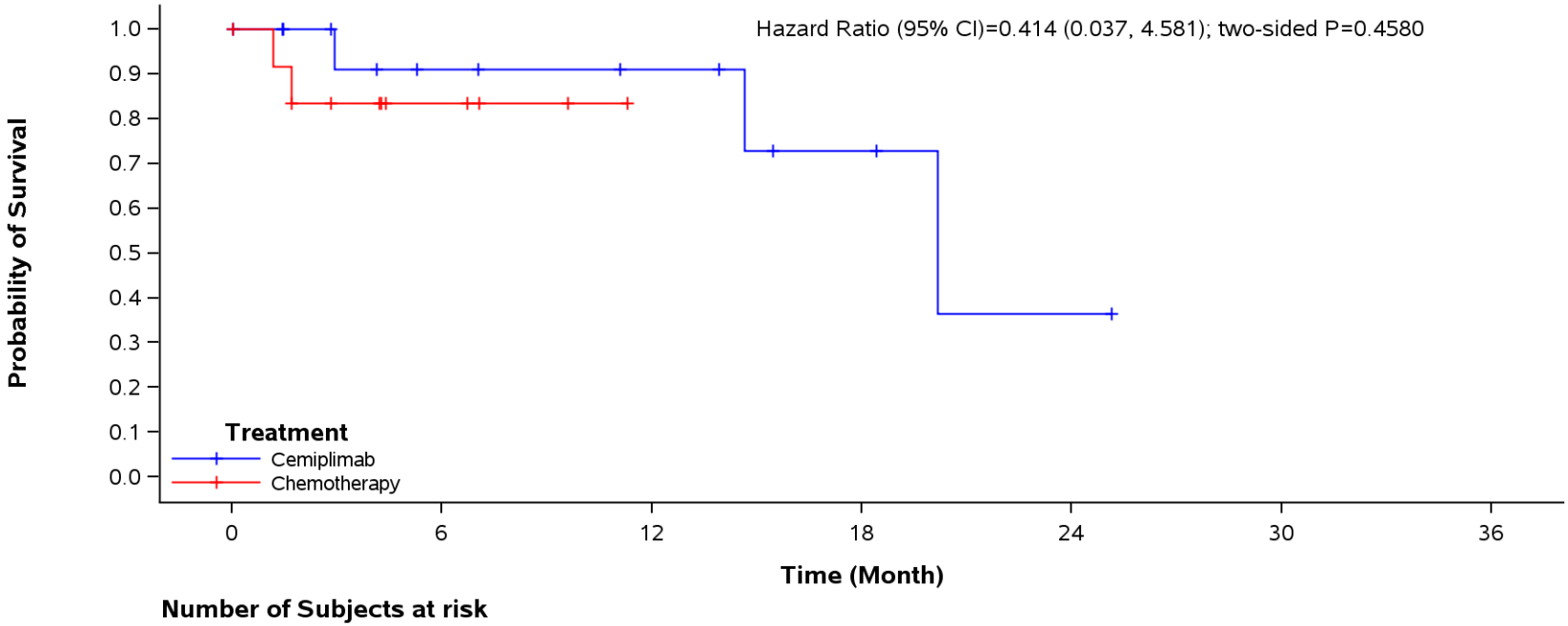
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:23:03, yingyuan.lin)

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts sustained deterioration



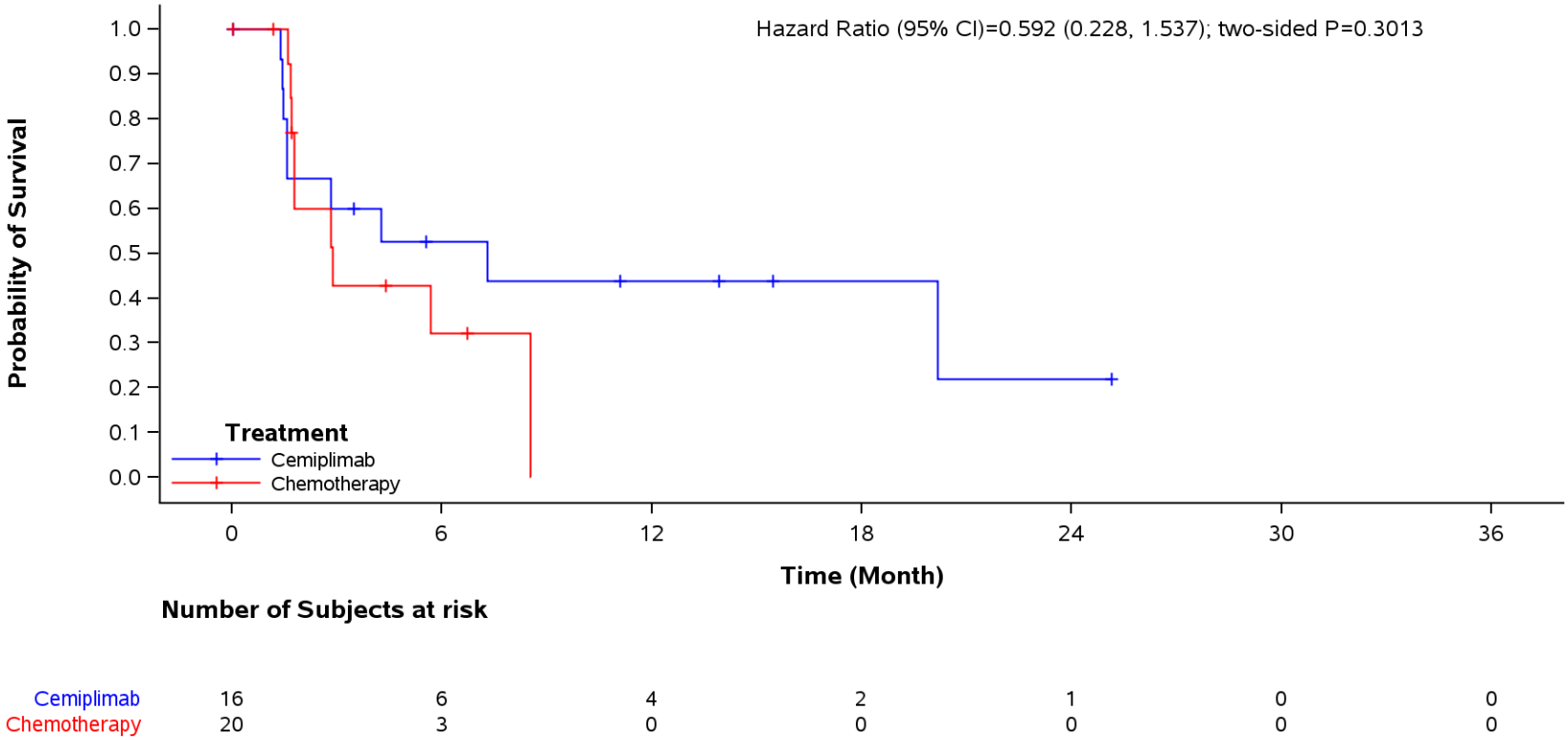

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

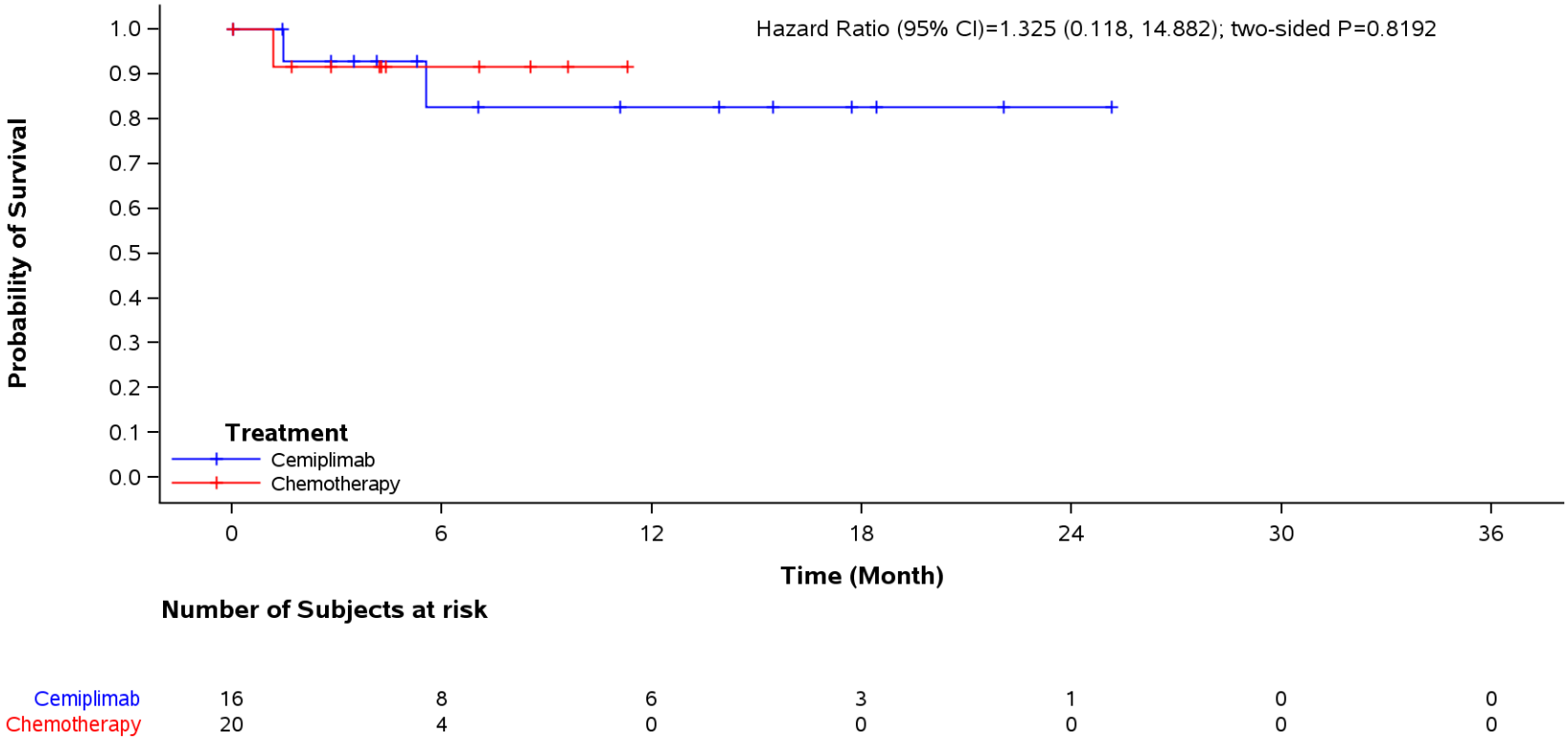
Age Group: >=65
Fatigue - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

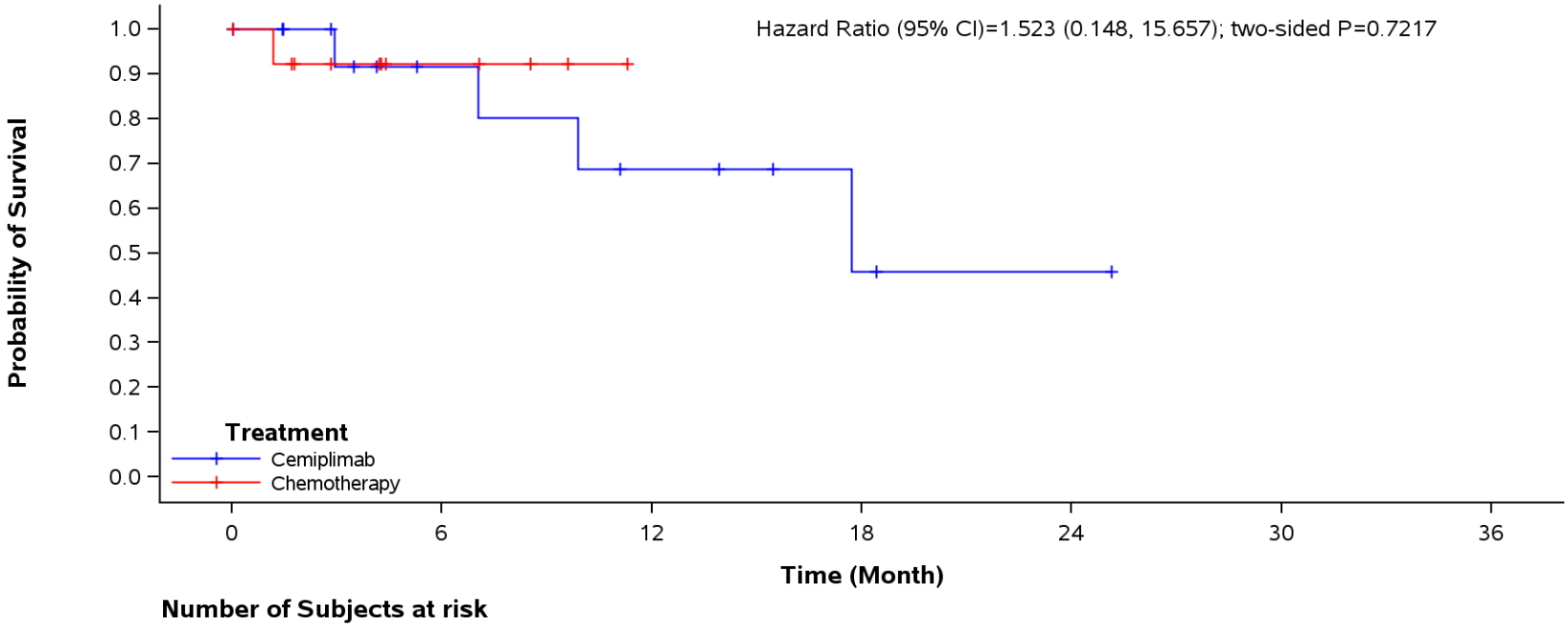
Age Group: >=65
Financial Problems - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Nausea / Vomiting - 10 pts sustained deterioration



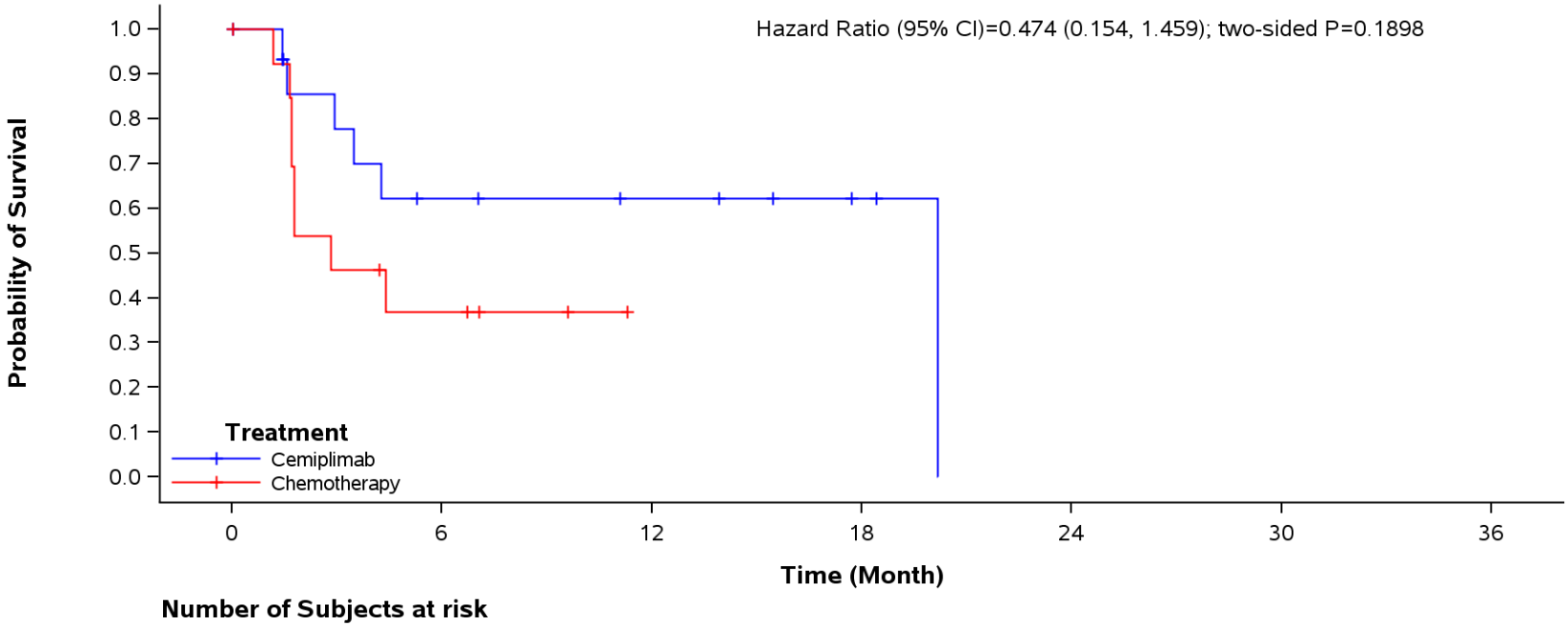

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts sustained deterioration



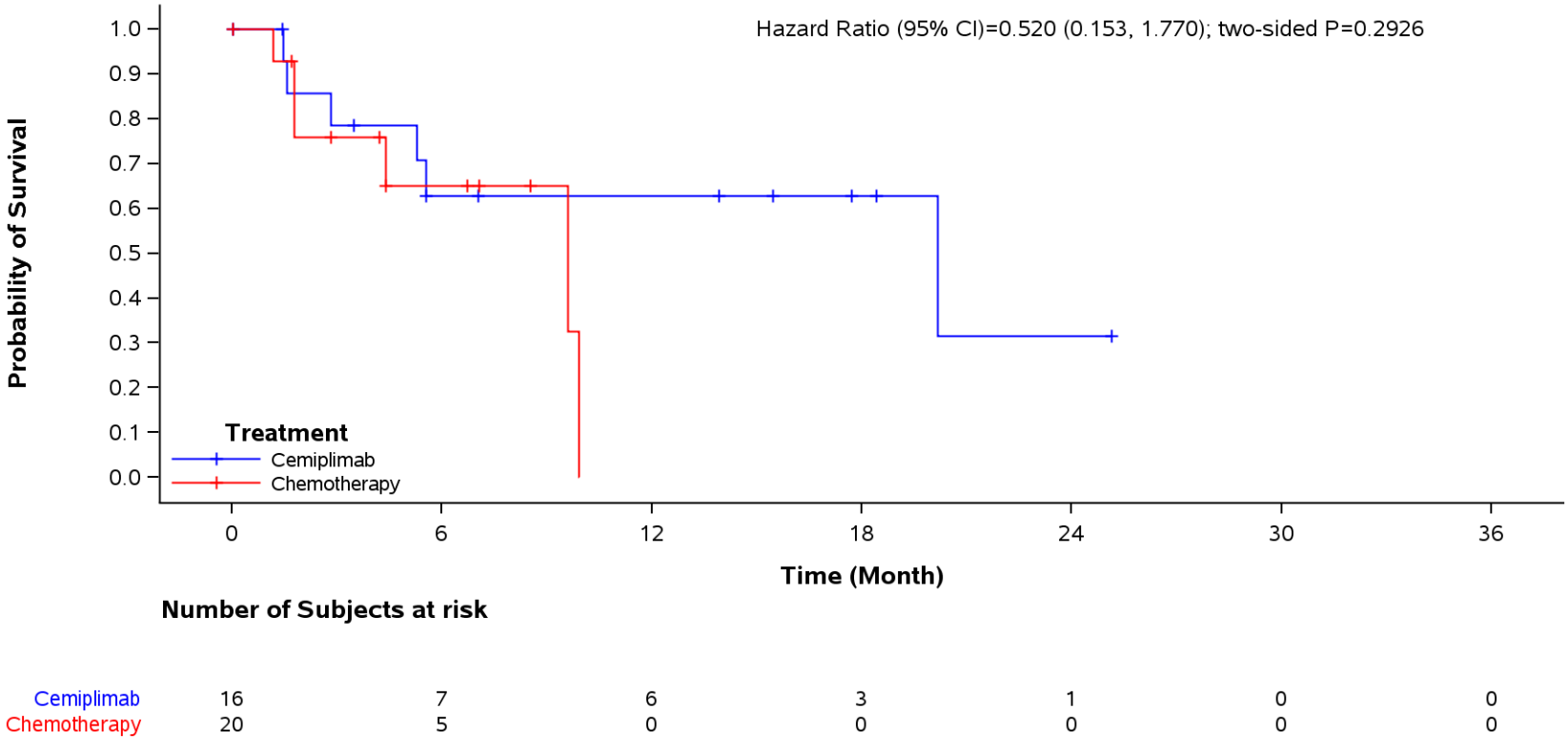

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Physical Functioning - 10 pts sustained deterioration



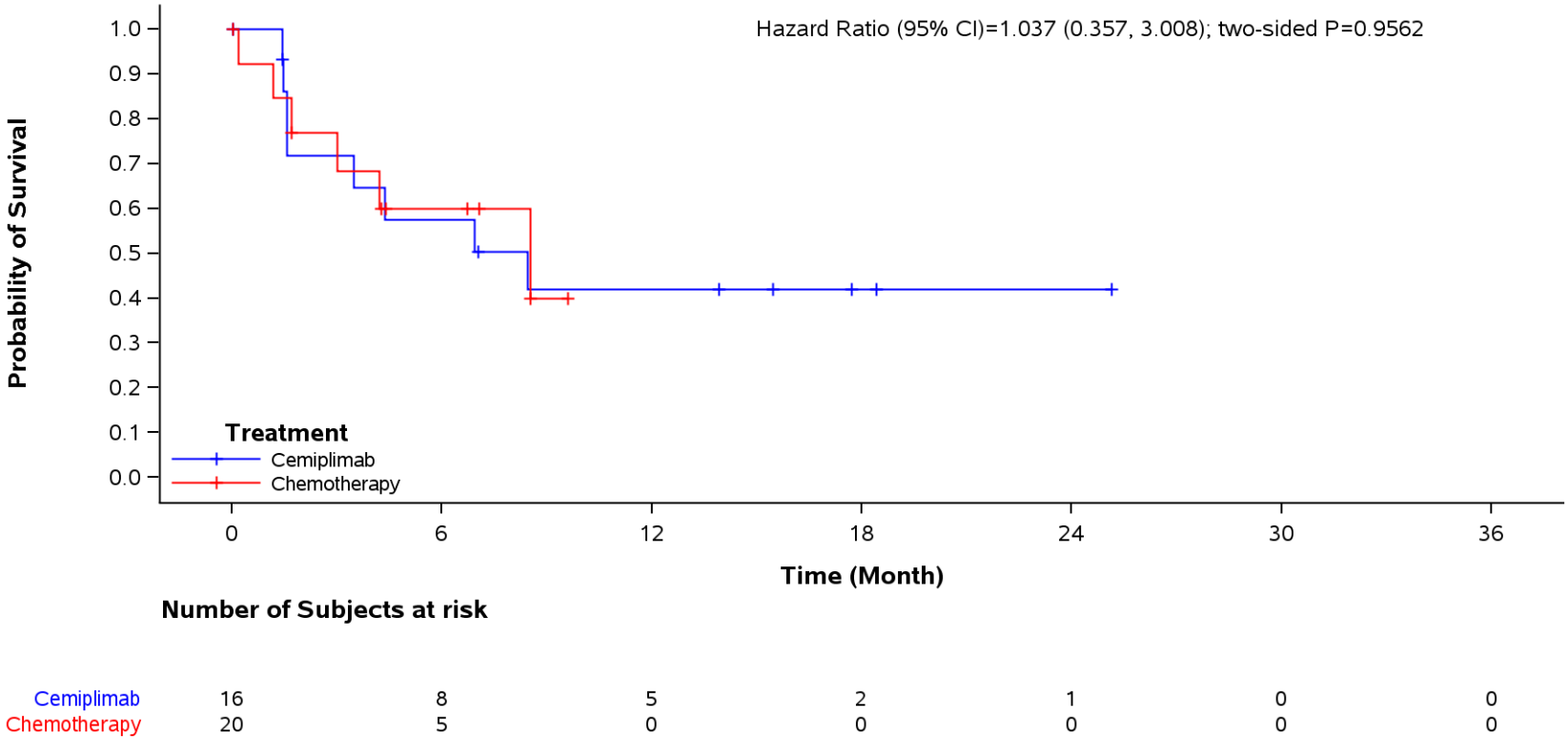

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

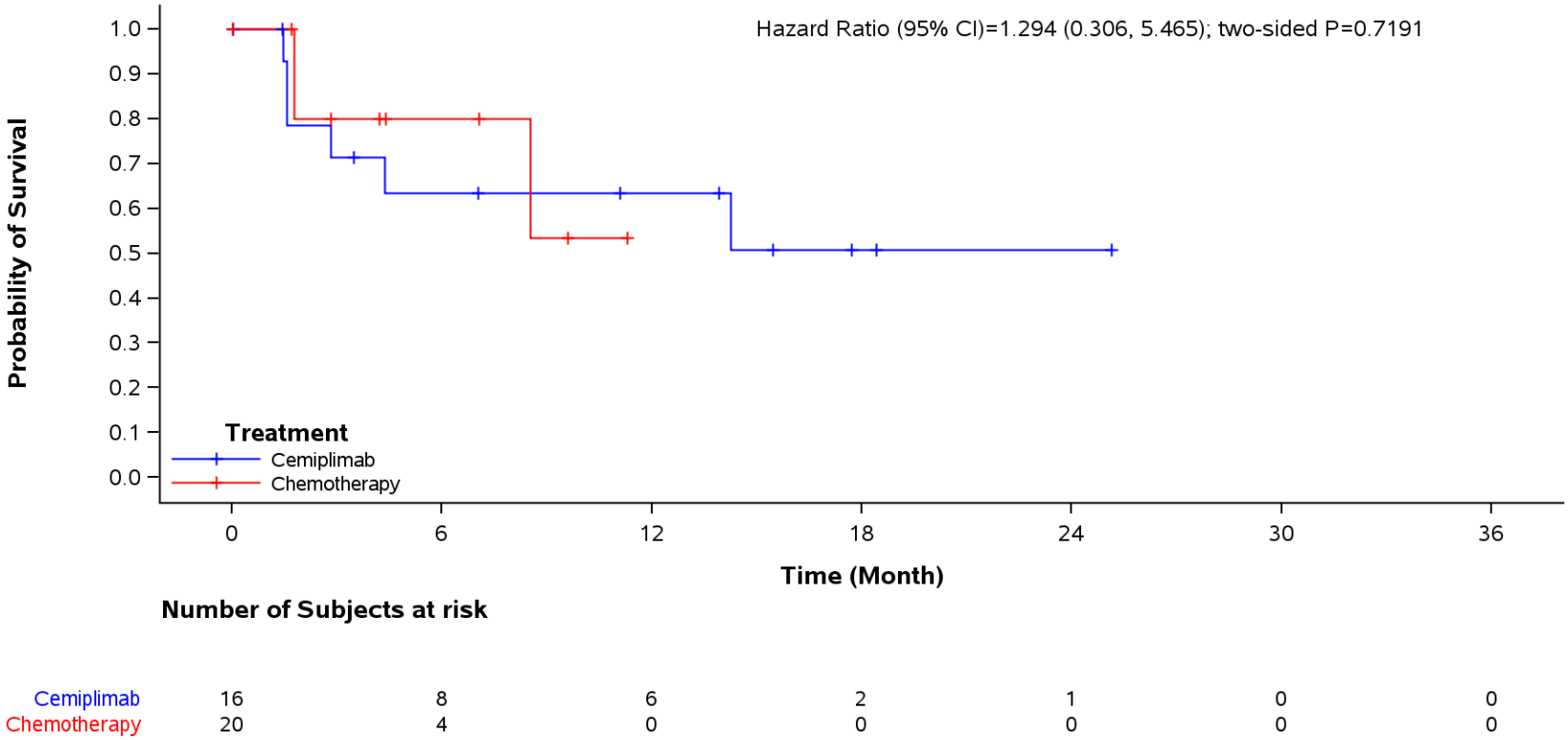
Age Group: >=65
Global health status / QoL - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts sustained deterioration



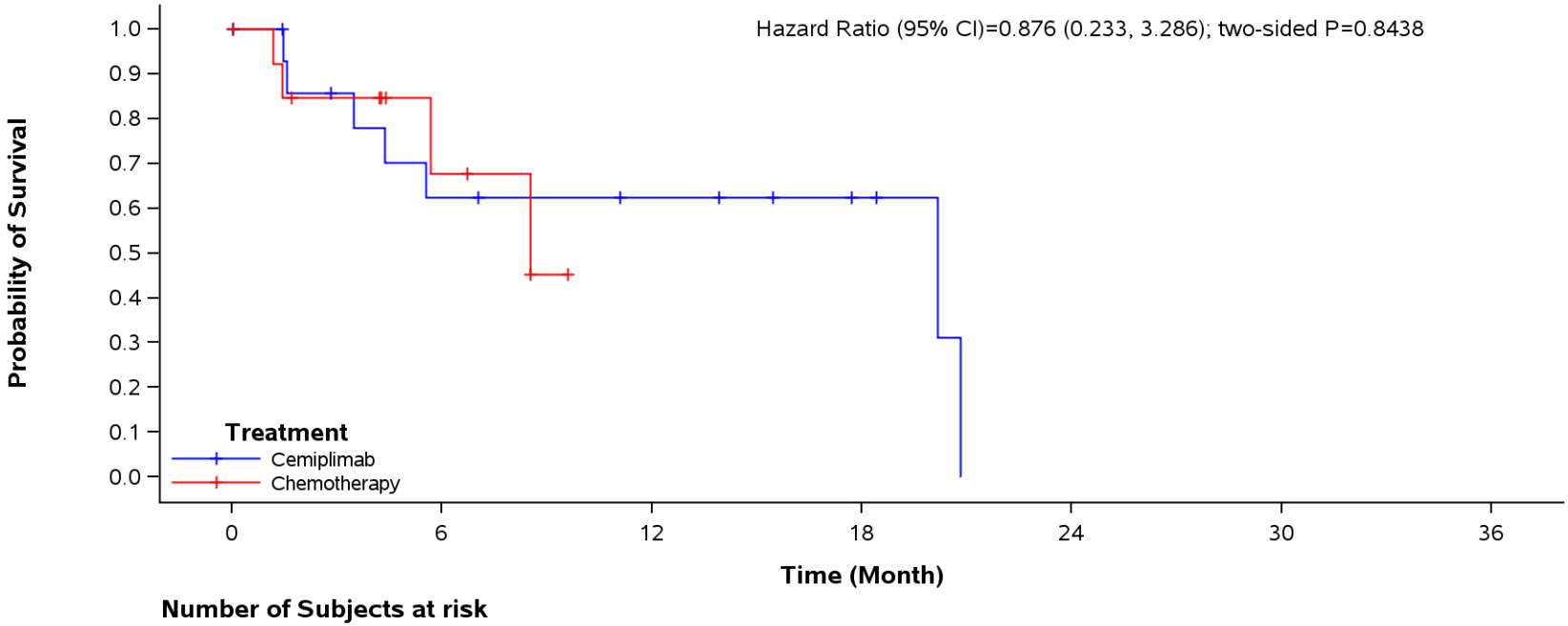

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Social Functioning - 10 pts sustained deterioration



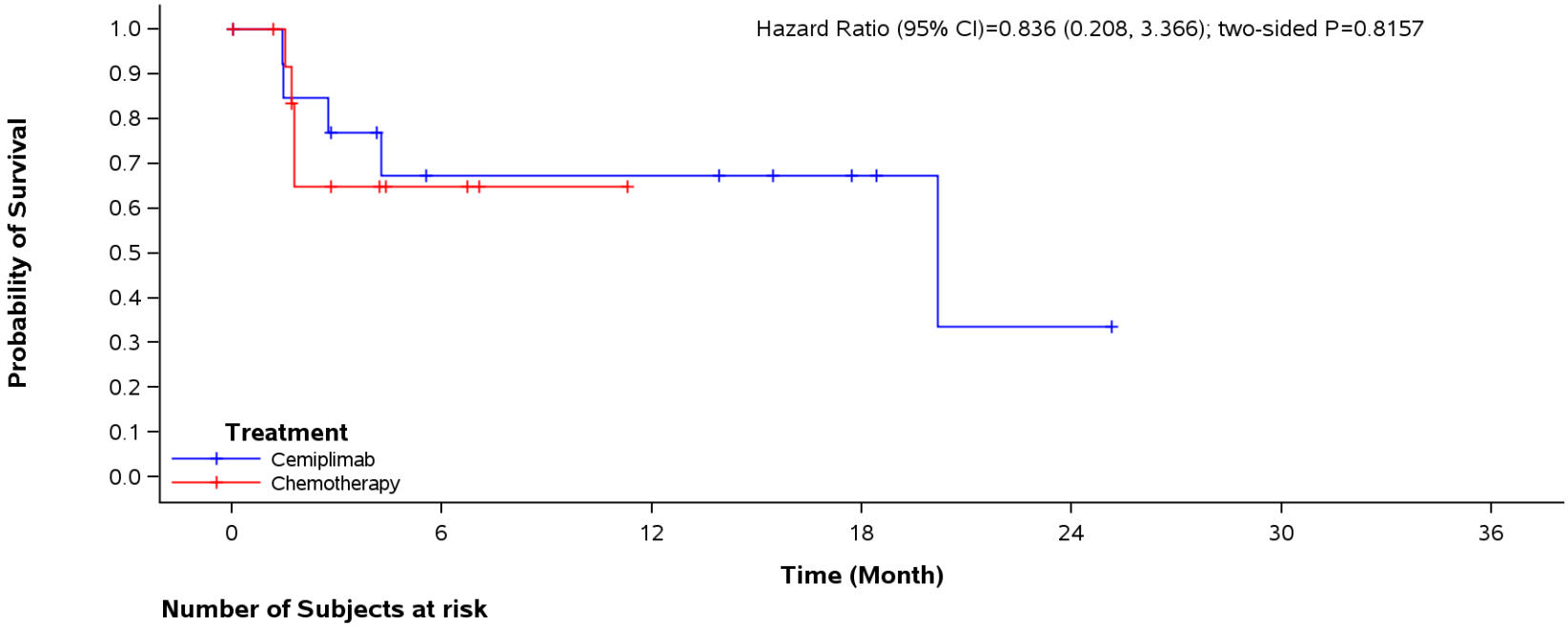

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts sustained deterioration




Number of Subjects at risk

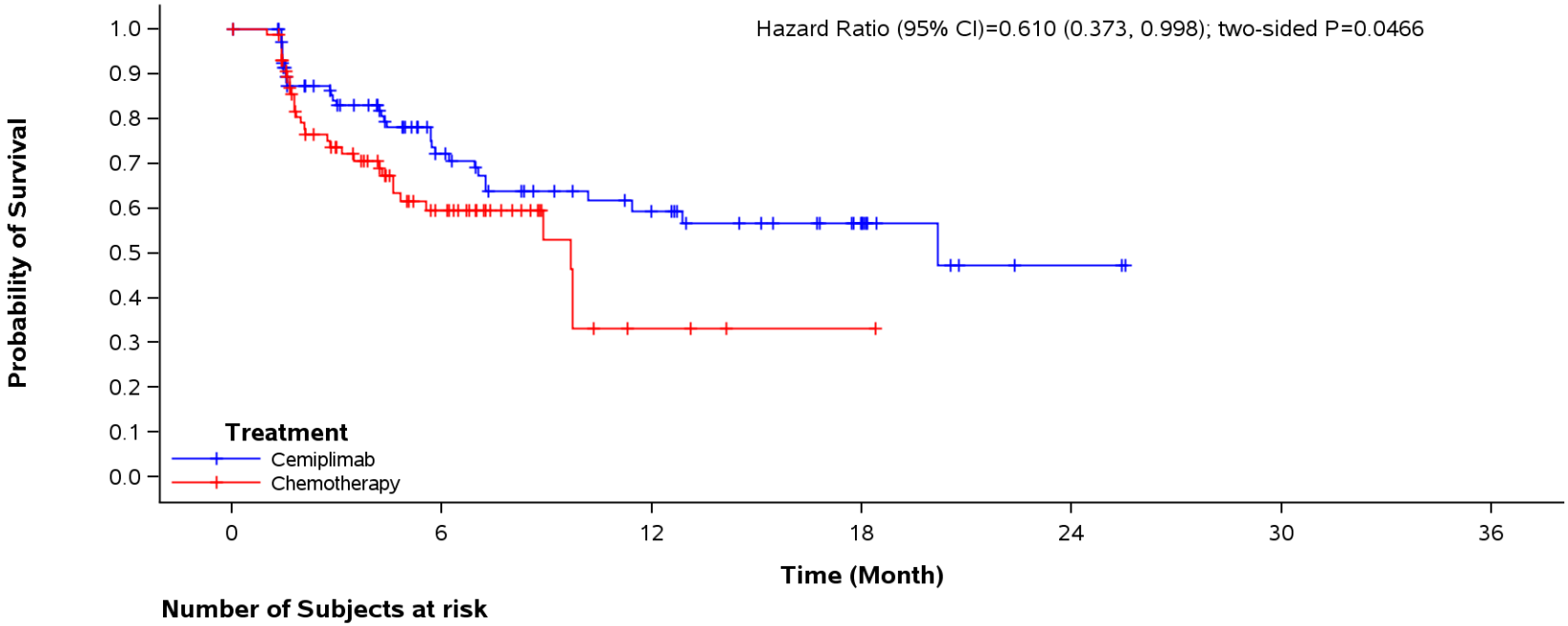
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Appetite loss - 10 pts sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 48 | 25 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 27 | 3 | 1 | 0 | 0 | 0 |

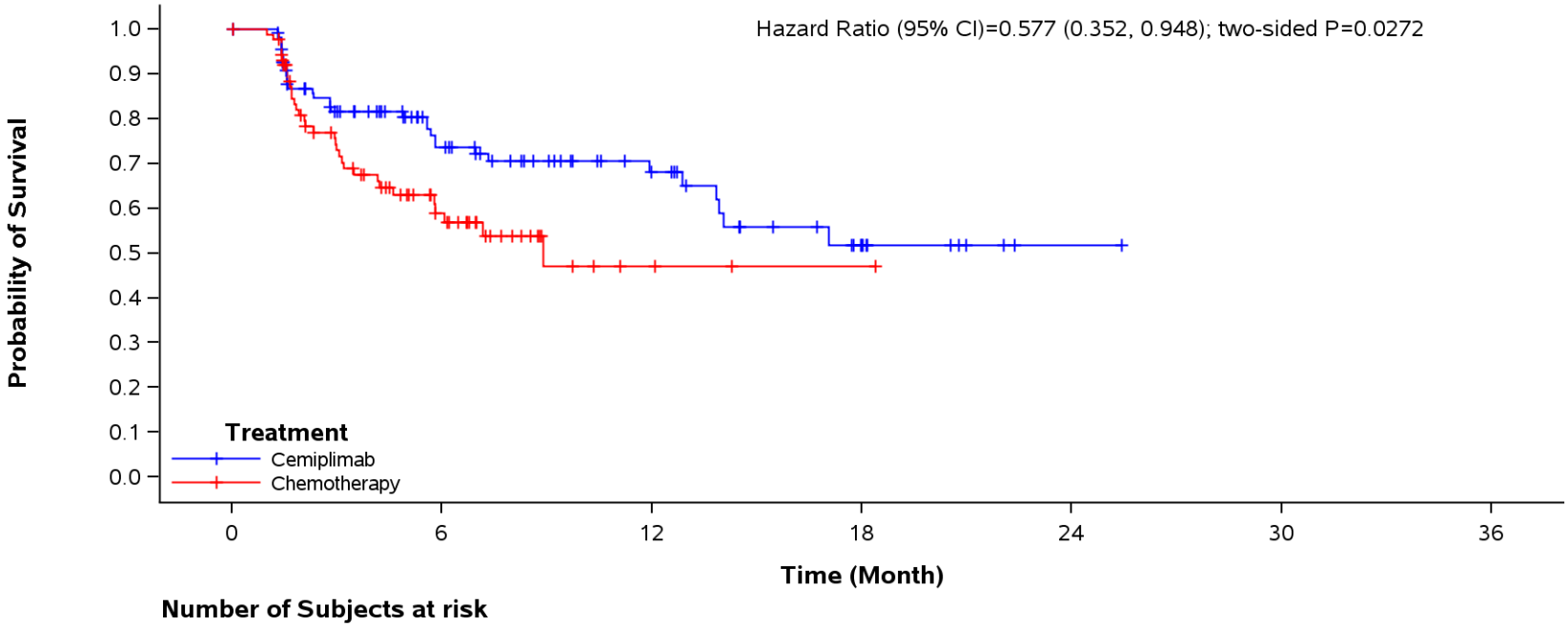
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Cognitive Functioning - 10 pts sustained deterioration




**Number of Subjects at risk**

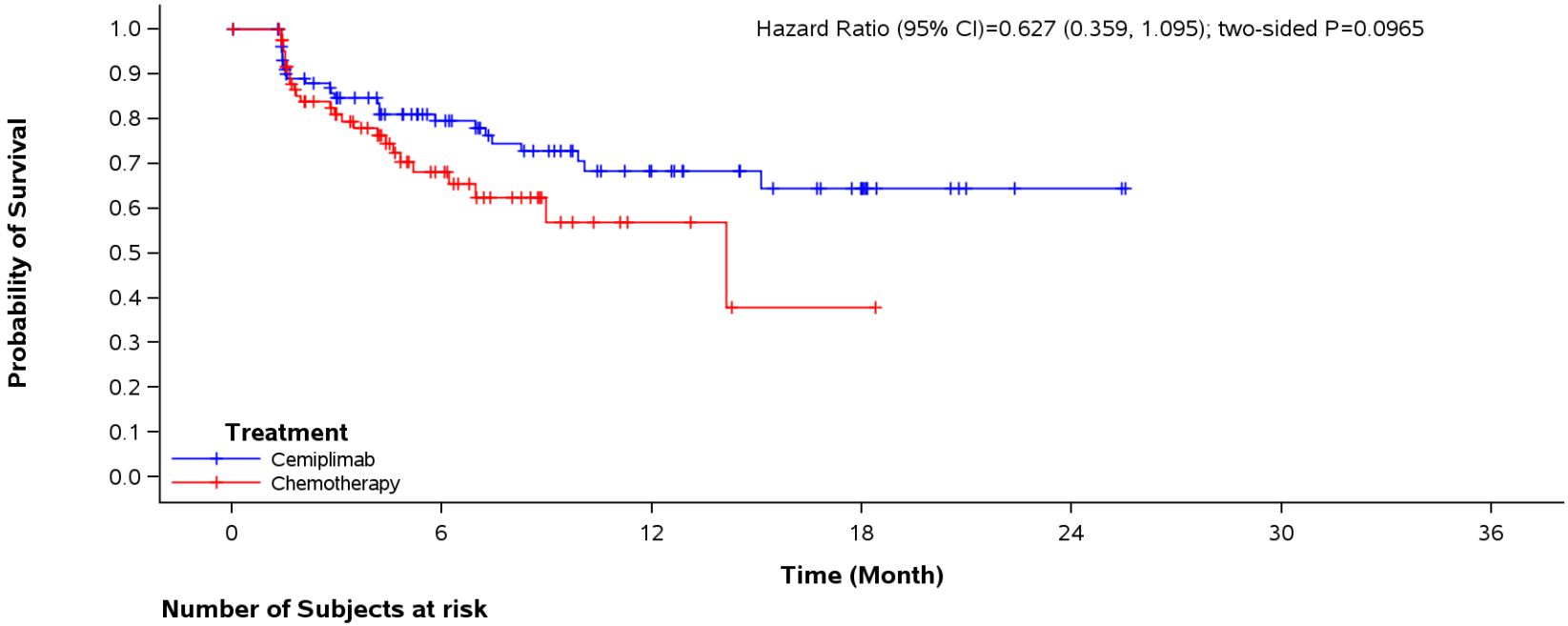
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 54 | 26 | 10 | 1 | 0 | 0 |
| Chemotherapy | 123 | 28 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Constipation - 10 pts sustained deterioration



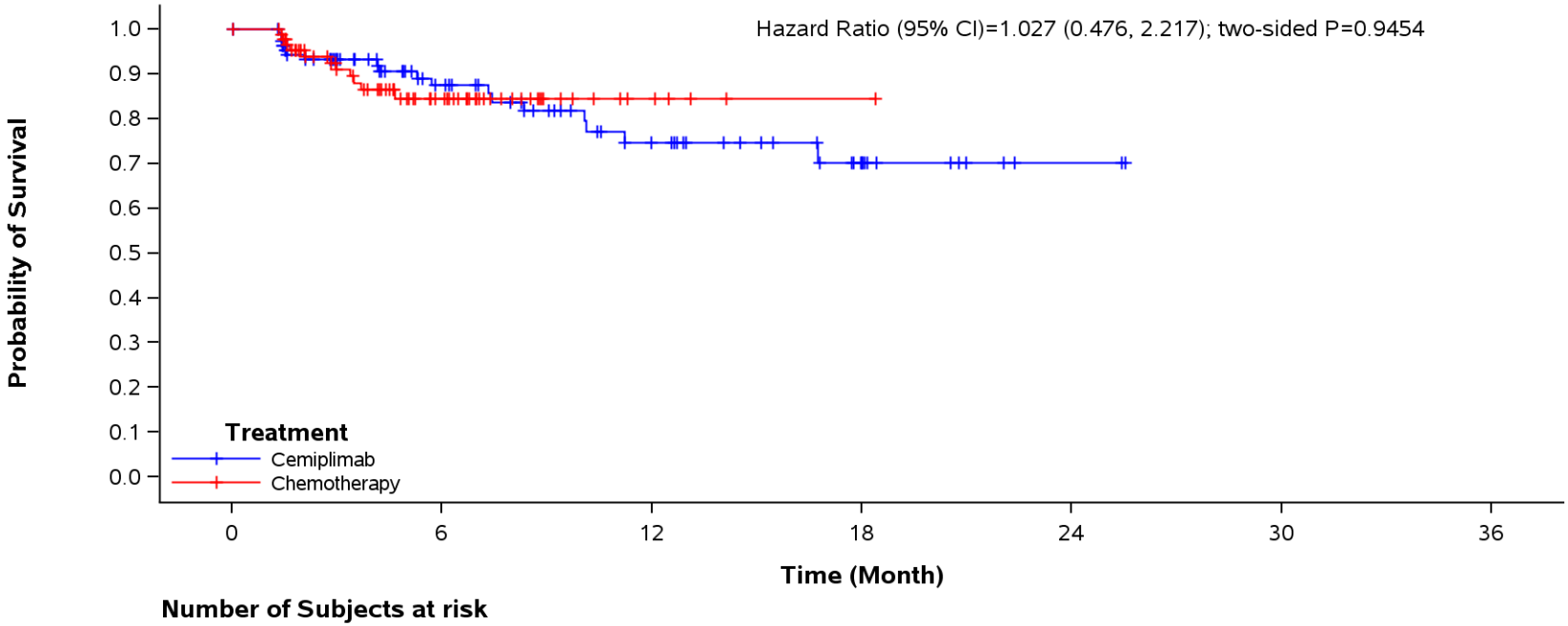

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 53 | 24 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 28 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts sustained deterioration



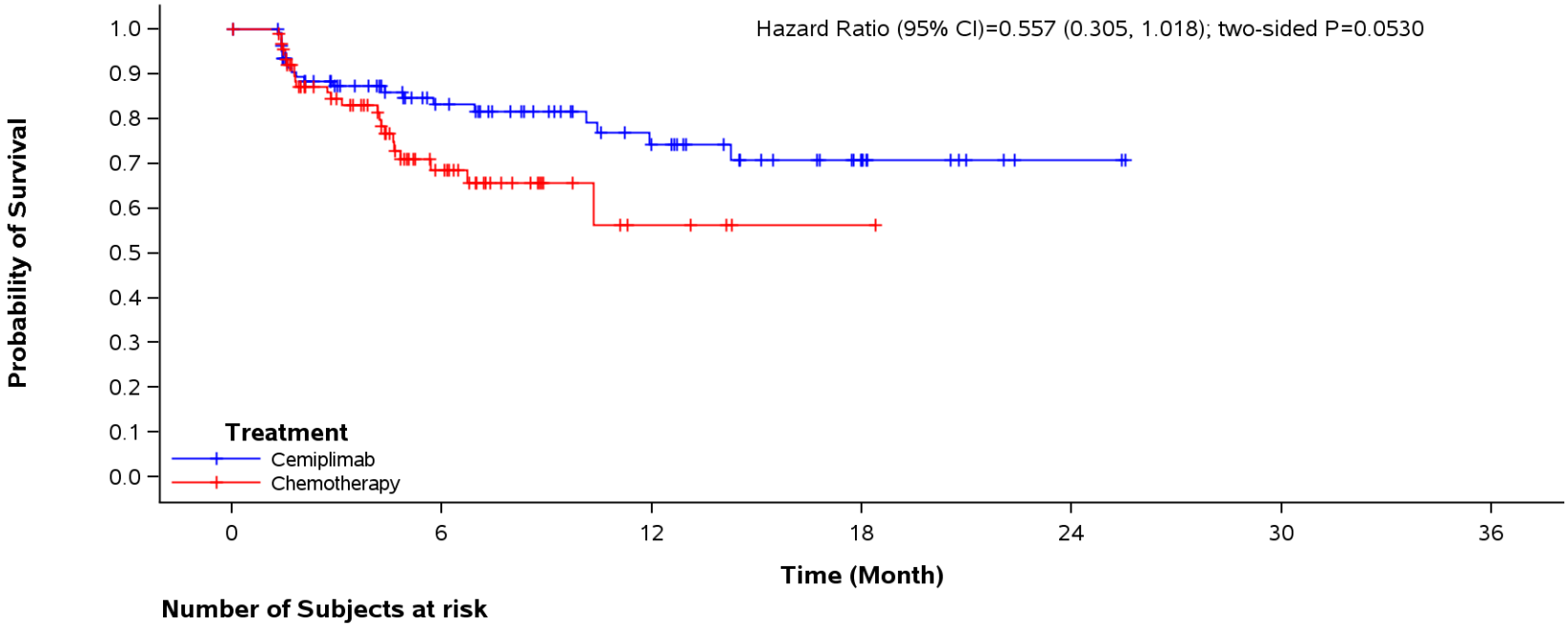

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 55 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 33 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Dyspnoea - 10 pts sustained deterioration



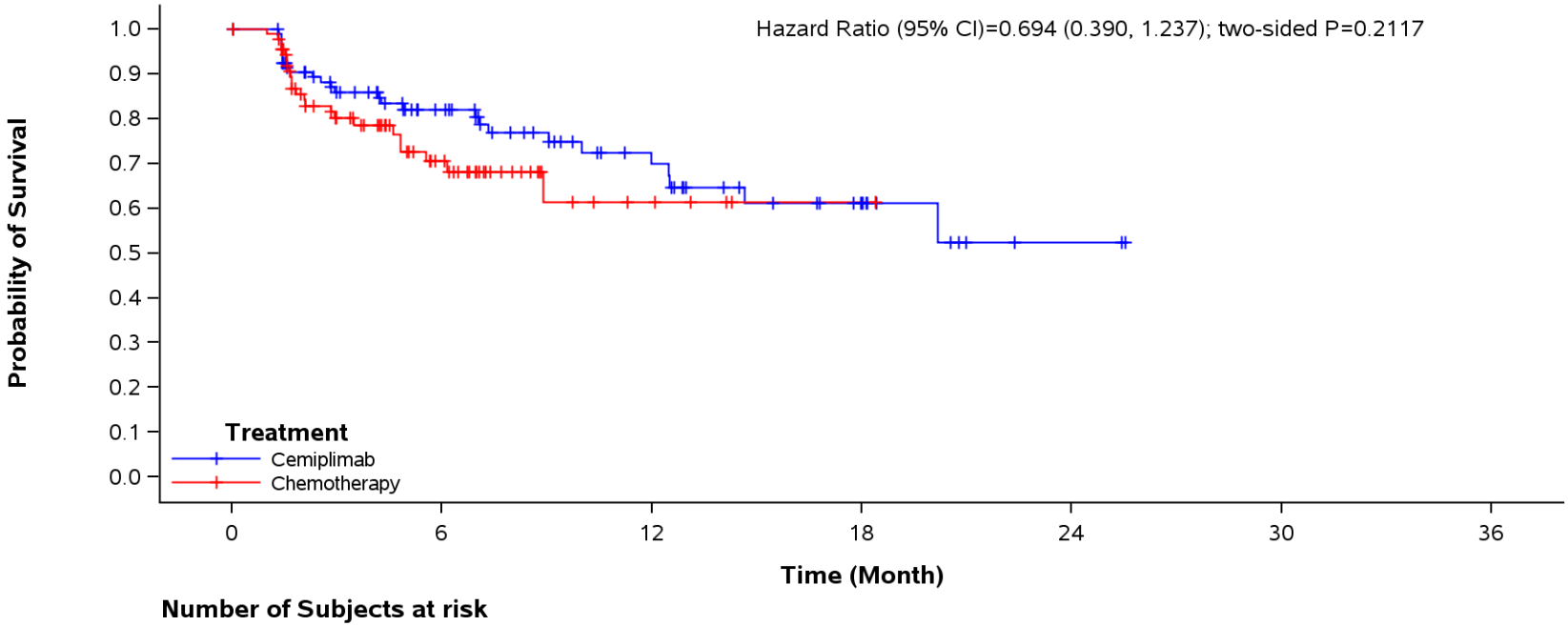

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 55 | 27 | 11 | 2 | 0 | 0 |
| Chemotherapy | 123 | 28 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Emotional Functioning - 10 pts sustained deterioration



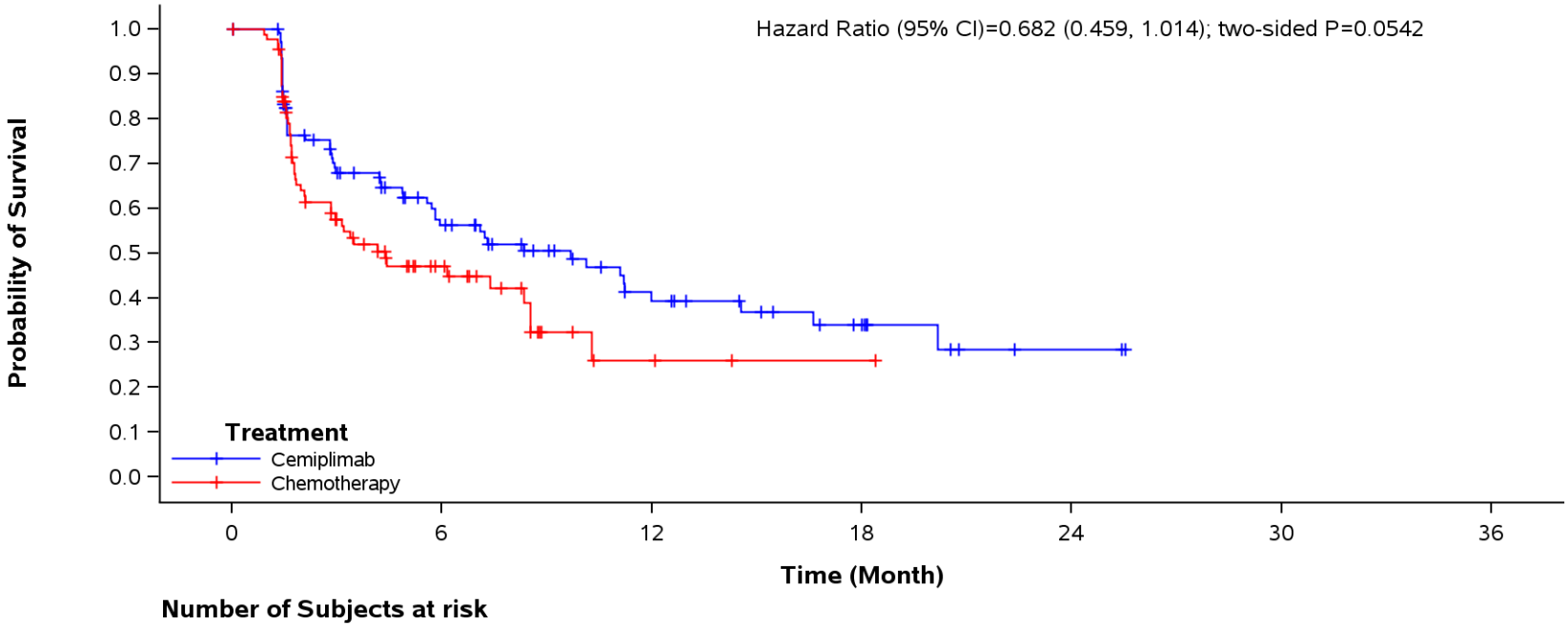

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 55 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 30 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts sustained deterioration



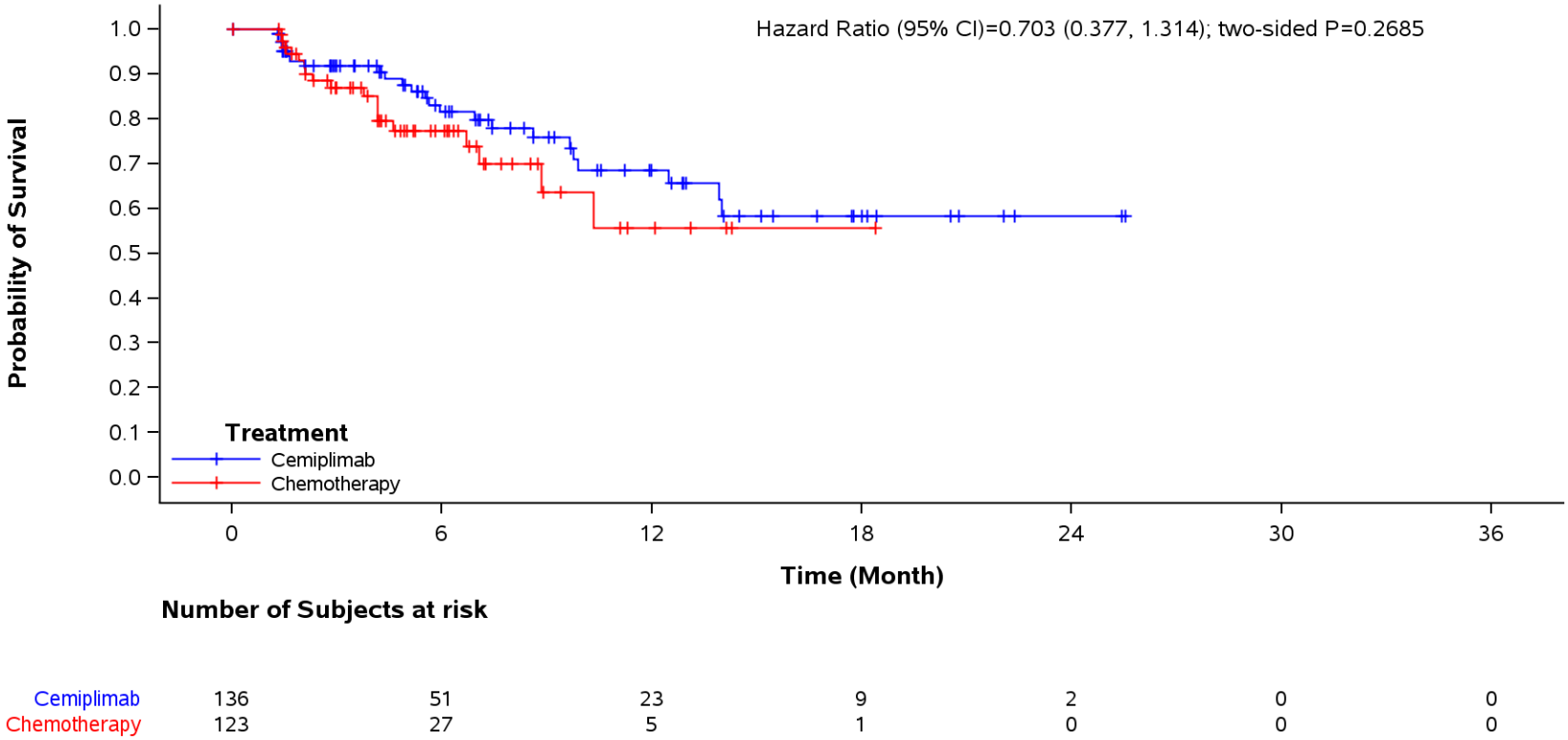

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 46 | 20 | 10 | 2 | 0 | 0 |
| Chemotherapy | 123 | 22 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Financial Problems - 10 pts sustained deterioration



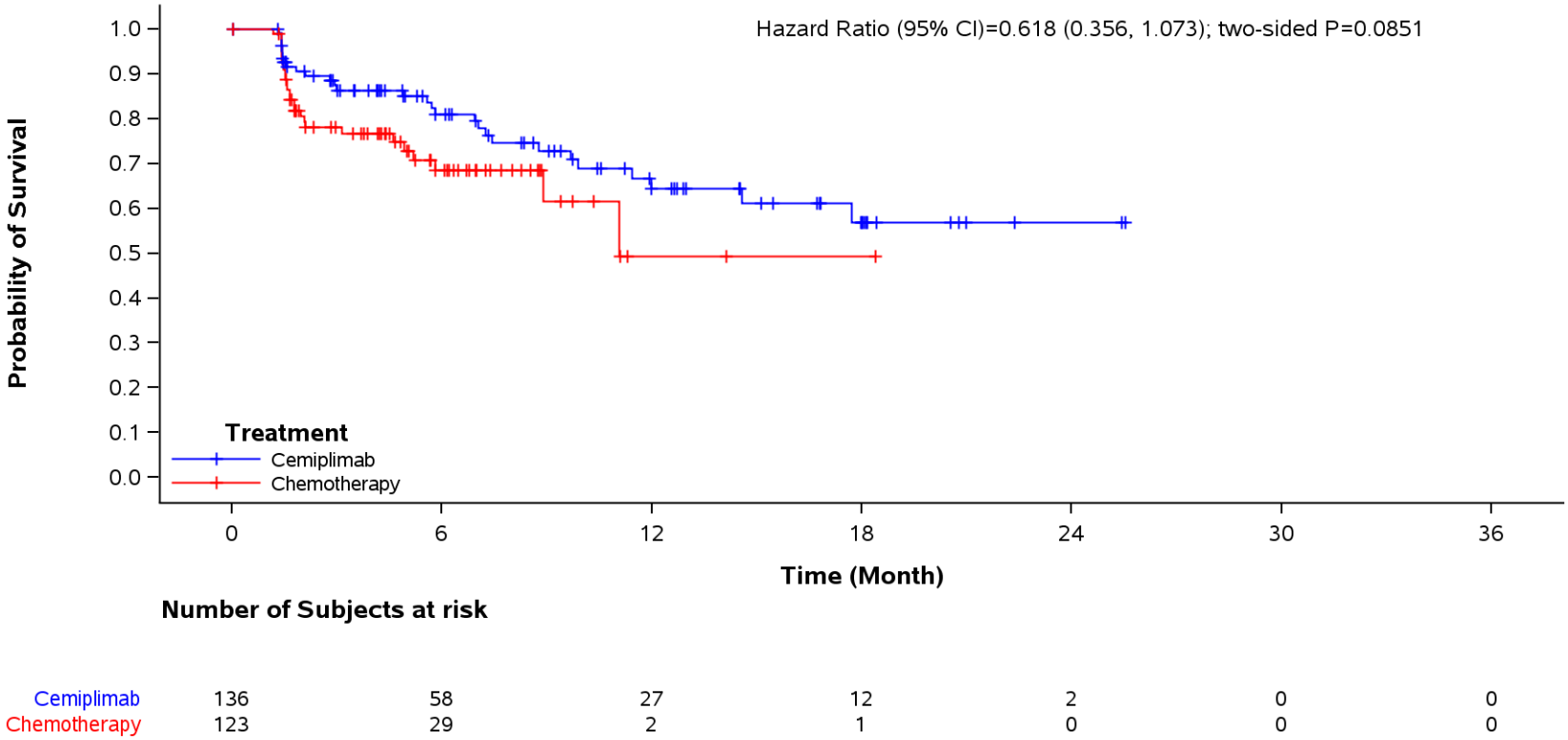

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 51 | 23 | 9 | 2 | 0 | 0 |
| Chemotherapy | 123 | 27 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Nausea / Vomiting - 10 pts sustained deterioration



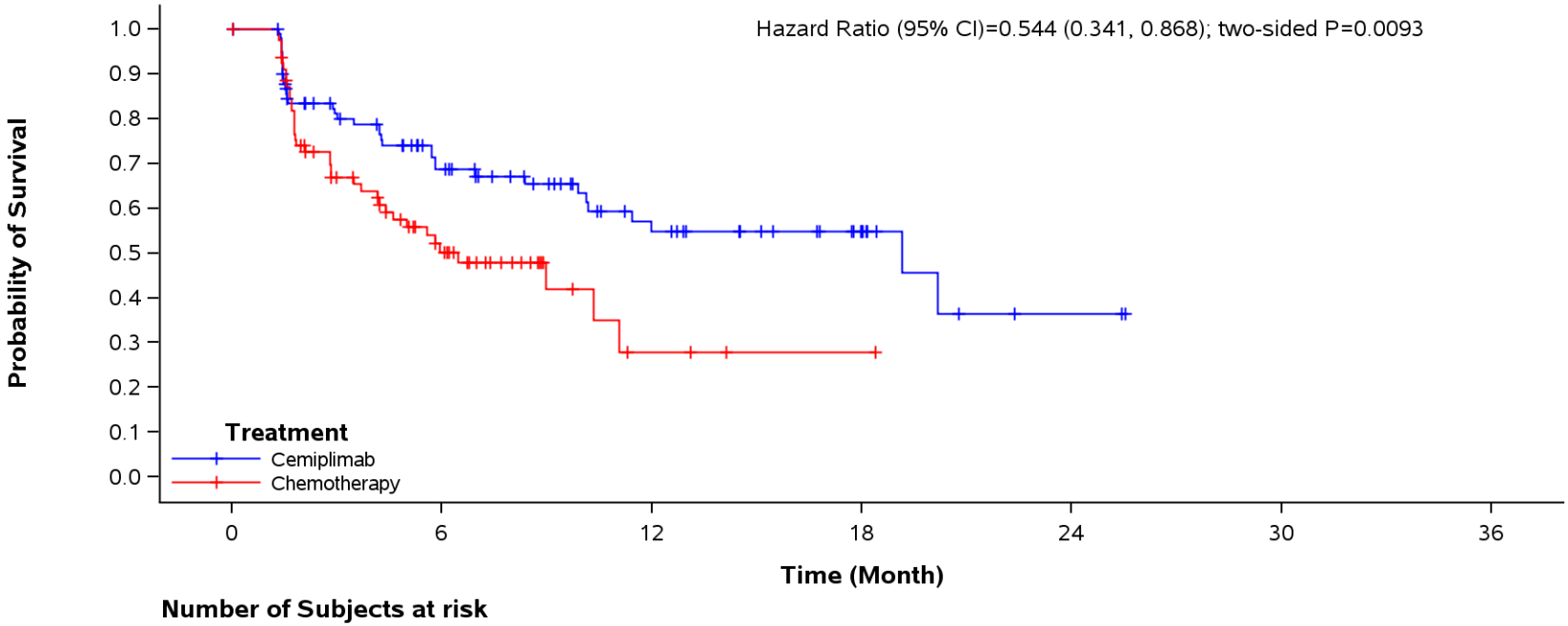

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 58 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 29 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts sustained deterioration



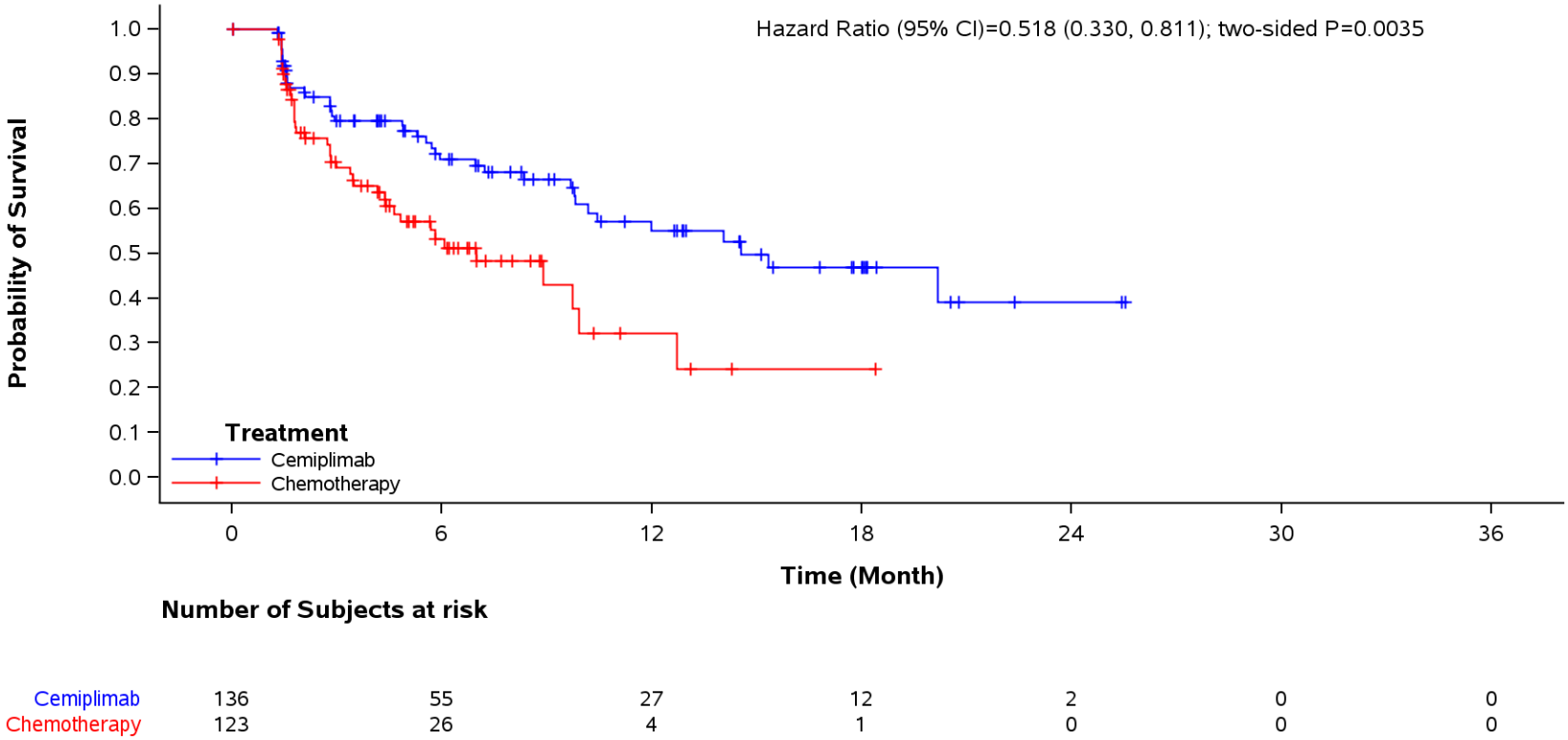

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 51 | 24 | 11 | 2 | 0 | 0 |
| Chemotherapy | 123 | 26 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Physical Functioning - 10 pts sustained deterioration



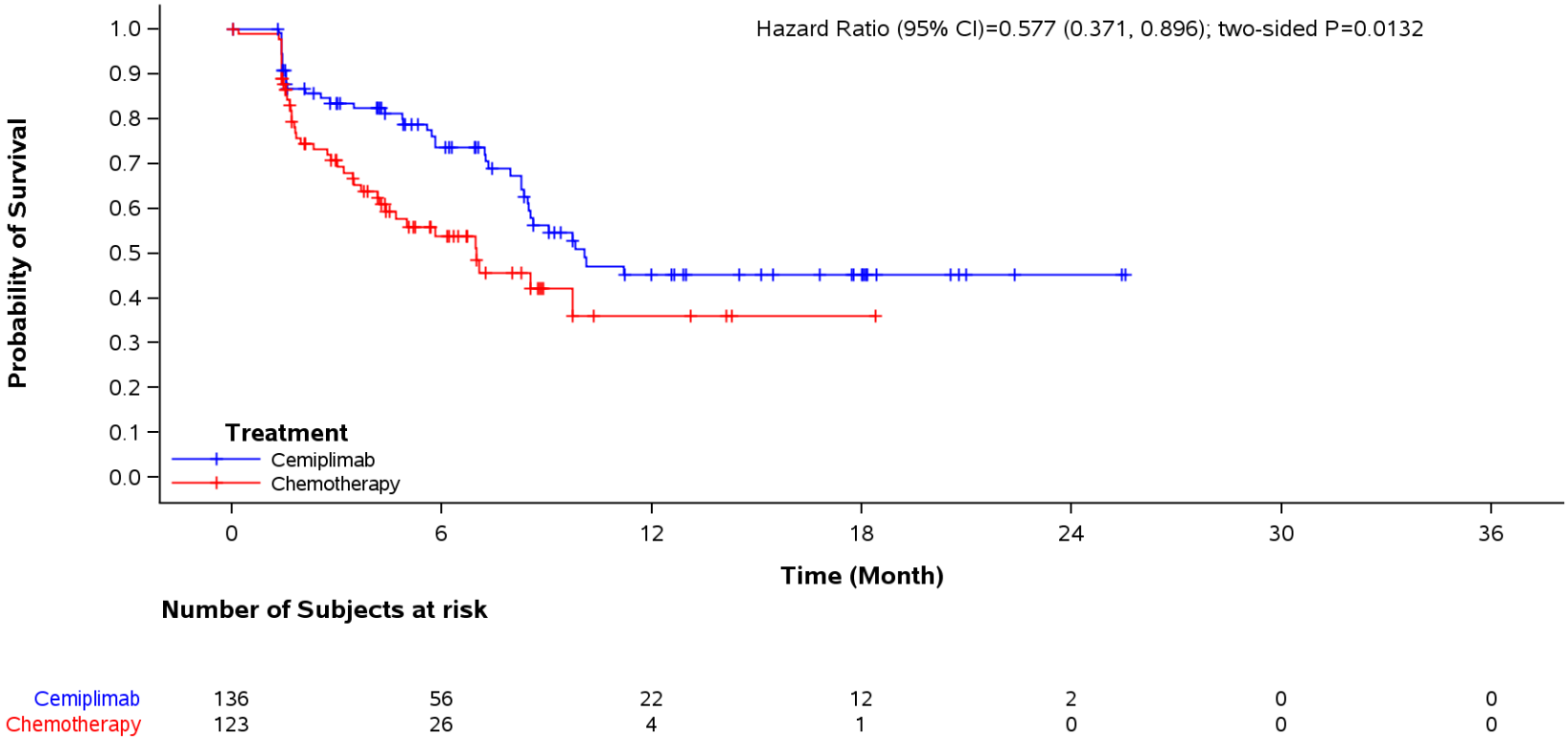

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 55 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Global health status / QoL - 10 pts sustained deterioration



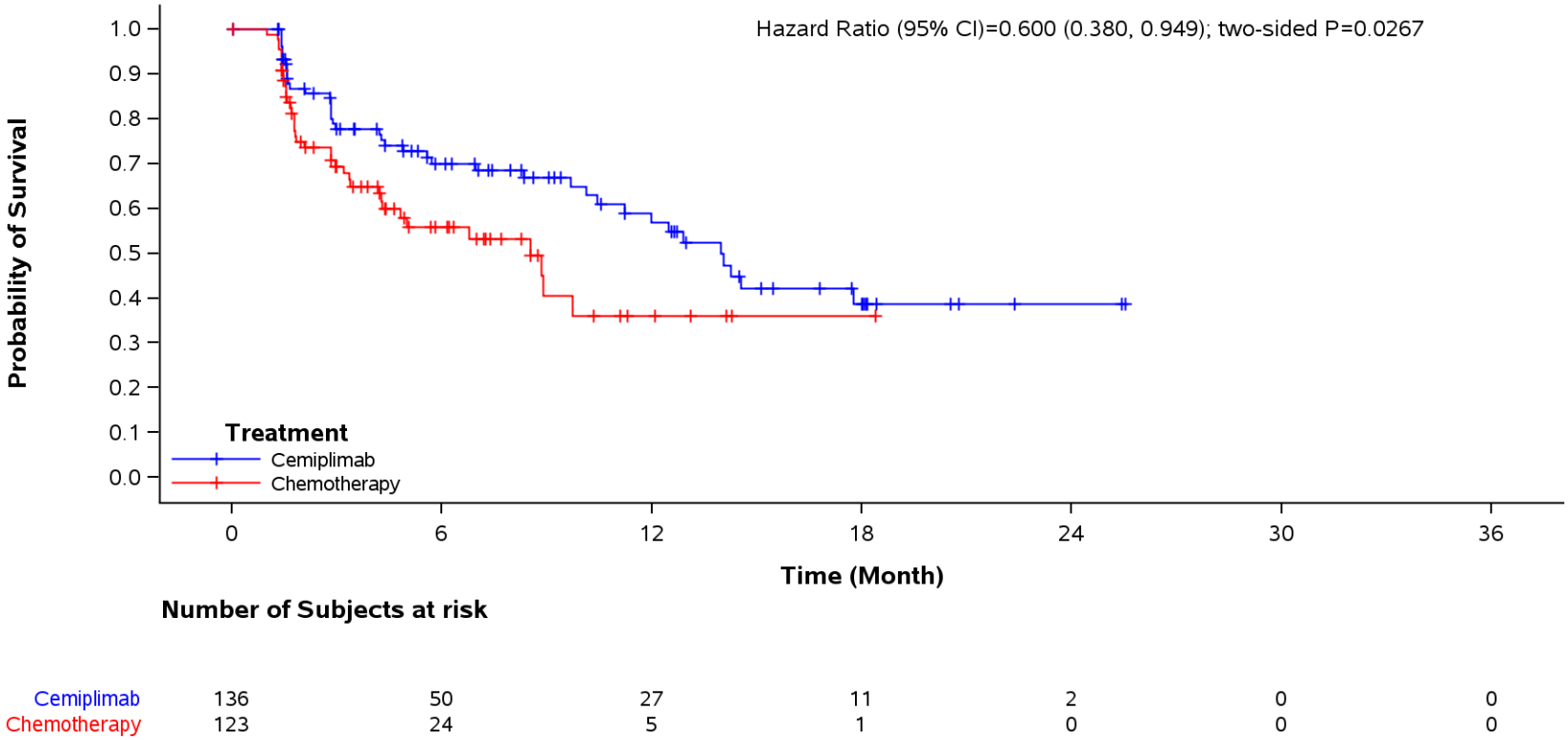

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 56 | 22 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts sustained deterioration



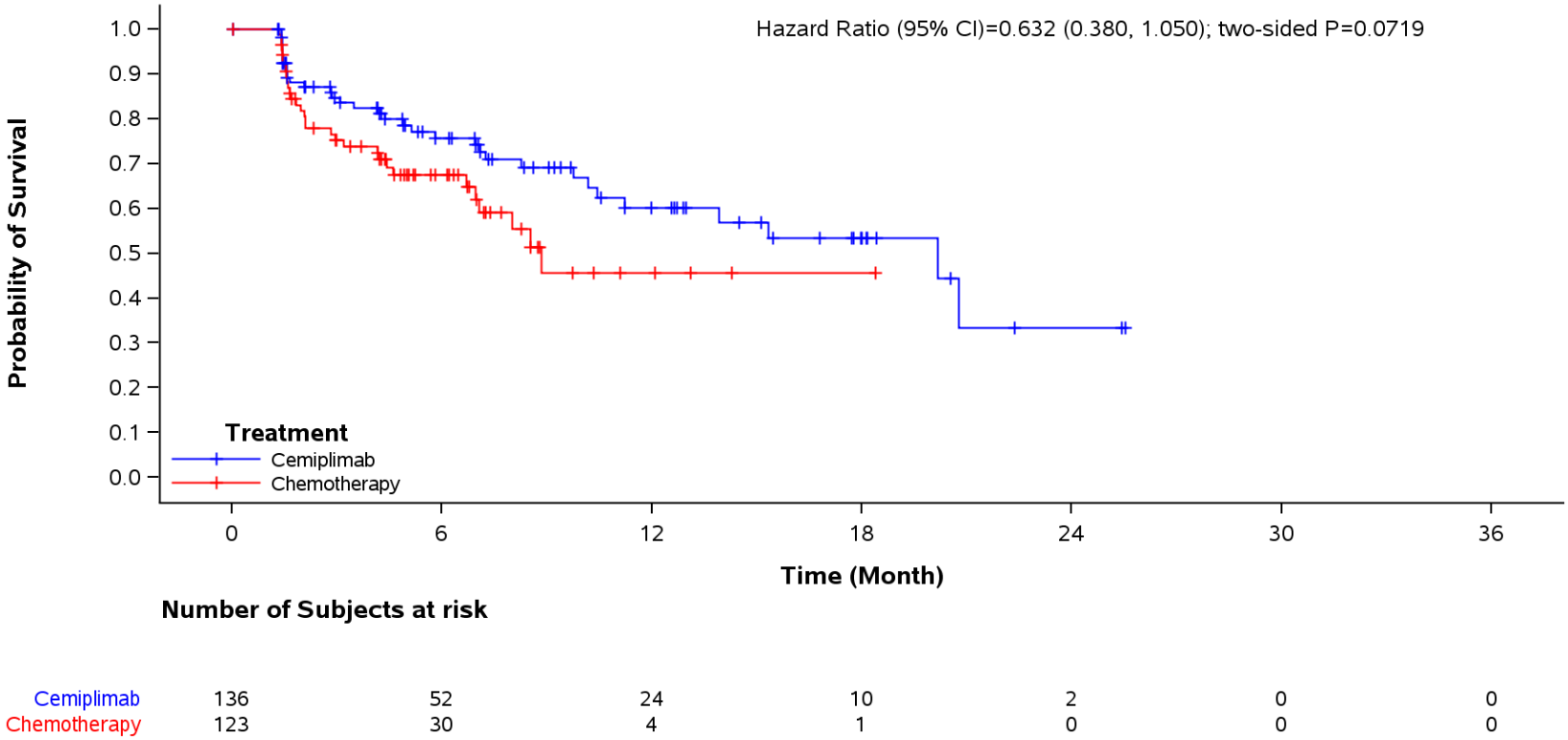

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 50 | 27 | 11 | 2 | 0 | 0 |
| Chemotherapy | 123 | 24 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Social Functioning - 10 pts sustained deterioration



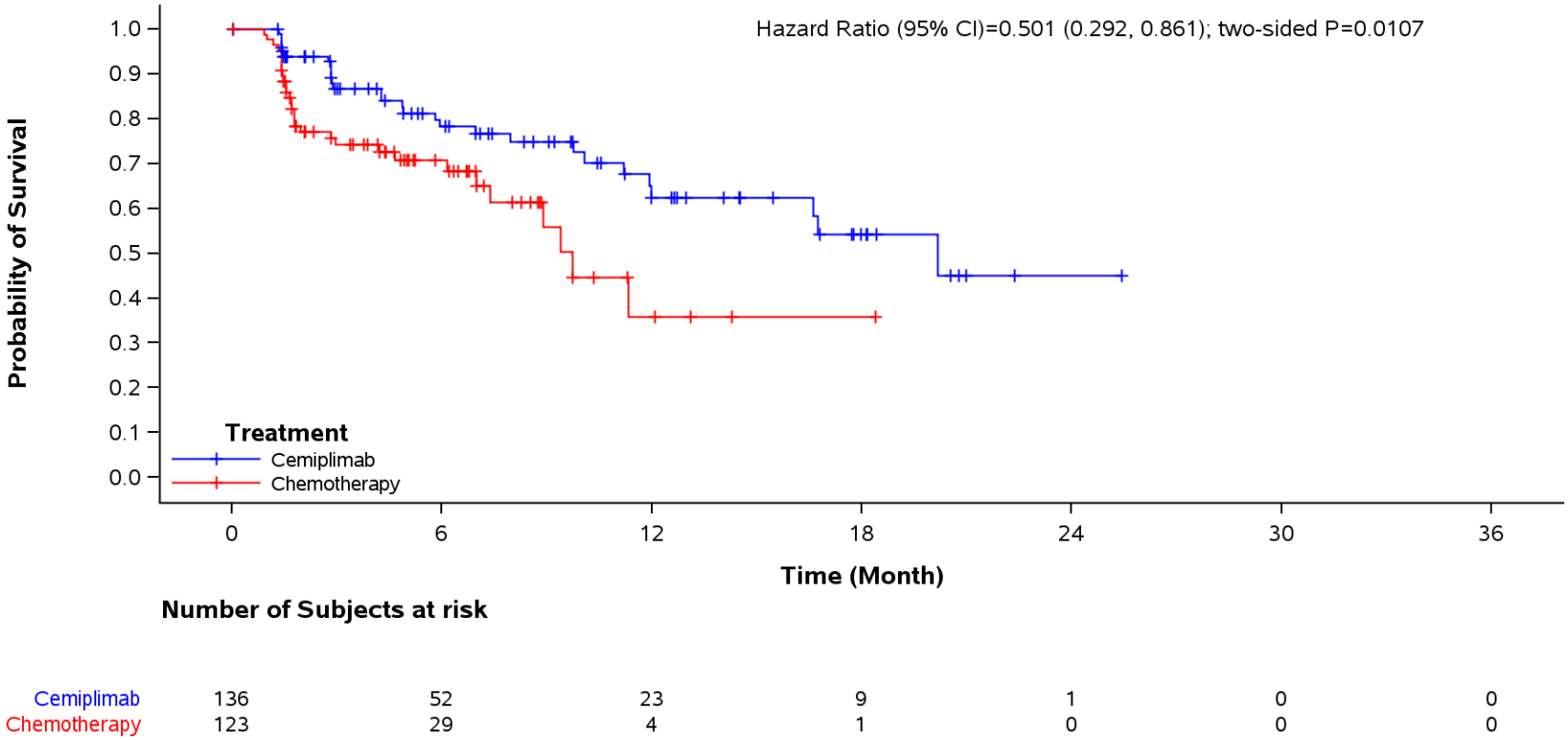

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 52 | 24 | 10 | 2 | 0 | 0 |
| Chemotherapy | 123 | 30 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts sustained deterioration



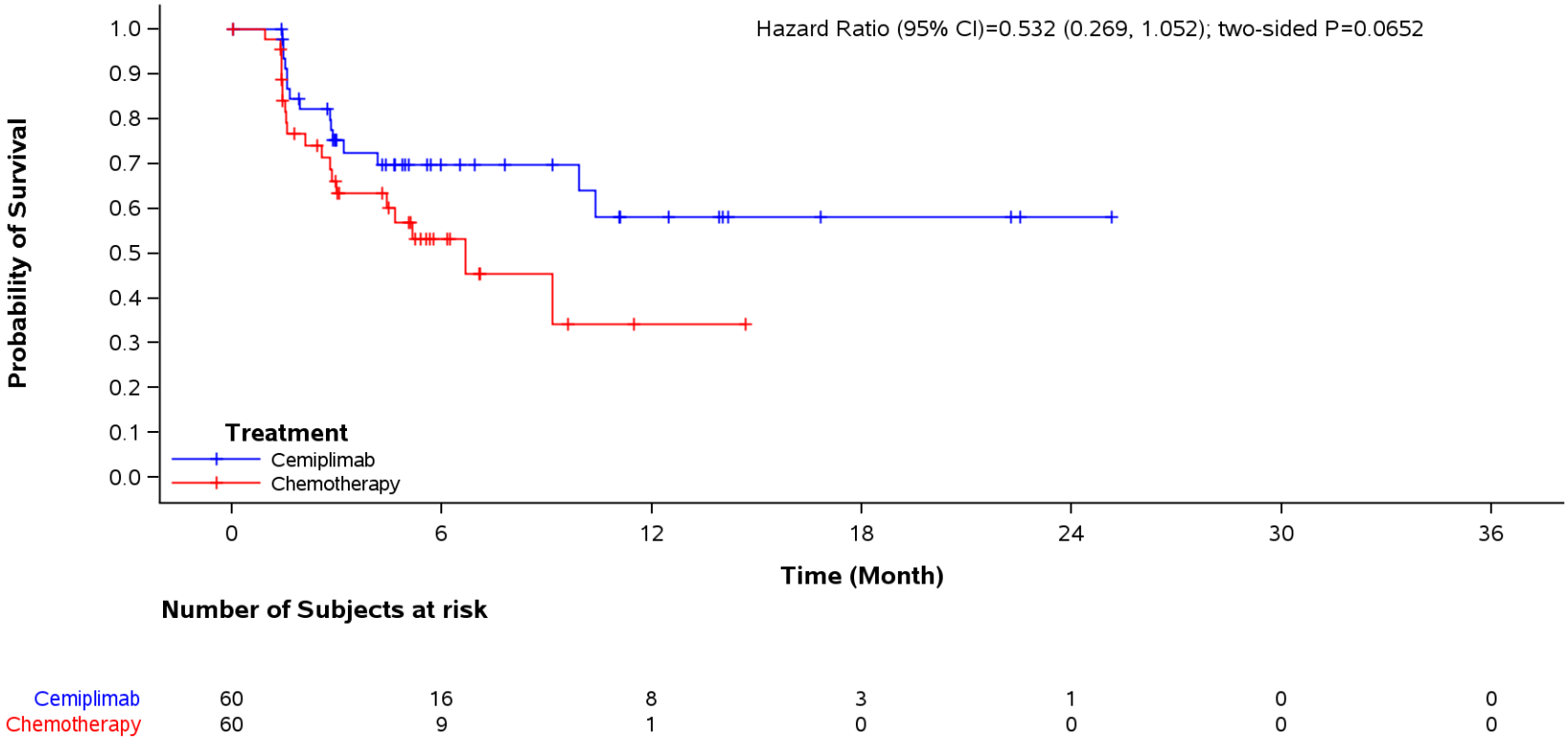

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 52 | 23 | 9 | 1 | 0 | 0 |
| Chemotherapy | 123 | 29 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts sustained deterioration



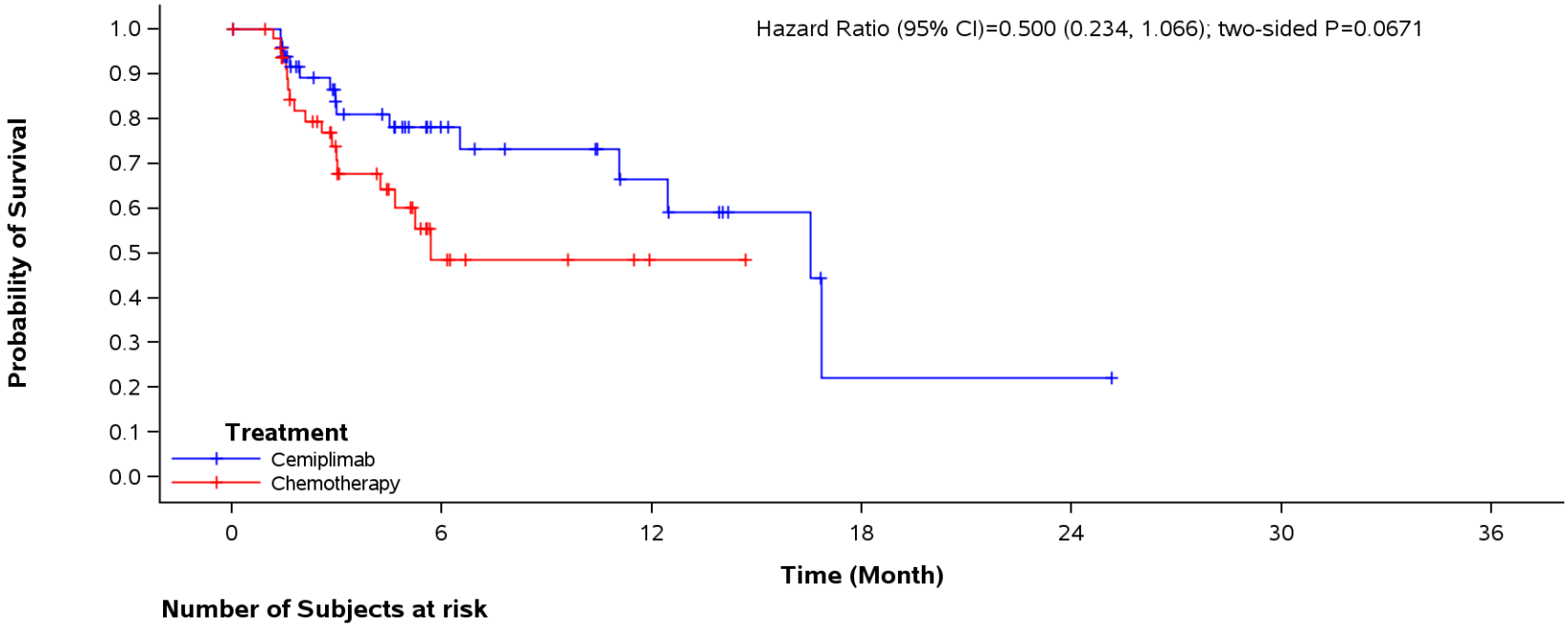

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 60 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts sustained deterioration



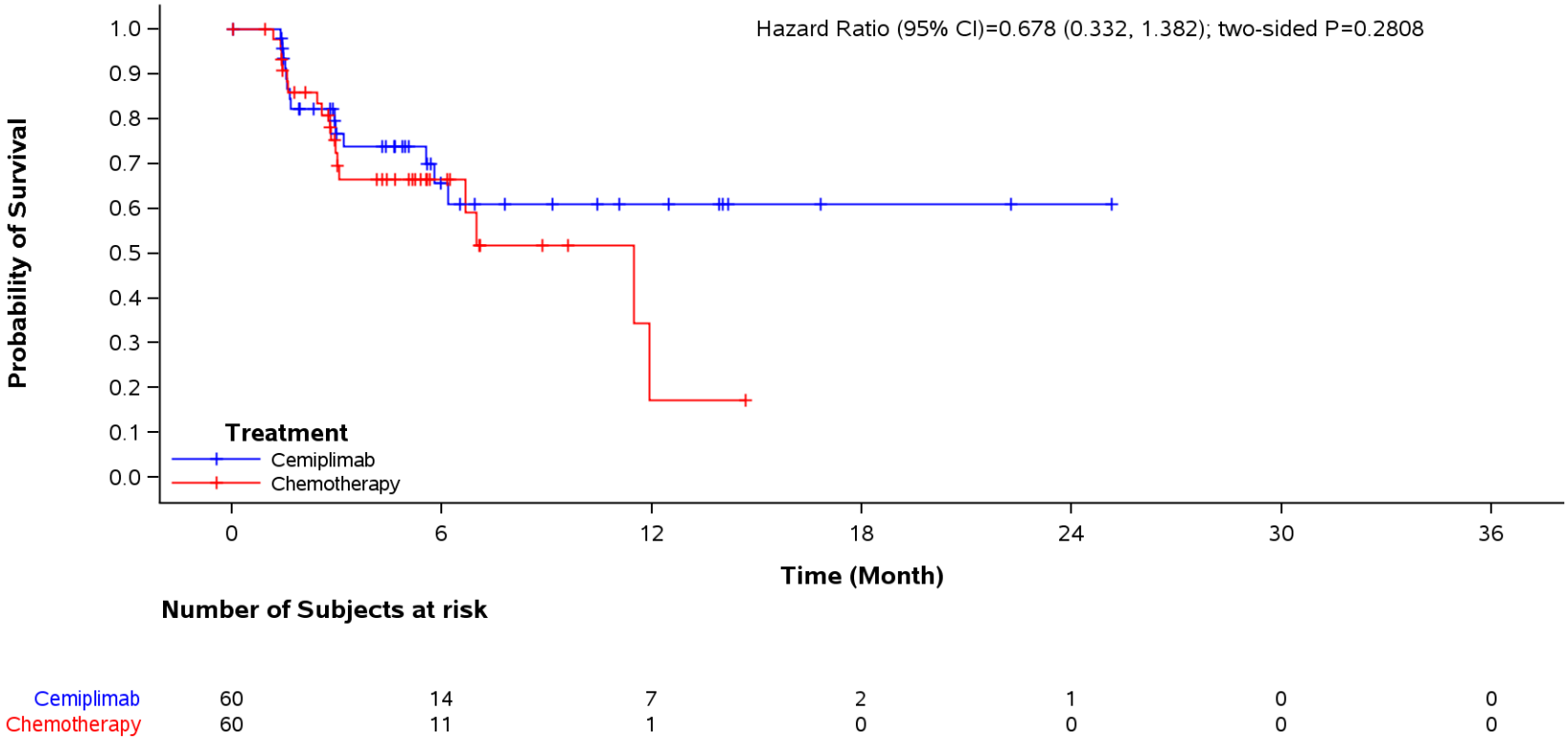

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 17 | 9 | 1 | 1 | 0 | 0 |
| Chemotherapy | 60 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts sustained deterioration



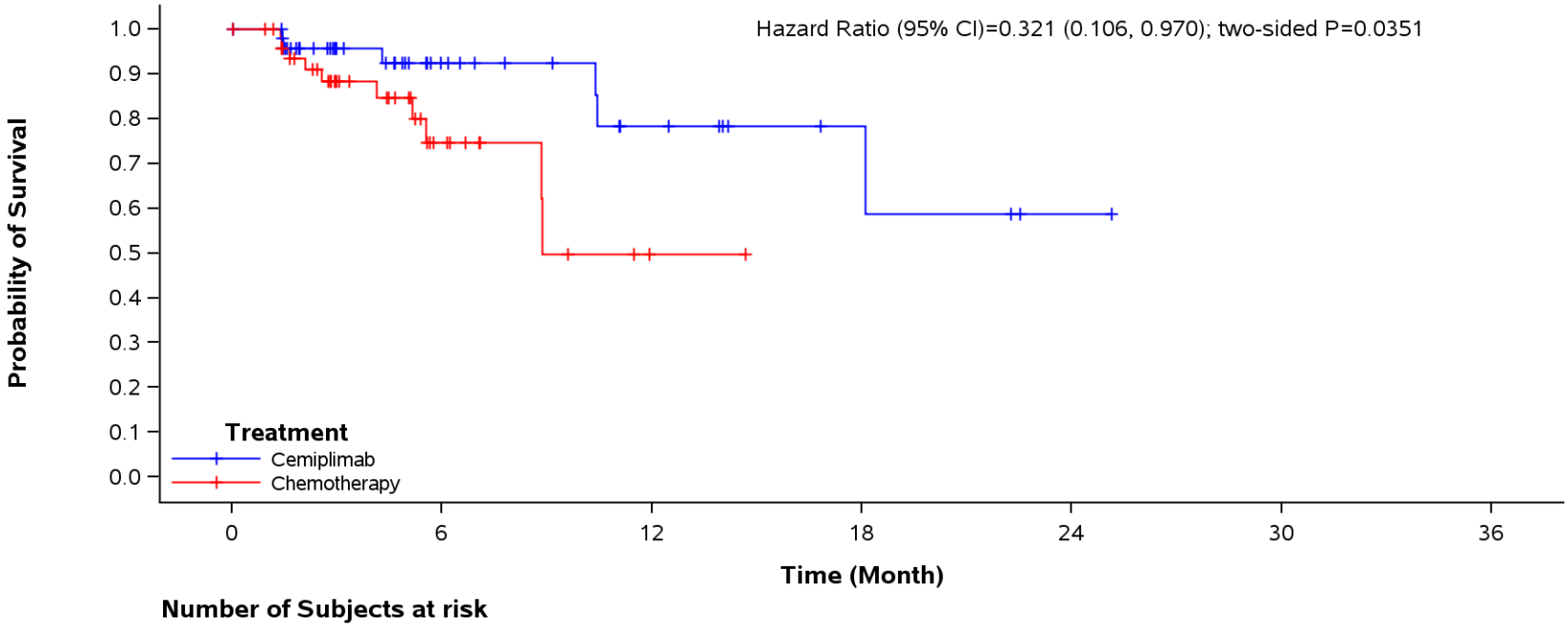

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 14 | 7 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts sustained deterioration



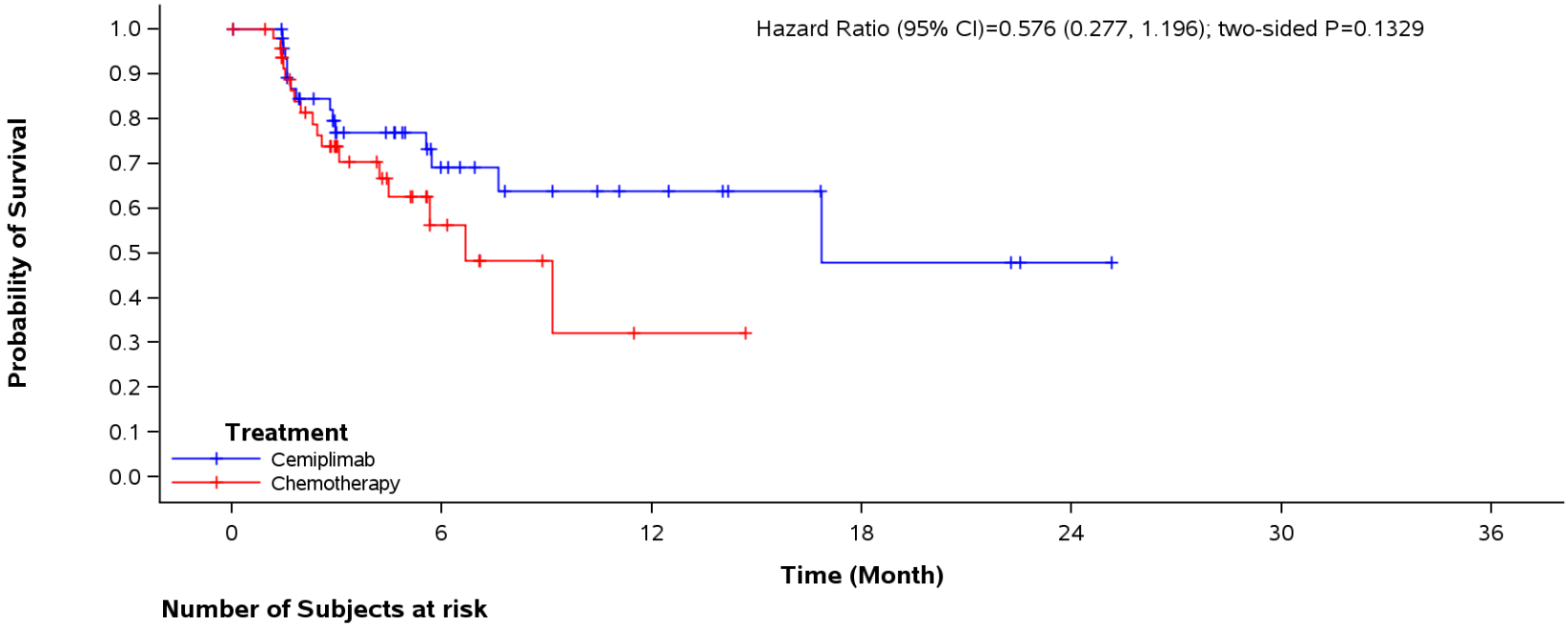

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts sustained deterioration



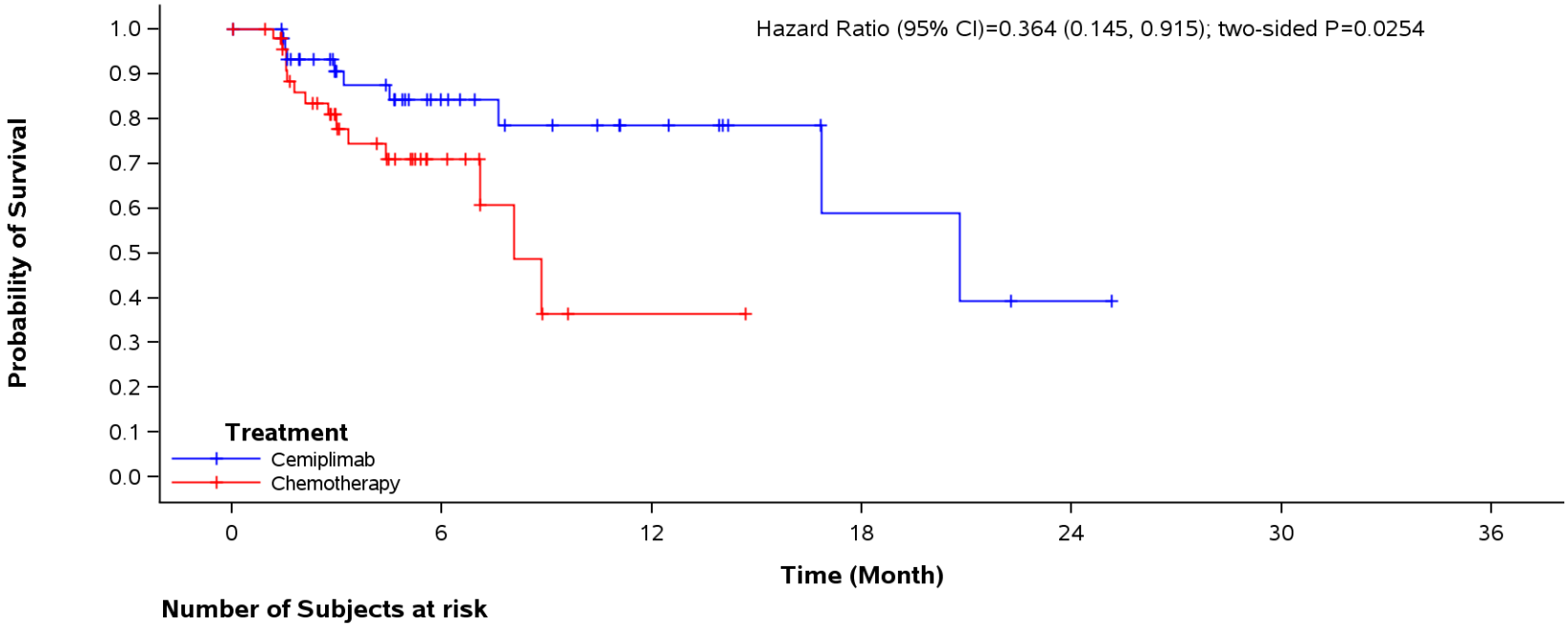

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 60 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts sustained deterioration



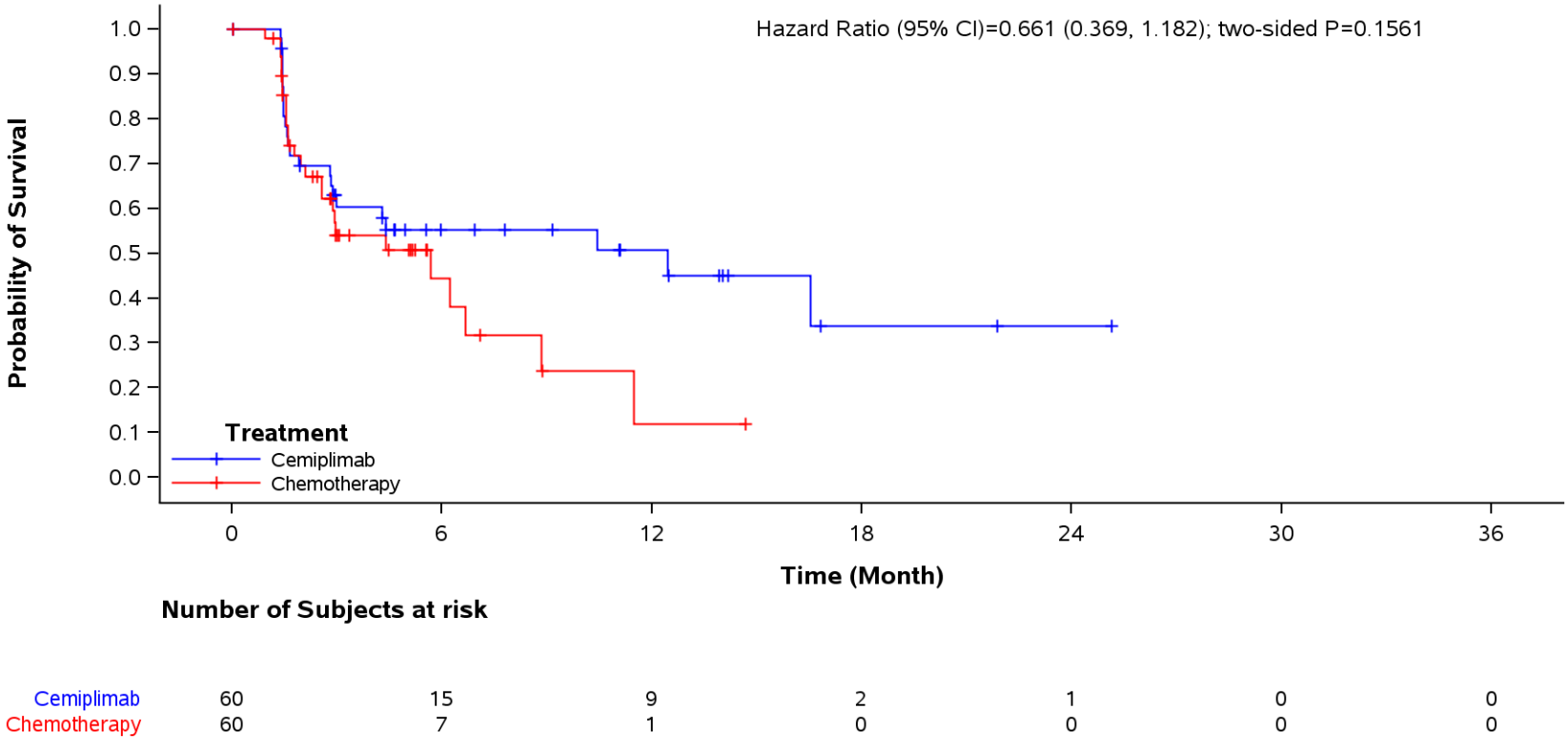

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 9 | 3 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

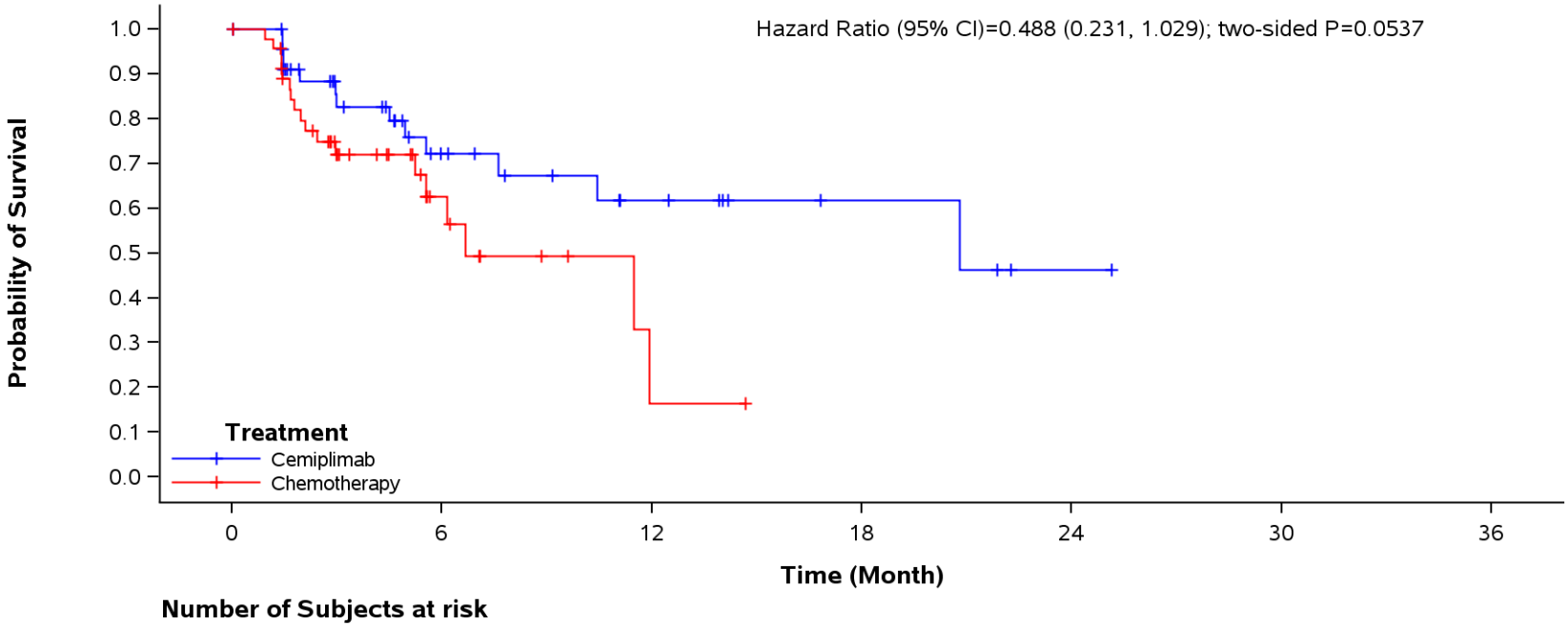
Race: Non-White
Fatigue - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts sustained deterioration



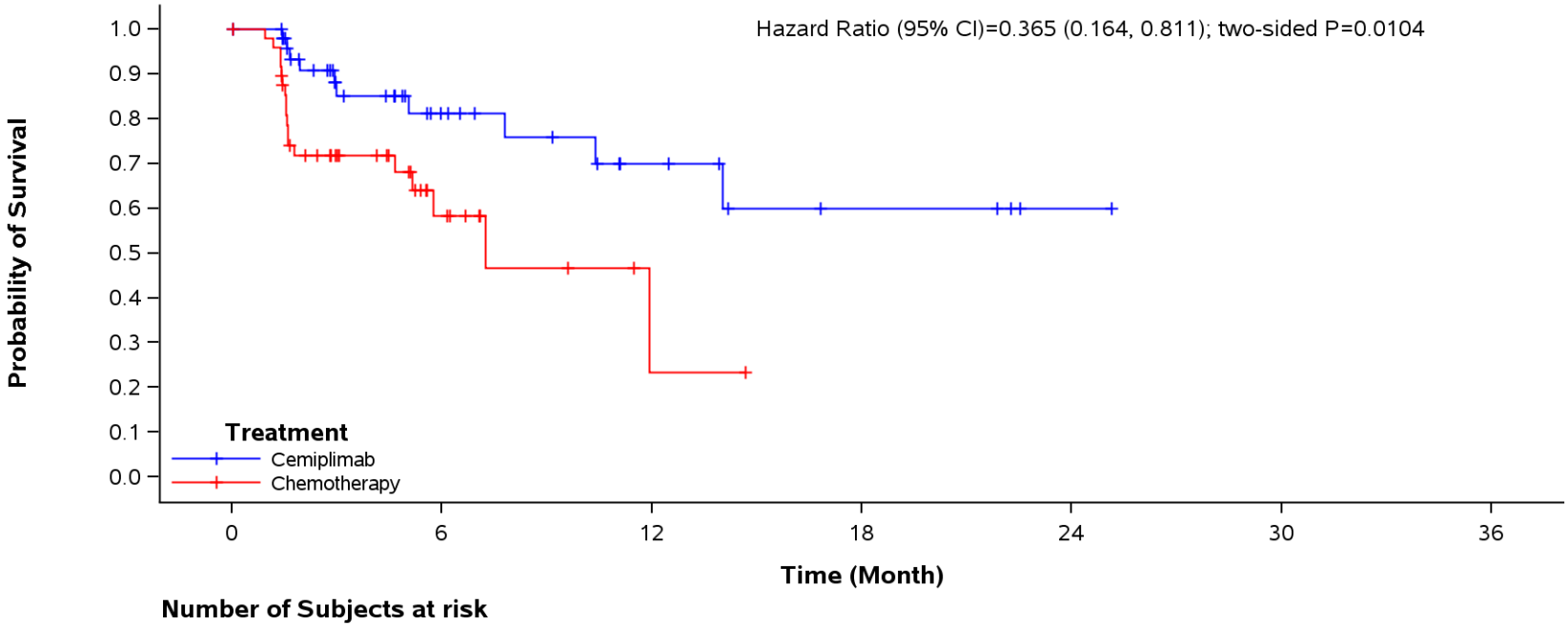

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 17 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts sustained deterioration



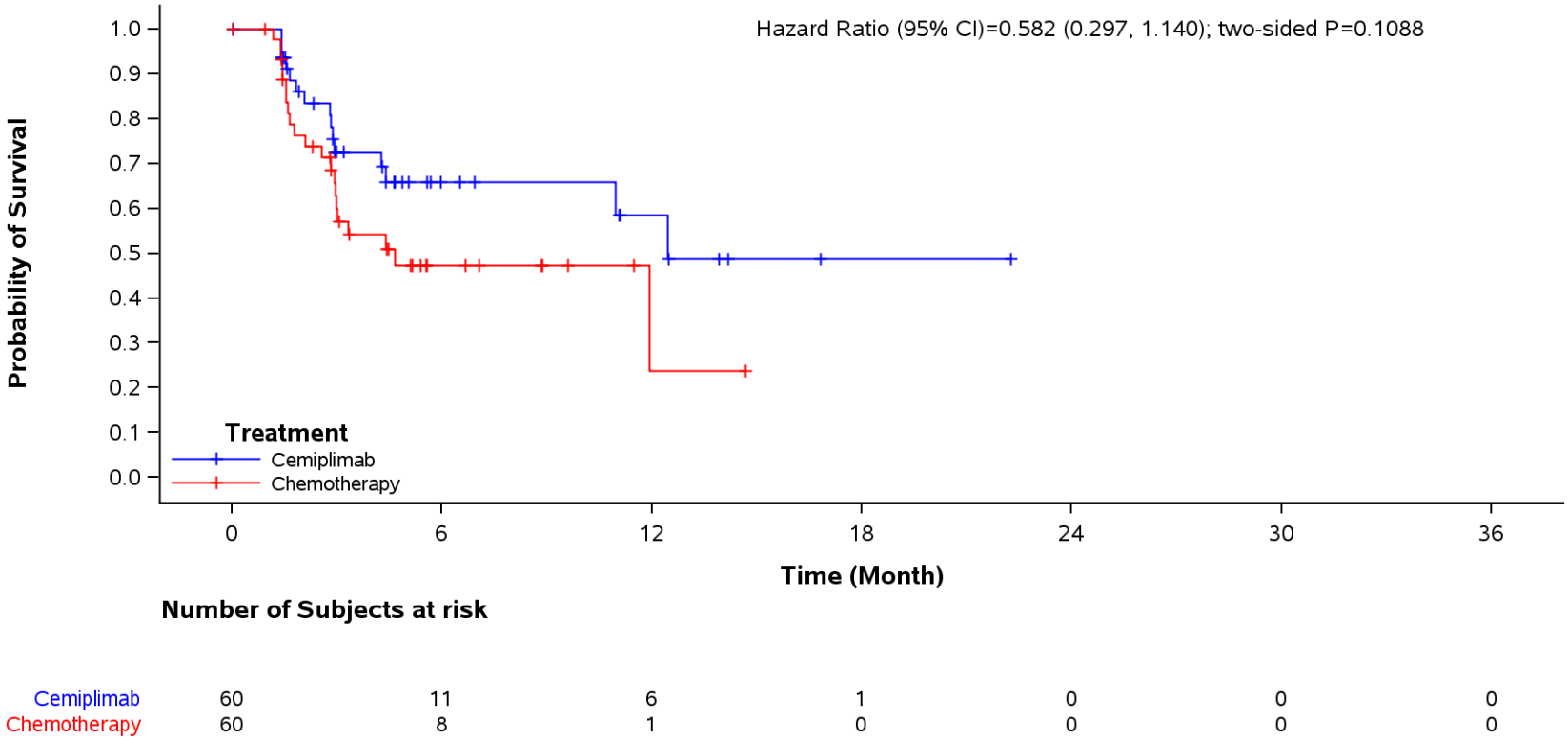

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts sustained deterioration



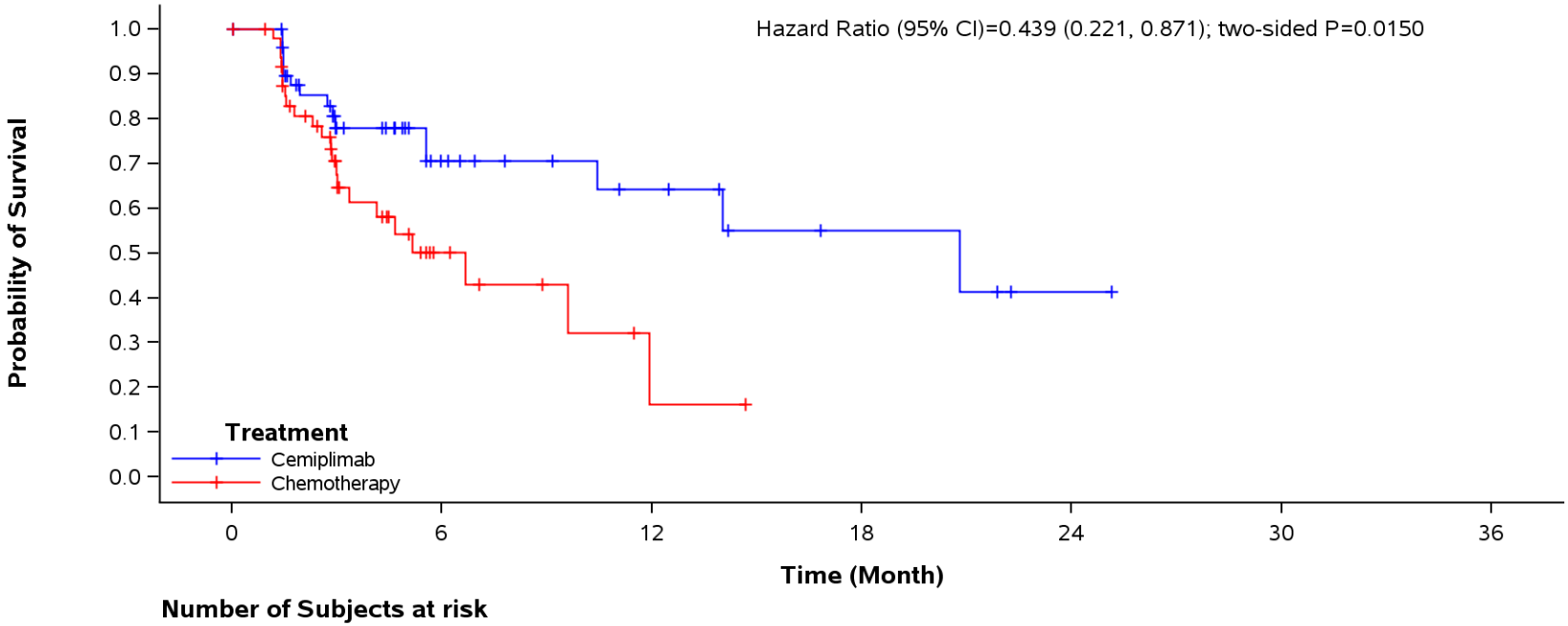

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 11 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts sustained deterioration



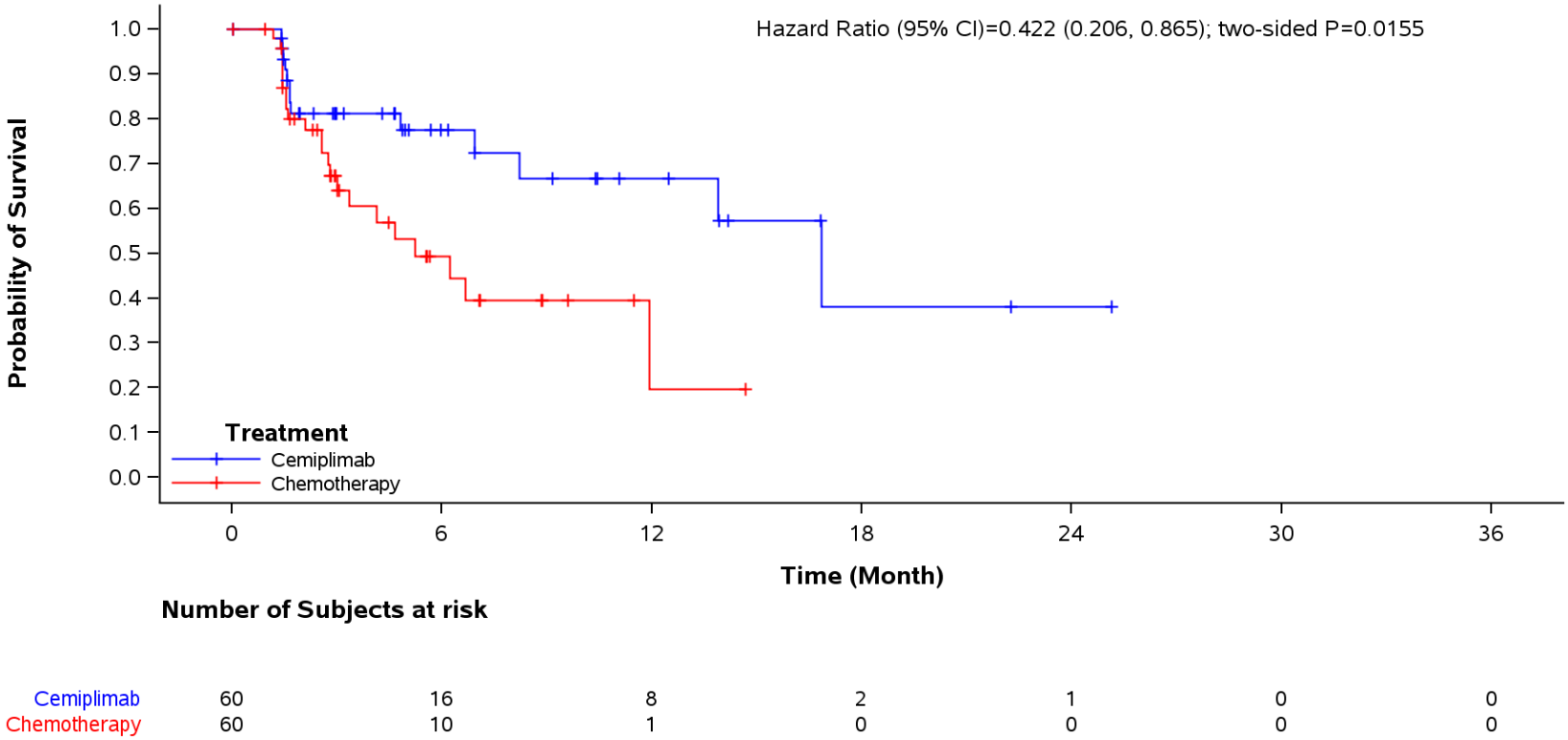

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Global health status / QoL - 10 pts sustained deterioration



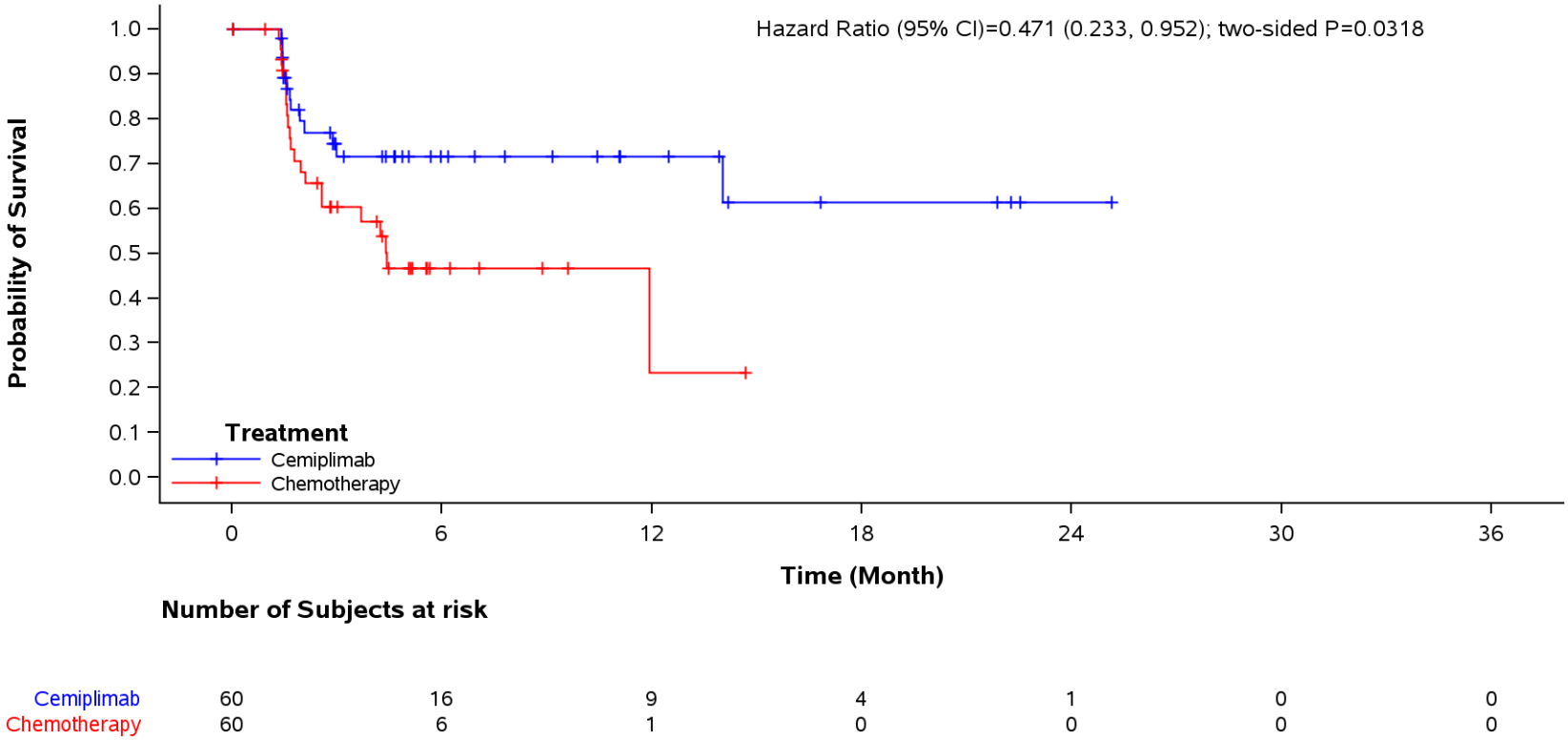

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts sustained deterioration



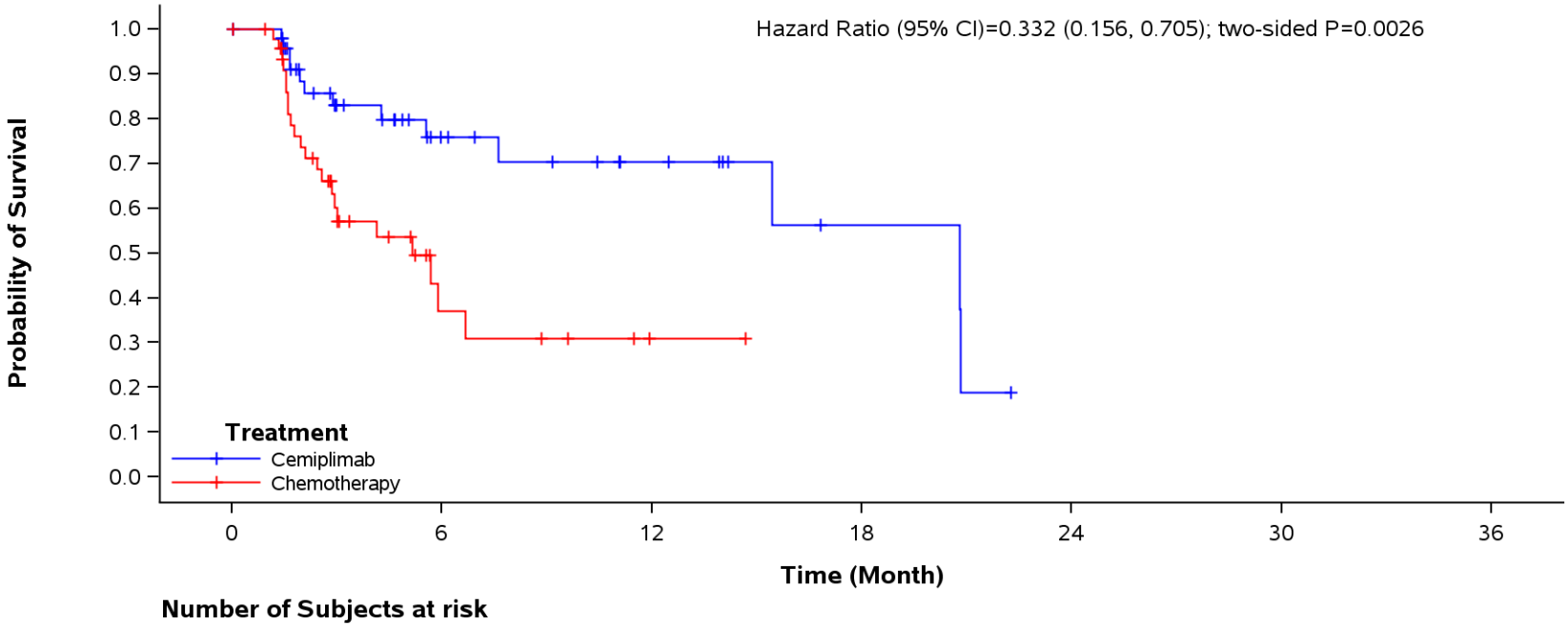

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Social Functioning - 10 pts sustained deterioration



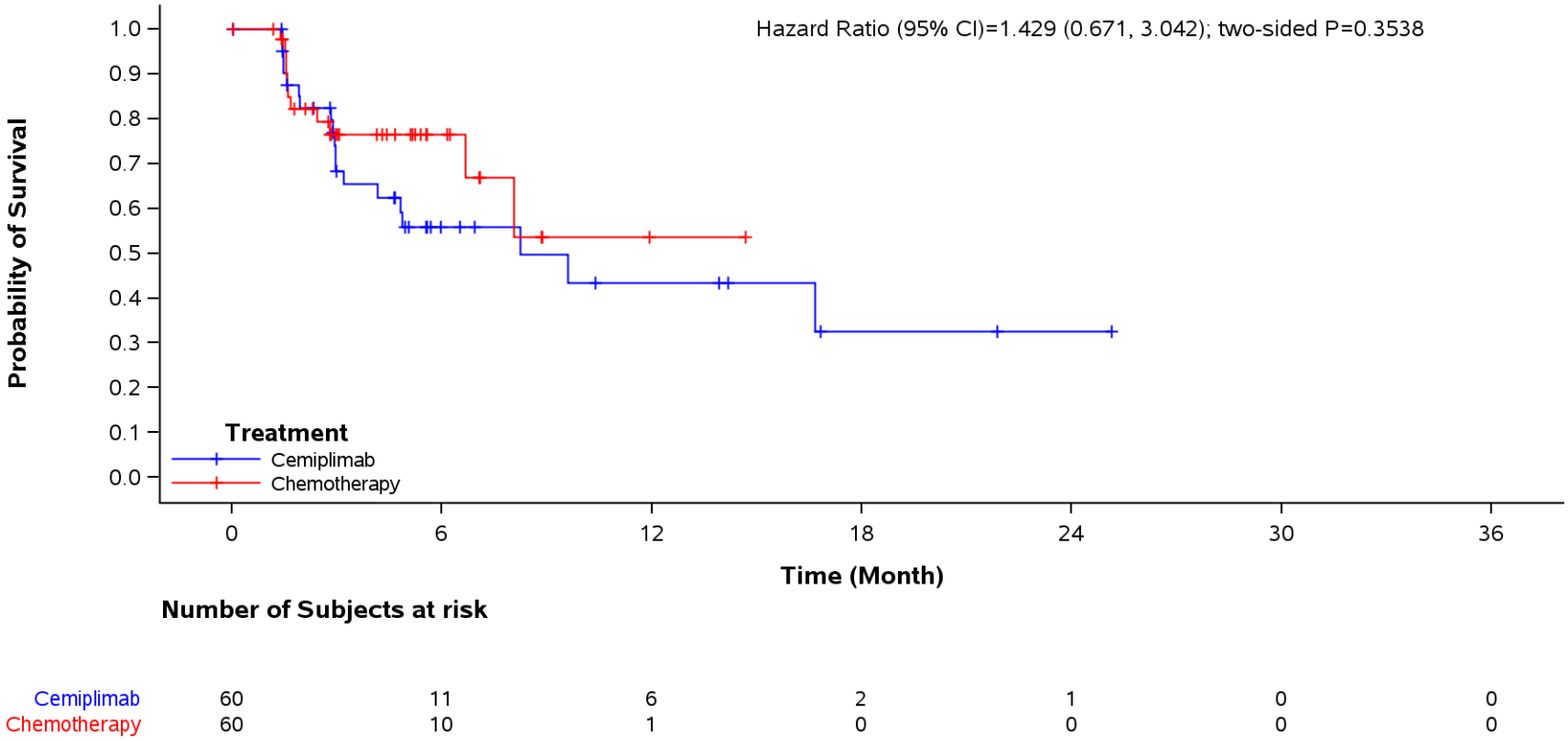

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 9 | 3 | 0 | 0 | 0 |
| Chemotherapy | 60 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts sustained deterioration



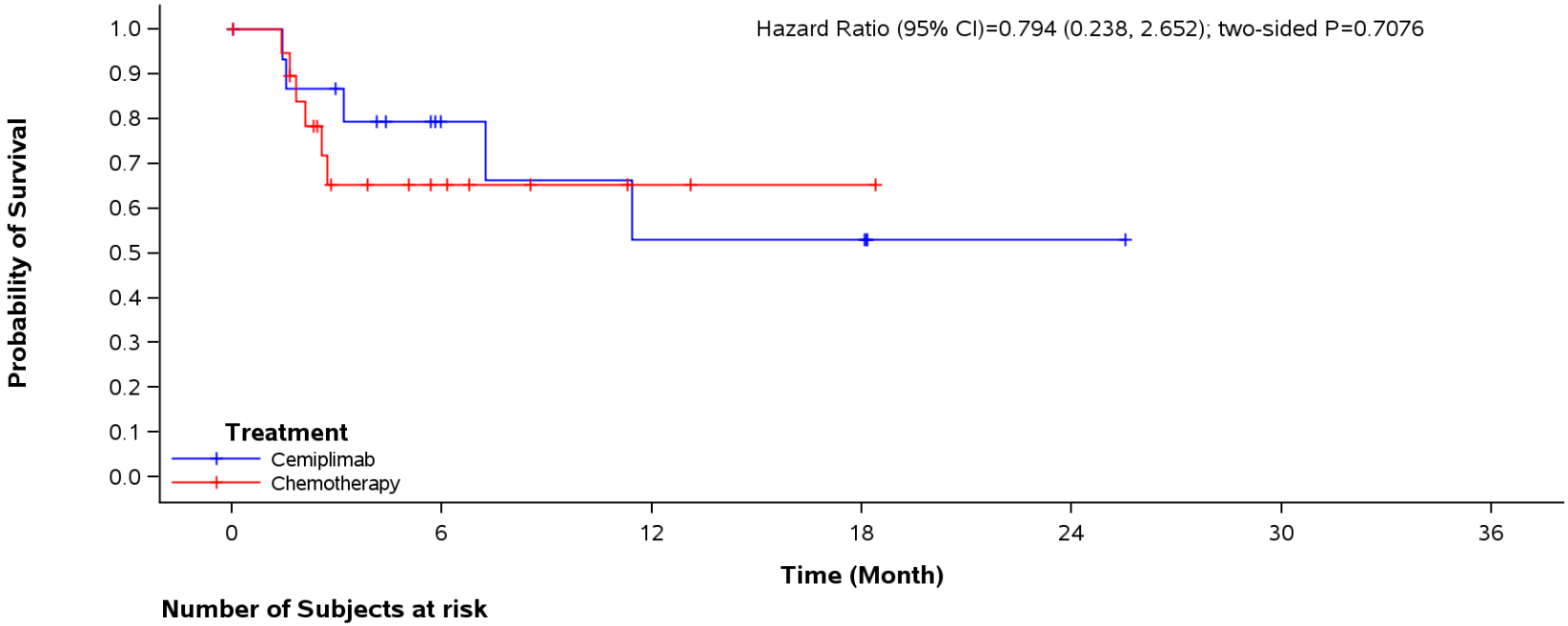

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 11 | 6 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts sustained deterioration



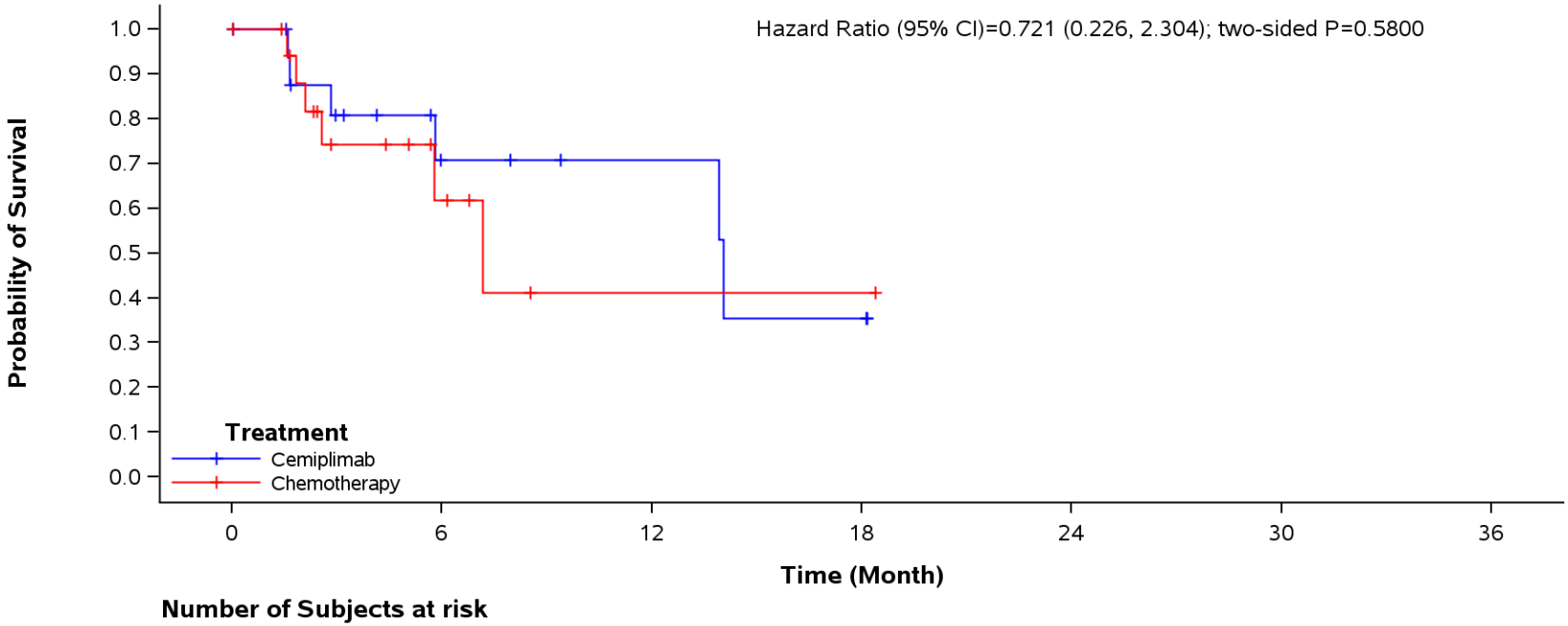

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts sustained deterioration



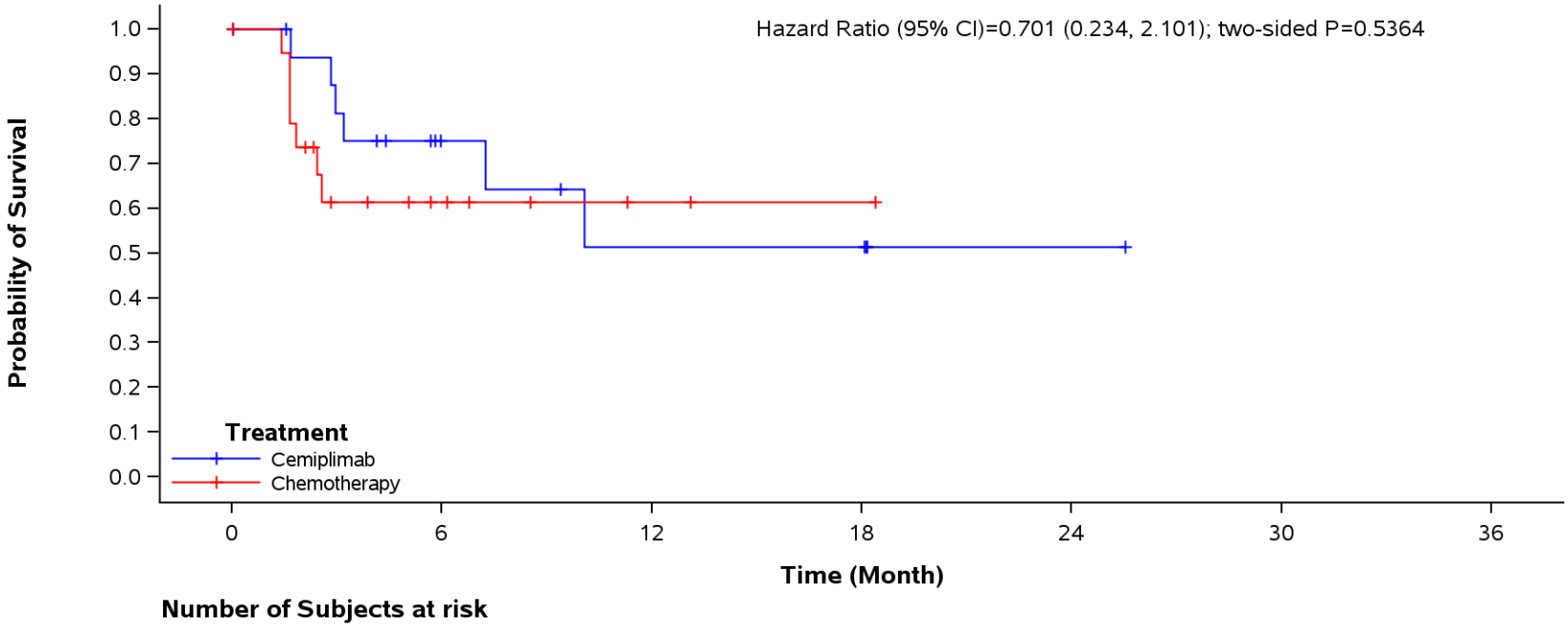

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts sustained deterioration



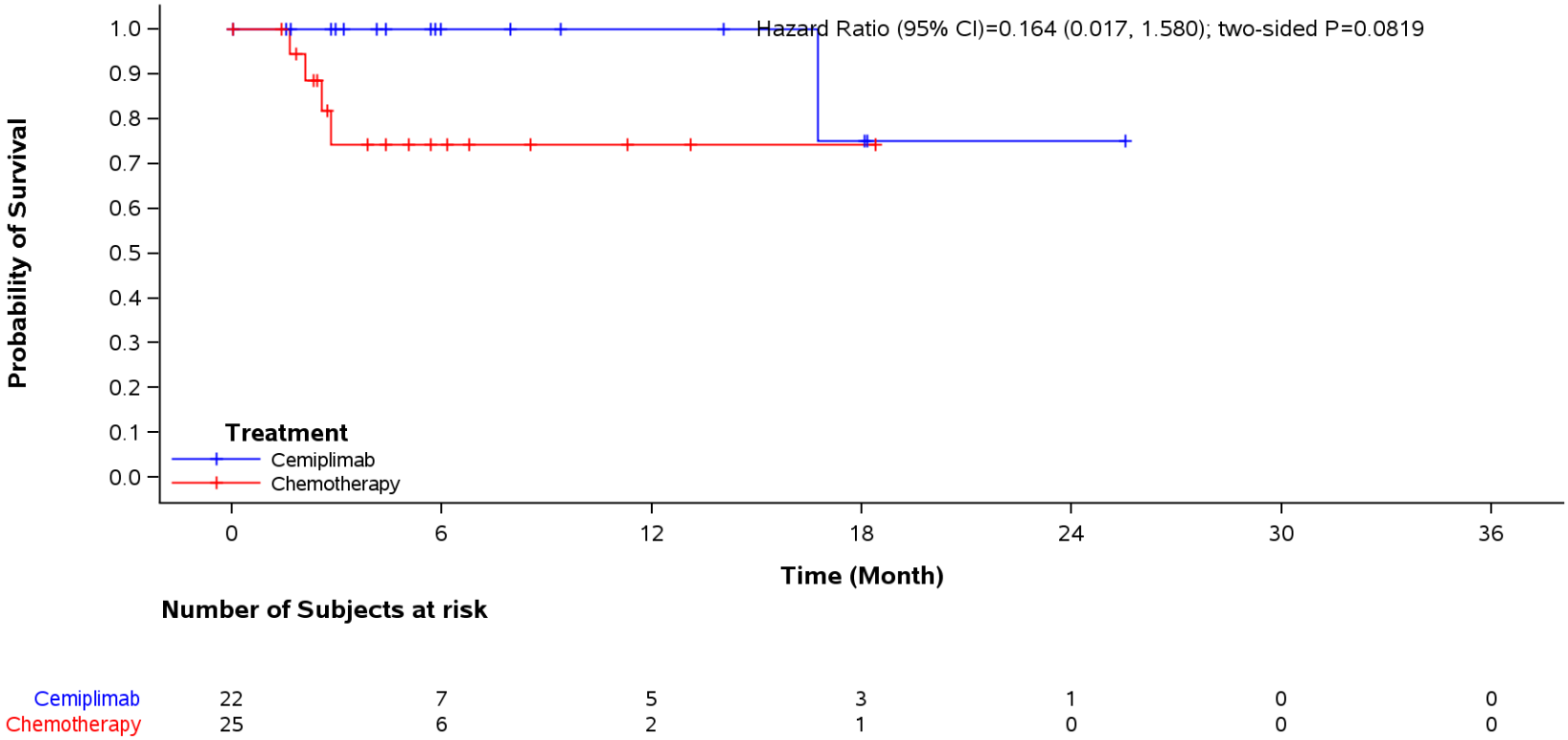

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts sustained deterioration



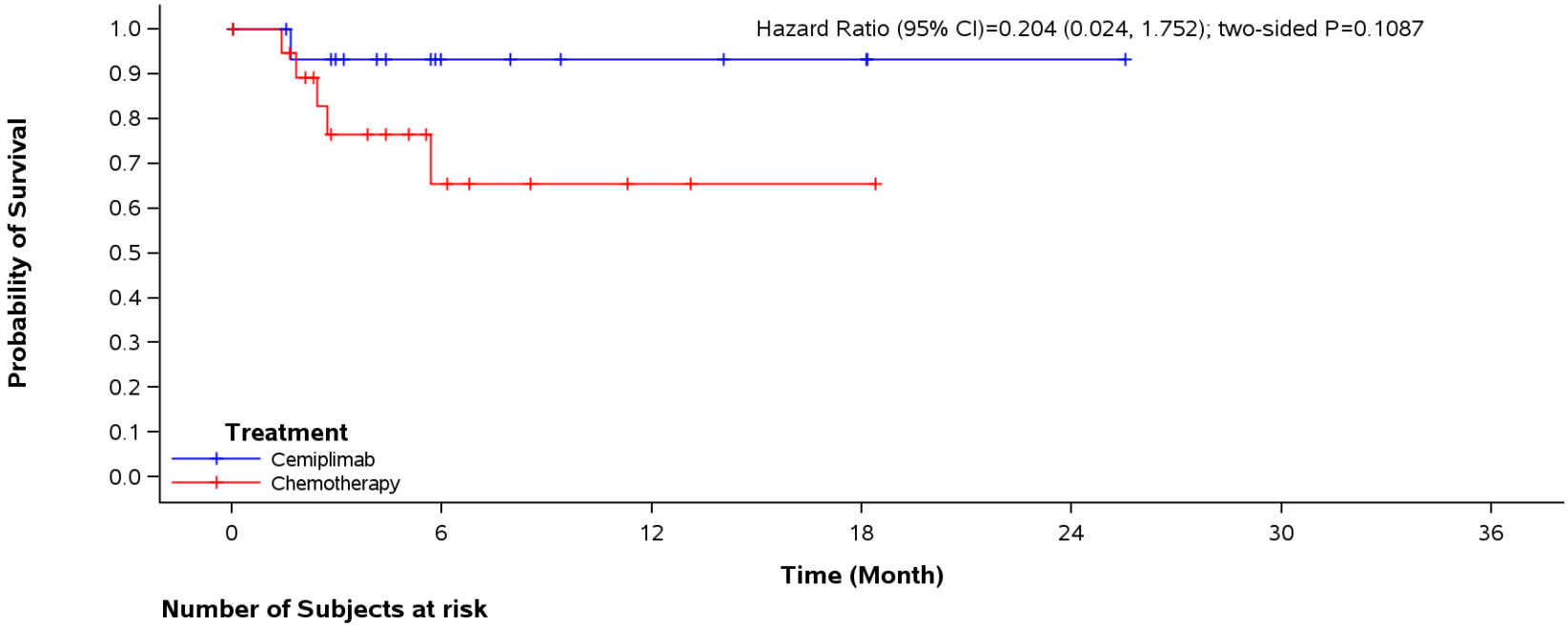

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts sustained deterioration



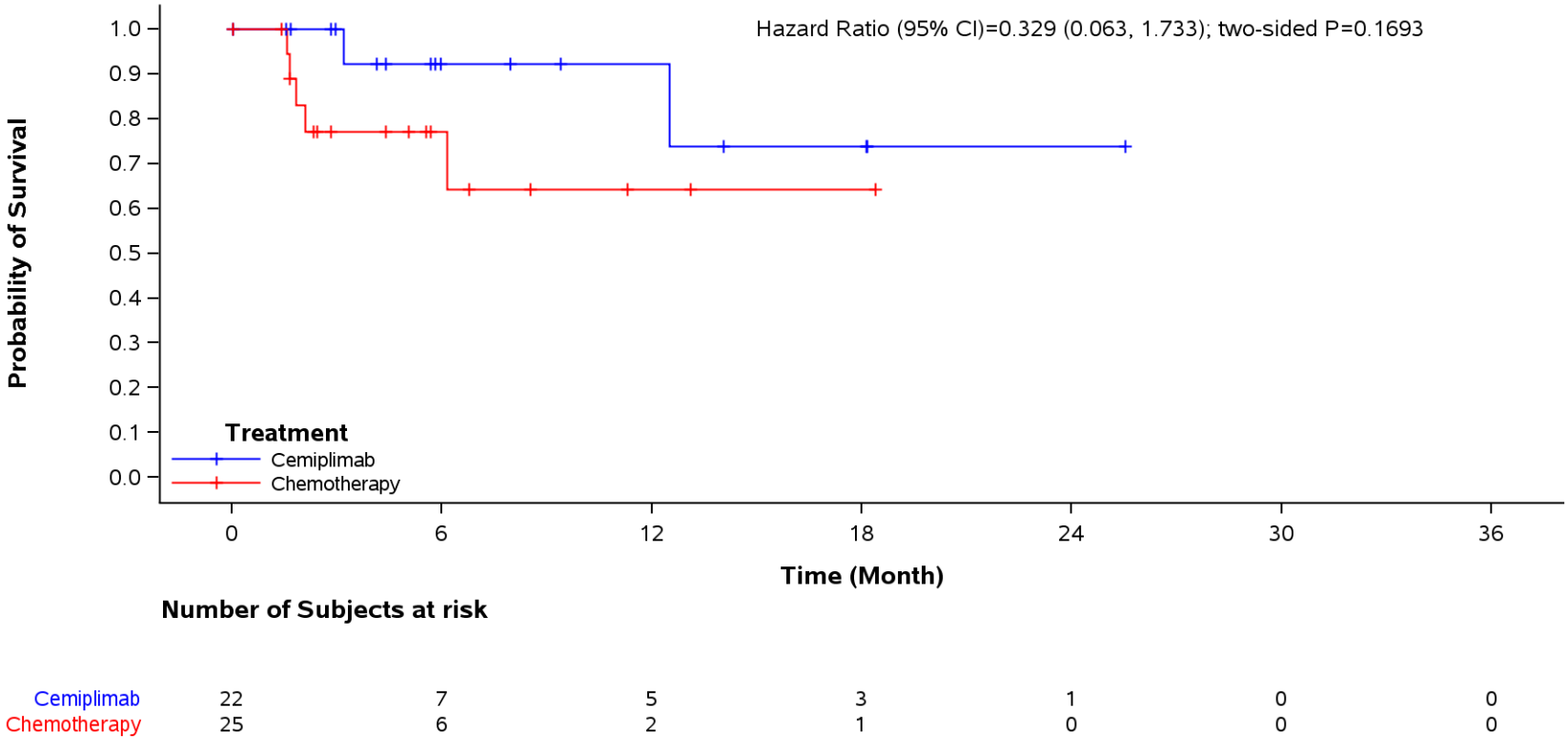

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts sustained deterioration



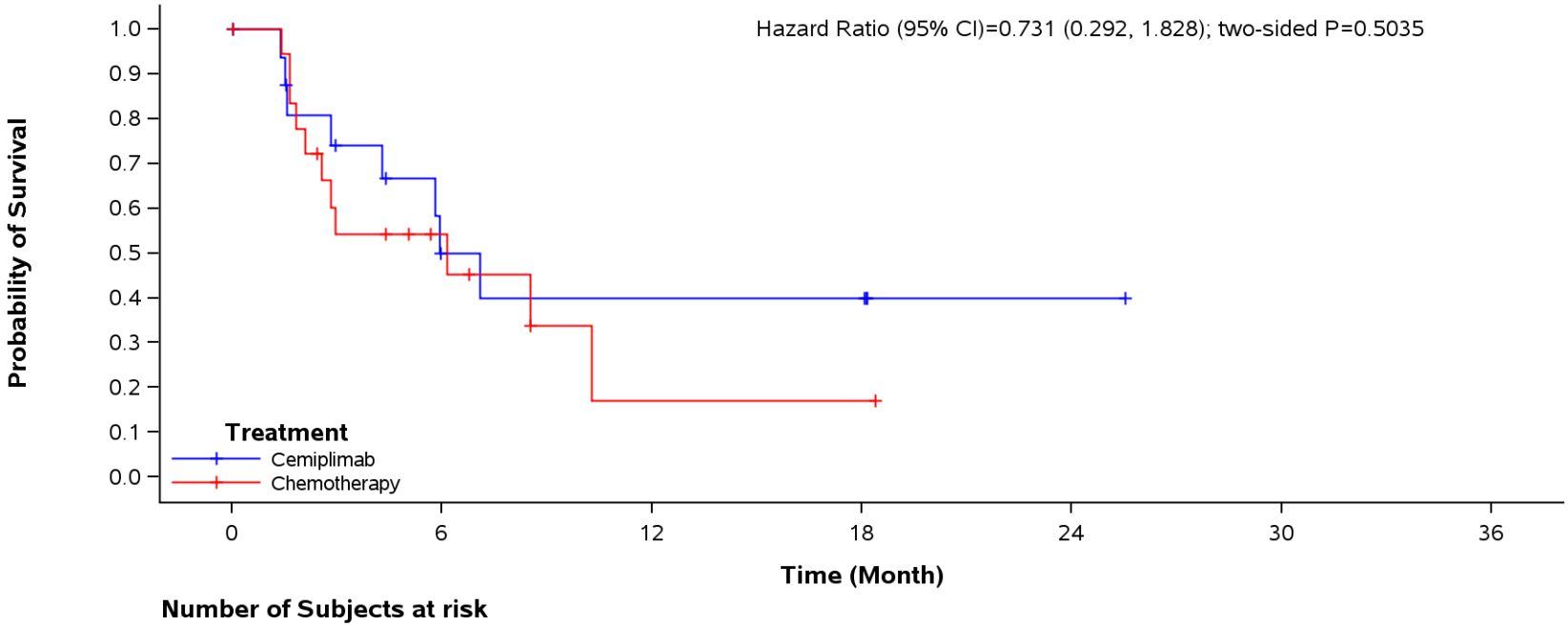

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts sustained deterioration



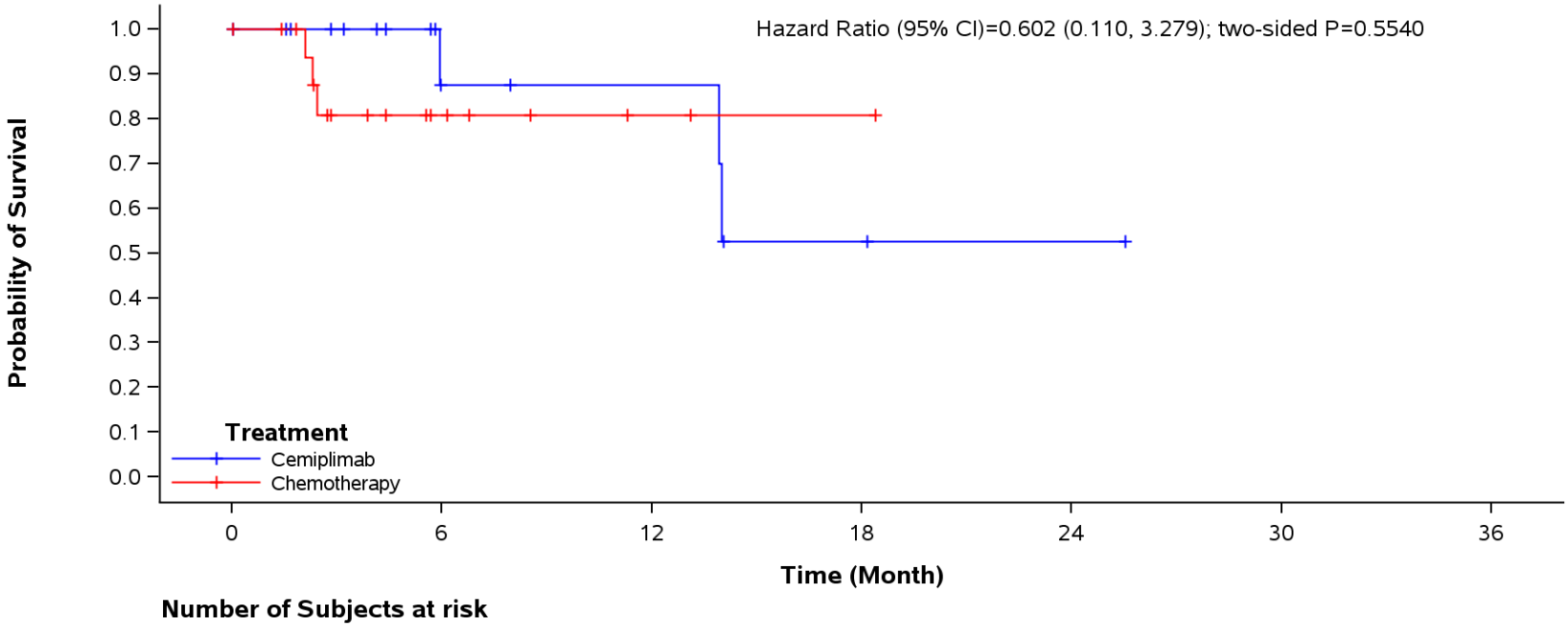

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts sustained deterioration



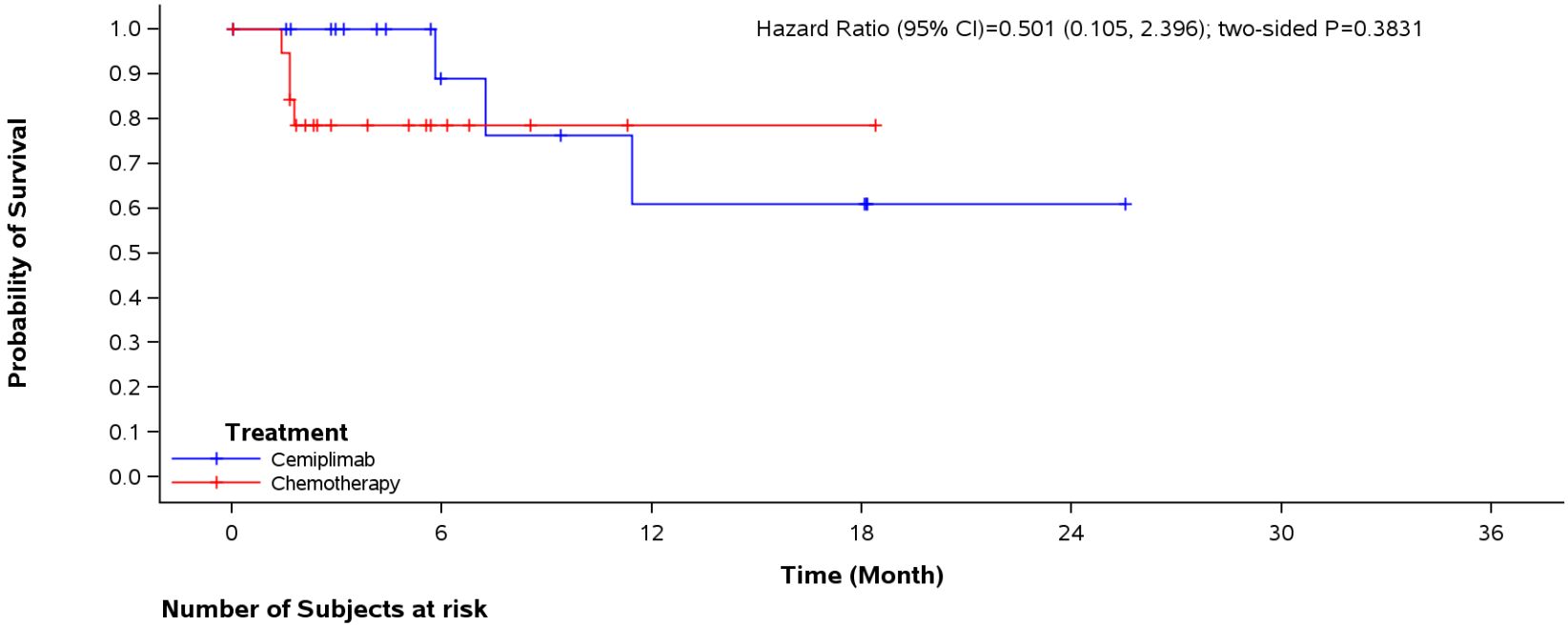

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts sustained deterioration



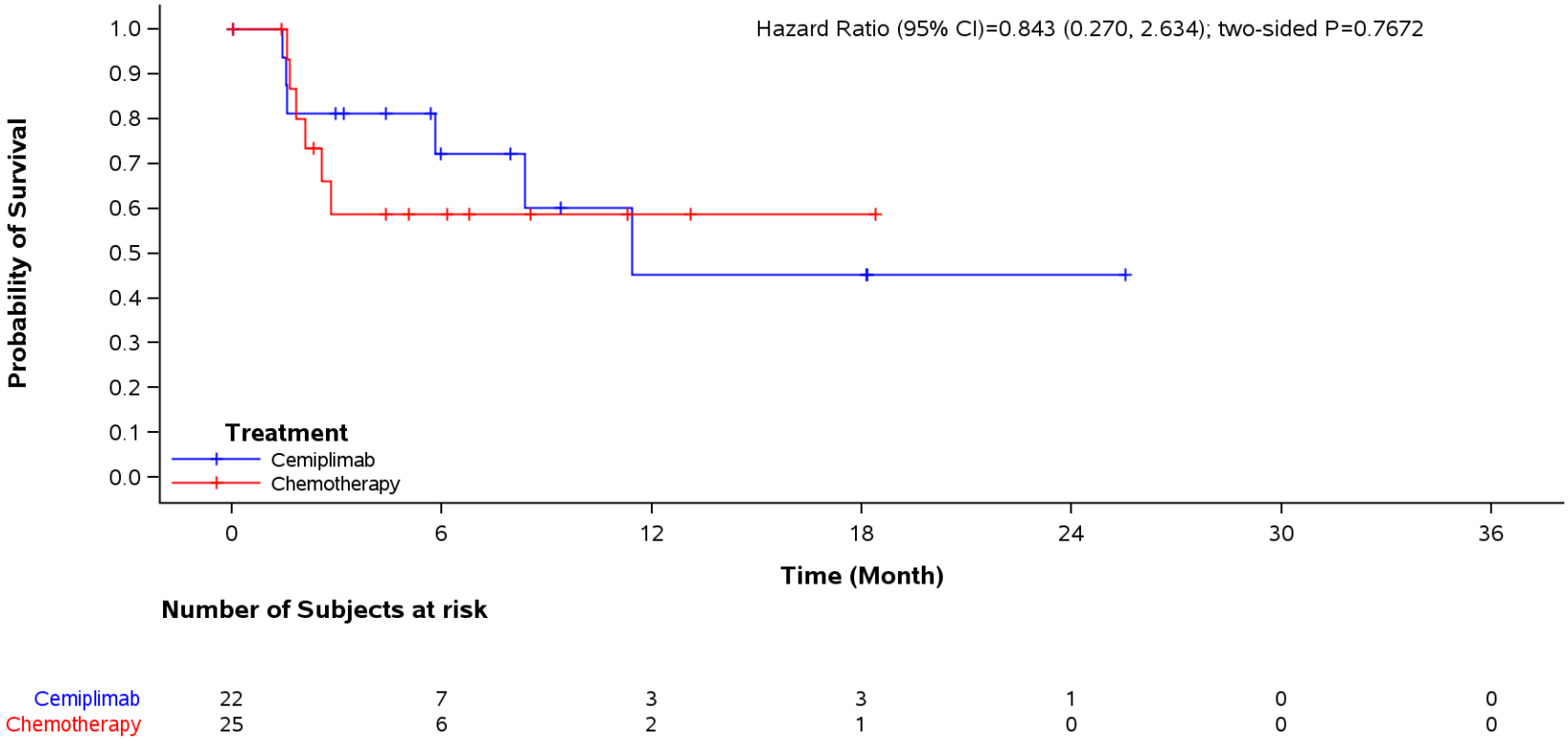

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

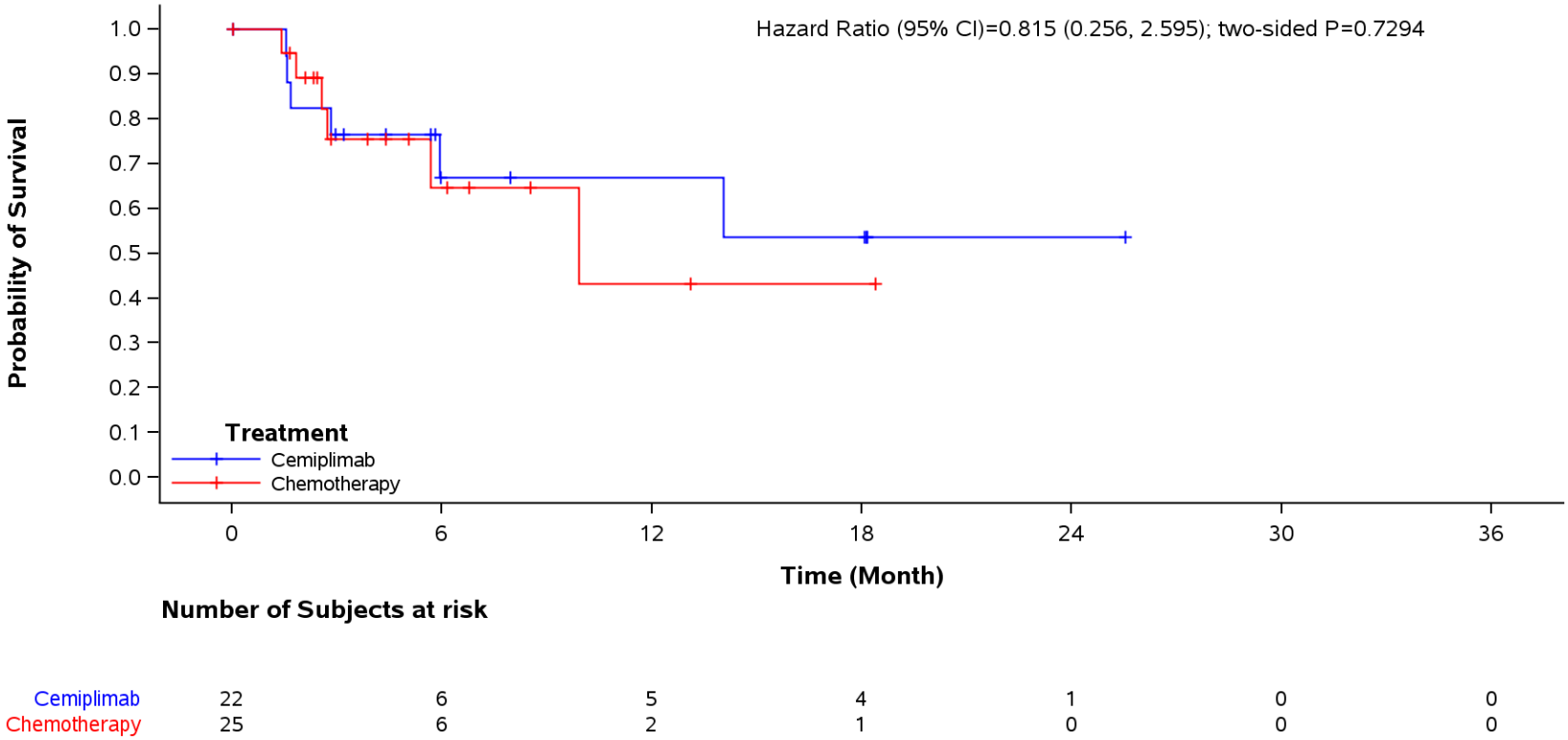
Geographic region: North America
Pain - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts sustained deterioration



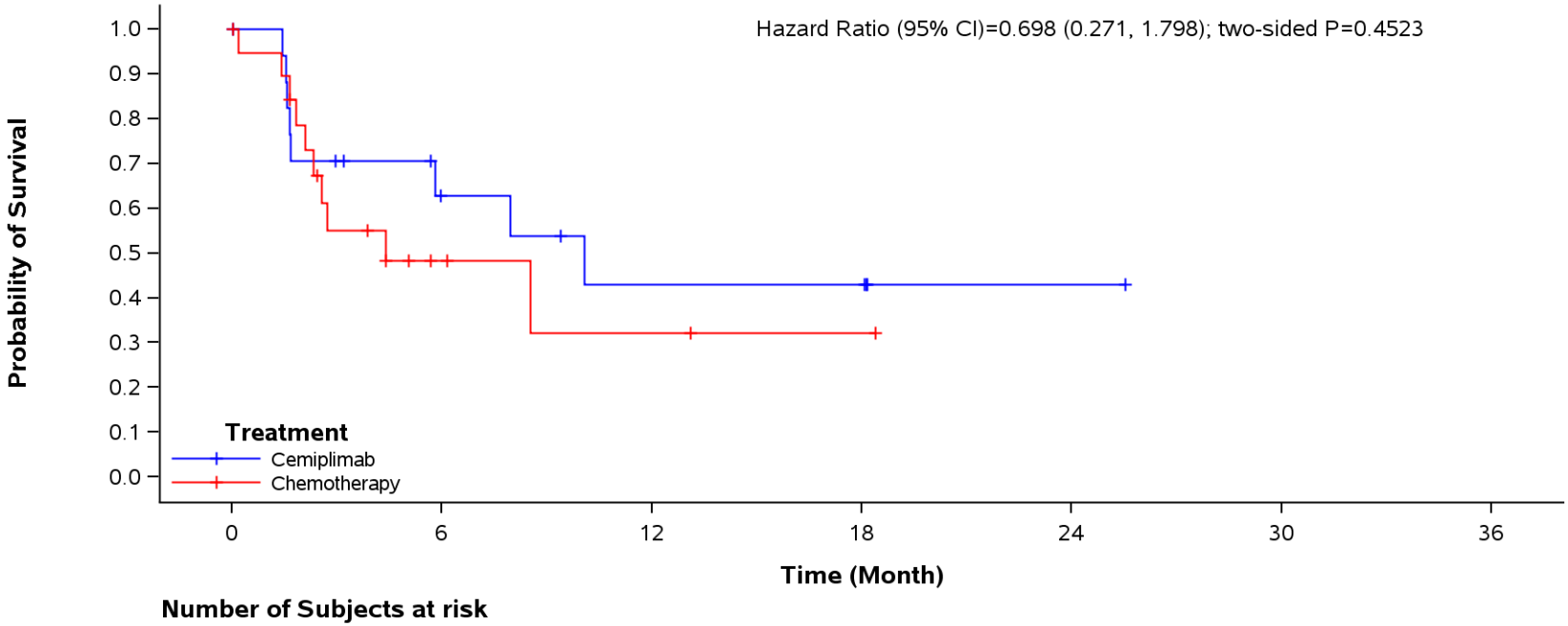

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts sustained deterioration



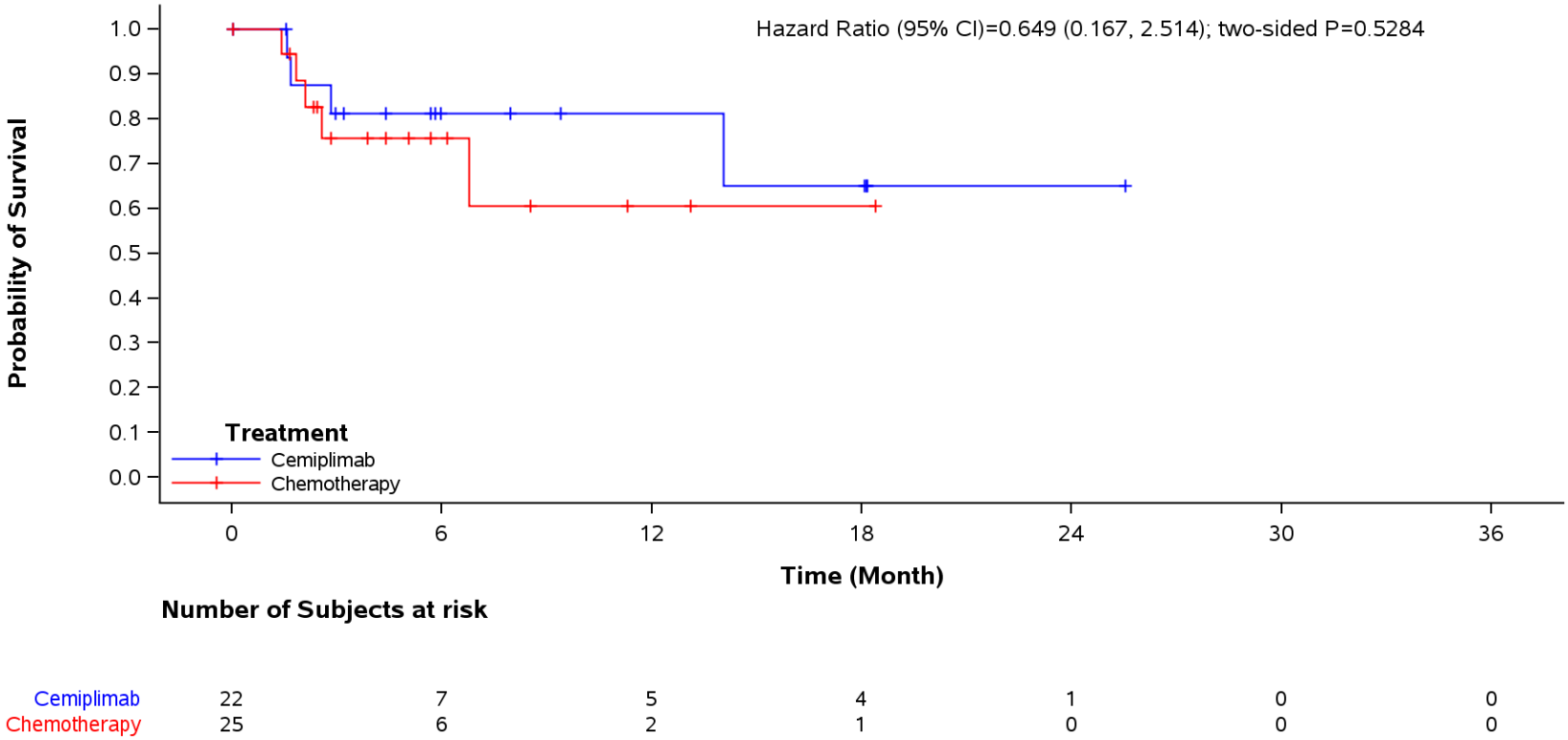

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 4 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts sustained deterioration



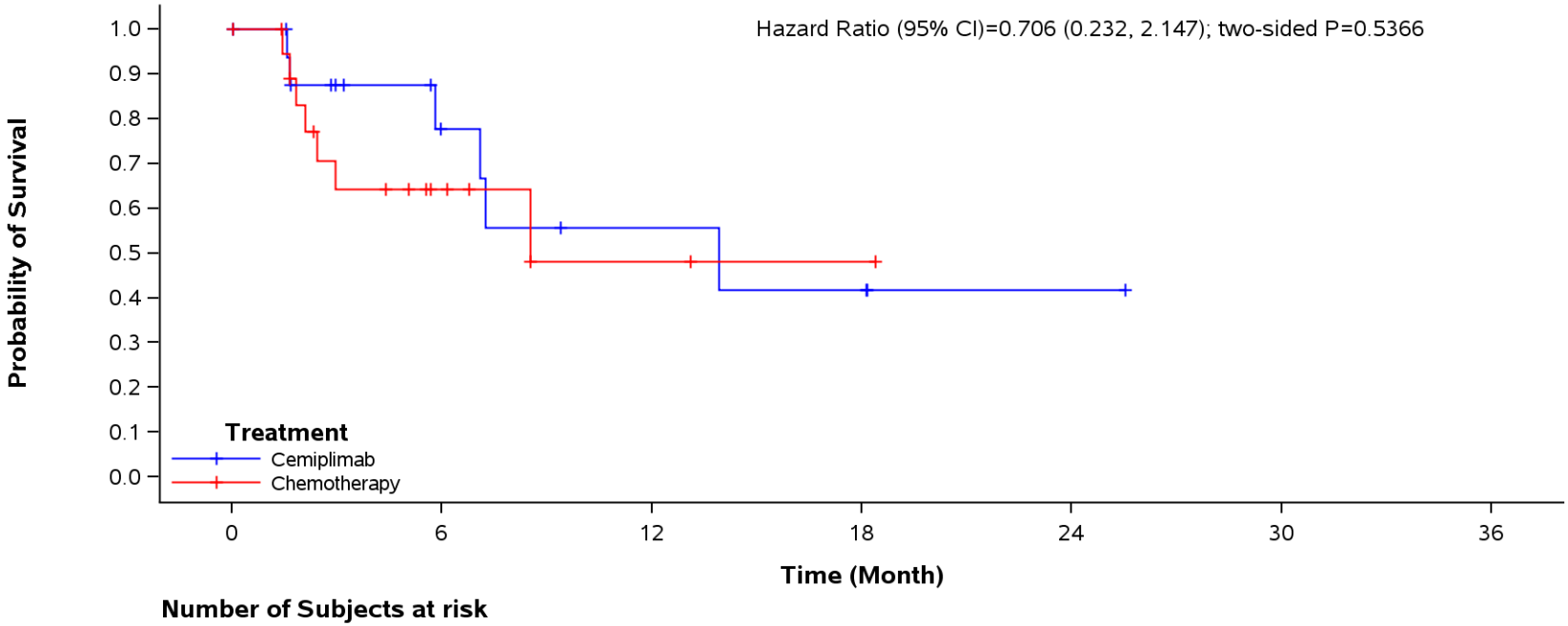

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts sustained deterioration



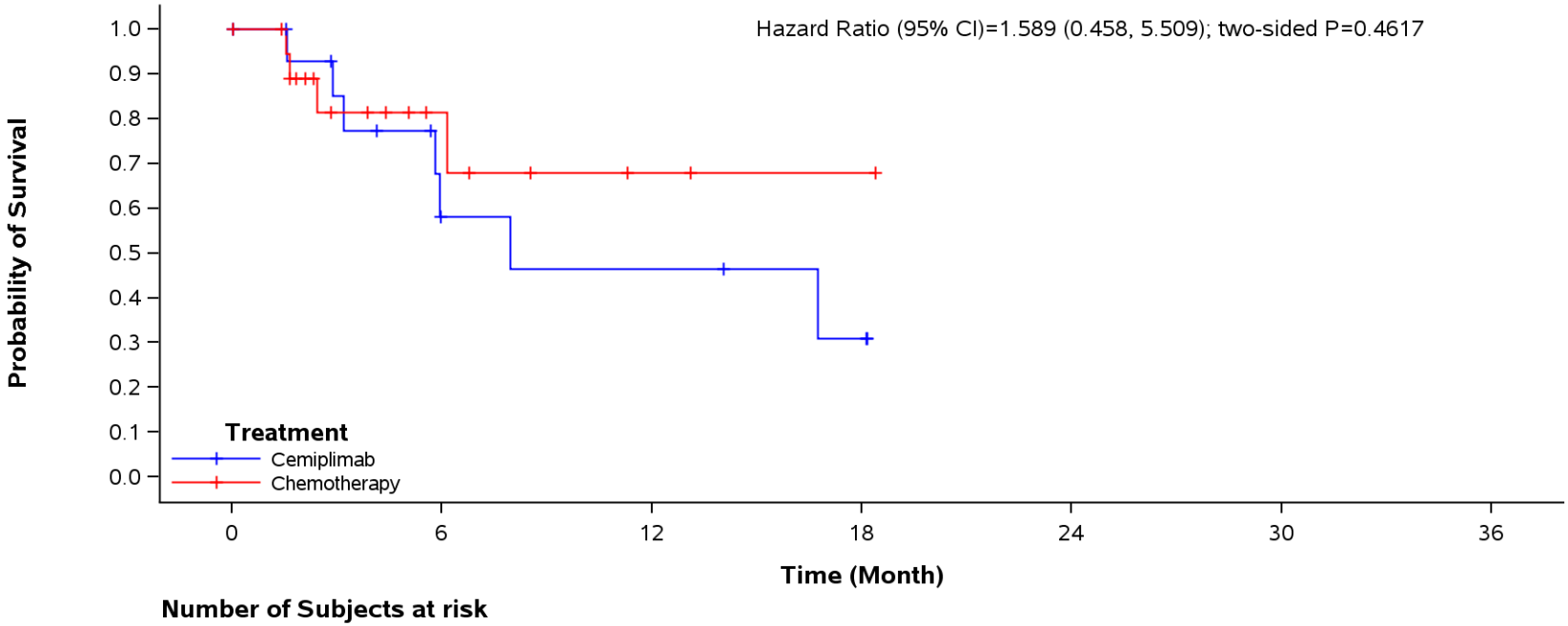

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts sustained deterioration



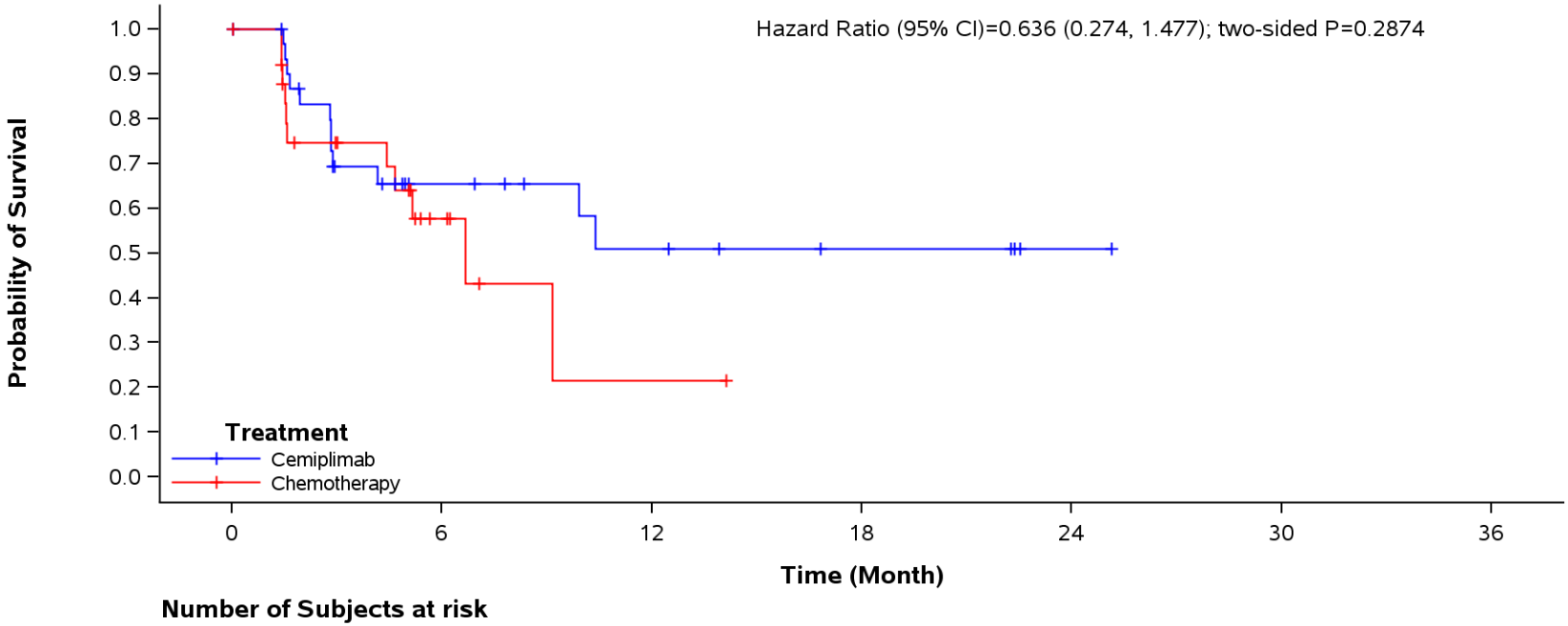

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts sustained deterioration



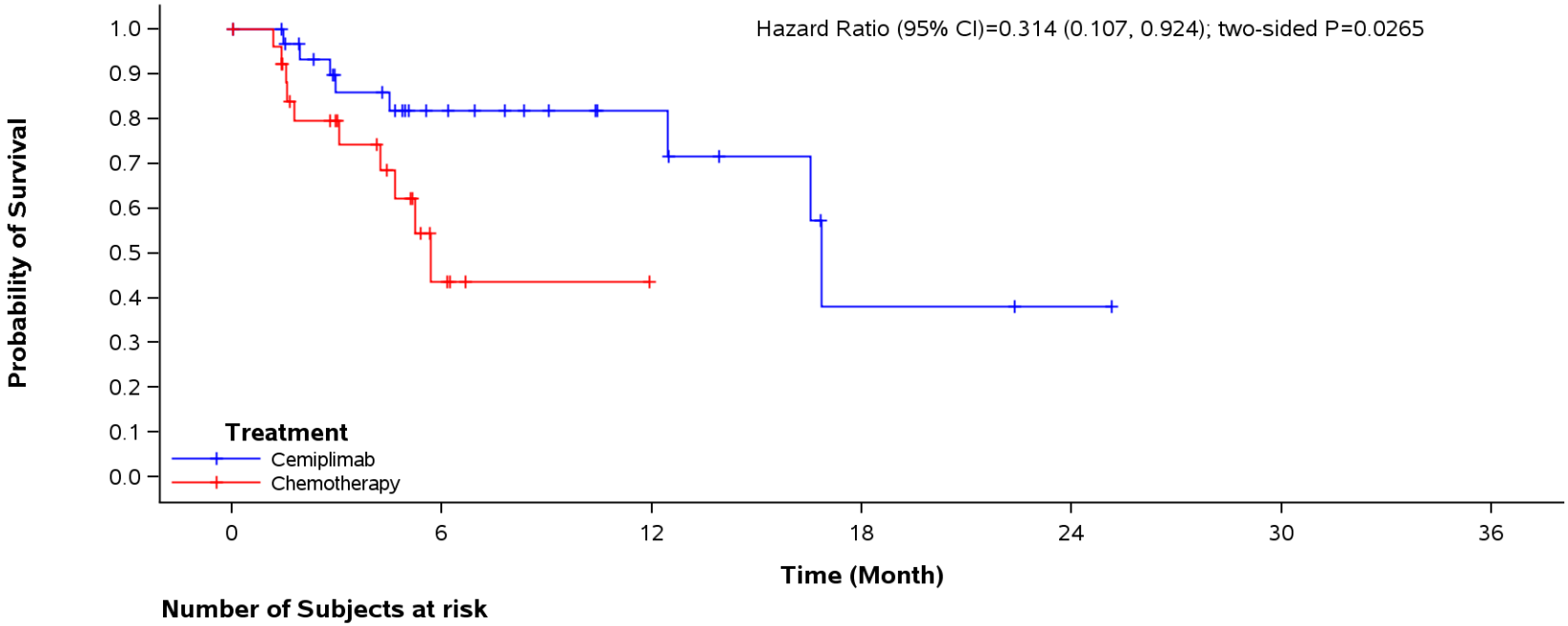

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 36 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts sustained deterioration




**Number of Subjects at risk**

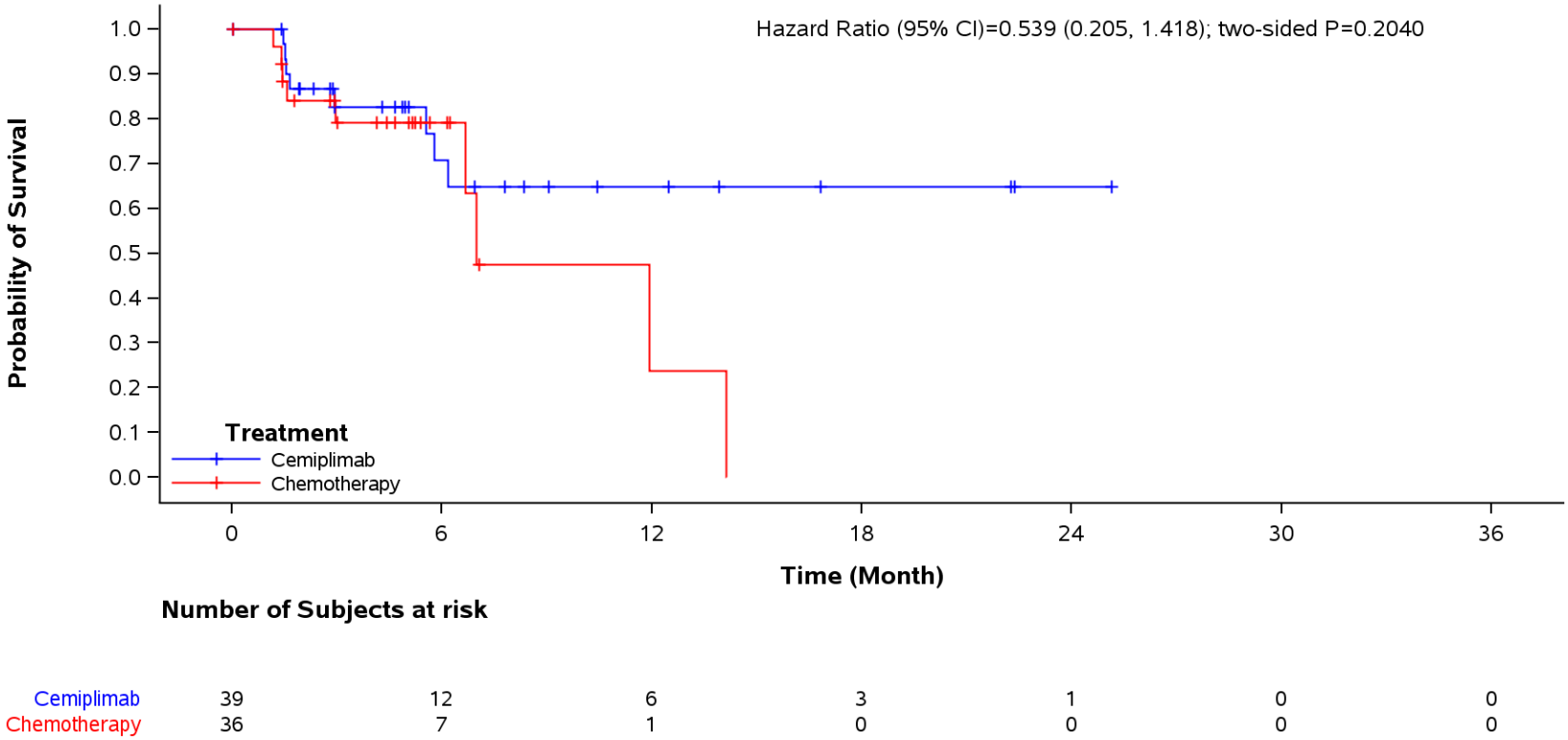
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 15 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 36 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:23:03, yingyuan.lin)

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts sustained deterioration



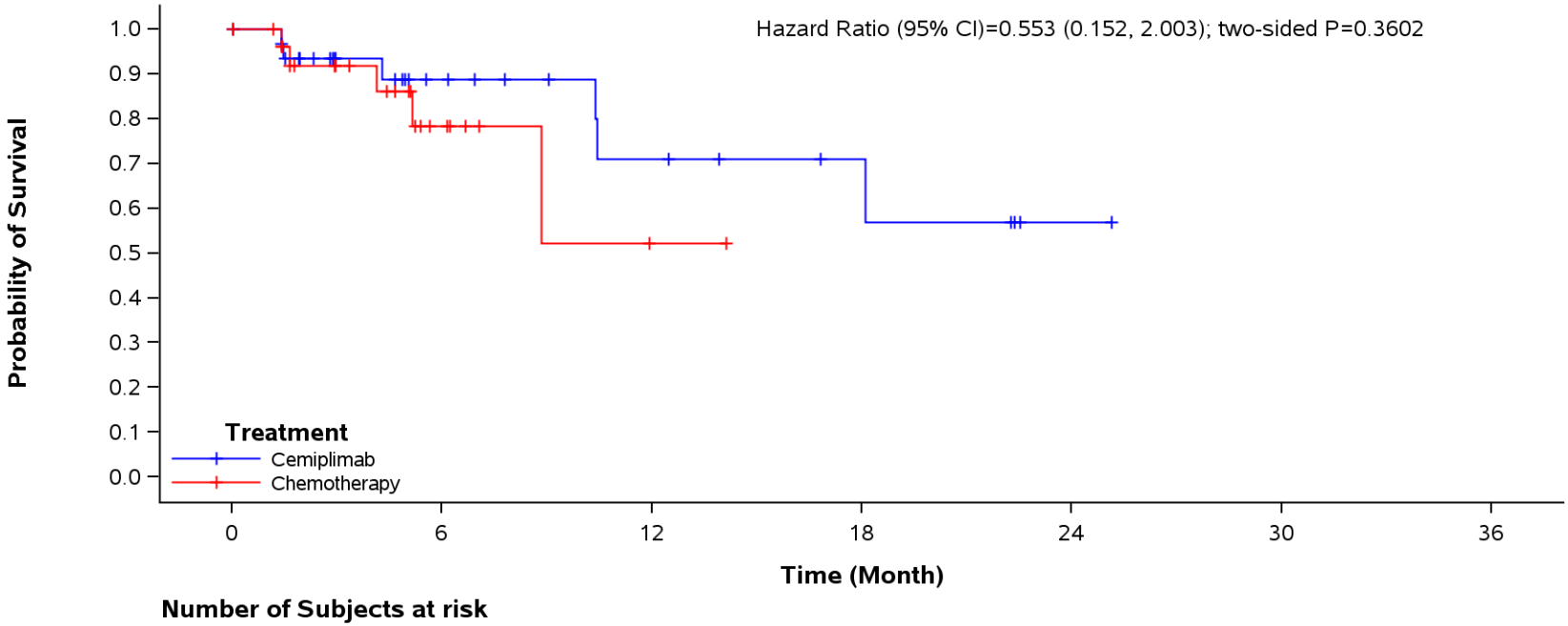

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts sustained deterioration



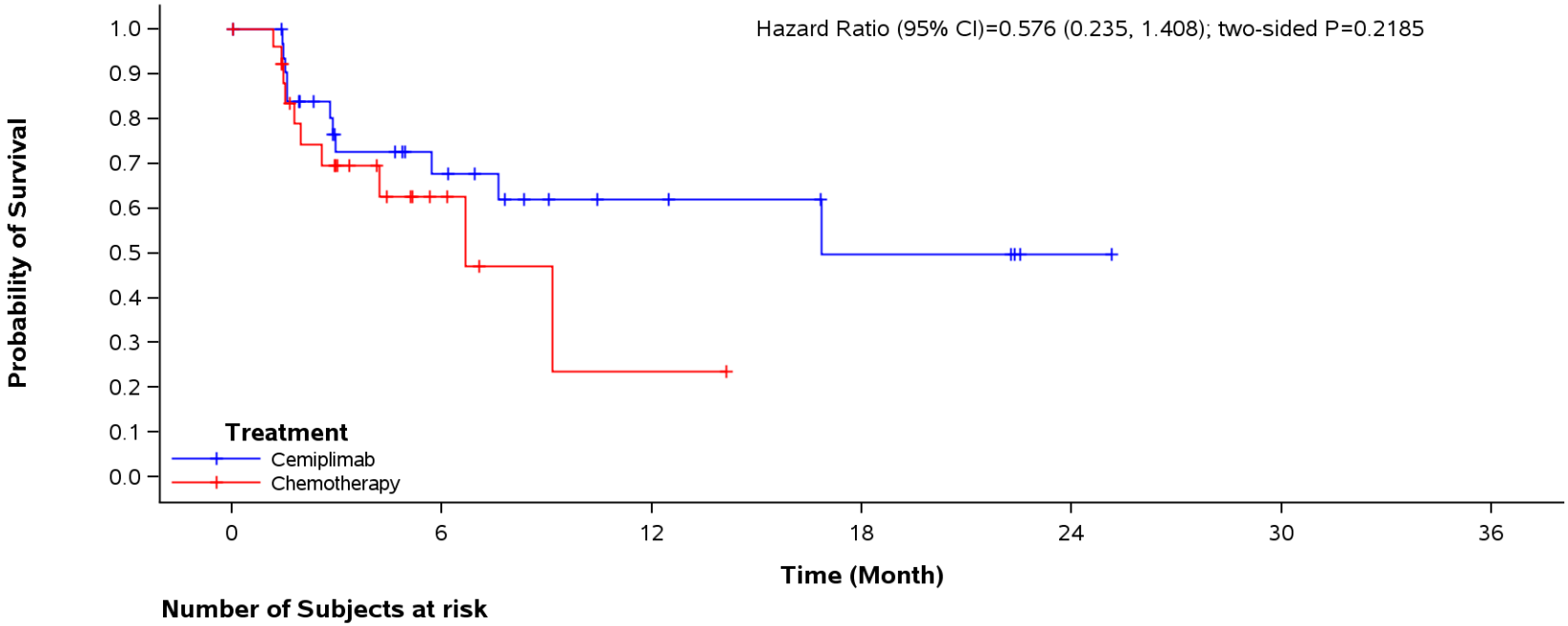

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 14 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts sustained deterioration



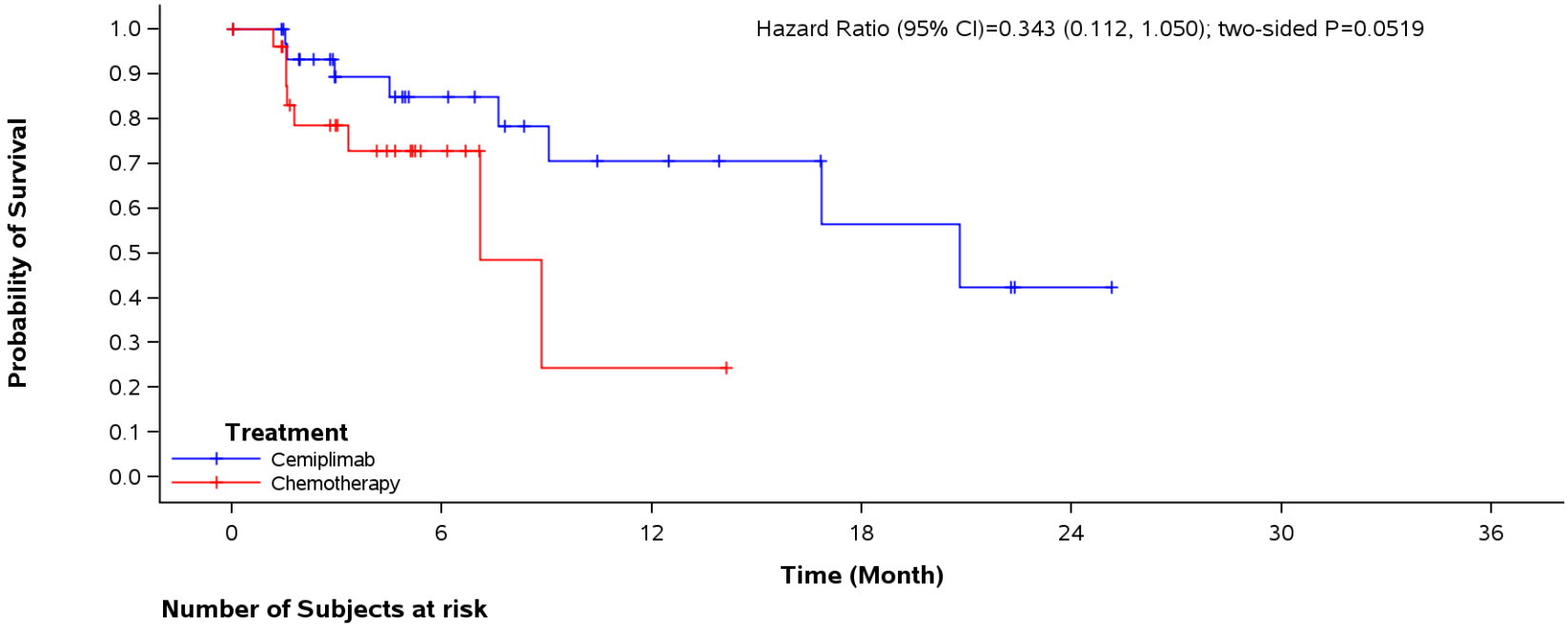

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 14 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 36 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts sustained deterioration



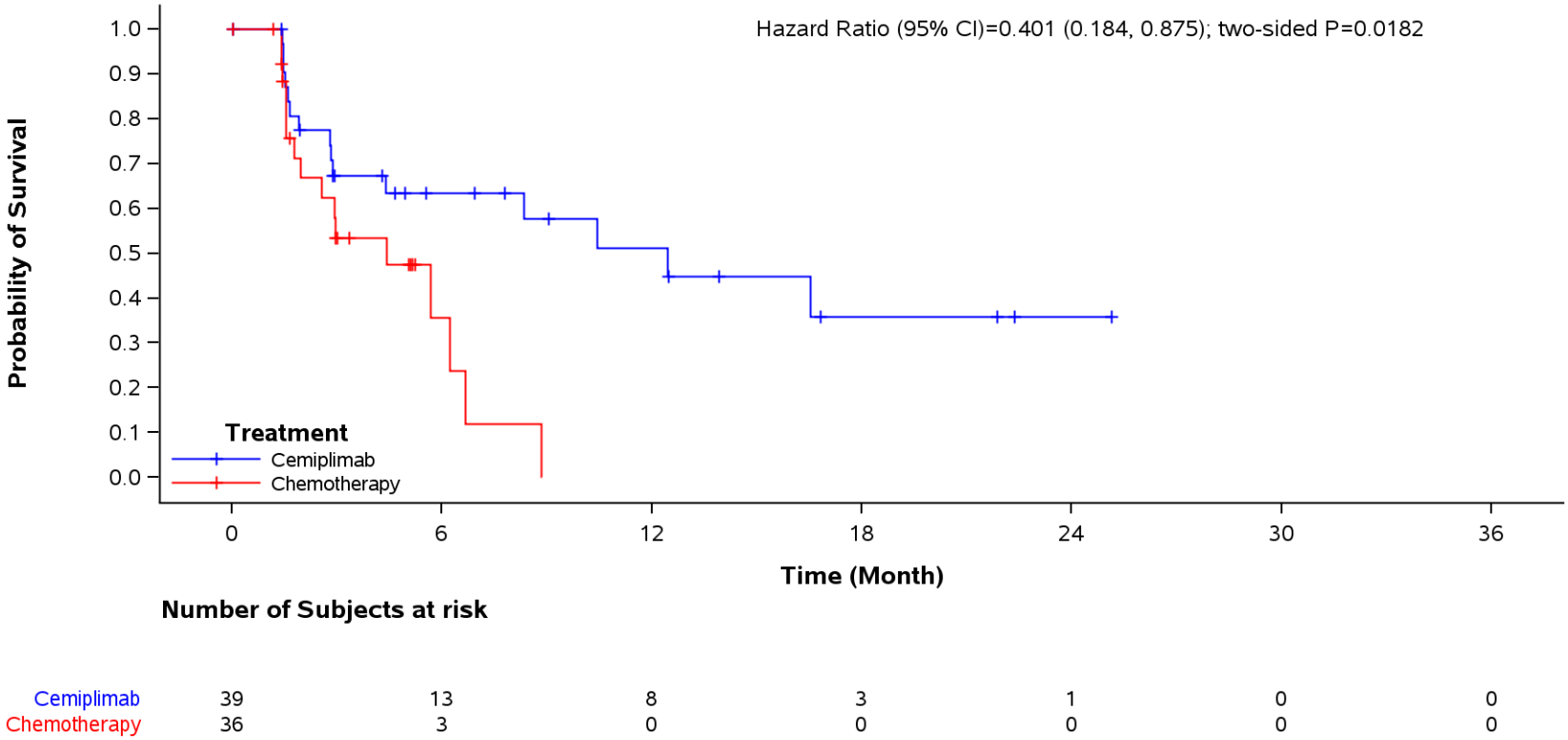

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 15 | 8 | 4 | 1 | 0 | 0 |
| Chemotherapy | 36 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

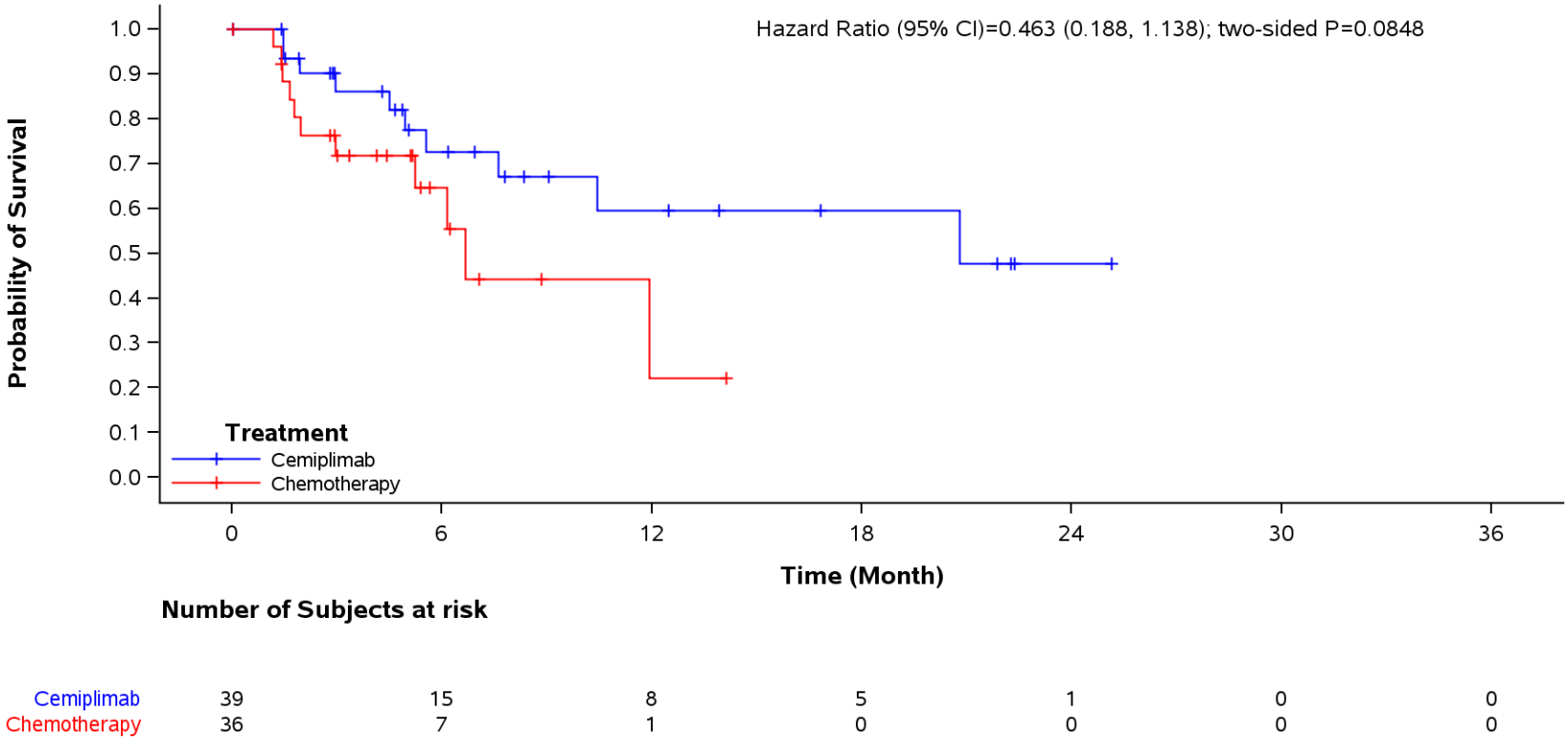
Geographic region: Asia
Fatigue - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts sustained deterioration



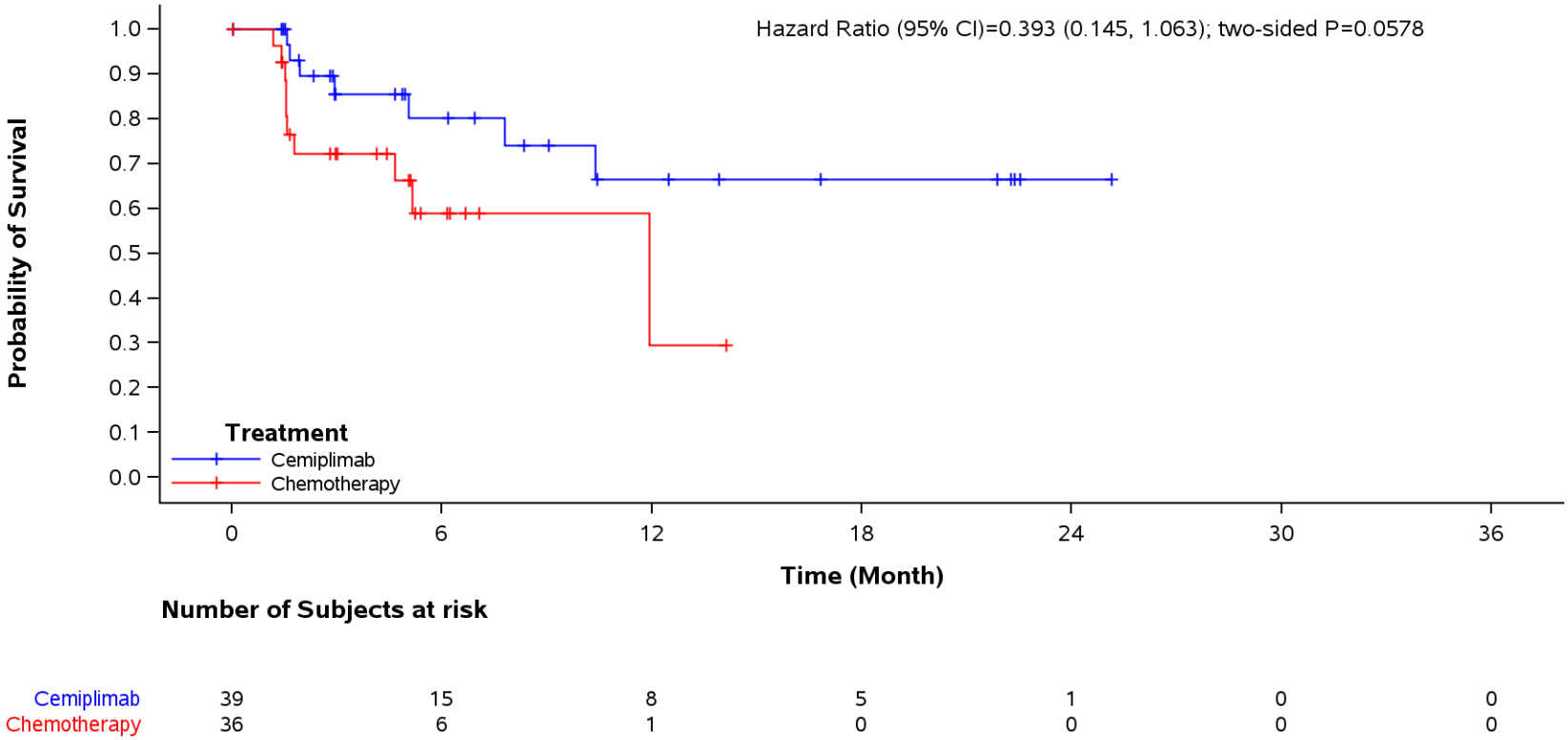

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 15 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts sustained deterioration



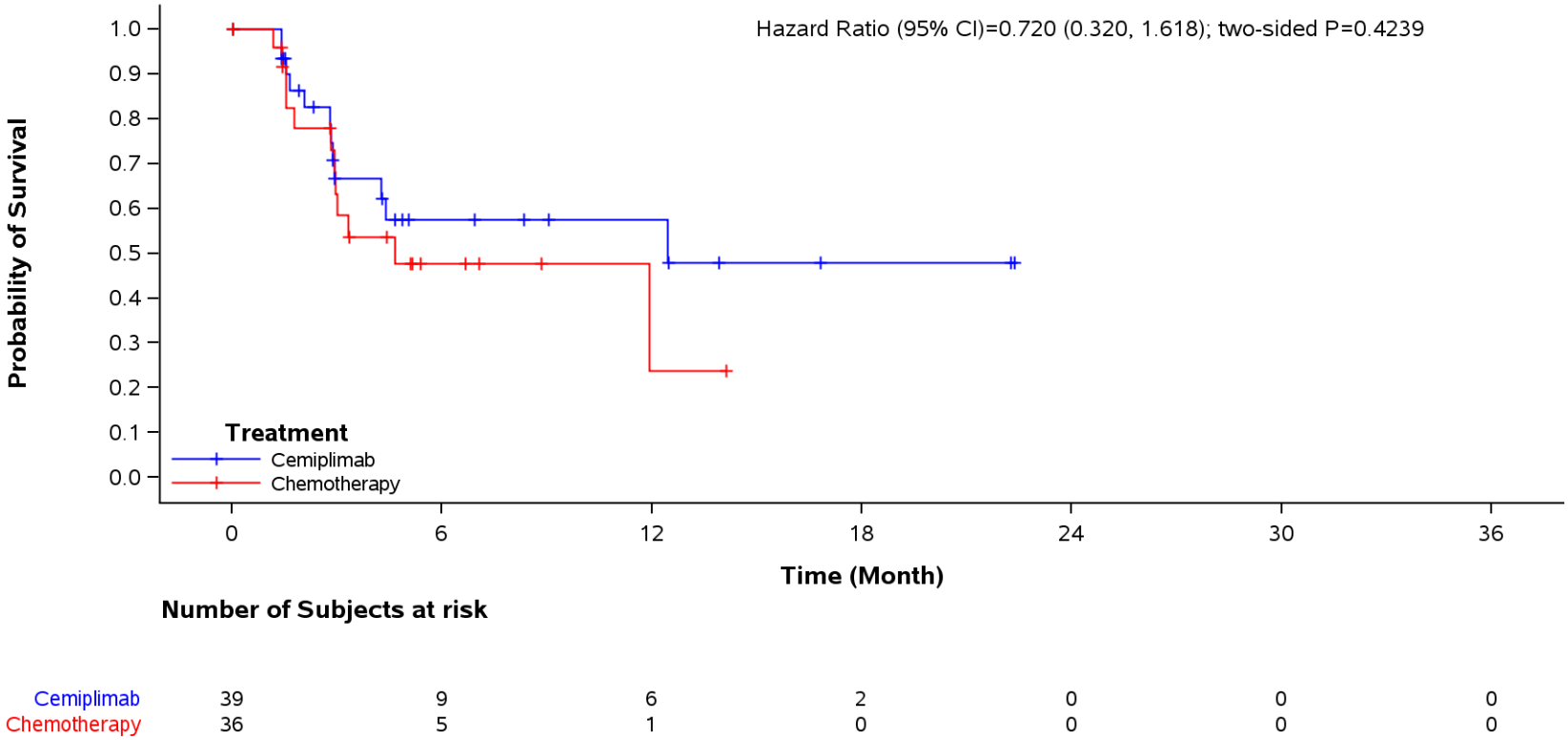

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 15 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts sustained deterioration



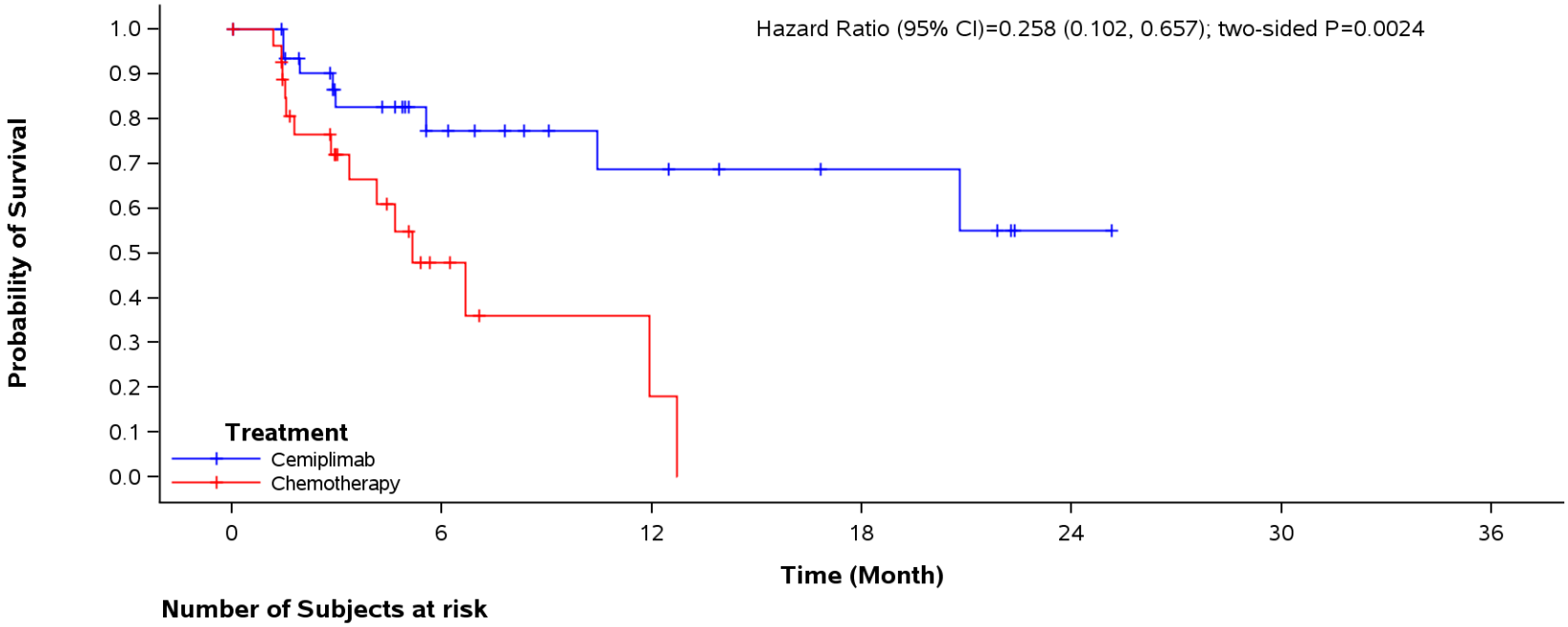

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts sustained deterioration



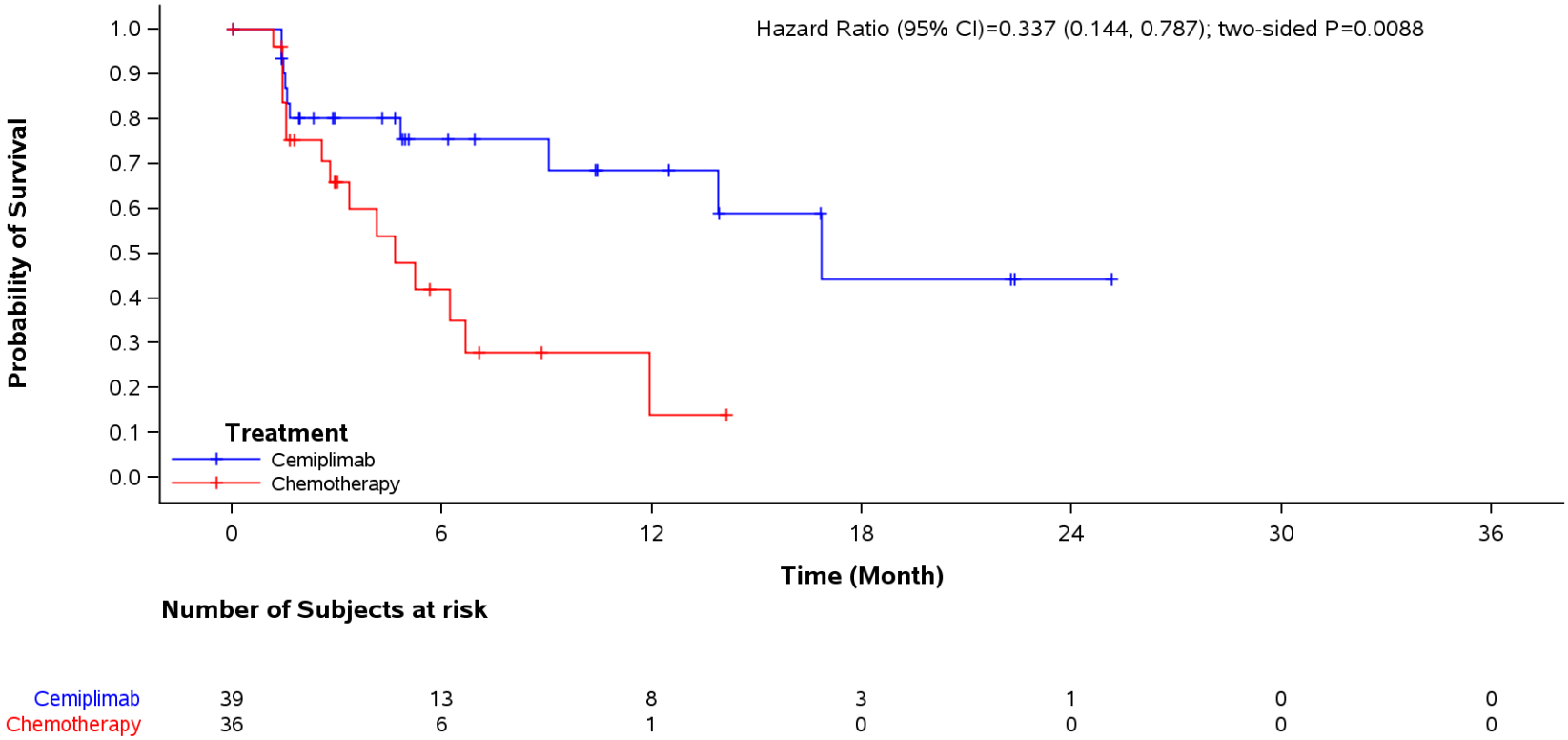

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 14 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Global health status / QoL - 10 pts sustained deterioration



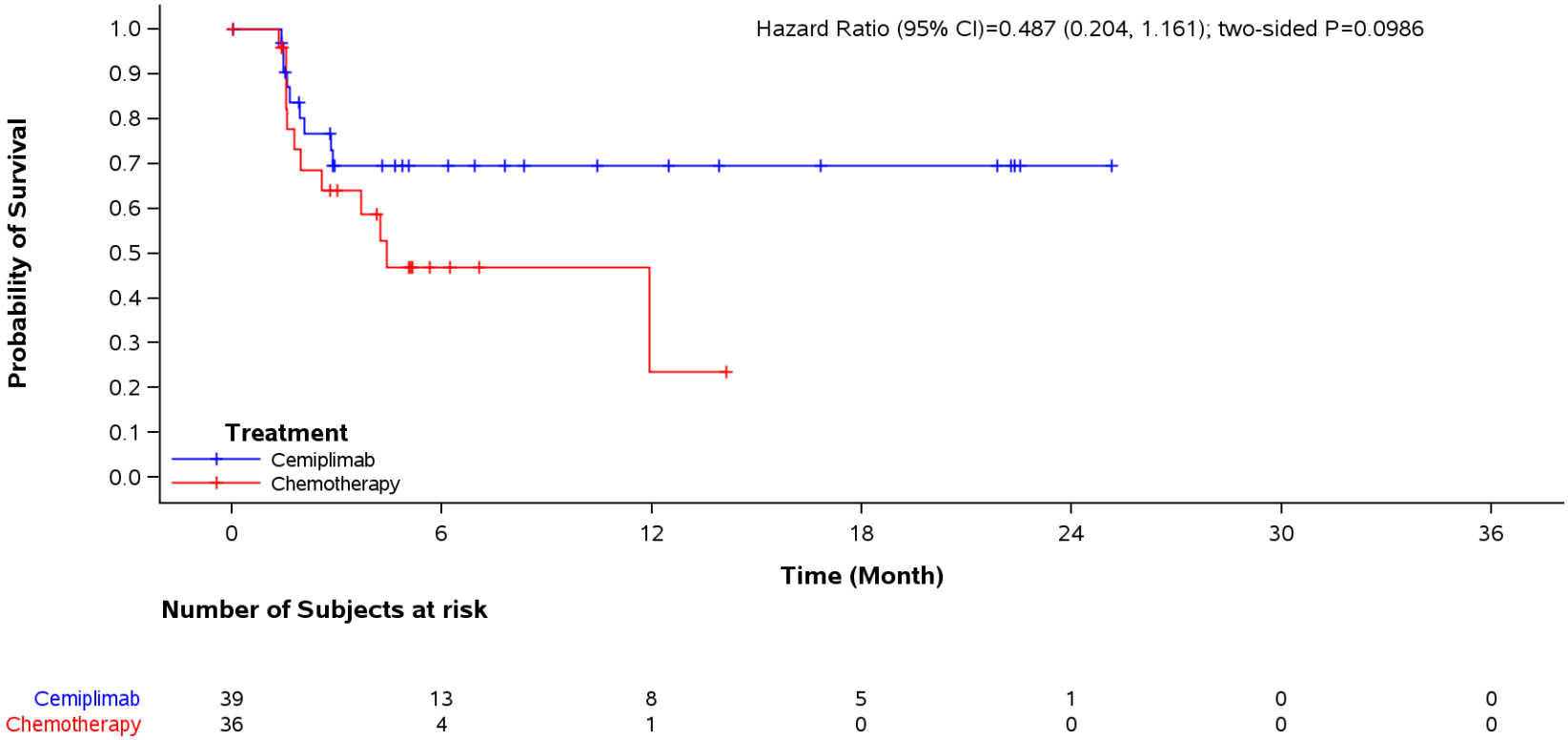

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts sustained deterioration



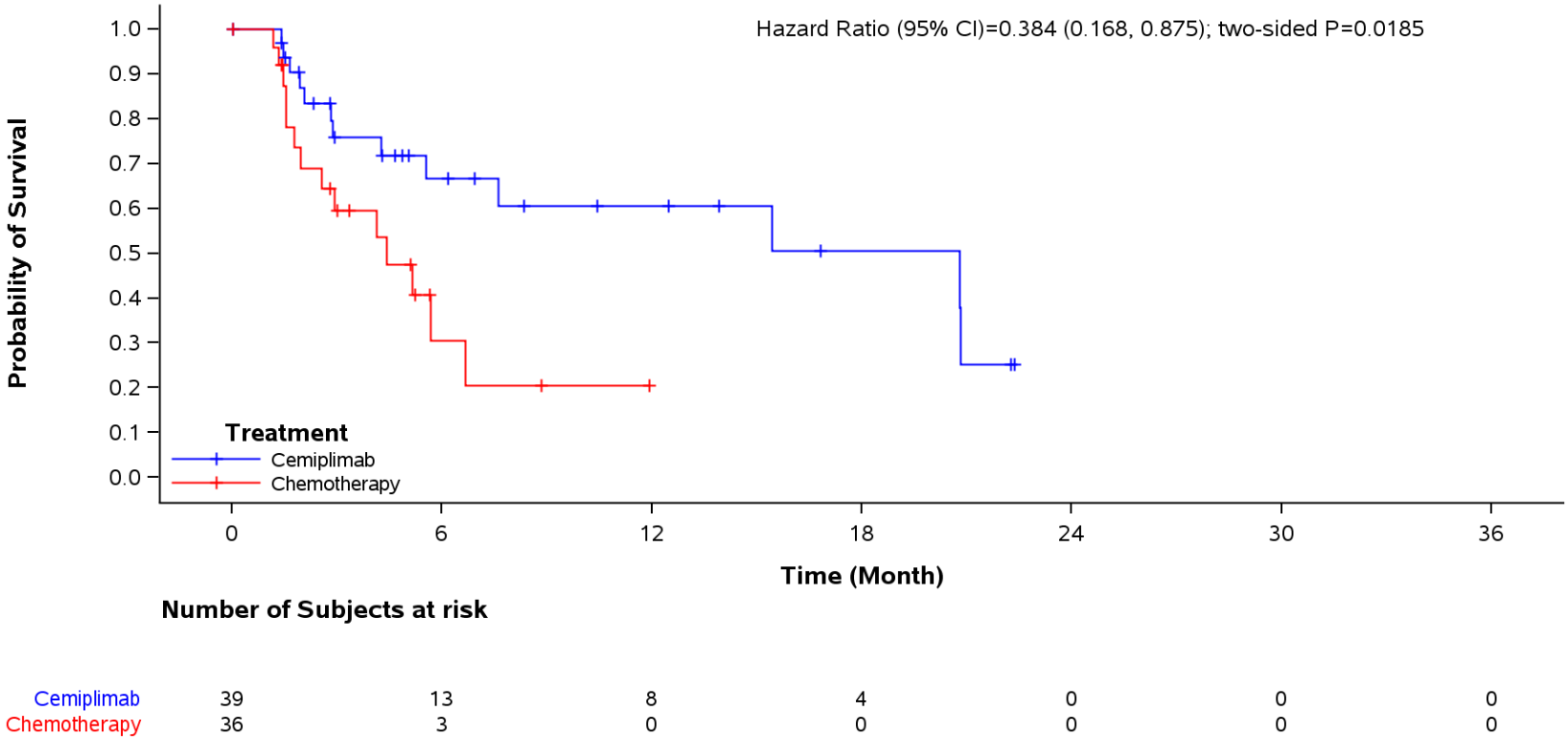

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts sustained deterioration



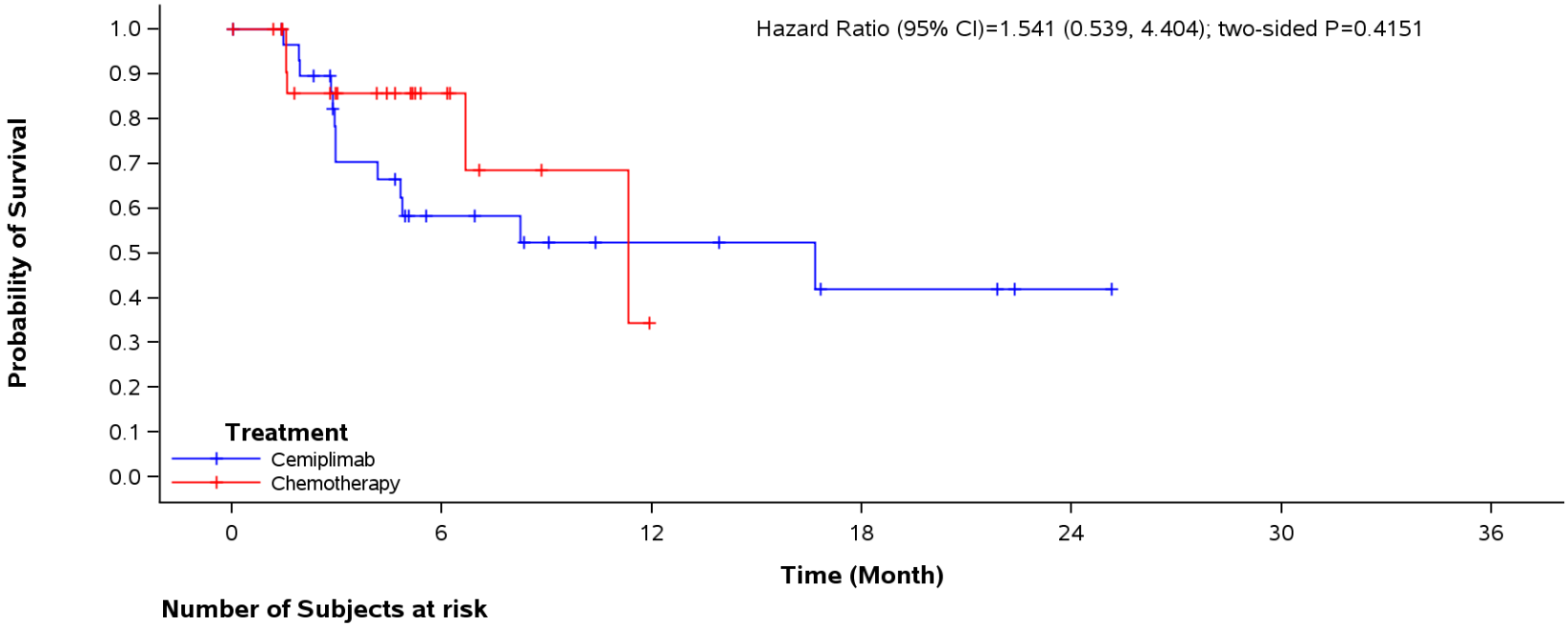

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 4 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts sustained deterioration



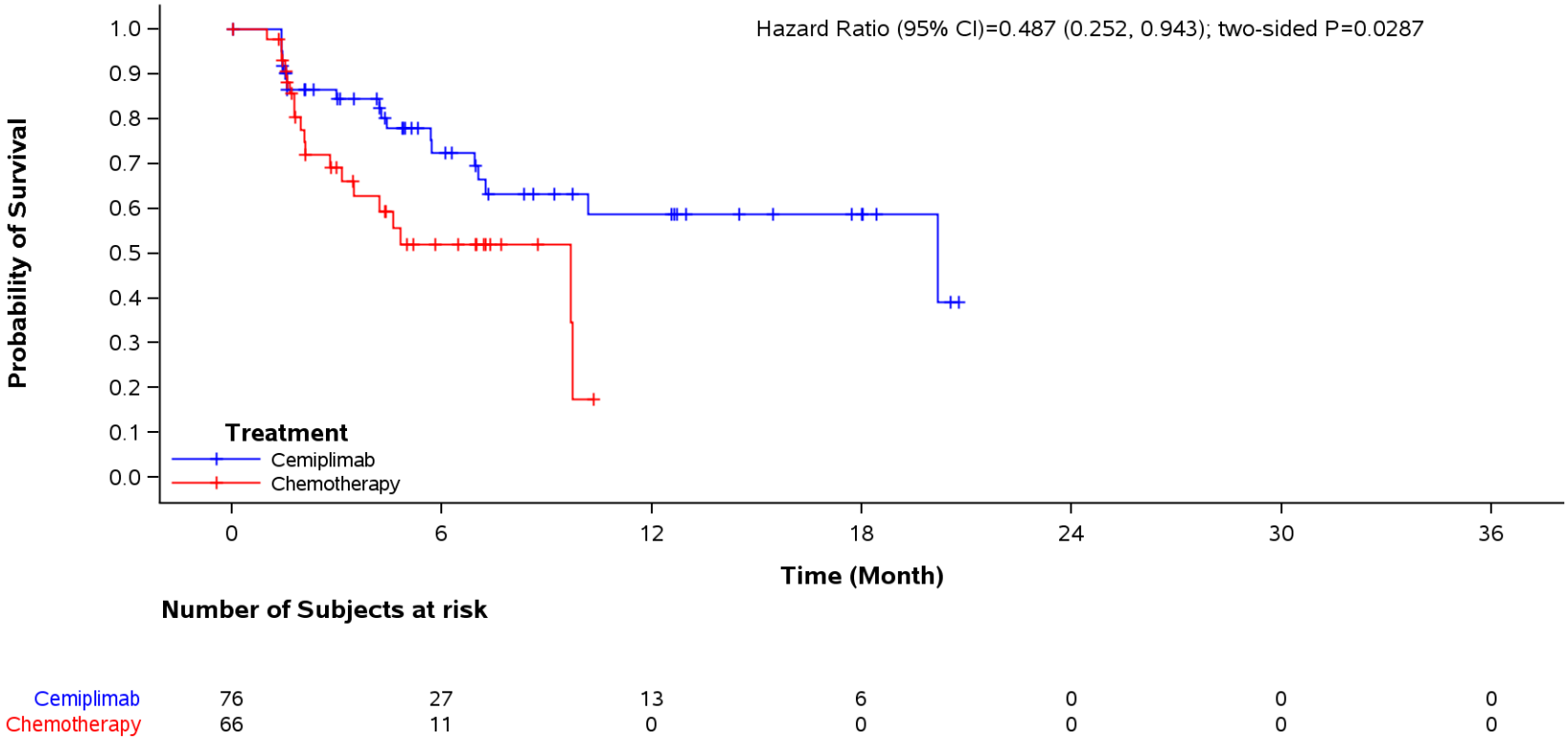

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 11 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts sustained deterioration



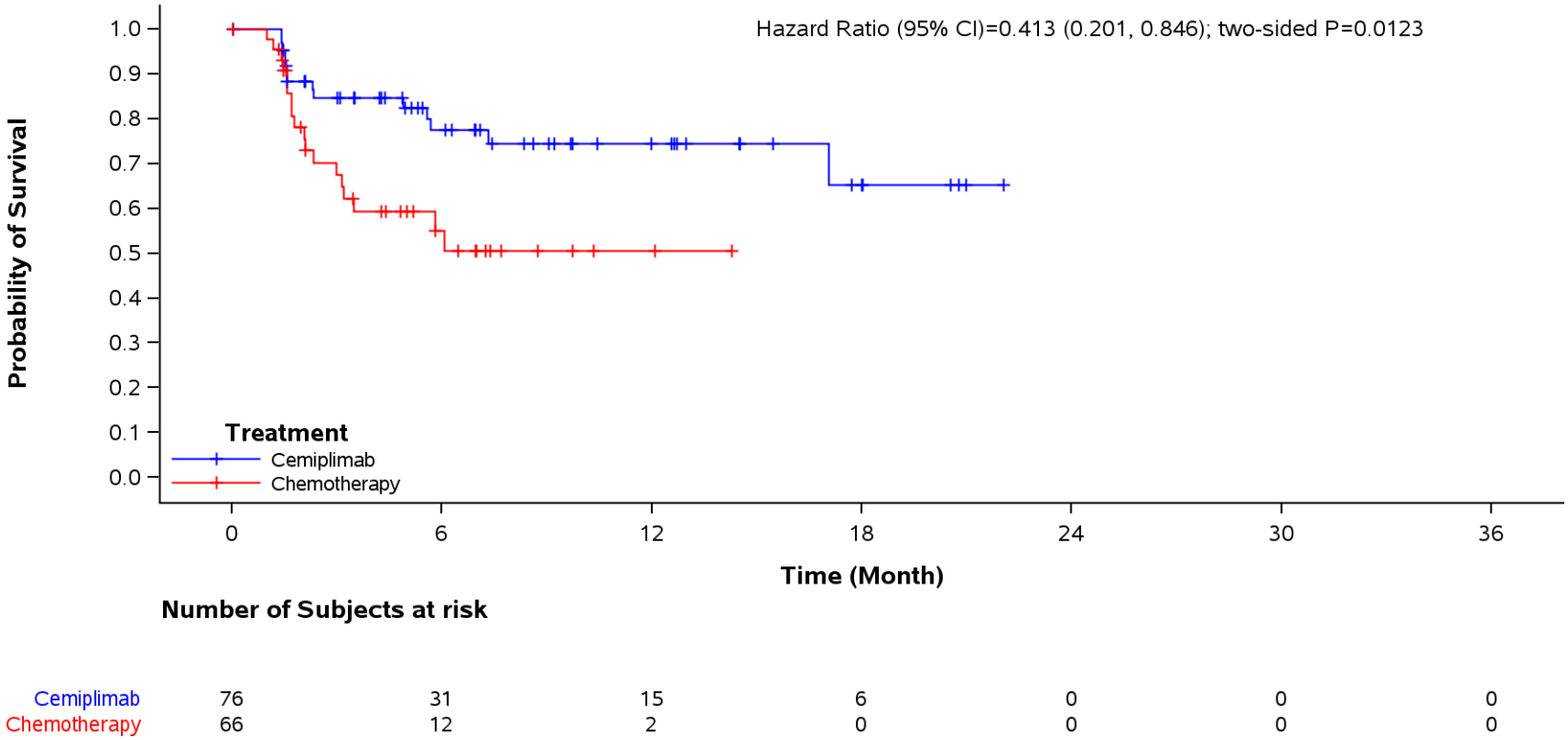

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 27 | 13 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts sustained deterioration



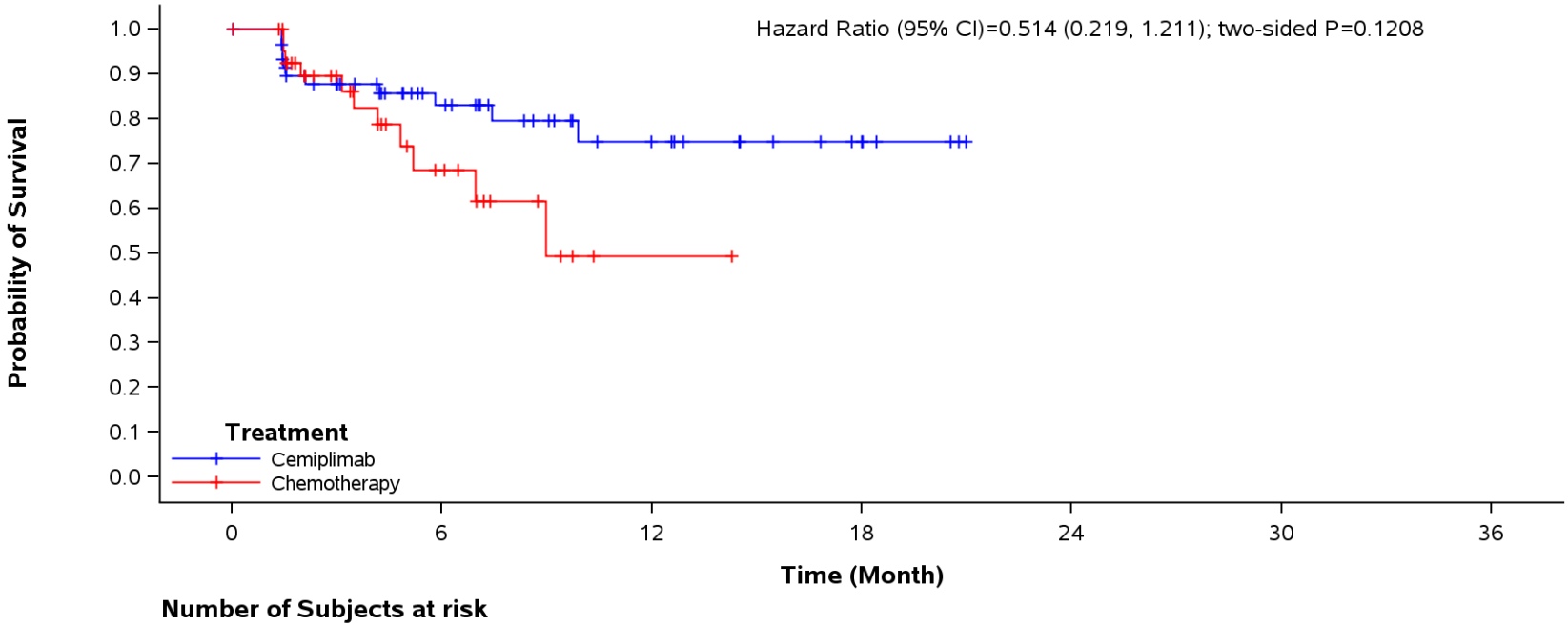

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 15 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts sustained deterioration



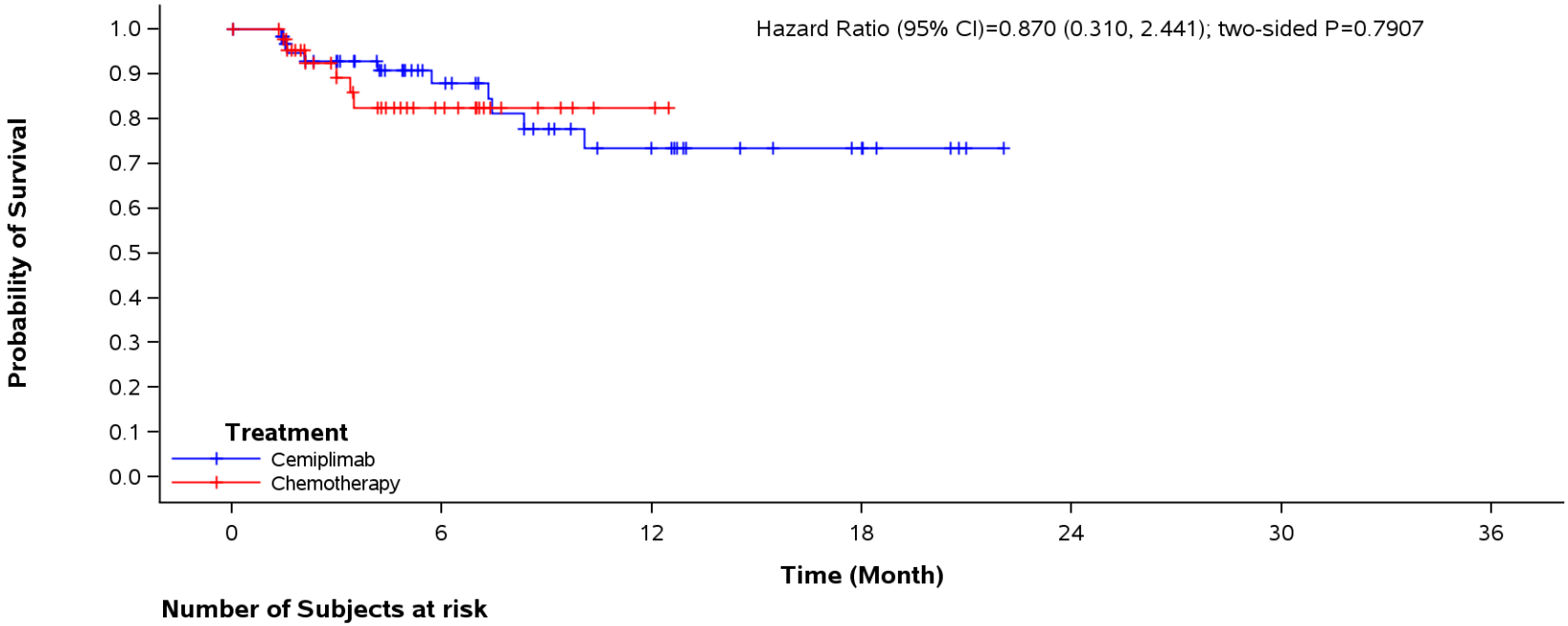

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 14 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts sustained deterioration



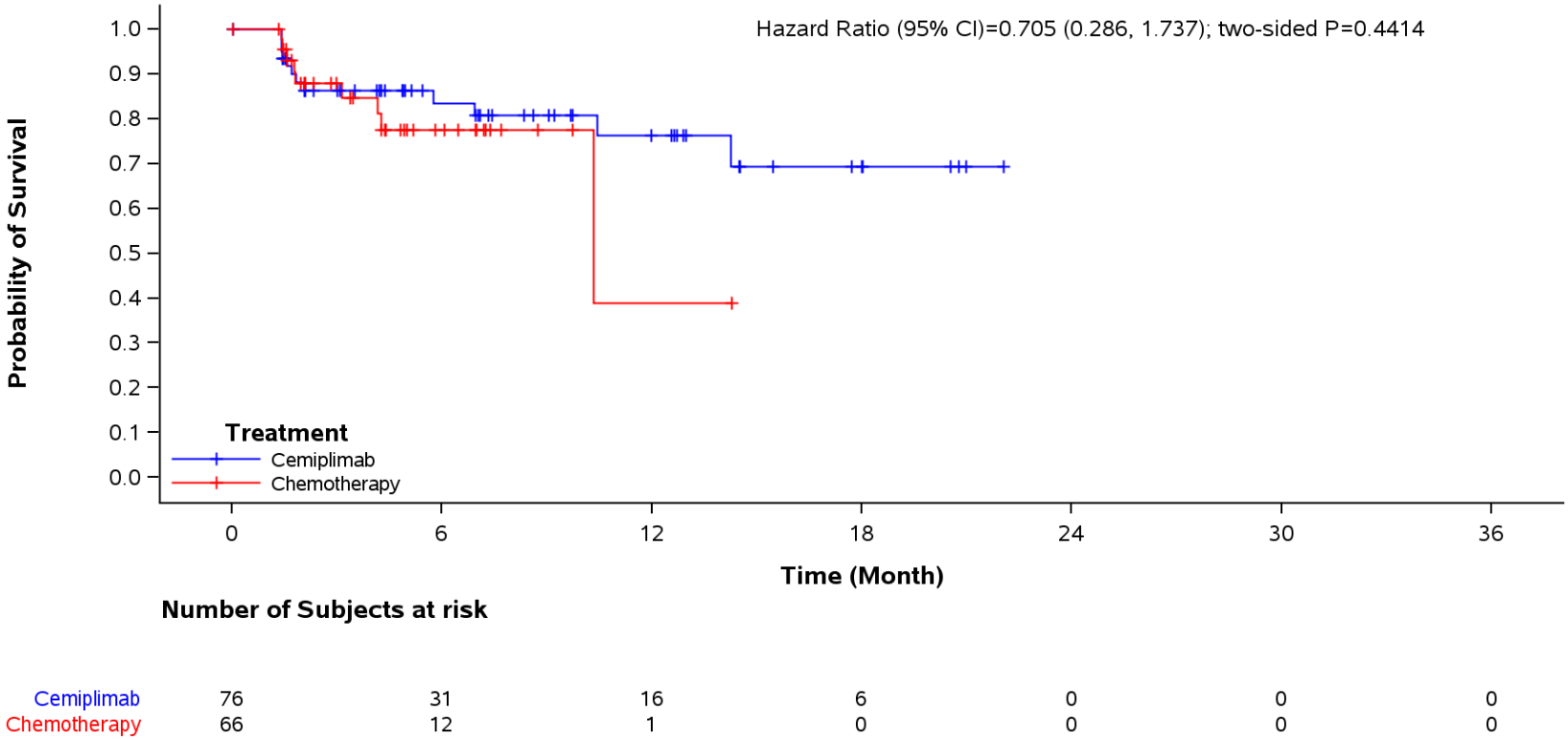

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 15 | 7 | 0 | 0 | 0 |
| Chemotherapy | 66 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts sustained deterioration



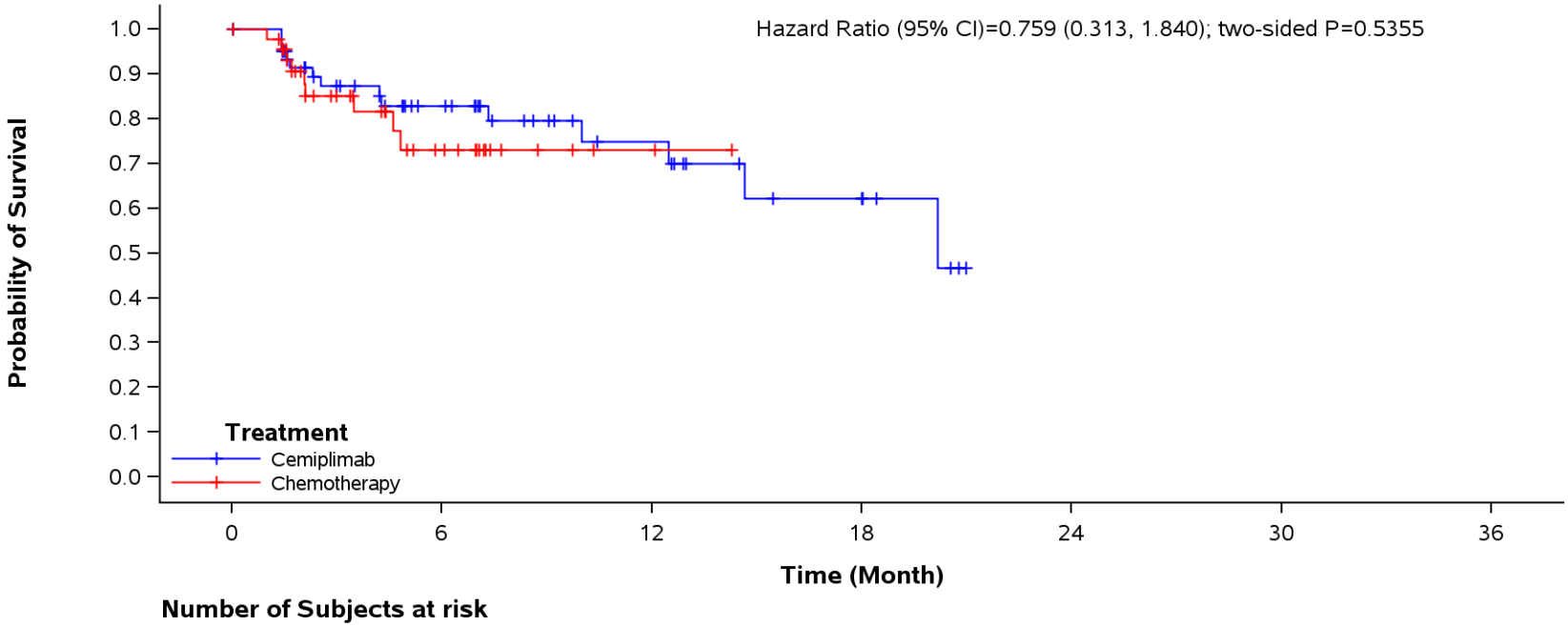

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 16 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts sustained deterioration



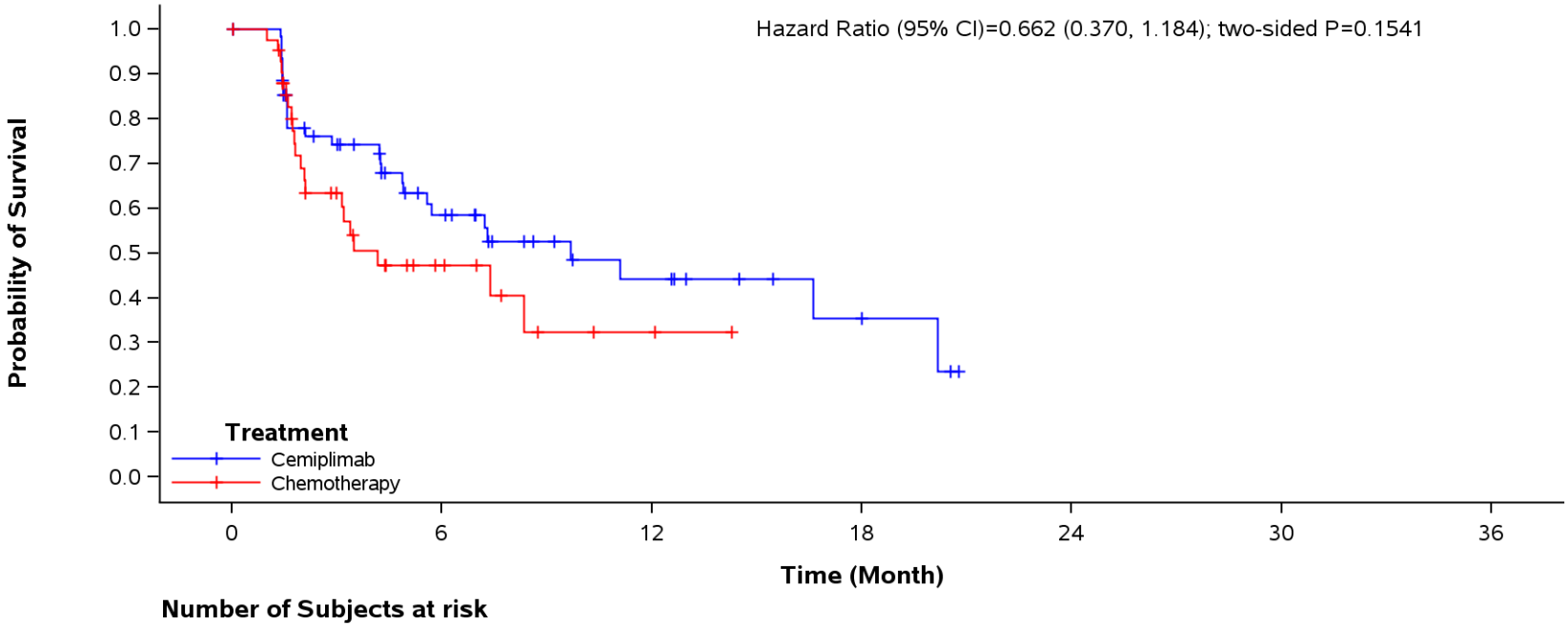

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 15 | 7 | 0 | 0 | 0 |
| Chemotherapy | 66 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts sustained deterioration



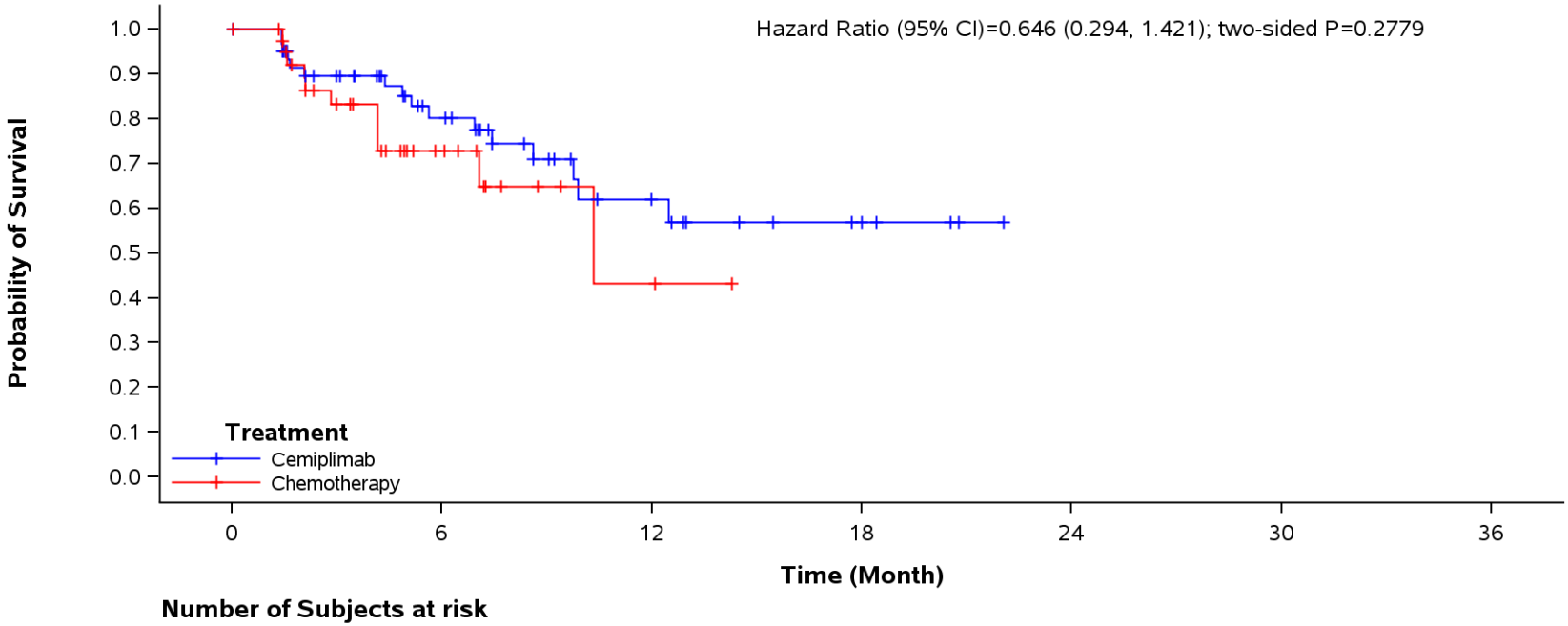

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 24 | 10 | 4 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts sustained deterioration



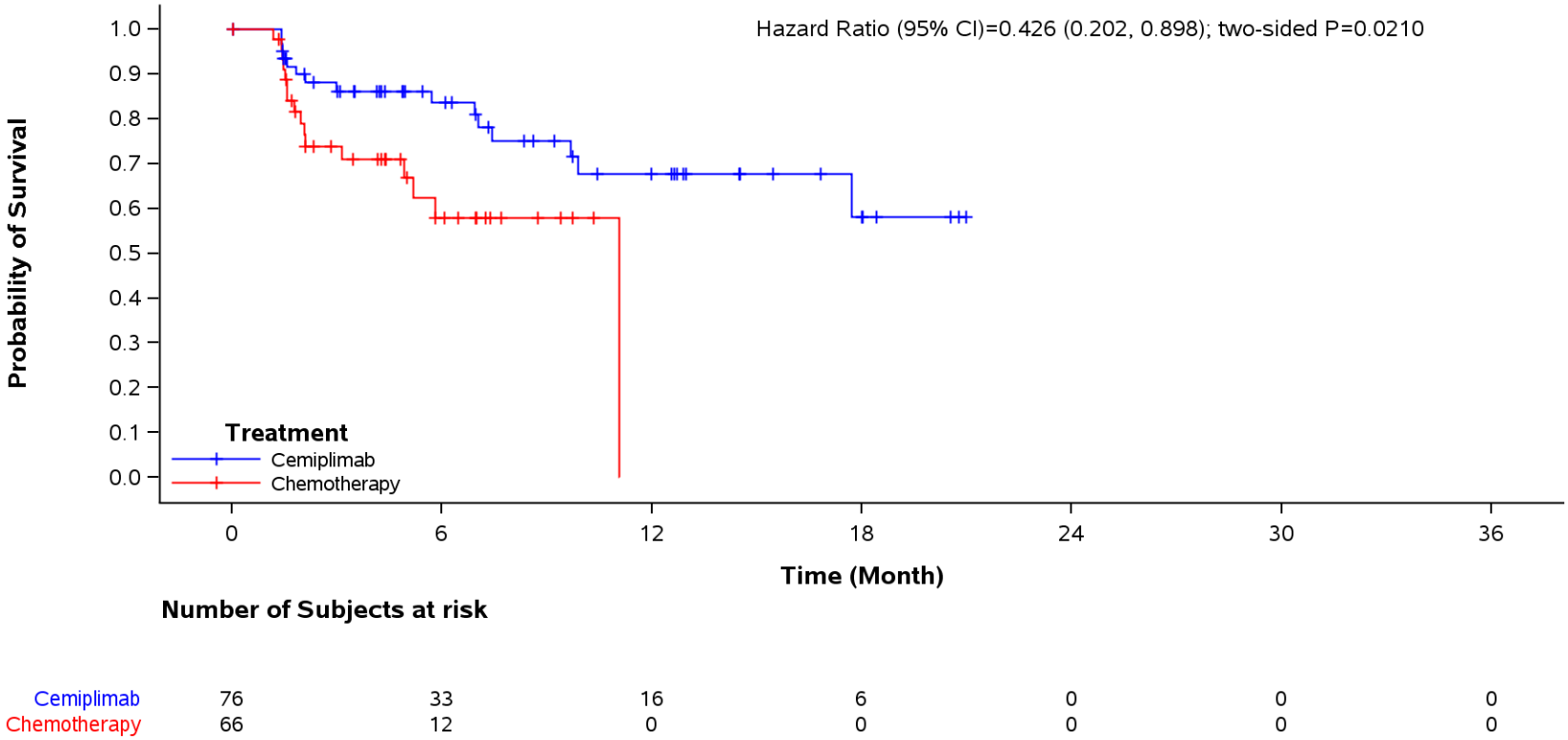

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 32 | 12 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts sustained deterioration



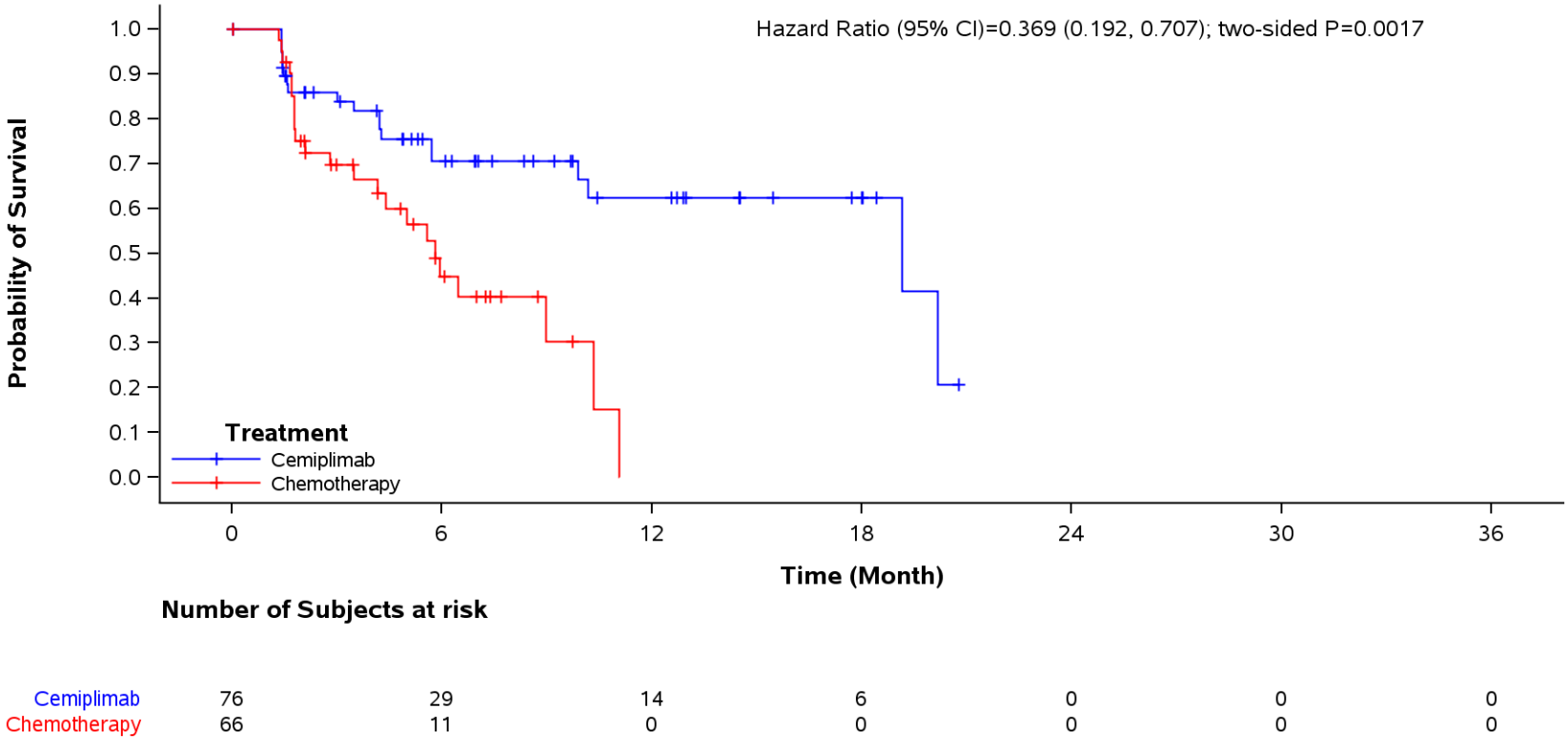

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 33 | 16 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts sustained deterioration



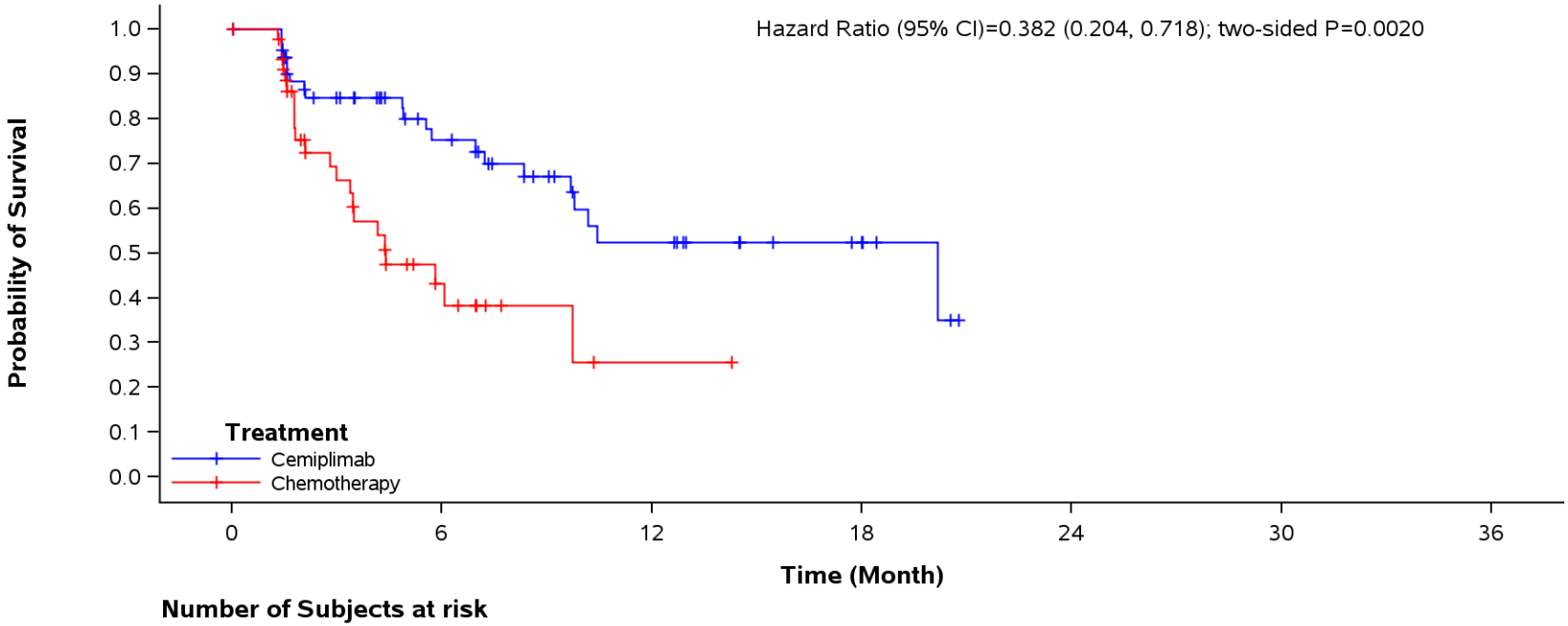

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 29 | 14 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts sustained deterioration



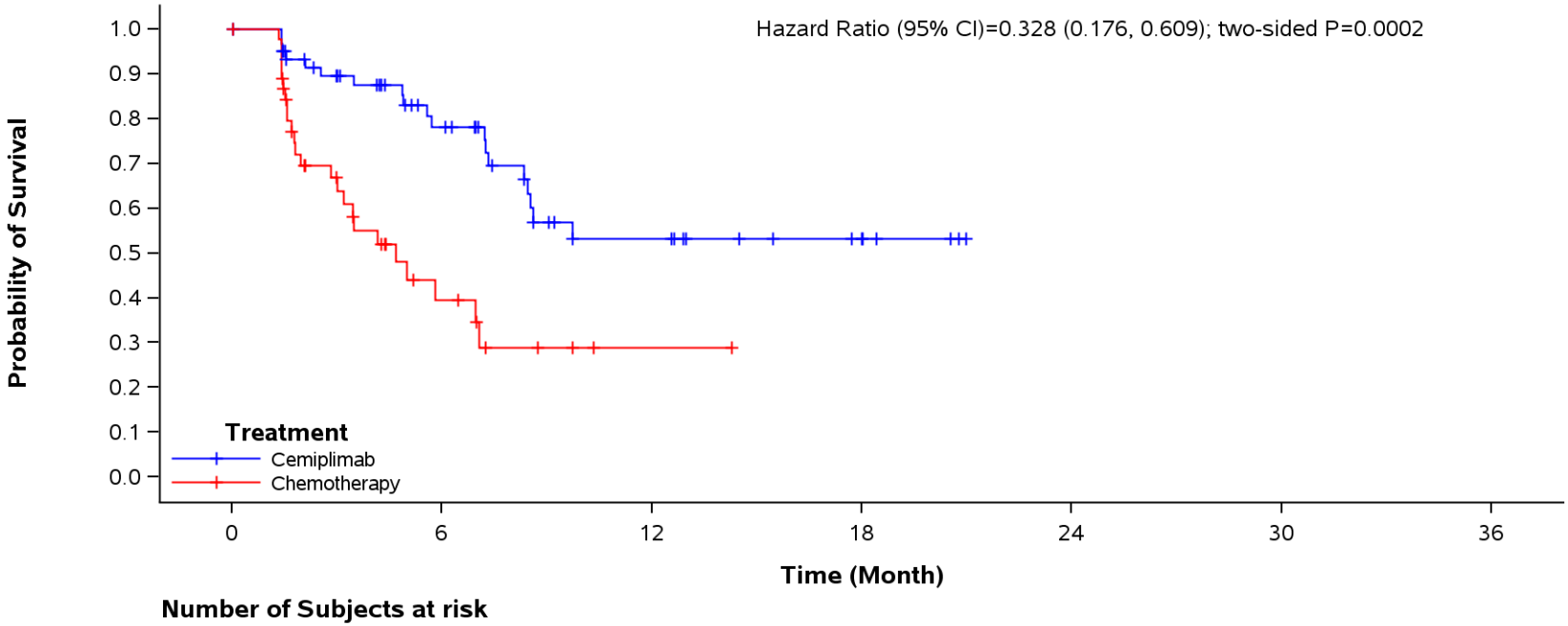

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 14 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts sustained deterioration



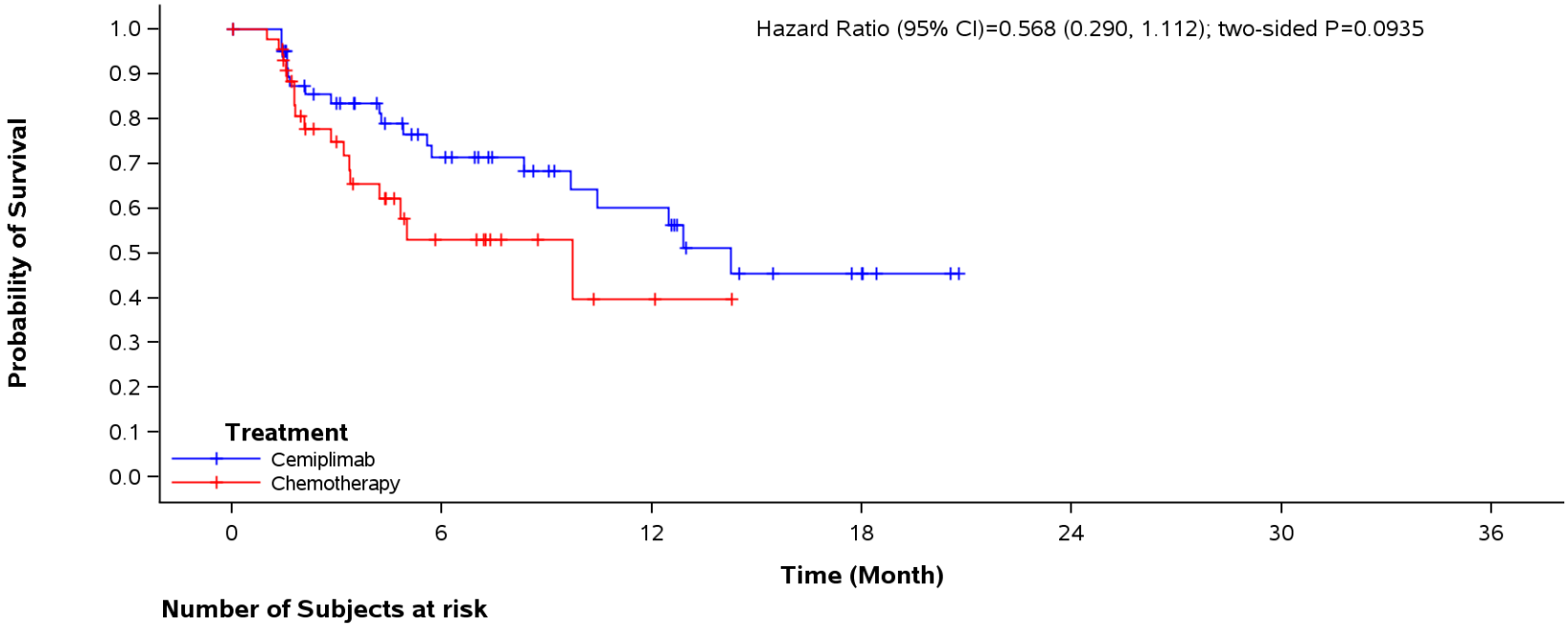

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 32 | 13 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts sustained deterioration



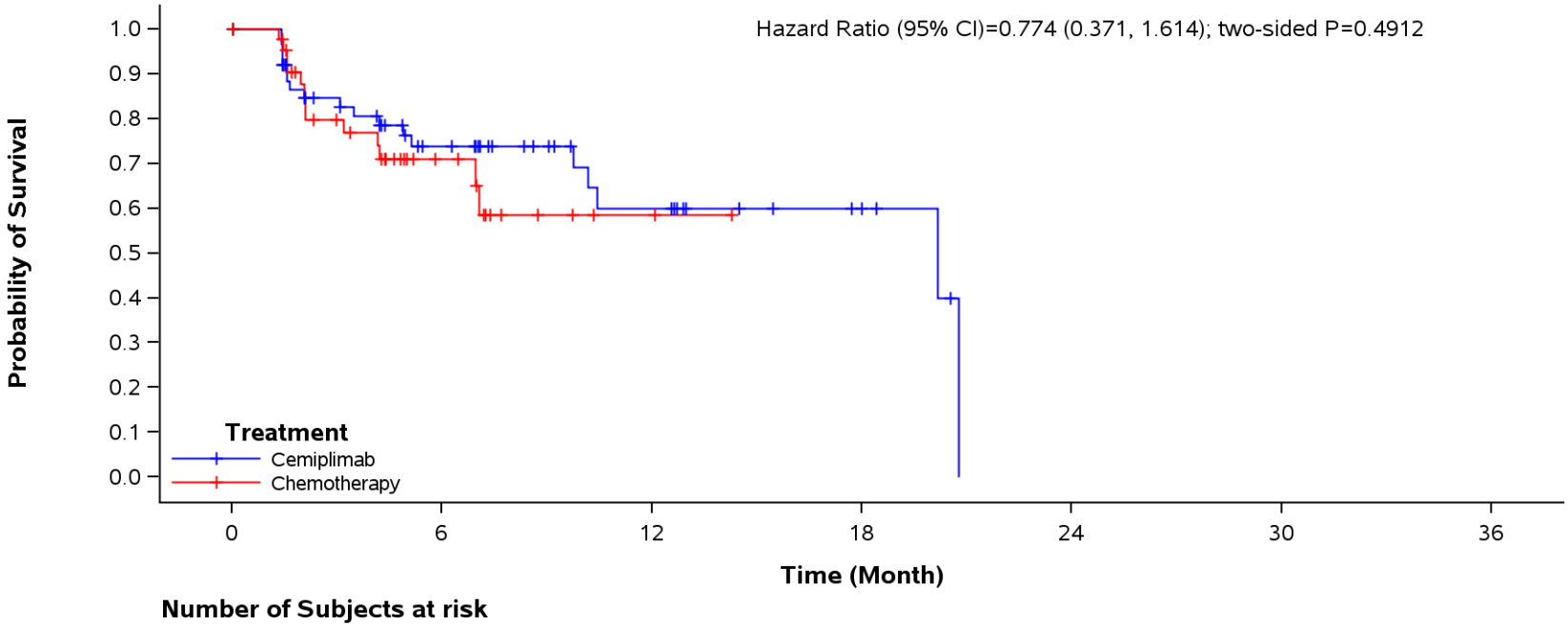

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 28 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts sustained deterioration



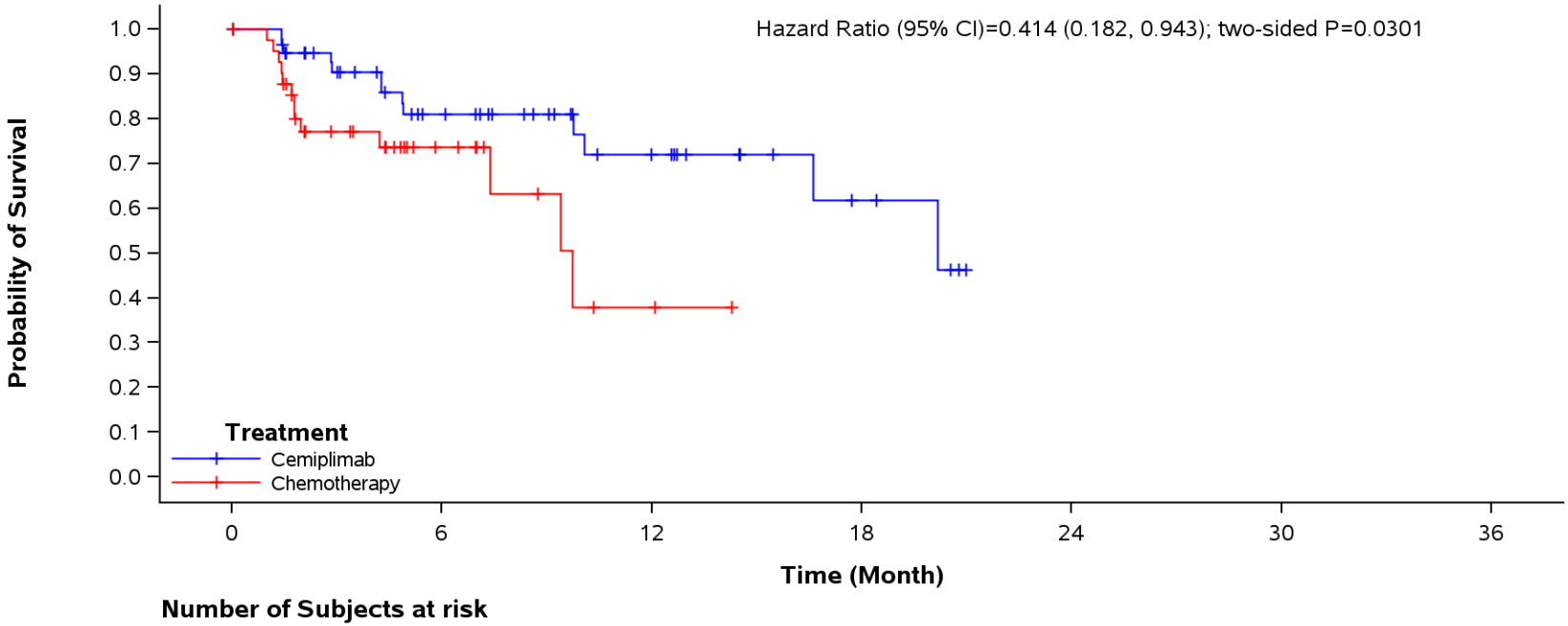

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 29 | 13 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts sustained deterioration



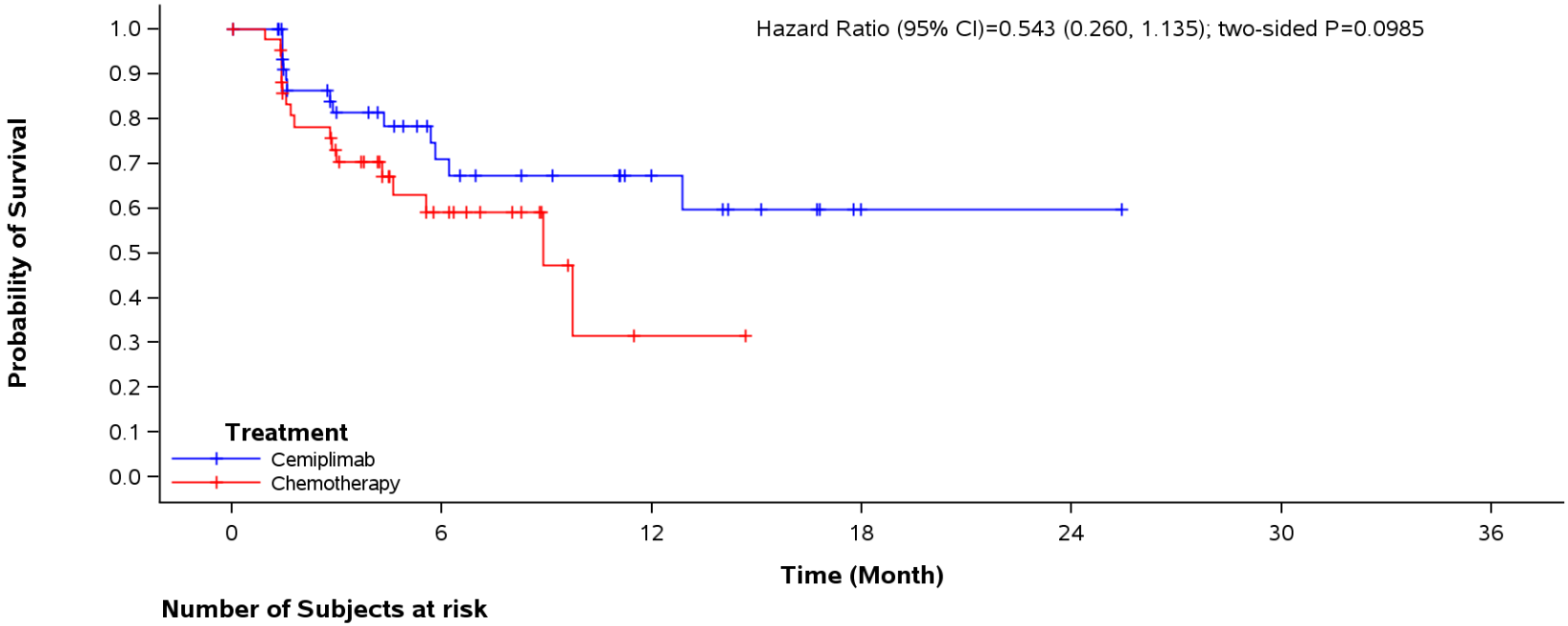

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 14 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts sustained deterioration



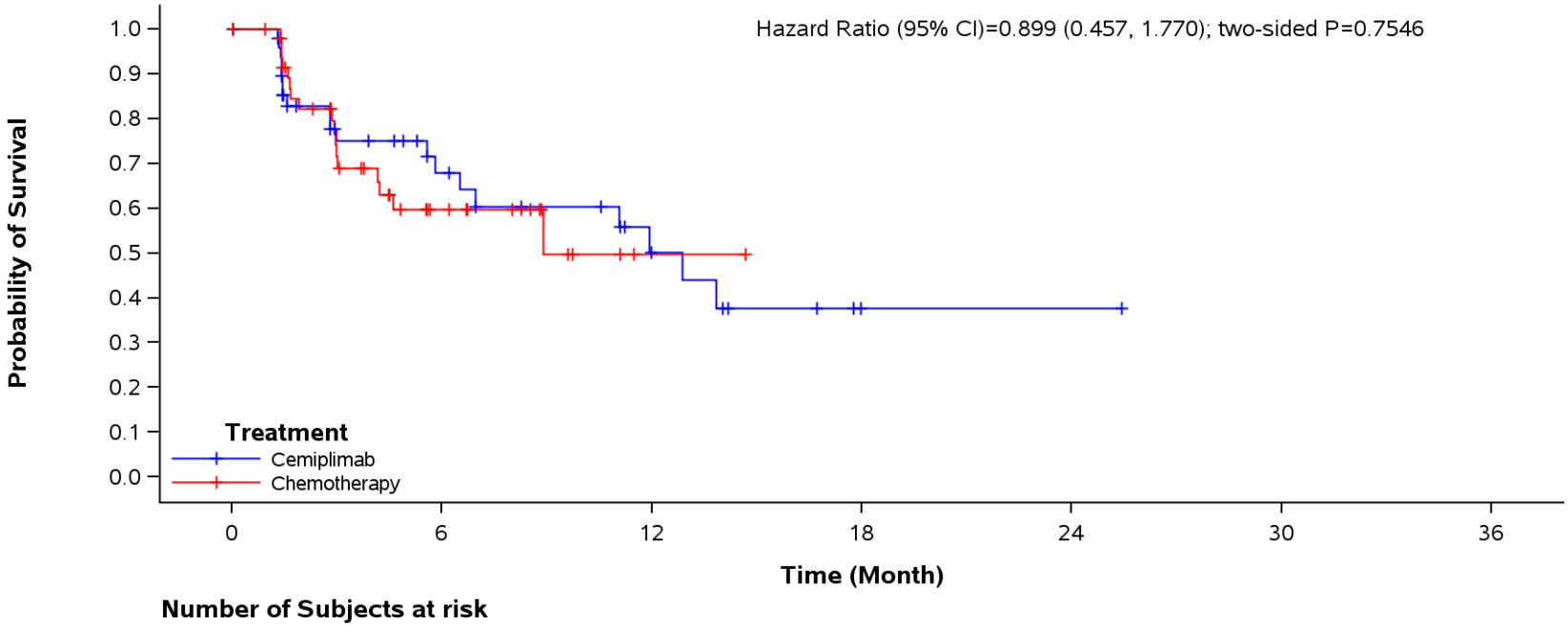

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 9 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts sustained deterioration



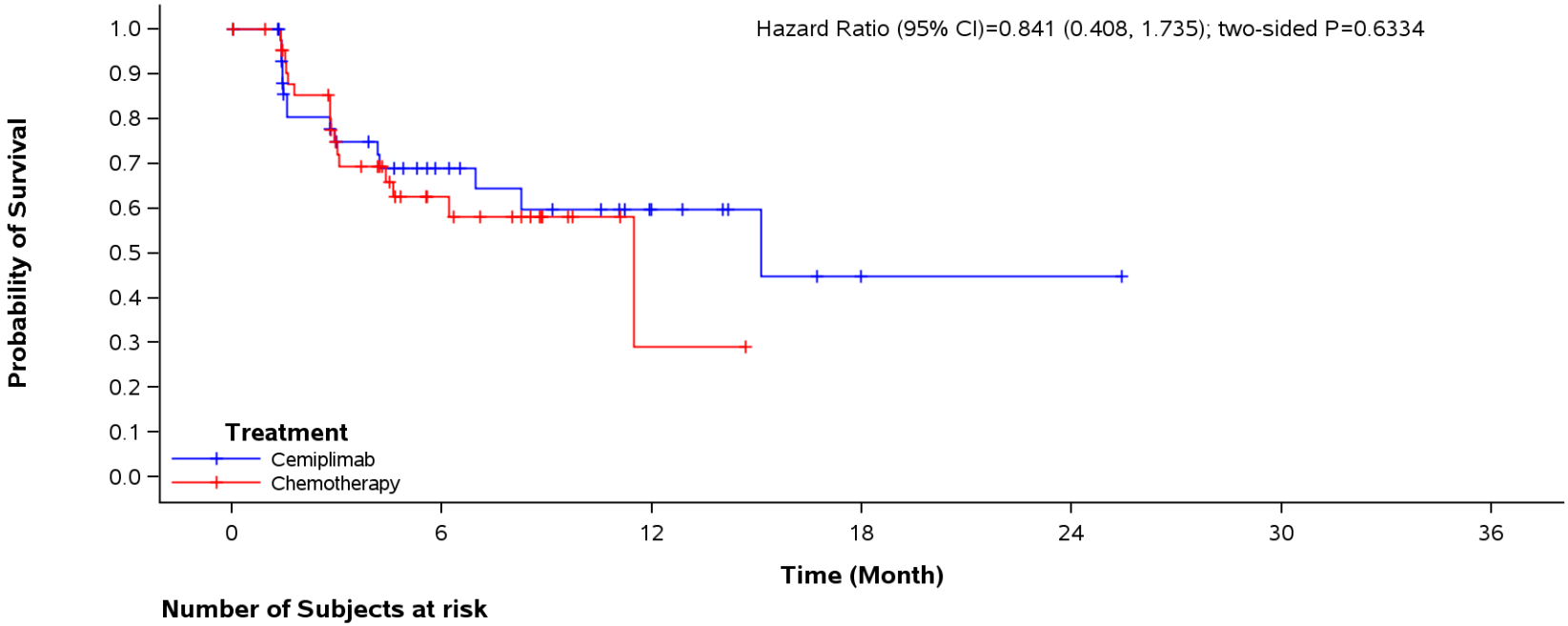

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts sustained deterioration



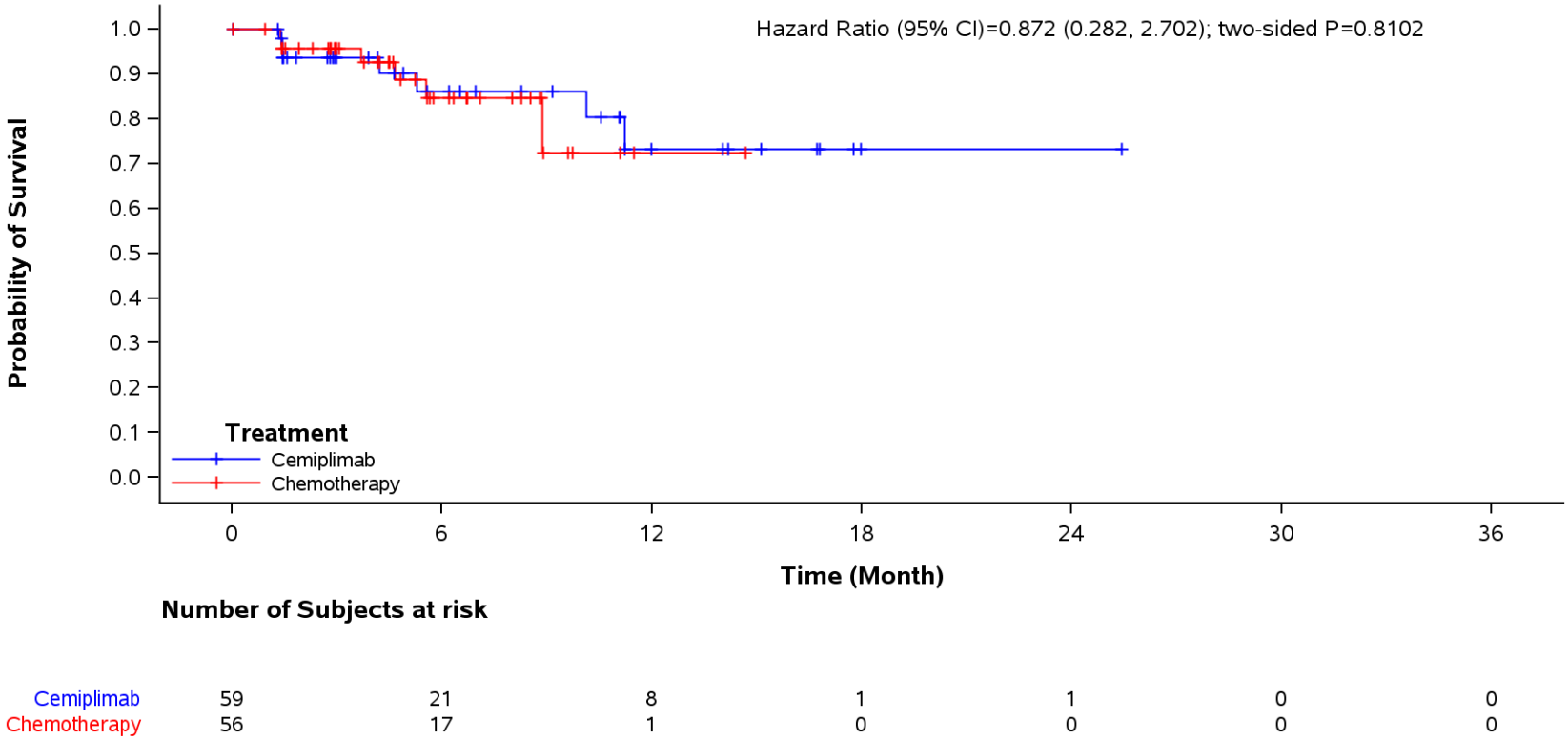

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 17 | 7 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts sustained deterioration



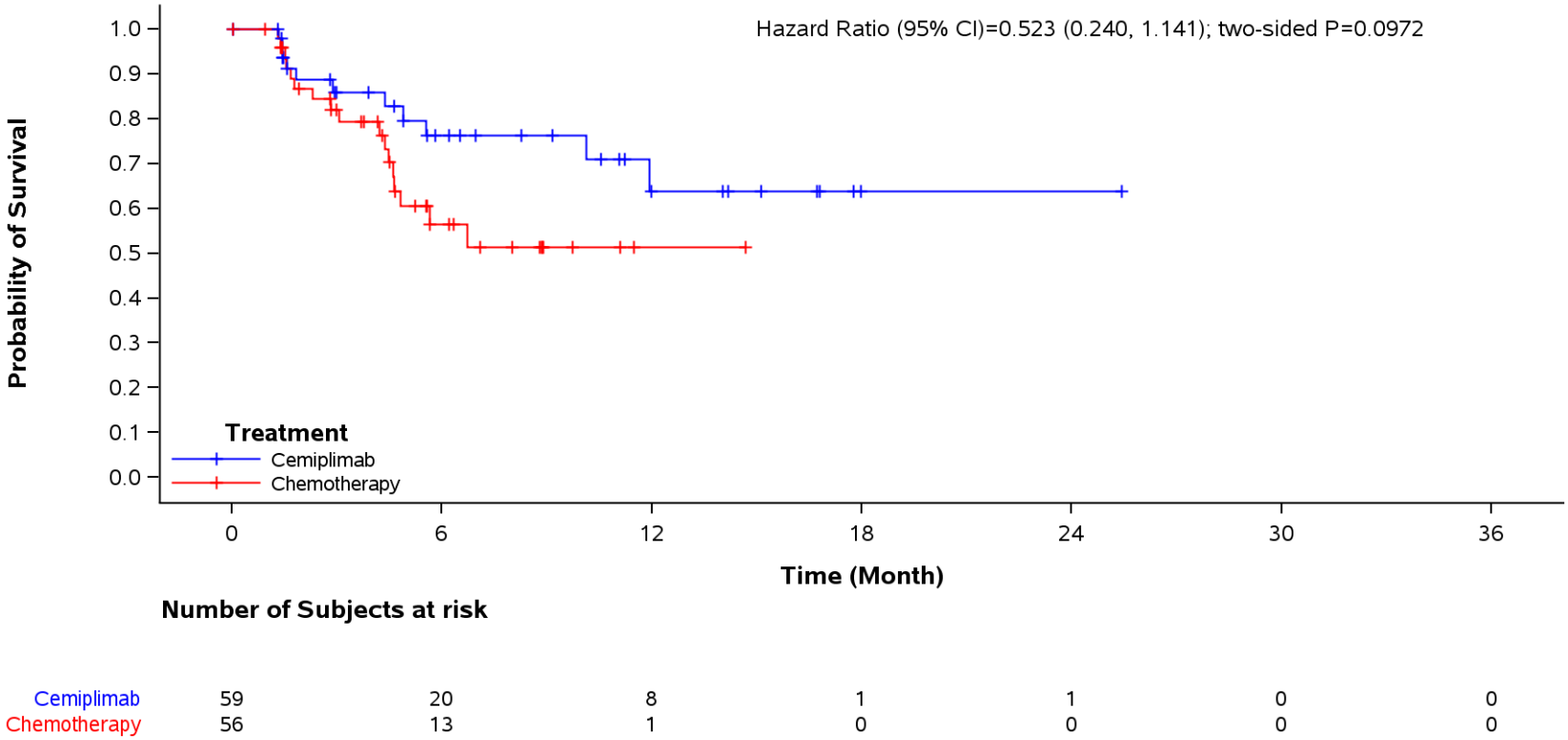

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 21 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 17 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts sustained deterioration



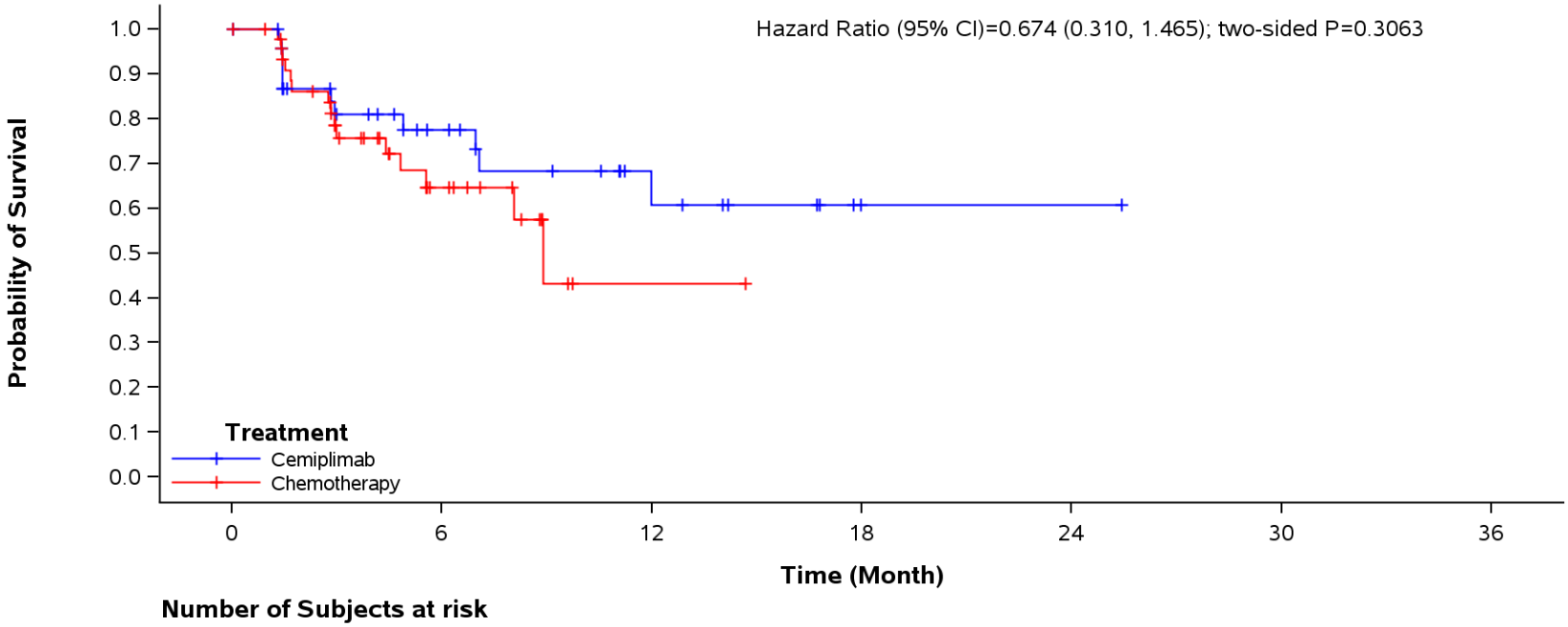

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts sustained deterioration



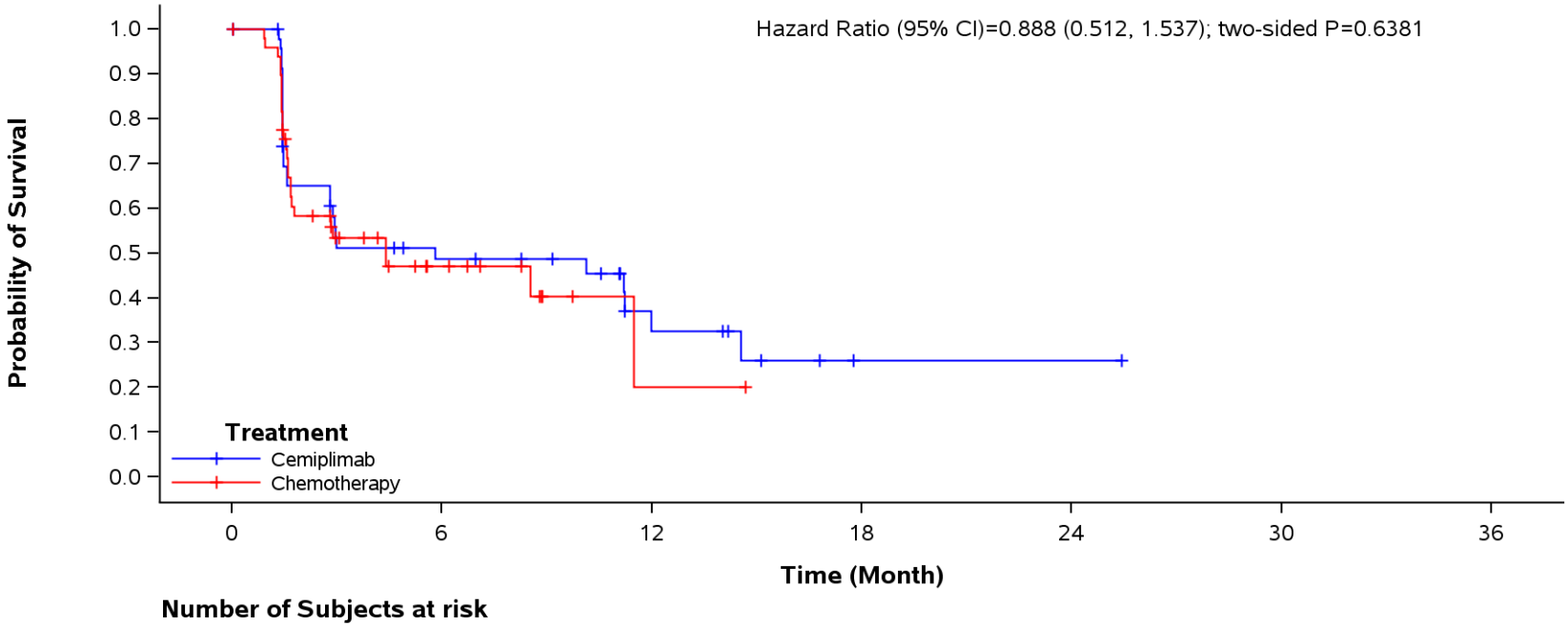

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts sustained deterioration



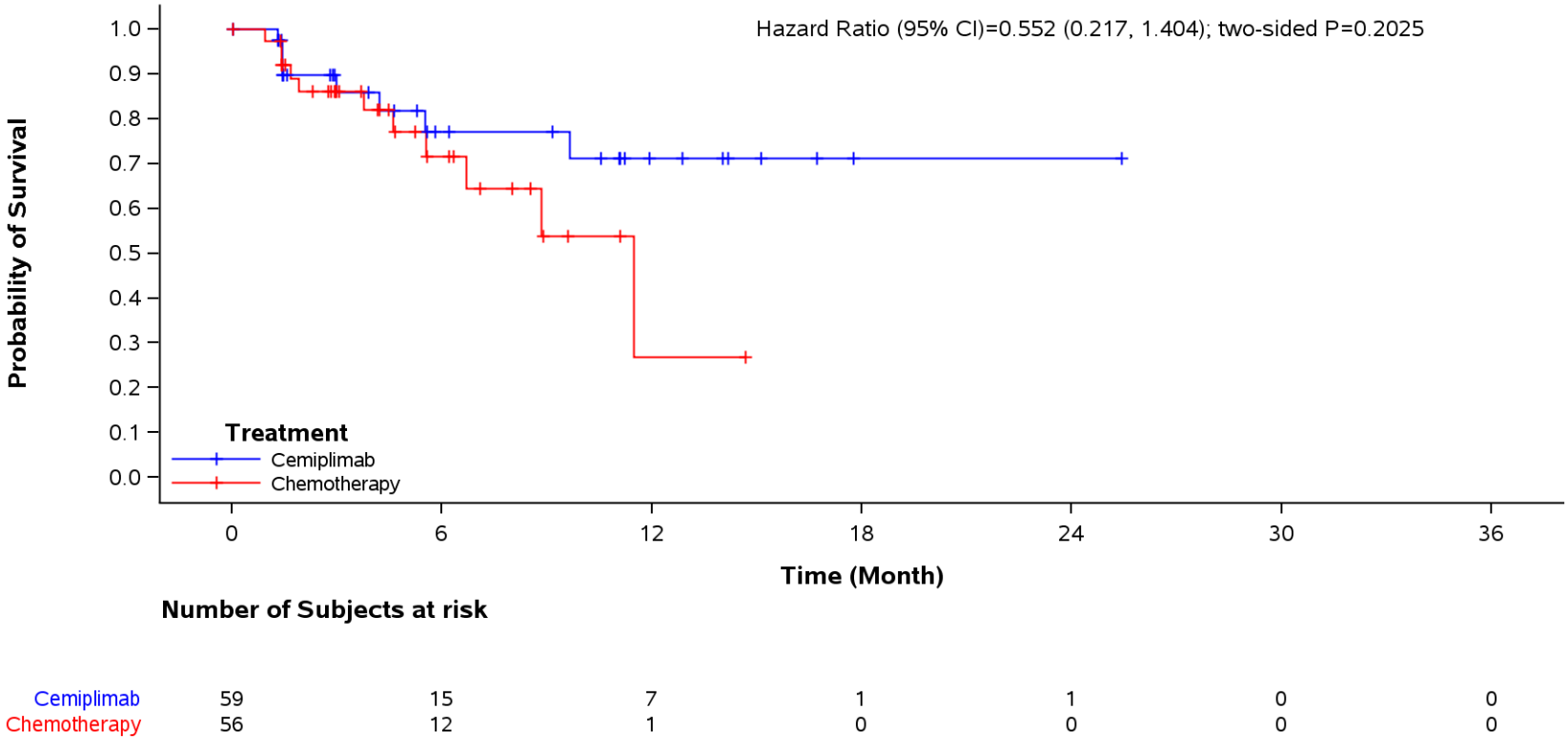

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 7 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts sustained deterioration



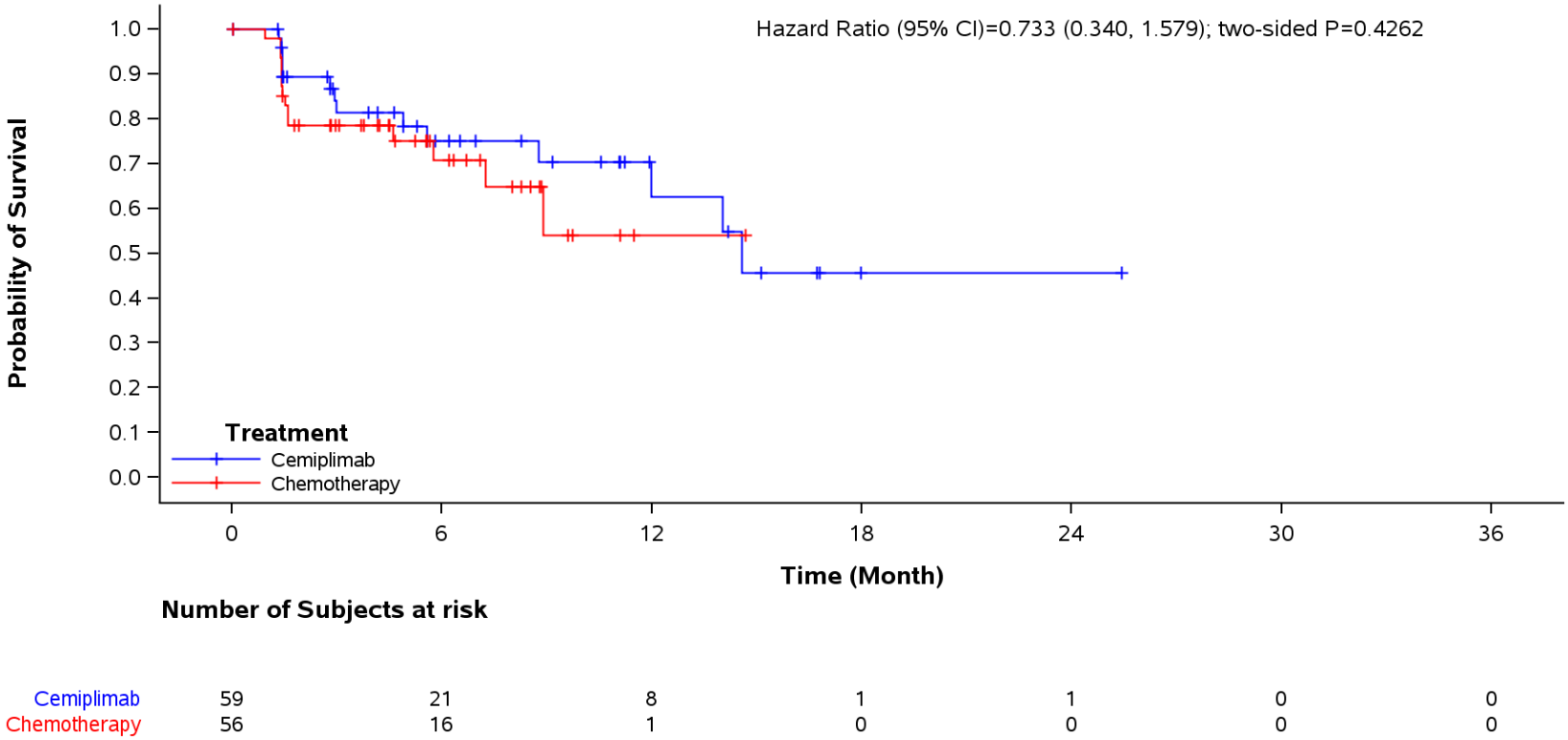

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 15 | 7 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts sustained deterioration



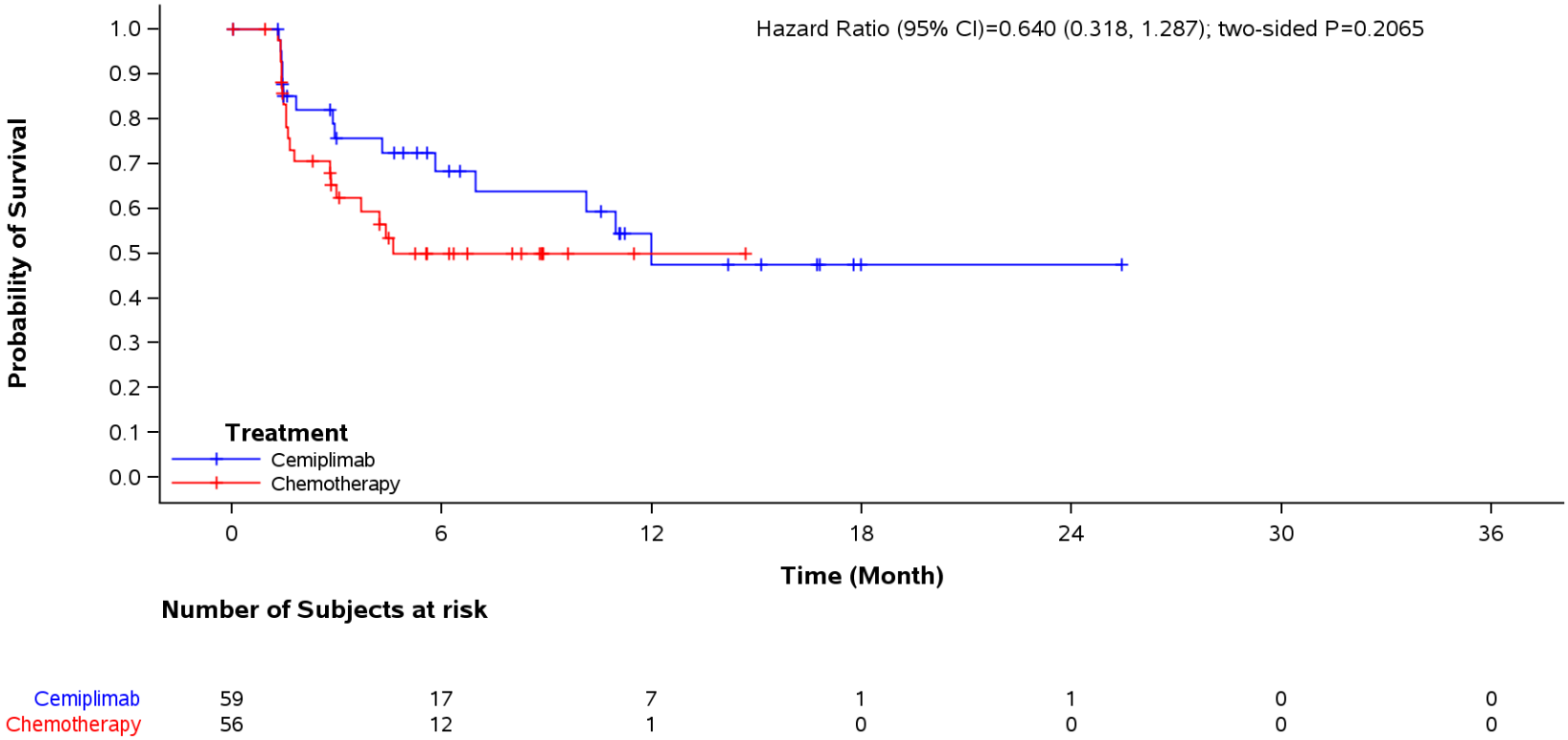

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 21 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 16 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts sustained deterioration



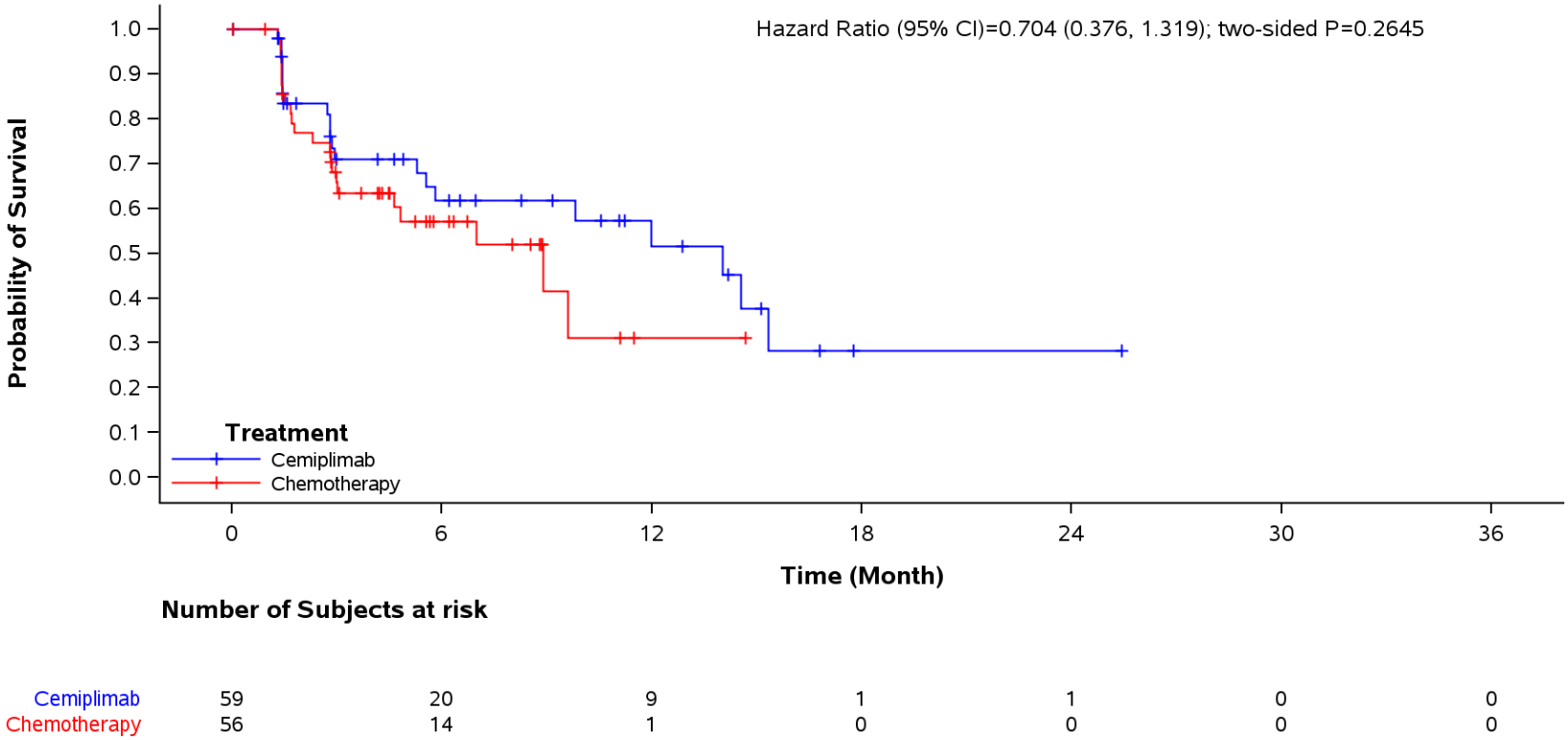

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 17 | 7 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts sustained deterioration



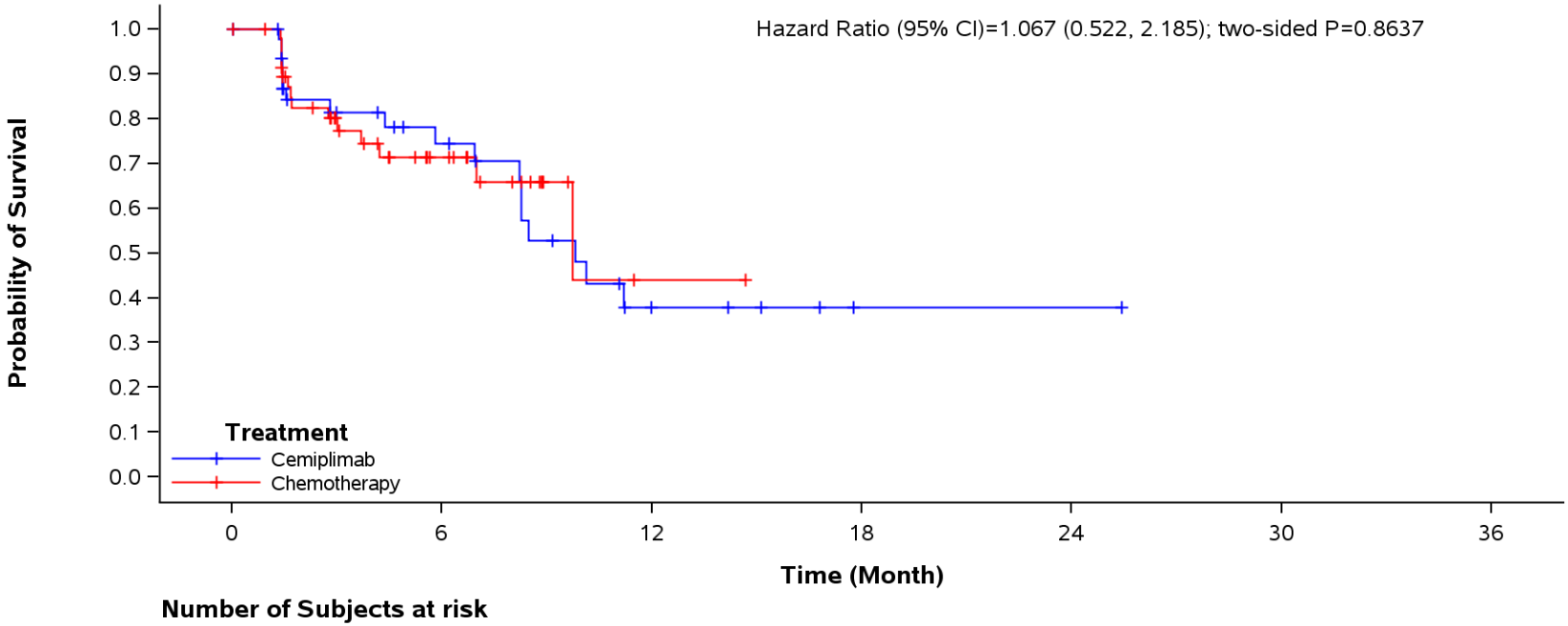

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 9 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts sustained deterioration



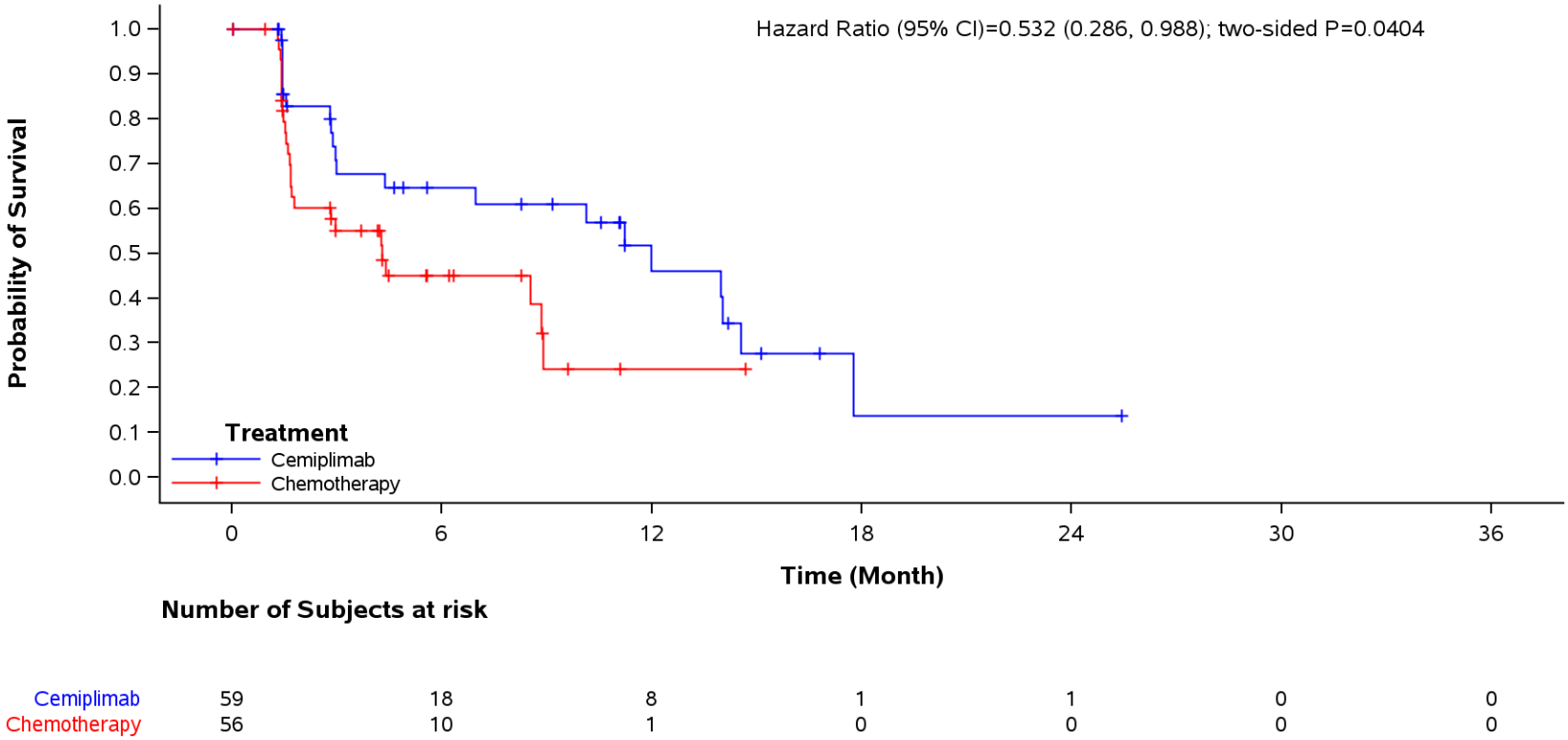

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 17 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts sustained deterioration



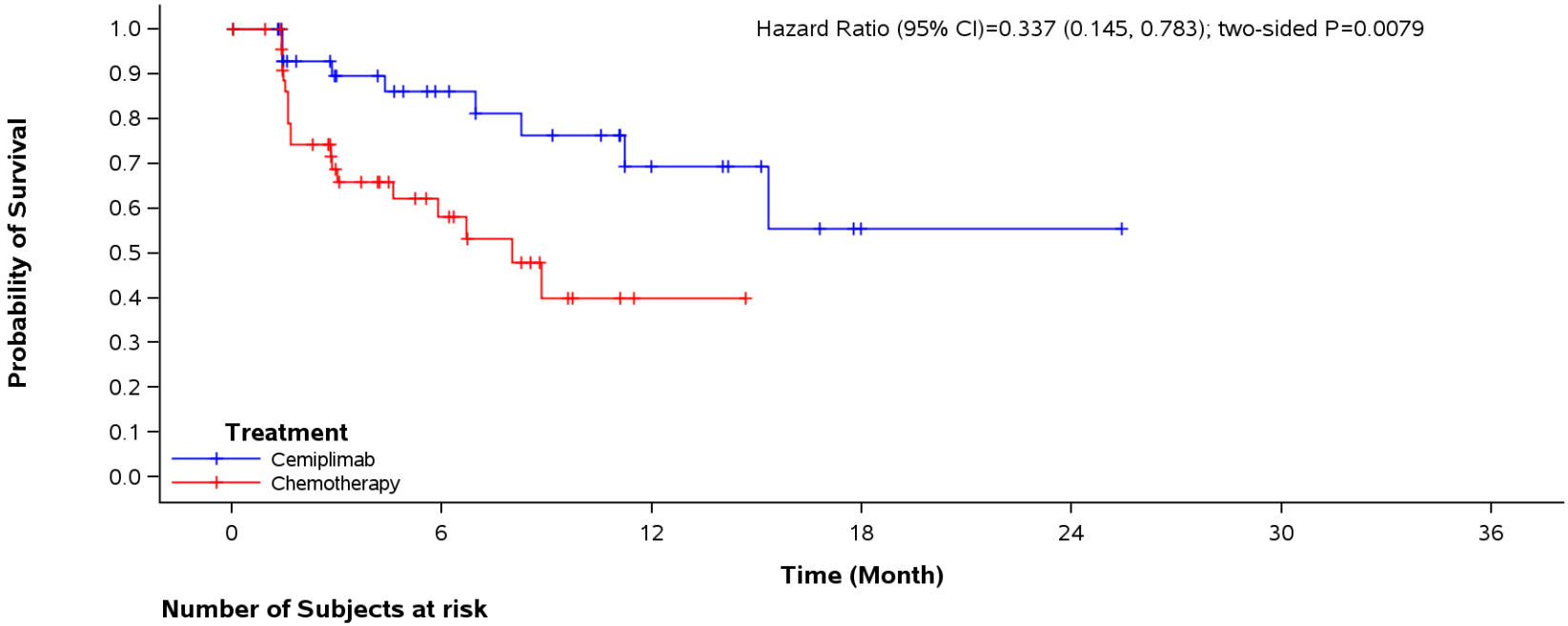

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 18 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts sustained deterioration



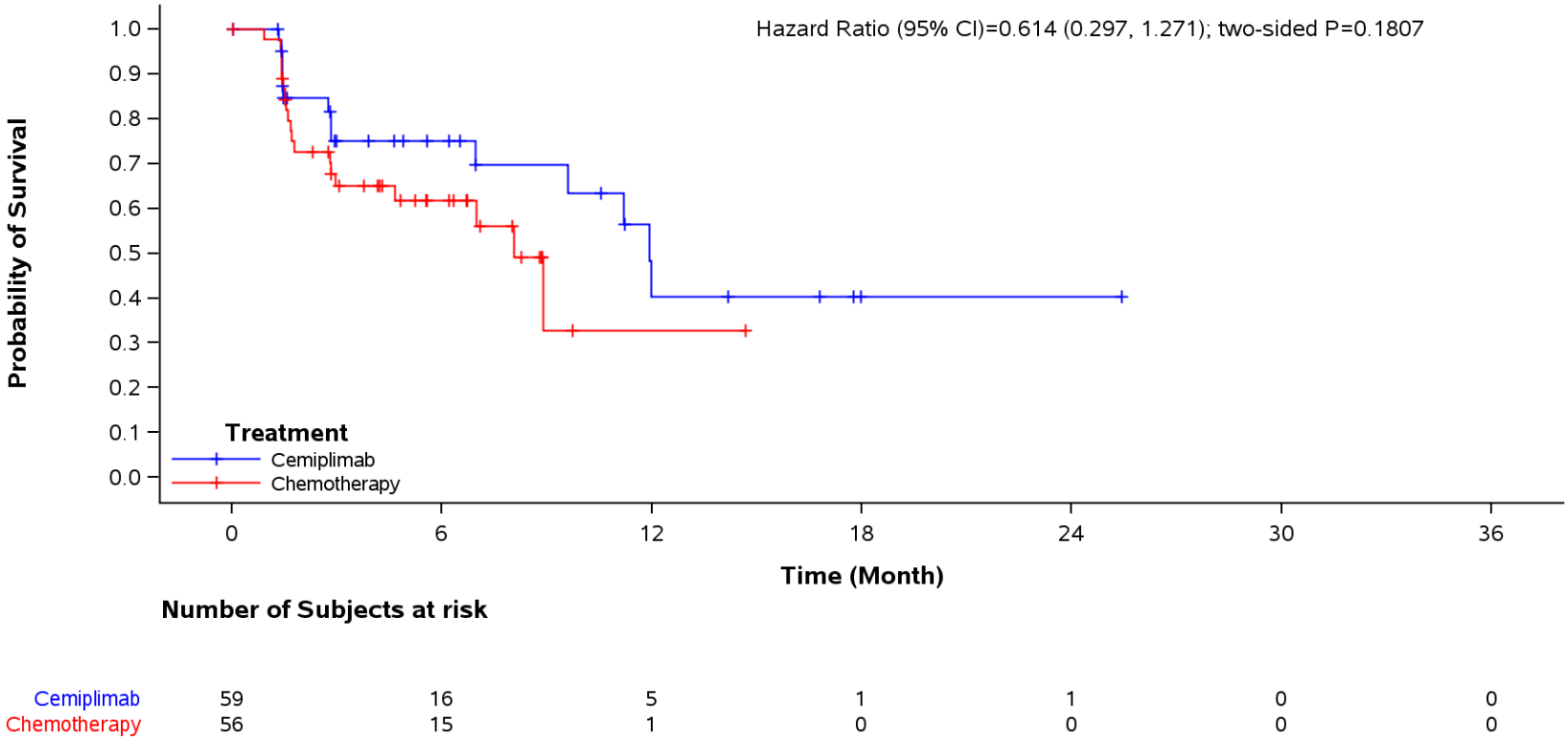

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts sustained deterioration



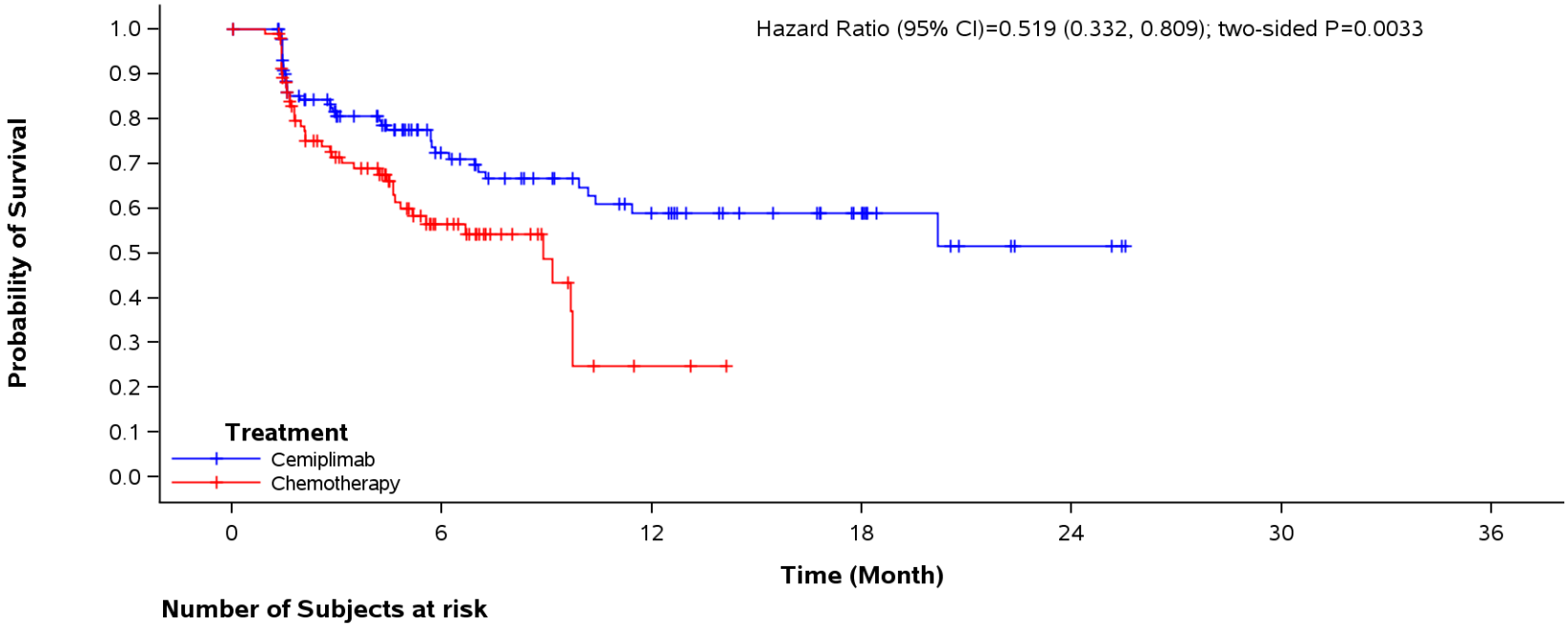

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 16 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts sustained deterioration



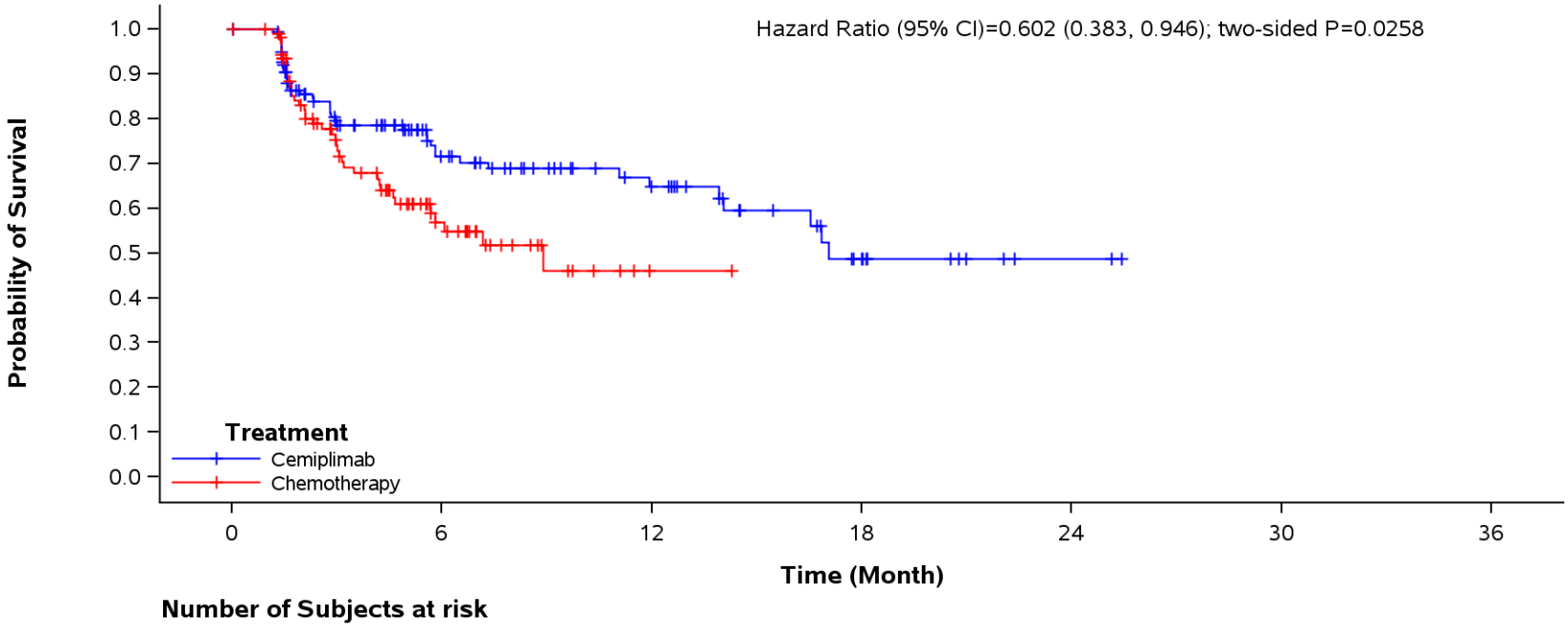

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 54 | 28 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 27 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts sustained deterioration



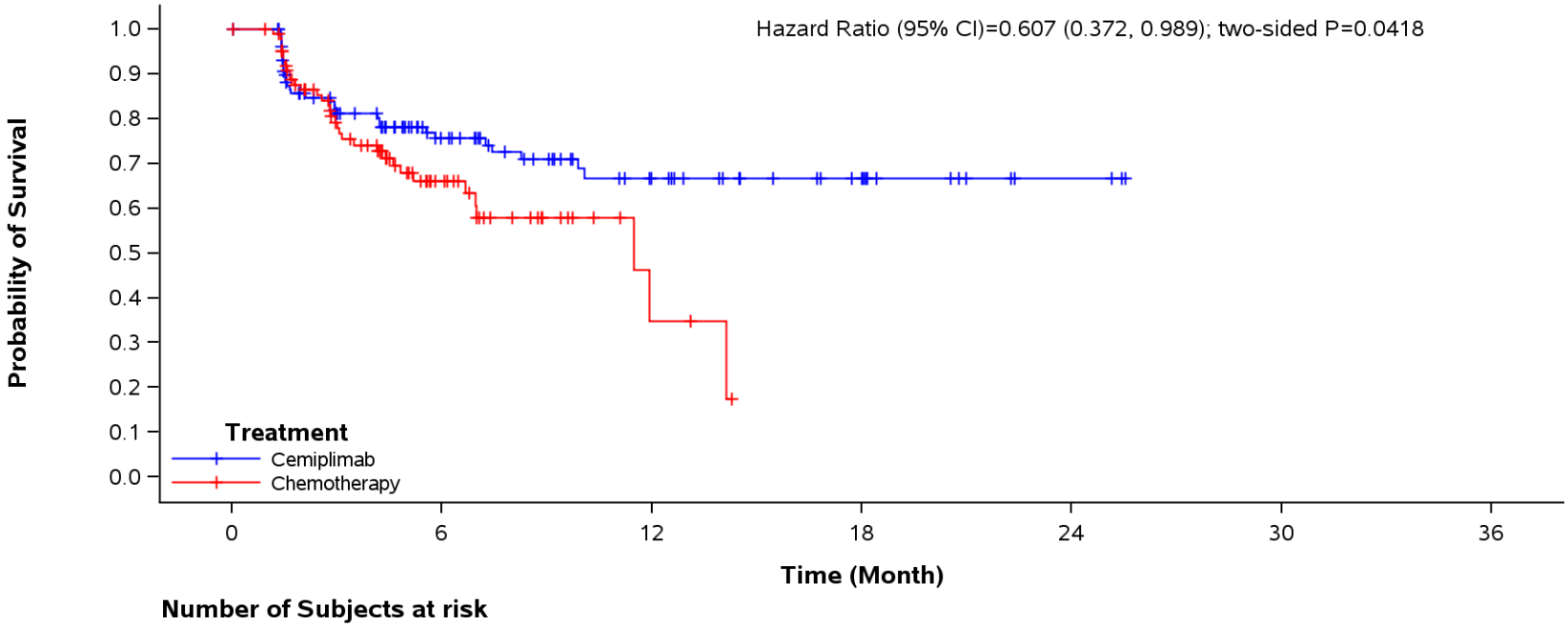

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 58 | 30 | 11 | 2 | 0 | 0 |
| Chemotherapy | 137 | 27 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Constipation - 10 pts sustained deterioration



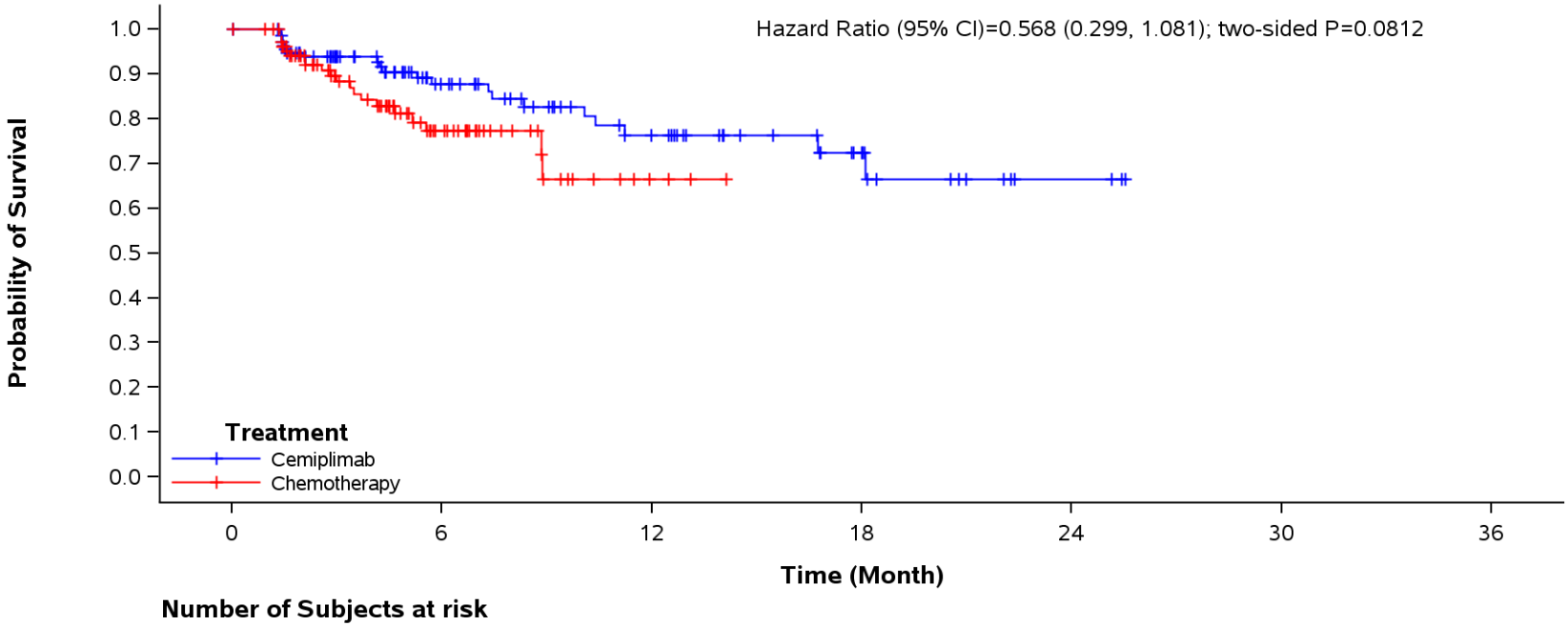

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 56 | 27 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 29 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Diarhoea - 10 pts sustained deterioration



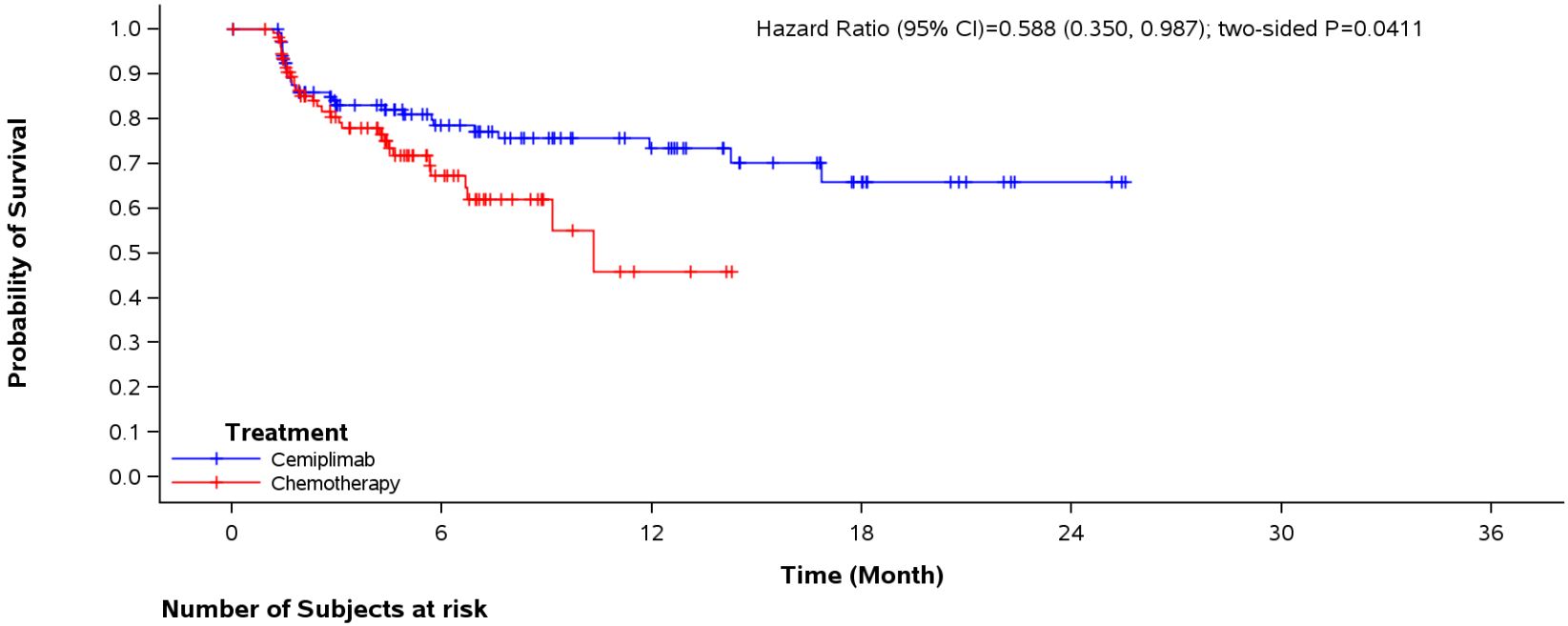

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 61 | 32 | 15 | 3 | 0 | 0 |
| Chemotherapy | 137 | 34 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Dyspnoea - 10 pts sustained deterioration



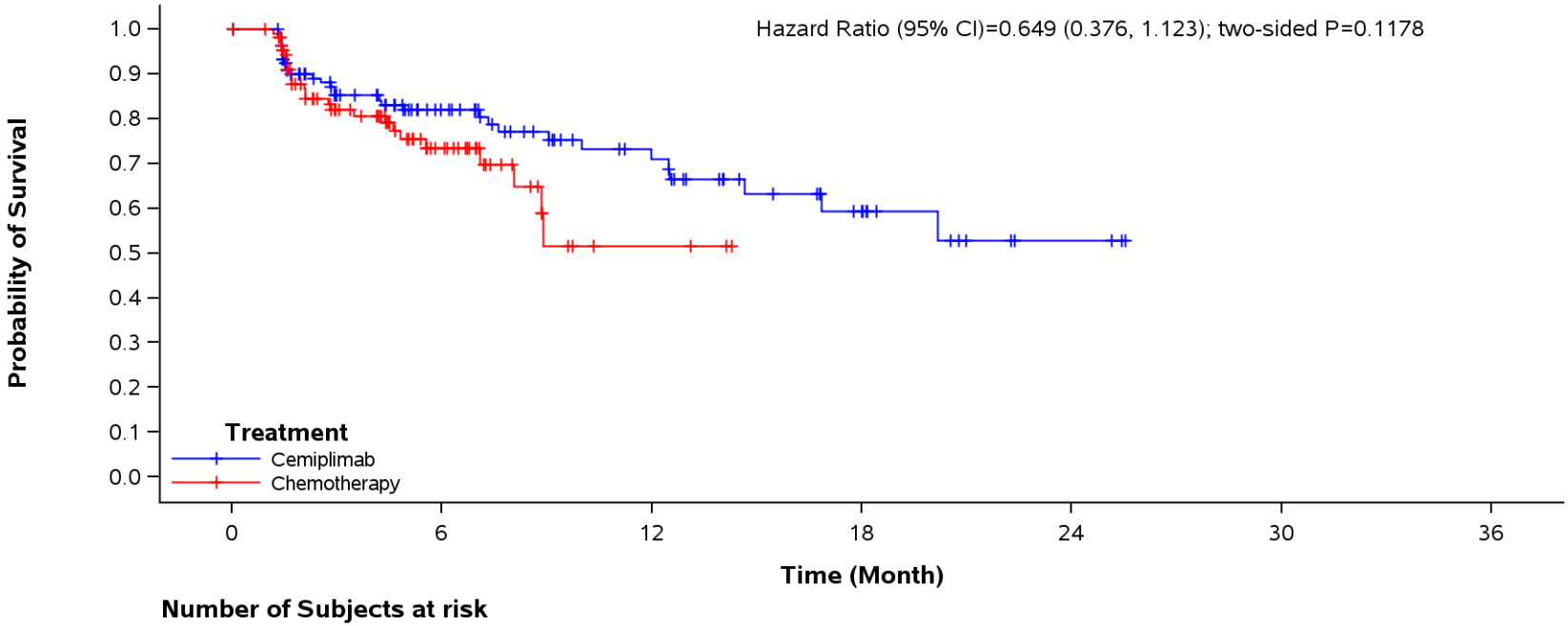

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 60 | 31 | 13 | 3 | 0 | 0 |
| Chemotherapy | 137 | 29 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts sustained deterioration



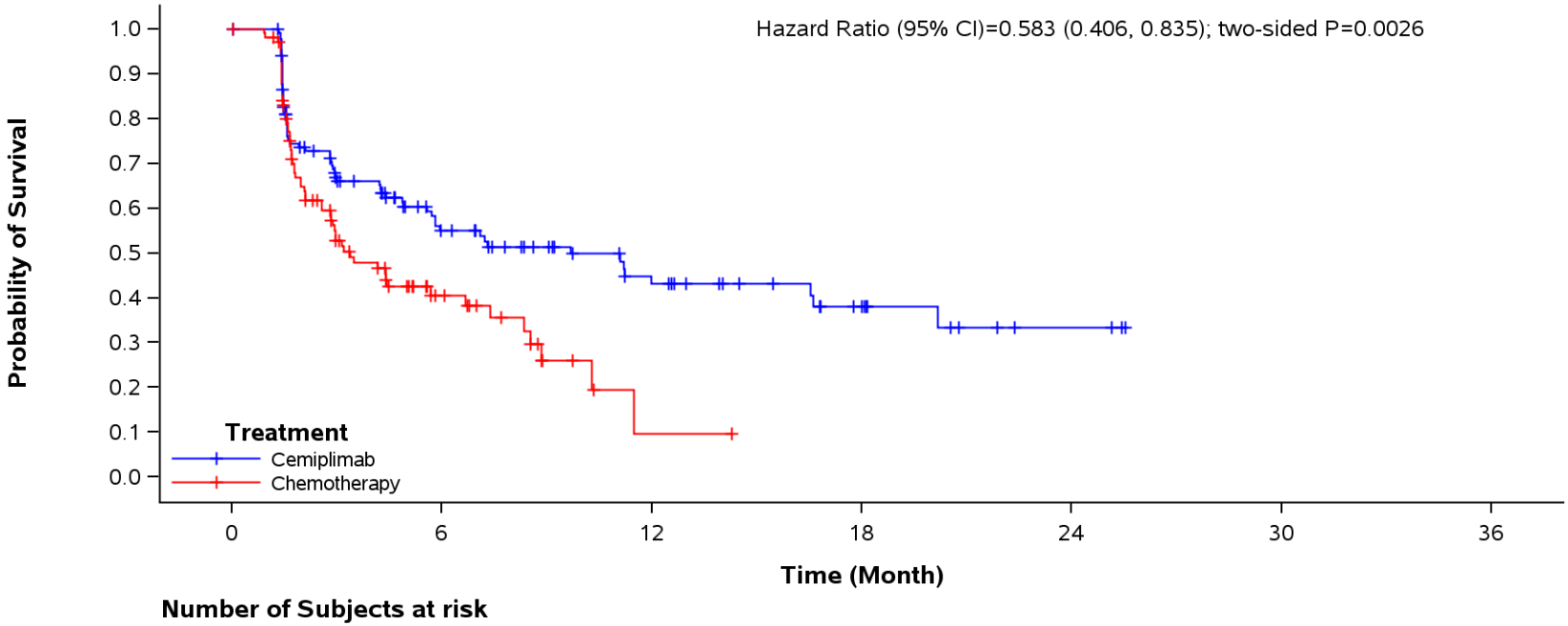

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 60 | 32 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 31 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts sustained deterioration



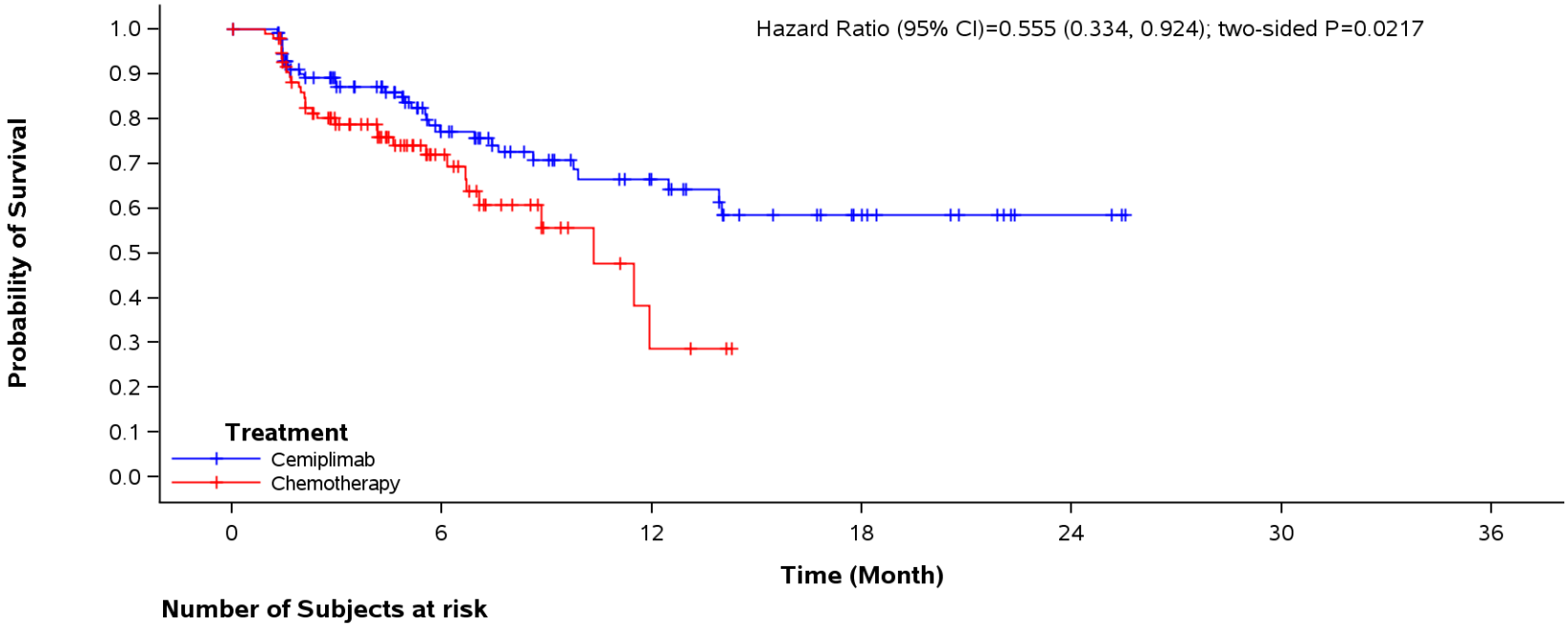

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 50 | 25 | 12 | 3 | 0 | 0 |
| Chemotherapy | 137 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts sustained deterioration



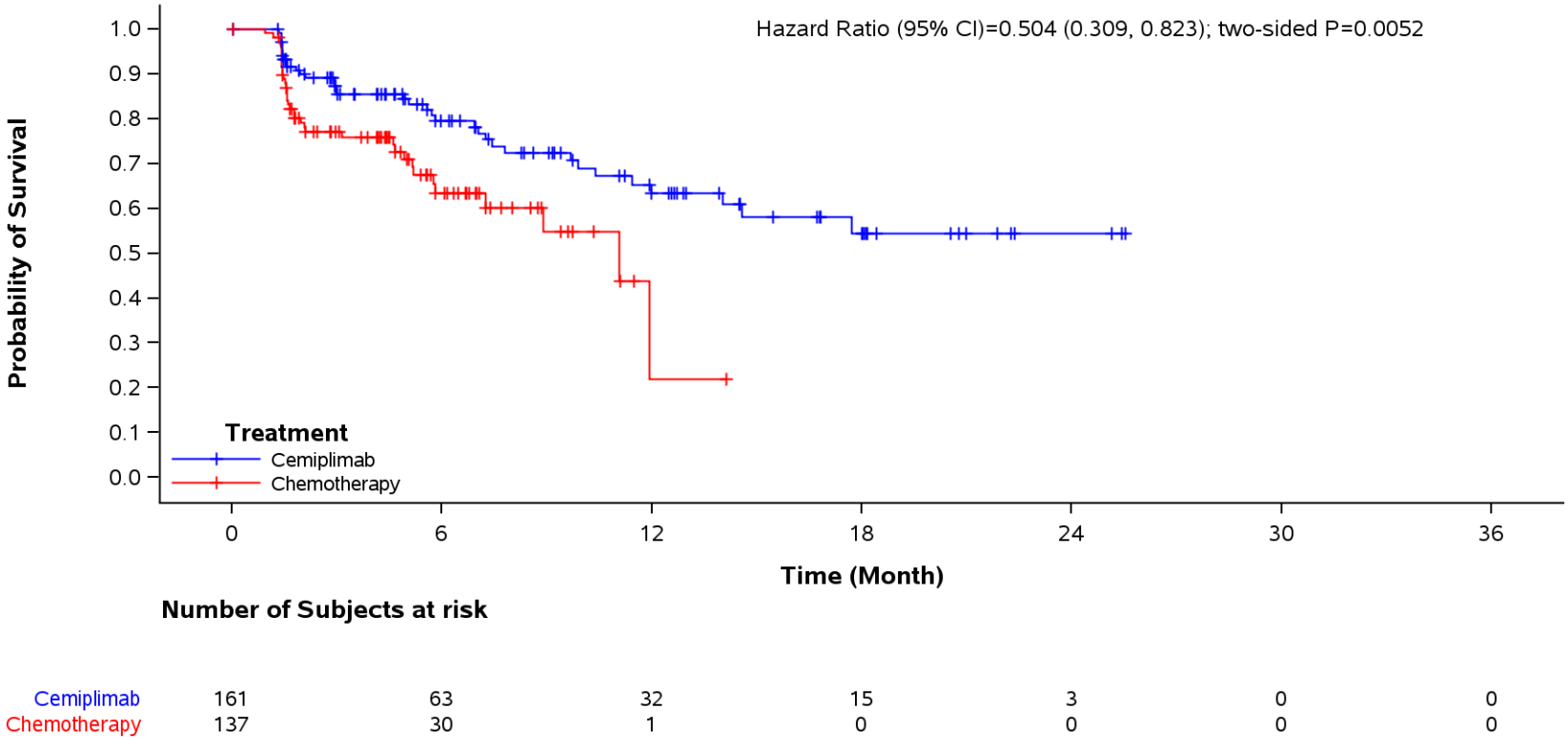

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 56 | 28 | 12 | 3 | 0 | 0 |
| Chemotherapy | 137 | 29 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Nausea / Vomiting - 10 pts sustained deterioration



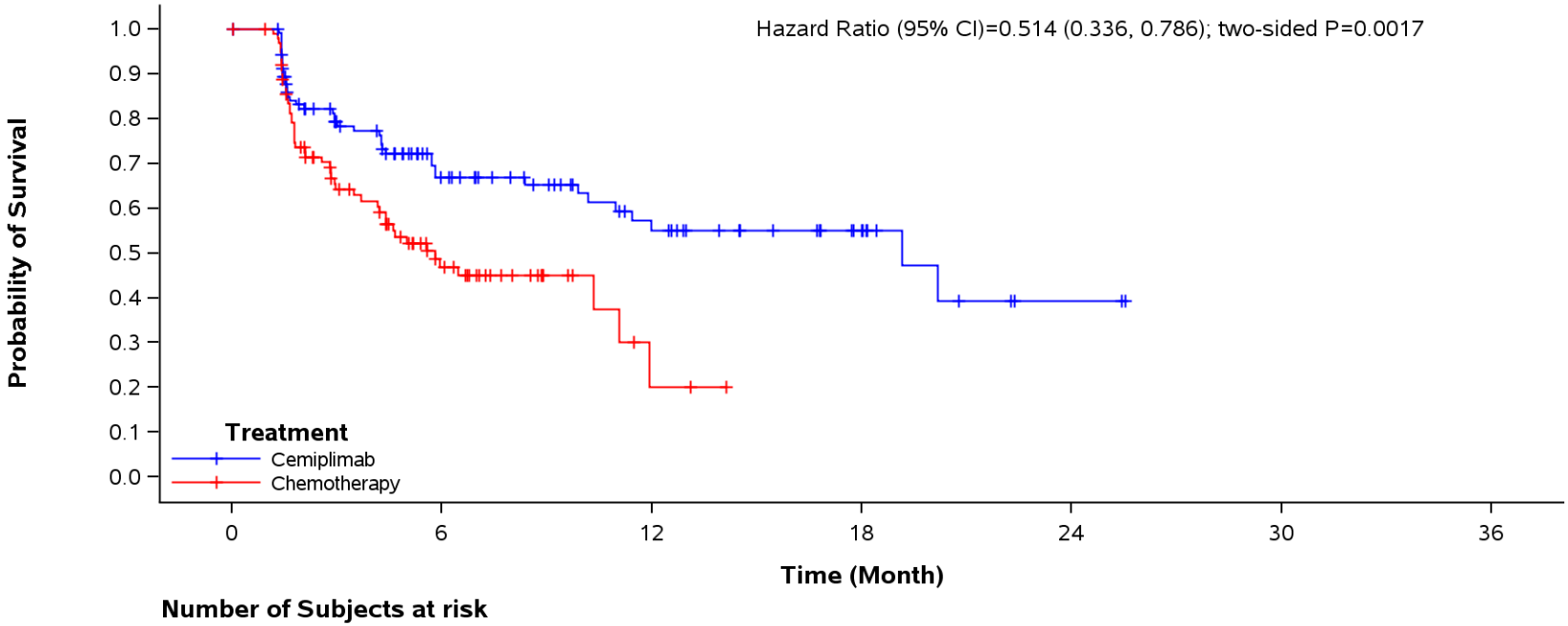

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 63 | 32 | 15 | 3 | 0 | 0 |
| Chemotherapy | 137 | 30 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts sustained deterioration



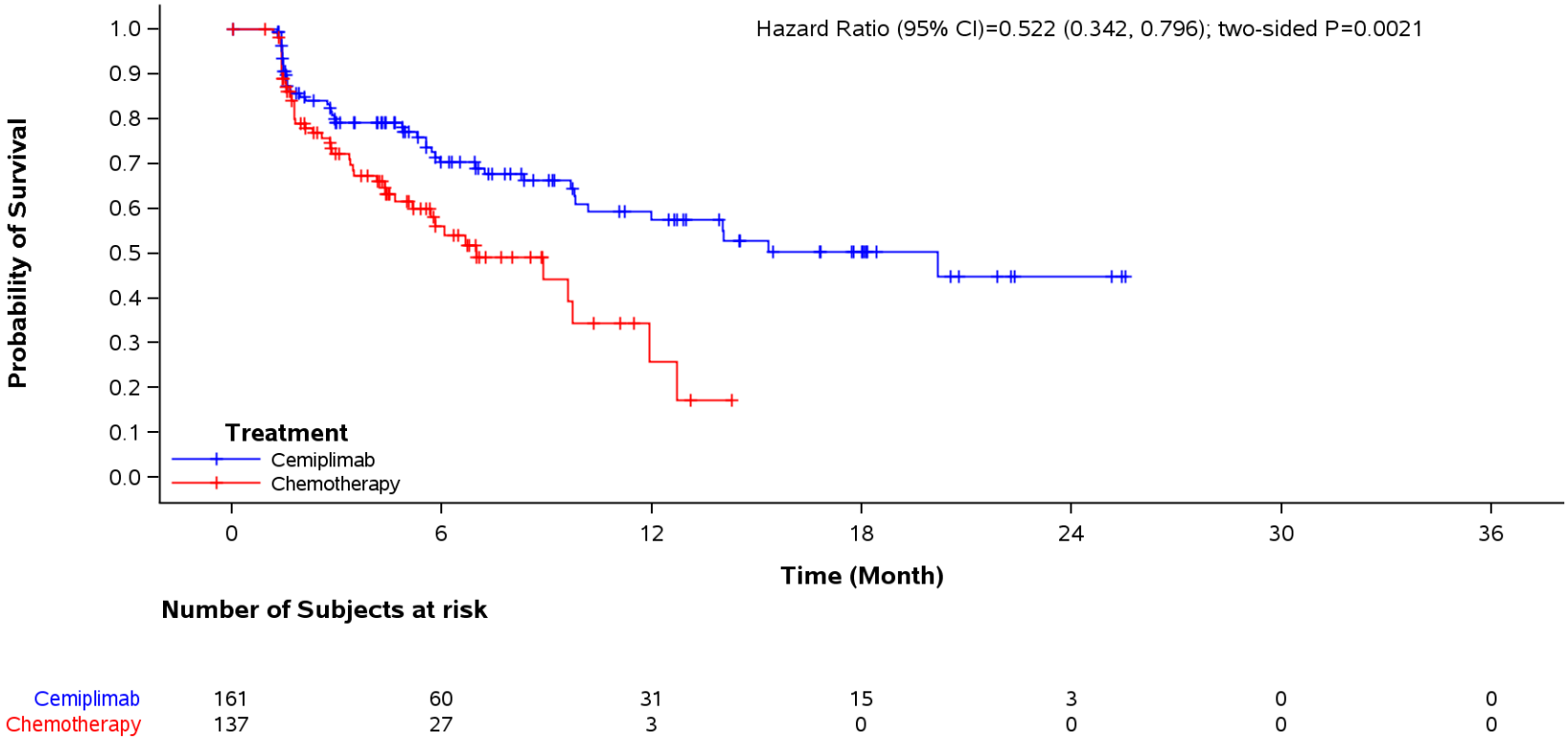

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 51 | 26 | 12 | 2 | 0 | 0 |
| Chemotherapy | 137 | 26 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Physical Functioning - 10 pts sustained deterioration



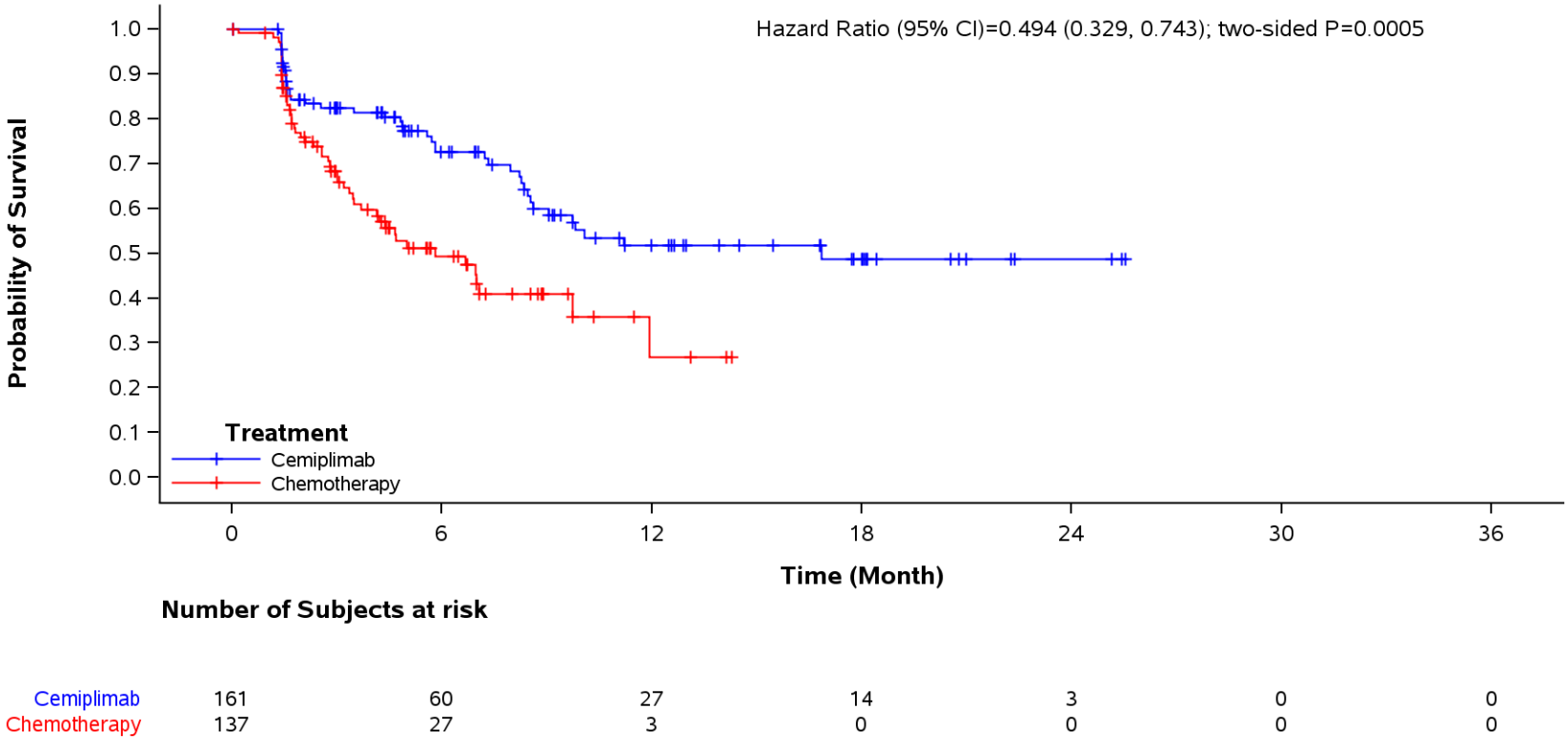

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 60 | 31 | 15 | 3 | 0 | 0 |
| Chemotherapy | 137 | 27 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Global health status / QoL - 10 pts sustained deterioration



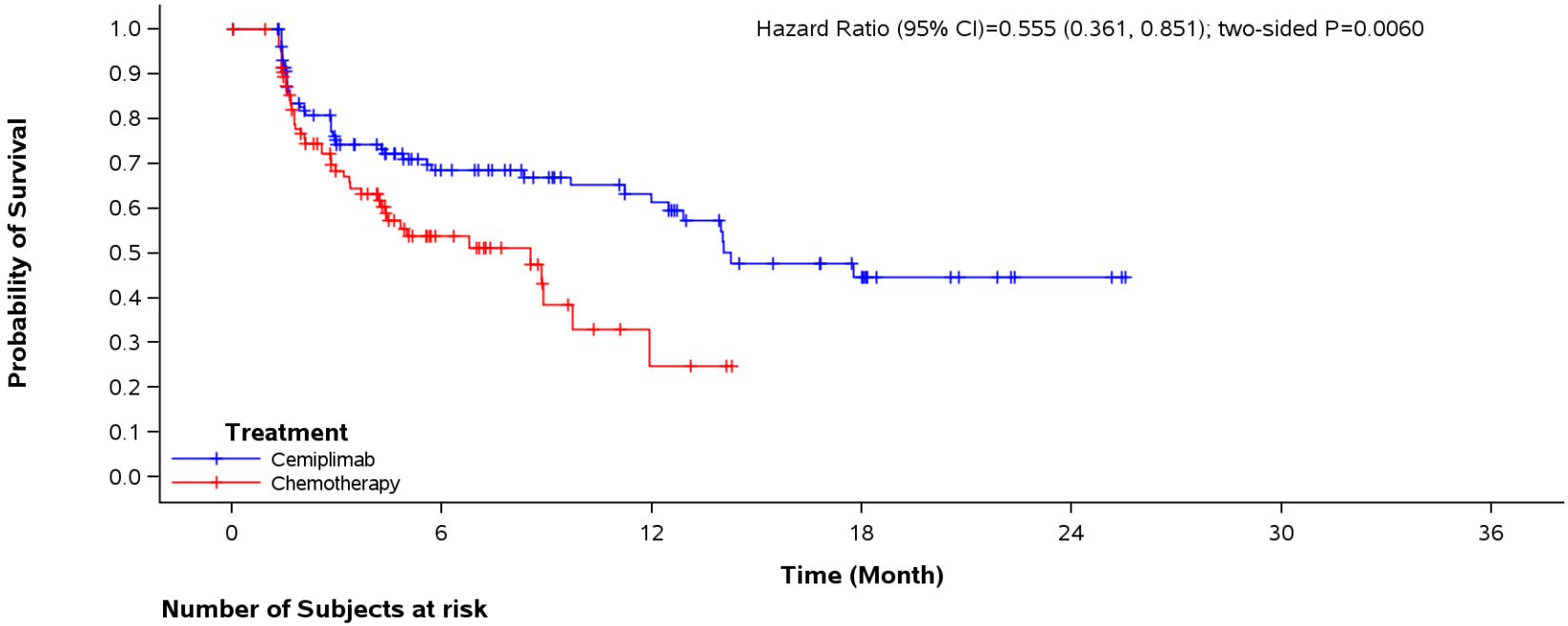

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 60 | 27 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 27 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts sustained deterioration



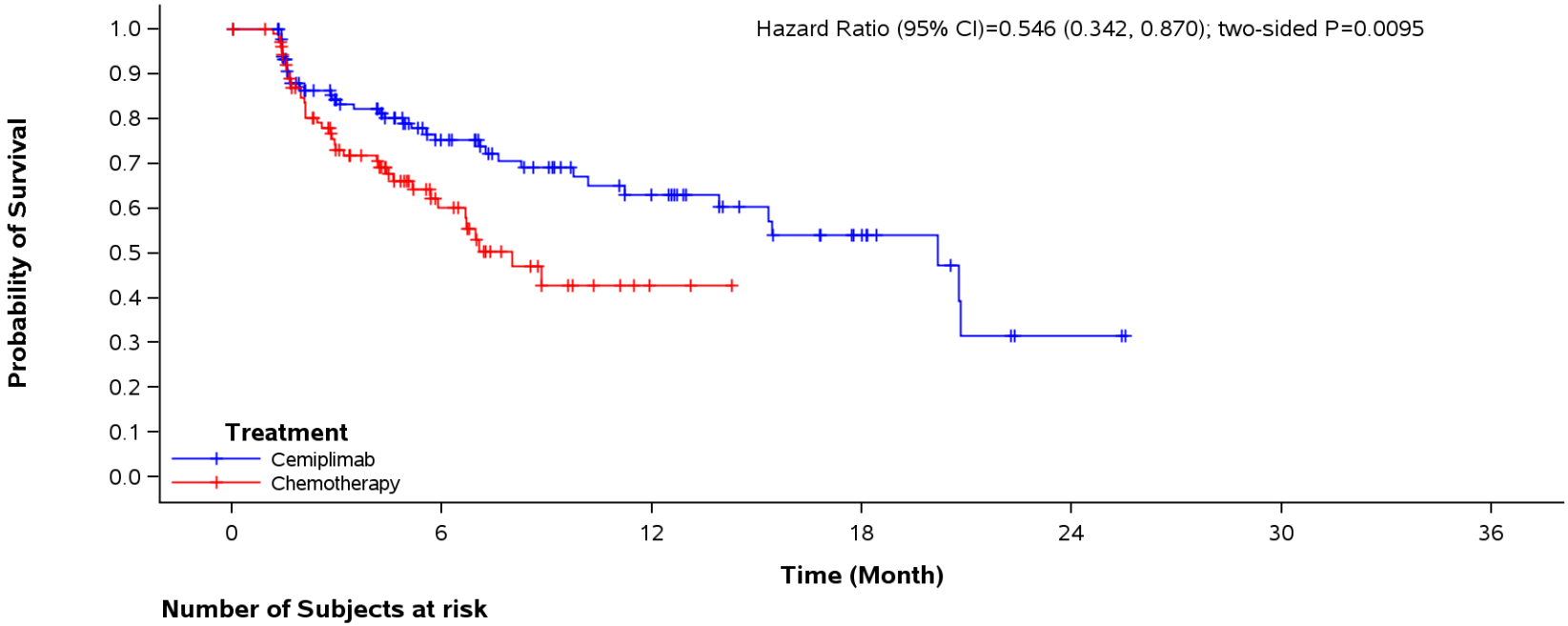

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 53 | 32 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 22 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Social Functioning - 10 pts sustained deterioration




Number of Subjects at risk

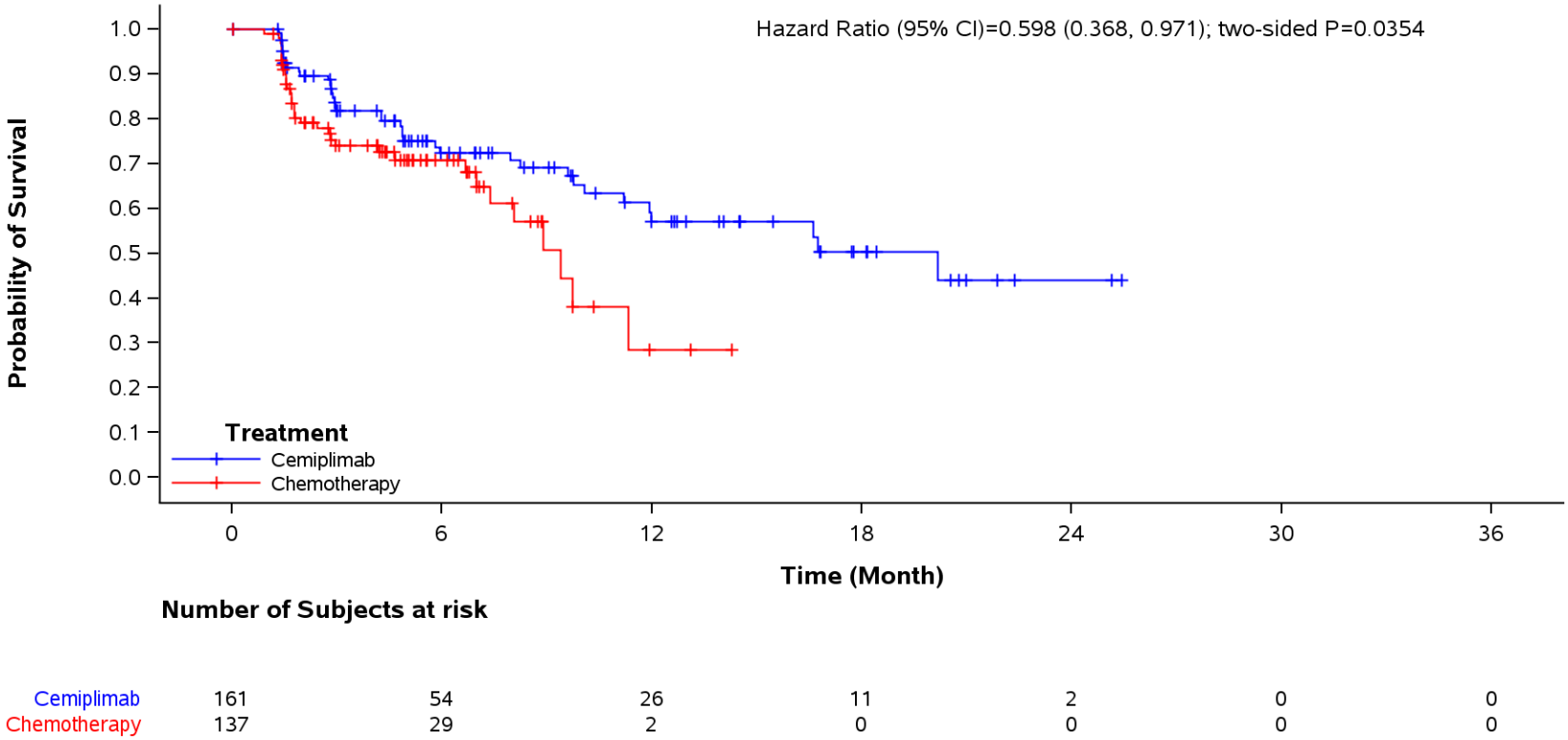
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 57 | 29 | 12 | 2 | 0 | 0 |
| Chemotherapy | 137 | 28 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:23:03, yingyuan.lin)

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Insomnia - 10 pts sustained deterioration



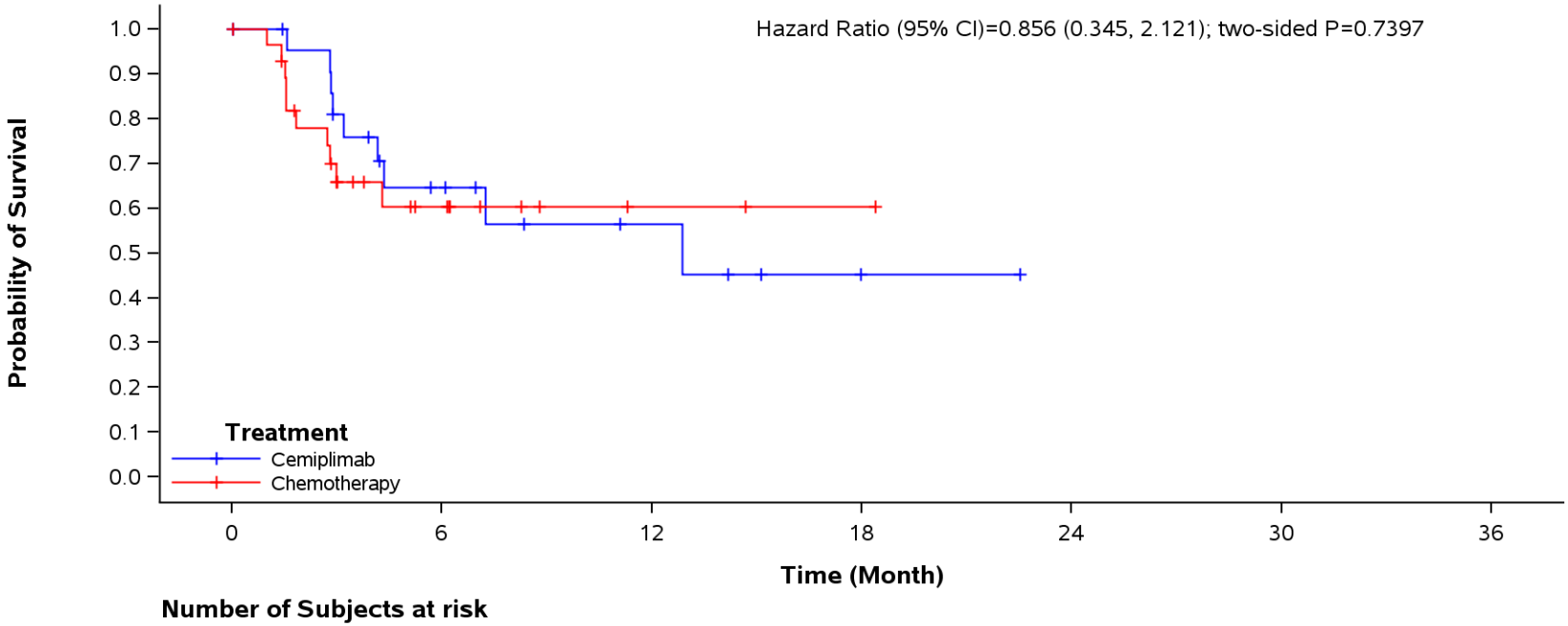

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 54 | 26 | 11 | 2 | 0 | 0 |
| Chemotherapy | 137 | 29 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts sustained deterioration



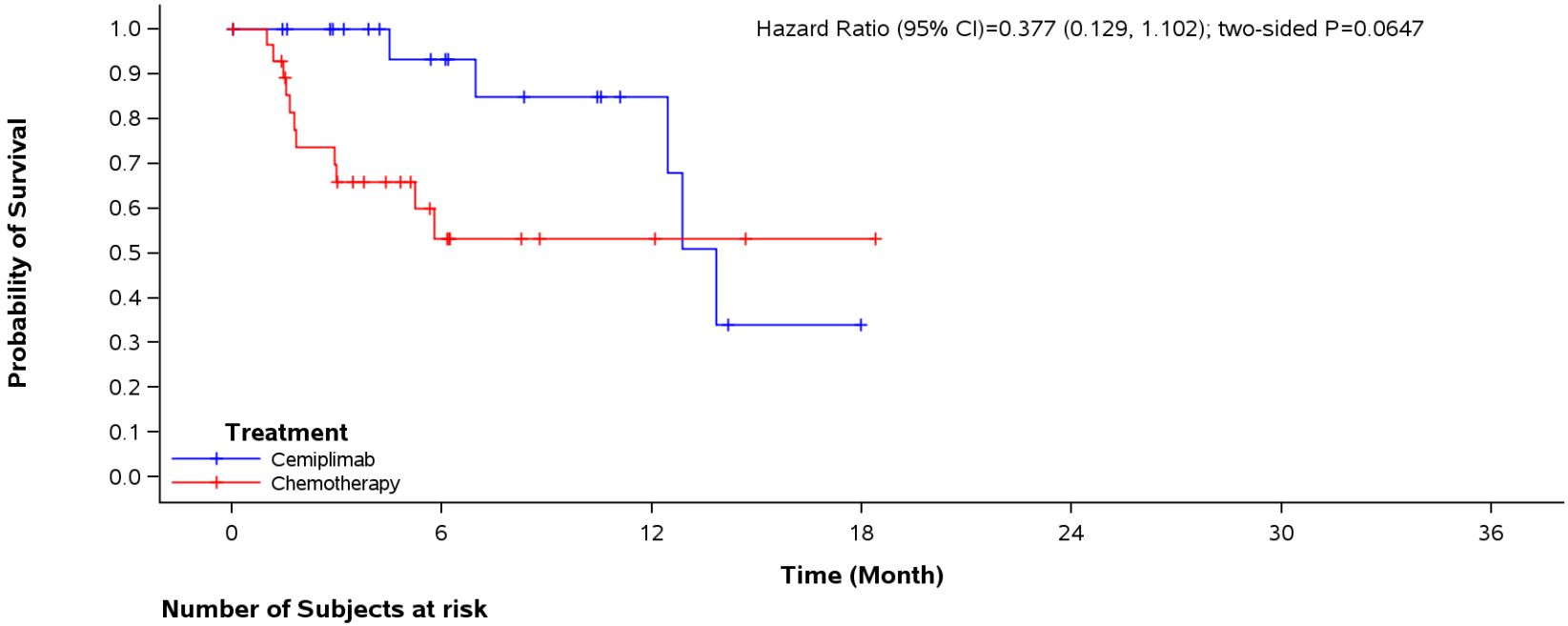

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts sustained deterioration



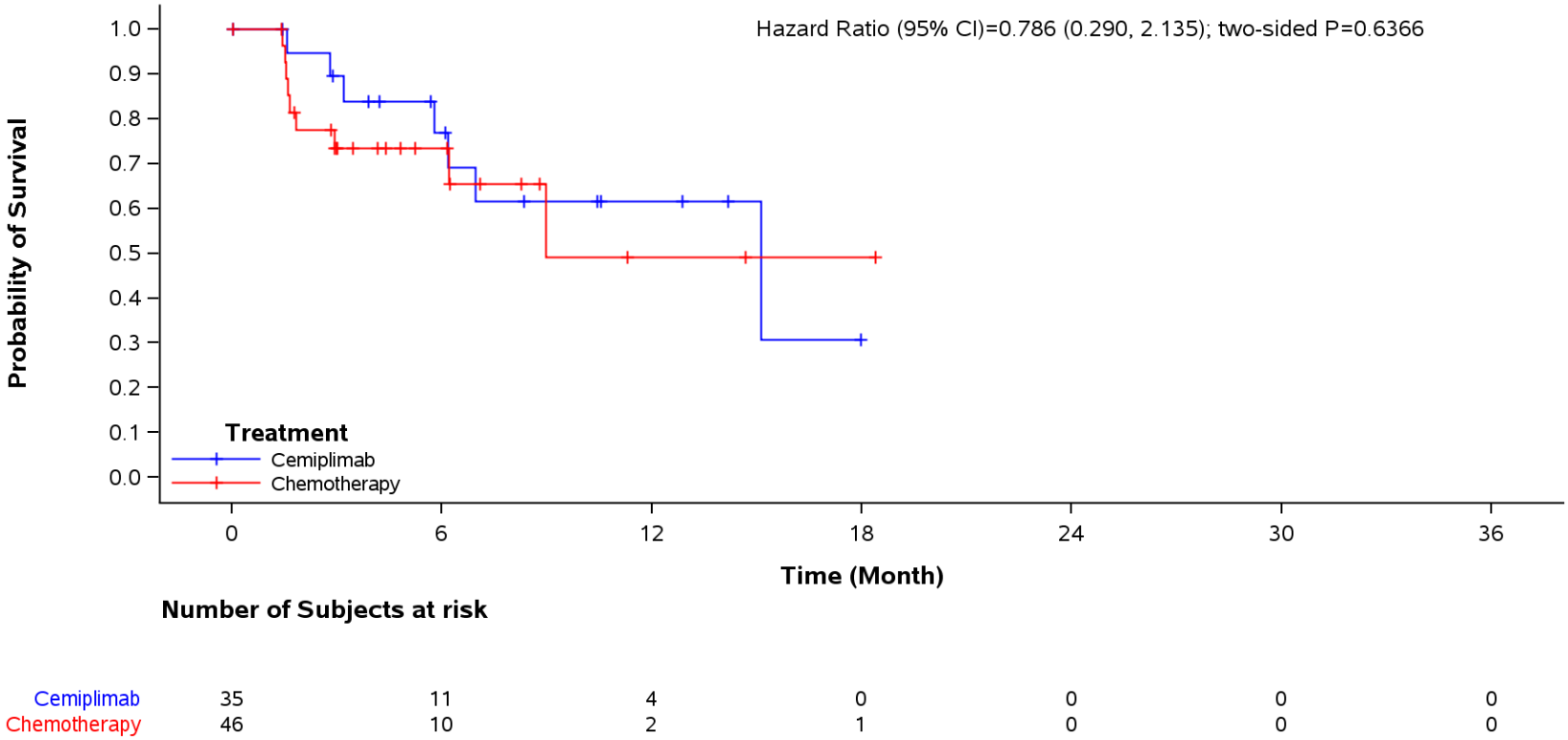

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 13 | 5 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts sustained deterioration



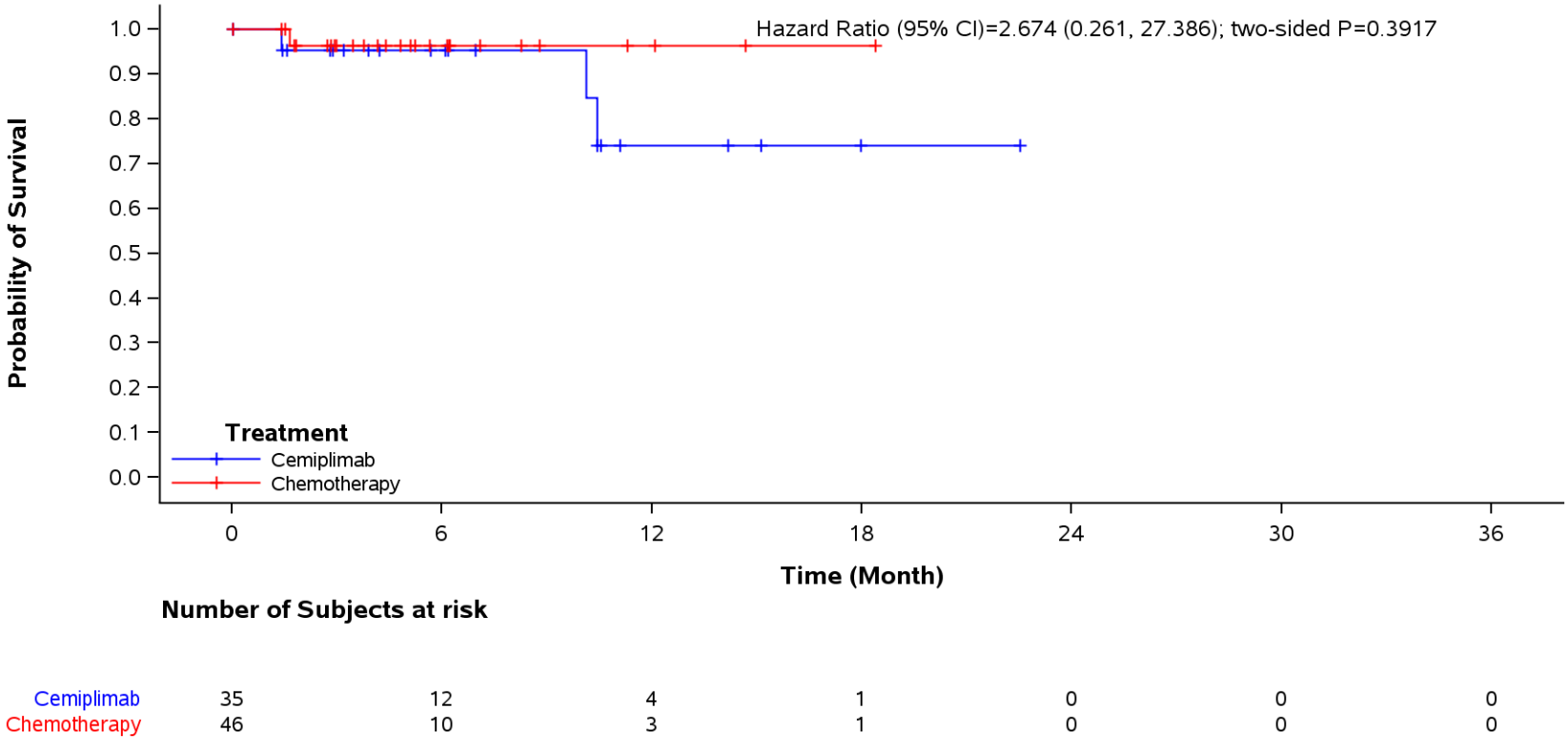

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 10 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts sustained deterioration



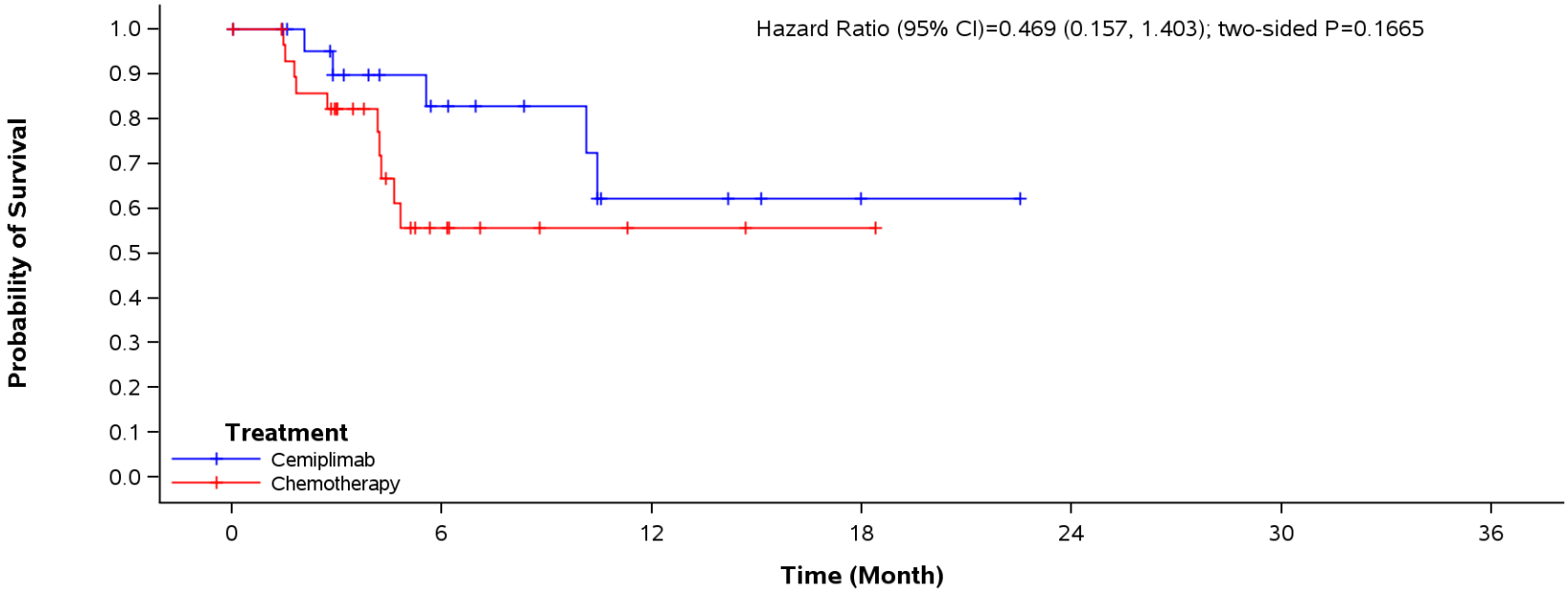

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts sustained deterioration



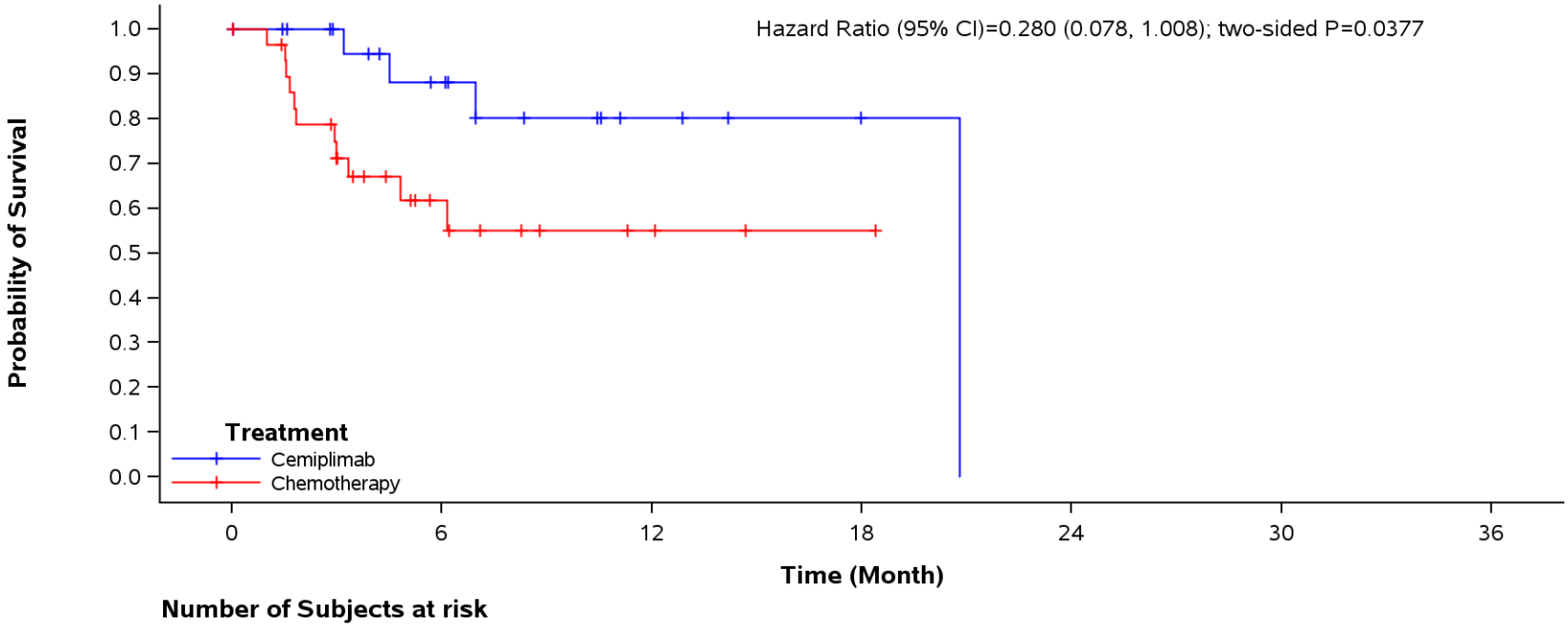

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts sustained deterioration



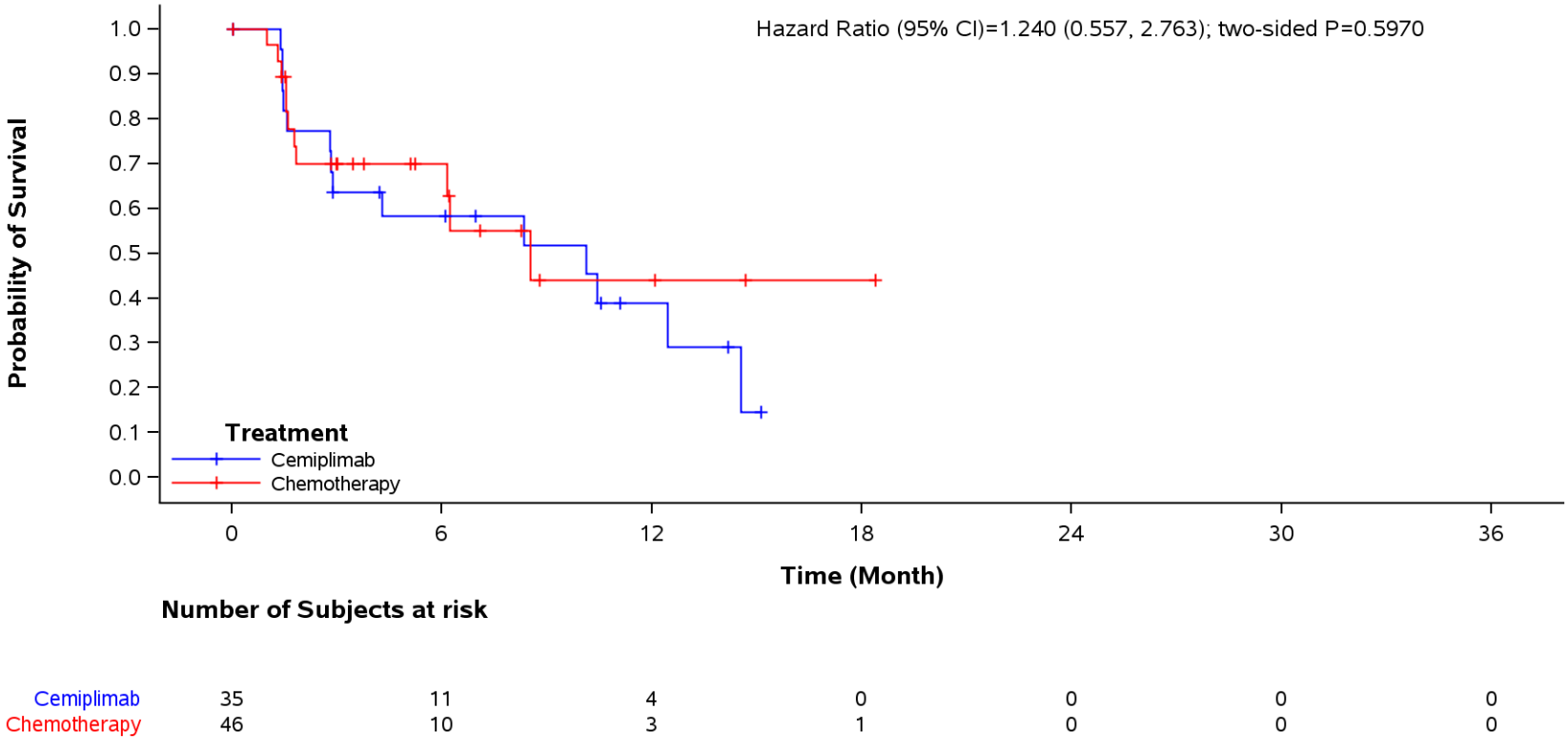

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 13 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts sustained deterioration



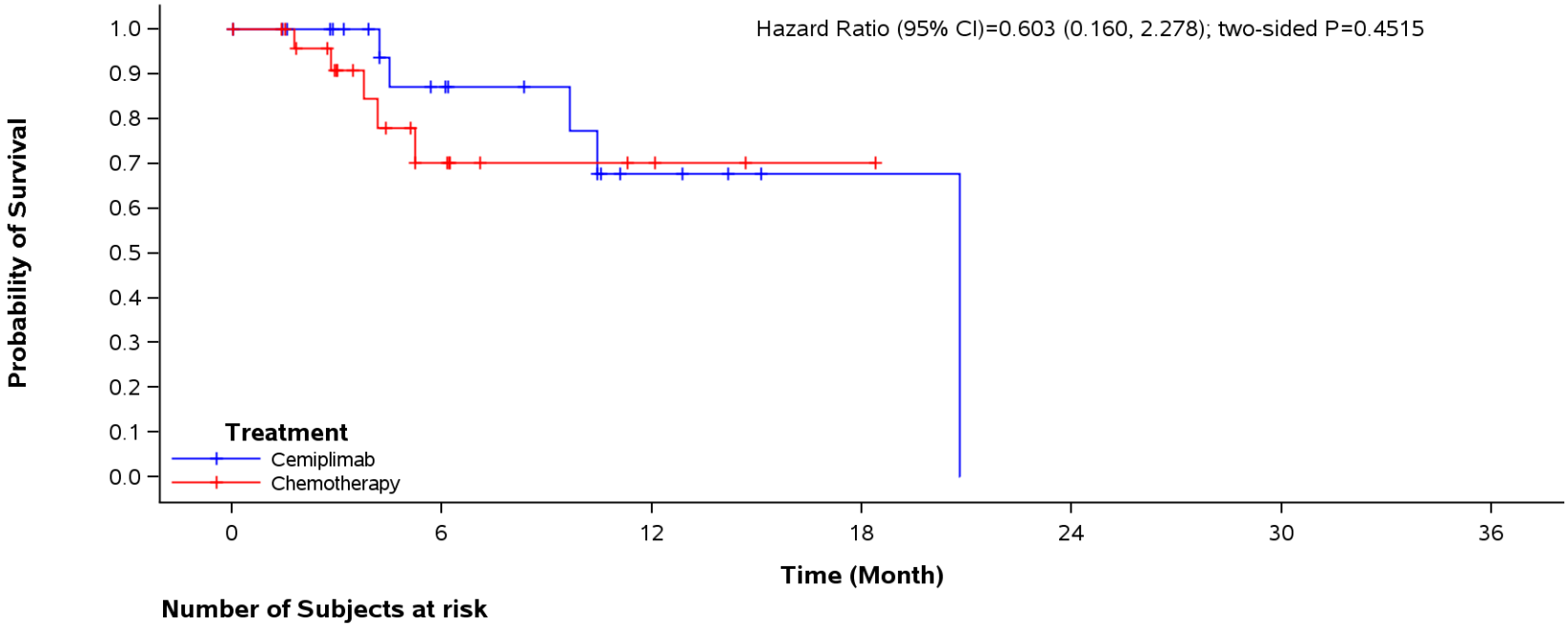

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts sustained deterioration



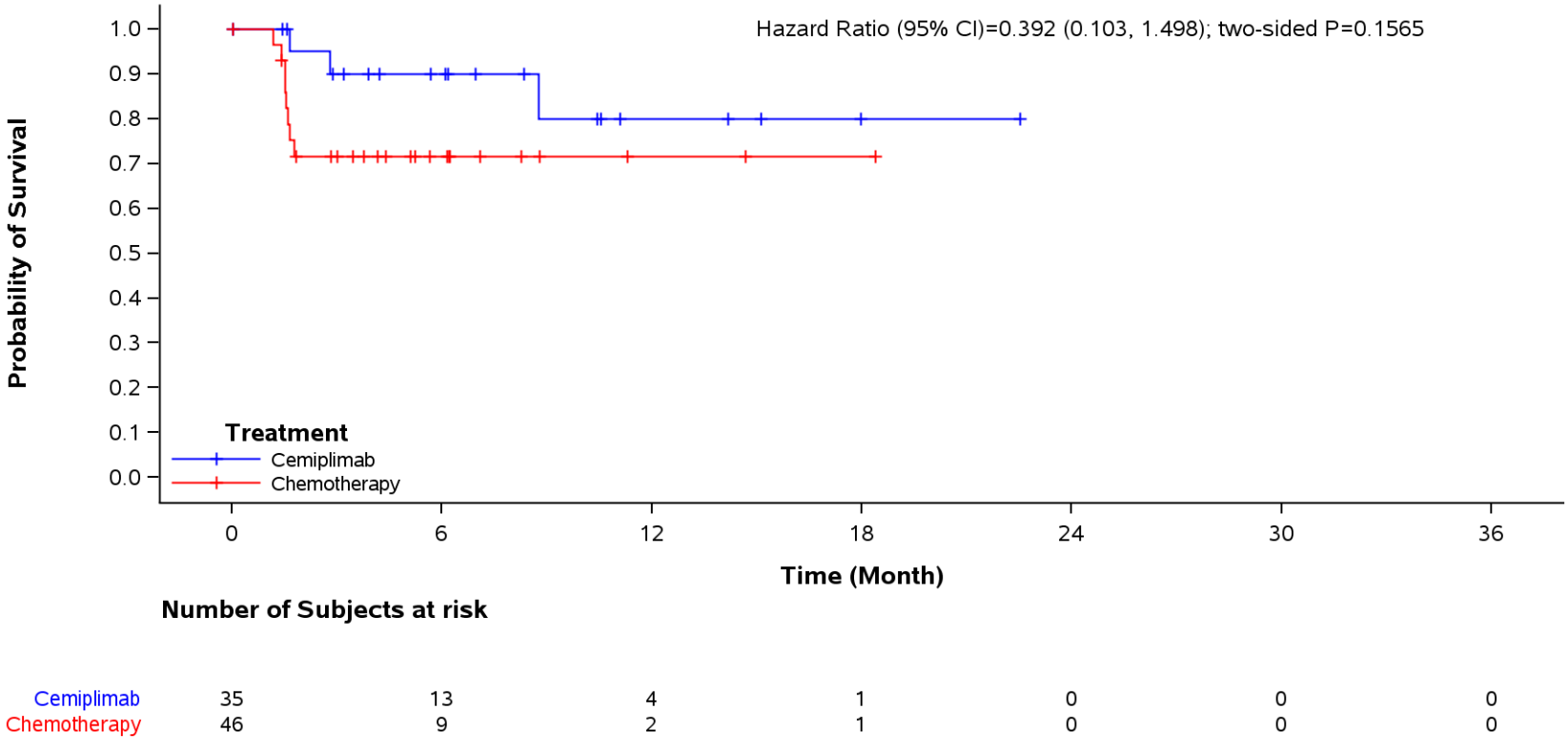

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Nausea / Vomiting - 10 pts sustained deterioration



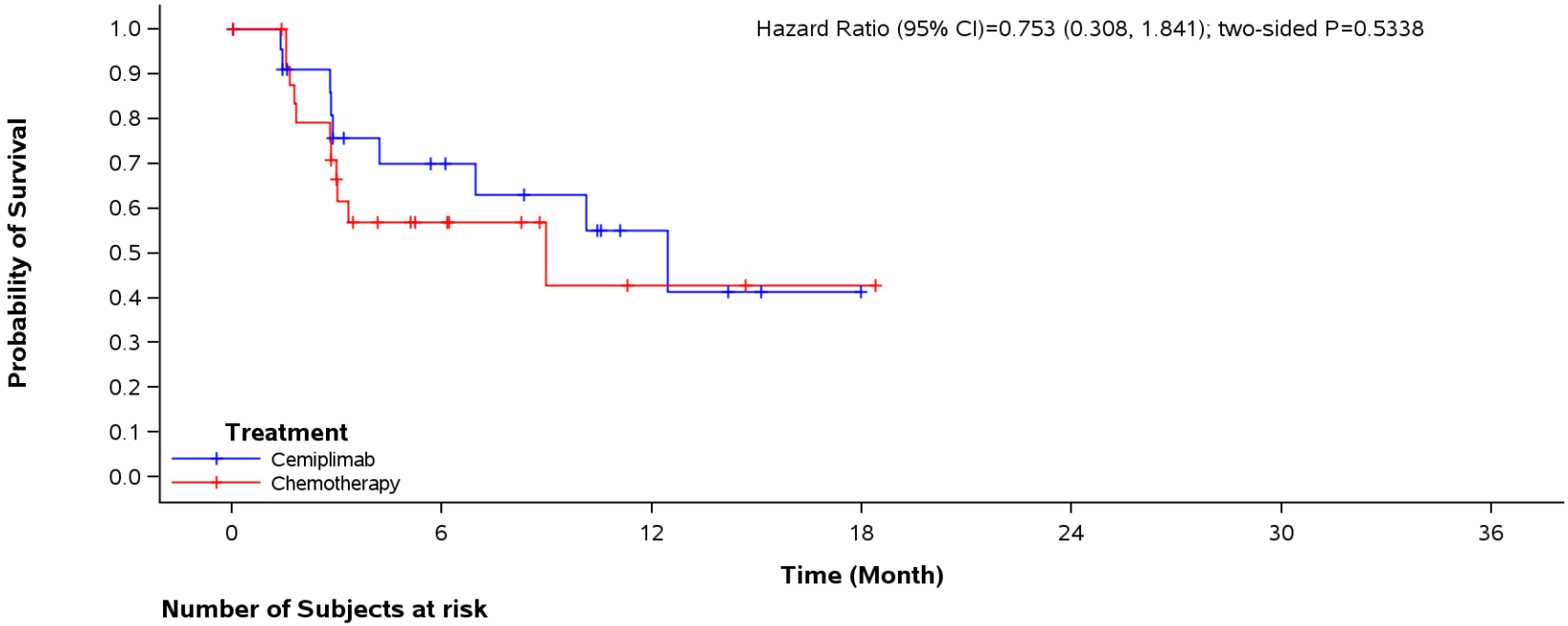

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 13 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts sustained deterioration



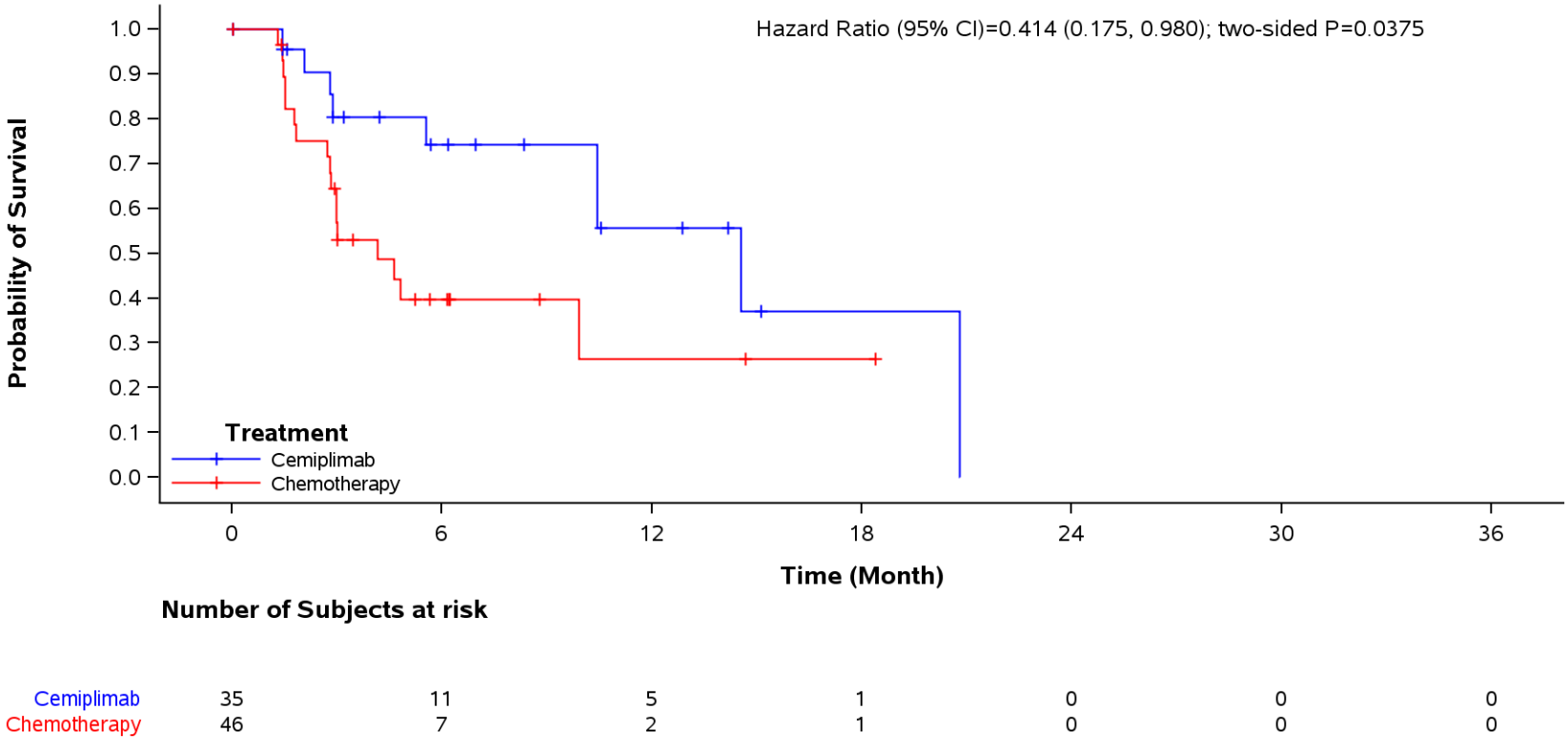

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts sustained deterioration



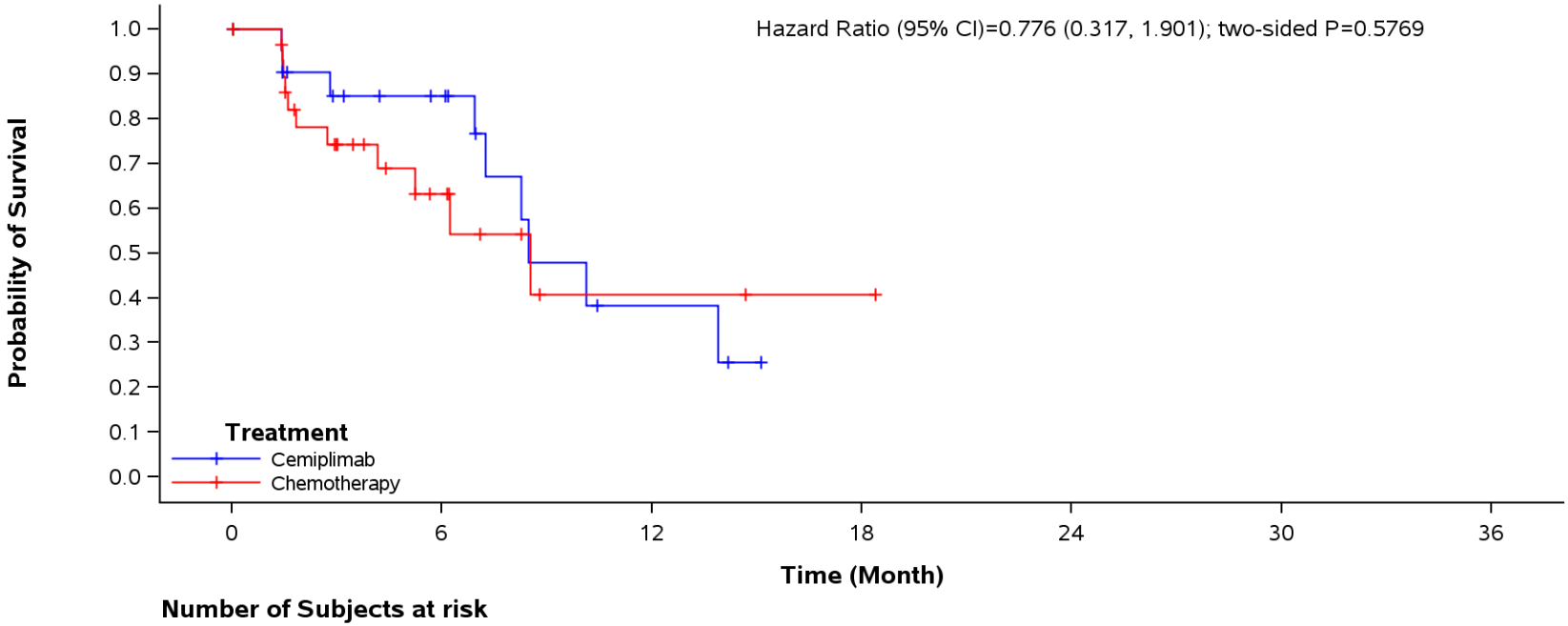

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts sustained deterioration



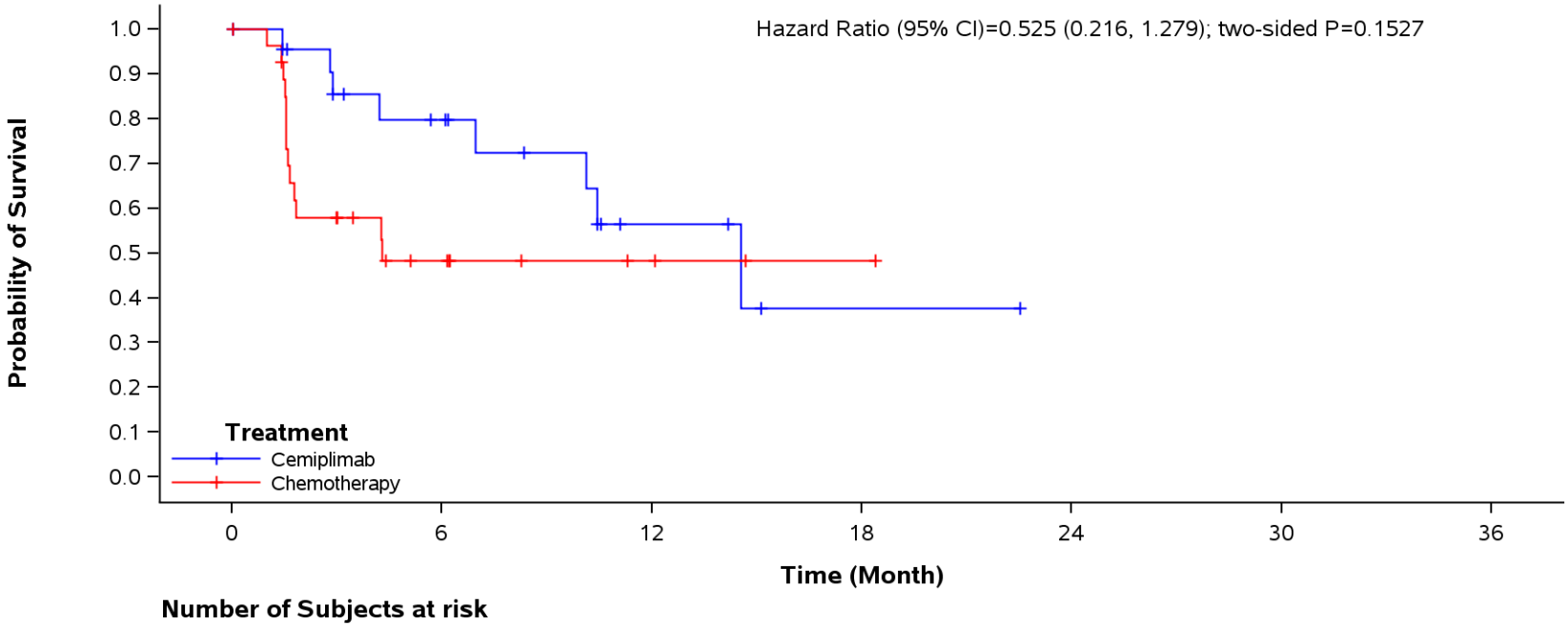

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts sustained deterioration



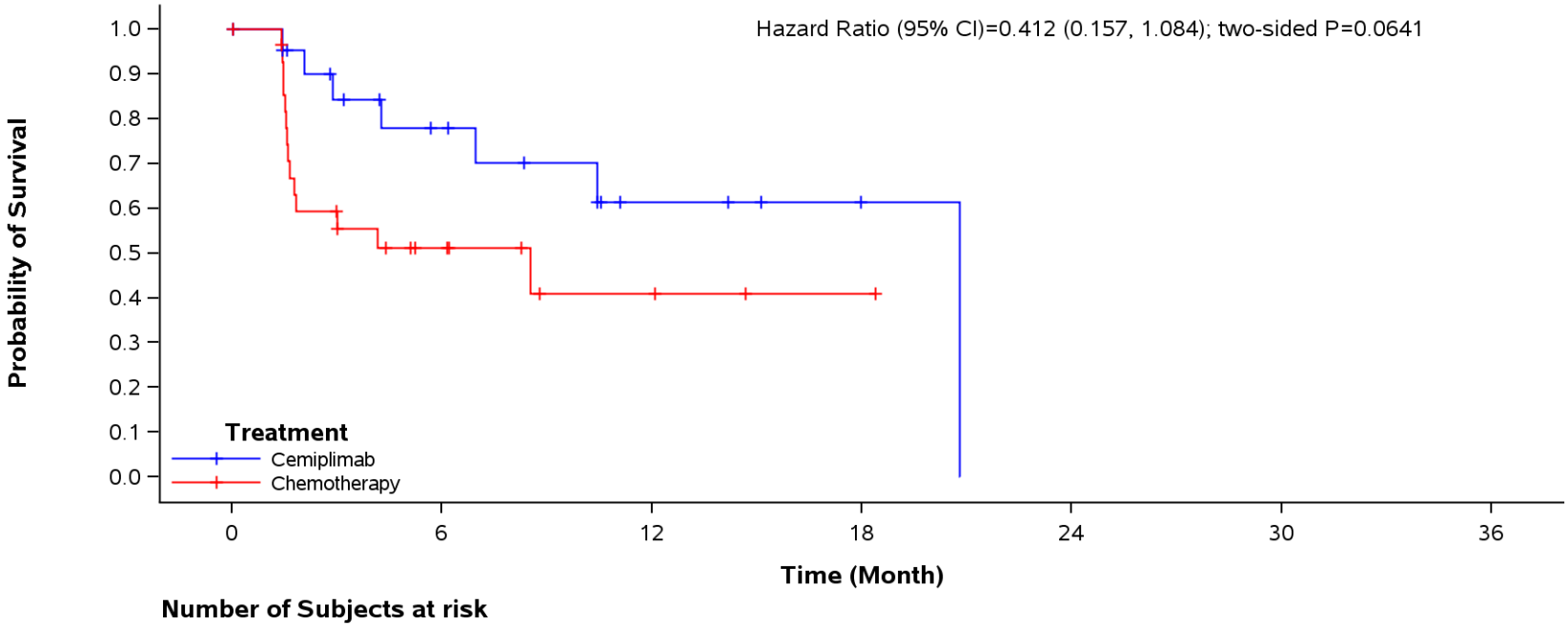

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 13 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts sustained deterioration



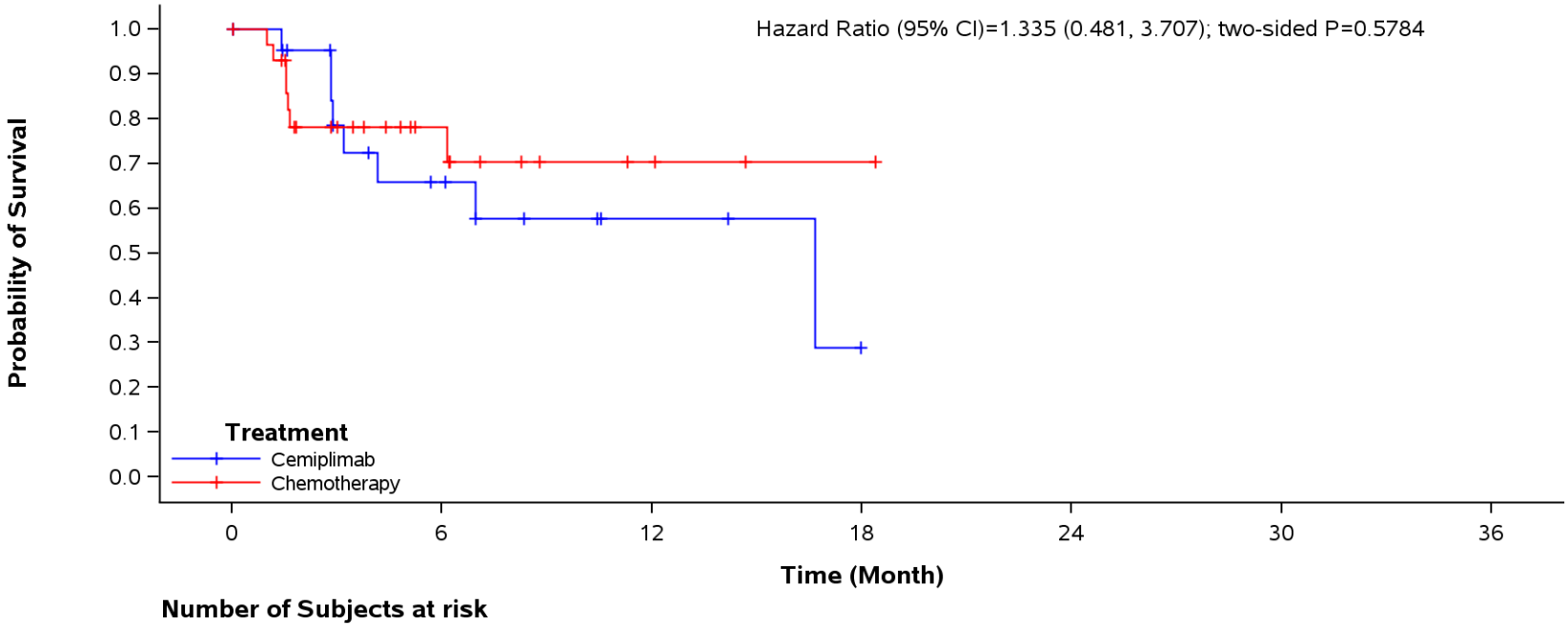

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts sustained deterioration



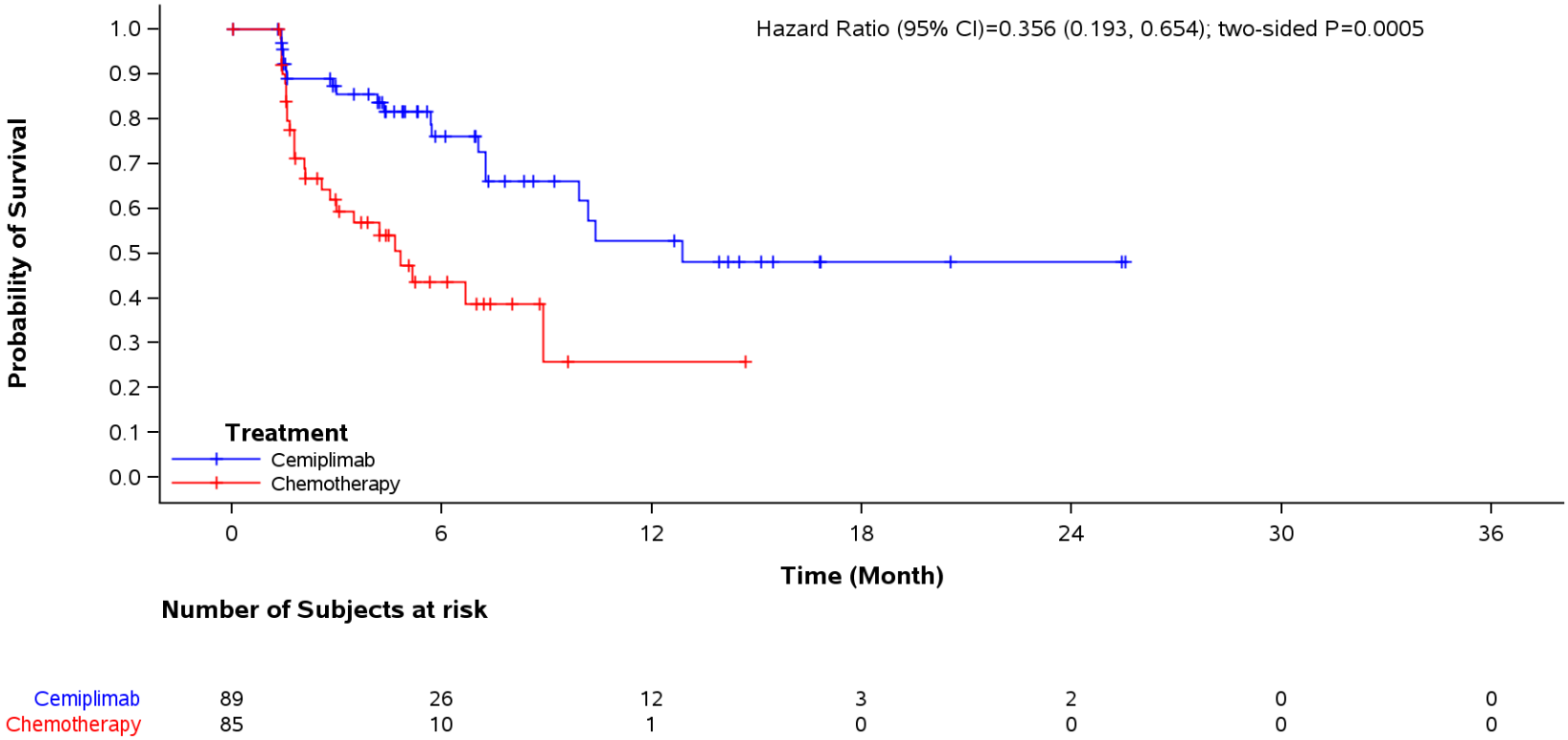

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts sustained deterioration



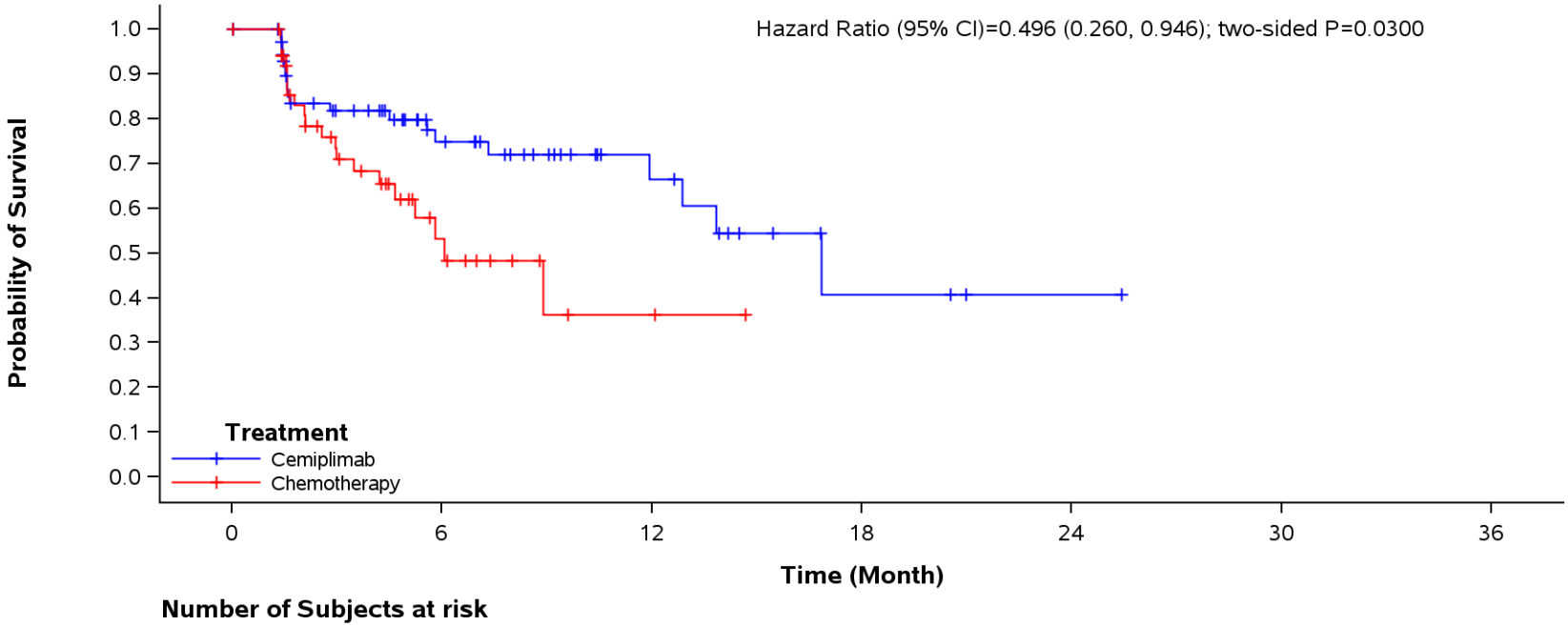

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 26 | 12 | 3 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Cognitive Functioning - 10 pts sustained deterioration



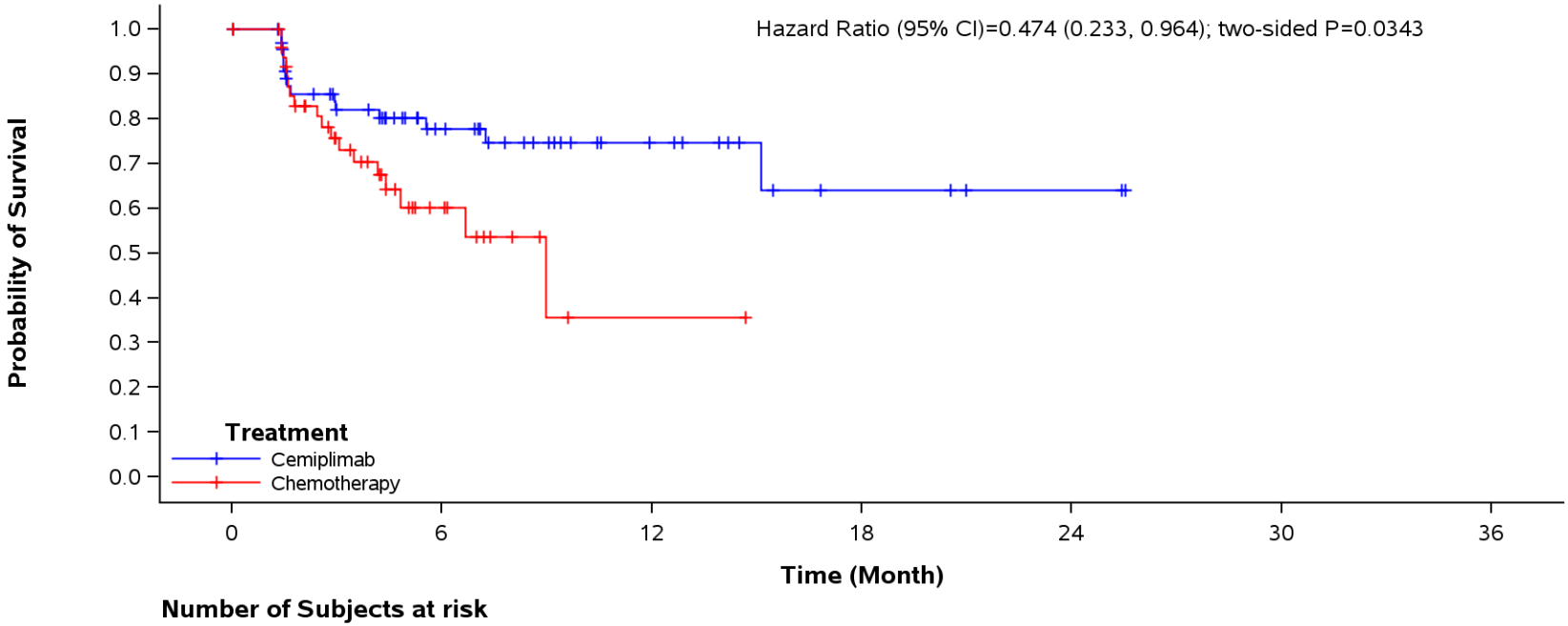

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 30 | 12 | 3 | 1 | 0 | 0 |
| Chemotherapy | 85 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts sustained deterioration



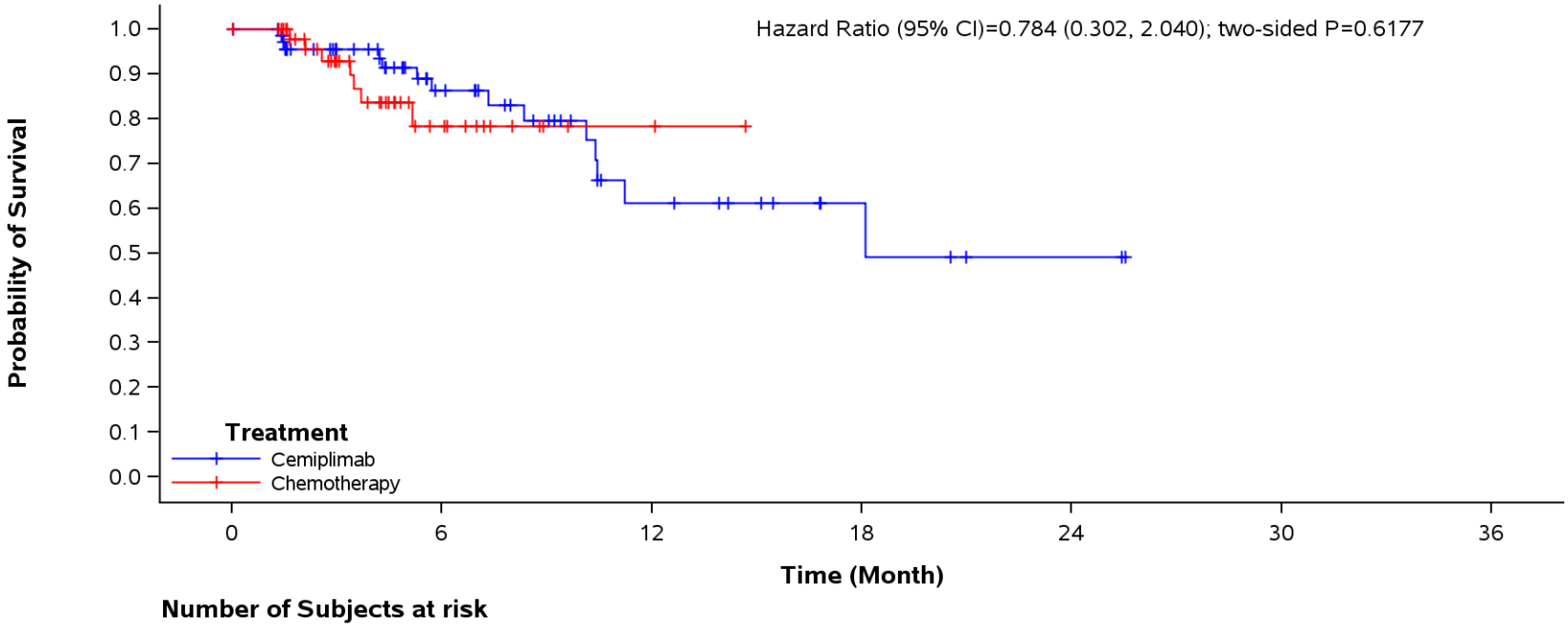

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 29 | 12 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts sustained deterioration



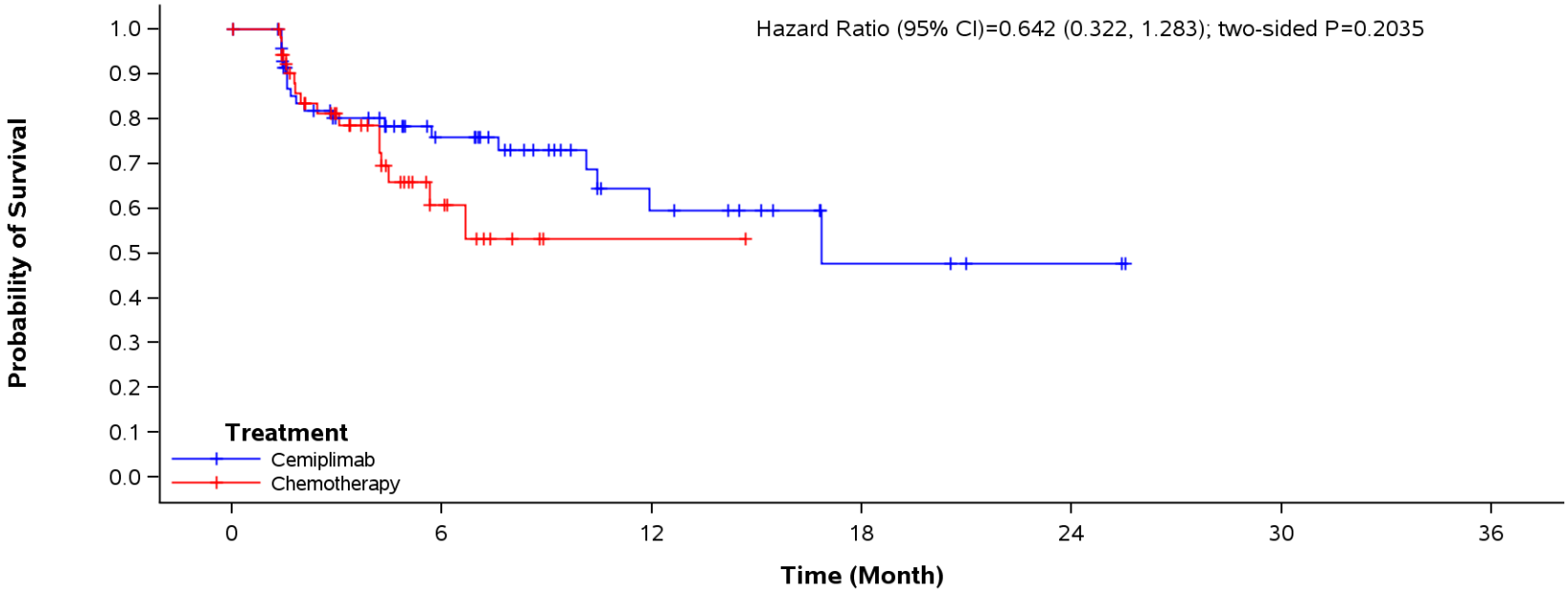

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 31 | 12 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Dyspnoea - 10 pts sustained deterioration



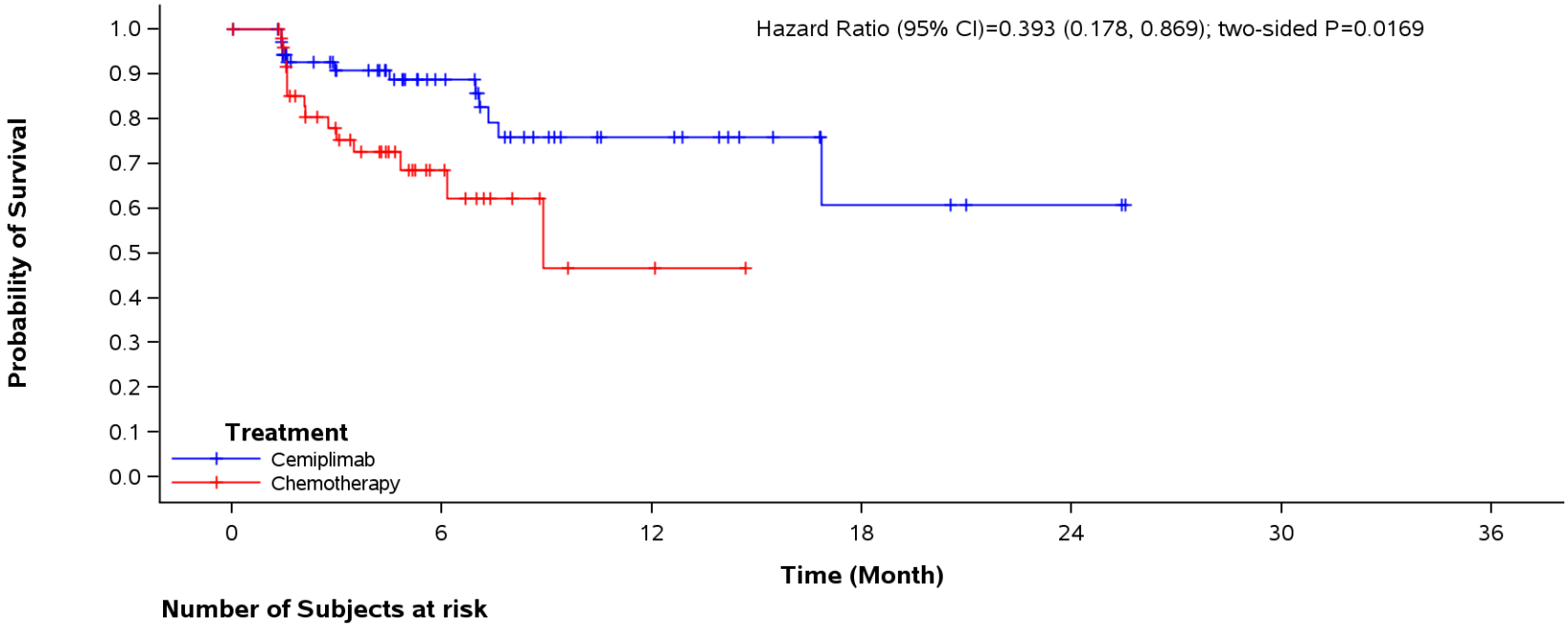

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 31 | 12 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Emotional Functioning - 10 pts sustained deterioration



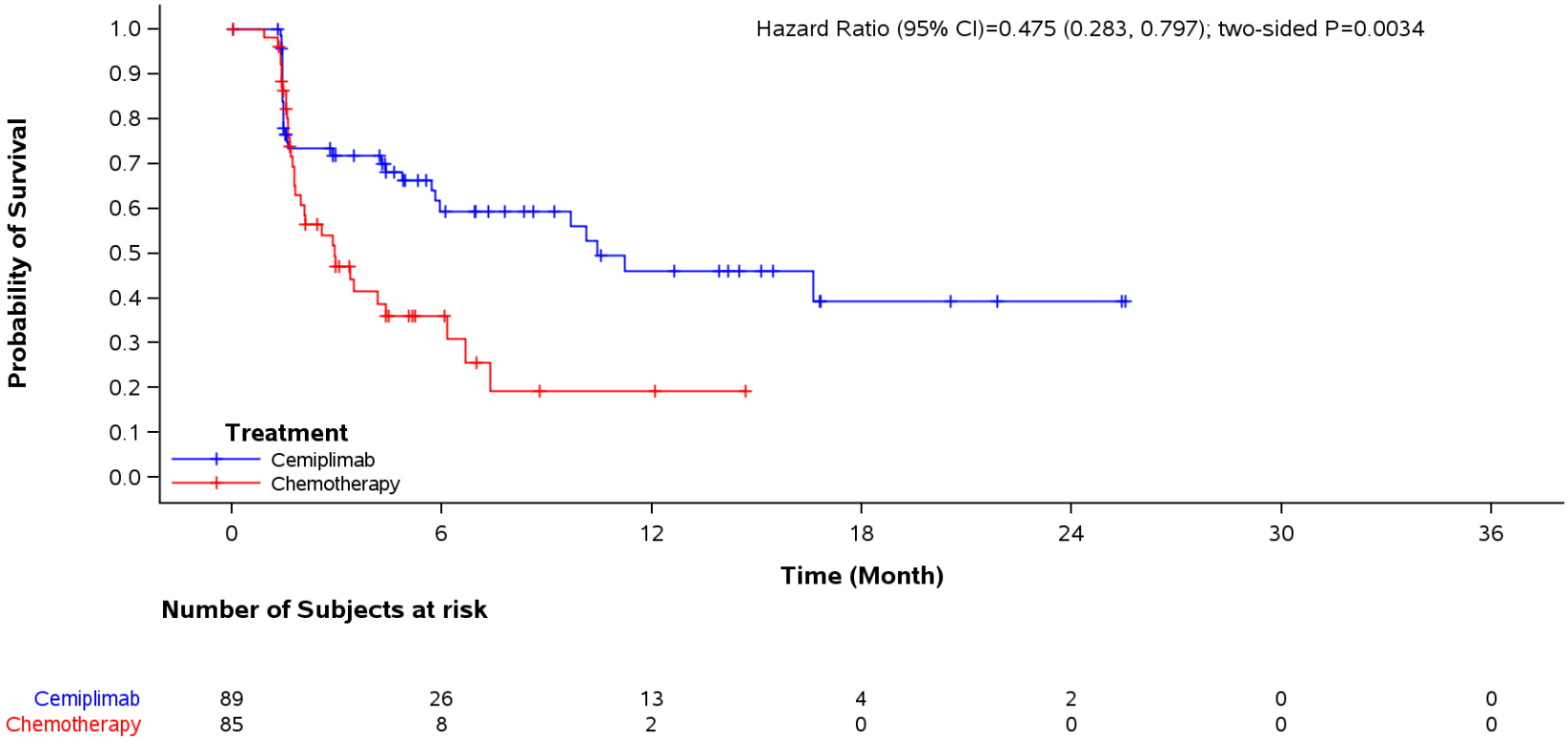

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 32 | 13 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts sustained deterioration



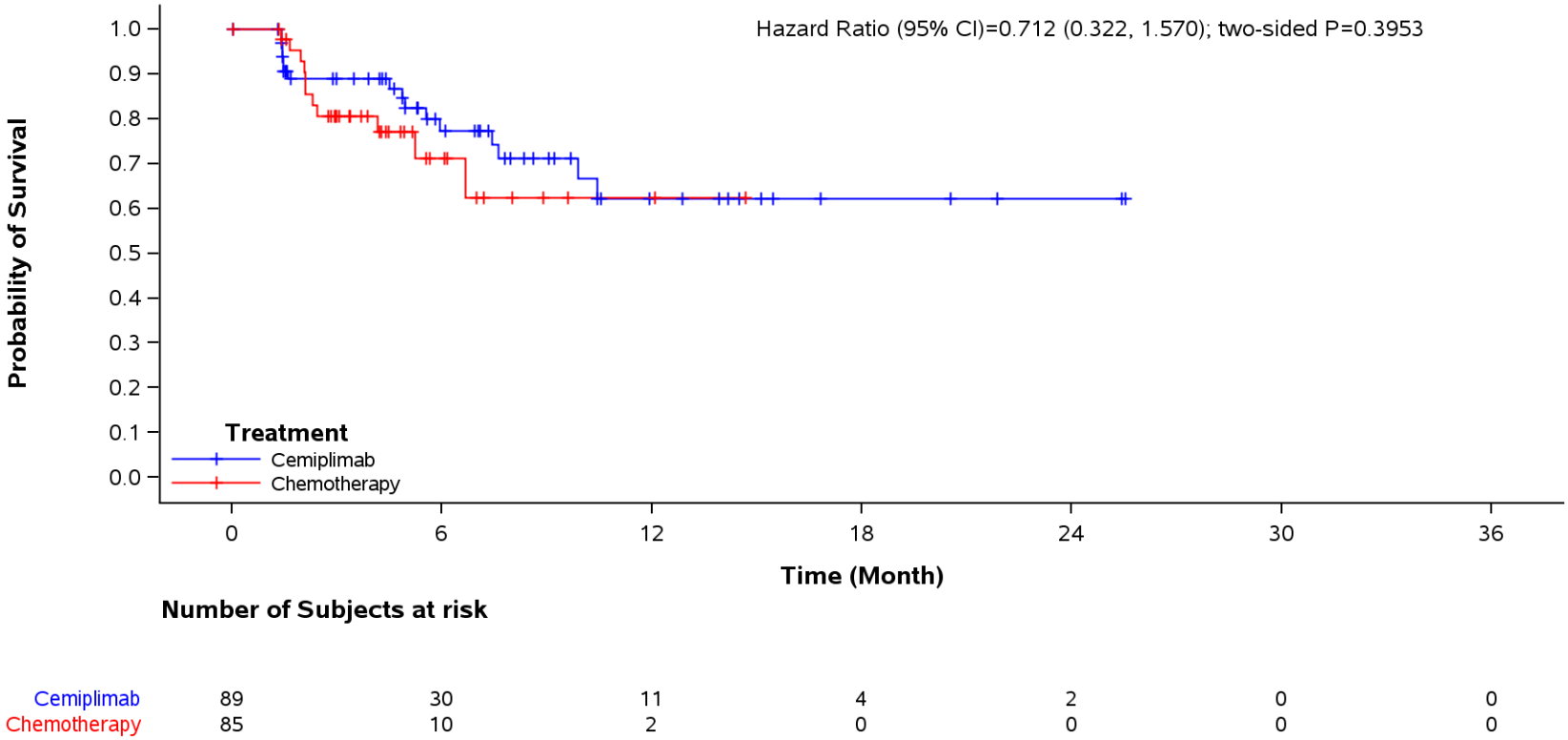

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 26 | 13 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Financial Problems - 10 pts sustained deterioration



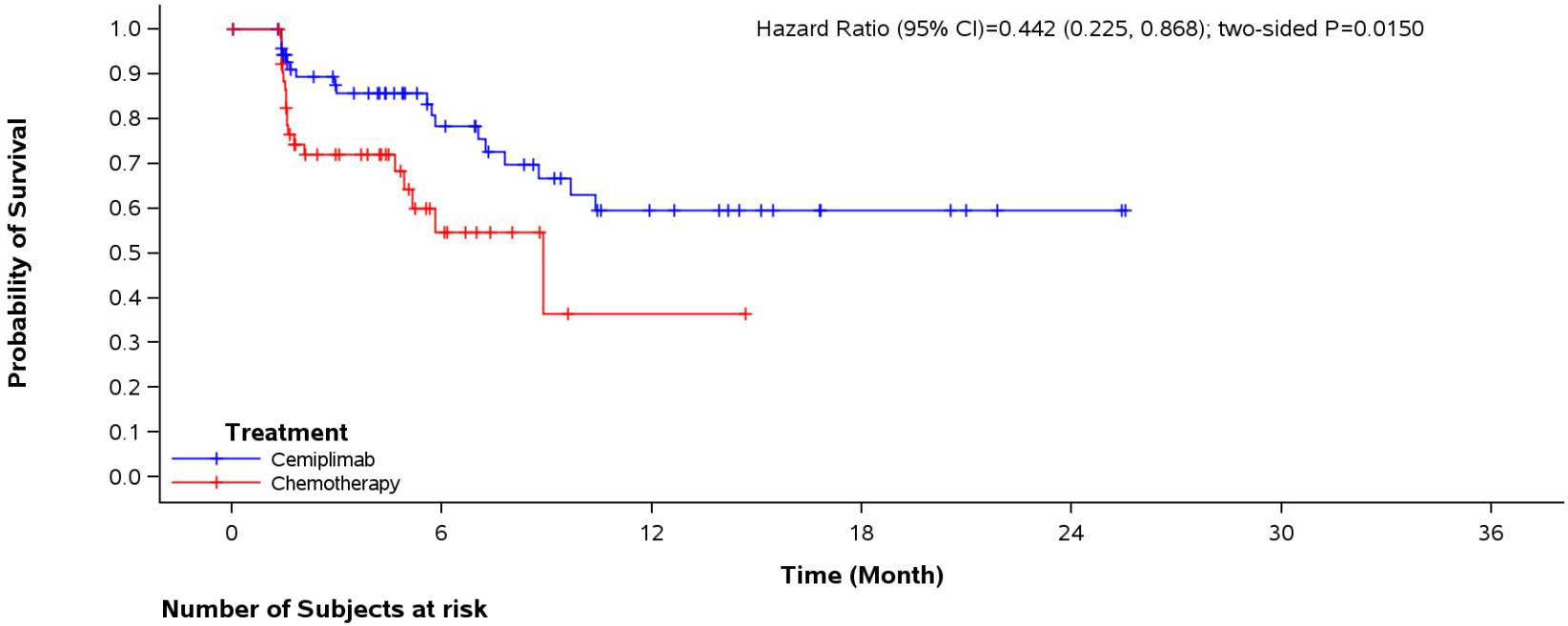

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 30 | 11 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts sustained deterioration



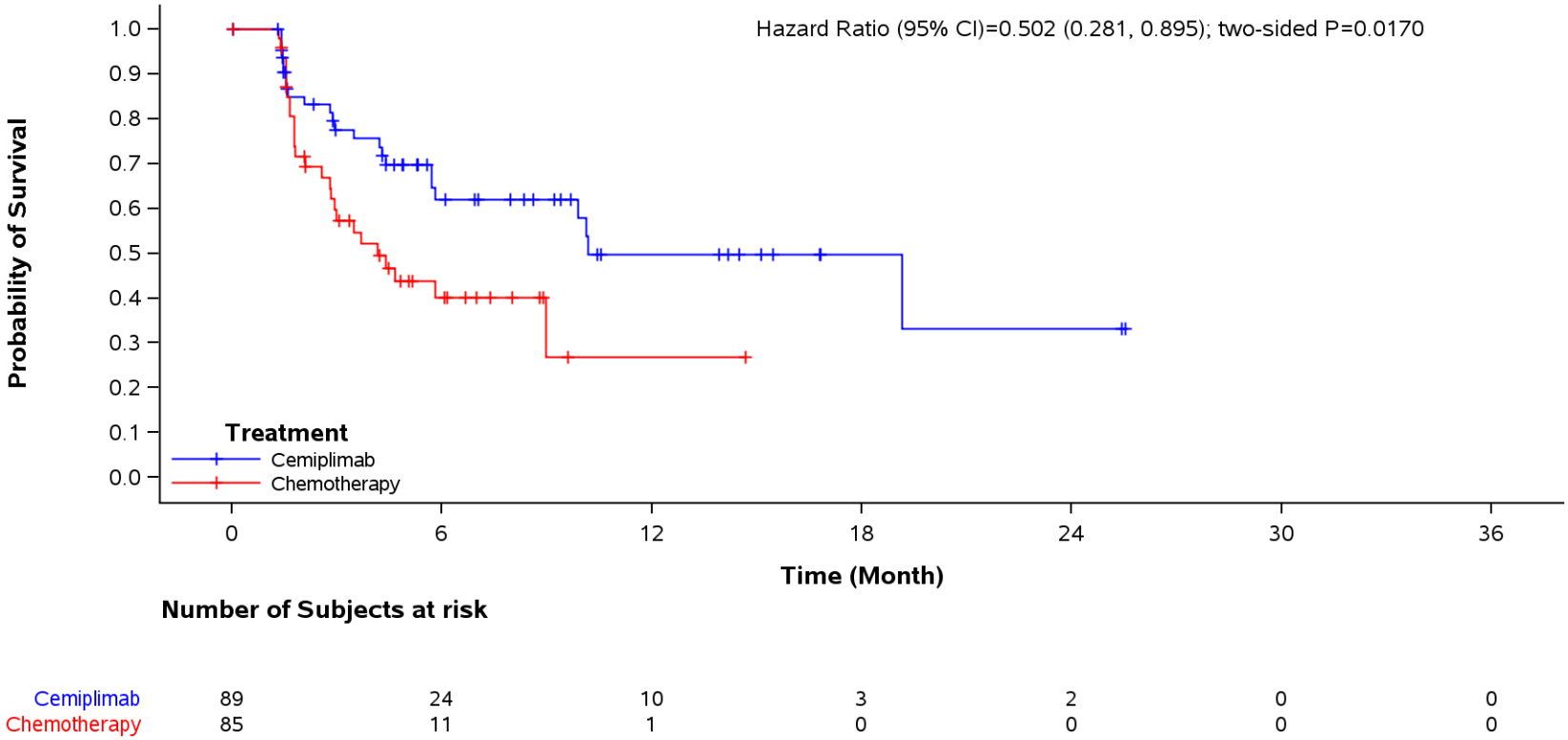

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 31 | 13 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts sustained deterioration



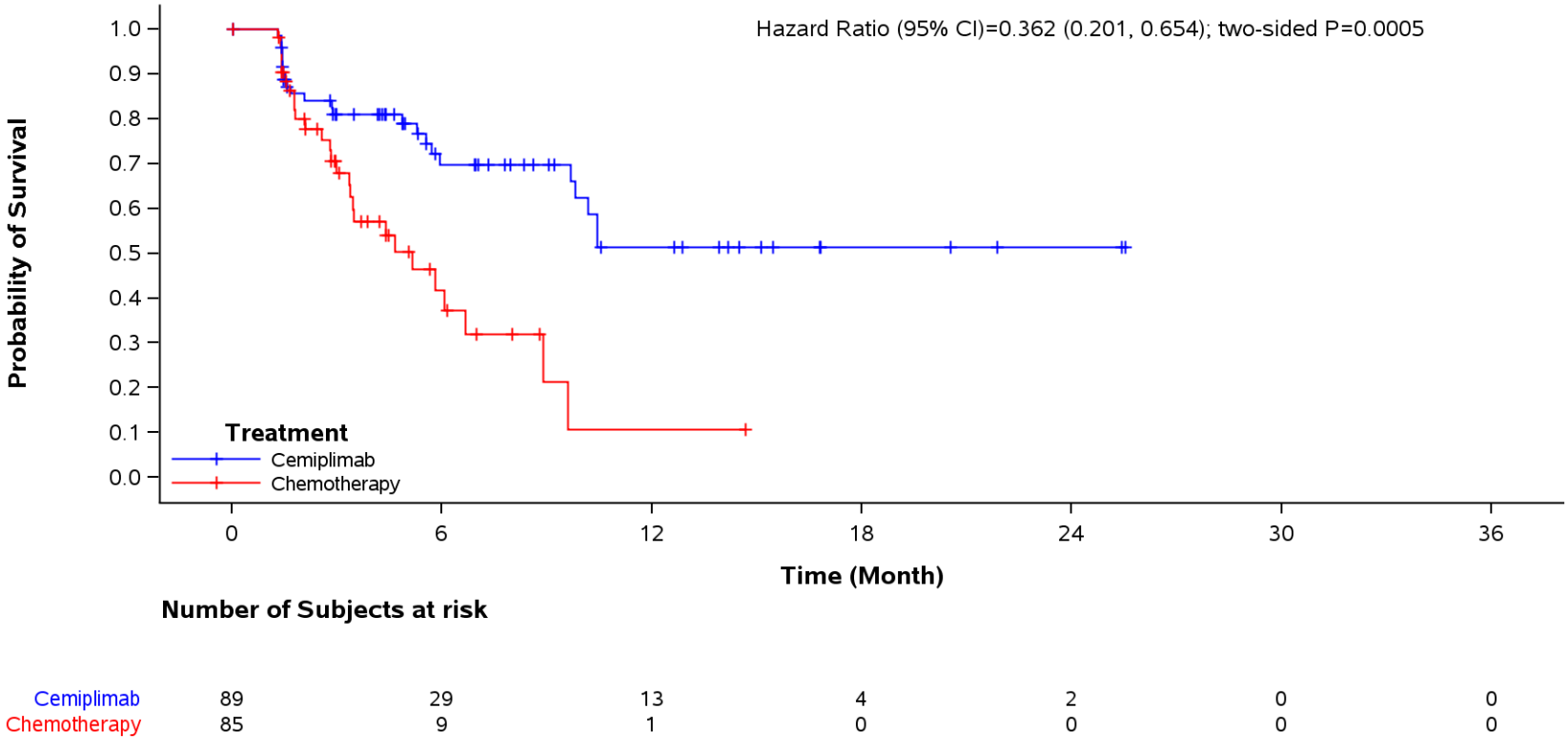

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 24 | 10 | 3 | 2 | 0 | 0 |
| Chemotherapy | 85 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Physical Functioning - 10 pts sustained deterioration



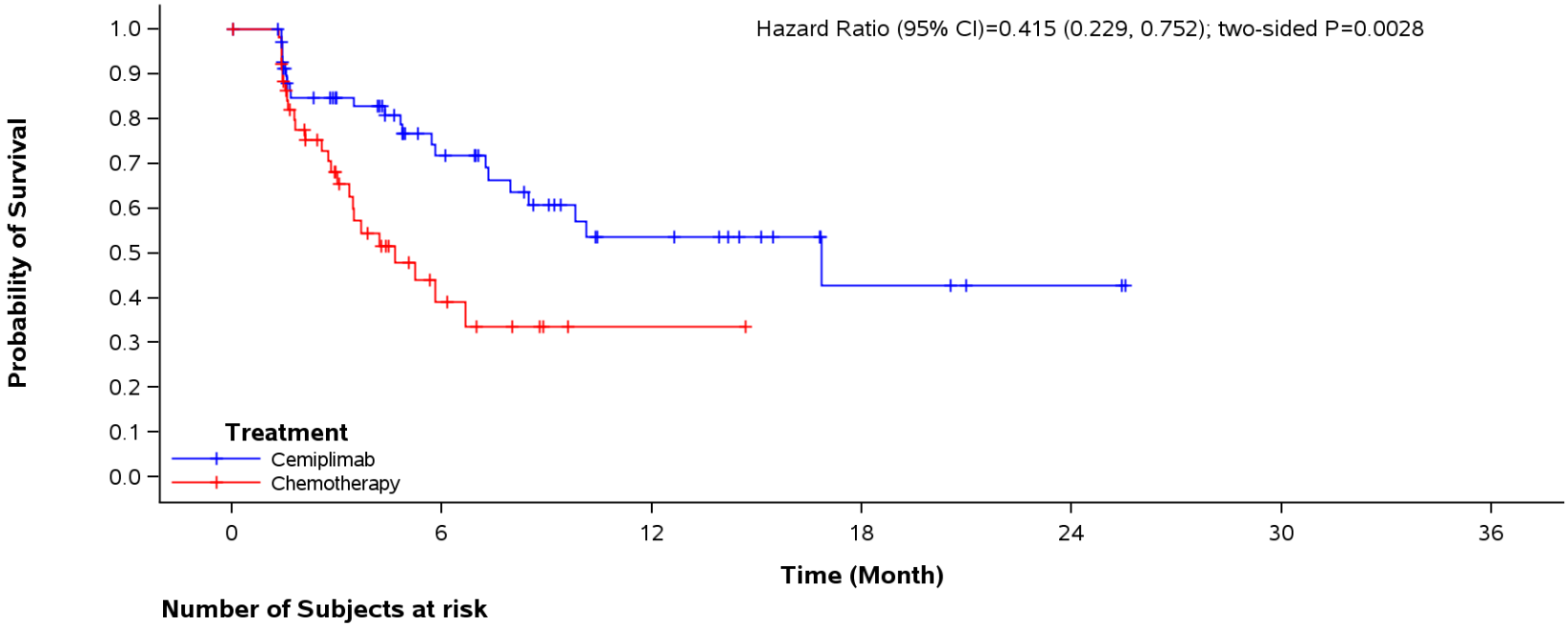

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 29 | 13 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Global health status / QoL - 10 pts sustained deterioration



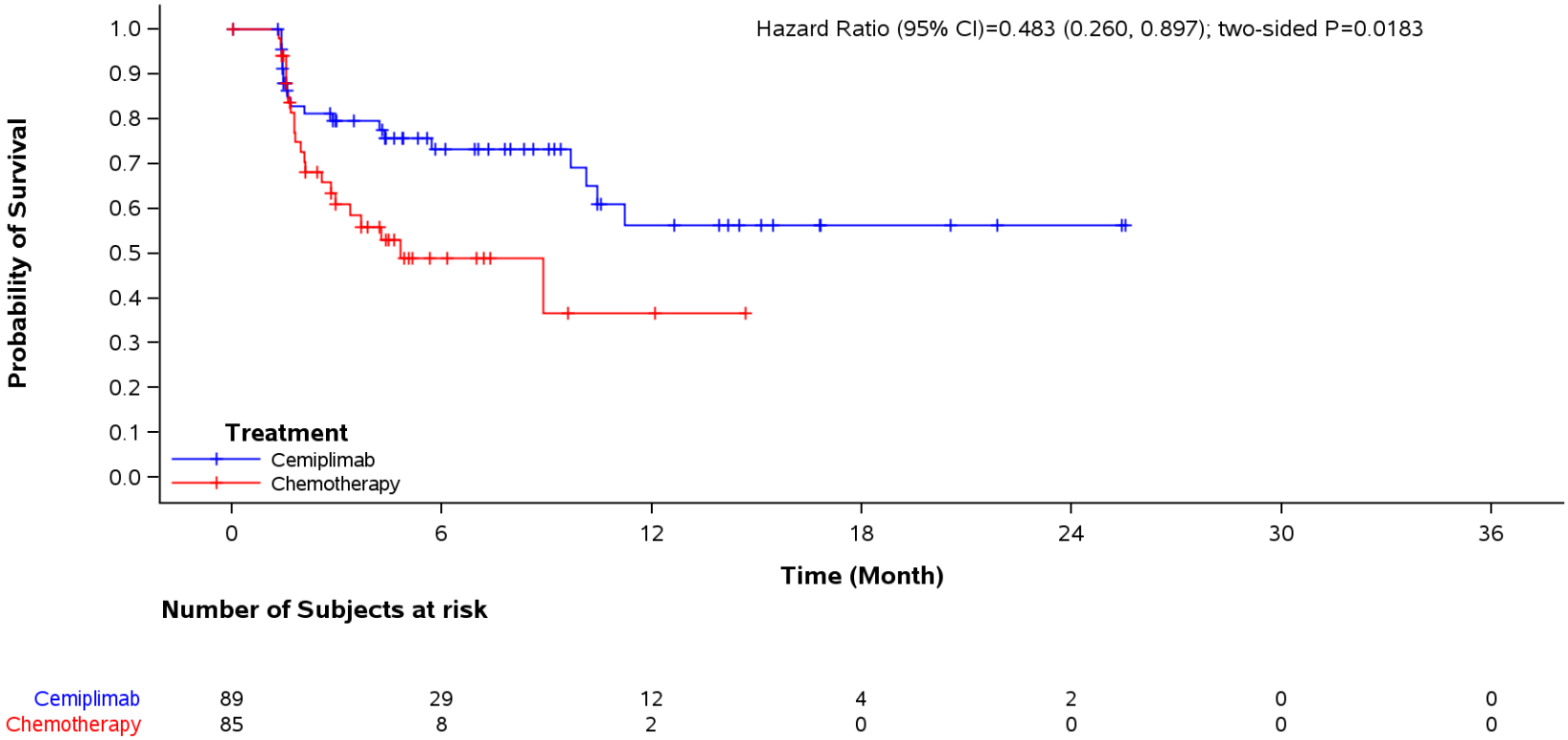

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 30 | 13 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Role Functioning - 10 pts sustained deterioration



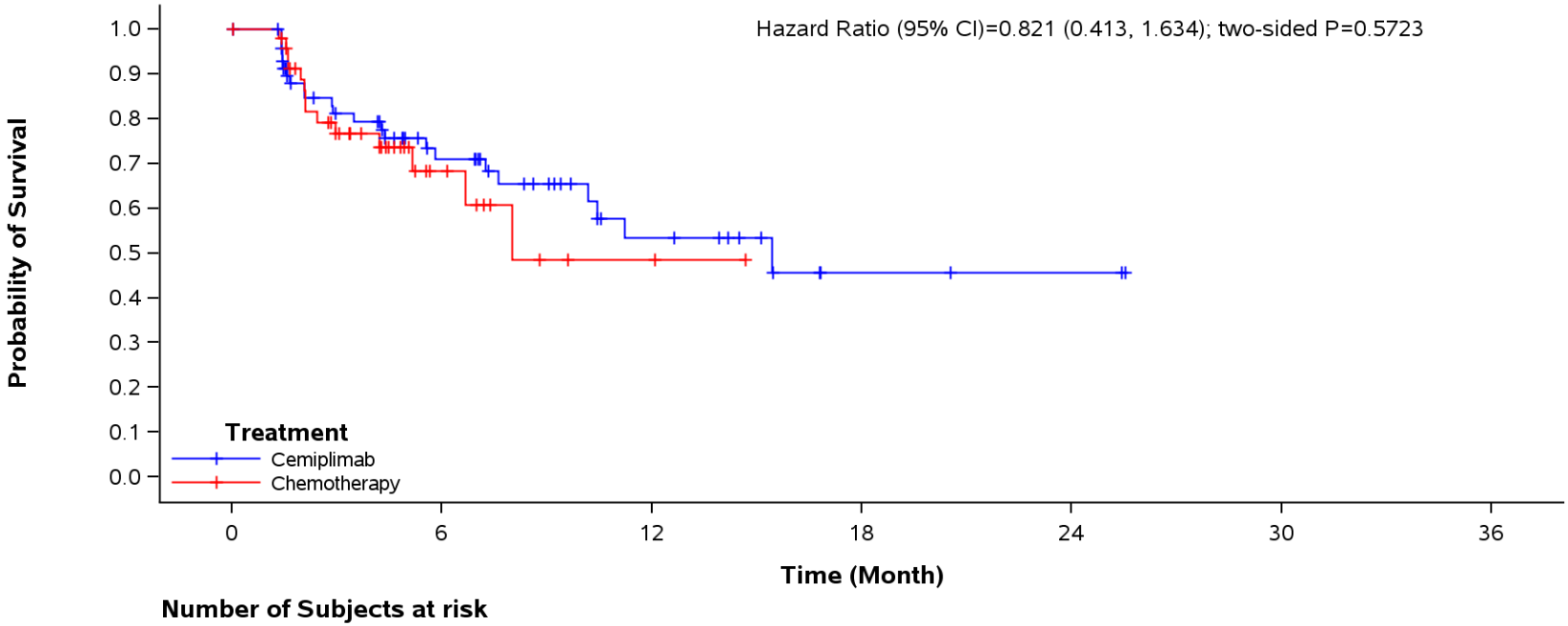

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 29 | 12 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Social Functioning - 10 pts sustained deterioration



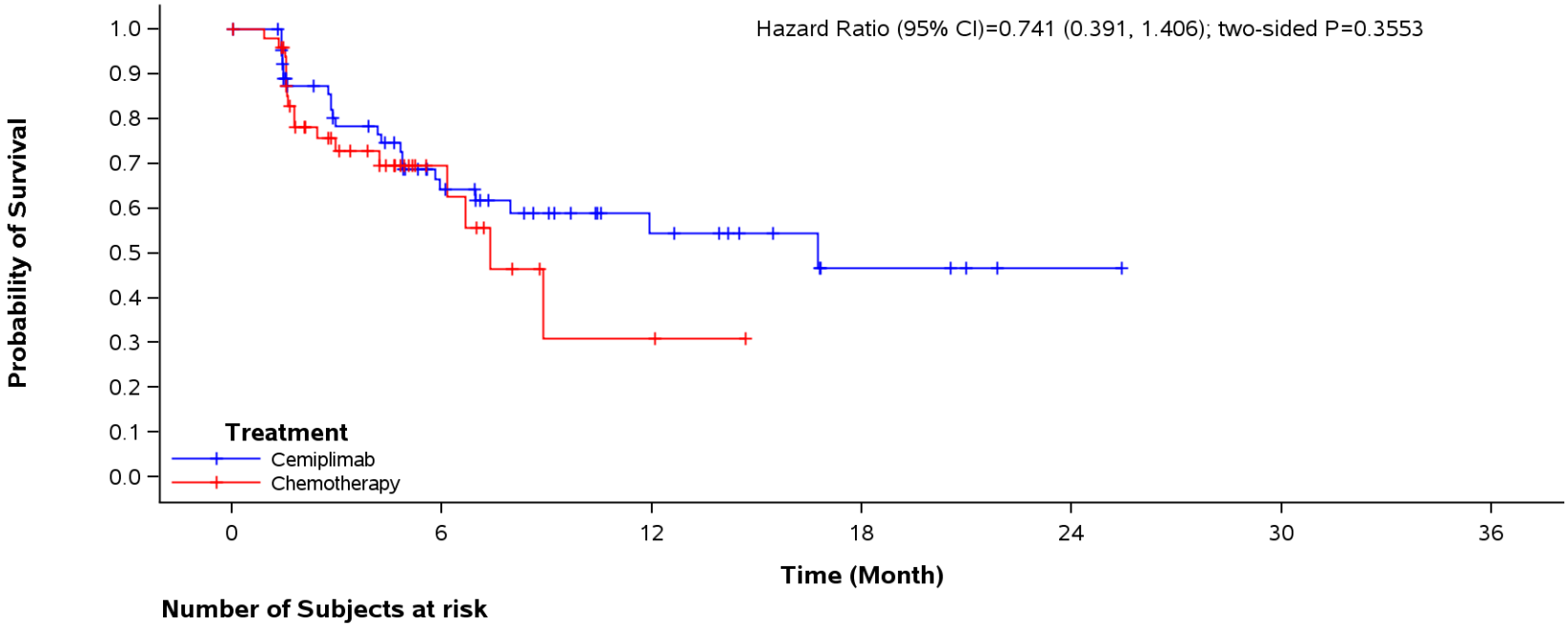

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 30 | 12 | 3 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts sustained deterioration



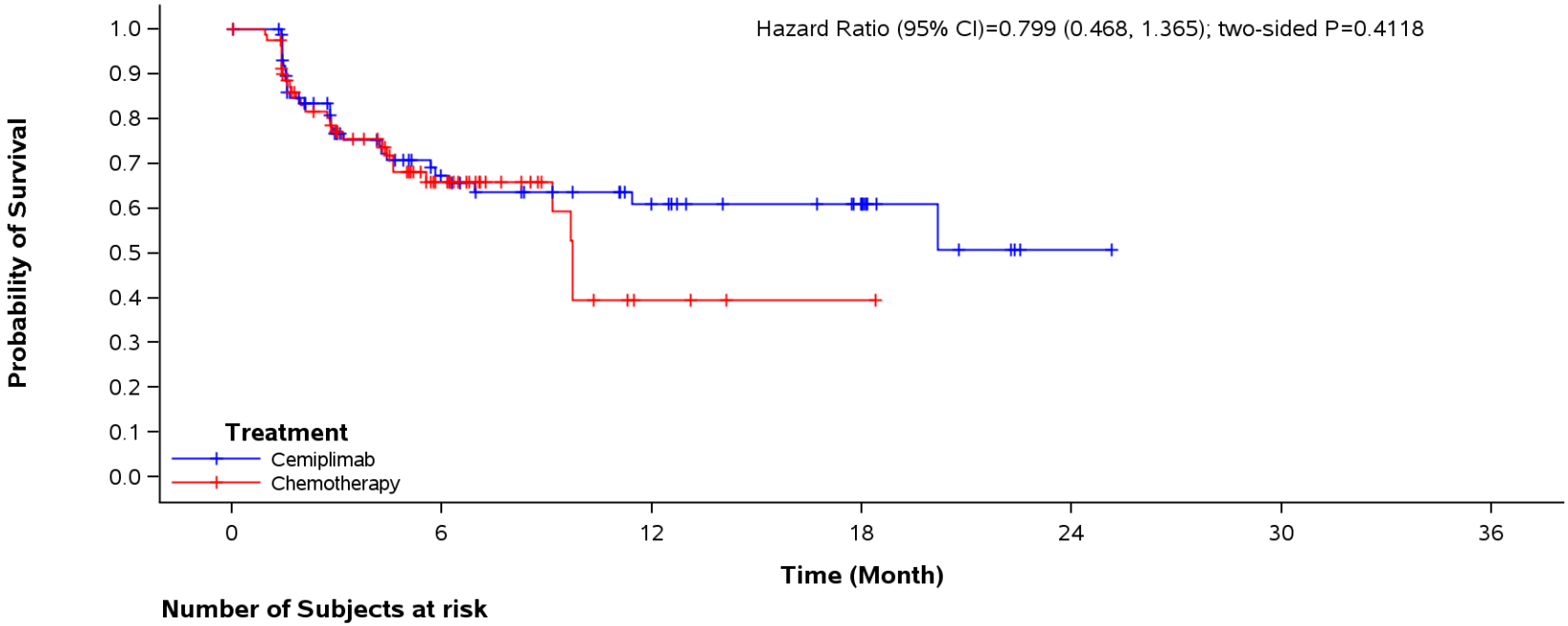

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 28 | 12 | 4 | 1 | 0 | 0 |
| Chemotherapy | 85 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts sustained deterioration



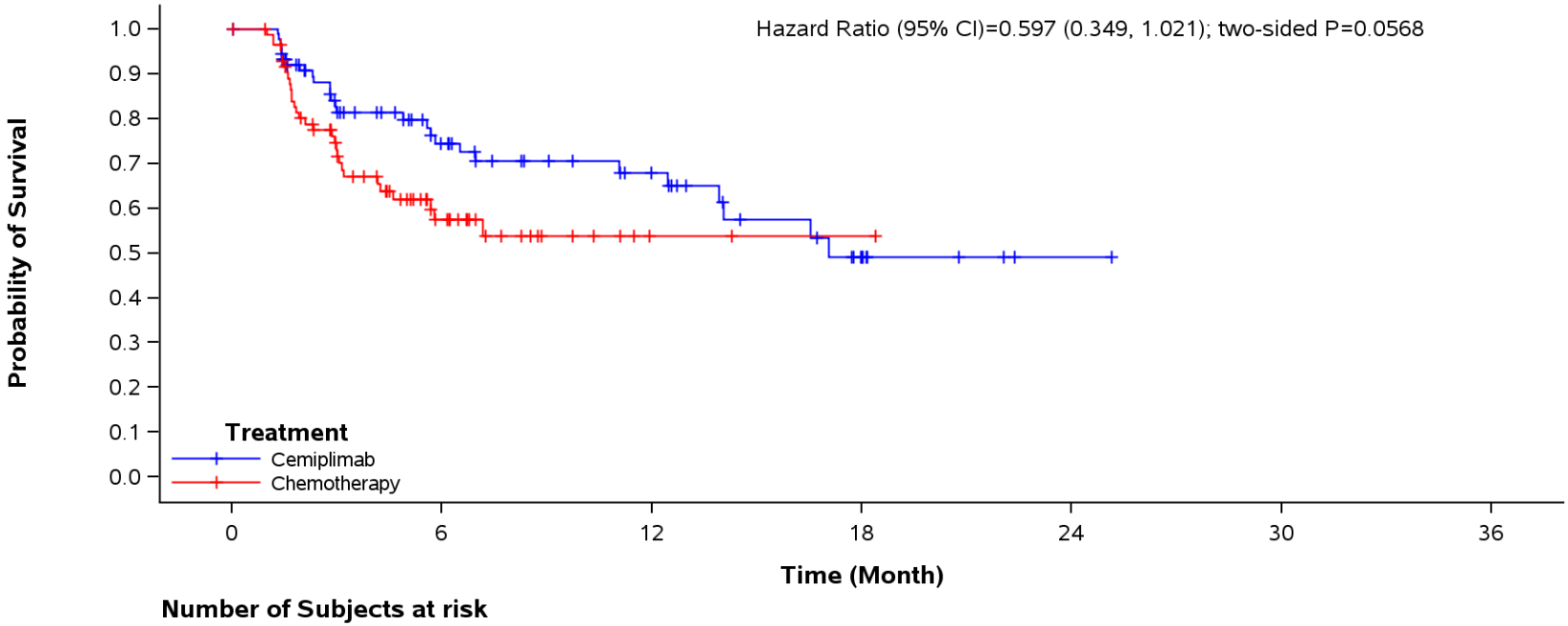

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 21 | 12 | 1 | 0 | 0 |
| Chemotherapy | 98 | 26 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Cognitive Functioning - 10 pts sustained deterioration



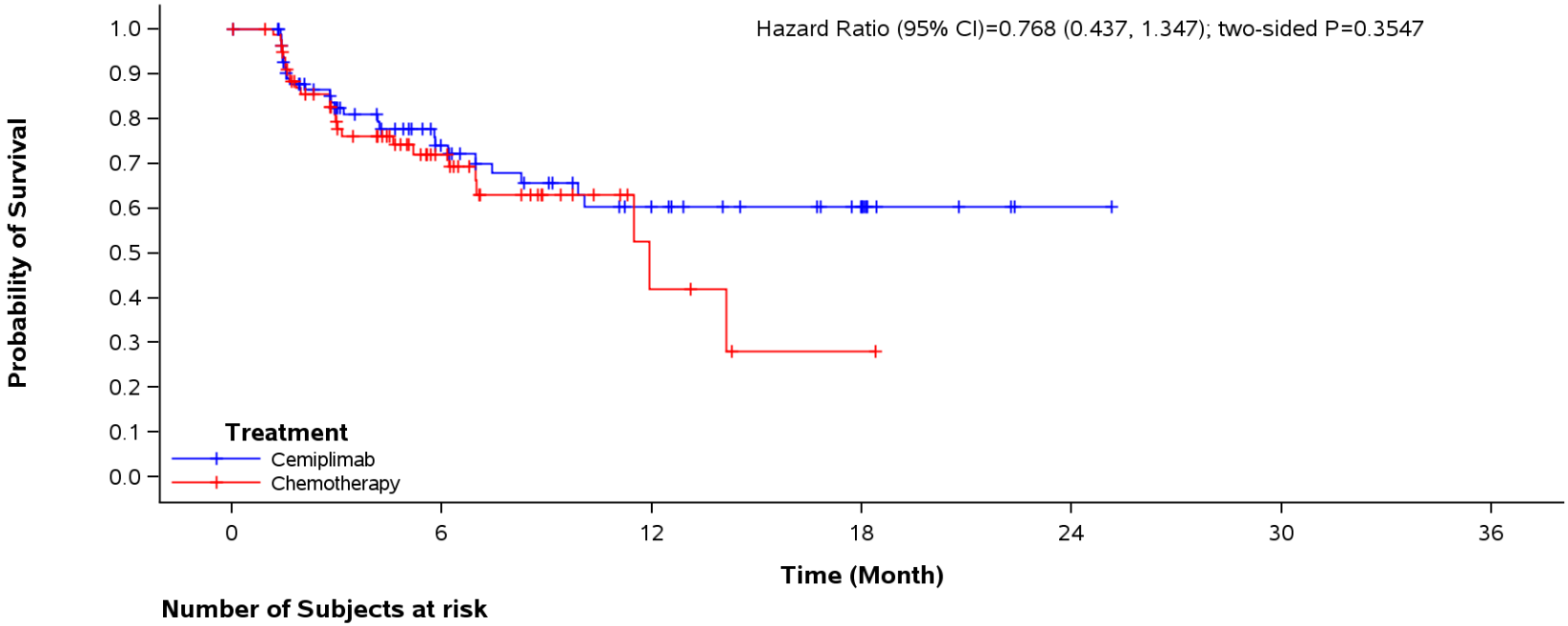

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 41 | 23 | 8 | 1 | 0 | 0 |
| Chemotherapy | 98 | 24 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts sustained deterioration



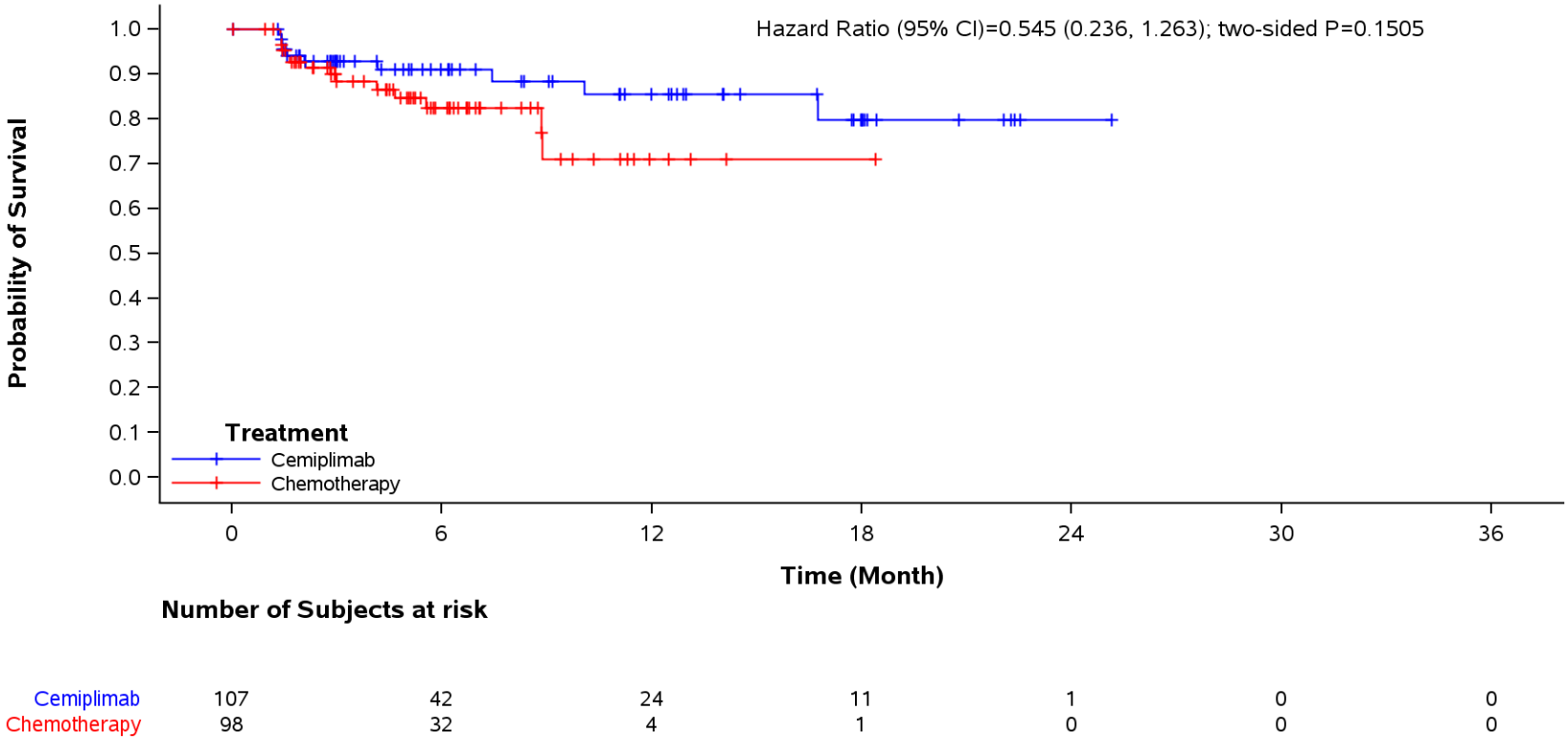

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 19 | 10 | 1 | 0 | 0 |
| Chemotherapy | 98 | 28 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts sustained deterioration



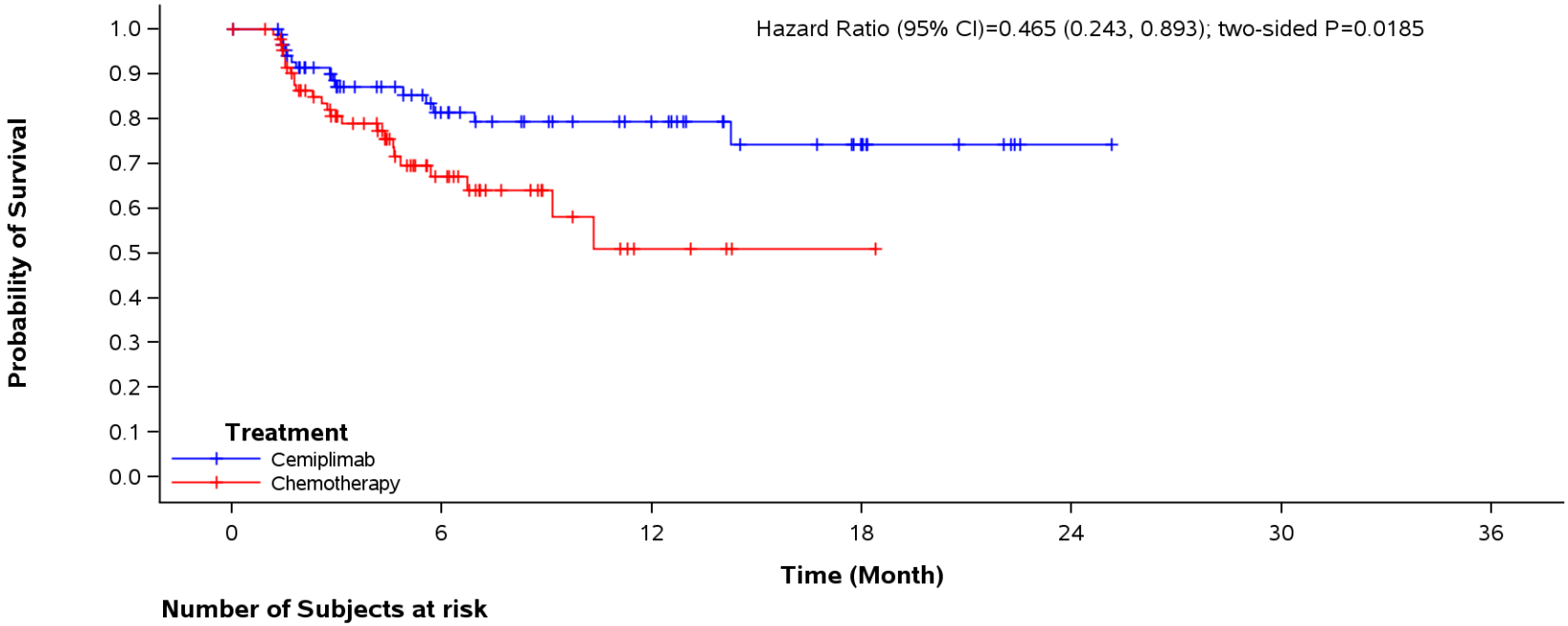

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 42 | 24 | 11 | 1 | 0 | 0 |
| Chemotherapy | 98 | 32 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Dyspnoea - 10 pts sustained deterioration



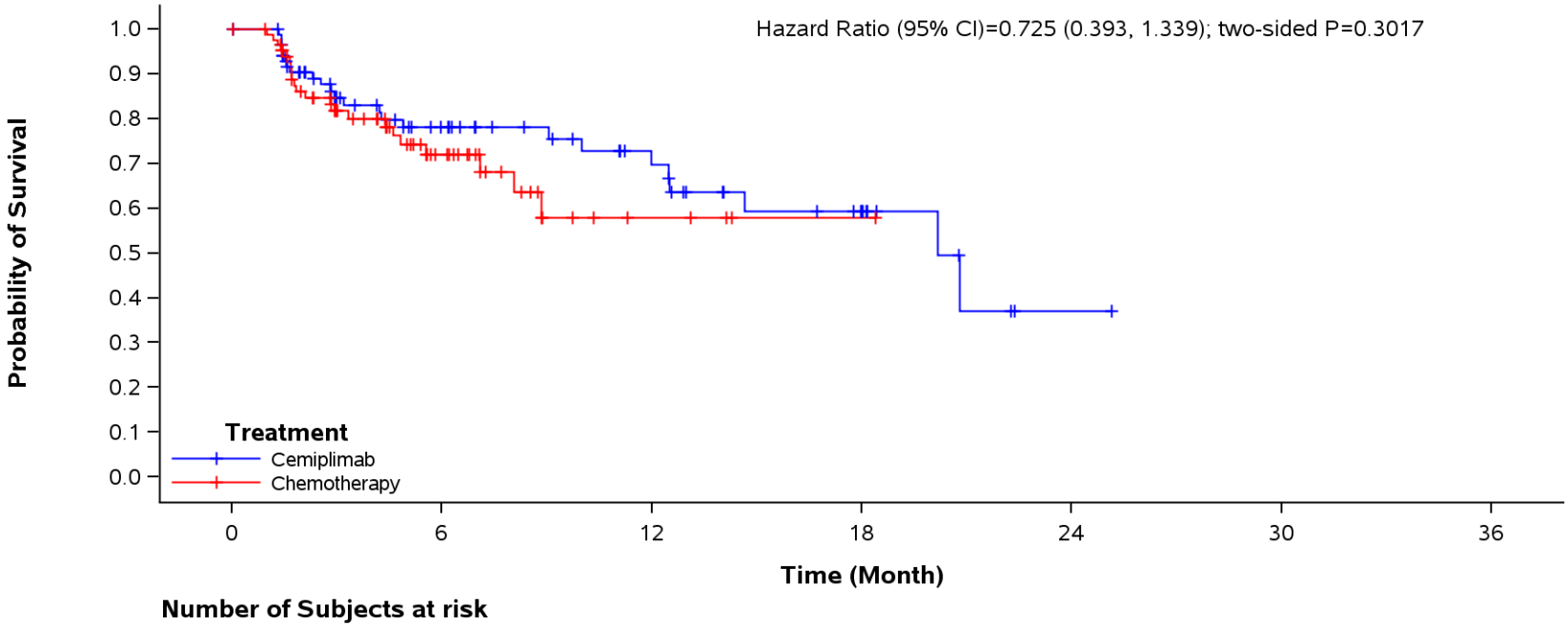

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 40 | 23 | 10 | 1 | 0 | 0 |
| Chemotherapy | 98 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Emotional Functioning - 10 pts sustained deterioration



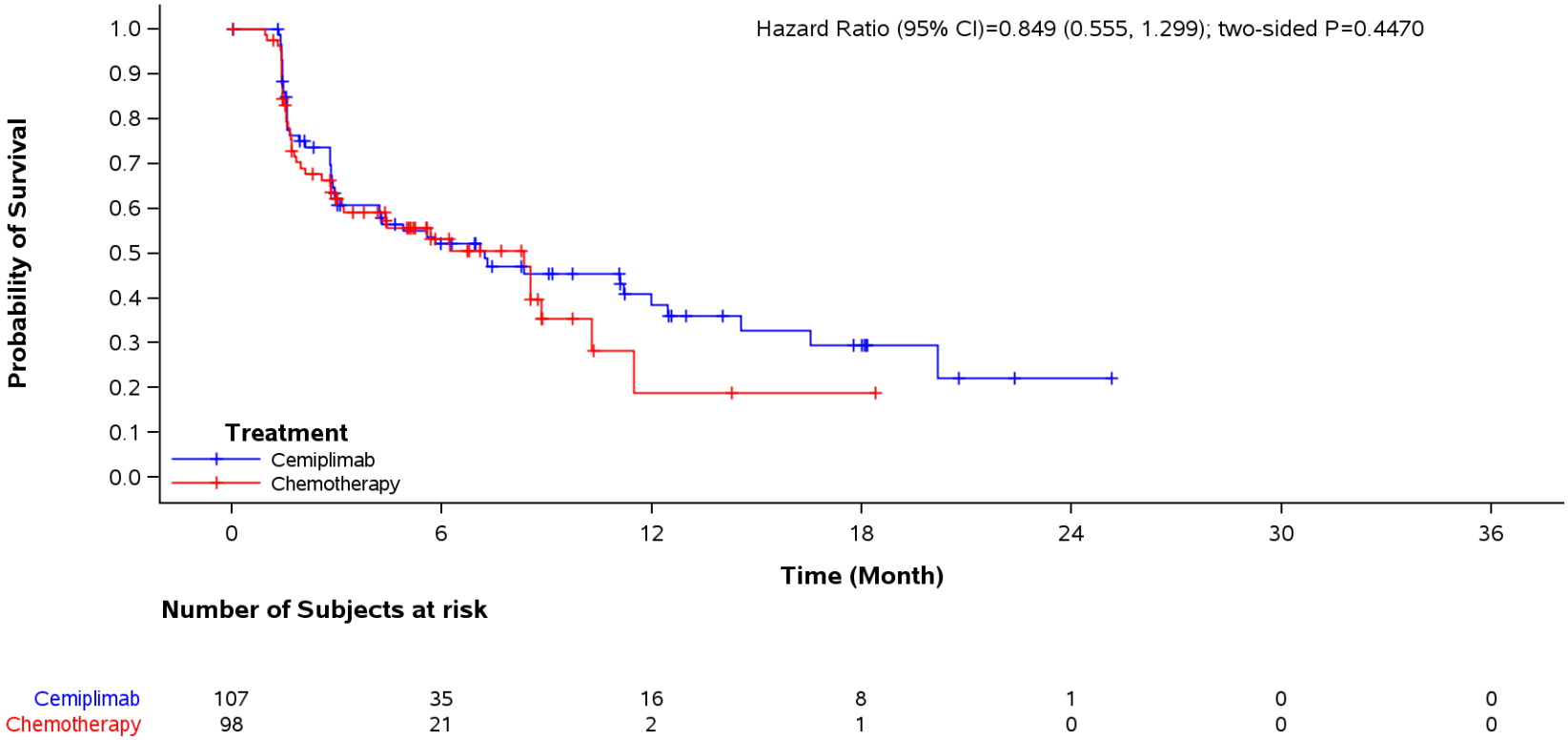

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 41 | 23 | 11 | 1 | 0 | 0 |
| Chemotherapy | 98 | 28 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts sustained deterioration



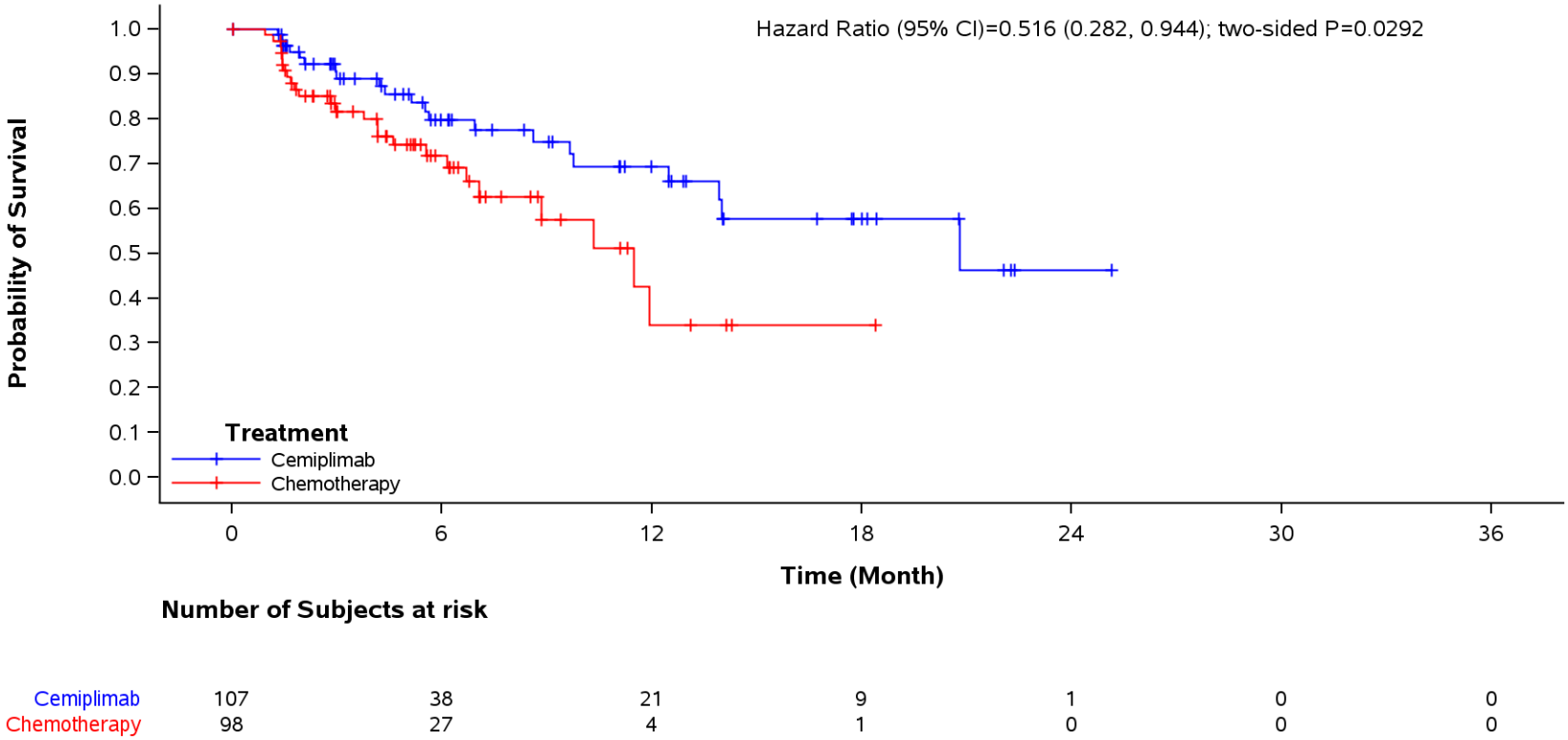

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 35 | 16 | 8 | 1 | 0 | 0 |
| Chemotherapy | 98 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts sustained deterioration



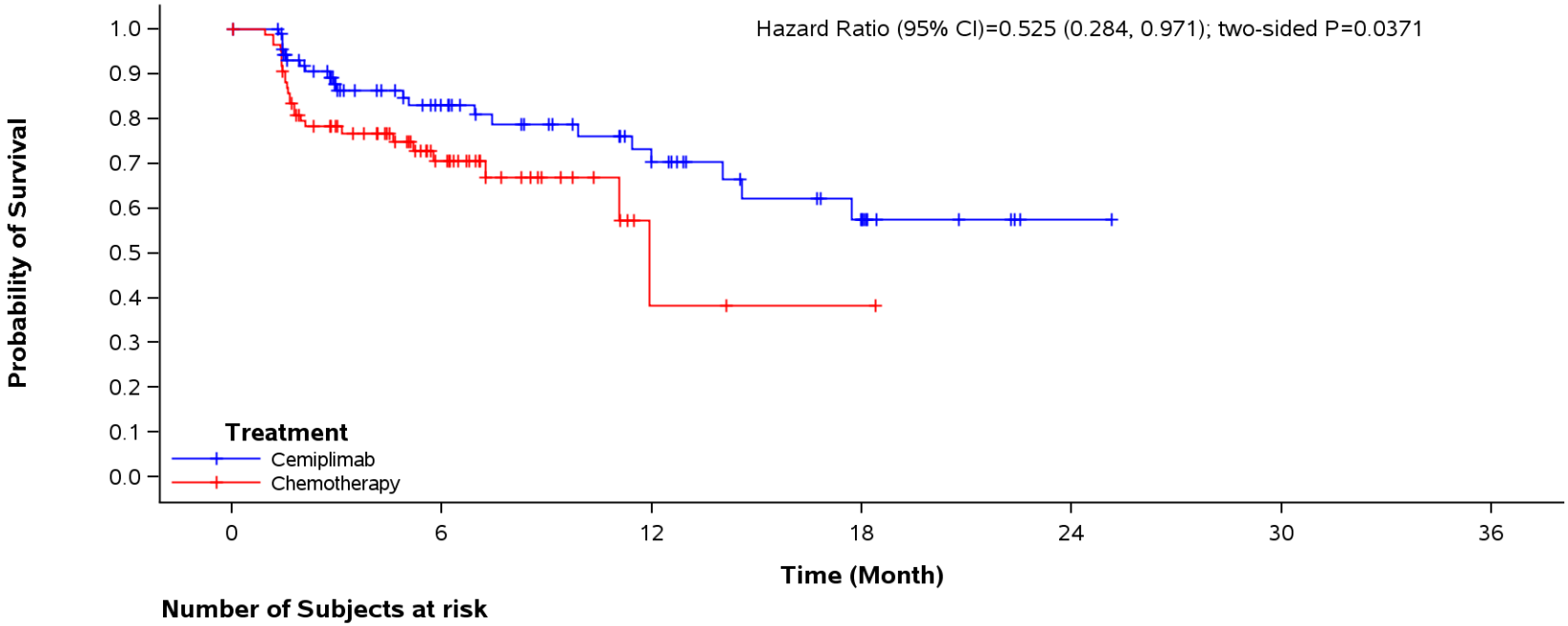

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 21 | 9 | 1 | 0 | 0 |
| Chemotherapy | 98 | 27 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts sustained deterioration



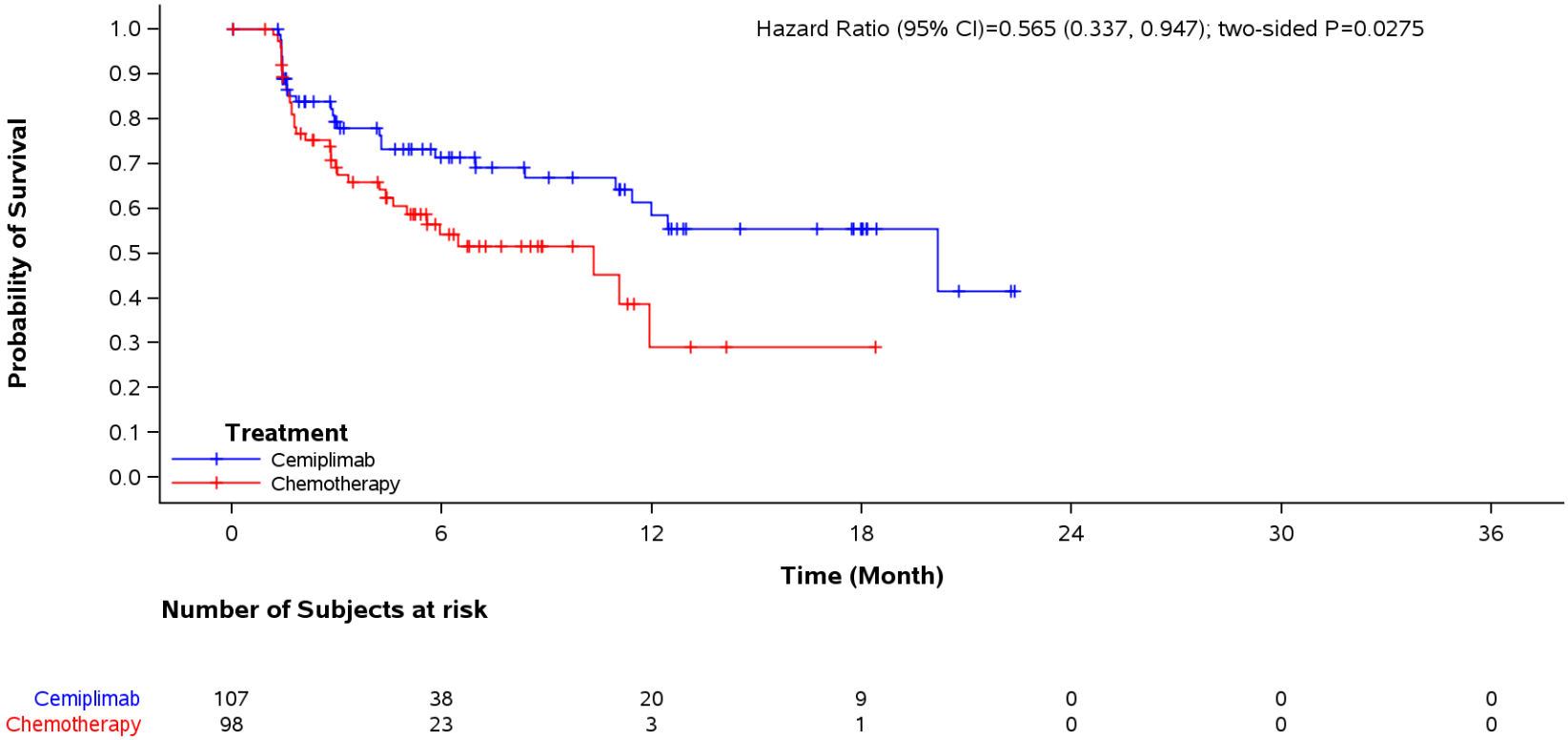

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 45 | 23 | 11 | 1 | 0 | 0 |
| Chemotherapy | 98 | 29 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts sustained deterioration



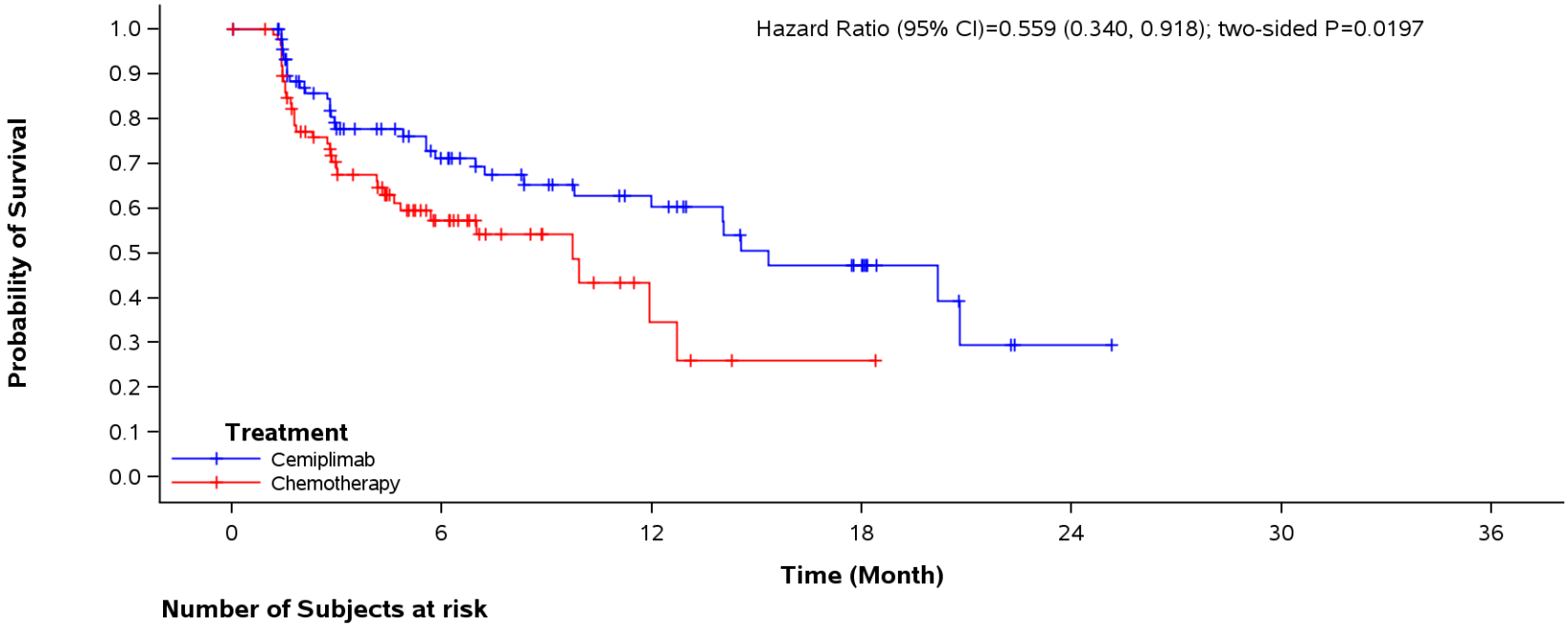

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 20 | 9 | 0 | 0 | 0 |
| Chemotherapy | 98 | 23 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Physical Functioning - 10 pts sustained deterioration



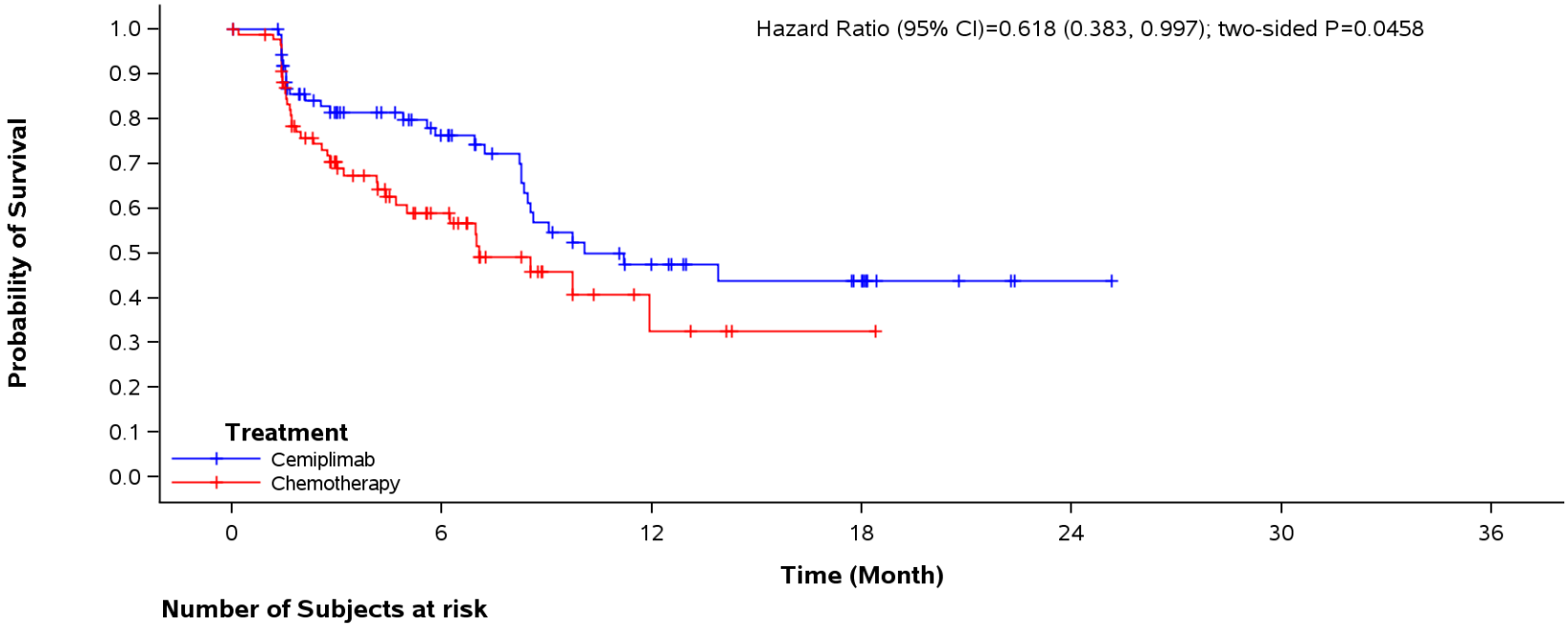

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 42 | 23 | 12 | 1 | 0 | 0 |
| Chemotherapy | 98 | 25 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Global health status / QoL - 10 pts sustained deterioration



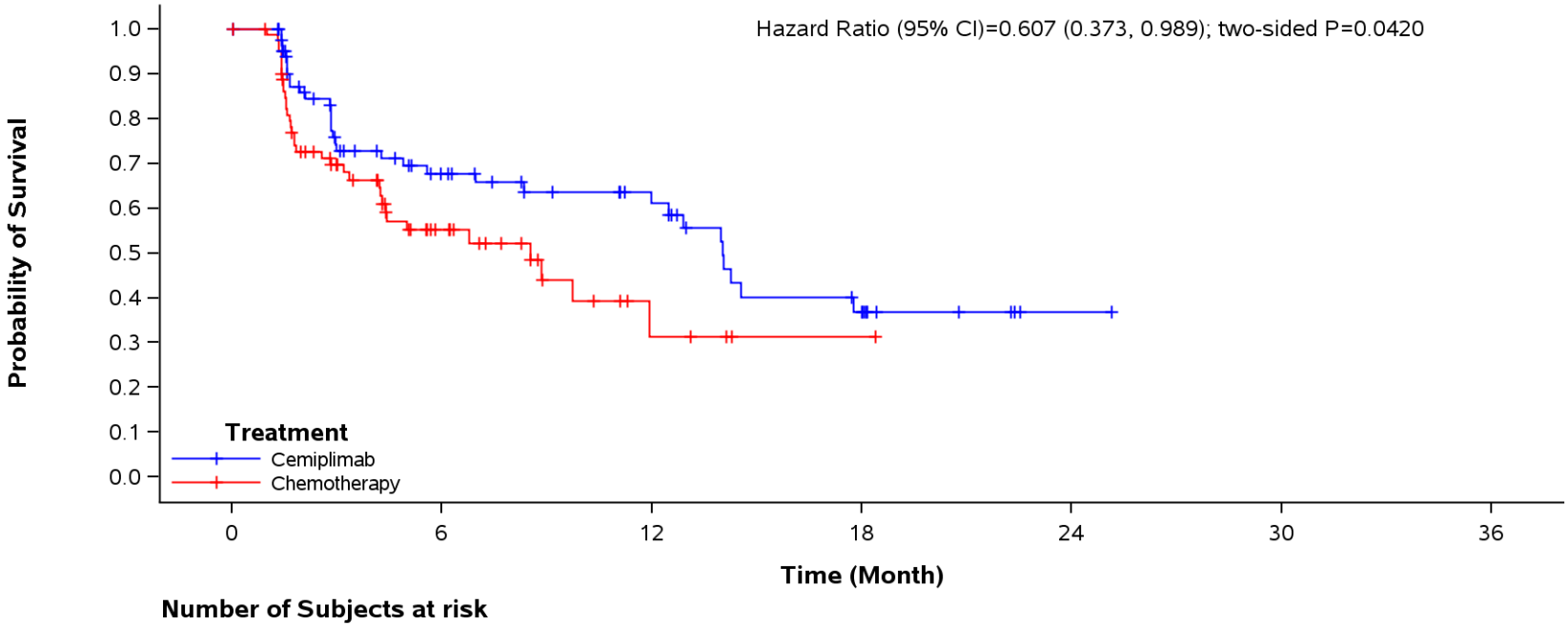

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 42 | 17 | 10 | 1 | 0 | 0 |
| Chemotherapy | 98 | 28 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Role Functioning - 10 pts sustained deterioration



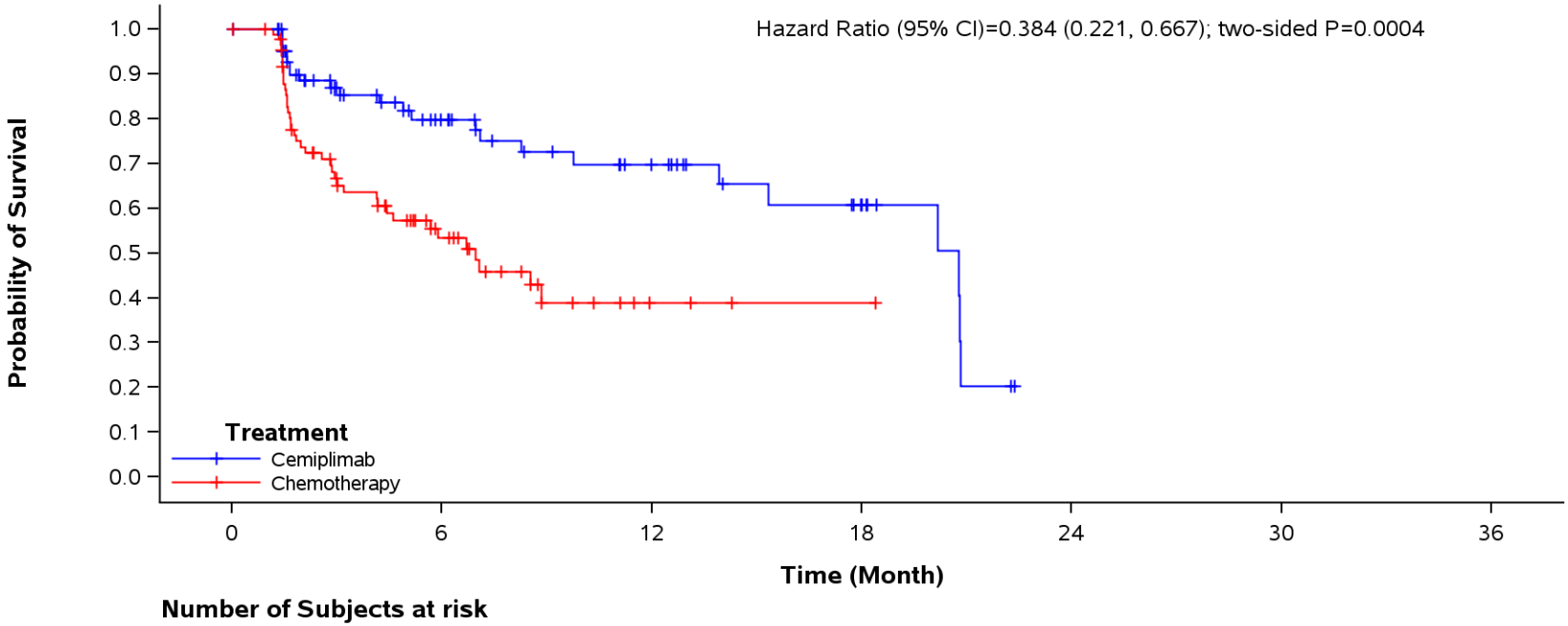

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 37 | 24 | 11 | 1 | 0 | 0 |
| Chemotherapy | 98 | 22 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Social Functioning - 10 pts sustained deterioration



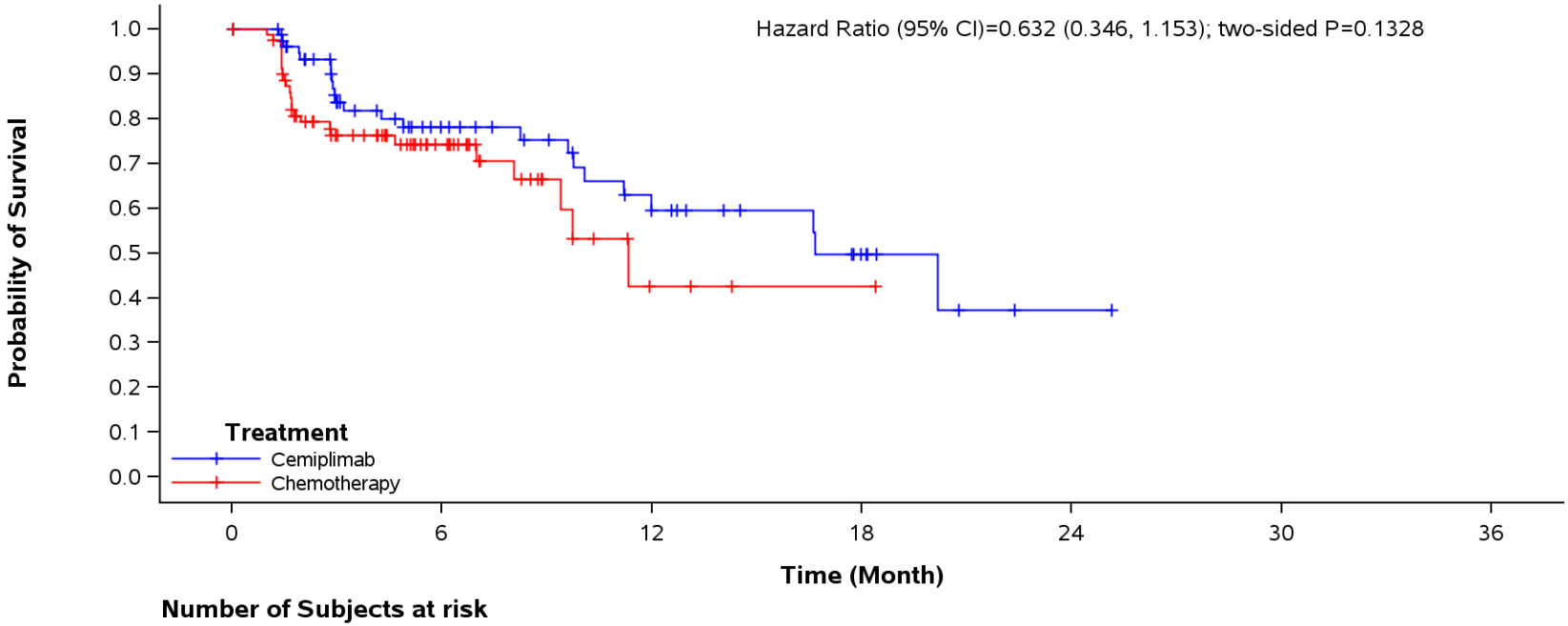

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 21 | 10 | 0 | 0 | 0 |
| Chemotherapy | 98 | 26 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts sustained deterioration



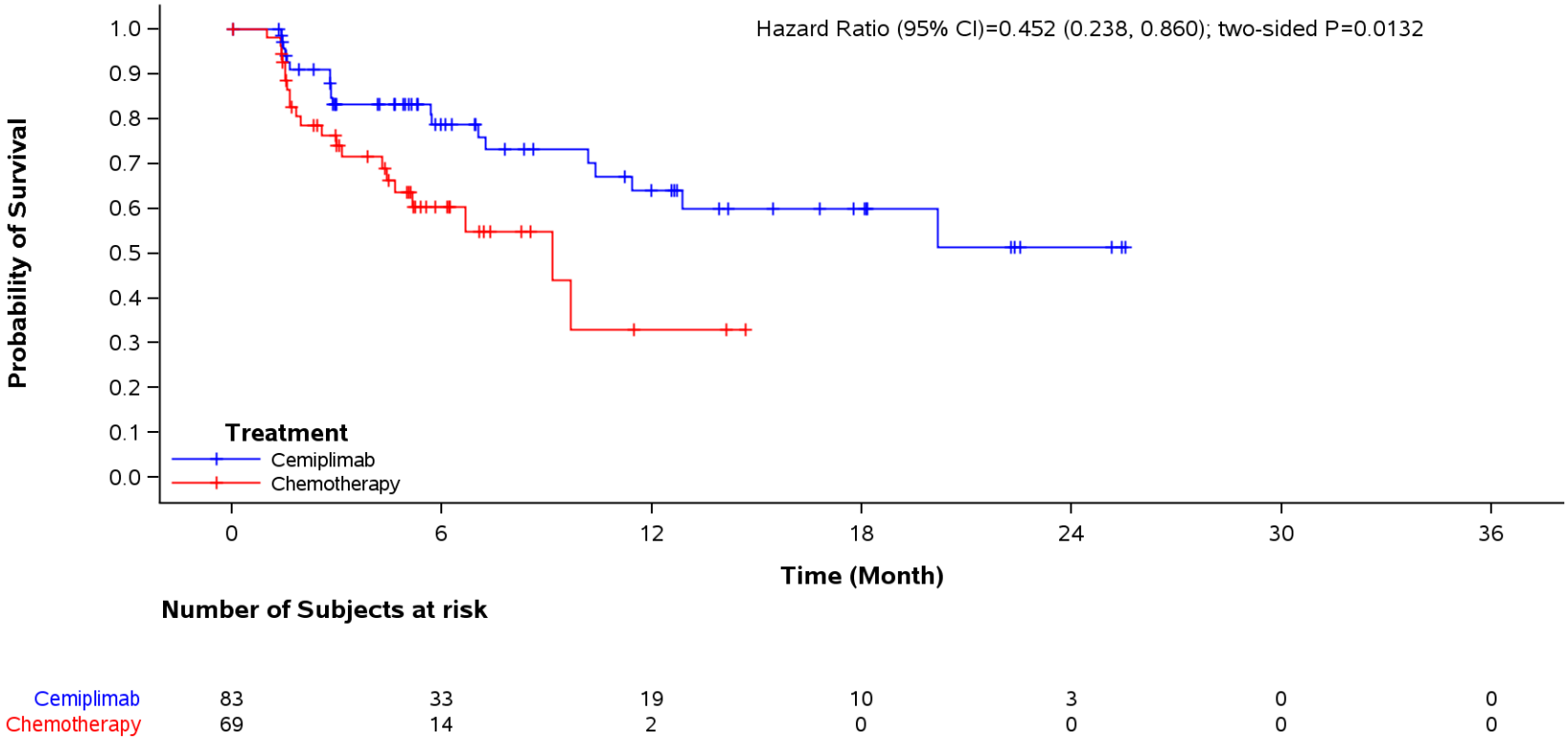

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 35 | 17 | 7 | 1 | 0 | 0 |
| Chemotherapy | 98 | 29 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Appetite loss - 10 pts sustained deterioration



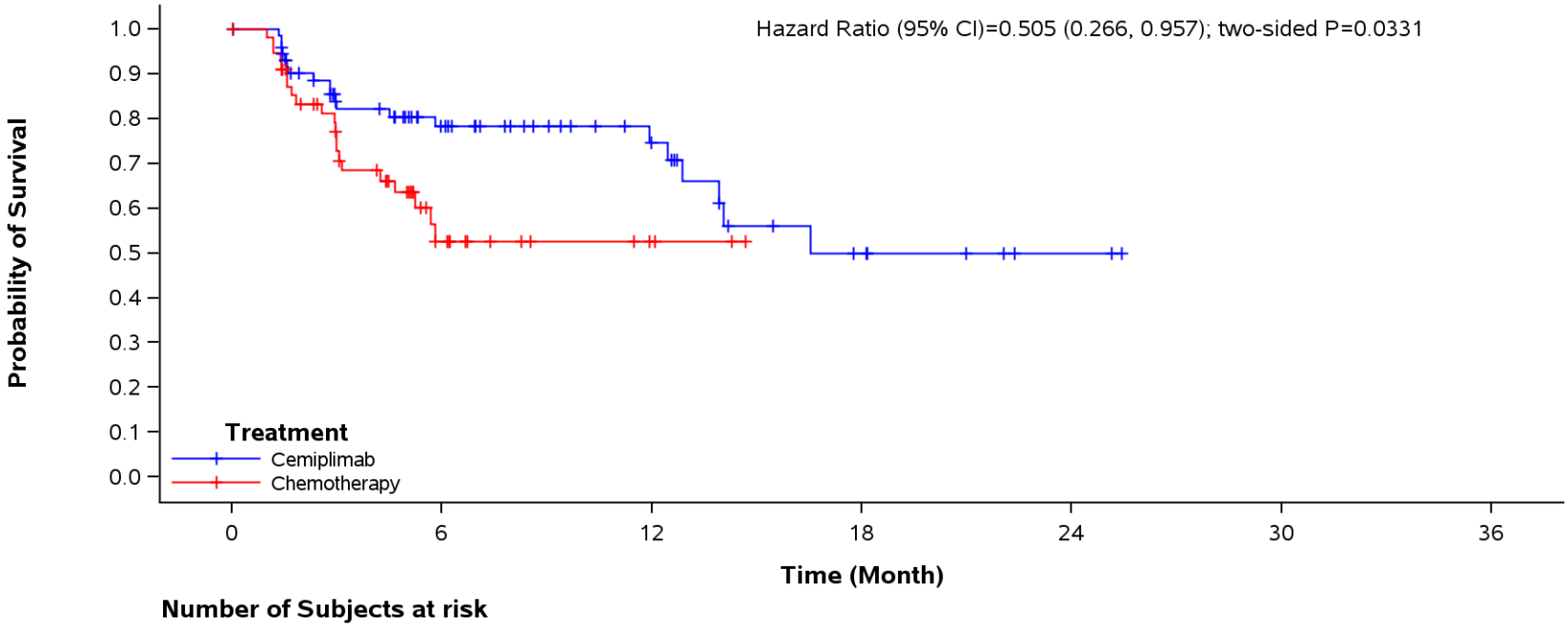

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 33 | 19 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Cognitive Functioning - 10 pts sustained deterioration



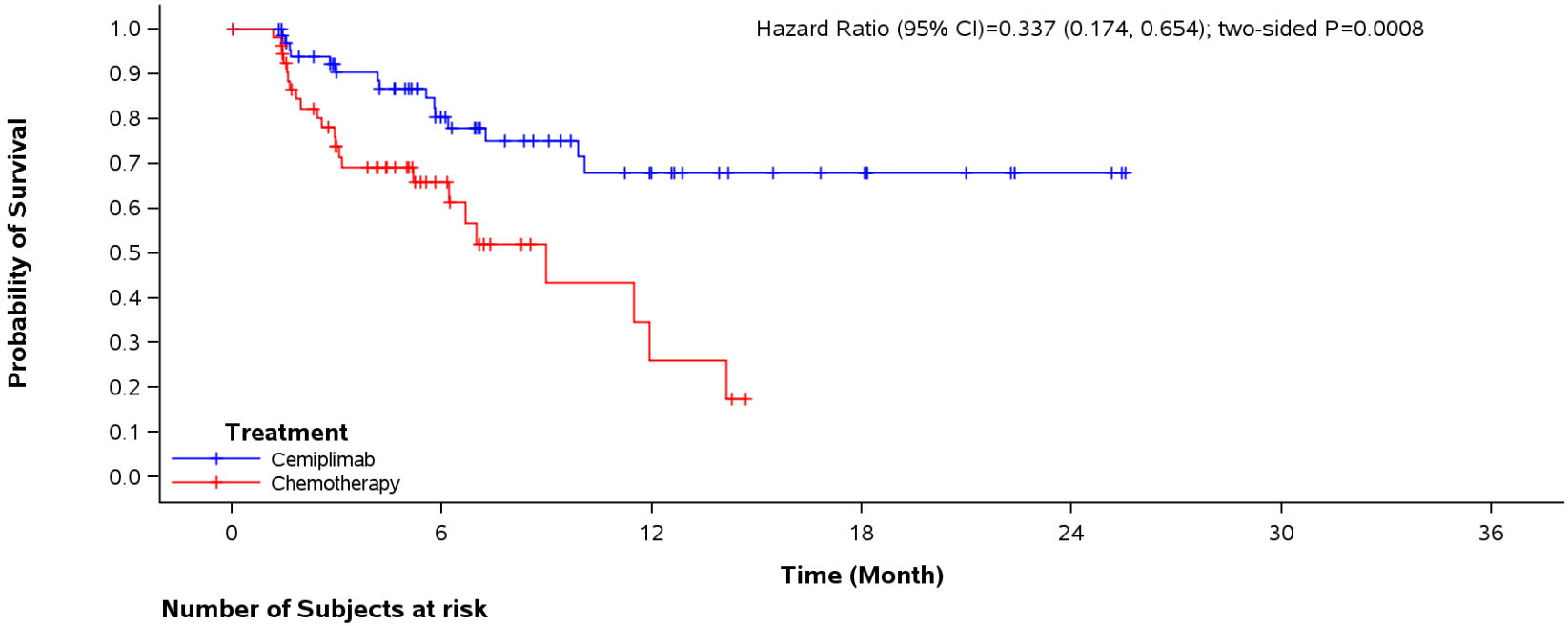

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 19 | 7 | 2 | 0 | 0 |
| Chemotherapy | 69 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Constipation - 10 pts sustained deterioration



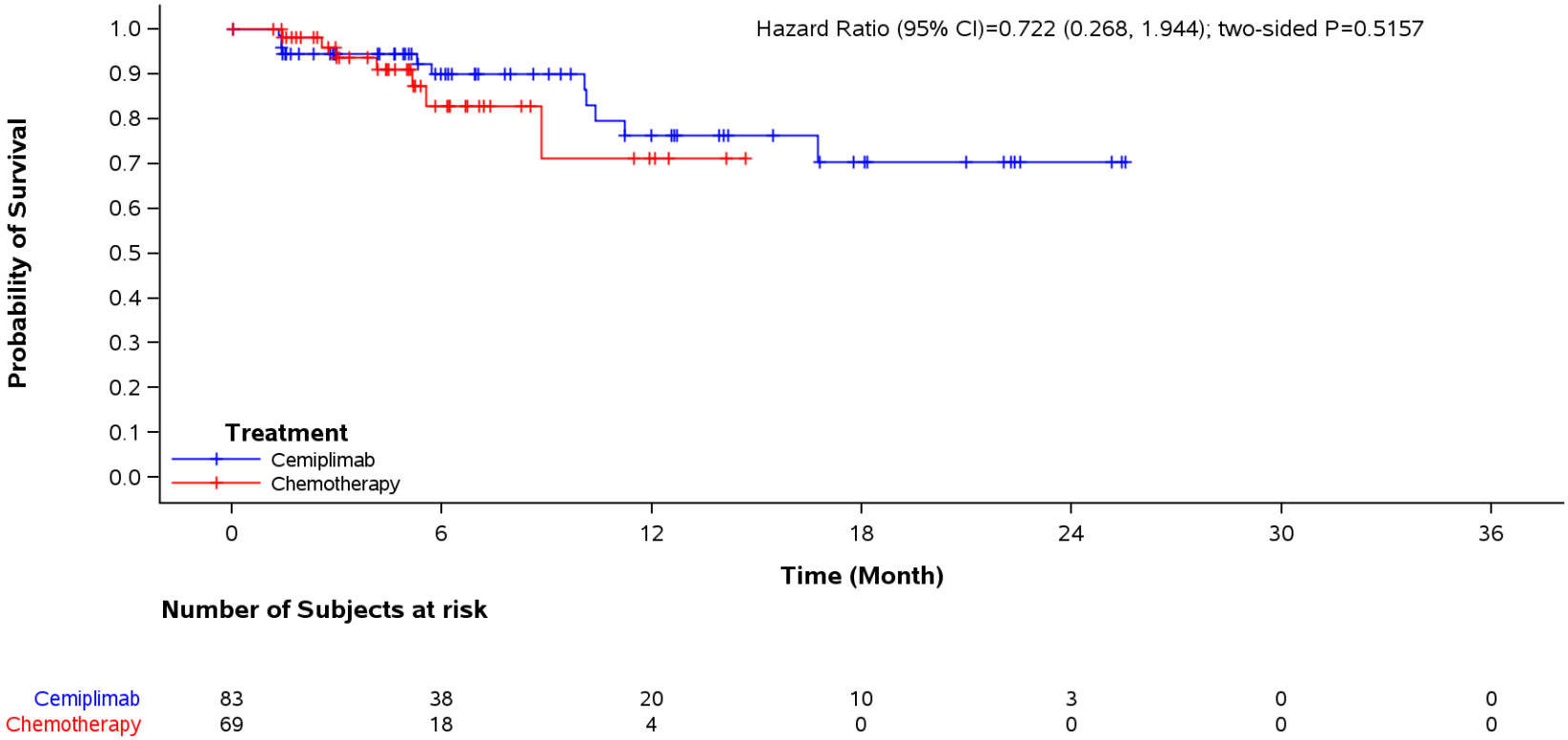

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 16 | 9 | 3 | 0 | 0 |
| Chemotherapy | 69 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Diarhoea - 10 pts sustained deterioration



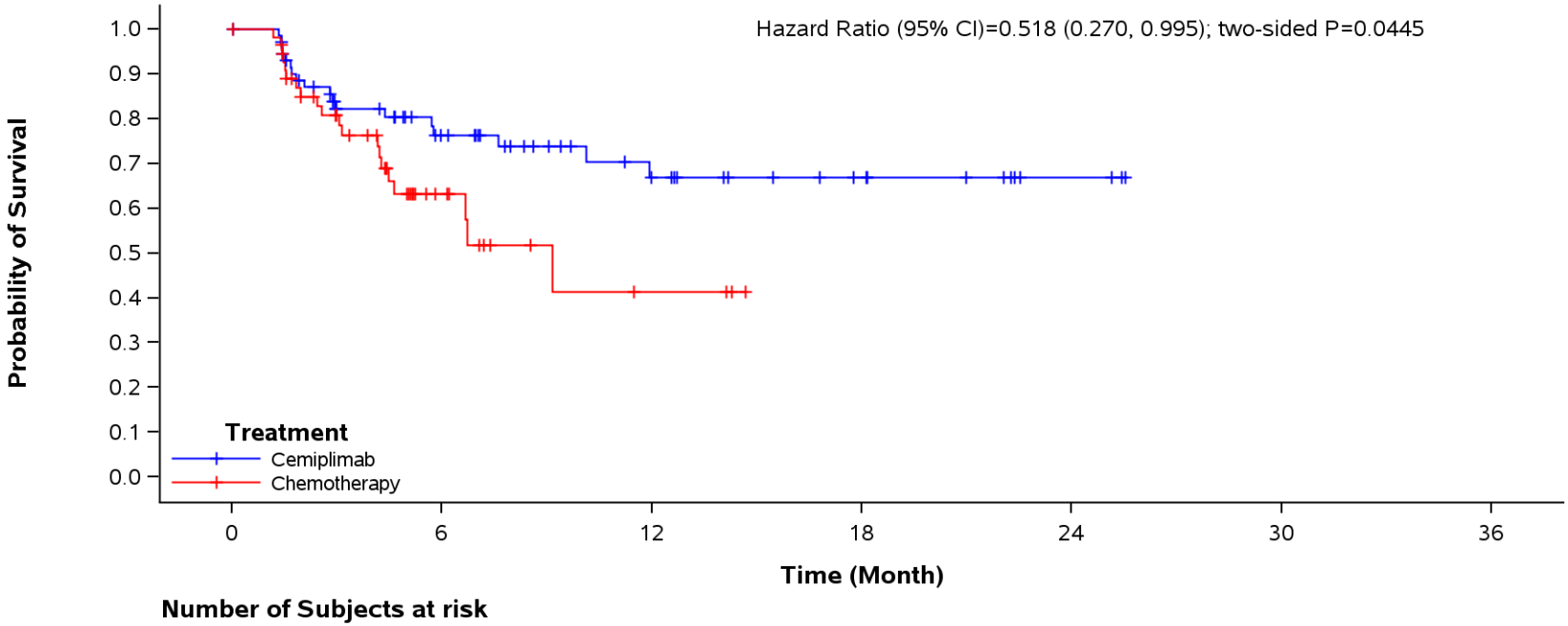

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 38 | 20 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 18 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Dyspnoea - 10 pts sustained deterioration



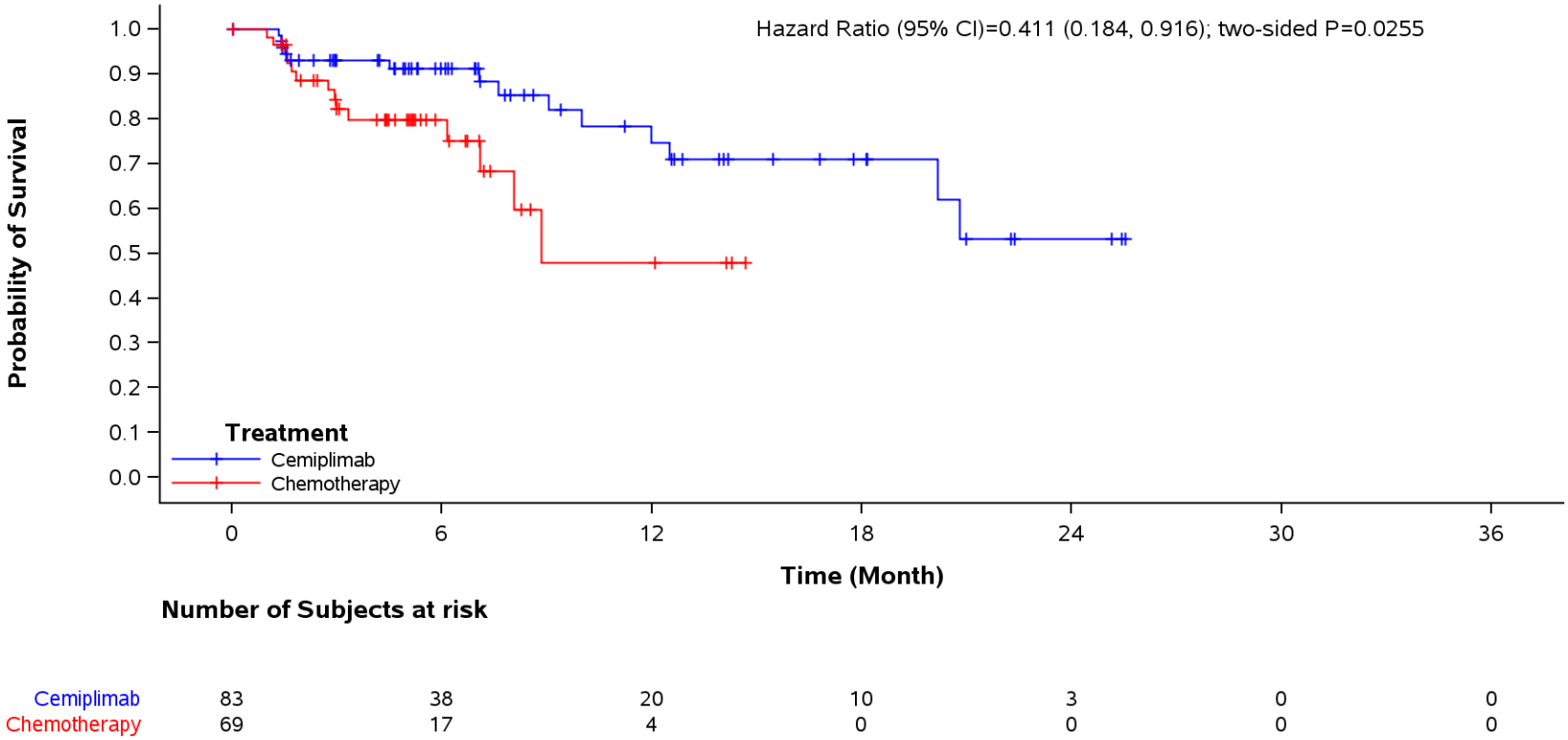

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 18 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Emotional Functioning - 10 pts sustained deterioration



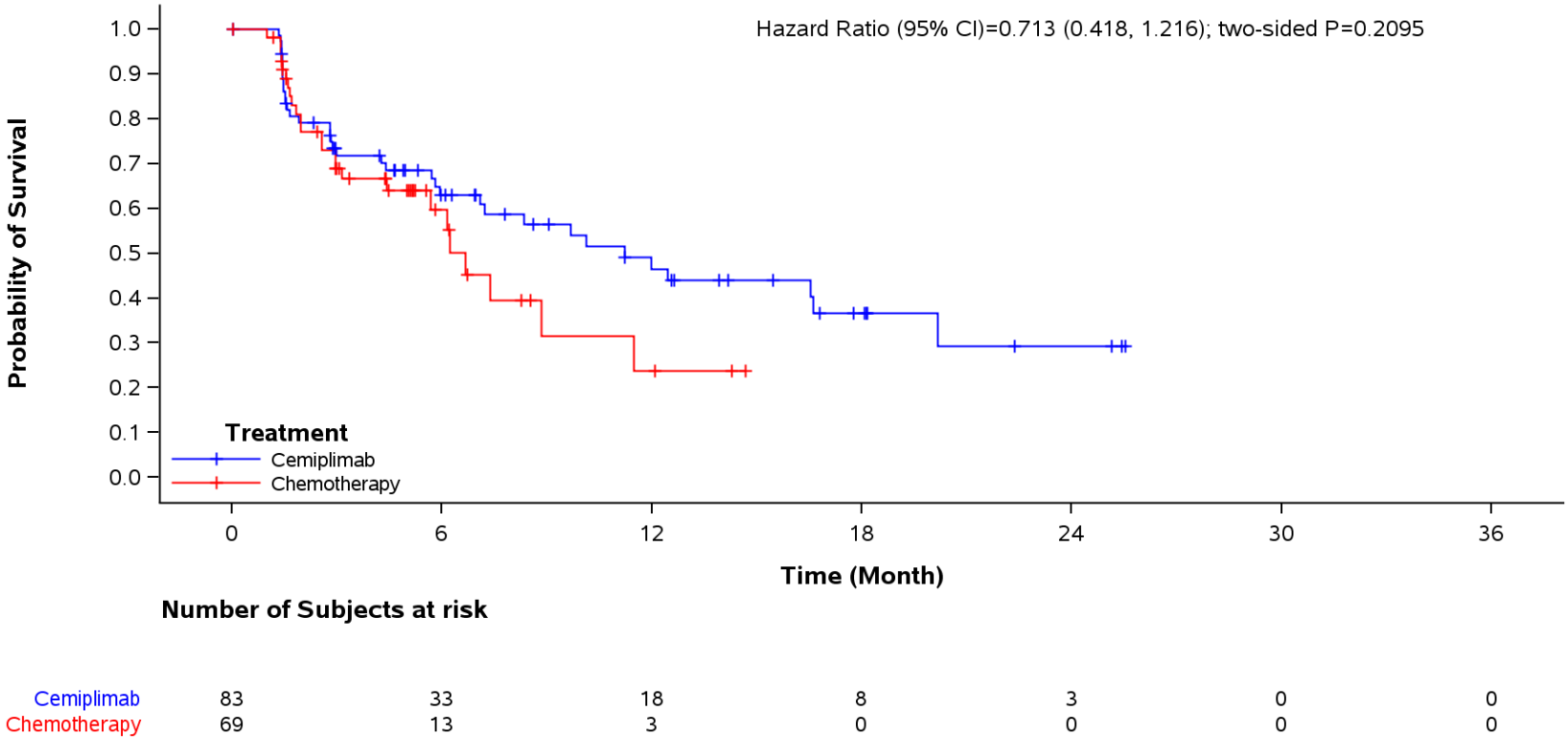

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 38 | 20 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 17 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Fatigue - 10 pts sustained deterioration



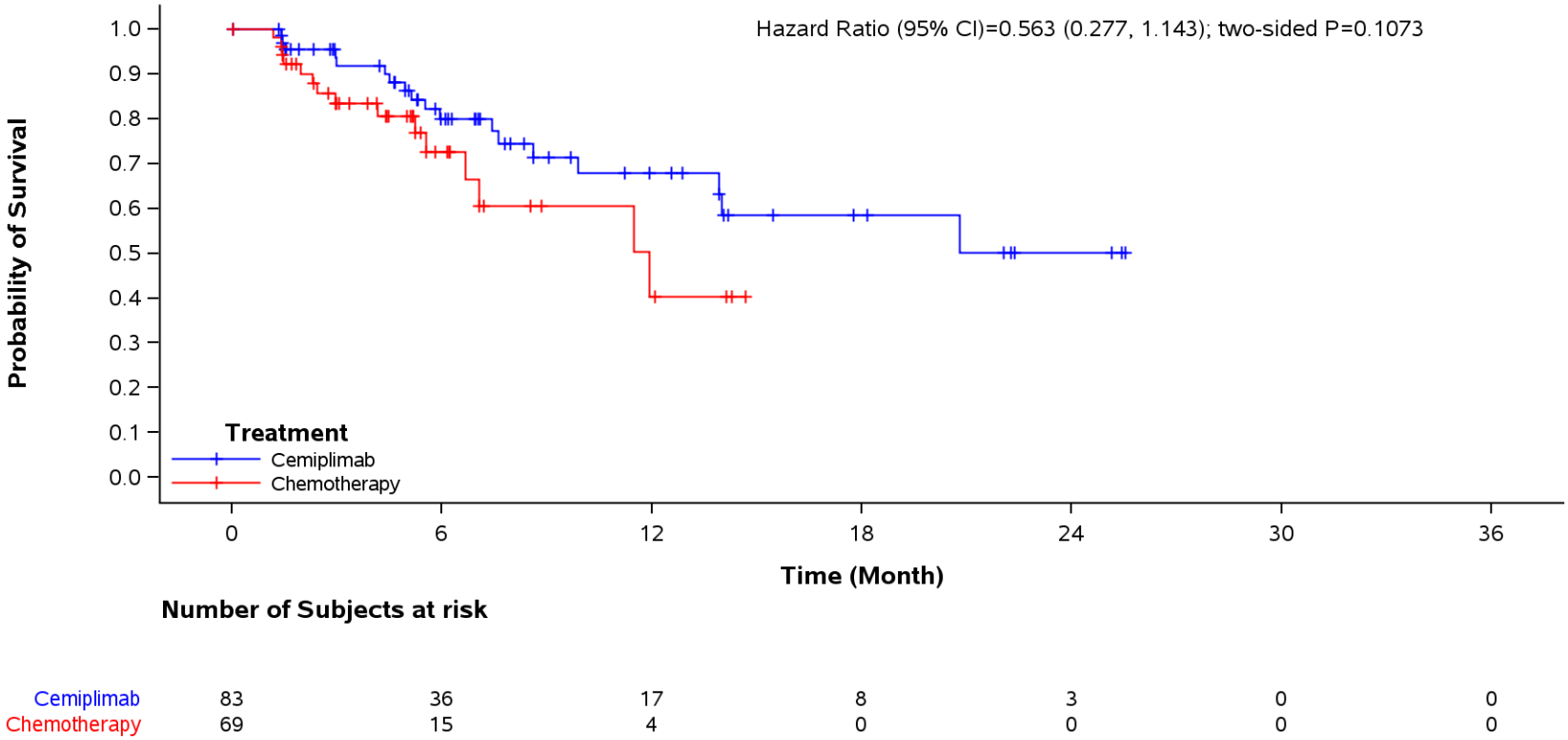

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 33 | 18 | 8 | 3 | 0 | 0 |
| Chemotherapy | 69 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Financial Problems - 10 pts sustained deterioration



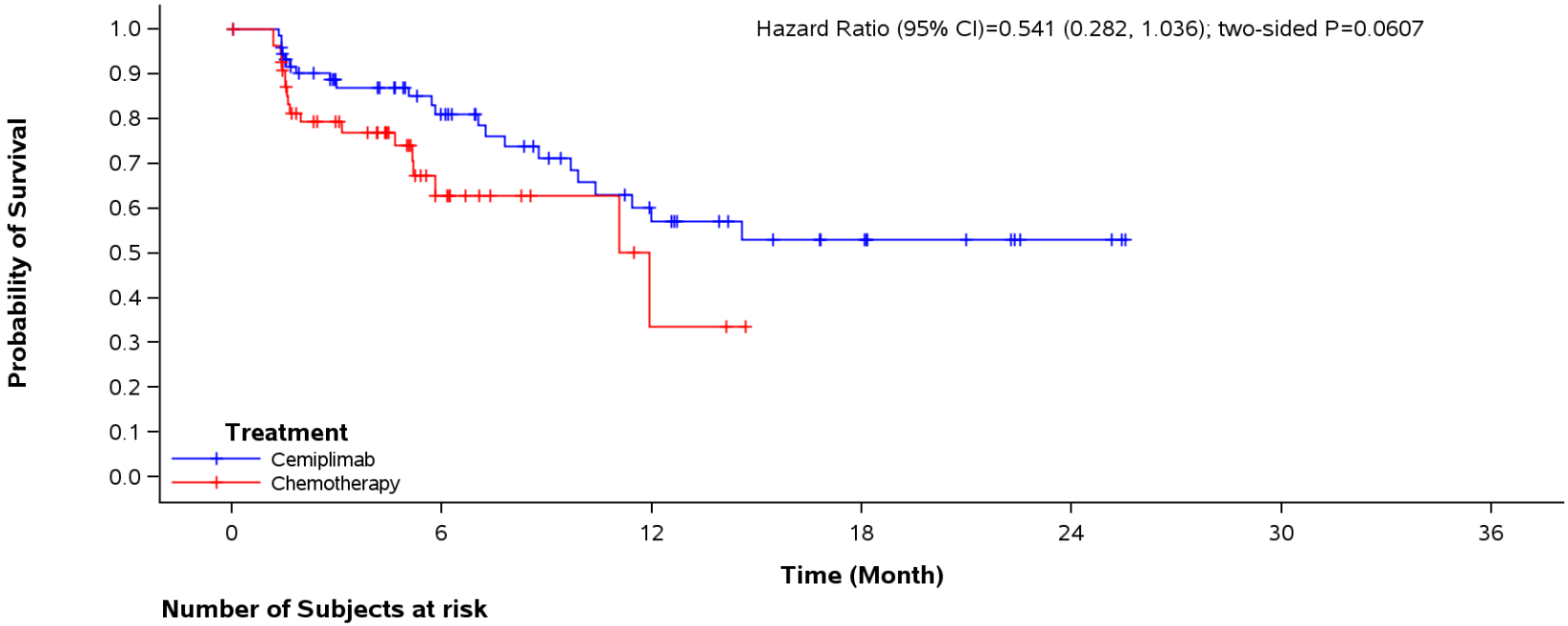

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 17 | 8 | 3 | 0 | 0 |
| Chemotherapy | 69 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Nausea / Vomiting - 10 pts sustained deterioration



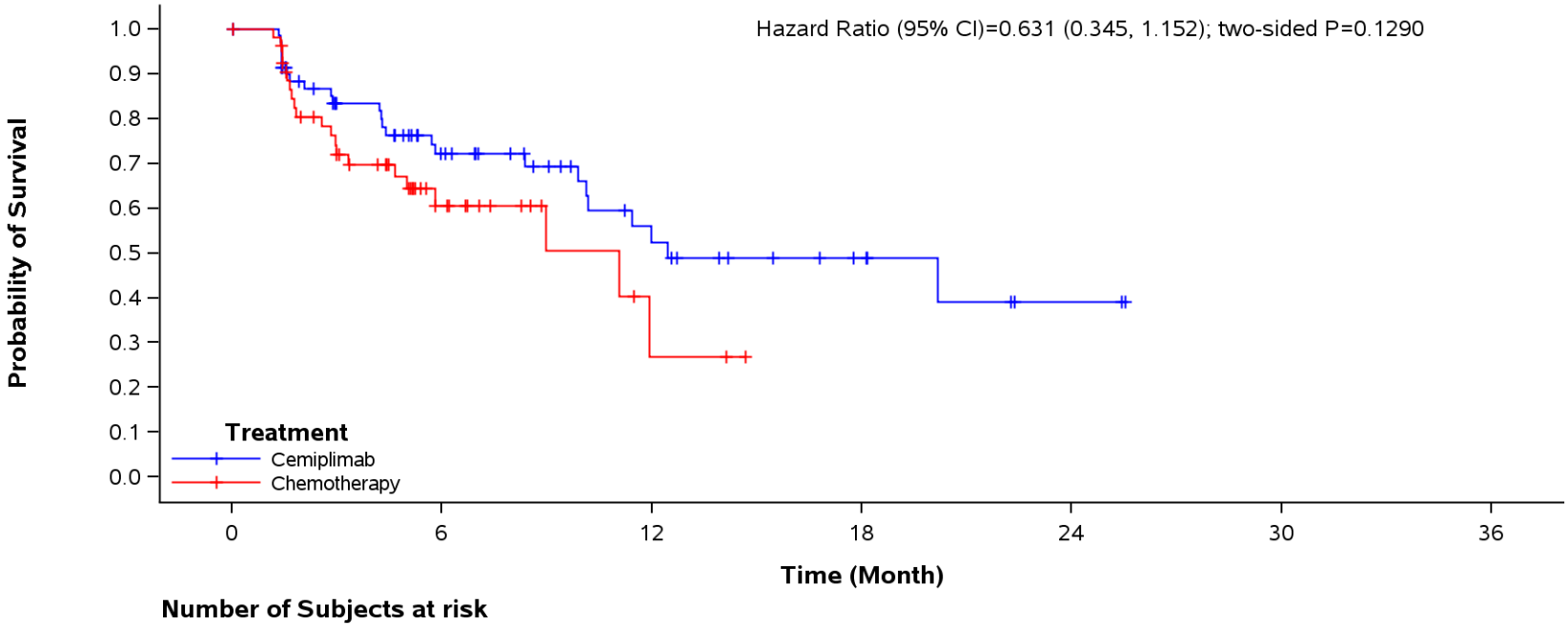

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 39 | 19 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Pain - 10 pts sustained deterioration



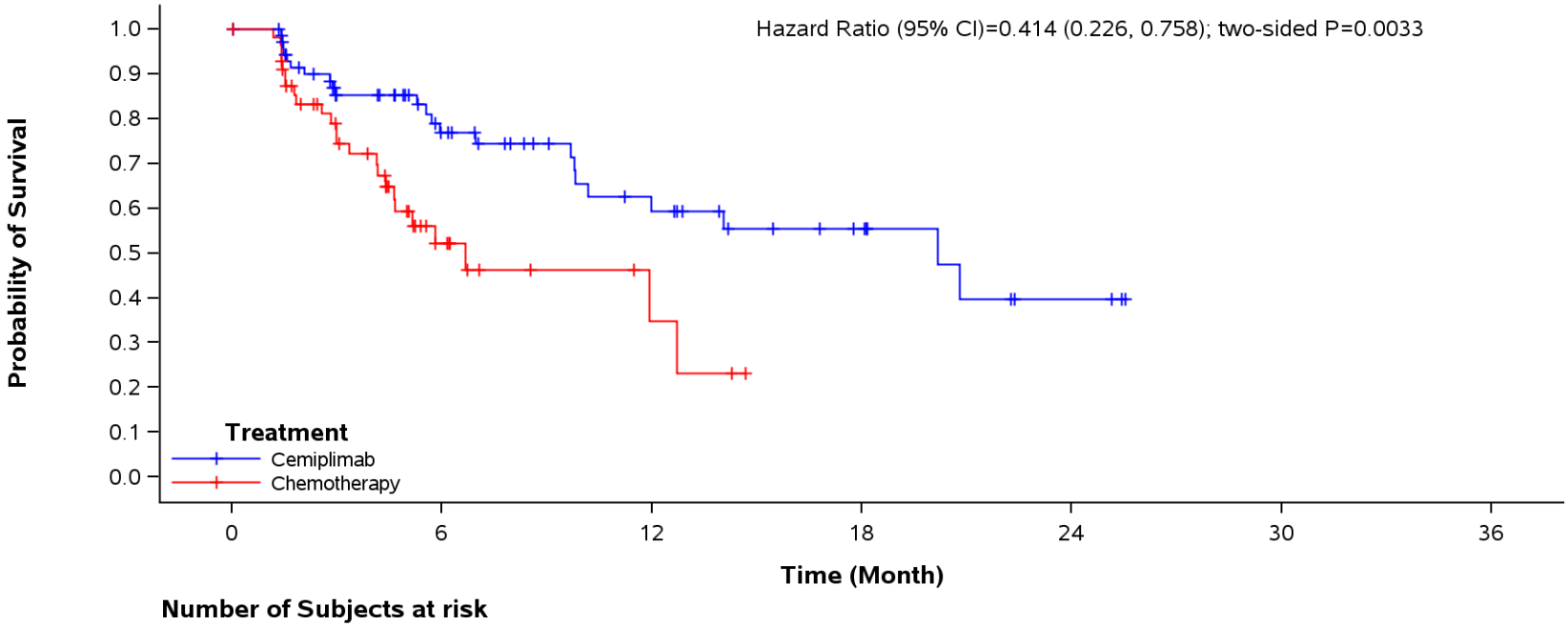

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 33 | 15 | 7 | 2 | 0 | 0 |
| Chemotherapy | 69 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Physical Functioning - 10 pts sustained deterioration



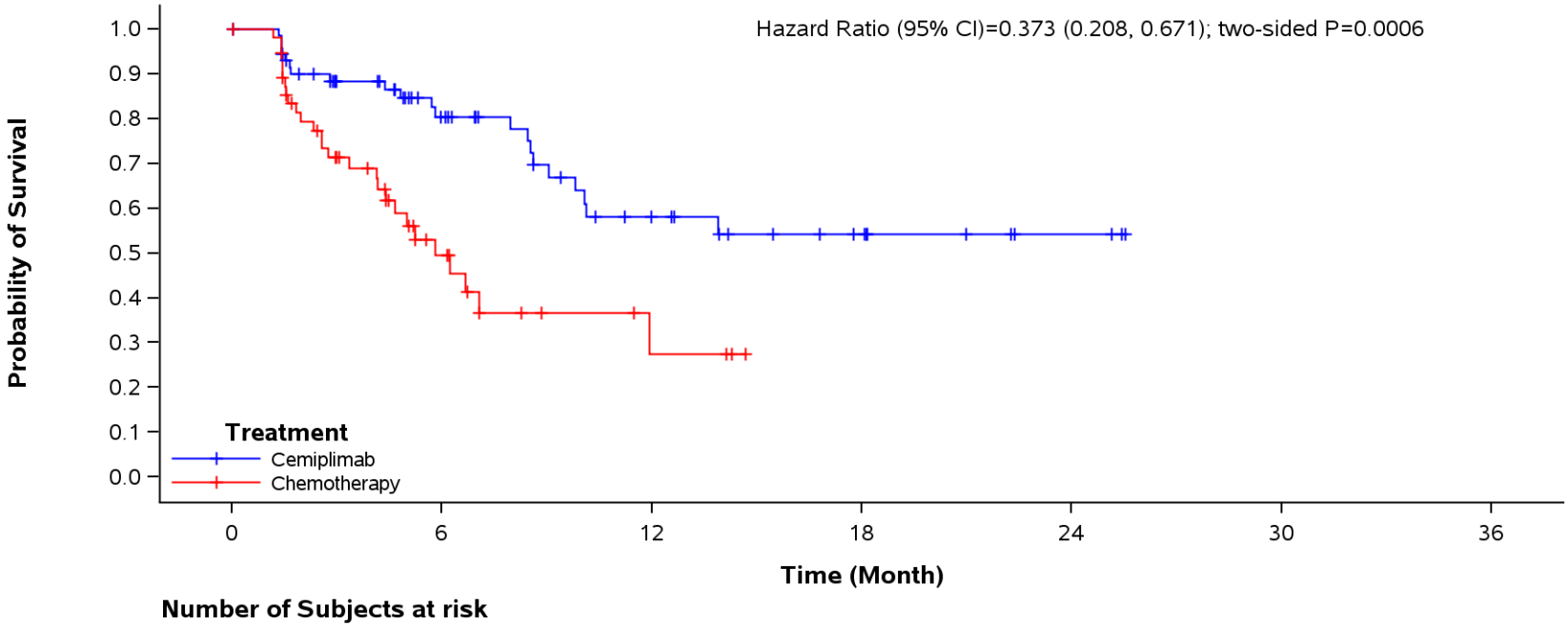

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 19 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 12 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Global health status / QoL - 10 pts sustained deterioration



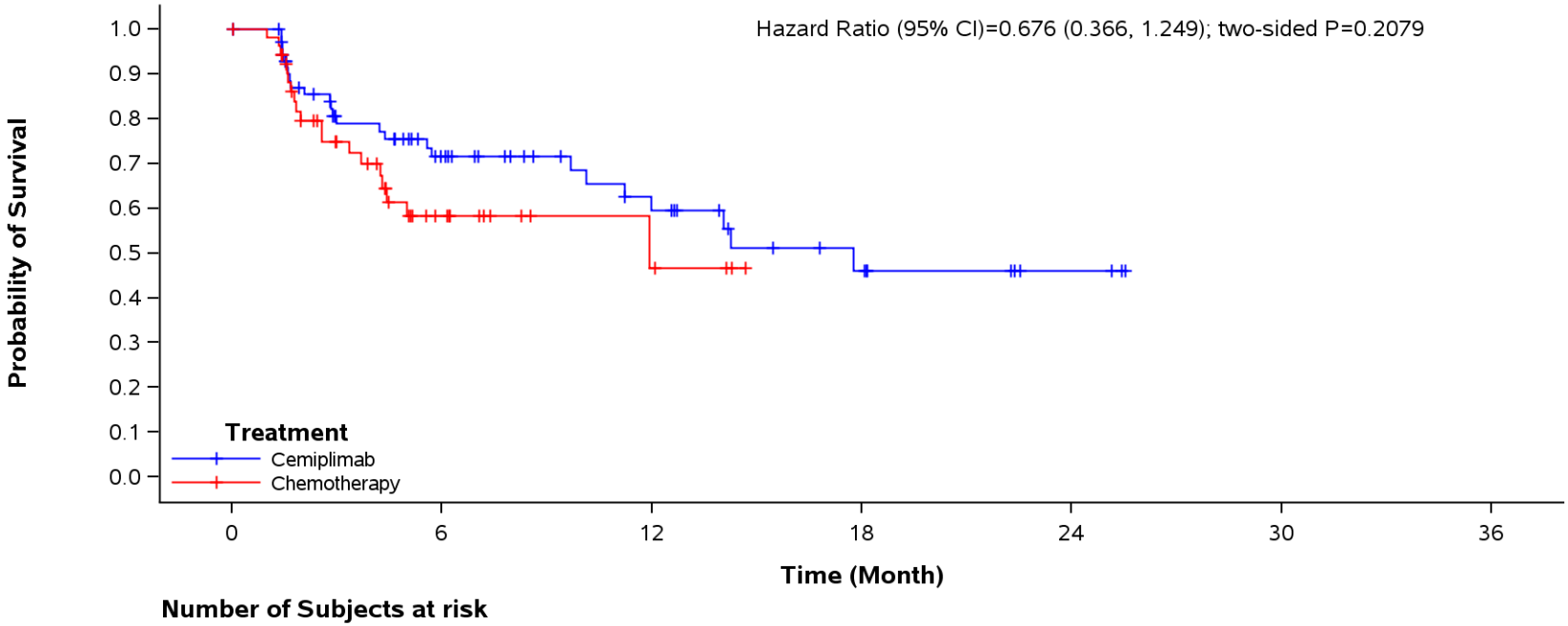

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 17 | 9 | 3 | 0 | 0 |
| Chemotherapy | 69 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Role Functioning - 10 pts sustained deterioration



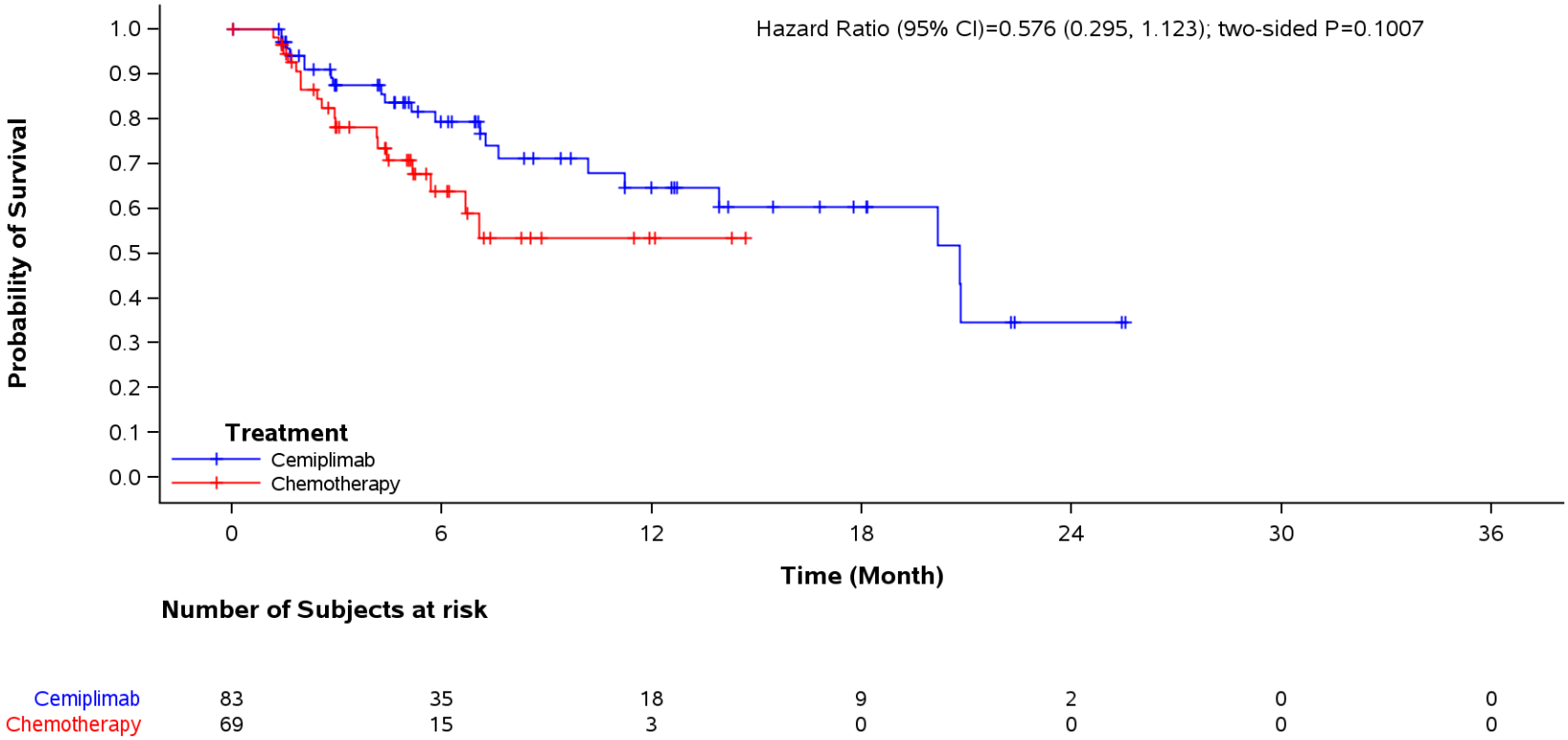

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 34 | 19 | 9 | 3 | 0 | 0 |
| Chemotherapy | 69 | 13 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Social Functioning - 10 pts sustained deterioration



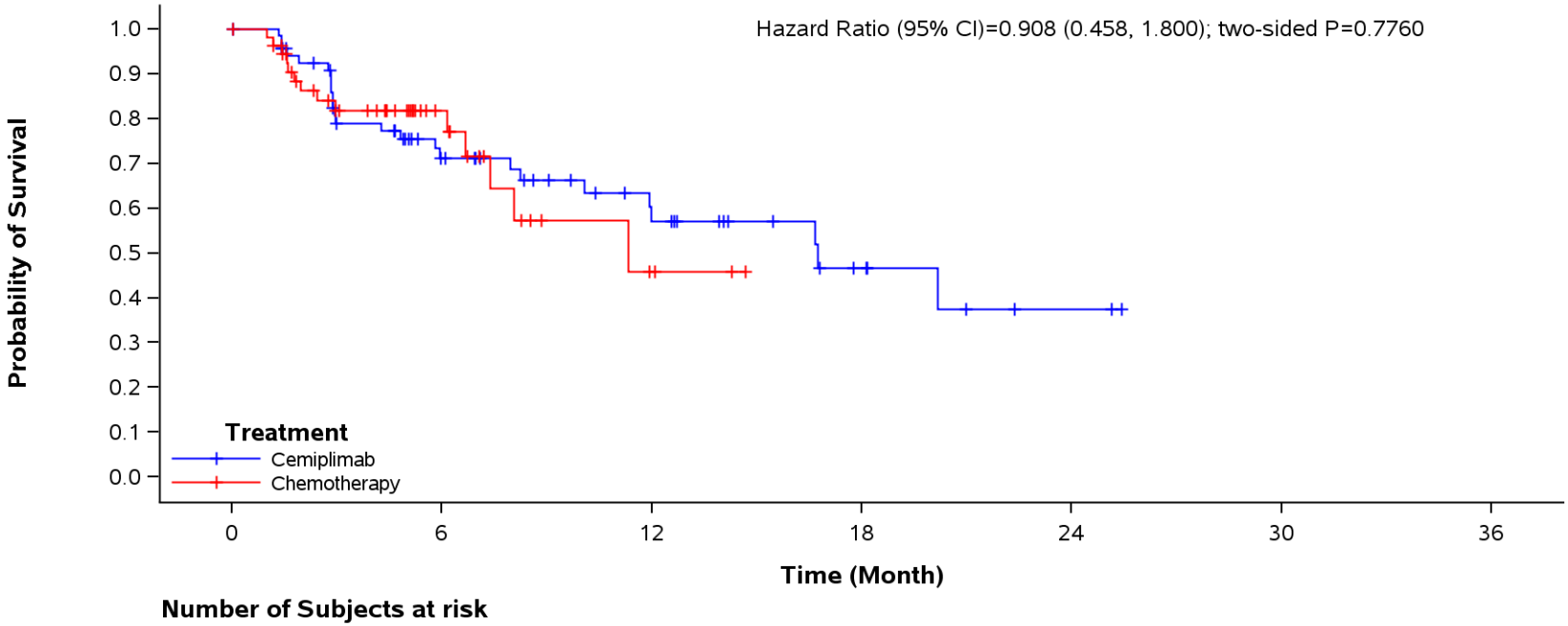

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 18 | 9 | 2 | 0 | 0 |
| Chemotherapy | 69 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts sustained deterioration



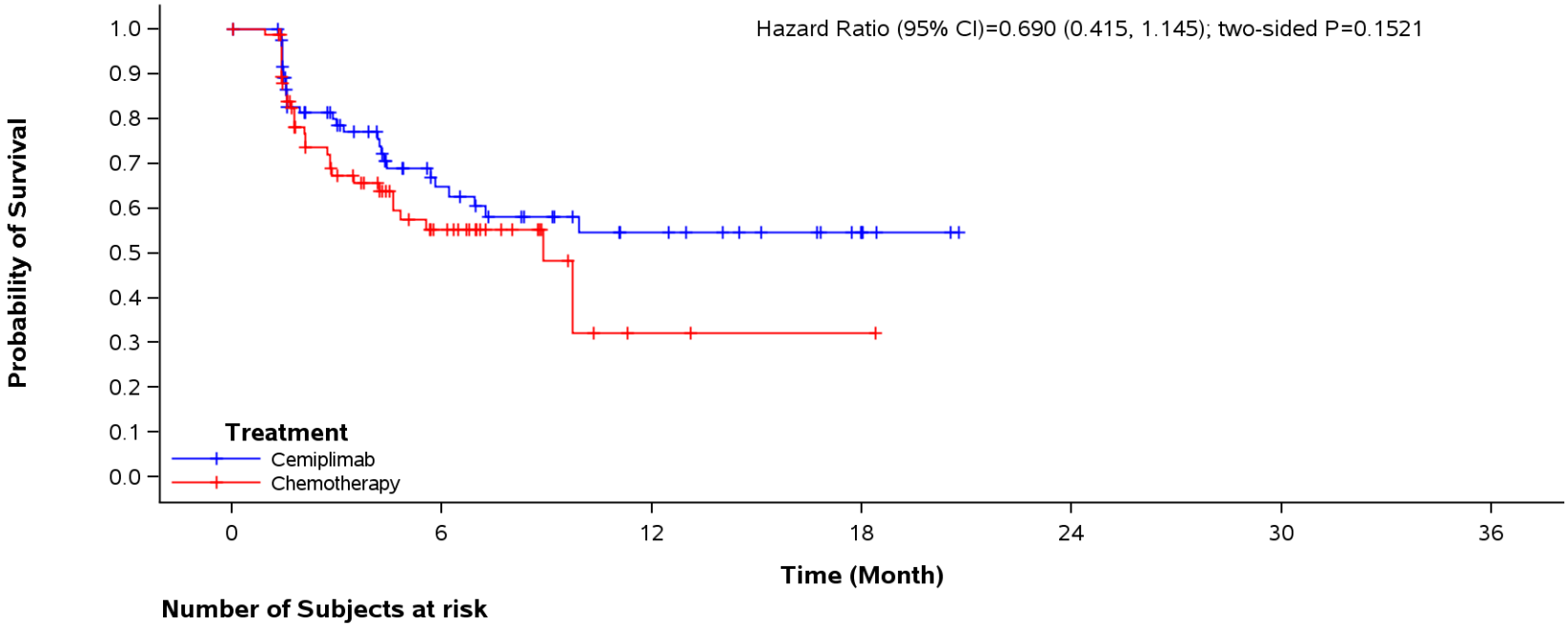

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 33 | 18 | 7 | 2 | 0 | 0 |
| Chemotherapy | 69 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts sustained deterioration



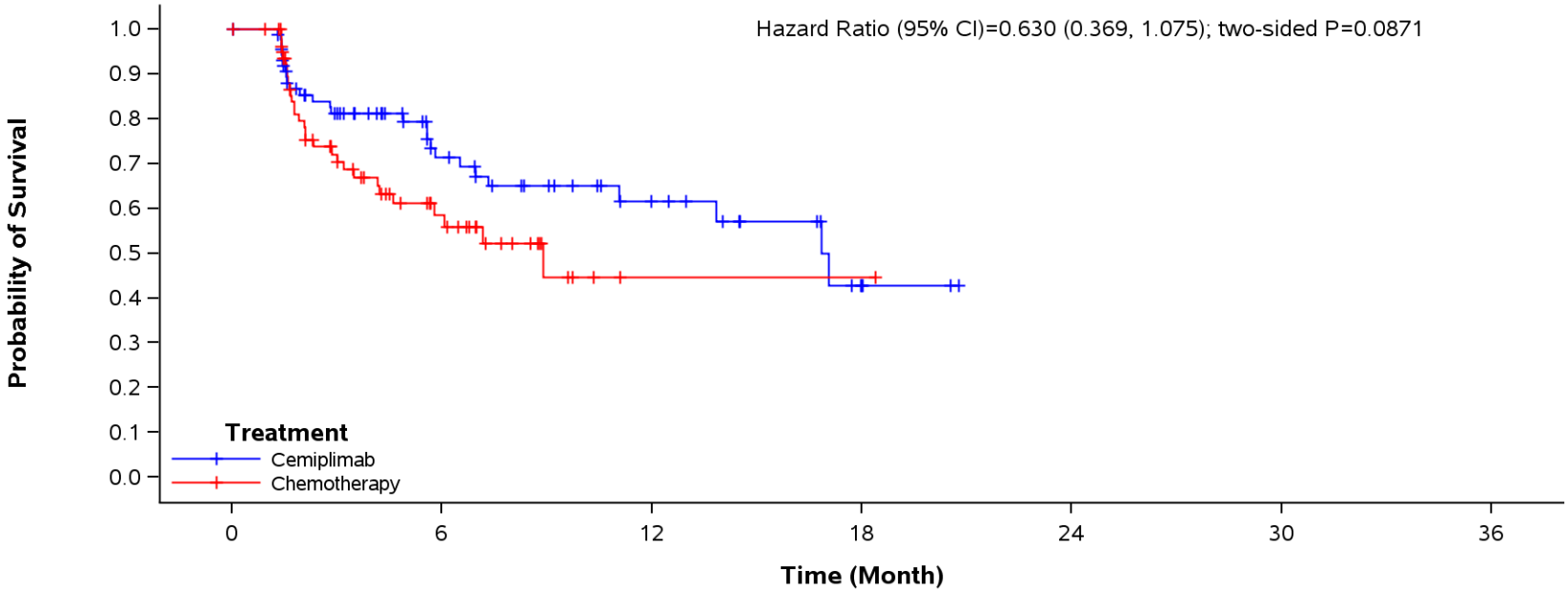

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 31 | 14 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts sustained deterioration



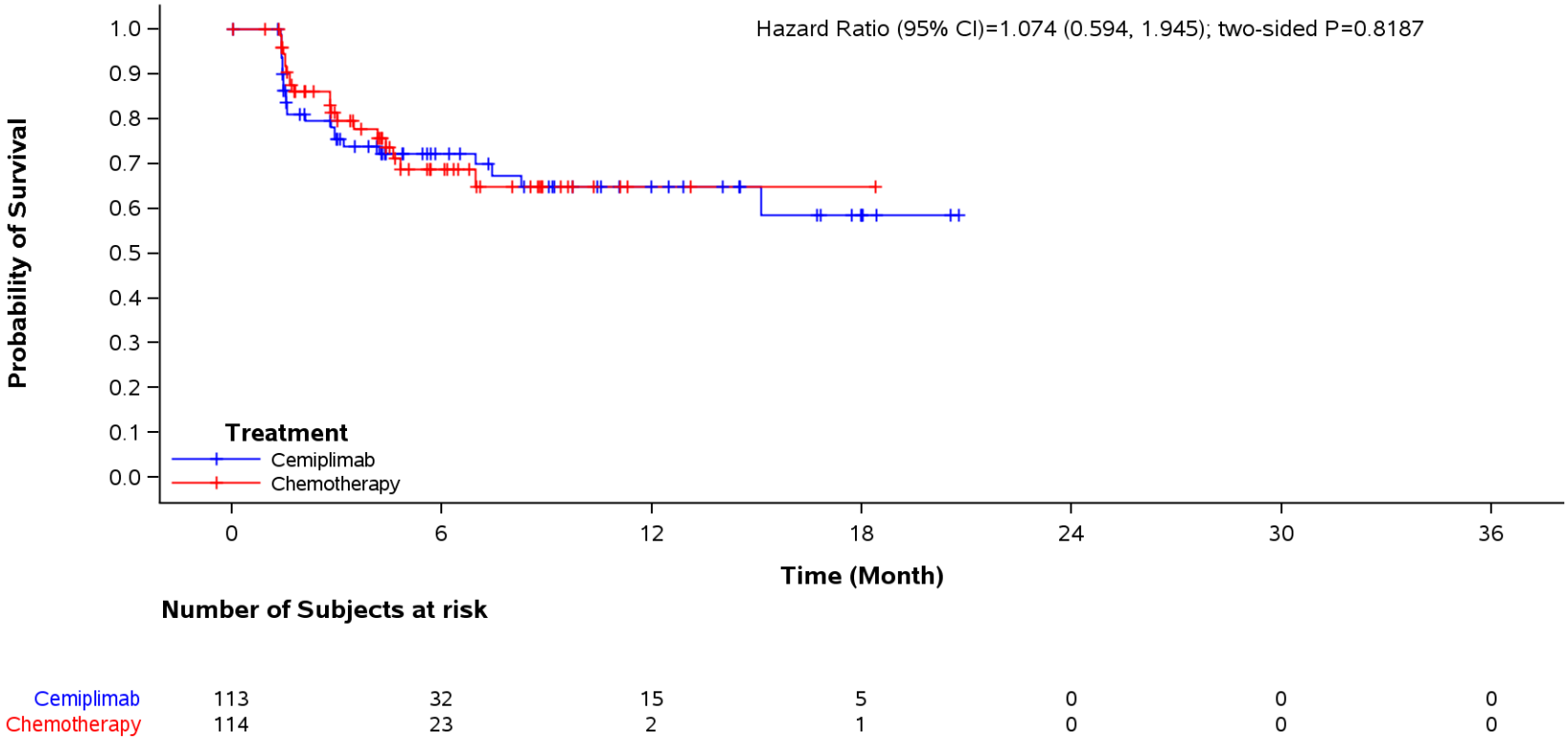

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 35 | 16 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts sustained deterioration



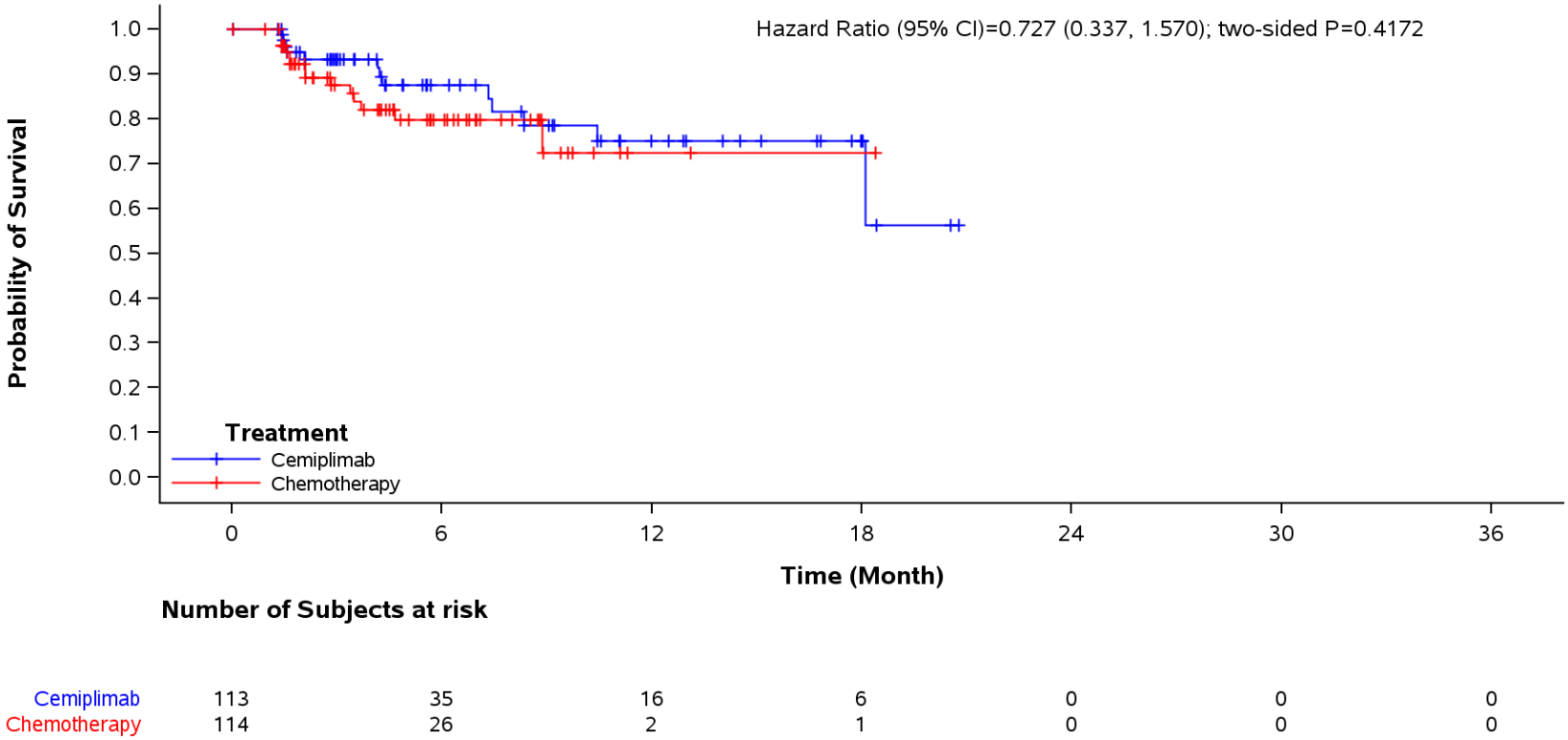

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 32 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 23 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts sustained deterioration



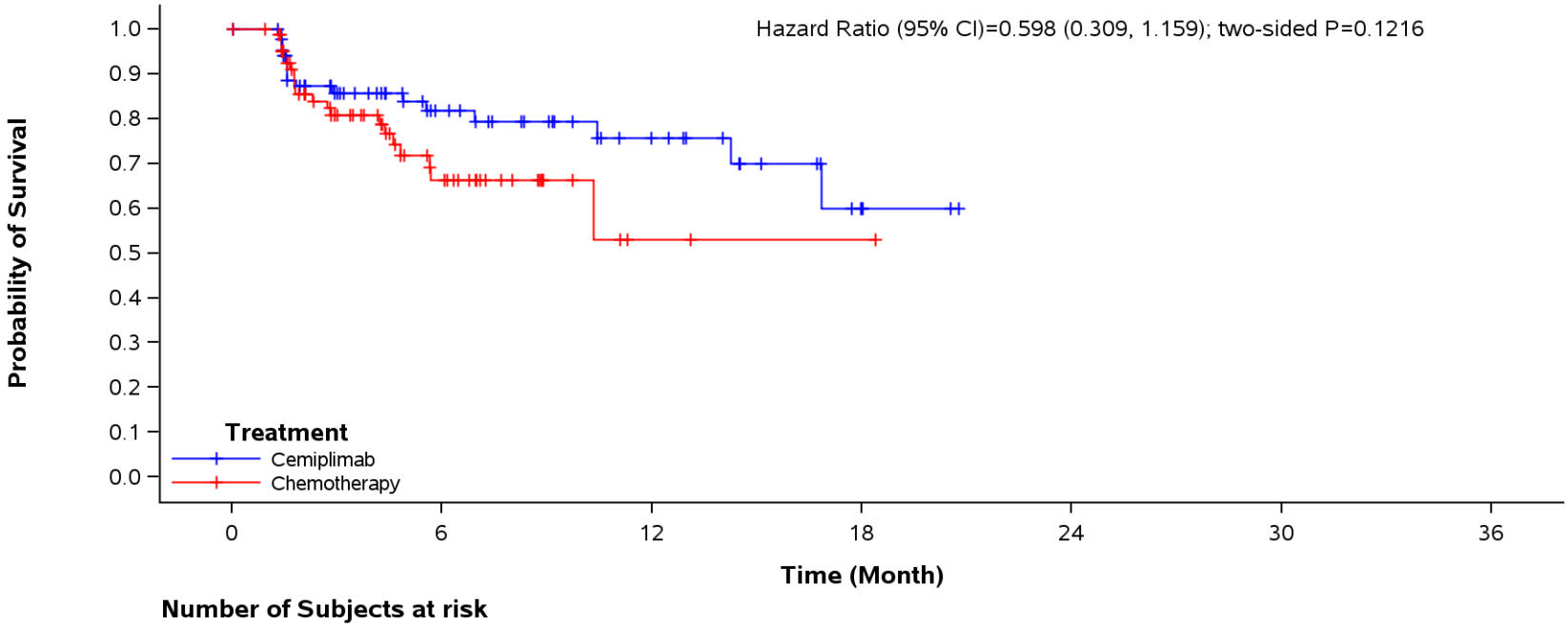

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 35 | 16 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 26 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Dyspnoea - 10 pts sustained deterioration



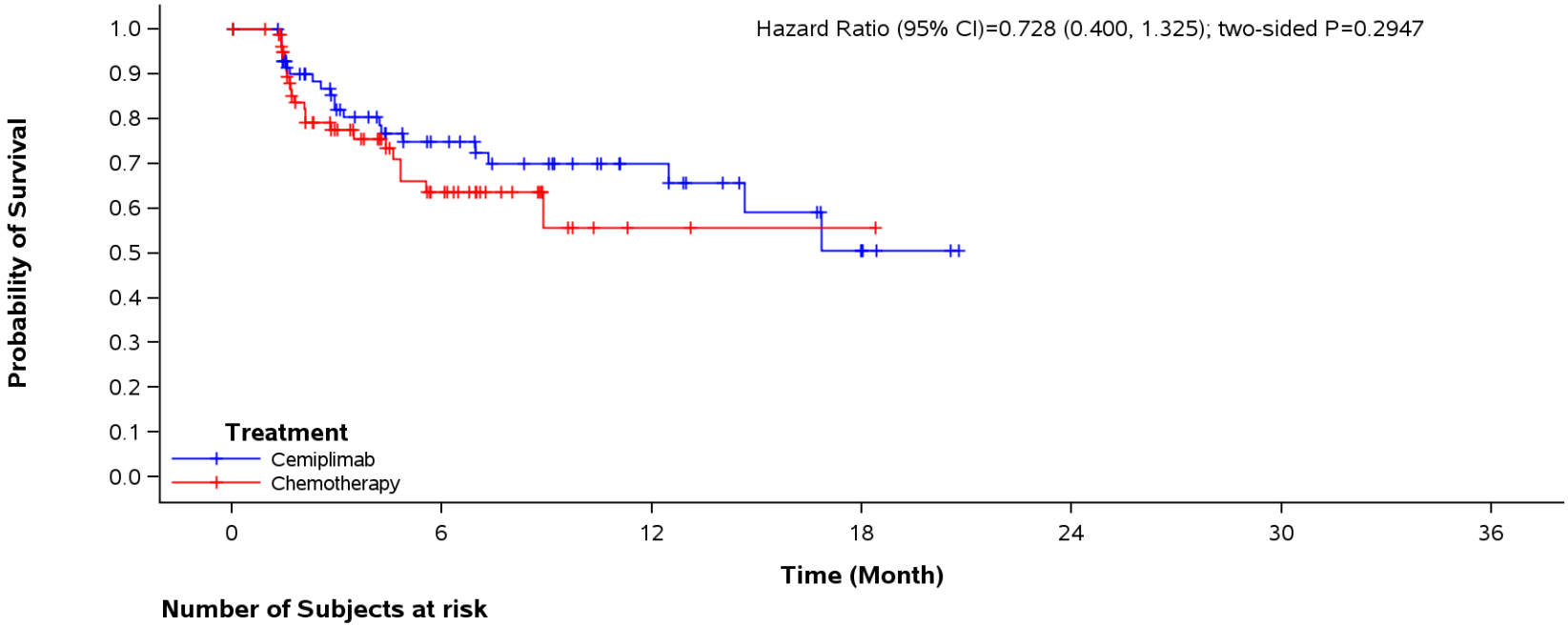

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 36 | 17 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 23 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Emotional Functioning - 10 pts sustained deterioration



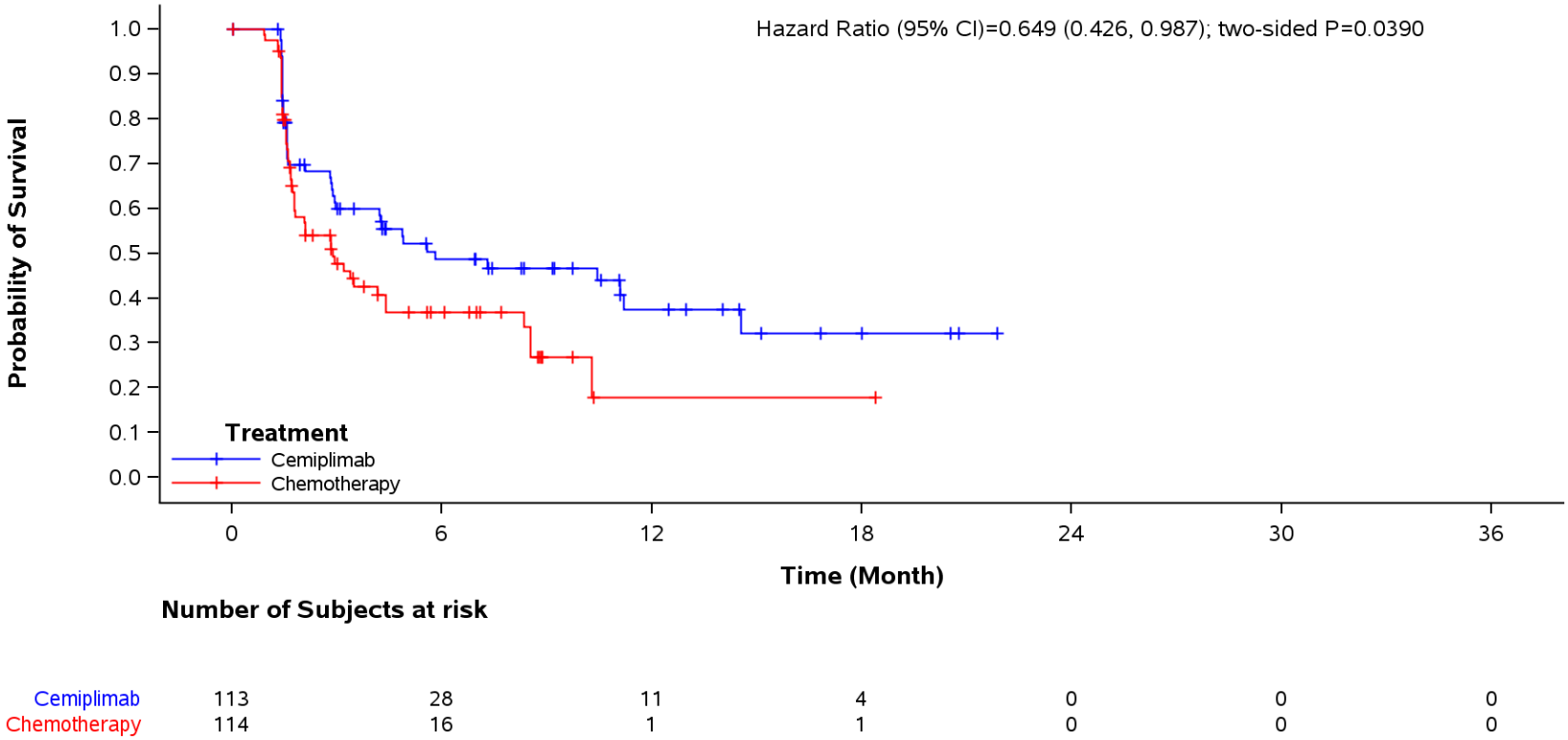

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 35 | 16 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 23 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts sustained deterioration



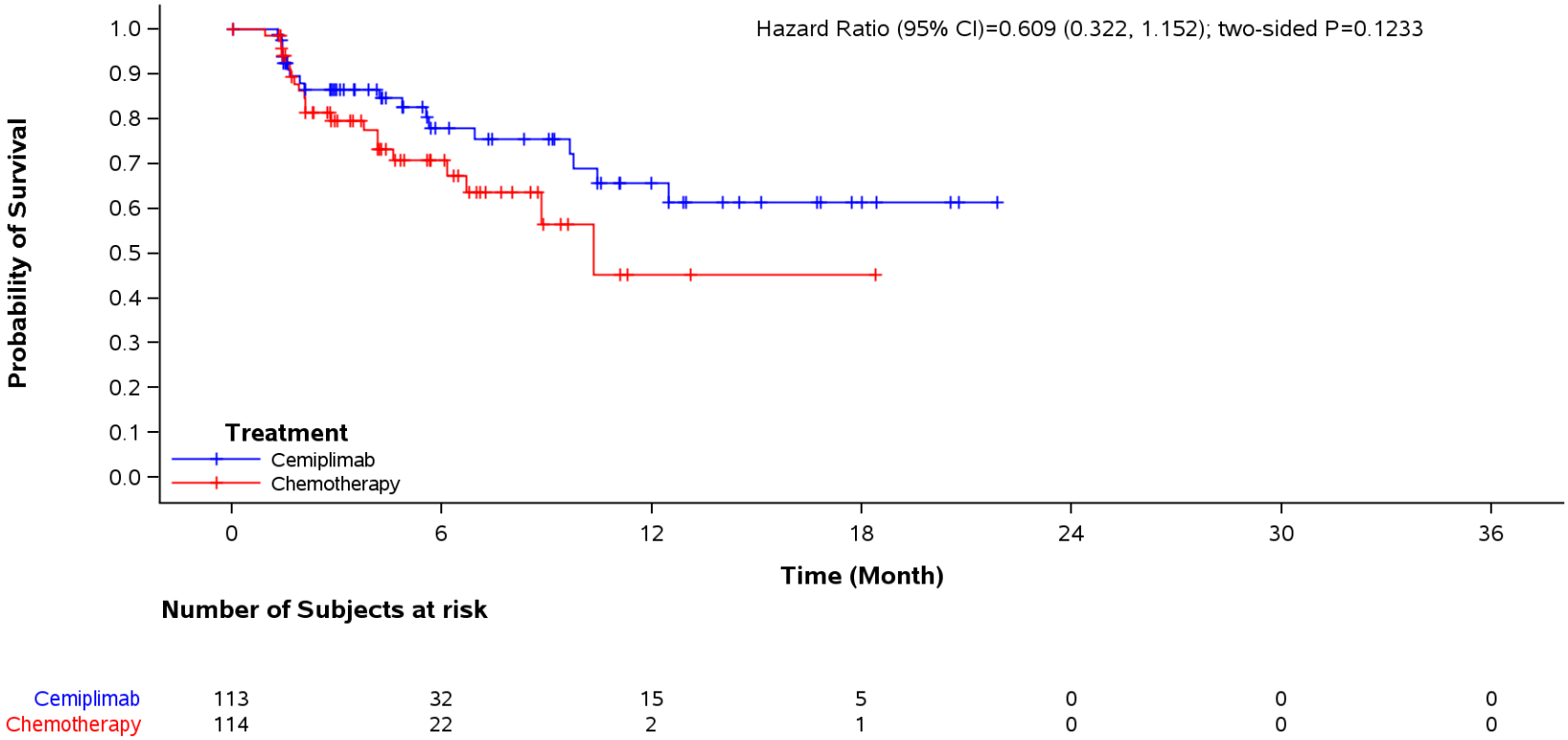

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 28 | 11 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 16 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Financial Problems - 10 pts sustained deterioration



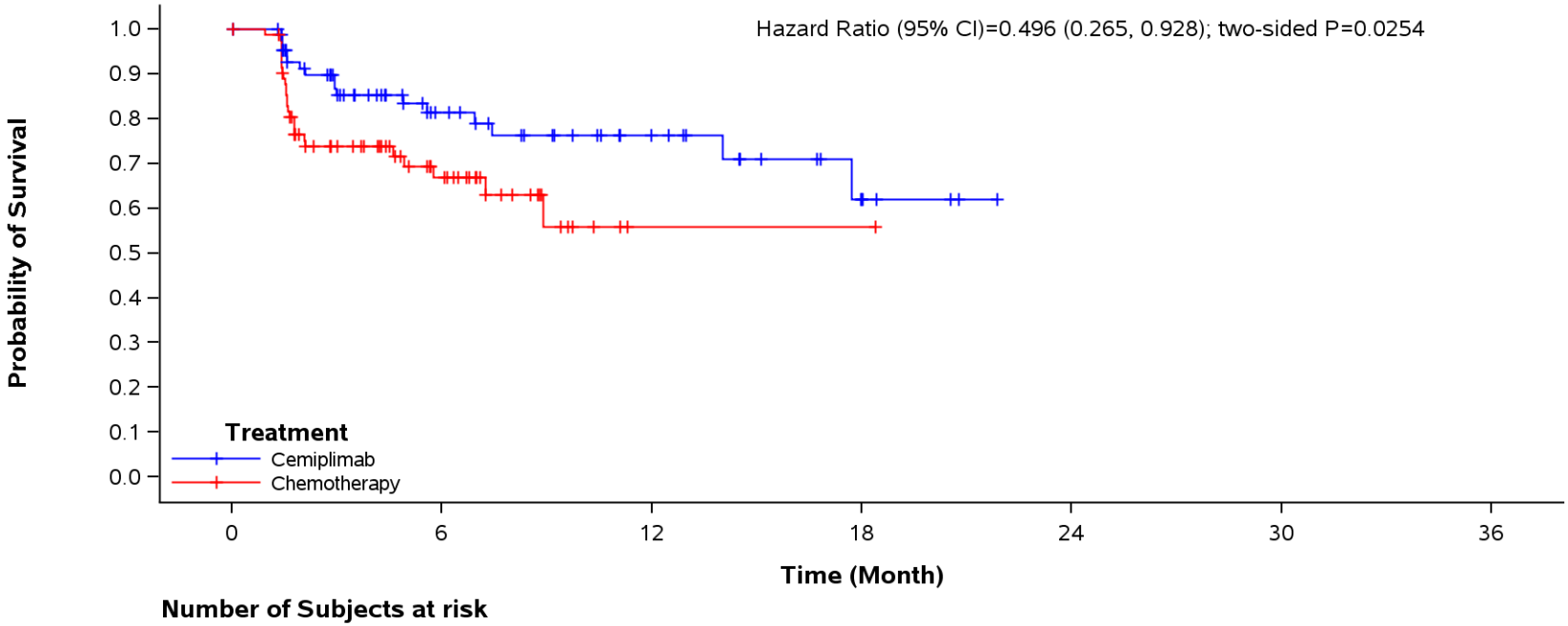

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 32 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Nausea / Vomiting - 10 pts sustained deterioration



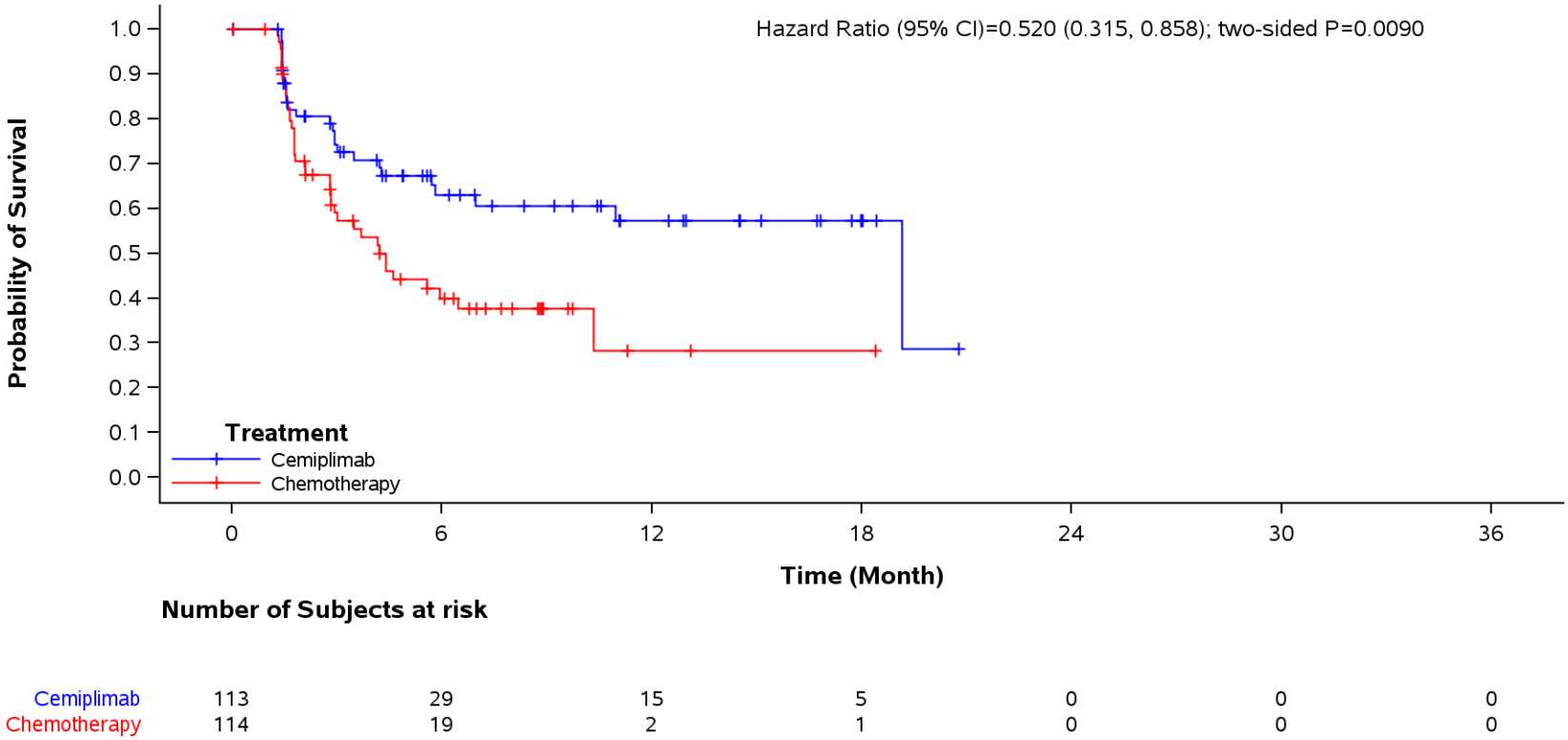

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 37 | 17 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 26 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Pain - 10 pts sustained deterioration



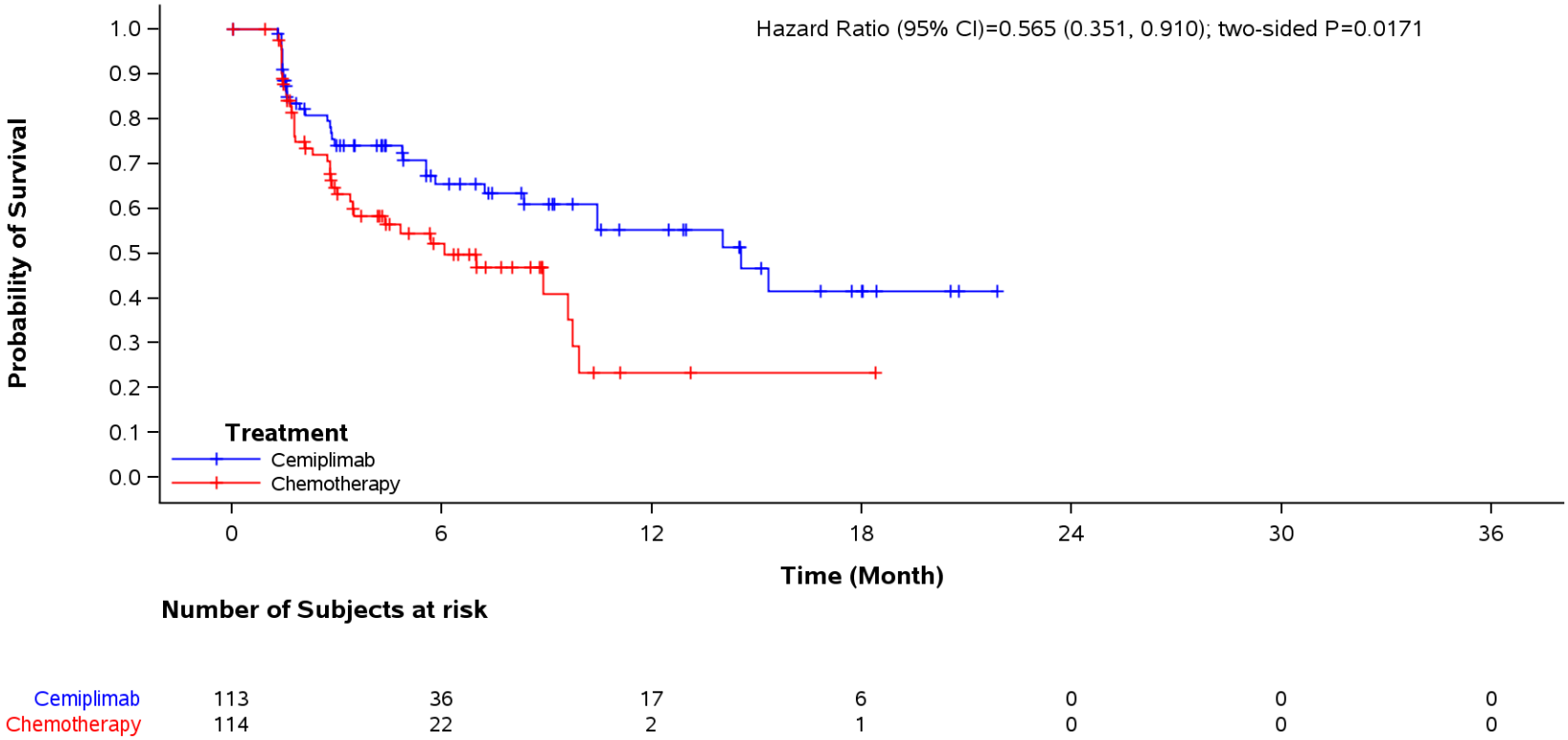

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 29 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Physical Functioning - 10 pts sustained deterioration



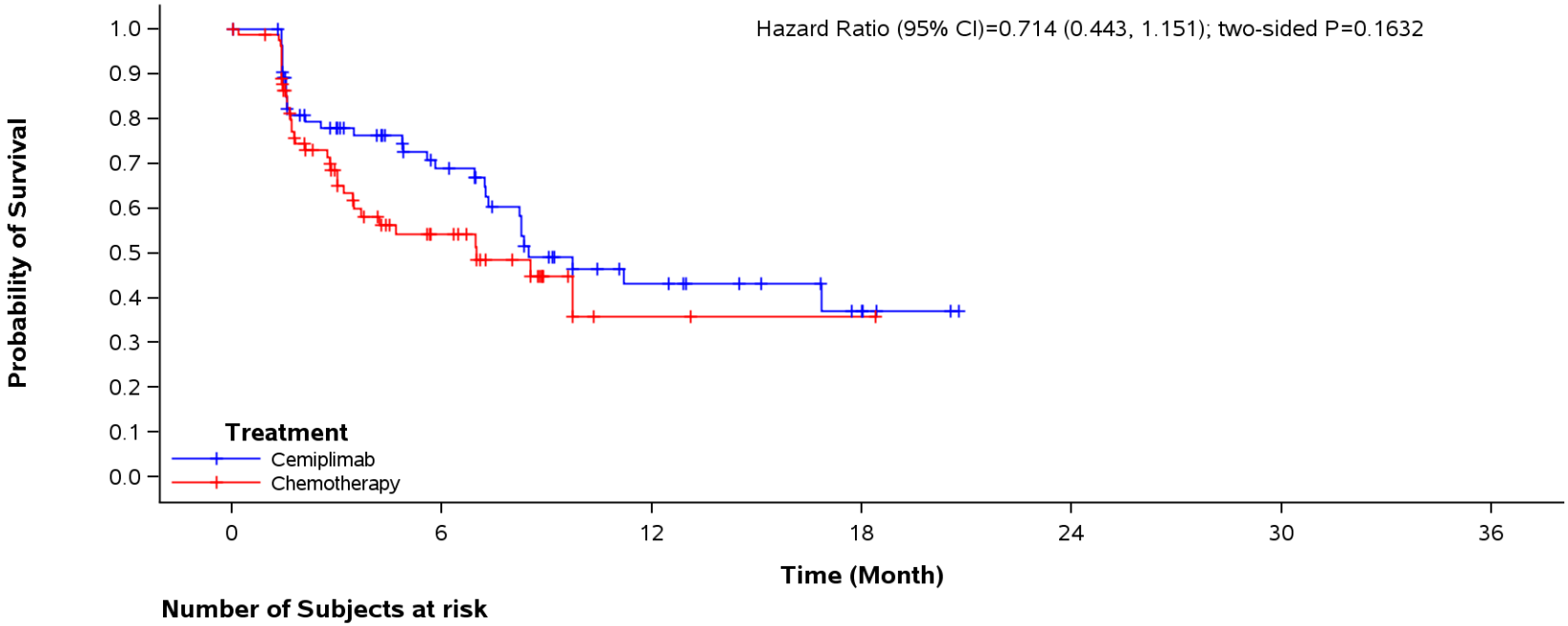

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 36 | 17 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Global health status / QoL - 10 pts sustained deterioration



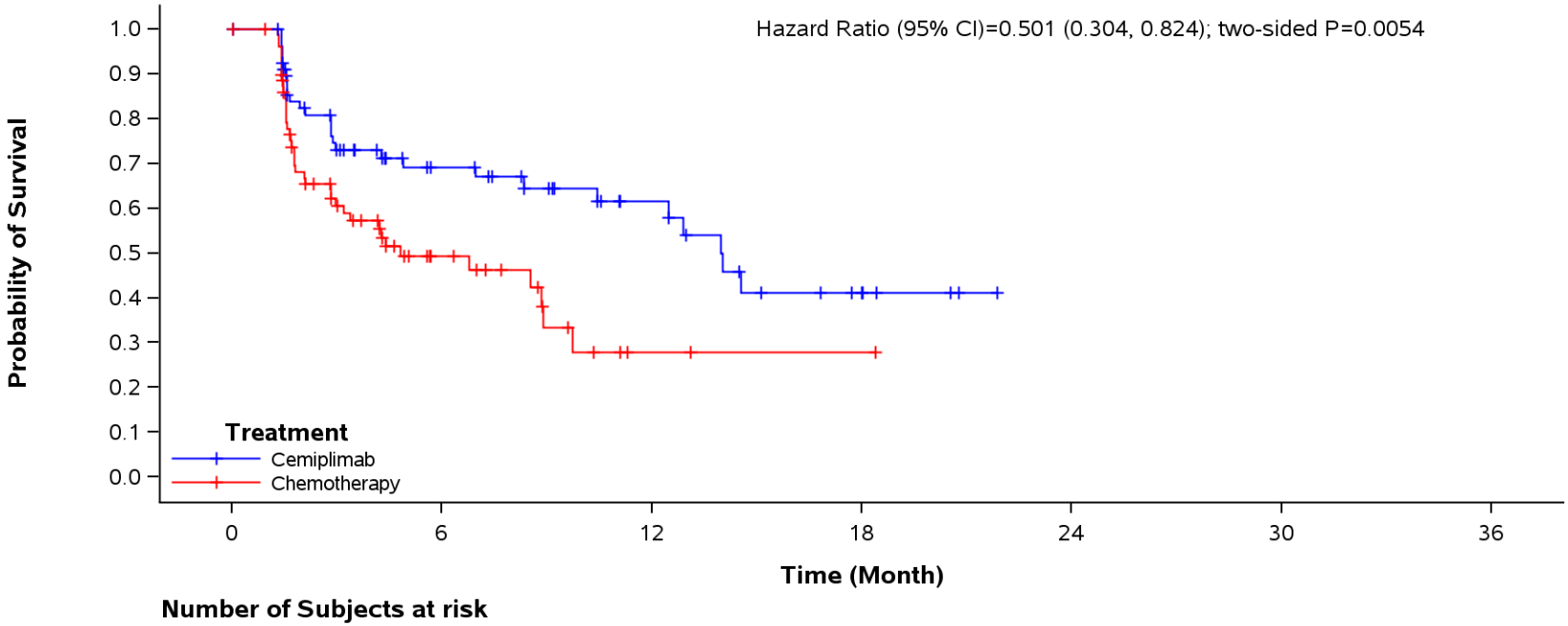

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 36 | 13 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts sustained deterioration



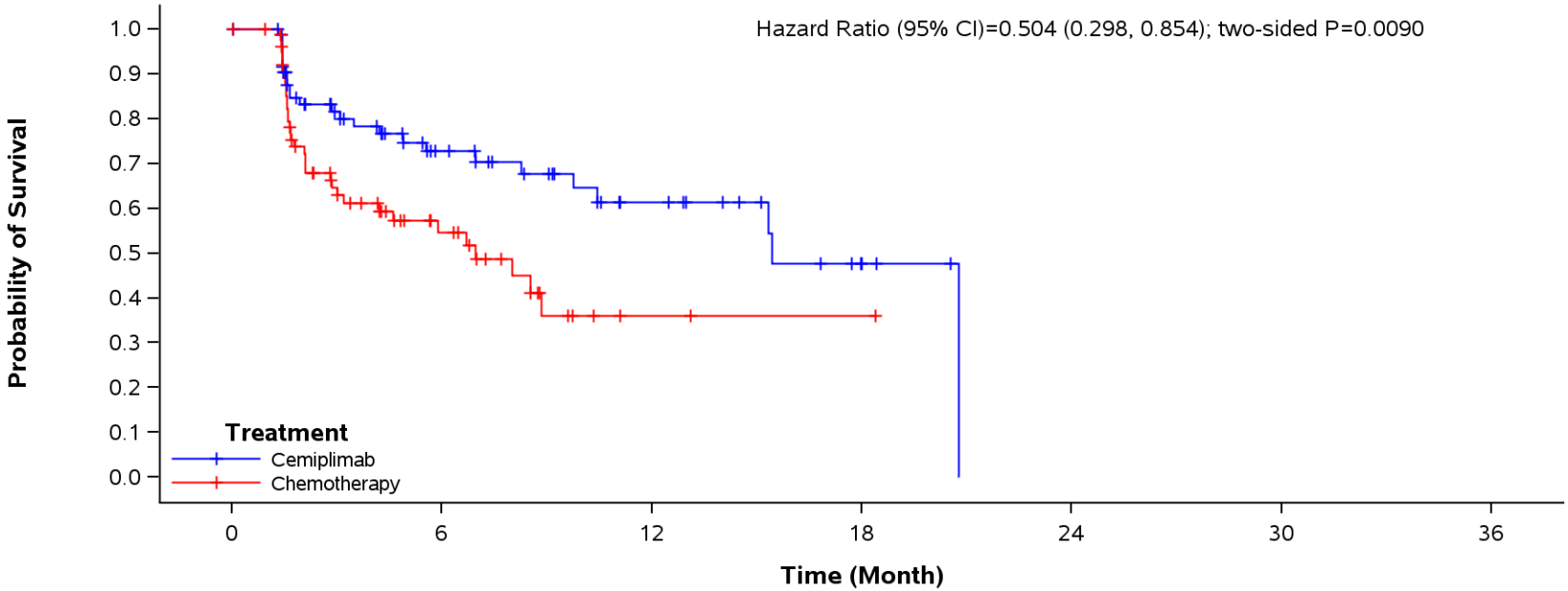

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 32 | 17 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts sustained deterioration



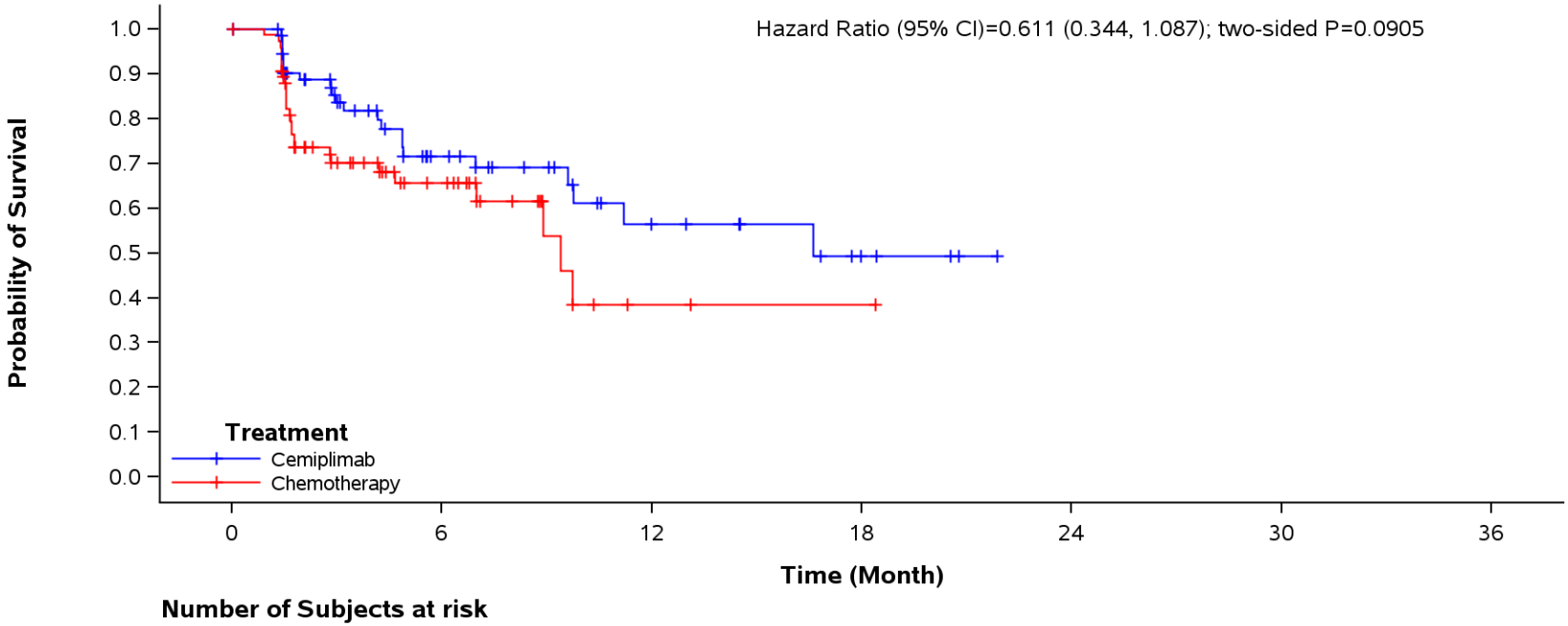

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 33 | 15 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts sustained deterioration



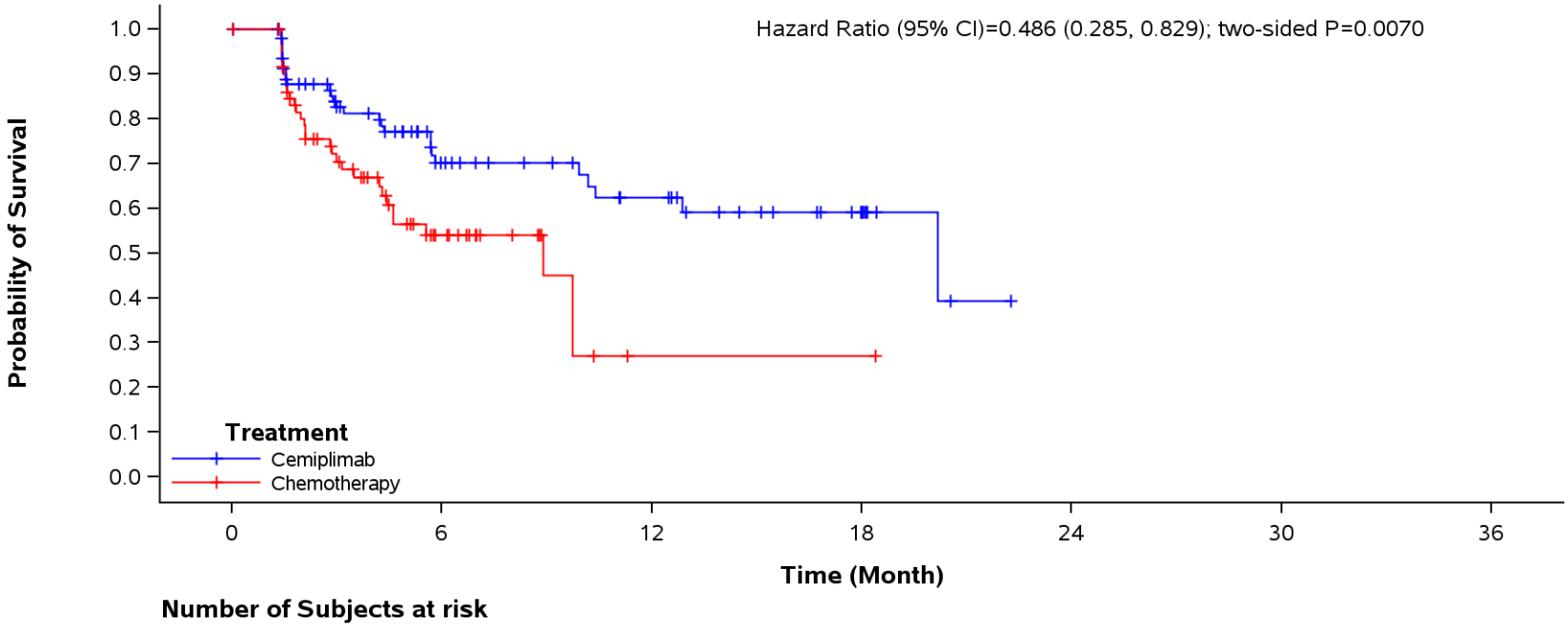

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 30 | 11 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts sustained deterioration



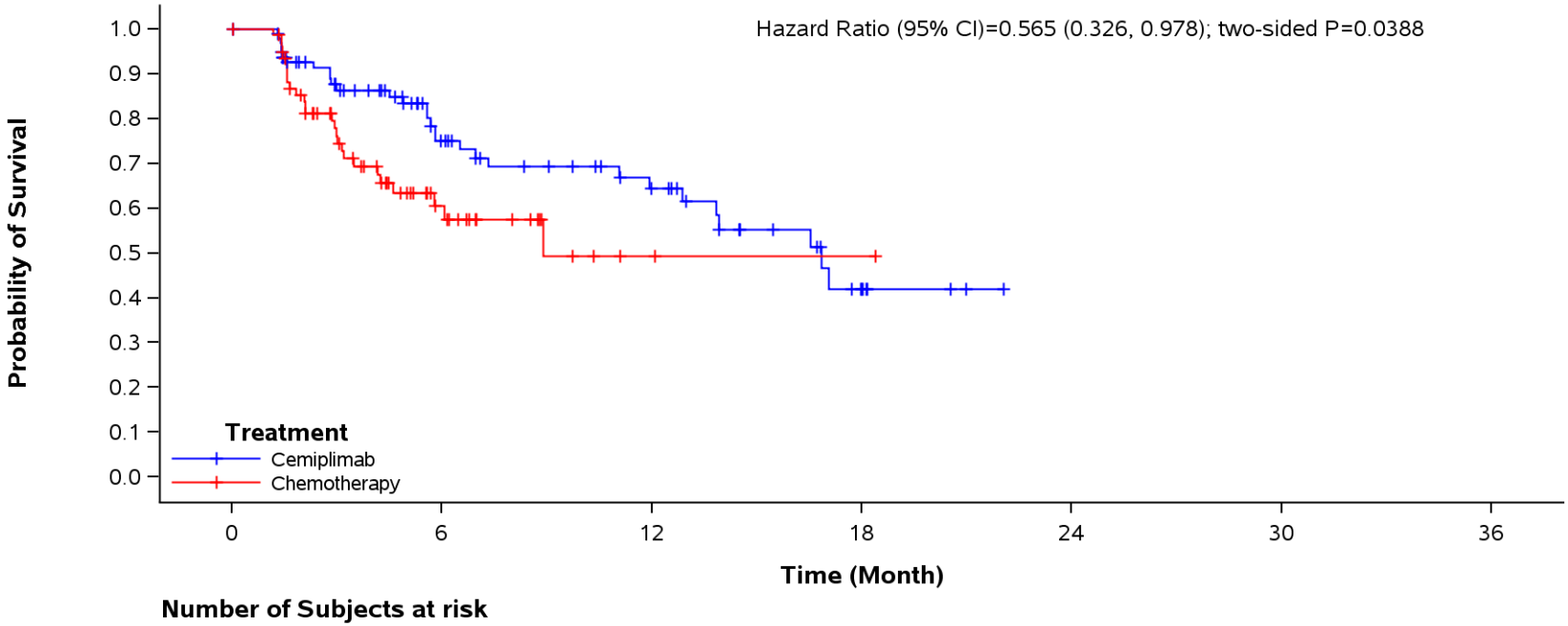

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 38 | 22 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 18 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts sustained deterioration



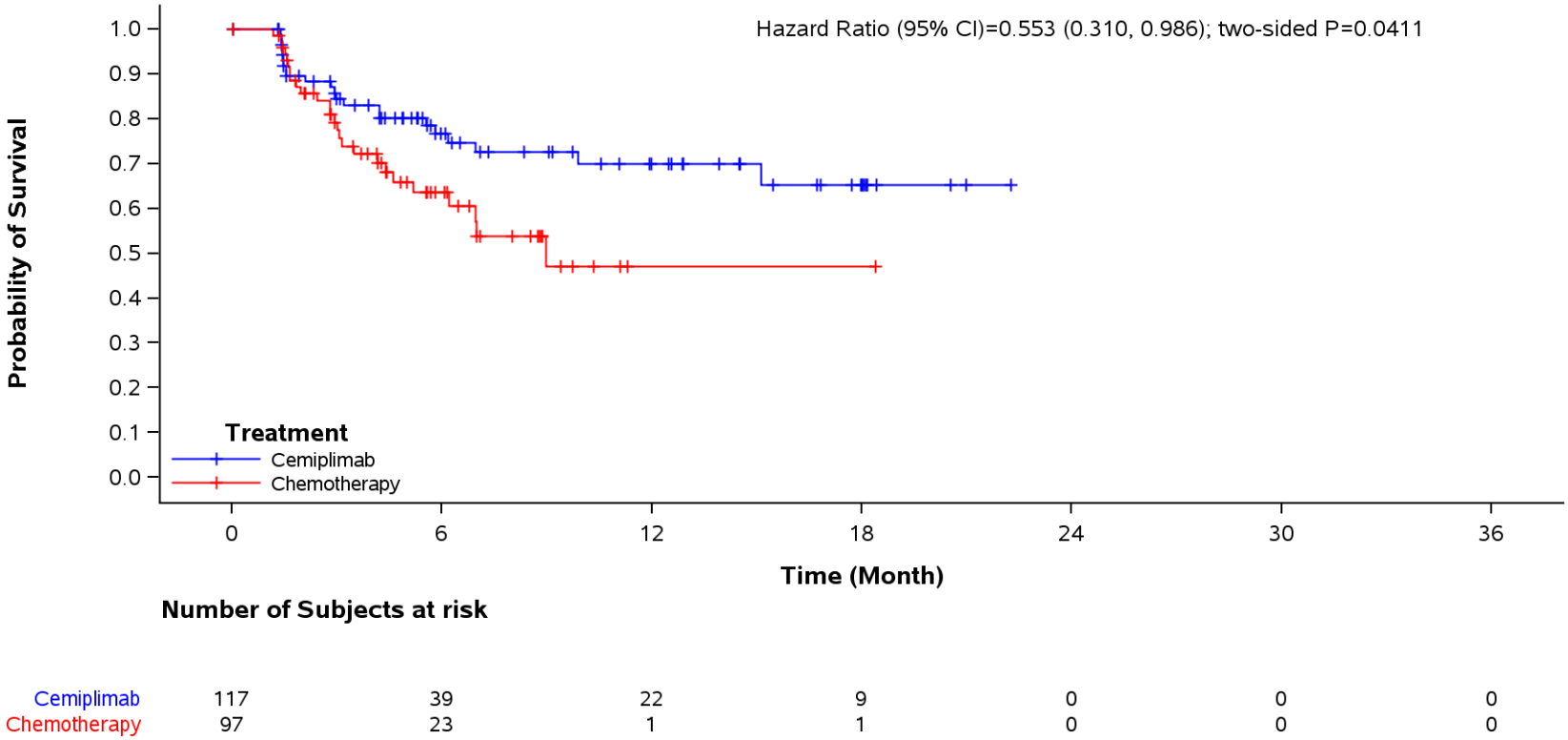

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 43 | 25 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts sustained deterioration



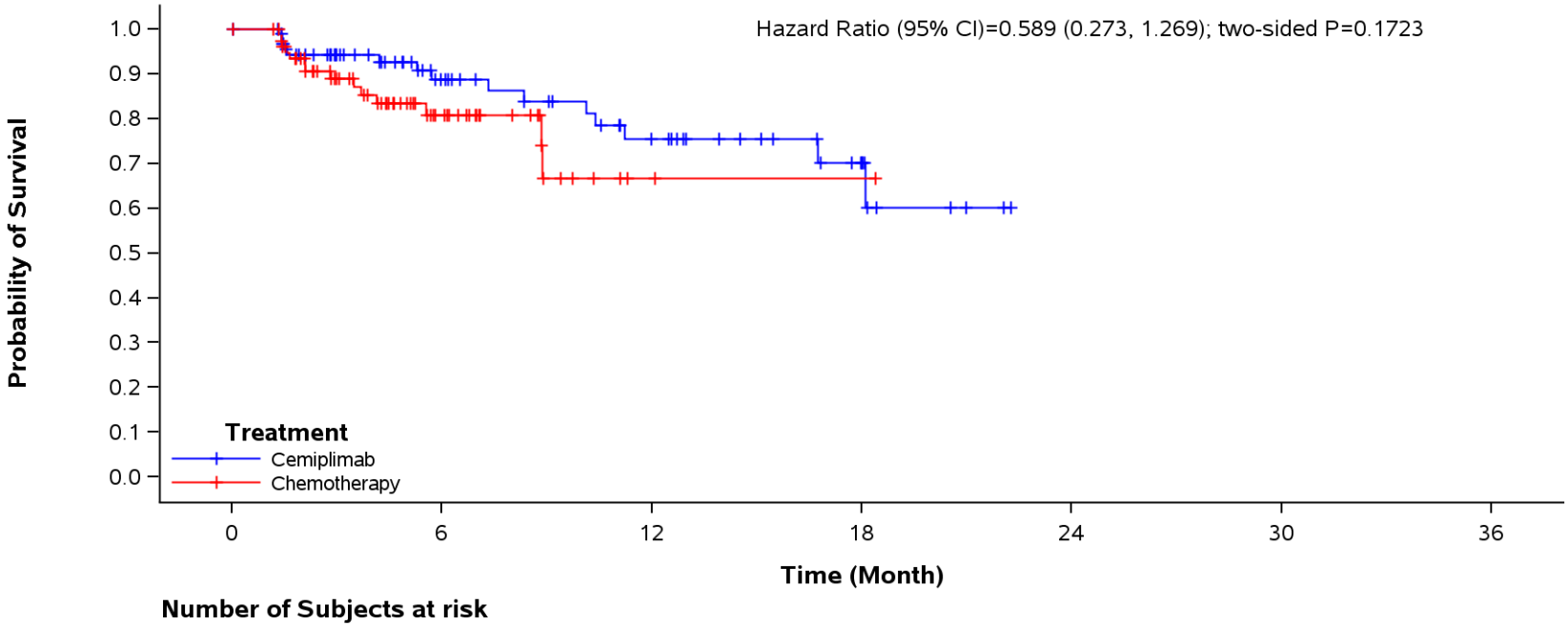

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 39 | 22 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 23 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts sustained deterioration



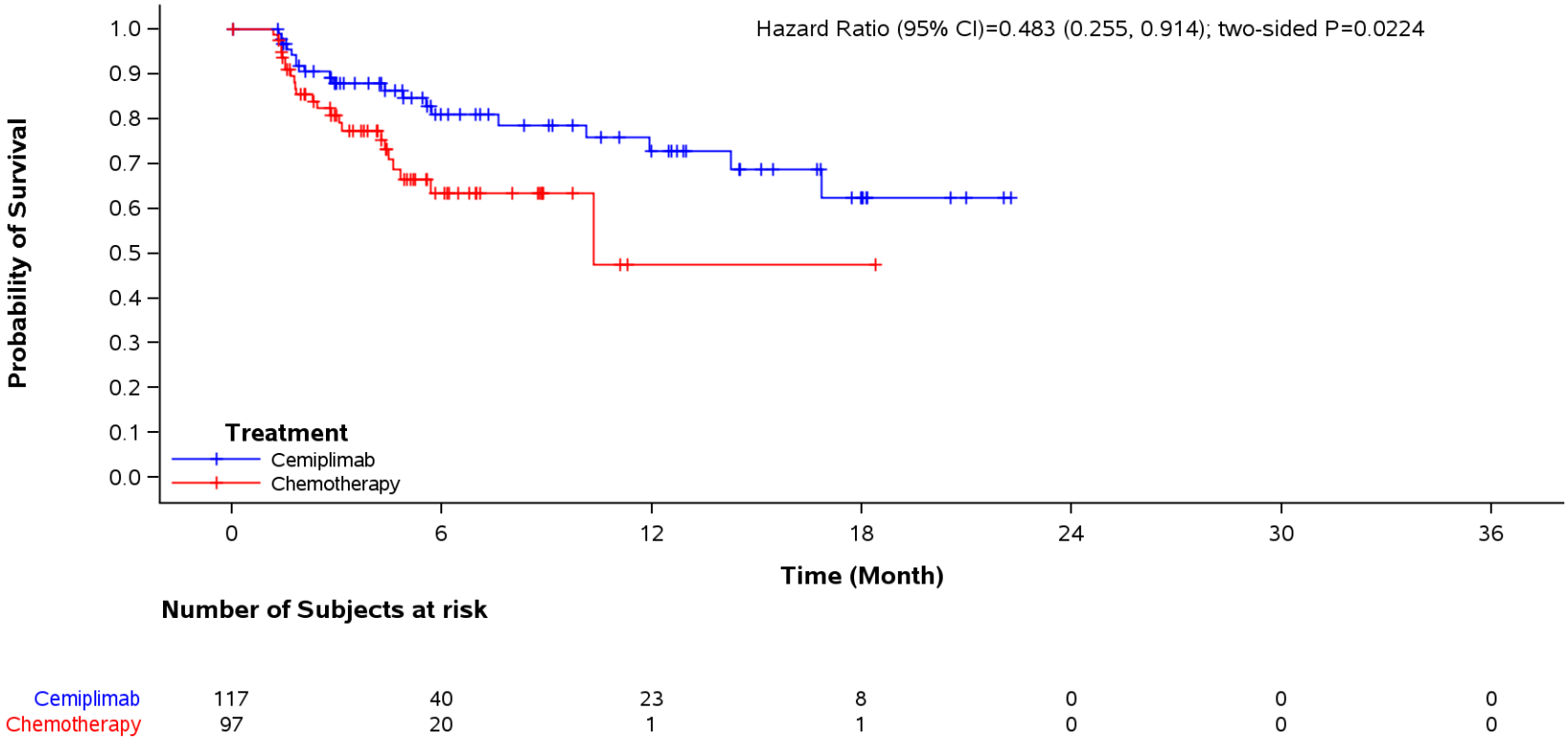

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 43 | 24 | 10 | 0 | 0 | 0 |
| Chemotherapy | 97 | 26 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts sustained deterioration



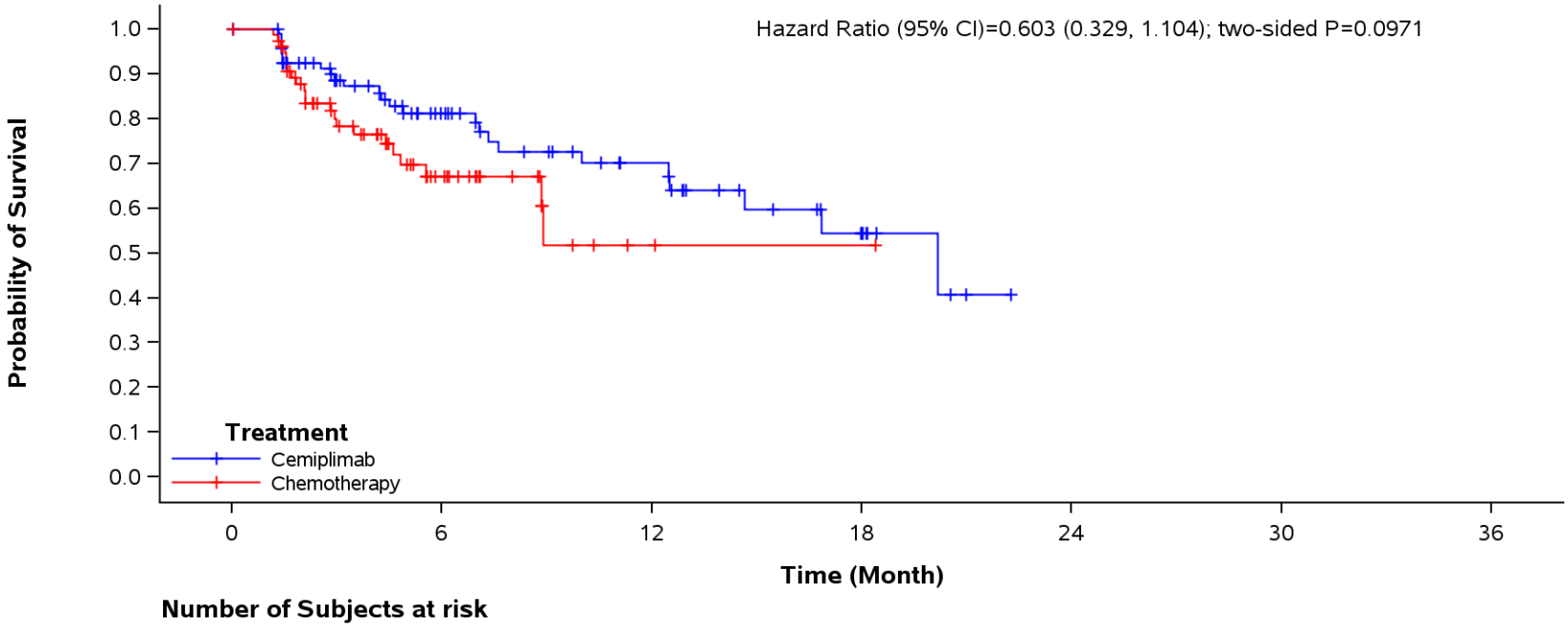

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 40 | 23 | 8 | 0 | 0 | 0 |
| Chemotherapy | 97 | 20 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Emotional Functioning - 10 pts sustained deterioration



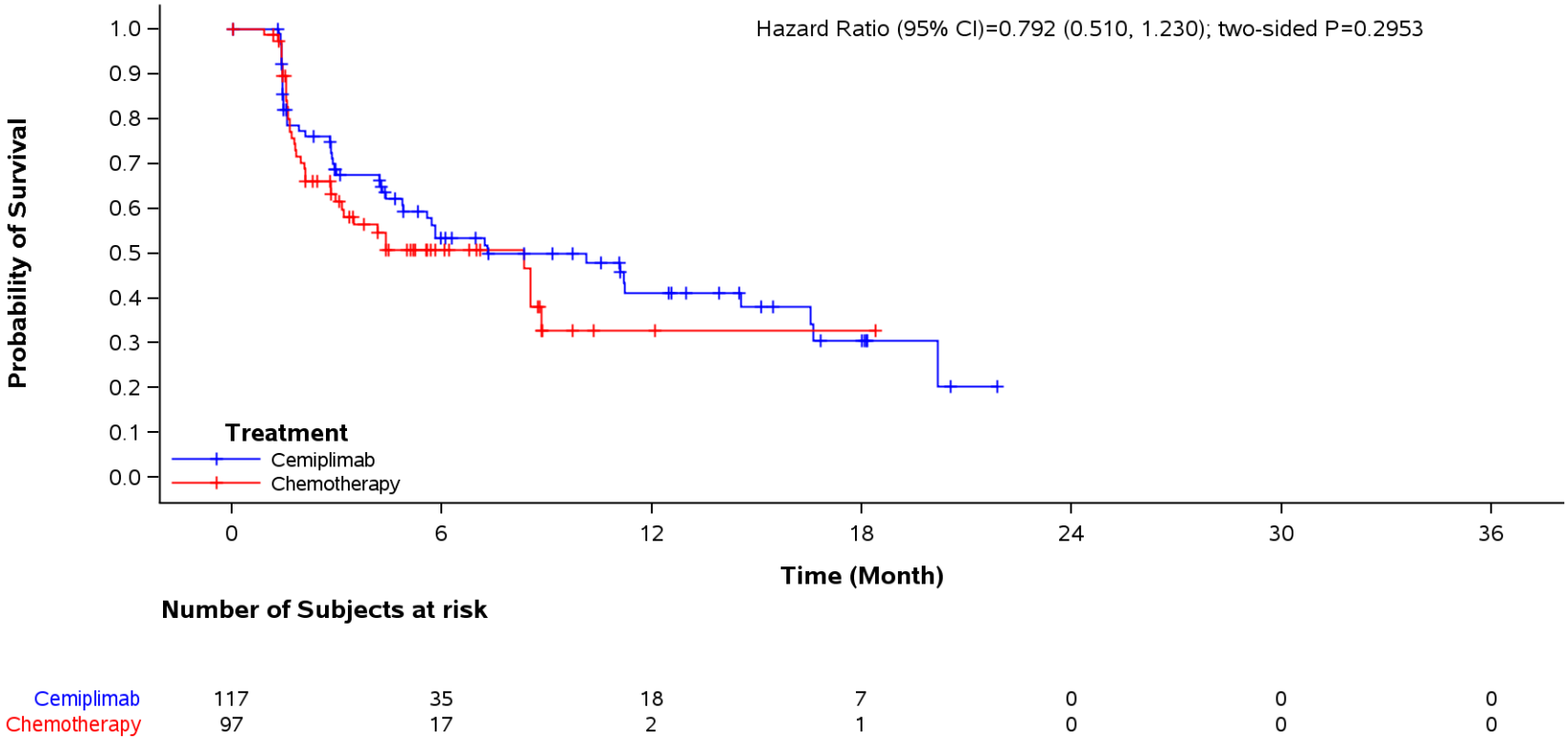

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 44 | 24 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

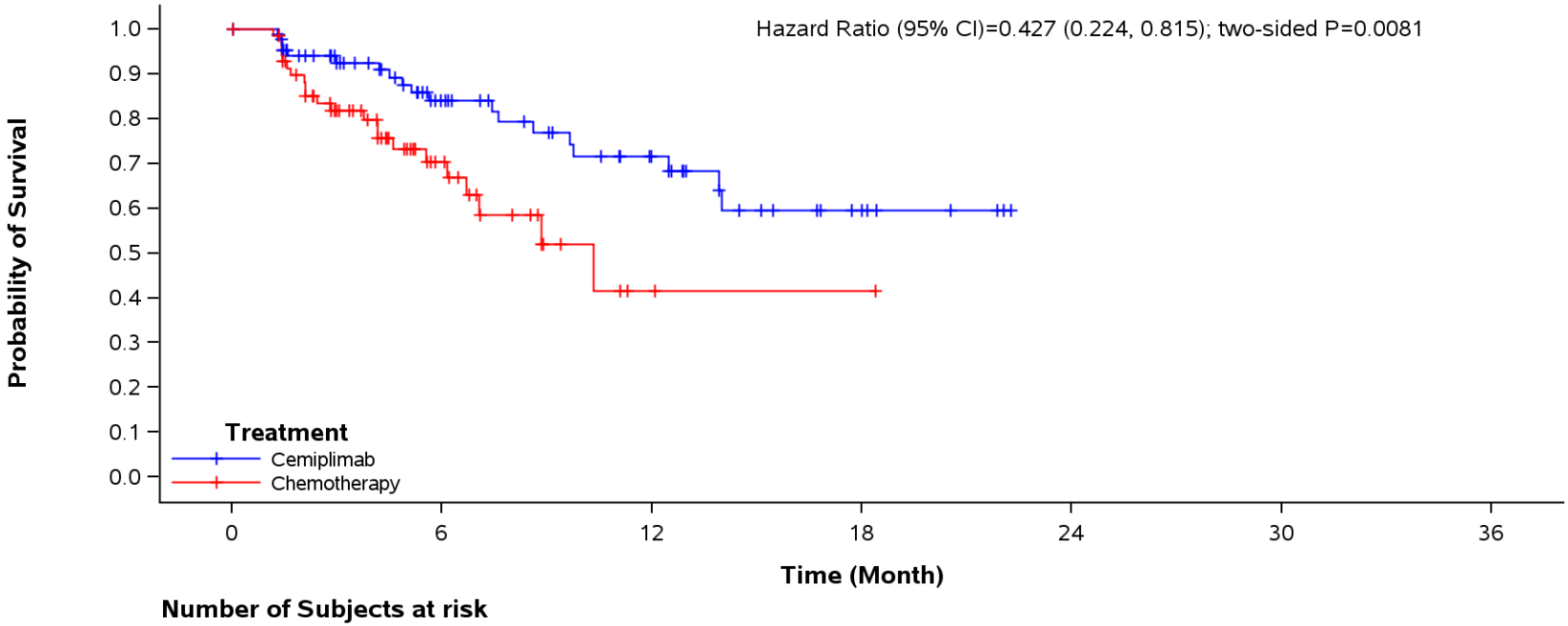
Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts sustained deterioration



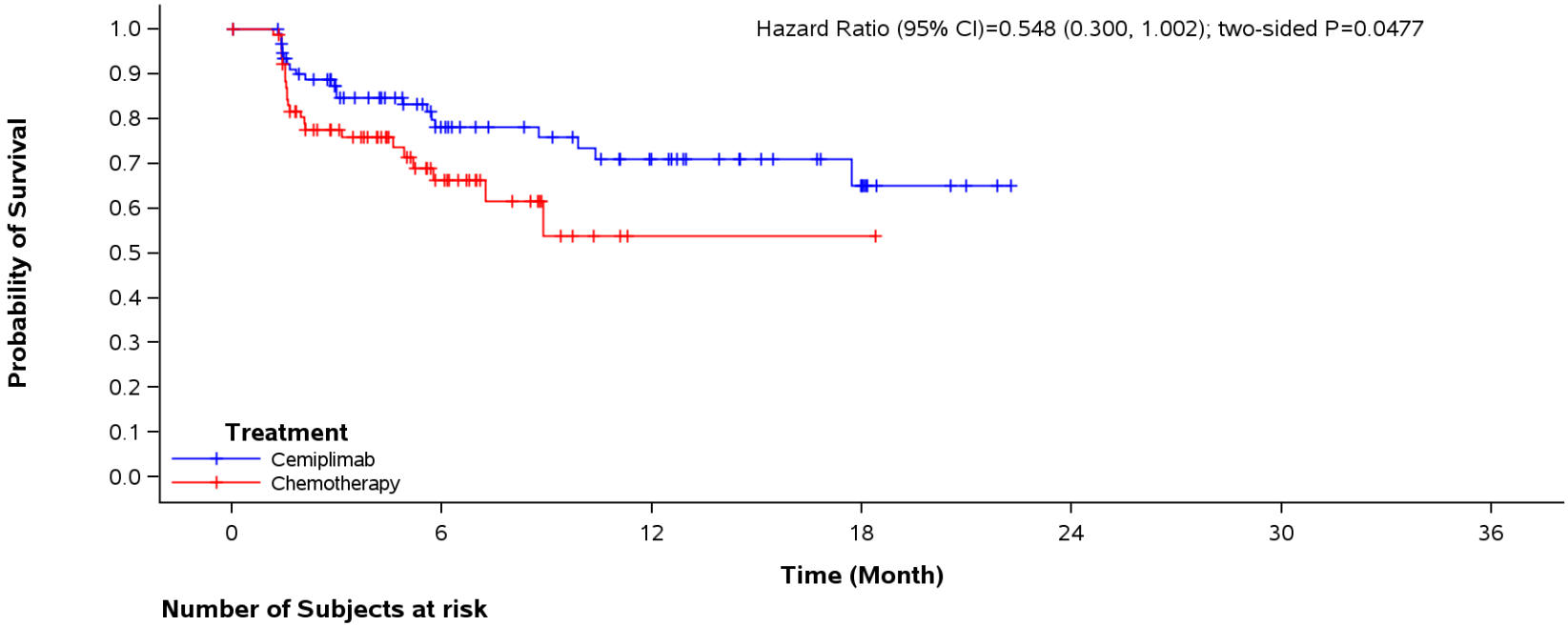

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 41 | 22 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts sustained deterioration



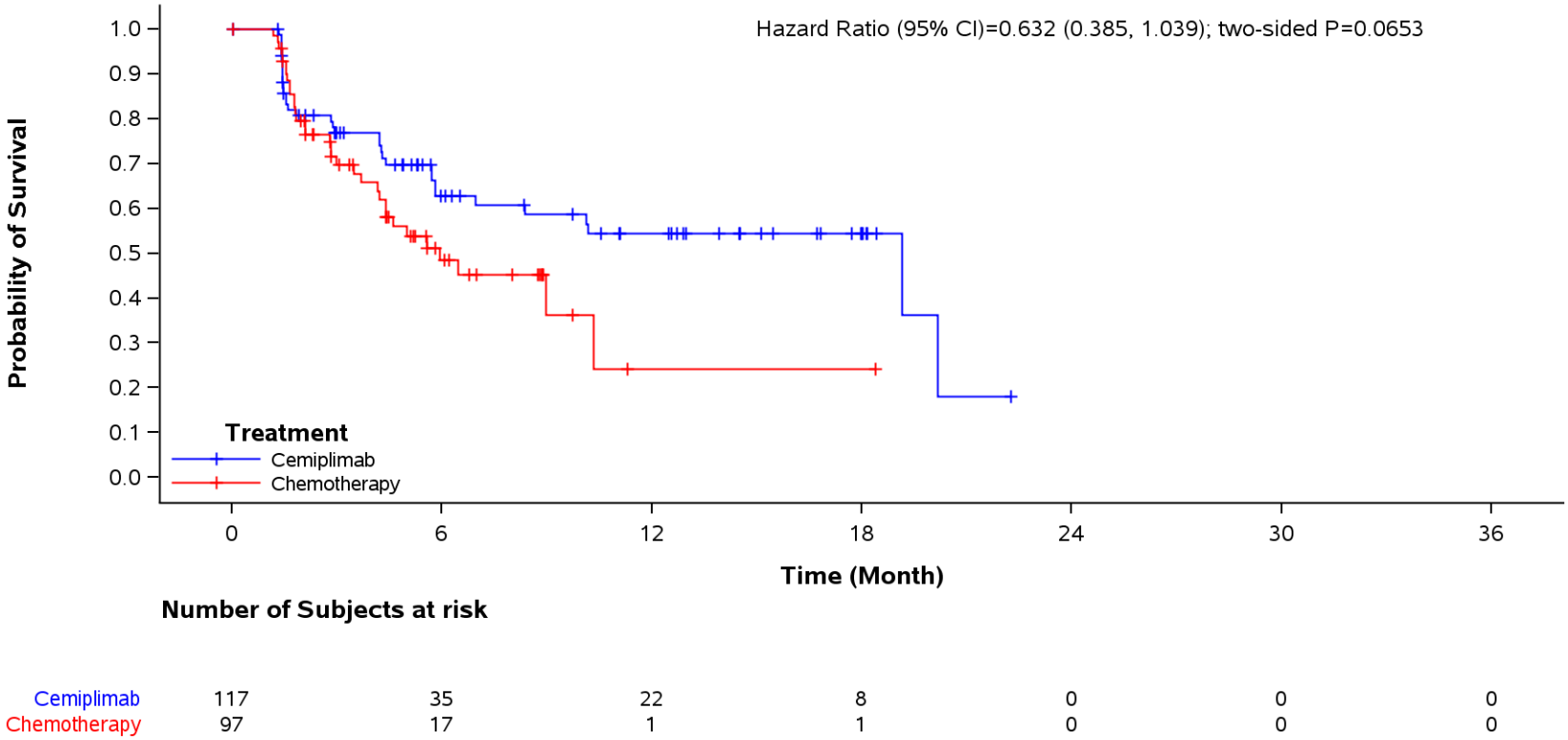

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 44 | 24 | 10 | 0 | 0 | 0 |
| Chemotherapy | 97 | 23 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

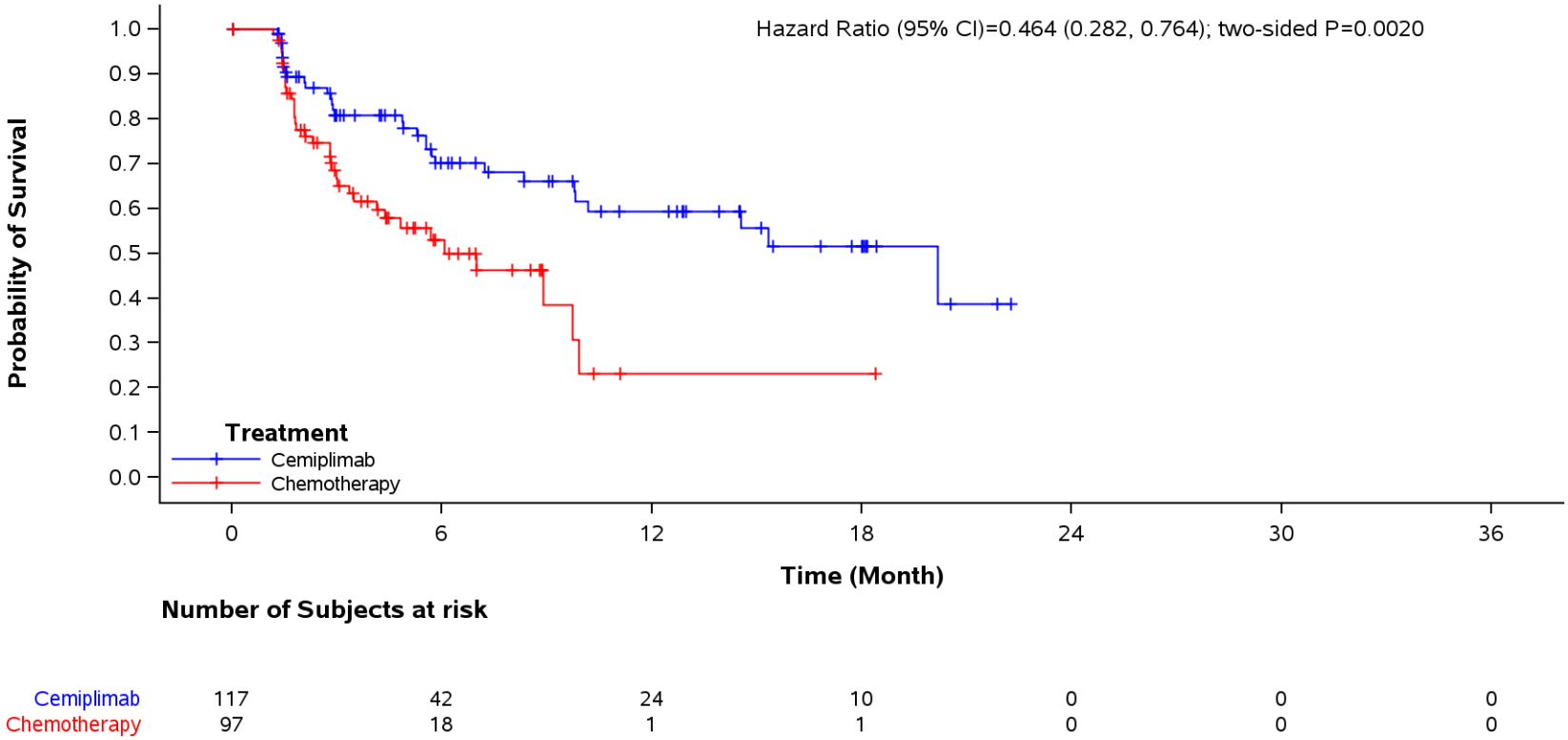
Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Pain - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Physical Functioning - 10 pts sustained deterioration



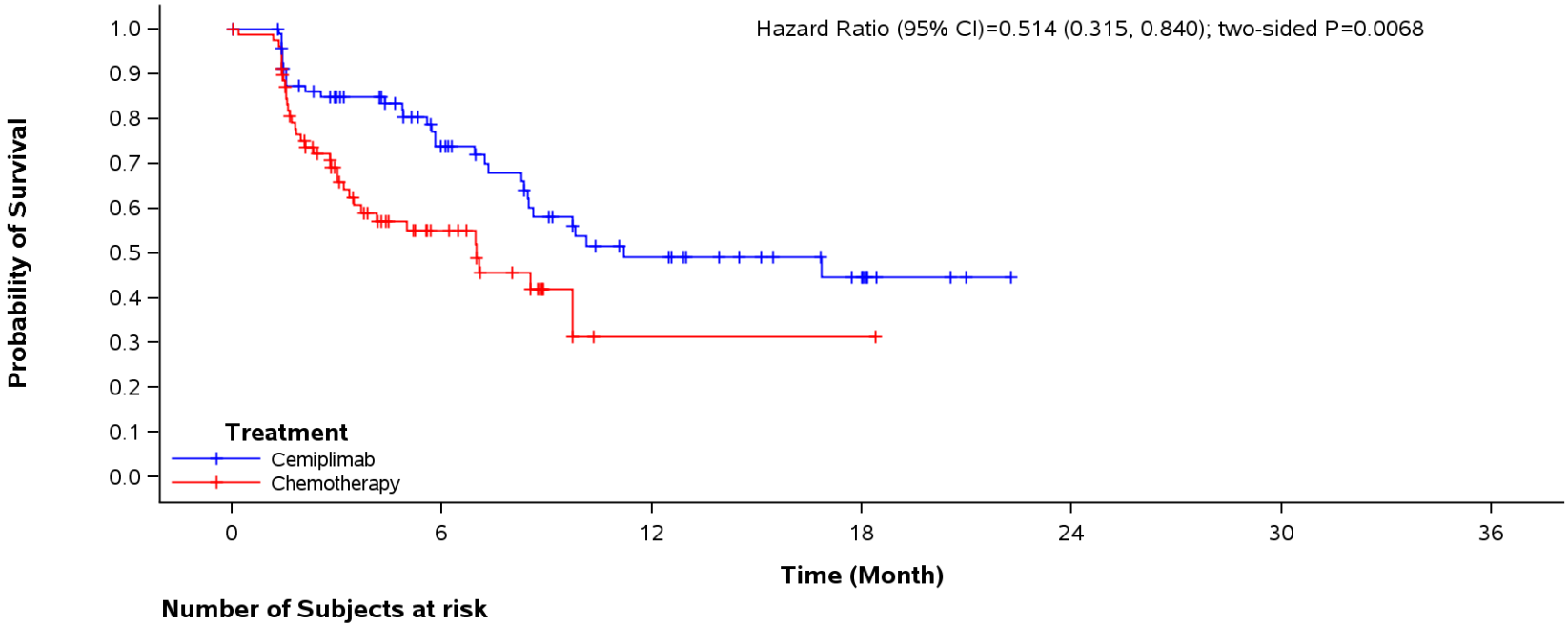

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 42 | 24 | 10 | 0 | 0 | 0 |
| Chemotherapy | 97 | 18 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts sustained deterioration



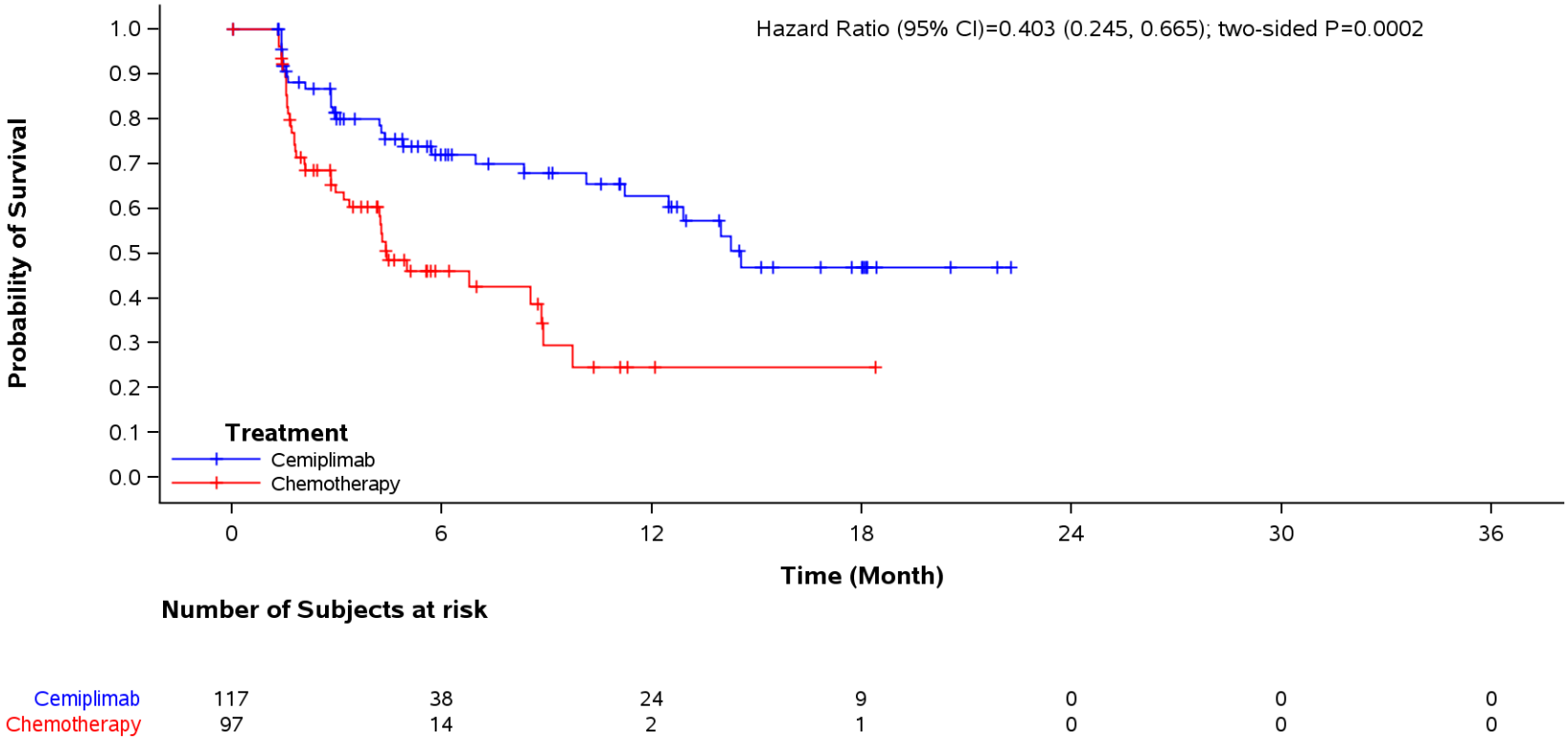

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 43 | 20 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 21 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts sustained deterioration



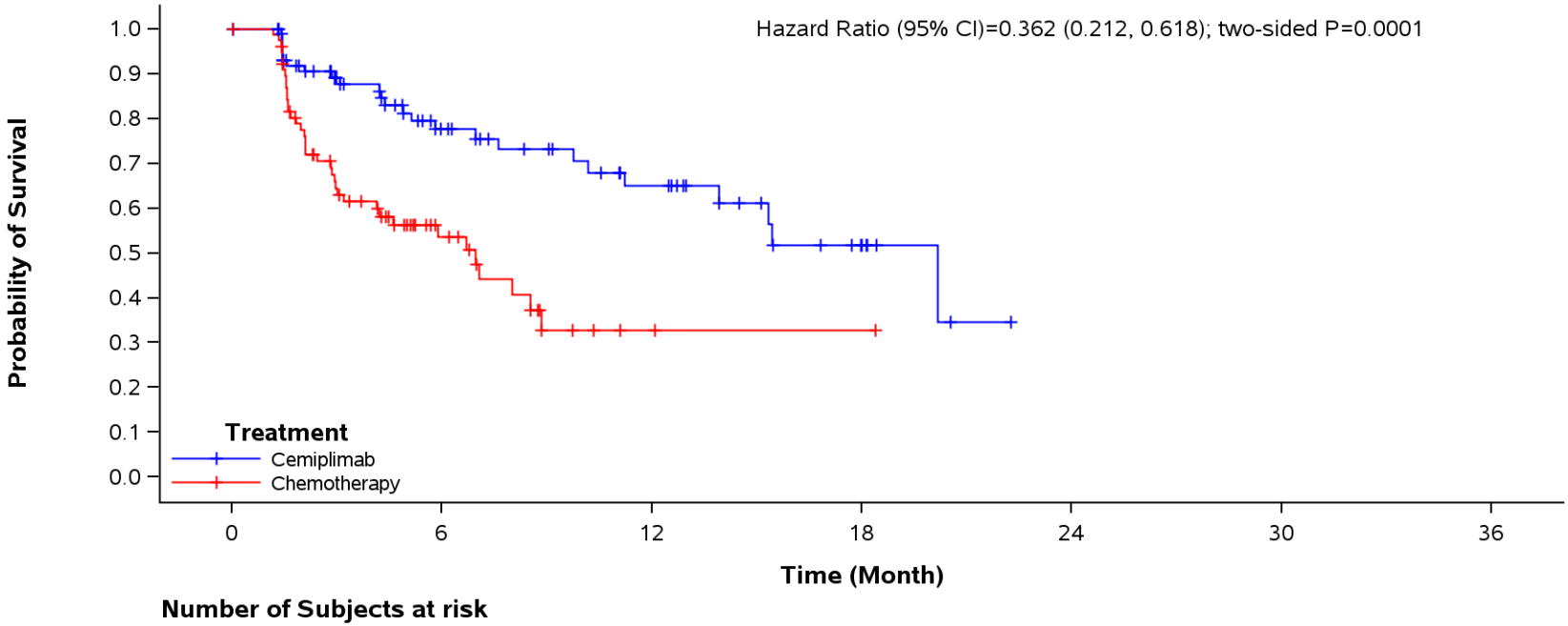

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 38 | 24 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 14 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts sustained deterioration



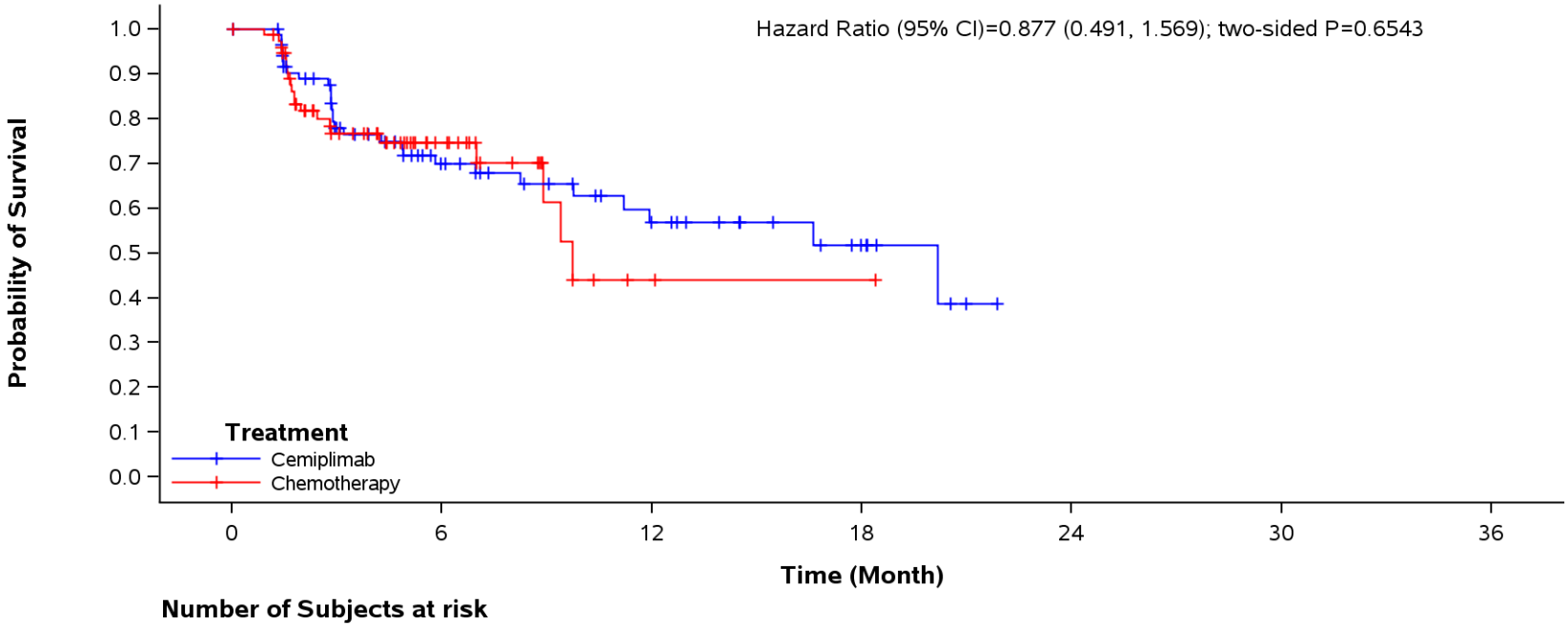

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 39 | 22 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts sustained deterioration



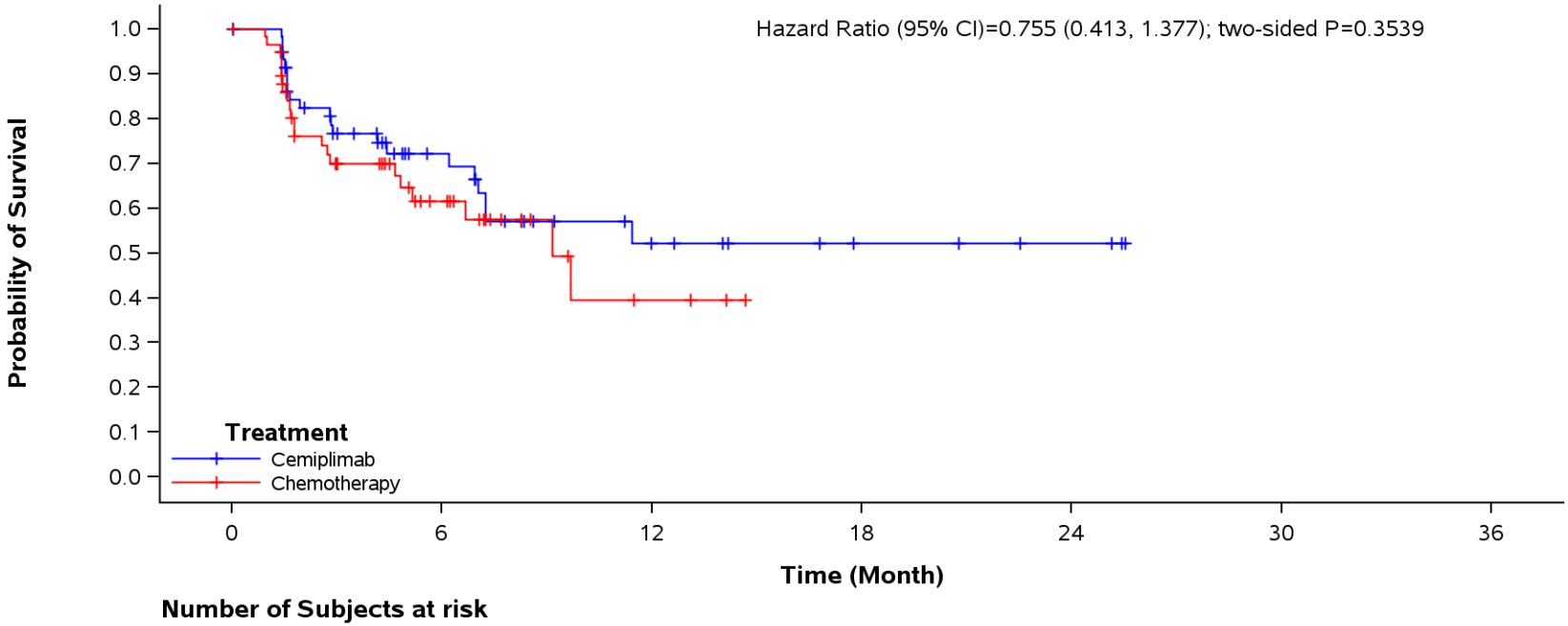

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 37 | 18 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 23 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts sustained deterioration



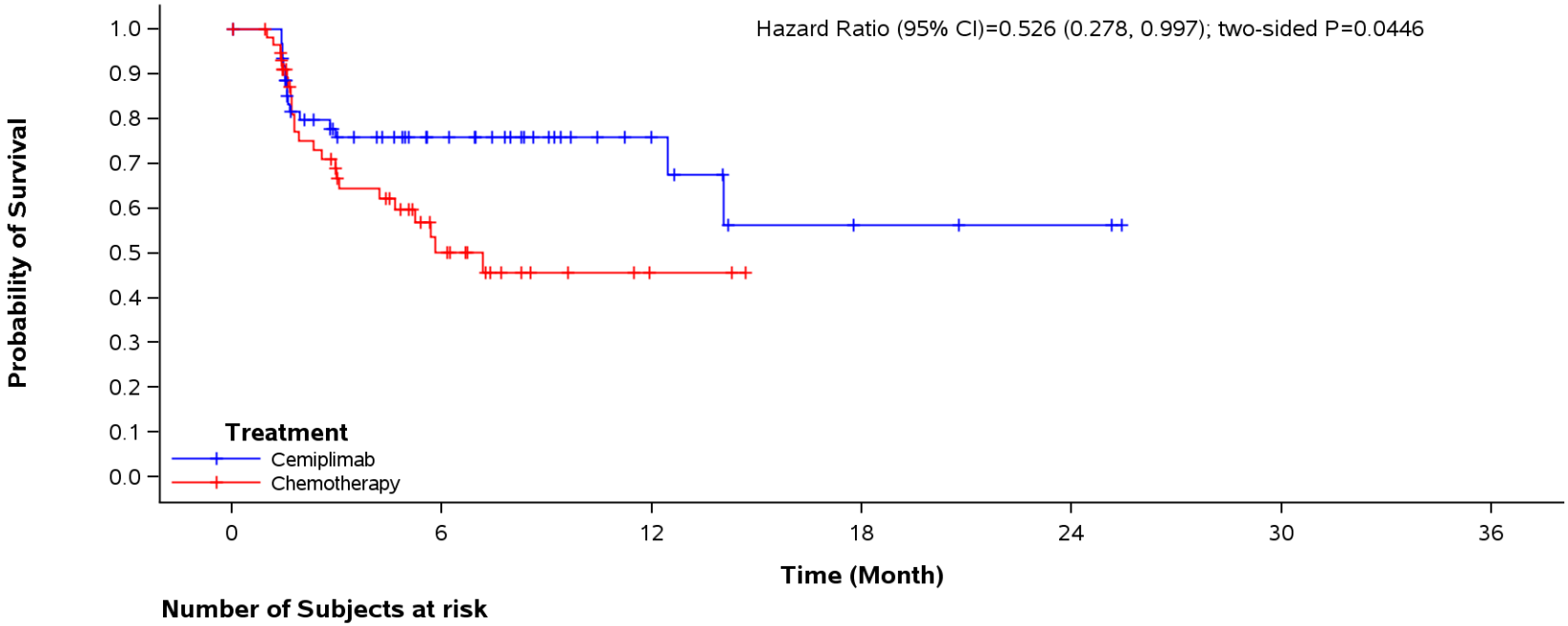

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 25 | 10 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts sustained deterioration



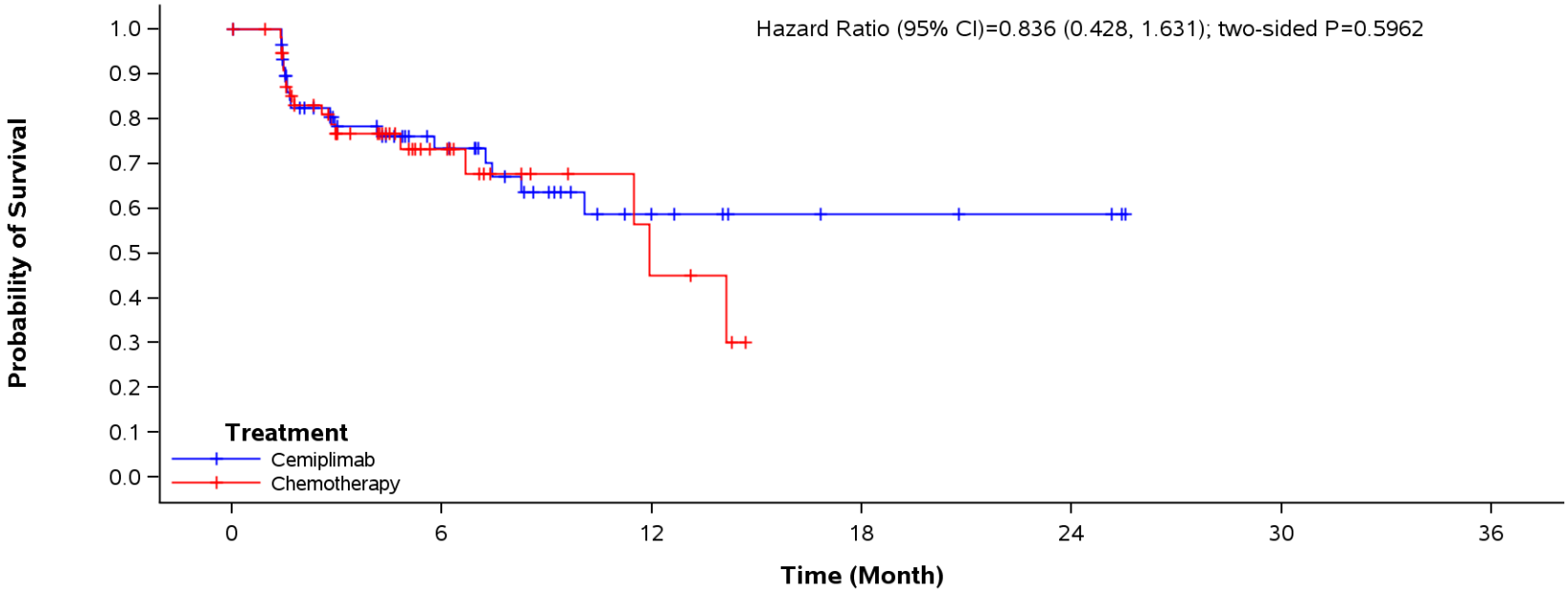

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 27 | 9 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts sustained deterioration



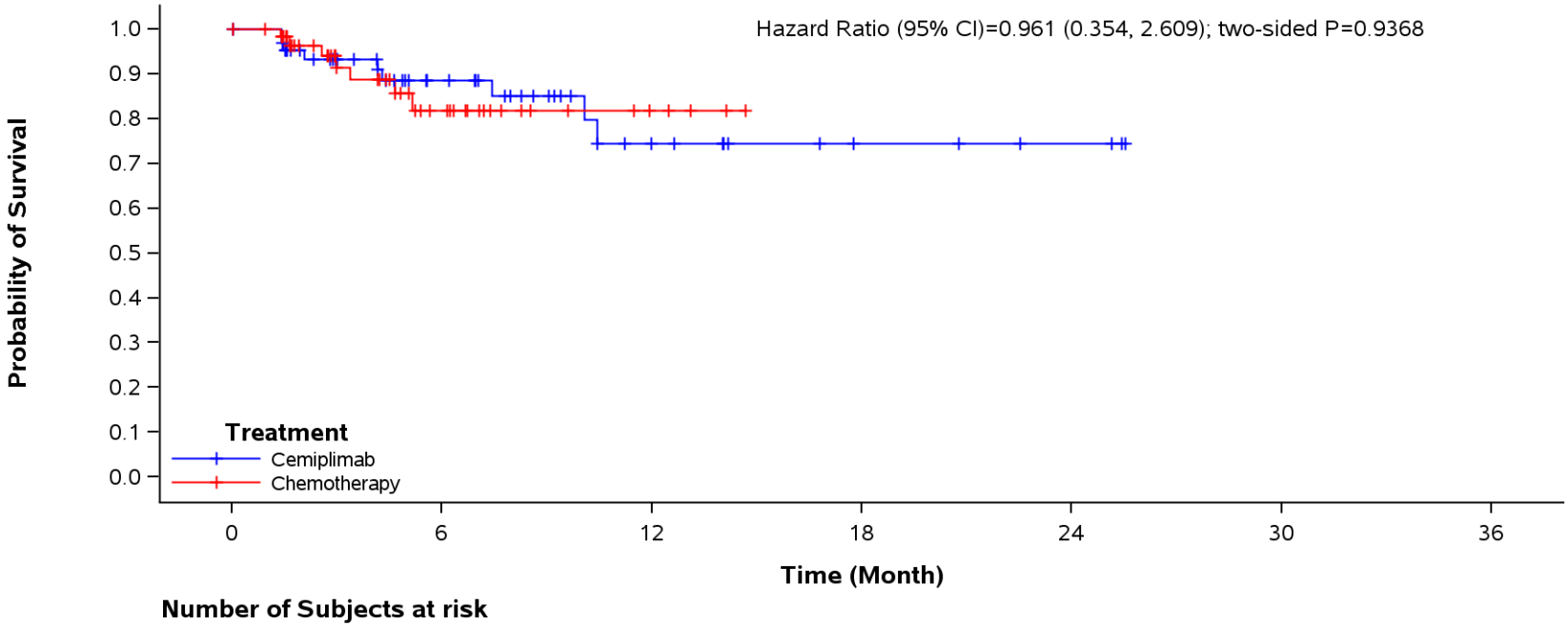

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 27 | 8 | 4 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts sustained deterioration



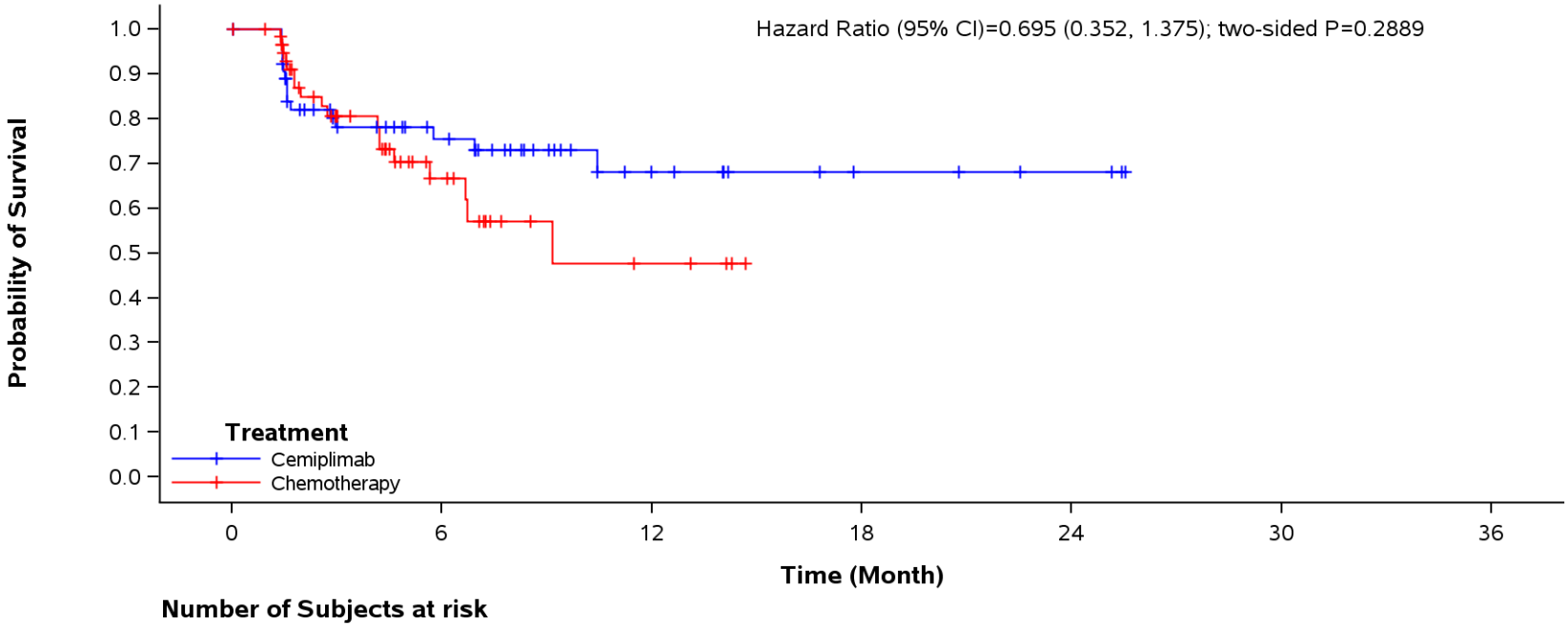

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 29 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 18 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts sustained deterioration



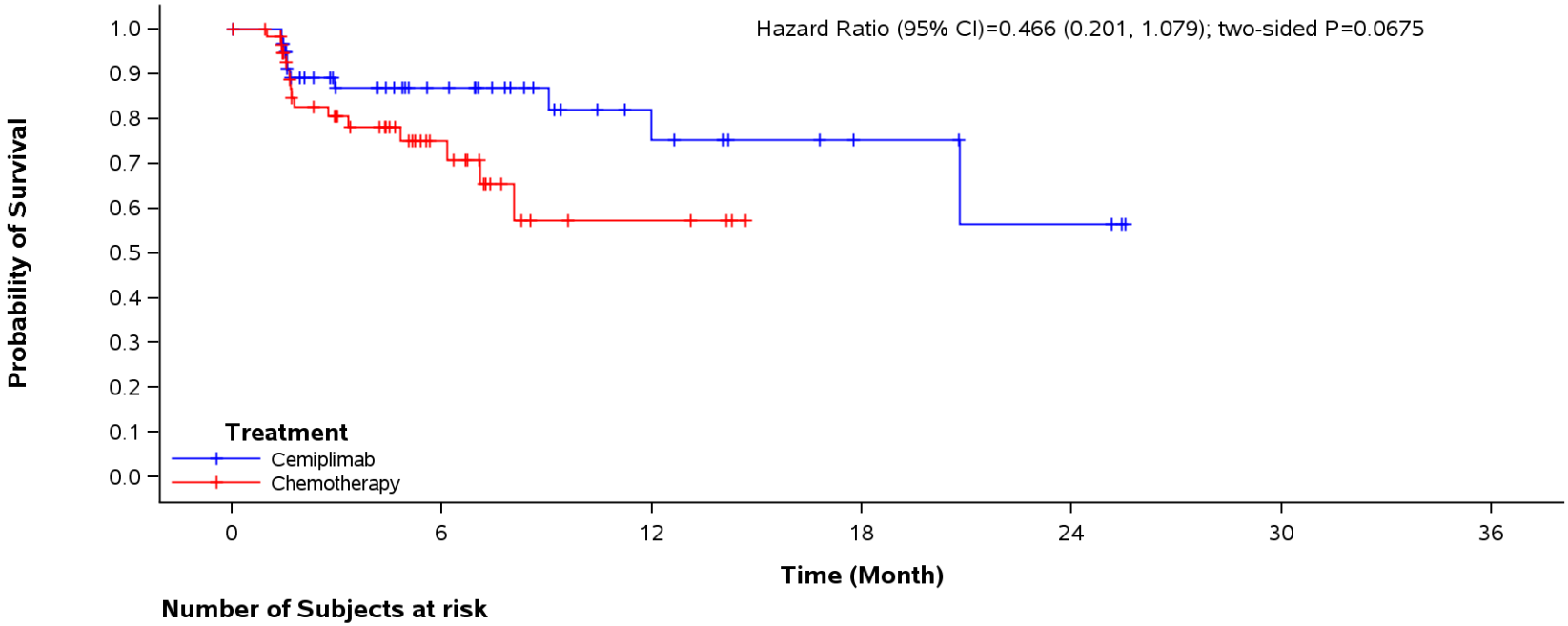

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 30 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts sustained deterioration



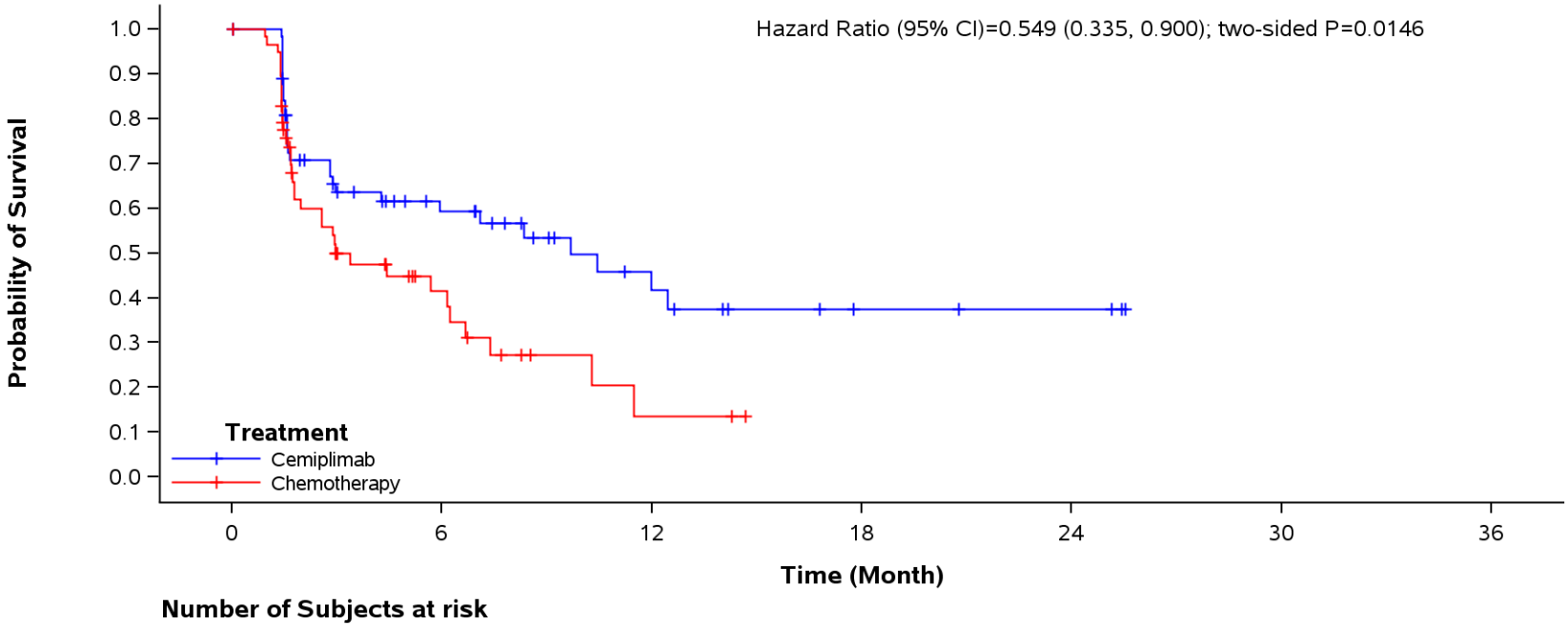

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 28 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 18 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts sustained deterioration



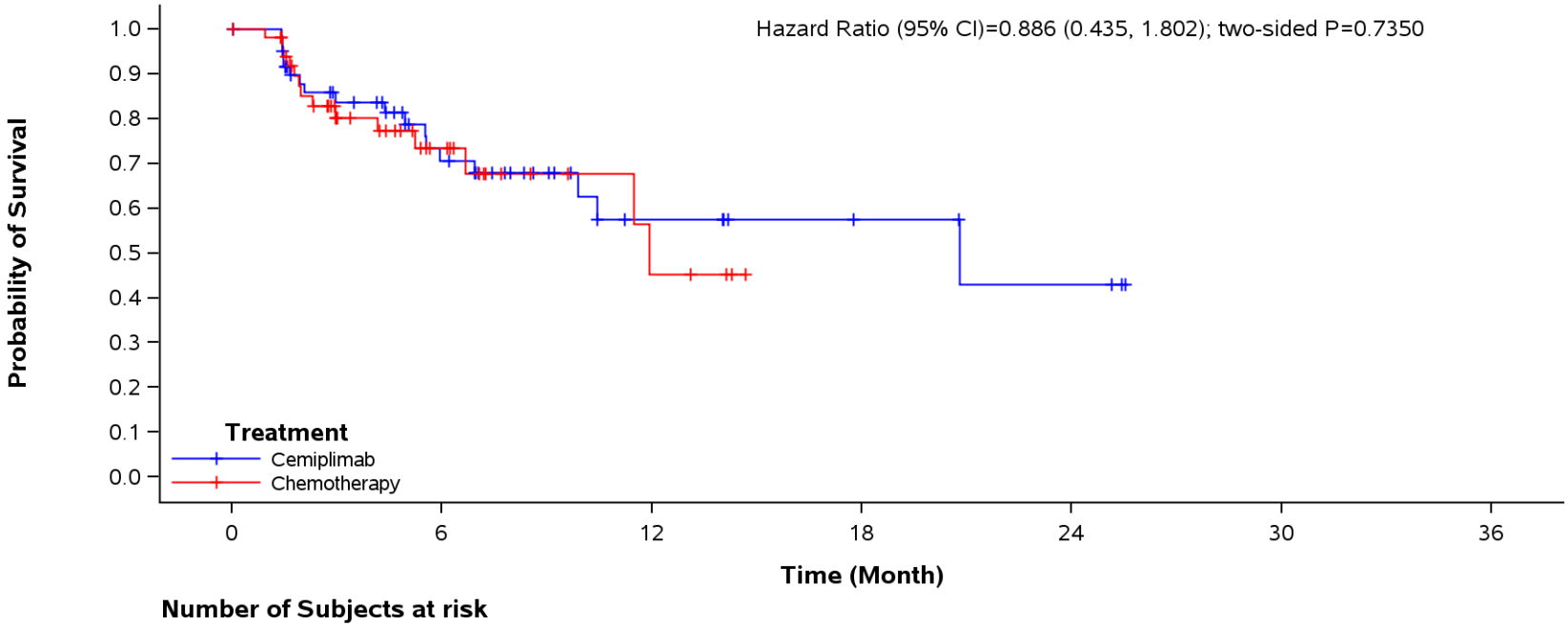

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 25 | 10 | 4 | 3 | 0 | 0 |
| Chemotherapy | 86 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts sustained deterioration



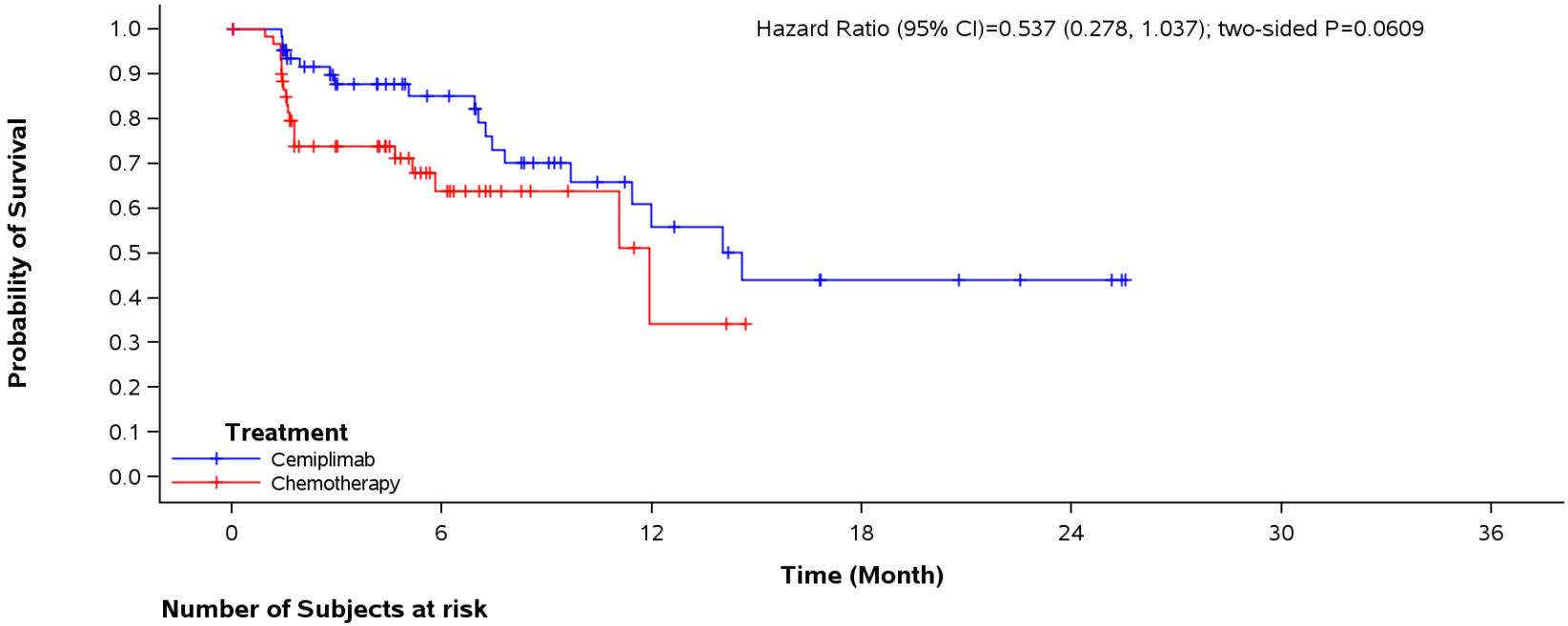

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 26 | 9 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts sustained deterioration



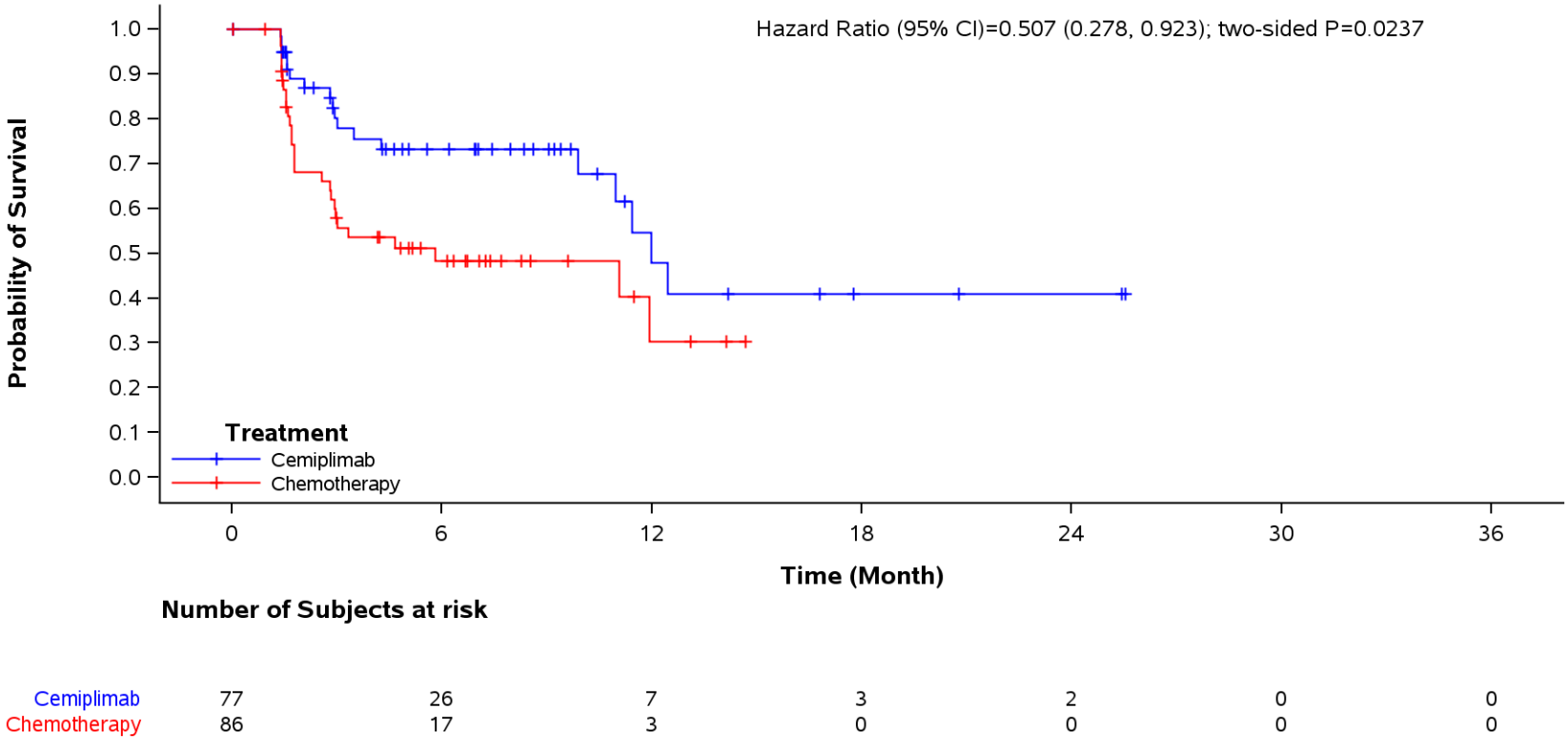

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 31 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts sustained deterioration



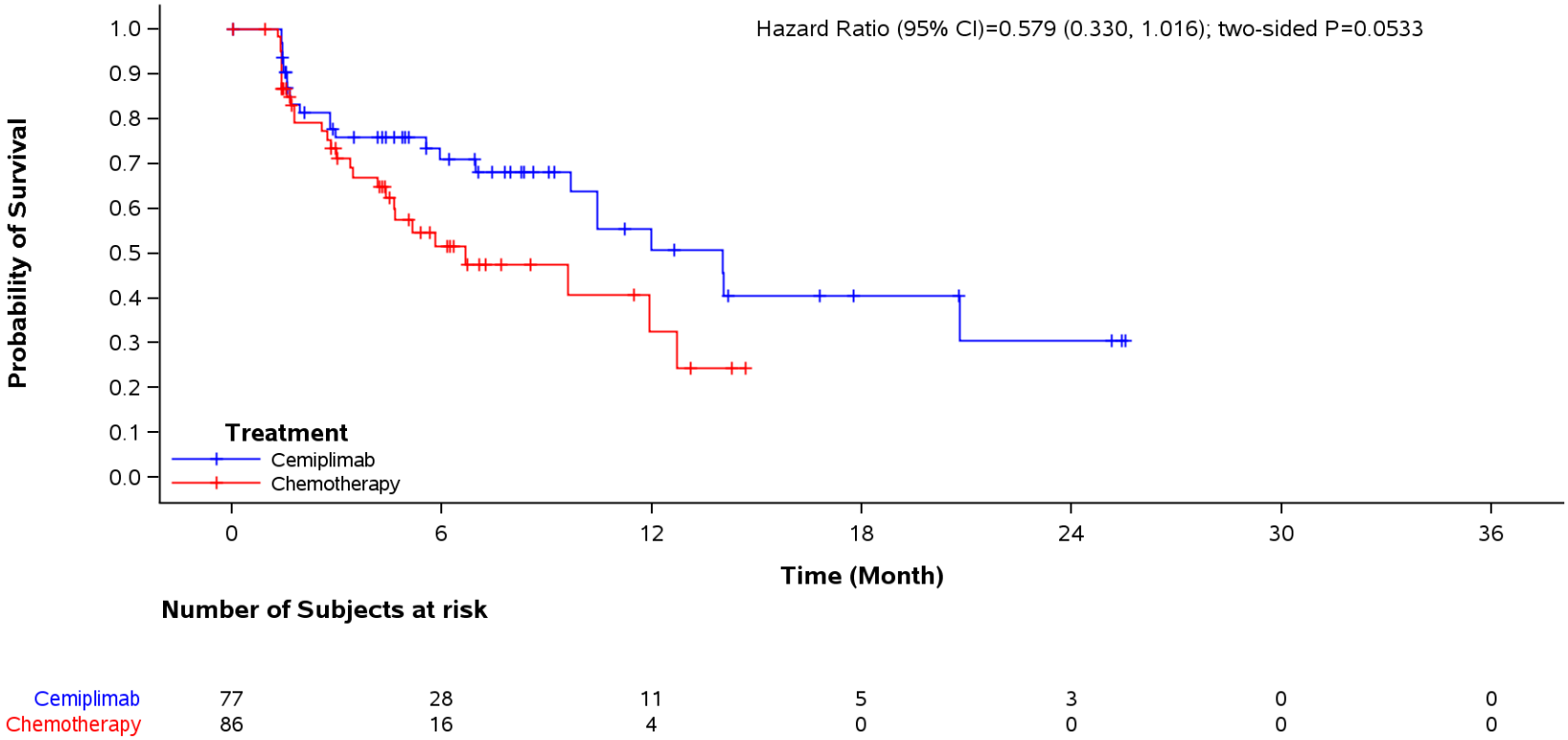

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 26 | 7 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts sustained deterioration



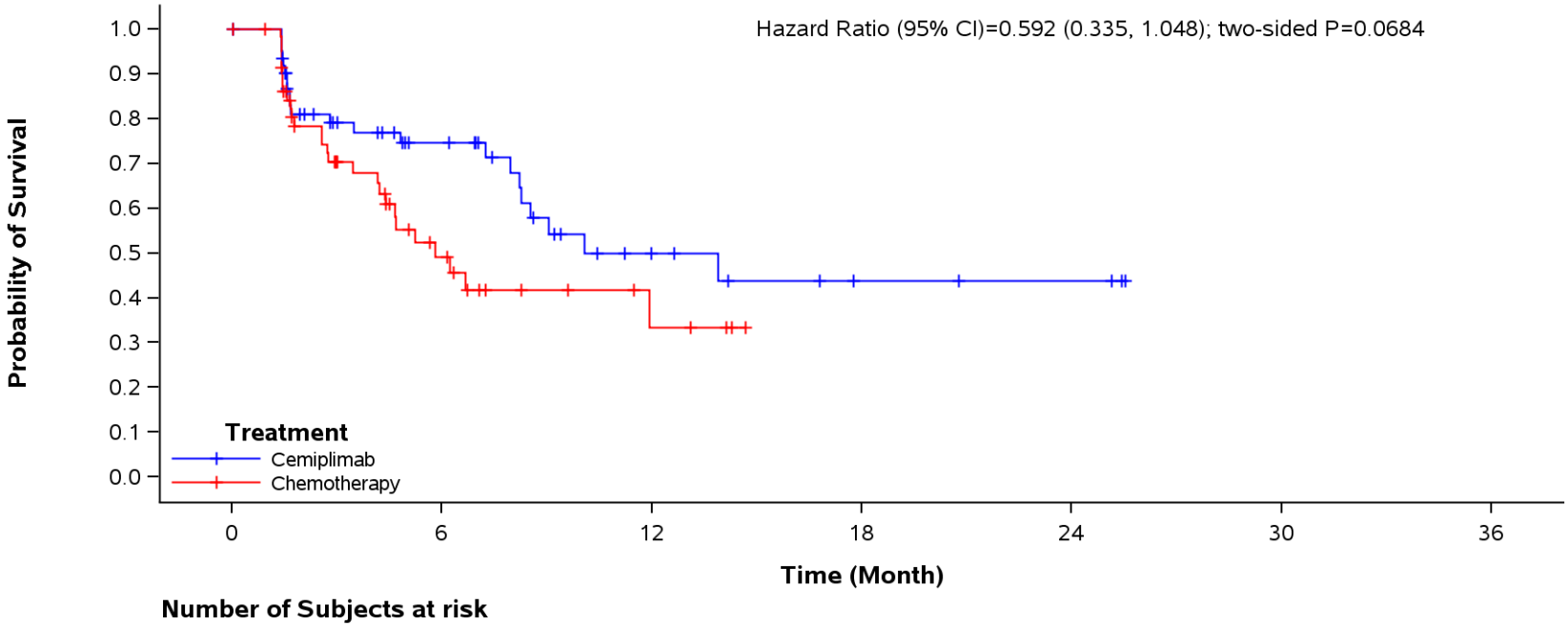

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 28 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts sustained deterioration




**Number of Subjects at risk**

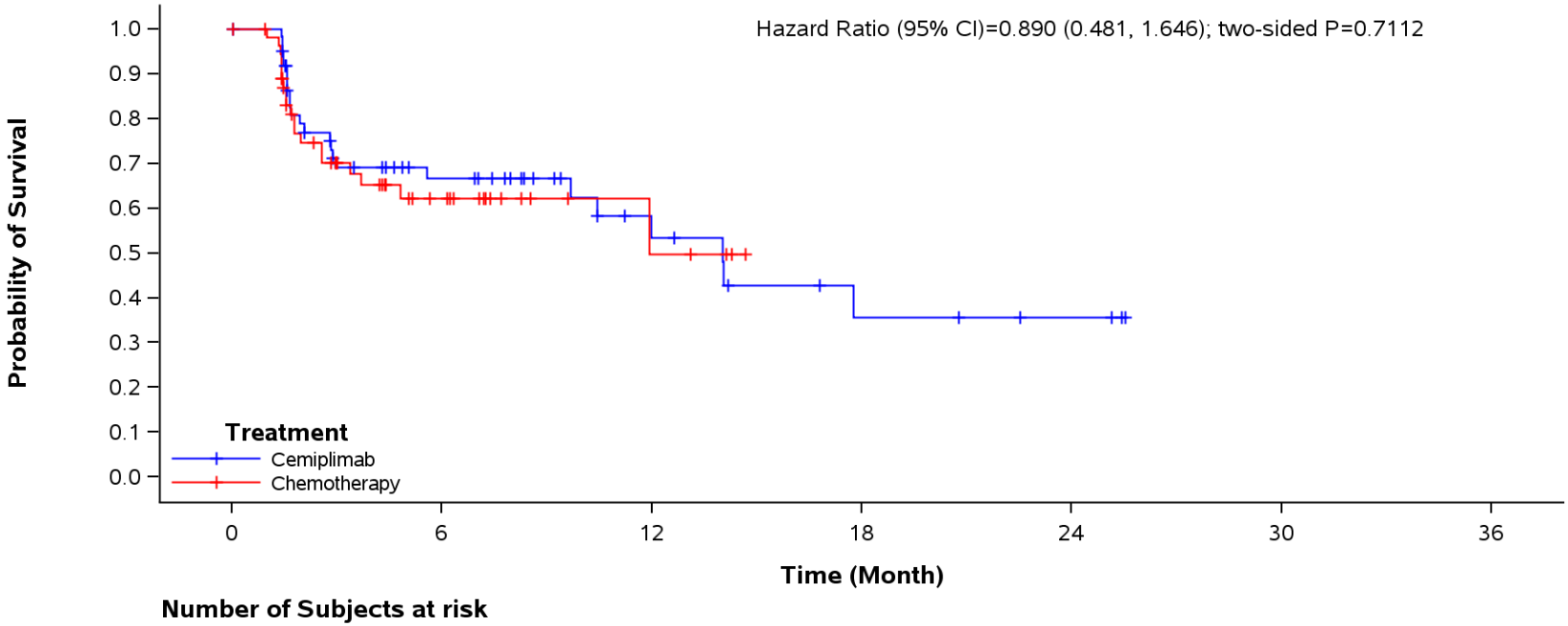
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 28 | 9 | 4 | 3 | 0 | 0 |
| Chemotherapy | 86 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

Role Functioning - 10 pts sustained deterioration




**Number of Subjects at risk**

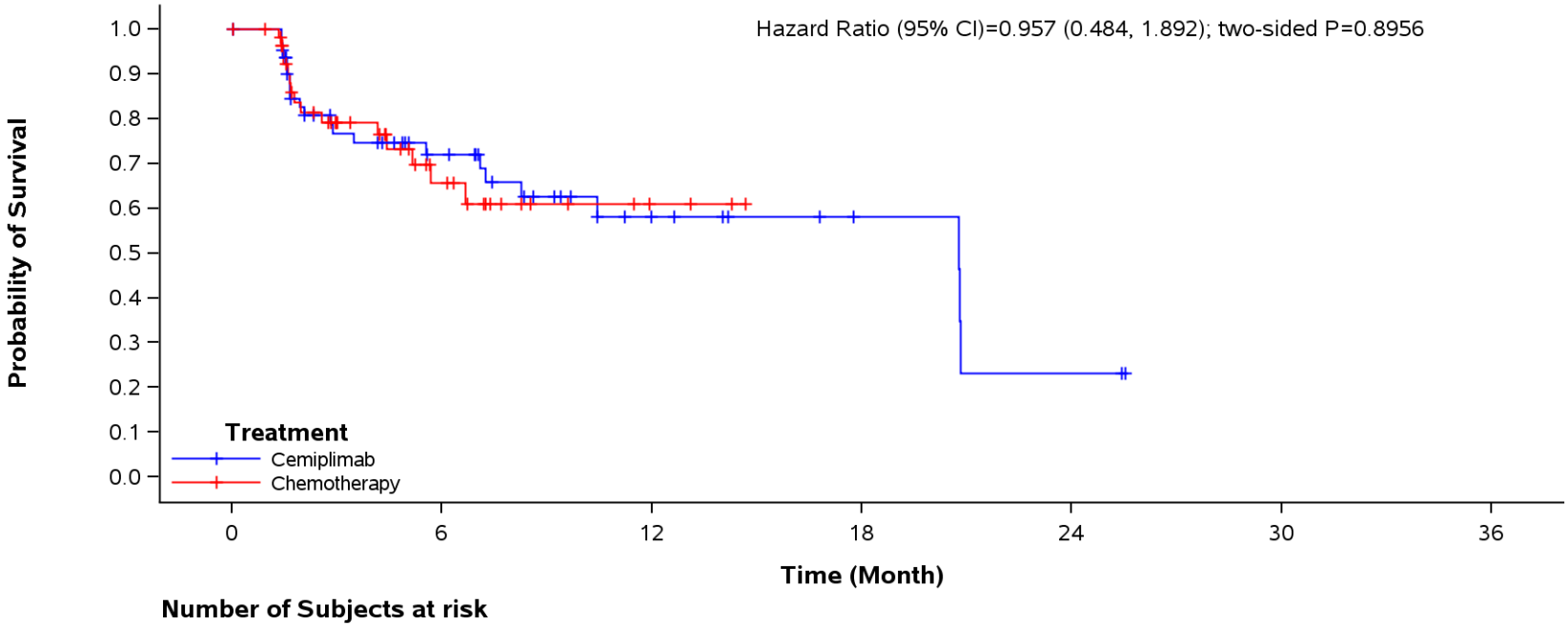
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 27 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts sustained deterioration



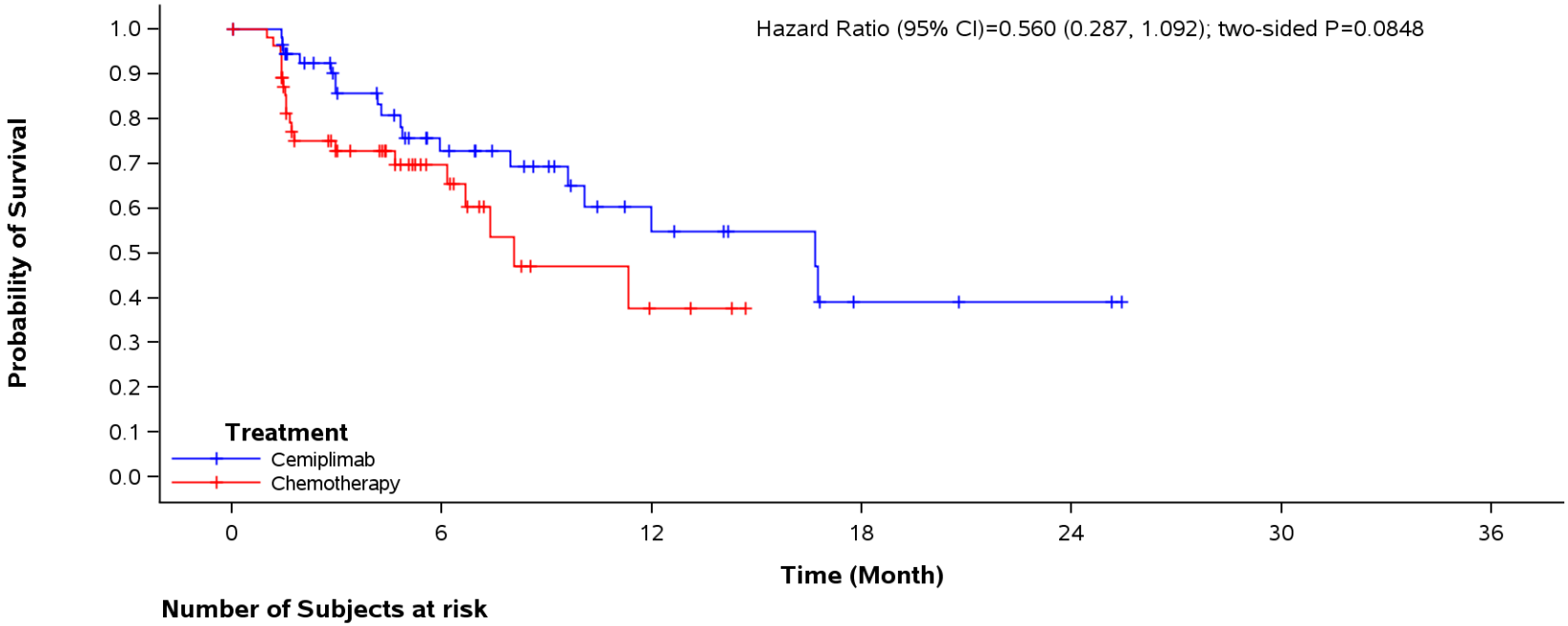

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 28 | 10 | 5 | 2 | 0 | 0 |
| Chemotherapy | 86 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts sustained deterioration



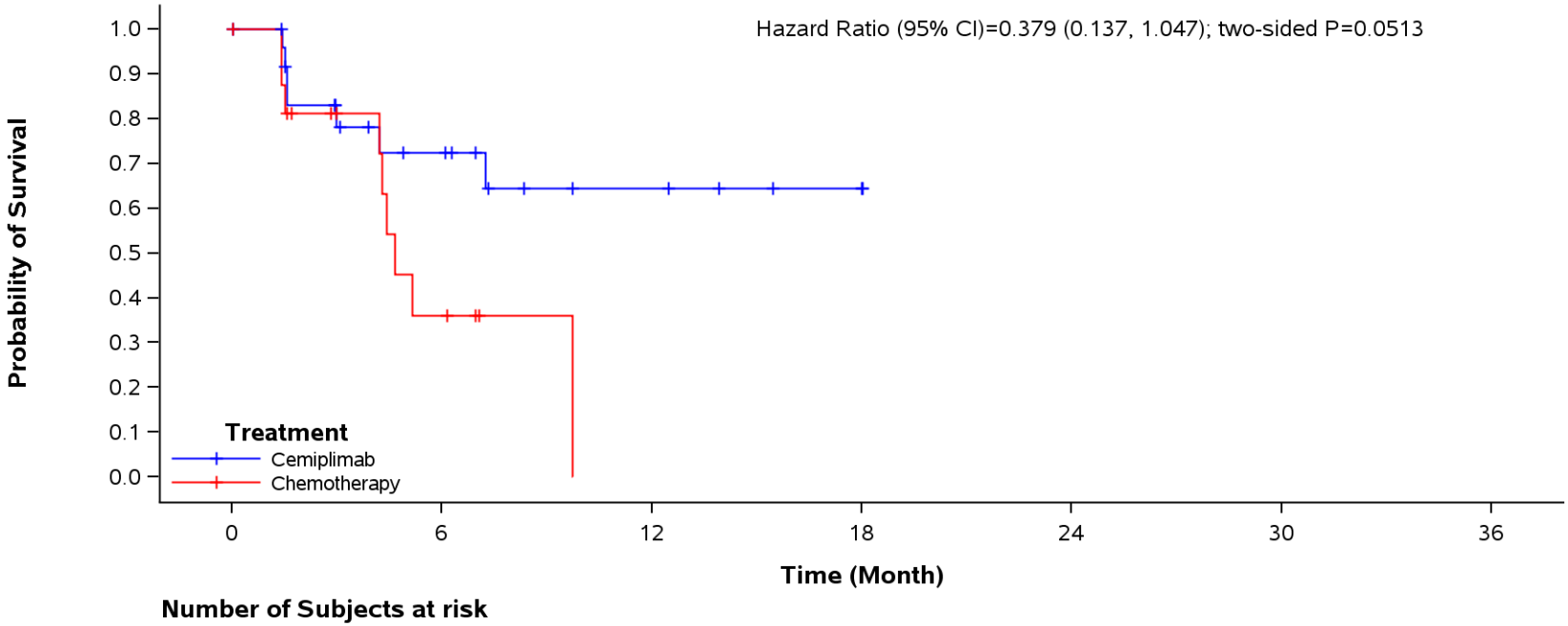

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 25 | 10 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts sustained deterioration



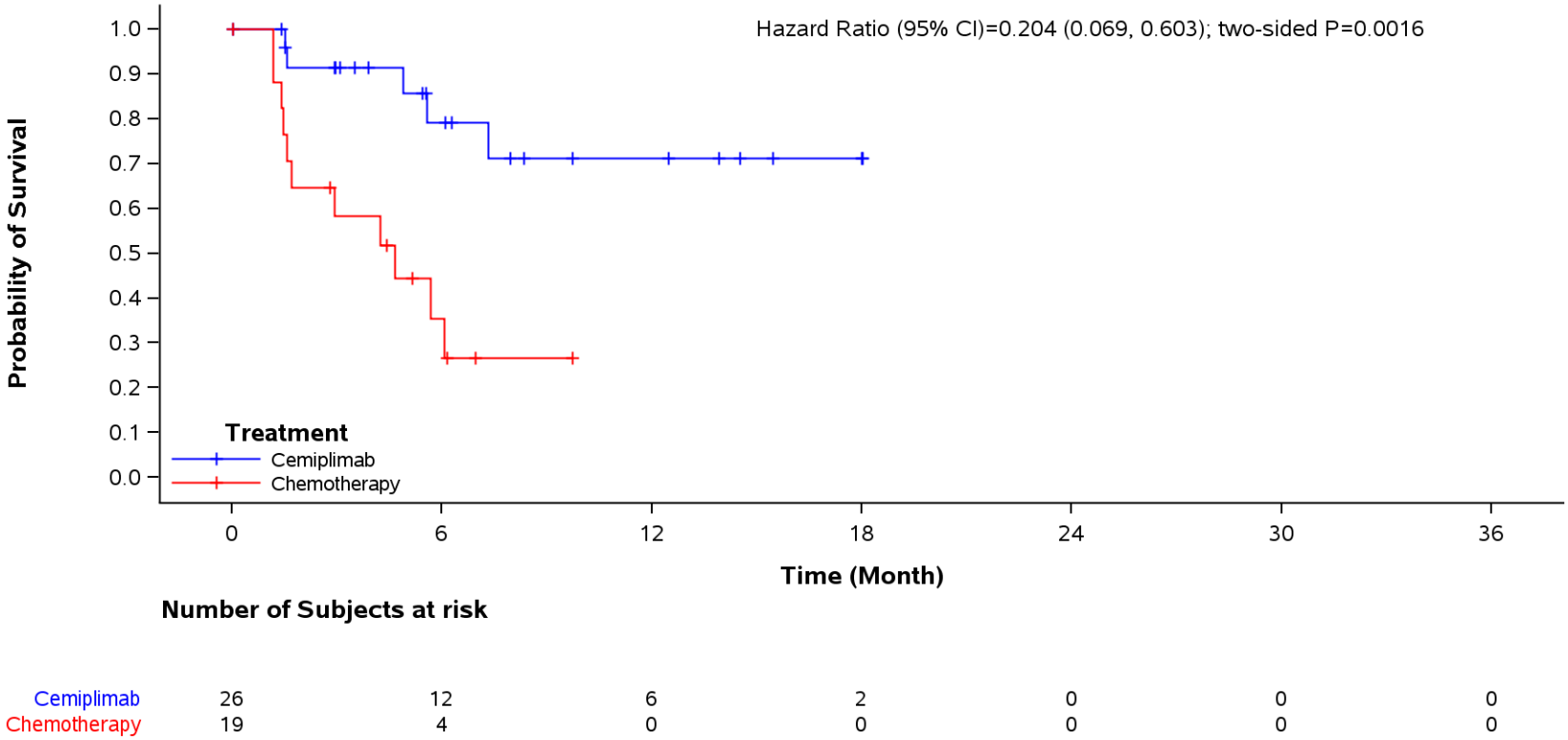

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts sustained deterioration



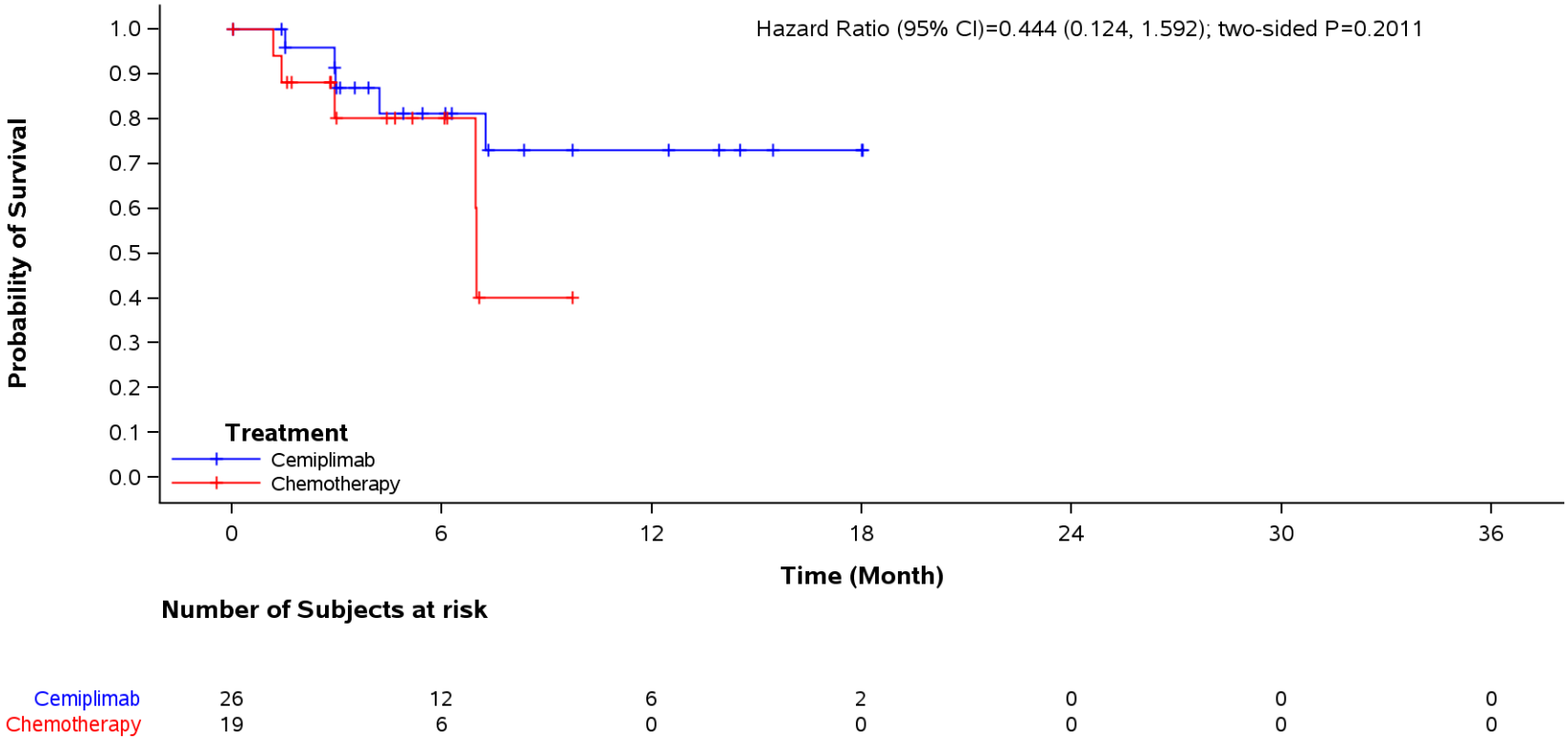

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts sustained deterioration



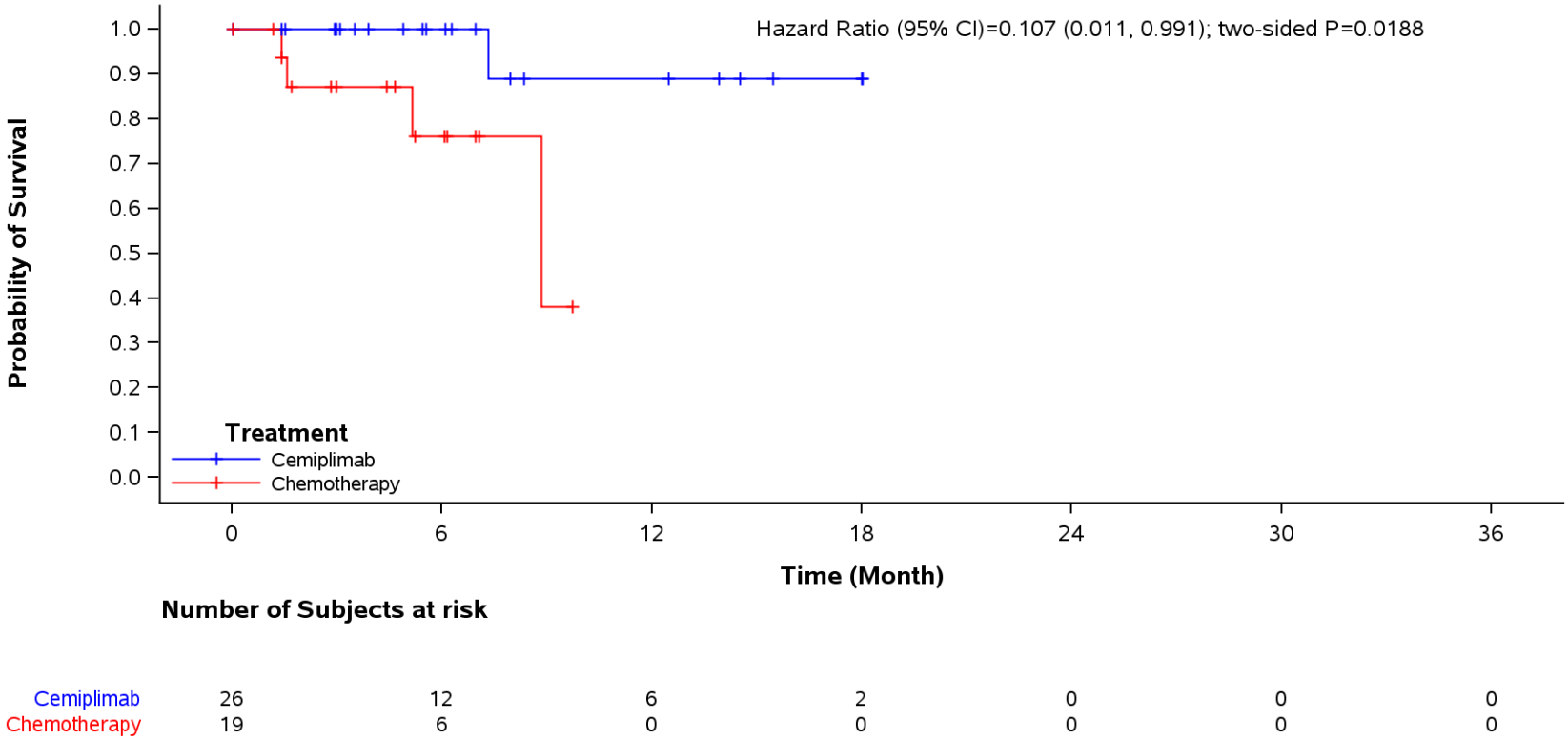

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts sustained deterioration



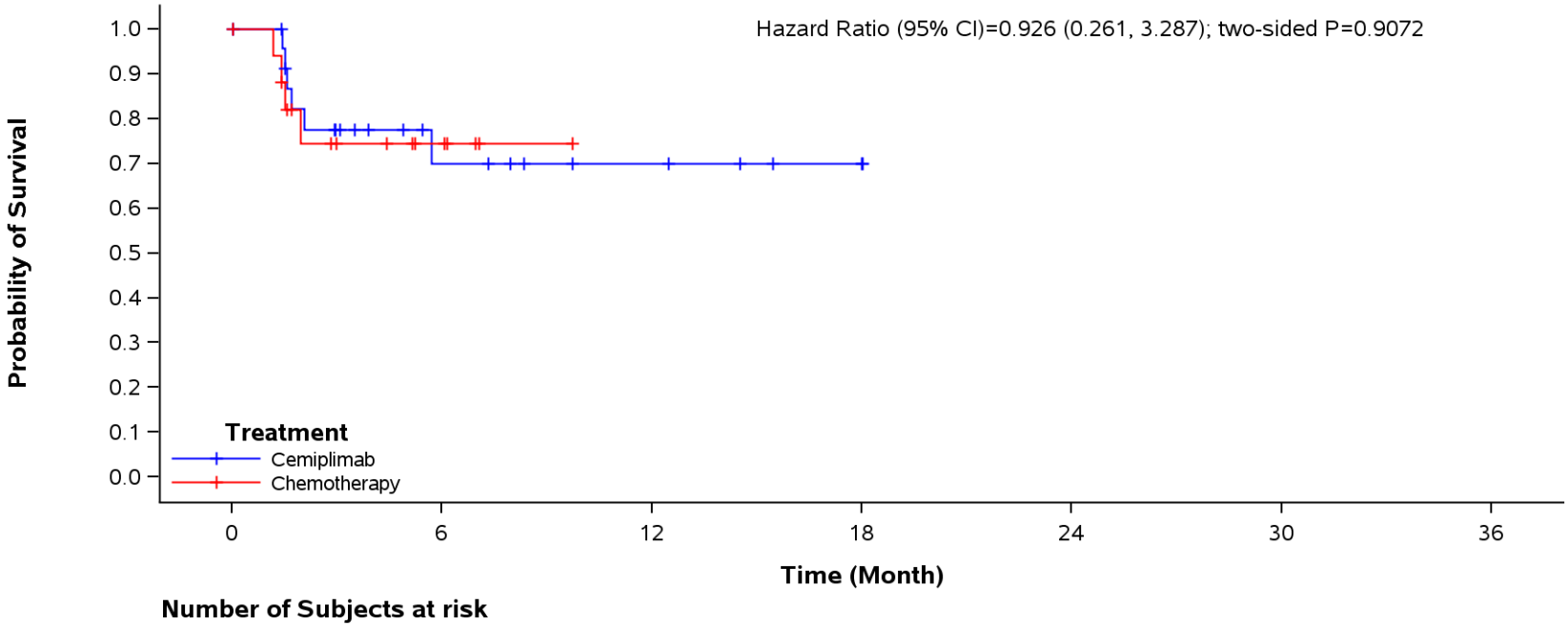

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts sustained deterioration



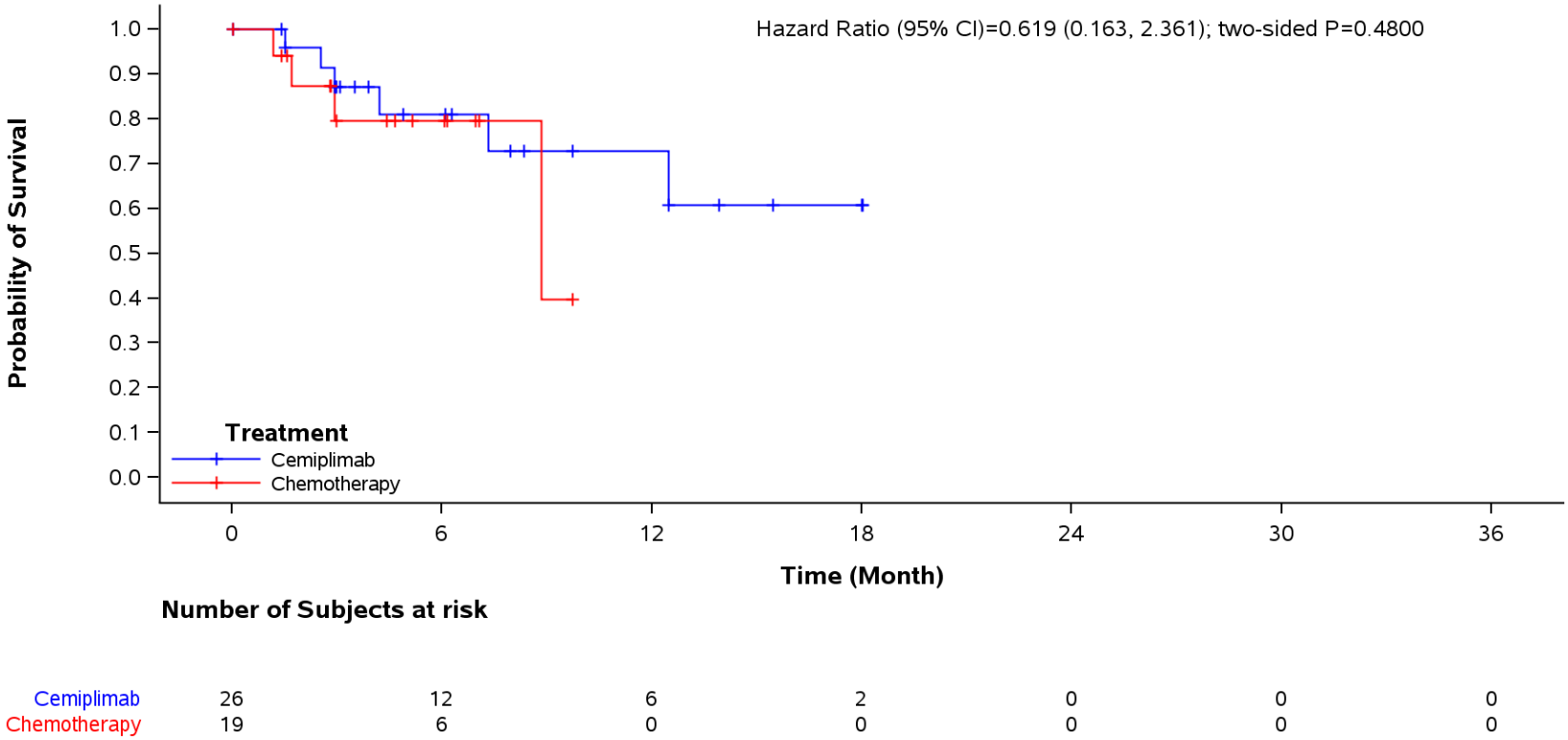

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 9 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts sustained deterioration



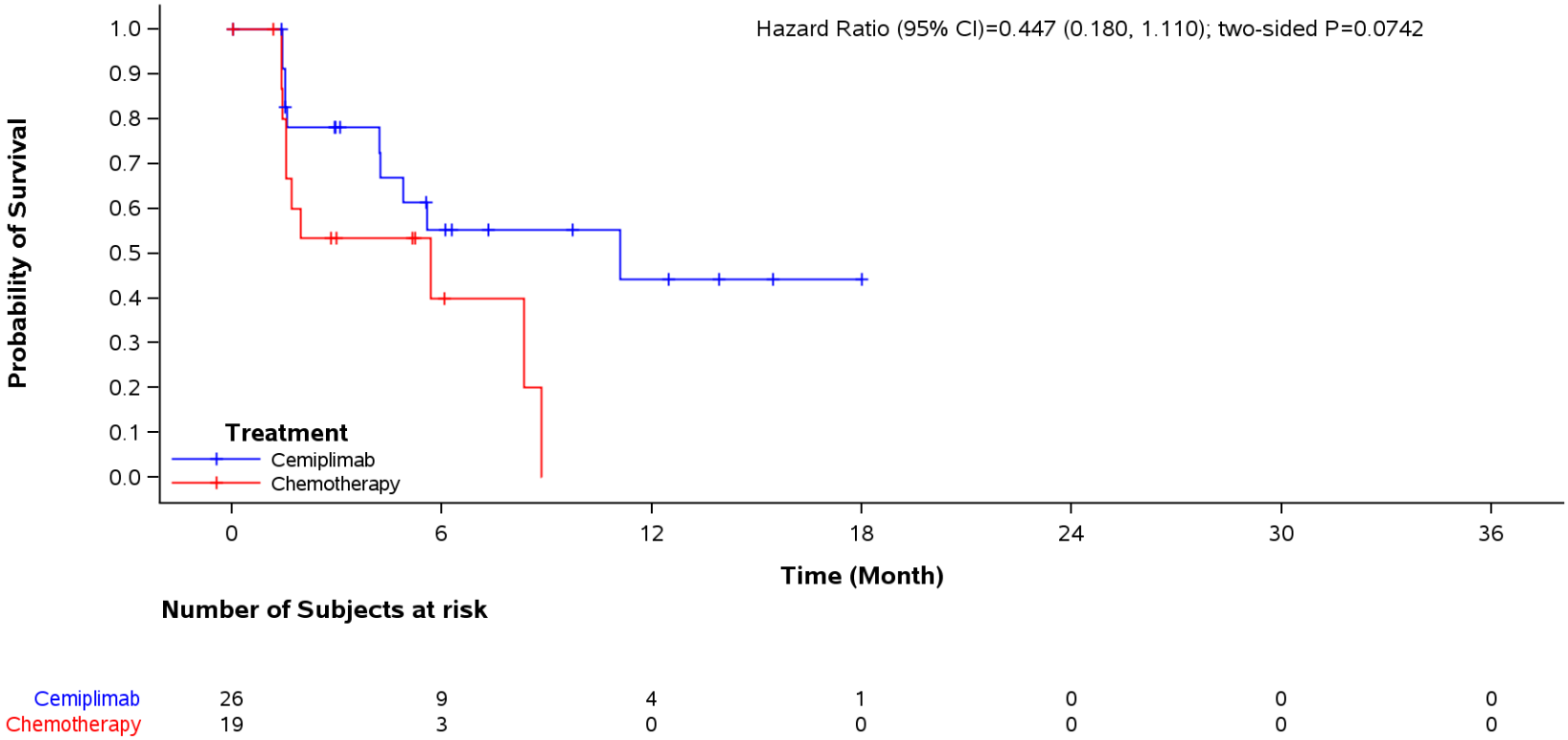

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts sustained deterioration



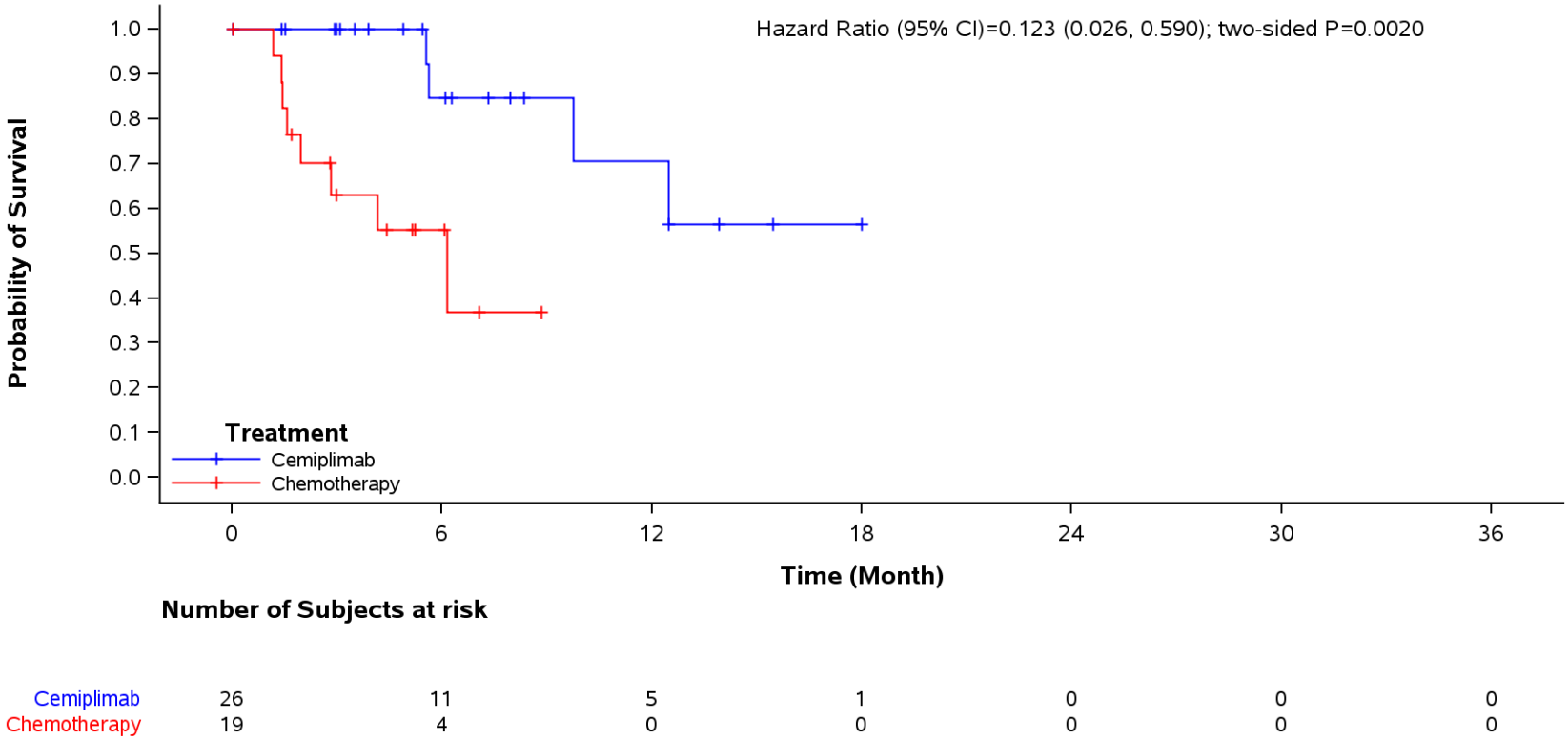

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 9 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts sustained deterioration



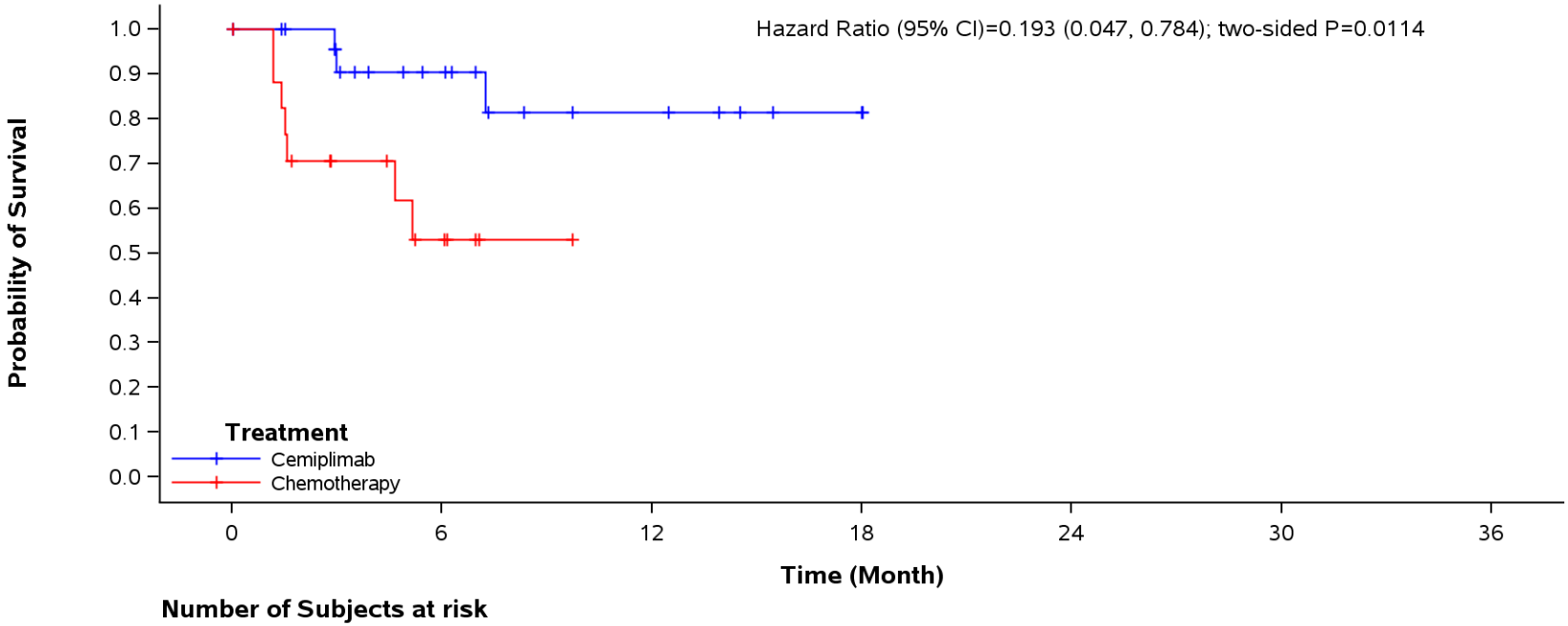

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts sustained deterioration



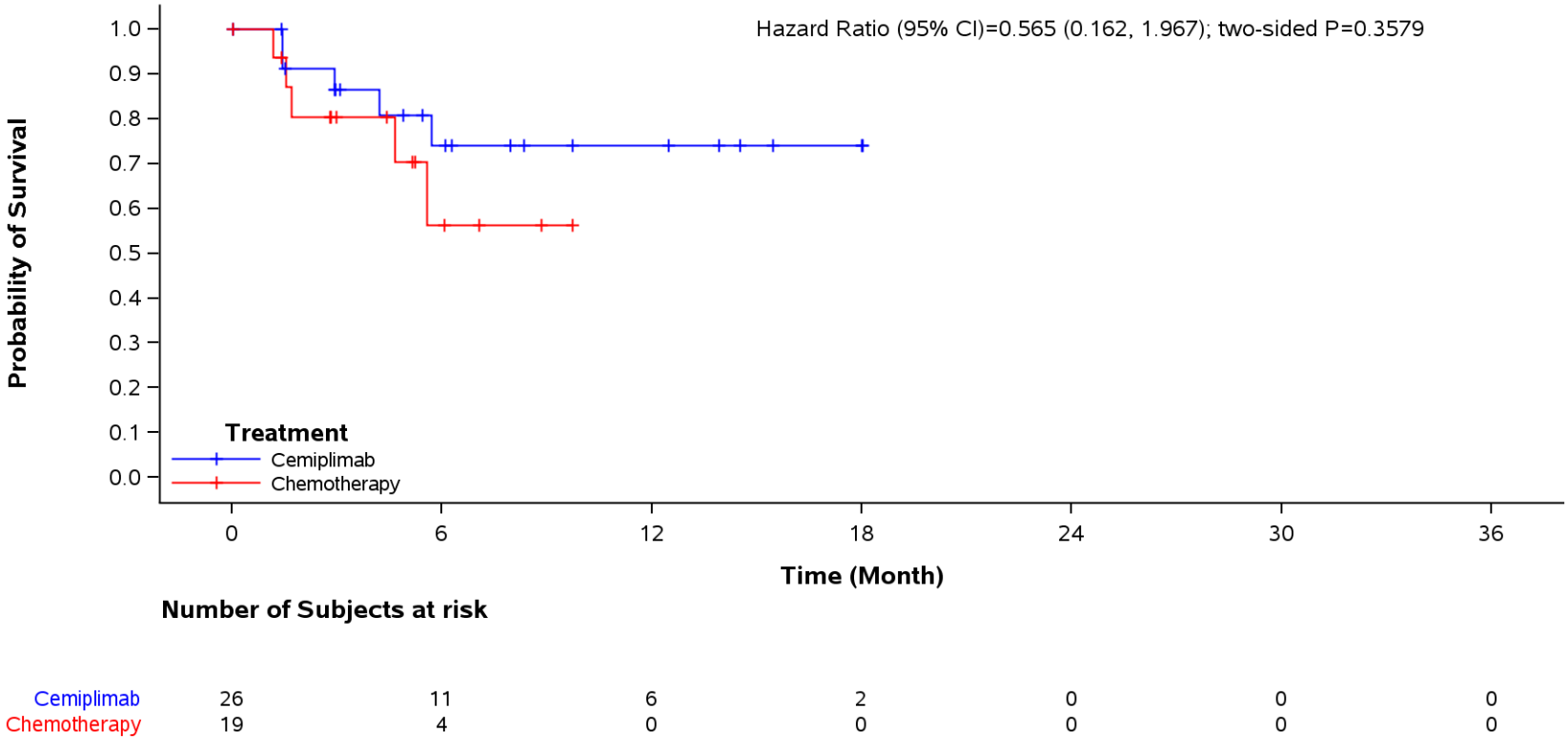

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 13 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts sustained deterioration



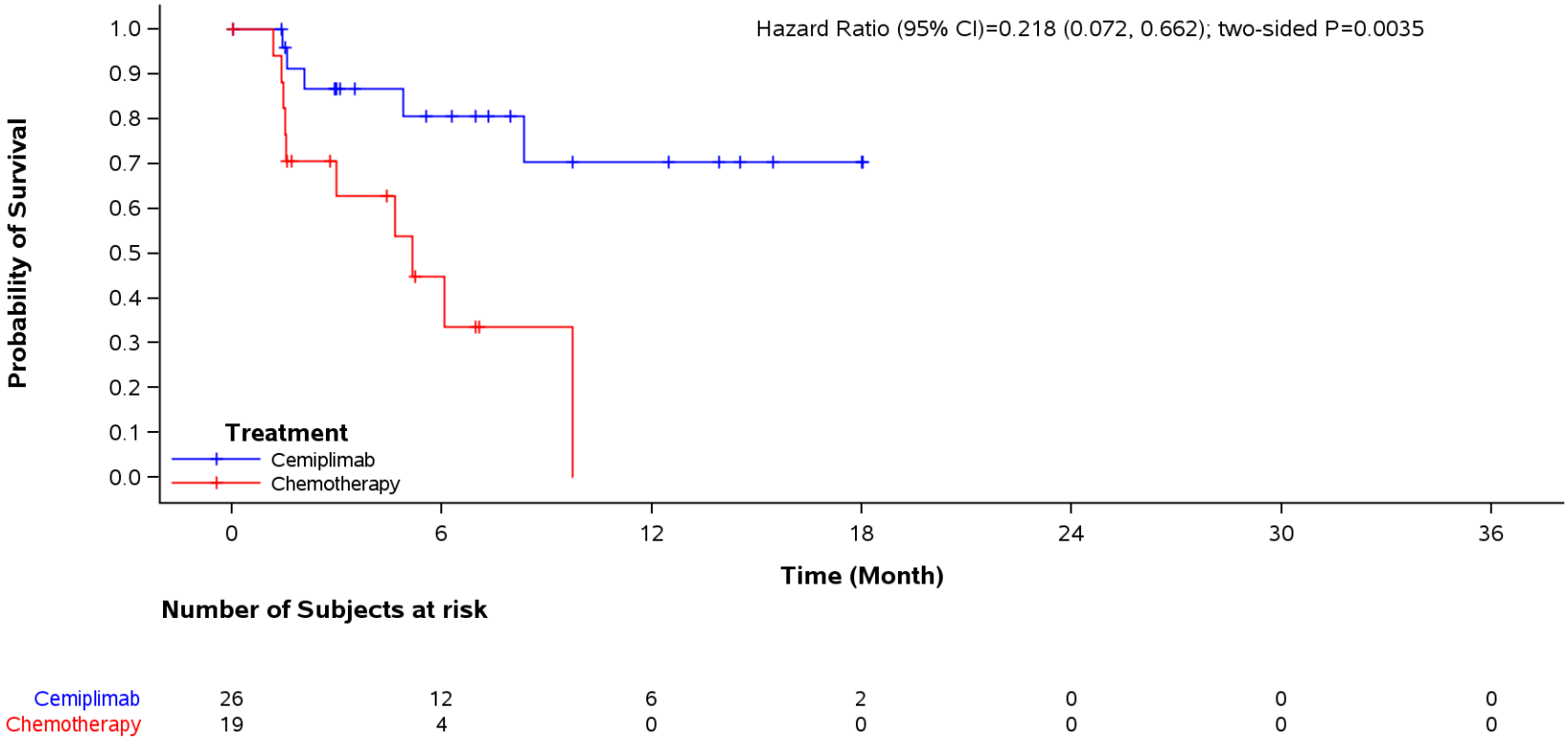

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts sustained deterioration



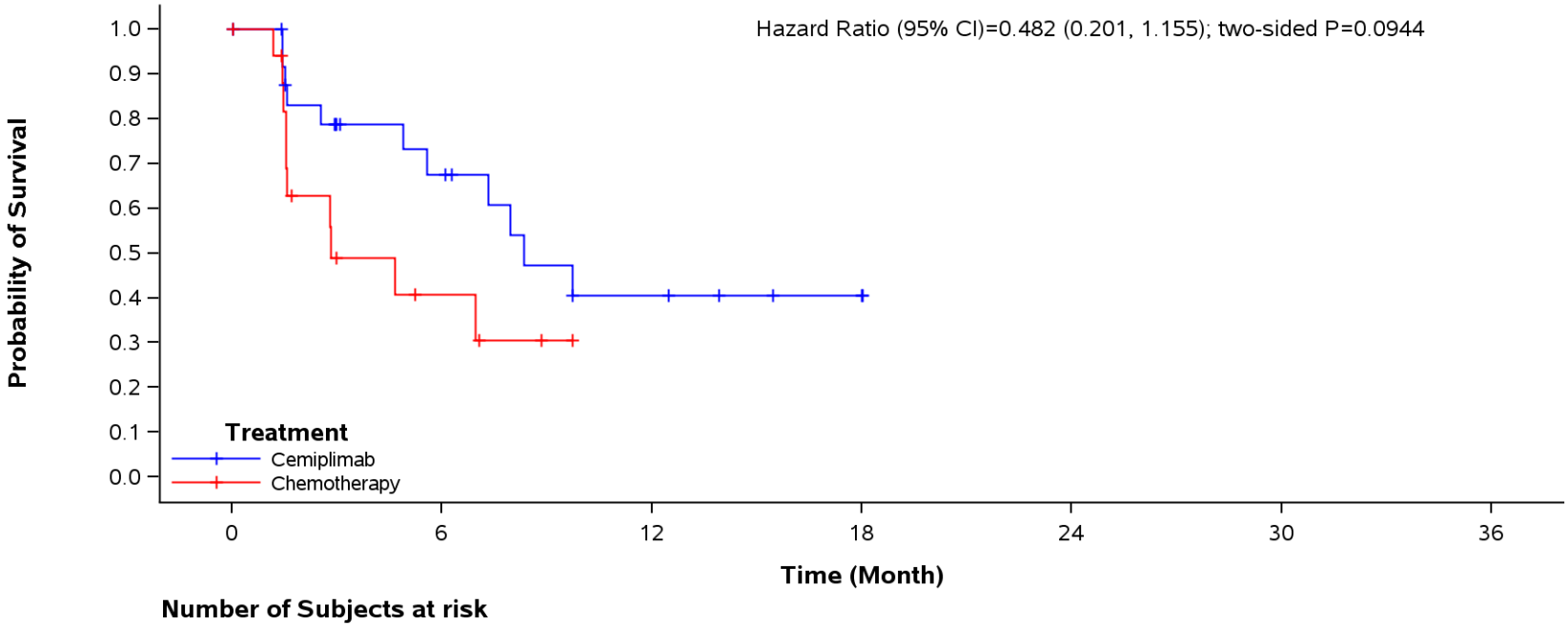

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Global health status / QoL - 10 pts sustained deterioration



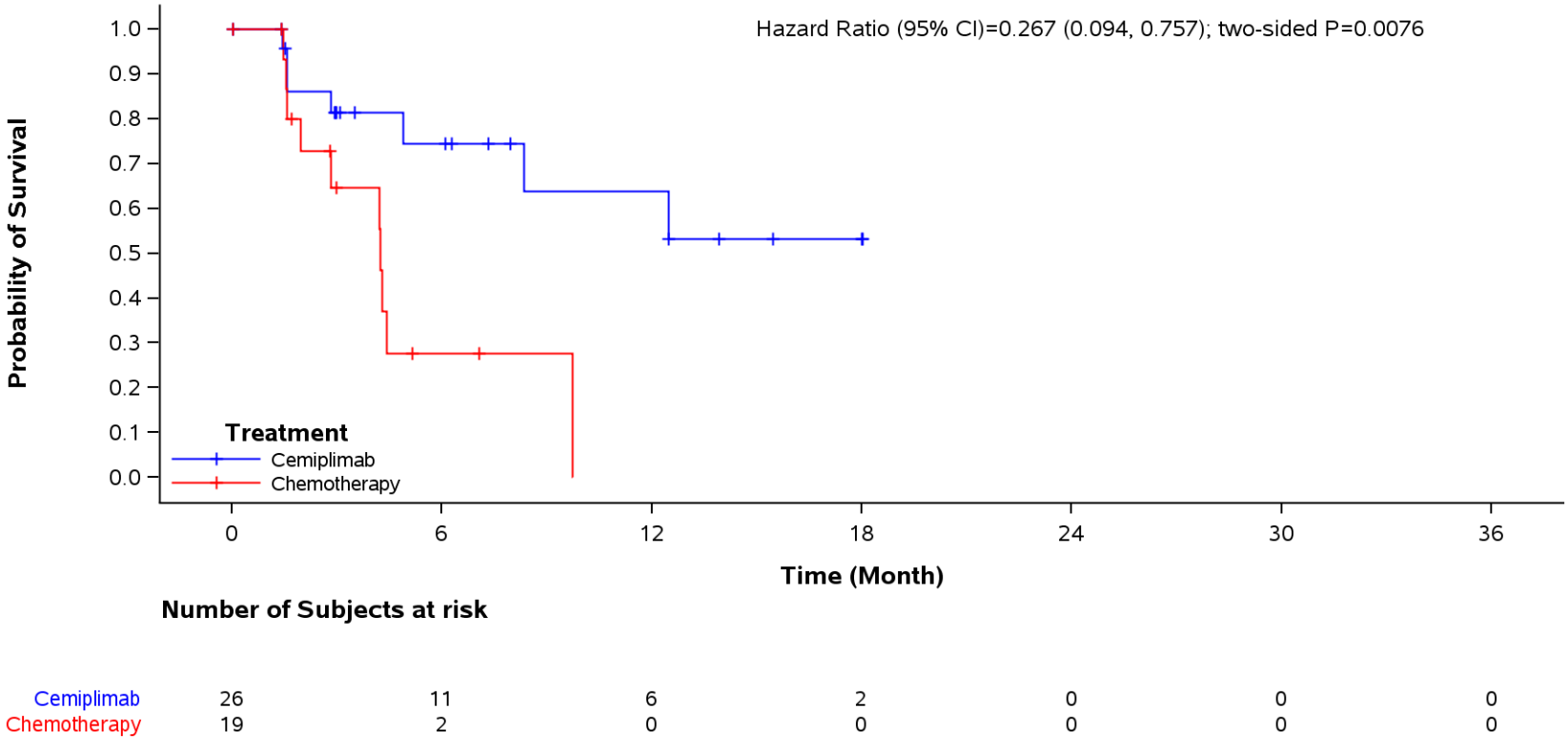

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts sustained deterioration



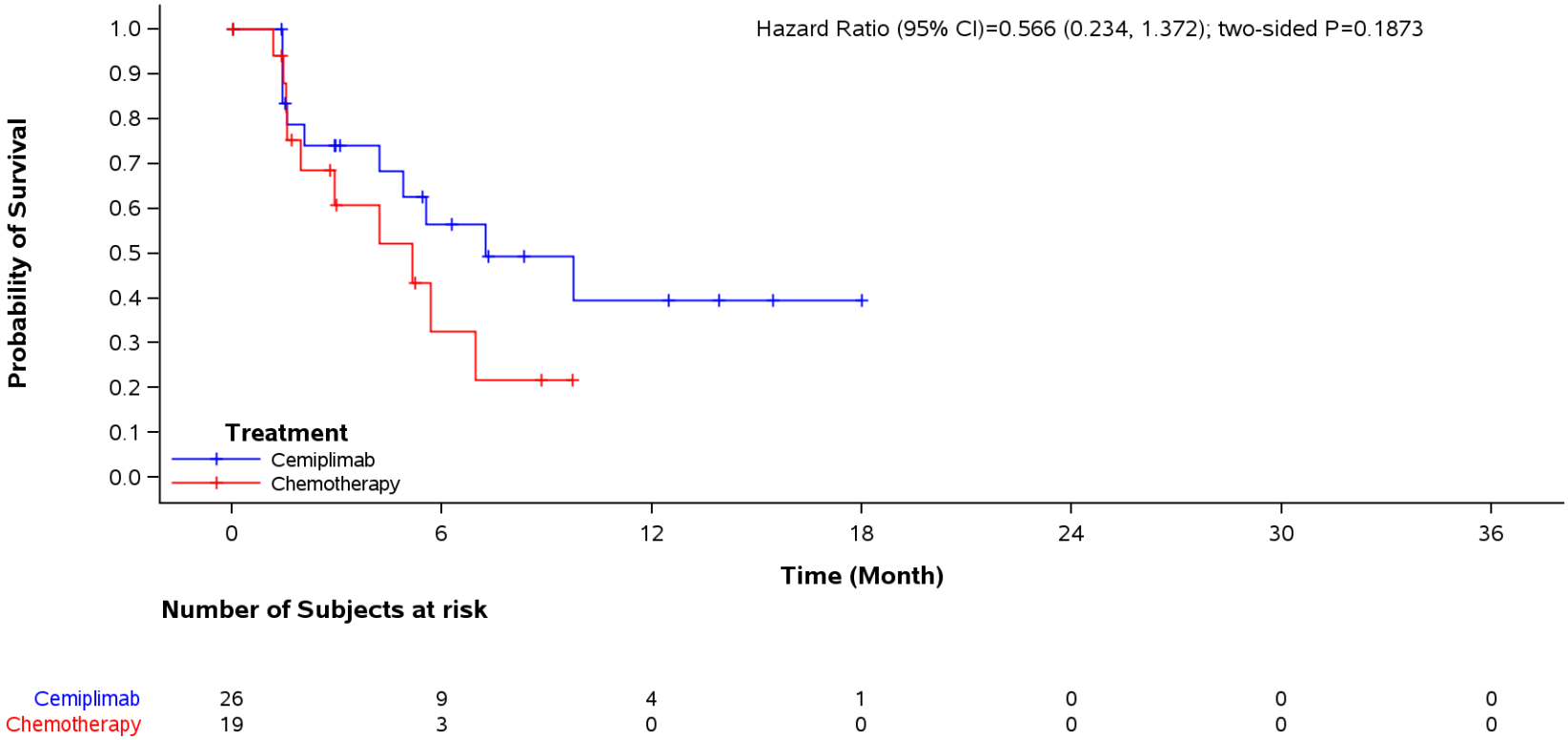

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts sustained deterioration



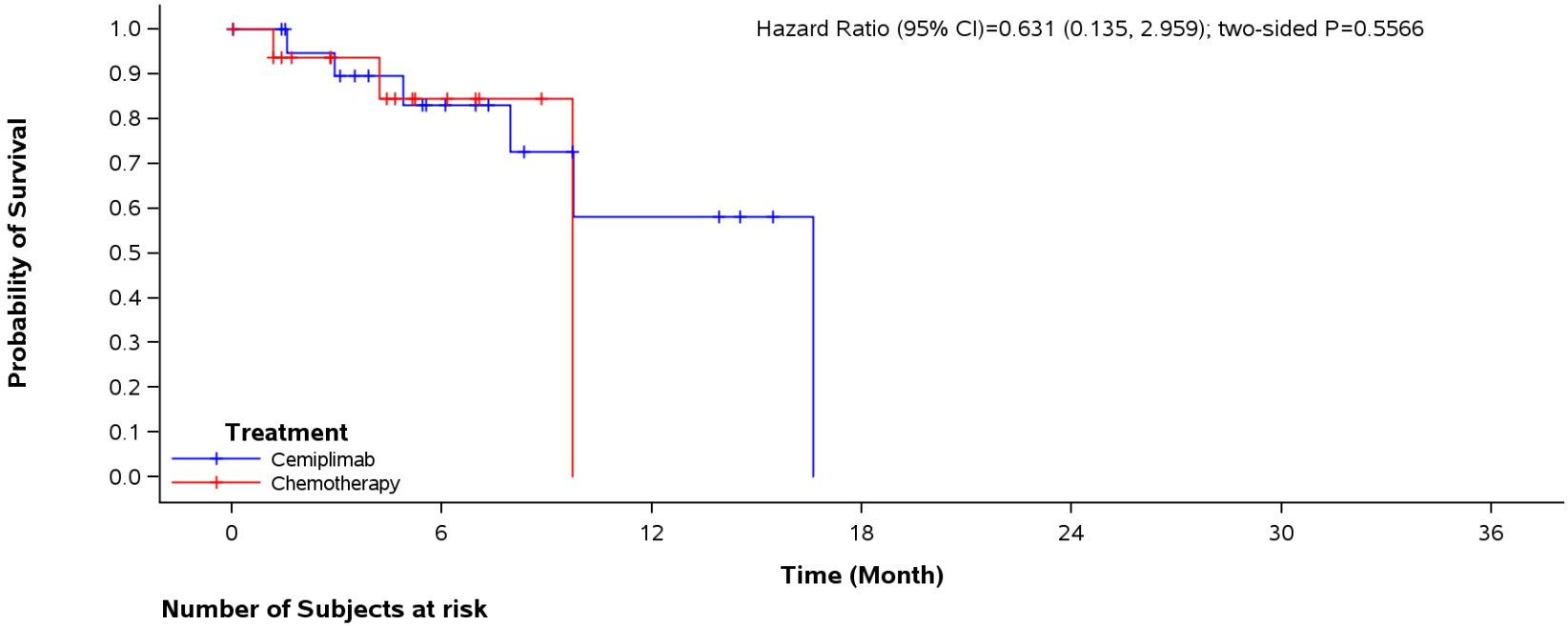

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 9 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts sustained deterioration




Number of Subjects at risk

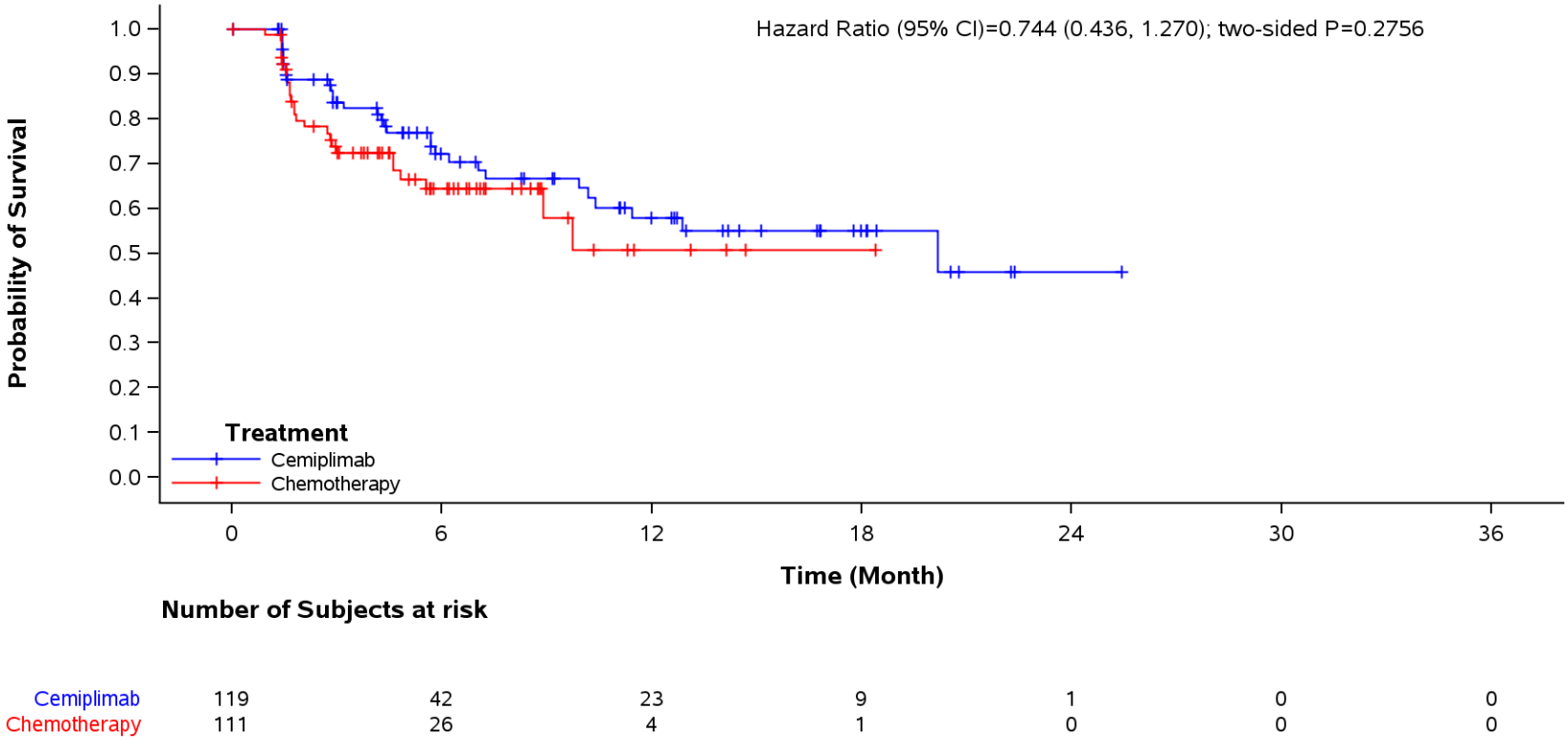
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:23:03, yingyuan.lin)

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts sustained deterioration



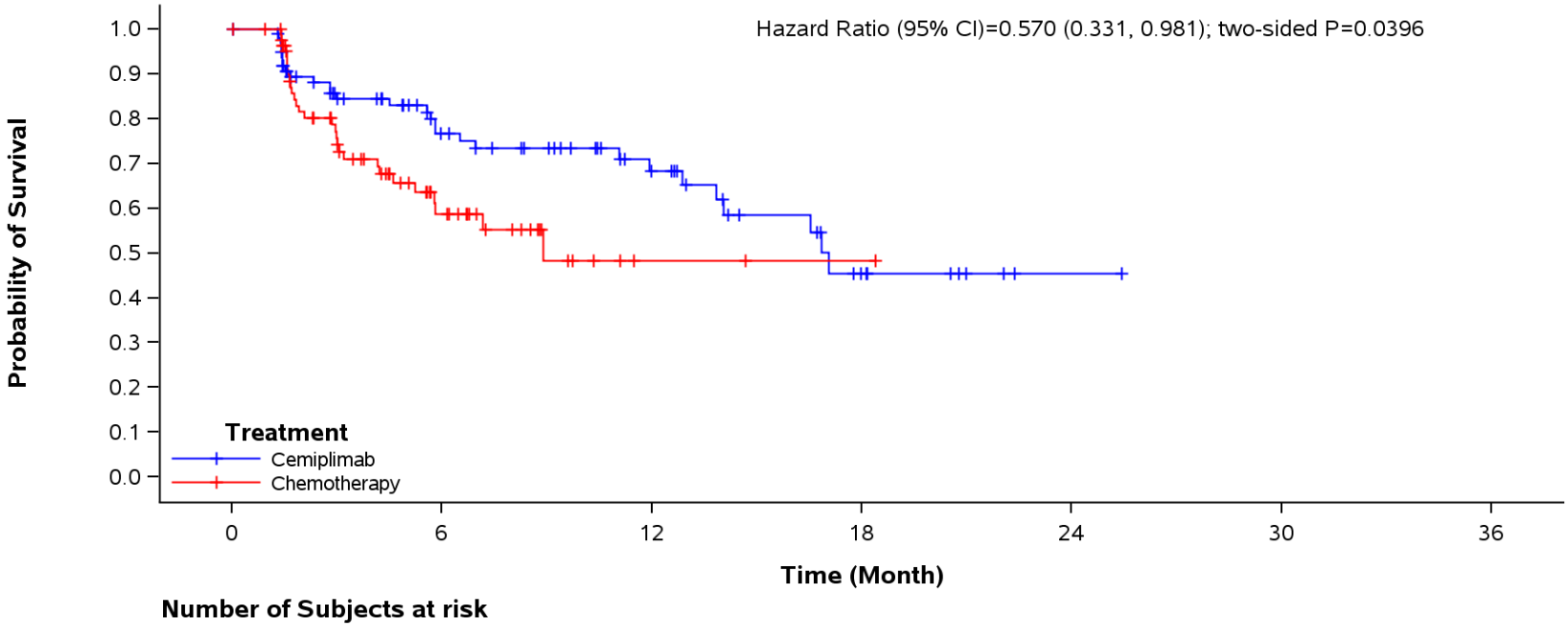

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 42 | 23 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts sustained deterioration



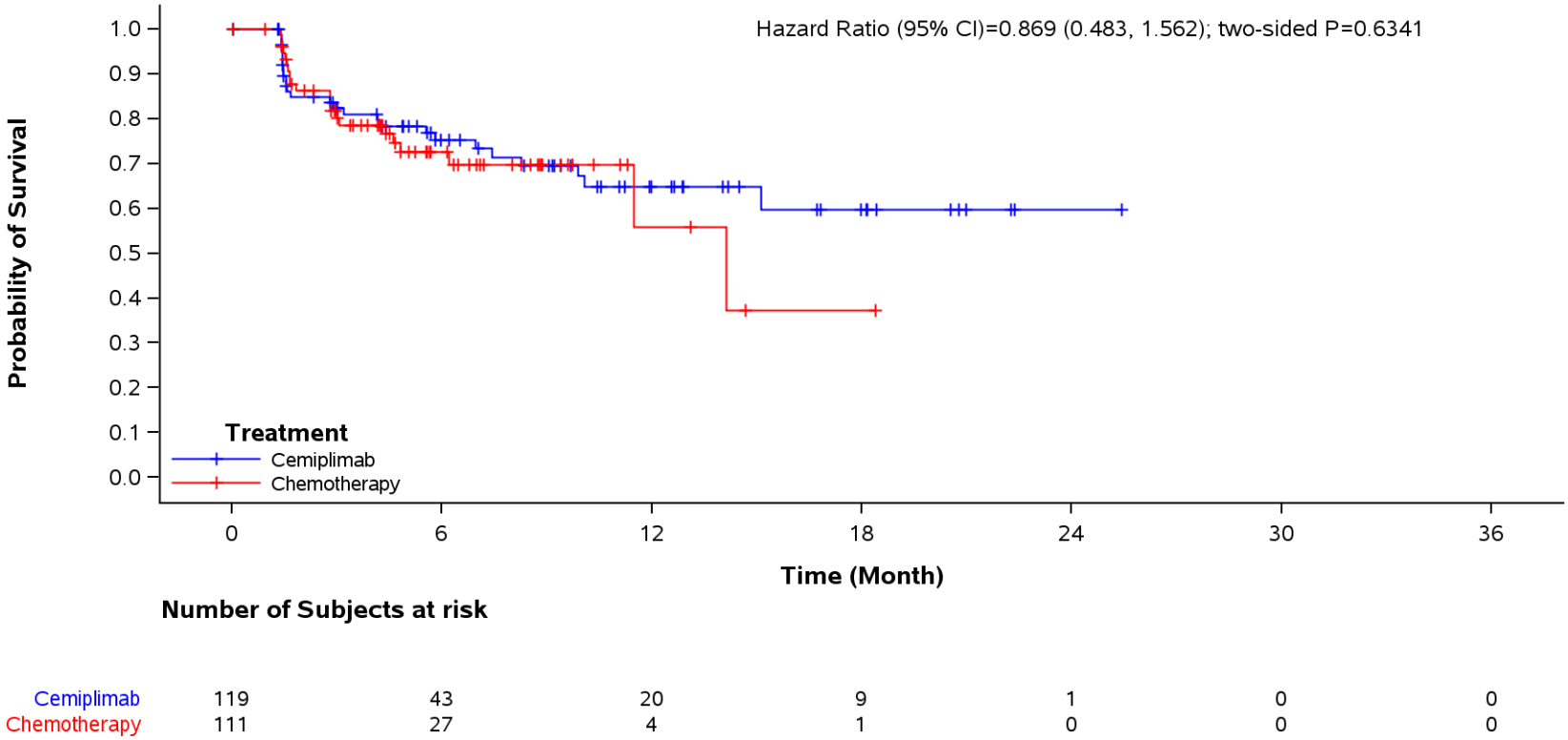

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 47 | 25 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 24 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts sustained deterioration



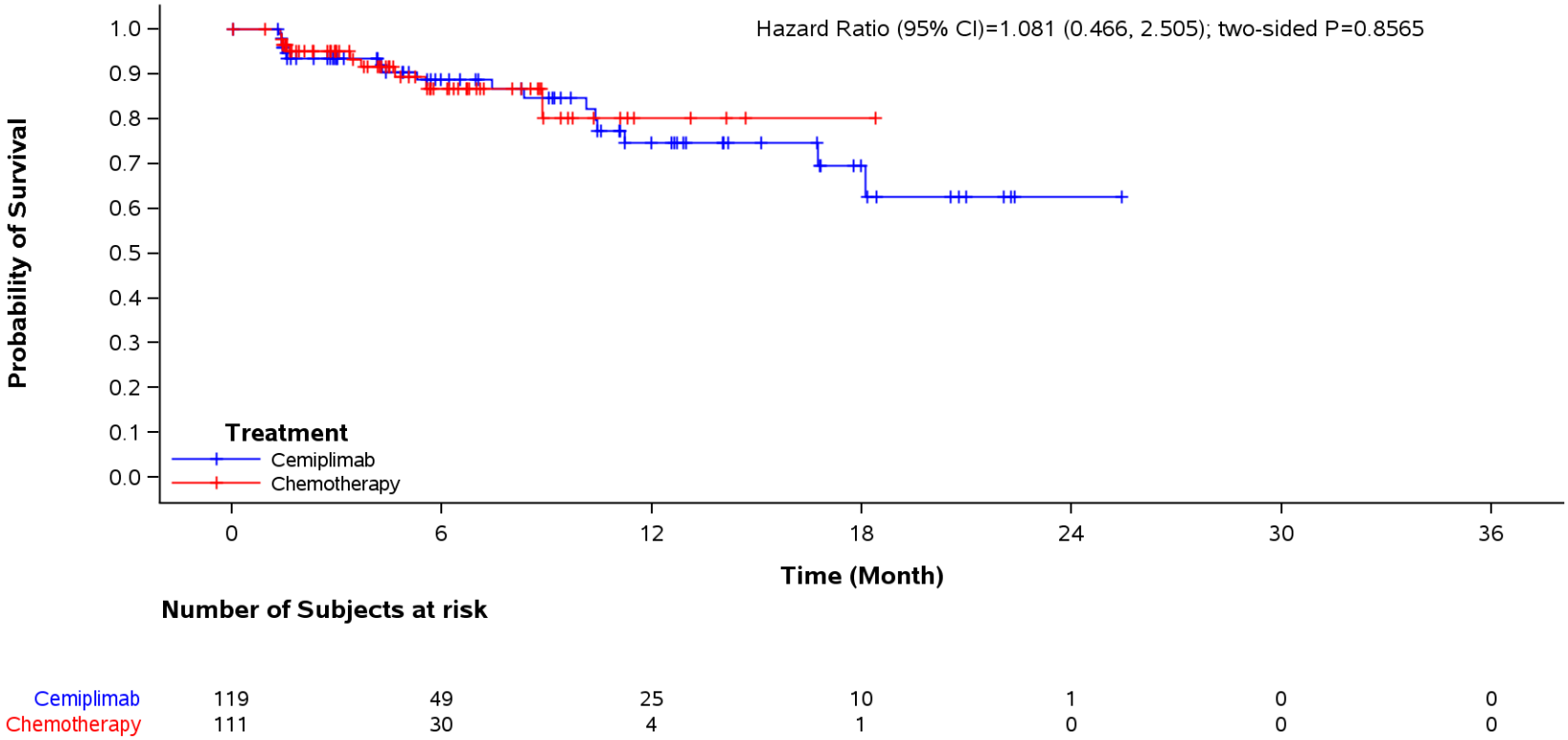

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 43 | 20 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 27 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts sustained deterioration



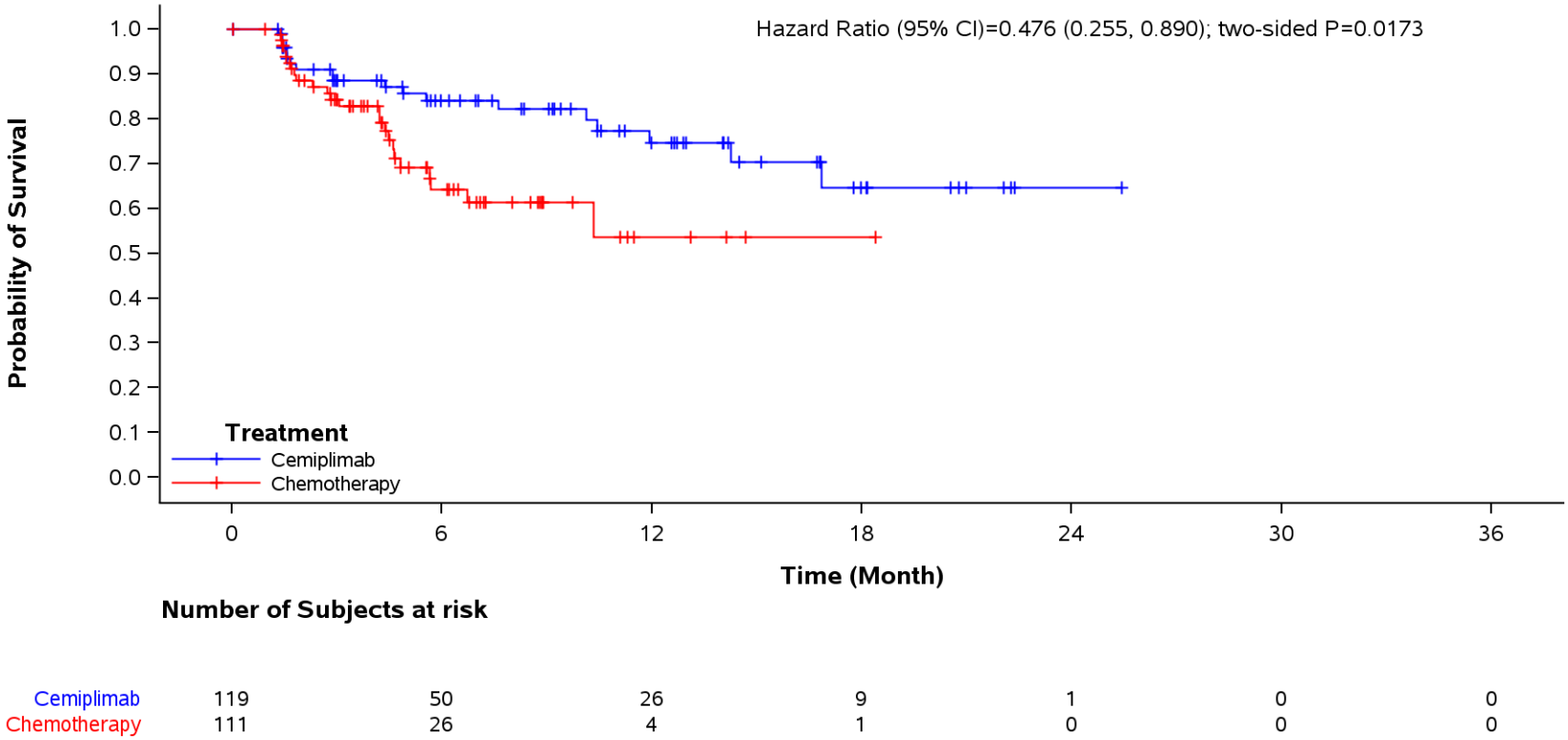

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 49 | 25 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 30 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts sustained deterioration



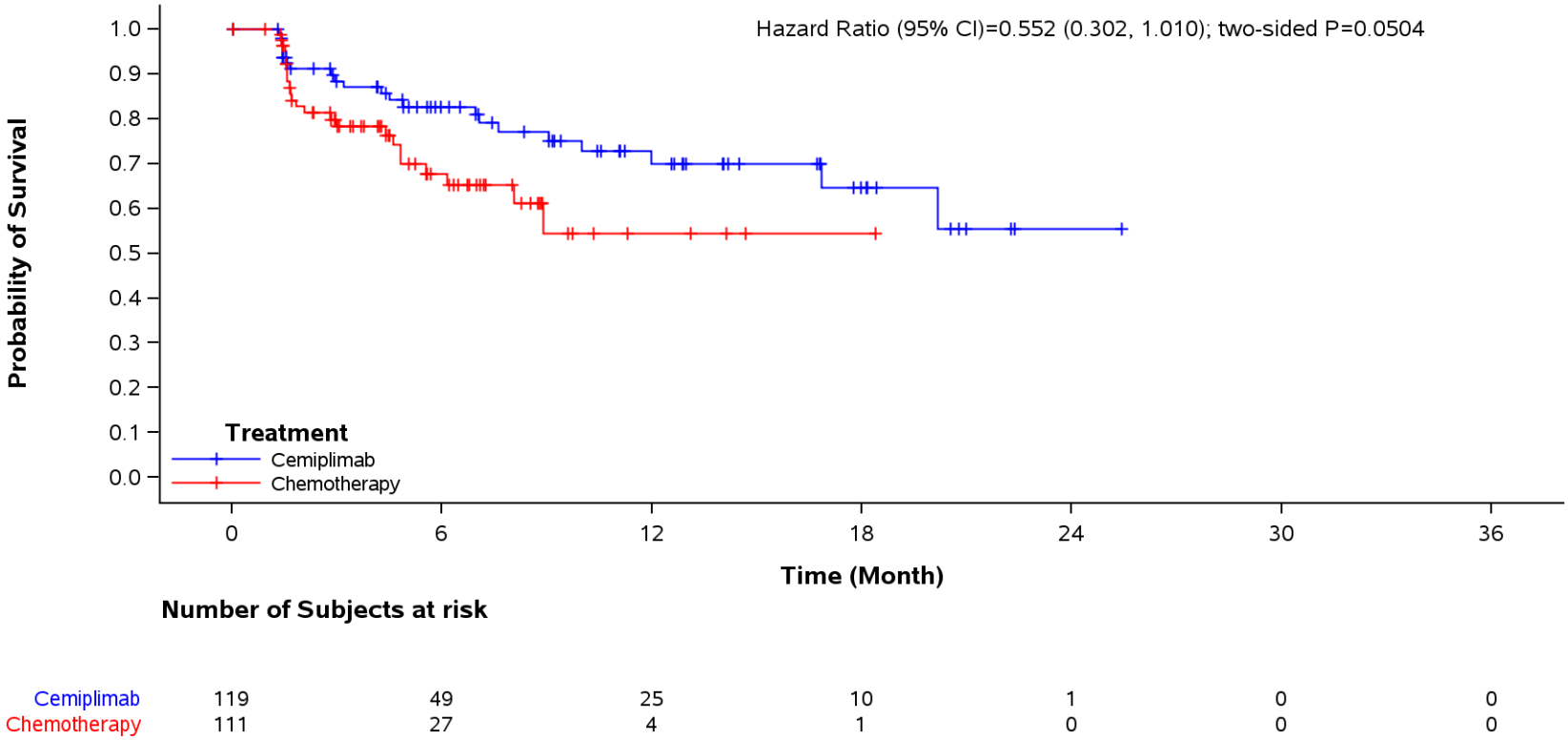

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 50 | 26 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts sustained deterioration



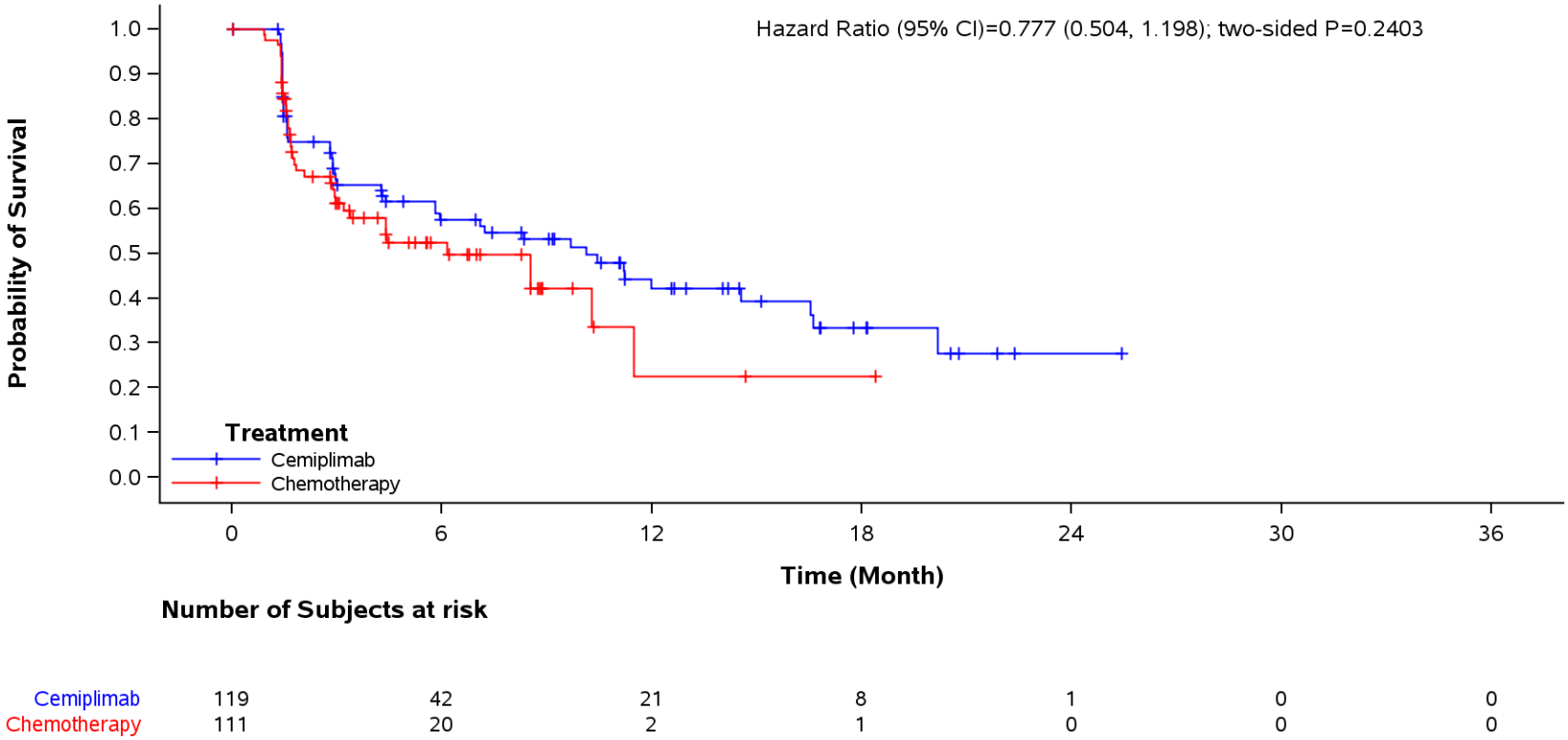

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 49 | 25 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 27 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts sustained deterioration



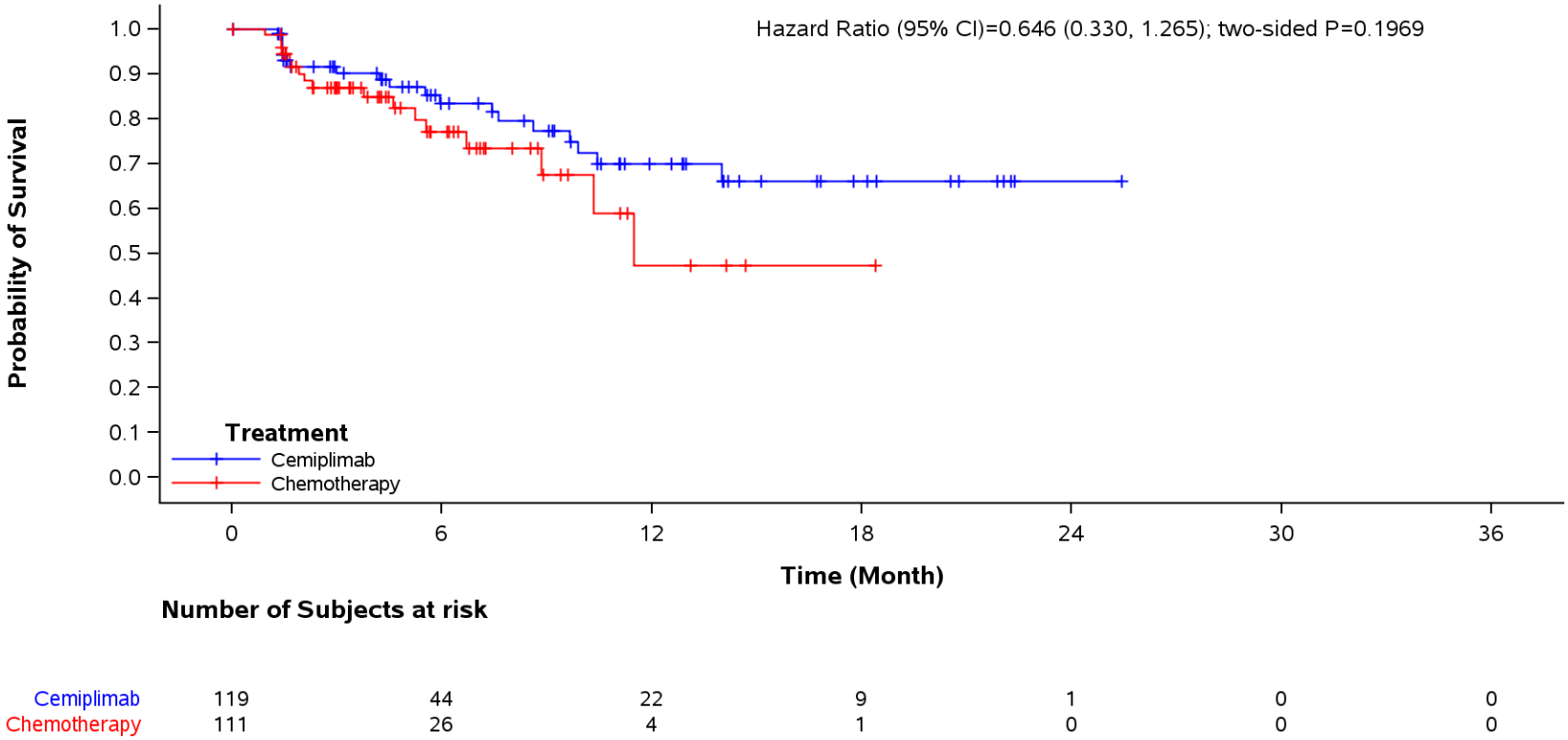

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 42 | 21 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts sustained deterioration



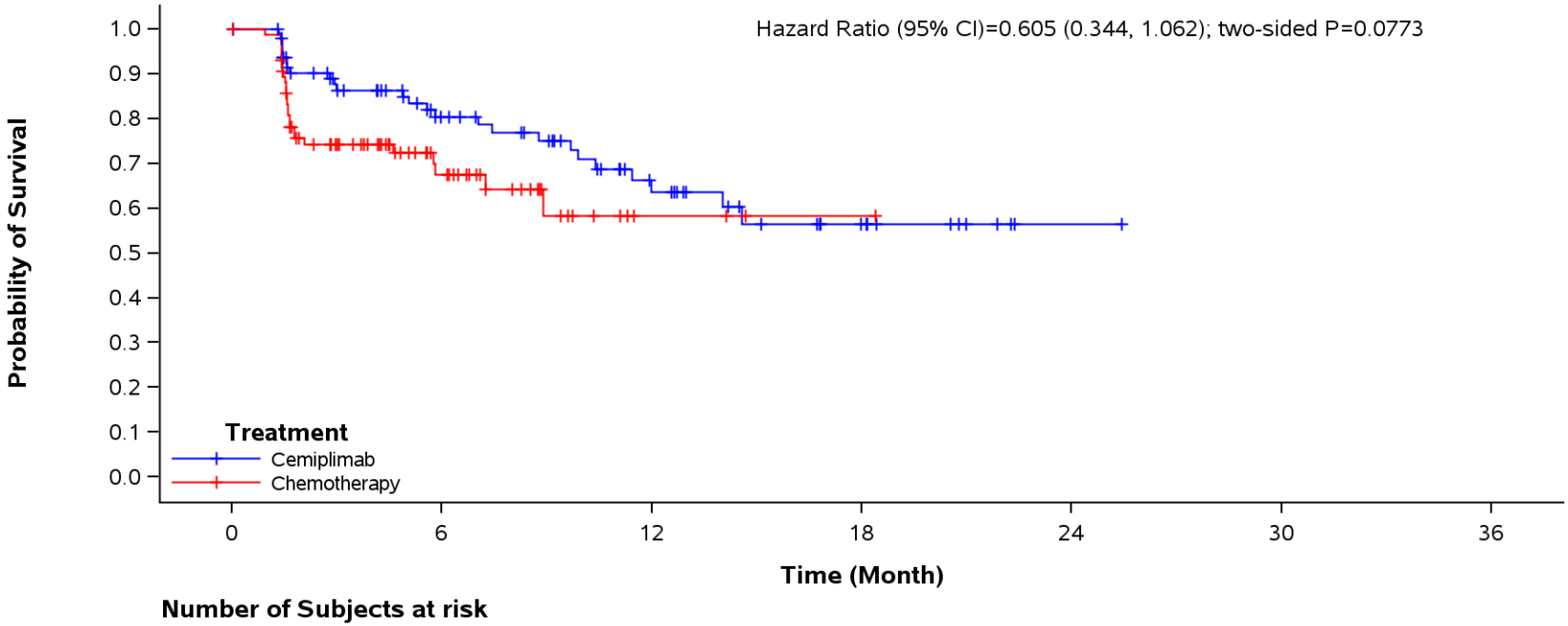

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 44 | 22 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts sustained deterioration



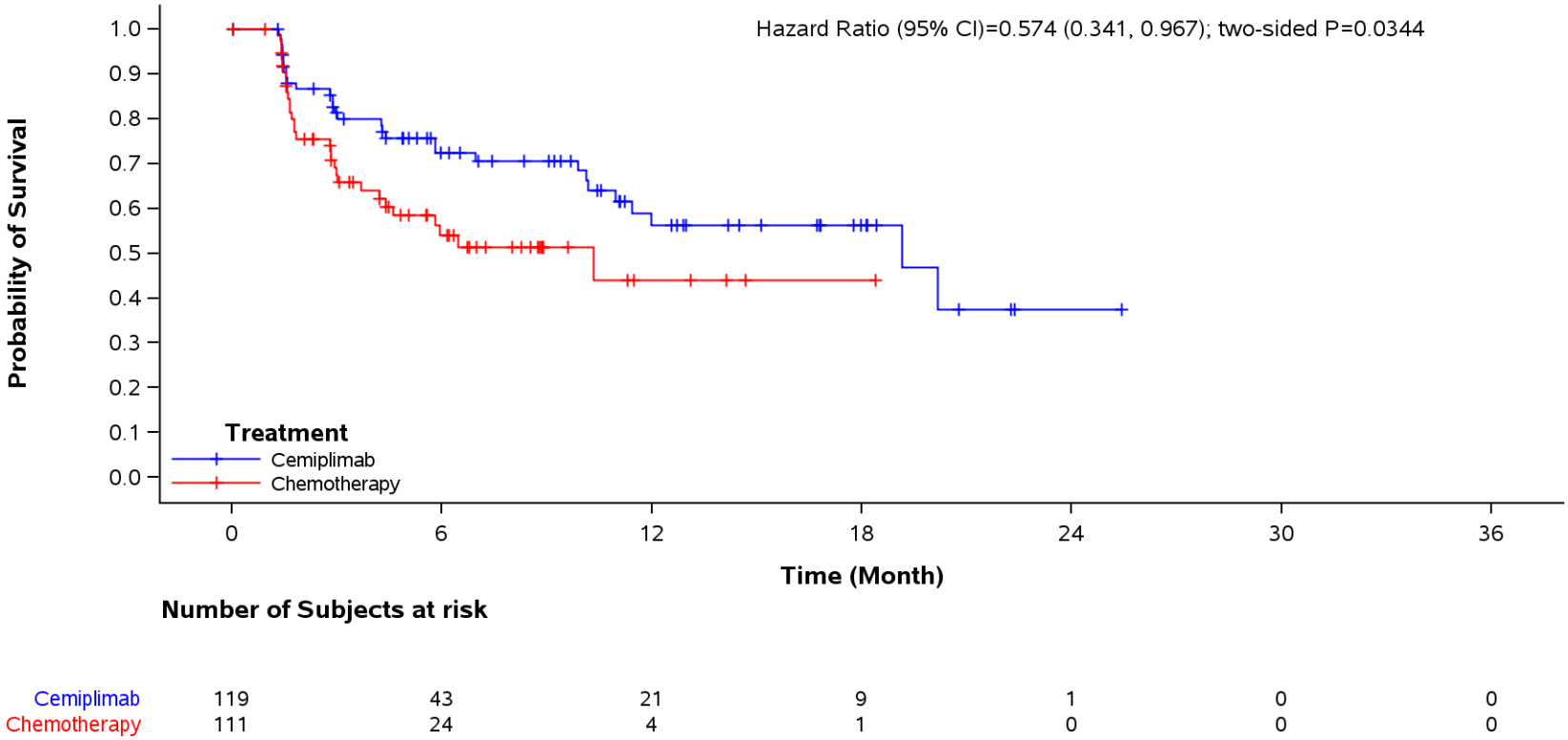

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 50 | 24 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 28 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts sustained deterioration



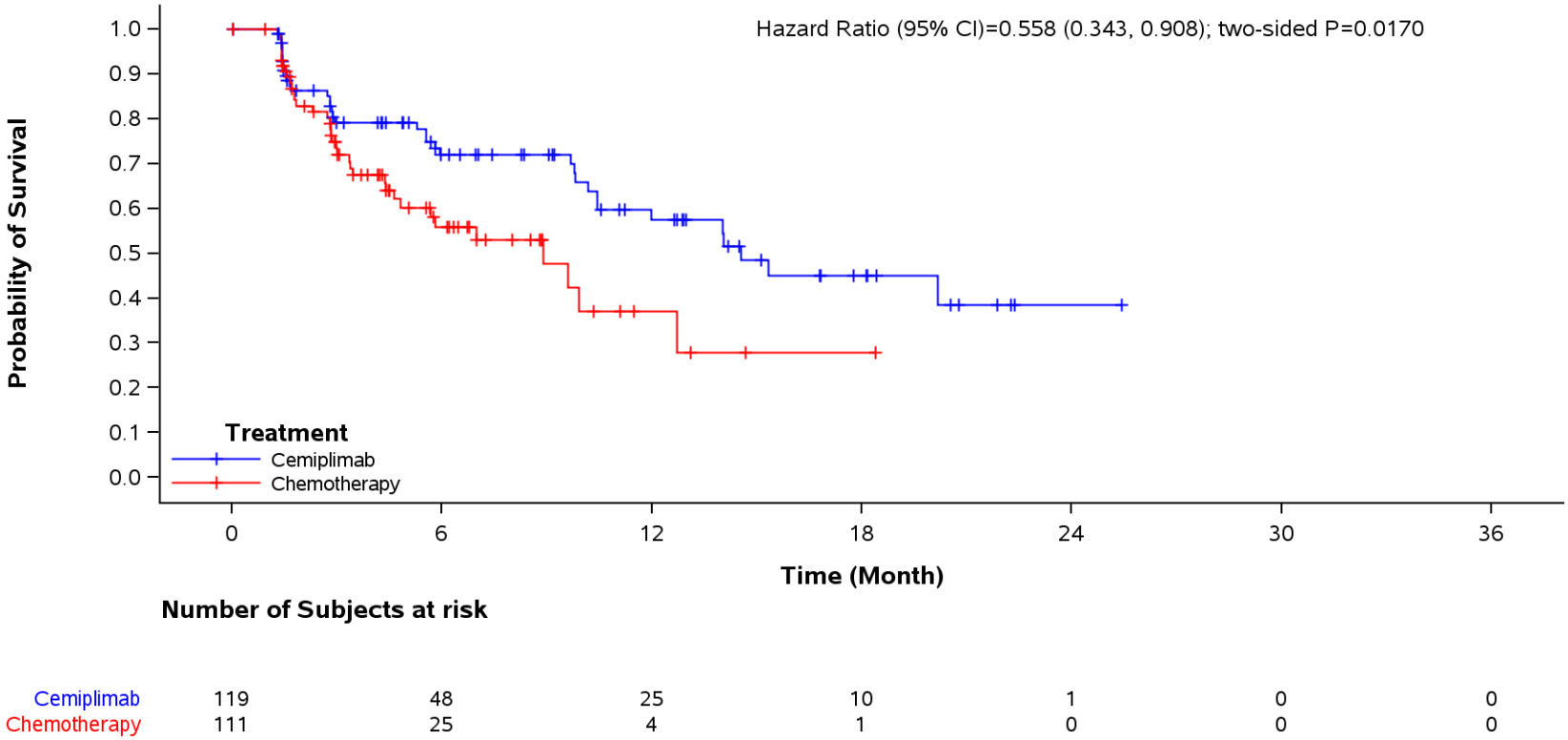

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 43 | 21 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 24 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts sustained deterioration



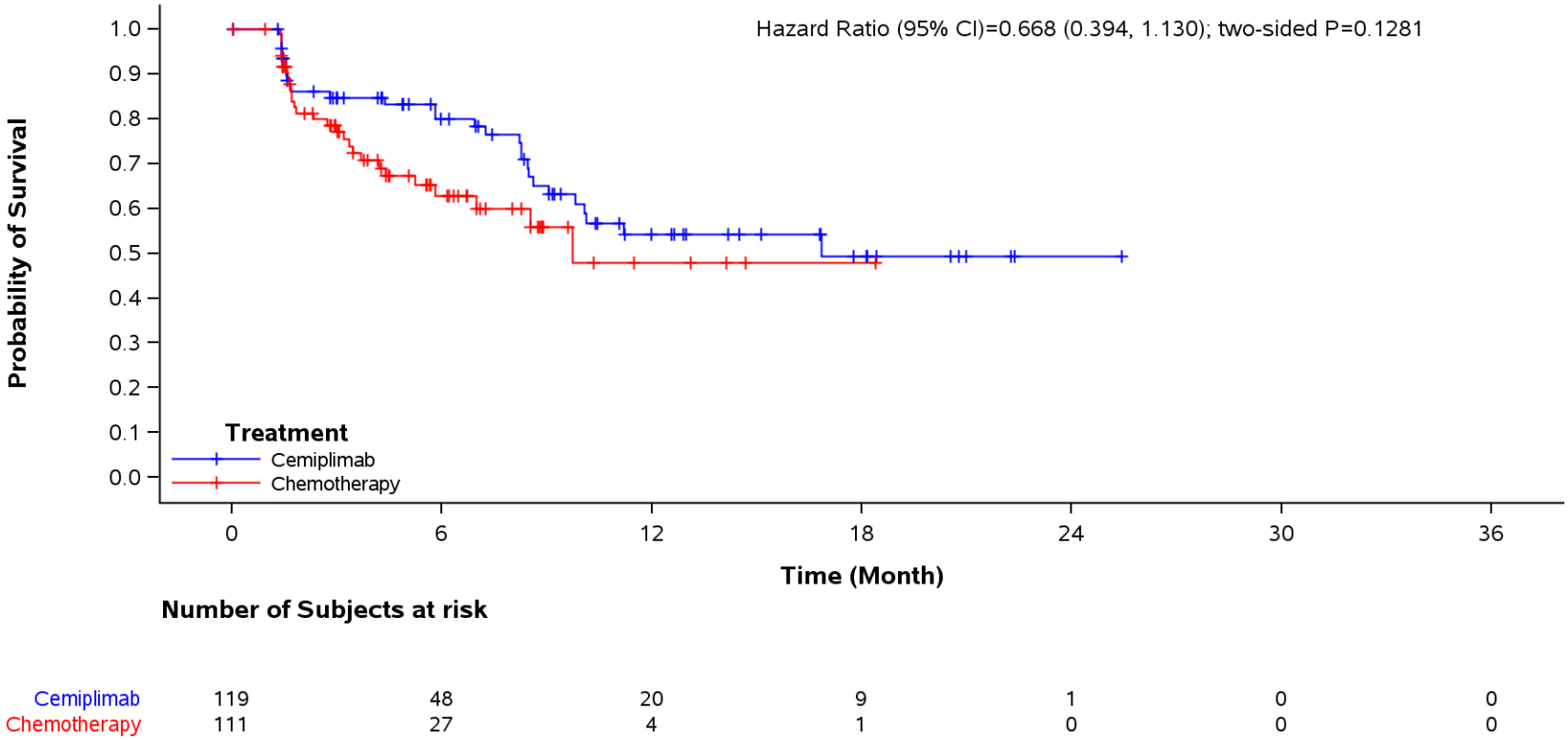

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 48 | 25 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 25 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Global health status / QoL - 10 pts sustained deterioration



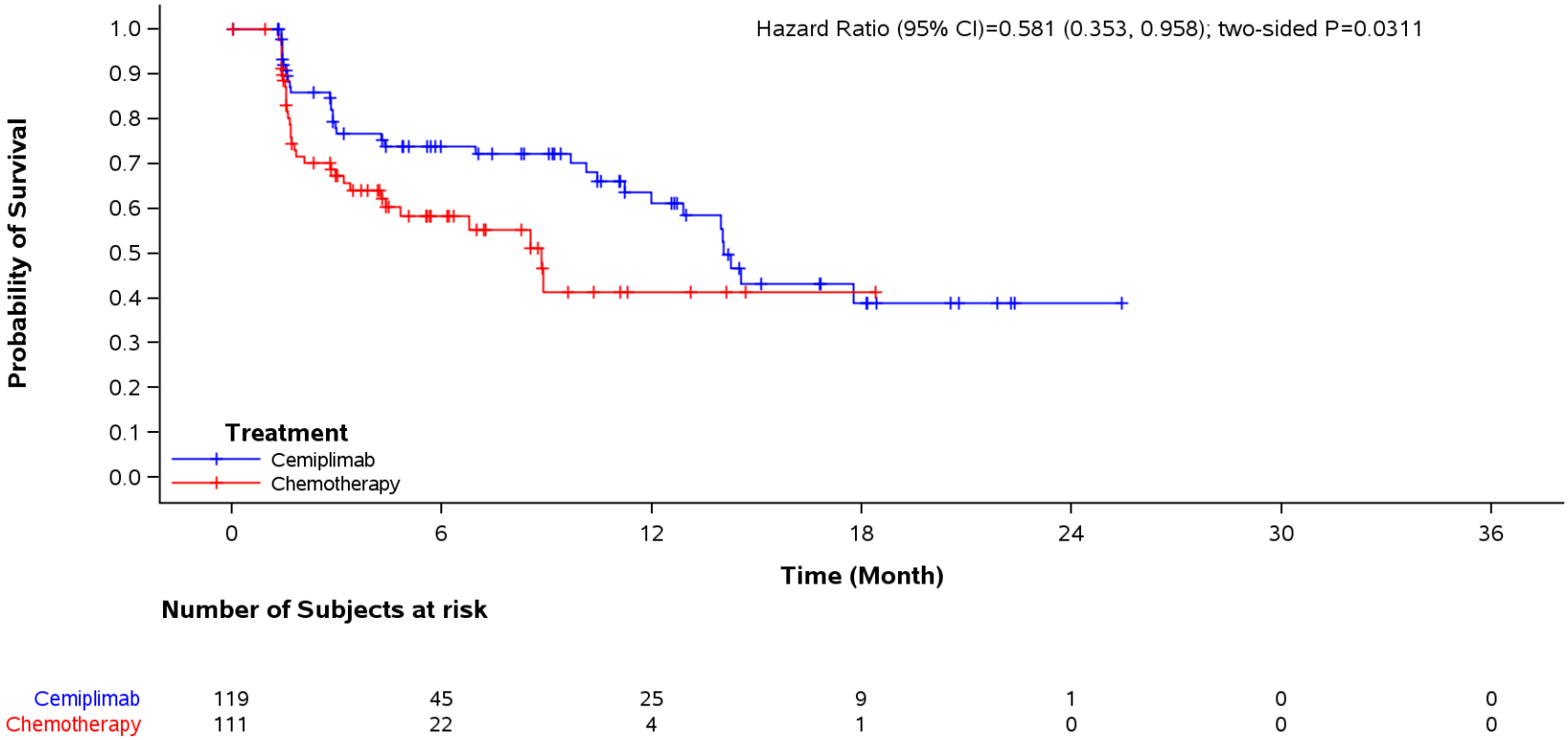

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 48 | 20 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 27 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts sustained deterioration



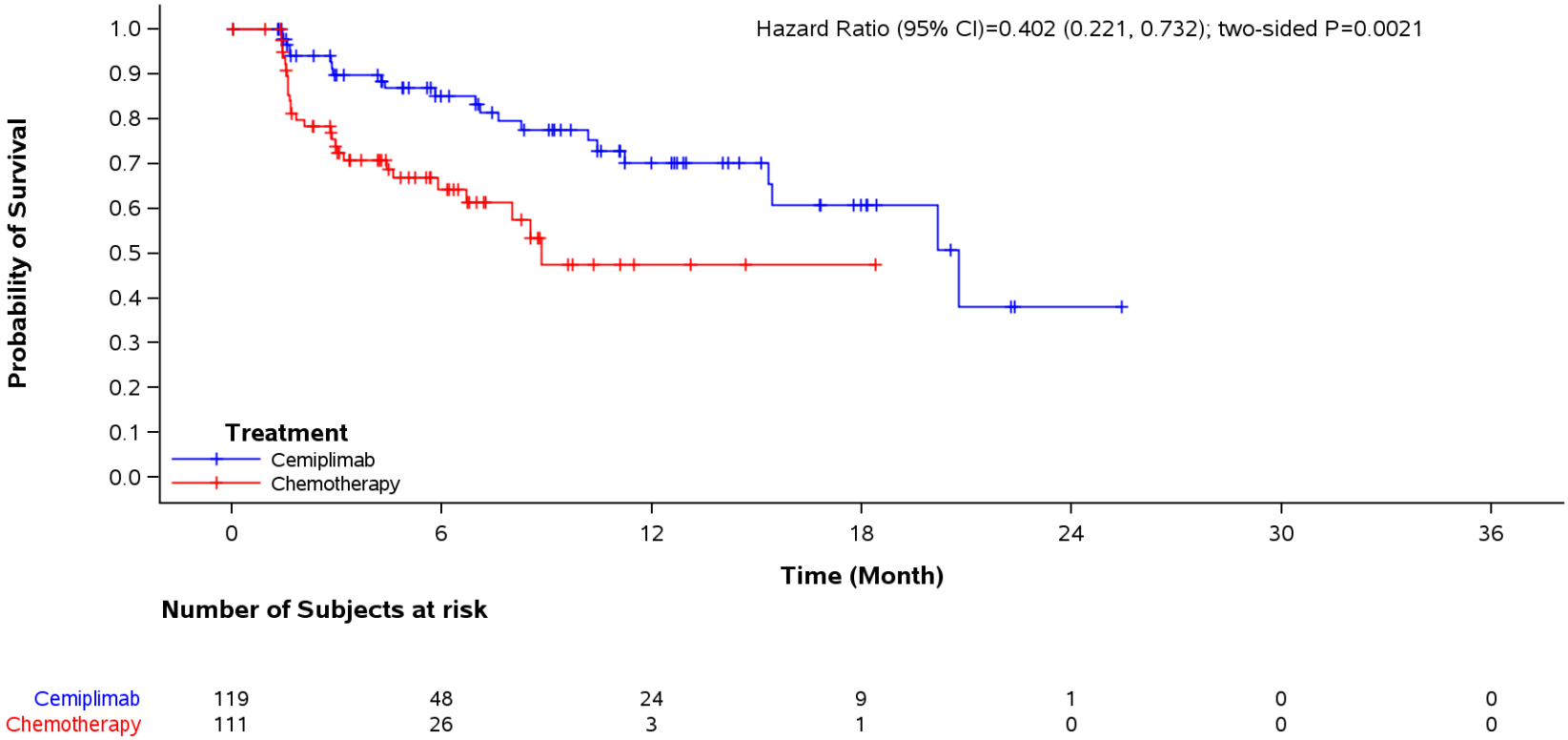

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 45 | 25 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 22 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts sustained deterioration



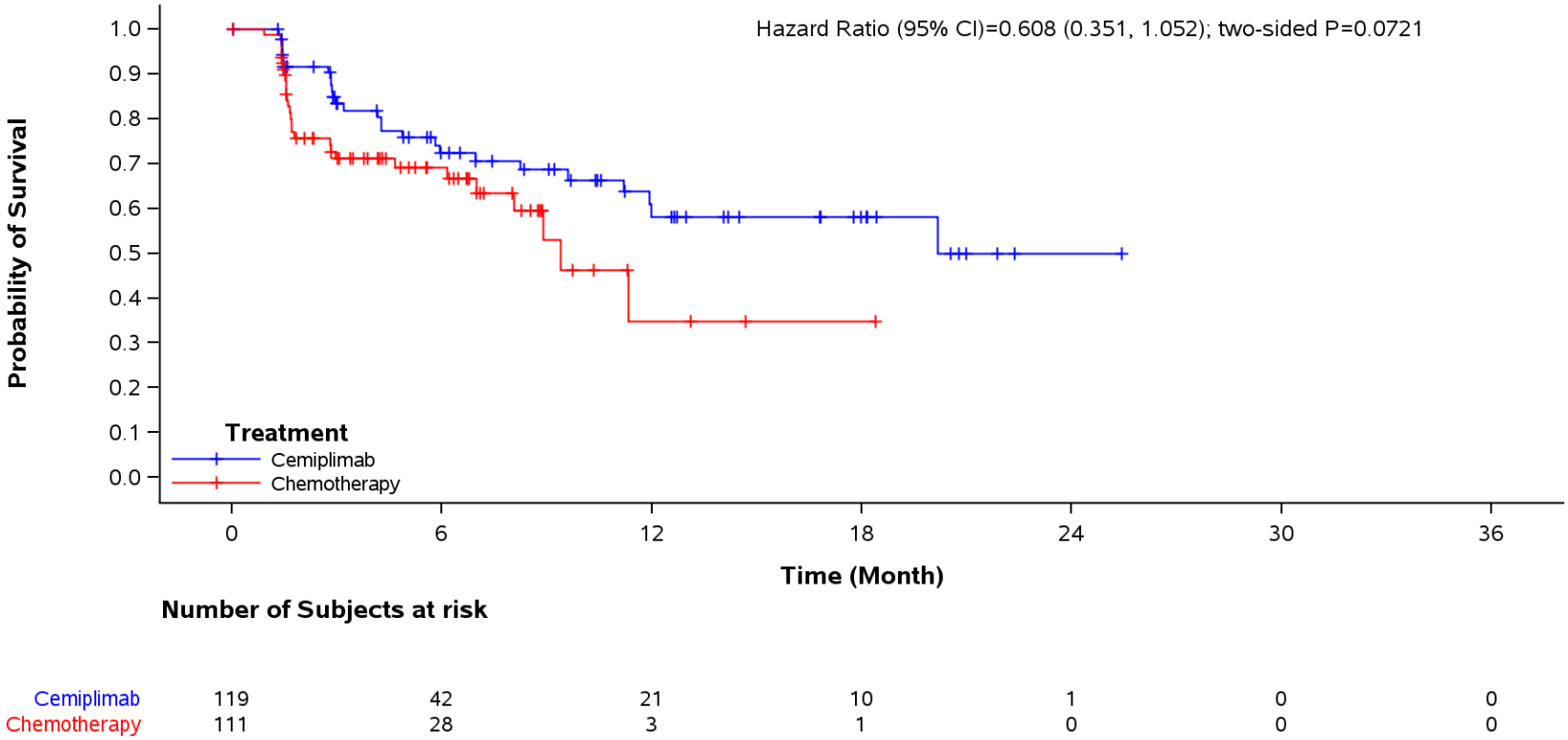

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 48 | 24 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts sustained deterioration



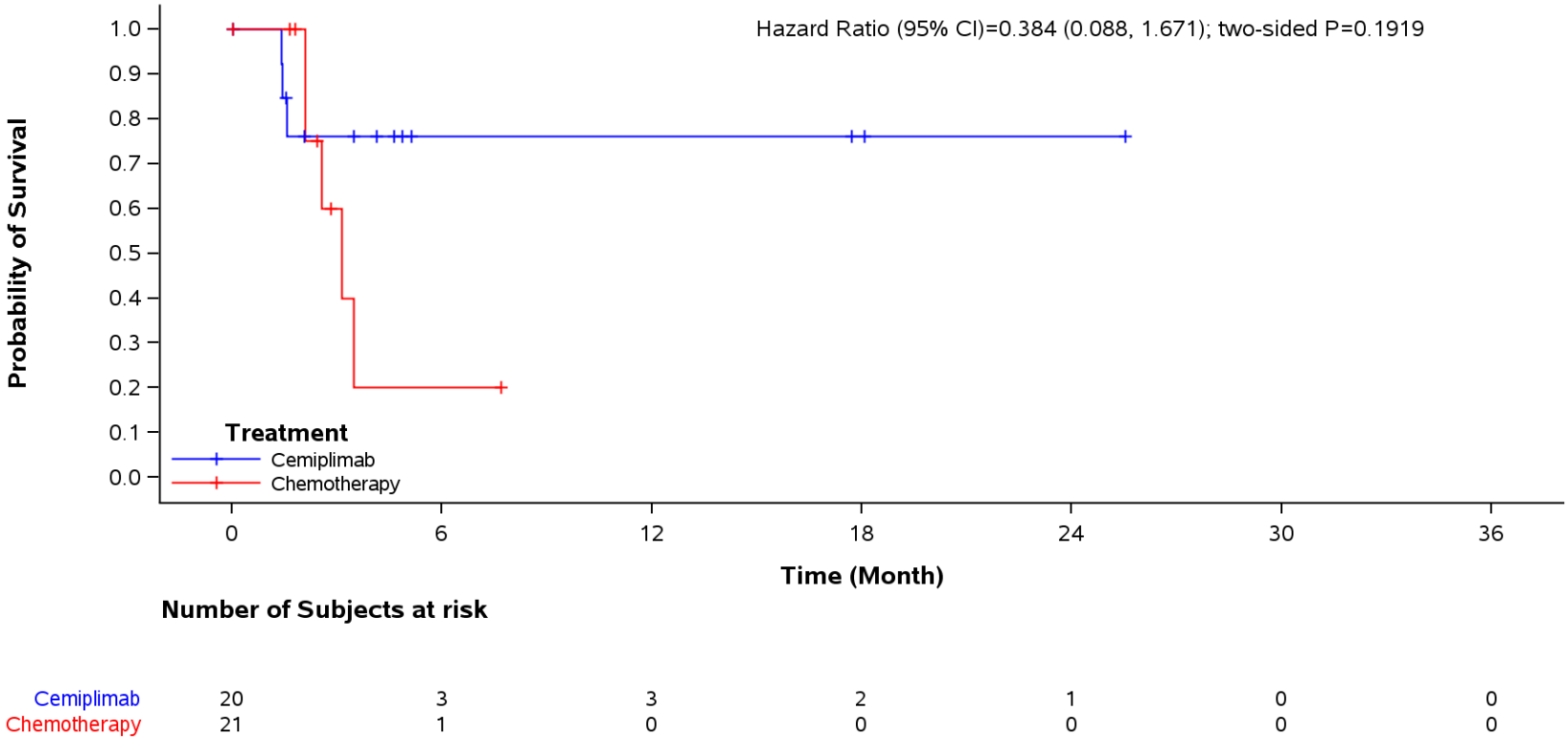

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 42 | 21 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 28 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

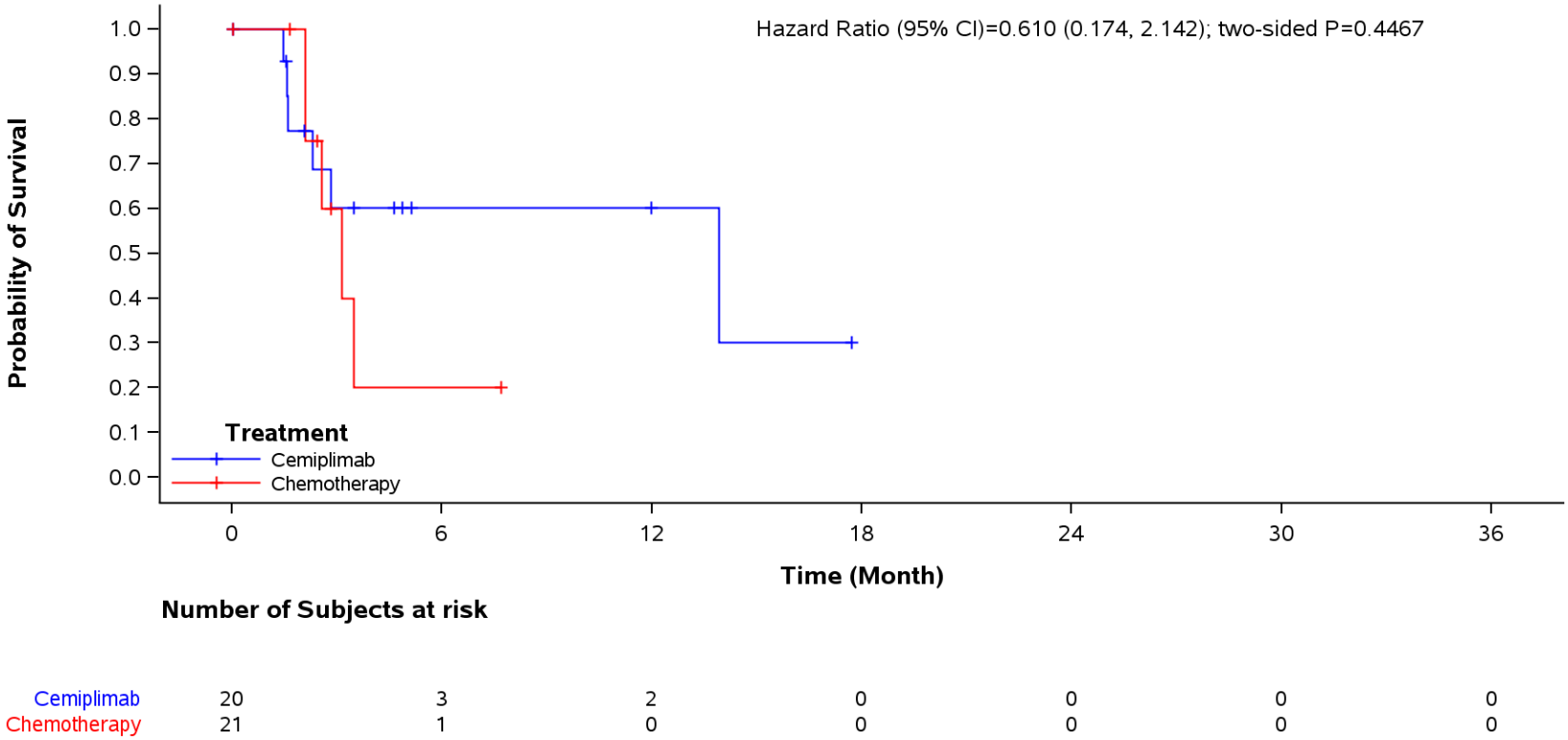
Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

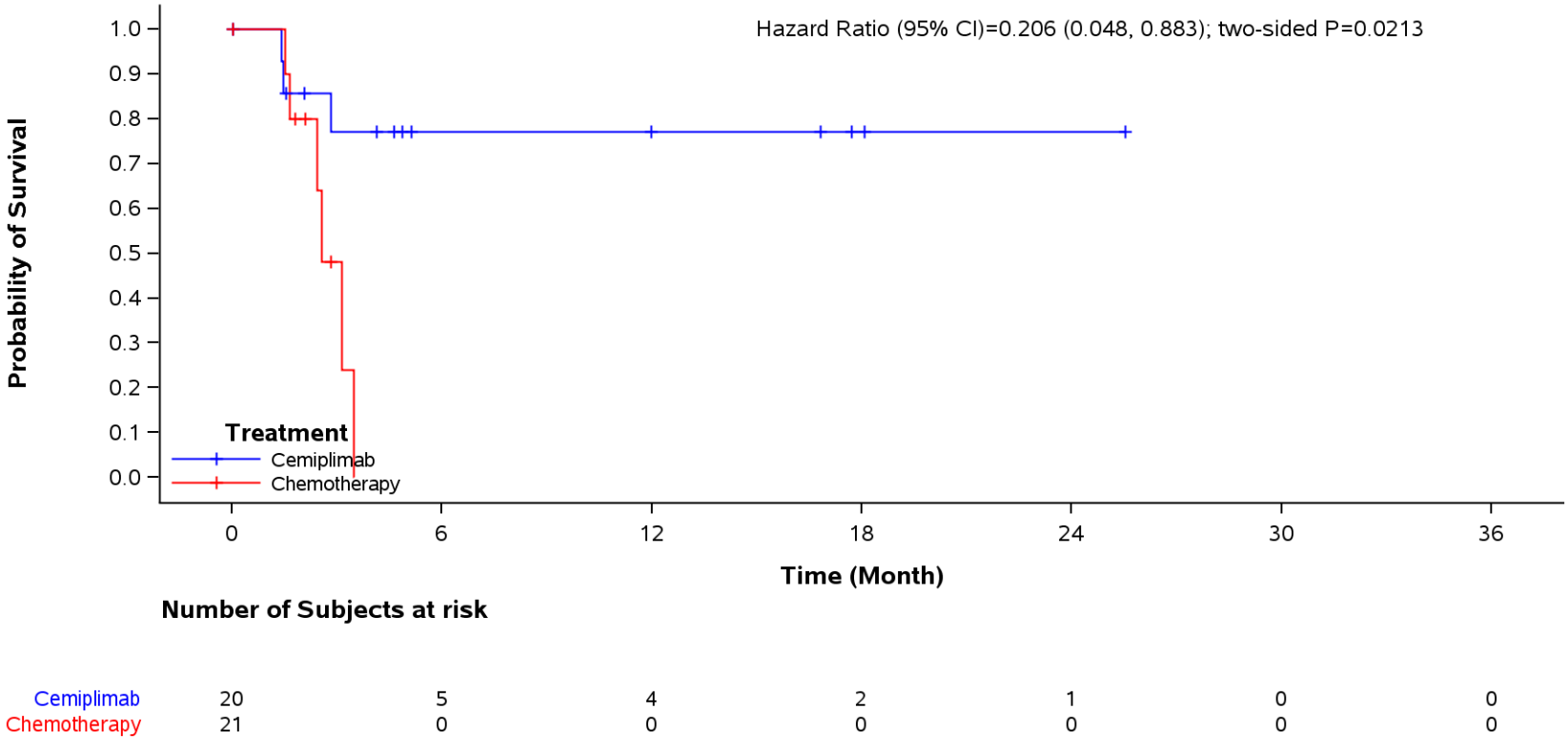
Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts sustained deterioration



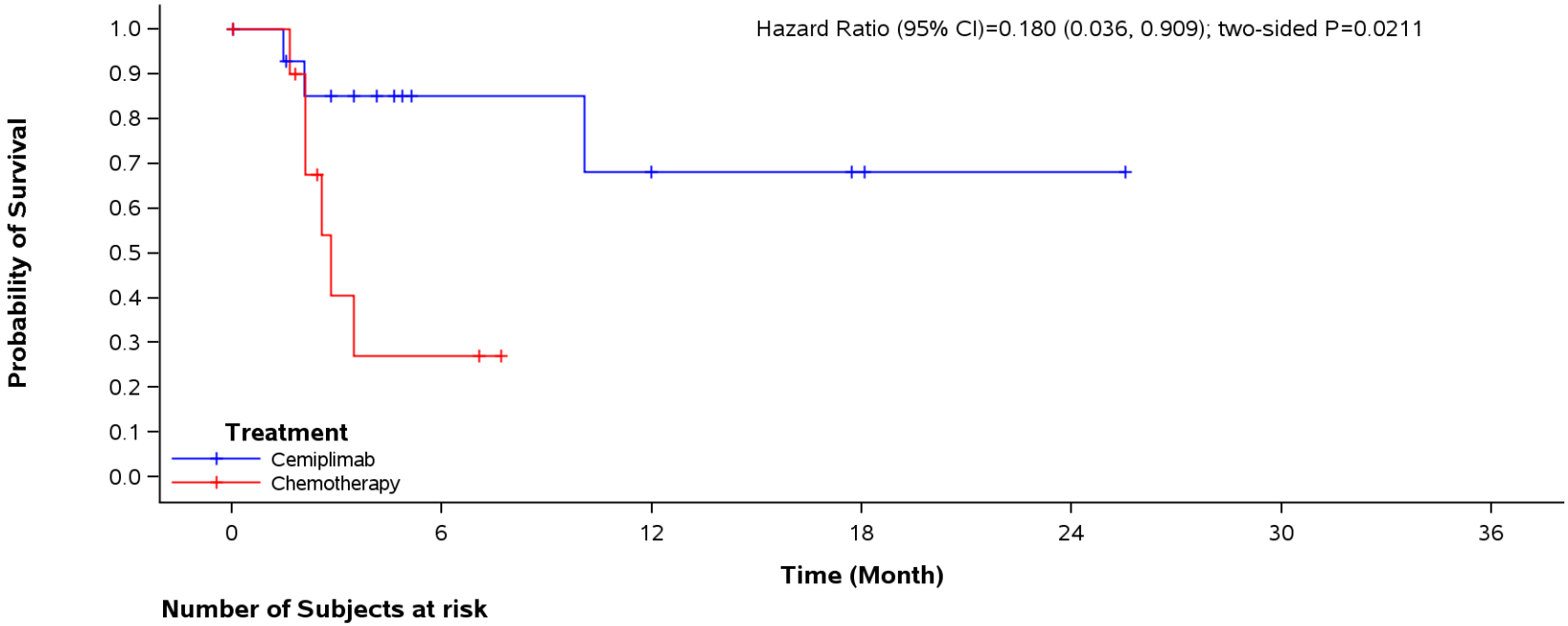

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts sustained deterioration



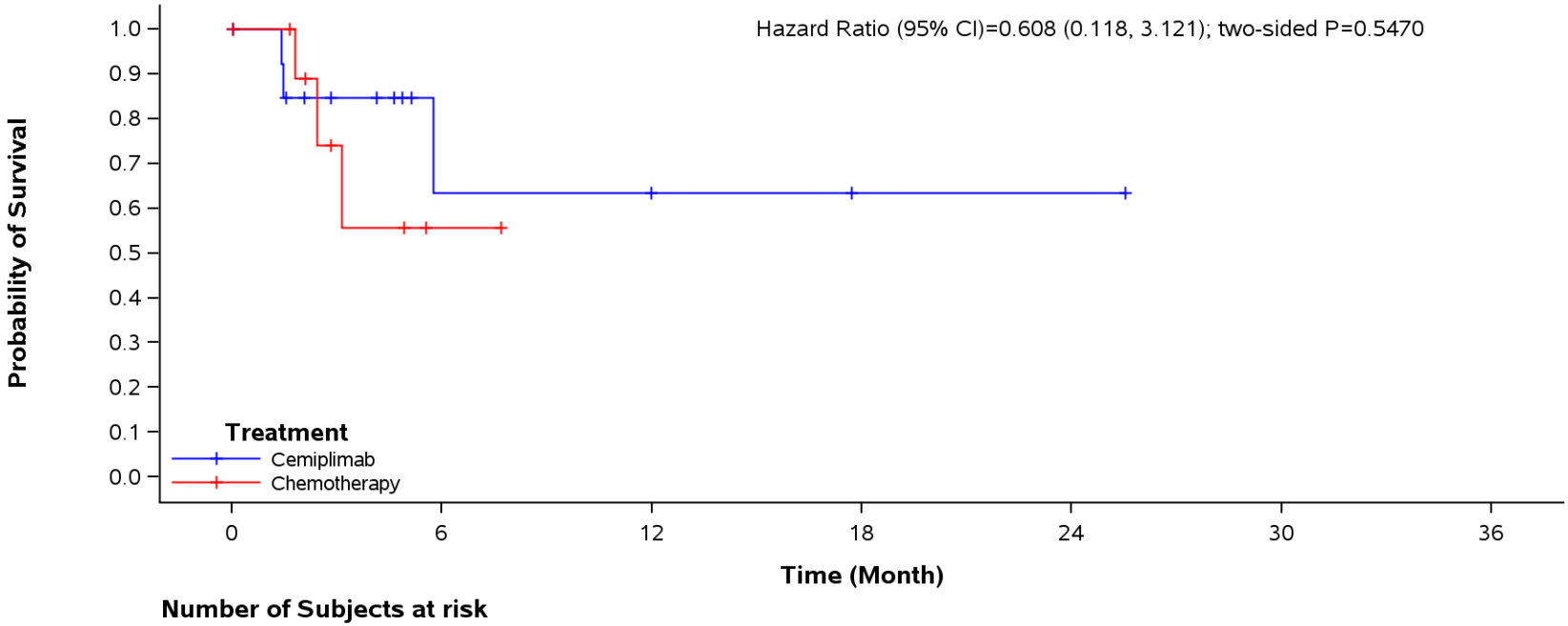

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts sustained deterioration



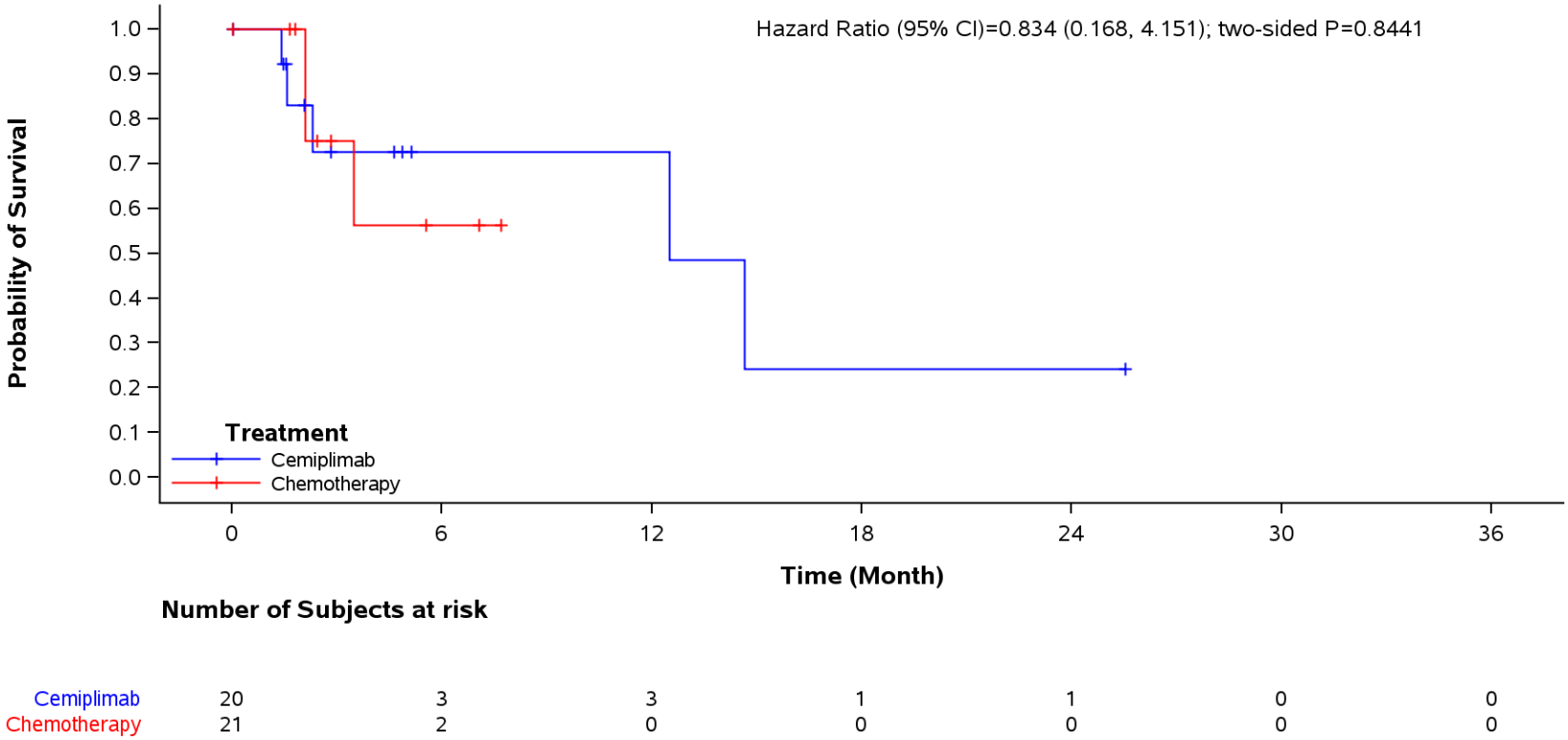

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

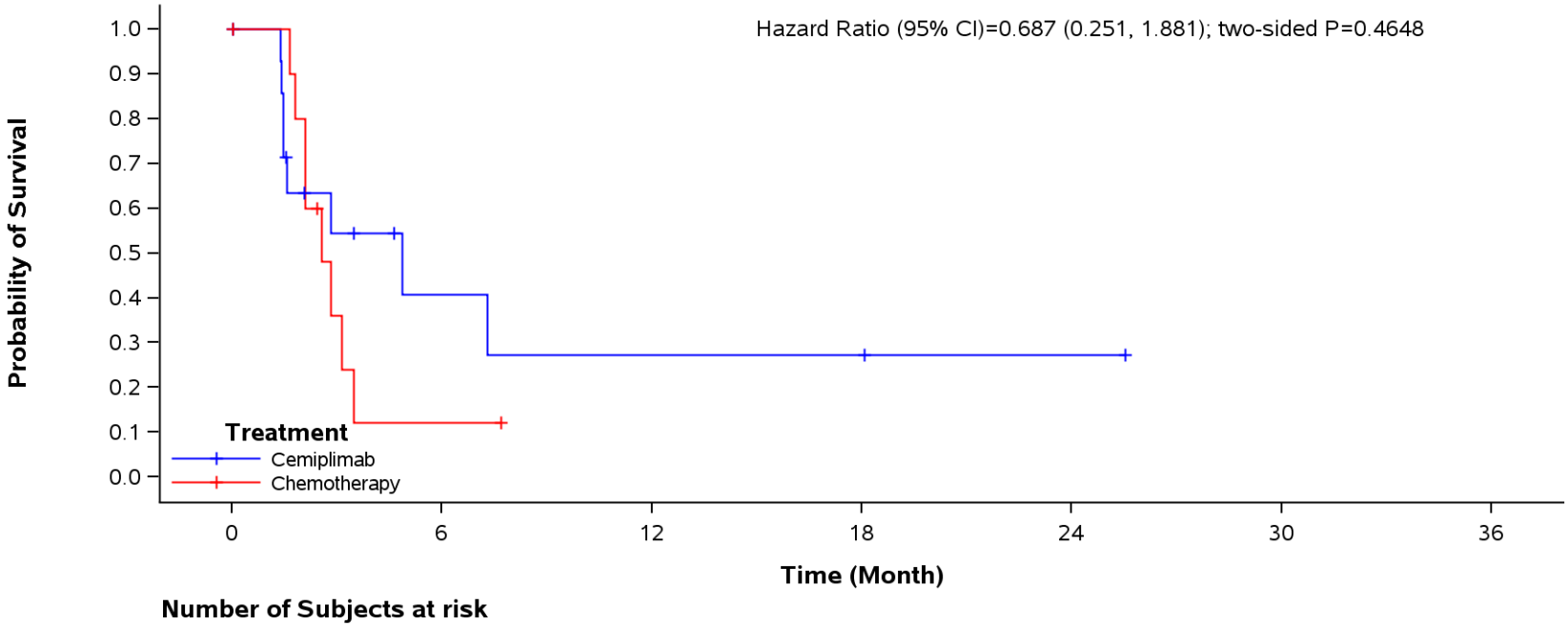
Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts sustained deterioration



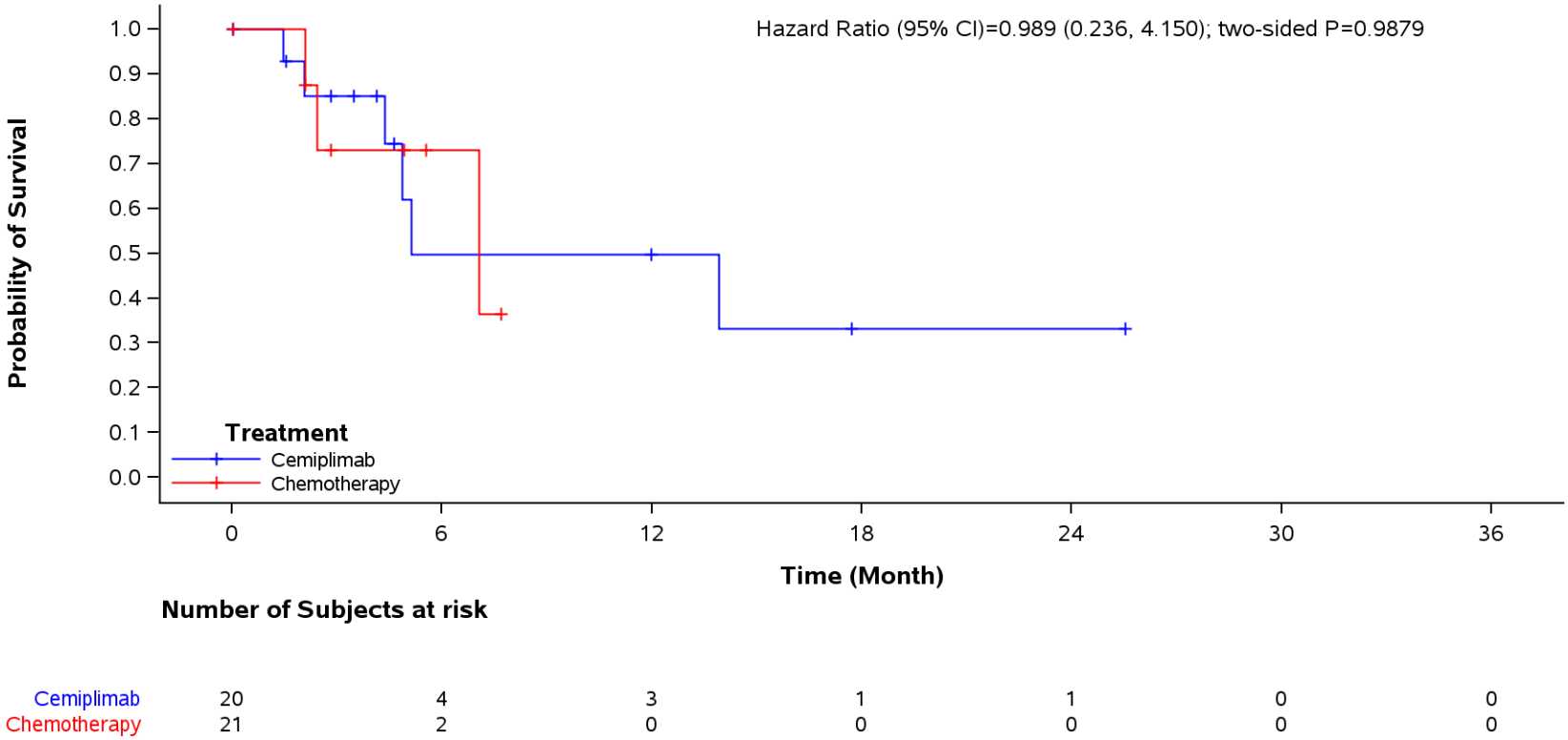

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts sustained deterioration



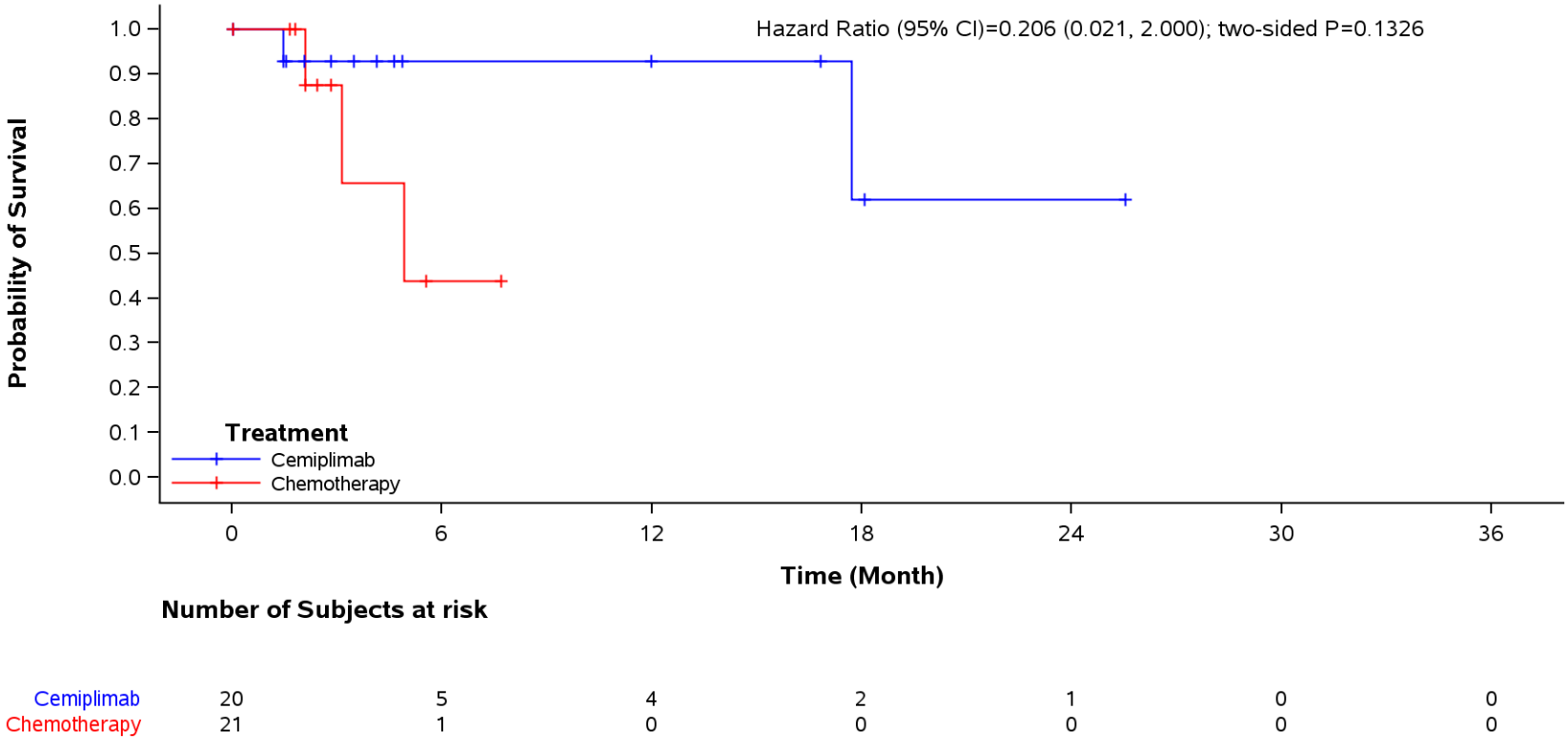

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts sustained deterioration



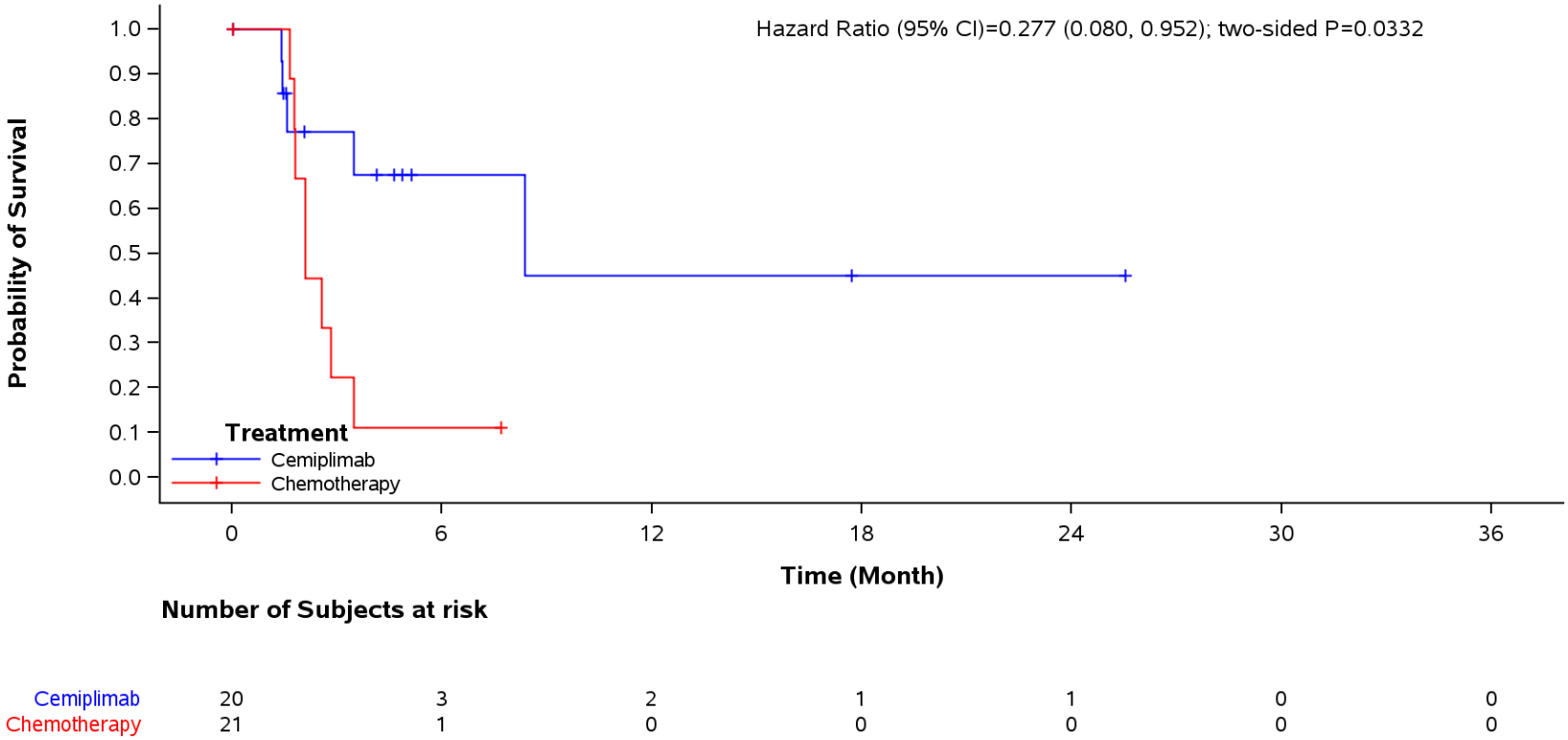

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts sustained deterioration



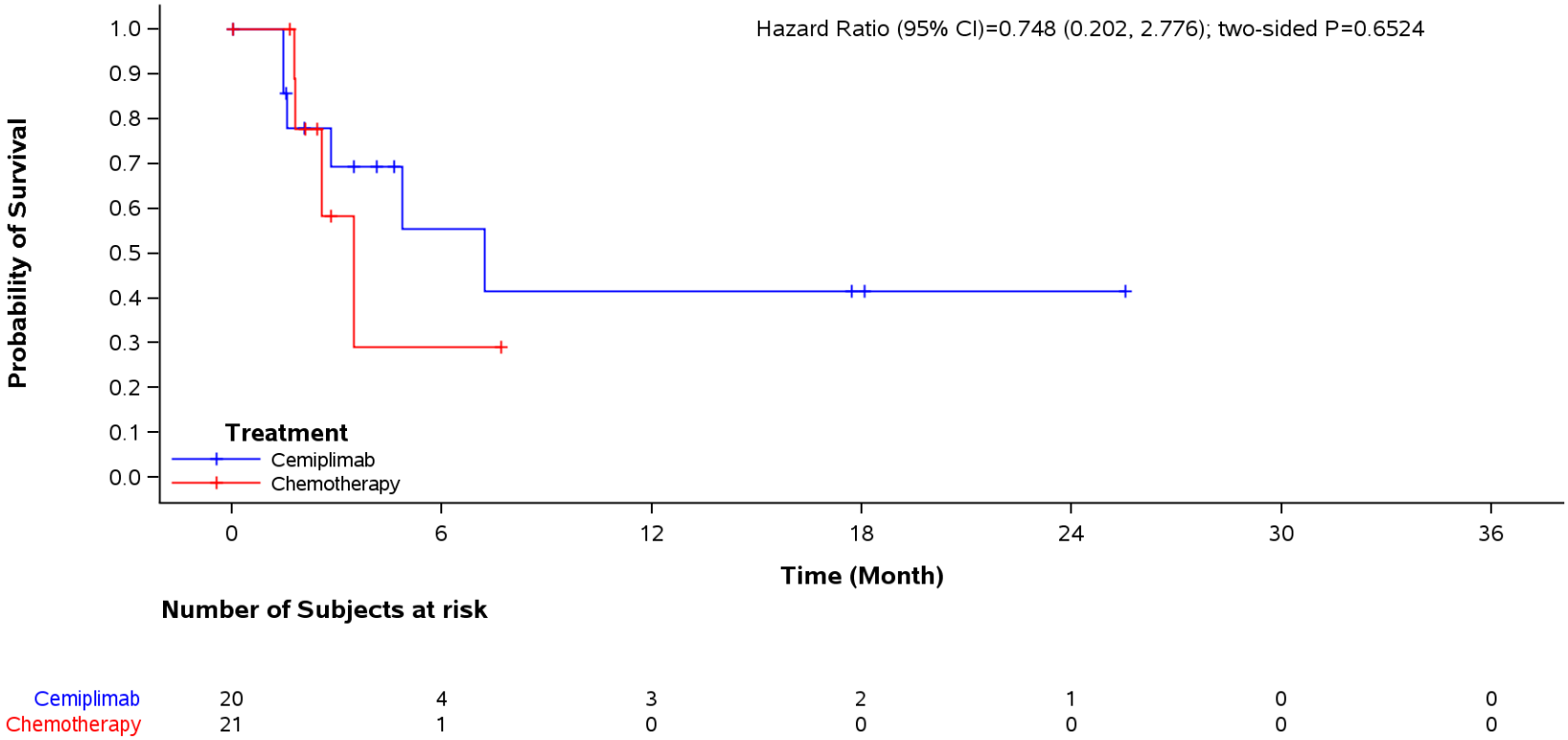

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts sustained deterioration



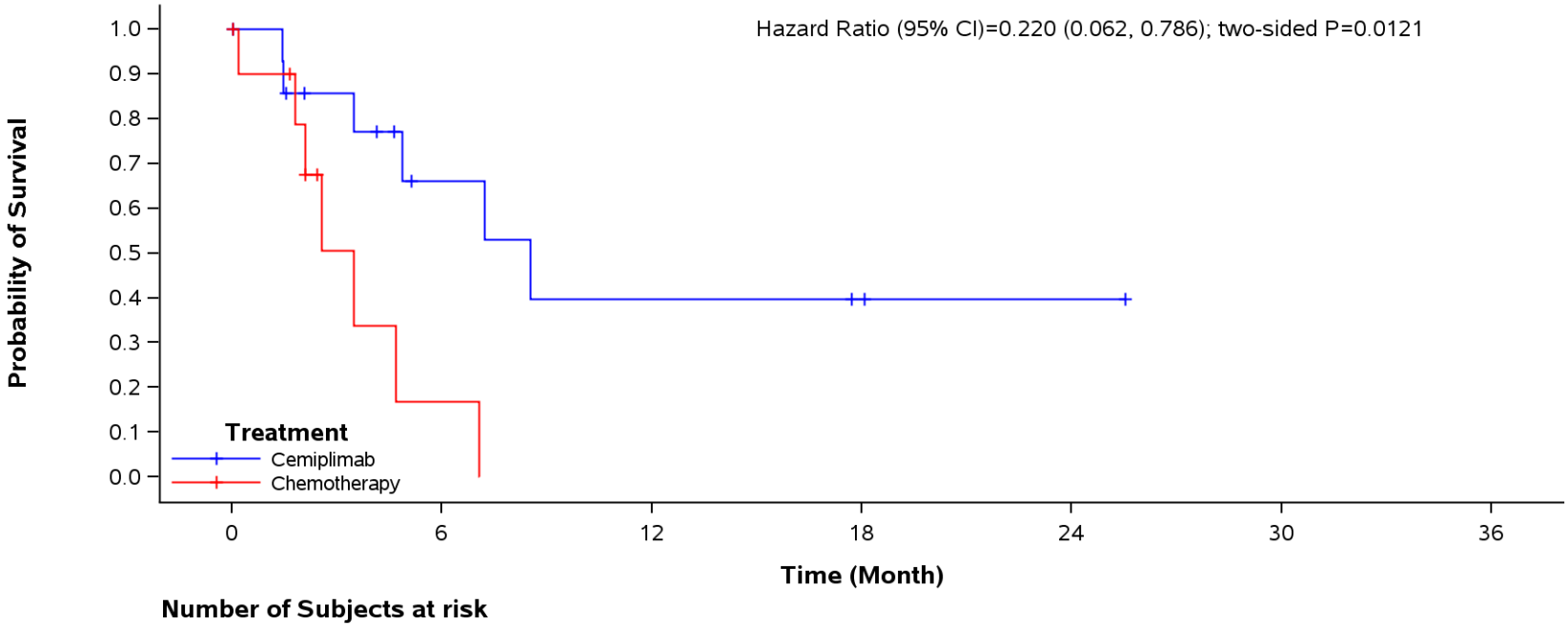

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Global health status / QoL - 10 pts sustained deterioration



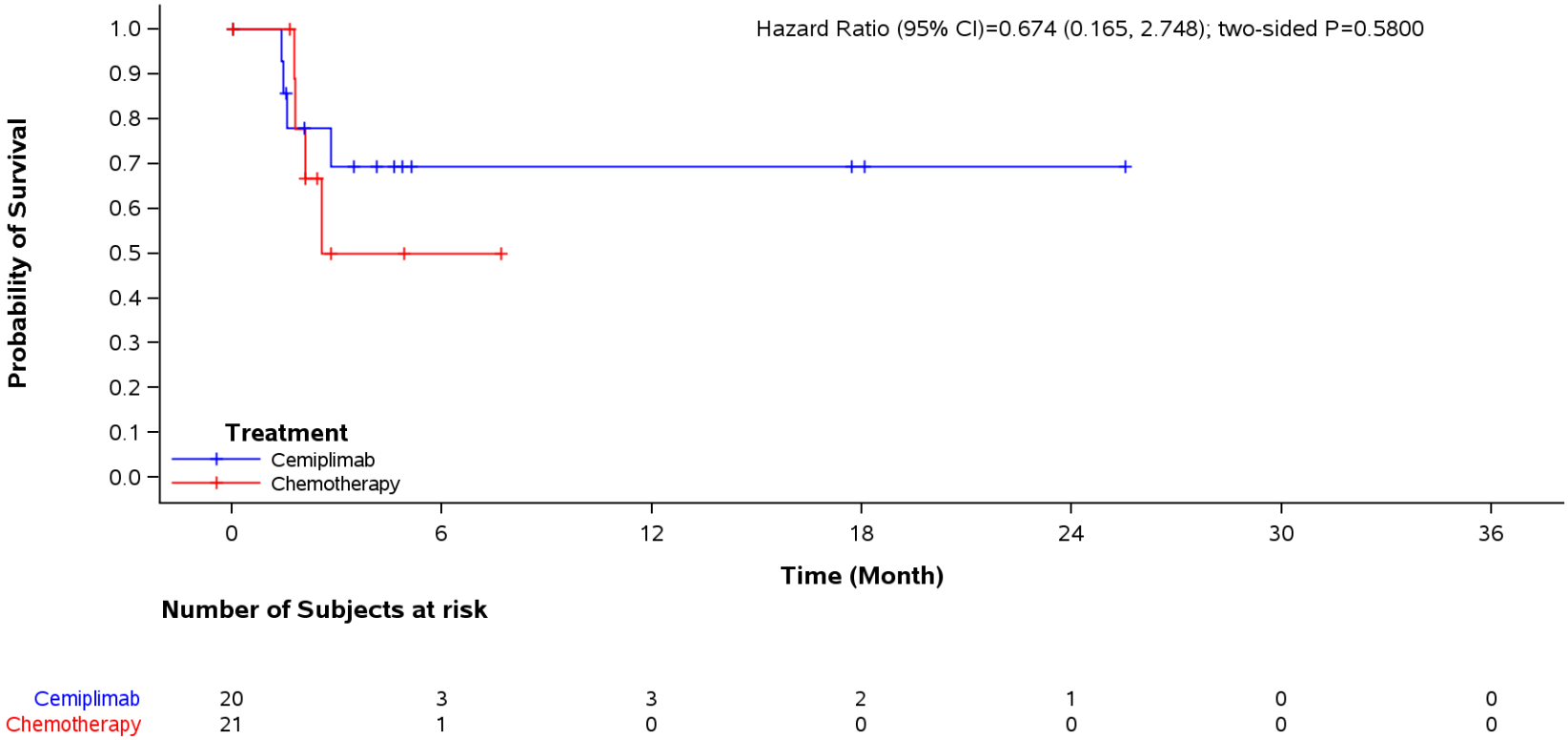

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts sustained deterioration



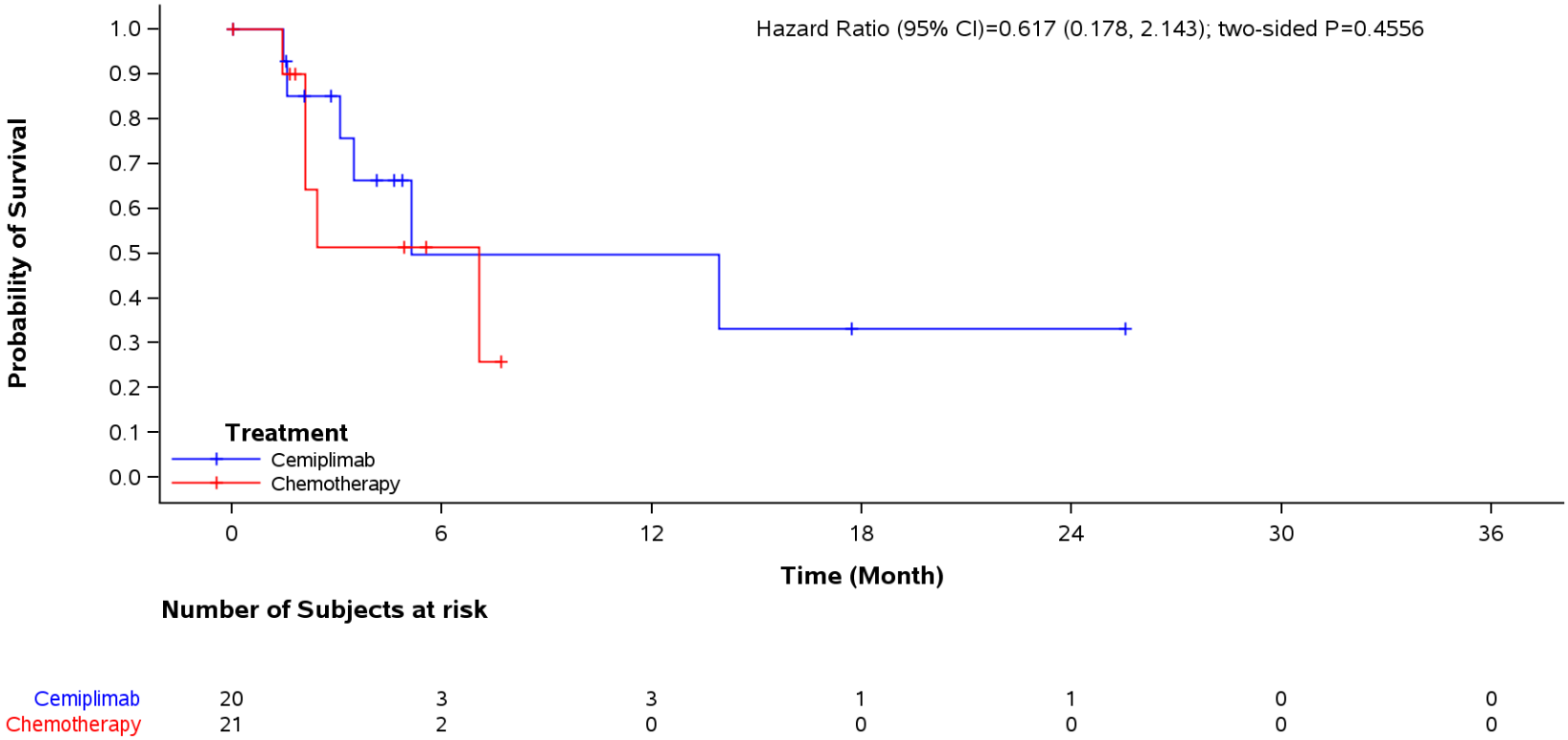

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

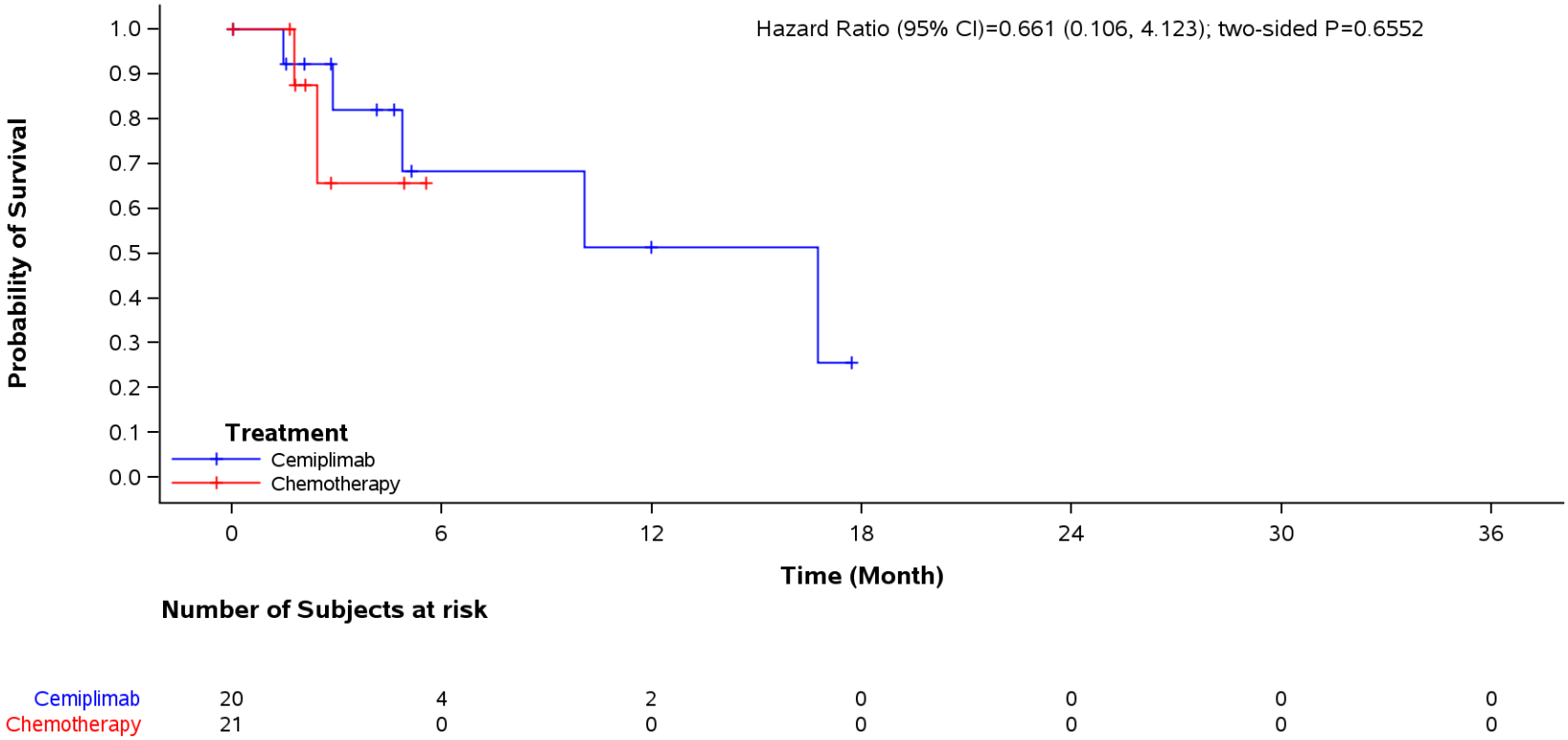
Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts sustained deterioration



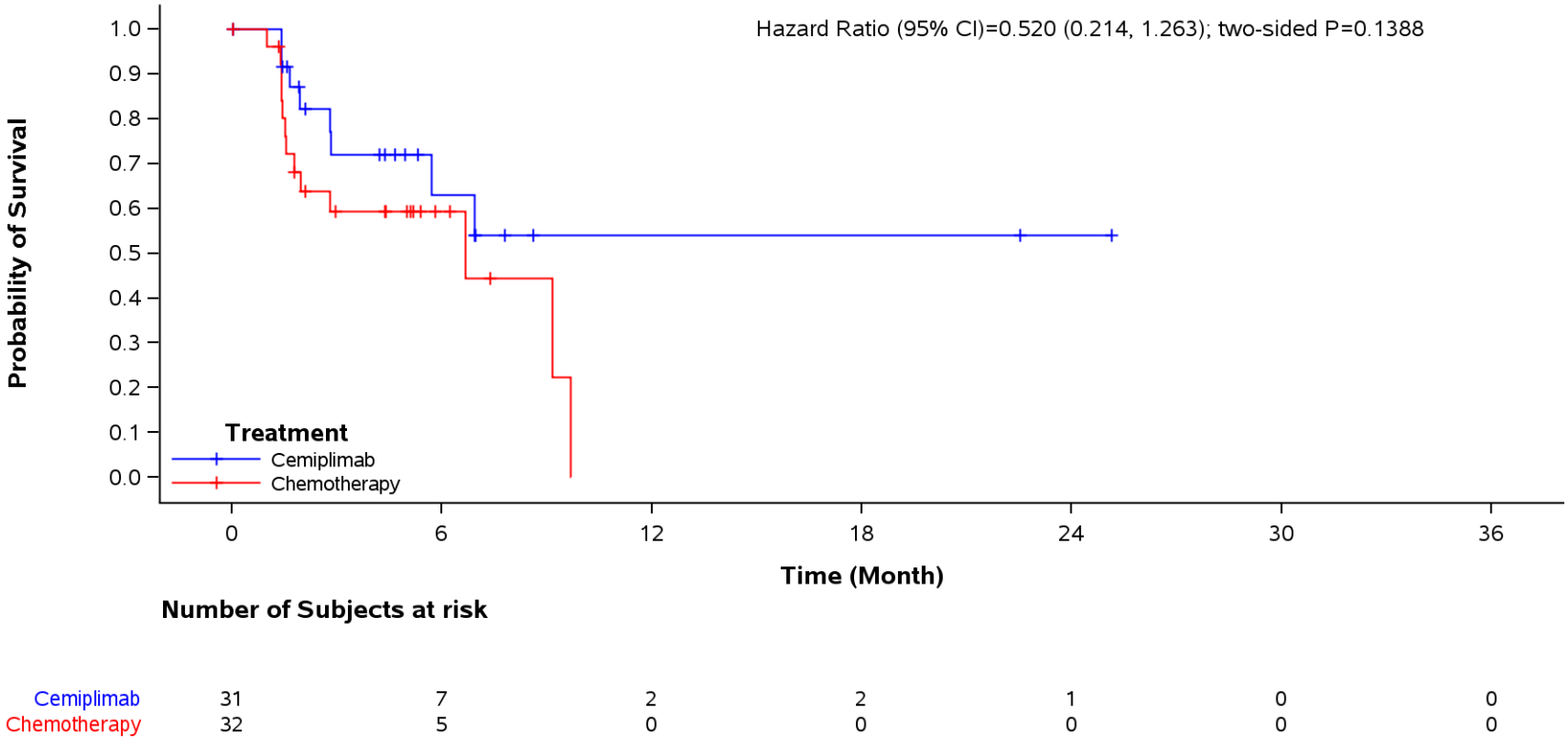

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts sustained deterioration



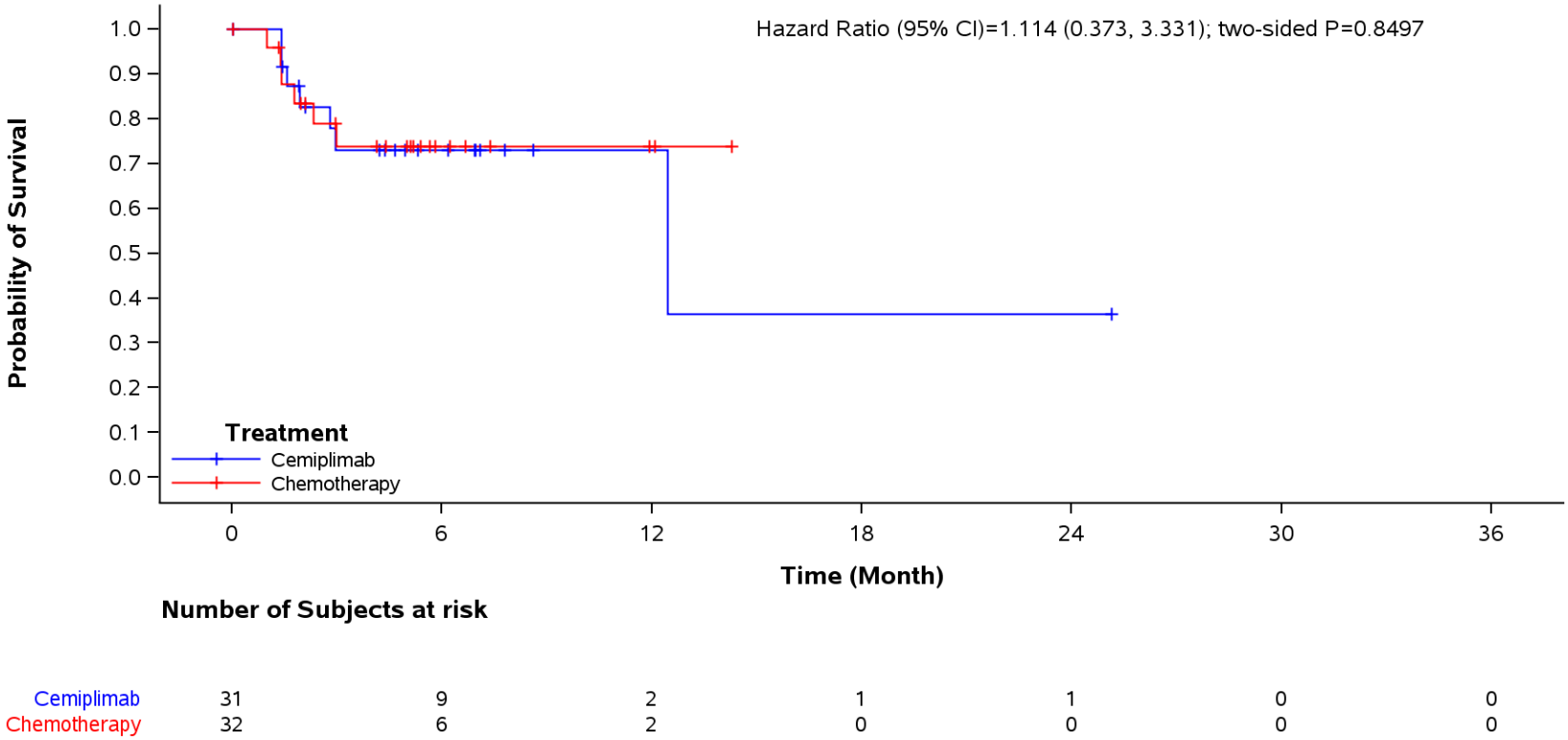

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

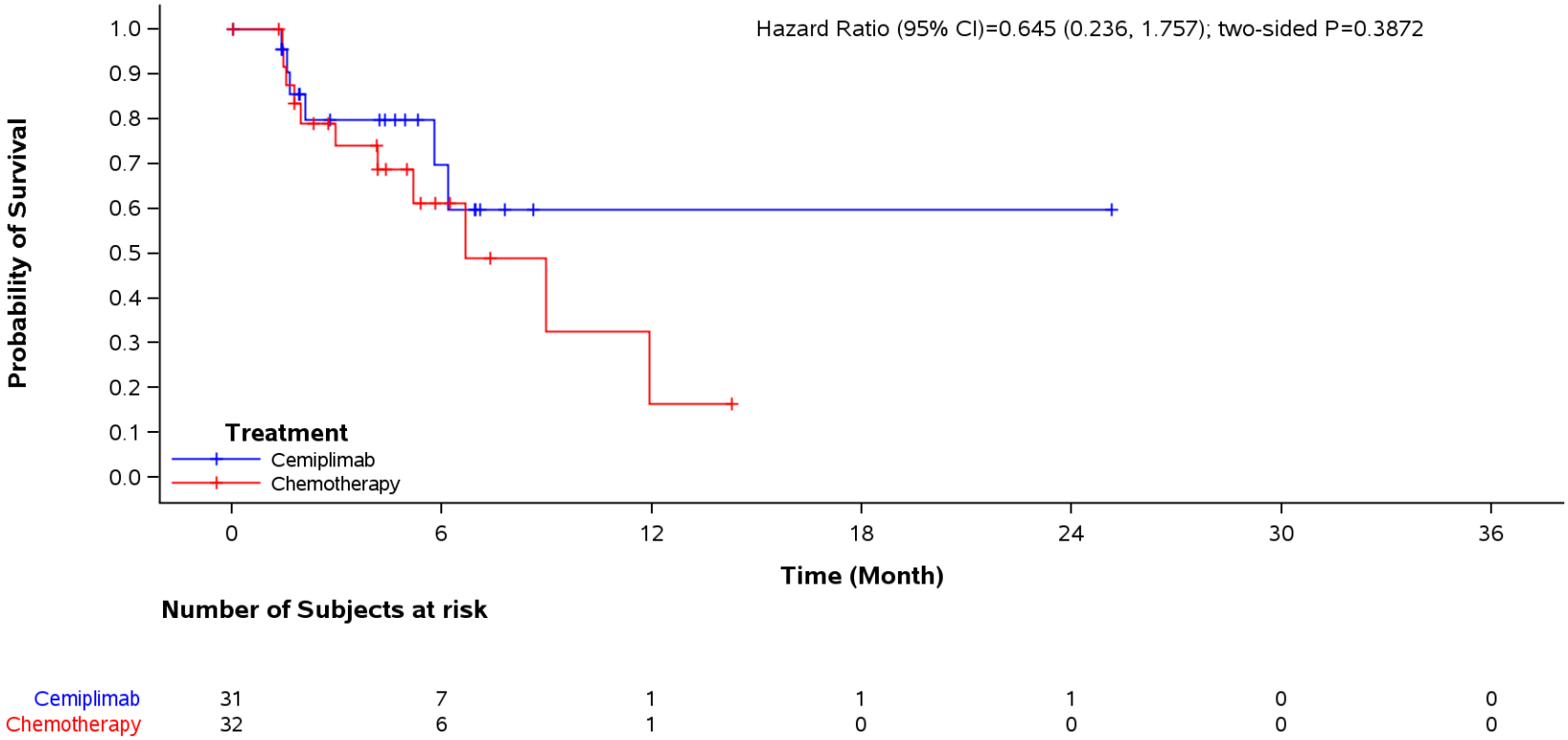
Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts sustained deterioration



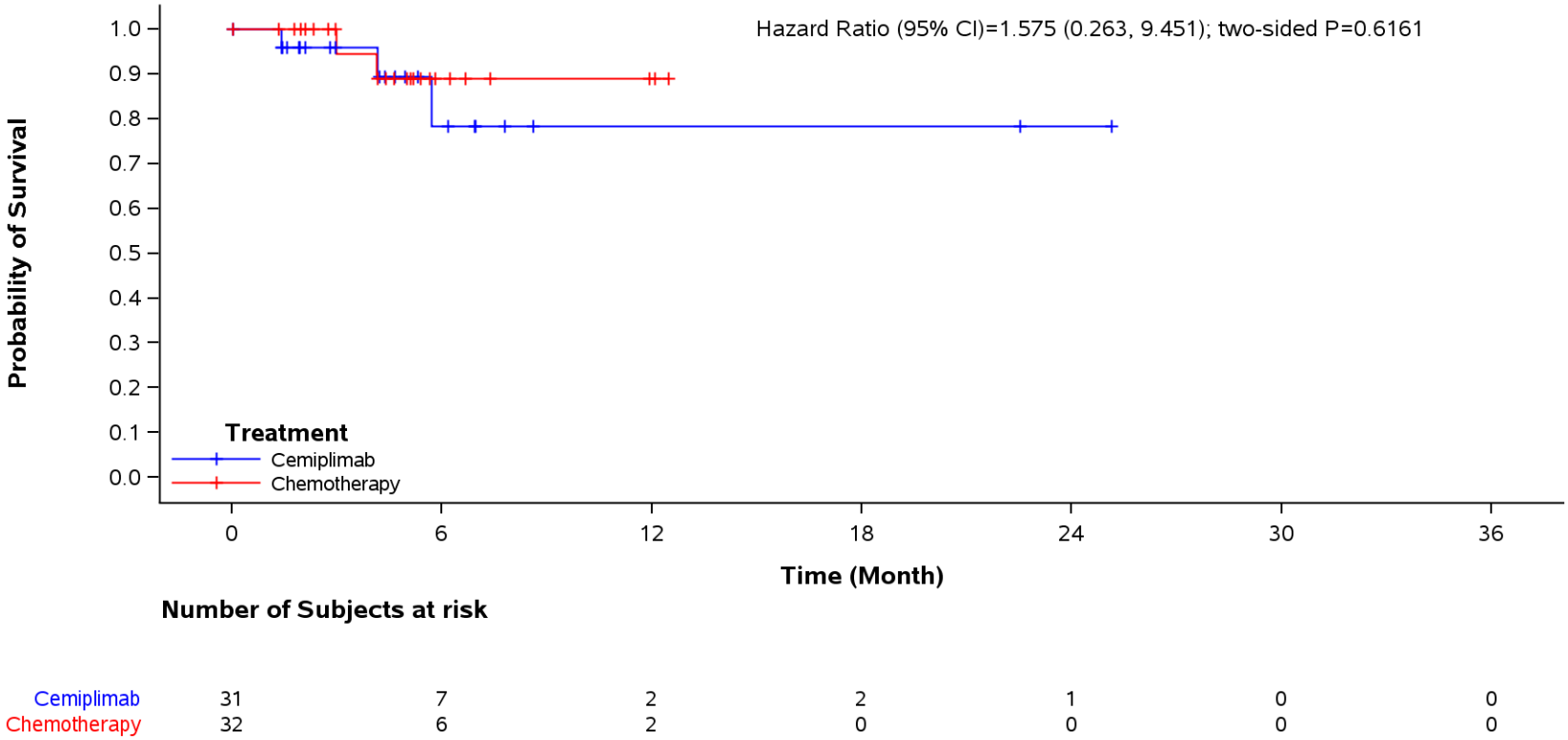

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts sustained deterioration



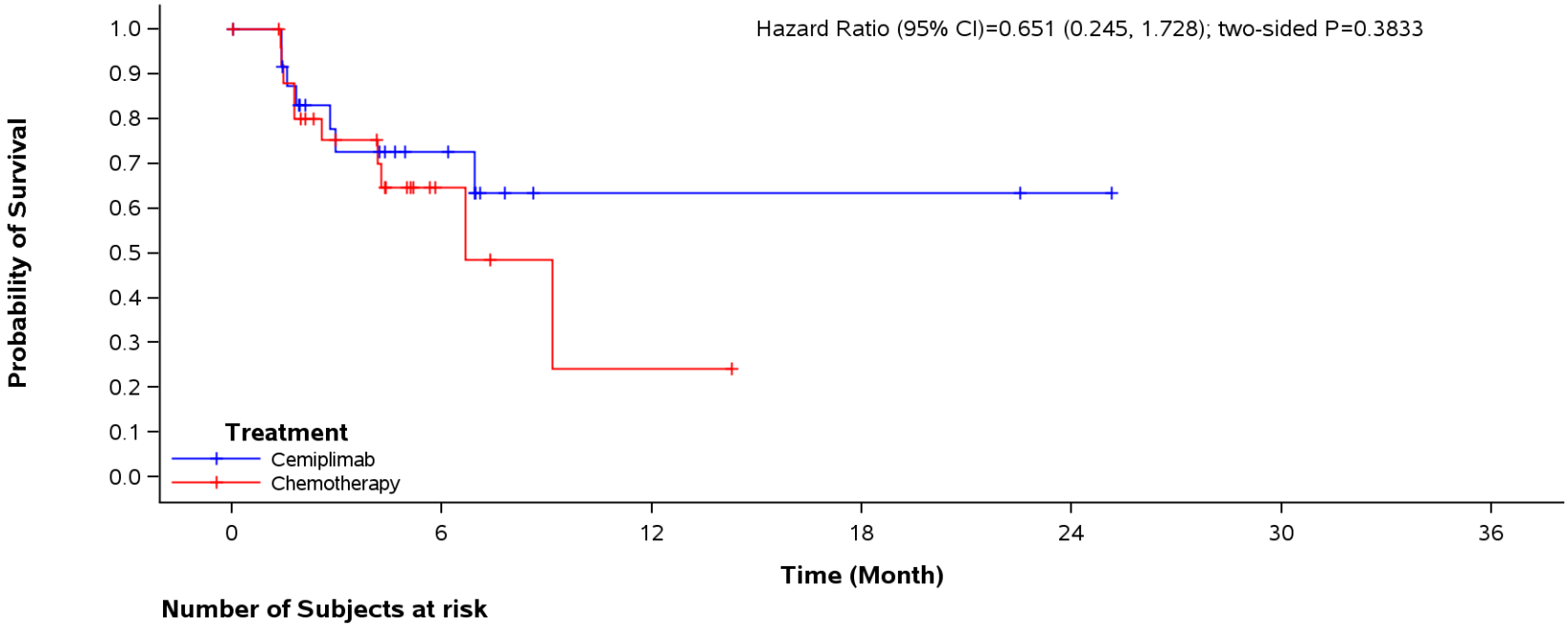

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts sustained deterioration



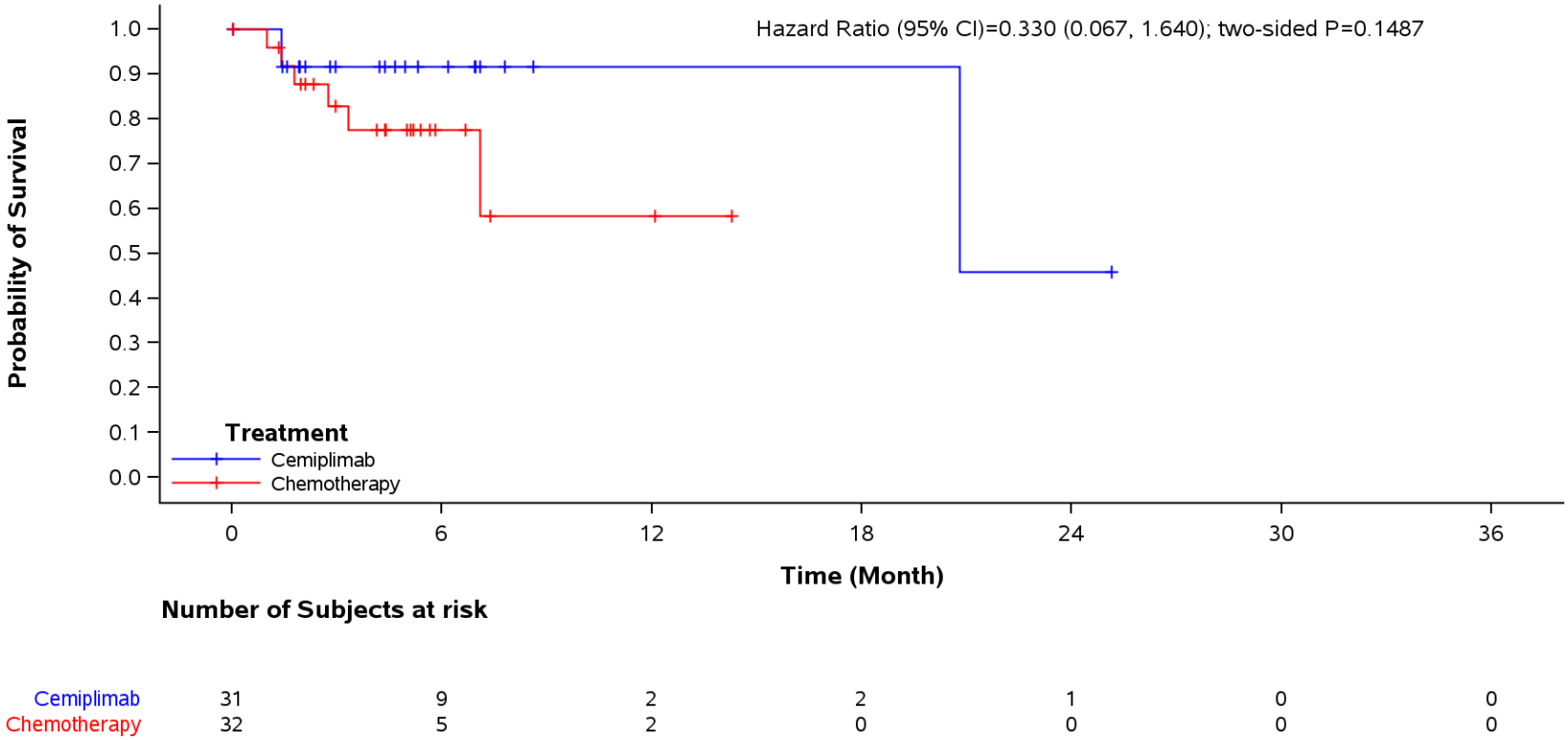

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 9 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts sustained deterioration



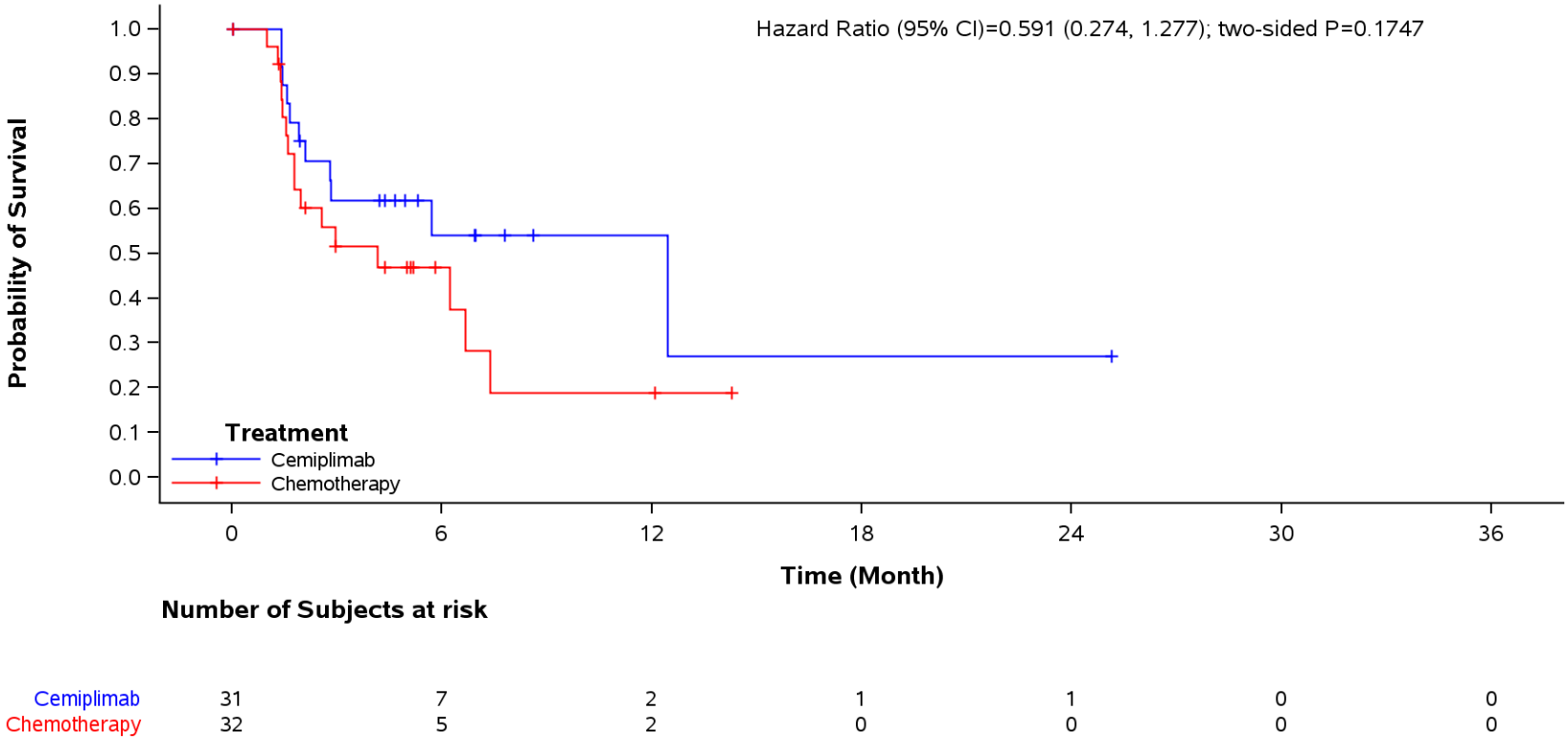

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 9 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts sustained deterioration



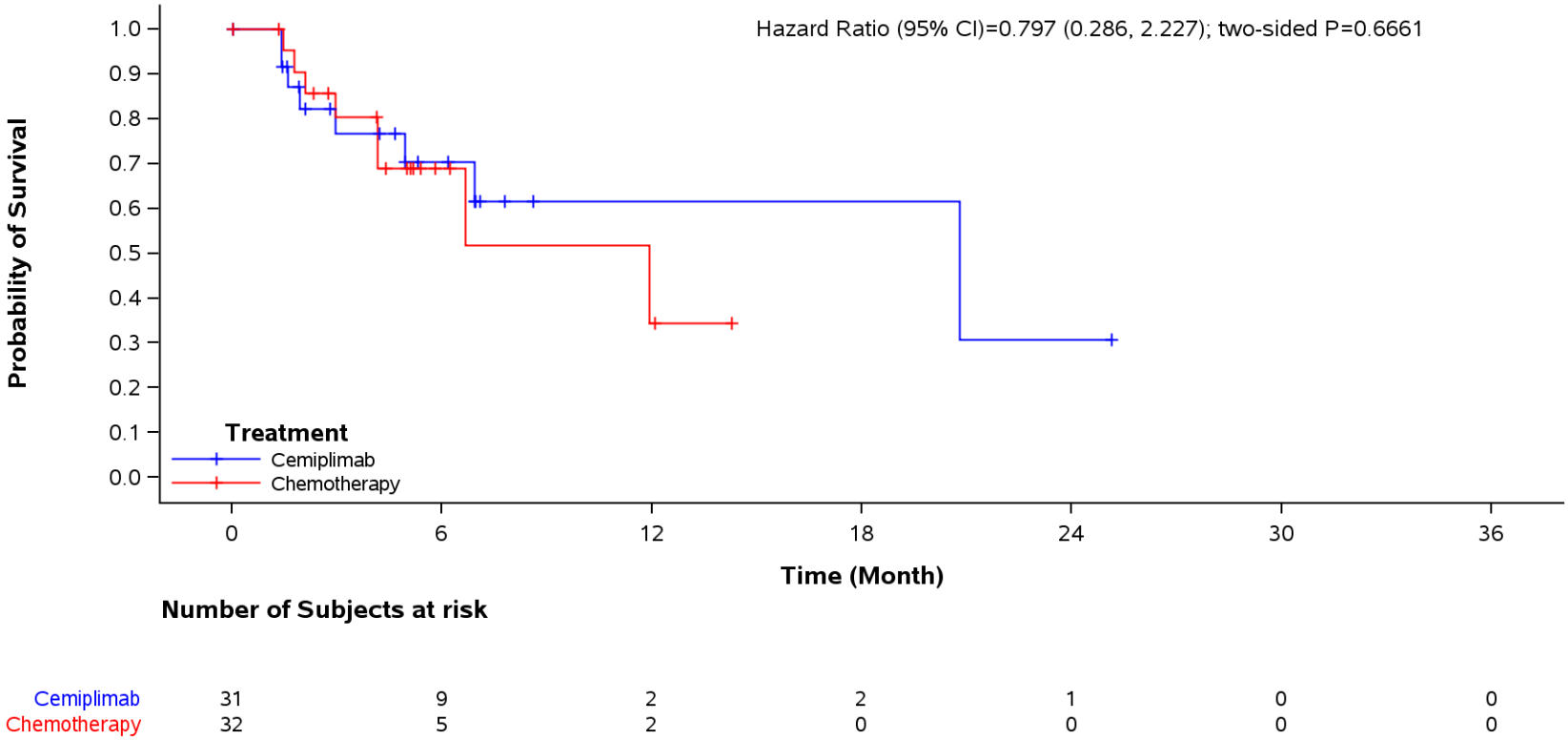

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts sustained deterioration



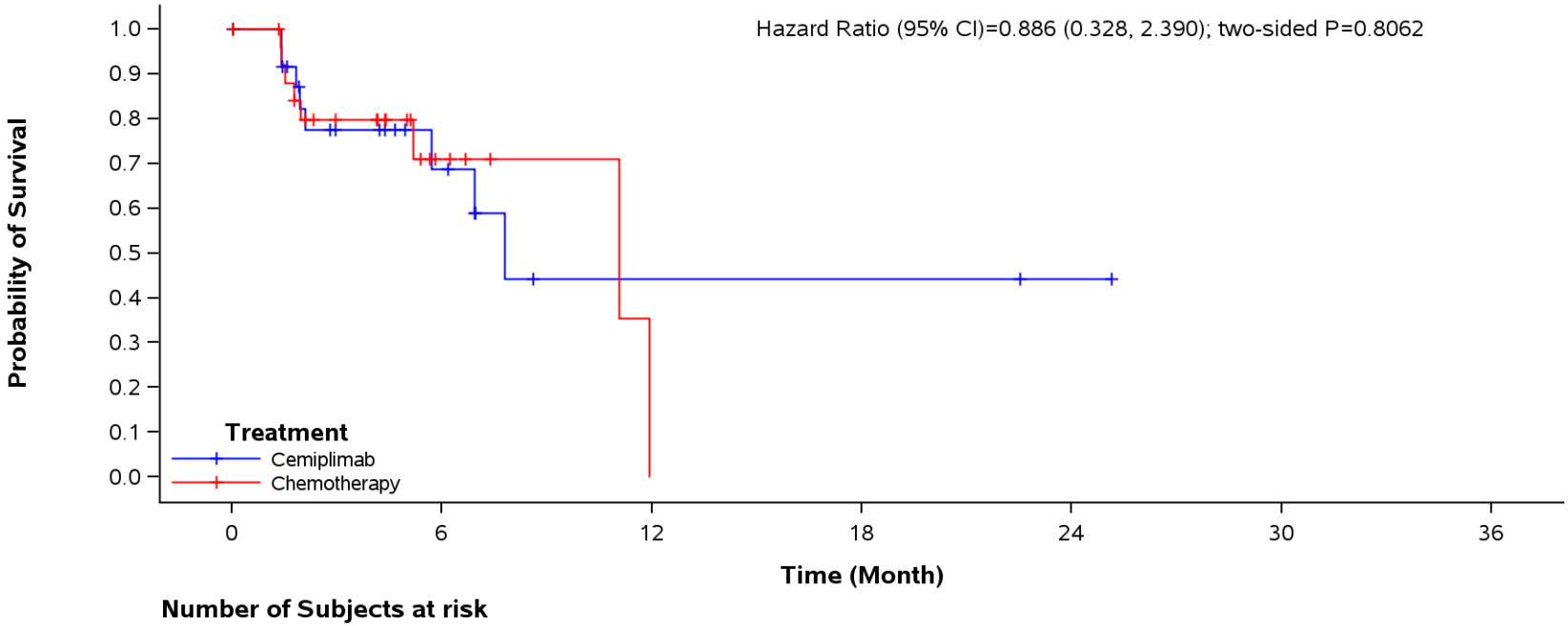

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 9 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts sustained deterioration



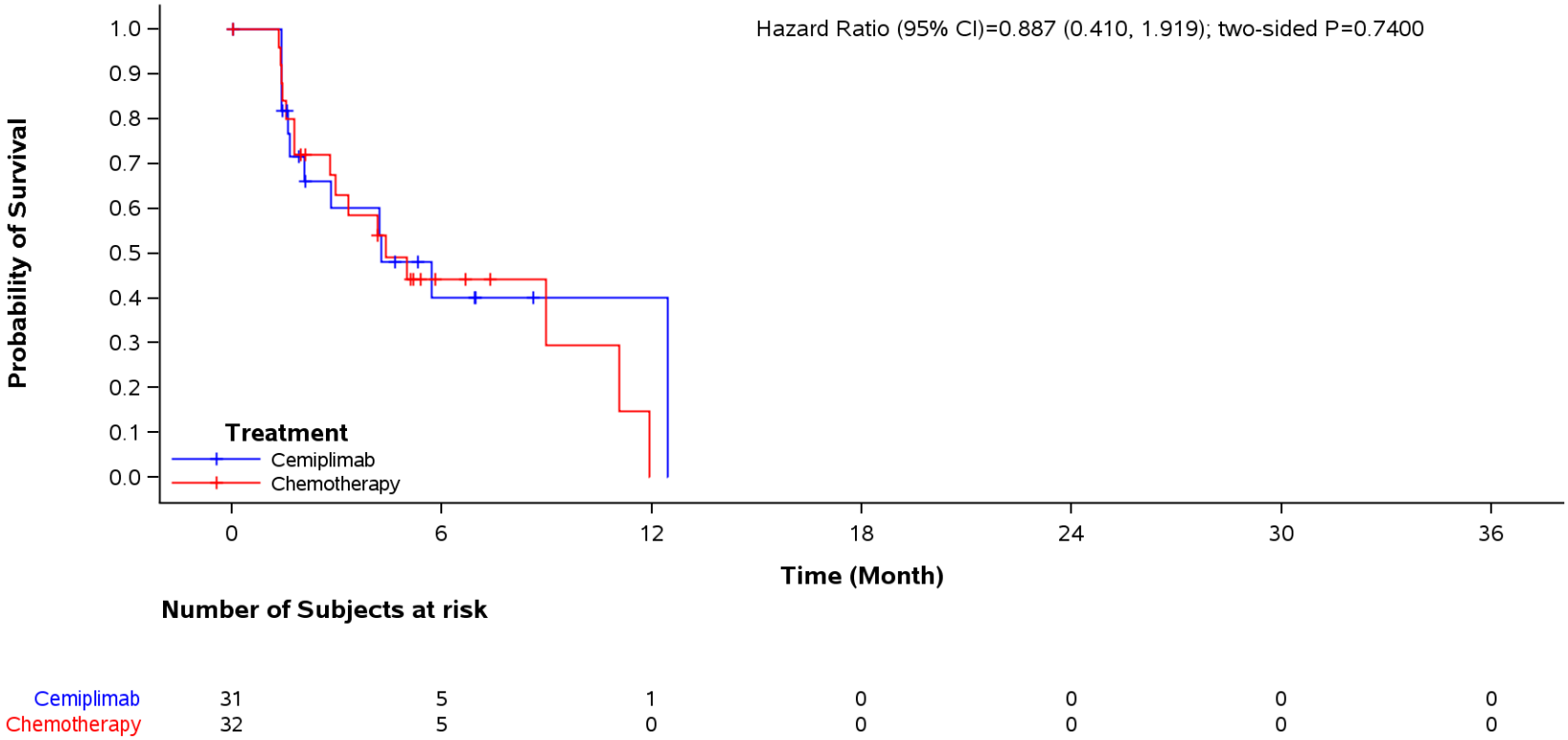

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 8 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts sustained deterioration



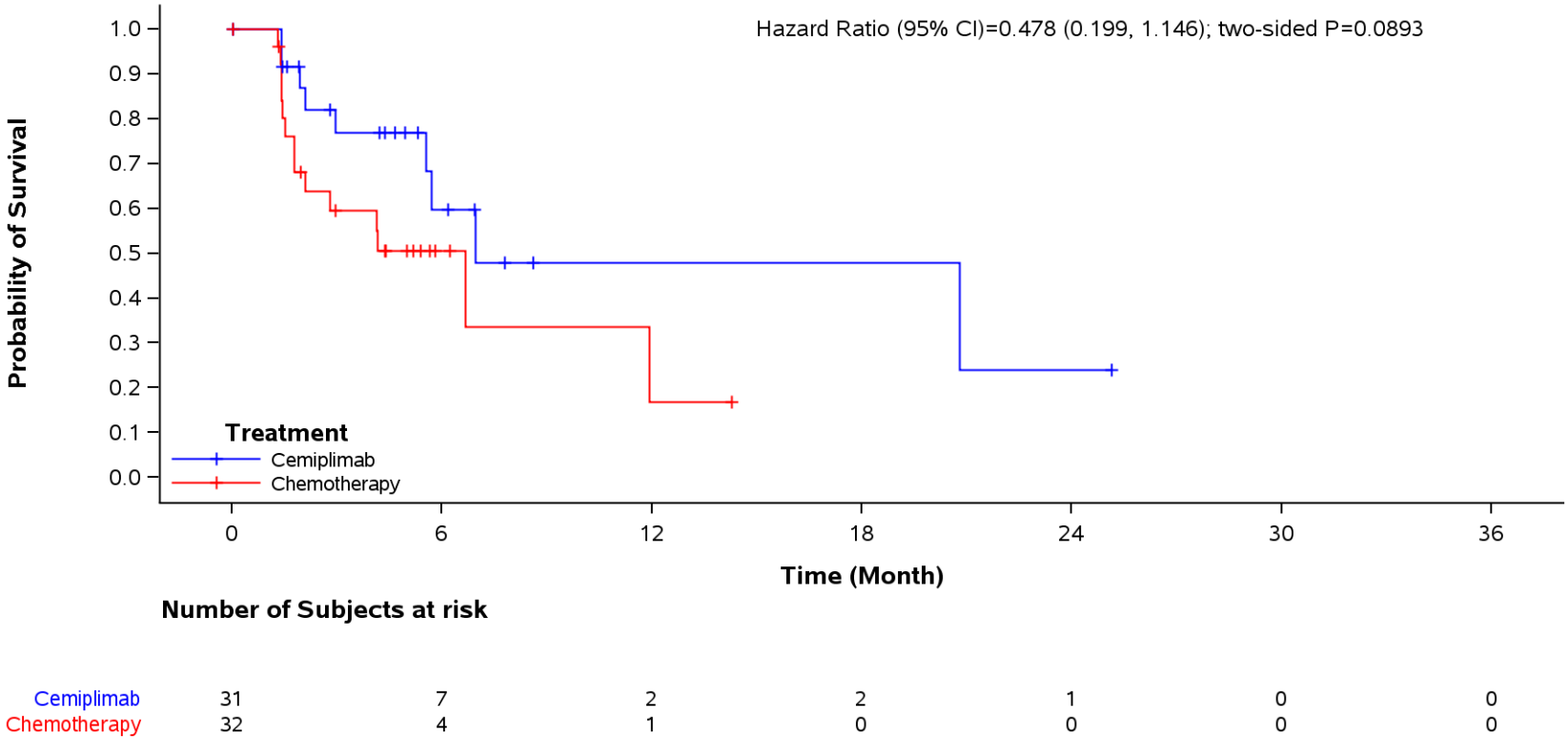

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts sustained deterioration



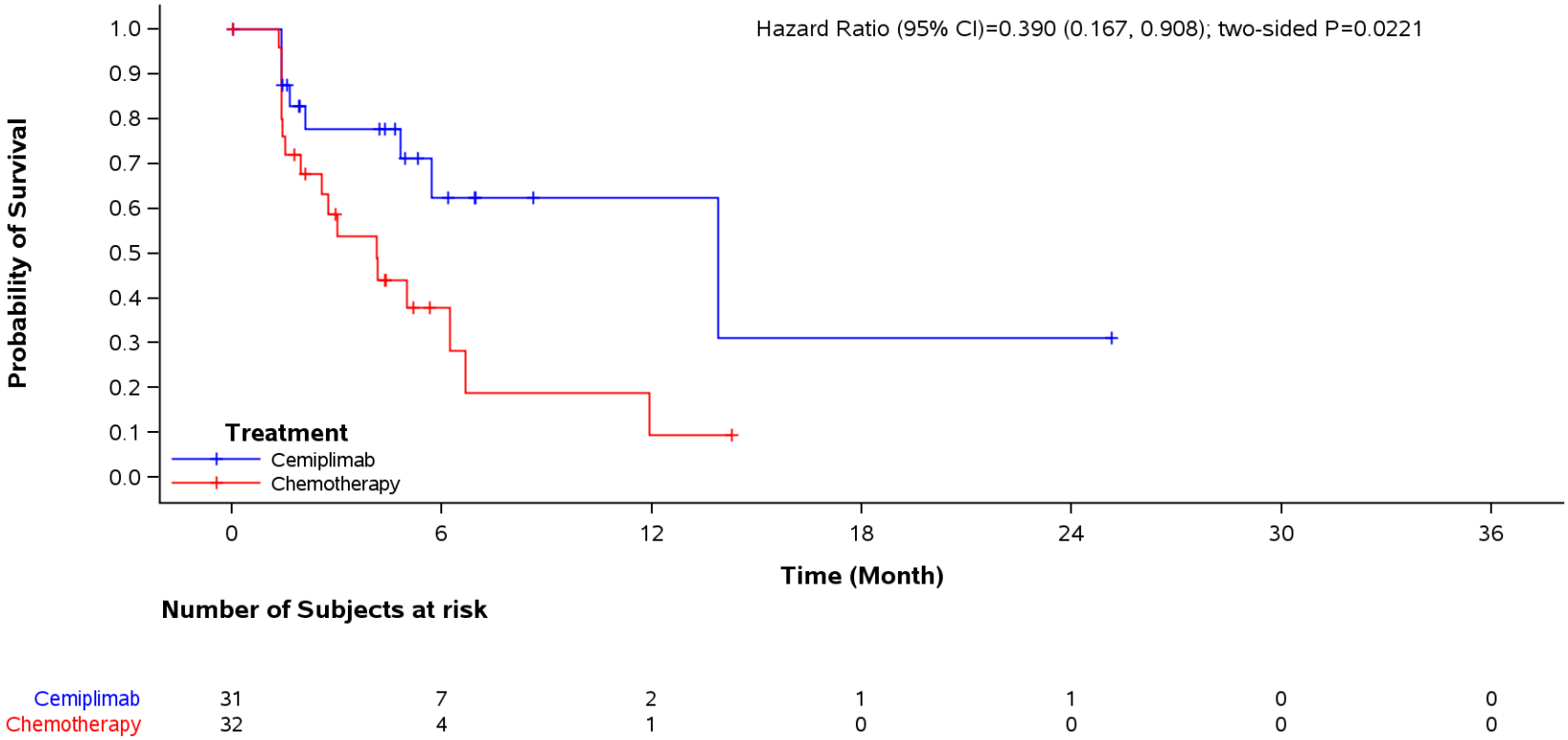

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts sustained deterioration



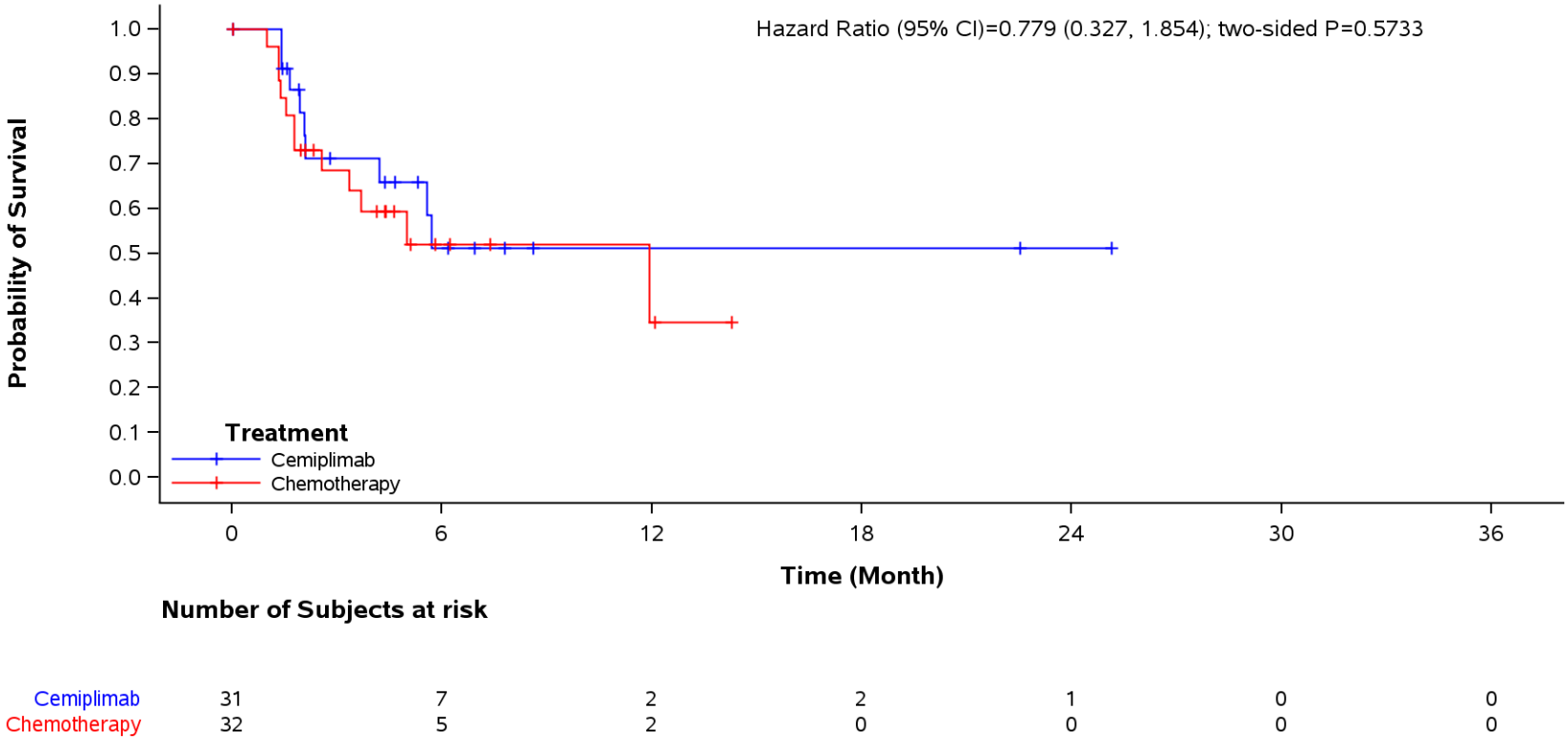

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts sustained deterioration



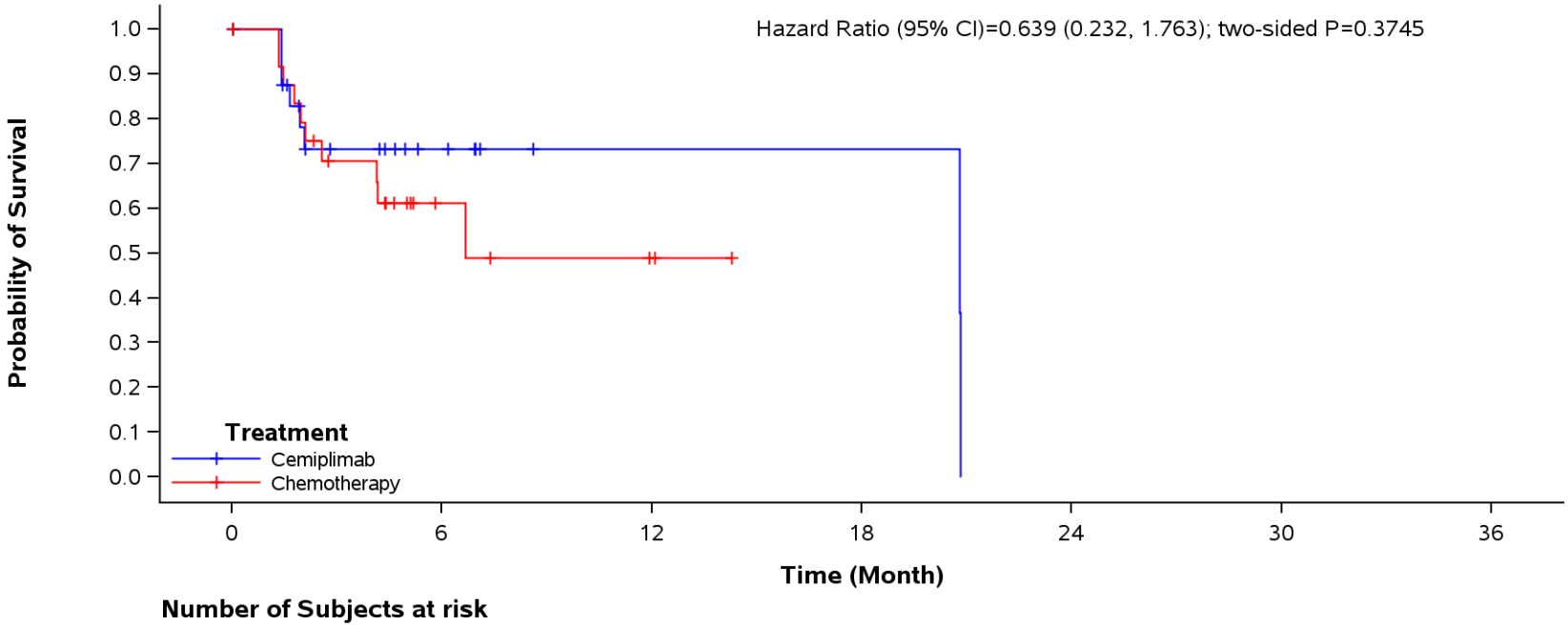

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts sustained deterioration



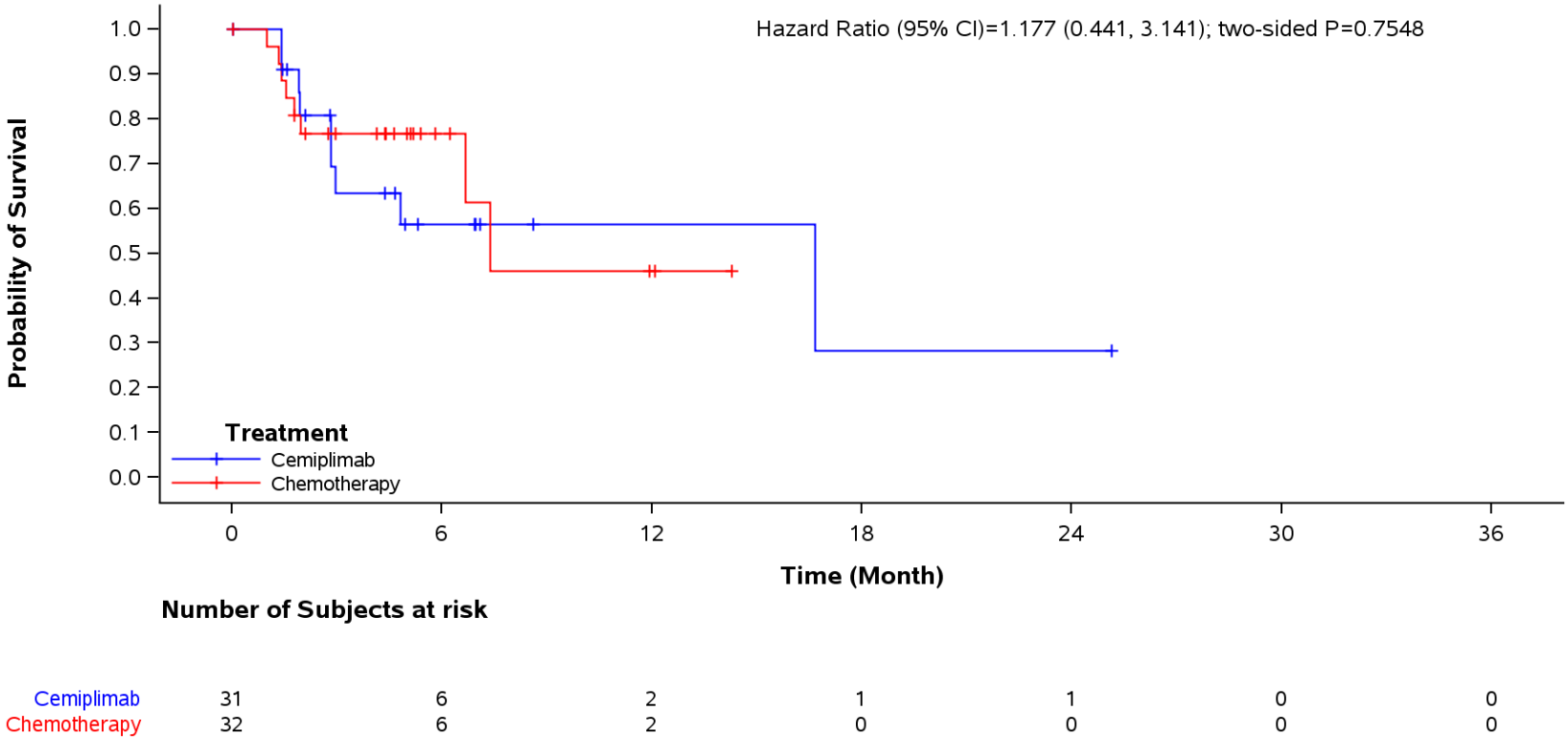

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 8 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts sustained deterioration



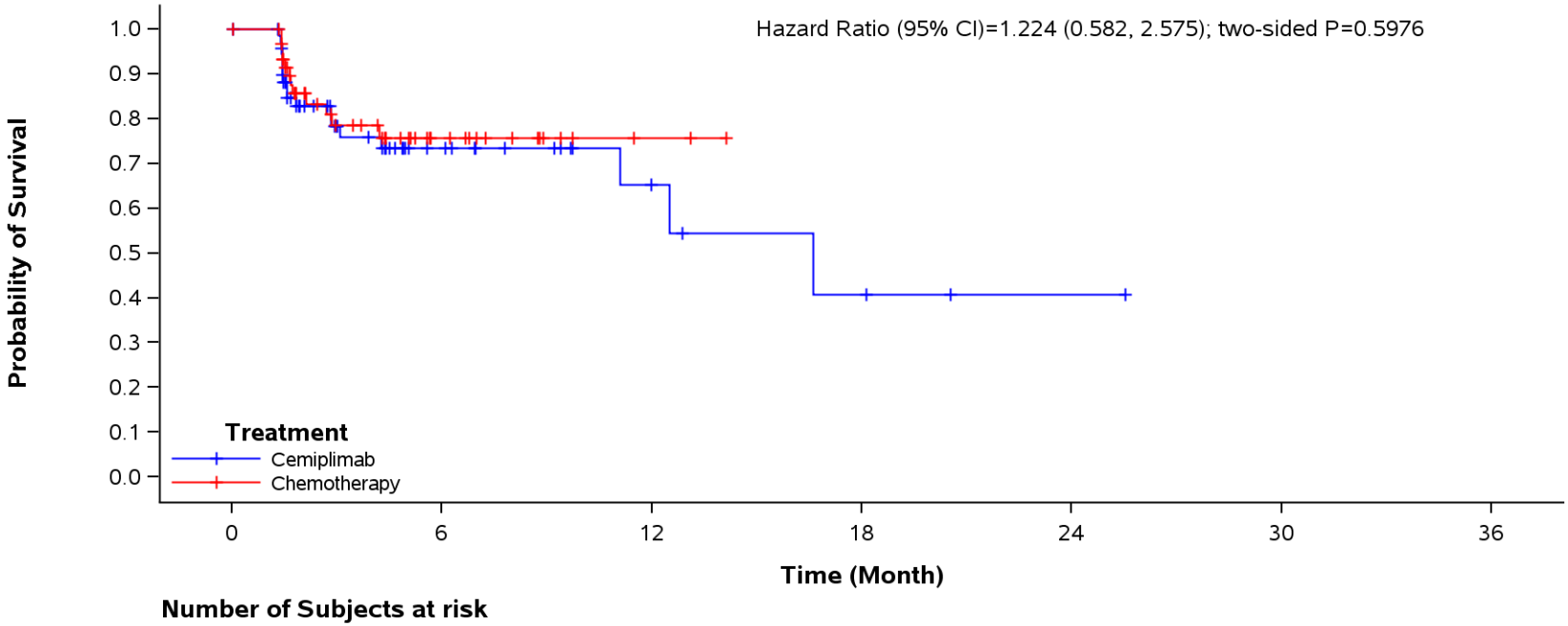

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Appetite loss - 10 pts sensitivity sustained improvement



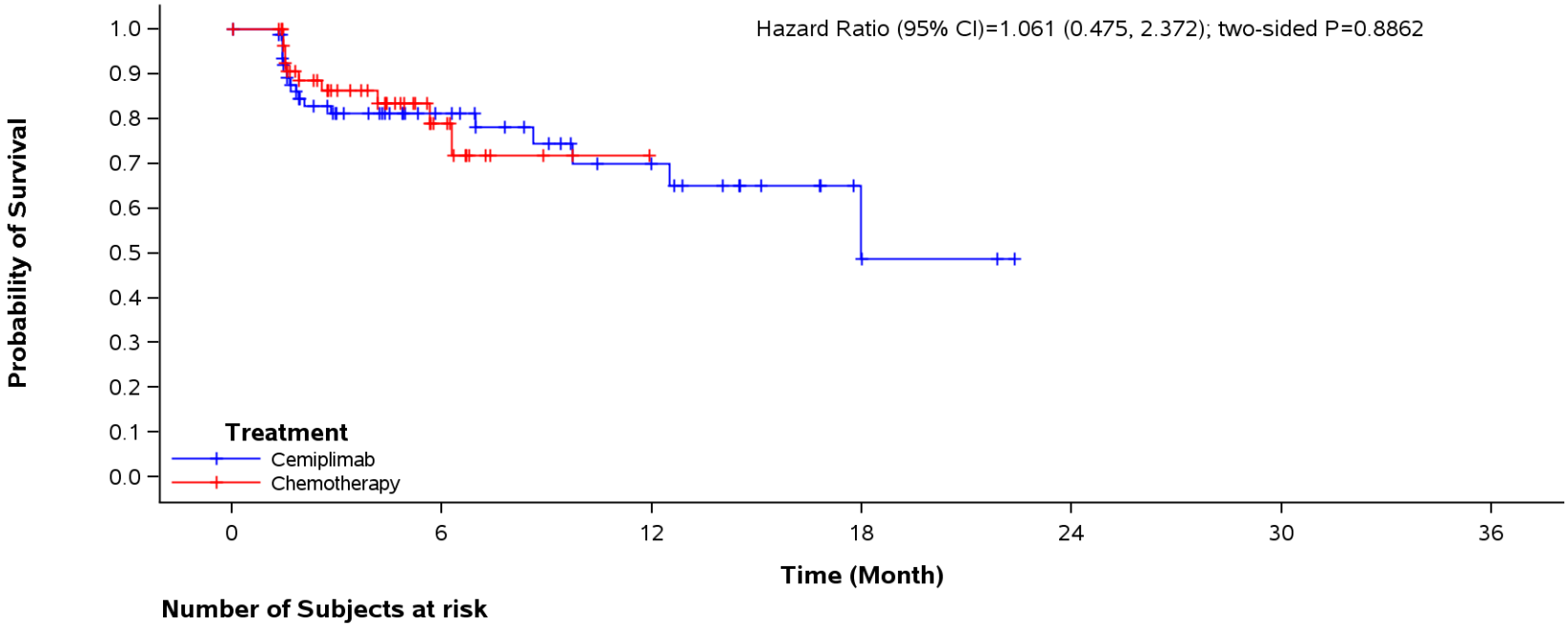

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 18 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 163 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts sensitivity sustained improvement



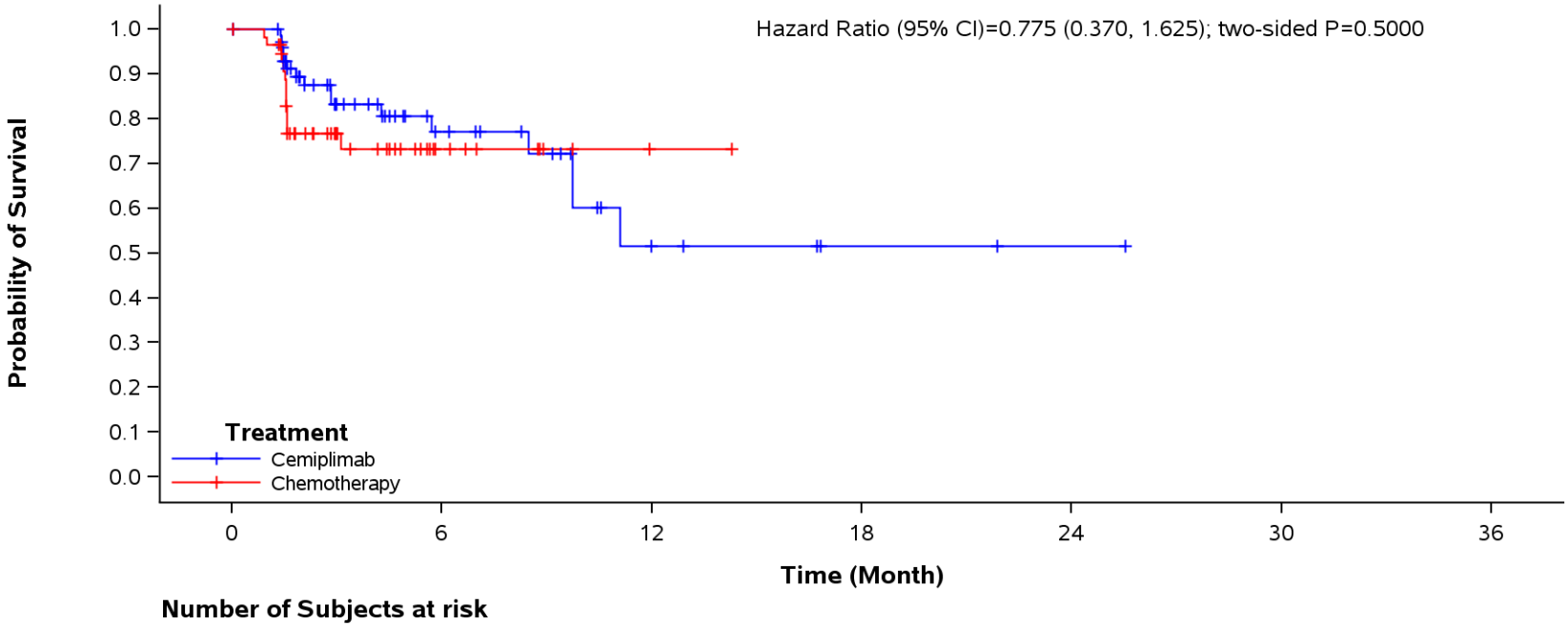

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 30 | 14 | 3 | 0 | 0 | 0 |
| Chemotherapy | 163 | 14 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts sensitivity sustained improvement



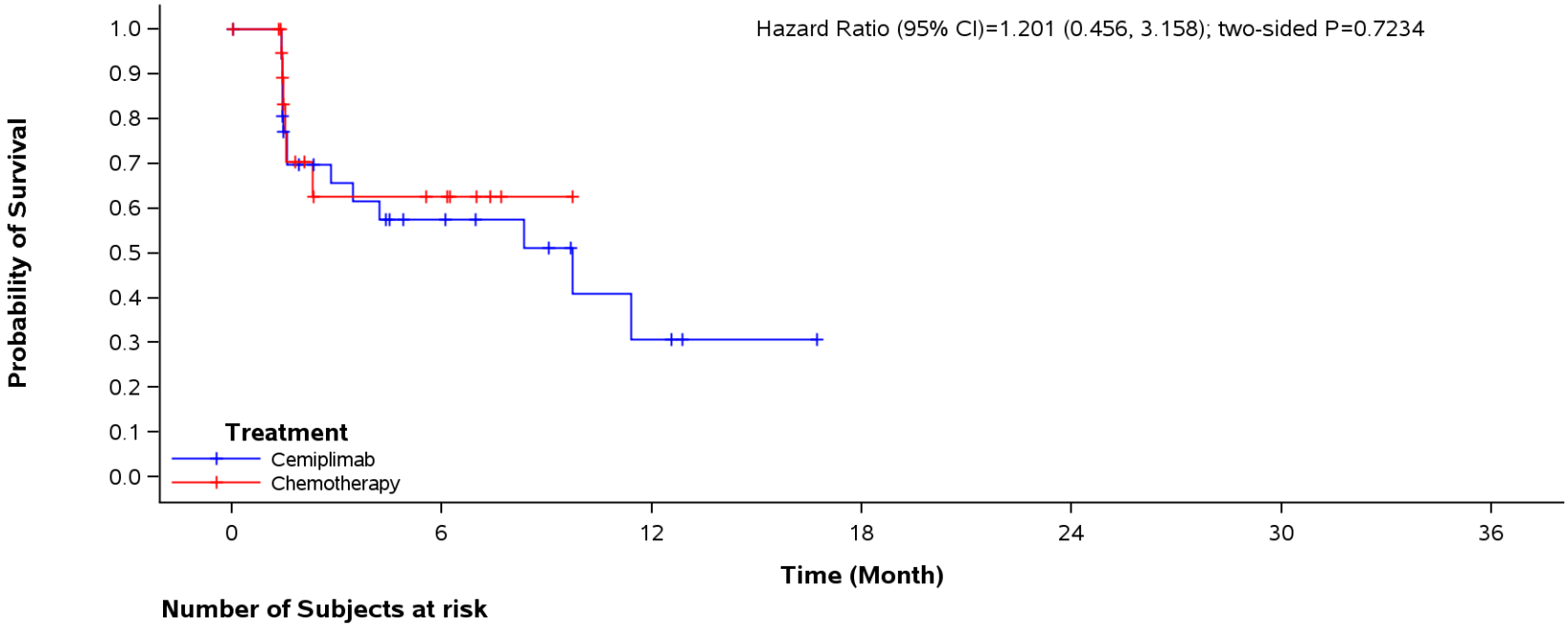

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 21 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 163 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts sensitivity sustained improvement



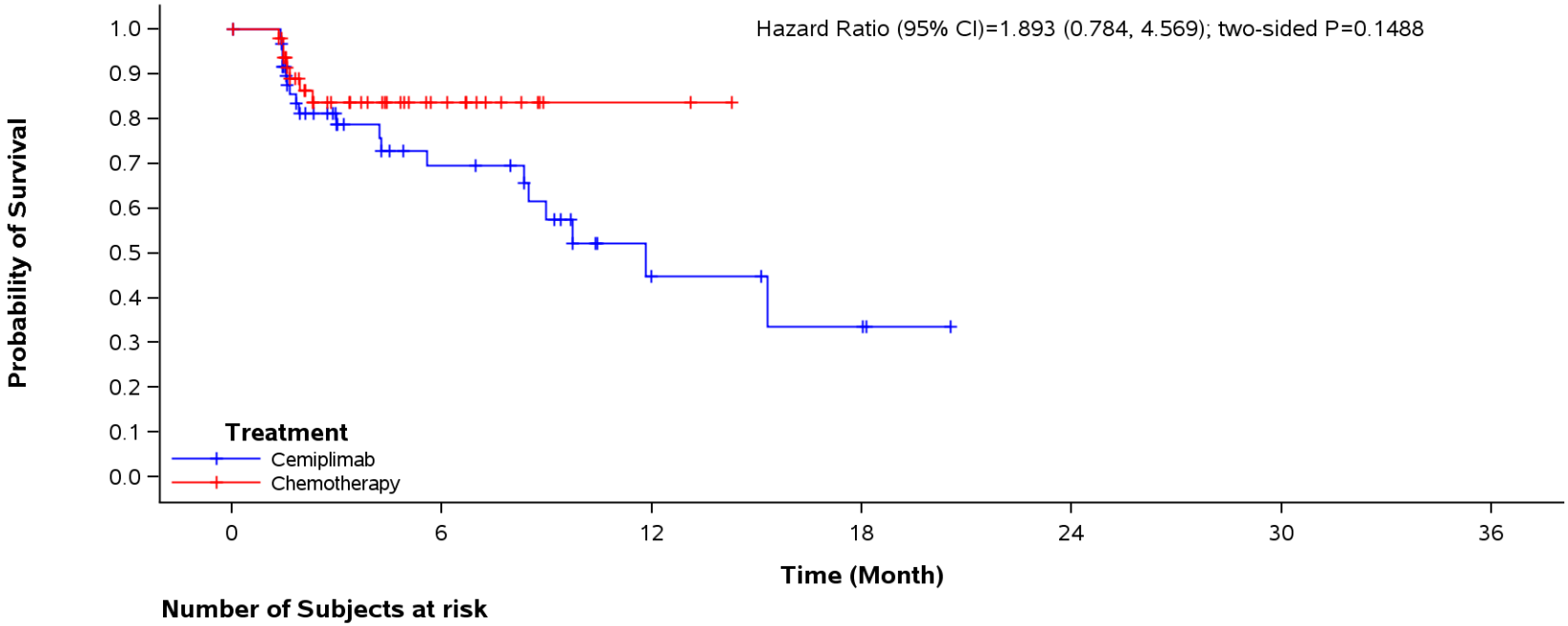

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 11 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 163 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts sensitivity sustained improvement



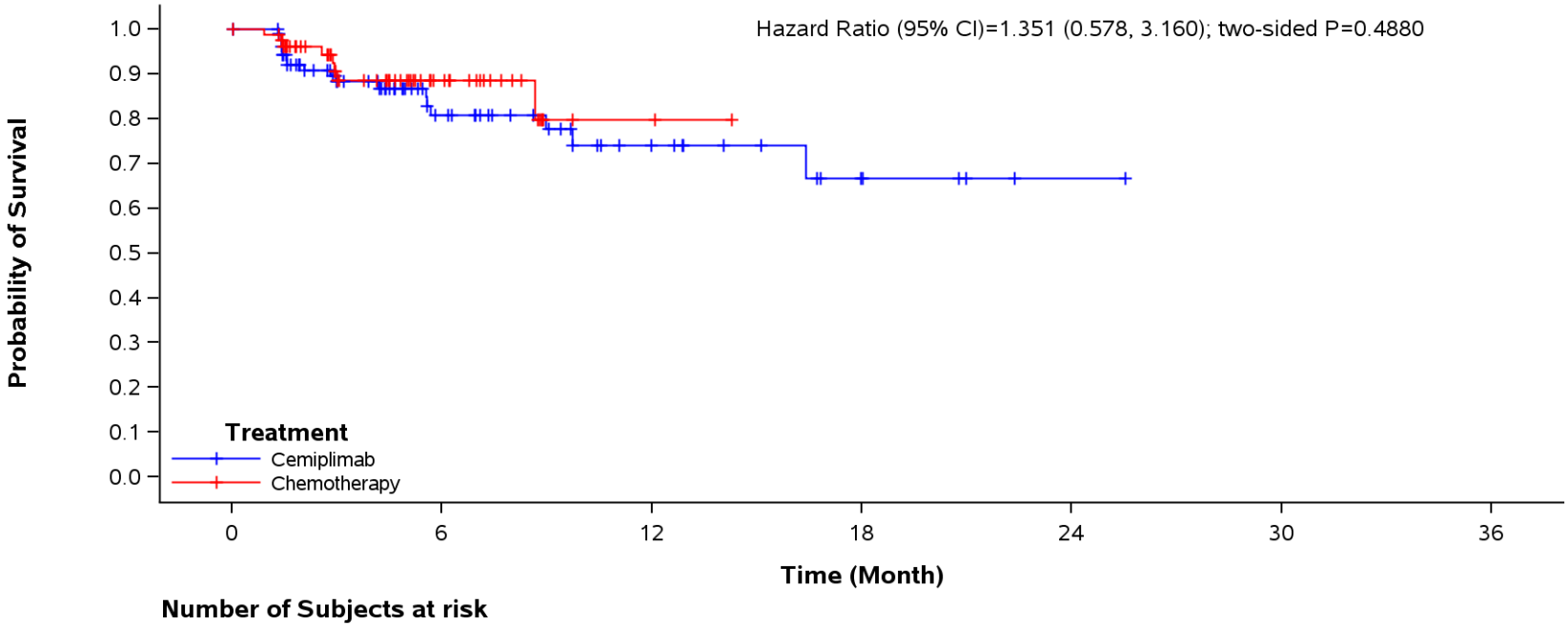

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 21 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 163 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts sensitivity sustained improvement



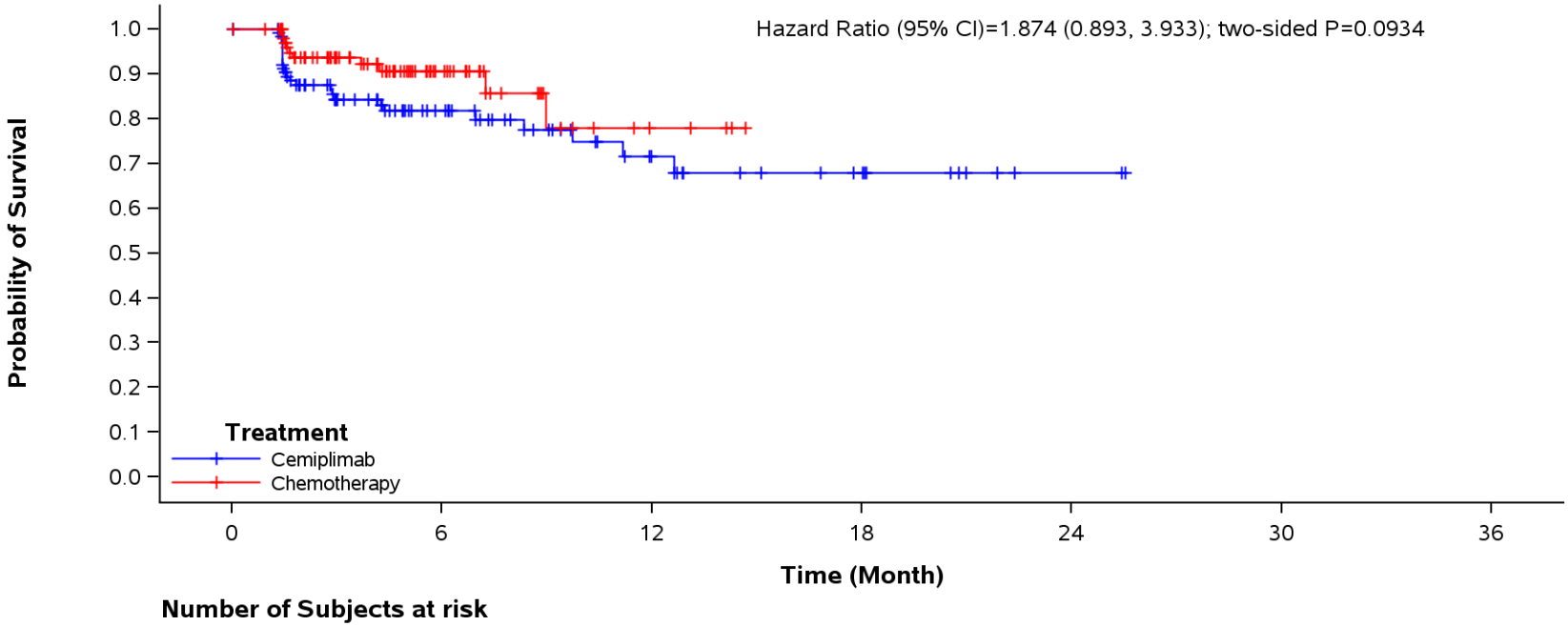

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 39 | 15 | 5 | 1 | 0 | 0 |
| Chemotherapy | 163 | 21 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts sensitivity sustained improvement



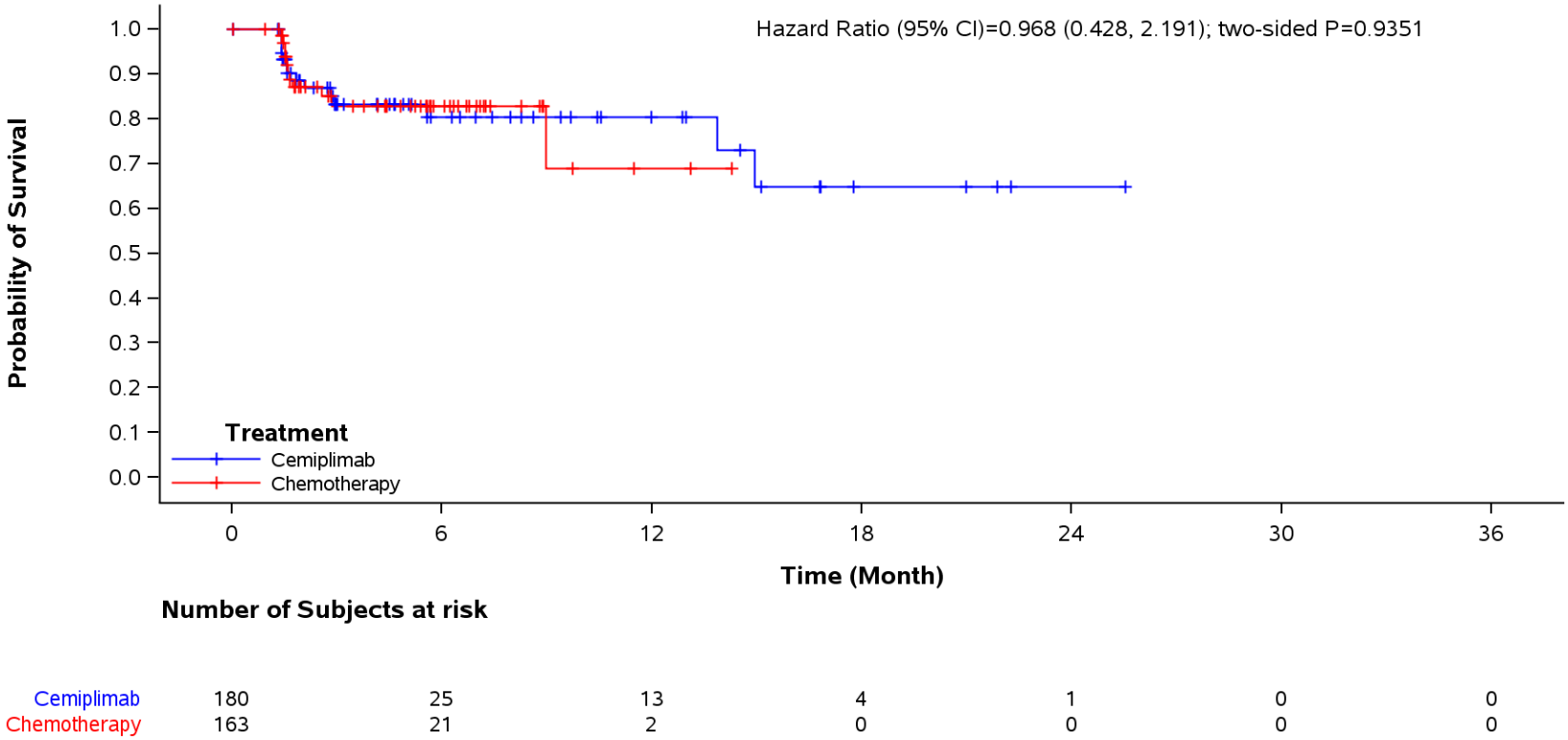

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 48 | 19 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 30 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

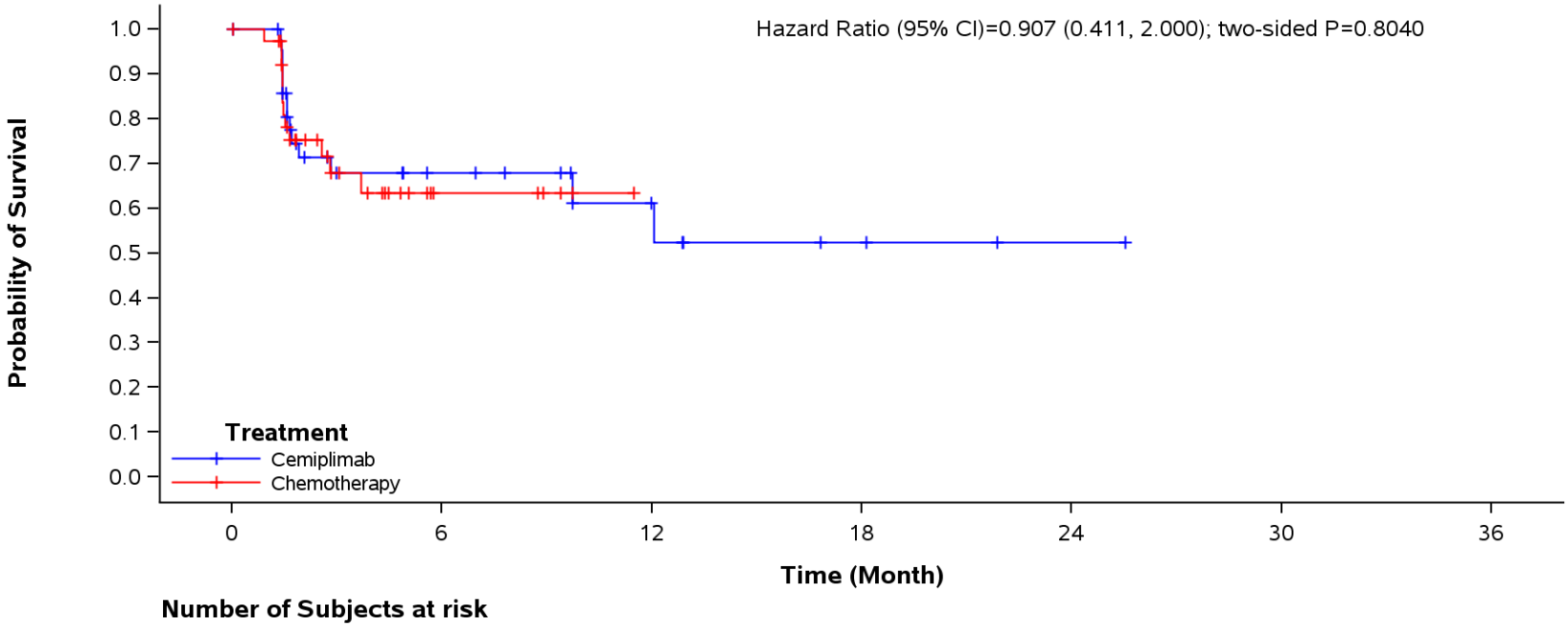
Age Group: <65
Financial Problems - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts sensitivity sustained improvement



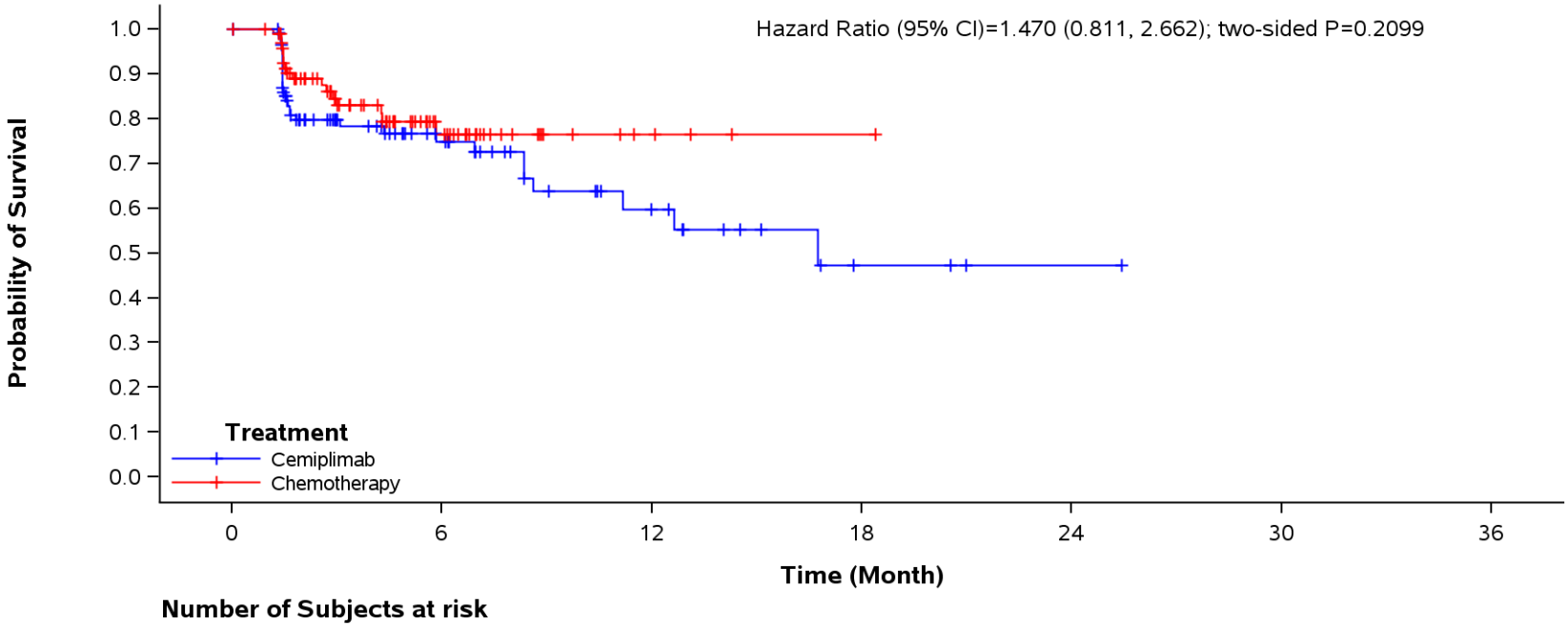

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 14 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 163 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts sensitivity sustained improvement



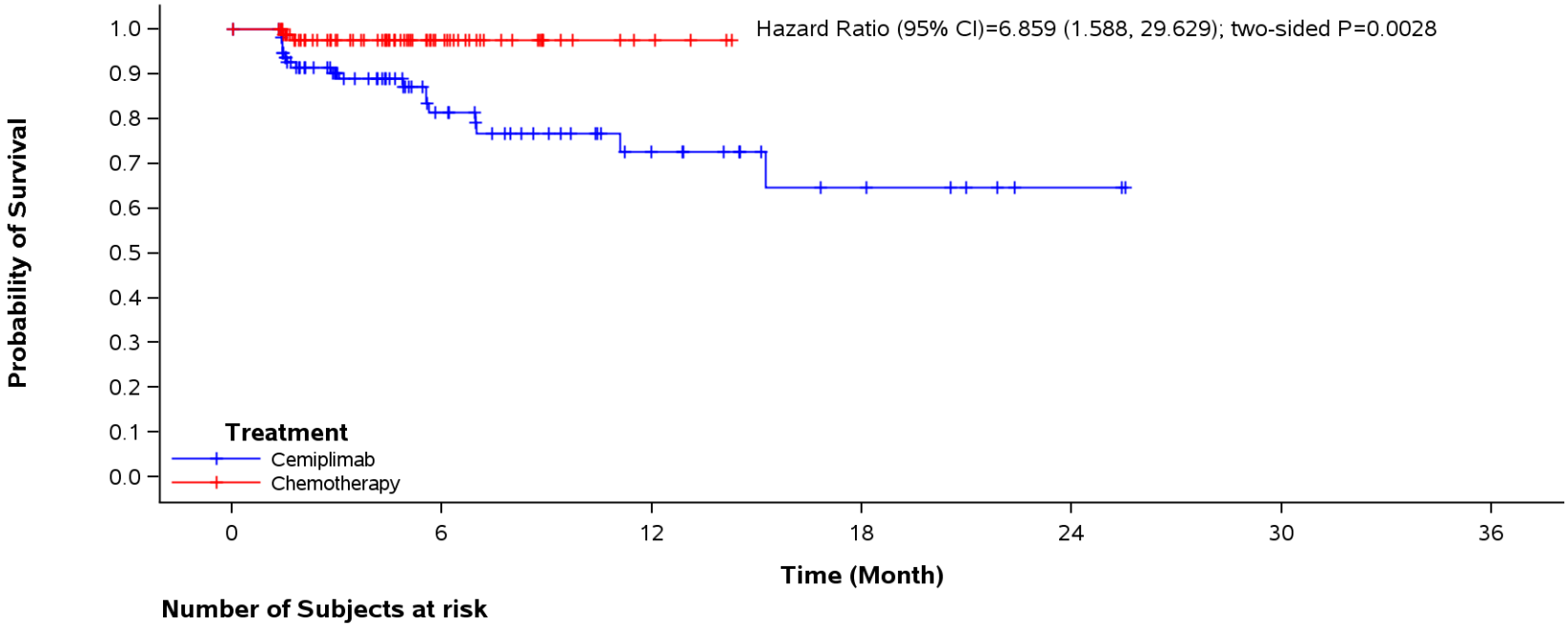

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 37 | 14 | 3 | 1 | 0 | 0 |
| Chemotherapy | 163 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

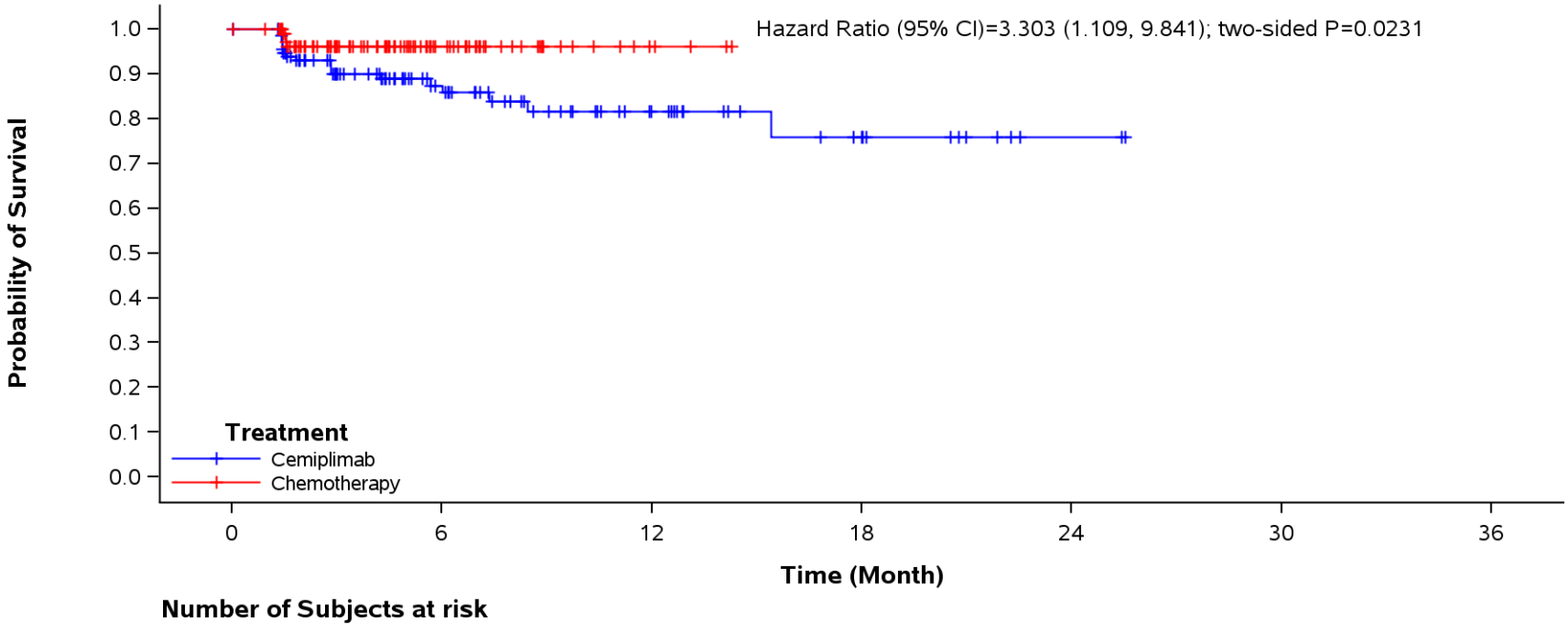
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 39 | 15 | 7 | 2 | 0 | 0 |
| Chemotherapy | 163 | 27 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65

Global health status / QoL - 10 pts sensitivity sustained improvement




Number of Subjects at risk

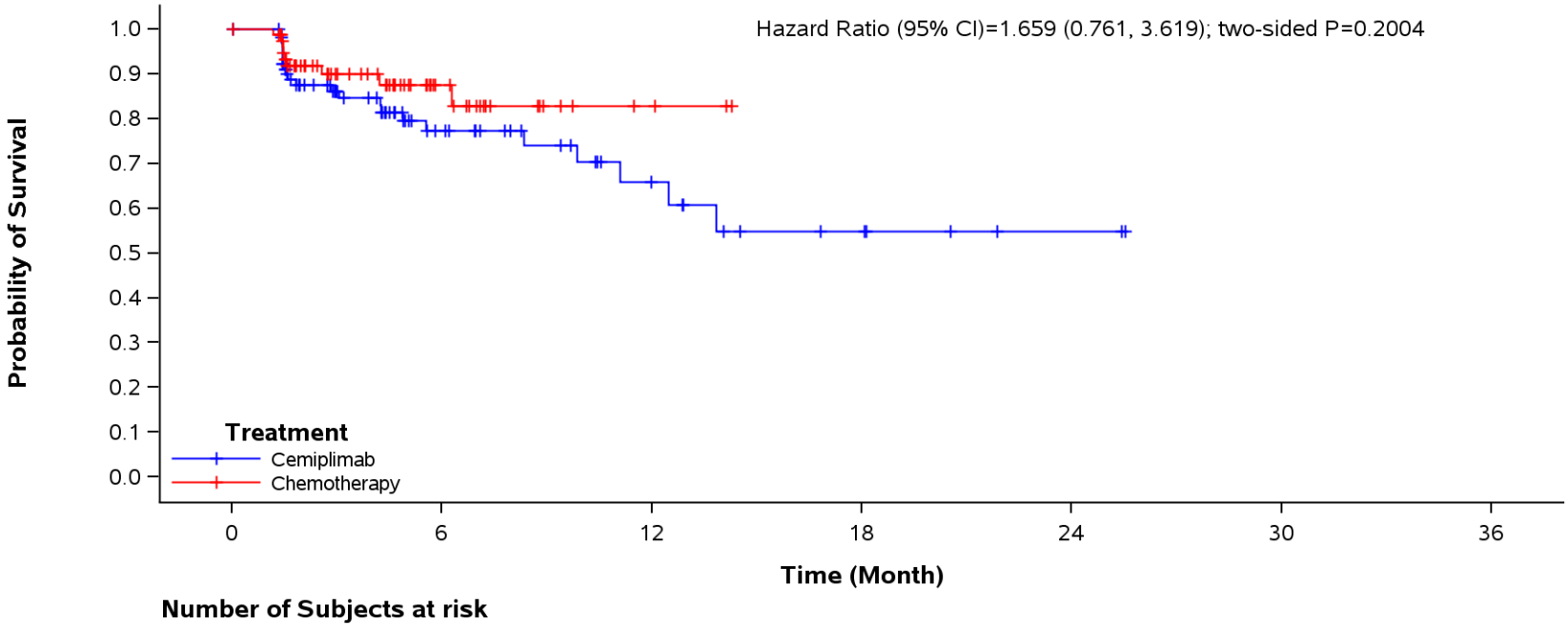
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 55 | 23 | 11 | 2 | 0 | 0 |
| Chemotherapy | 163 | 34 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts sensitivity sustained improvement



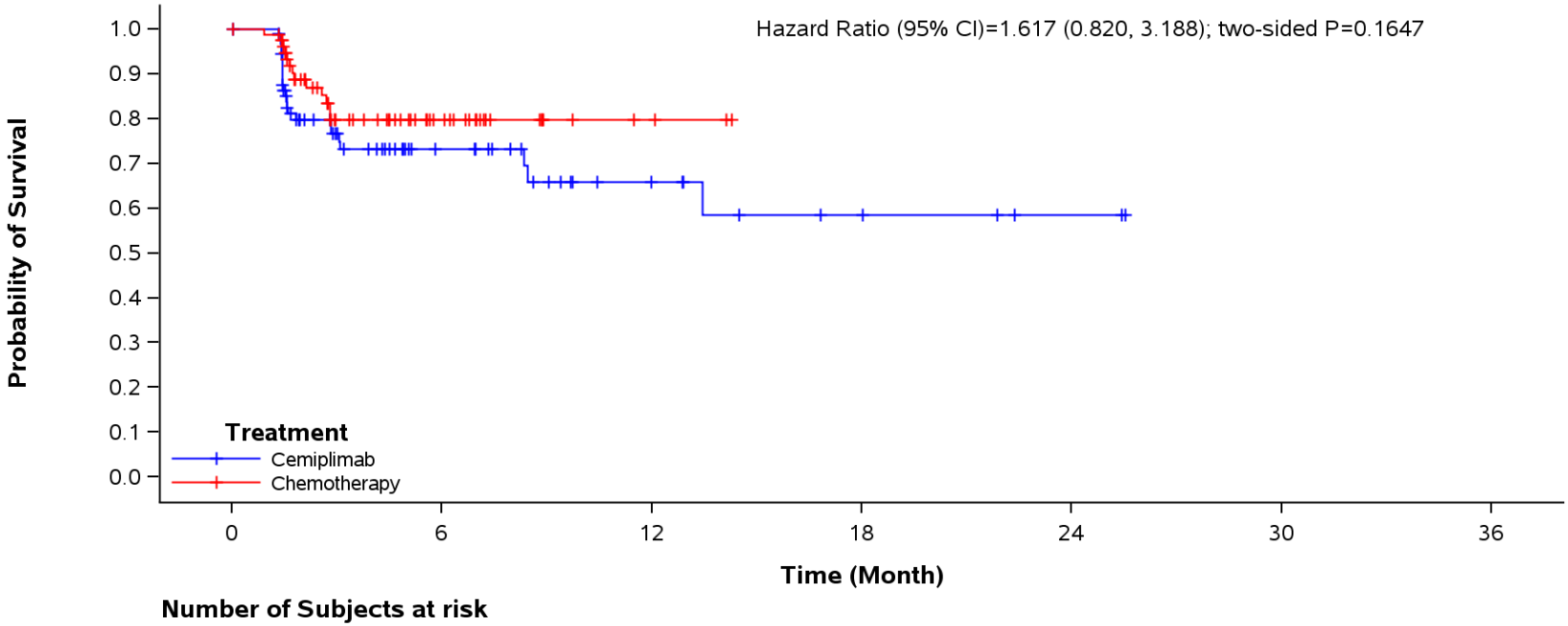

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 33 | 13 | 6 | 2 | 0 | 0 |
| Chemotherapy | 163 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts sensitivity sustained improvement



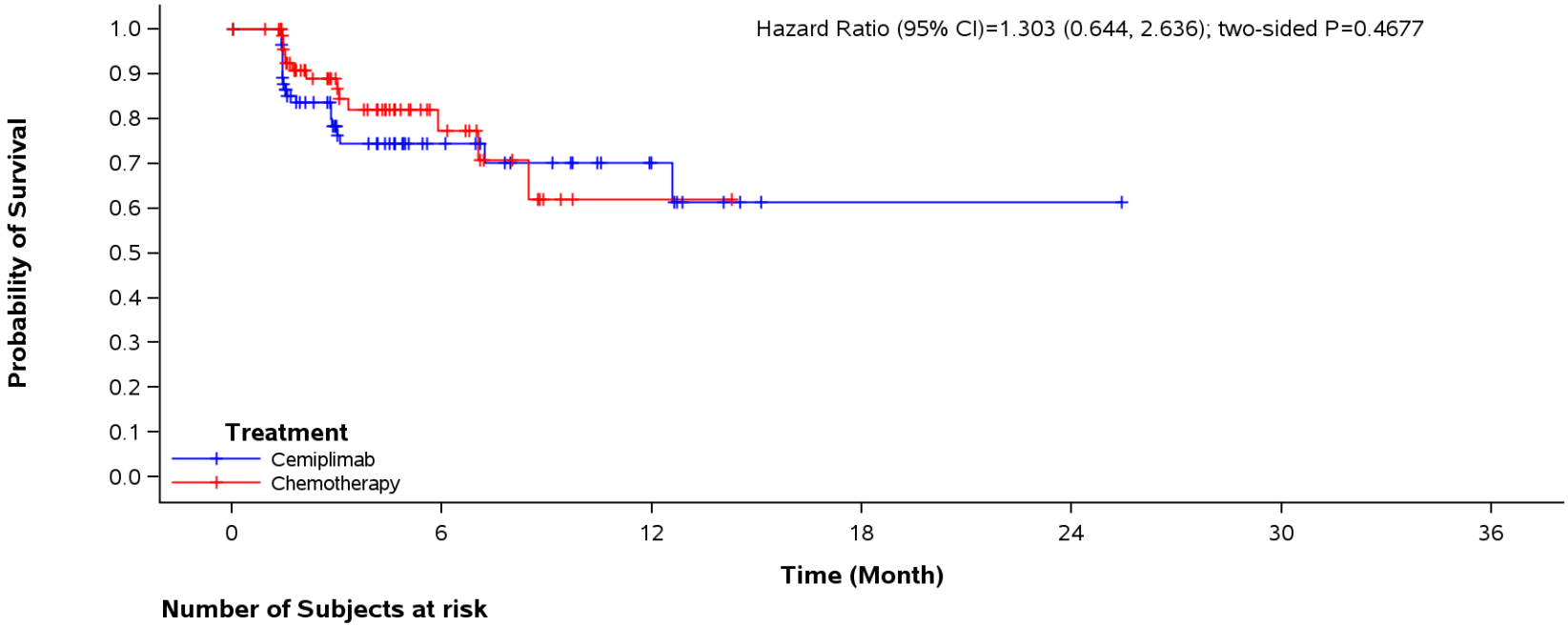

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 28 | 11 | 5 | 2 | 0 | 0 |
| Chemotherapy | 163 | 21 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts sensitivity sustained improvement



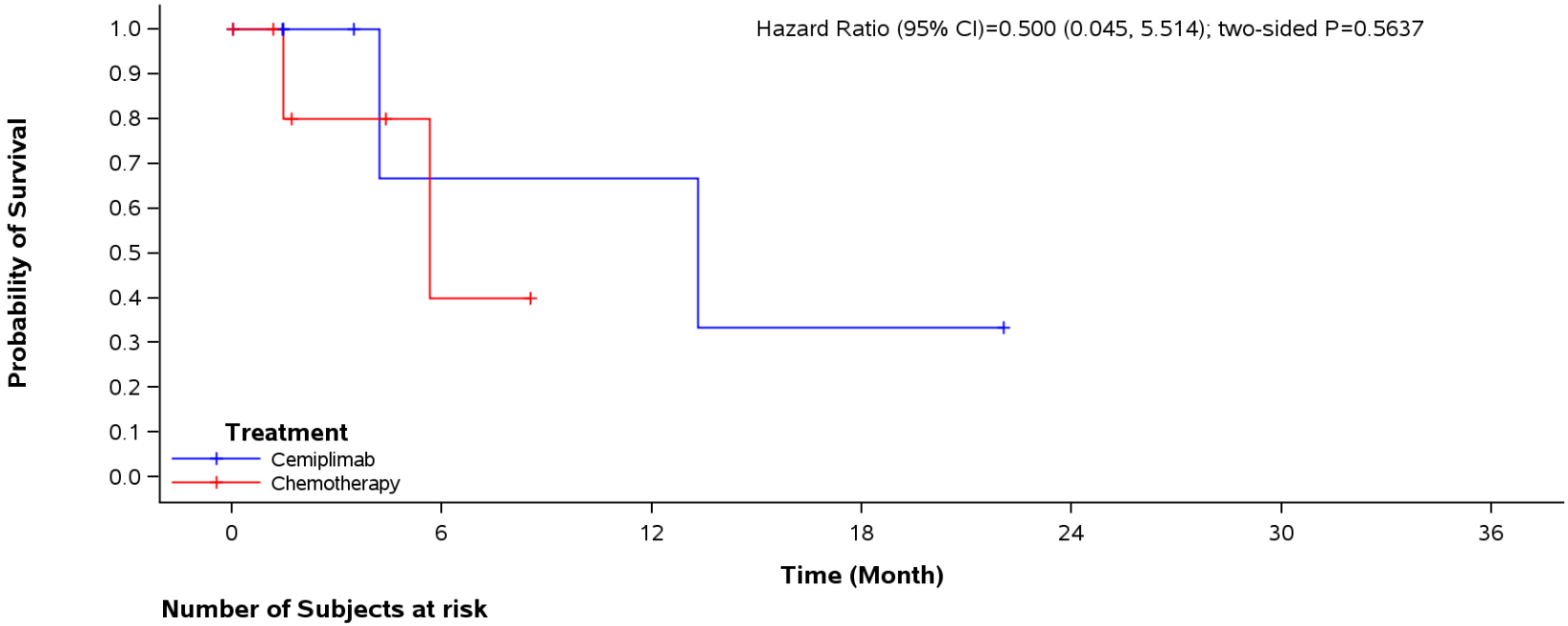

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 23 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 163 | 16 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Appetite loss - 10 pts sensitivity sustained improvement



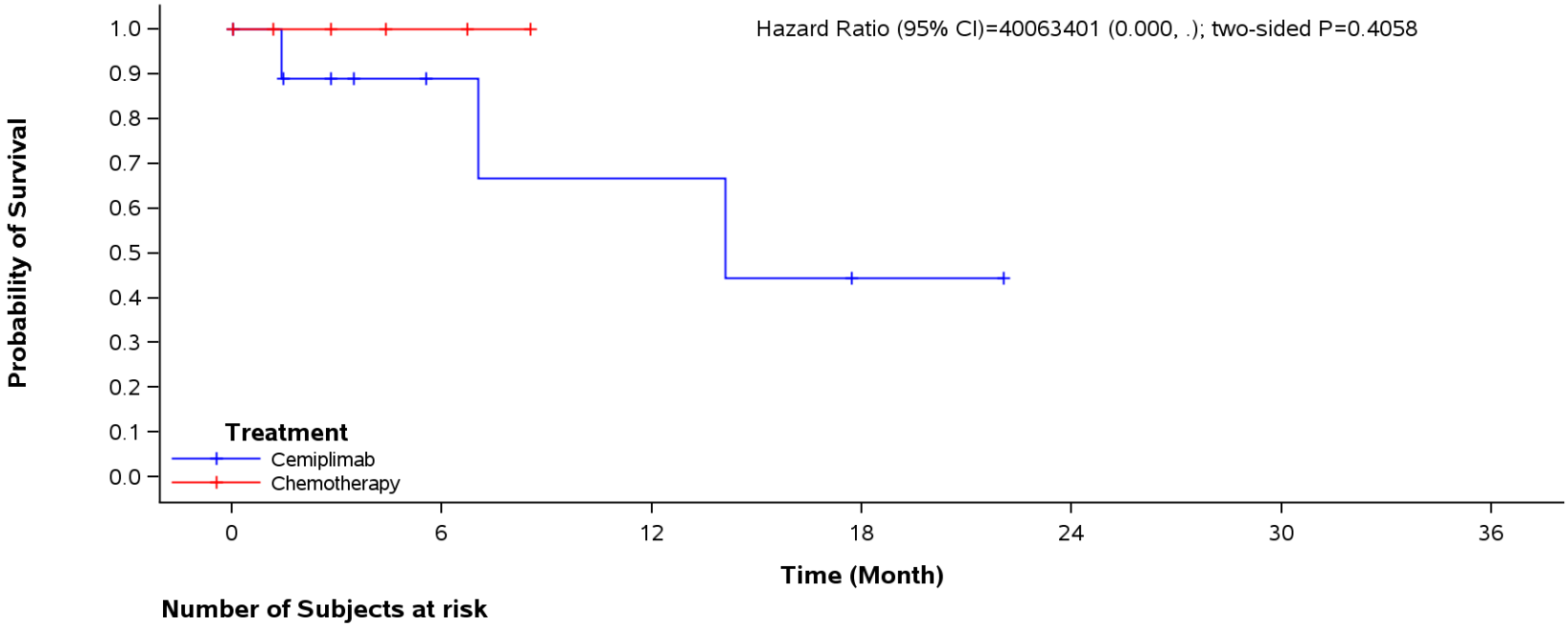

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts sensitivity sustained improvement



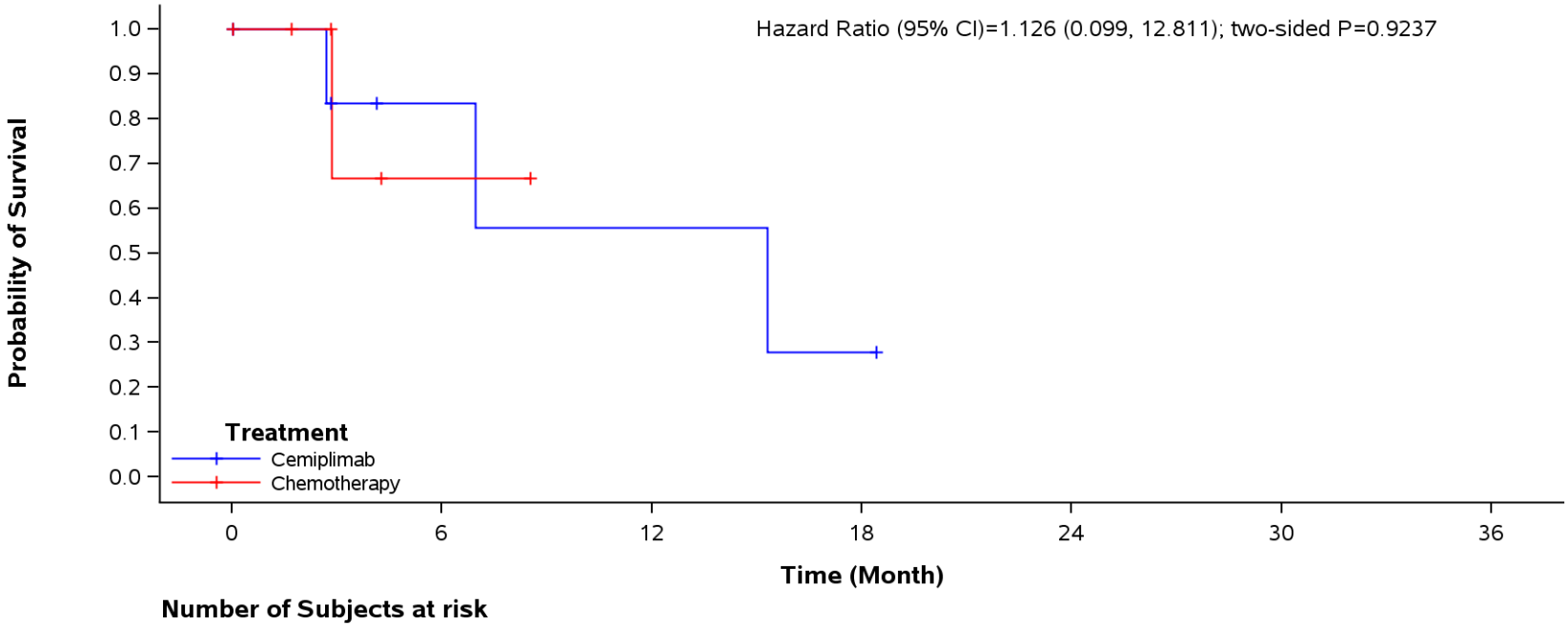

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 4 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts sensitivity sustained improvement



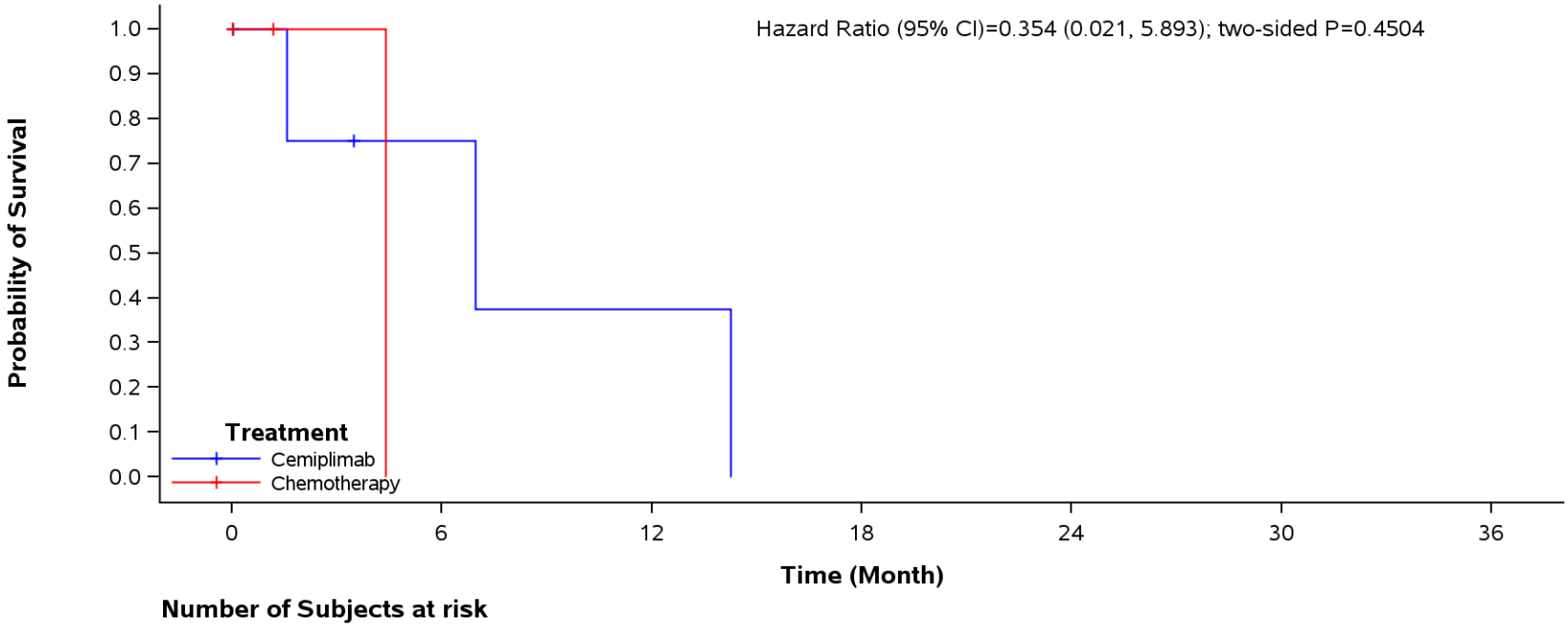

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Diarhoea - 10 pts sensitivity sustained improvement



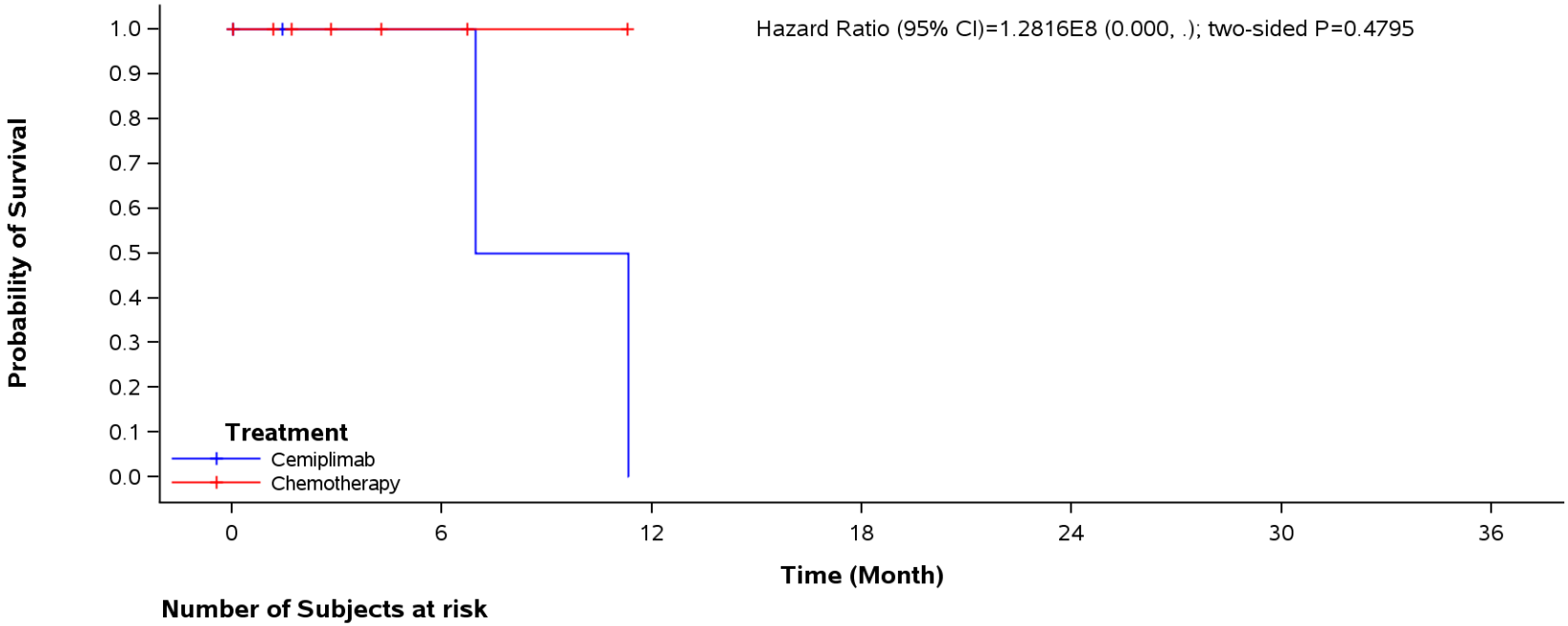

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts sensitivity sustained improvement



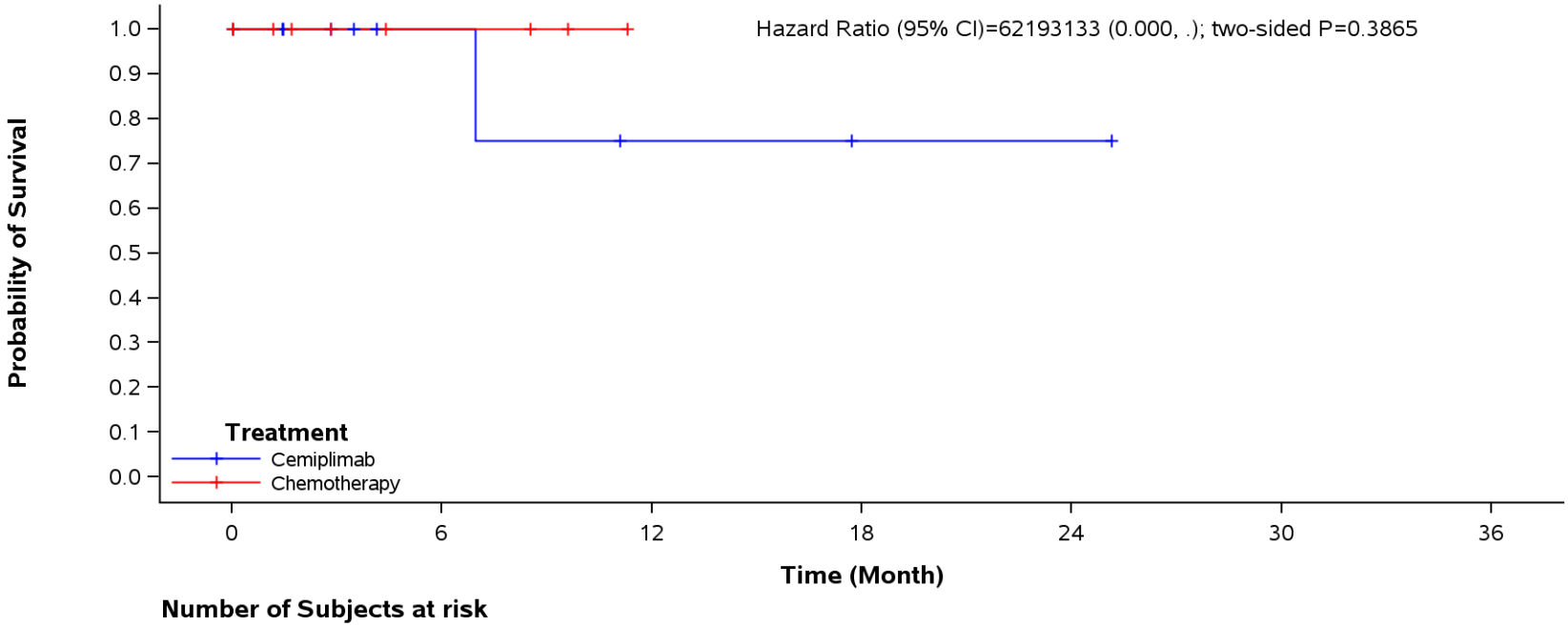

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Emotional Functioning - 10 pts sensitivity sustained improvement



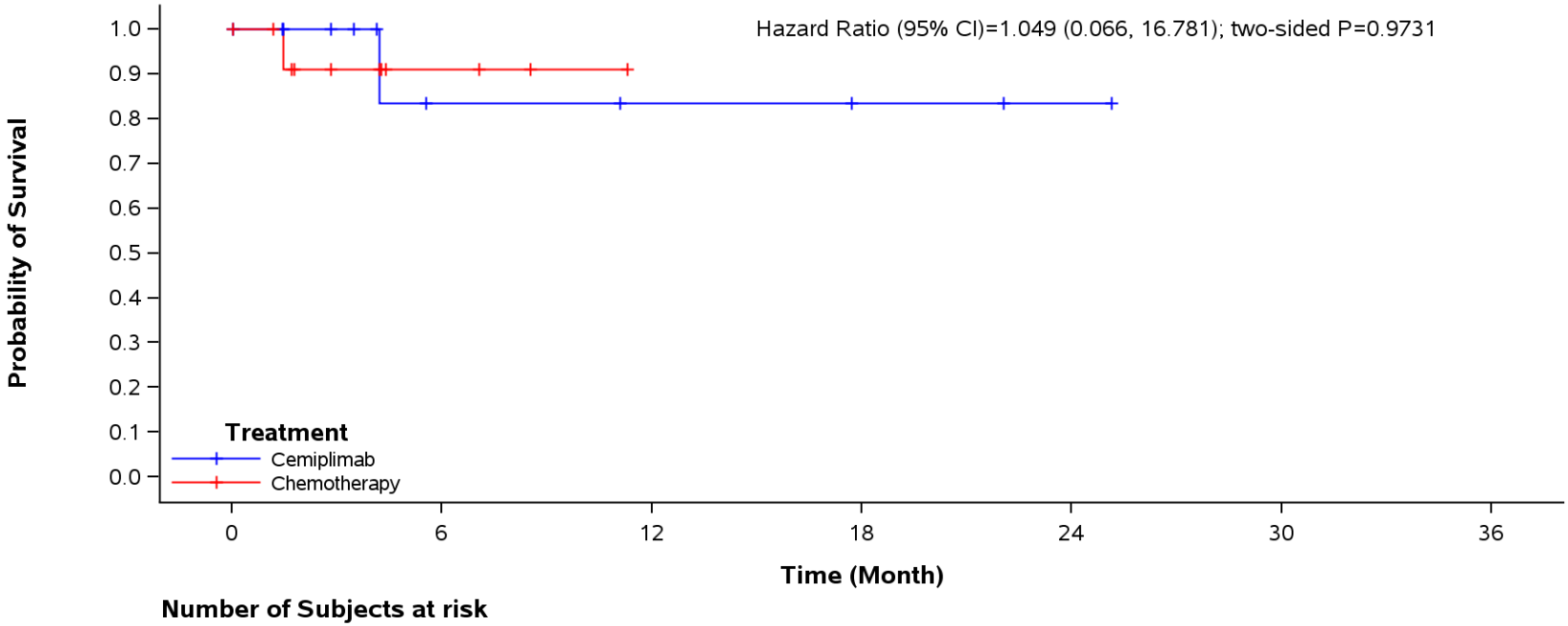

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 4 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts sensitivity sustained improvement



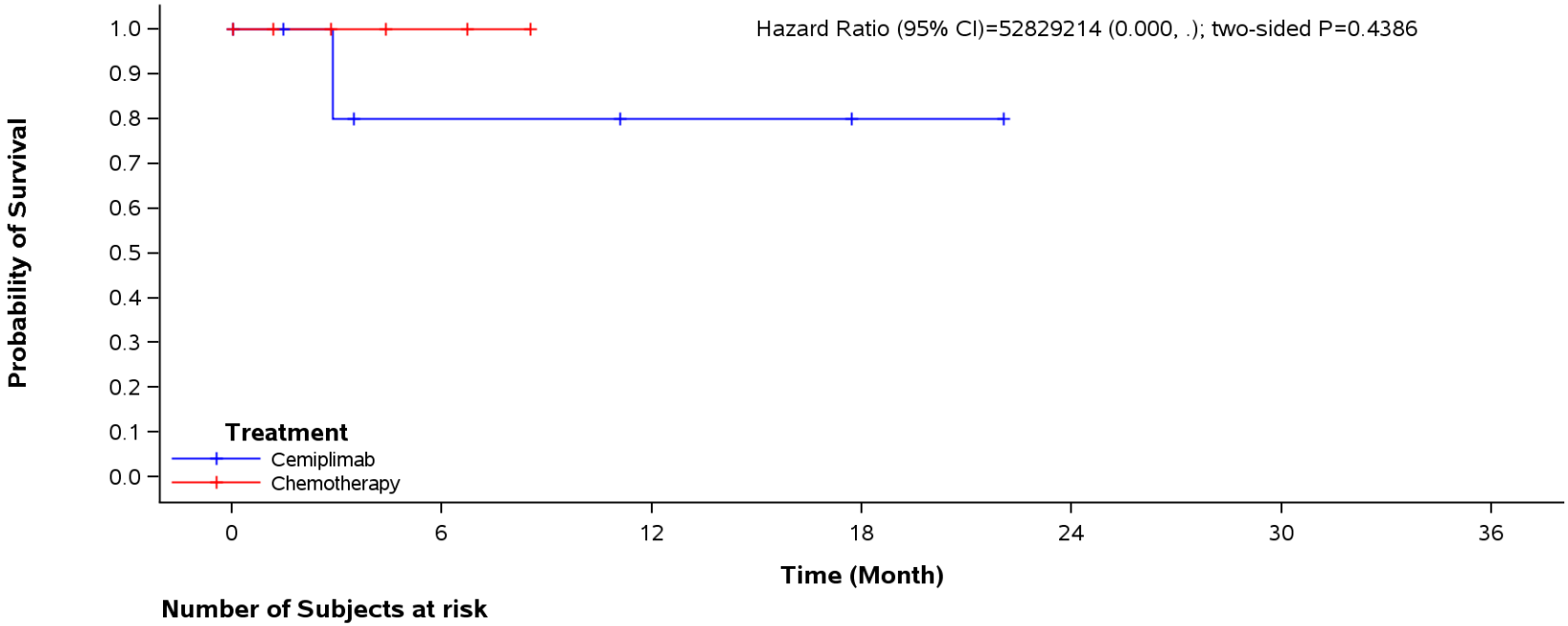

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 4 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts sensitivity sustained improvement




Number of Subjects at risk

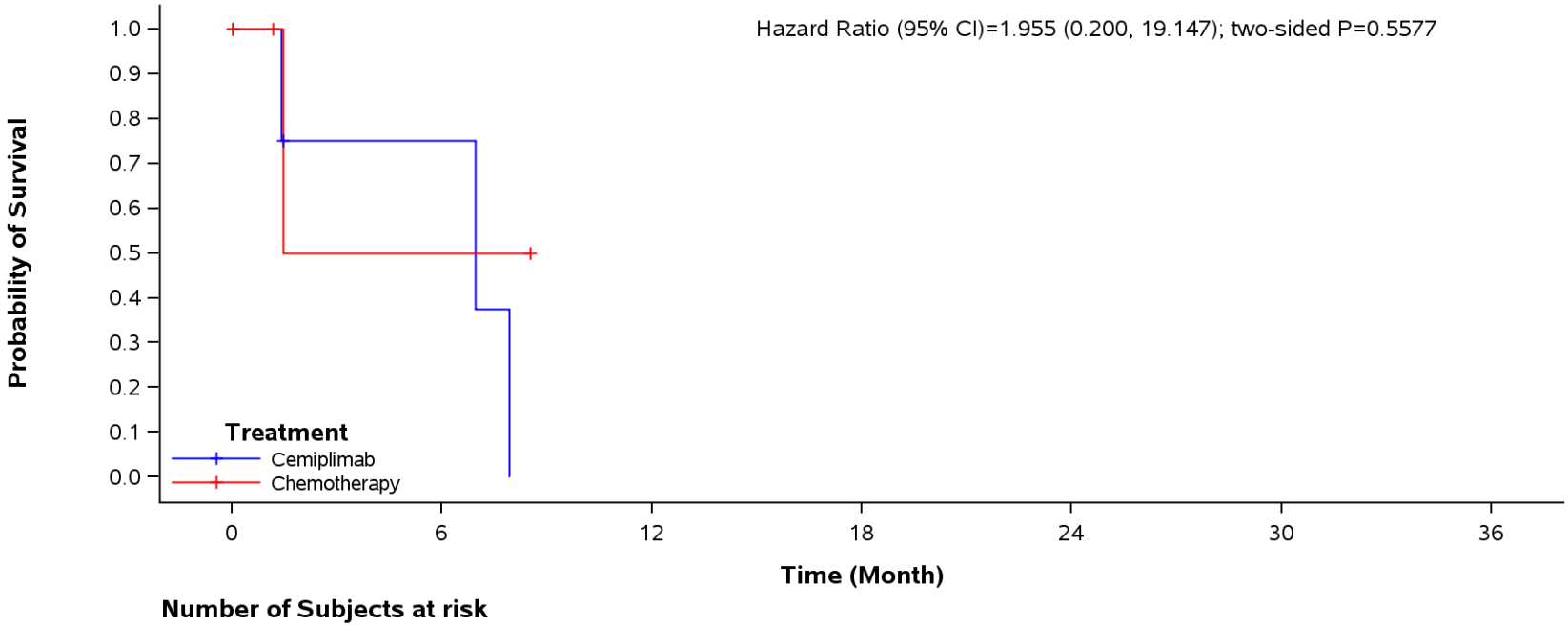
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Nausea / Vomiting - 10 pts sensitivity sustained improvement




Number of Subjects at risk

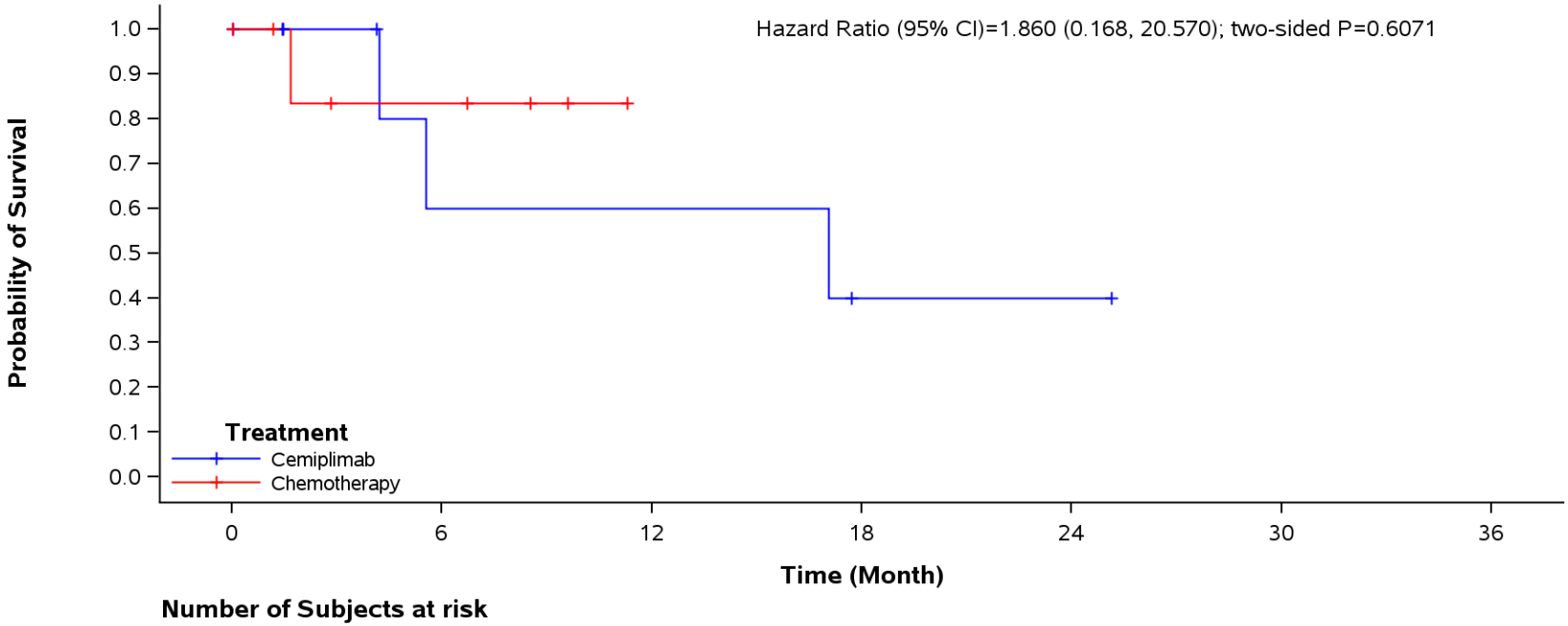
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts sensitivity sustained improvement




Number of Subjects at risk

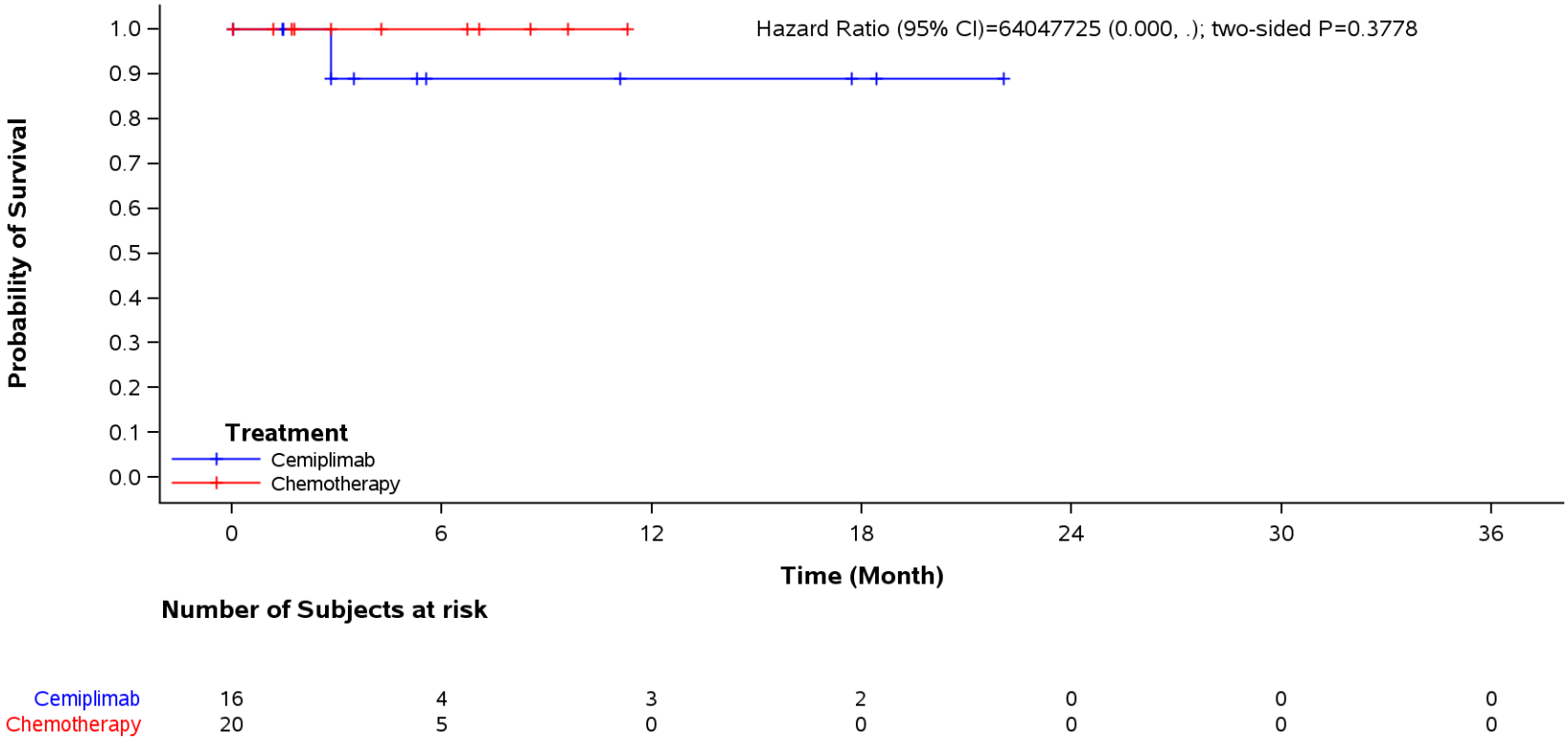
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 3 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Physical Functioning - 10 pts sensitivity sustained improvement



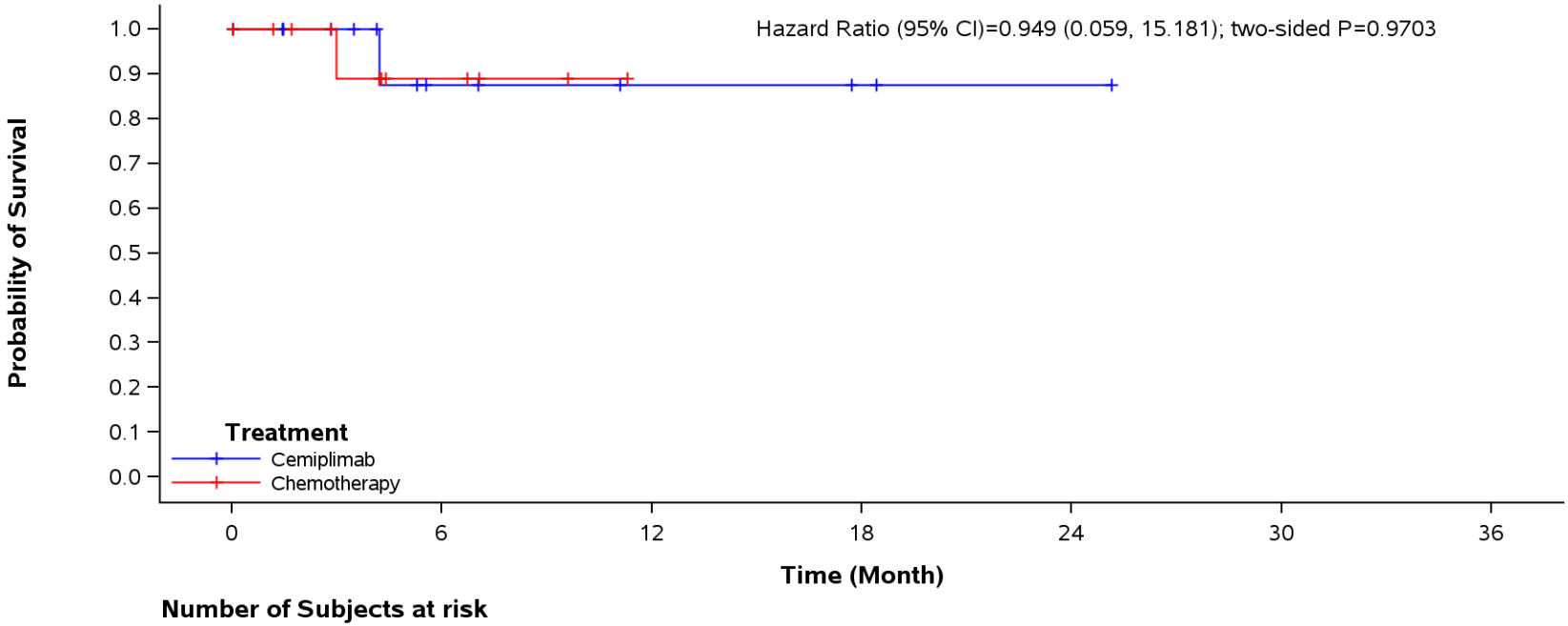

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

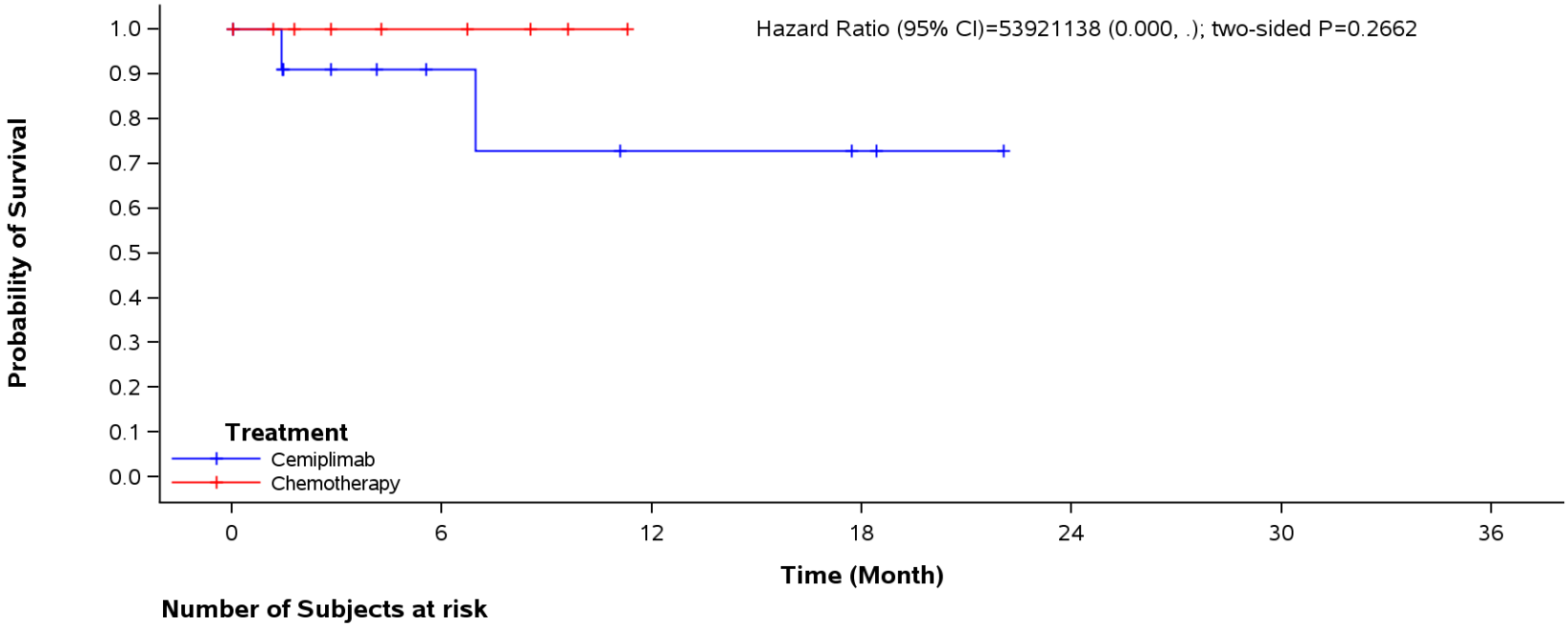
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Role Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 5 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

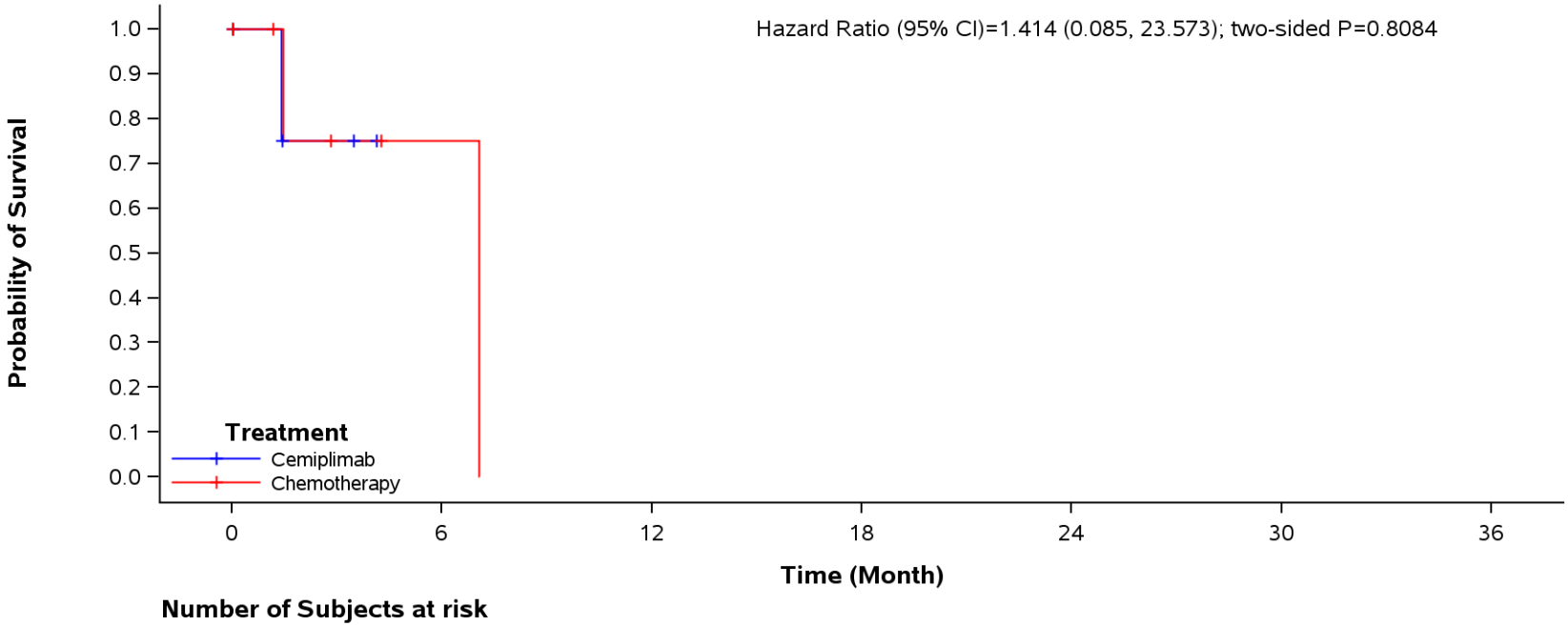
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Social Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

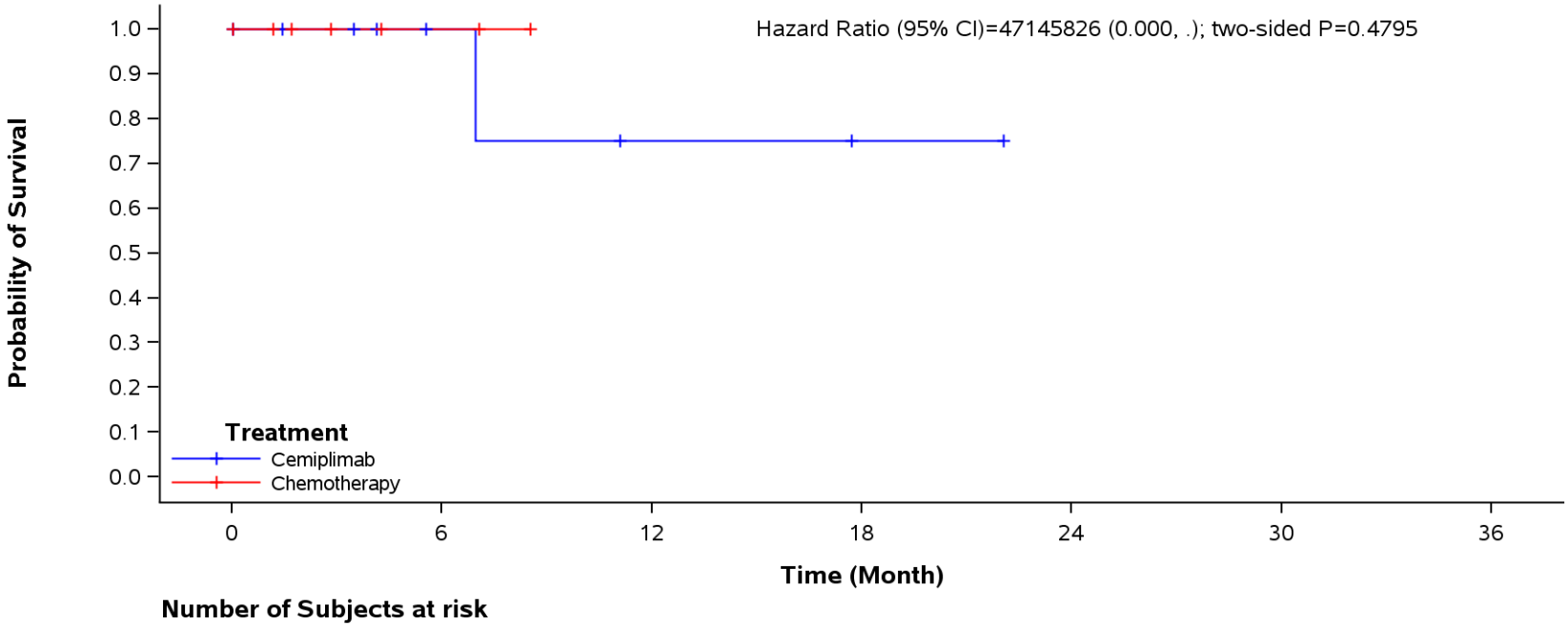
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 20 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

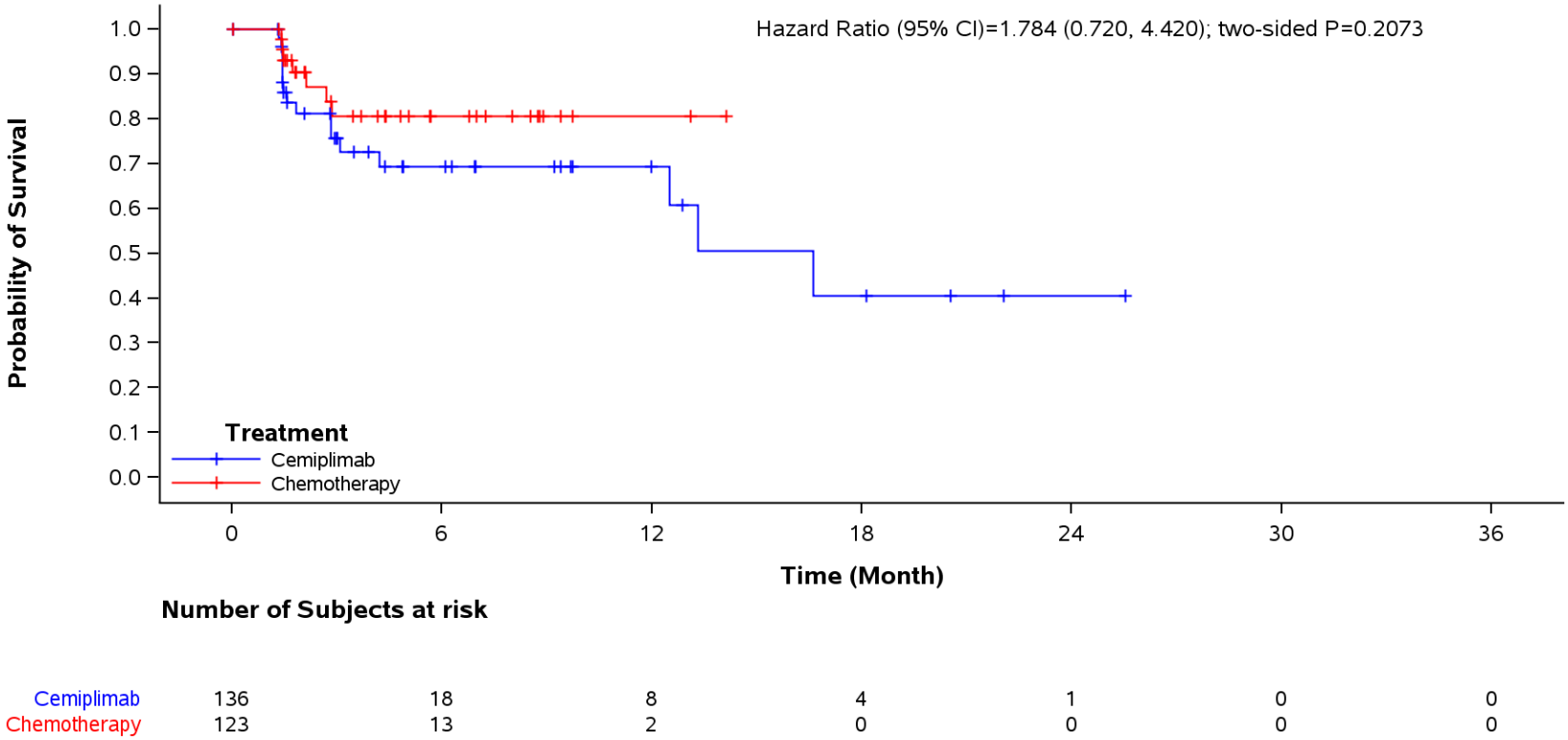
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 20 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Appetite loss - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 18 | 8 | 4 | 1 | 0 | 0 |
| Chemotherapy | 123 | 13 | 2 | 0 | 0 | 0 | 0 |

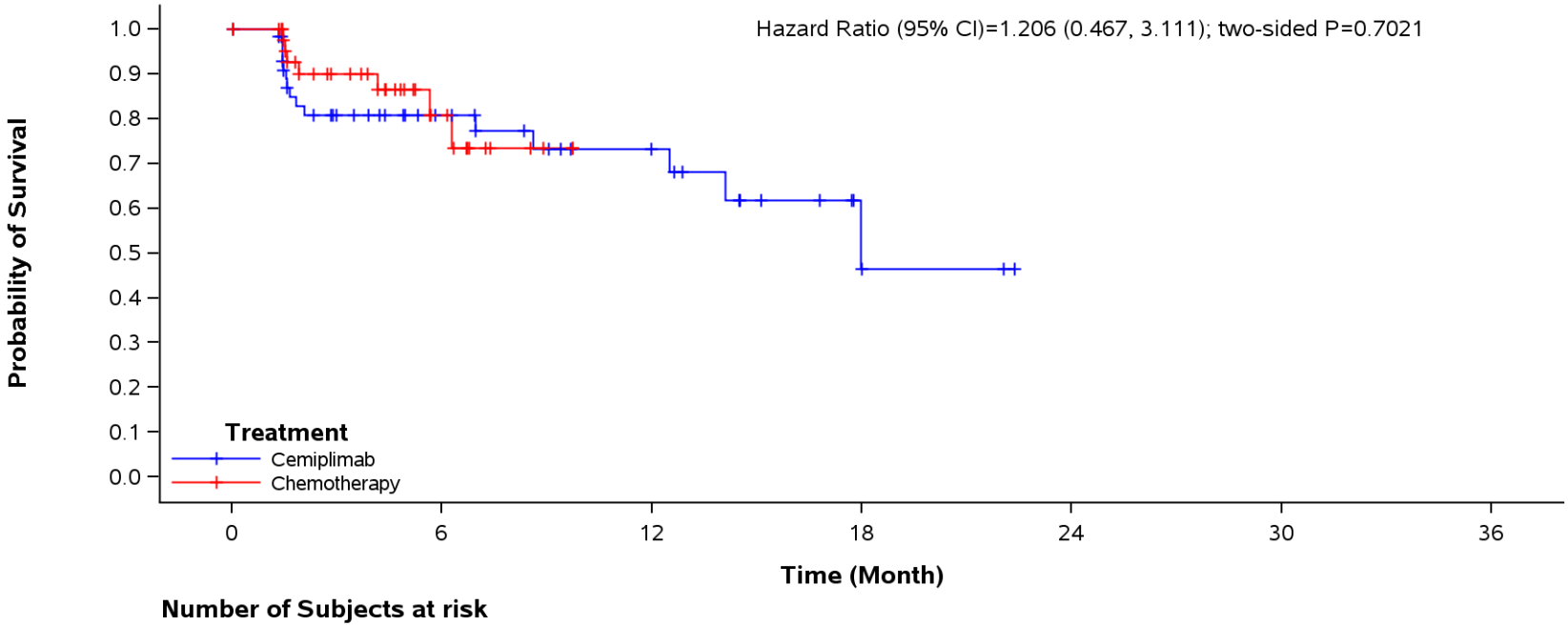
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Cognitive Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 26 | 14 | 3 | 0 | 0 | 0 |
| Chemotherapy | 123 | 12 | 0 | 0 | 0 | 0 | 0 |

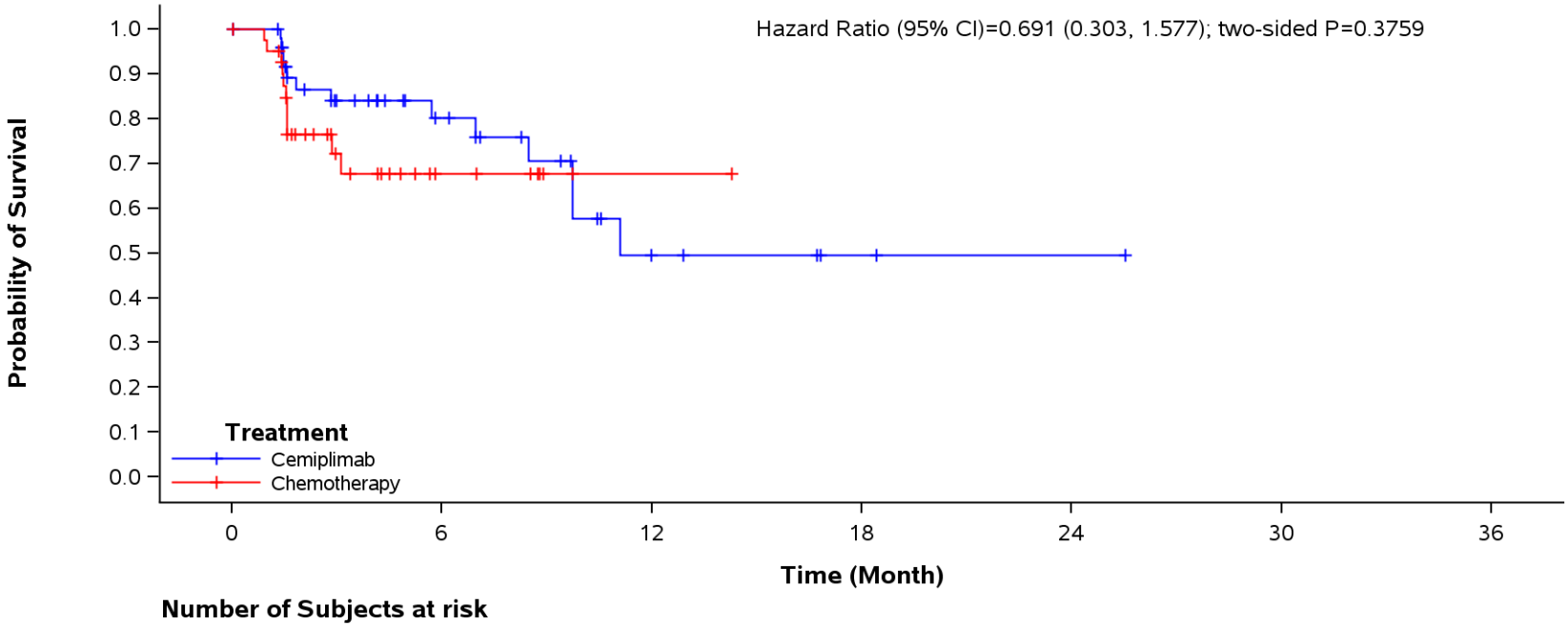
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Constipation - 10 pts sensitivity sustained improvement




Number of Subjects at risk

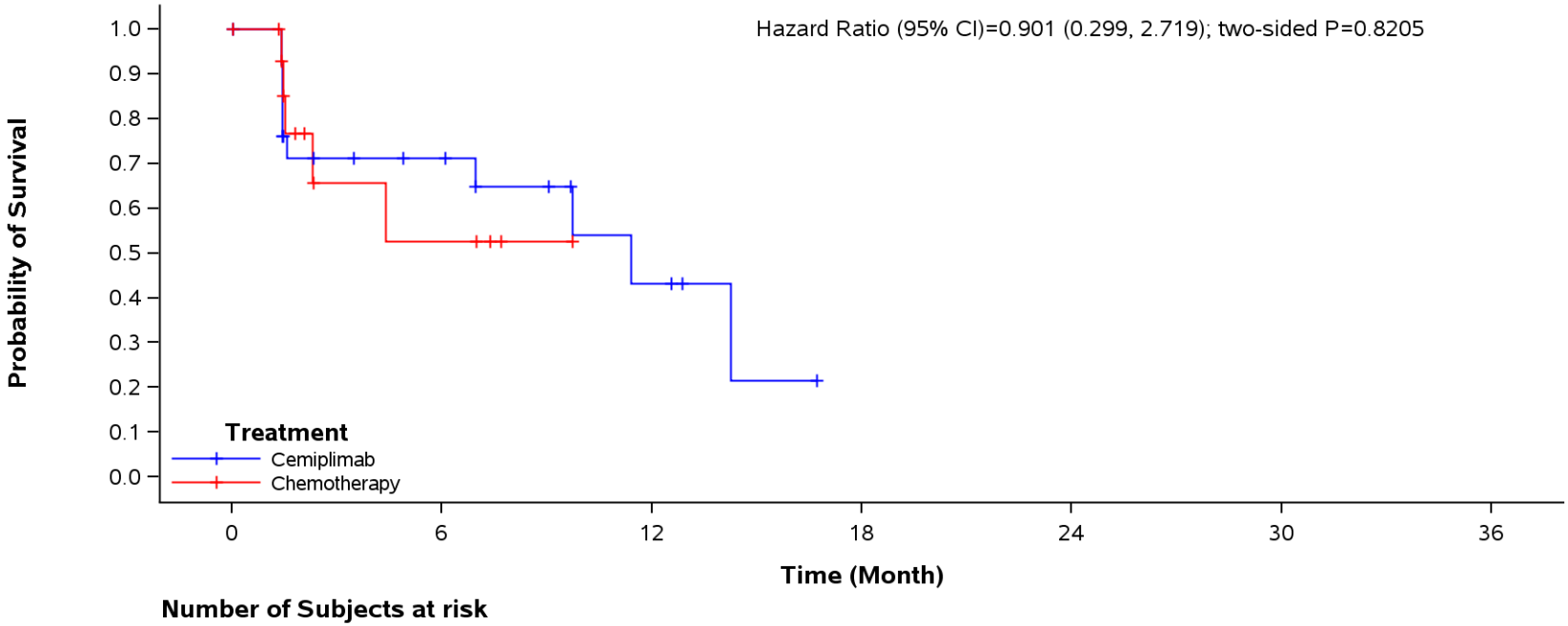
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 20 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 123 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

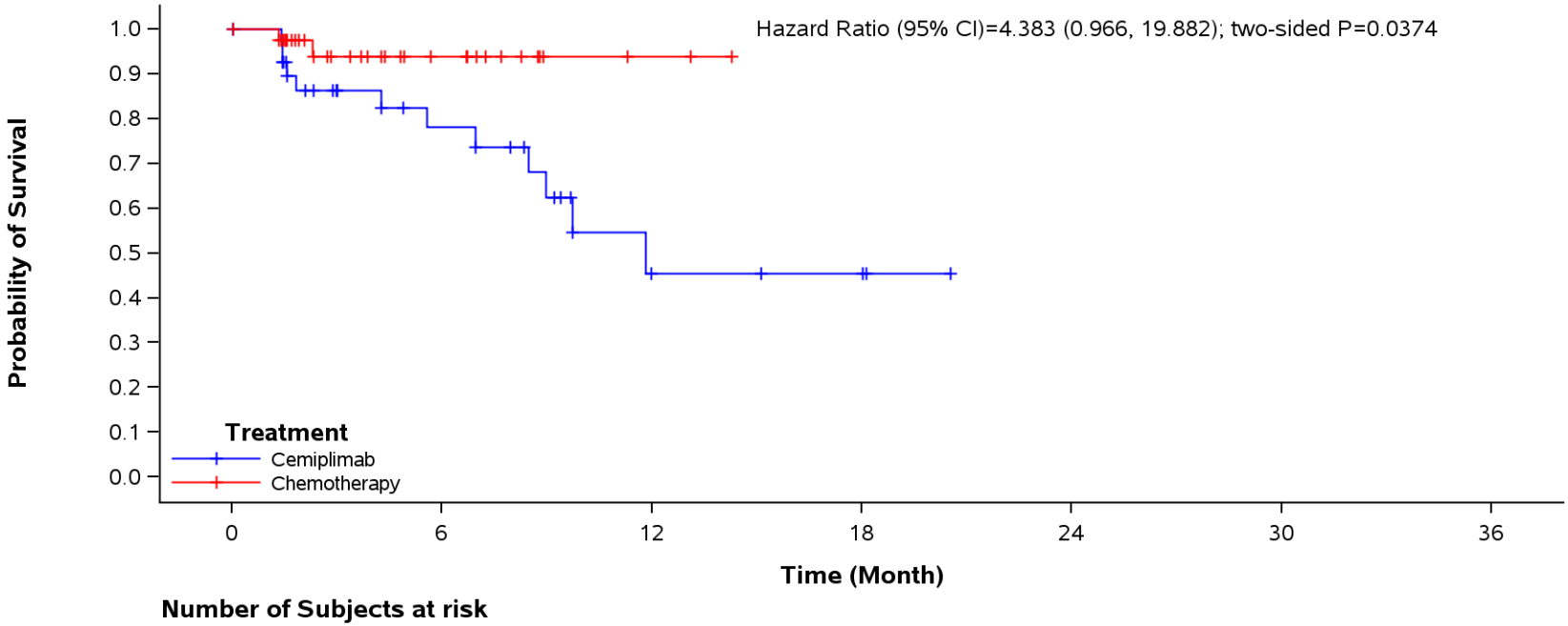
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 12 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 123 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Dyspnoea - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 18 | 4 | 3 | 0 | 0 | 0 |
| Chemotherapy | 123 | 12 | 2 | 0 | 0 | 0 | 0 |

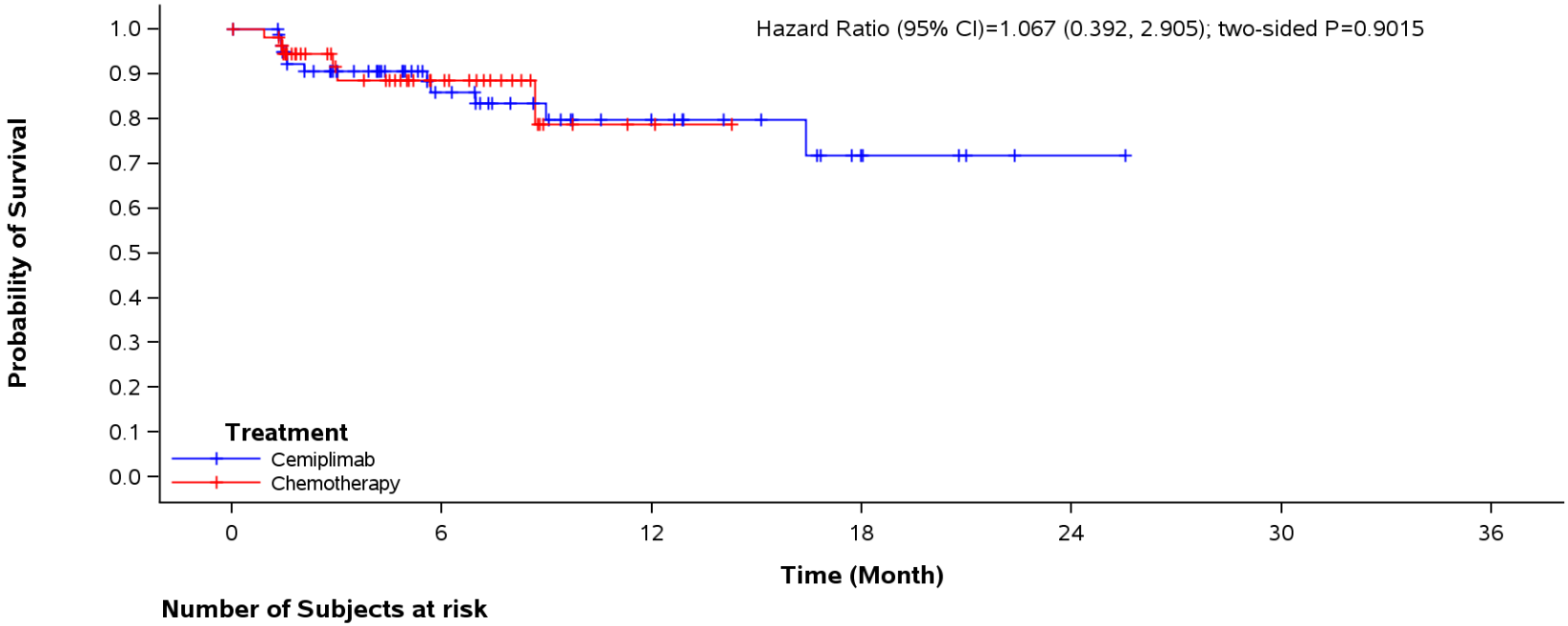
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Emotional Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

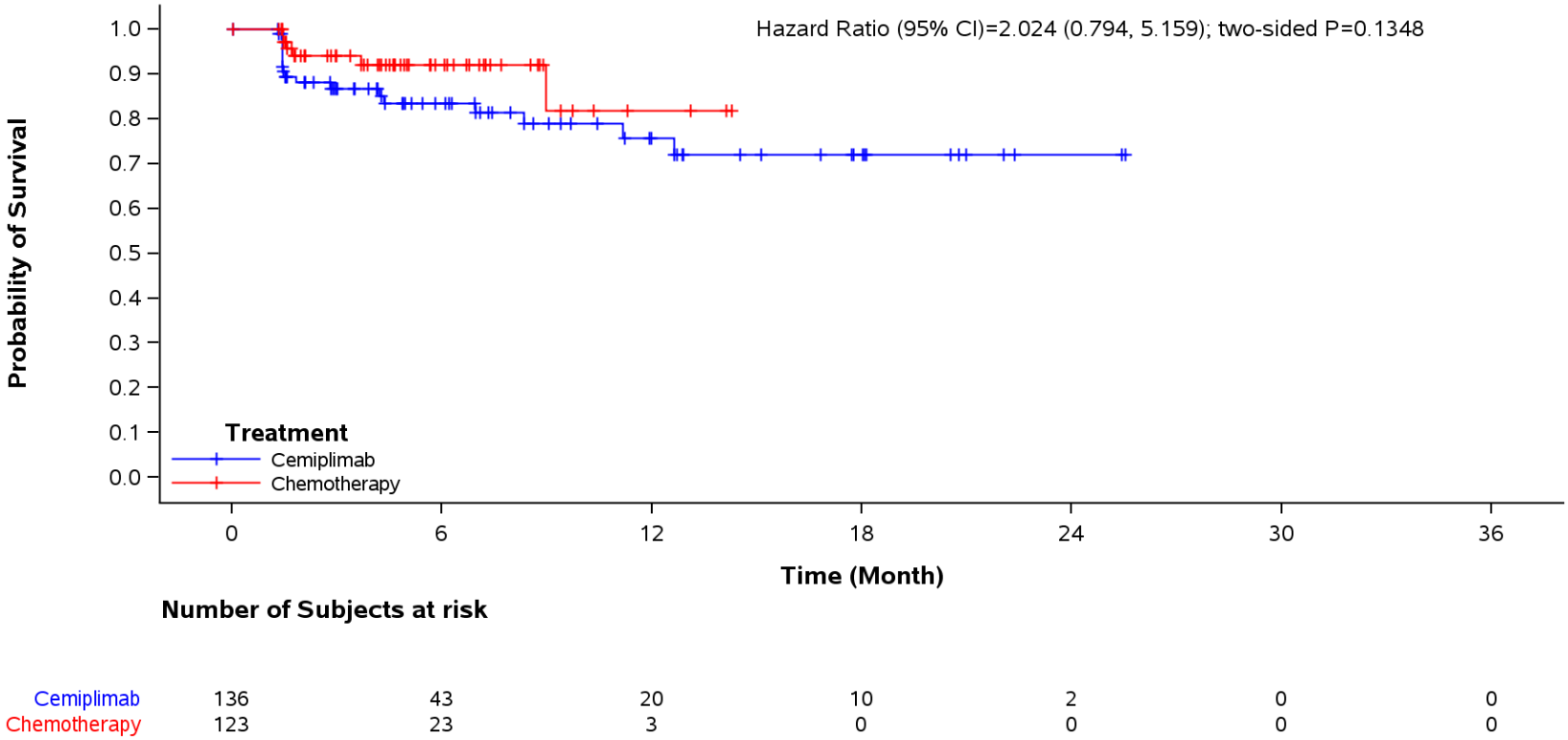
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 35 | 15 | 5 | 1 | 0 | 0 |
| Chemotherapy | 123 | 19 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts sensitivity sustained improvement




Number of Subjects at risk

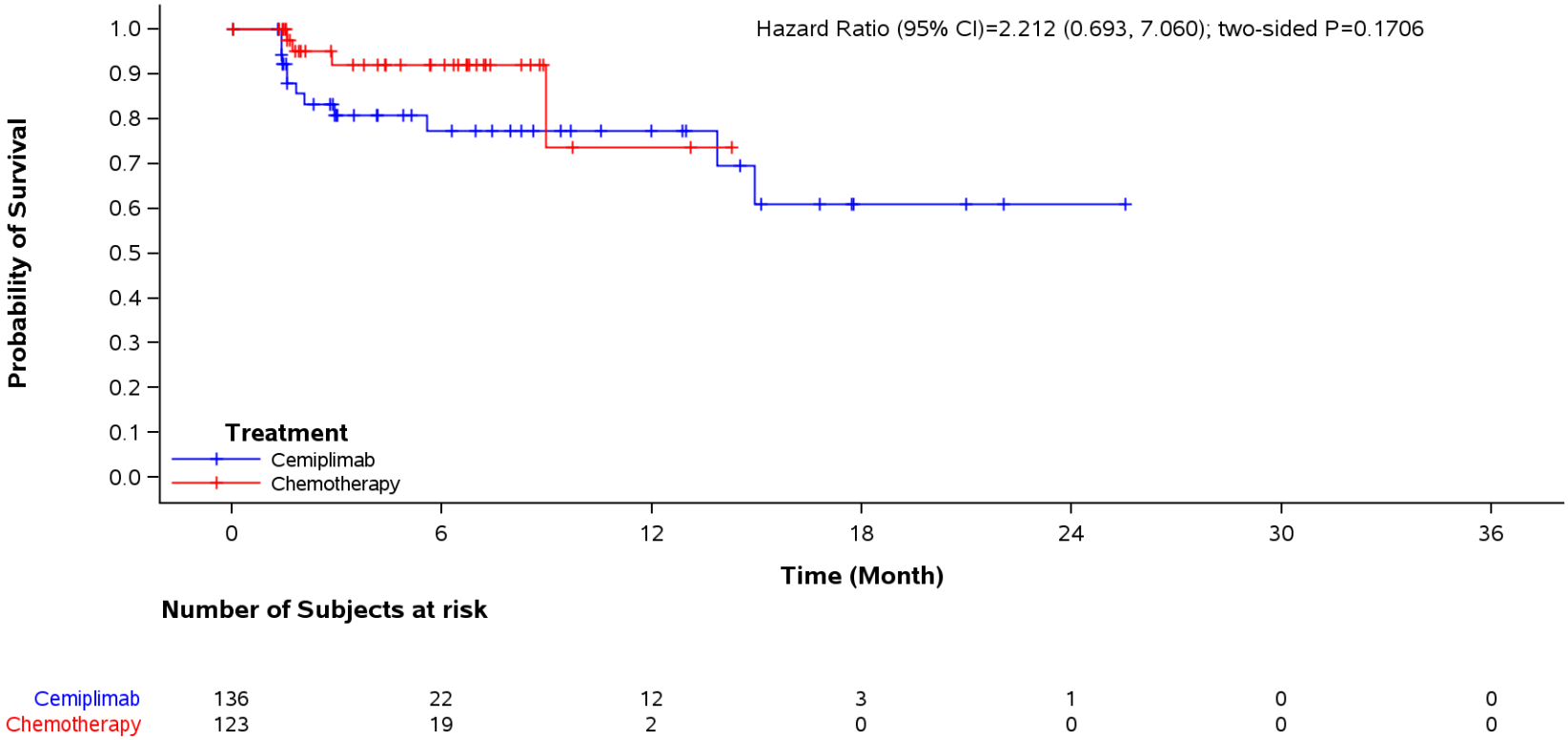
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 43 | 20 | 10 | 2 | 0 | 0 |
| Chemotherapy | 123 | 23 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 22 | 12 | 3 | 1 | 0 | 0 |
| Chemotherapy | 123 | 19 | 2 | 0 | 0 | 0 | 0 |

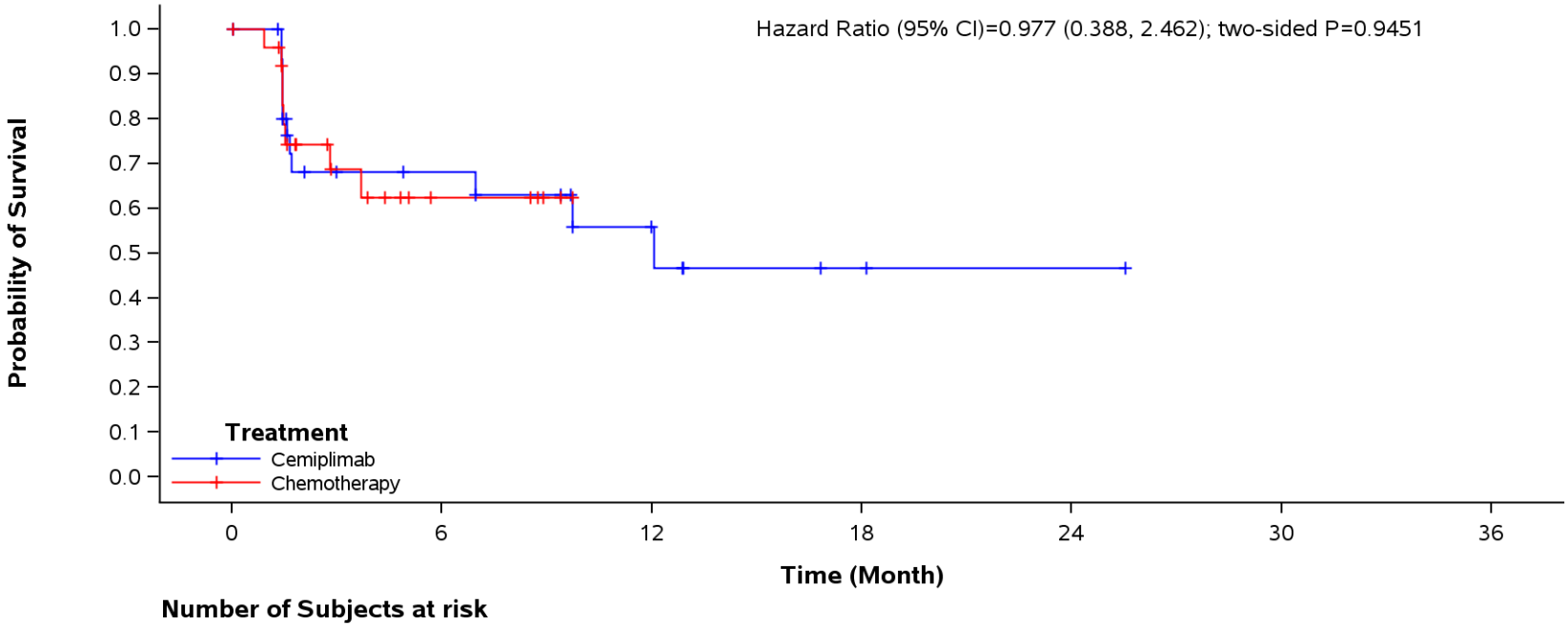
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Nausea / Vomiting - 10 pts sensitivity sustained improvement




Number of Subjects at risk

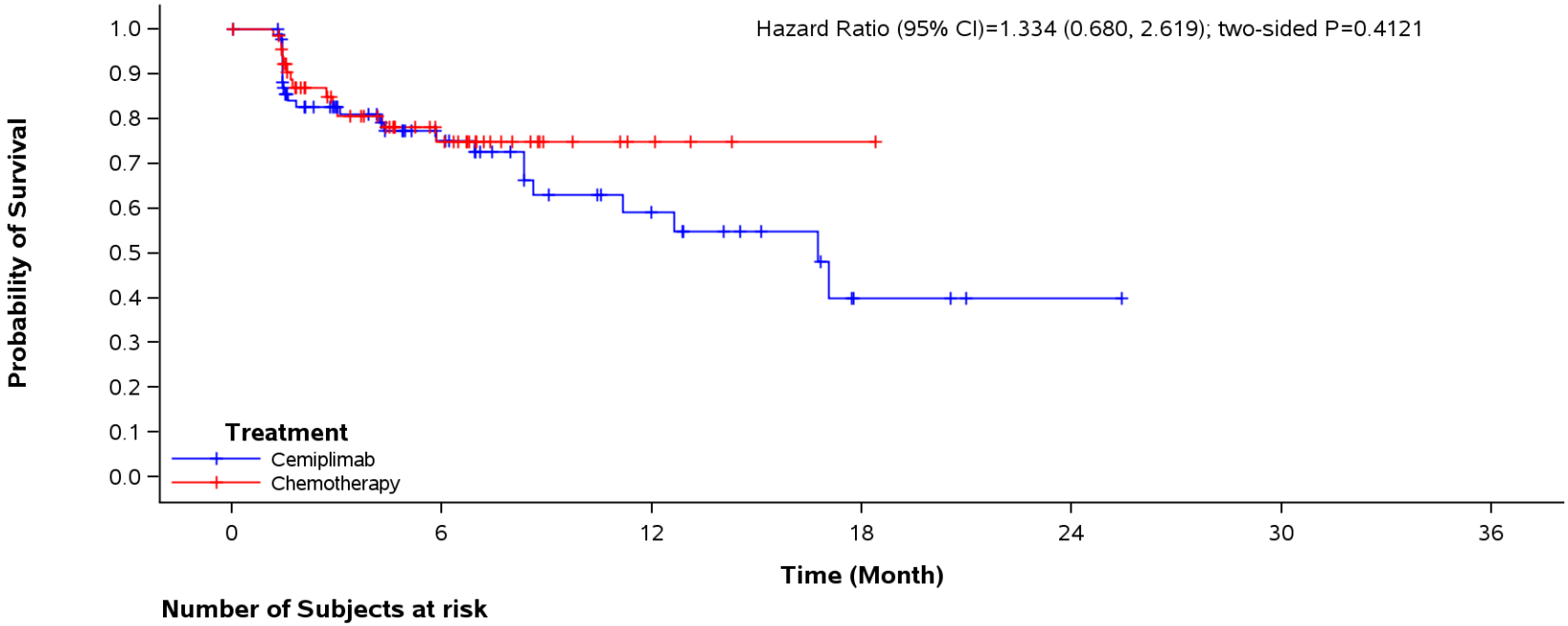
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 13 | 6 | 2 | 1 | 0 | 0 |
| Chemotherapy | 123 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

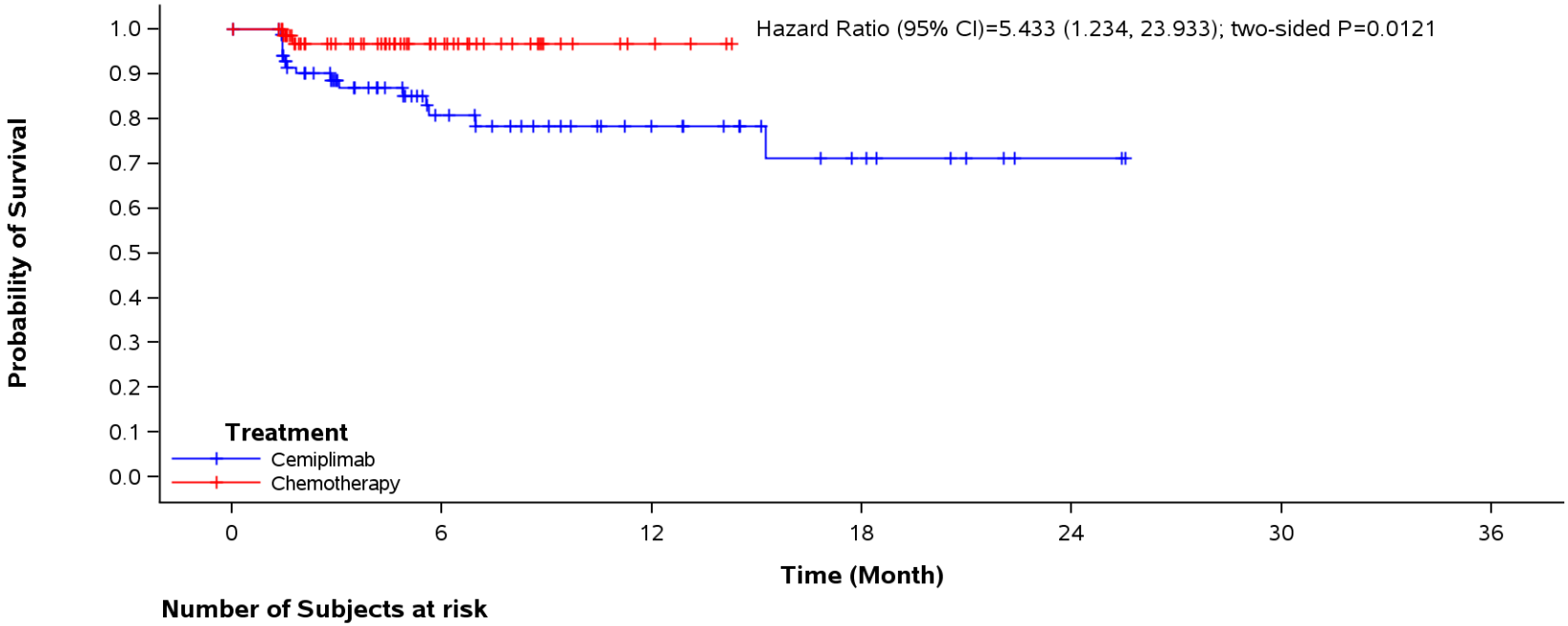
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 33 | 14 | 3 | 1 | 0 | 0 |
| Chemotherapy | 123 | 23 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Physical Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 35 | 17 | 8 | 2 | 0 | 0 |
| Chemotherapy | 123 | 24 | 4 | 0 | 0 | 0 | 0 |

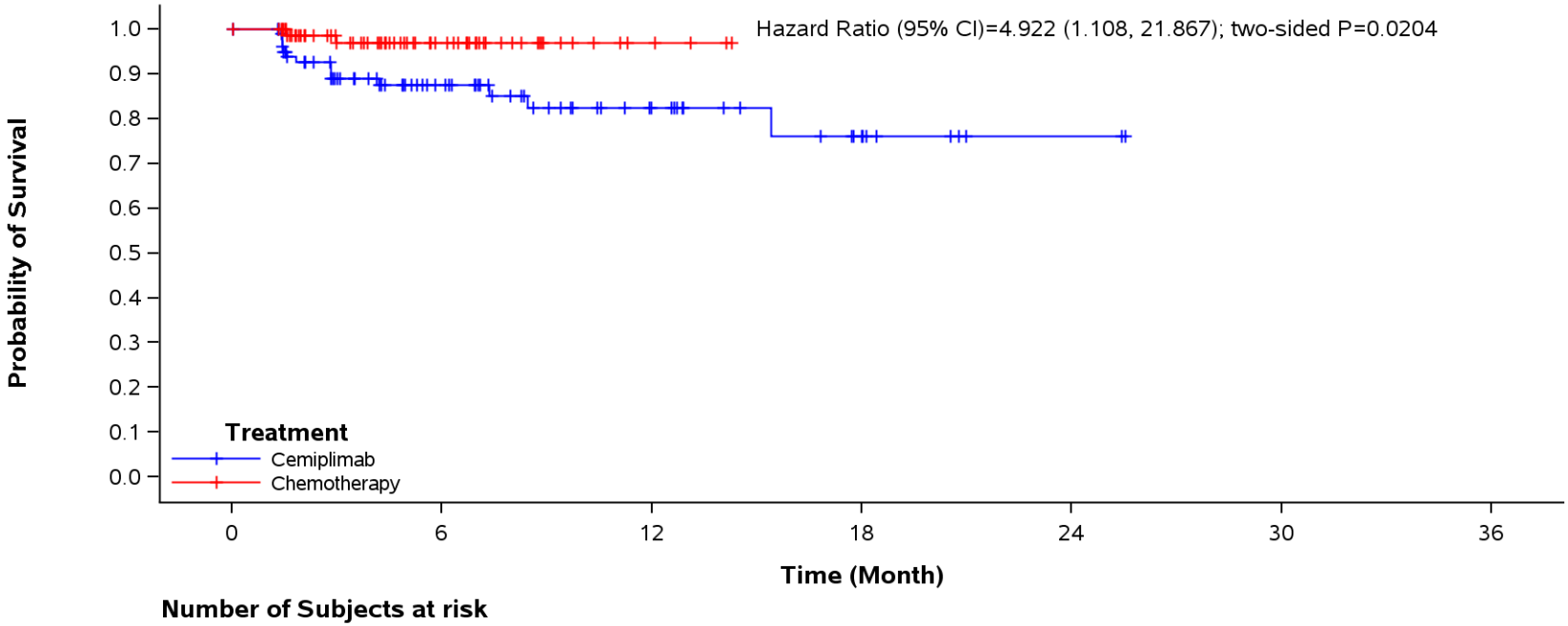
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Global health status / QoL - 10 pts sensitivity sustained improvement




Number of Subjects at risk

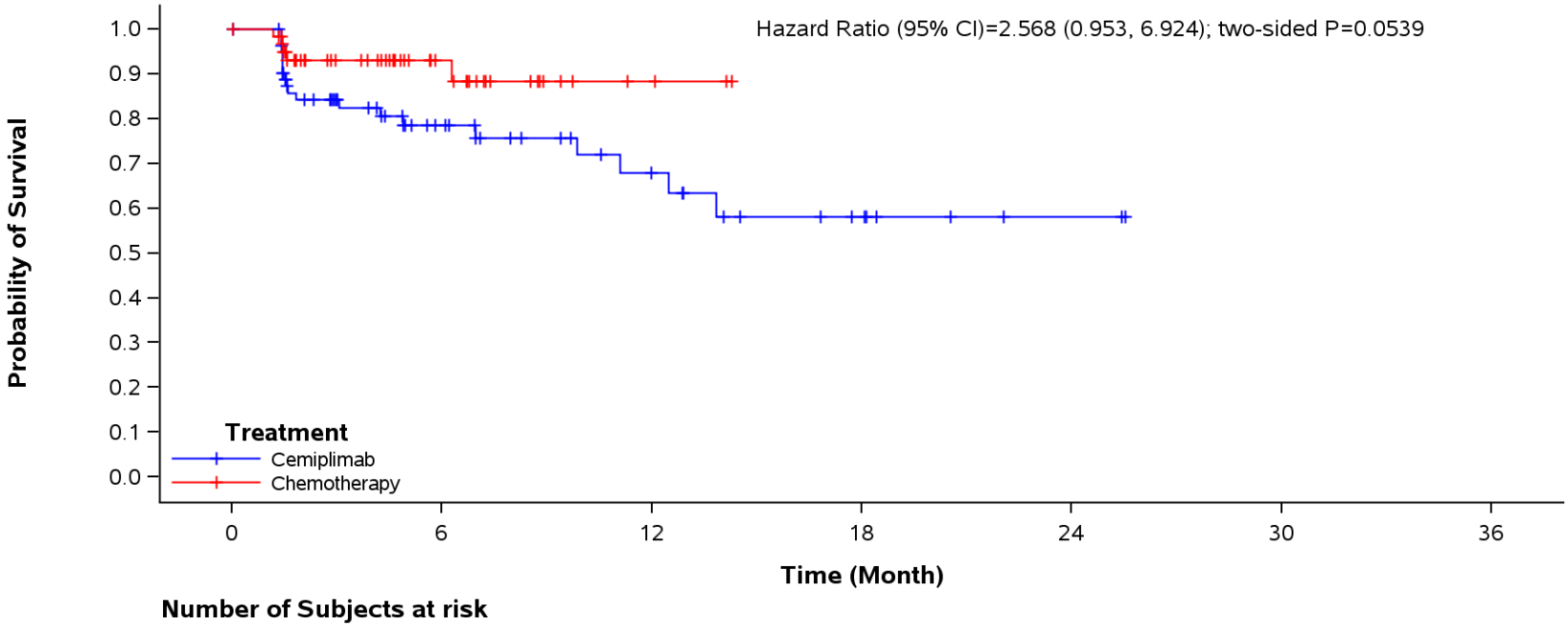
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 47 | 20 | 9 | 2 | 0 | 0 |
| Chemotherapy | 123 | 28 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Role Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

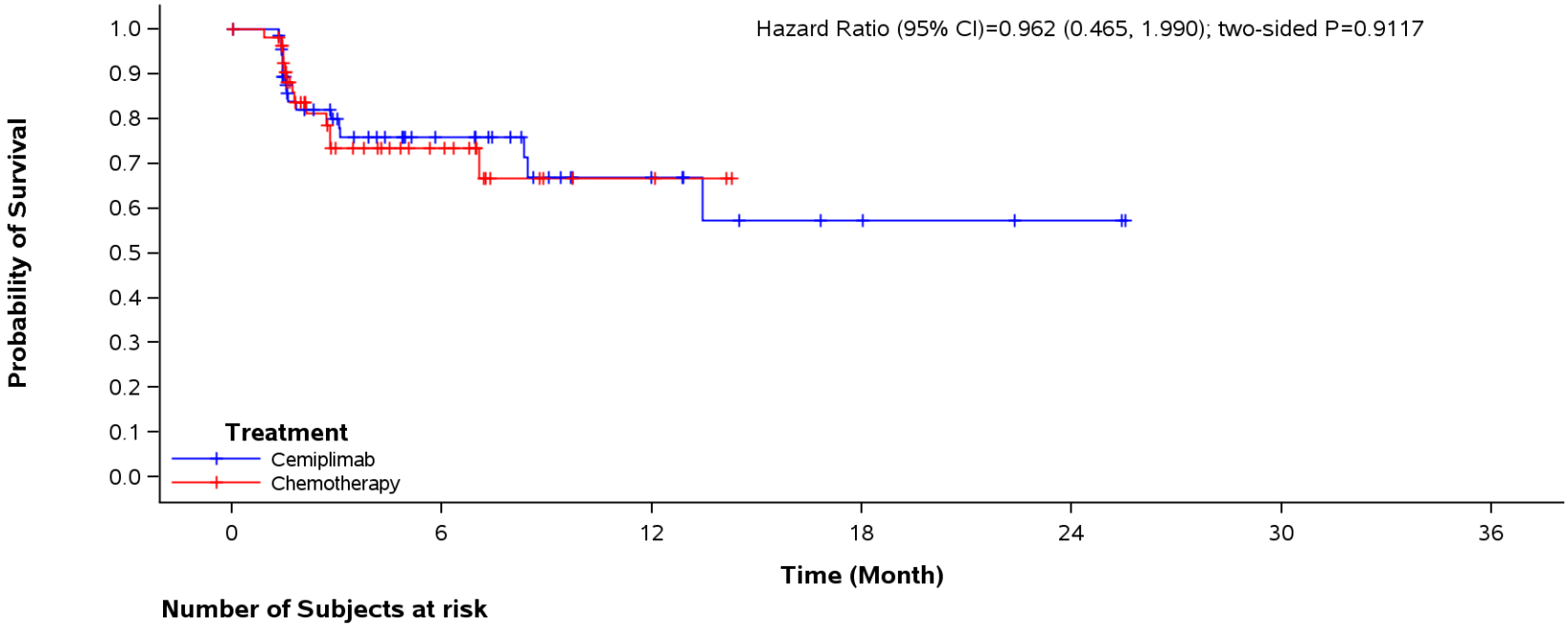
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 32 | 15 | 7 | 2 | 0 | 0 |
| Chemotherapy | 123 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Social Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

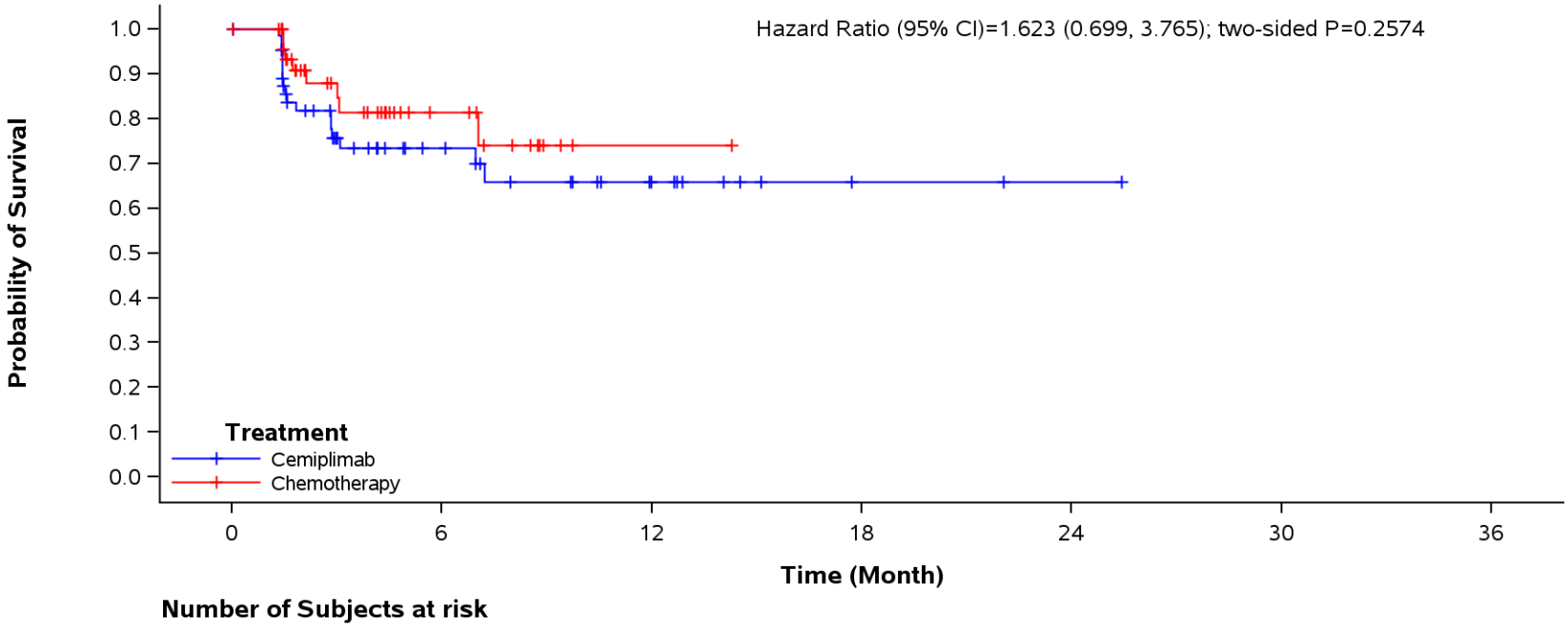
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 25 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 123 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts sensitivity sustained improvement



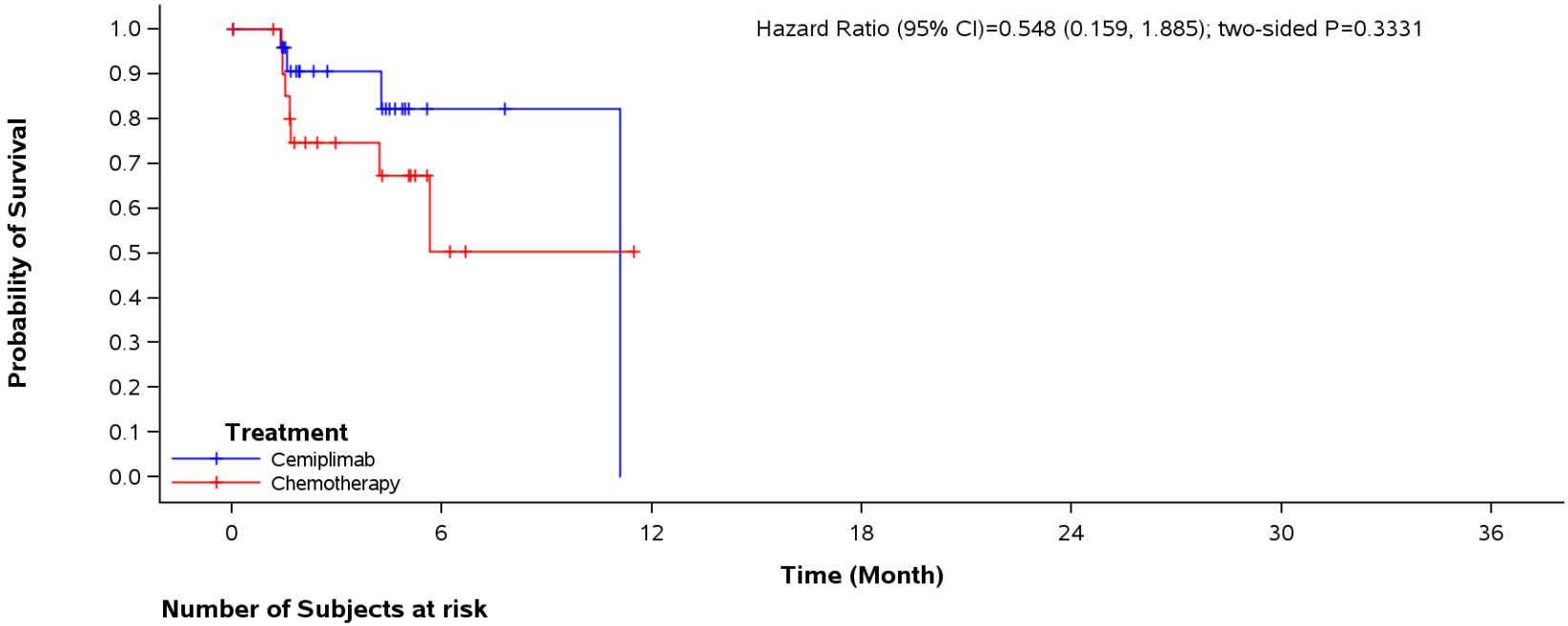

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 23 | 9 | 2 | 1 | 0 | 0 |
| Chemotherapy | 123 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Appetite loss - 10 pts sensitivity sustained improvement



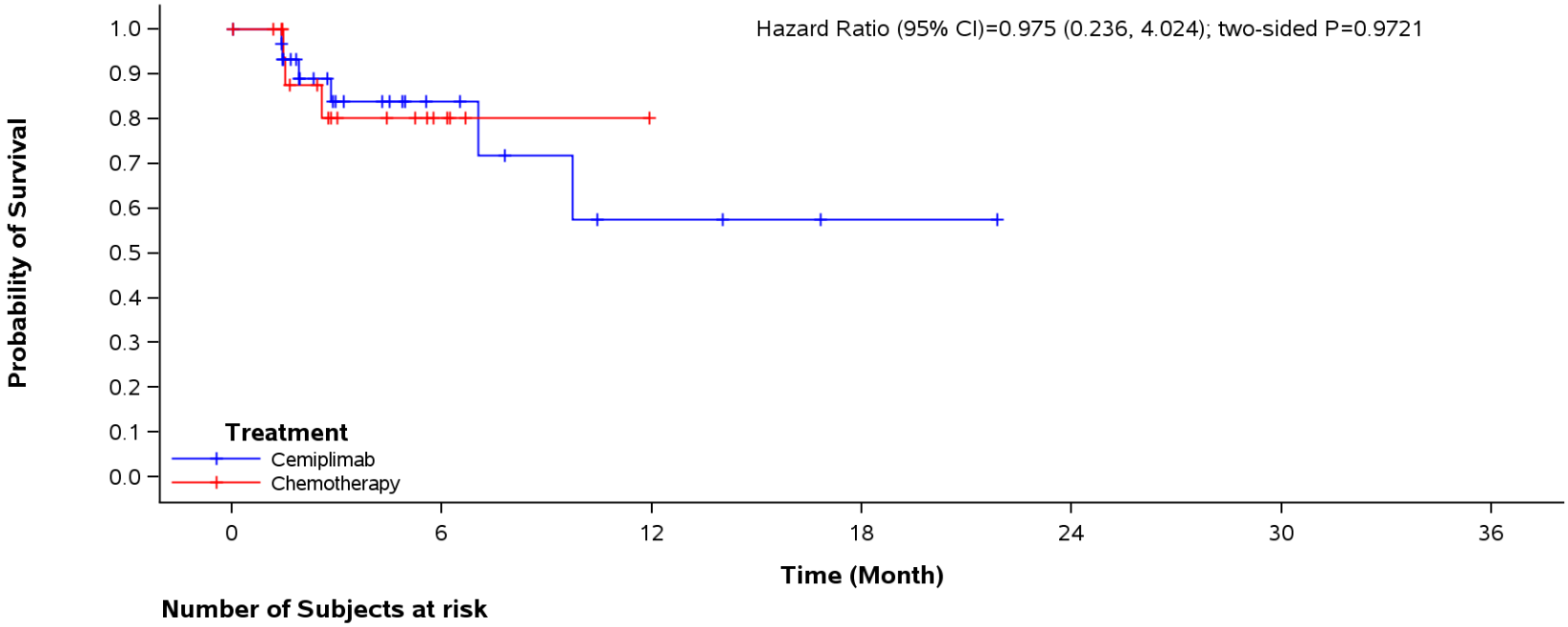

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Cognitive Functioning - 10 pts sensitivity sustained improvement



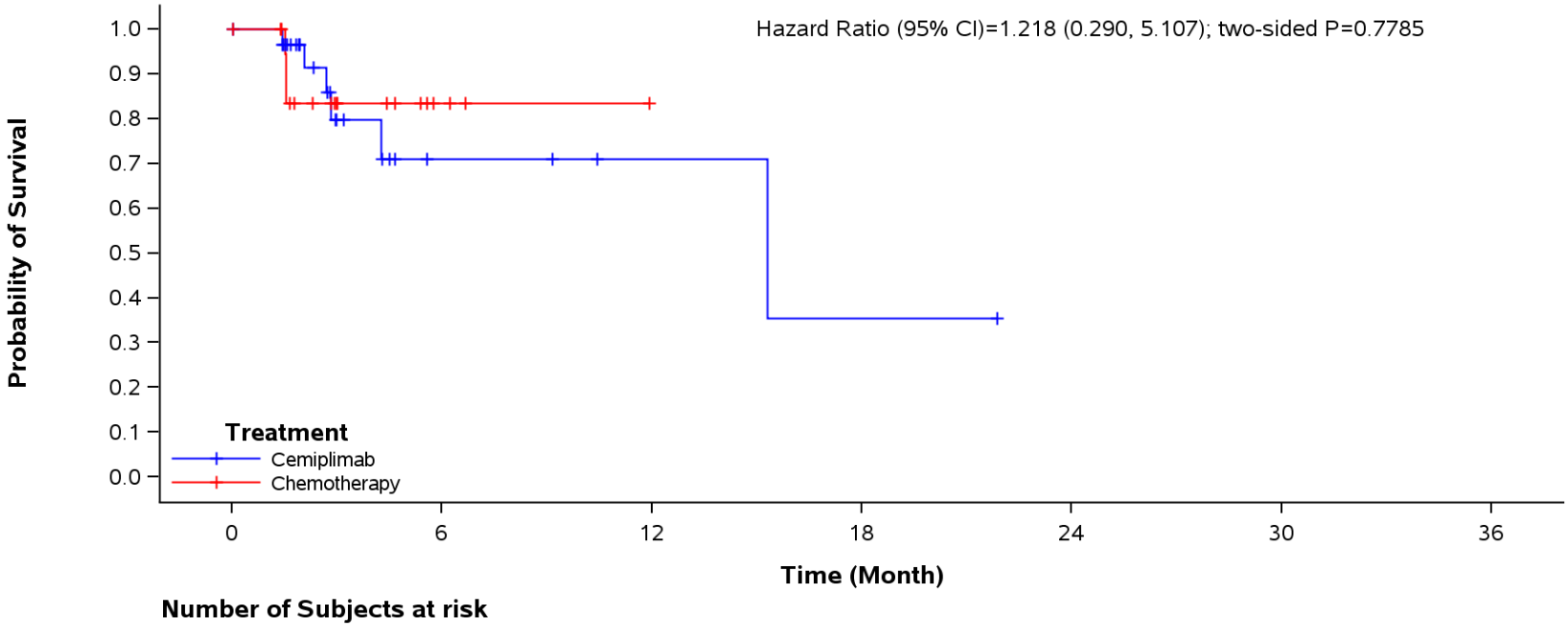

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 8 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts sensitivity sustained improvement



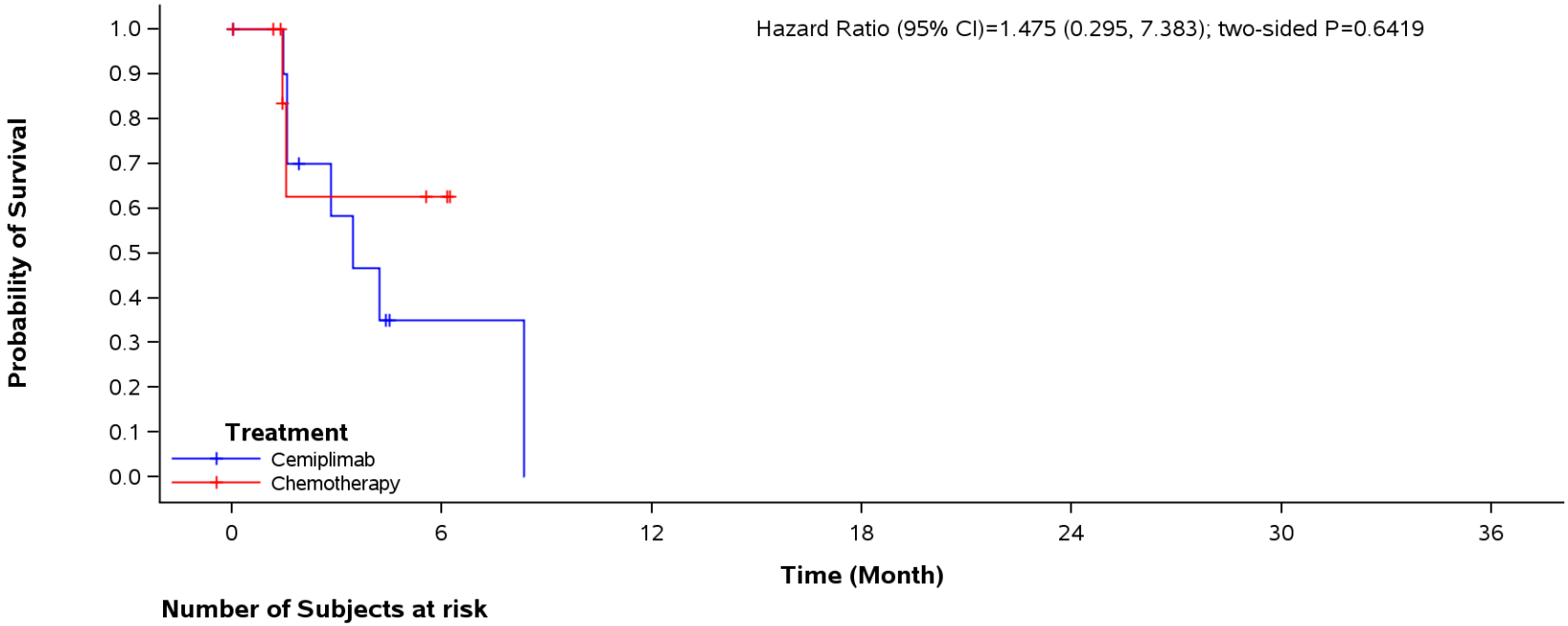

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts sensitivity sustained improvement



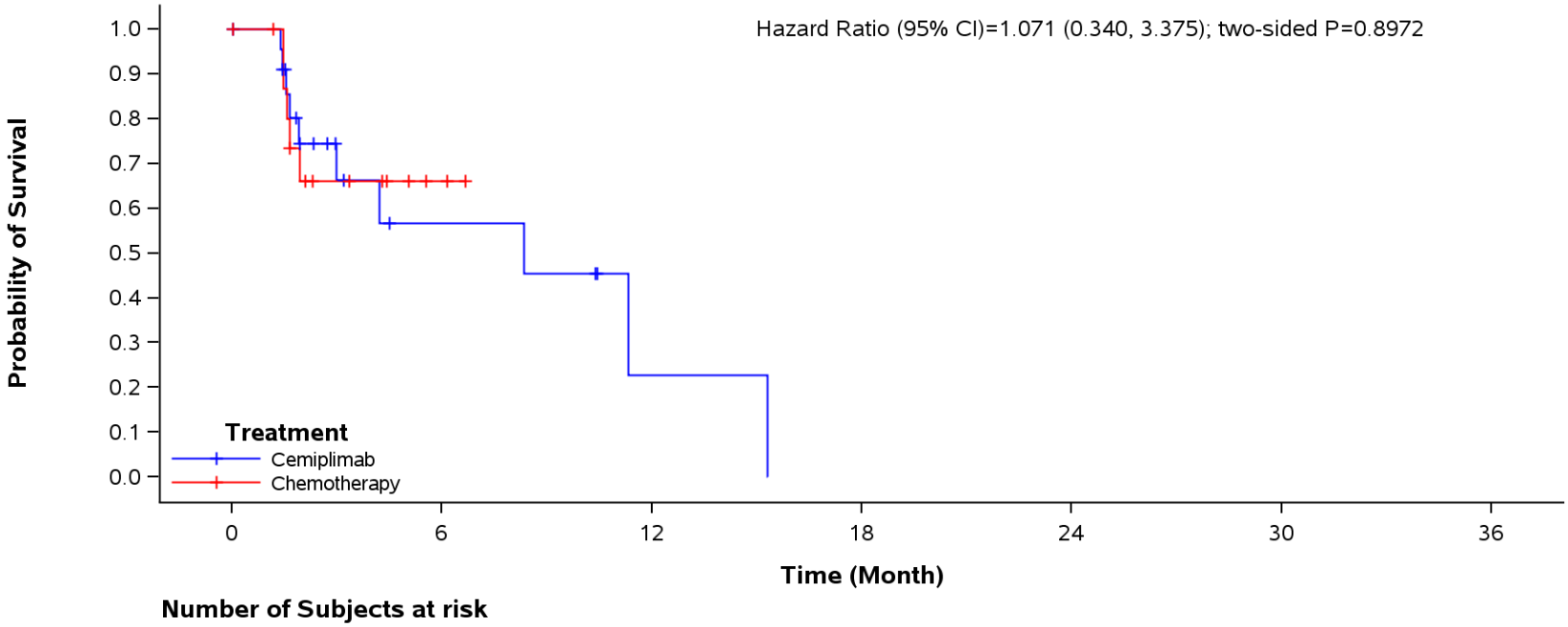

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts sensitivity sustained improvement



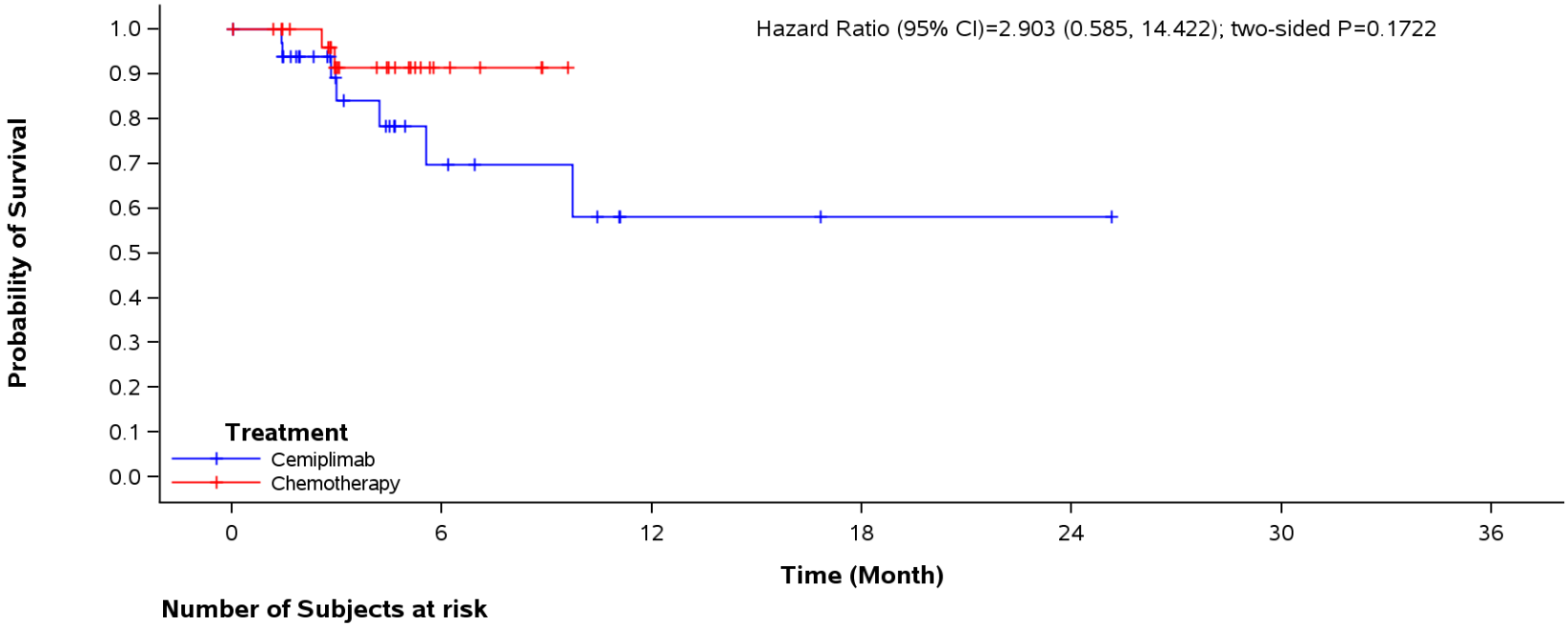

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Emotional Functioning - 10 pts sensitivity sustained improvement



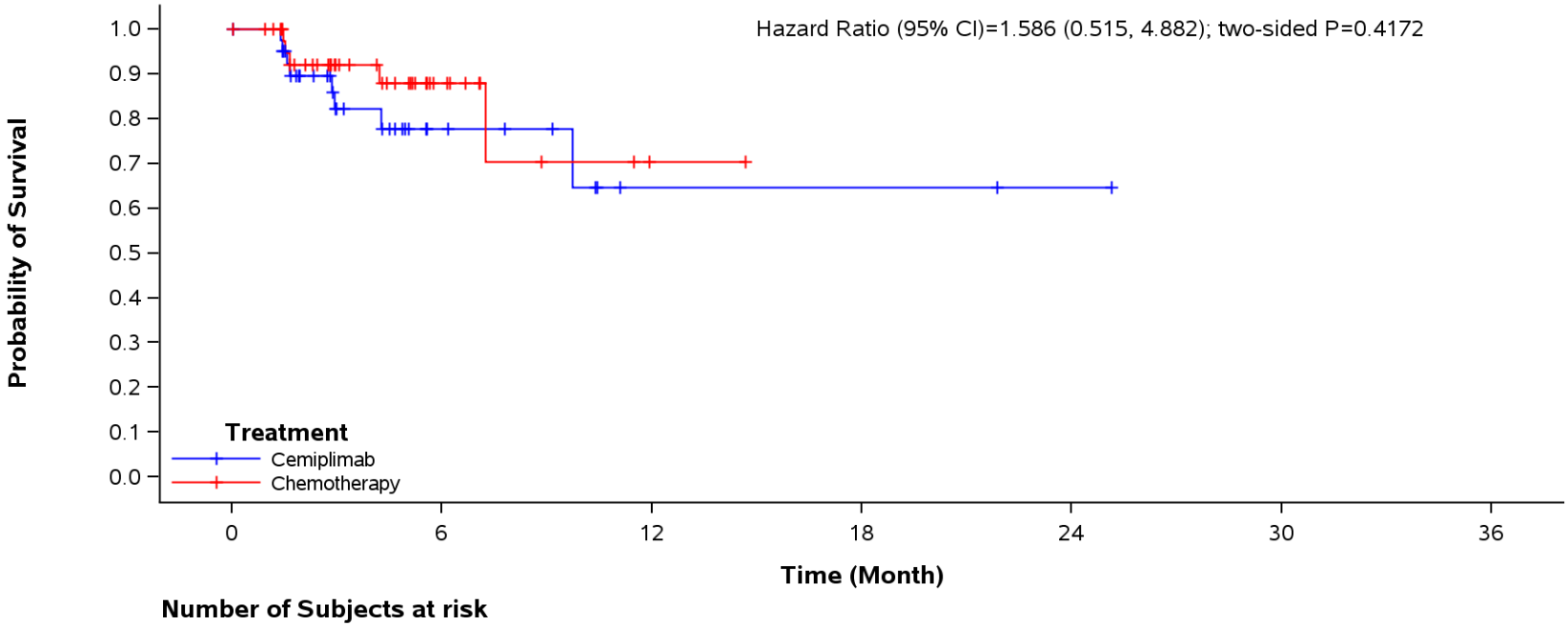

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 8 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 60 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts sensitivity sustained improvement



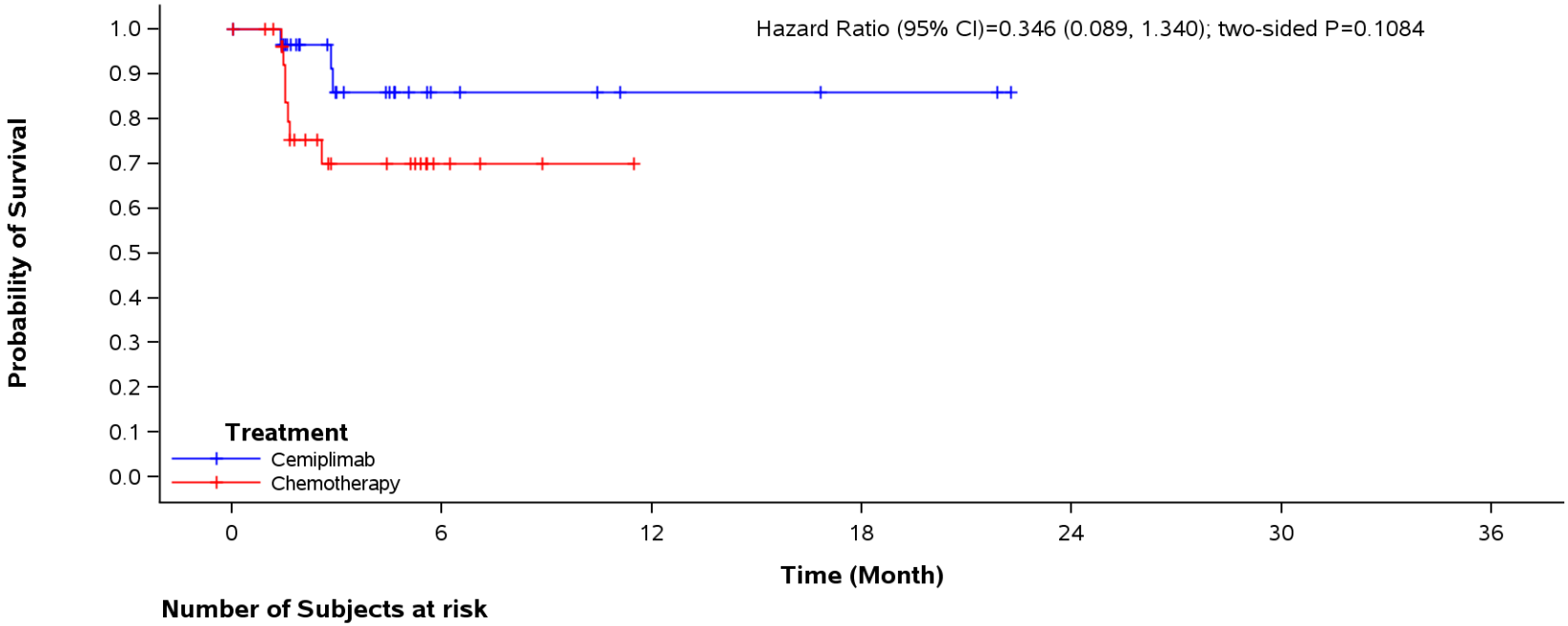

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 9 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Financial Problems - 10 pts sensitivity sustained improvement



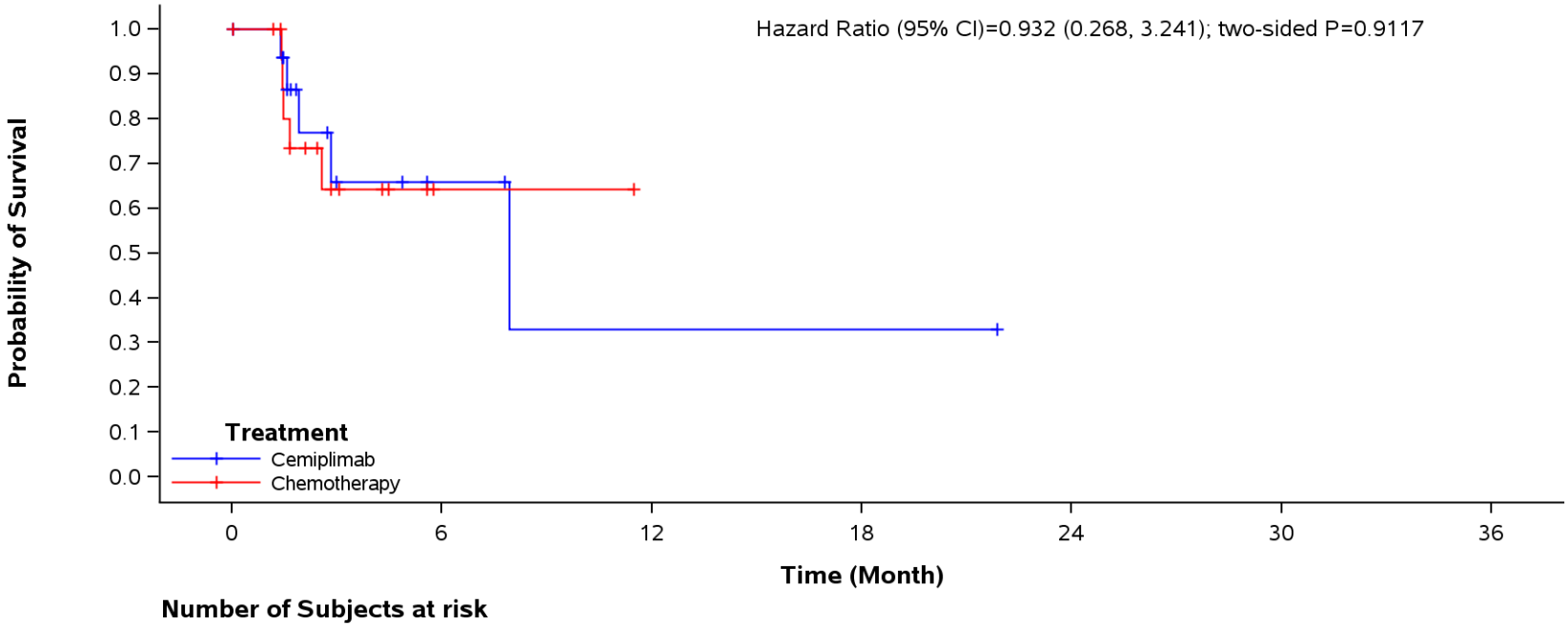

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 6 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts sensitivity sustained improvement



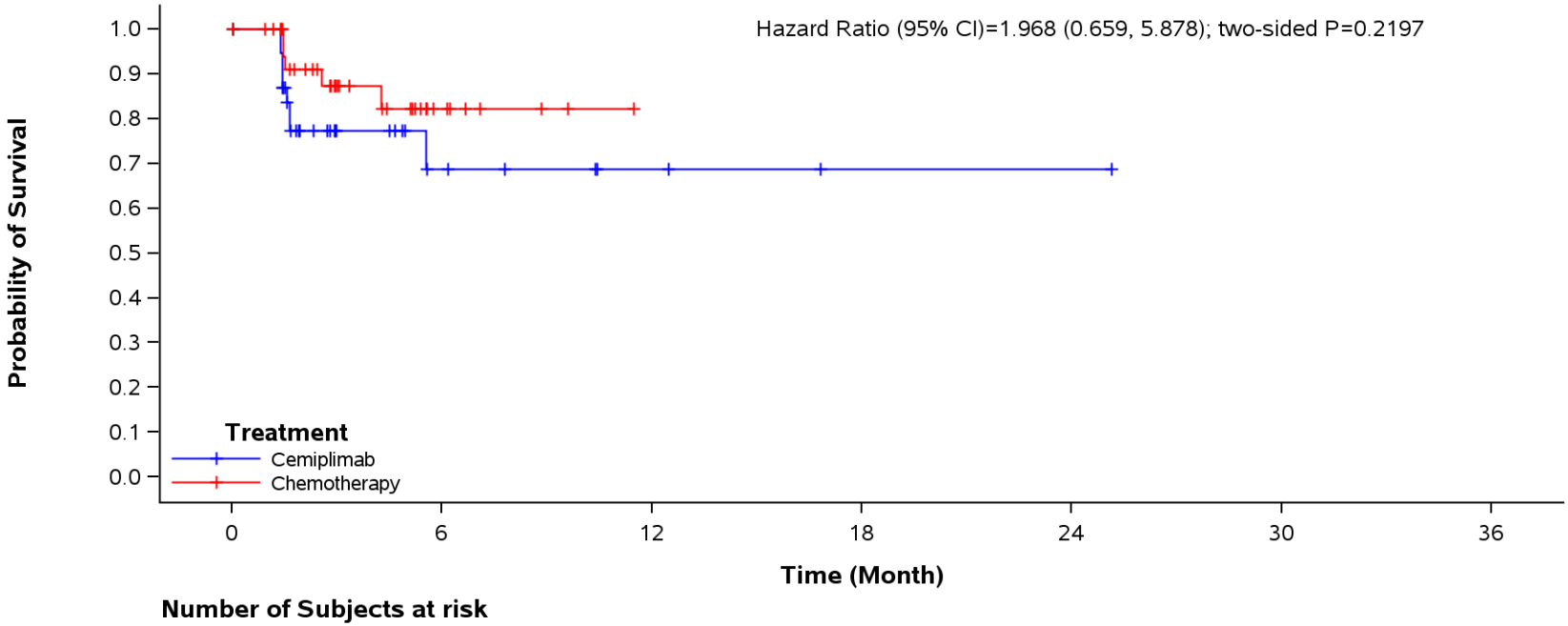

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts sensitivity sustained improvement



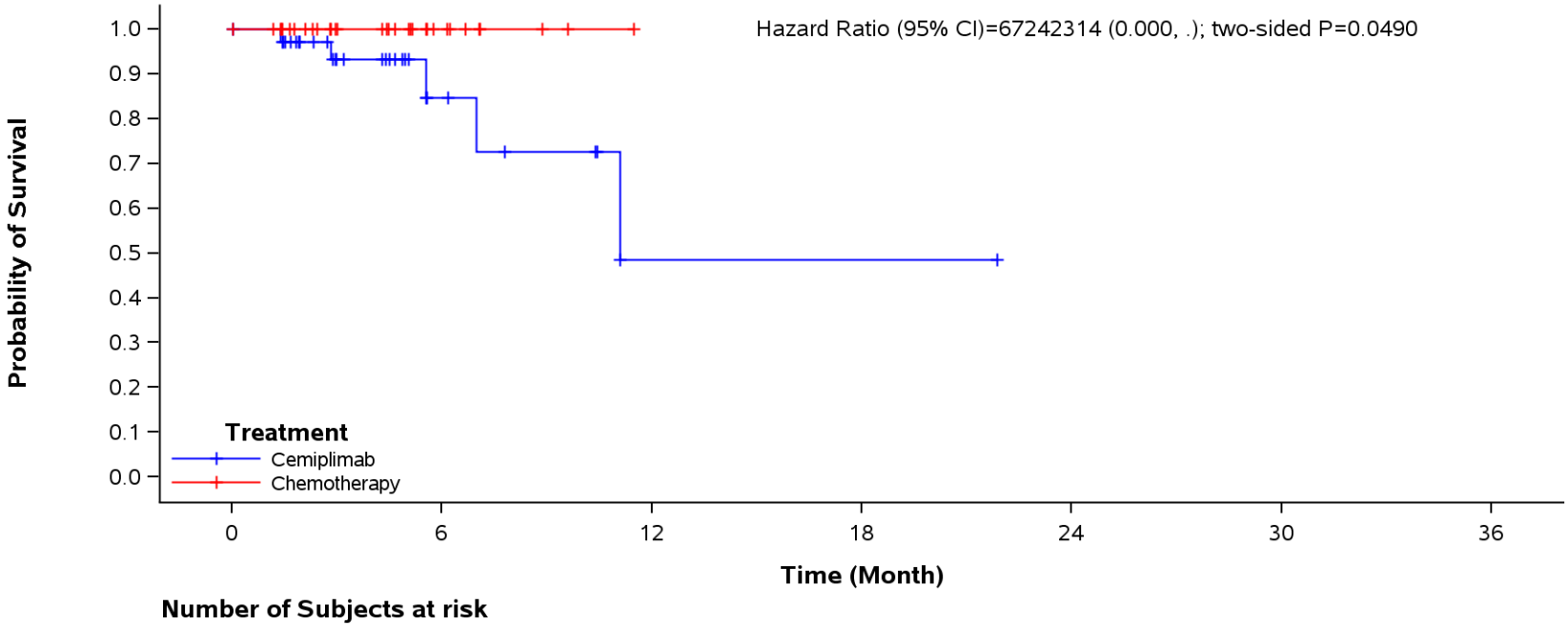

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 7 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 60 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Physical Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

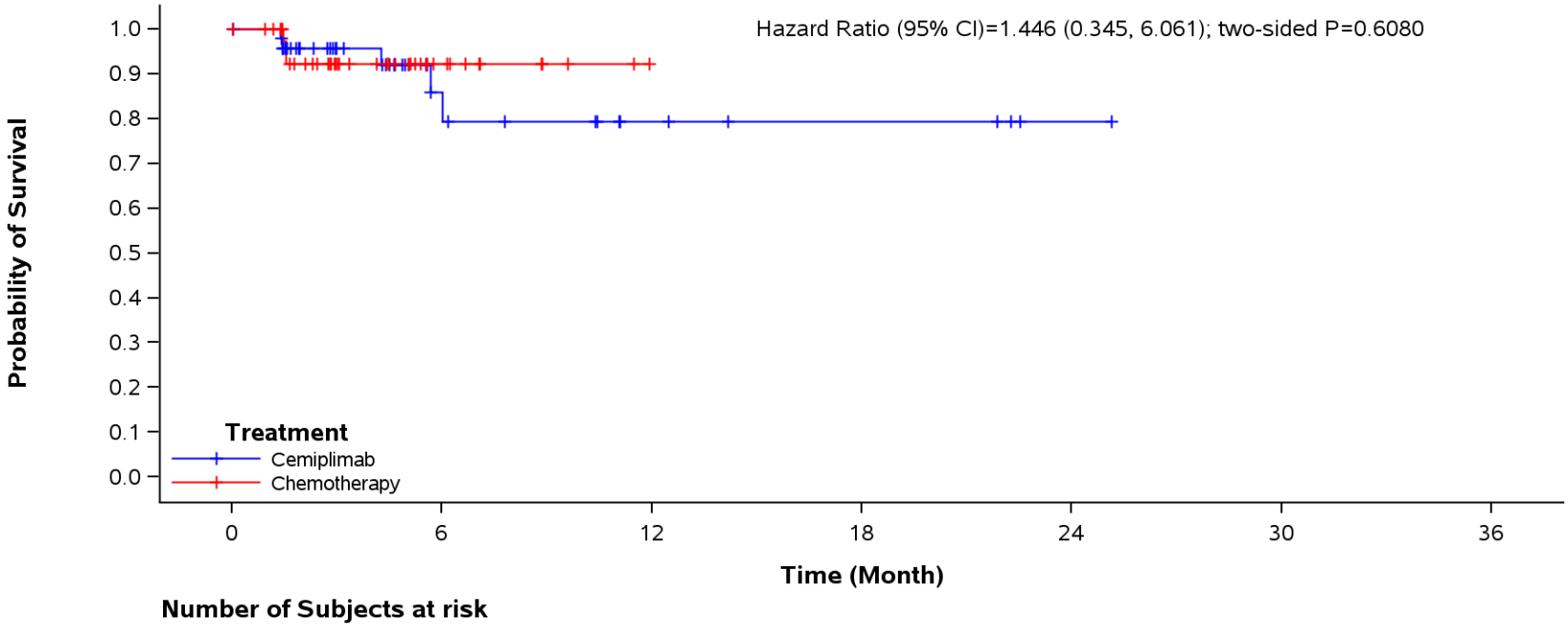
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 8 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

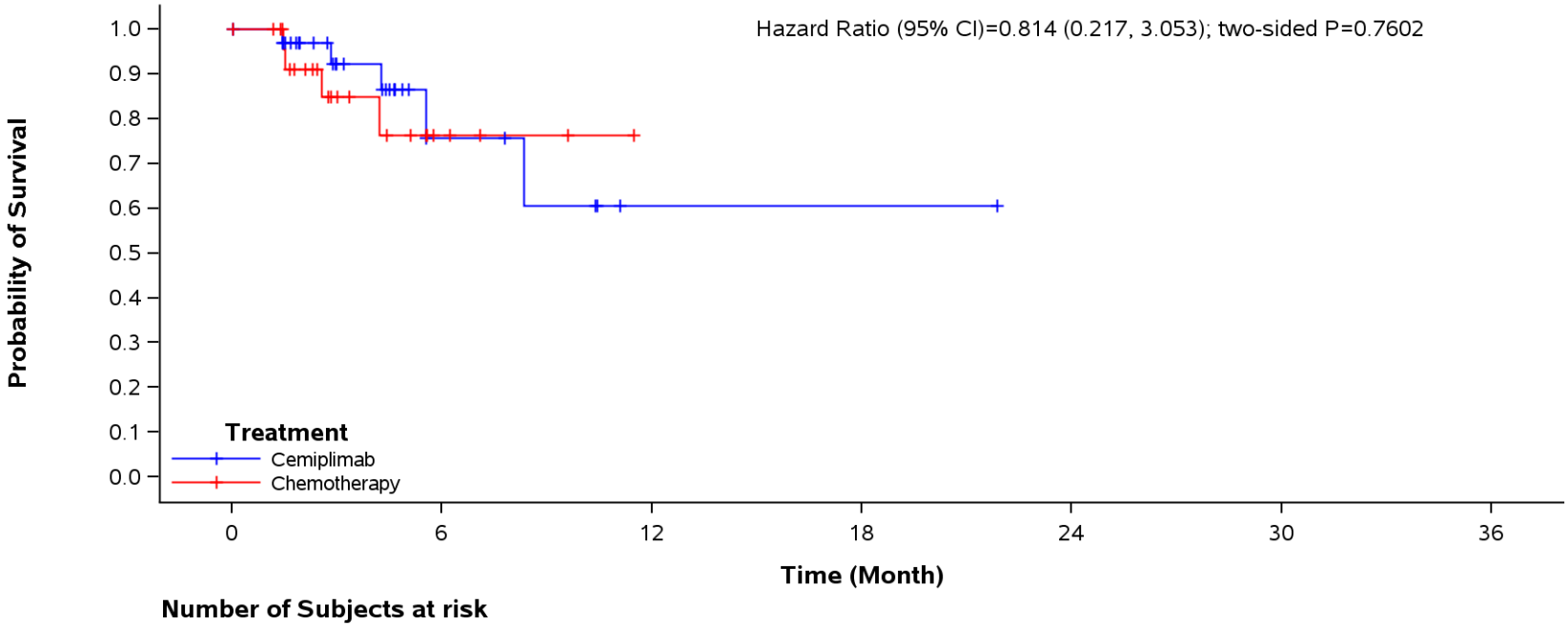
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 6 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

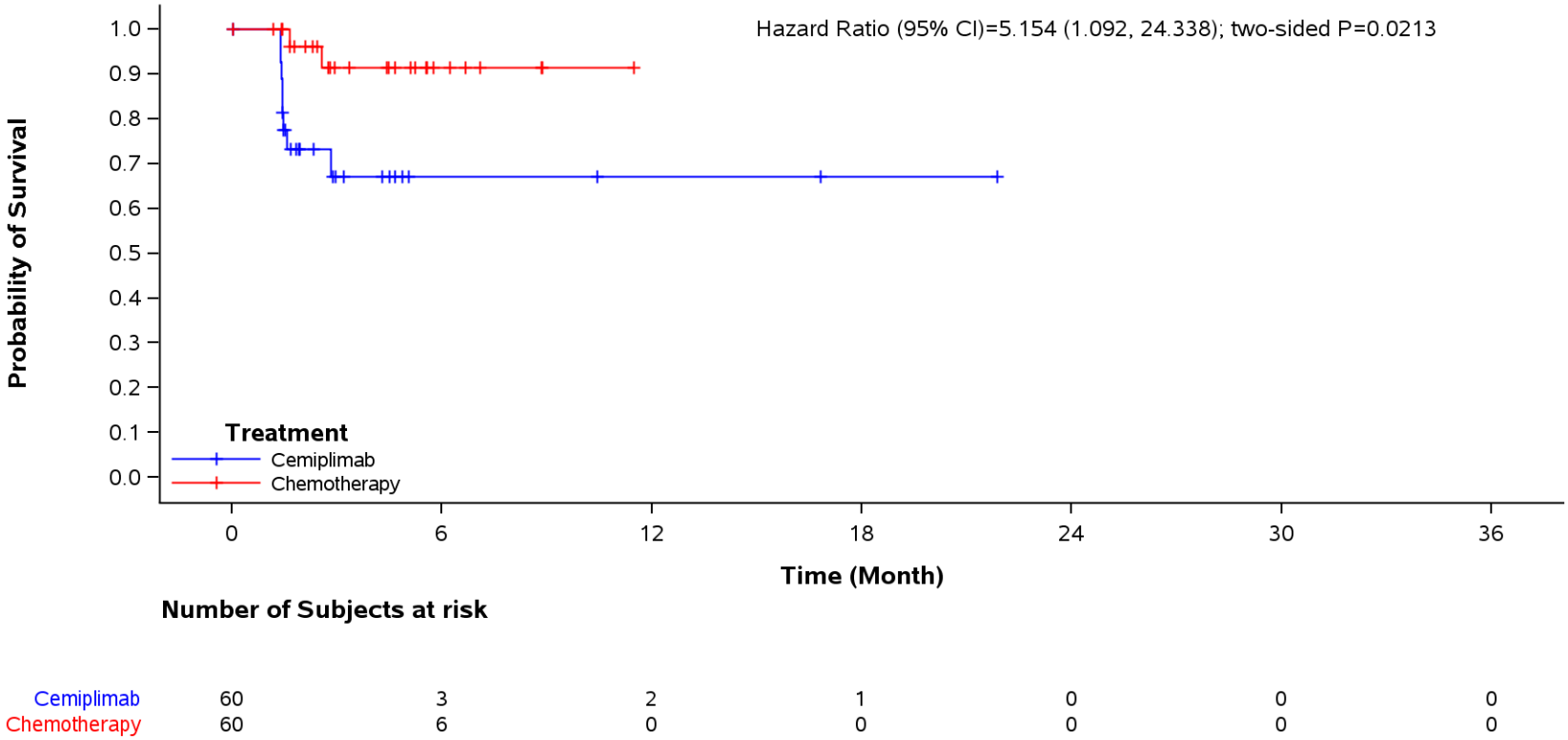
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 6 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Social Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

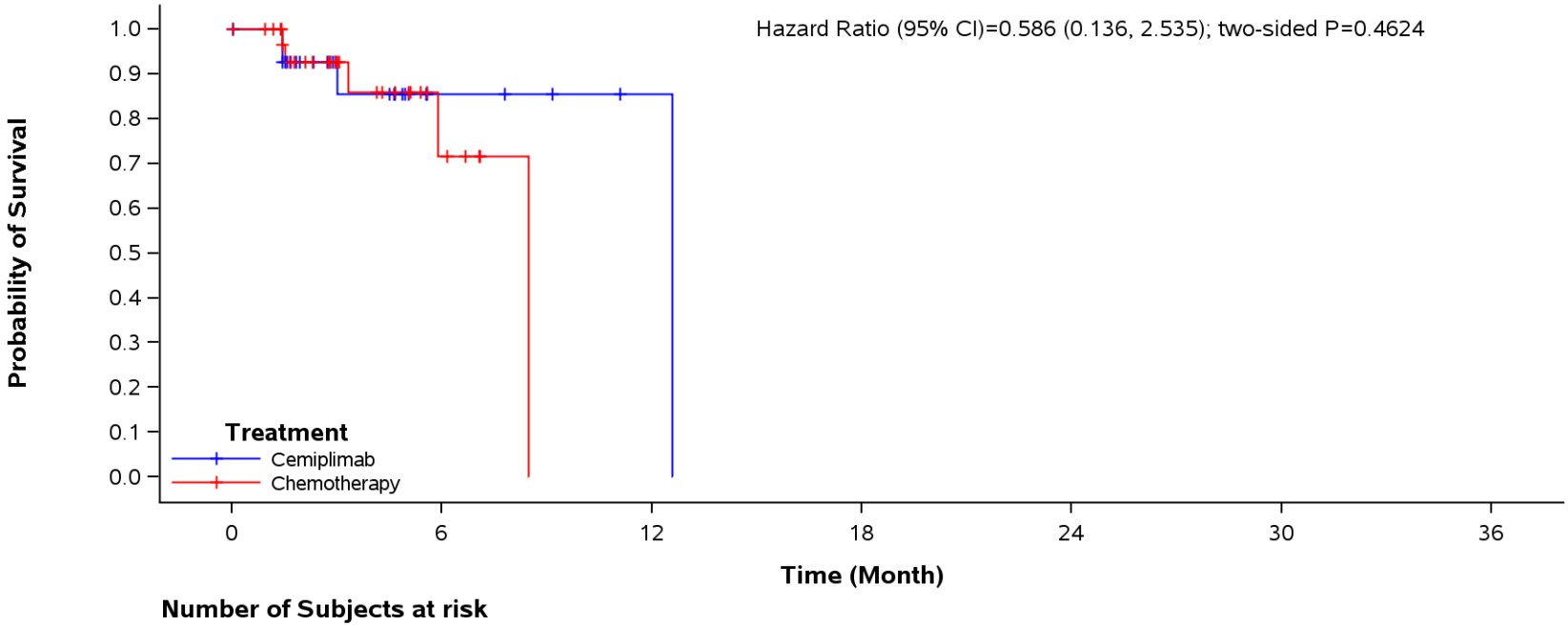
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts sensitivity sustained improvement



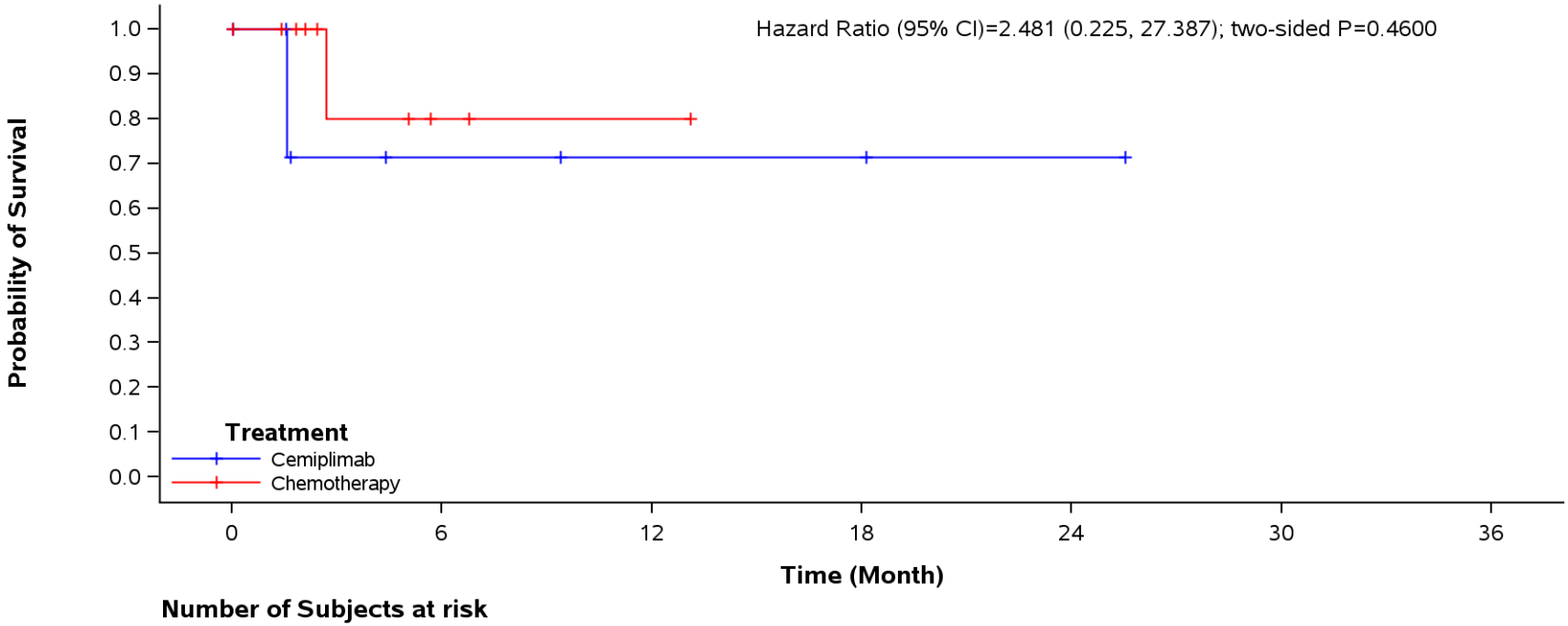

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 60 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts sensitivity sustained improvement



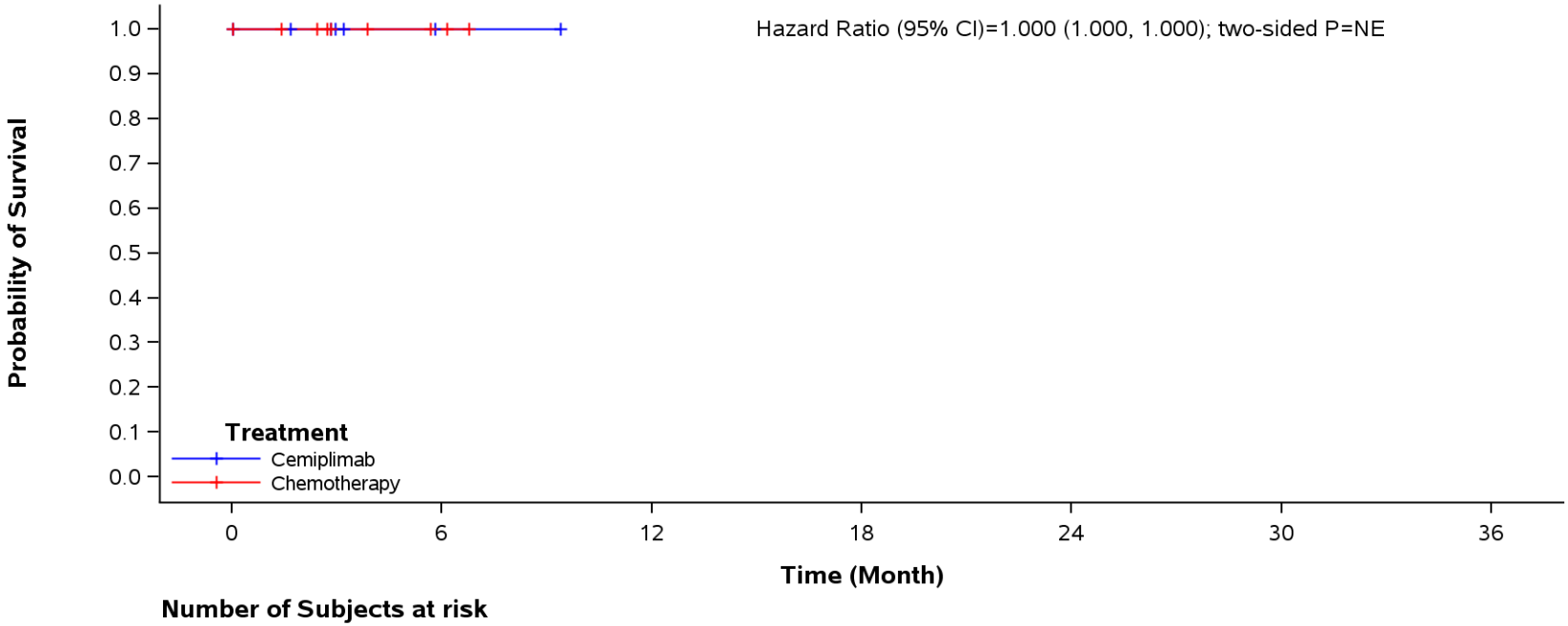

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts sensitivity sustained improvement



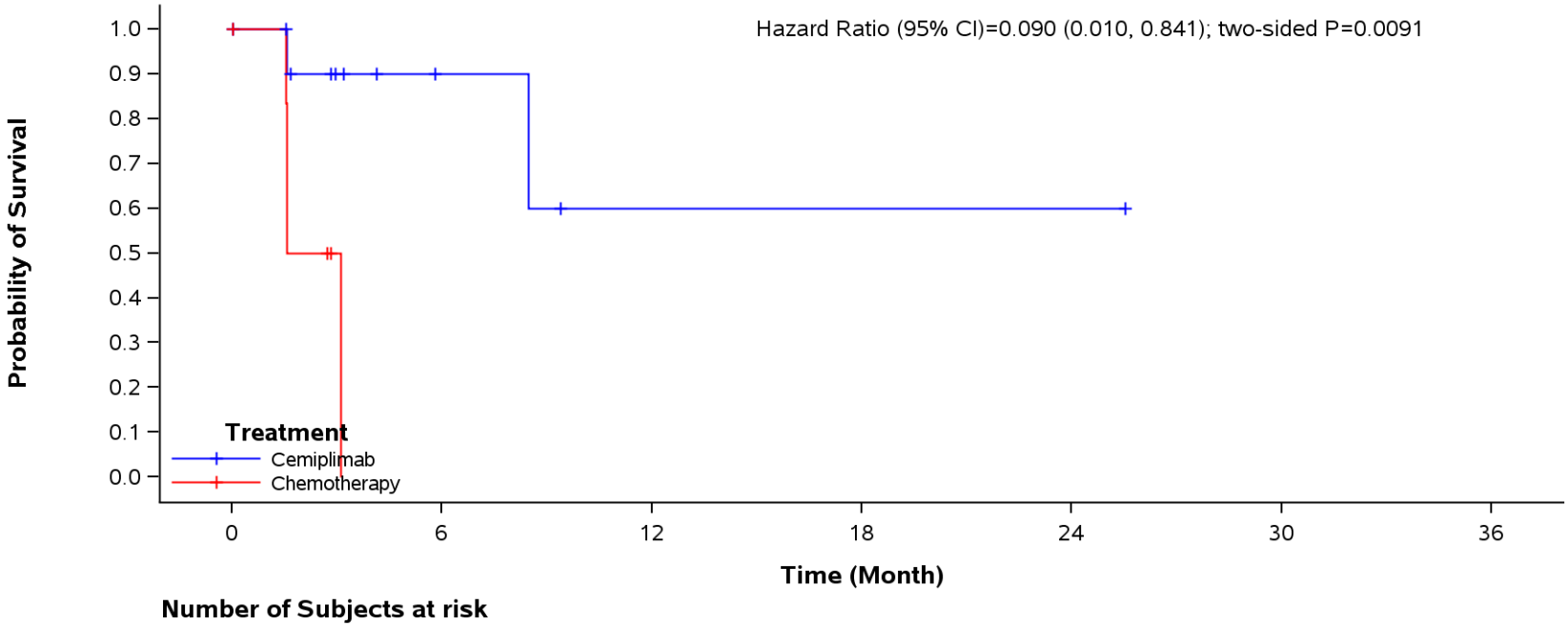

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts sensitivity sustained improvement



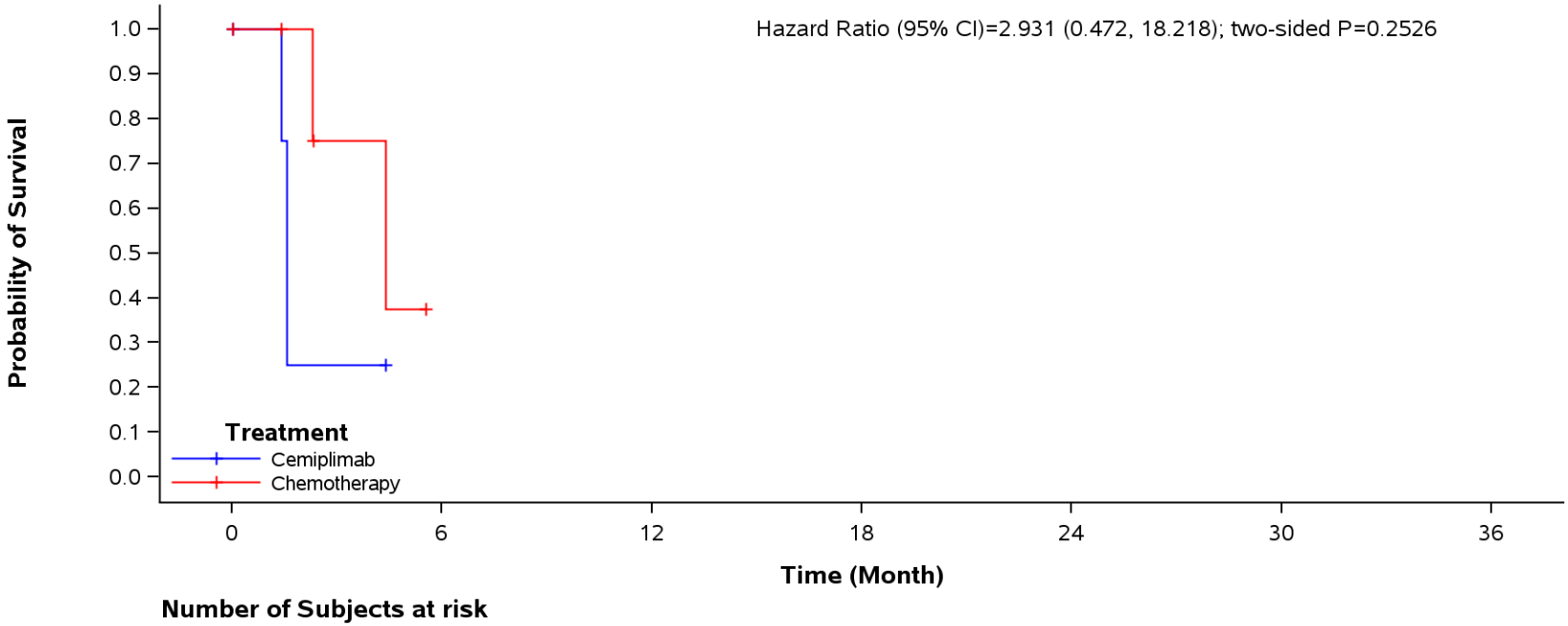

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts sensitivity sustained improvement



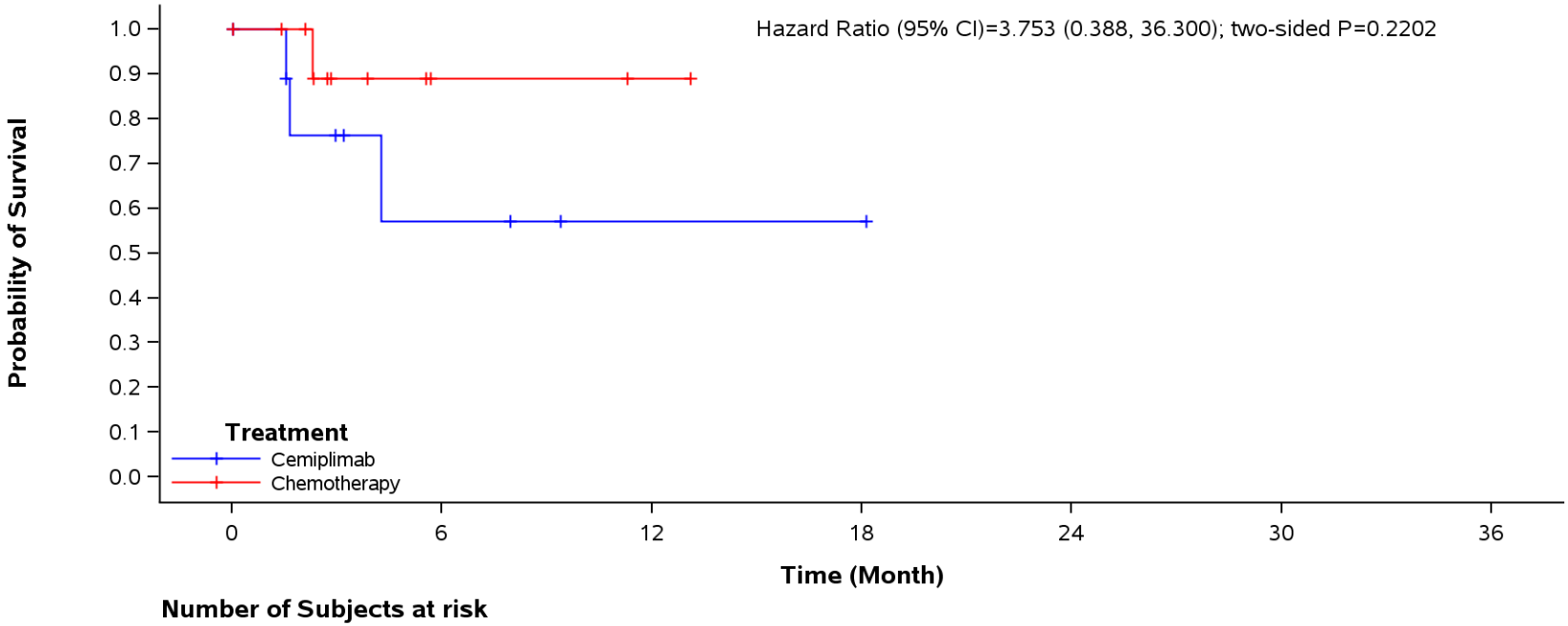

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts sensitivity sustained improvement



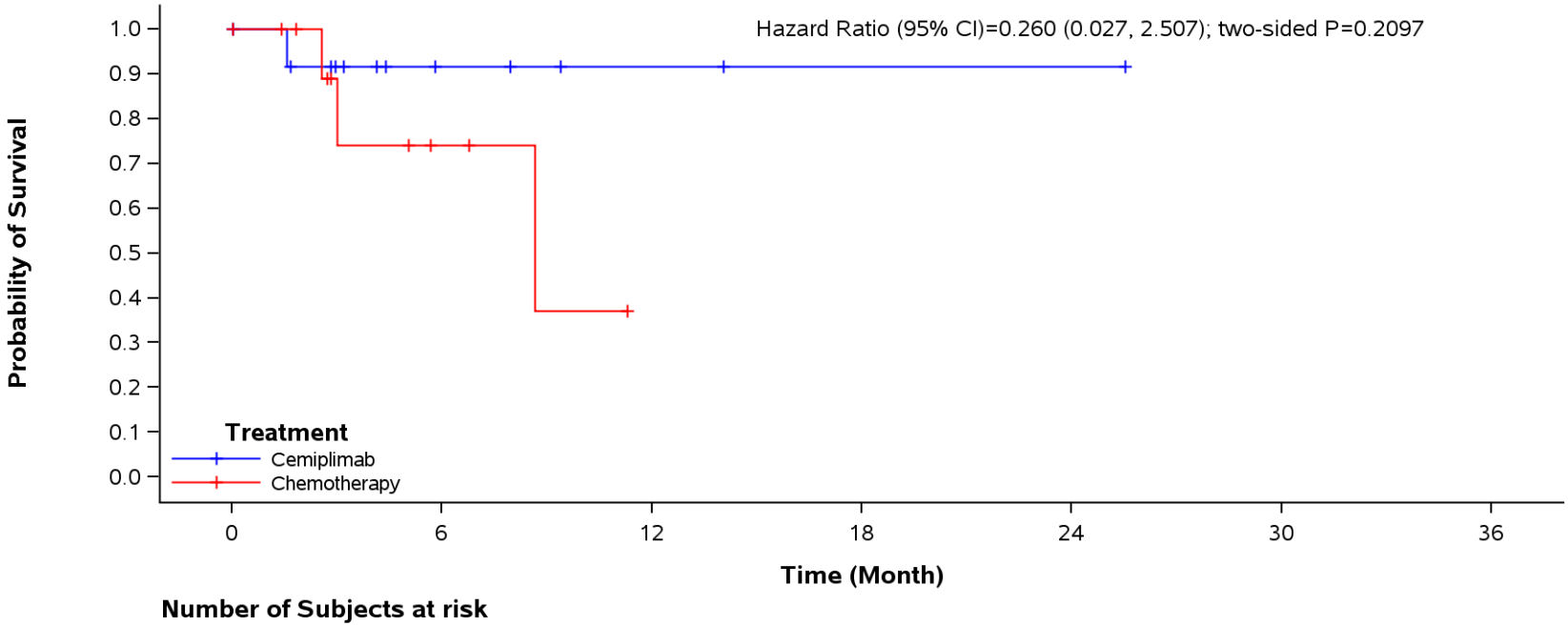

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 25 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts sensitivity sustained improvement



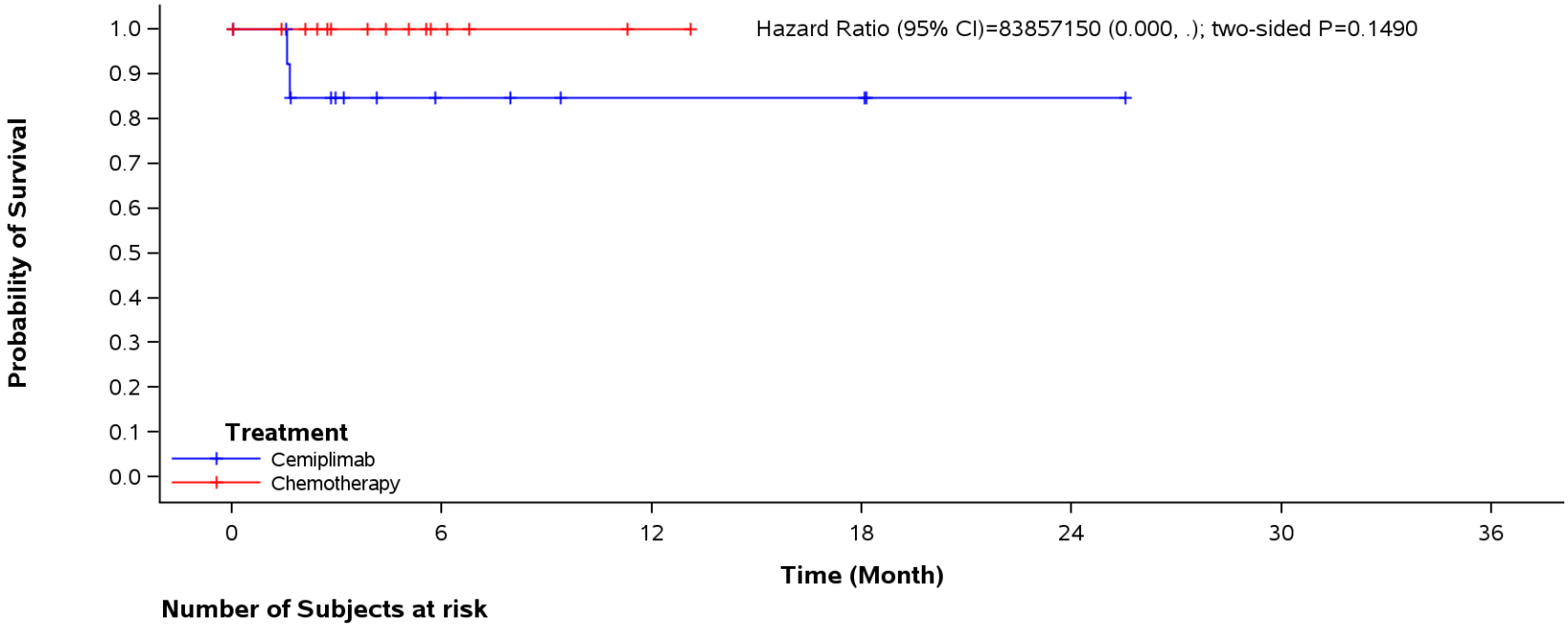

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 4 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 25 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts sensitivity sustained improvement



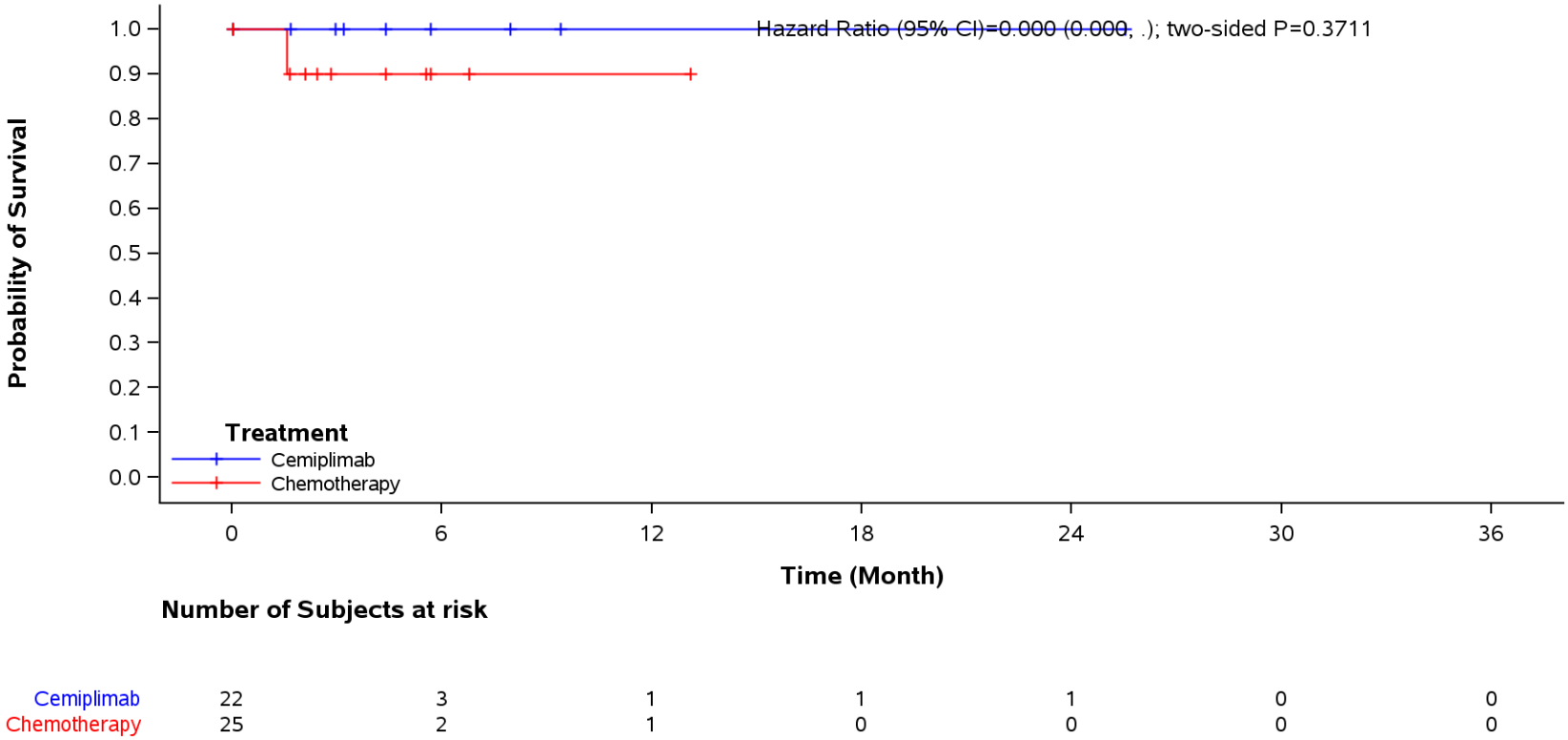

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 3 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

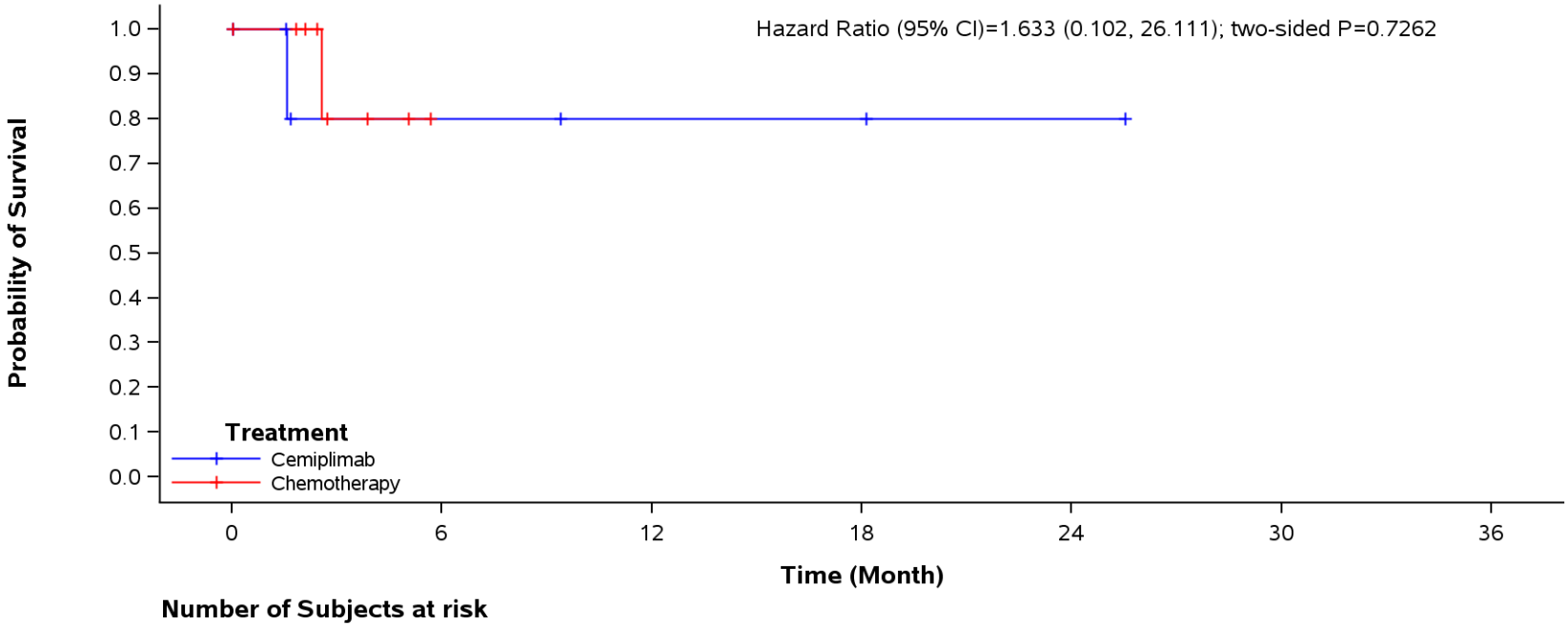
Geographic region: North America
Financial Problems - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts sensitivity sustained improvement



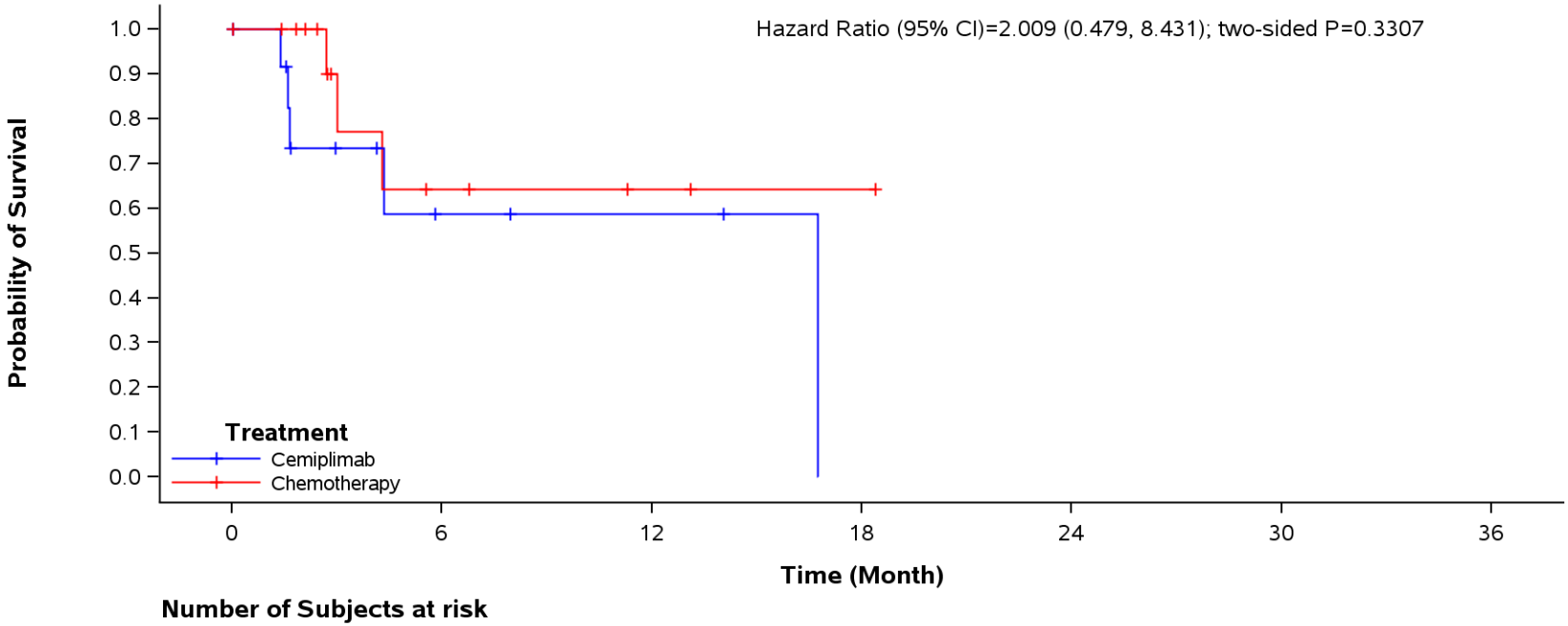

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts sensitivity sustained improvement



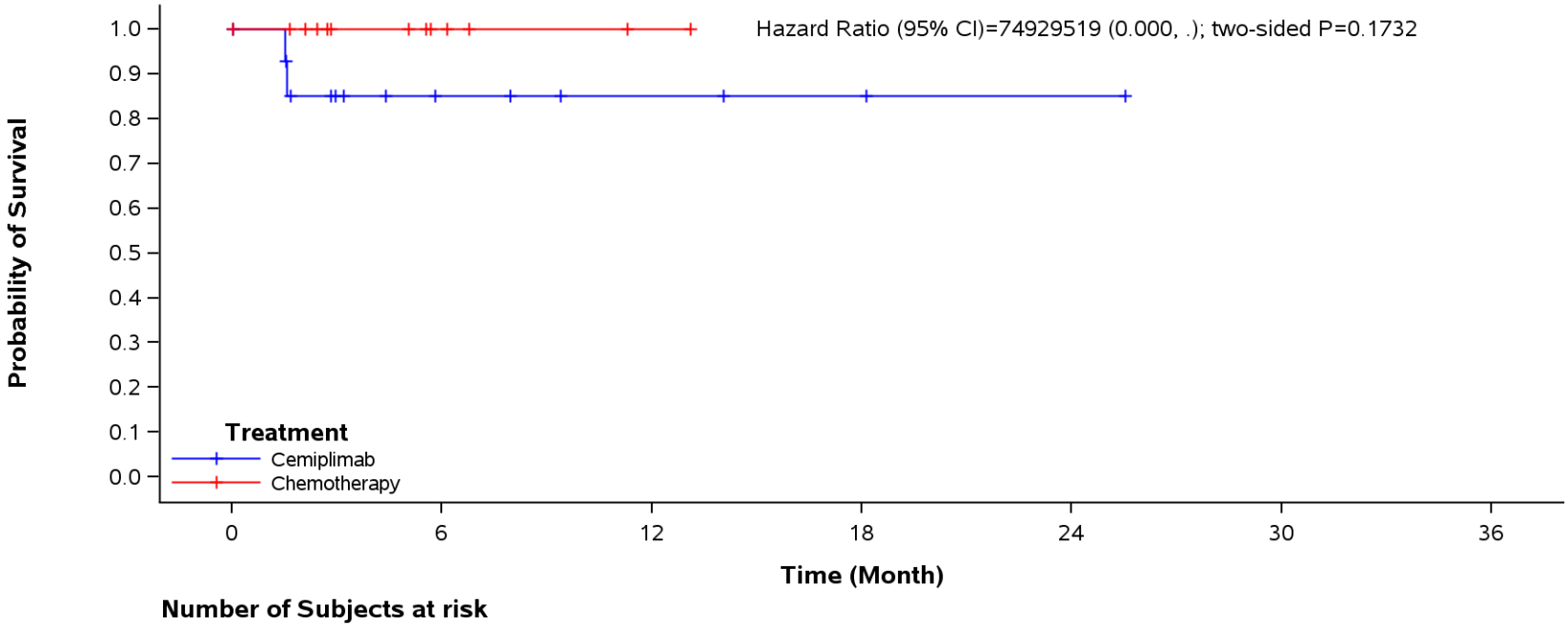

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 4 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts sensitivity sustained improvement



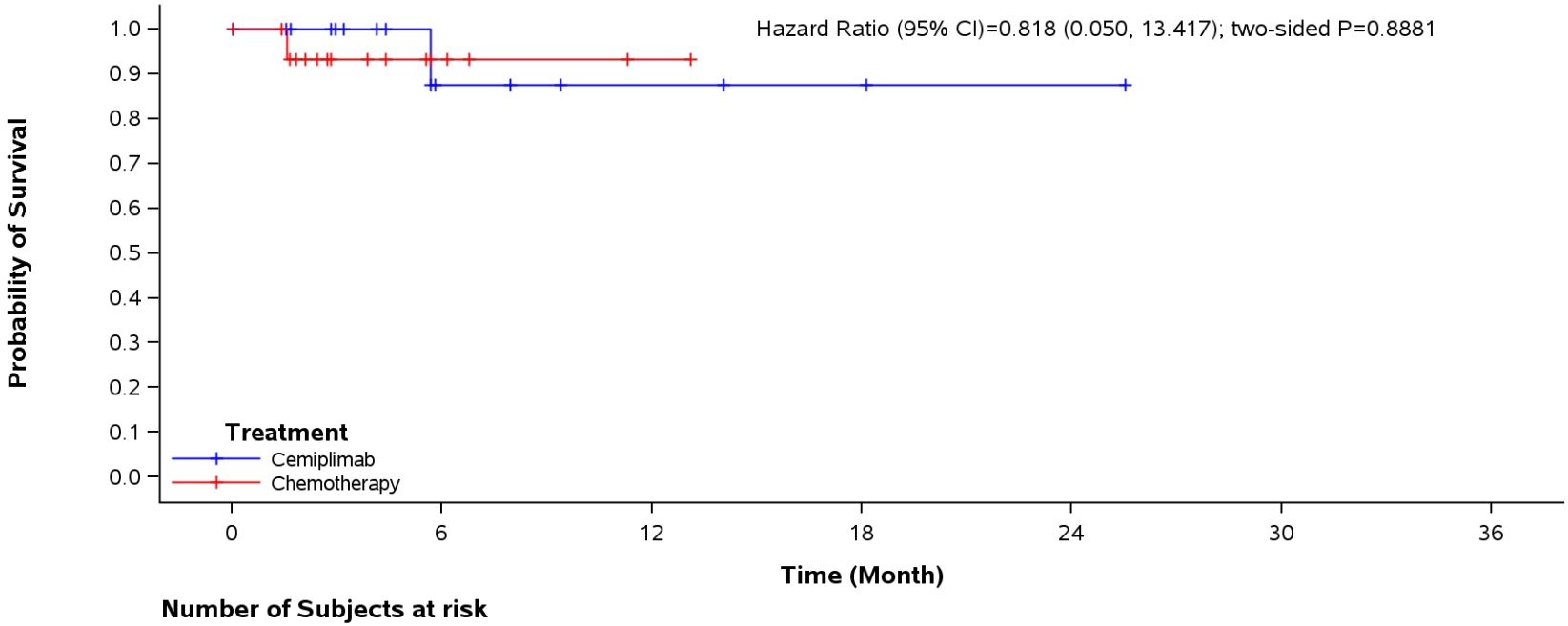

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts sensitivity sustained improvement



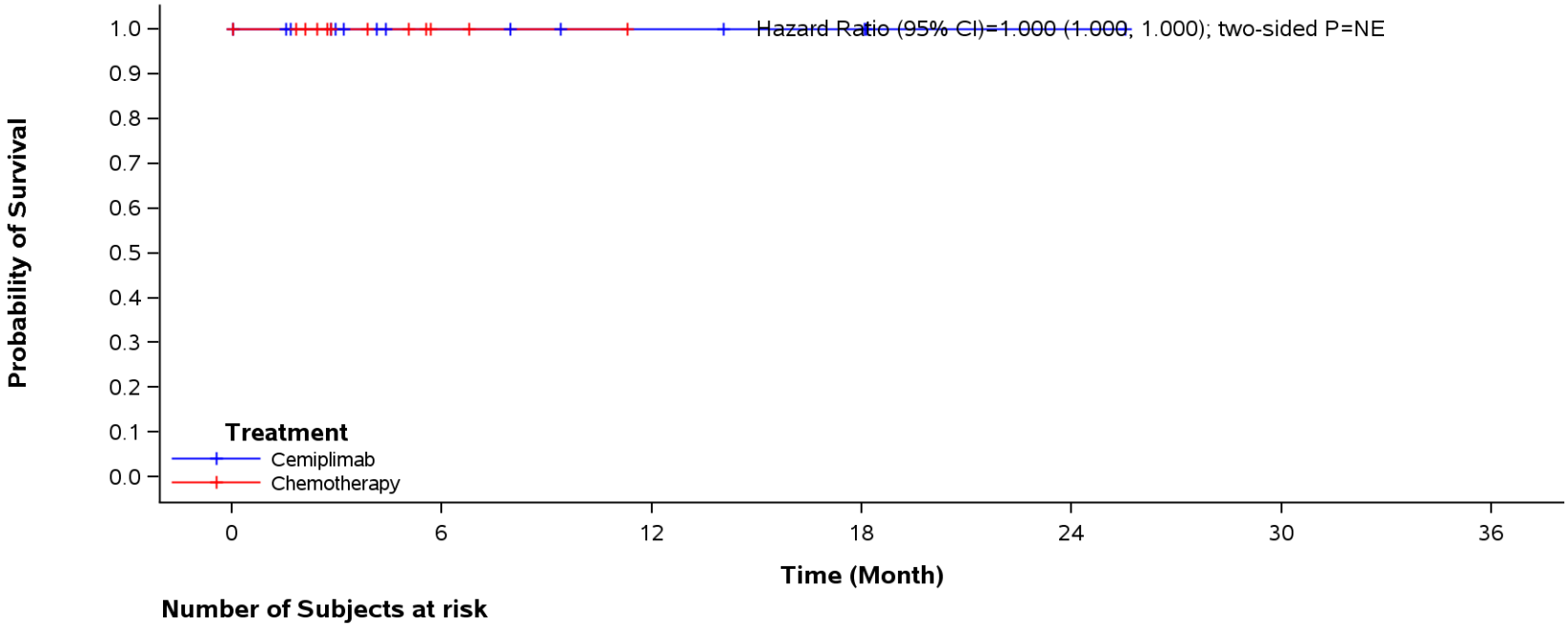

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Role Functioning - 10 pts sensitivity sustained improvement



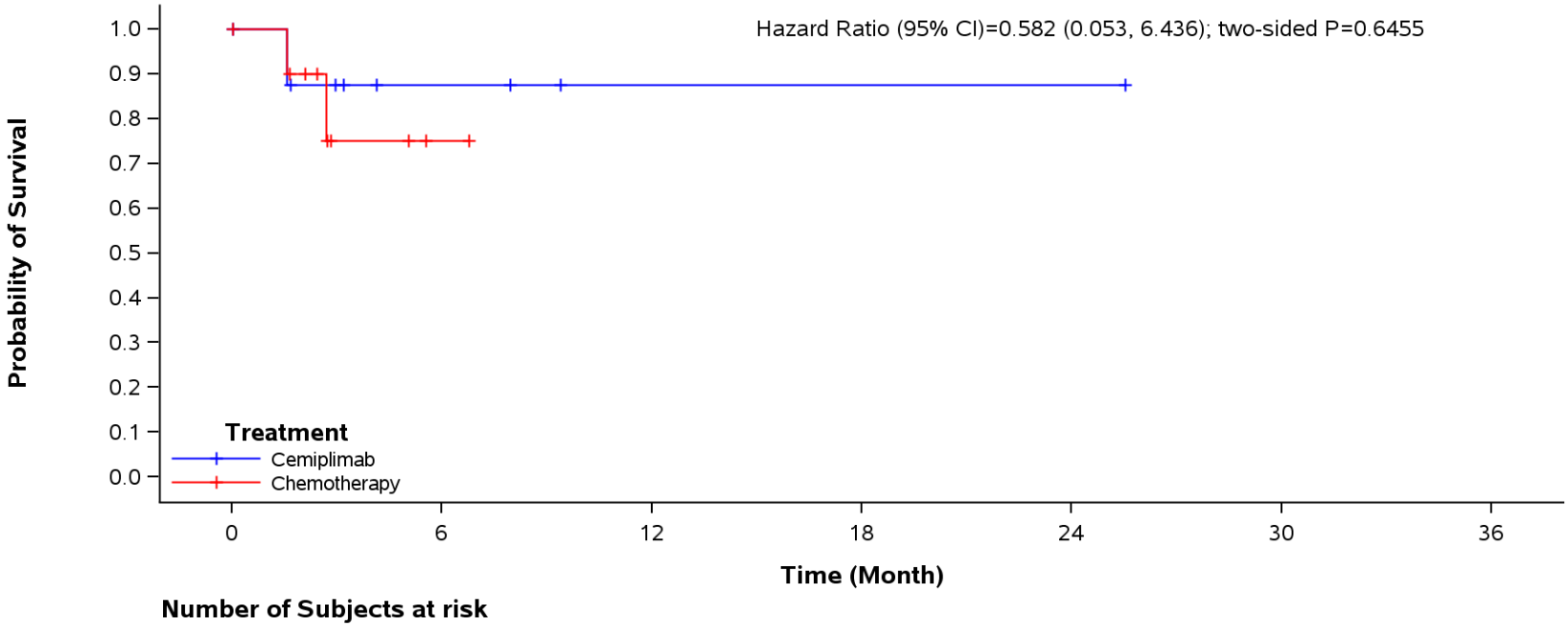

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts sensitivity sustained improvement



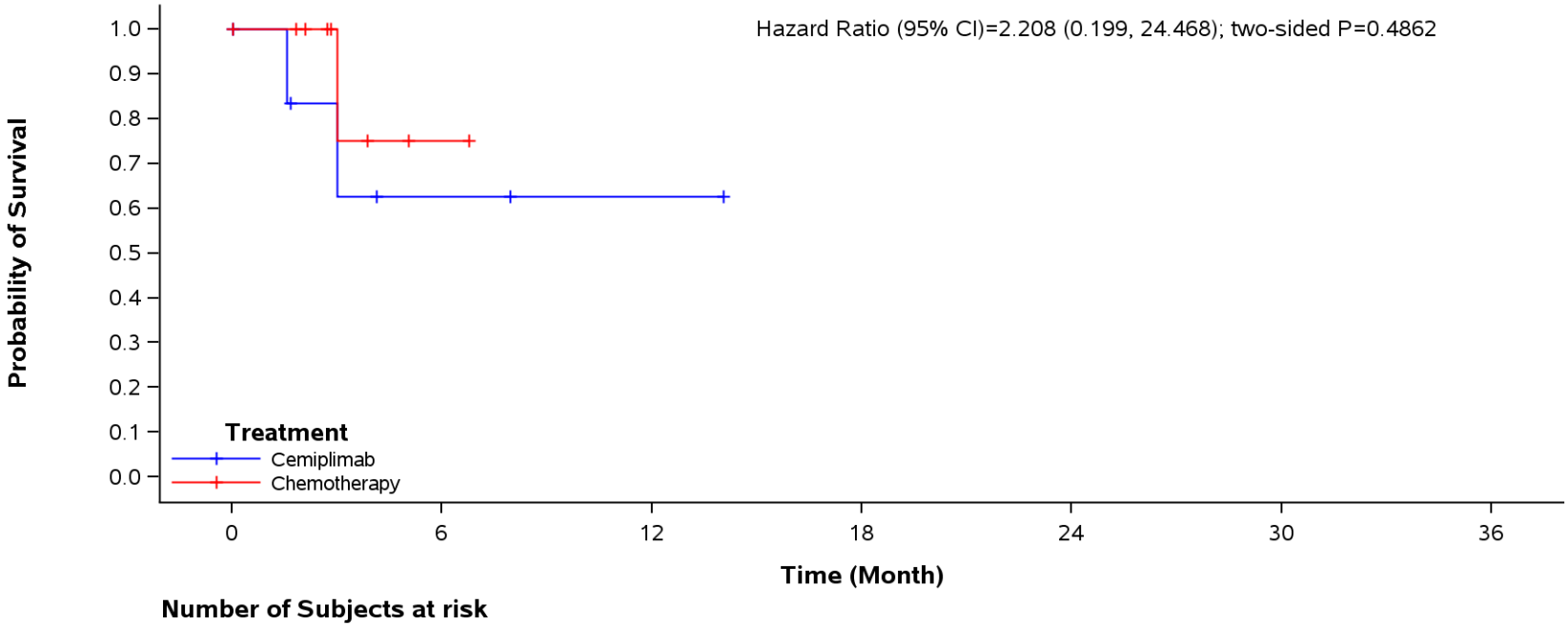

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 25 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts sensitivity sustained improvement



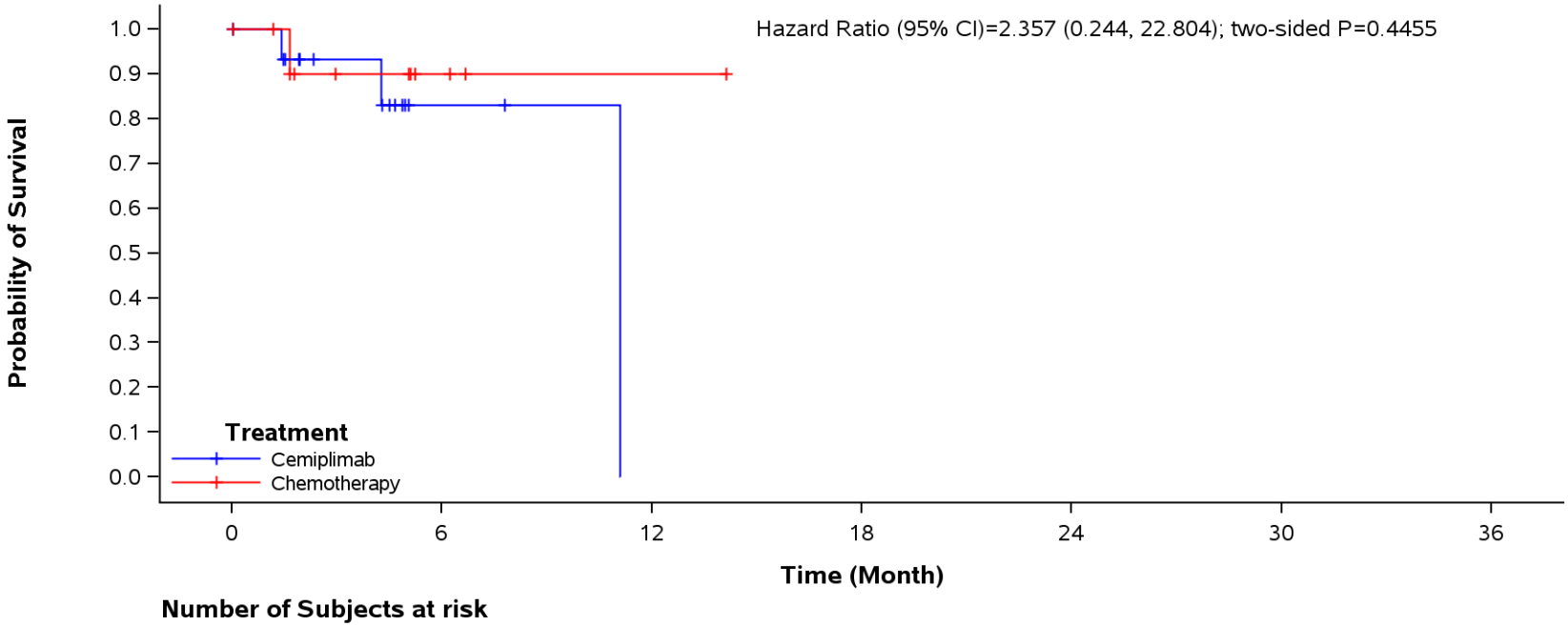

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 25 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts sensitivity sustained improvement



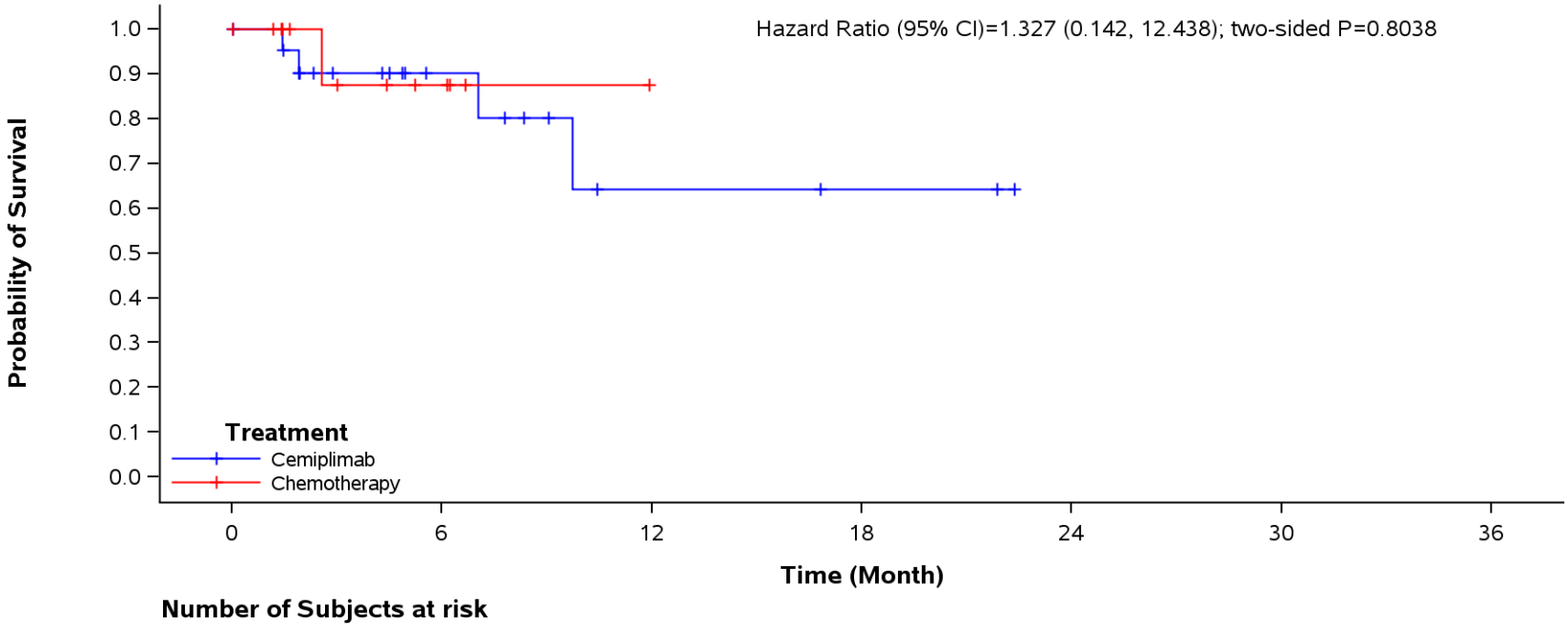

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts sensitivity sustained improvement



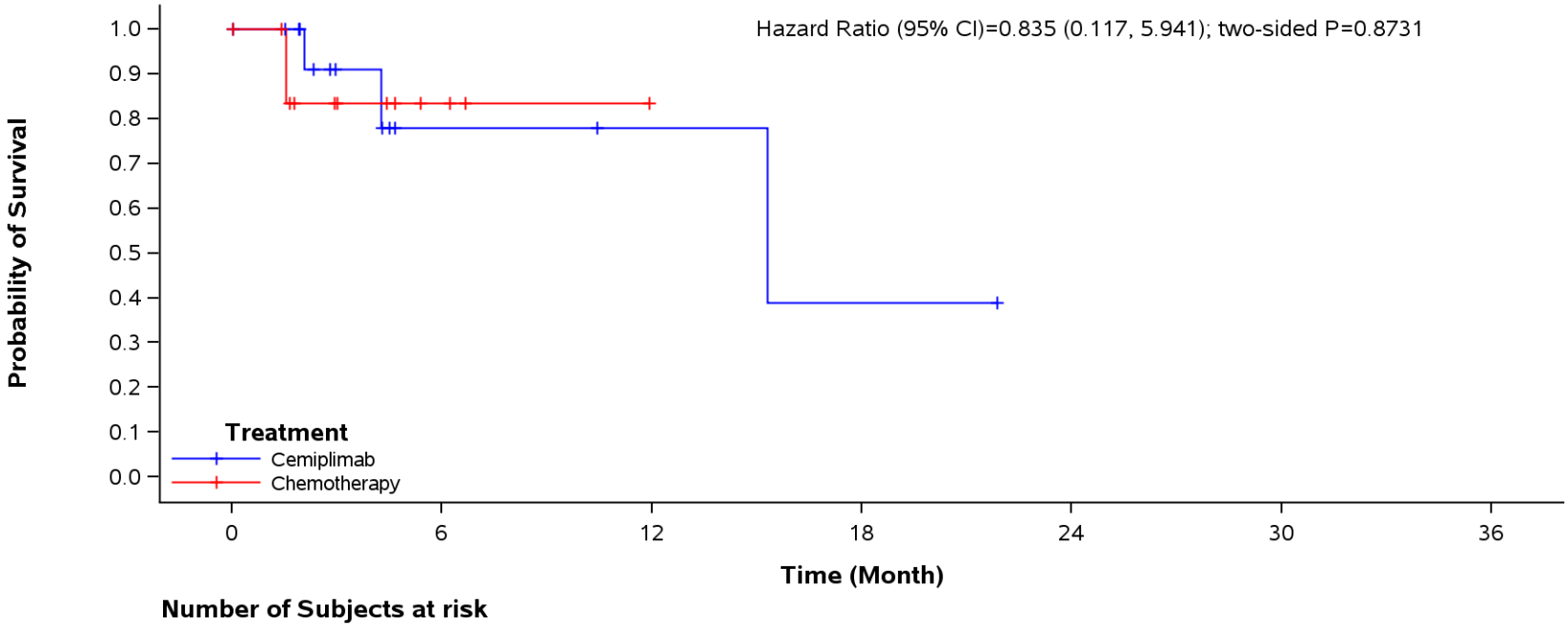

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts sensitivity sustained improvement



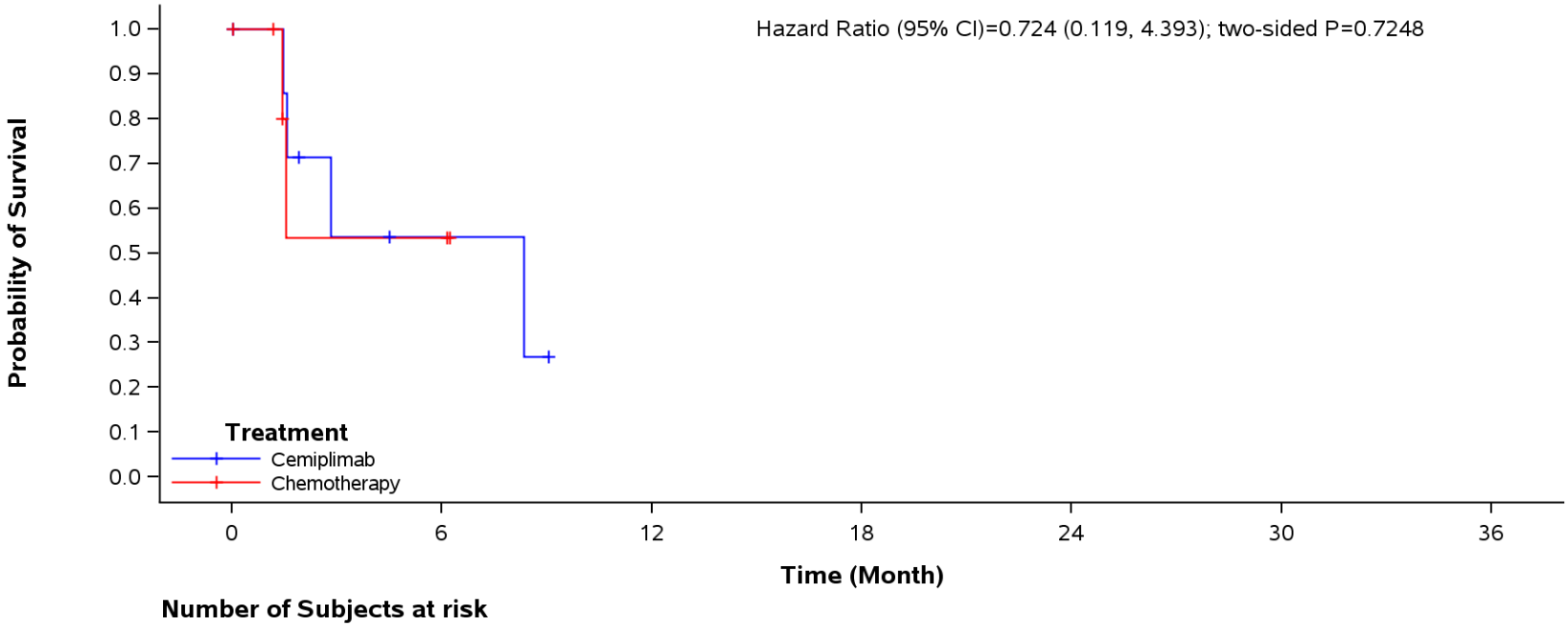

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts sensitivity sustained improvement



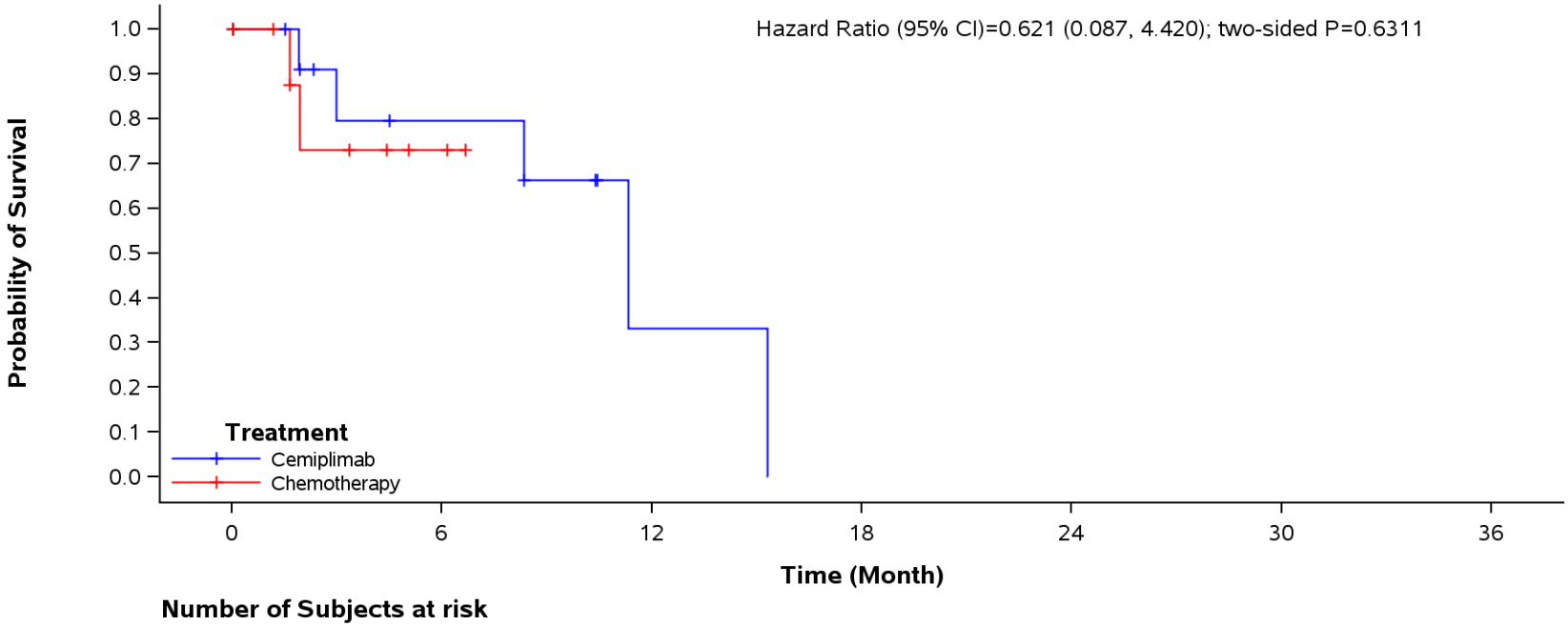

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts sensitivity sustained improvement



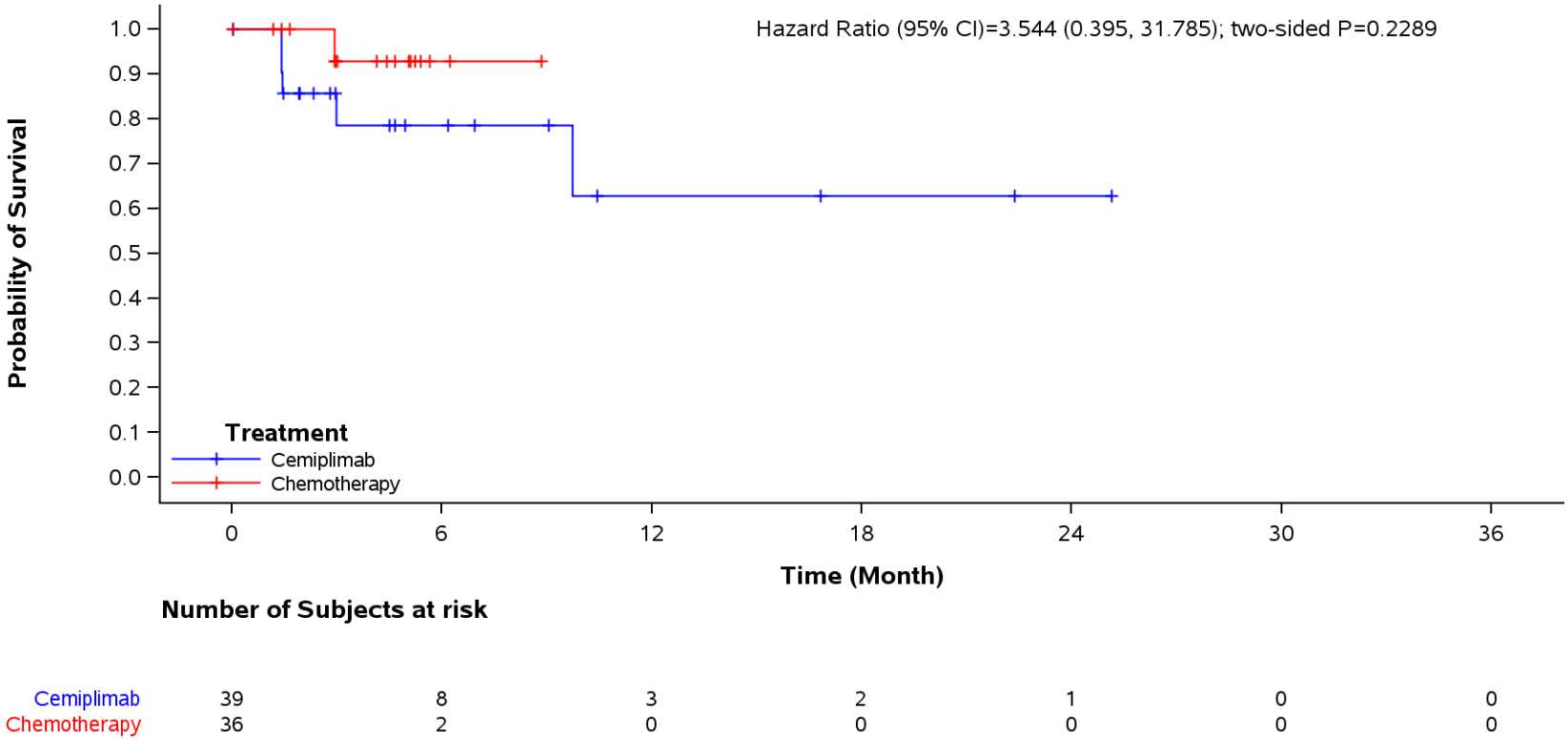

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts sensitivity sustained improvement



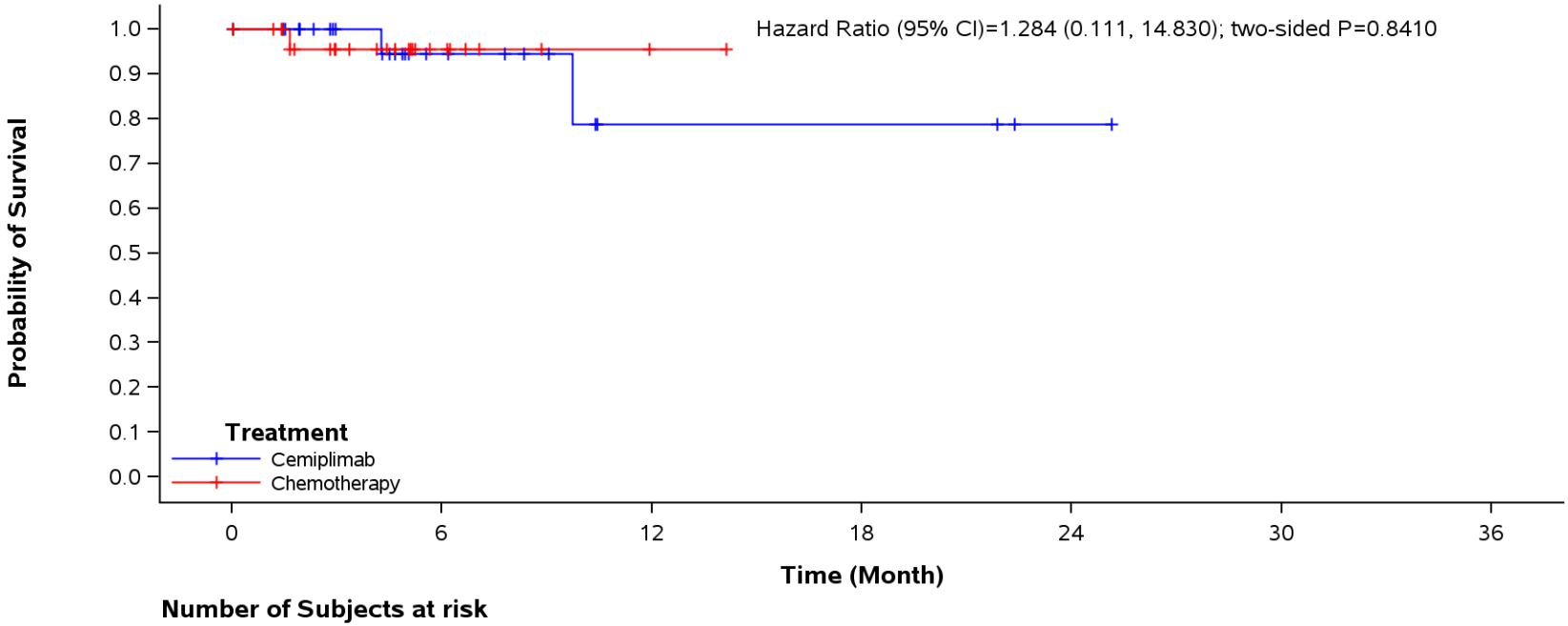

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 8 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 36 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts sensitivity sustained improvement



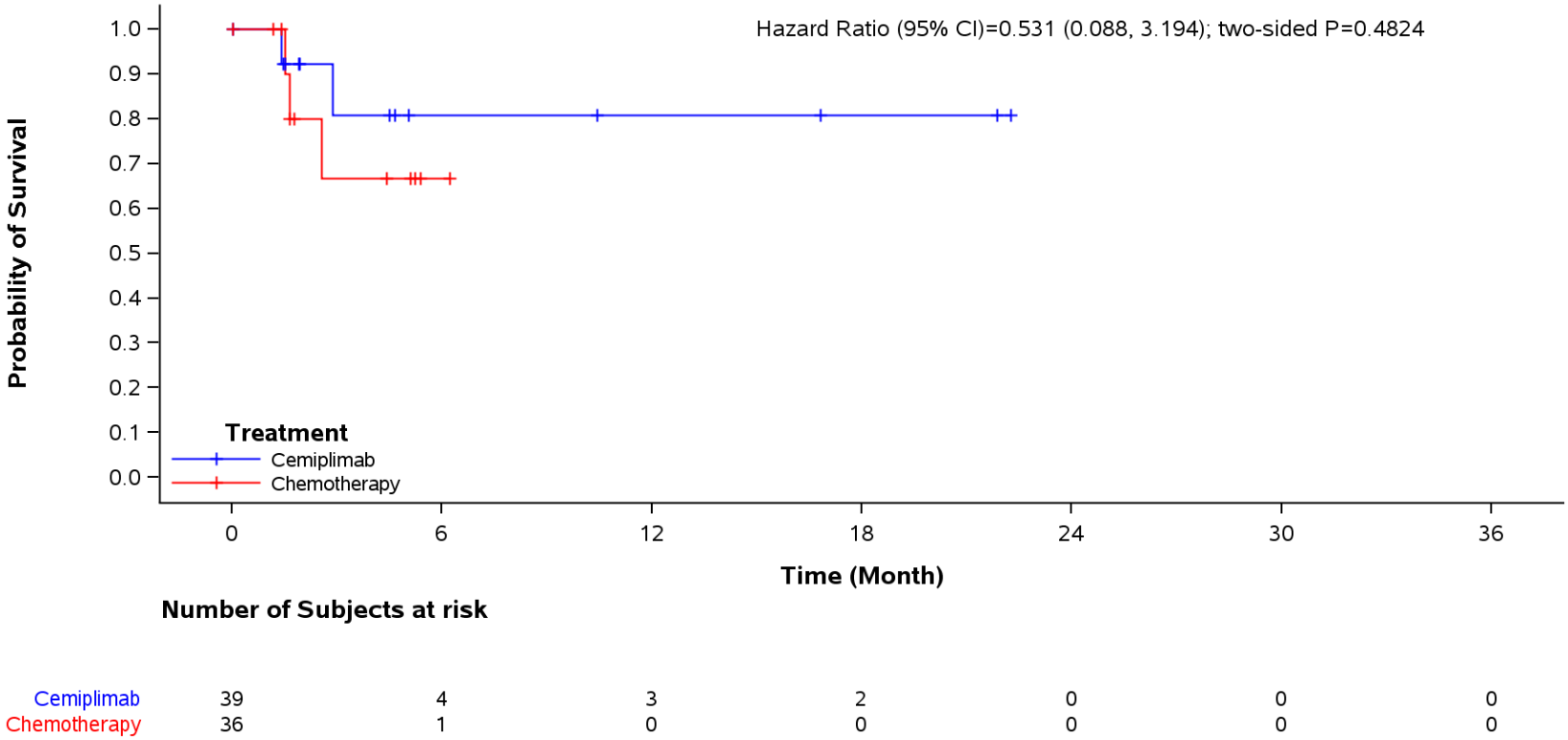

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 3 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

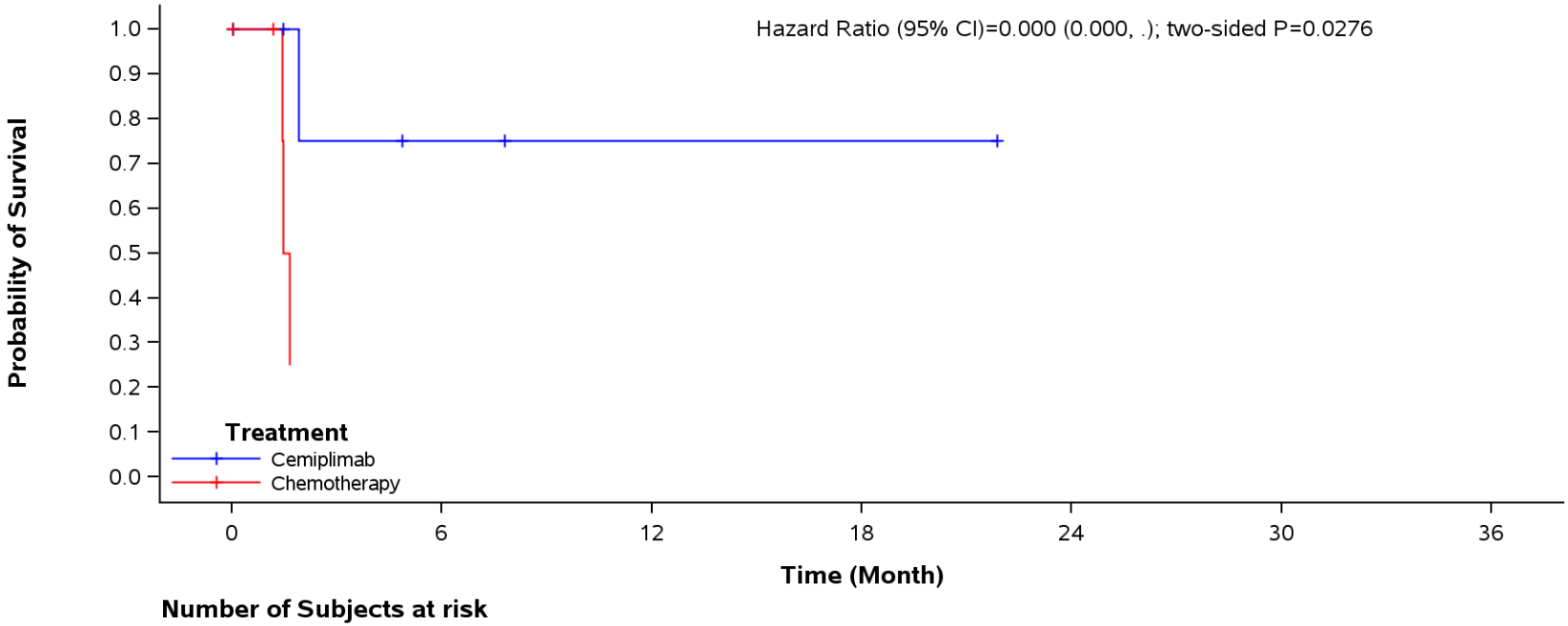
Geographic region: Asia
Financial Problems - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts sensitivity sustained improvement



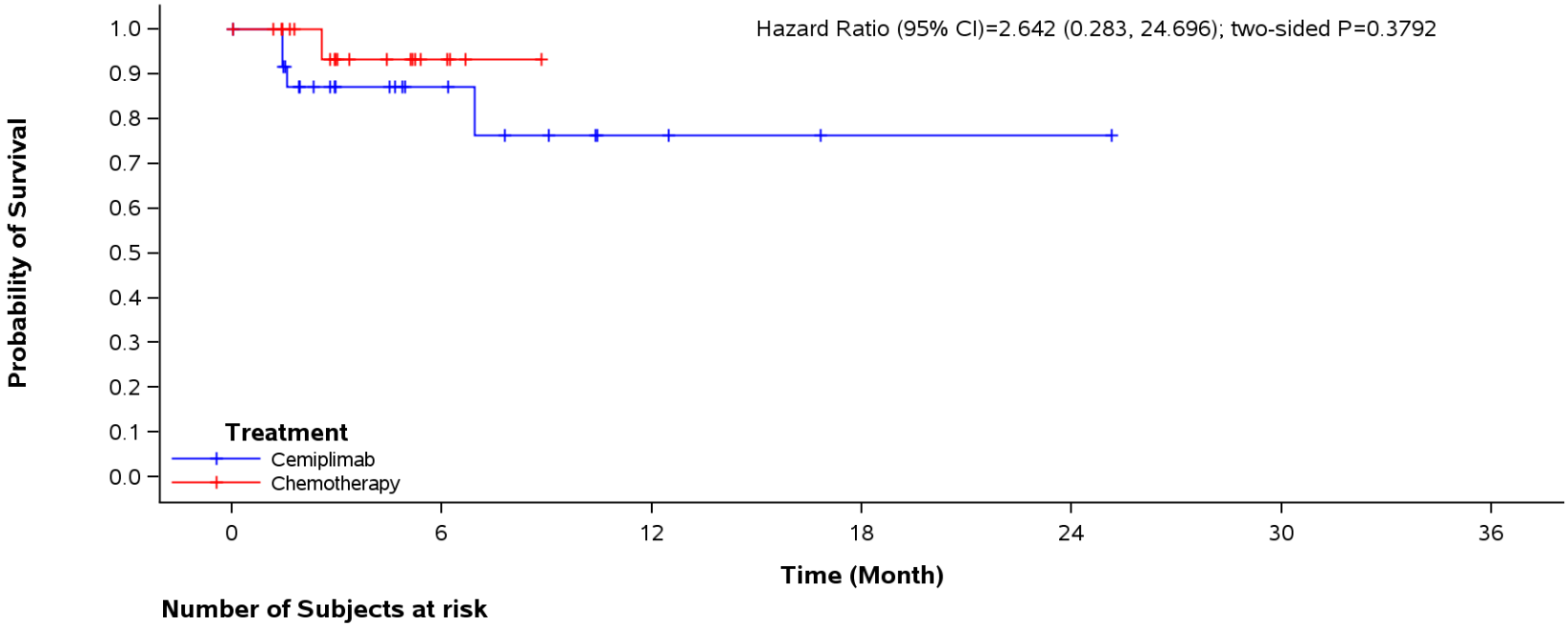

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 2 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts sensitivity sustained improvement



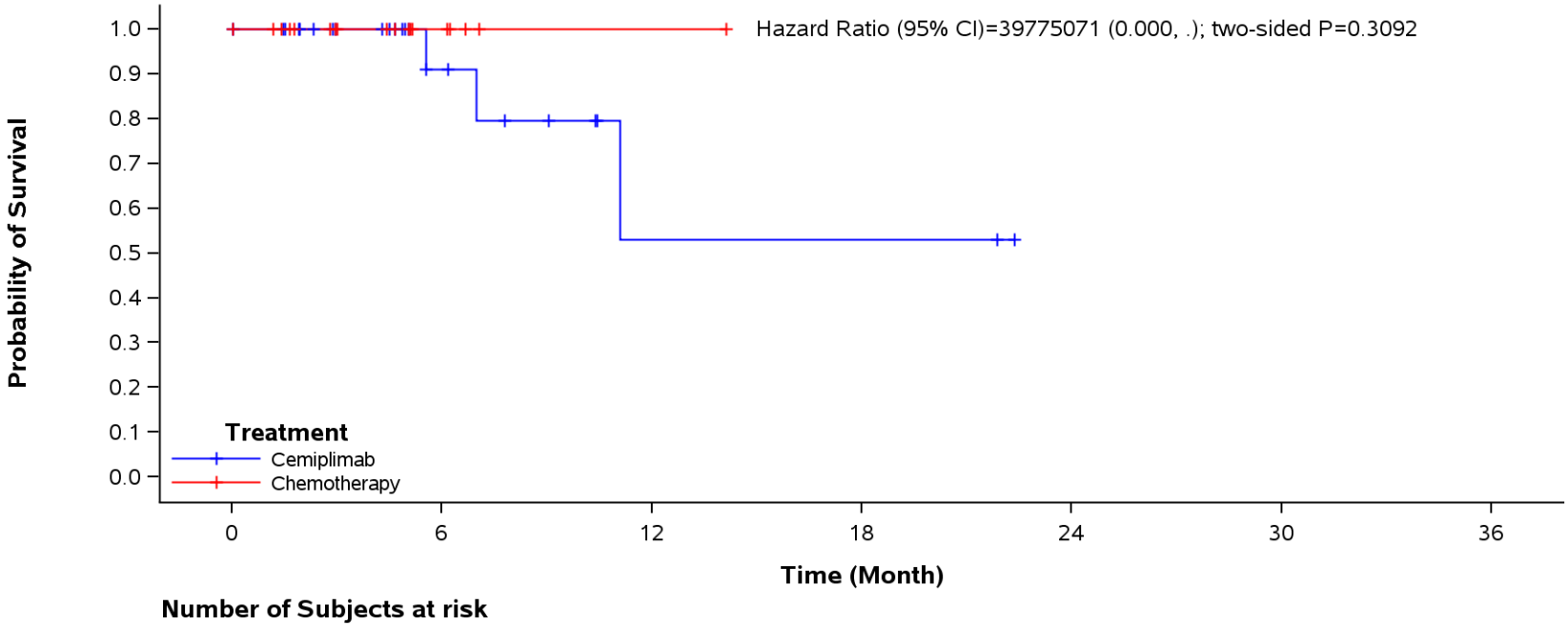

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 36 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts sensitivity sustained improvement



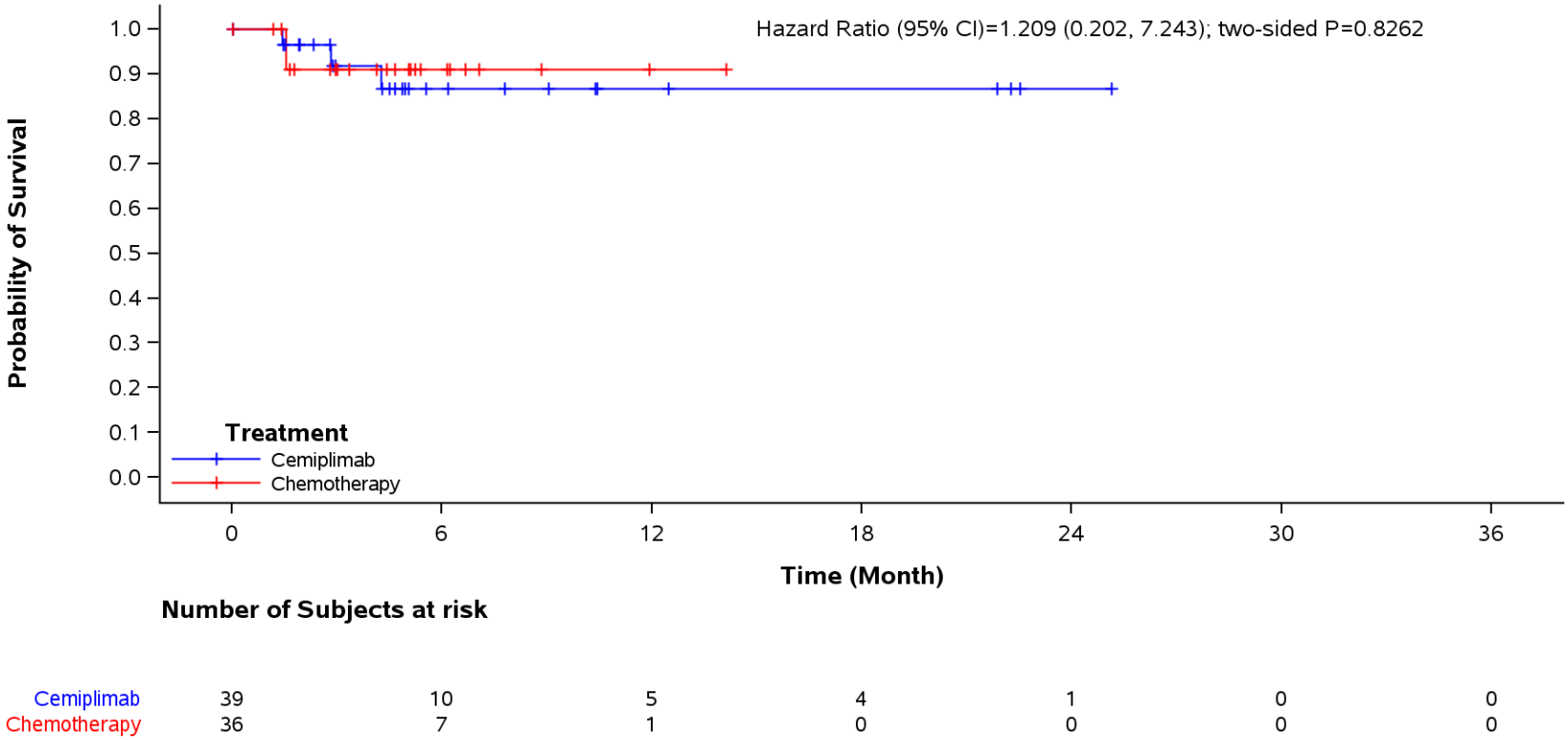

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

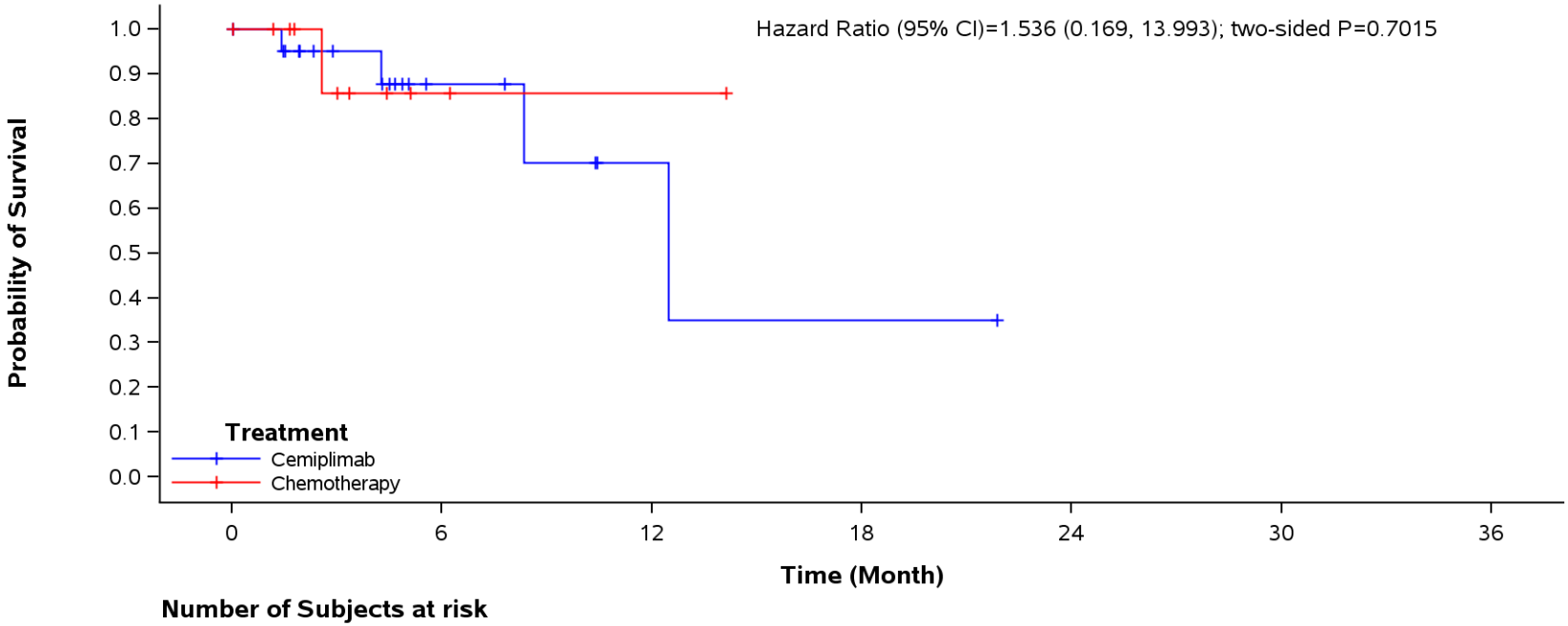
Geographic region: Asia
Global health status / QoL - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts sensitivity sustained improvement



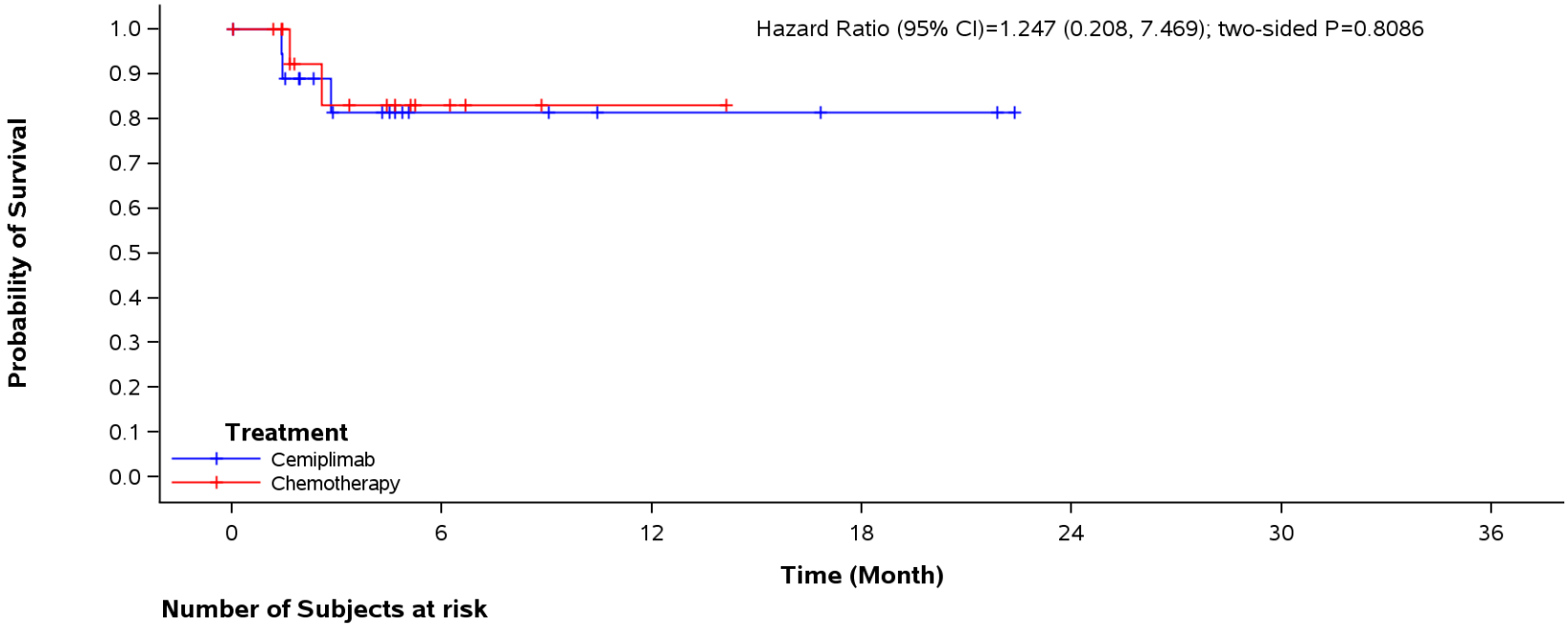

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 36 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts sensitivity sustained improvement



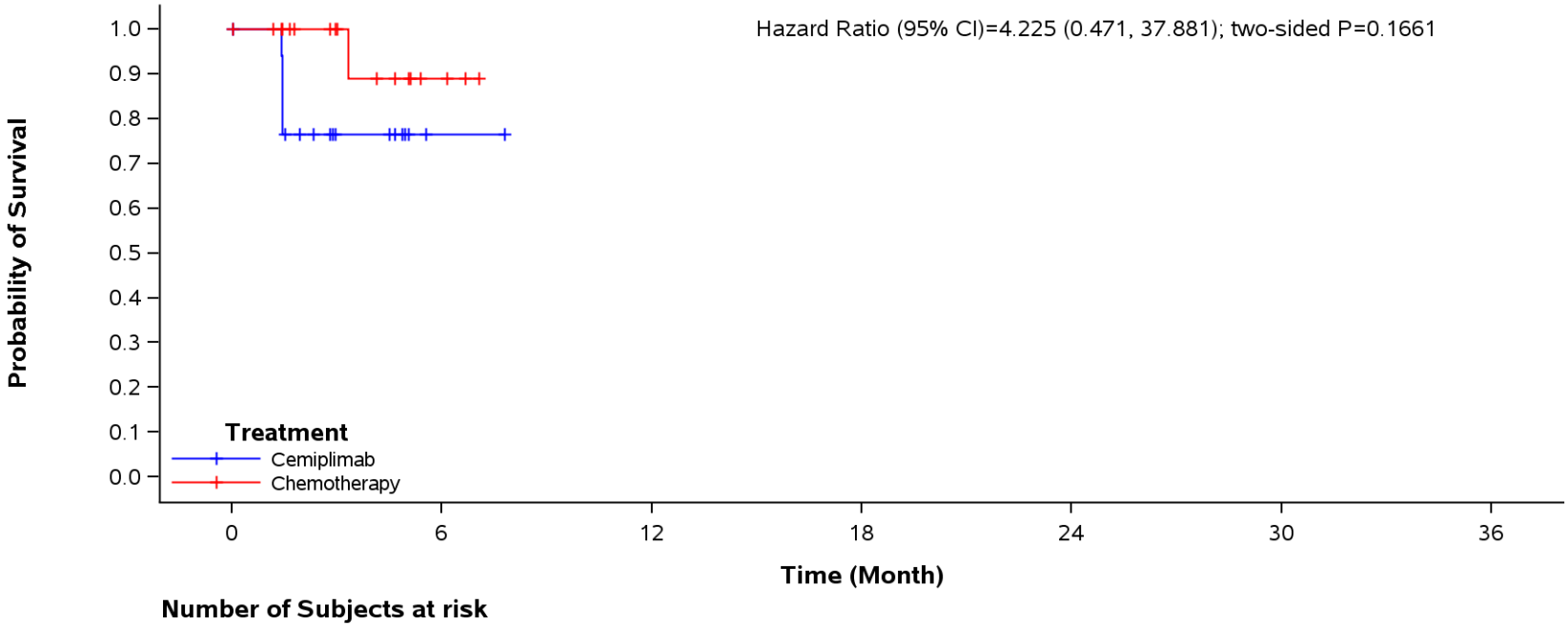

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 5 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts sensitivity sustained improvement



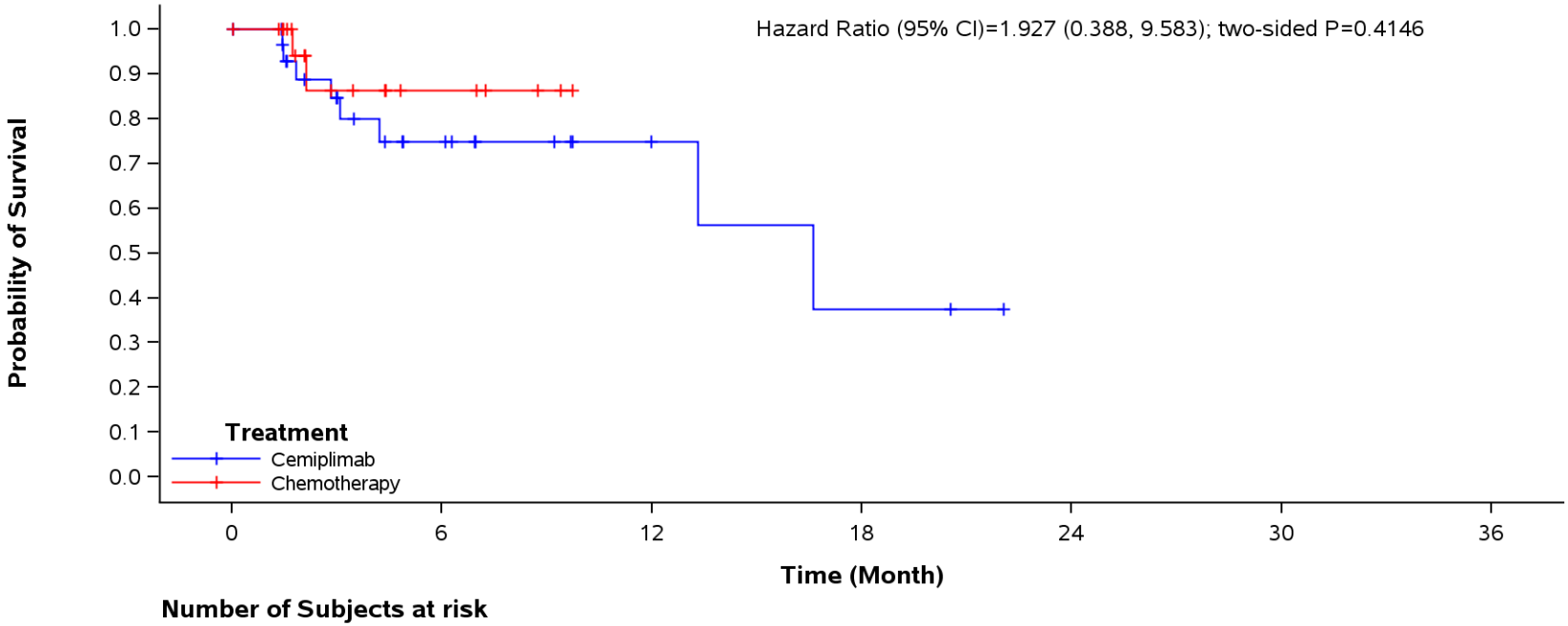

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts sensitivity sustained improvement



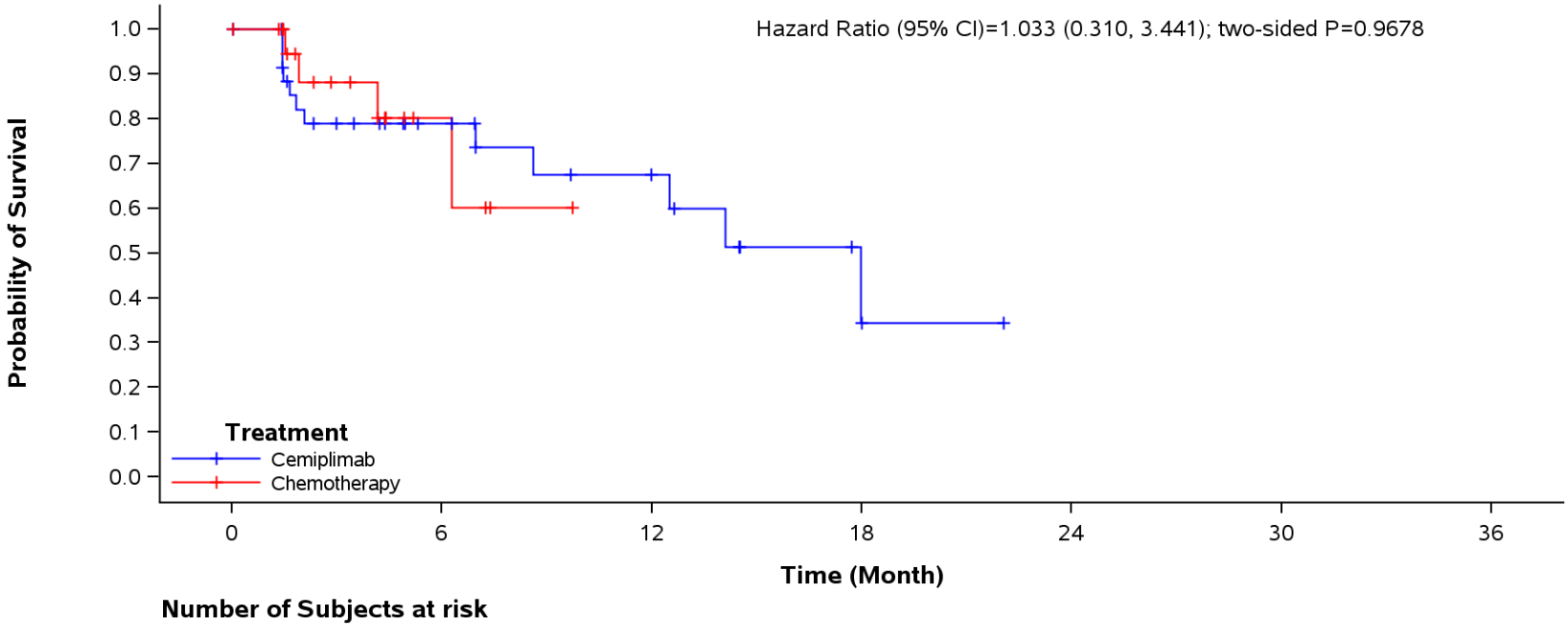

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 12 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts sensitivity sustained improvement



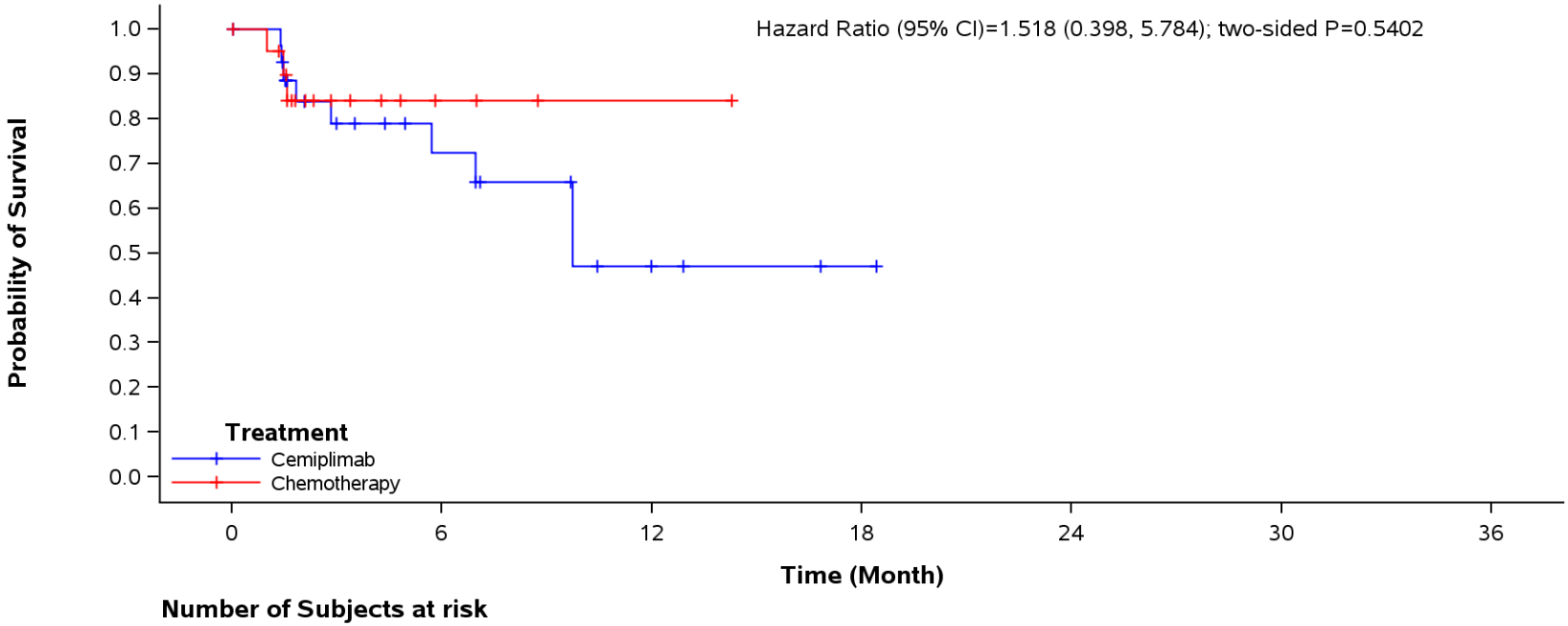

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 17 | 9 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts sensitivity sustained improvement



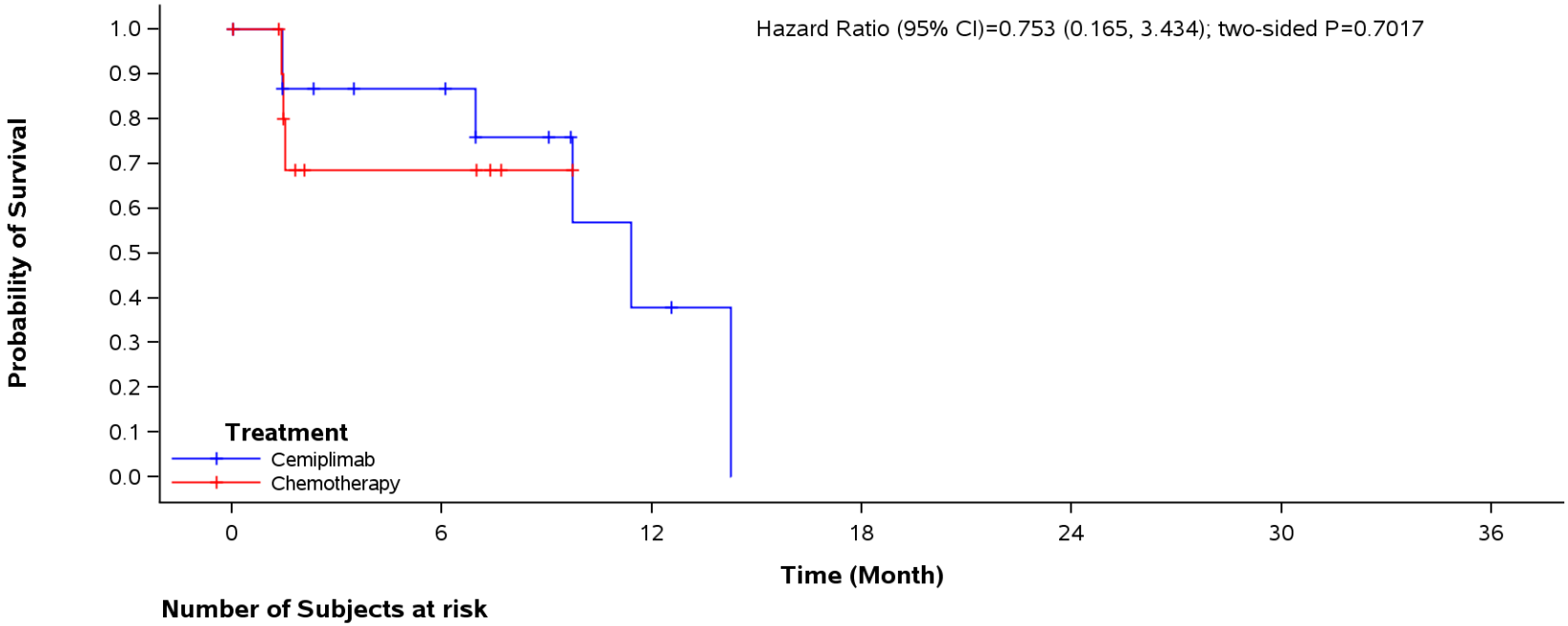

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 11 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts sensitivity sustained improvement



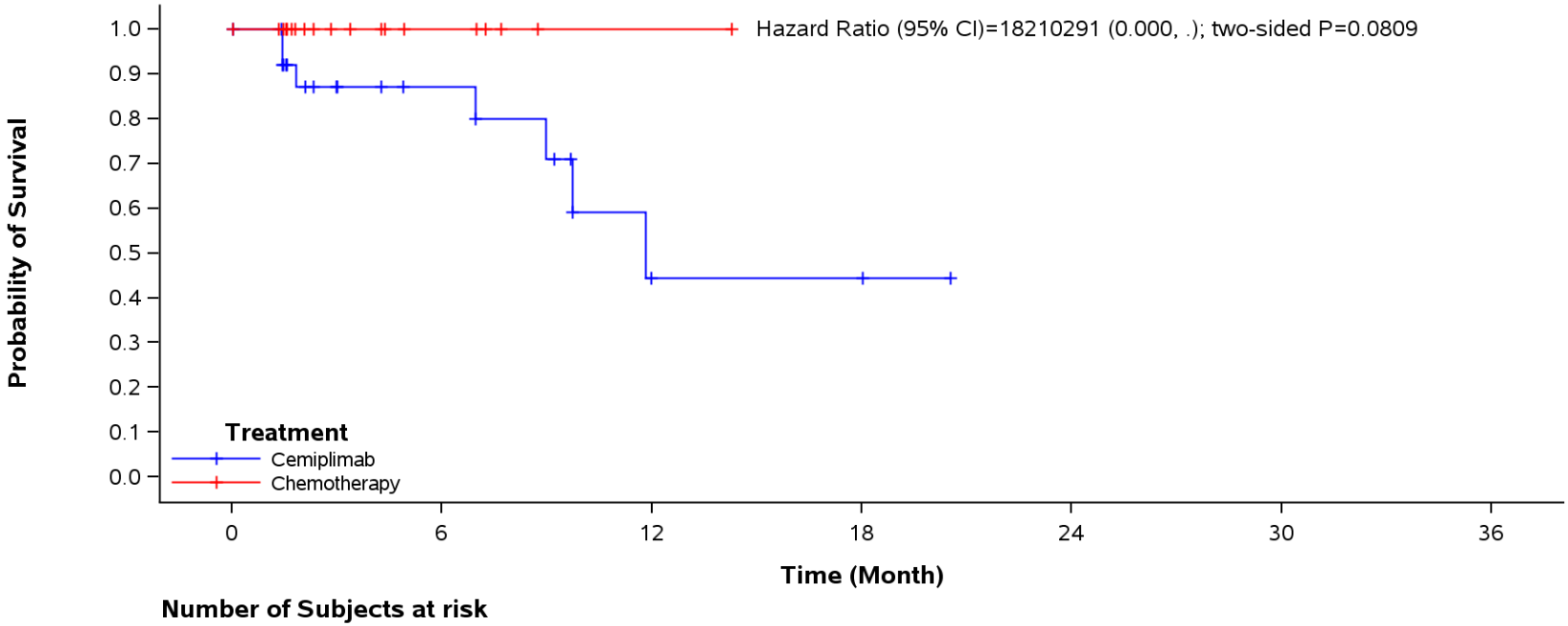

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 9 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts sensitivity sustained improvement



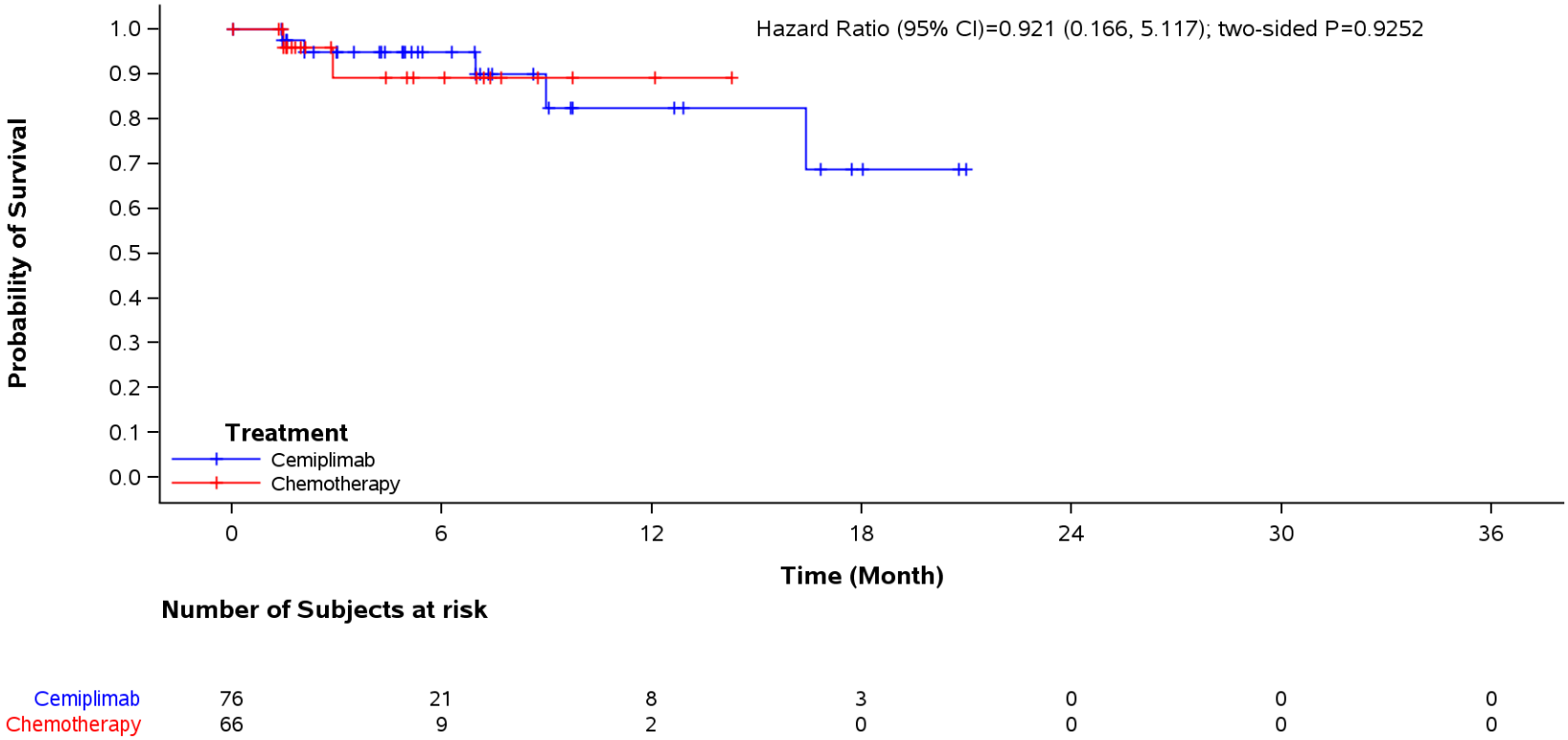

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 12 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts sensitivity sustained improvement



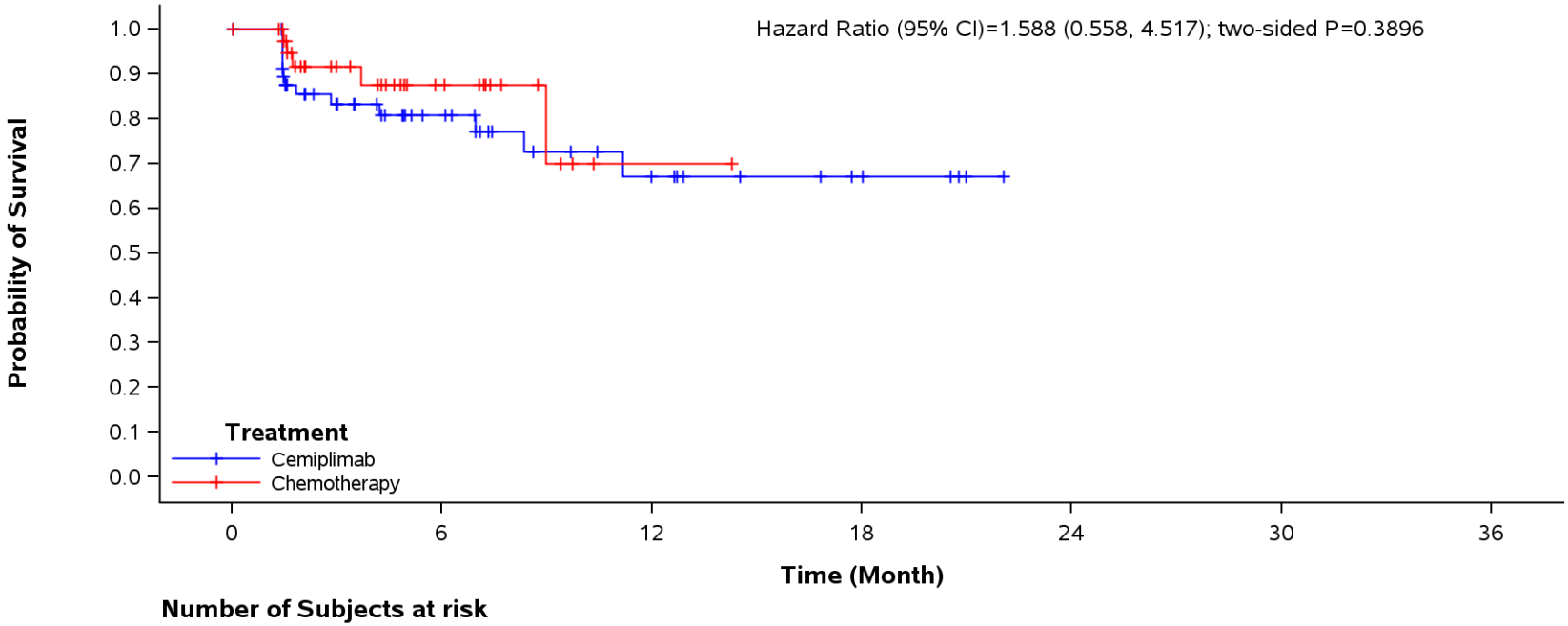

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 21 | 8 | 3 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts sensitivity sustained improvement



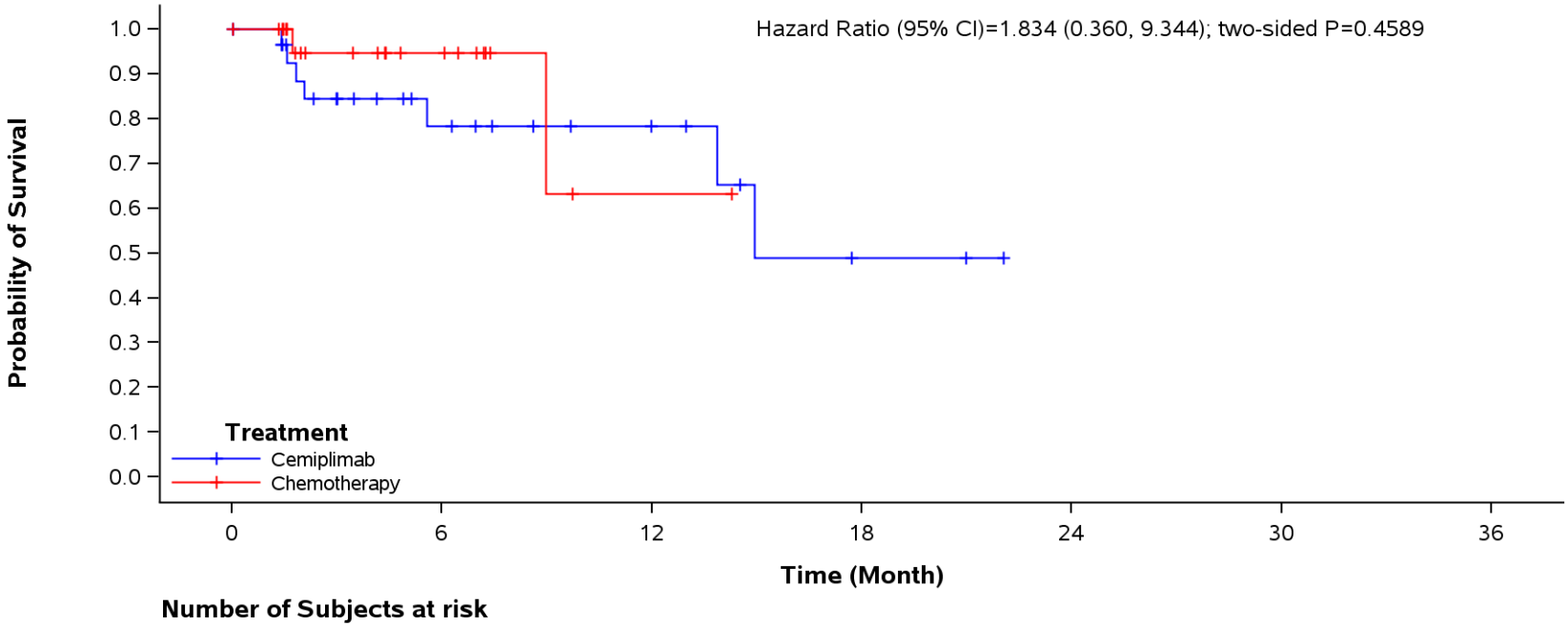

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 25 | 11 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts sensitivity sustained improvement



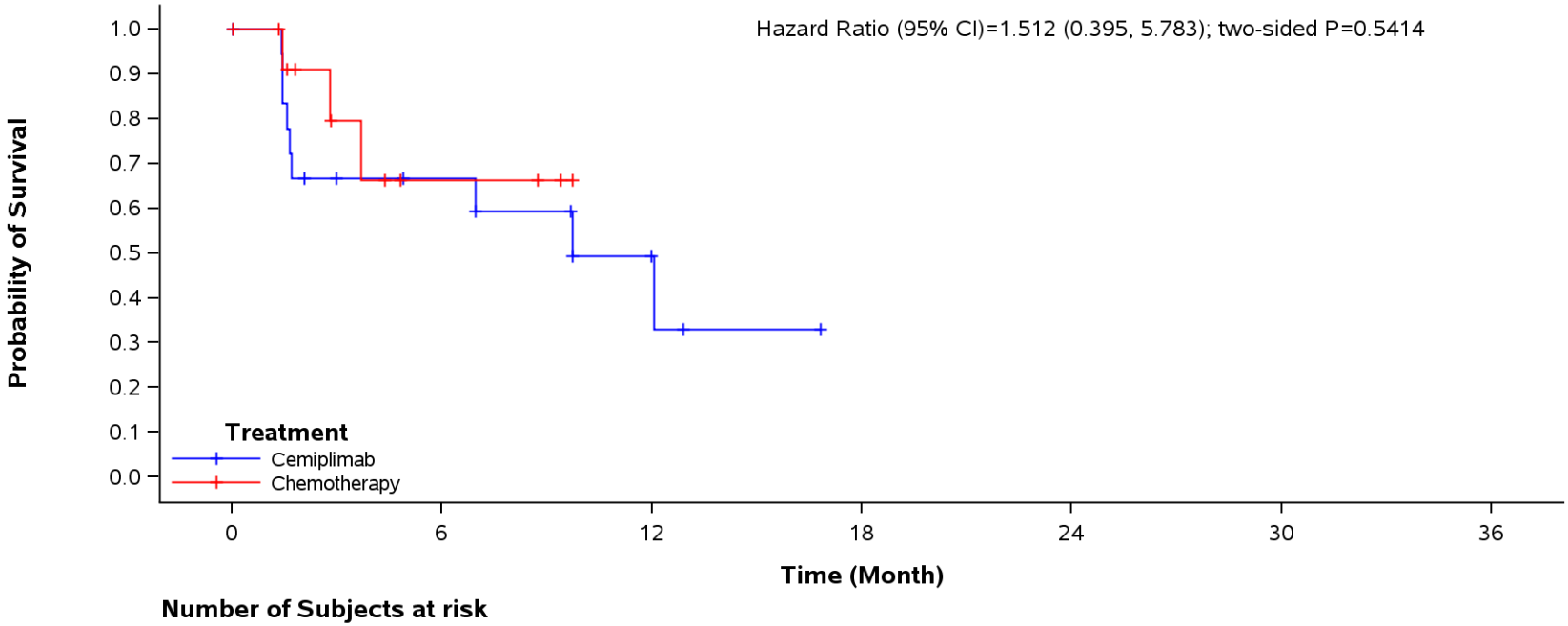

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 13 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts sensitivity sustained improvement



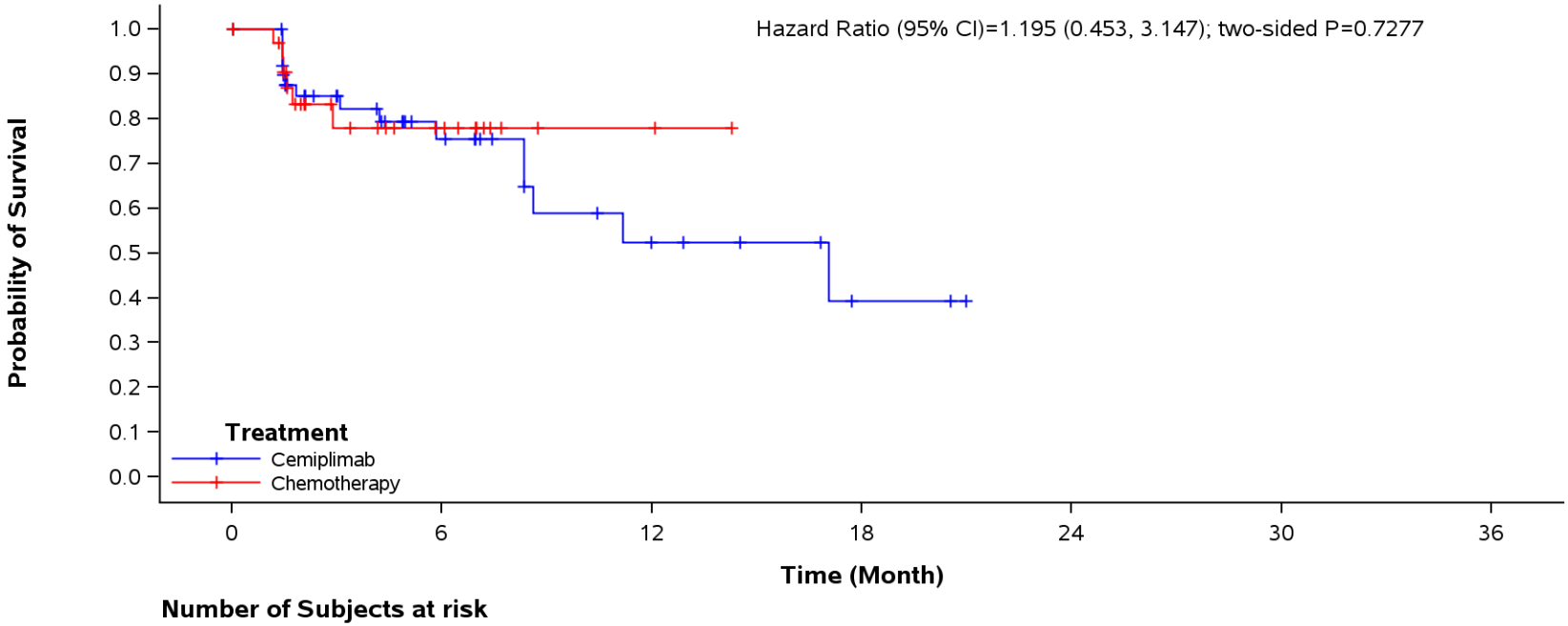

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 9 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 66 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts sensitivity sustained improvement



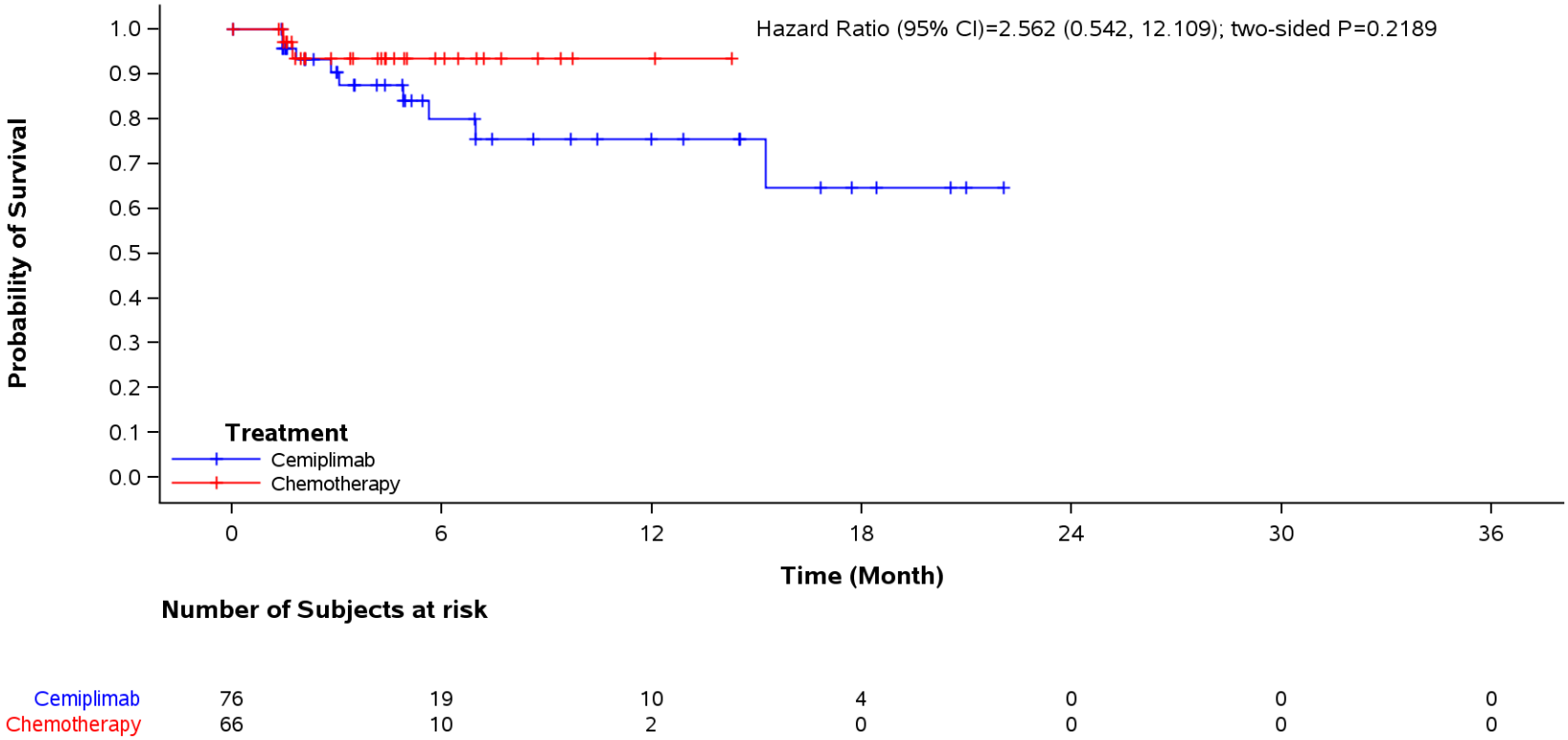

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 20 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts sensitivity sustained improvement



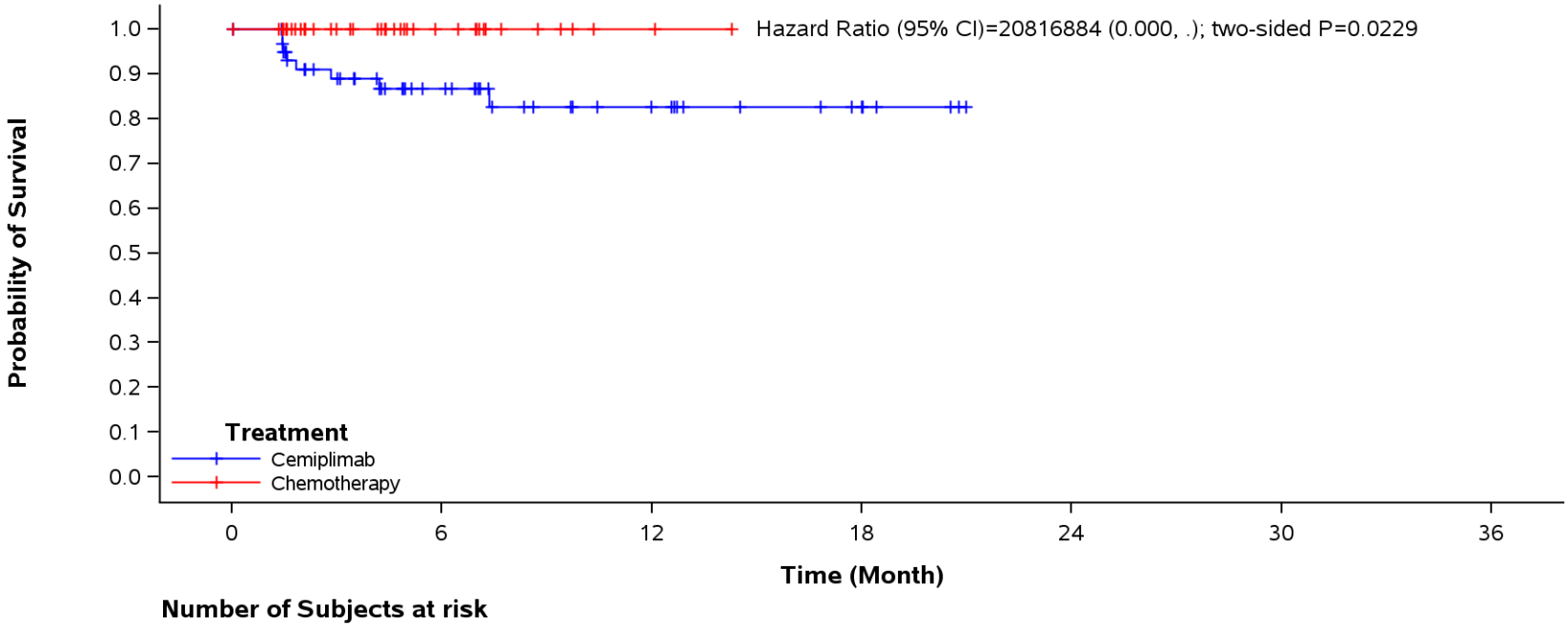

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 19 | 10 | 4 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts sensitivity sustained improvement



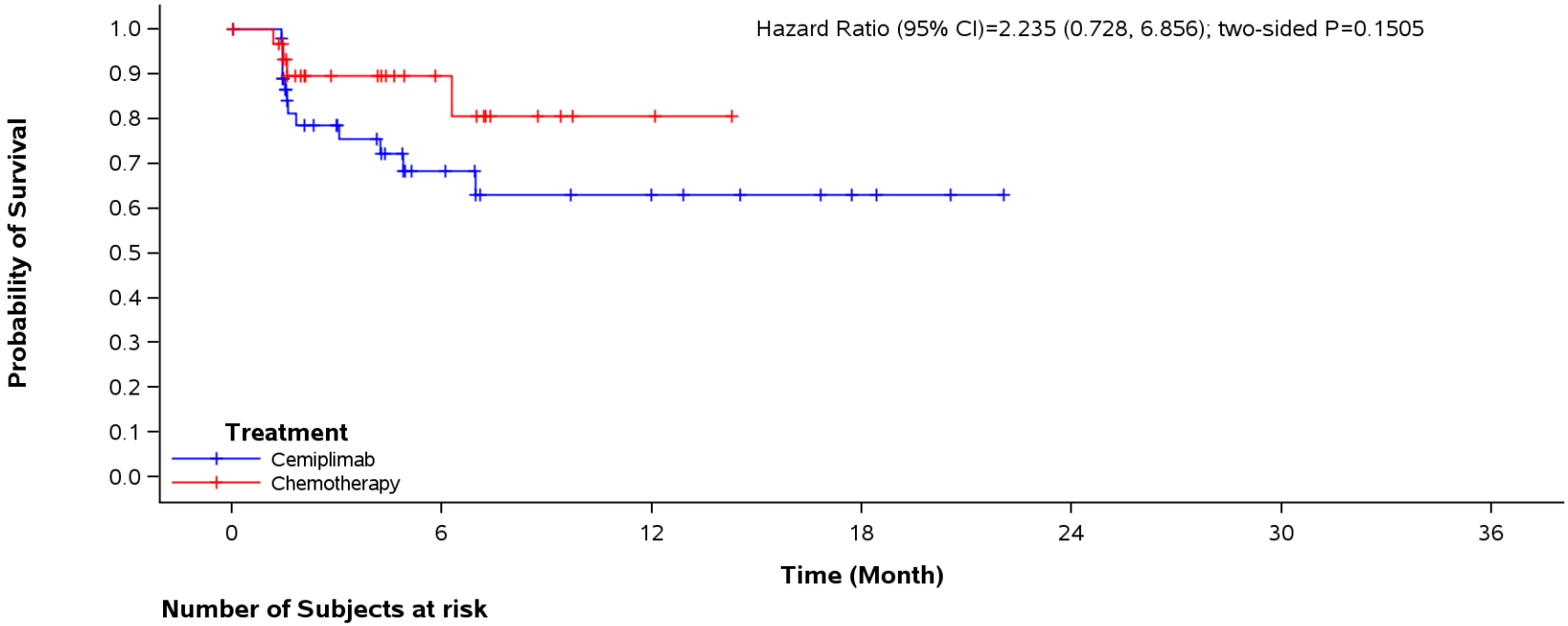

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 29 | 13 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts sensitivity sustained improvement



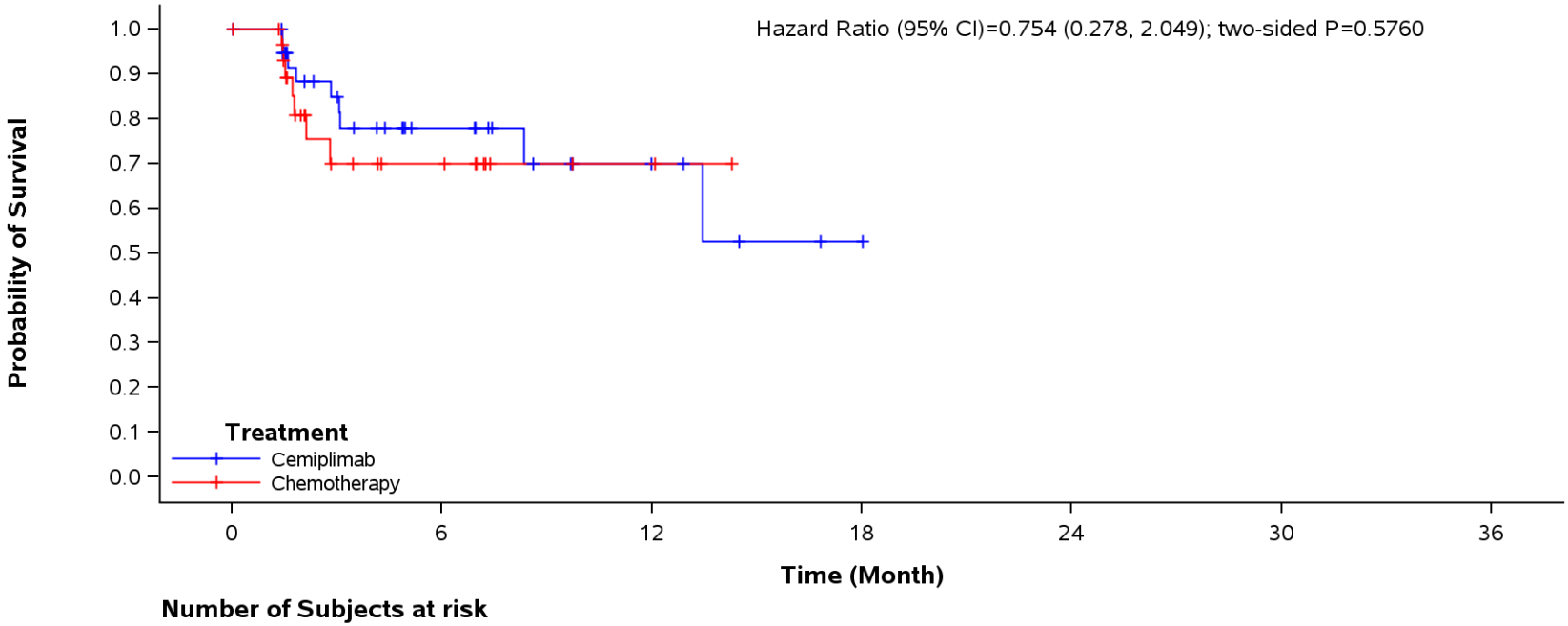

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 15 | 7 | 3 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts sensitivity sustained improvement



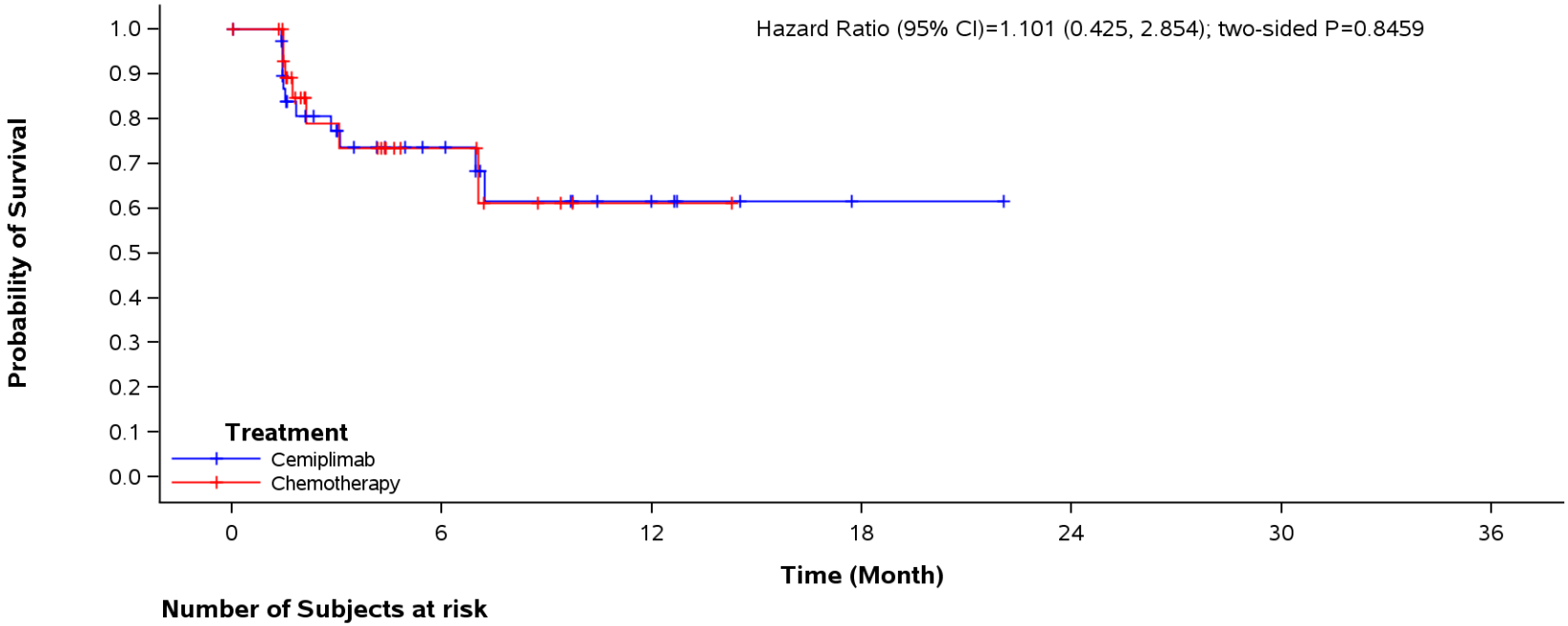

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 15 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts sensitivity sustained improvement



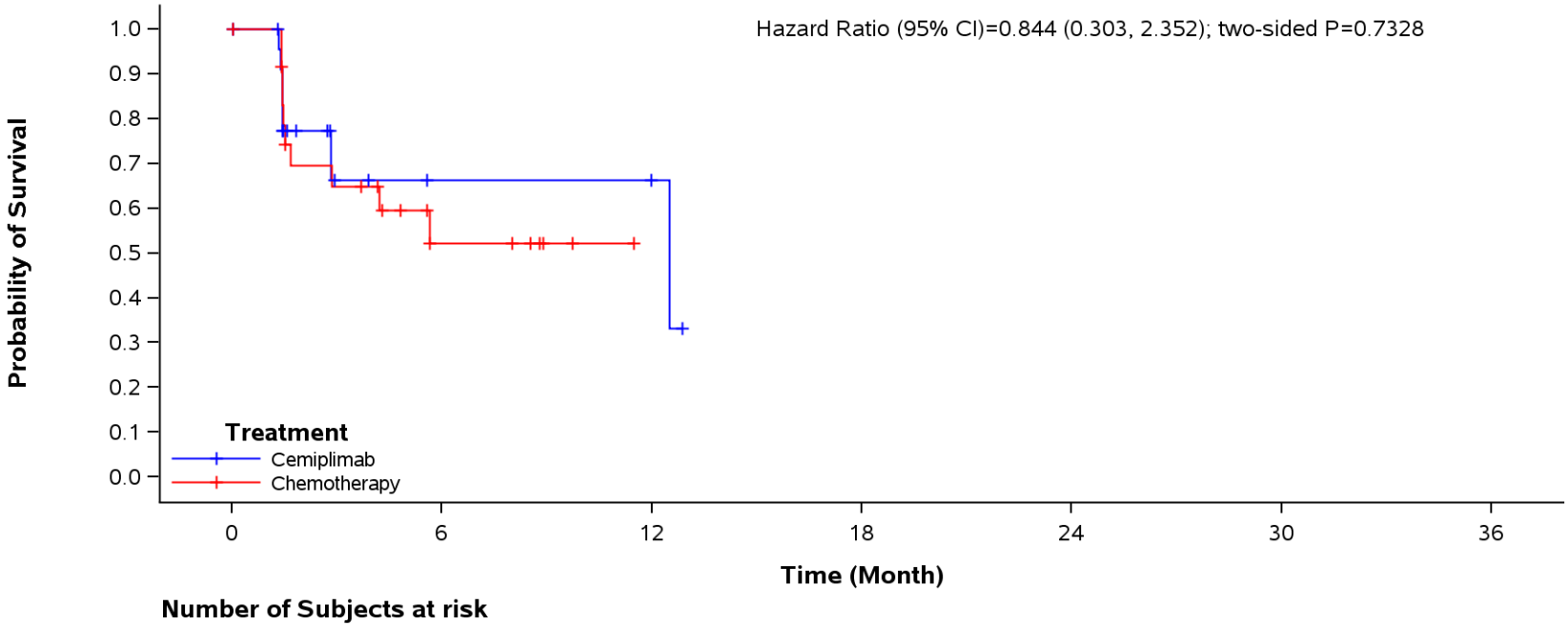

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 15 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 66 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts sensitivity sustained improvement



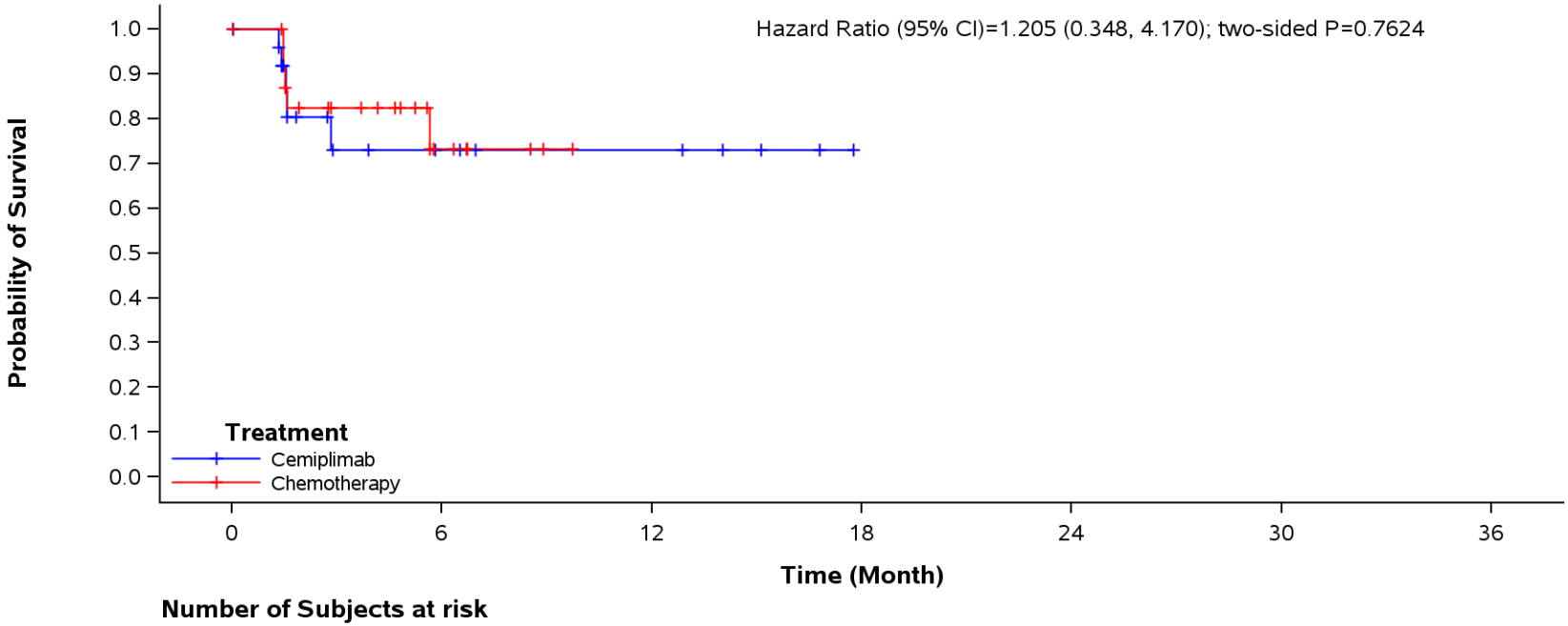

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts sensitivity sustained improvement



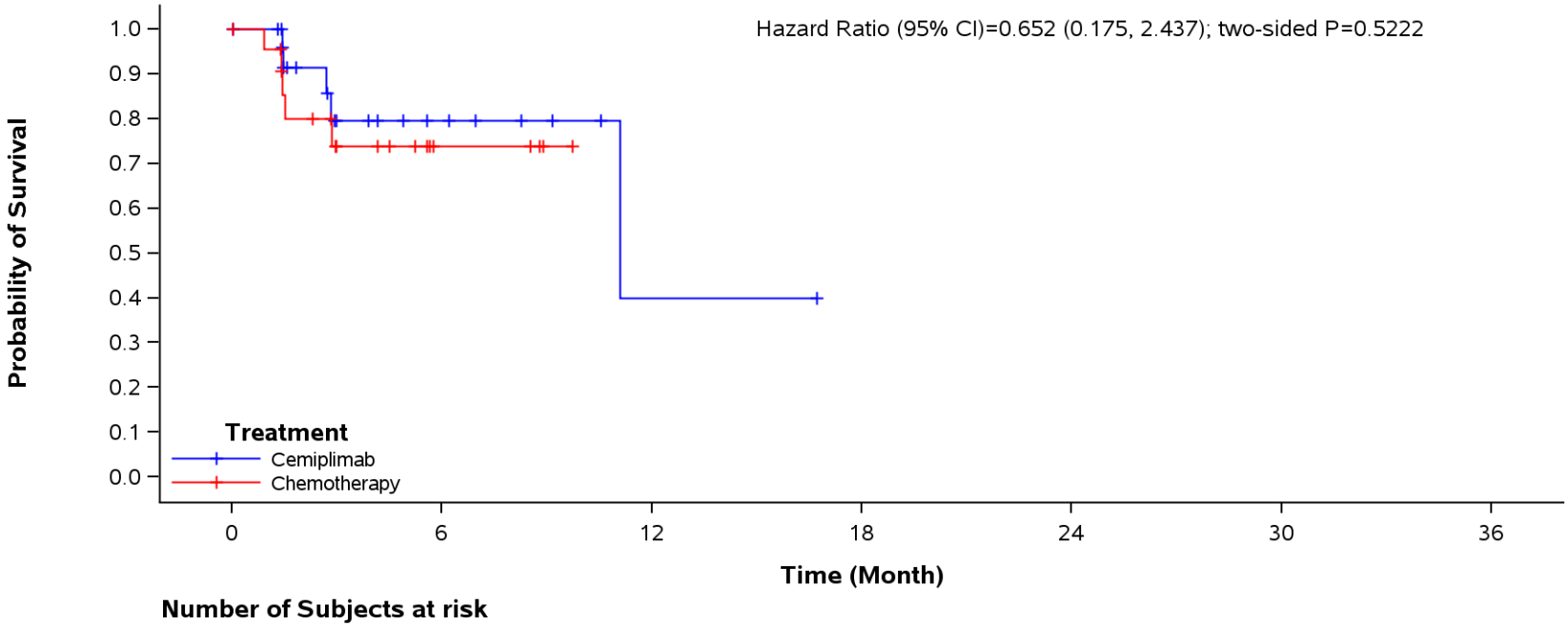

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 7 | 5 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts sensitivity sustained improvement



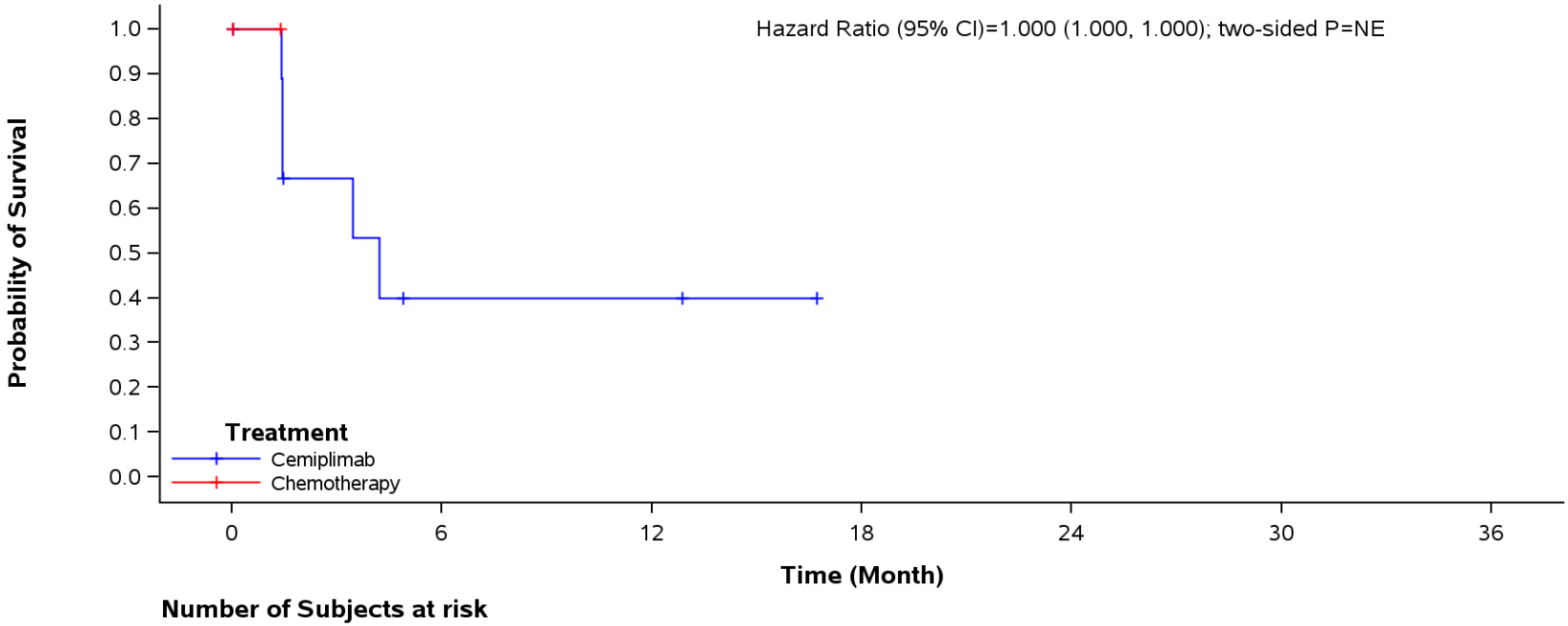

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 7 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts sensitivity sustained improvement



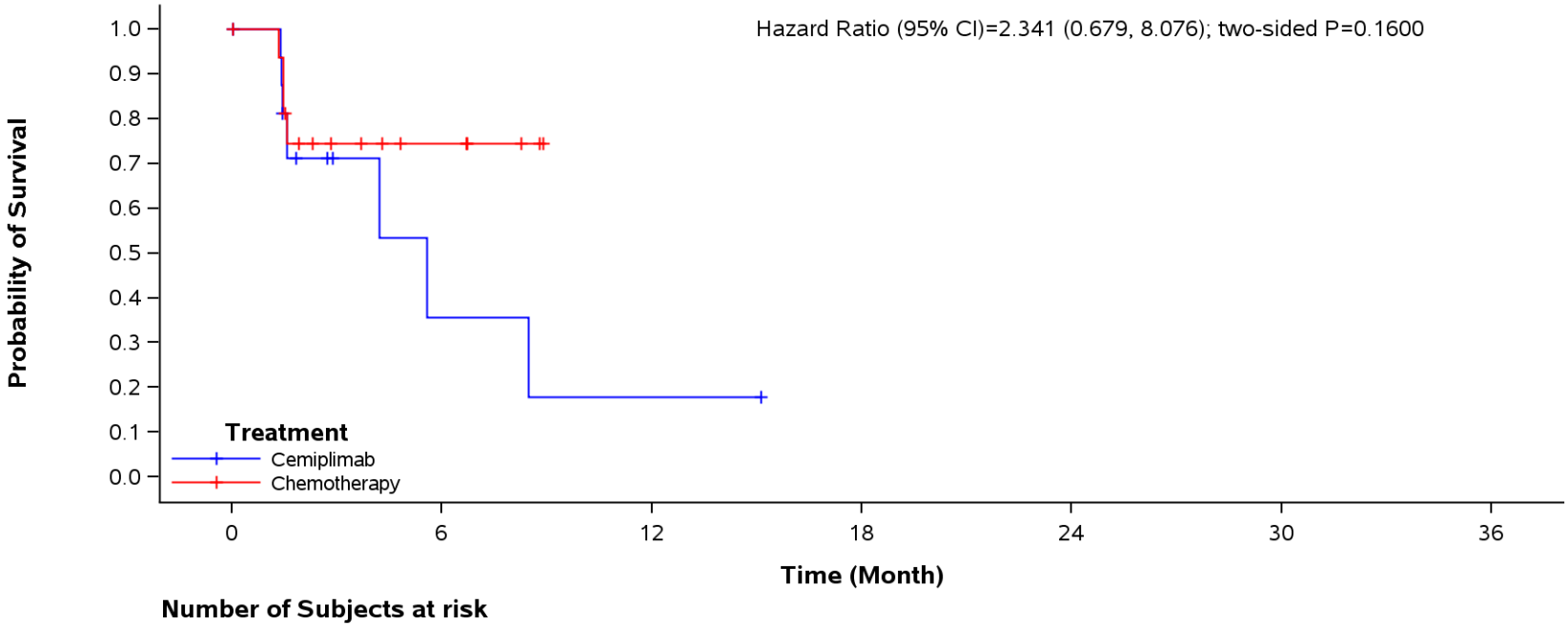

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 2 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts sensitivity sustained improvement



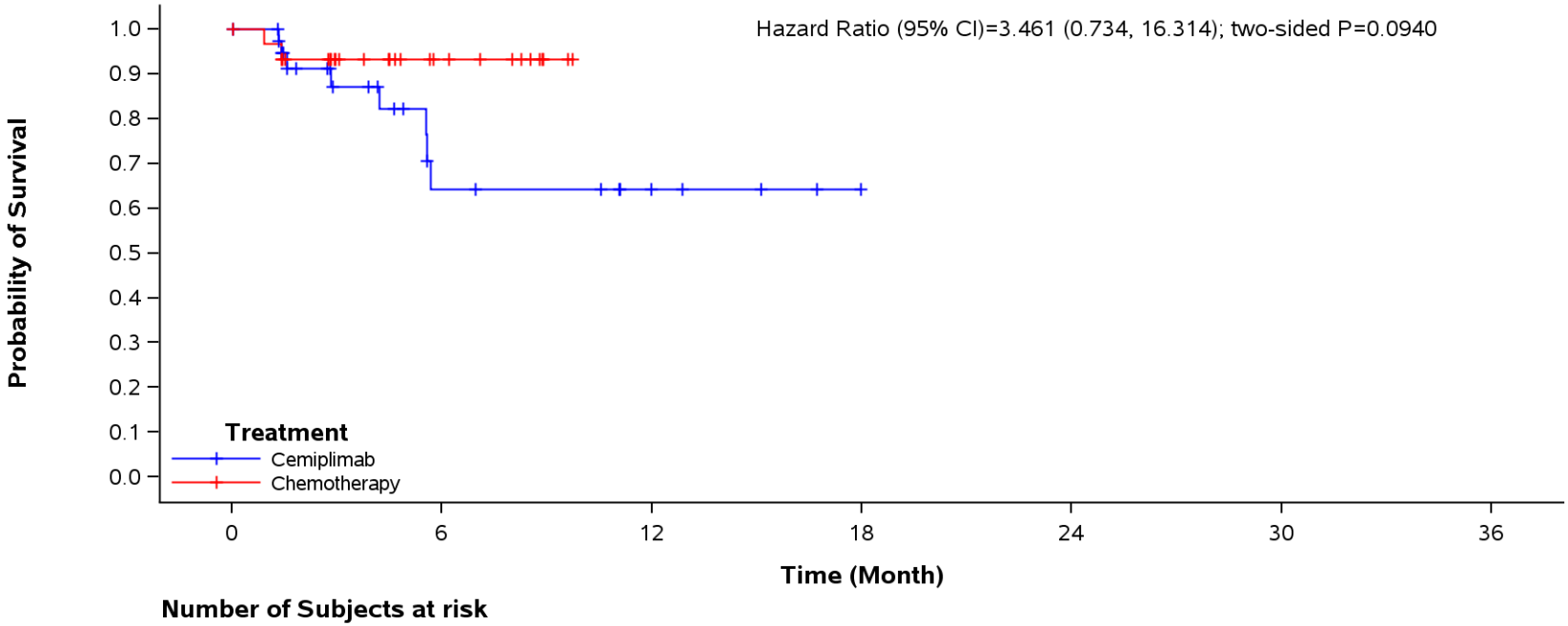

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts sensitivity sustained improvement



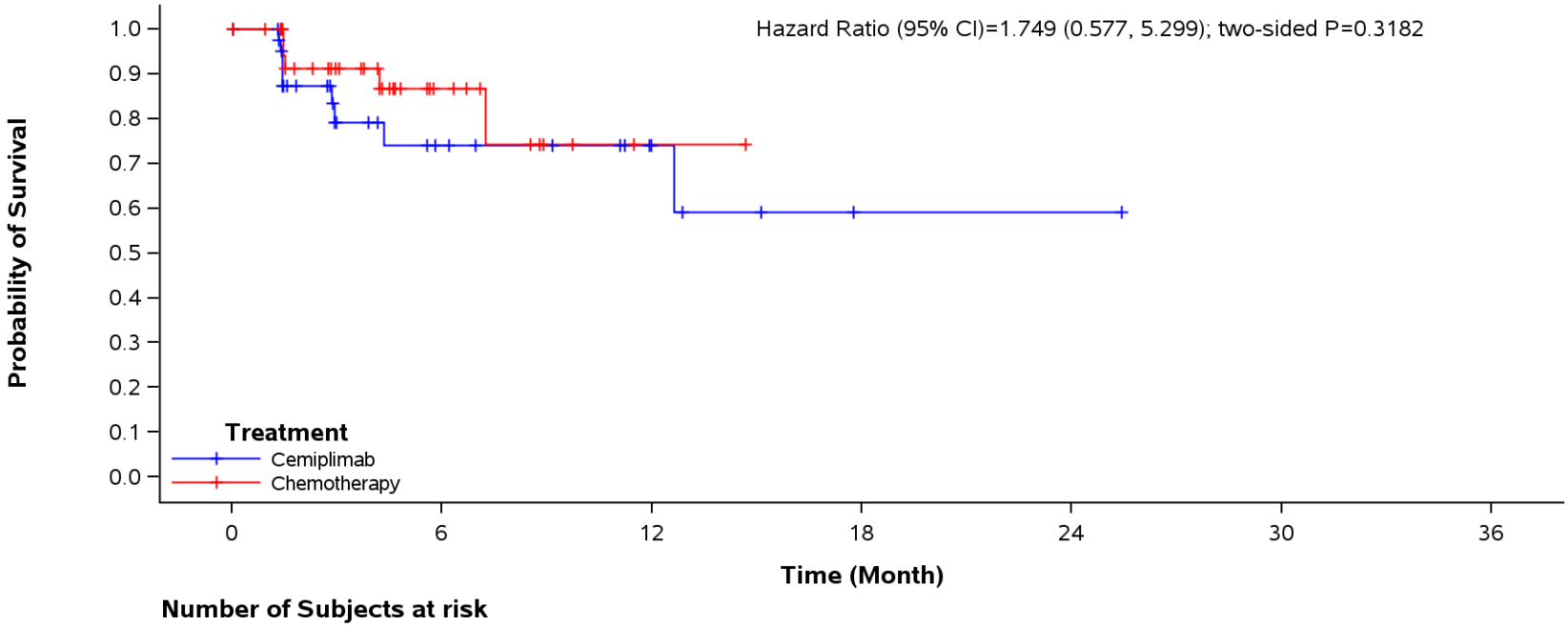

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 10 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts sensitivity sustained improvement



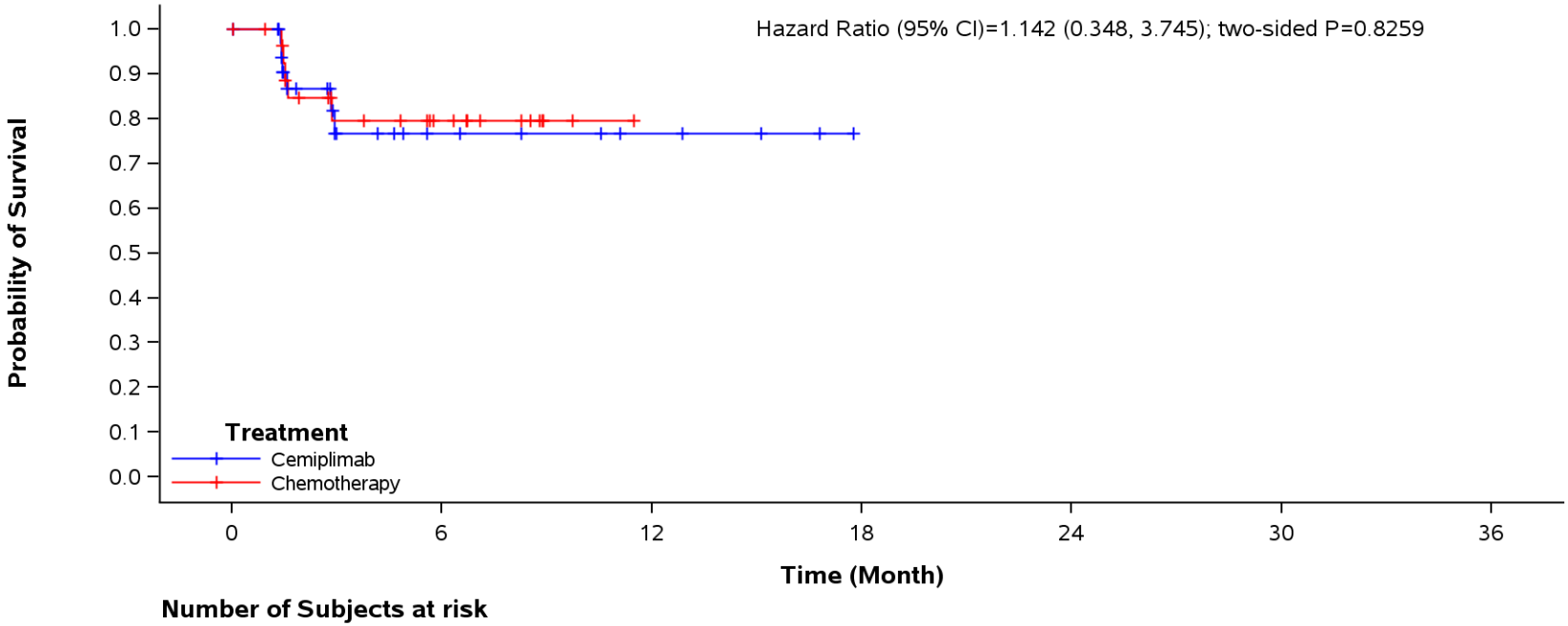

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts sensitivity sustained improvement



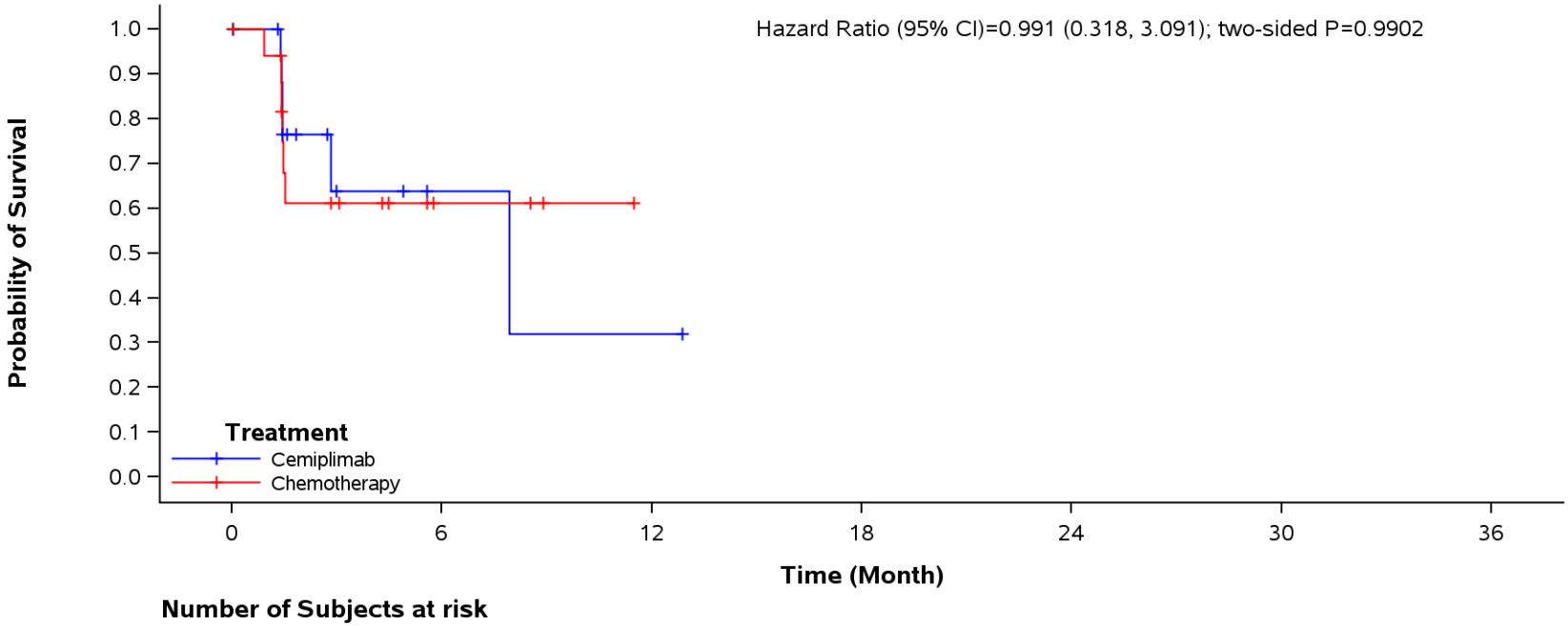

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 8 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts sensitivity sustained improvement



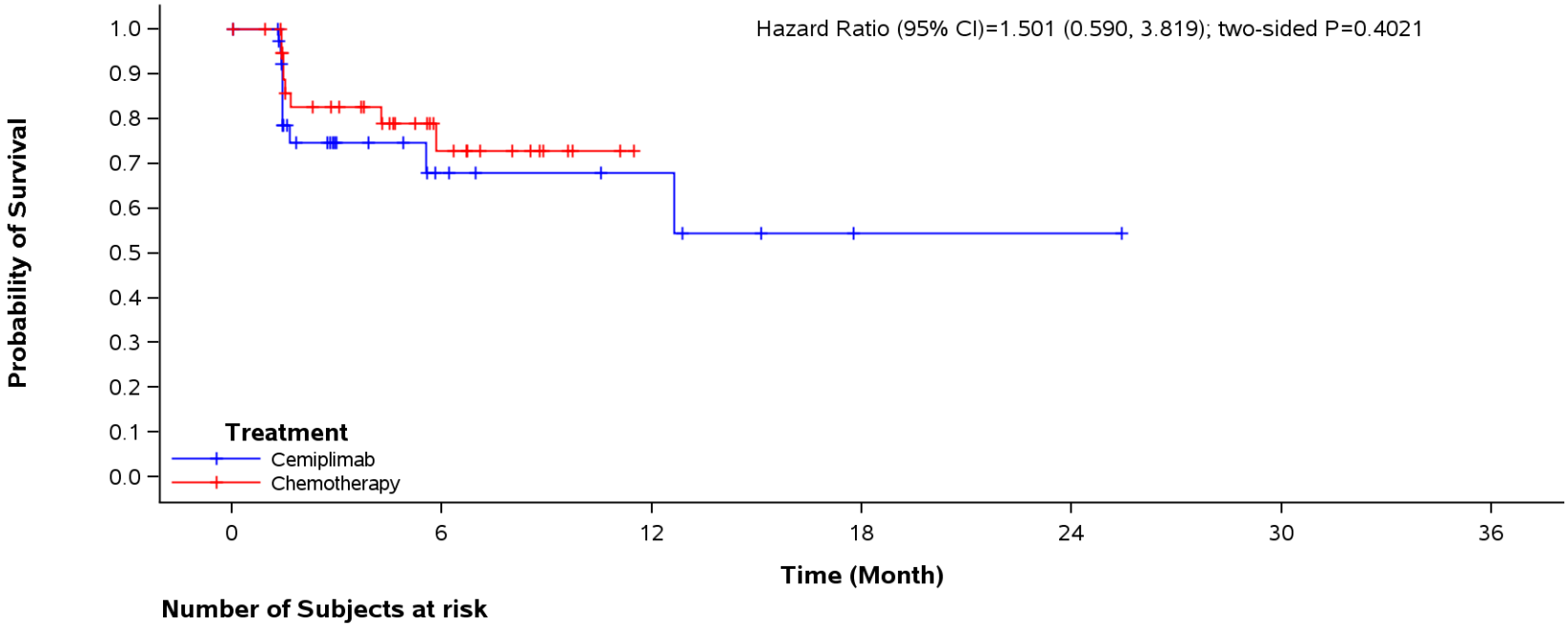

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 56 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts sensitivity sustained improvement



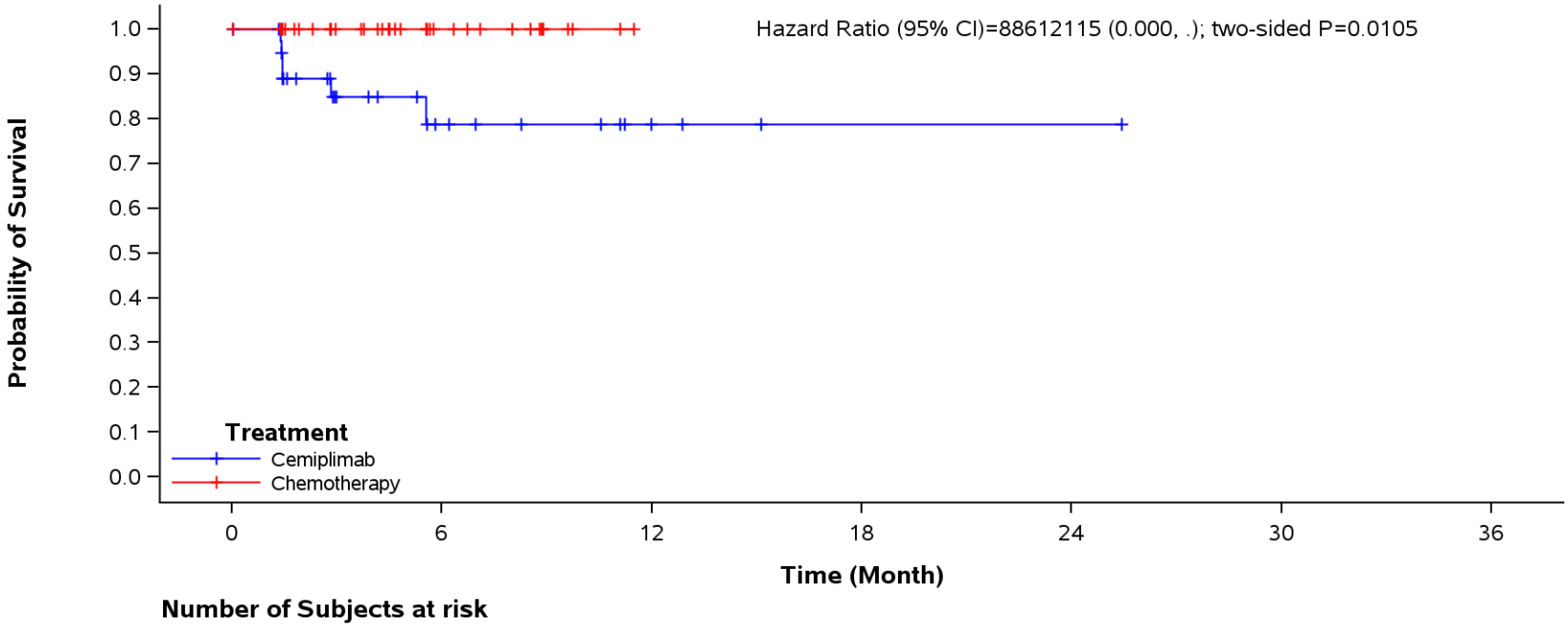

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 8 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts sensitivity sustained improvement



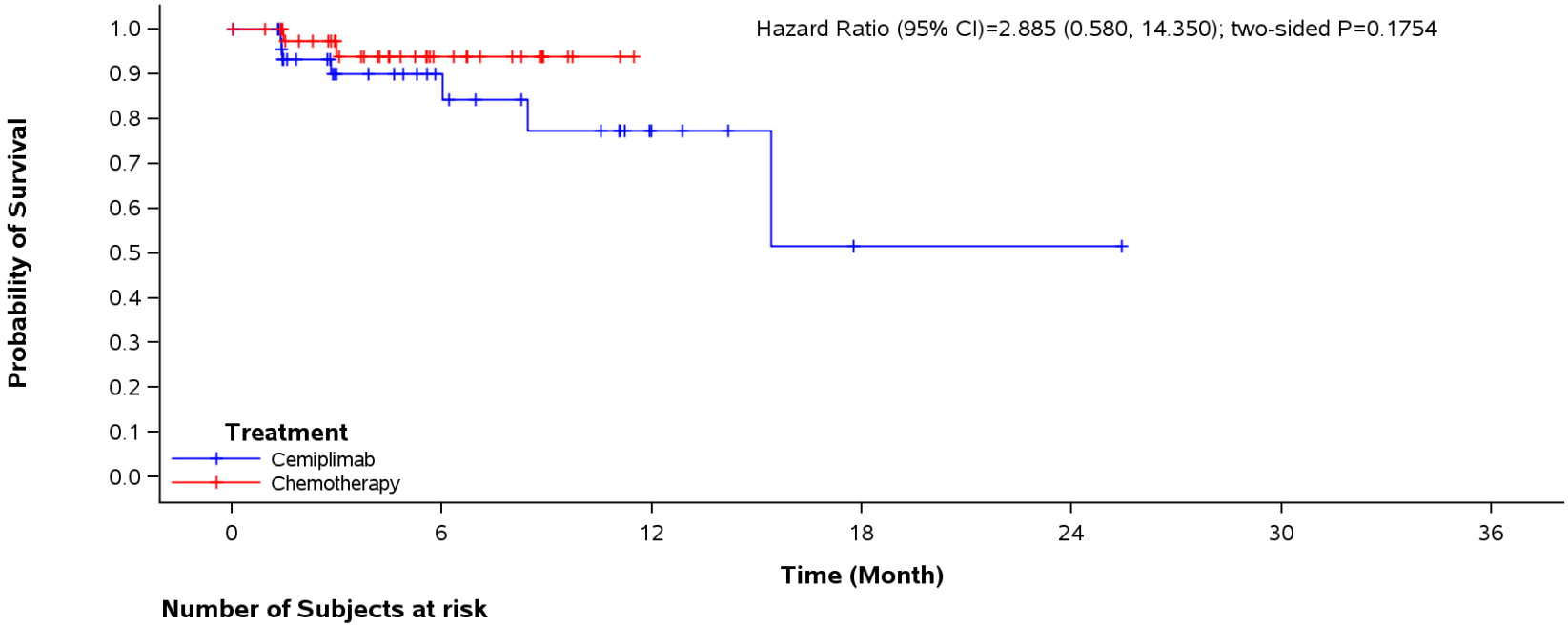

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 10 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts sensitivity sustained improvement



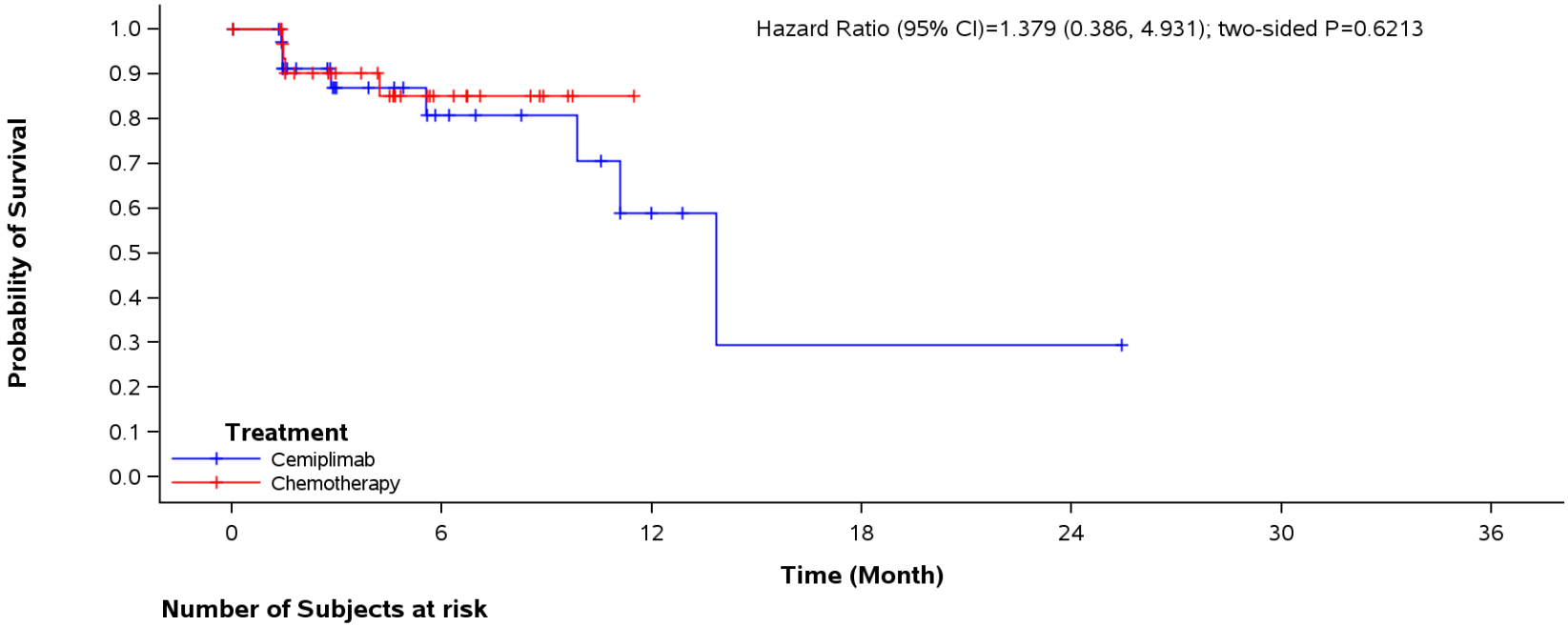

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 16 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts sensitivity sustained improvement



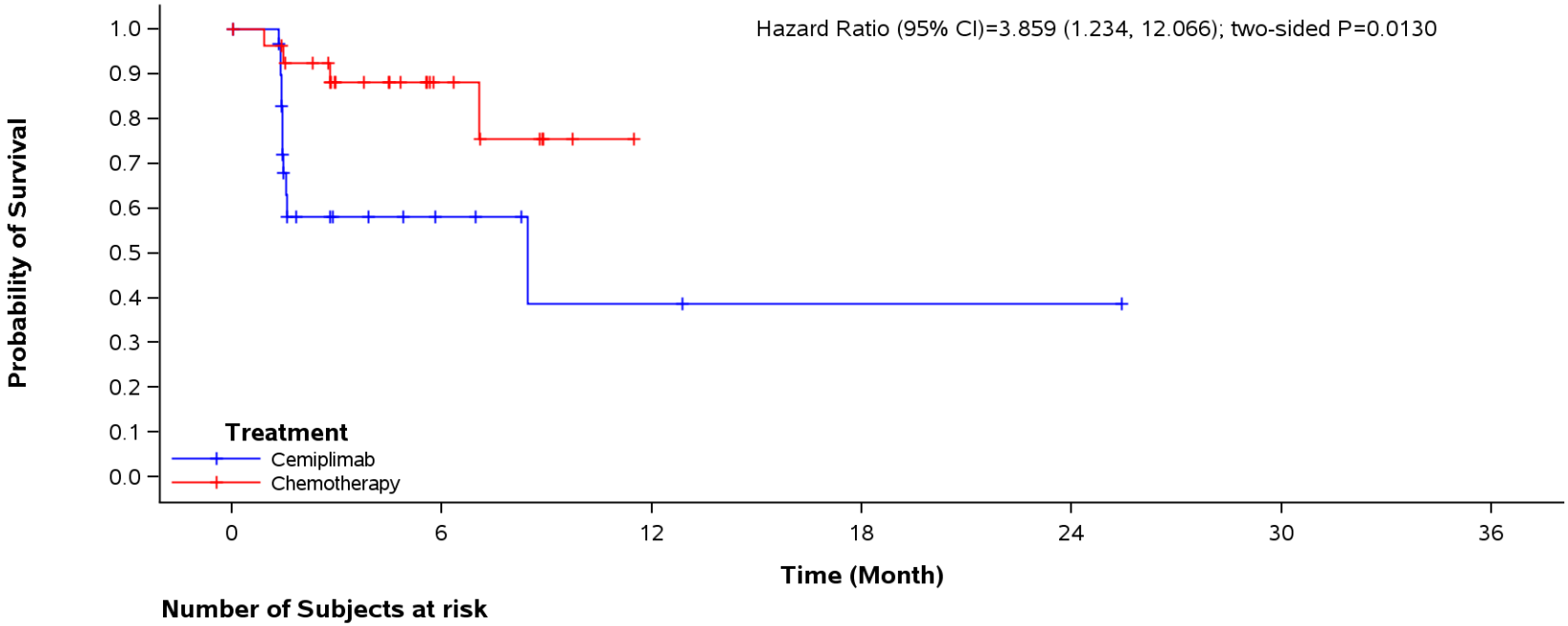

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 11 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts sensitivity sustained improvement



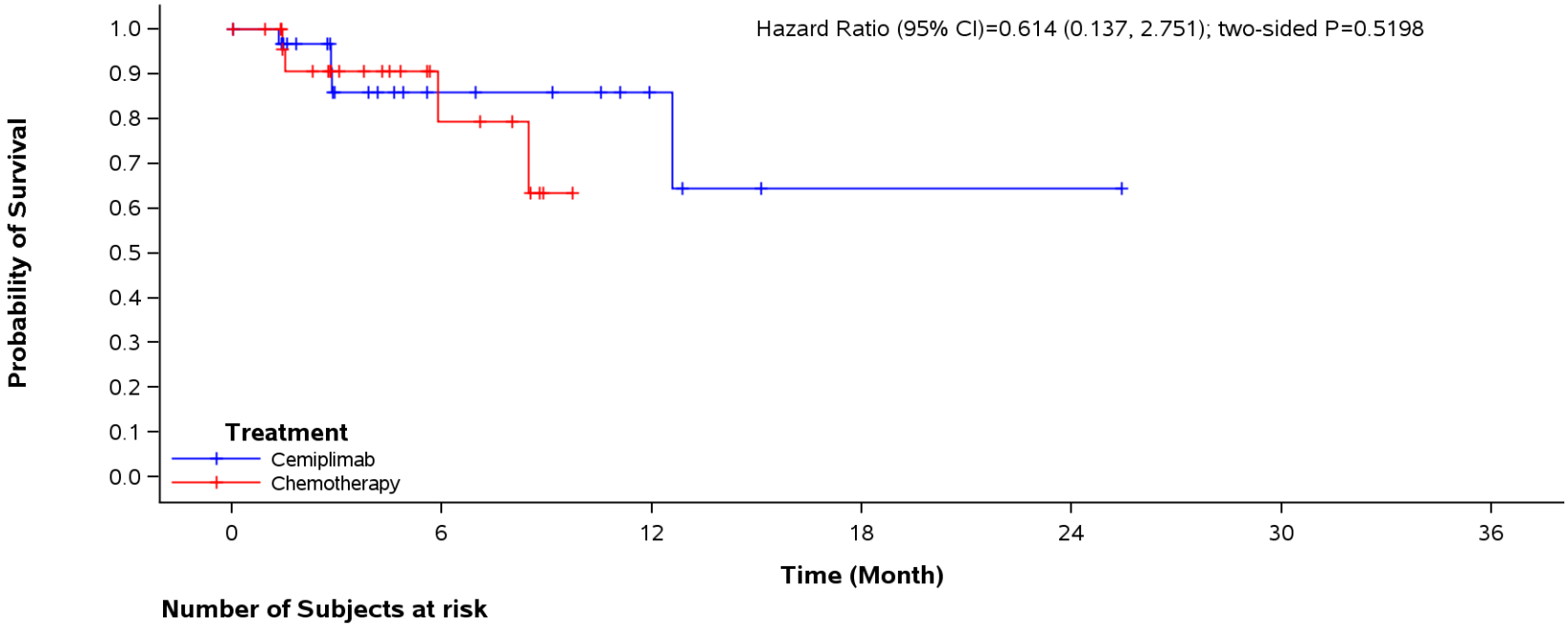

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 5 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts sensitivity sustained improvement



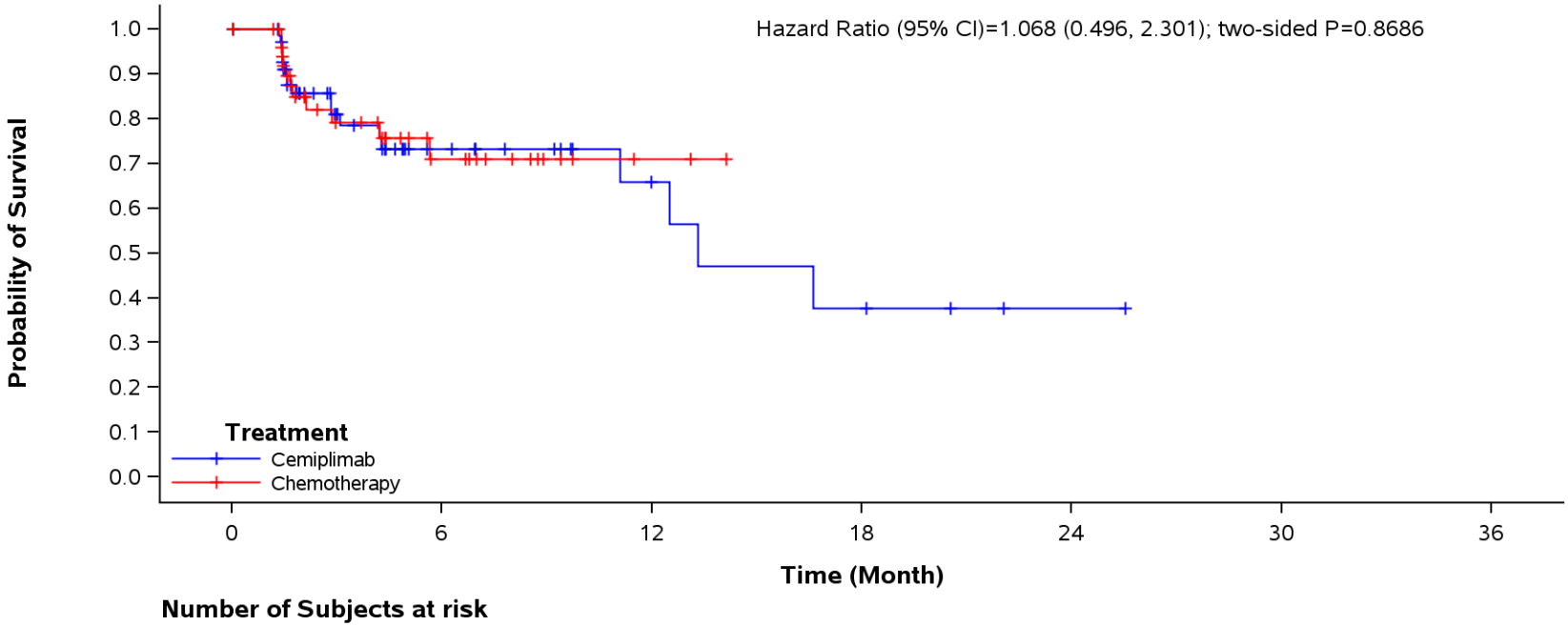

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 9 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Appetite loss - 10 pts sensitivity sustained improvement



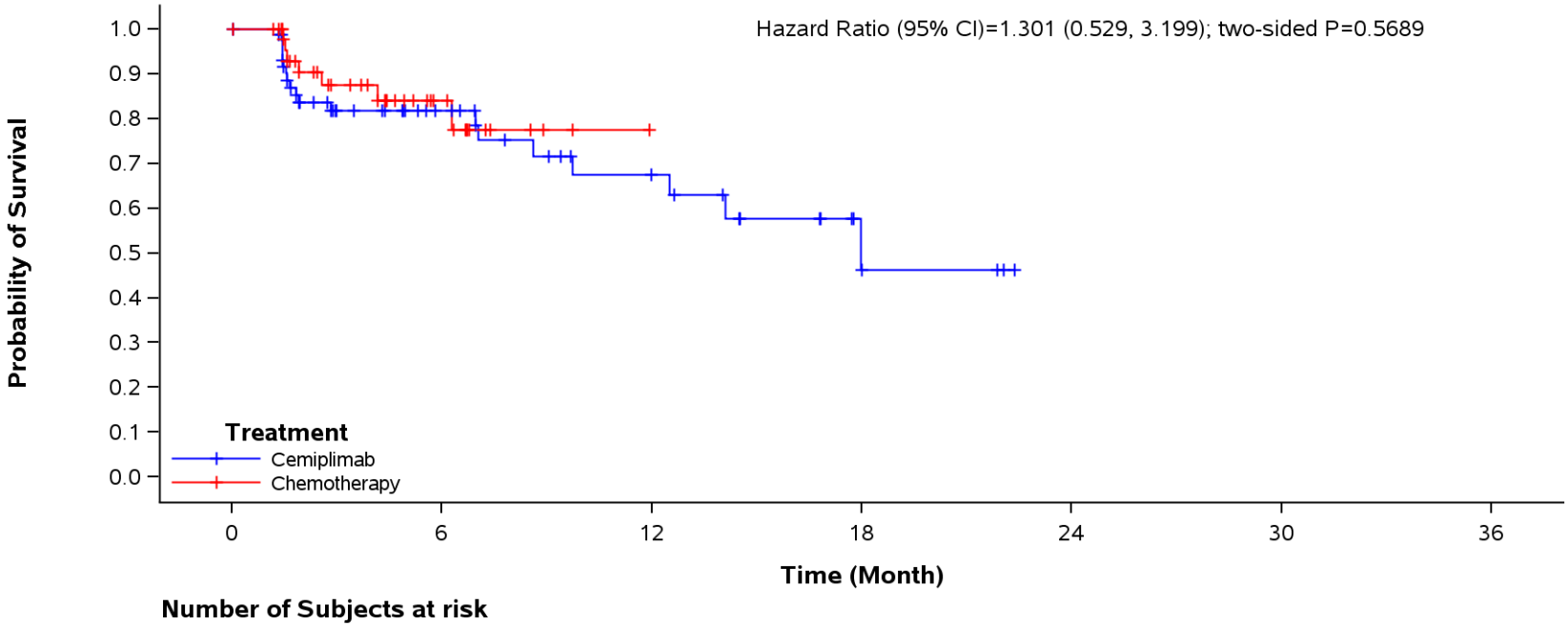

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 18 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 137 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

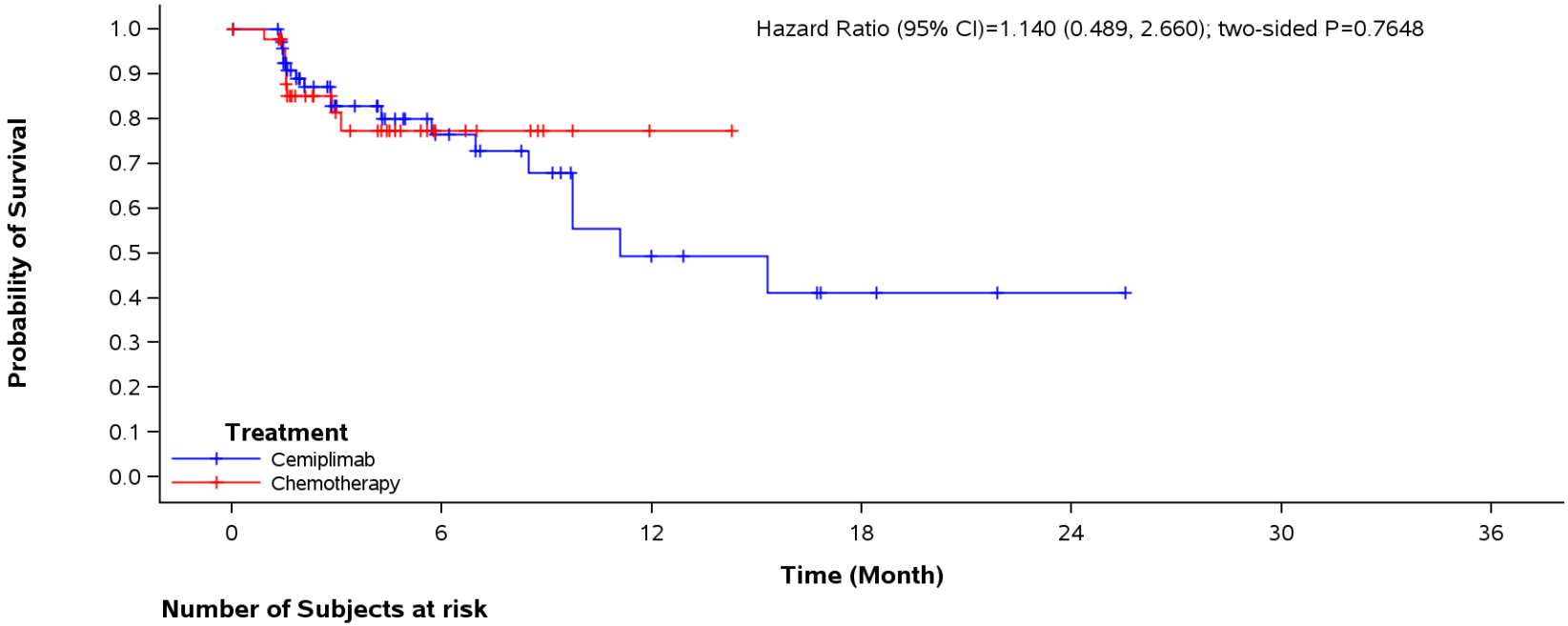
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 29 | 15 | 4 | 0 | 0 | 0 |
| Chemotherapy | 137 | 14 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Constipation - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 21 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 137 | 8 | 1 | 0 | 0 | 0 | 0 |

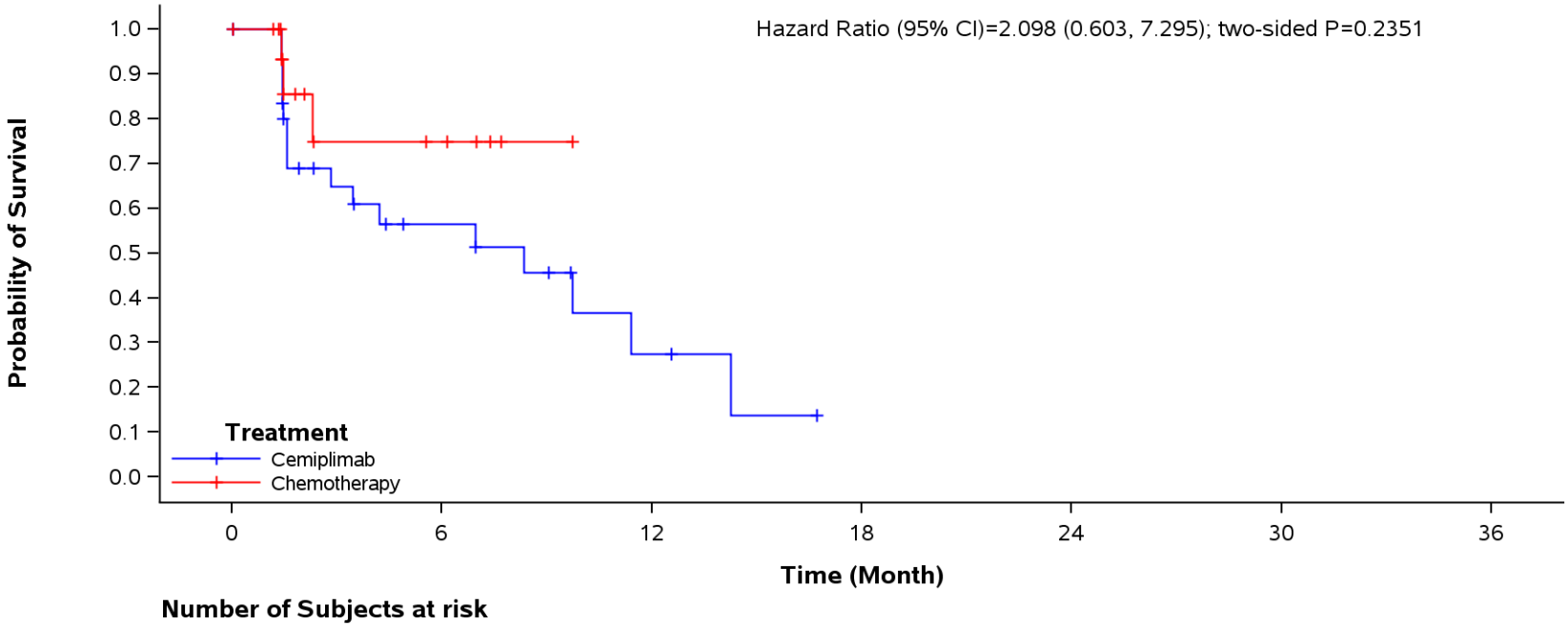
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Diarhoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 11 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 137 | 5 | 0 | 0 | 0 | 0 | 0 |

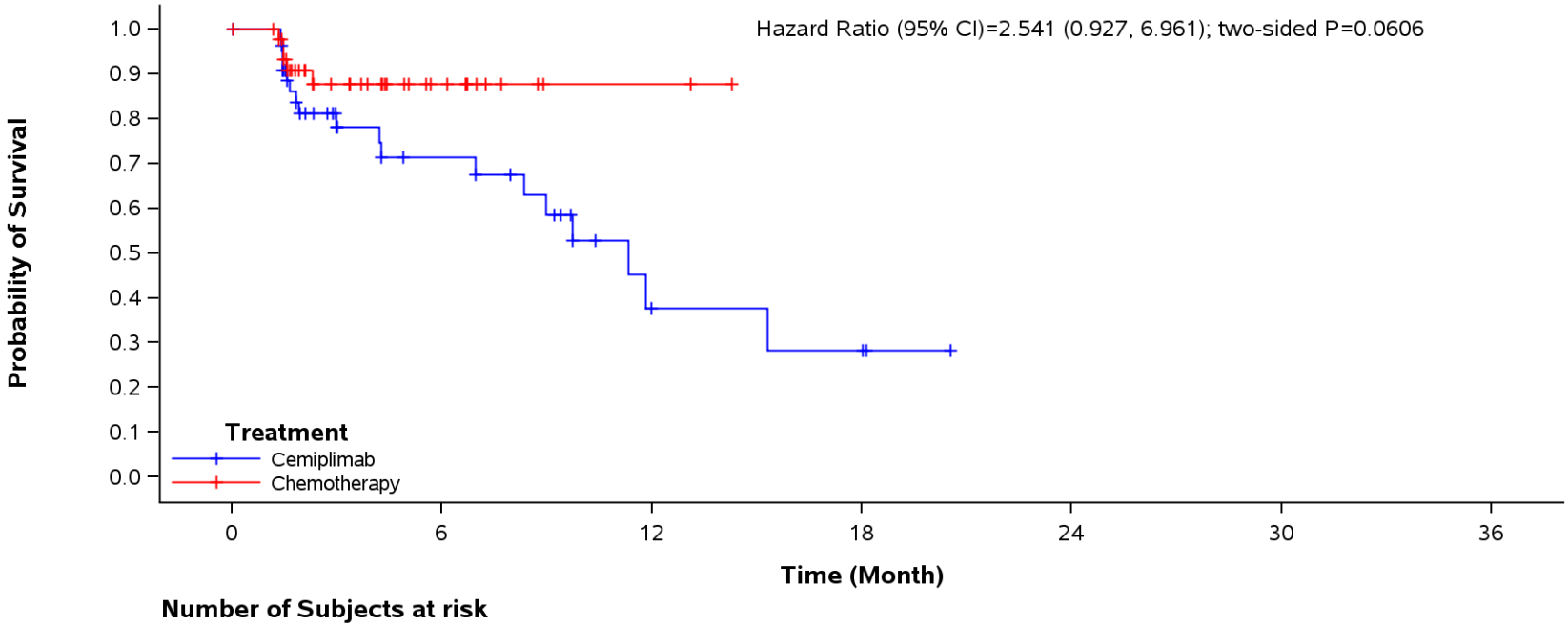
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Dyspnoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

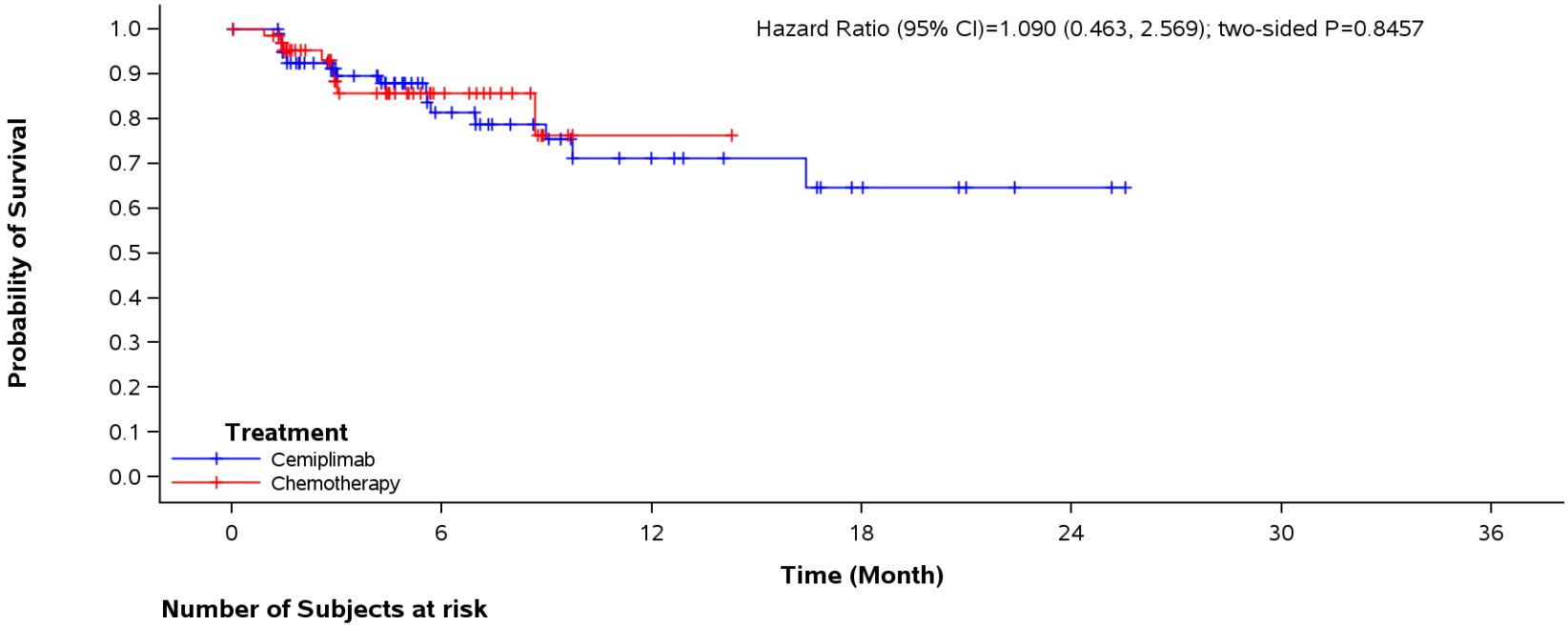
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 19 | 4 | 3 | 0 | 0 | 0 |
| Chemotherapy | 137 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts sensitivity sustained improvement



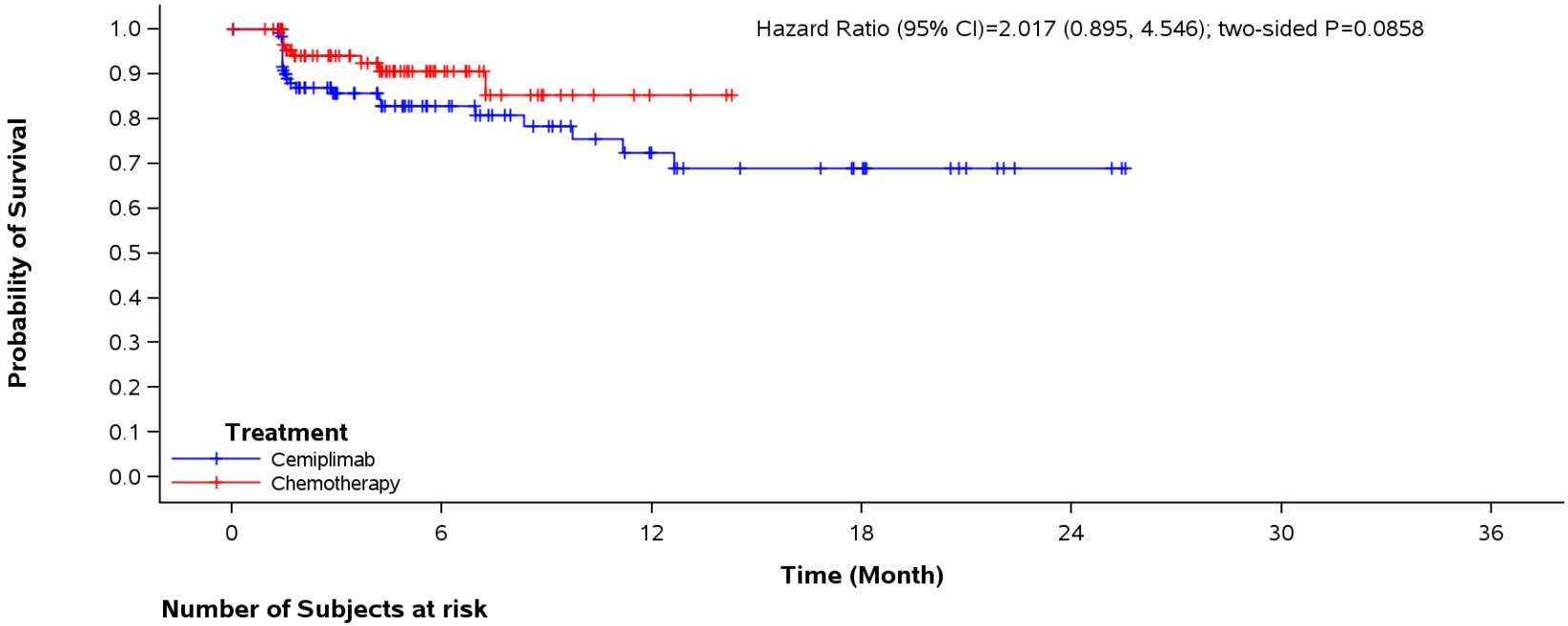

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 35 | 14 | 6 | 2 | 0 | 0 |
| Chemotherapy | 137 | 17 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts sensitivity sustained improvement



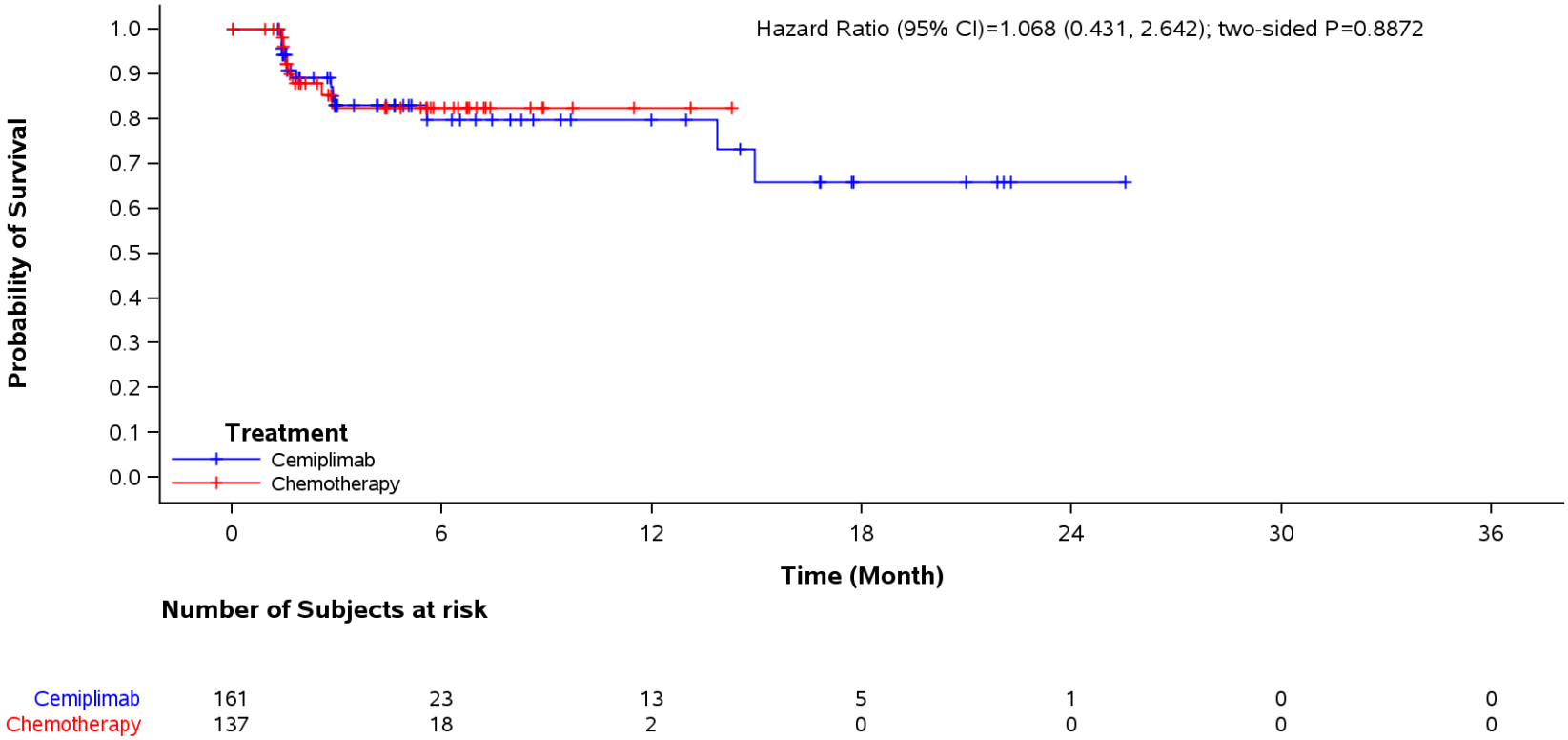

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 43 | 20 | 12 | 3 | 0 | 0 |
| Chemotherapy | 137 | 26 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

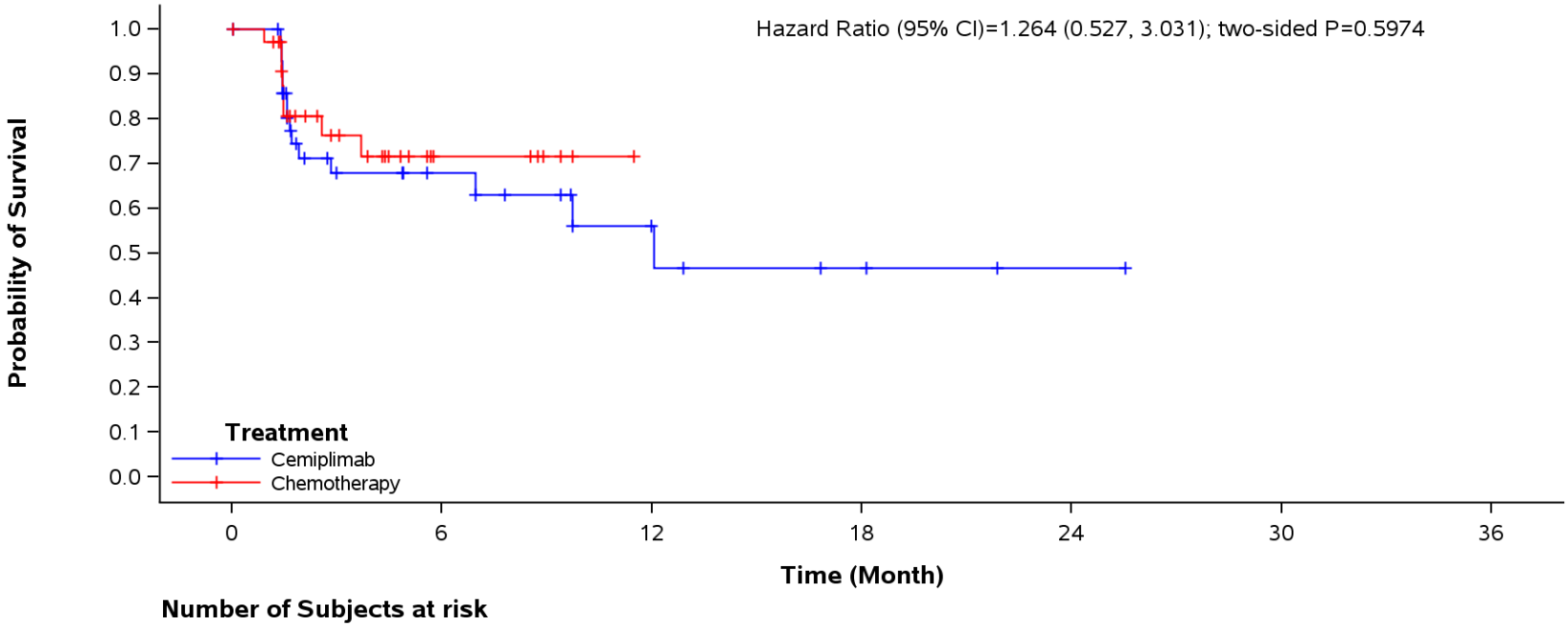
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 23 | 13 | 5 | 1 | 0 | 0 |
| Chemotherapy | 137 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Nausea / Vomiting - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

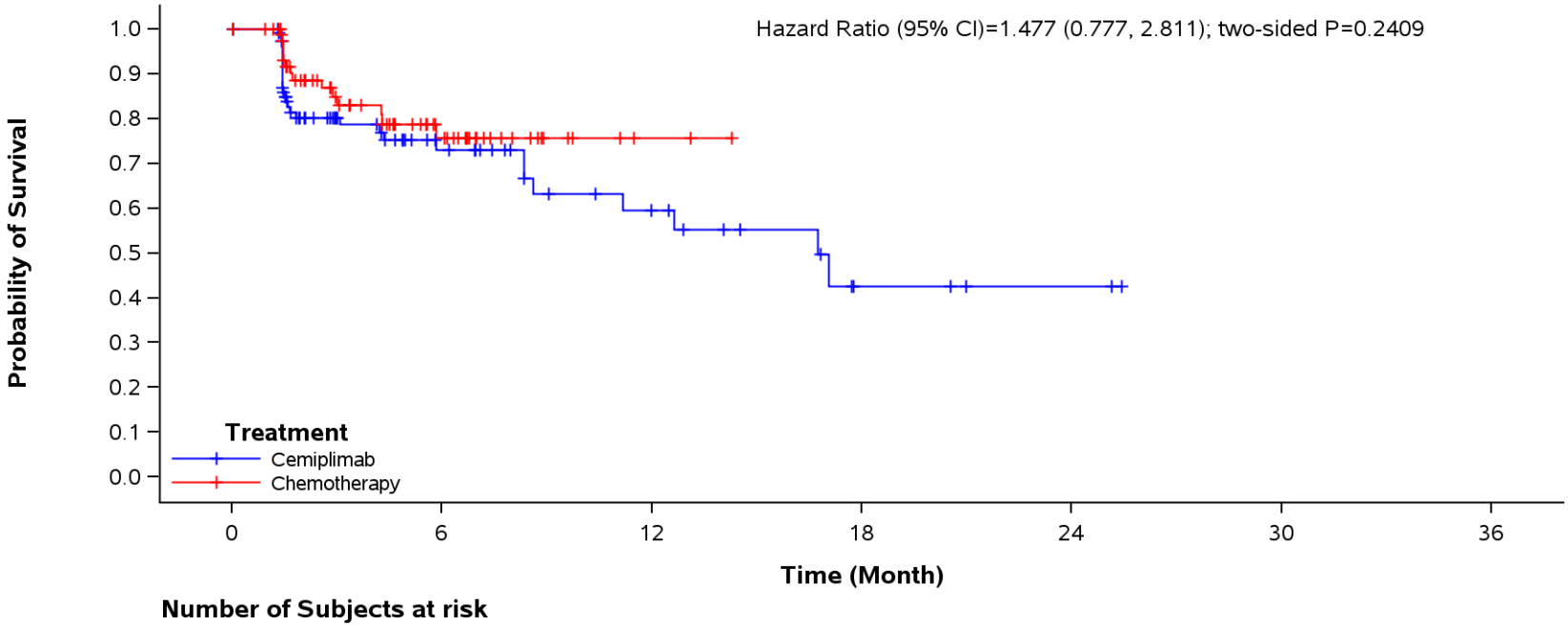
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 14 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 137 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts sensitivity sustained improvement




Number of Subjects at risk

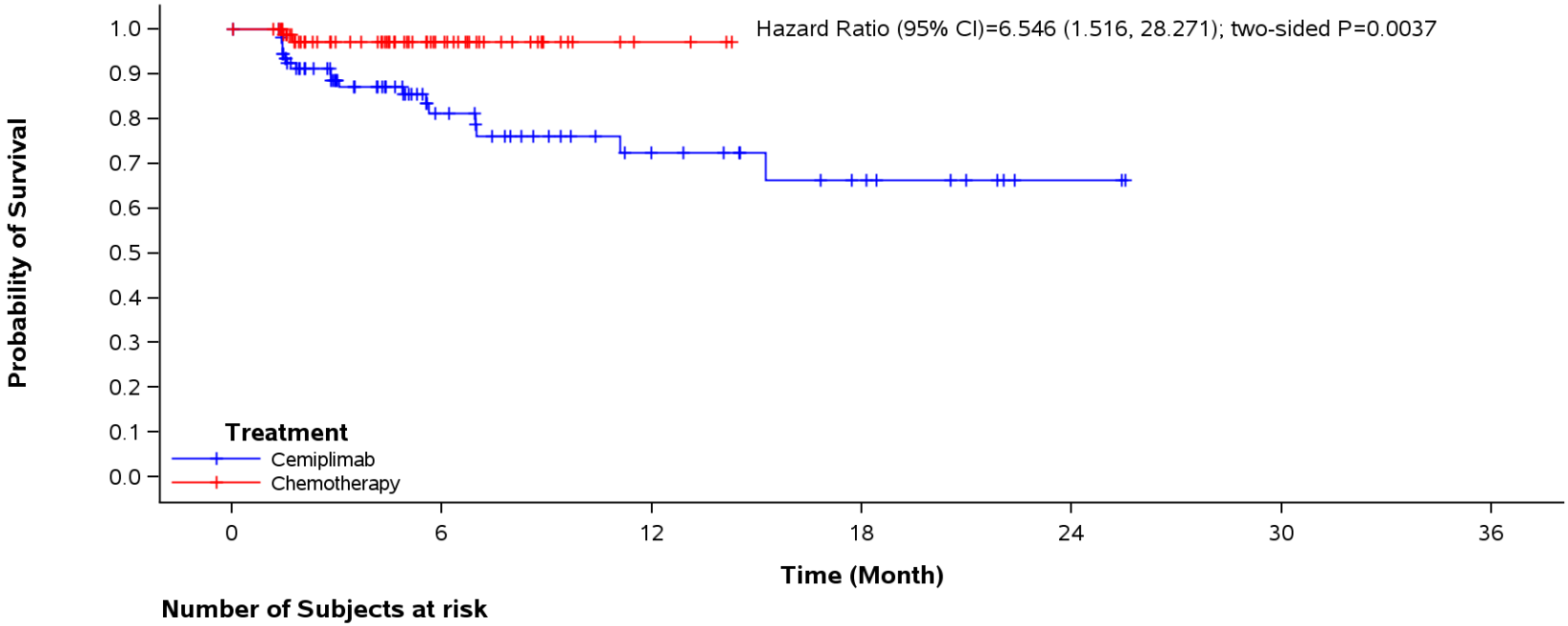
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 31 | 15 | 4 | 2 | 0 | 0 |
| Chemotherapy | 137 | 24 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Physical Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 35 | 16 | 9 | 2 | 0 | 0 |
| Chemotherapy | 137 | 26 | 3 | 0 | 0 | 0 | 0 |

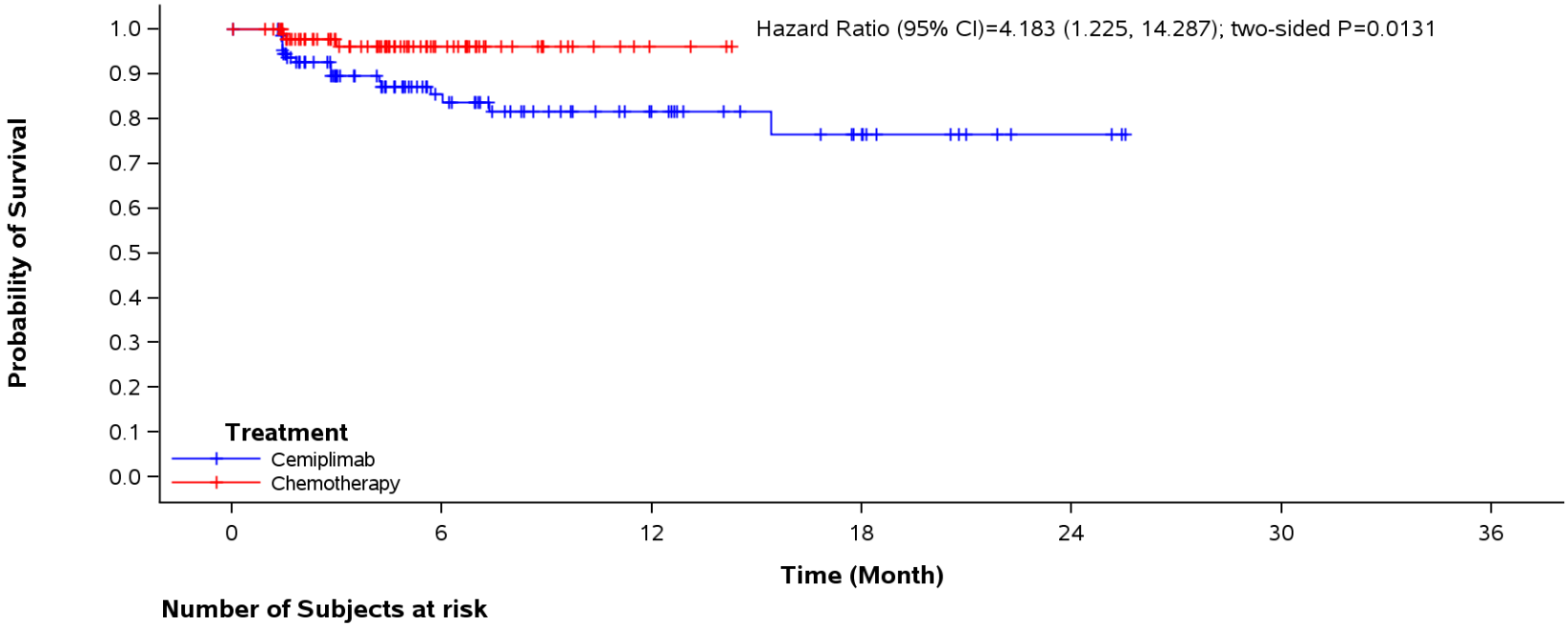
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Global health status / QoL - 10 pts sensitivity sustained improvement




Number of Subjects at risk

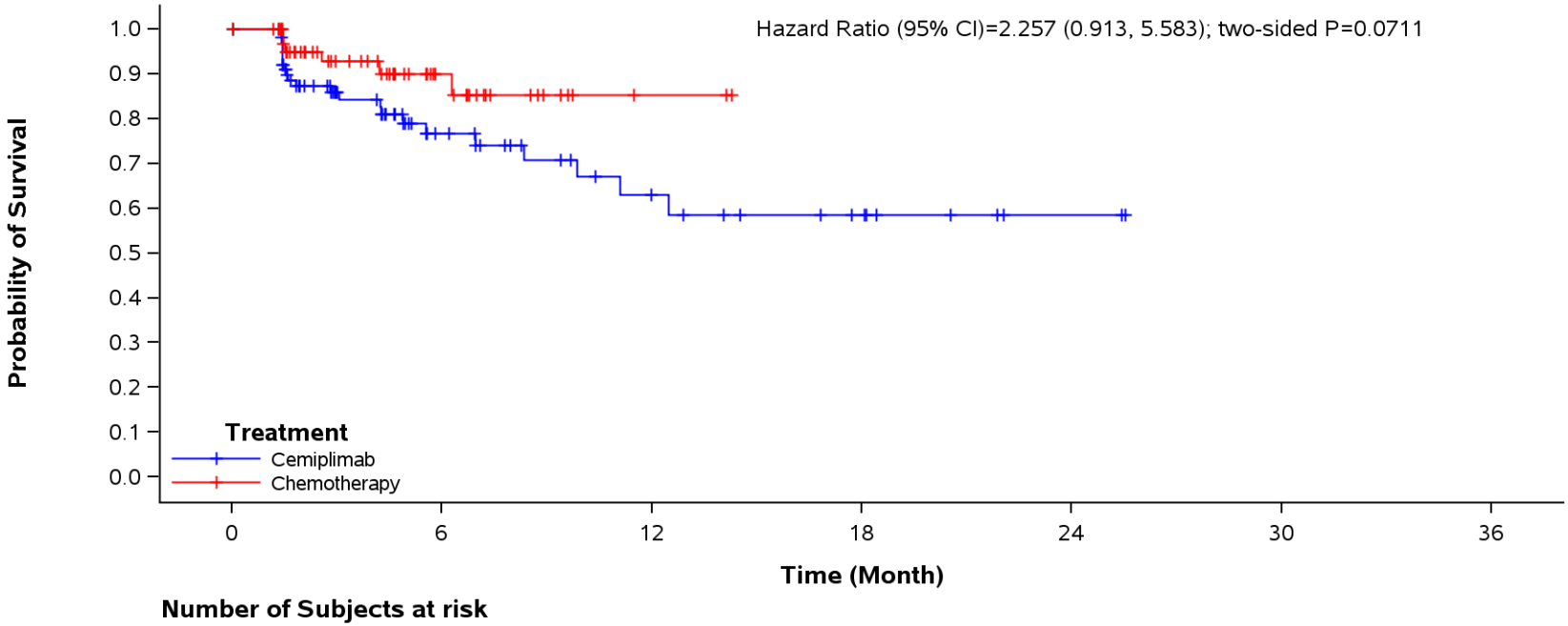
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 49 | 23 | 12 | 3 | 0 | 0 |
| Chemotherapy | 137 | 31 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Role Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

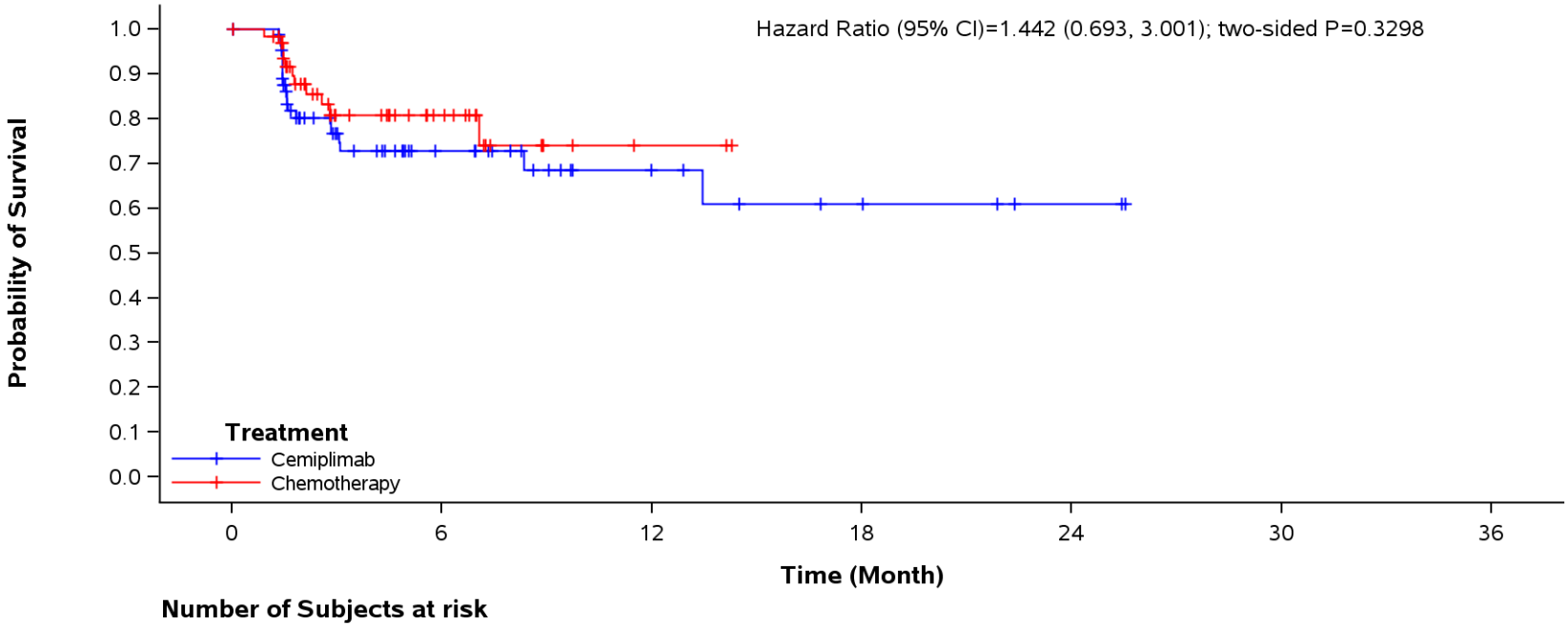
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 31 | 14 | 8 | 2 | 0 | 0 |
| Chemotherapy | 137 | 19 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Social Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

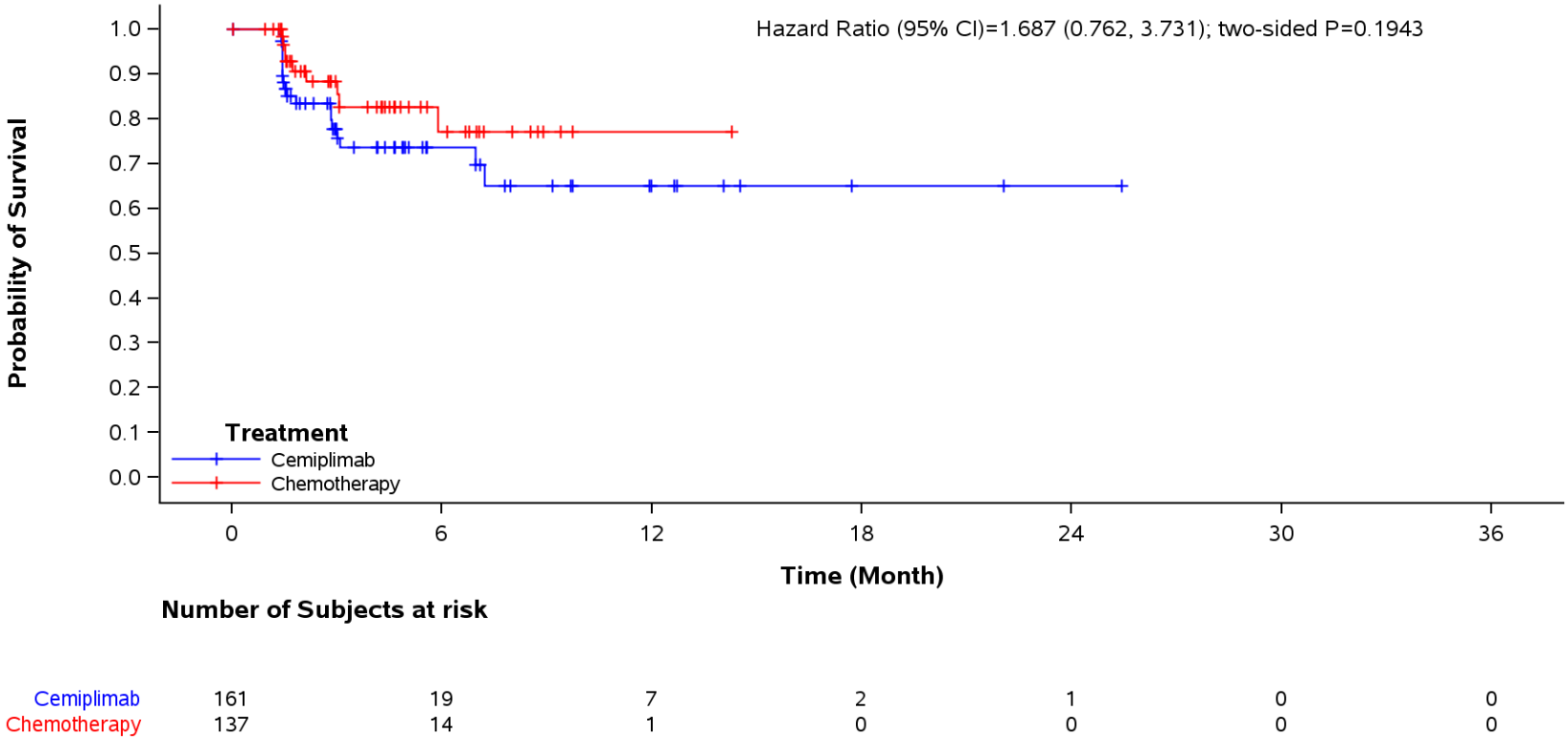
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 24 | 10 | 5 | 2 | 0 | 0 |
| Chemotherapy | 137 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

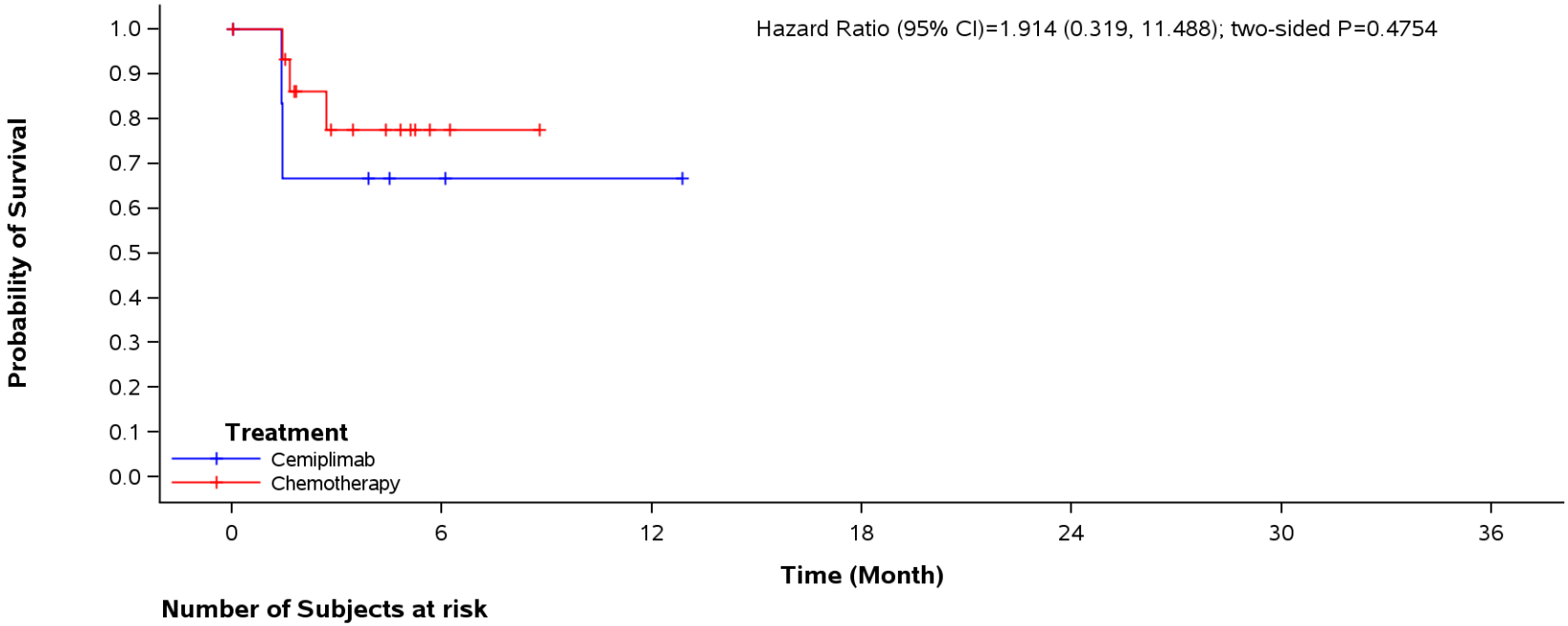
Histology: Squamous
Insomnia - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts sensitivity sustained improvement



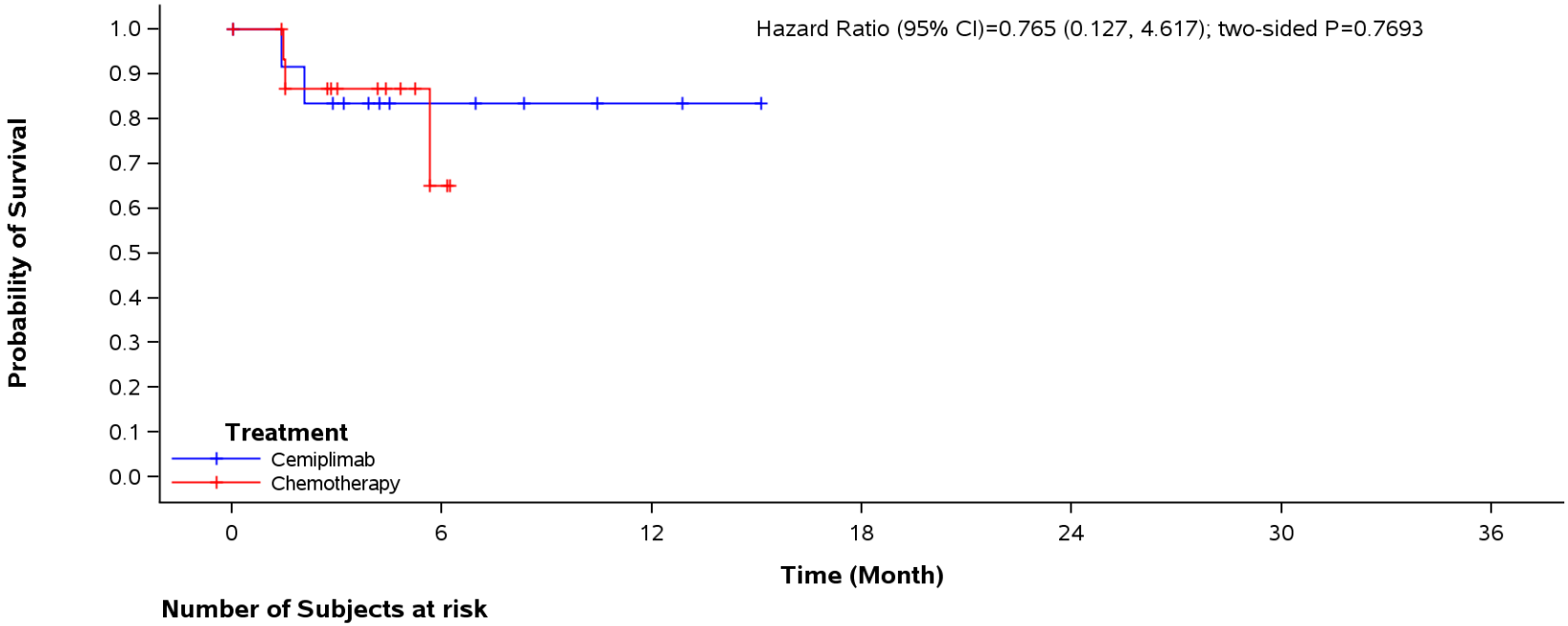

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts sensitivity sustained improvement



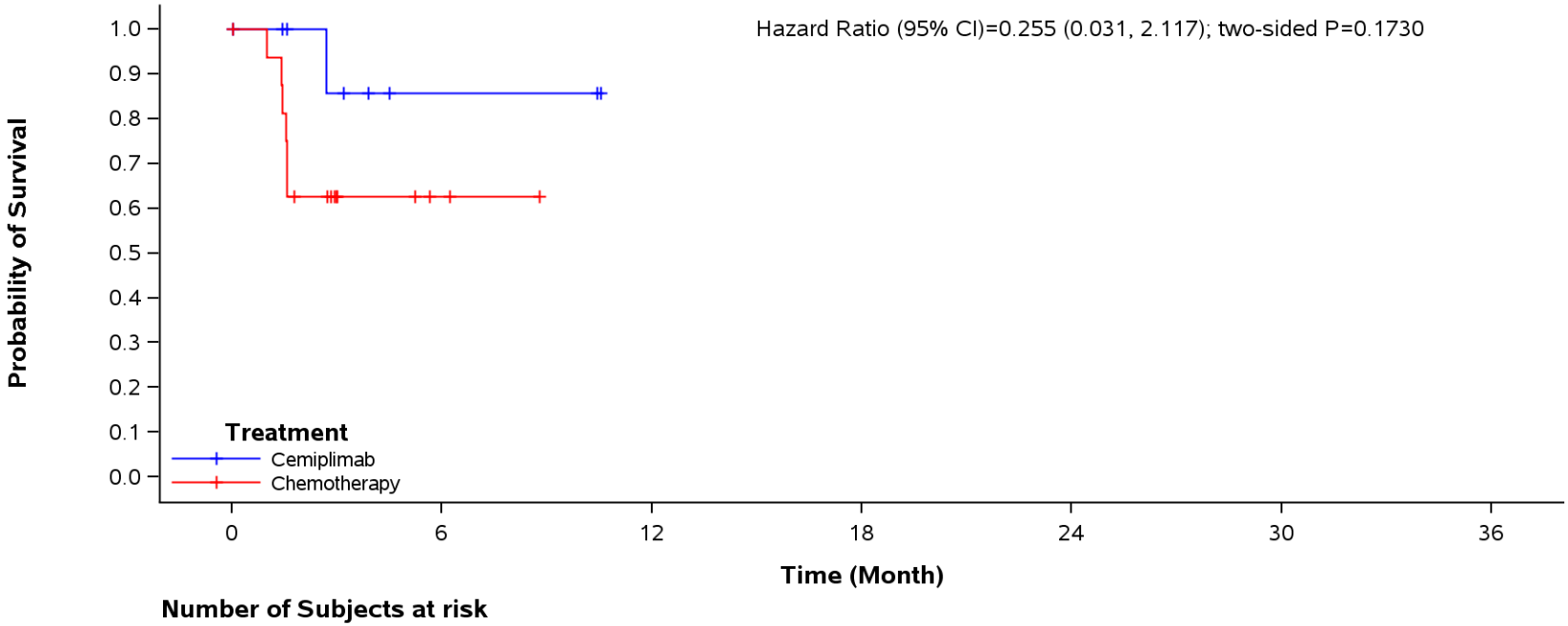

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts sensitivity sustained improvement



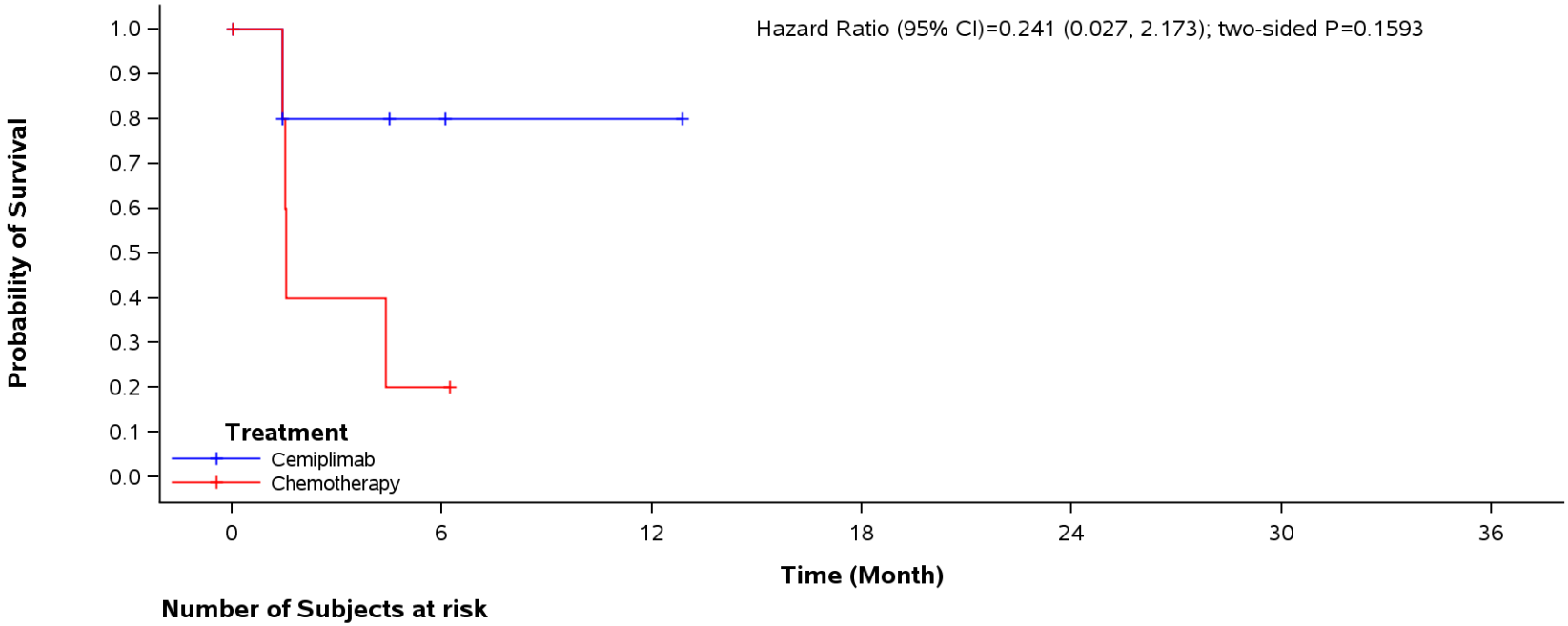

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts sensitivity sustained improvement



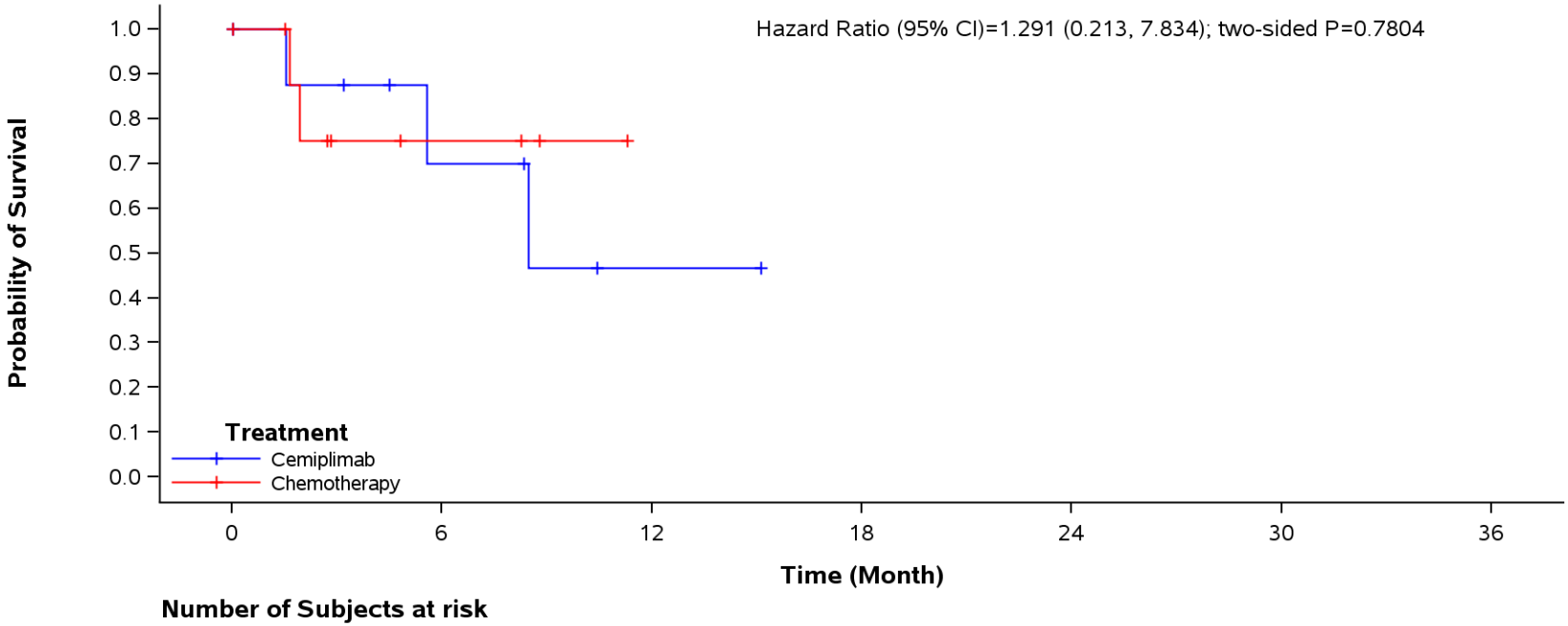

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

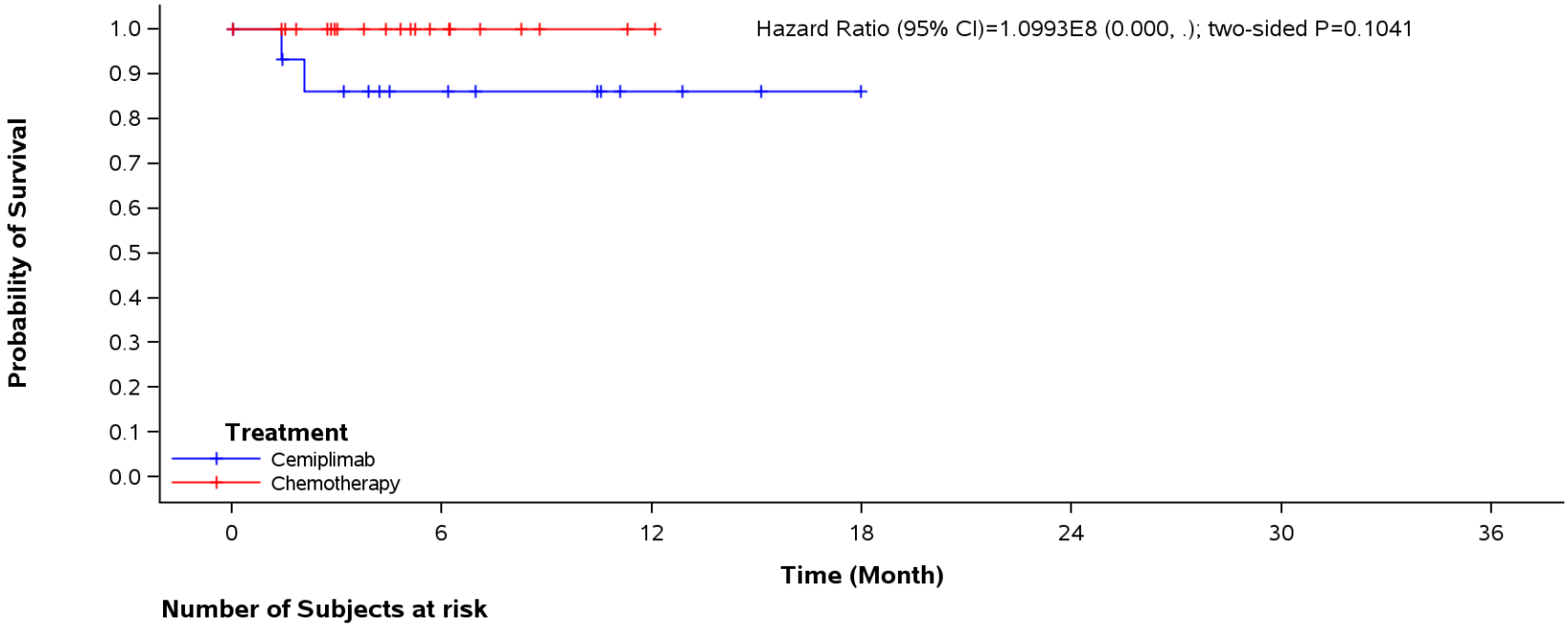
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

Emotional Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

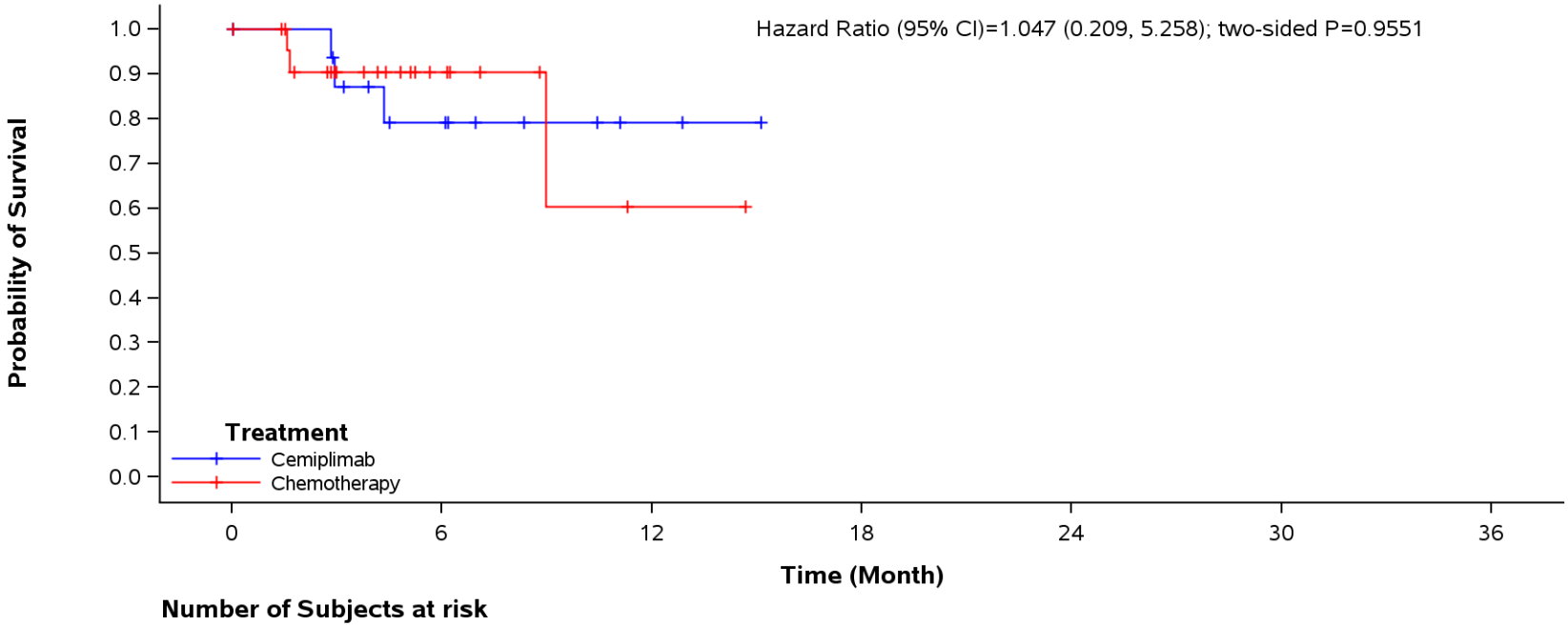
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts sensitivity sustained improvement



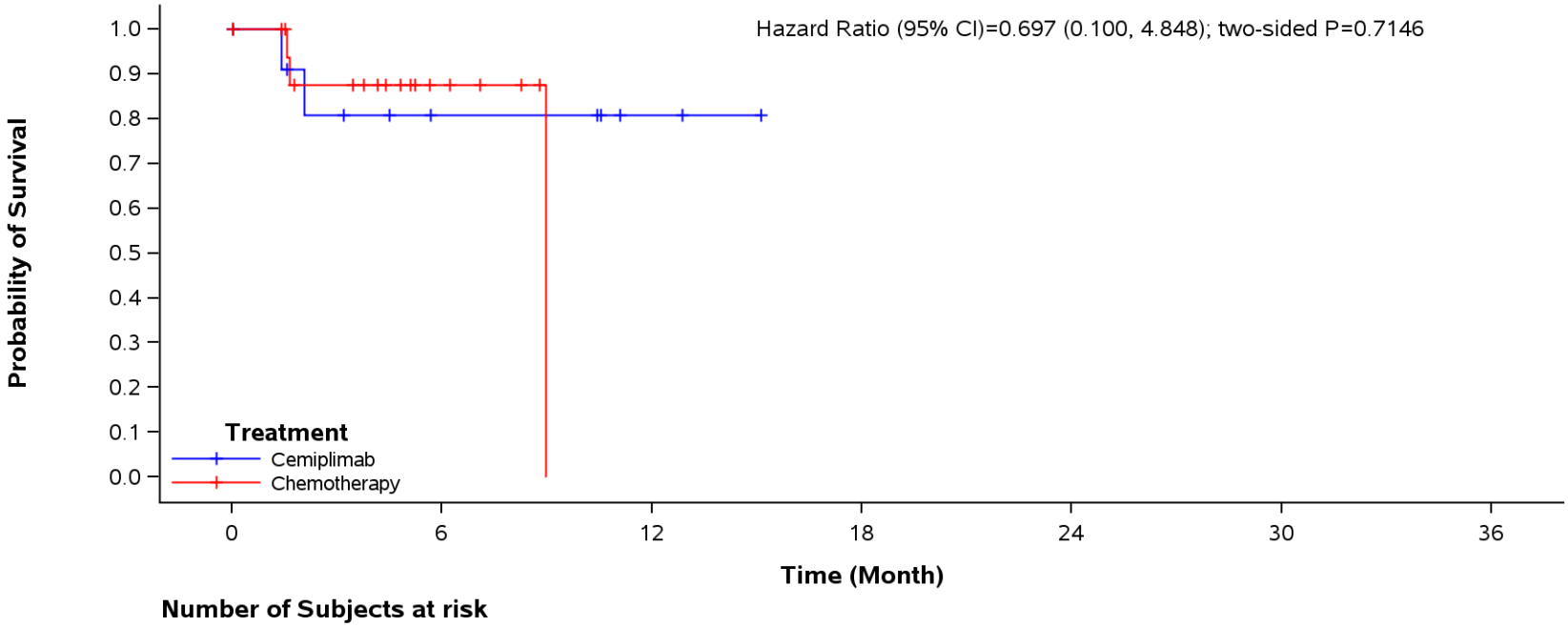

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

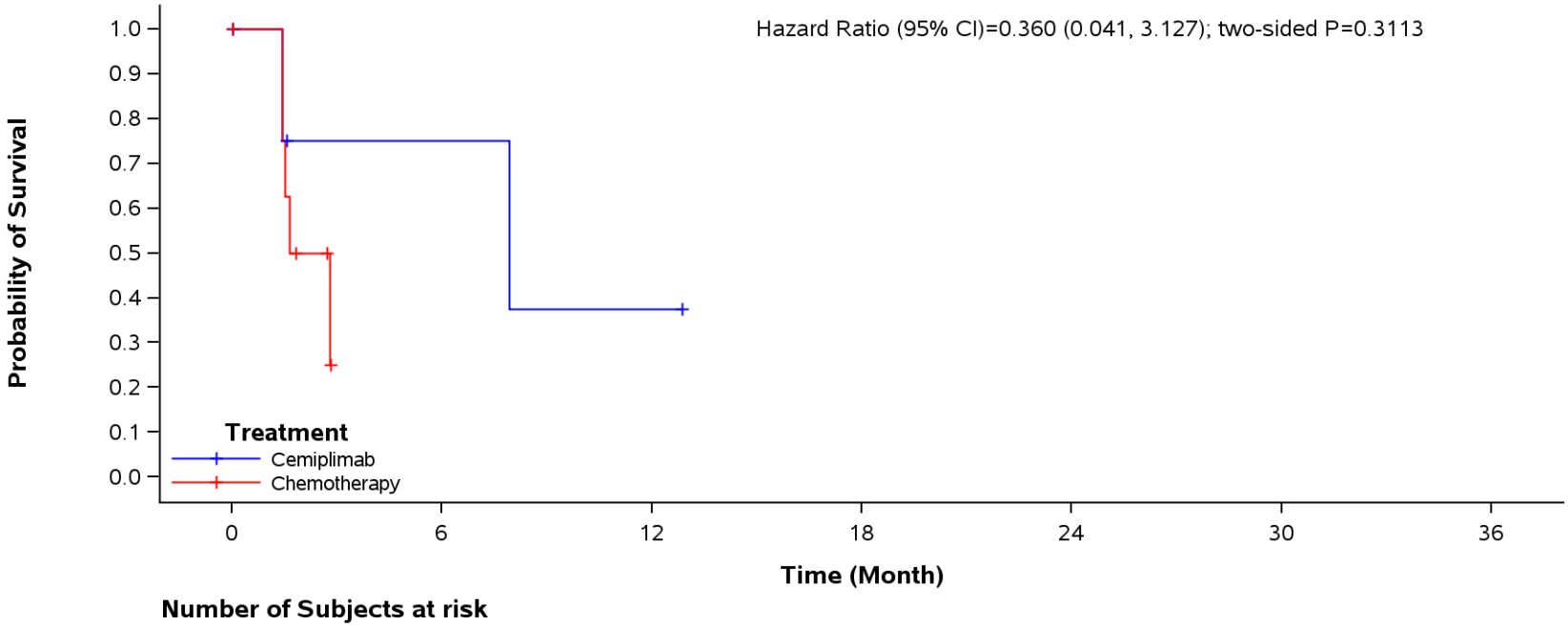
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

Nausea / Vomiting - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

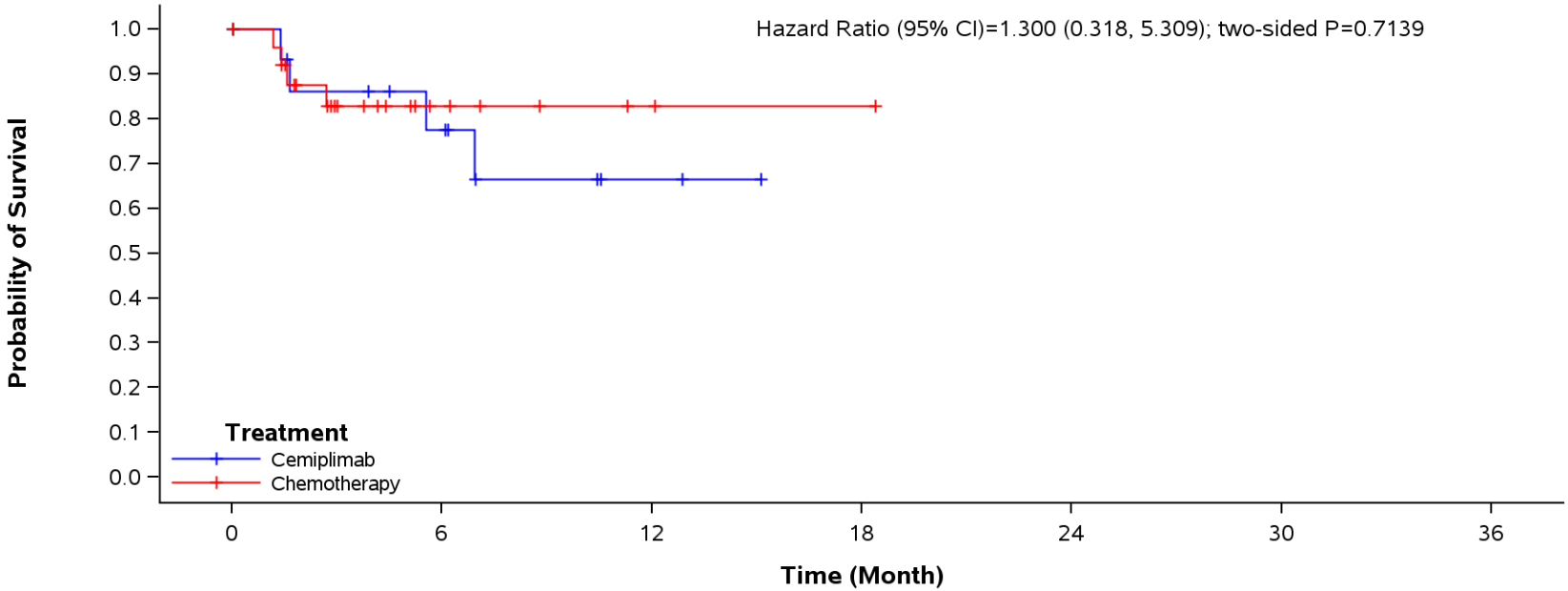
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts sensitivity sustained improvement



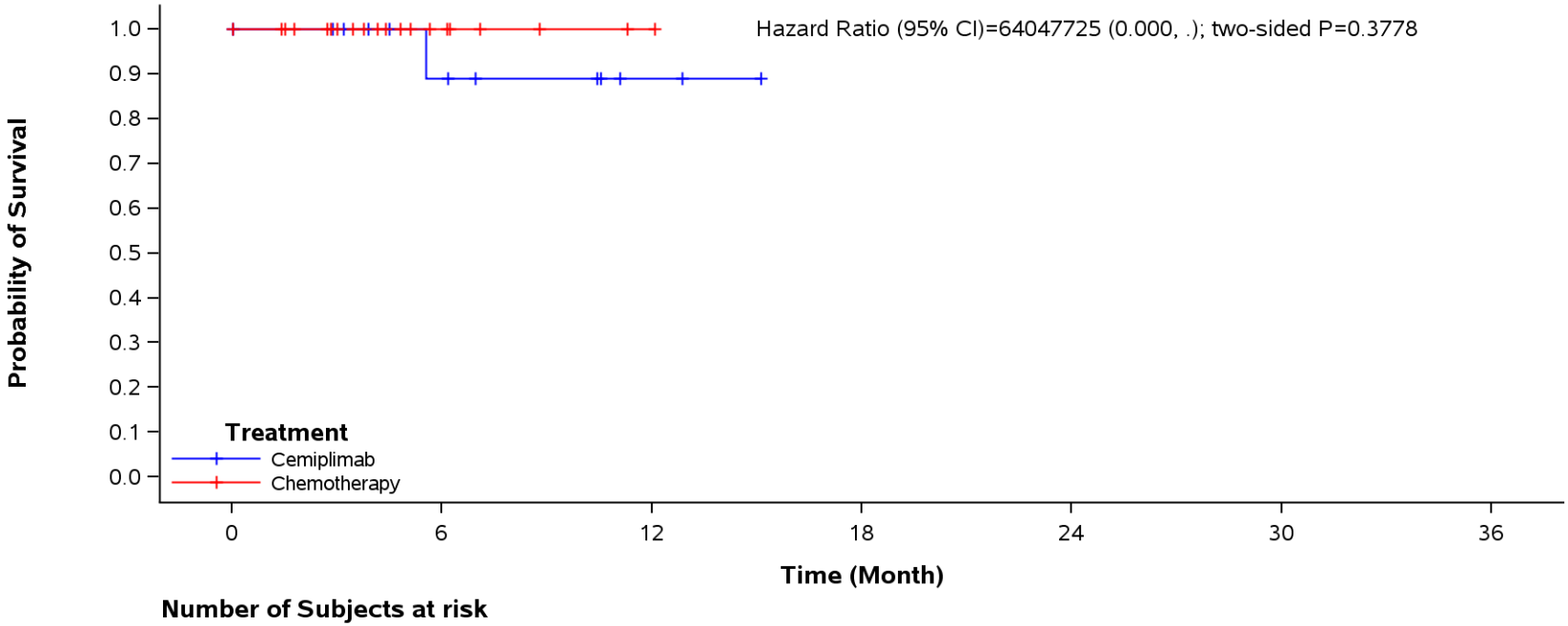

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

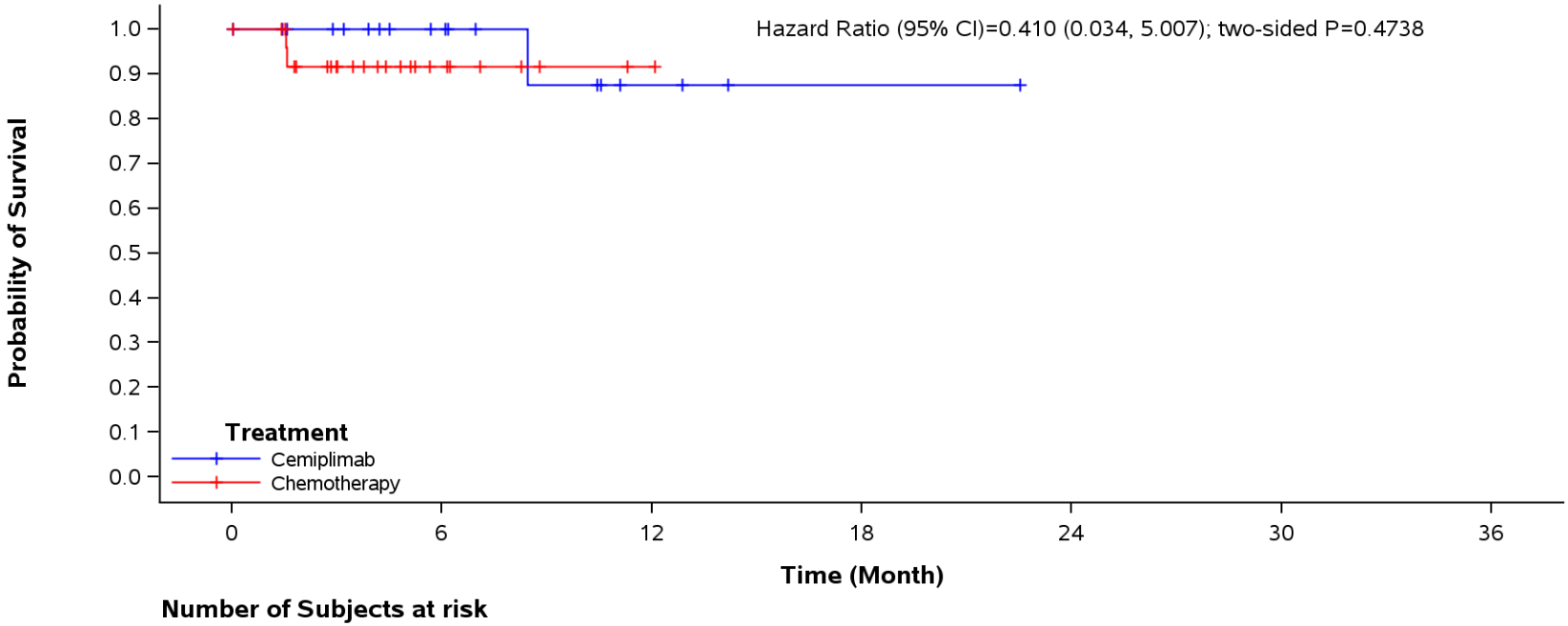
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

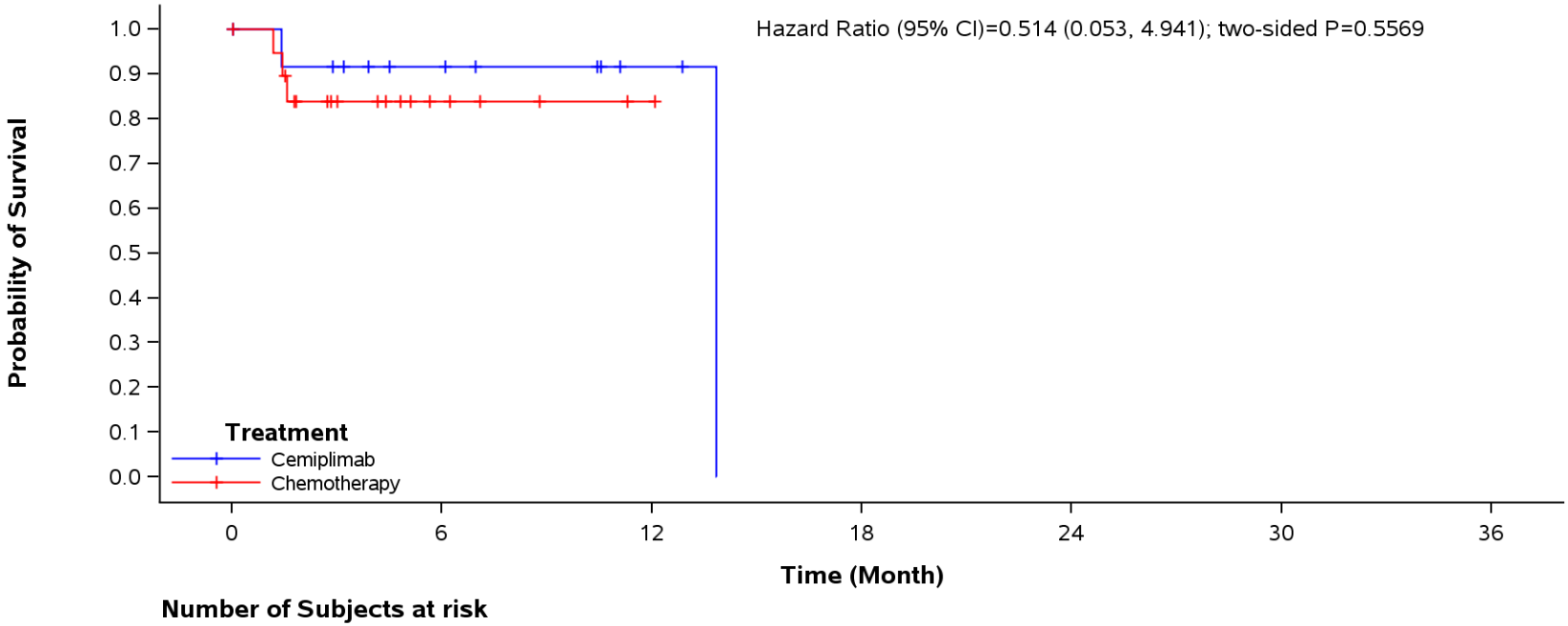
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

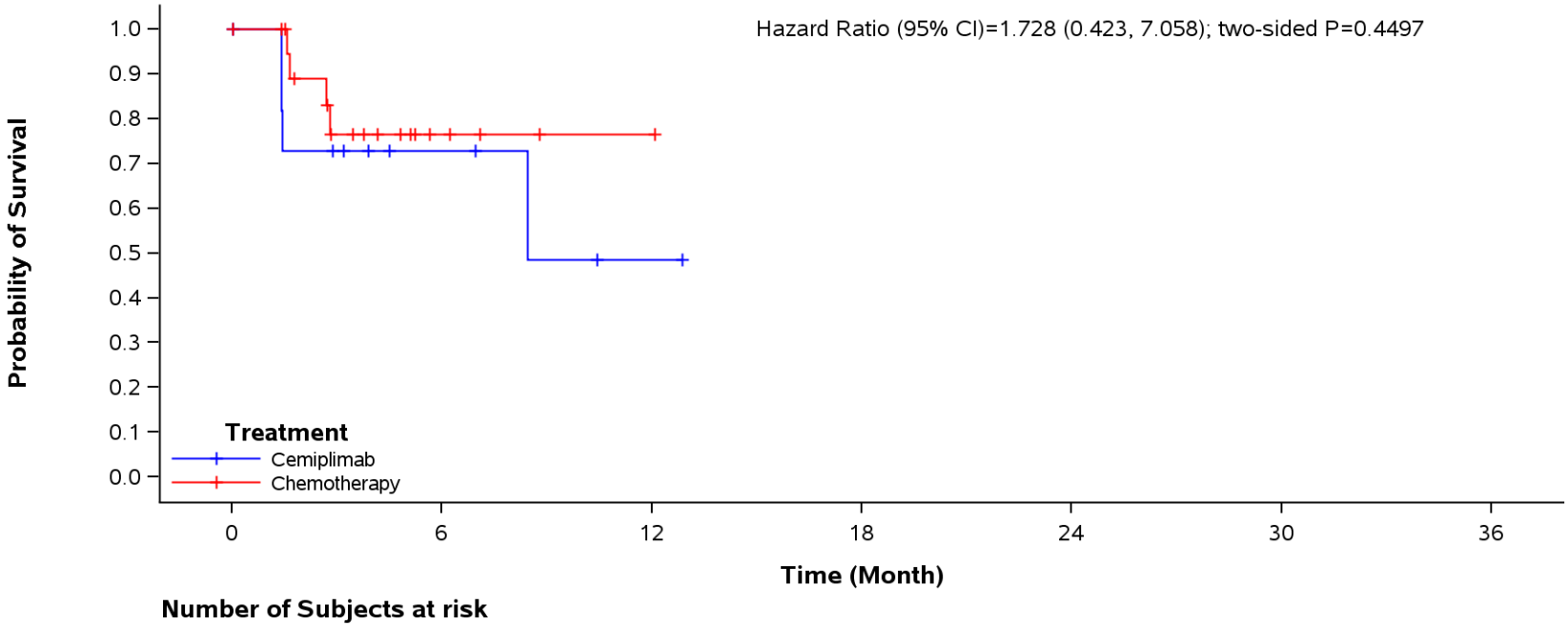
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 7 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

Social Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

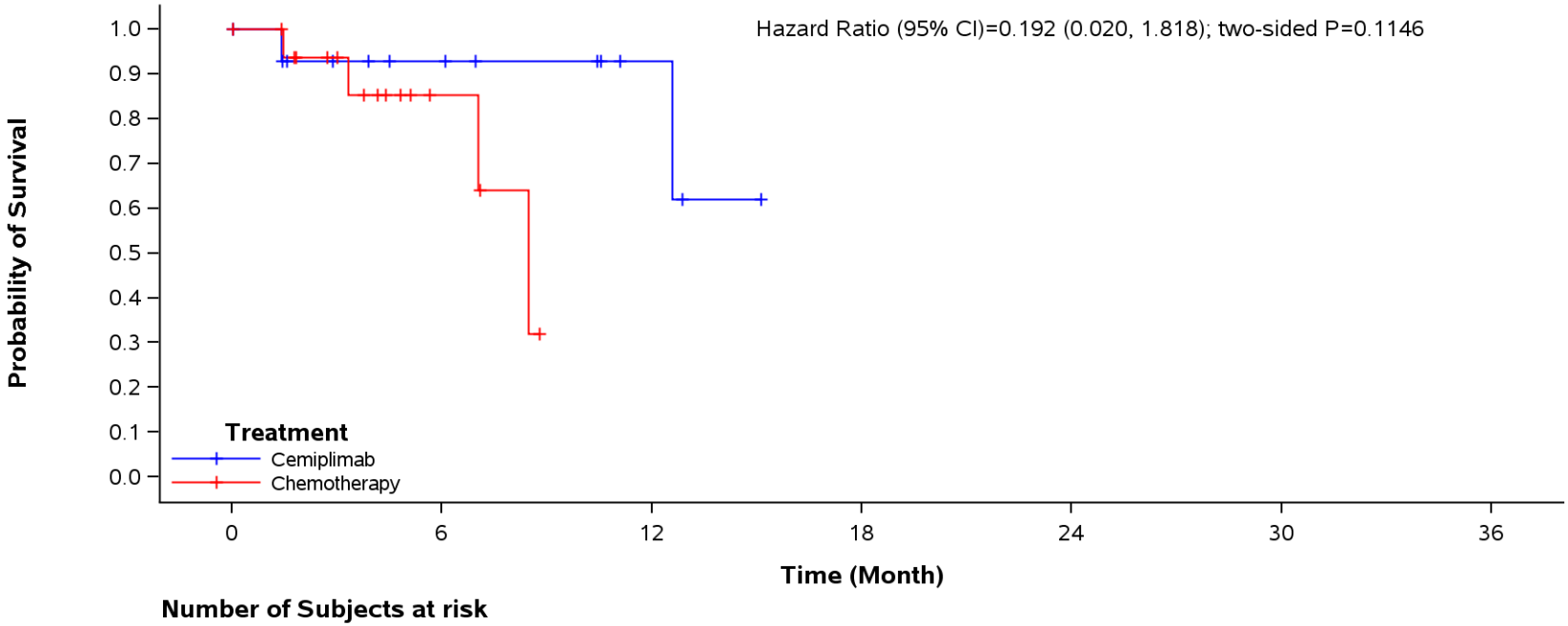
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts sensitivity sustained improvement



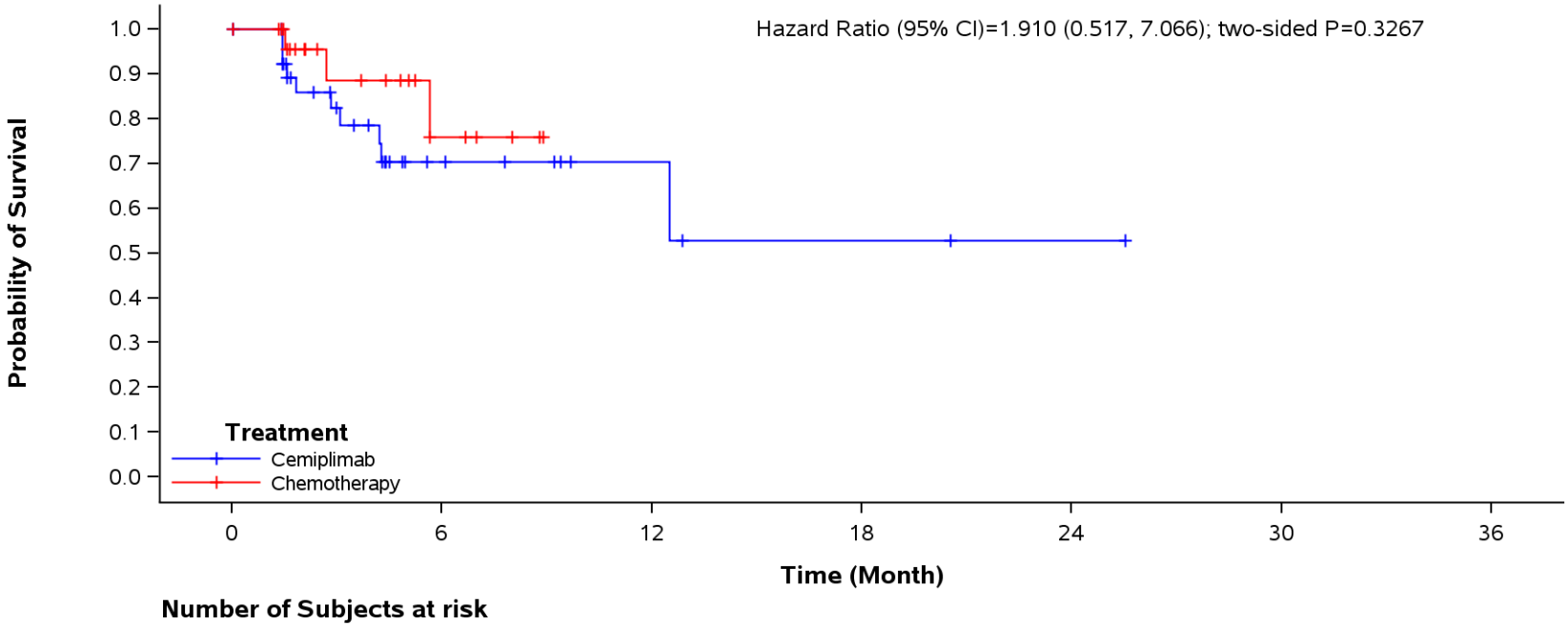

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Appetite loss - 10 pts sensitivity sustained improvement




Number of Subjects at risk

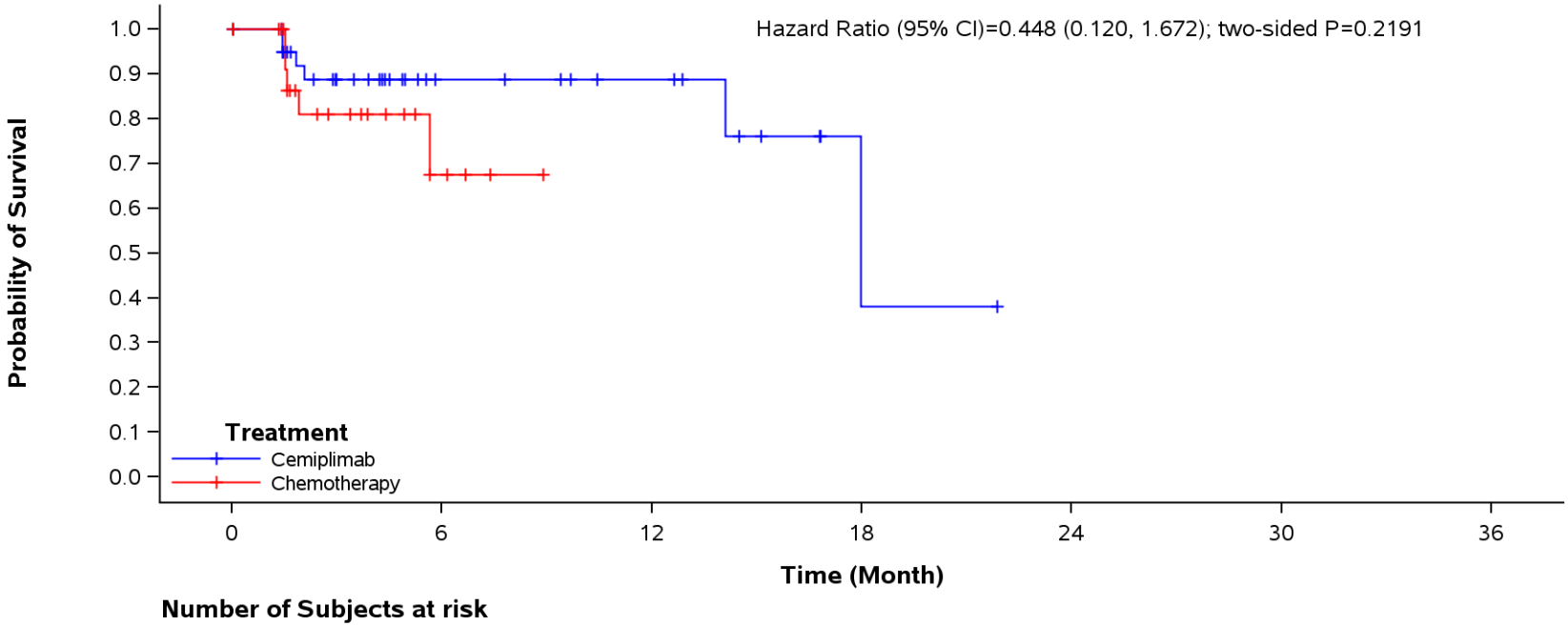
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 9 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 85 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Cognitive Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

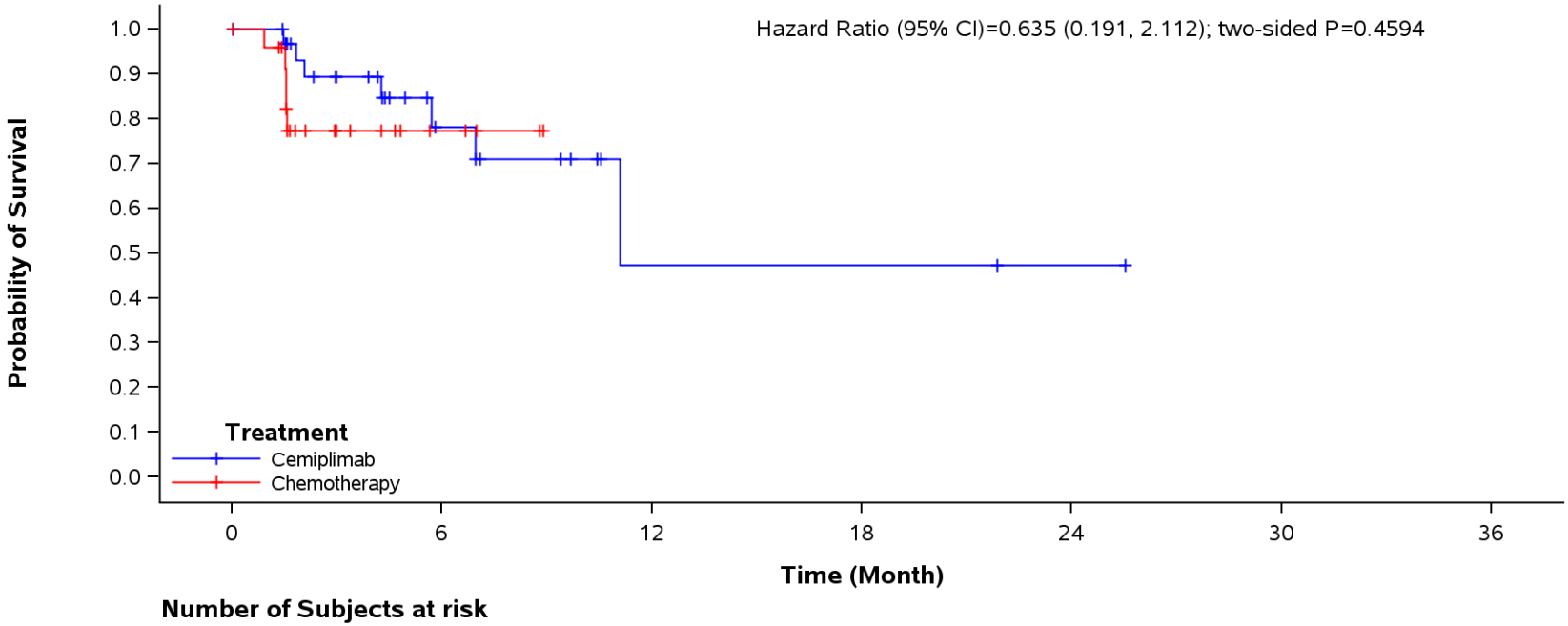
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 13 | 9 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Constipation - 10 pts sensitivity sustained improvement



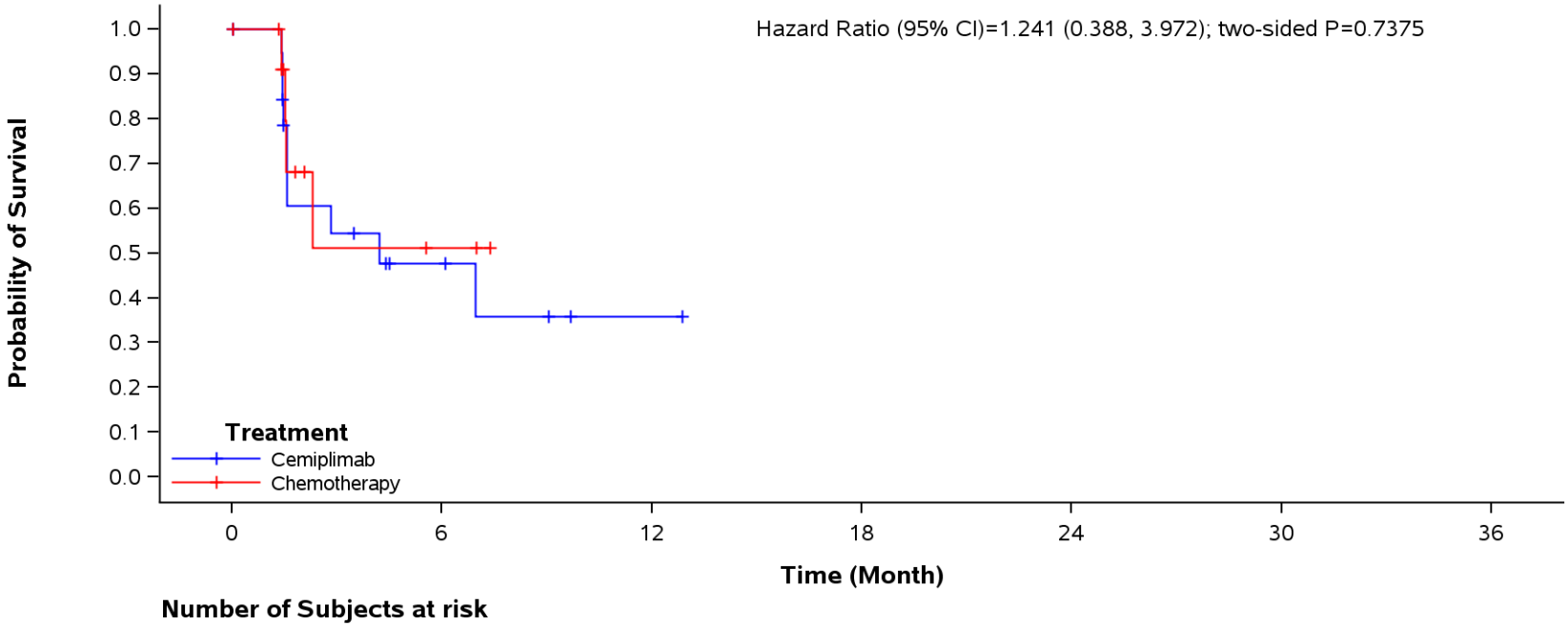

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 11 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 85 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts sensitivity sustained improvement




Number of Subjects at risk

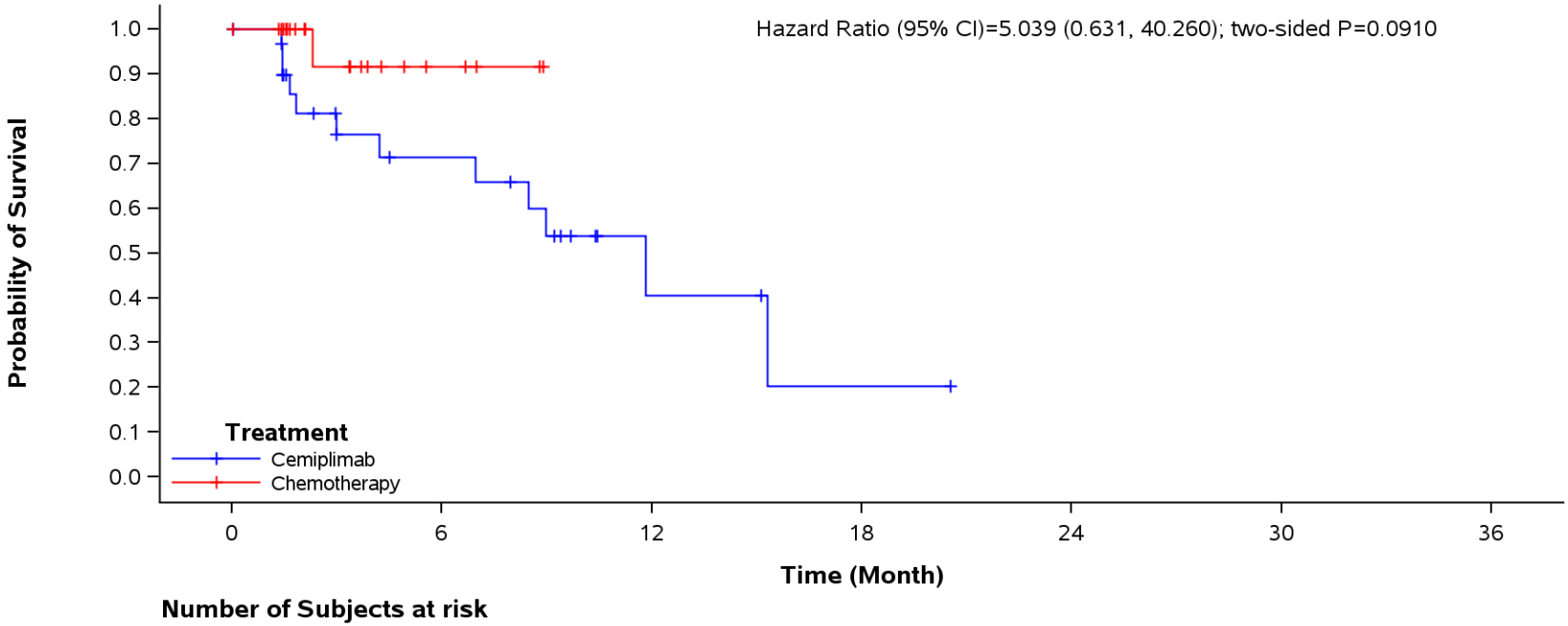
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 85 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Dyspnoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 13 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 85 | 4 | 0 | 0 | 0 | 0 | 0 |

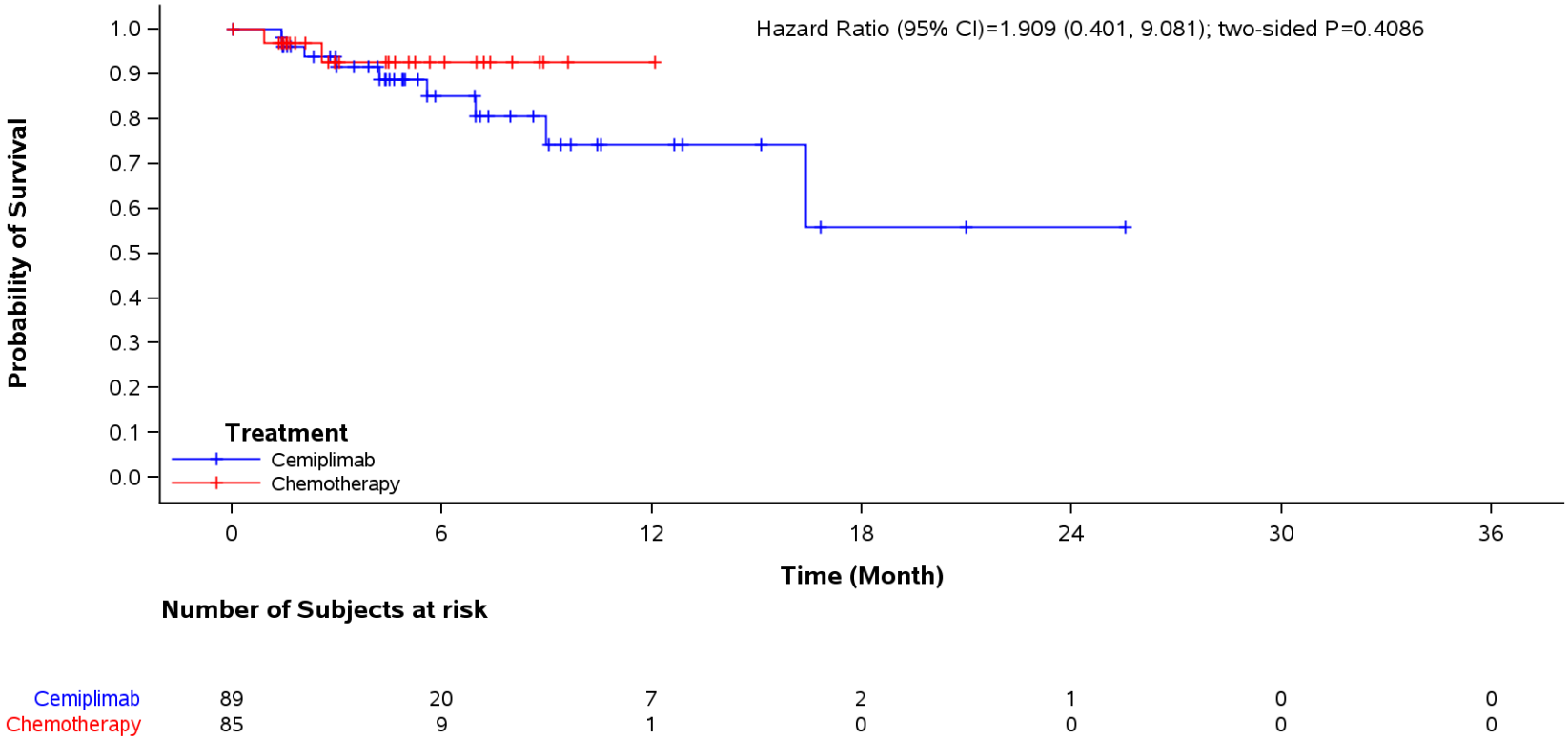
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Emotional Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

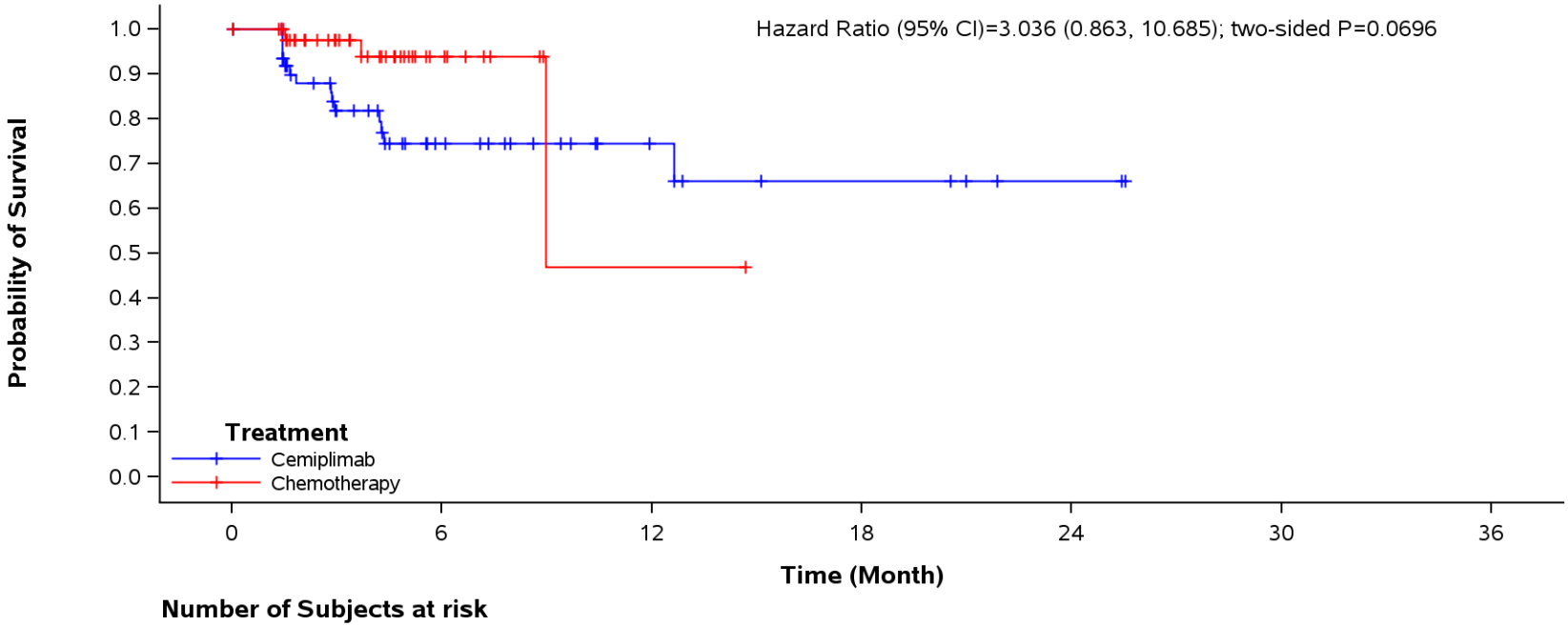
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 20 | 7 | 2 | 1 | 0 | 0 |
| Chemotherapy | 85 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts sensitivity sustained improvement




Number of Subjects at risk

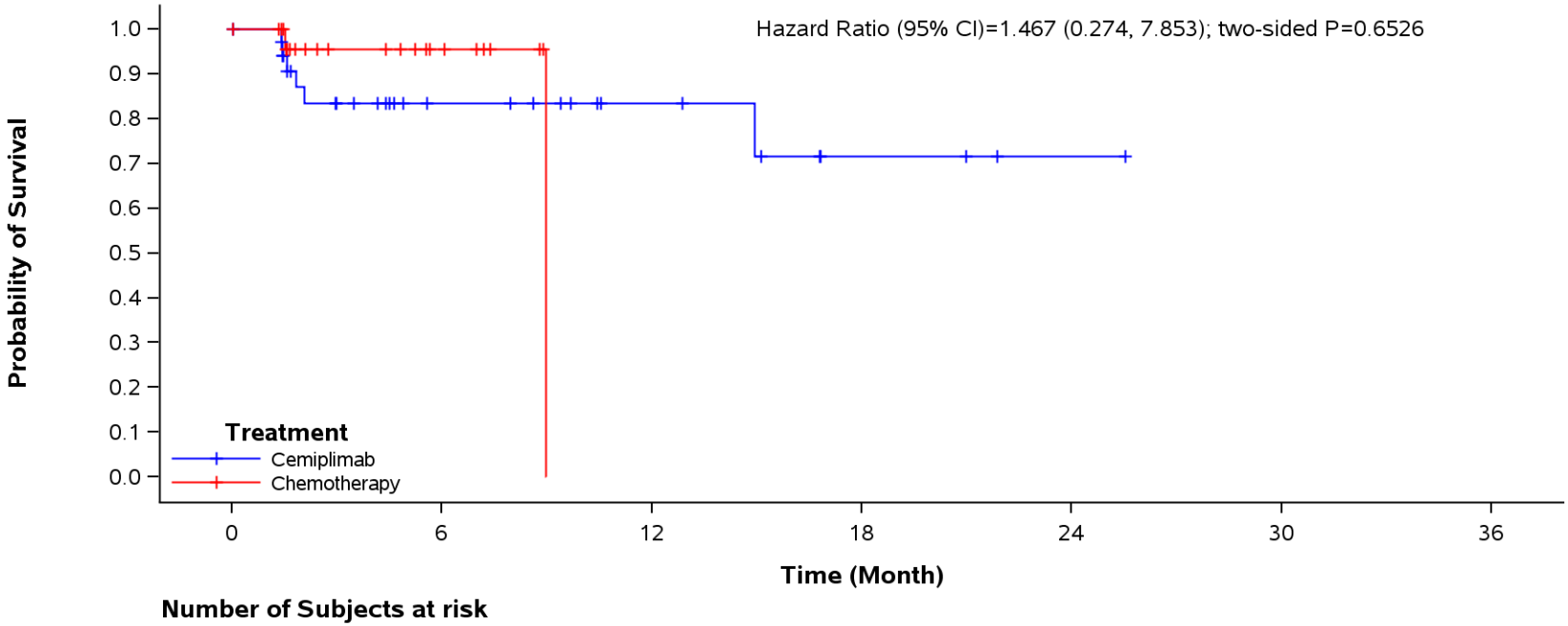
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 21 | 9 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

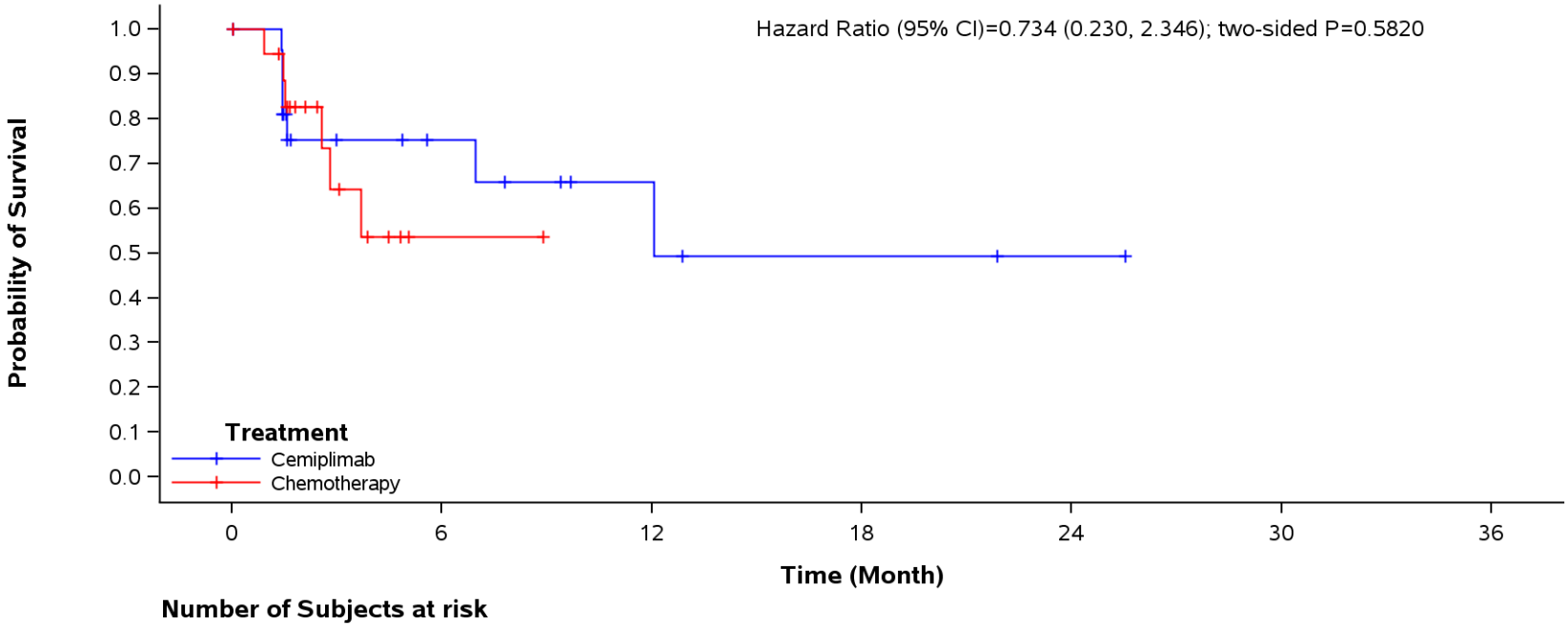
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 14 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 85 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Nausea / Vomiting - 10 pts sensitivity sustained improvement



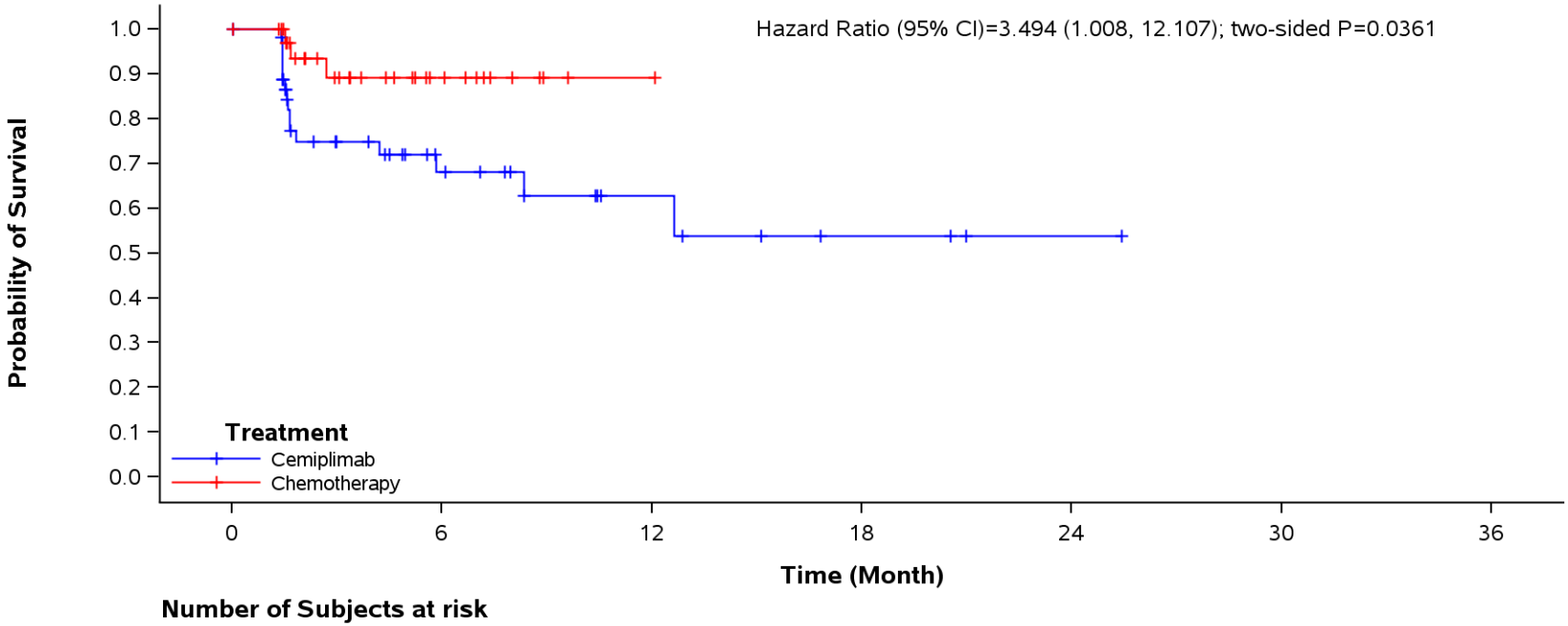

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 8 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 85 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts sensitivity sustained improvement




Number of Subjects at risk

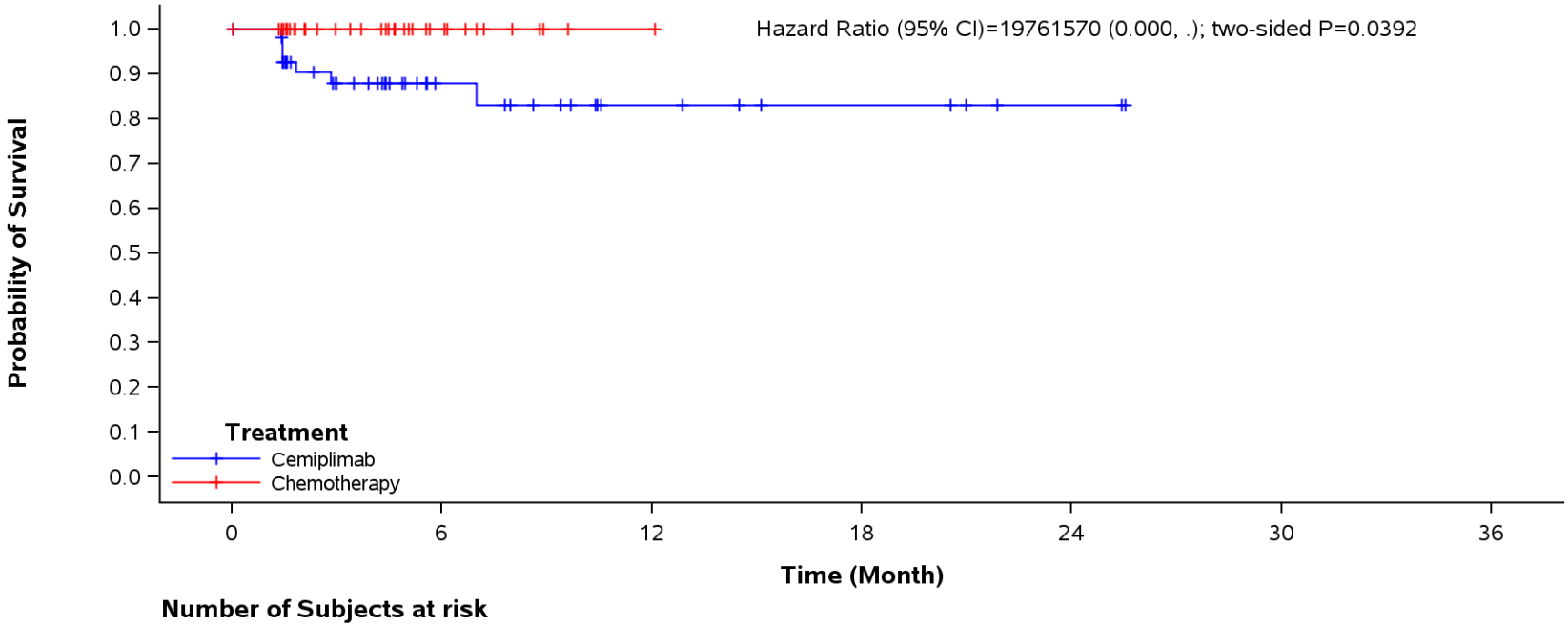
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 17 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Physical Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 18 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

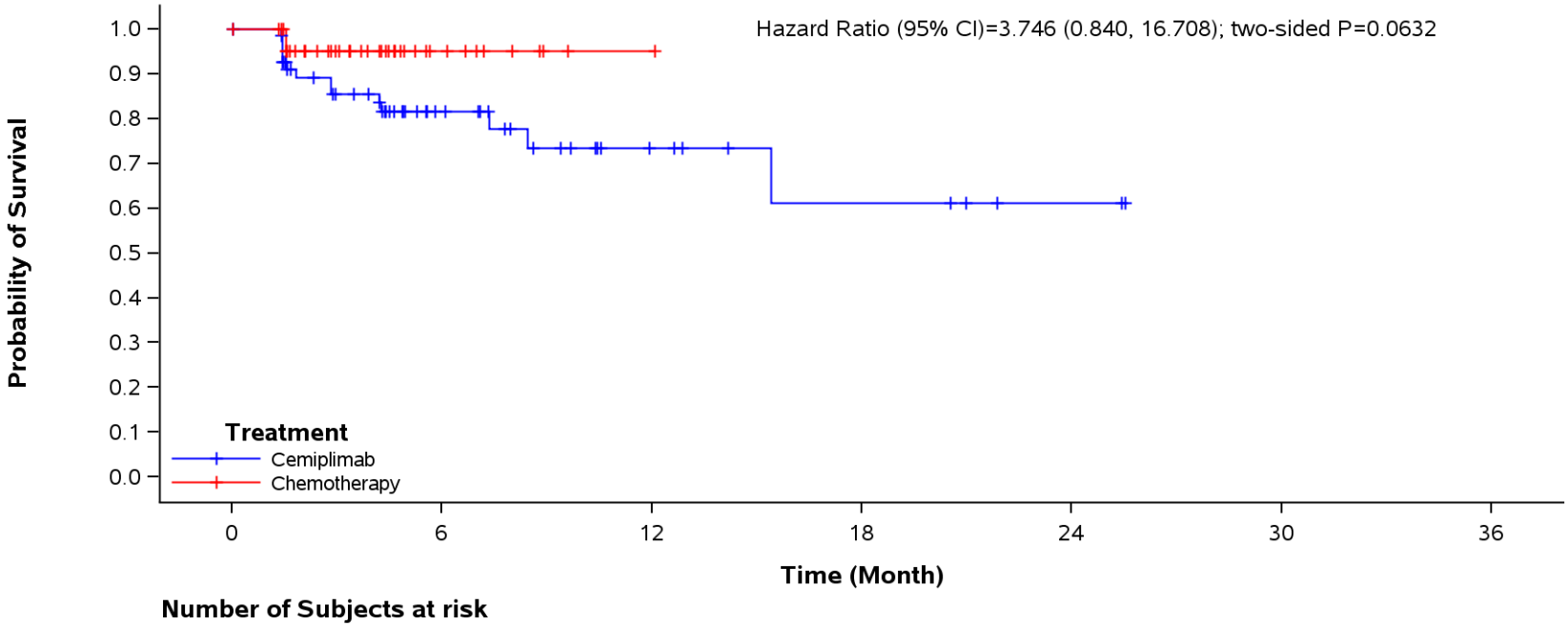
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 25 | 9 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 9 | 1 | 0 | 0 | 0 | 0 |

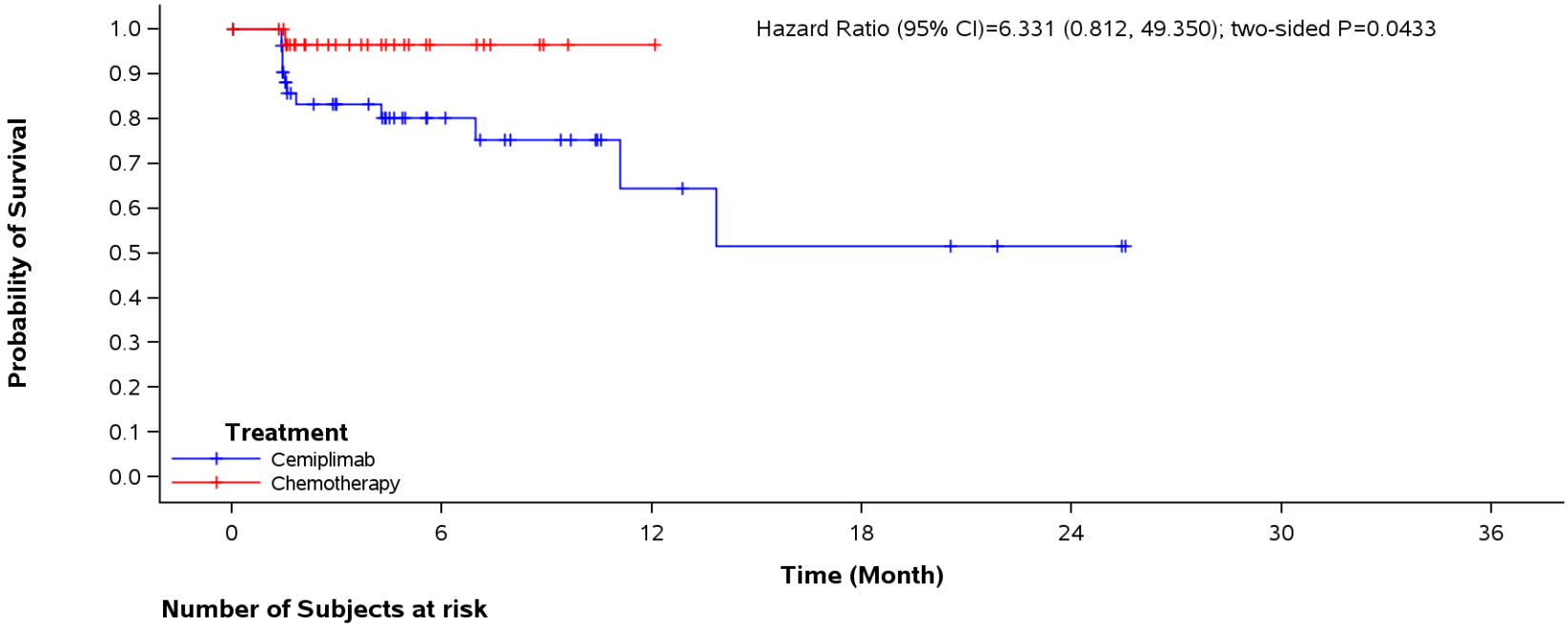
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Role Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 17 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 7 | 1 | 0 | 0 | 0 | 0 |

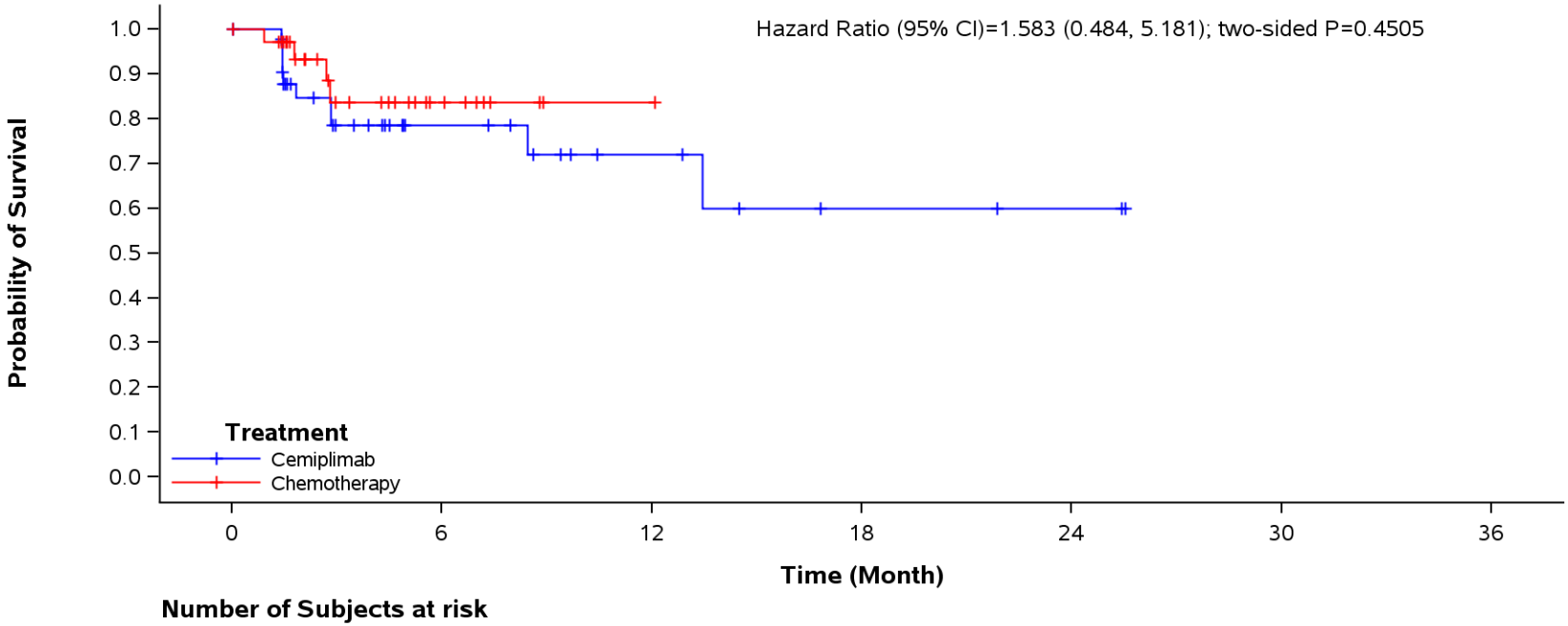
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Social Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

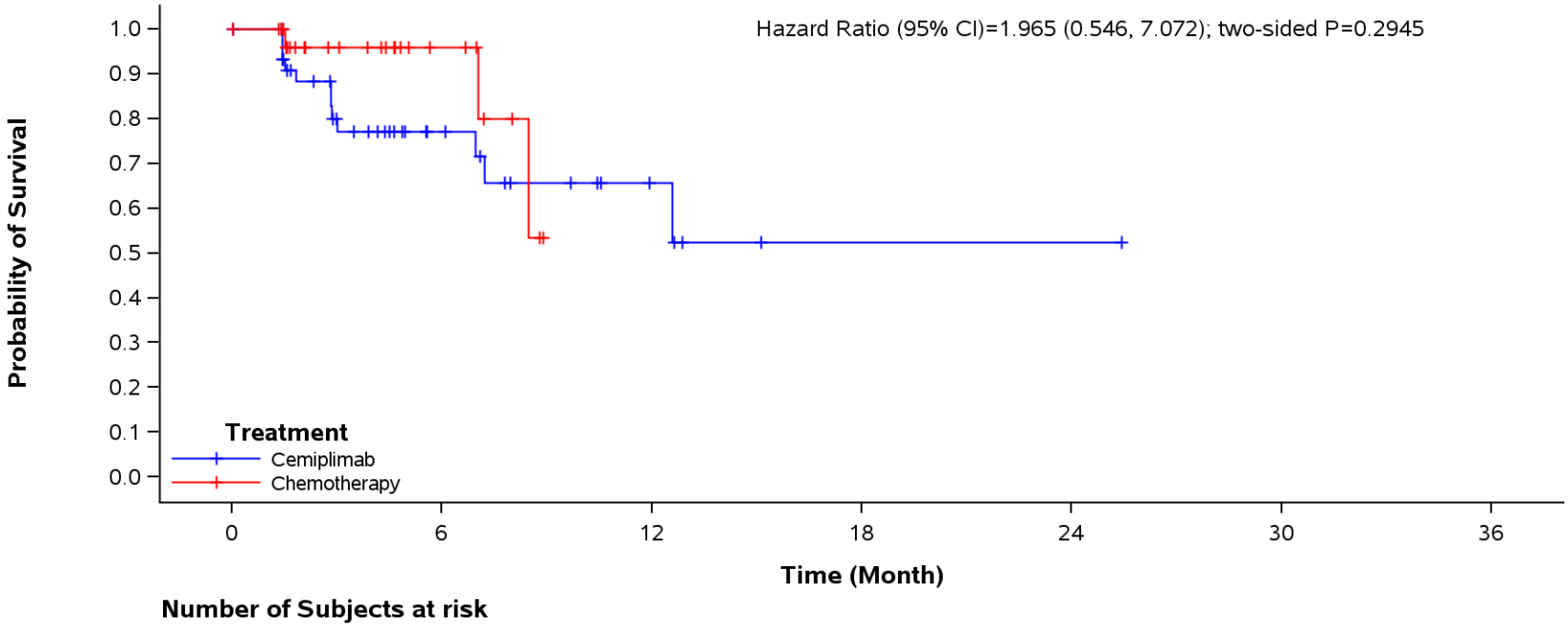
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 14 | 7 | 3 | 2 | 0 | 0 |
| Chemotherapy | 85 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts sensitivity sustained improvement



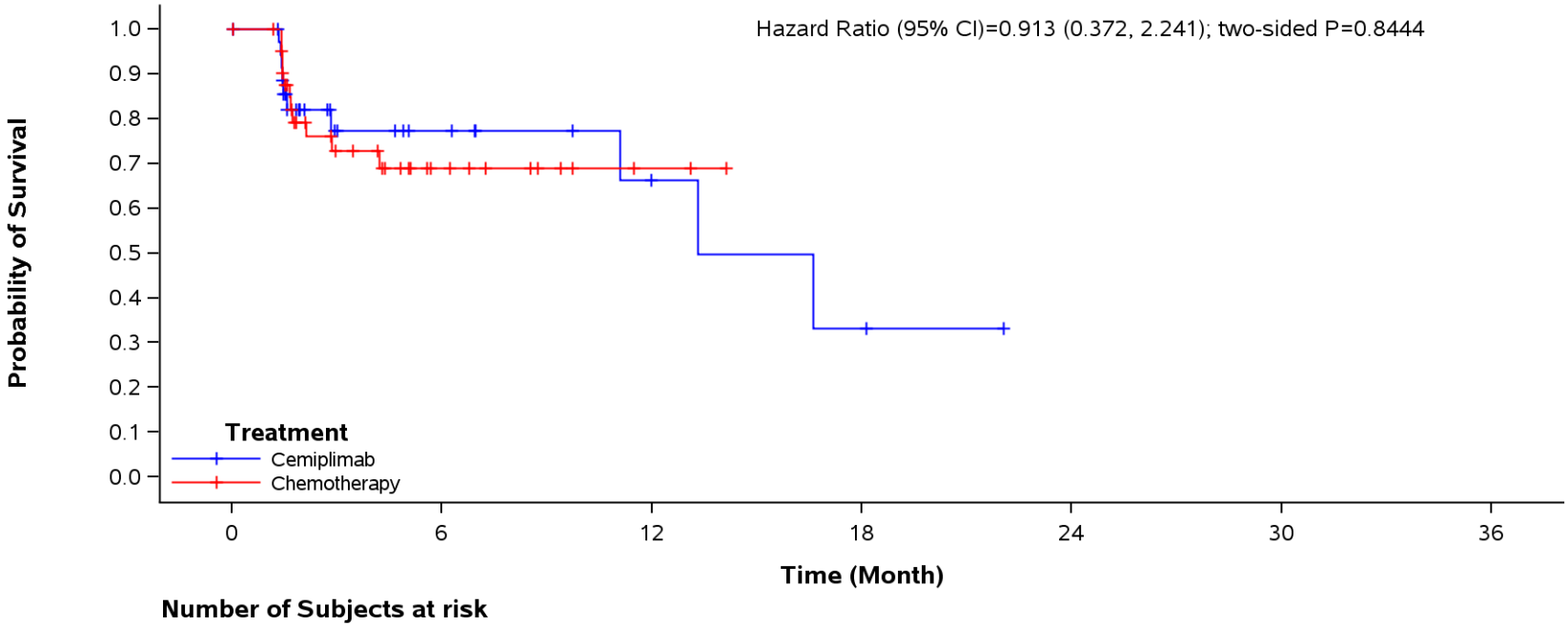

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 15 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 85 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Appetite loss - 10 pts sensitivity sustained improvement




Number of Subjects at risk

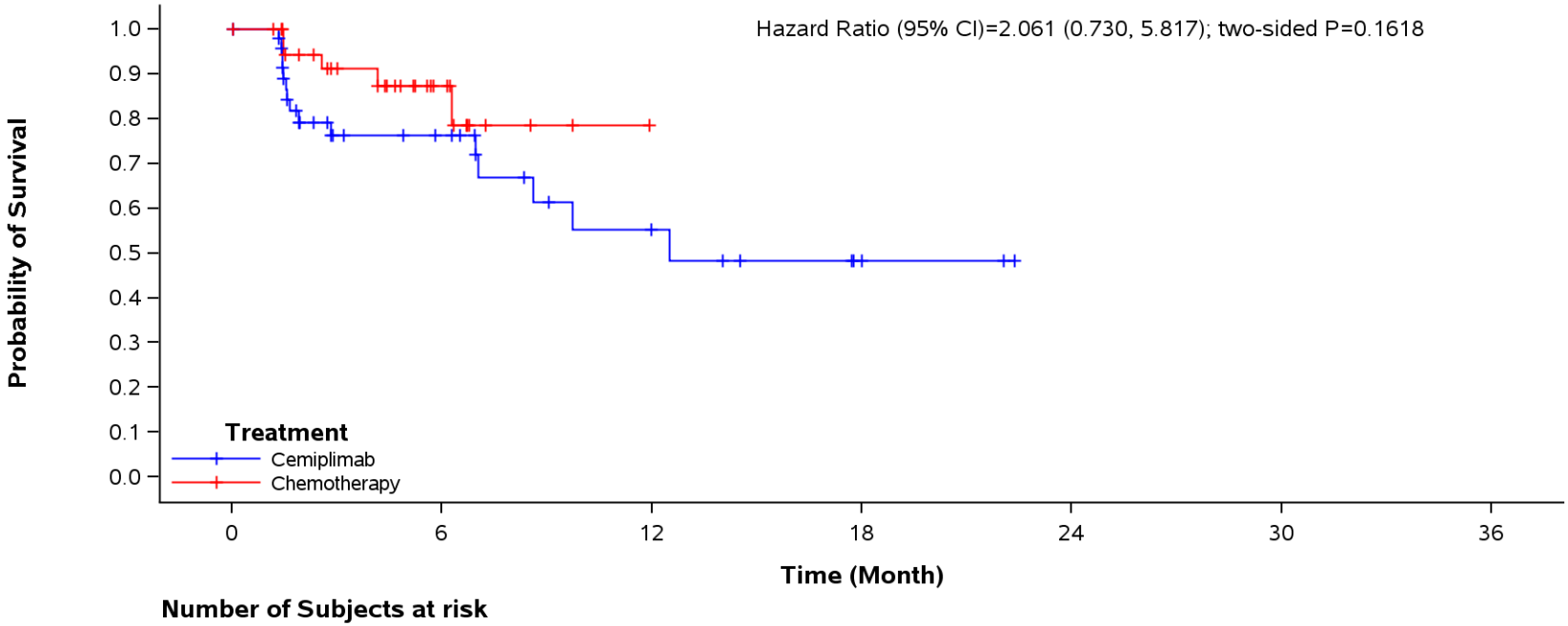
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 11 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 98 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Cognitive Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

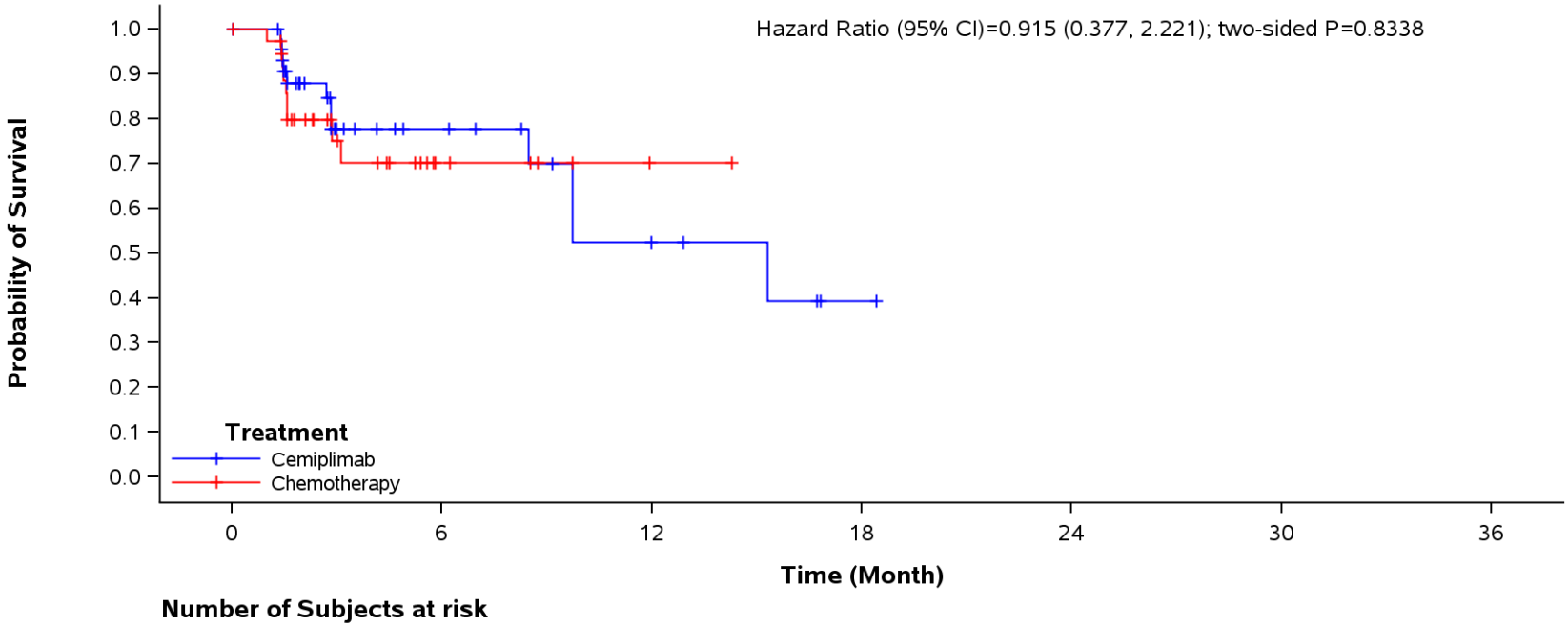
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 21 | 8 | 3 | 0 | 0 | 0 |
| Chemotherapy | 98 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Constipation - 10 pts sensitivity sustained improvement



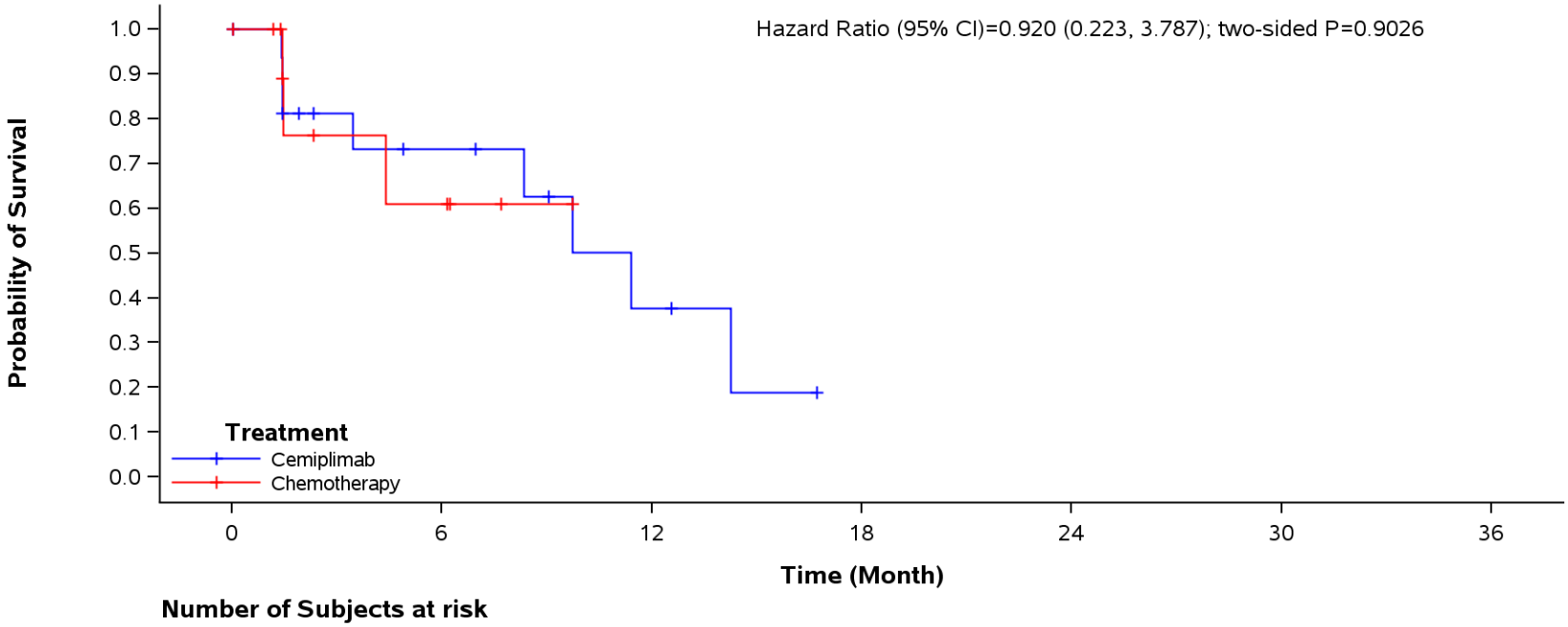

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 13 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Diarhoea - 10 pts sensitivity sustained improvement



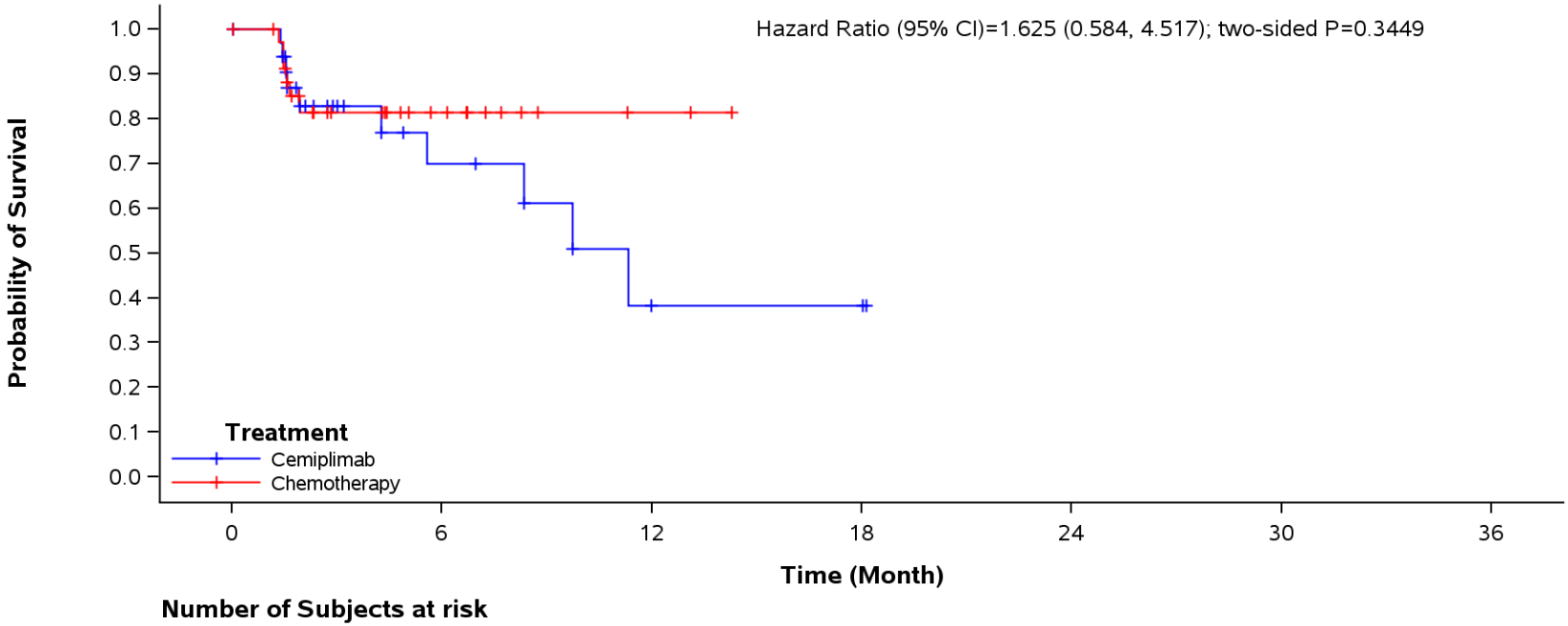

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 98 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Dyspnoea - 10 pts sensitivity sustained improvement



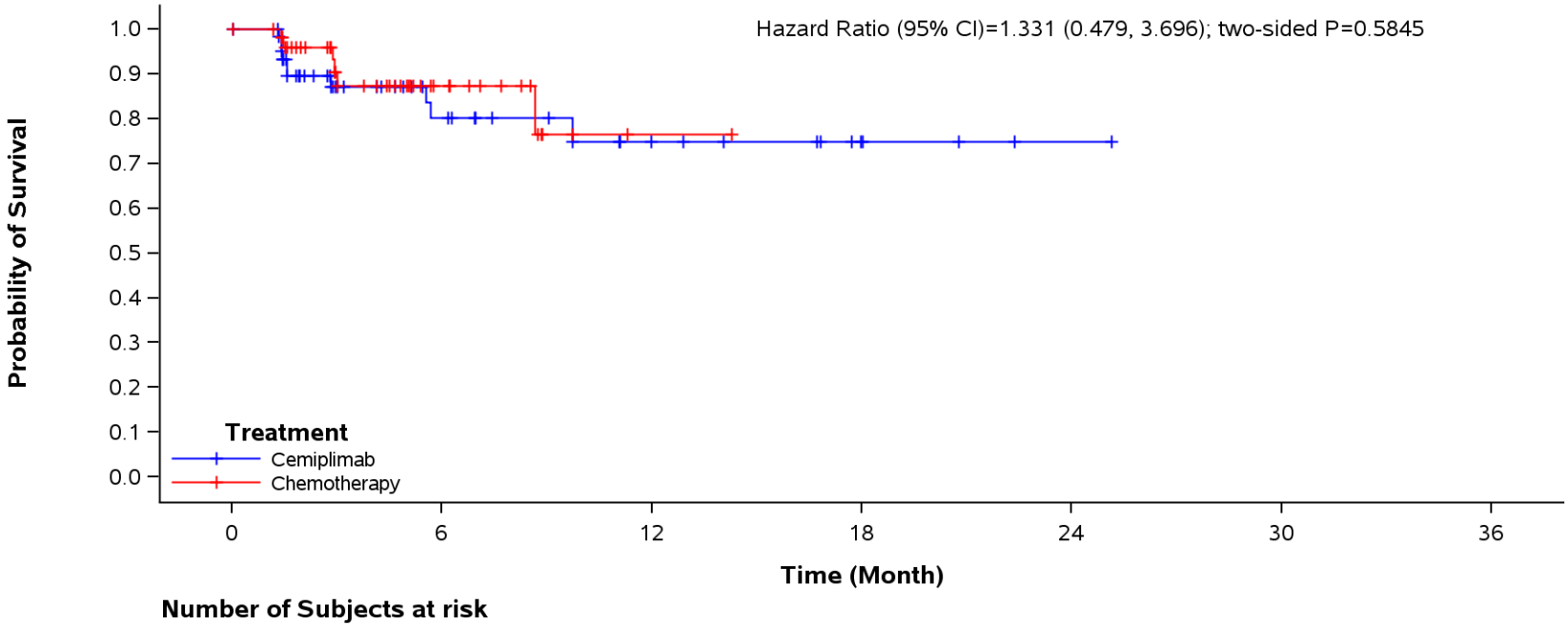

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 10 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 98 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Emotional Functioning - 10 pts sensitivity sustained improvement



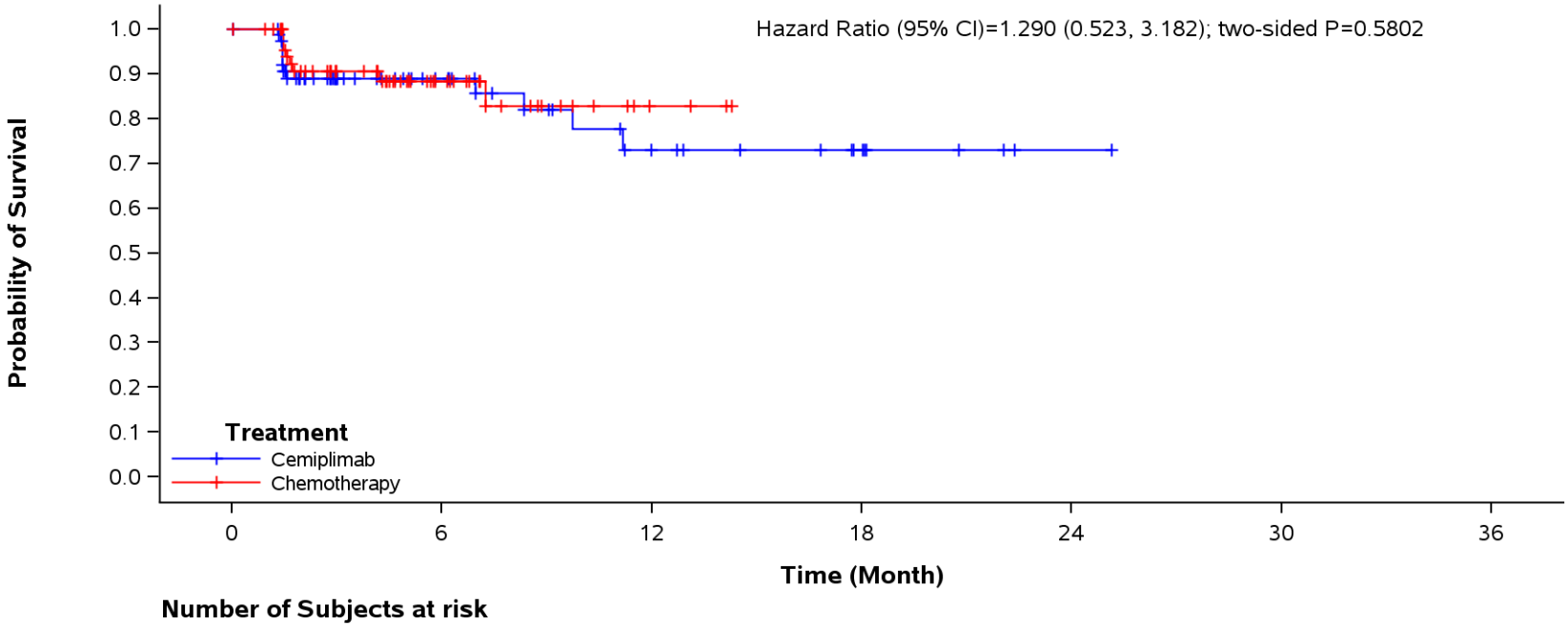

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 23 | 10 | 4 | 1 | 0 | 0 |
| Chemotherapy | 98 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts sensitivity sustained improvement



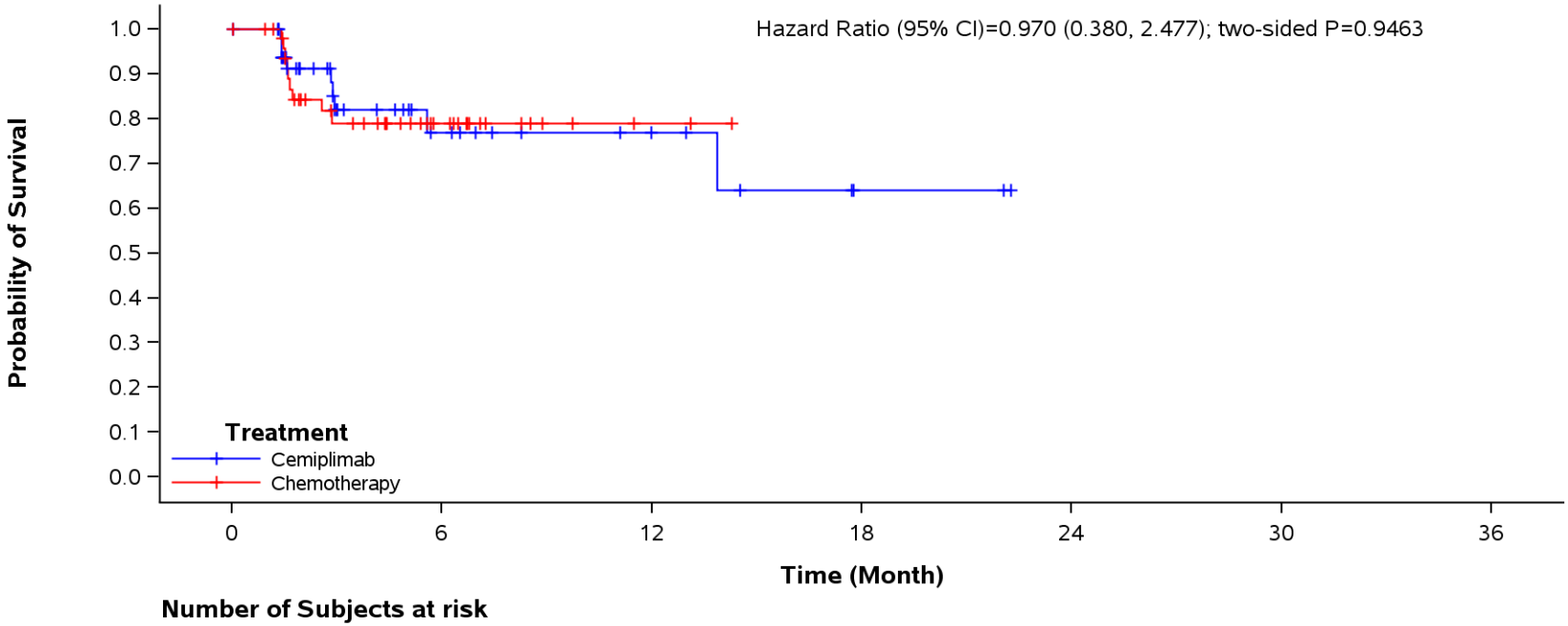

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 31 | 13 | 7 | 1 | 0 | 0 |
| Chemotherapy | 98 | 24 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Financial Problems - 10 pts sensitivity sustained improvement



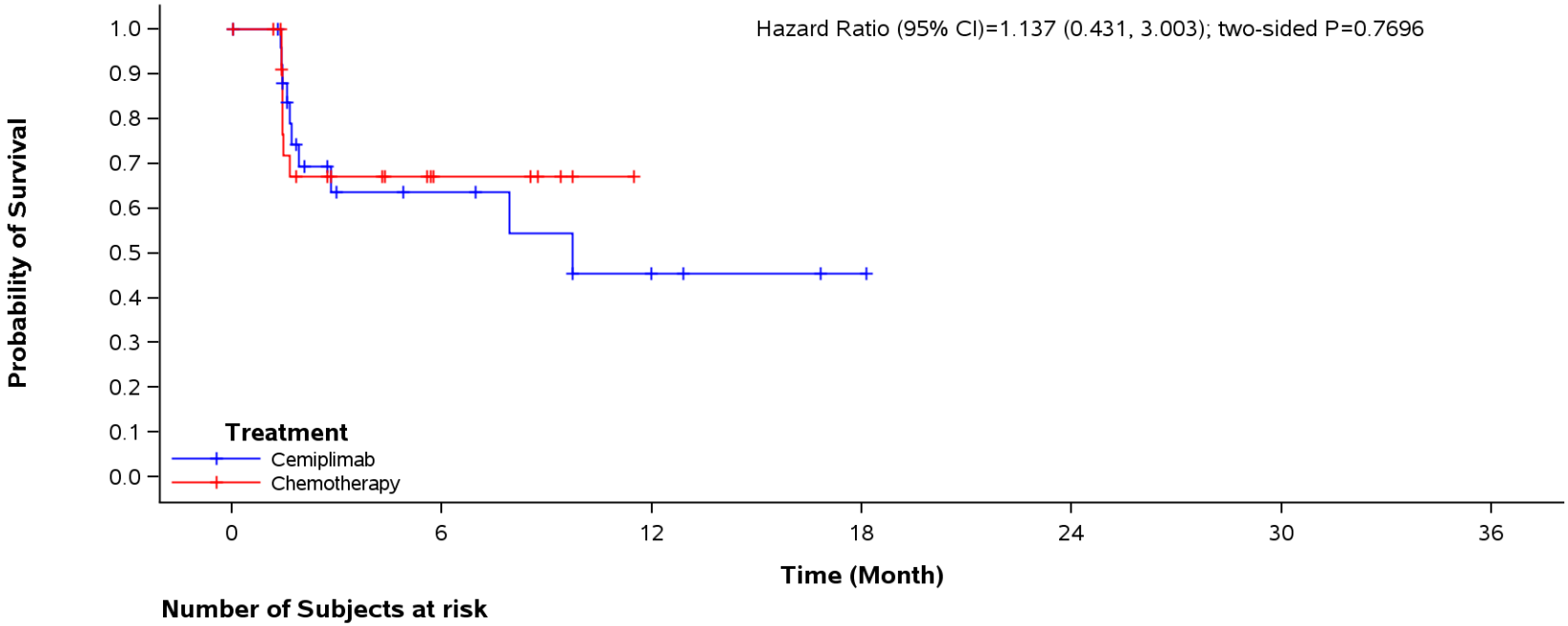

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 14 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 98 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts sensitivity sustained improvement



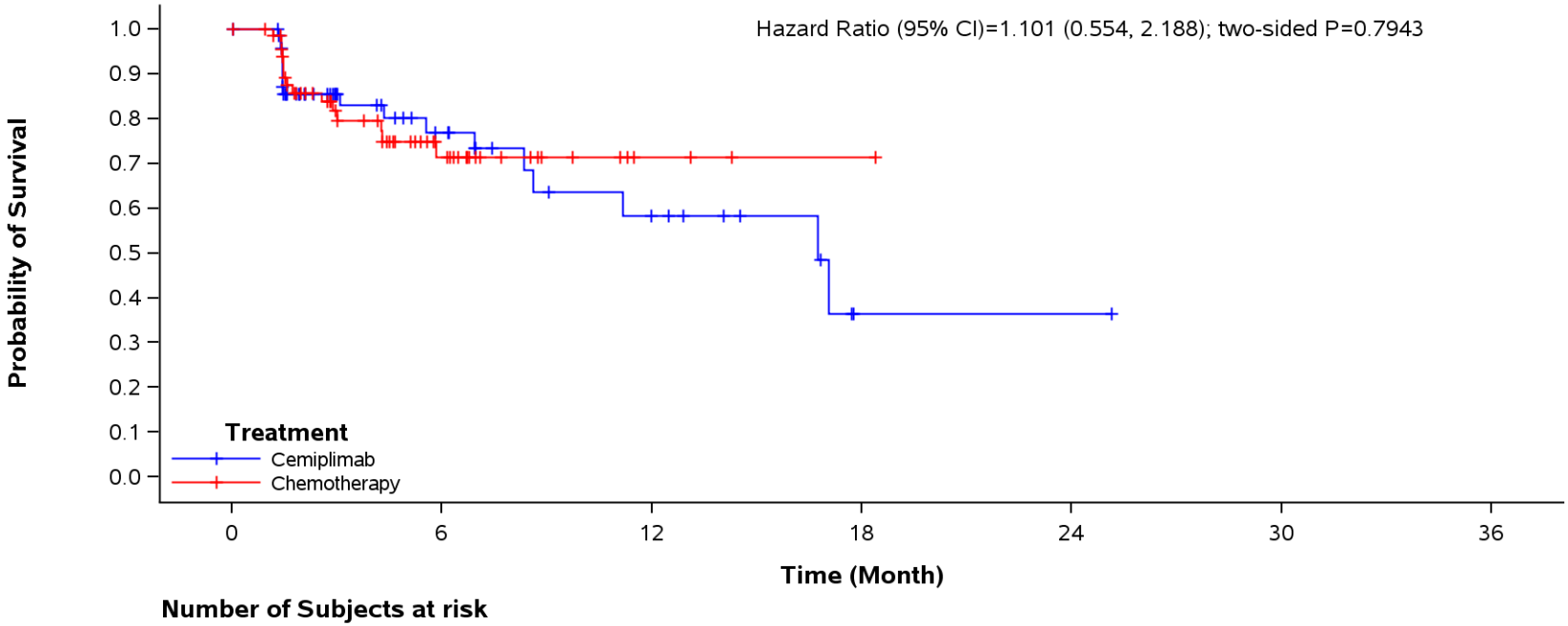

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 8 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

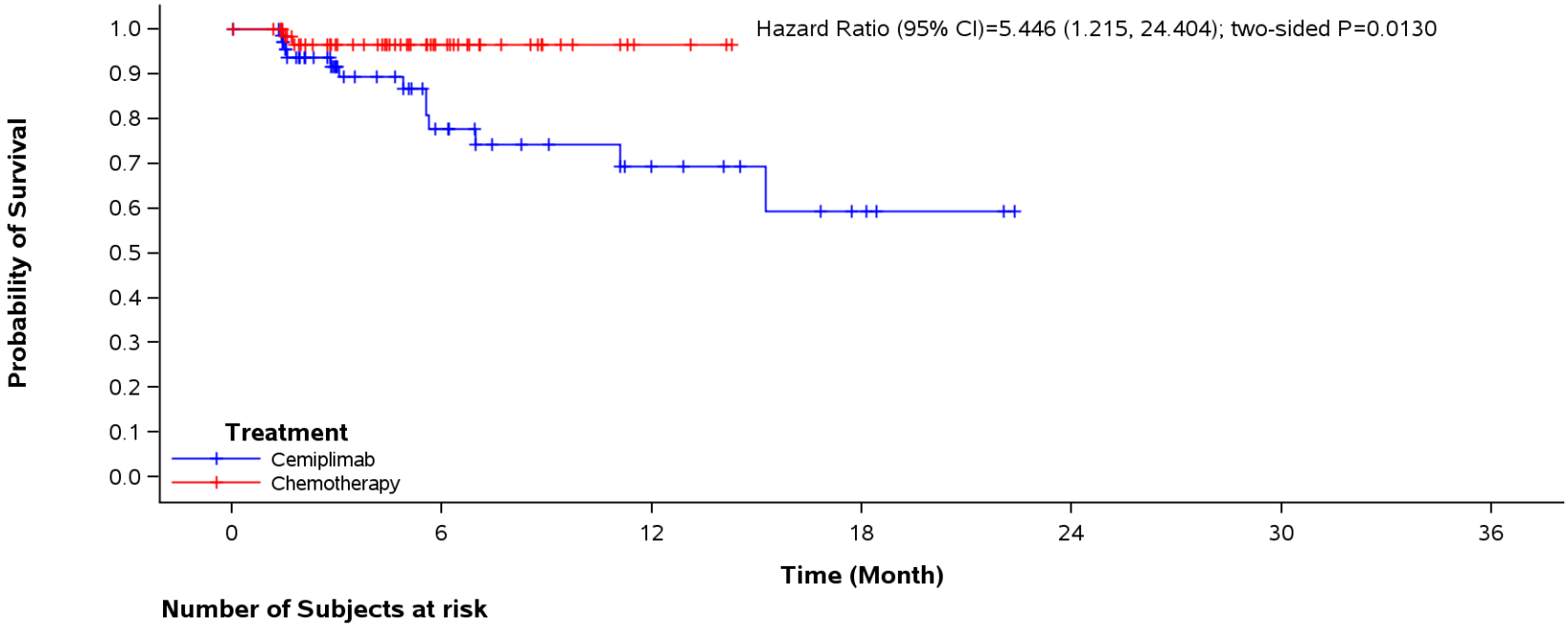
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 23 | 10 | 1 | 1 | 0 | 0 |
| Chemotherapy | 98 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Physical Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 25 | 10 | 4 | 0 | 0 | 0 |
| Chemotherapy | 98 | 22 | 3 | 0 | 0 | 0 | 0 |

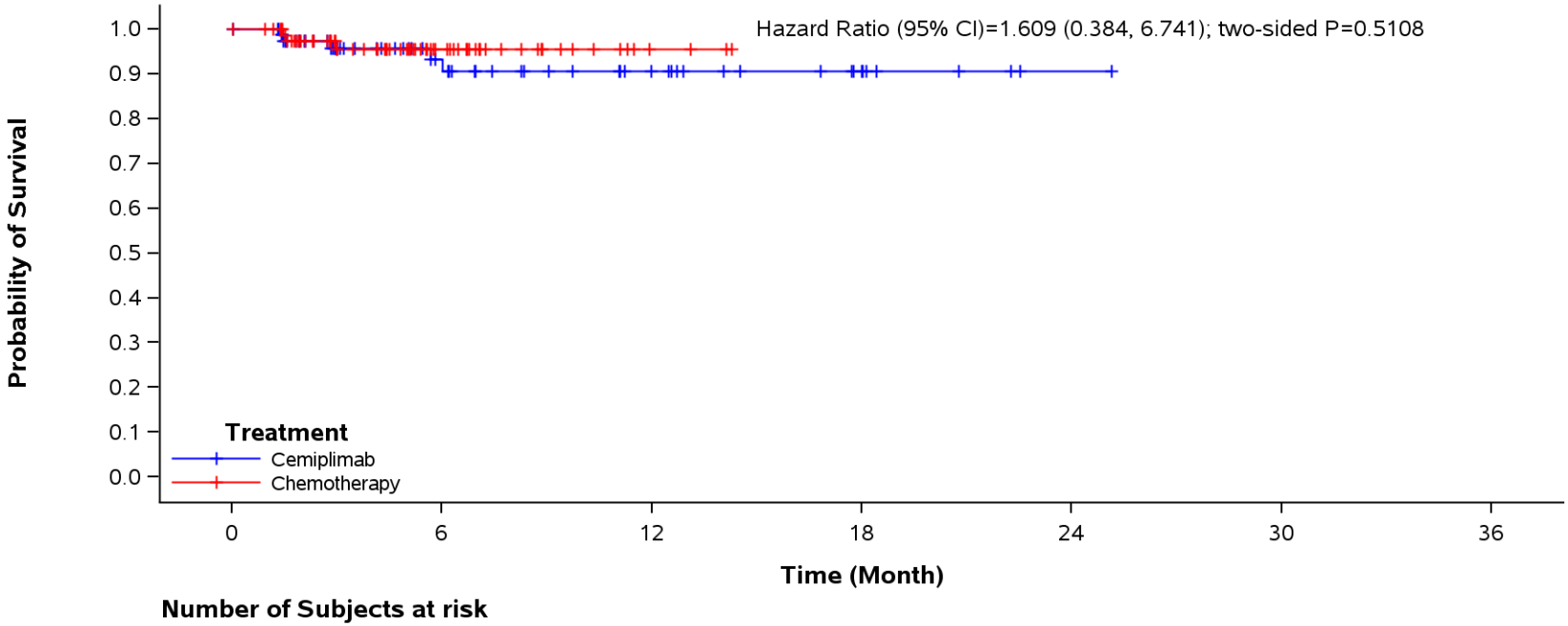
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 35 | 17 | 8 | 1 | 0 | 0 |
| Chemotherapy | 98 | 29 | 3 | 0 | 0 | 0 | 0 |

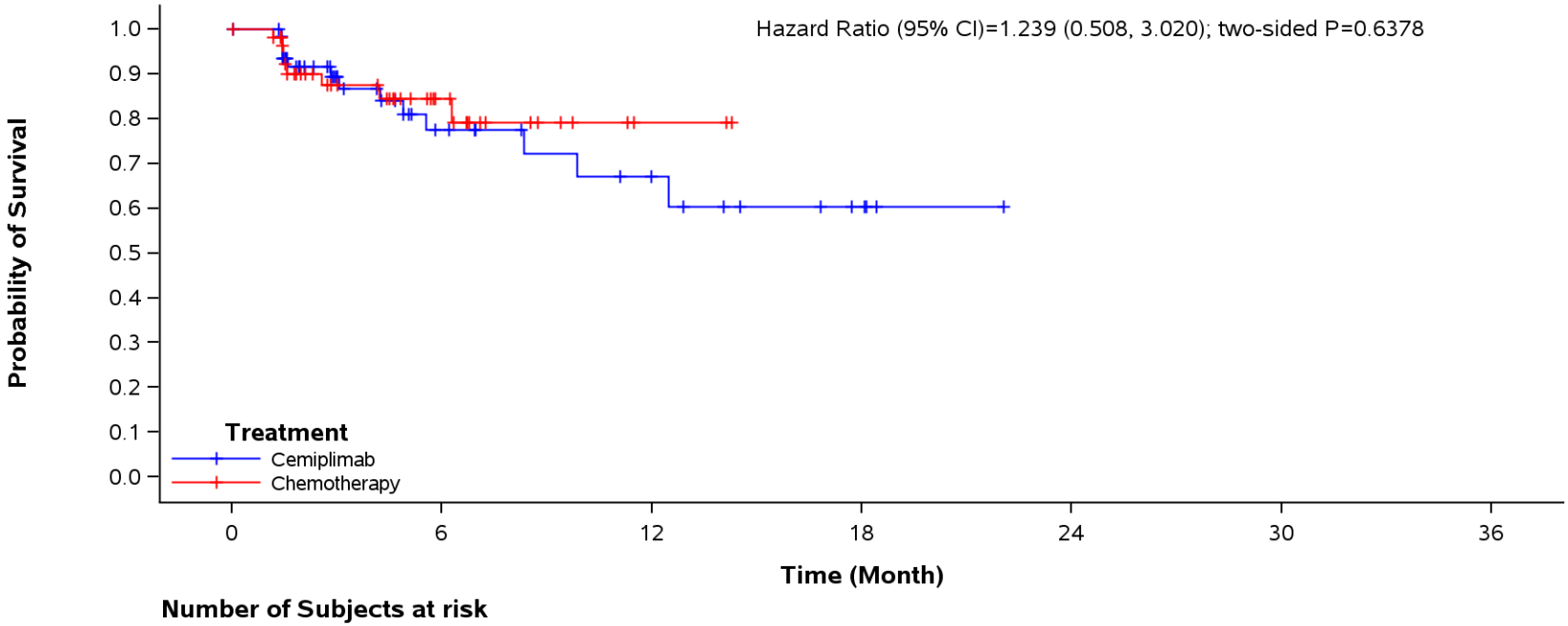
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Role Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 21 | 10 | 4 | 0 | 0 | 0 |
| Chemotherapy | 98 | 17 | 2 | 0 | 0 | 0 | 0 |

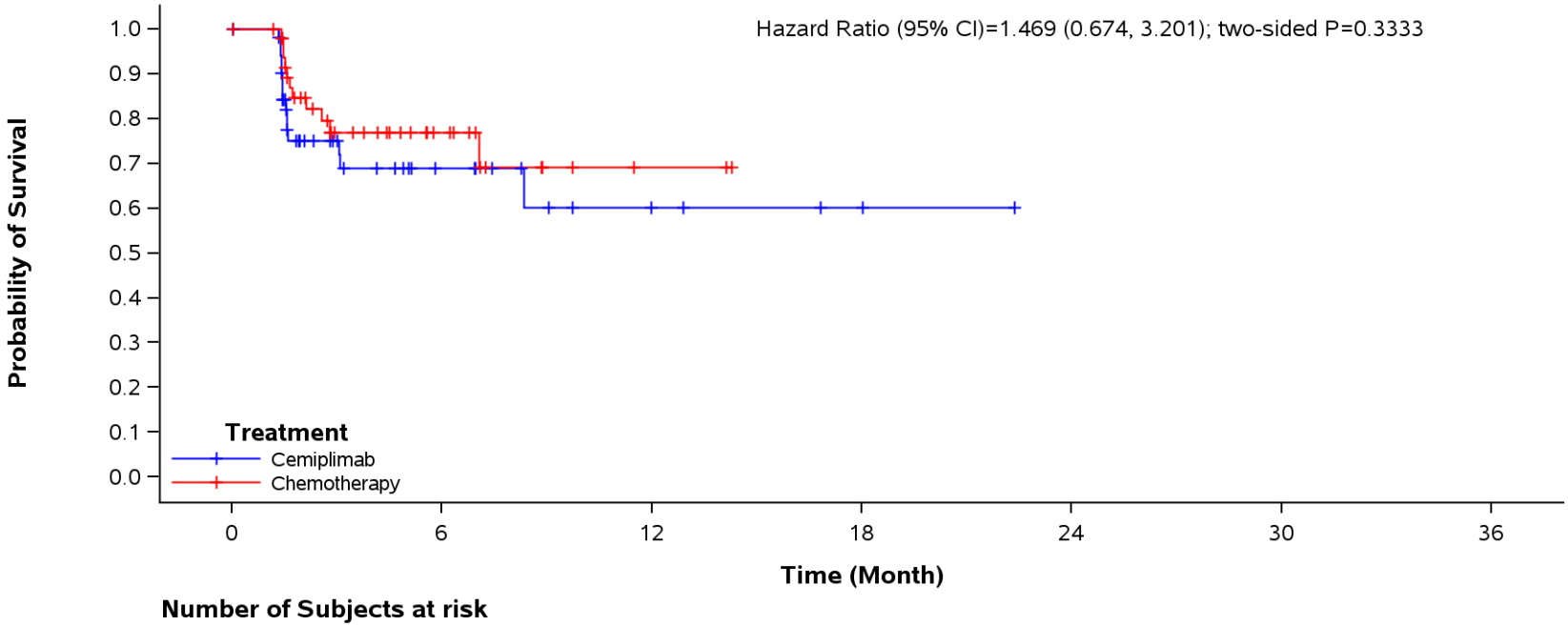
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Social Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

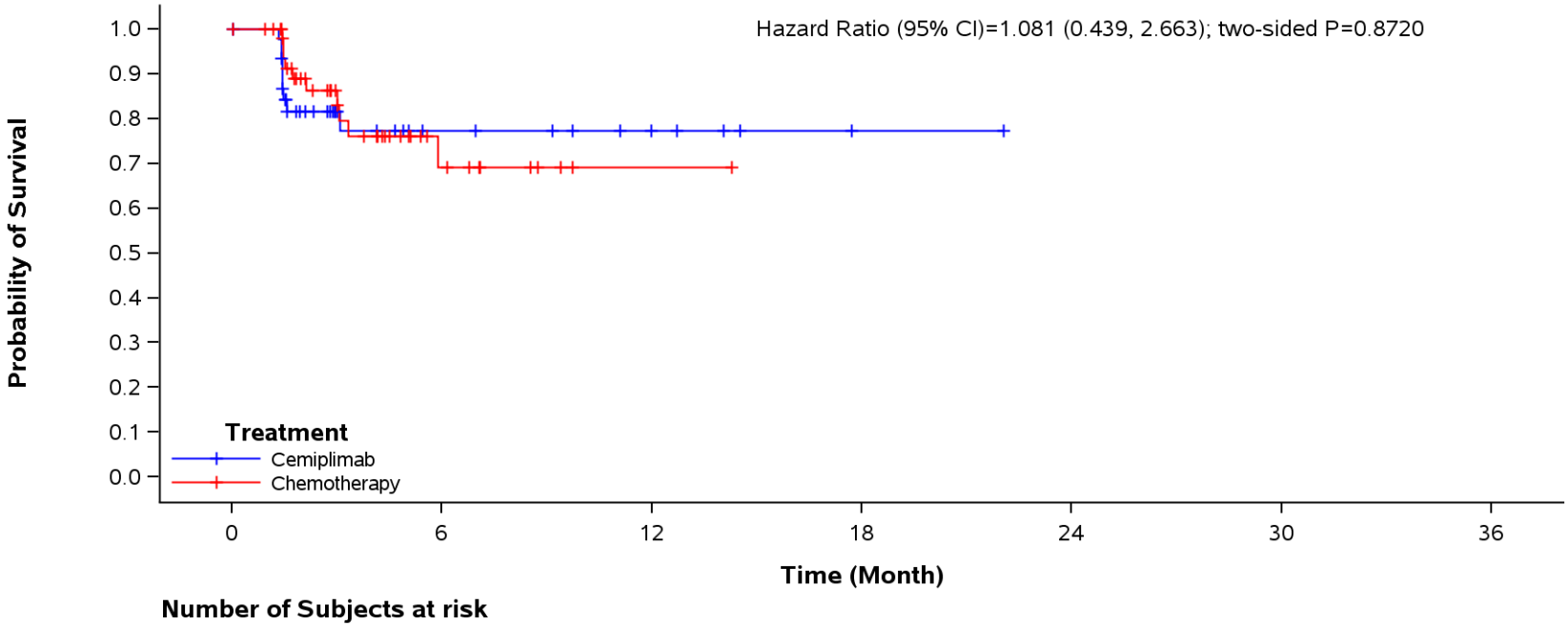
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 14 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 98 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

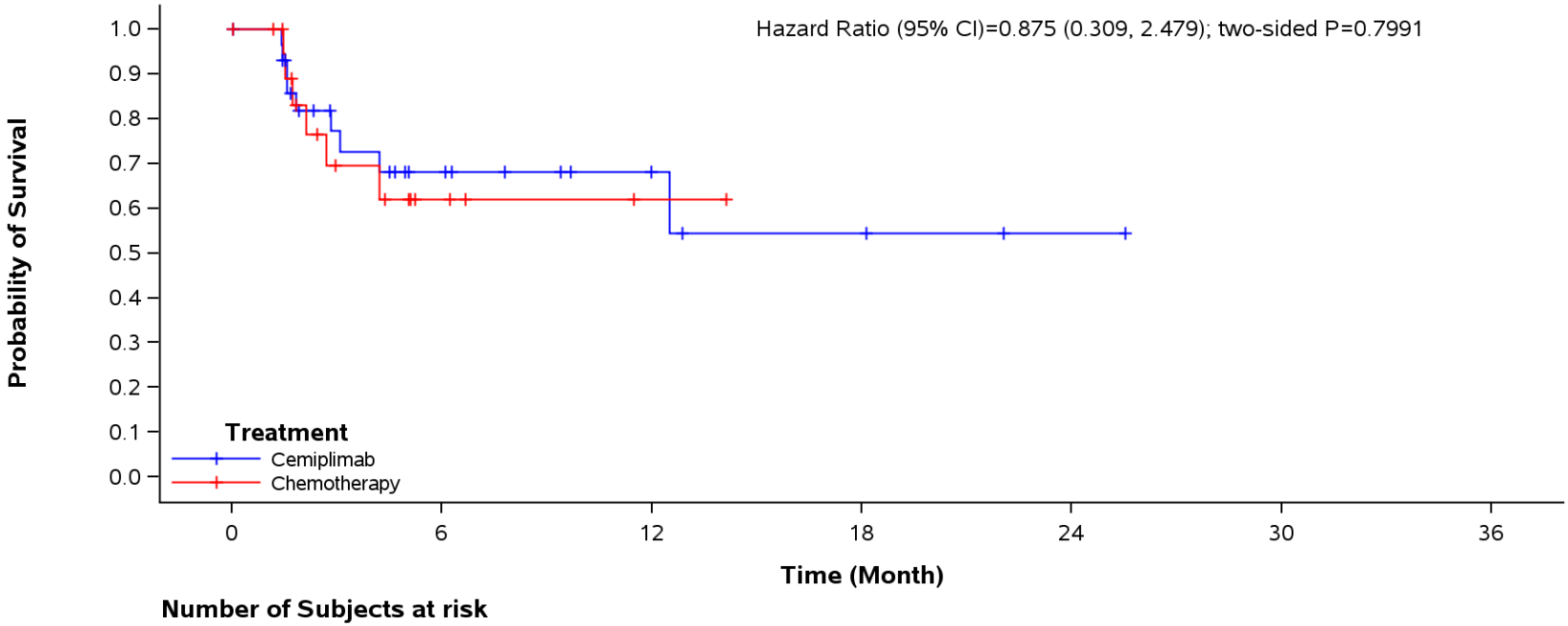
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 12 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 98 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Appetite loss - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 11 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 69 | 4 | 1 | 0 | 0 | 0 | 0 |

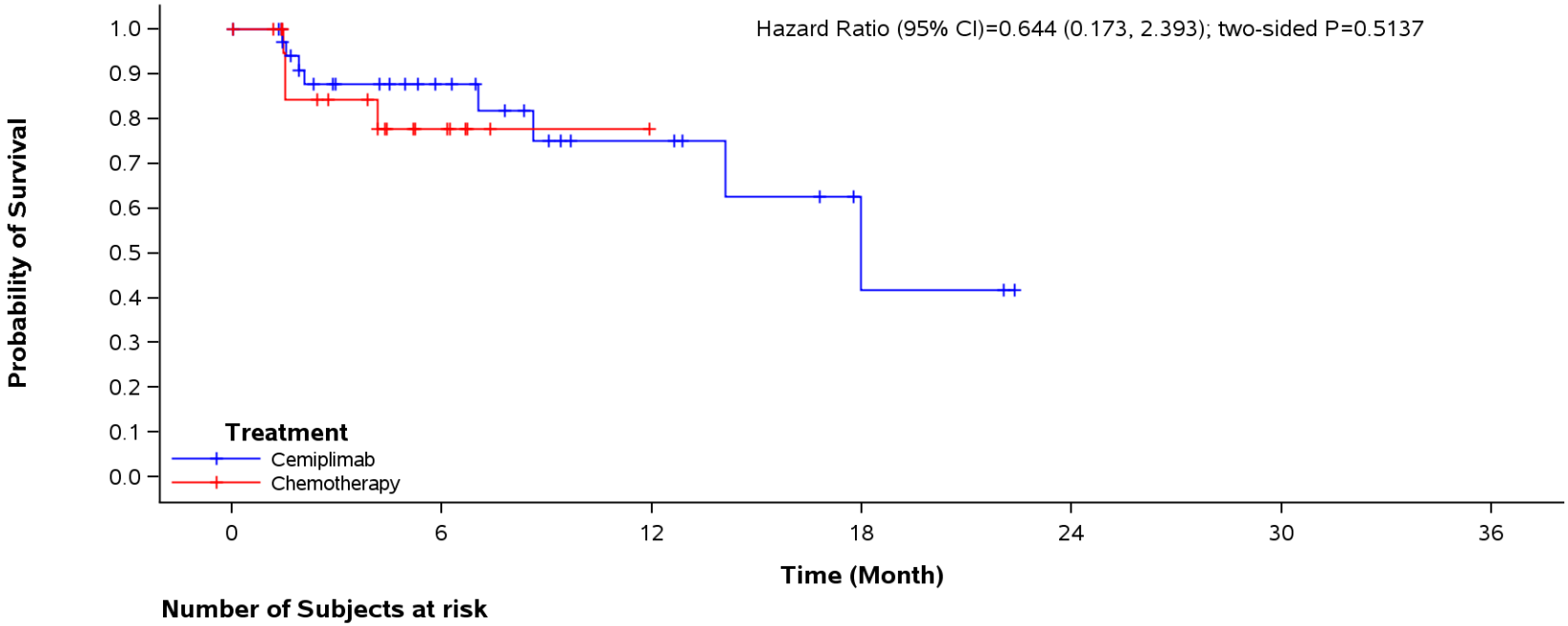
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Cognitive Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 17 | 8 | 2 | 0 | 0 | 0 |
| Chemotherapy | 69 | 6 | 0 | 0 | 0 | 0 | 0 |

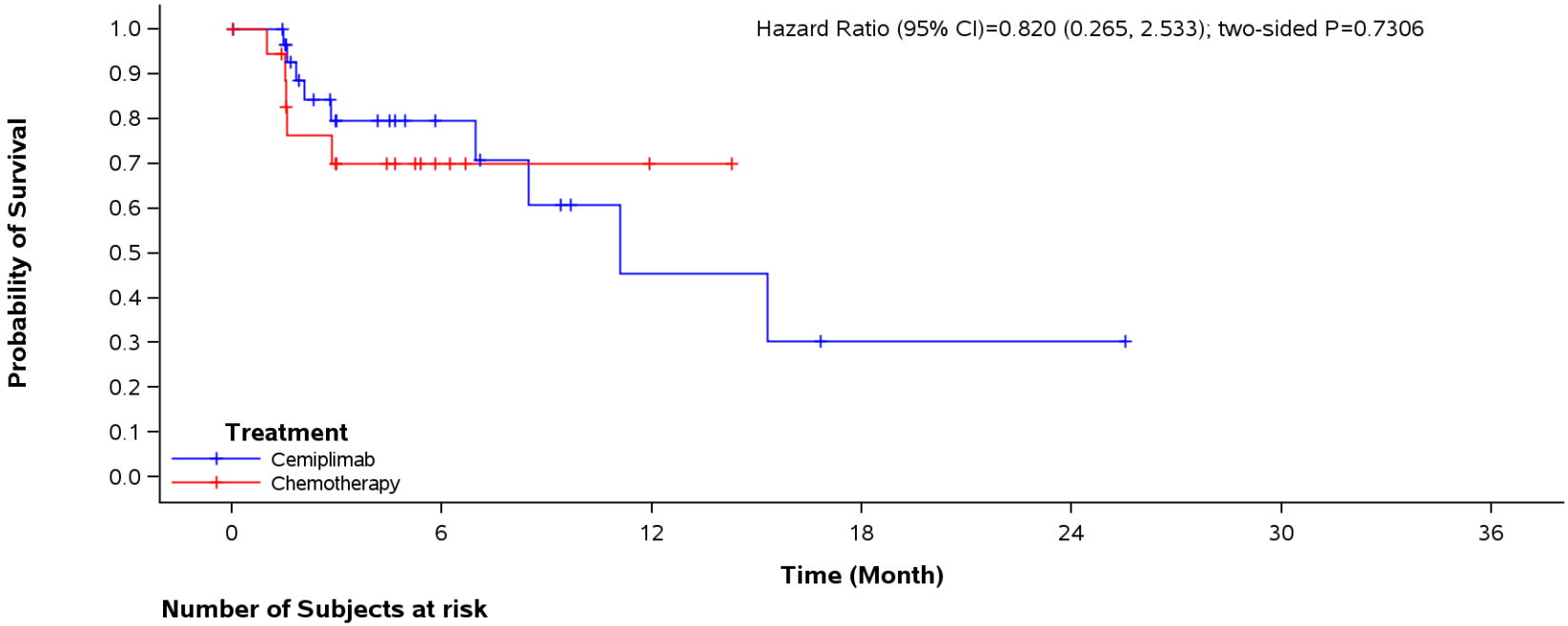
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Constipation - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 9 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 69 | 4 | 1 | 0 | 0 | 0 | 0 |

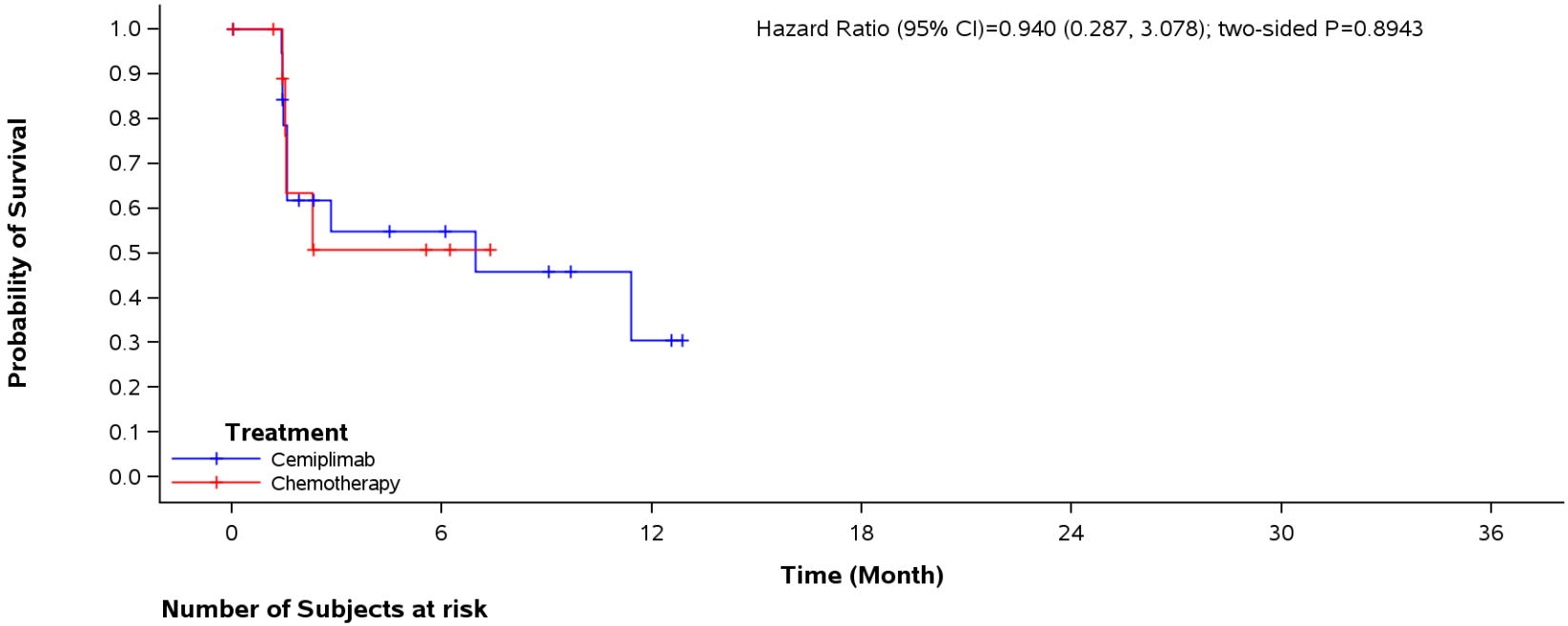
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Diarhoea - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 7 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 69 | 2 | 0 | 0 | 0 | 0 | 0 |

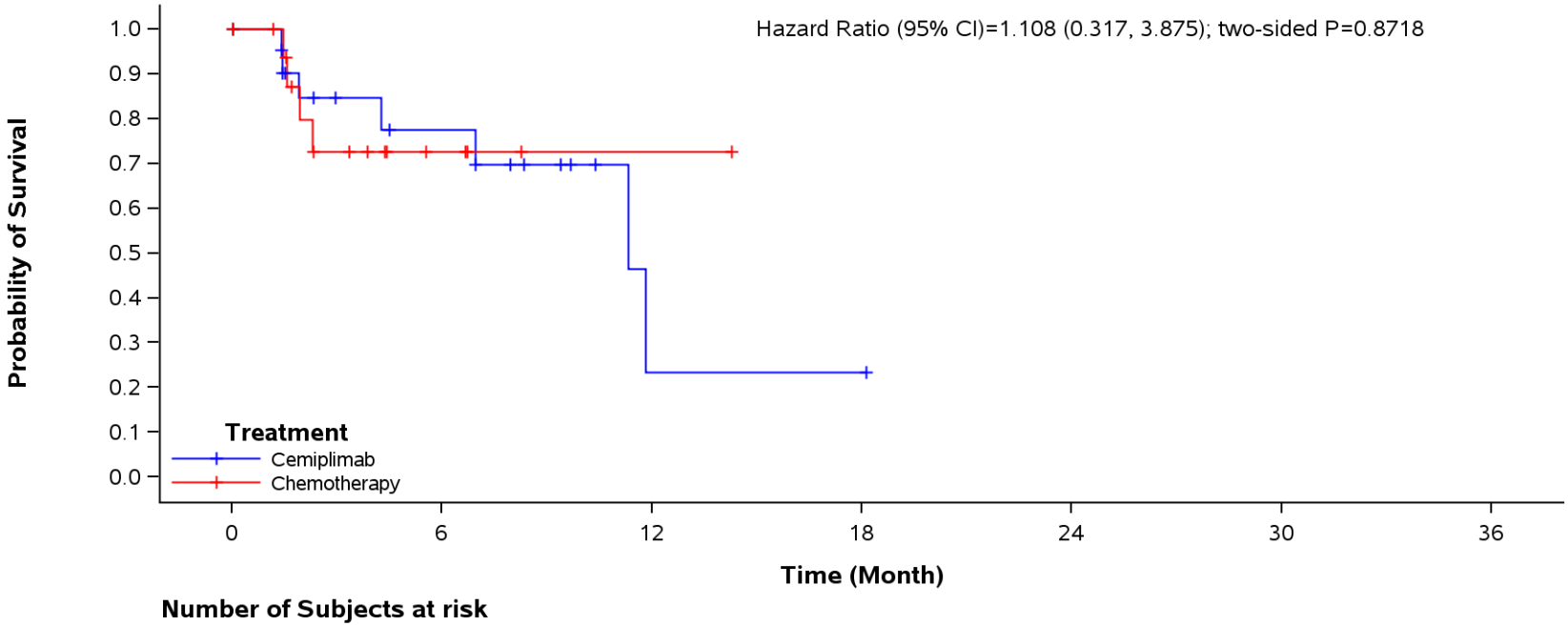
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Dyspnoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 10 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 69 | 4 | 1 | 0 | 0 | 0 | 0 |

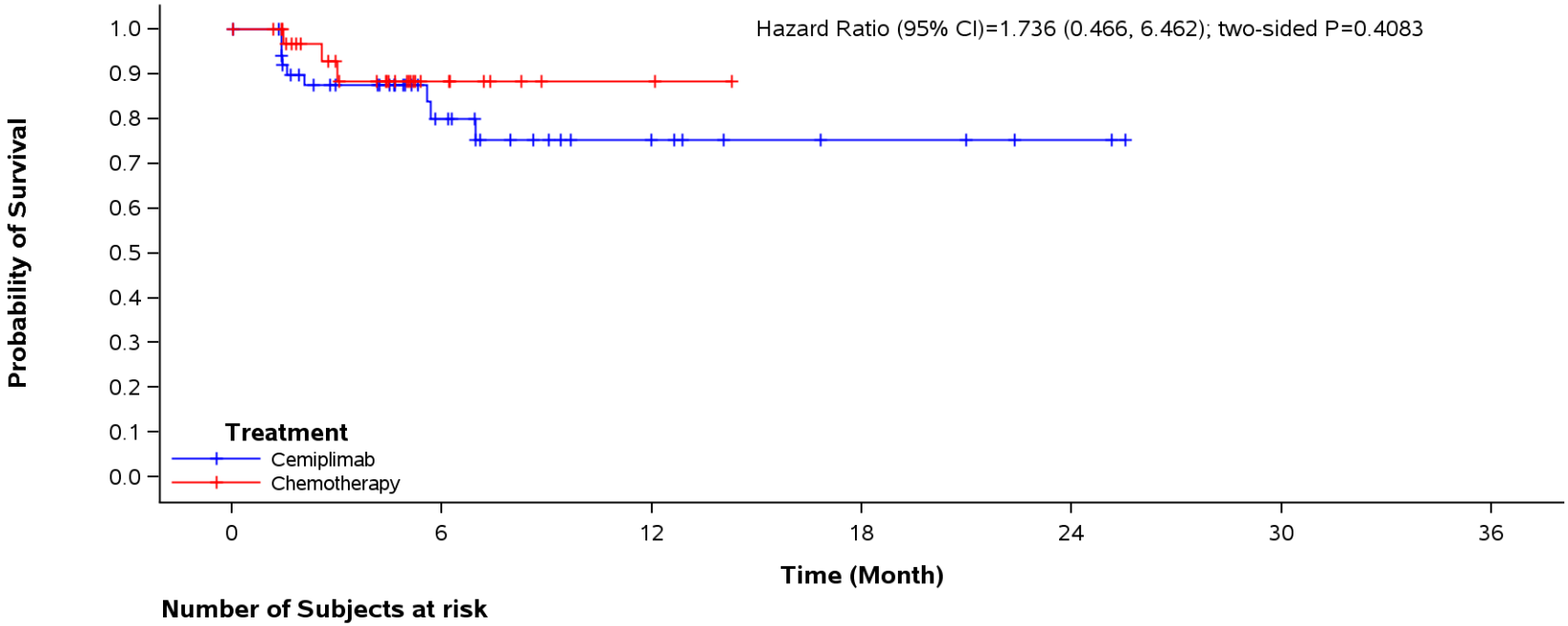
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Emotional Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 20 | 8 | 4 | 2 | 0 | 0 |
| Chemotherapy | 69 | 8 | 2 | 0 | 0 | 0 | 0 |

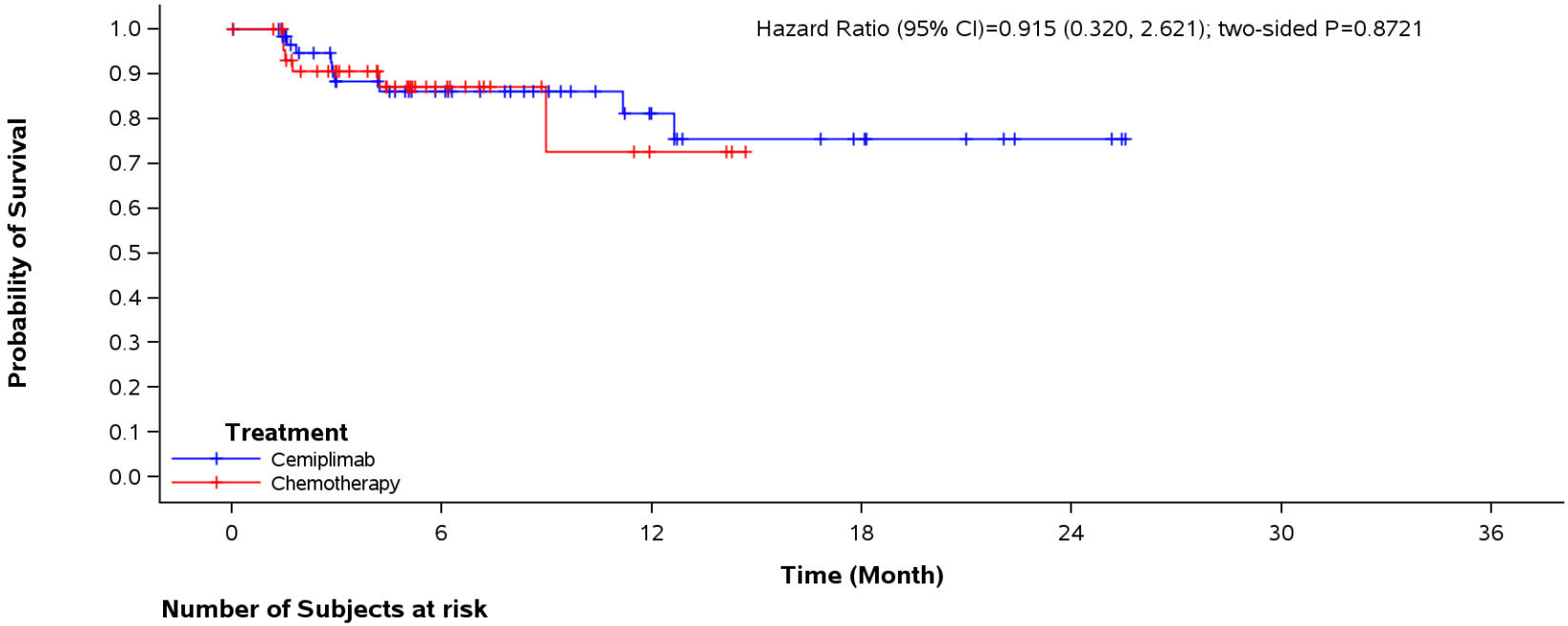
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Fatigue - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 30 | 14 | 8 | 3 | 0 | 0 |
| Chemotherapy | 69 | 14 | 3 | 0 | 0 | 0 | 0 |

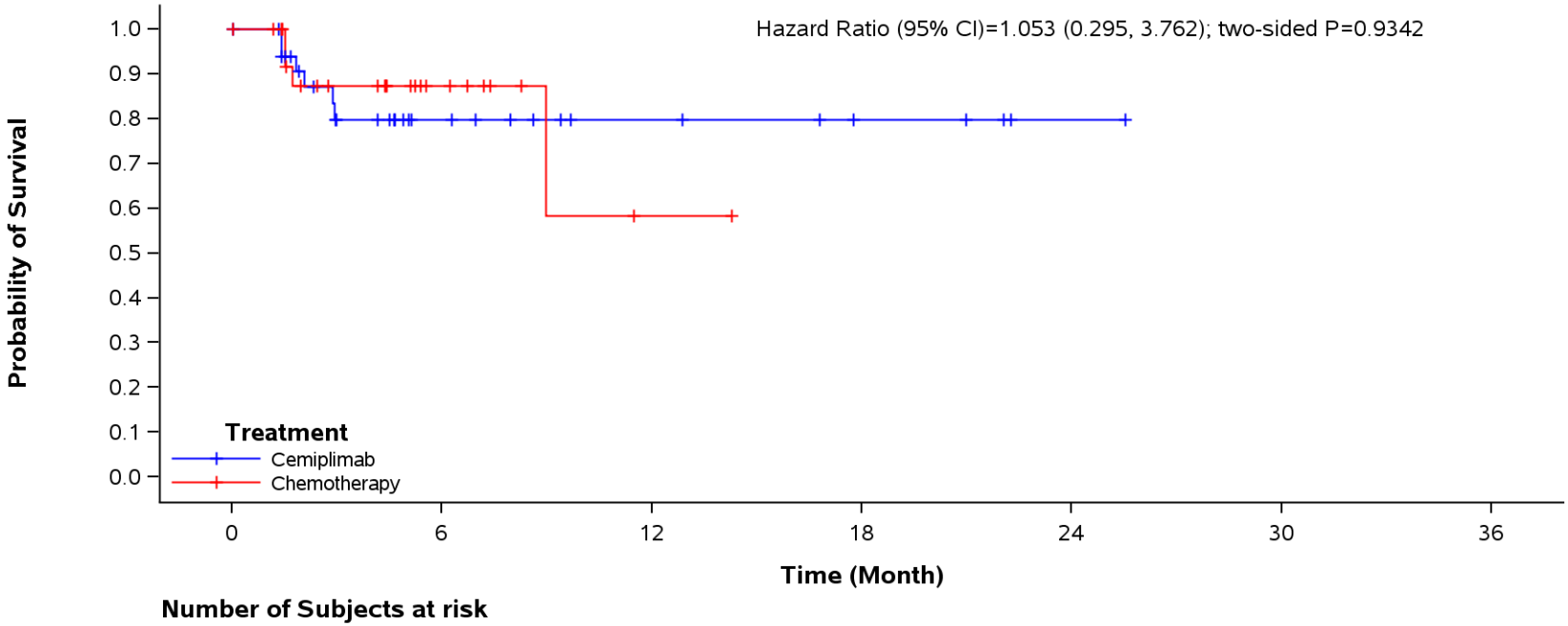
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 13 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 69 | 8 | 1 | 0 | 0 | 0 | 0 |

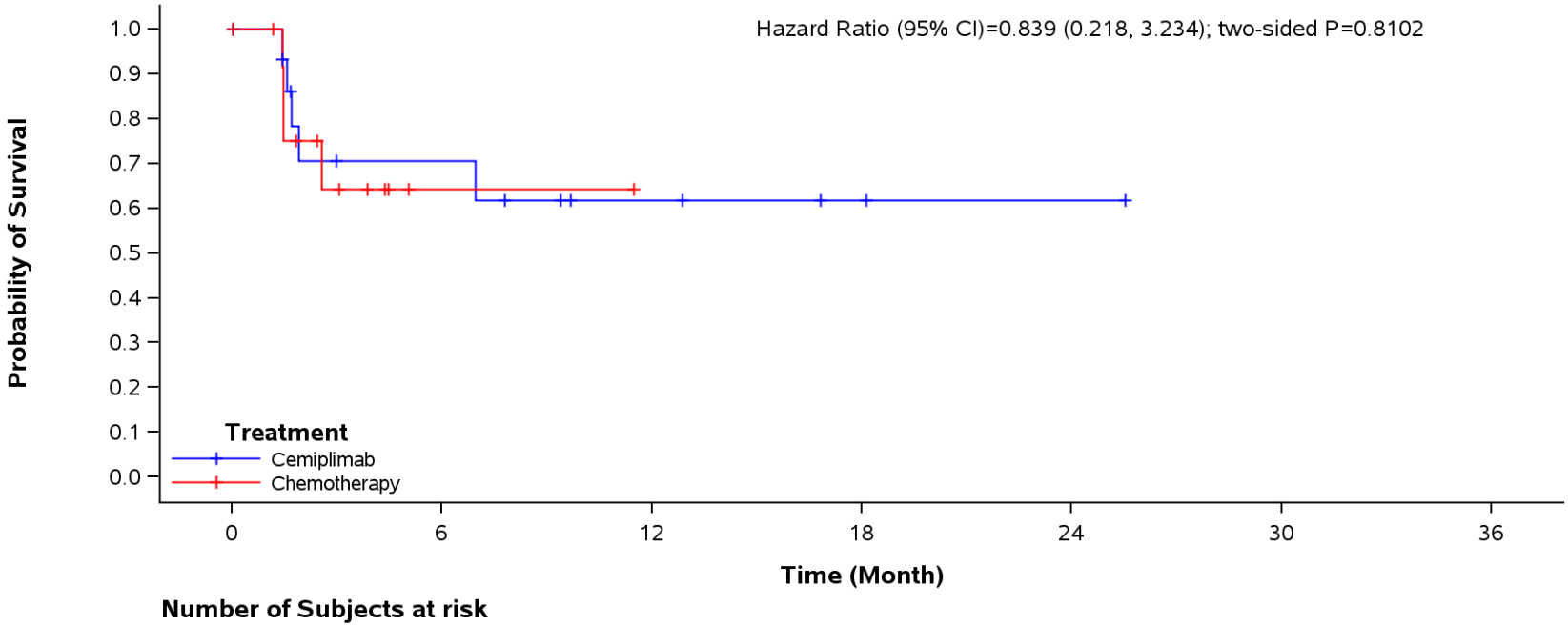
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Nausea / Vomiting - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 8 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 69 | 1 | 0 | 0 | 0 | 0 | 0 |

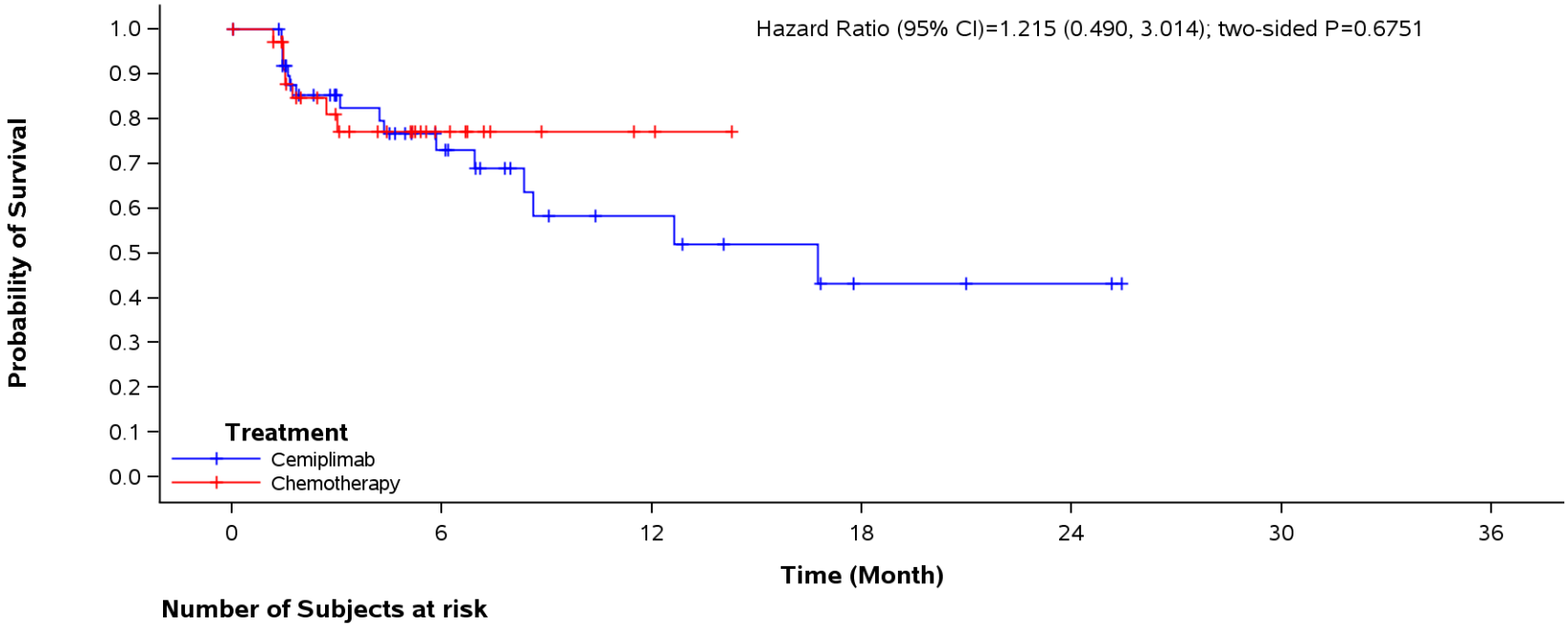
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Pain - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 20 | 9 | 3 | 2 | 0 | 0 |
| Chemotherapy | 69 | 9 | 2 | 0 | 0 | 0 | 0 |

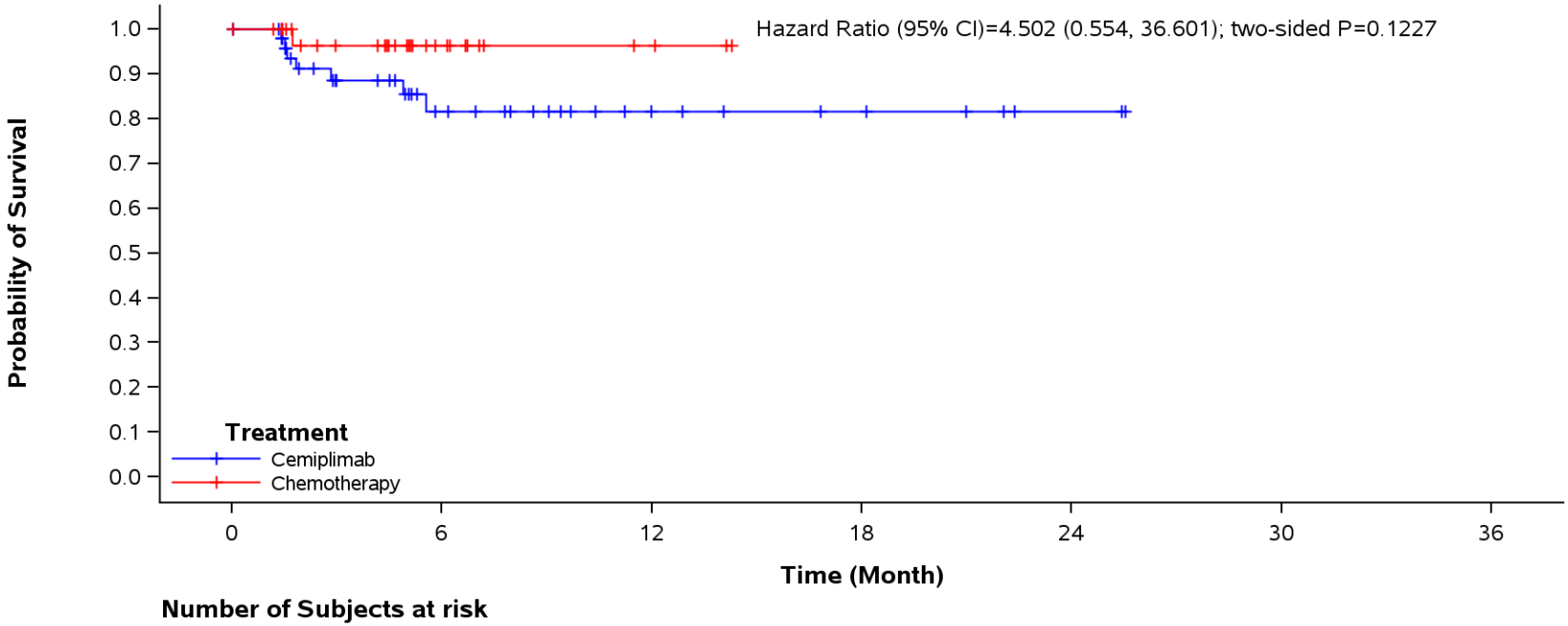
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Physical Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 20 | 9 | 6 | 2 | 0 | 0 |
| Chemotherapy | 69 | 10 | 3 | 0 | 0 | 0 | 0 |

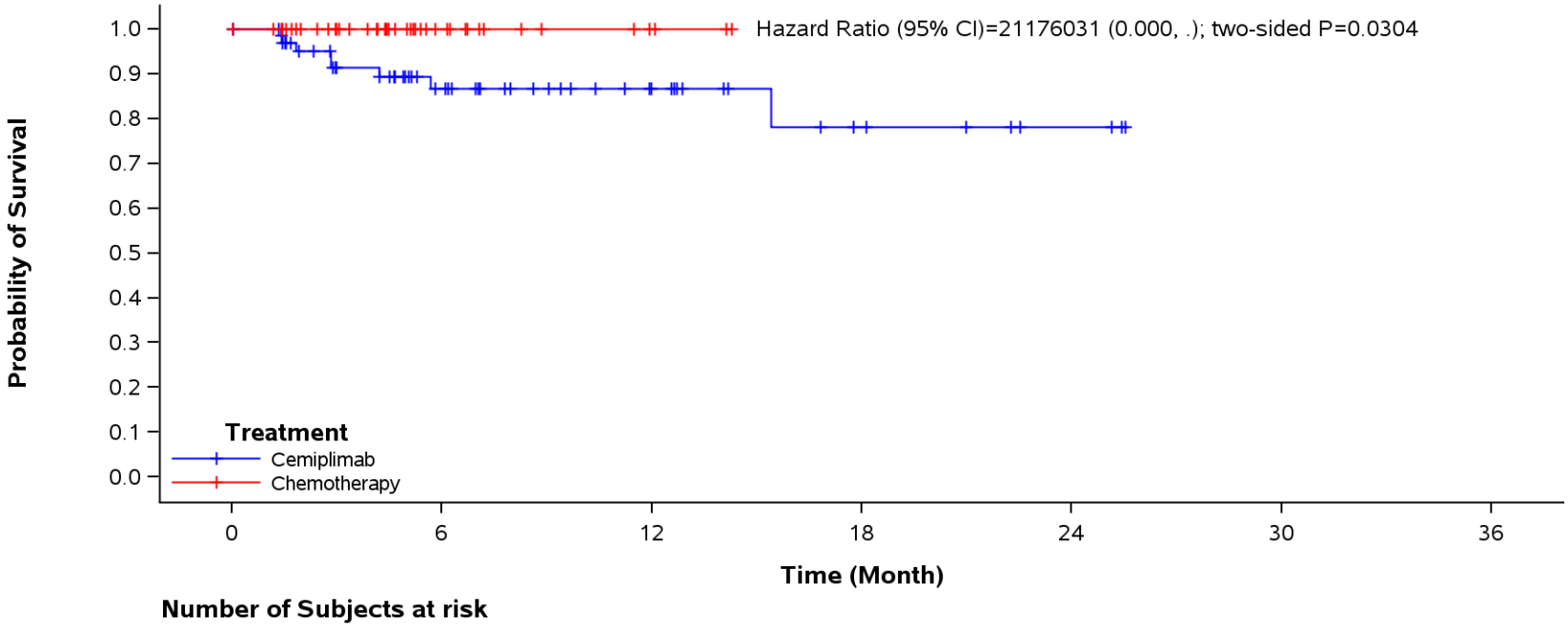
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 32 | 16 | 7 | 3 | 0 | 0 |
| Chemotherapy | 69 | 14 | 3 | 0 | 0 | 0 | 0 |

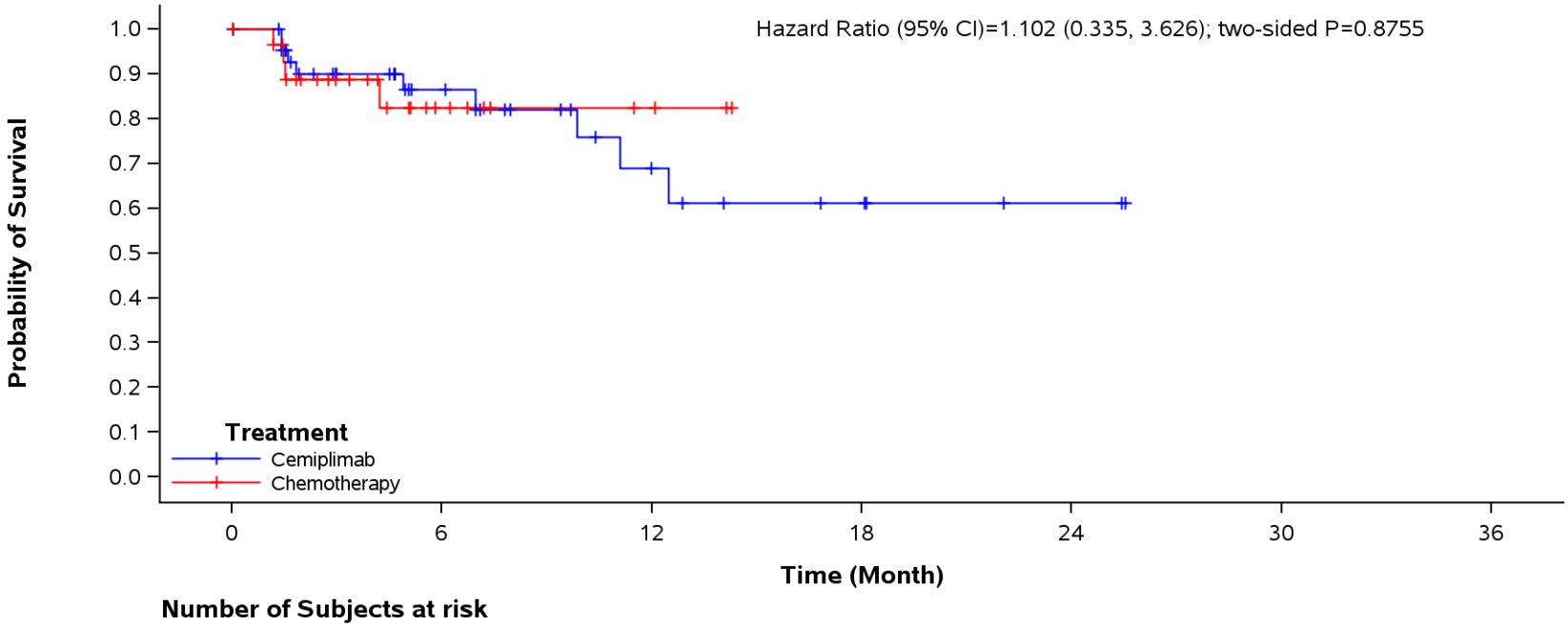
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Role Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 21 | 9 | 5 | 2 | 0 | 0 |
| Chemotherapy | 69 | 8 | 3 | 0 | 0 | 0 | 0 |

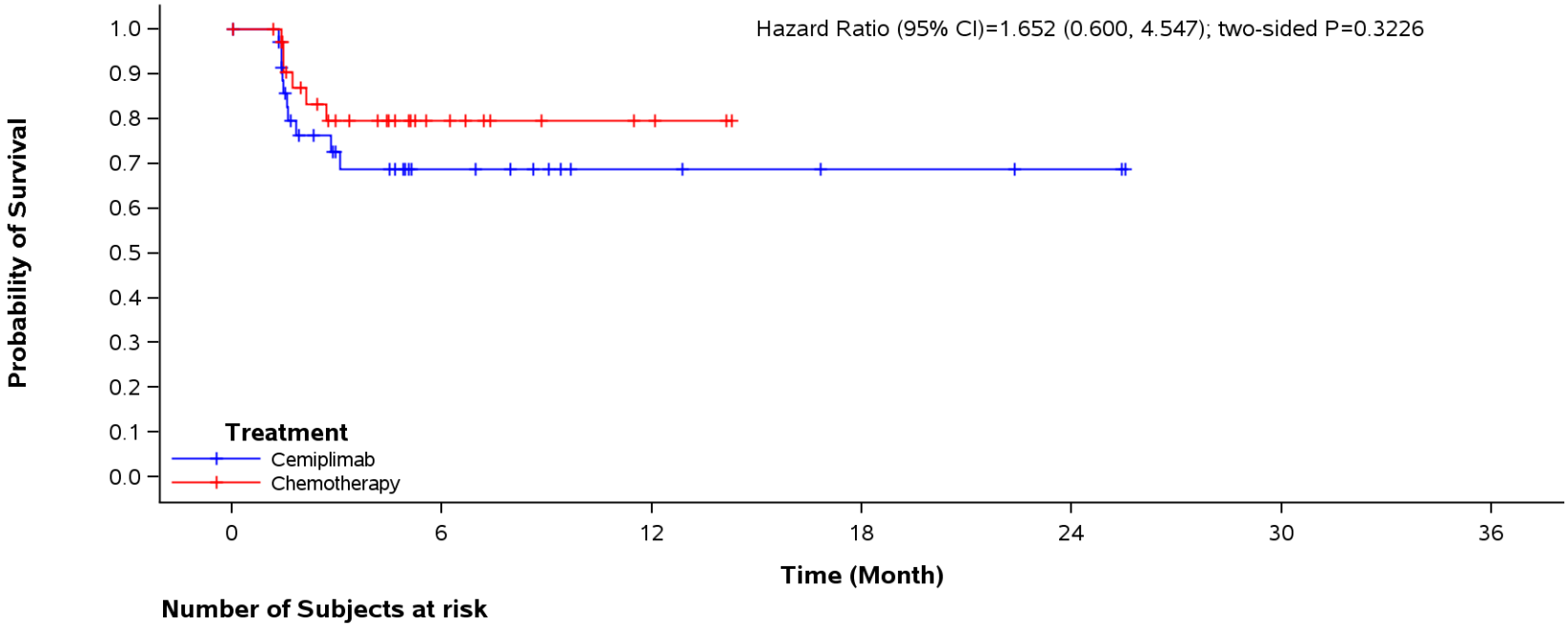
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Social Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

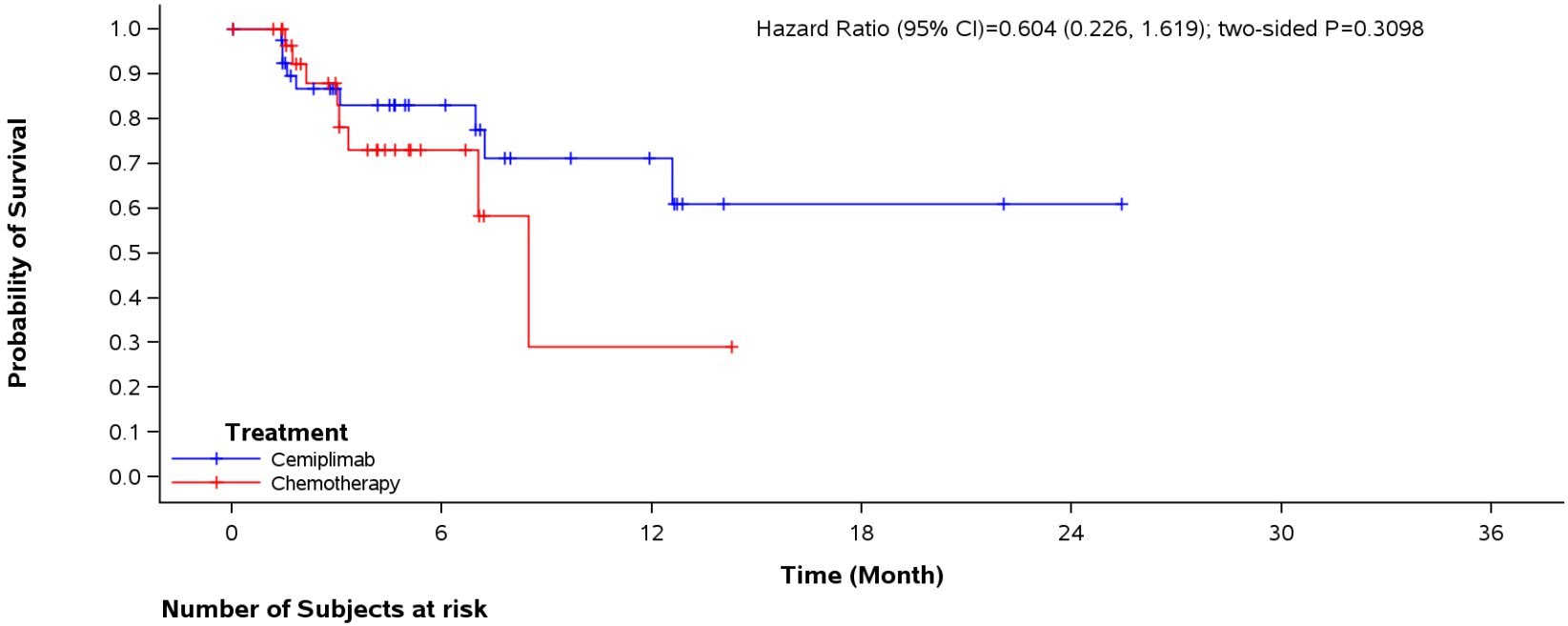
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 11 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 69 | 9 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts sensitivity sustained improvement



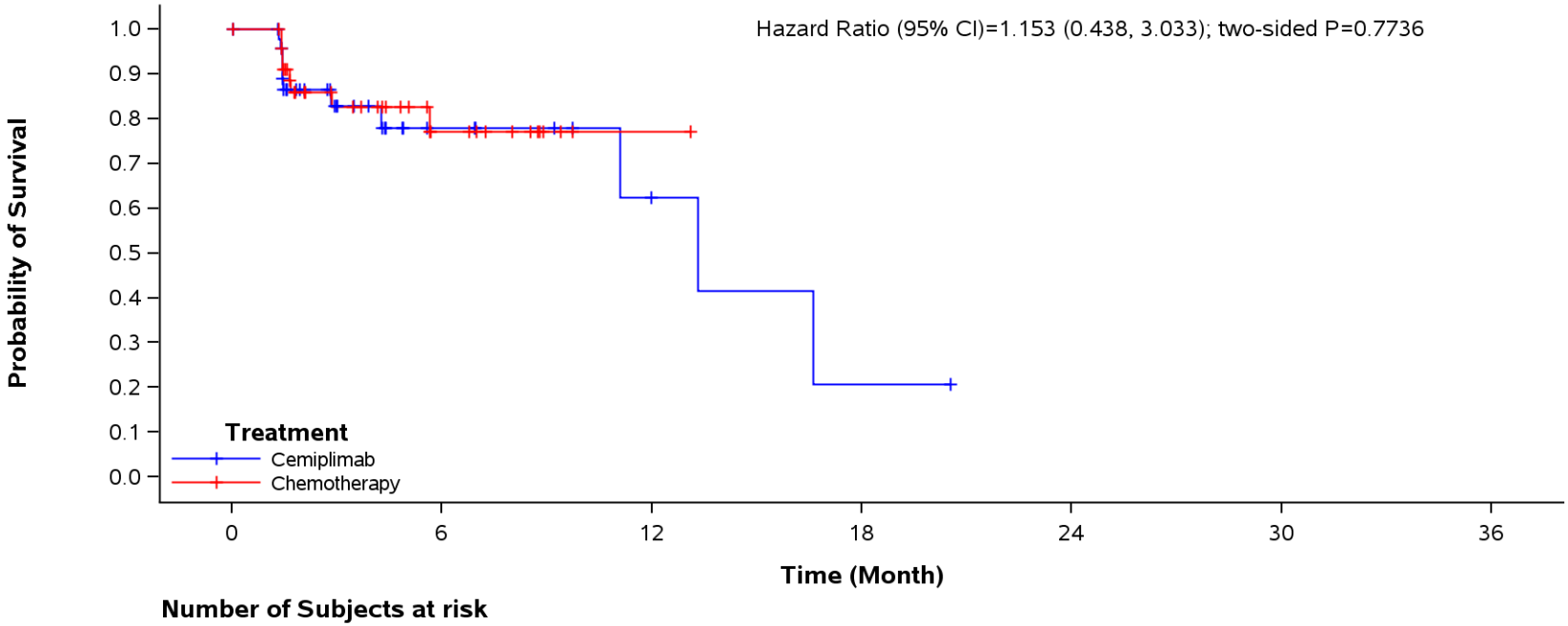

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 16 | 7 | 2 | 1 | 0 | 0 |
| Chemotherapy | 69 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Appetite loss - 10 pts sensitivity sustained improvement



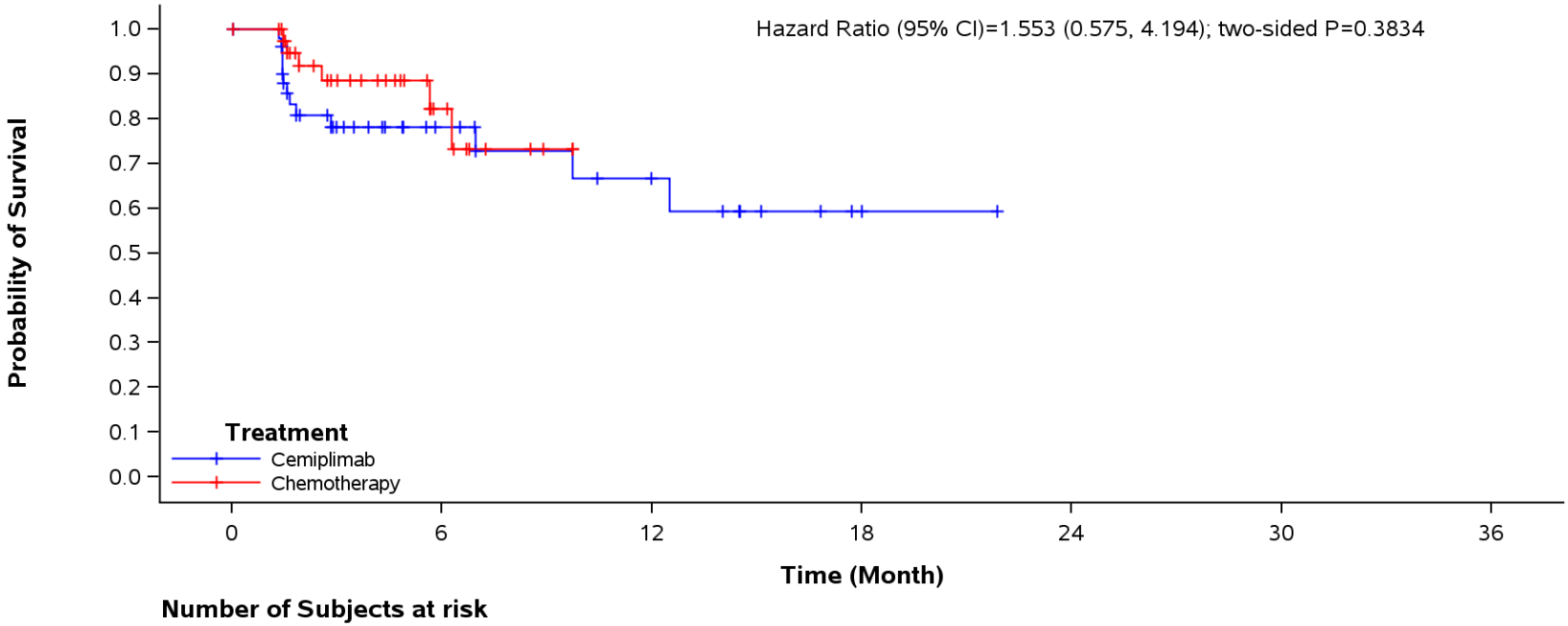

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 9 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Cognitive Functioning - 10 pts sensitivity sustained improvement



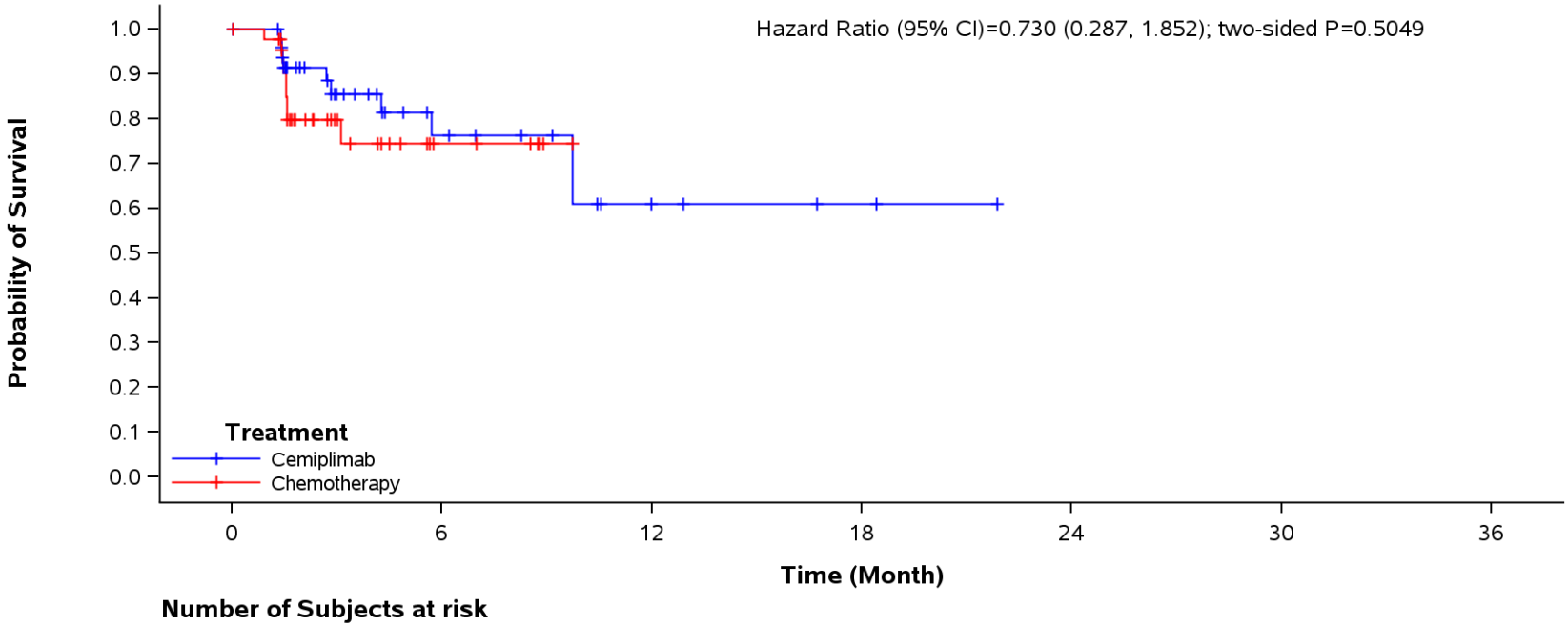

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 17 | 9 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Constipation - 10 pts sensitivity sustained improvement



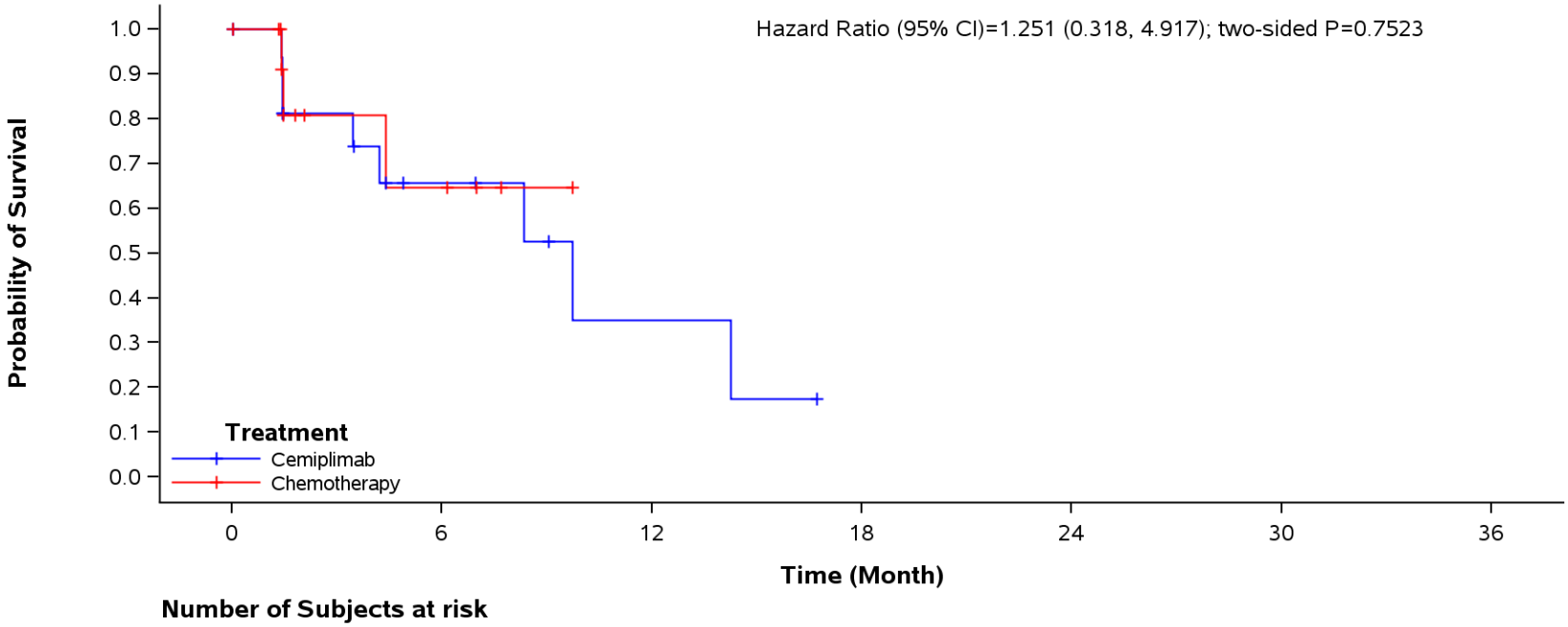

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 15 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Diarhoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

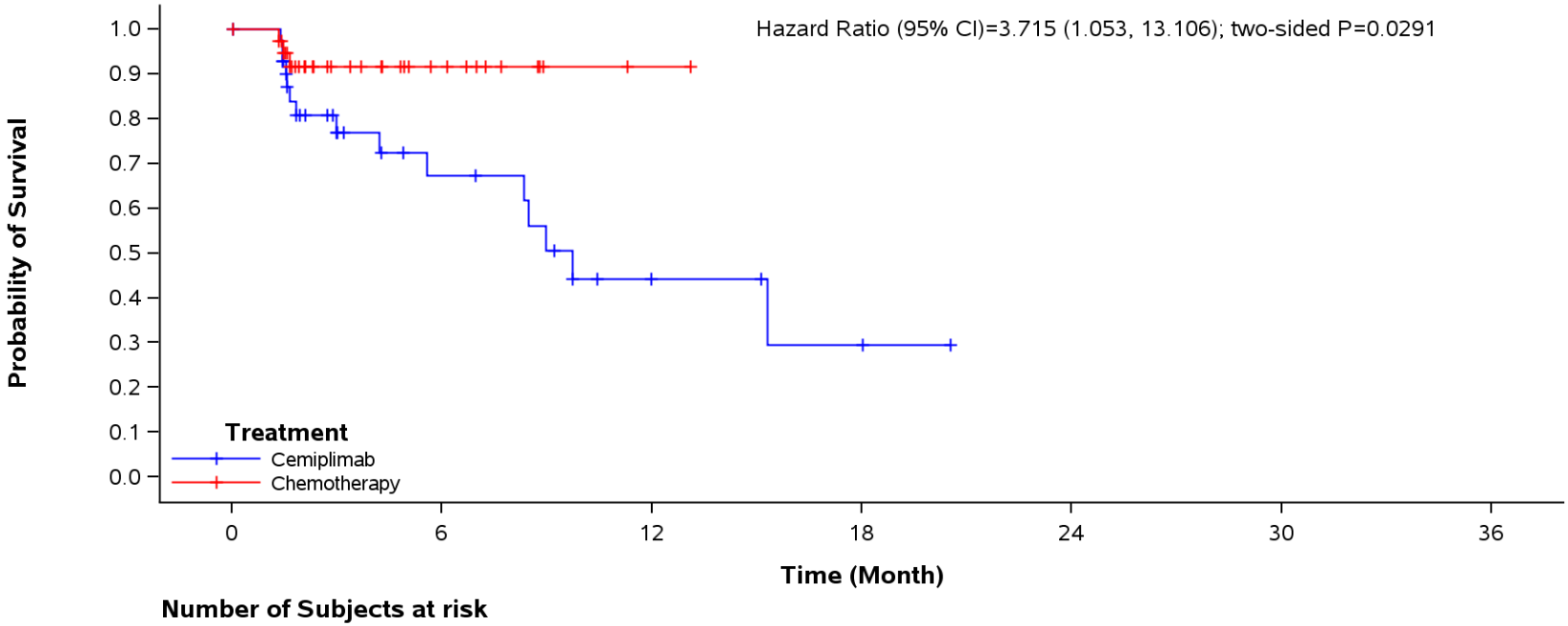
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Dyspnoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 13 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 10 | 1 | 0 | 0 | 0 | 0 |

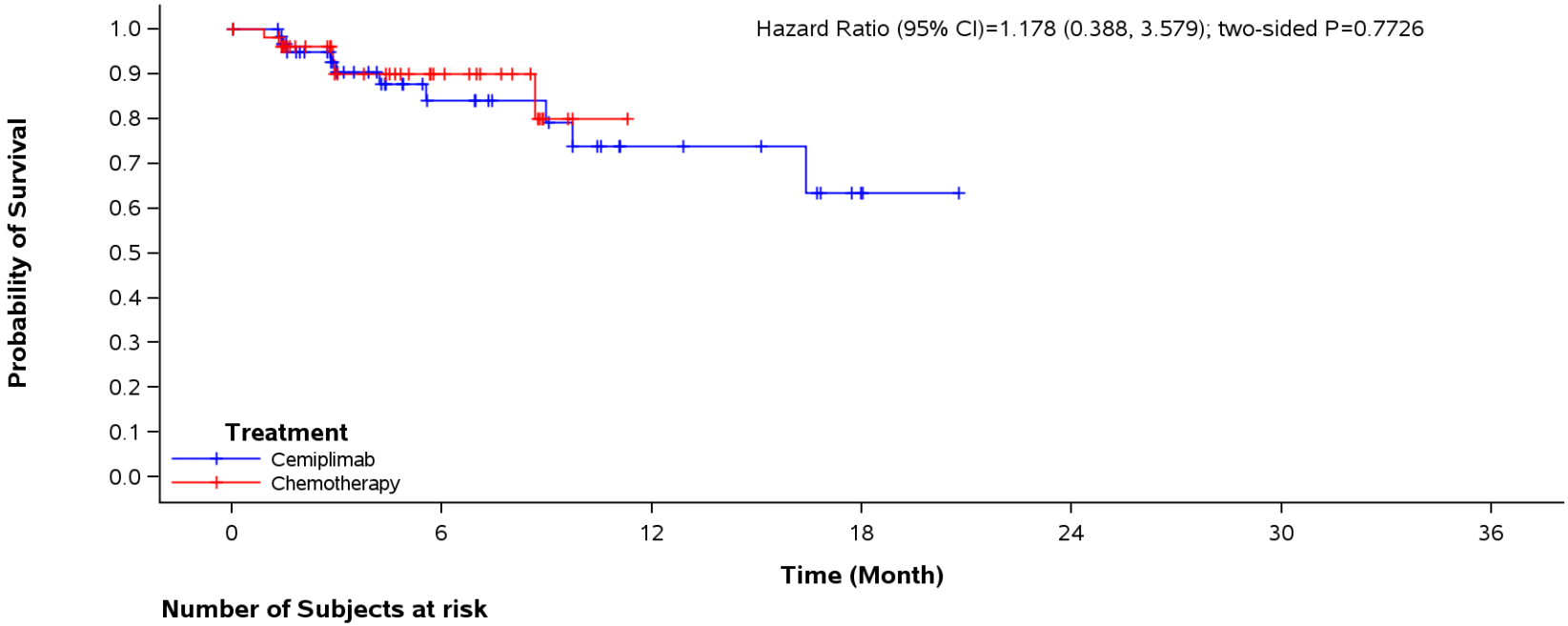
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Emotional Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

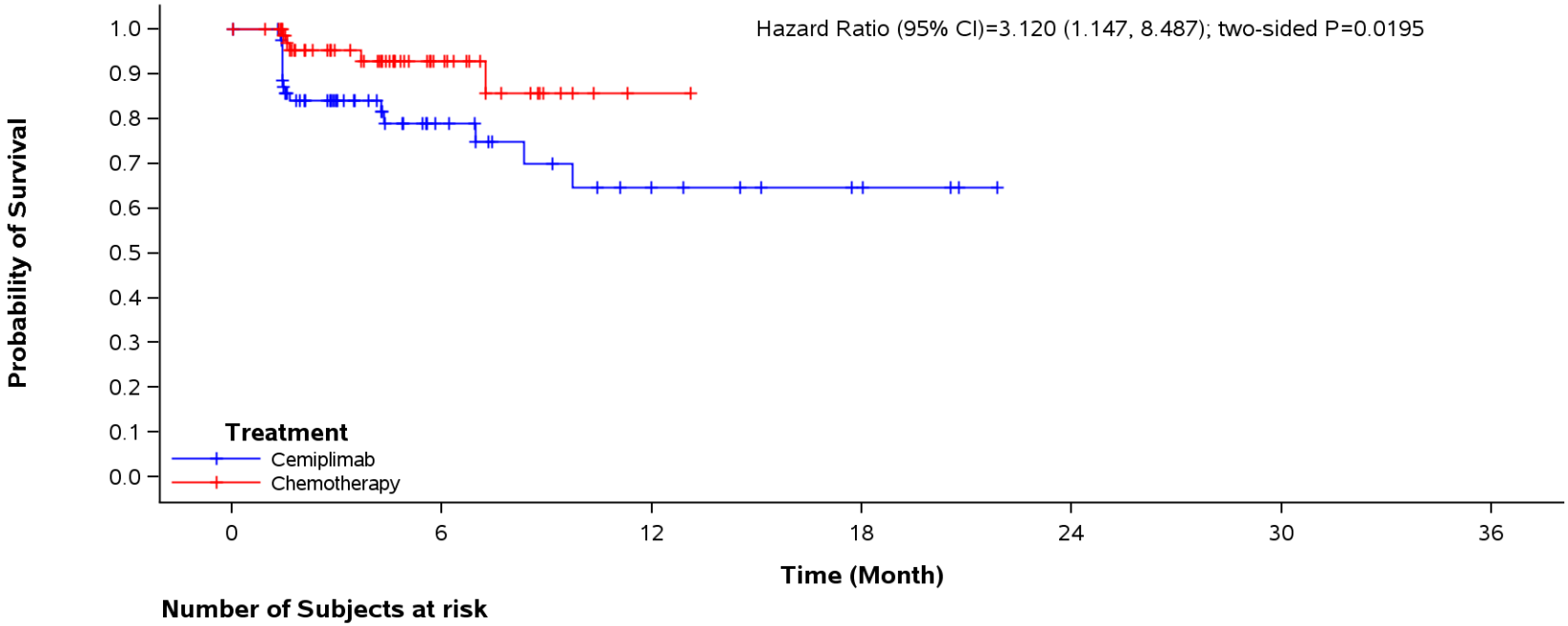
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 23 | 9 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Fatigue - 10 pts sensitivity sustained improvement




Number of Subjects at risk

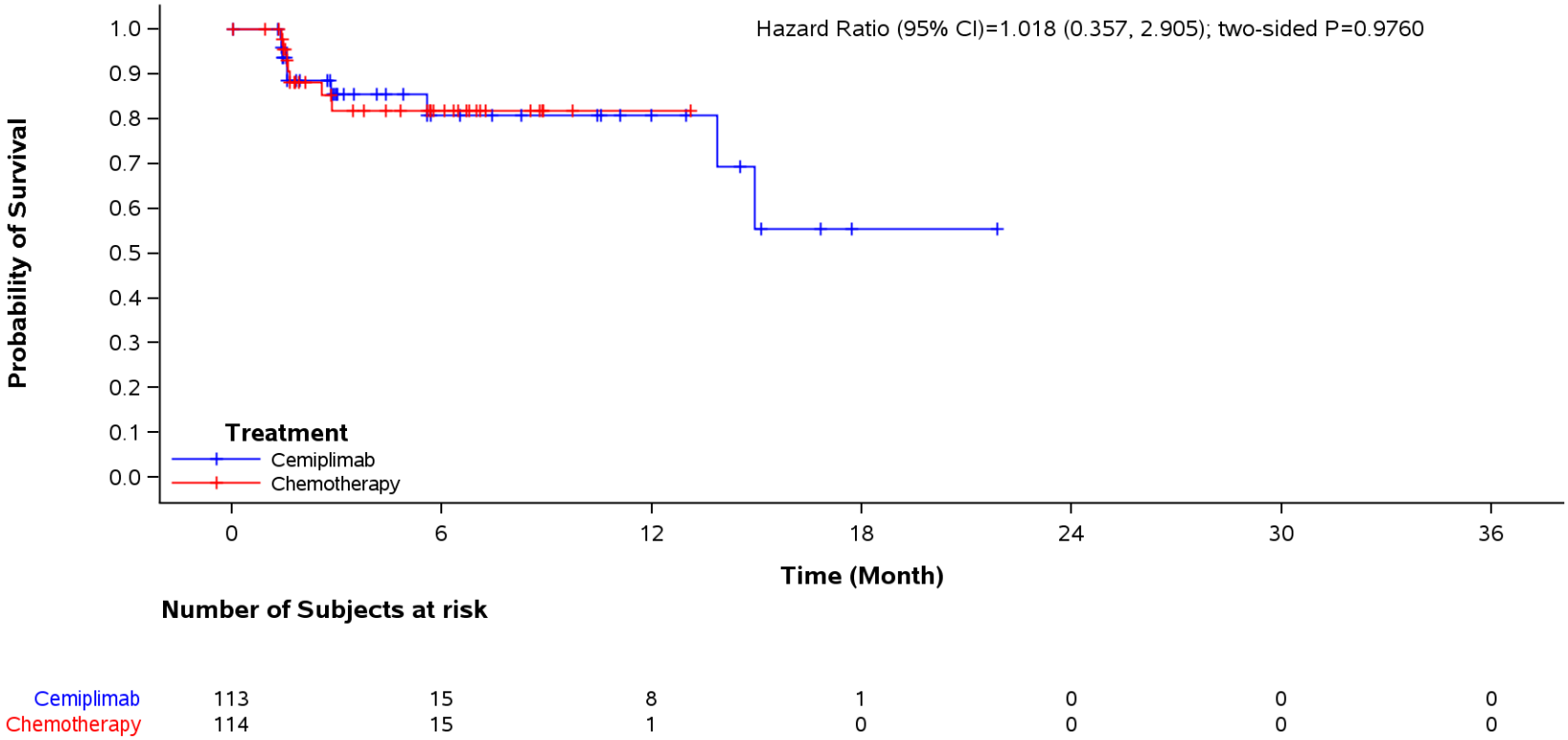
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 22 | 8 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 15 | 8 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 15 | 1 | 0 | 0 | 0 | 0 |

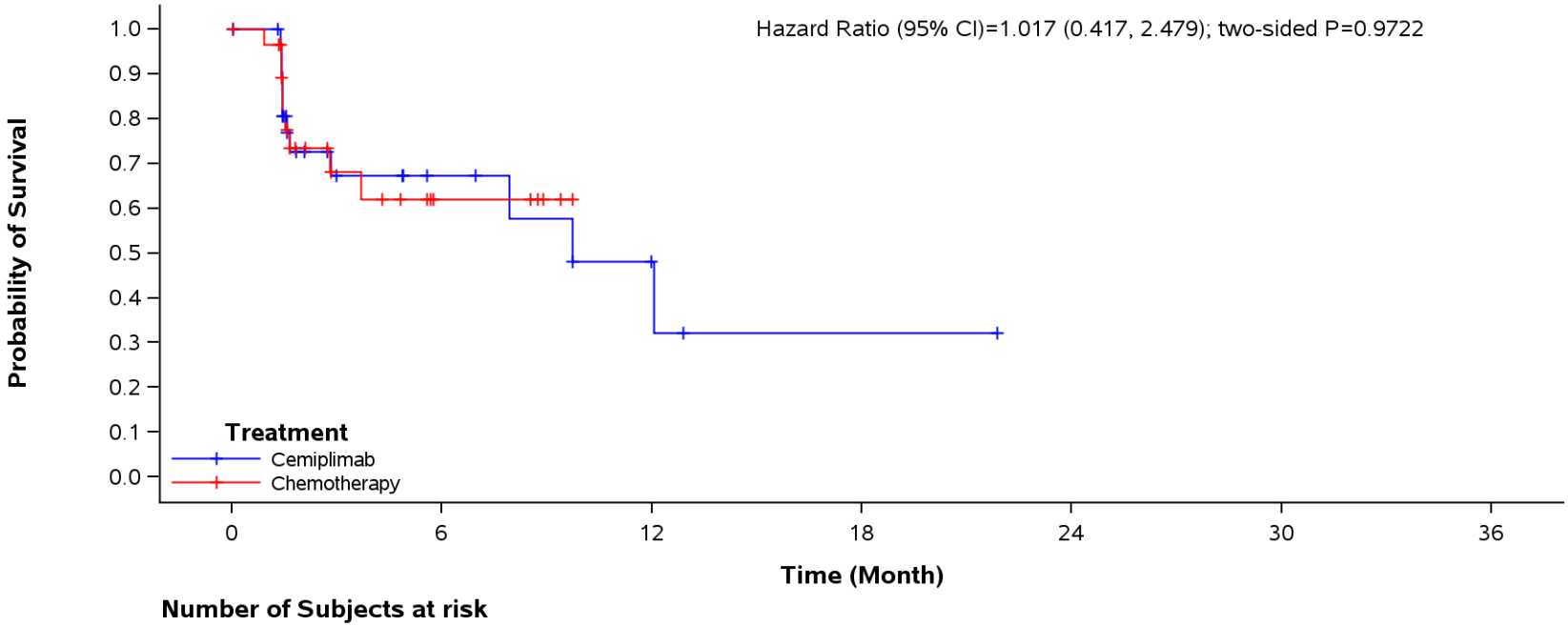
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Nausea / Vomiting - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 8 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 5 | 0 | 0 | 0 | 0 | 0 |

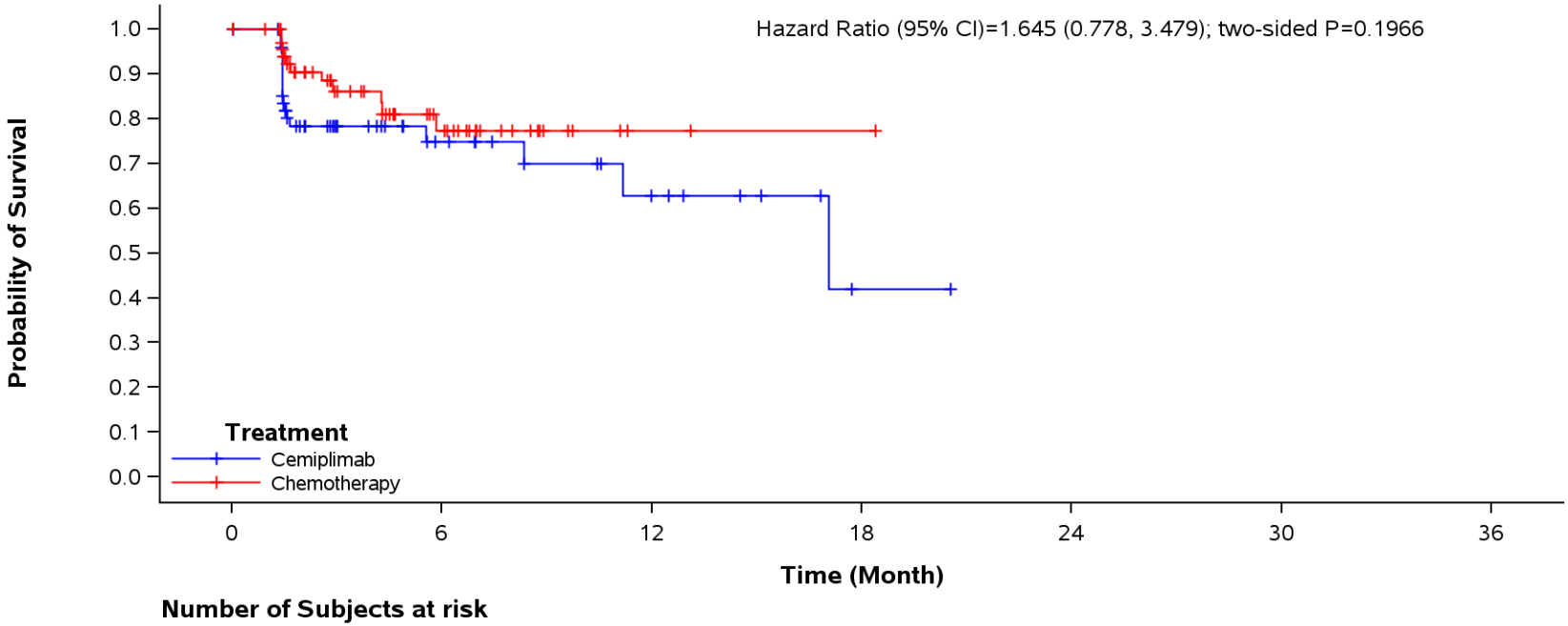
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Pain - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 20 | 8 | 1 | 0 | 0 | 0 |
| Chemotherapy | 114 | 21 | 2 | 1 | 0 | 0 | 0 |

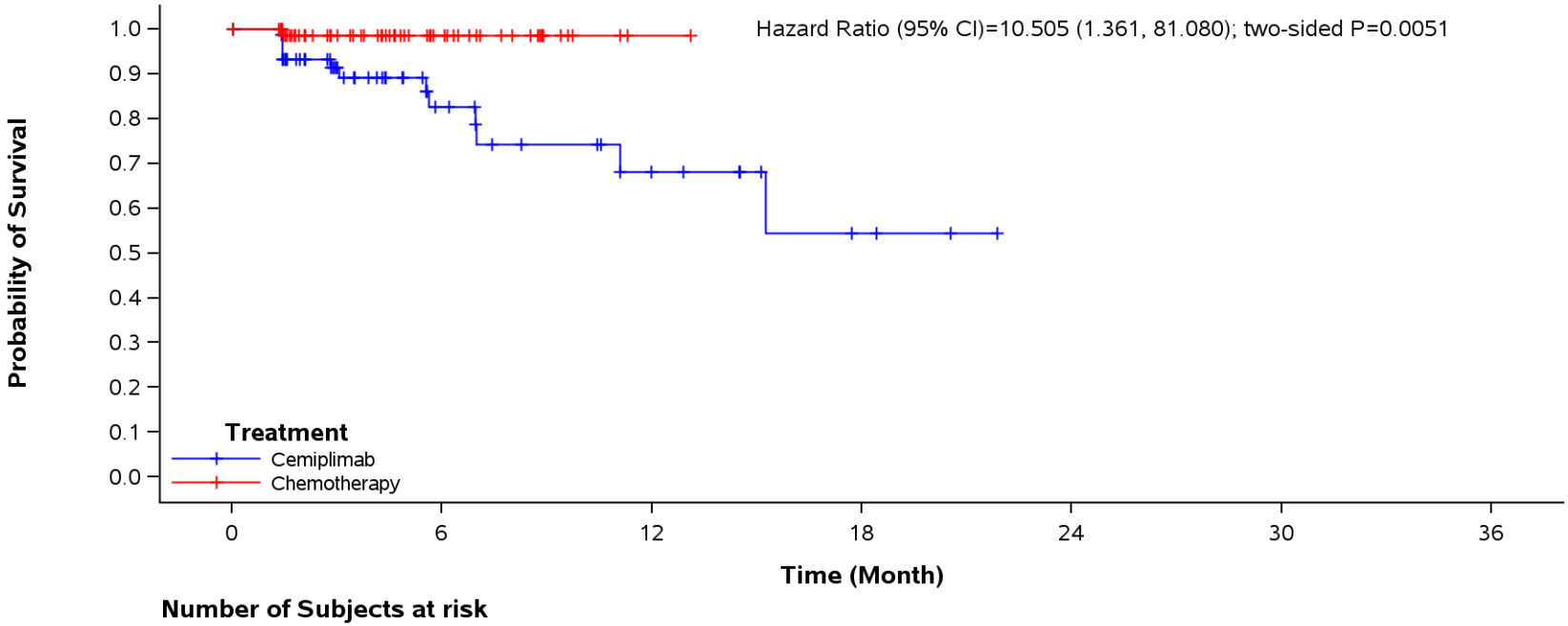
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Physical Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 23 | 9 | 3 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 1 | 0 | 0 | 0 | 0 |

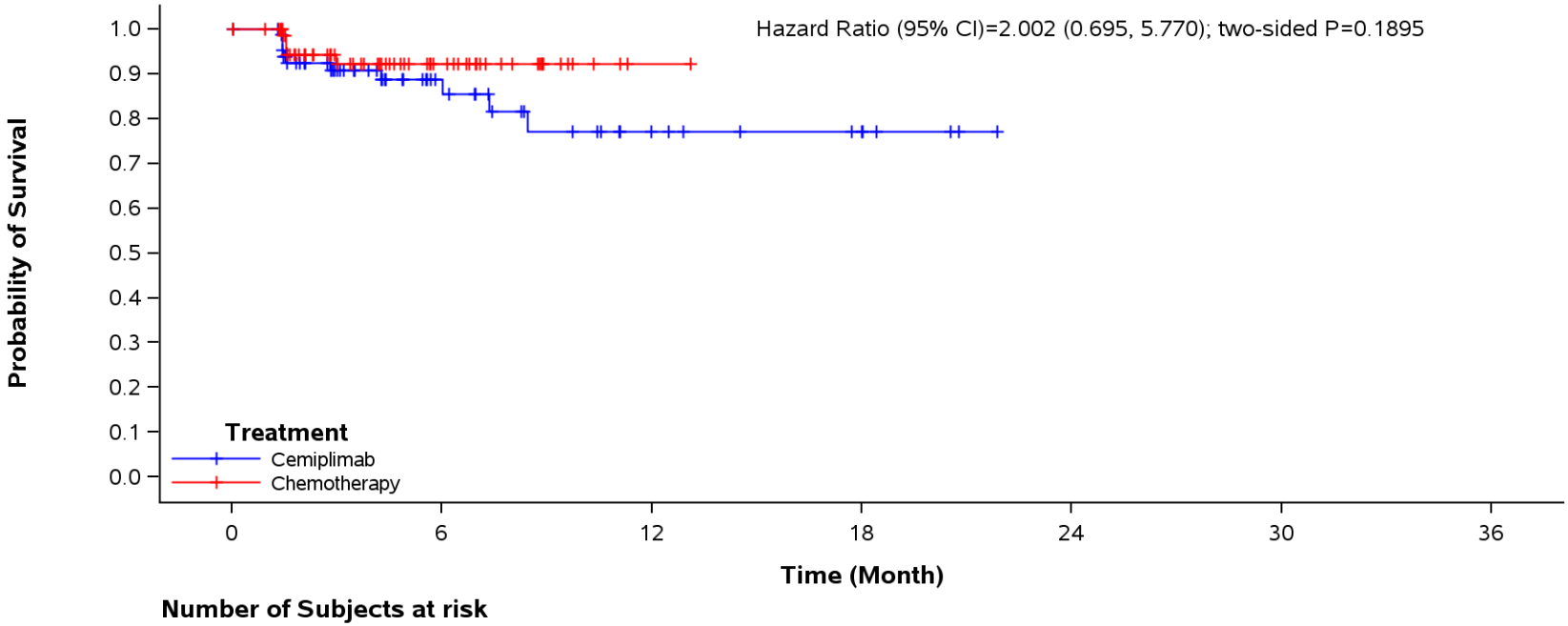
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

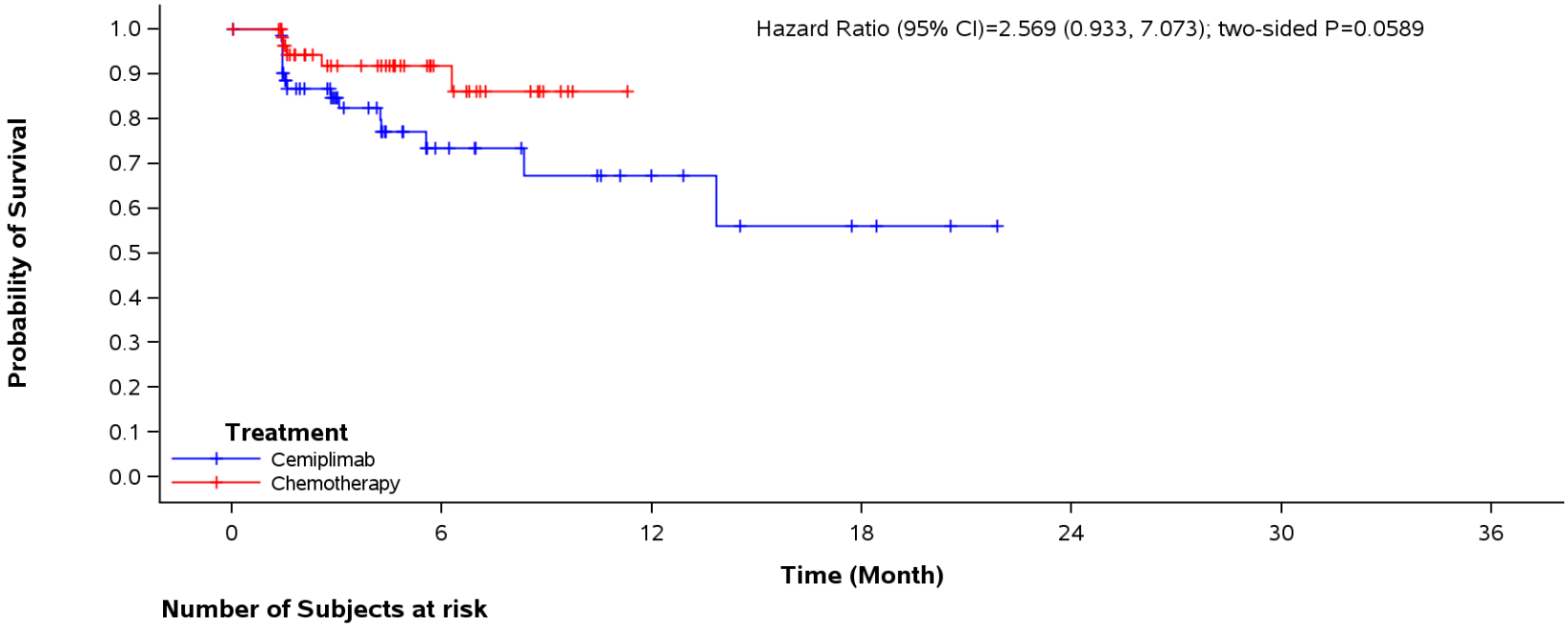
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 28 | 10 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 24 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Role Functioning - 10 pts sensitivity sustained improvement



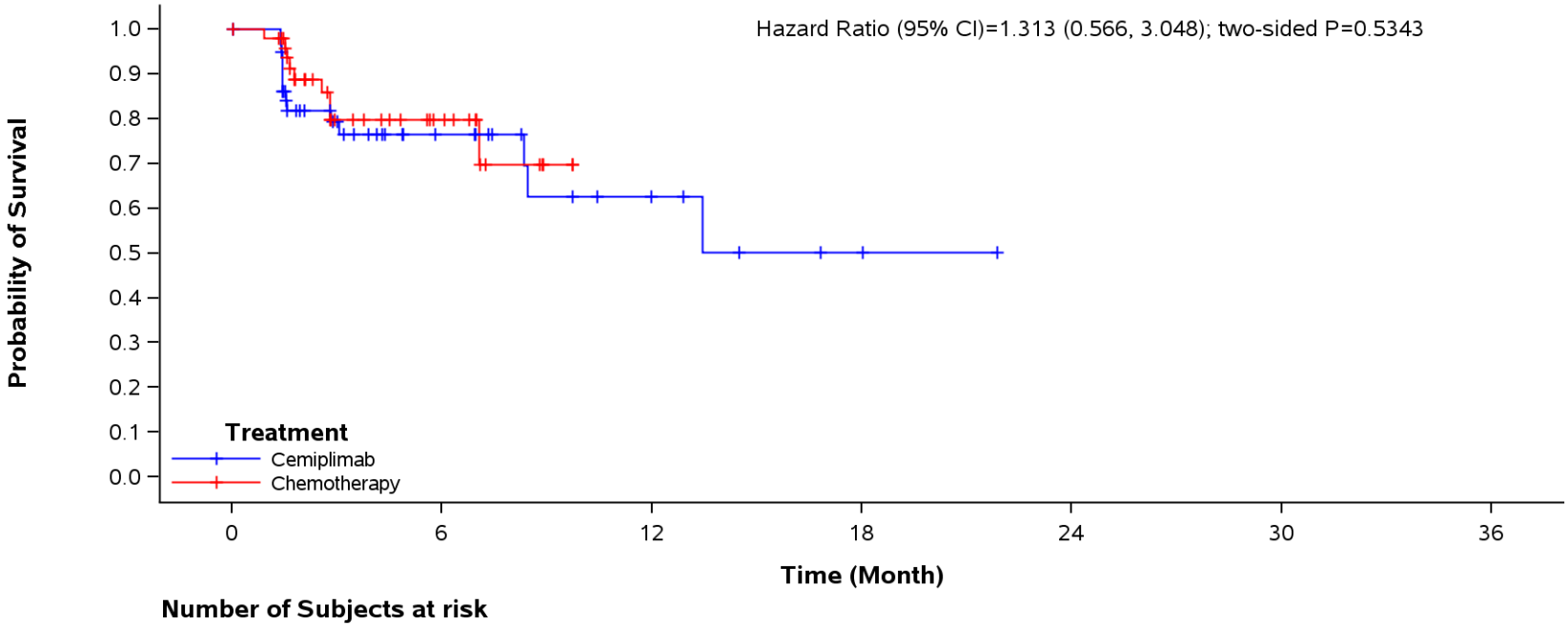

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 17 | 7 | 3 | 0 | 0 | 0 |
| Chemotherapy | 114 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Social Functioning - 10 pts sensitivity sustained improvement



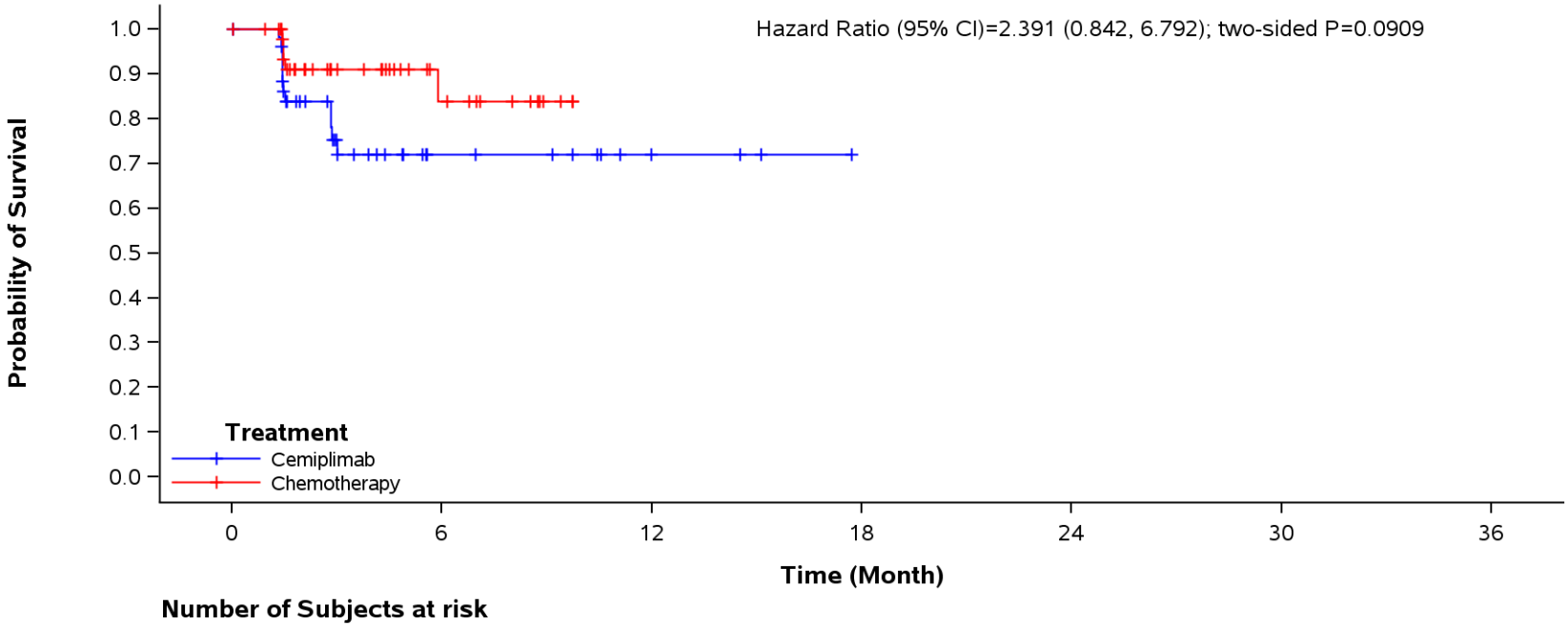

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 17 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 114 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts sensitivity sustained improvement



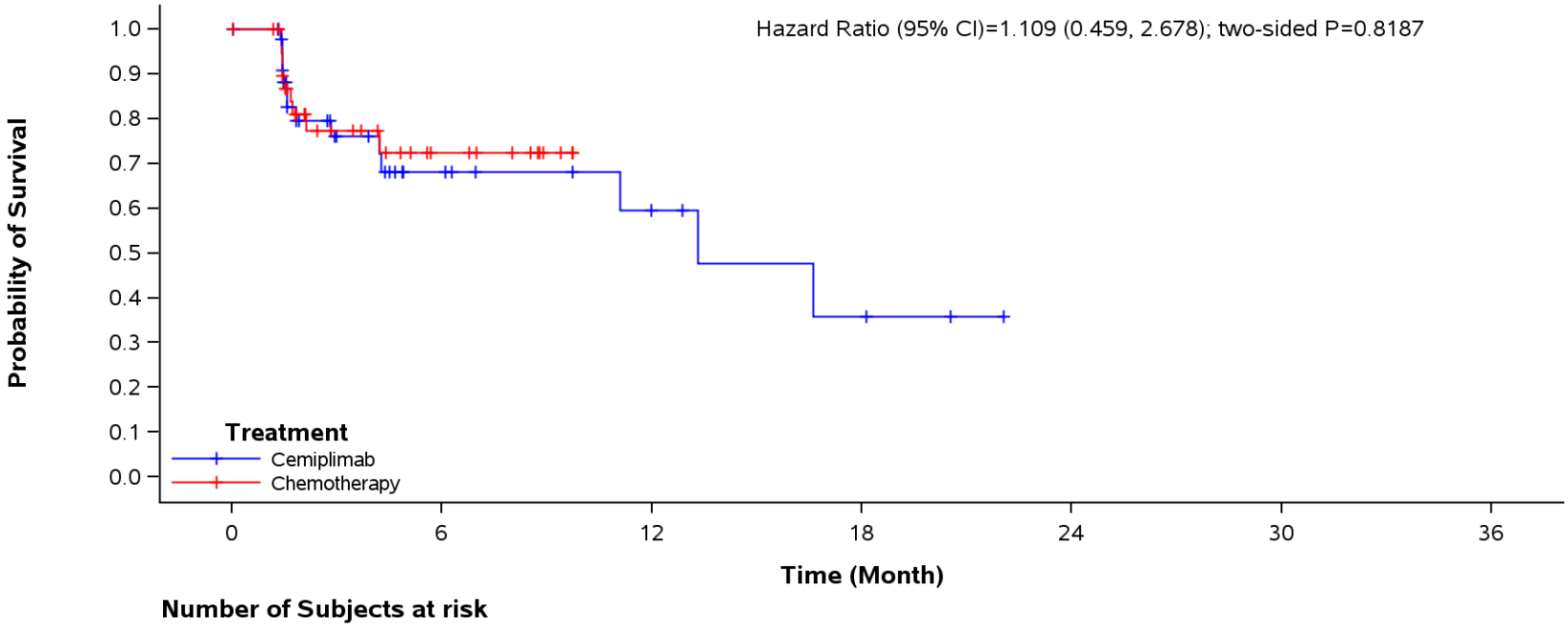

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 11 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 114 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Appetite loss - 10 pts sensitivity sustained improvement



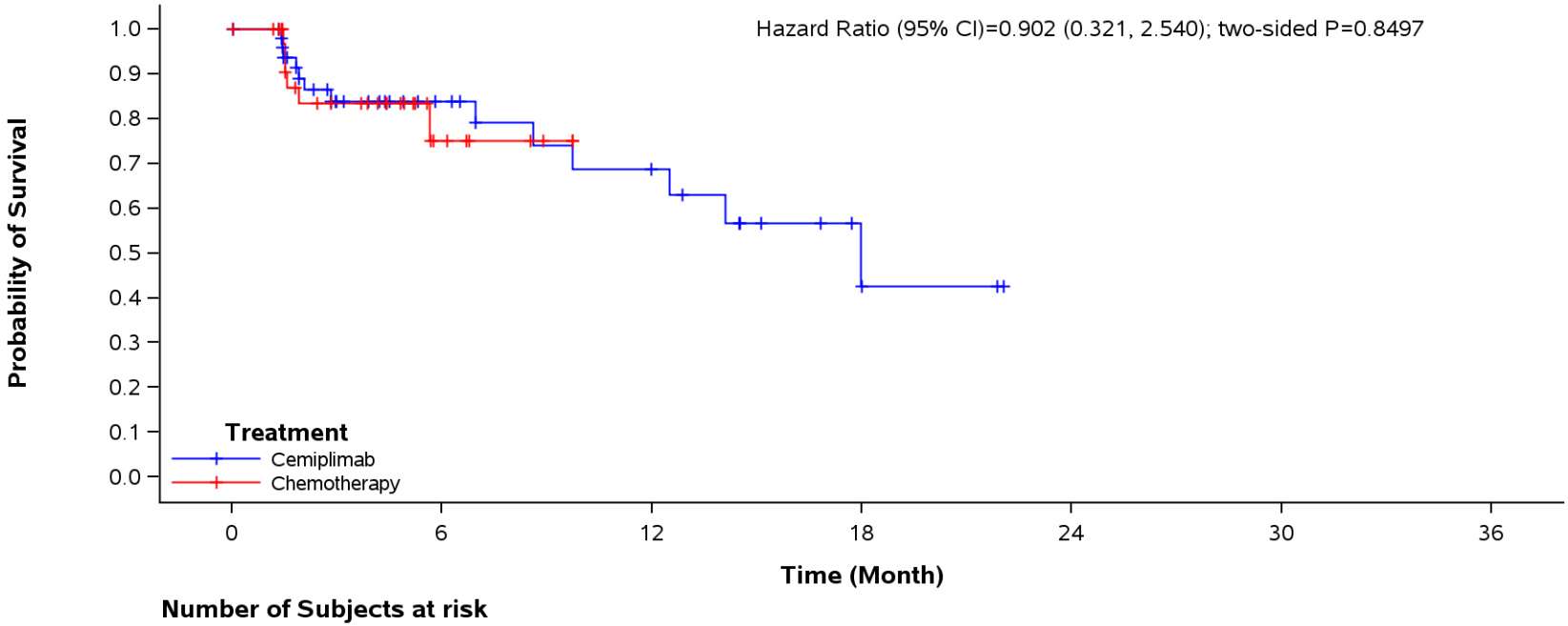

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 12 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Cognitive Functioning - 10 pts sensitivity sustained improvement



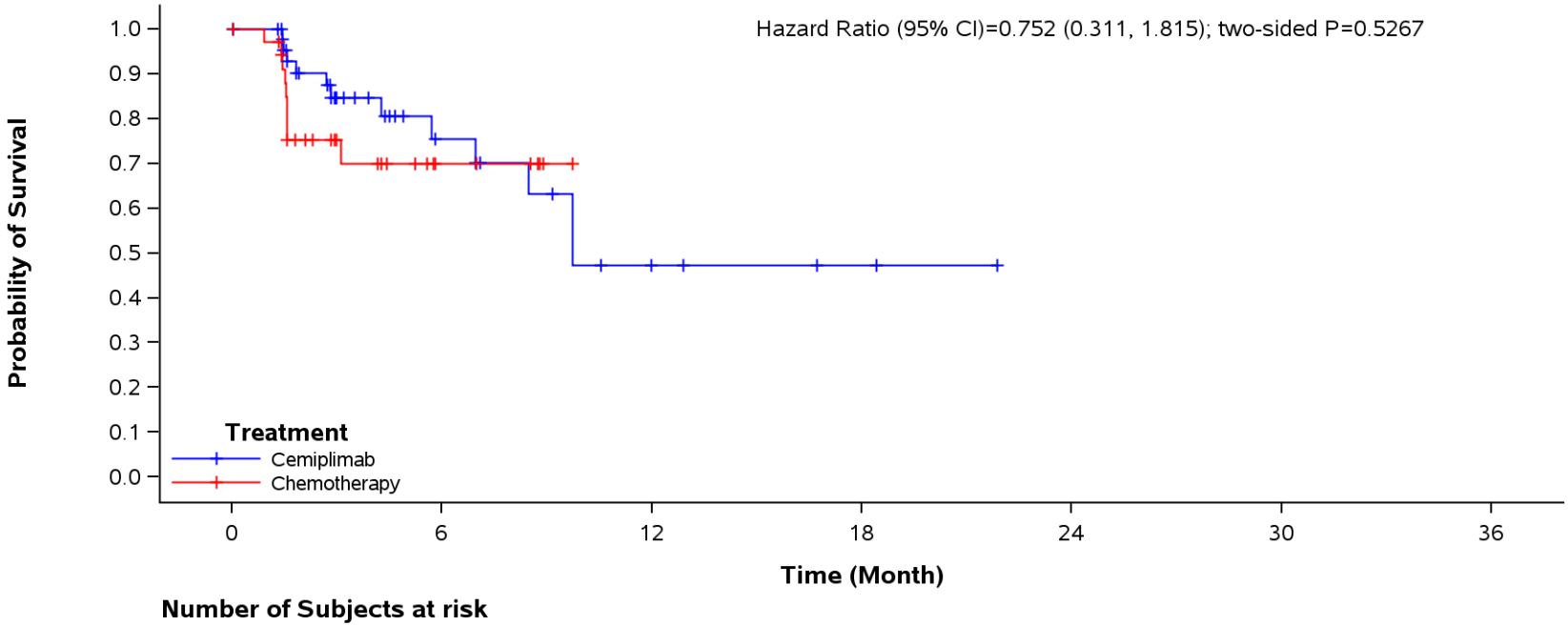

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 20 | 12 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Constipation - 10 pts sensitivity sustained improvement



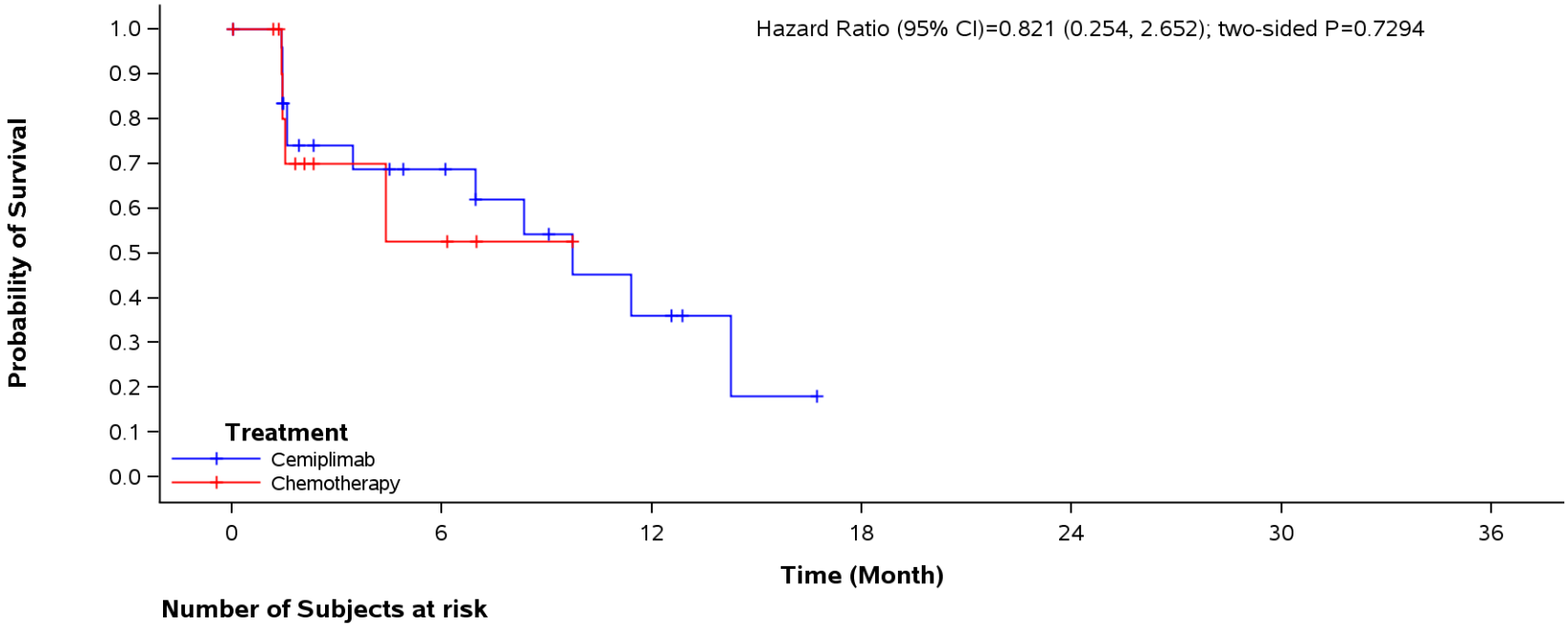

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 14 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Diarhoea - 10 pts sensitivity sustained improvement



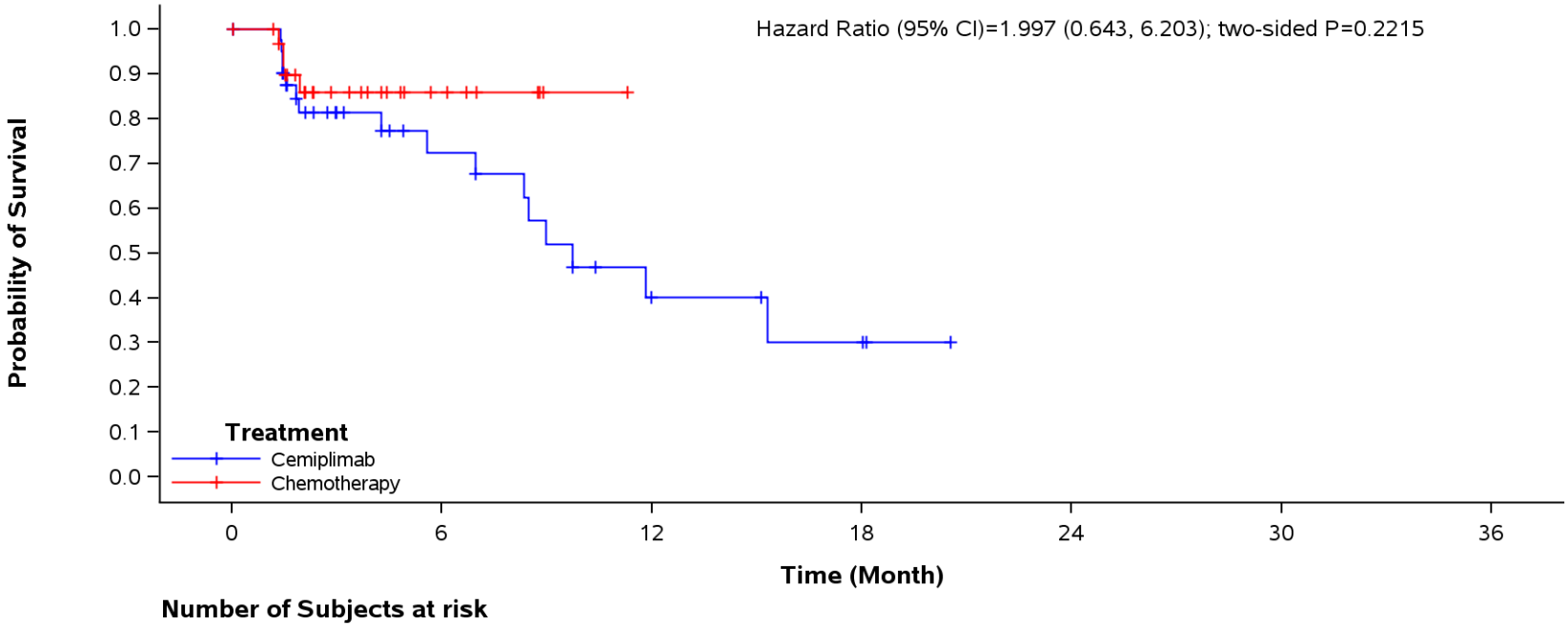

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 97 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Dyspnoea - 10 pts sensitivity sustained improvement



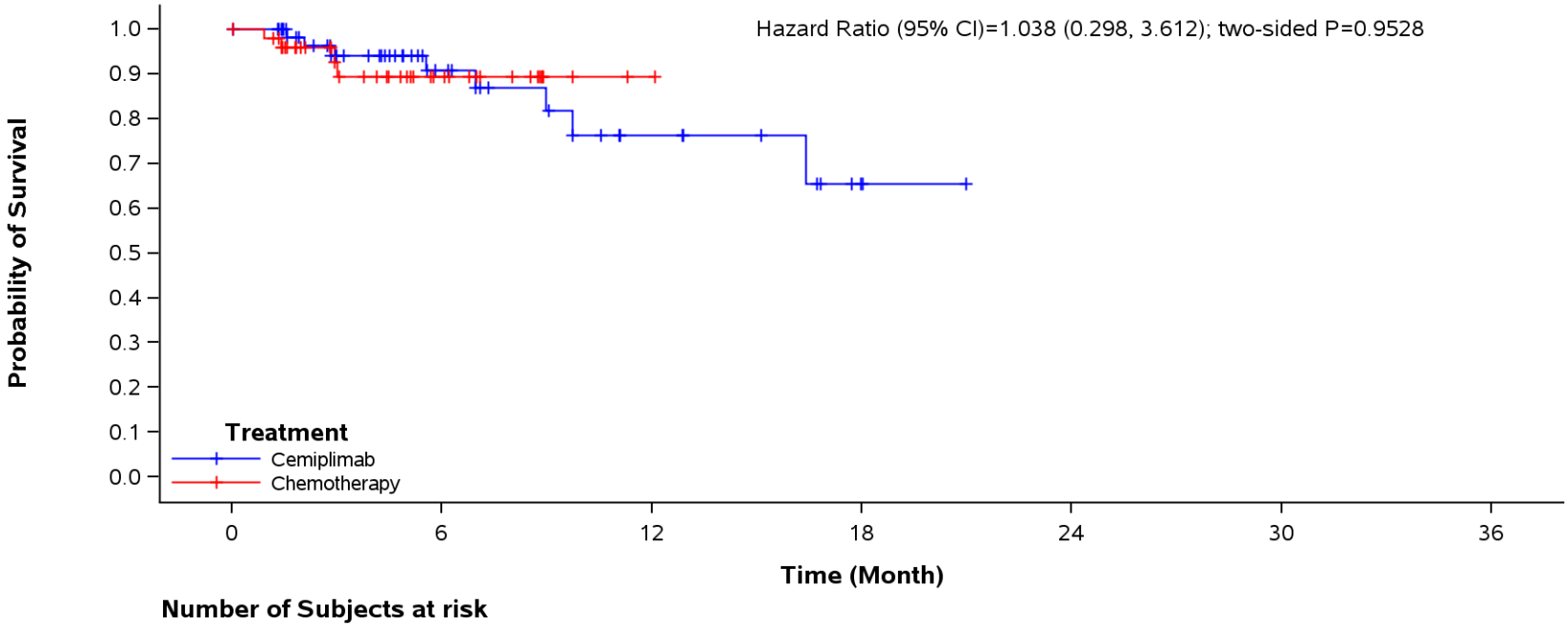

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 15 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 97 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Emotional Functioning - 10 pts sensitivity sustained improvement



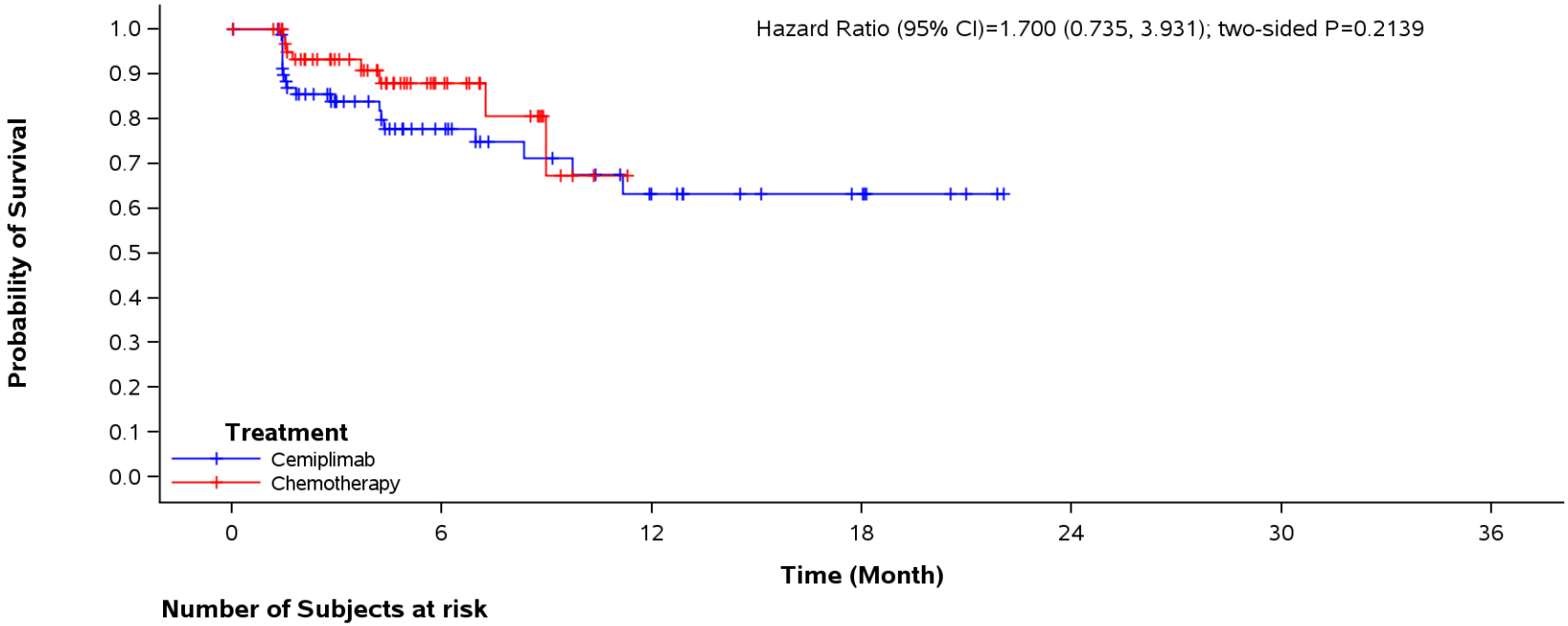

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 25 | 10 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 16 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts sensitivity sustained improvement



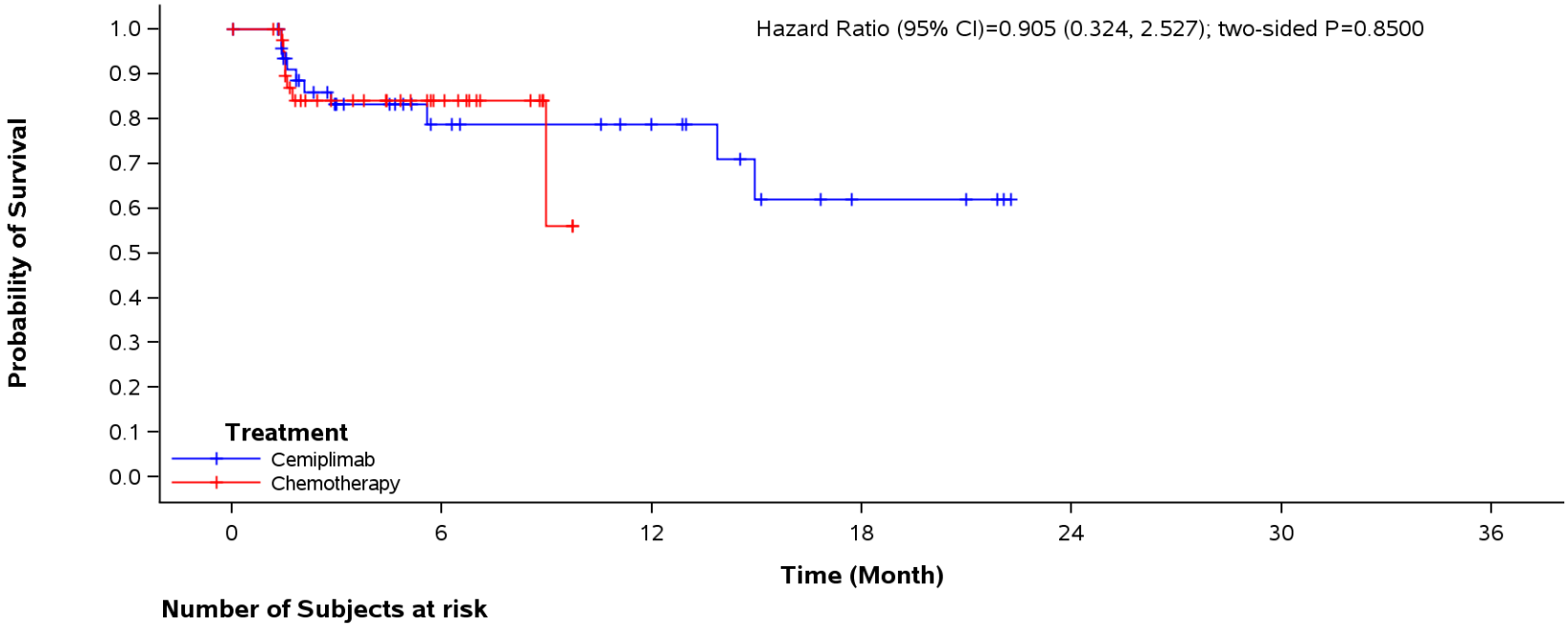

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 29 | 13 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 18 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Financial Problems - 10 pts sensitivity sustained improvement



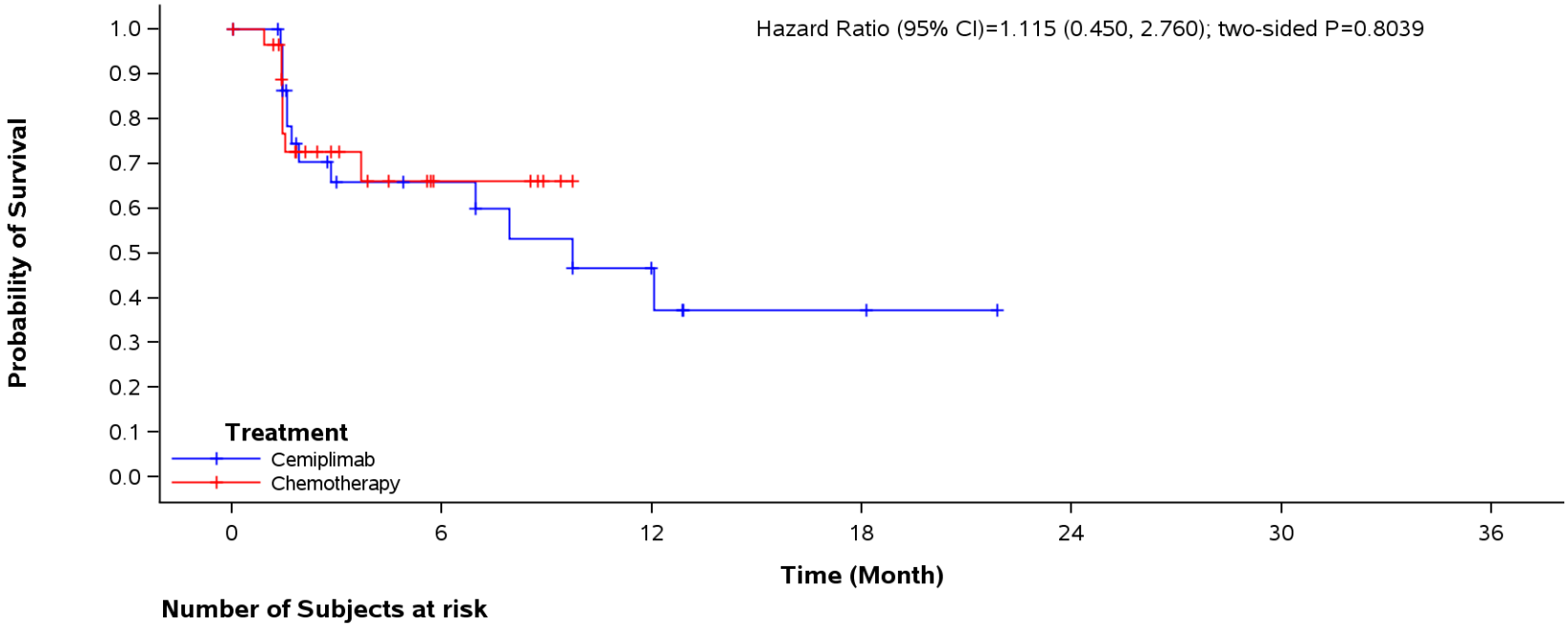

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 17 | 12 | 4 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts sensitivity sustained improvement



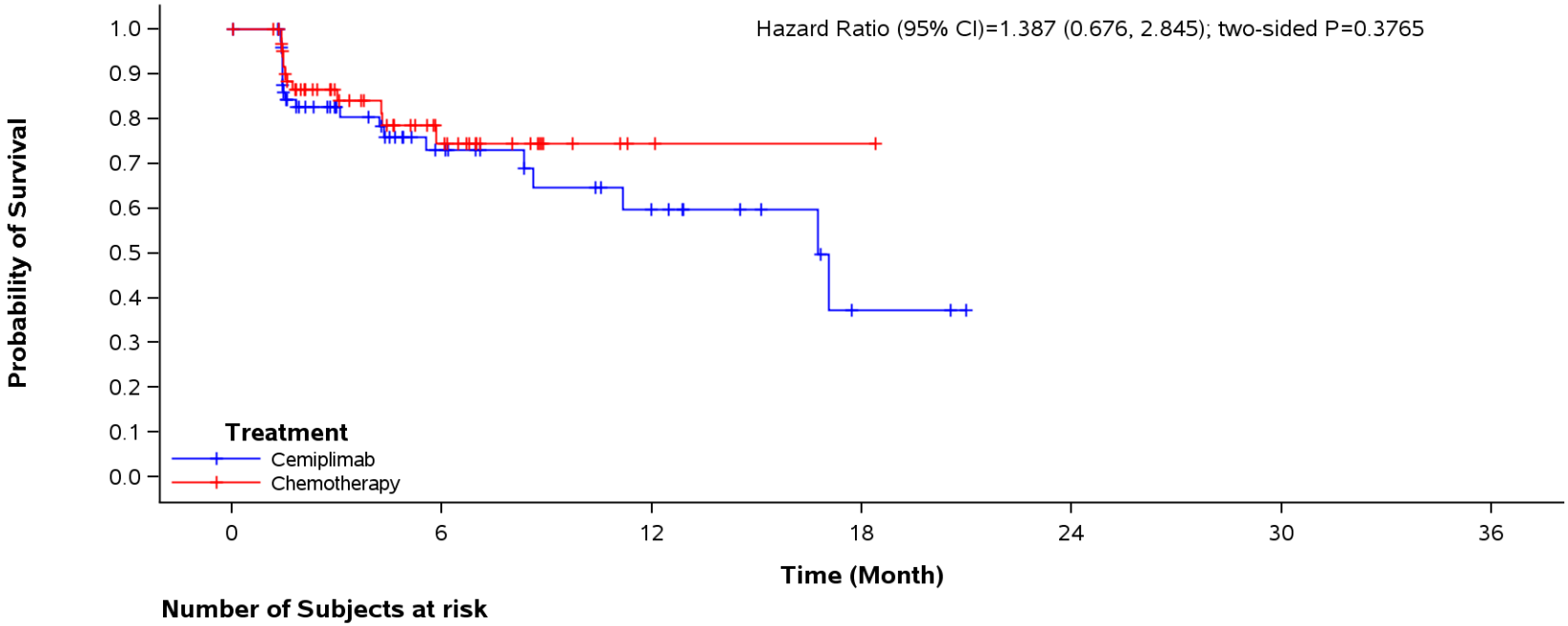

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 11 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Pain - 10 pts sensitivity sustained improvement



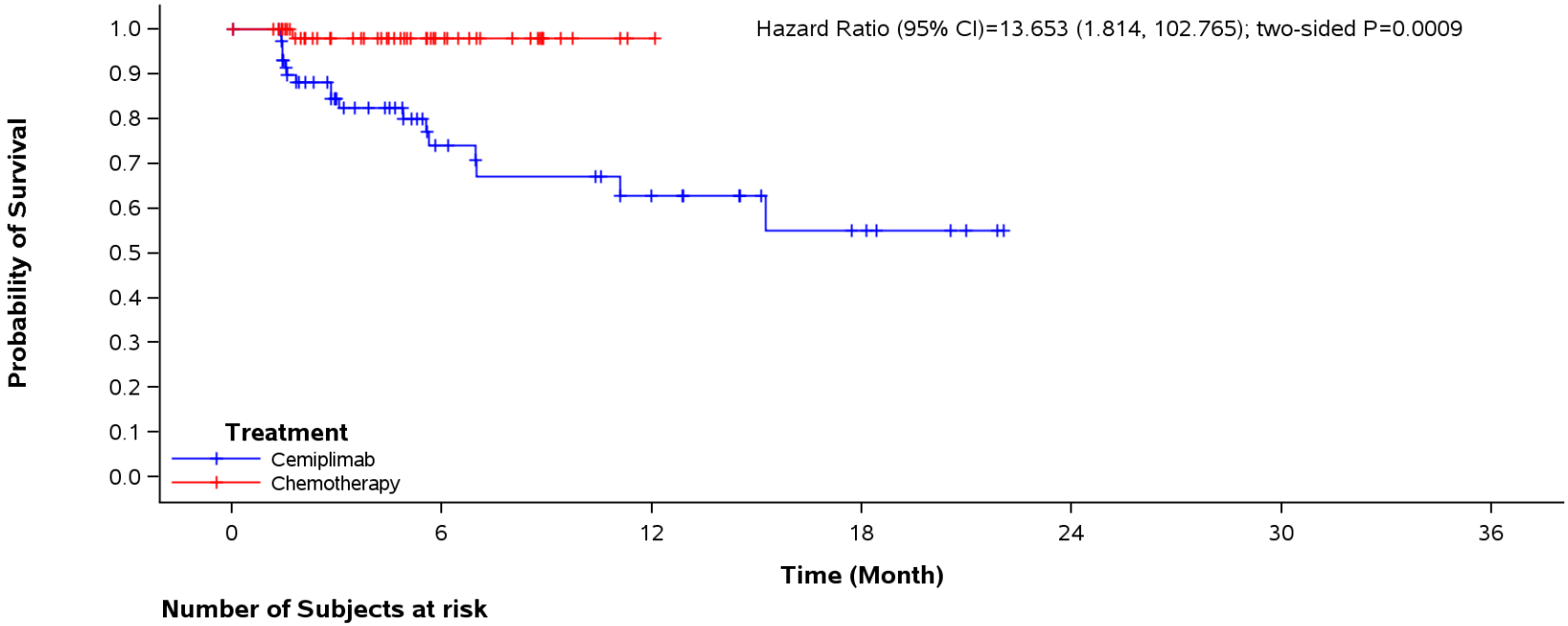

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 23 | 11 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Physical Functioning - 10 pts sensitivity sustained improvement



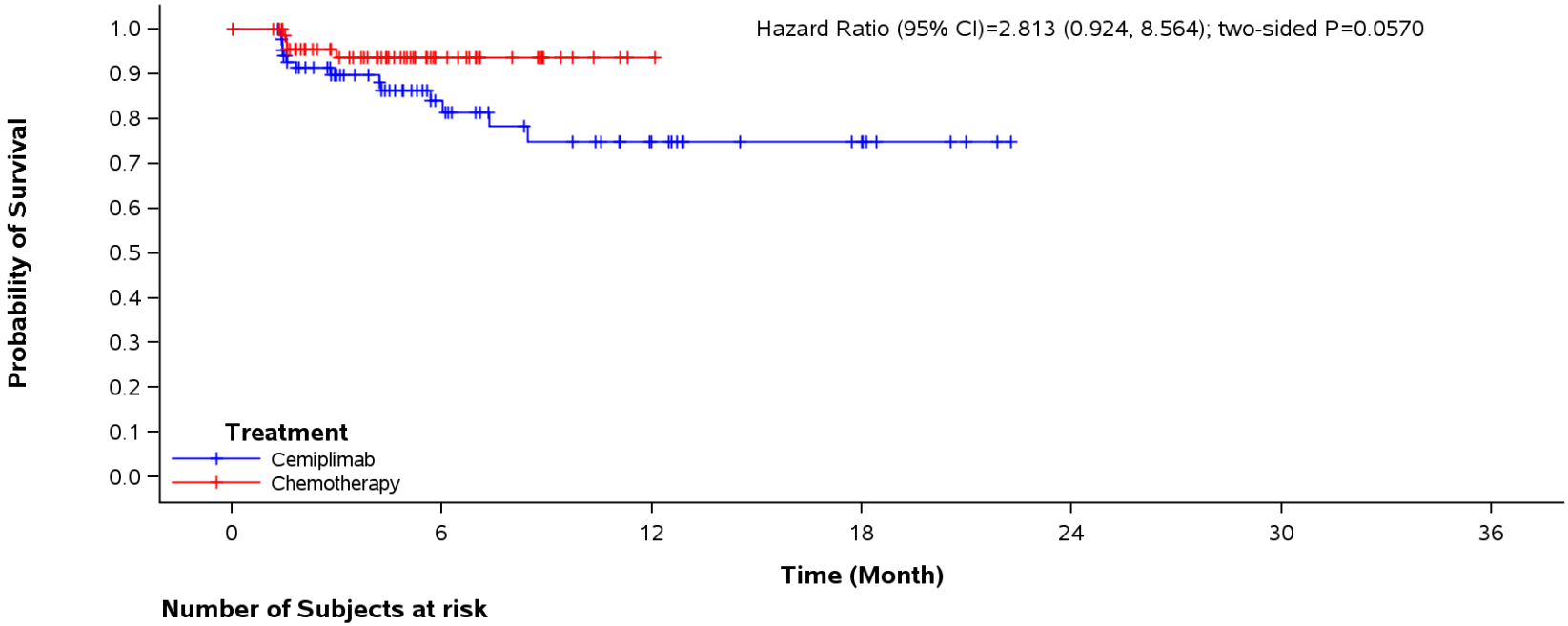

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 23 | 13 | 6 | 0 | 0 | 0 |
| Chemotherapy | 97 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts sensitivity sustained improvement



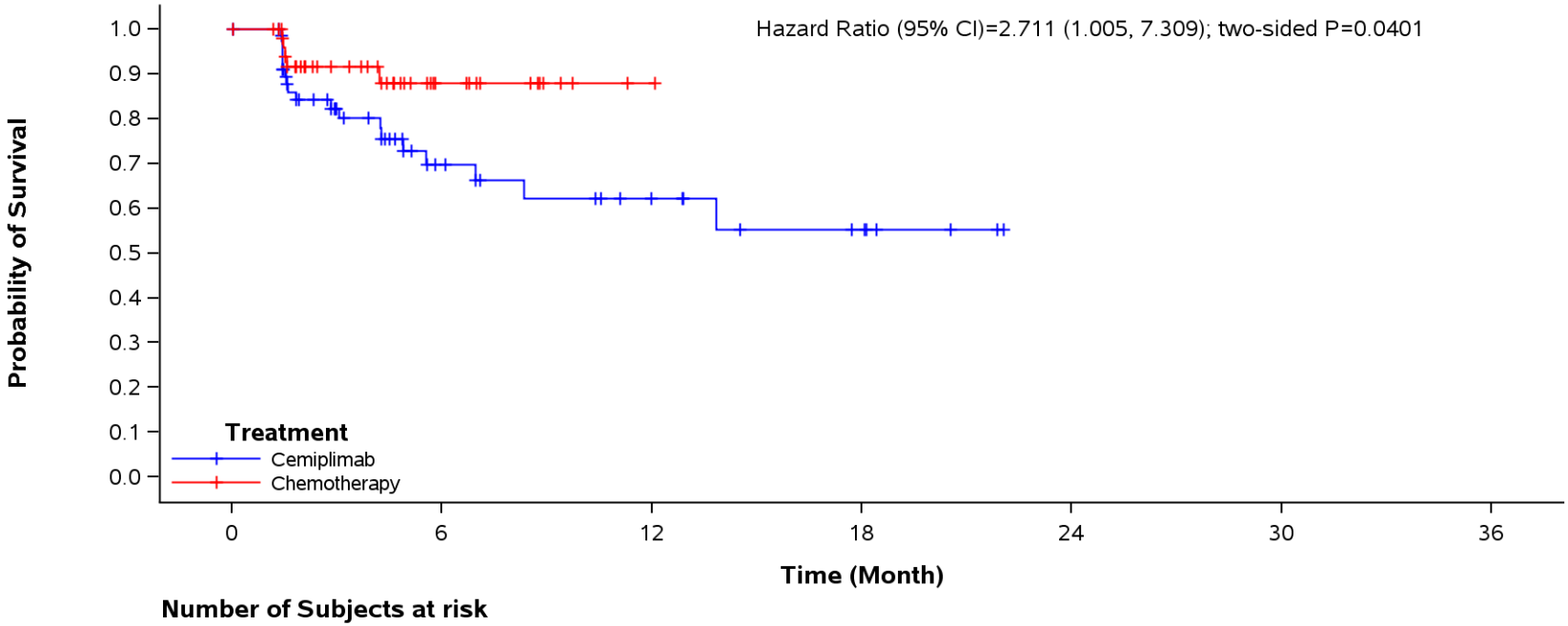

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 33 | 15 | 8 | 0 | 0 | 0 |
| Chemotherapy | 97 | 22 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Role Functioning - 10 pts sensitivity sustained improvement



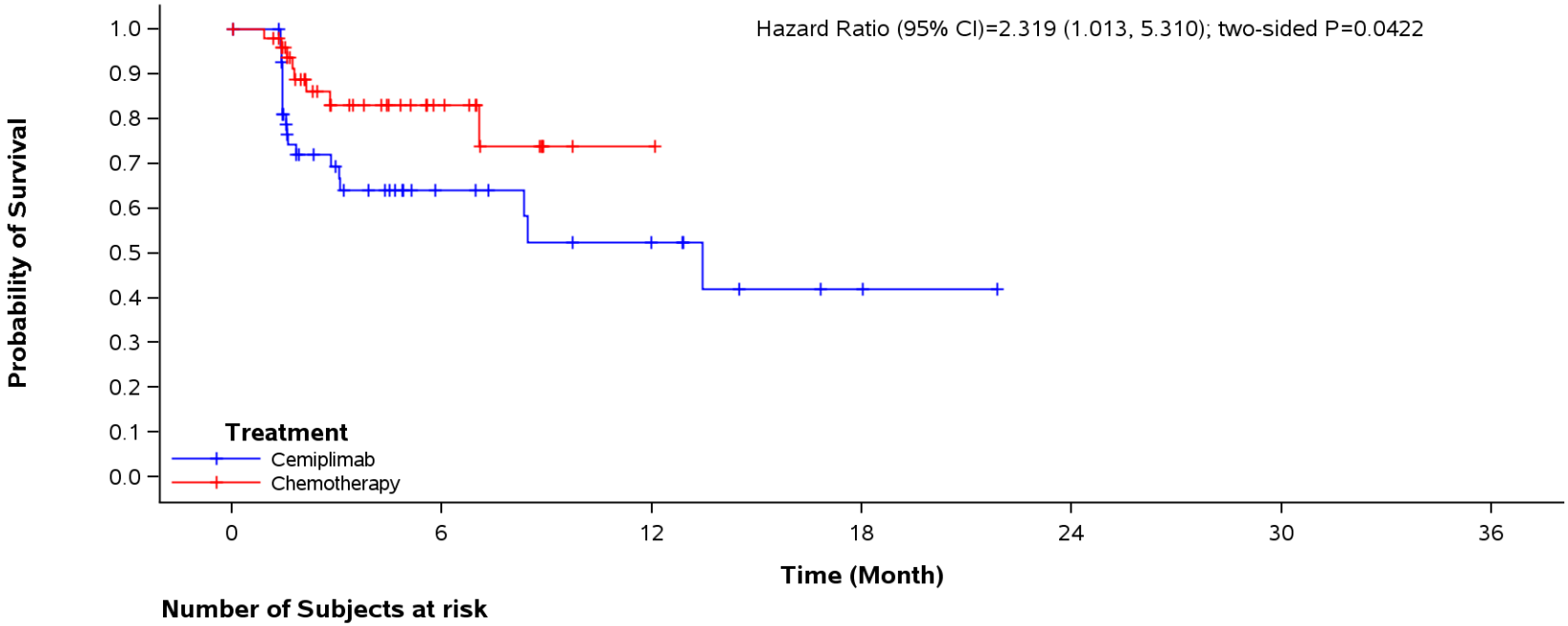

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 21 | 11 | 6 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts sensitivity sustained improvement



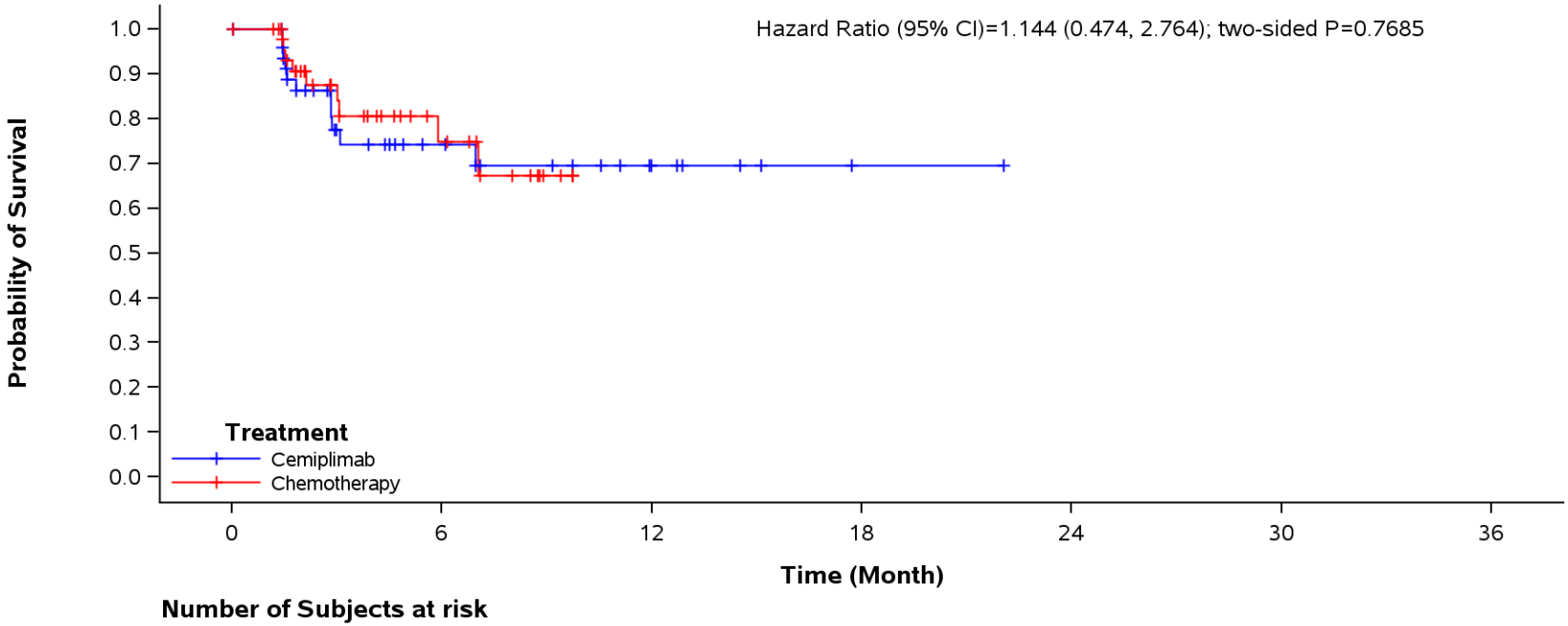

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 14 | 7 | 2 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts sensitivity sustained improvement



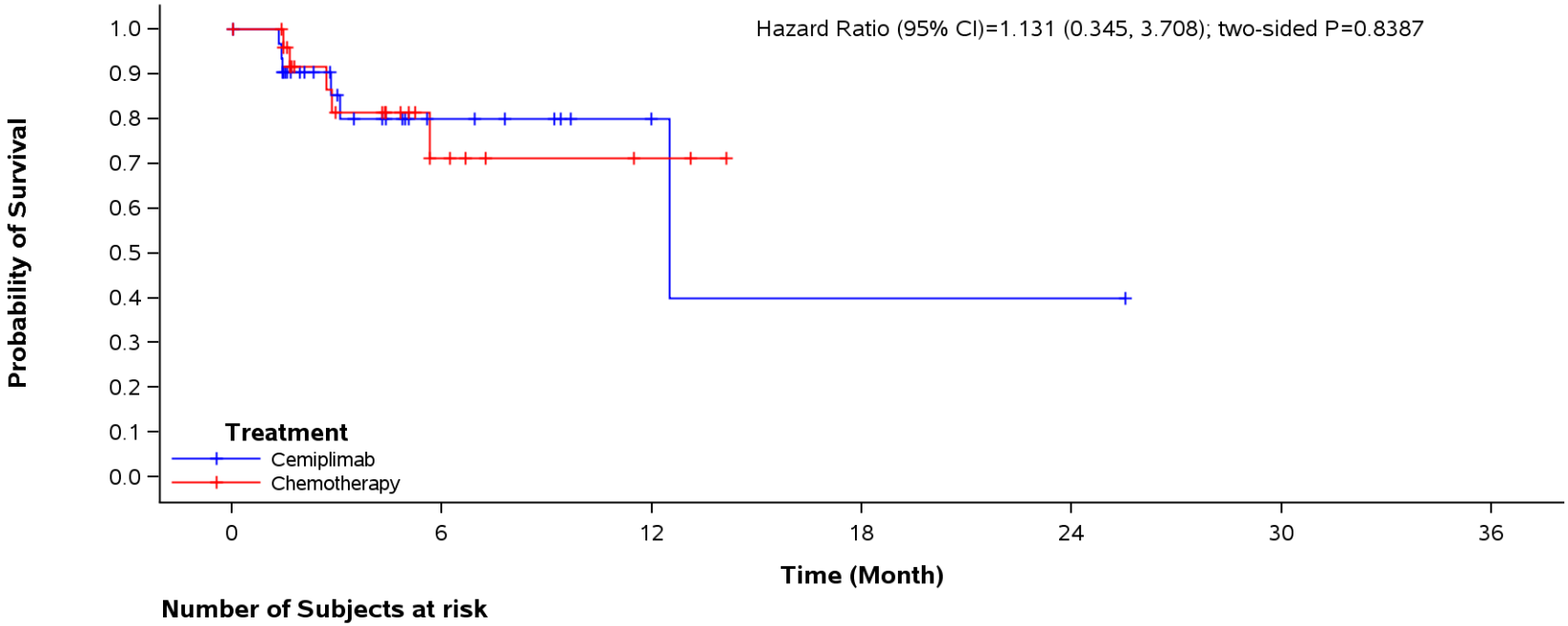

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 17 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 97 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Appetite loss - 10 pts sensitivity sustained improvement



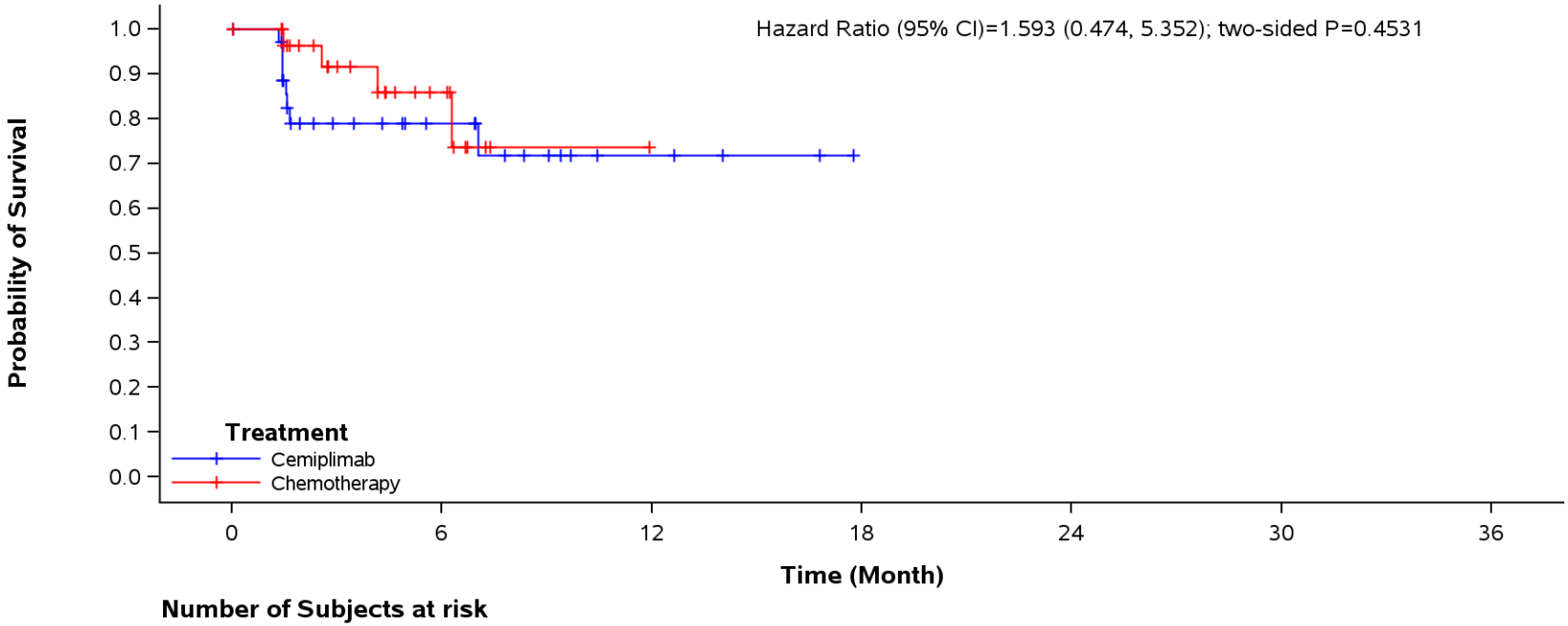

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 8 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 86 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts sensitivity sustained improvement



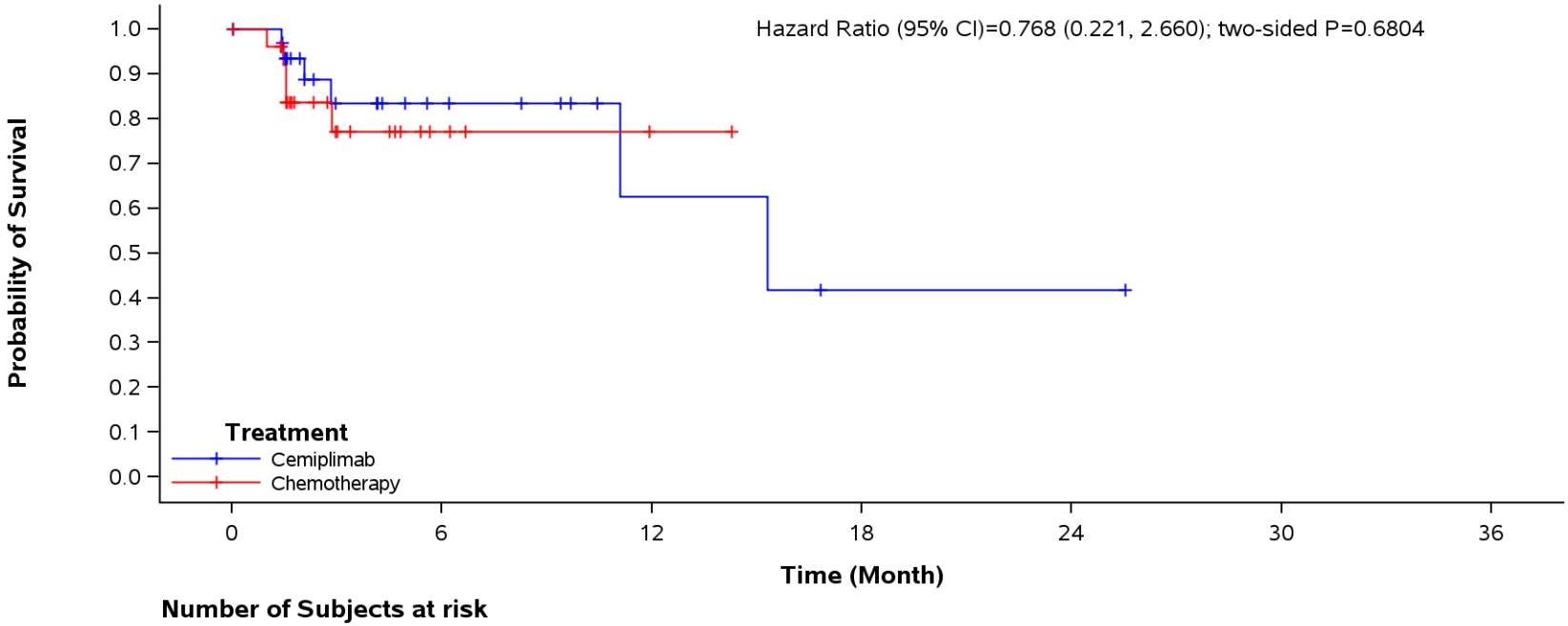

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 13 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts sensitivity sustained improvement



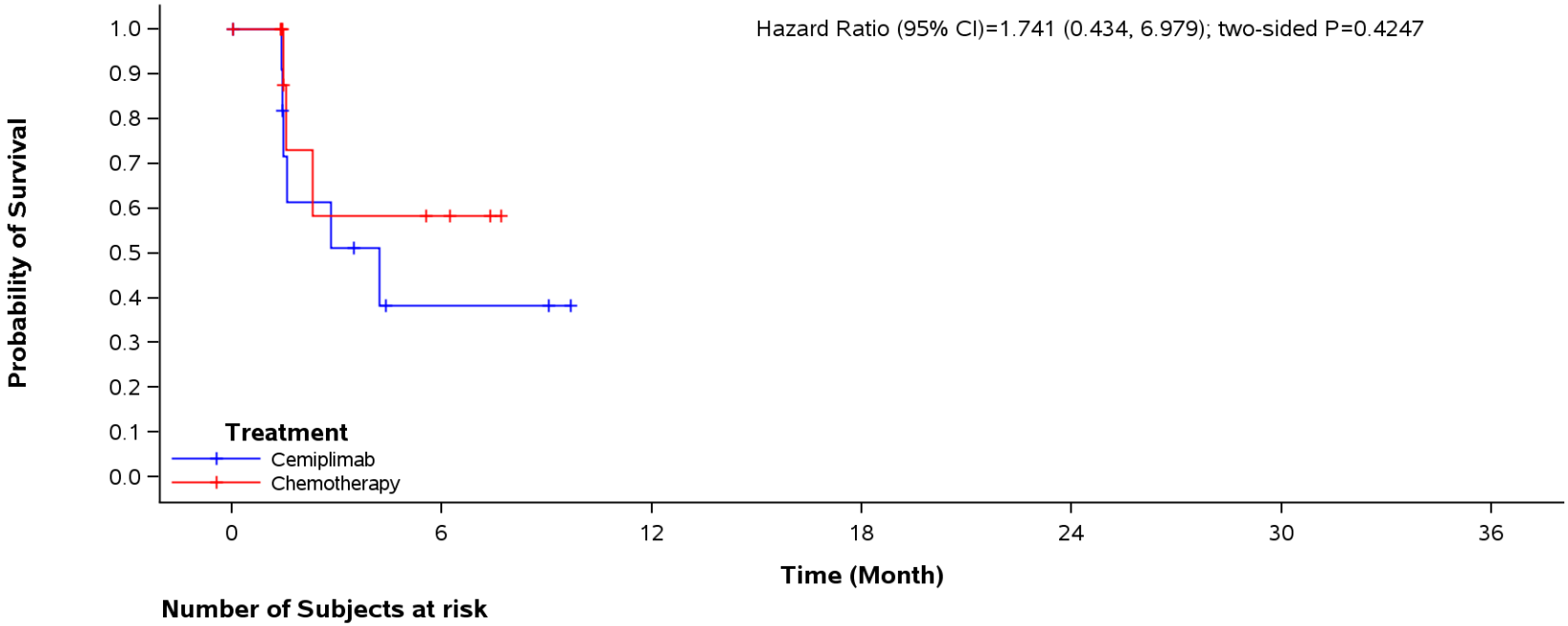

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 10 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 86 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts sensitivity sustained improvement



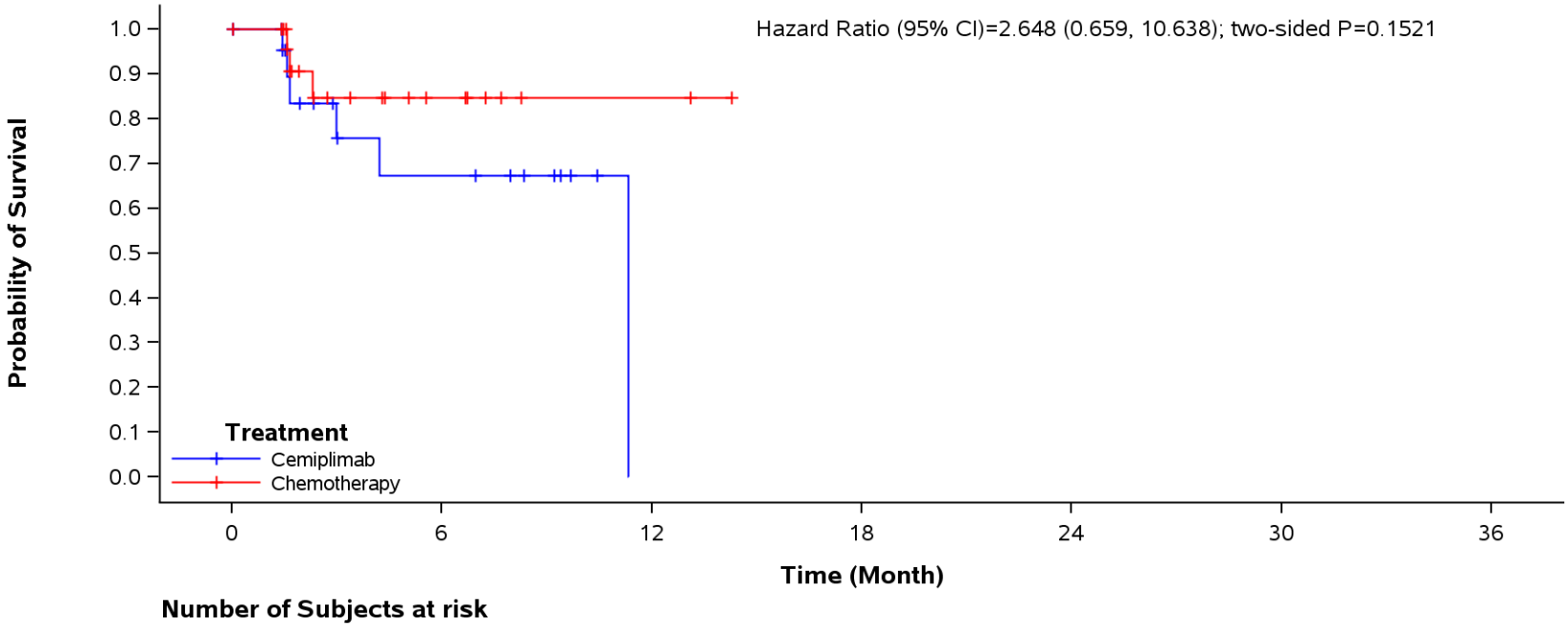

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts sensitivity sustained improvement



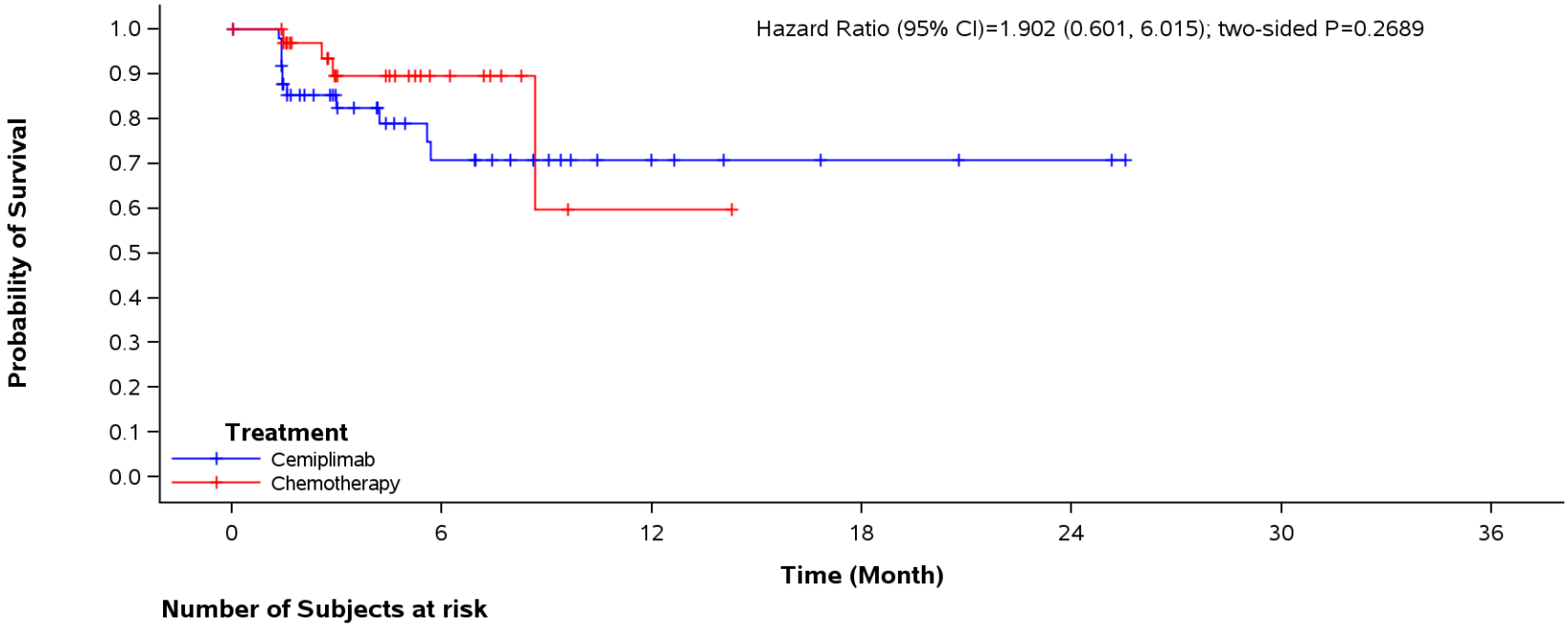

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 8 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 86 | 7 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Emotional Functioning - 10 pts sensitivity sustained improvement



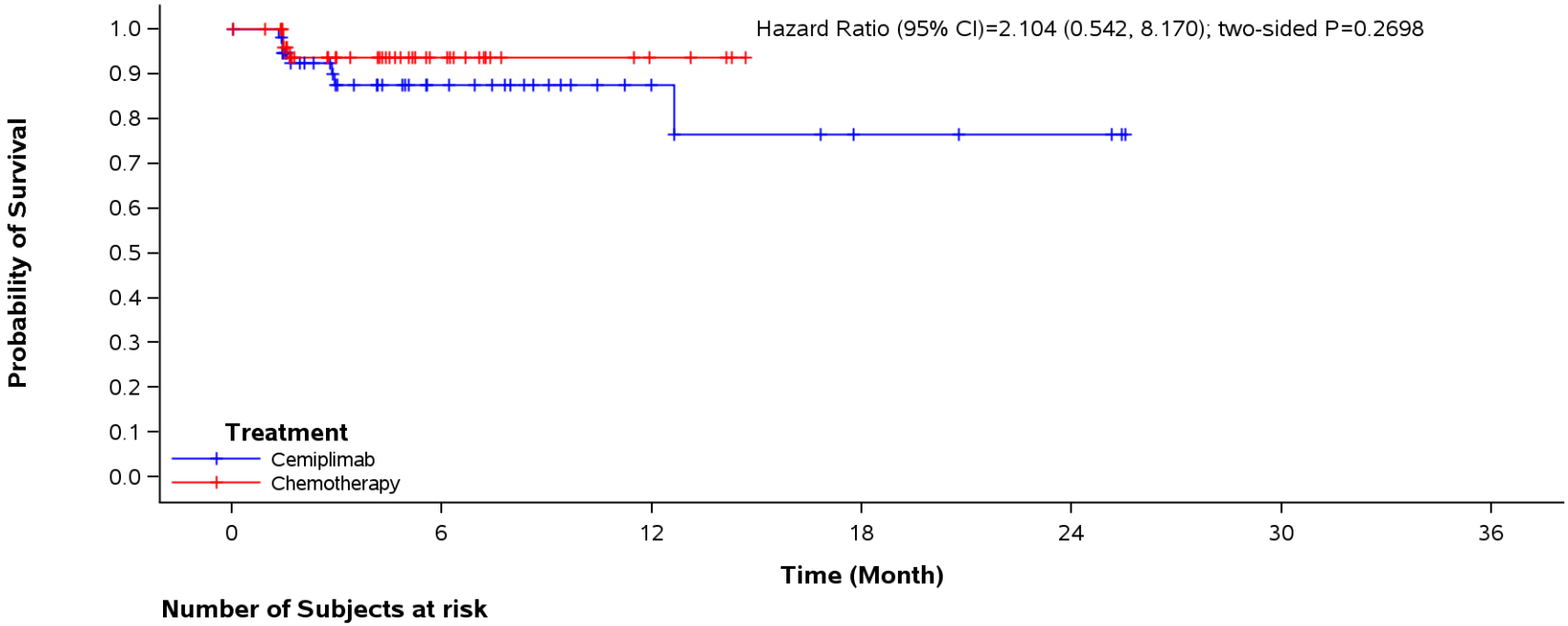

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 17 | 6 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Fatigue - 10 pts sensitivity sustained improvement



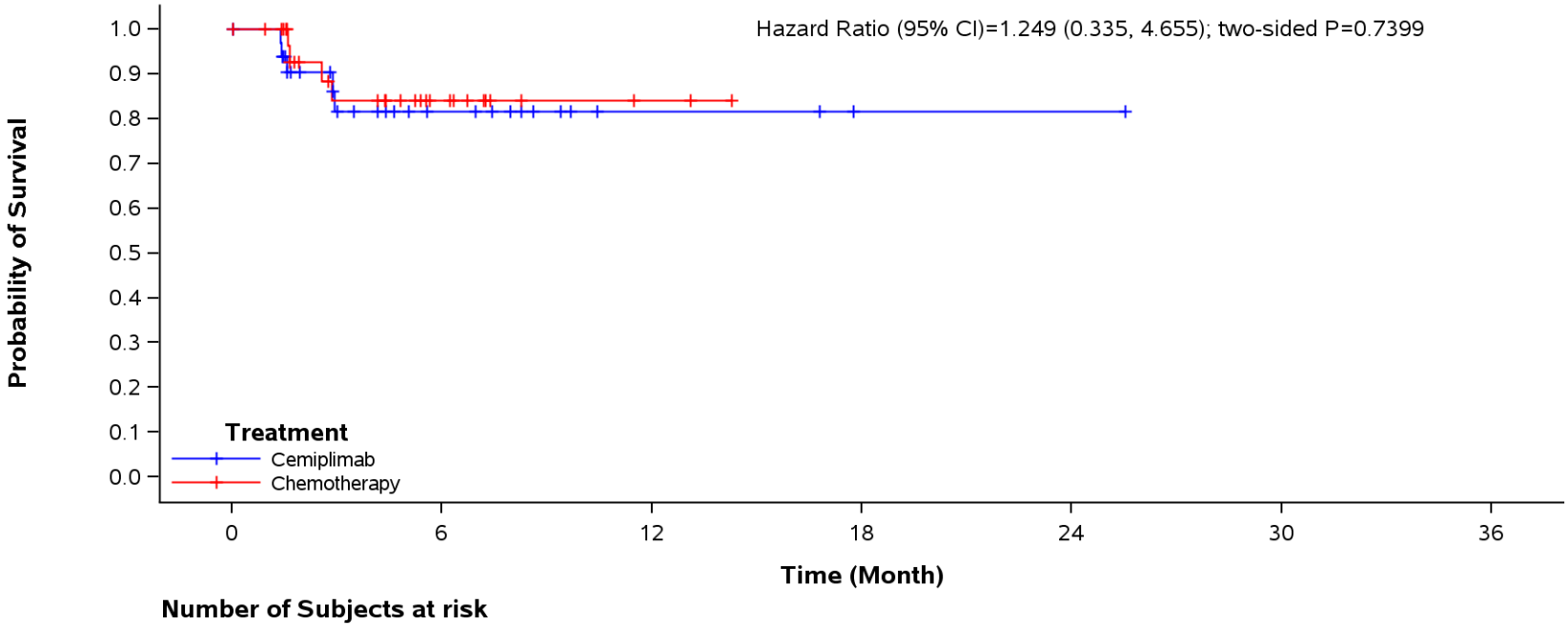

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 22 | 8 | 4 | 3 | 0 | 0 |
| Chemotherapy | 86 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Financial Problems - 10 pts sensitivity sustained improvement



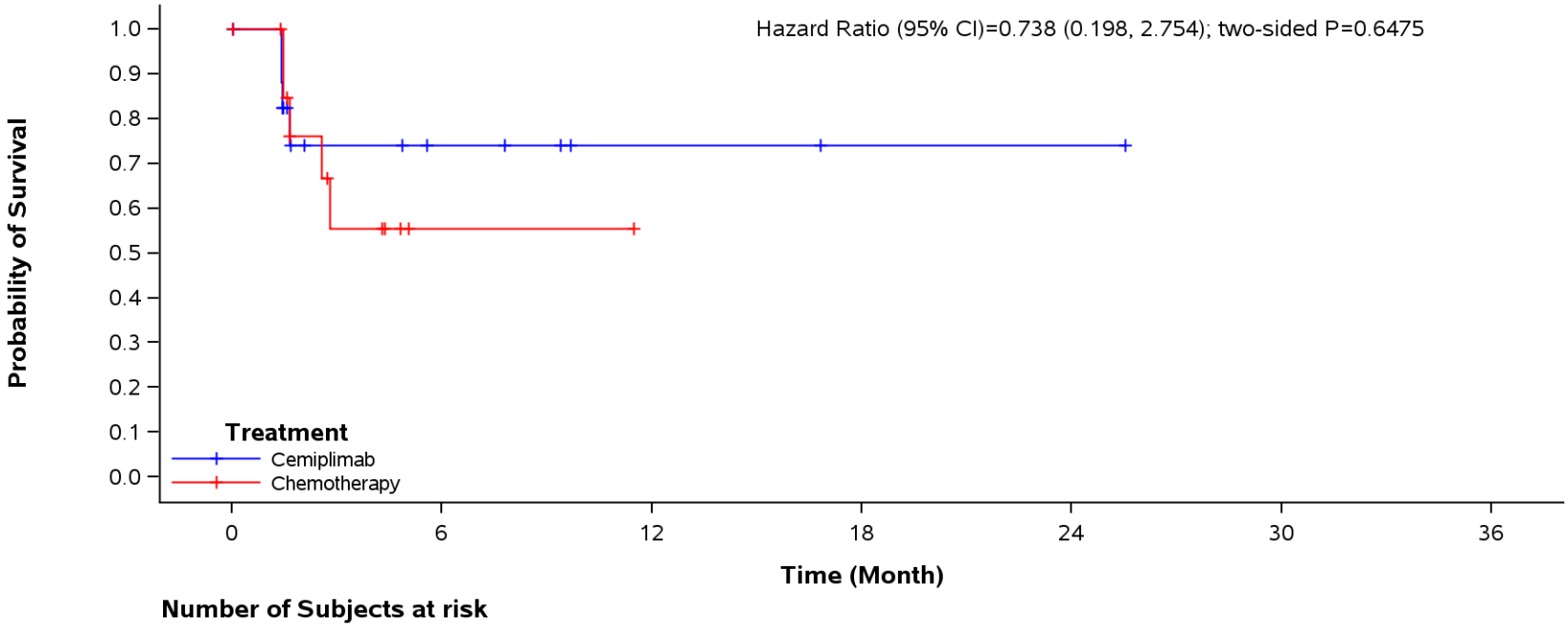

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 11 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 86 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts sensitivity sustained improvement



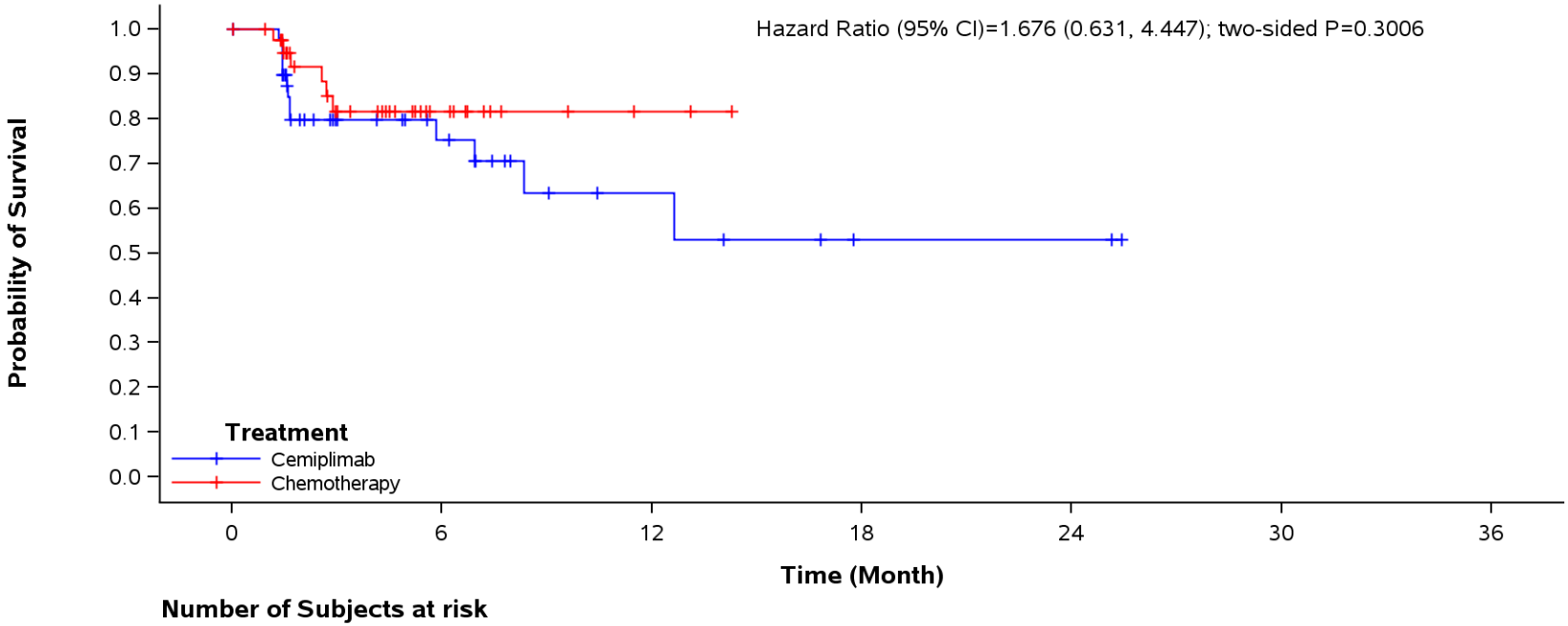

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 5 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 86 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts sensitivity sustained improvement



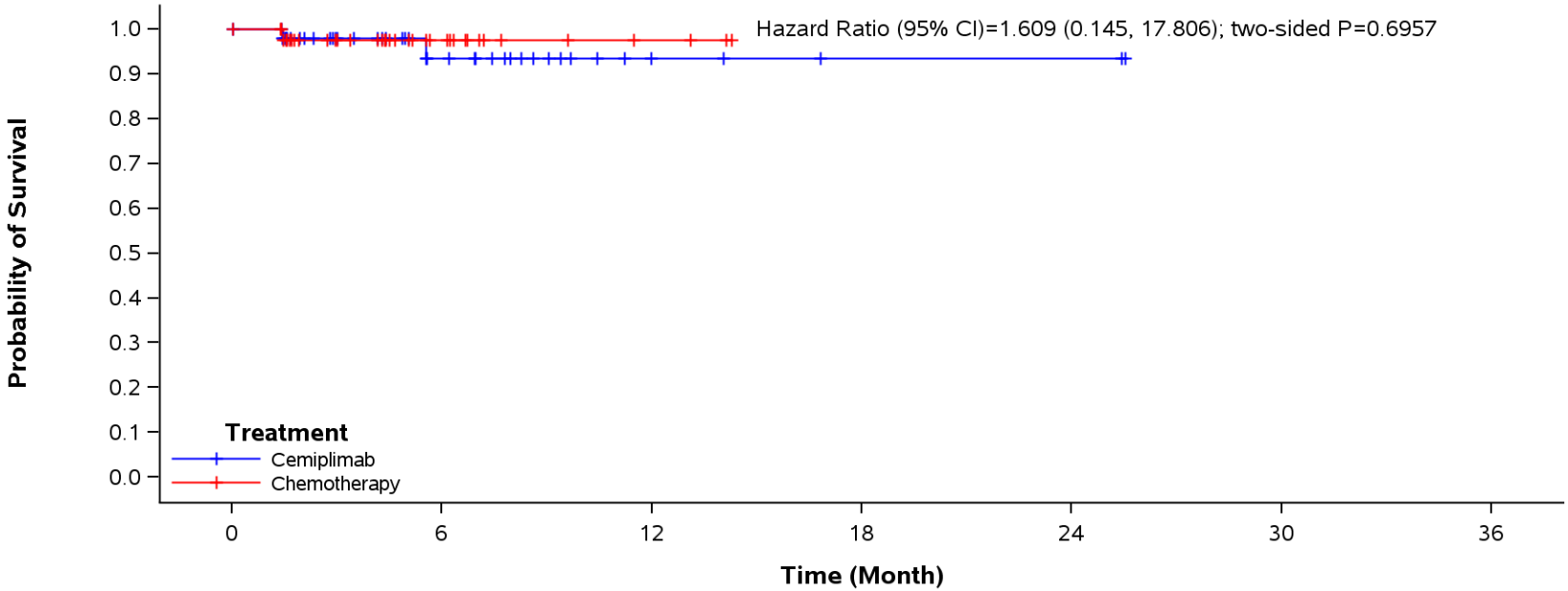

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 17 | 6 | 2 | 2 | 0 | 0 |
| Chemotherapy | 86 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Physical Functioning - 10 pts sensitivity sustained improvement



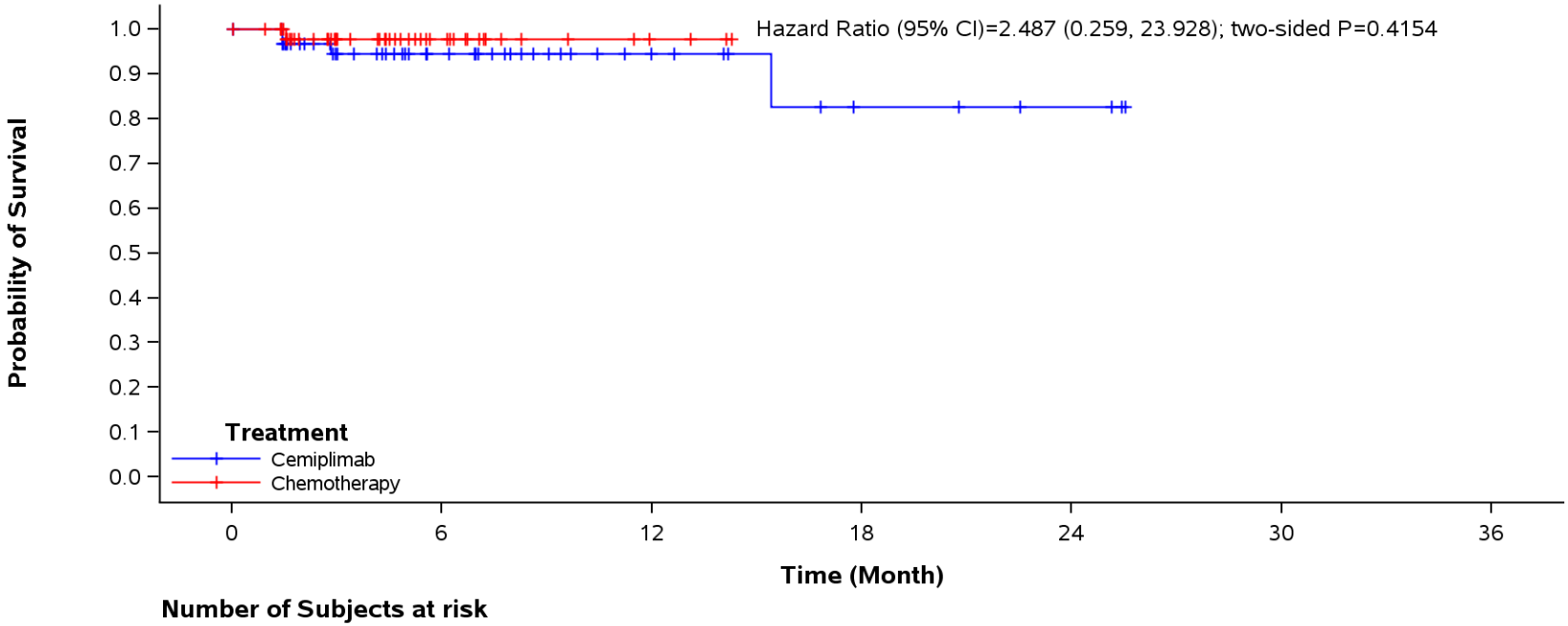

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 19 | 4 | 2 | 2 | 0 | 0 |
| Chemotherapy | 86 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts sensitivity sustained improvement



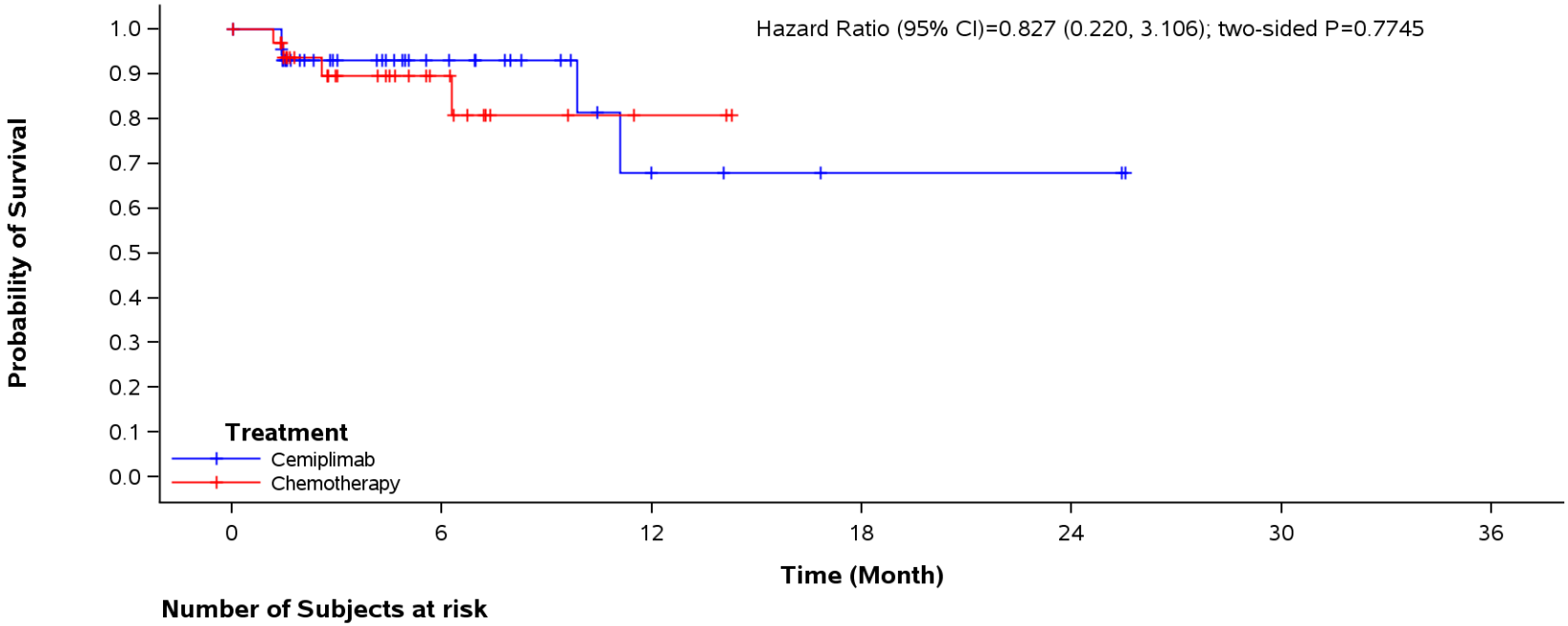

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 27 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts sensitivity sustained improvement



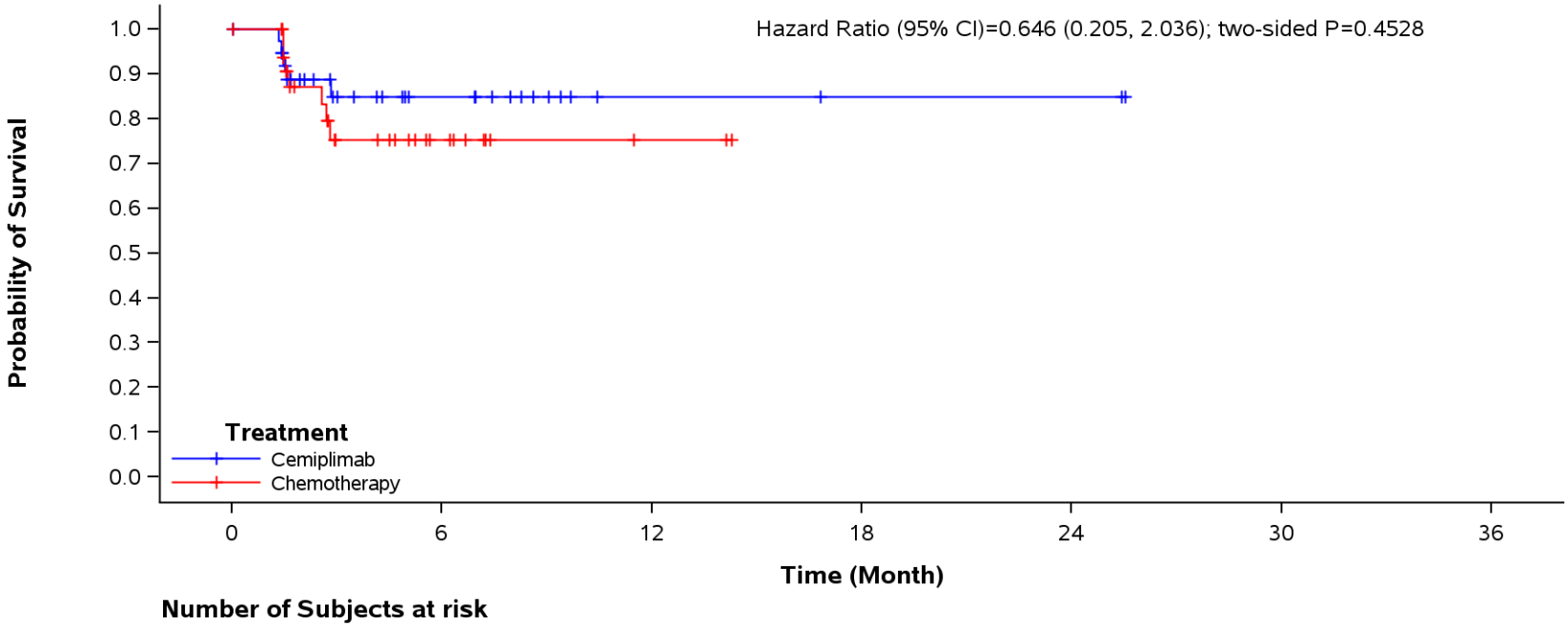

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 16 | 4 | 2 | 2 | 0 | 0 |
| Chemotherapy | 86 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts sensitivity sustained improvement



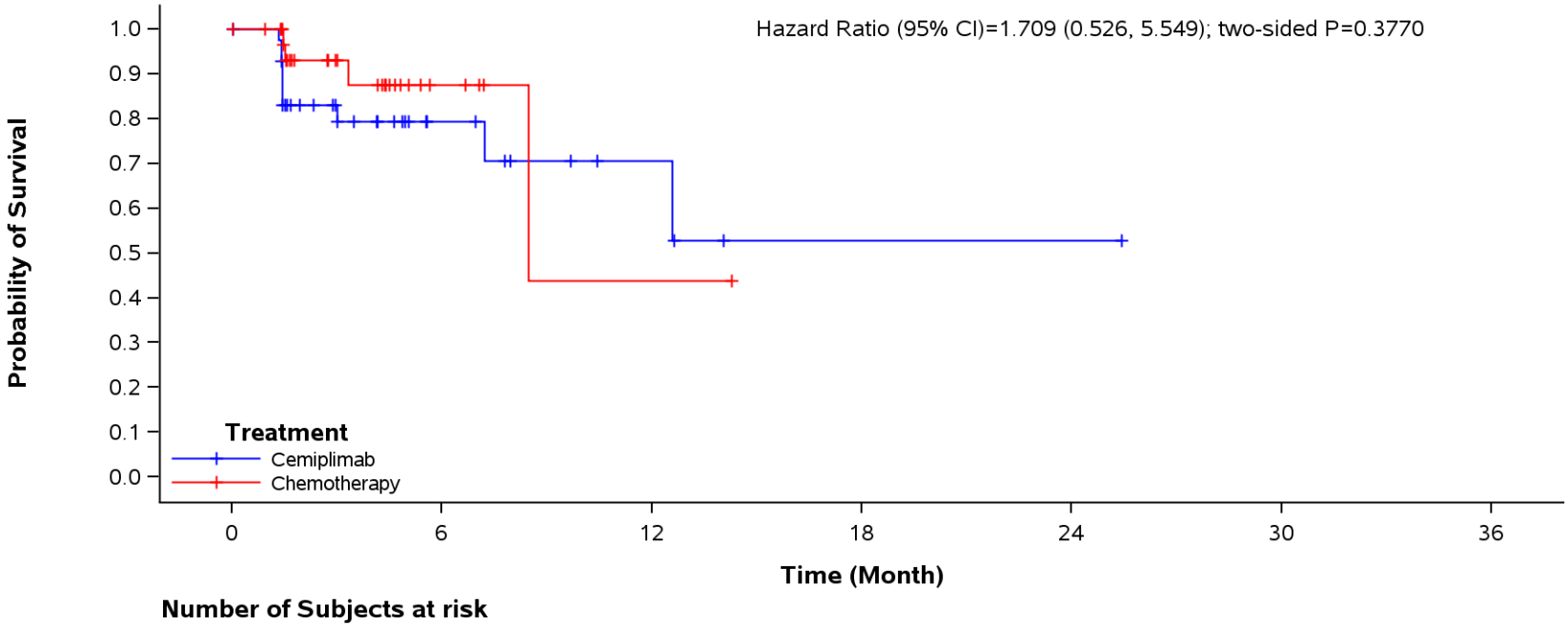

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 13 | 3 | 2 | 2 | 0 | 0 |
| Chemotherapy | 86 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts sensitivity sustained improvement



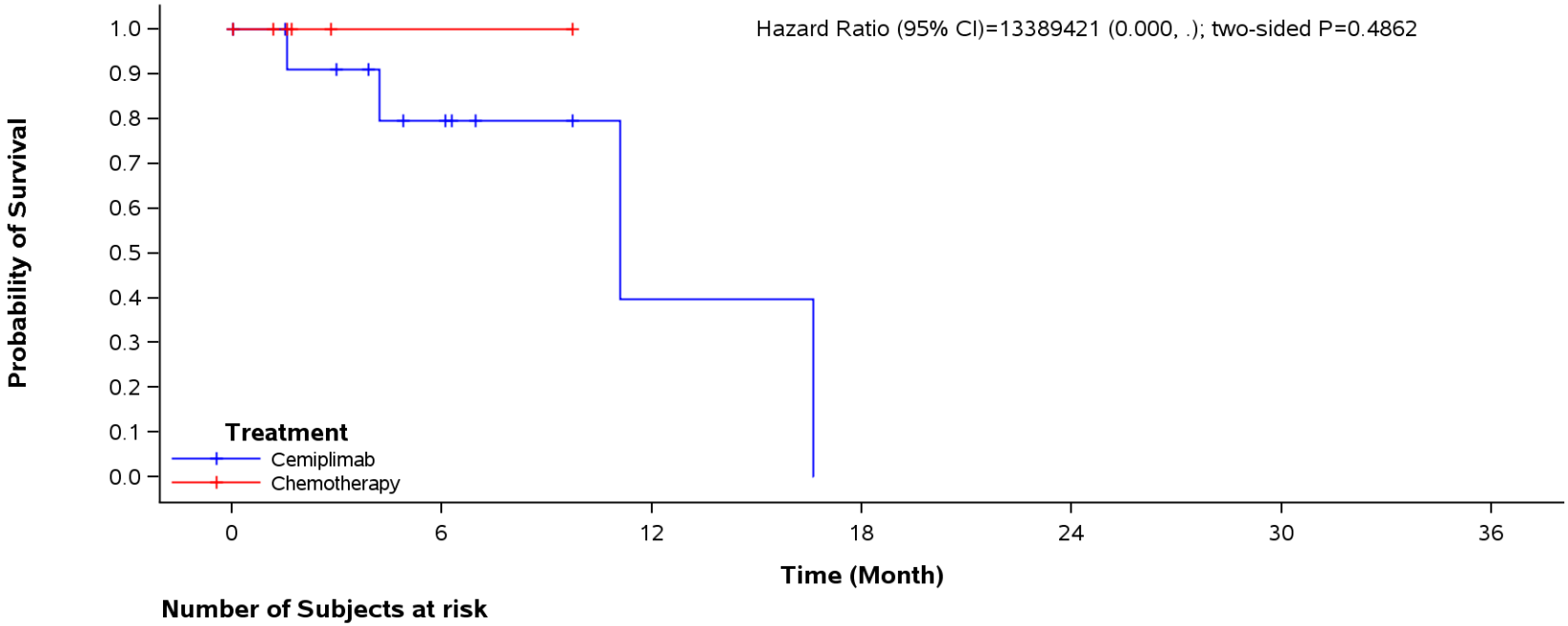

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 10 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 86 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts sensitivity sustained improvement



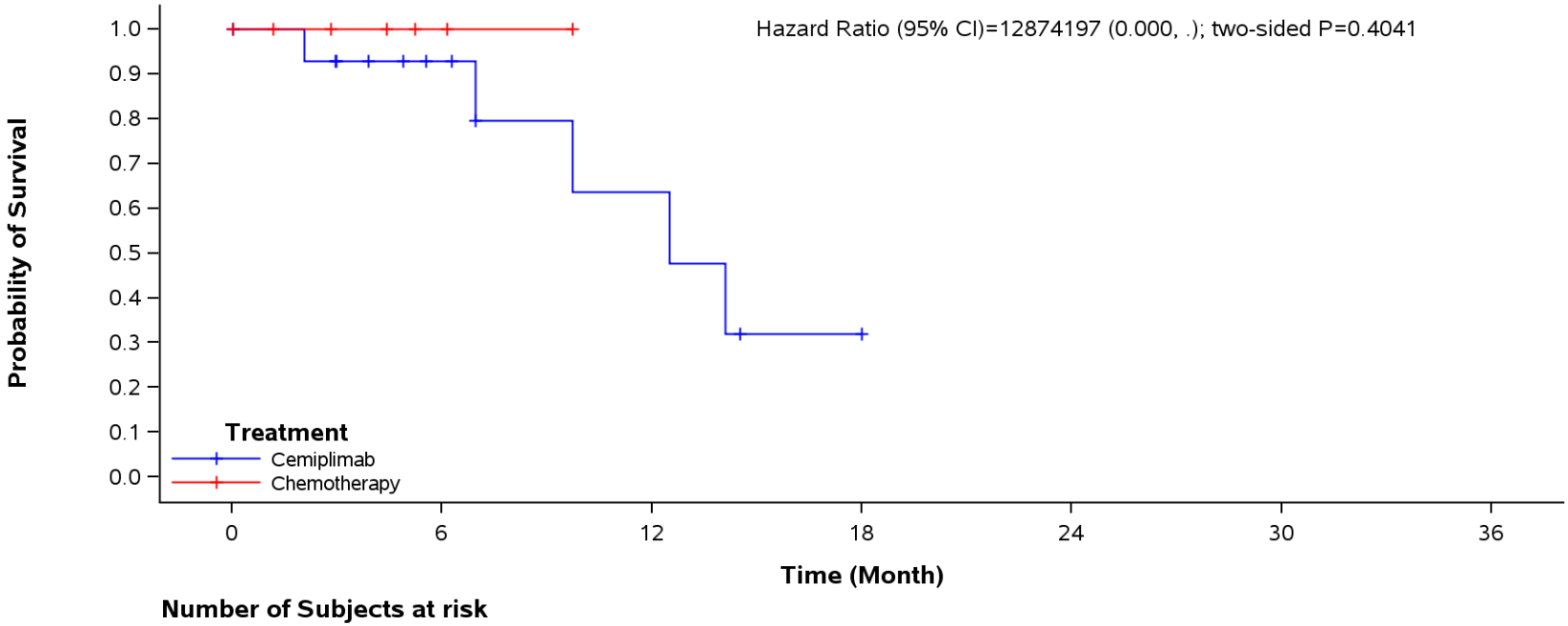

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Cognitive Functioning - 10 pts sensitivity sustained improvement



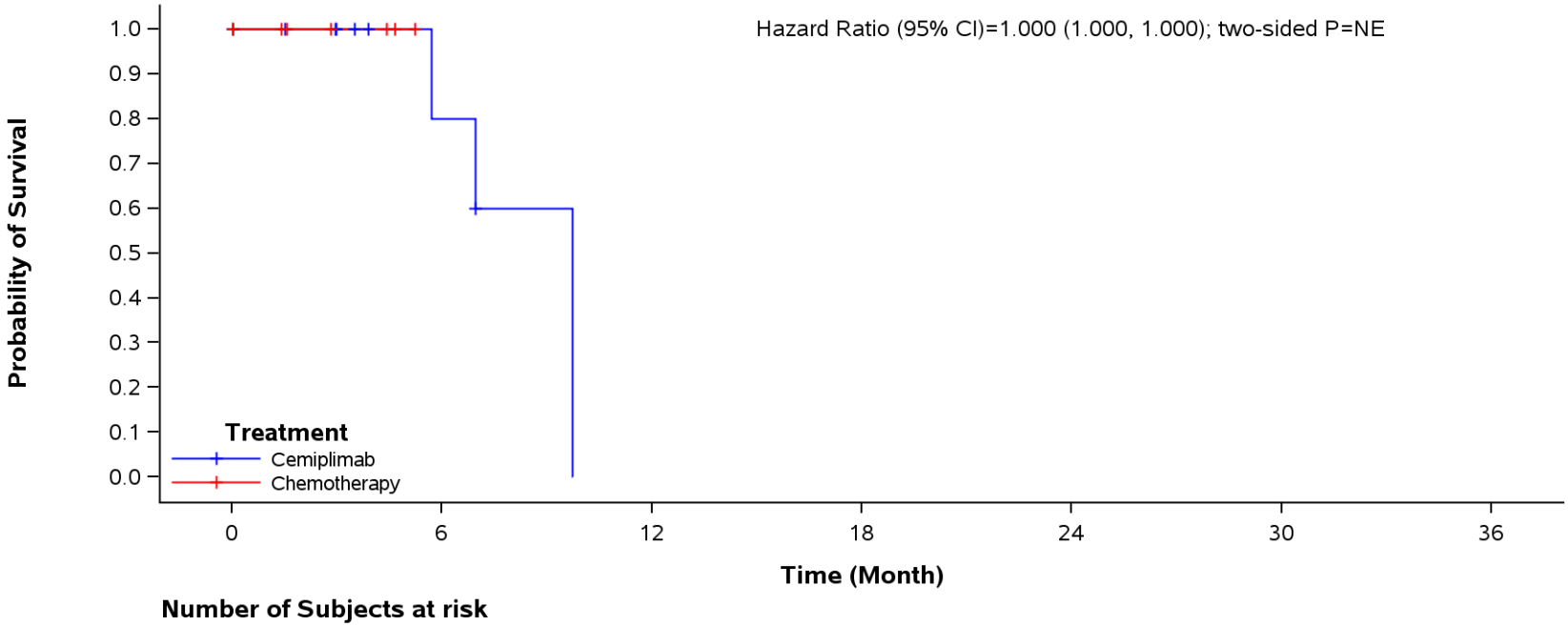

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 8 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts sensitivity sustained improvement



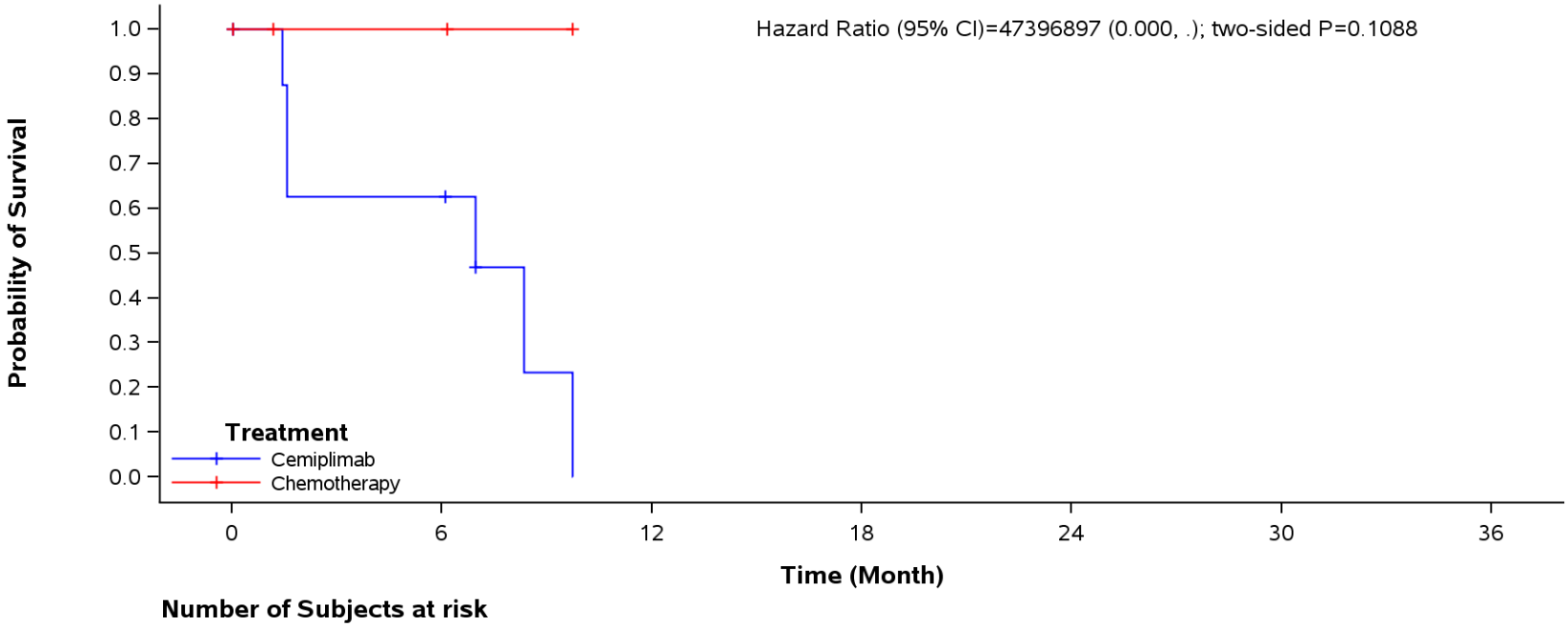

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts sensitivity sustained improvement



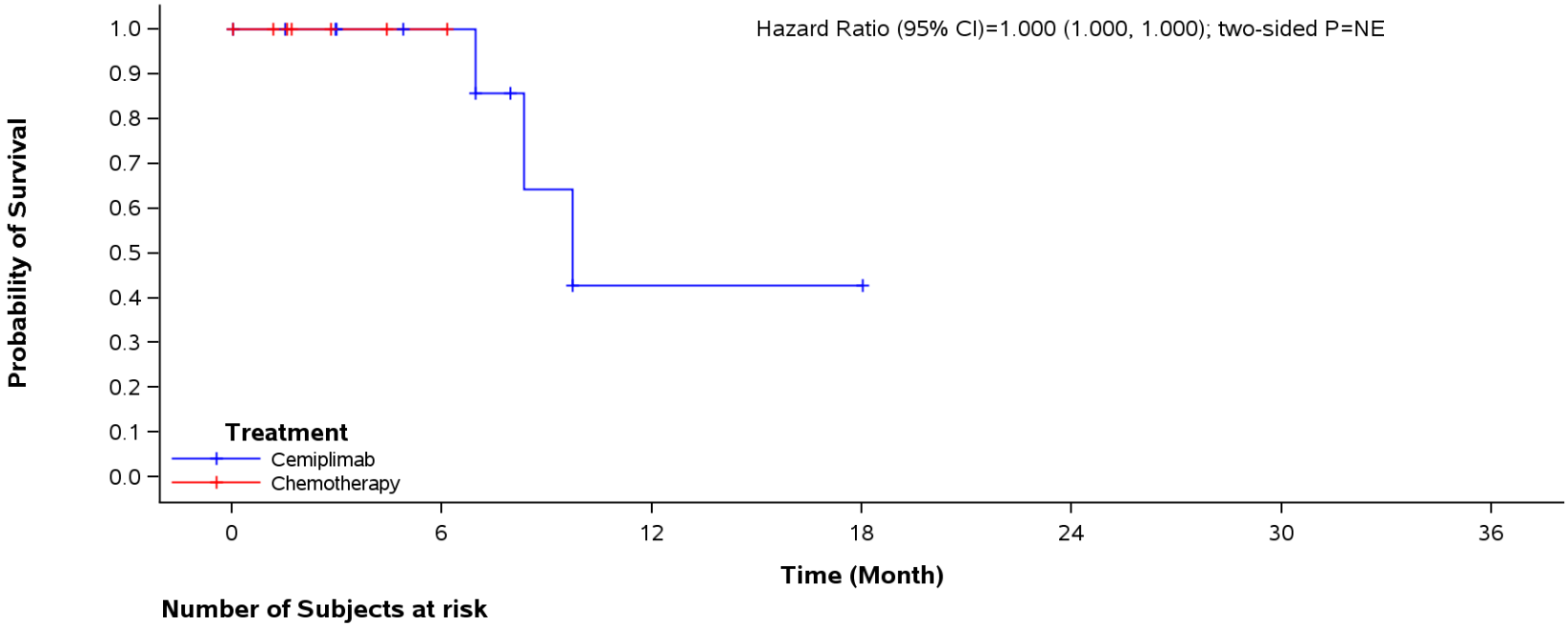

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts sensitivity sustained improvement



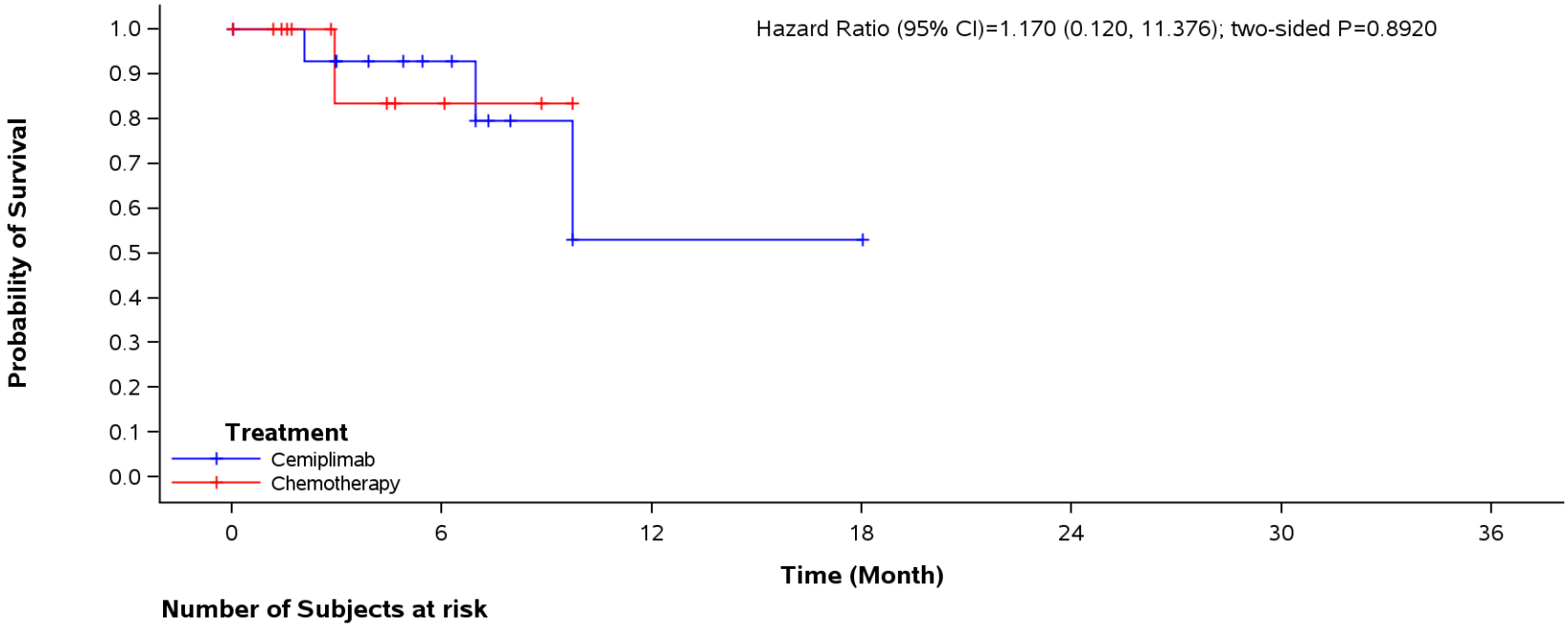

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 7 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts sensitivity sustained improvement



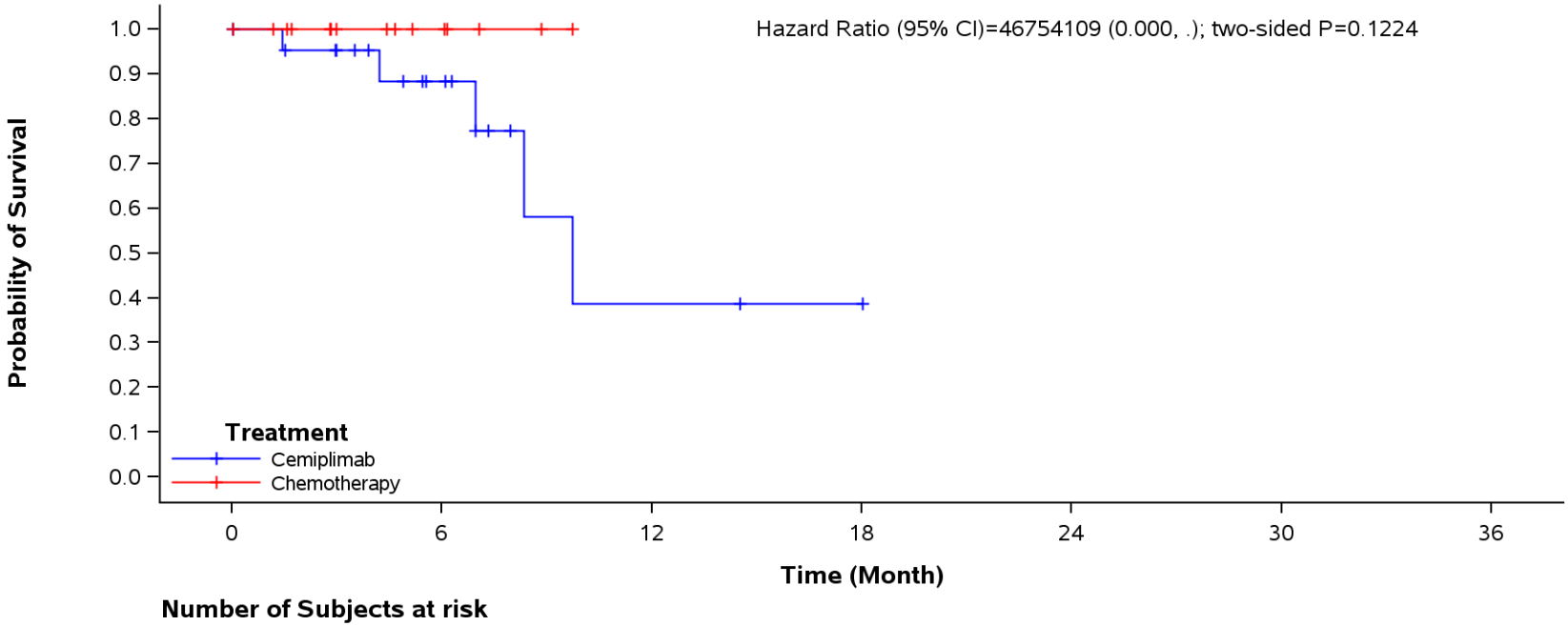

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 8 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts sensitivity sustained improvement



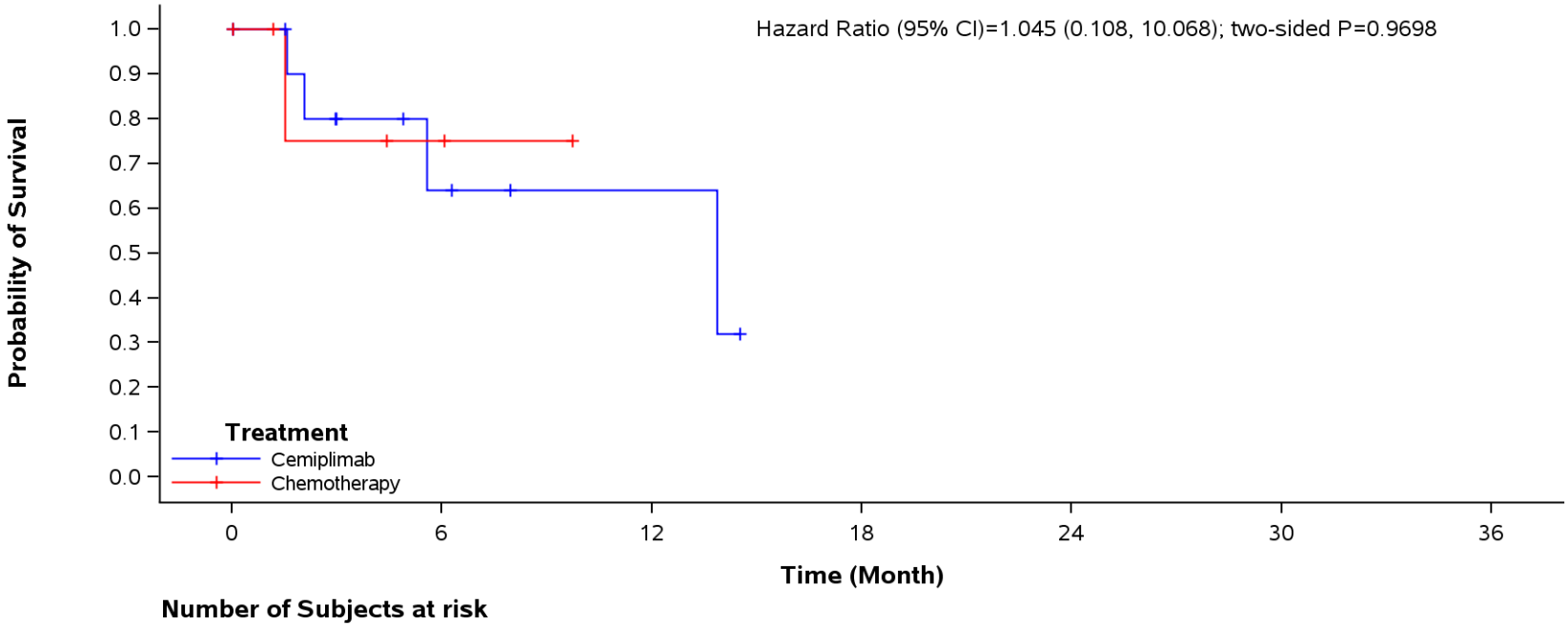

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 10 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts sensitivity sustained improvement



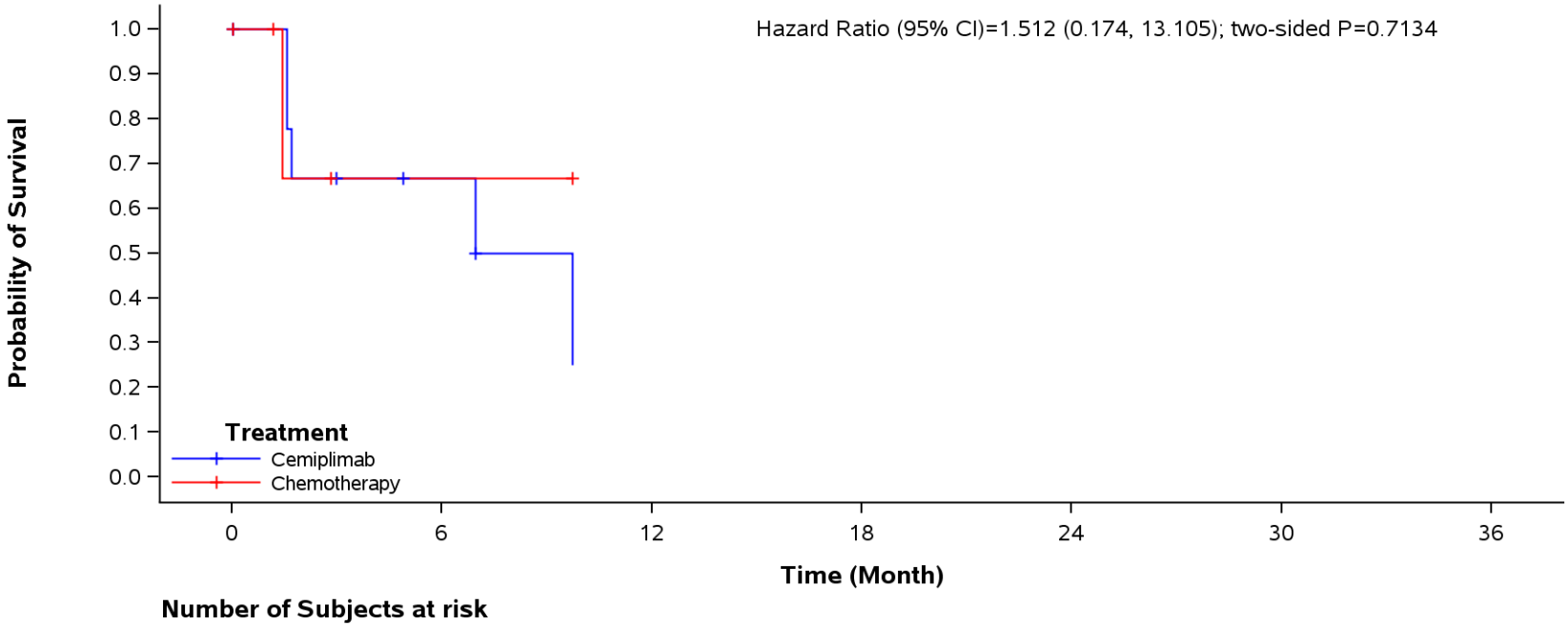

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 4 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts sensitivity sustained improvement



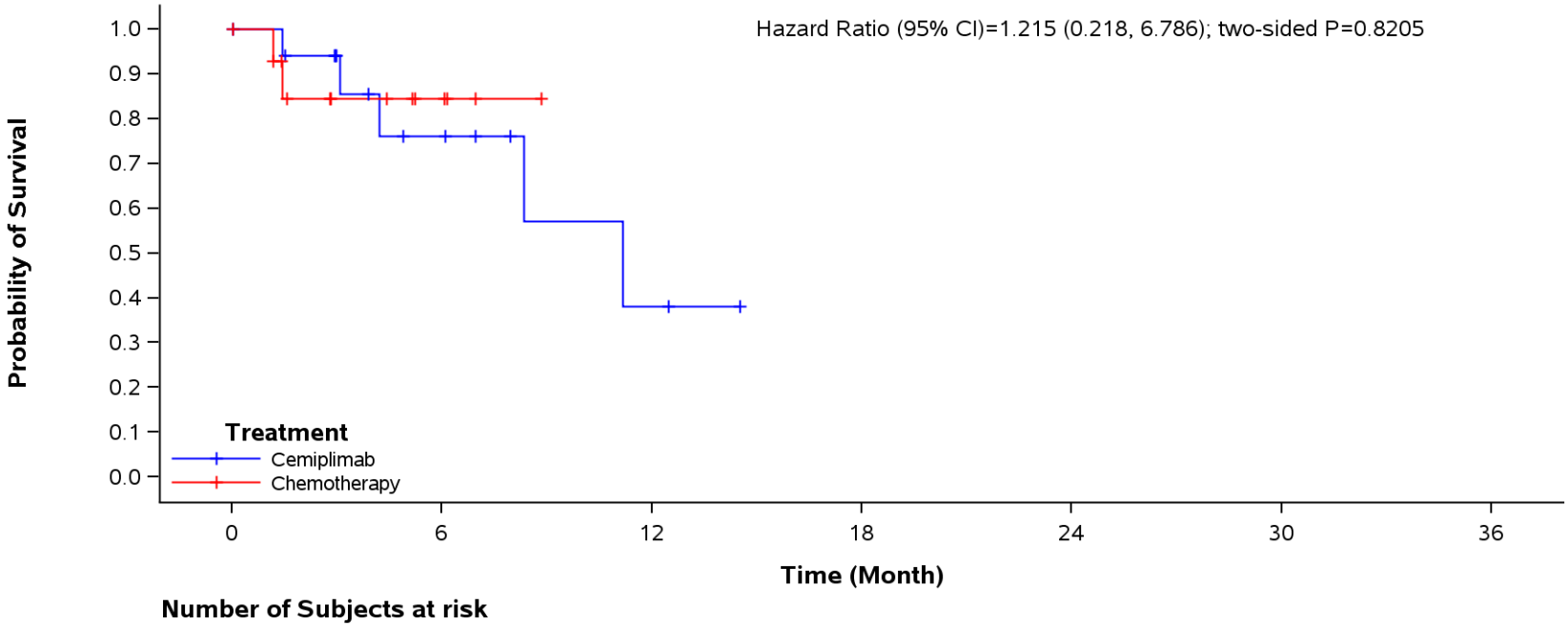

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts sensitivity sustained improvement



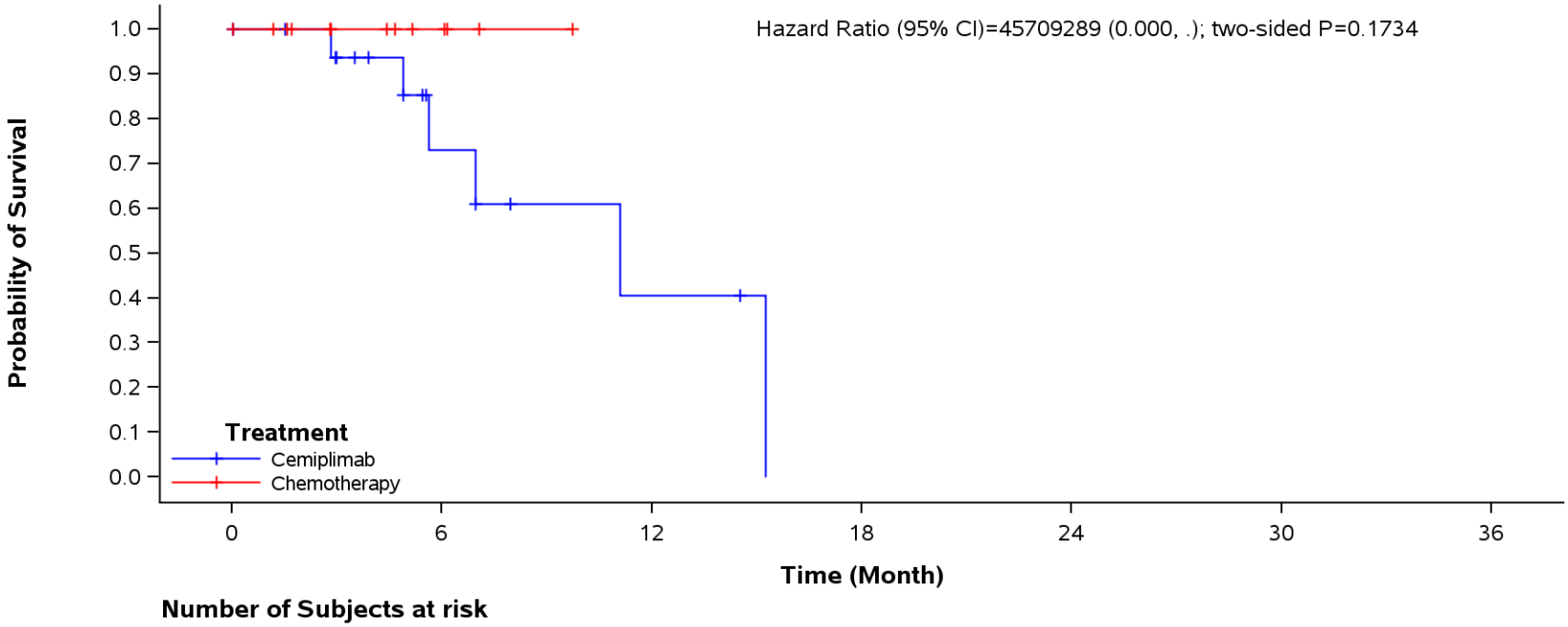

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 7 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

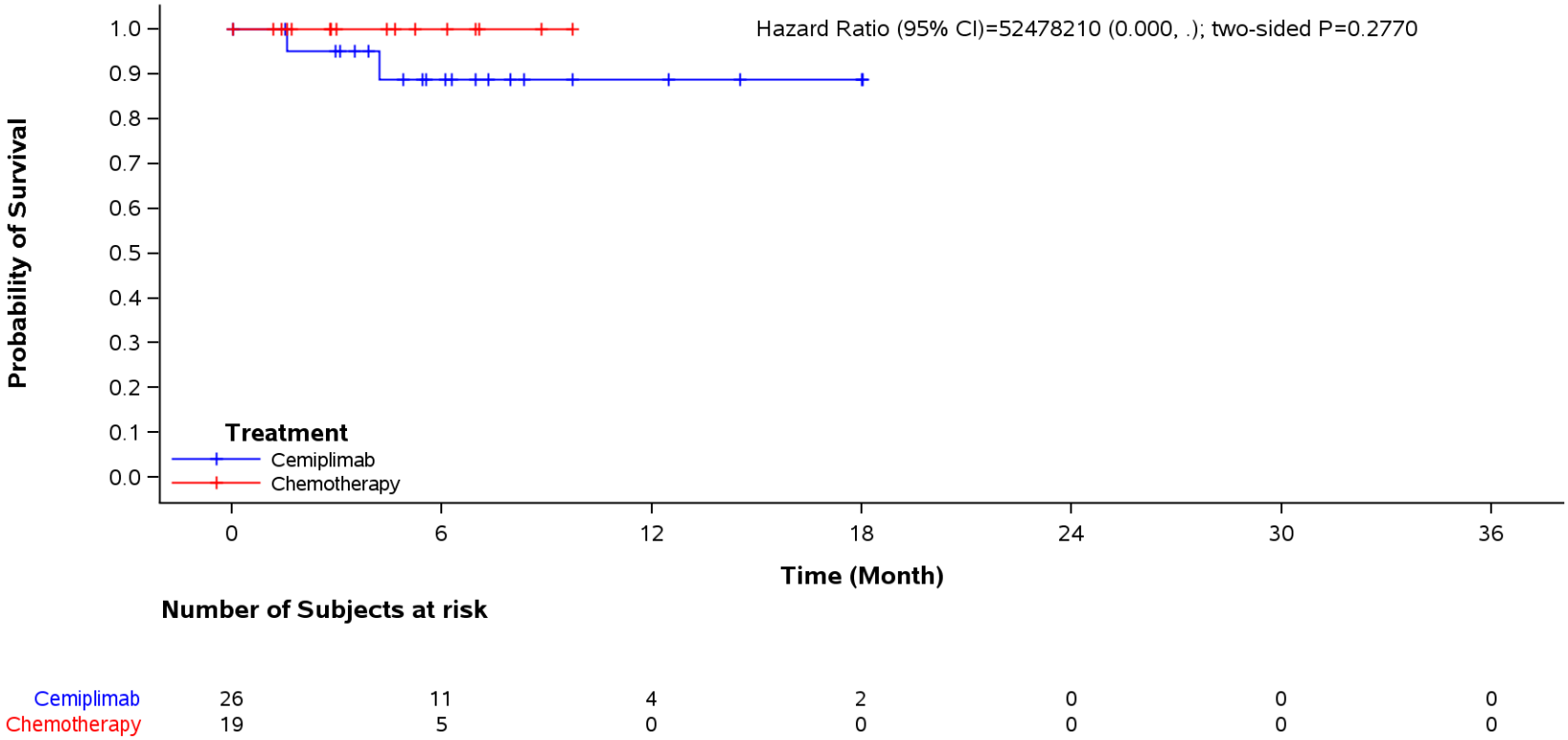
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan

Global health status / QoL - 10 pts sensitivity sustained improvement

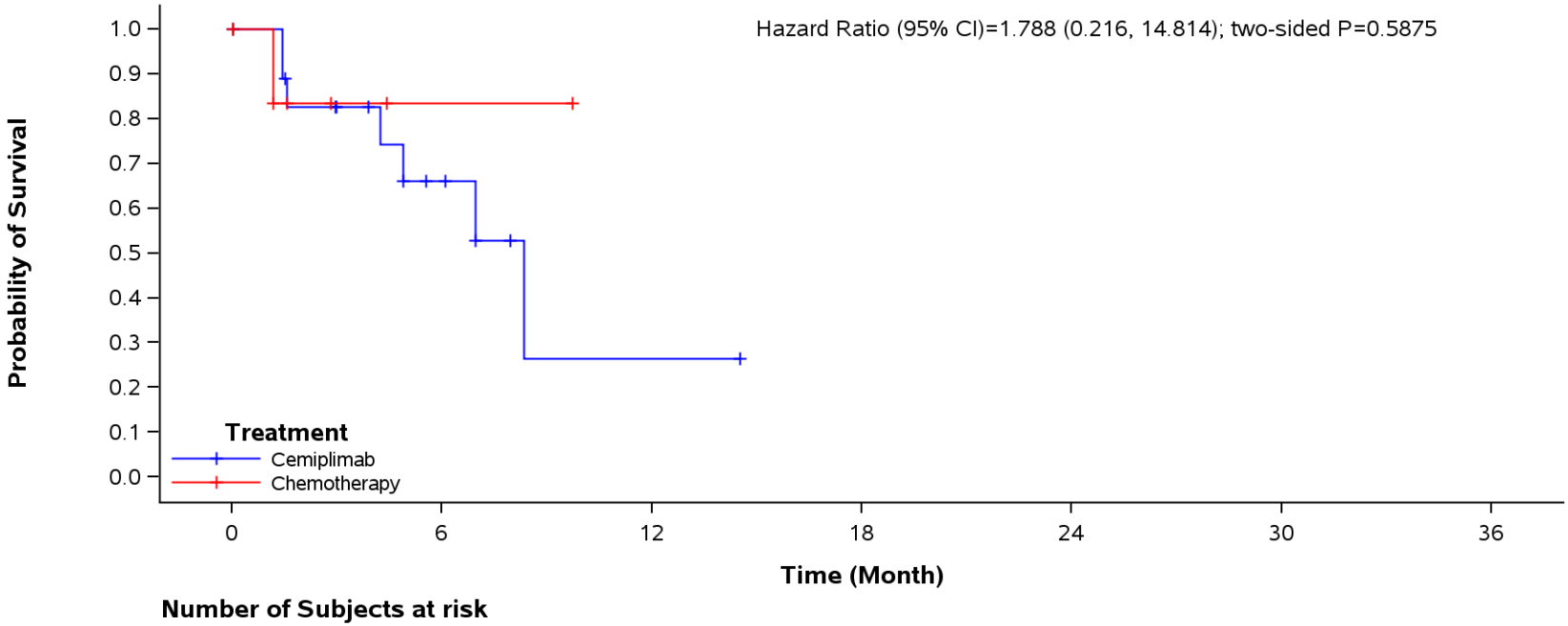



Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts sensitivity sustained improvement



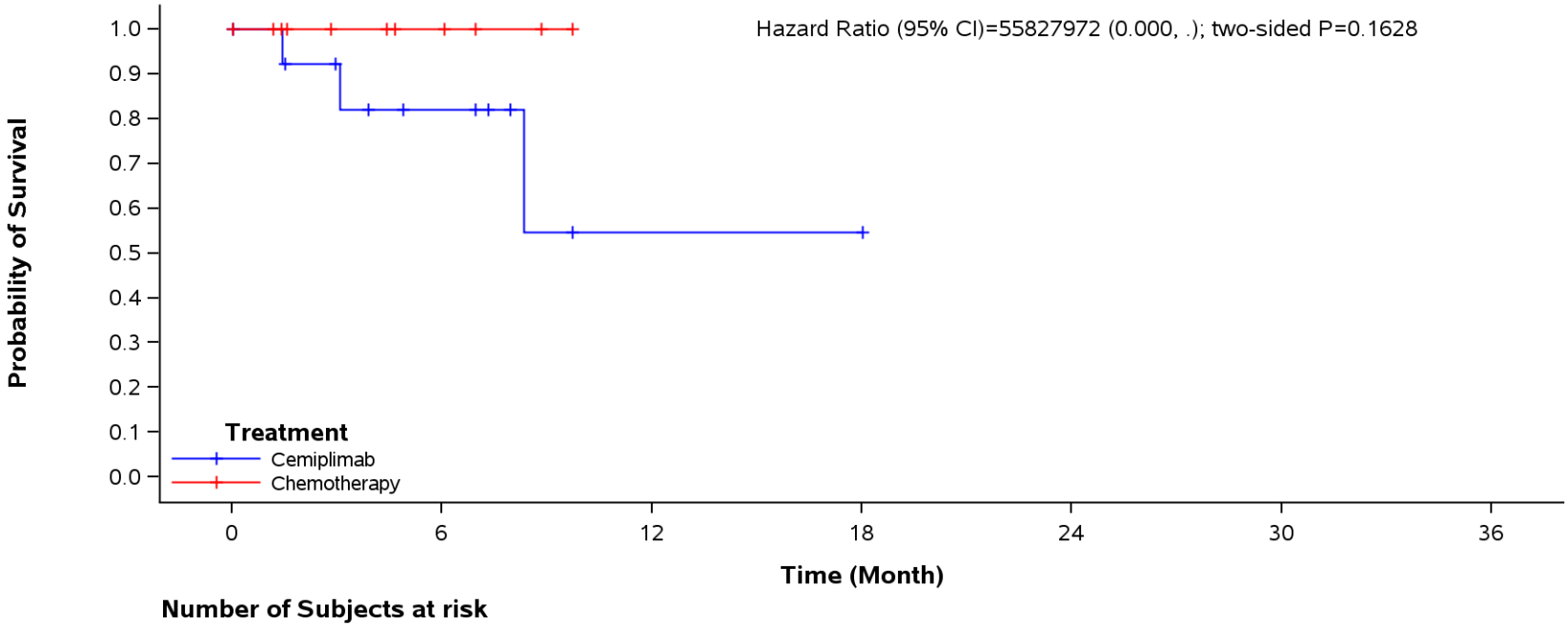

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts sensitivity sustained improvement



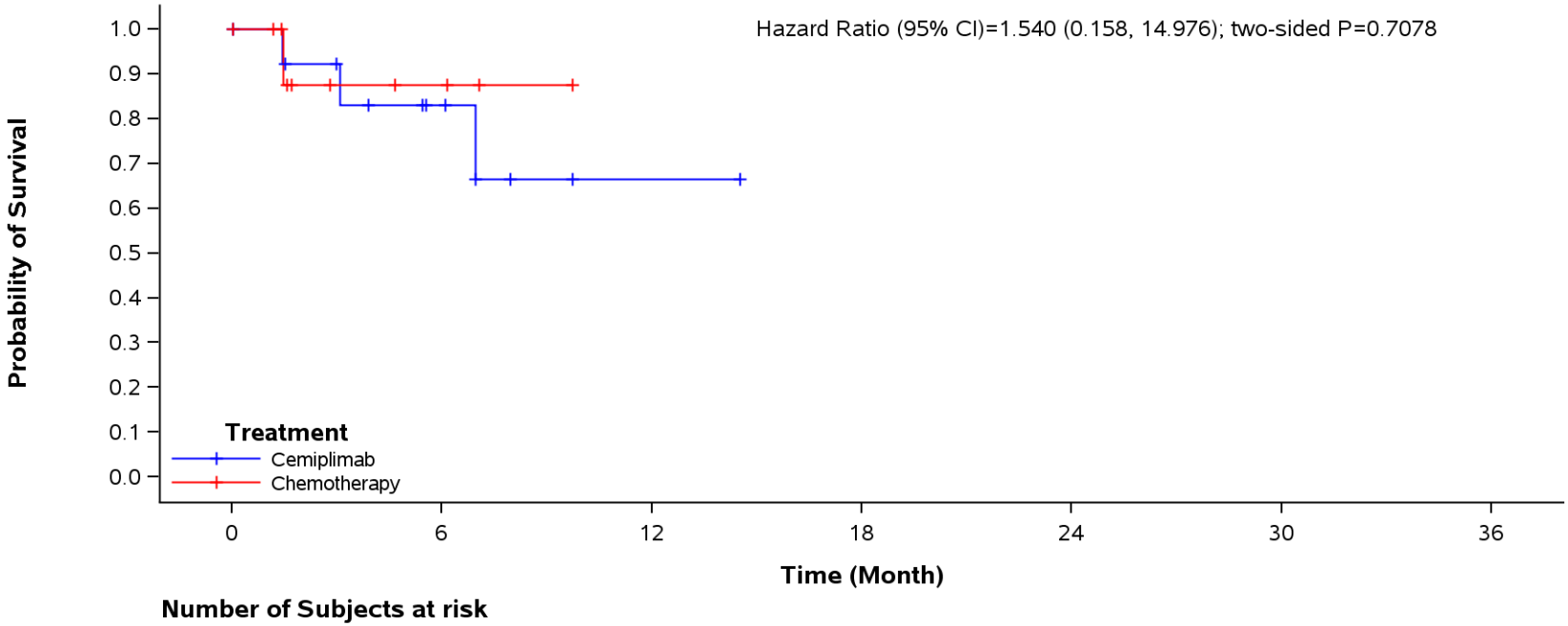

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts sensitivity sustained improvement



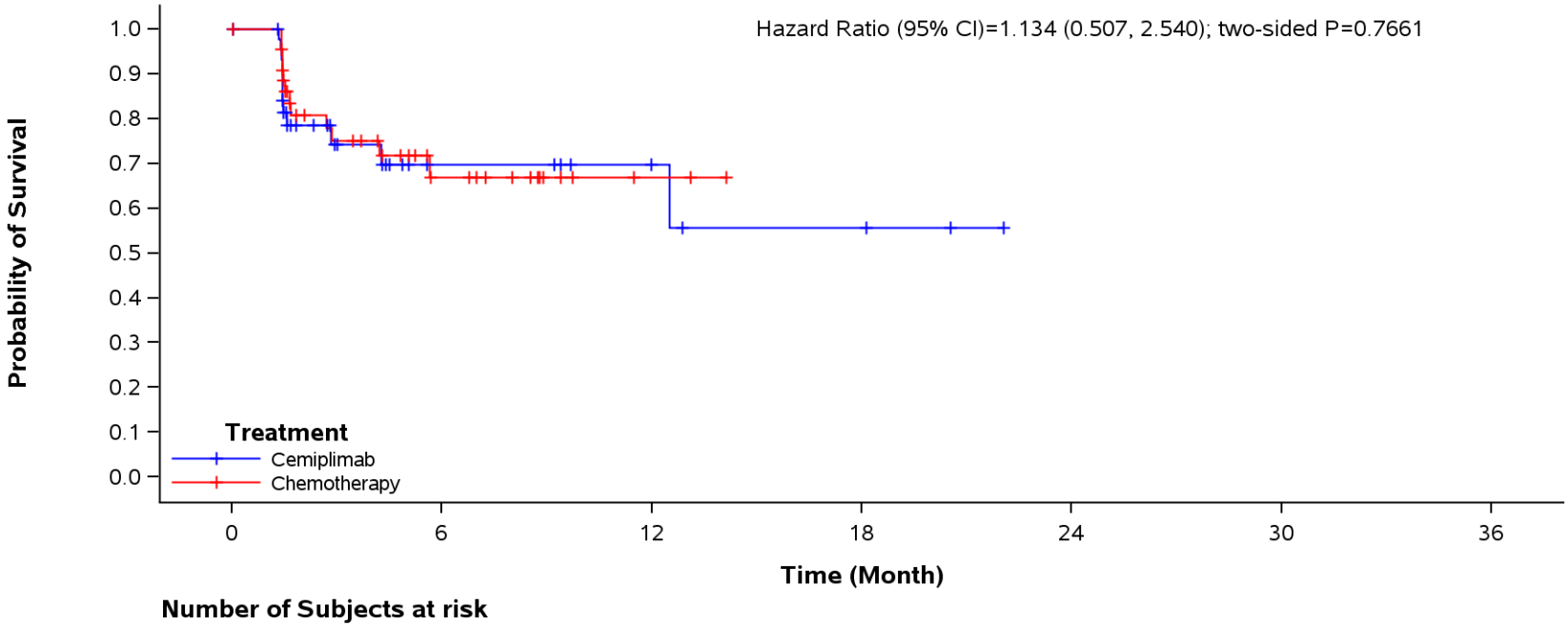

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts sensitivity sustained improvement



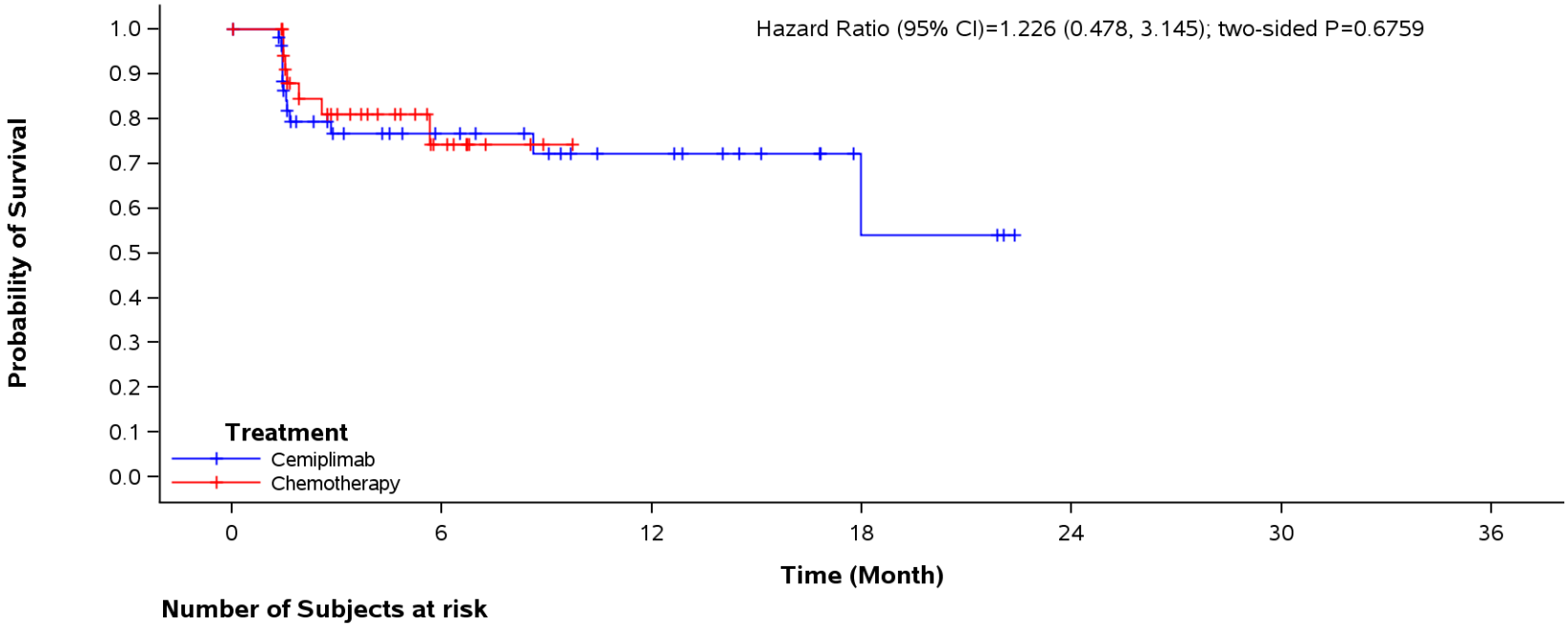

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 9 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 111 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts sensitivity sustained improvement



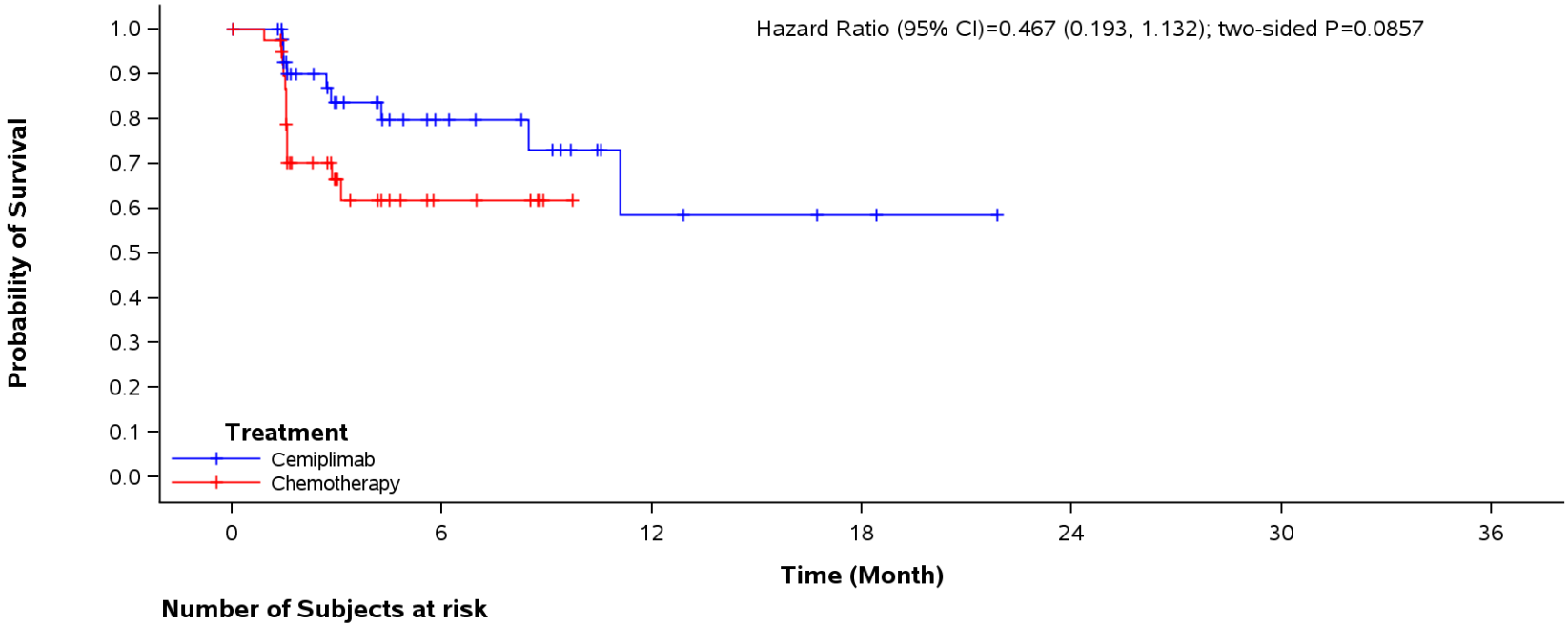

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 20 | 12 | 3 | 0 | 0 | 0 |
| Chemotherapy | 111 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts sensitivity sustained improvement



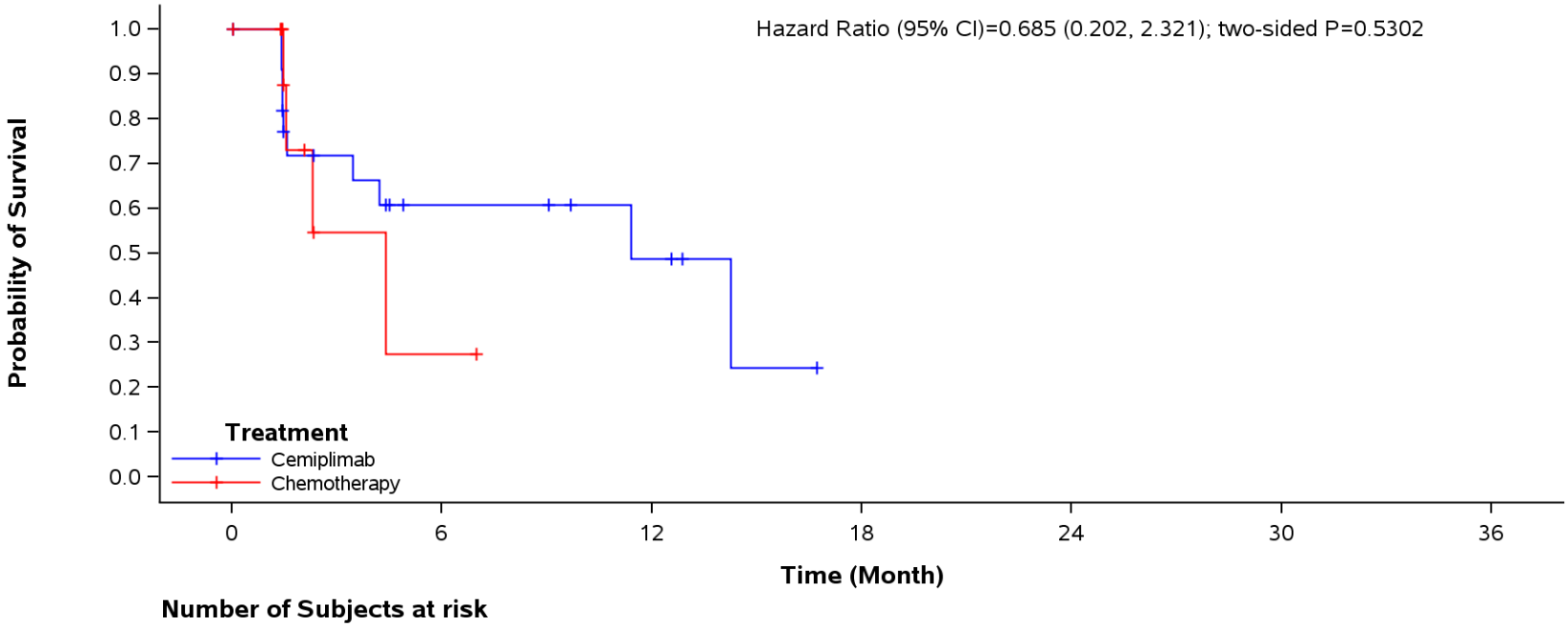

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 15 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 111 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts sensitivity sustained improvement



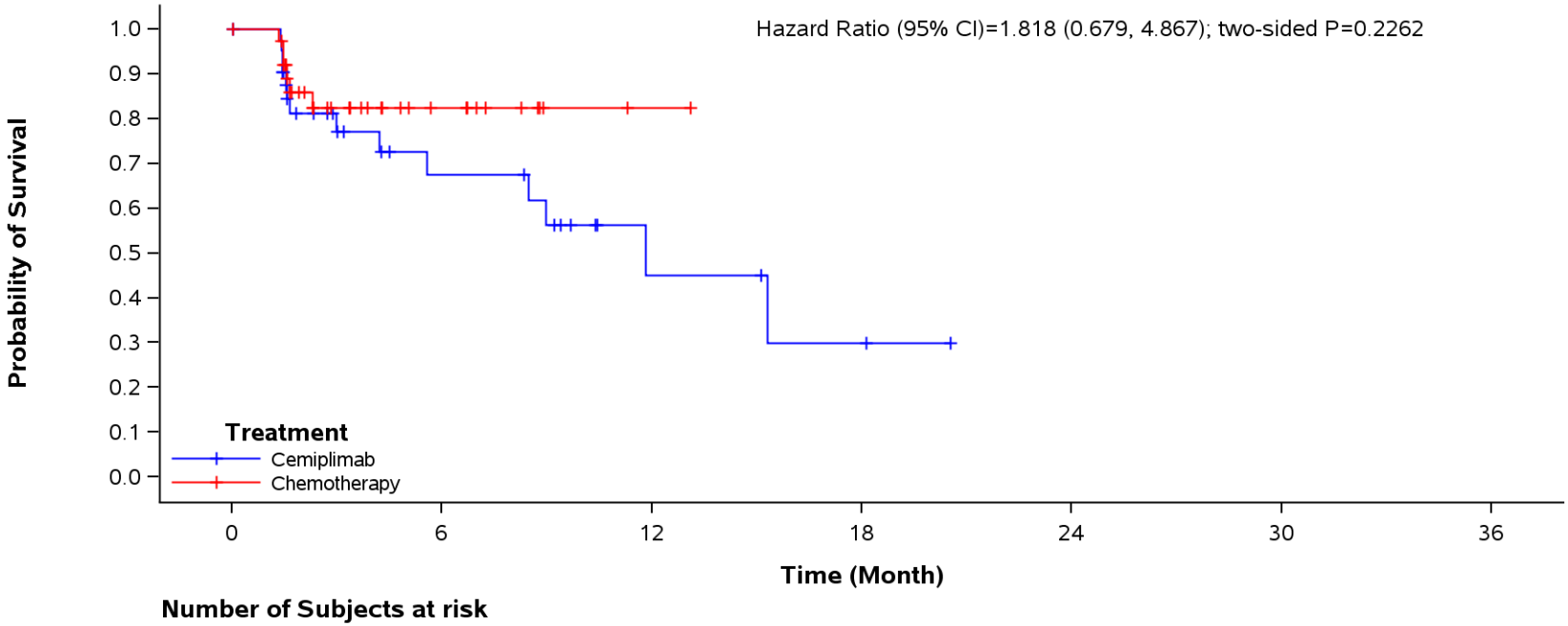

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 8 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 111 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts sensitivity sustained improvement



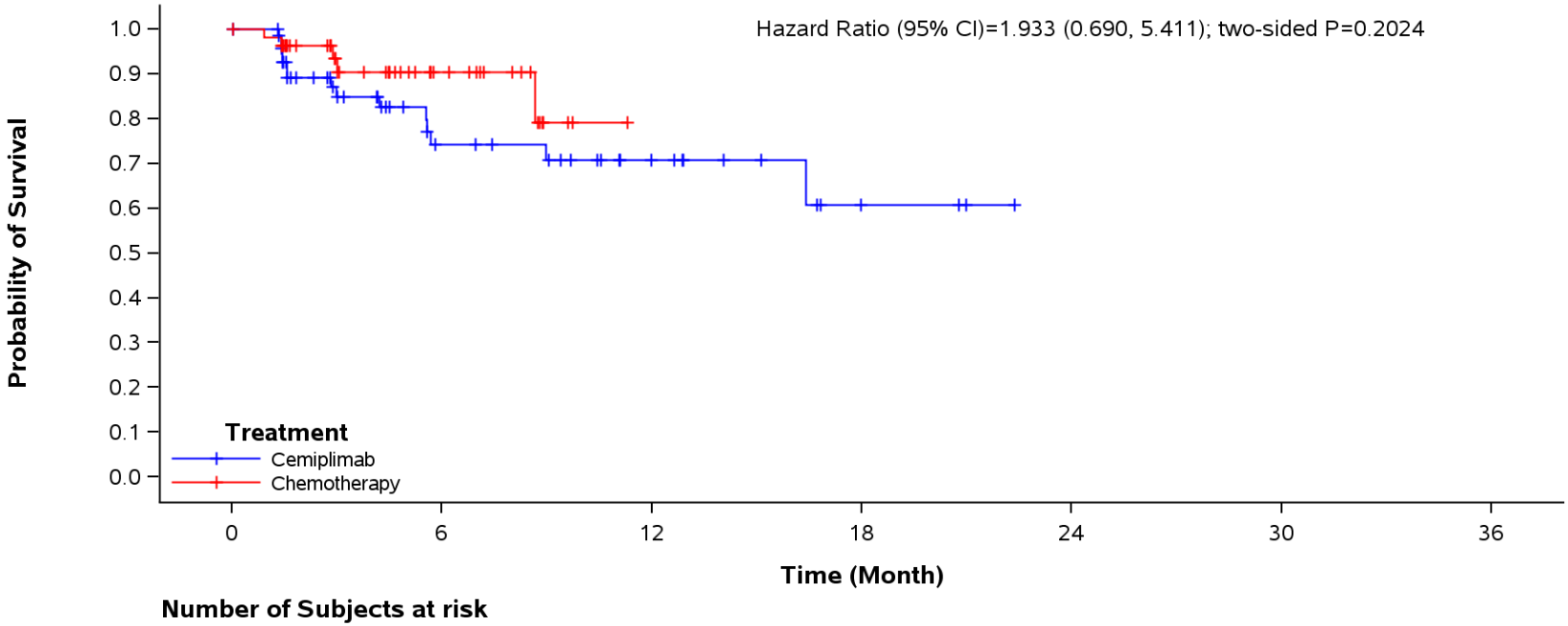

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 13 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 111 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts sensitivity sustained improvement



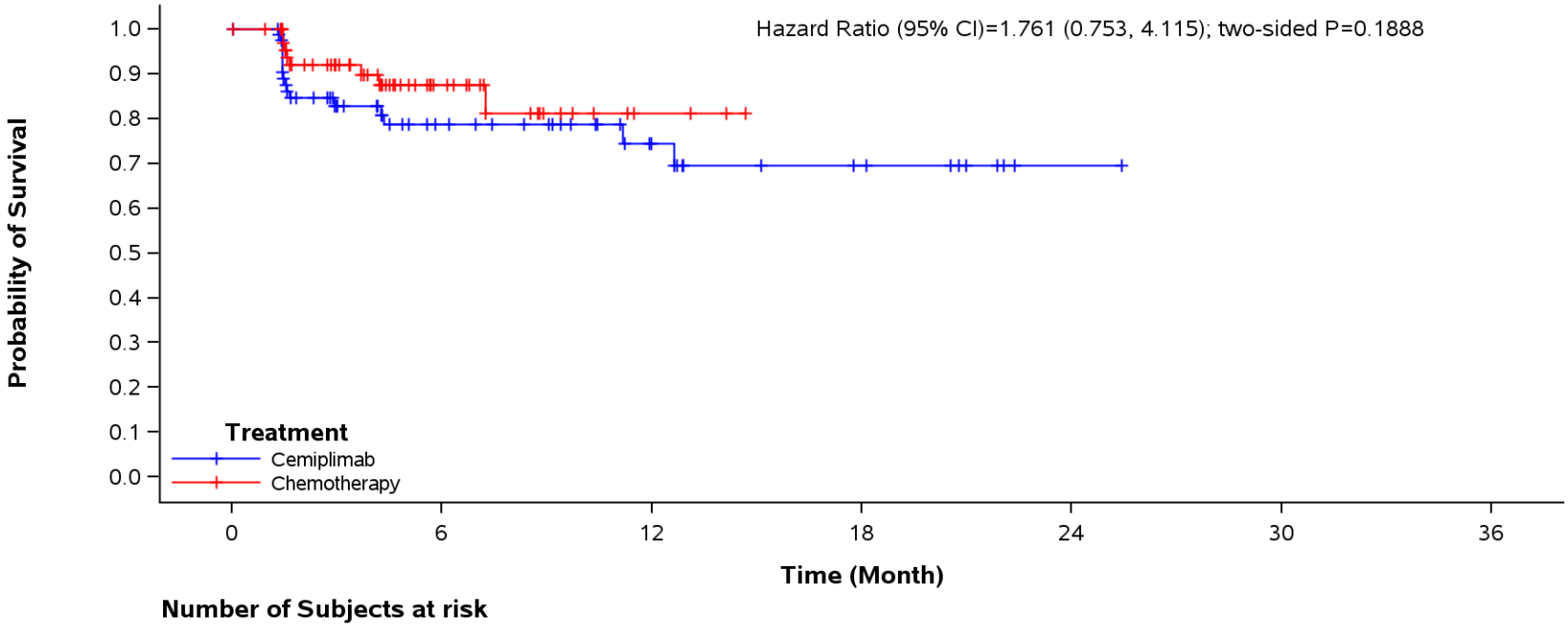

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 25 | 12 | 3 | 0 | 0 | 0 |
| Chemotherapy | 111 | 16 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts sensitivity sustained improvement



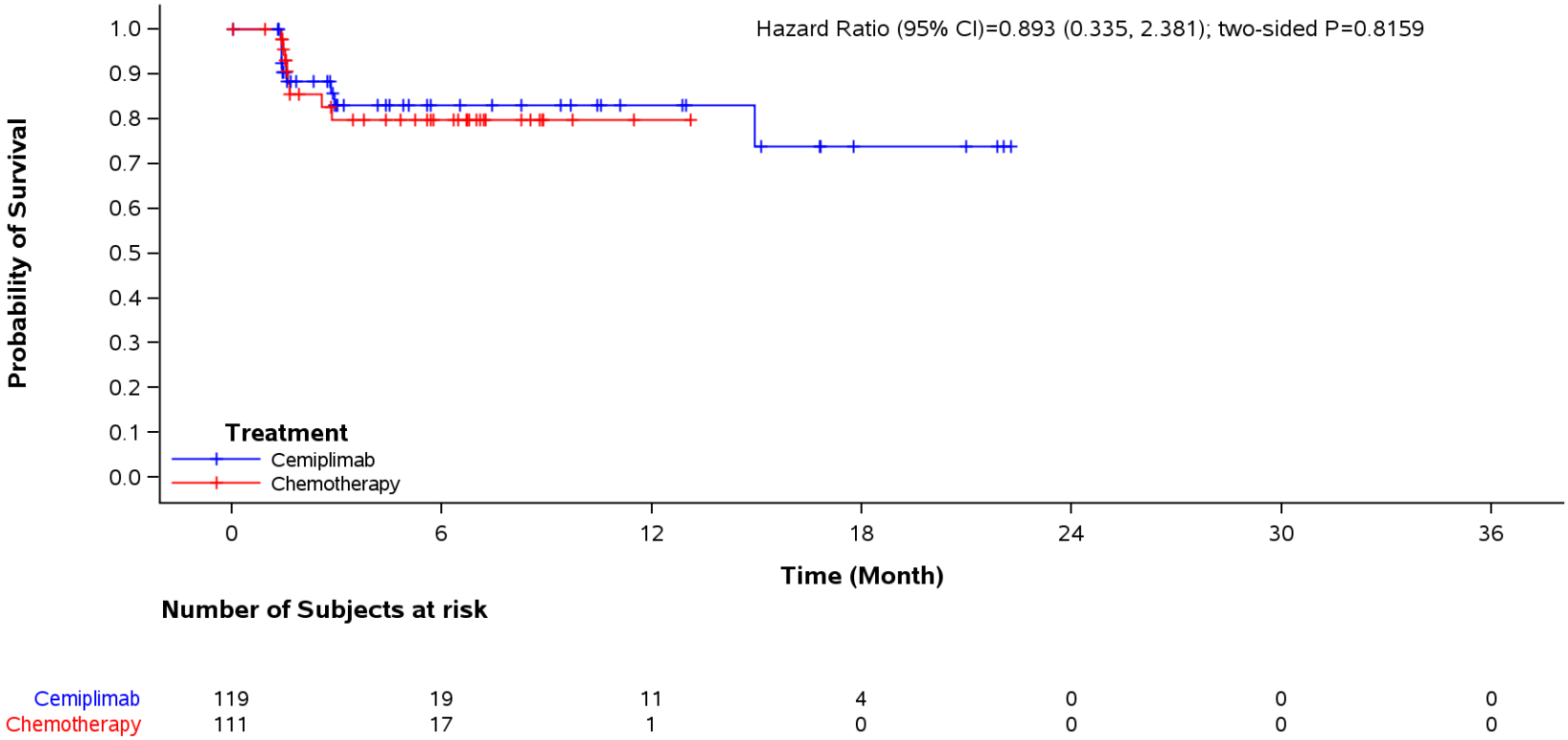

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 31 | 15 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

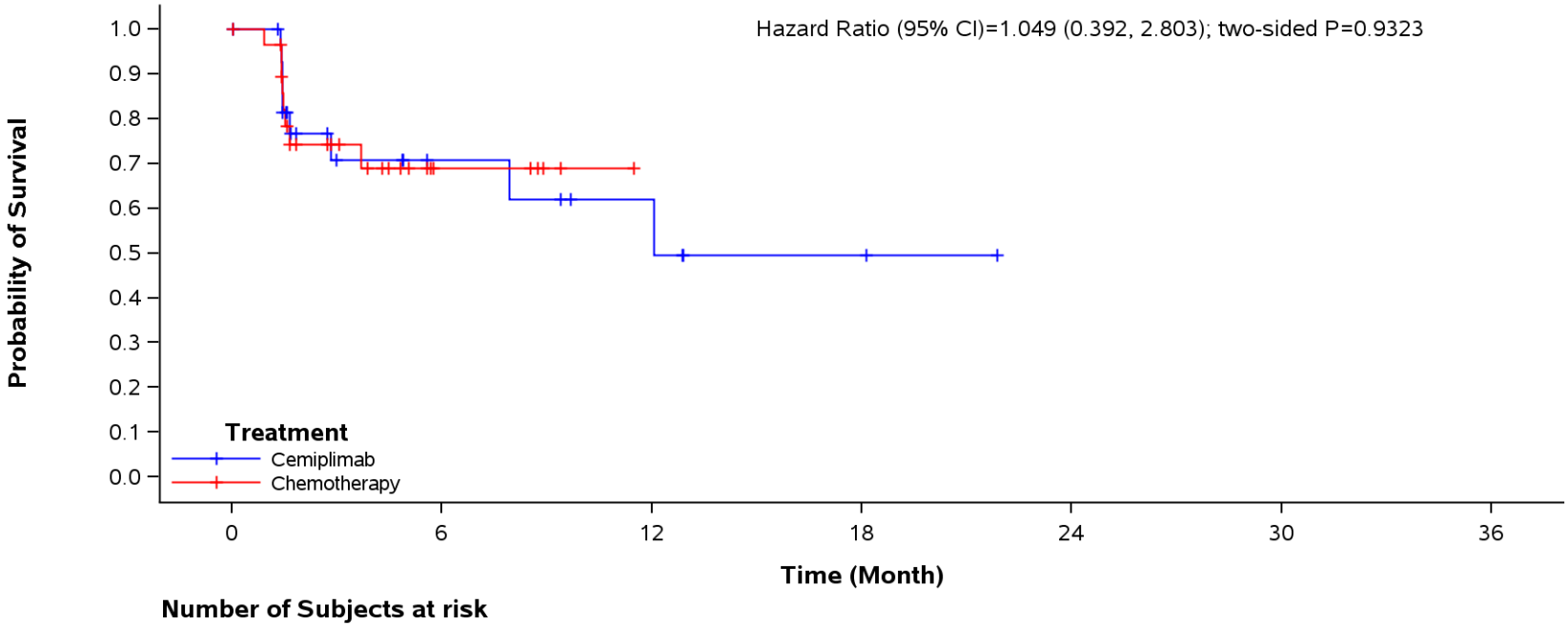
Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts sensitivity sustained improvement



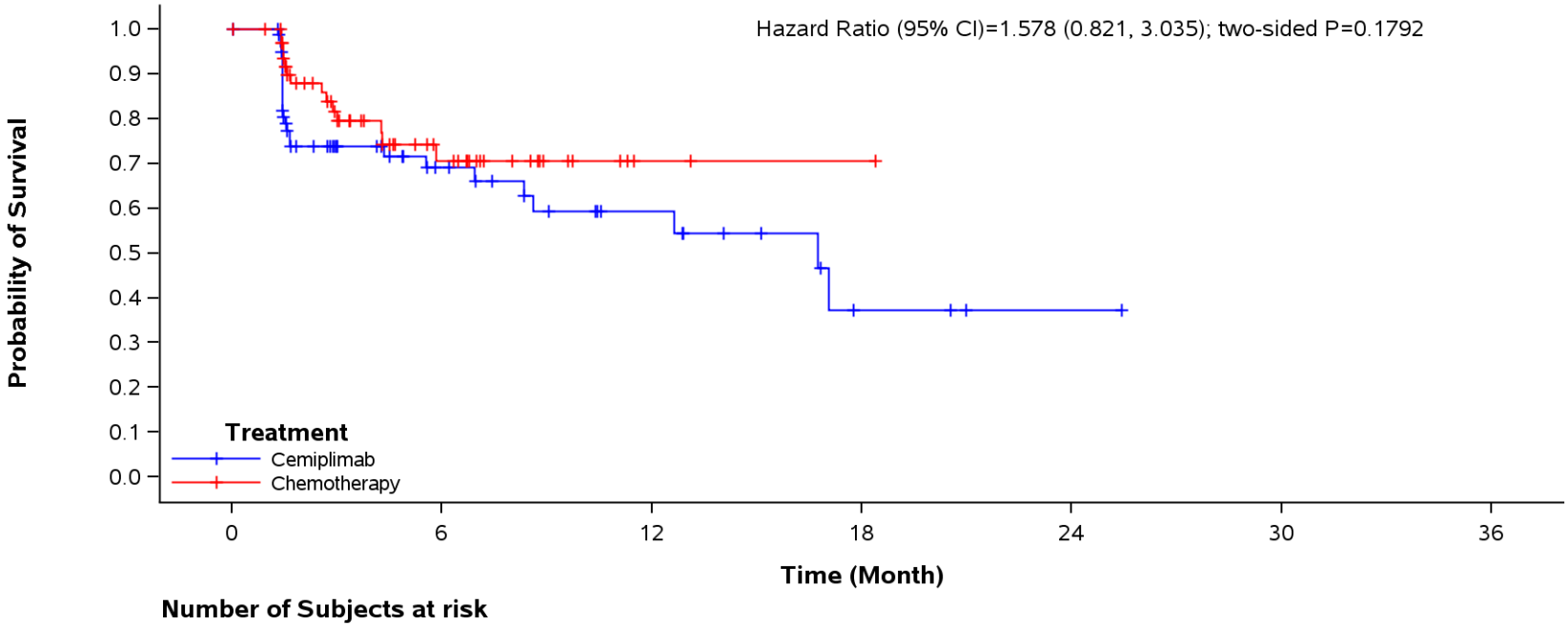

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 8 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 111 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts sensitivity sustained improvement



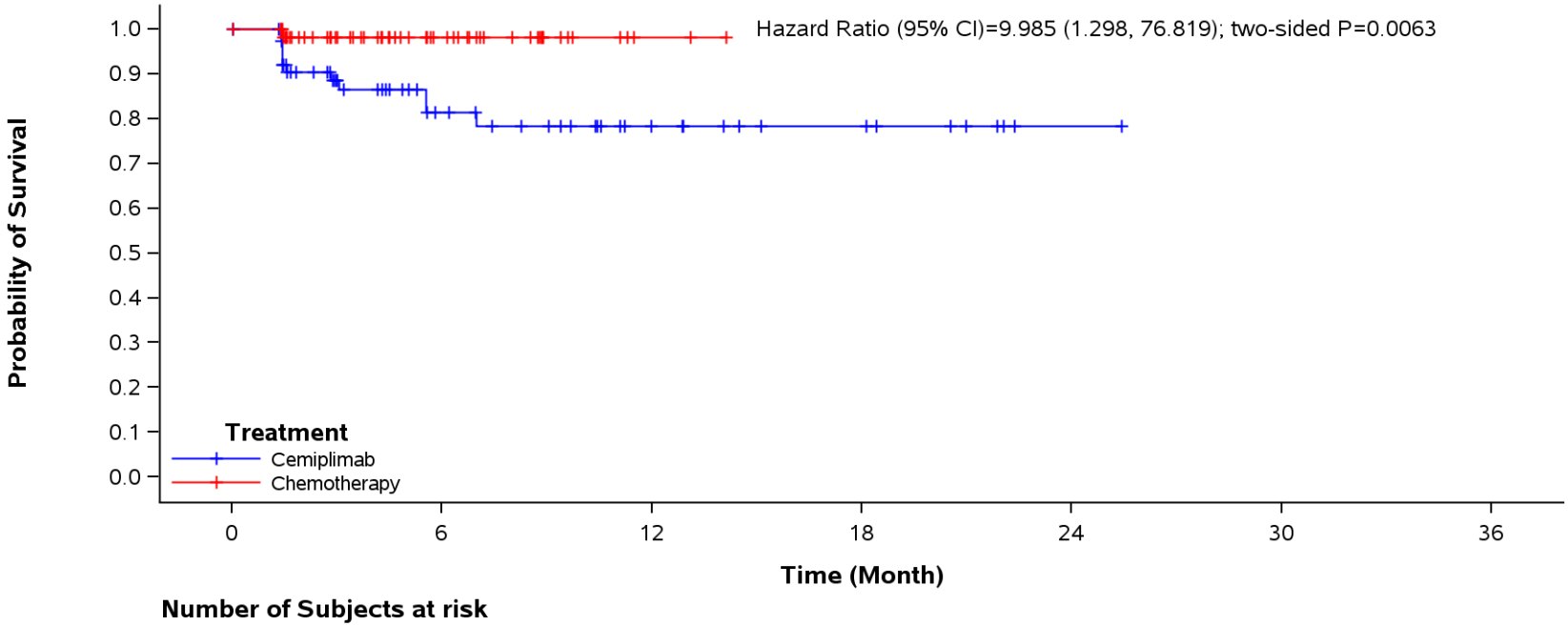

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 24 | 12 | 3 | 1 | 0 | 0 |
| Chemotherapy | 111 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

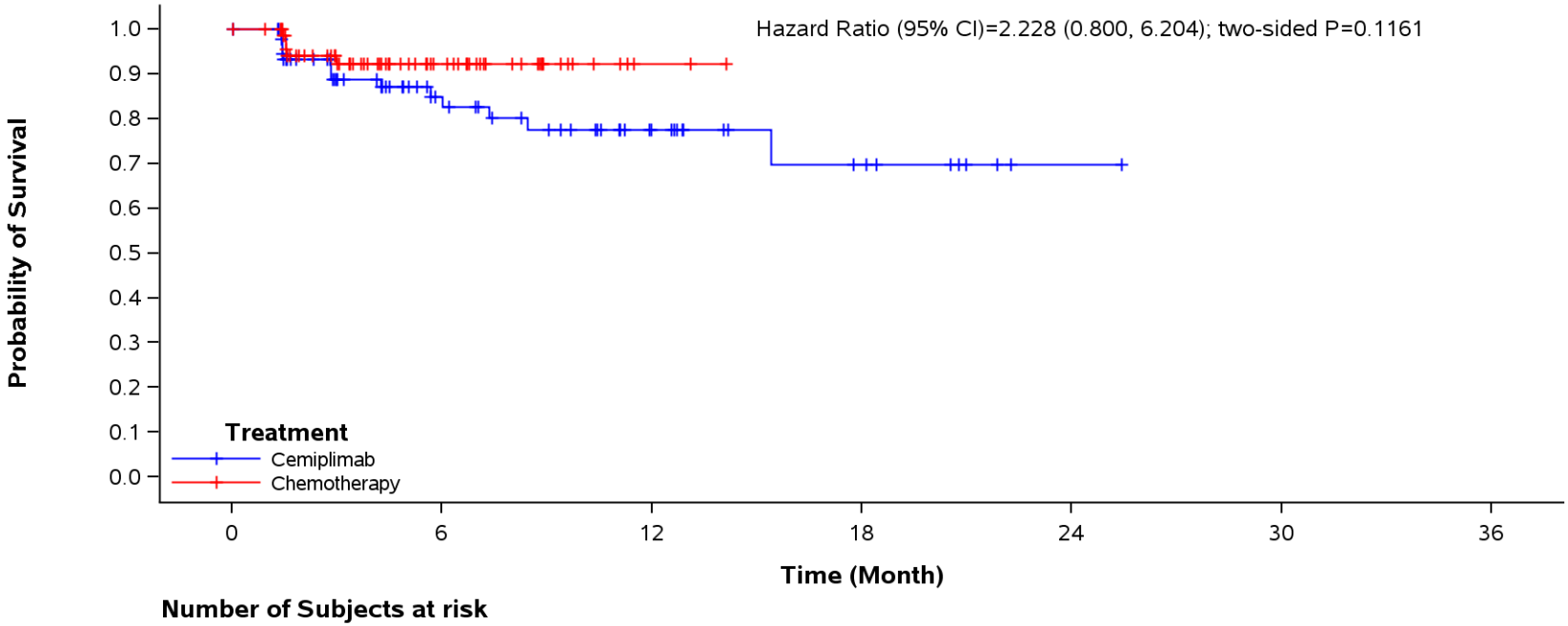
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 28 | 13 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 23 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

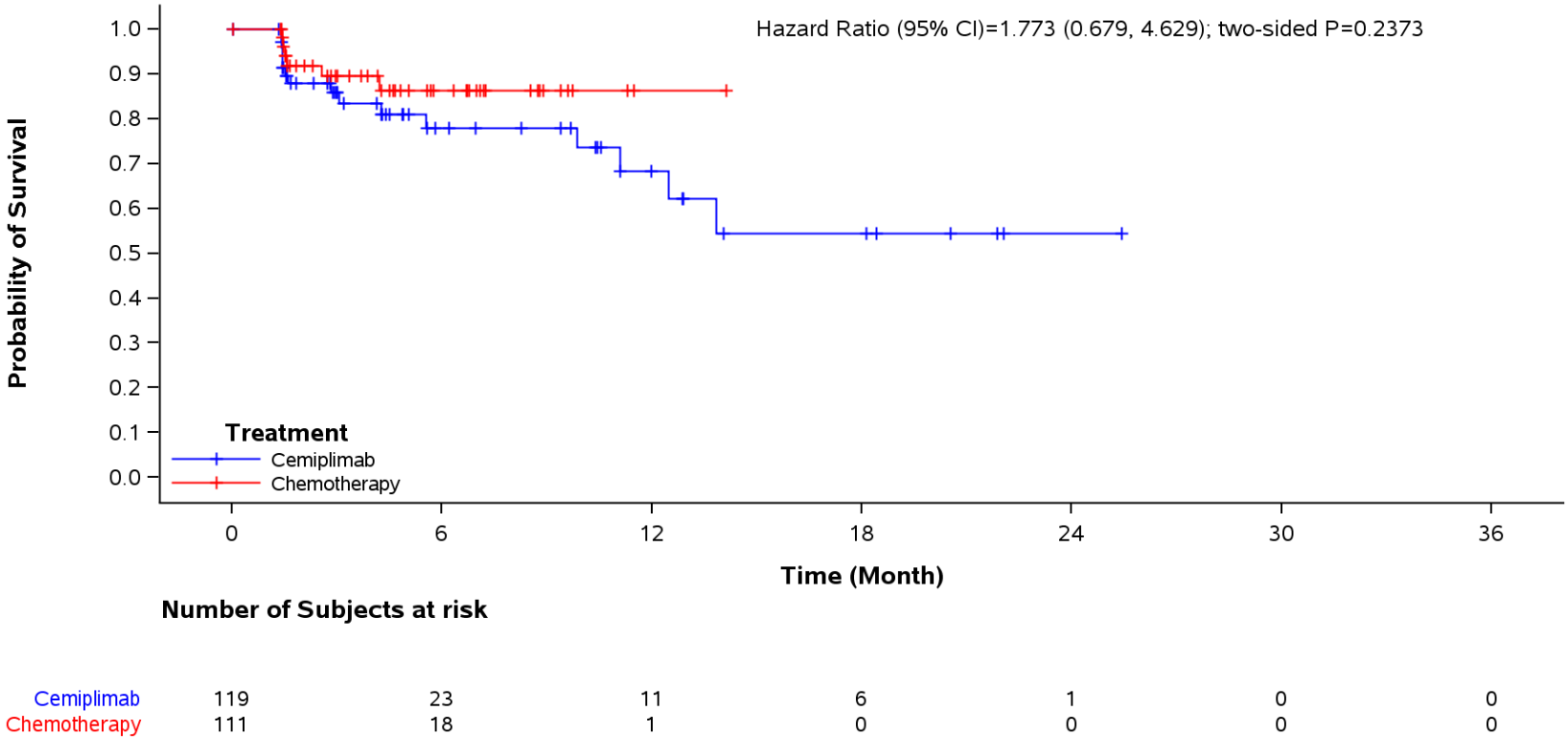
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 37 | 17 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

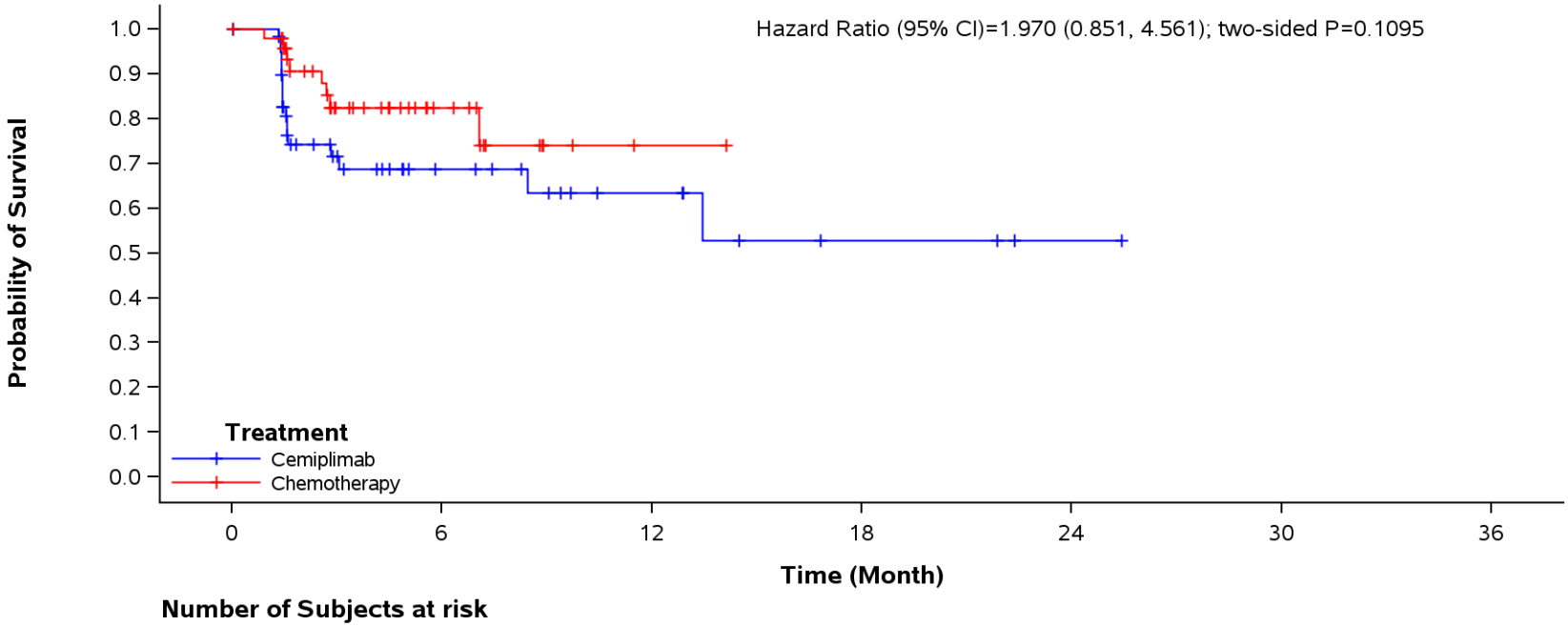
Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts sensitivity sustained improvement



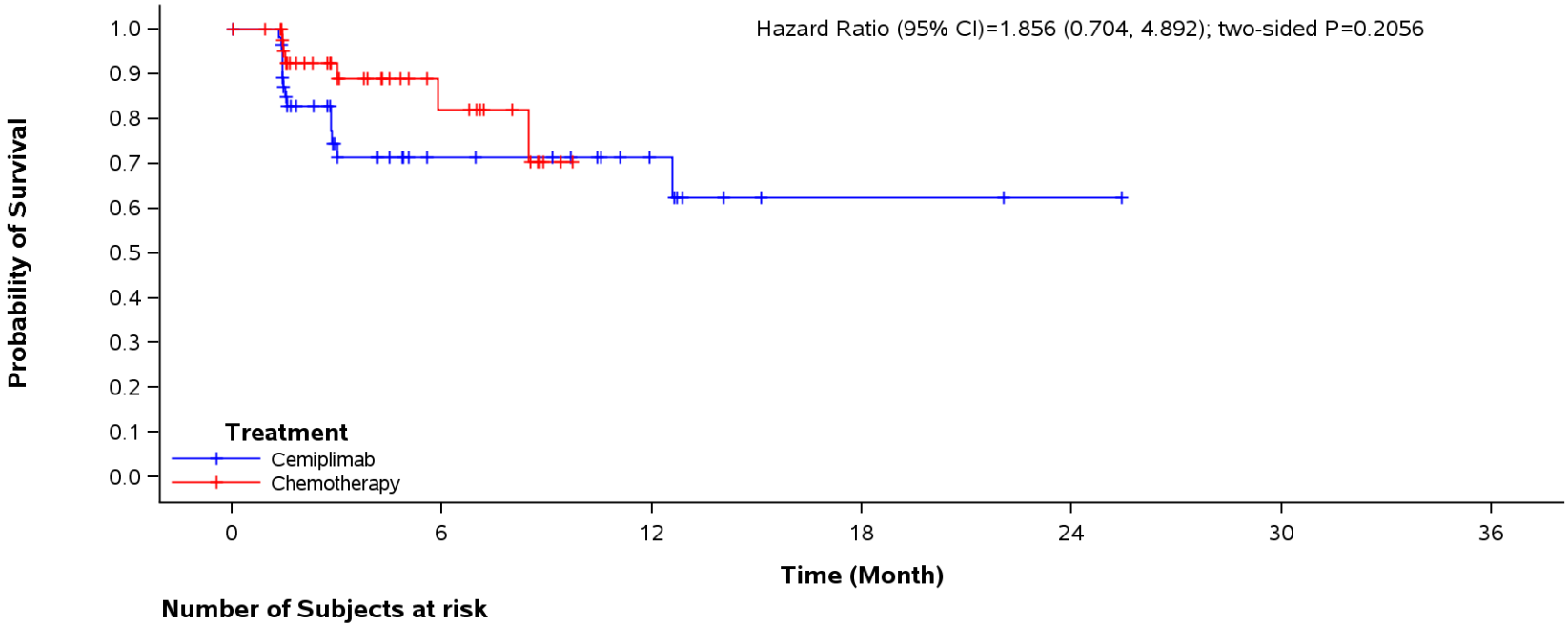

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 16 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 111 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts sensitivity sustained improvement



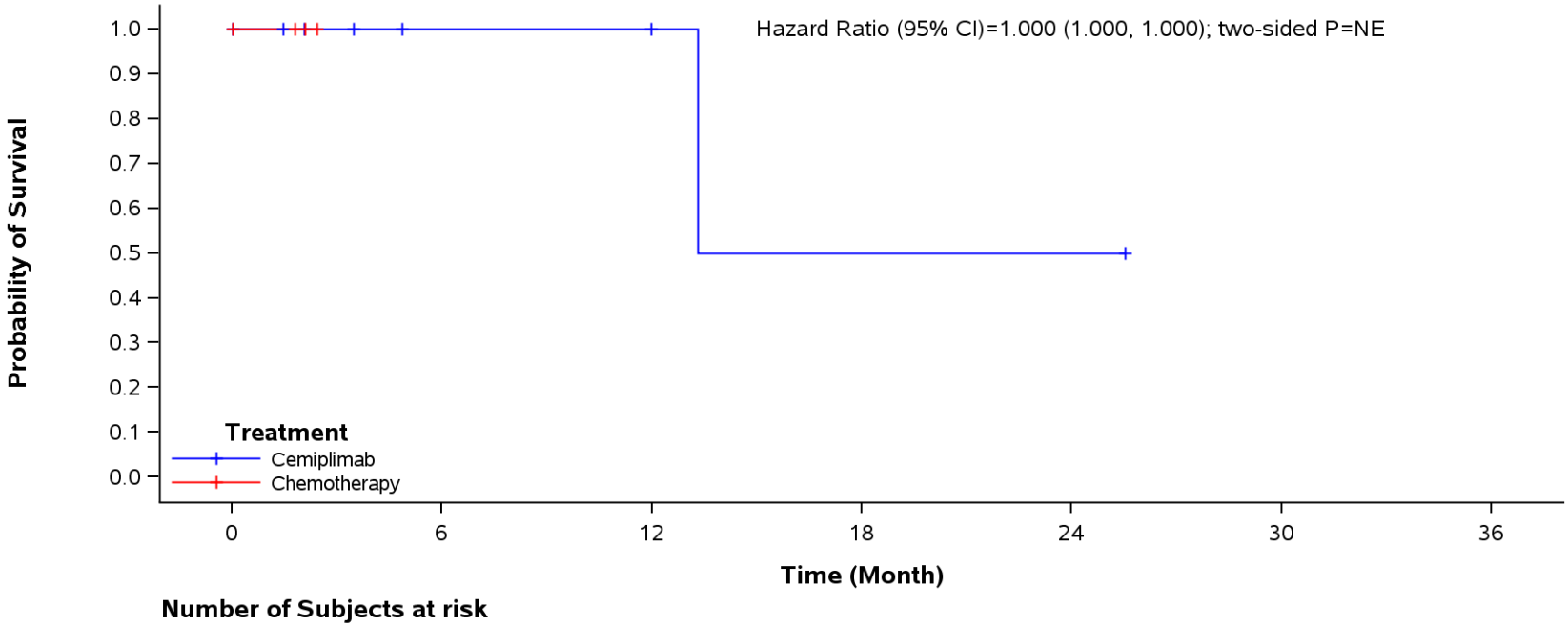

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 15 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 111 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts sensitivity sustained improvement



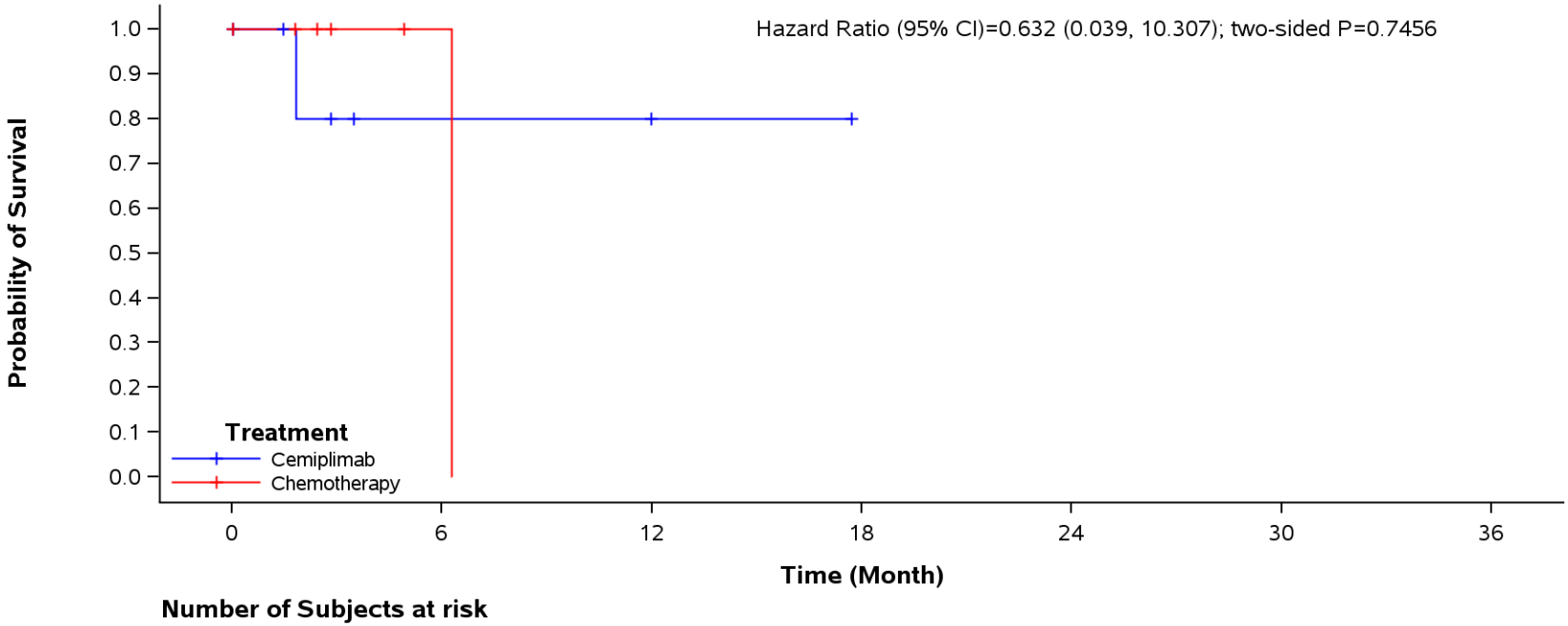

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts sensitivity sustained improvement



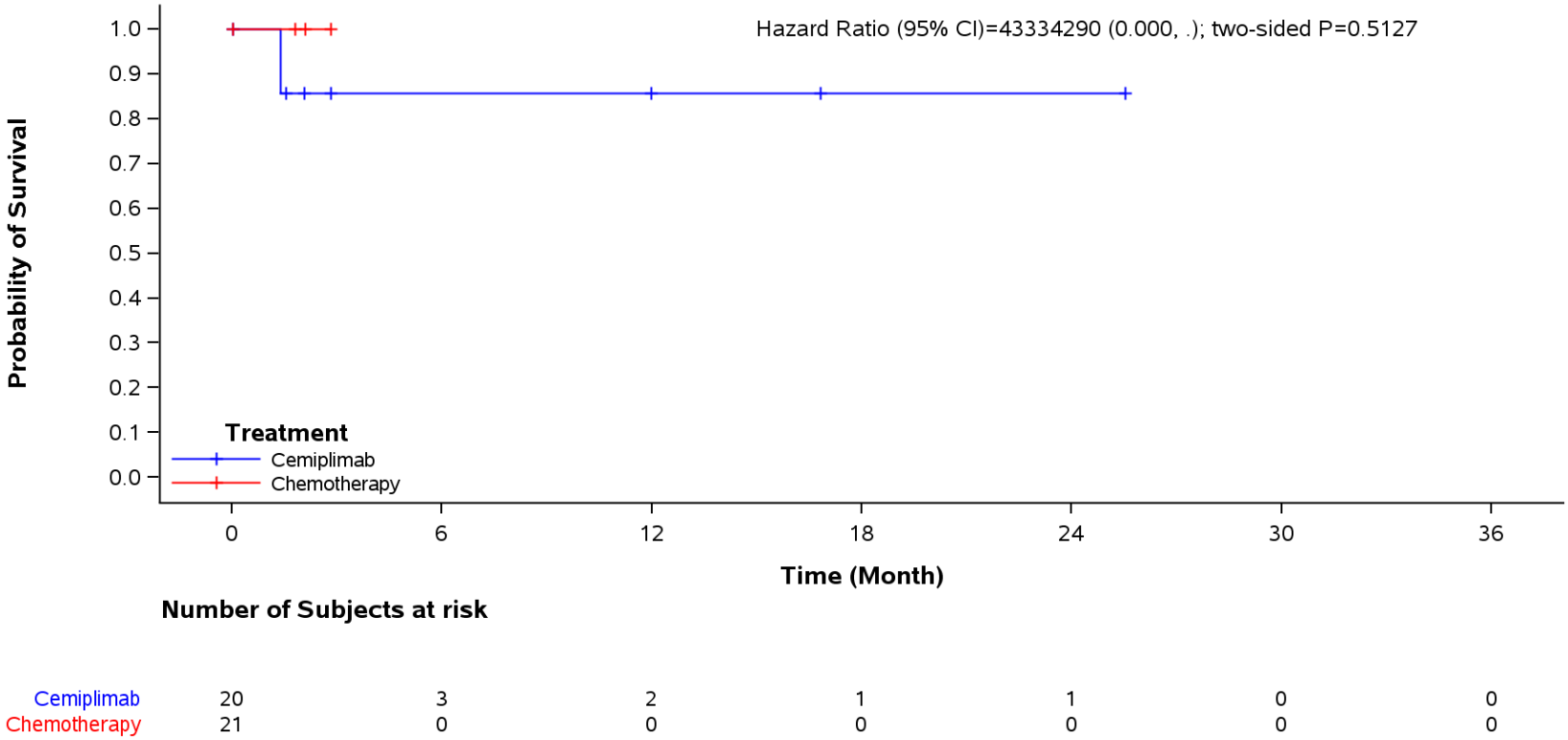

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

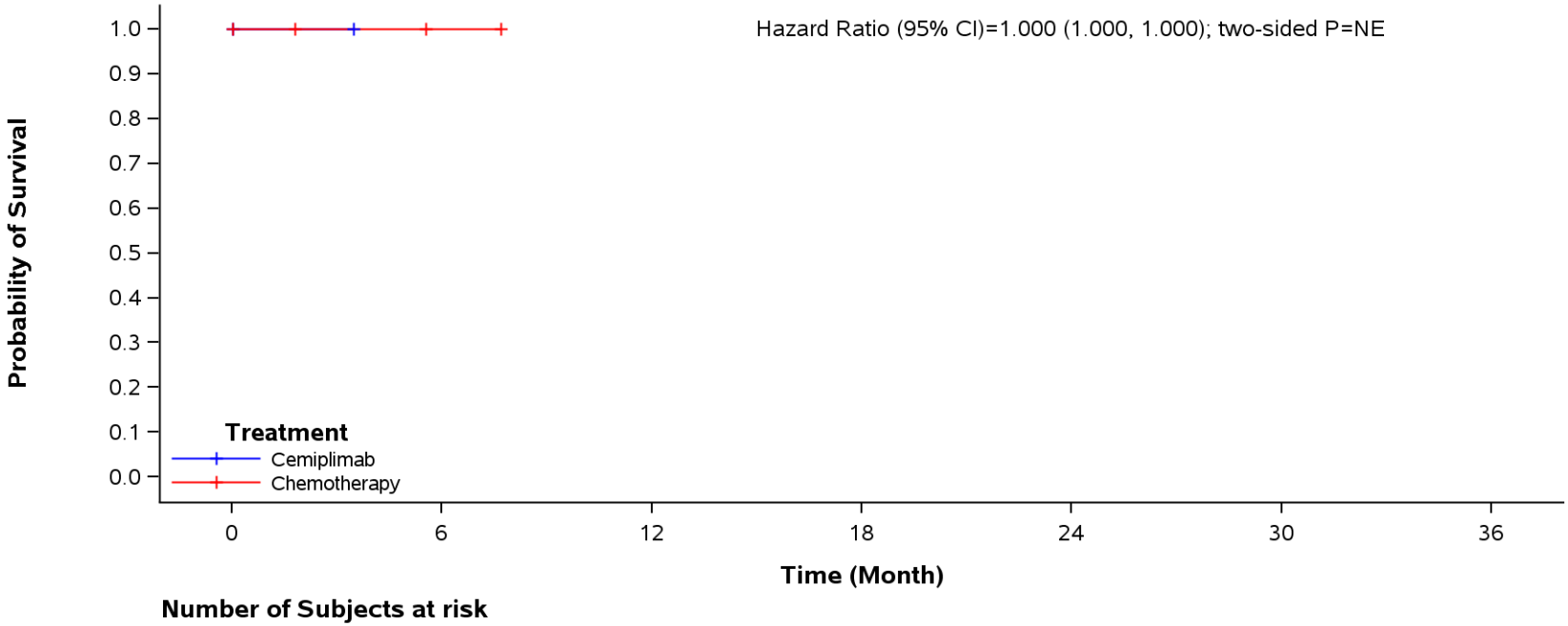
Choice of IC chemotherapy: Topotecan
Constipation - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts sensitivity sustained improvement



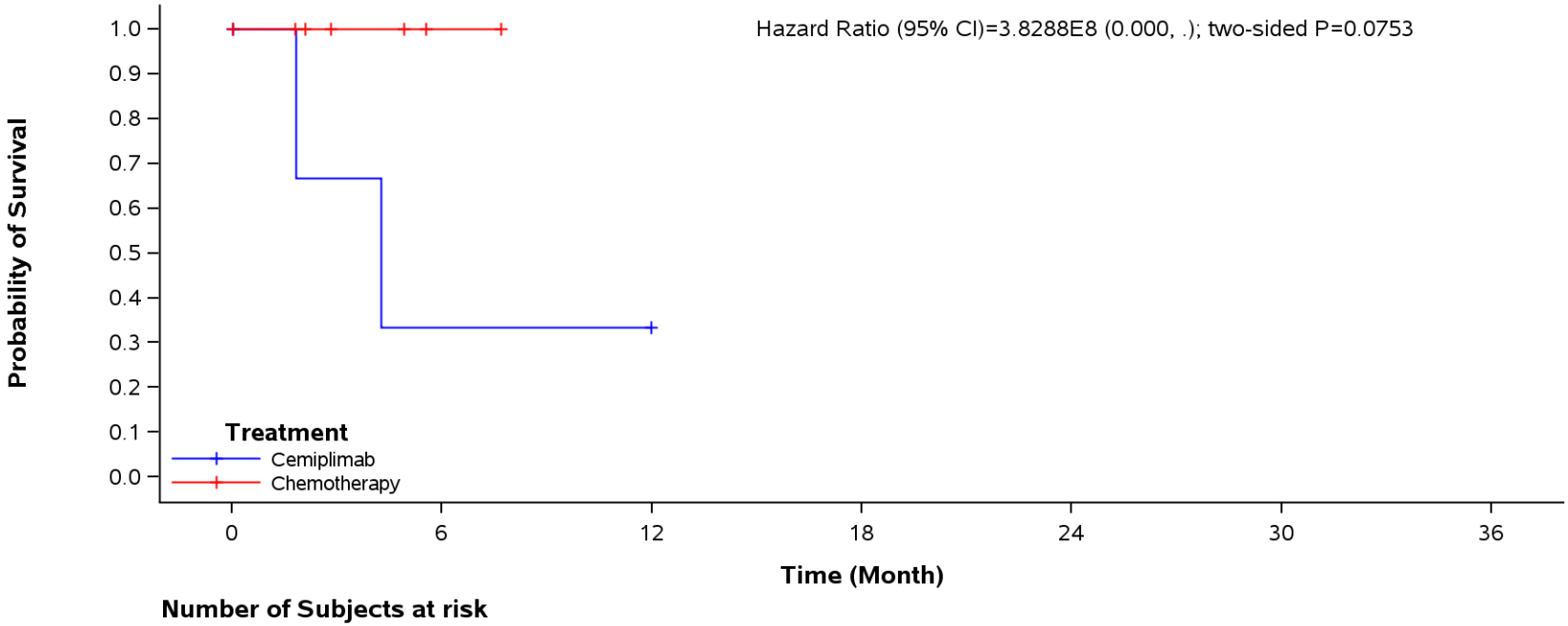

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts sensitivity sustained improvement



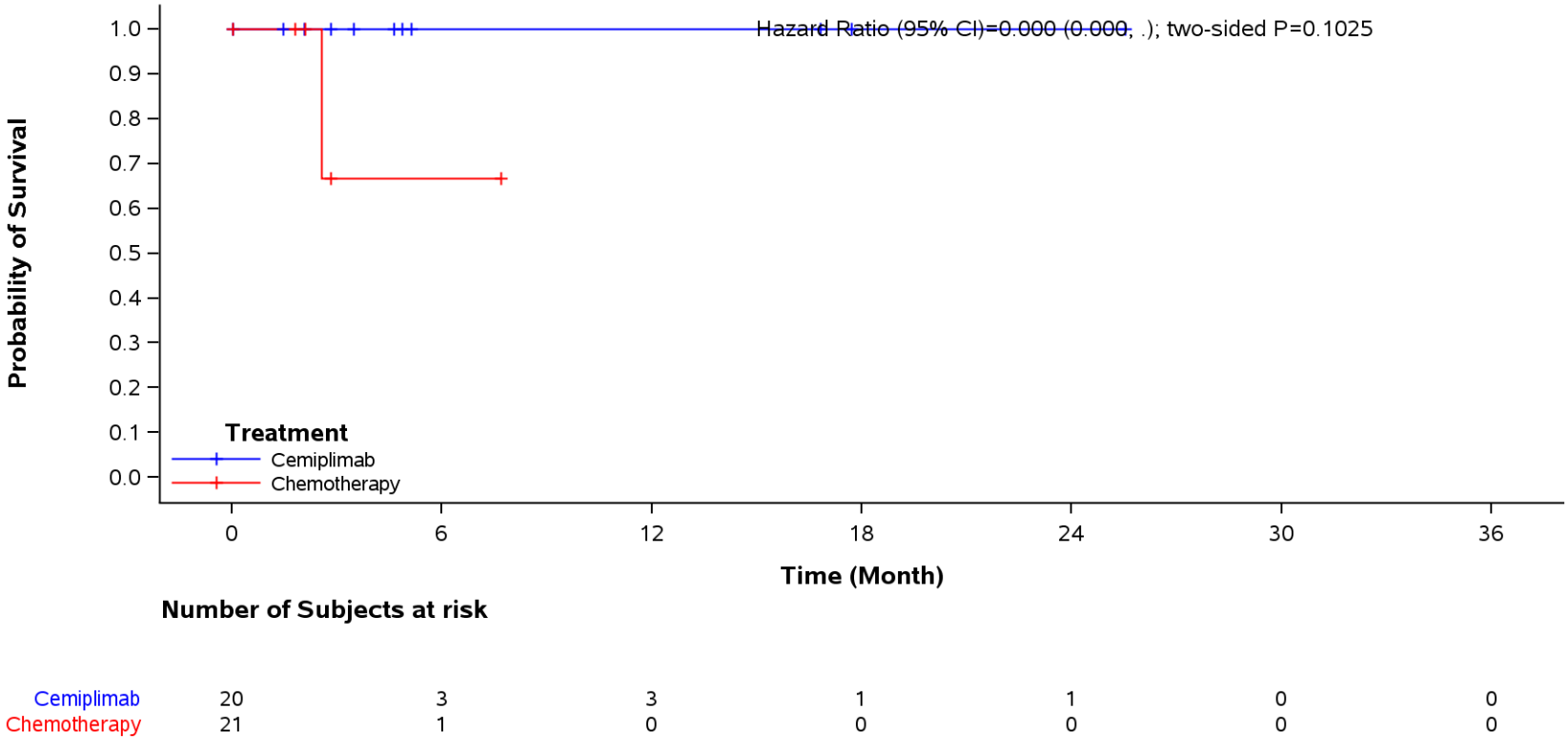

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts sensitivity sustained improvement



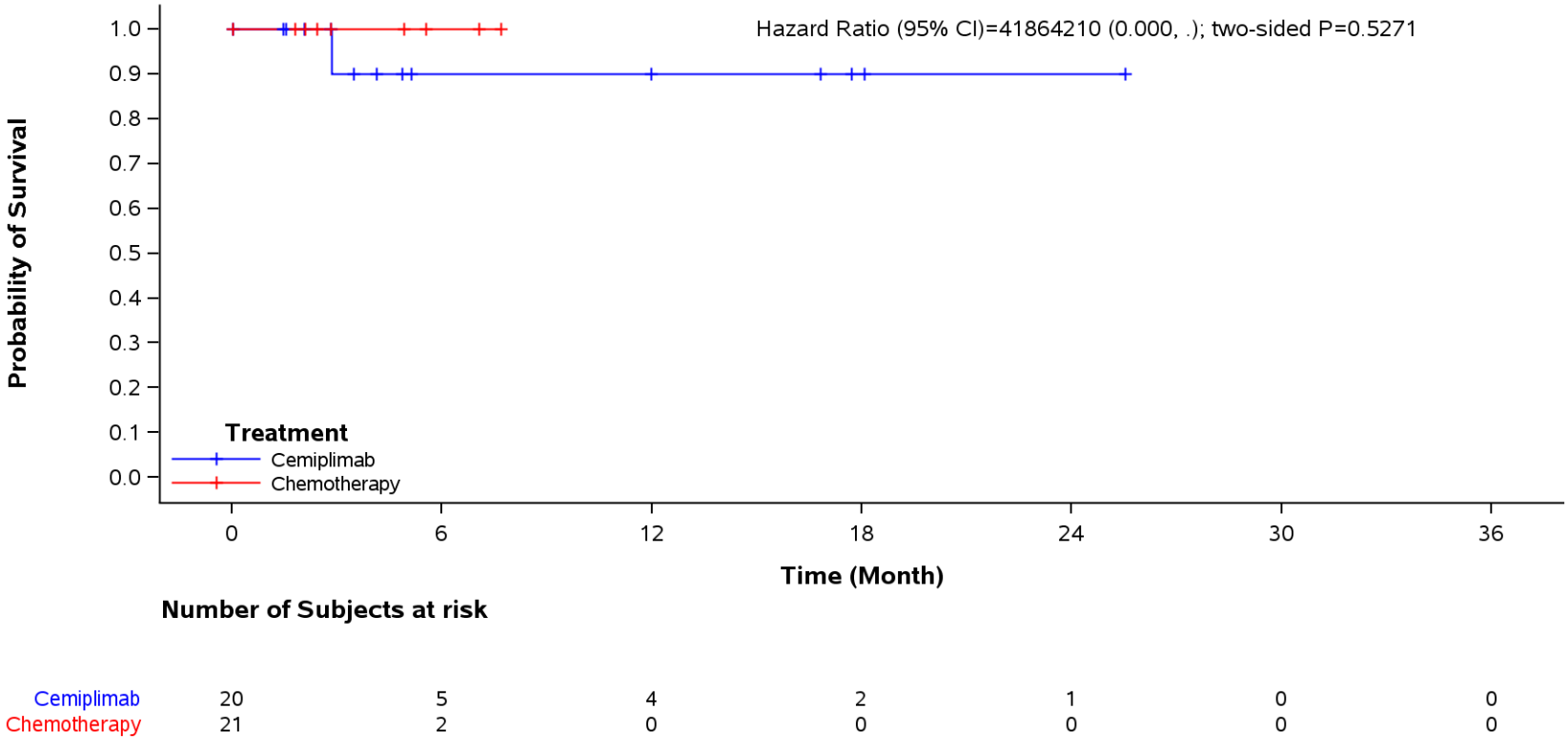

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

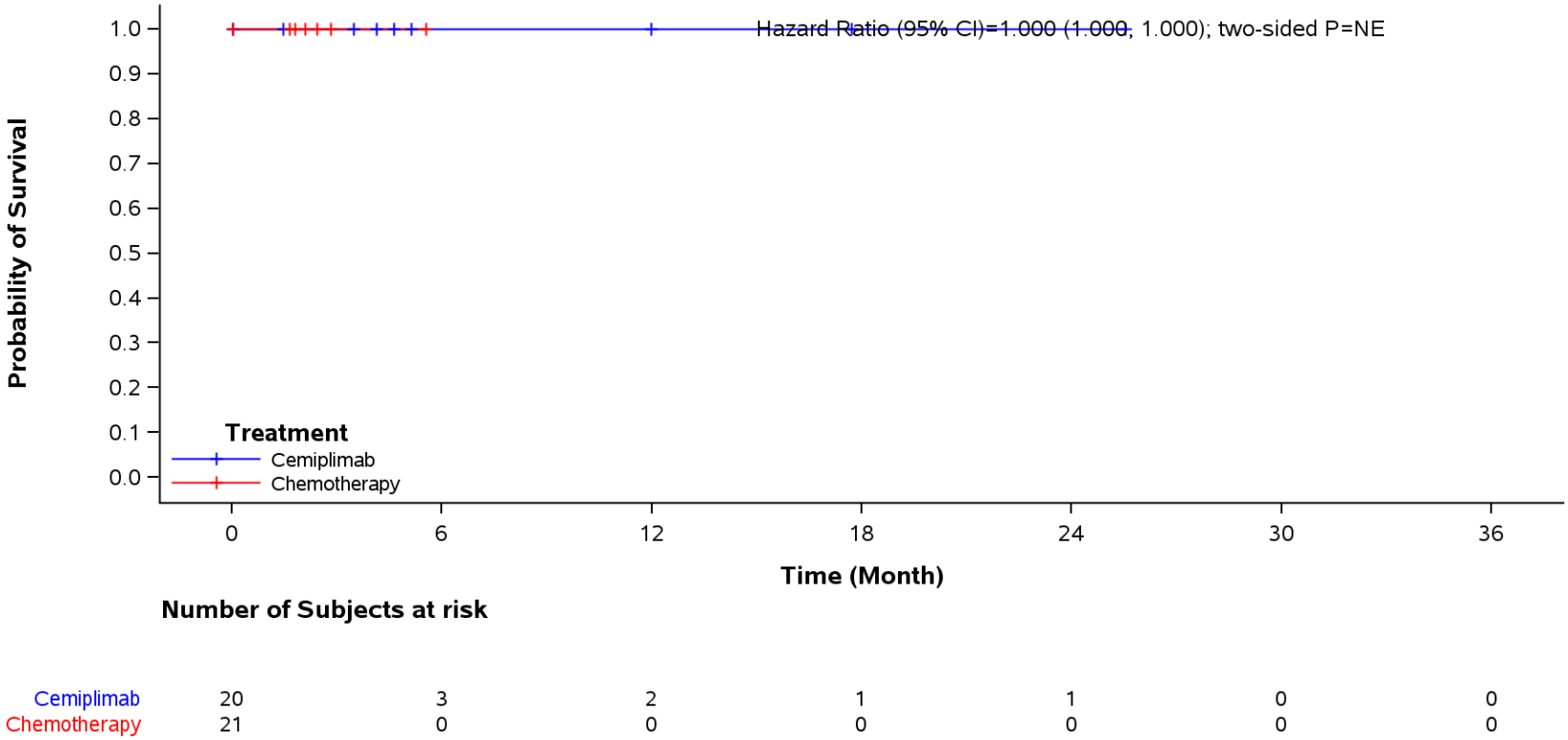
Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

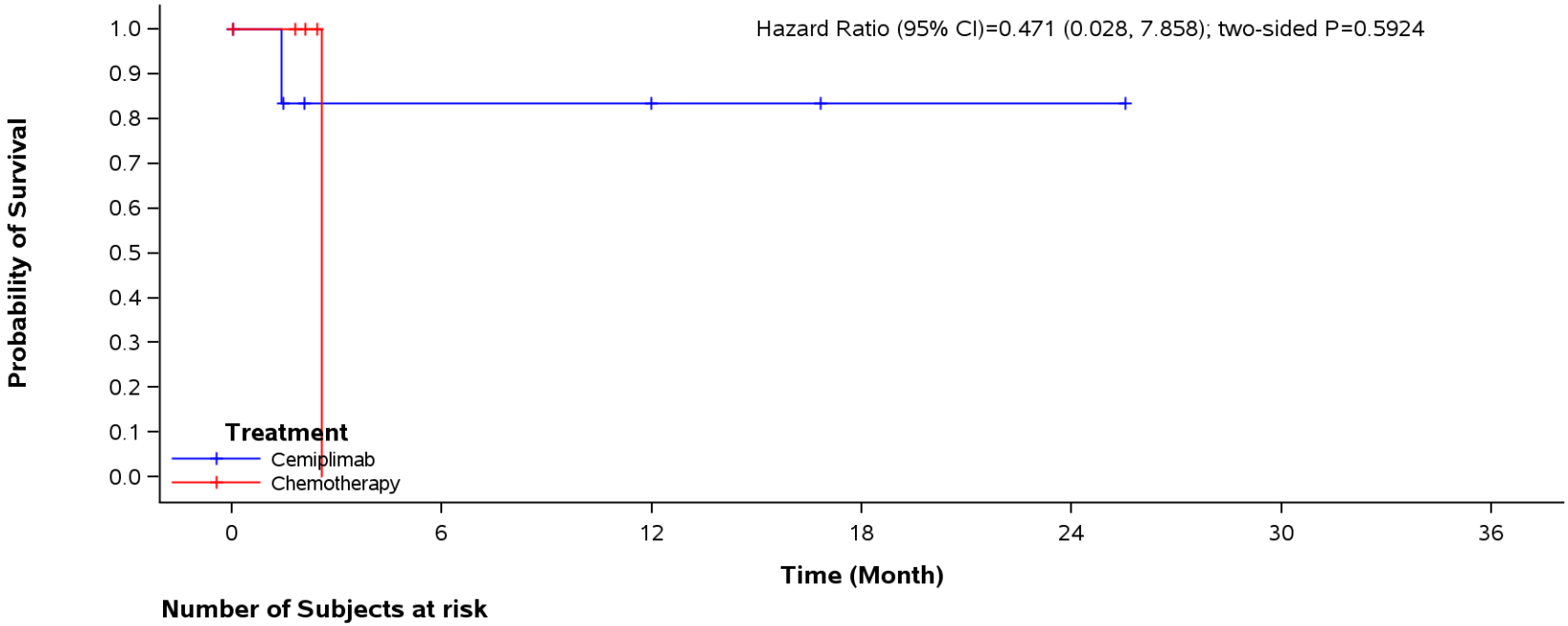
Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts sensitivity sustained improvement



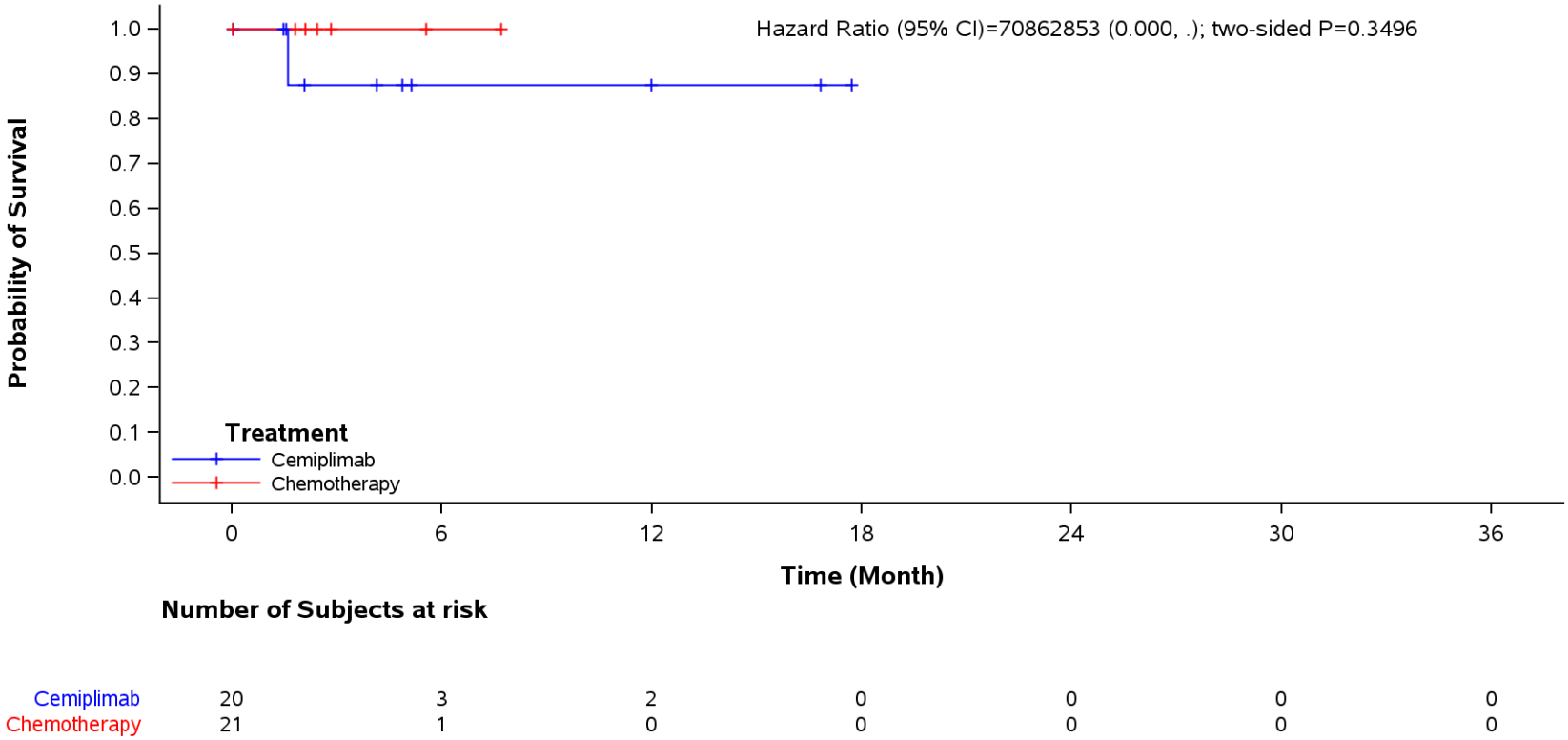

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

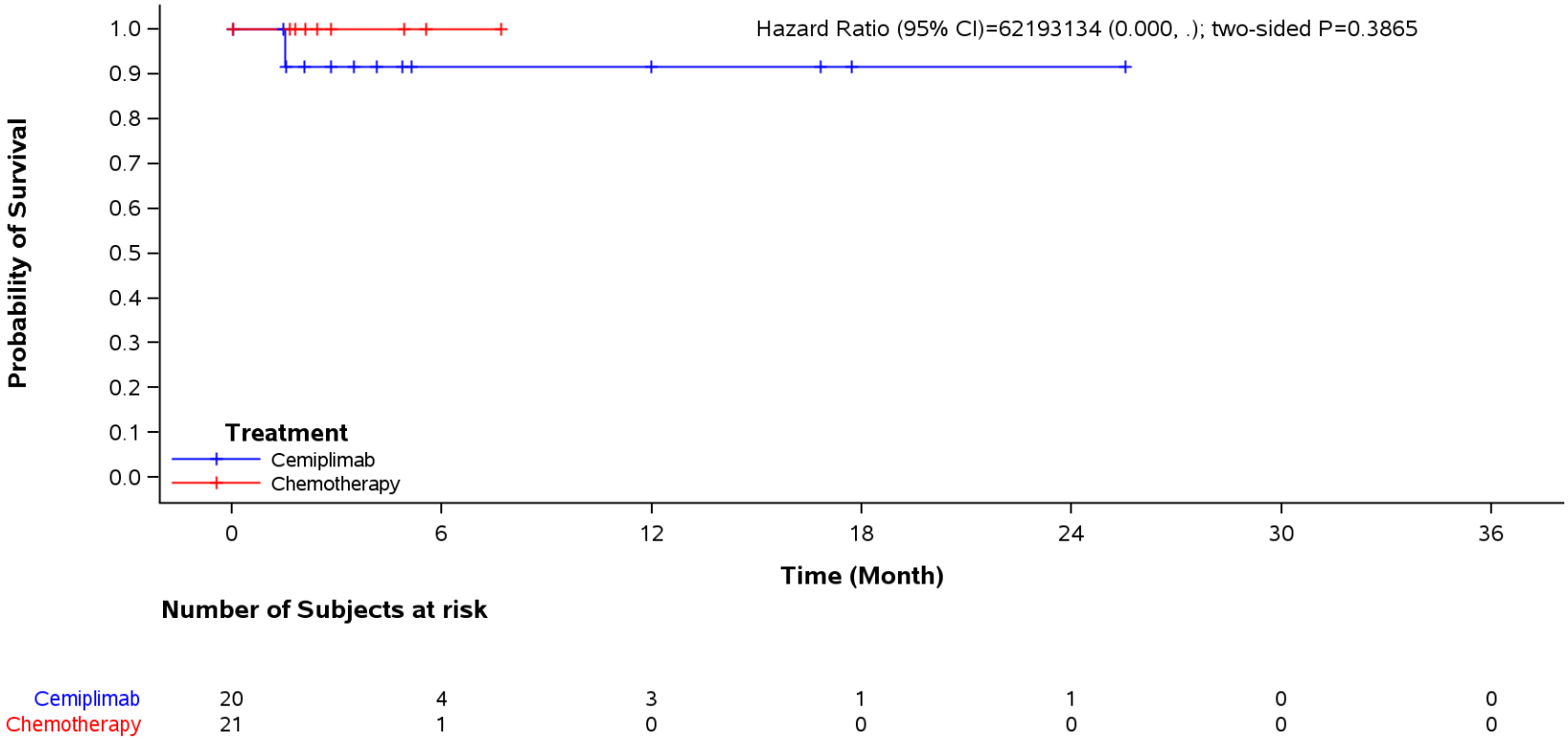
Choice of IC chemotherapy: Topotecan
Pain - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts sensitivity sustained improvement

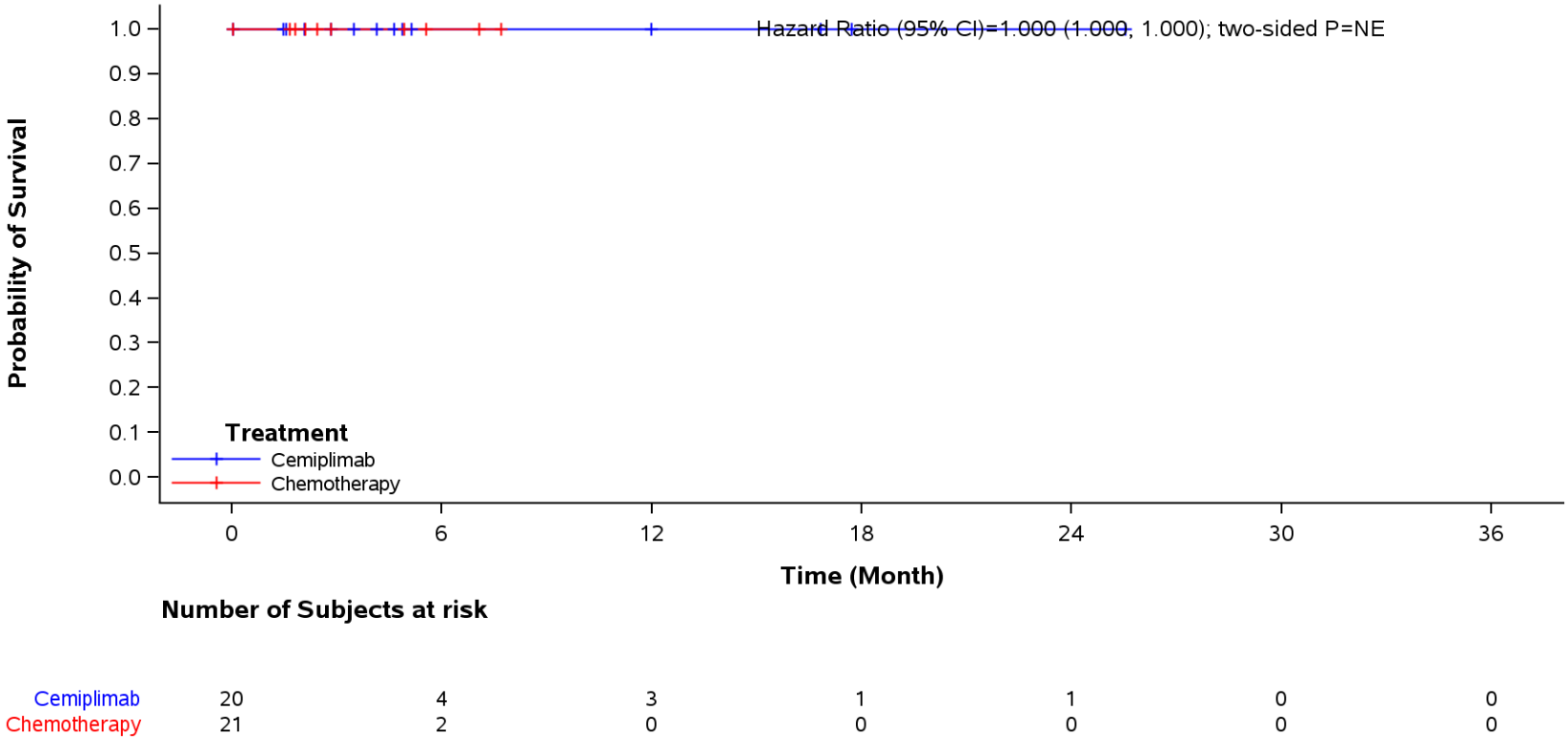



Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

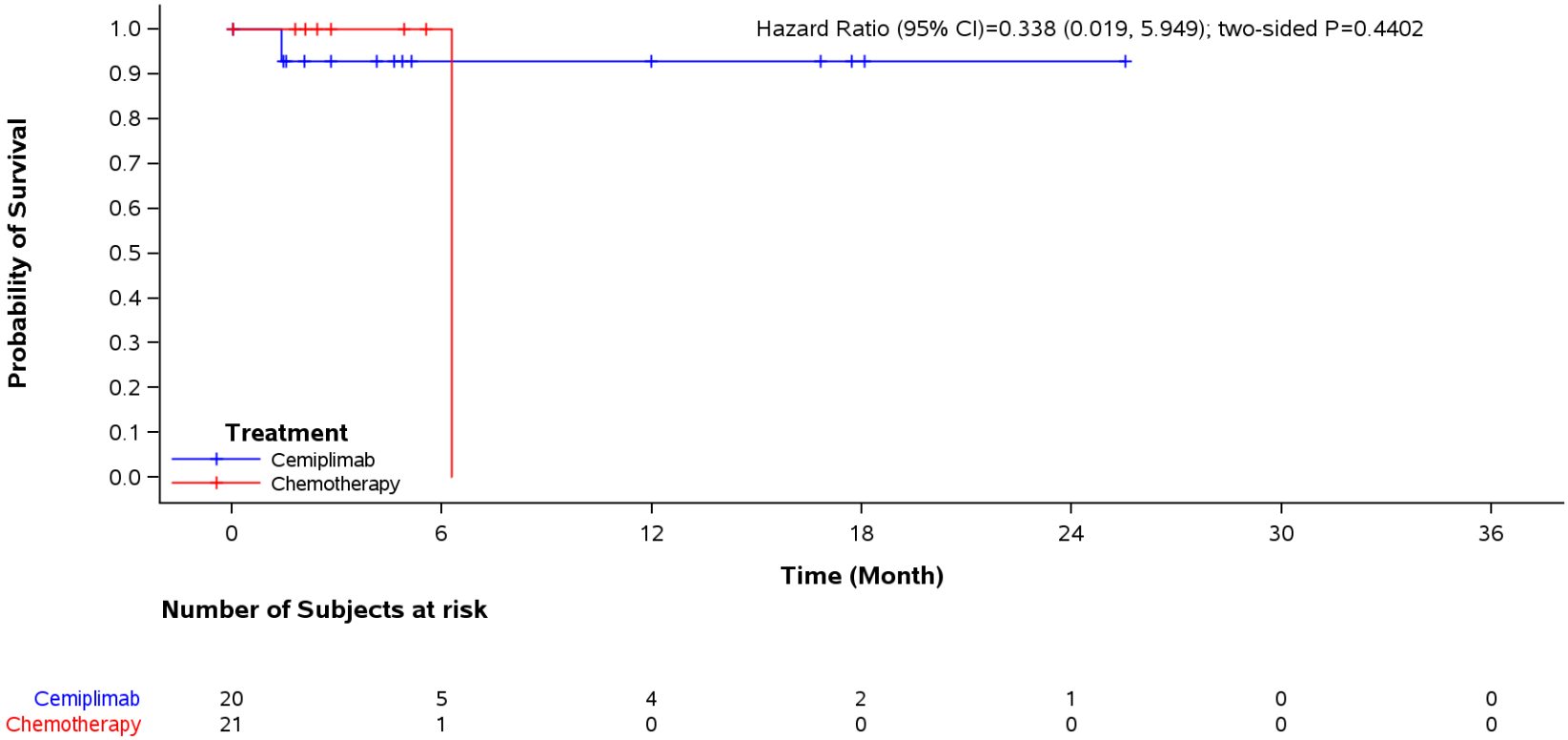
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

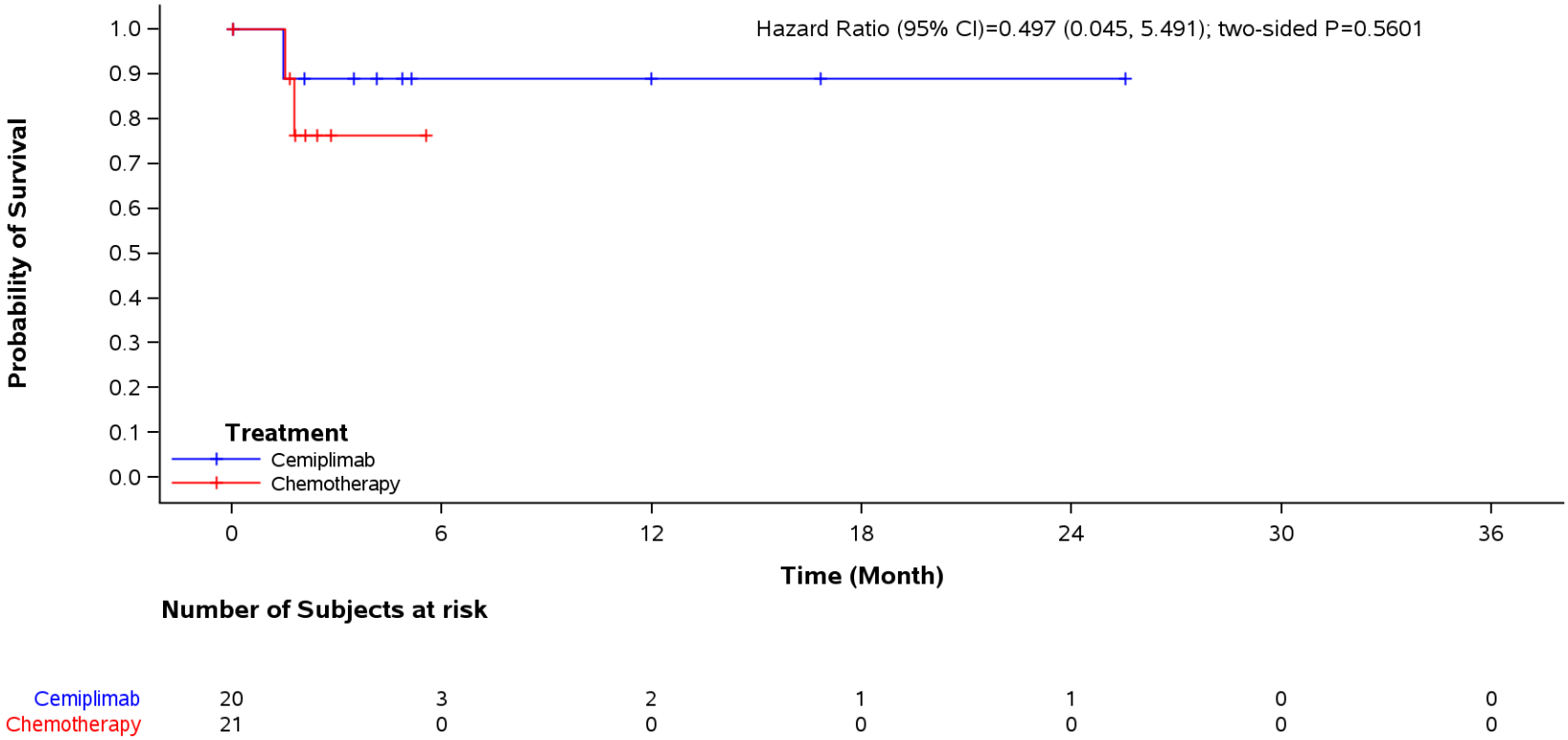
Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

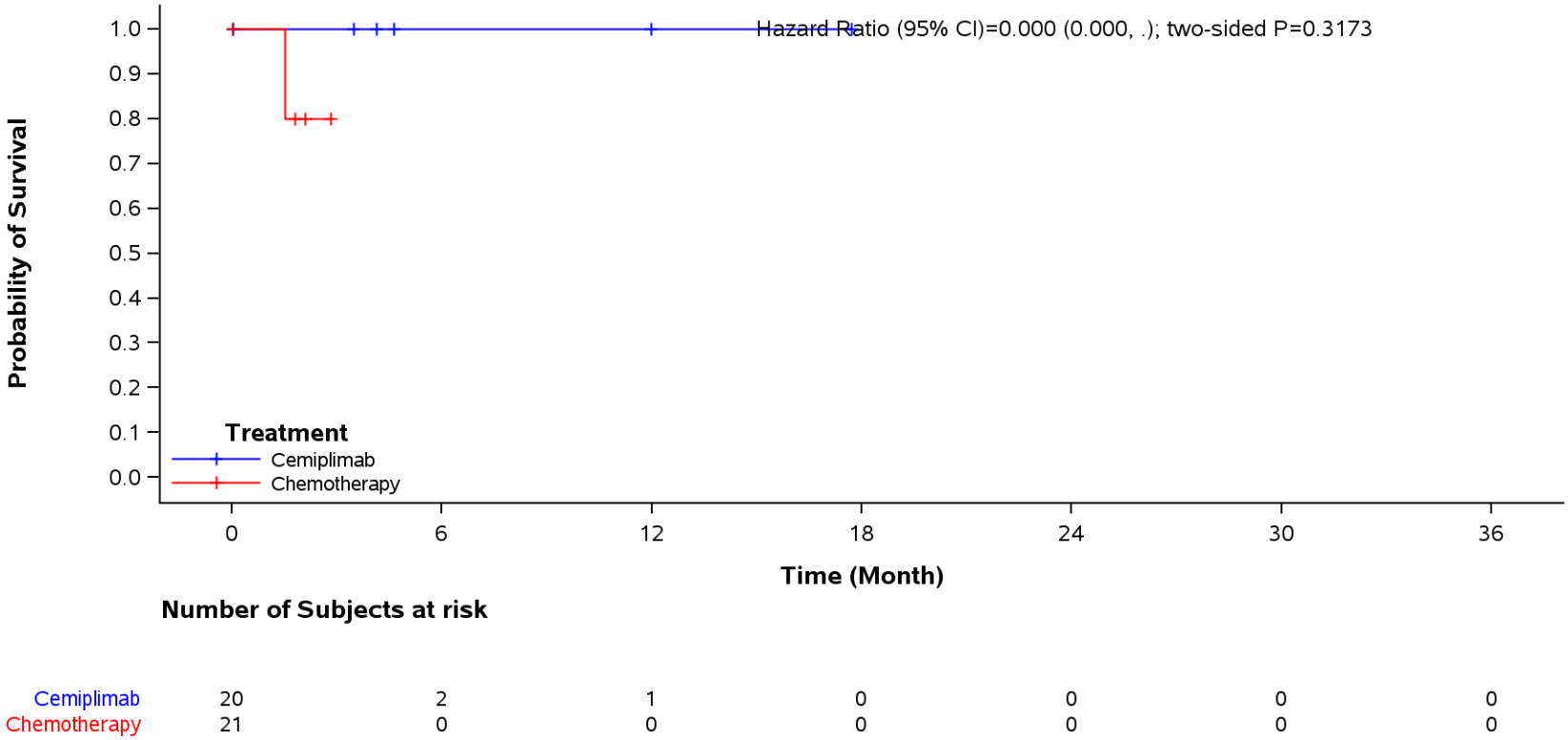
Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

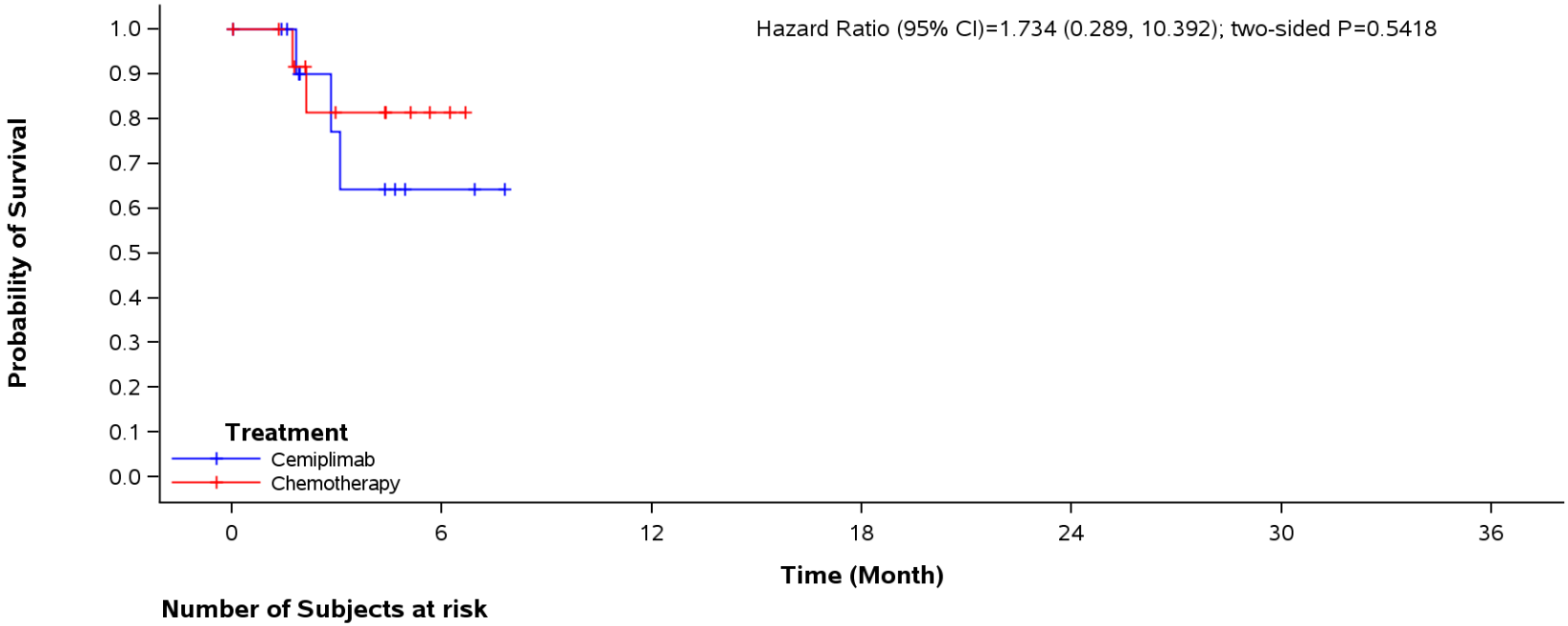
Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts sensitivity sustained improvement



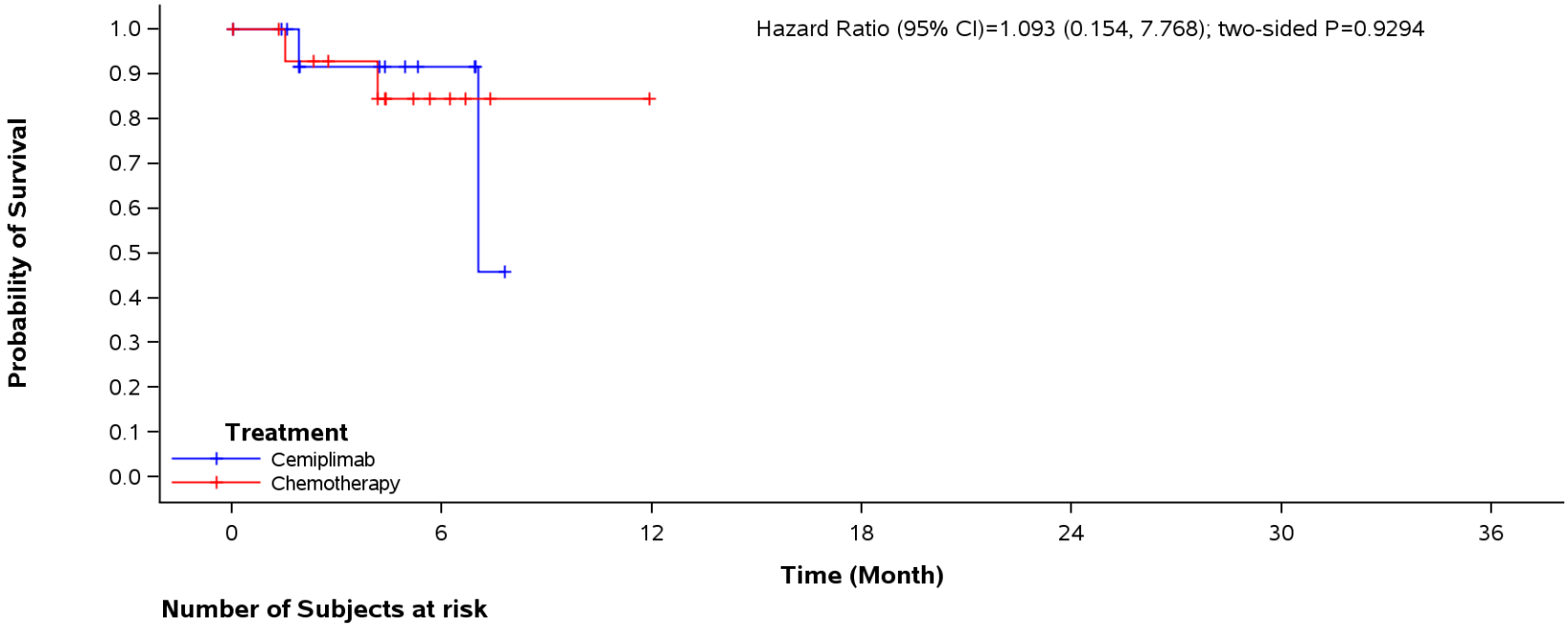

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts sensitivity sustained improvement



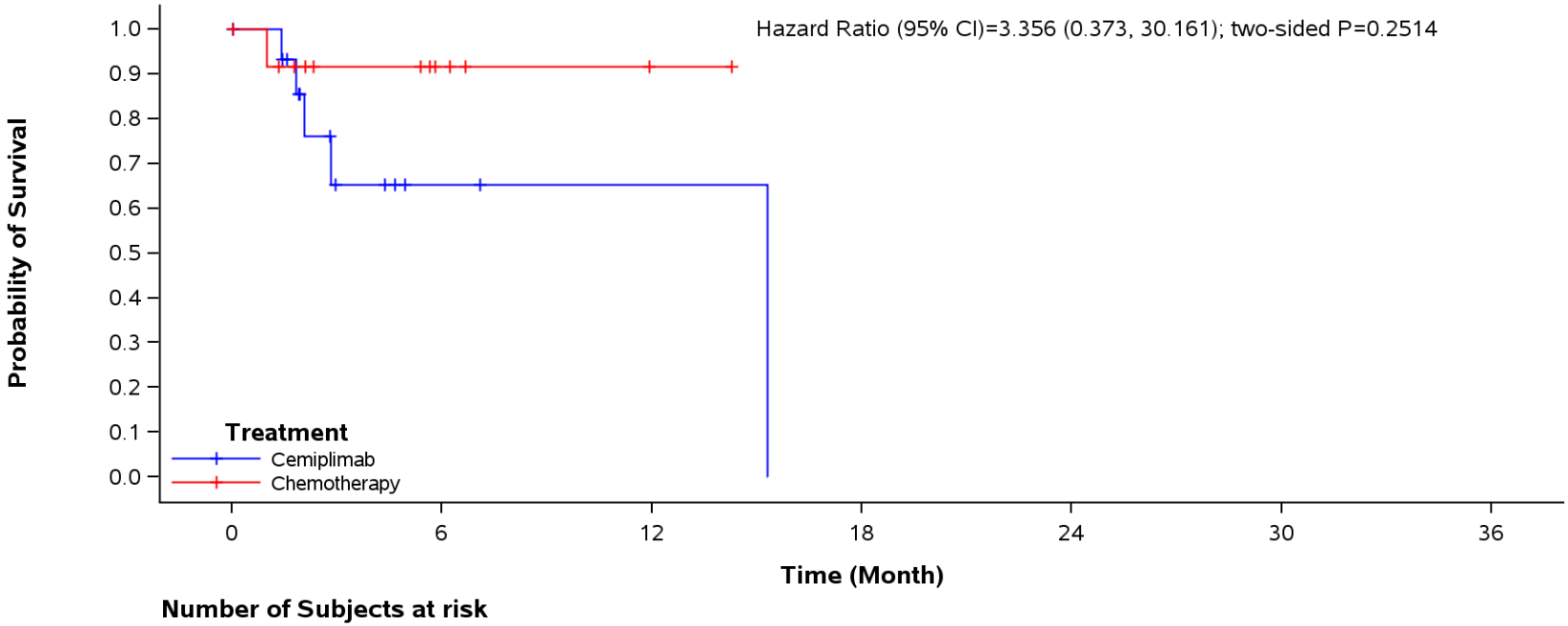

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts sensitivity sustained improvement



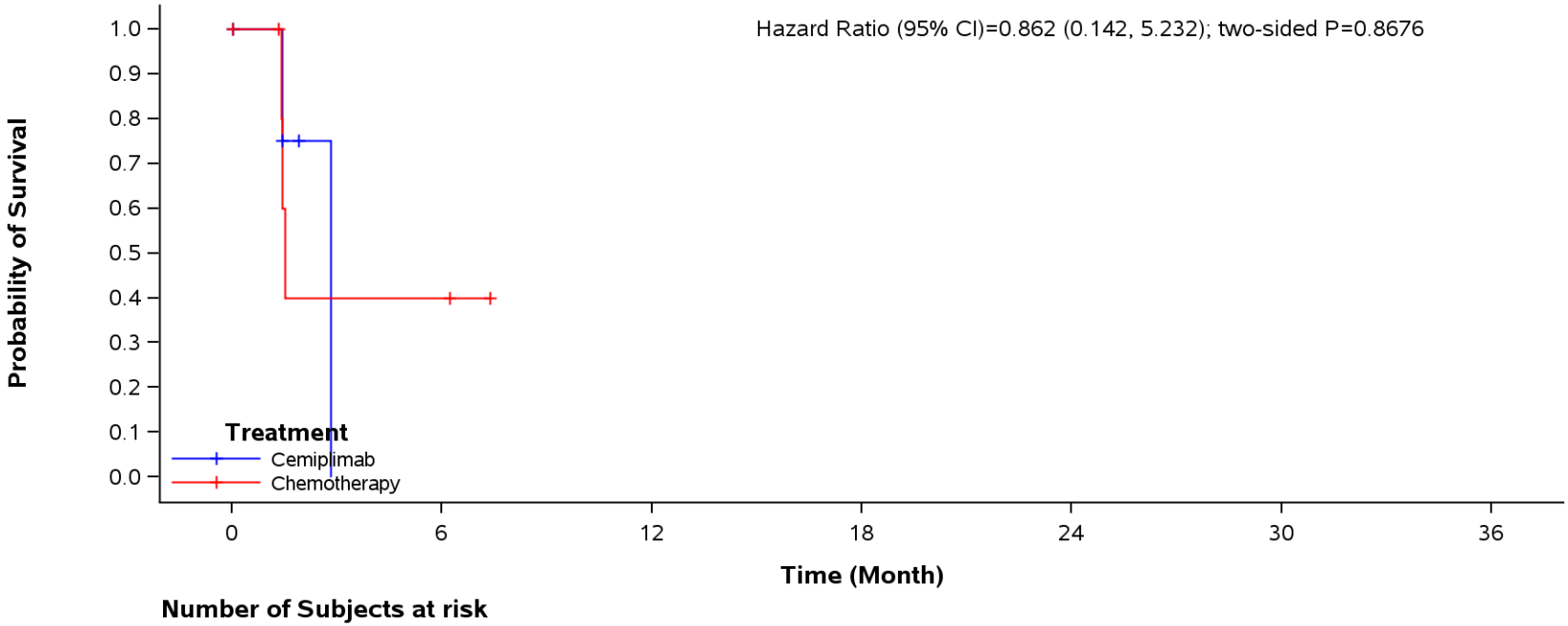

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts sensitivity sustained improvement



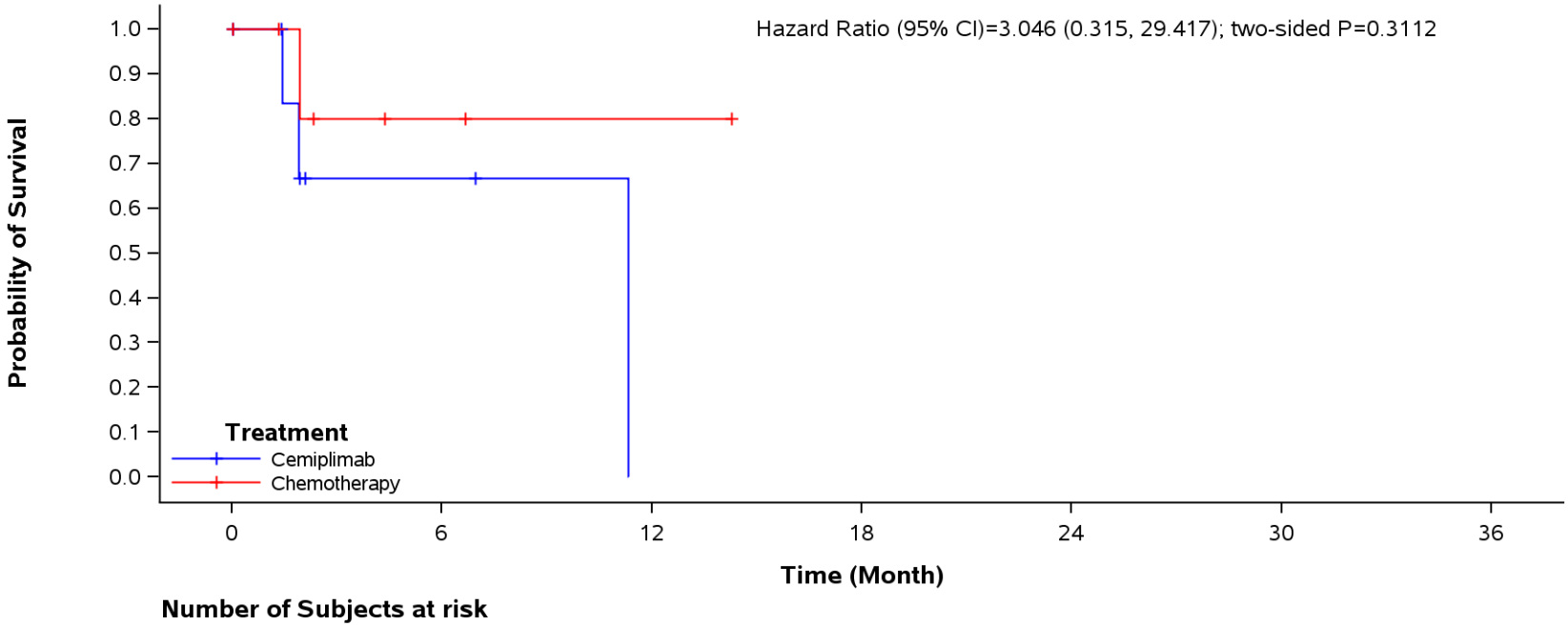

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts sensitivity sustained improvement



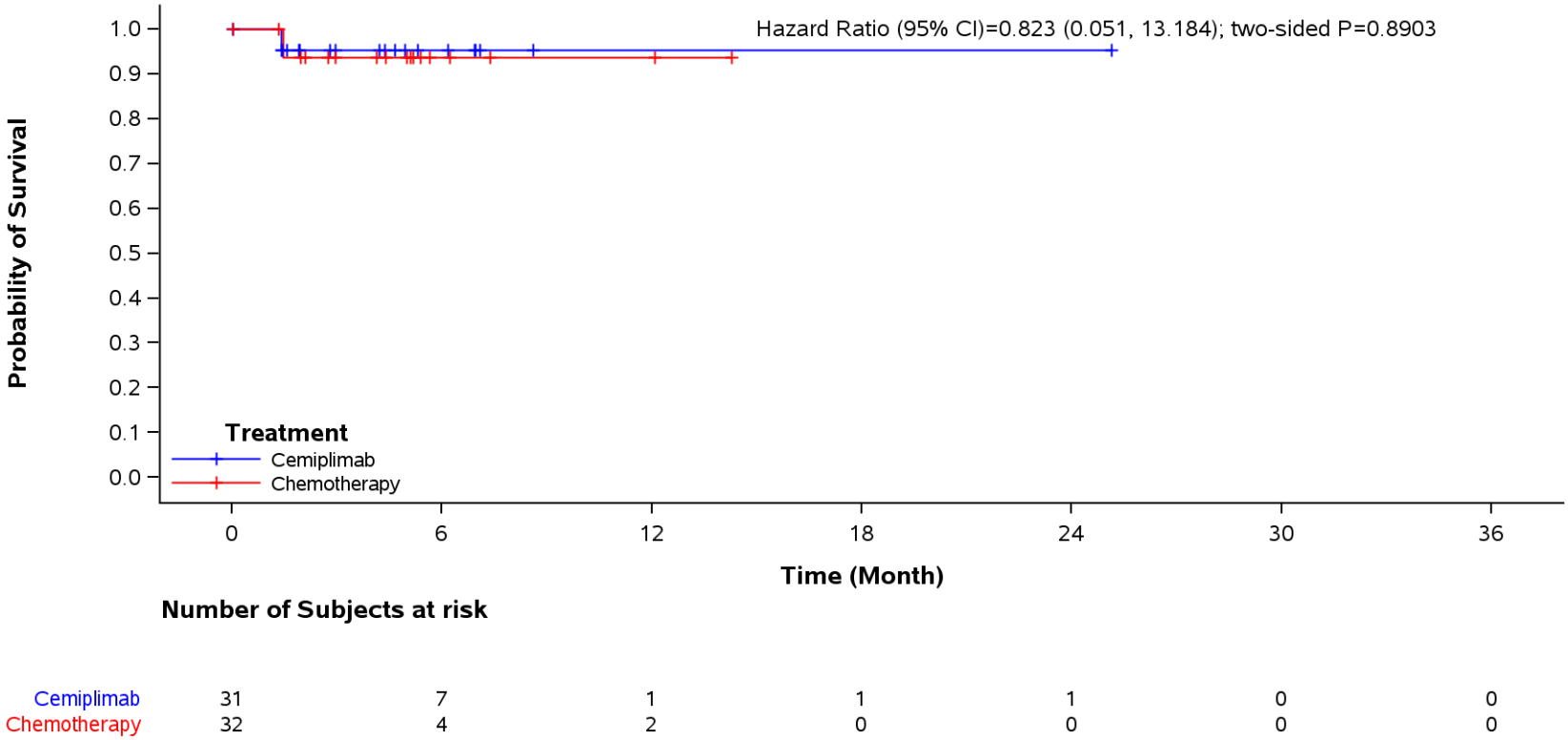

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

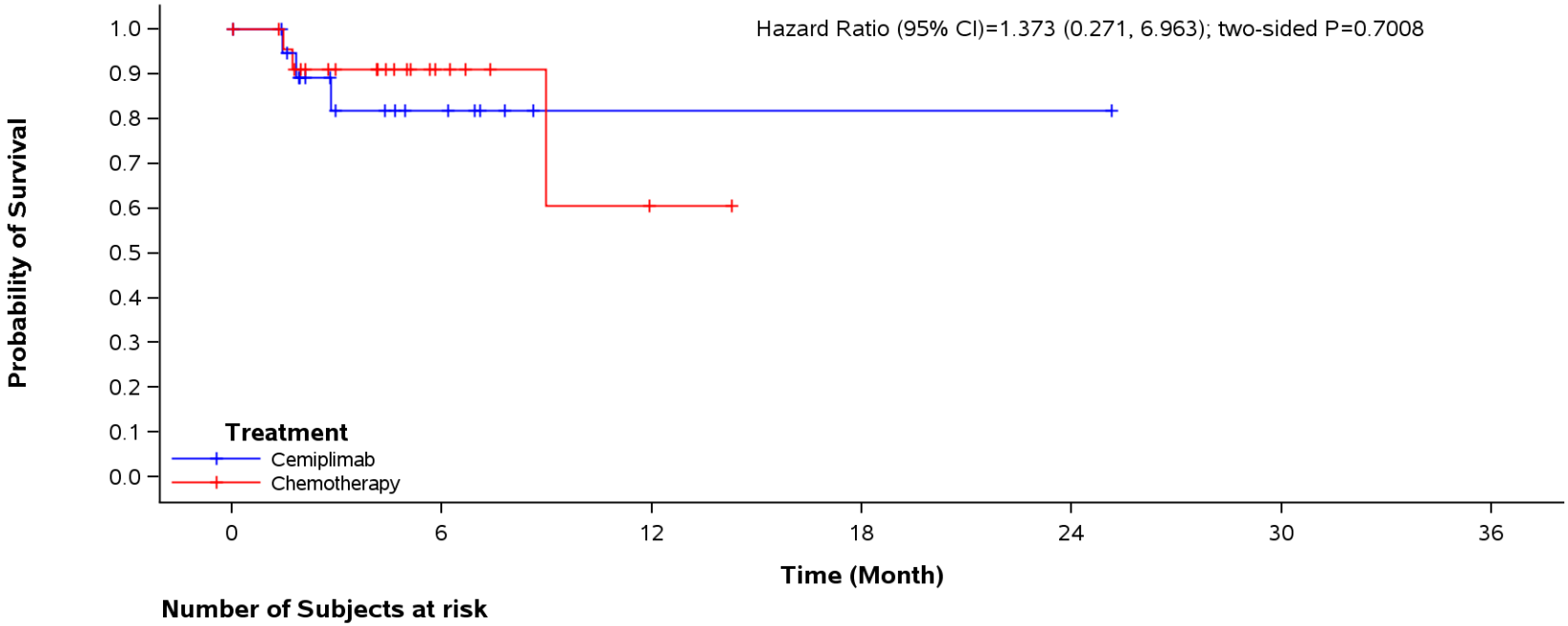
Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts sensitivity sustained improvement



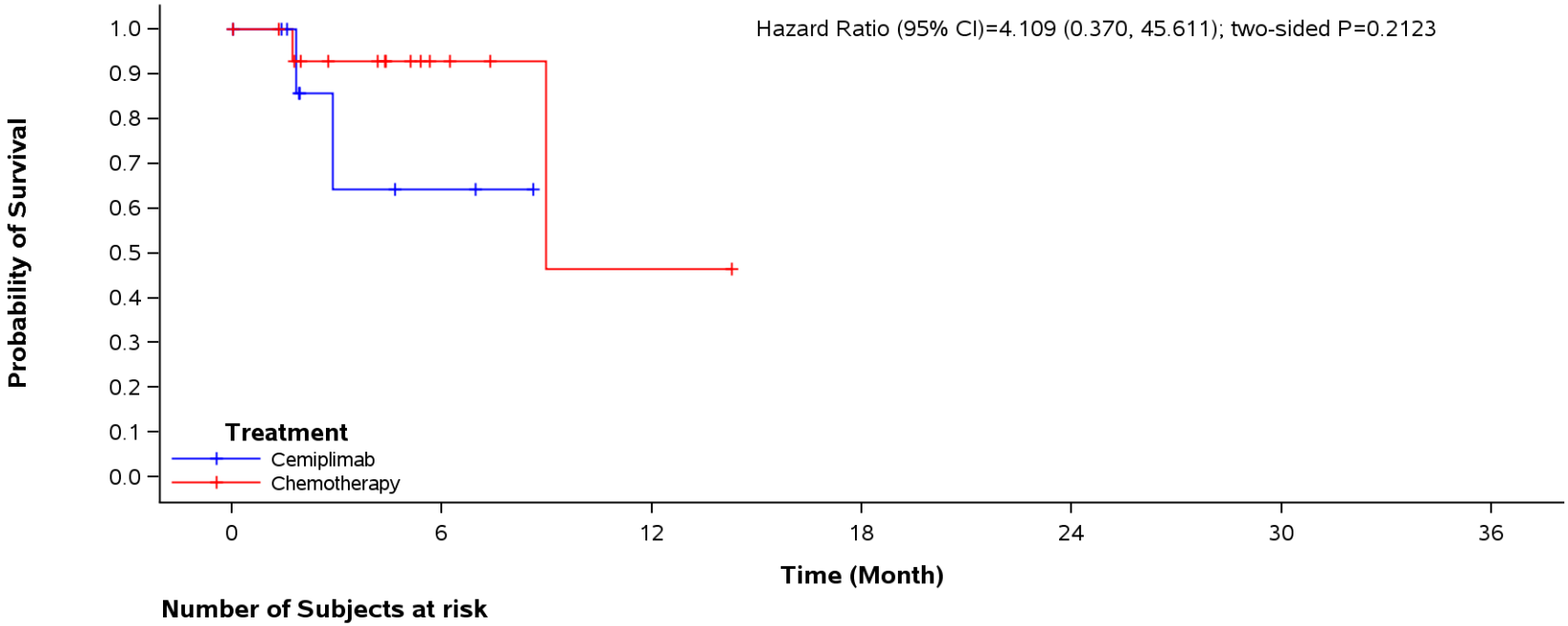

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts sensitivity sustained improvement



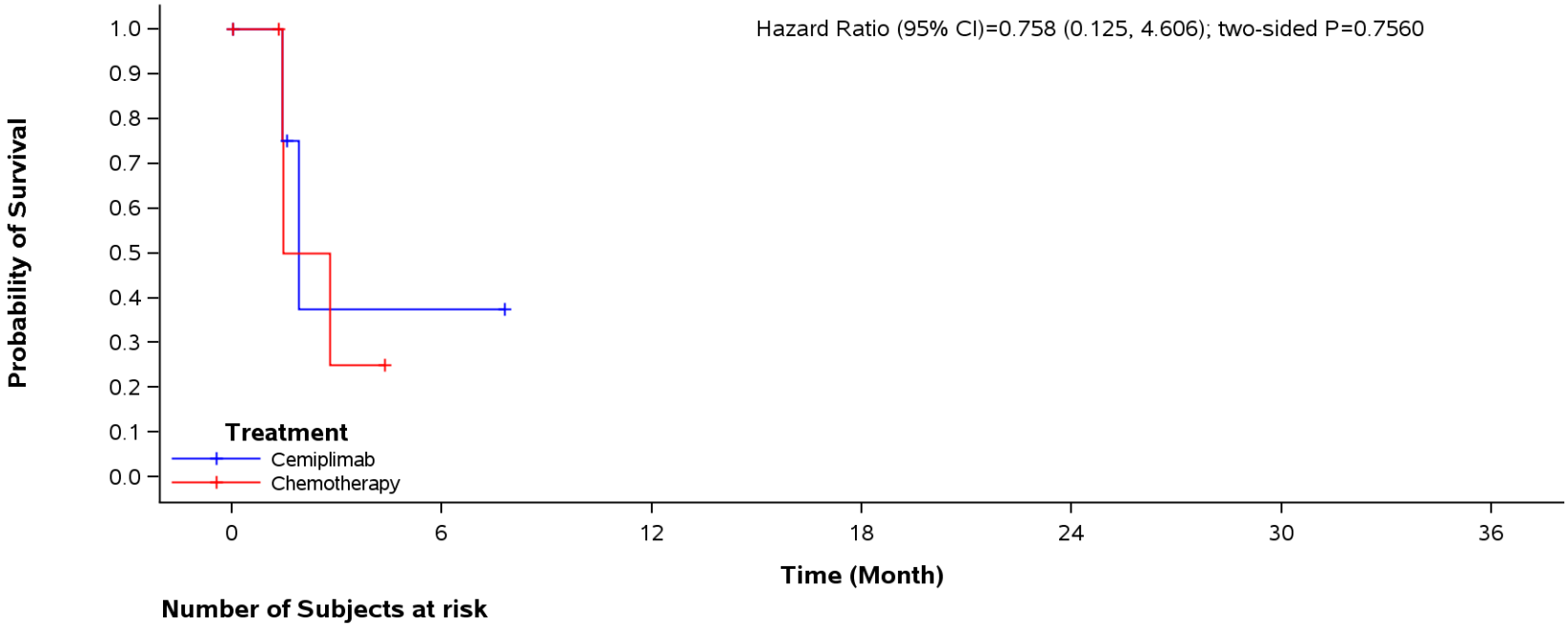

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts sensitivity sustained improvement



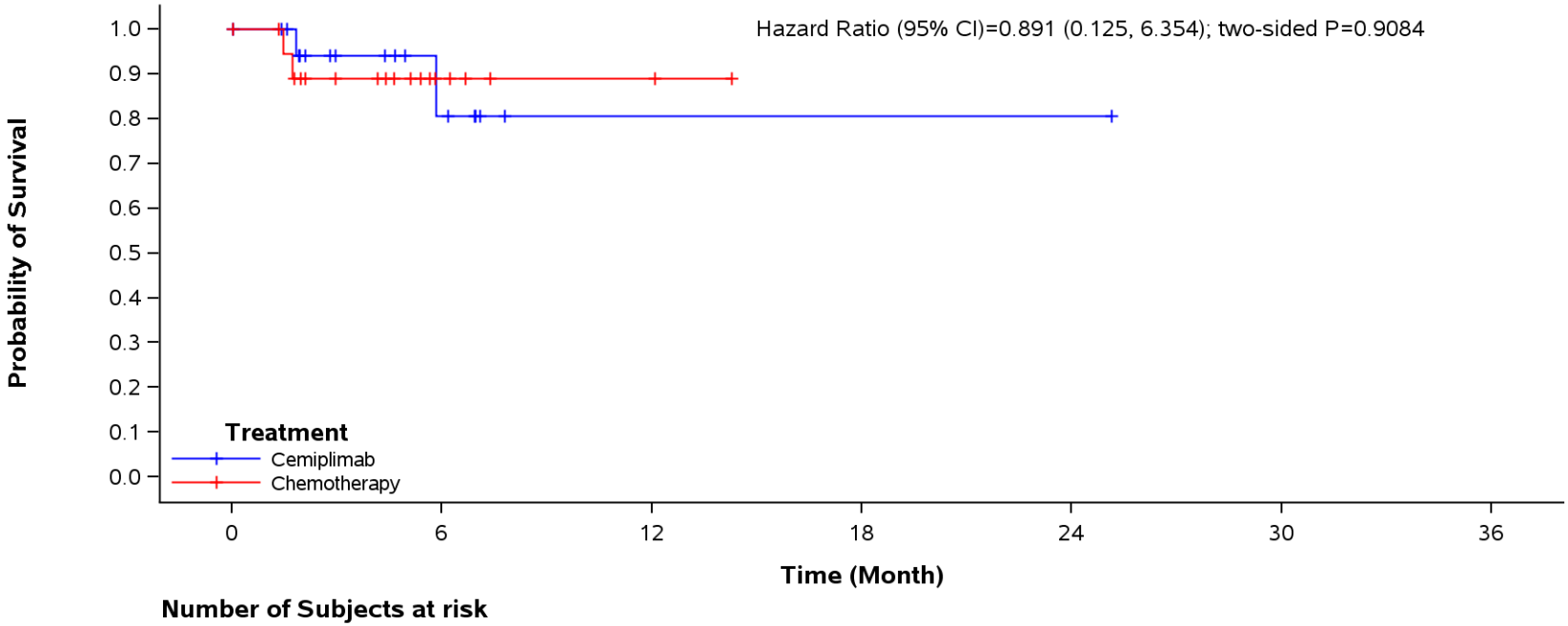

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts sensitivity sustained improvement



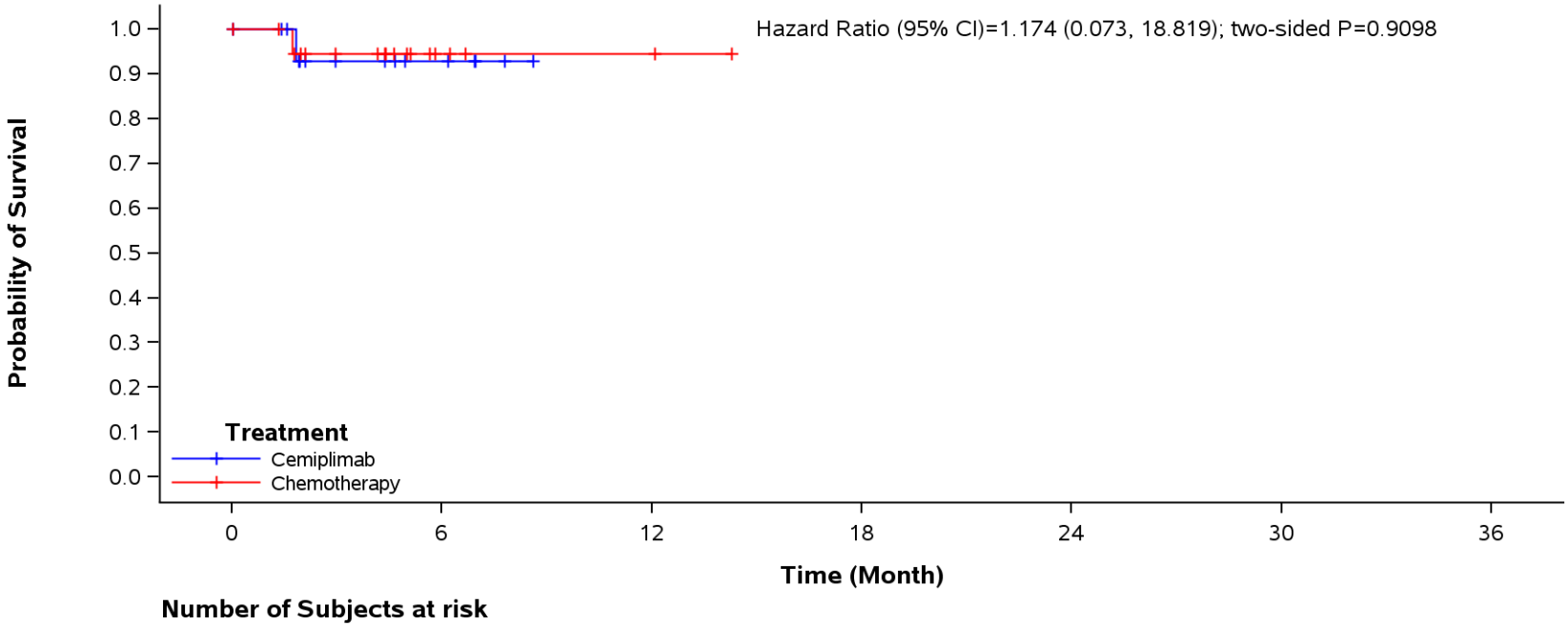

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts sensitivity sustained improvement



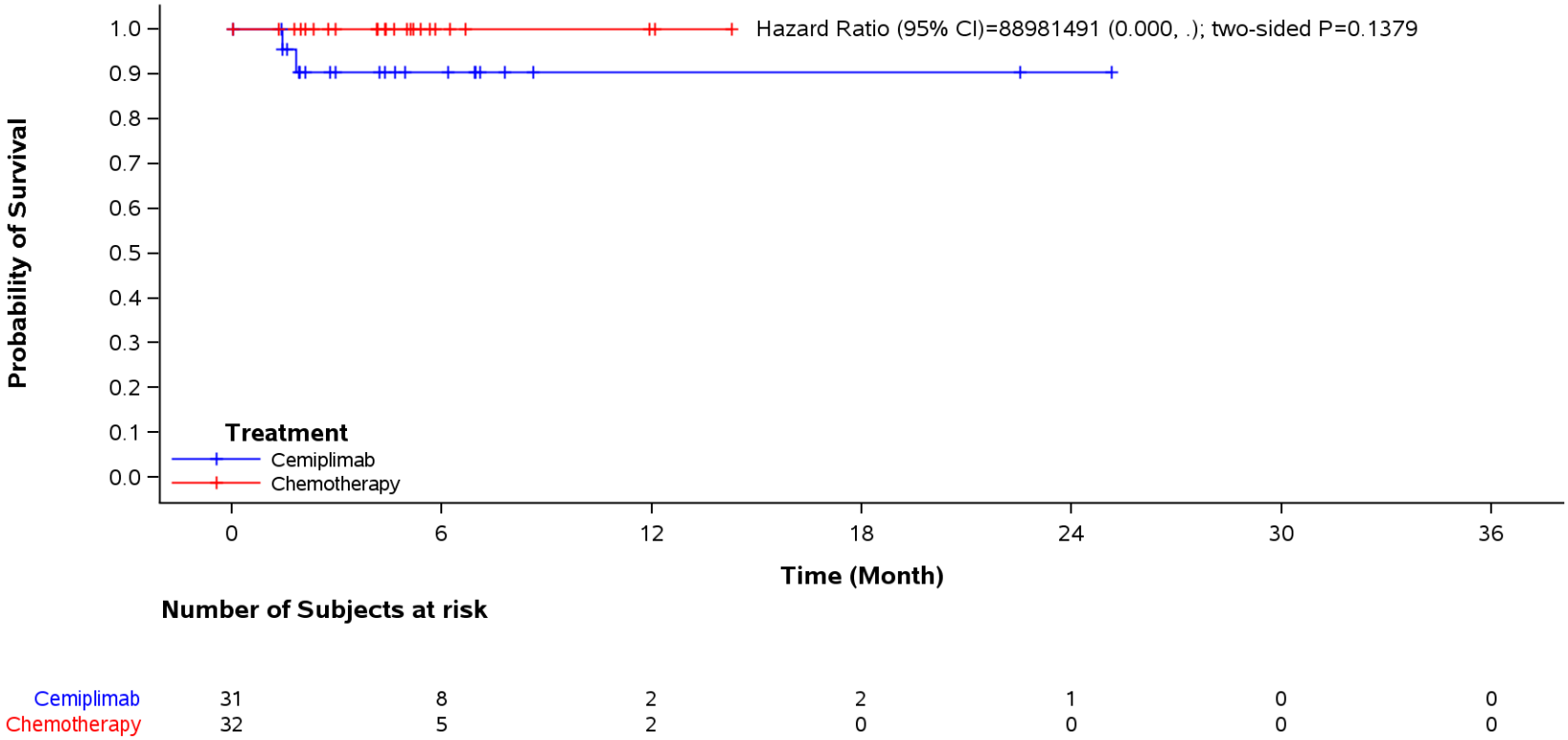

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

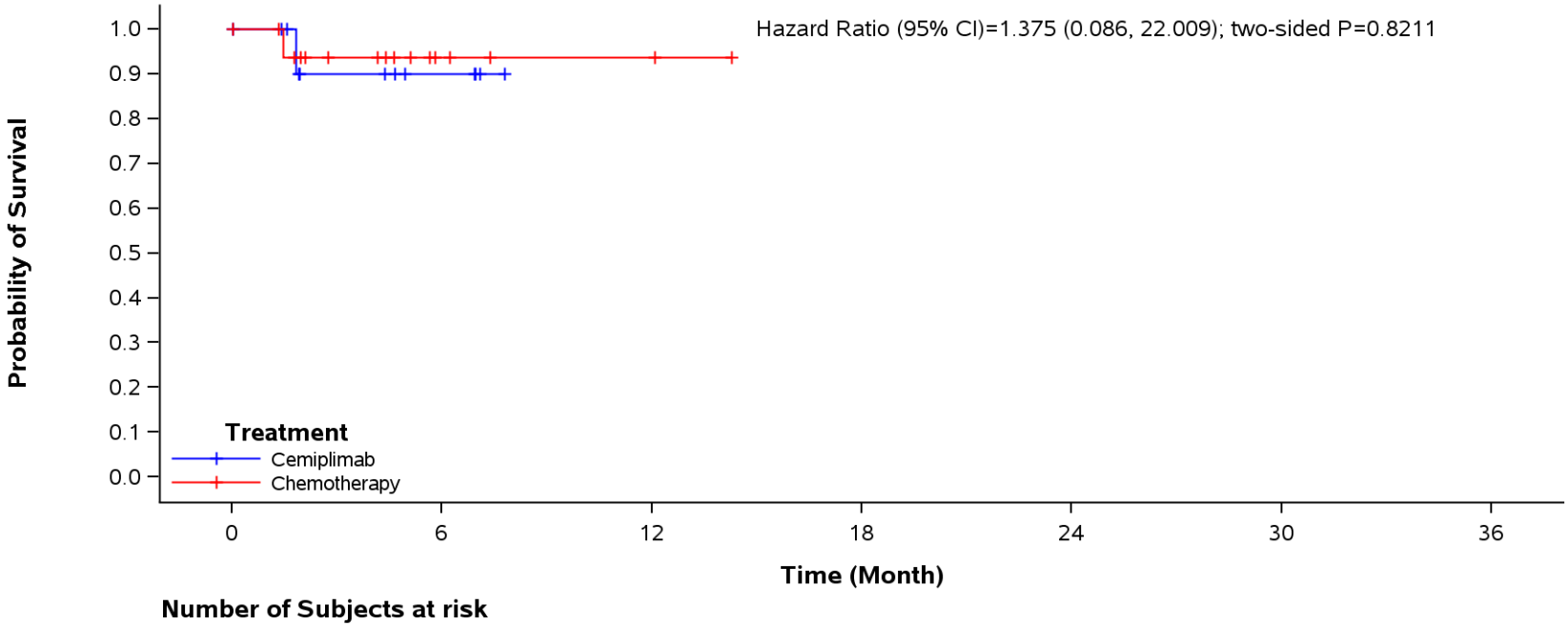
Choice of IC chemotherapy: Vinorelbine
Global health status / QoL - 10 pts sensitivity sustained improvement




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts sensitivity sustained improvement



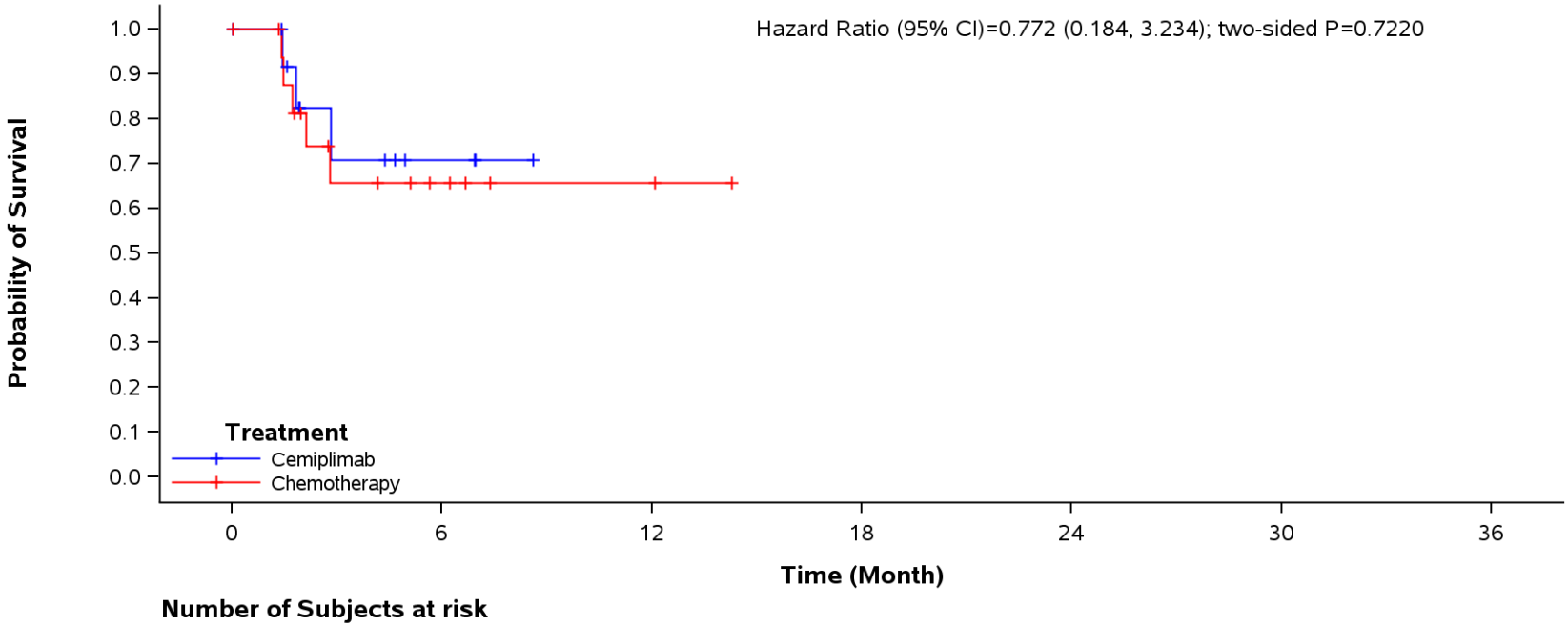

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts sensitivity sustained improvement



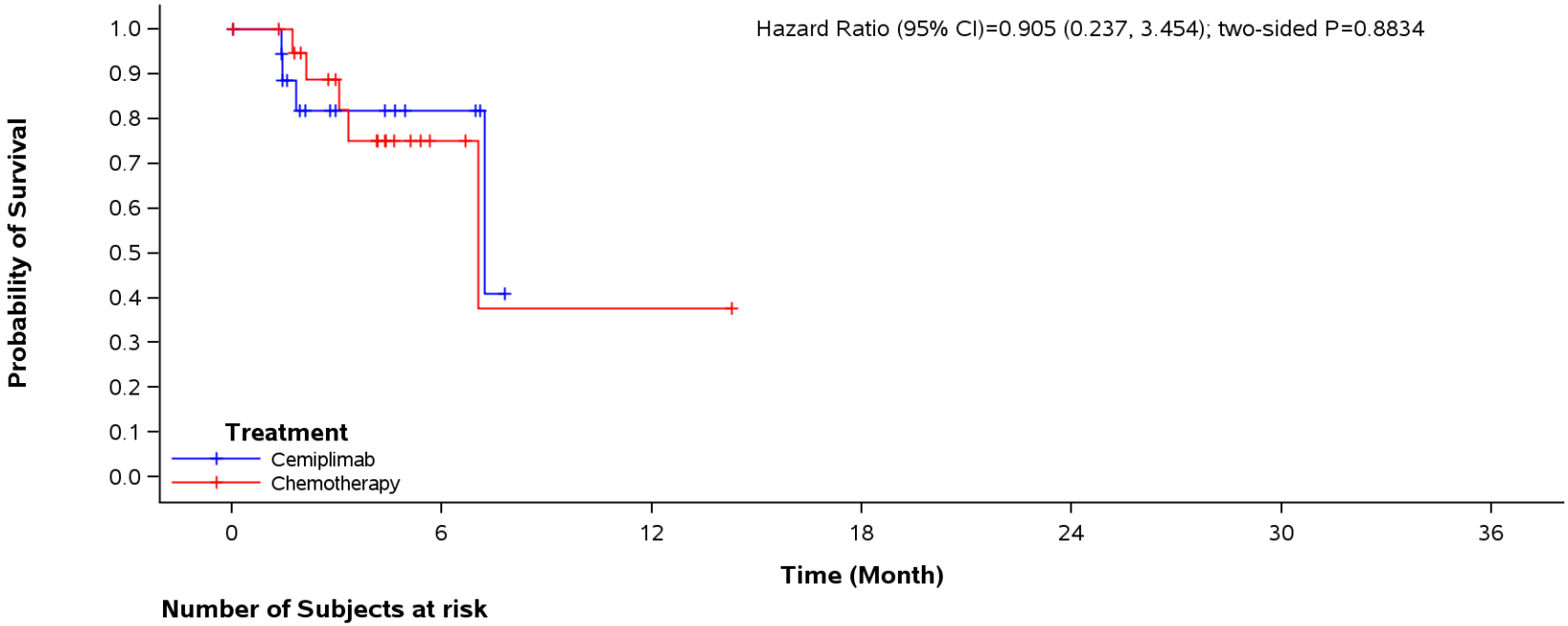

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

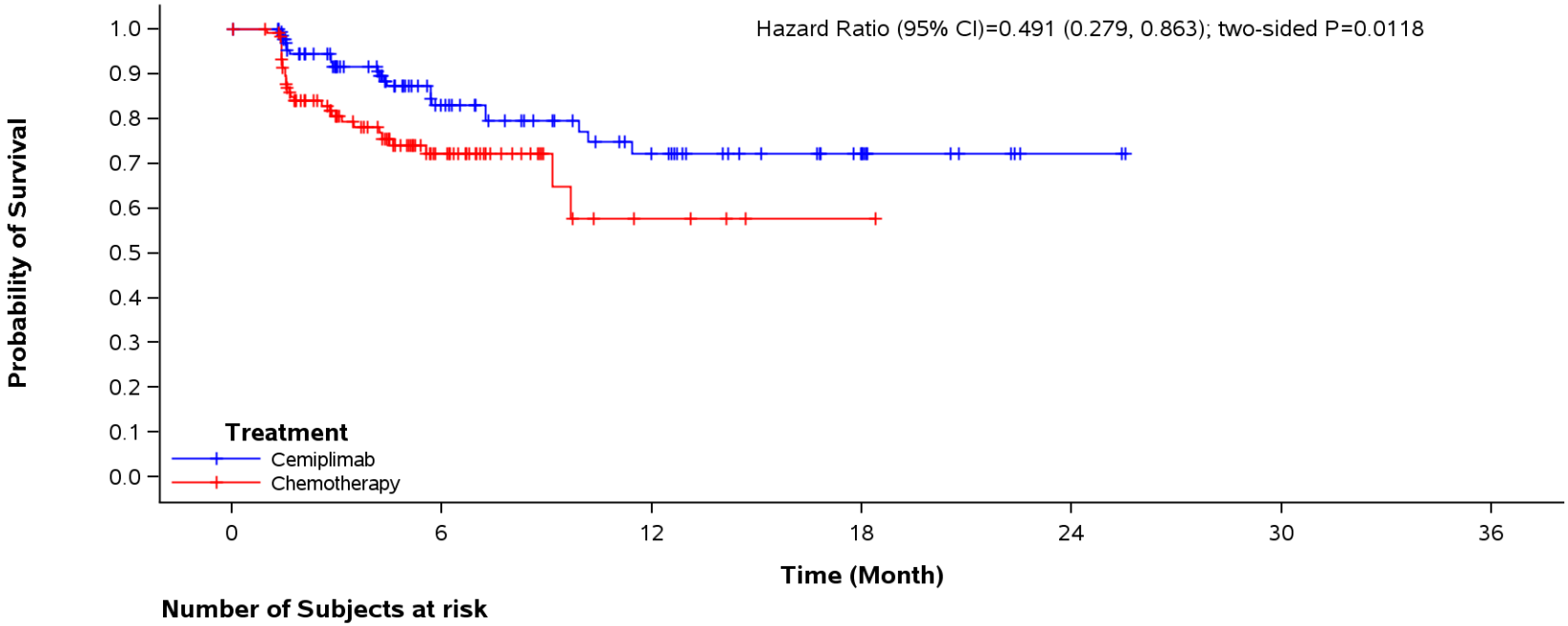
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65

Appetite loss - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

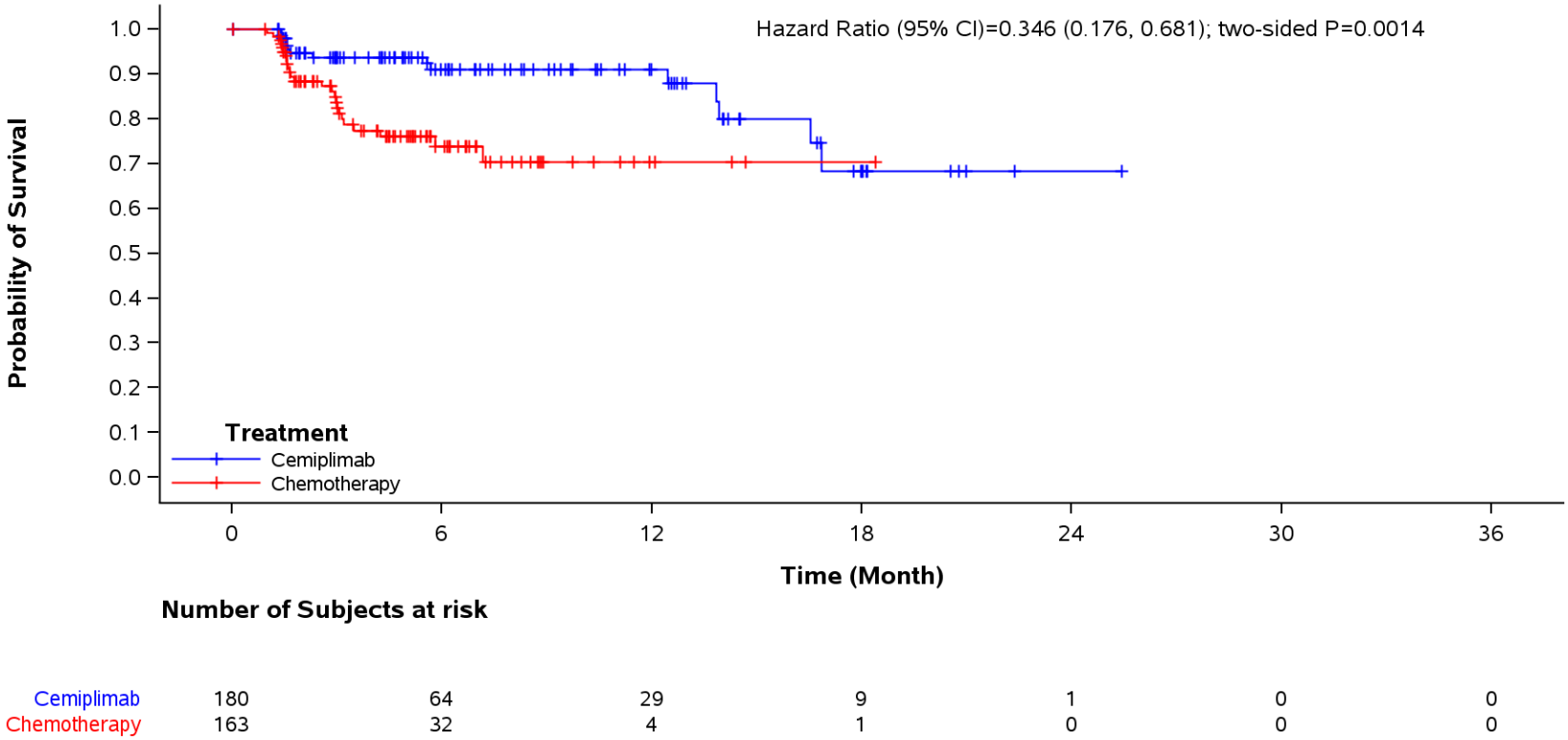
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 56 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 33 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Cognitive Functioning - 10 pts sensitivity sustained deterioration



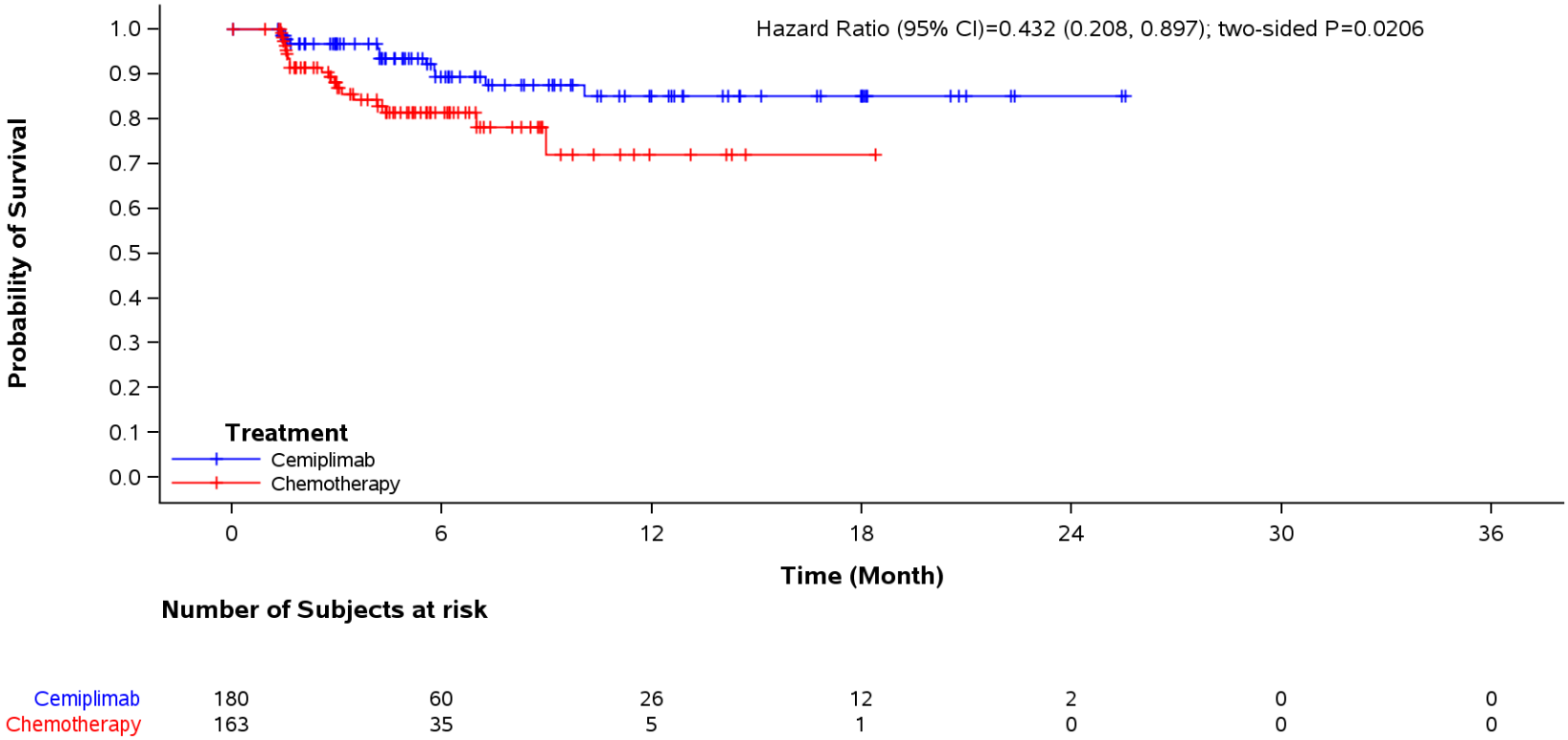

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 64 | 29 | 9 | 1 | 0 | 0 |
| Chemotherapy | 163 | 32 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Constipation - 10 pts sensitivity sustained deterioration



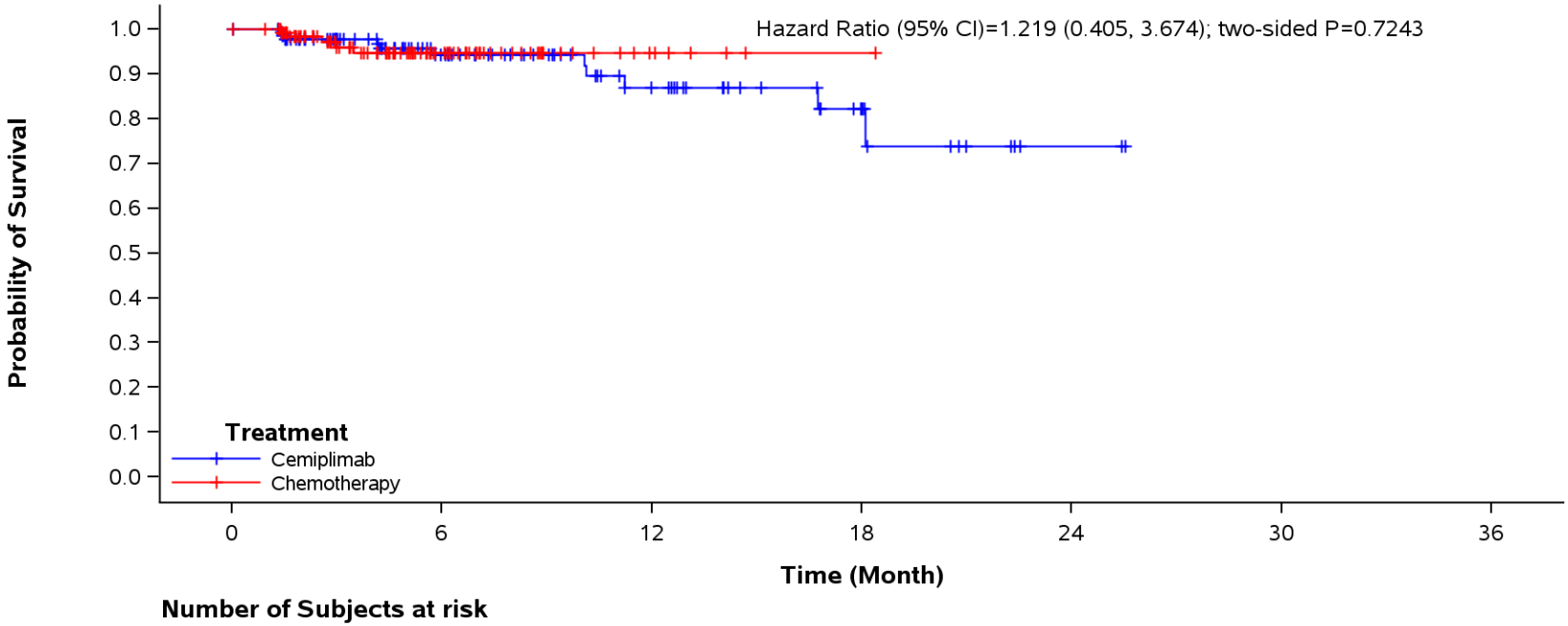

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 60 | 26 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 35 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Diarhoea - 10 pts sensitivity sustained deterioration



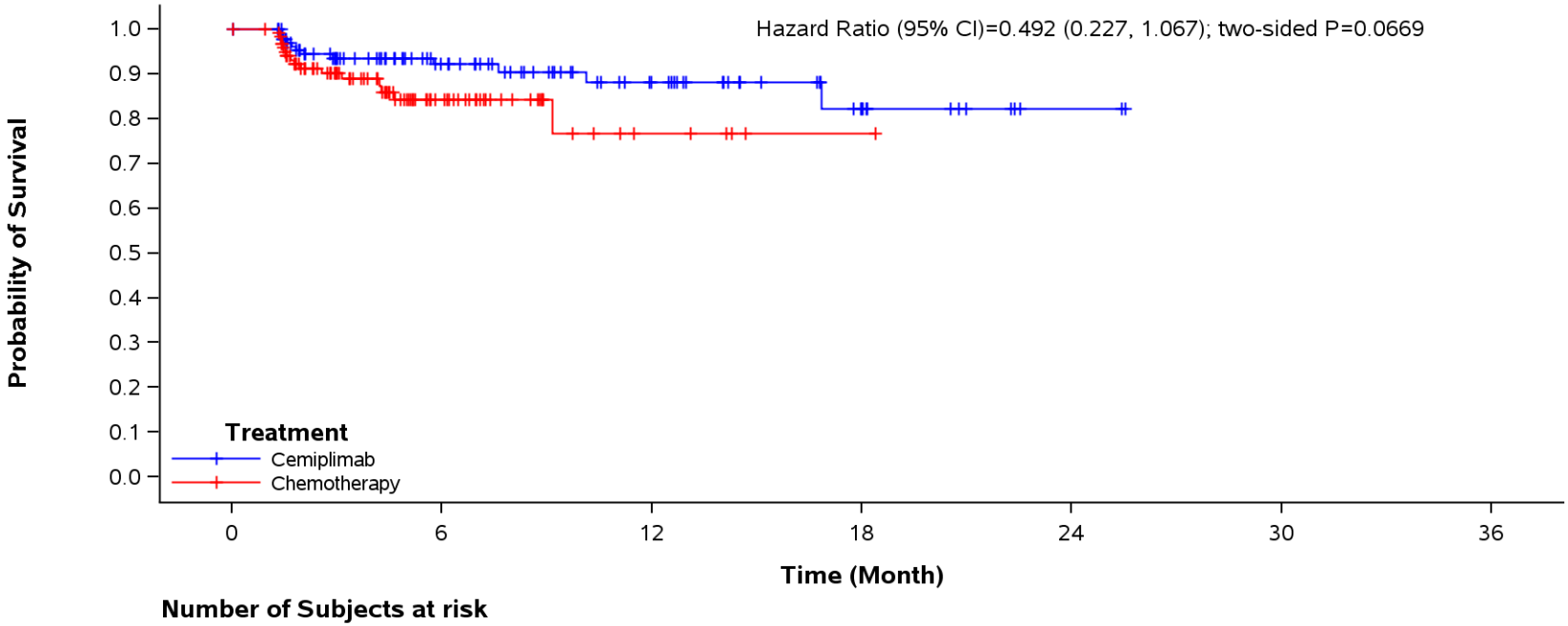

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 65 | 30 | 13 | 2 | 0 | 0 |
| Chemotherapy | 163 | 39 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Dyspnoea - 10 pts sensitivity sustained deterioration



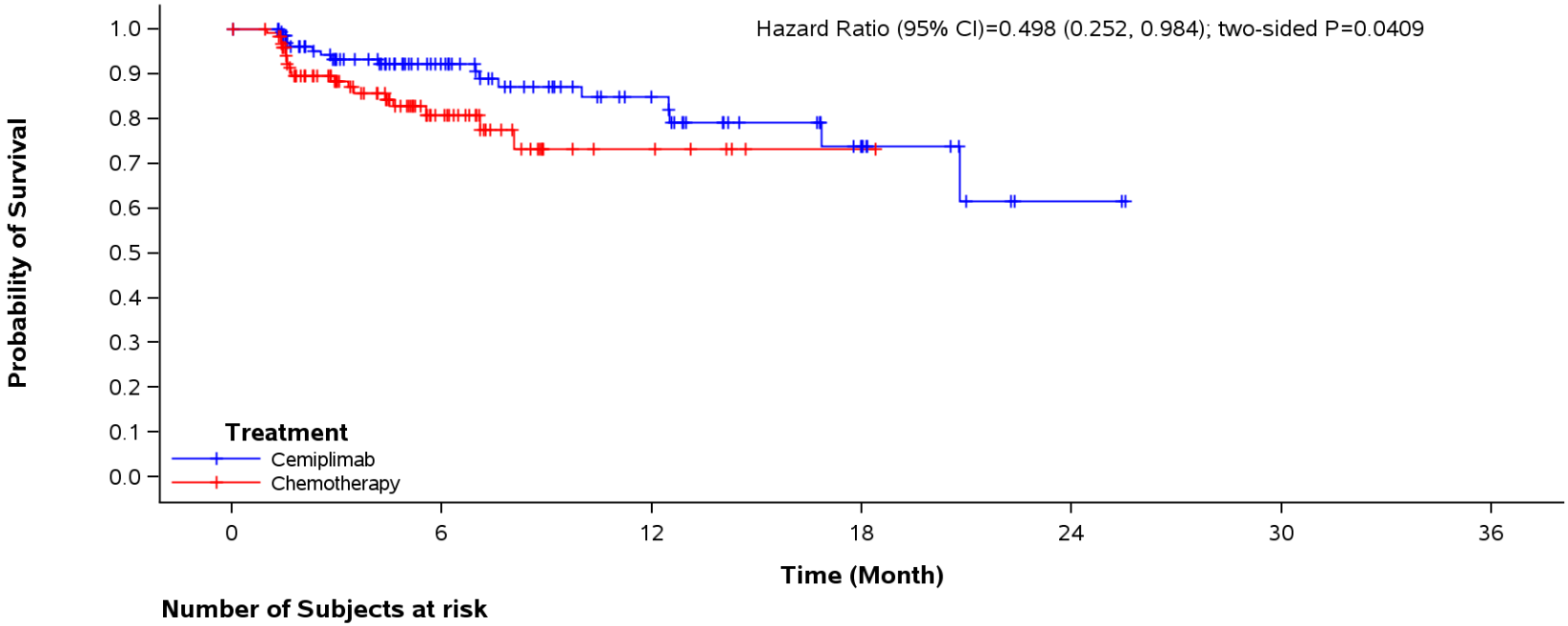

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 65 | 30 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 33 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Emotional Functioning - 10 pts sensitivity sustained deterioration



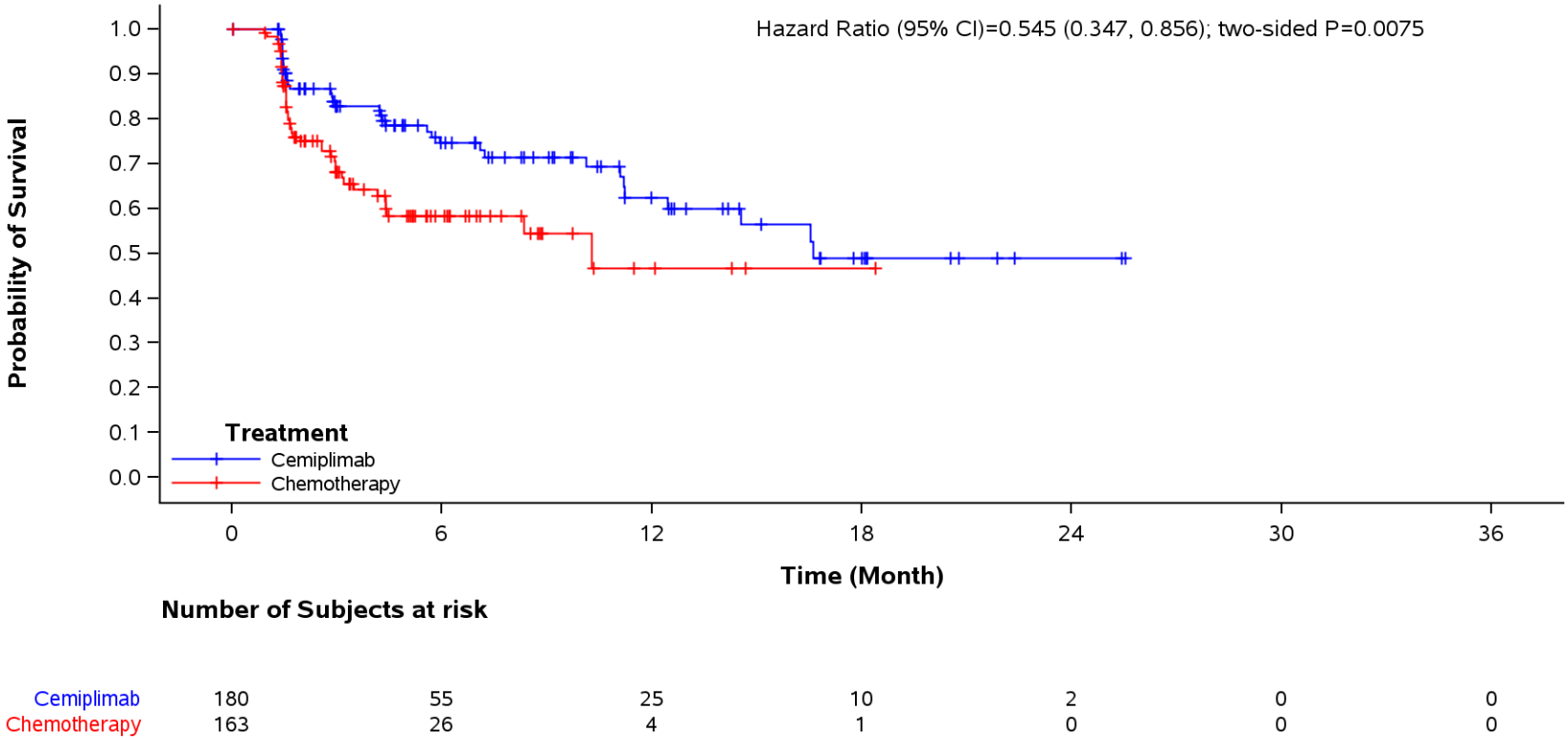

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 65 | 30 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 36 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Fatigue - 10 pts sensitivity sustained deterioration



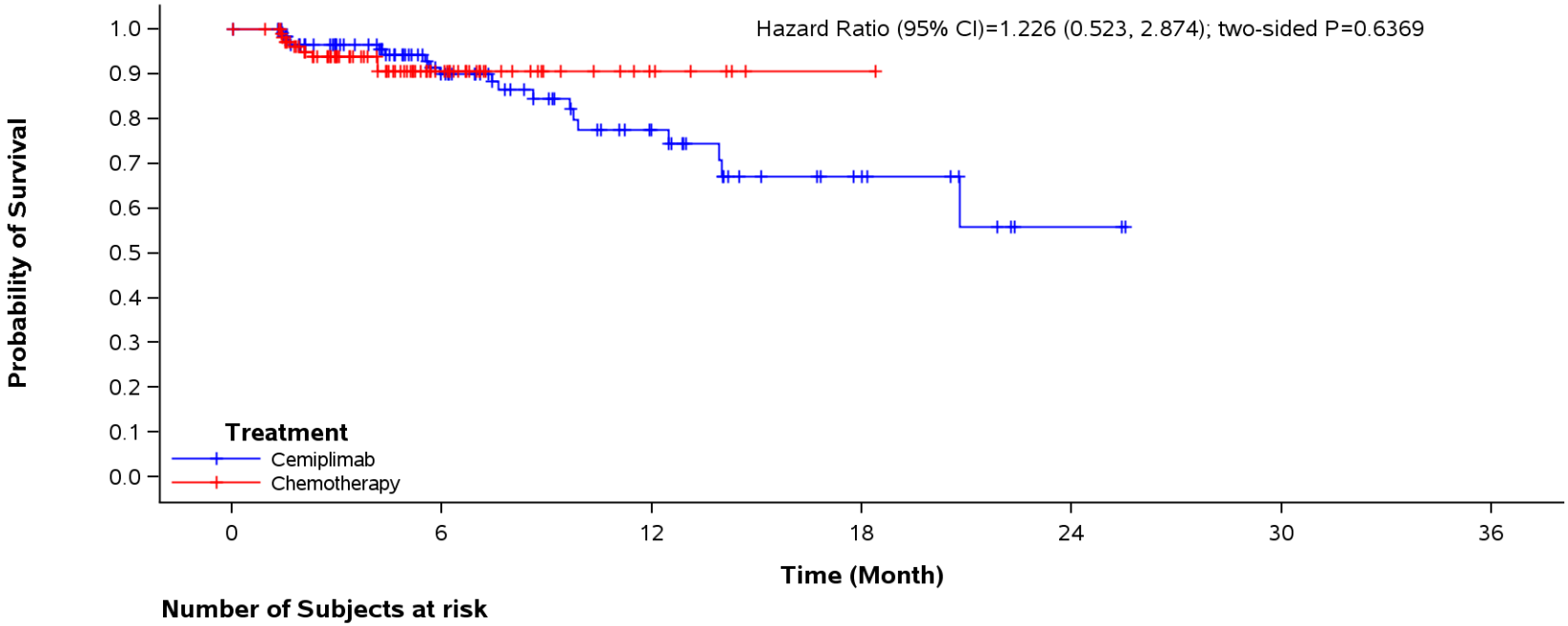

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 55 | 25 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Financial Problems - 10 pts sensitivity sustained deterioration



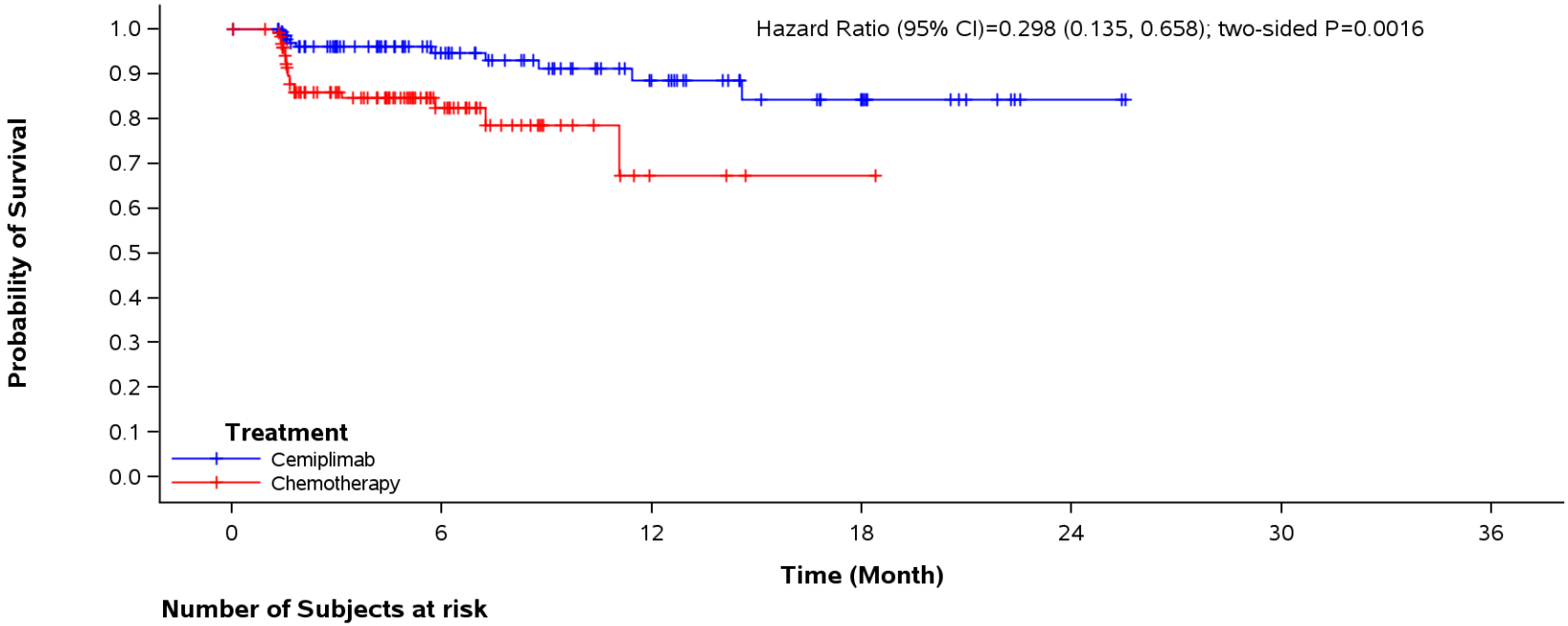

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 60 | 26 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



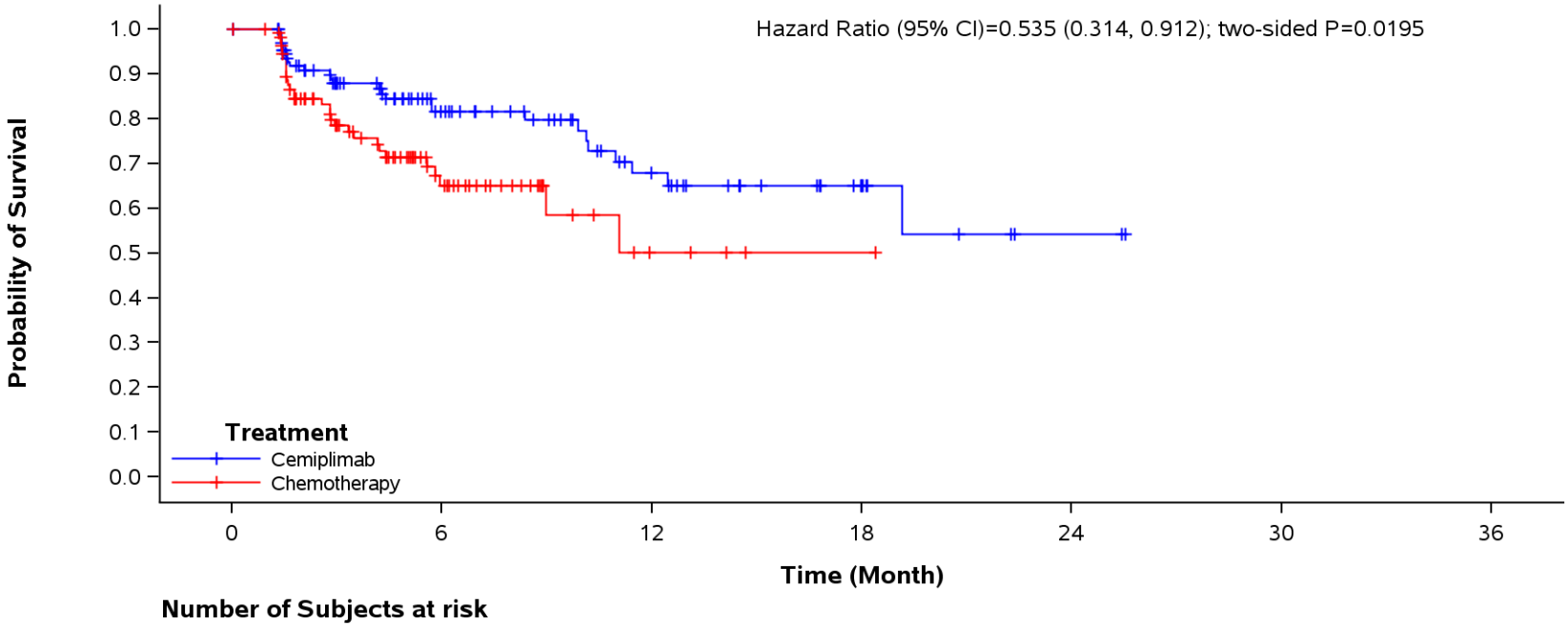

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 68 | 31 | 14 | 2 | 0 | 0 |
| Chemotherapy | 163 | 35 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Pain - 10 pts sensitivity sustained deterioration



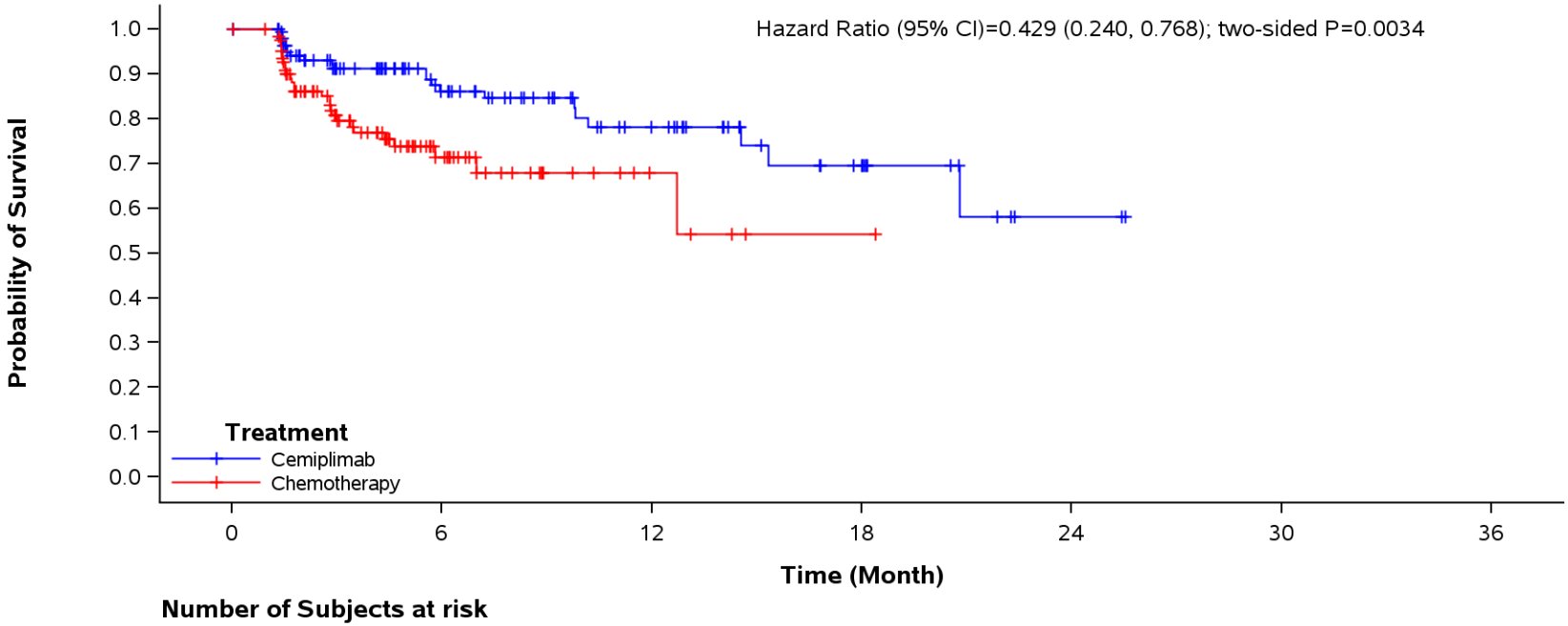

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 55 | 25 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 30 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

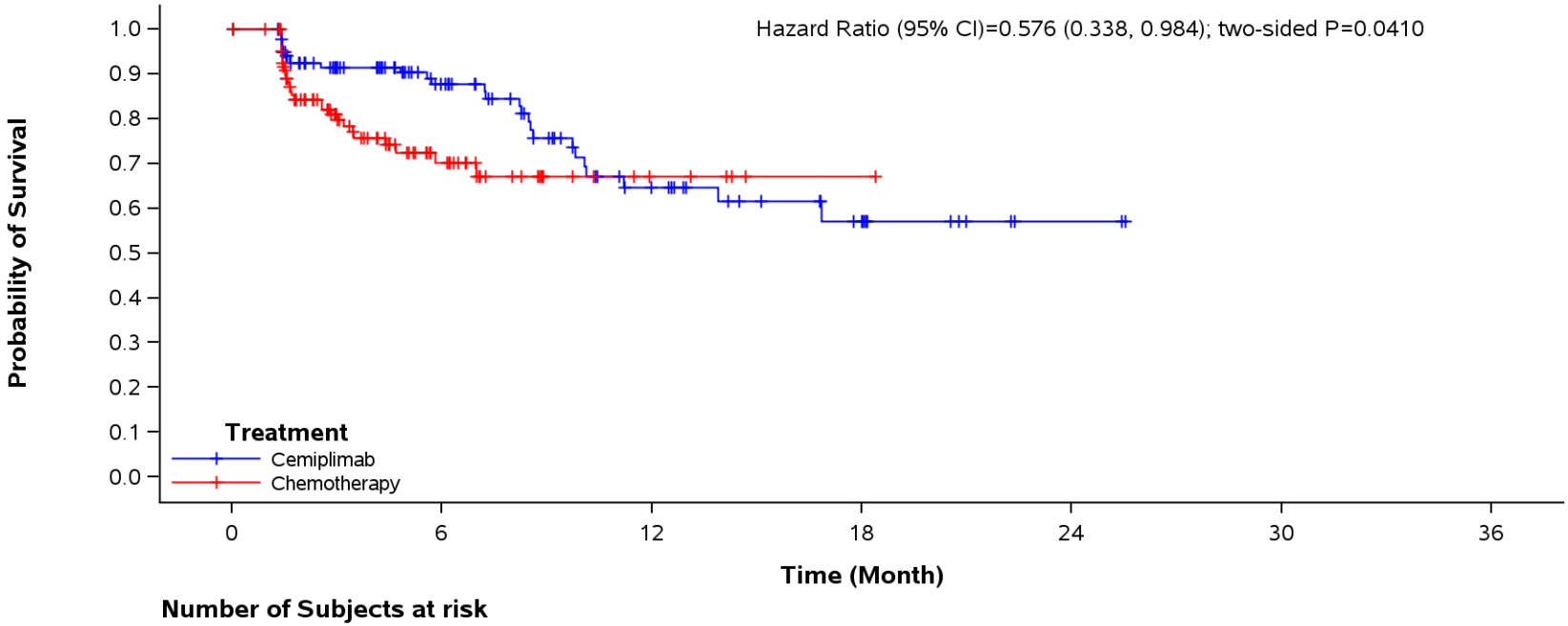
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 64 | 30 | 13 | 2 | 0 | 0 |
| Chemotherapy | 163 | 29 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65

Global health status / QoL - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

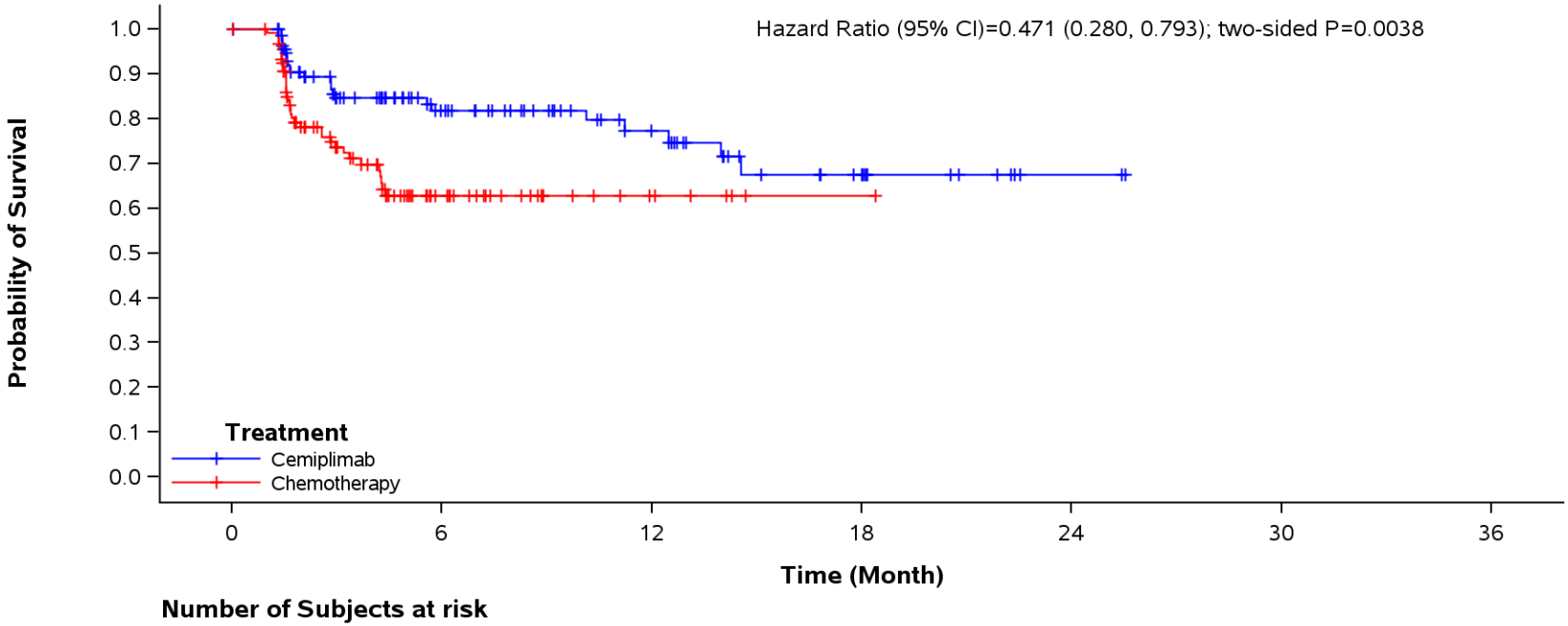
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 64 | 25 | 12 | 2 | 0 | 0 |
| Chemotherapy | 163 | 31 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Role Functioning - 10 pts sensitivity sustained deterioration



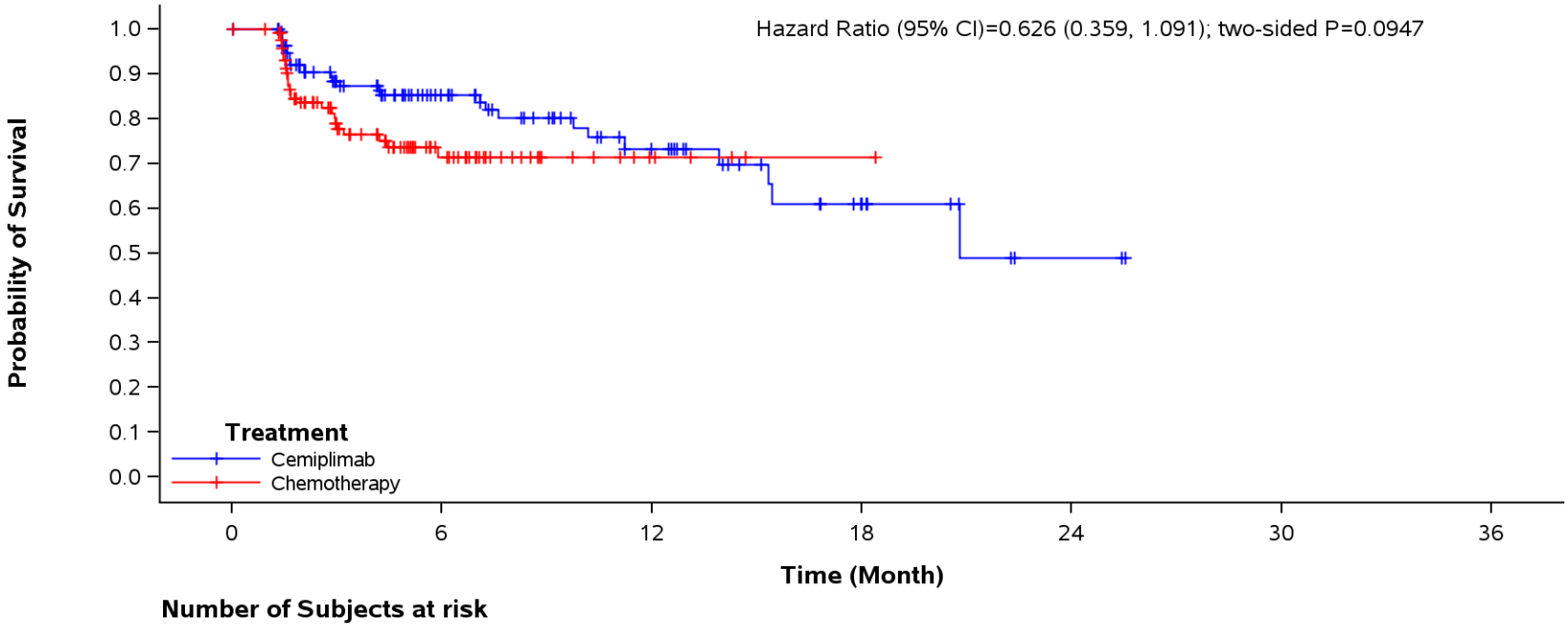

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 58 | 30 | 13 | 2 | 0 | 0 |
| Chemotherapy | 163 | 26 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Social Functioning - 10 pts sensitivity sustained deterioration



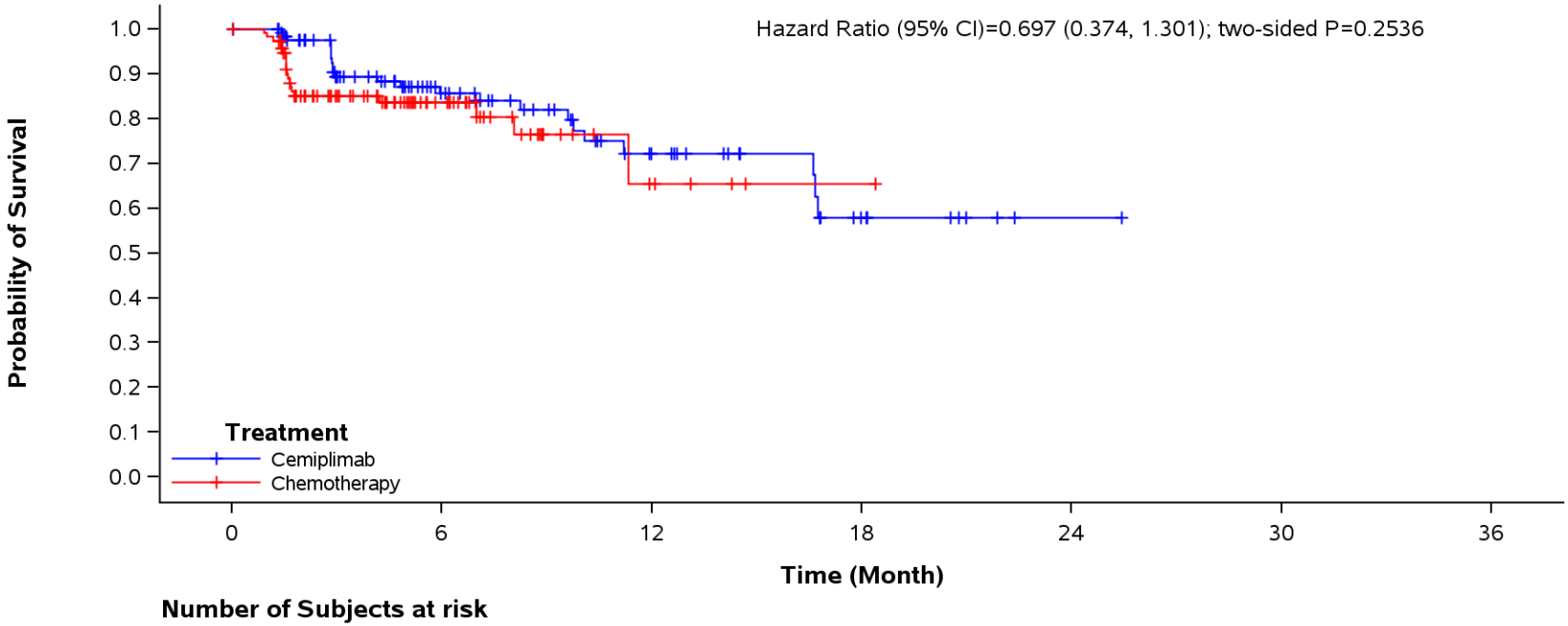

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 60 | 27 | 10 | 2 | 0 | 0 |
| Chemotherapy | 163 | 32 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

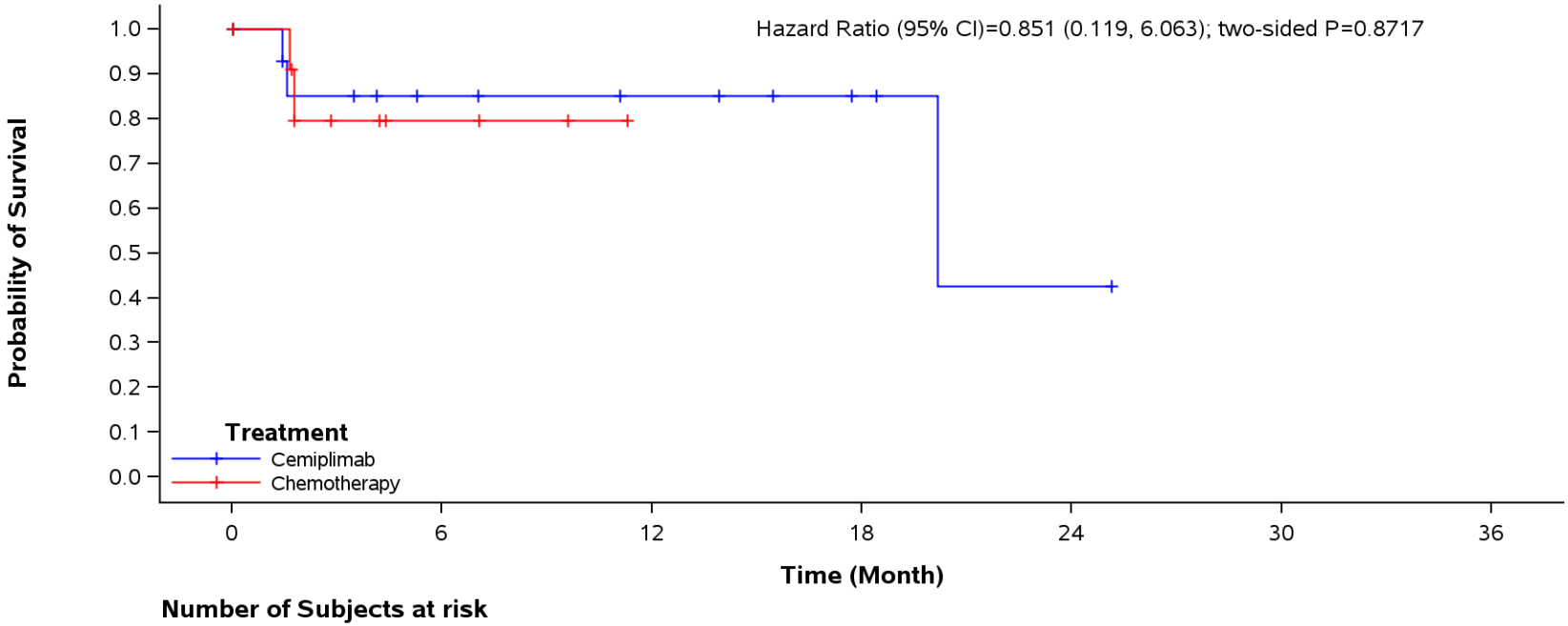
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 57 | 23 | 8 | 1 | 0 | 0 |
| Chemotherapy | 163 | 36 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

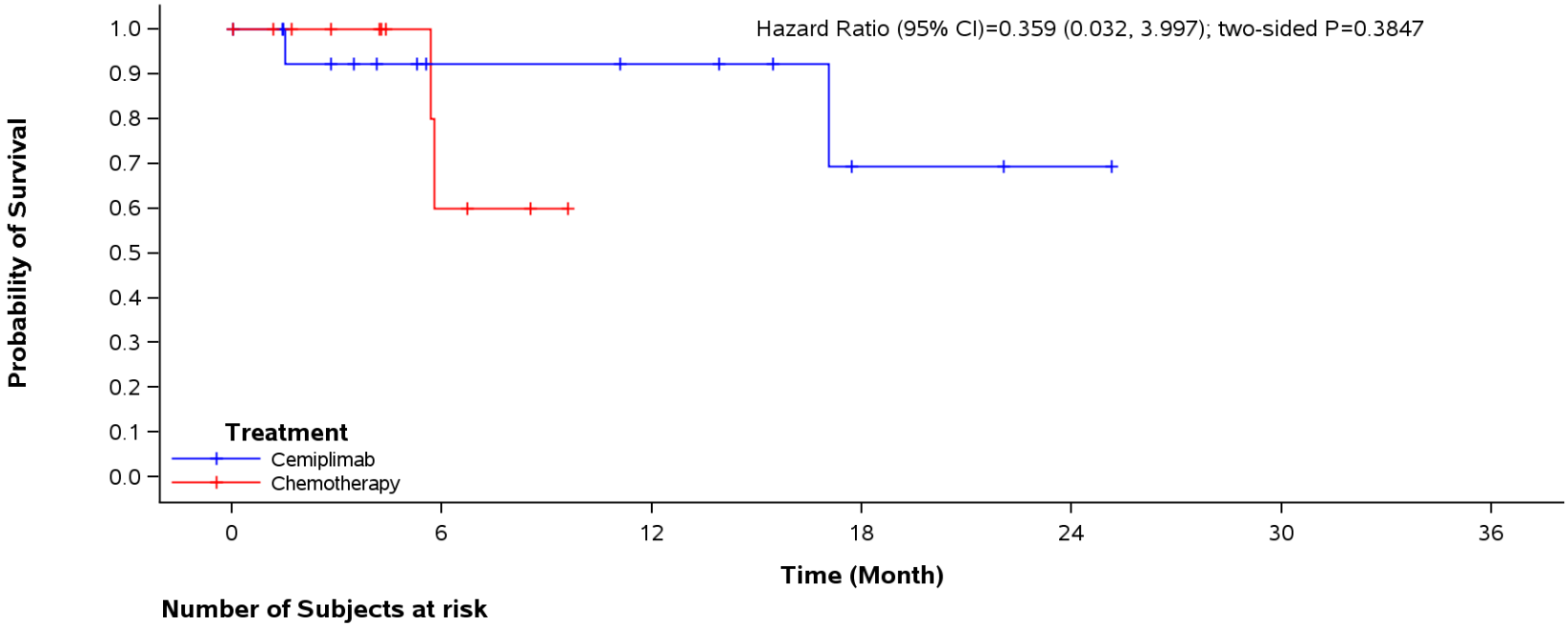
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Cognitive Functioning - 10 pts sensitivity sustained deterioration



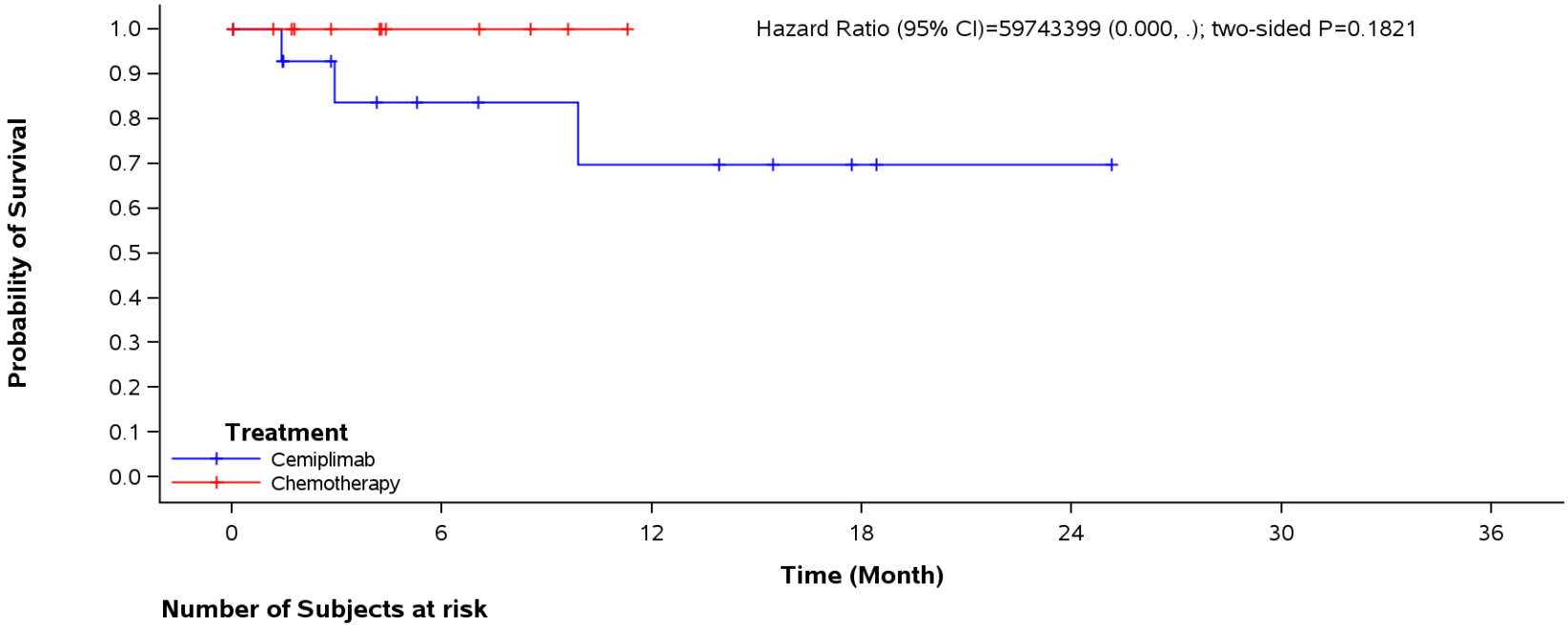

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 6 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Constipation - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

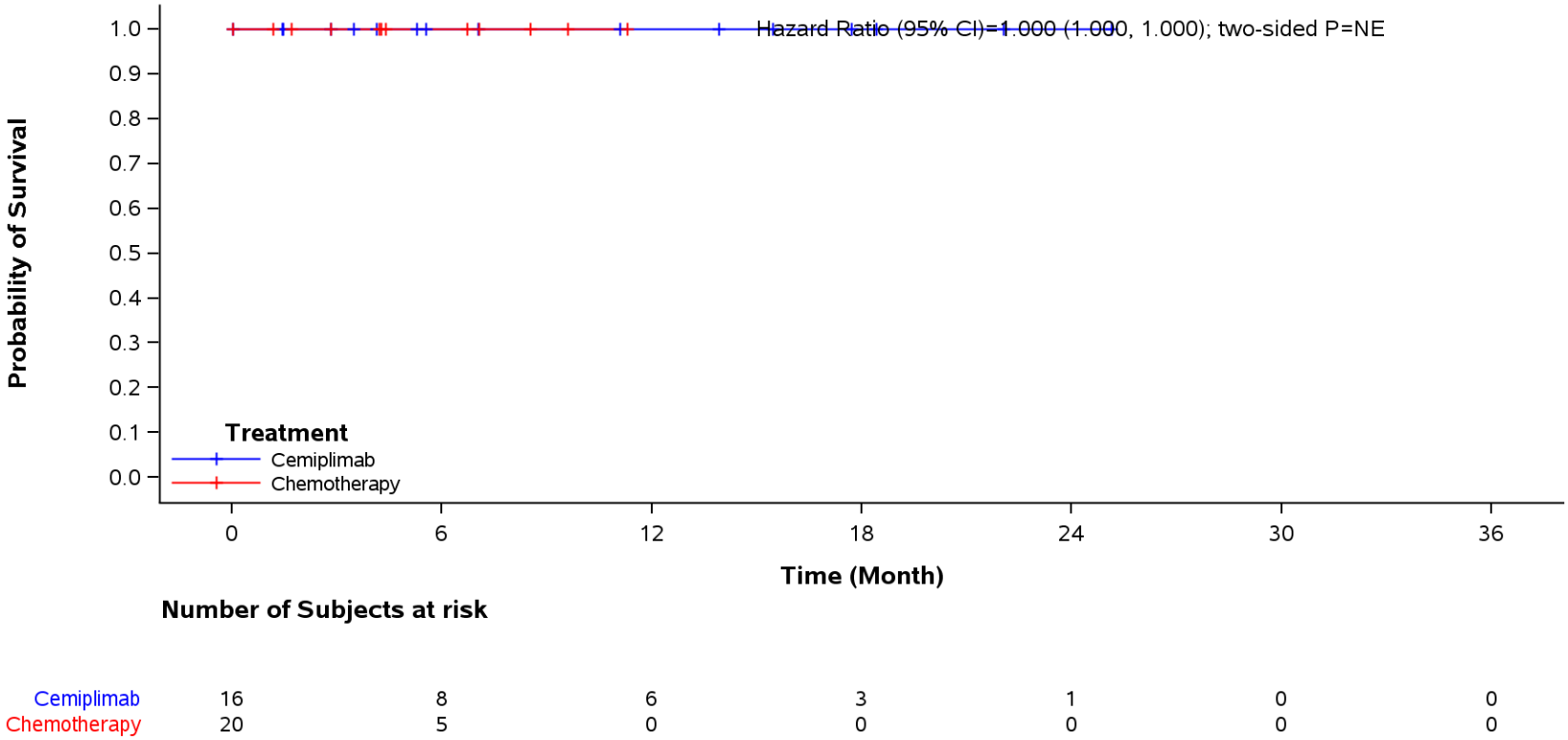
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Diarhoea - 10 pts sensitivity sustained deterioration

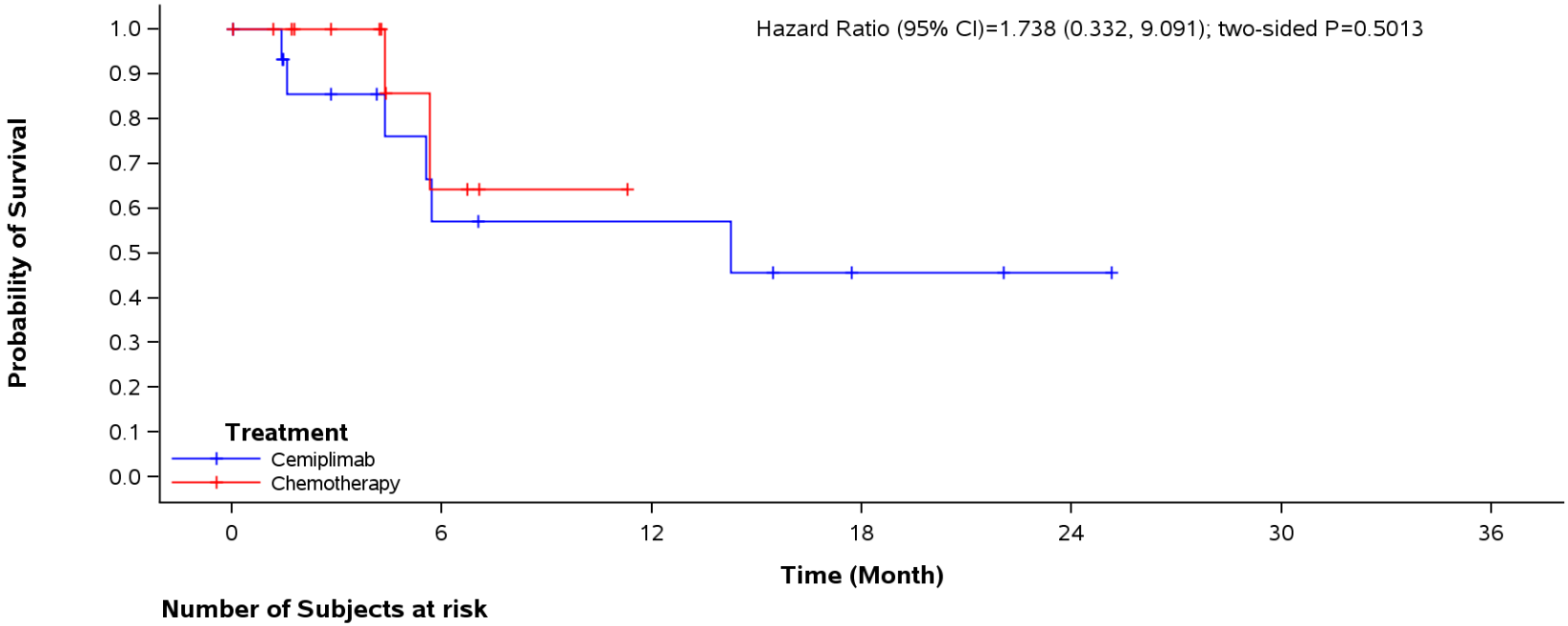



Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Dyspnoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

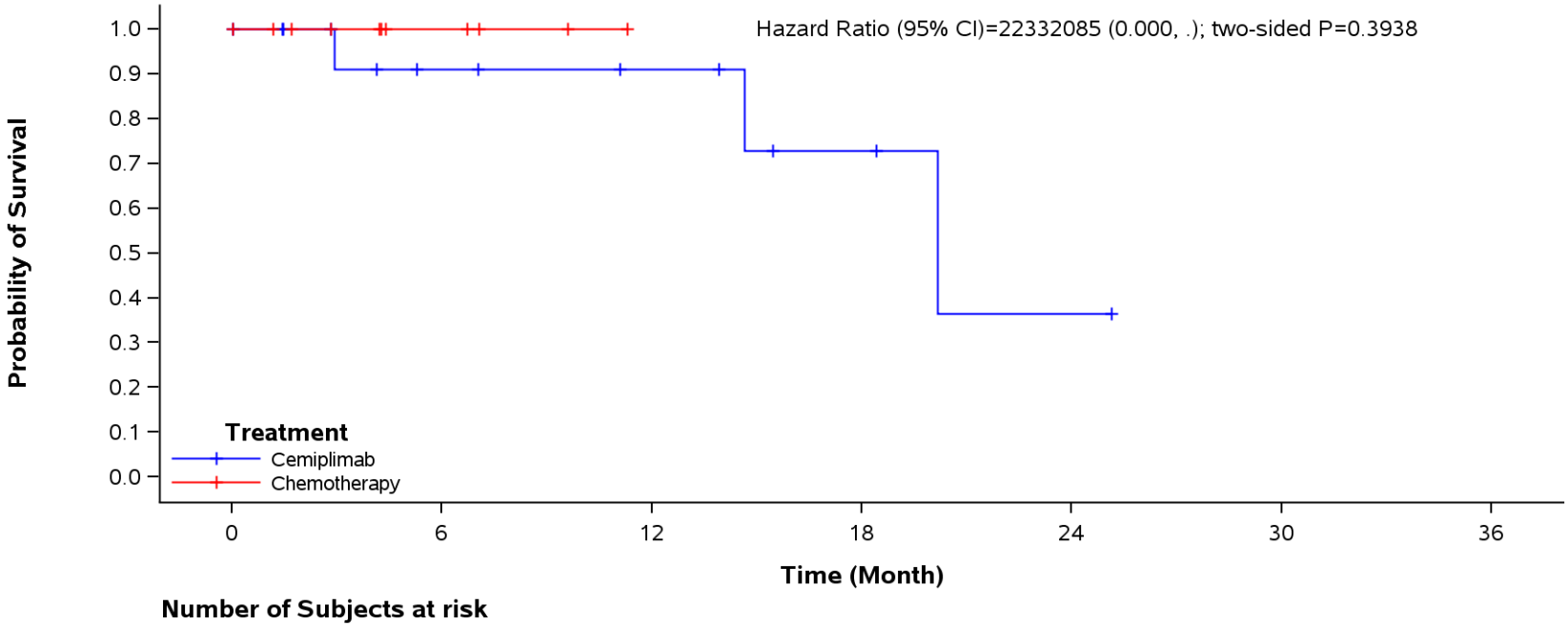
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Emotional Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

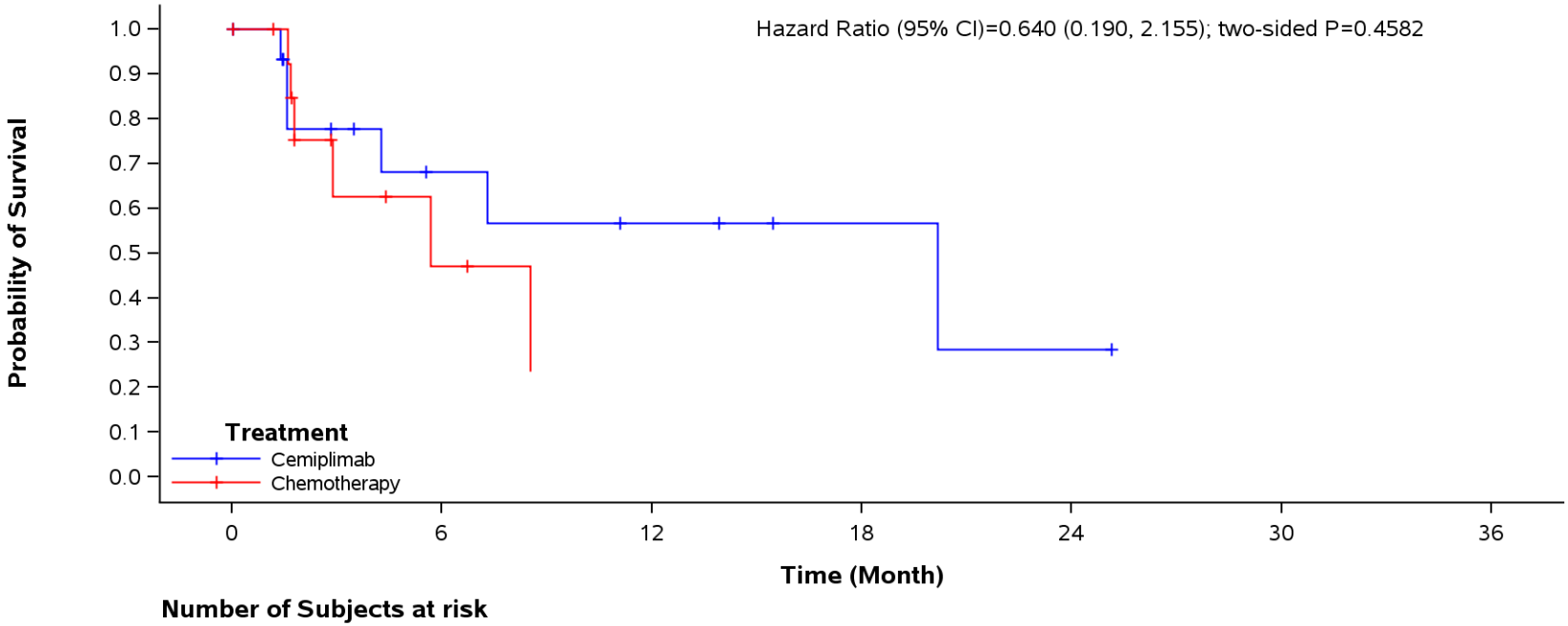
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Fatigue - 10 pts sensitivity sustained deterioration



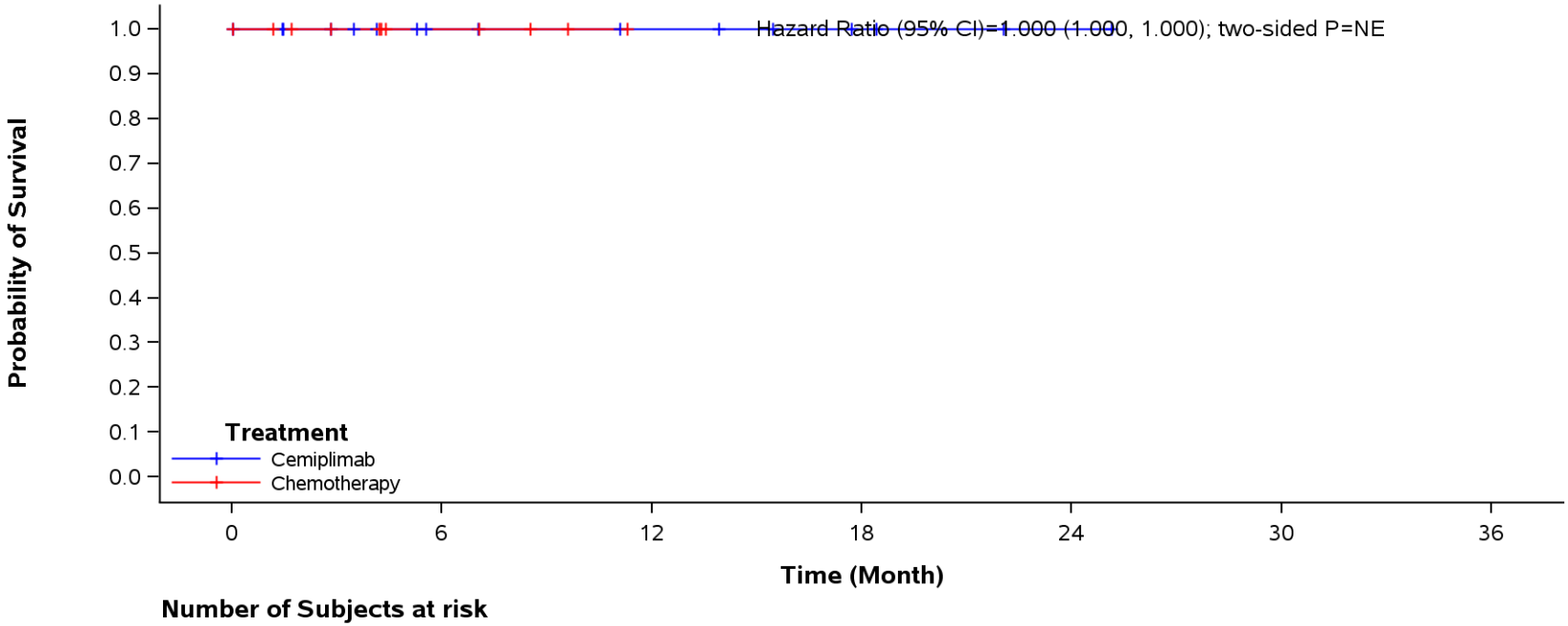

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

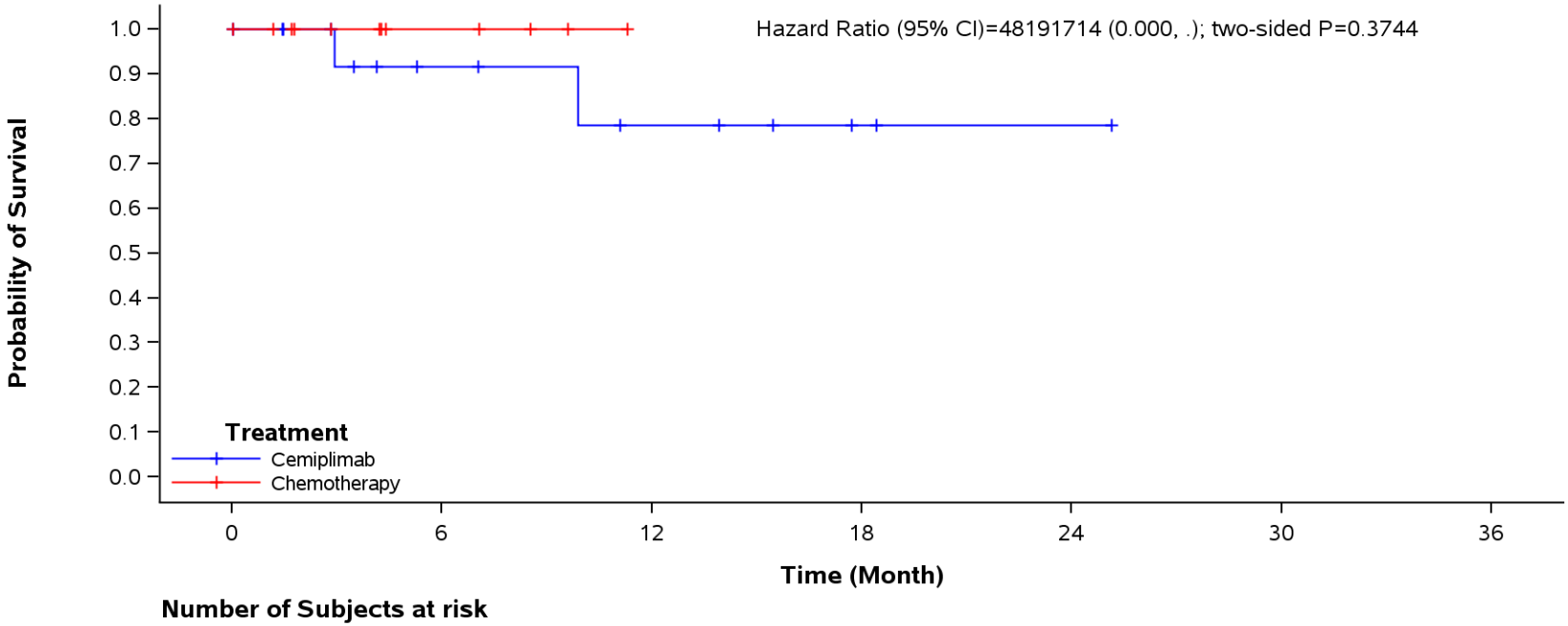
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

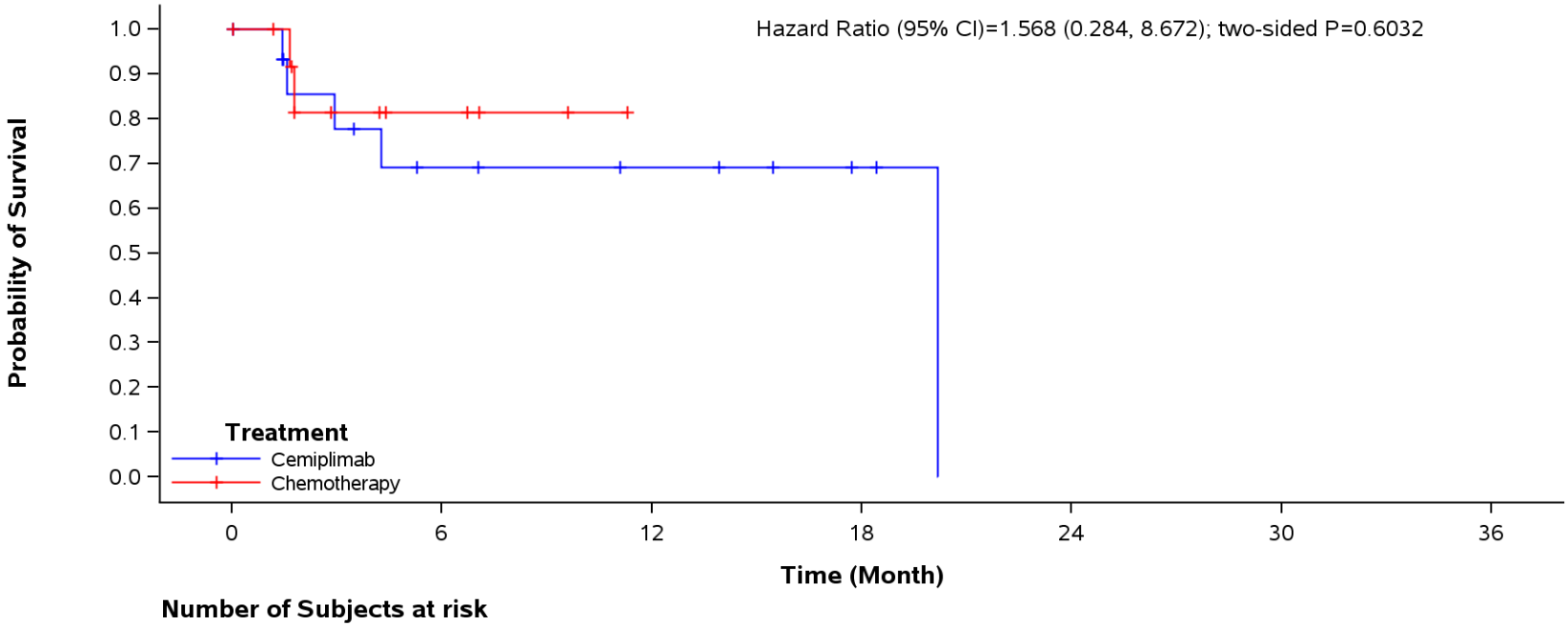
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

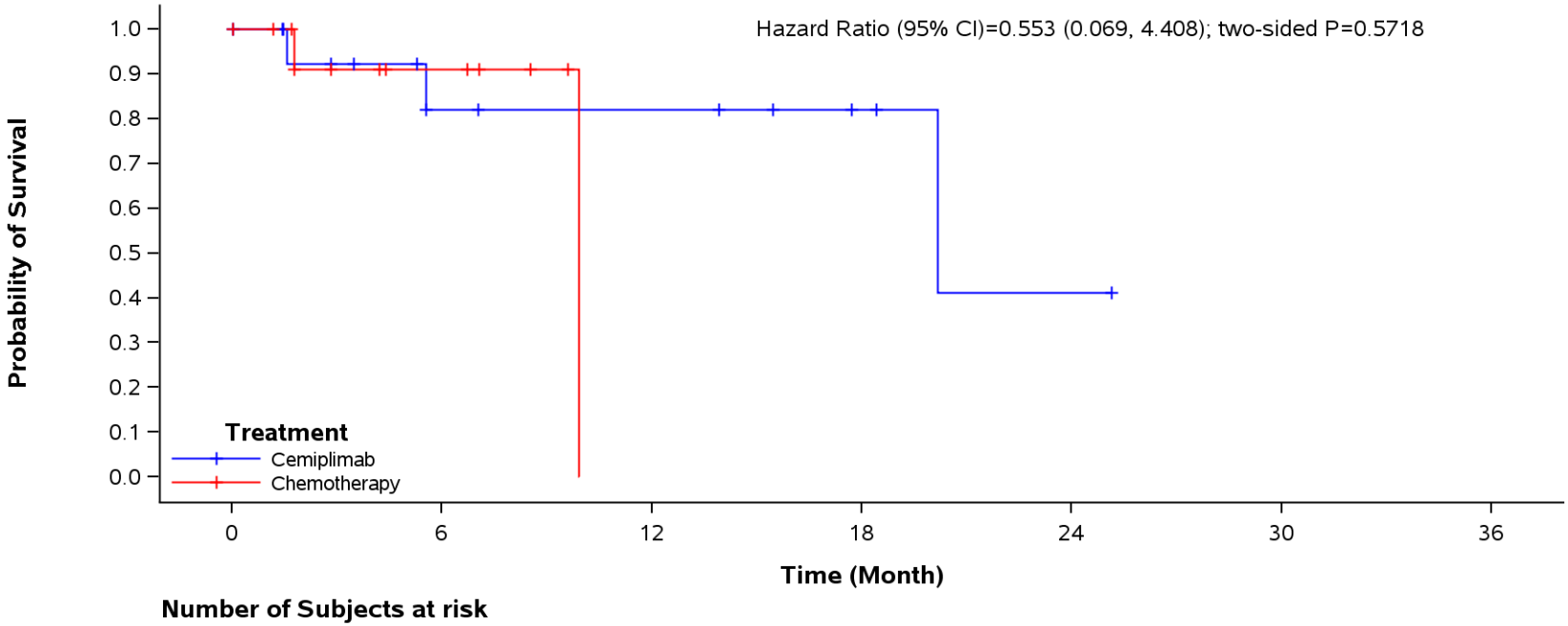
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 5 | 0 | 0 | 0 | 0 | 0 |

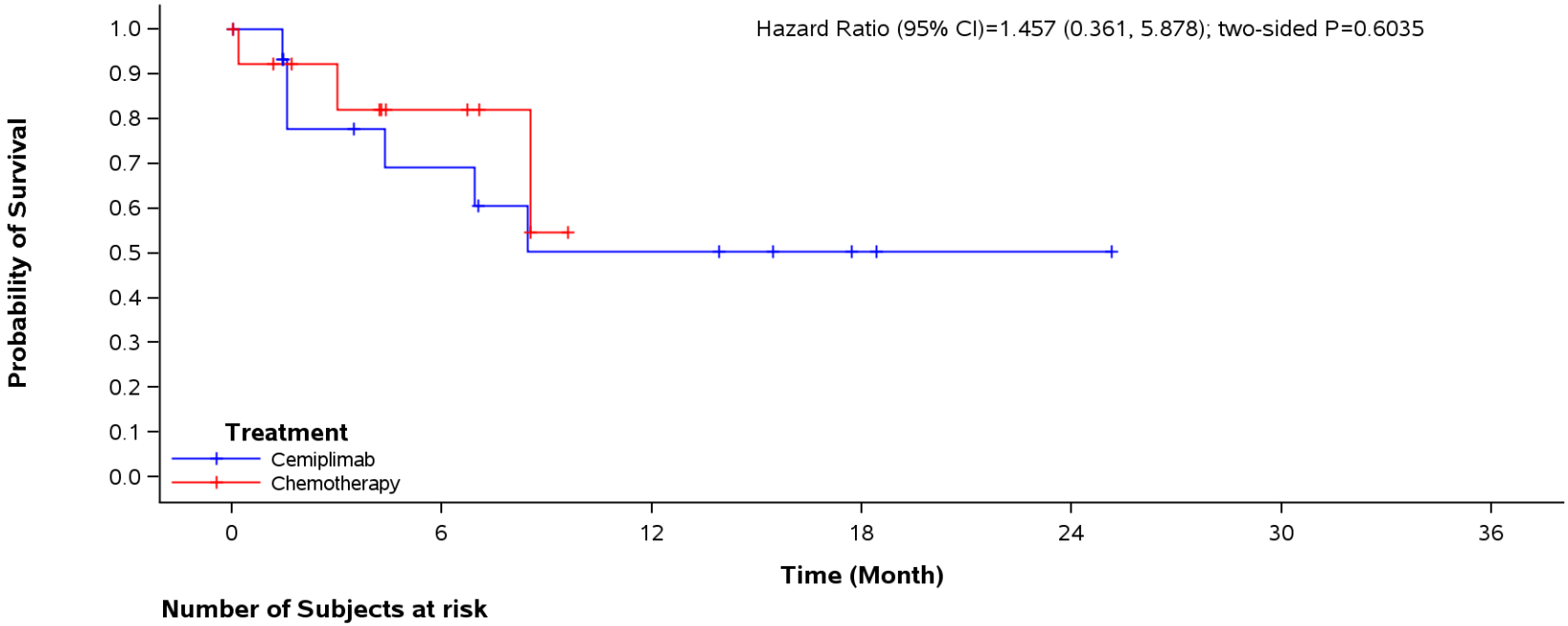
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

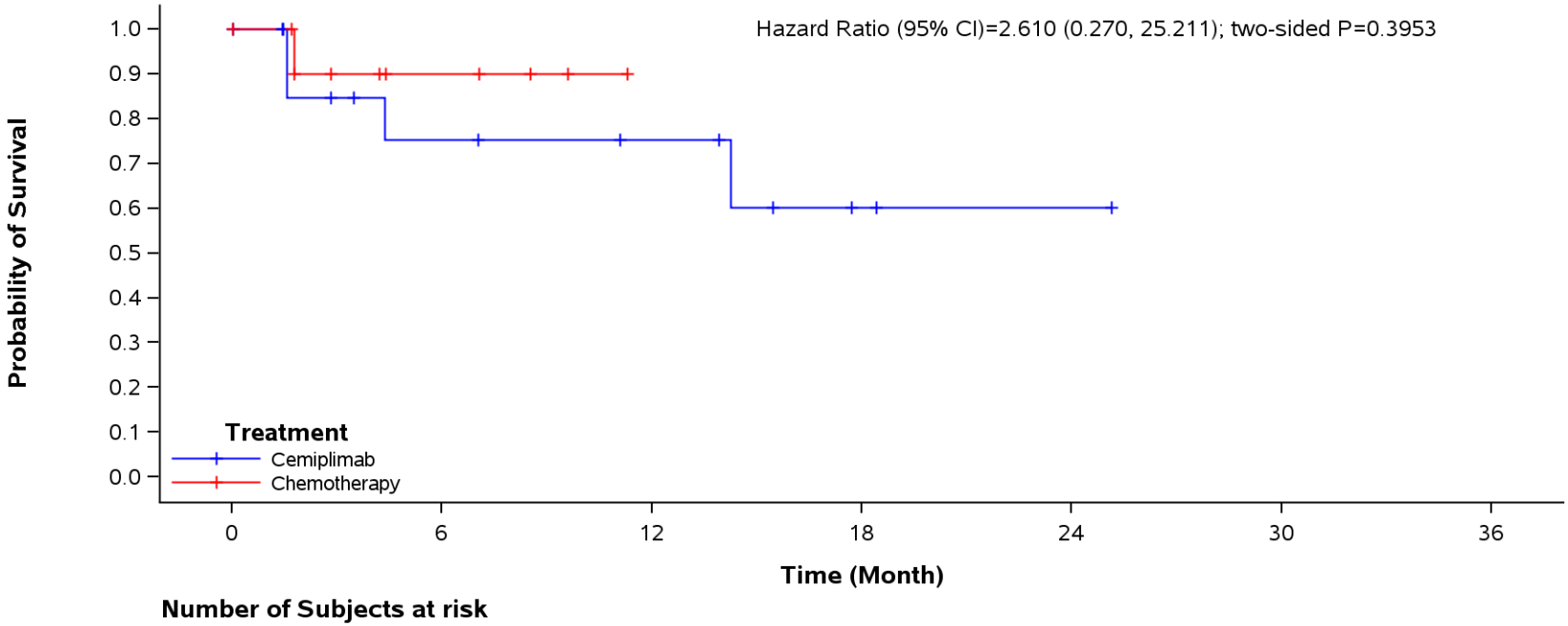
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Role Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

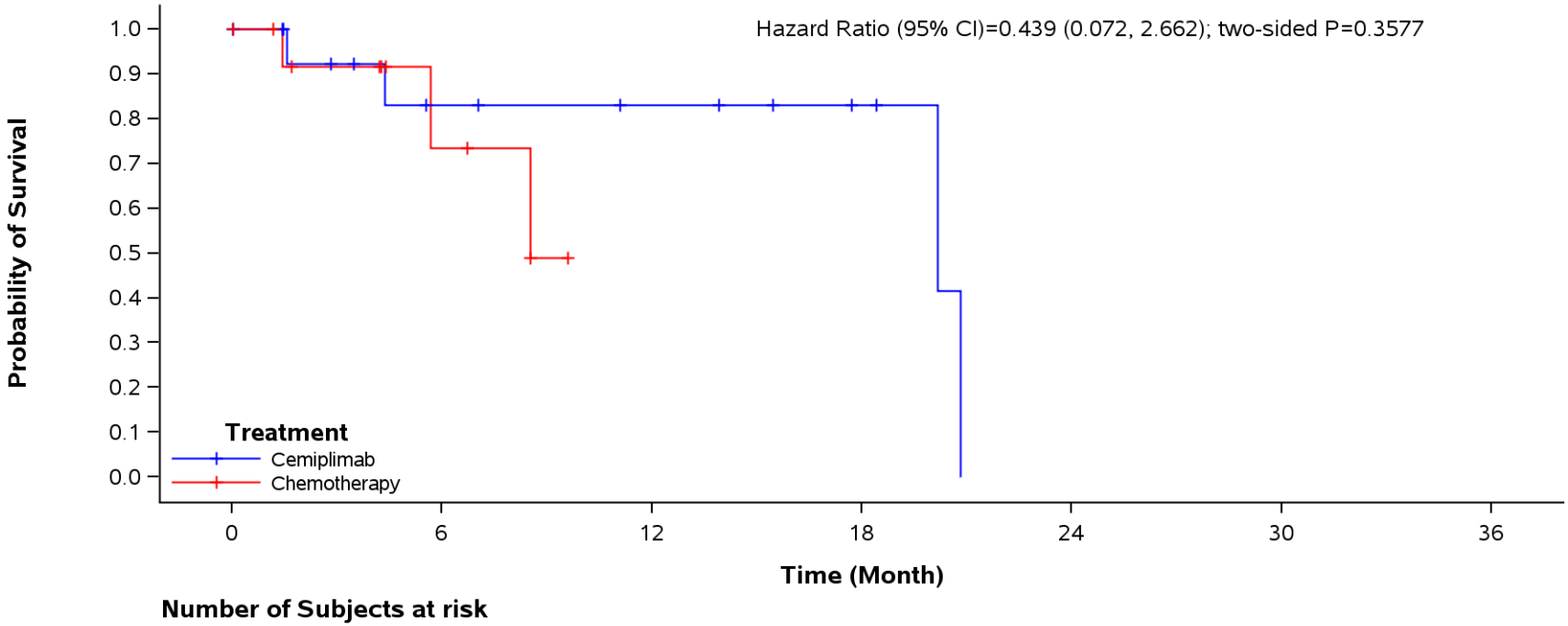
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 2 | 1 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Social Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

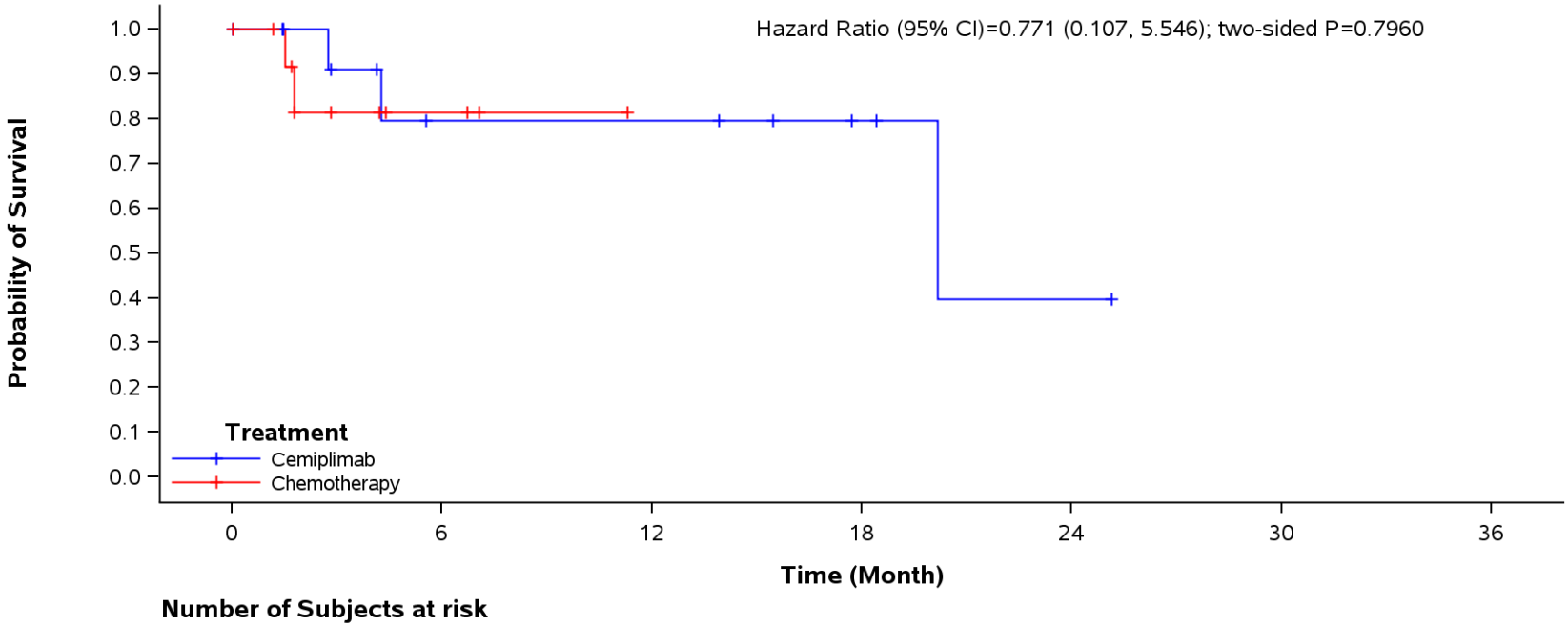
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 20 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

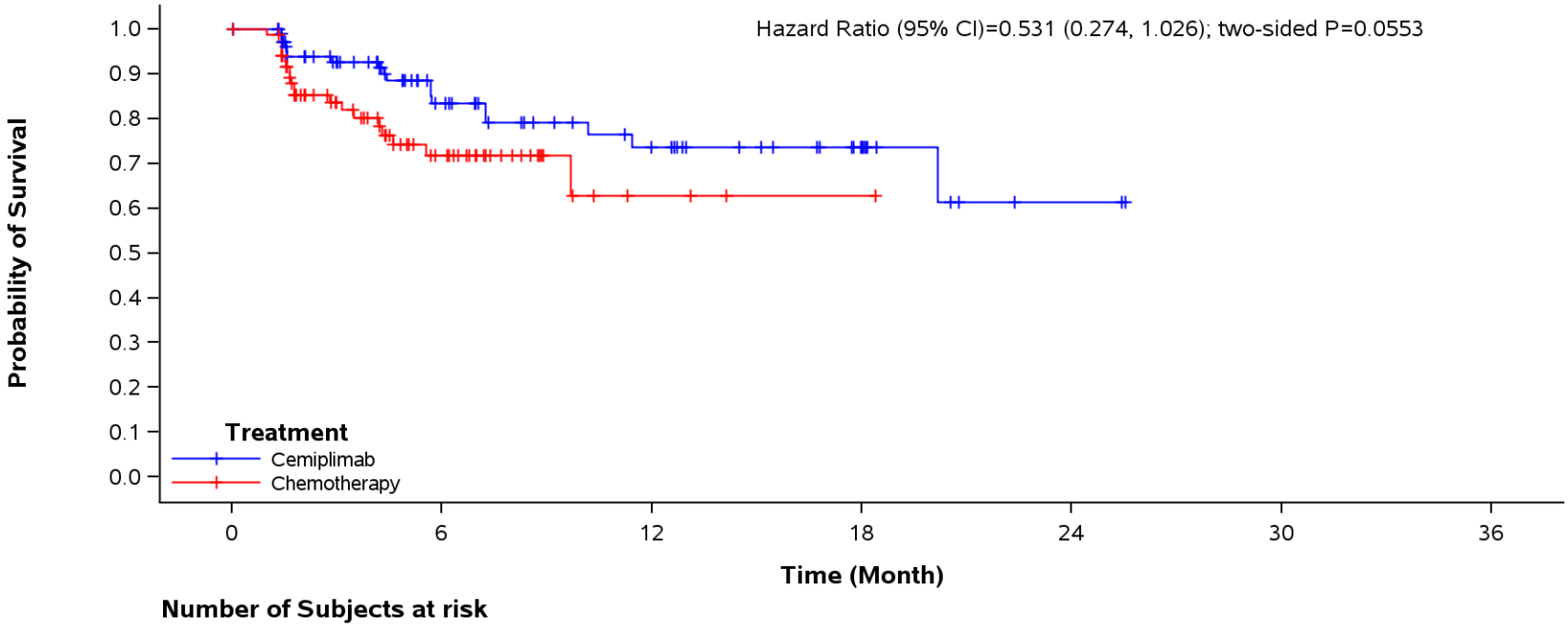
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 20 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Appetite loss - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 48 | 25 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 27 | 3 | 1 | 0 | 0 | 0 |

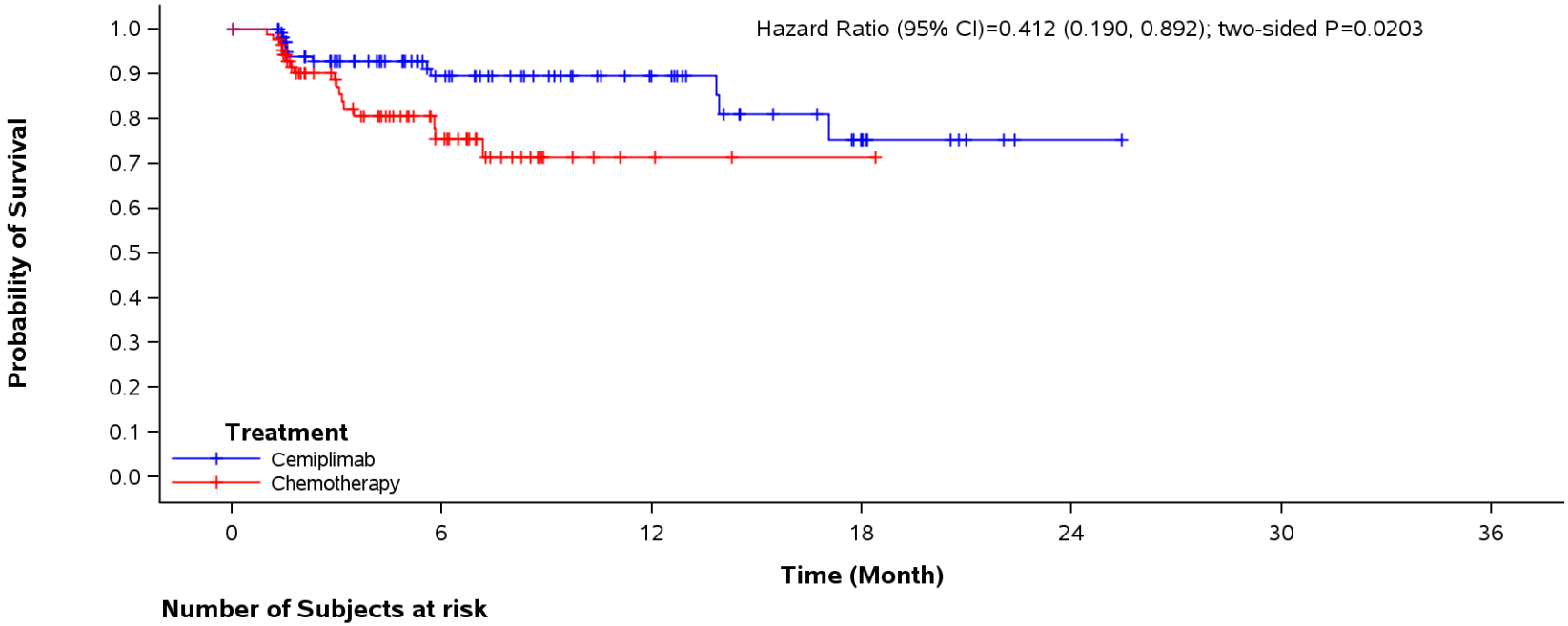
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 54 | 26 | 10 | 1 | 0 | 0 |
| Chemotherapy | 123 | 28 | 3 | 1 | 0 | 0 | 0 |

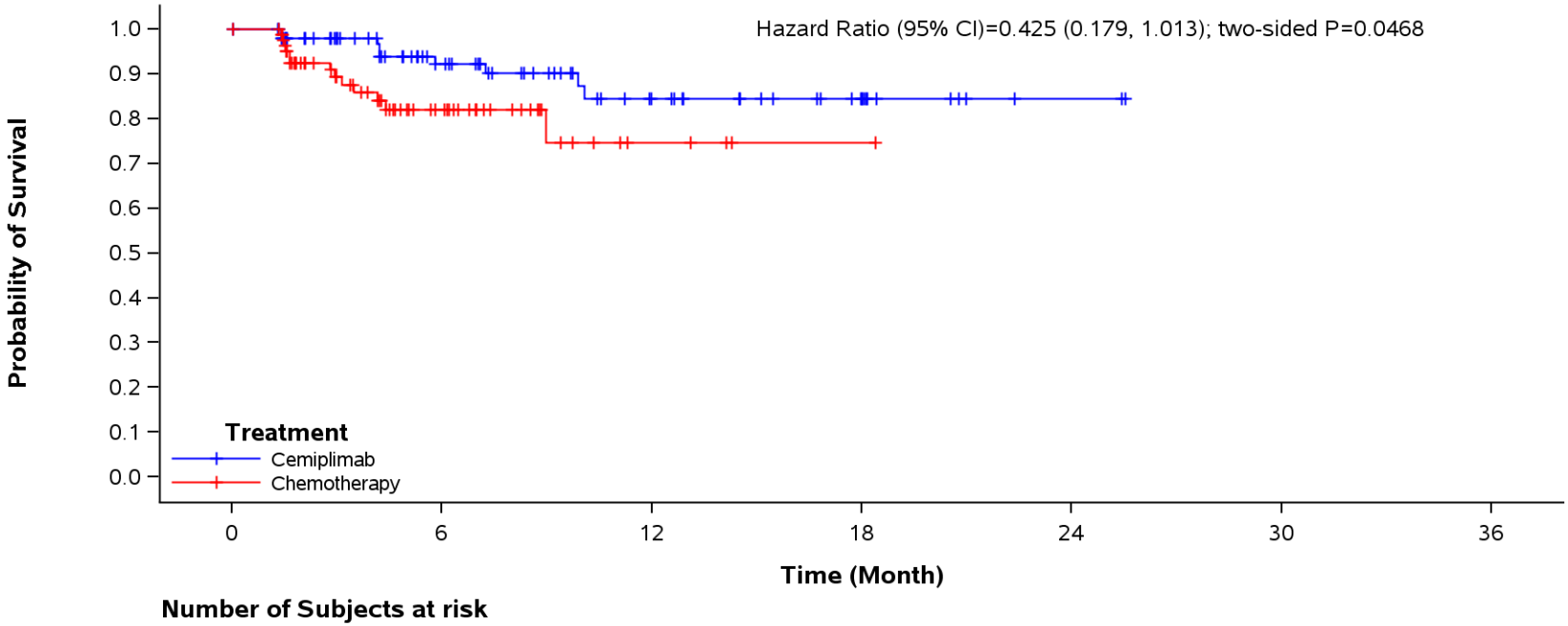
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Constipation - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

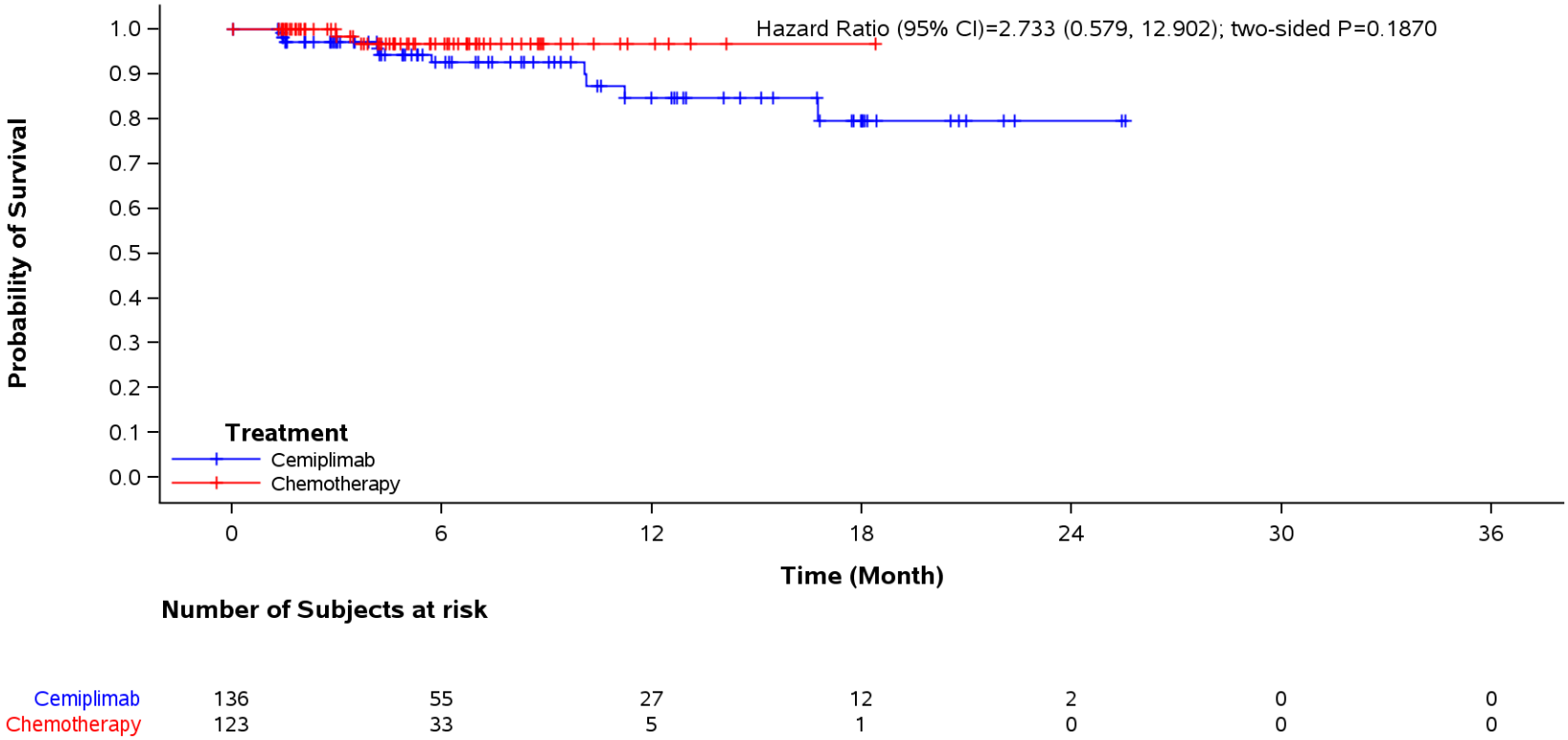
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 53 | 24 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 28 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Diarhoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

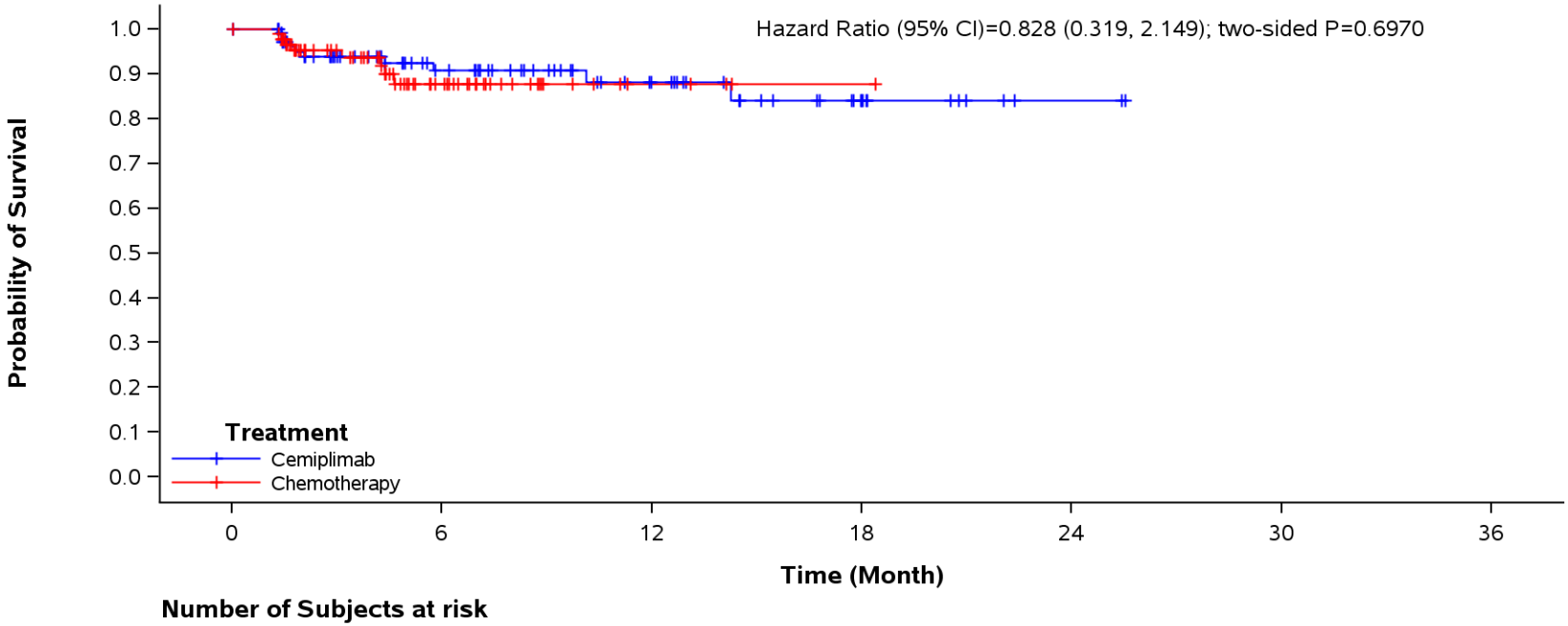
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 55 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 33 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Dyspnoea - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 55 | 27 | 11 | 2 | 0 | 0 |
| Chemotherapy | 123 | 28 | 4 | 1 | 0 | 0 | 0 |

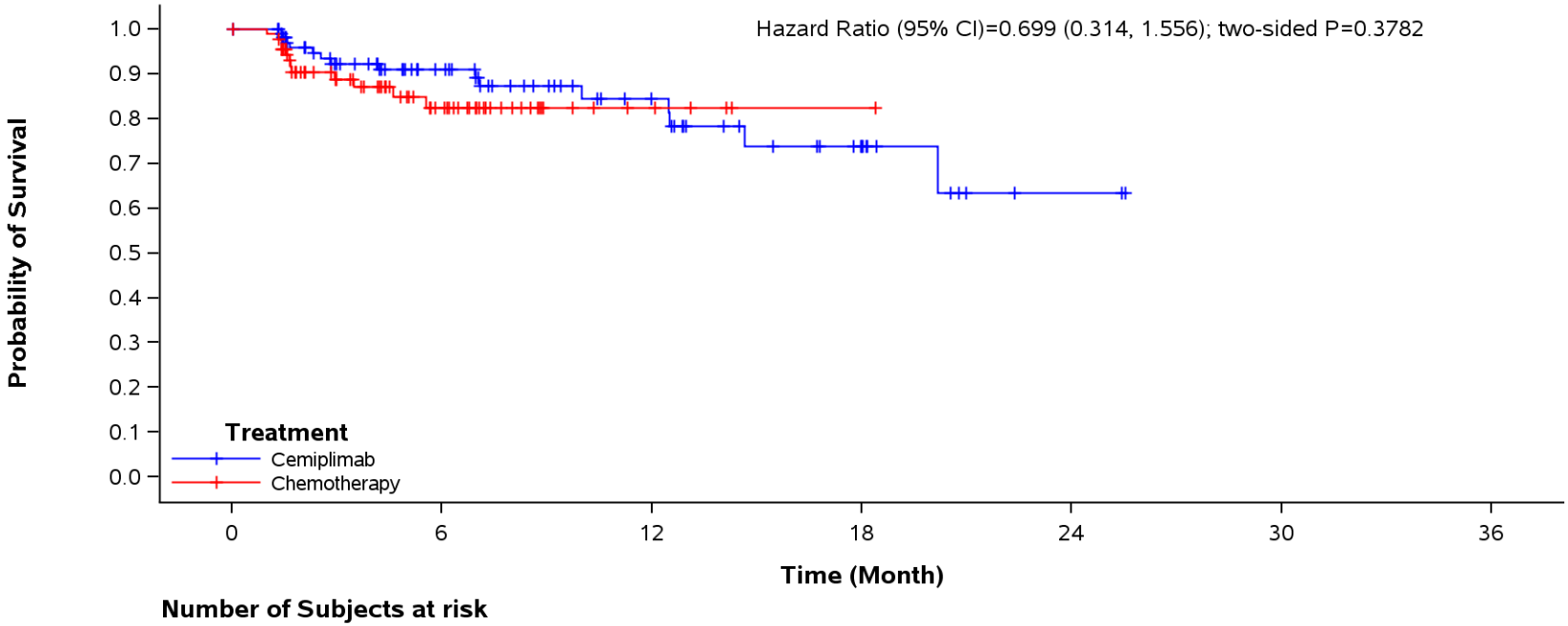
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Emotional Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

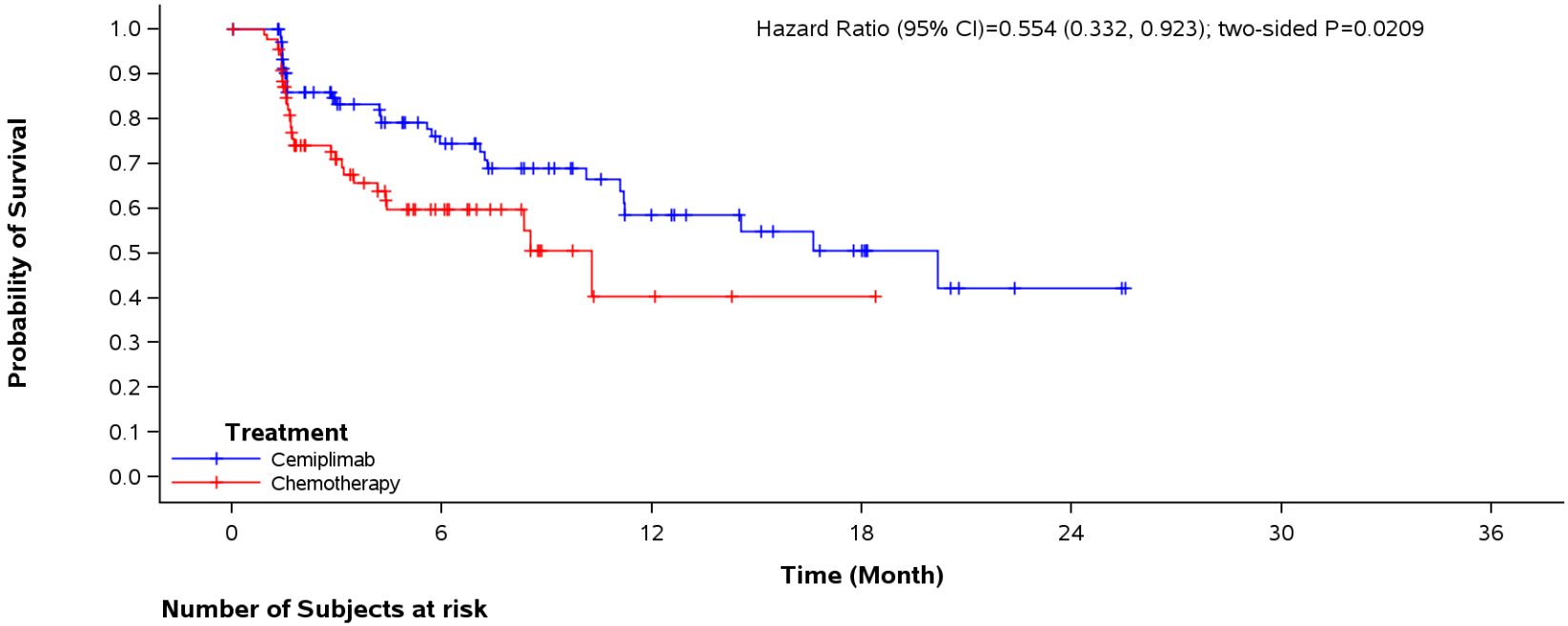
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 55 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 30 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Fatigue - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

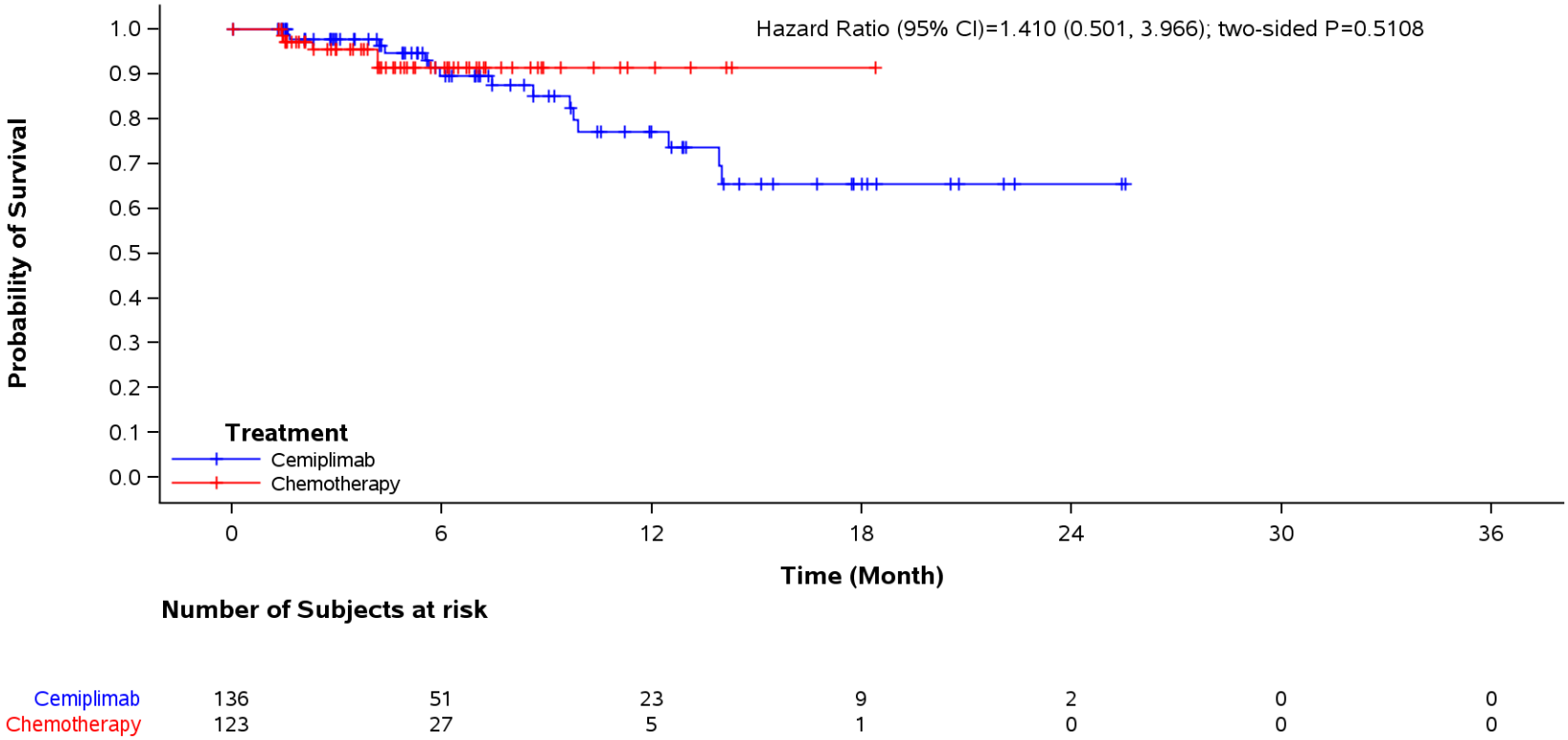
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 46 | 20 | 10 | 2 | 0 | 0 |
| Chemotherapy | 123 | 22 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 51 | 23 | 9 | 2 | 0 | 0 |
| Chemotherapy | 123 | 27 | 5 | 1 | 0 | 0 | 0 |

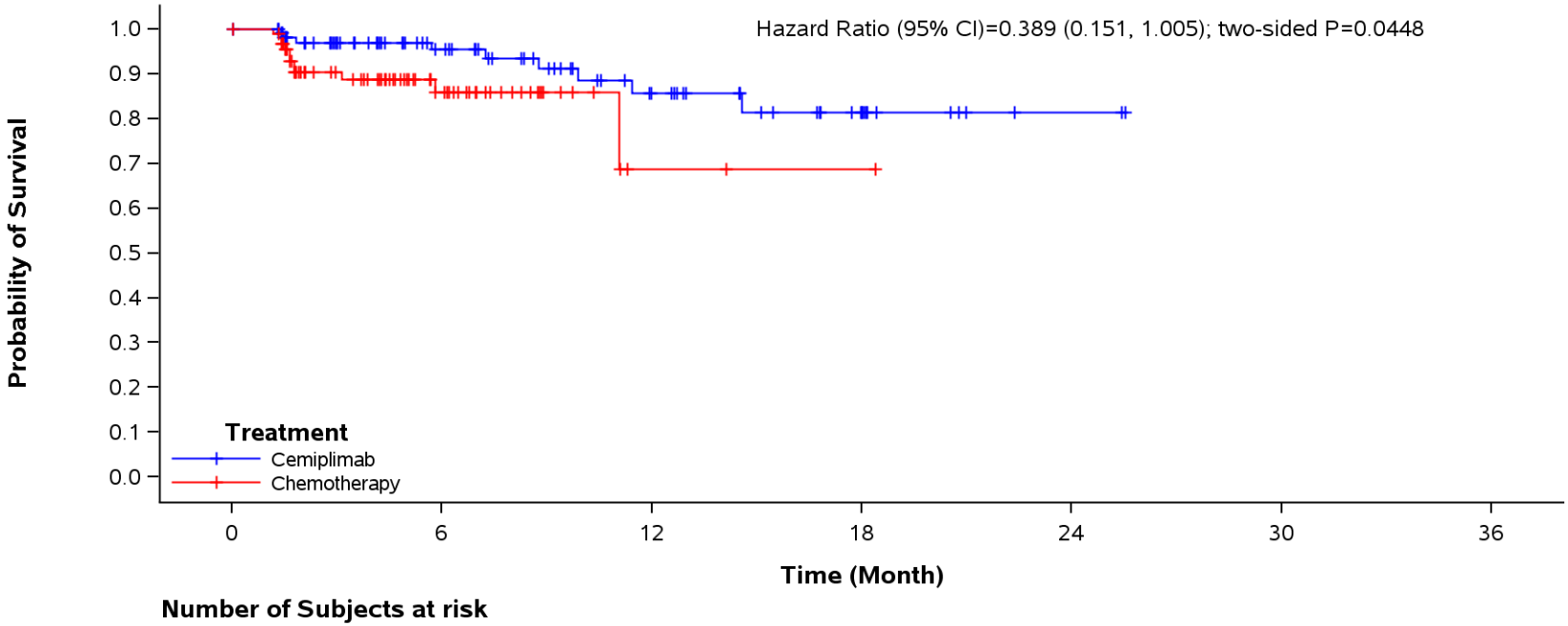
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

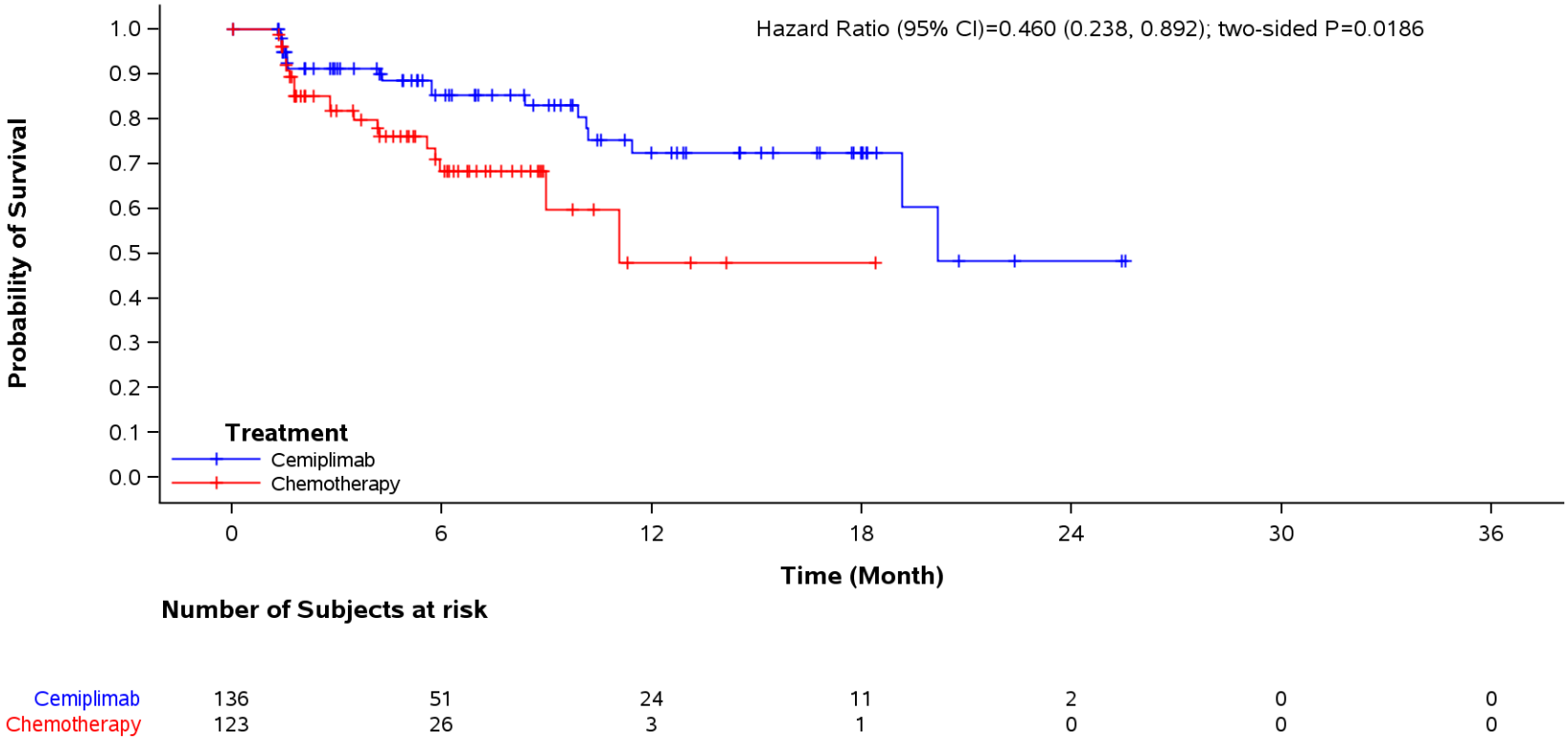
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 58 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 29 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Pain - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

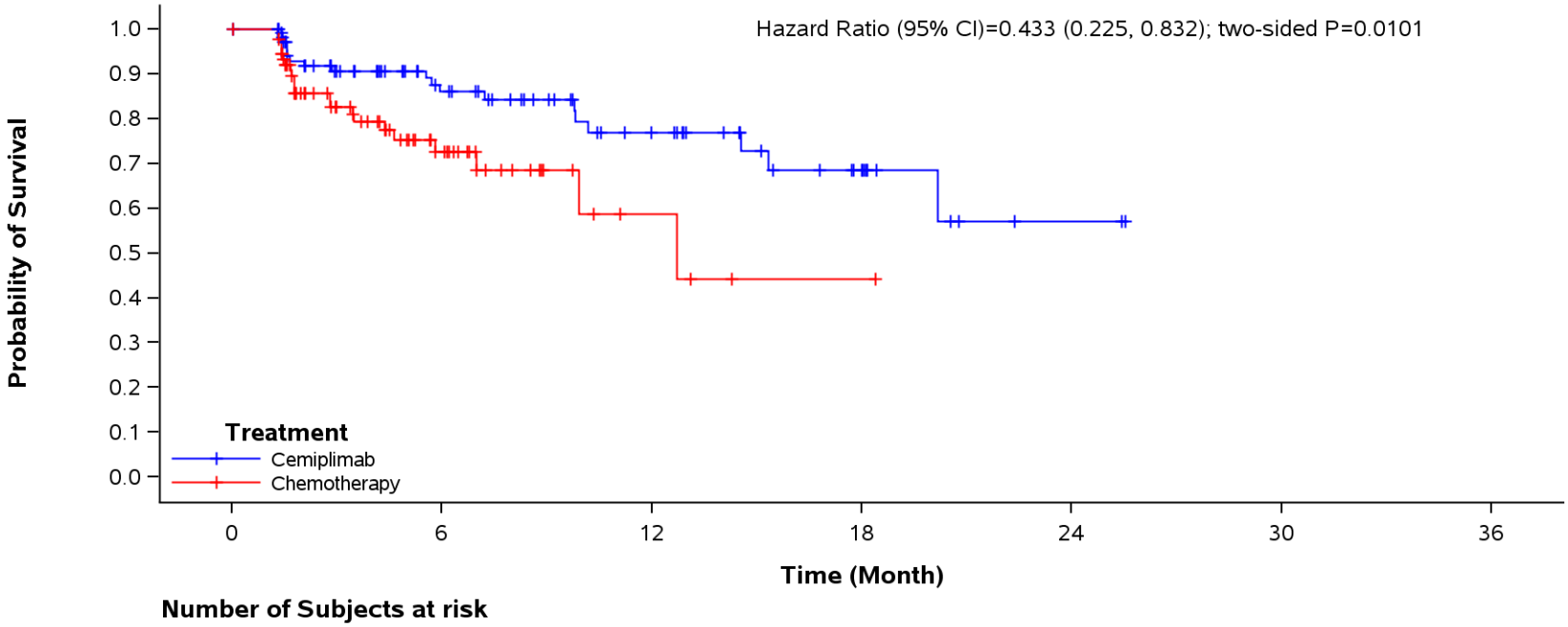
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 51 | 24 | 11 | 2 | 0 | 0 |
| Chemotherapy | 123 | 26 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Physical Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 55 | 27 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 26 | 4 | 1 | 0 | 0 | 0 |

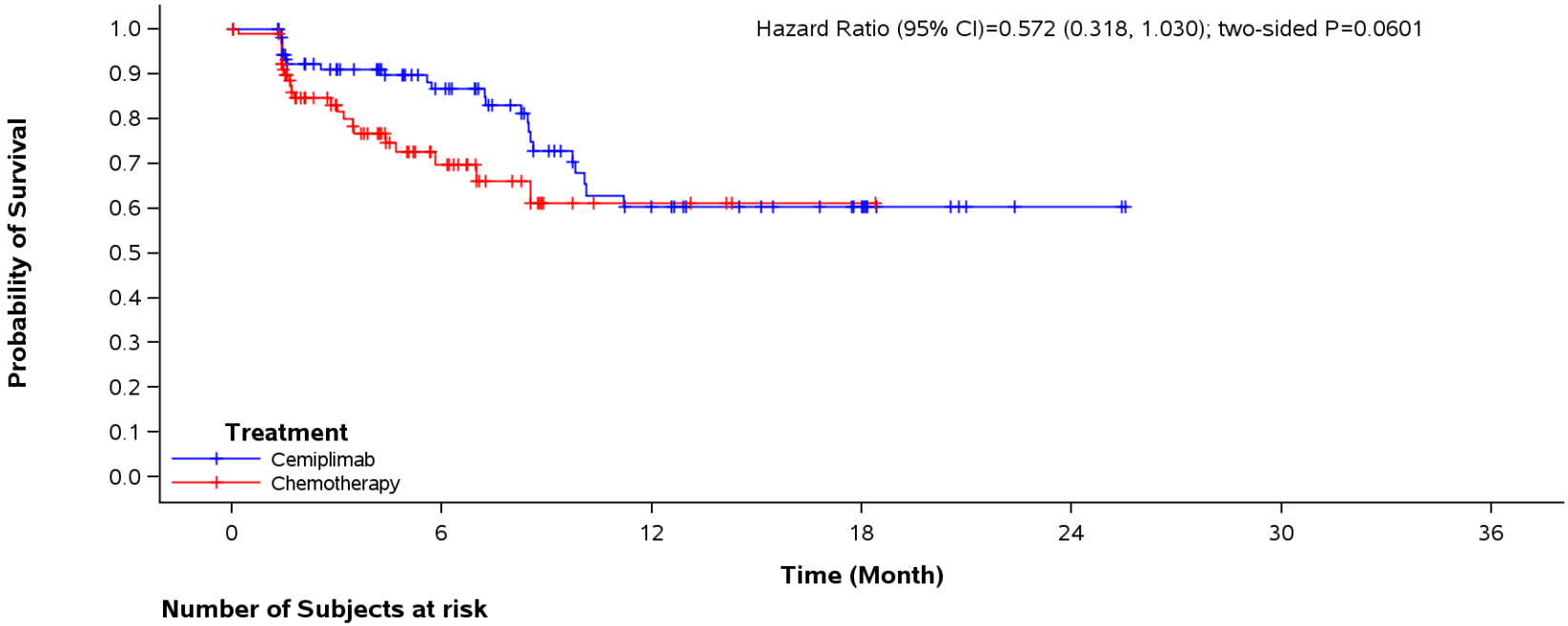
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 56 | 22 | 12 | 2 | 0 | 0 |
| Chemotherapy | 123 | 26 | 4 | 1 | 0 | 0 | 0 |

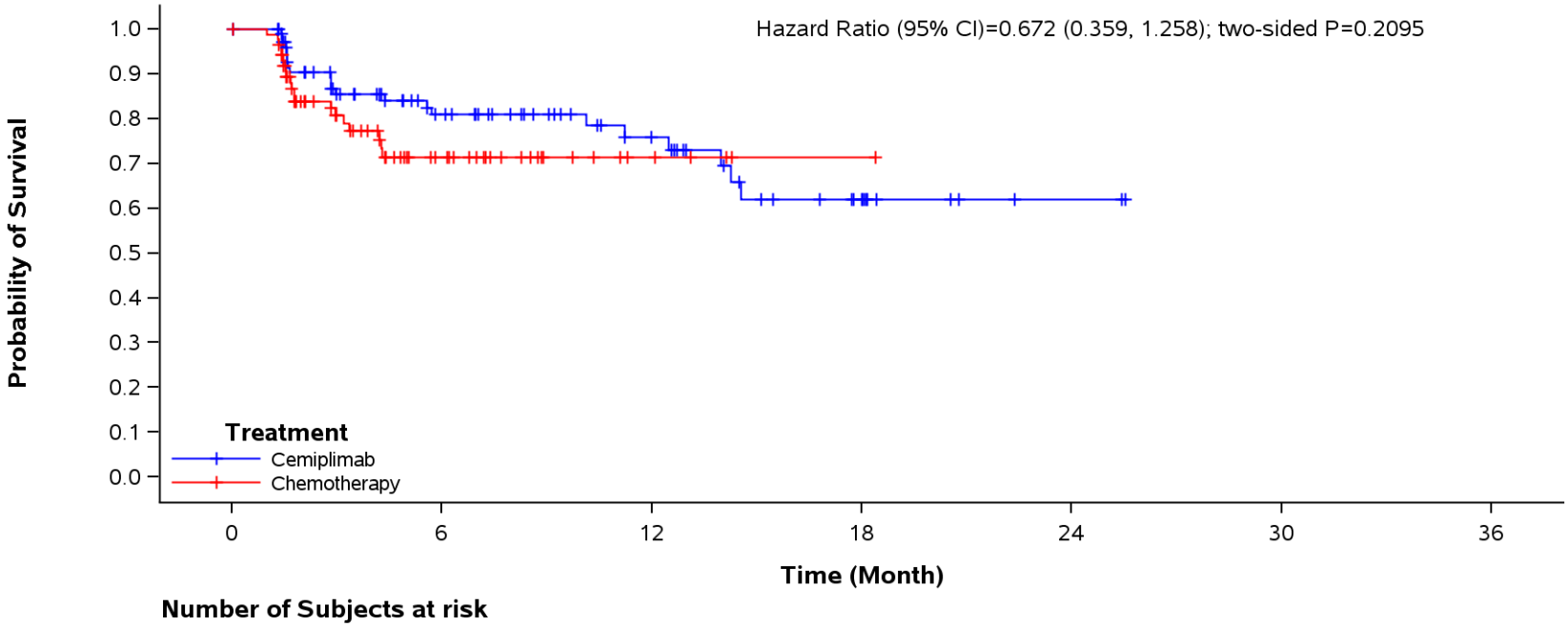
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Role Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 50 | 27 | 11 | 2 | 0 | 0 |
| Chemotherapy | 123 | 24 | 5 | 1 | 0 | 0 | 0 |

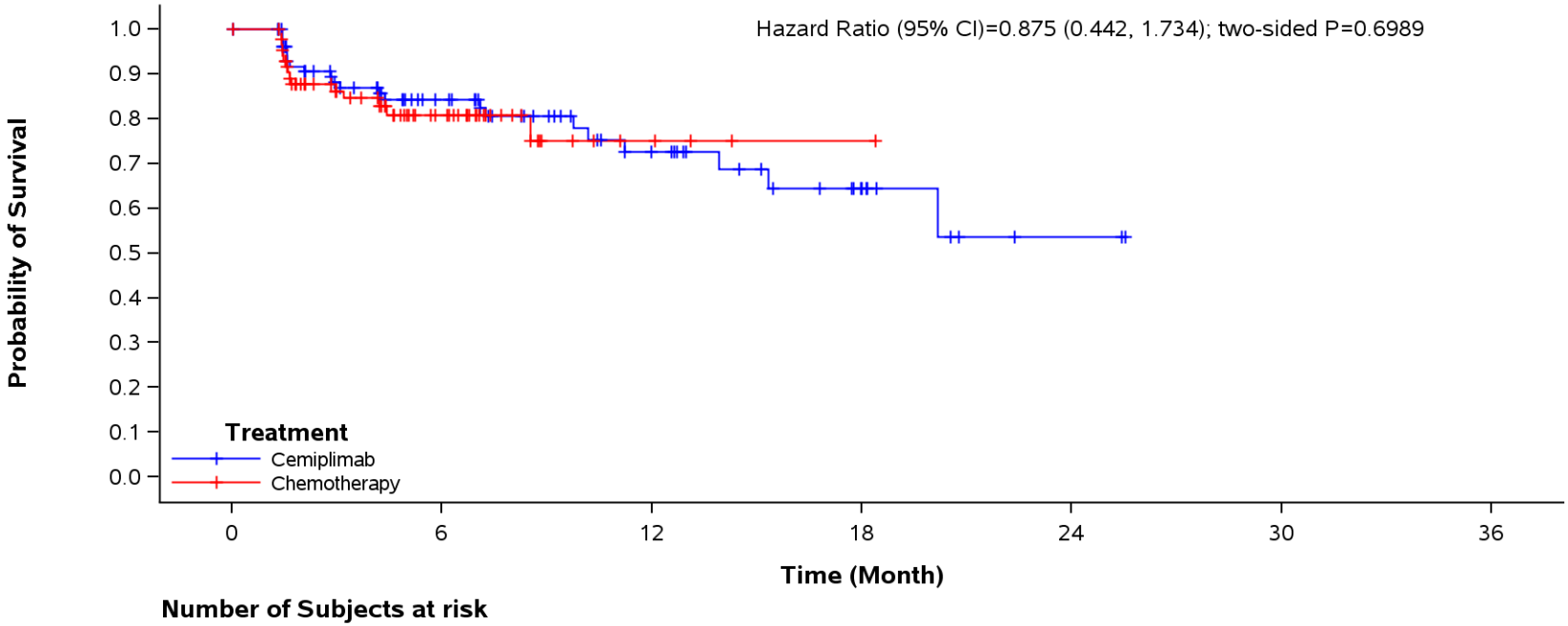
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Social Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

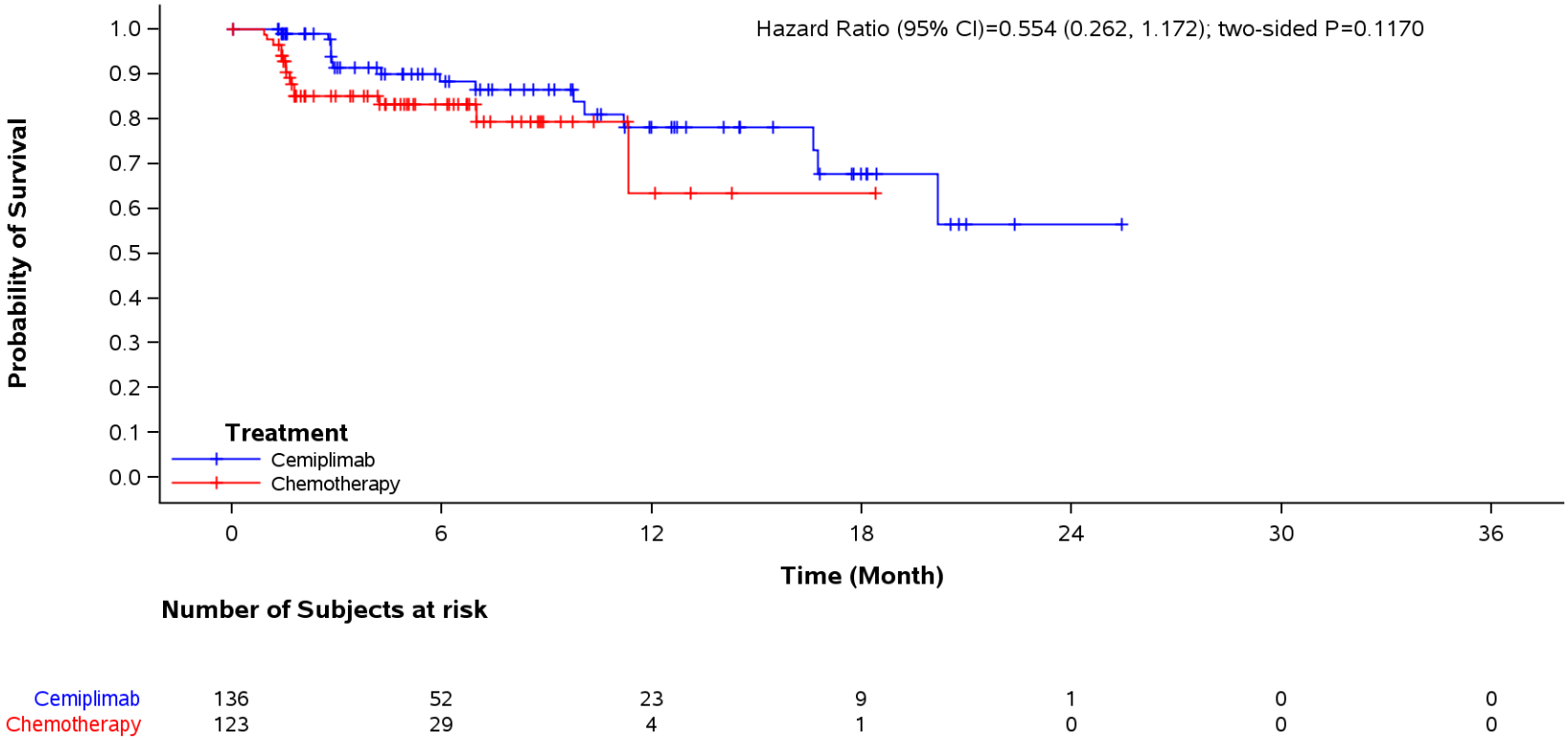
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 52 | 24 | 10 | 2 | 0 | 0 |
| Chemotherapy | 123 | 30 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Insomnia - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

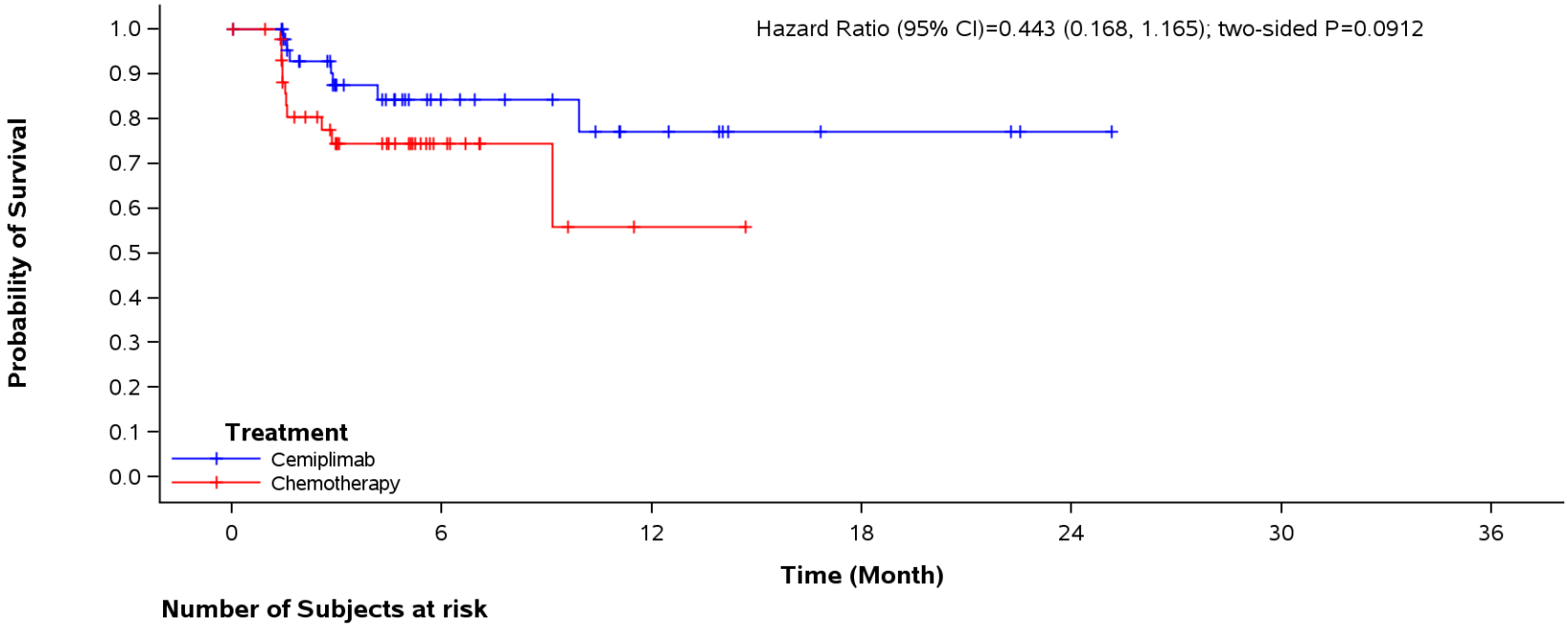
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 52 | 23 | 9 | 1 | 0 | 0 |
| Chemotherapy | 123 | 29 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 60 | 9 | 1 | 0 | 0 | 0 | 0 |

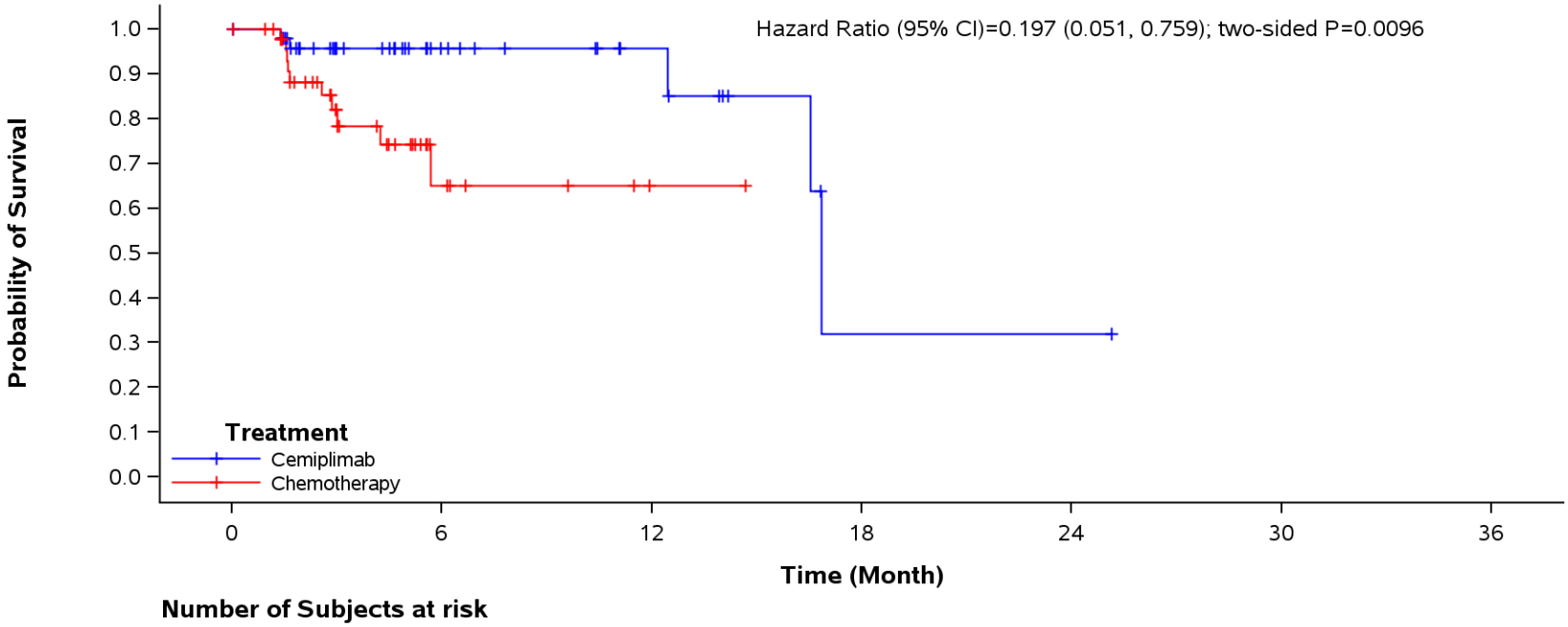
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

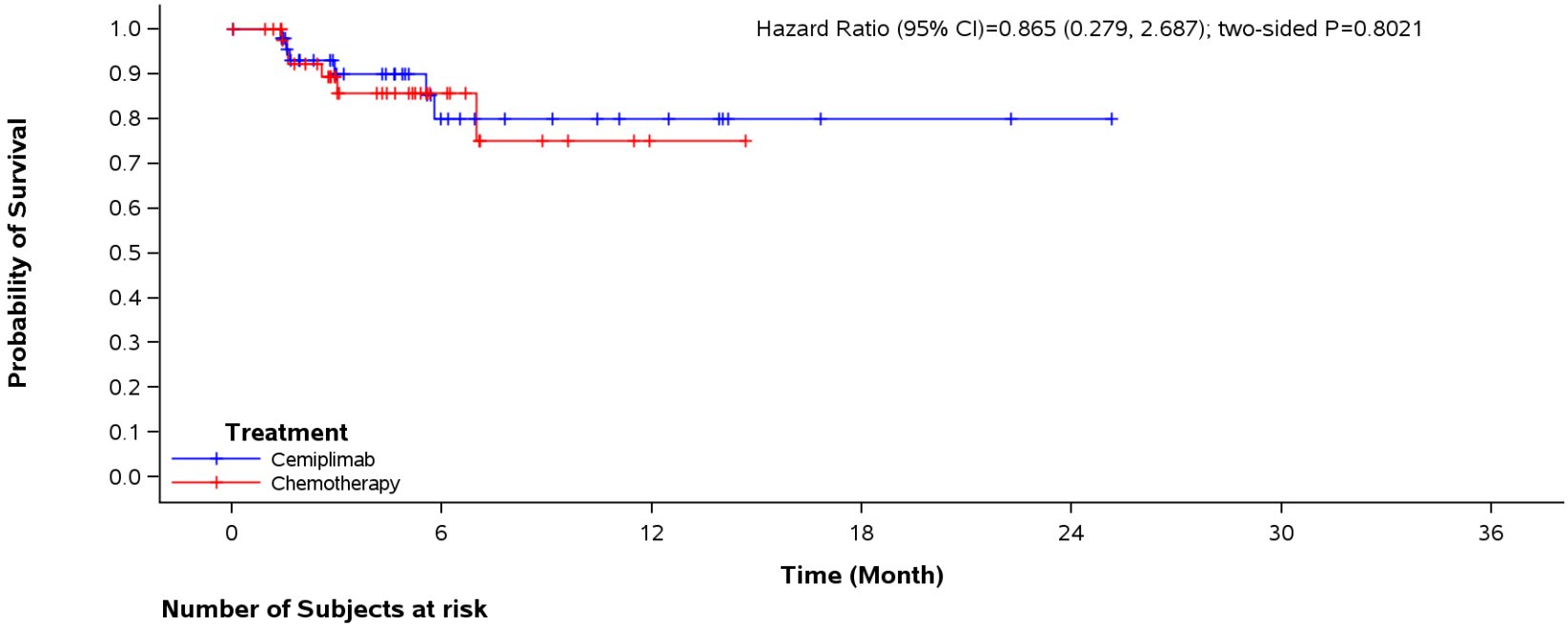
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 17 | 9 | 1 | 1 | 0 | 0 |
| Chemotherapy | 60 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Constipation - 10 pts sensitivity sustained deterioration



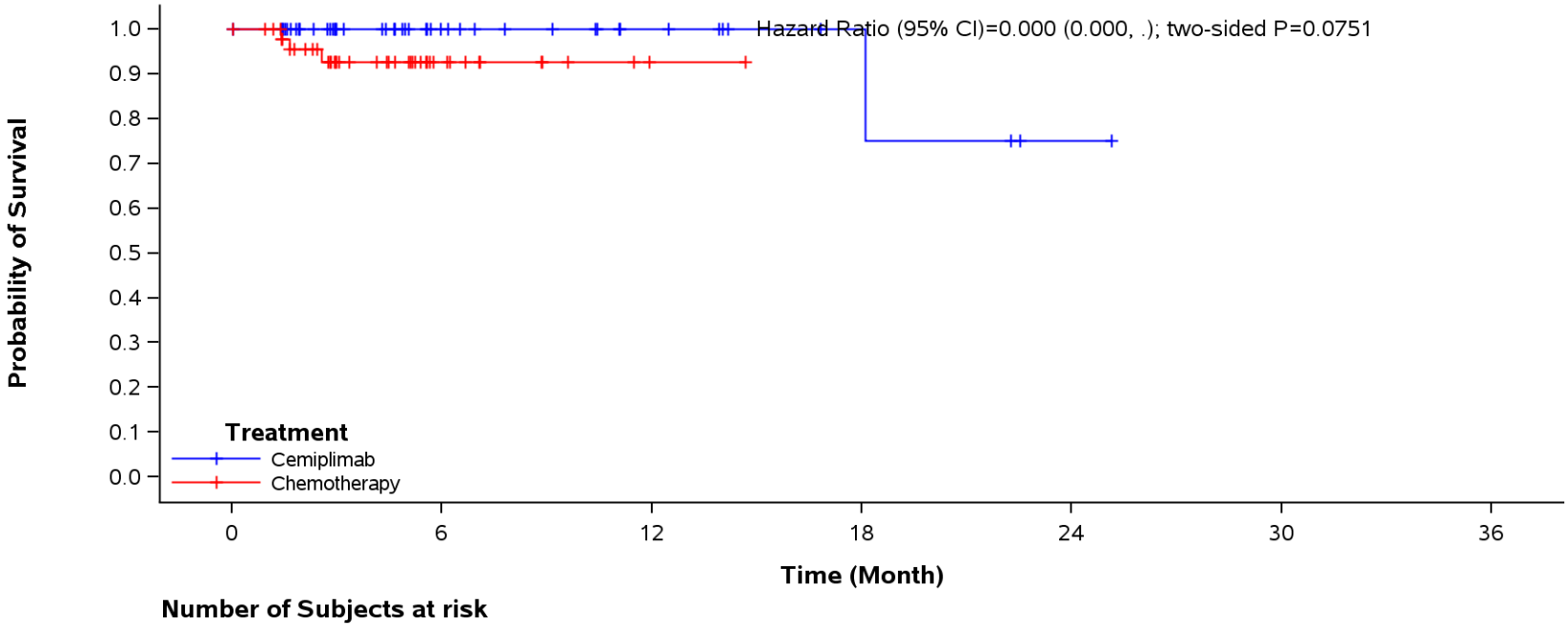

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 14 | 7 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Diarhoea - 10 pts sensitivity sustained deterioration



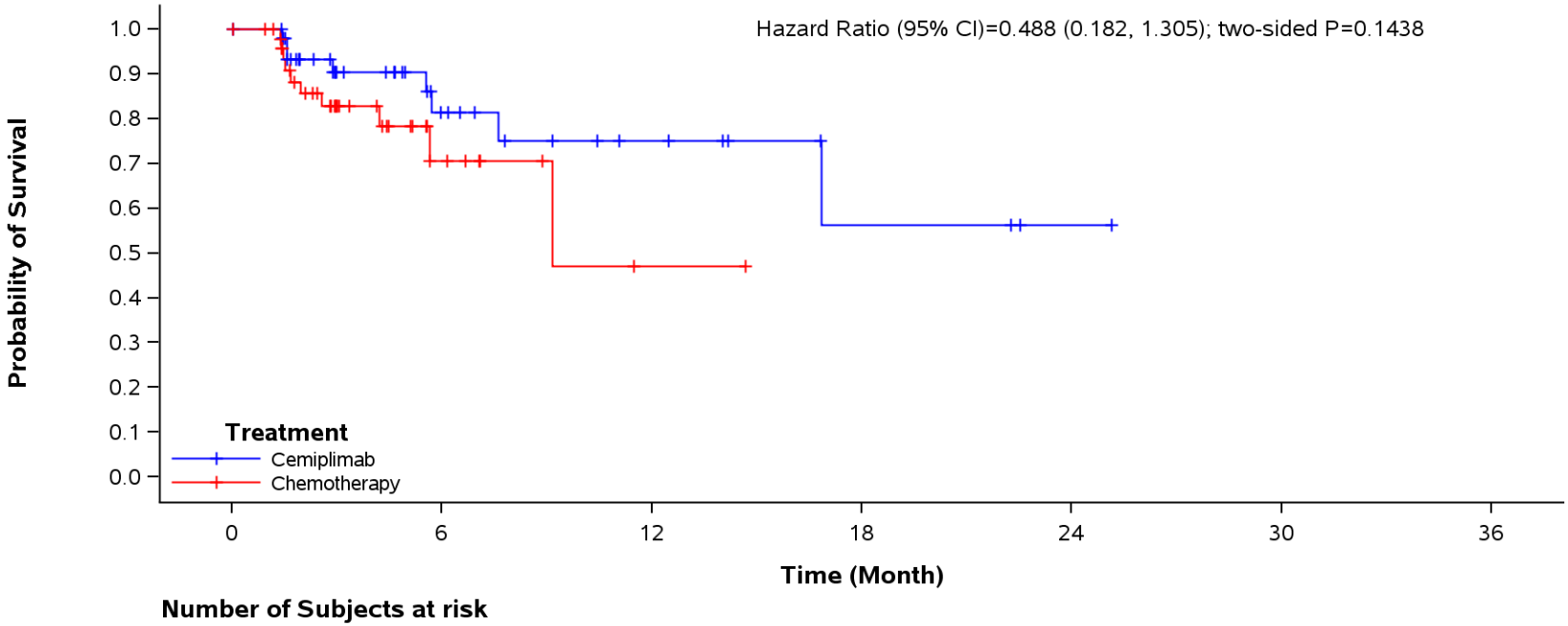

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Dyspnoea - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

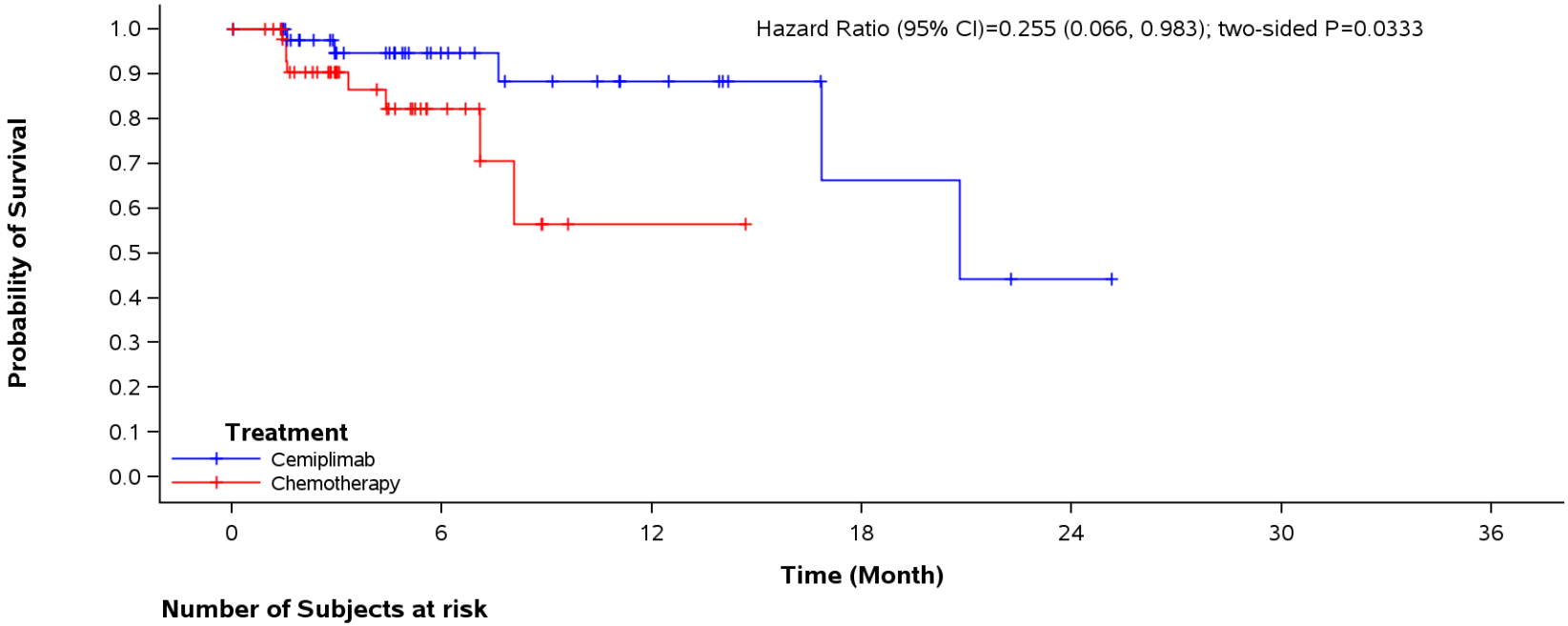
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 60 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Emotional Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

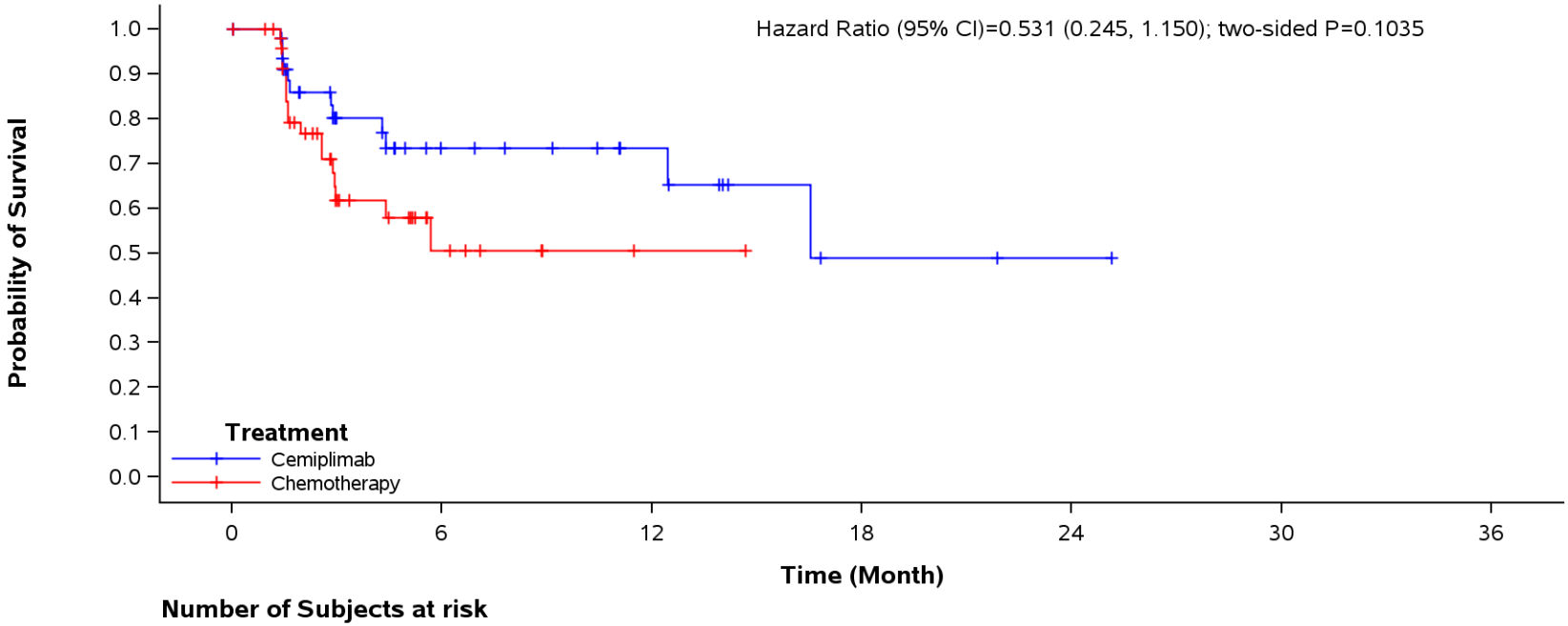
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 9 | 3 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

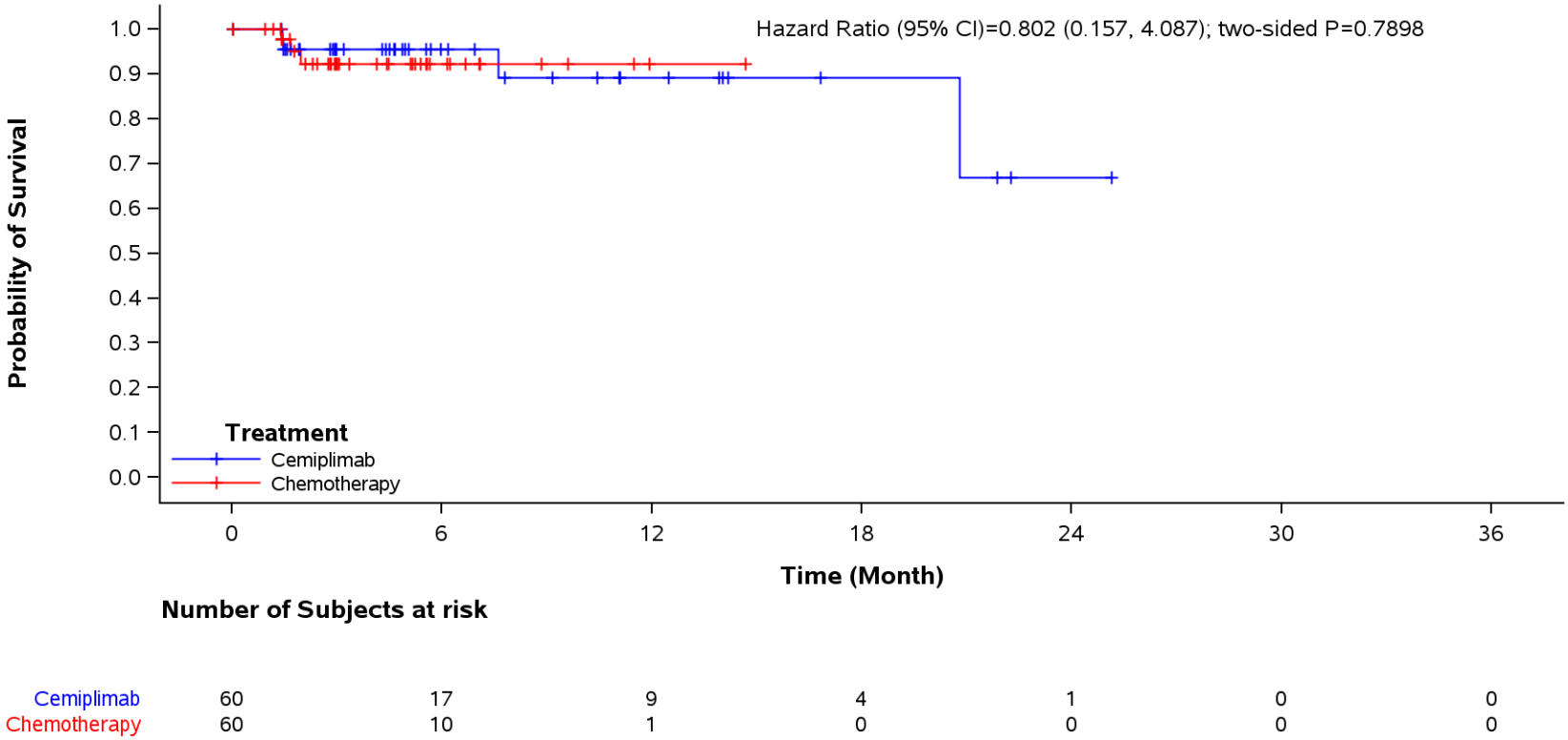
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 15 | 9 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

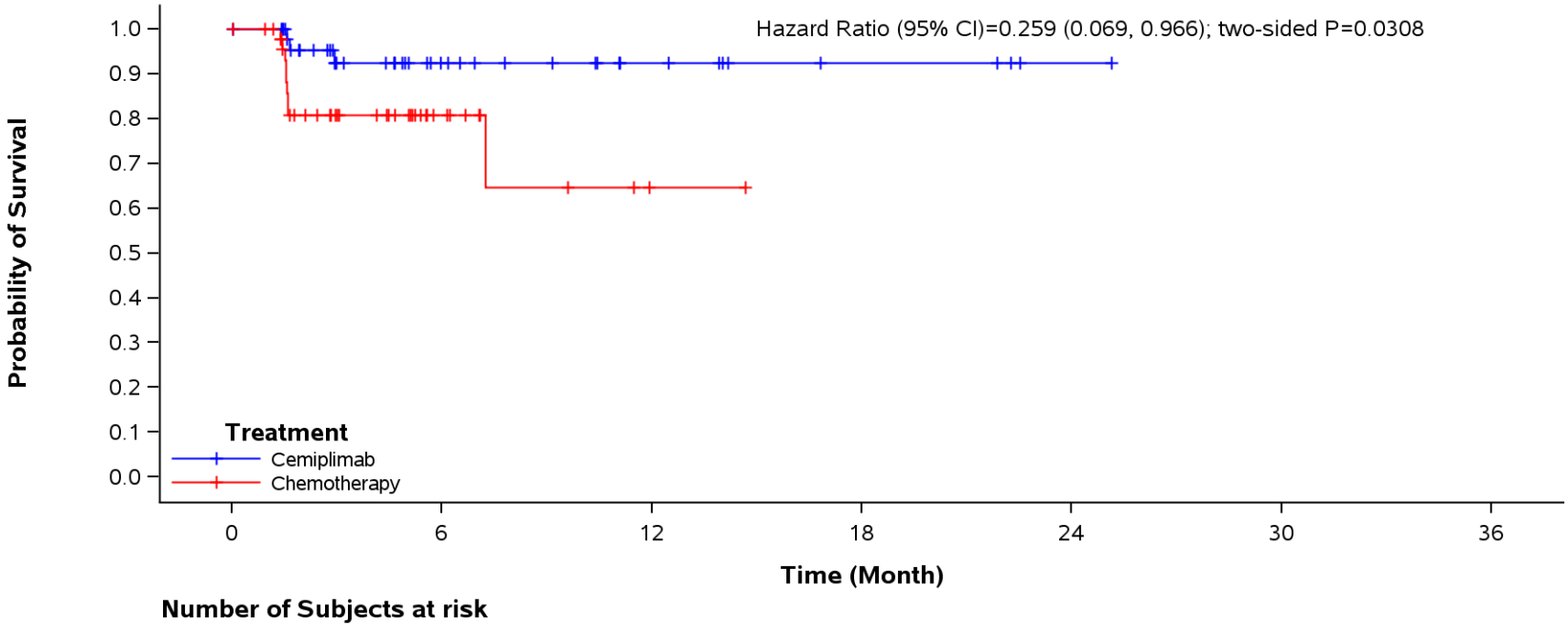
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 17 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



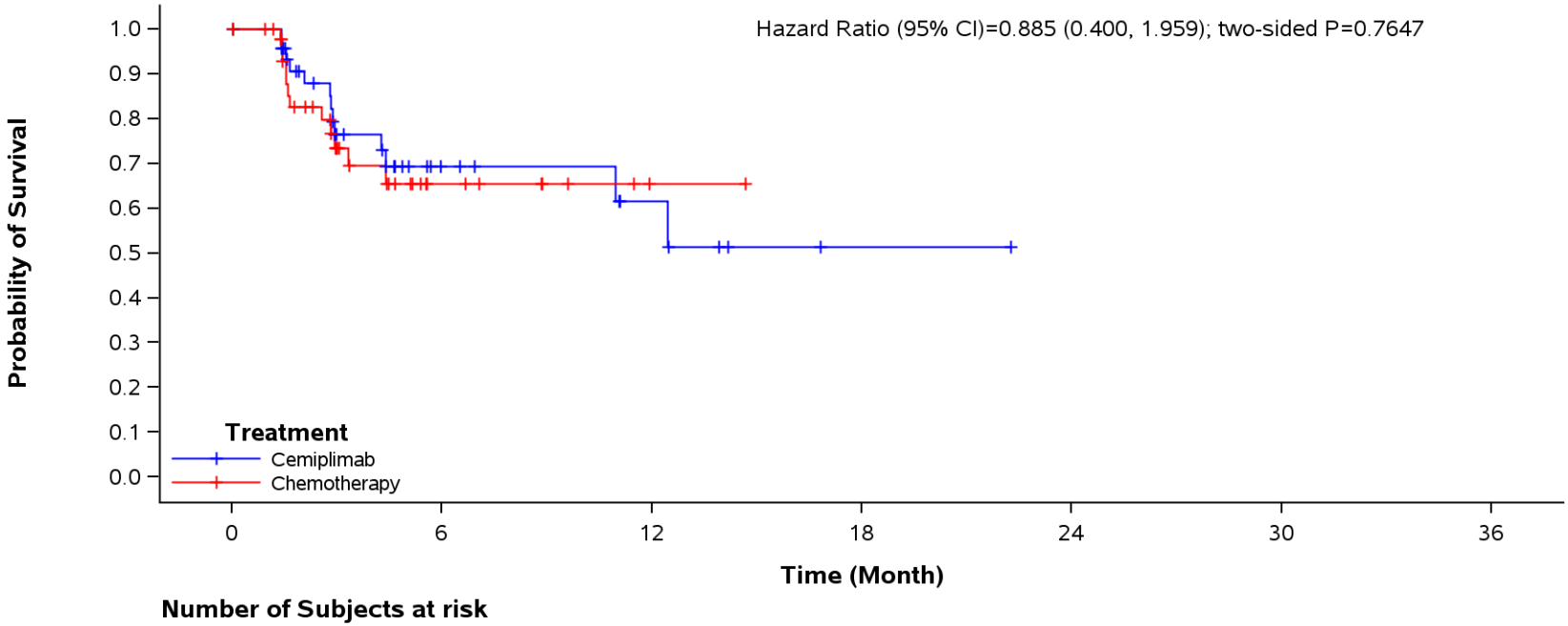

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

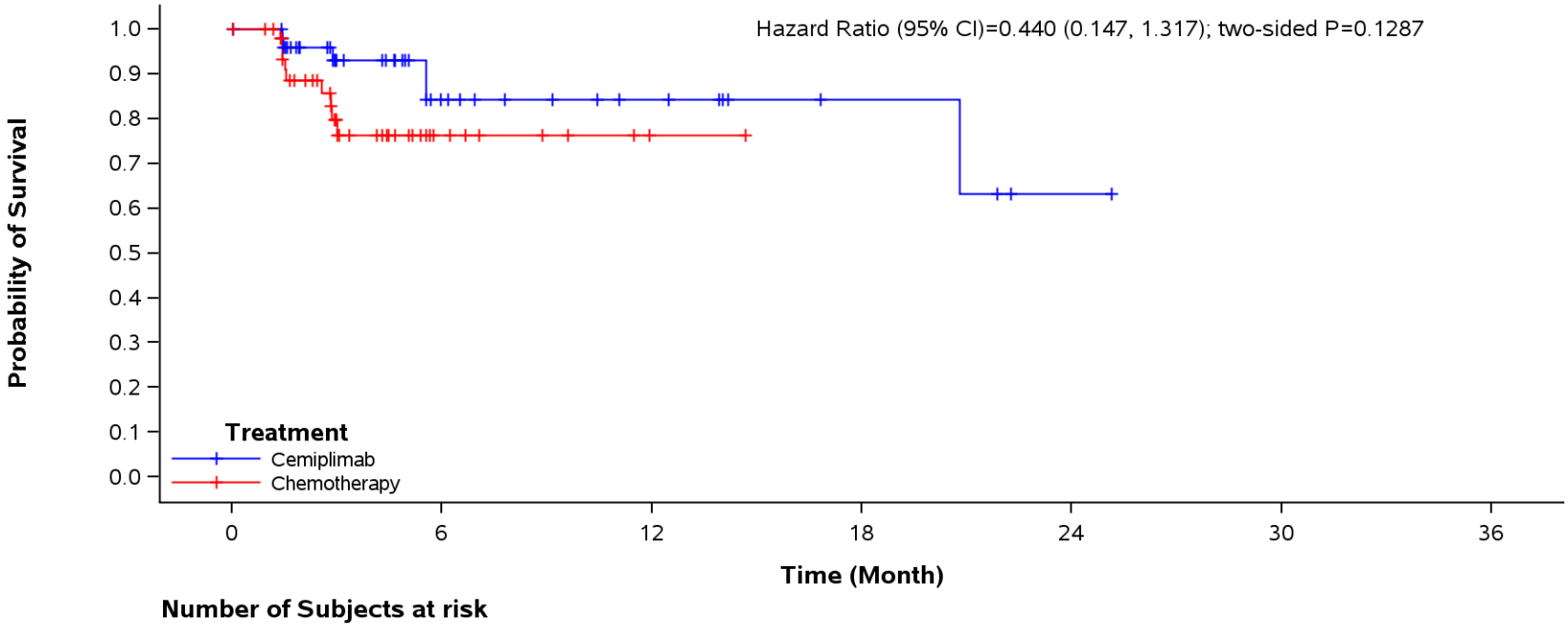
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 11 | 6 | 1 | 0 | 0 | 0 |
| Chemotherapy | 60 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Physical Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 8 | 1 | 0 | 0 | 0 | 0 |

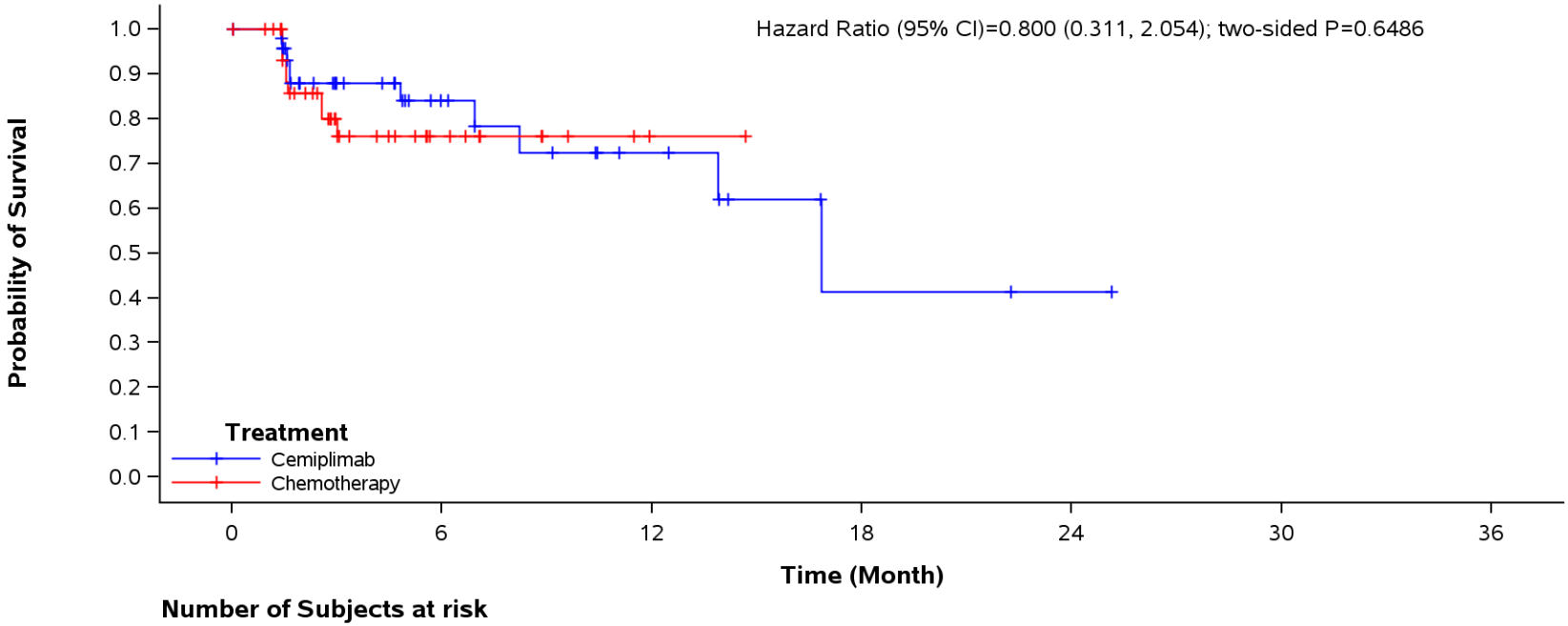
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

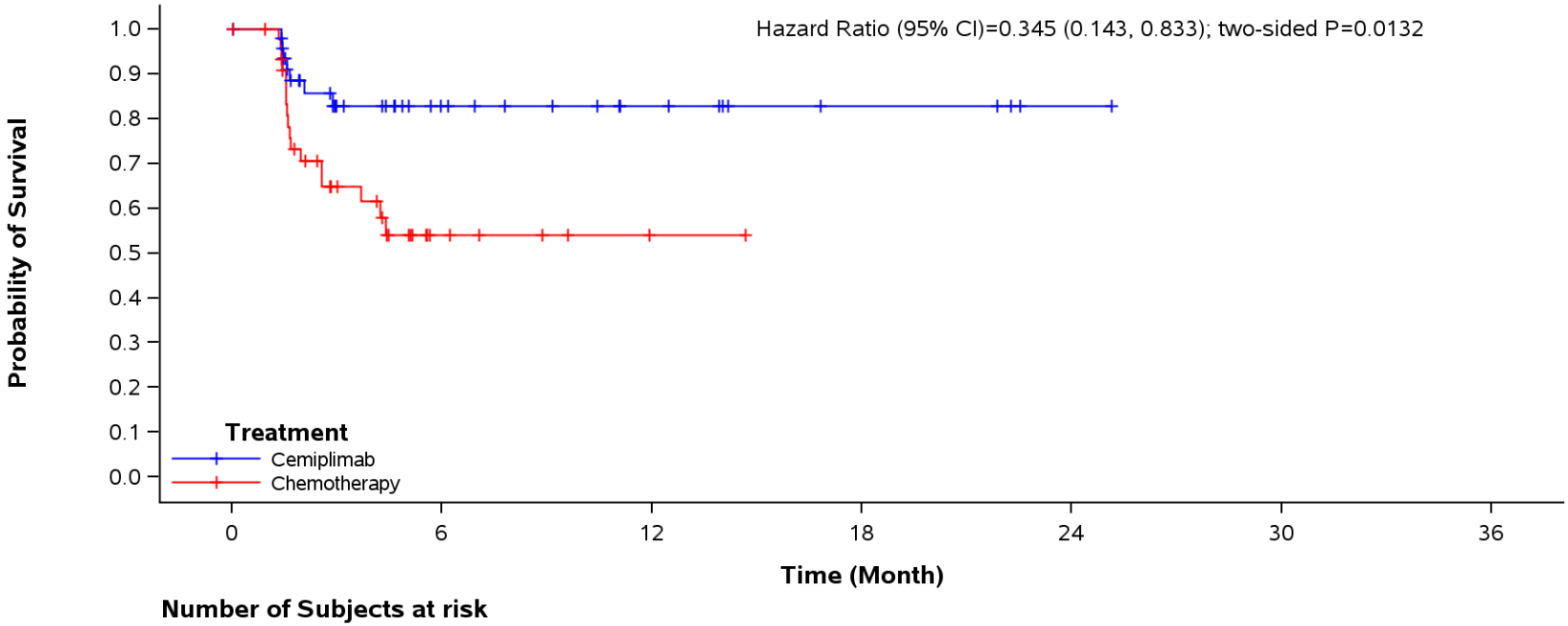
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Role Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

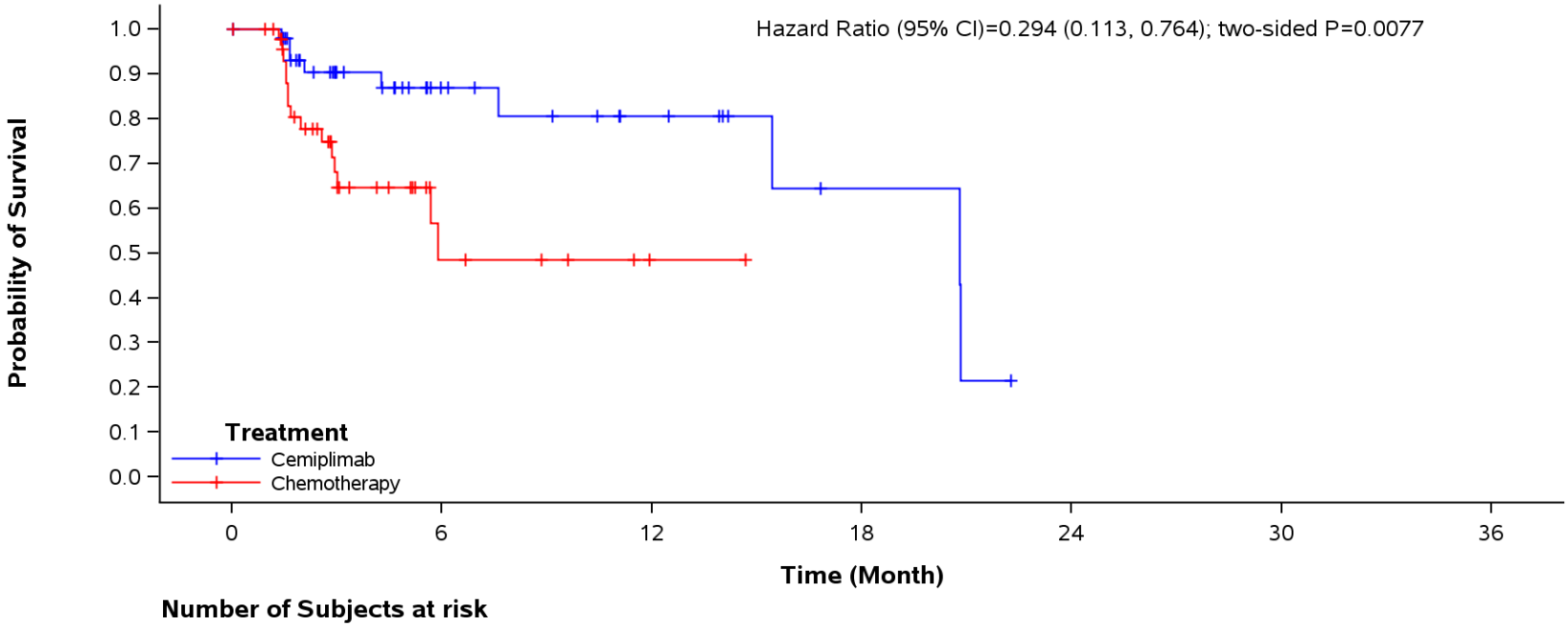
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 9 | 4 | 1 | 0 | 0 |
| Chemotherapy | 60 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Social Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

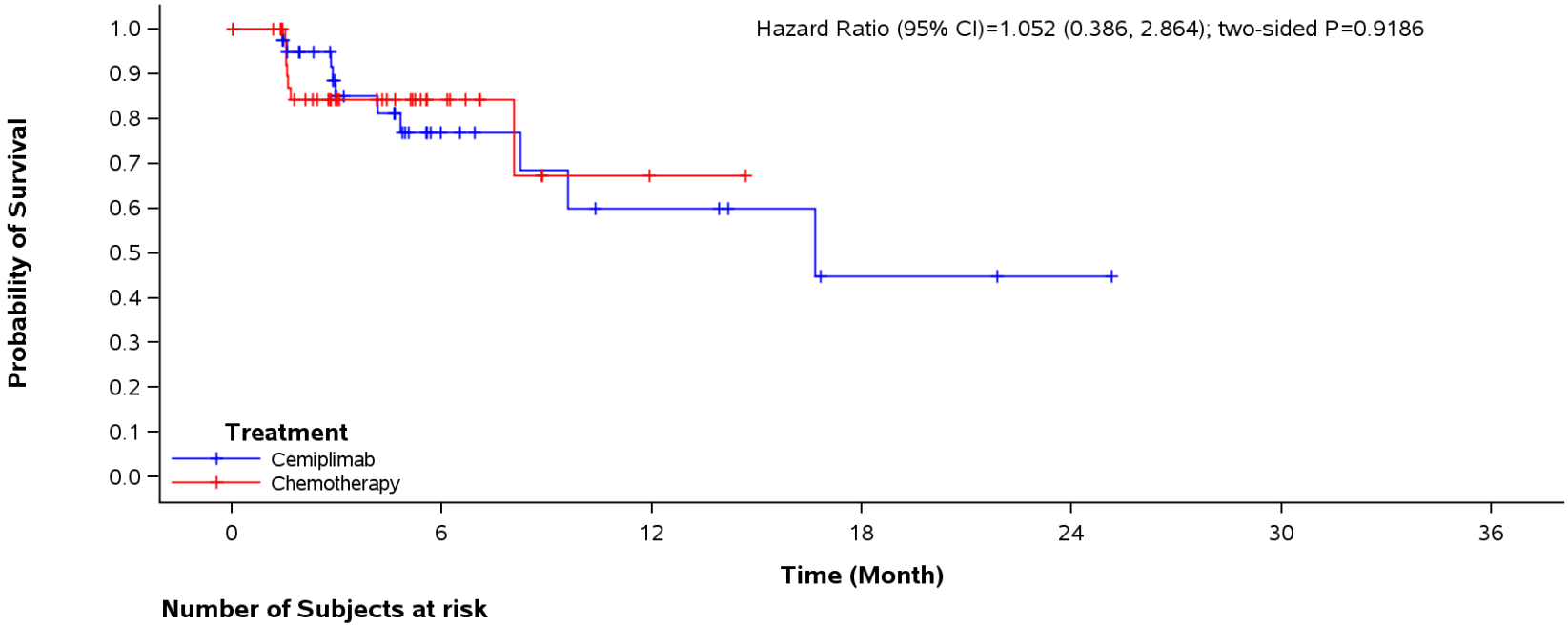
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 9 | 3 | 0 | 0 | 0 |
| Chemotherapy | 60 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Insomnia - 10 pts sensitivity sustained deterioration



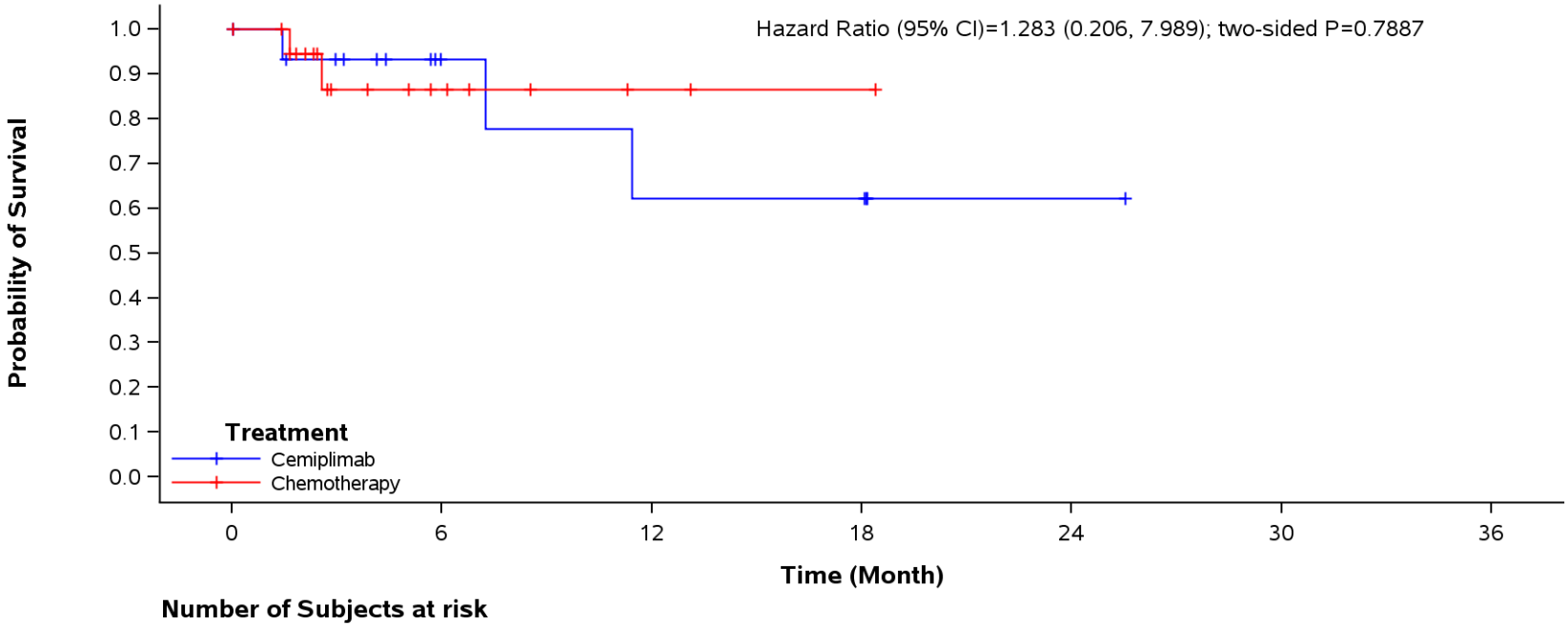

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 11 | 6 | 2 | 1 | 0 | 0 |
| Chemotherapy | 60 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Appetite loss - 10 pts sensitivity sustained deterioration



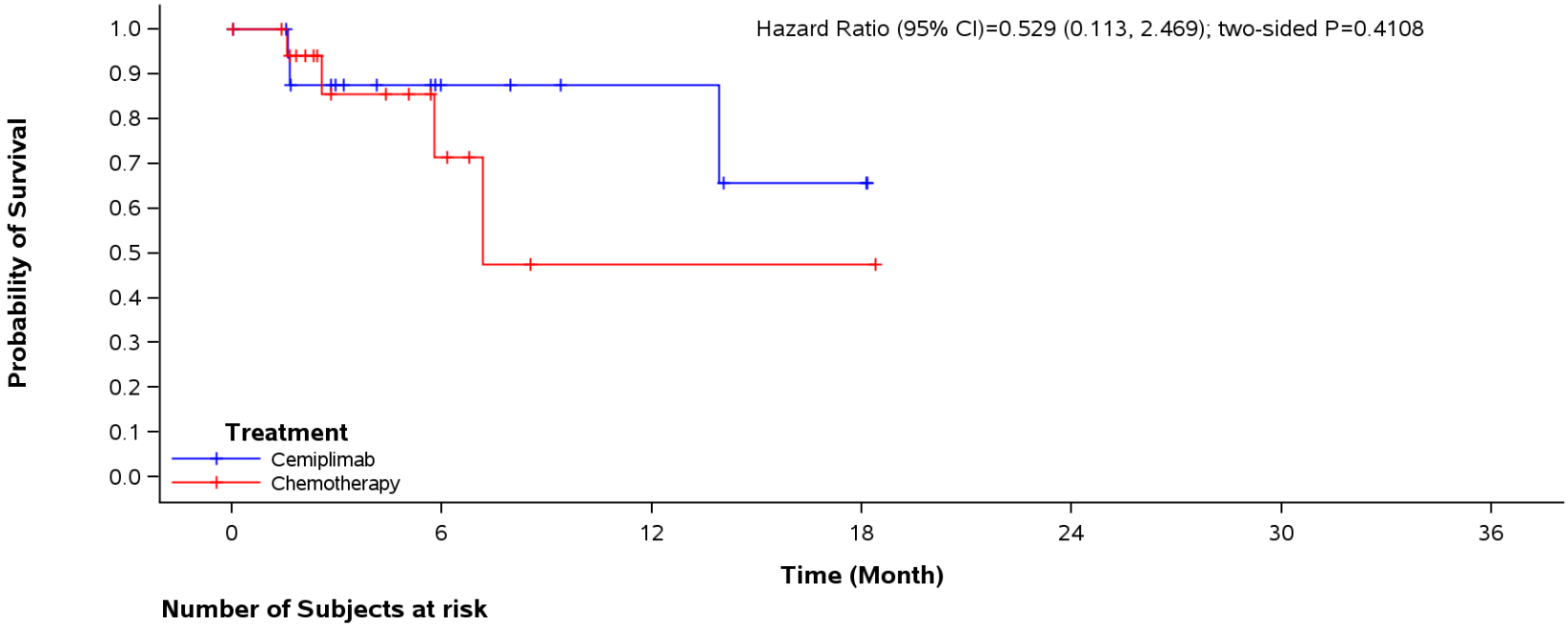

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Cognitive Functioning - 10 pts sensitivity sustained deterioration



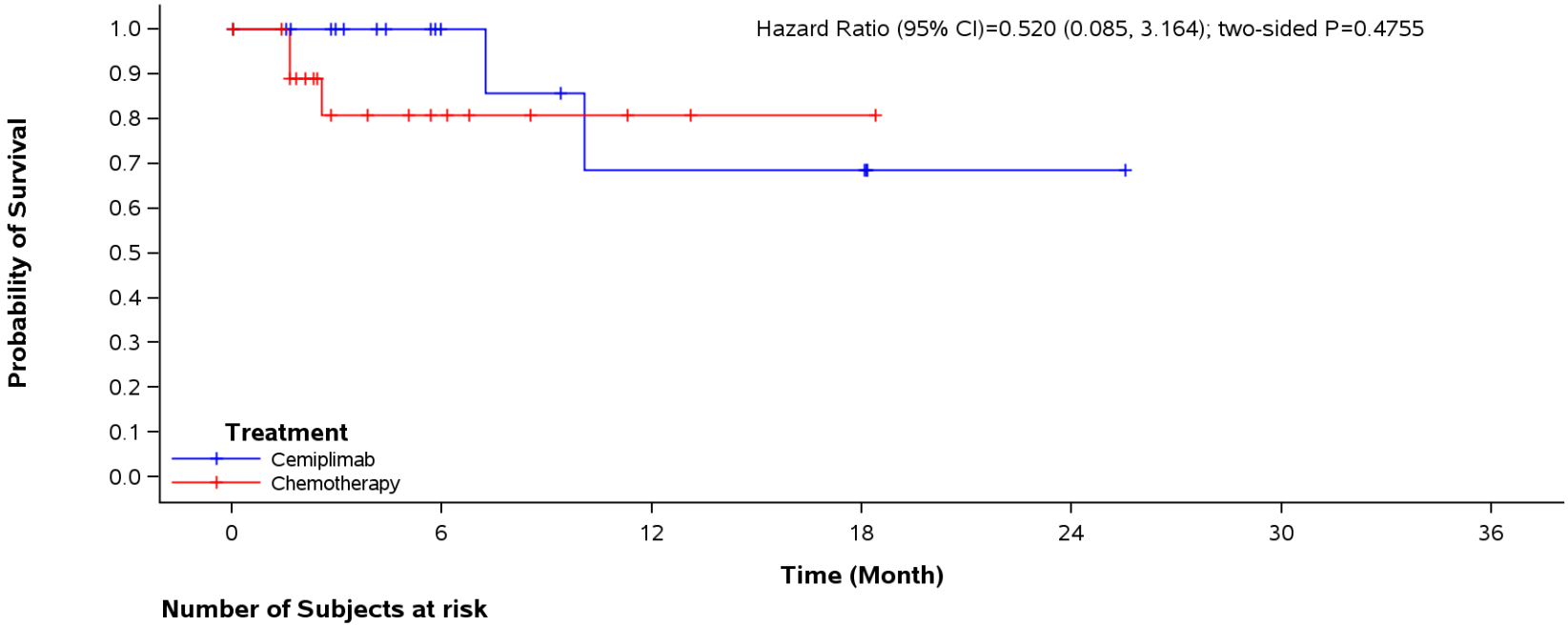

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Constipation - 10 pts sensitivity sustained deterioration



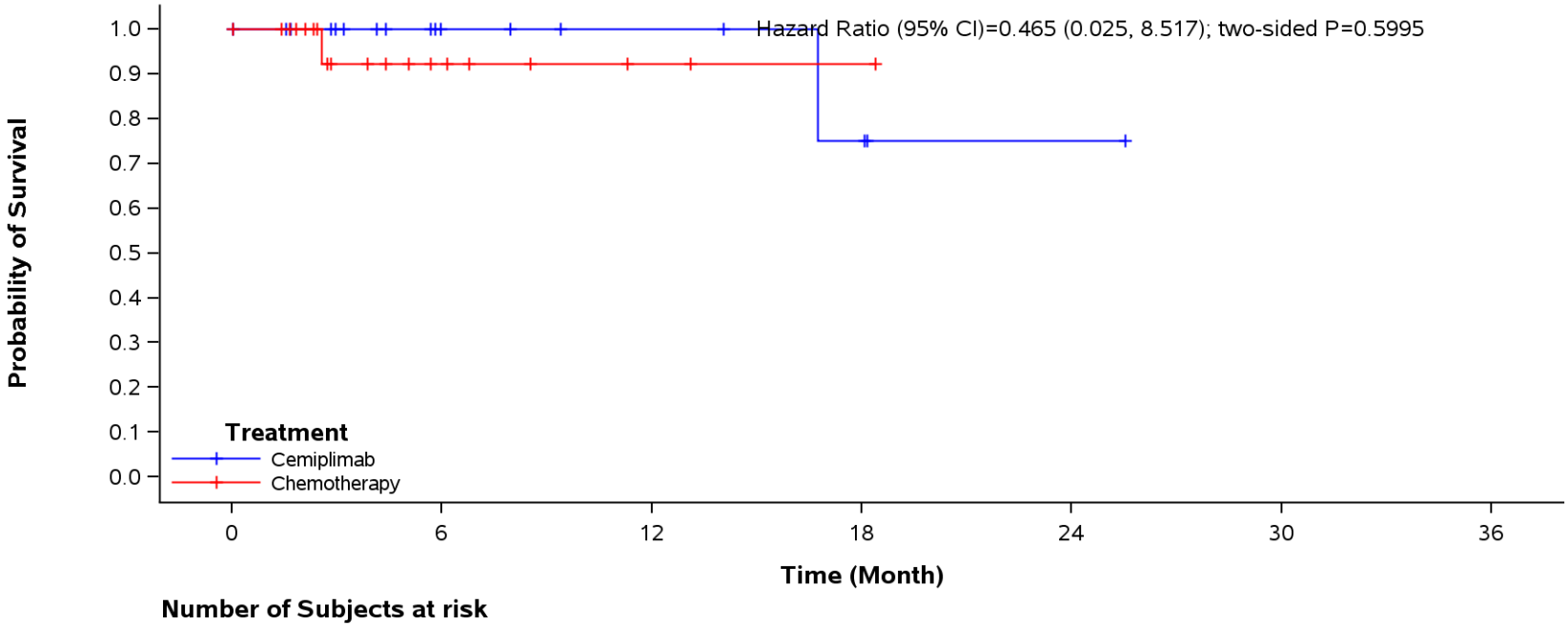

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Diarhoea - 10 pts sensitivity sustained deterioration



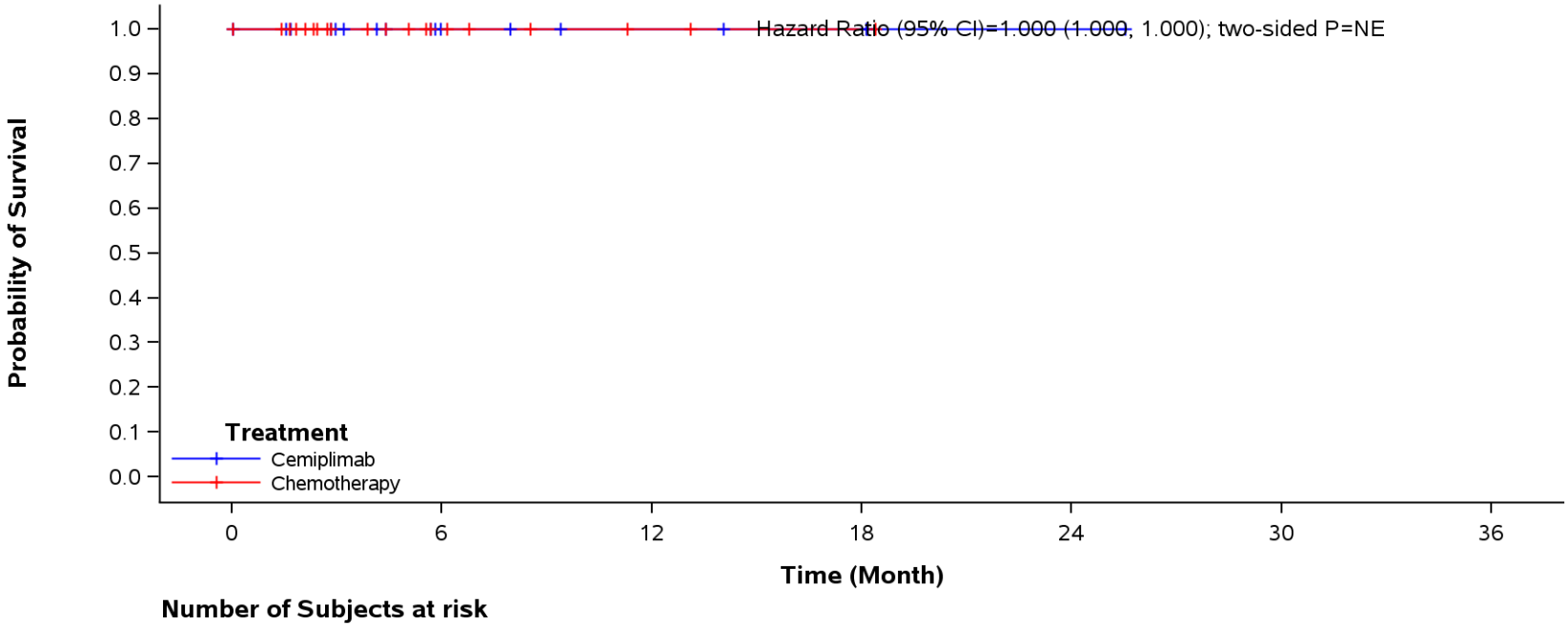

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Dyspnoea - 10 pts sensitivity sustained deterioration



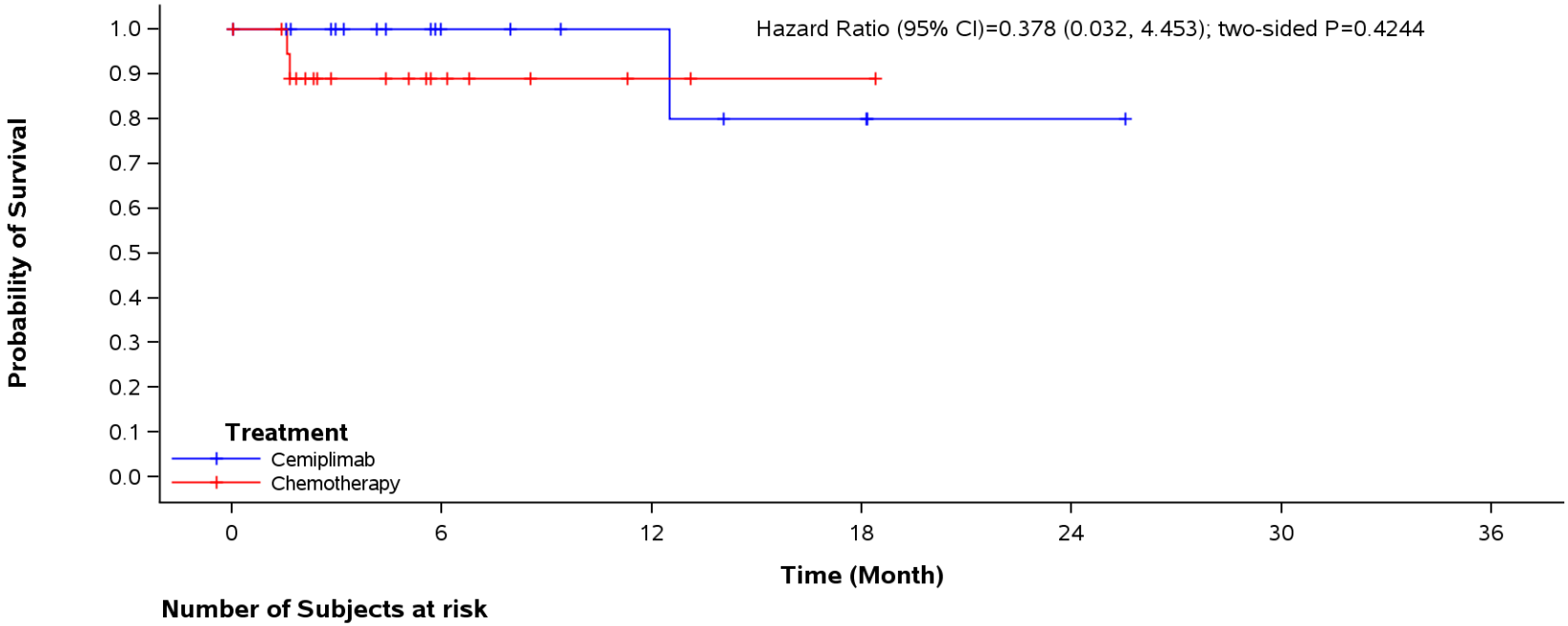

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Emotional Functioning - 10 pts sensitivity sustained deterioration



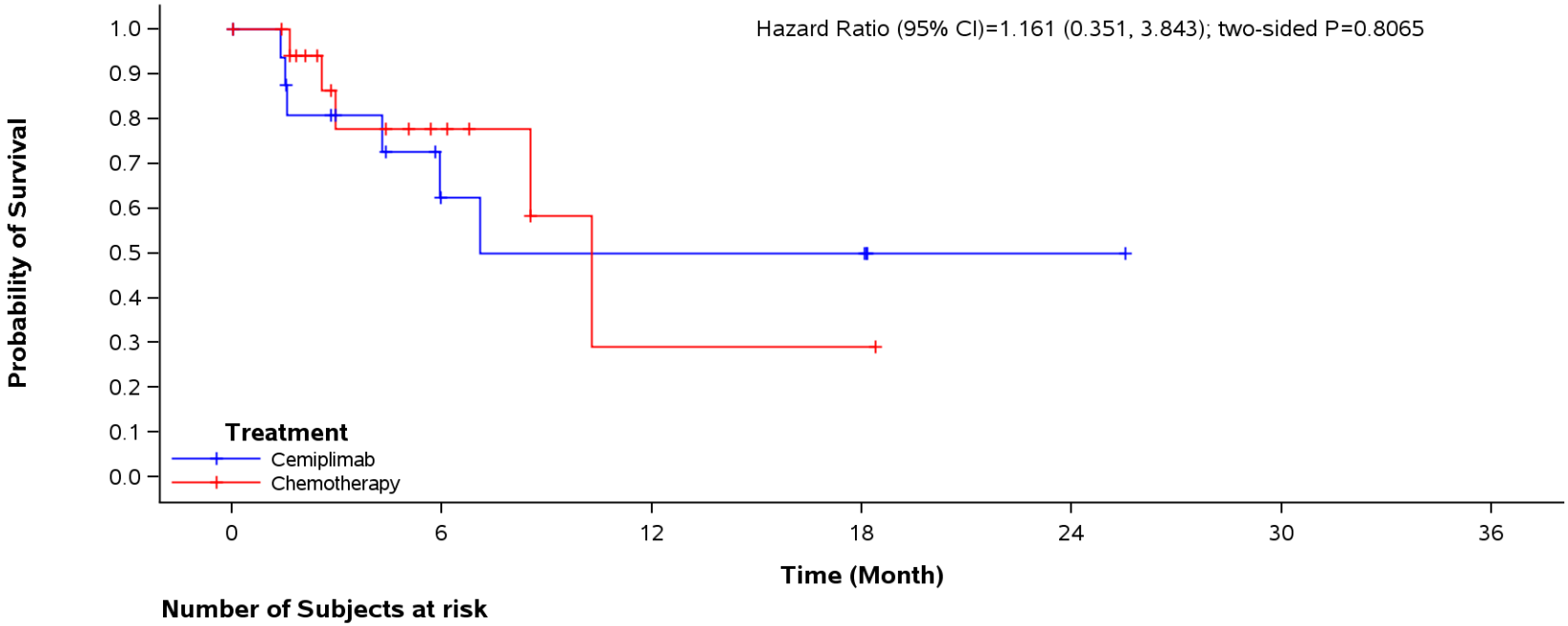

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Fatigue - 10 pts sensitivity sustained deterioration



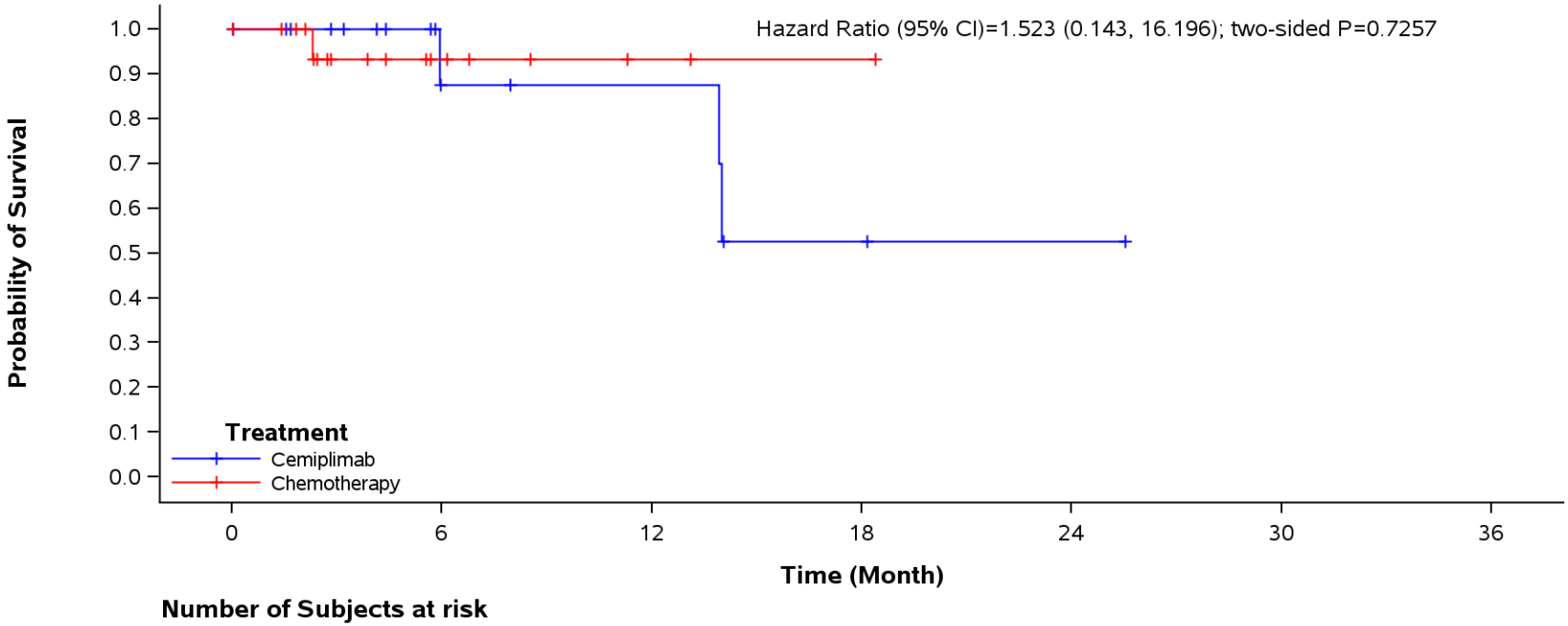

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Financial Problems - 10 pts sensitivity sustained deterioration



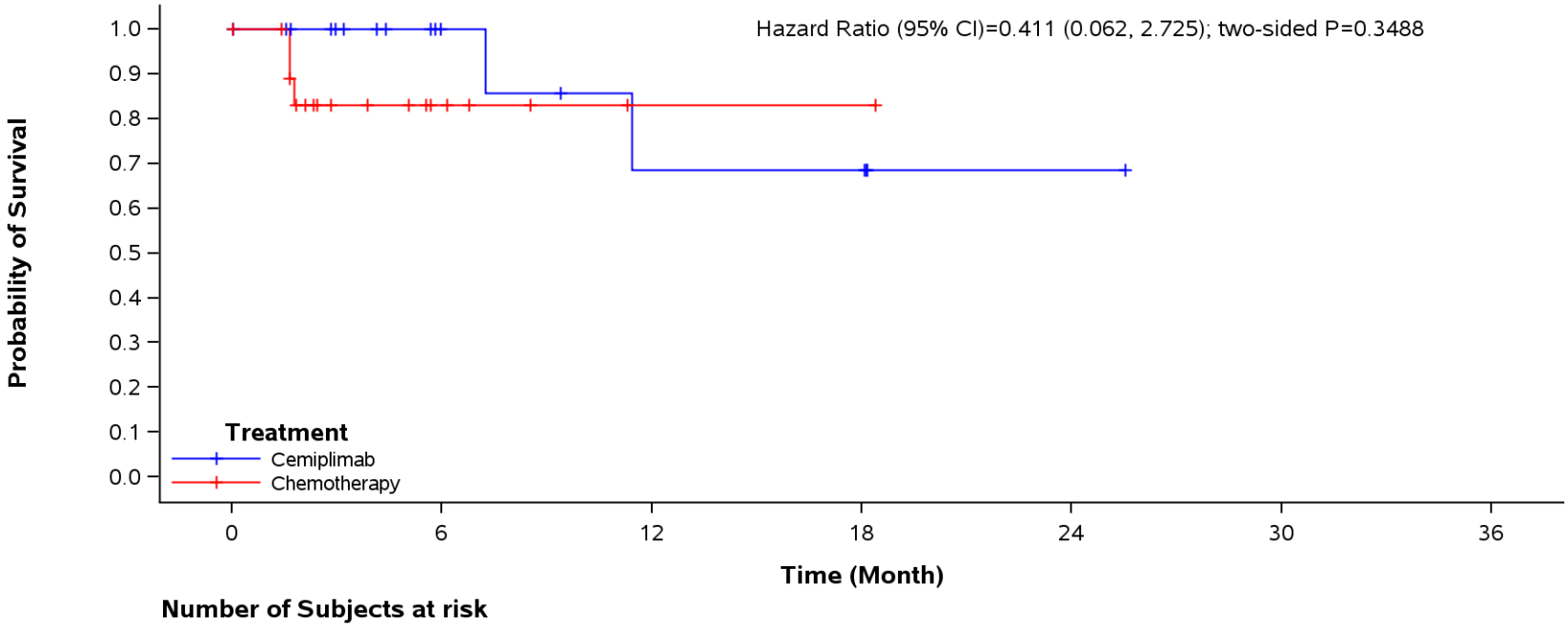

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



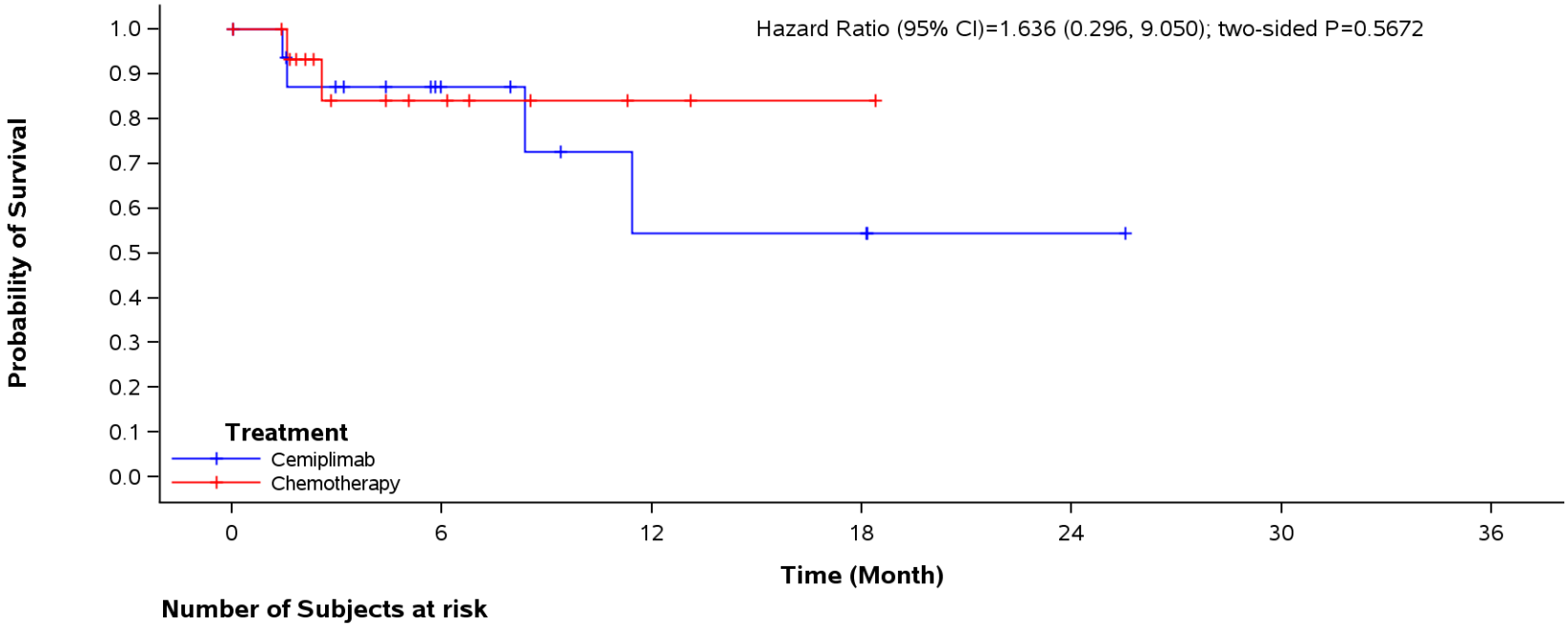

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Pain - 10 pts sensitivity sustained deterioration



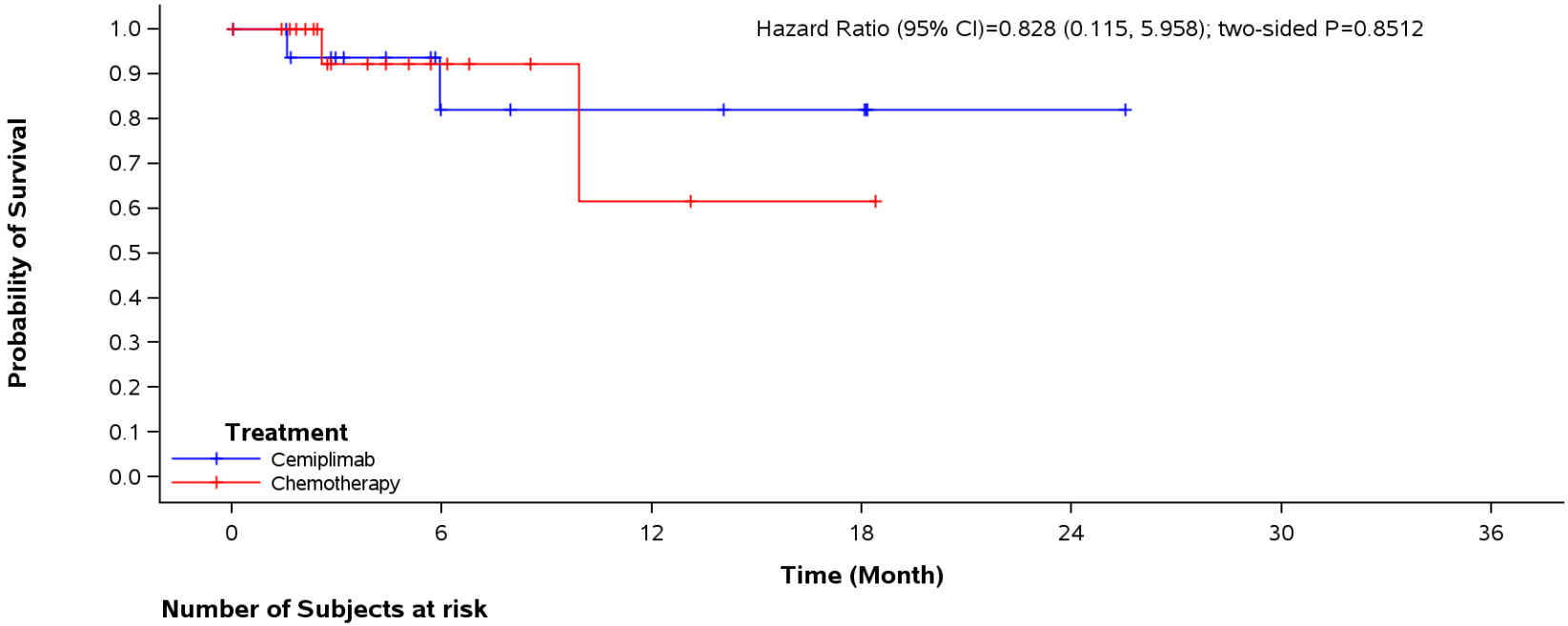

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 3 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Physical Functioning - 10 pts sensitivity sustained deterioration



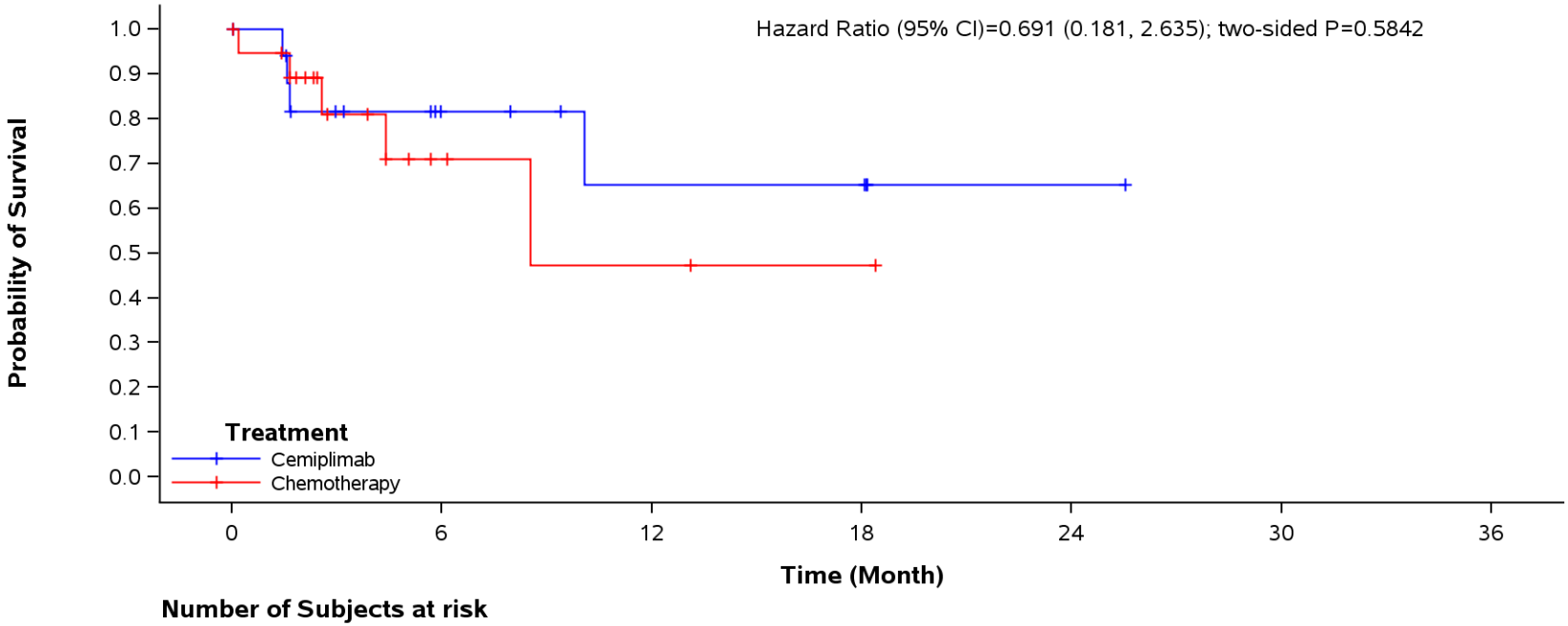

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Global health status / QoL - 10 pts sensitivity sustained deterioration



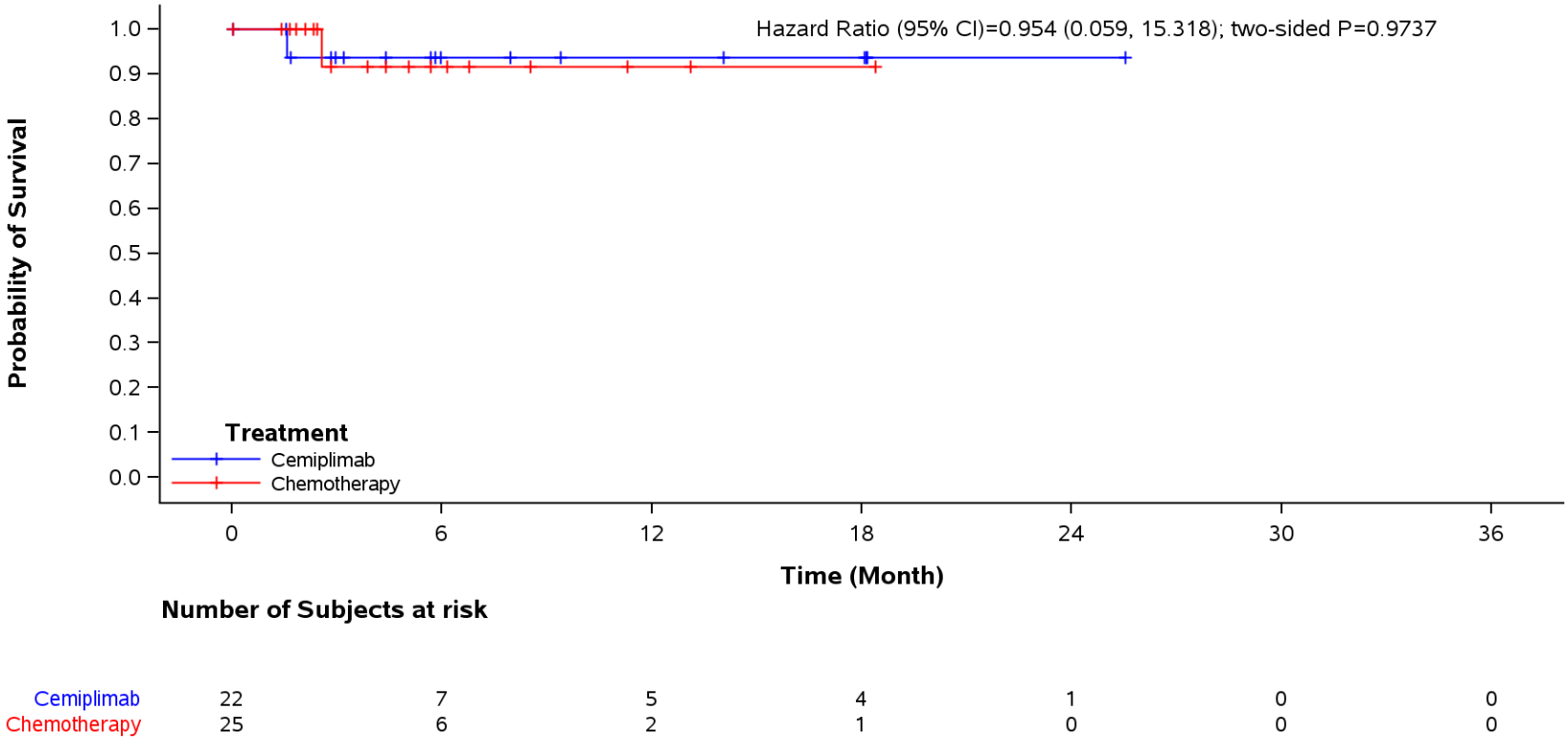

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 25 | 4 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

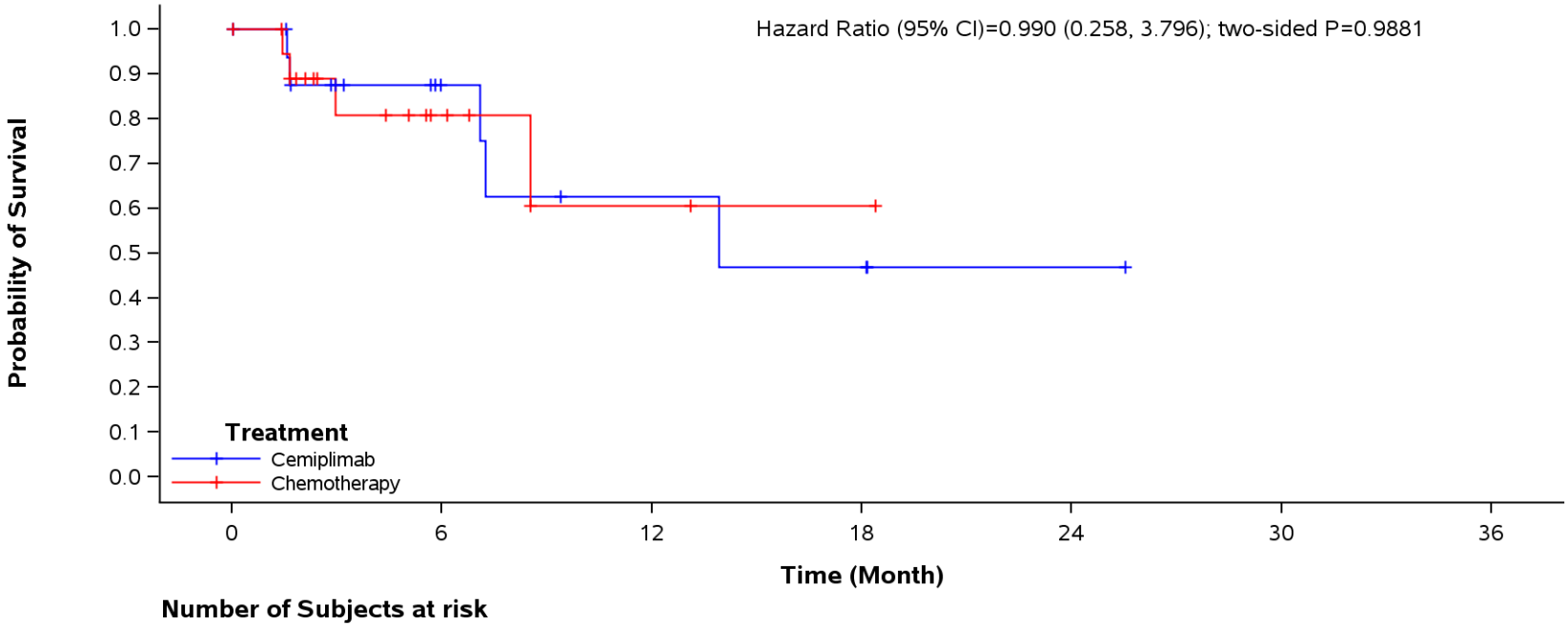
Geographic region: North America
Role Functioning - 10 pts sensitivity sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Social Functioning - 10 pts sensitivity sustained deterioration



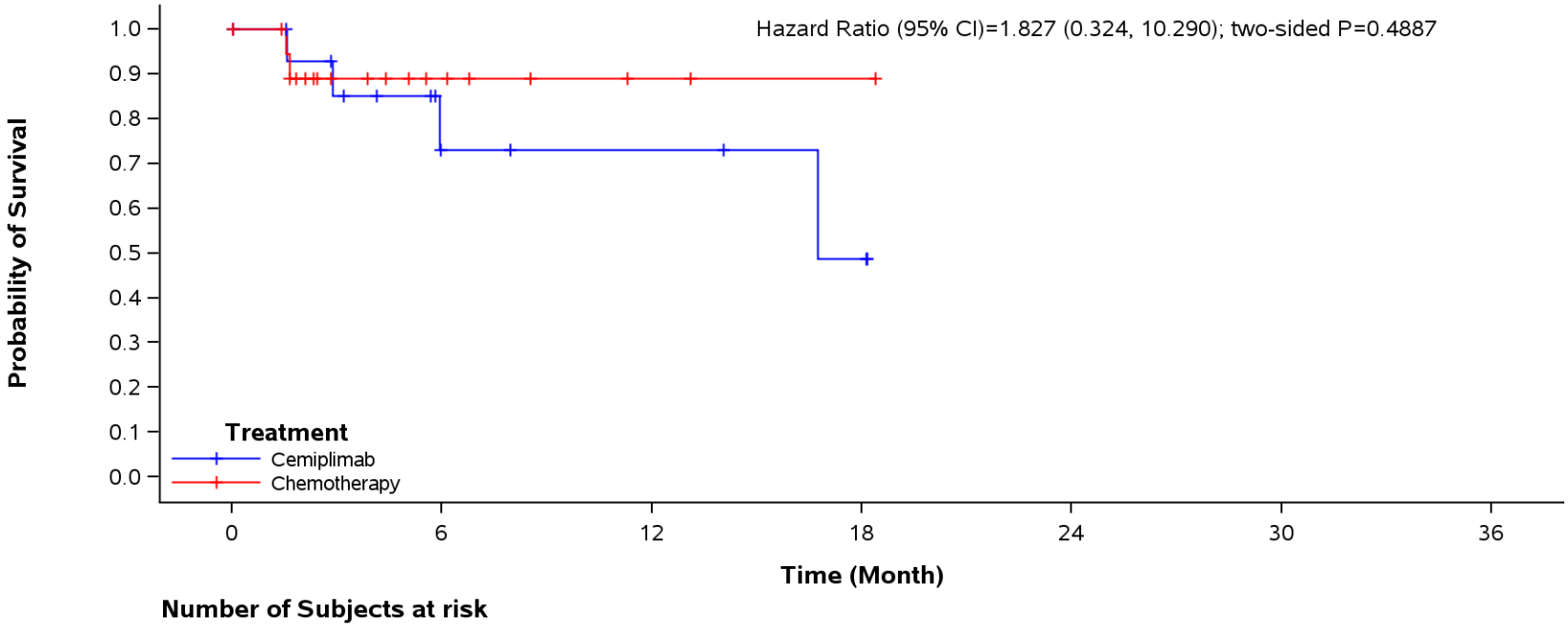

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 7 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Insomnia - 10 pts sensitivity sustained deterioration



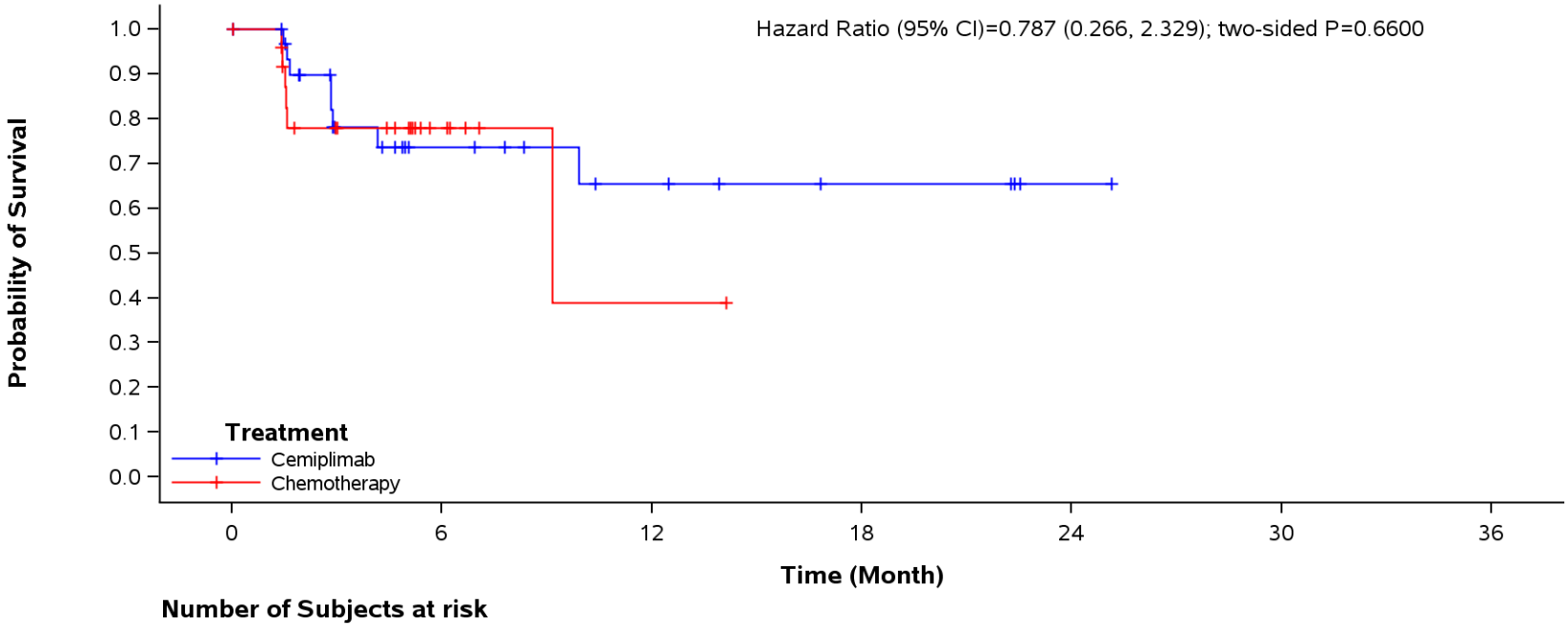

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 25 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Appetite loss - 10 pts sensitivity sustained deterioration



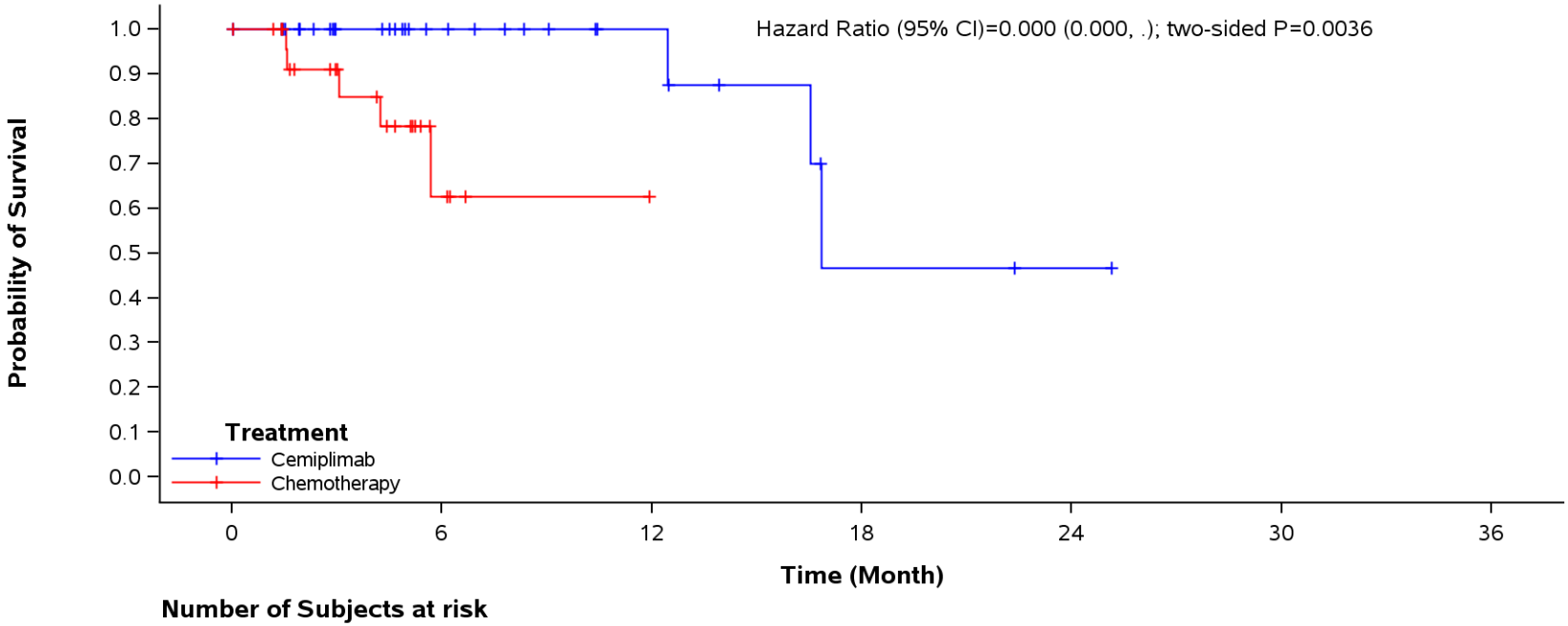

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 36 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Cognitive Functioning - 10 pts sensitivity sustained deterioration



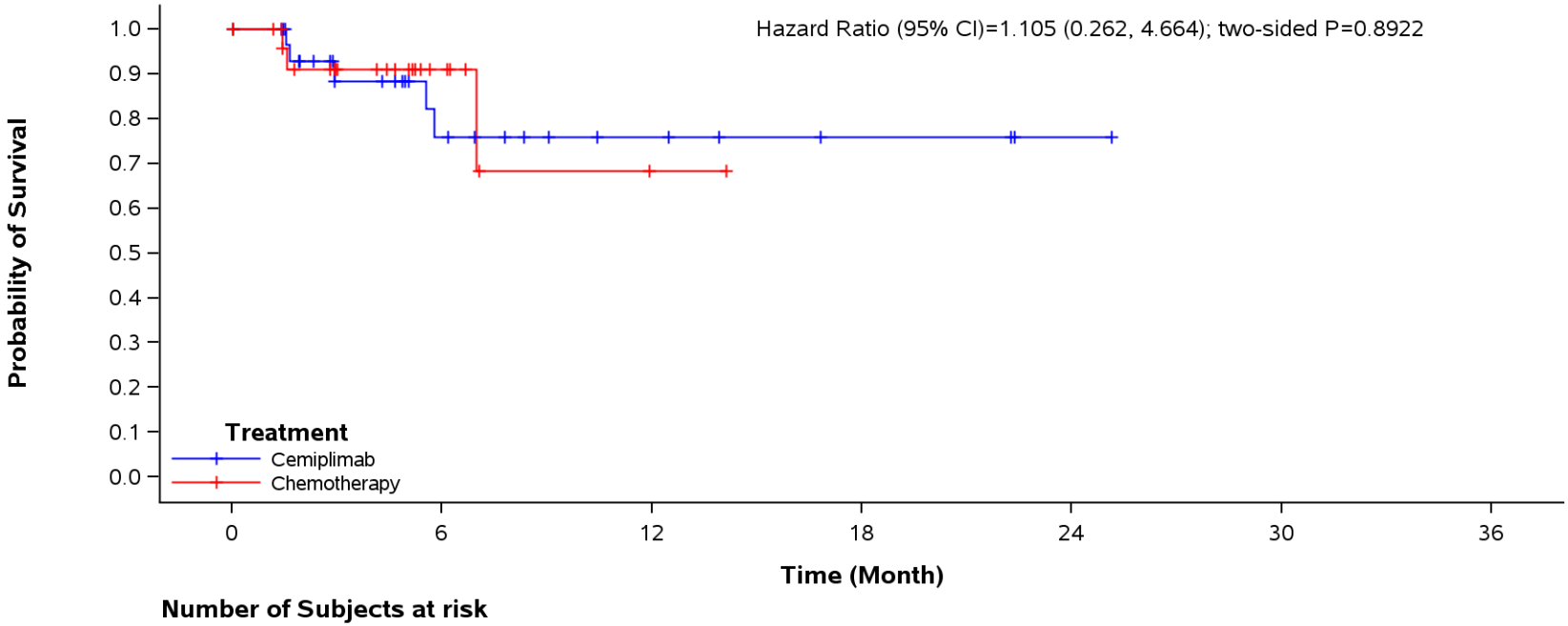

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 15 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 36 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Constipation - 10 pts sensitivity sustained deterioration



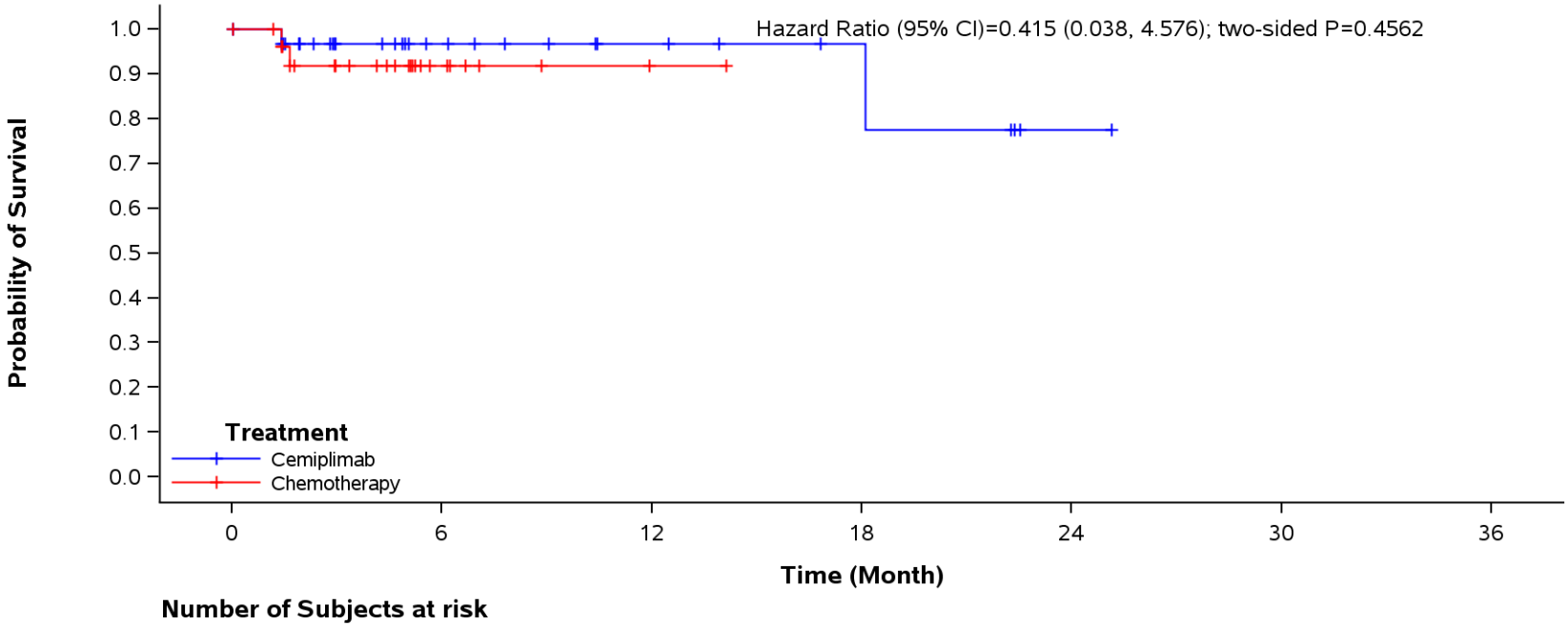

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Diarhoea - 10 pts sensitivity sustained deterioration



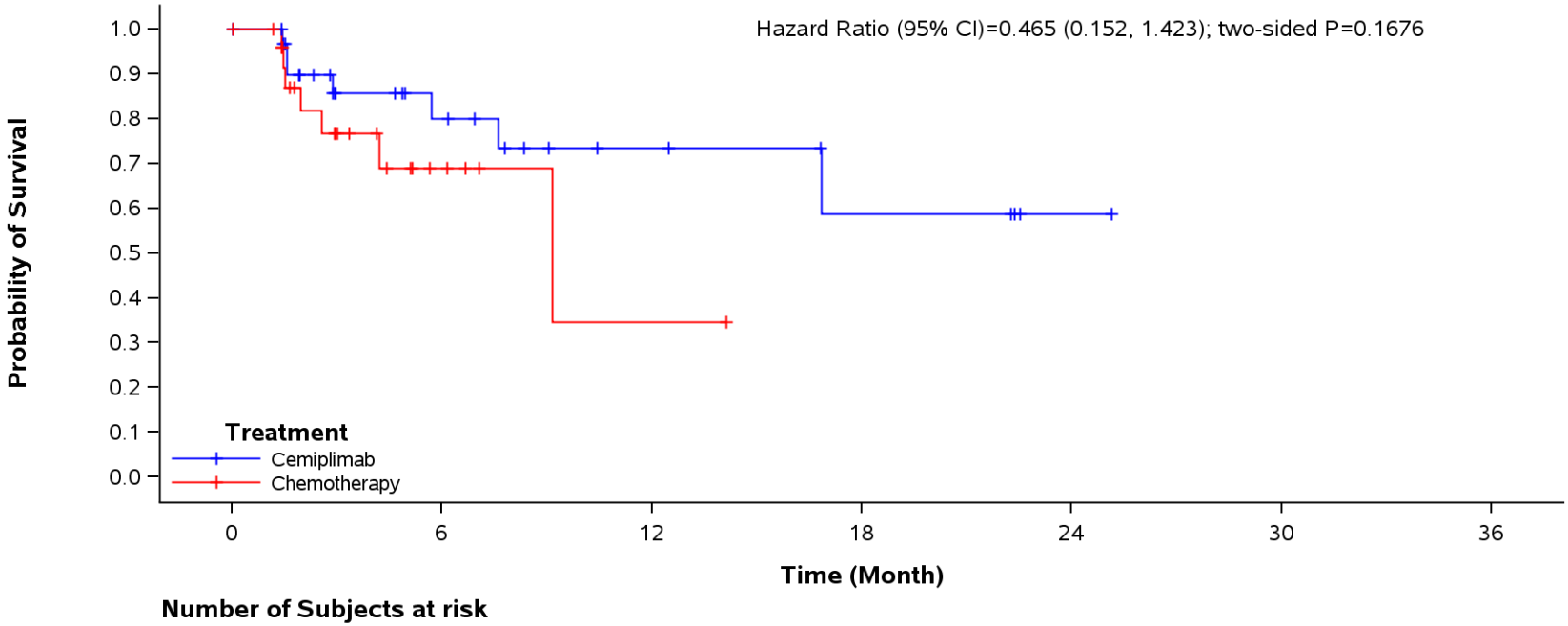

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 14 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Dyspnoea - 10 pts sensitivity sustained deterioration



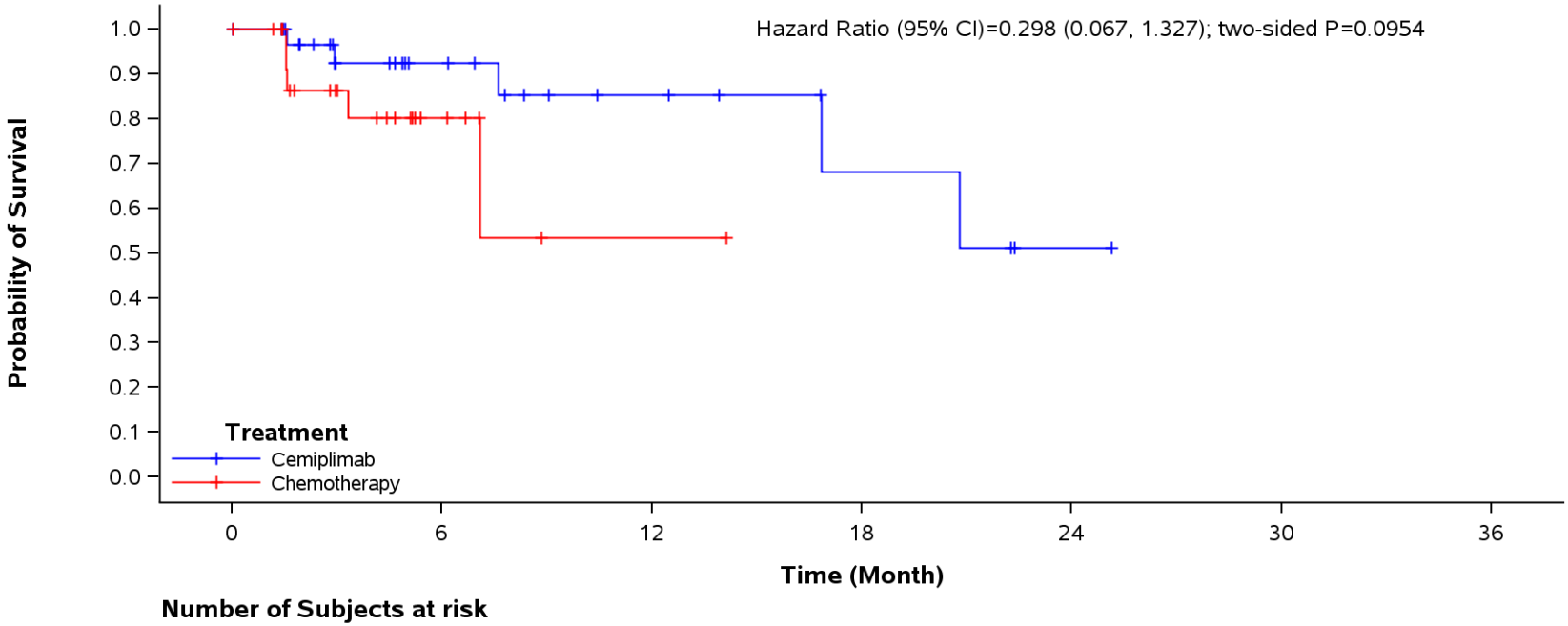

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 14 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 36 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Emotional Functioning - 10 pts sensitivity sustained deterioration



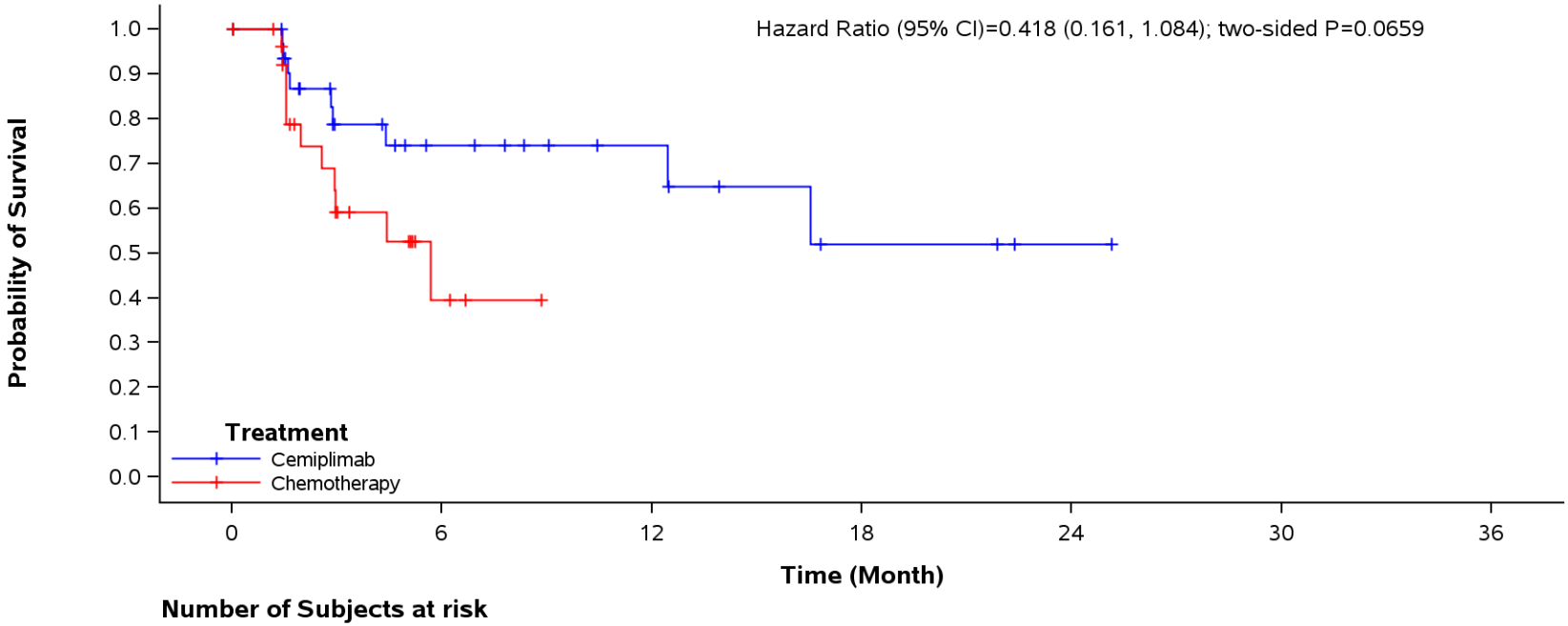

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 15 | 8 | 4 | 1 | 0 | 0 |
| Chemotherapy | 36 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Fatigue - 10 pts sensitivity sustained deterioration



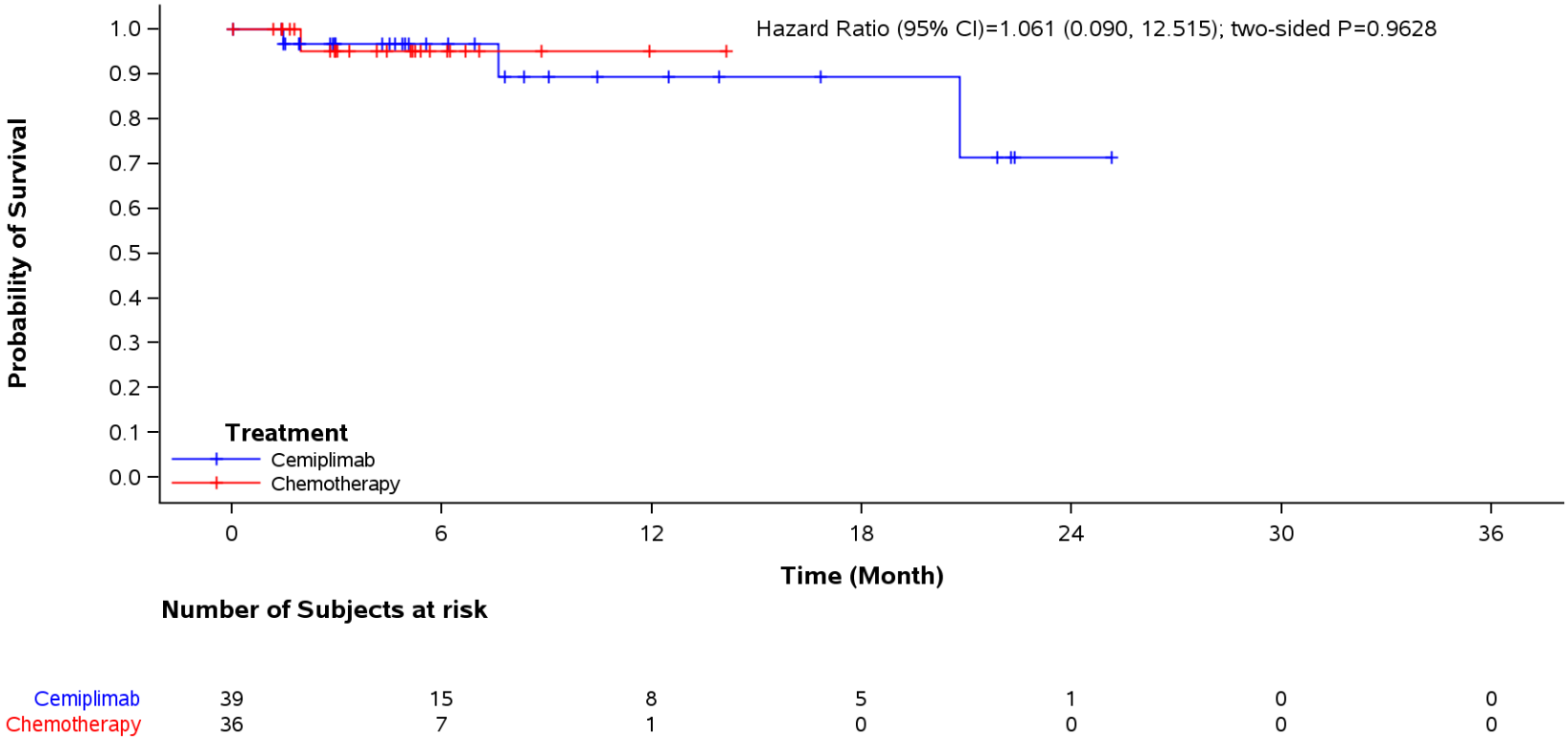

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Financial Problems - 10 pts sensitivity sustained deterioration



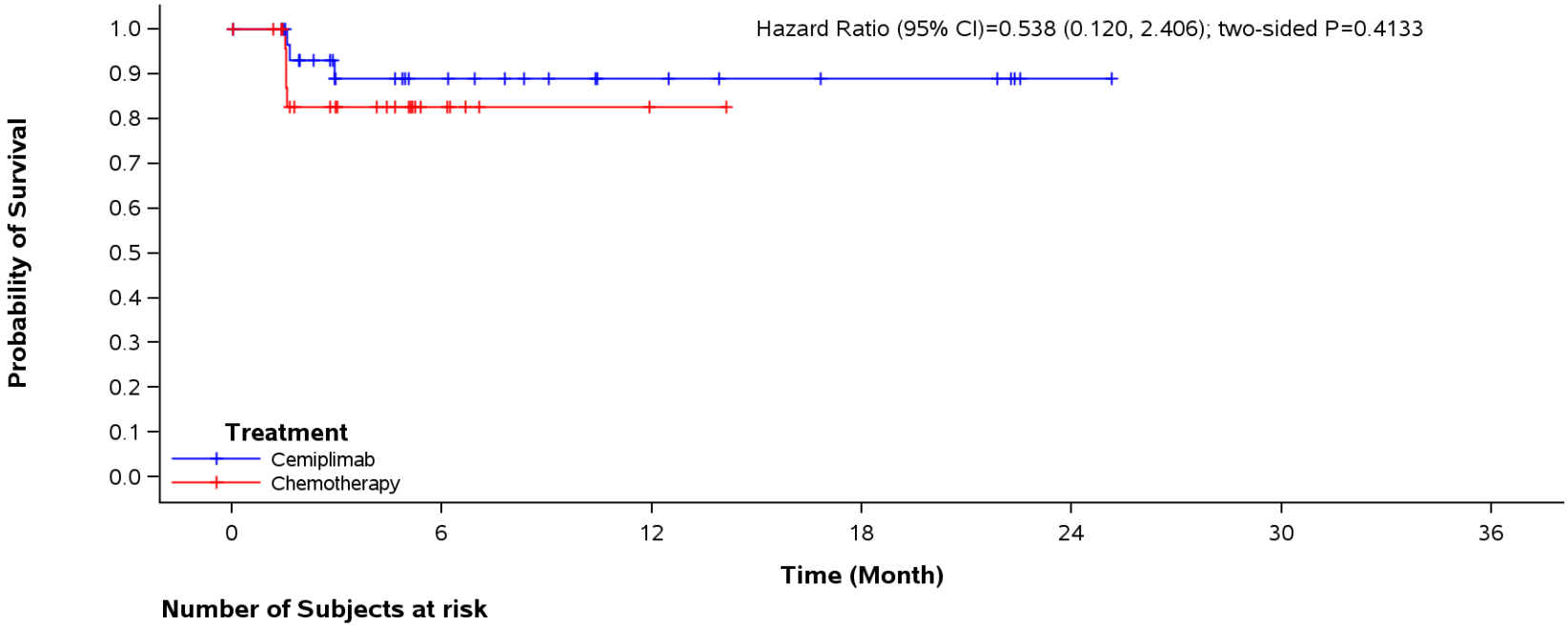

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 15 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



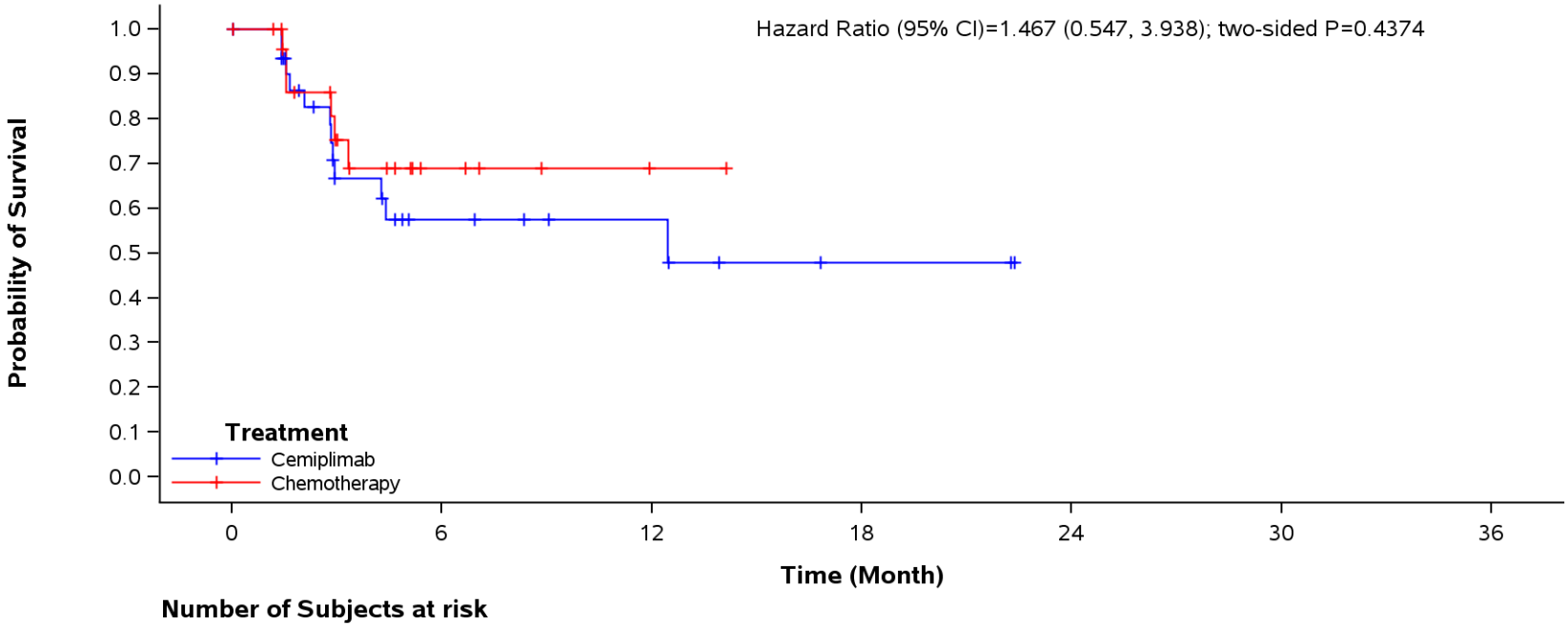

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 15 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Pain - 10 pts sensitivity sustained deterioration



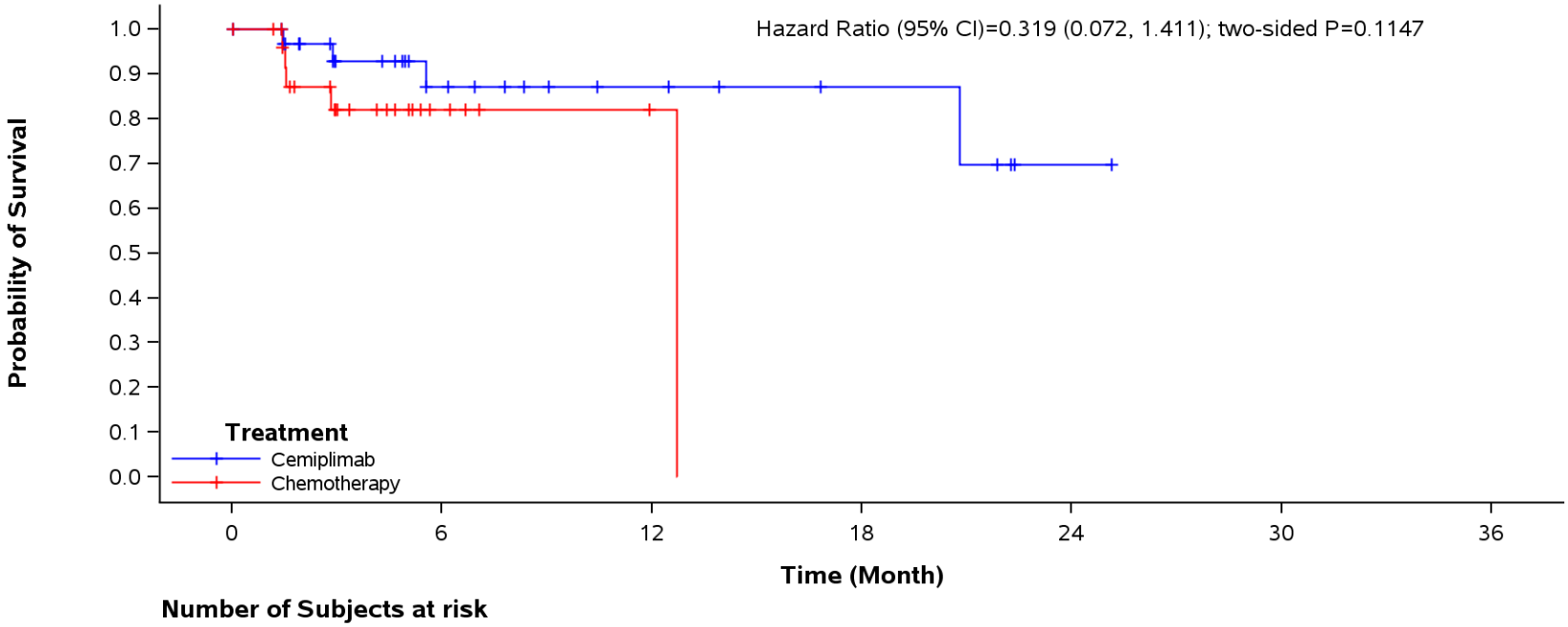

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 36 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

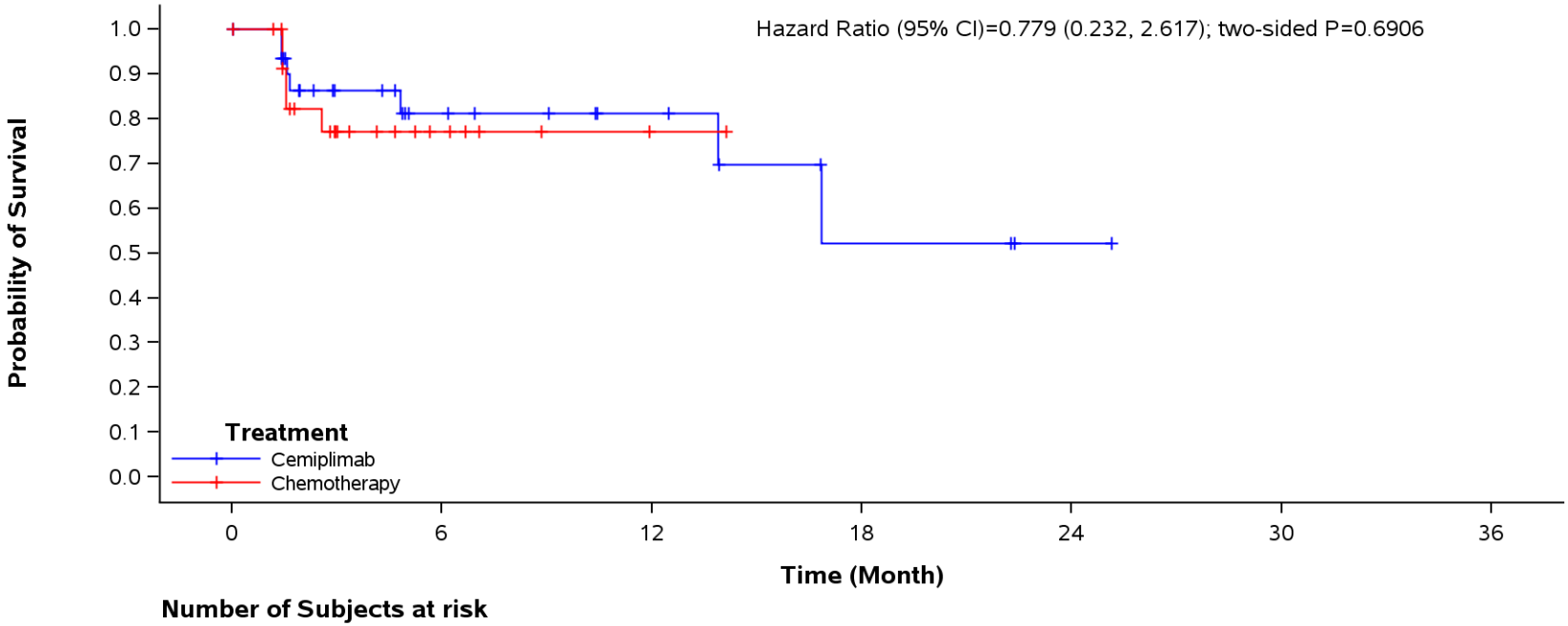
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 14 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

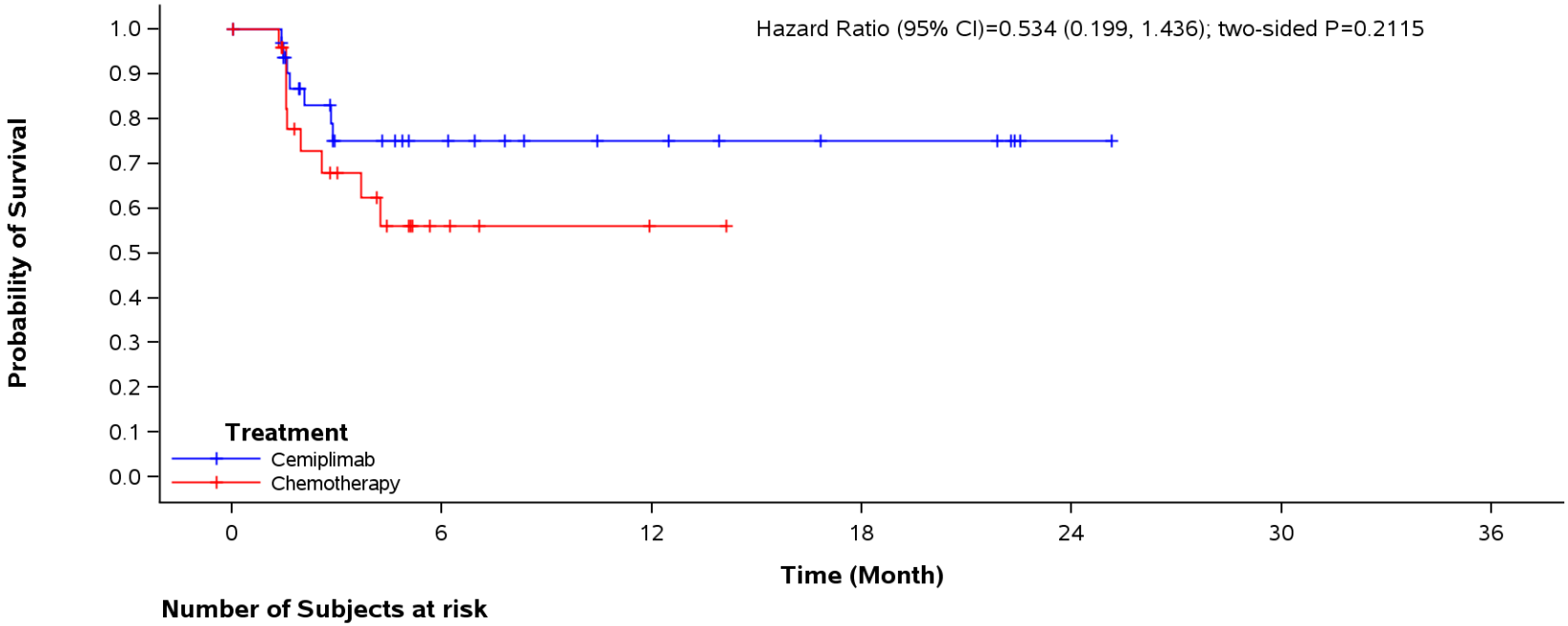
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Role Functioning - 10 pts sensitivity sustained deterioration



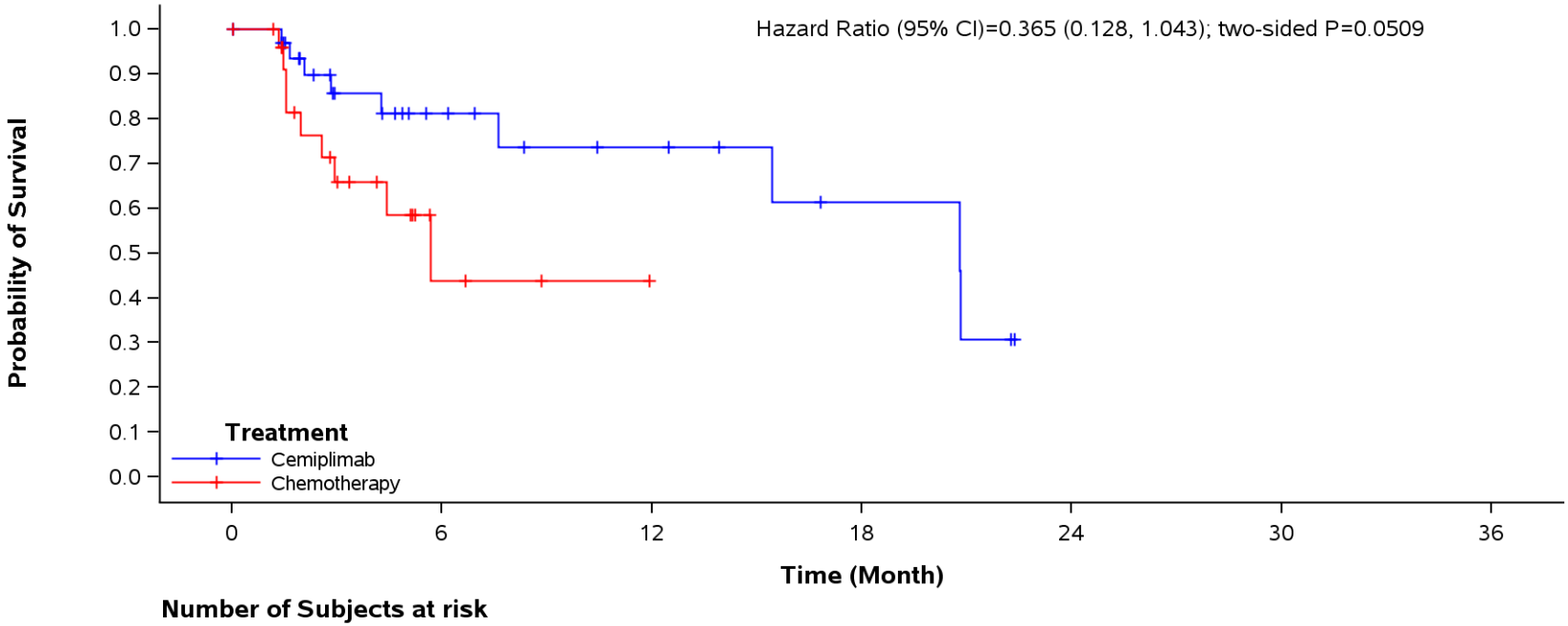

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 1 | 0 | 0 |
| Chemotherapy | 36 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Social Functioning - 10 pts sensitivity sustained deterioration



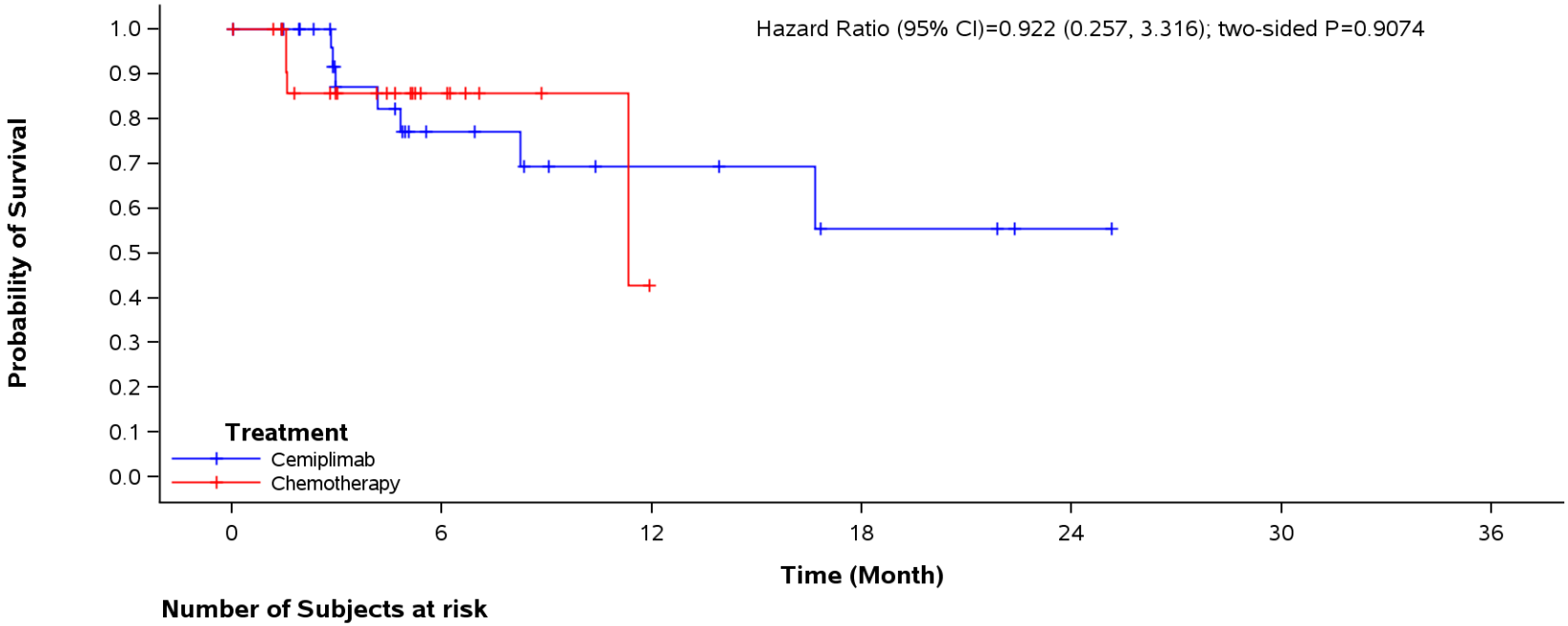

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 4 | 0 | 0 | 0 |
| Chemotherapy | 36 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Insomnia - 10 pts sensitivity sustained deterioration



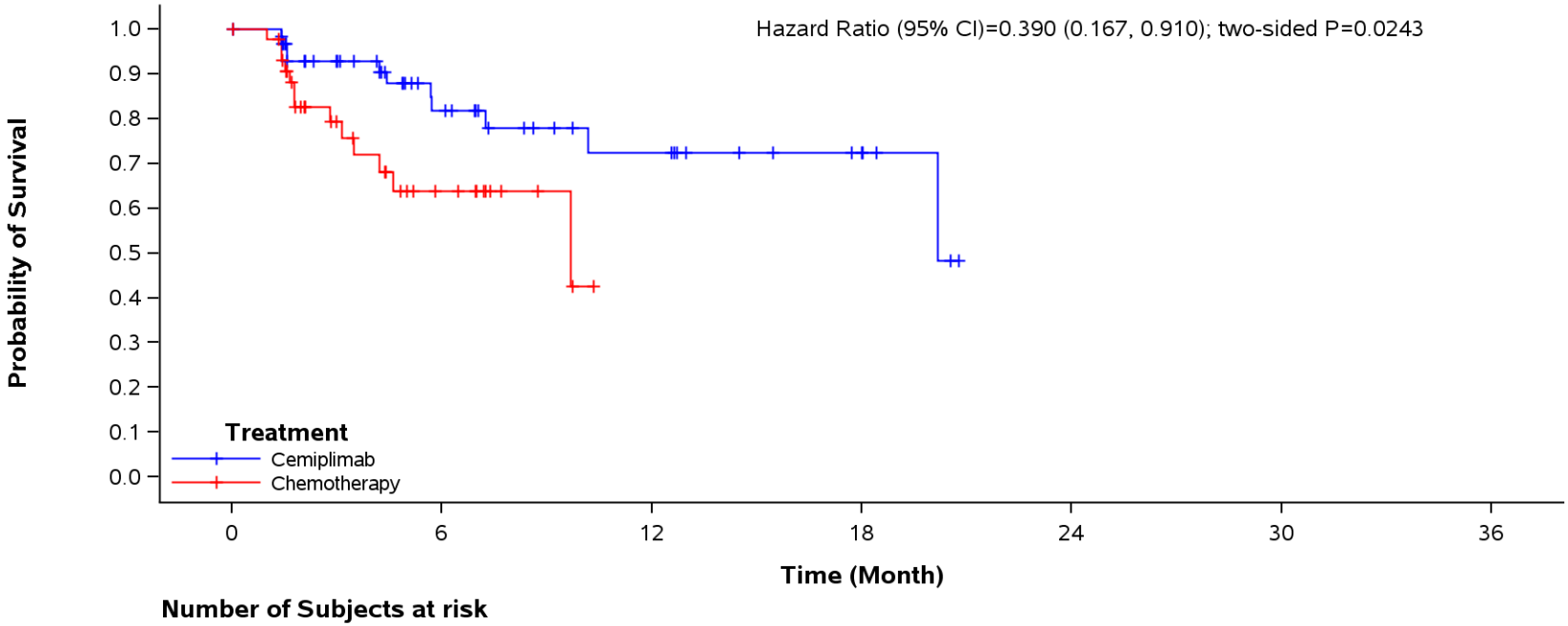

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 11 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 36 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Appetite loss - 10 pts sensitivity sustained deterioration



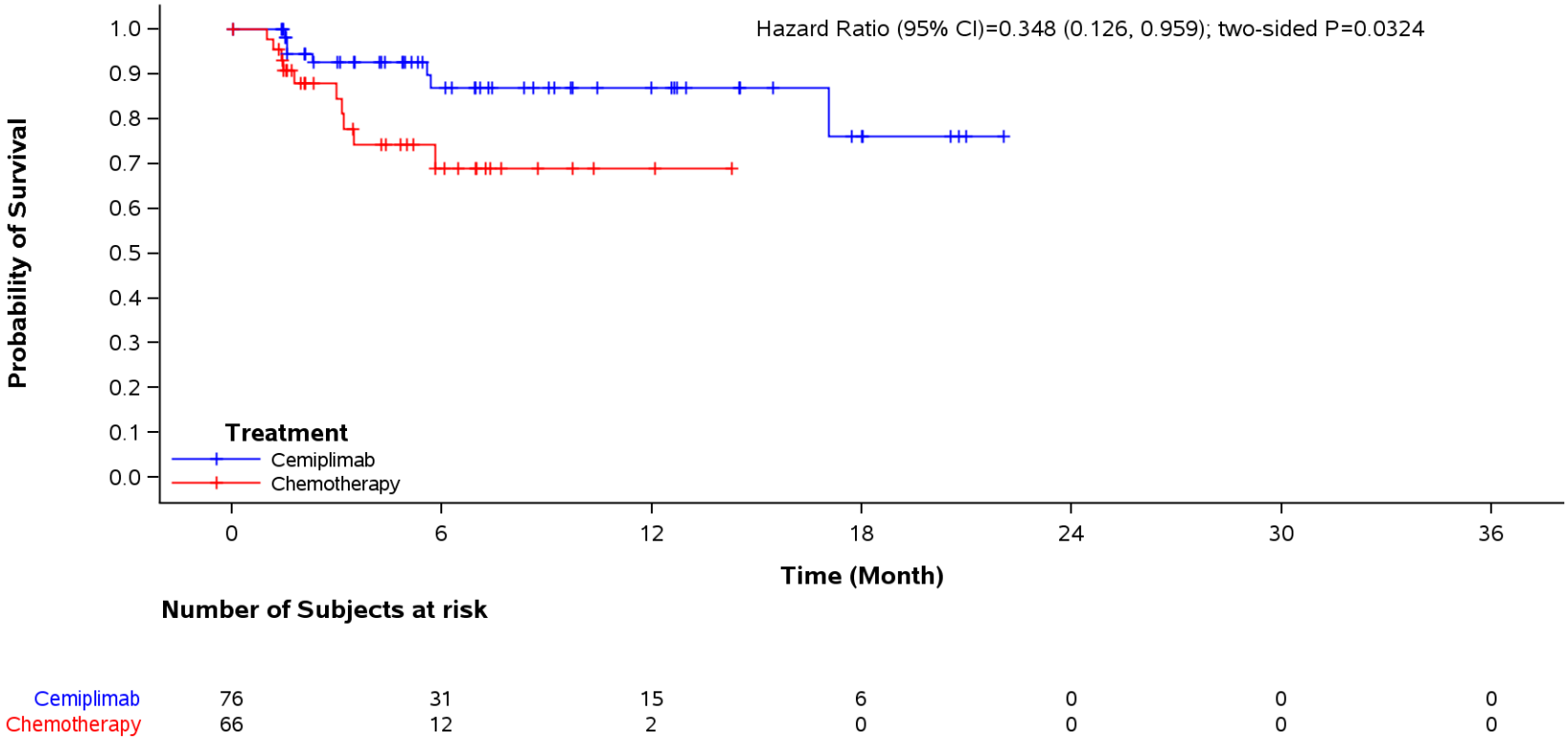

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 27 | 13 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Cognitive Functioning - 10 pts sensitivity sustained deterioration



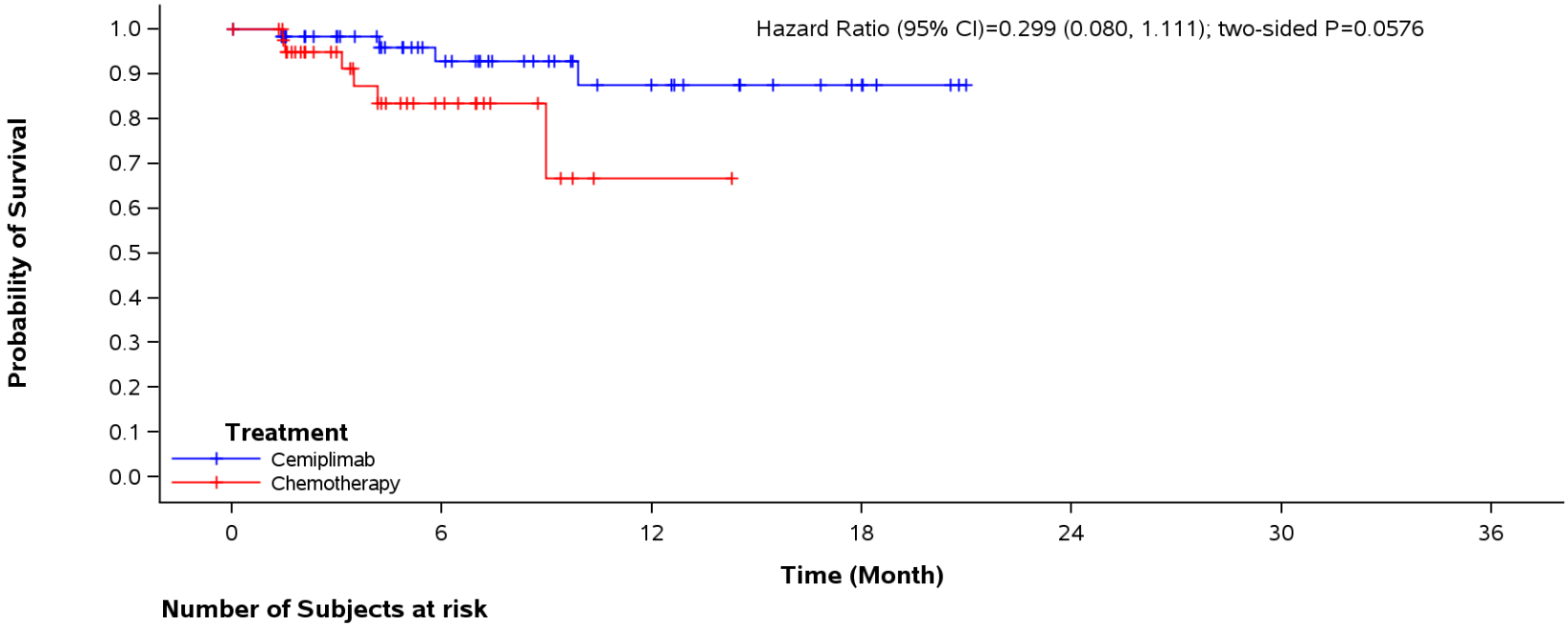

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 15 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Constipation - 10 pts sensitivity sustained deterioration



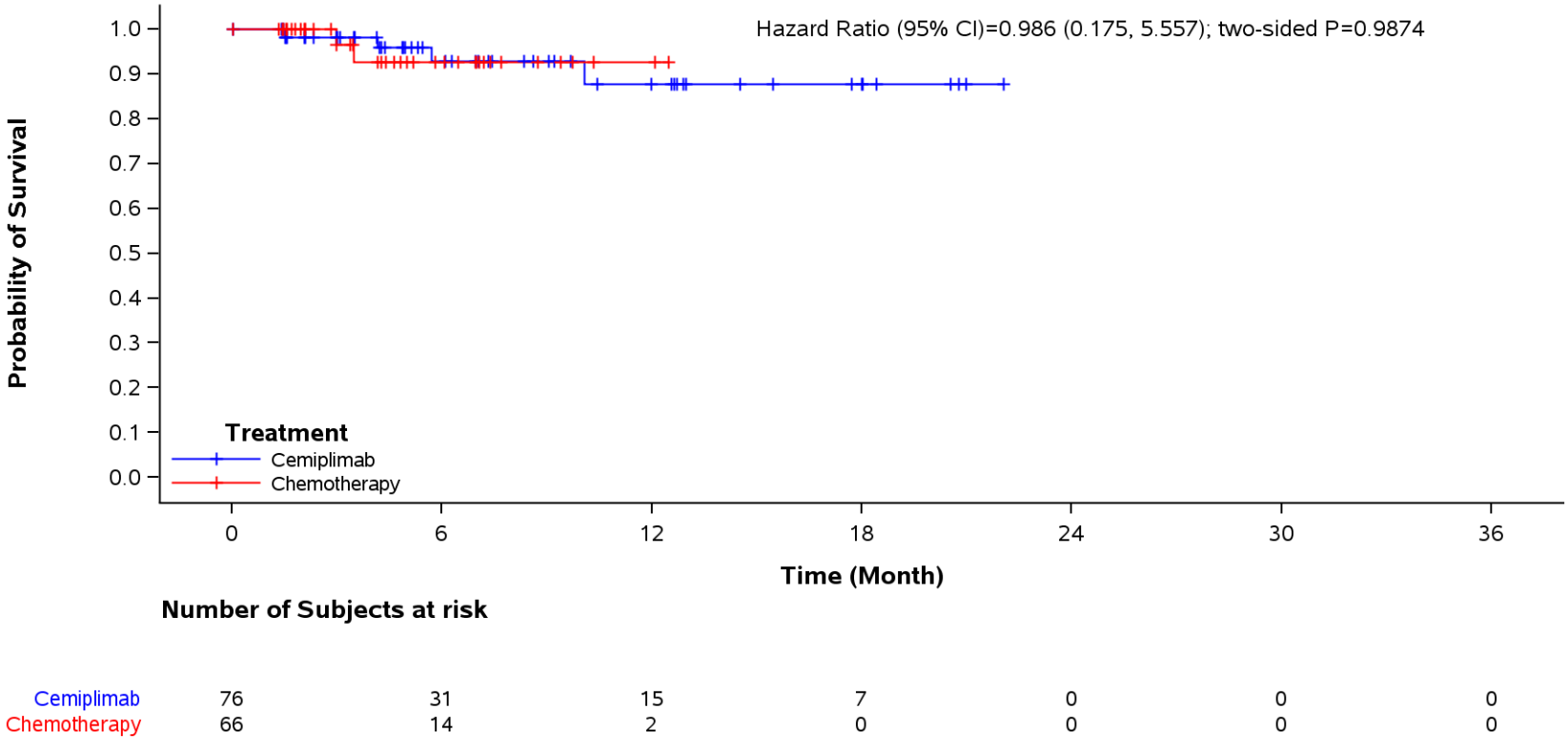

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 14 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Diarhoea - 10 pts sensitivity sustained deterioration



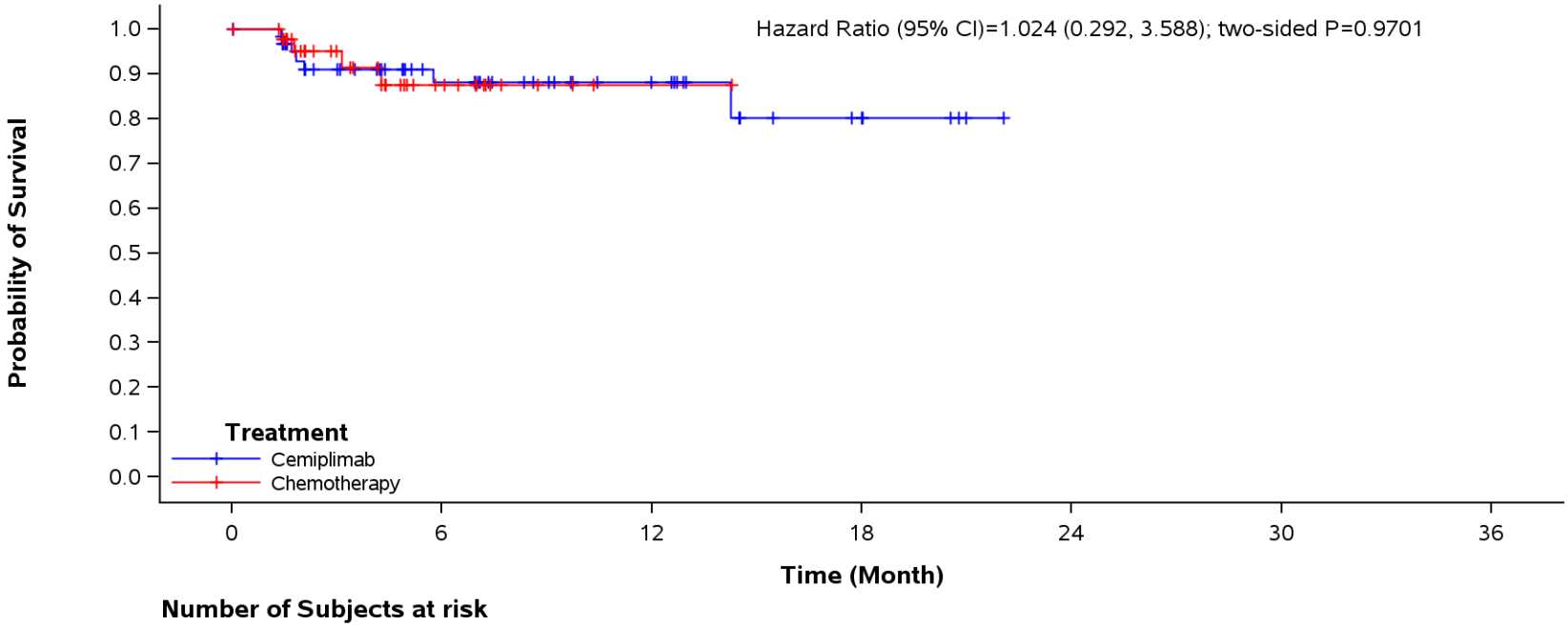

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 15 | 7 | 0 | 0 | 0 |
| Chemotherapy | 66 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Dyspnoea - 10 pts sensitivity sustained deterioration



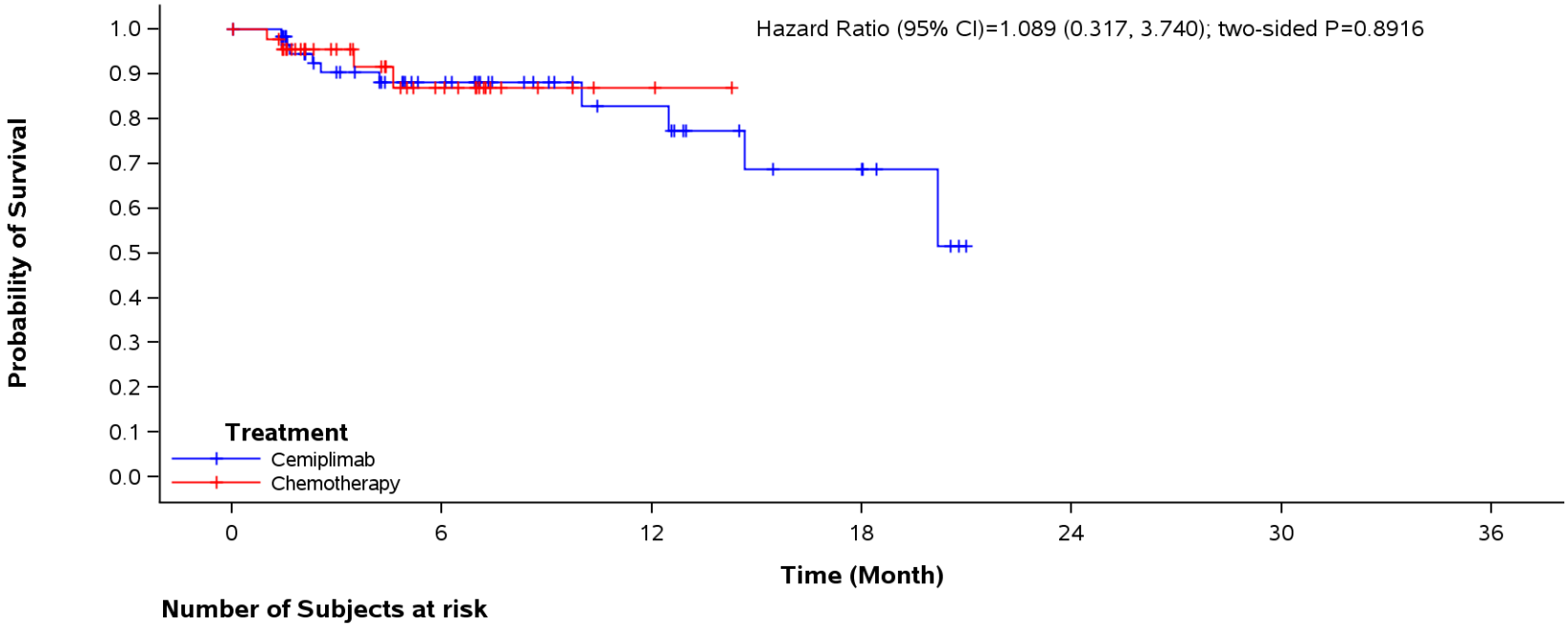

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 16 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Emotional Functioning - 10 pts sensitivity sustained deterioration



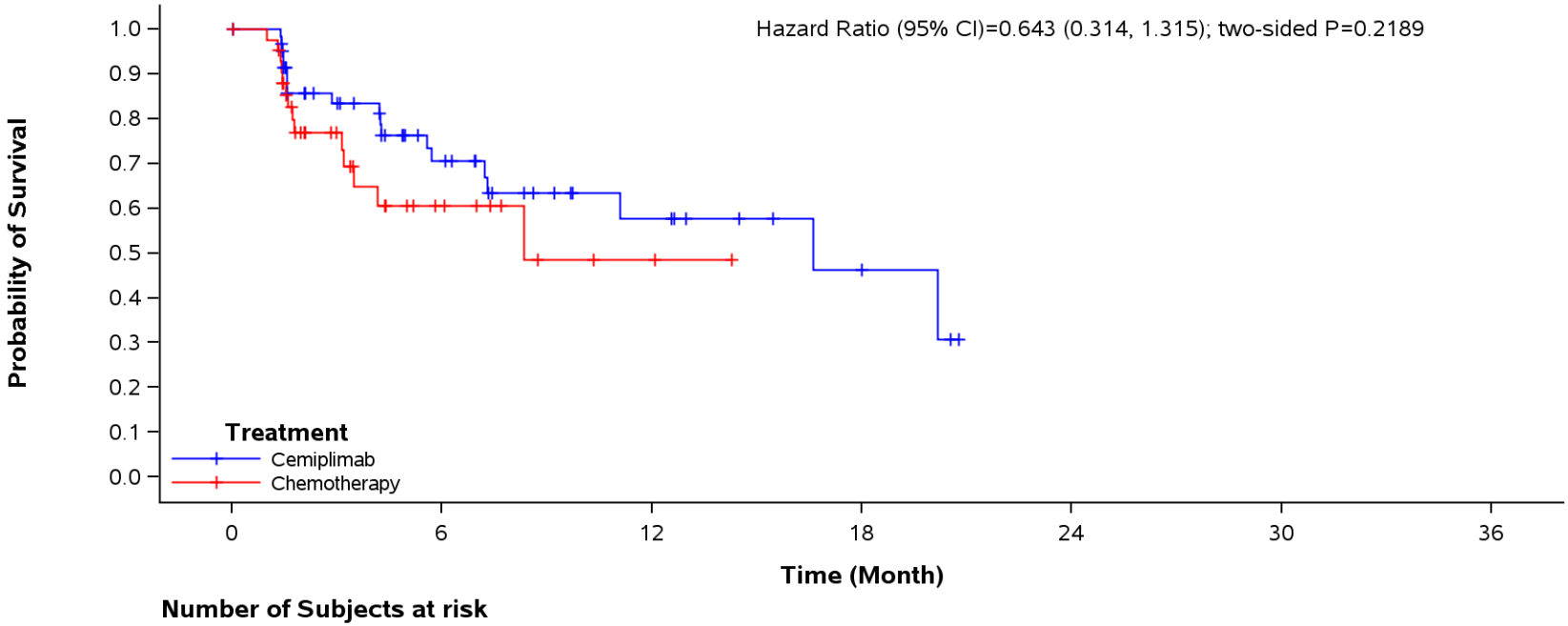

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 15 | 7 | 0 | 0 | 0 |
| Chemotherapy | 66 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Fatigue - 10 pts sensitivity sustained deterioration



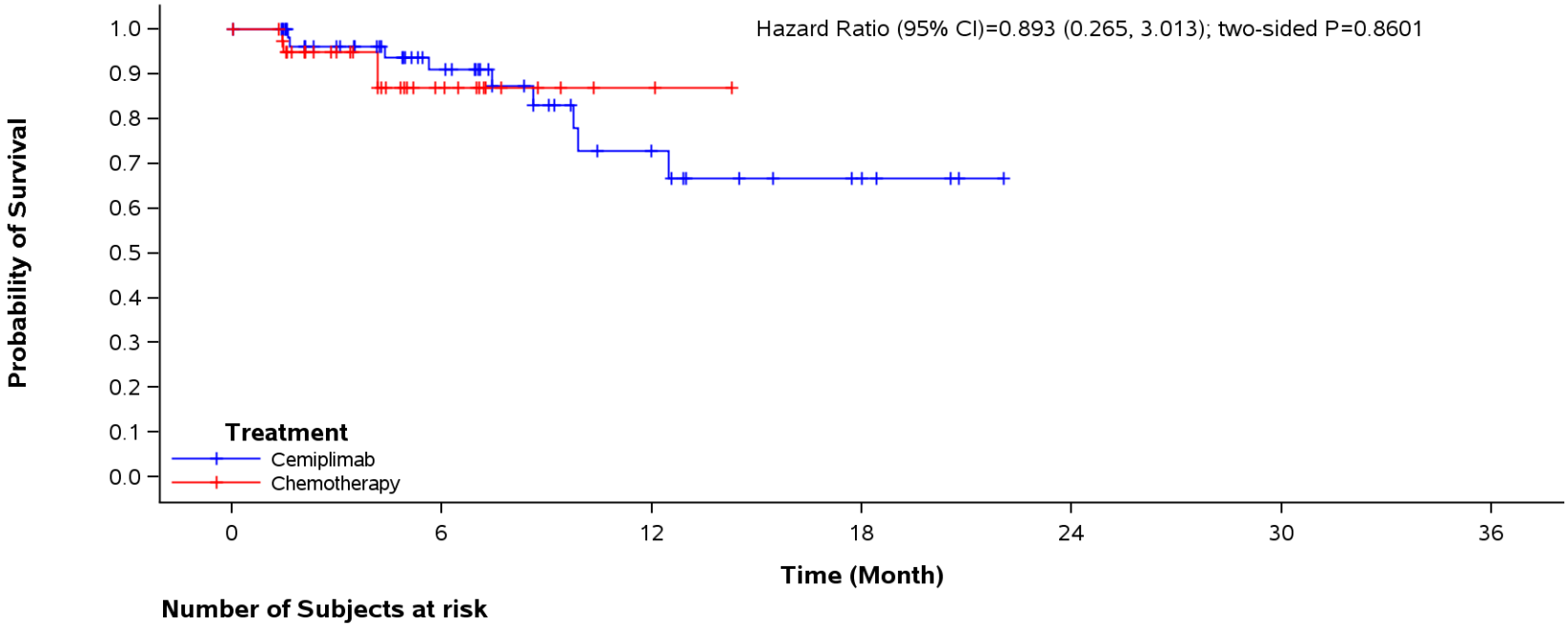

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 24 | 10 | 4 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Financial Problems - 10 pts sensitivity sustained deterioration



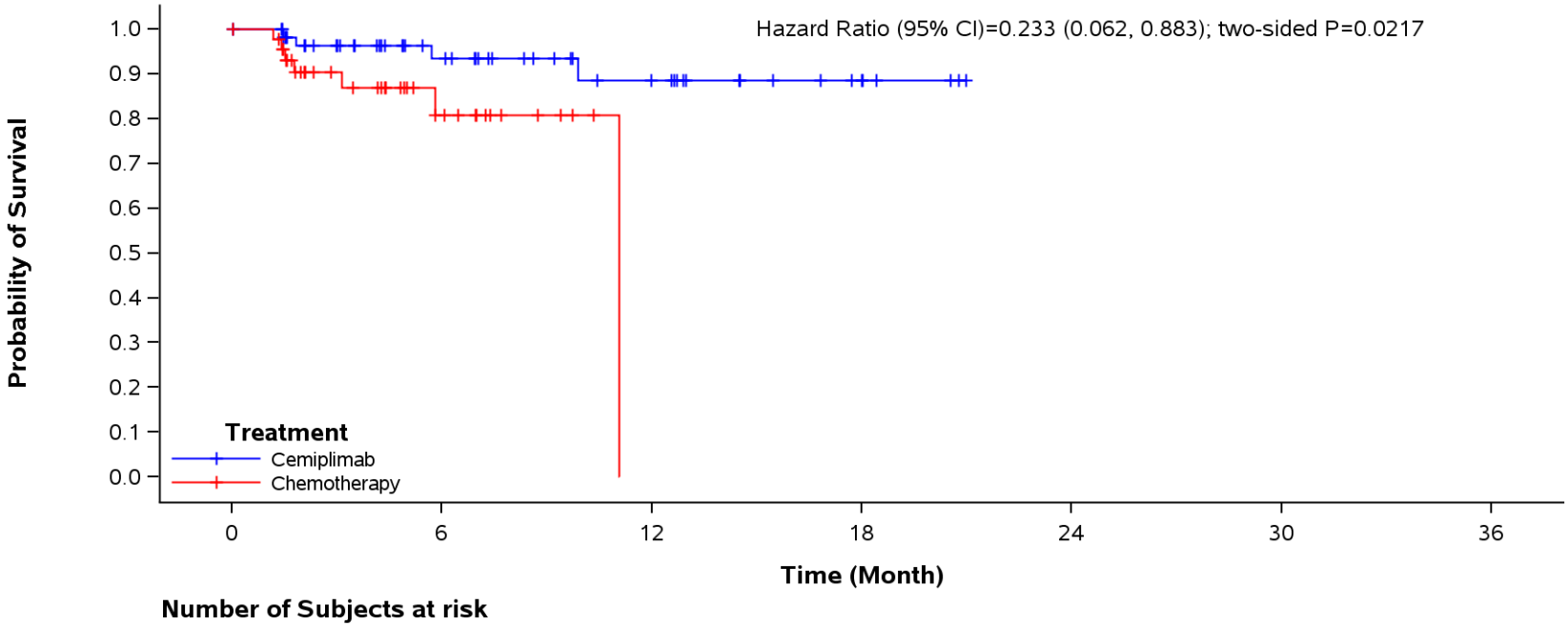

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 32 | 12 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



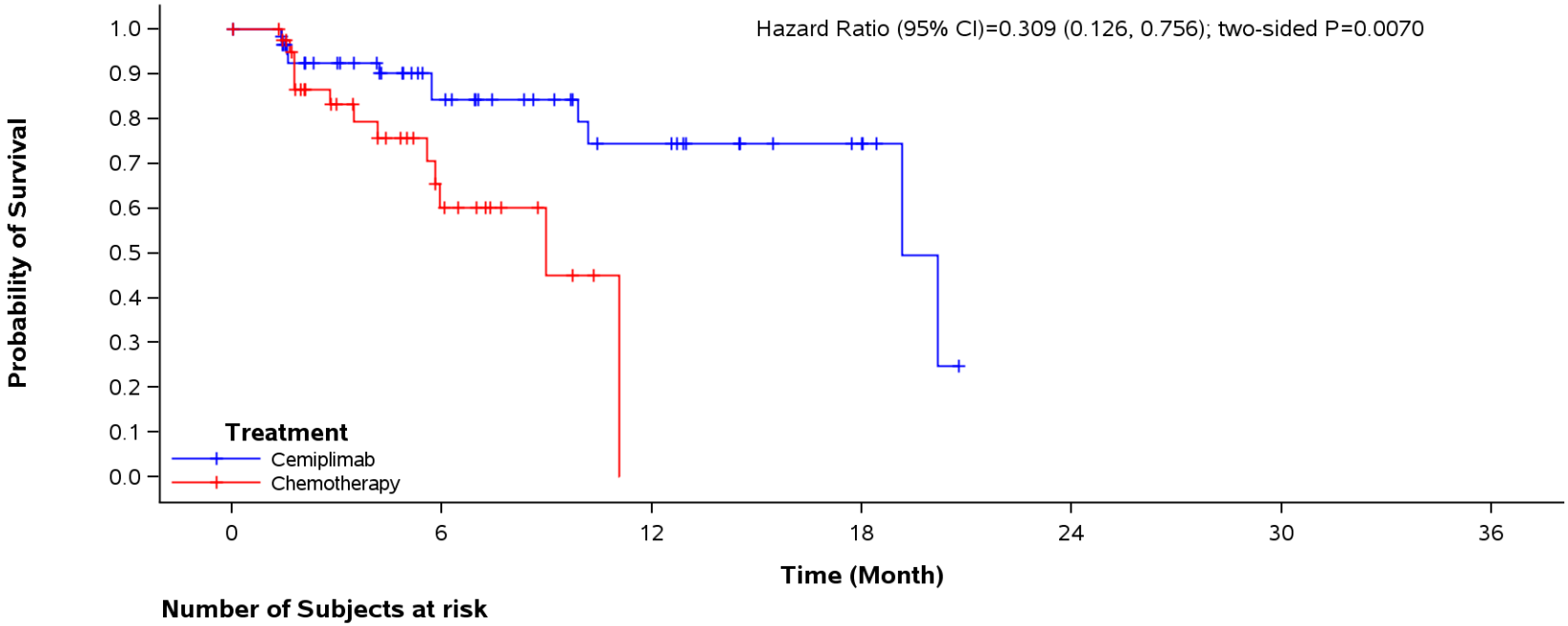

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 33 | 16 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Pain - 10 pts sensitivity sustained deterioration



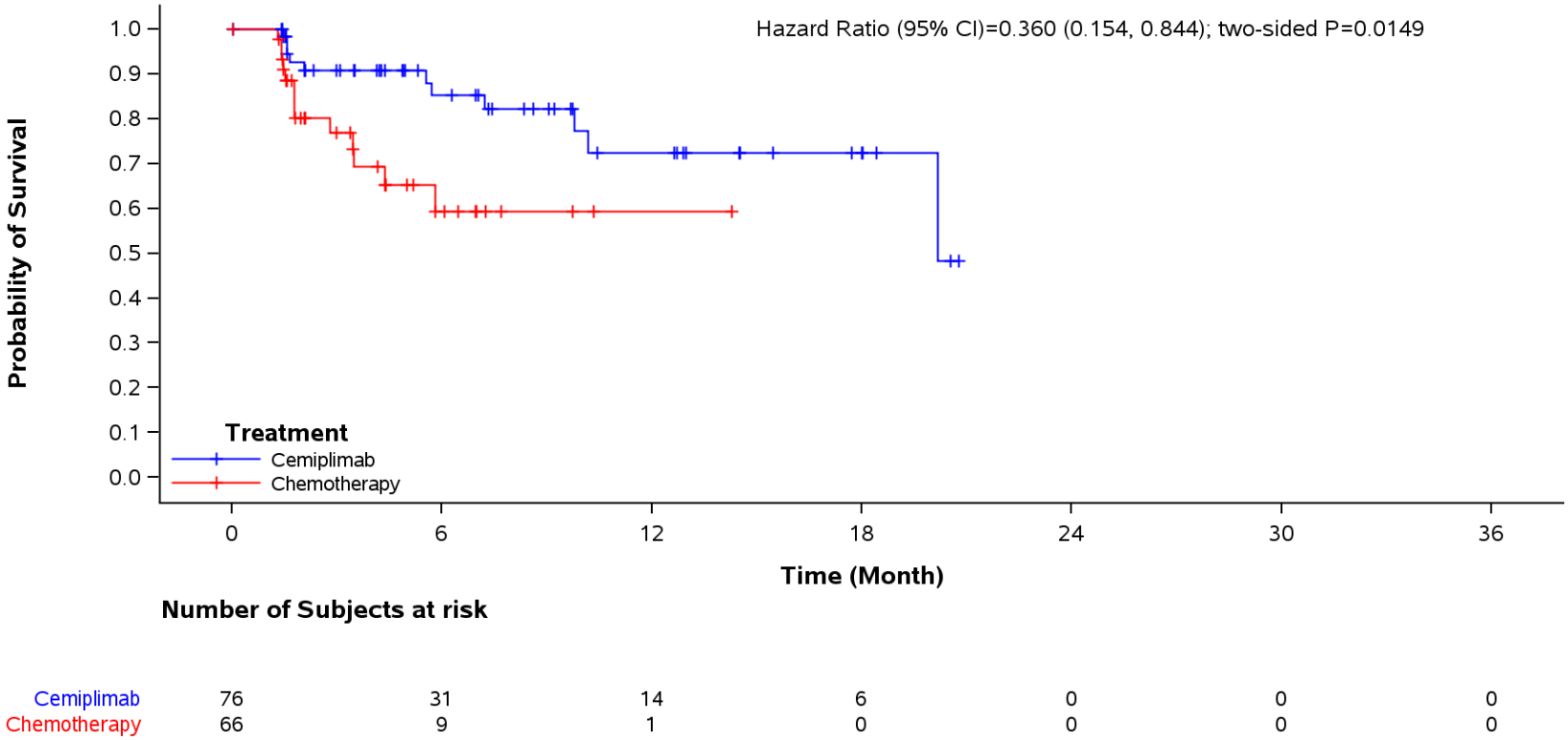

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 29 | 14 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Physical Functioning - 10 pts sensitivity sustained deterioration



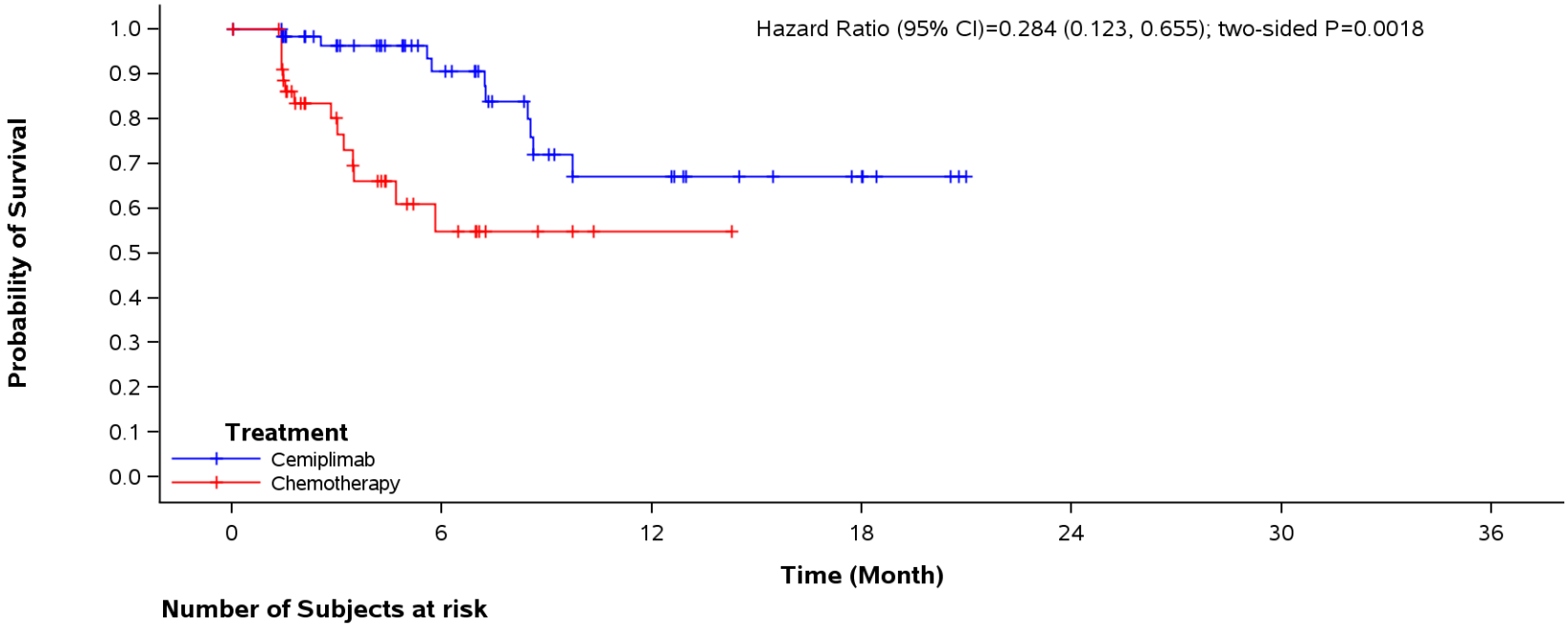

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 14 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Global health status / QoL - 10 pts sensitivity sustained deterioration



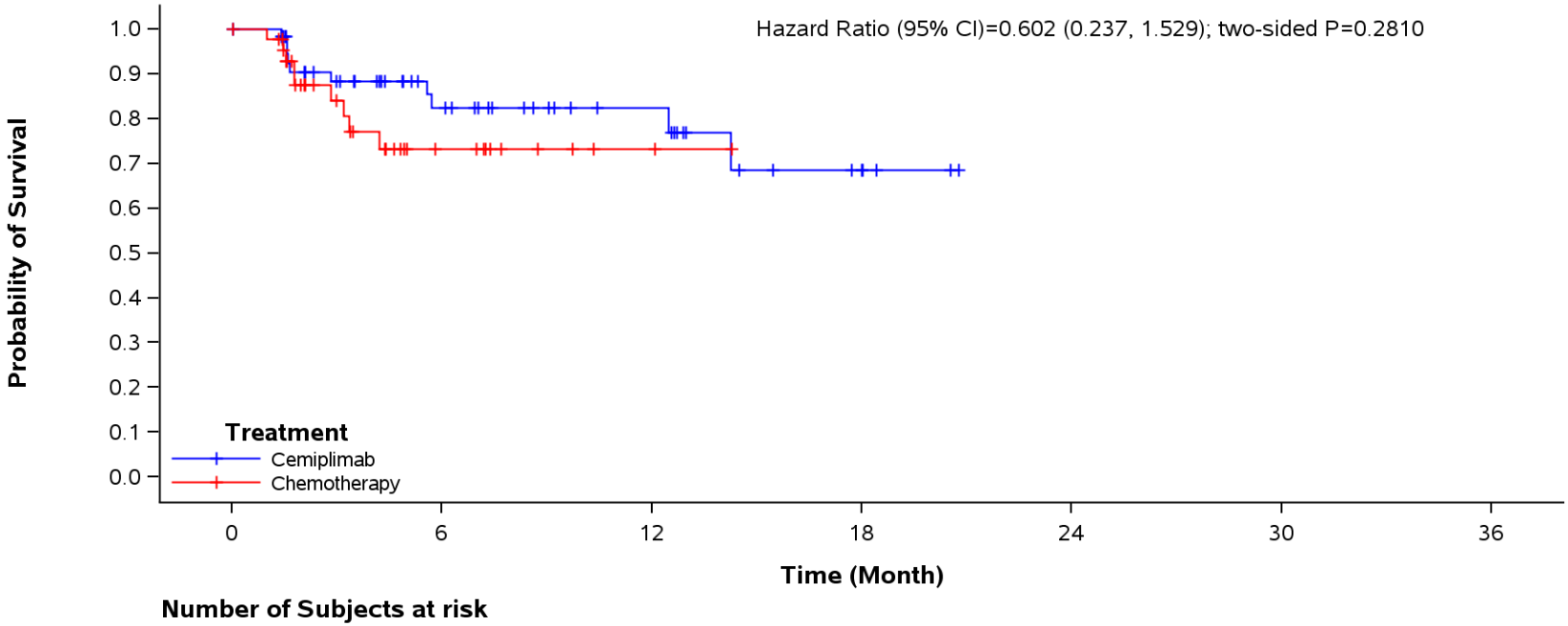

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 32 | 13 | 6 | 0 | 0 | 0 |
| Chemotherapy | 66 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Role Functioning - 10 pts sensitivity sustained deterioration



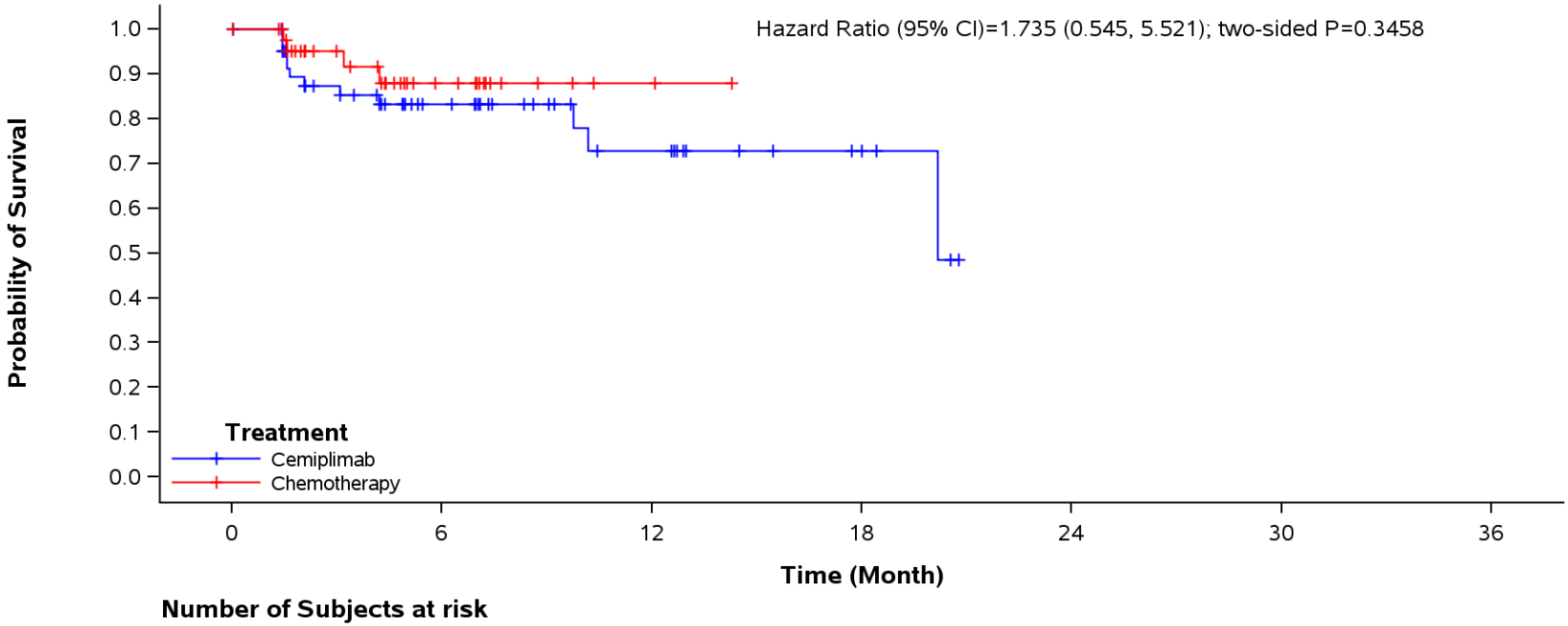

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 28 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Social Functioning - 10 pts sensitivity sustained deterioration



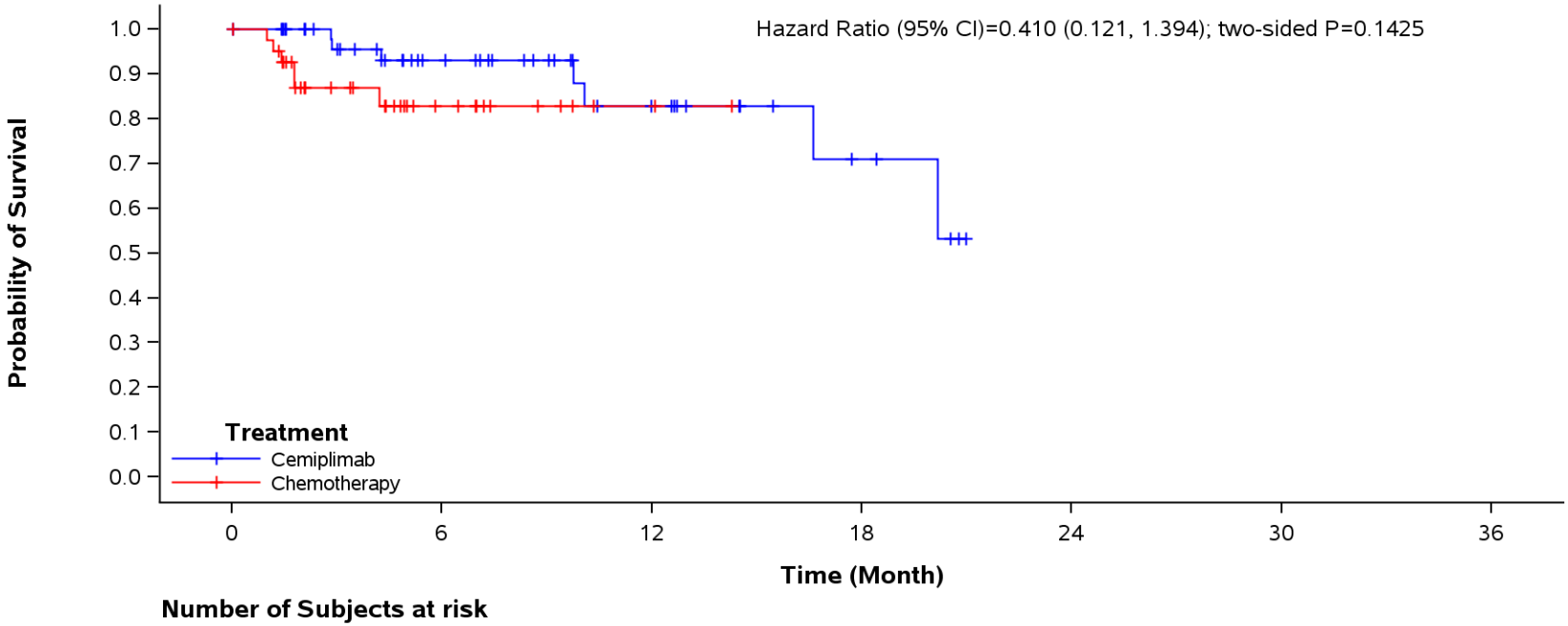

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 29 | 13 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Insomnia - 10 pts sensitivity sustained deterioration



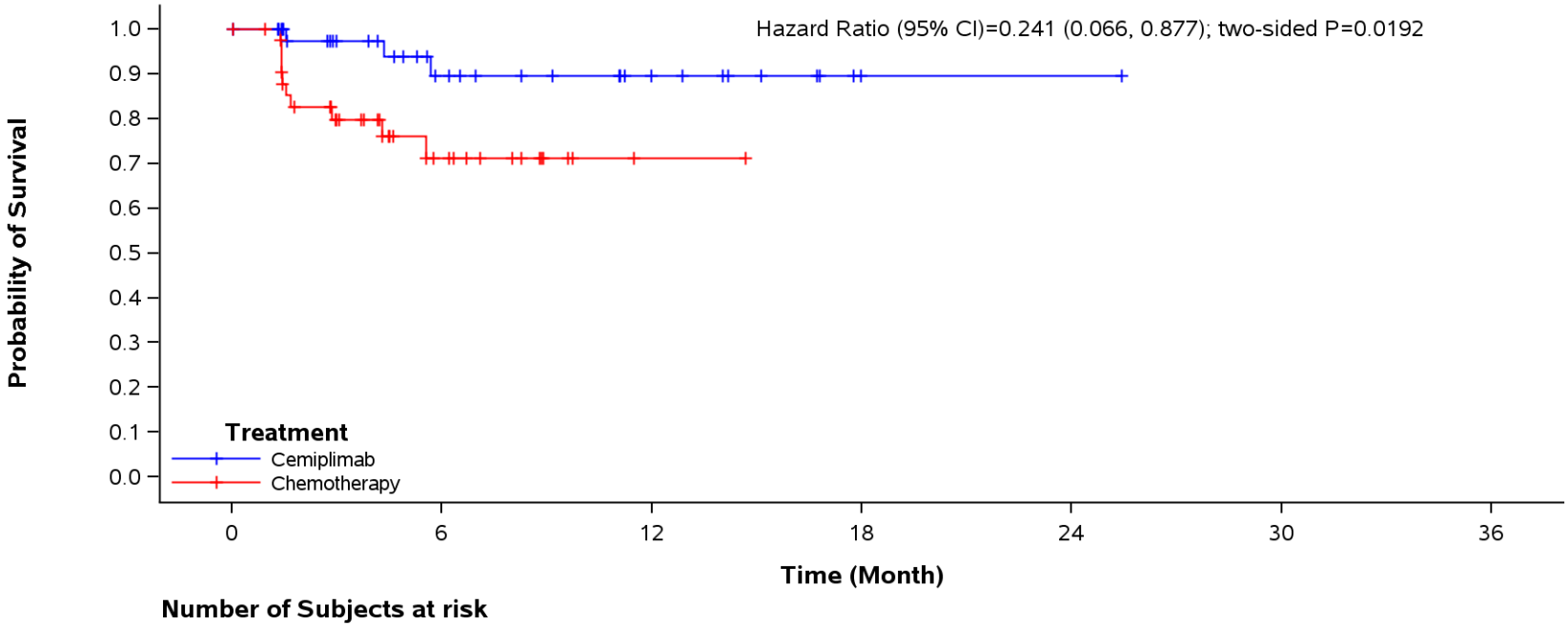

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 31 | 14 | 5 | 0 | 0 | 0 |
| Chemotherapy | 66 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Appetite loss - 10 pts sensitivity sustained deterioration



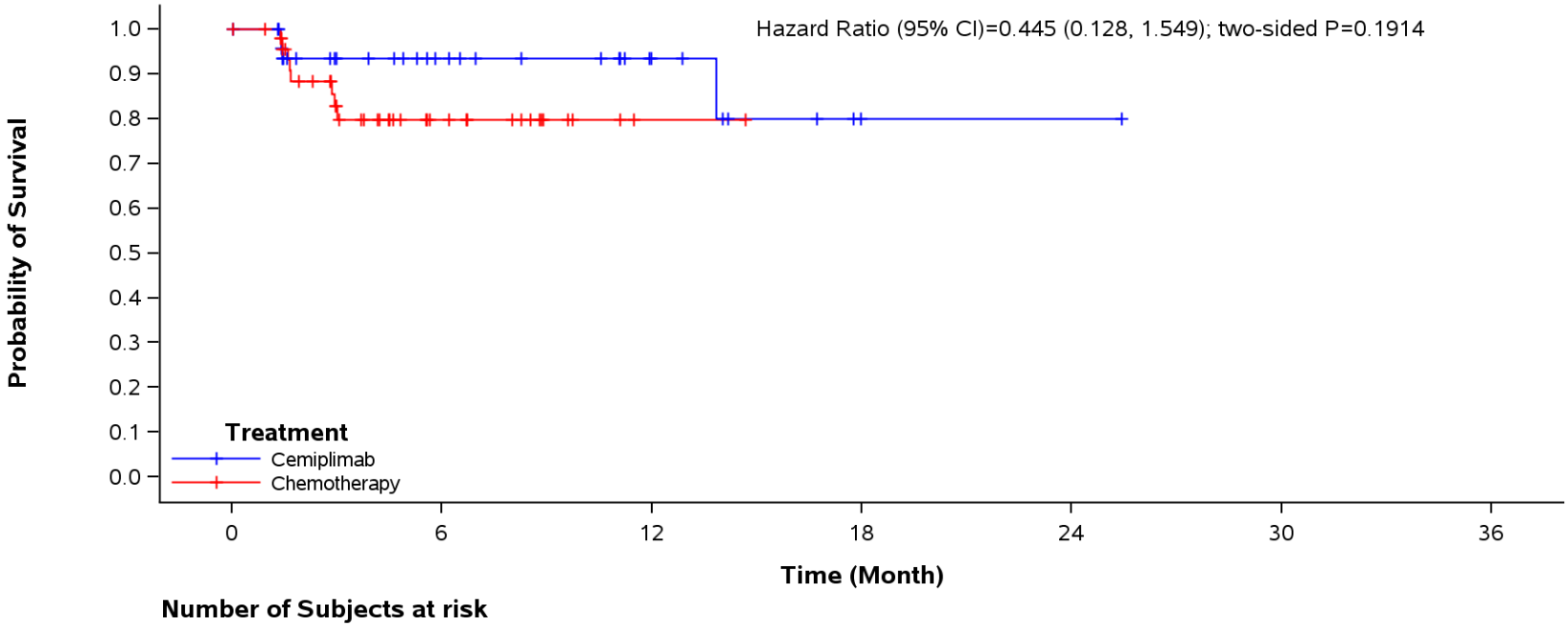

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 9 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Cognitive Functioning - 10 pts sensitivity sustained deterioration



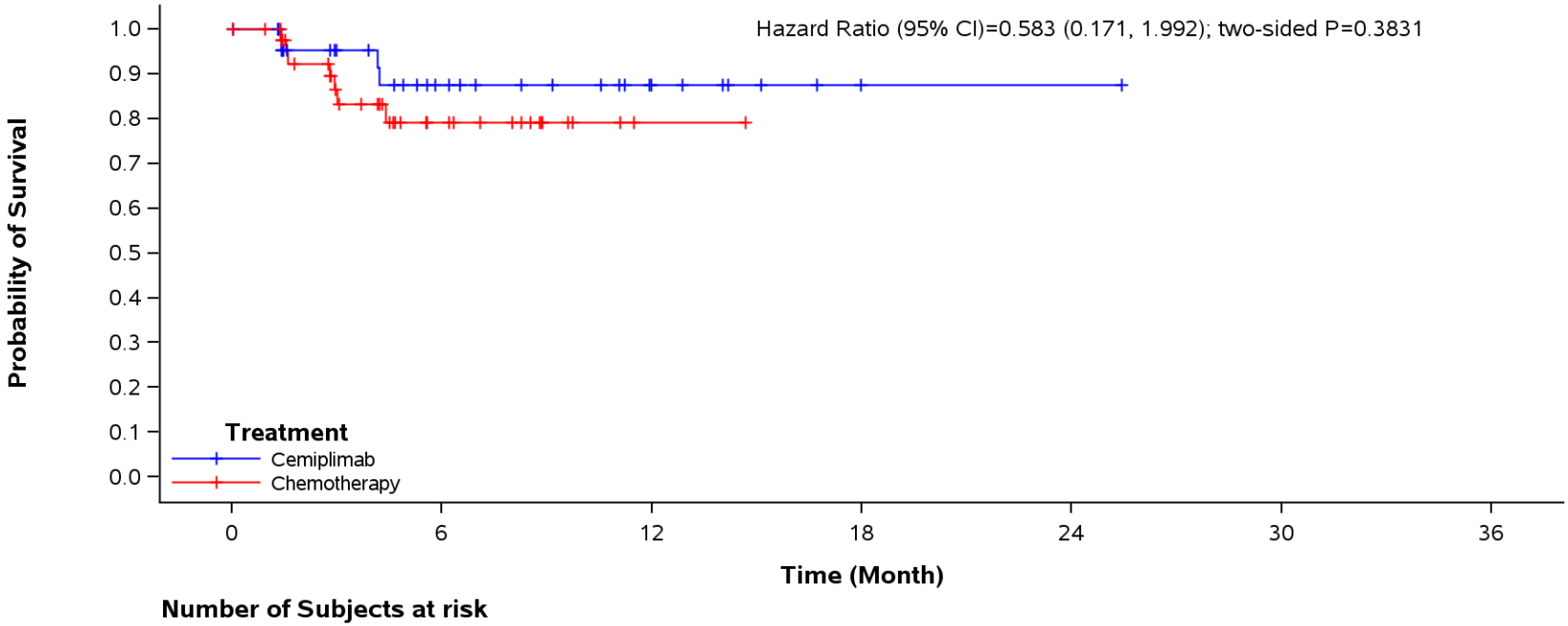

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Constipation - 10 pts sensitivity sustained deterioration



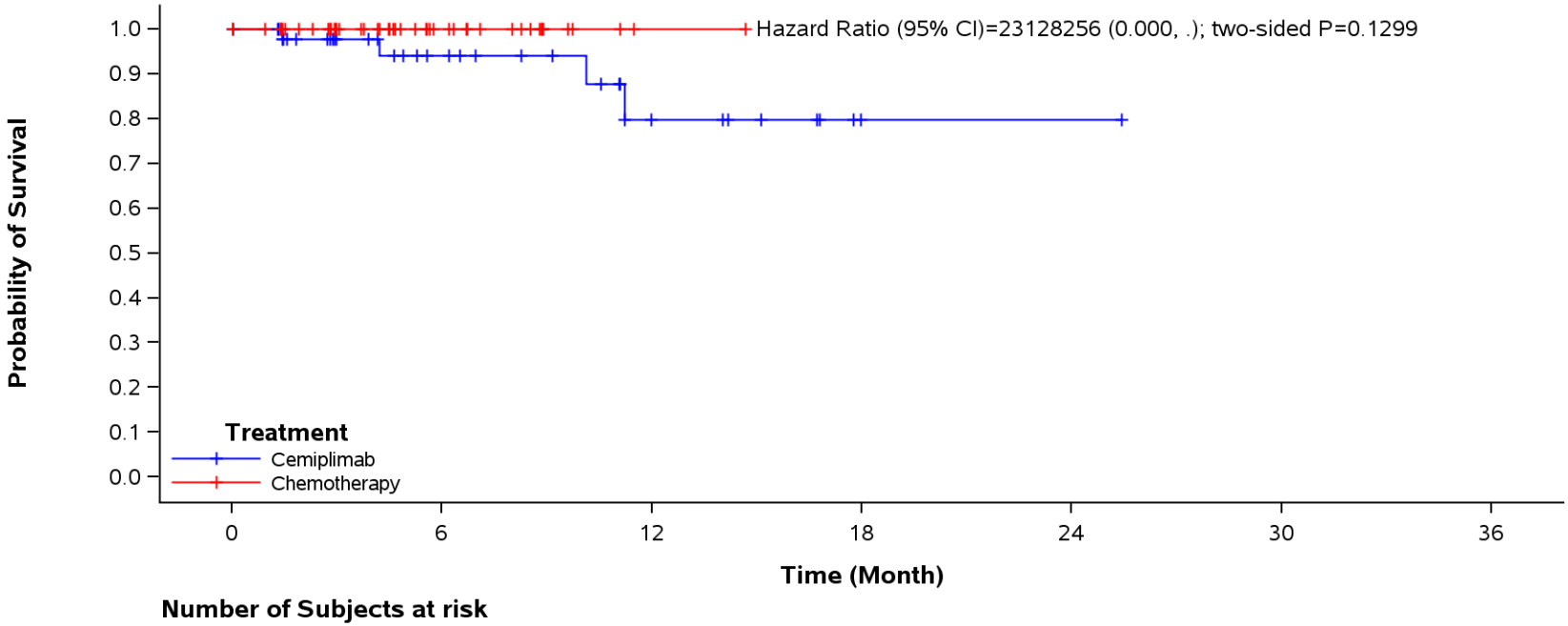

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 17 | 7 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Diarhoea - 10 pts sensitivity sustained deterioration



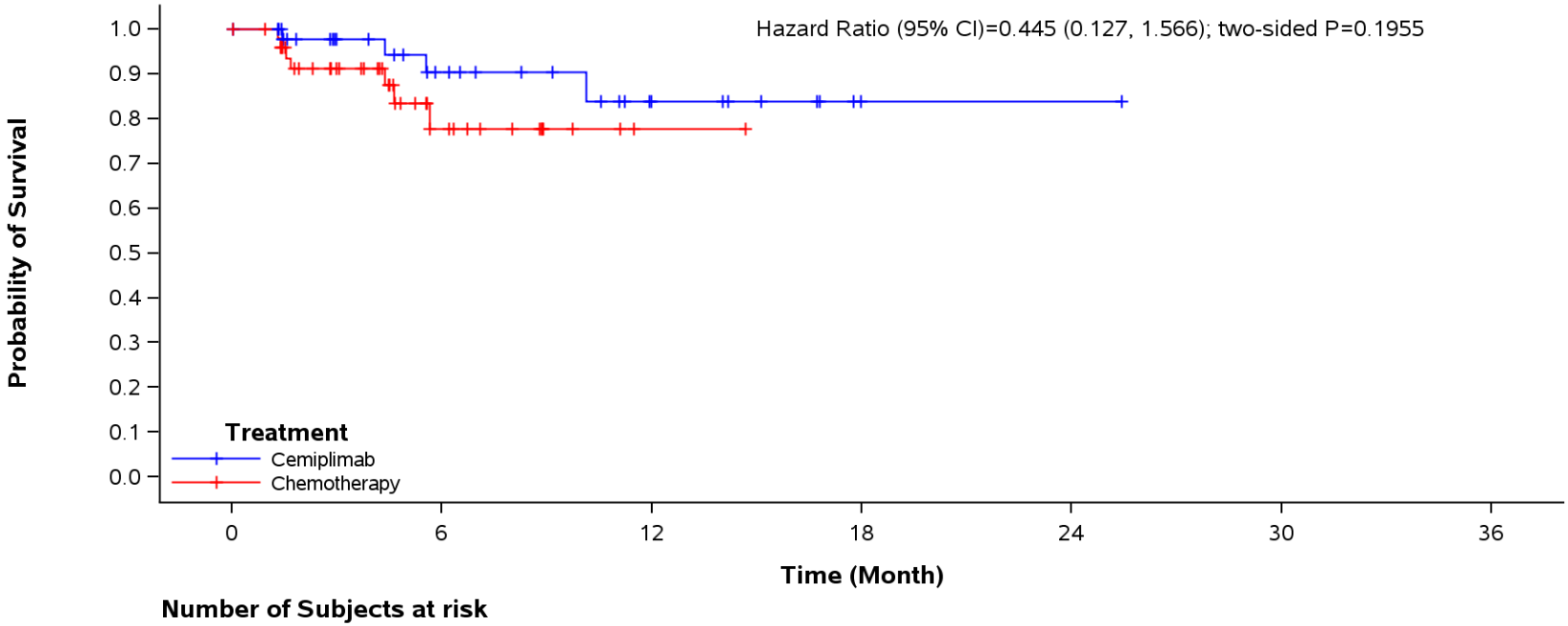

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 21 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 17 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Dyspnoea - 10 pts sensitivity sustained deterioration



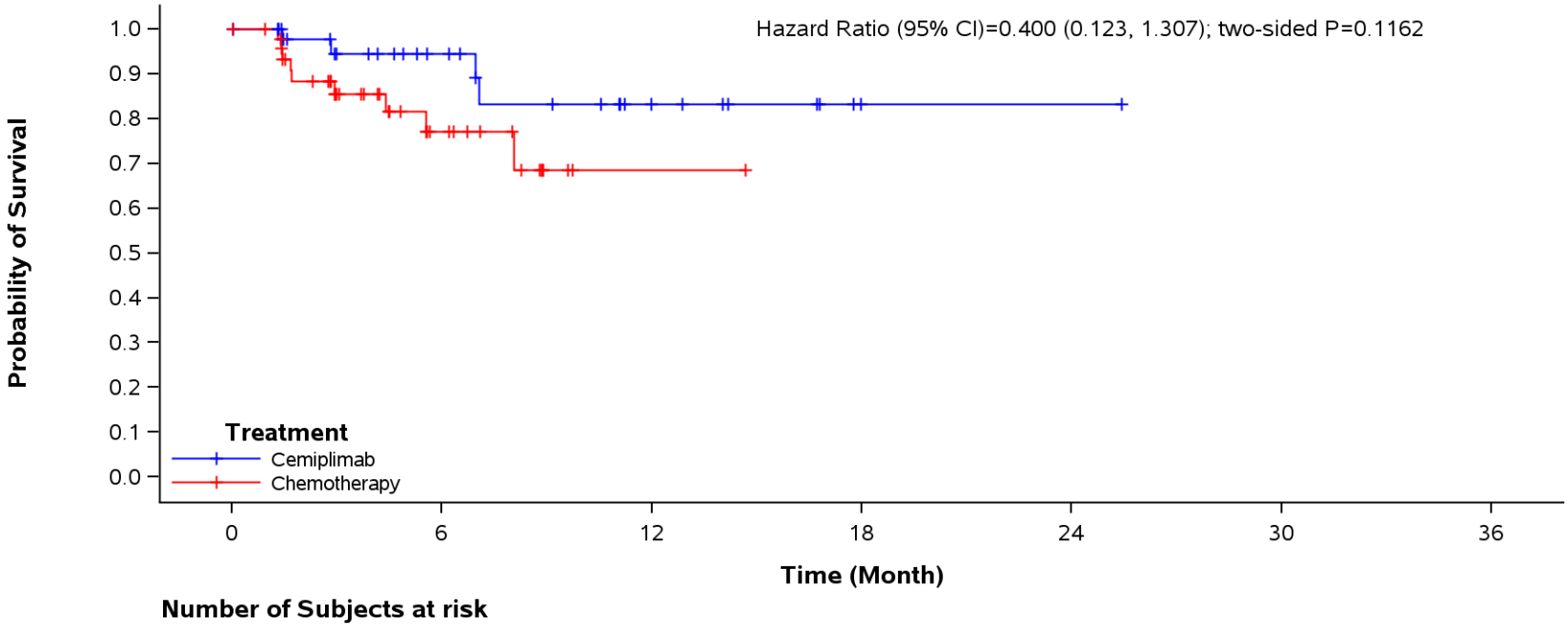

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Emotional Functioning - 10 pts sensitivity sustained deterioration



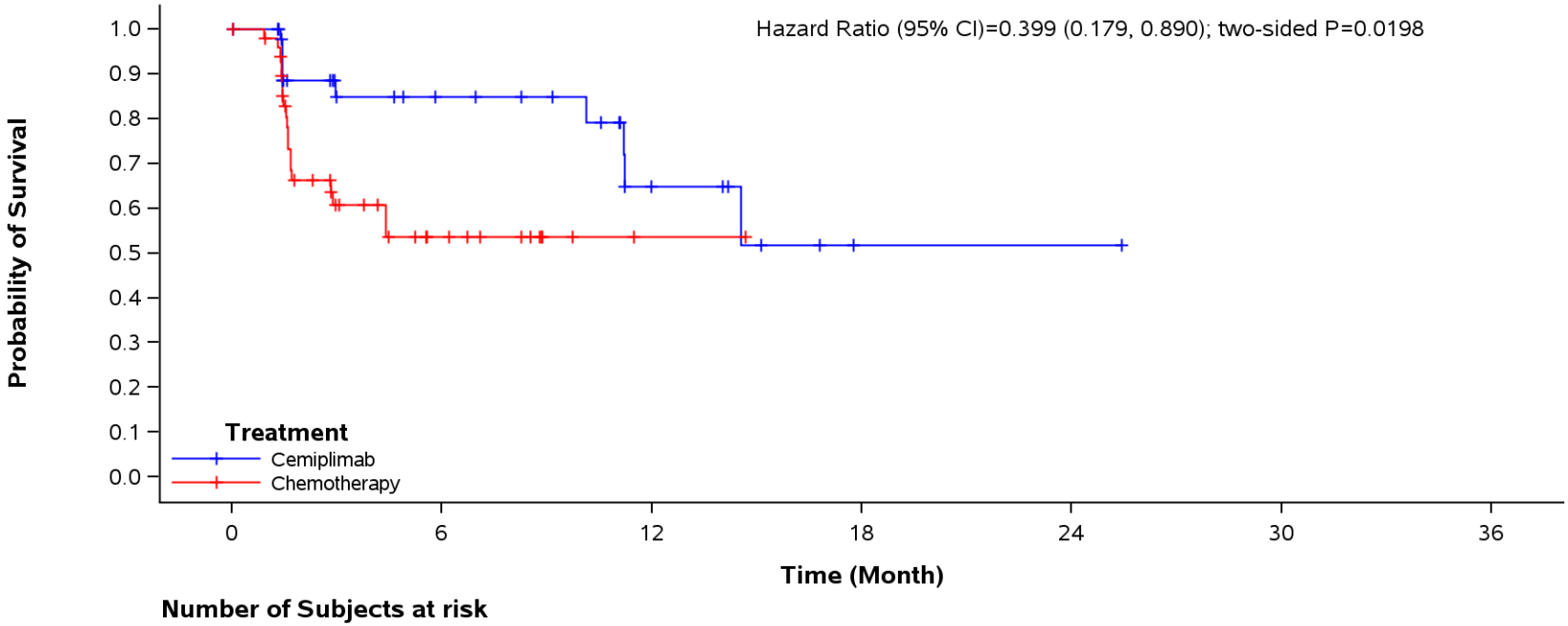

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Fatigue - 10 pts sensitivity sustained deterioration



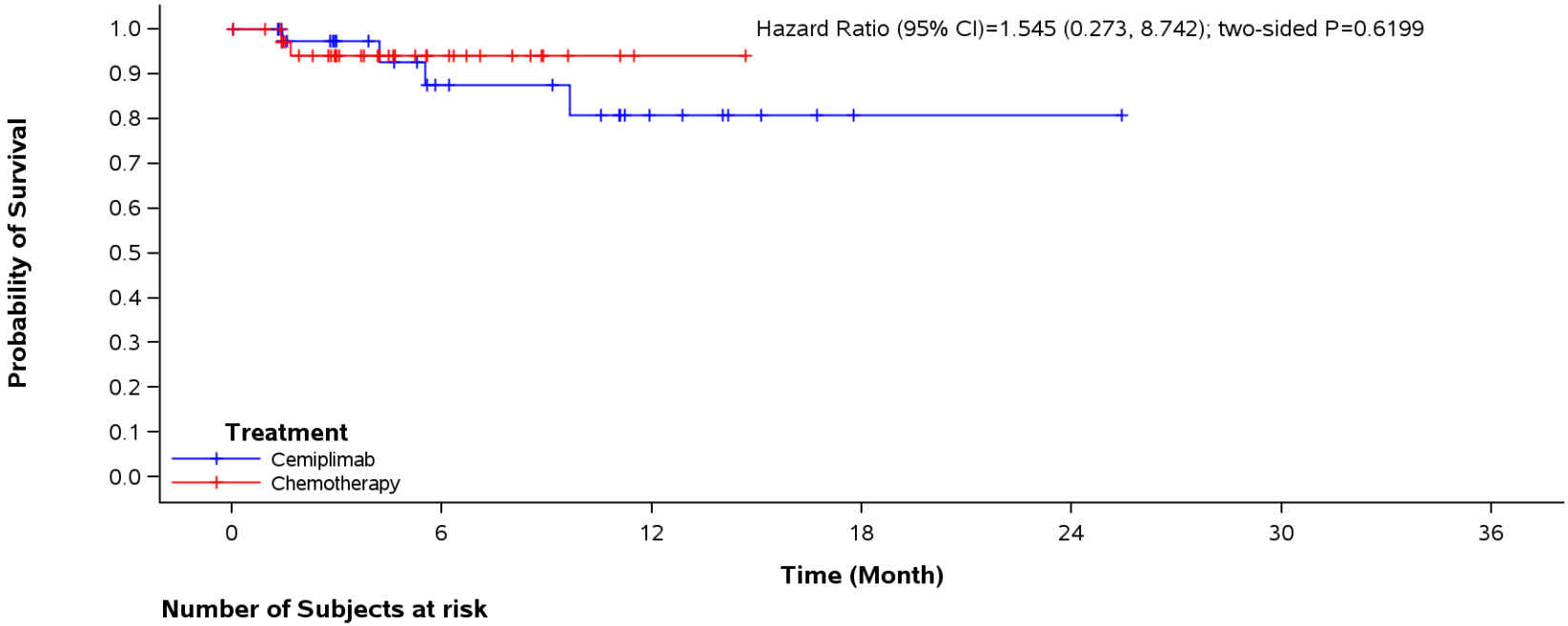

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 7 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Financial Problems - 10 pts sensitivity sustained deterioration



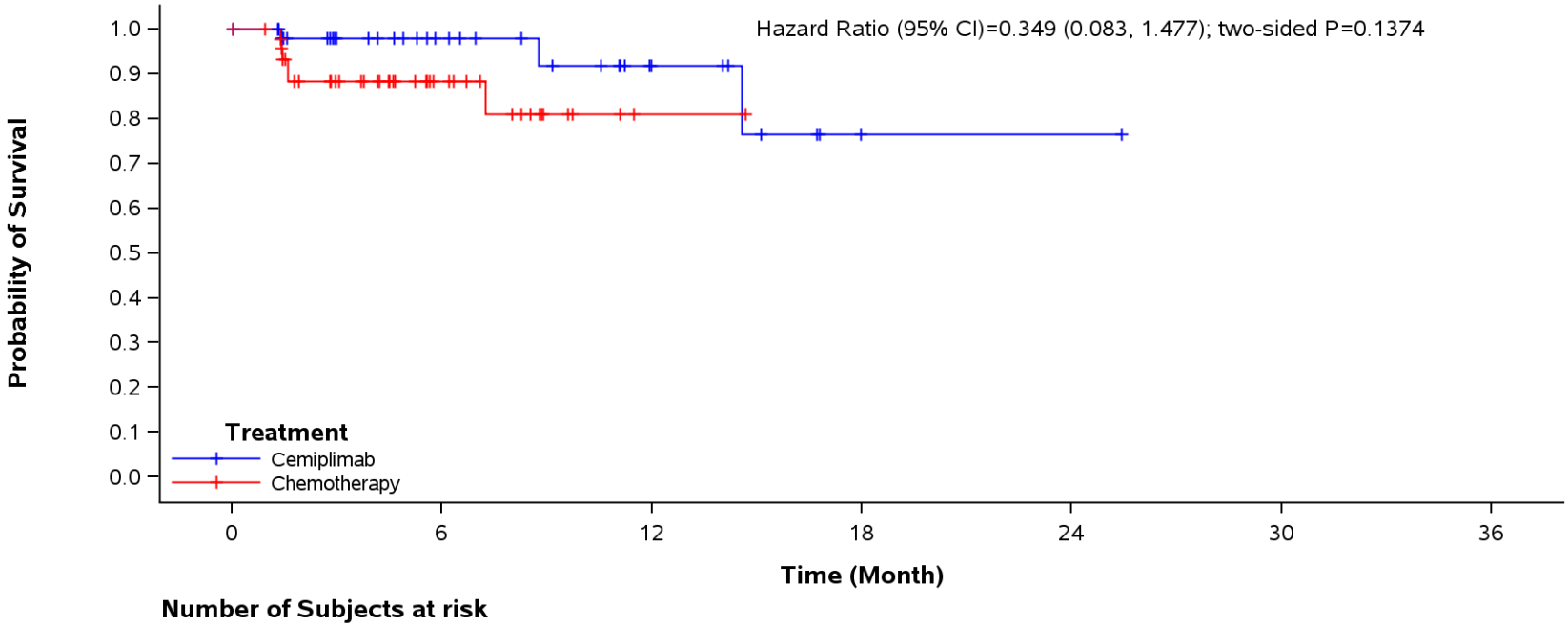

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 15 | 7 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



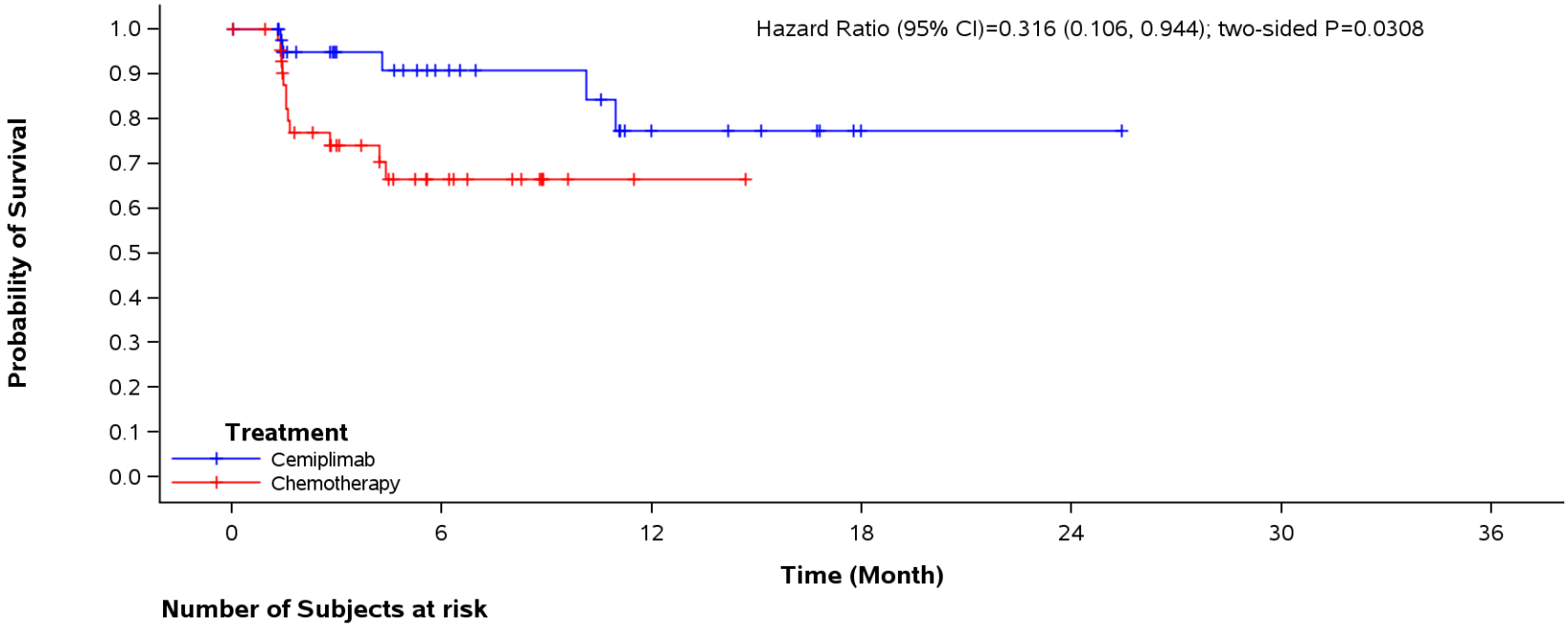

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 21 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 16 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Pain - 10 pts sensitivity sustained deterioration



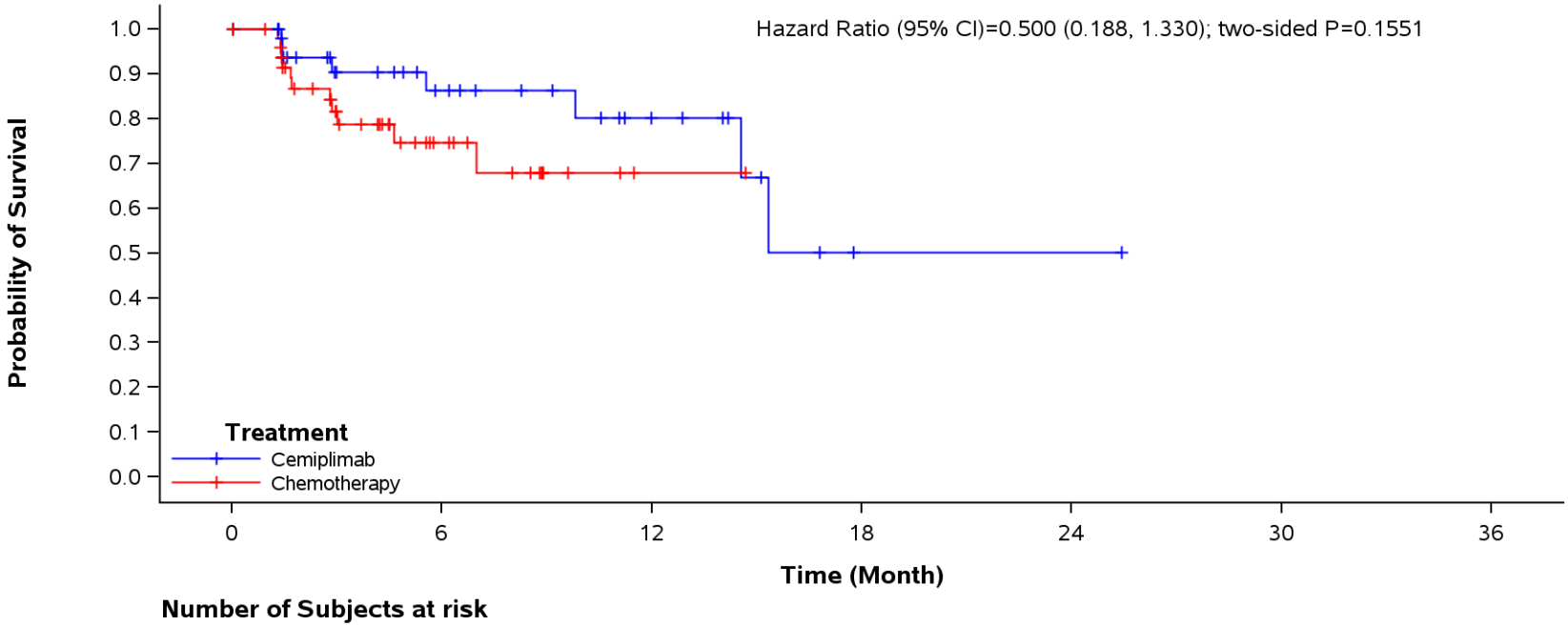

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 17 | 7 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Physical Functioning - 10 pts sensitivity sustained deterioration



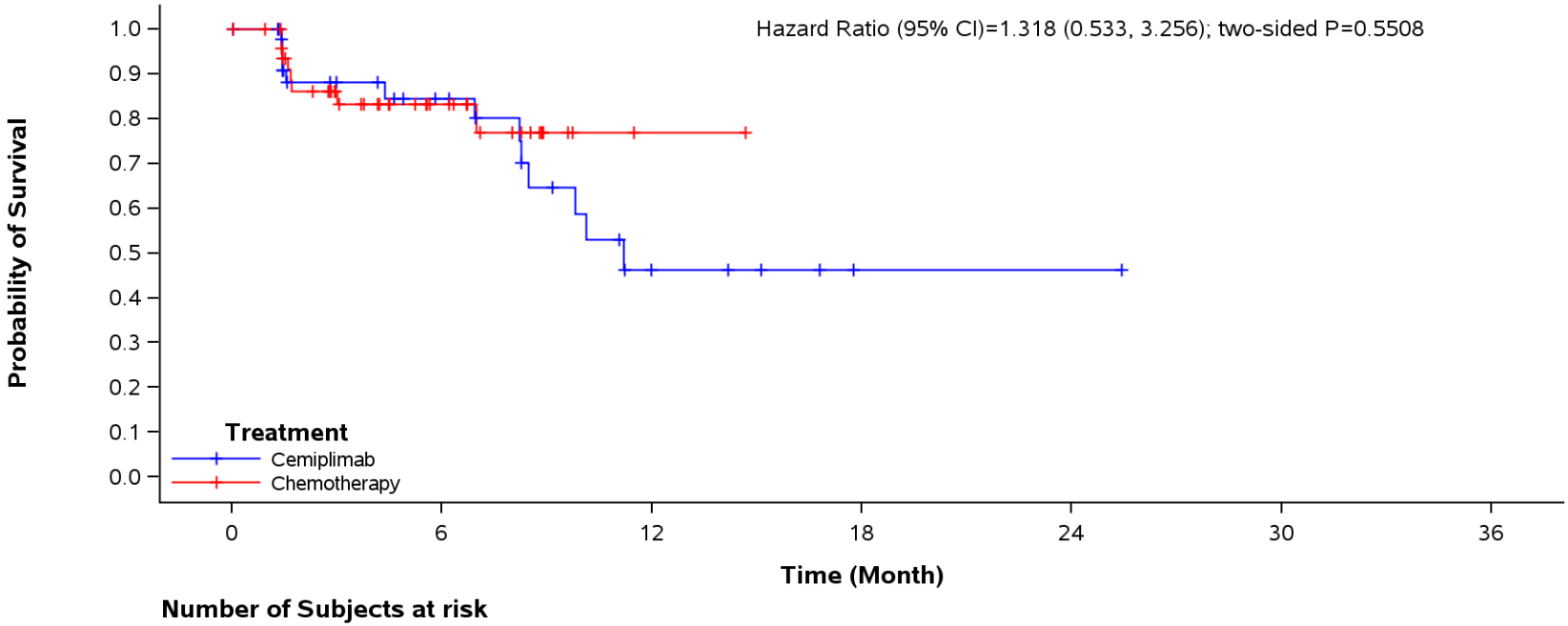

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 9 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Global health status / QoL - 10 pts sensitivity sustained deterioration



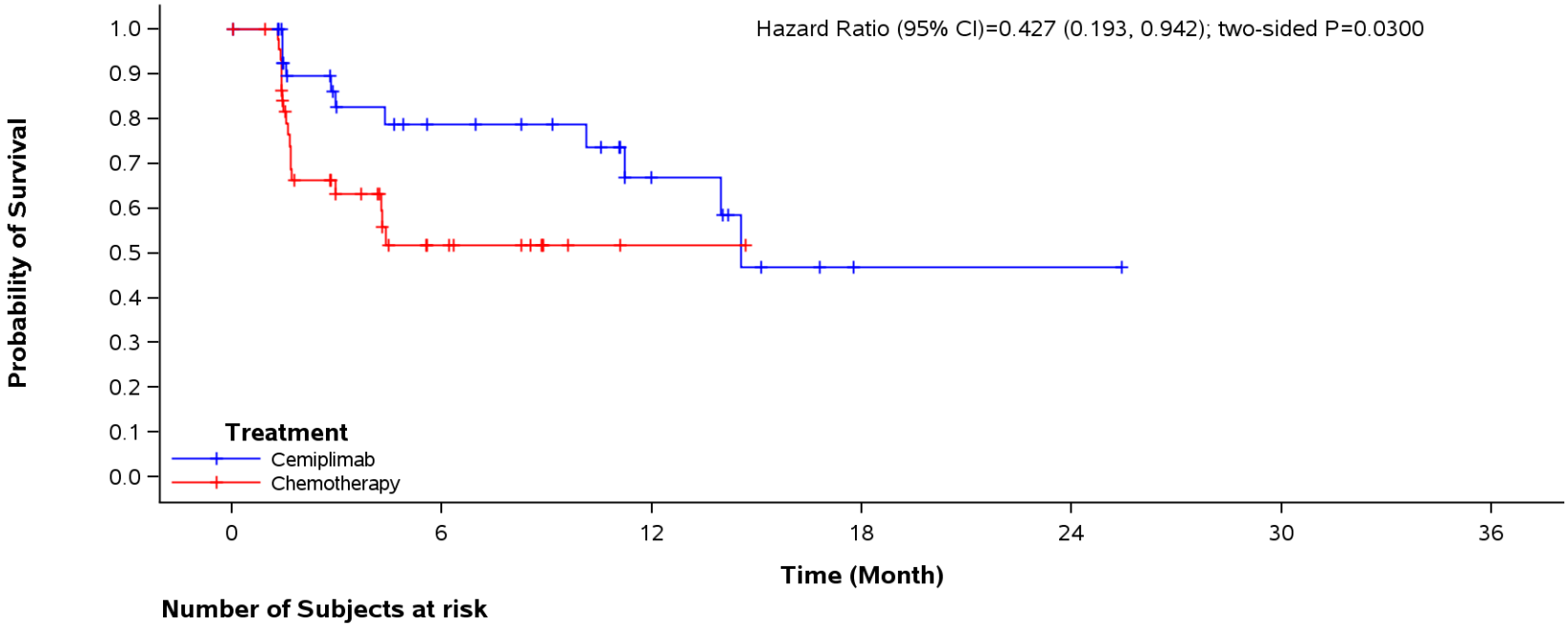

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 17 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Role Functioning - 10 pts sensitivity sustained deterioration



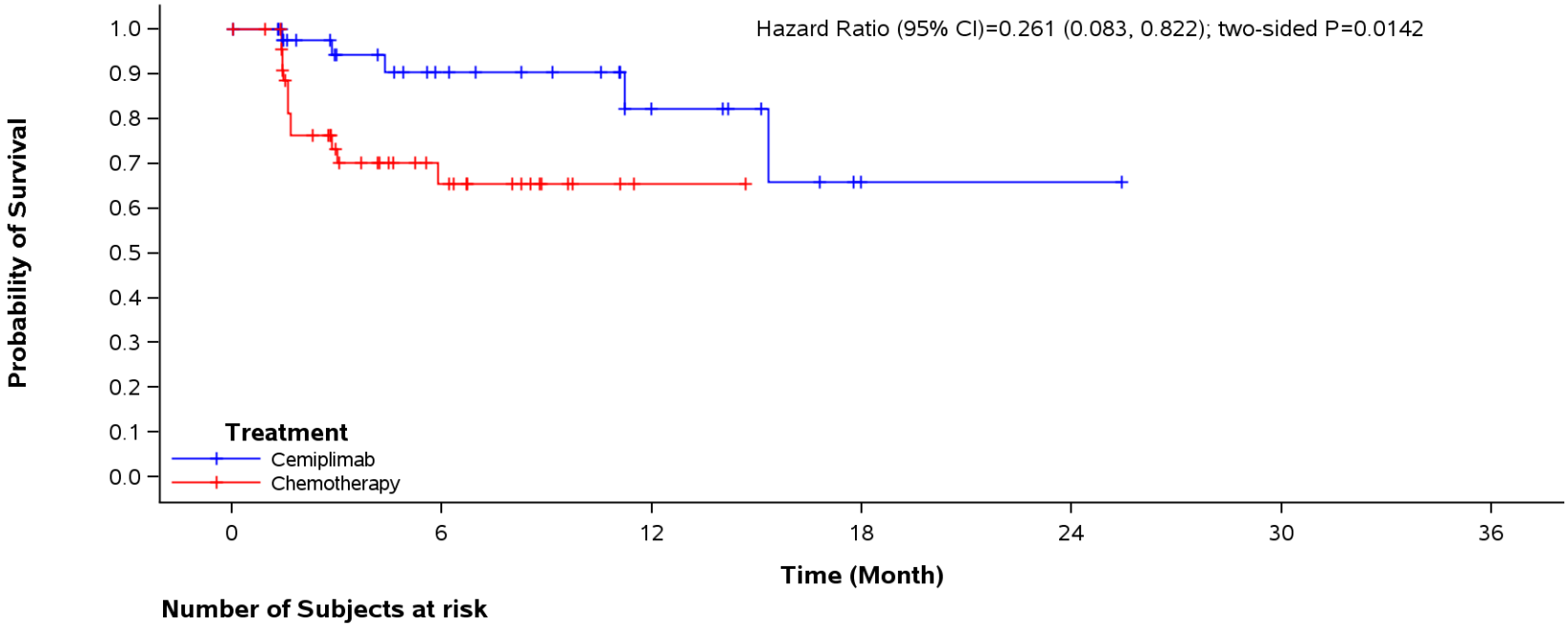

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 18 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Social Functioning - 10 pts sensitivity sustained deterioration



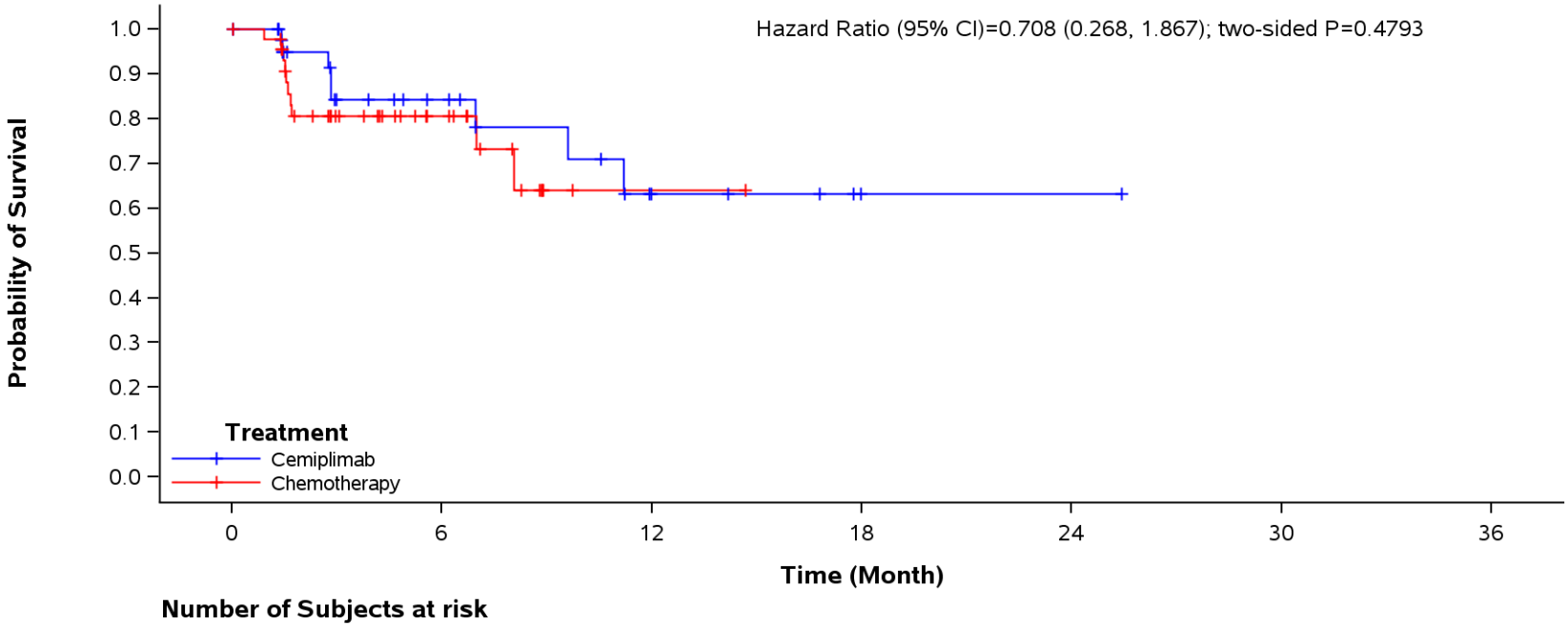

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 8 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

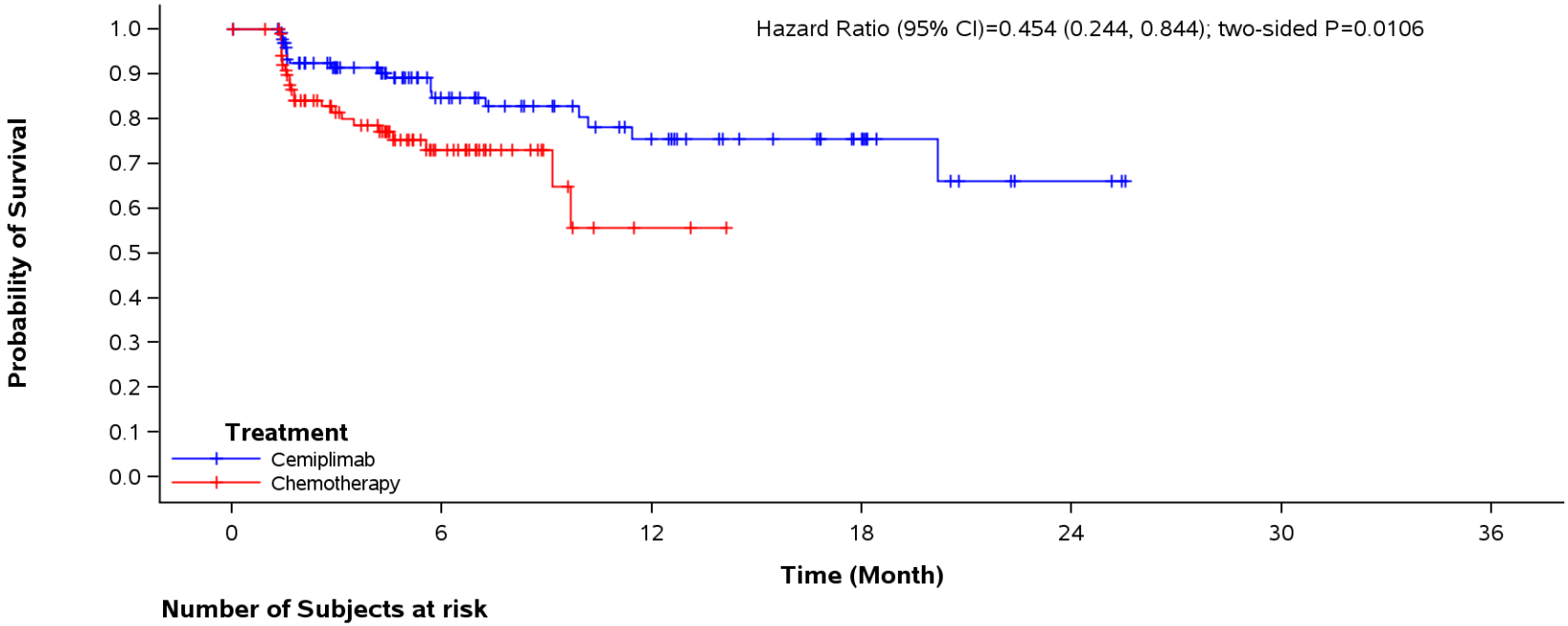
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 16 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 56 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Appetite loss - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

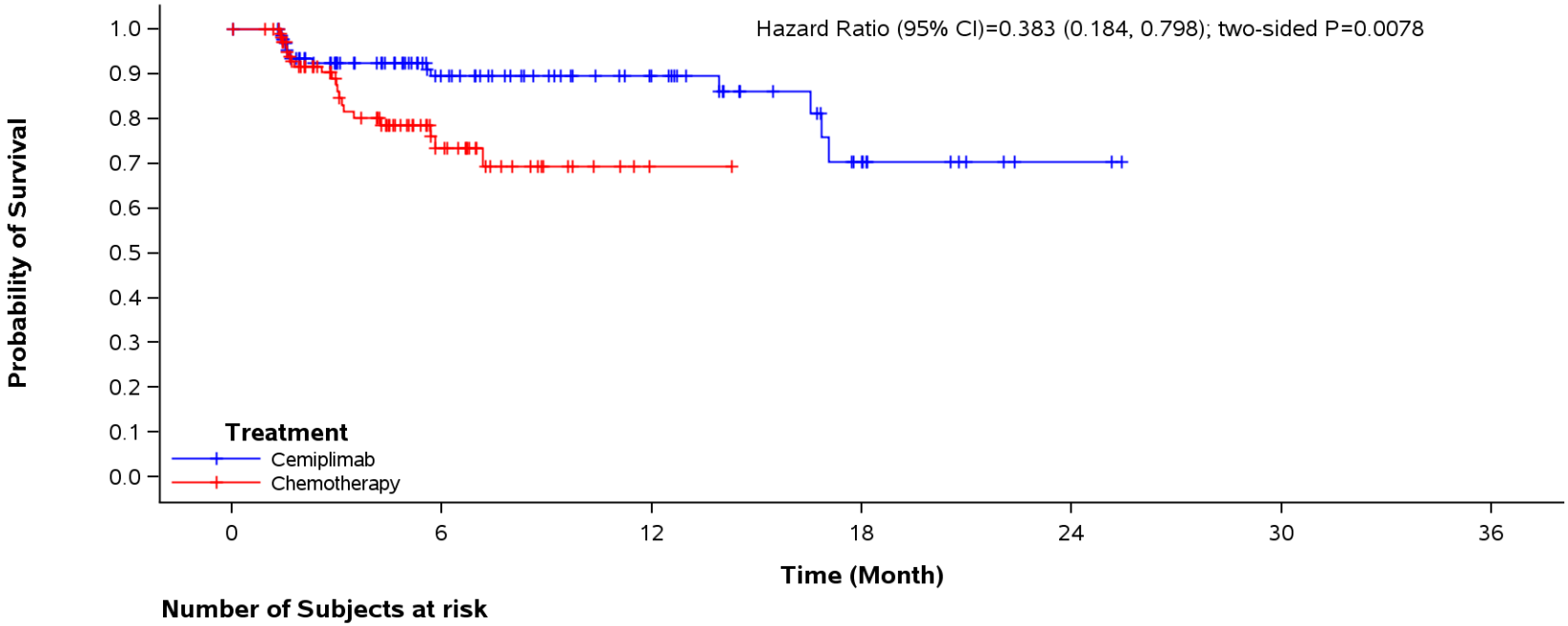
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 54 | 28 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 27 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Cognitive Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

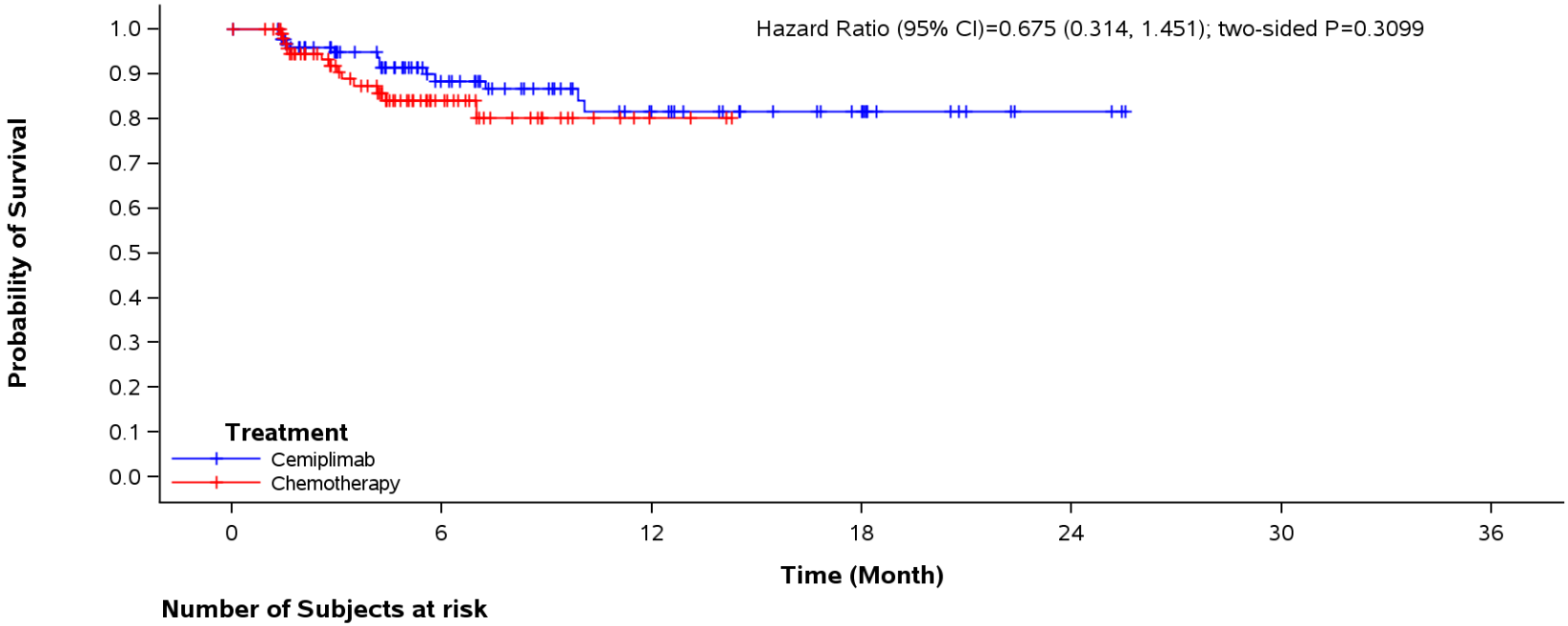
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 58 | 30 | 11 | 2 | 0 | 0 |
| Chemotherapy | 137 | 27 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Constipation - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 56 | 27 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 29 | 3 | 0 | 0 | 0 | 0 |

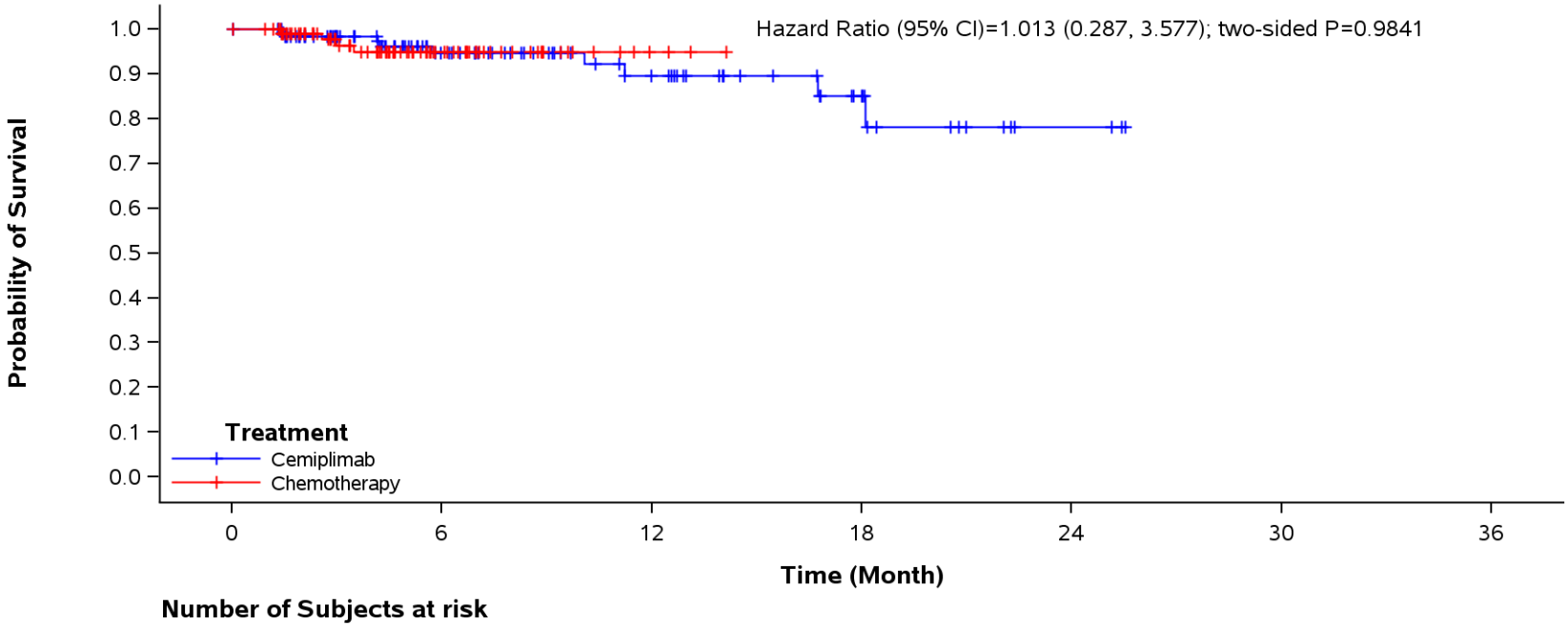
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Diarhoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 61 | 32 | 15 | 3 | 0 | 0 |
| Chemotherapy | 137 | 34 | 3 | 0 | 0 | 0 | 0 |

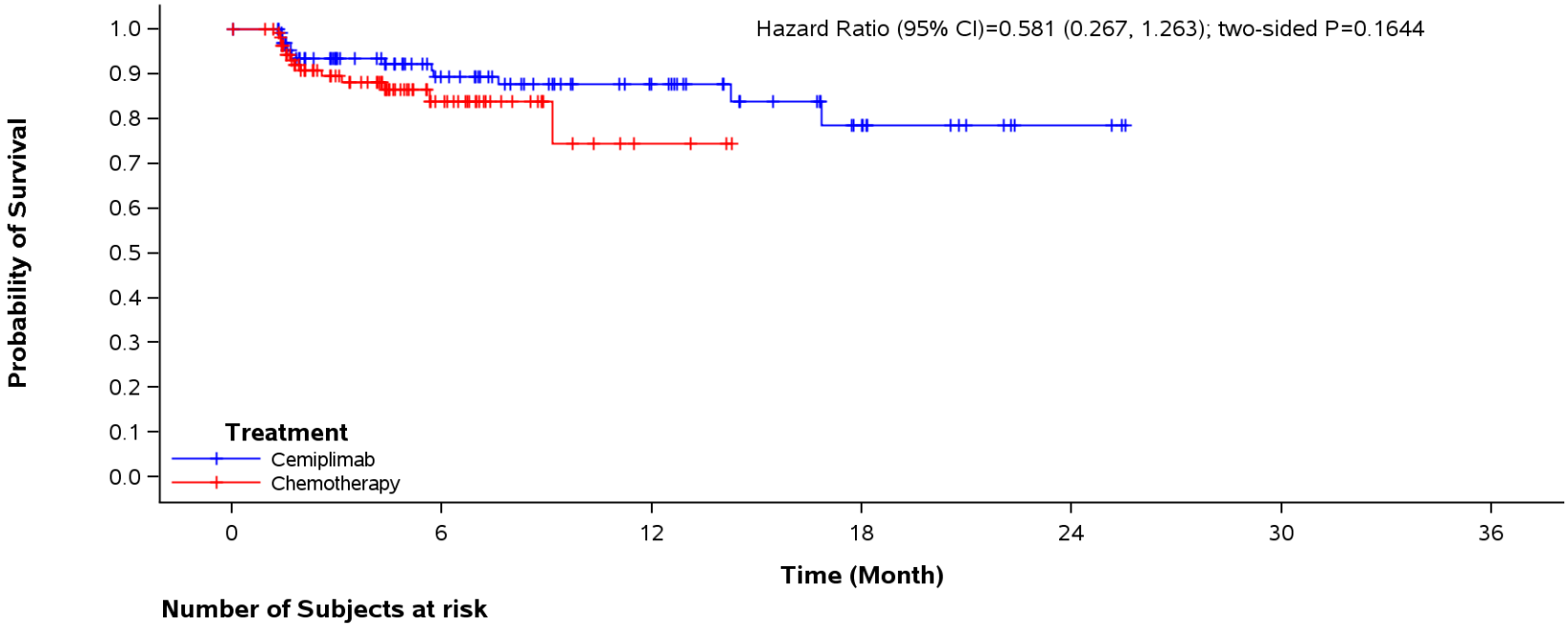
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Dyspnoea - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

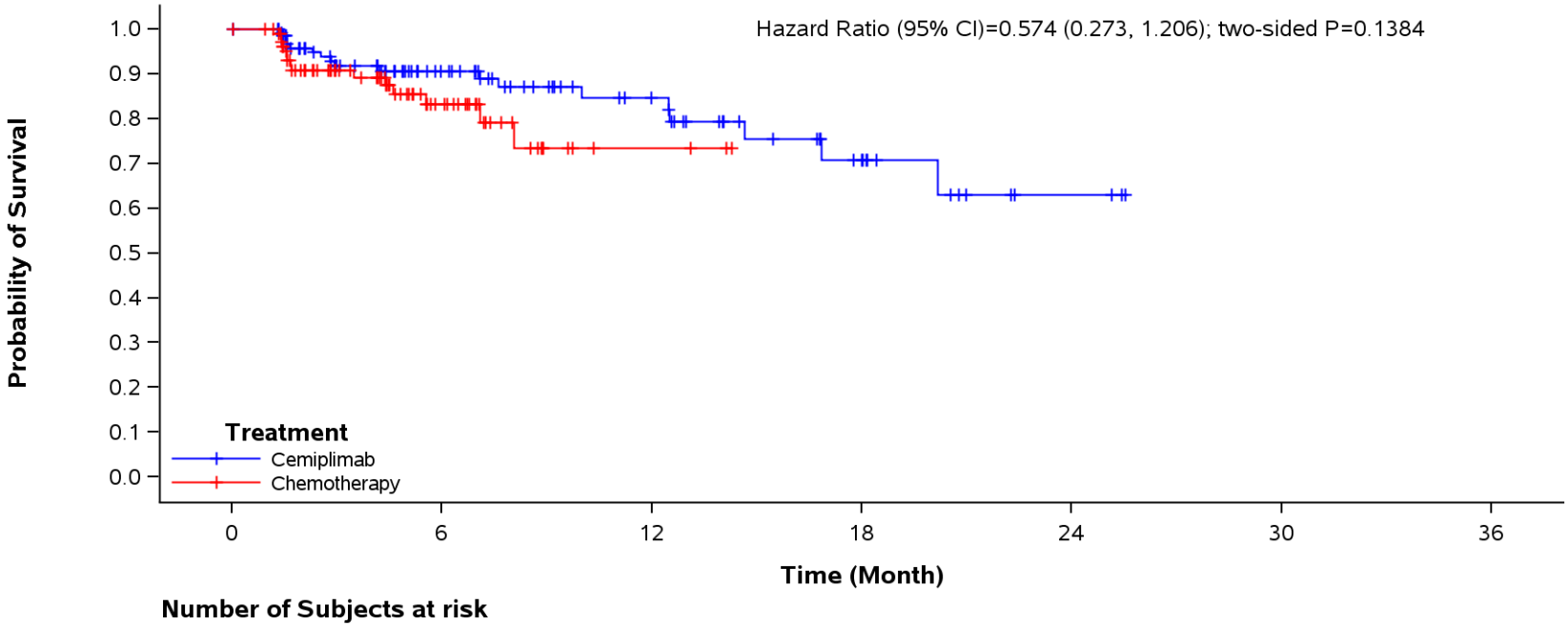
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 60 | 31 | 13 | 3 | 0 | 0 |
| Chemotherapy | 137 | 29 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Emotional Functioning - 10 pts sensitivity sustained deterioration



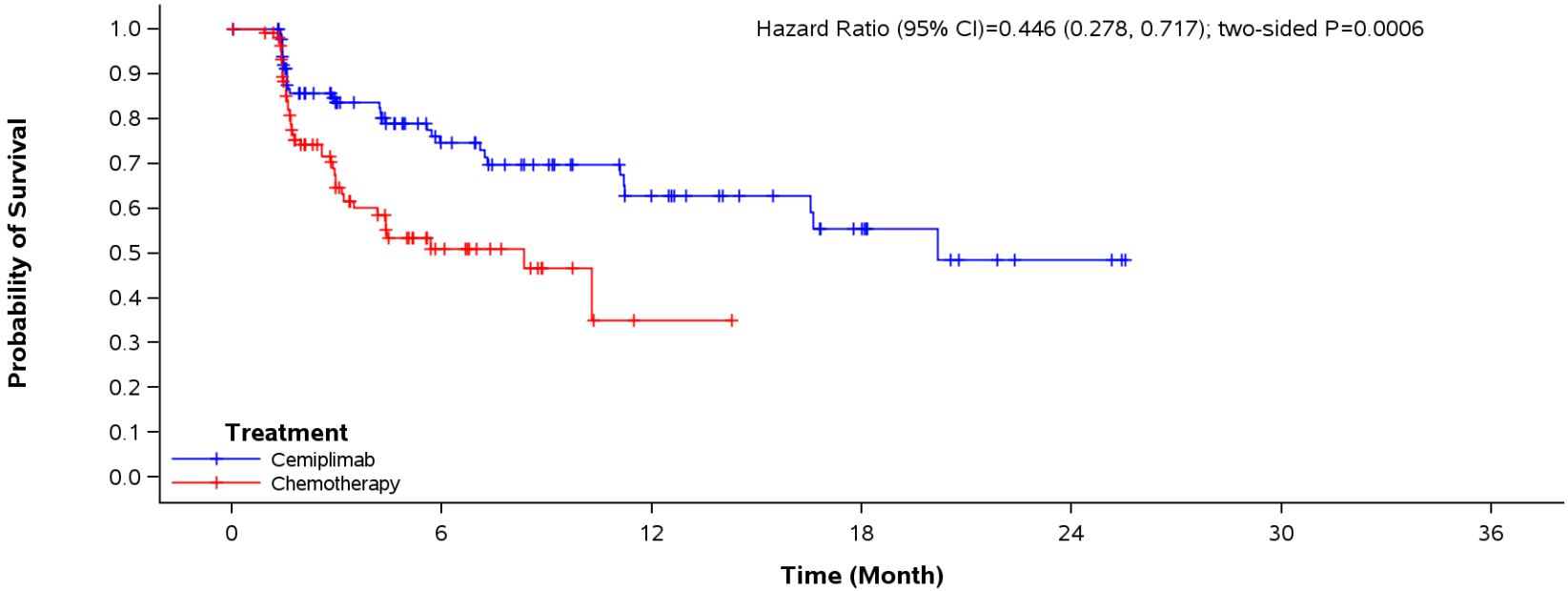

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 60 | 32 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 31 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

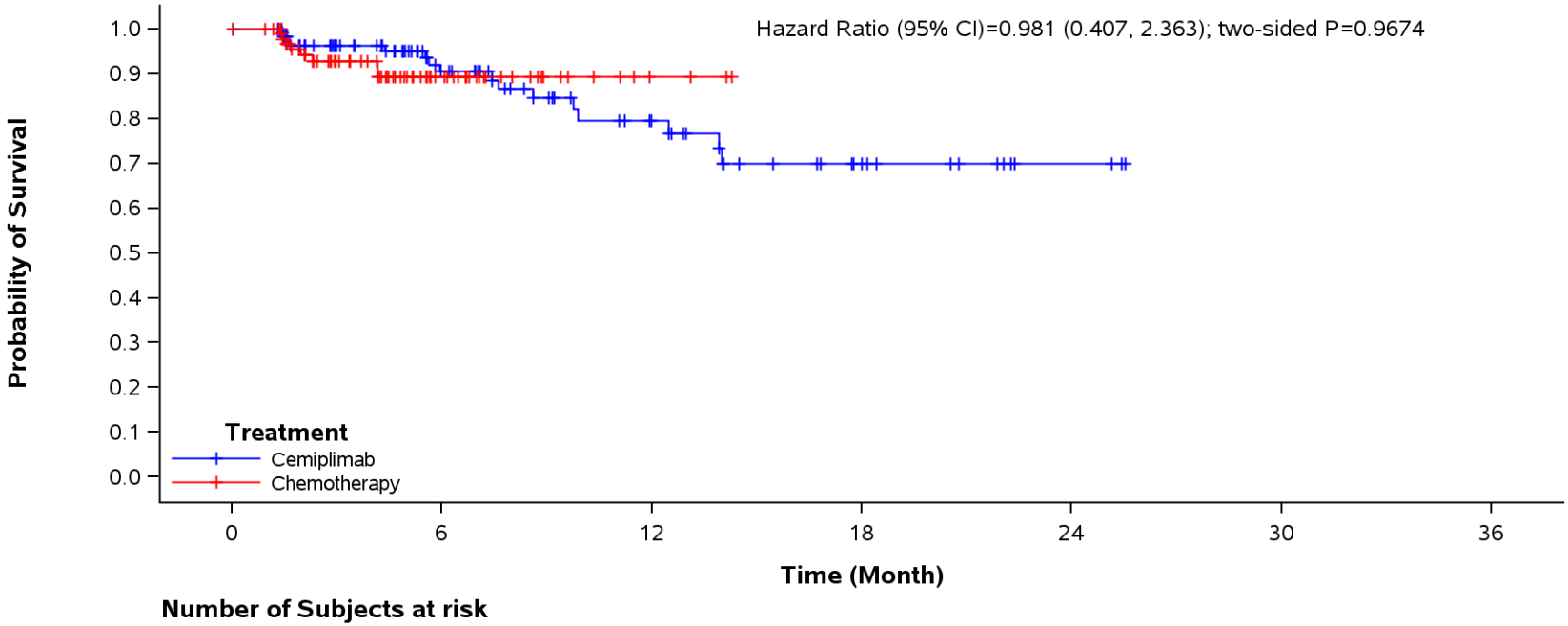
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 50 | 25 | 12 | 3 | 0 | 0 |
| Chemotherapy | 137 | 19 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 56 | 28 | 12 | 3 | 0 | 0 |
| Chemotherapy | 137 | 29 | 3 | 0 | 0 | 0 | 0 |

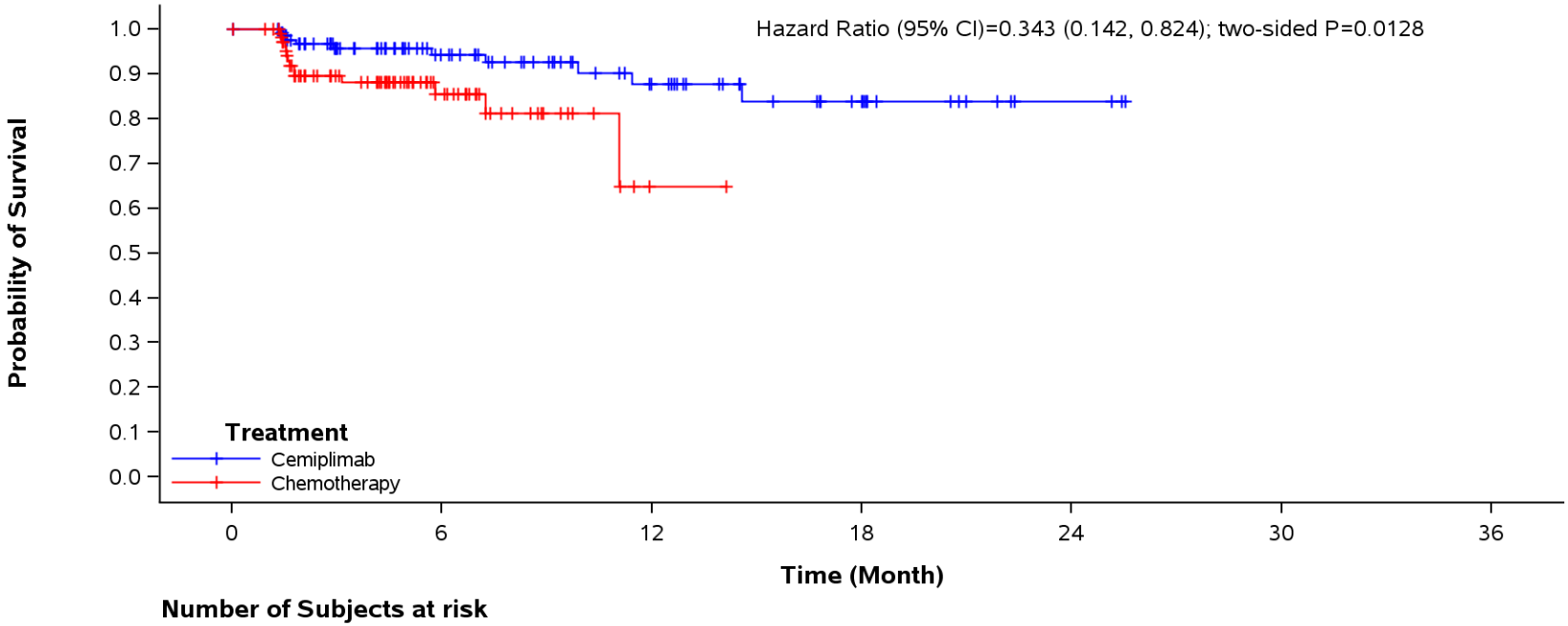
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

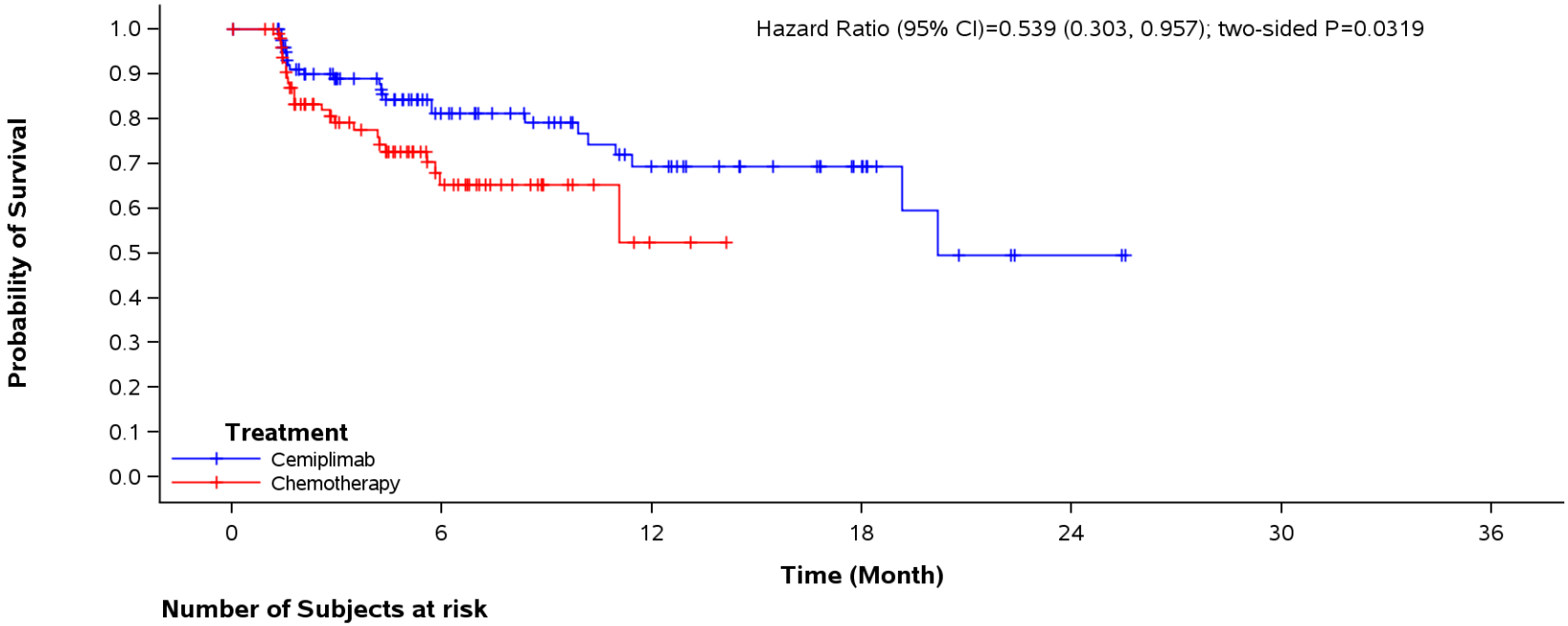
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 63 | 32 | 15 | 3 | 0 | 0 |
| Chemotherapy | 137 | 30 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

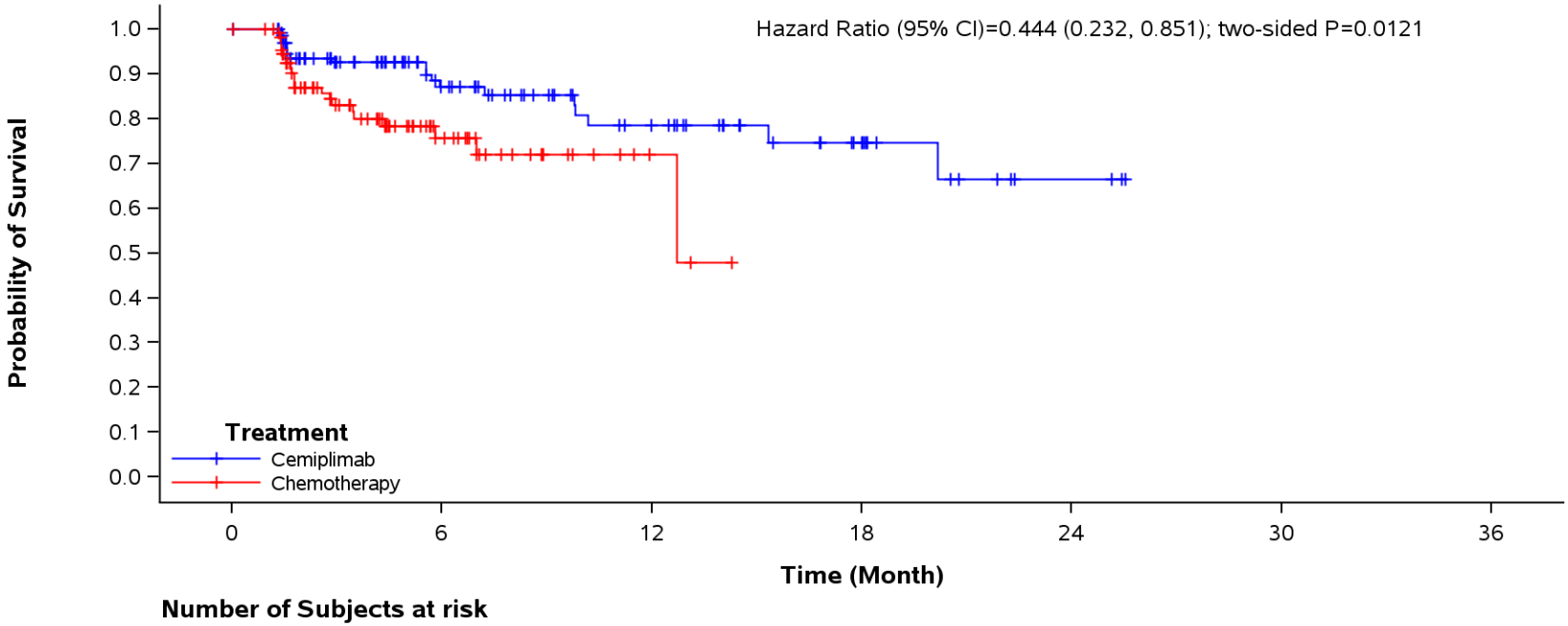
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 51 | 26 | 12 | 2 | 0 | 0 |
| Chemotherapy | 137 | 26 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 60 | 31 | 15 | 3 | 0 | 0 |
| Chemotherapy | 137 | 27 | 3 | 0 | 0 | 0 | 0 |

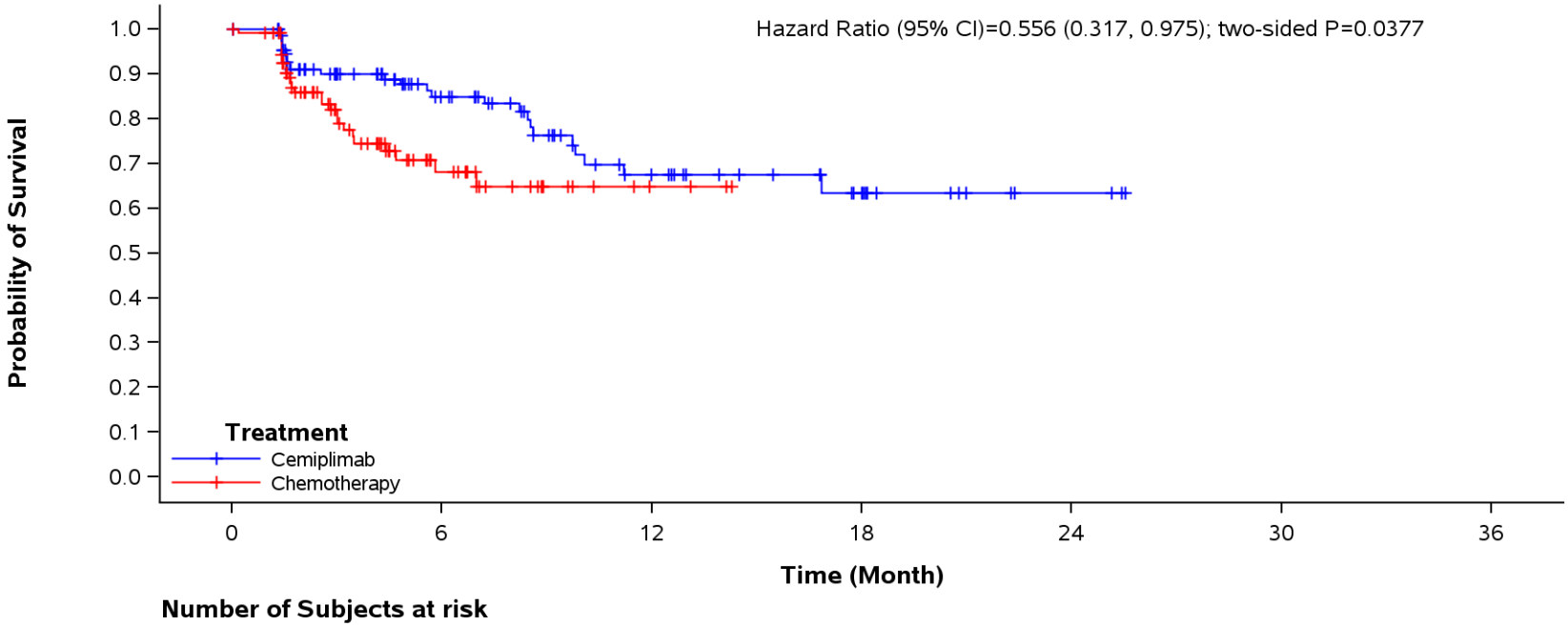
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Global health status / QoL - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 60 | 27 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 27 | 3 | 0 | 0 | 0 | 0 |

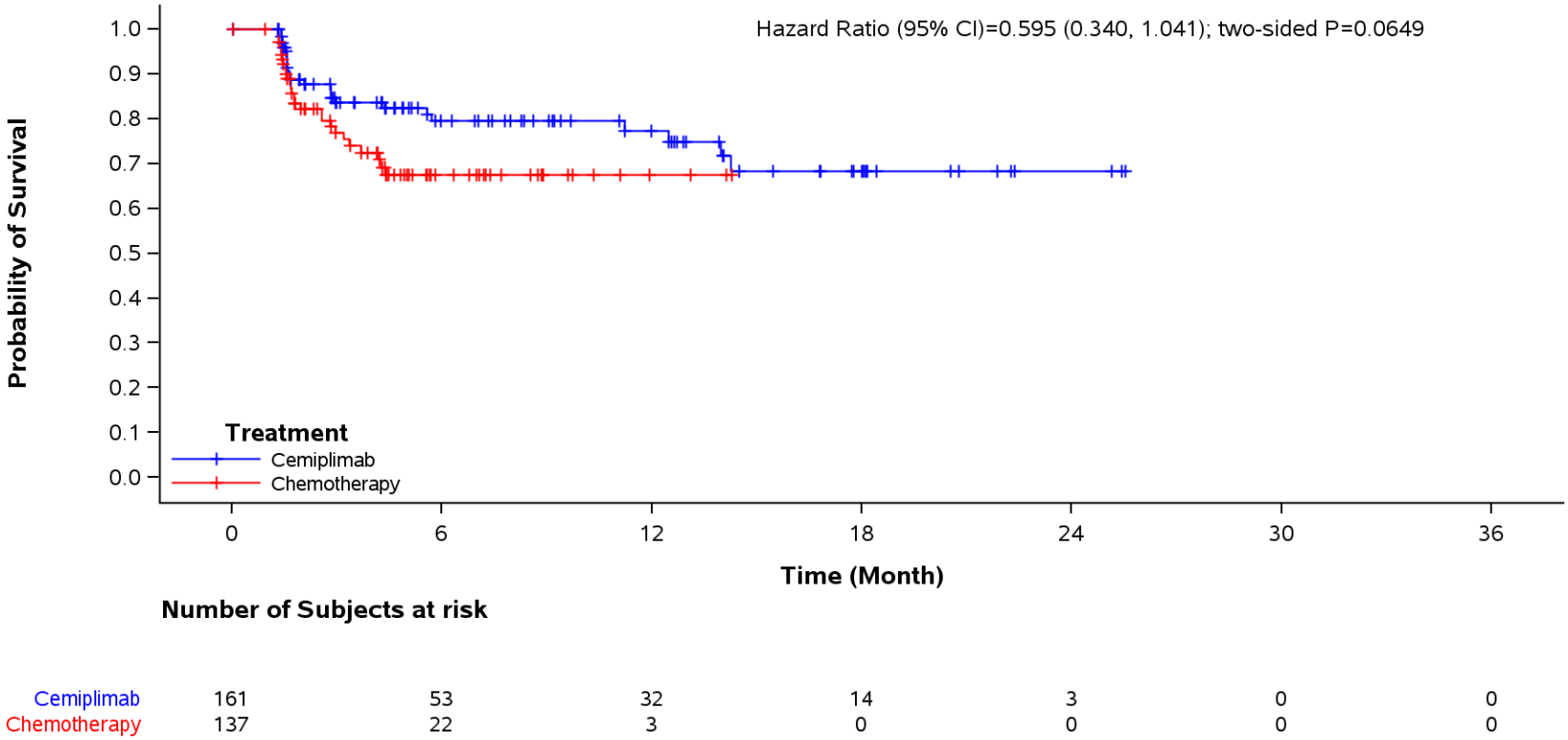
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Role Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 53 | 32 | 14 | 3 | 0 | 0 |
| Chemotherapy | 137 | 22 | 3 | 0 | 0 | 0 | 0 |

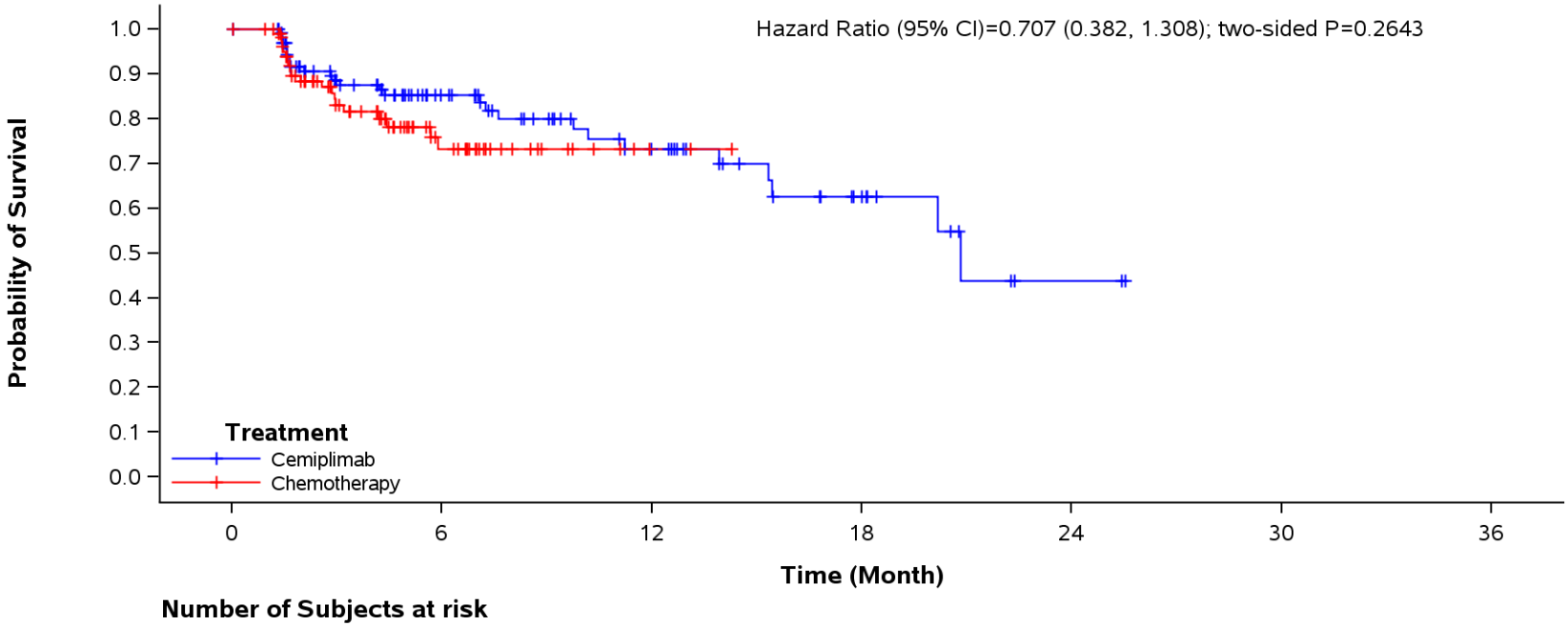
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Social Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 57 | 29 | 12 | 2 | 0 | 0 |
| Chemotherapy | 137 | 28 | 2 | 0 | 0 | 0 | 0 |

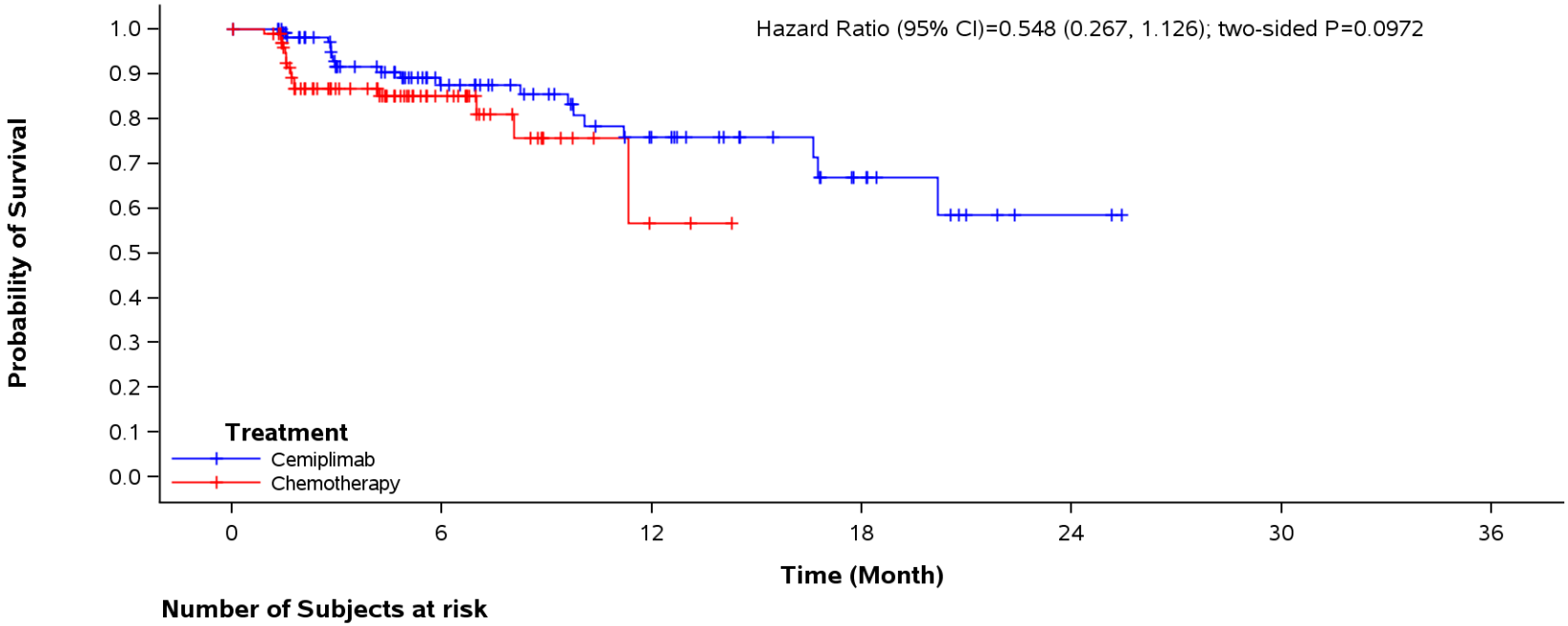
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

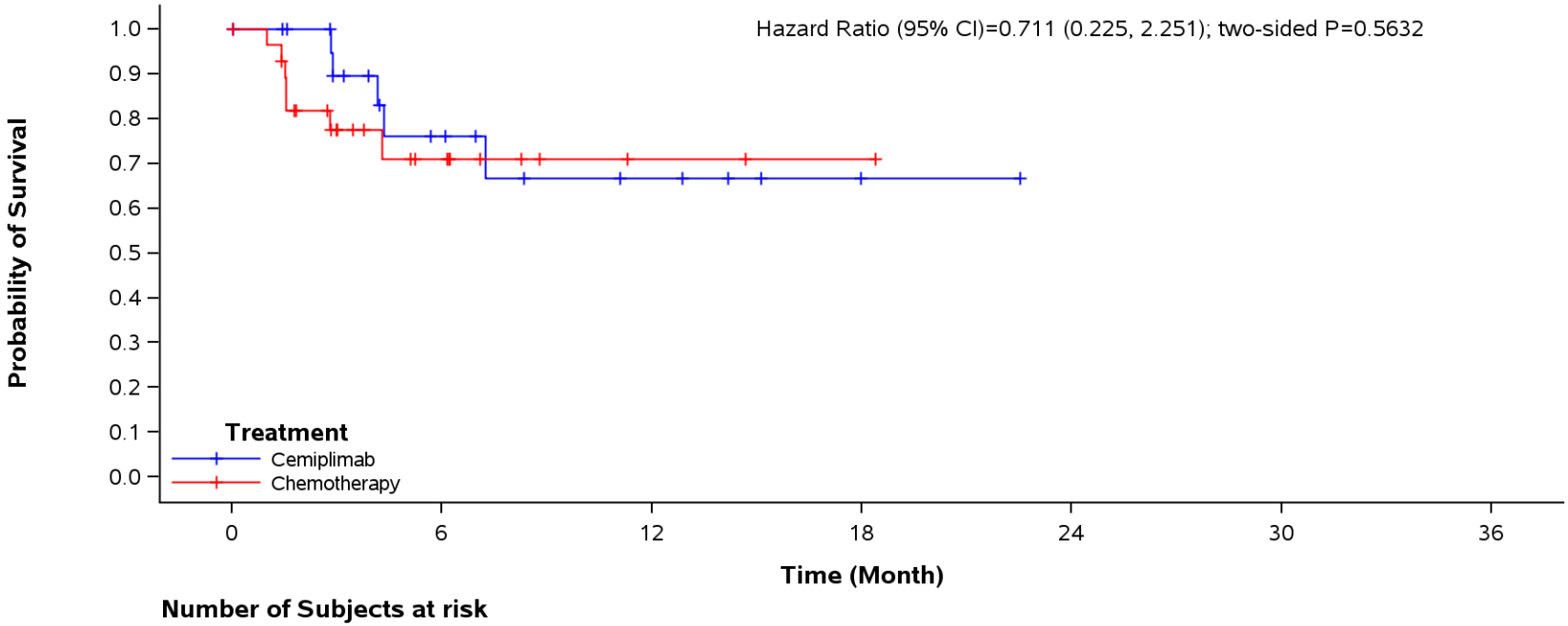
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 54 | 26 | 11 | 2 | 0 | 0 |
| Chemotherapy | 137 | 29 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Appetite loss - 10 pts sensitivity sustained deterioration



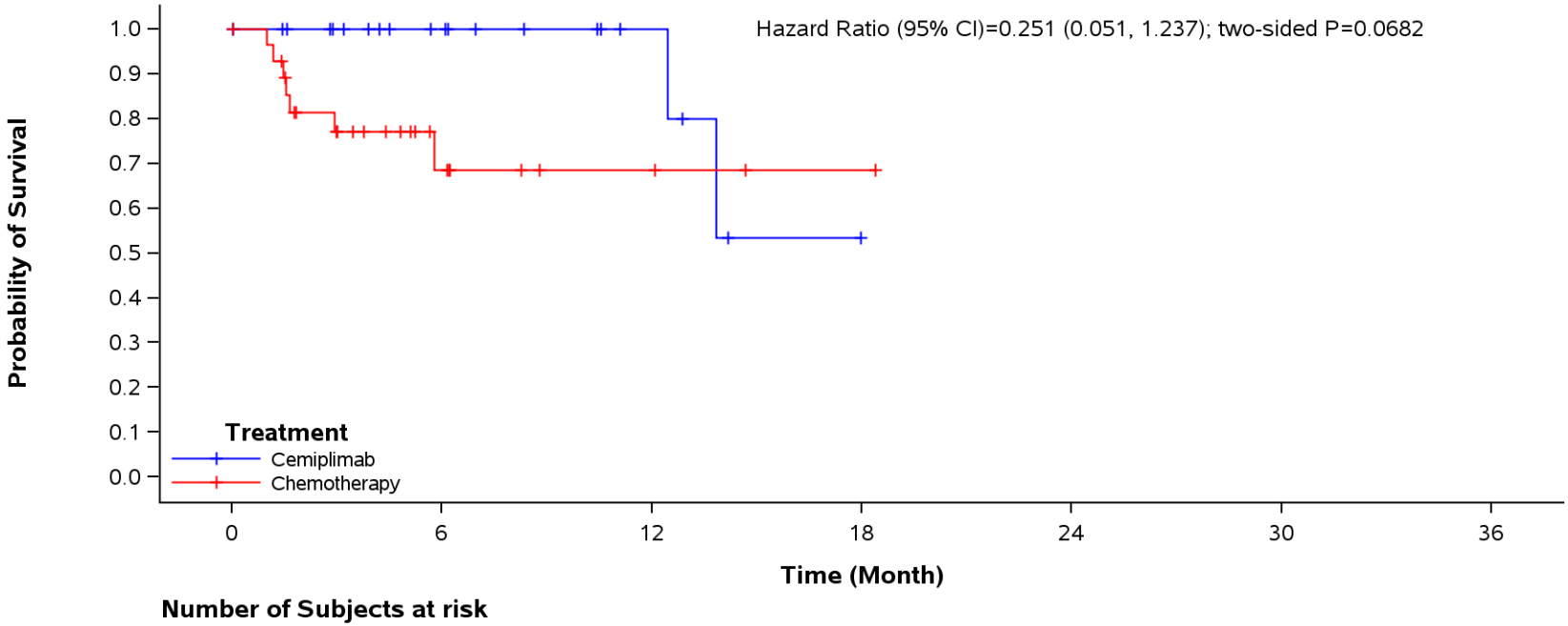

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Cognitive Functioning - 10 pts sensitivity sustained deterioration



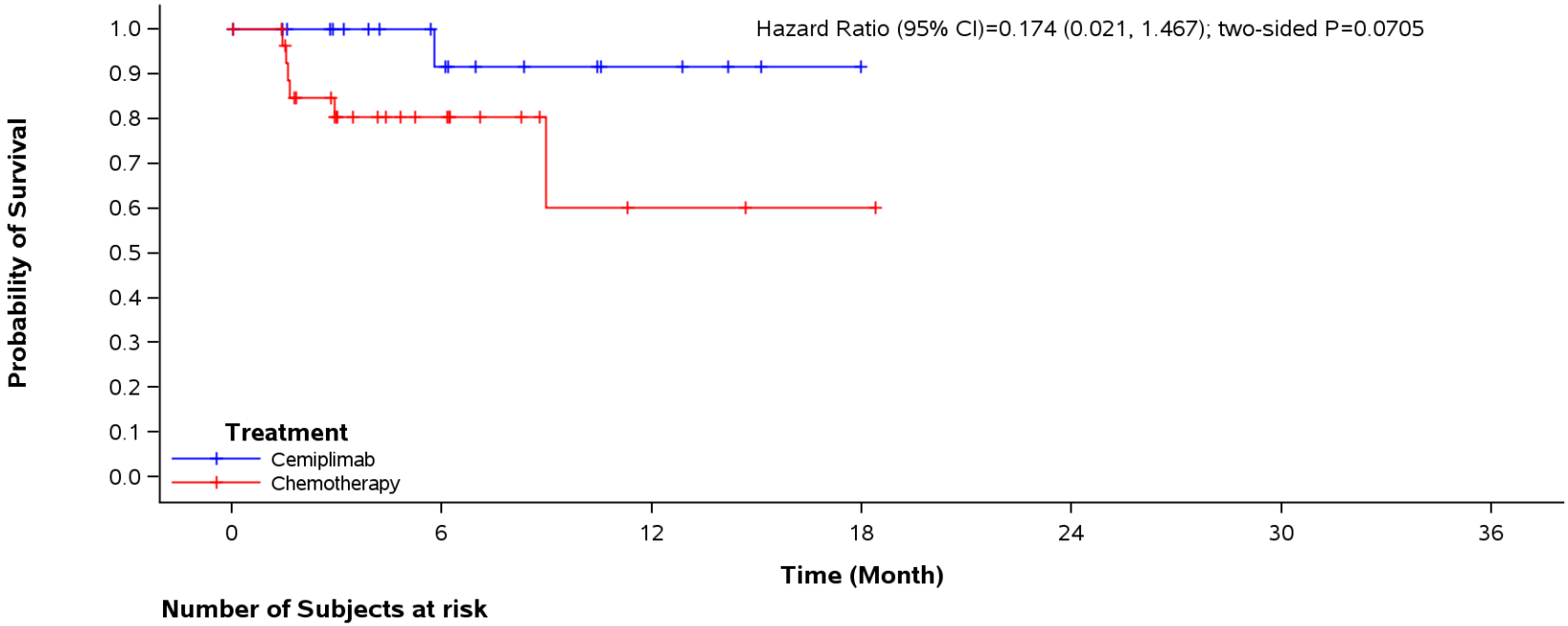

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 13 | 5 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Constipation - 10 pts sensitivity sustained deterioration



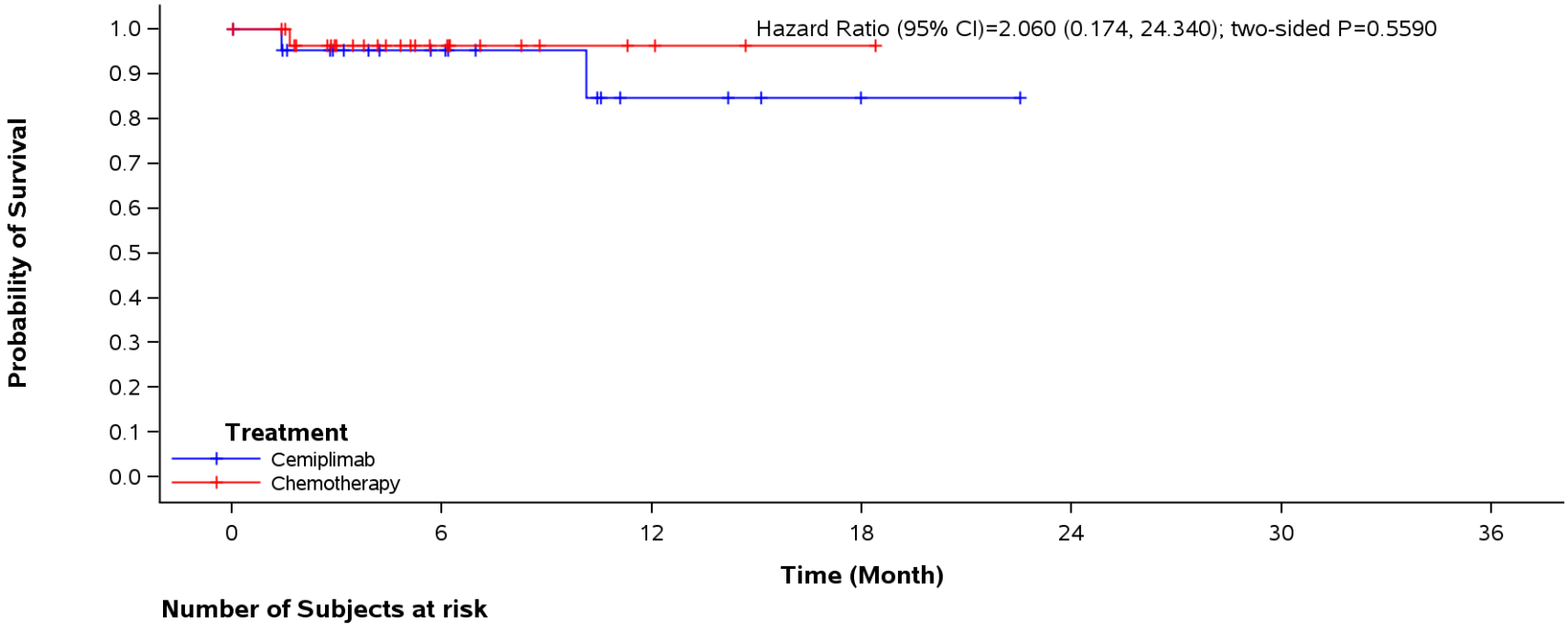

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 10 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Diarhoea - 10 pts sensitivity sustained deterioration



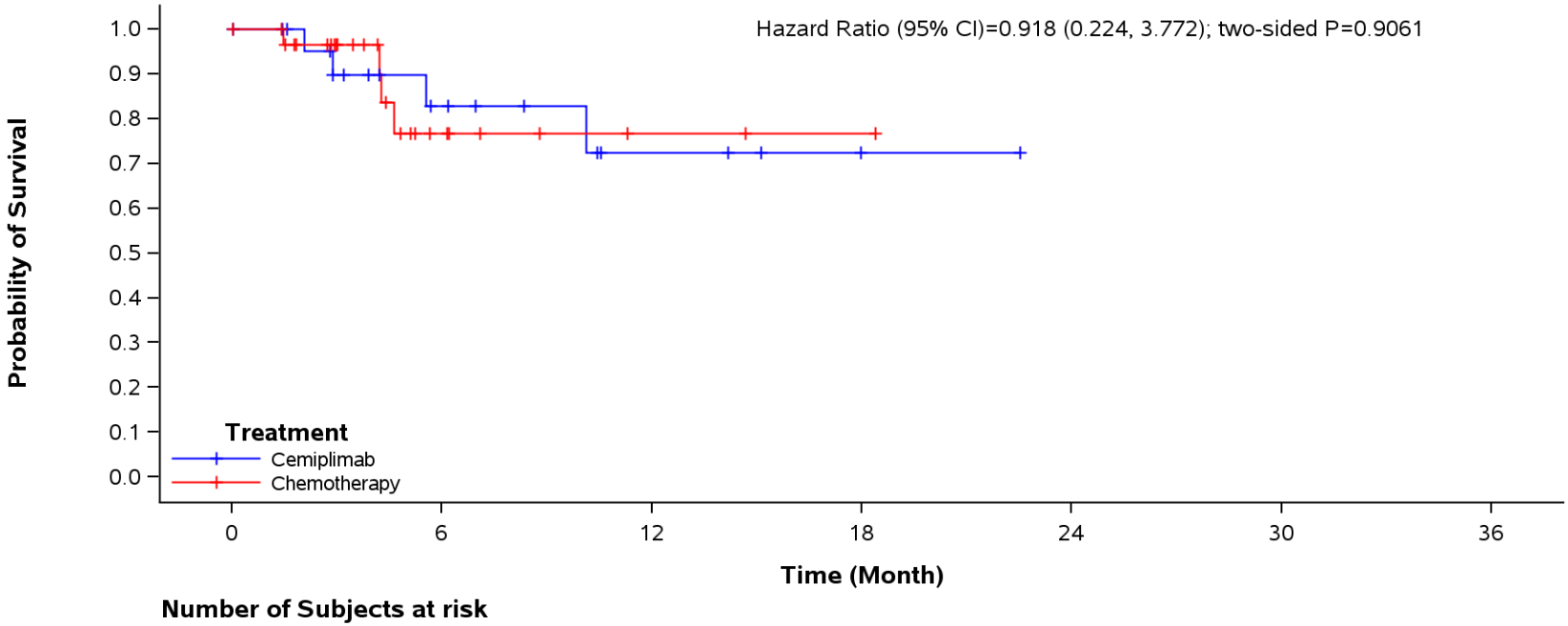

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Dyspnoea - 10 pts sensitivity sustained deterioration



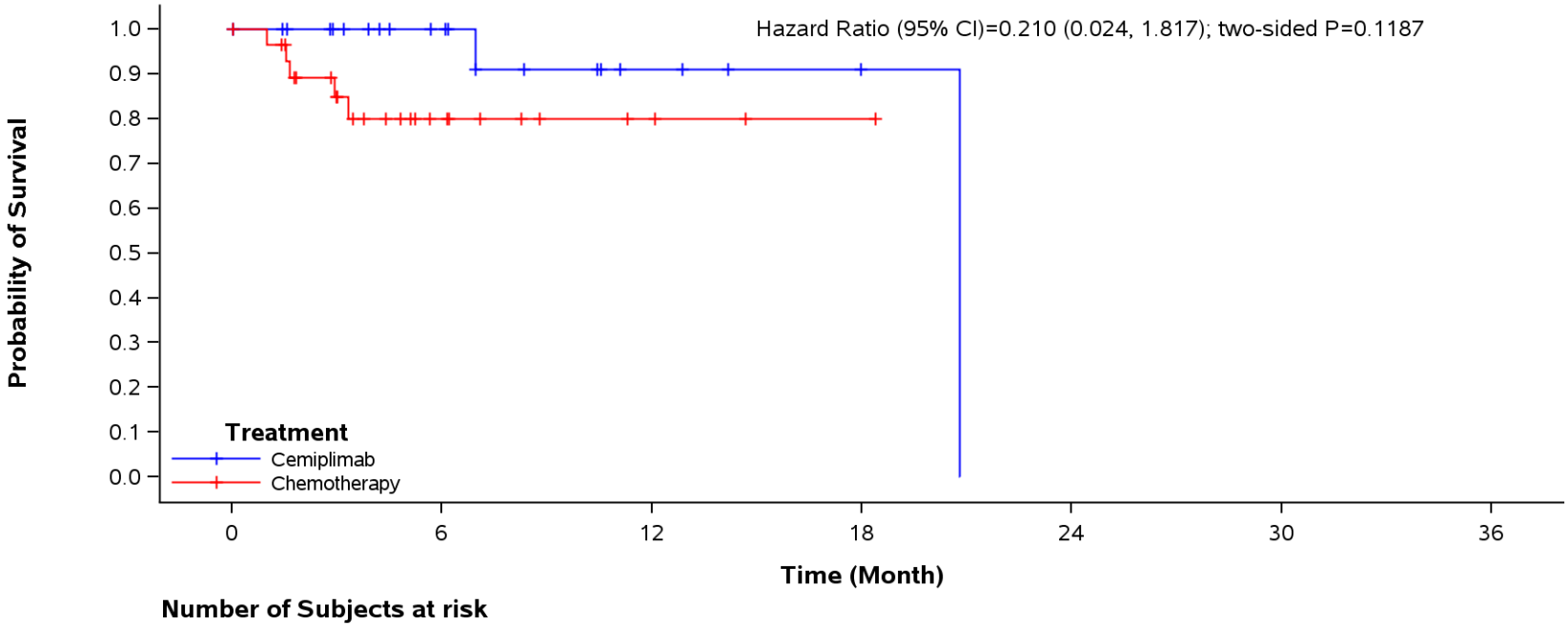

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Emotional Functioning - 10 pts sensitivity sustained deterioration



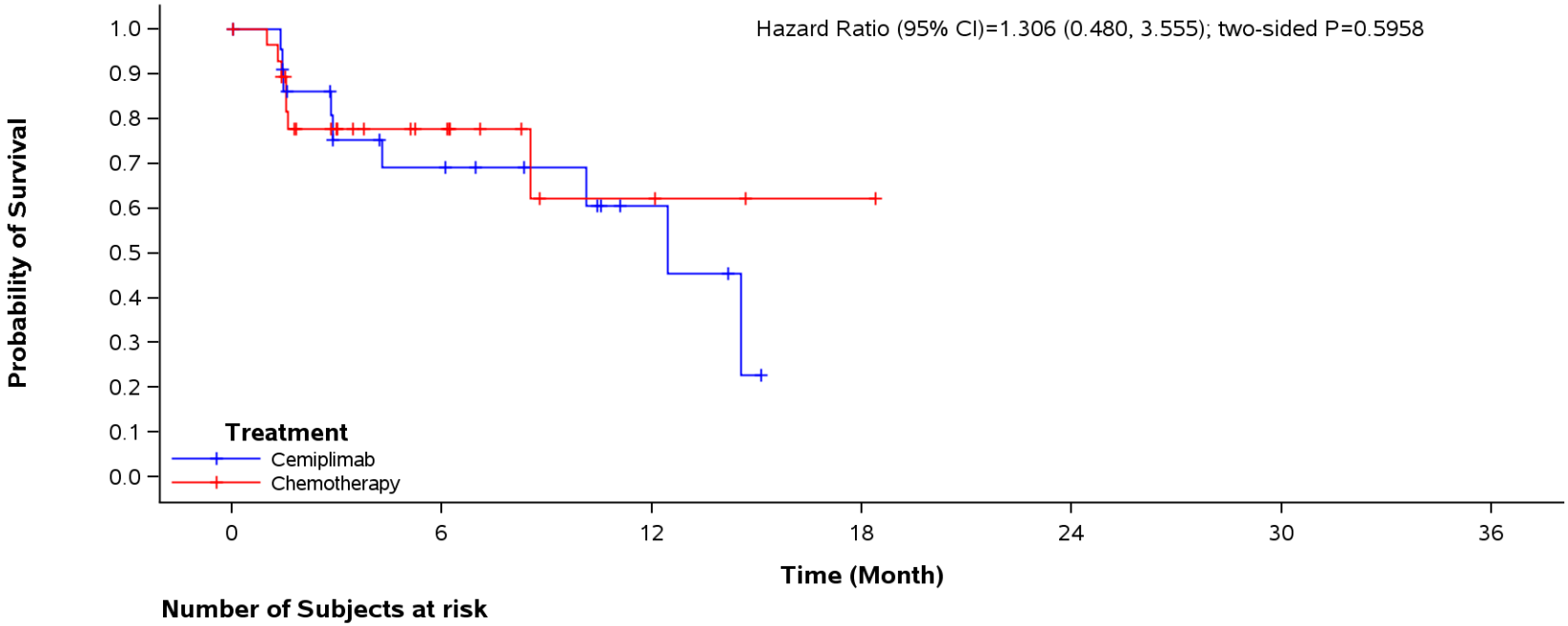

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 13 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Fatigue - 10 pts sensitivity sustained deterioration



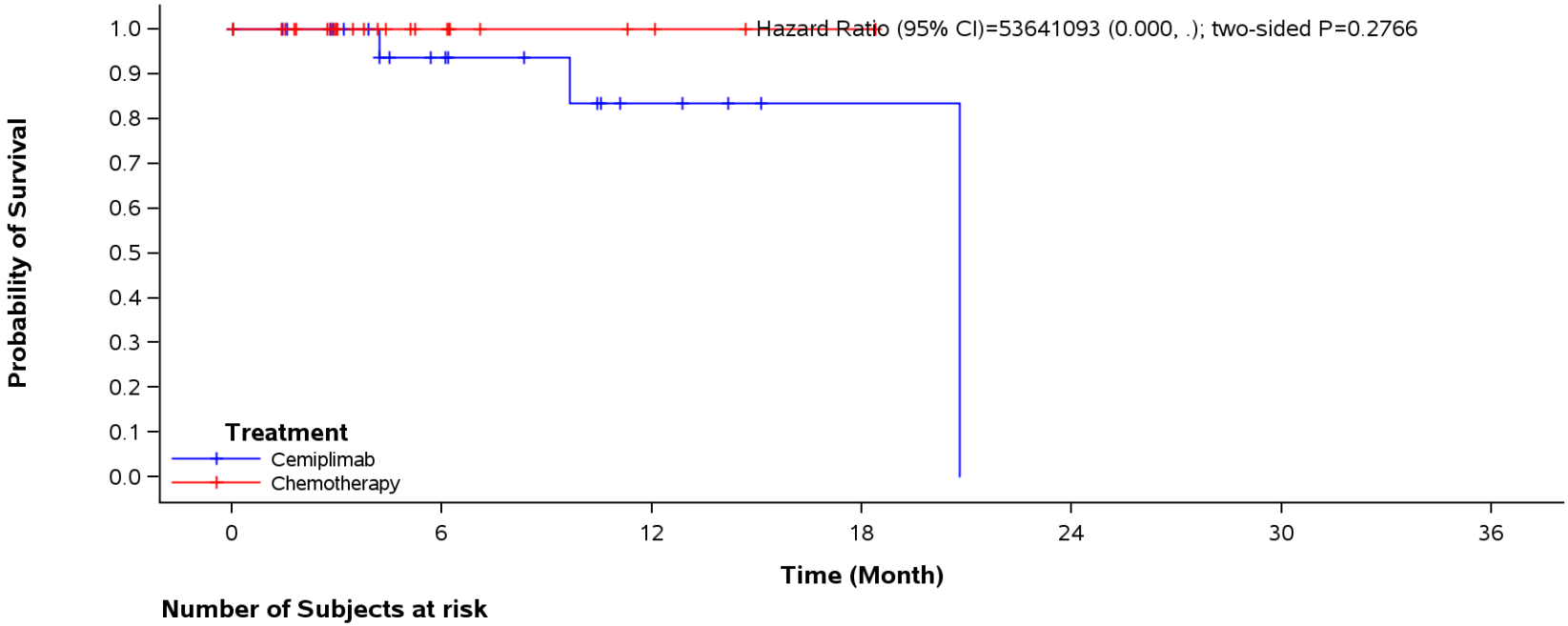

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

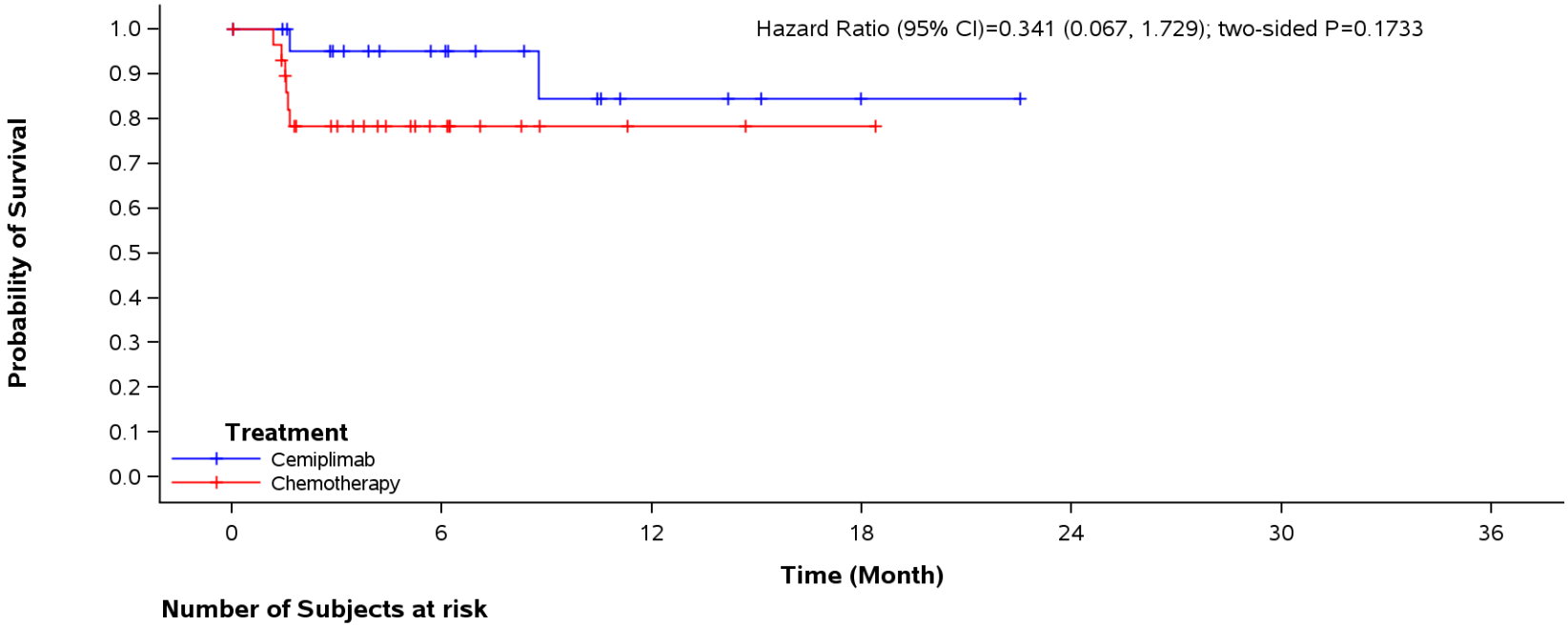
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

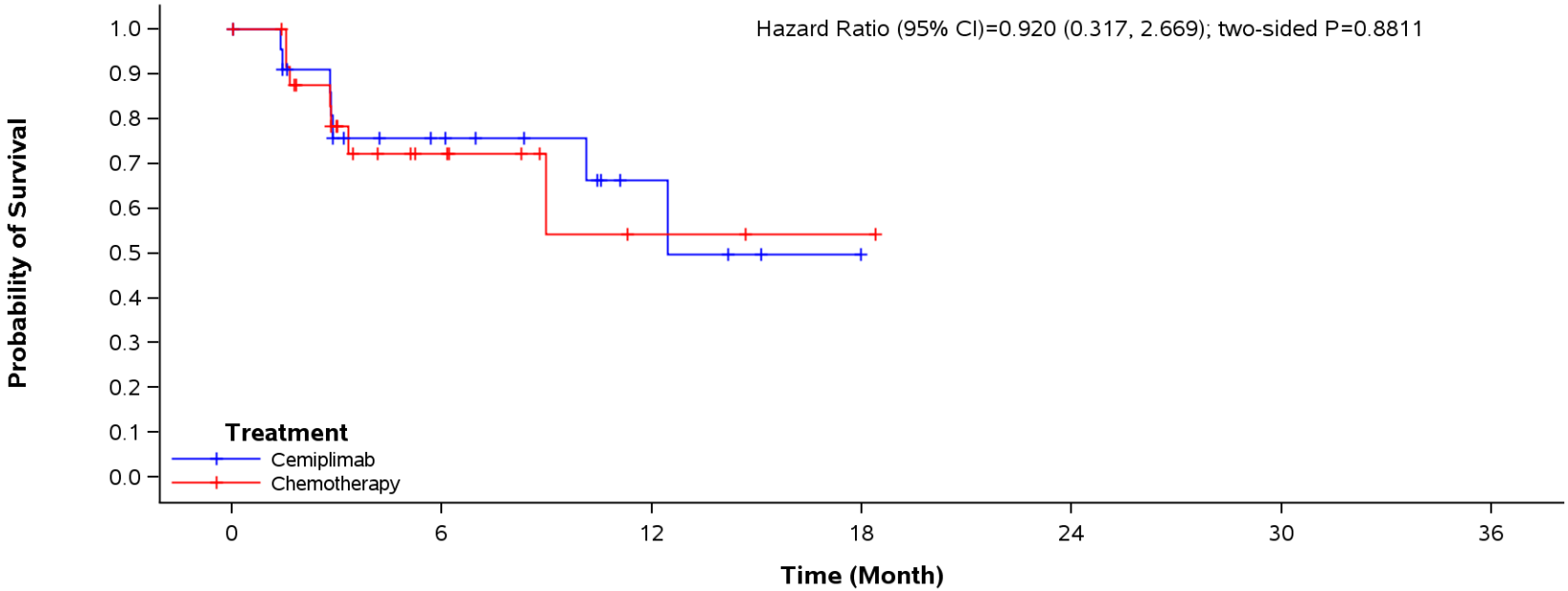
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 13 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Pain - 10 pts sensitivity sustained deterioration



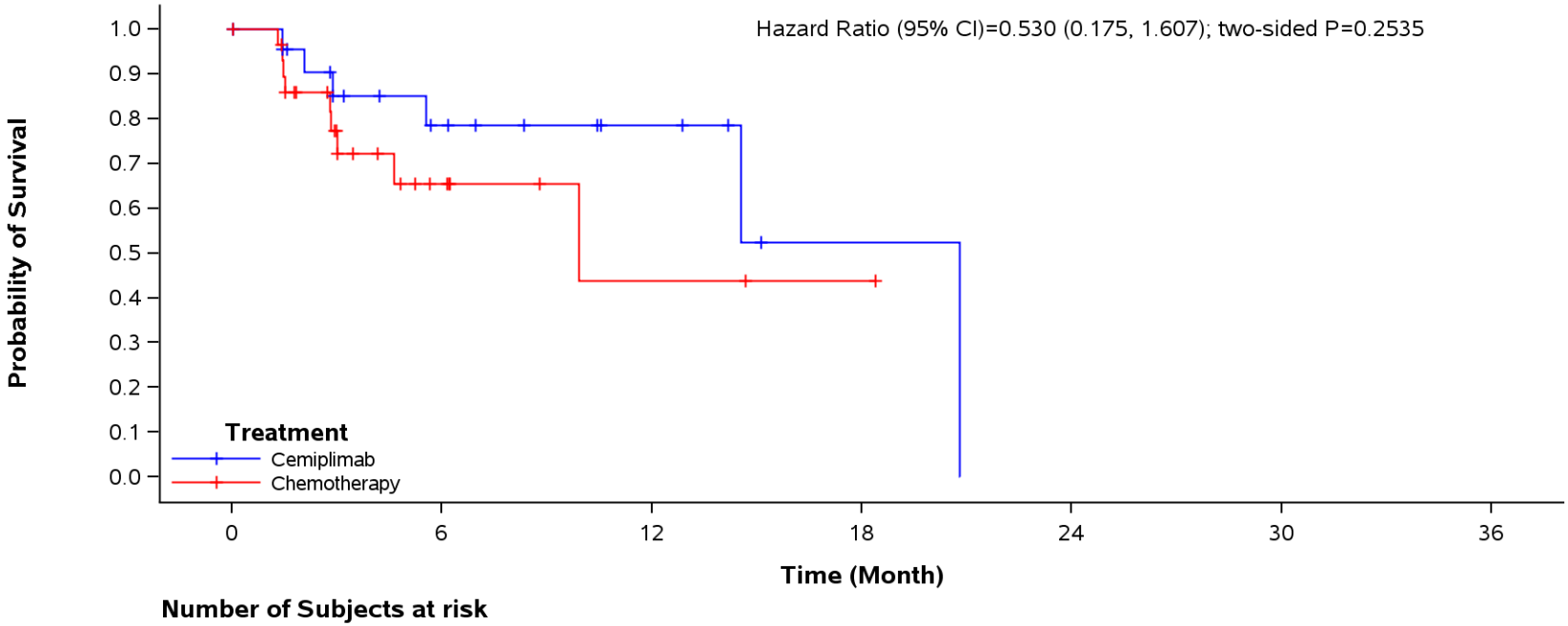

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Physical Functioning - 10 pts sensitivity sustained deterioration



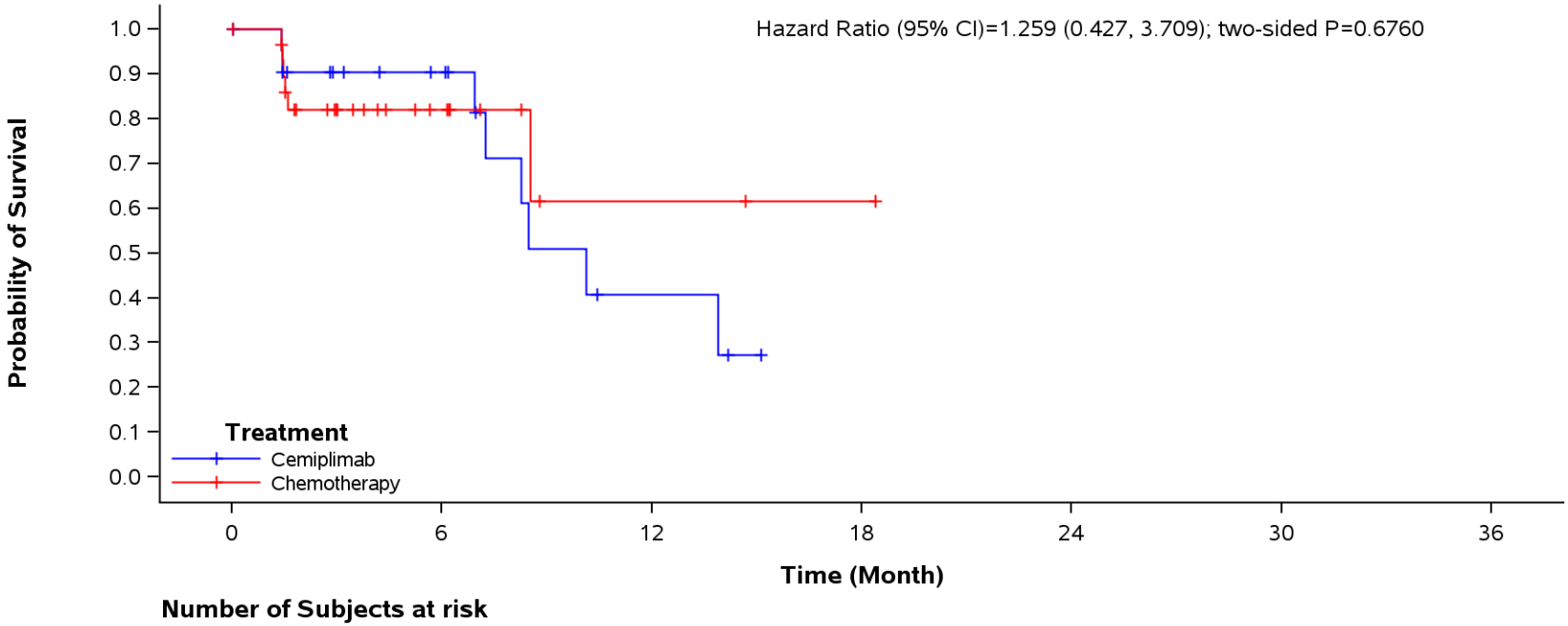

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 7 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Global health status / QoL - 10 pts sensitivity sustained deterioration



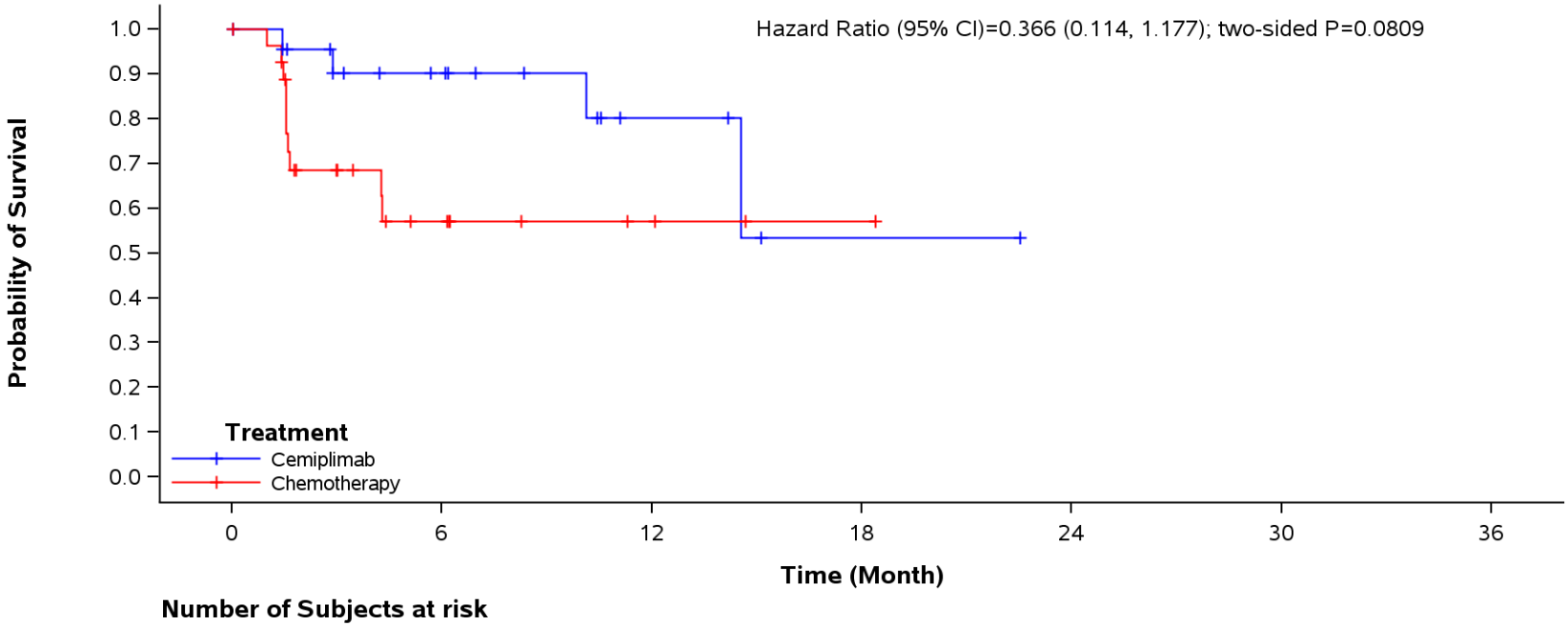

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Role Functioning - 10 pts sensitivity sustained deterioration



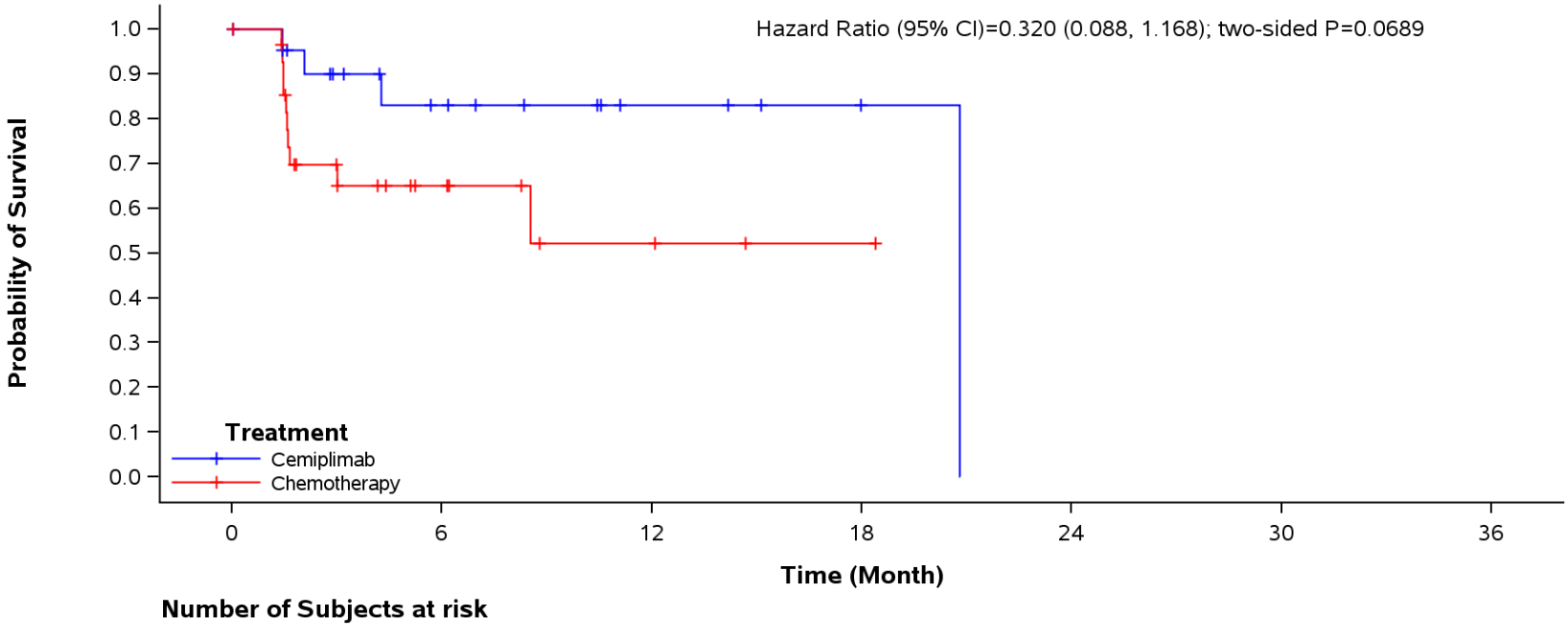

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 13 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Social Functioning - 10 pts sensitivity sustained deterioration



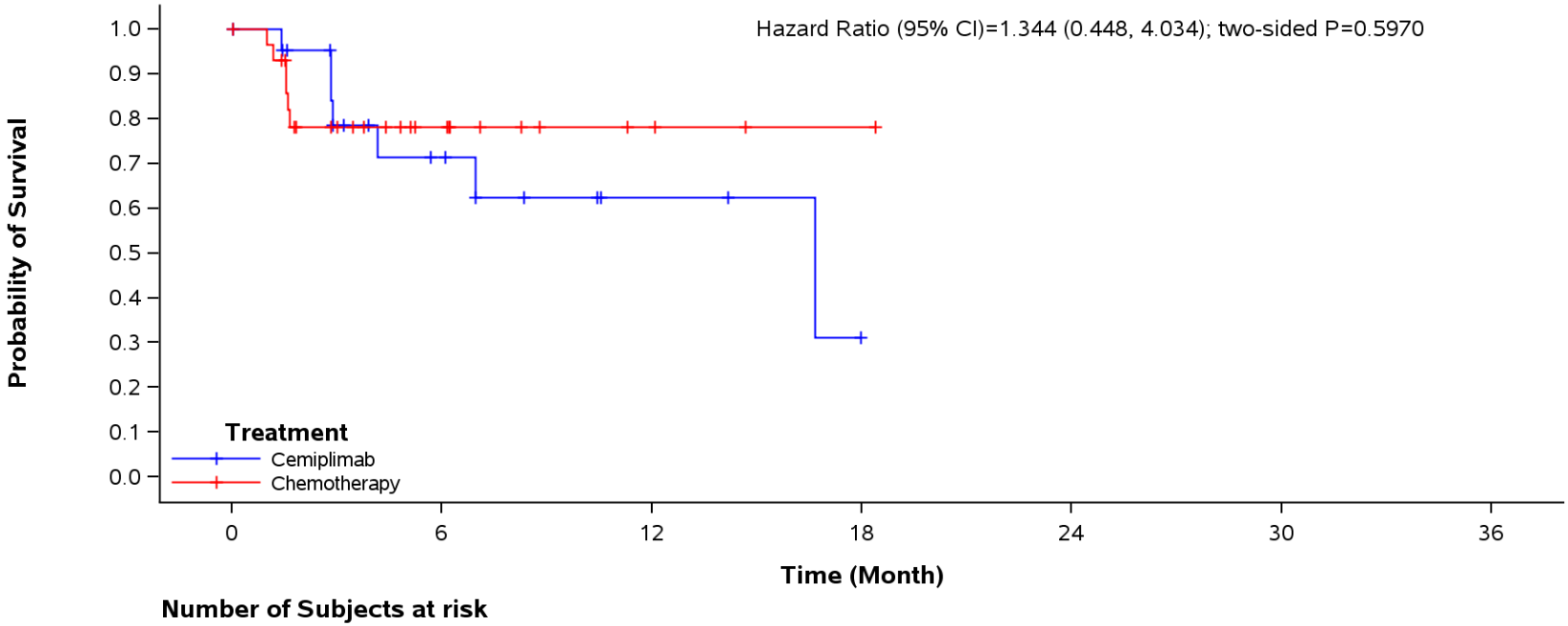

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 46 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

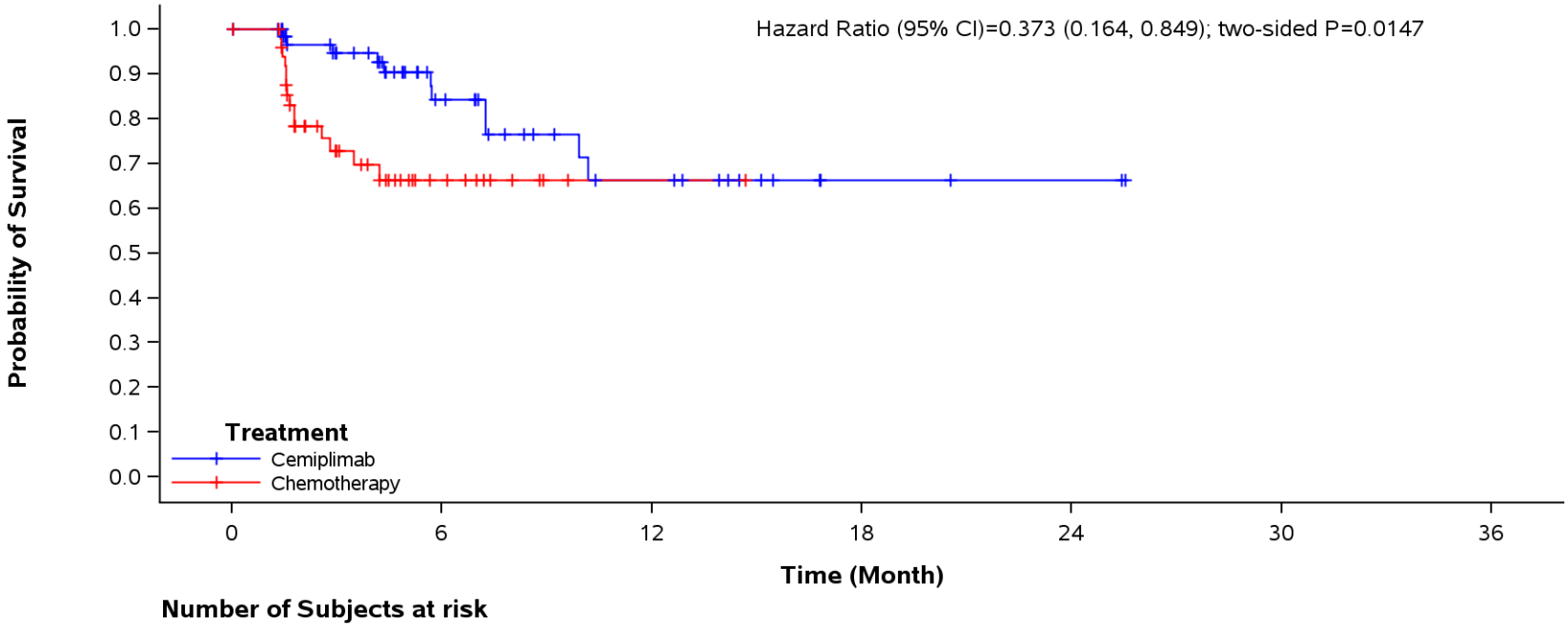
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 46 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 26 | 12 | 3 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

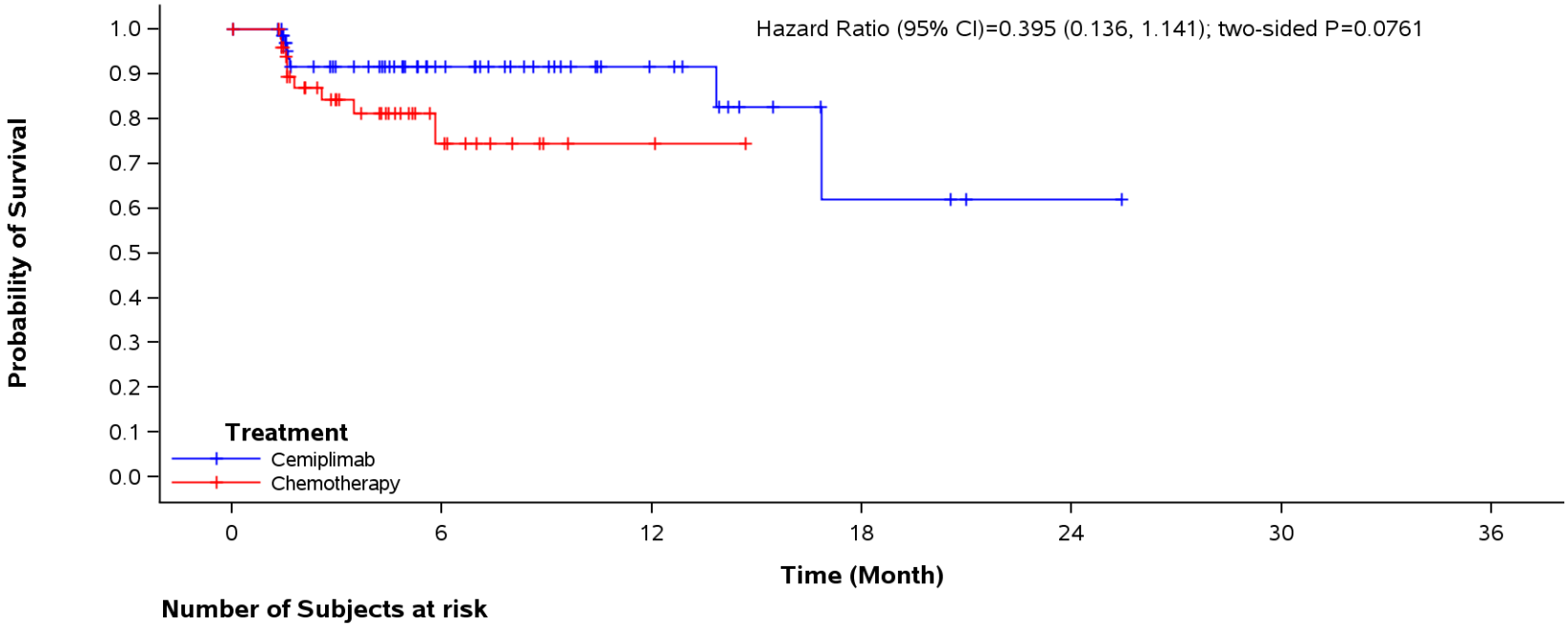
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 30 | 12 | 3 | 1 | 0 | 0 |
| Chemotherapy | 85 | 11 | 2 | 0 | 0 | 0 | 0 |

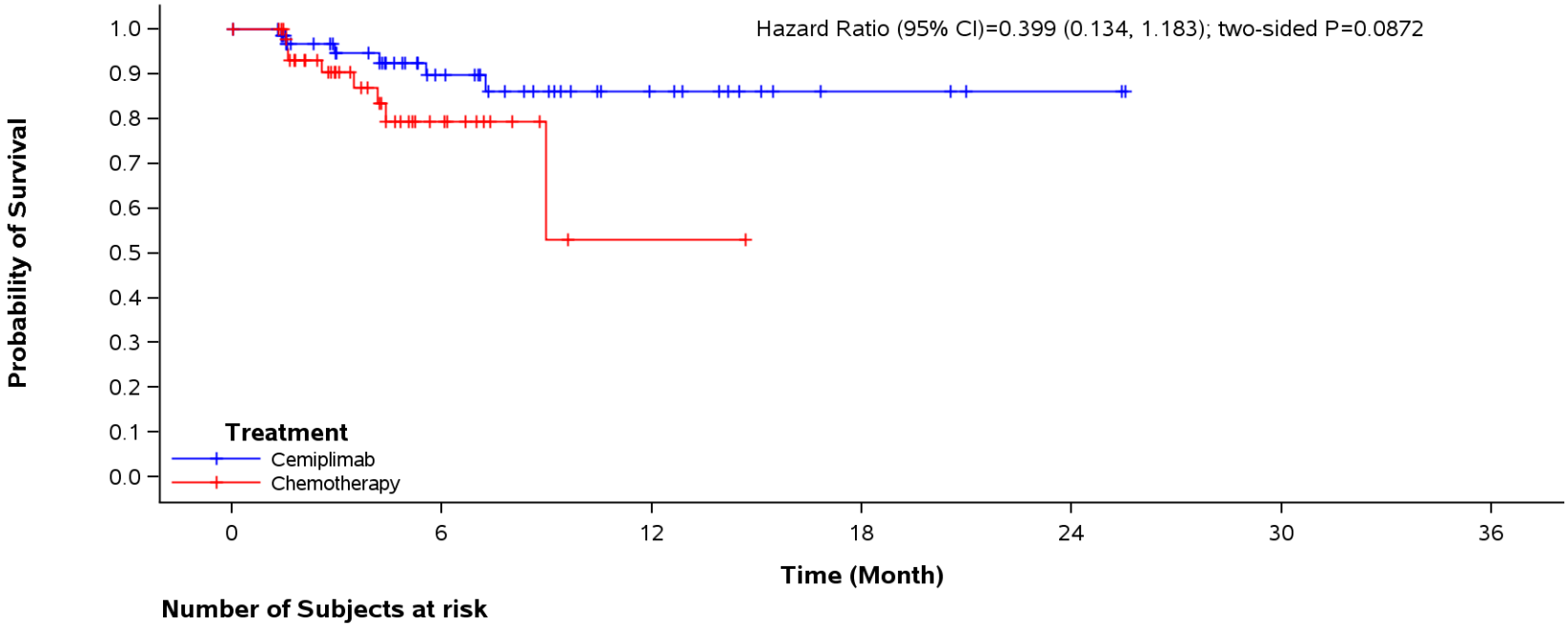
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Constipation - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

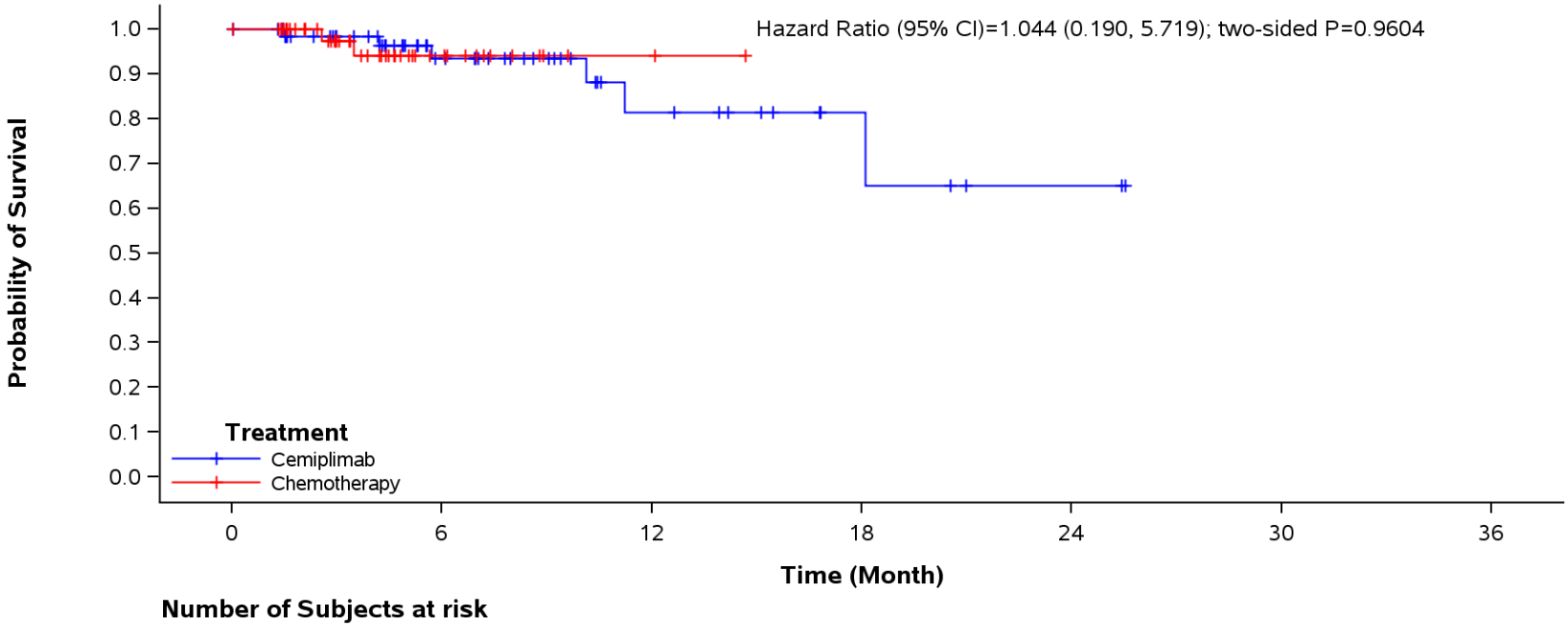
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 29 | 12 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Diarhoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

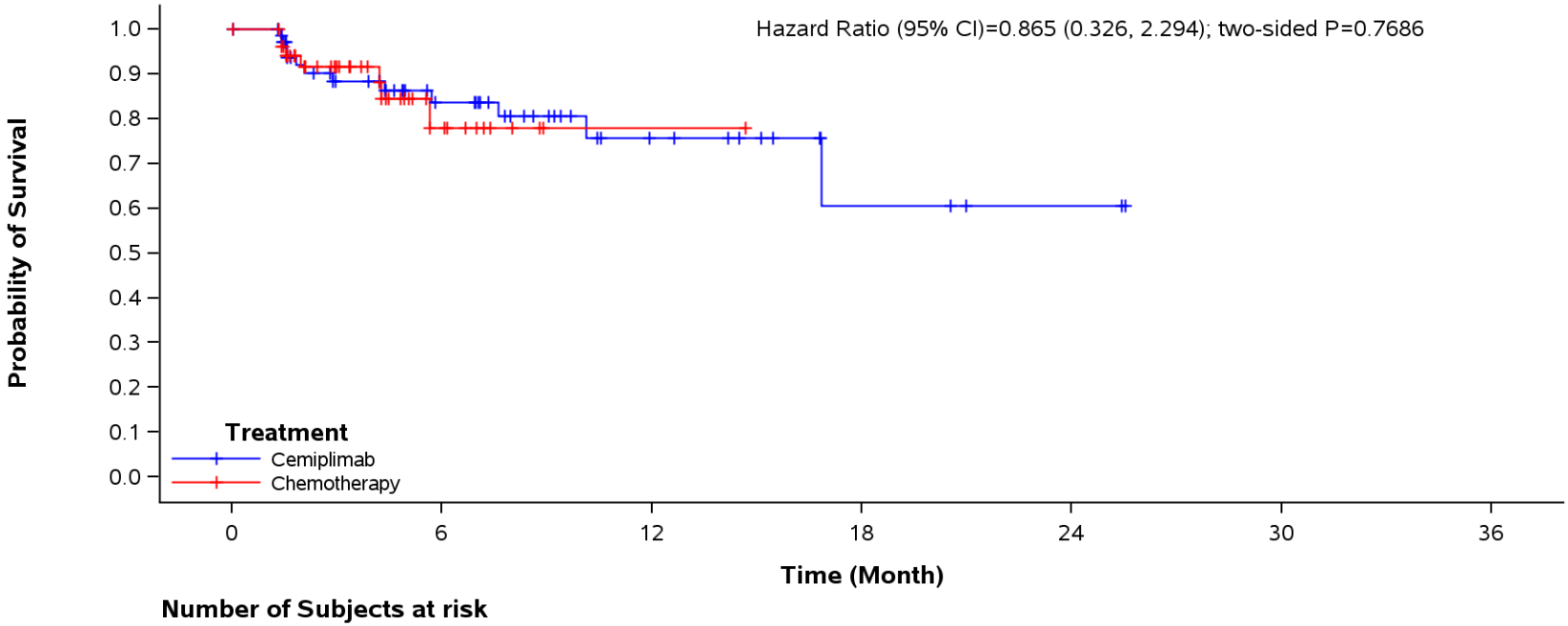
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 31 | 12 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Dyspnoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 31 | 12 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

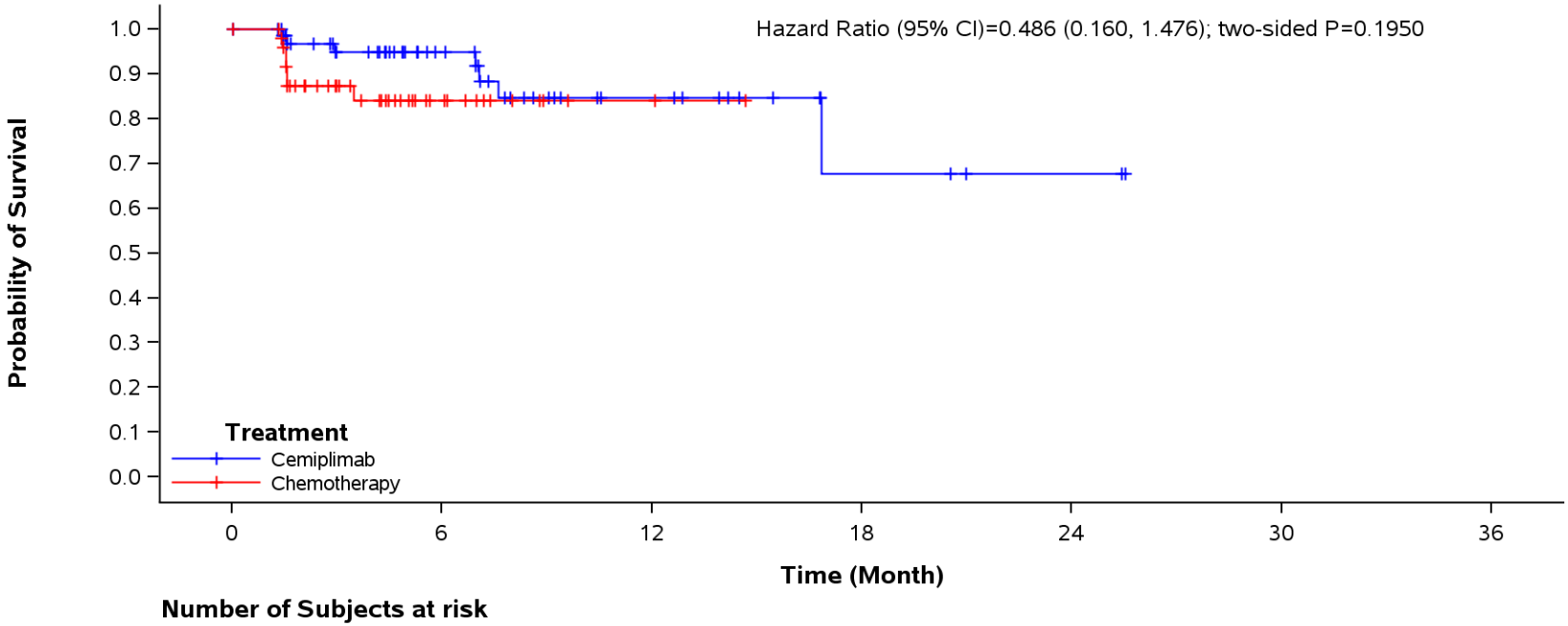
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Emotional Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

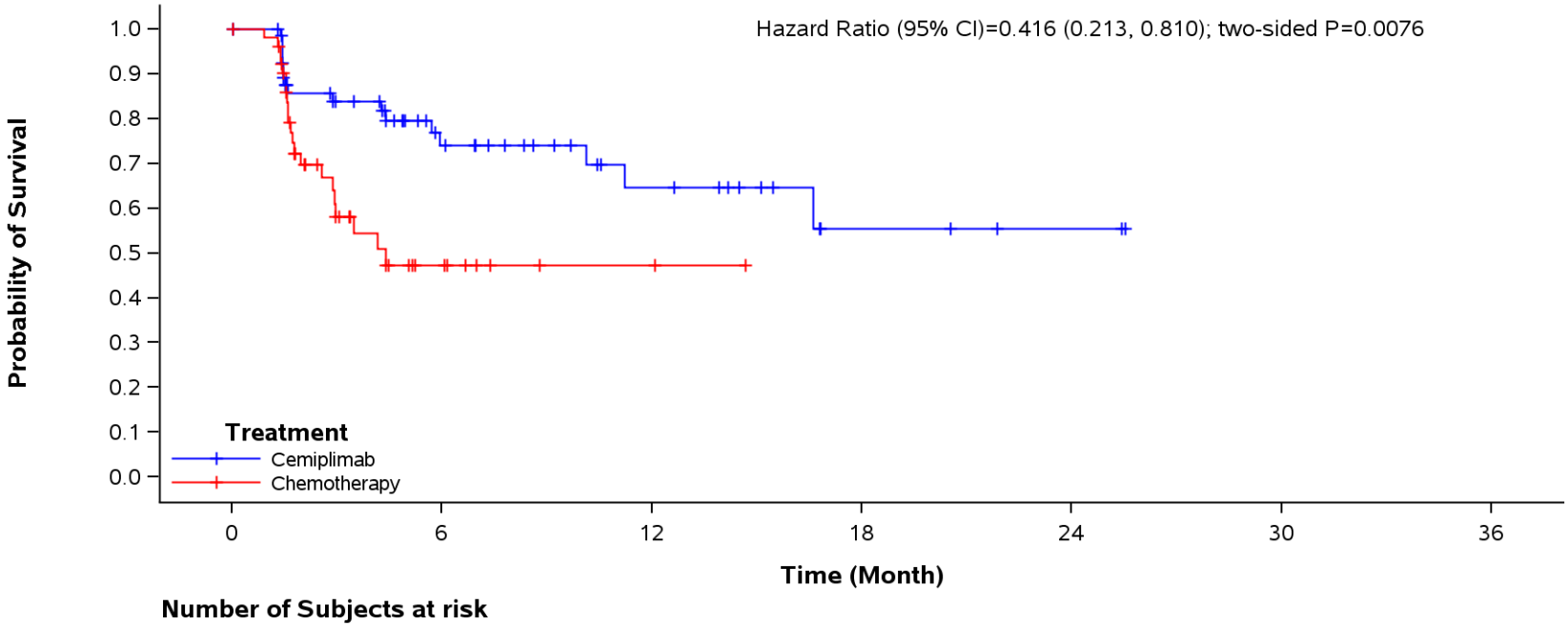
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 32 | 13 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

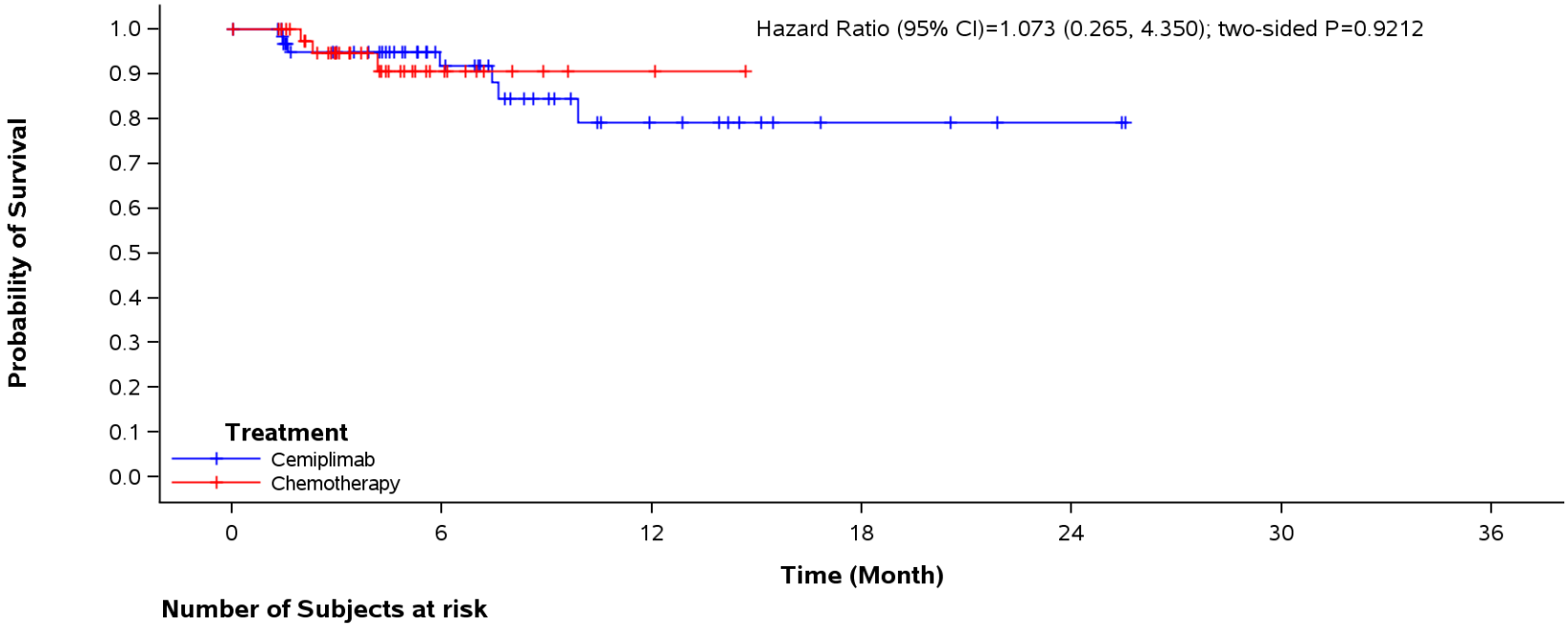
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 26 | 13 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 30 | 11 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 2 | 0 | 0 | 0 | 0 |

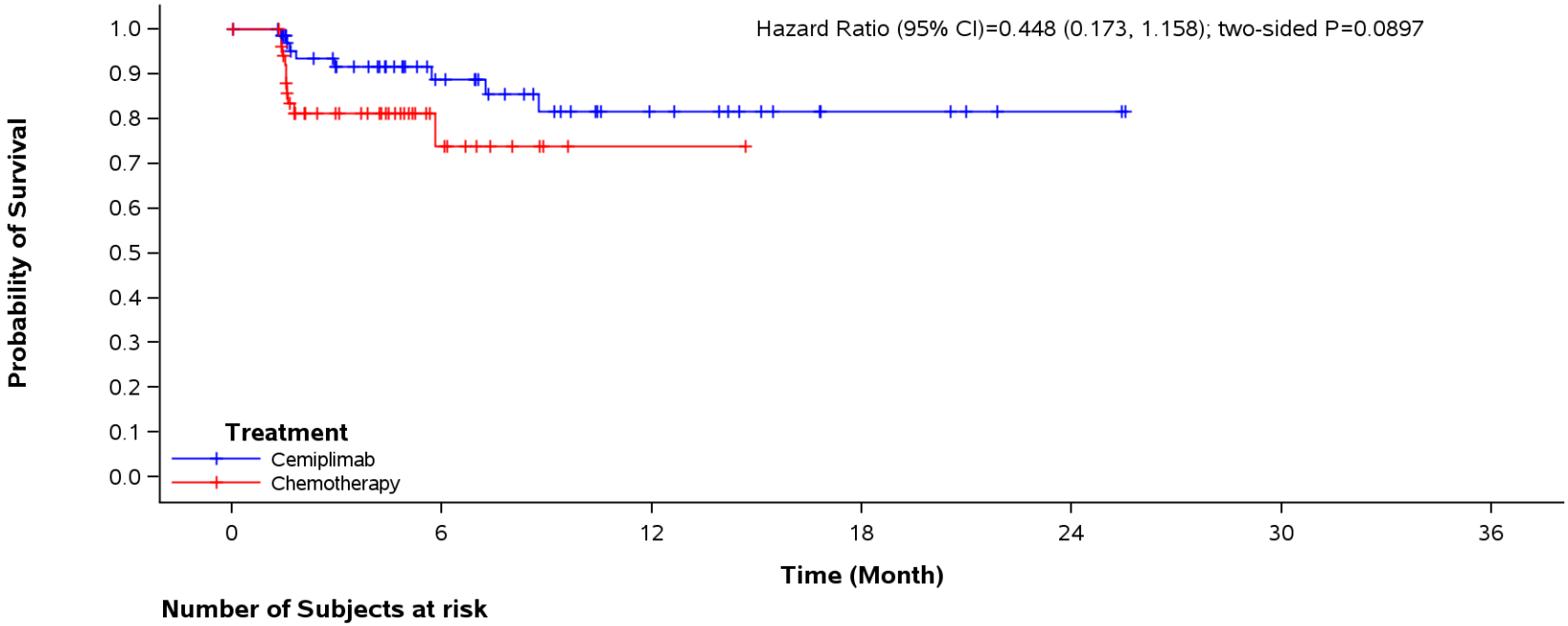
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

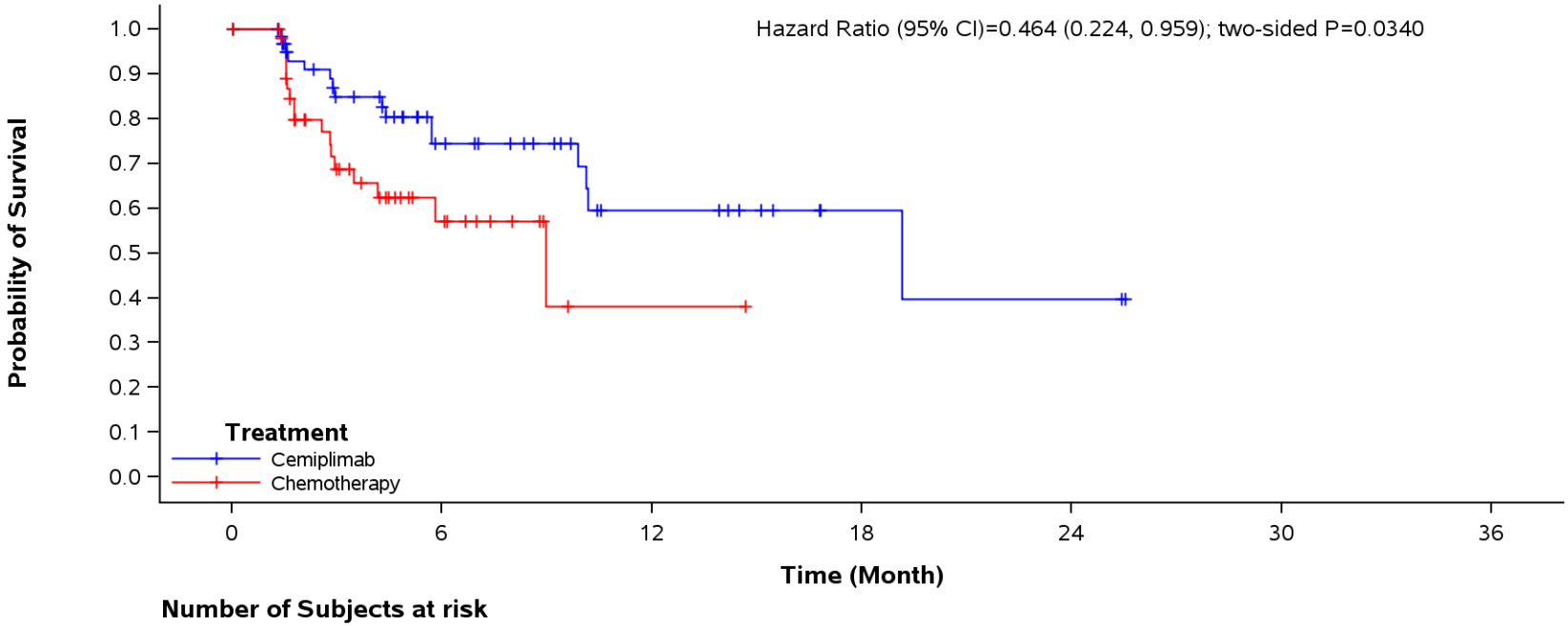
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 31 | 13 | 5 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

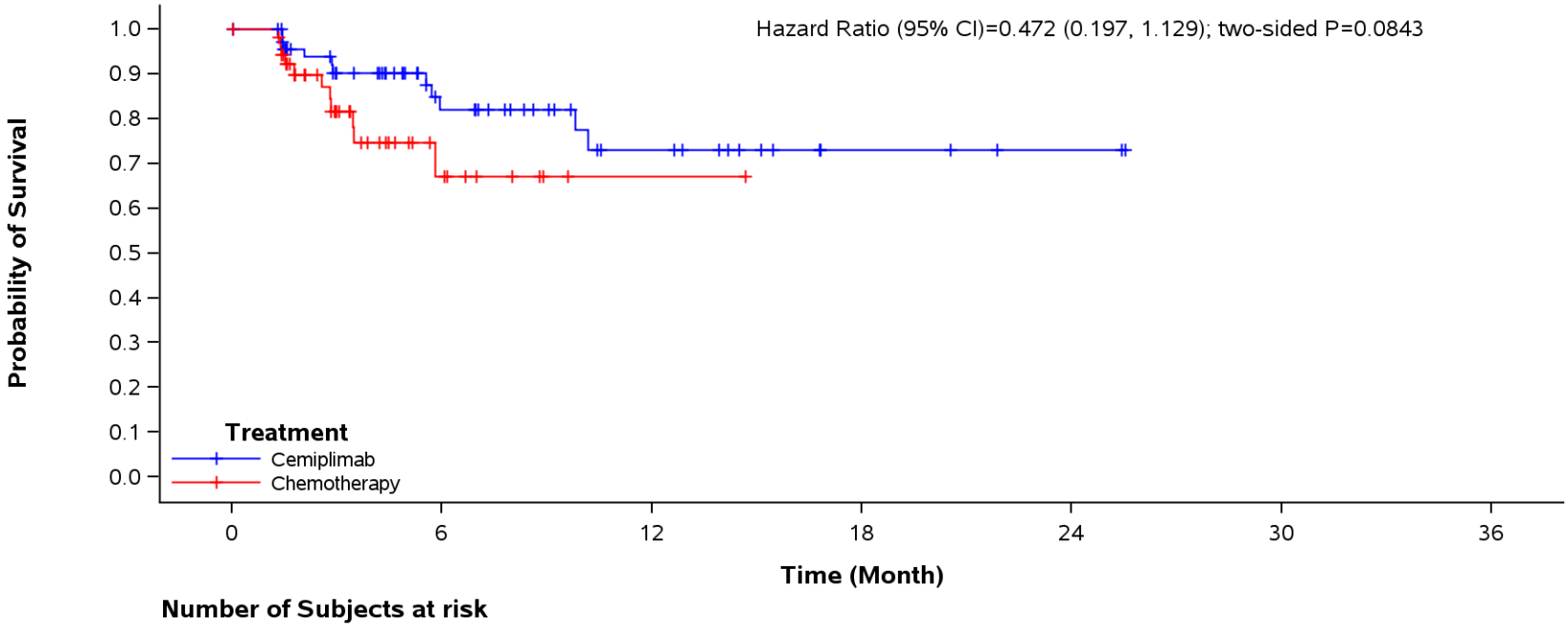
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 24 | 10 | 3 | 2 | 0 | 0 |
| Chemotherapy | 85 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 29 | 13 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 9 | 1 | 0 | 0 | 0 | 0 |

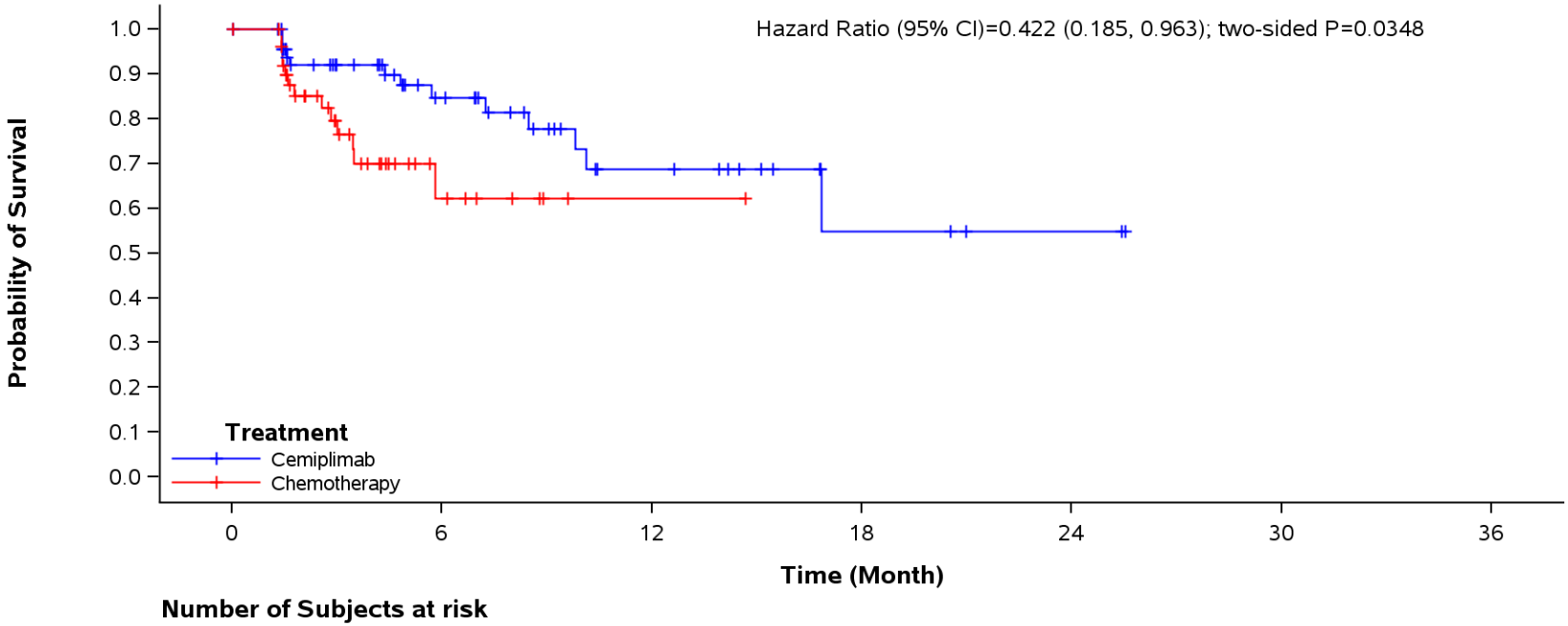
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 30 | 13 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 8 | 1 | 0 | 0 | 0 | 0 |

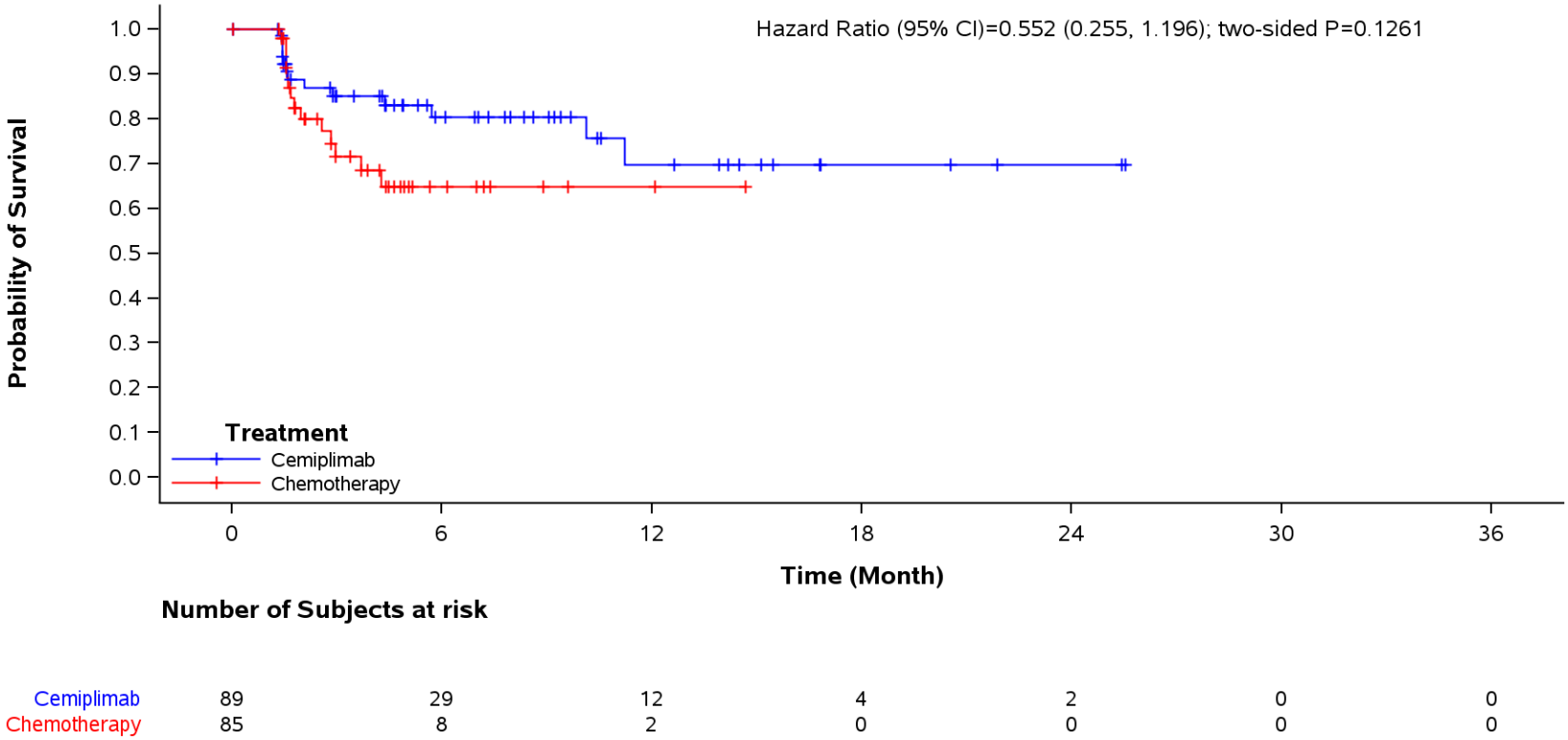
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Role Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 29 | 12 | 4 | 2 | 0 | 0 |
| Chemotherapy | 85 | 8 | 2 | 0 | 0 | 0 | 0 |

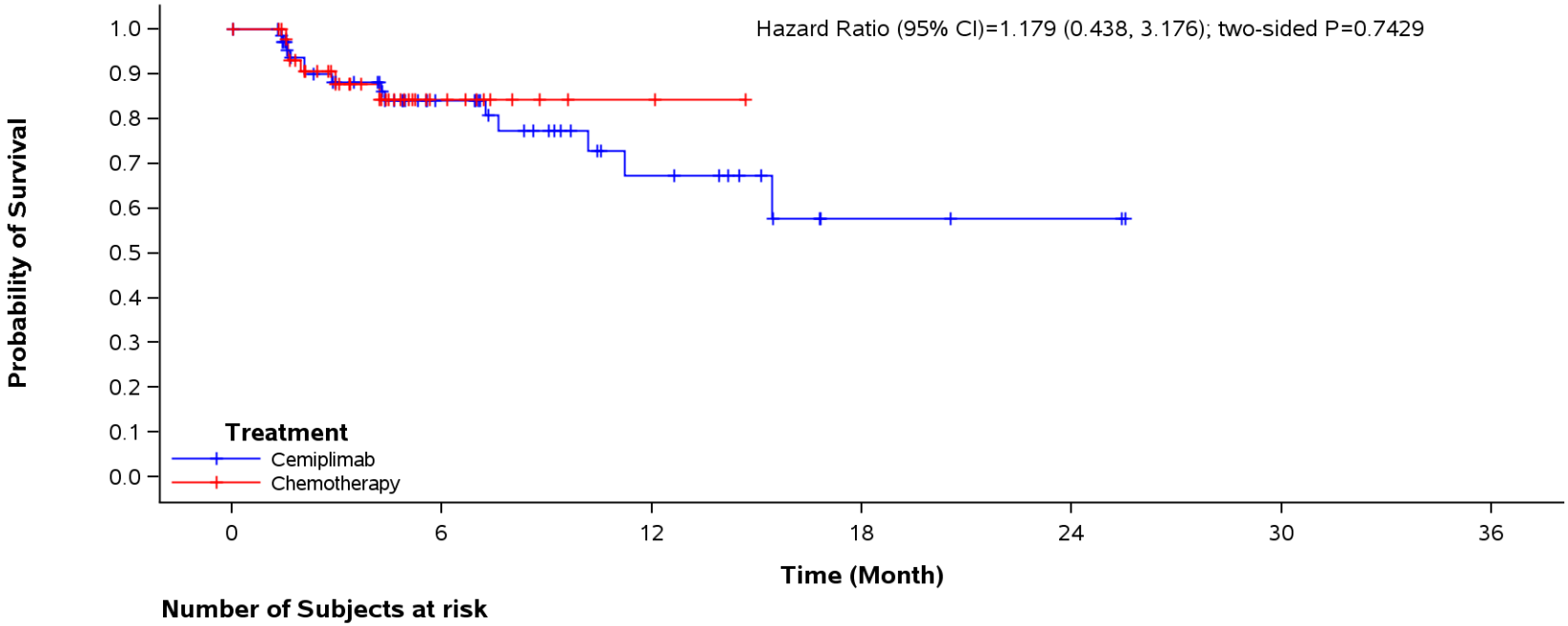
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

Social Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

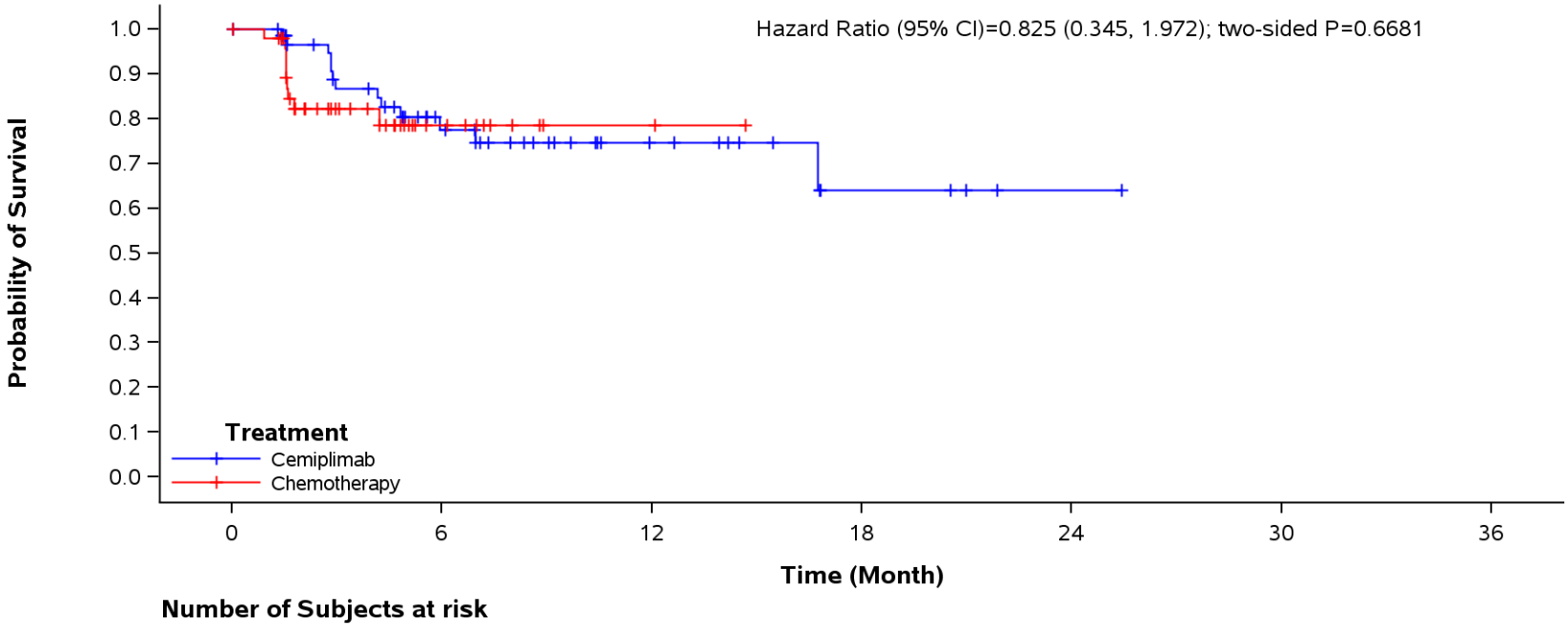
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 30 | 12 | 3 | 2 | 0 | 0 |
| Chemotherapy | 85 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

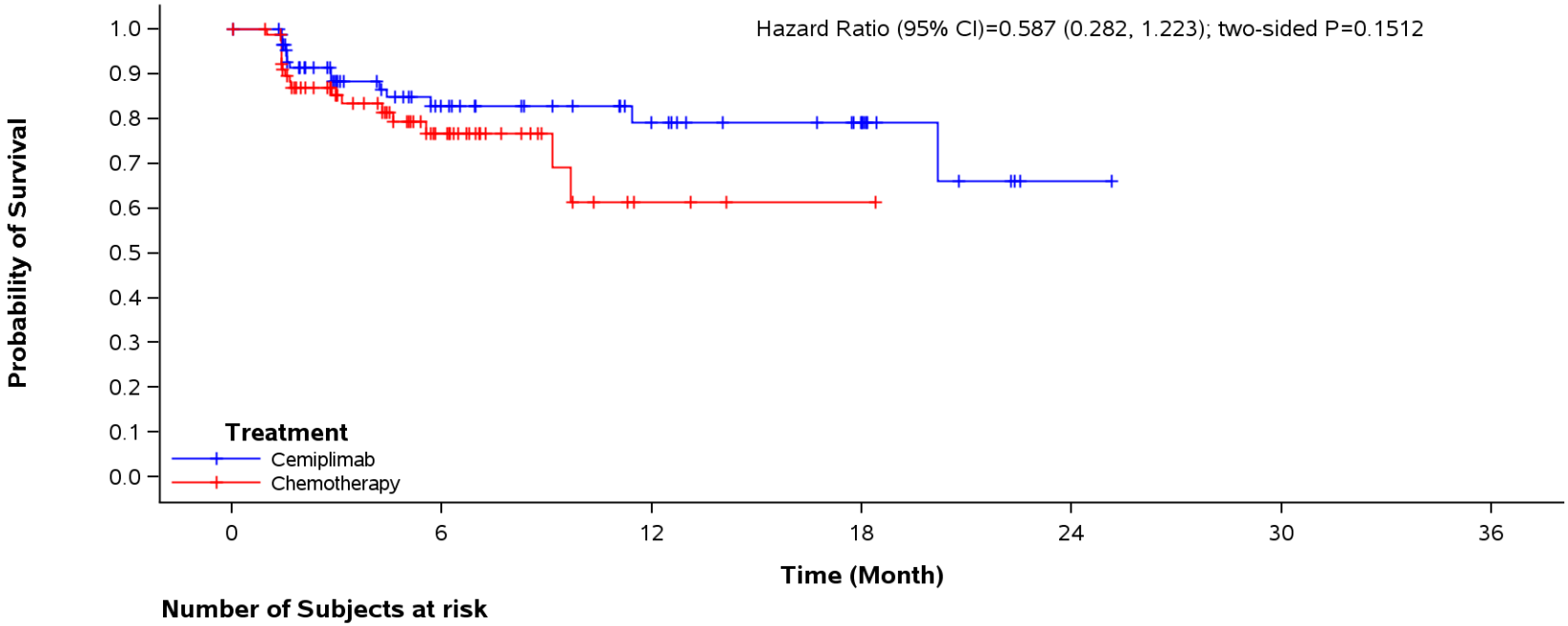
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 28 | 12 | 4 | 1 | 0 | 0 |
| Chemotherapy | 85 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 21 | 12 | 1 | 0 | 0 |
| Chemotherapy | 98 | 26 | 3 | 1 | 0 | 0 | 0 |

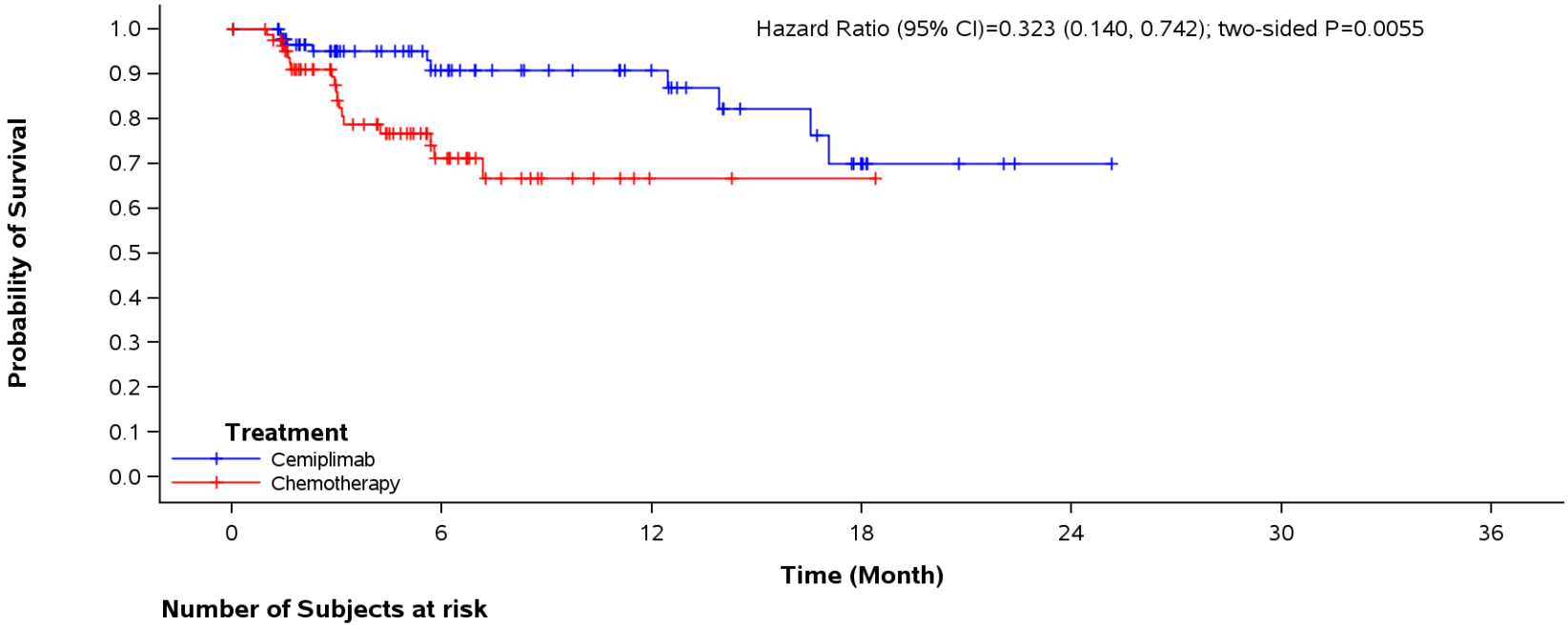
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 41 | 23 | 8 | 1 | 0 | 0 |
| Chemotherapy | 98 | 24 | 2 | 1 | 0 | 0 | 0 |

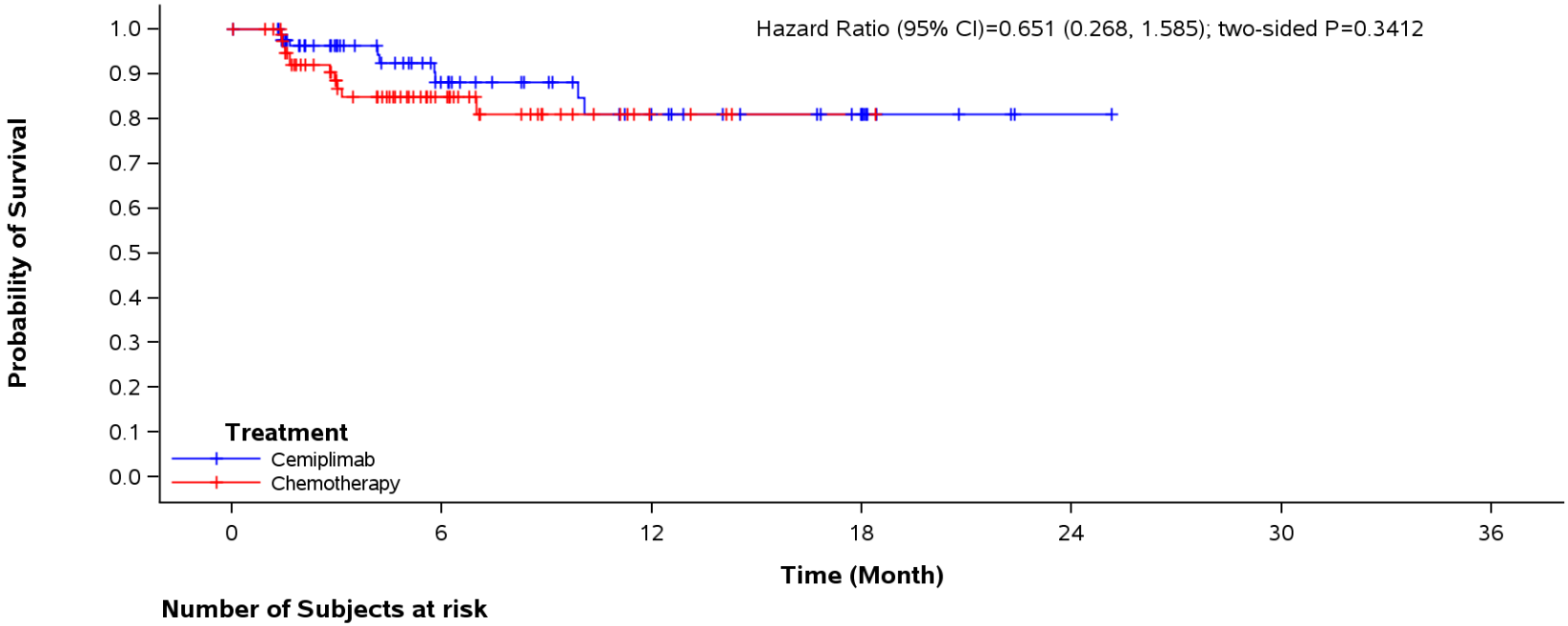
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Constipation - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 19 | 10 | 1 | 0 | 0 |
| Chemotherapy | 98 | 28 | 4 | 1 | 0 | 0 | 0 |

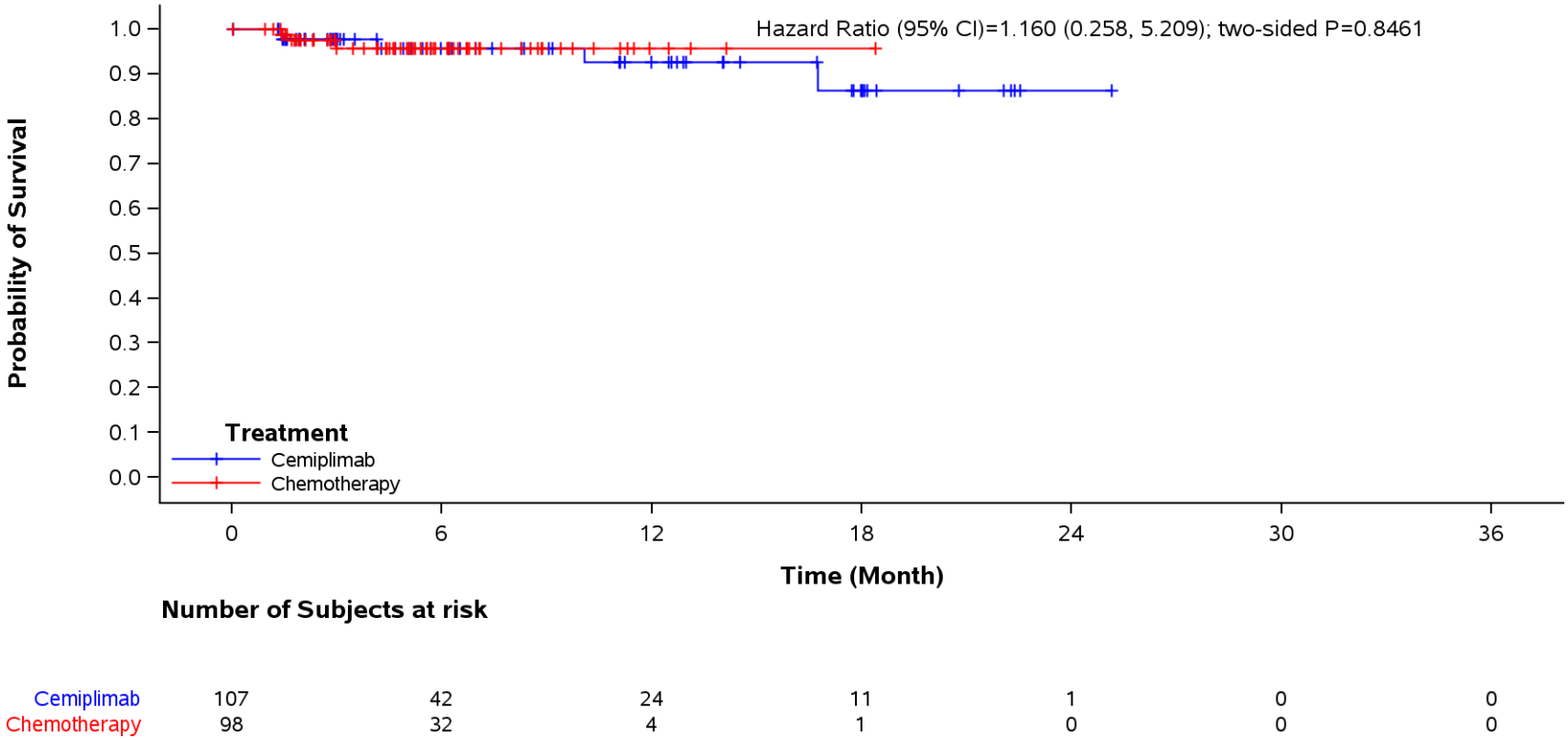
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Diarhoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 42 | 24 | 11 | 1 | 0 | 0 |
| Chemotherapy | 98 | 32 | 4 | 1 | 0 | 0 | 0 |

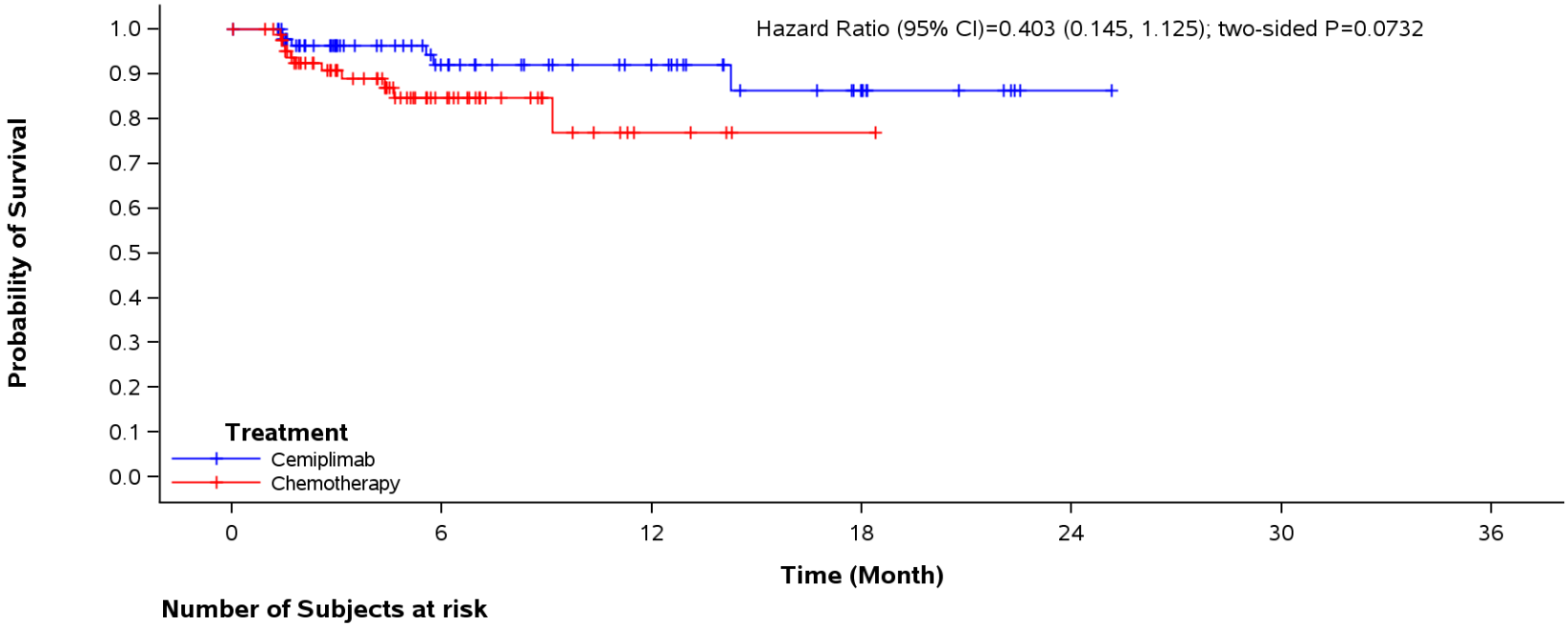
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Dyspnoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 40 | 23 | 10 | 1 | 0 | 0 |
| Chemotherapy | 98 | 26 | 4 | 1 | 0 | 0 | 0 |

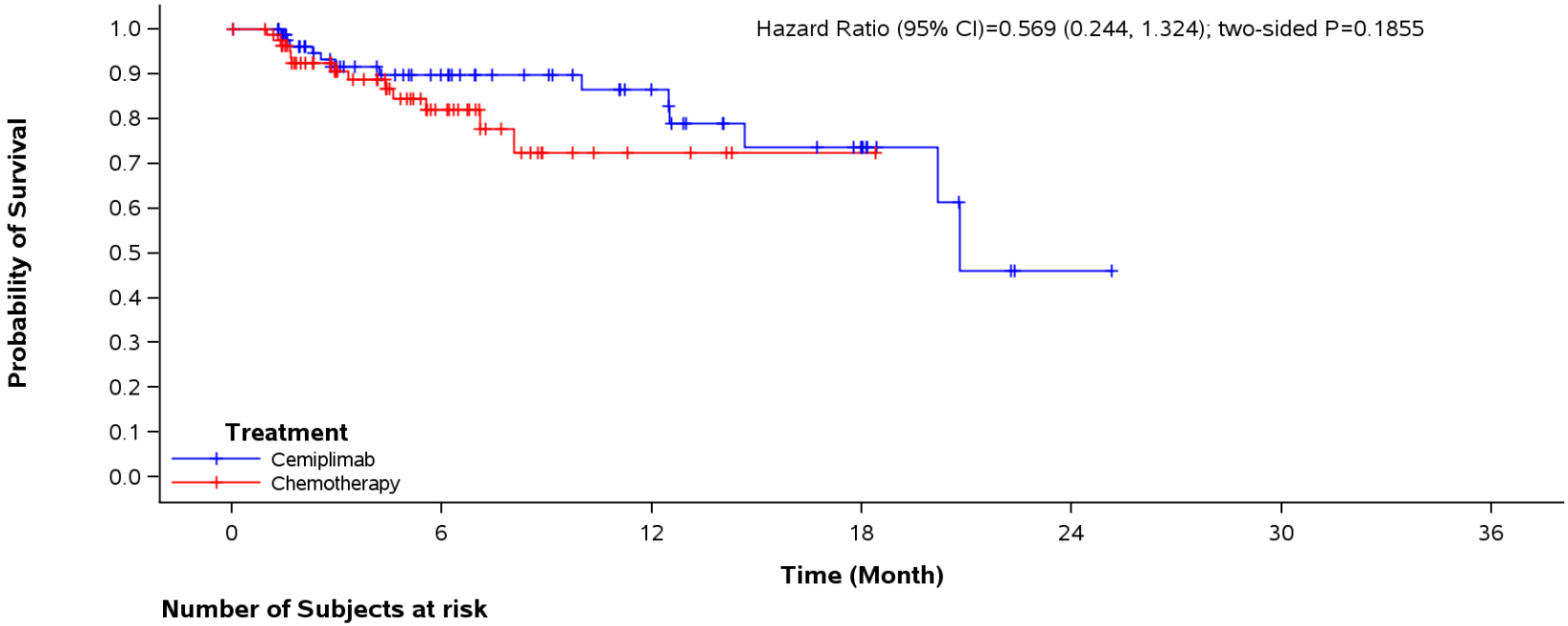
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Emotional Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

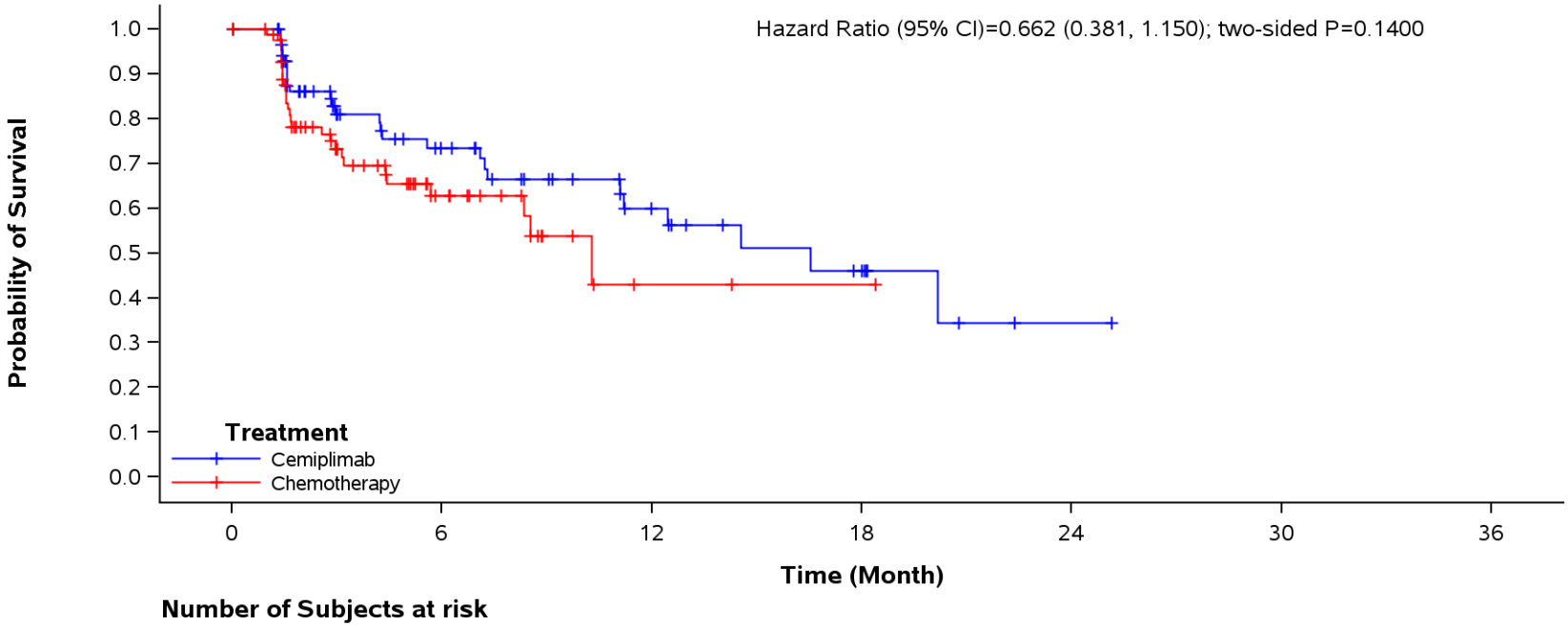
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 41 | 23 | 11 | 1 | 0 | 0 |
| Chemotherapy | 98 | 28 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

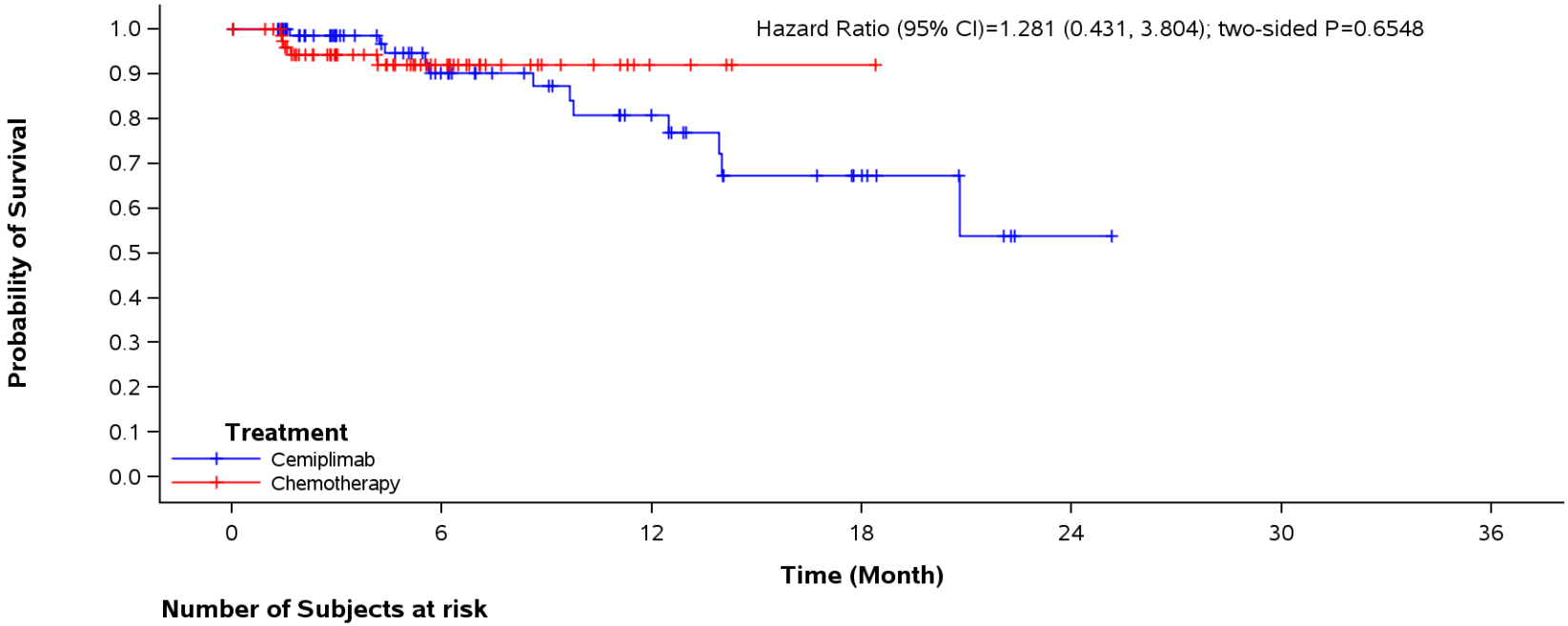
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 35 | 16 | 8 | 1 | 0 | 0 |
| Chemotherapy | 98 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

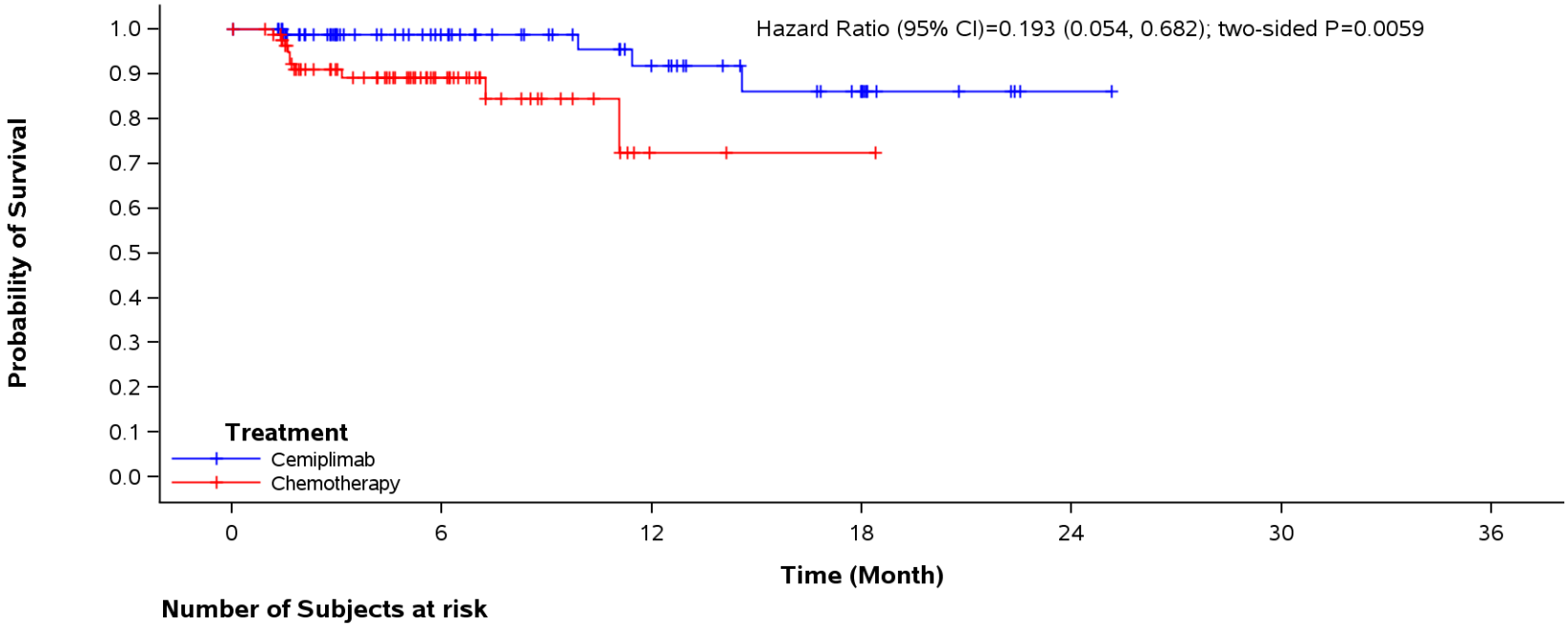
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 21 | 9 | 1 | 0 | 0 |
| Chemotherapy | 98 | 27 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



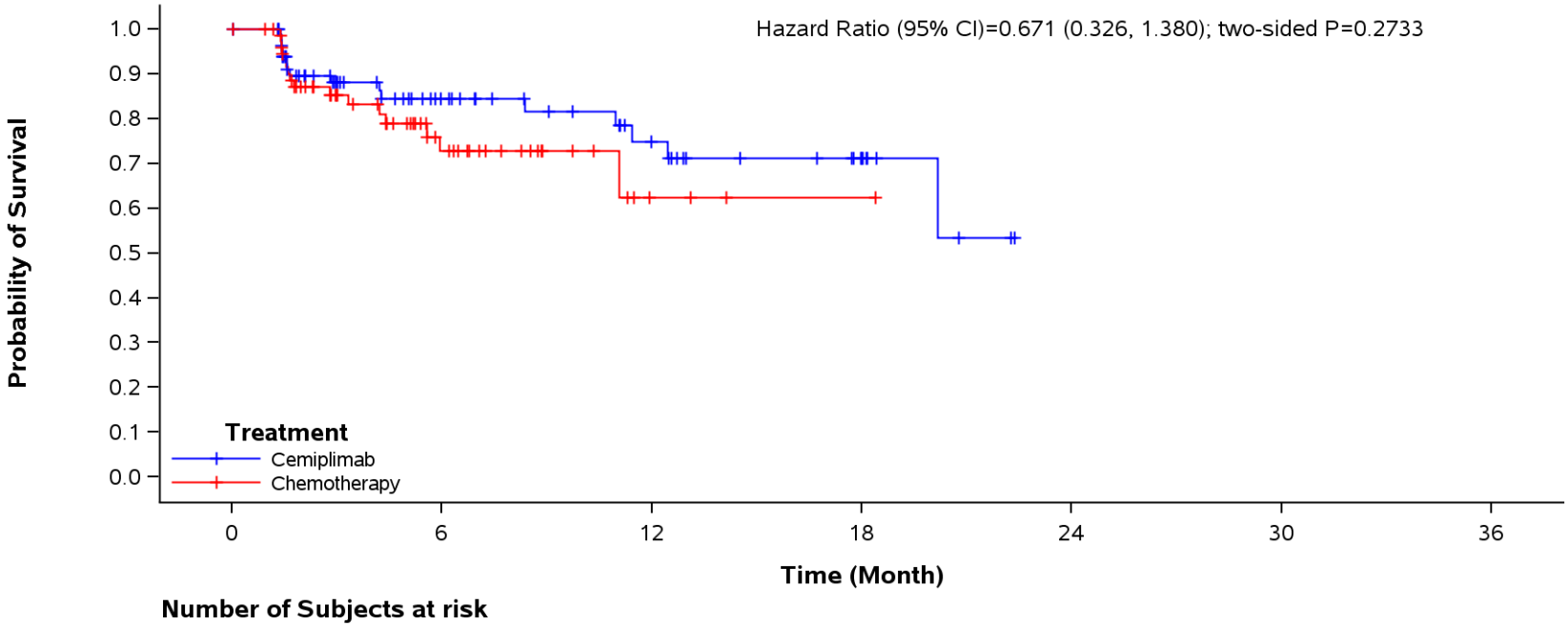

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 45 | 23 | 11 | 1 | 0 | 0 |
| Chemotherapy | 98 | 29 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Pain - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

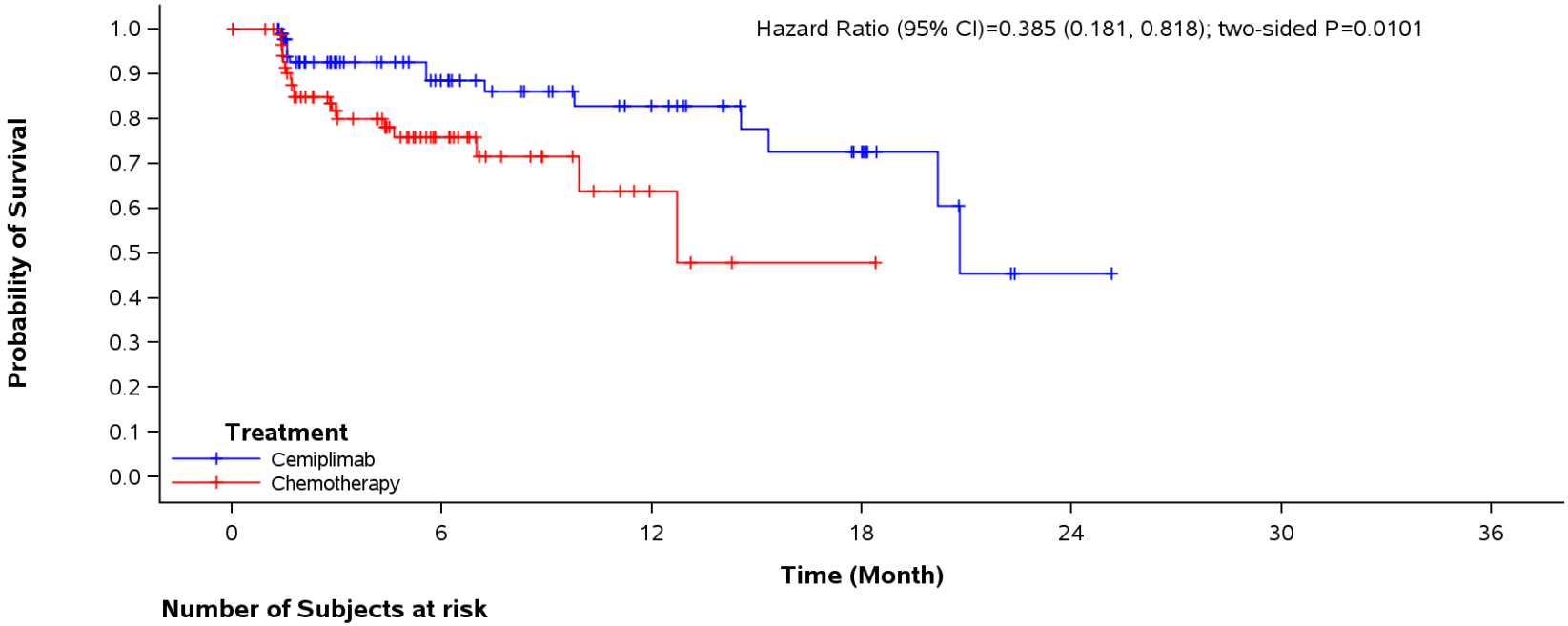
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 20 | 9 | 0 | 0 | 0 |
| Chemotherapy | 98 | 23 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 42 | 23 | 12 | 1 | 0 | 0 |
| Chemotherapy | 98 | 25 | 4 | 1 | 0 | 0 | 0 |

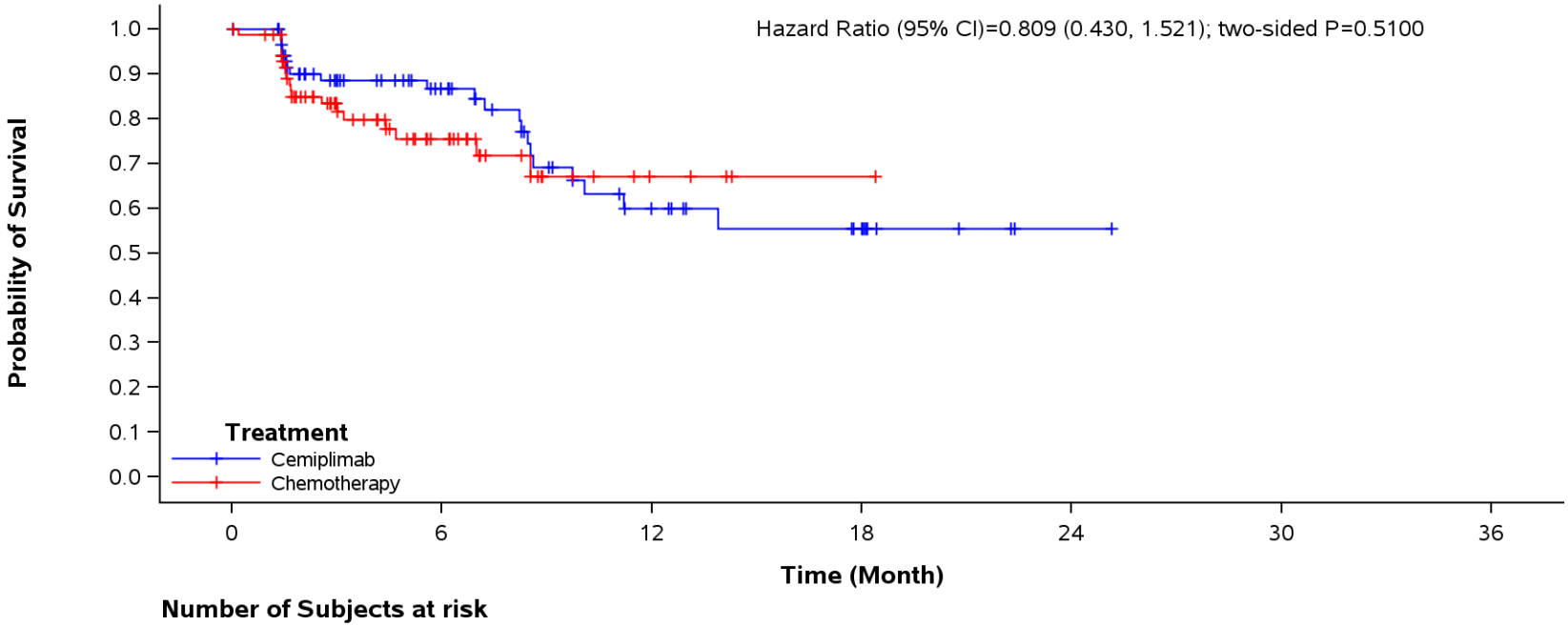
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 42 | 17 | 10 | 1 | 0 | 0 |
| Chemotherapy | 98 | 28 | 4 | 1 | 0 | 0 | 0 |

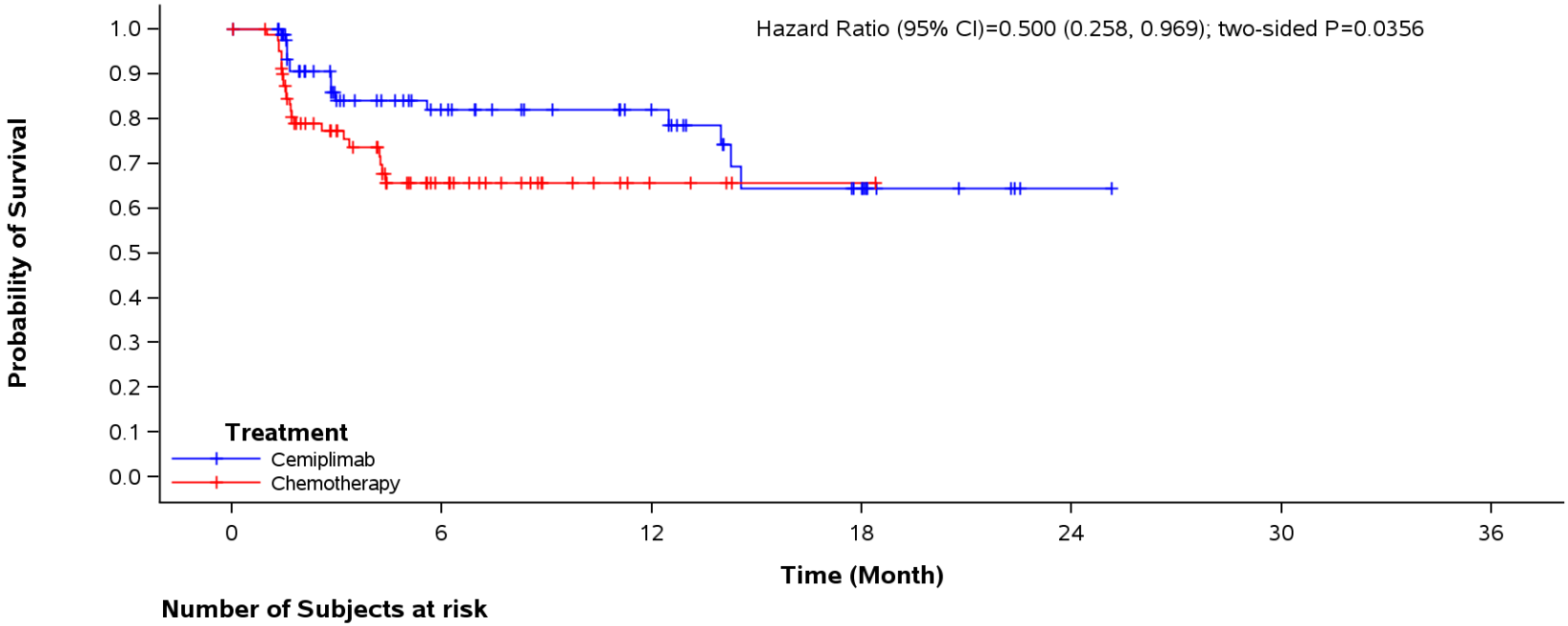
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Role Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 37 | 24 | 11 | 1 | 0 | 0 |
| Chemotherapy | 98 | 22 | 4 | 1 | 0 | 0 | 0 |

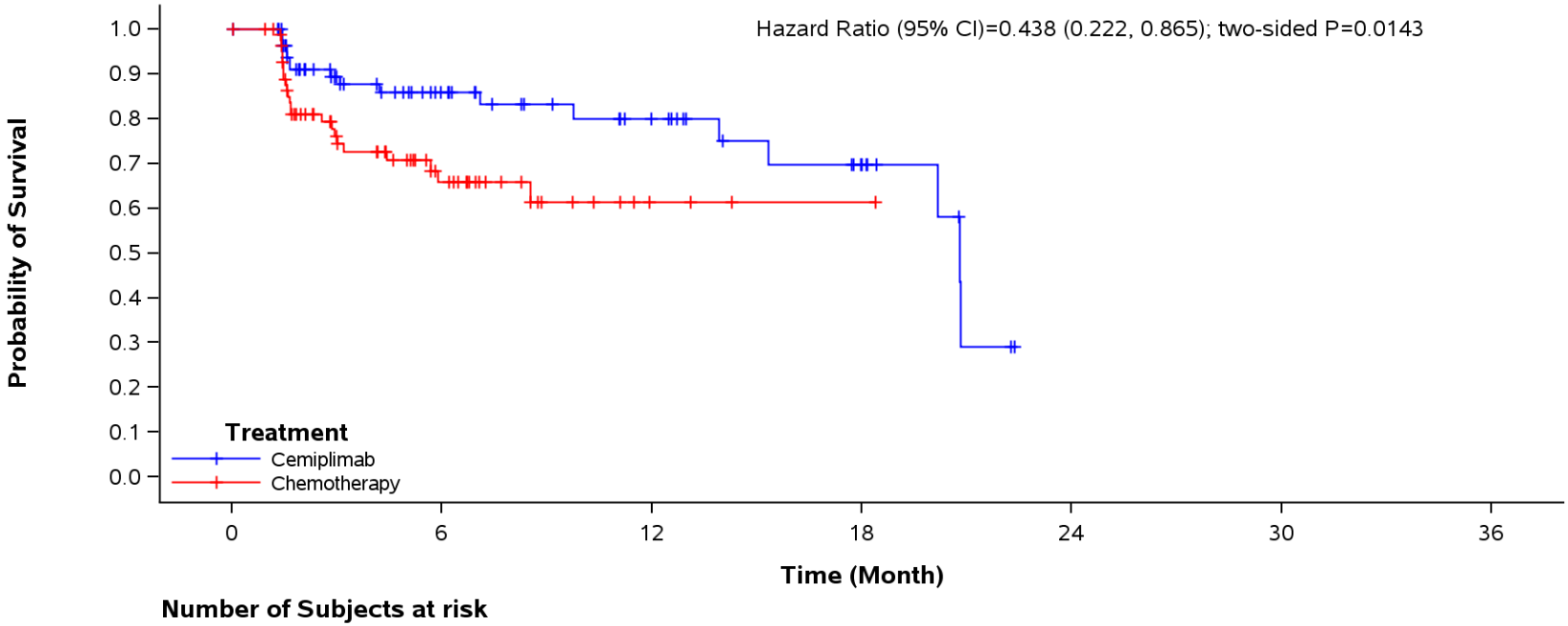
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

Social Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

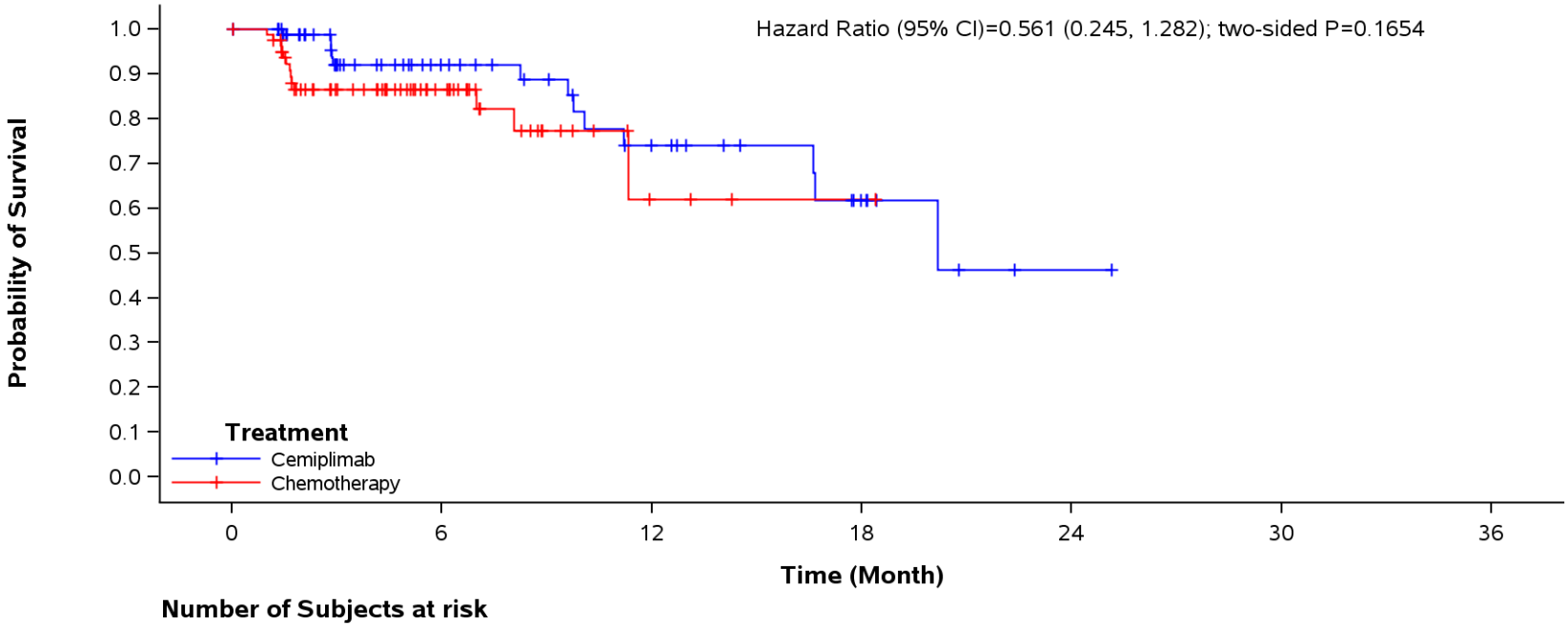
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 38 | 21 | 10 | 0 | 0 | 0 |
| Chemotherapy | 98 | 26 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

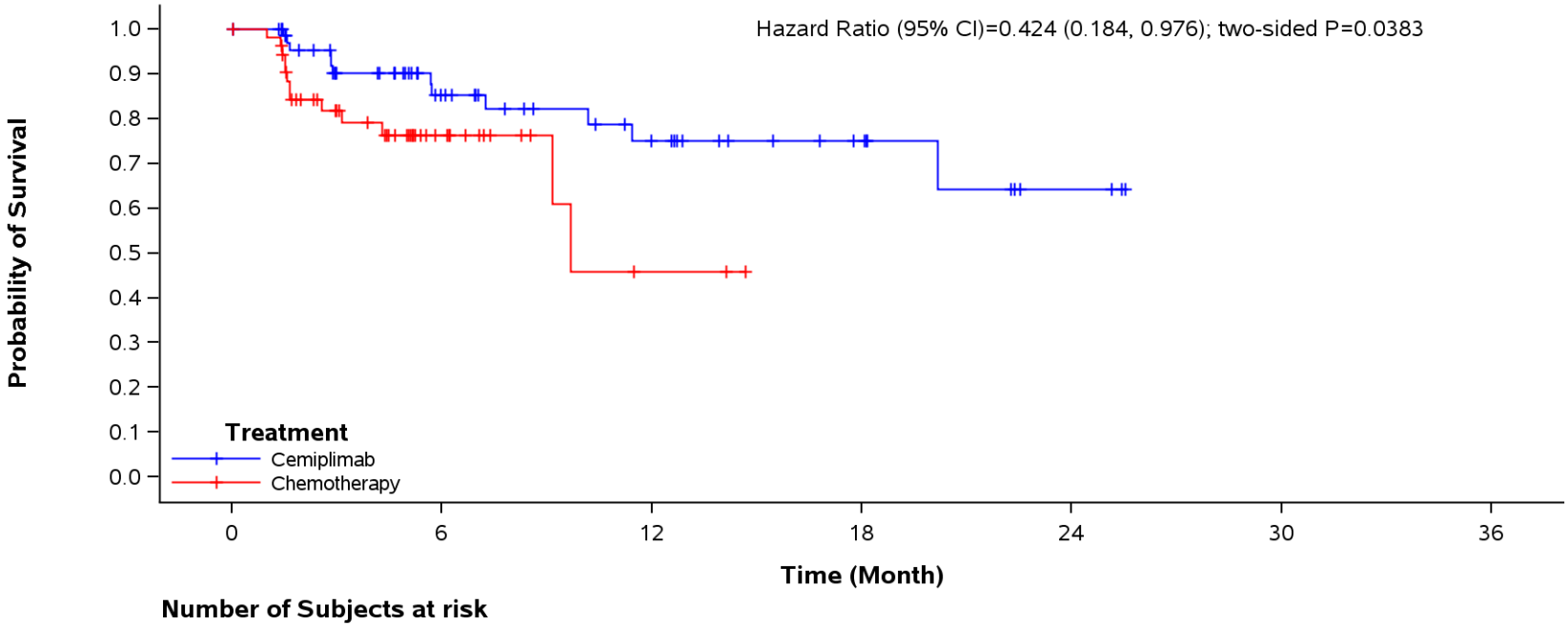
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 35 | 17 | 7 | 1 | 0 | 0 |
| Chemotherapy | 98 | 29 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 33 | 19 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 14 | 2 | 0 | 0 | 0 | 0 |

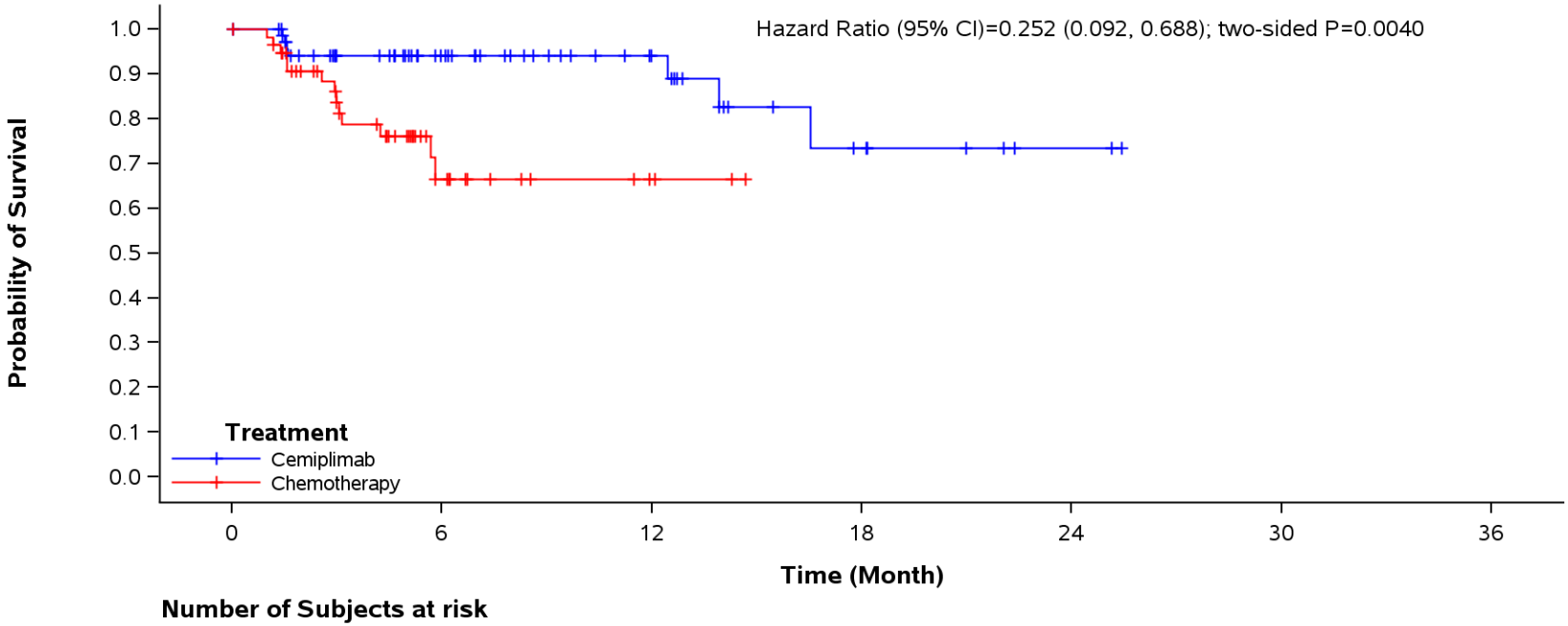
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 19 | 7 | 2 | 0 | 0 |
| Chemotherapy | 69 | 13 | 3 | 0 | 0 | 0 | 0 |

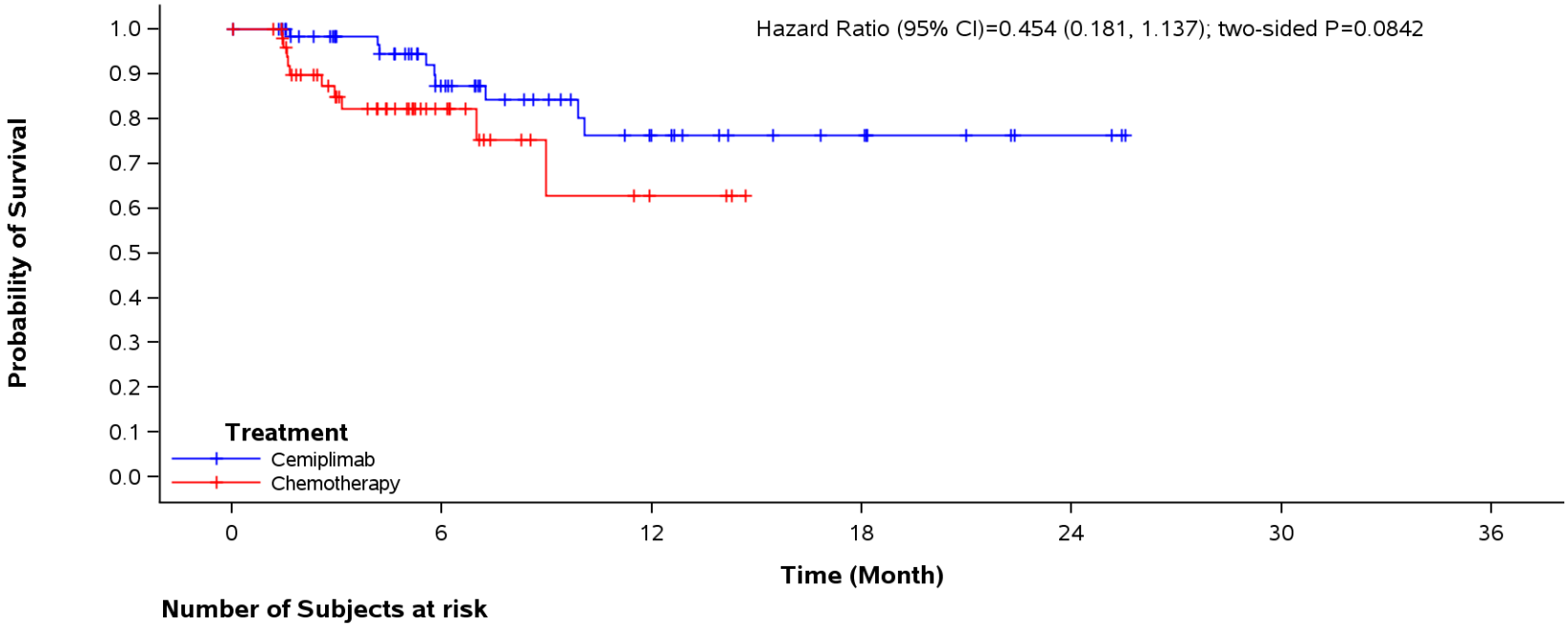
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Constipation - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 16 | 9 | 3 | 0 | 0 |
| Chemotherapy | 69 | 16 | 3 | 0 | 0 | 0 | 0 |

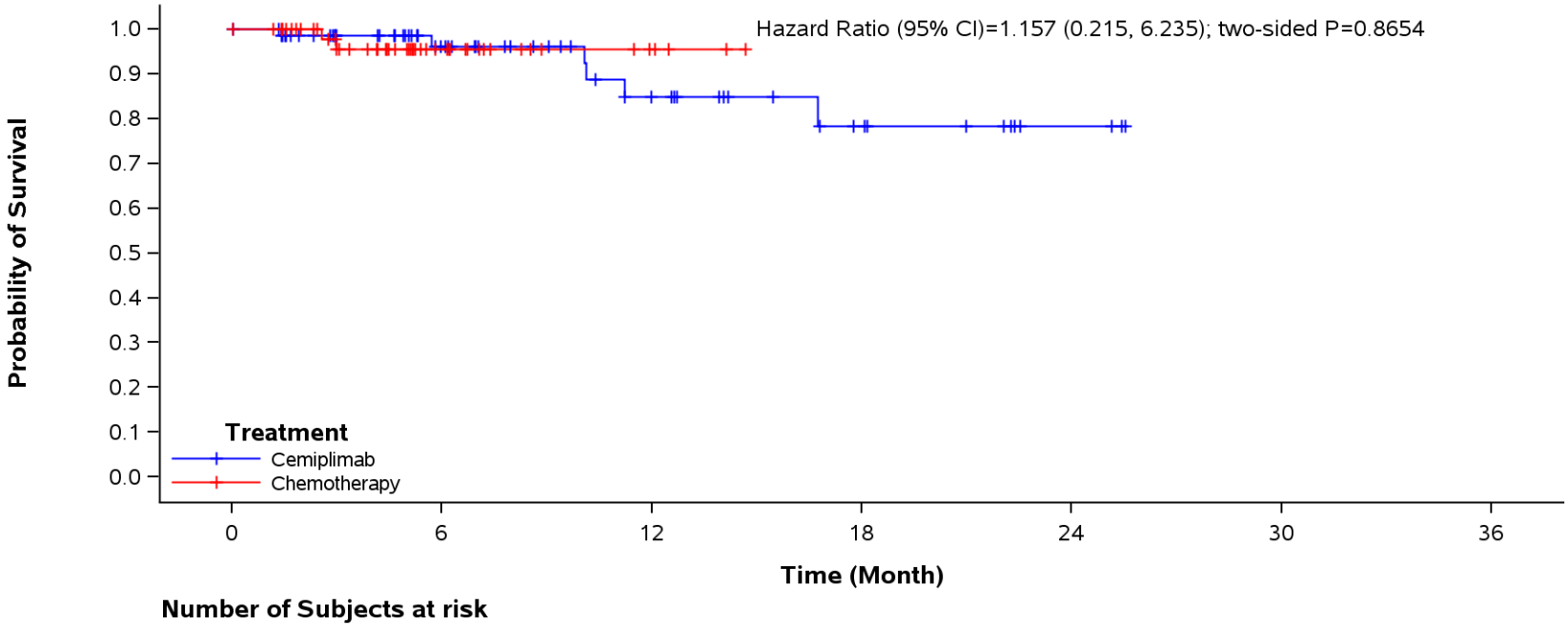
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Diarhoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 38 | 20 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 18 | 4 | 0 | 0 | 0 | 0 |

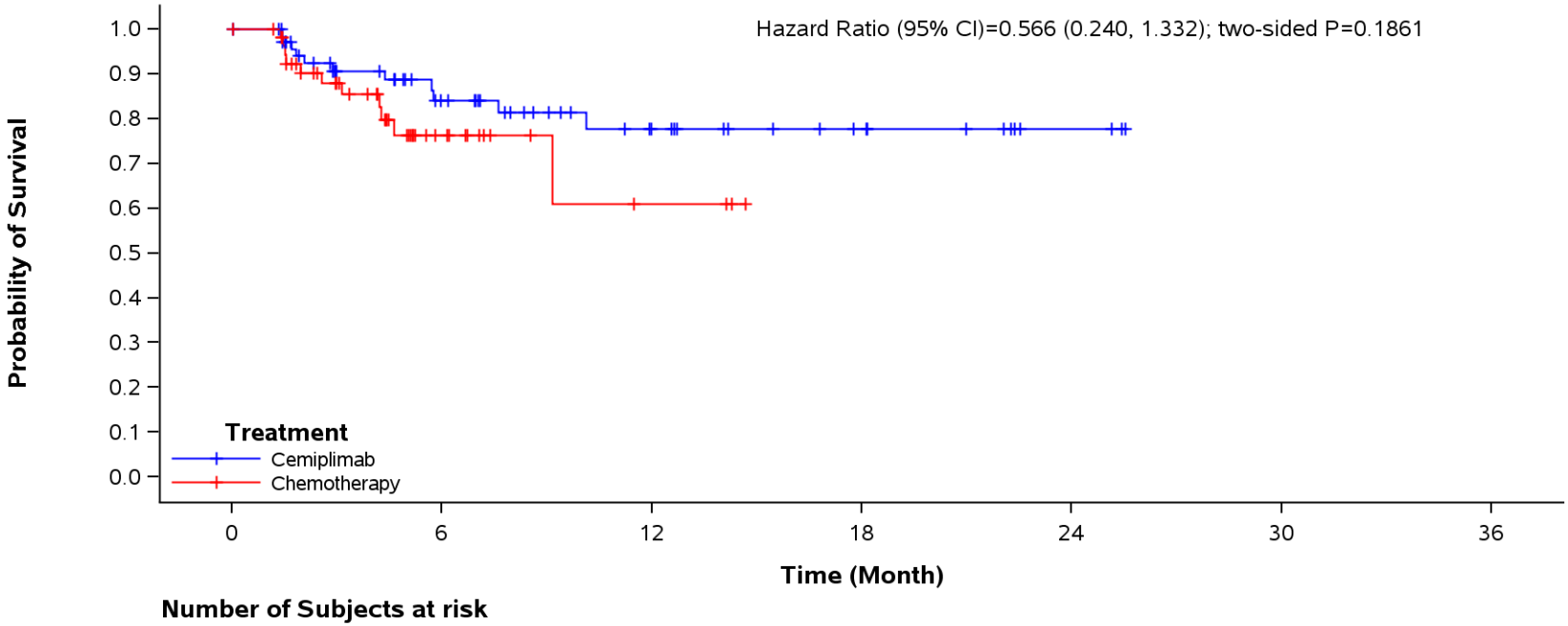
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Dyspnoea - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 18 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 13 | 3 | 0 | 0 | 0 | 0 |

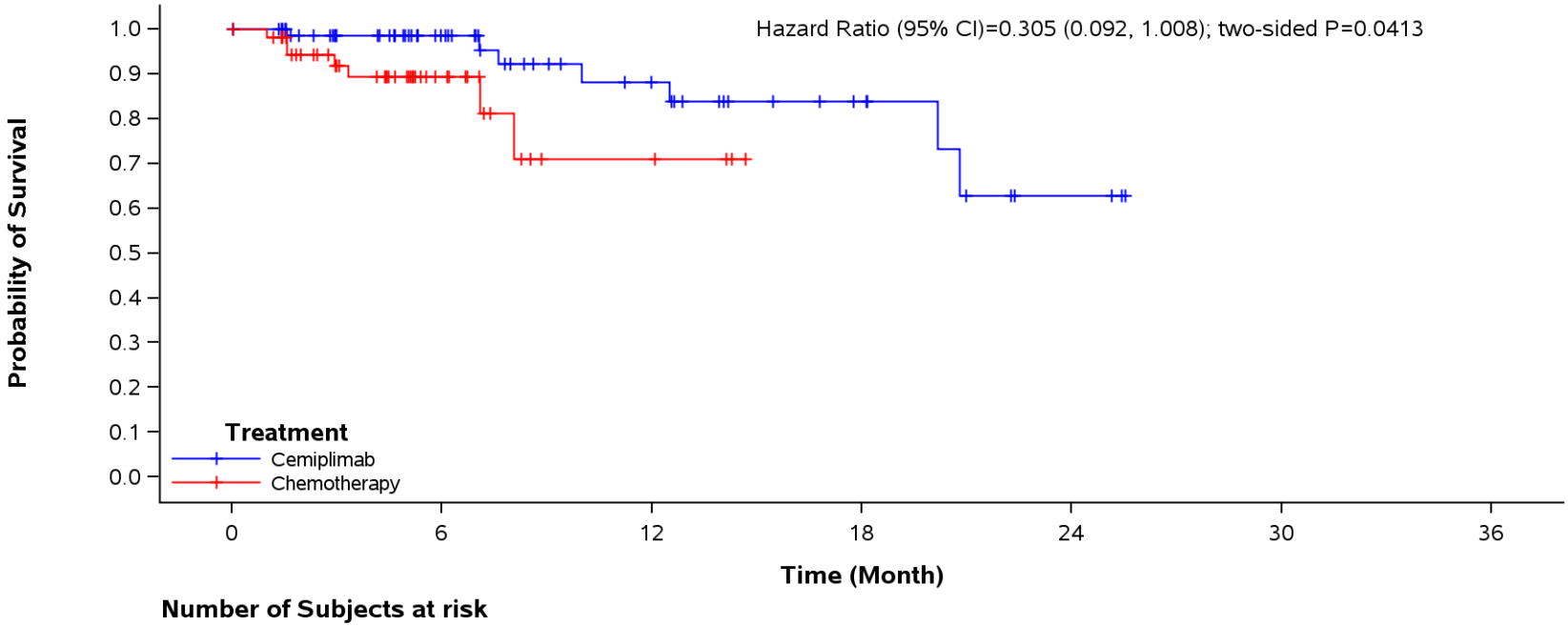
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Emotional Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 38 | 20 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 17 | 4 | 0 | 0 | 0 | 0 |

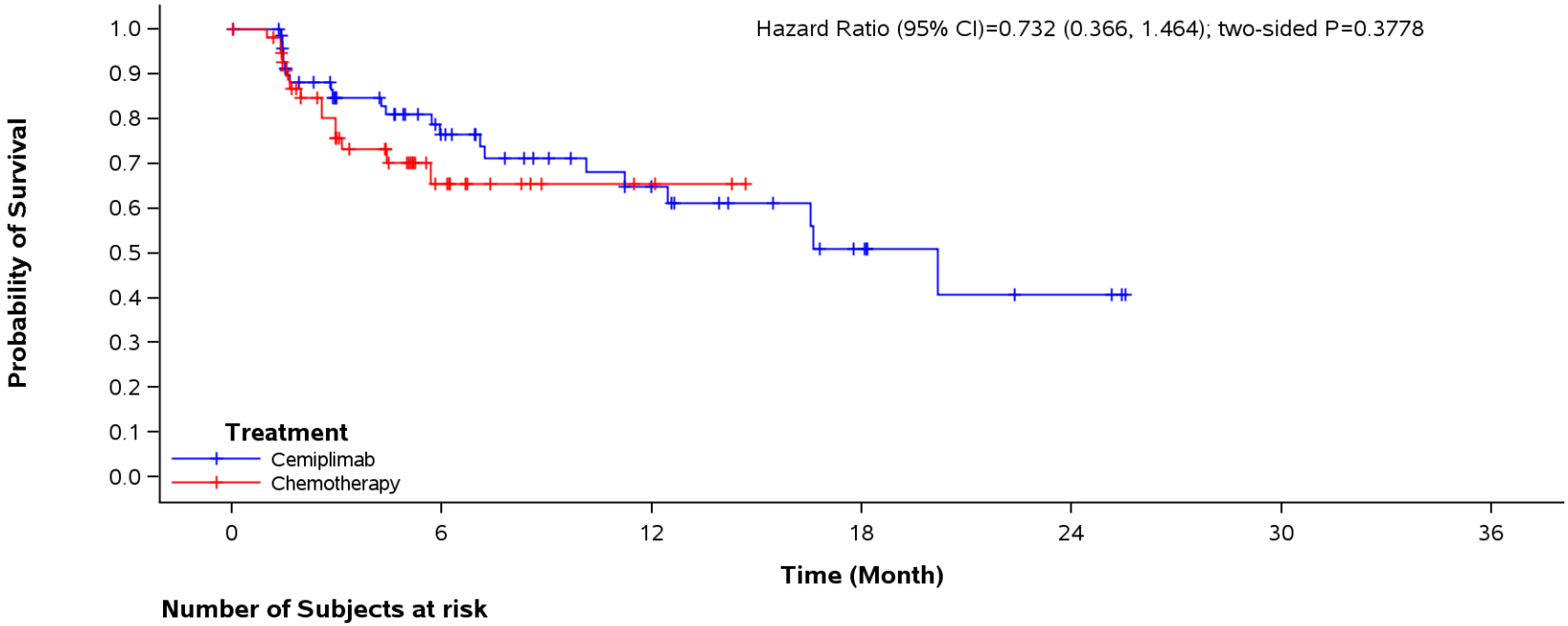
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 33 | 18 | 8 | 3 | 0 | 0 |
| Chemotherapy | 69 | 13 | 3 | 0 | 0 | 0 | 0 |

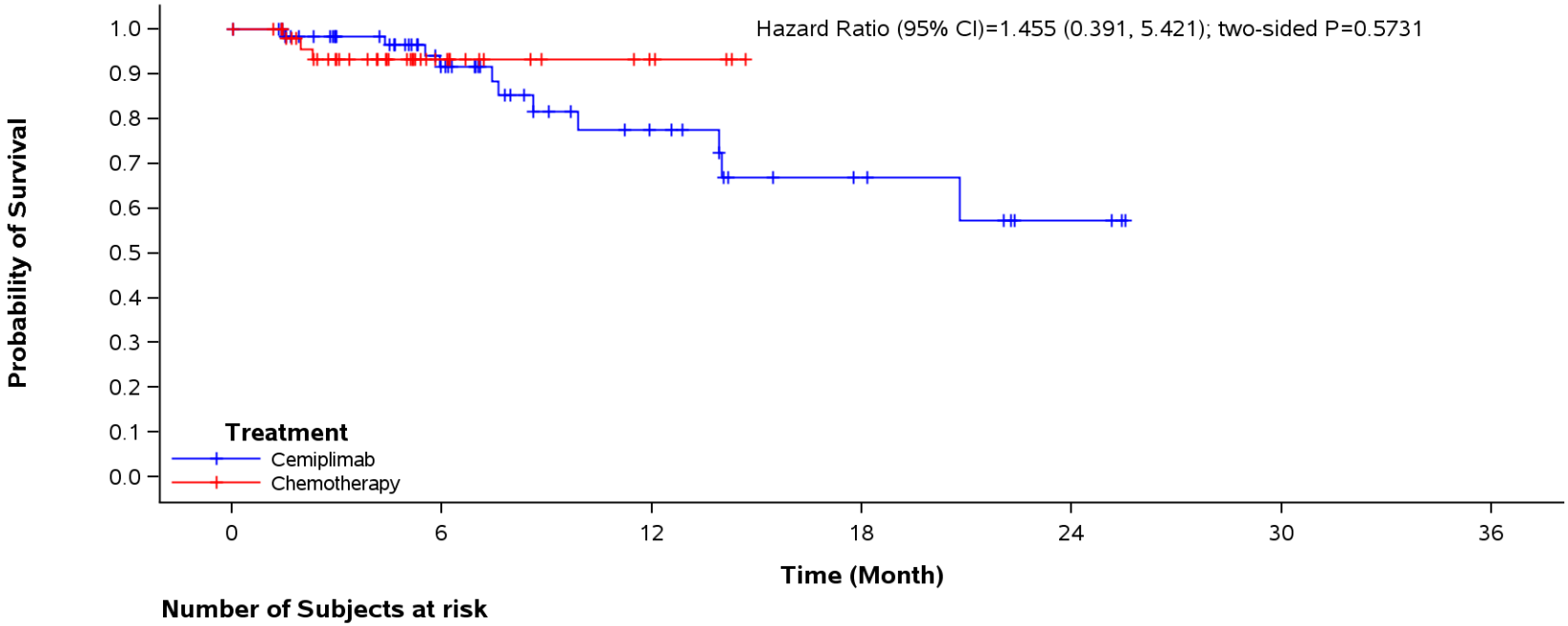
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 17 | 8 | 3 | 0 | 0 |
| Chemotherapy | 69 | 15 | 4 | 0 | 0 | 0 | 0 |

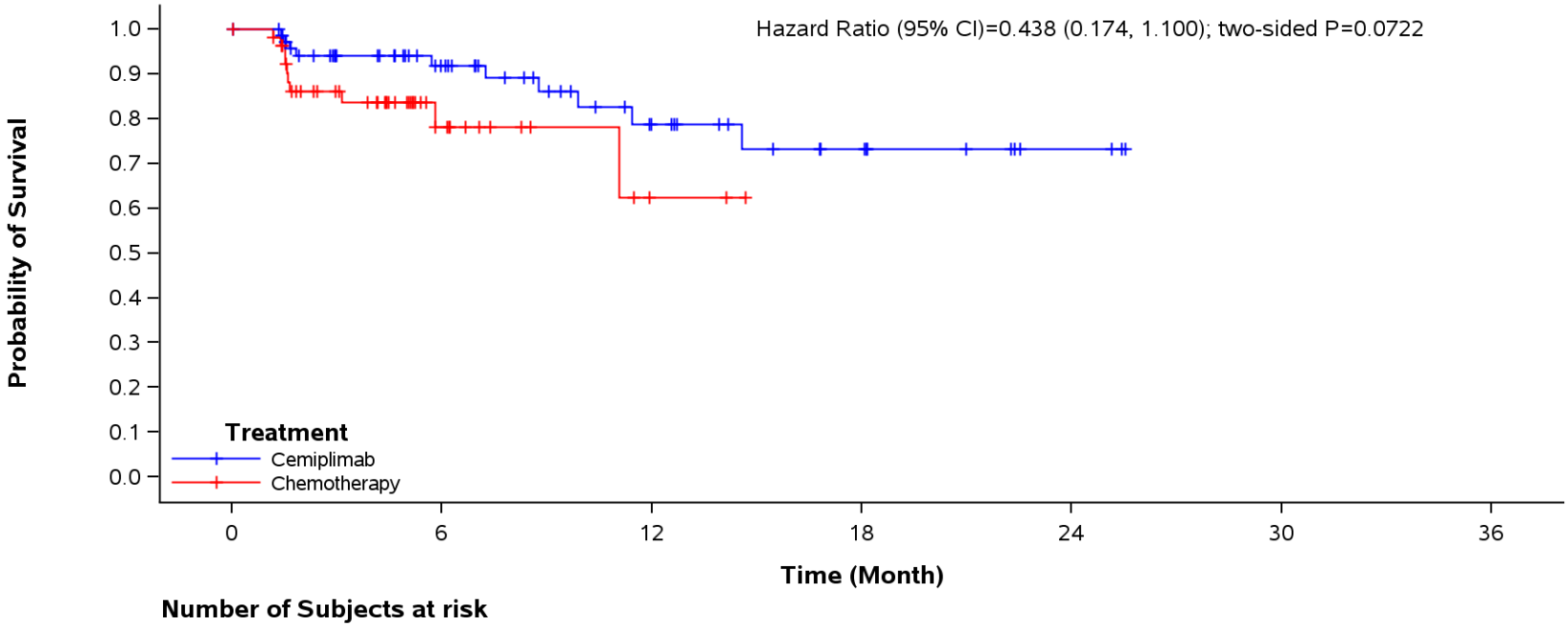
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 39 | 19 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 13 | 2 | 0 | 0 | 0 | 0 |

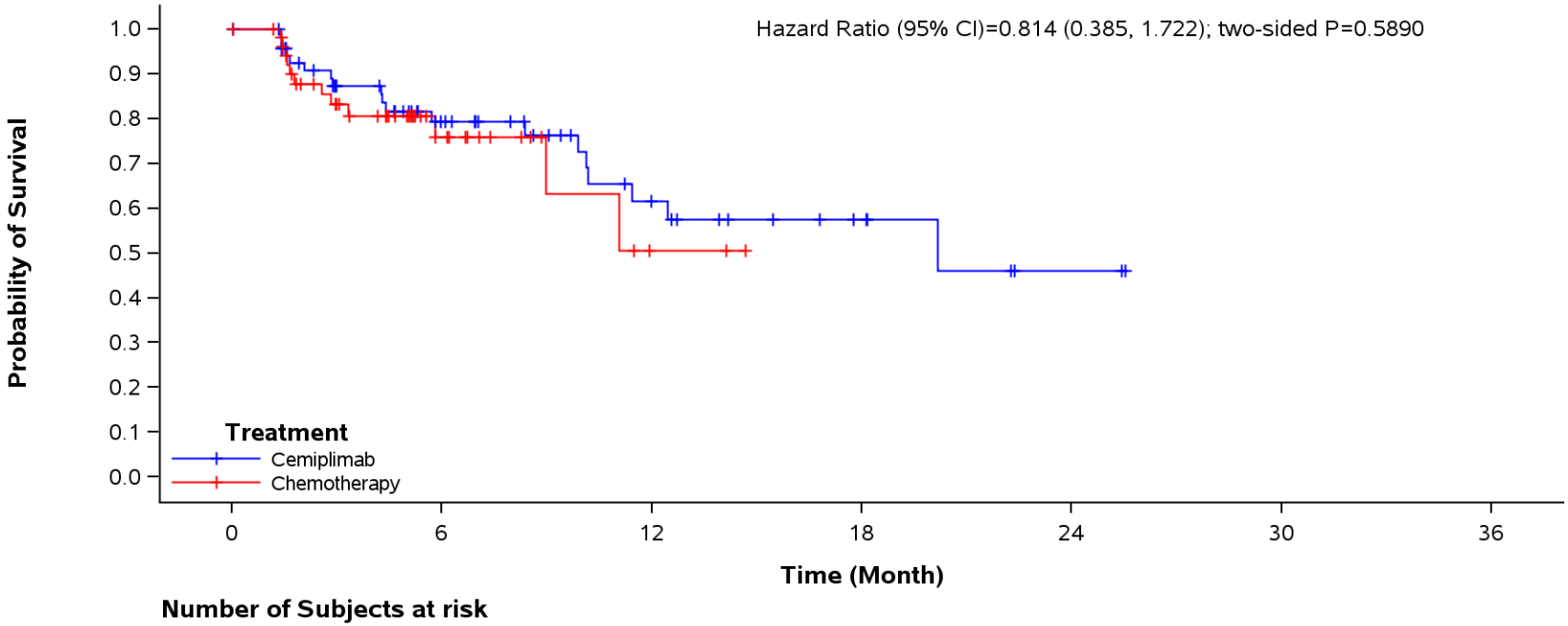
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 33 | 15 | 7 | 2 | 0 | 0 |
| Chemotherapy | 69 | 15 | 2 | 0 | 0 | 0 | 0 |

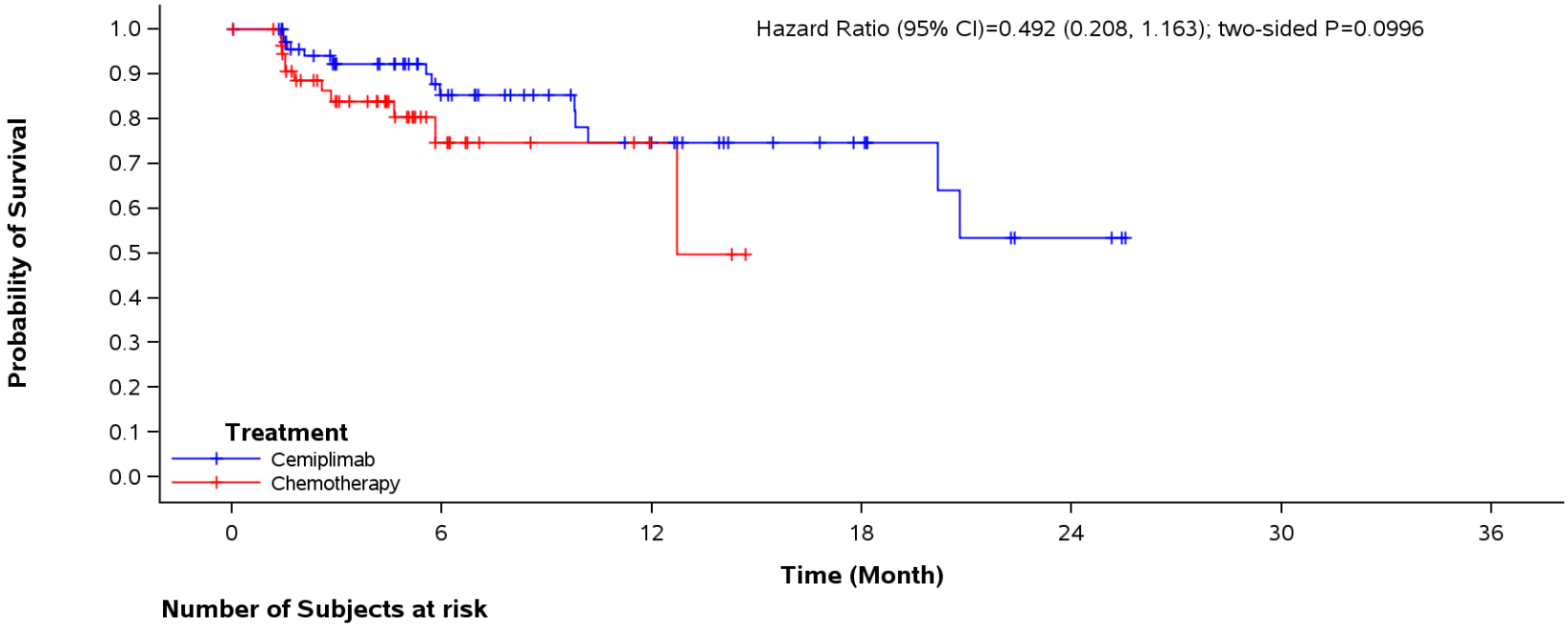
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 19 | 10 | 3 | 0 | 0 |
| Chemotherapy | 69 | 12 | 3 | 0 | 0 | 0 | 0 |

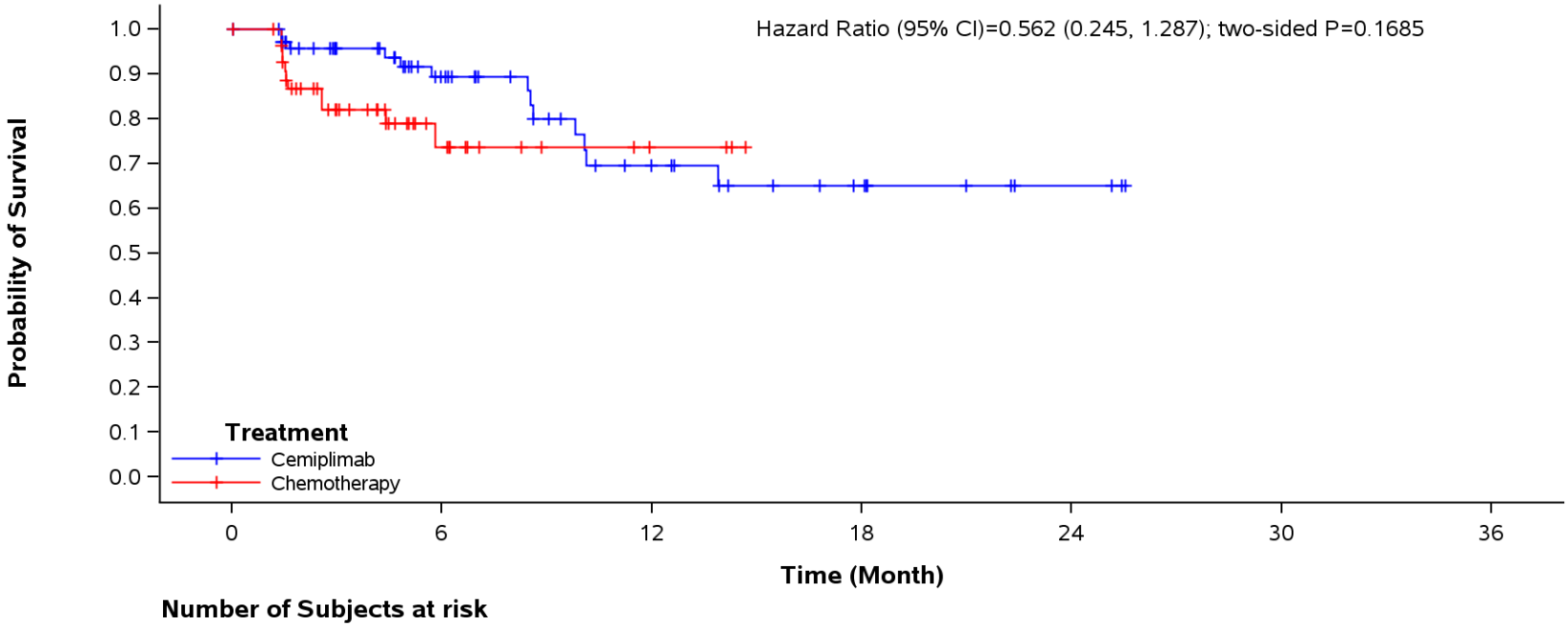
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Global health status / QoL - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 17 | 9 | 3 | 0 | 0 |
| Chemotherapy | 69 | 14 | 3 | 0 | 0 | 0 | 0 |

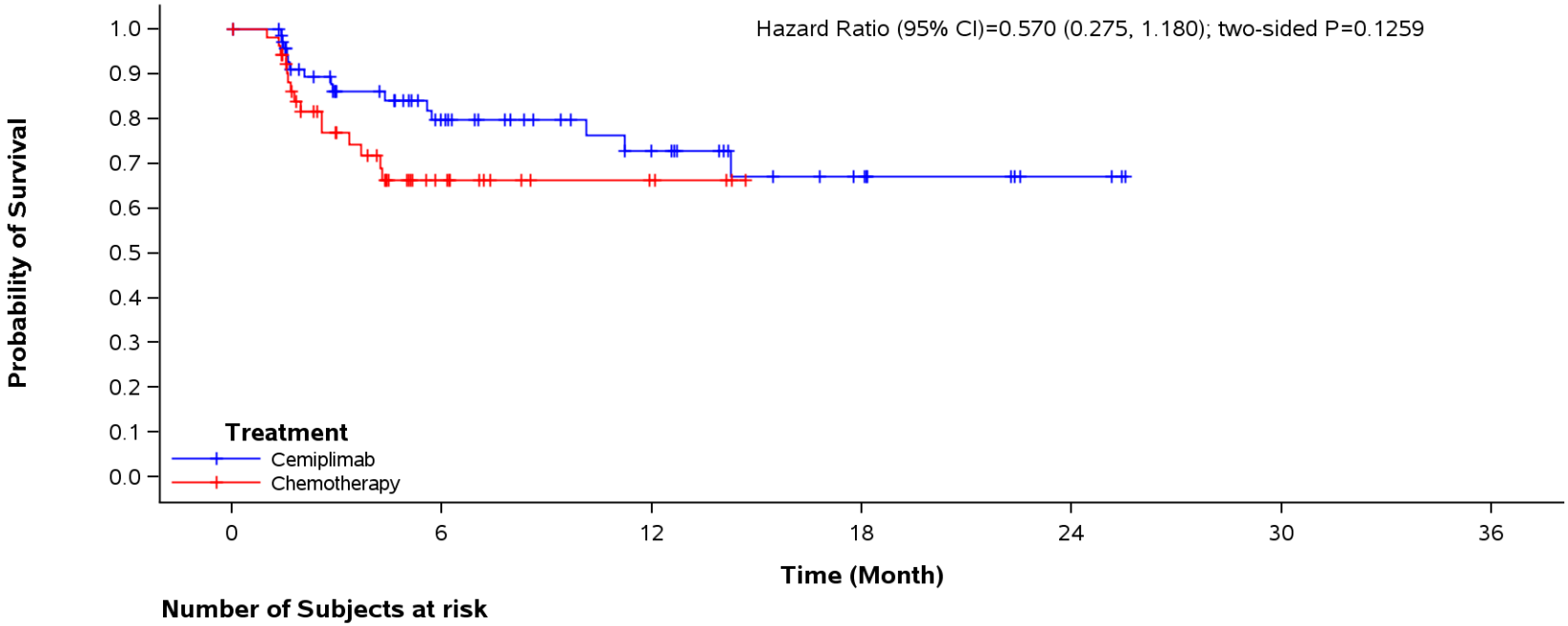
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Role Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 34 | 19 | 9 | 3 | 0 | 0 |
| Chemotherapy | 69 | 13 | 4 | 0 | 0 | 0 | 0 |

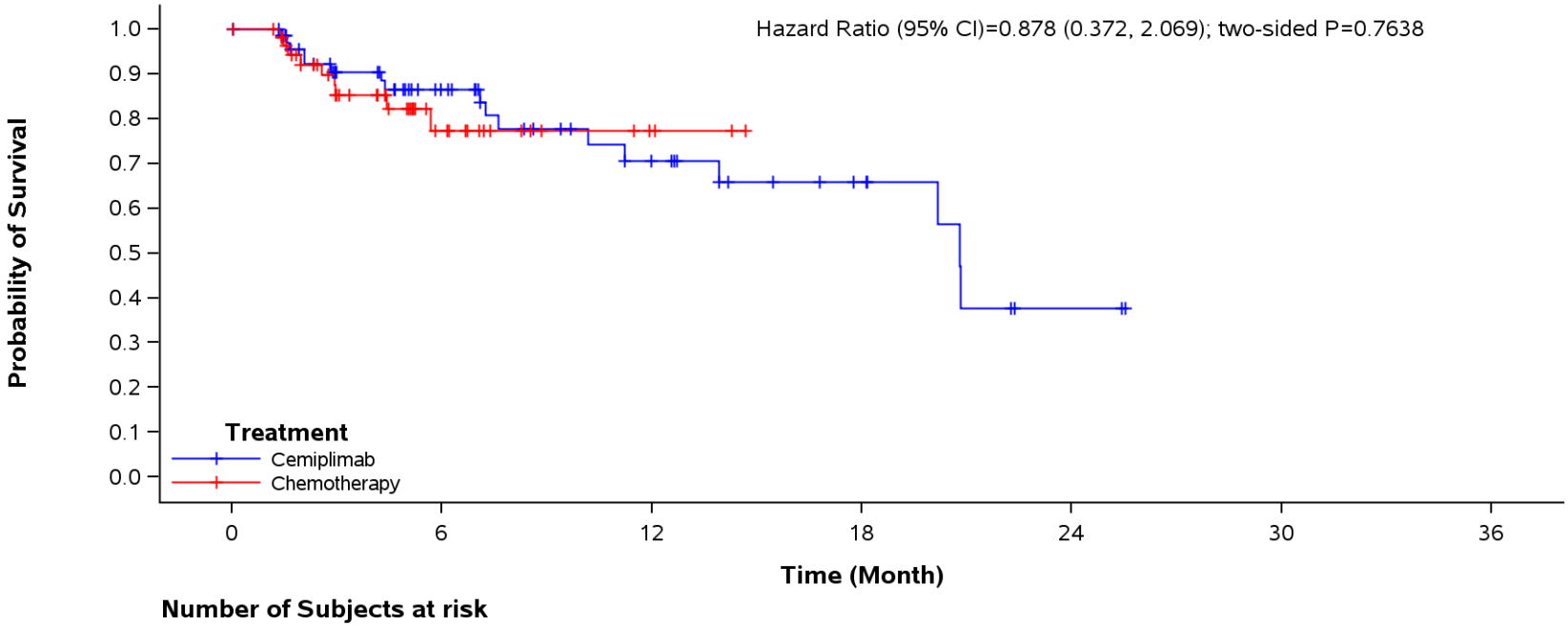
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Social Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

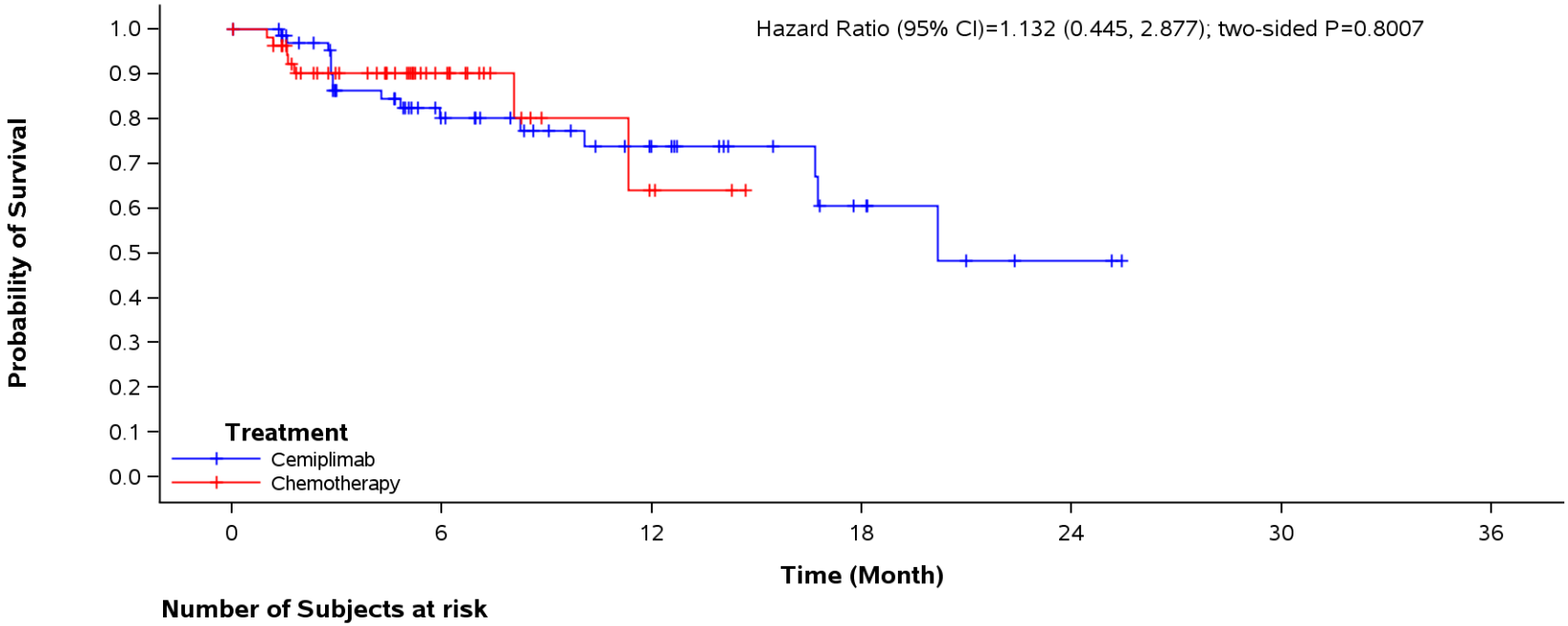
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 18 | 9 | 2 | 0 | 0 |
| Chemotherapy | 69 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

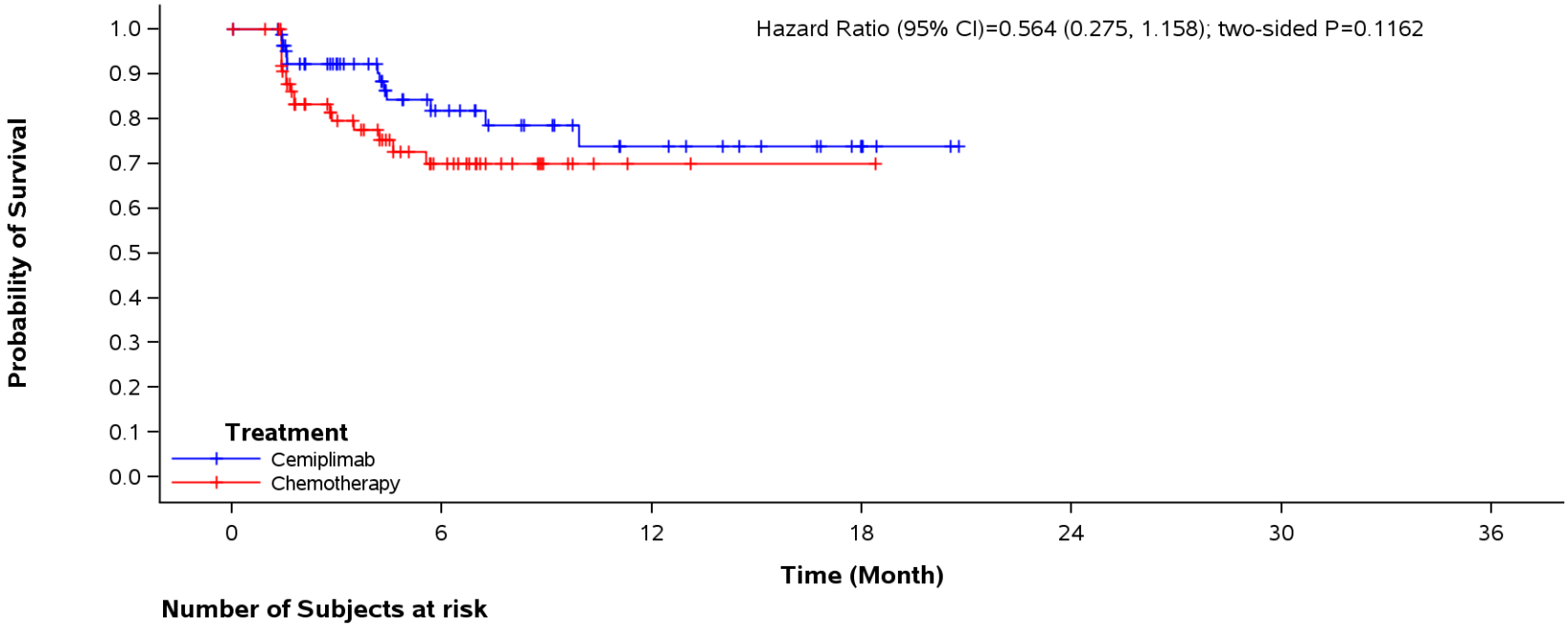
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 33 | 18 | 7 | 2 | 0 | 0 |
| Chemotherapy | 69 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 31 | 14 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

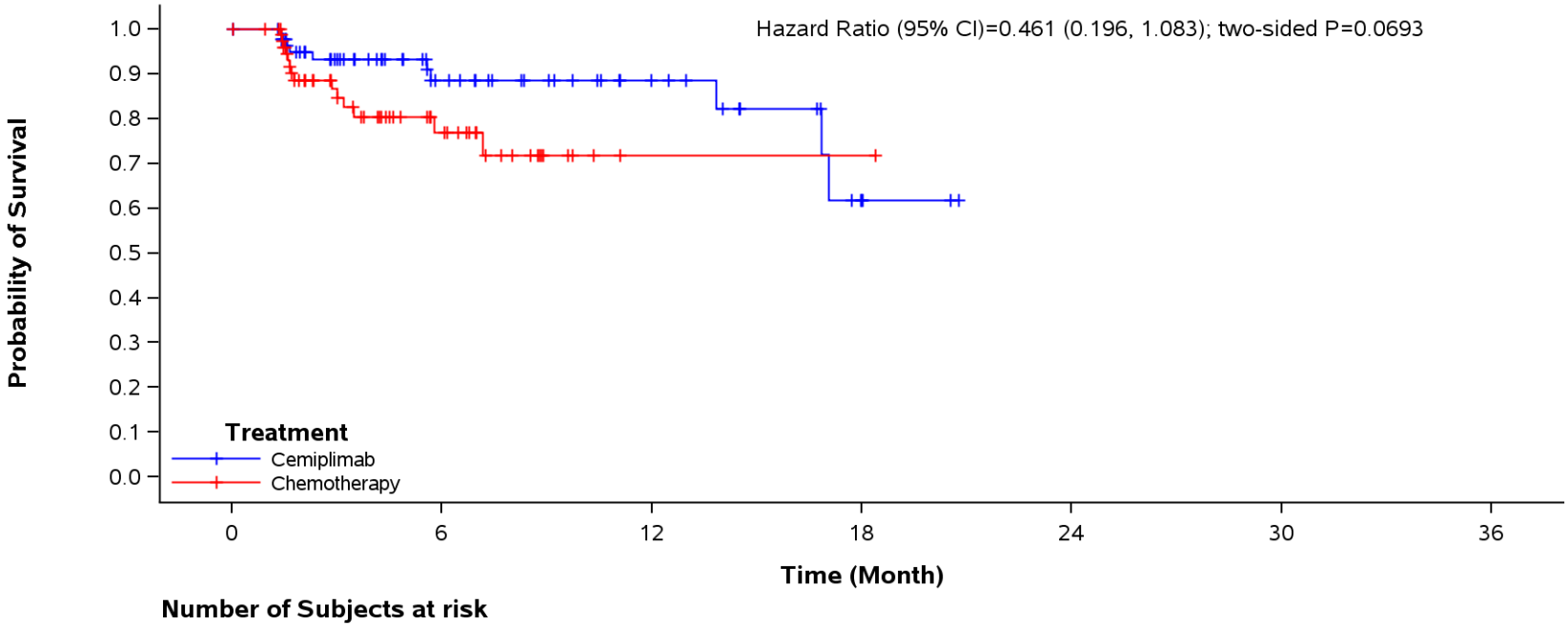
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 35 | 16 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 1 | 1 | 0 | 0 | 0 |

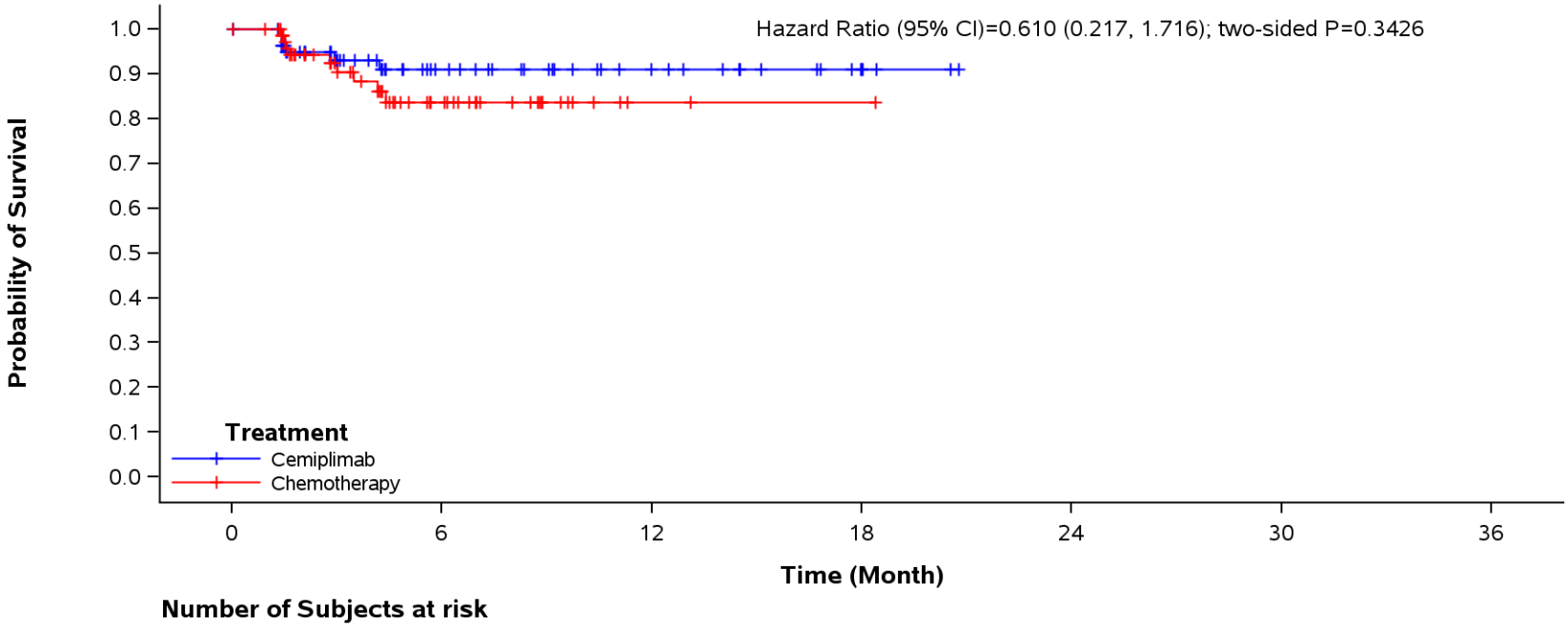
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Constipation - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 32 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 23 | 2 | 1 | 0 | 0 | 0 |

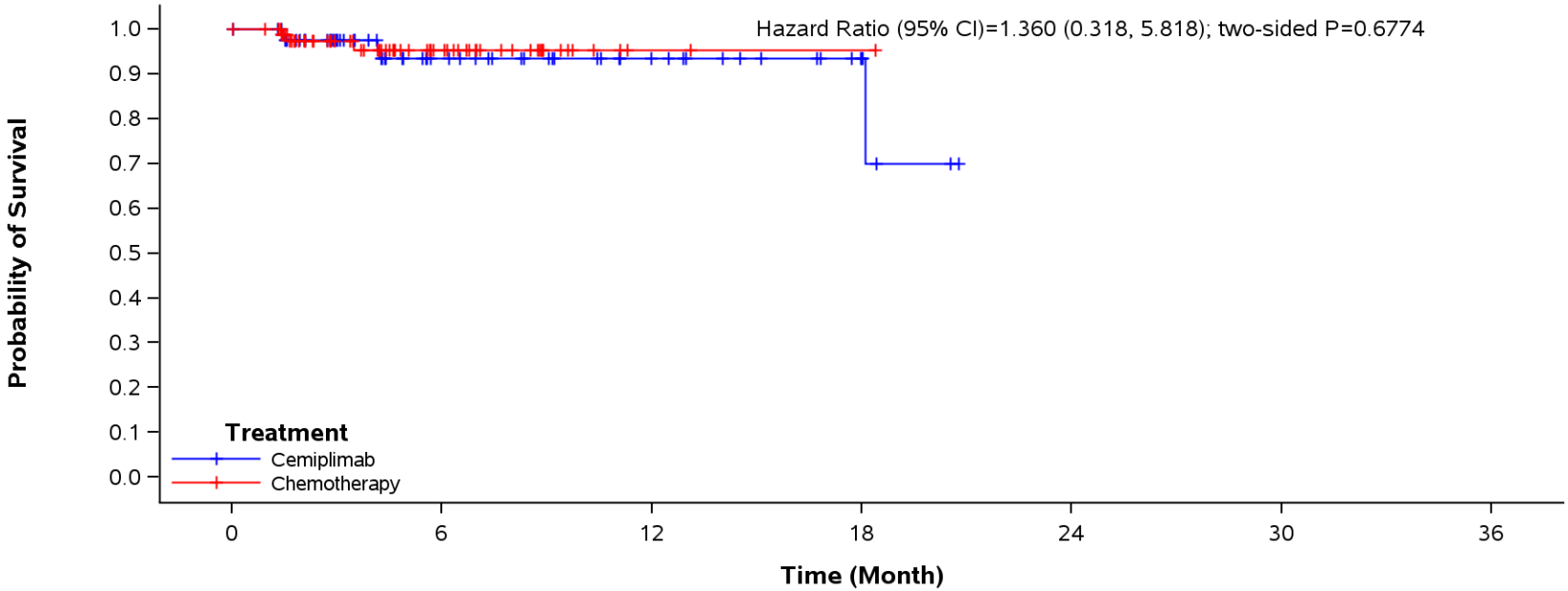
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Diarhoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 35 | 16 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 26 | 2 | 1 | 0 | 0 | 0 |

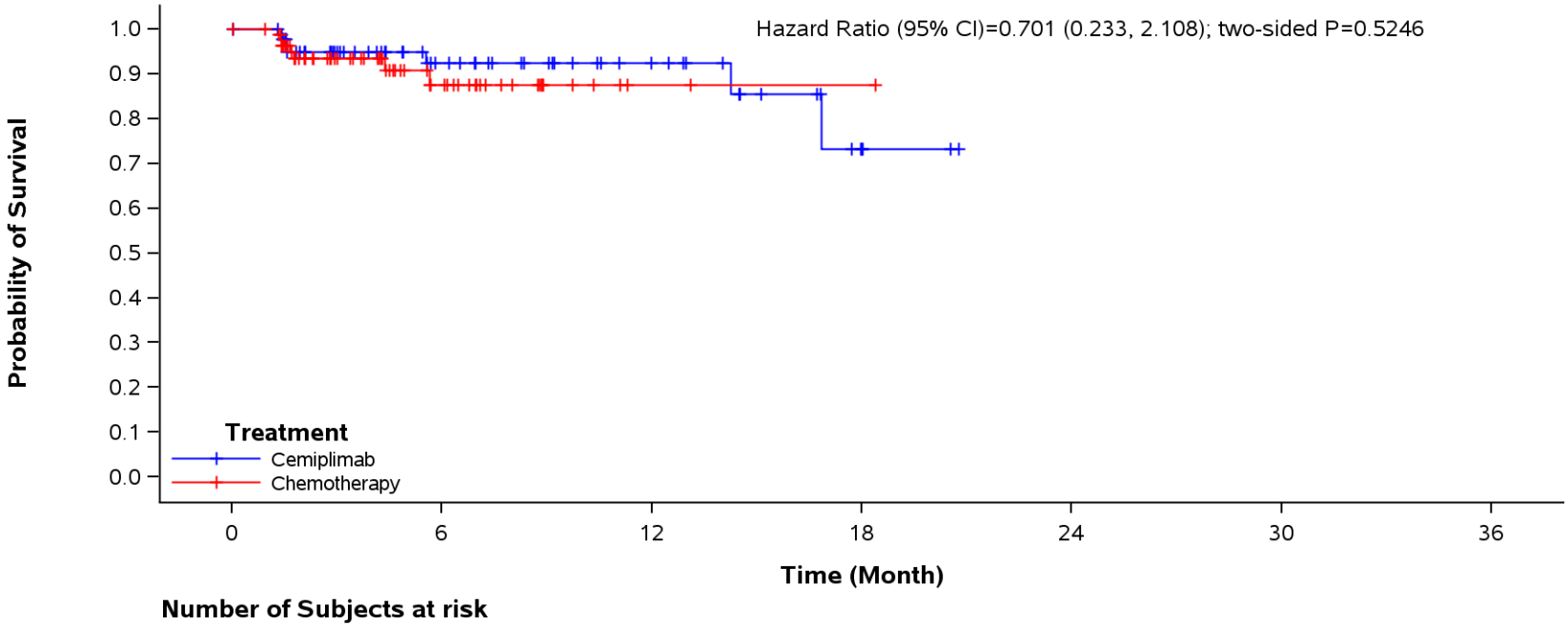
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Dyspnoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 36 | 17 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 23 | 2 | 1 | 0 | 0 | 0 |

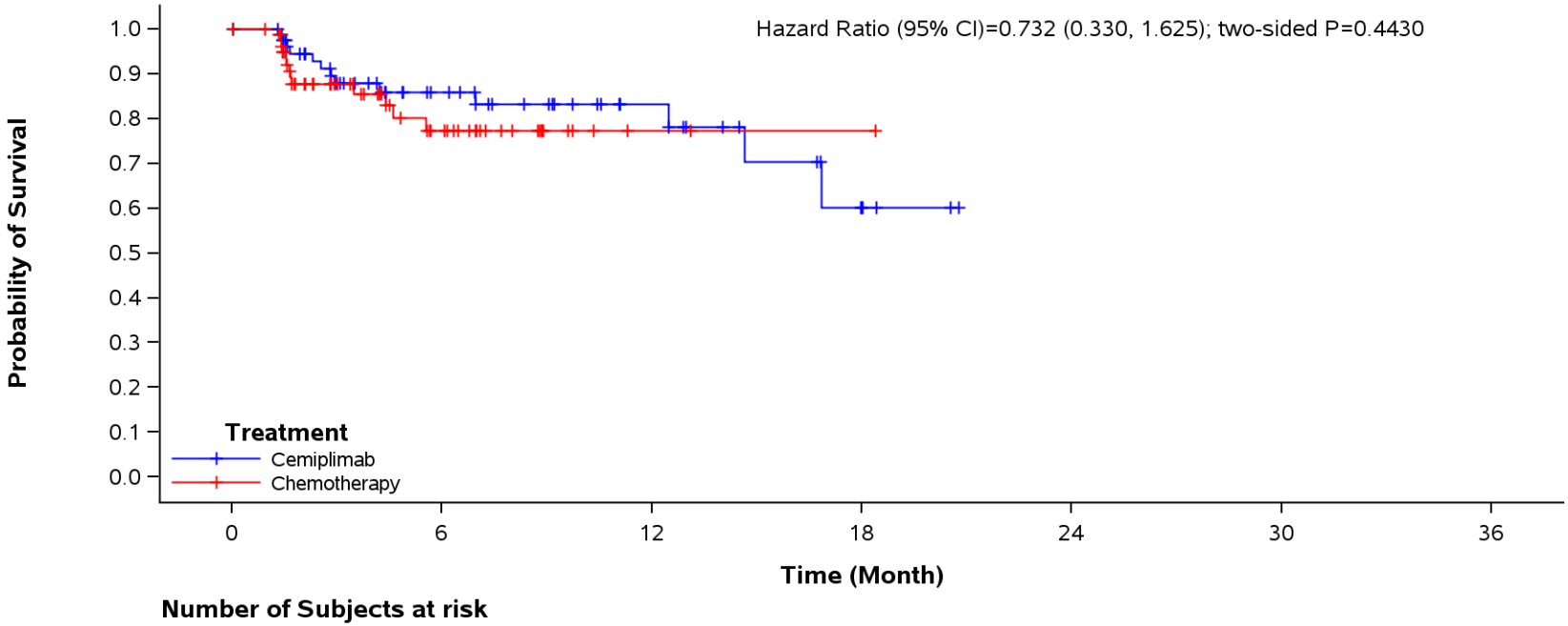
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Emotional Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 35 | 16 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 23 | 2 | 1 | 0 | 0 | 0 |

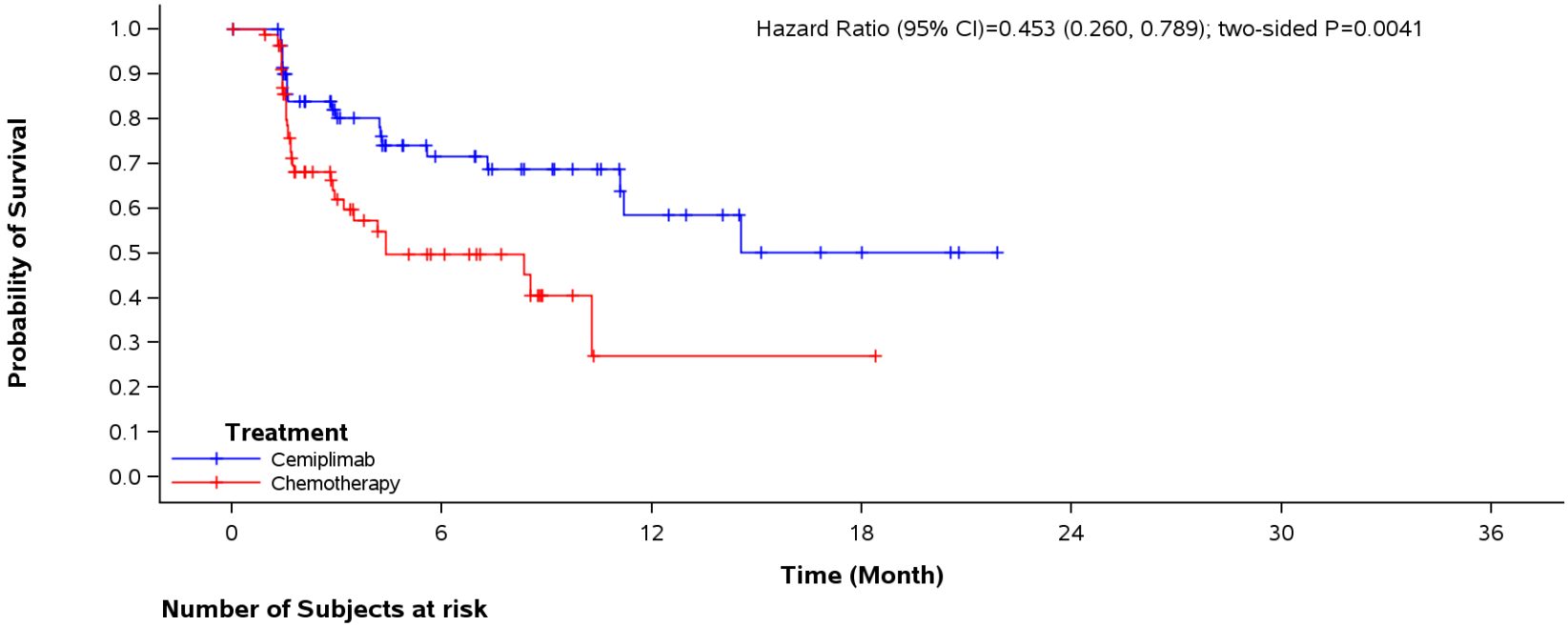
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 28 | 11 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 16 | 1 | 1 | 0 | 0 | 0 |

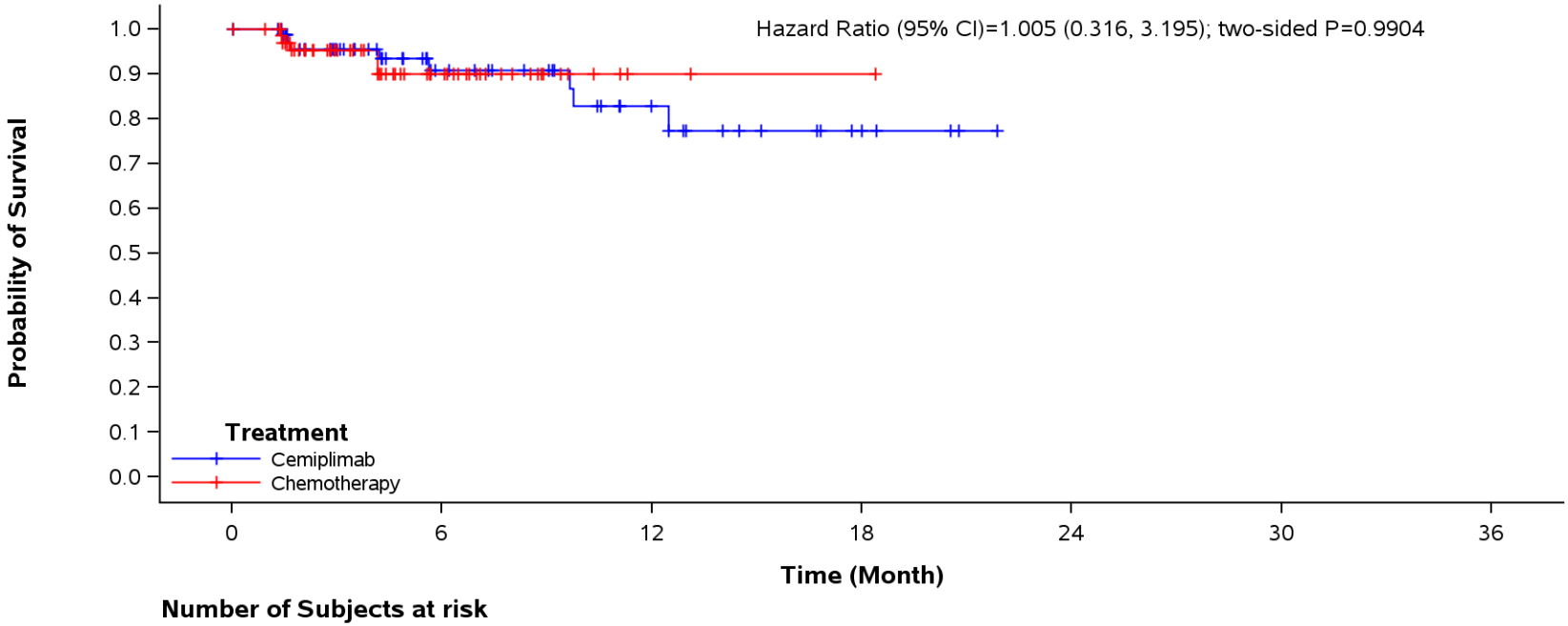
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 32 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

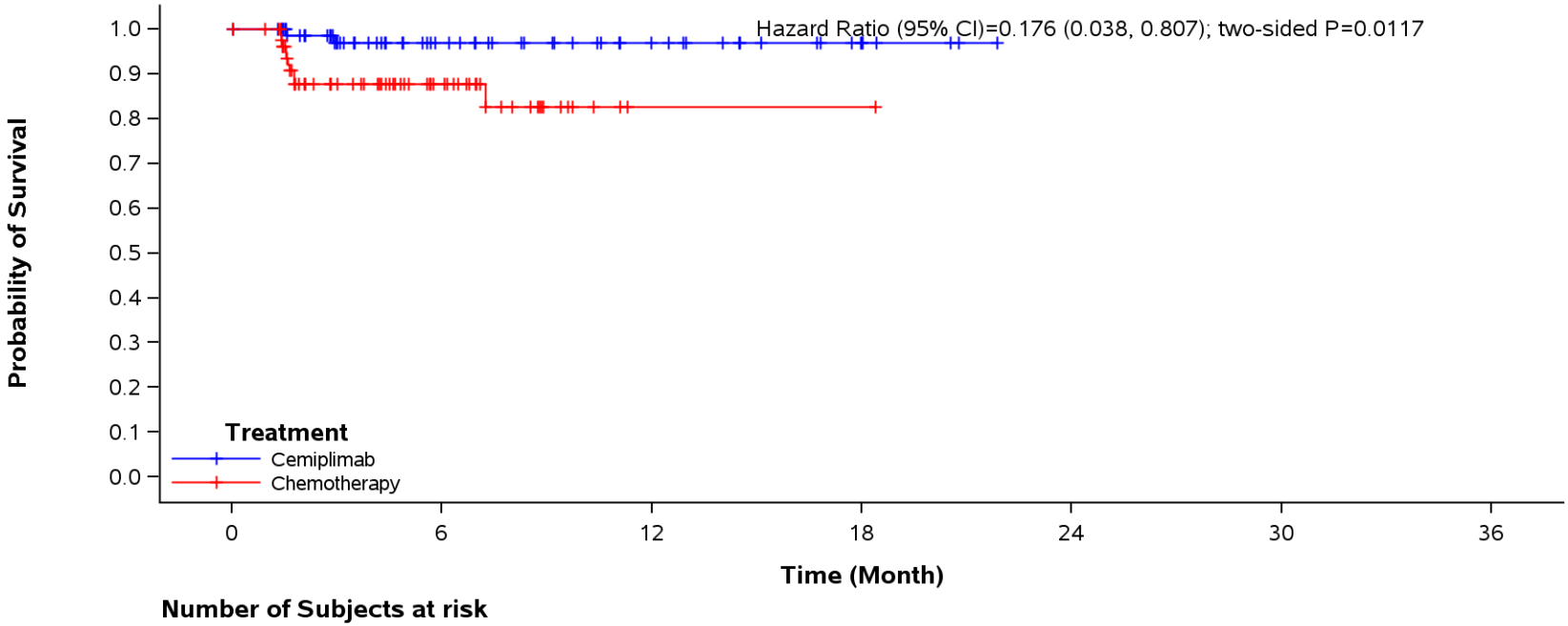
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 37 | 17 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 26 | 1 | 1 | 0 | 0 | 0 |

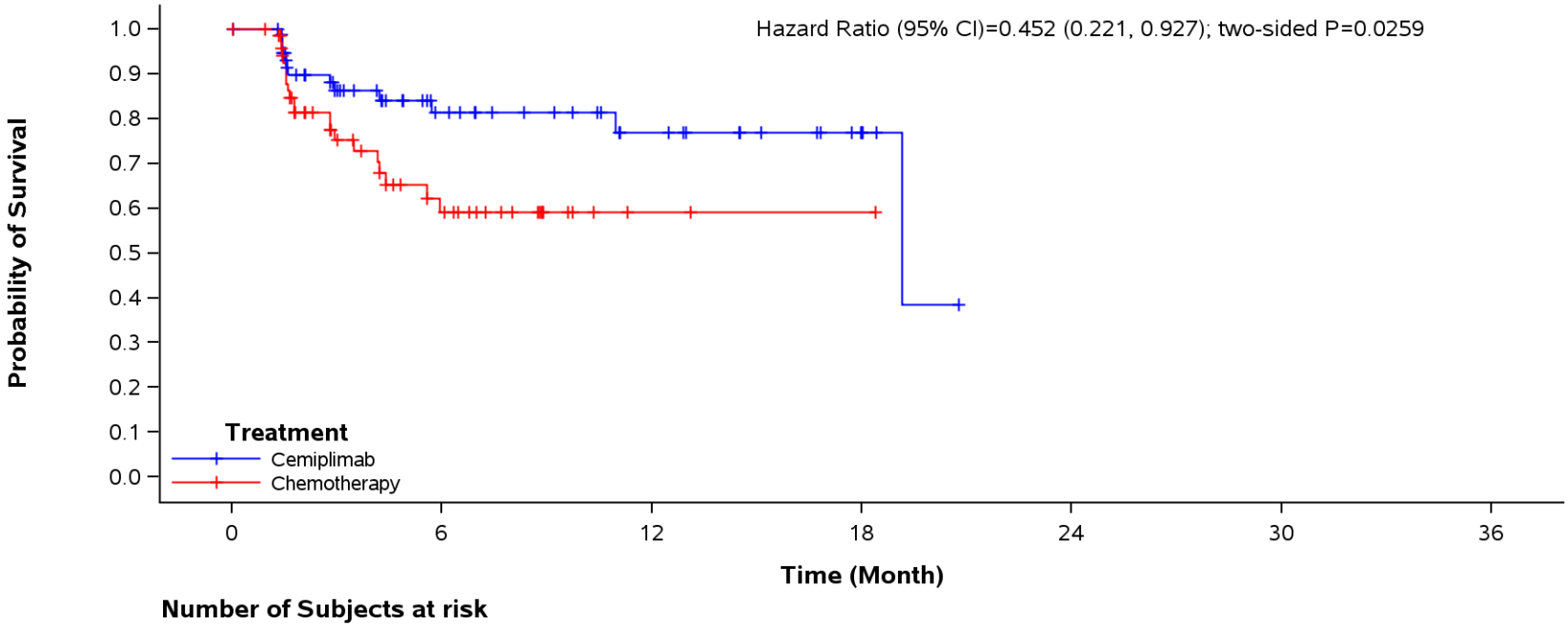
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 29 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 19 | 2 | 1 | 0 | 0 | 0 |

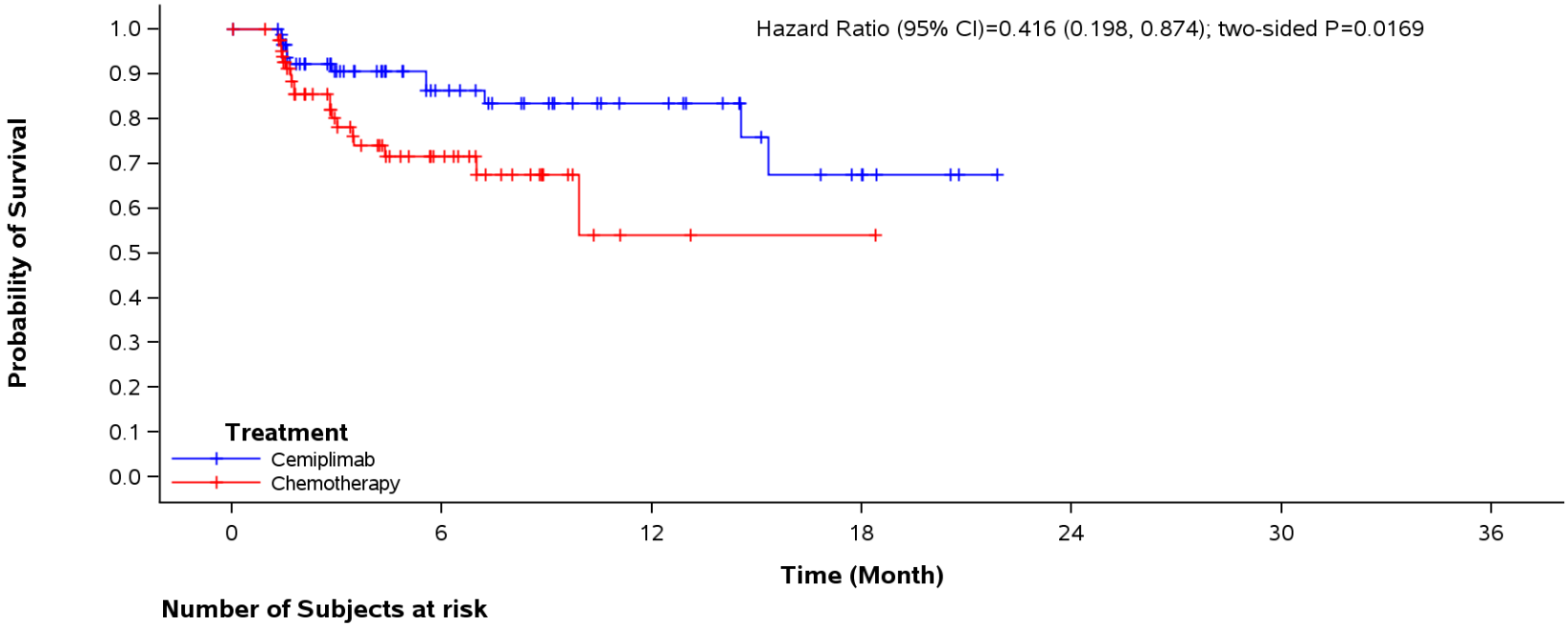
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 36 | 17 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

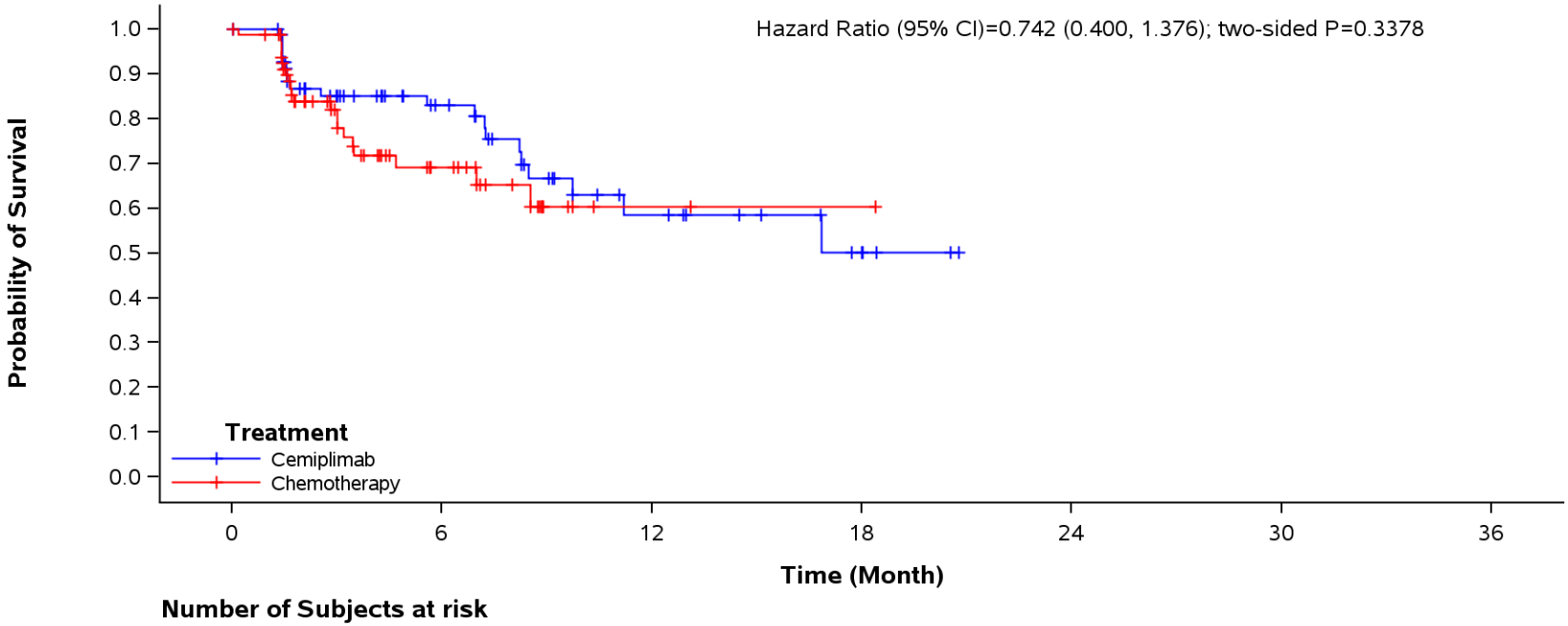
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Global health status / QoL - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 36 | 13 | 5 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

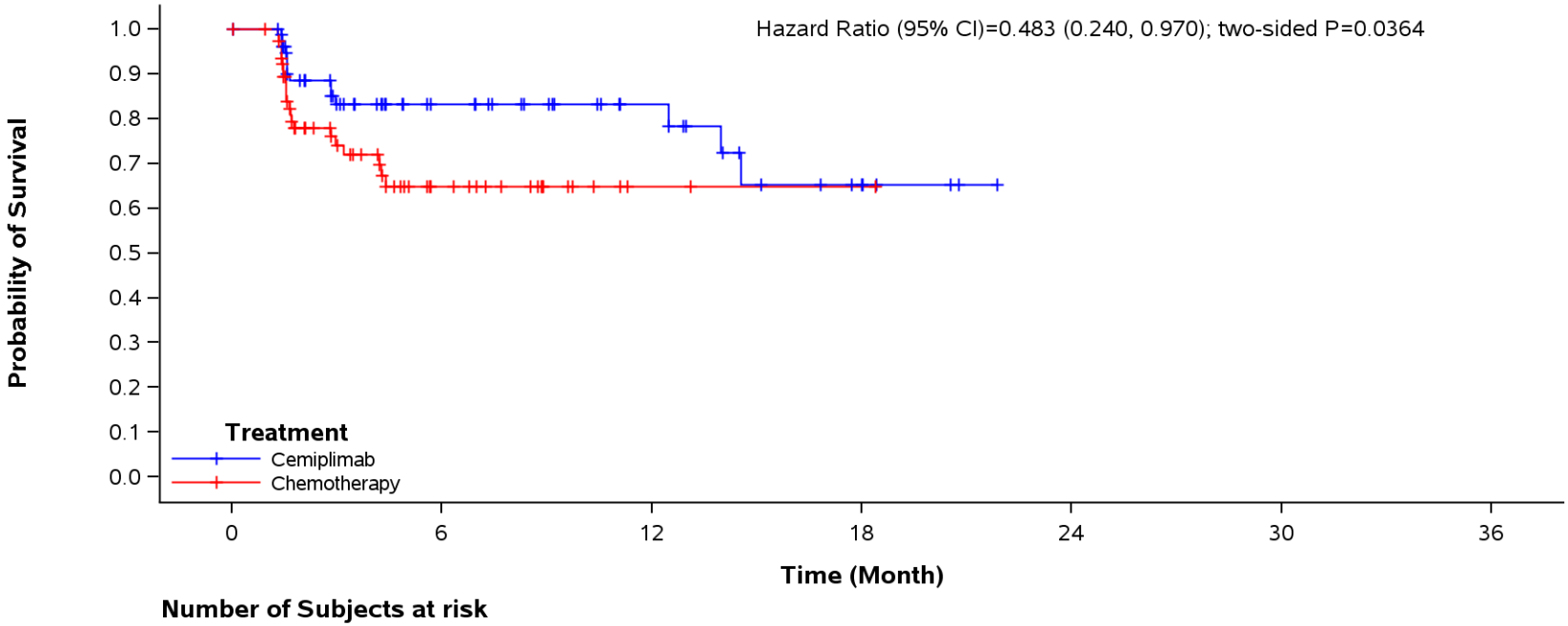
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Role Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 32 | 17 | 6 | 0 | 0 | 0 |
| Chemotherapy | 114 | 17 | 2 | 1 | 0 | 0 | 0 |

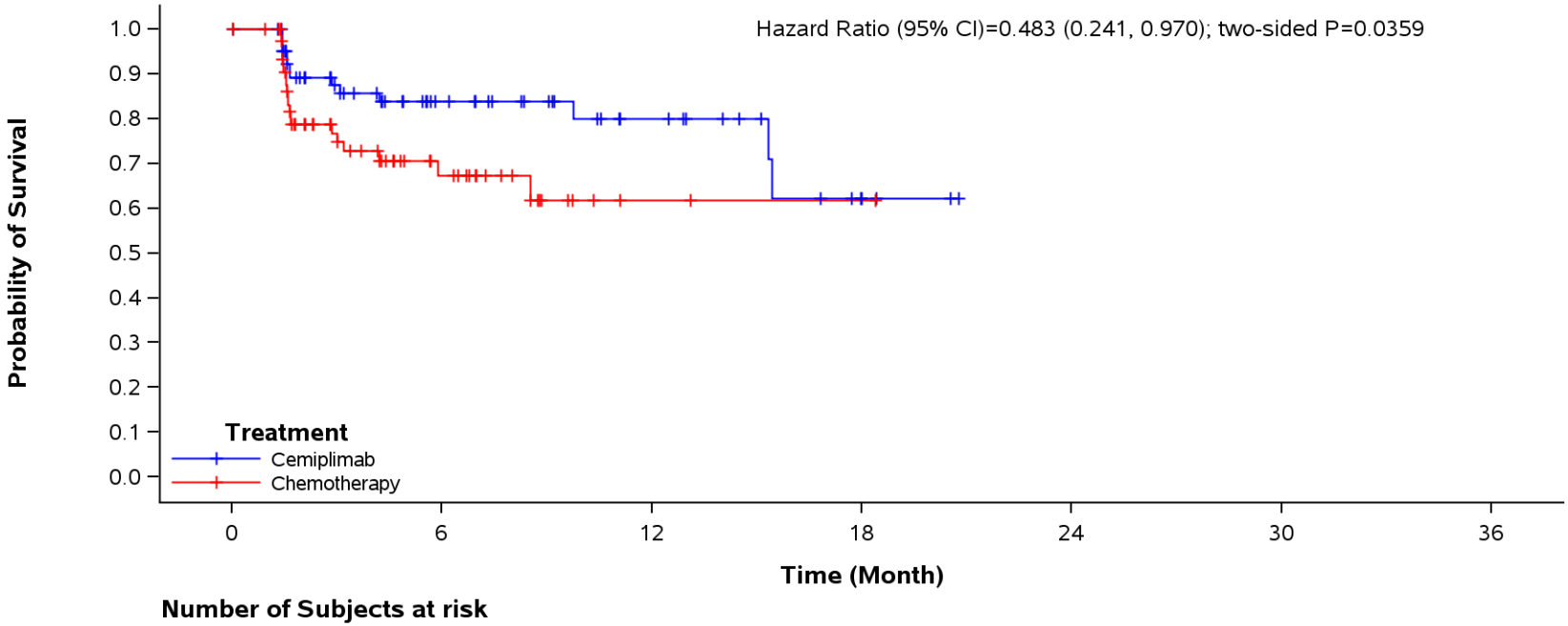
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Social Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

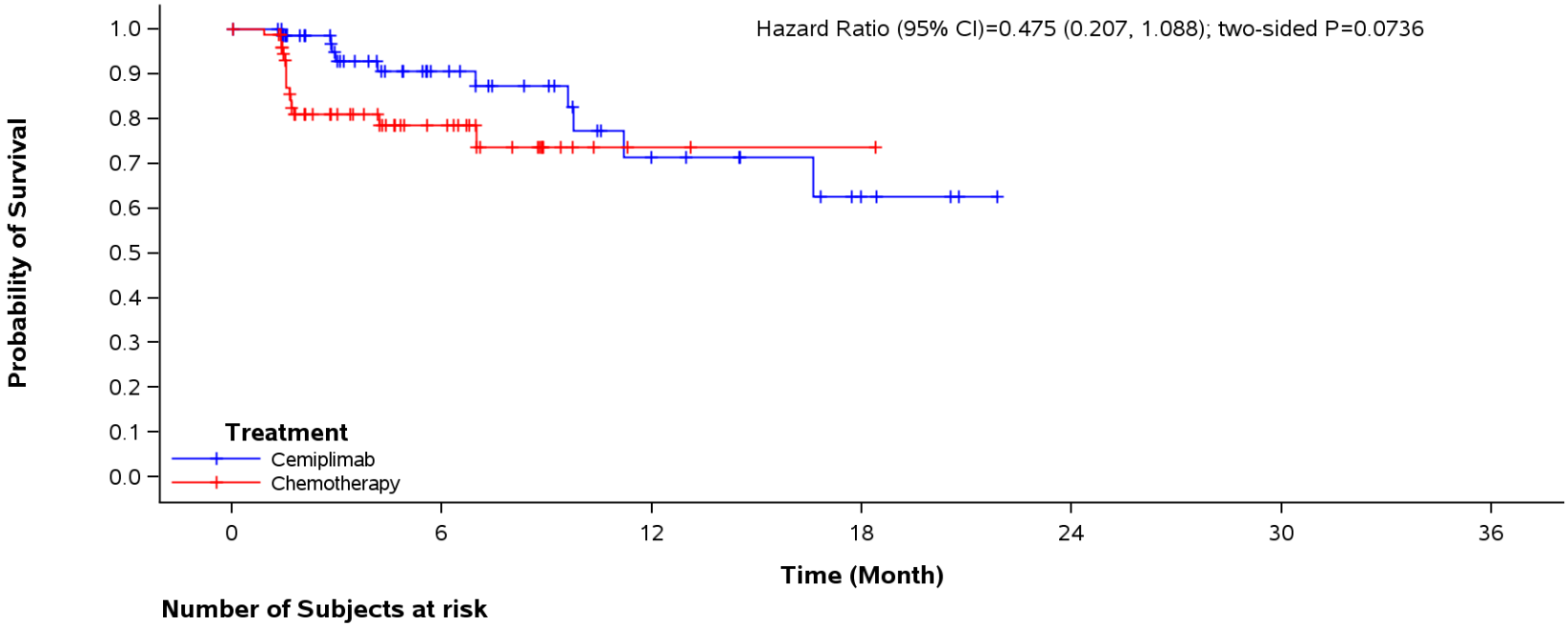
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 33 | 15 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

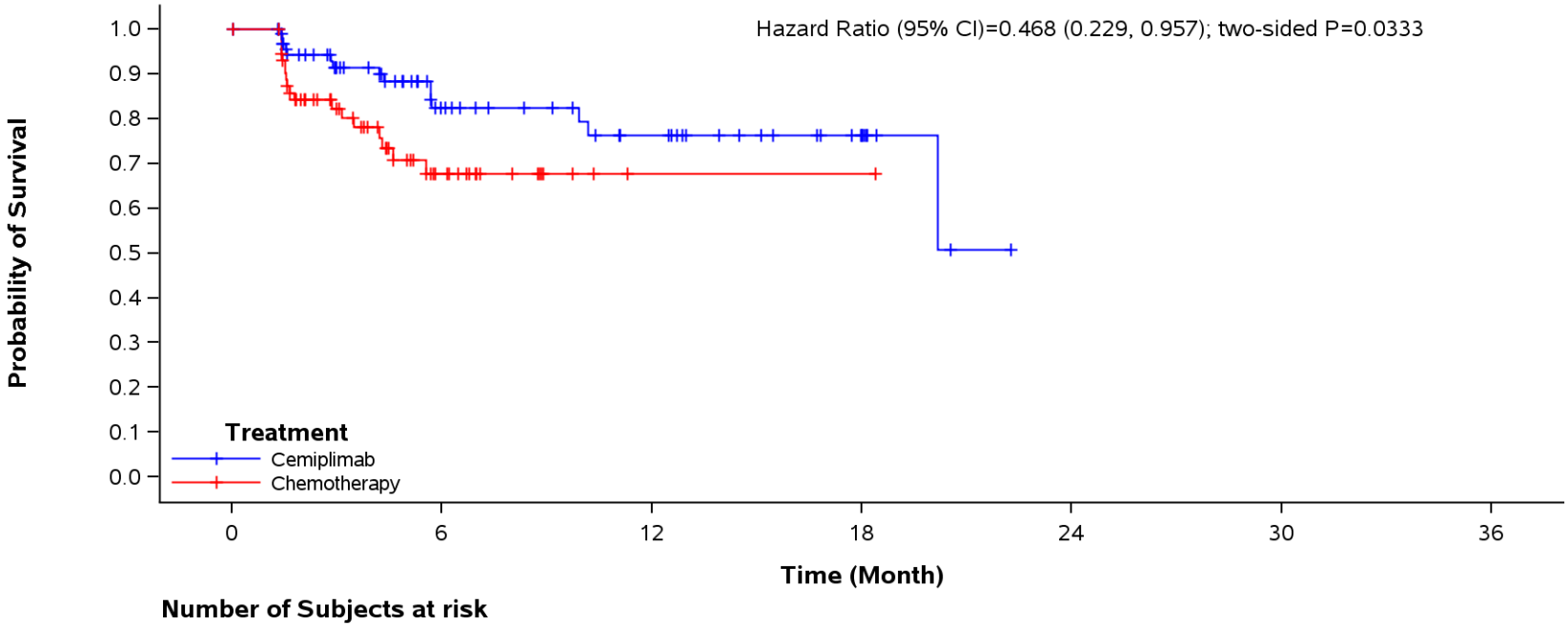
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 30 | 11 | 4 | 0 | 0 | 0 |
| Chemotherapy | 114 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 38 | 22 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 18 | 1 | 1 | 0 | 0 | 0 |

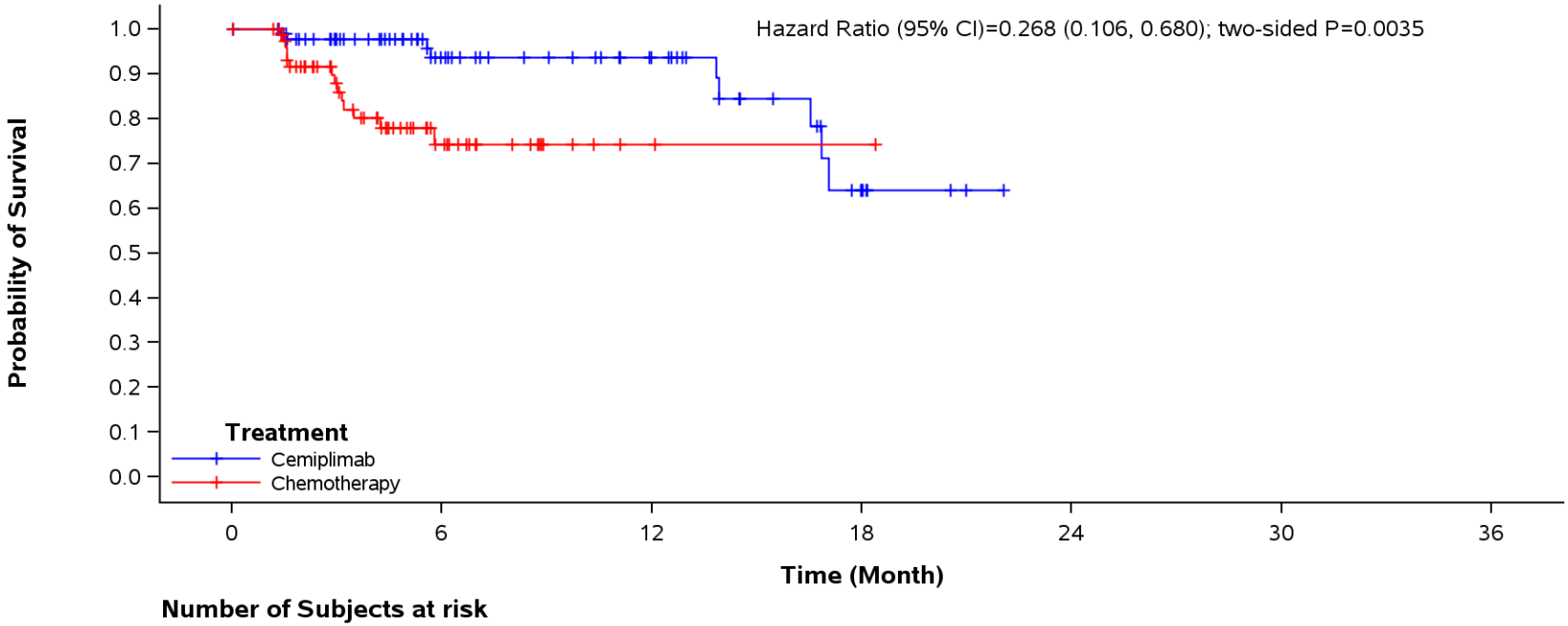
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 43 | 25 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 20 | 2 | 1 | 0 | 0 | 0 |

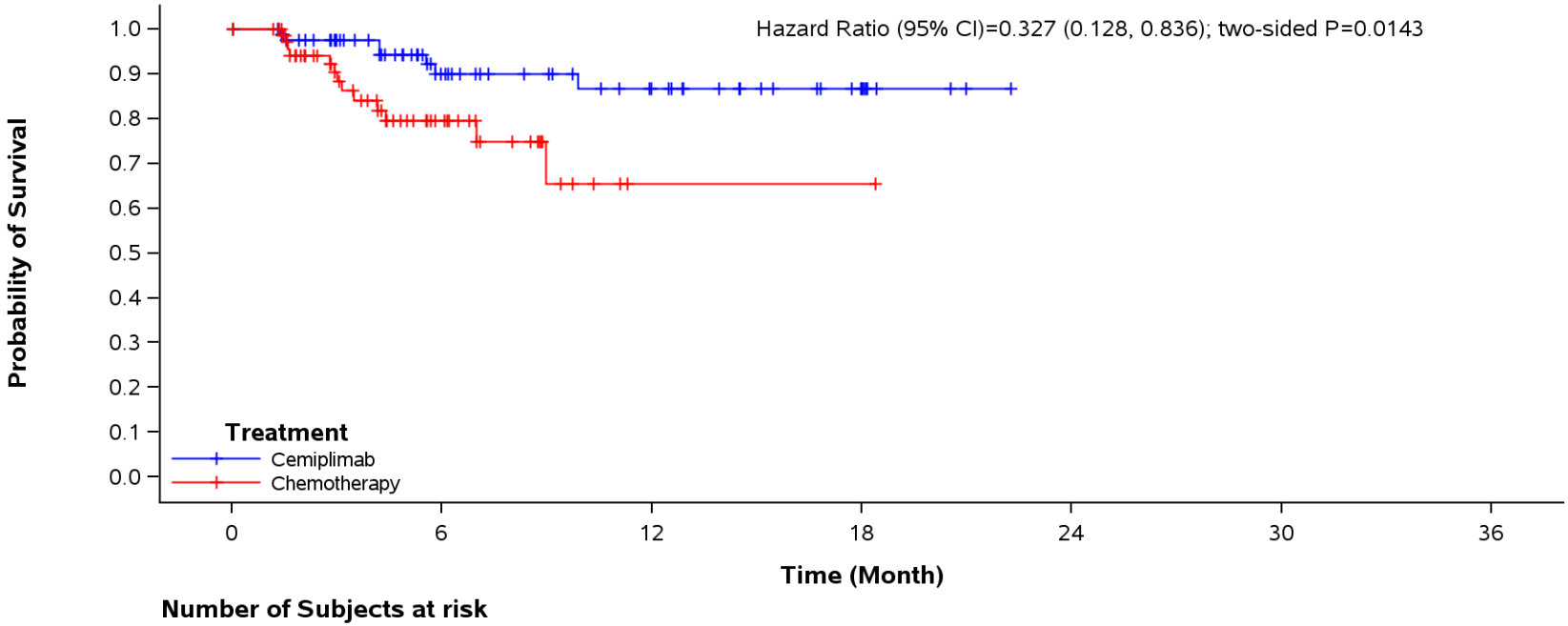
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Constipation - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 39 | 22 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 23 | 1 | 1 | 0 | 0 | 0 |

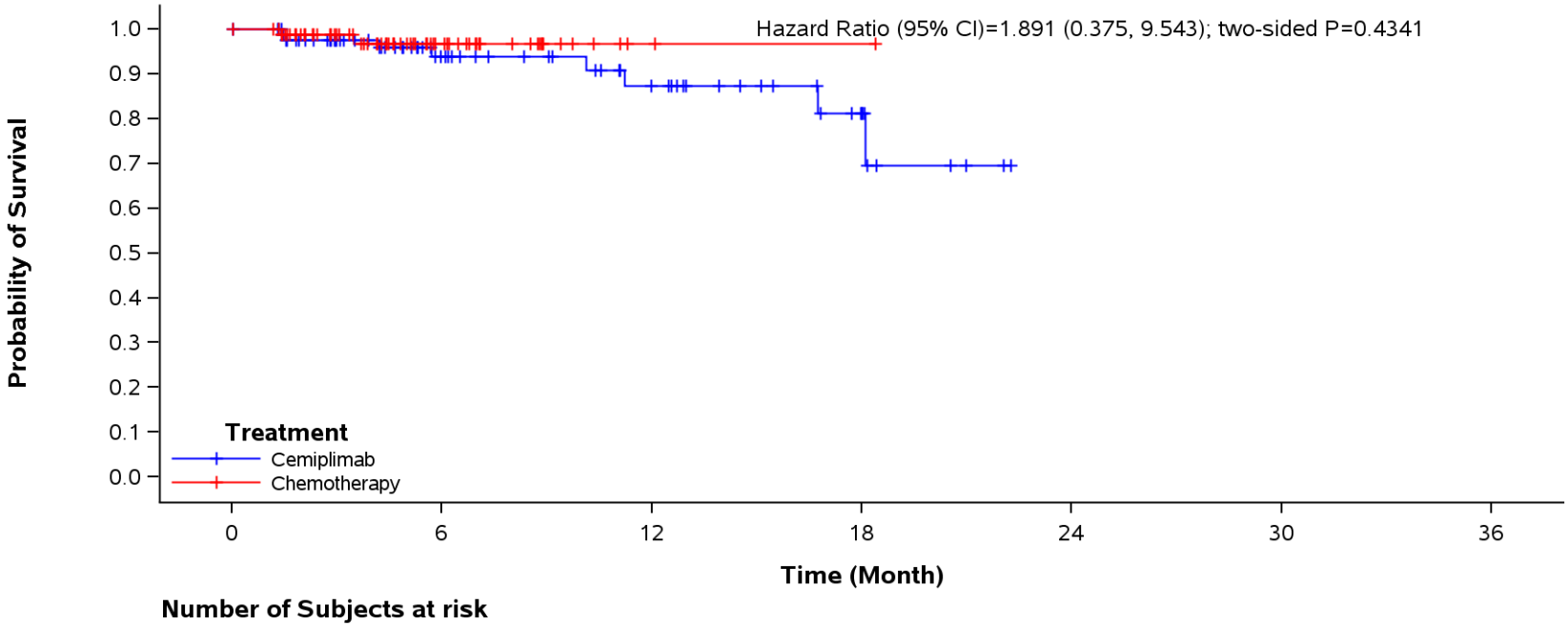
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Diarhoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 43 | 24 | 10 | 0 | 0 | 0 |
| Chemotherapy | 97 | 26 | 2 | 1 | 0 | 0 | 0 |

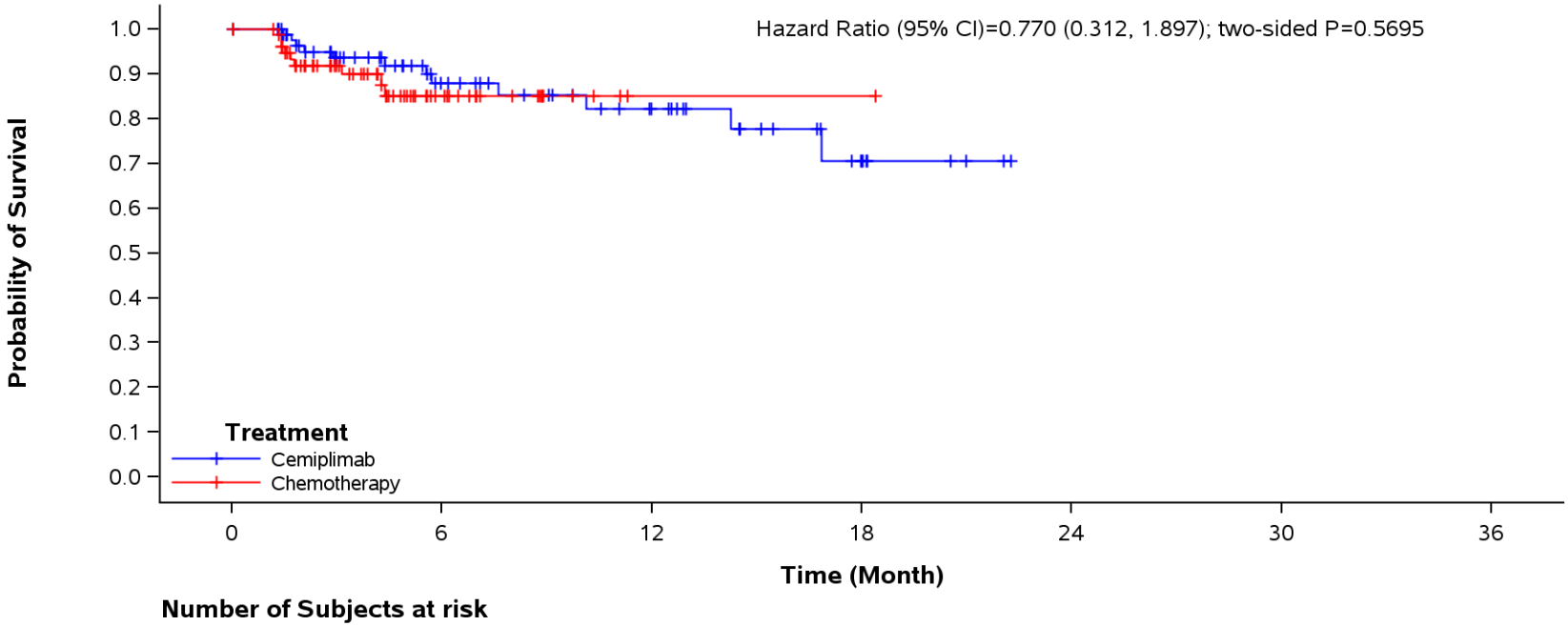
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Dyspnoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 40 | 23 | 8 | 0 | 0 | 0 |
| Chemotherapy | 97 | 20 | 1 | 1 | 0 | 0 | 0 |

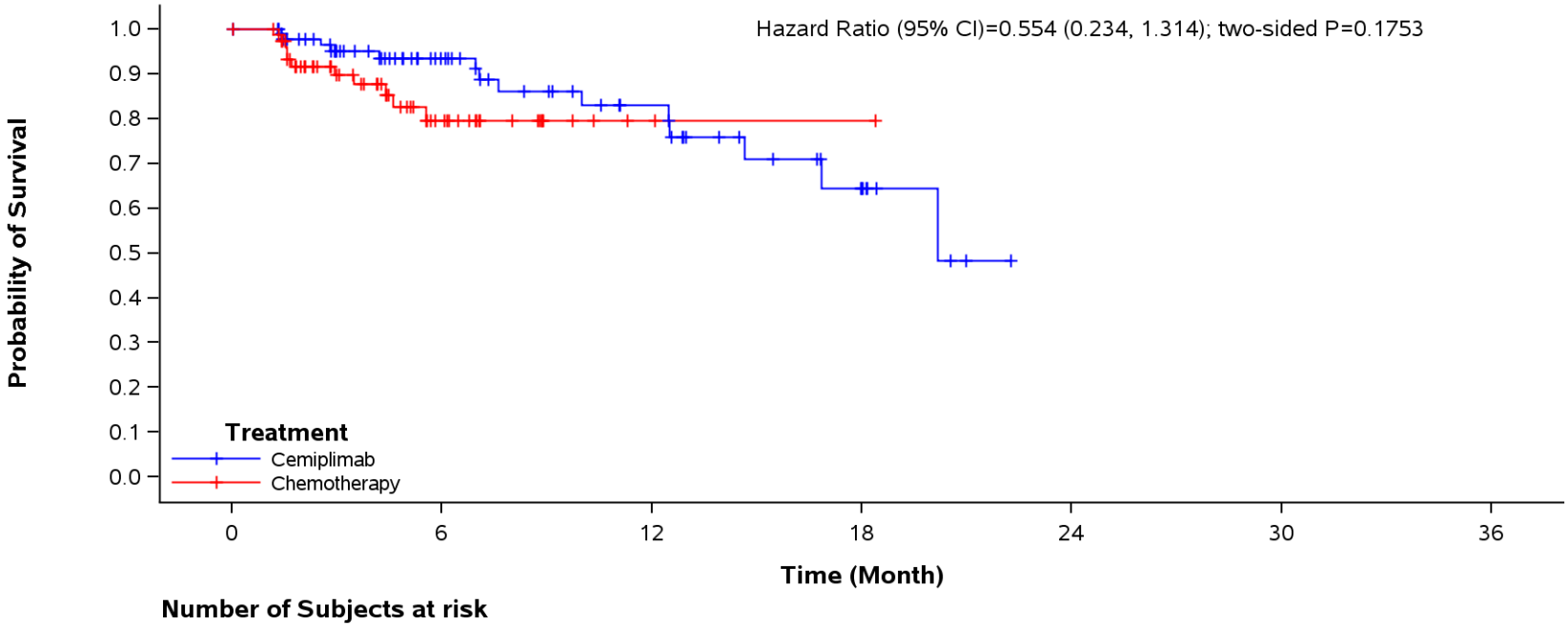
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Emotional Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

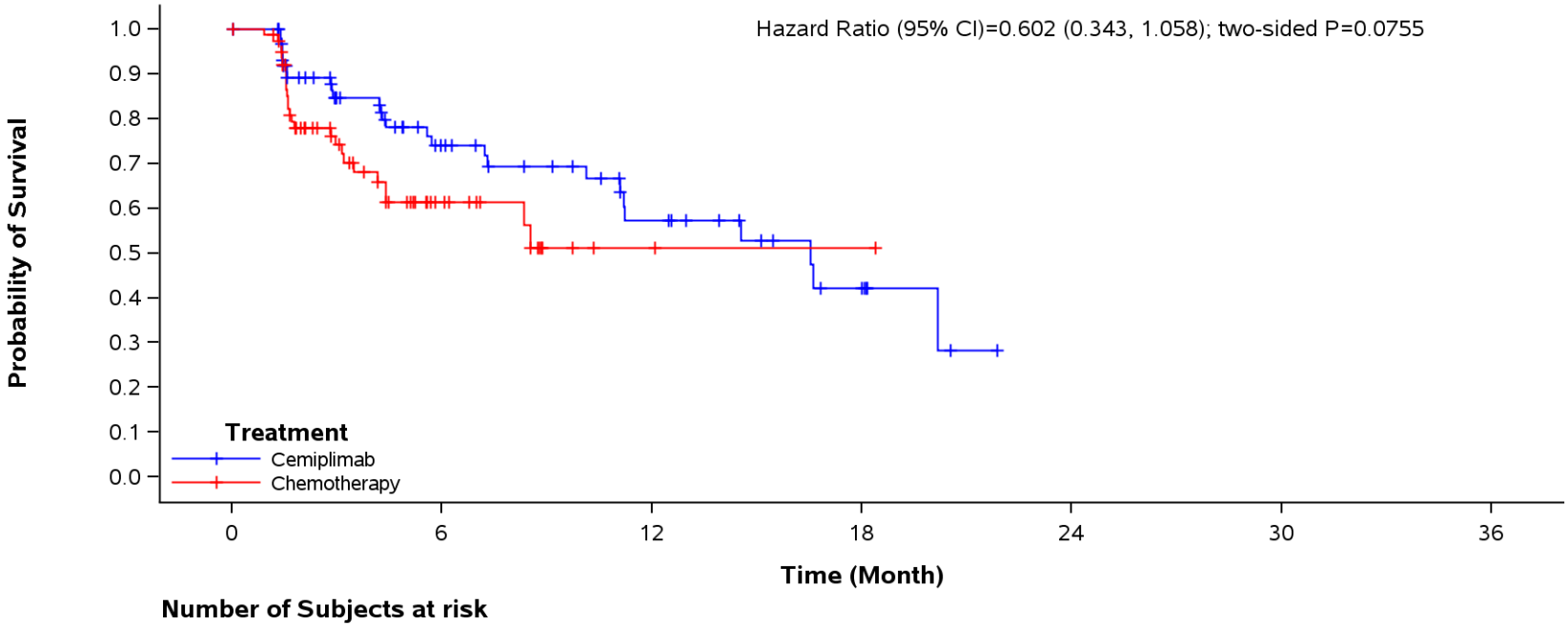
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 44 | 24 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 22 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

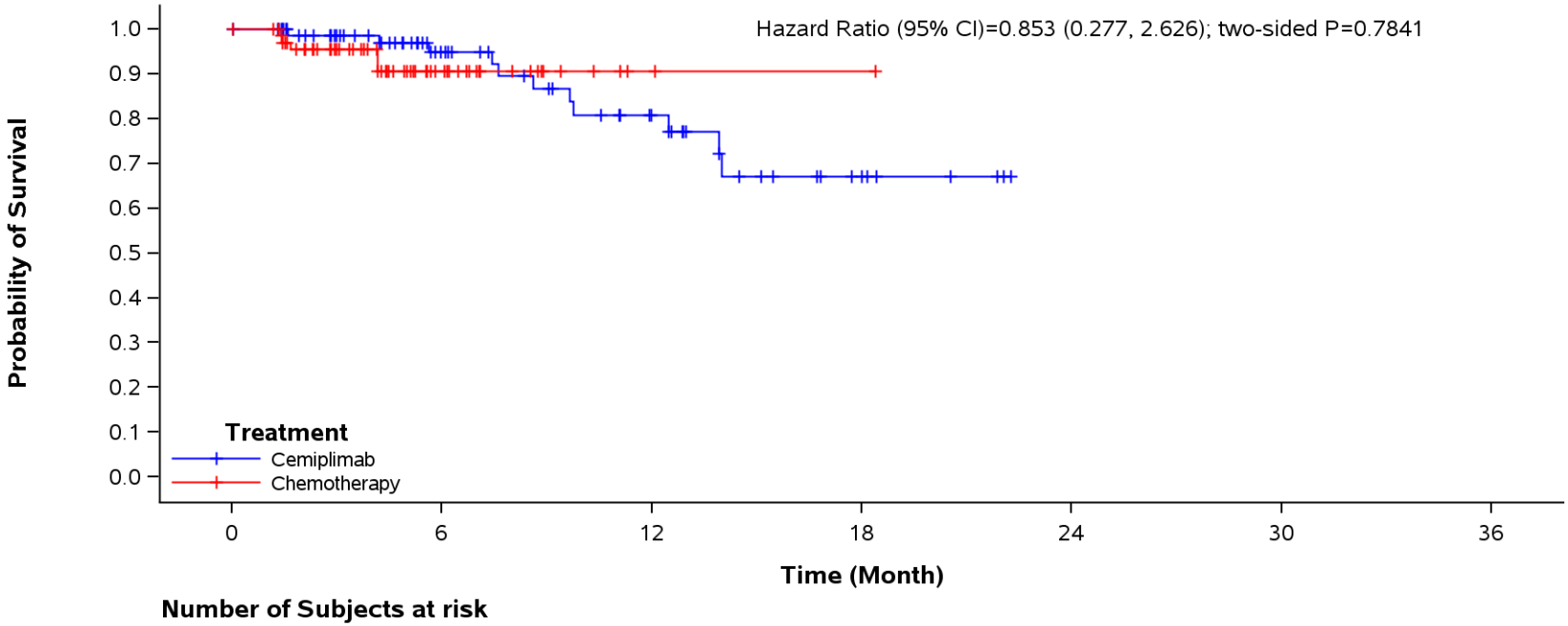
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 35 | 18 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

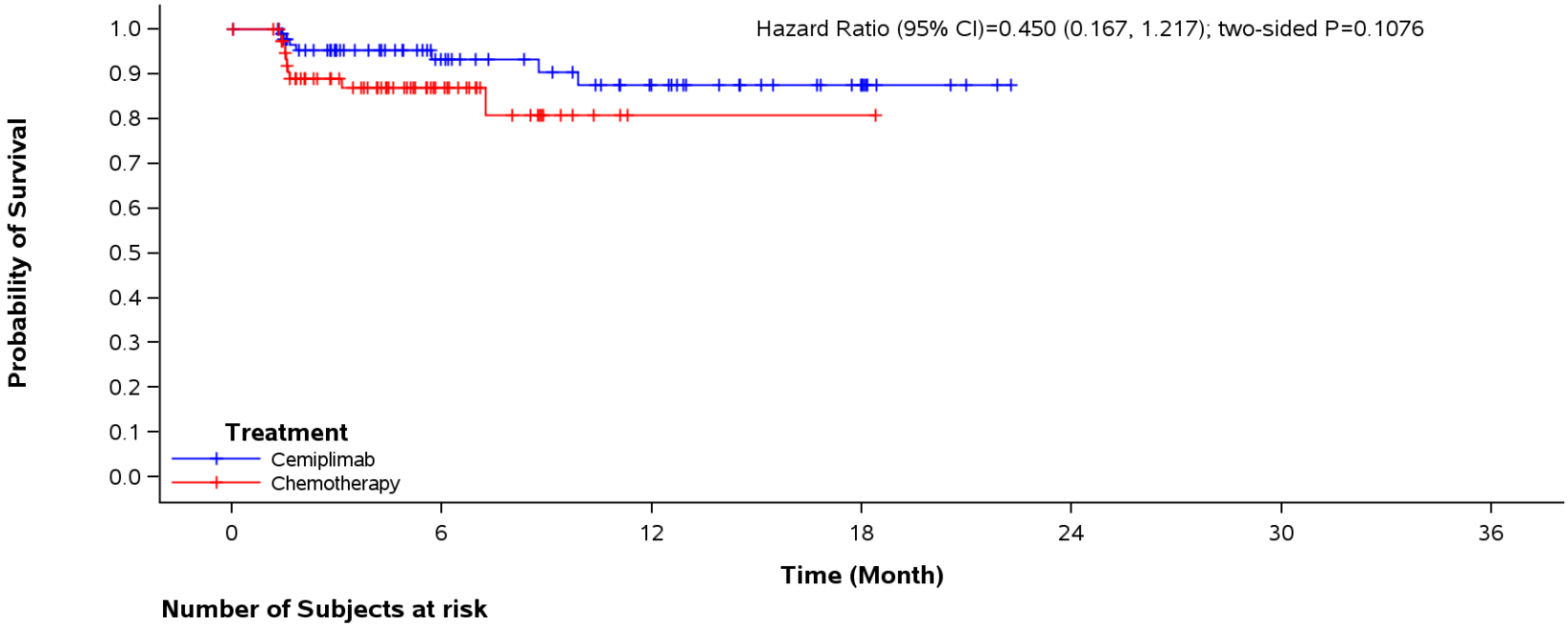
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 41 | 22 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

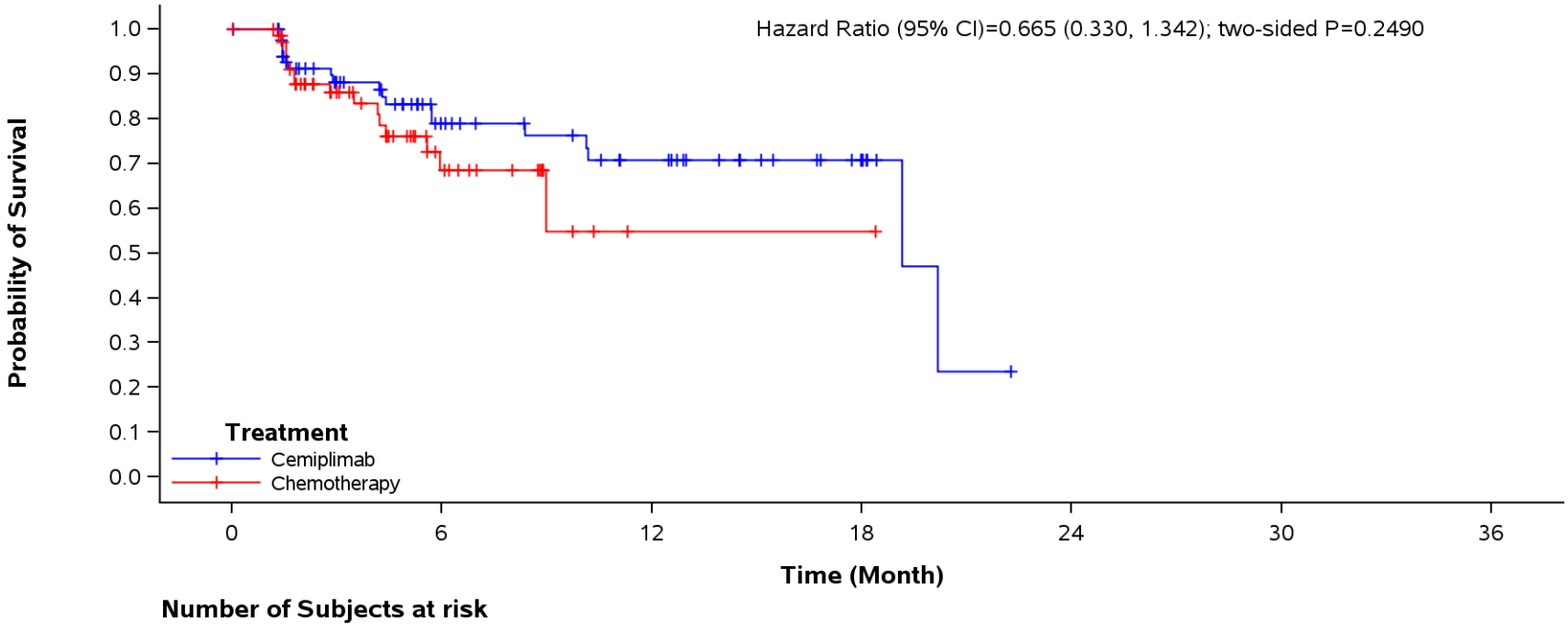
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 44 | 24 | 10 | 0 | 0 | 0 |
| Chemotherapy | 97 | 23 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 35 | 22 | 8 | 0 | 0 | 0 |
| Chemotherapy | 97 | 17 | 1 | 1 | 0 | 0 | 0 |

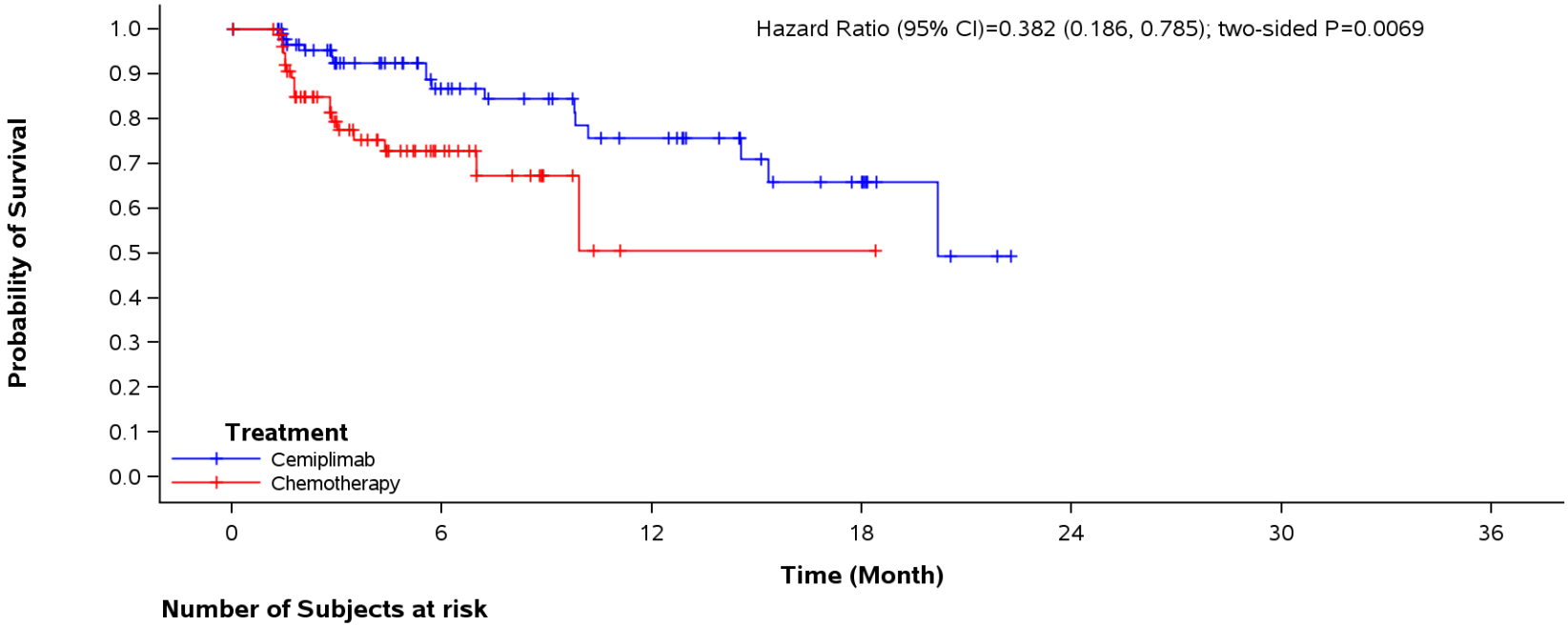
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

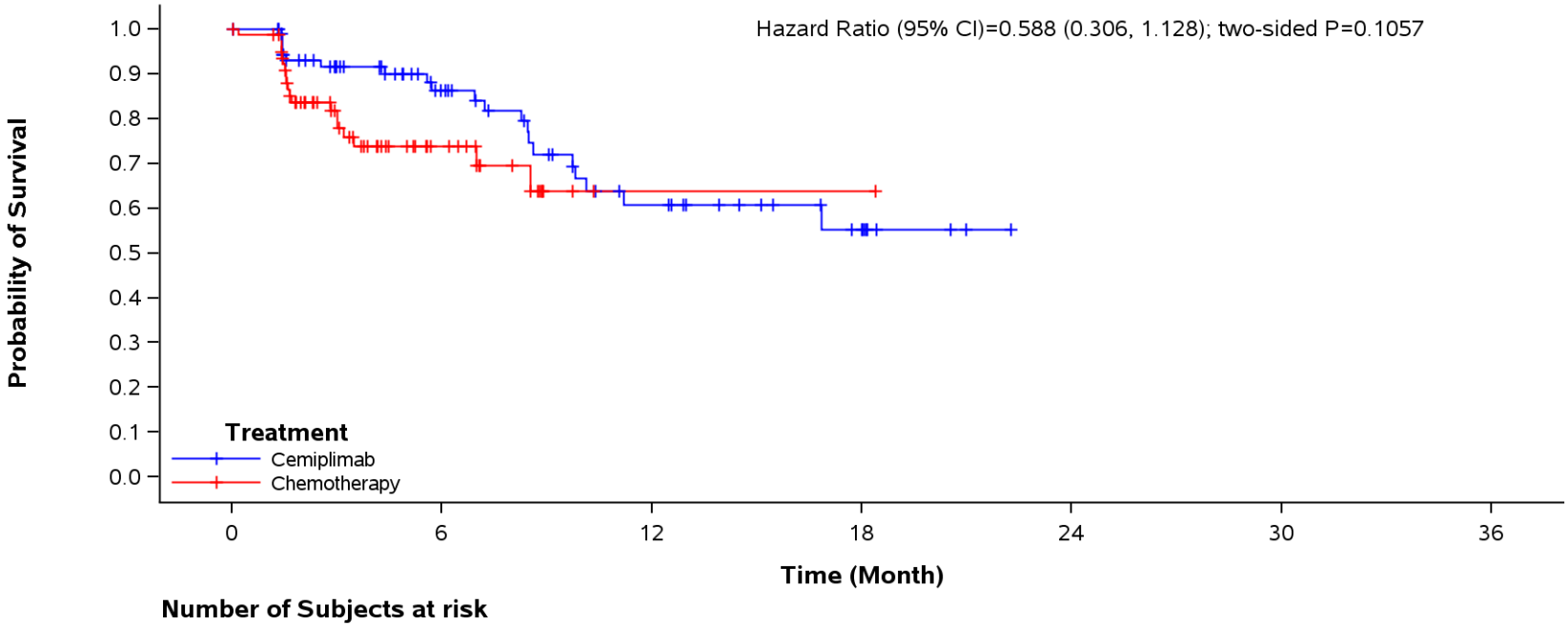
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 42 | 24 | 10 | 0 | 0 | 0 |
| Chemotherapy | 97 | 18 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

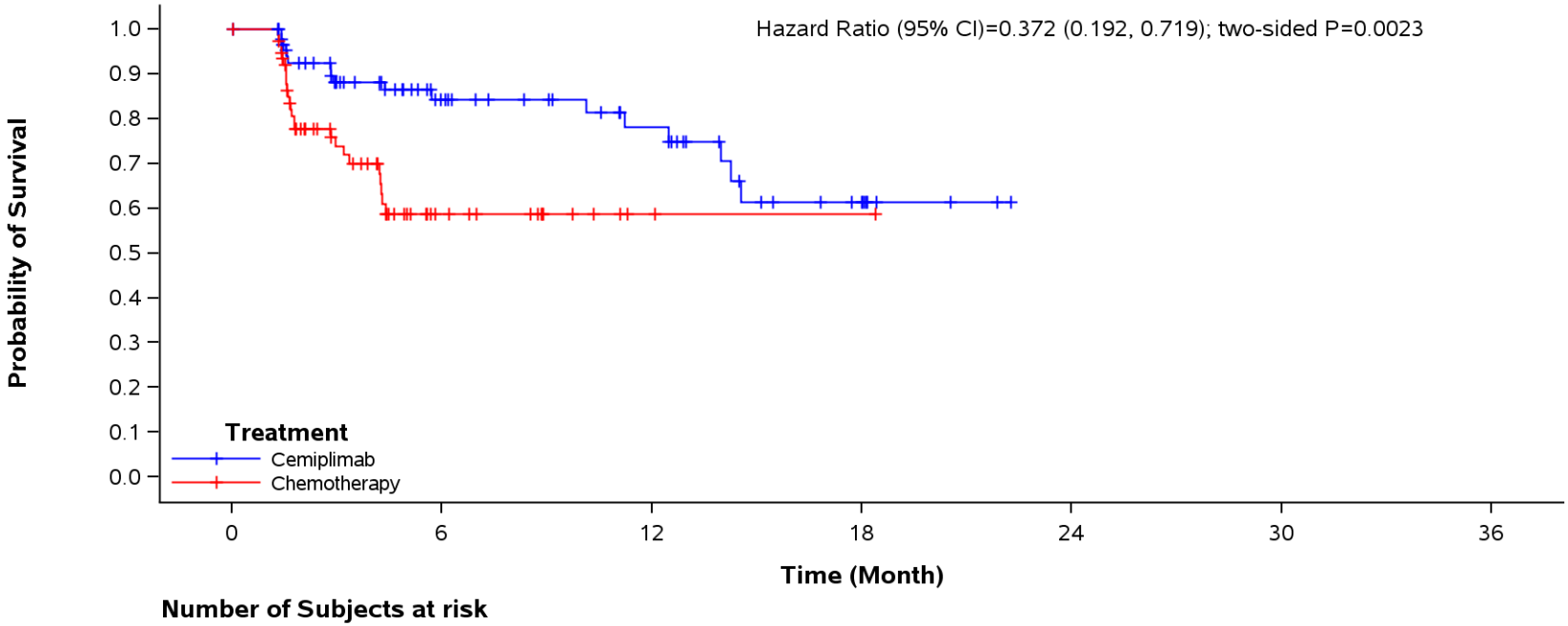
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 43 | 20 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 21 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Role Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

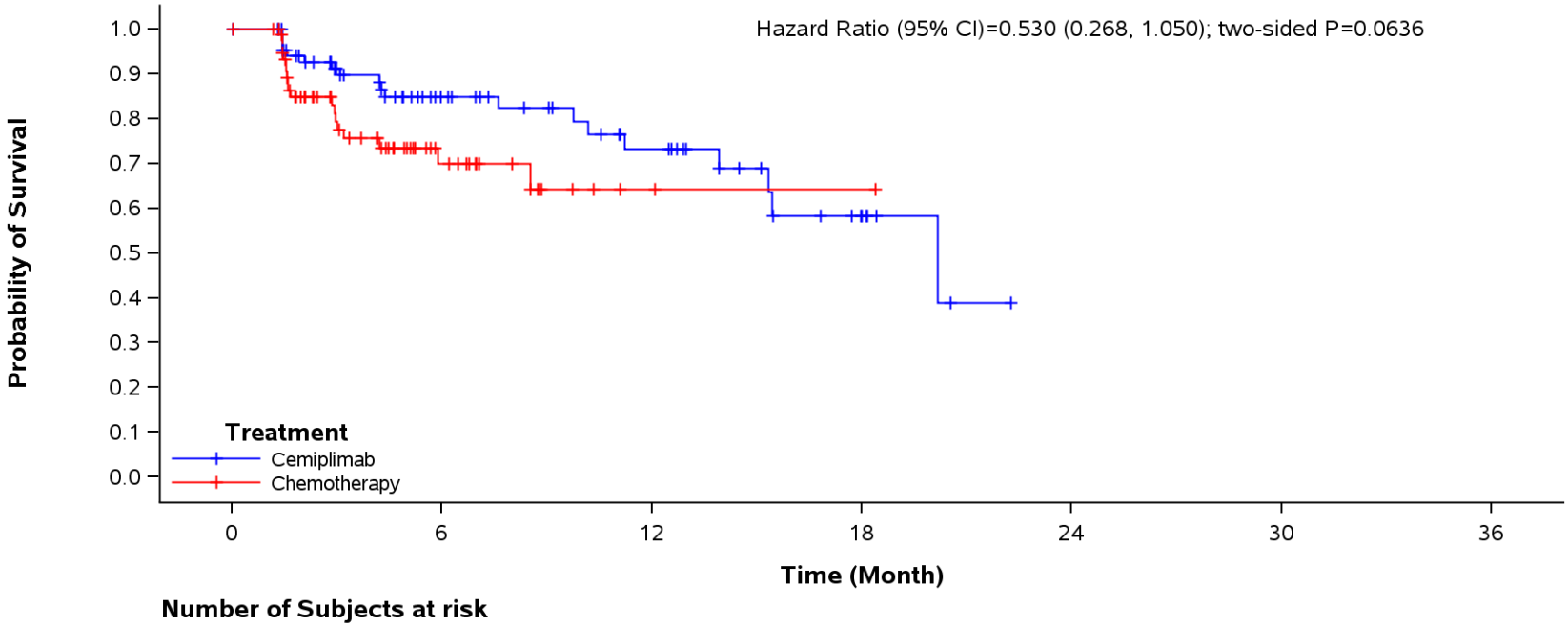
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 38 | 24 | 9 | 0 | 0 | 0 |
| Chemotherapy | 97 | 14 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Social Functioning - 10 pts sensitivity sustained deterioration



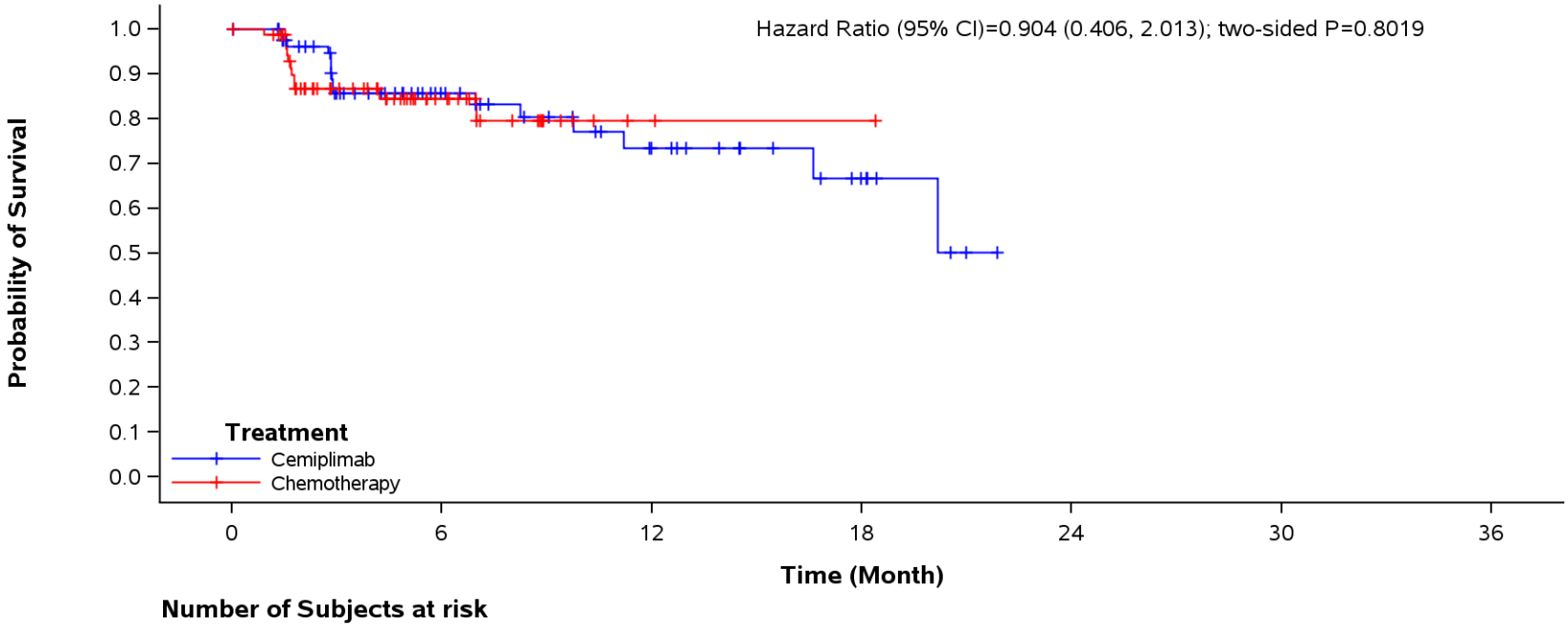

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 39 | 22 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

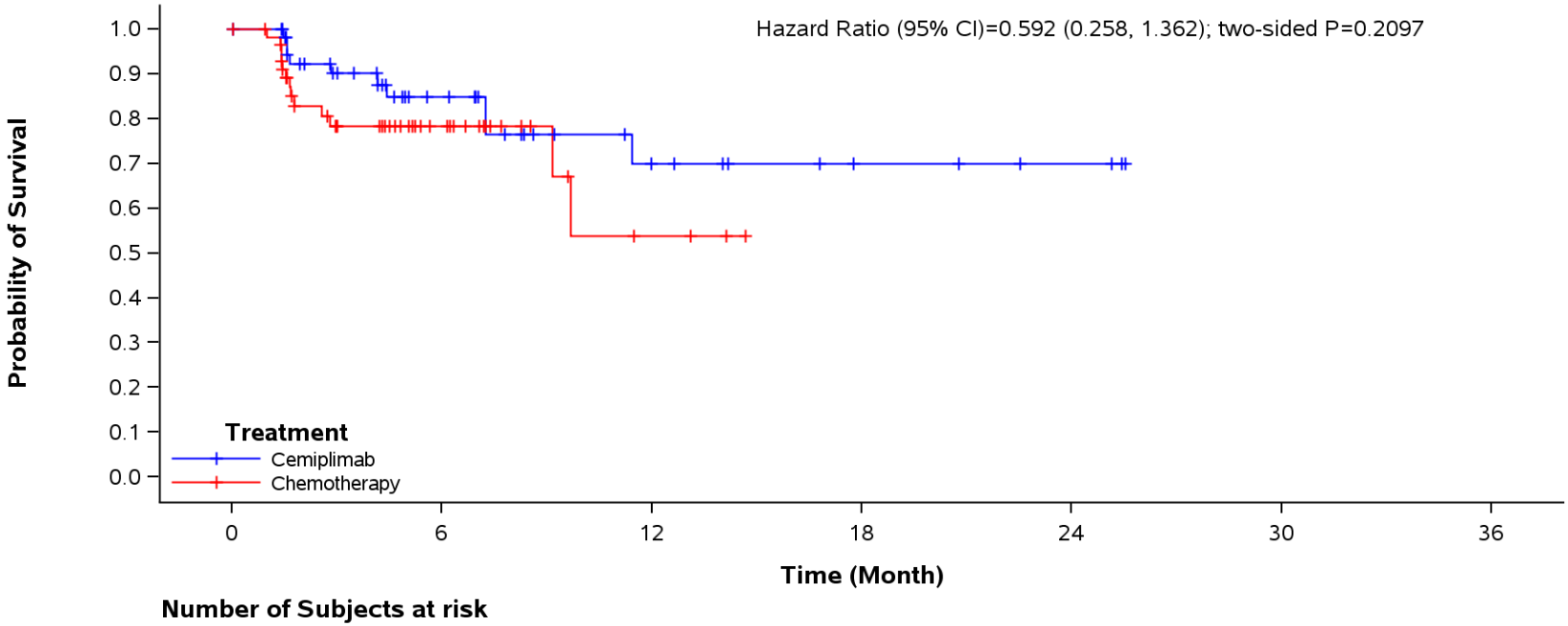
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 37 | 18 | 7 | 0 | 0 | 0 |
| Chemotherapy | 97 | 23 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

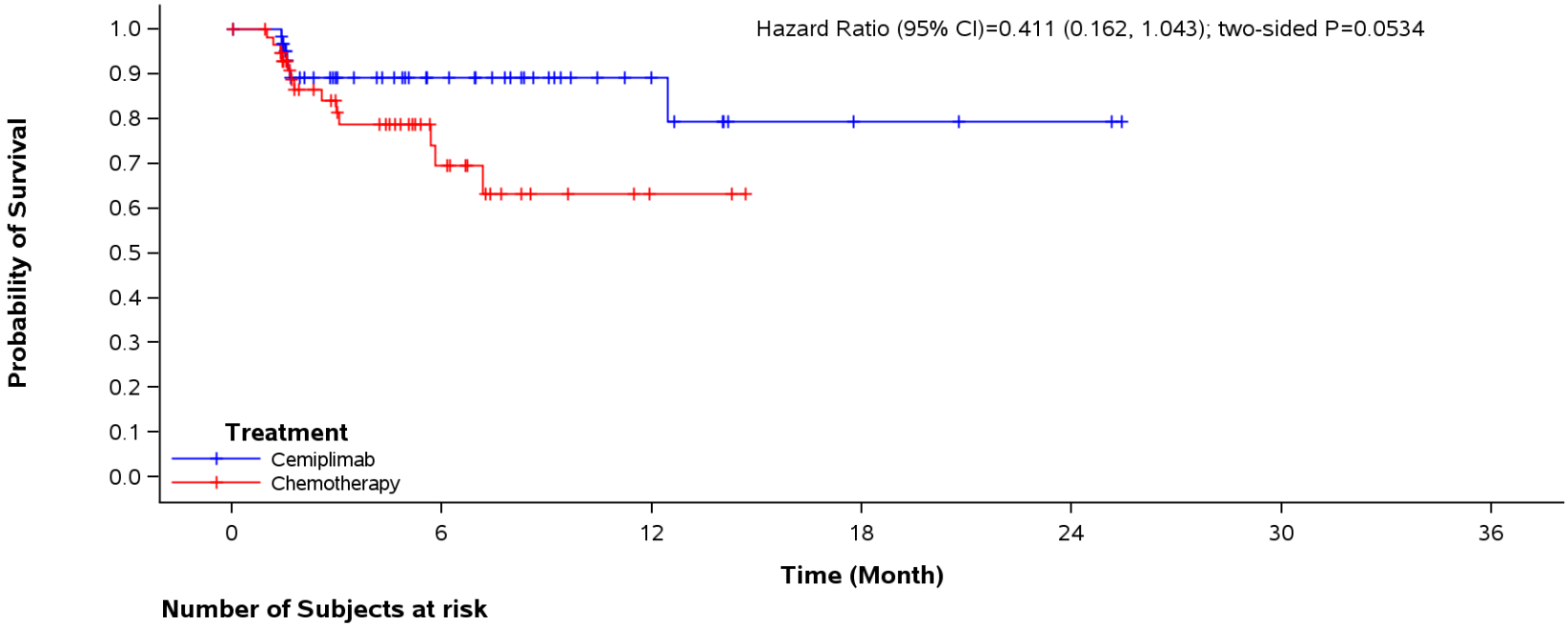
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 25 | 10 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Cognitive Functioning - 10 pts sensitivity sustained deterioration



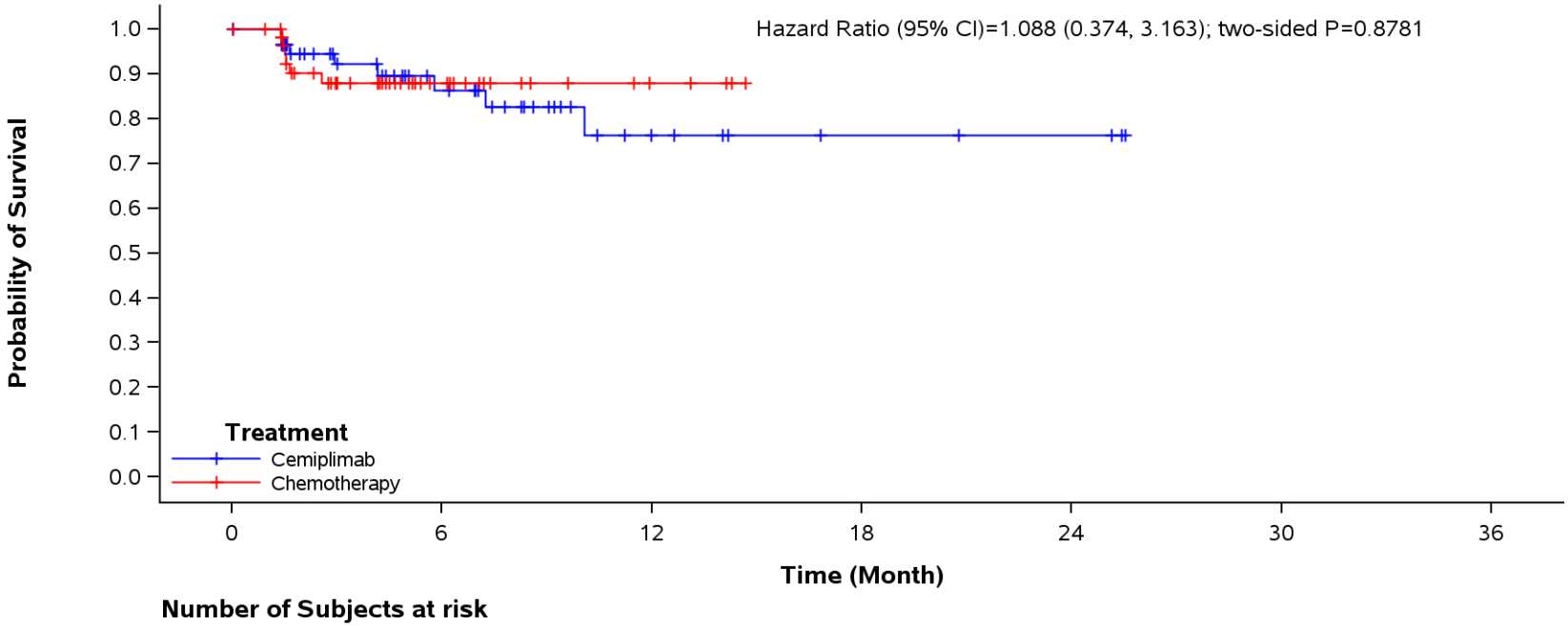

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 27 | 9 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Constipation - 10 pts sensitivity sustained deterioration



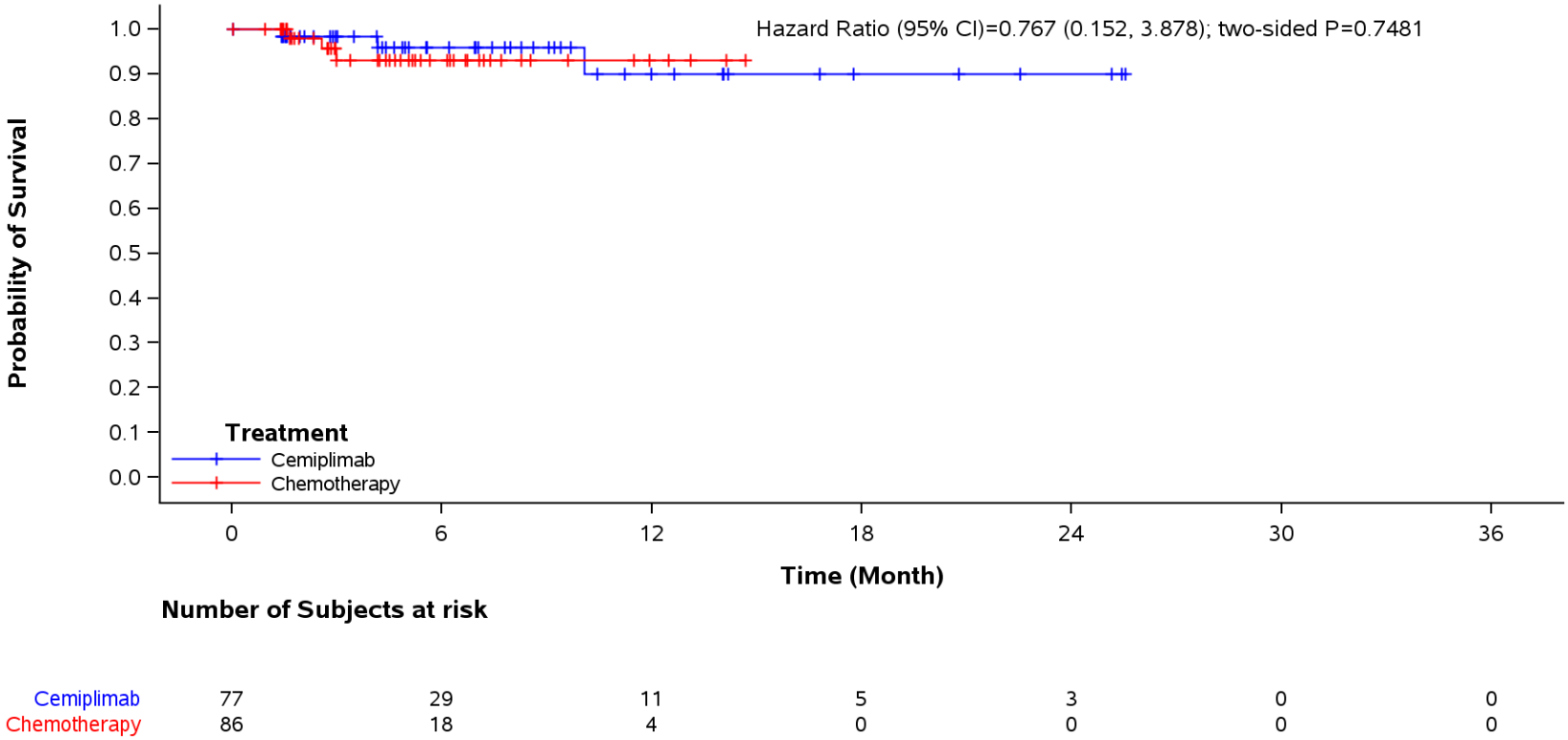

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 27 | 8 | 4 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Diarhoea - 10 pts sensitivity sustained deterioration



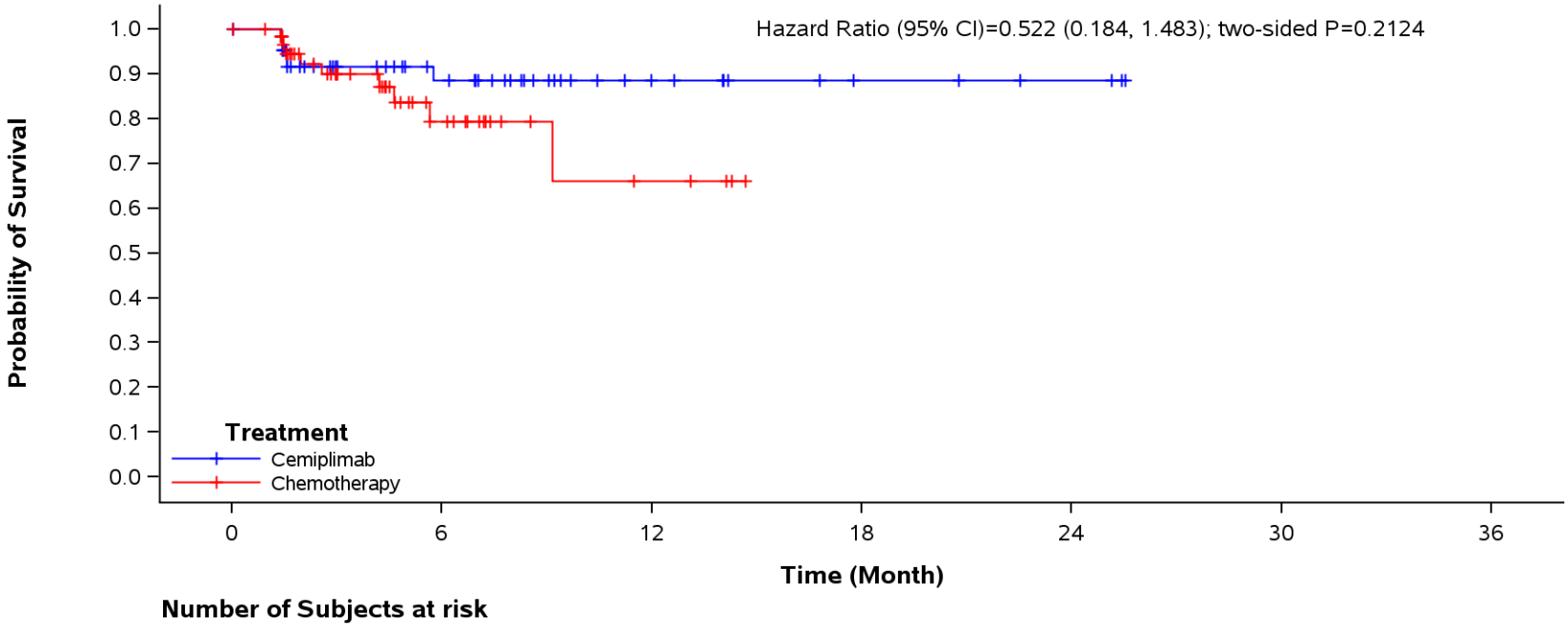

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 29 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 18 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Dyspnoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

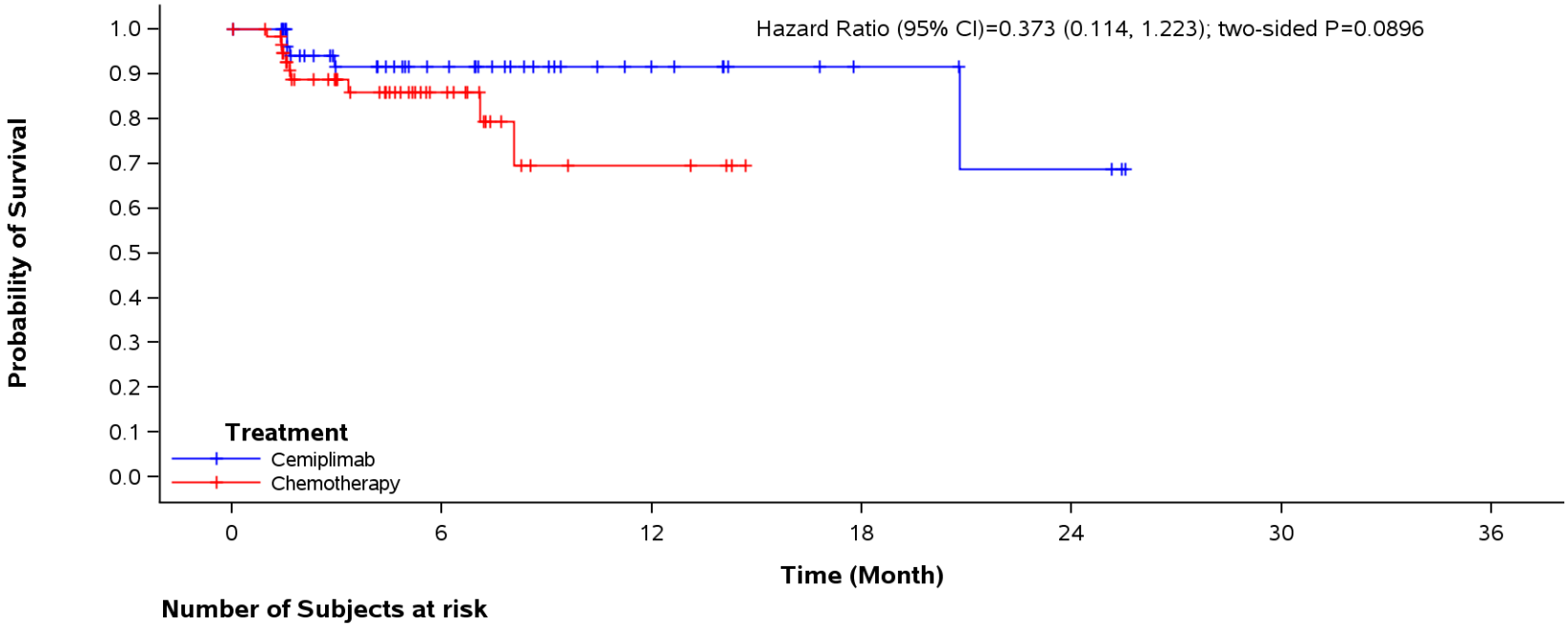
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 30 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

Emotional Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 28 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 18 | 4 | 0 | 0 | 0 | 0 |

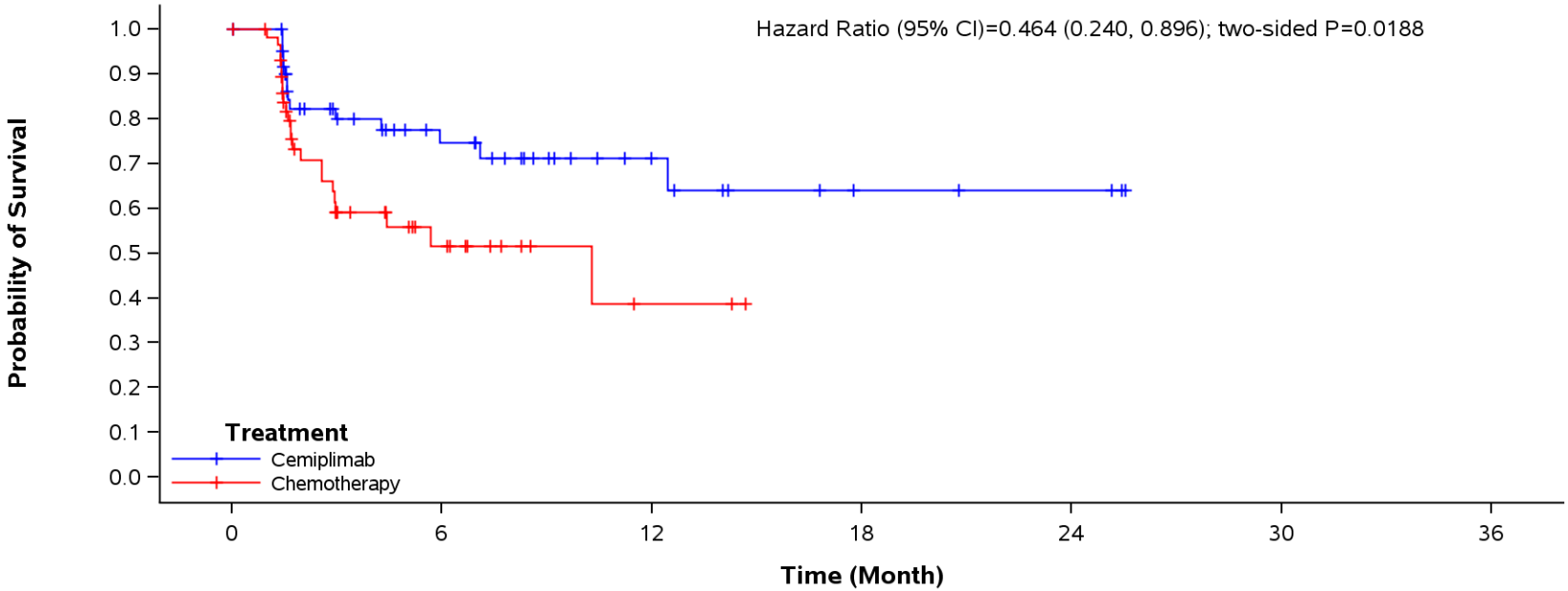
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 25 | 10 | 4 | 3 | 0 | 0 |
| Chemotherapy | 86 | 12 | 2 | 0 | 0 | 0 | 0 |

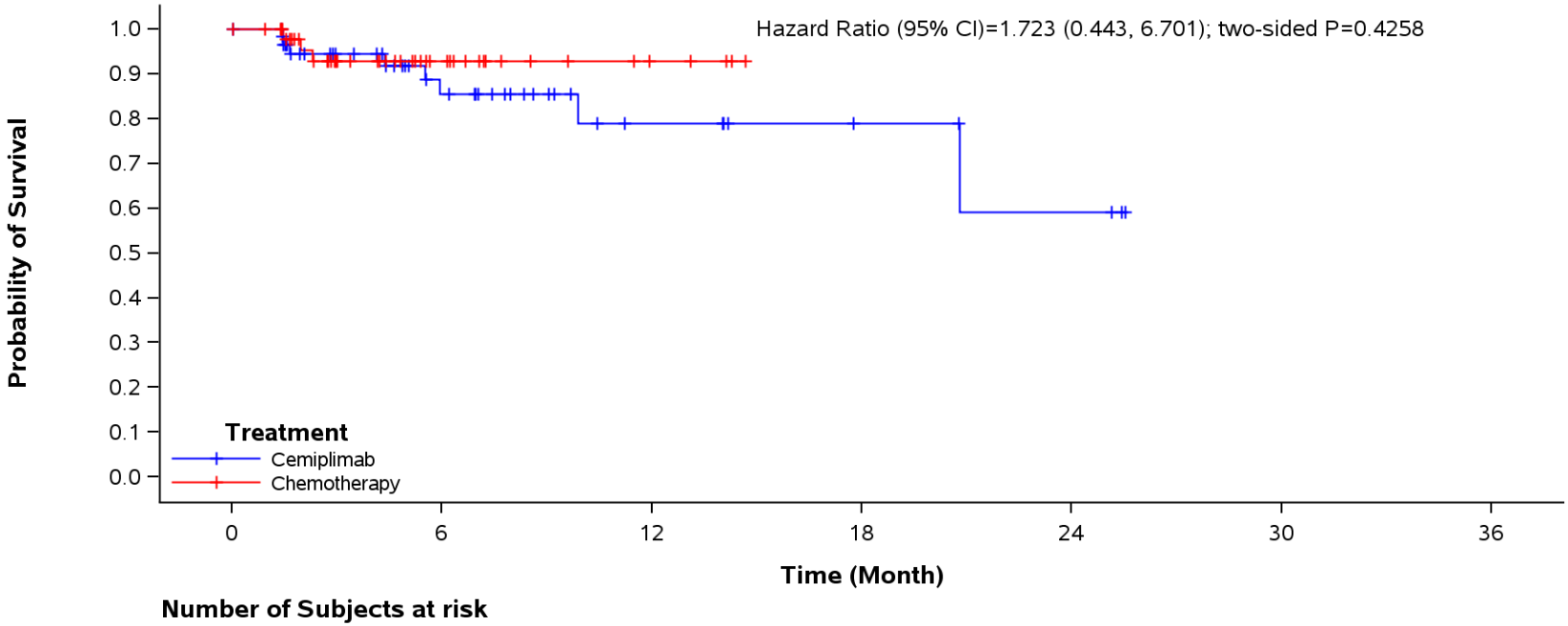
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

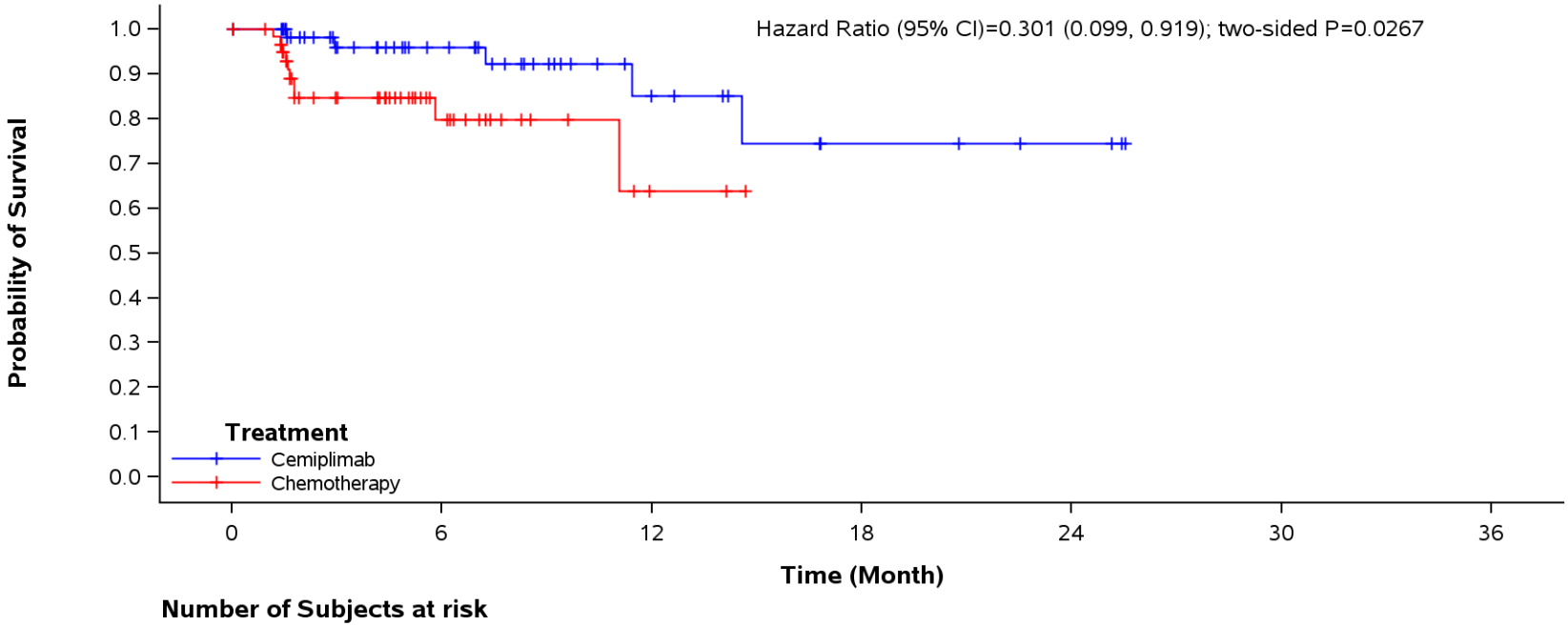
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 26 | 9 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



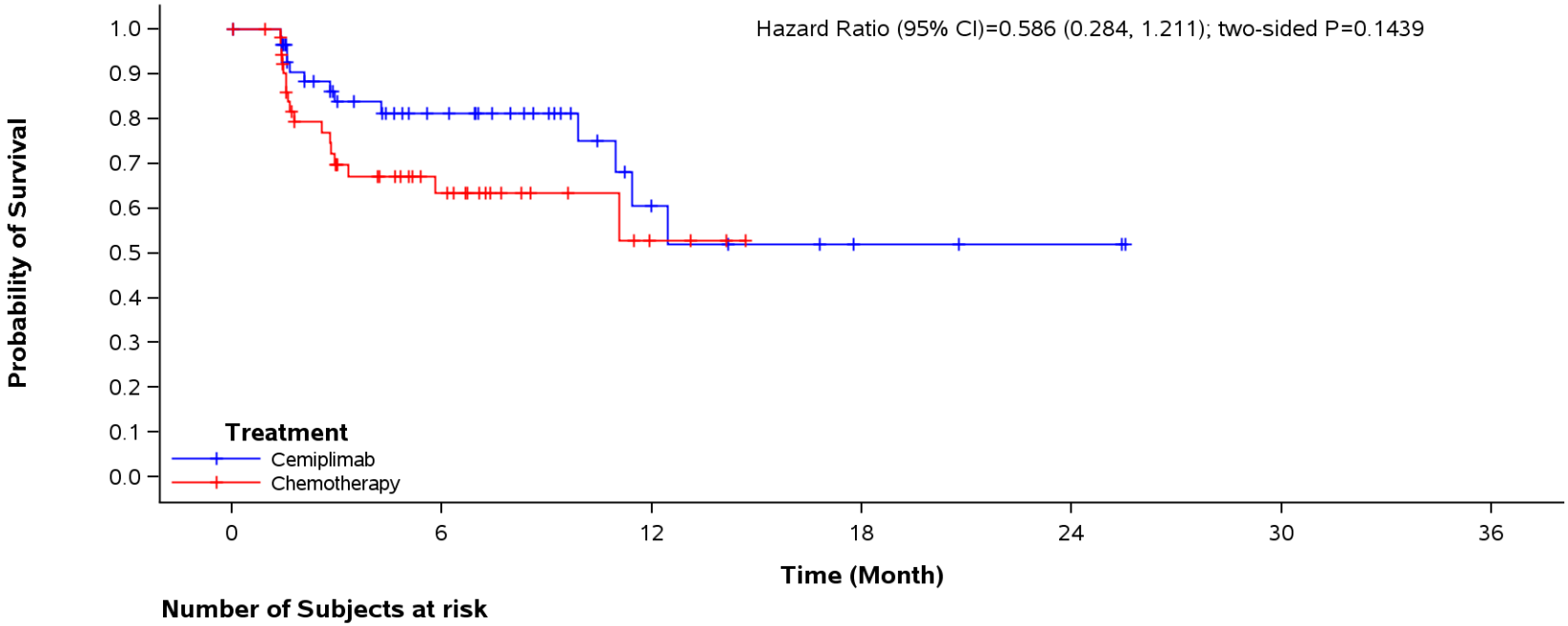

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 31 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

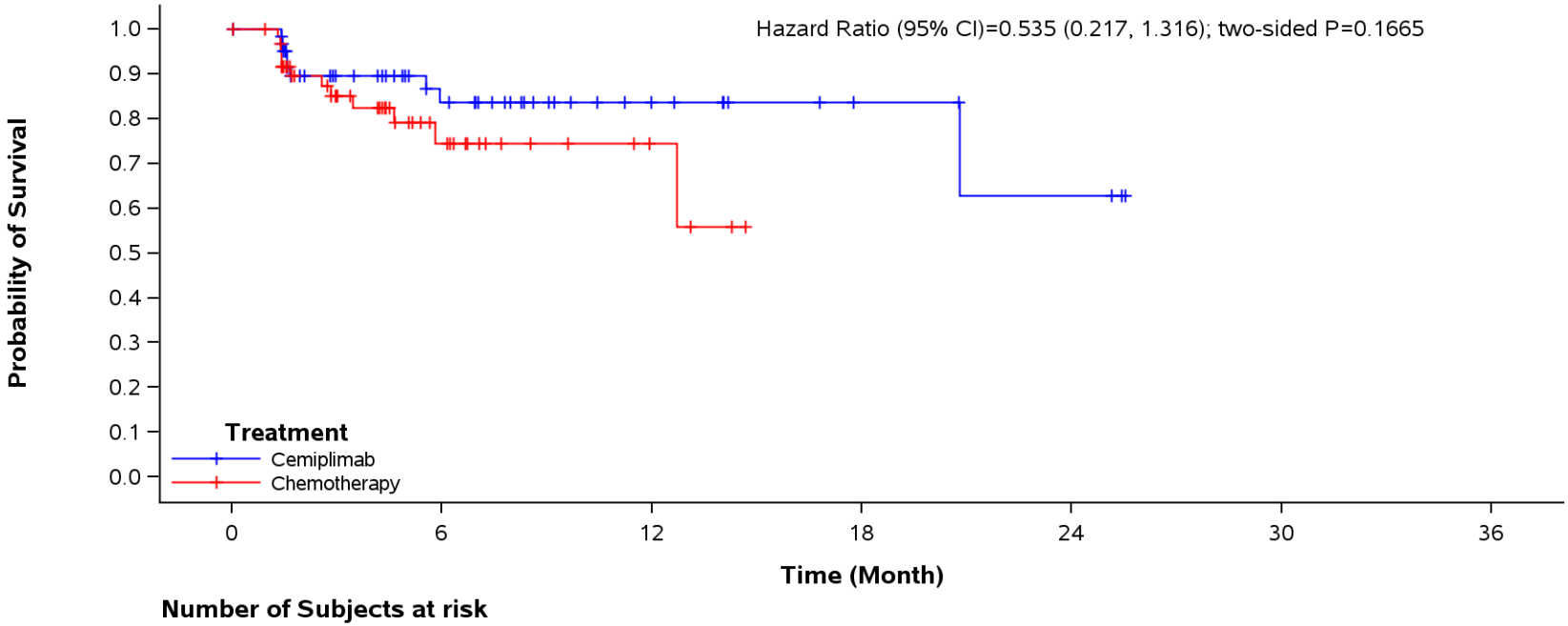
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 26 | 7 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

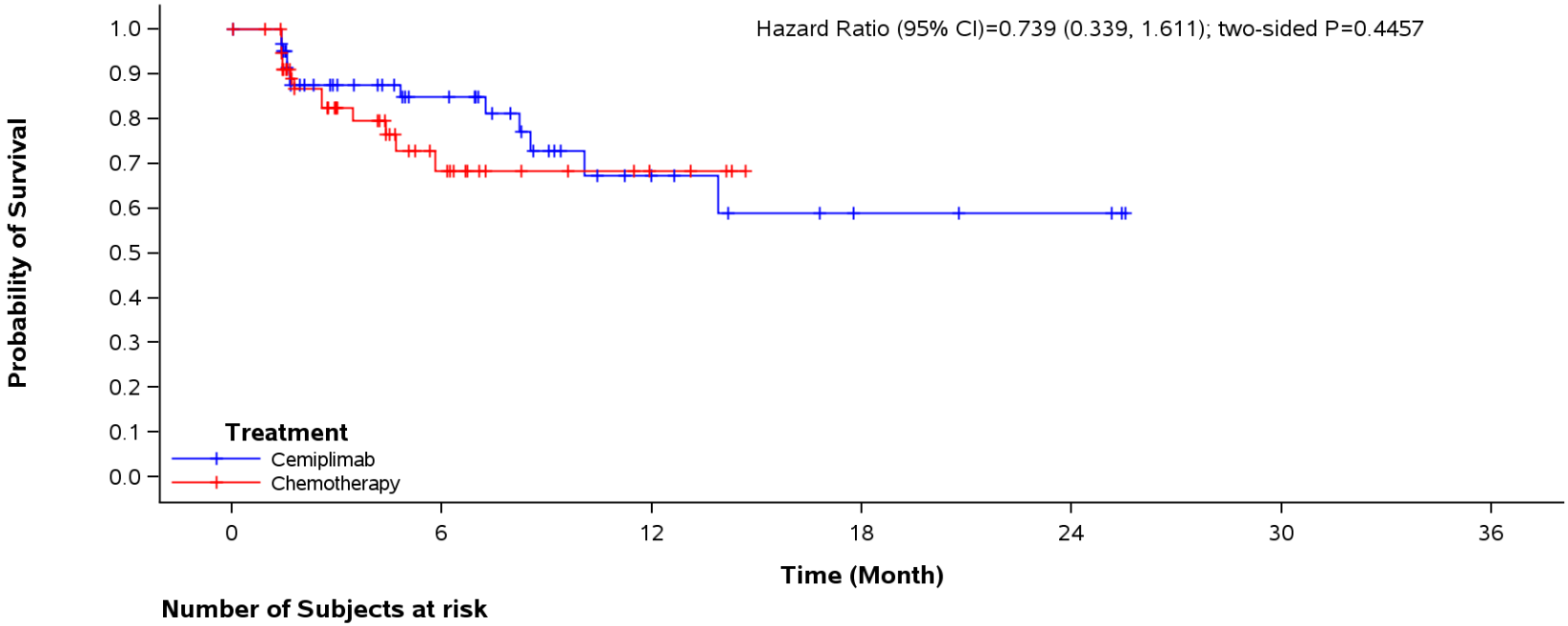
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 28 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Global health status / QoL - 10 pts sensitivity sustained deterioration



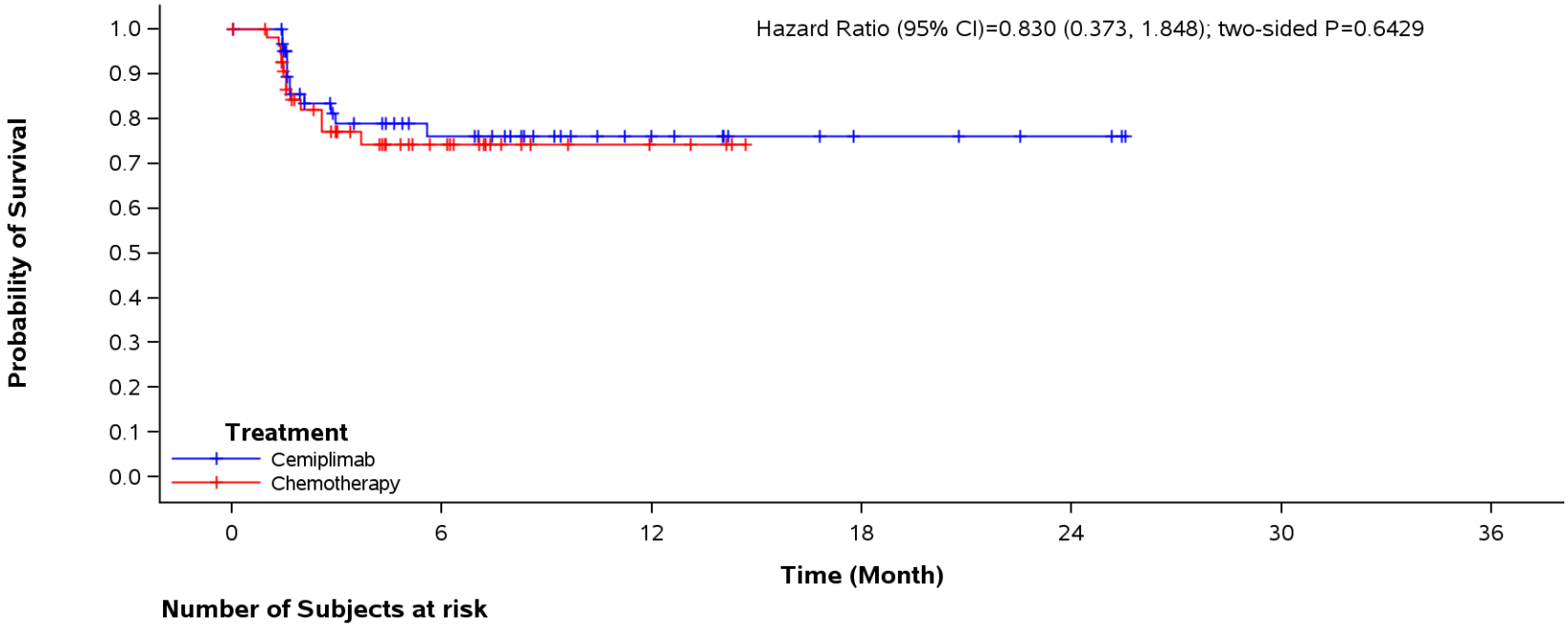

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 28 | 9 | 4 | 3 | 0 | 0 |
| Chemotherapy | 86 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Role Functioning - 10 pts sensitivity sustained deterioration



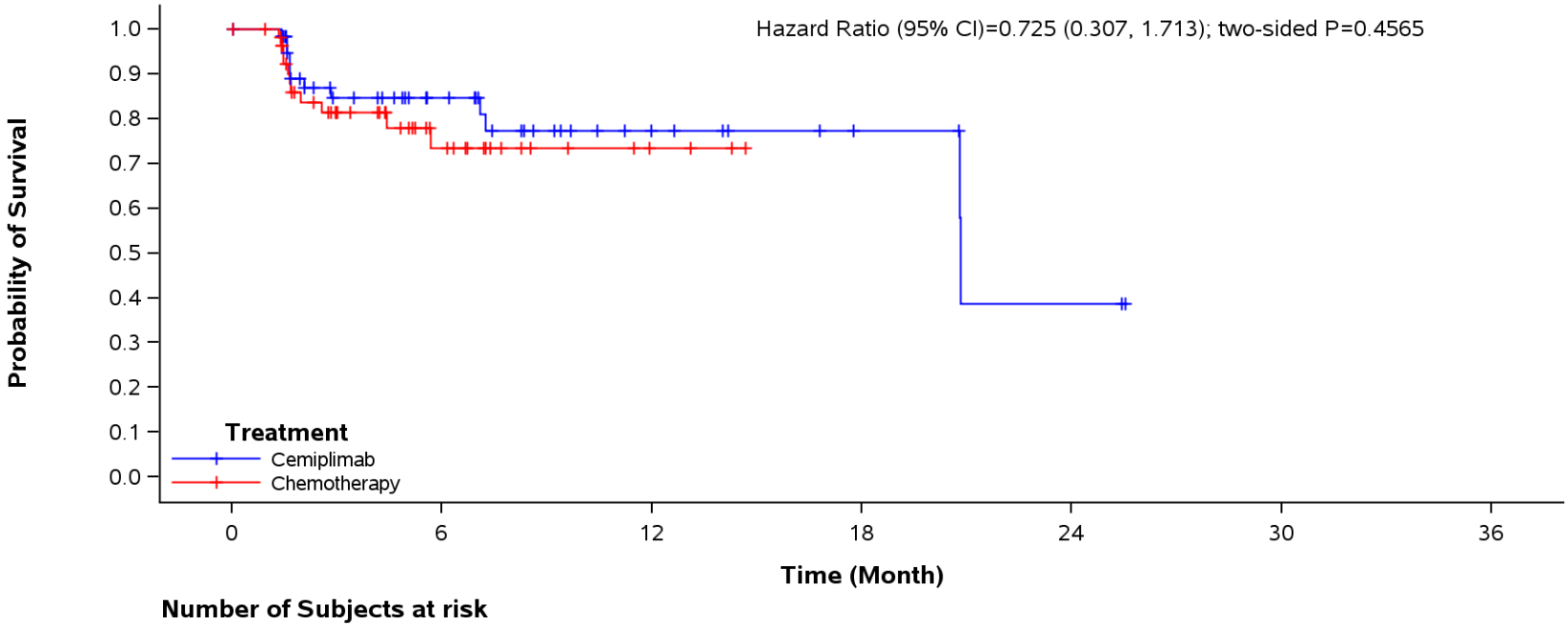

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 27 | 11 | 5 | 3 | 0 | 0 |
| Chemotherapy | 86 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Social Functioning - 10 pts sensitivity sustained deterioration



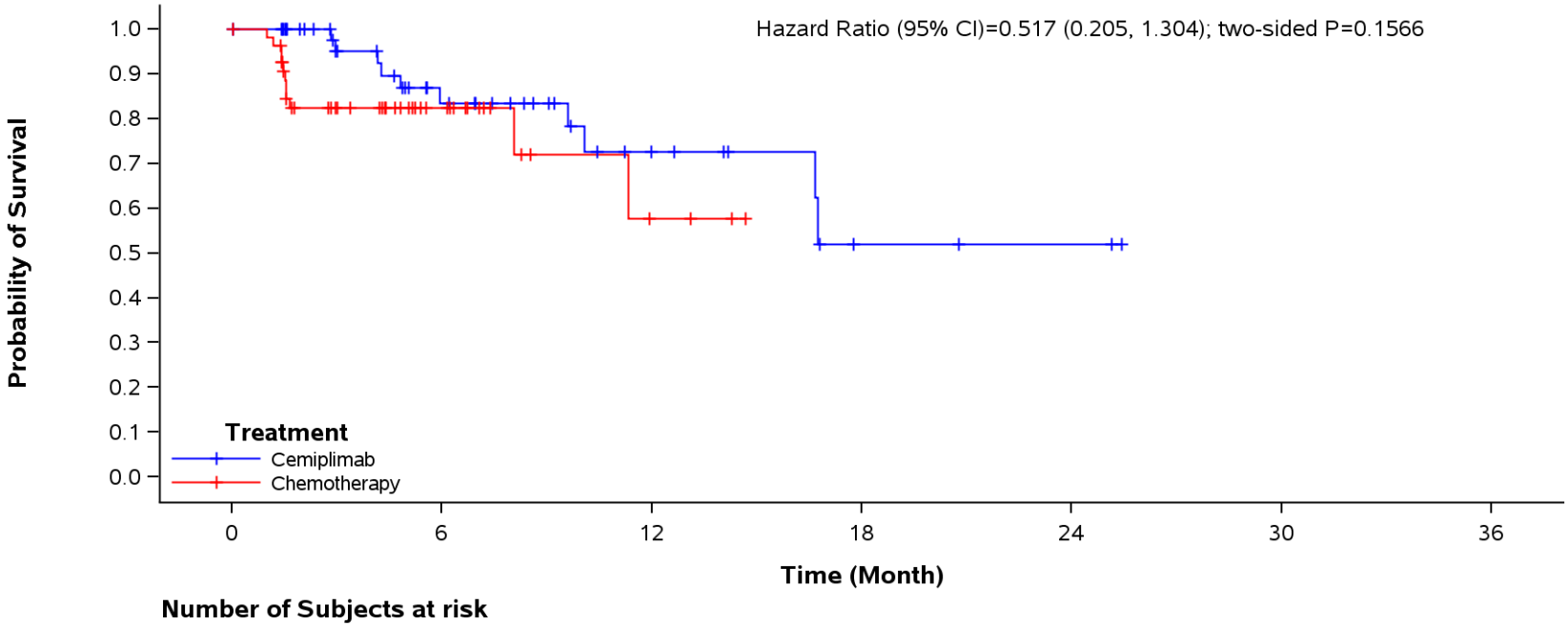

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 28 | 10 | 5 | 2 | 0 | 0 |
| Chemotherapy | 86 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Insomnia - 10 pts sensitivity sustained deterioration



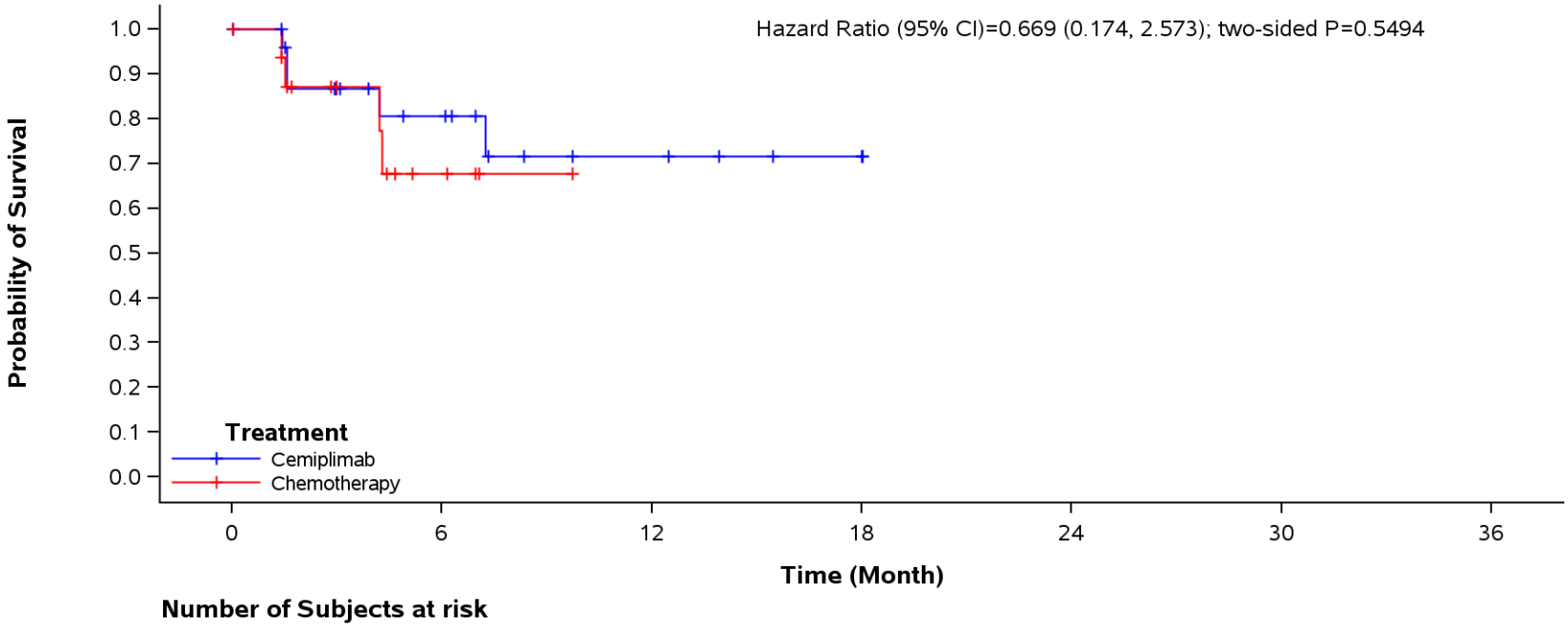

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 25 | 10 | 3 | 2 | 0 | 0 |
| Chemotherapy | 86 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Appetite loss - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

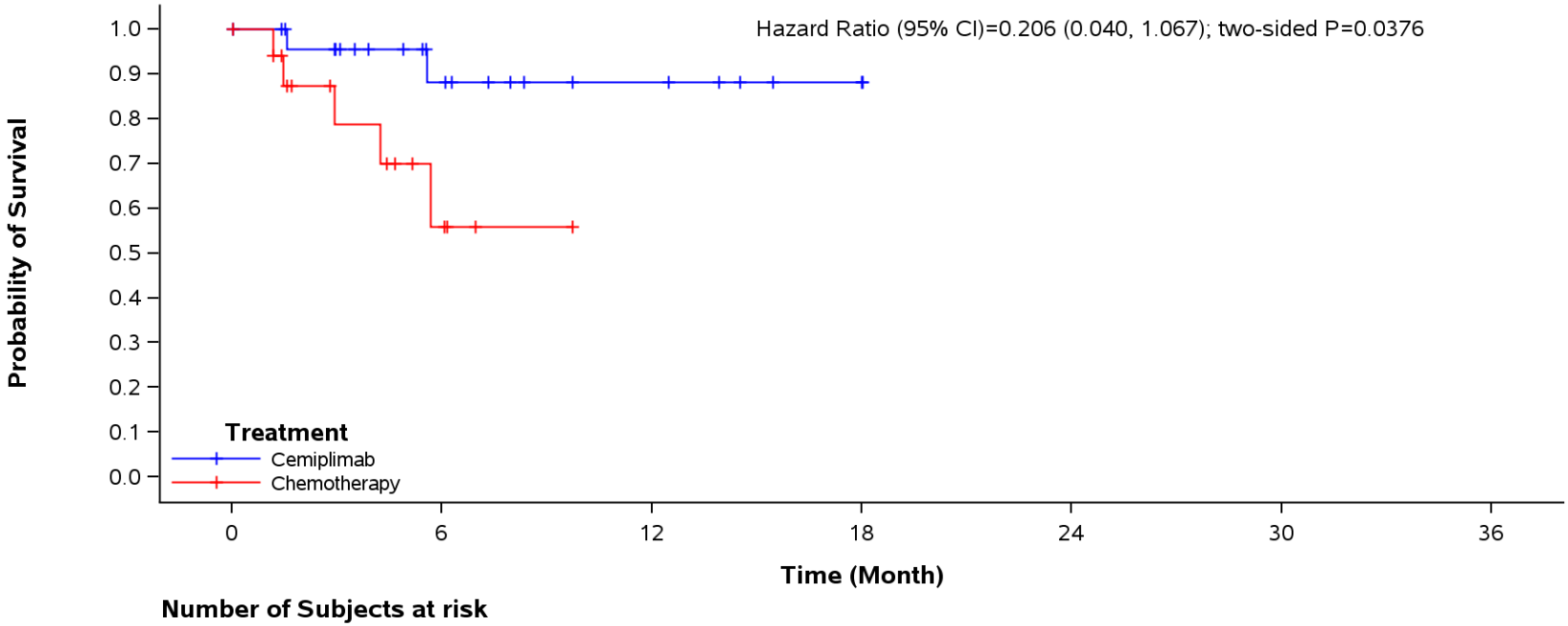
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

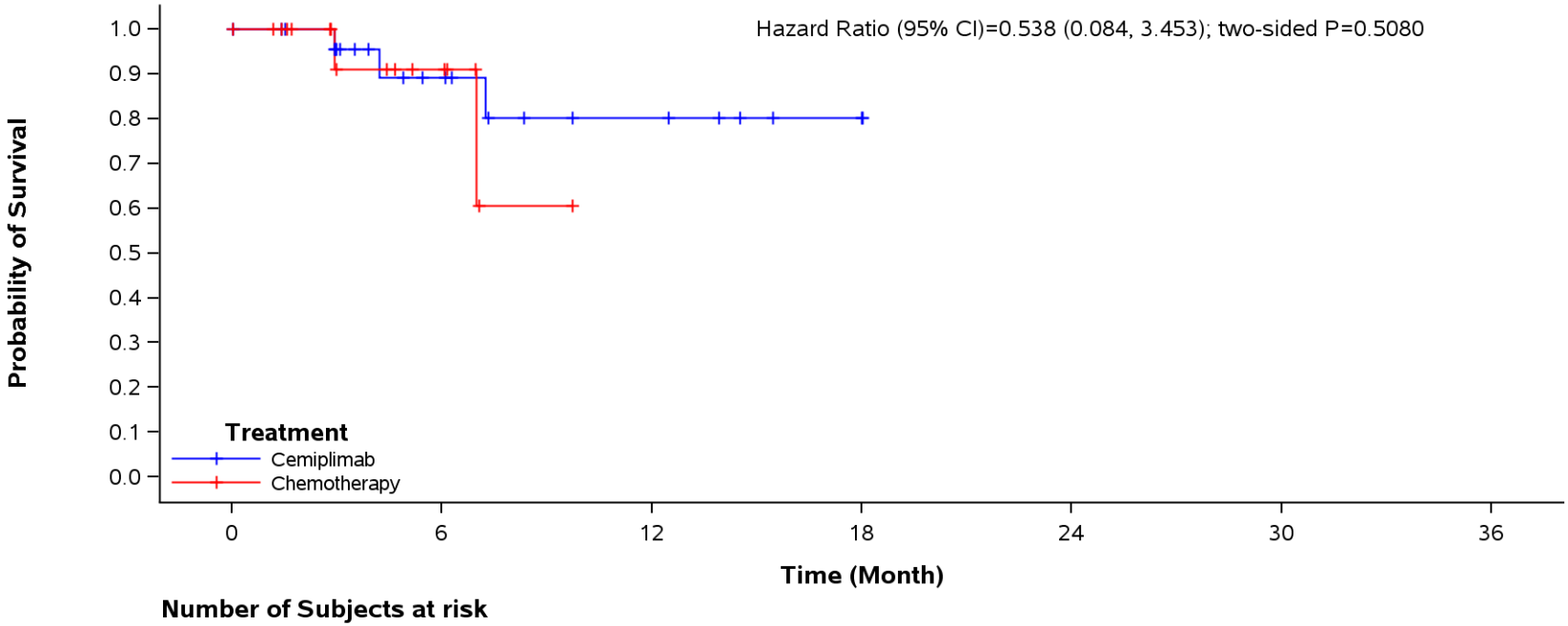
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Constipation - 10 pts sensitivity sustained deterioration



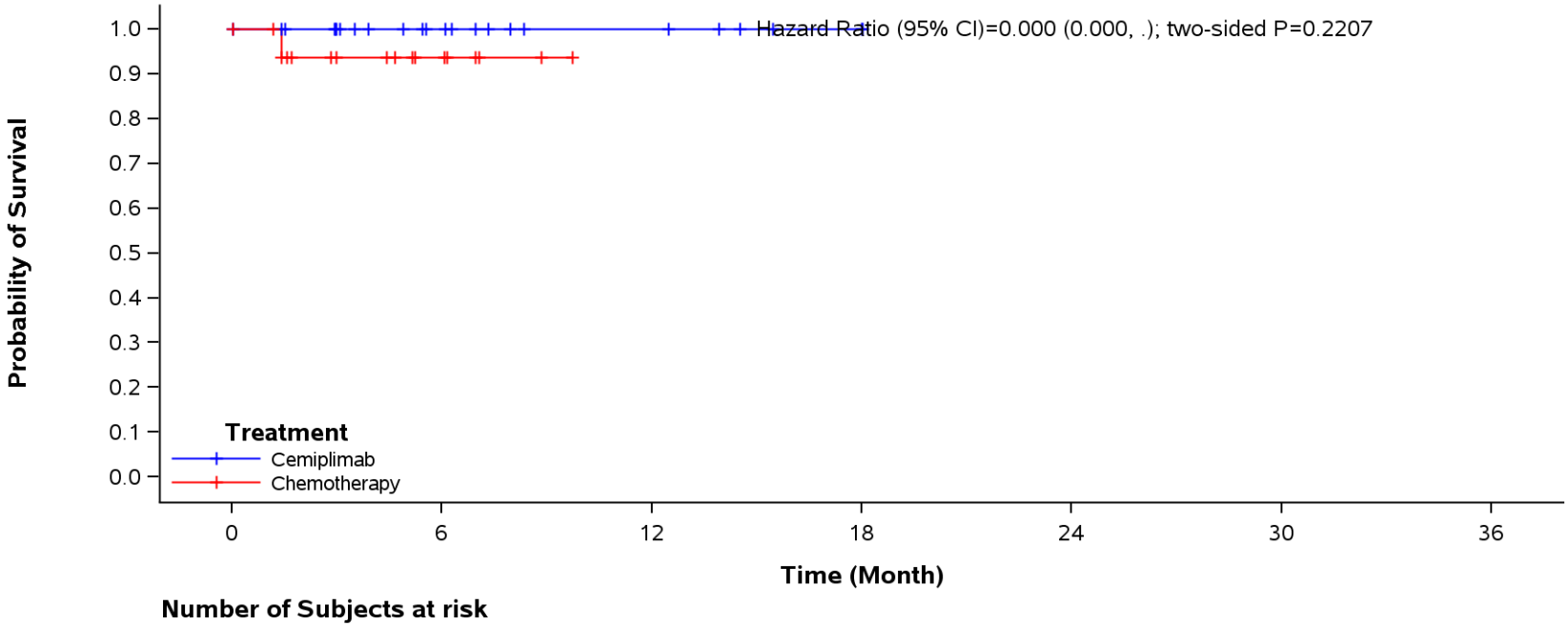

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Diarhoea - 10 pts sensitivity sustained deterioration



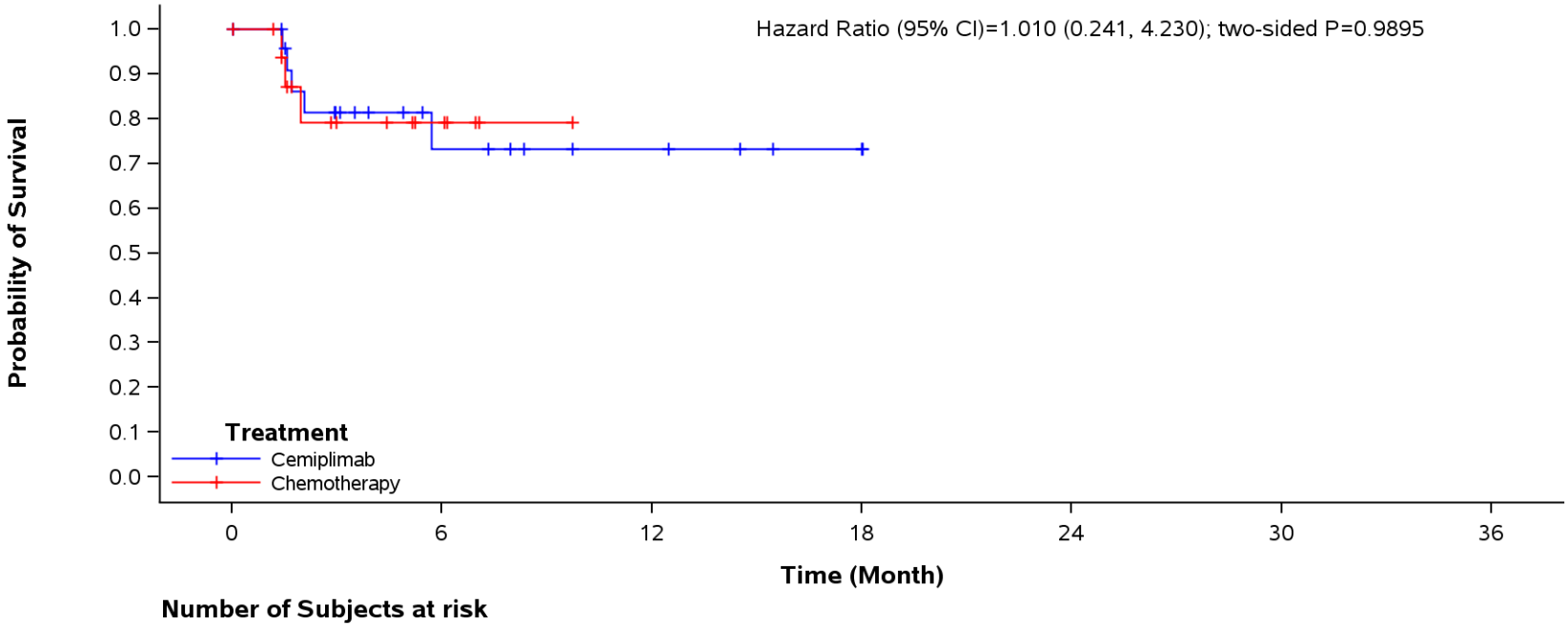

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Dyspnoea - 10 pts sensitivity sustained deterioration



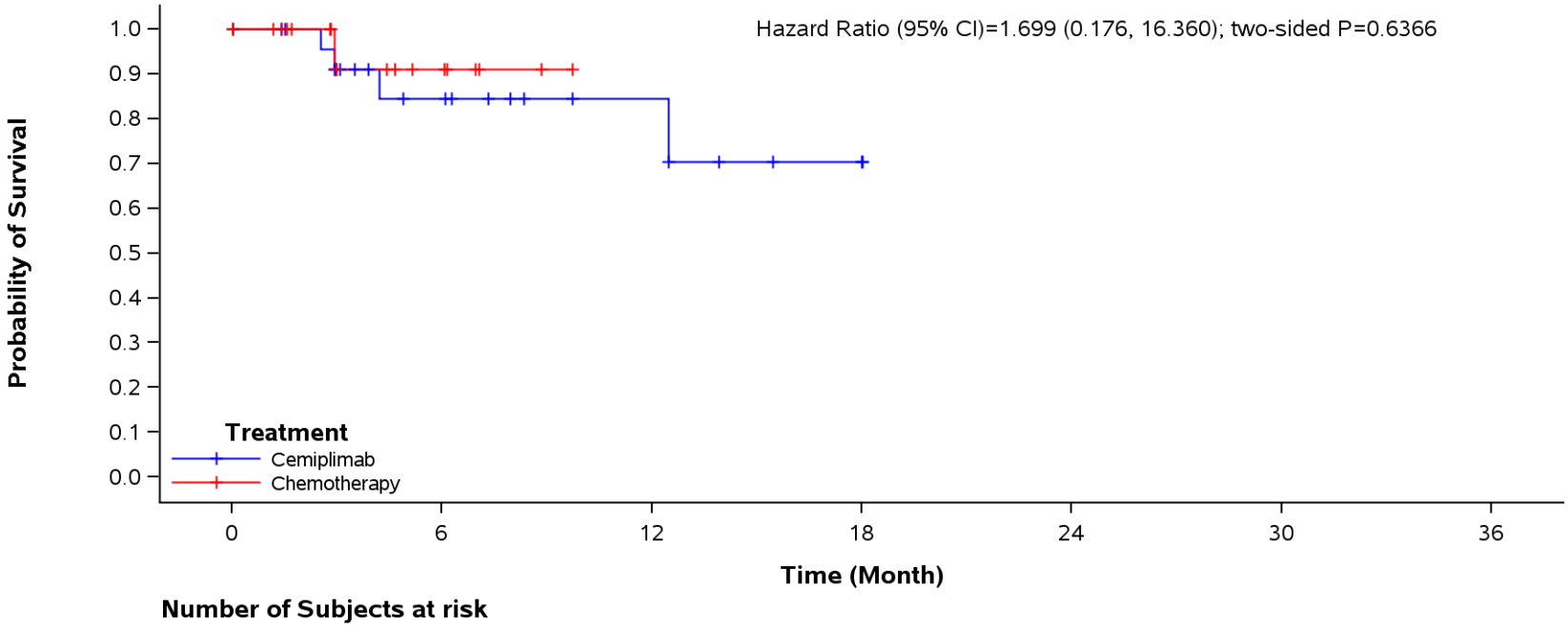

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 9 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Emotional Functioning - 10 pts sensitivity sustained deterioration



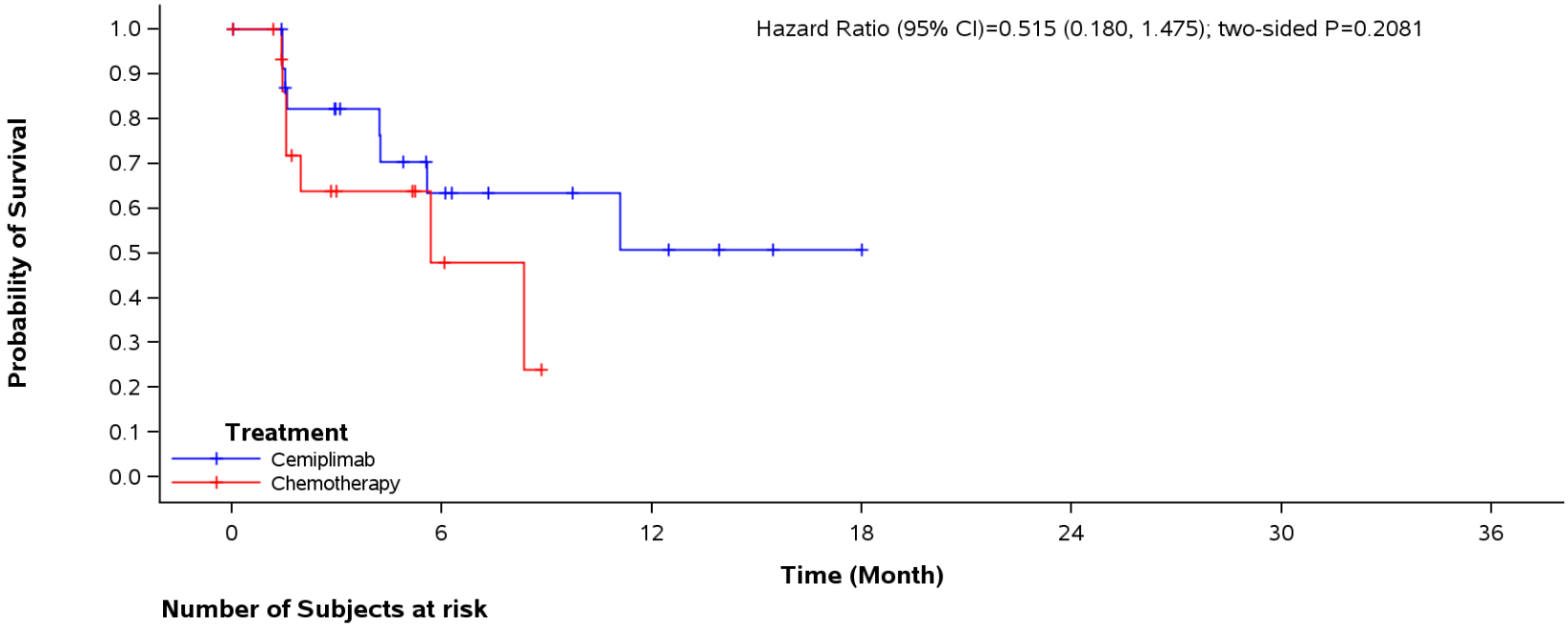

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Fatigue - 10 pts sensitivity sustained deterioration



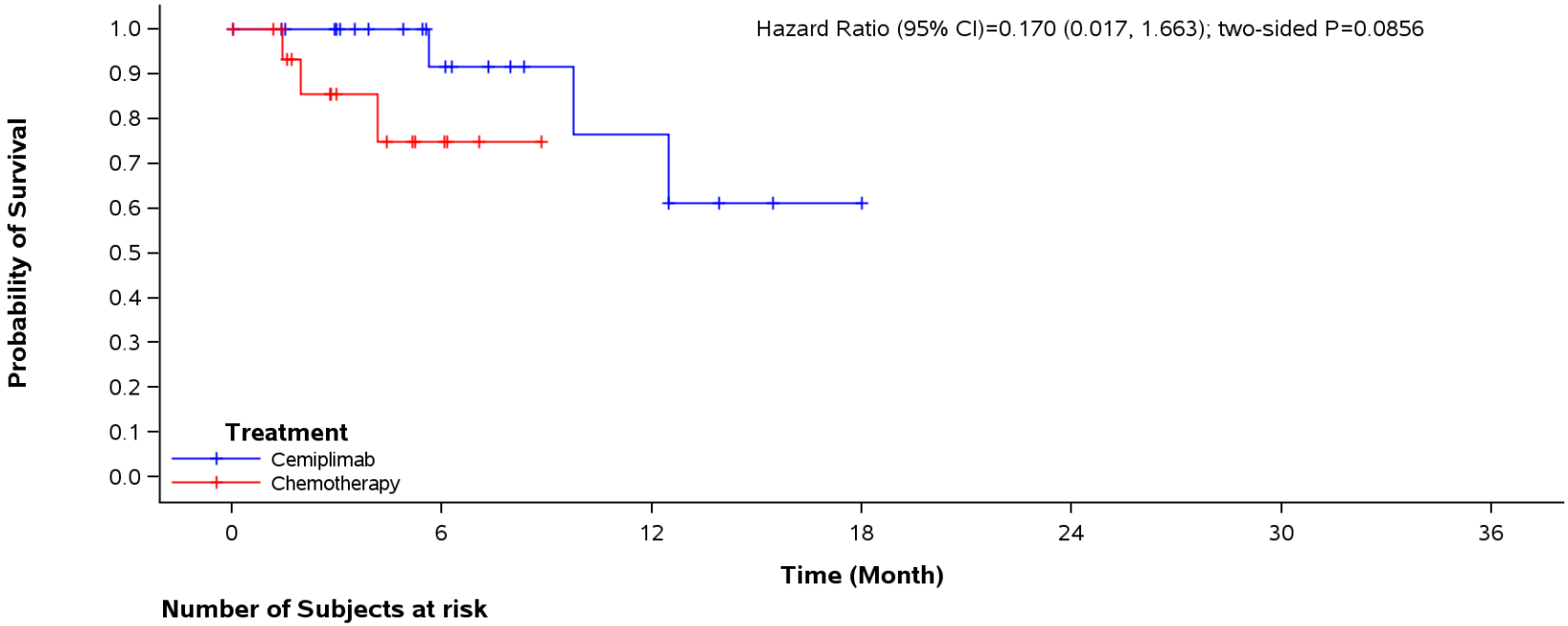

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 9 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Financial Problems - 10 pts sensitivity sustained deterioration



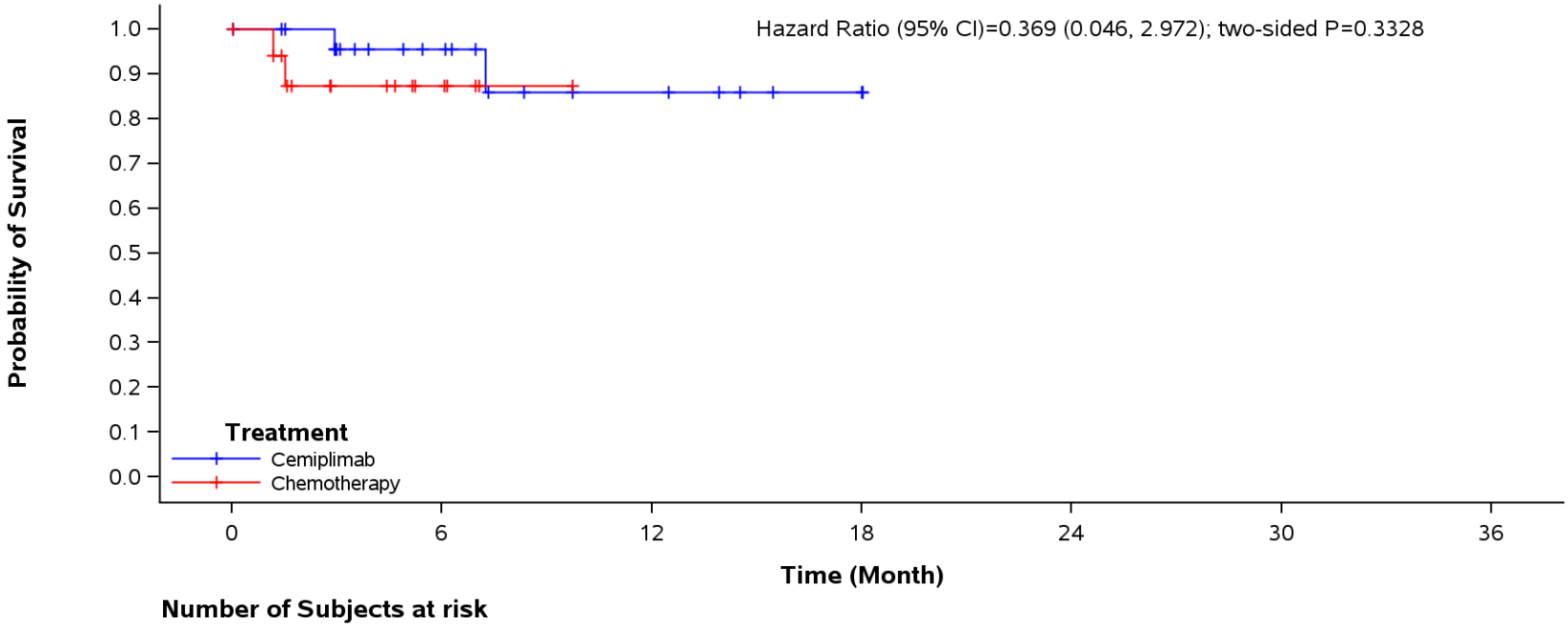

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



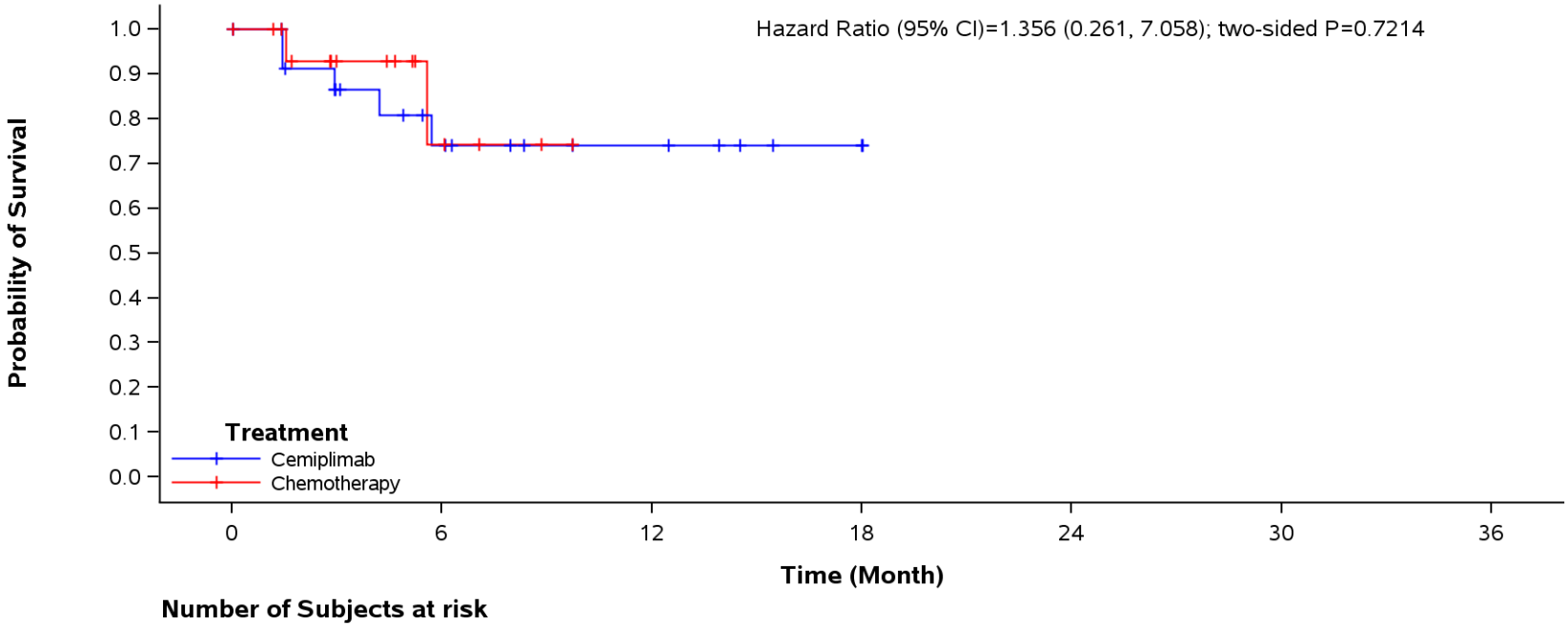

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 13 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Pain - 10 pts sensitivity sustained deterioration



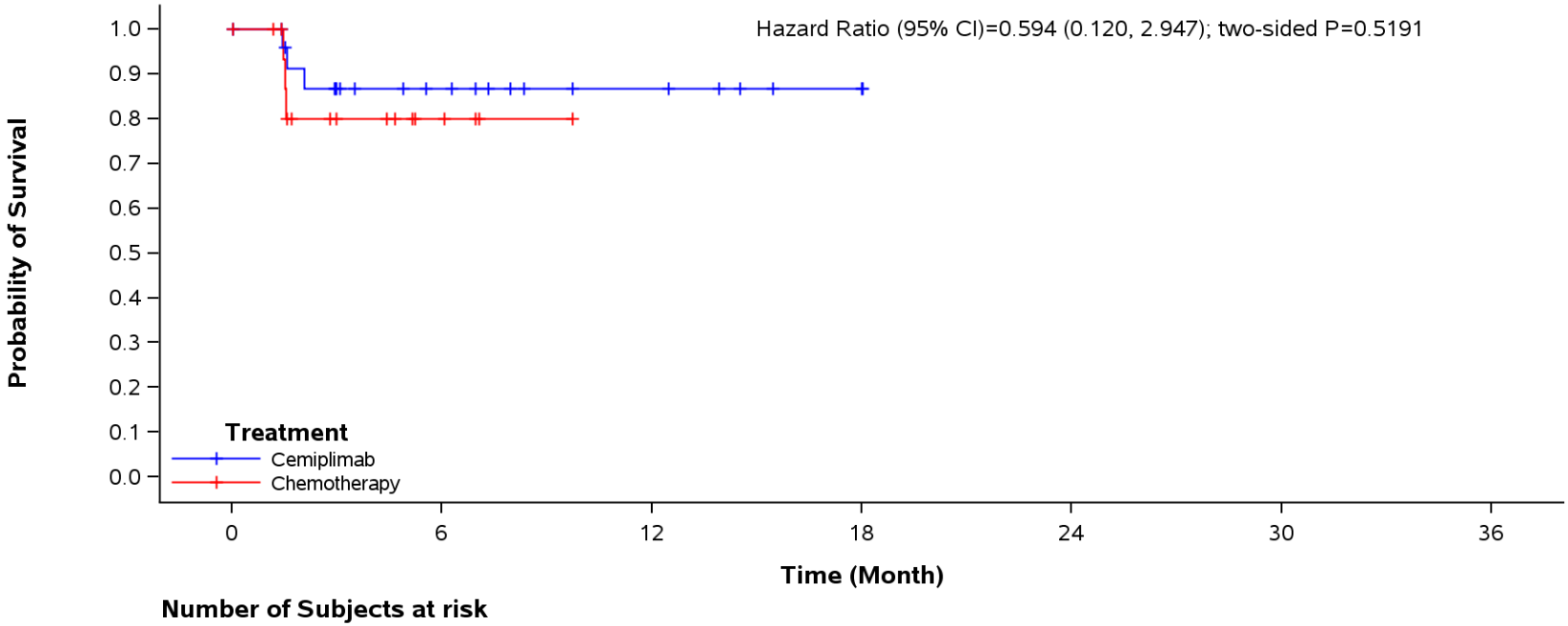

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

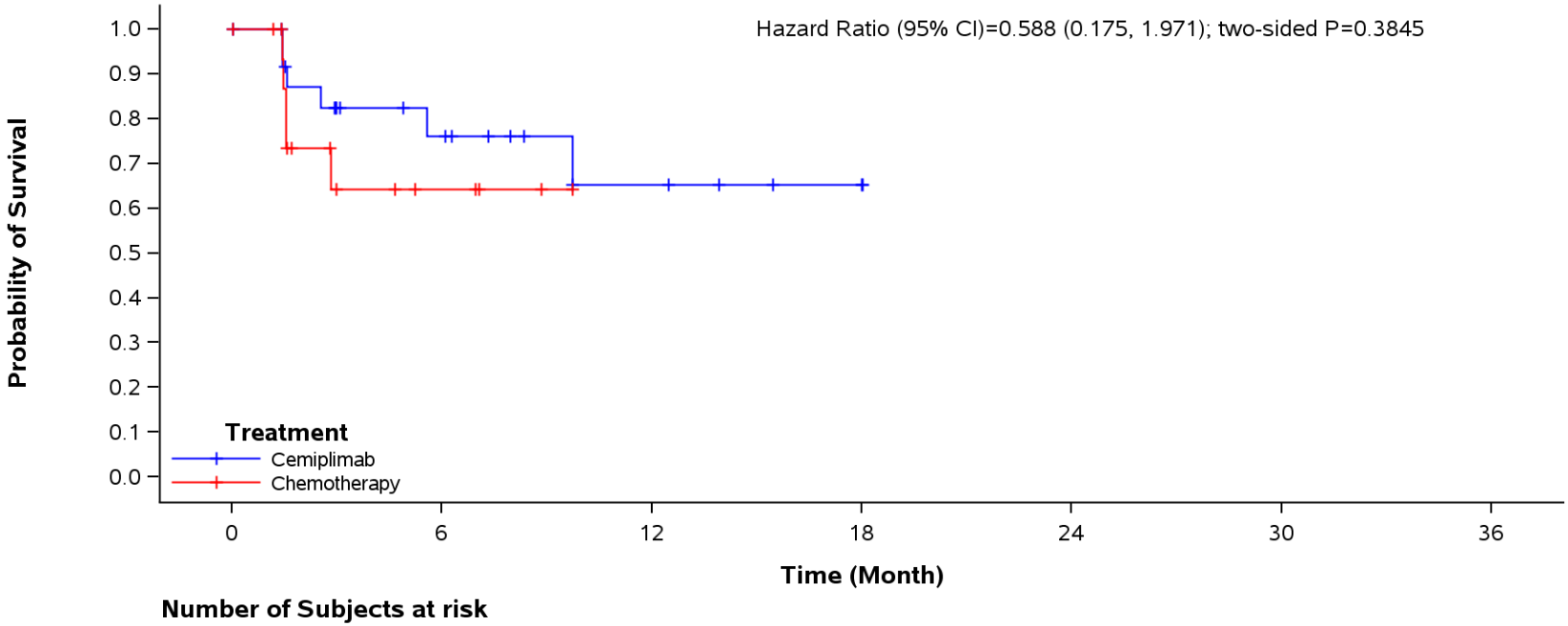
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

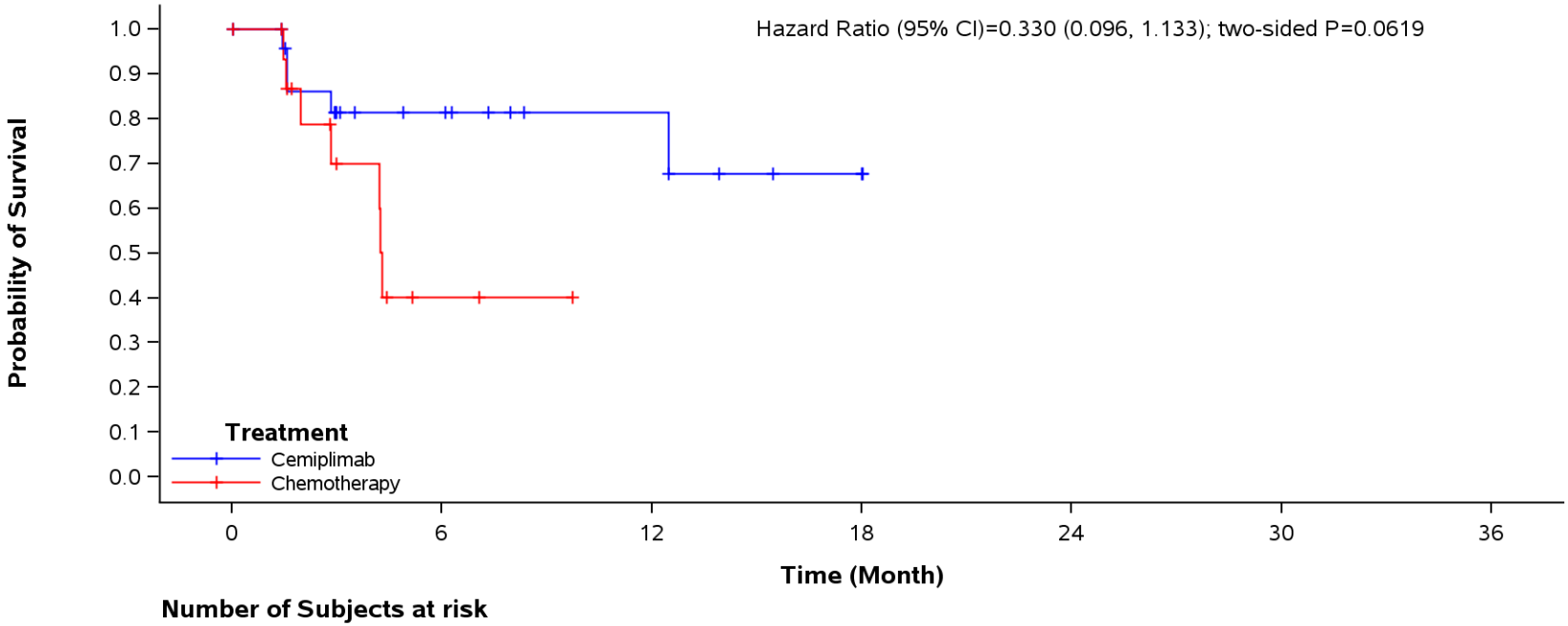
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Role Functioning - 10 pts sensitivity sustained deterioration



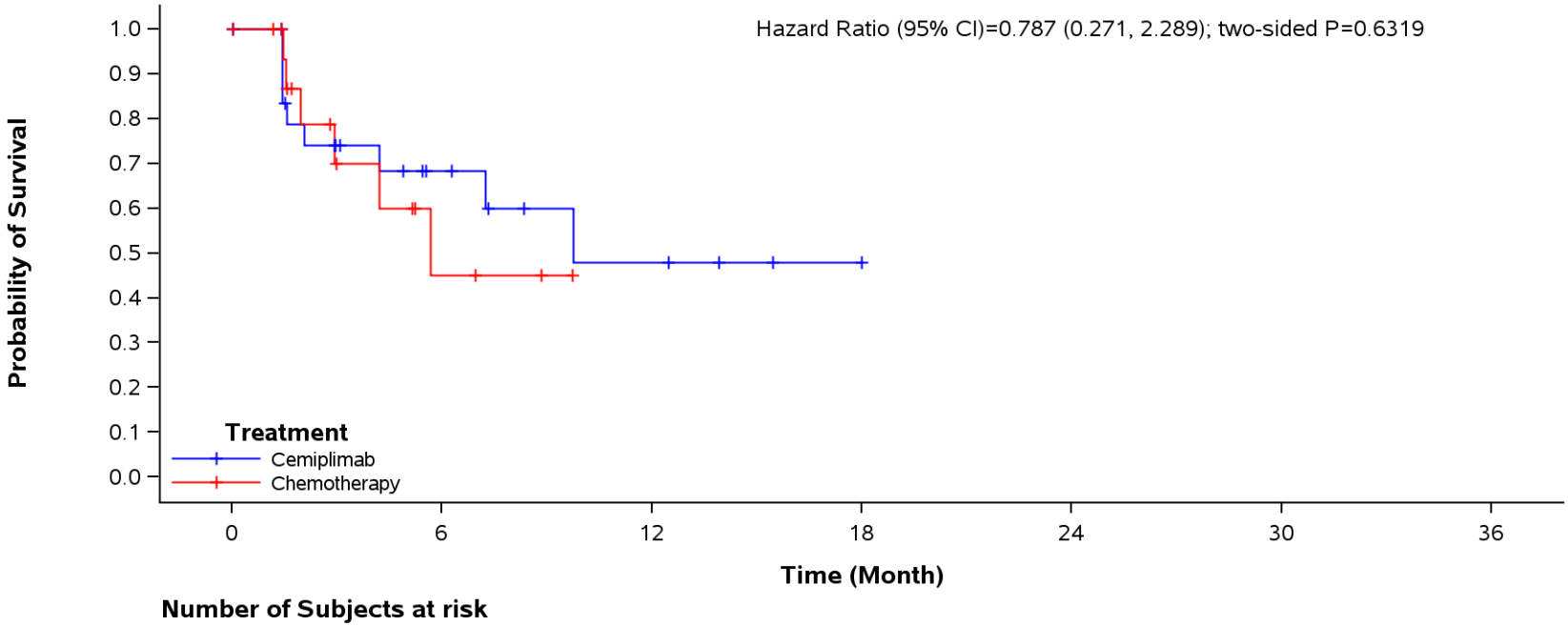

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Social Functioning - 10 pts sensitivity sustained deterioration



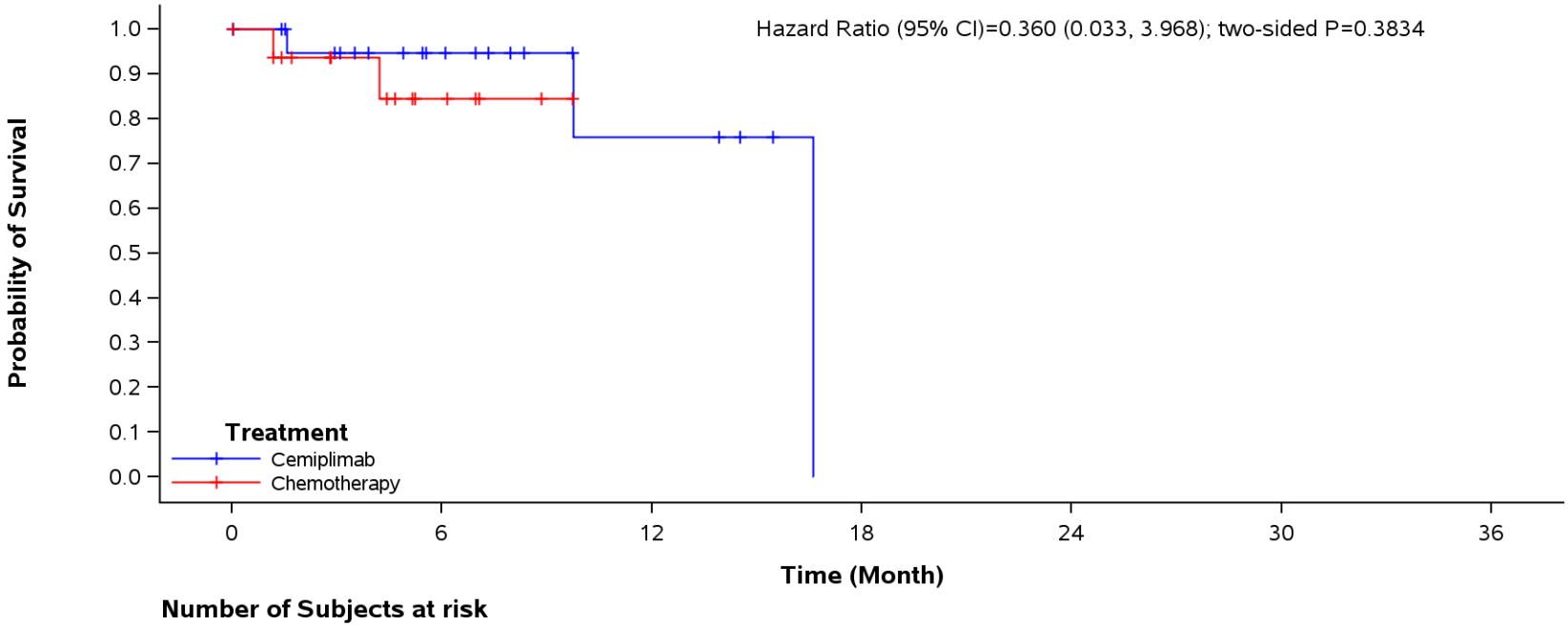

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 9 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Insomnia - 10 pts sensitivity sustained deterioration



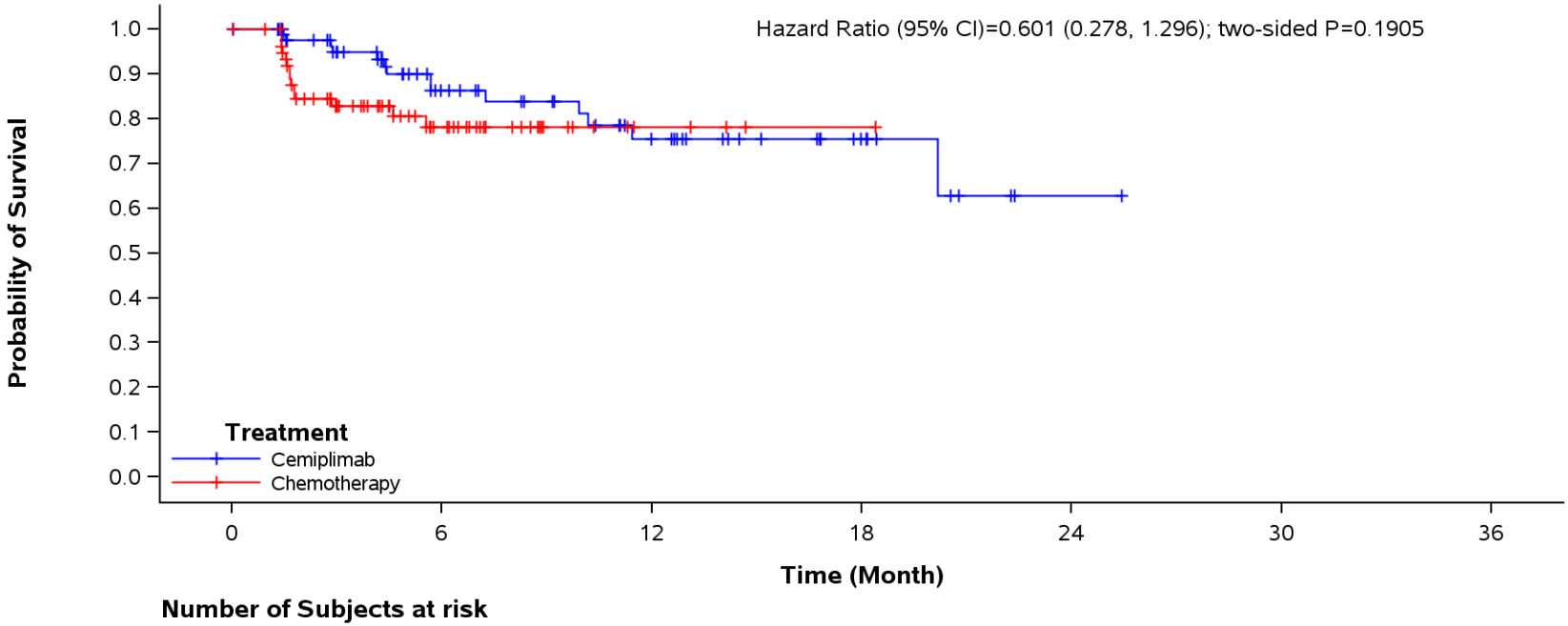

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Appetite loss - 10 pts sensitivity sustained deterioration



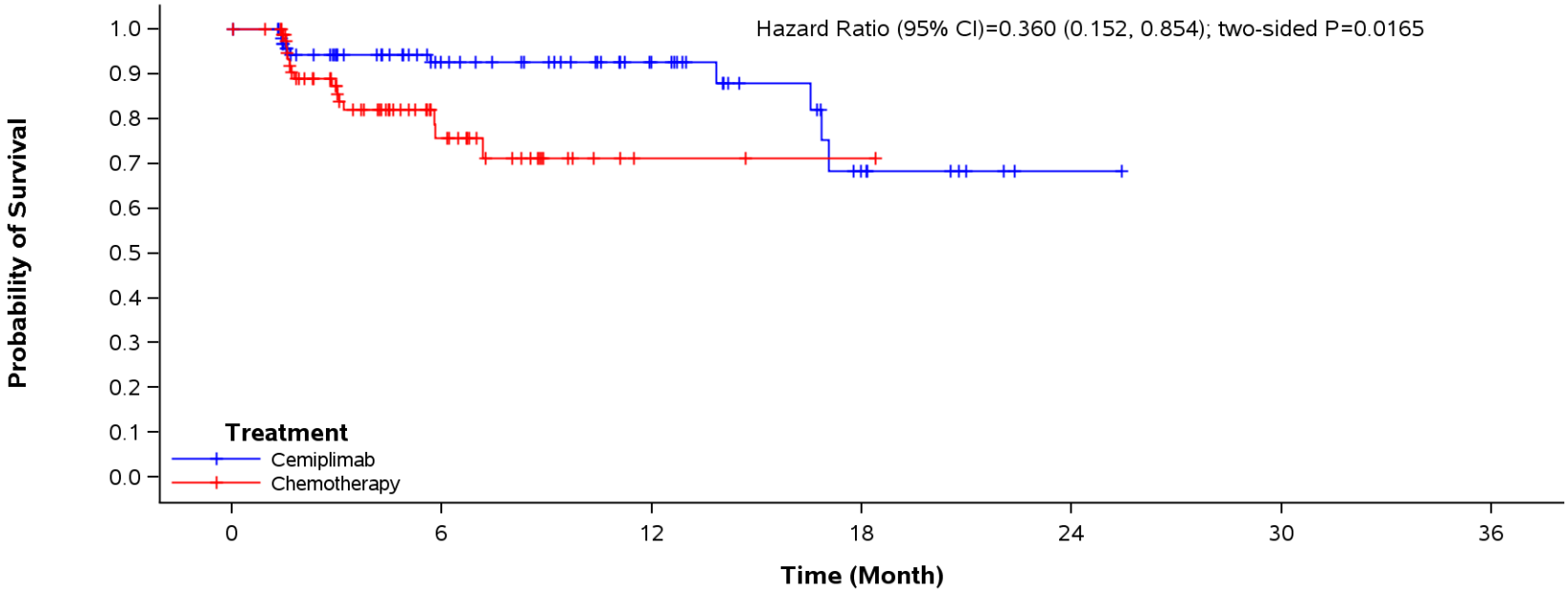

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 42 | 23 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Cognitive Functioning - 10 pts sensitivity sustained deterioration



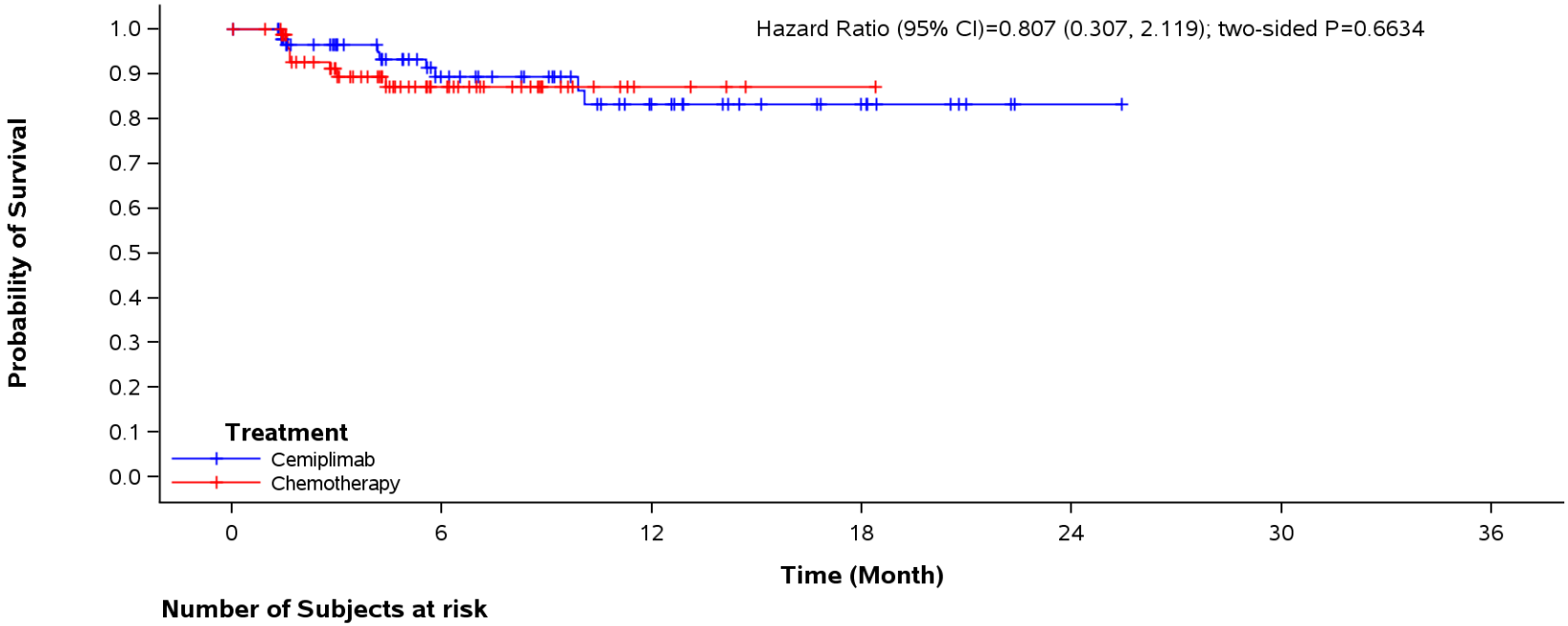

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 47 | 25 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 24 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Constipation - 10 pts sensitivity sustained deterioration



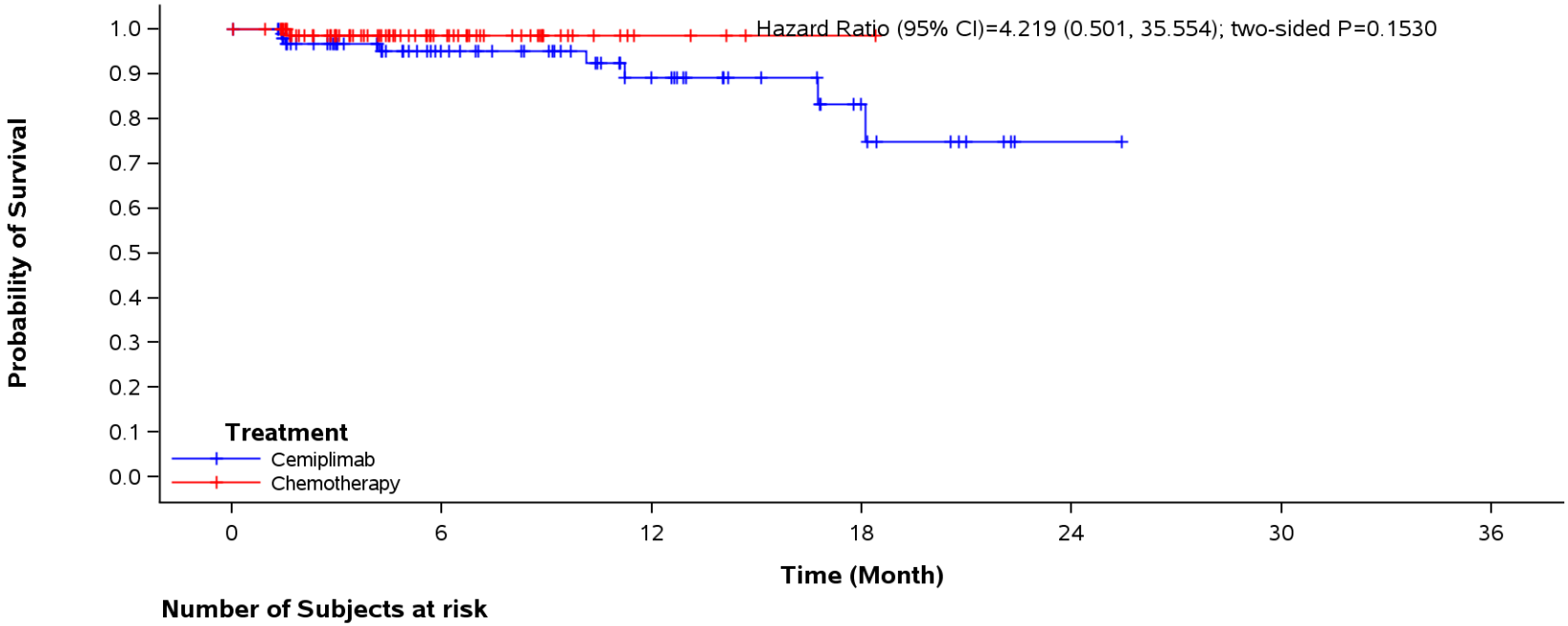

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 43 | 20 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 27 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Diarhoea - 10 pts sensitivity sustained deterioration



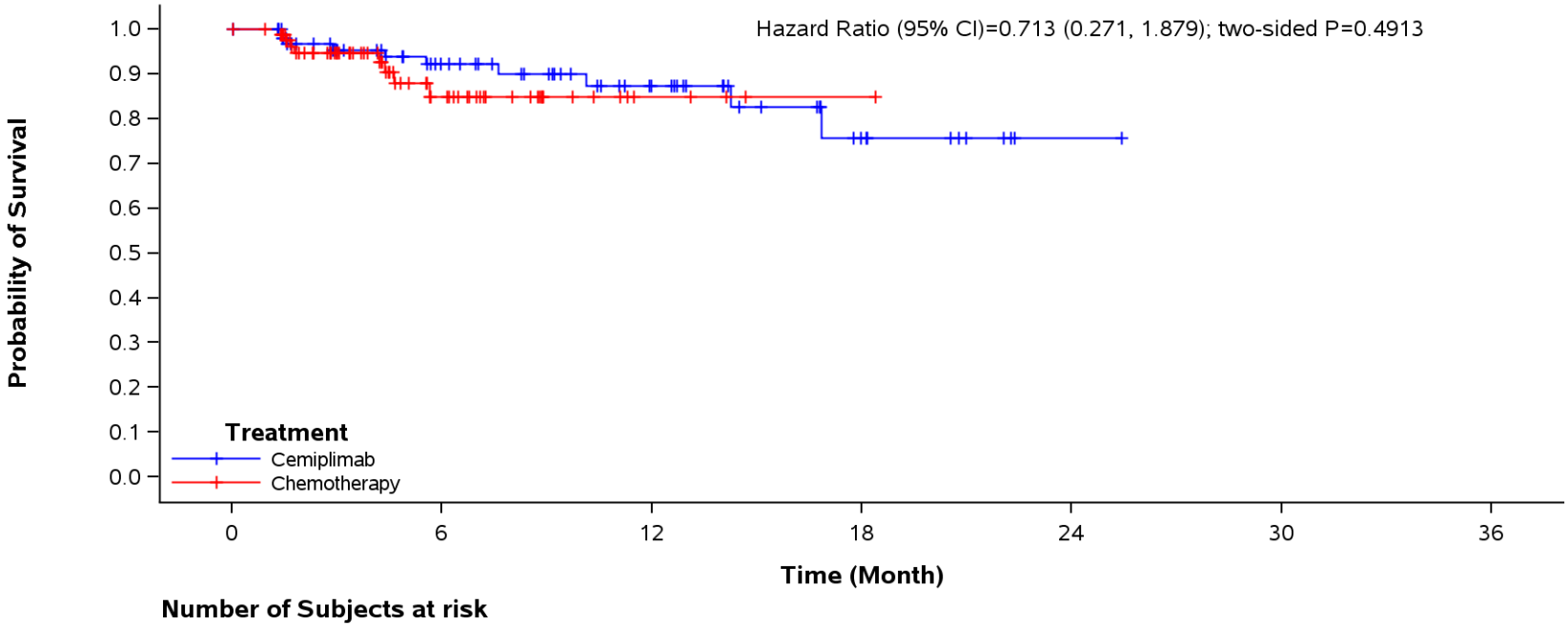

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 49 | 25 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 30 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Dyspnoea - 10 pts sensitivity sustained deterioration



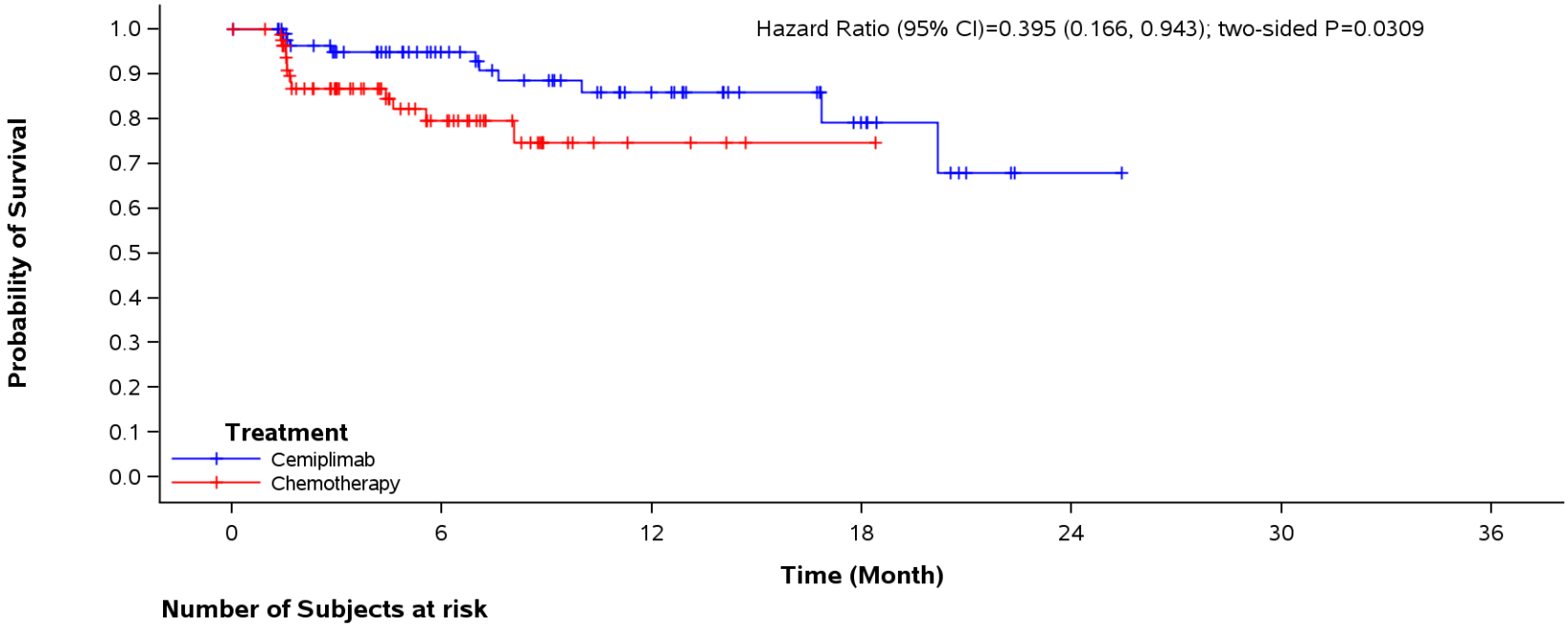

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 50 | 26 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Emotional Functioning - 10 pts sensitivity sustained deterioration



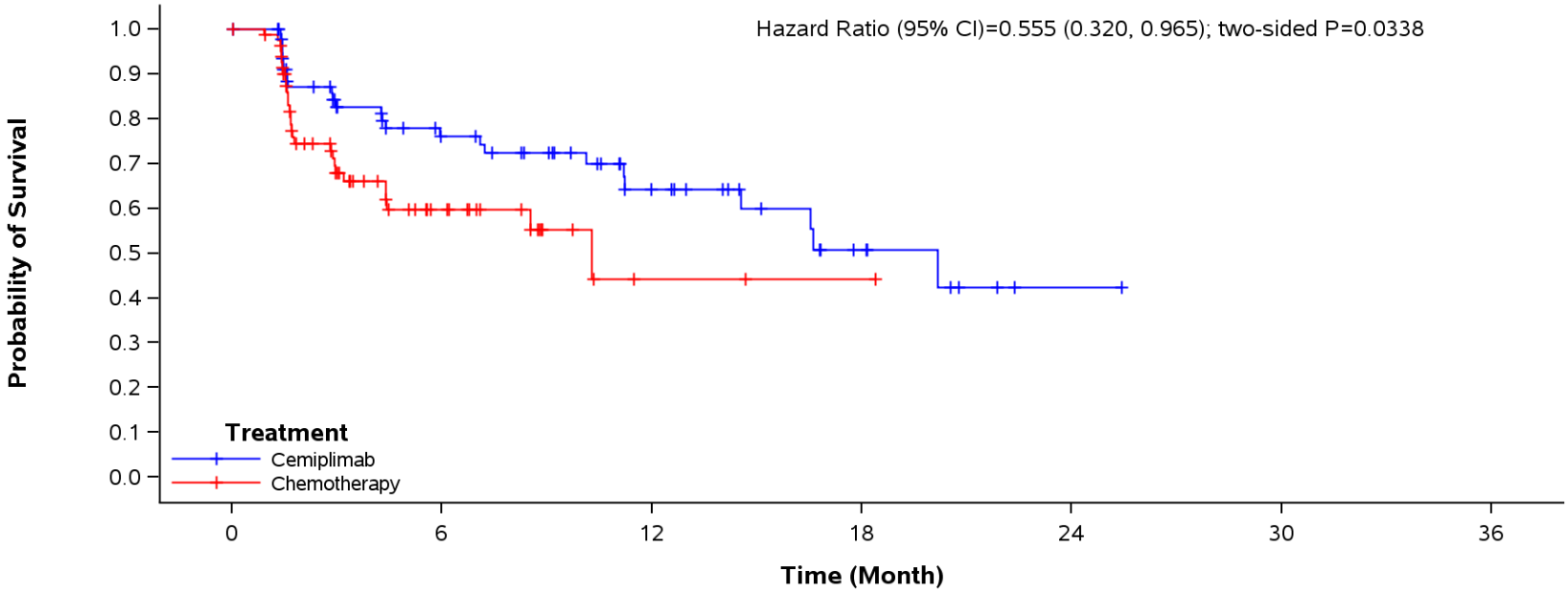

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 49 | 25 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 27 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Fatigue - 10 pts sensitivity sustained deterioration



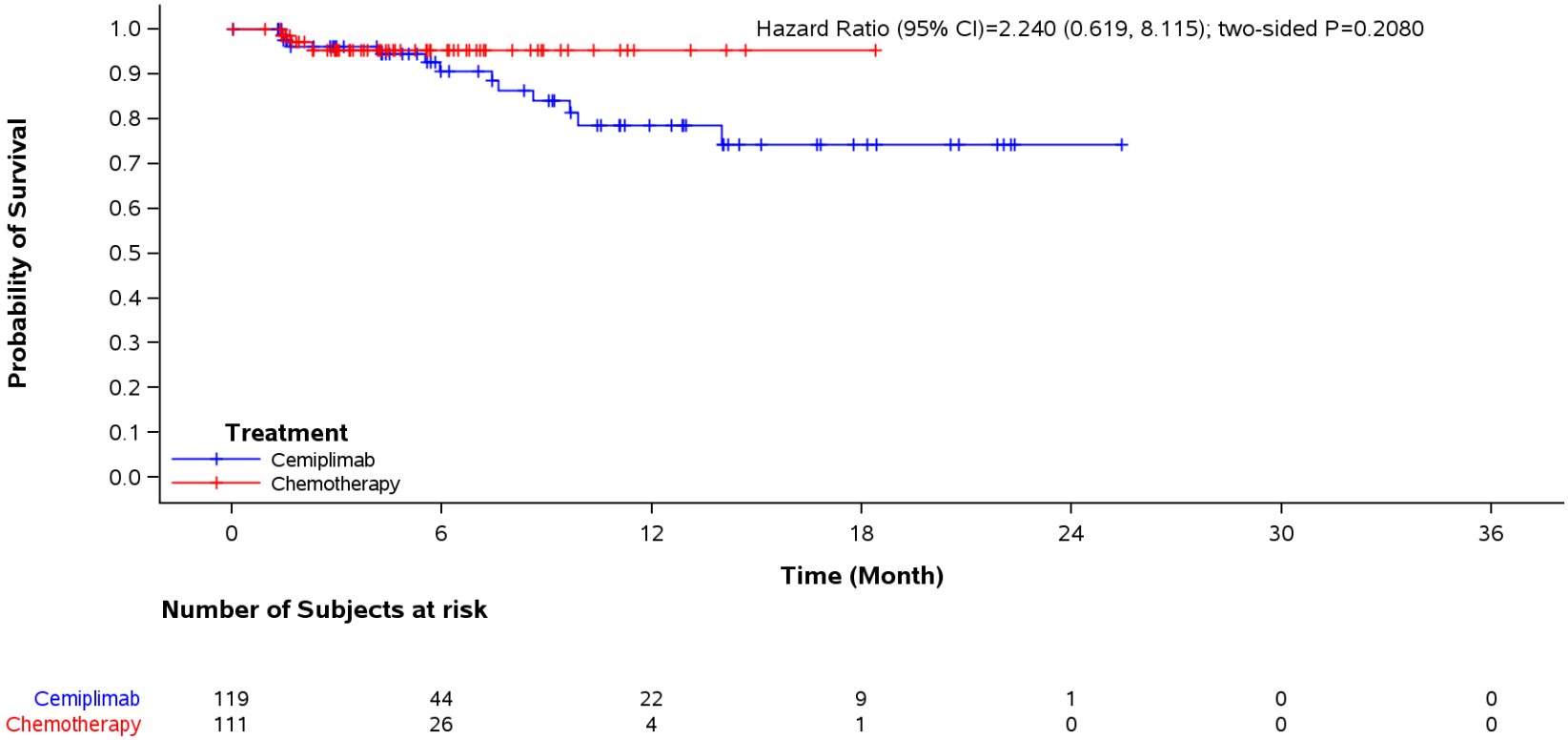

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 42 | 21 | 8 | 1 | 0 | 0 |
| Chemotherapy | 111 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Financial Problems - 10 pts sensitivity sustained deterioration



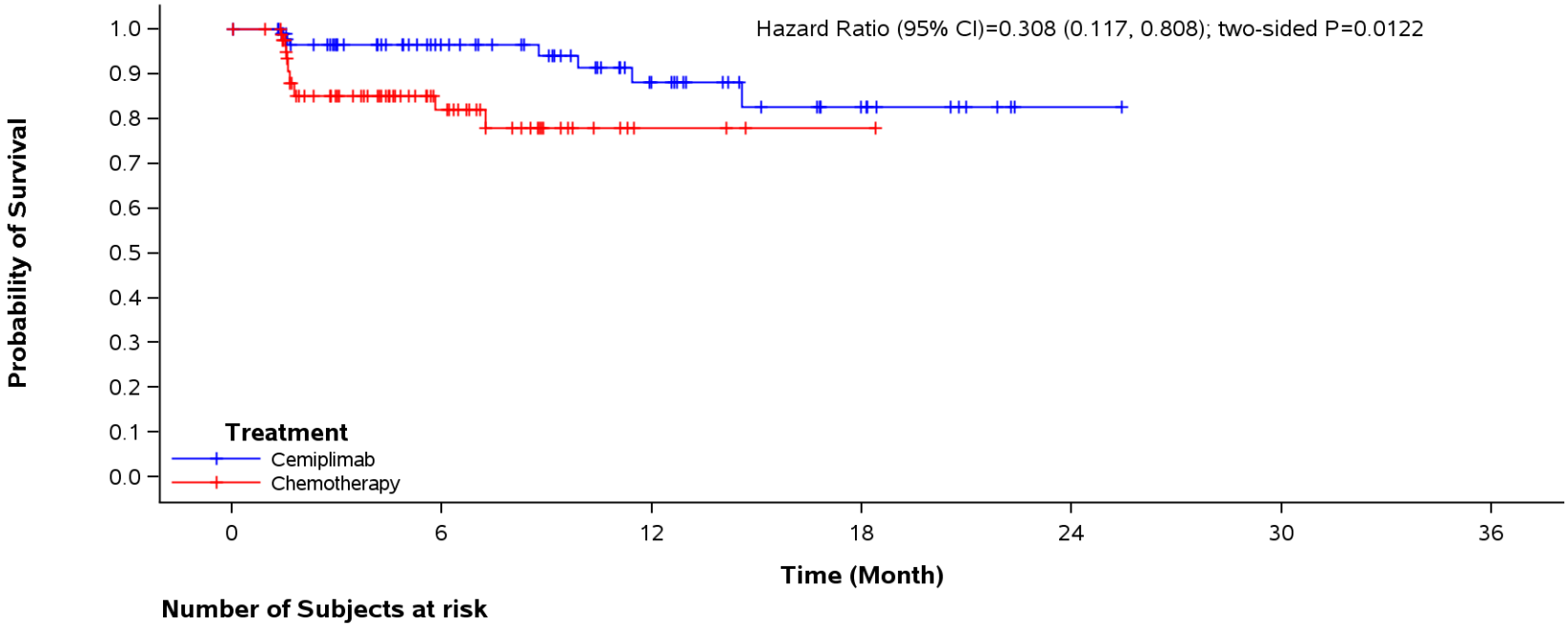

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 44 | 22 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



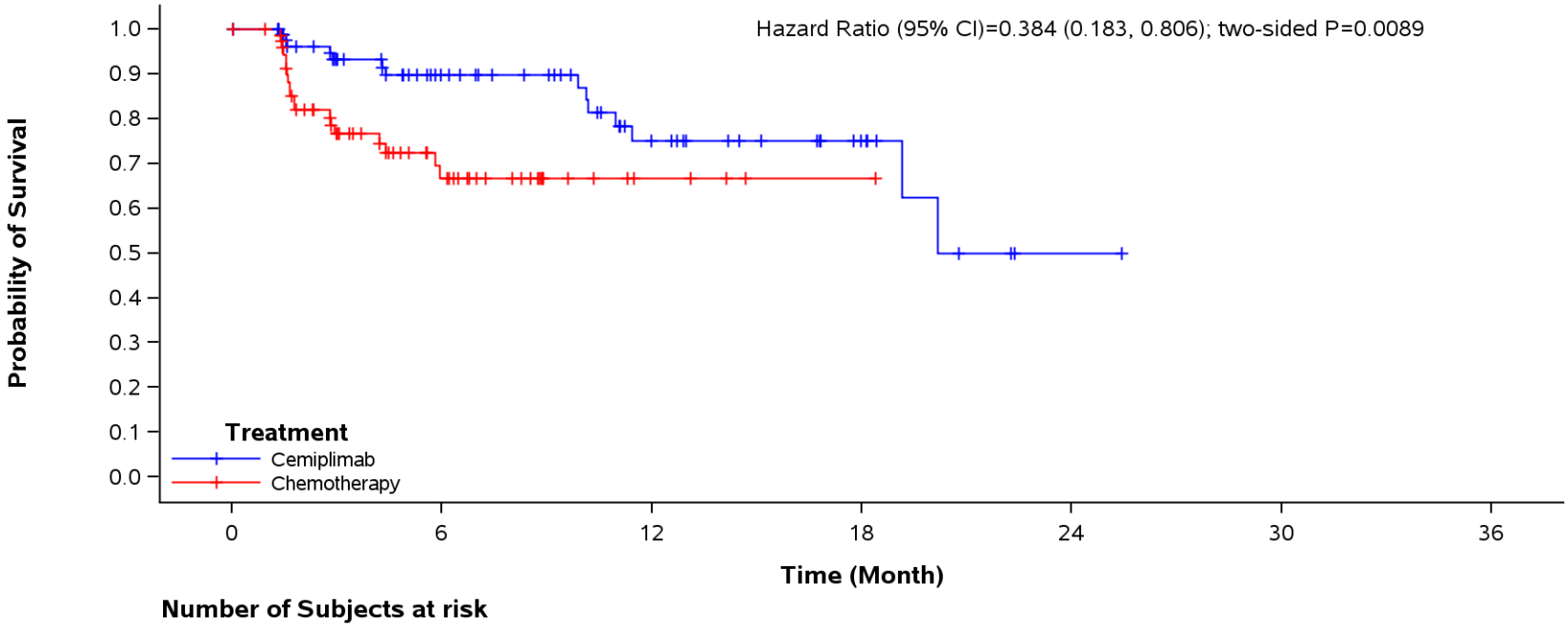

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 50 | 24 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 28 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Pain - 10 pts sensitivity sustained deterioration



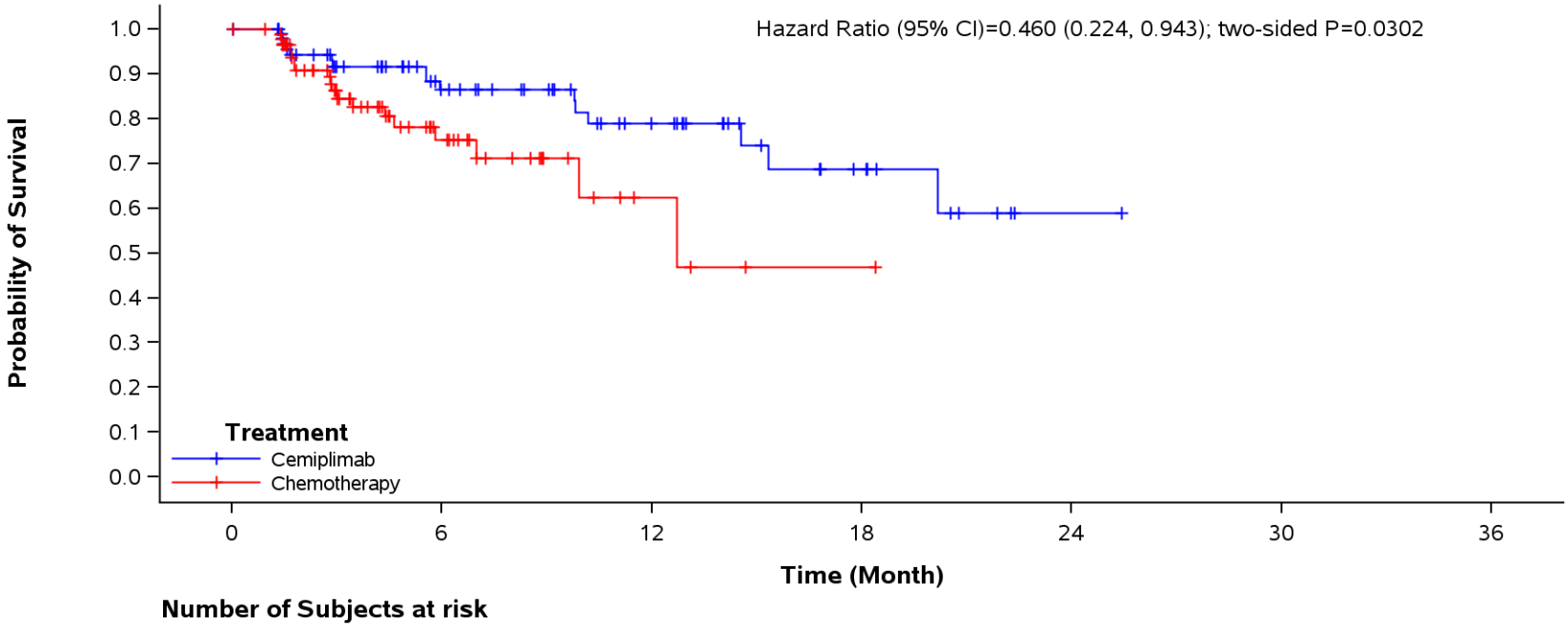

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 43 | 21 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 24 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

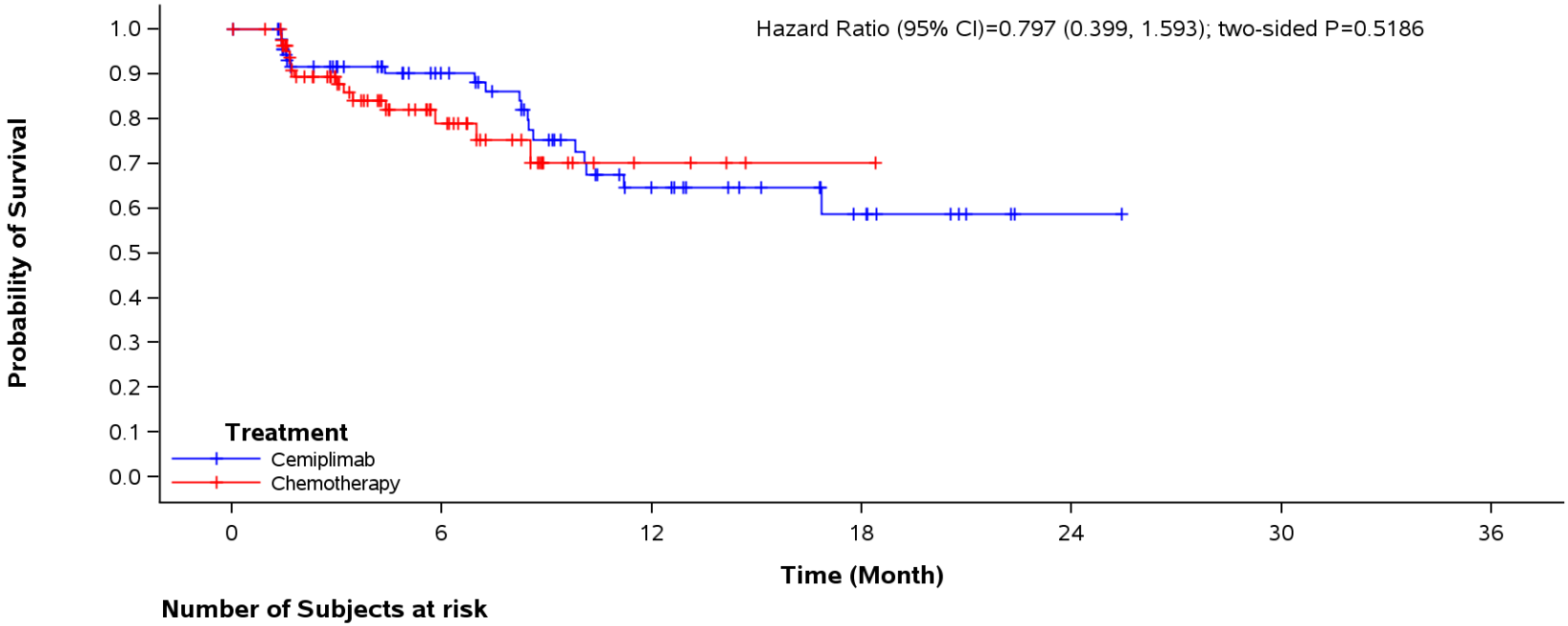
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 48 | 25 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 25 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

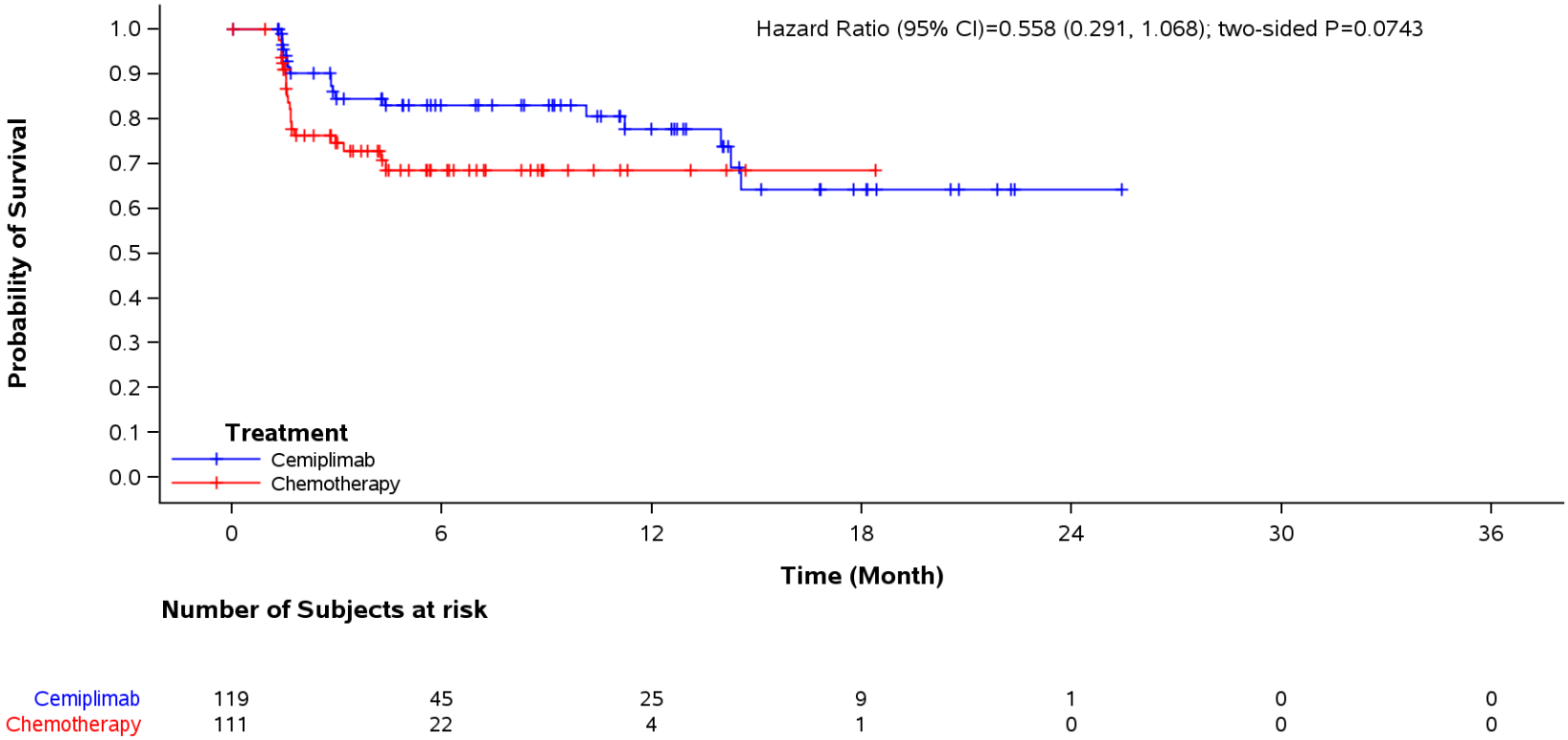
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 48 | 20 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 27 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Role Functioning - 10 pts sensitivity sustained deterioration



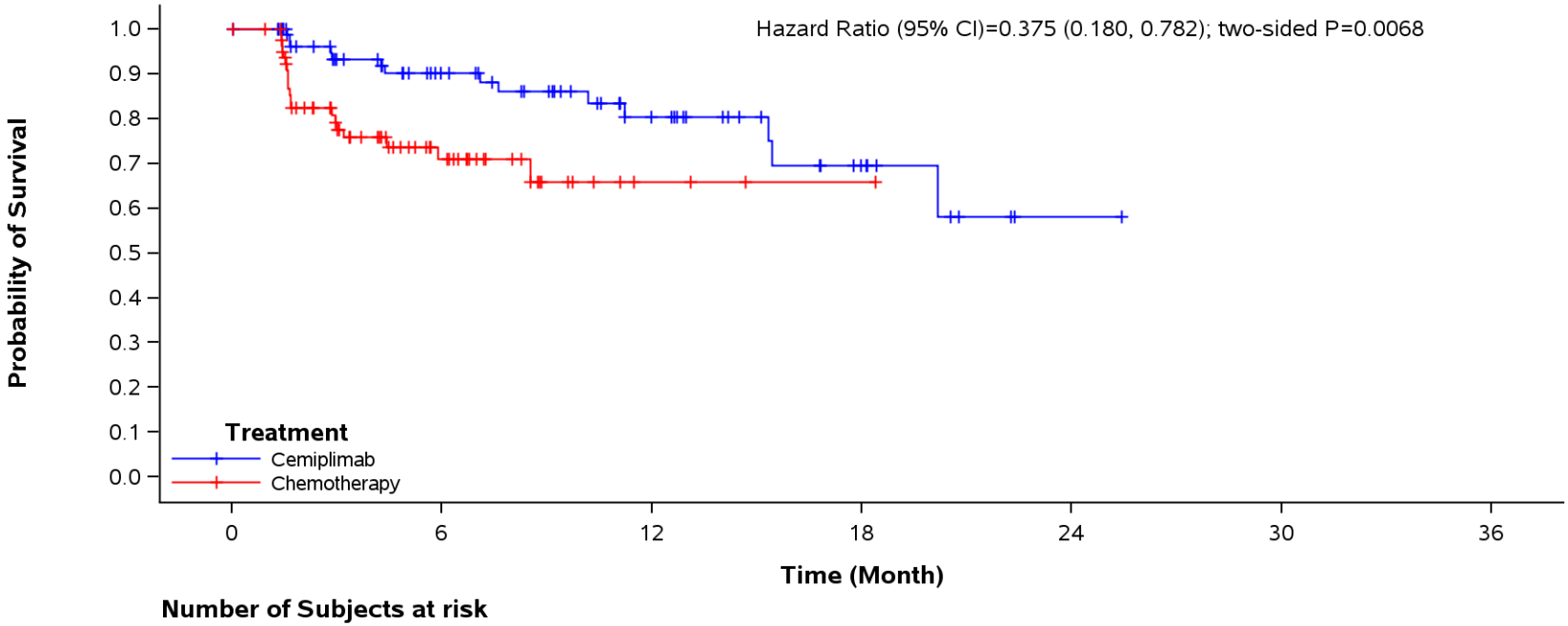

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 45 | 25 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 22 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Social Functioning - 10 pts sensitivity sustained deterioration



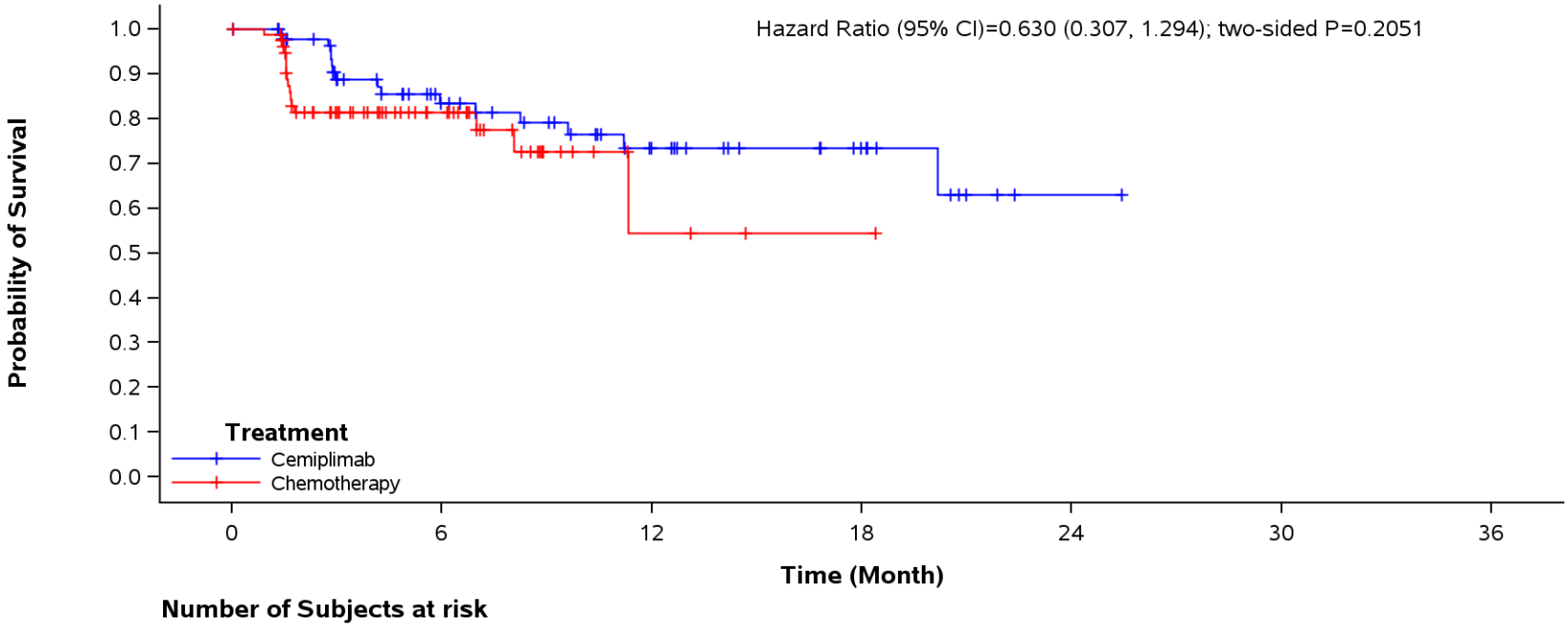

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 48 | 24 | 9 | 1 | 0 | 0 |
| Chemotherapy | 111 | 26 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Insomnia - 10 pts sensitivity sustained deterioration



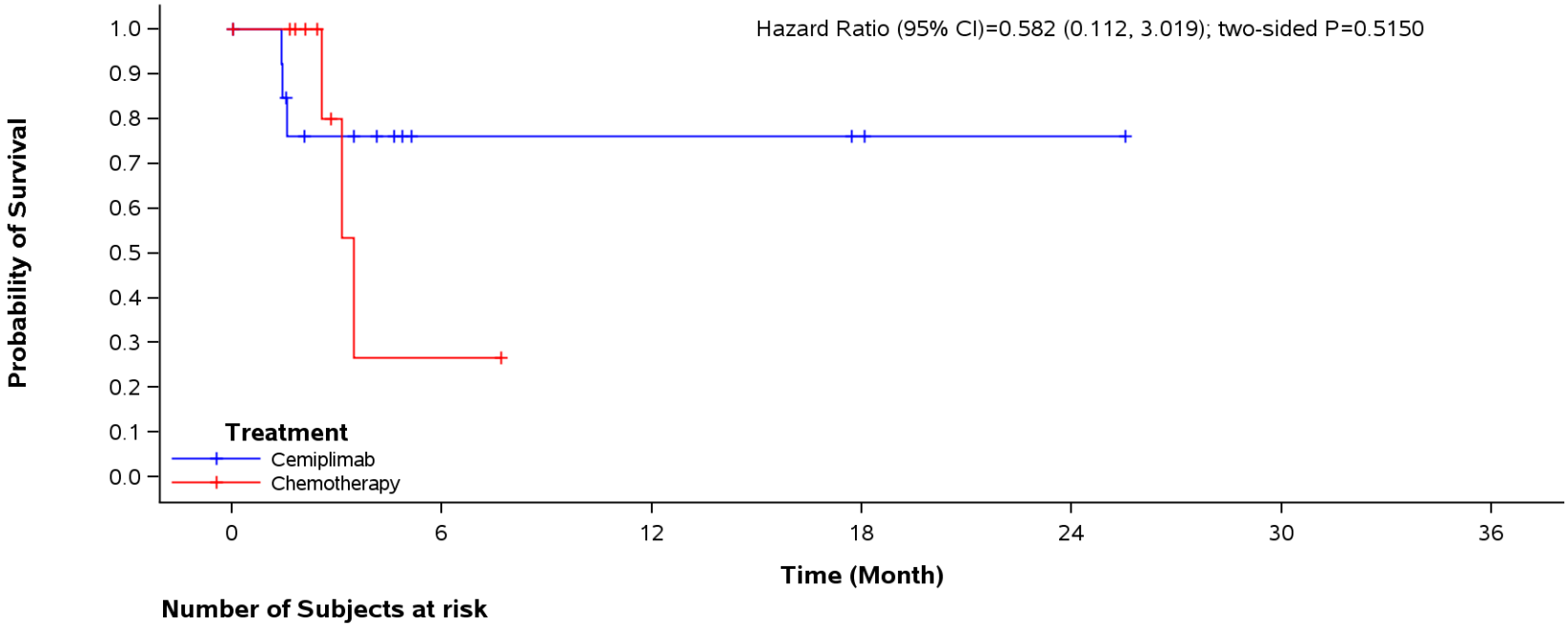

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 42 | 21 | 10 | 1 | 0 | 0 |
| Chemotherapy | 111 | 28 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Appetite loss - 10 pts sensitivity sustained deterioration



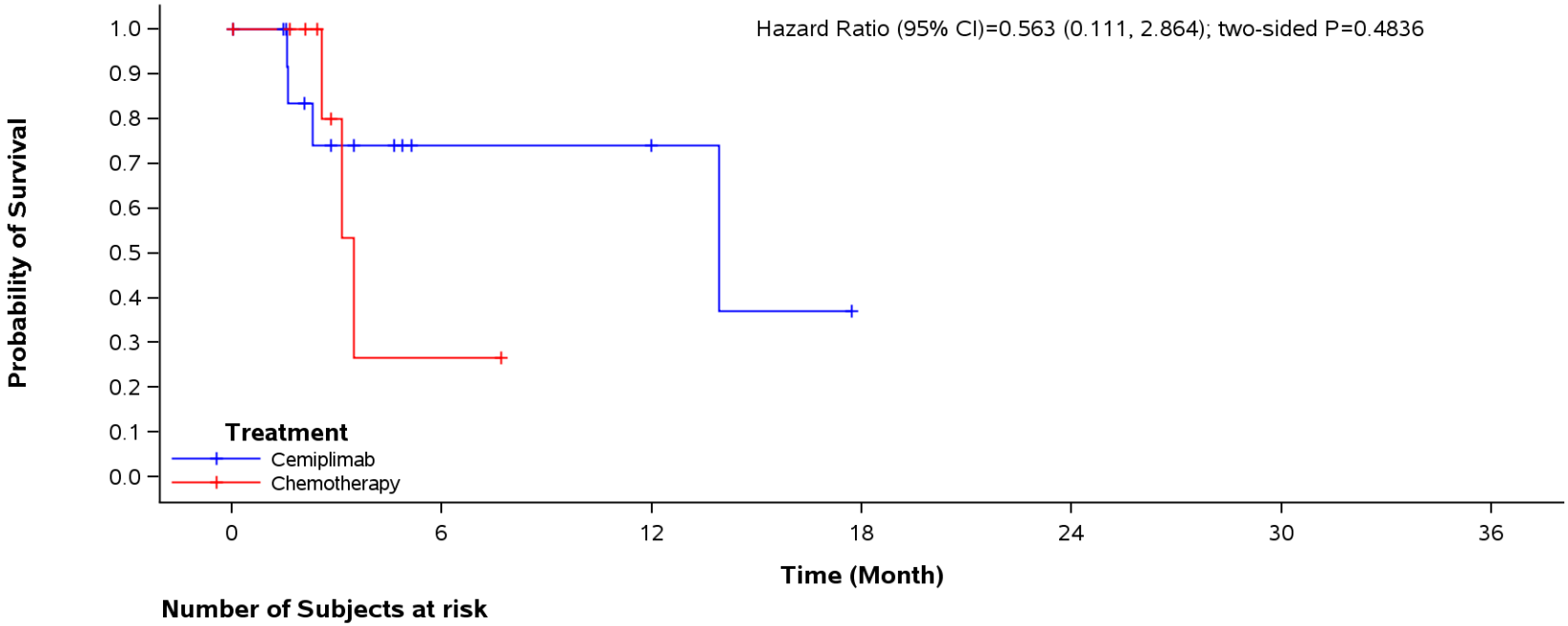

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Cognitive Functioning - 10 pts sensitivity sustained deterioration



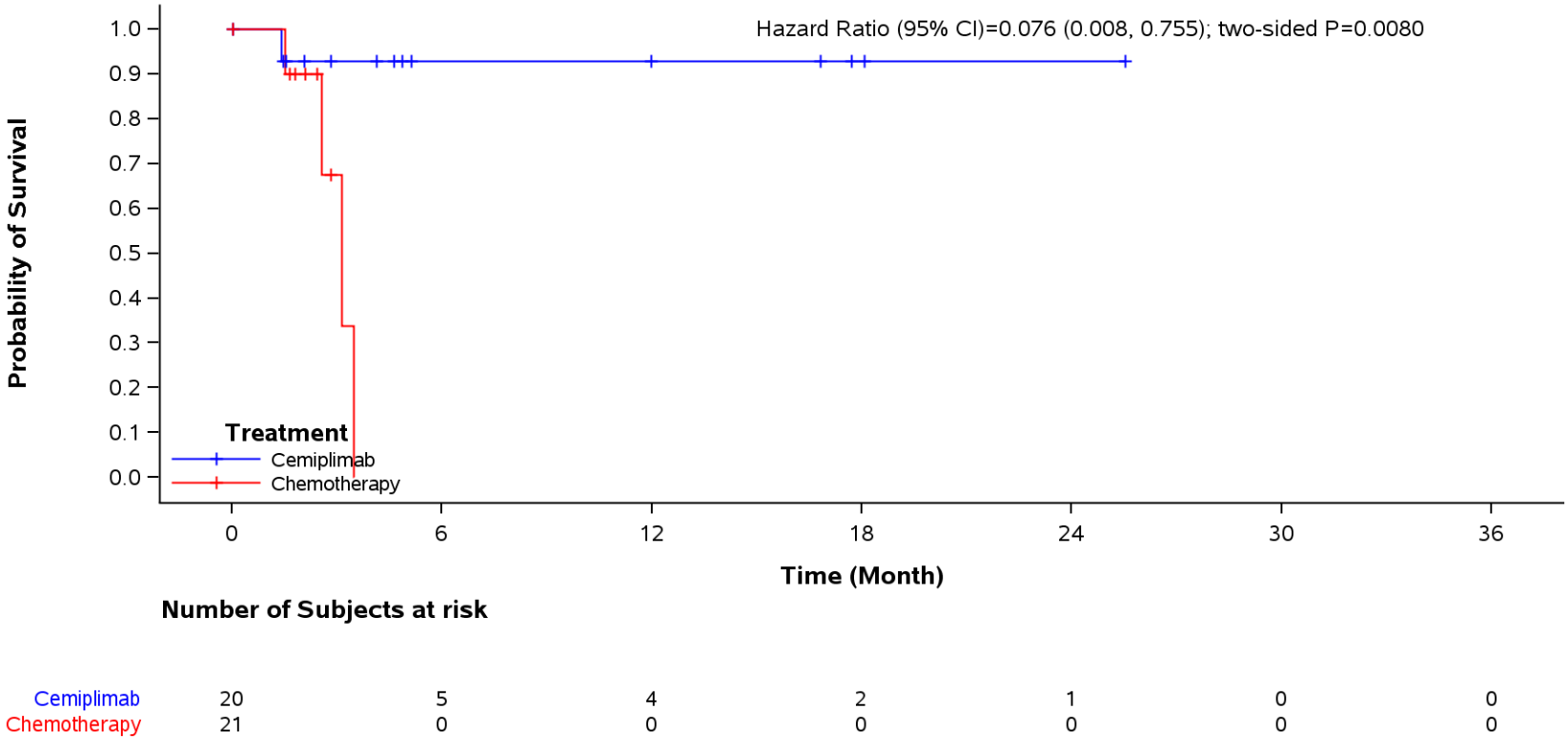

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Constipation - 10 pts sensitivity sustained deterioration



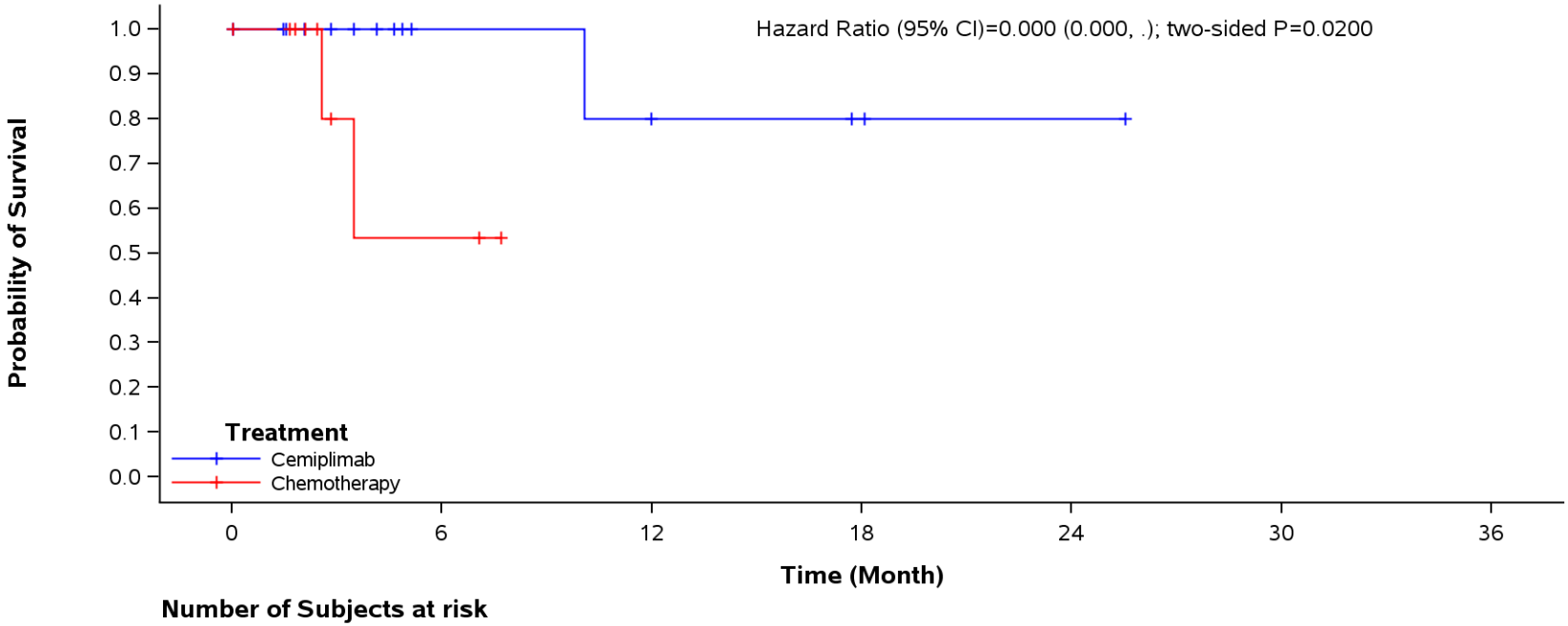

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Diarhoea - 10 pts sensitivity sustained deterioration



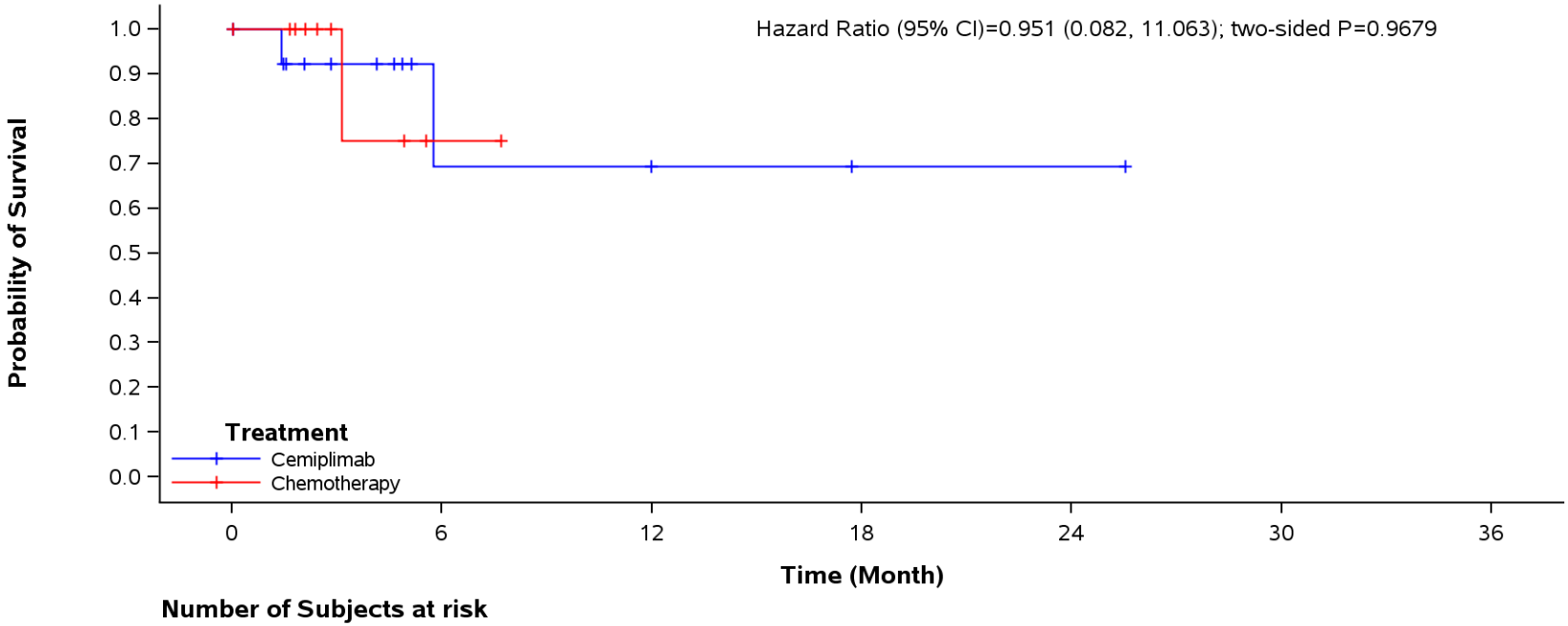

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Dyspnoea - 10 pts sensitivity sustained deterioration



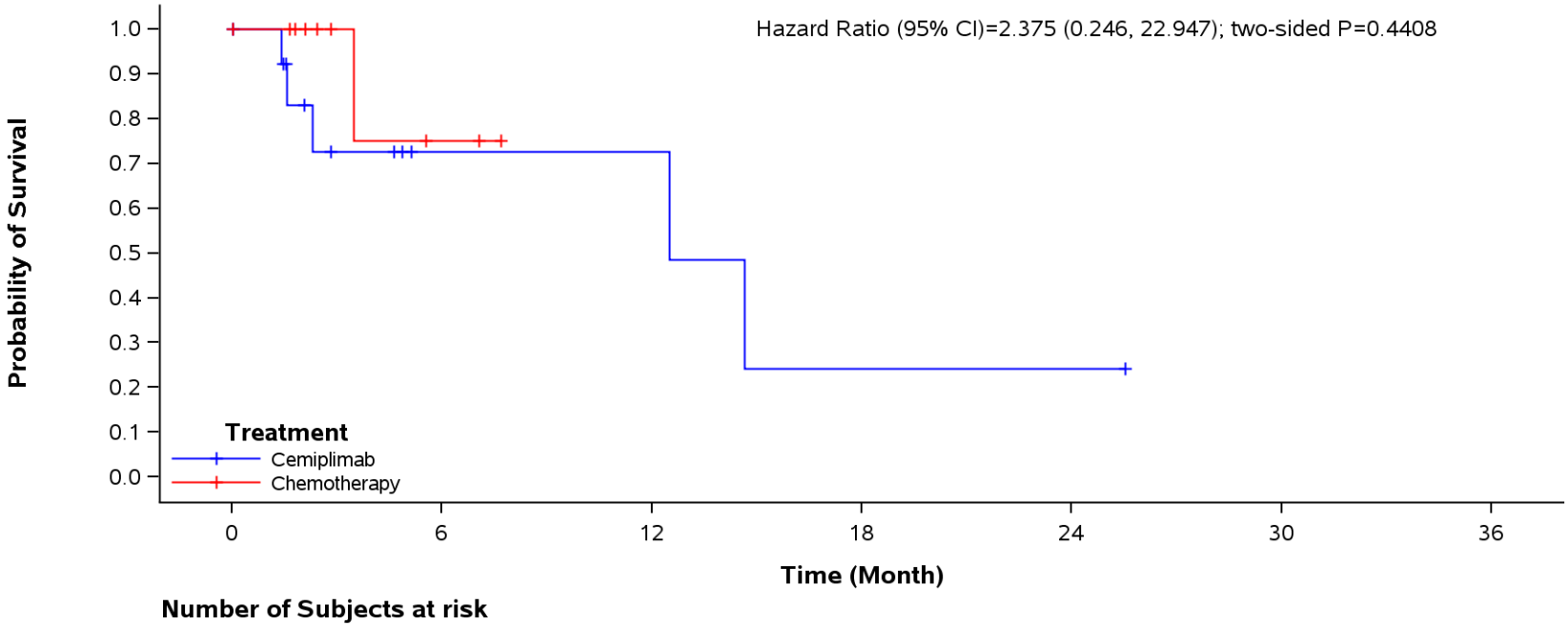

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Emotional Functioning - 10 pts sensitivity sustained deterioration



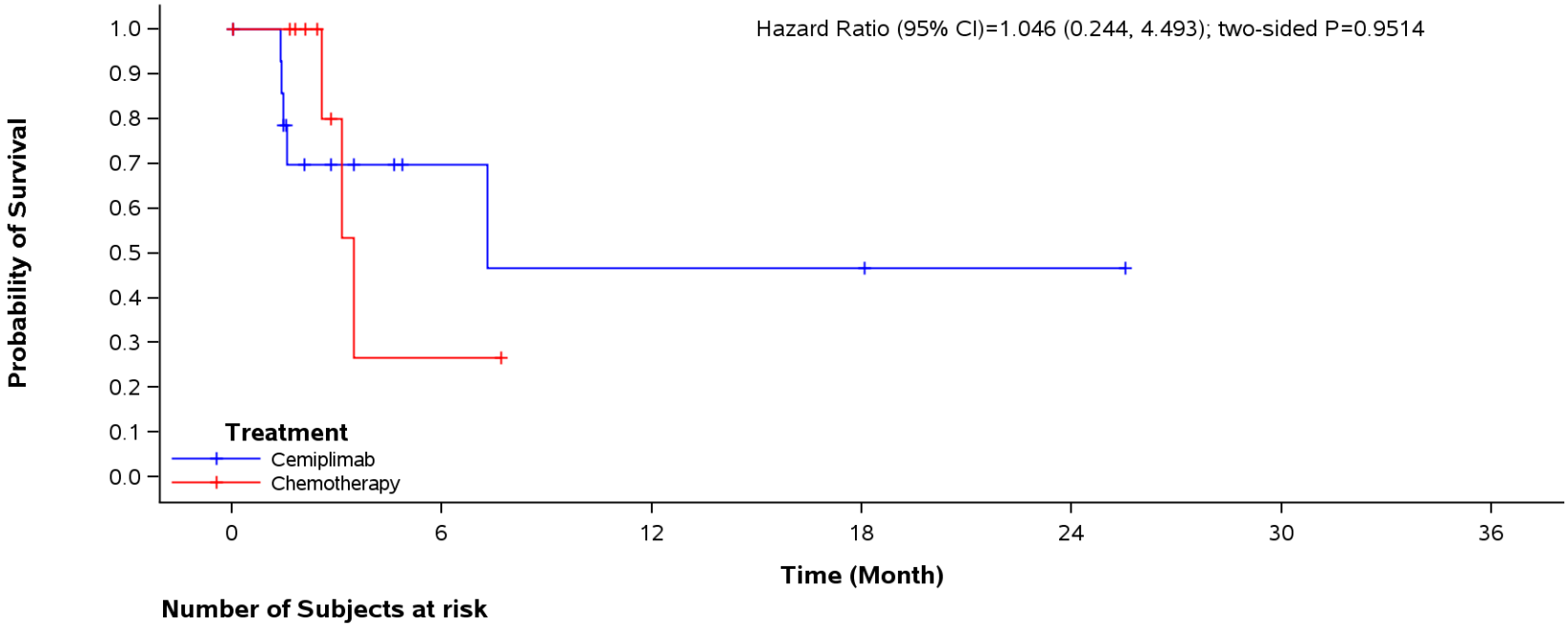

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Fatigue - 10 pts sensitivity sustained deterioration



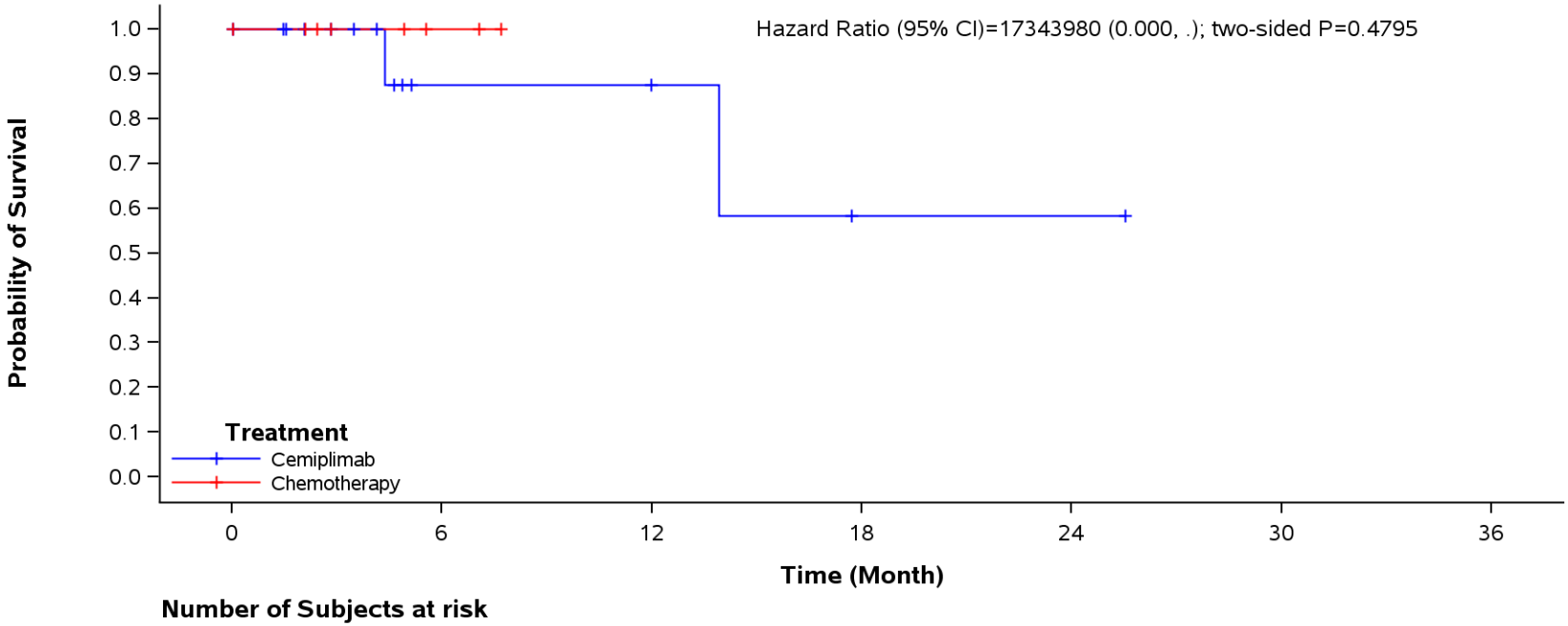

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Financial Problems - 10 pts sensitivity sustained deterioration



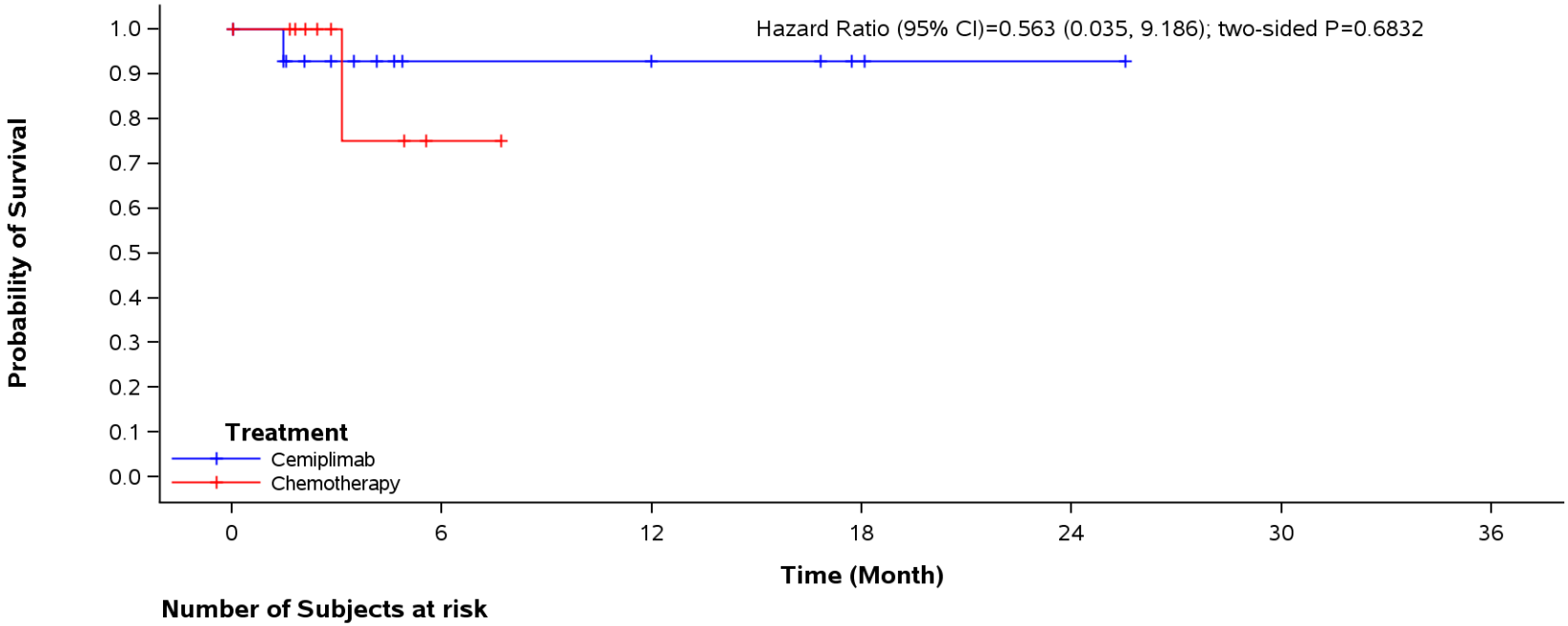

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



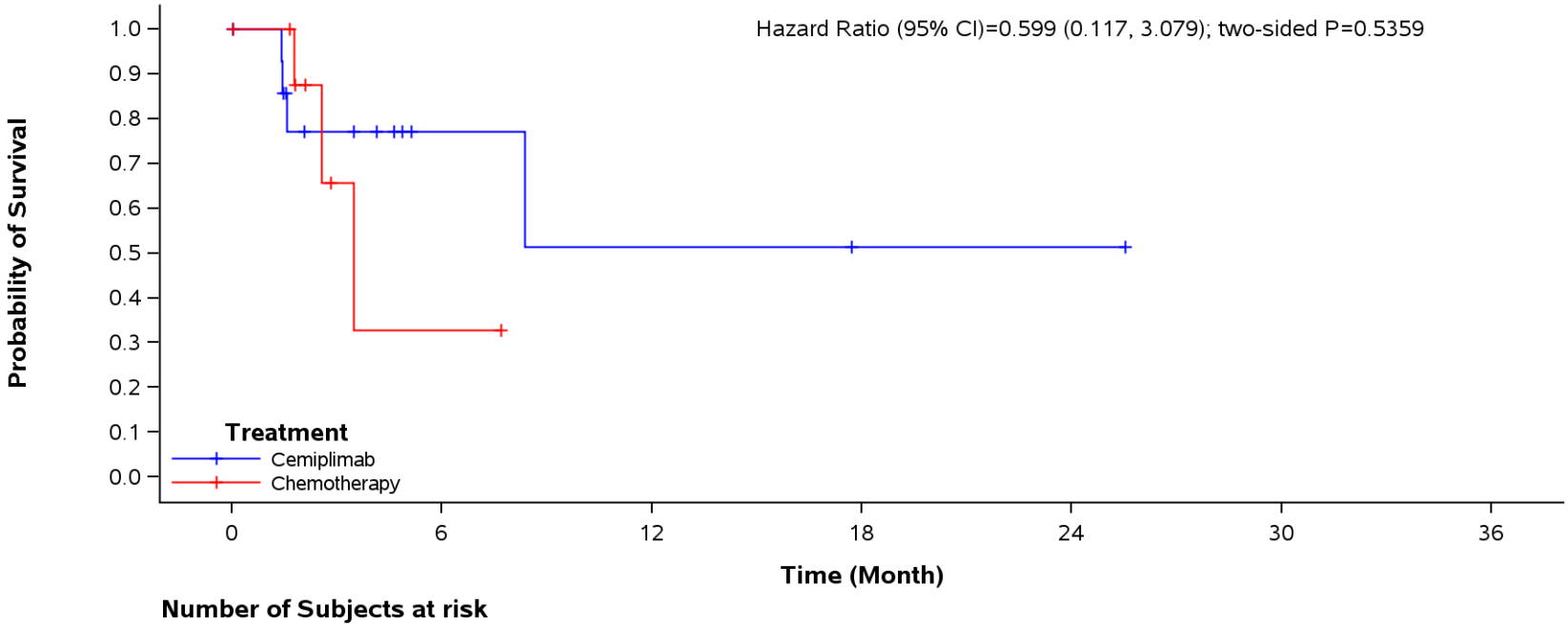

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Pain - 10 pts sensitivity sustained deterioration



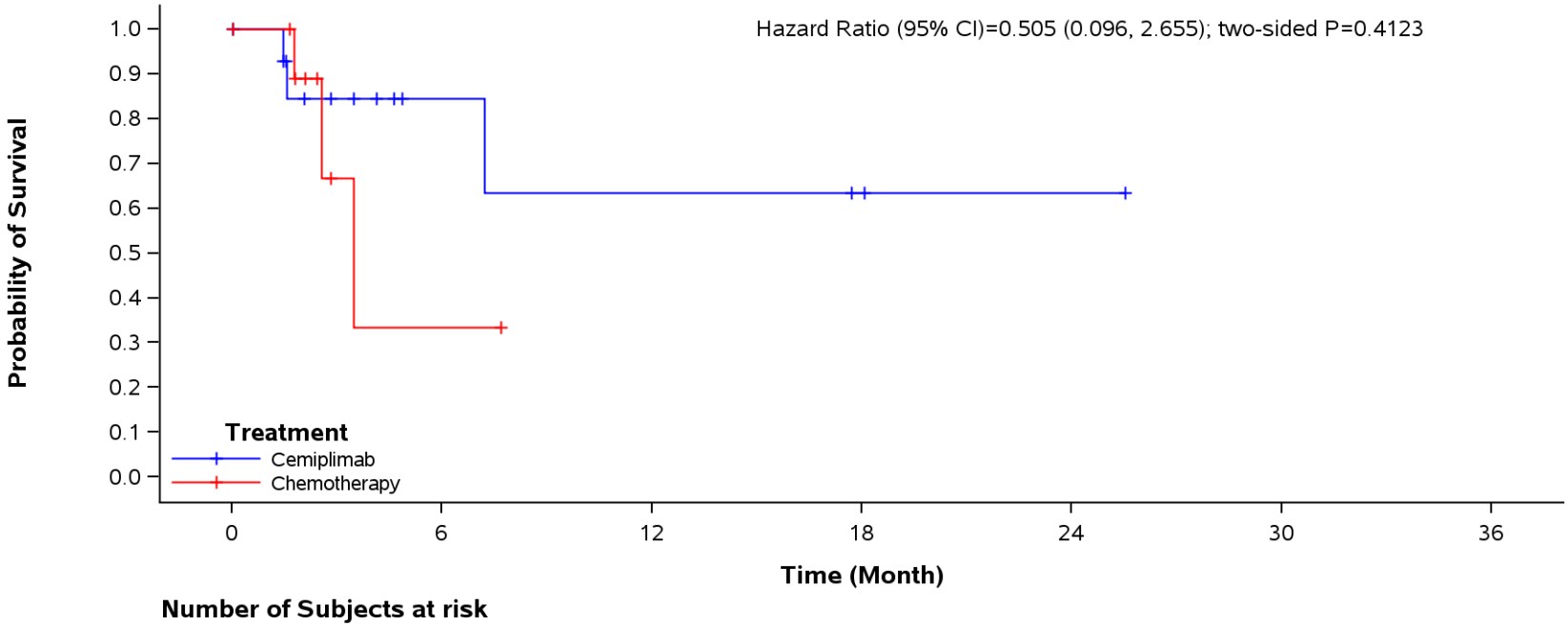

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Physical Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

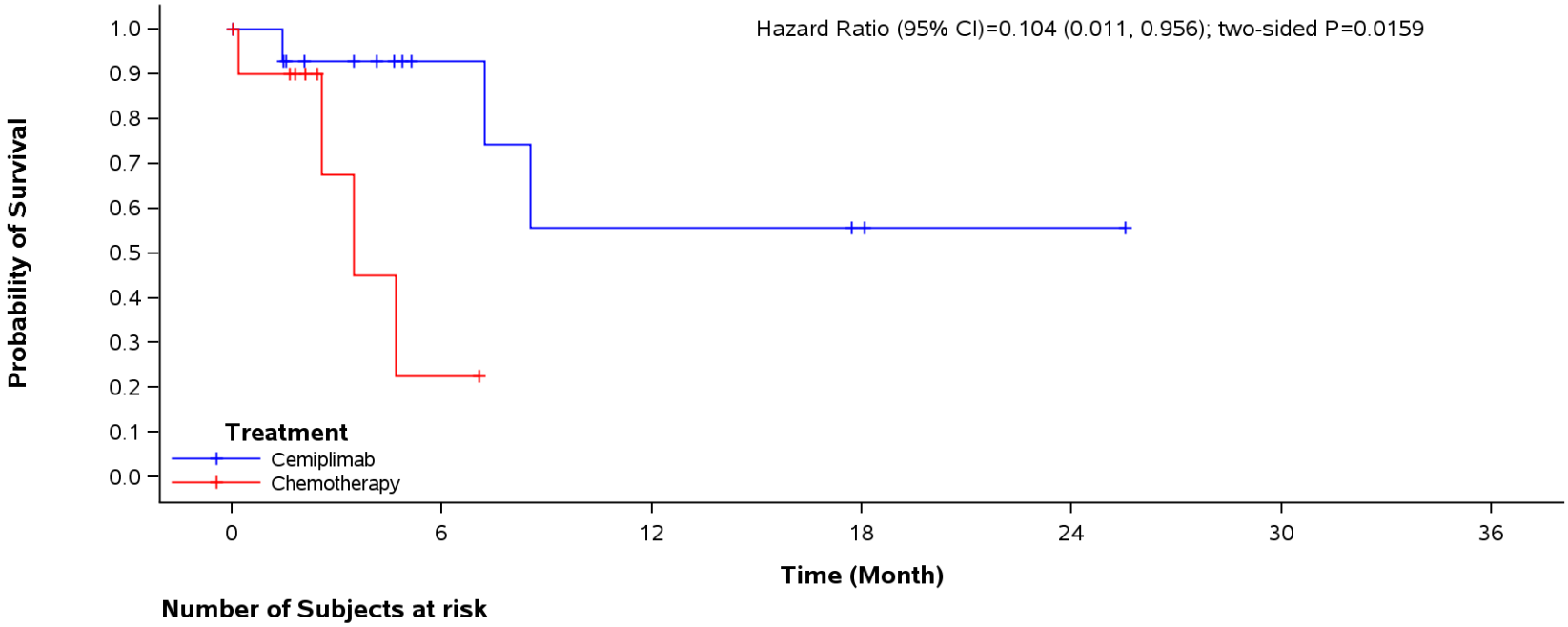
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

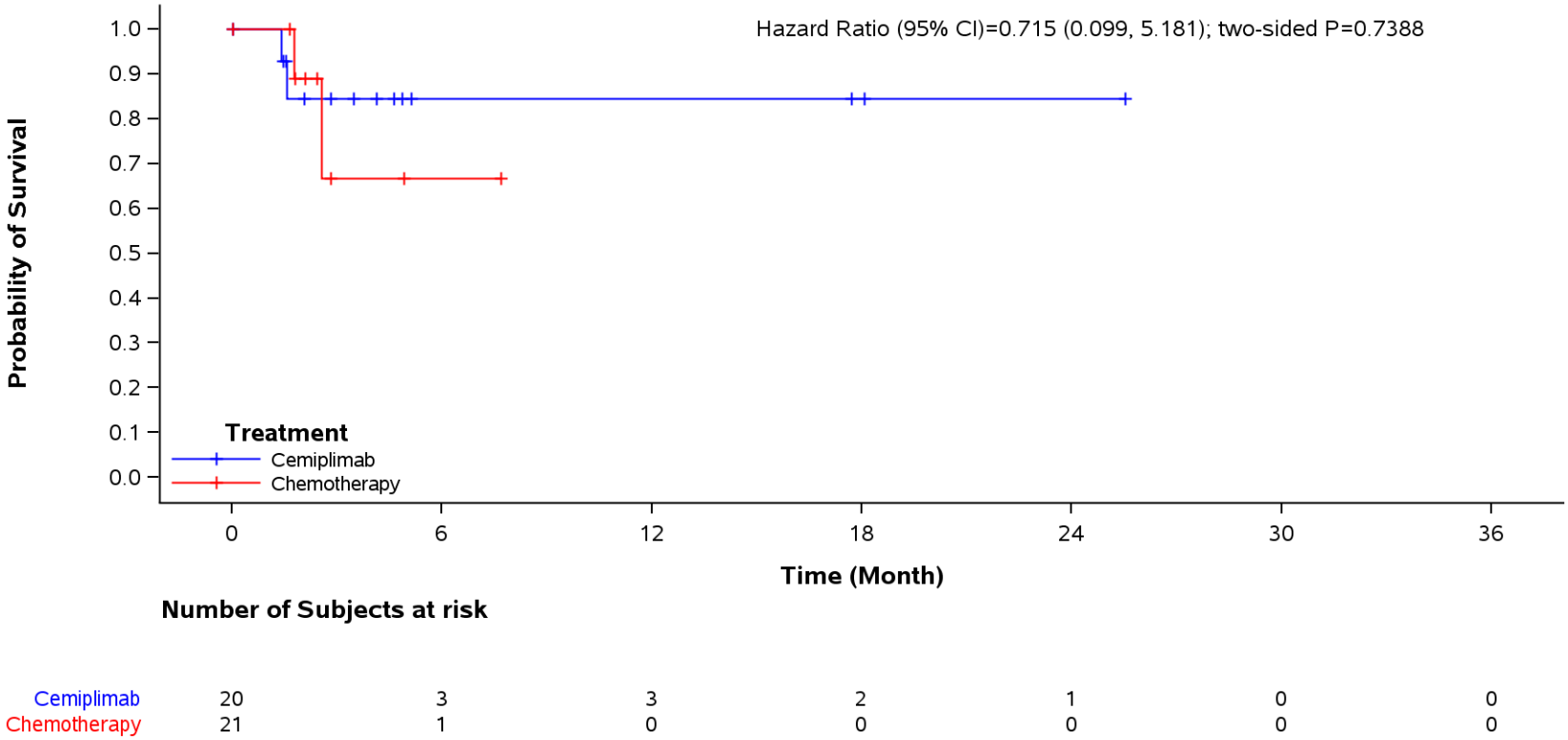
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Role Functioning - 10 pts sensitivity sustained deterioration



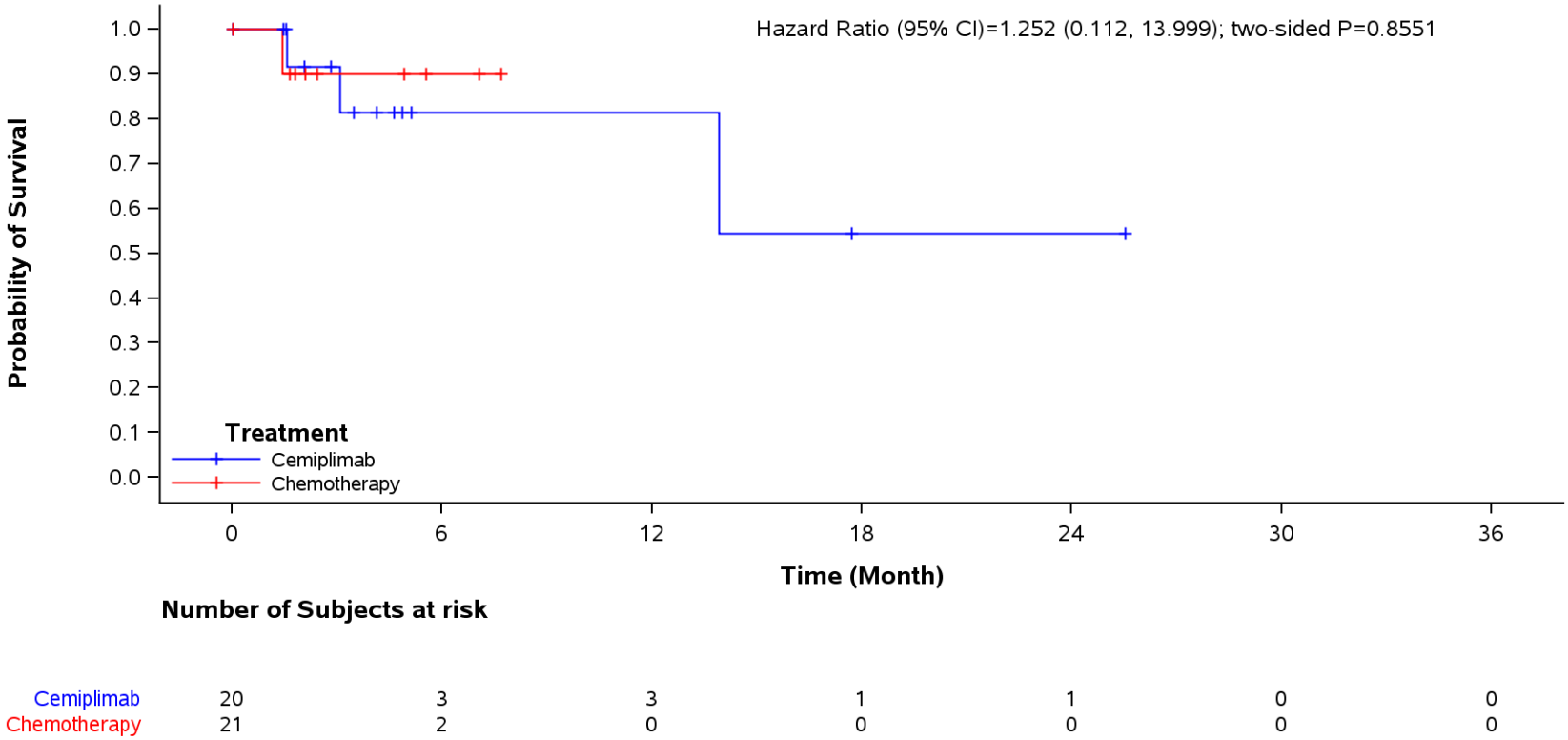

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

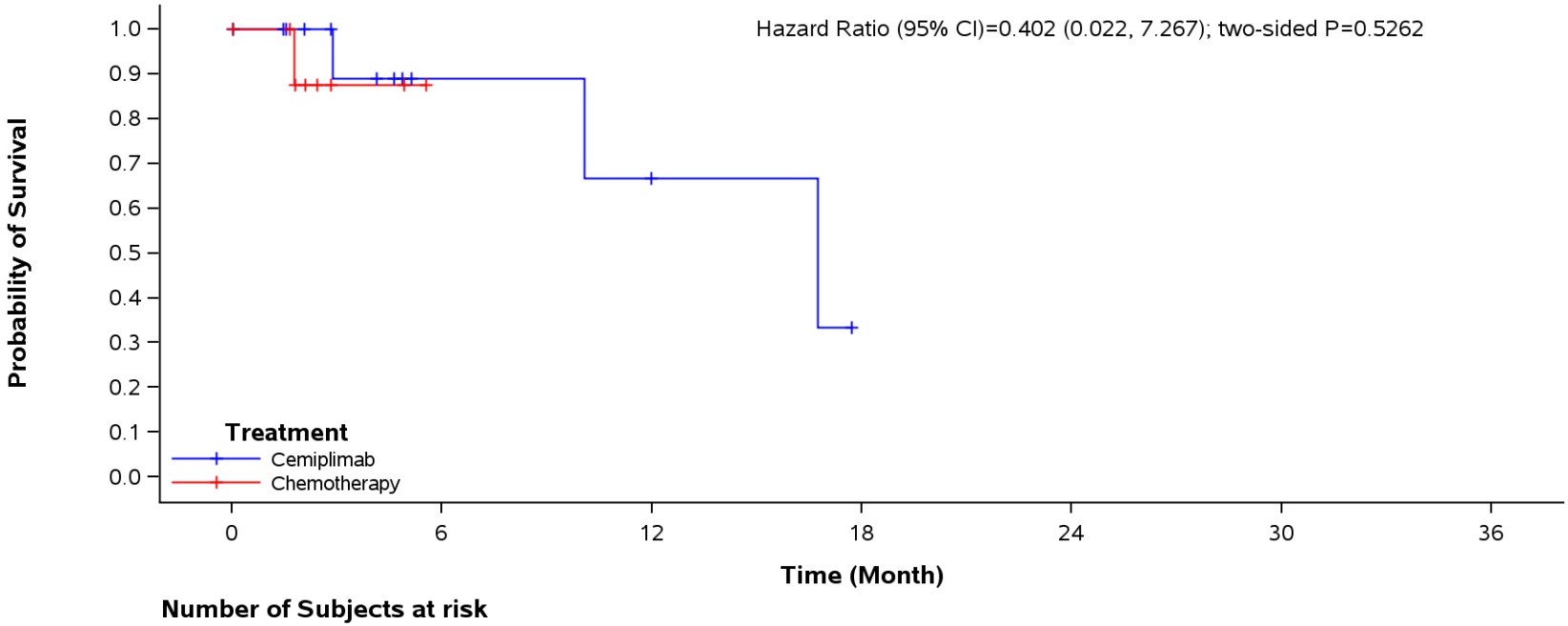
Choice of IC chemotherapy: Topotecan
Social Functioning - 10 pts sensitivity sustained deterioration




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Insomnia - 10 pts sensitivity sustained deterioration



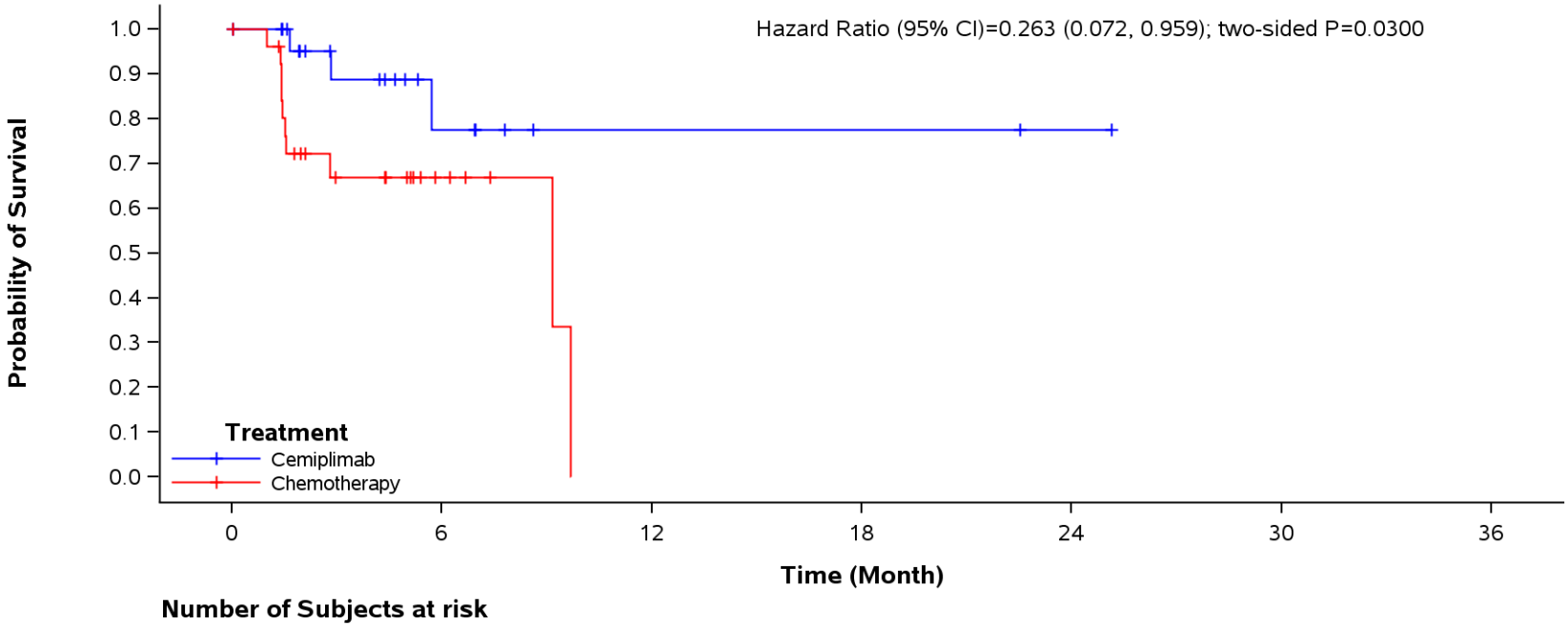

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Appetite loss - 10 pts sensitivity sustained deterioration



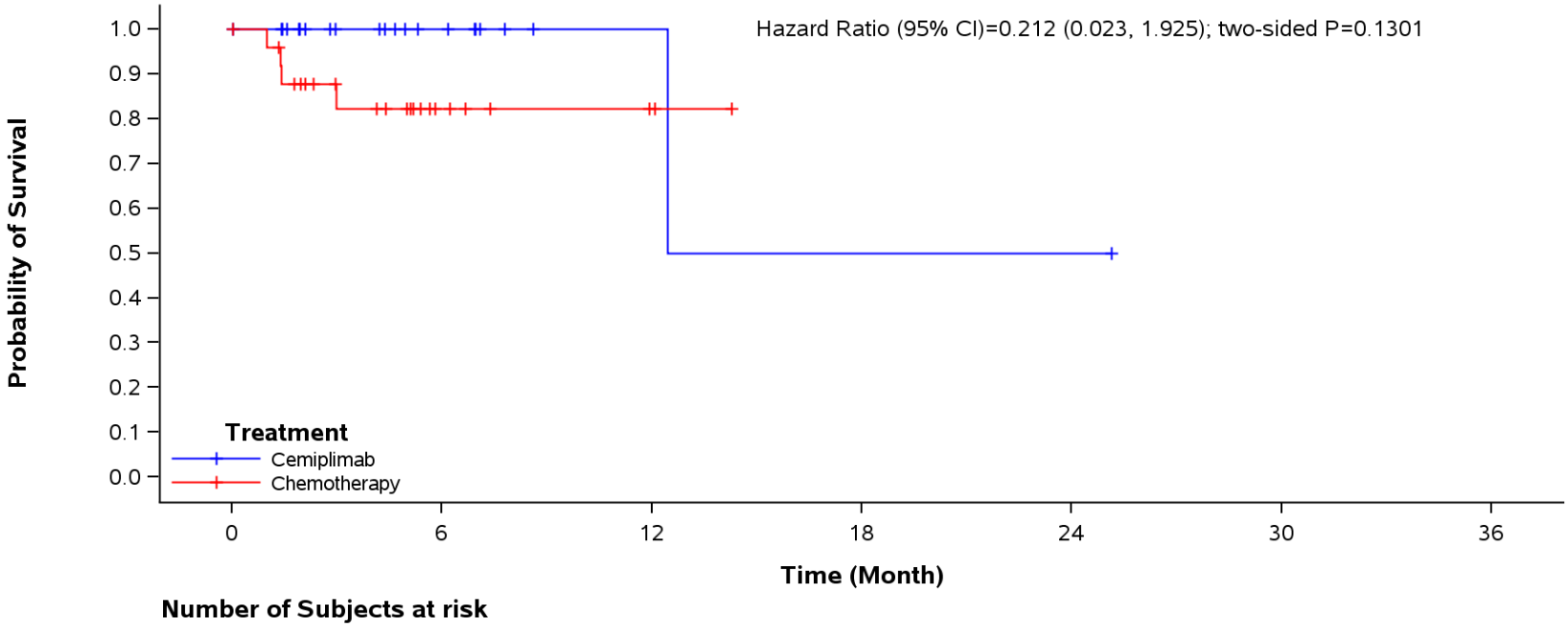

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Cognitive Functioning - 10 pts sensitivity sustained deterioration



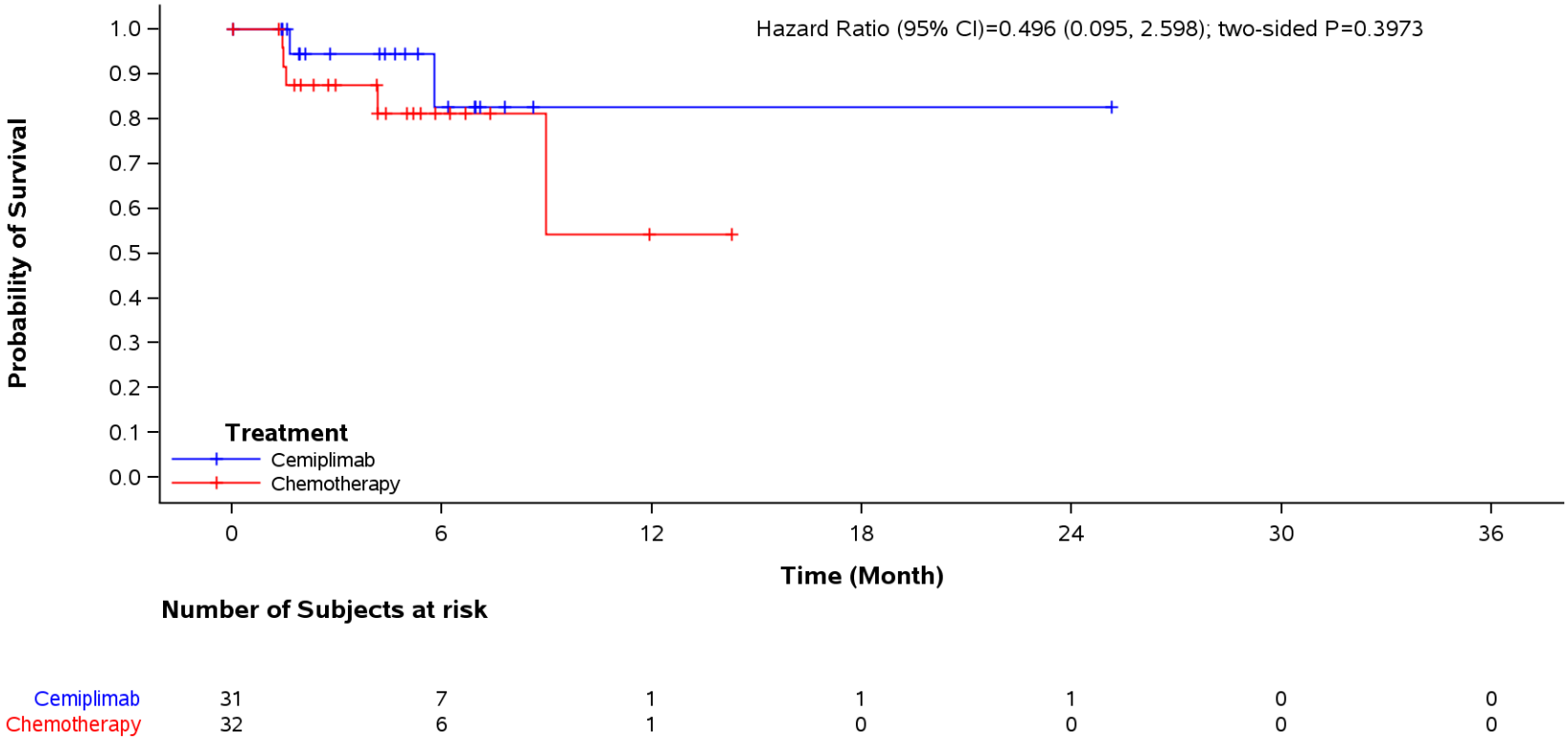

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 9 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Constipation - 10 pts sensitivity sustained deterioration



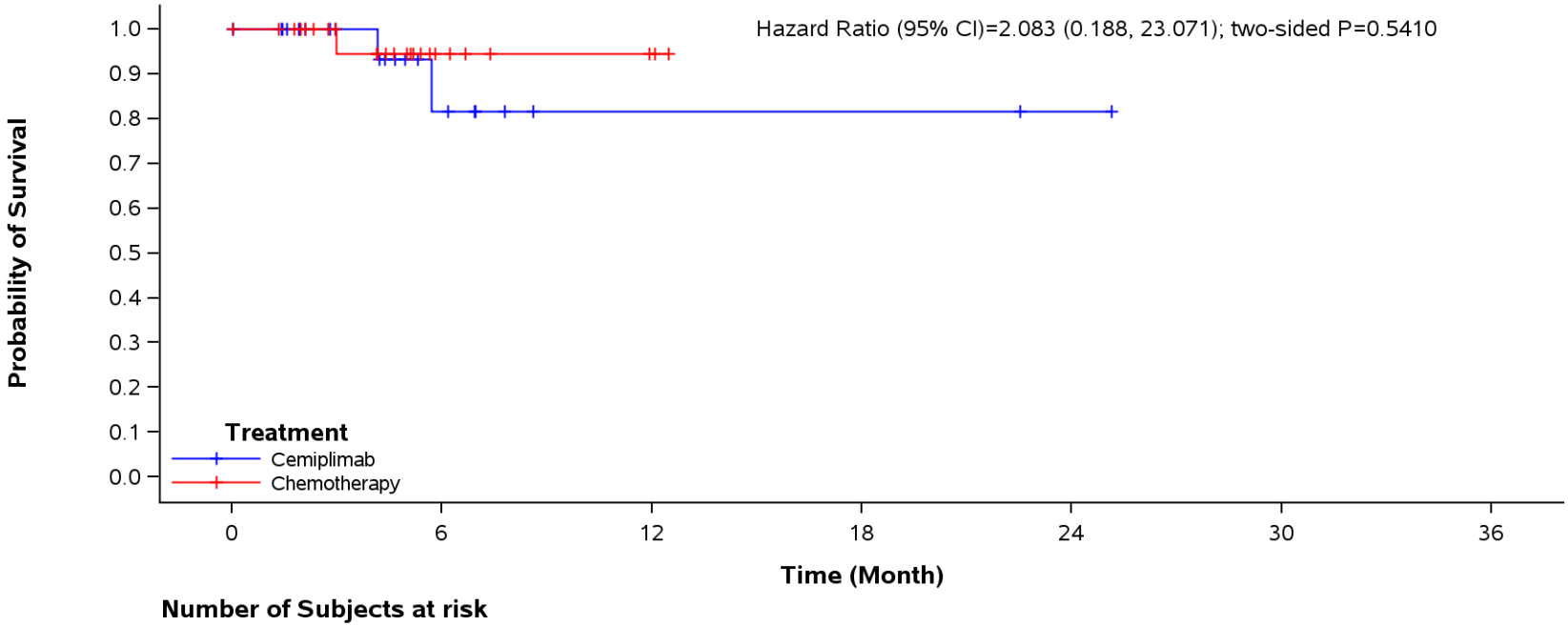

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Diarhoea - 10 pts sensitivity sustained deterioration



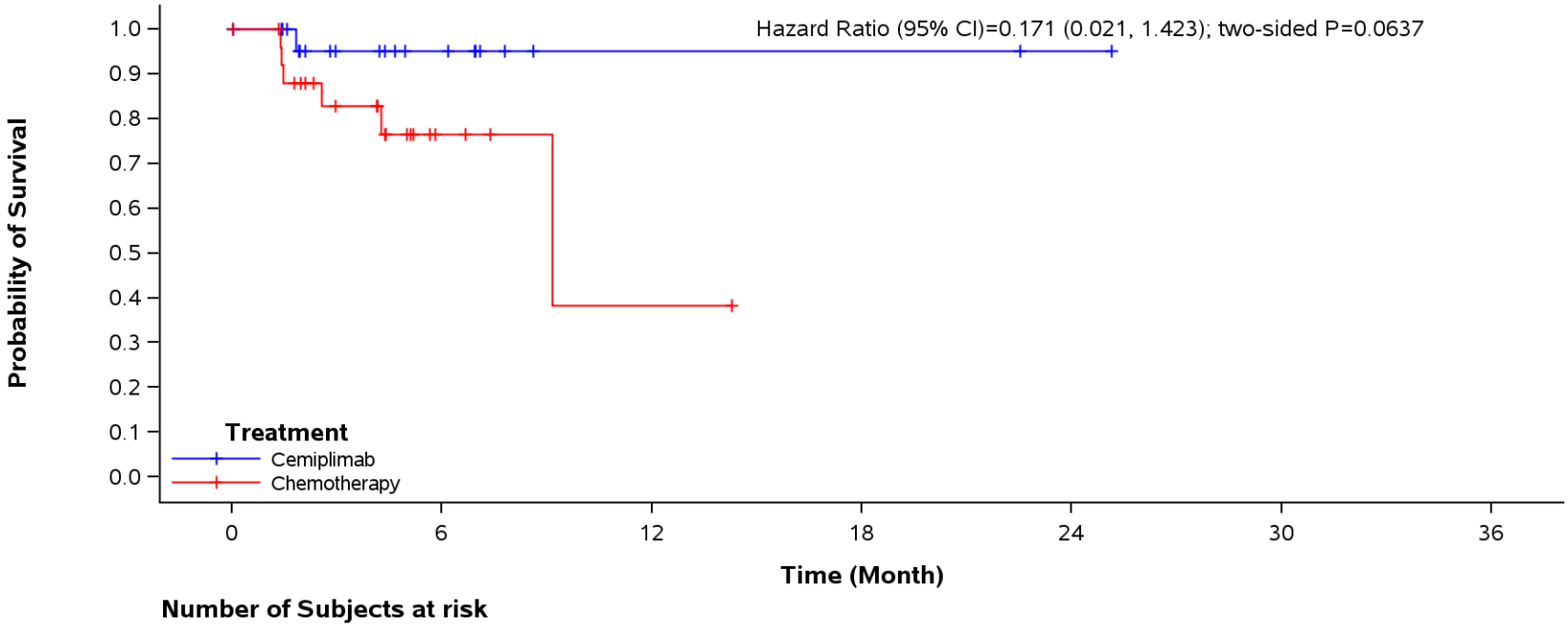

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Dyspnoea - 10 pts sensitivity sustained deterioration



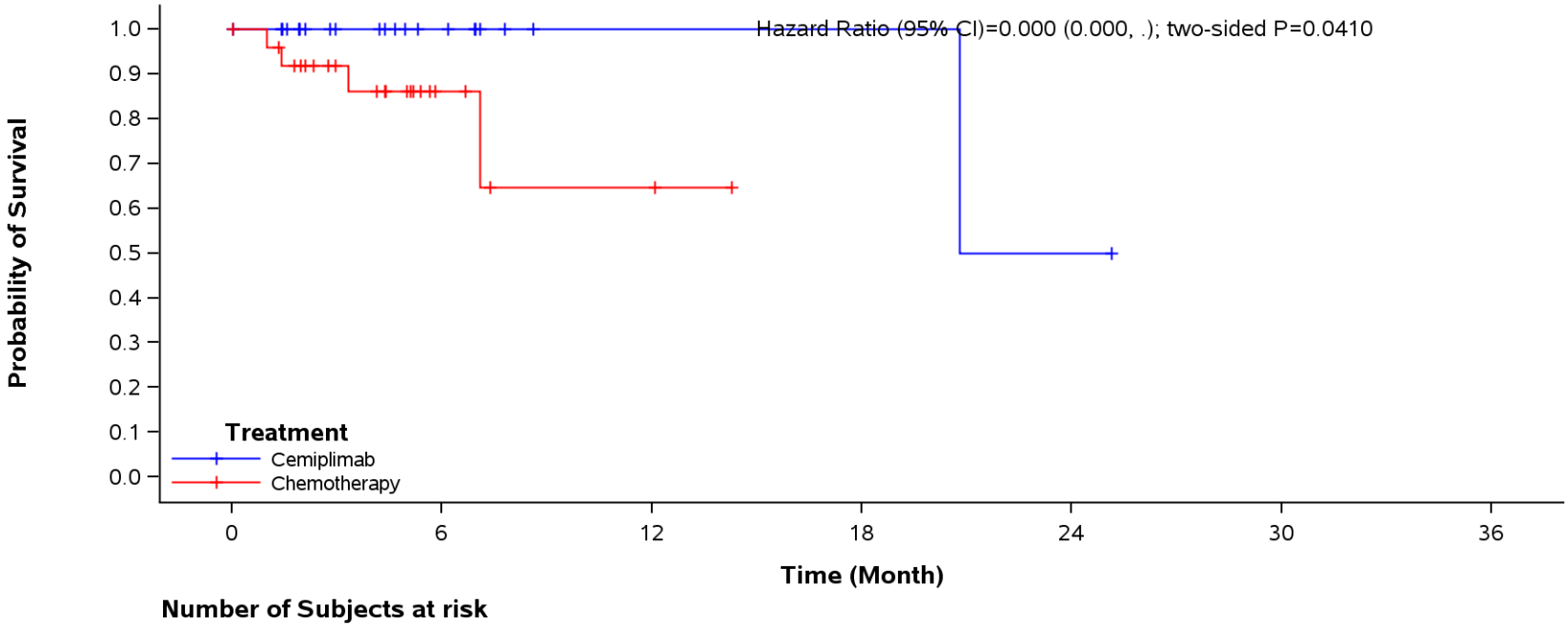

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 9 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Emotional Functioning - 10 pts sensitivity sustained deterioration



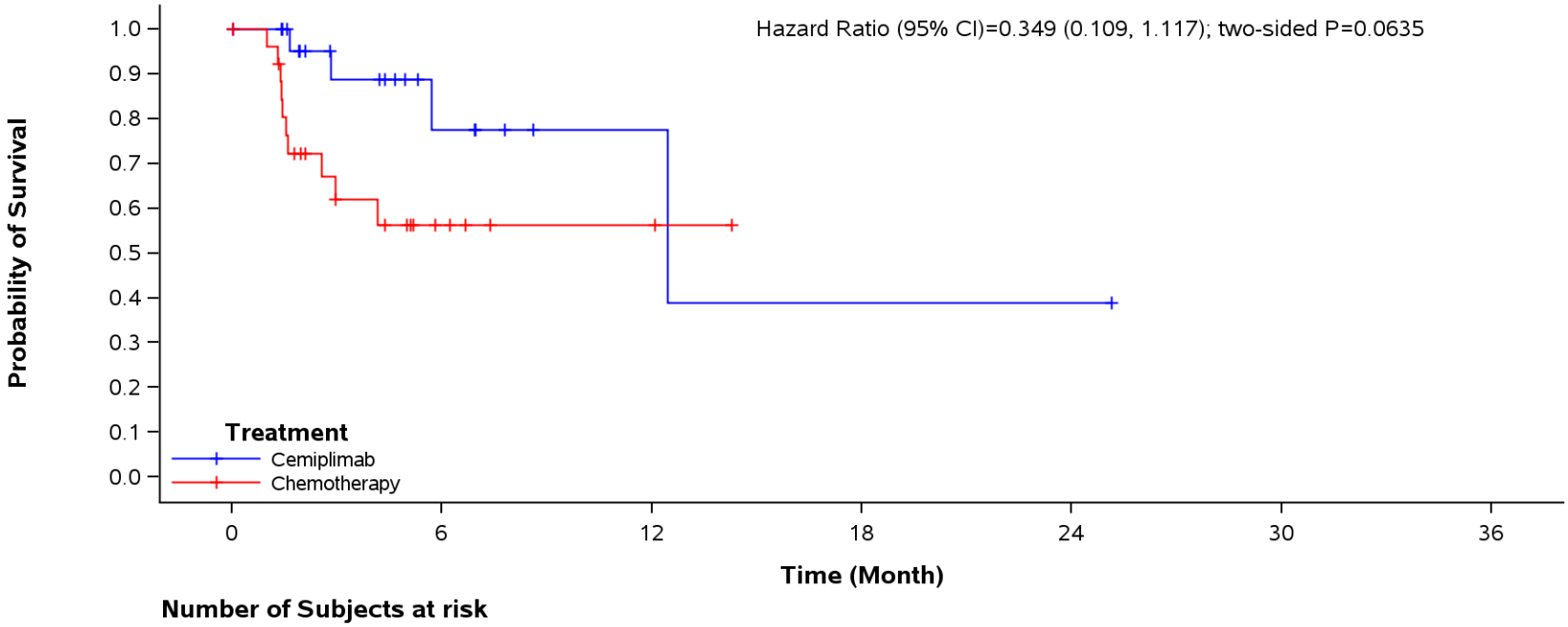

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 9 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Fatigue - 10 pts sensitivity sustained deterioration



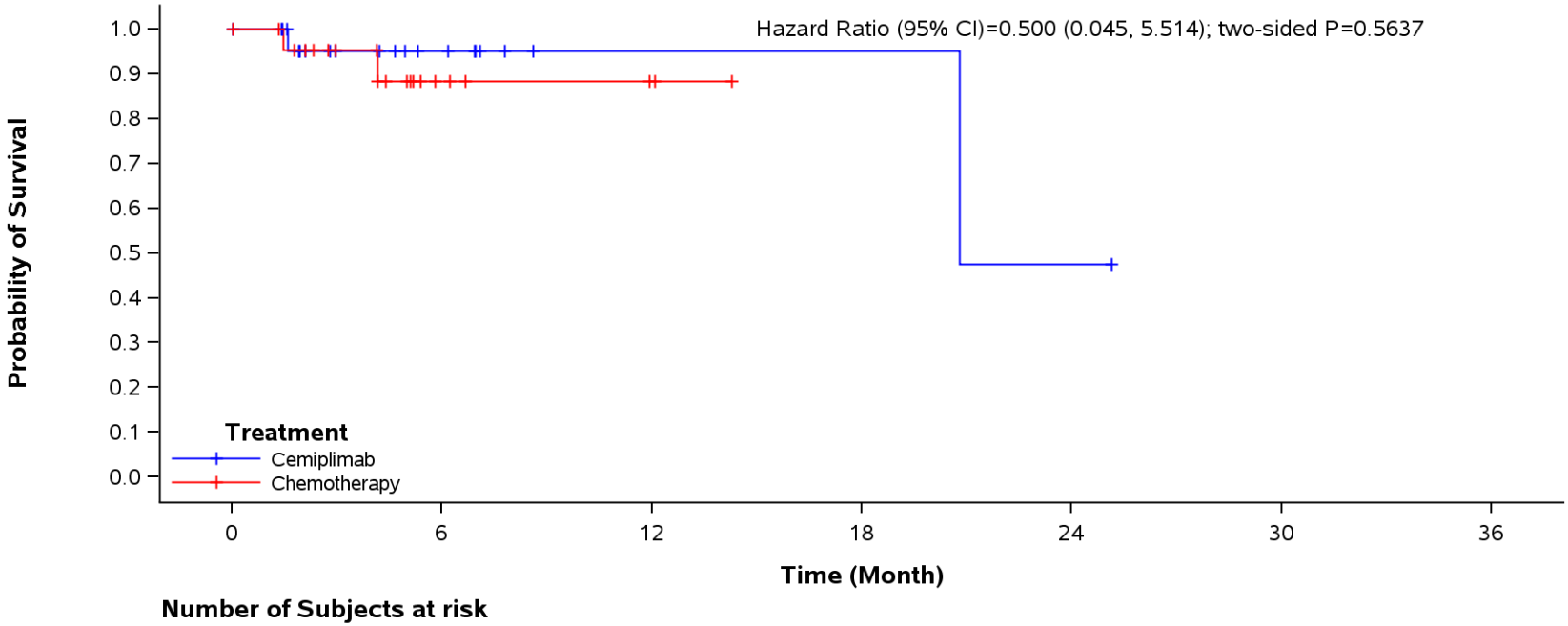

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Financial Problems - 10 pts sensitivity sustained deterioration



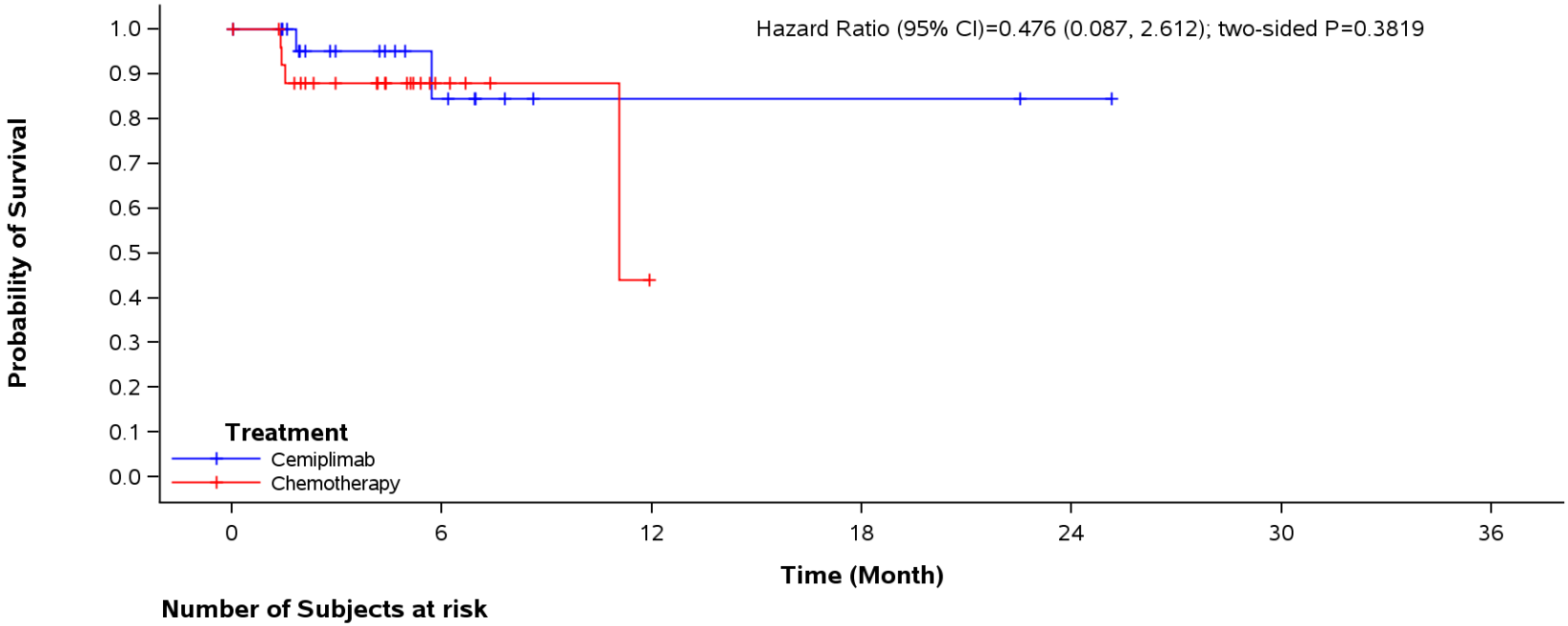

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 9 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



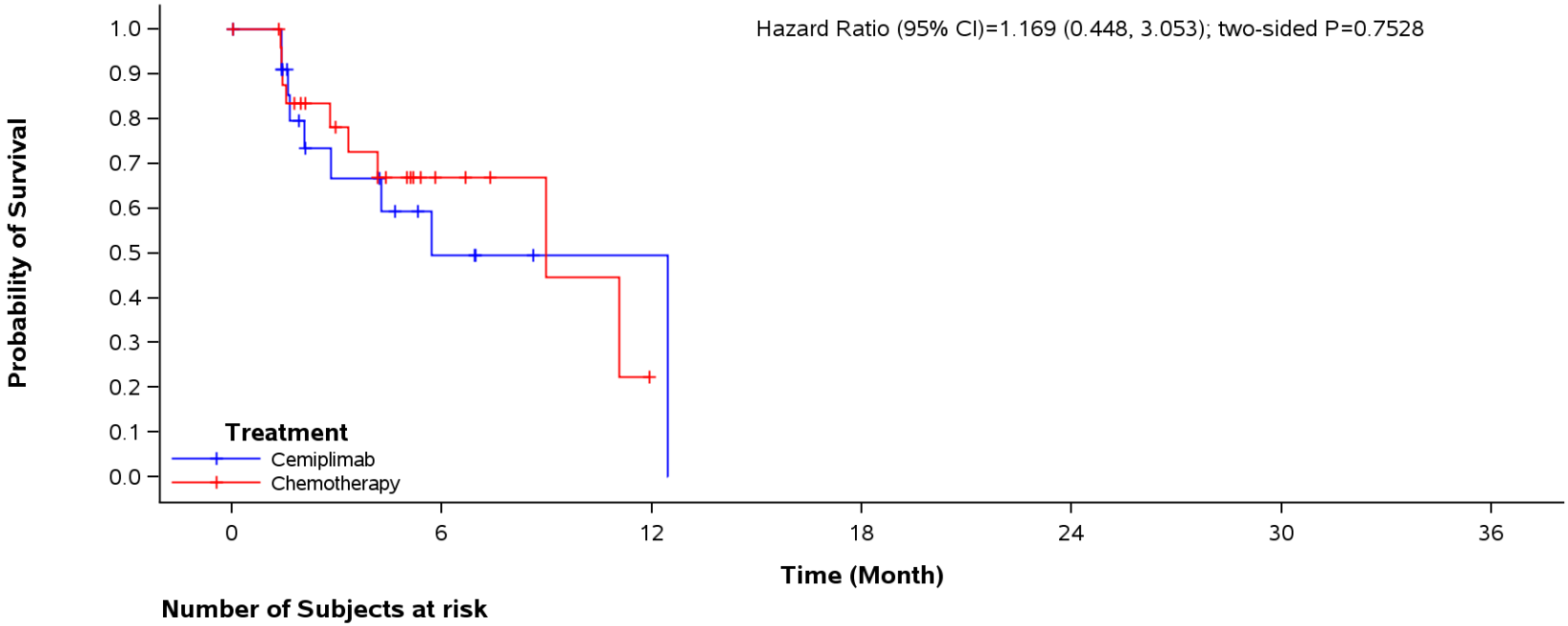

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 8 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Pain - 10 pts sensitivity sustained deterioration



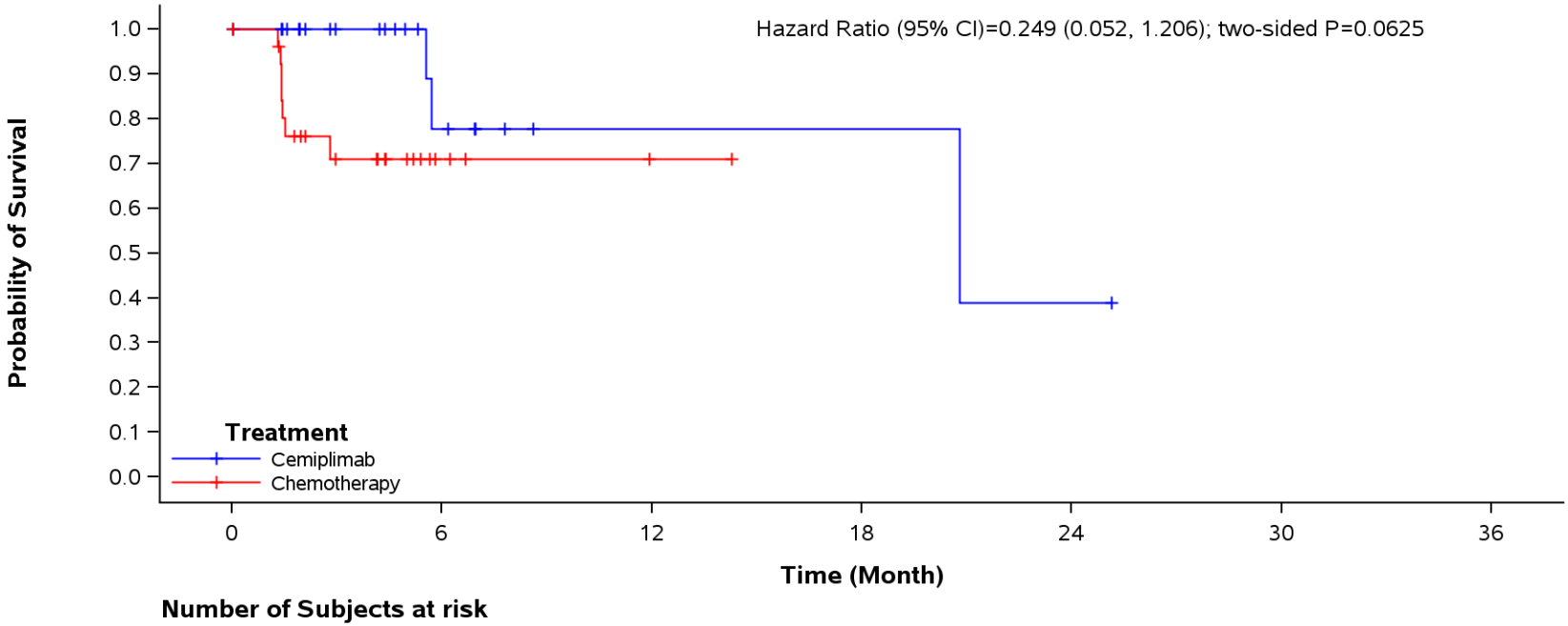

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 32 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

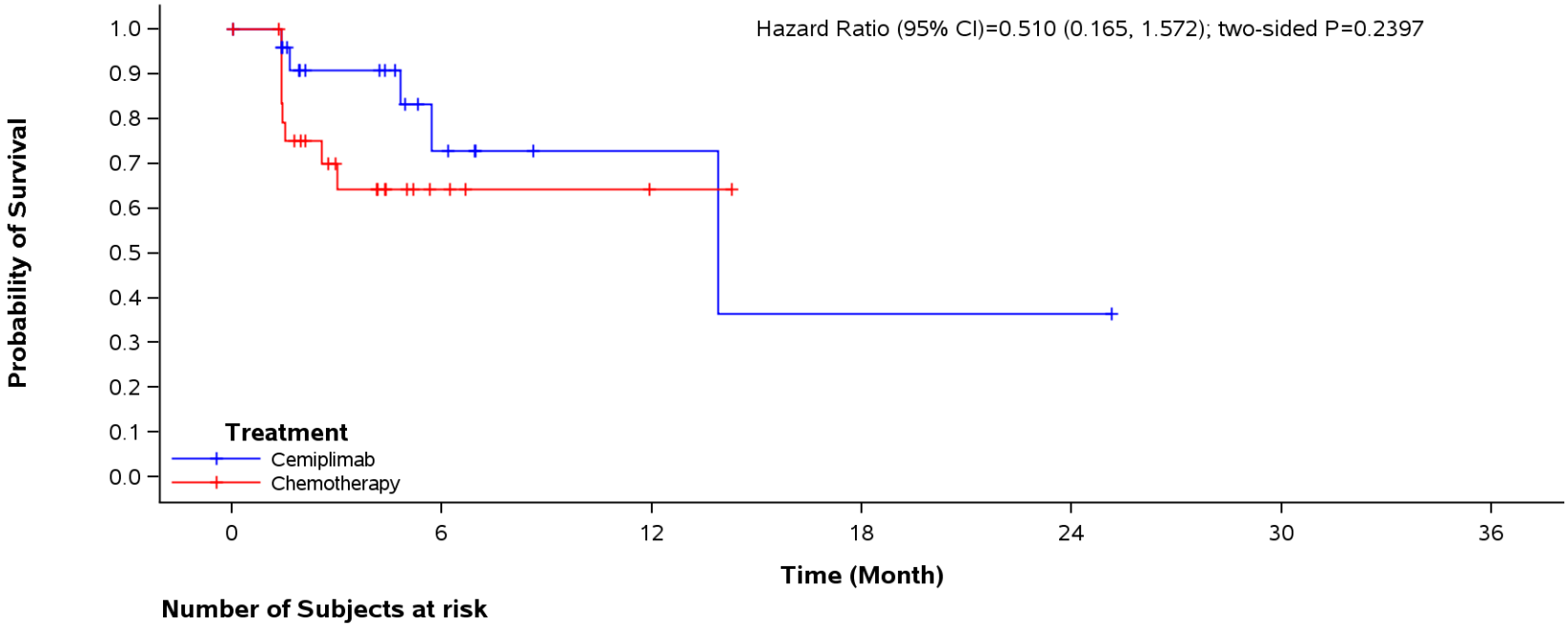
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

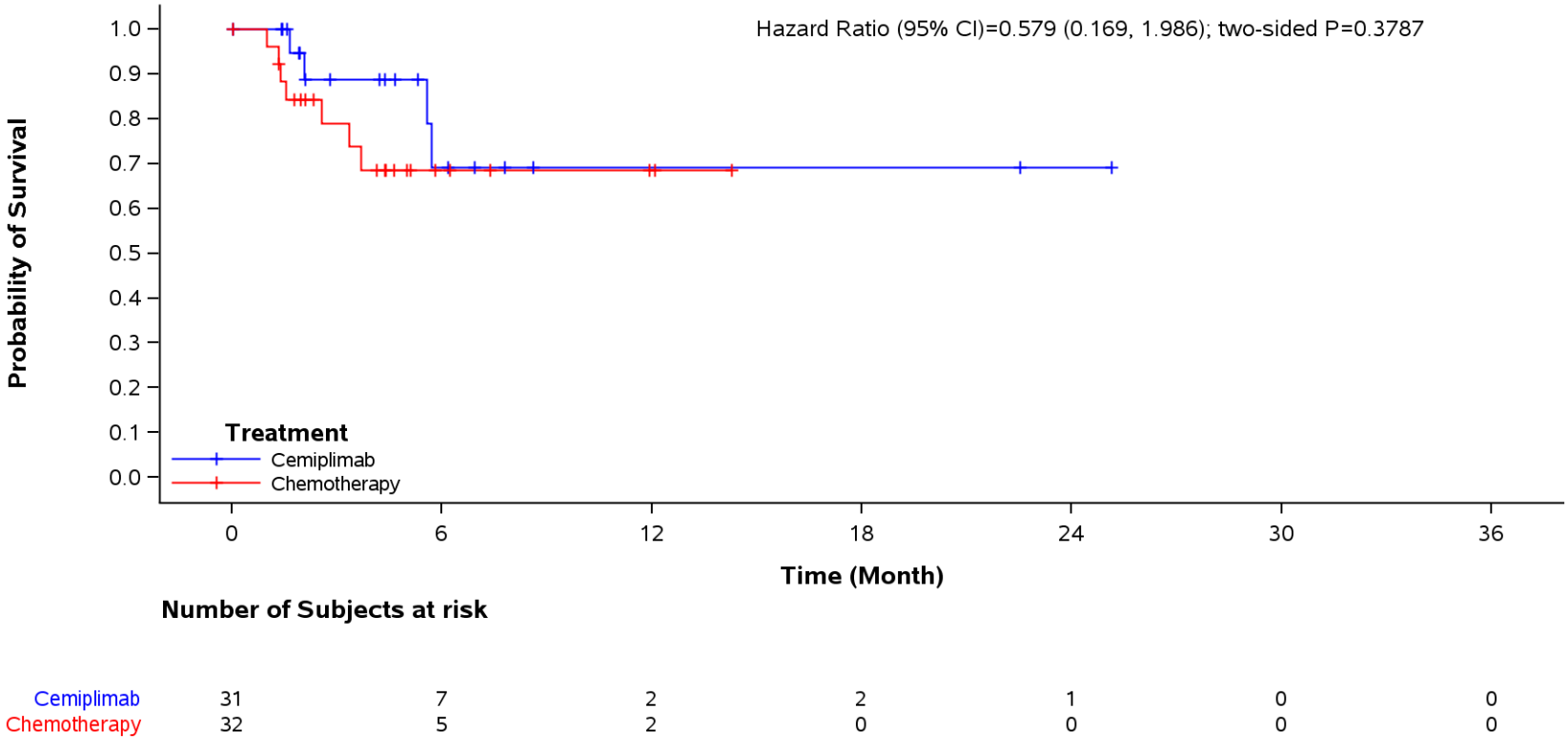
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Role Functioning - 10 pts sensitivity sustained deterioration



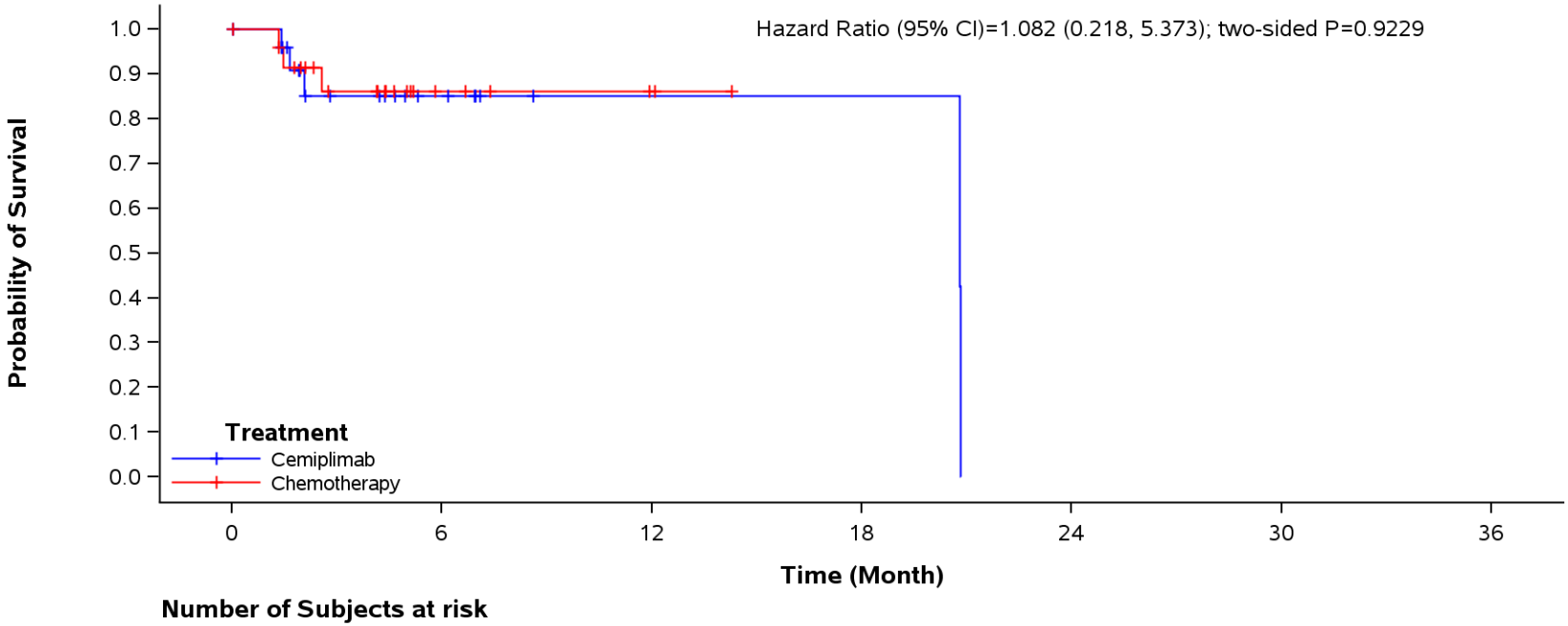

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Social Functioning - 10 pts sensitivity sustained deterioration



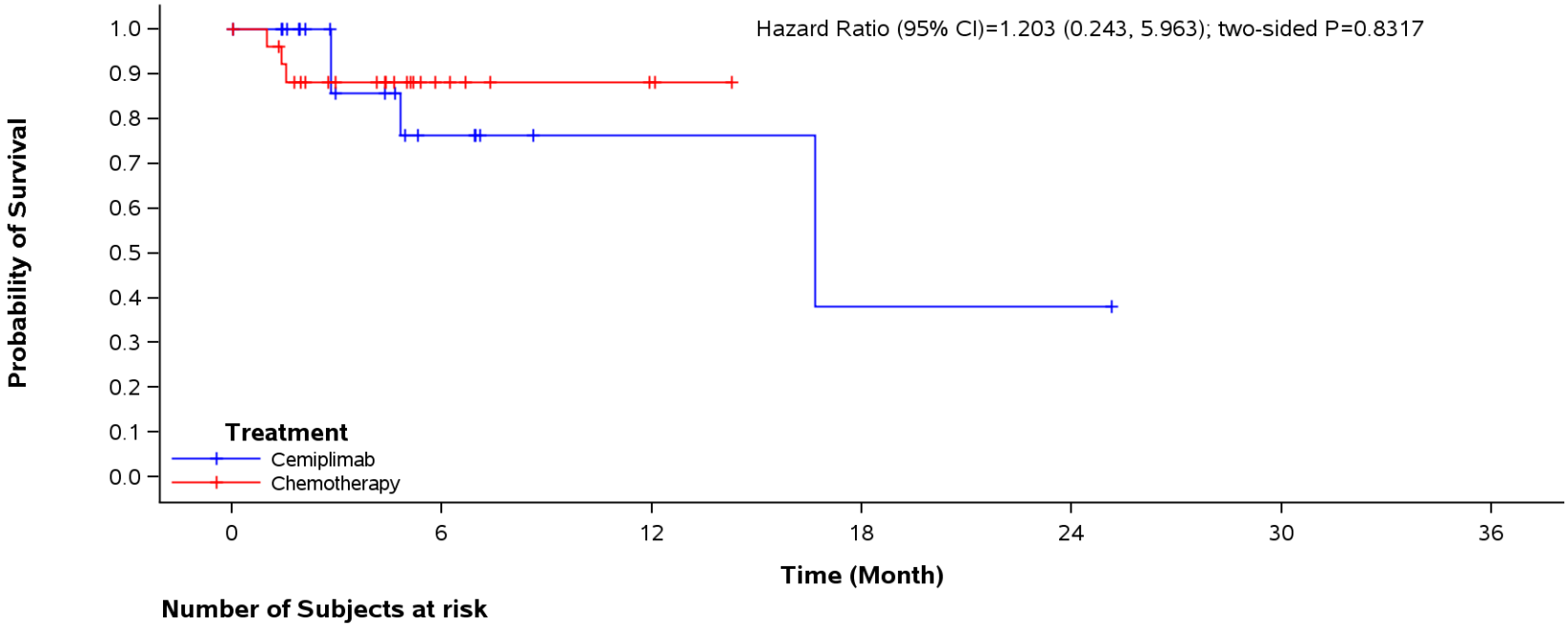

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 8 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 32 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup without PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Insomnia - 10 pts sensitivity sustained deterioration



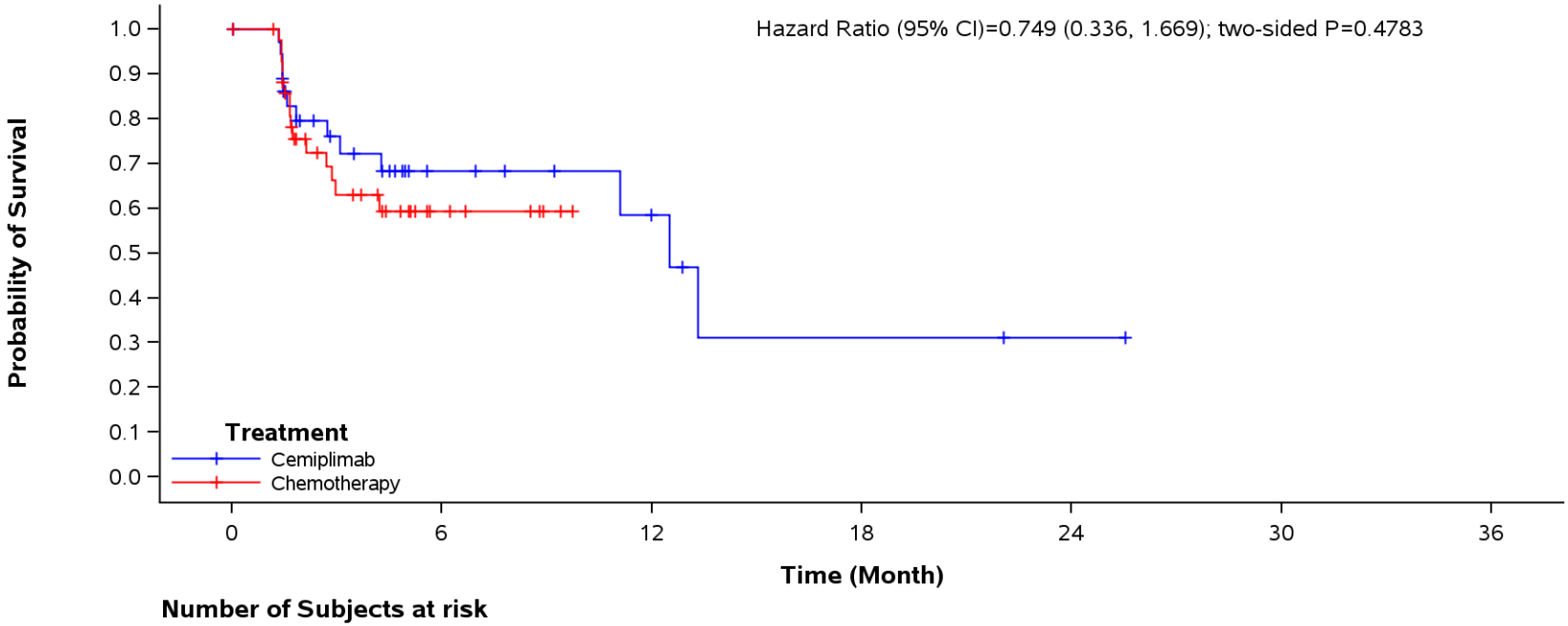

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 31 | 6 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 32 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Appetite loss - 10 pts sustained improvement



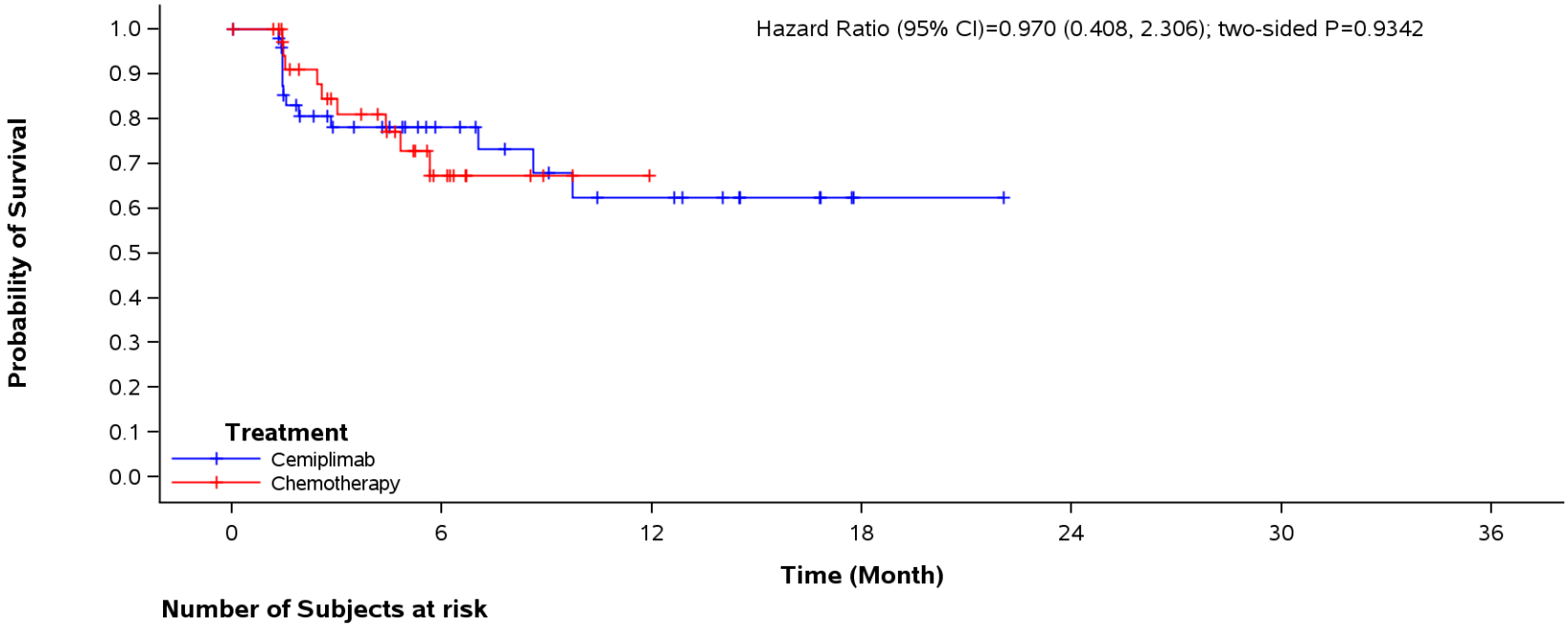

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 10 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Cognitive Functioning - 10 pts sustained improvement



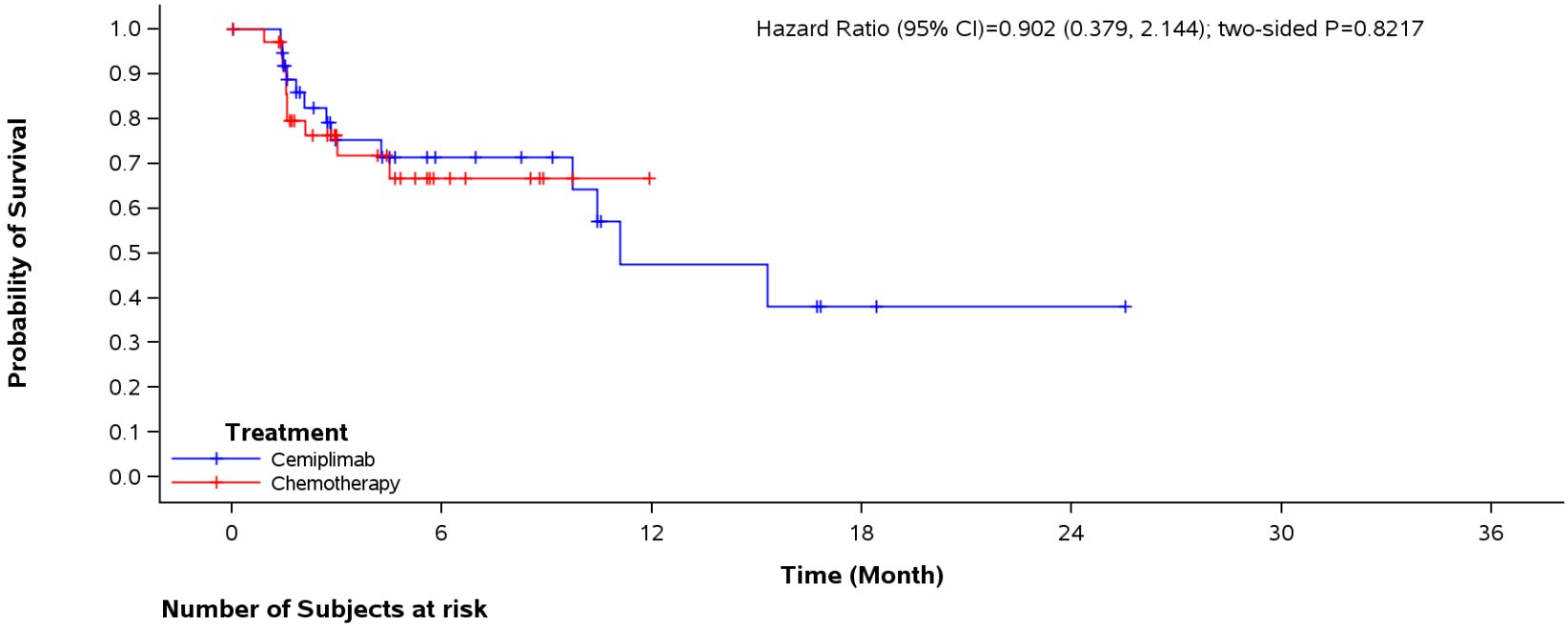

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 19 | 10 | 1 | 0 | 0 | 0 |
| Chemotherapy | 103 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Constipation - 10 pts sustained improvement



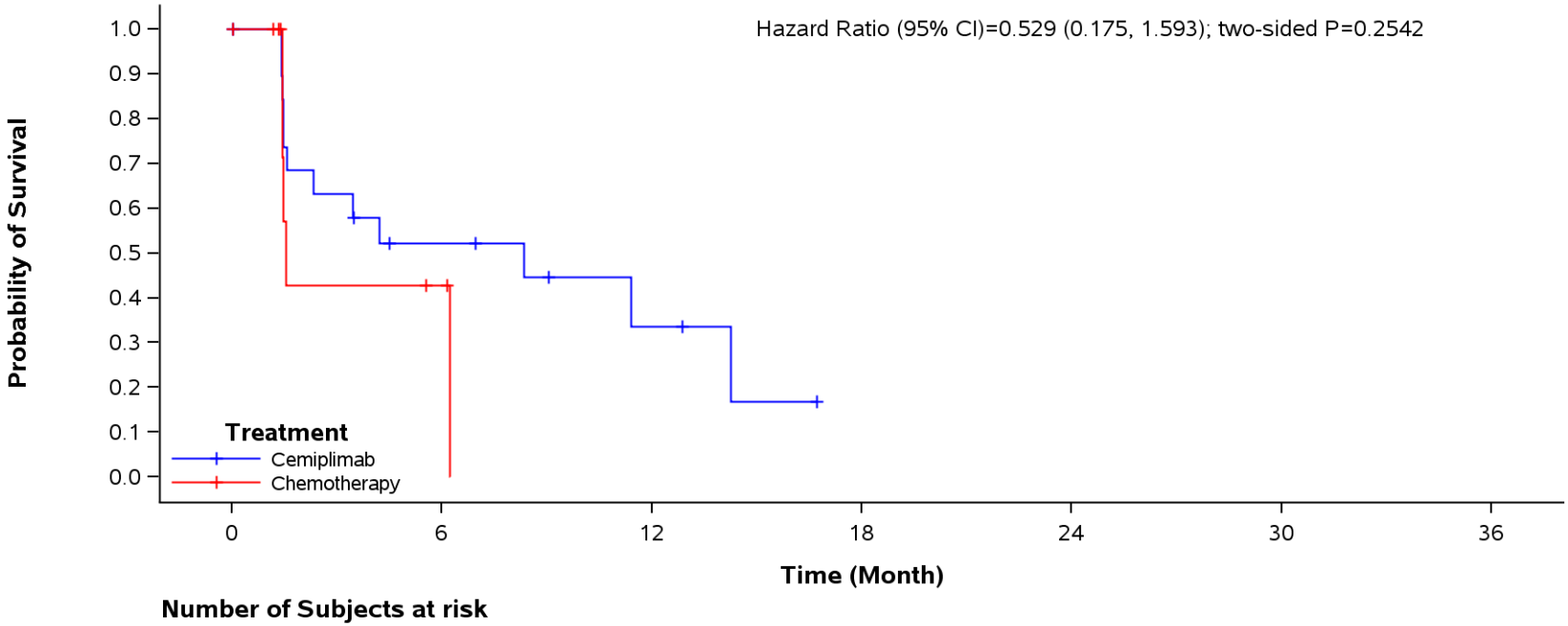

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 13 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Diarhoea - 10 pts sustained improvement



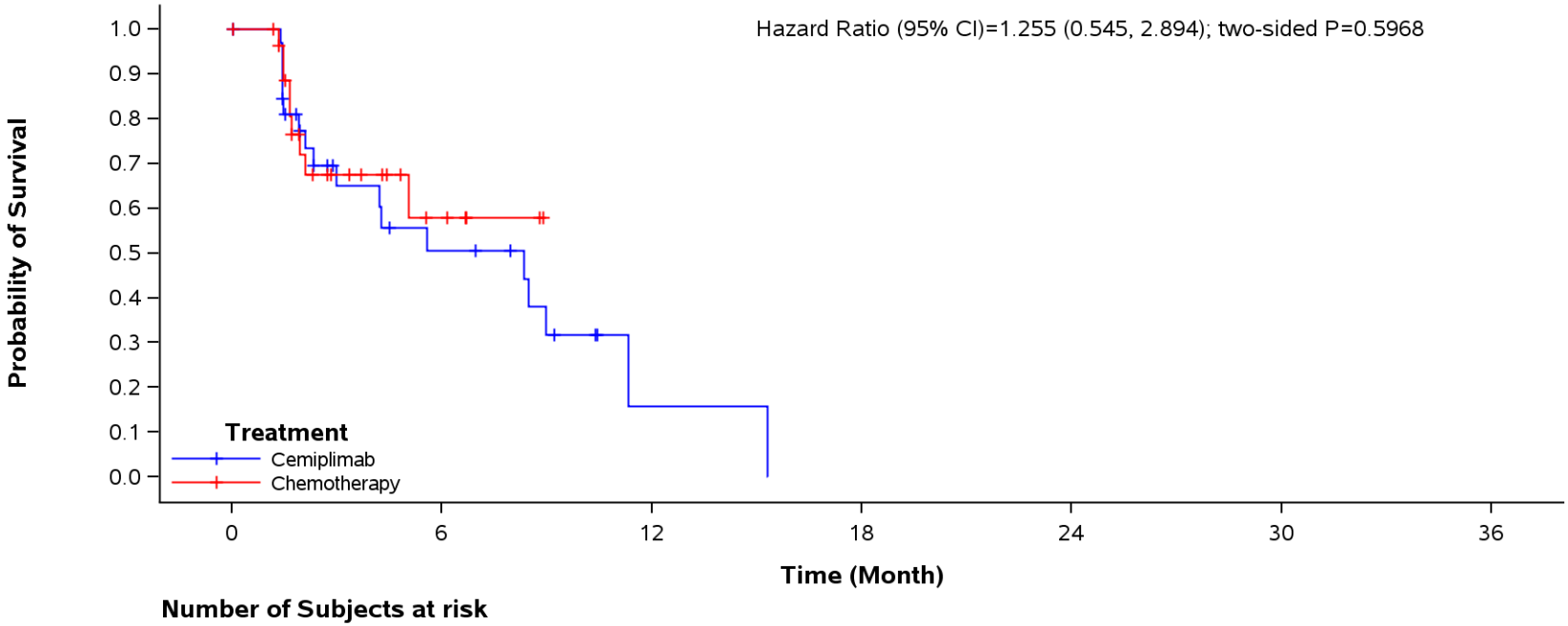

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Dyspnoea - 10 pts sustained improvement



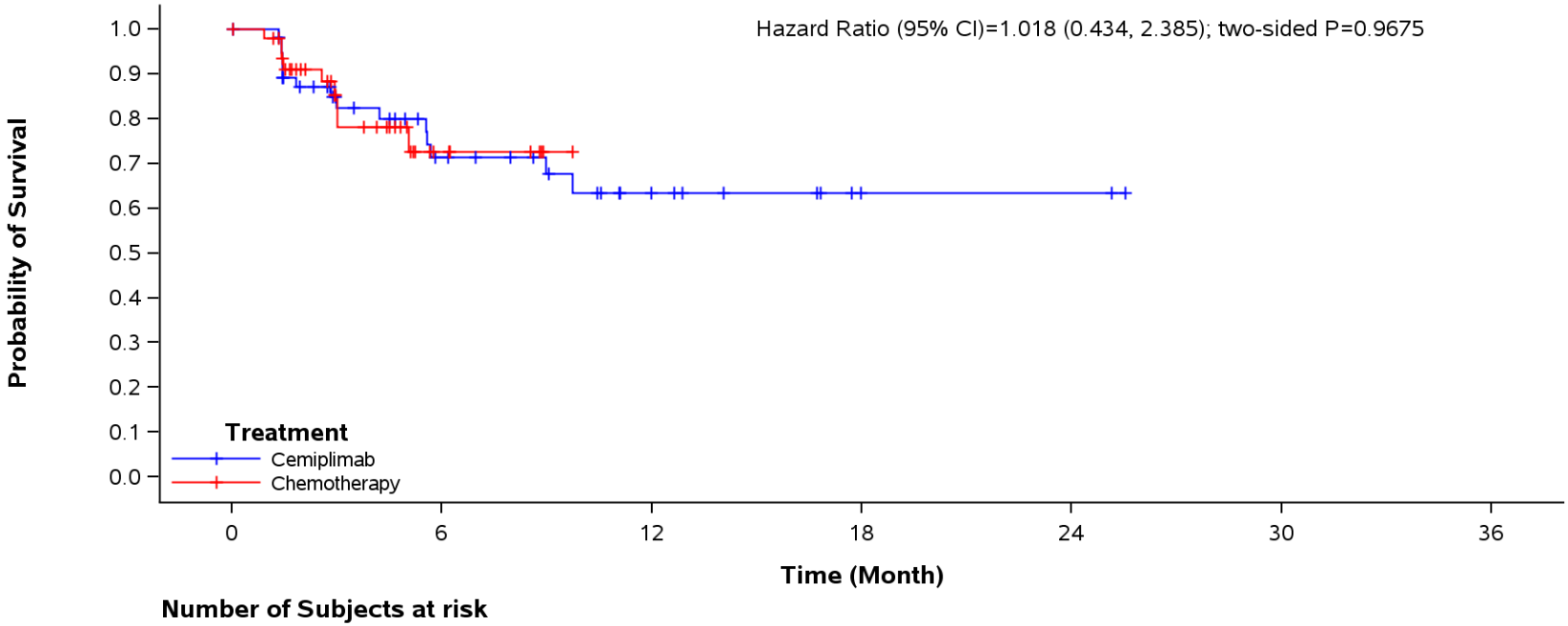

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 10 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Emotional Functioning - 10 pts sustained improvement



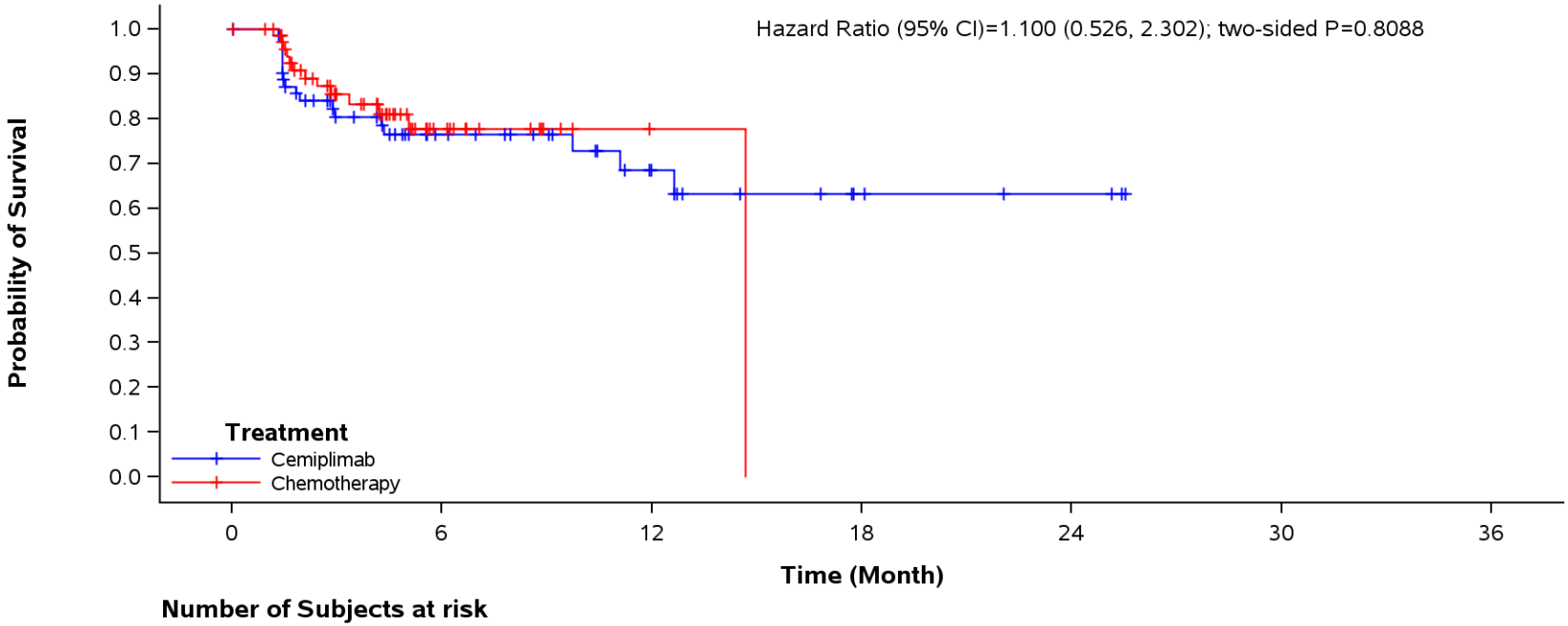

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 24 | 10 | 2 | 2 | 0 | 0 |
| Chemotherapy | 103 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Fatigue - 10 pts sustained improvement



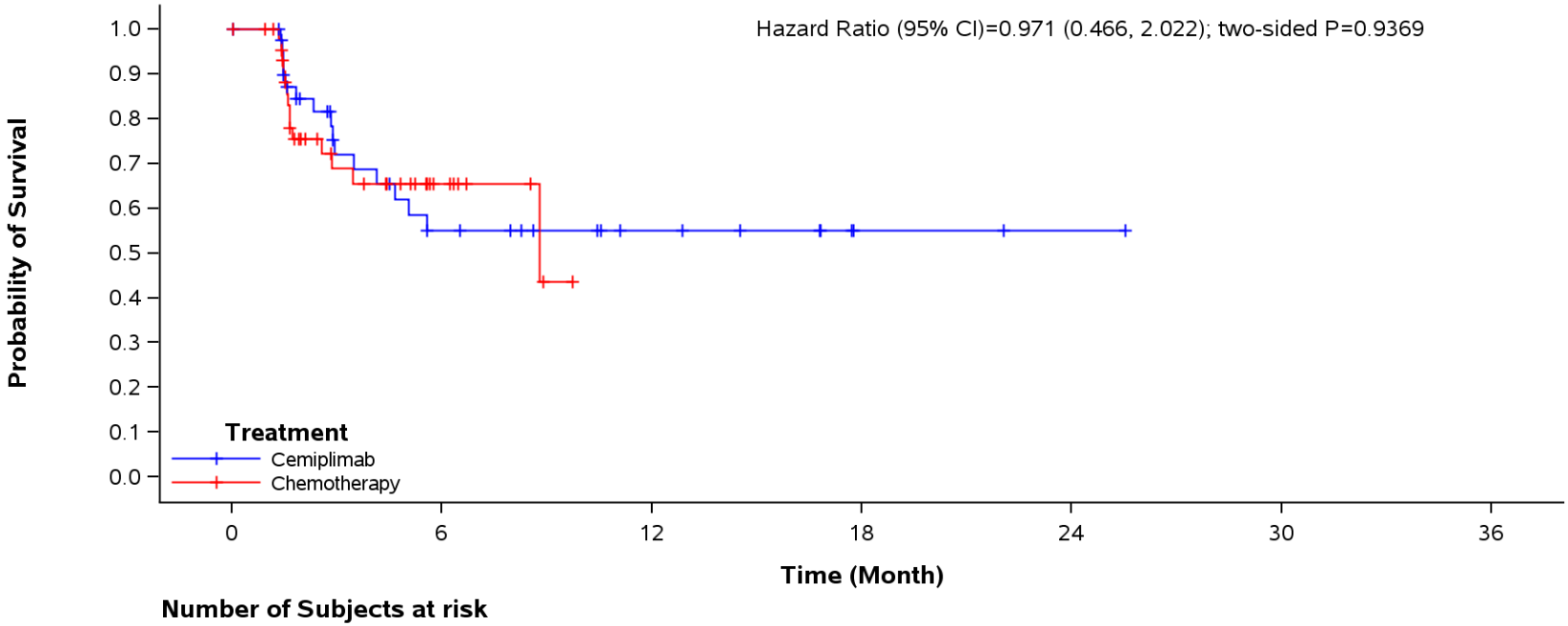

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 29 | 13 | 5 | 3 | 0 | 0 |
| Chemotherapy | 103 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Financial Problems - 10 pts sustained improvement



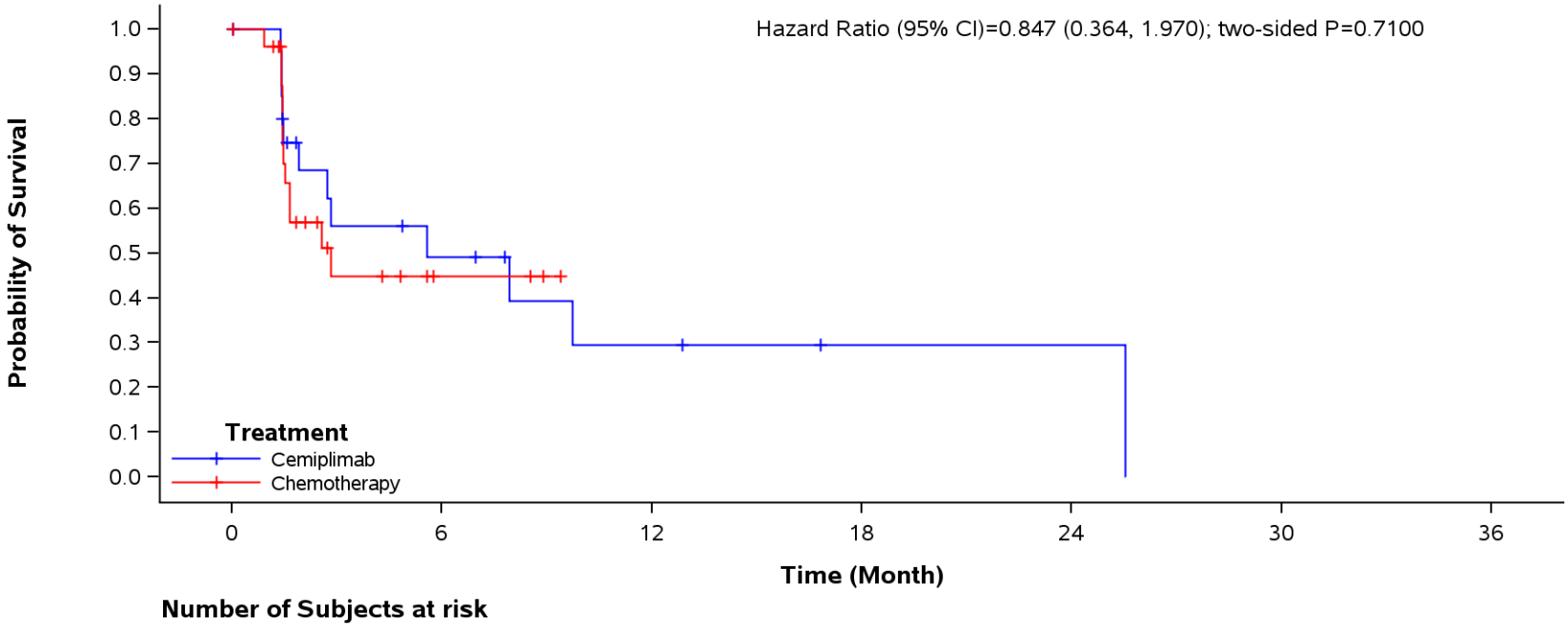

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 15 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Nausea / Vomiting - 10 pts sustained improvement



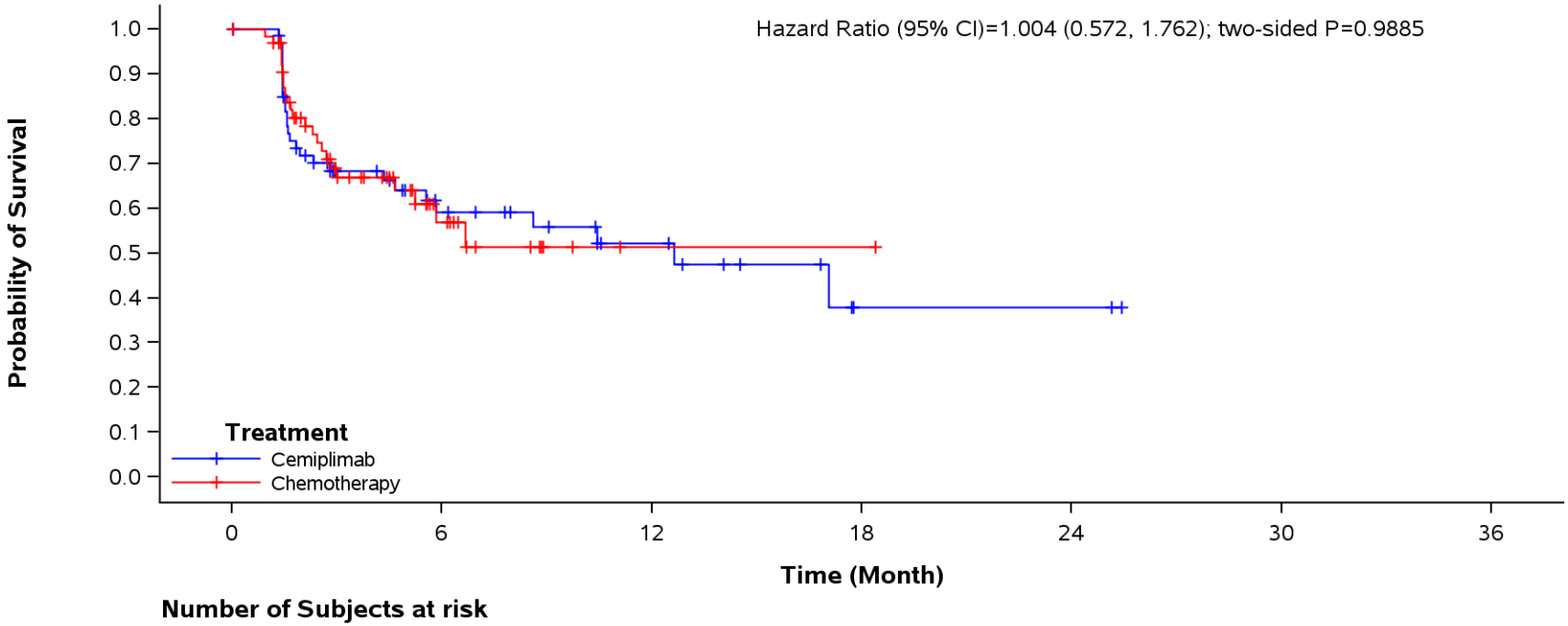

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 7 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 103 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Pain - 10 pts sustained improvement



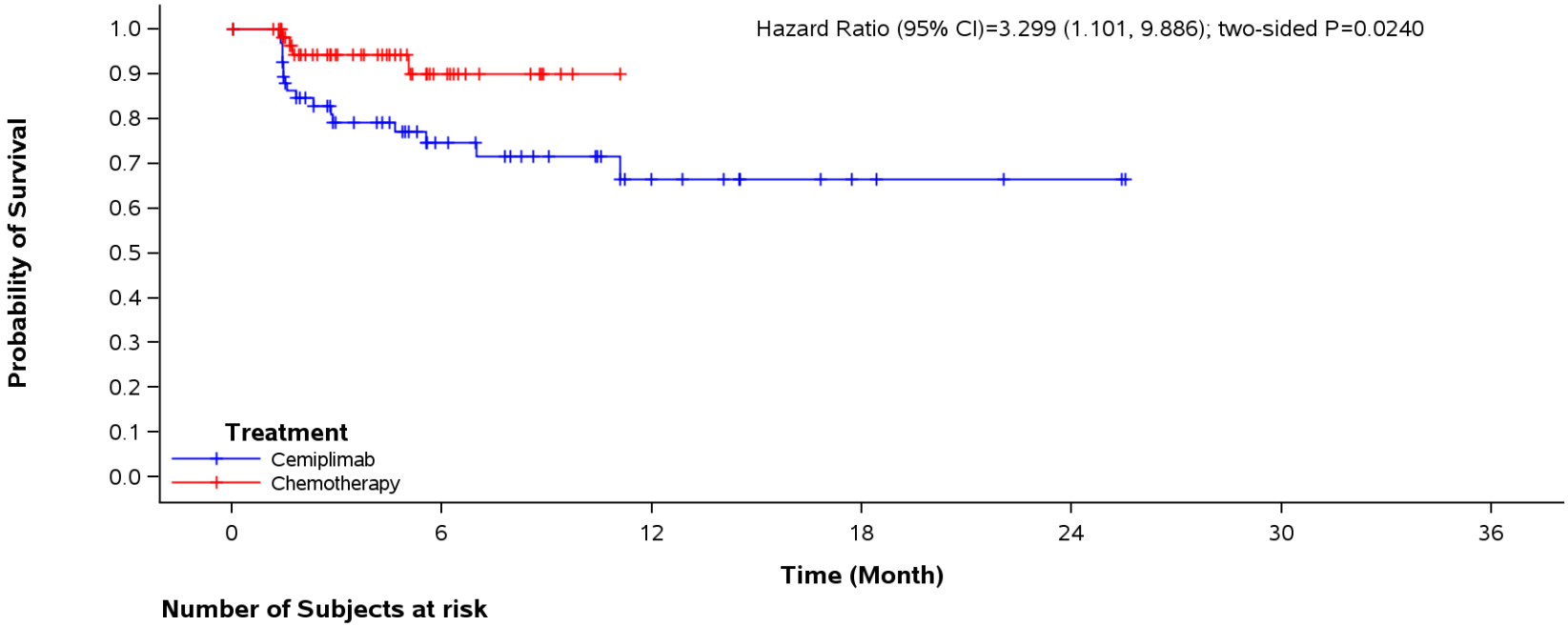

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 23 | 12 | 2 | 2 | 0 | 0 |
| Chemotherapy | 103 | 14 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Physical Functioning - 10 pts sustained improvement



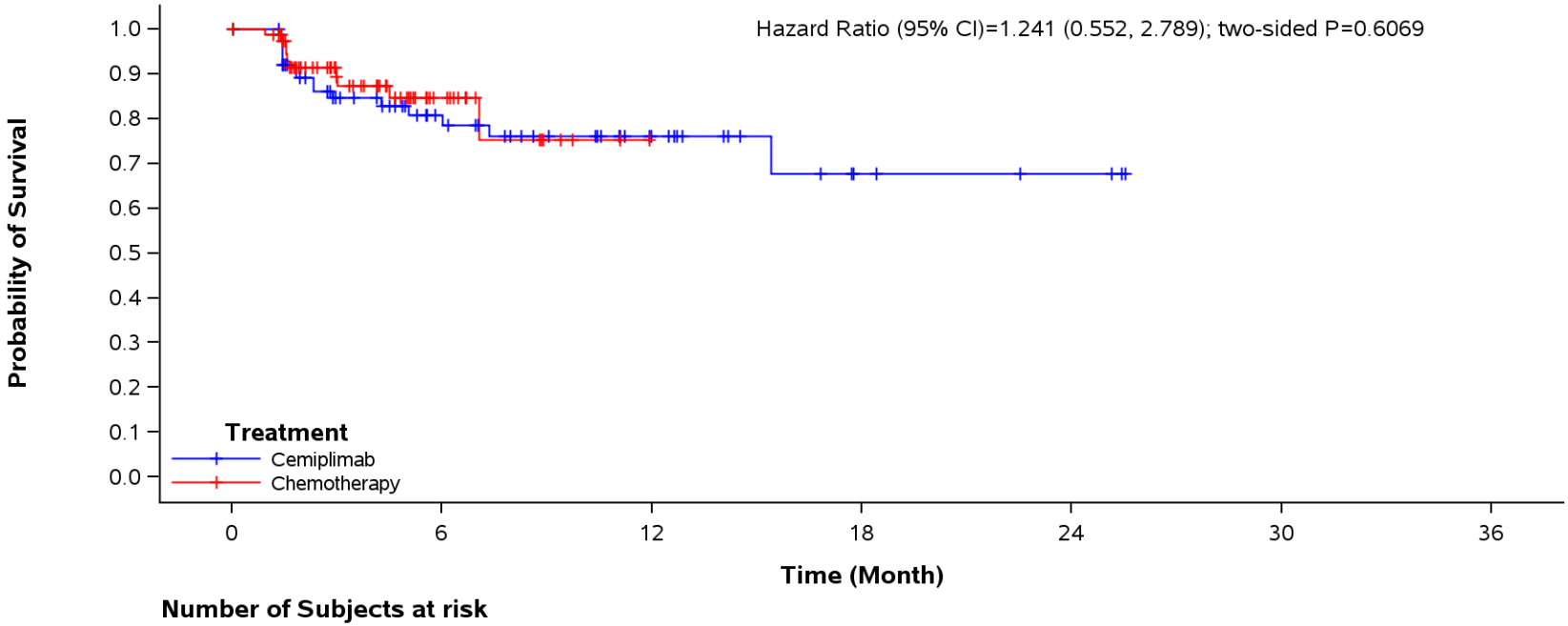

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 27 | 10 | 4 | 2 | 0 | 0 |
| Chemotherapy | 103 | 14 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Global health status / QoL - 10 pts sustained improvement



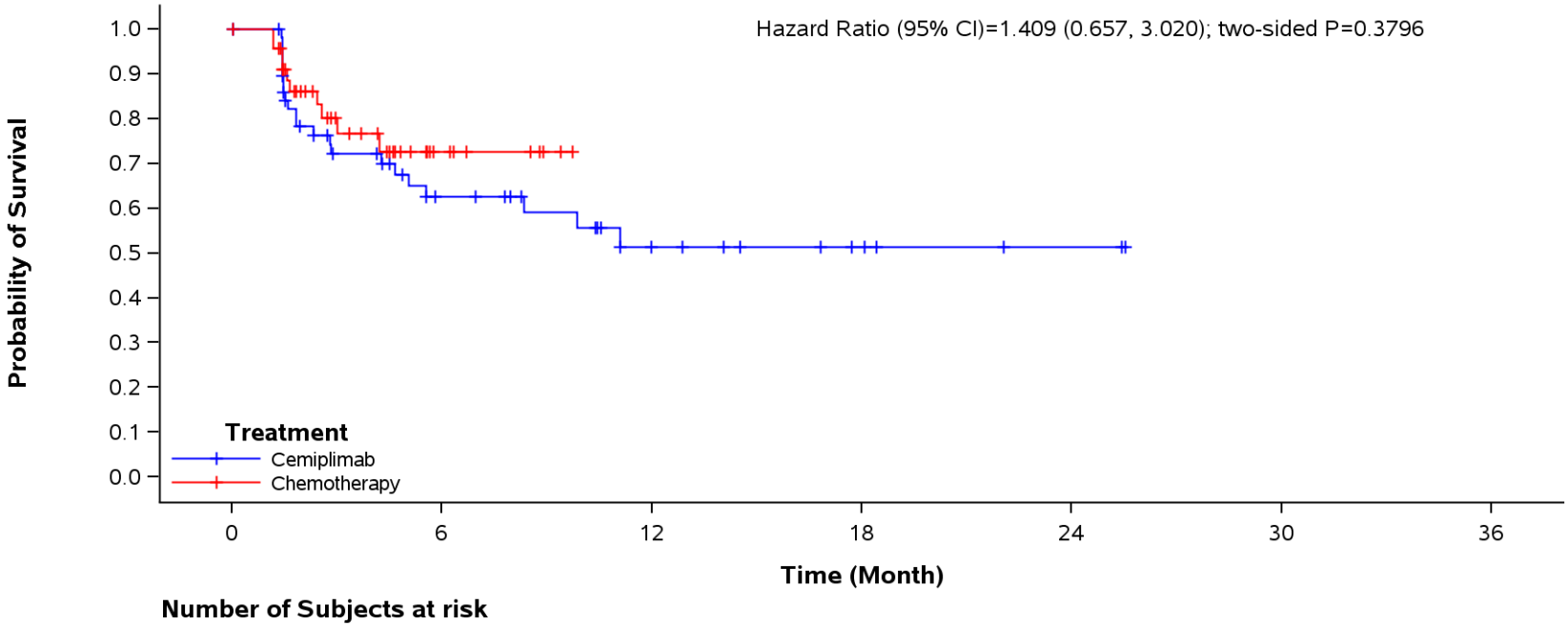

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 36 | 16 | 5 | 3 | 0 | 0 |
| Chemotherapy | 103 | 17 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Role Functioning - 10 pts sustained improvement



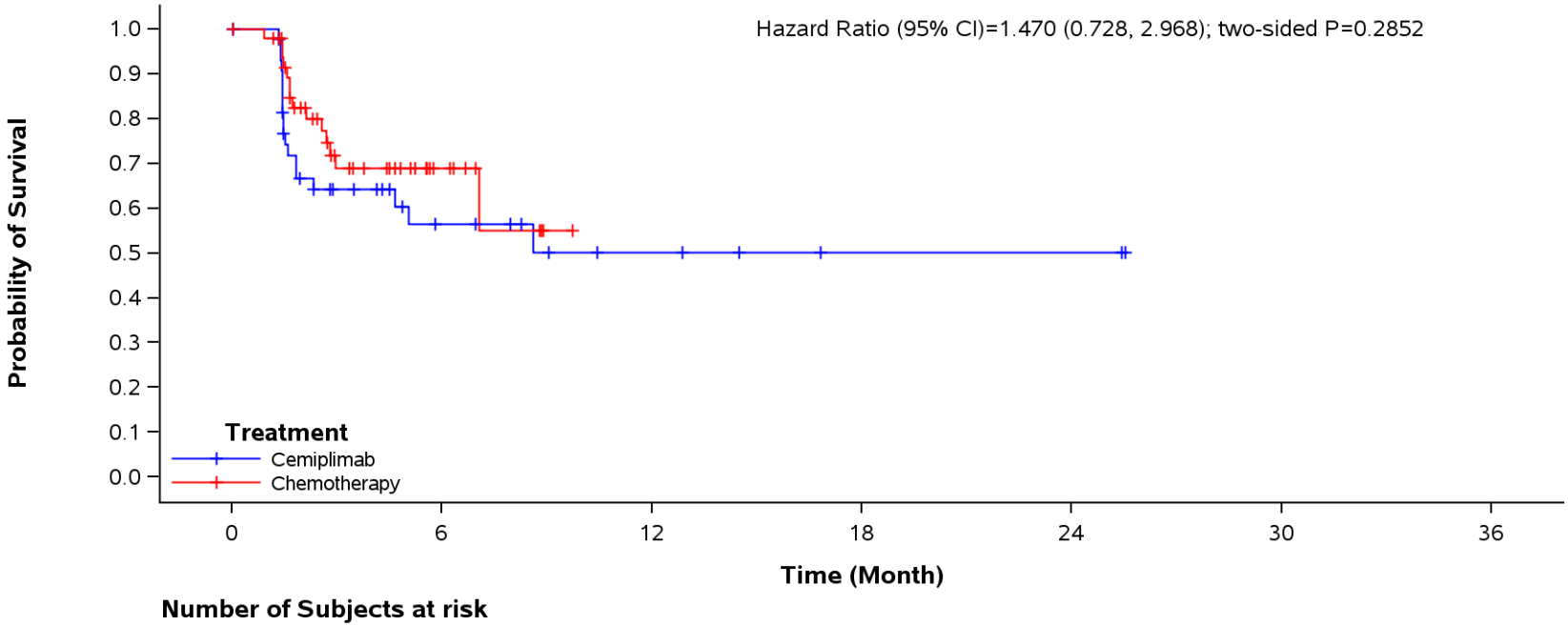

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 23 | 10 | 5 | 2 | 0 | 0 |
| Chemotherapy | 103 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Social Functioning - 10 pts sustained improvement



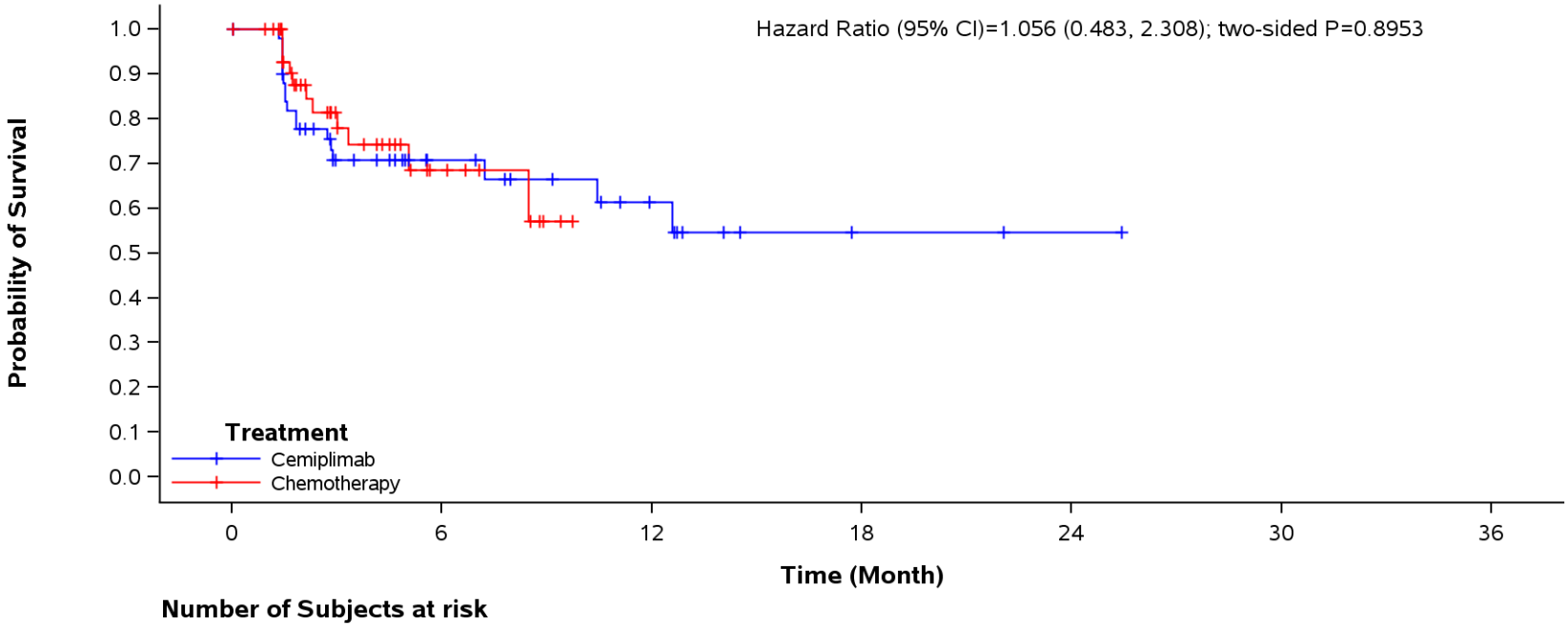

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 13 | 6 | 2 | 2 | 0 | 0 |
| Chemotherapy | 103 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Insomnia - 10 pts sustained improvement



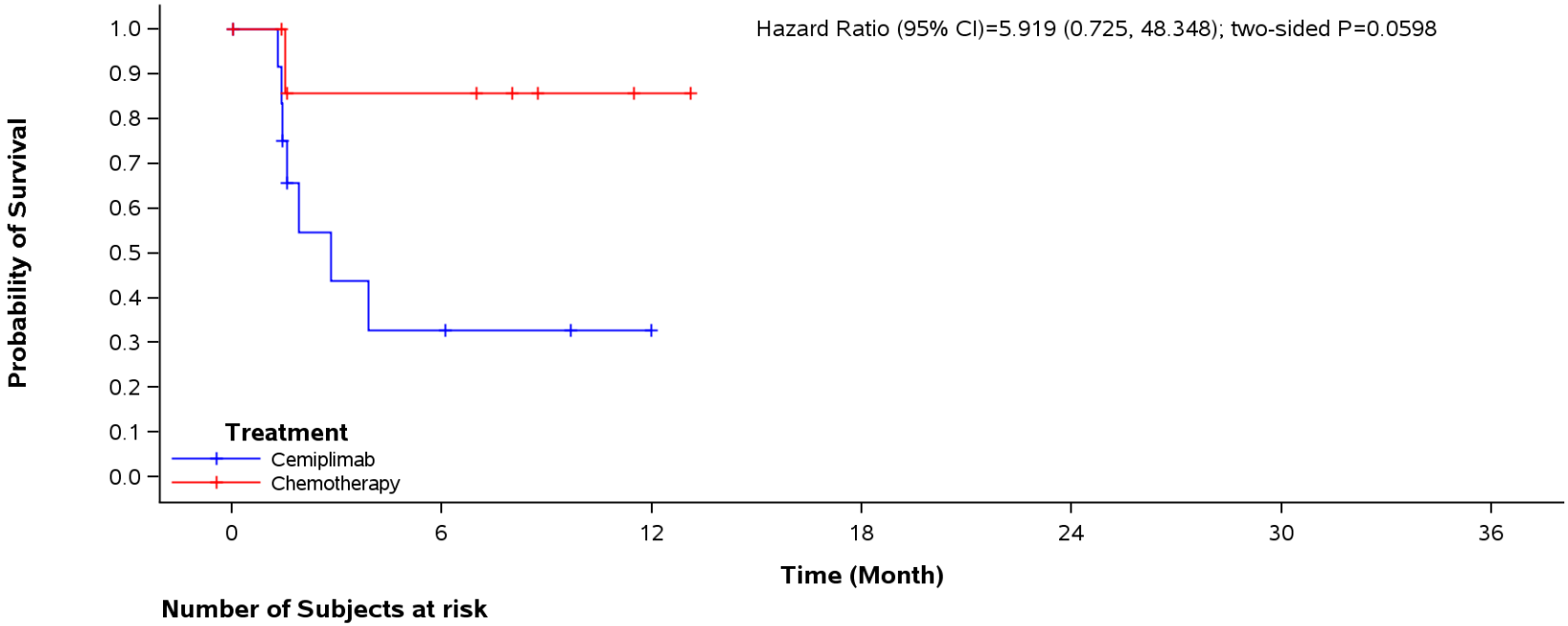

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 19 | 9 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Appetite loss - 10 pts sustained improvement



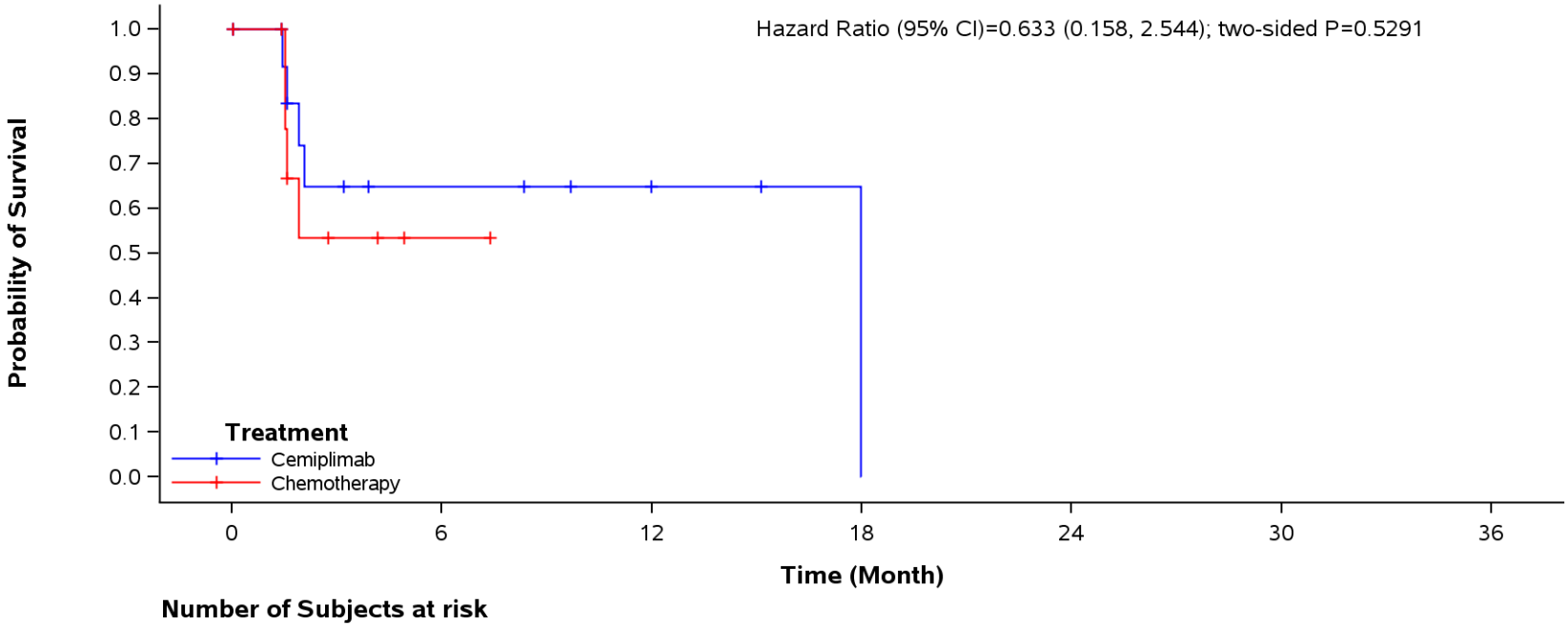

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Cognitive Functioning - 10 pts sustained improvement



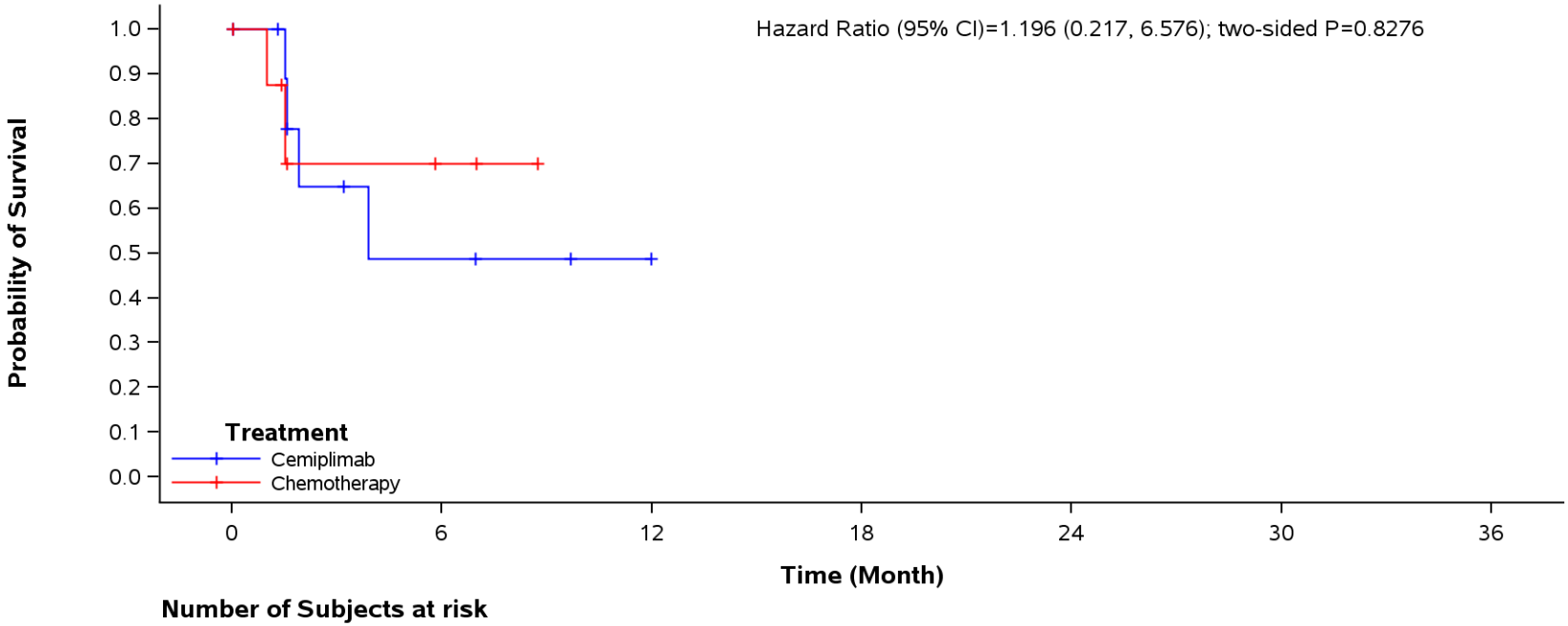

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Constipation - 10 pts sustained improvement



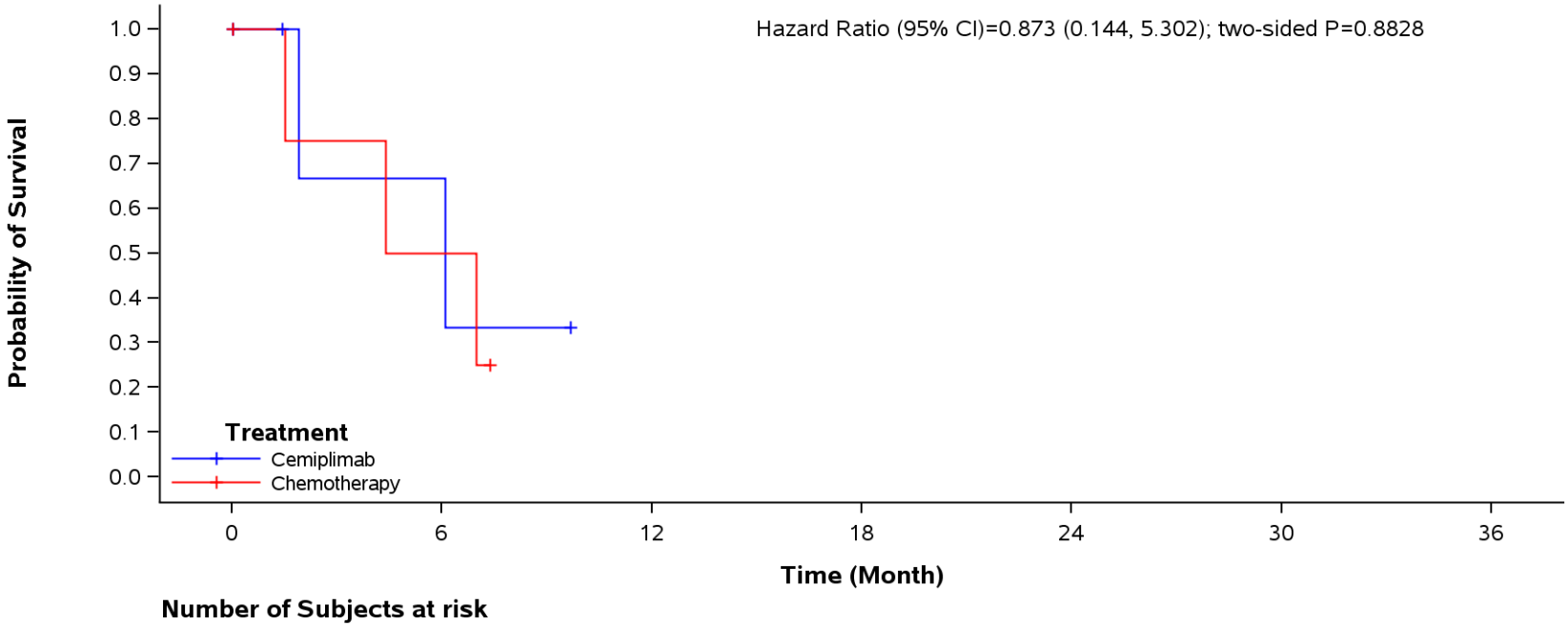

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Diarhoea - 10 pts sustained improvement



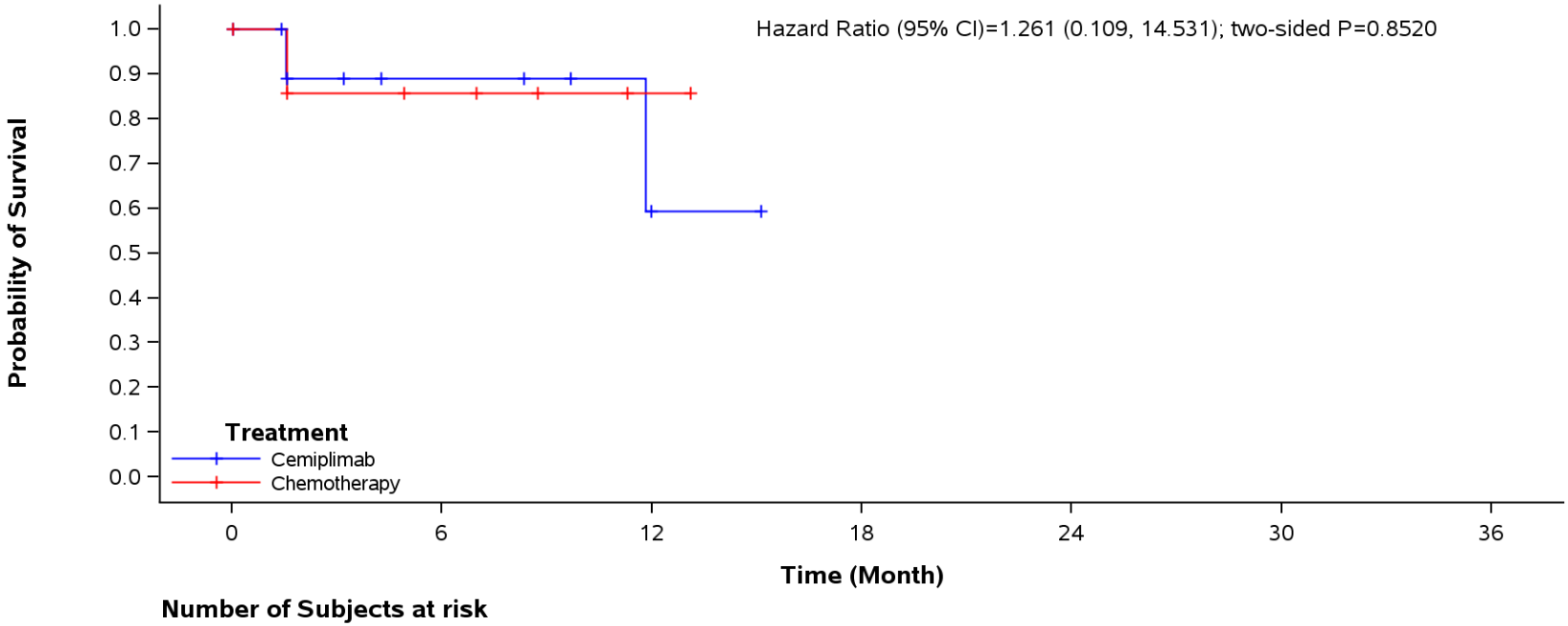

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Dyspnoea - 10 pts sustained improvement



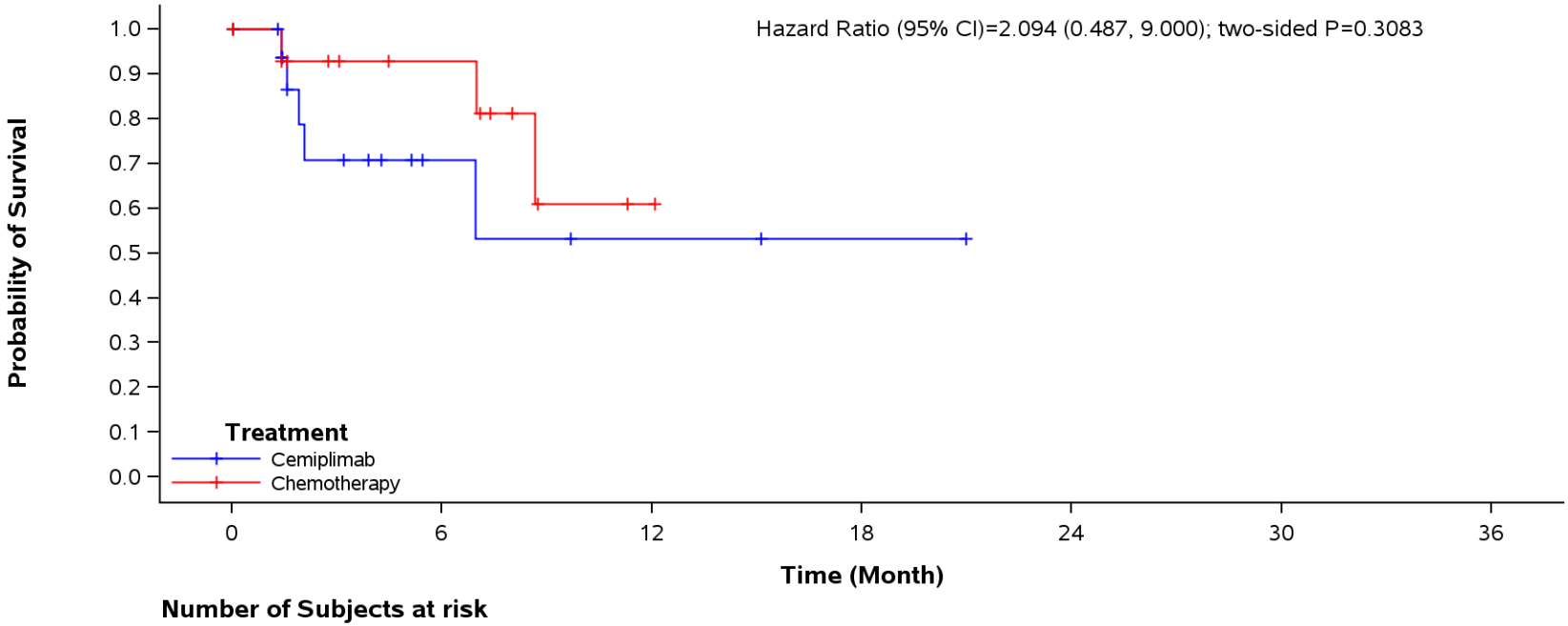

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Emotional Functioning - 10 pts sustained improvement



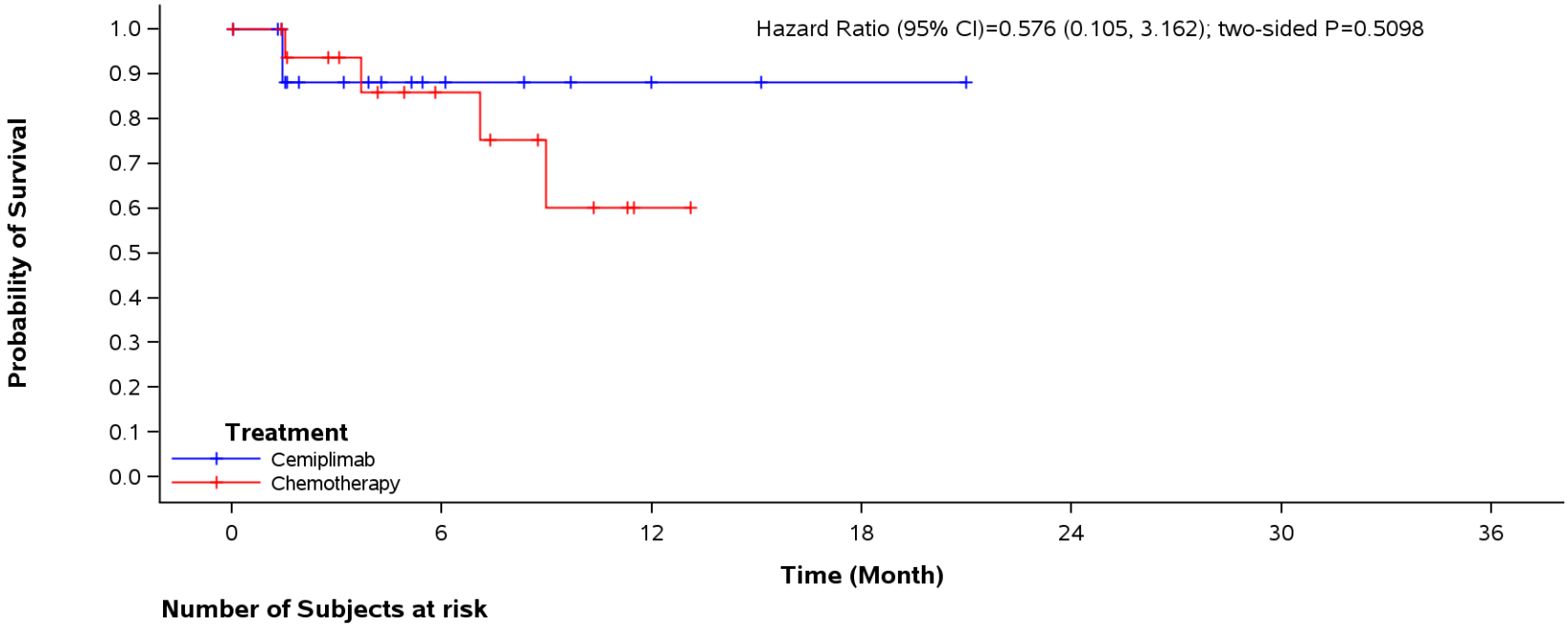

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Fatigue - 10 pts sustained improvement



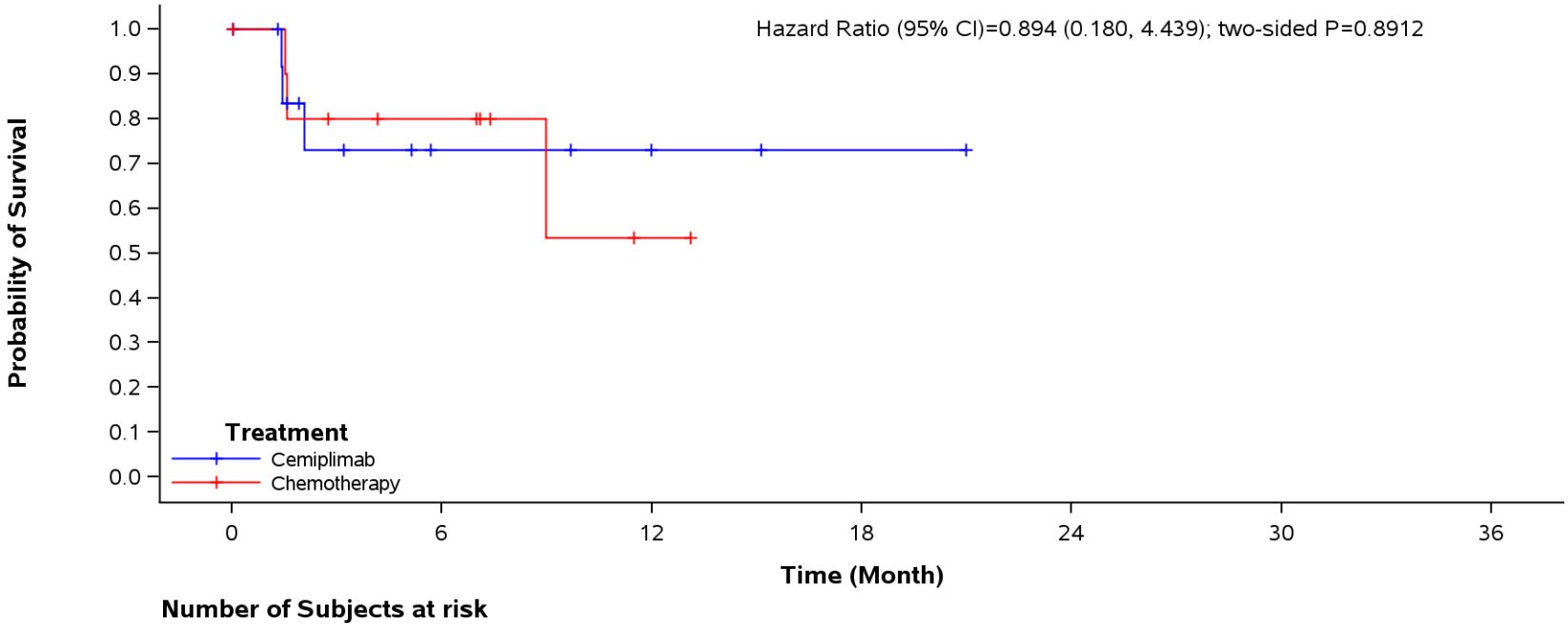

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Financial Problems - 10 pts sustained improvement



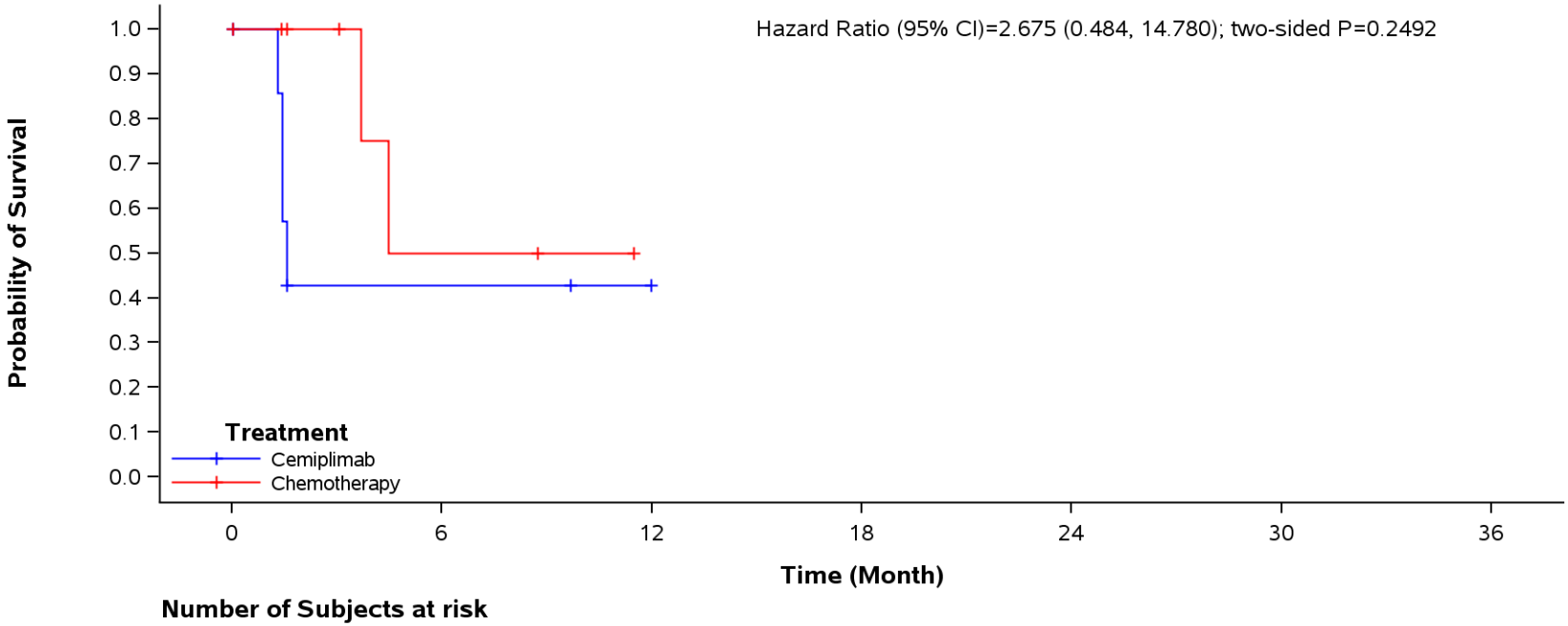

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Nausea / Vomiting - 10 pts sustained improvement



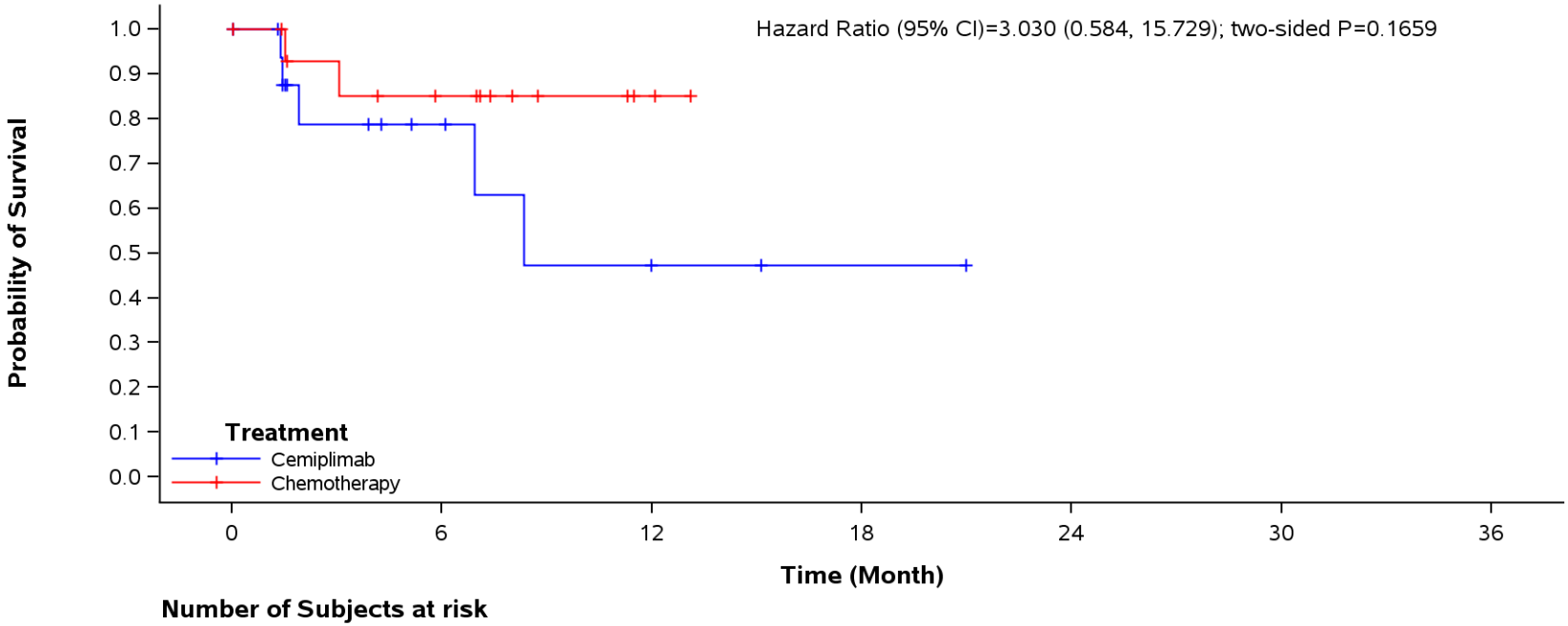

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Pain - 10 pts sustained improvement



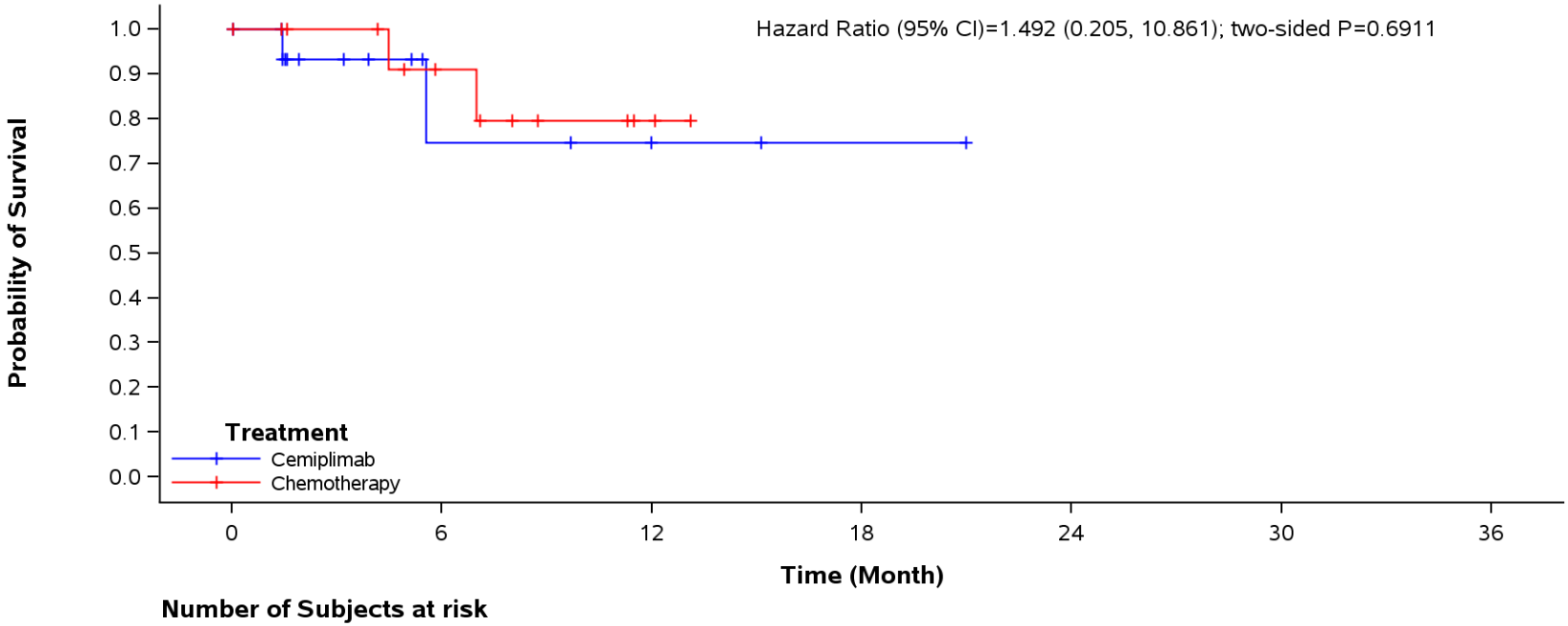

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Physical Functioning - 10 pts sustained improvement



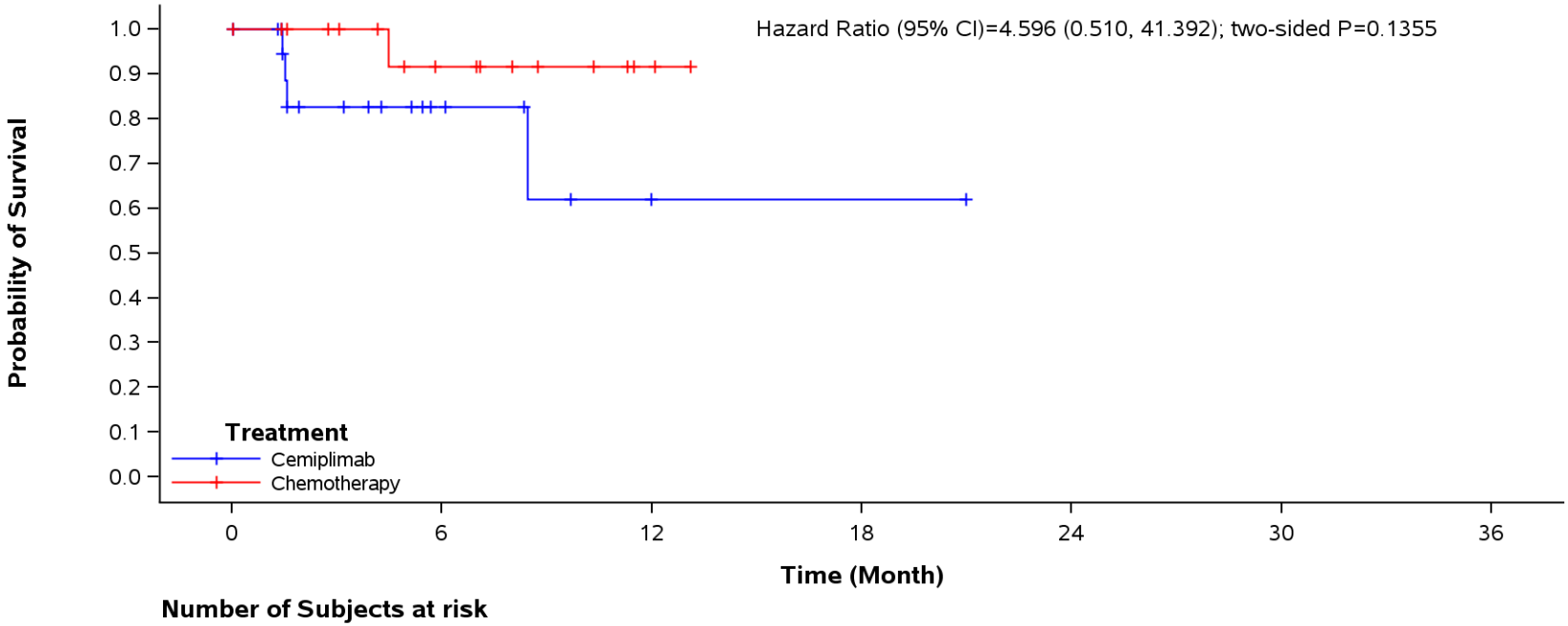

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Global health status / QoL - 10 pts sustained improvement



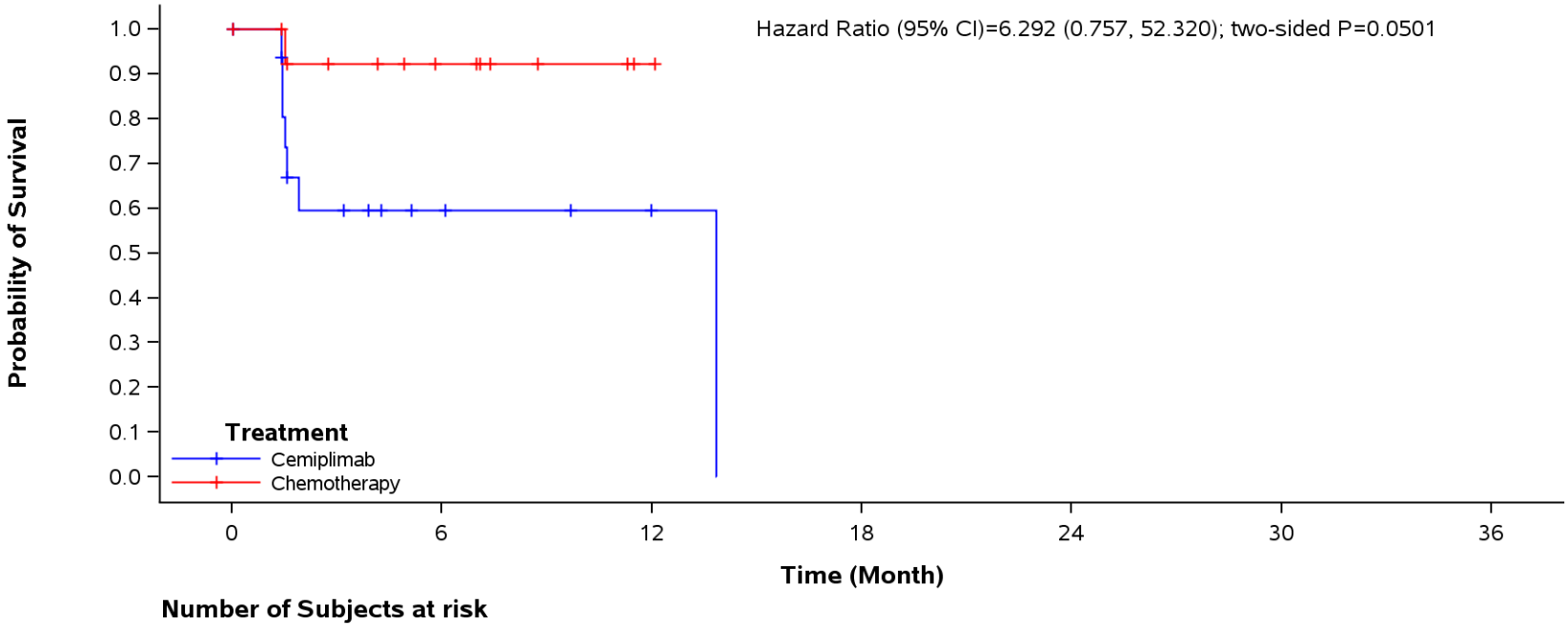

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Role Functioning - 10 pts sustained improvement



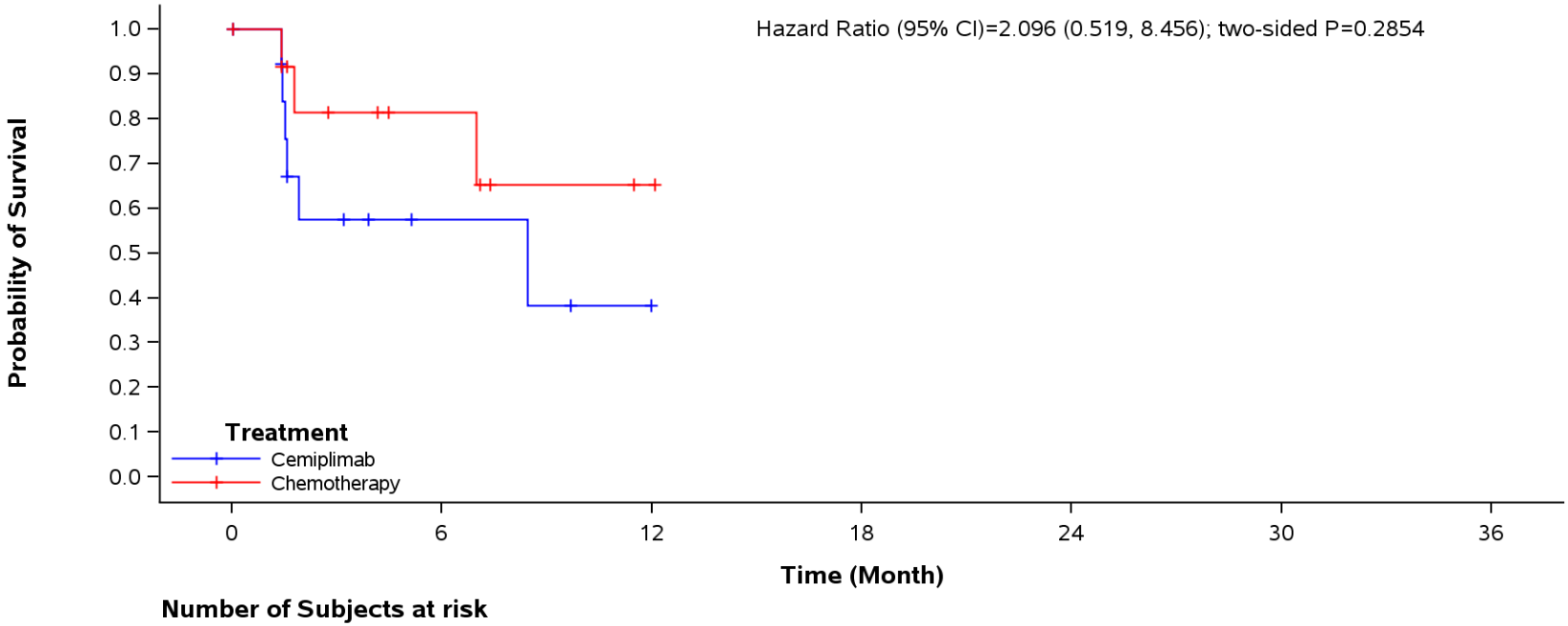

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Social Functioning - 10 pts sustained improvement



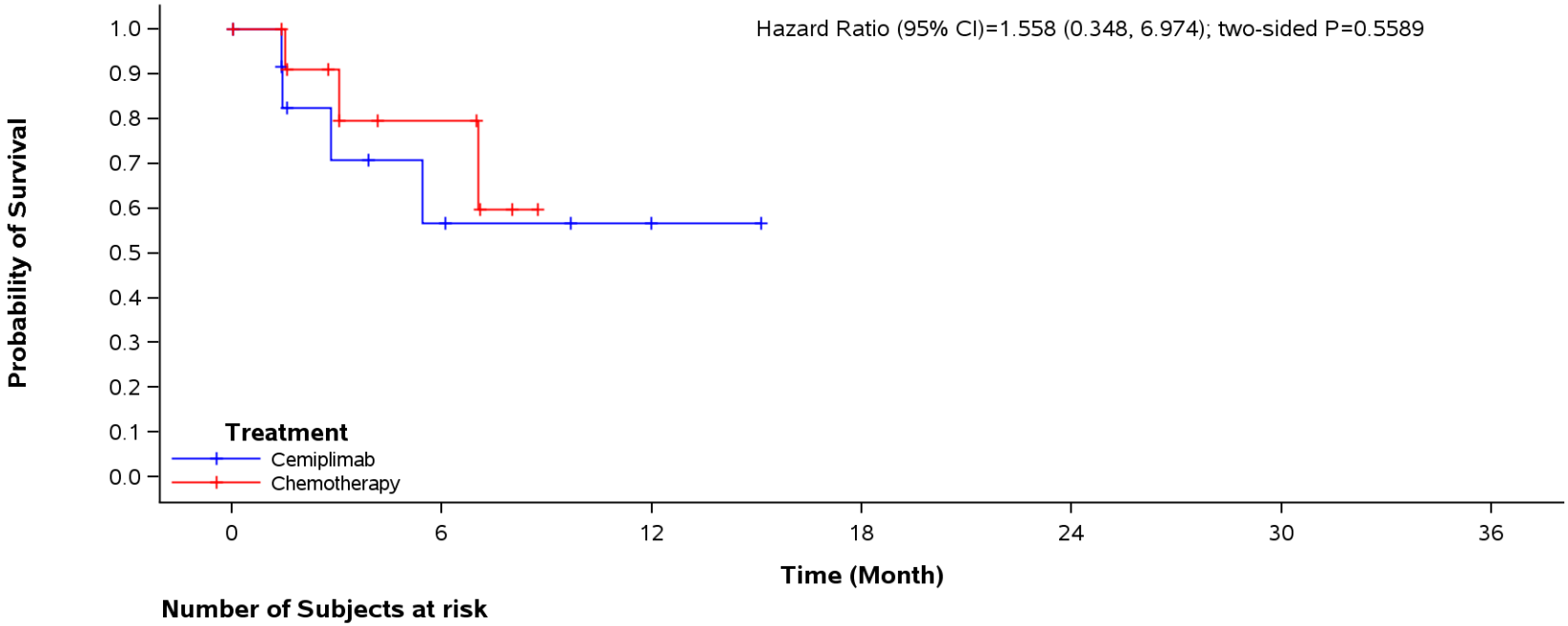

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Insomnia - 10 pts sustained improvement



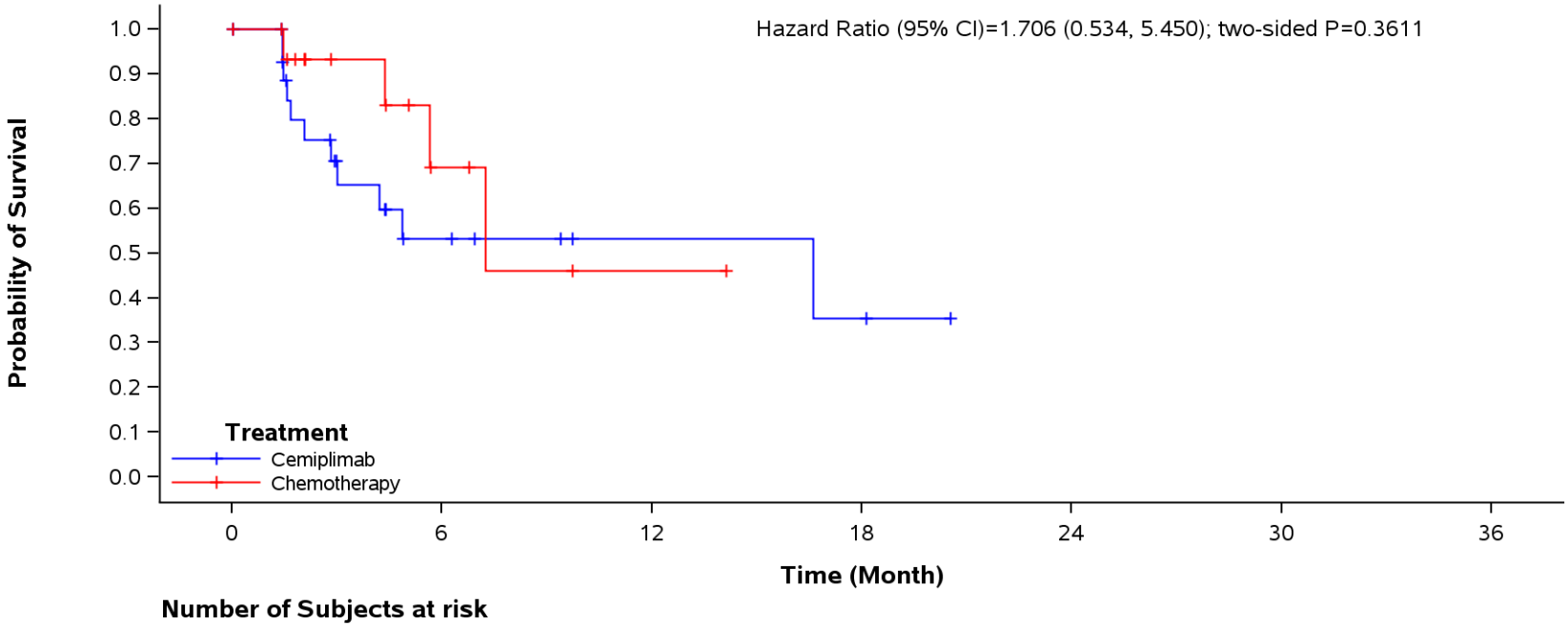

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Appetite loss - 10 pts sustained improvement



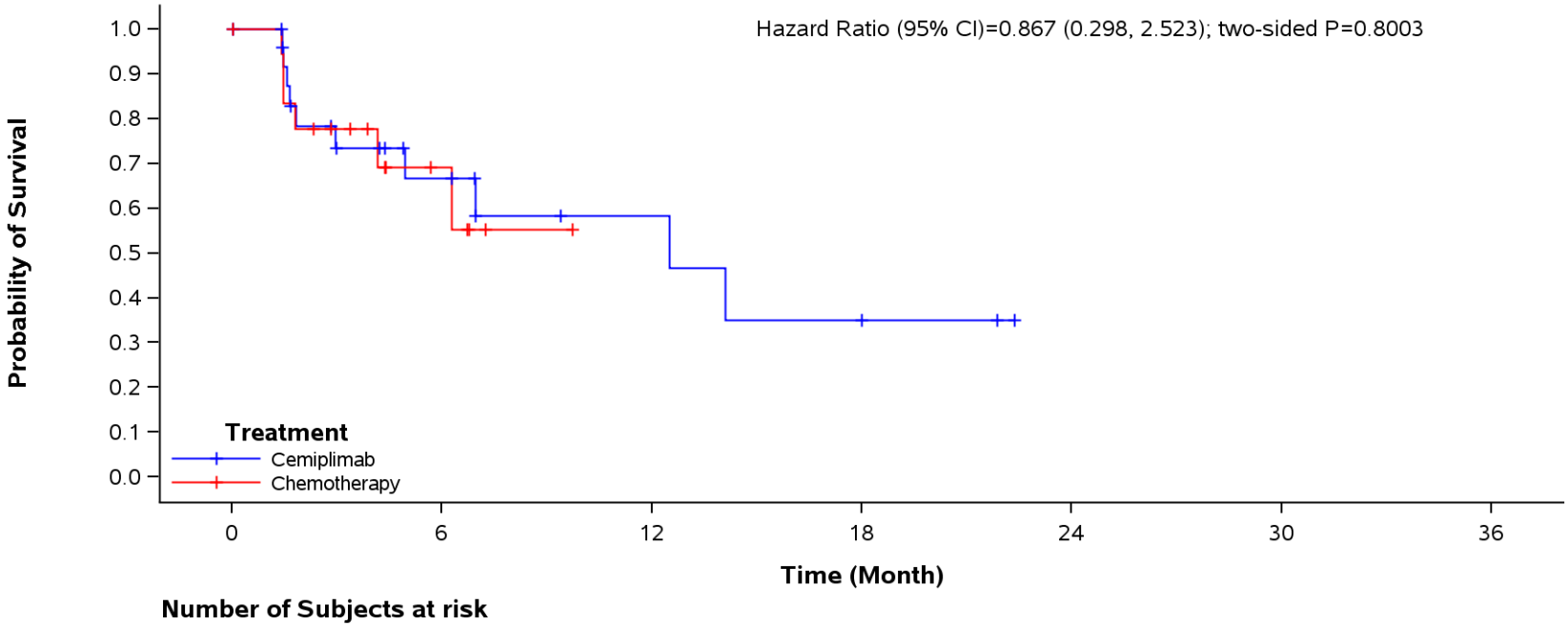

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 7 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Cognitive Functioning - 10 pts sustained improvement



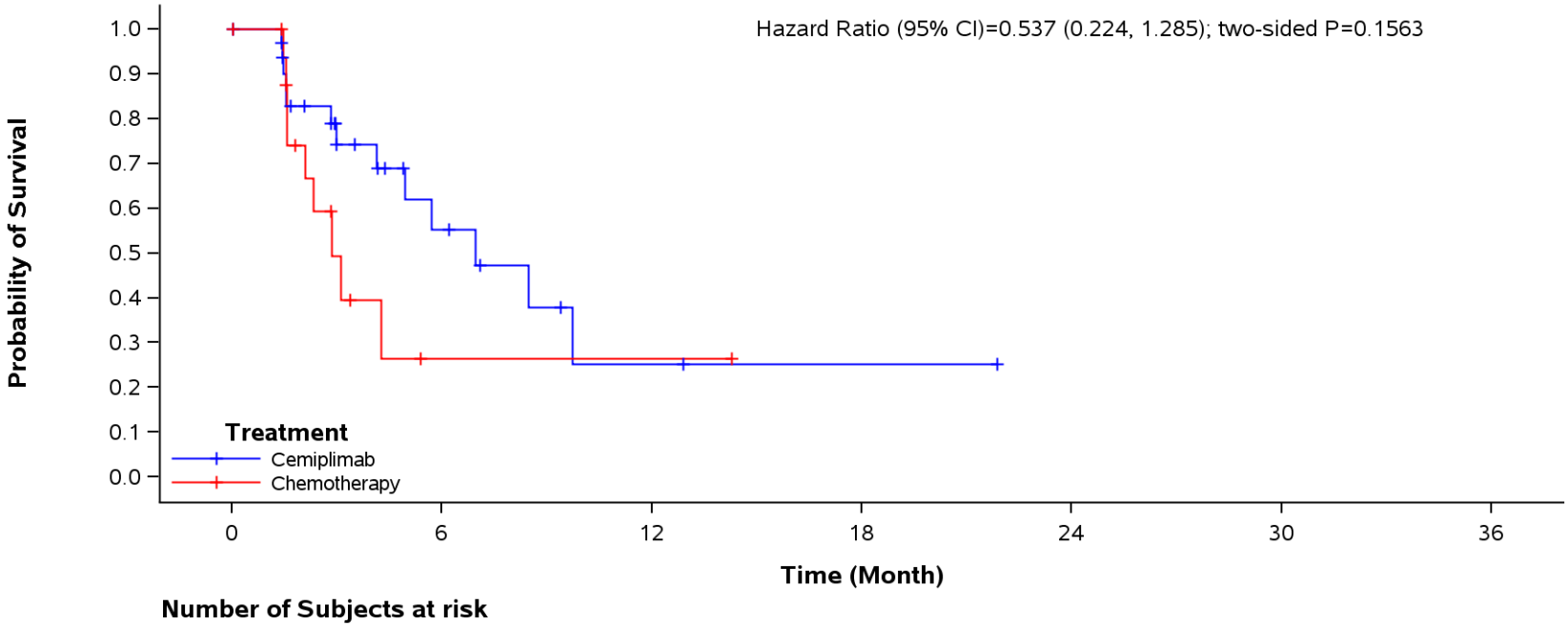

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 10 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Constipation - 10 pts sustained improvement



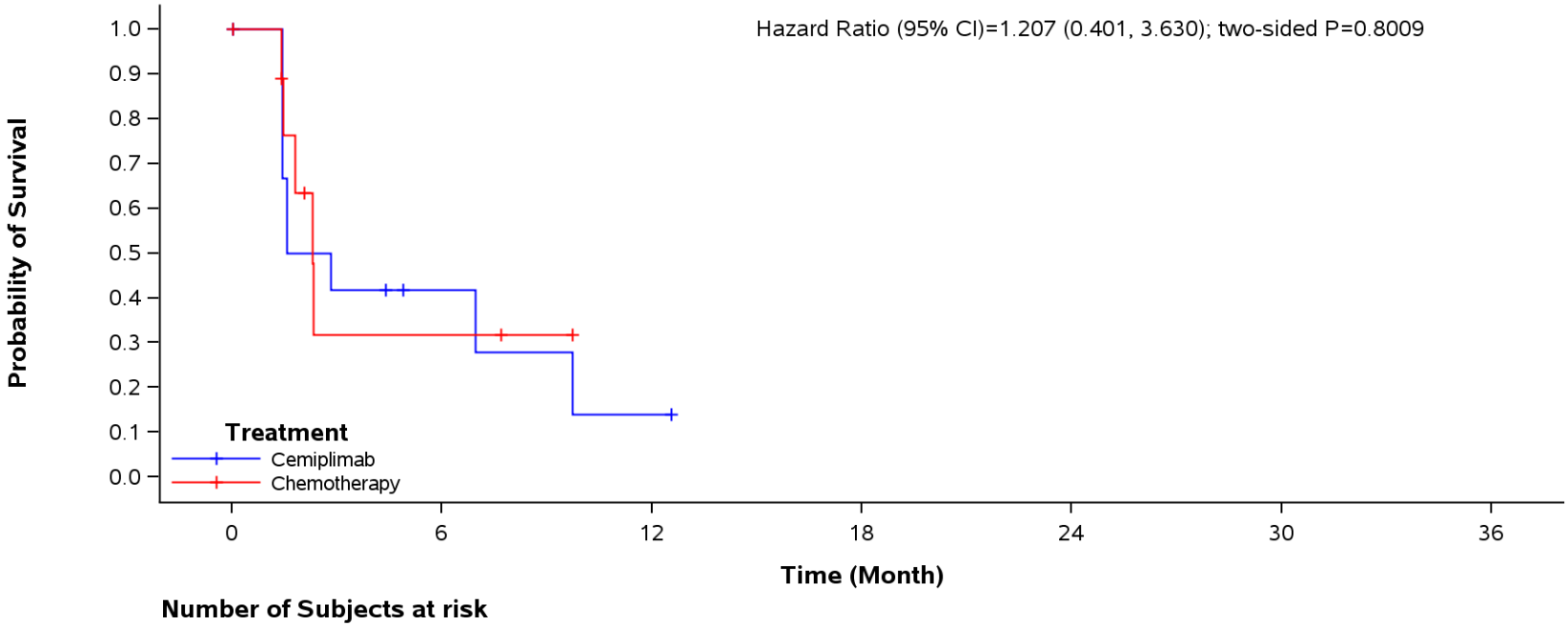

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 50 | 1 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Diarhoea - 10 pts sustained improvement



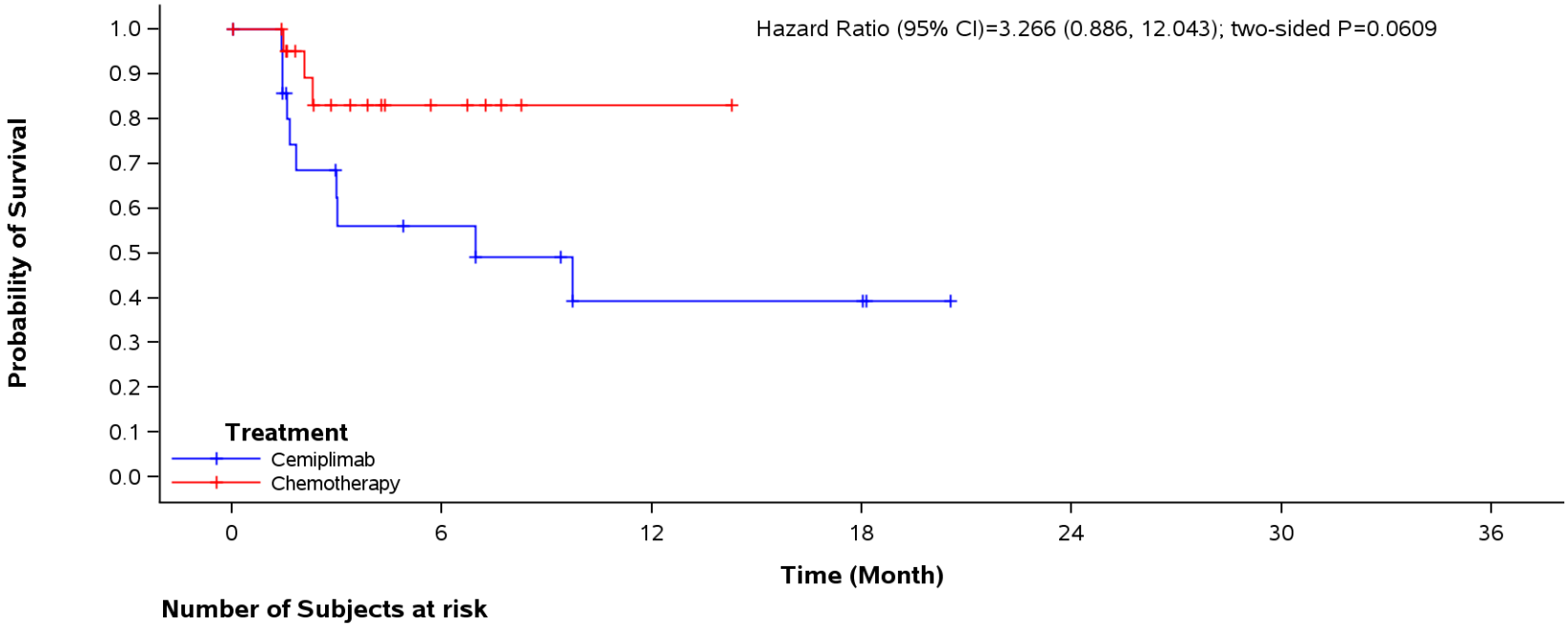

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Dyspnoea - 10 pts sustained improvement



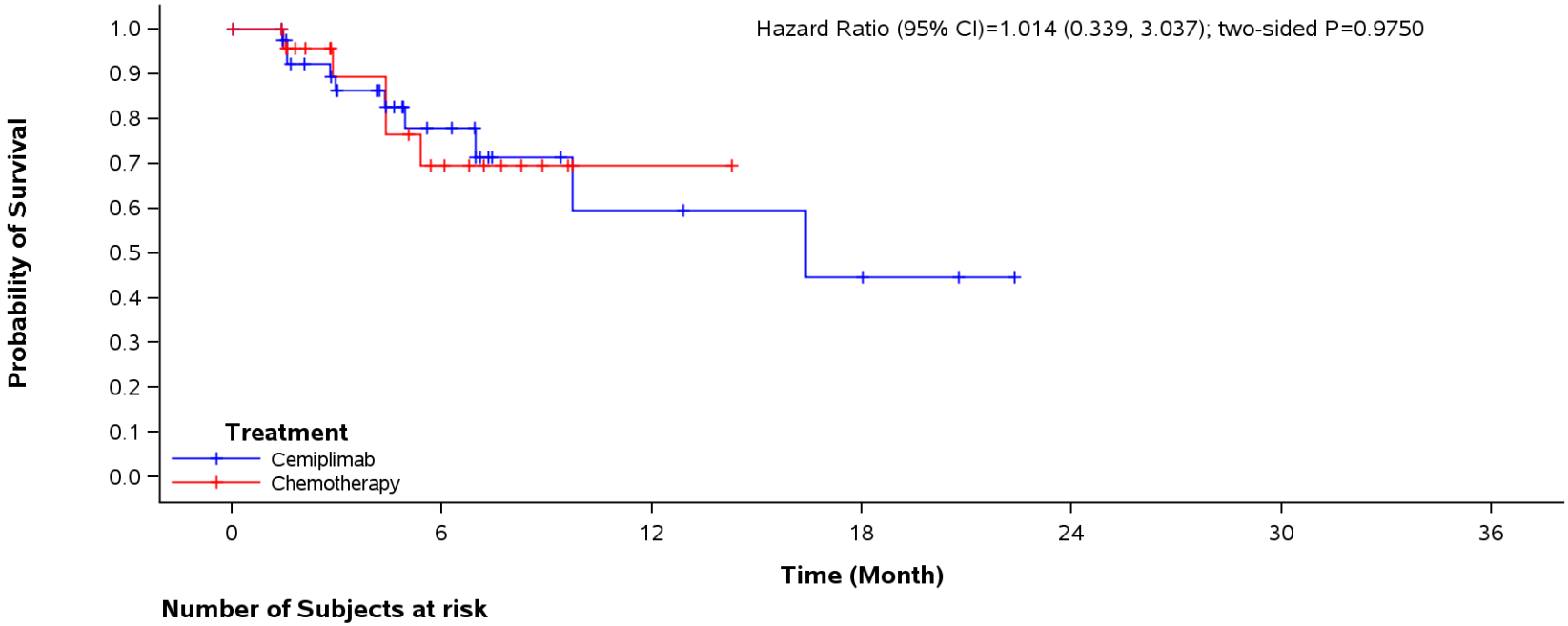

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 8 | 3 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Emotional Functioning - 10 pts sustained improvement



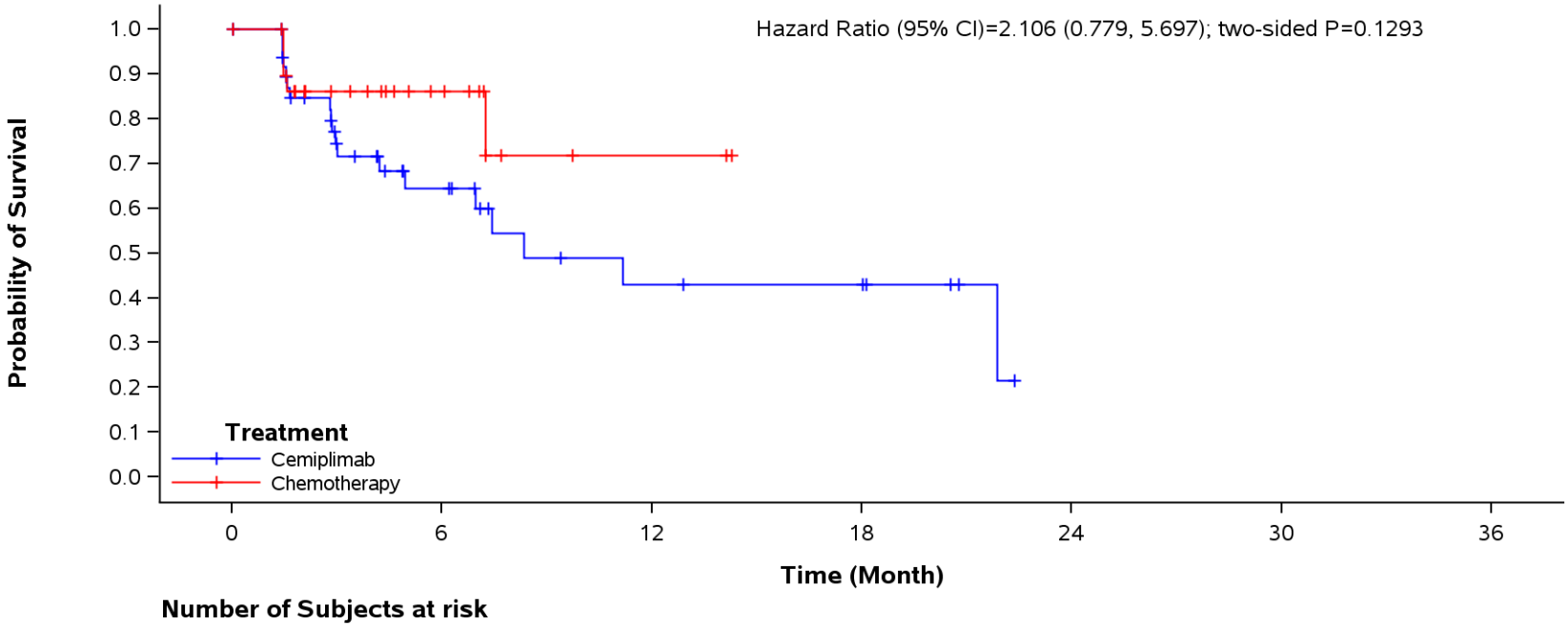

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 15 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Fatigue - 10 pts sustained improvement



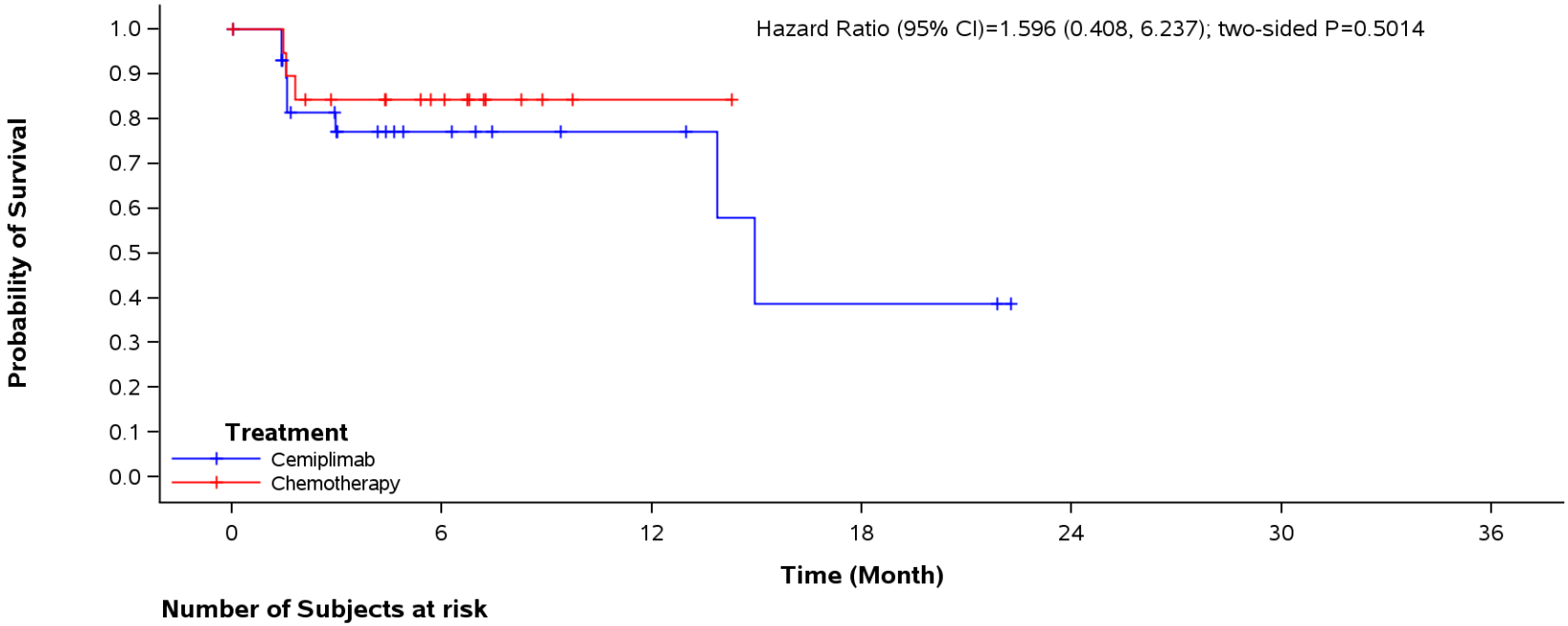

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 17 | 7 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Financial Problems - 10 pts sustained improvement



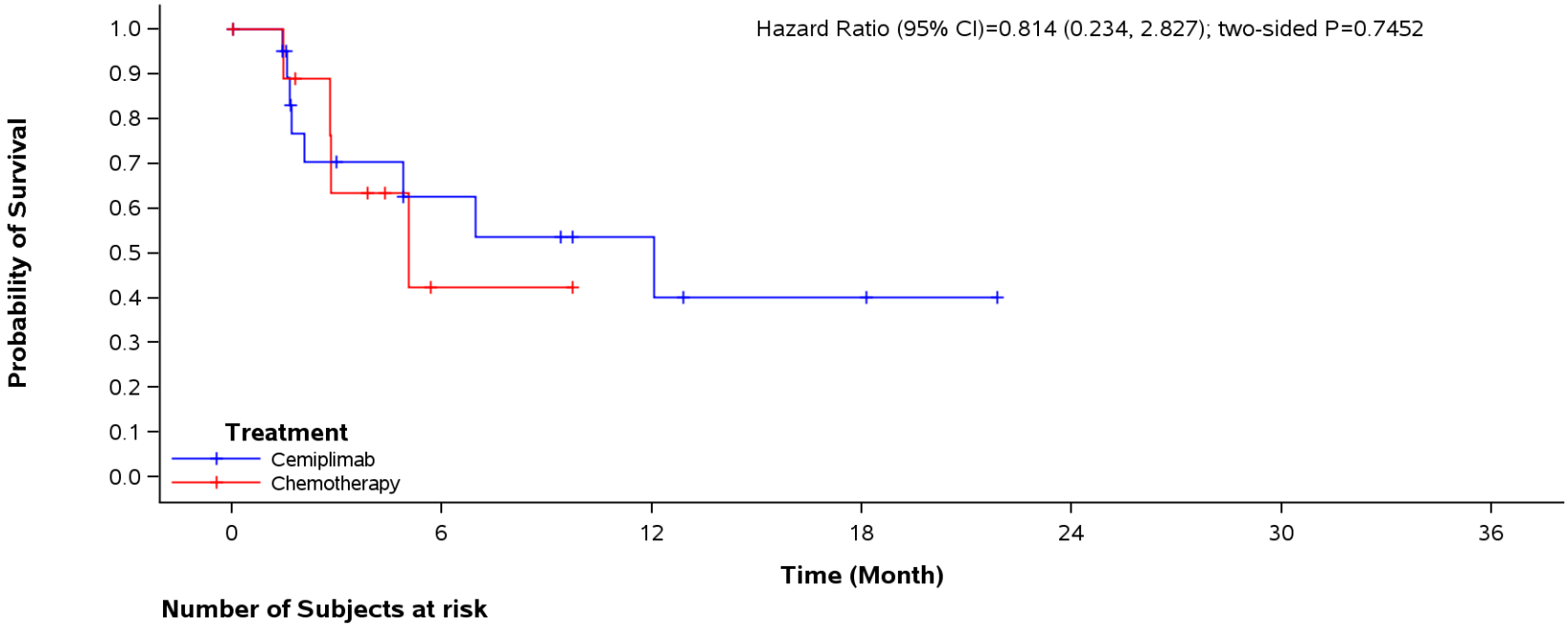

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 9 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Nausea / Vomiting - 10 pts sustained improvement



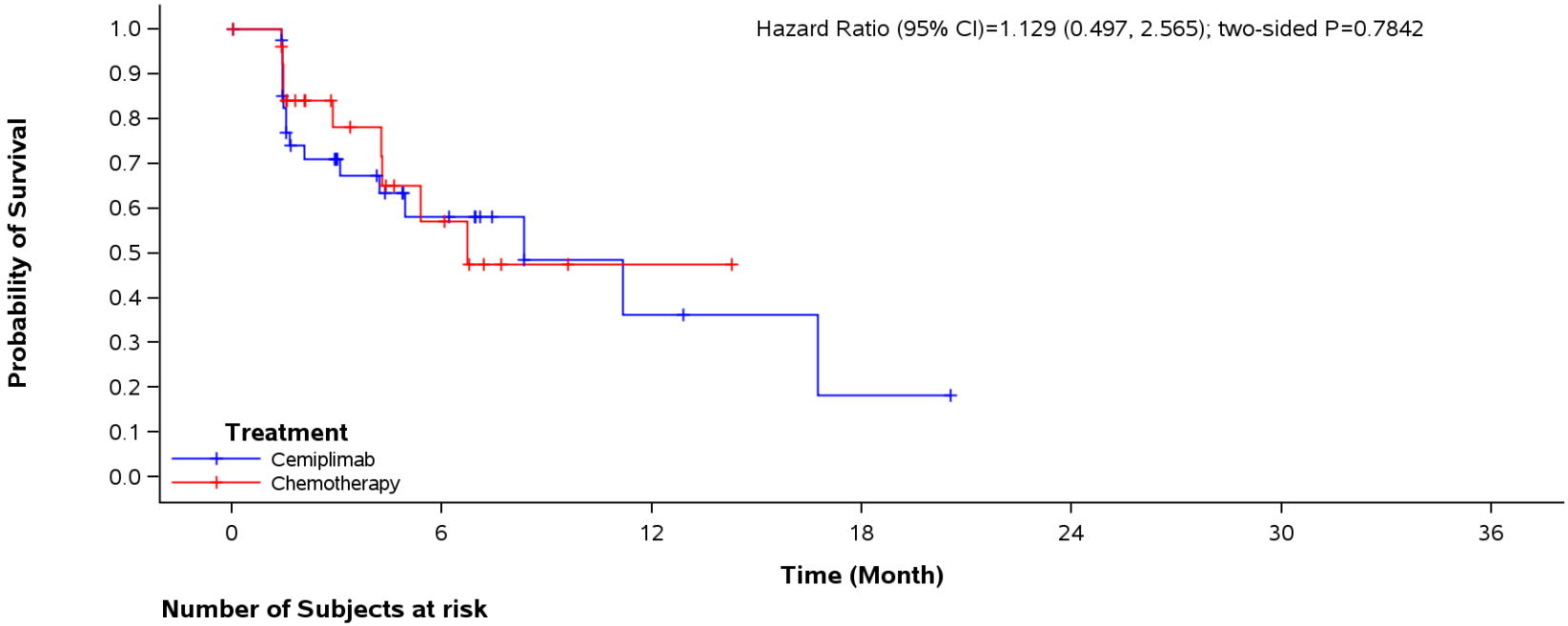

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 7 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Pain - 10 pts sustained improvement



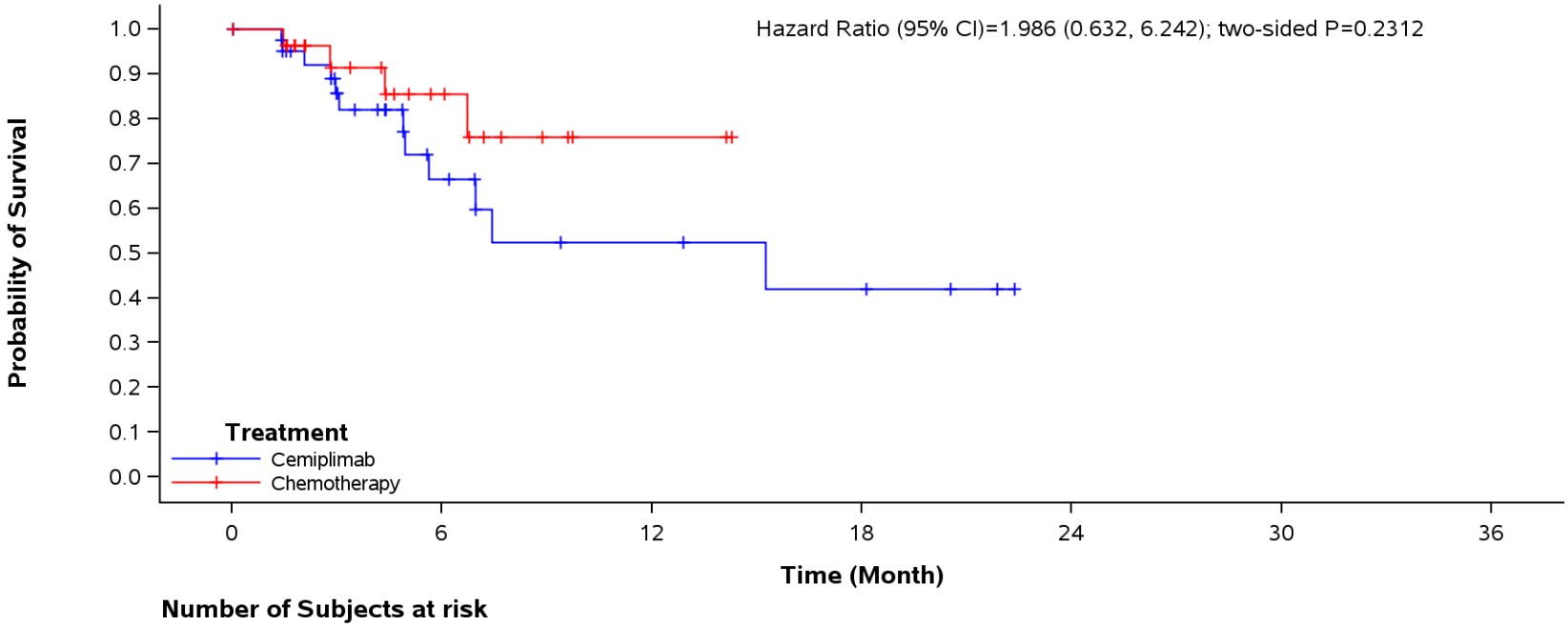

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 11 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 50 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Physical Functioning - 10 pts sustained improvement



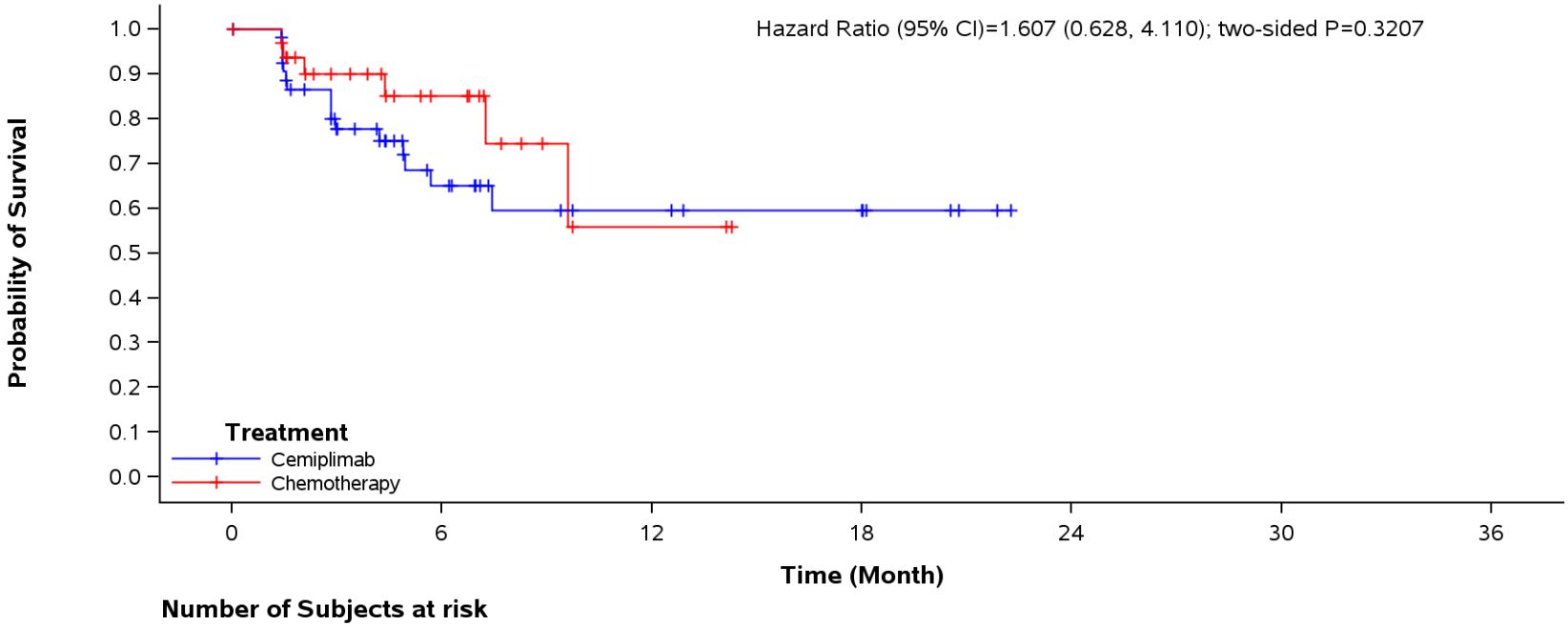

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 12 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Global health status / QoL - 10 pts sustained improvement



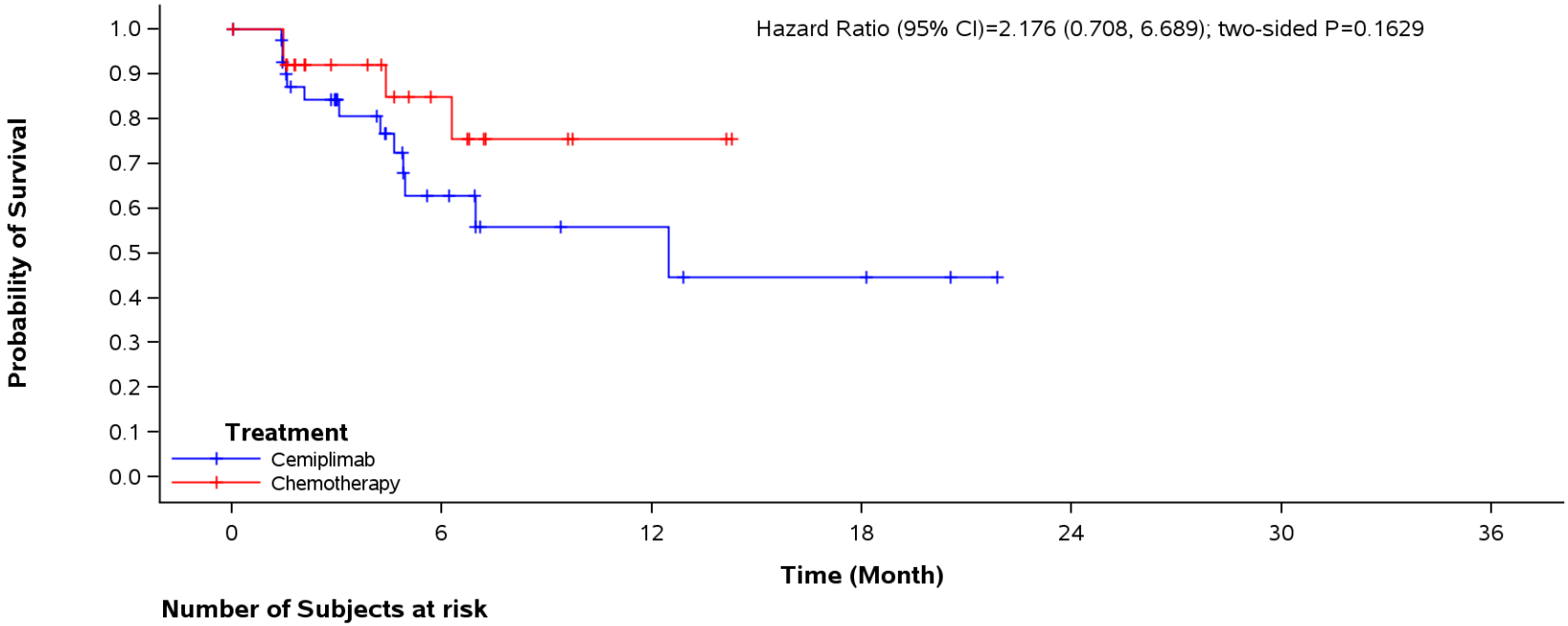

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 18 | 9 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Role Functioning - 10 pts sustained improvement



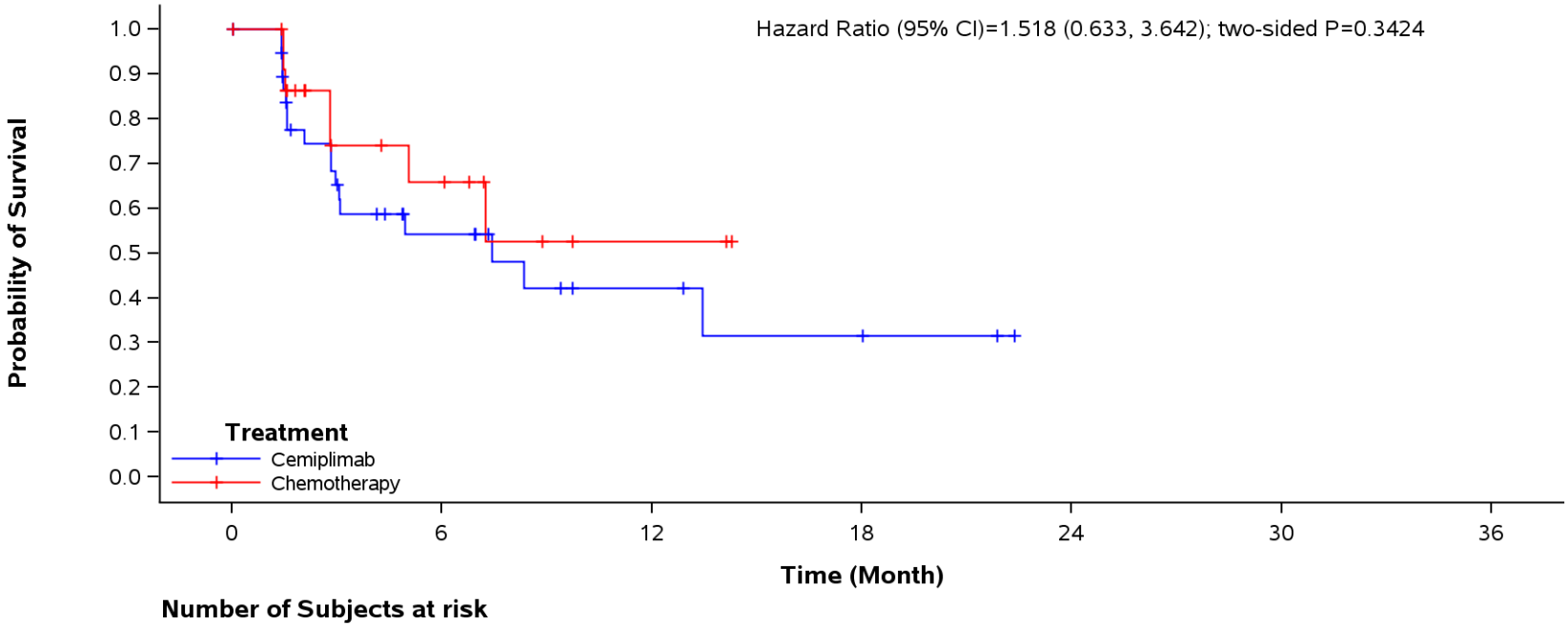

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 11 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Social Functioning - 10 pts sustained improvement



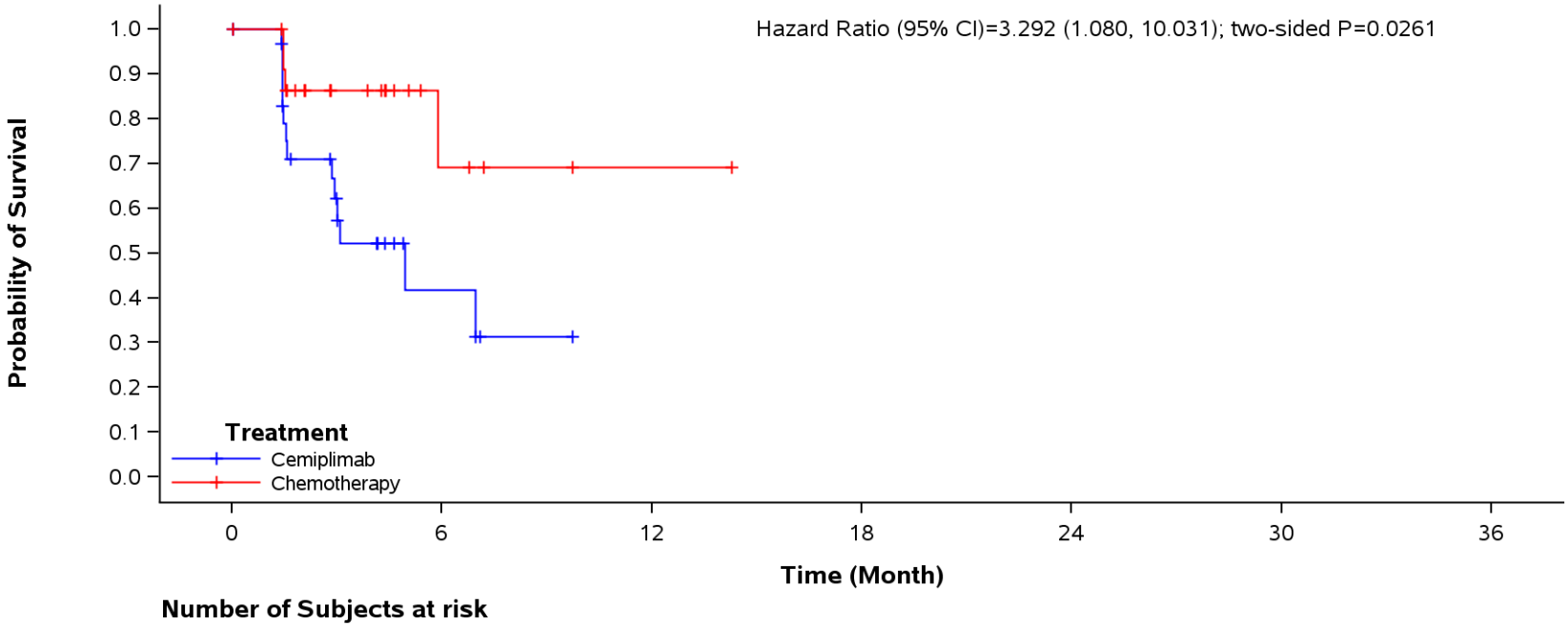

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 12 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.5a. Time to First Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Insomnia - 10 pts sustained improvement



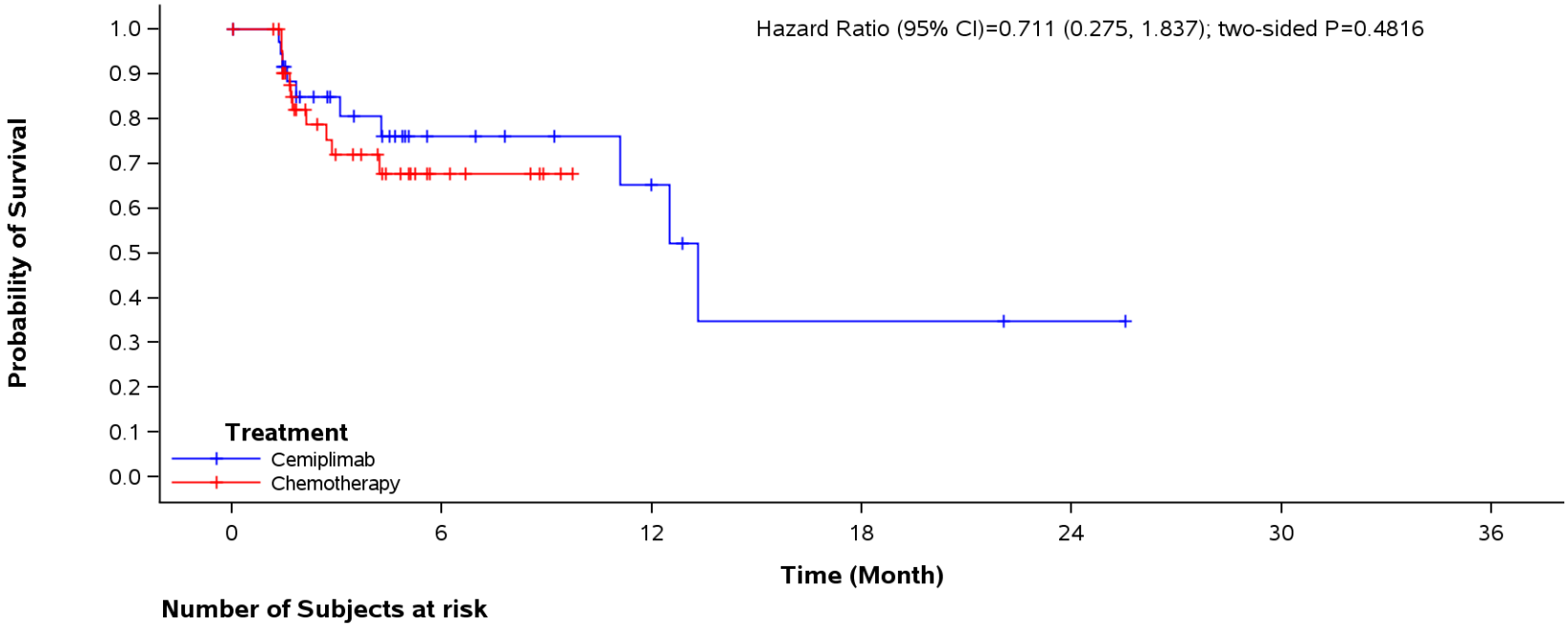

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Appetite loss - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

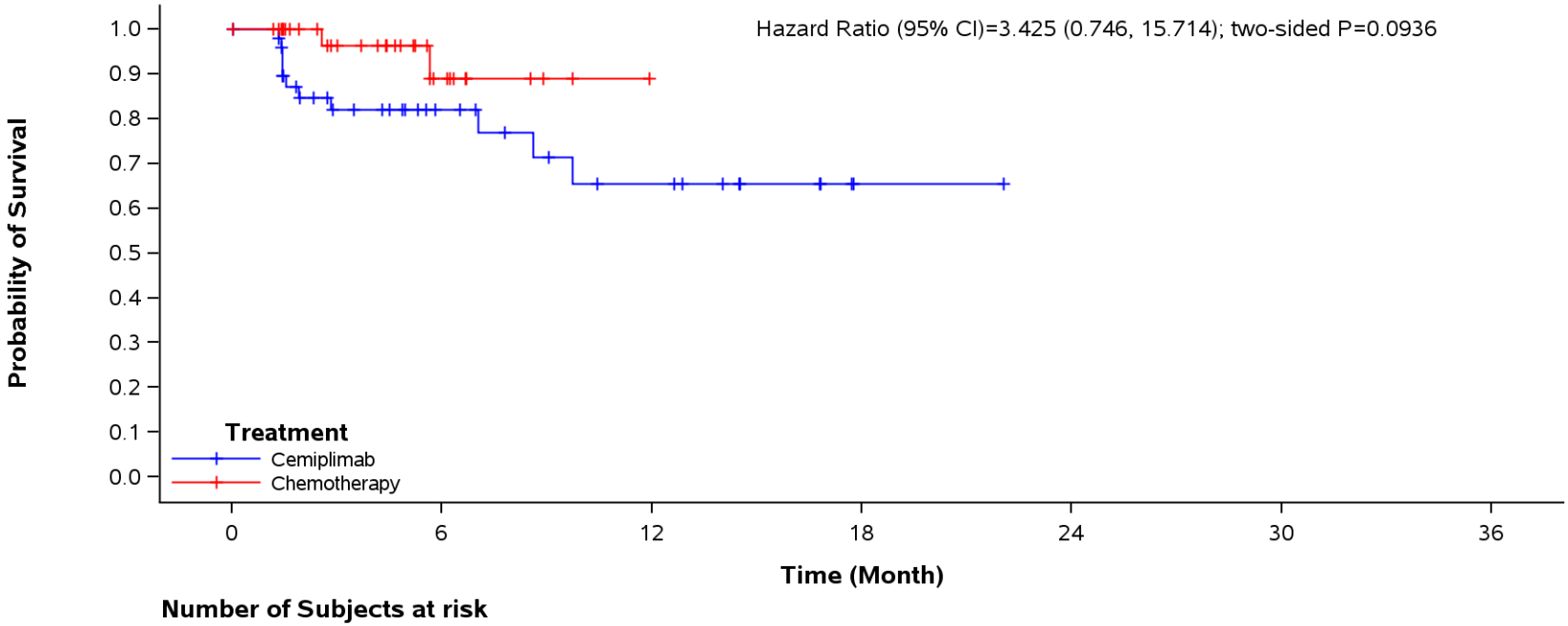
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 10 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)

Cognitive Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 19 | 10 | 1 | 0 | 0 | 0 |
| Chemotherapy | 103 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

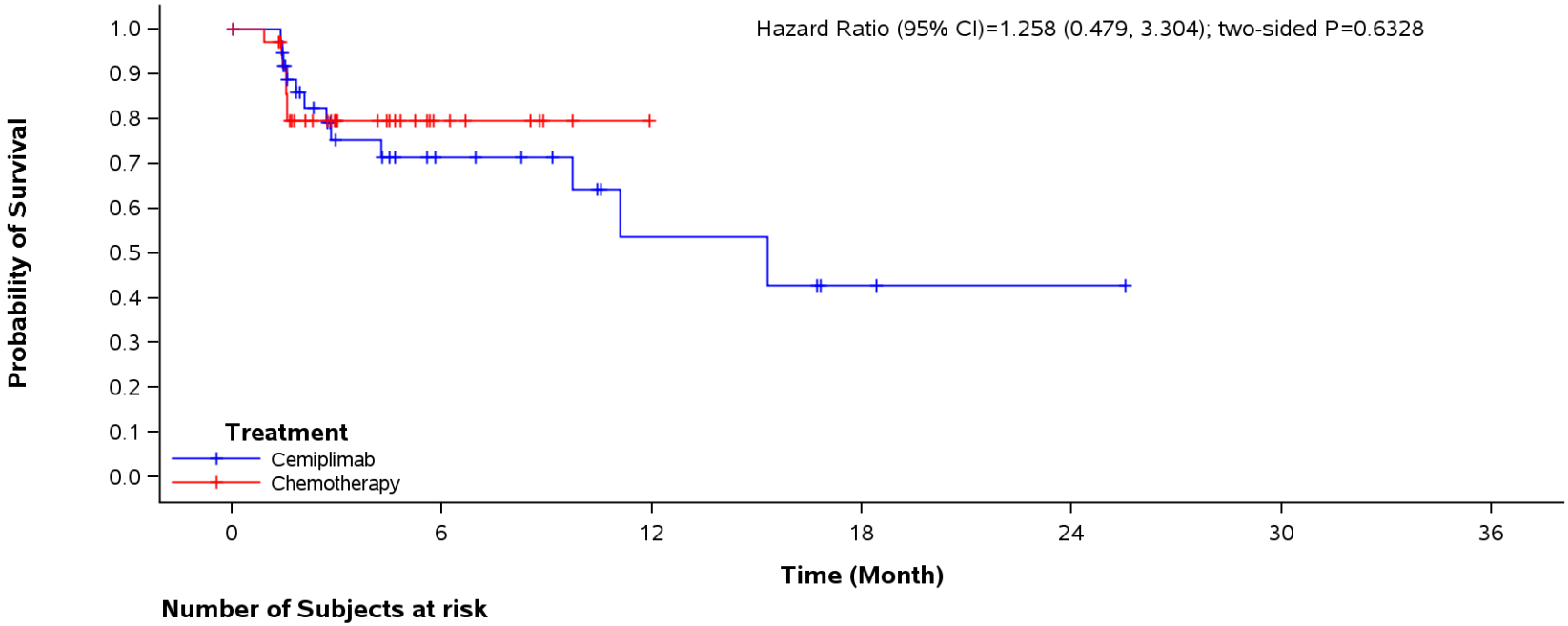
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Constipation - 10 pts sensitivity sustained improvement



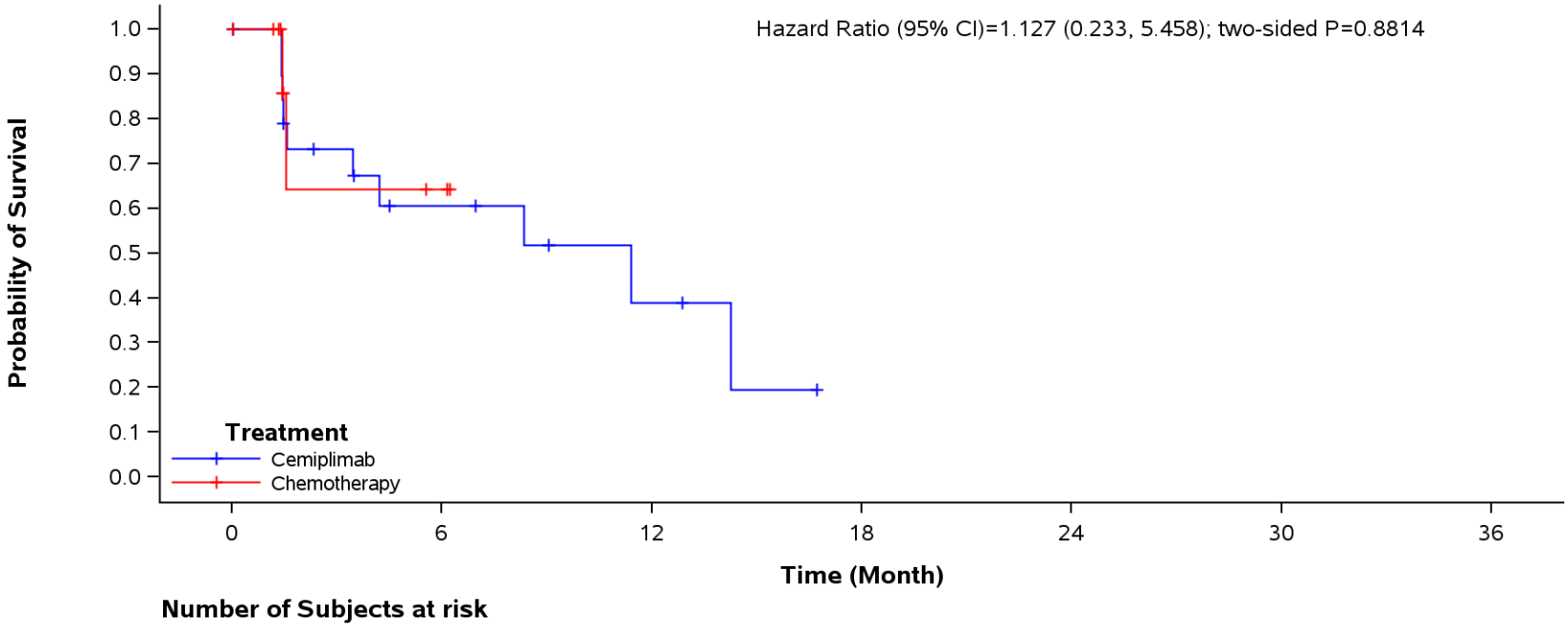

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 13 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Diarhoea - 10 pts sensitivity sustained improvement



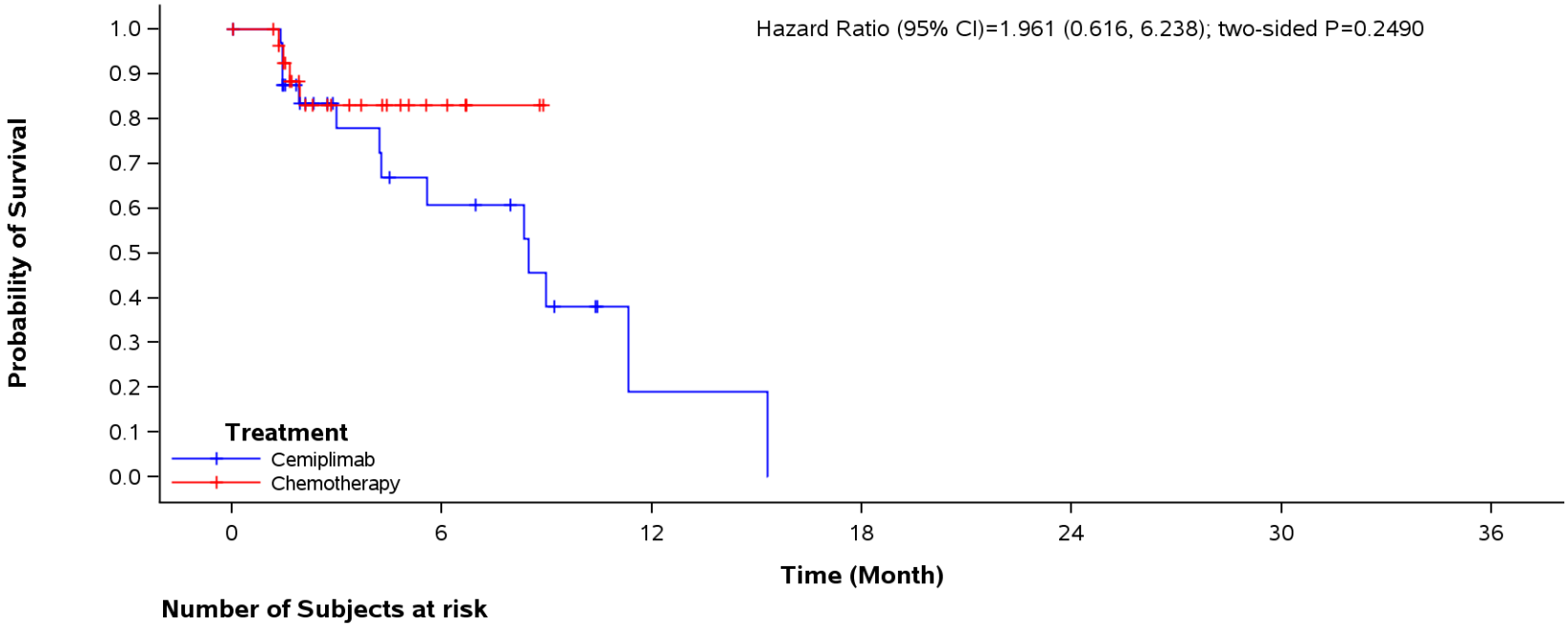

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Dyspnoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

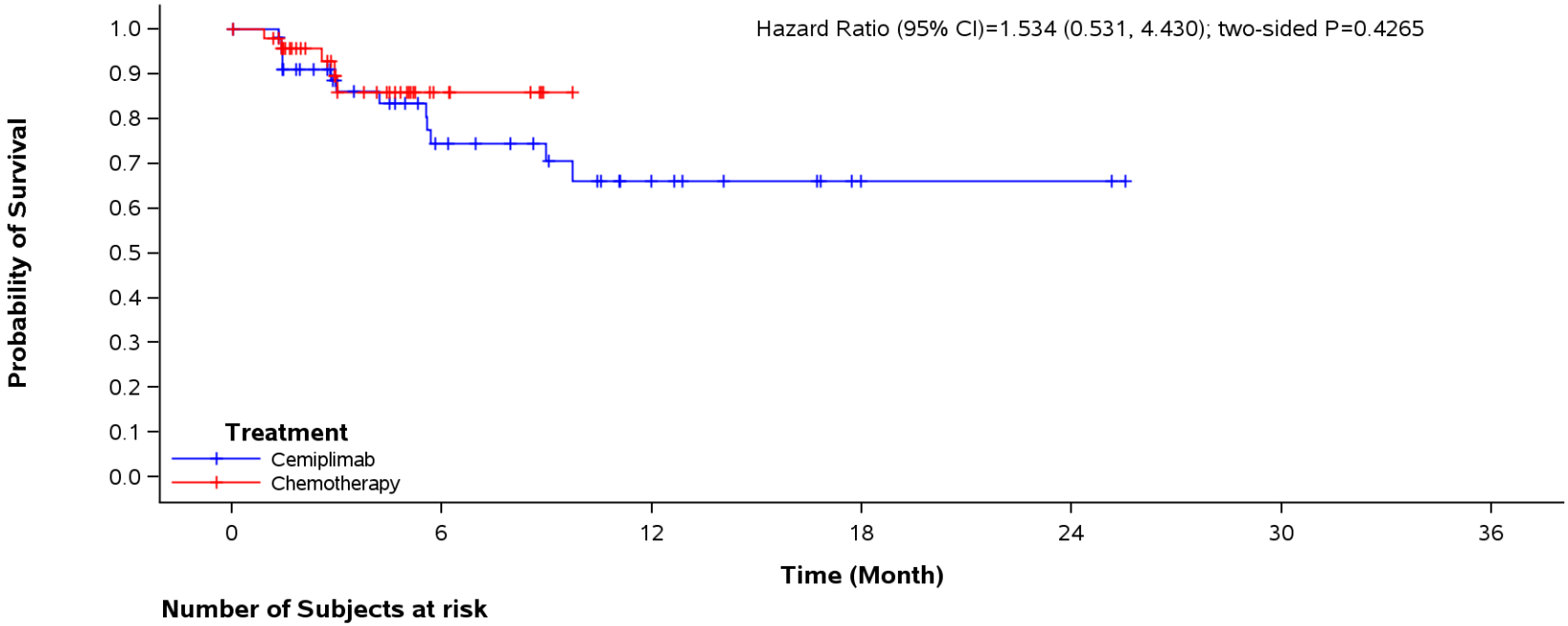
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 10 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)

Emotional Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 24 | 10 | 2 | 2 | 0 | 0 |
| Chemotherapy | 103 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

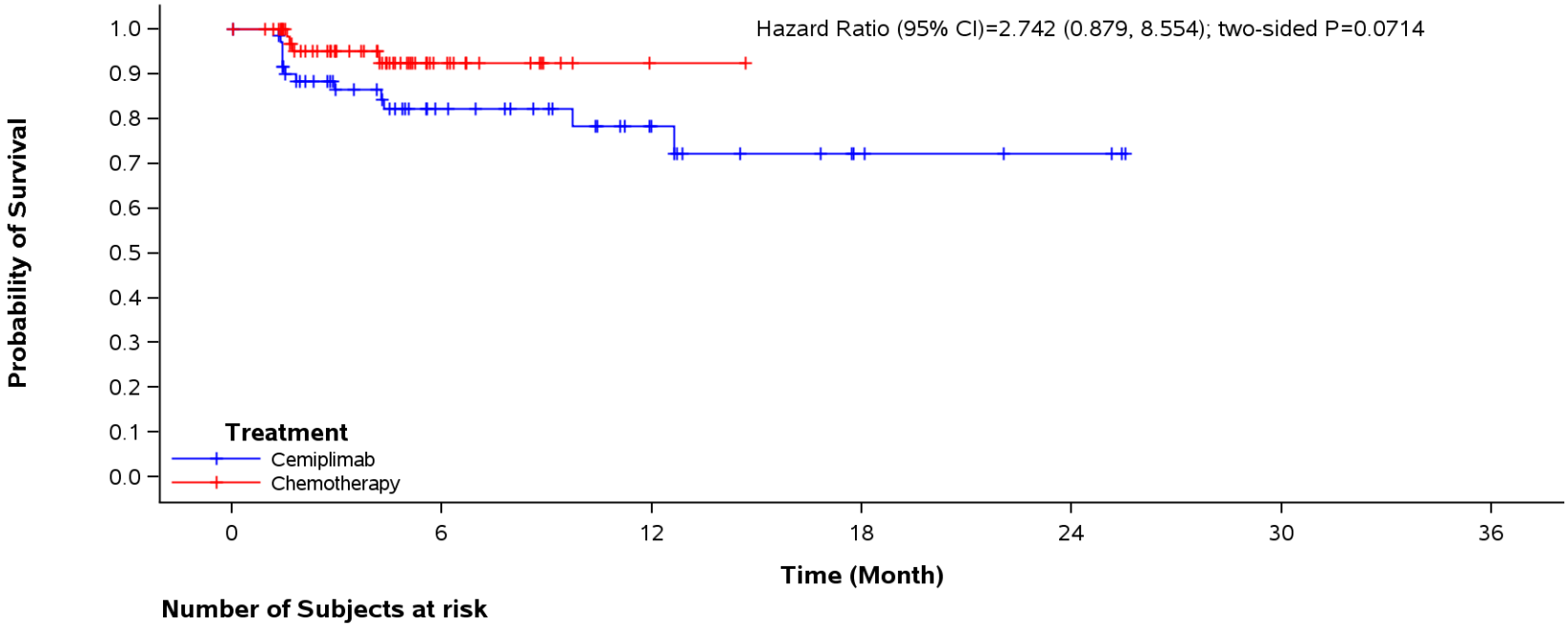
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Fatigue - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

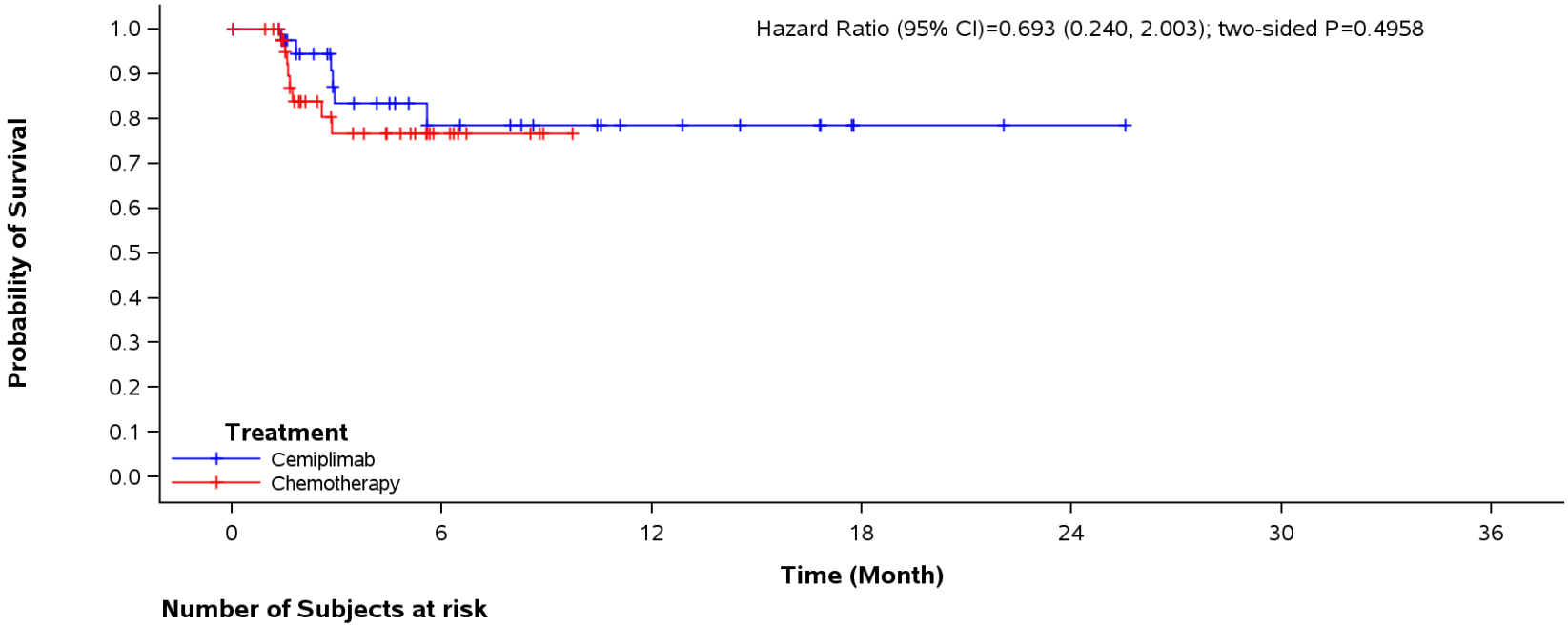
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 29 | 13 | 5 | 3 | 0 | 0 |
| Chemotherapy | 103 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)

Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 15 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

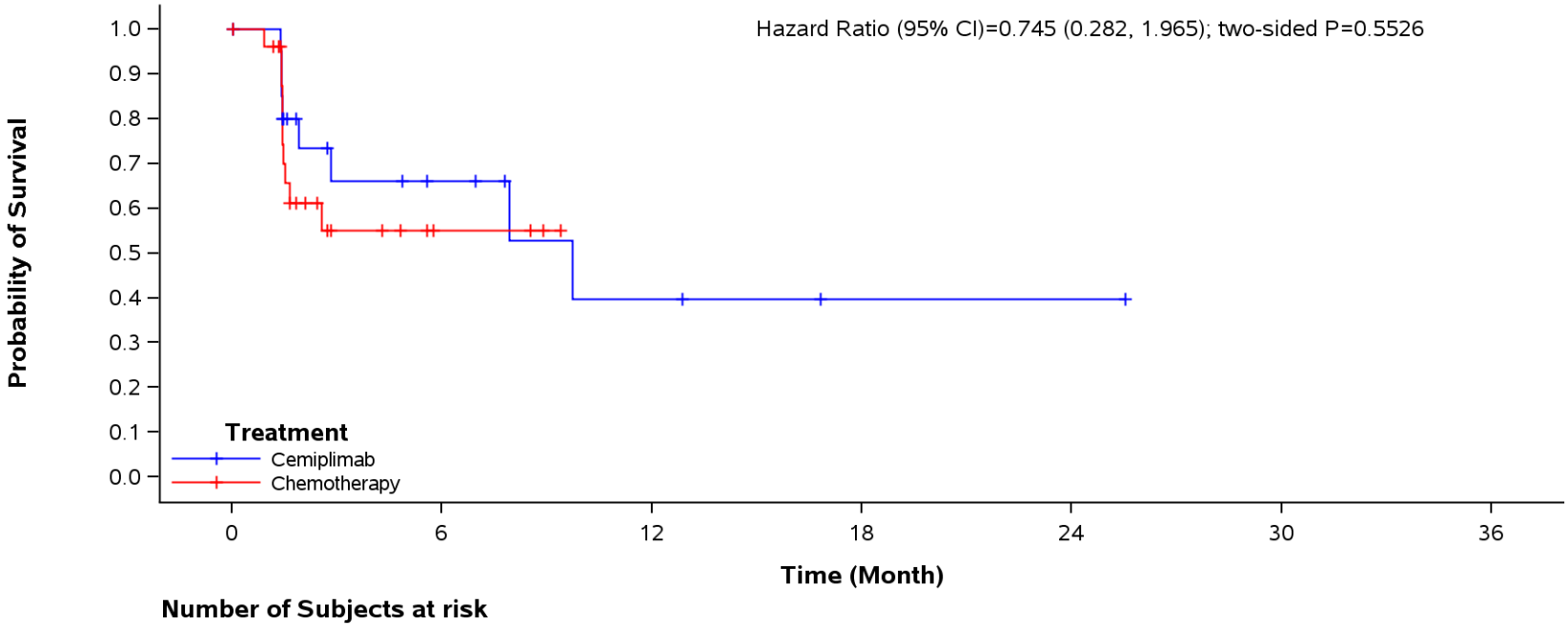
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)

Nausea / Vomiting - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 7 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 103 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

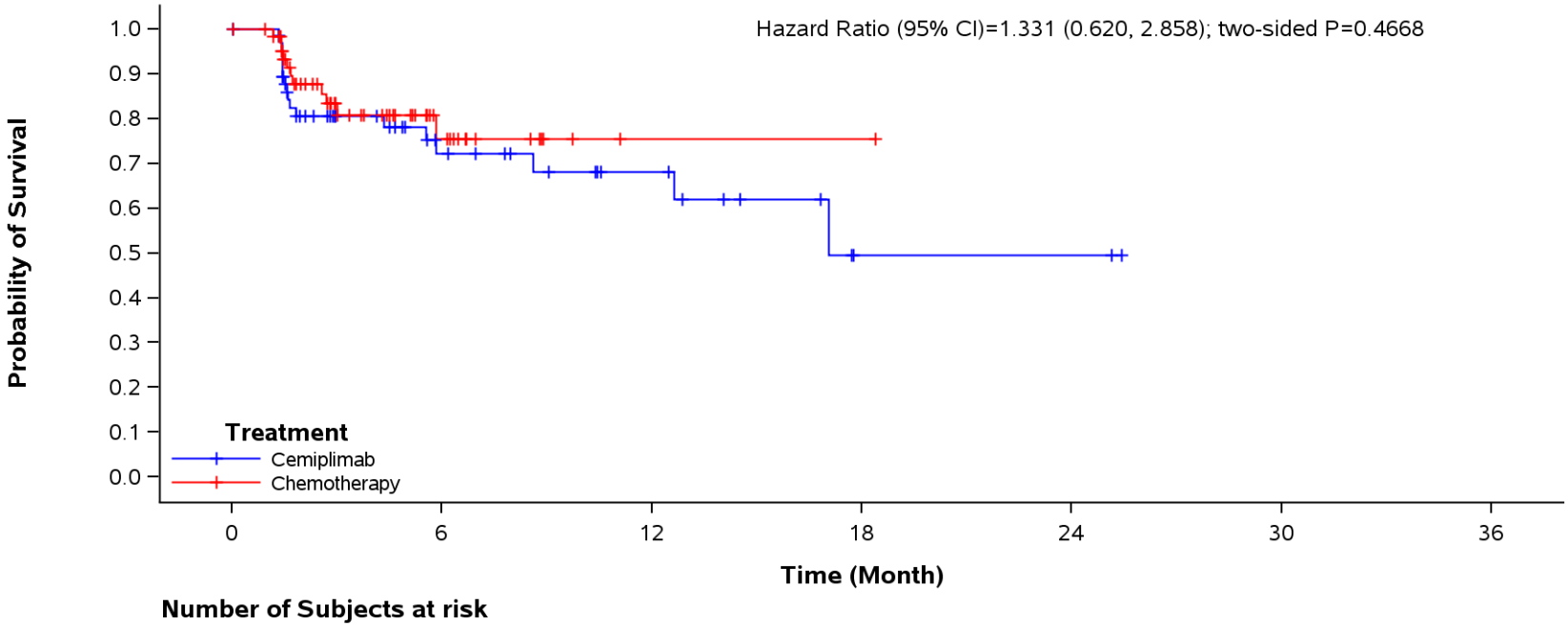
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Pain - 10 pts sensitivity sustained improvement



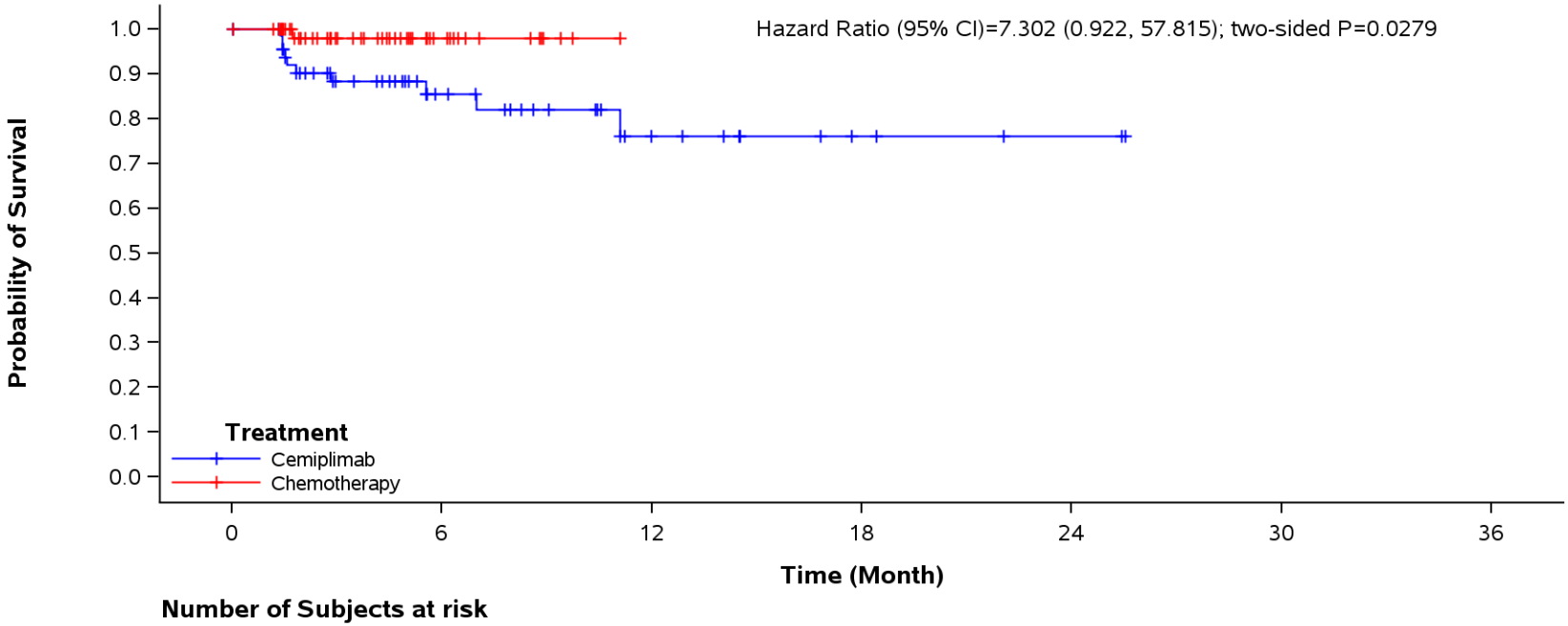

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 23 | 12 | 2 | 2 | 0 | 0 |
| Chemotherapy | 103 | 14 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Physical Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

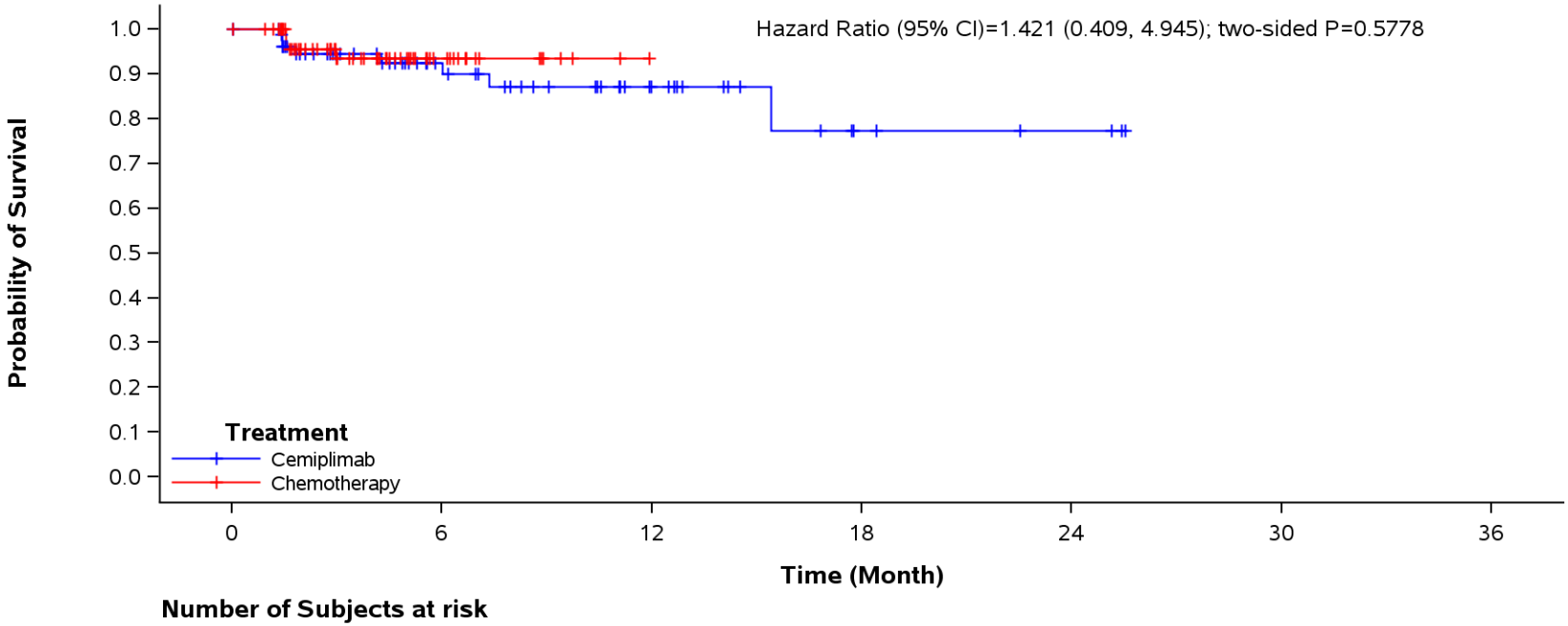
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 27 | 10 | 4 | 2 | 0 | 0 |
| Chemotherapy | 103 | 14 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 36 | 16 | 5 | 3 | 0 | 0 |
| Chemotherapy | 103 | 17 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

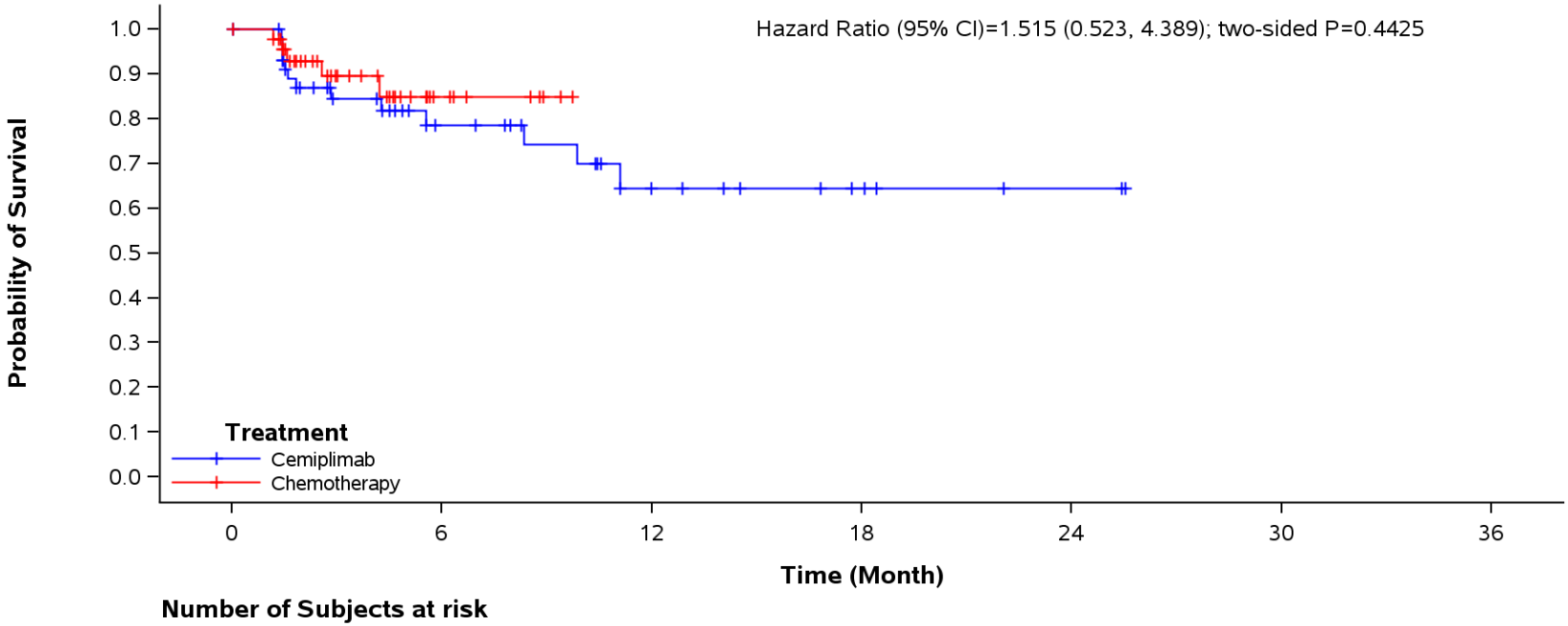
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Role Functioning - 10 pts sensitivity sustained improvement



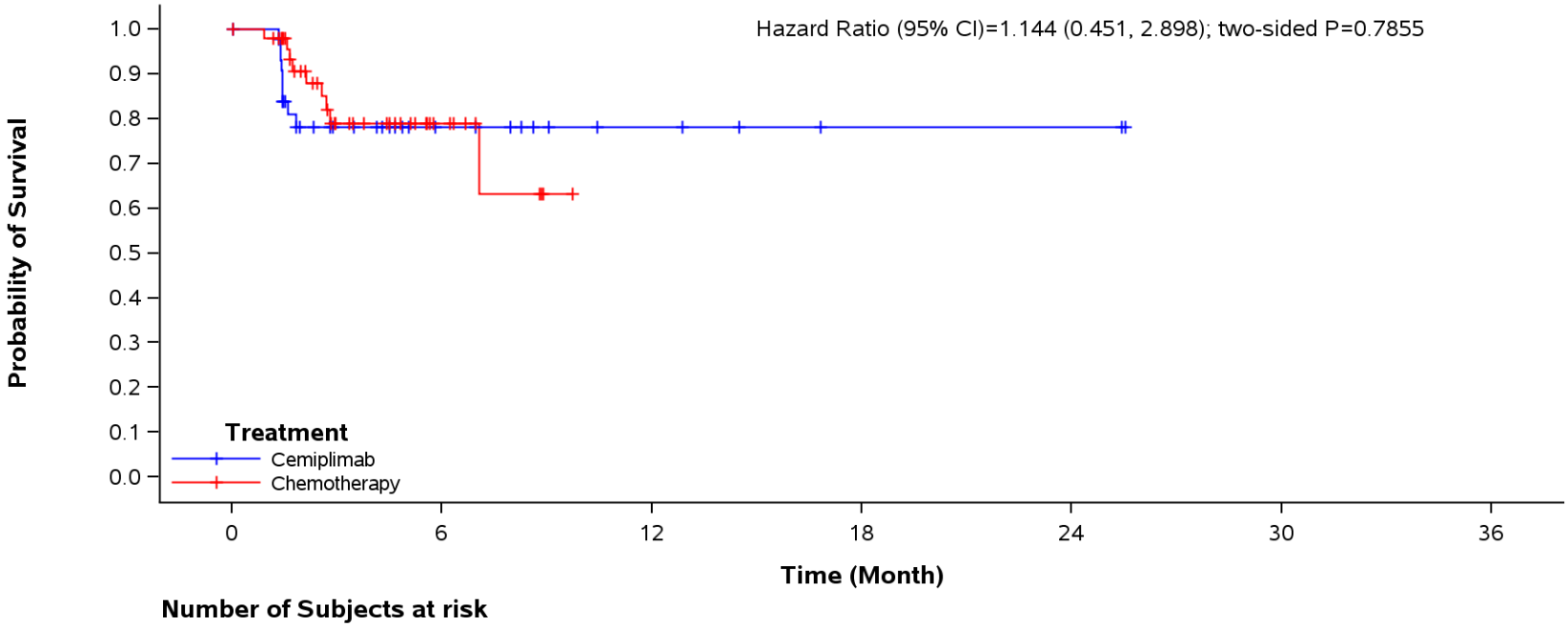

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 23 | 10 | 5 | 2 | 0 | 0 |
| Chemotherapy | 103 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Social Functioning - 10 pts sensitivity sustained improvement



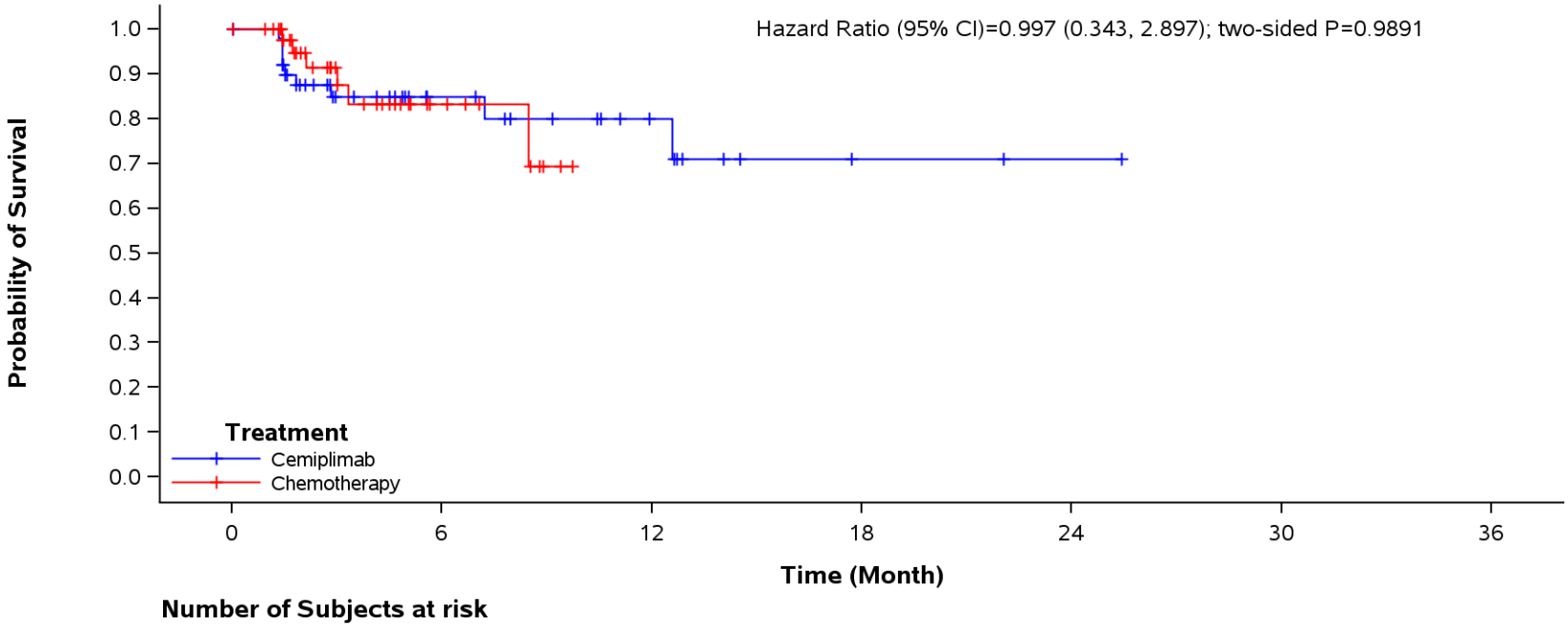

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 13 | 6 | 2 | 2 | 0 | 0 |
| Chemotherapy | 103 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Insomnia - 10 pts sensitivity sustained improvement




Number of Subjects at risk

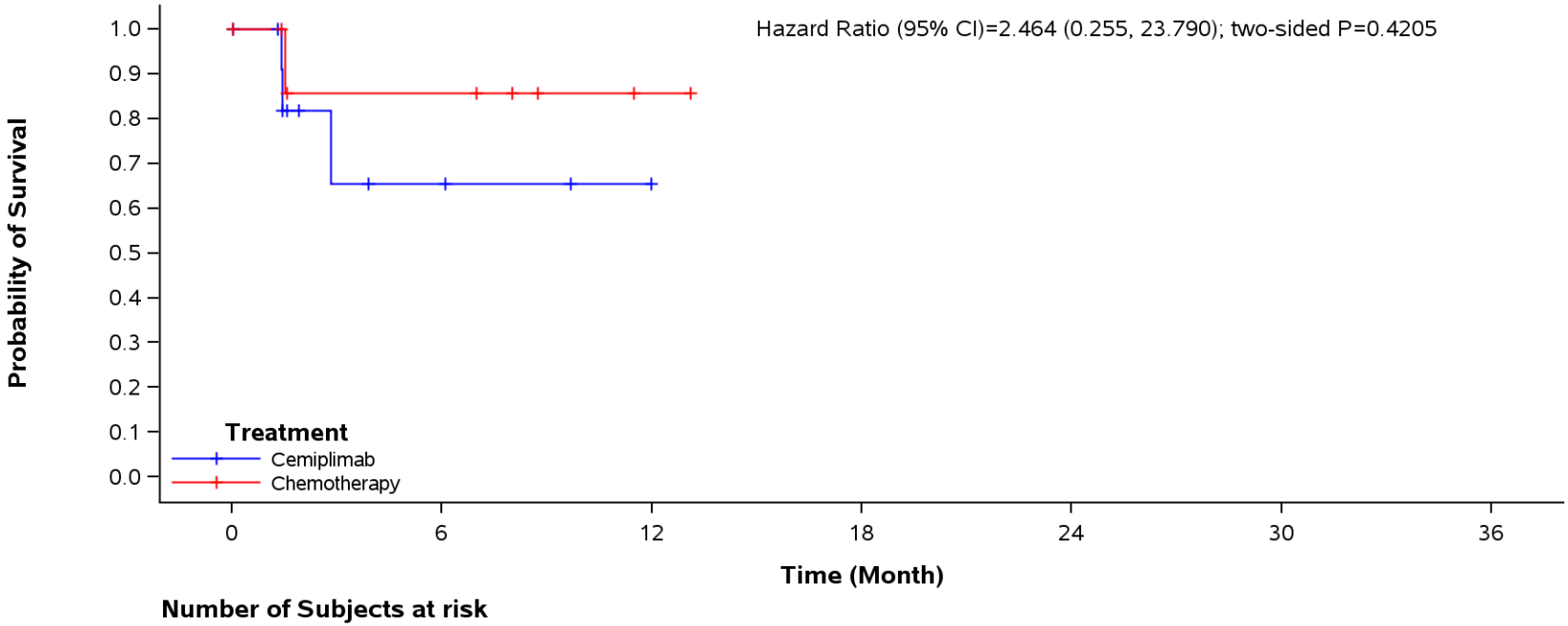
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 19 | 9 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Appetite loss - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

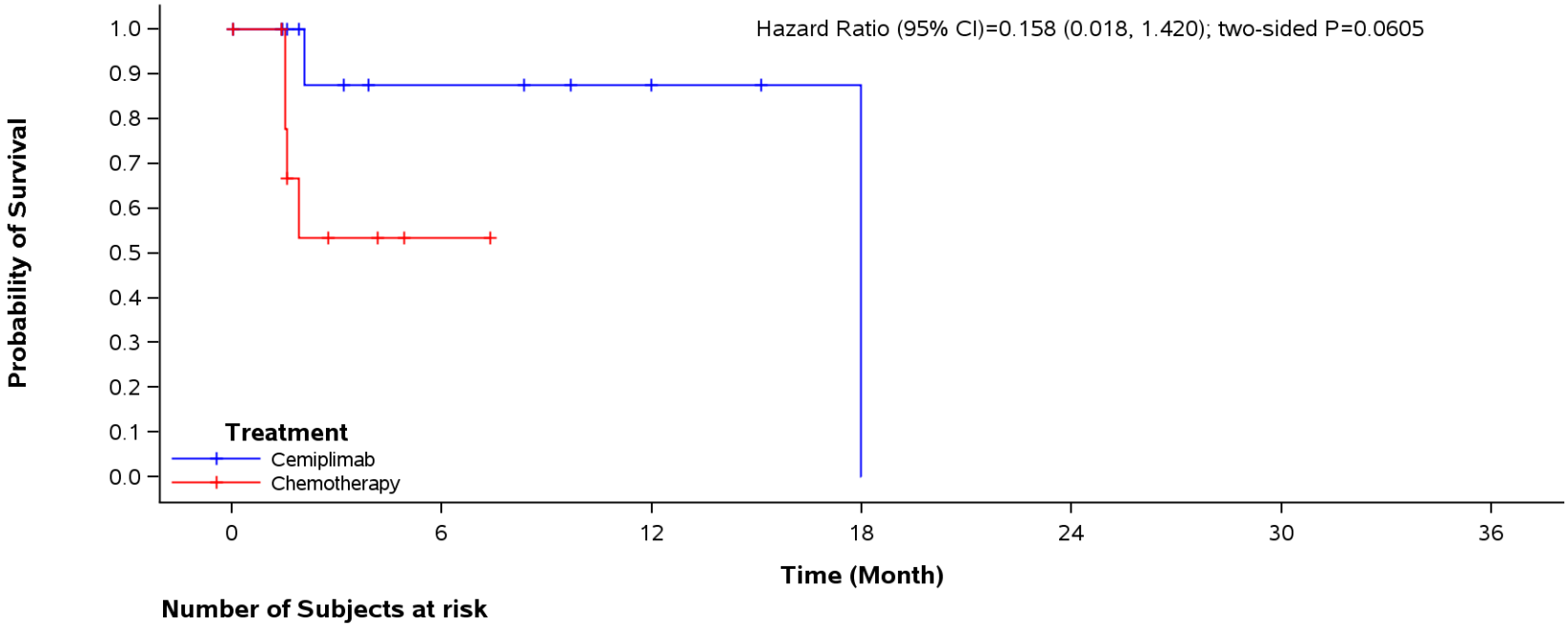
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Cognitive Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

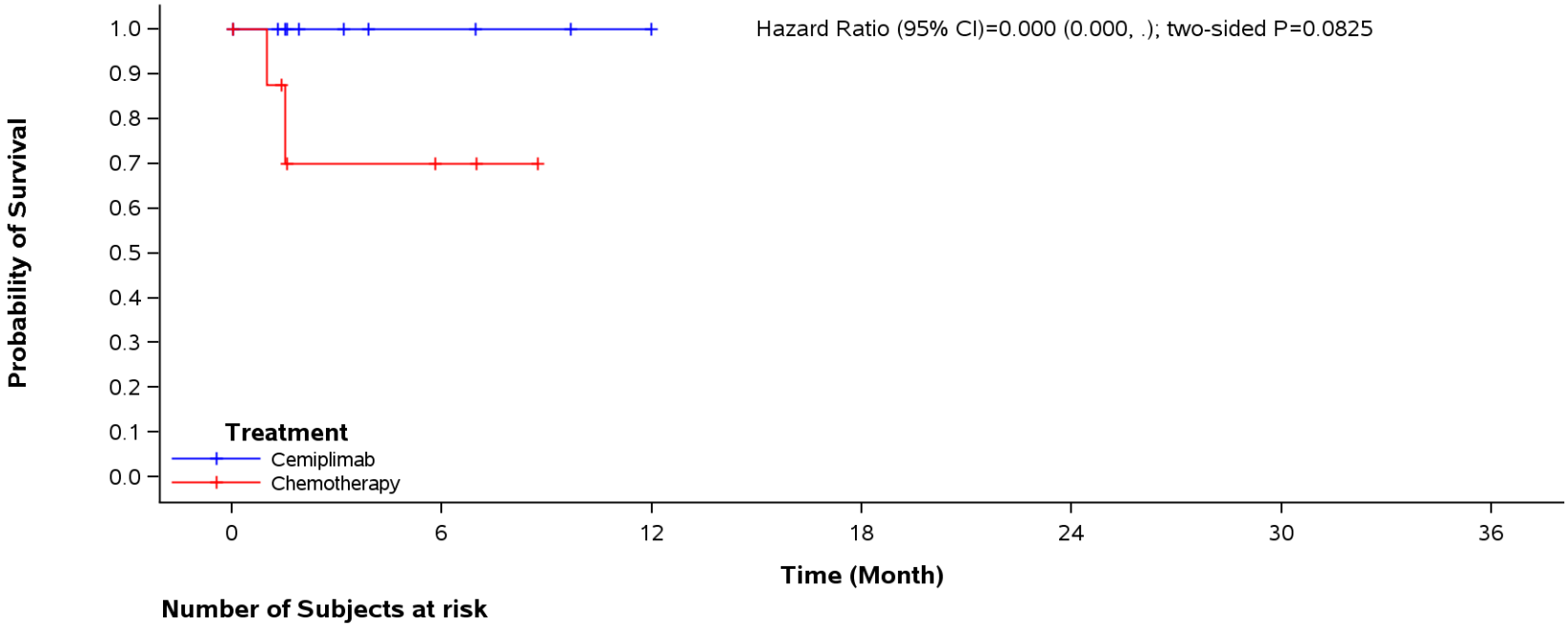
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Constipation - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

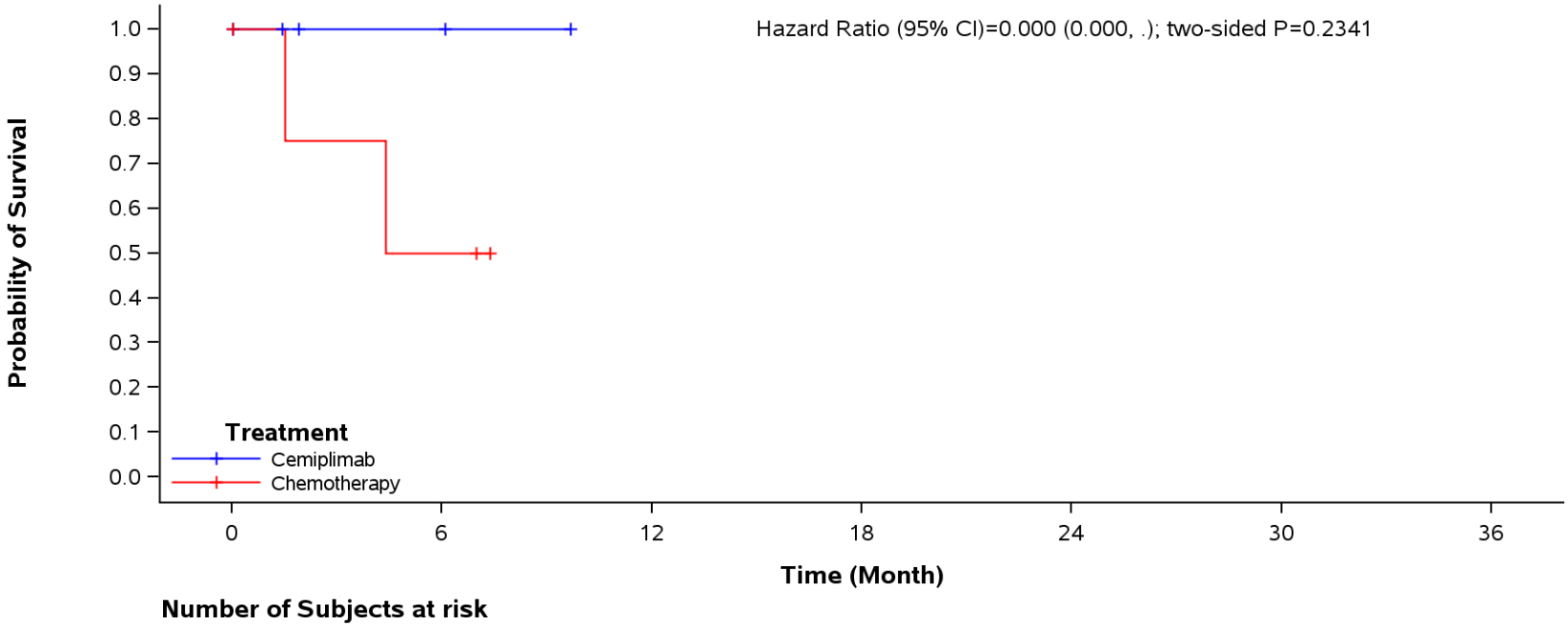
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Diarhoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

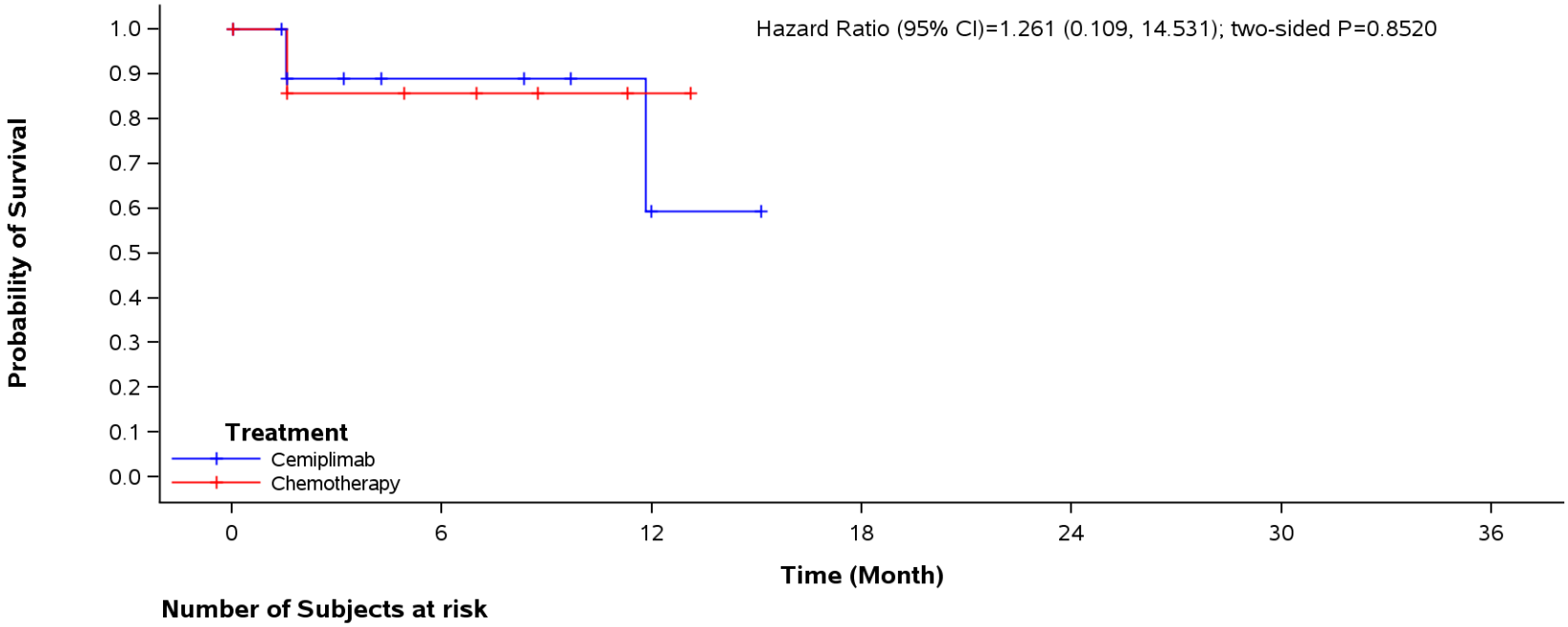
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Dyspnoea - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

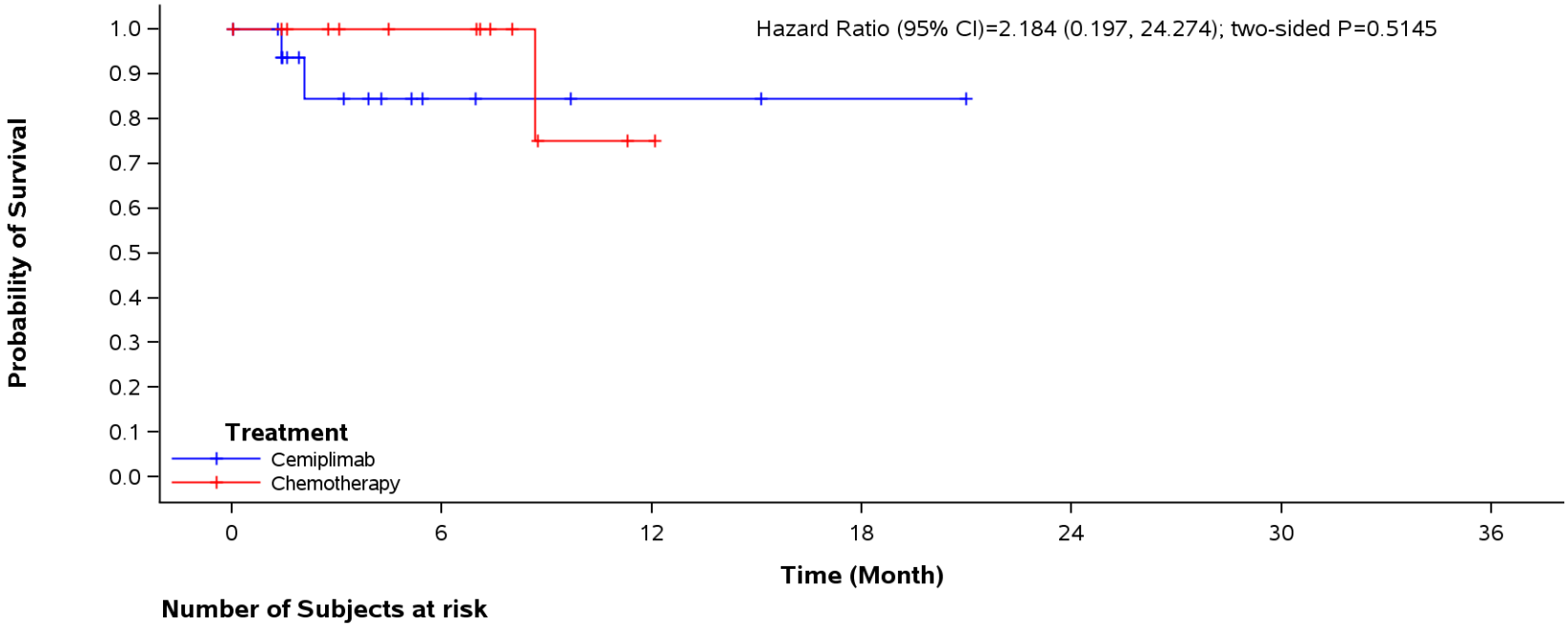
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Emotional Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

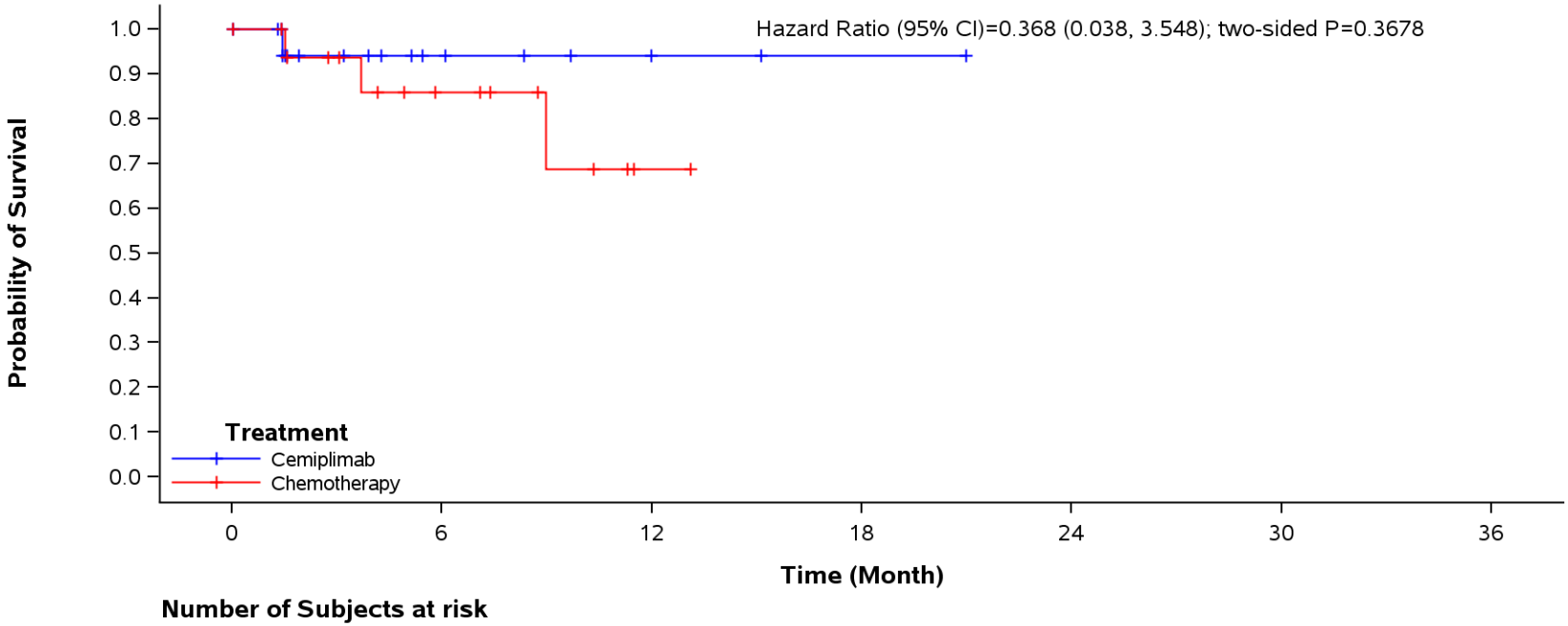
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Fatigue - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

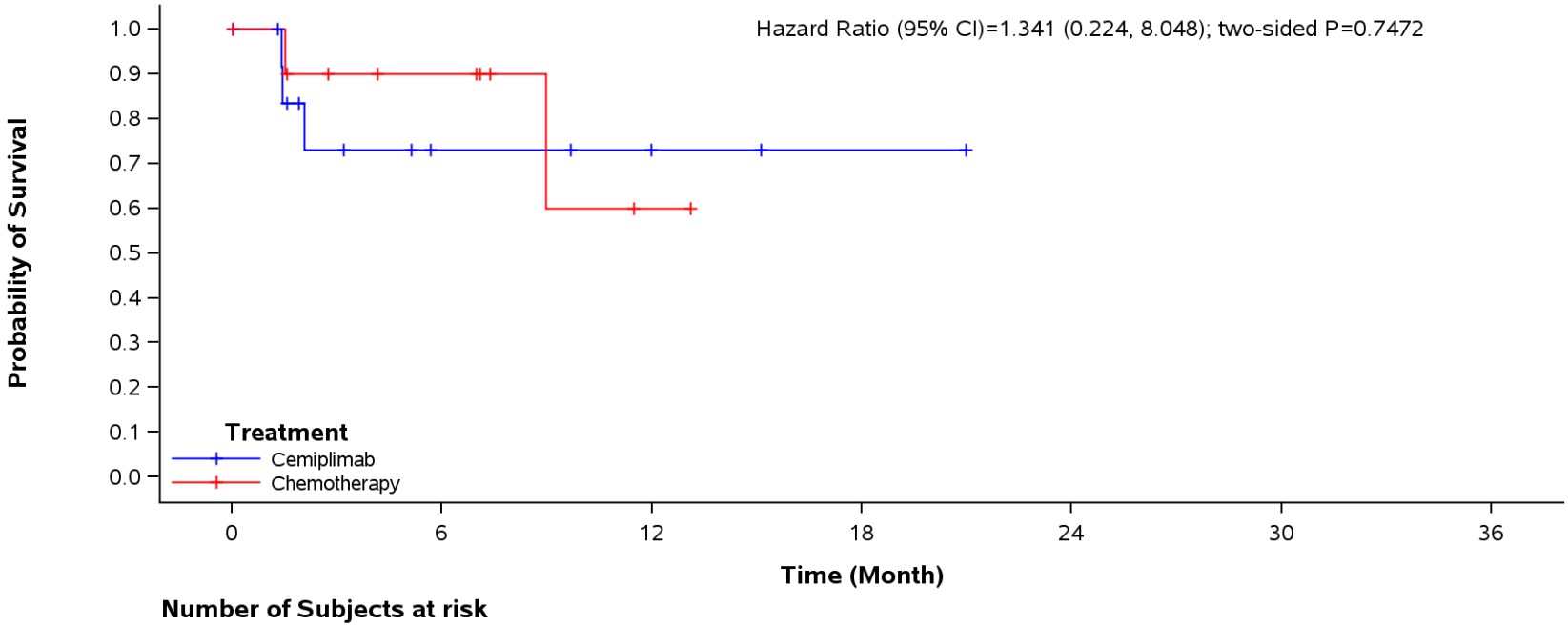
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

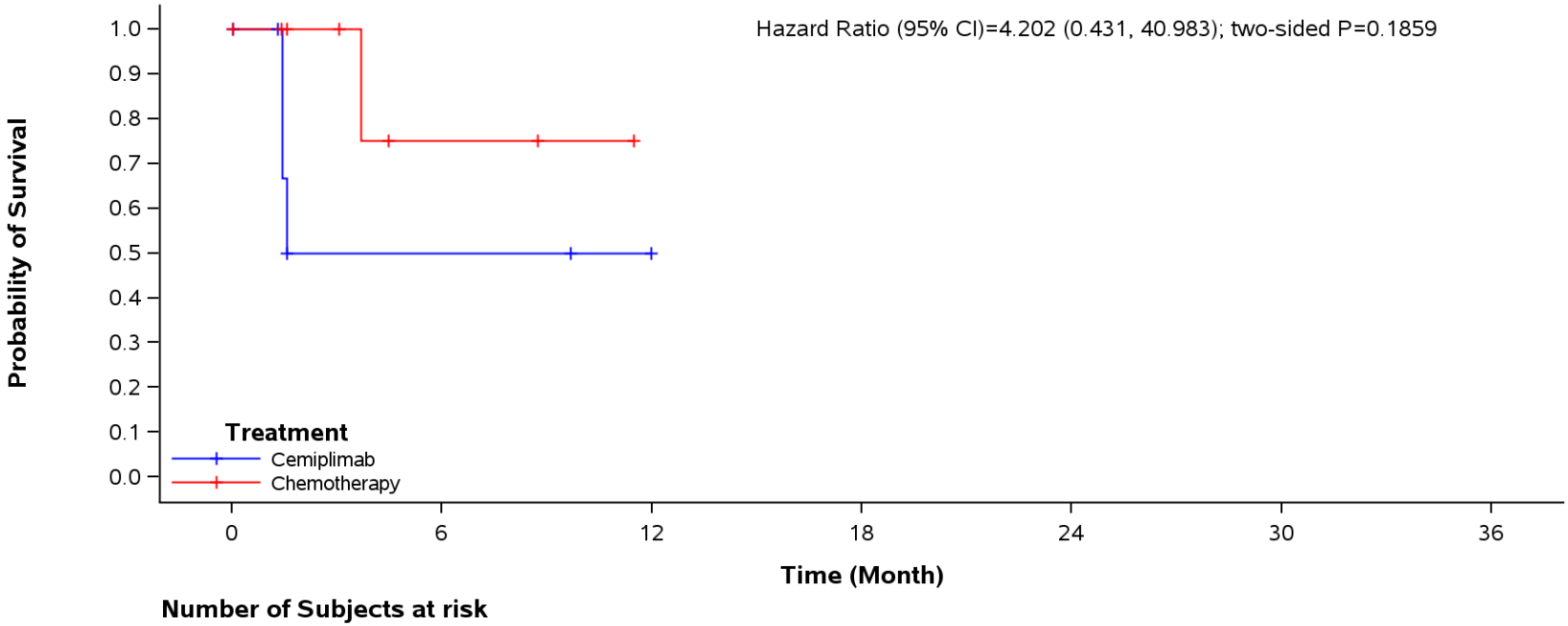
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Nausea / Vomiting - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

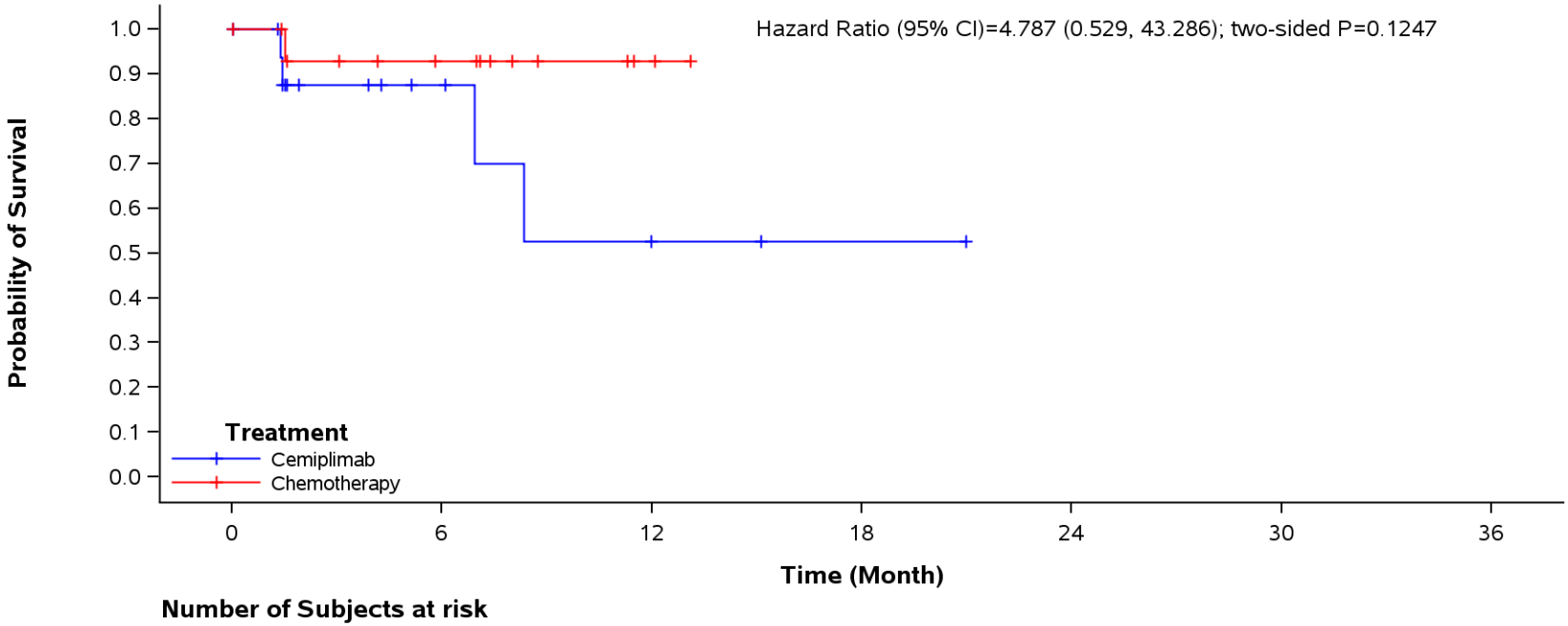
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Pain - 10 pts sensitivity sustained improvement




Number of Subjects at risk

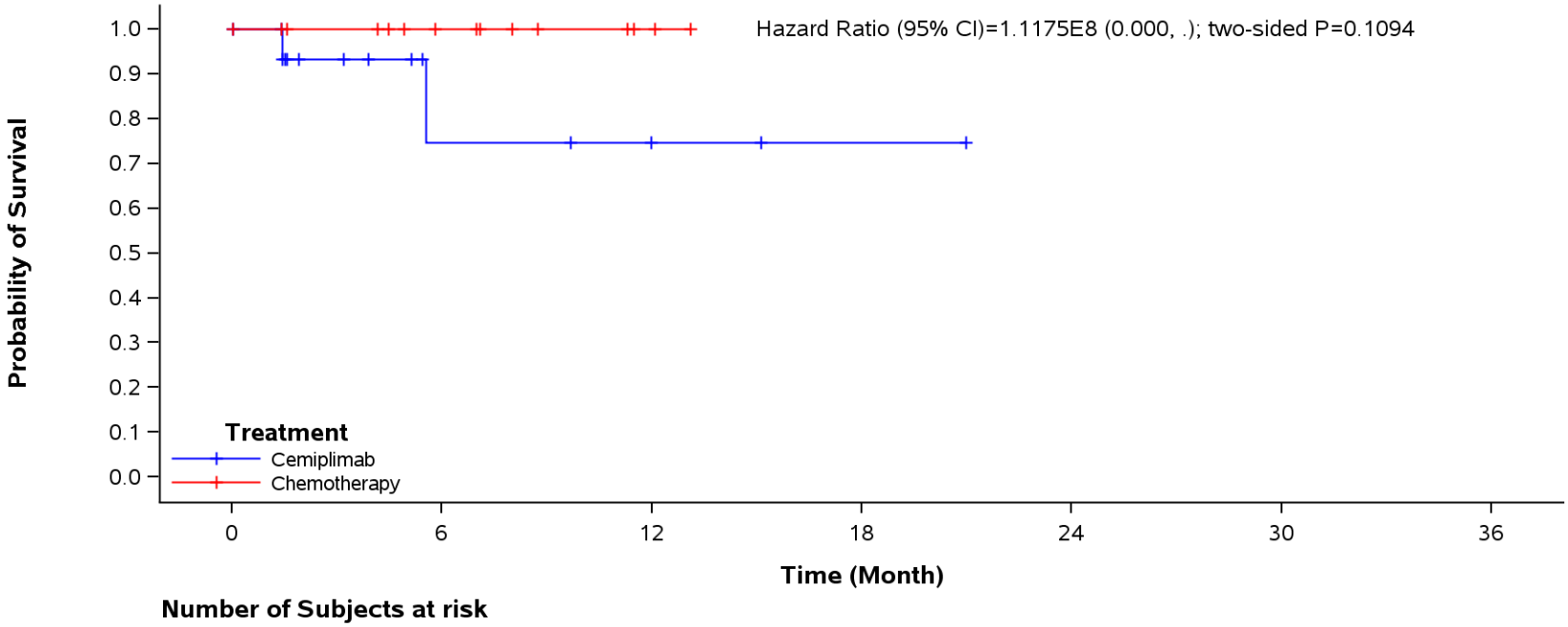
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Physical Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

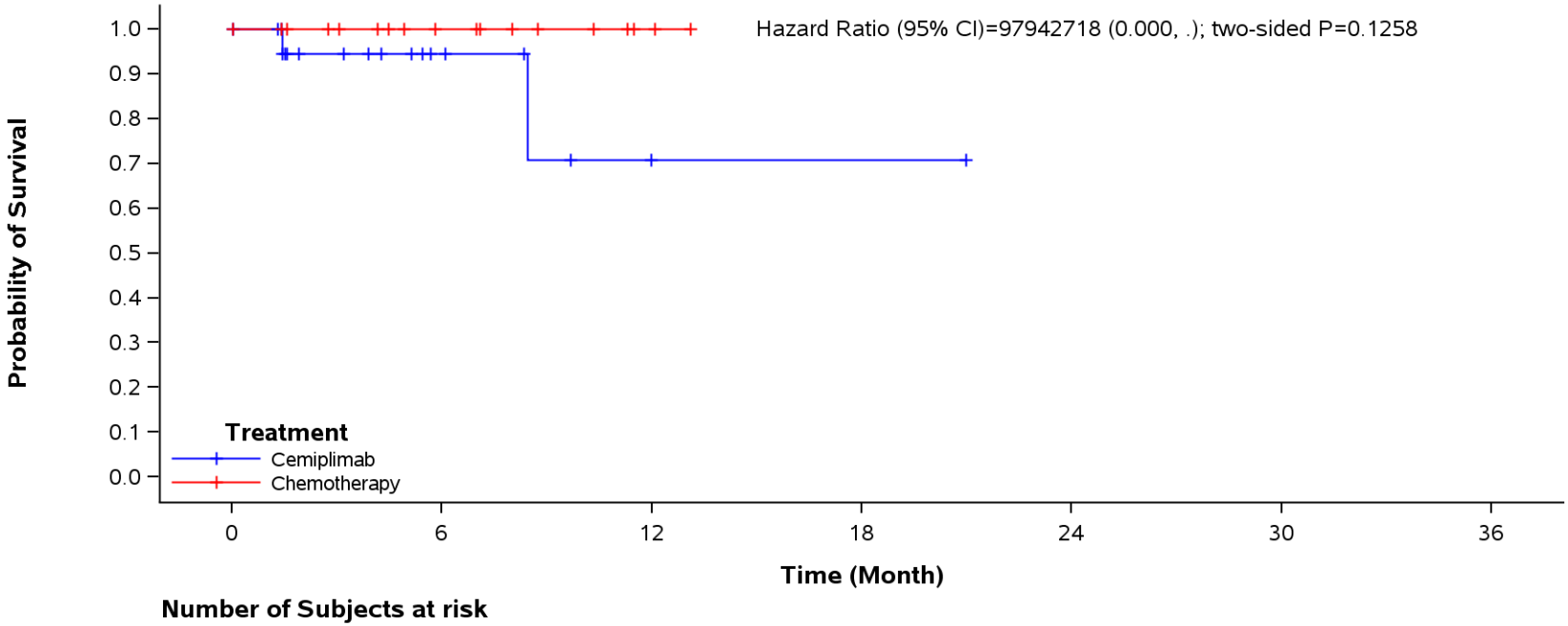
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Global health status / QoL - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

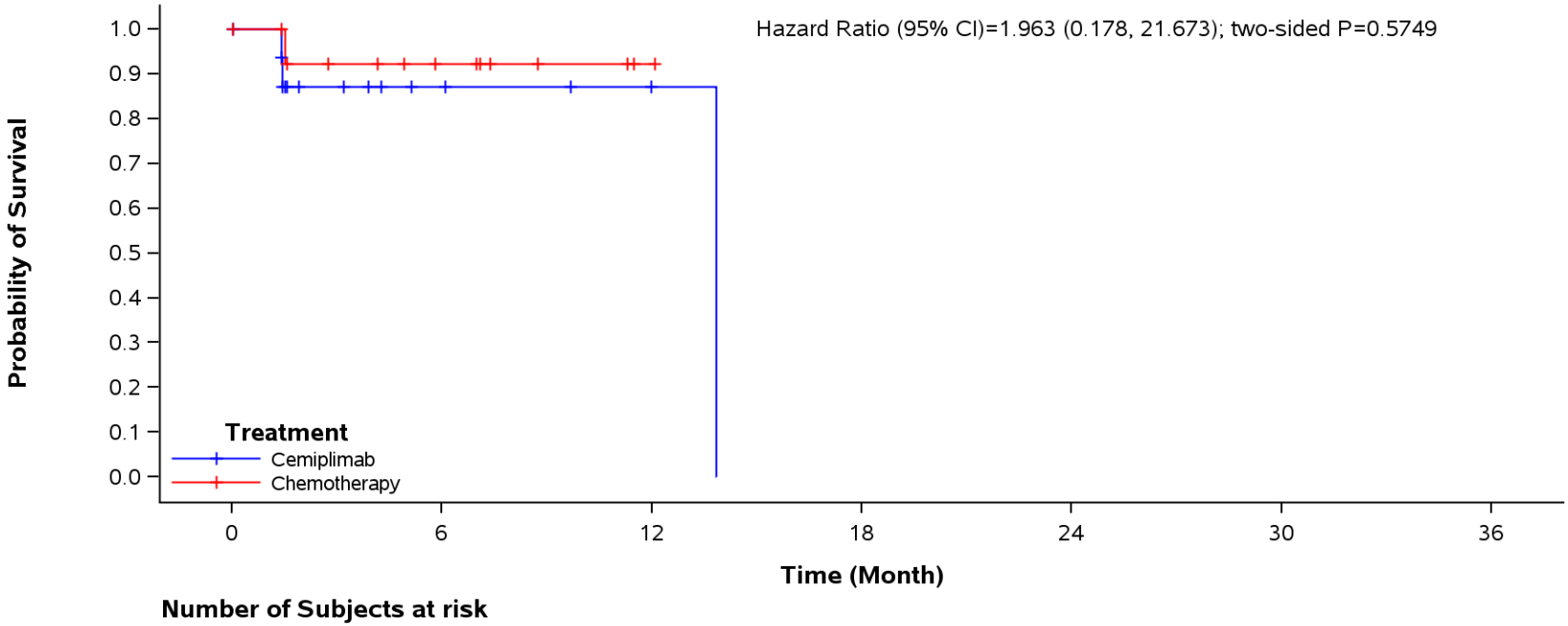
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Role Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

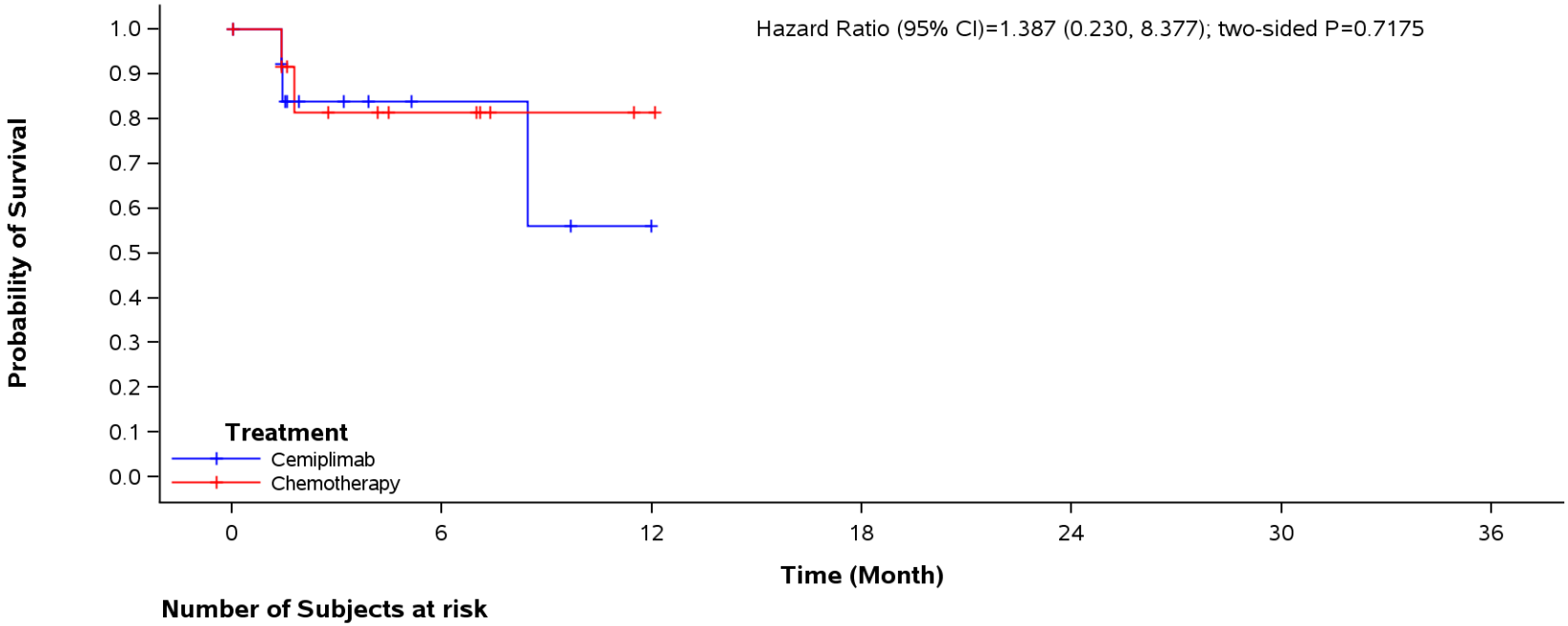
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Social Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

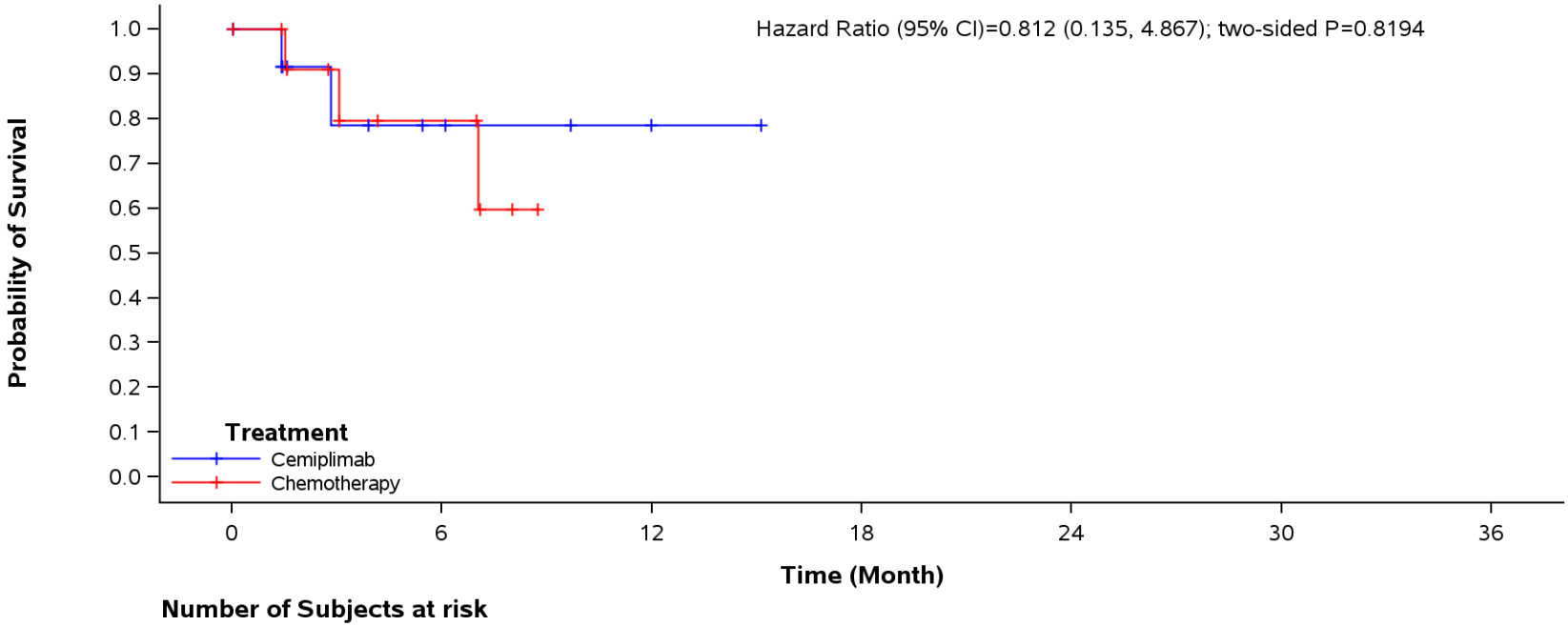
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Insomnia - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

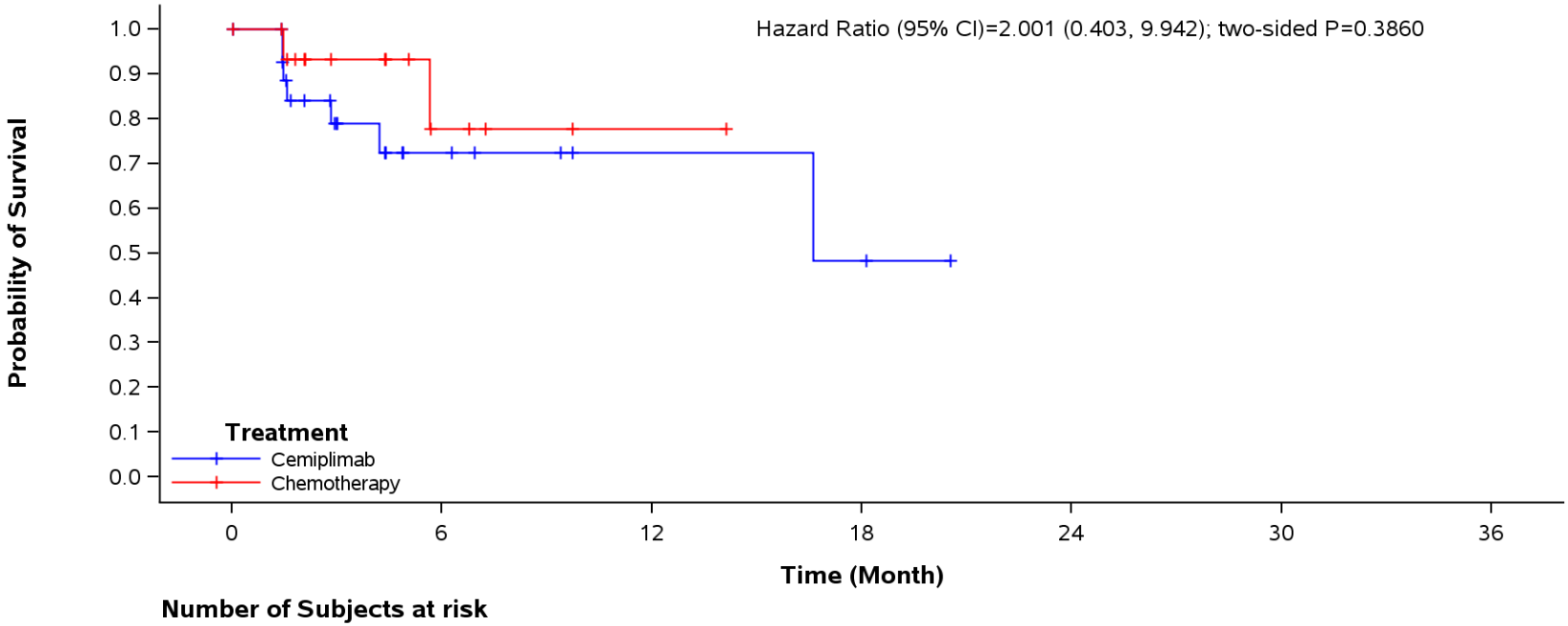
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Appetite loss - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 7 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

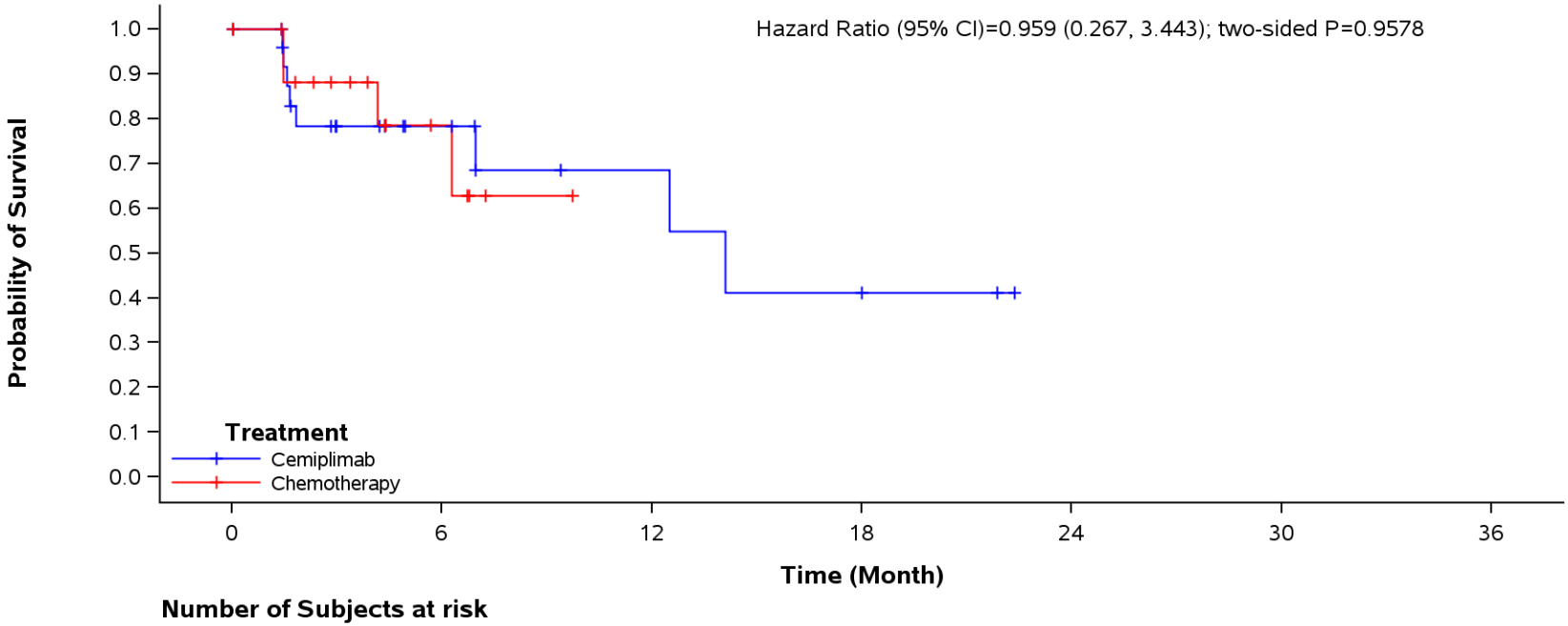
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Cognitive Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 10 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

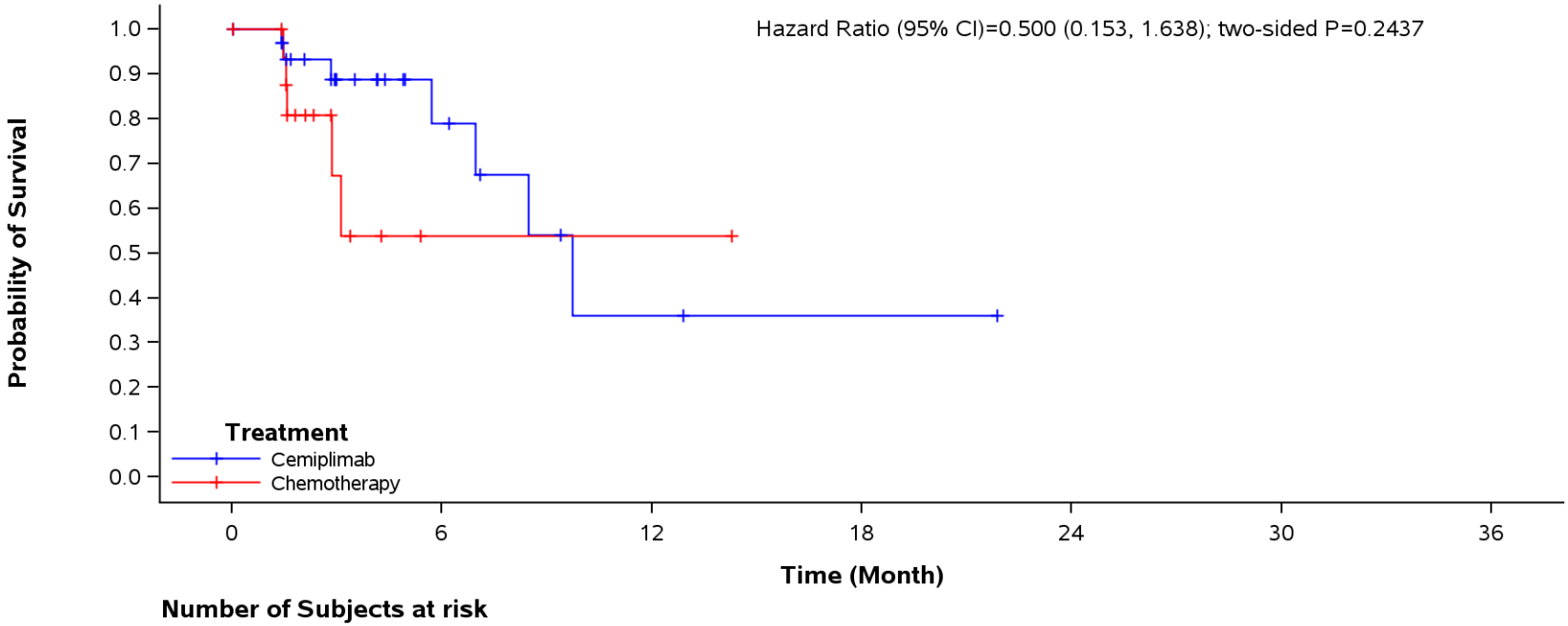
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Constipation - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 50 | 1 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

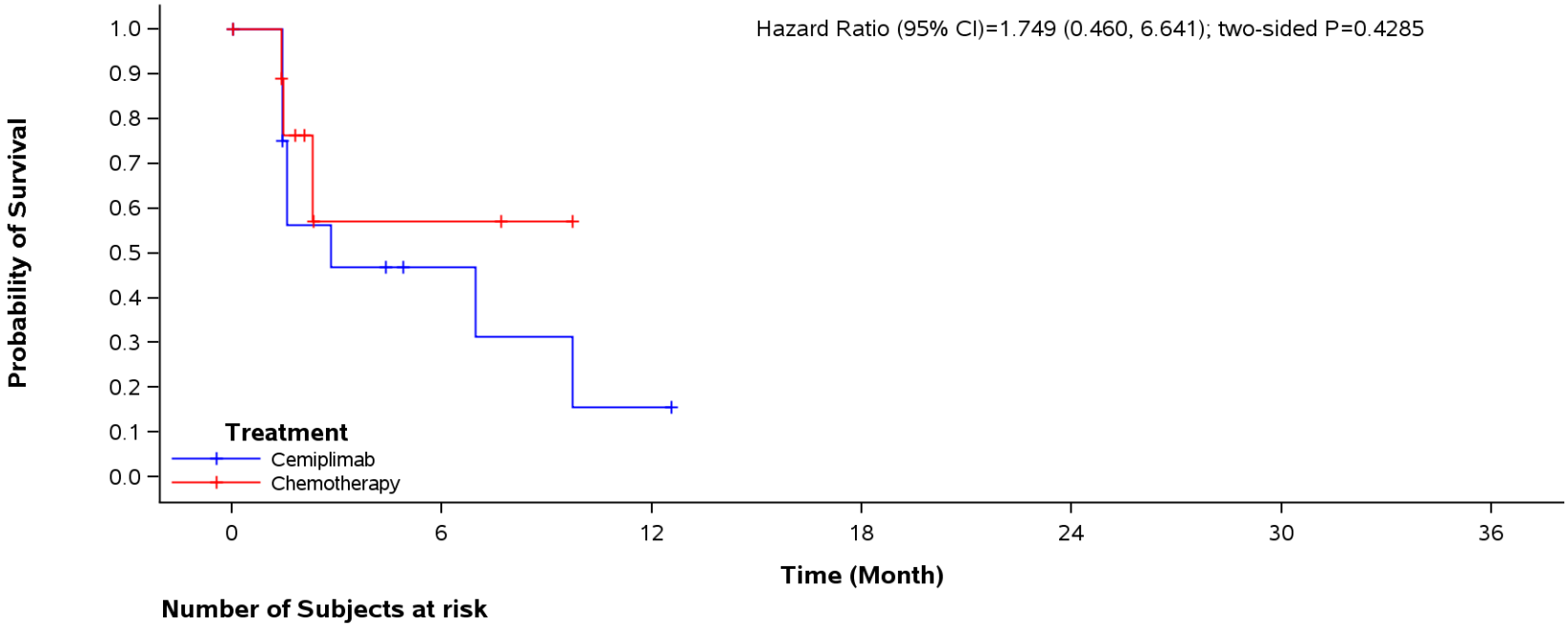
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Diarhoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 2 | 0 | 0 | 0 | 0 | 0 |

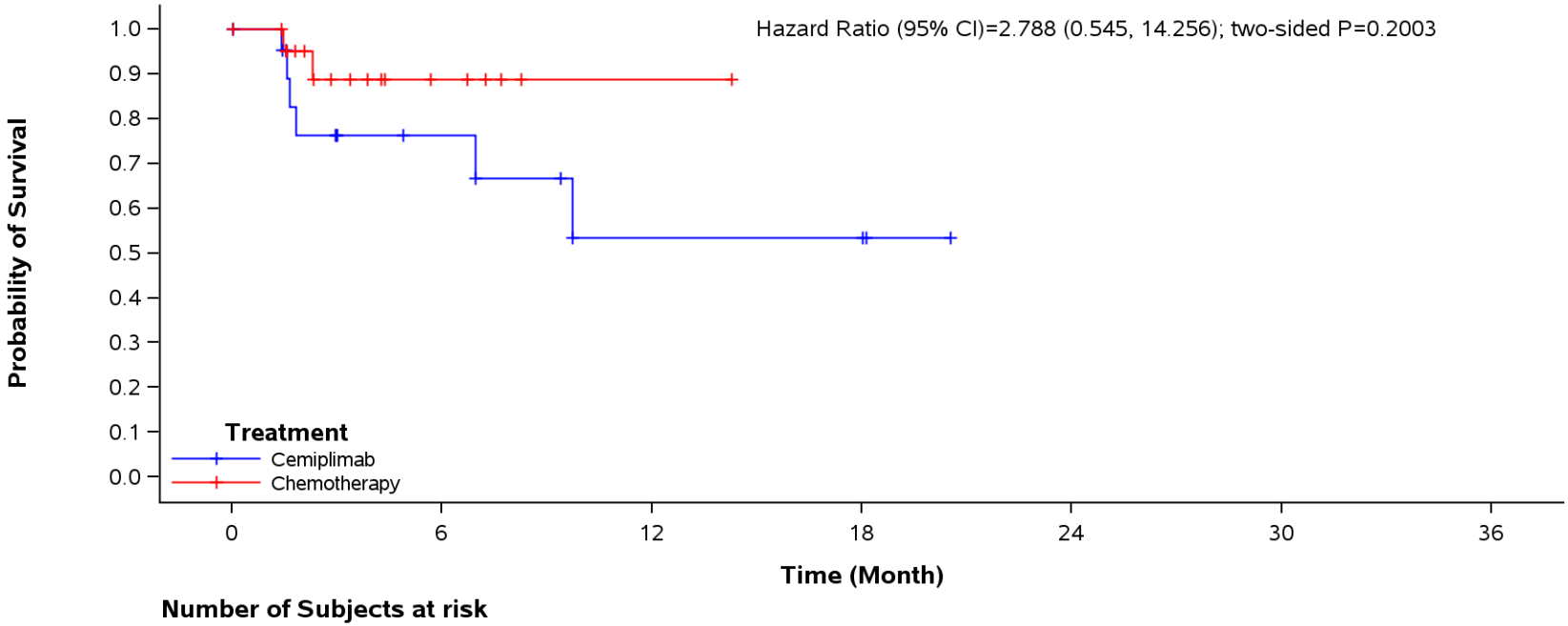
Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:30:31, yingyuan.lin)

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Dyspnoea - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 8 | 3 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

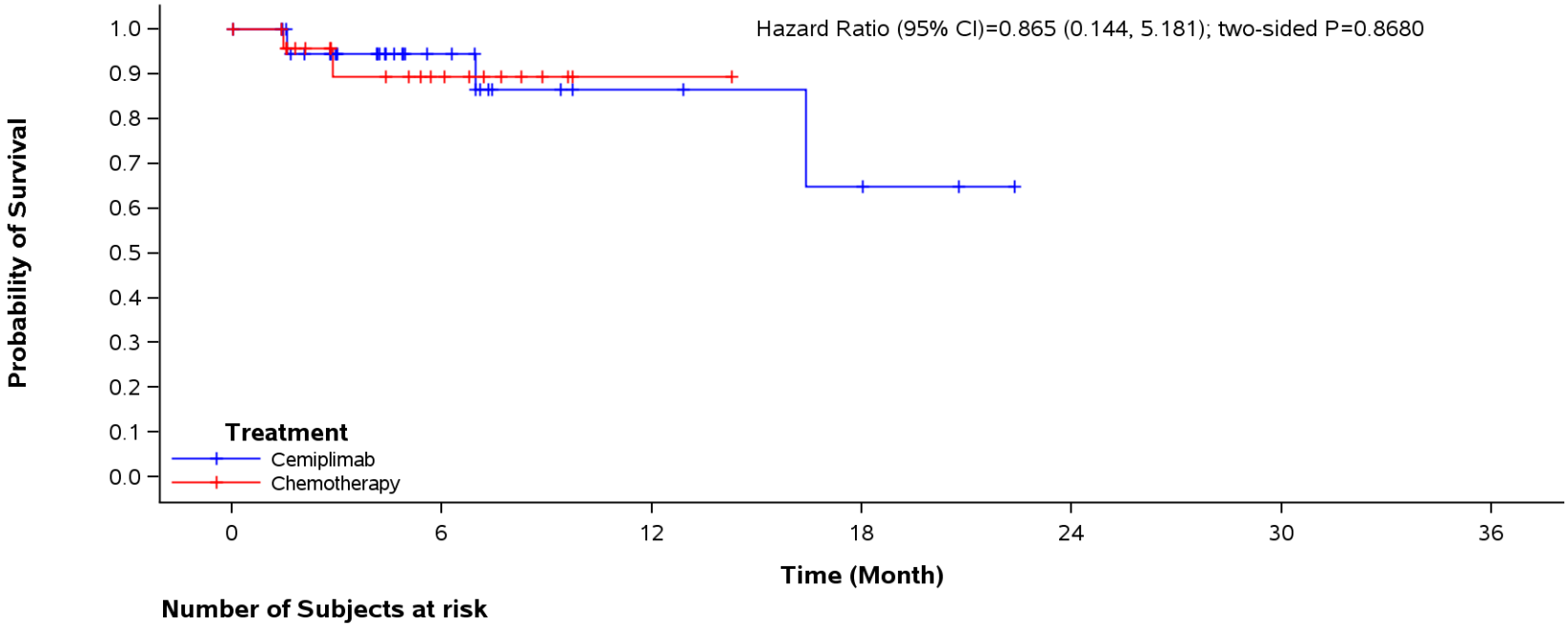
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Emotional Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 15 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

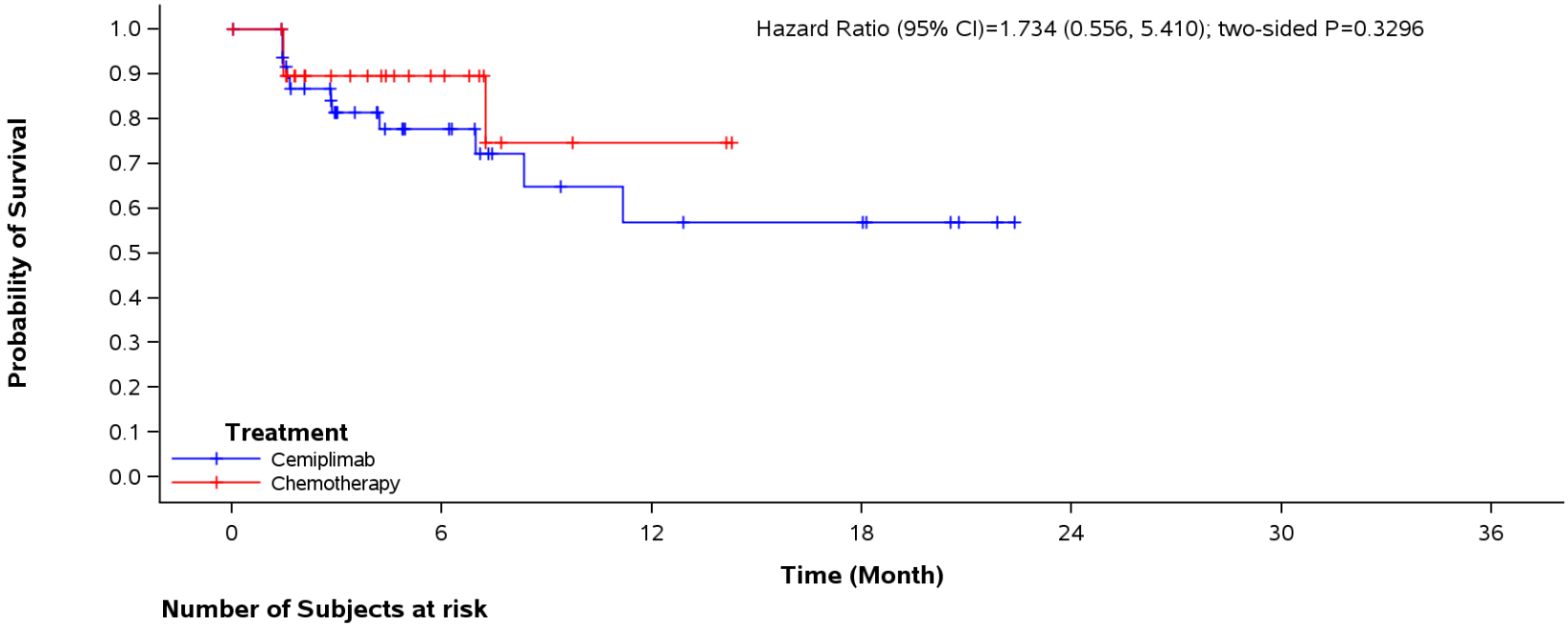
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Fatigue - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

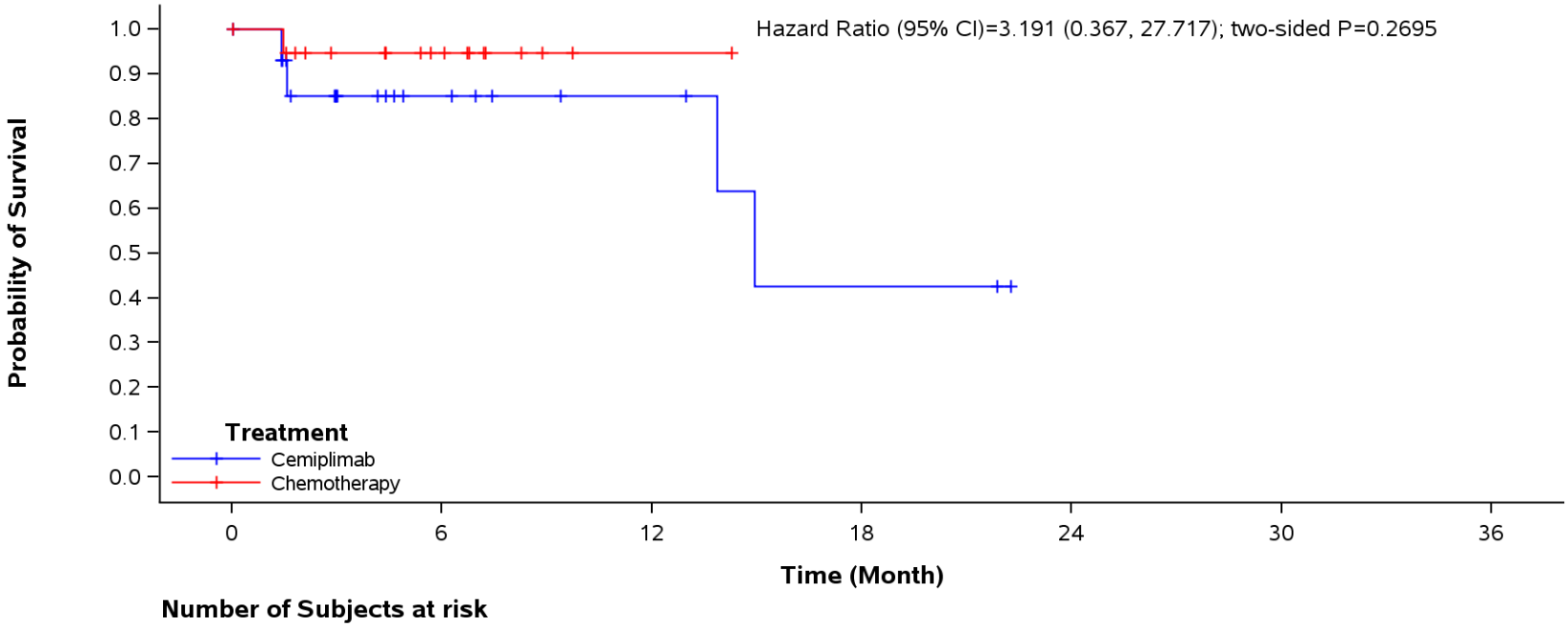
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 17 | 7 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Financial Problems - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 9 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

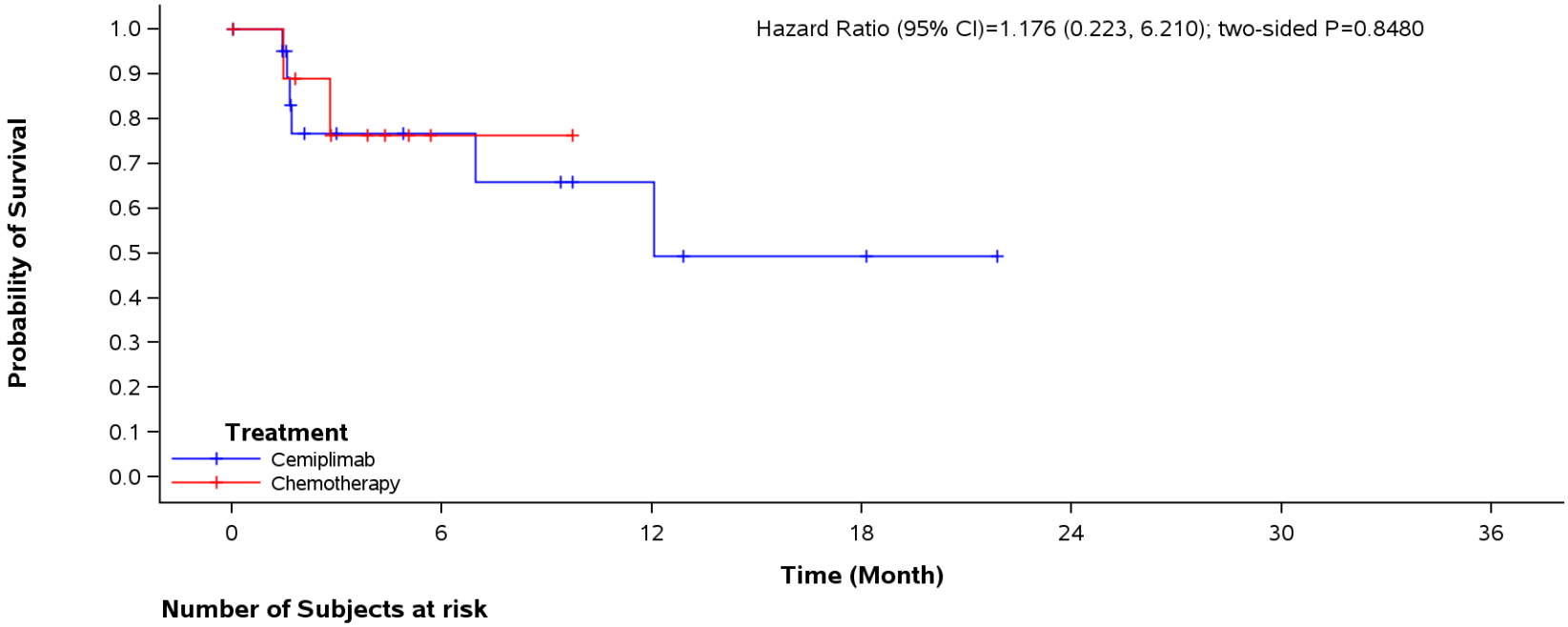
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Nausea / Vomiting - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 7 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

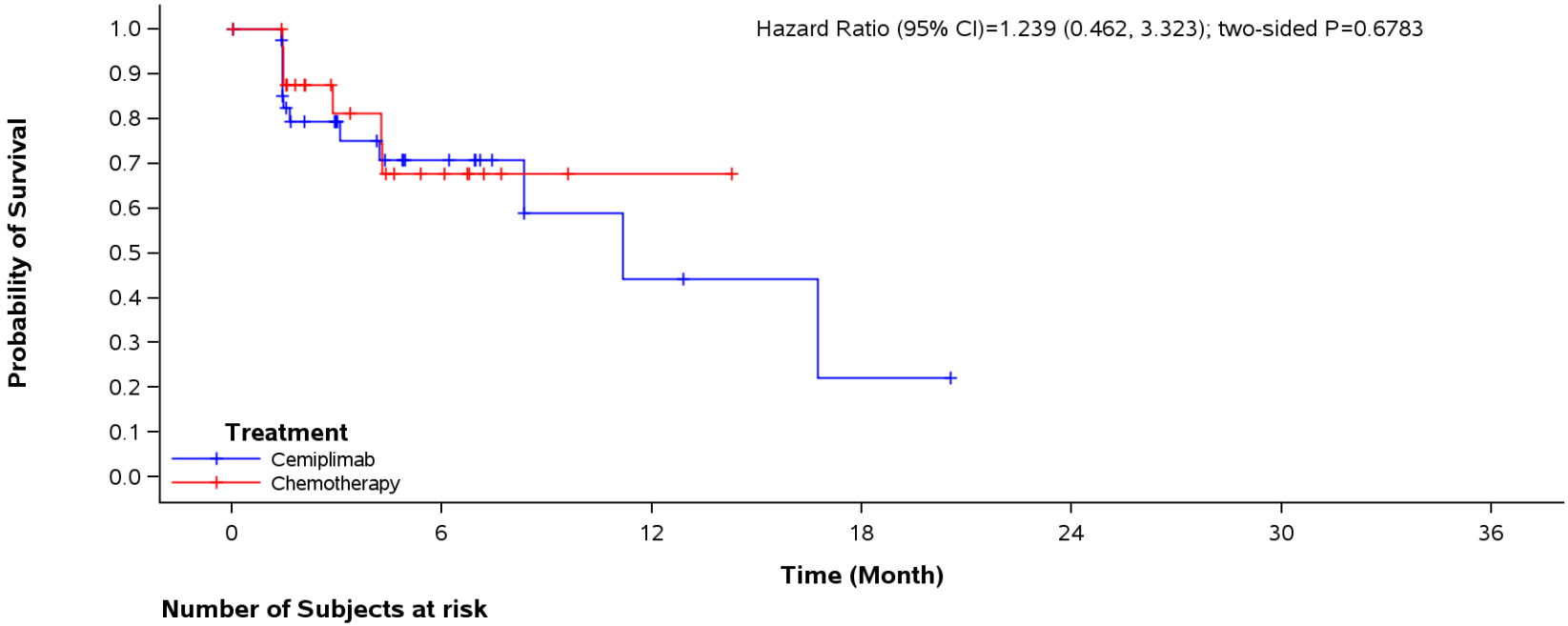
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Pain - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

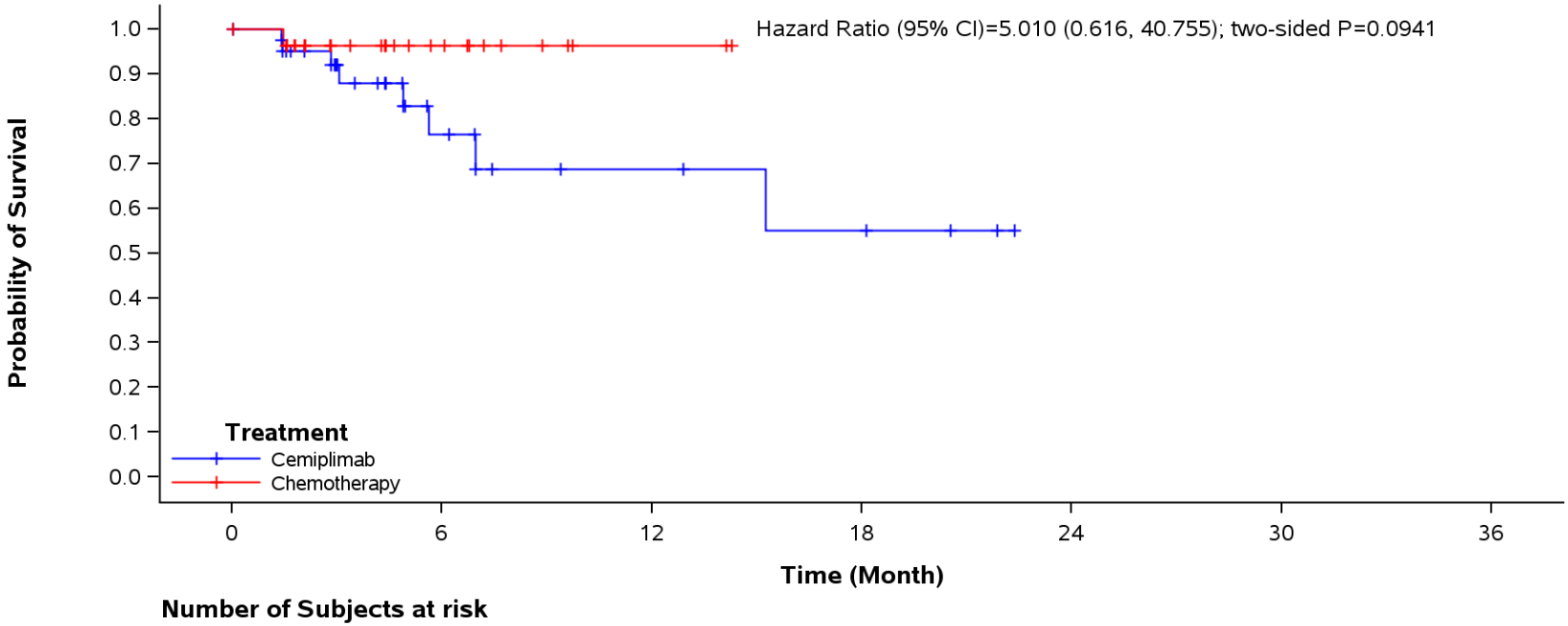
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 11 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 50 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Physical Functioning - 10 pts sensitivity sustained improvement




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 12 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

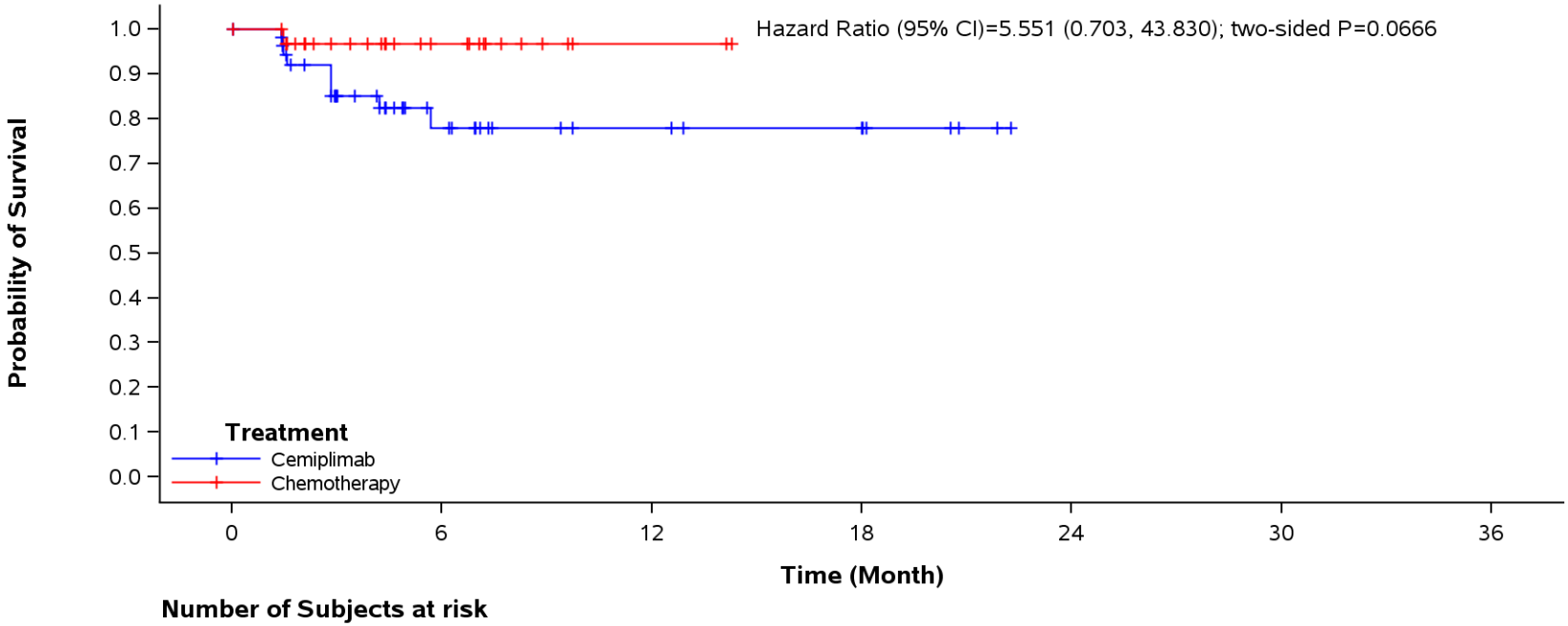
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Global health status / QoL - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 18 | 9 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

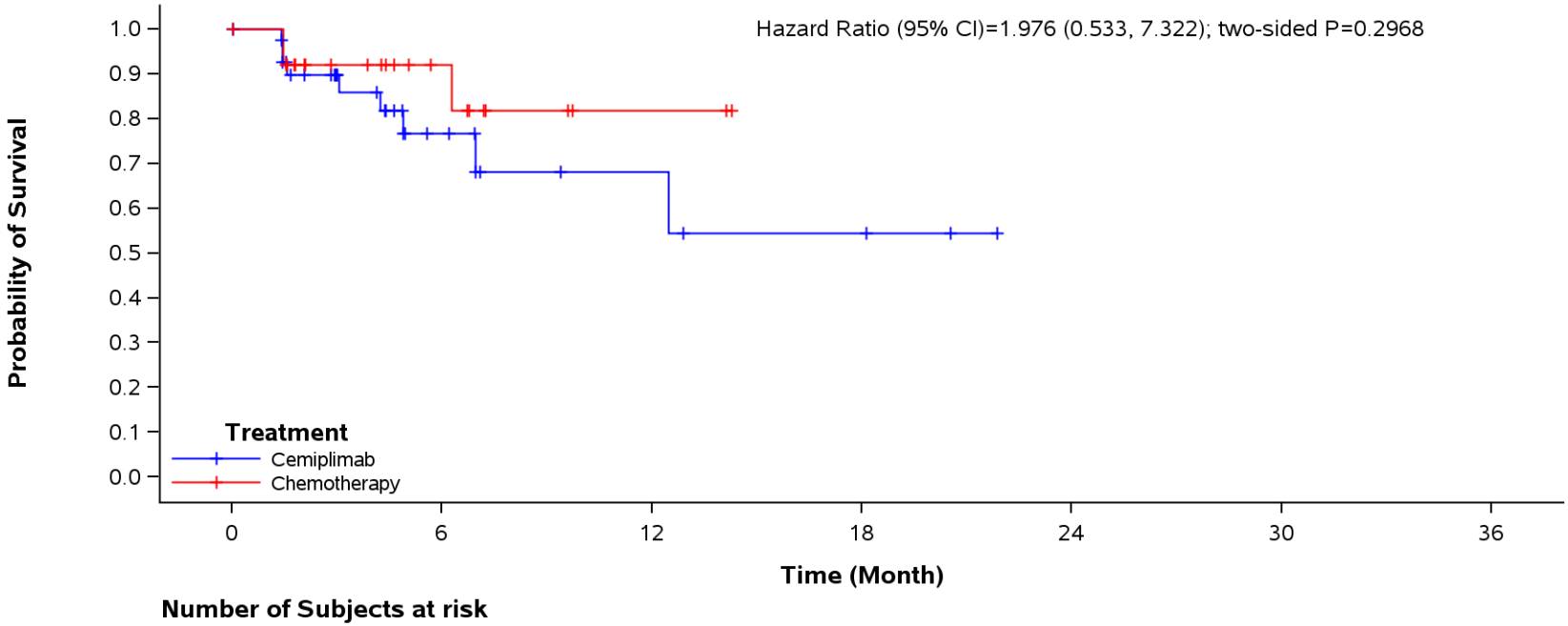
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Role Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 11 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

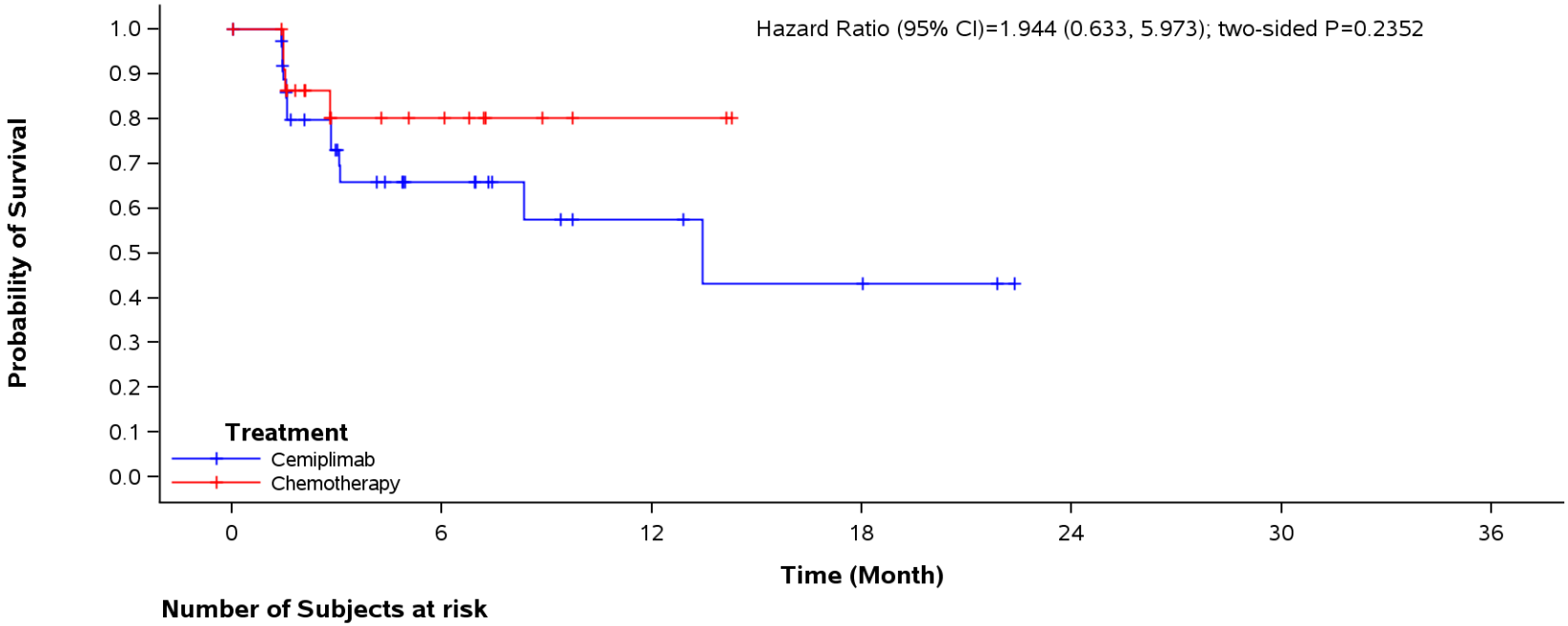
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Social Functioning - 10 pts sensitivity sustained improvement




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 12 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

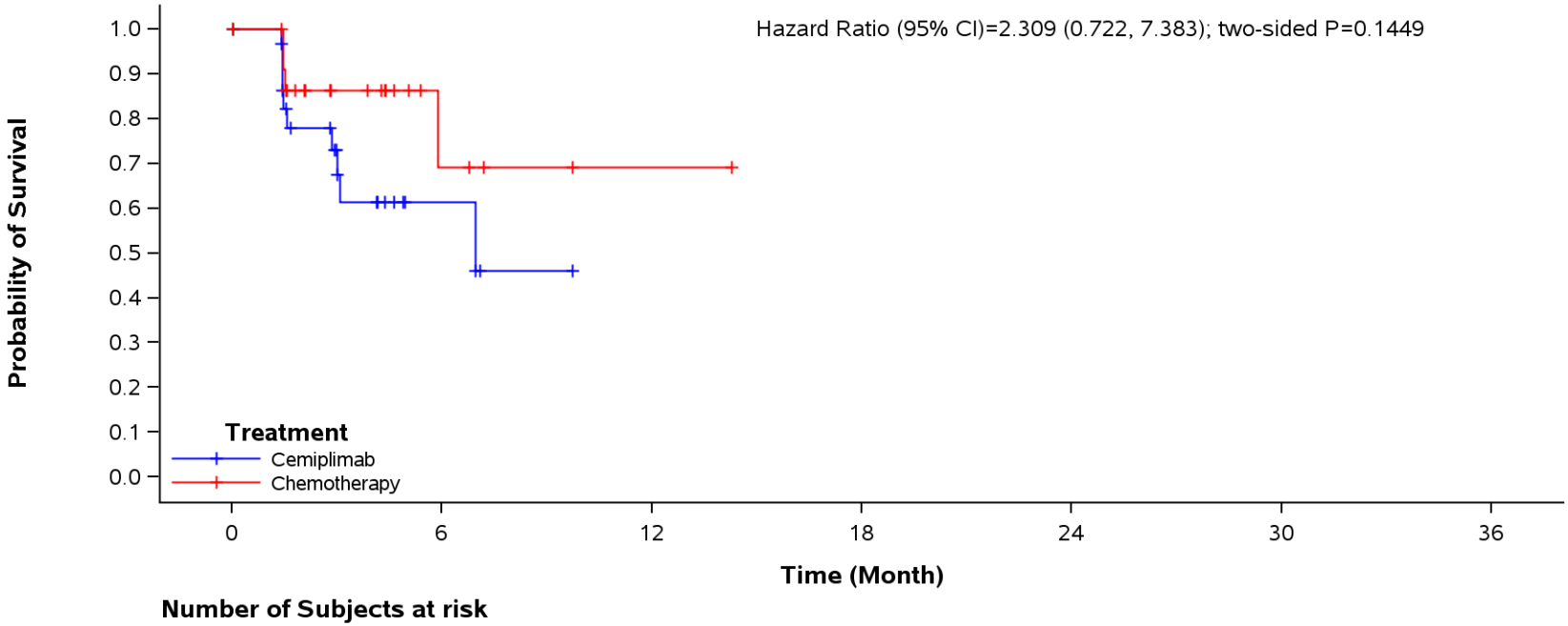
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.7a. Time to First Sensitivity Sustained Improvement with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Insomnia - 10 pts sensitivity sustained improvement



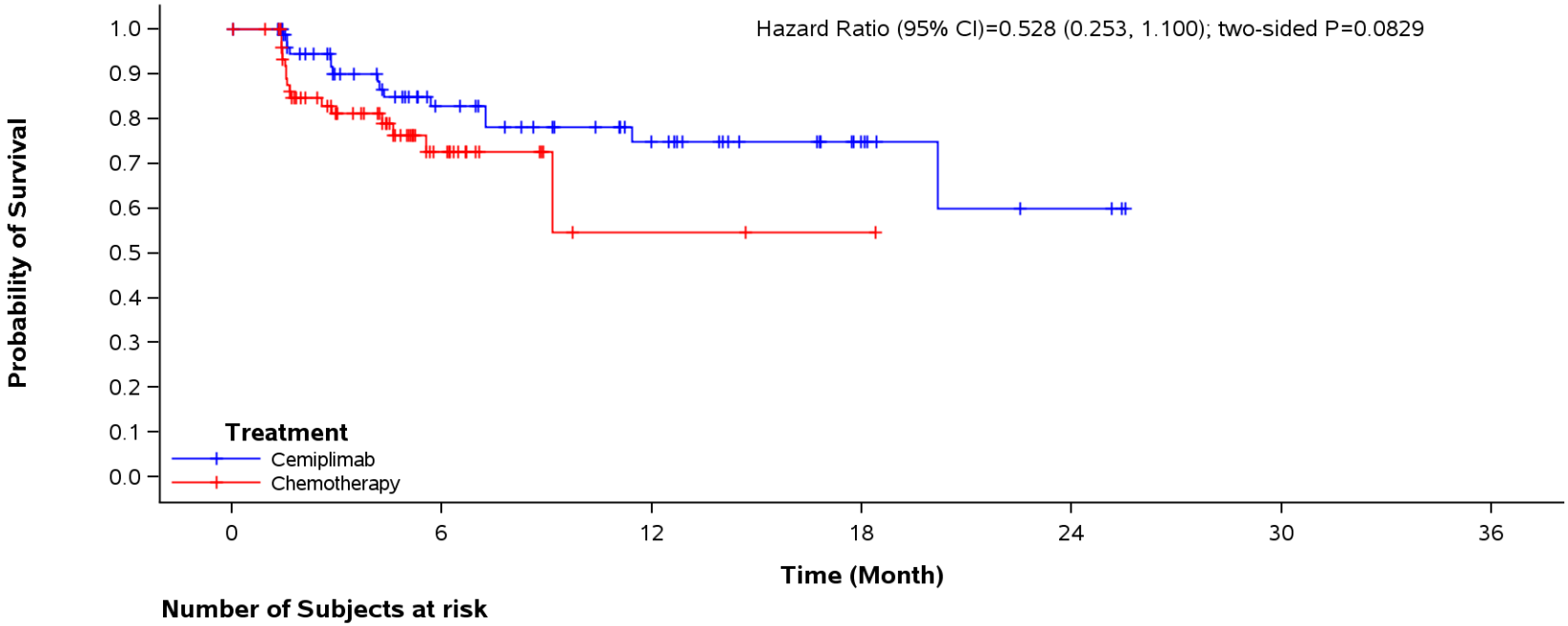

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained improvement means those with consecutive achievement of 10 points improvement till the last assessment. For all 10 points improvement included in sustained improvement, the date of first 10 points improvement is used in the calculation of time. Time is defined as (date of first 10 points sustained improvement - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

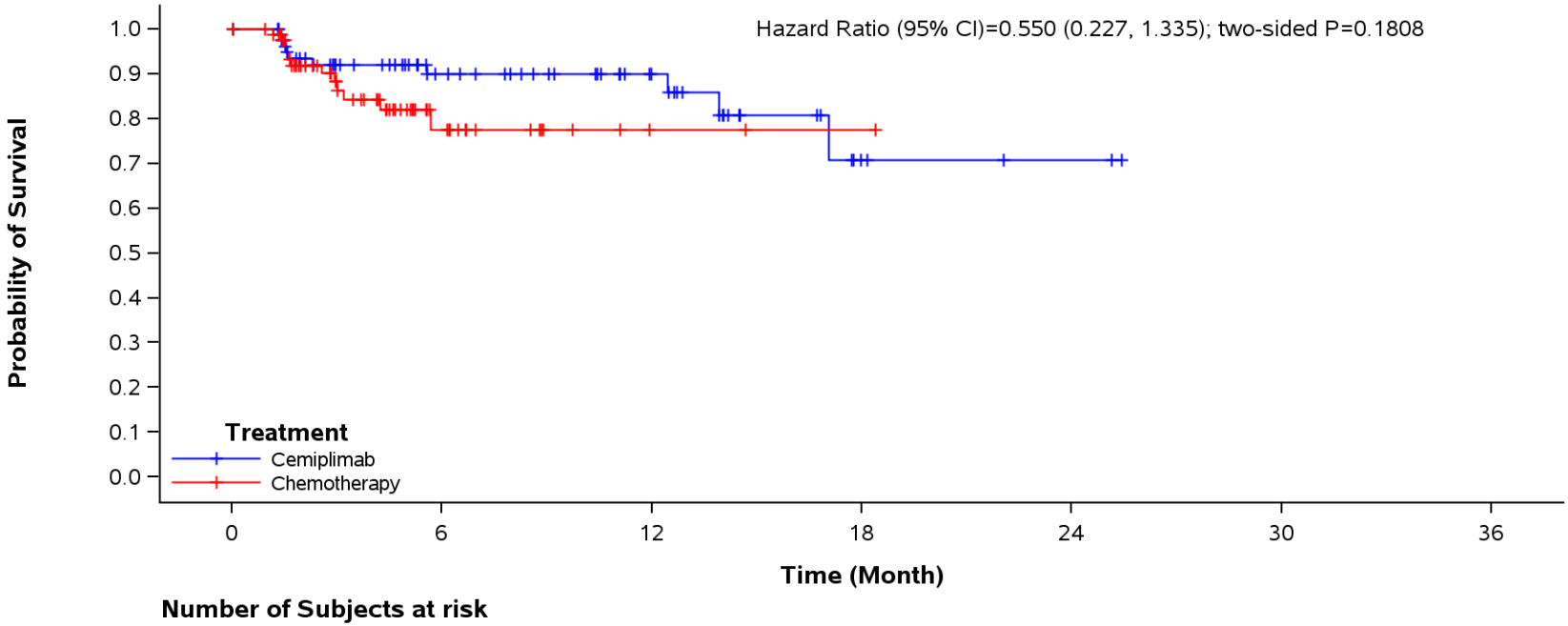
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 39 | 22 | 8 | 3 | 0 | 0 |
| Chemotherapy | 103 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 41 | 22 | 4 | 2 | 0 | 0 |
| Chemotherapy | 103 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

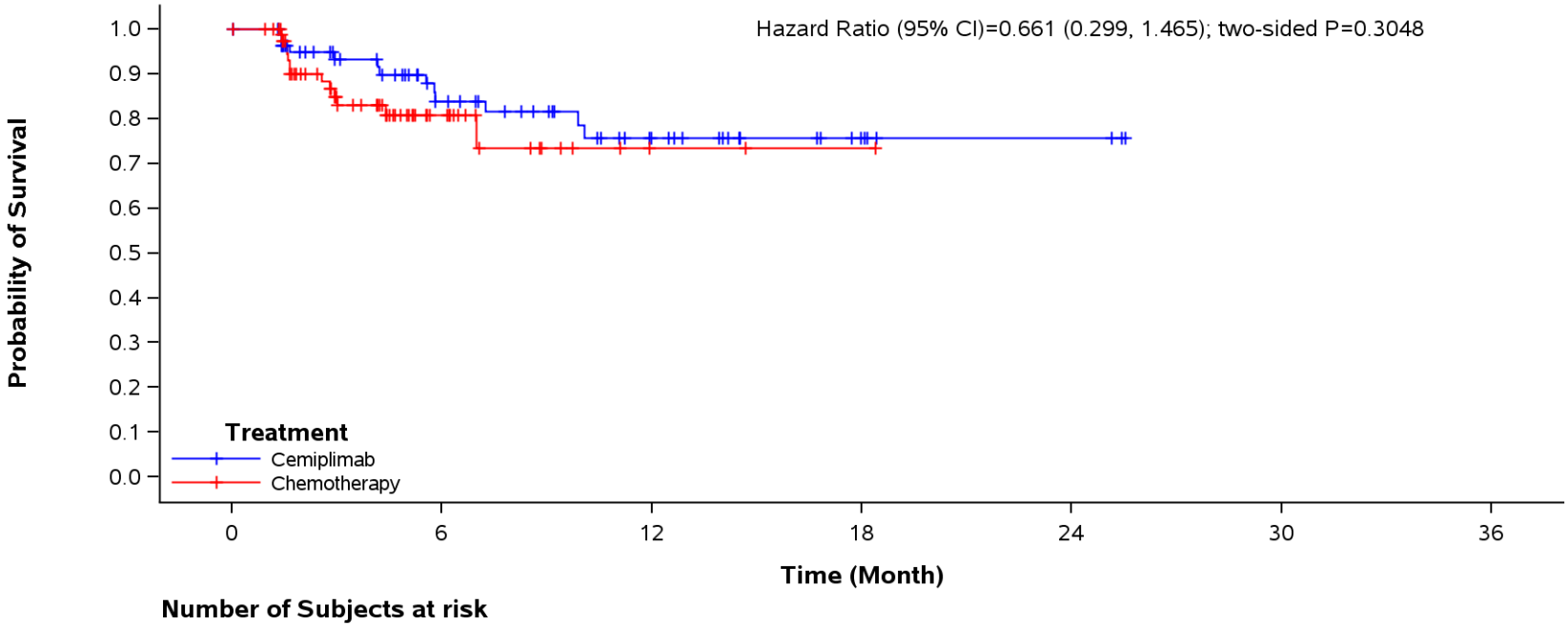
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Constipation - 10 pts sensitivity sustained deterioration



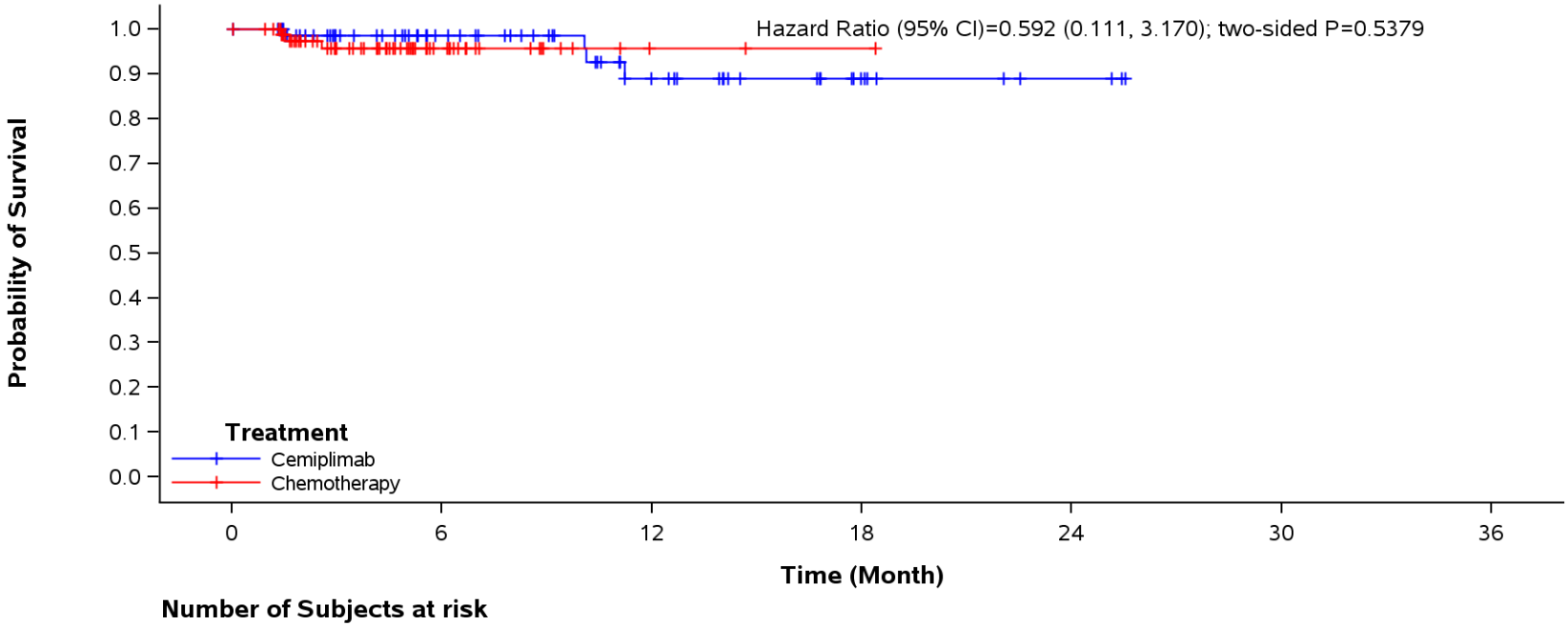

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 40 | 19 | 6 | 3 | 0 | 0 |
| Chemotherapy | 103 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Diarhoea - 10 pts sensitivity sustained deterioration



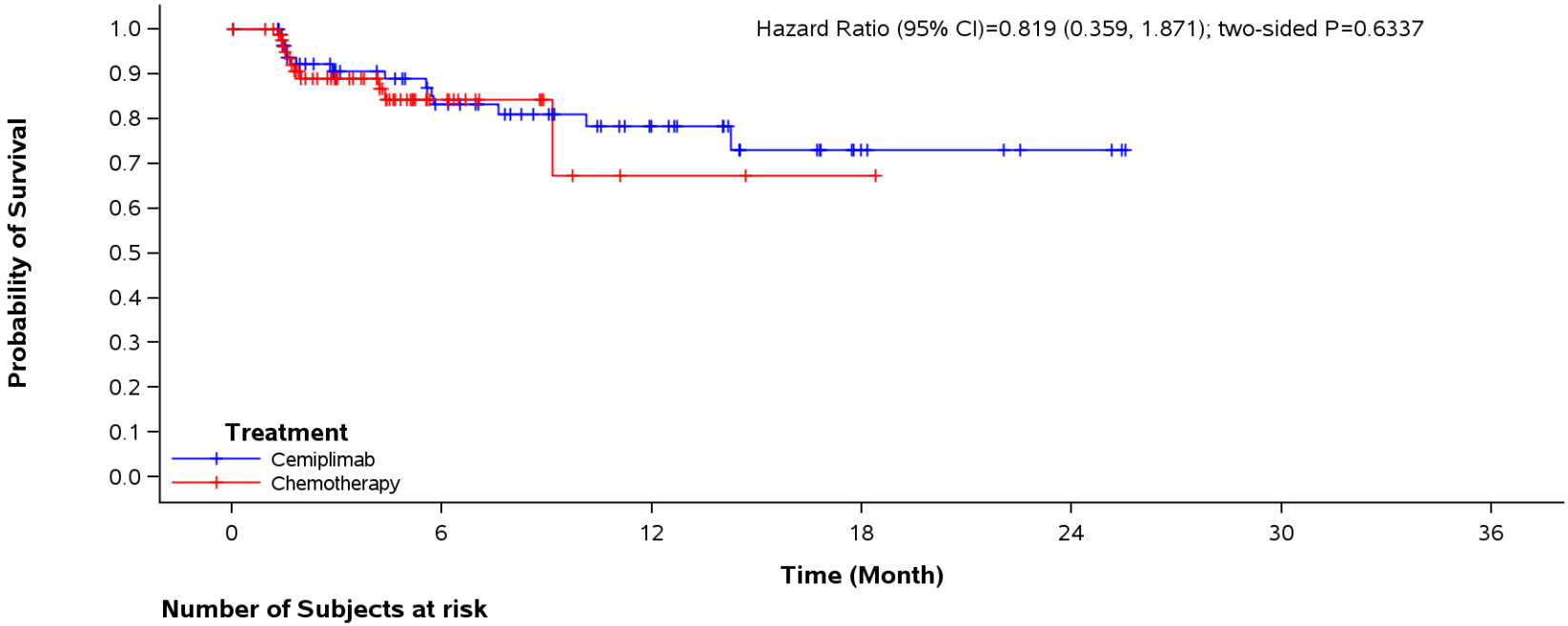

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 46 | 22 | 8 | 3 | 0 | 0 |
| Chemotherapy | 103 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Dyspnoea - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

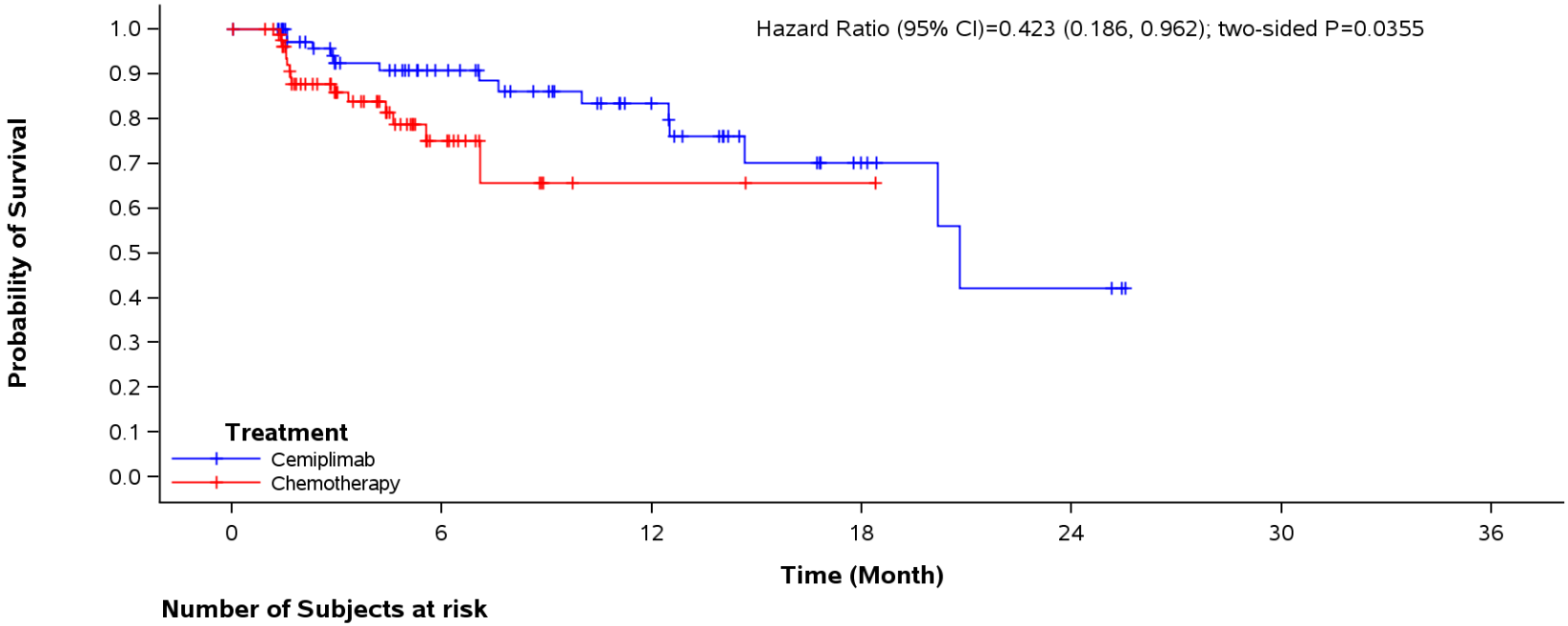
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 42 | 21 | 6 | 3 | 0 | 0 |
| Chemotherapy | 103 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)

Emotional Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 44 | 23 | 7 | 3 | 0 | 0 |
| Chemotherapy | 103 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

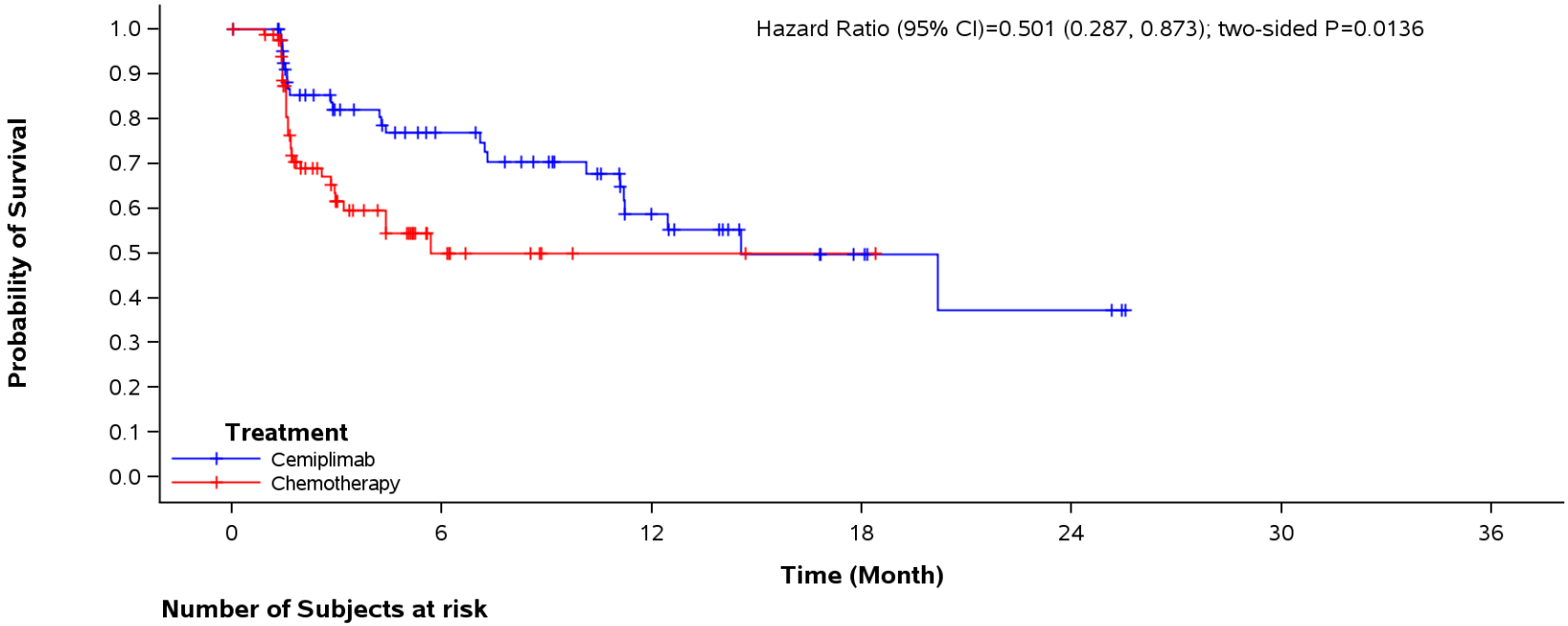
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

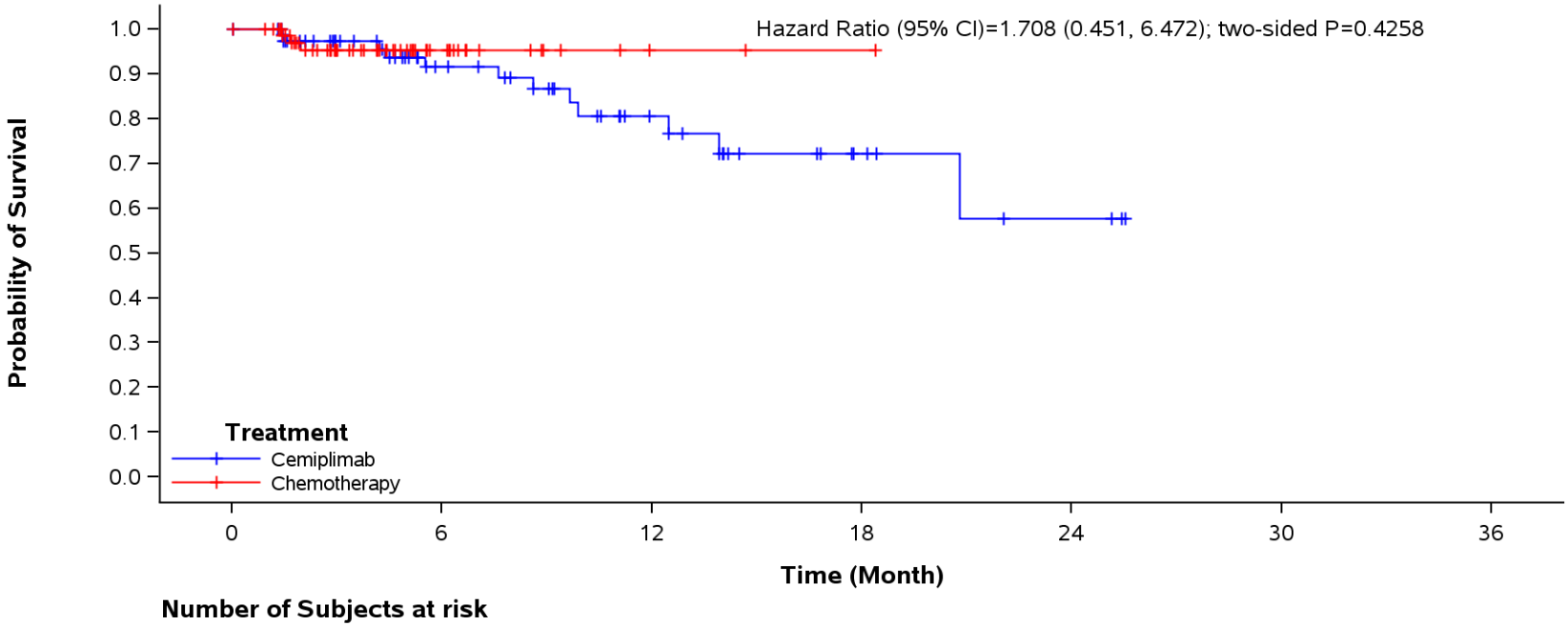
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 37 | 17 | 6 | 3 | 0 | 0 |
| Chemotherapy | 103 | 11 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 40 | 20 | 7 | 3 | 0 | 0 |
| Chemotherapy | 103 | 18 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

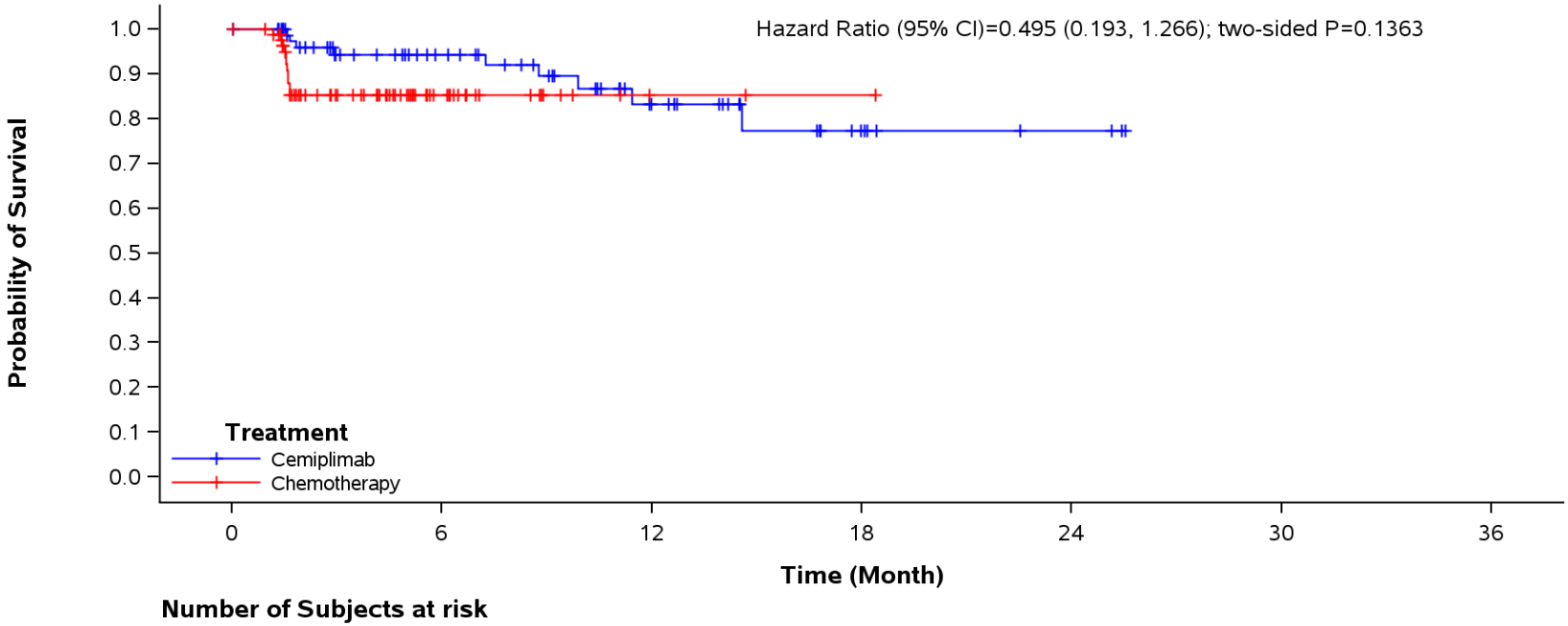
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Nausea / Vomiting - 10 pts sensitivity sustained deterioration



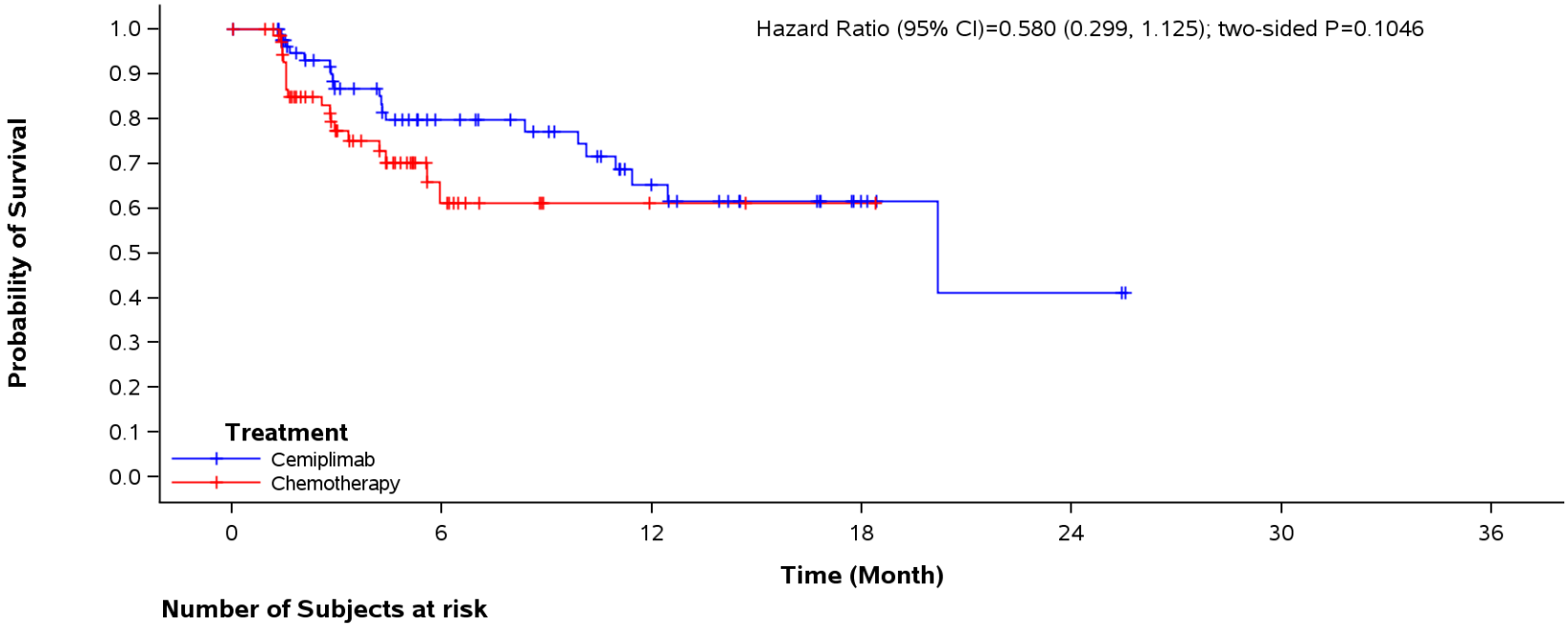

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 46 | 22 | 7 | 3 | 0 | 0 |
| Chemotherapy | 103 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

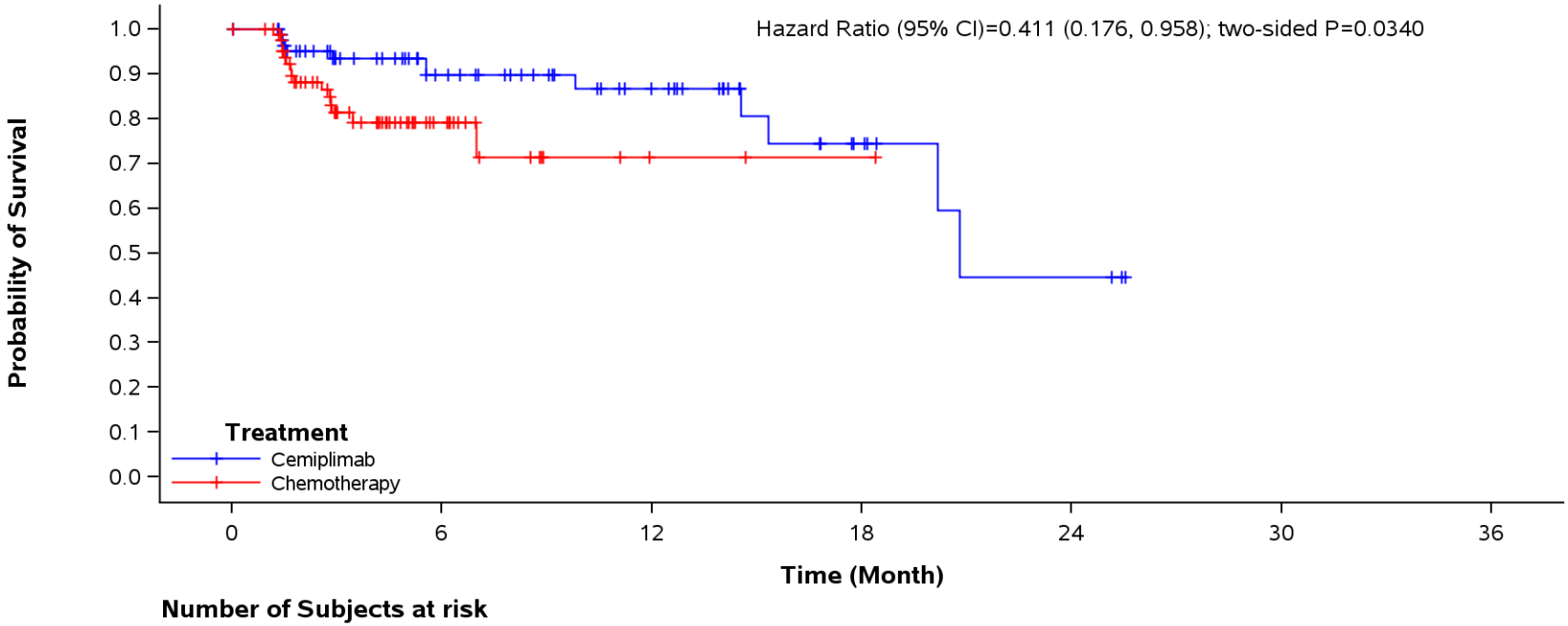
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 36 | 18 | 5 | 2 | 0 | 0 |
| Chemotherapy | 103 | 13 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:30:56, yingyuan.lin)

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

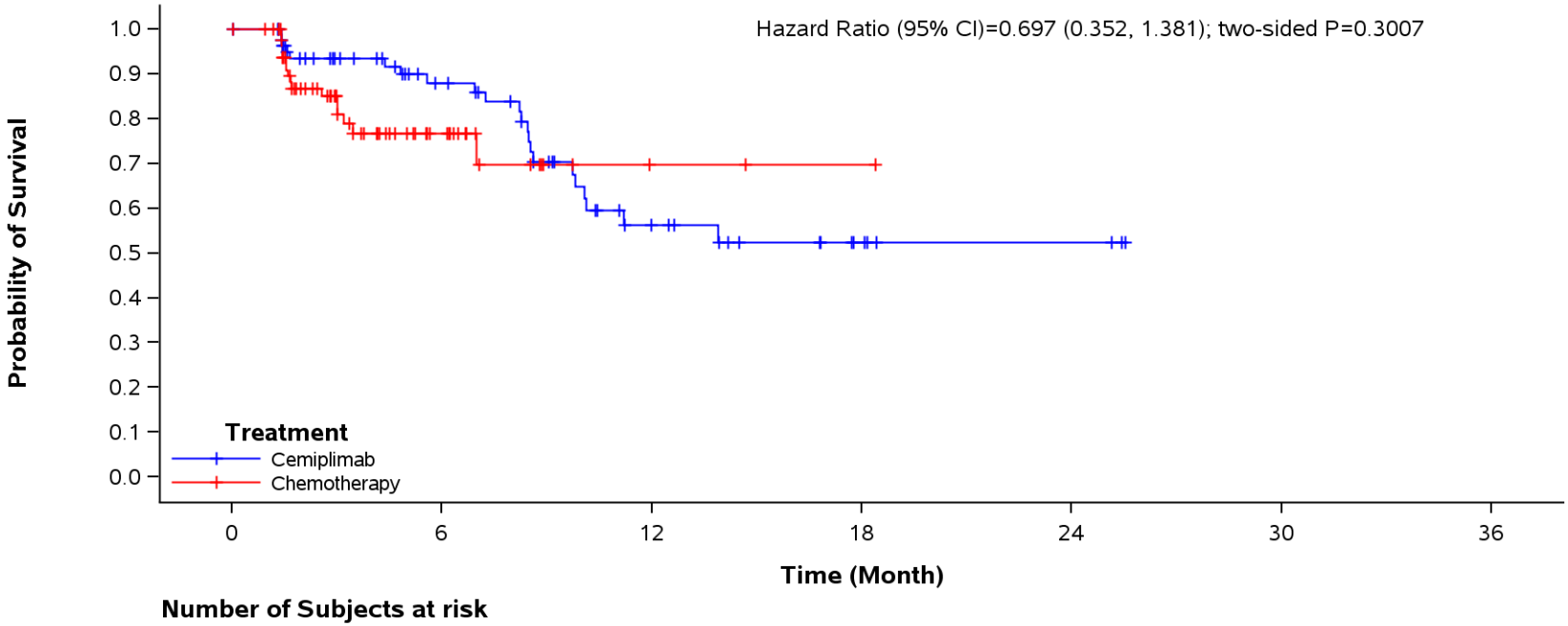
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 44 | 24 | 8 | 3 | 0 | 0 |
| Chemotherapy | 103 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 44 | 16 | 6 | 3 | 0 | 0 |
| Chemotherapy | 103 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

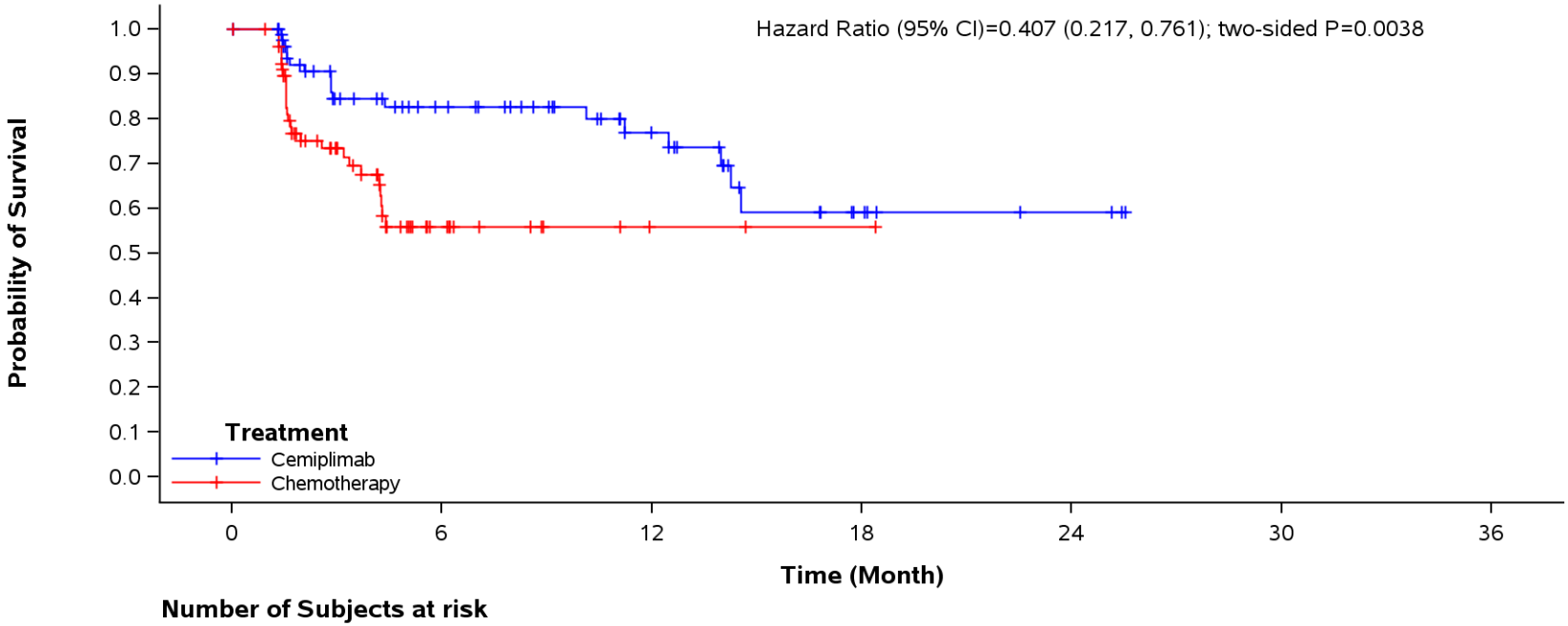
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Role Functioning - 10 pts sensitivity sustained deterioration



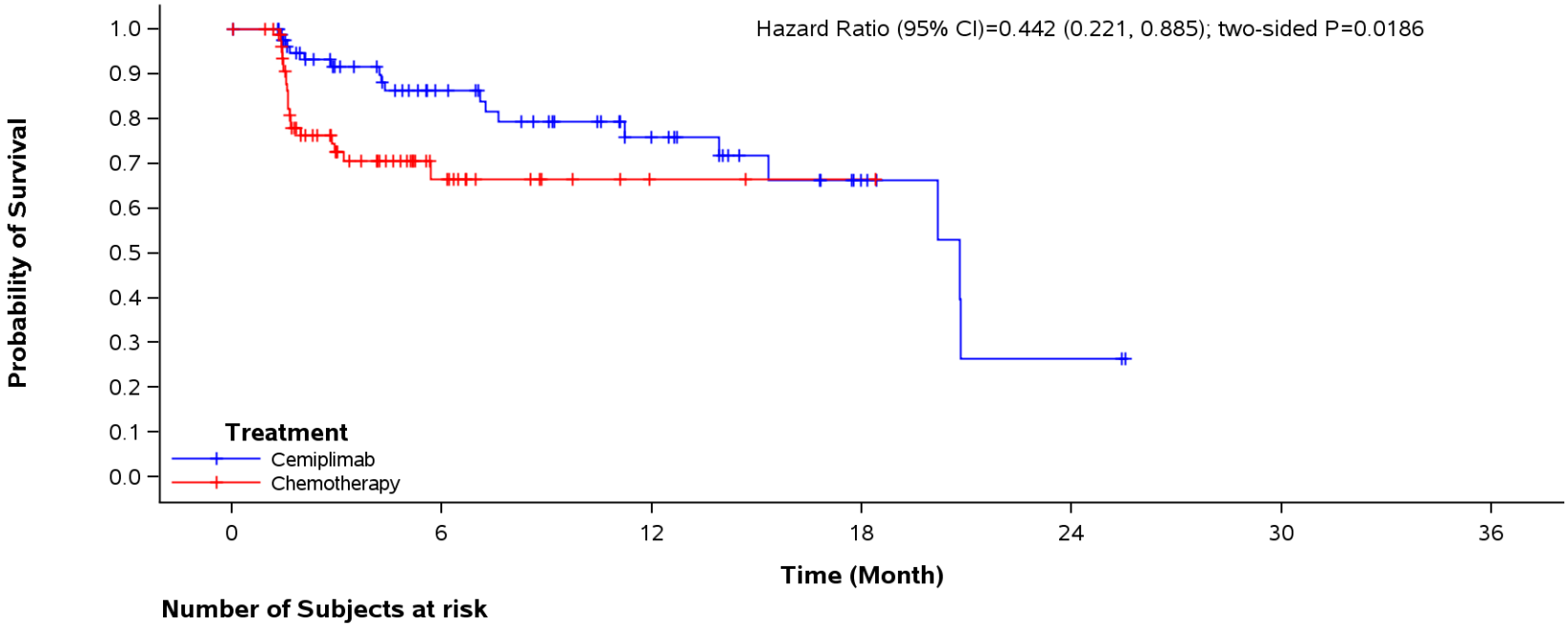

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 42 | 23 | 7 | 3 | 0 | 0 |
| Chemotherapy | 103 | 12 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Social Functioning - 10 pts sensitivity sustained deterioration



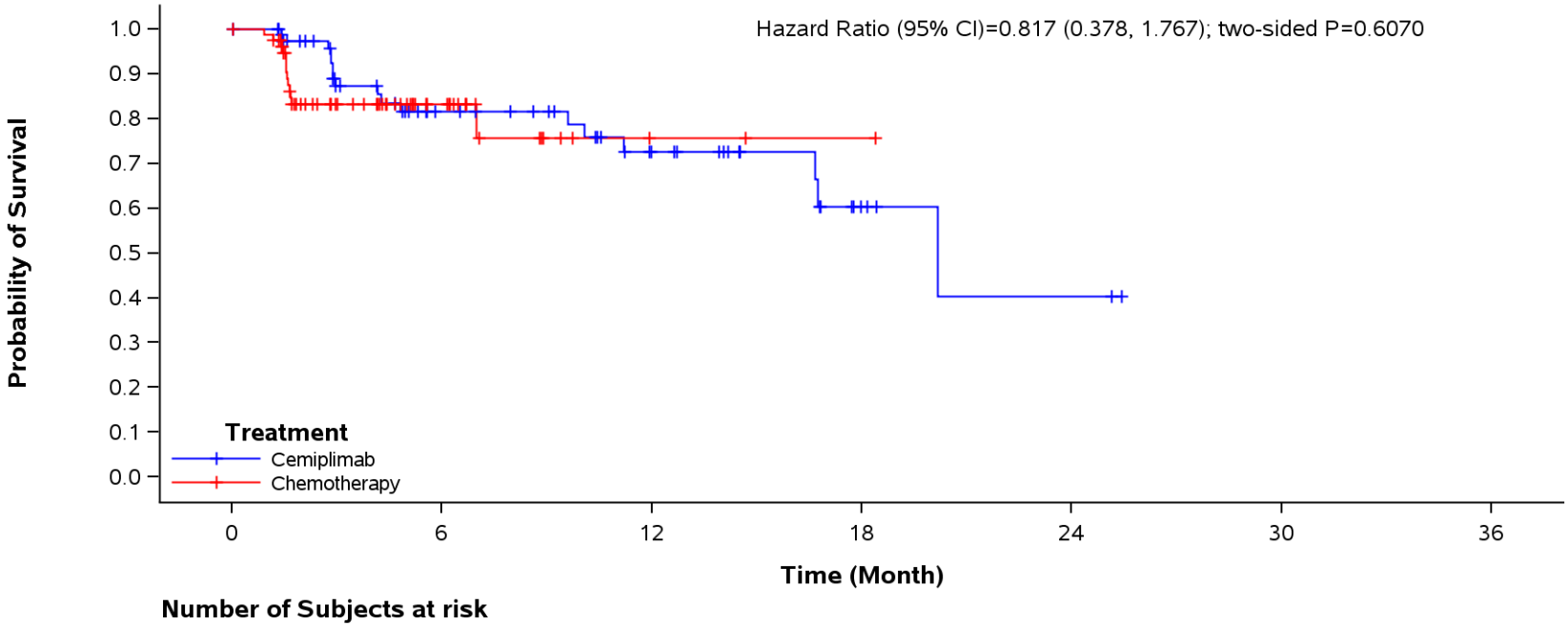

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 40 | 21 | 7 | 2 | 0 | 0 |
| Chemotherapy | 103 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 36 | 19 | 5 | 2 | 0 | 0 |
| Chemotherapy | 103 | 20 | 2 | 1 | 0 | 0 | 0 |

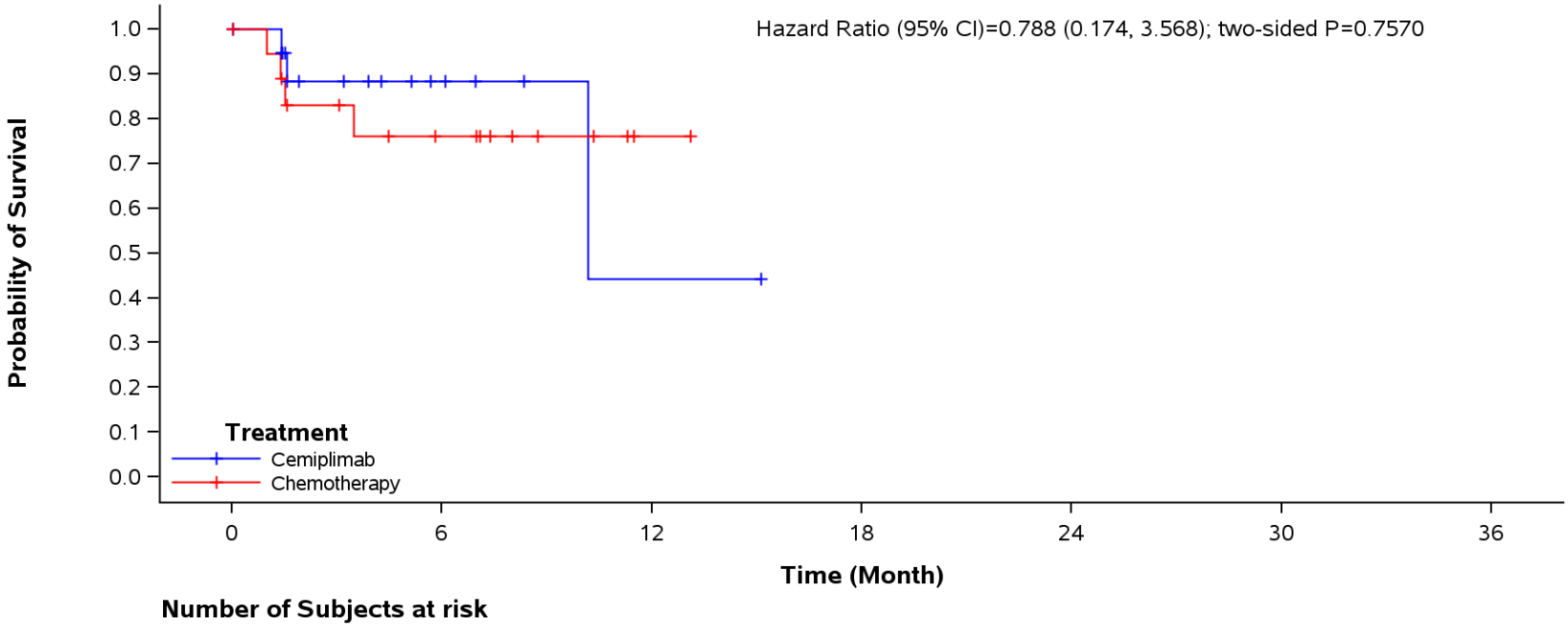
Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:30:56, yingyuan.lin)

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

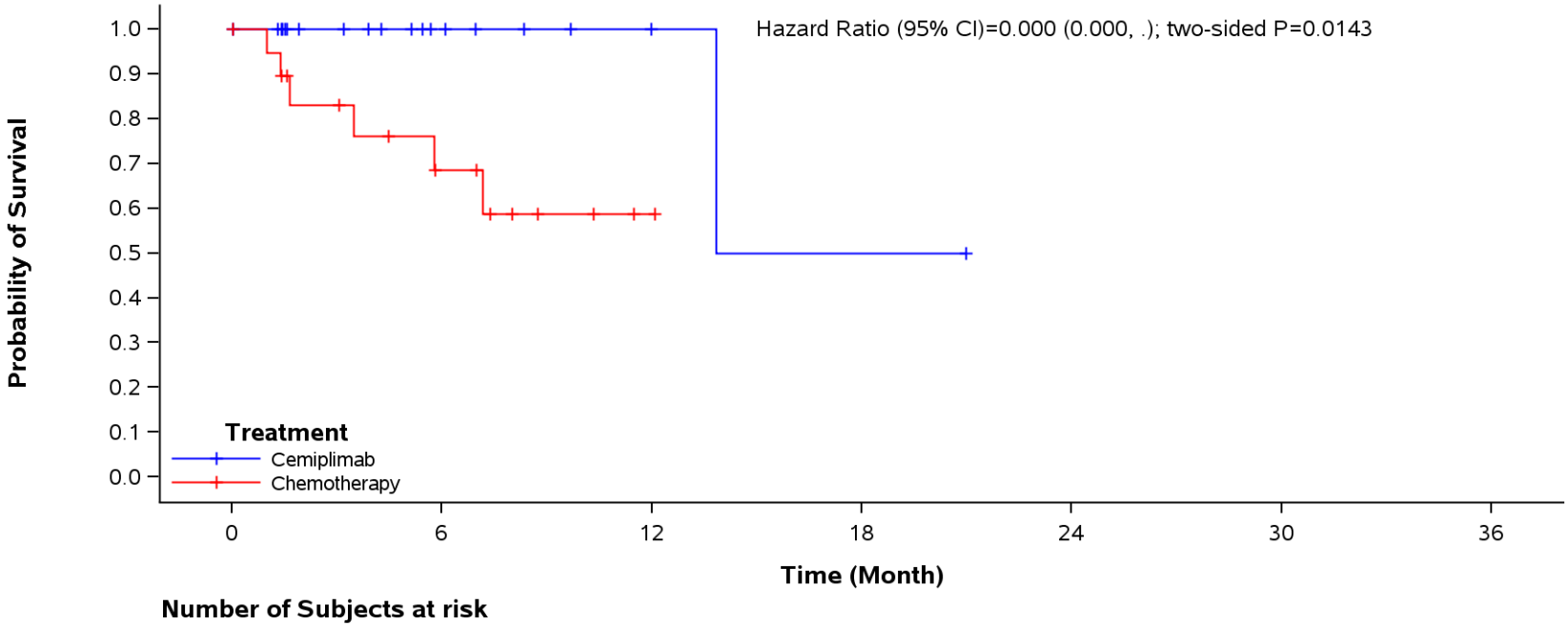
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Cognitive Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

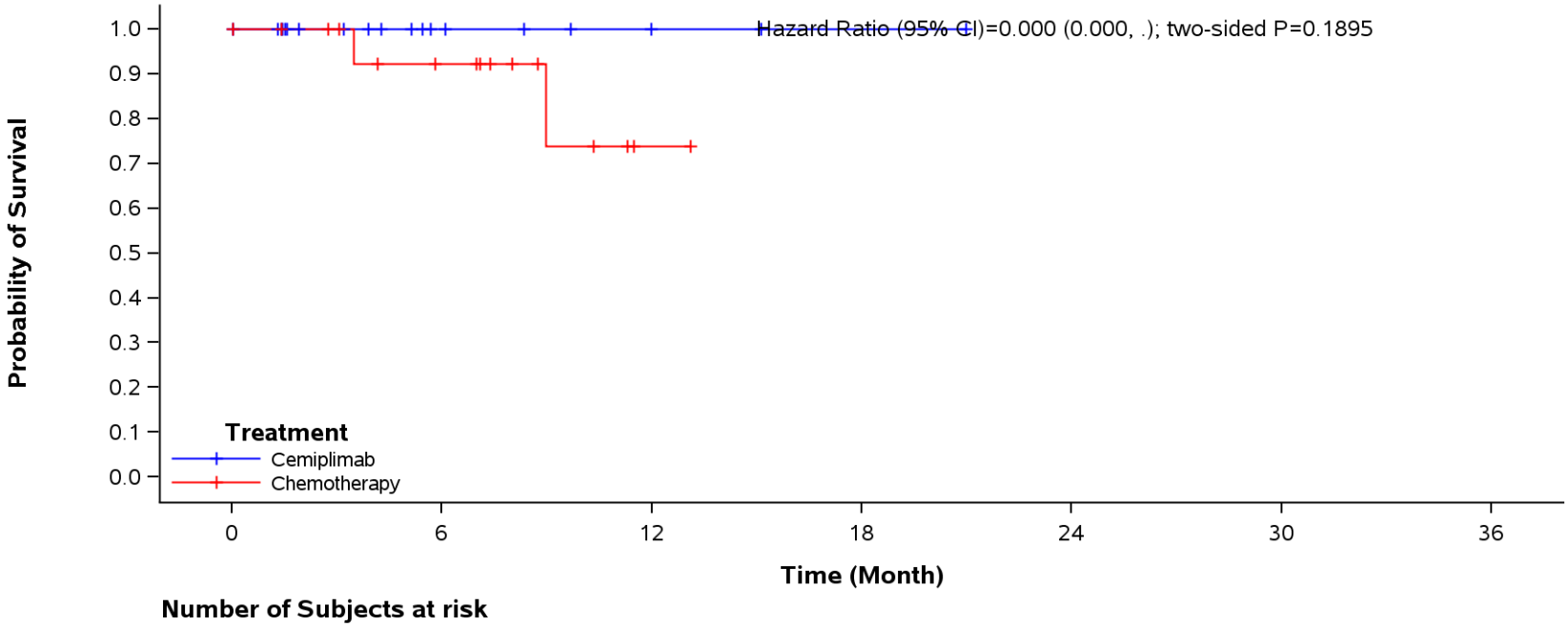
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Constipation - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

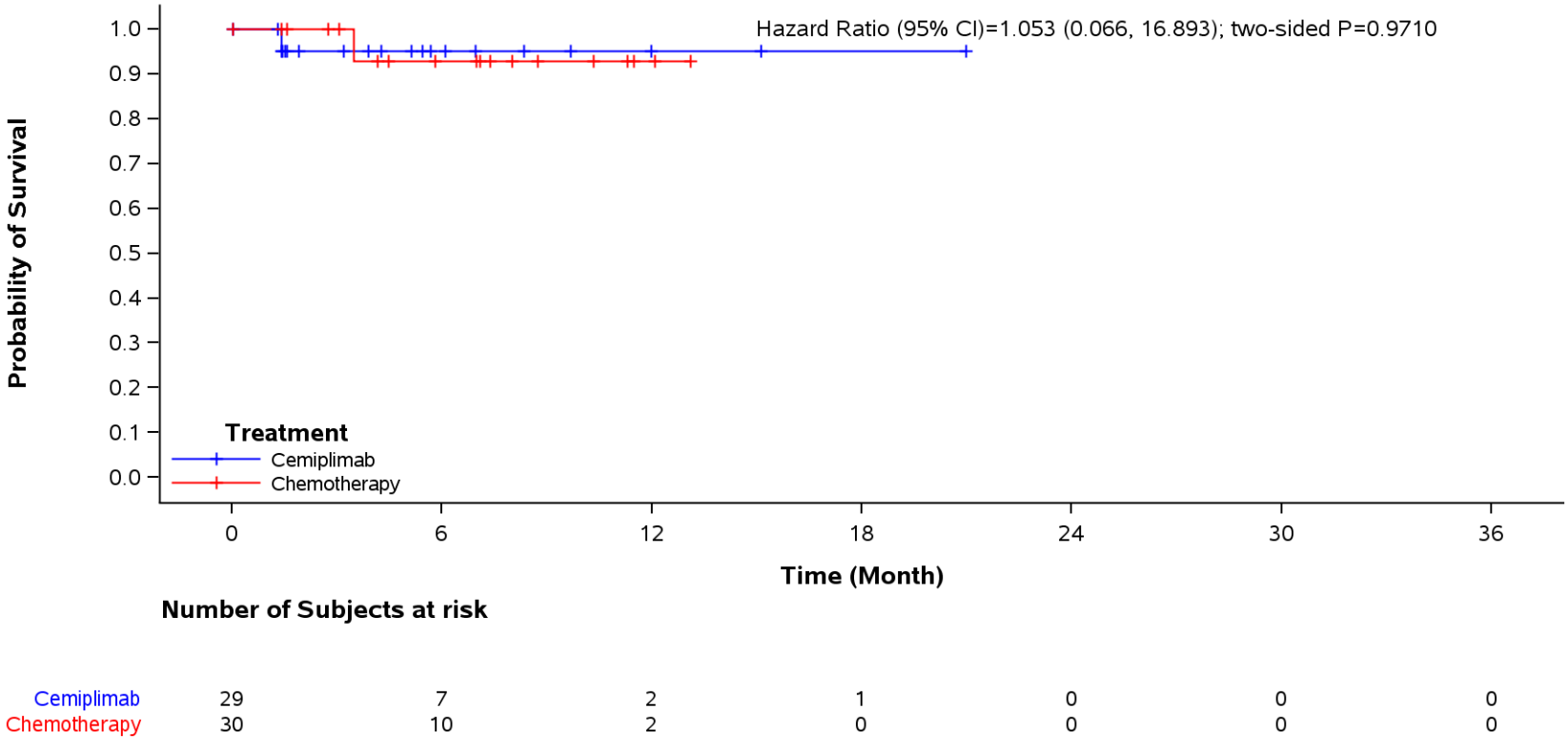
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Diarhoea - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

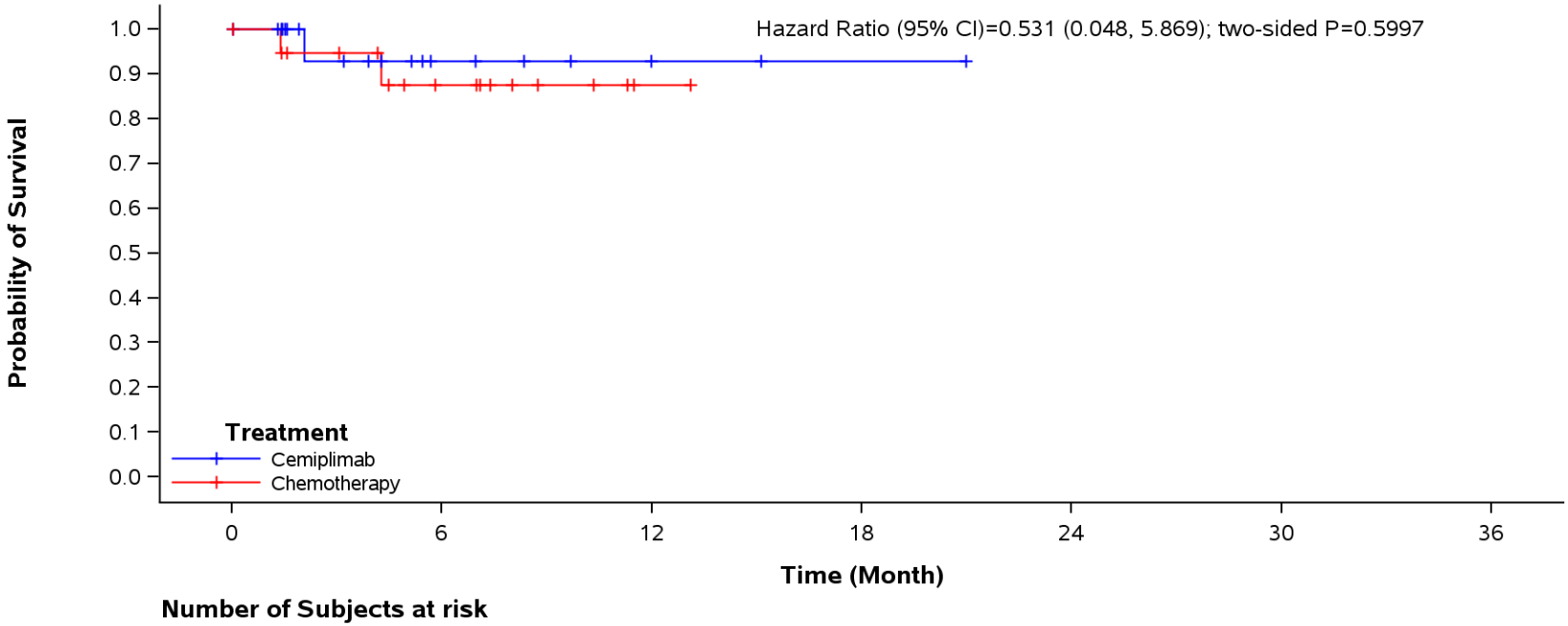
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Dyspnoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

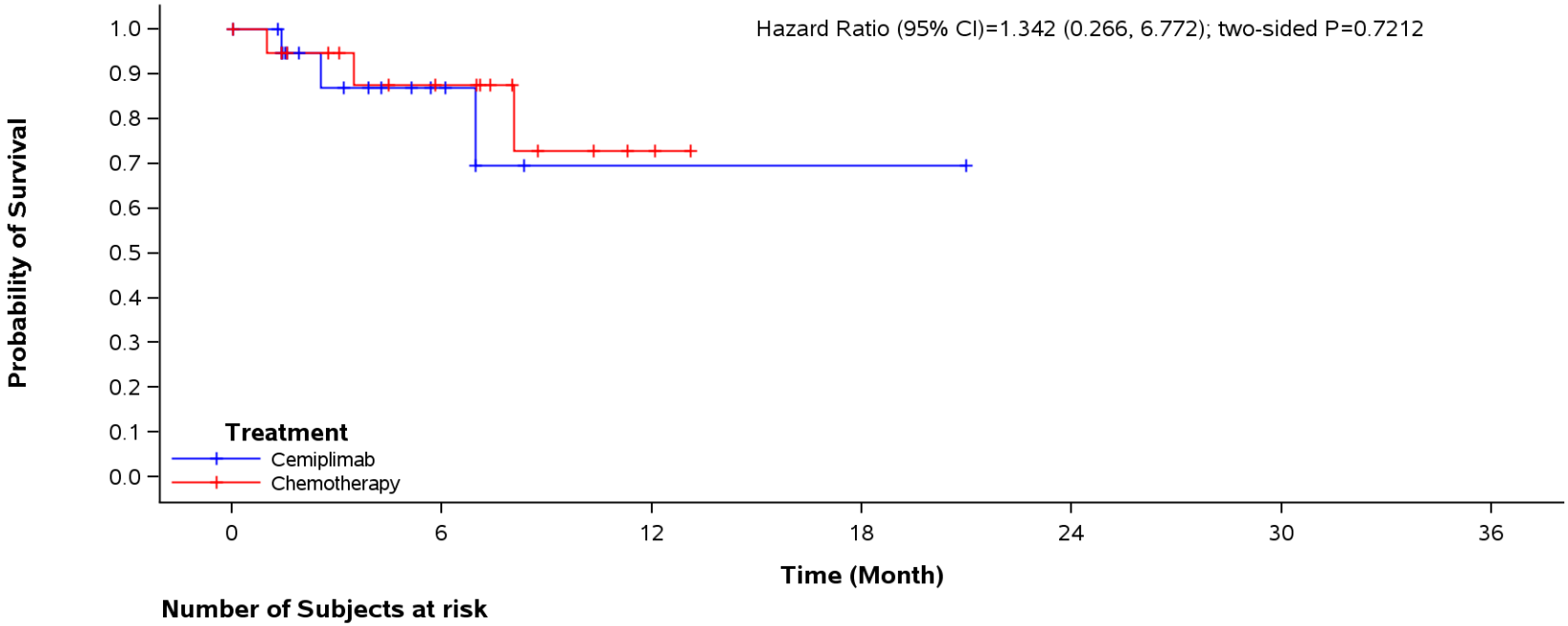
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Emotional Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

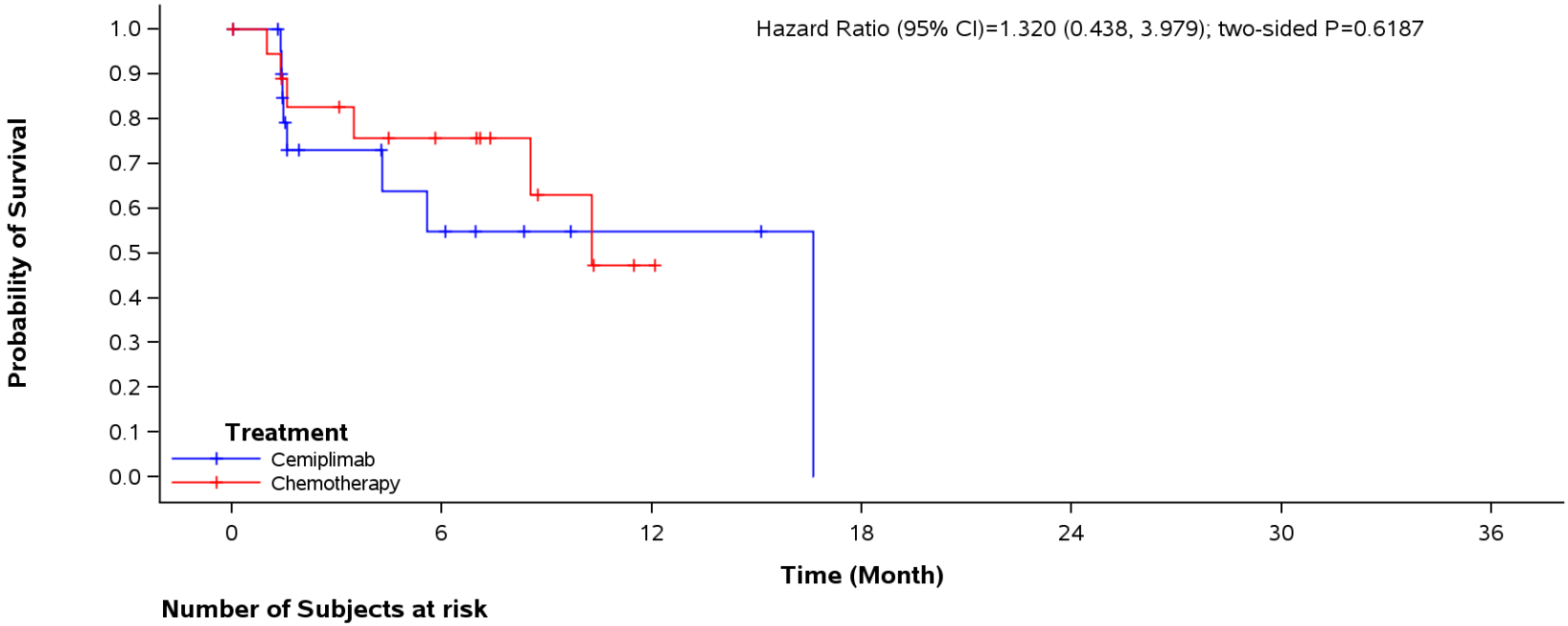
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

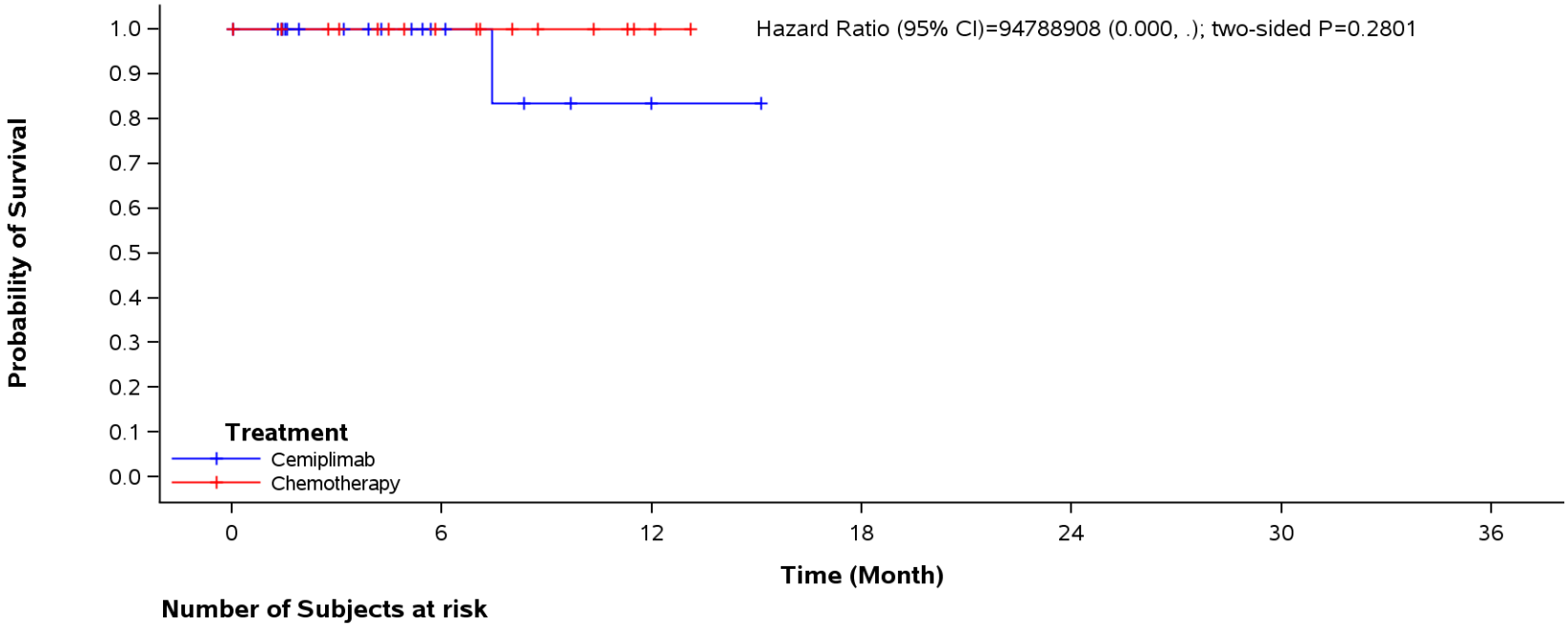
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Financial Problems - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

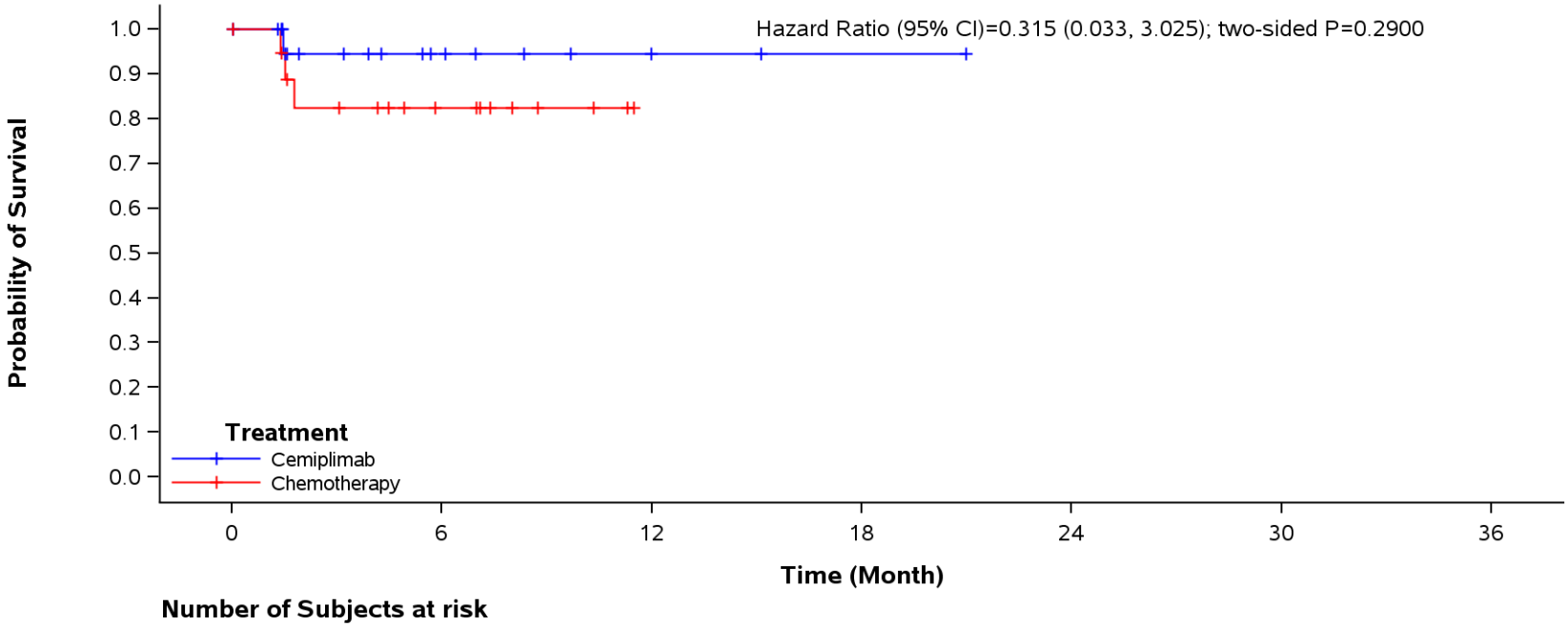
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

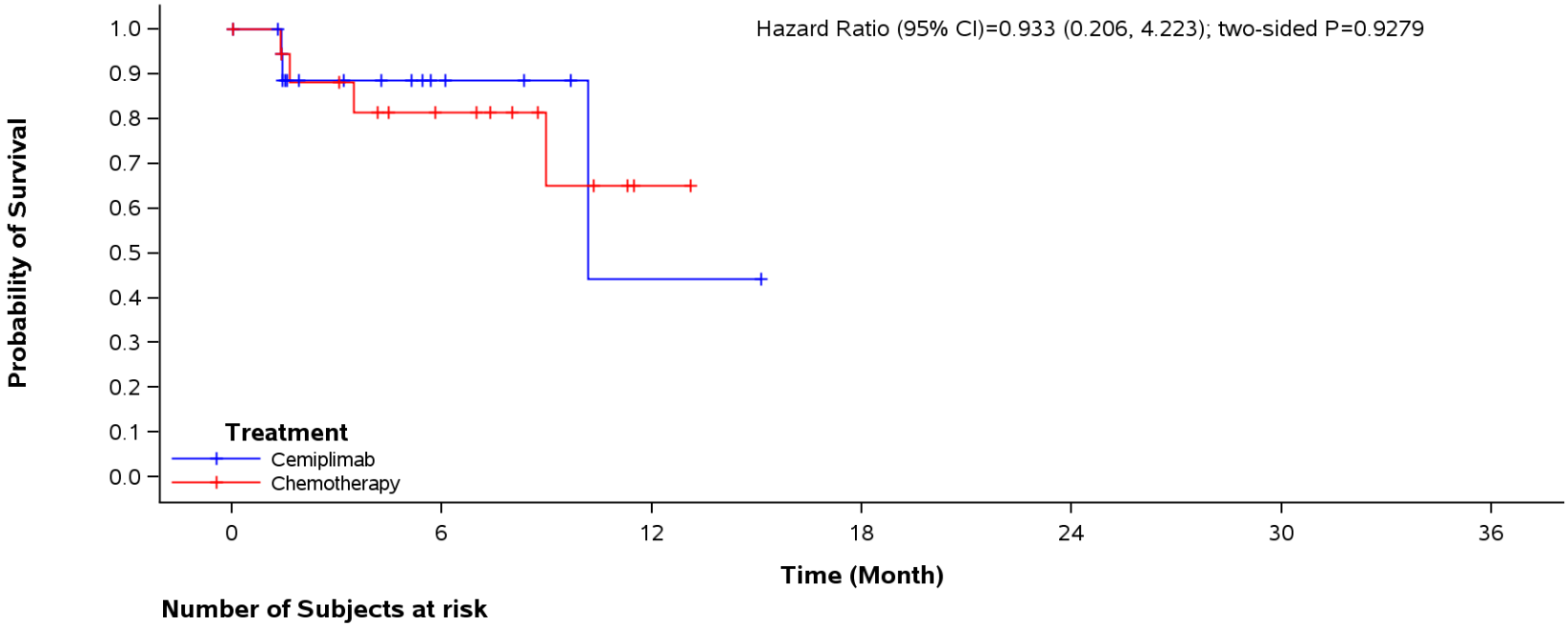
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

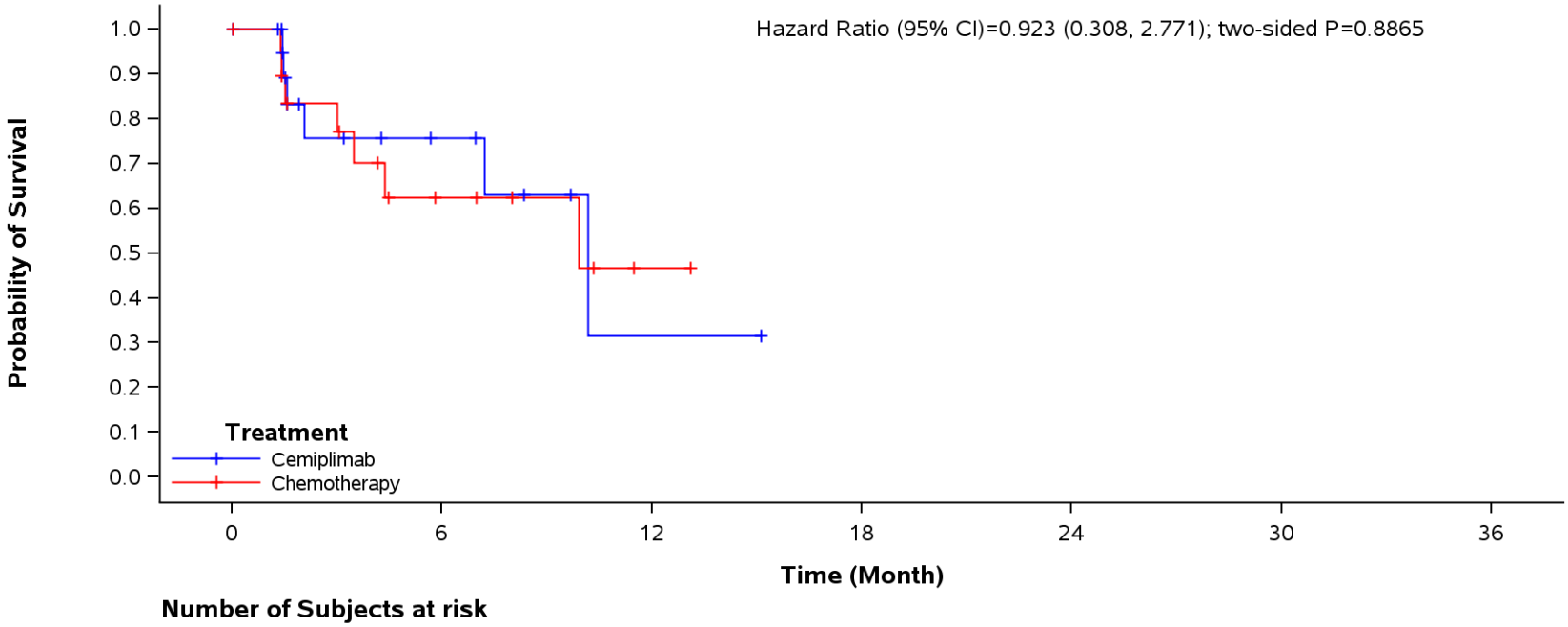
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Physical Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

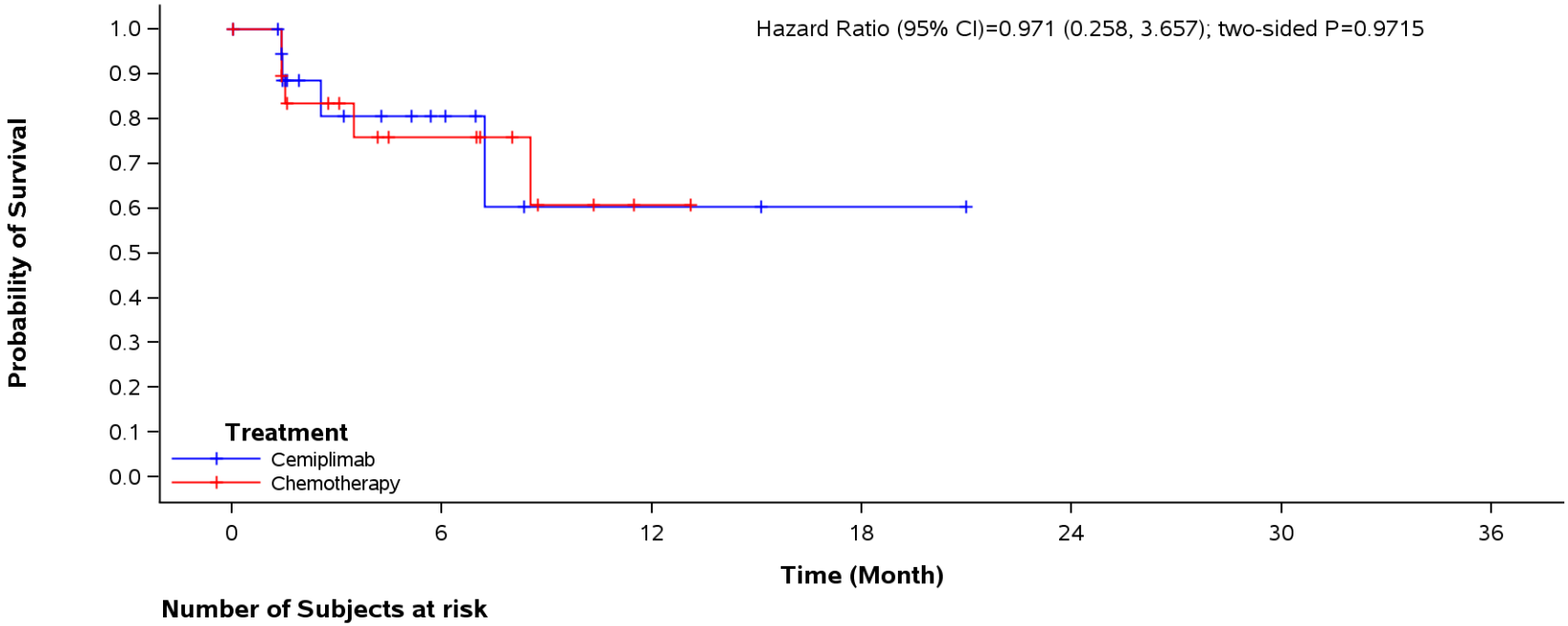
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

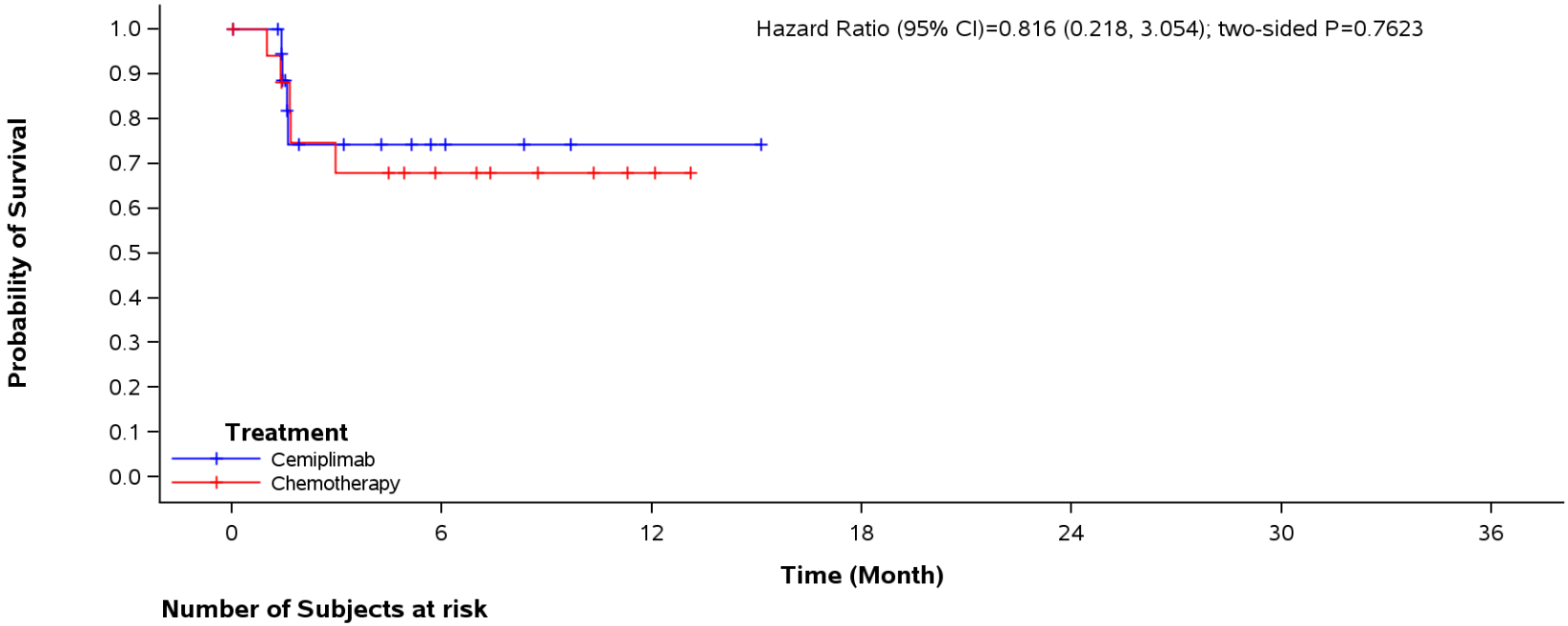
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Role Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 7 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

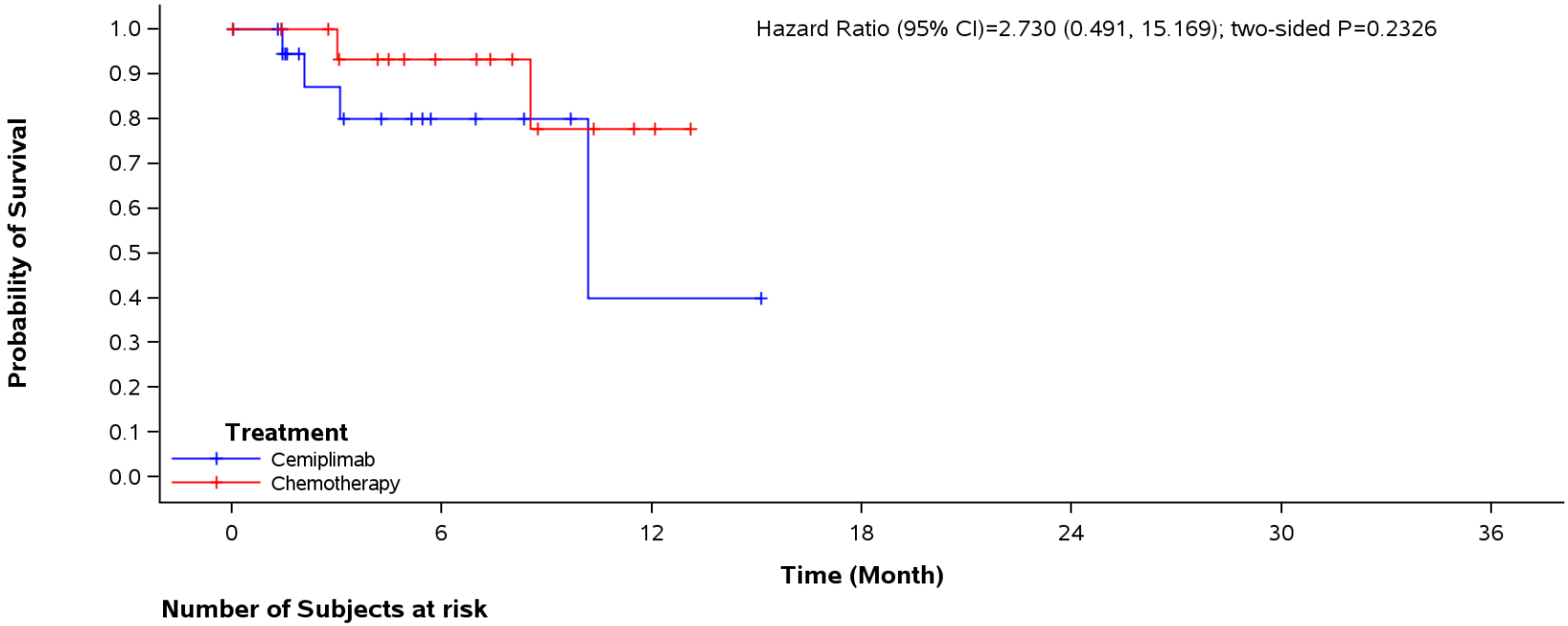
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%

Social Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

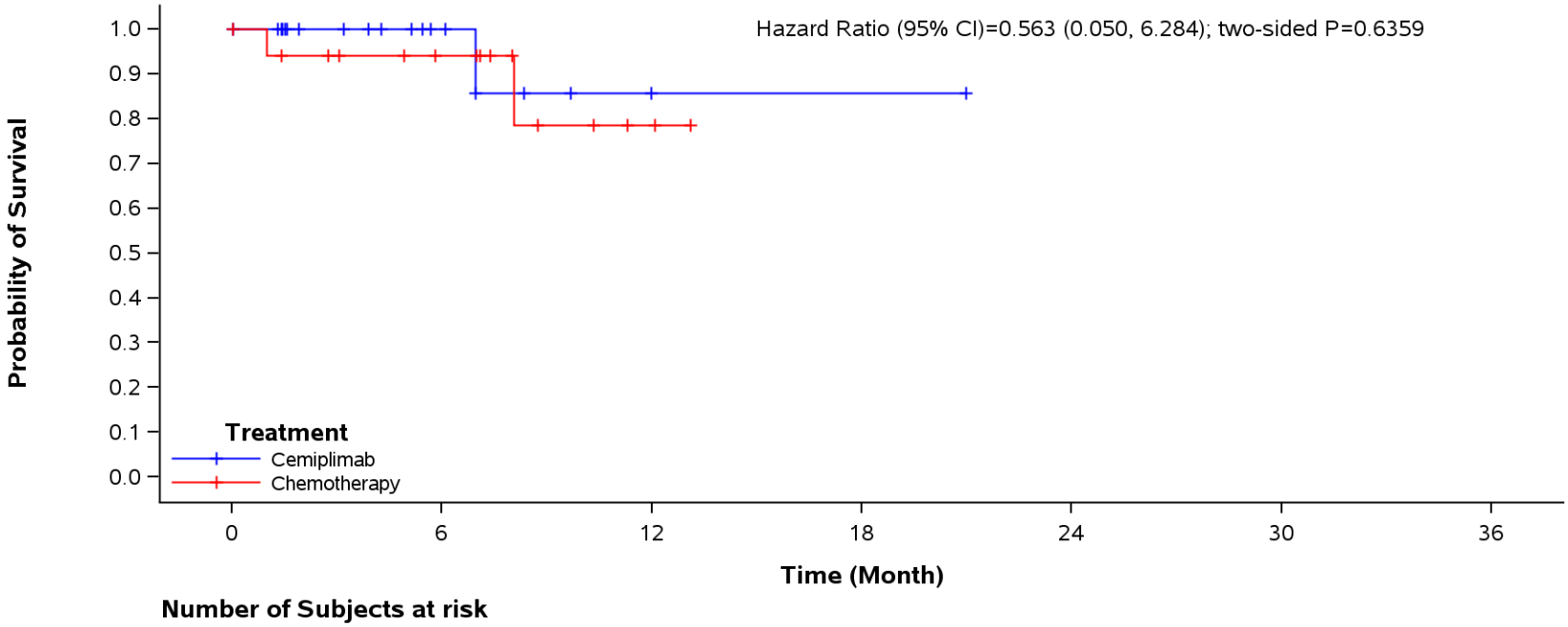
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Insomnia - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

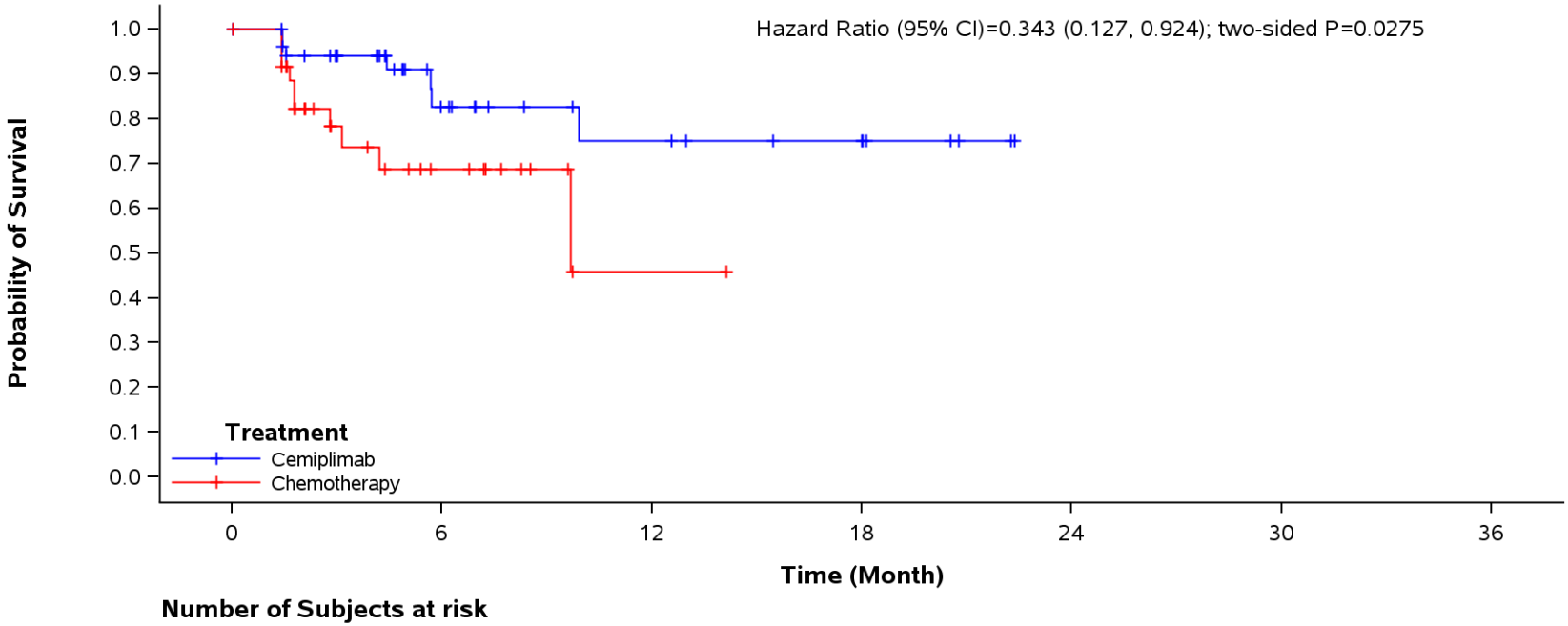
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 8 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Appetite loss - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 19 | 10 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

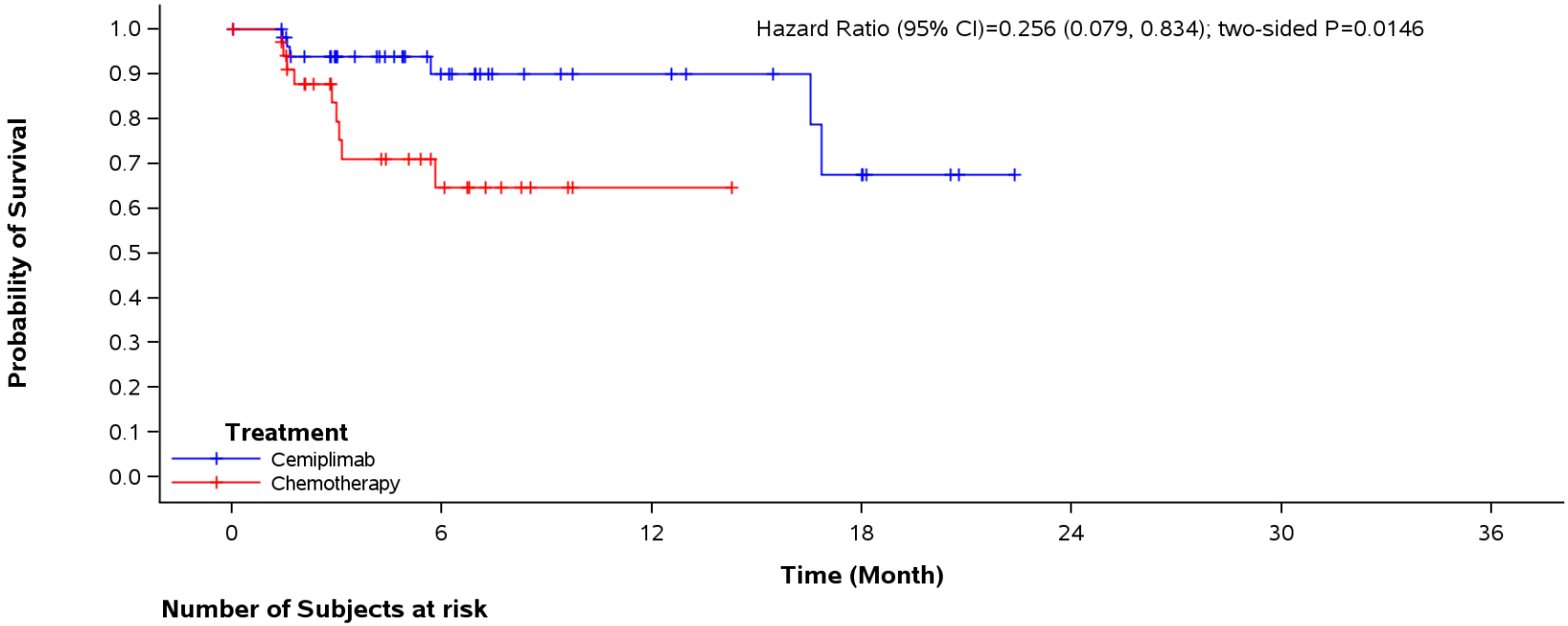
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Cognitive Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 11 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

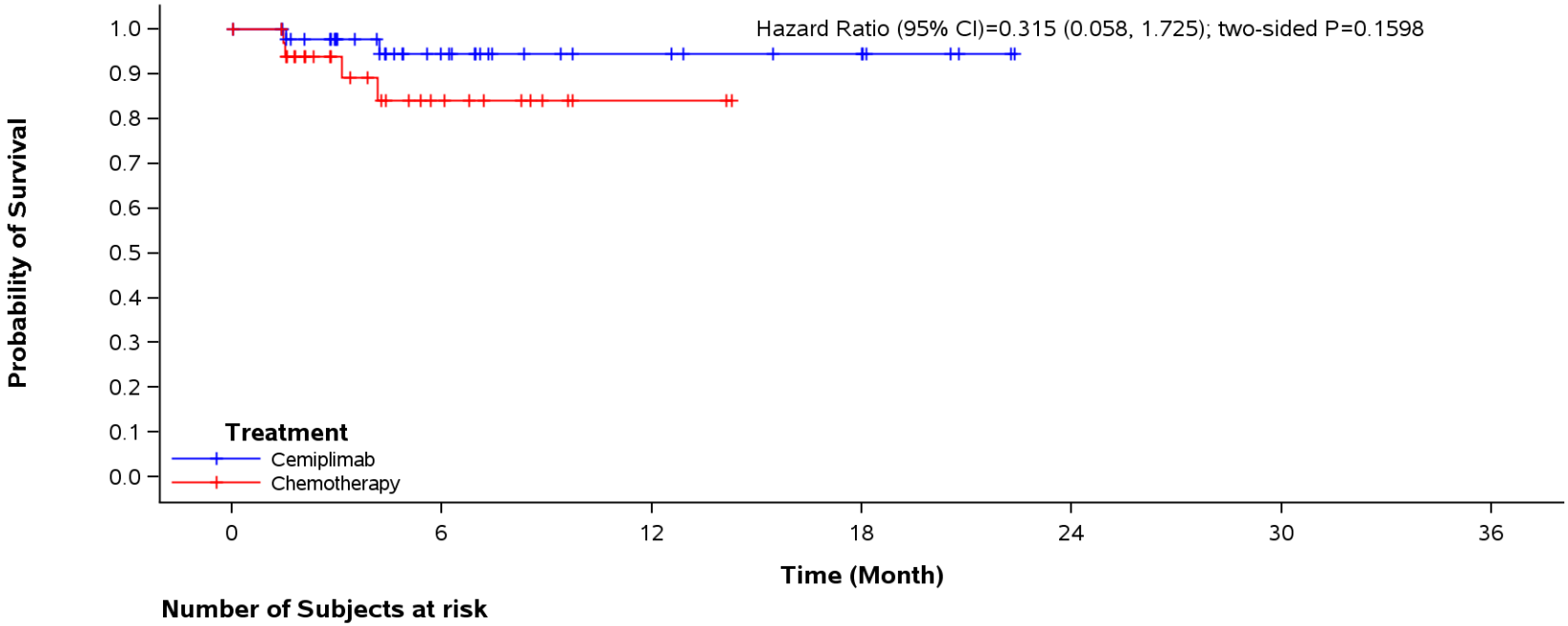
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Constipation - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 20 | 10 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

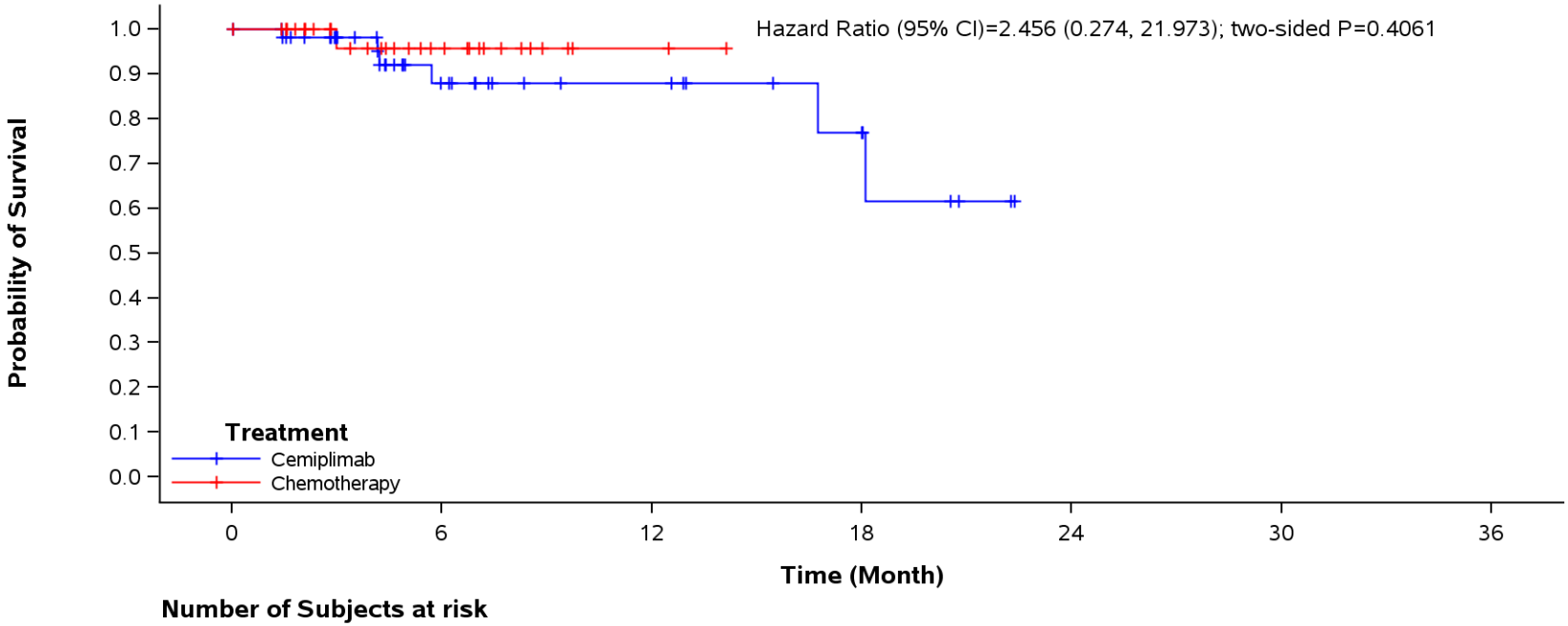
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Diarhoea - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 20 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

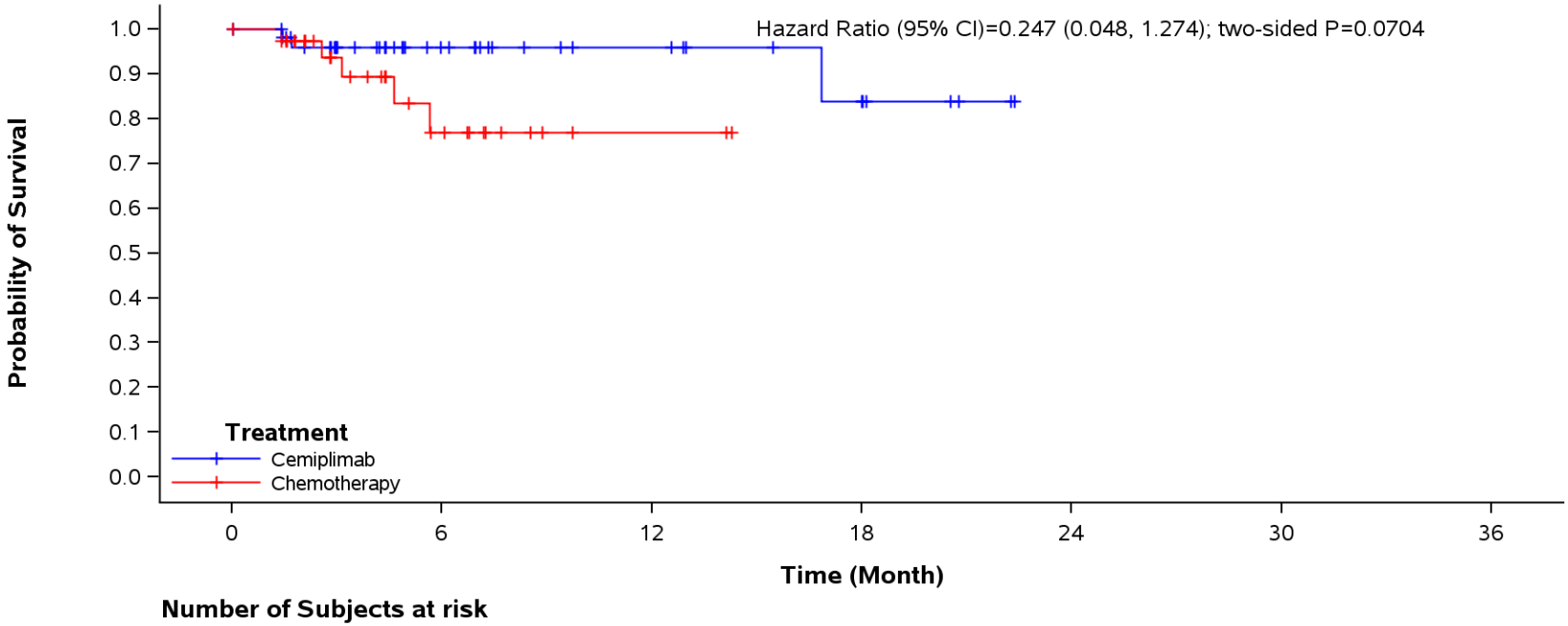
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Dyspnoea - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

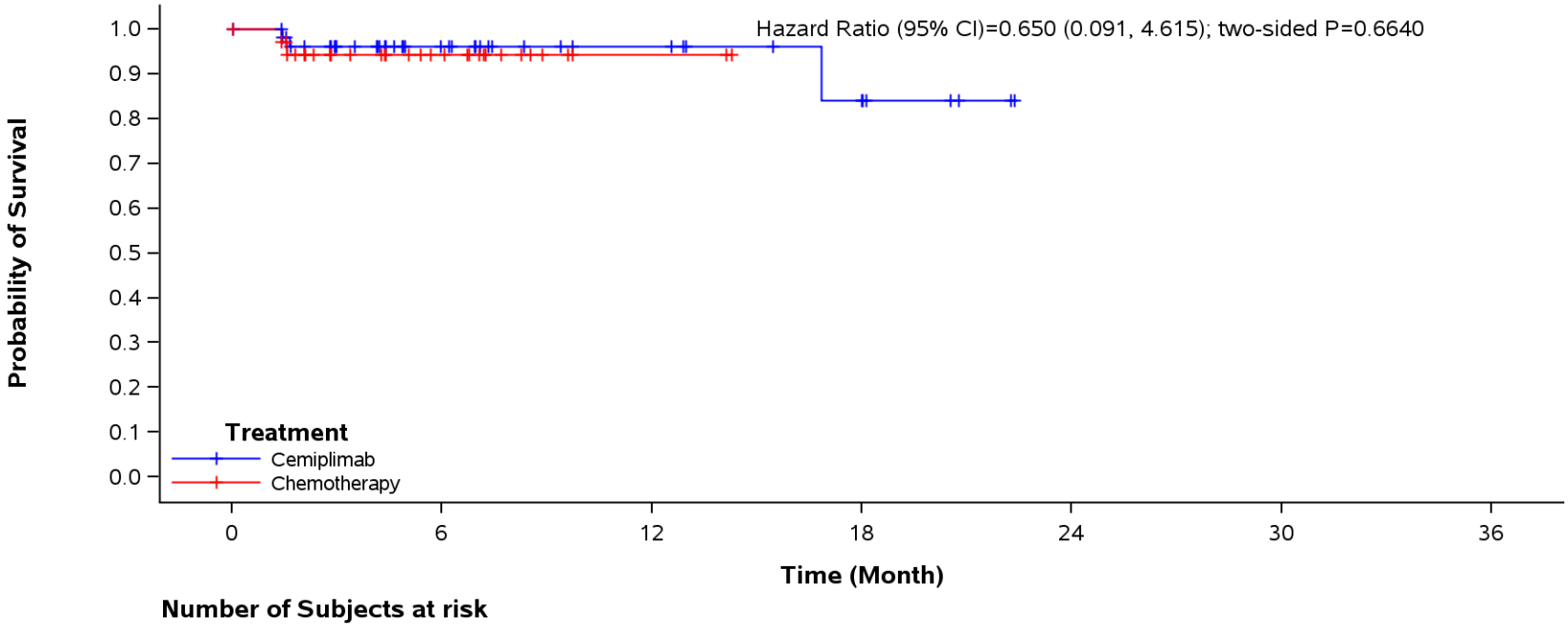
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Emotional Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 23 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

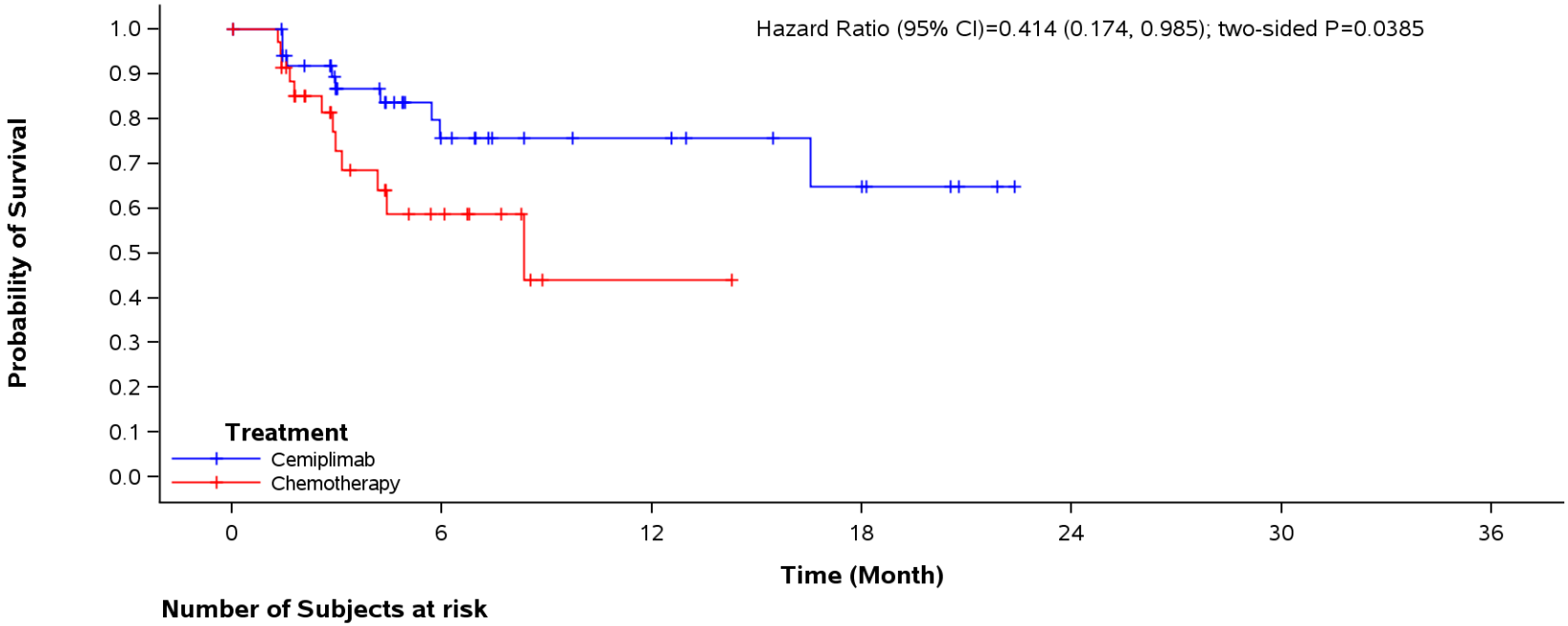
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Fatigue - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

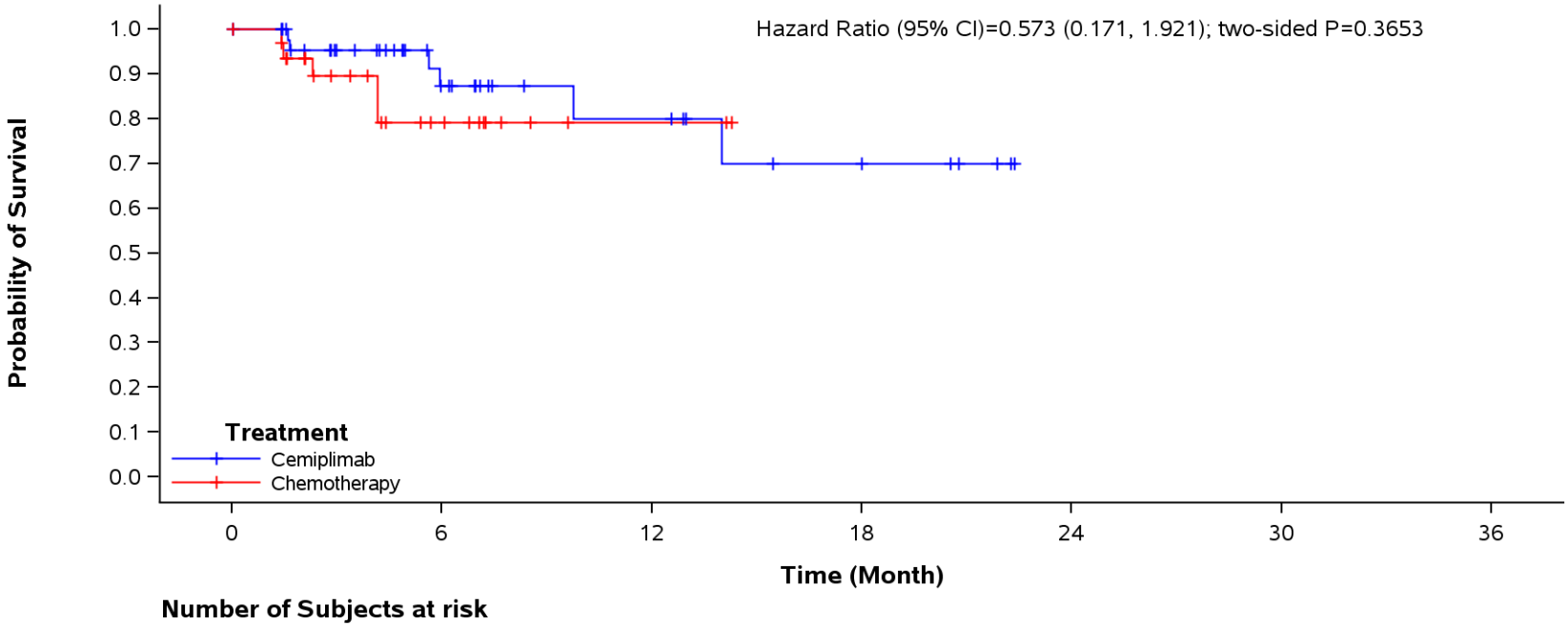
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 18 | 10 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Financial Problems - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 21 | 11 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

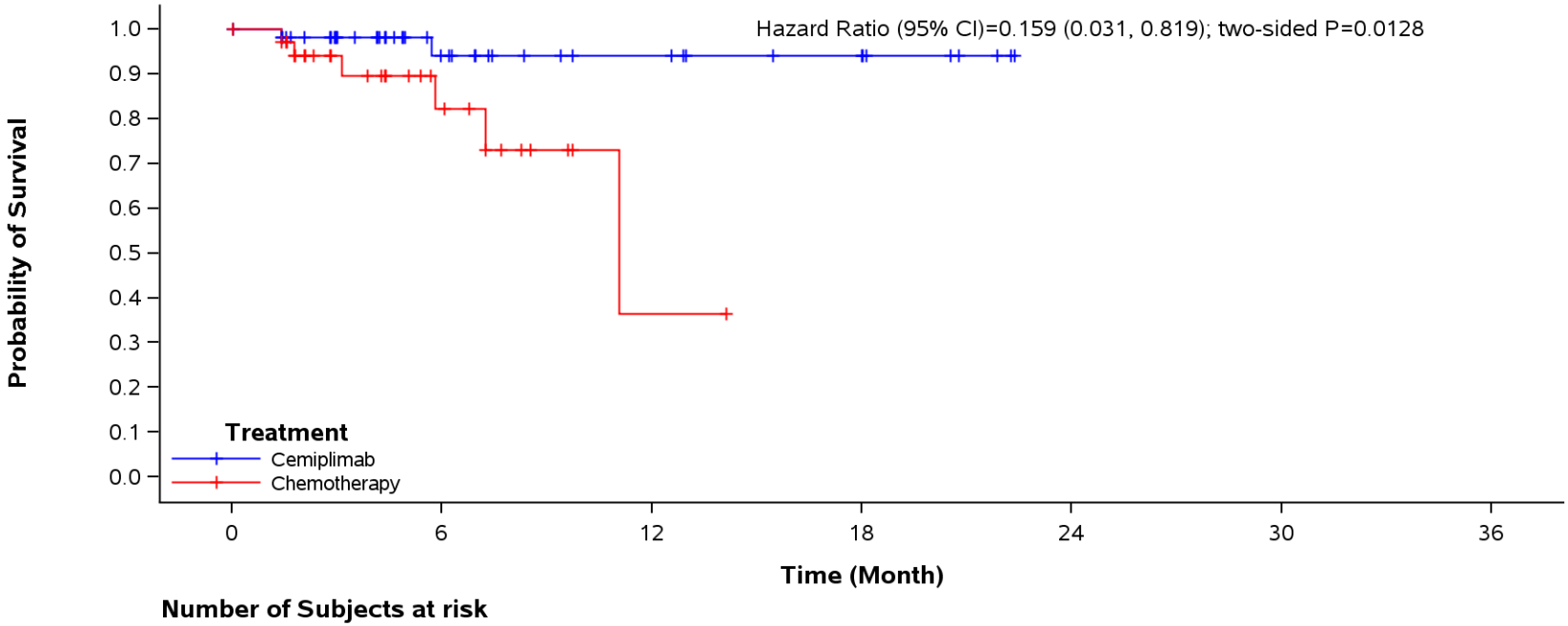
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Nausea / Vomiting - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 12 | 8 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

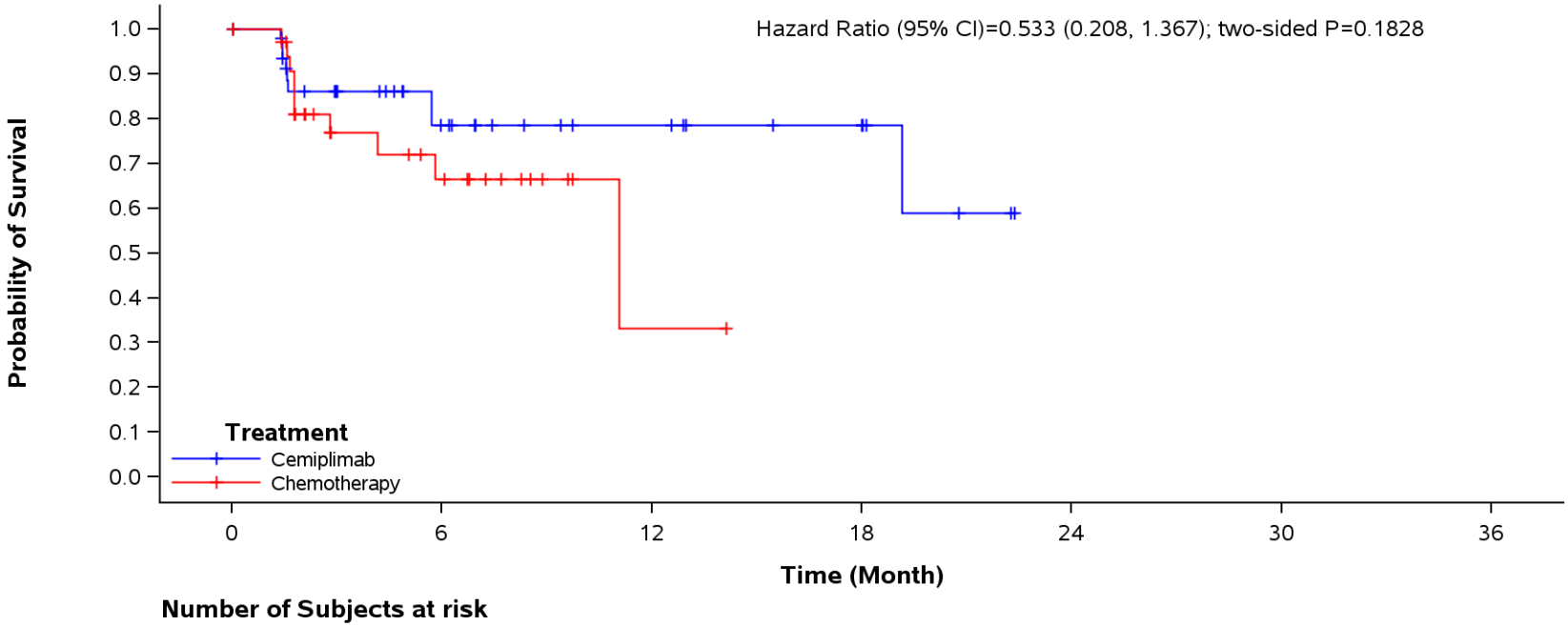
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Pain - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

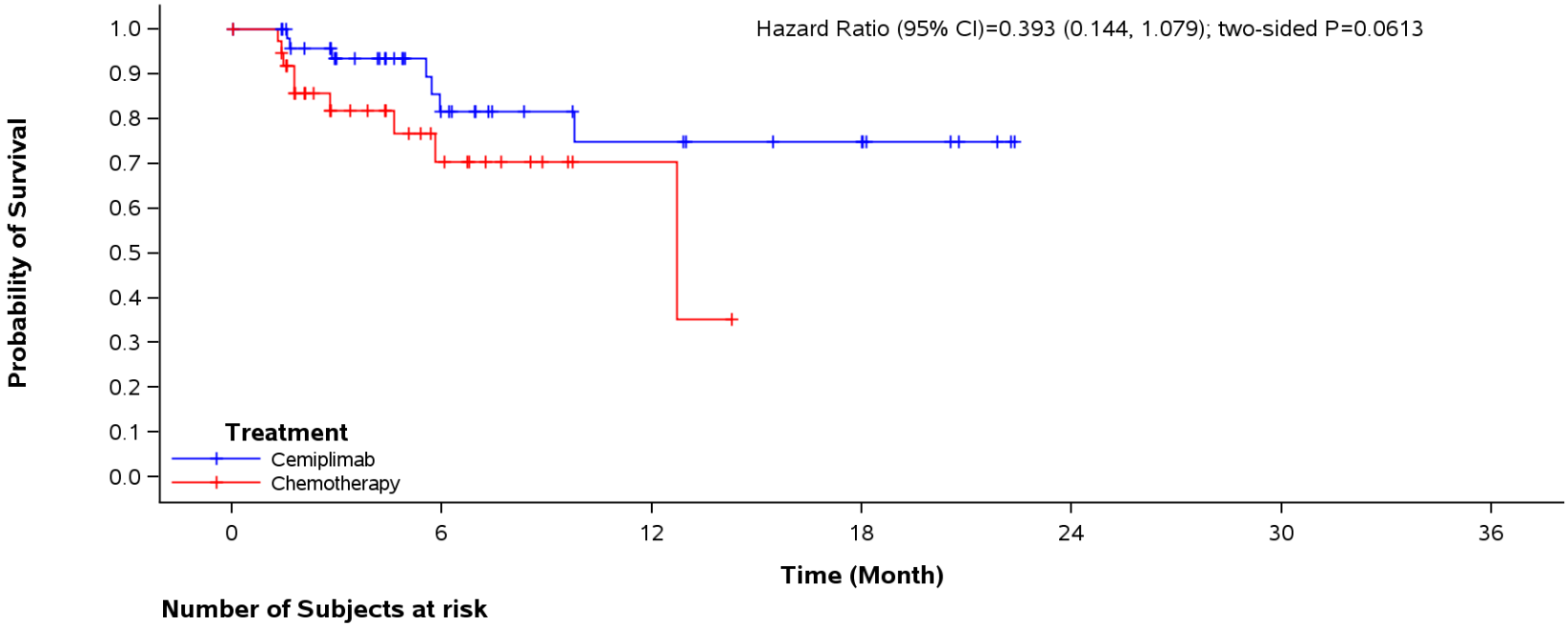
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 20 | 11 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Physical Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 20 | 11 | 8 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

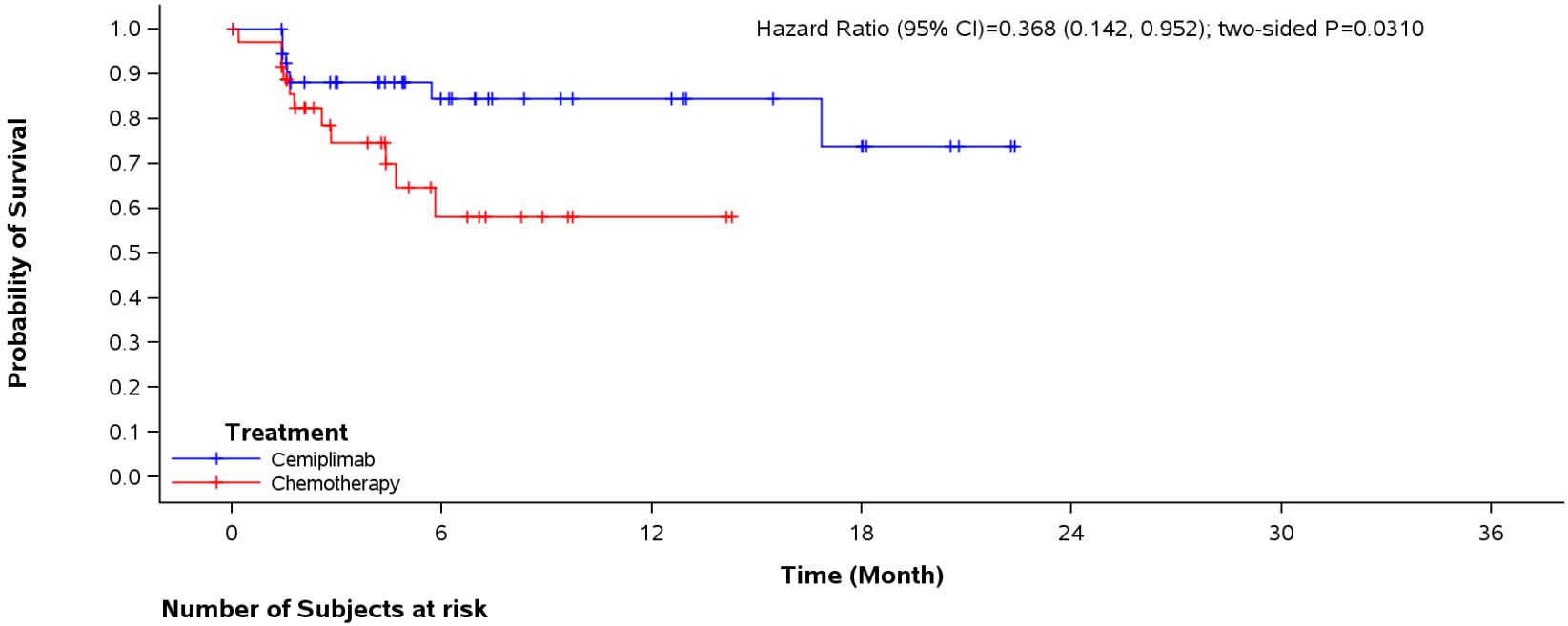
Patients who reach the threshold for the first time at the last documented visit are censored

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:30:56, yingyuan.lin)

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Global health status / QoL - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

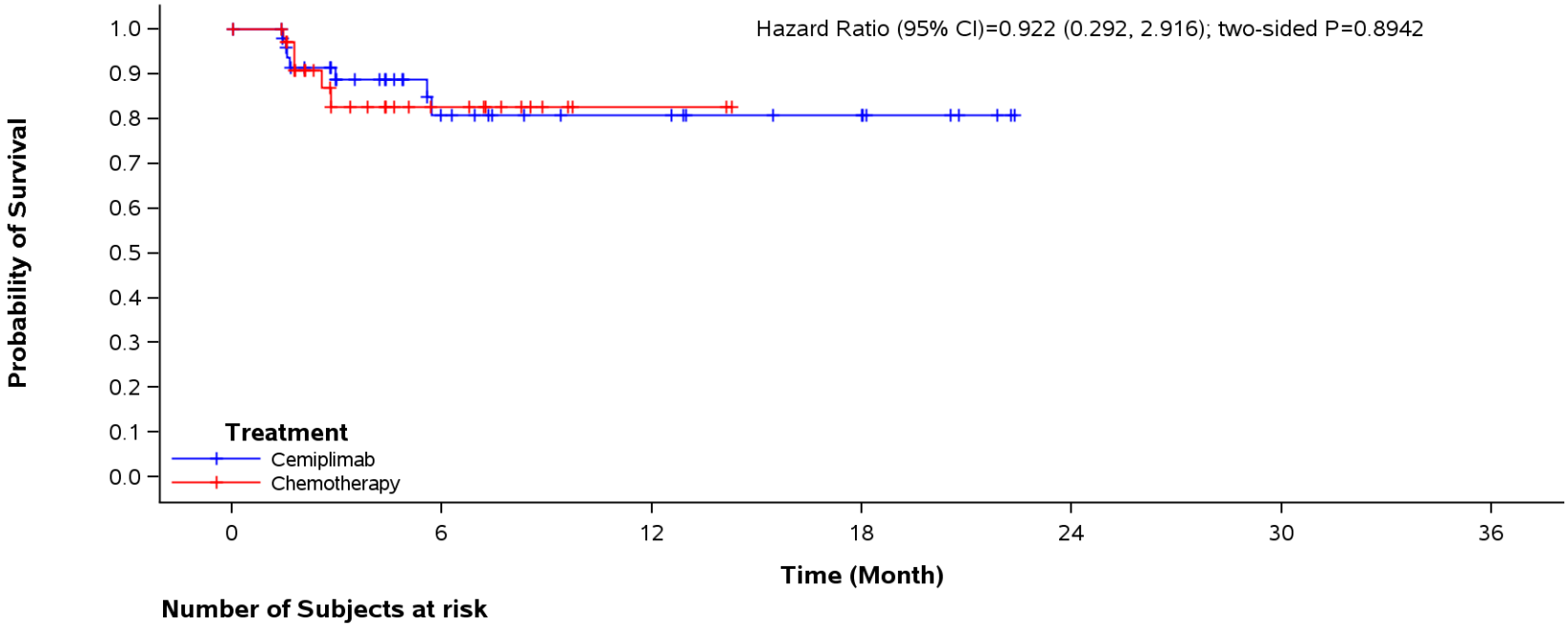
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Role Functioning - 10 pts sensitivity sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 19 | 12 | 8 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

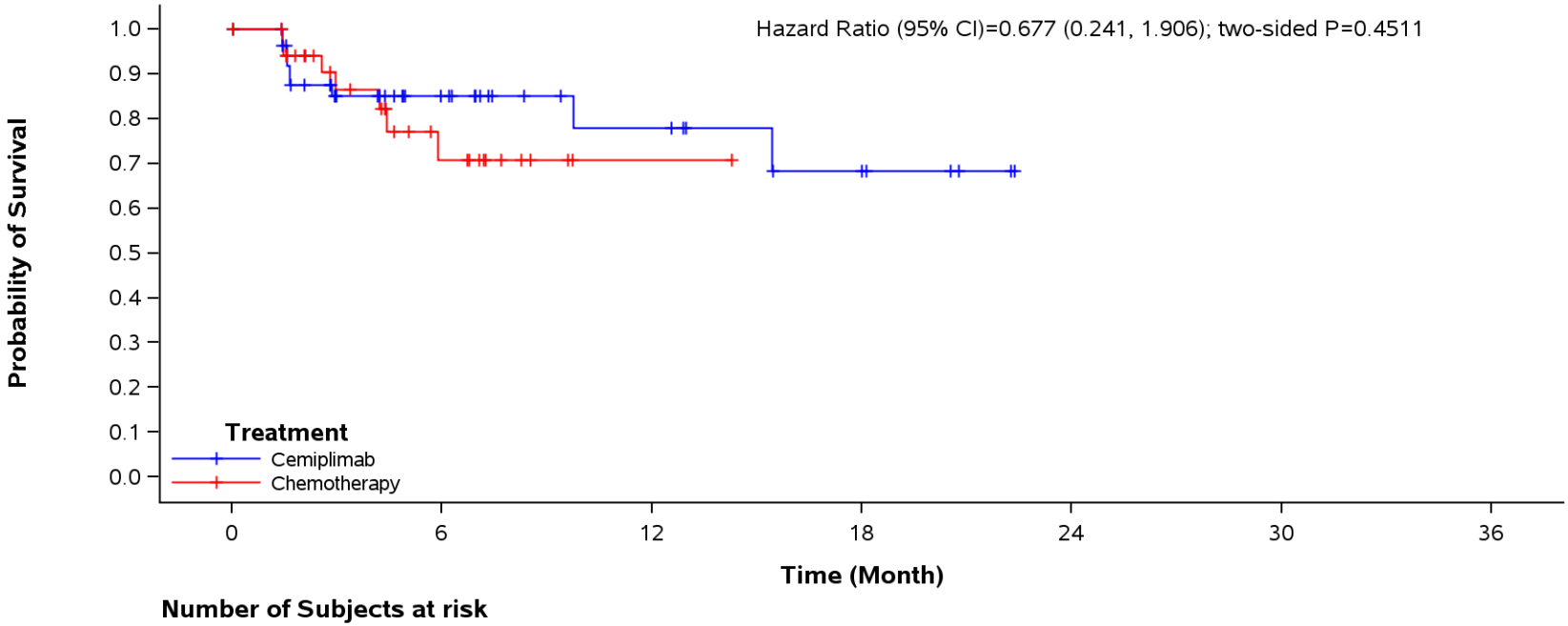
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Social Functioning - 10 pts sensitivity sustained deterioration




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 11 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.

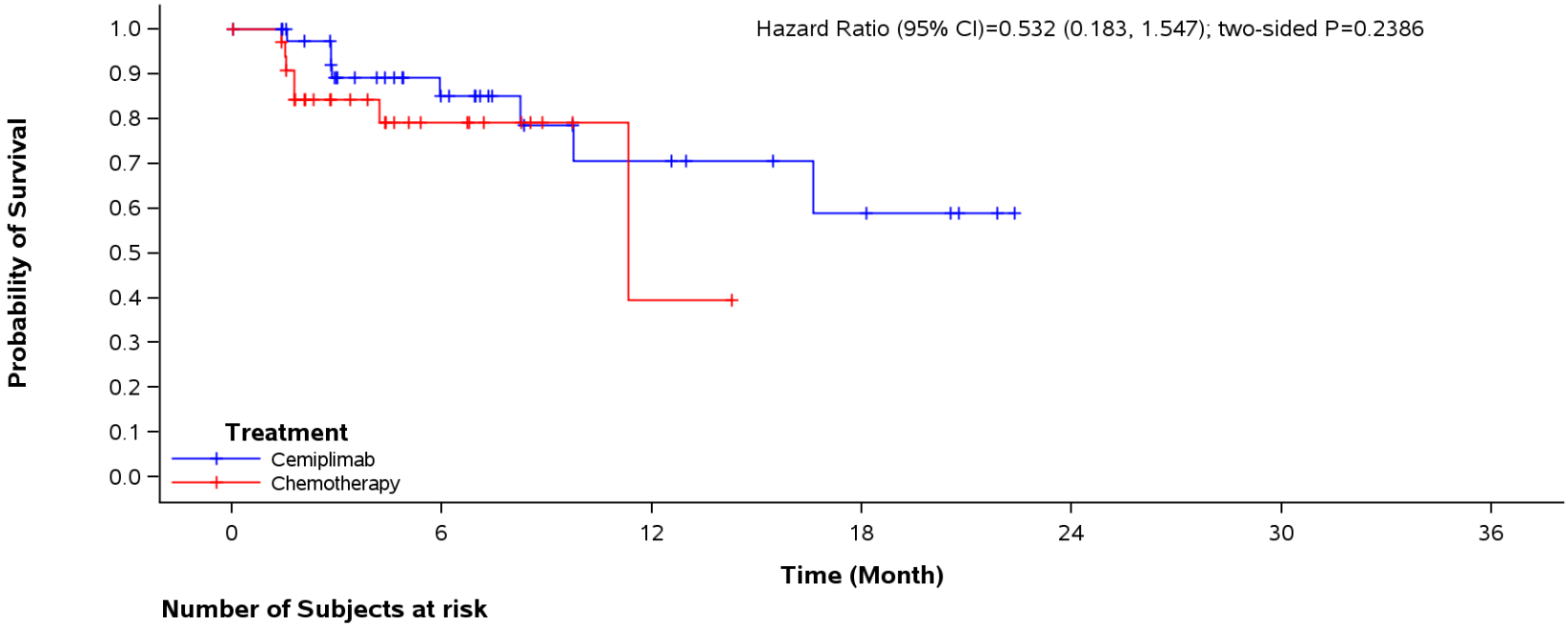
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.8a. Time to First Sensitivity Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Insomnia - 10 pts sensitivity sustained deterioration



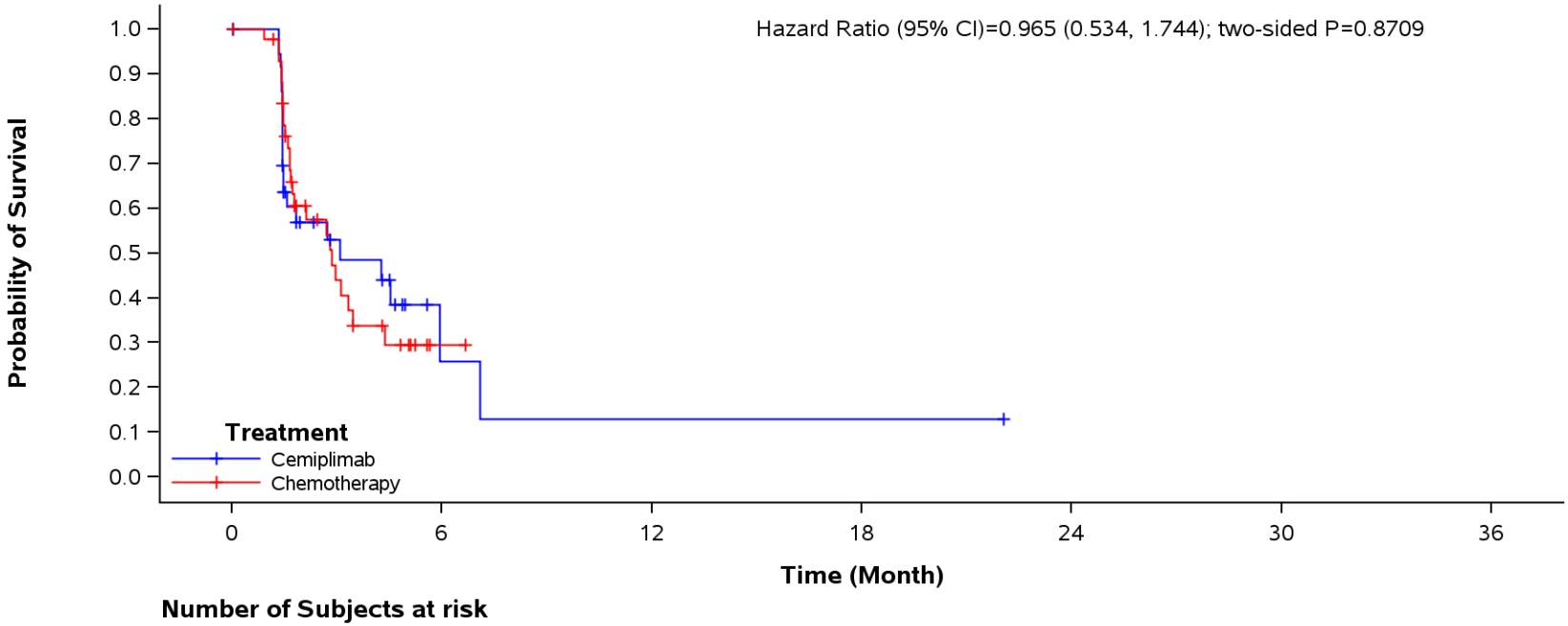

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 19 | 9 | 5 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12
Patients who reach the threshold for the first time at the last documented visit are censored

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Appetite loss - 10 pts improvement



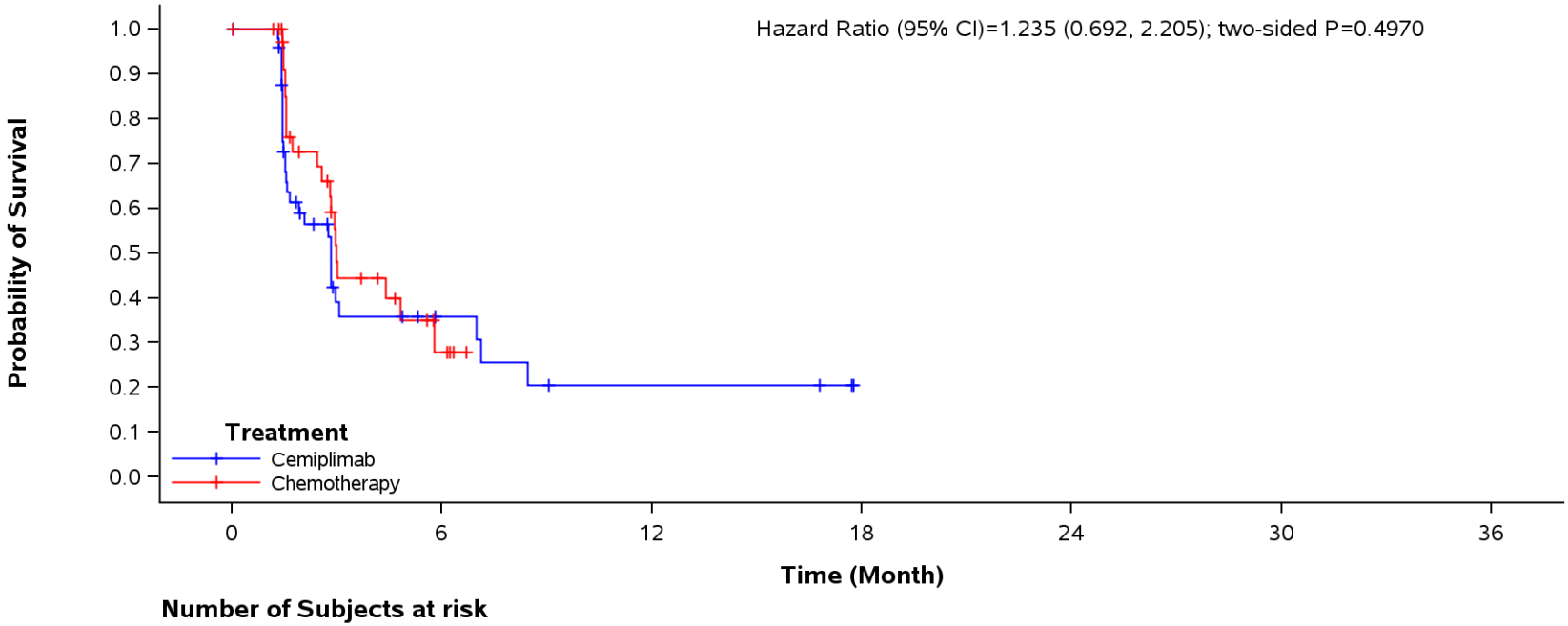

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 2 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 103 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Cognitive Functioning - 10 pts improvement




Number of Subjects at risk

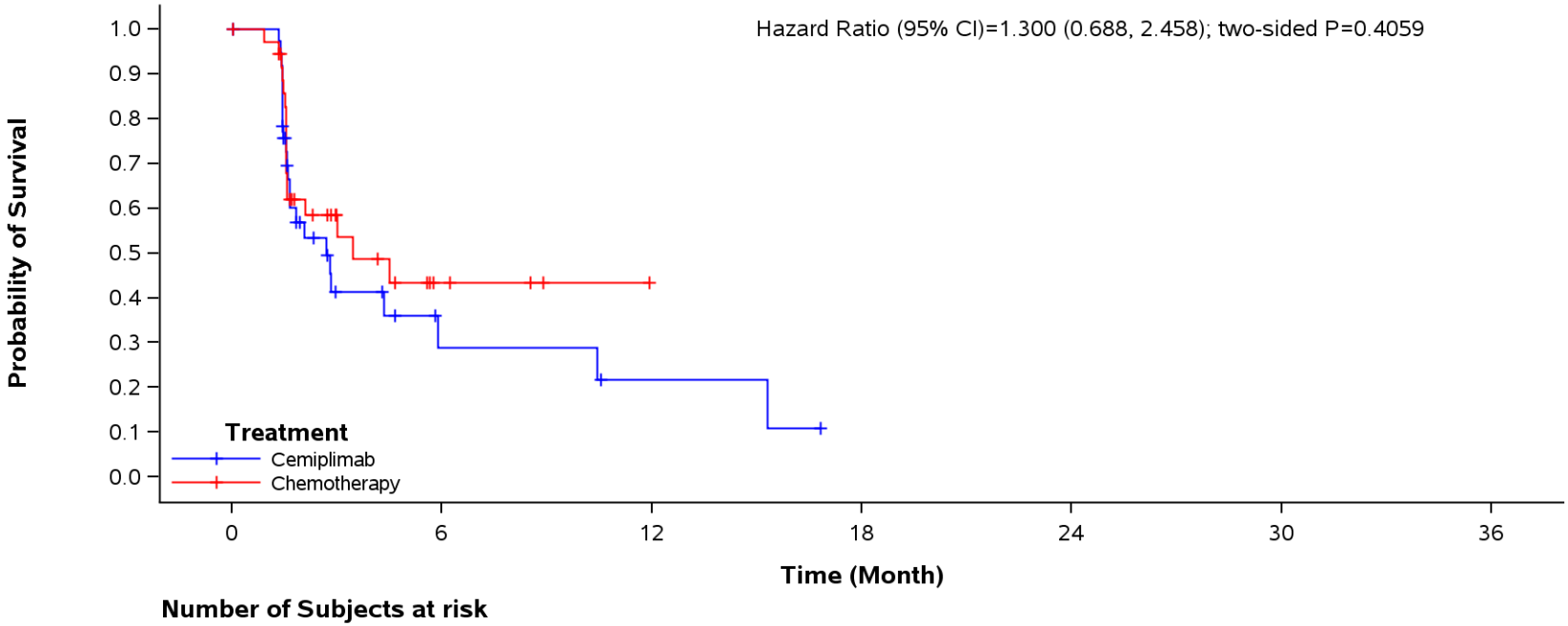
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 7 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Constipation - 10 pts improvement




**Number of Subjects at risk**

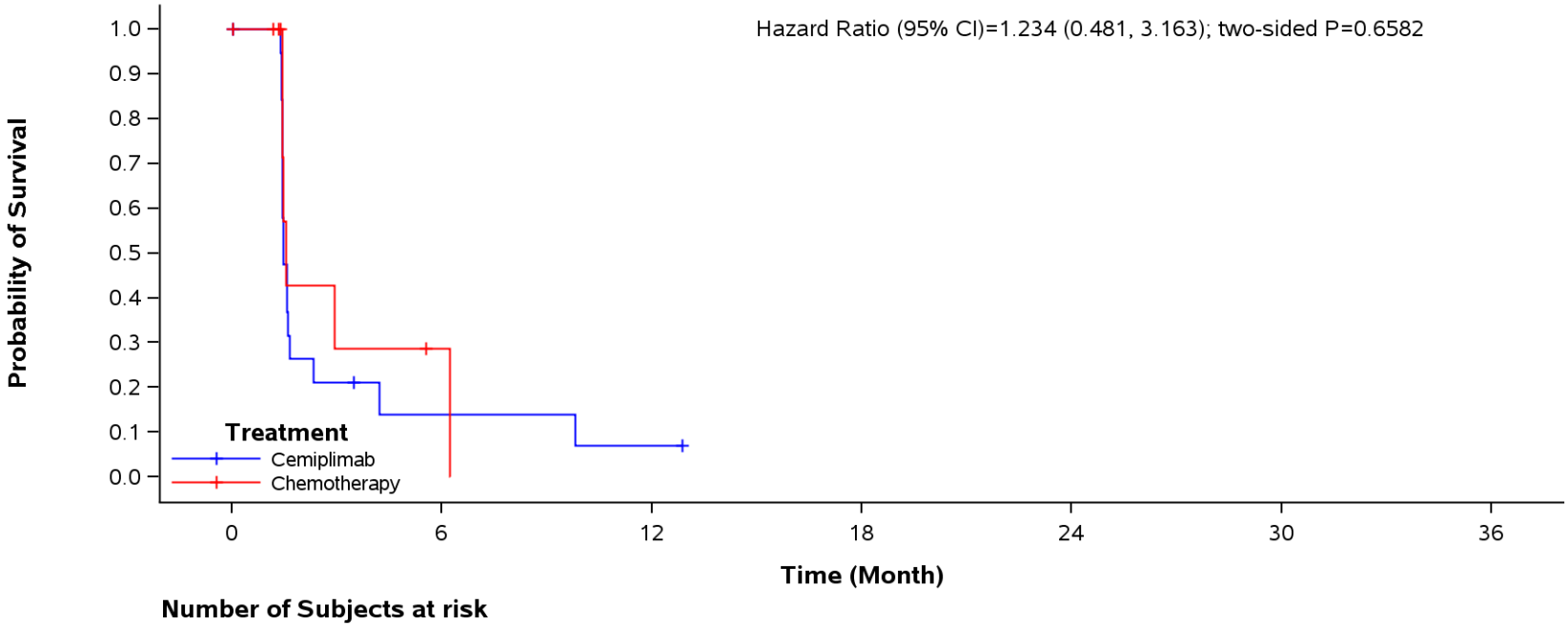
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 4 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Diarhoea - 10 pts improvement



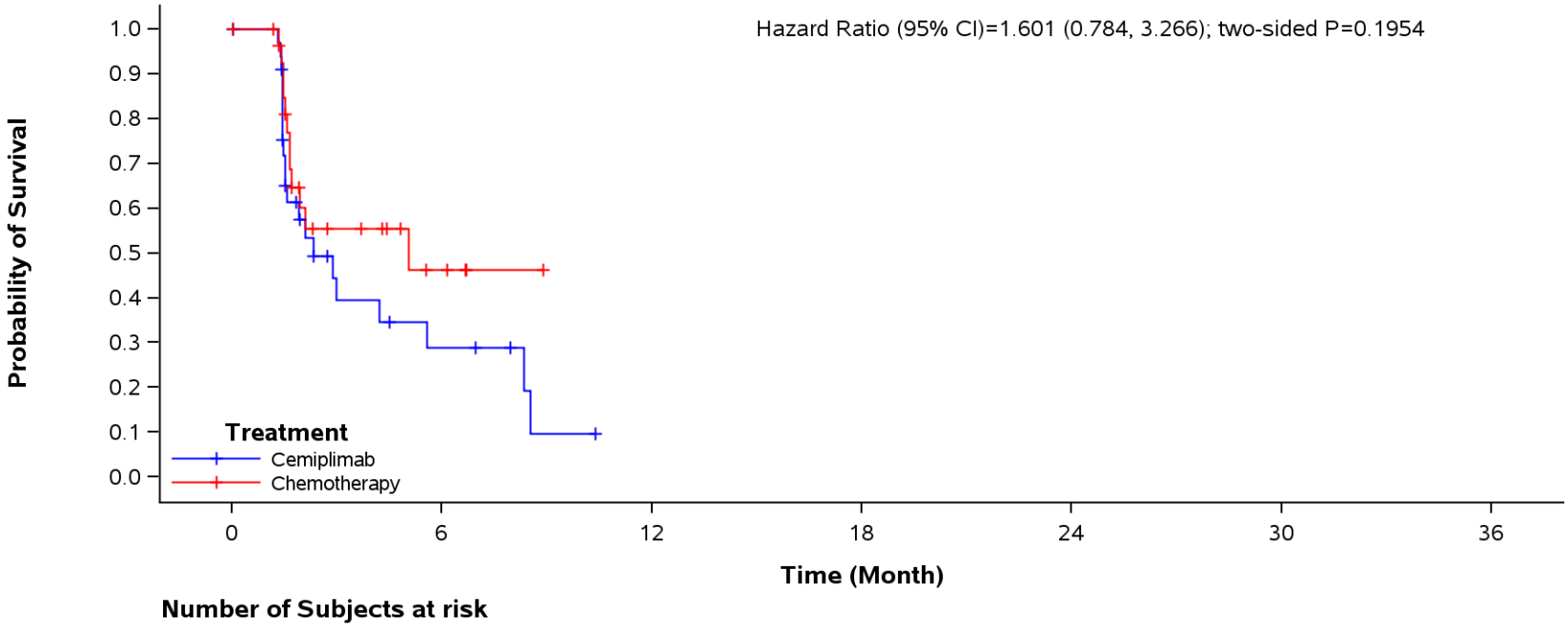

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Dyspnoea - 10 pts improvement




**Number of Subjects at risk**

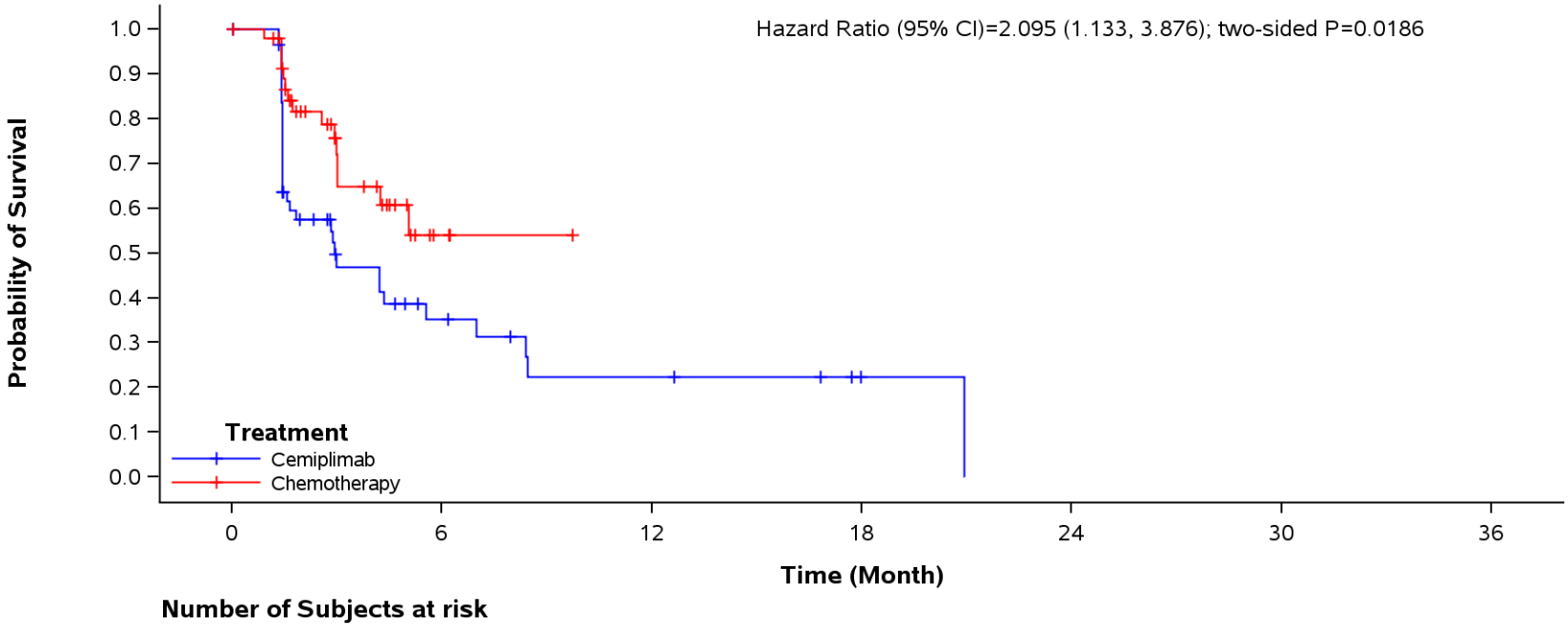
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Emotional Functioning - 10 pts improvement



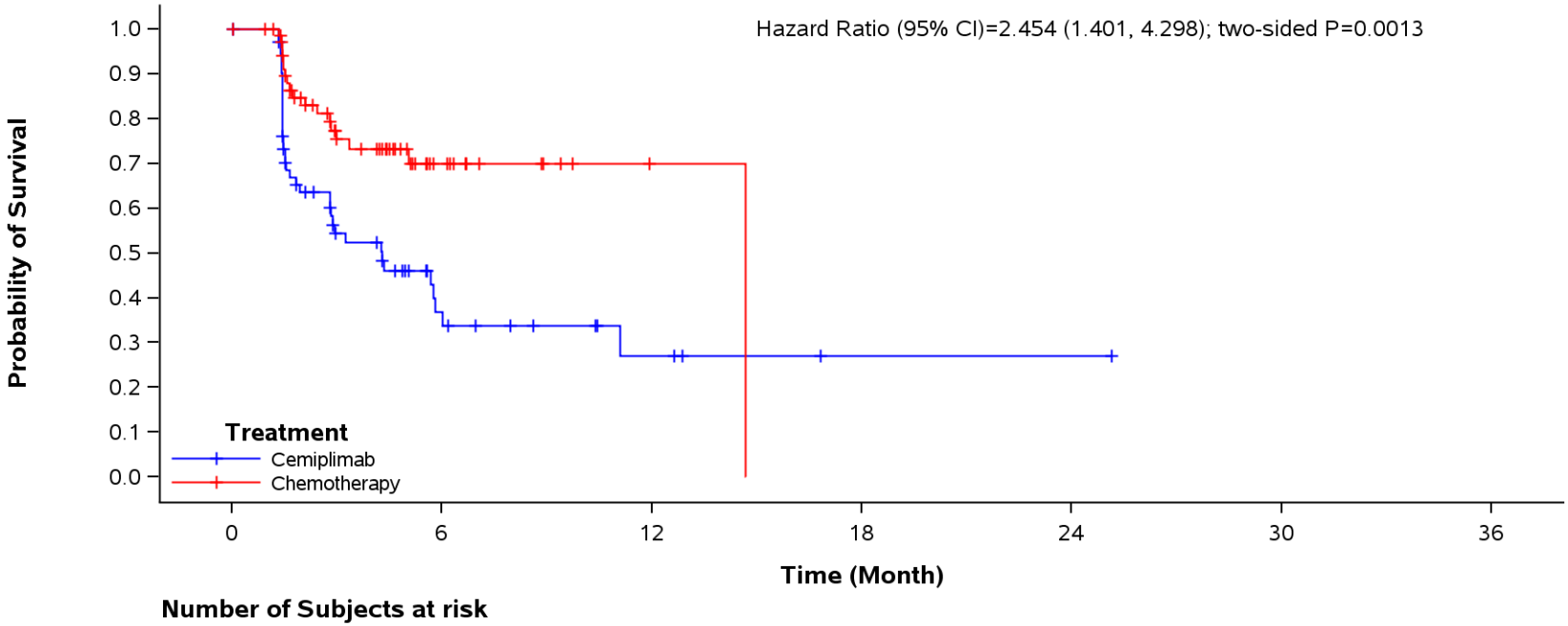

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 10 | 5 | 1 | 0 | 0 | 0 |
| Chemotherapy | 103 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Fatigue - 10 pts improvement




**Number of Subjects at risk**

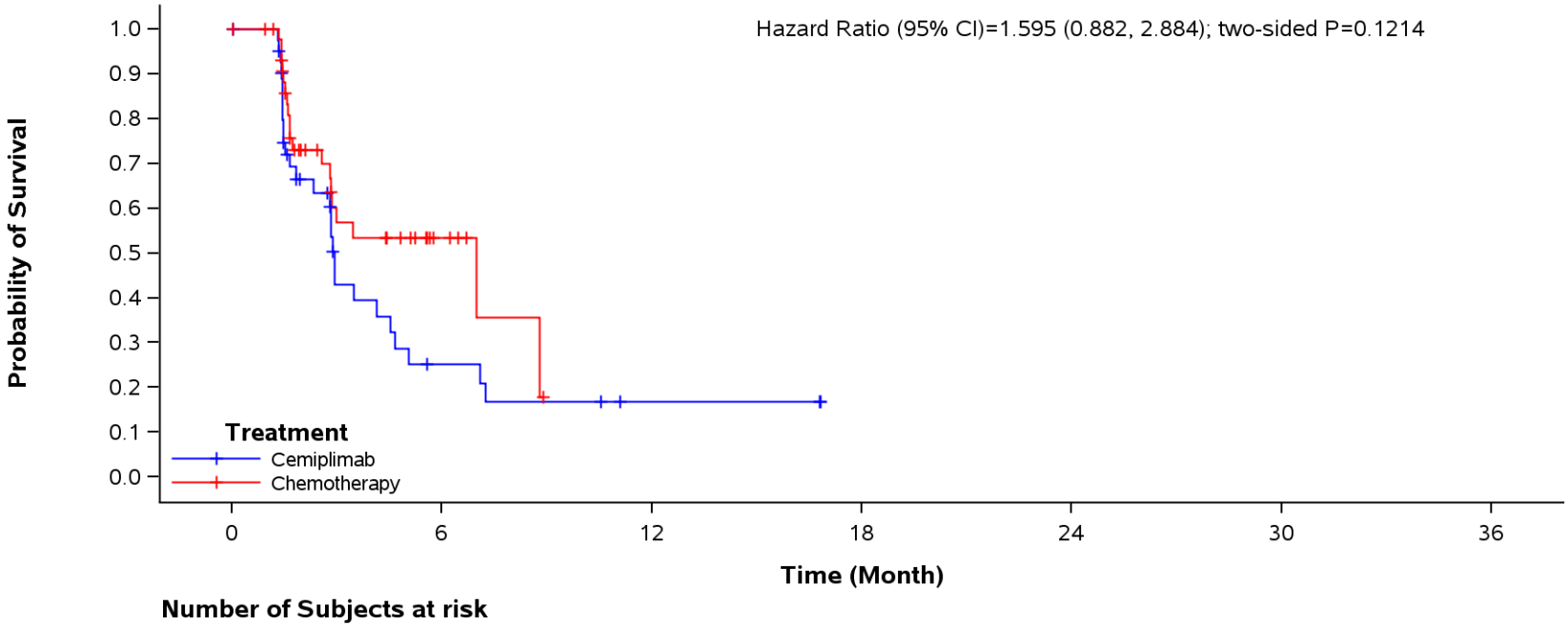
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 12 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 103 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Financial Problems - 10 pts improvement




**Number of Subjects at risk**

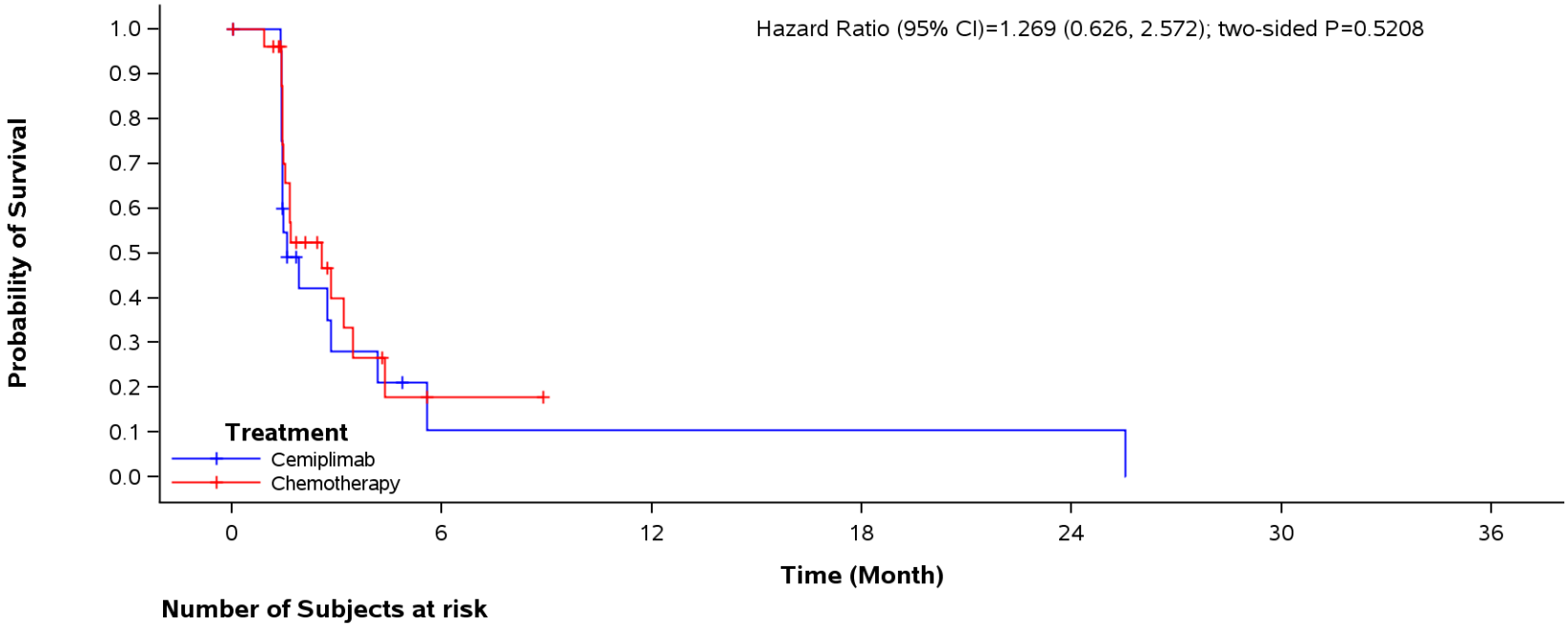
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Nausea / Vomiting - 10 pts improvement



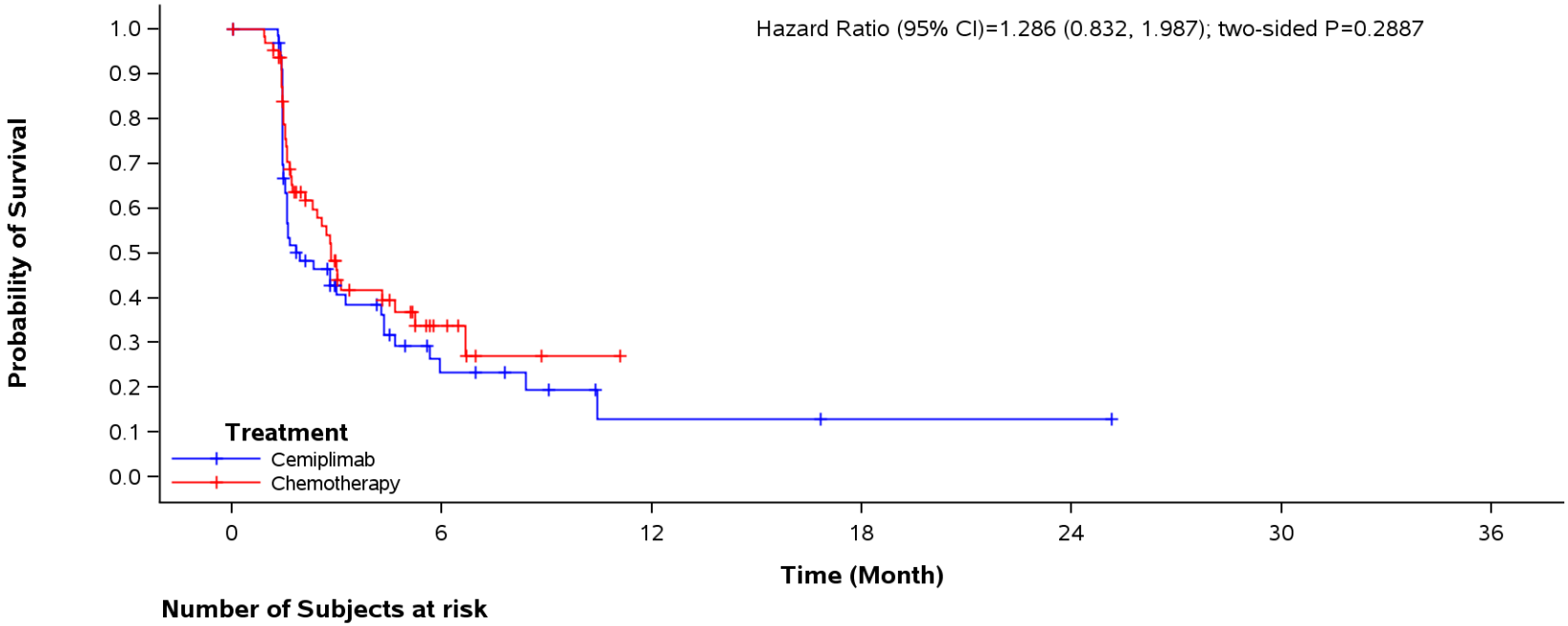

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 1 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 103 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Pain - 10 pts improvement




**Number of Subjects at risk**

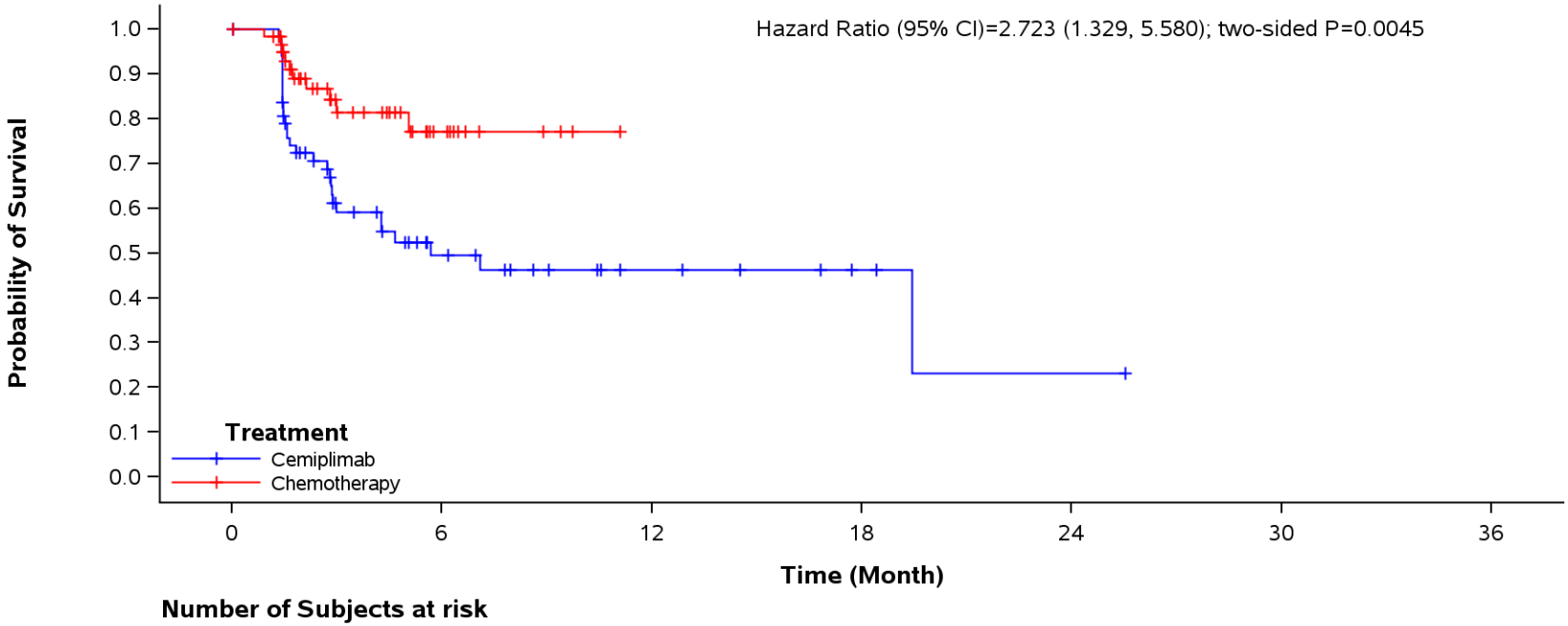
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 8 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 103 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Physical Functioning - 10 pts improvement



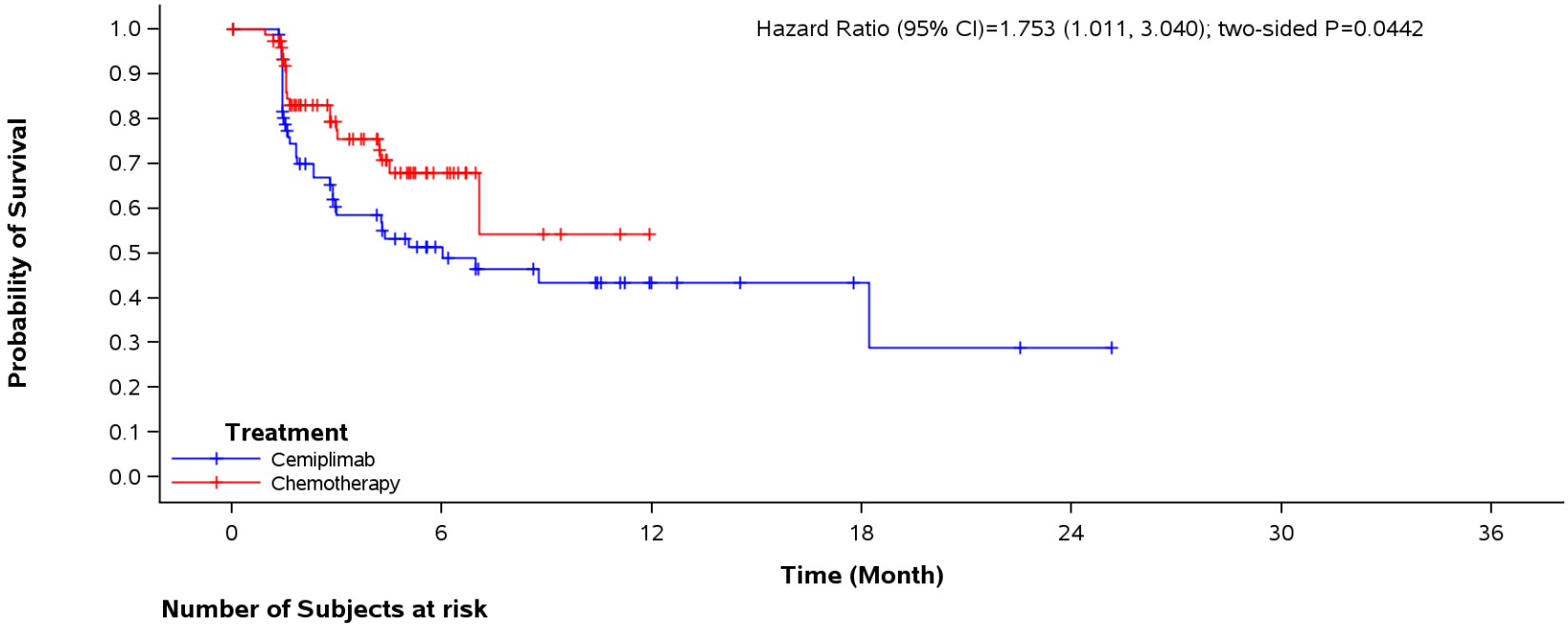

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 17 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 103 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Global health status / QoL - 10 pts improvement



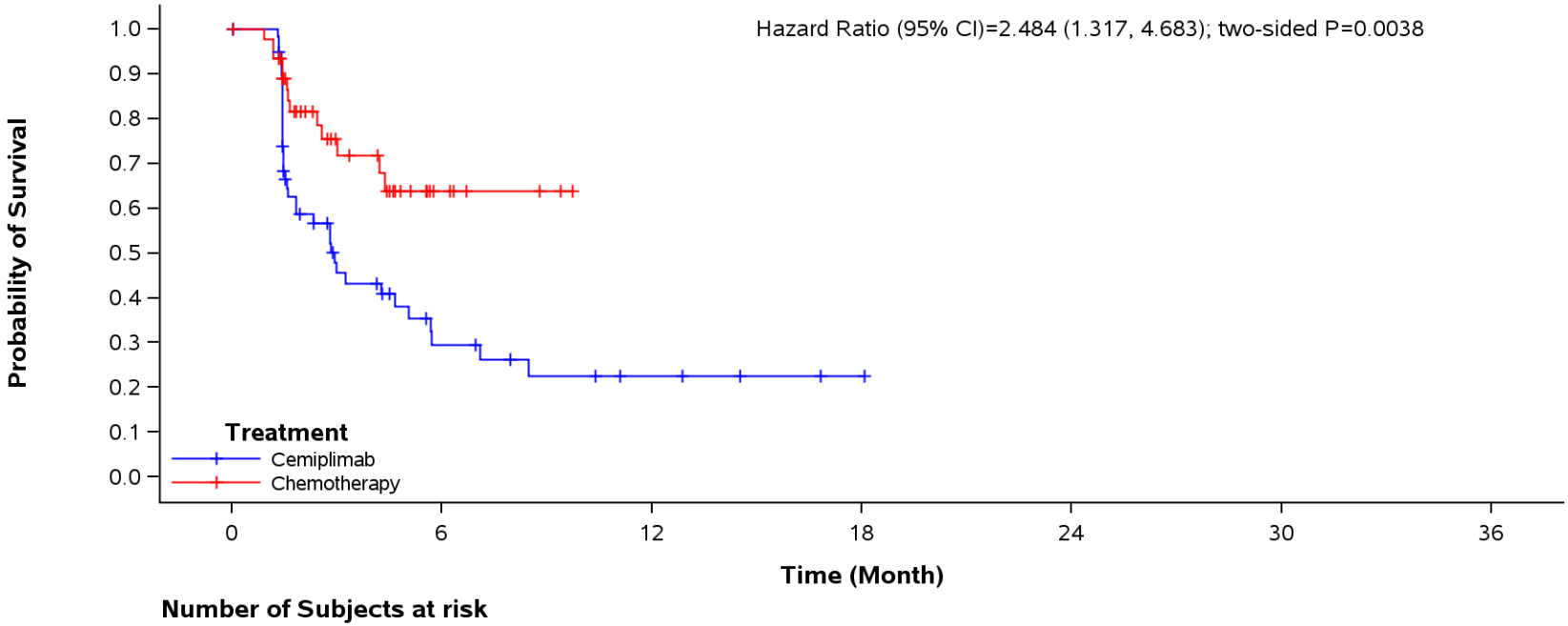

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 22 | 6 | 3 | 1 | 0 | 0 |
| Chemotherapy | 103 | 13 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Role Functioning - 10 pts improvement




**Number of Subjects at risk**

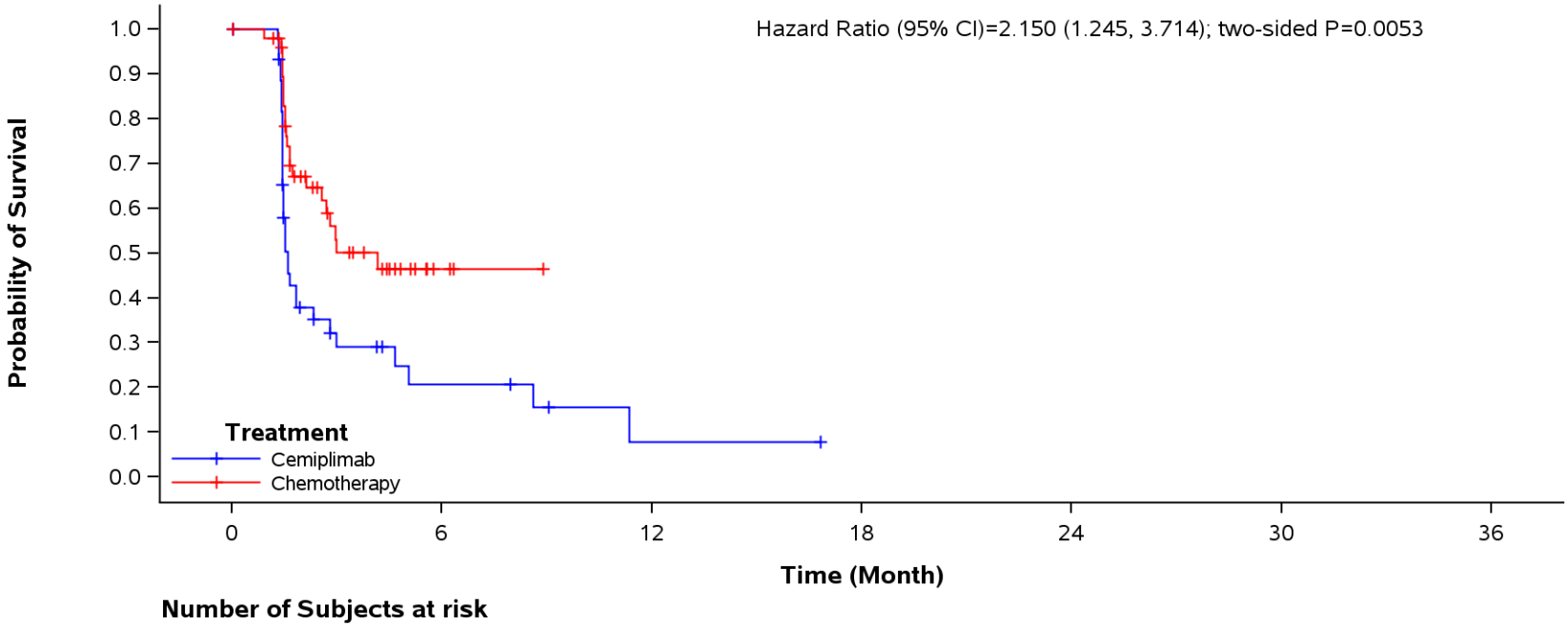
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 10 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 103 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Social Functioning - 10 pts improvement



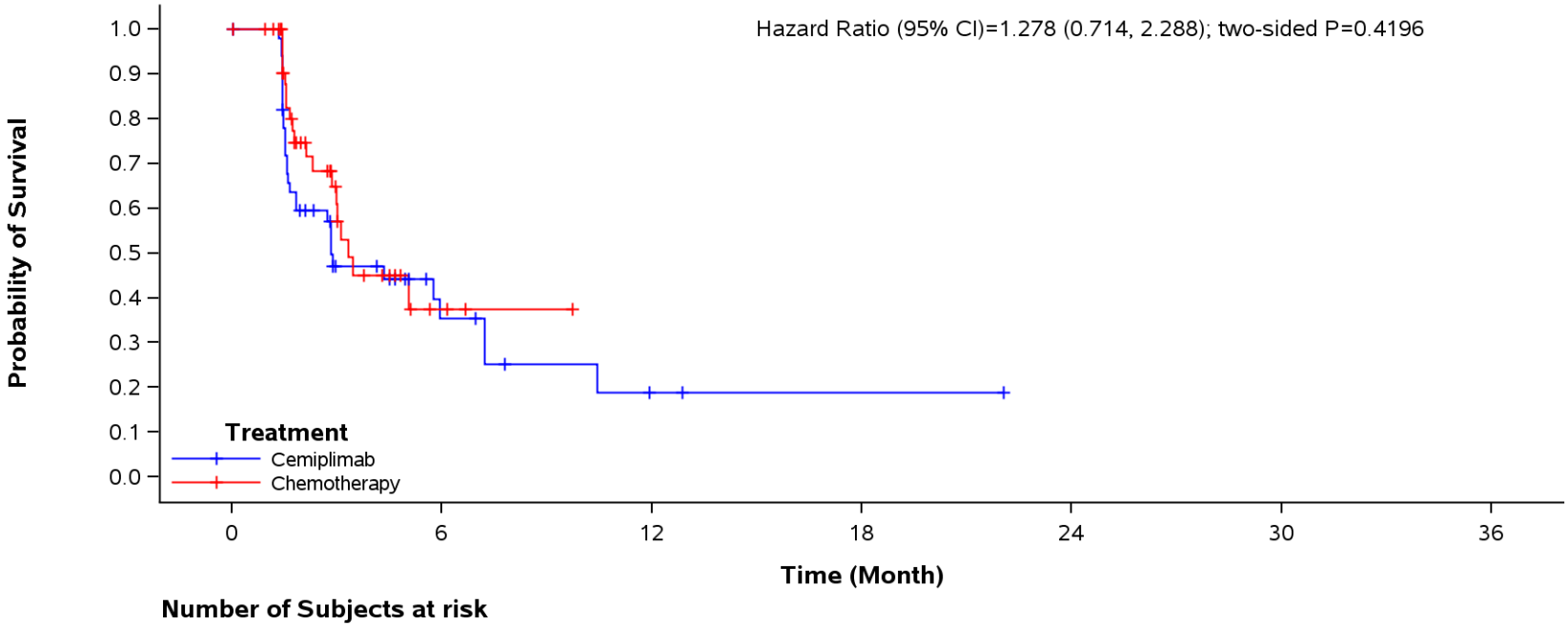

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 103 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Insomnia - 10 pts improvement




**Number of Subjects at risk**

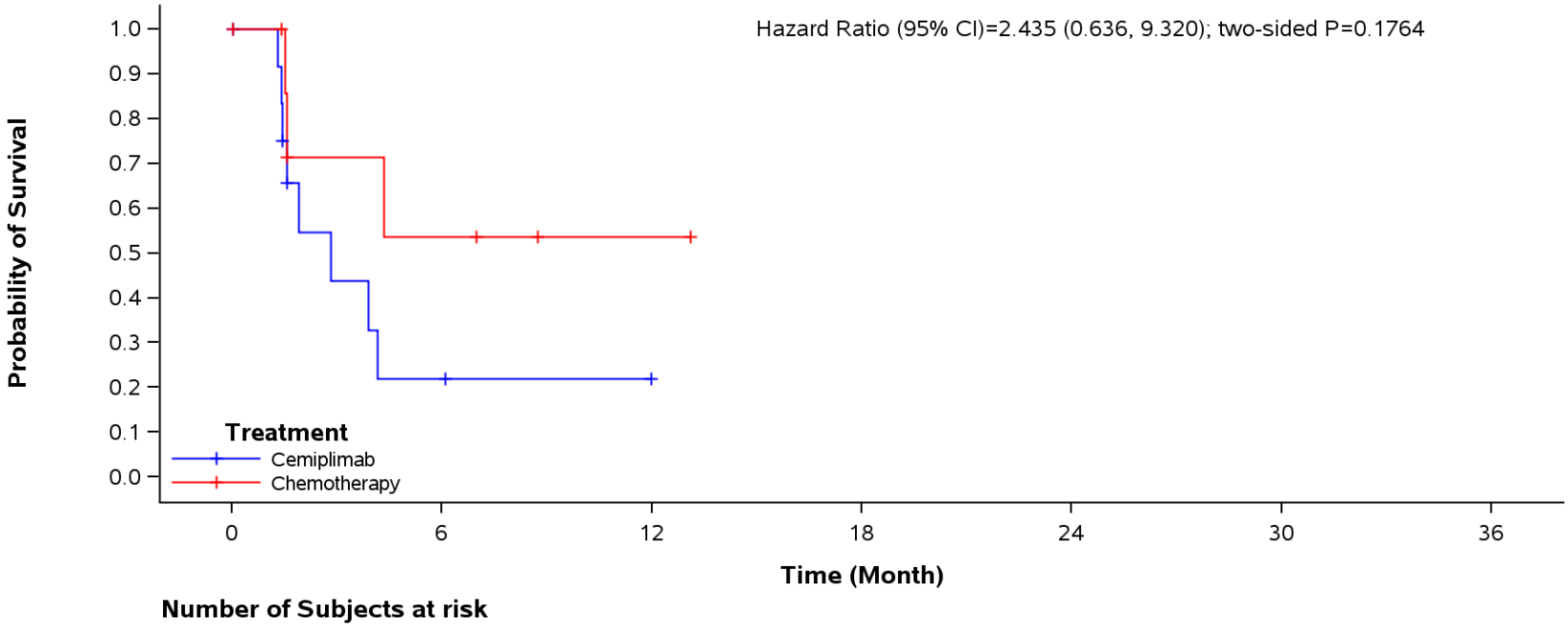
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 103 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Appetite loss - 10 pts improvement




Number of Subjects at risk

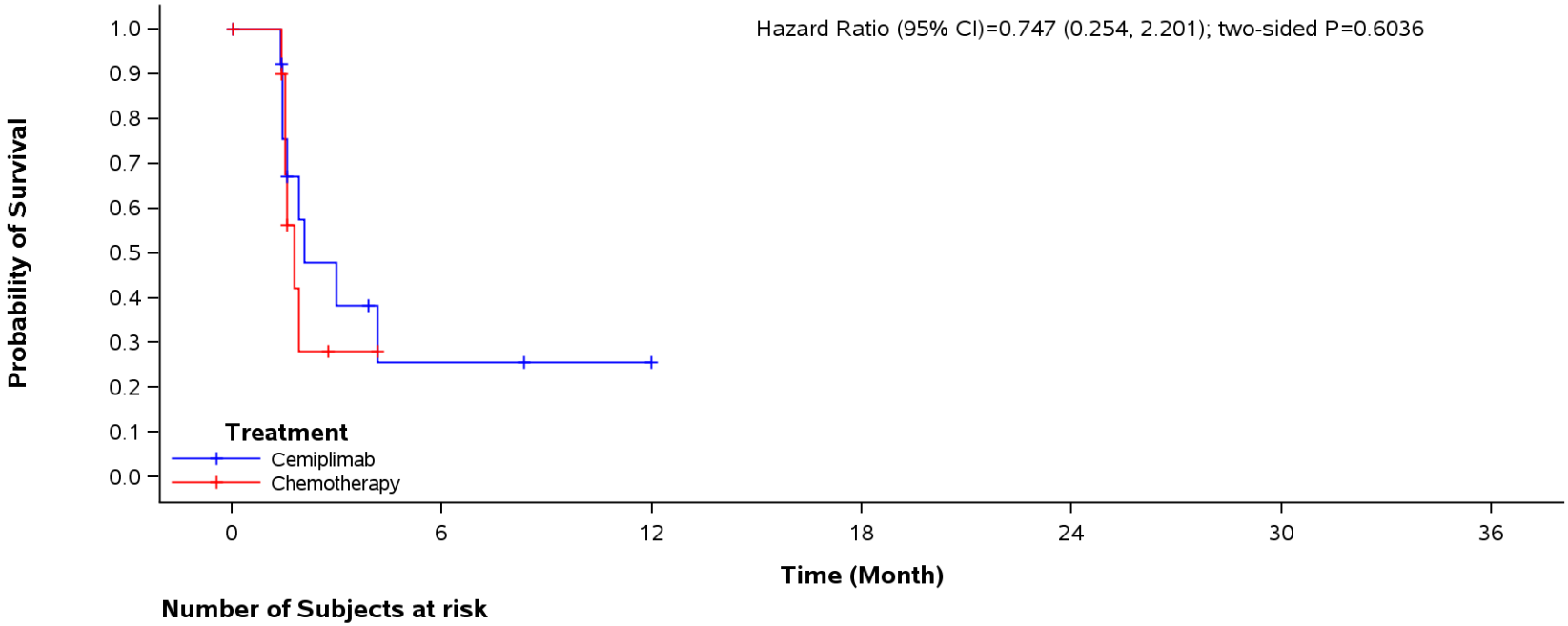
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Cognitive Functioning - 10 pts improvement




Number of Subjects at risk

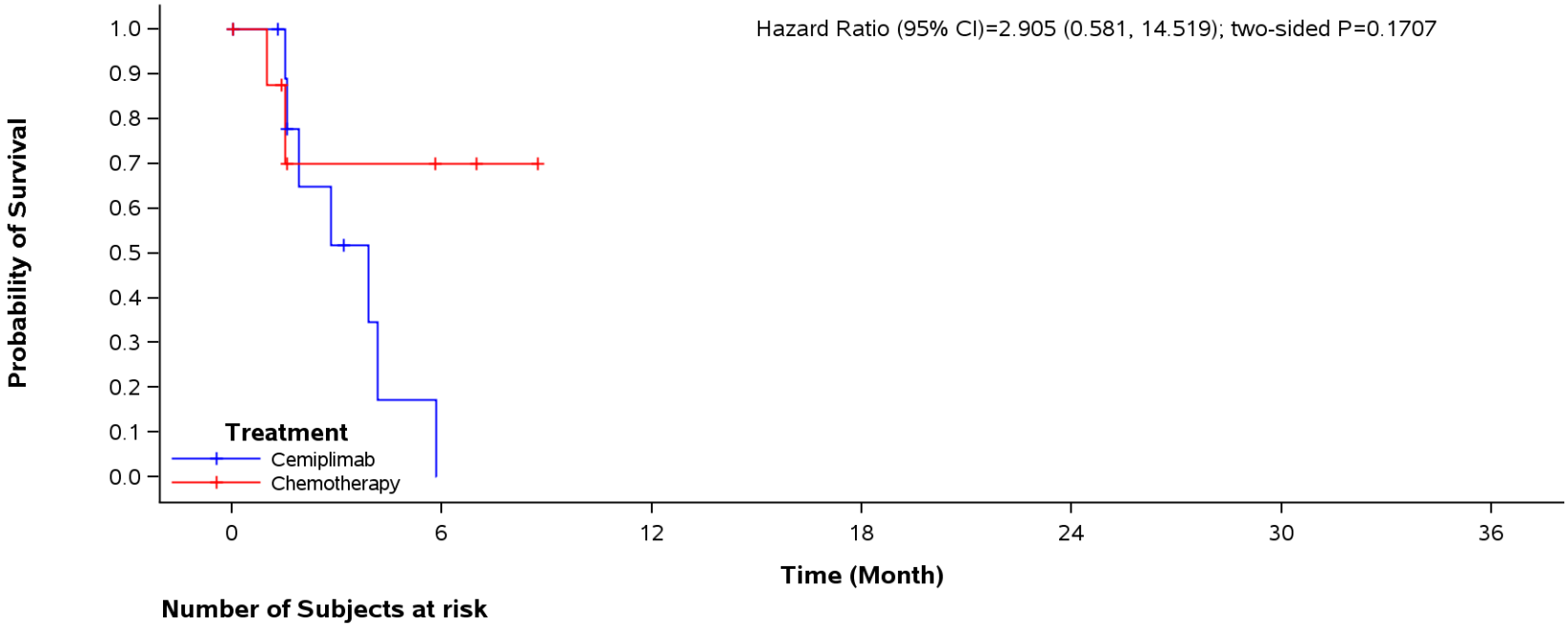
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Constipation - 10 pts improvement




**Number of Subjects at risk**

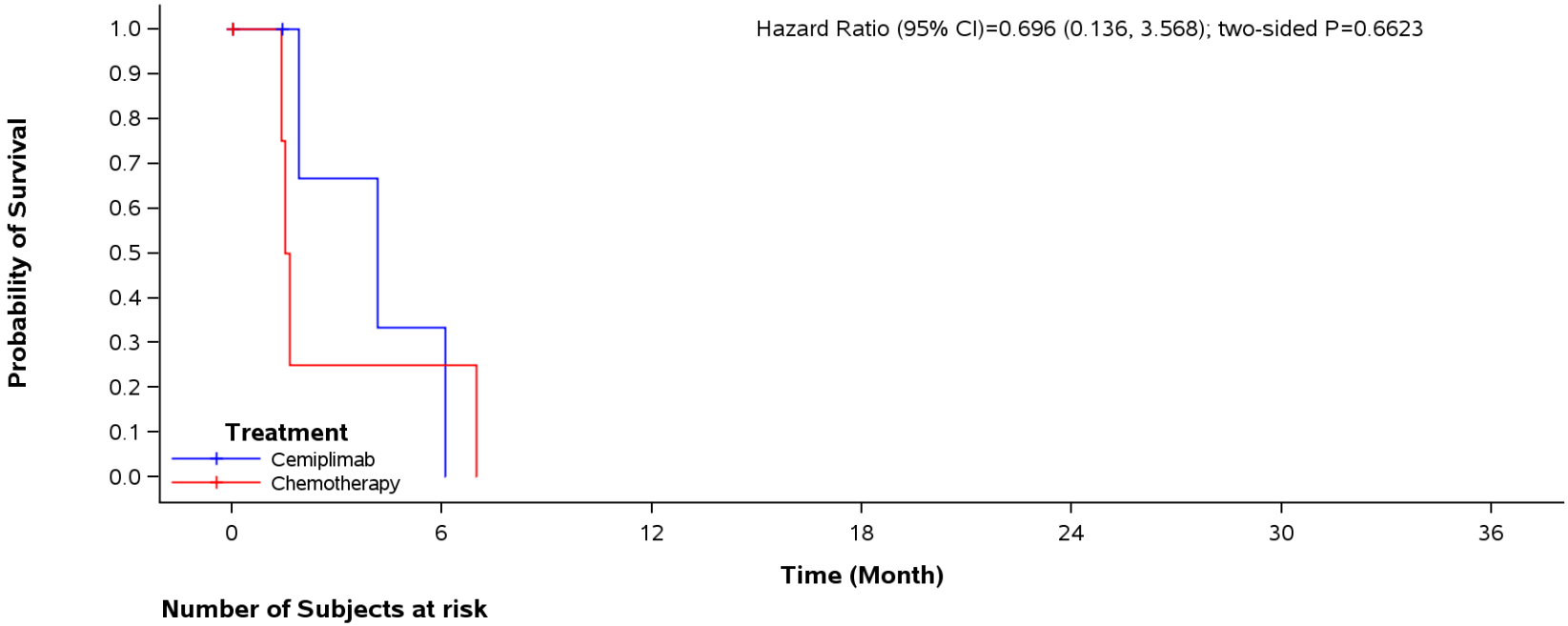
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Diarhoea - 10 pts improvement




**Number of Subjects at risk**

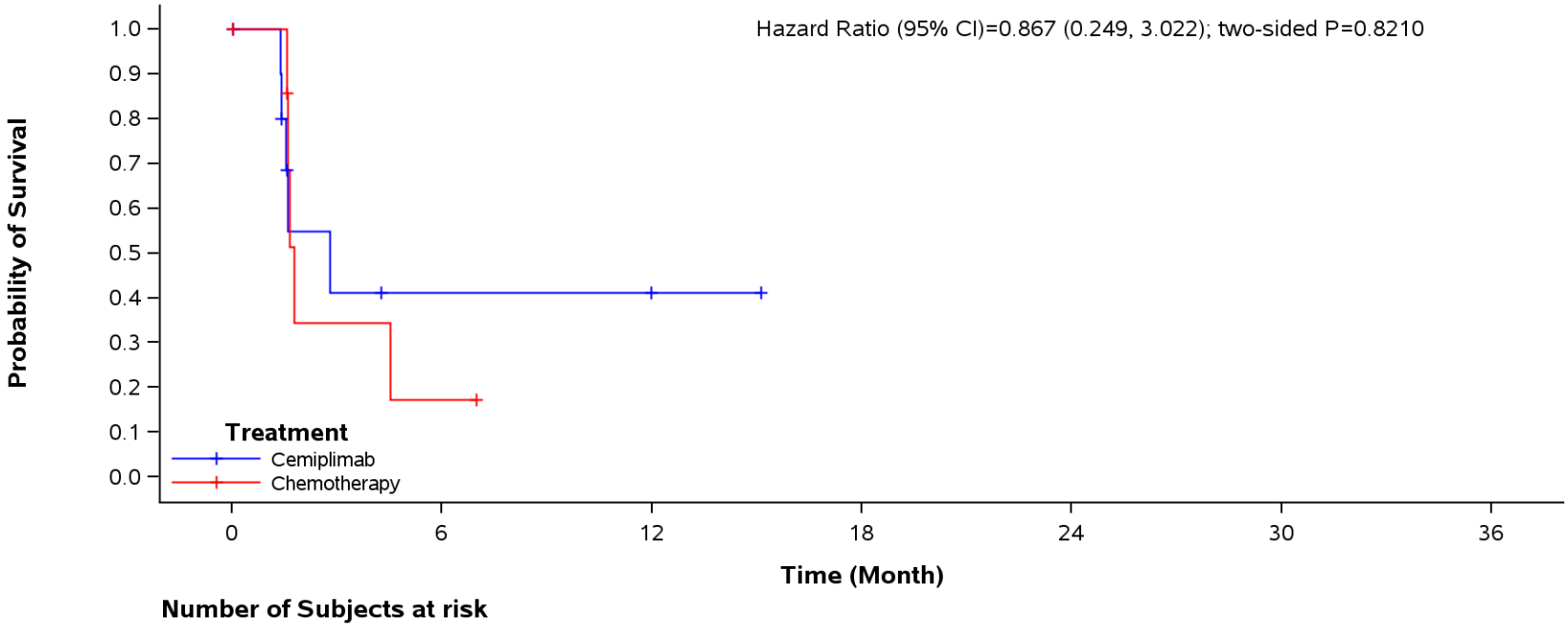
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Dyspnoea - 10 pts improvement




Number of Subjects at risk

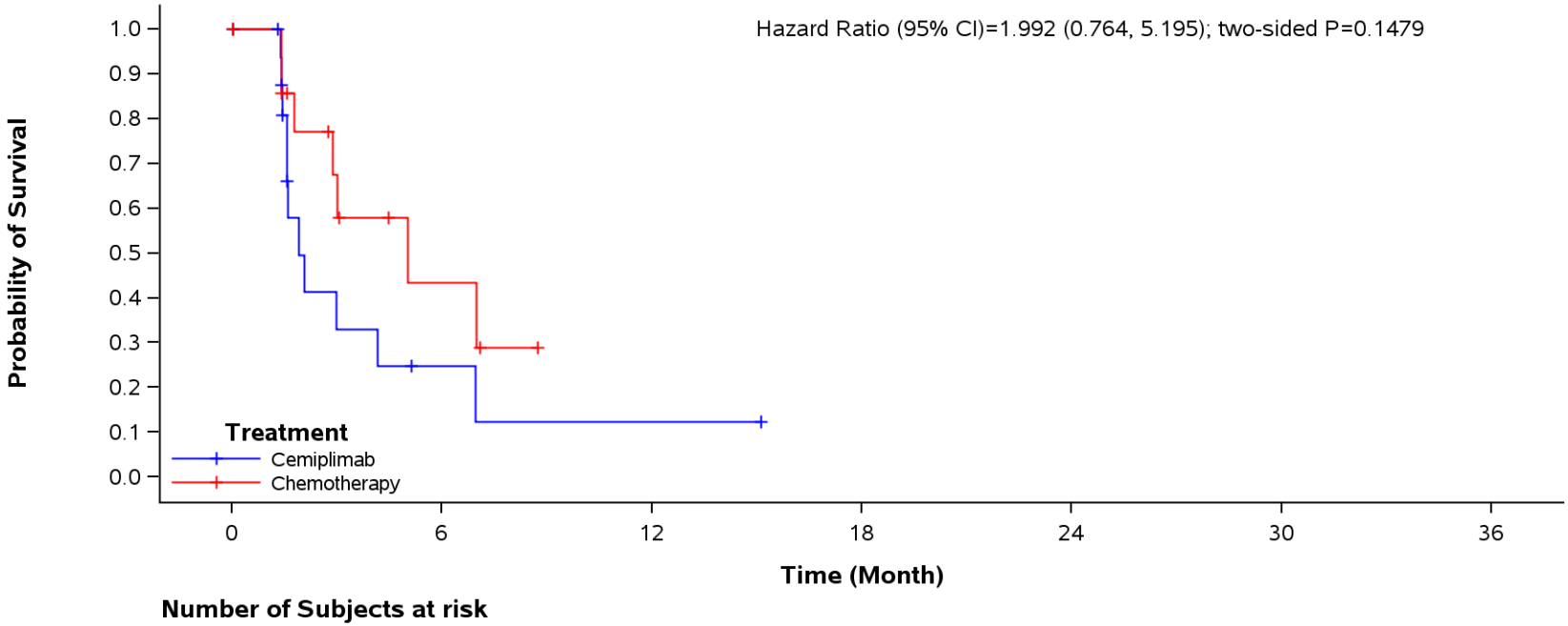
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Emotional Functioning - 10 pts improvement




Number of Subjects at risk

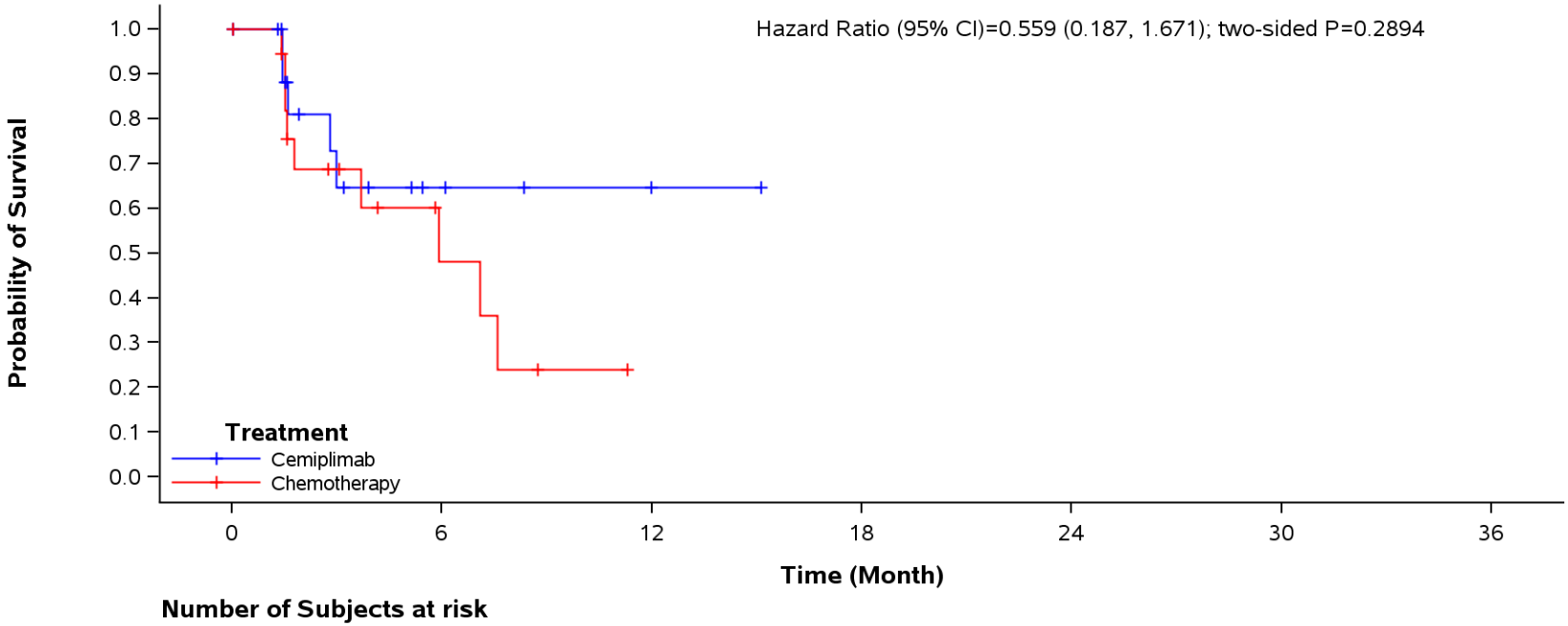
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Fatigue - 10 pts improvement



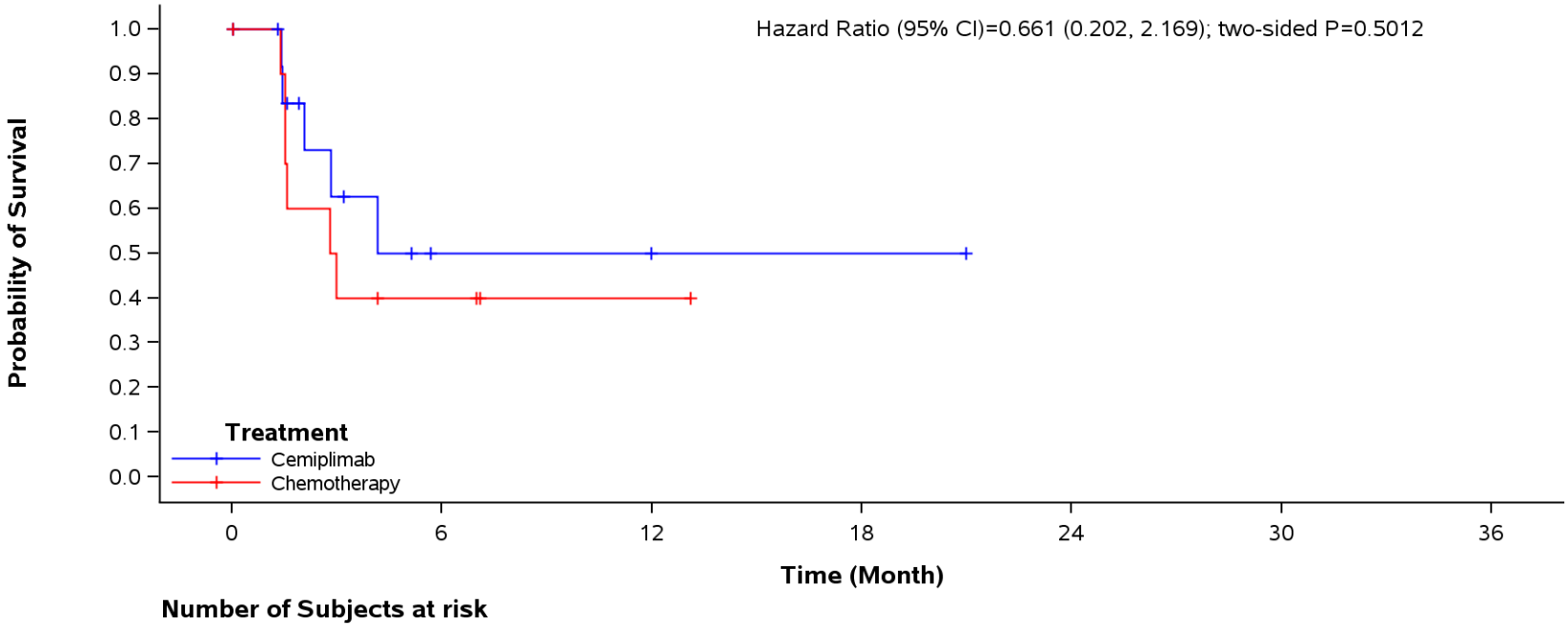

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Financial Problems - 10 pts improvement



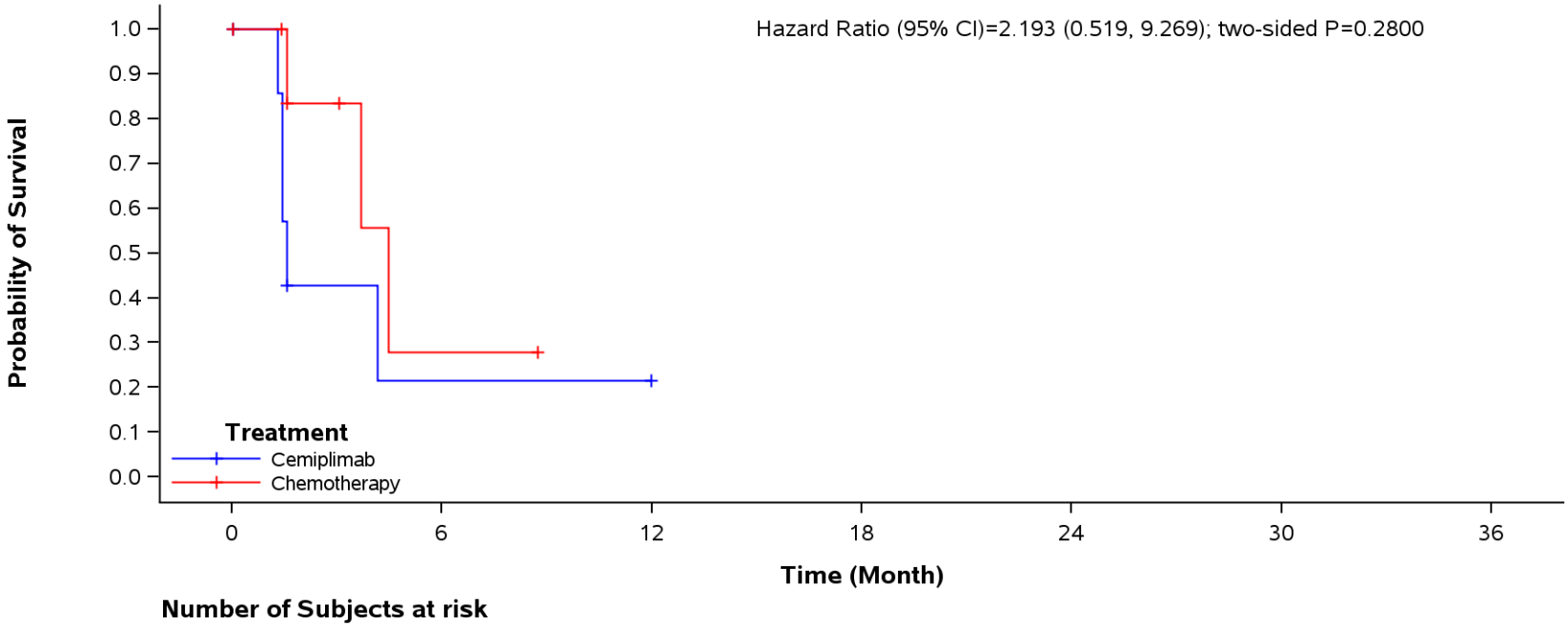

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Nausea / Vomiting - 10 pts improvement



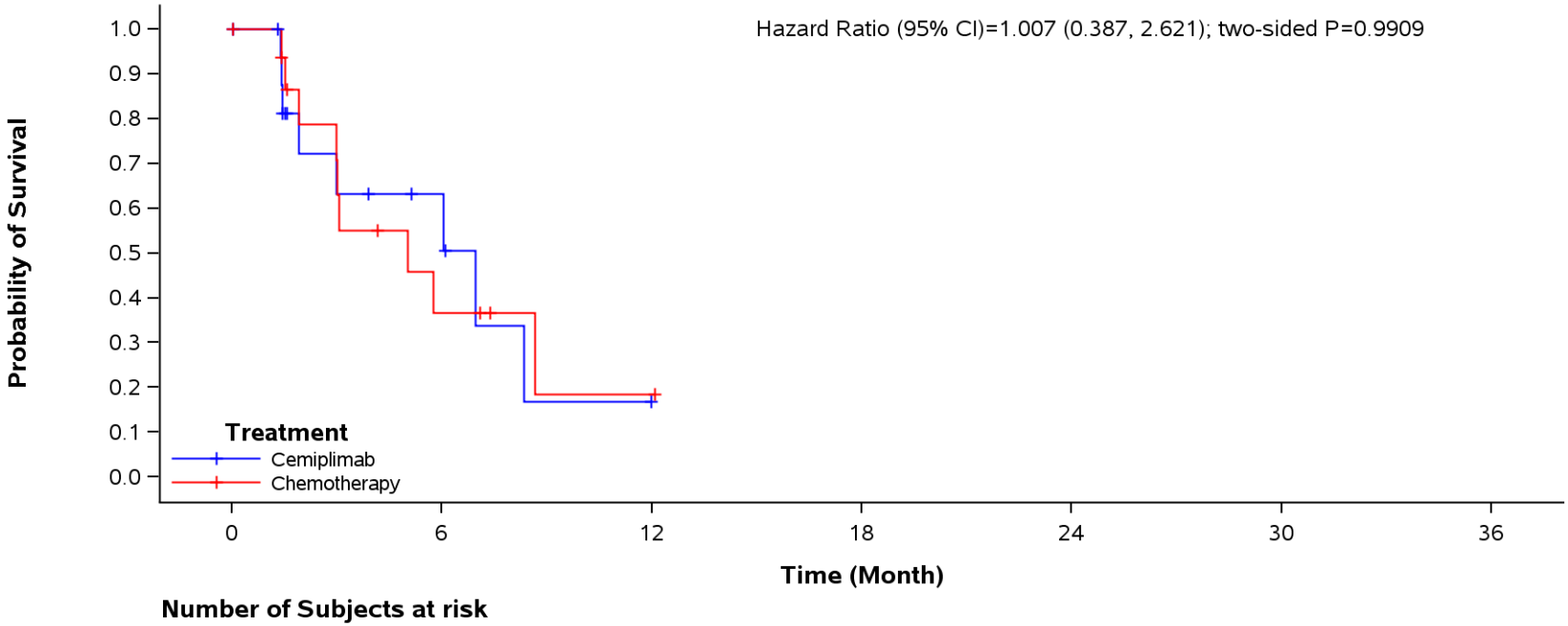

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Pain - 10 pts improvement




**Number of Subjects at risk**

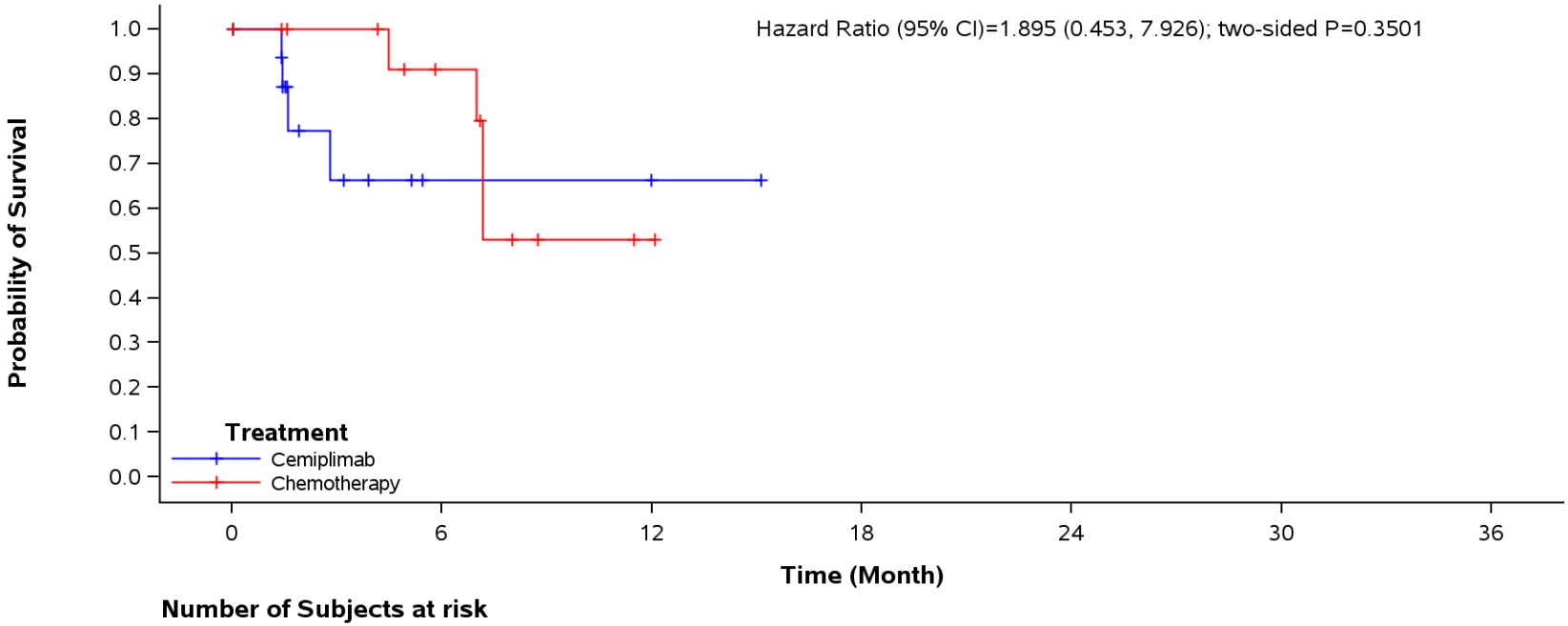
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Physical Functioning - 10 pts improvement




**Number of Subjects at risk**

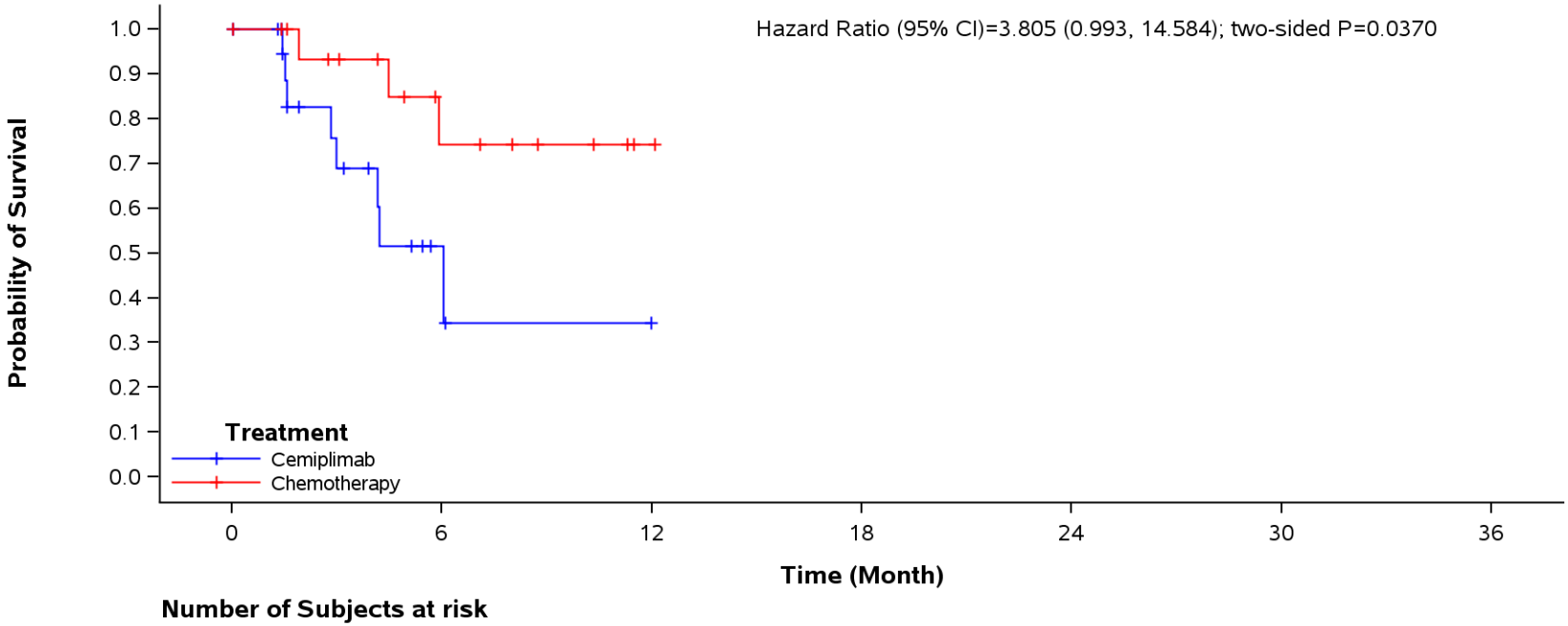
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Global health status / QoL - 10 pts improvement




**Number of Subjects at risk**

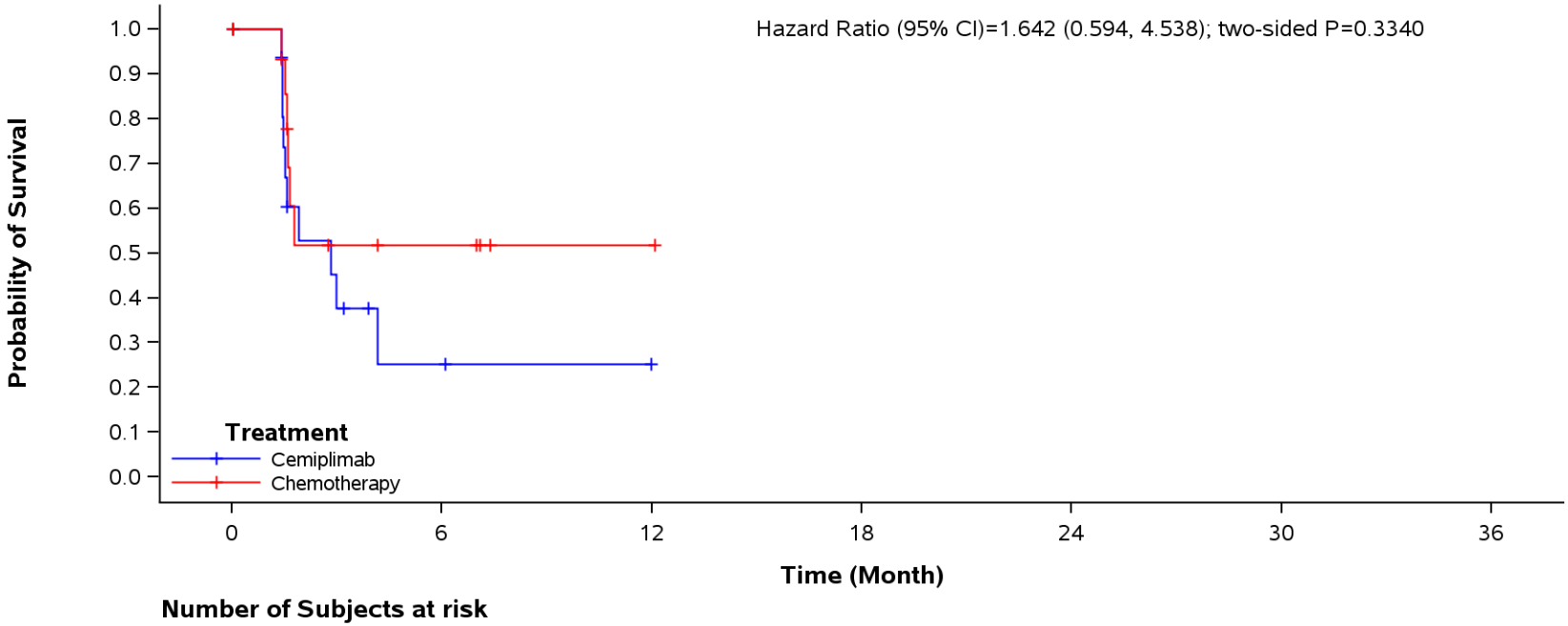
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Role Functioning - 10 pts improvement



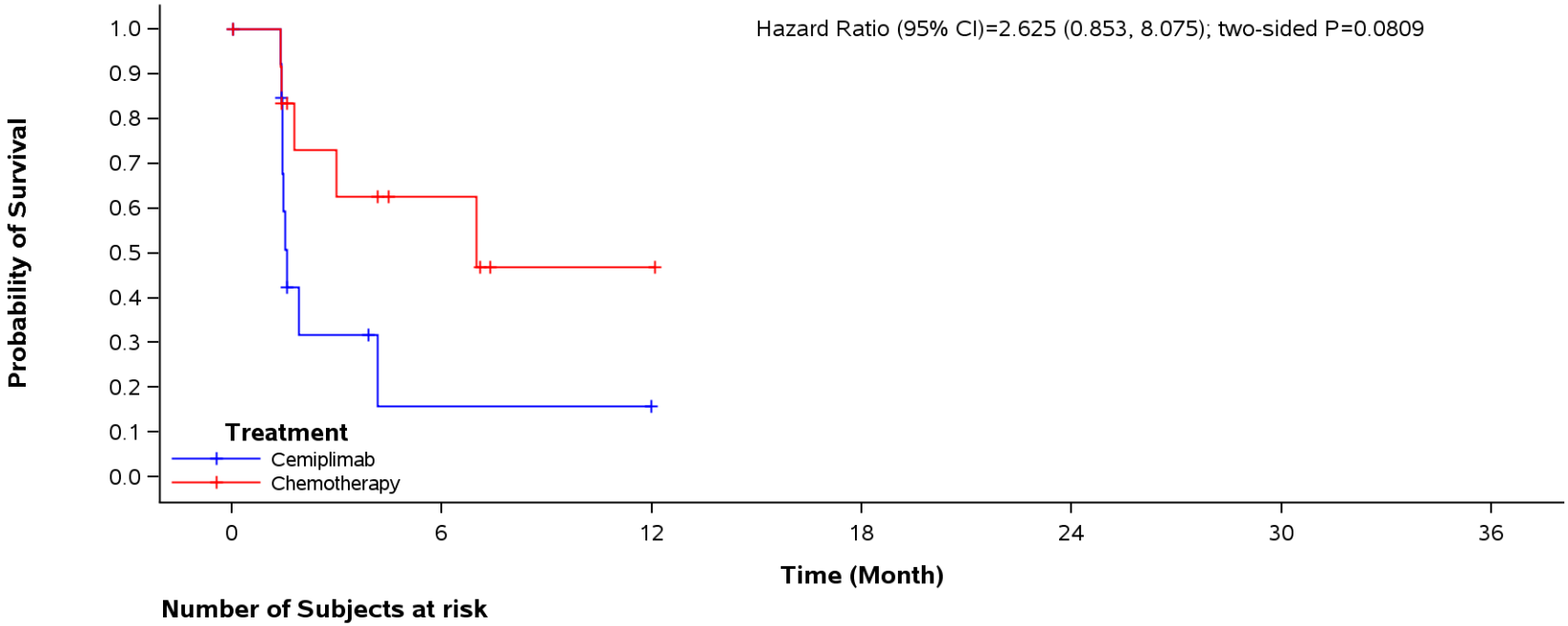

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Social Functioning - 10 pts improvement




Number of Subjects at risk

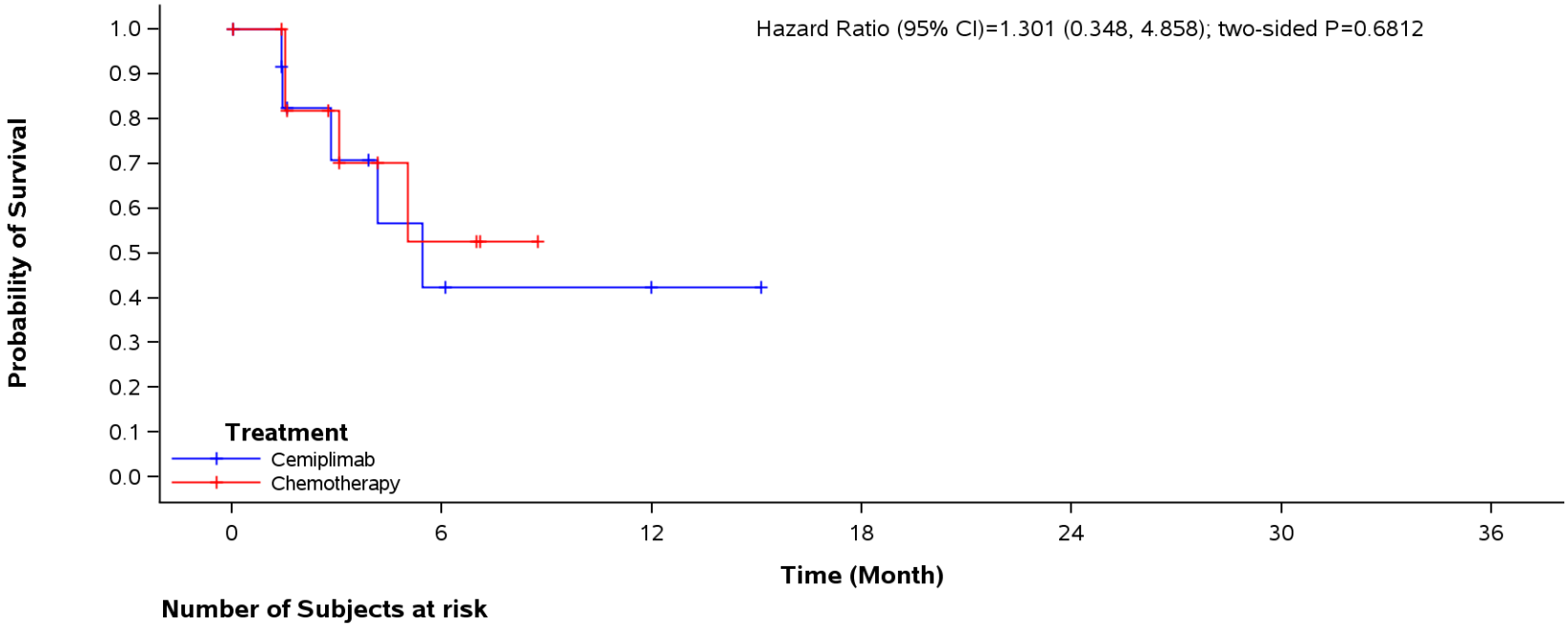
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Insomnia - 10 pts improvement



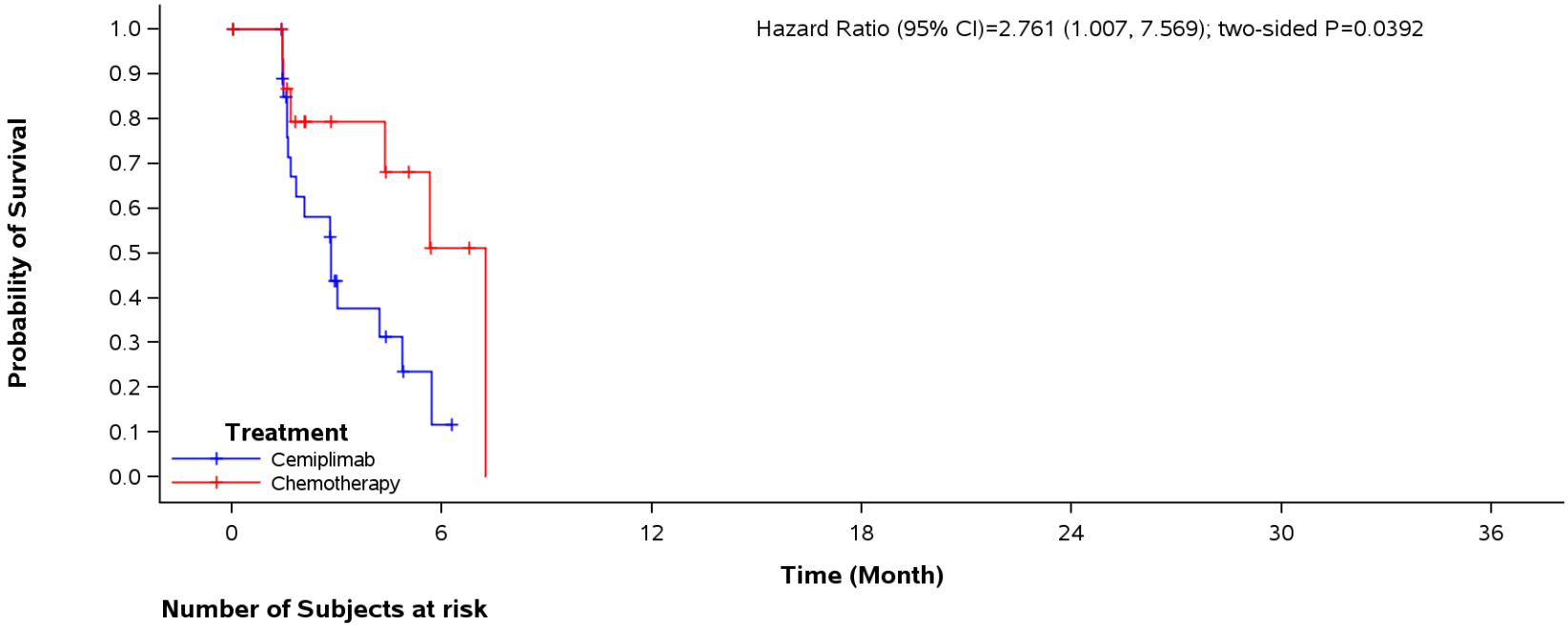

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Appetite loss - 10 pts improvement




**Number of Subjects at risk**

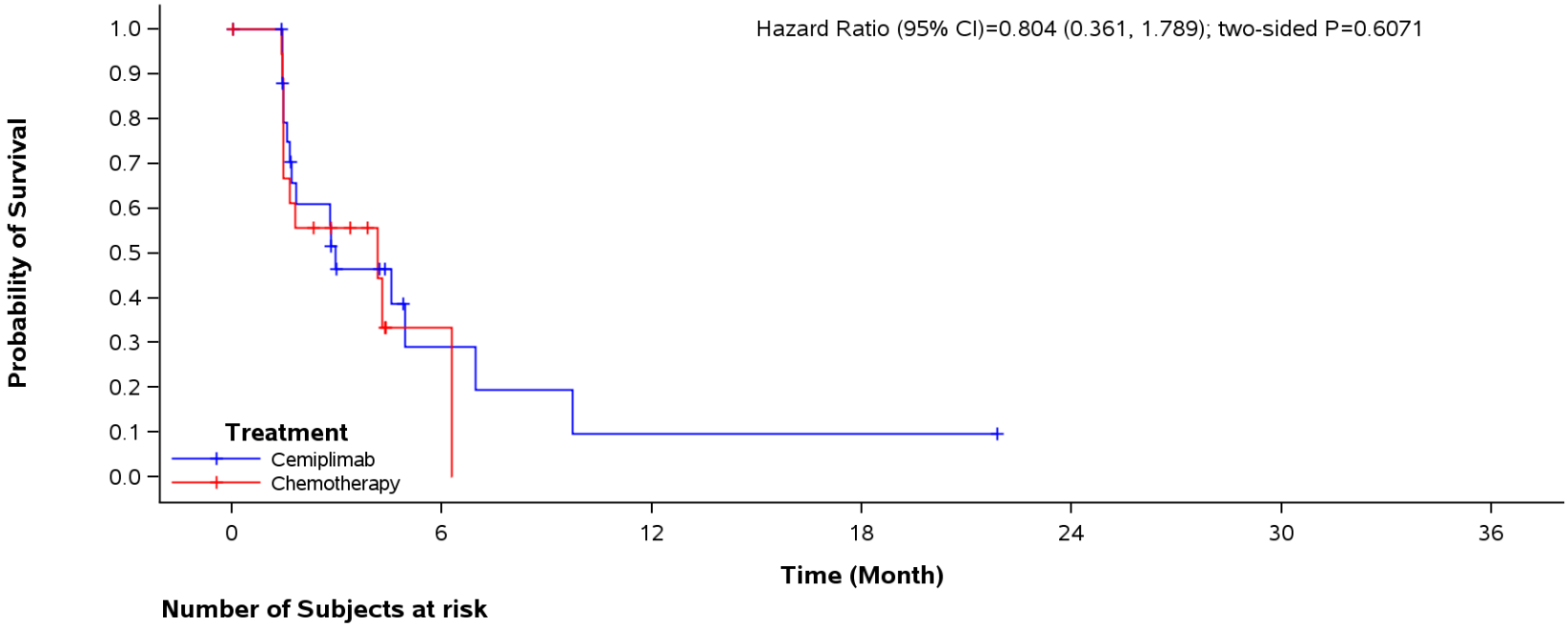
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Cognitive Functioning - 10 pts improvement




**Number of Subjects at risk**

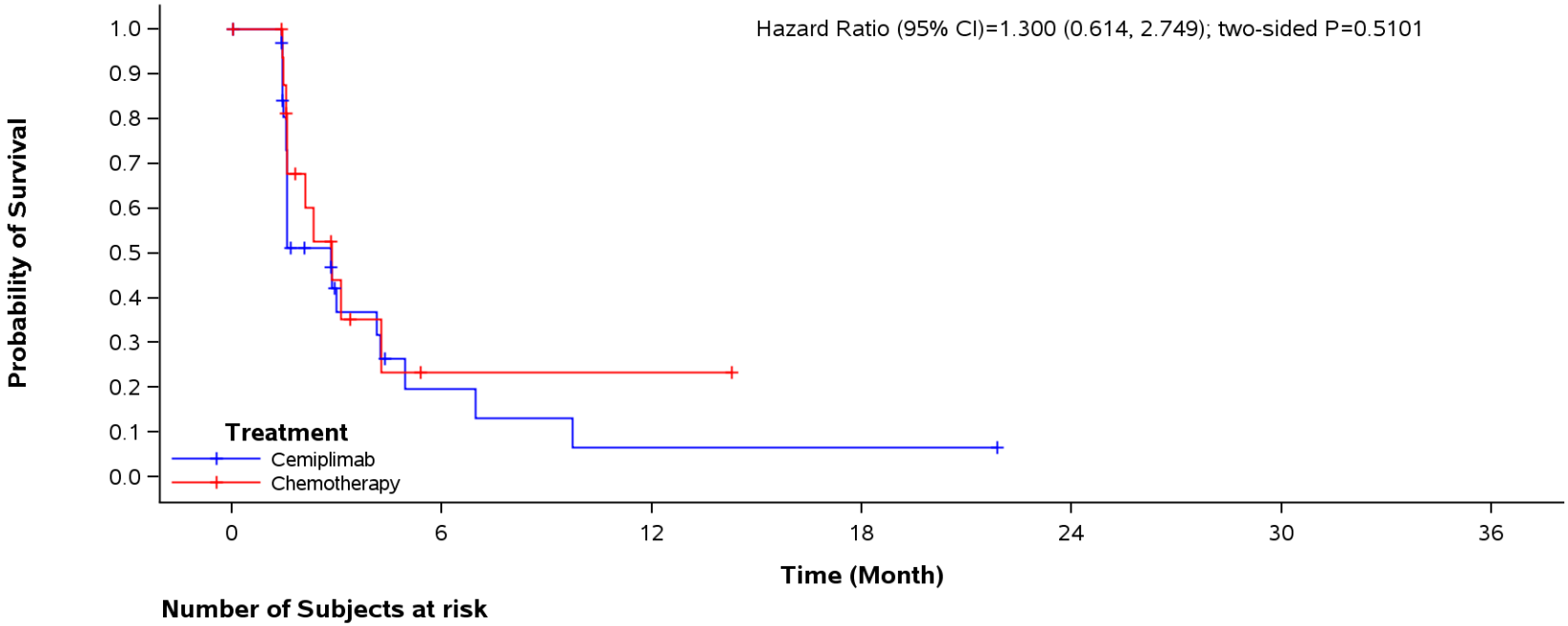
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 50 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Constipation - 10 pts improvement



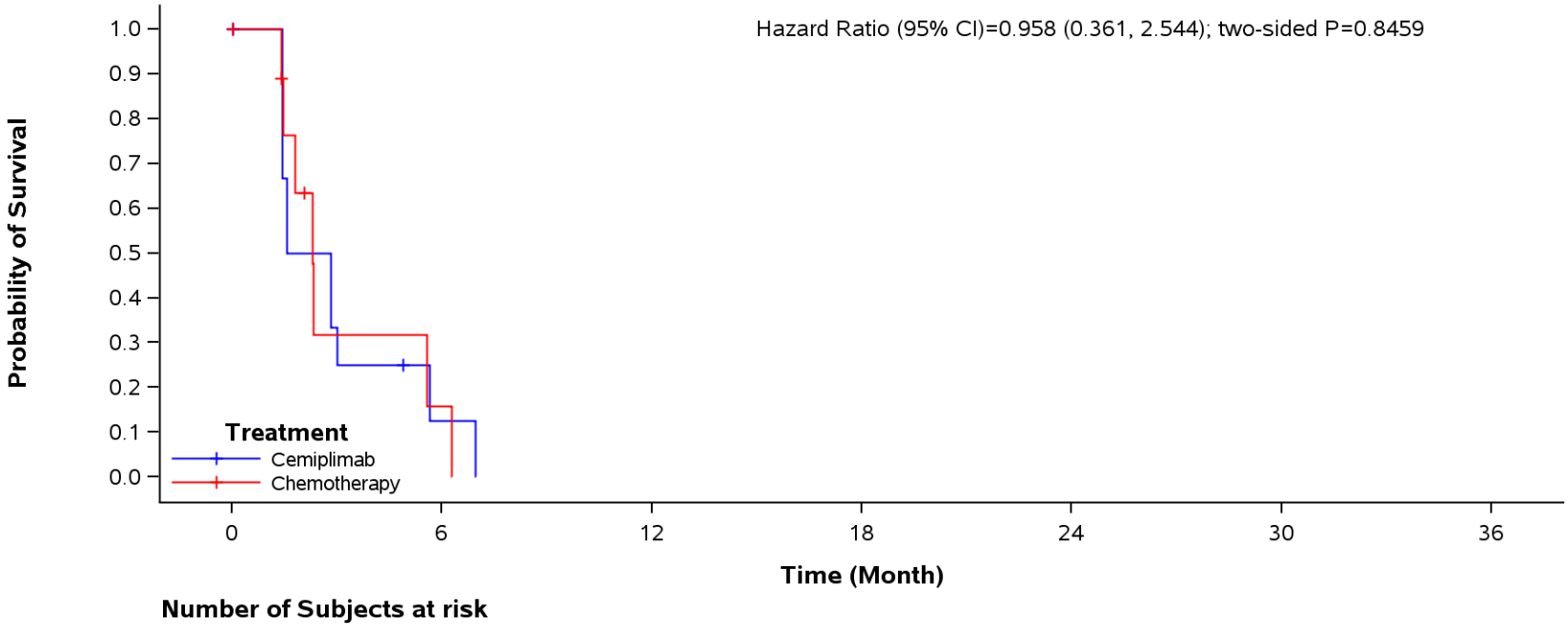

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 50 | 1 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Diarhoea - 10 pts improvement




**Number of Subjects at risk**

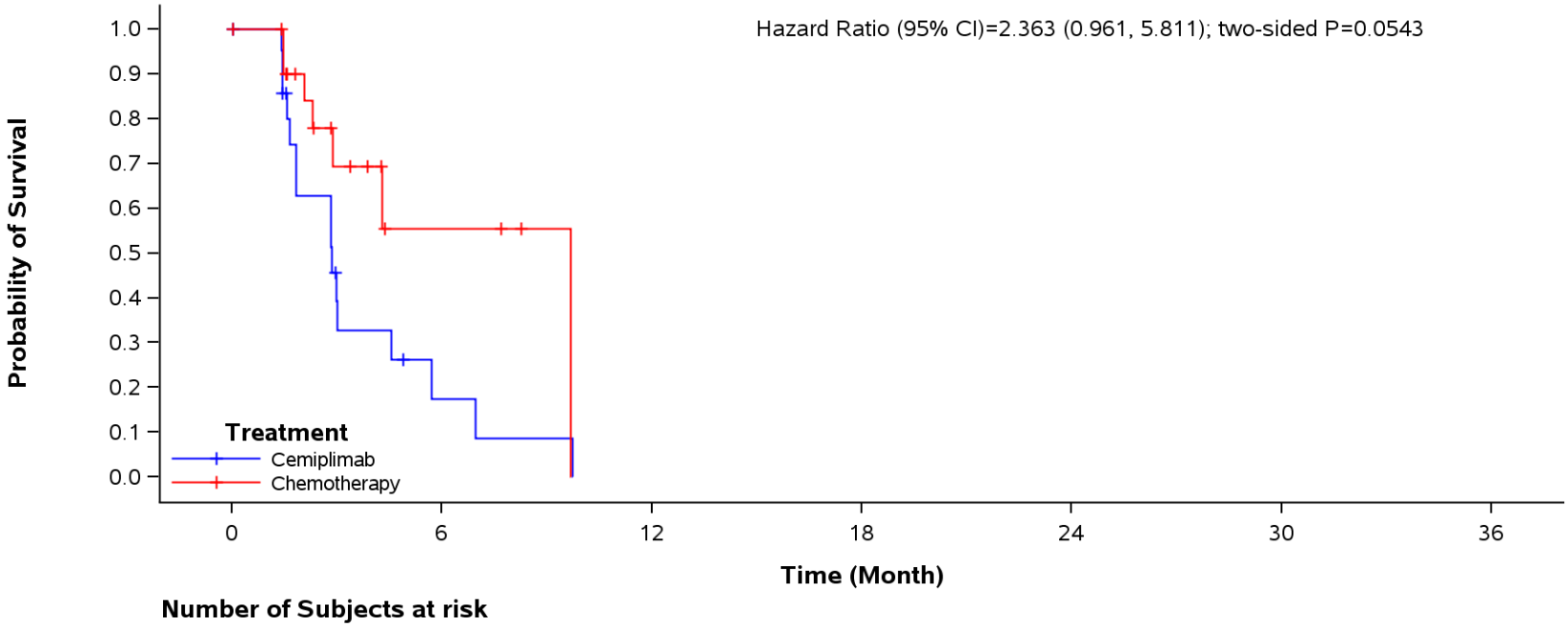
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Dyspnoea - 10 pts improvement




**Number of Subjects at risk**

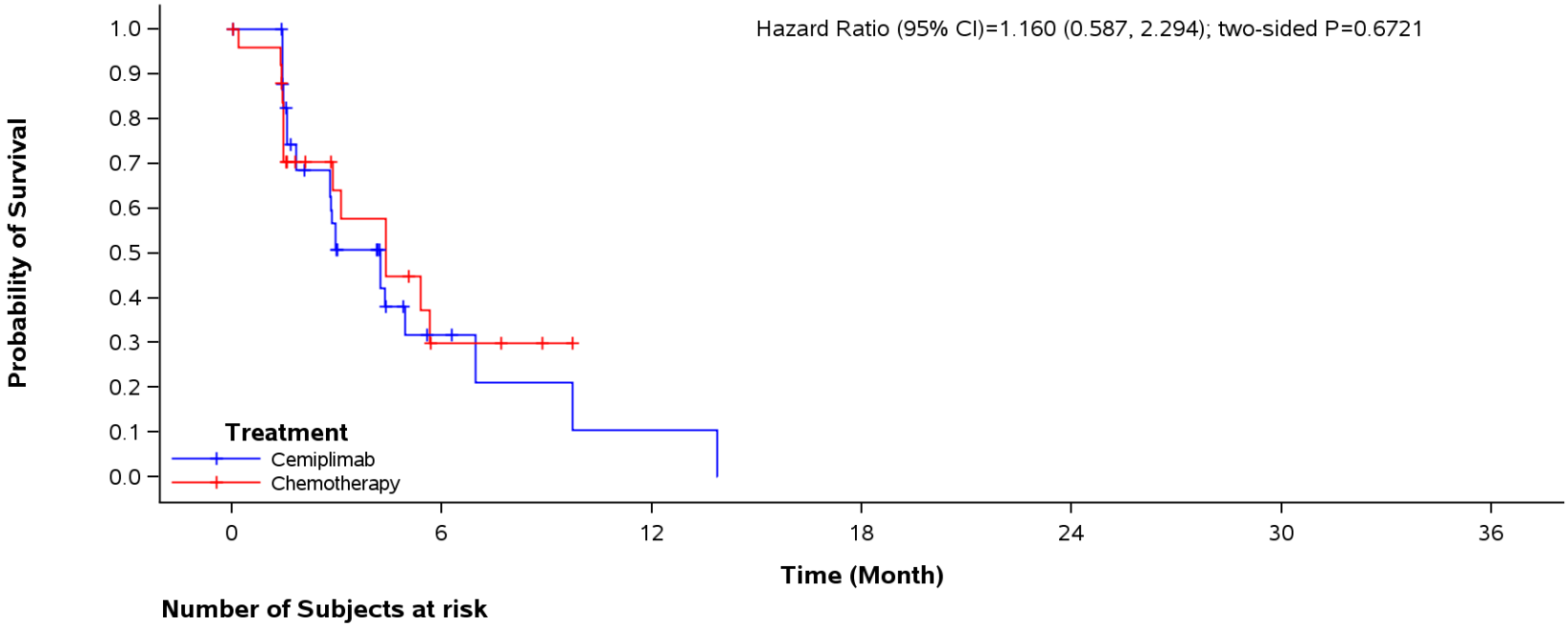
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Emotional Functioning - 10 pts improvement




**Number of Subjects at risk**

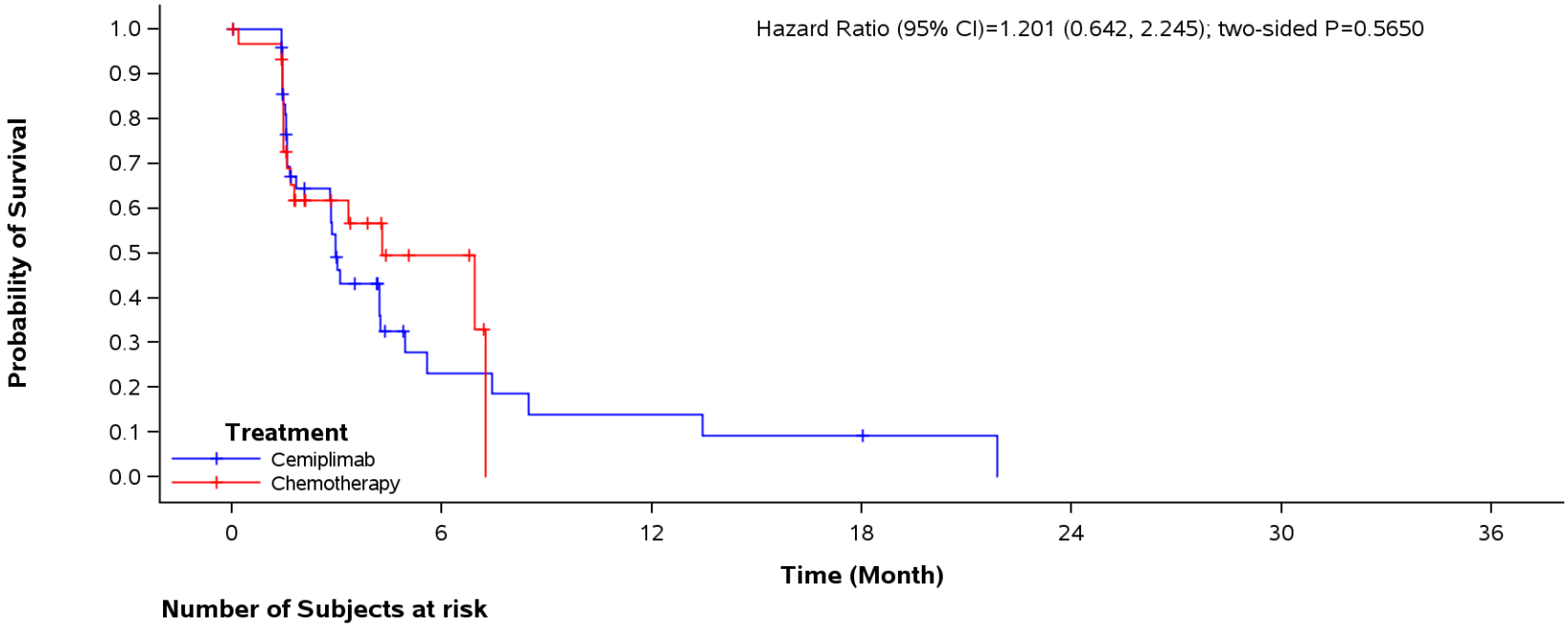
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Fatigue - 10 pts improvement




**Number of Subjects at risk**

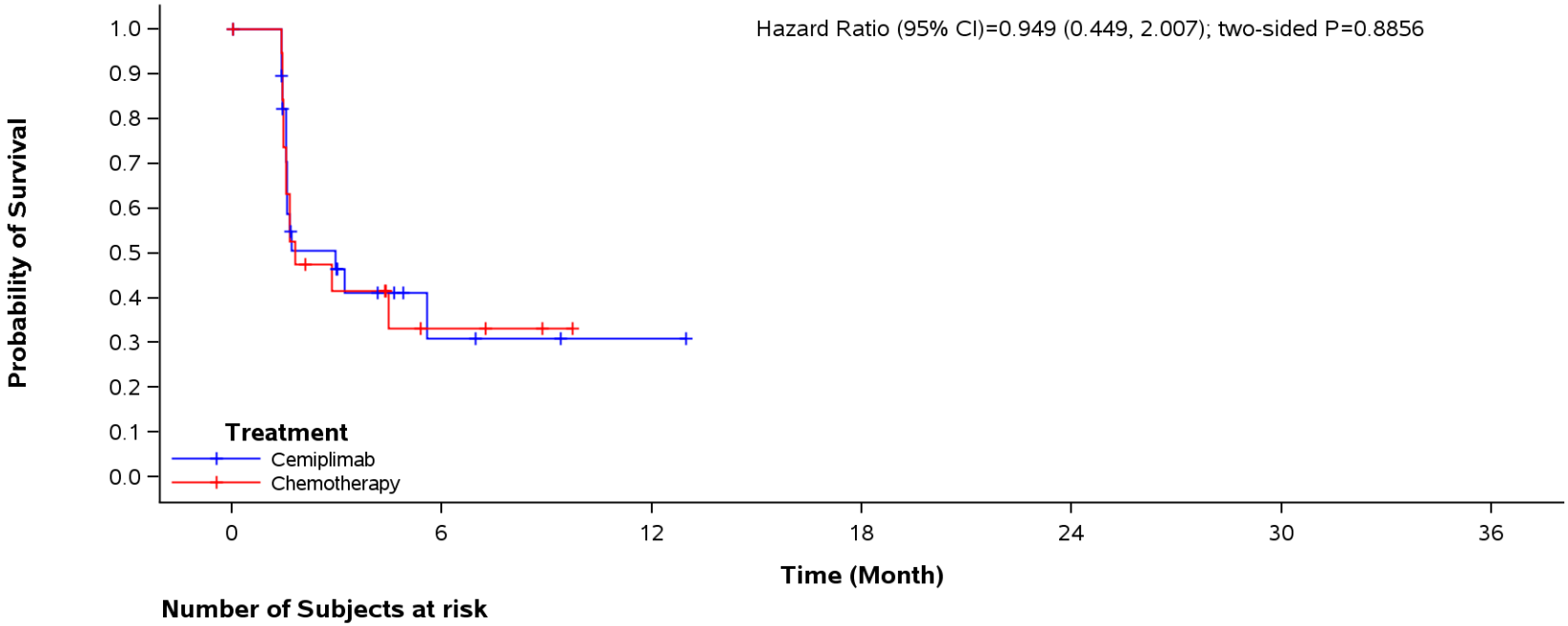
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 5 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Financial Problems - 10 pts improvement



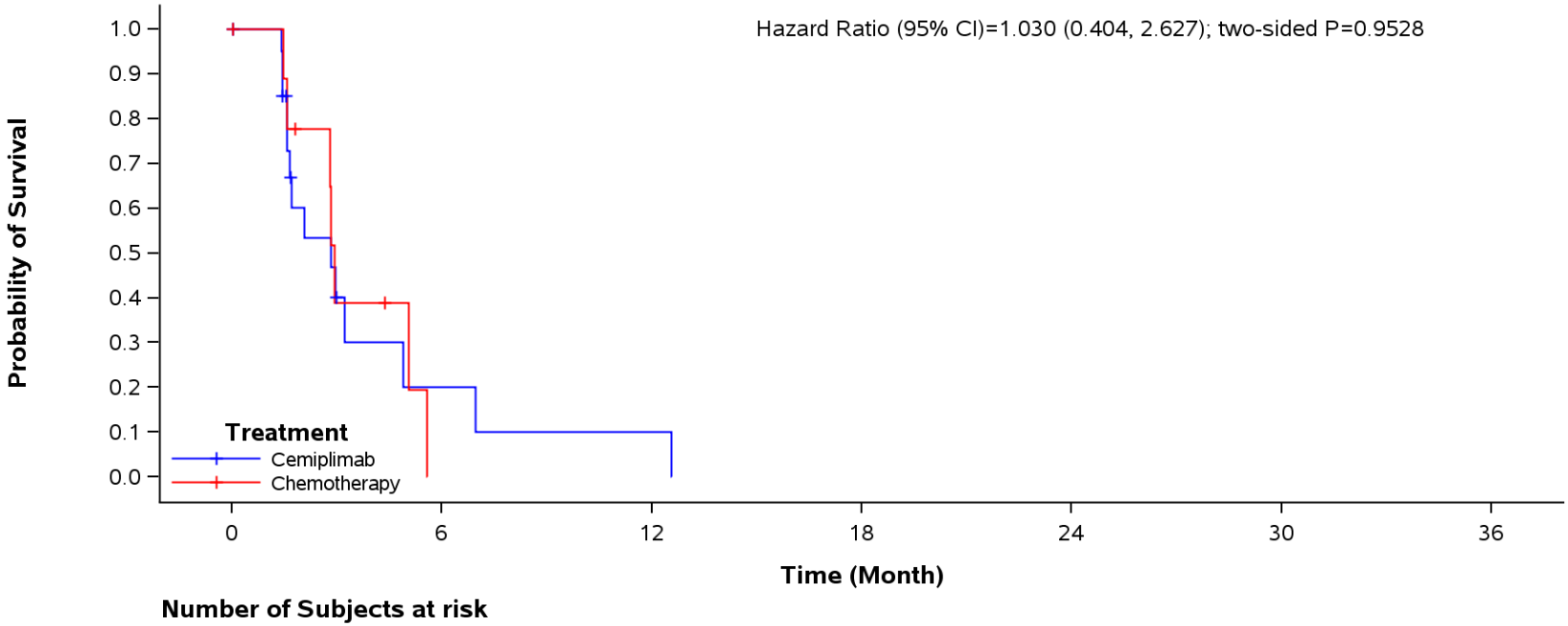

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Nausea / Vomiting - 10 pts improvement




Number of Subjects at risk

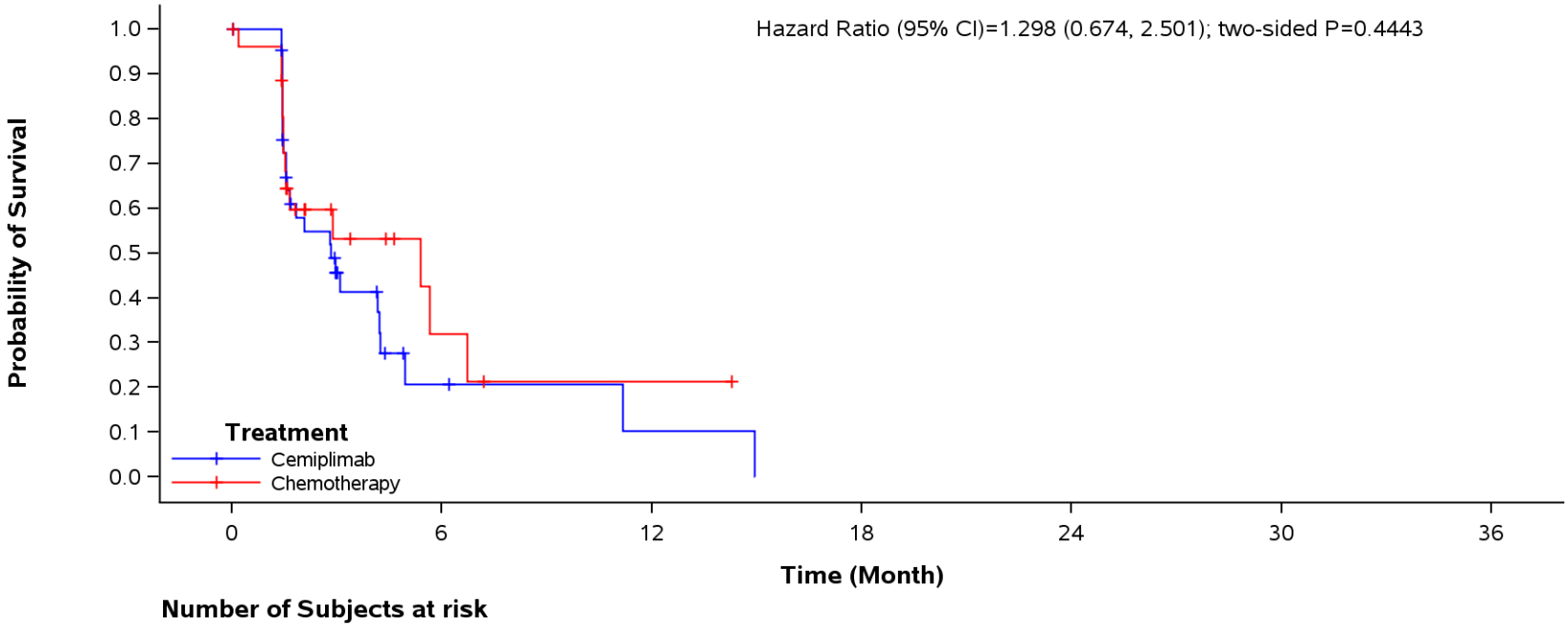
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Pain - 10 pts improvement




**Number of Subjects at risk**

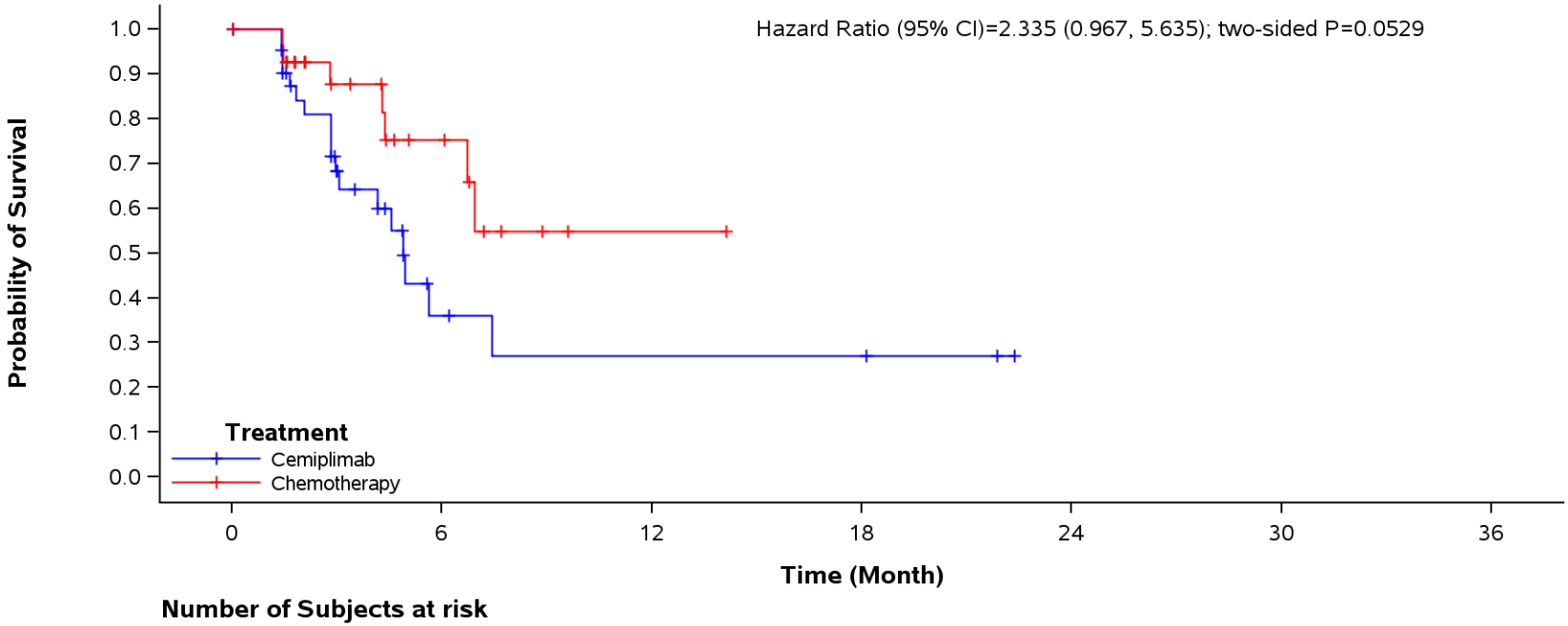
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Physical Functioning - 10 pts improvement



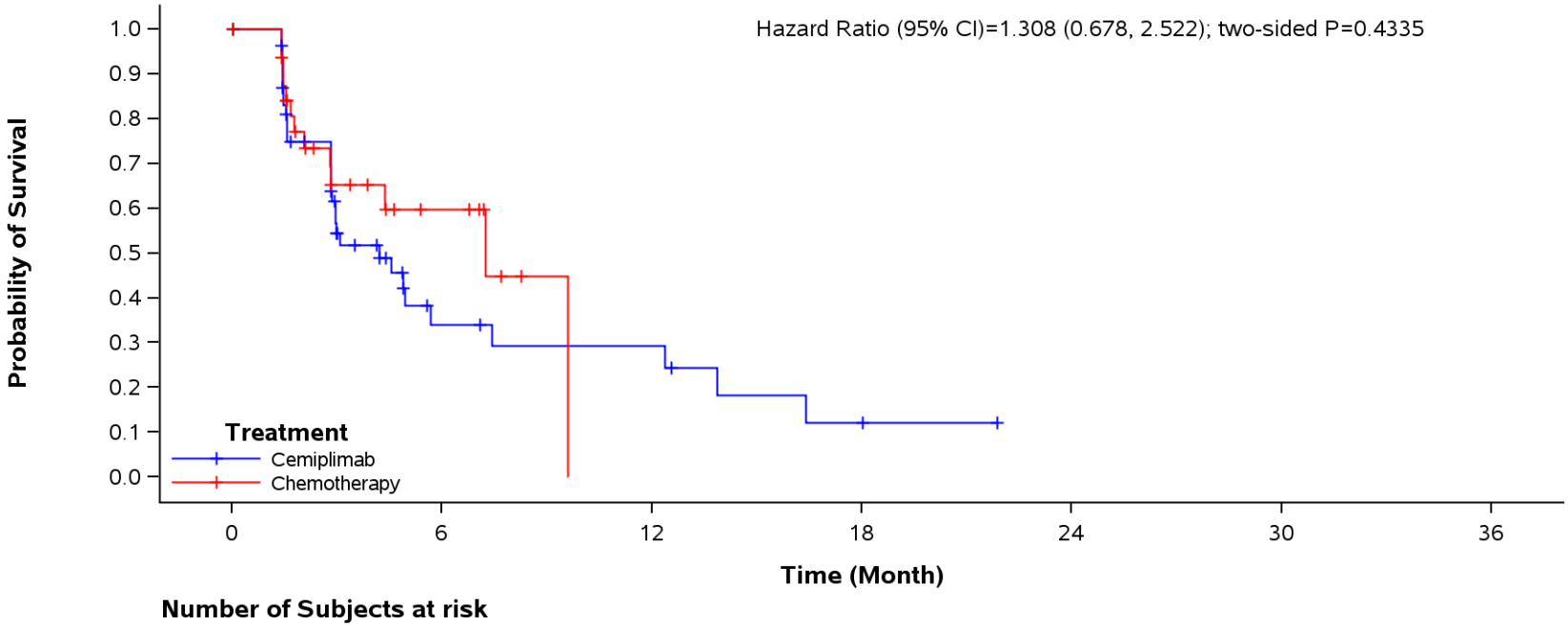

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 5 | 3 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Global health status / QoL - 10 pts improvement




**Number of Subjects at risk**

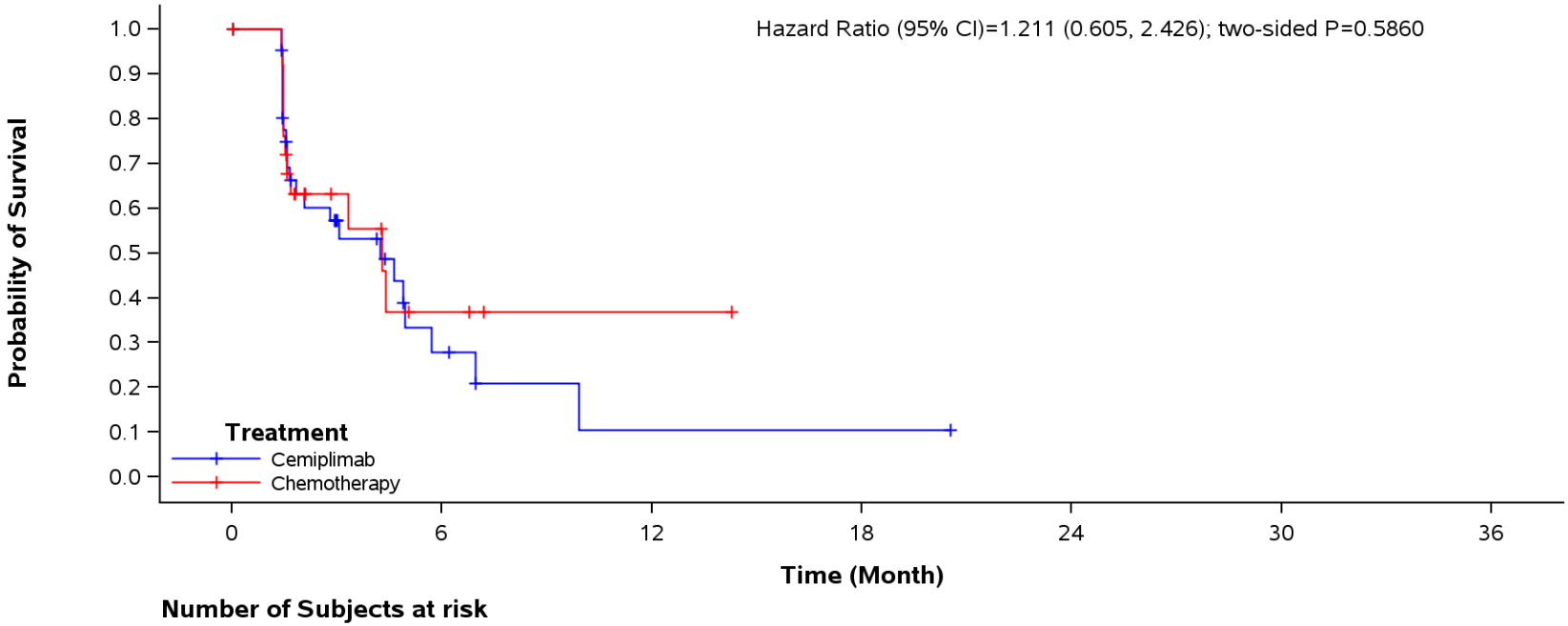
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 8 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Role Functioning - 10 pts improvement



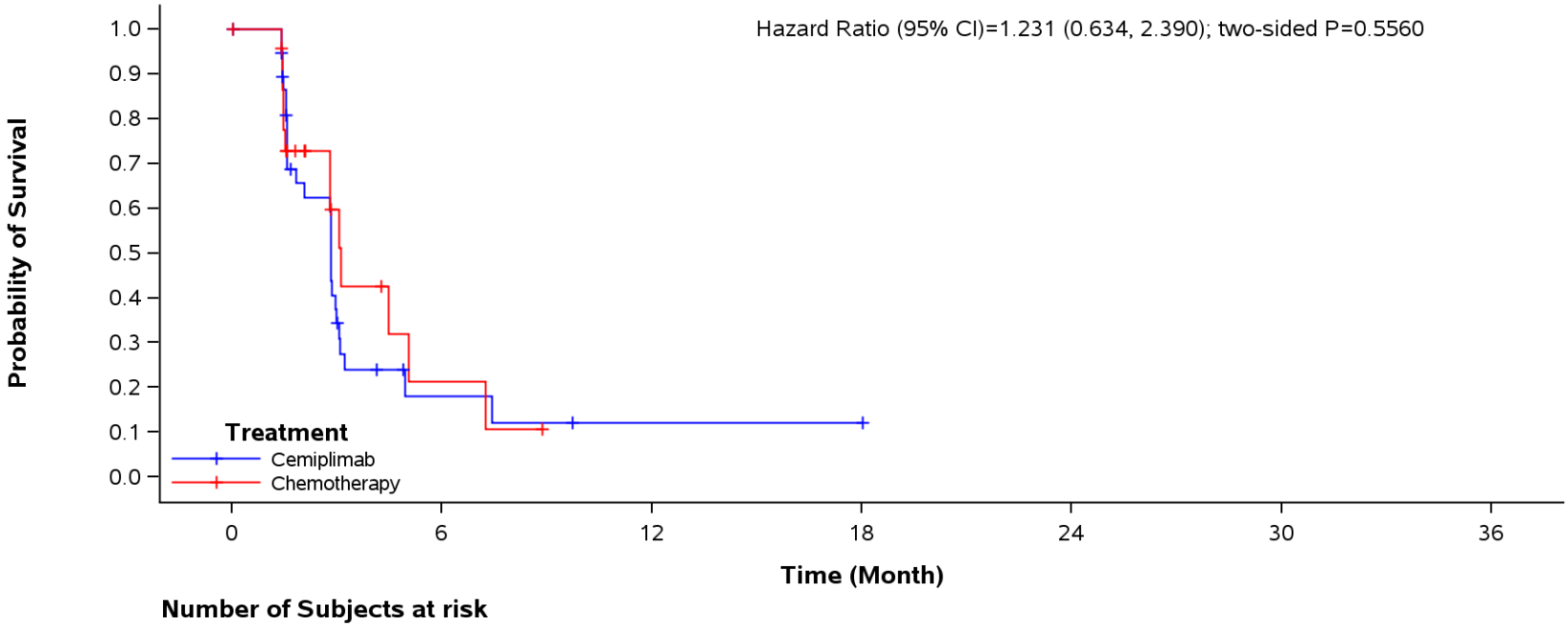

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 50 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Social Functioning - 10 pts improvement



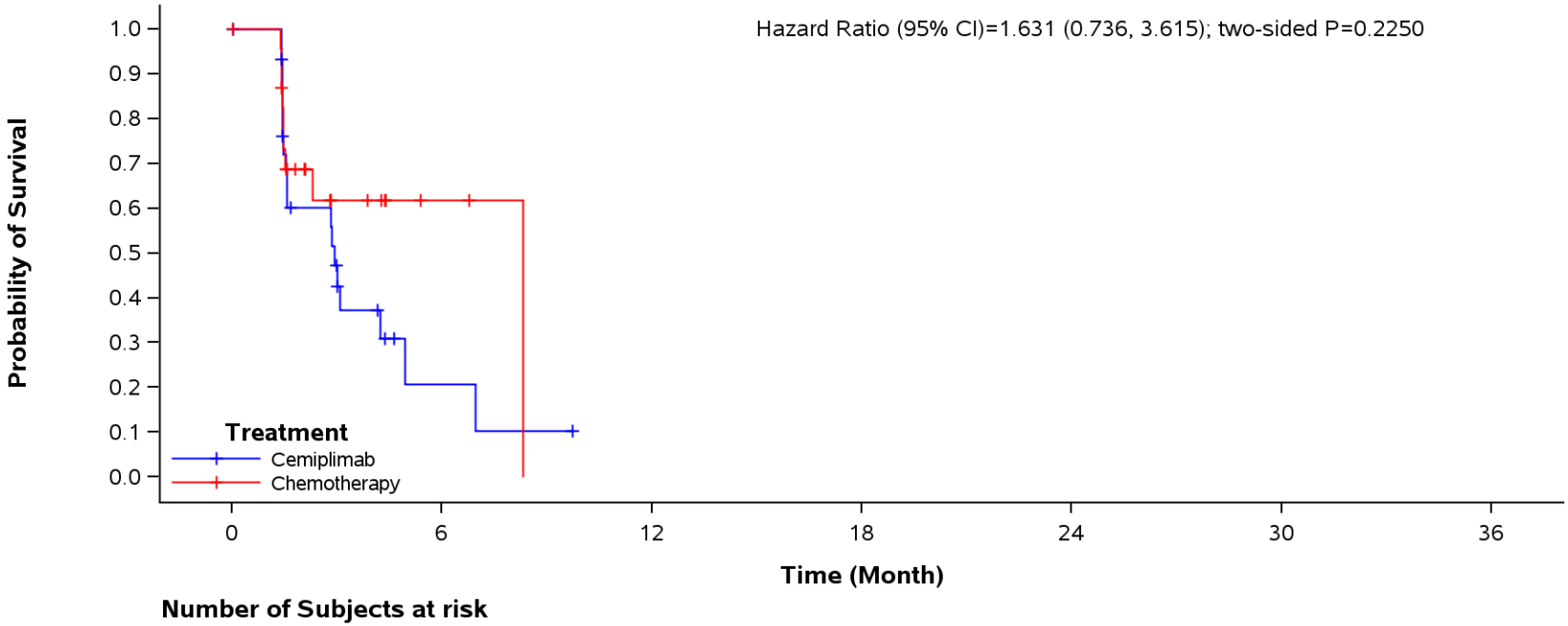

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 50 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Figure 2.3.3a. Time to First Improvement with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Insomnia - 10 pts improvement




**Number of Subjects at risk**

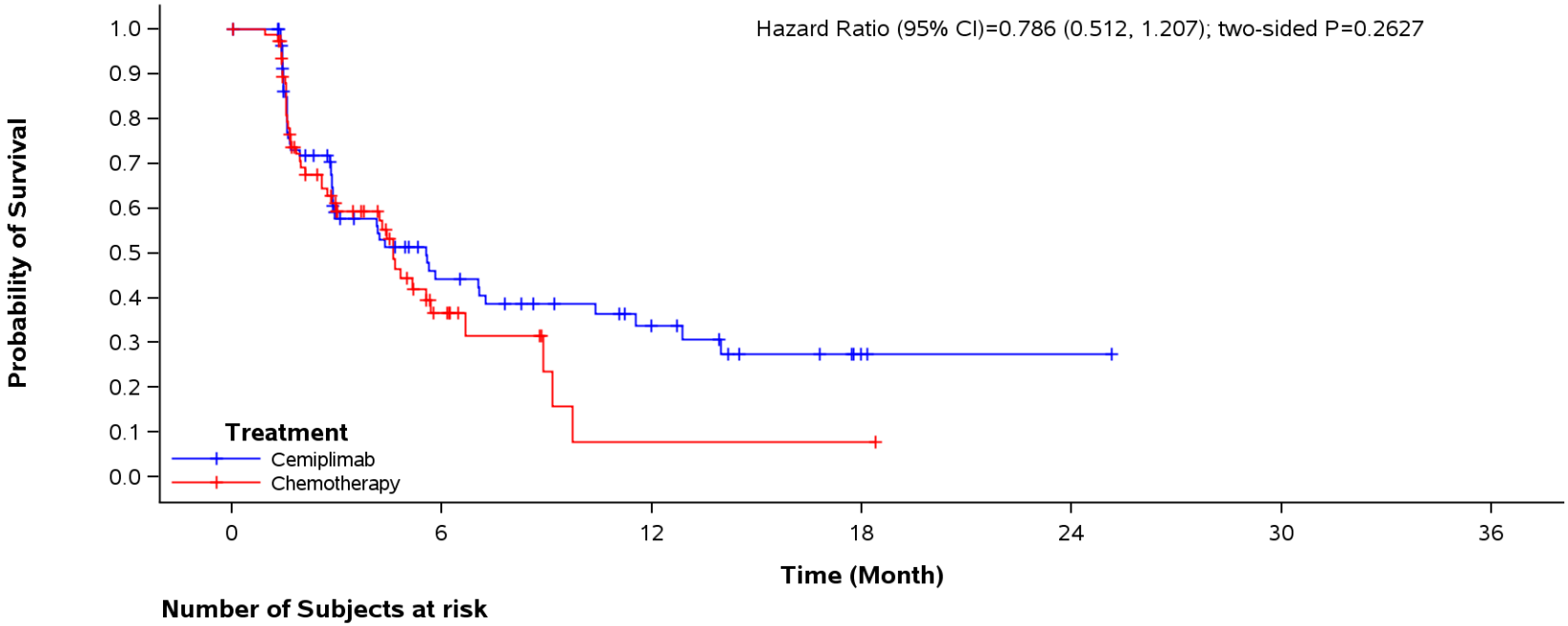
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 50 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points improvement first time - Date of Randomization +1)/365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:02, yingyuan.lin)

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Appetite loss - 10 pts deterioration



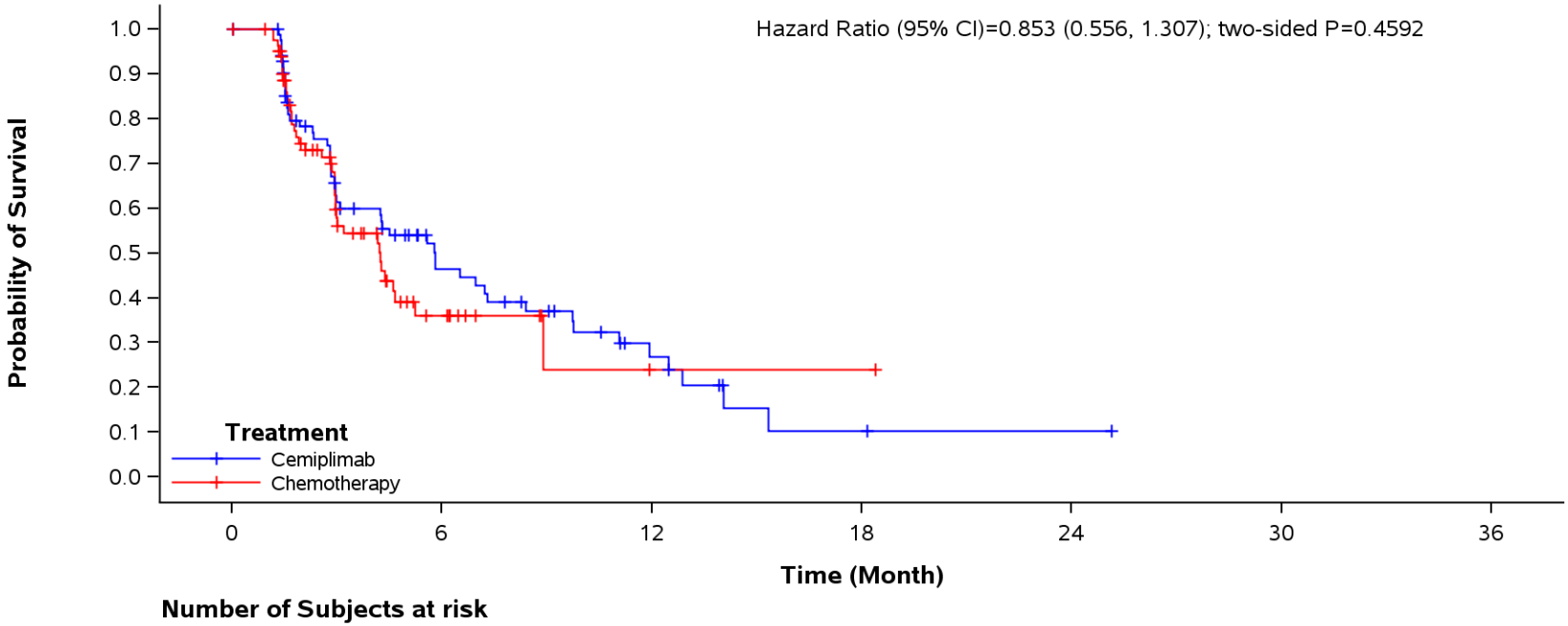

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 25 | 12 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 12 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Cognitive Functioning - 10 pts deterioration



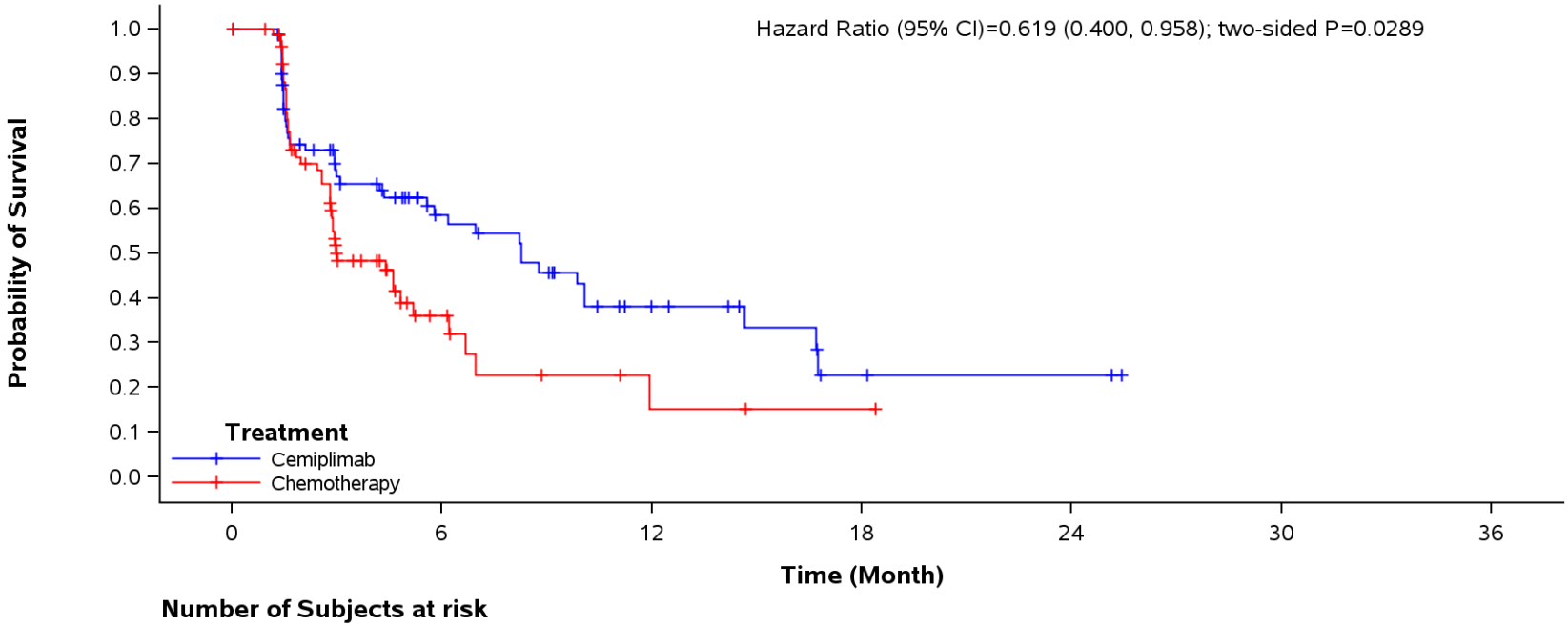

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 25 | 9 | 2 | 1 | 0 | 0 |
| Chemotherapy | 103 | 11 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Constipation - 10 pts deterioration



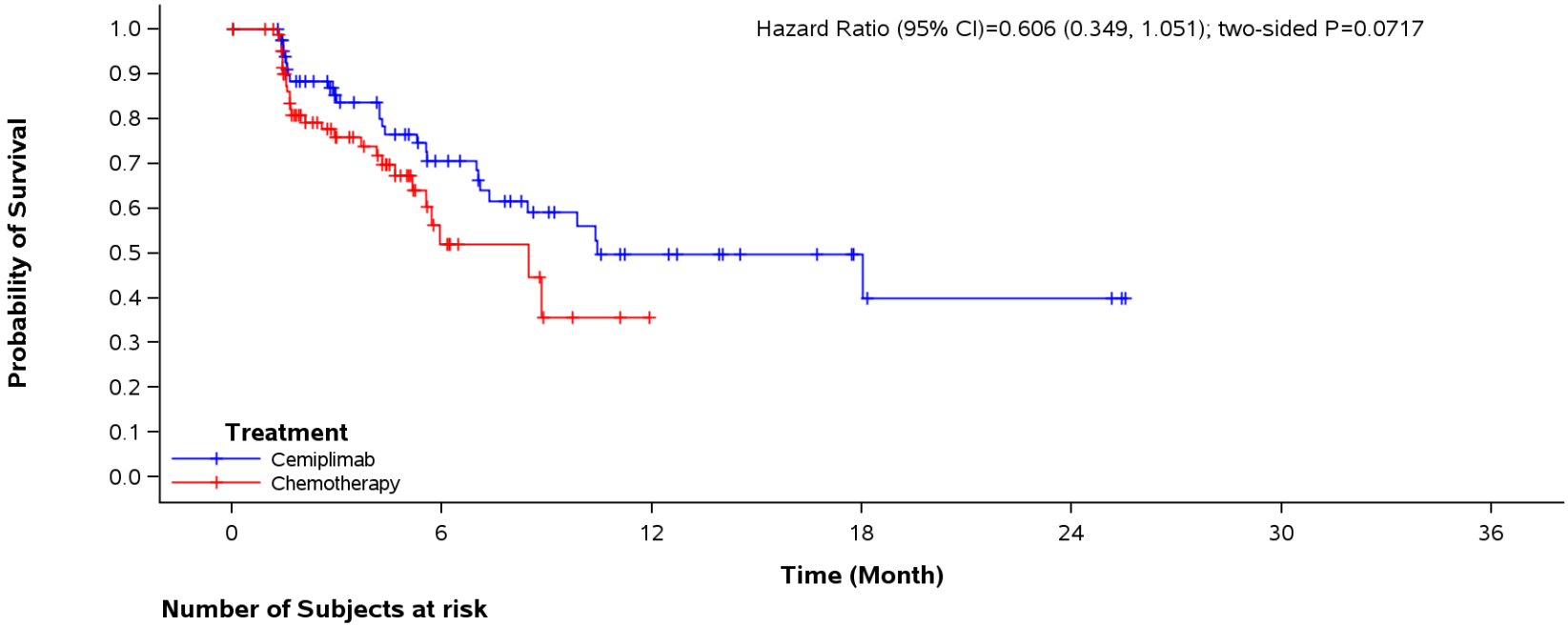

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 28 | 11 | 3 | 2 | 0 | 0 |
| Chemotherapy | 103 | 10 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Diarhoea - 10 pts deterioration



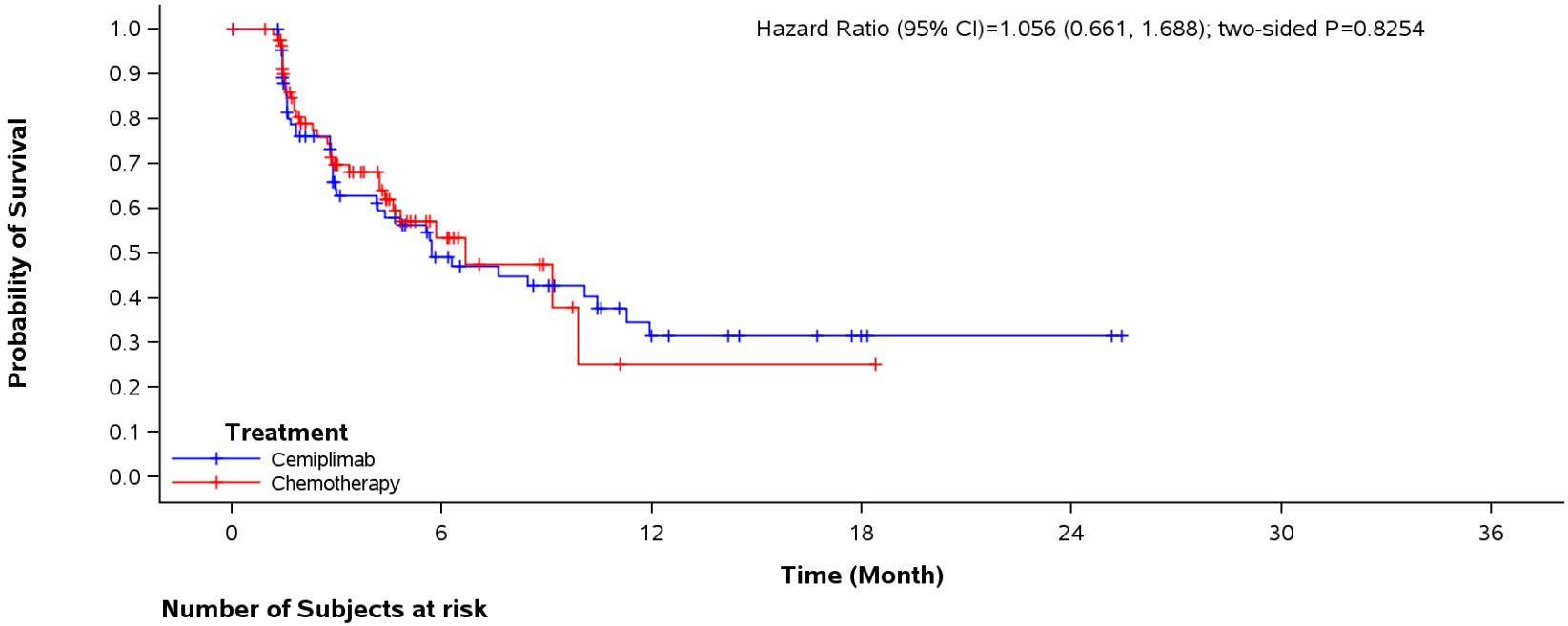

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 34 | 13 | 5 | 3 | 0 | 0 |
| Chemotherapy | 103 | 12 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Dyspnoea - 10 pts deterioration



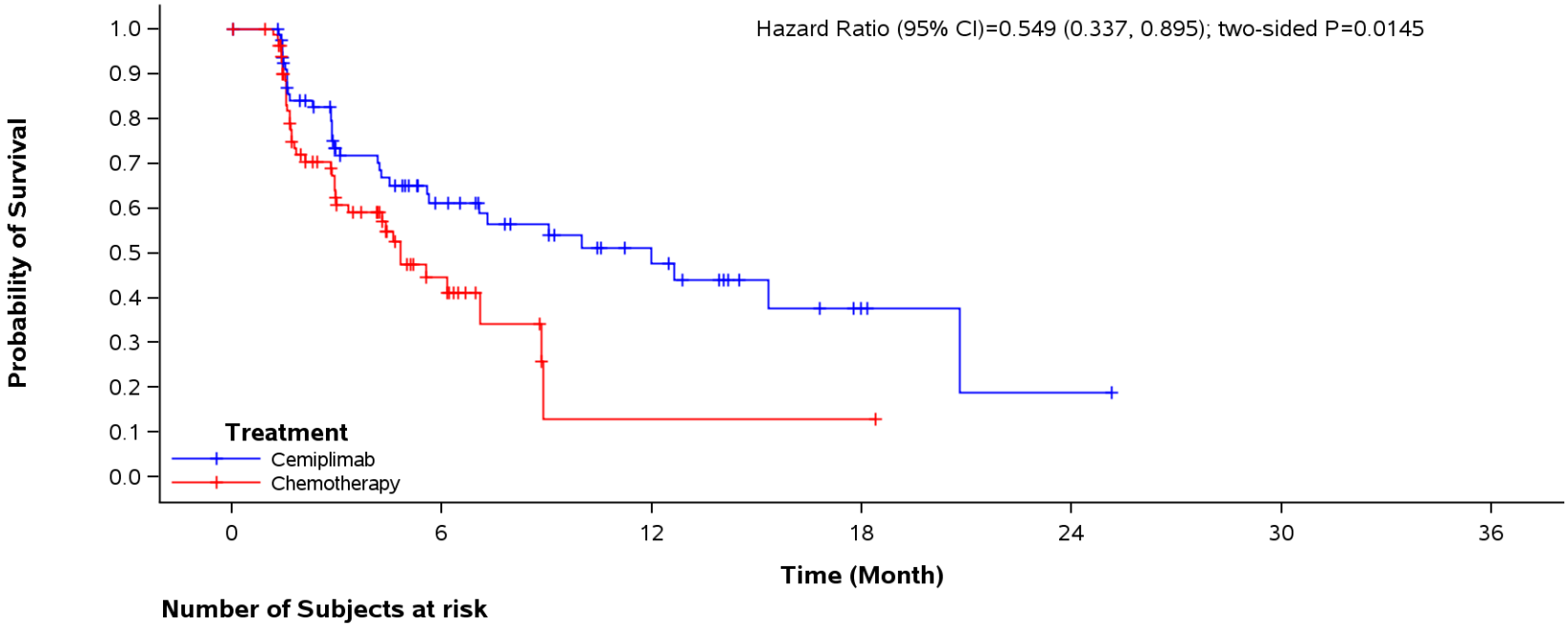

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 25 | 9 | 3 | 2 | 0 | 0 |
| Chemotherapy | 103 | 14 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Emotional Functioning - 10 pts deterioration



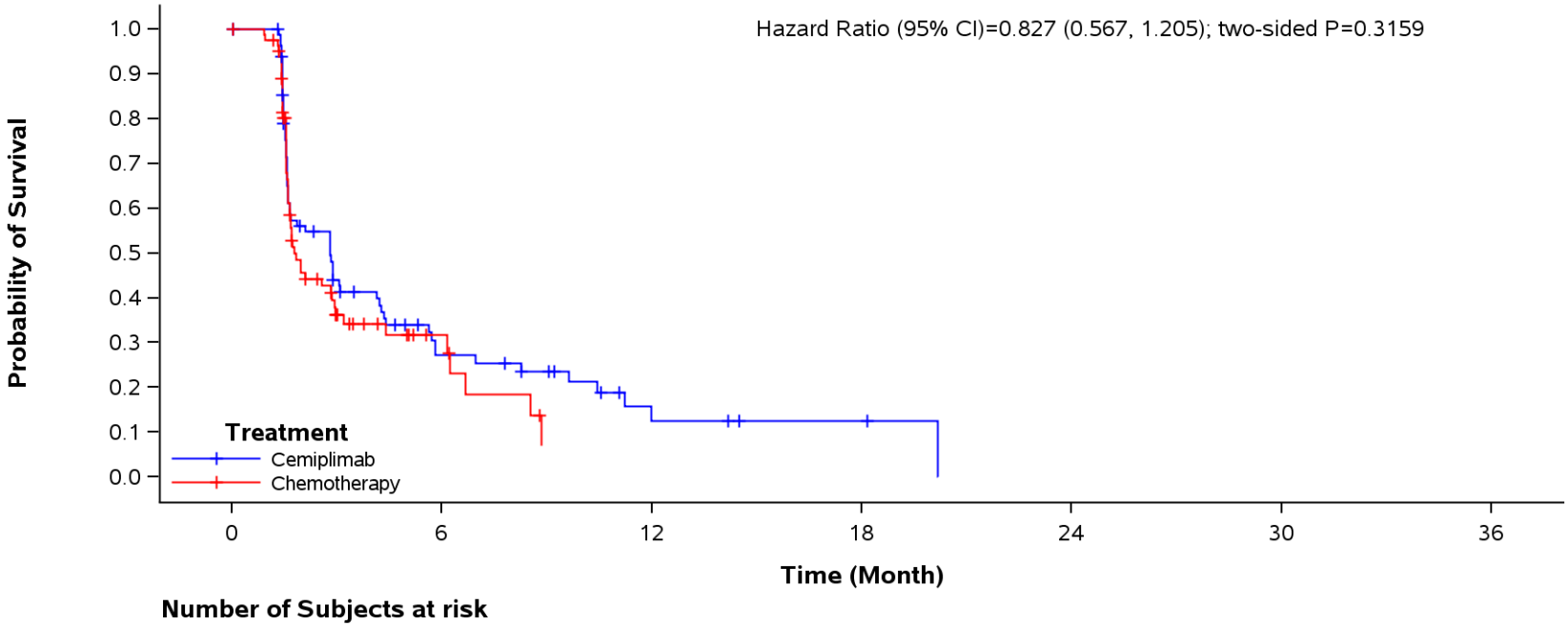

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 30 | 14 | 3 | 1 | 0 | 0 |
| Chemotherapy | 103 | 13 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Fatigue - 10 pts deterioration



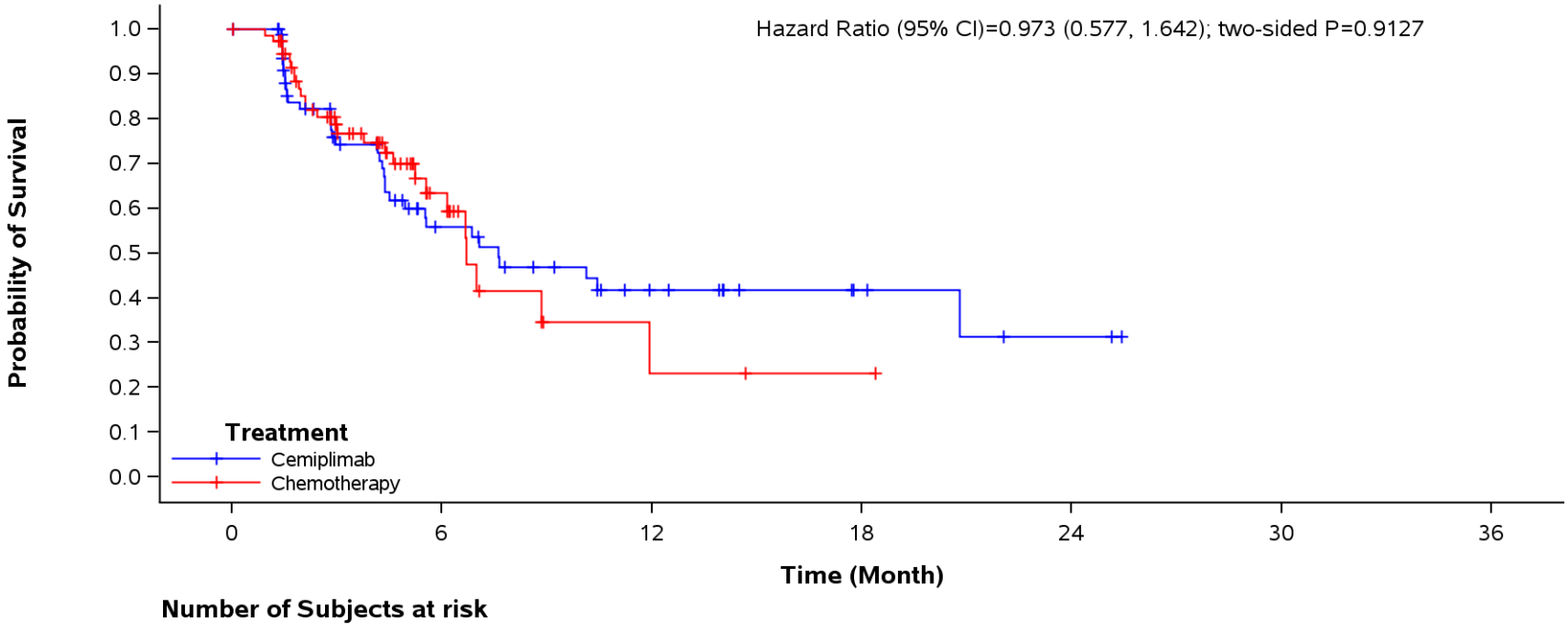

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 16 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 103 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Financial Problems - 10 pts deterioration




**Number of Subjects at risk**

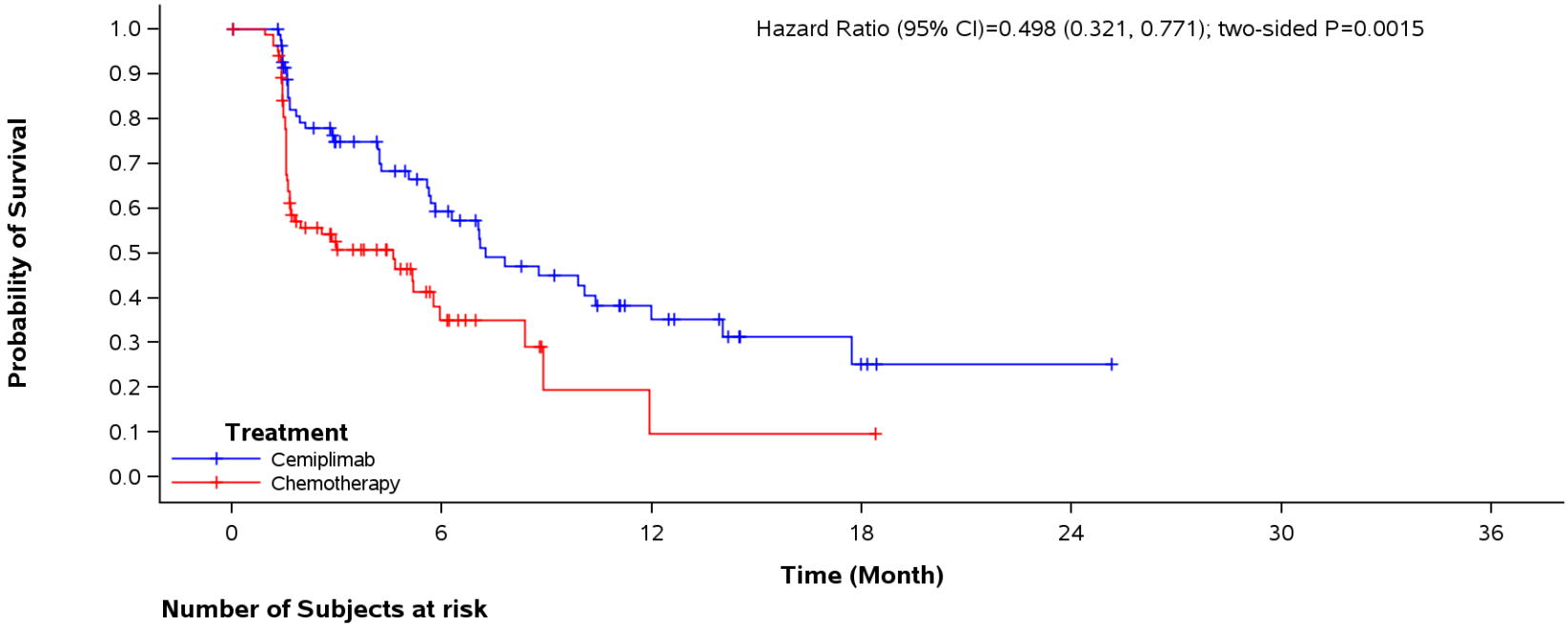
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 26 | 12 | 5 | 2 | 0 | 0 |
| Chemotherapy | 103 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:23, yingyuan.lin)

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Nausea / Vomiting - 10 pts deterioration



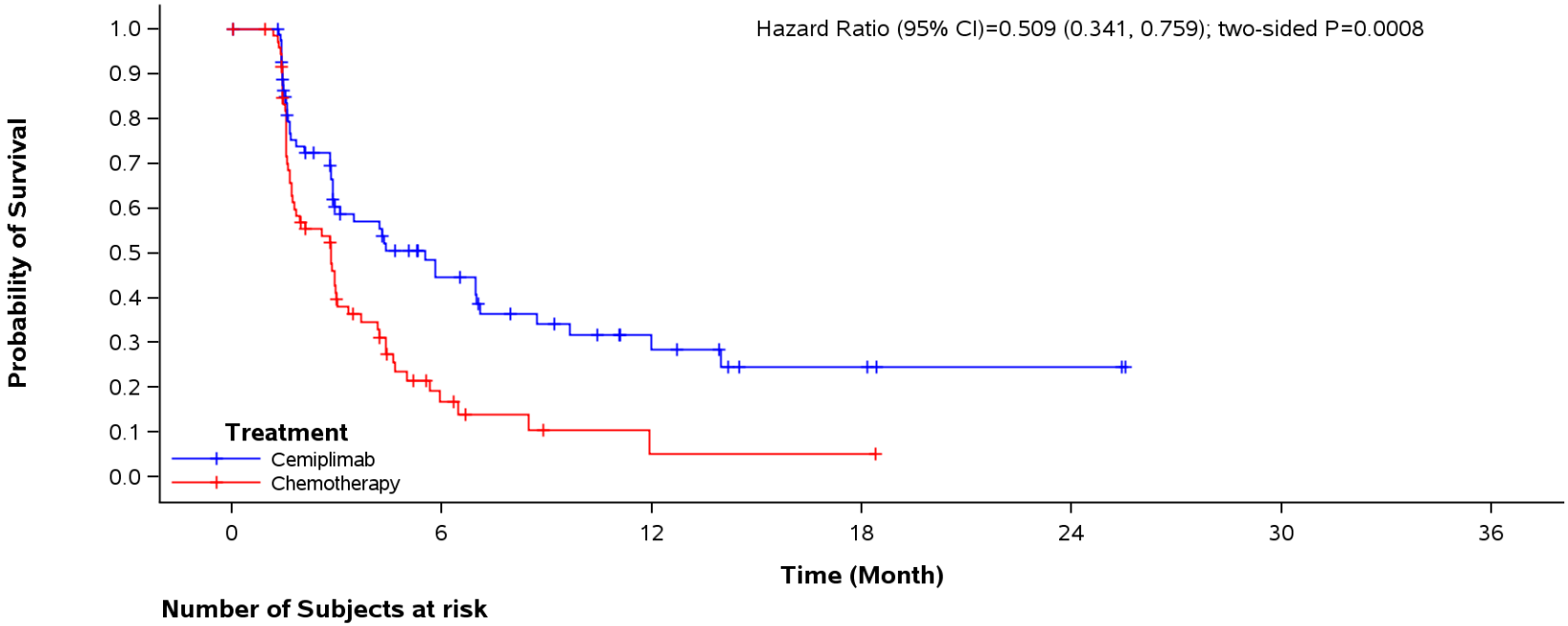

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 32 | 12 | 3 | 1 | 0 | 0 |
| Chemotherapy | 103 | 11 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Pain - 10 pts deterioration



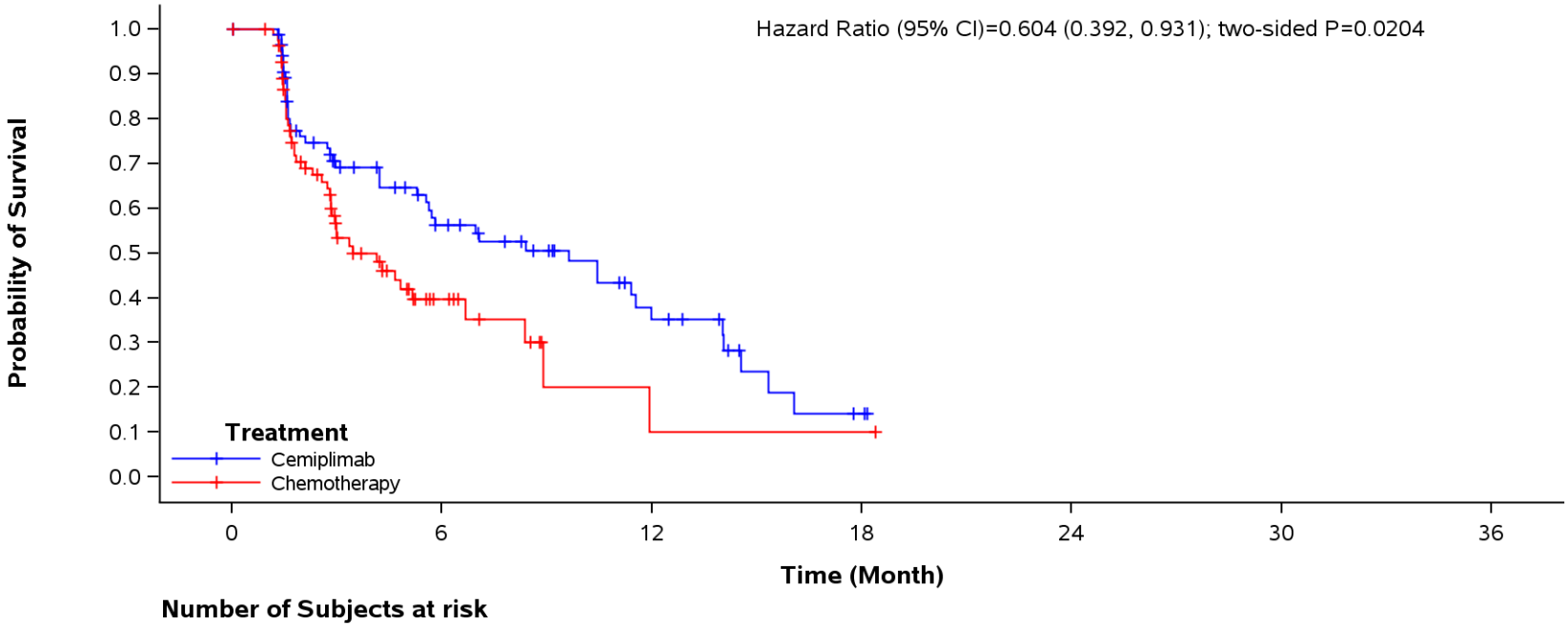

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 23 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 103 | 7 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Physical Functioning - 10 pts deterioration



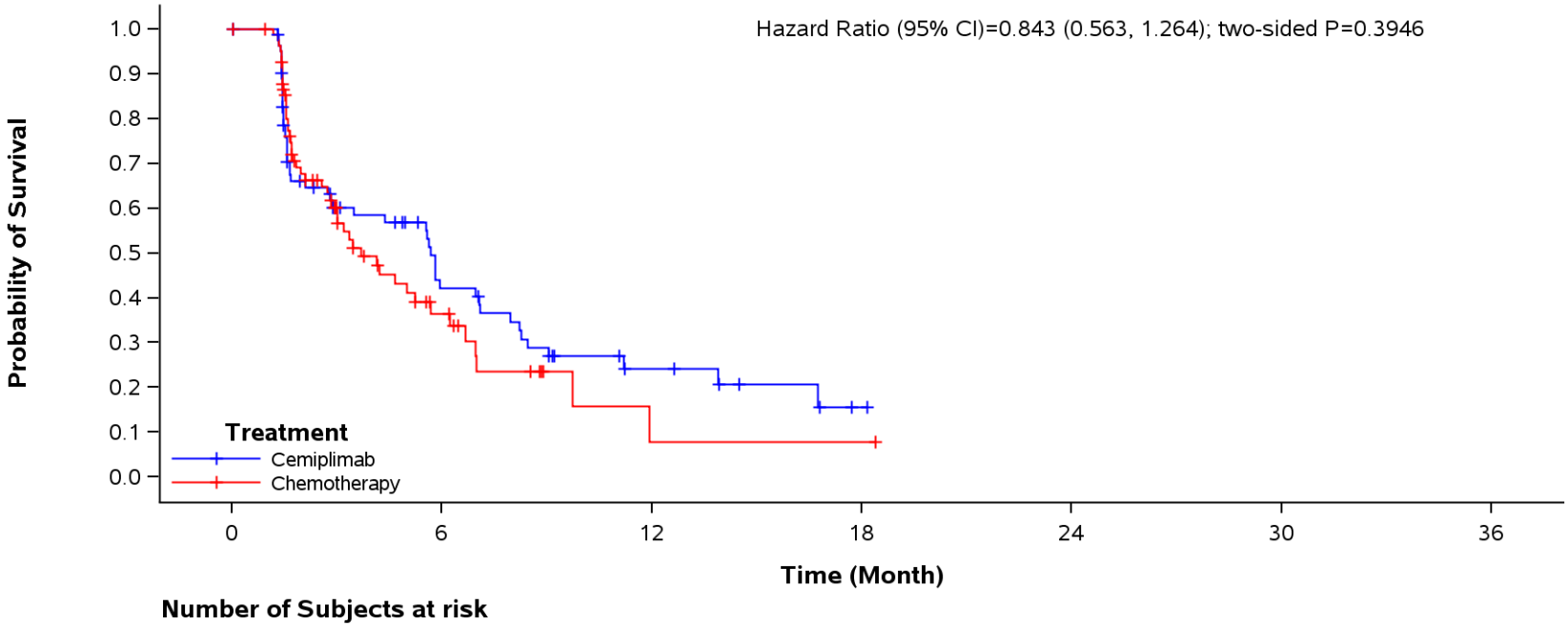

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 33 | 13 | 2 | 0 | 0 | 0 |
| Chemotherapy | 103 | 12 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Global health status / QoL - 10 pts deterioration



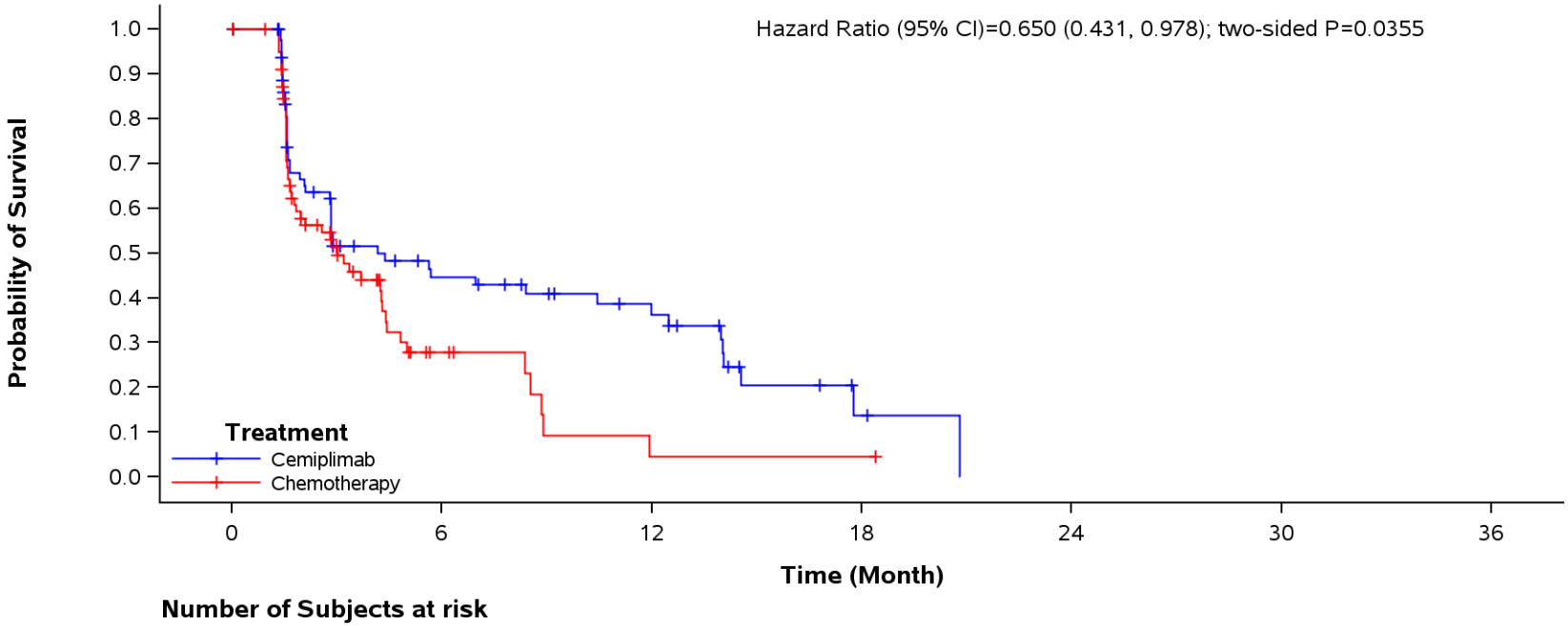

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 23 | 8 | 1 | 0 | 0 | 0 |
| Chemotherapy | 103 | 14 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Role Functioning - 10 pts deterioration



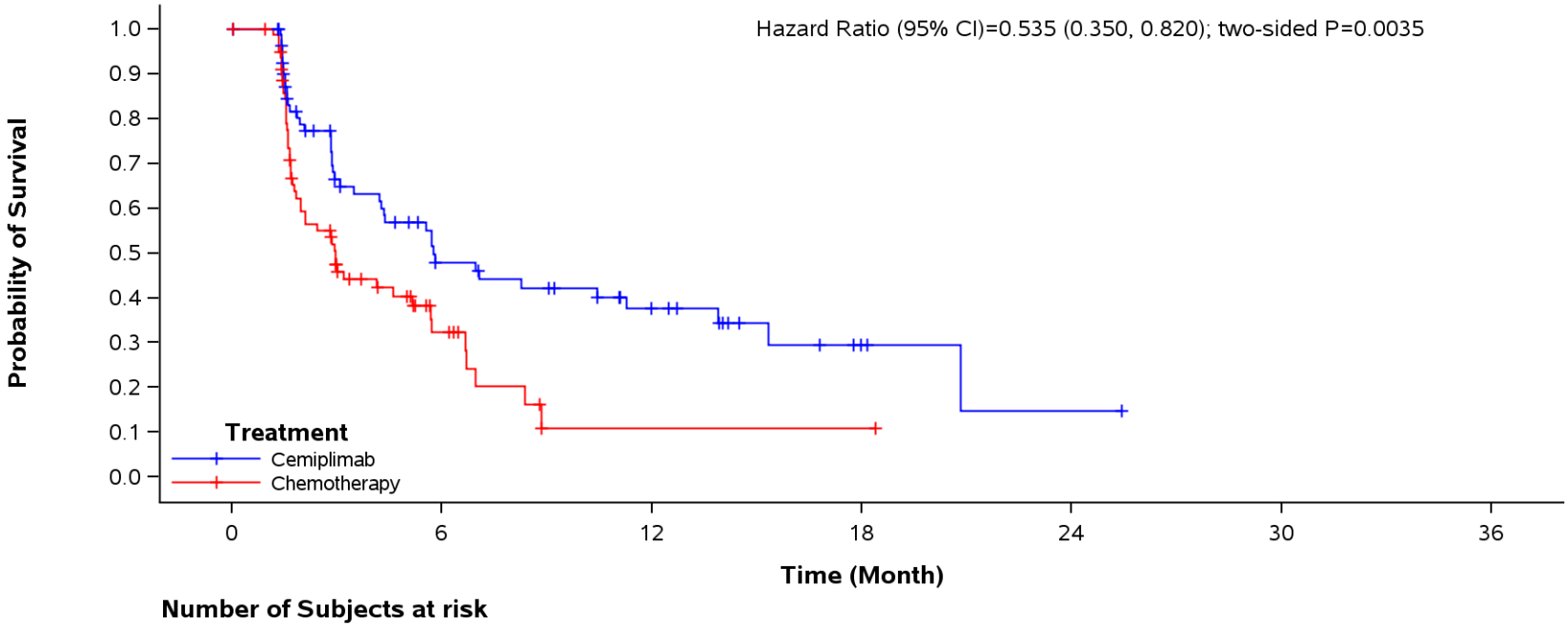

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 25 | 15 | 2 | 0 | 0 | 0 |
| Chemotherapy | 103 | 8 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Social Functioning - 10 pts deterioration



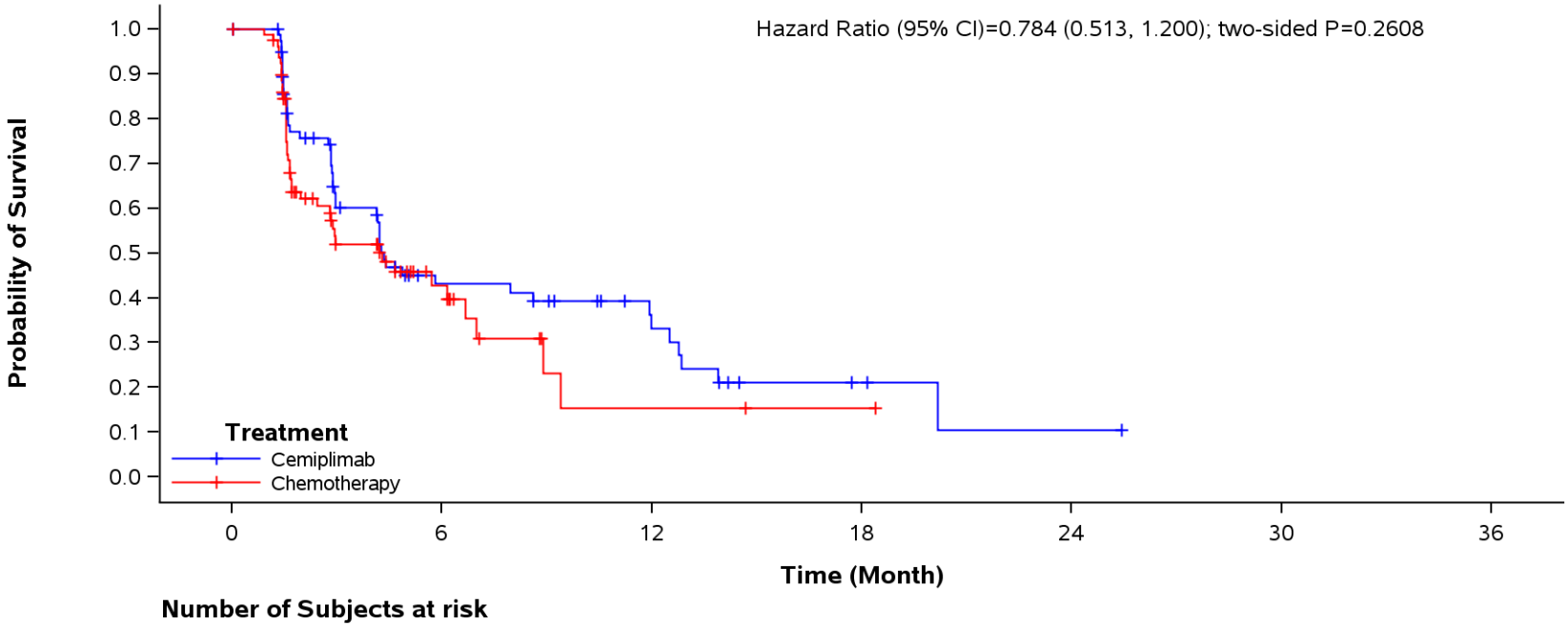

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 26 | 14 | 3 | 1 | 0 | 0 |
| Chemotherapy | 103 | 11 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Insomnia - 10 pts deterioration



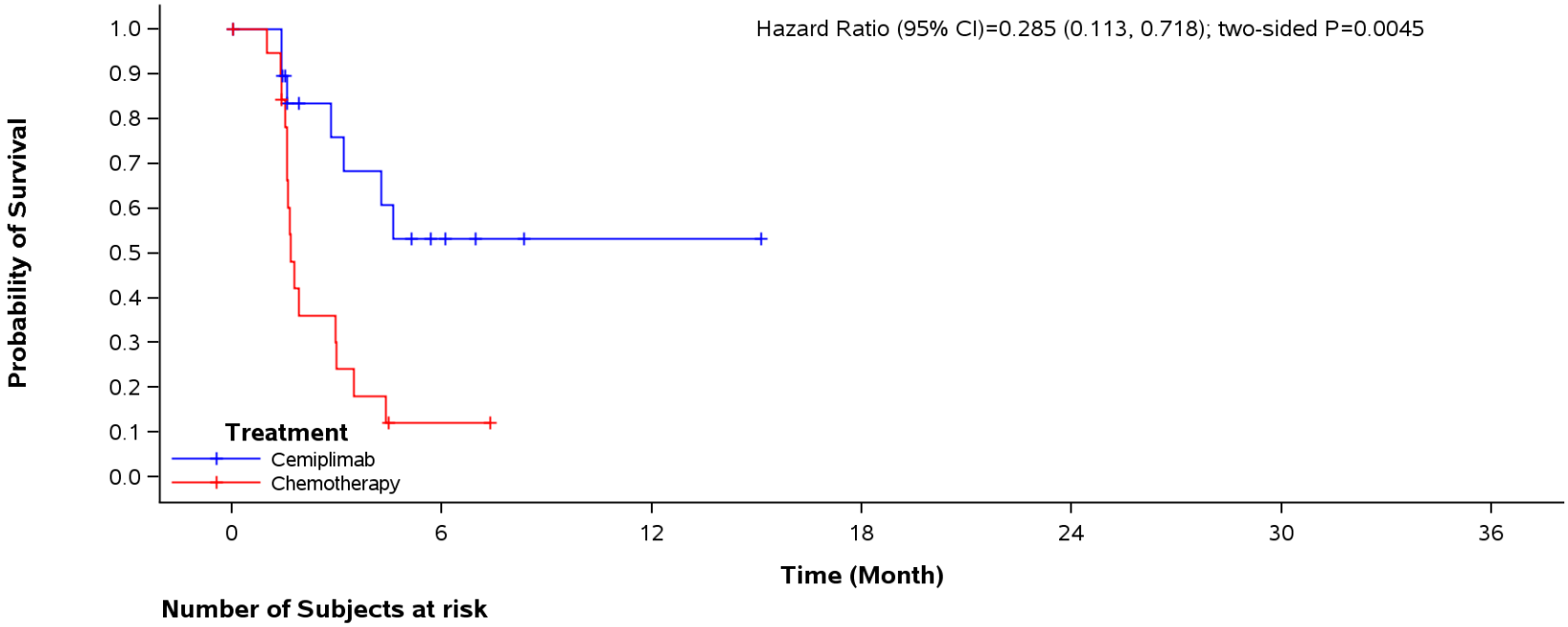

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 22 | 11 | 3 | 1 | 0 | 0 |
| Chemotherapy | 103 | 14 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Appetite loss - 10 pts deterioration



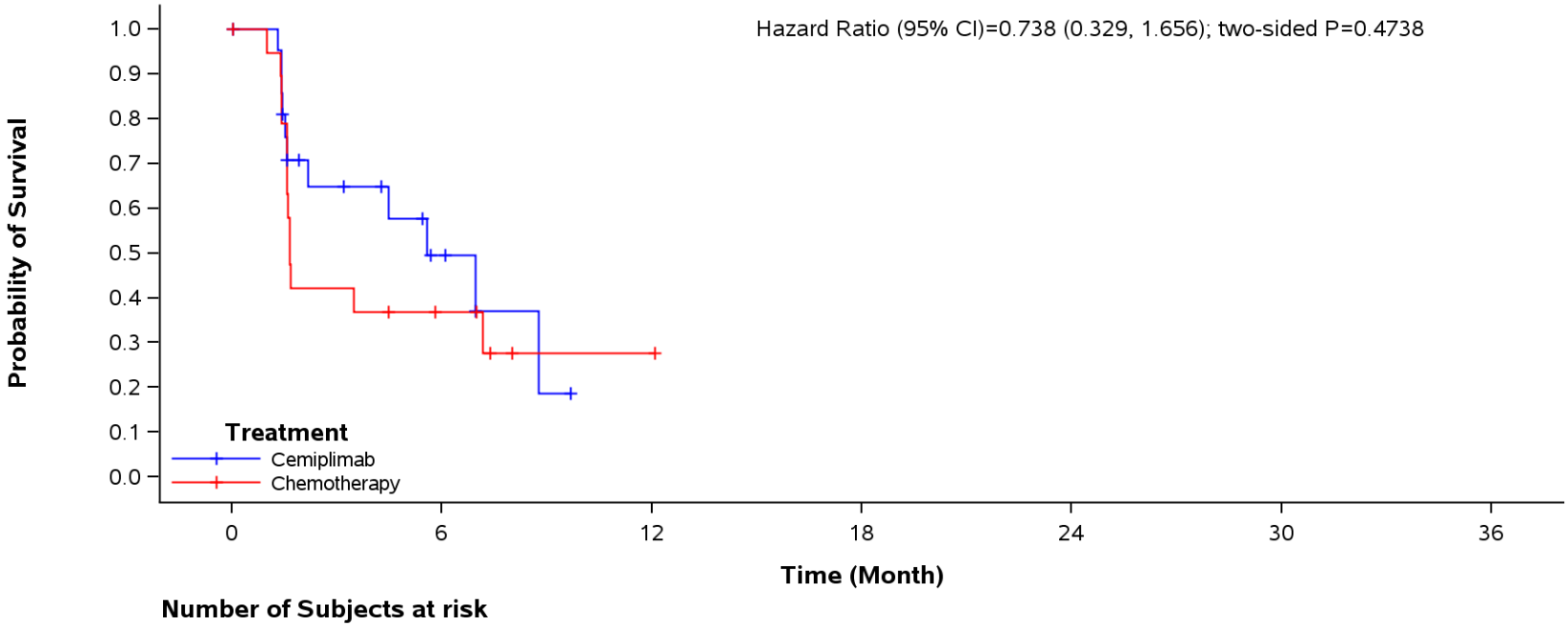

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Cognitive Functioning - 10 pts deterioration




Number of Subjects at risk

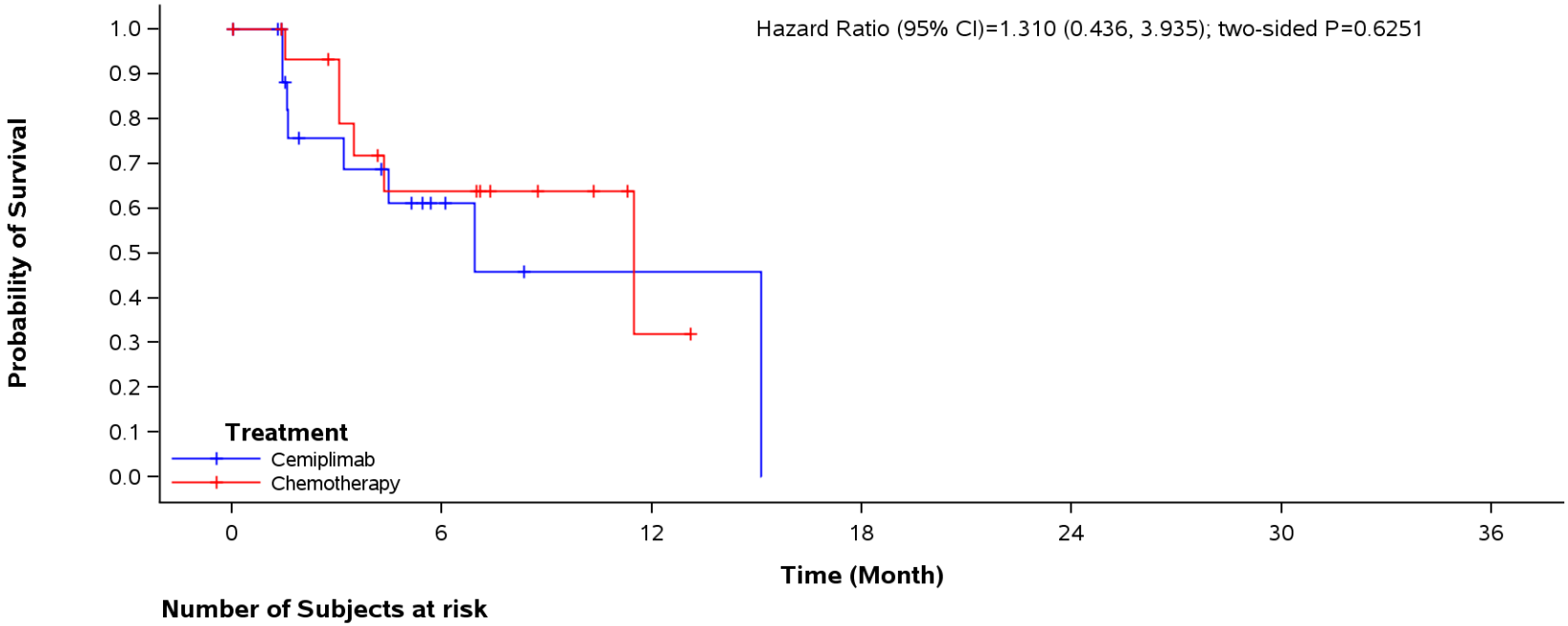
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:23, yingyuan.lin)

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Constipation - 10 pts deterioration



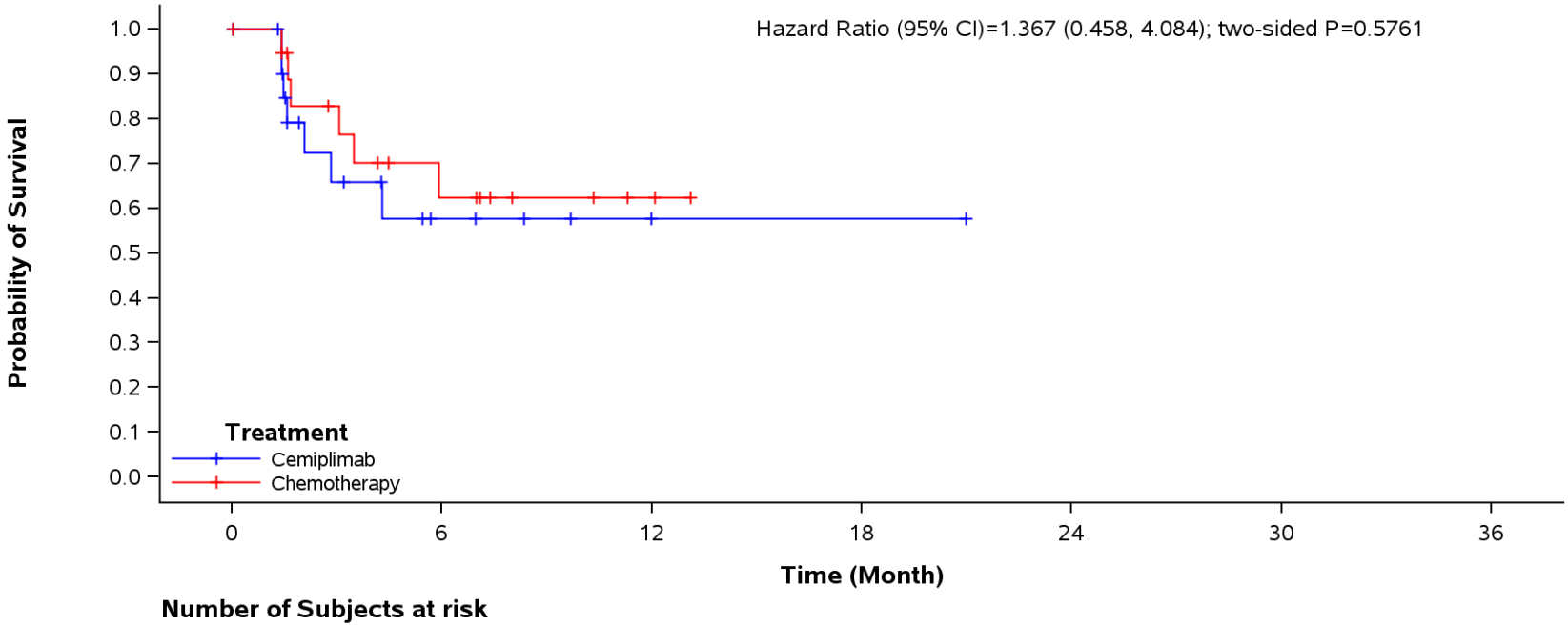

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Diarhoea - 10 pts deterioration



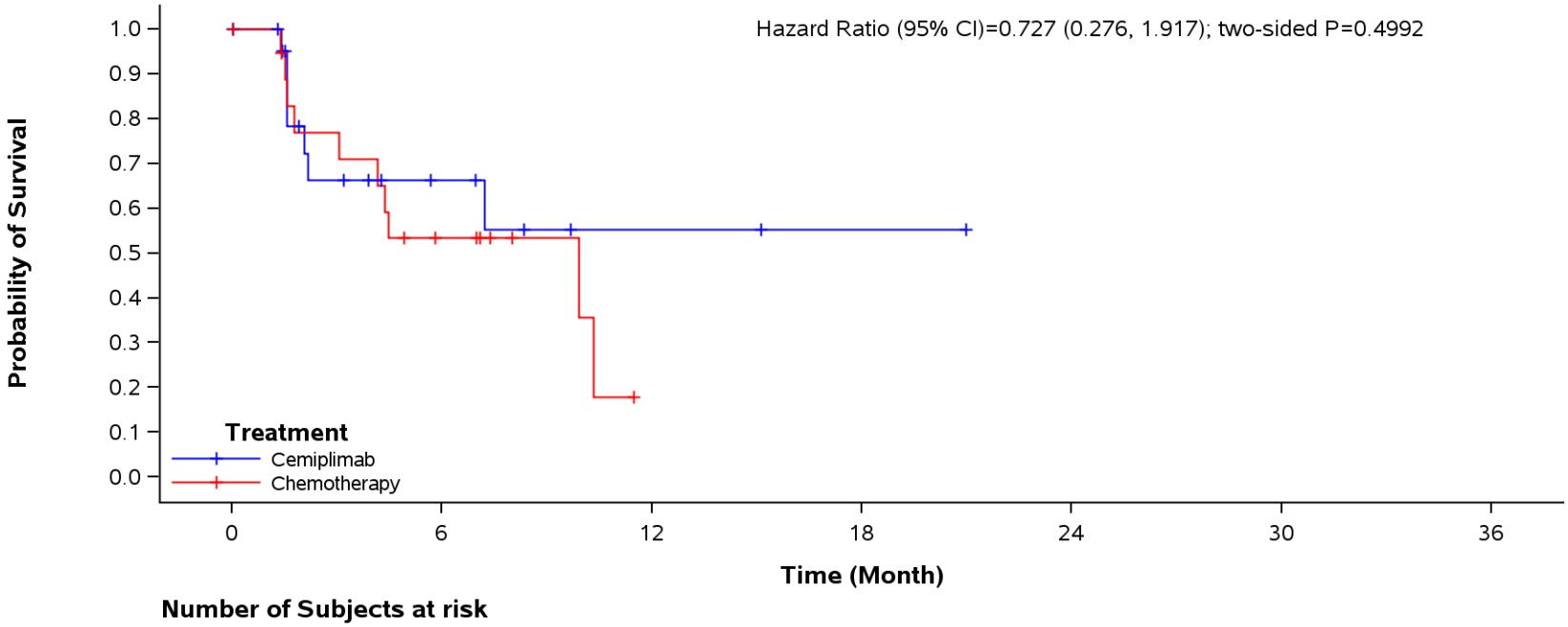

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Dyspnoea - 10 pts deterioration



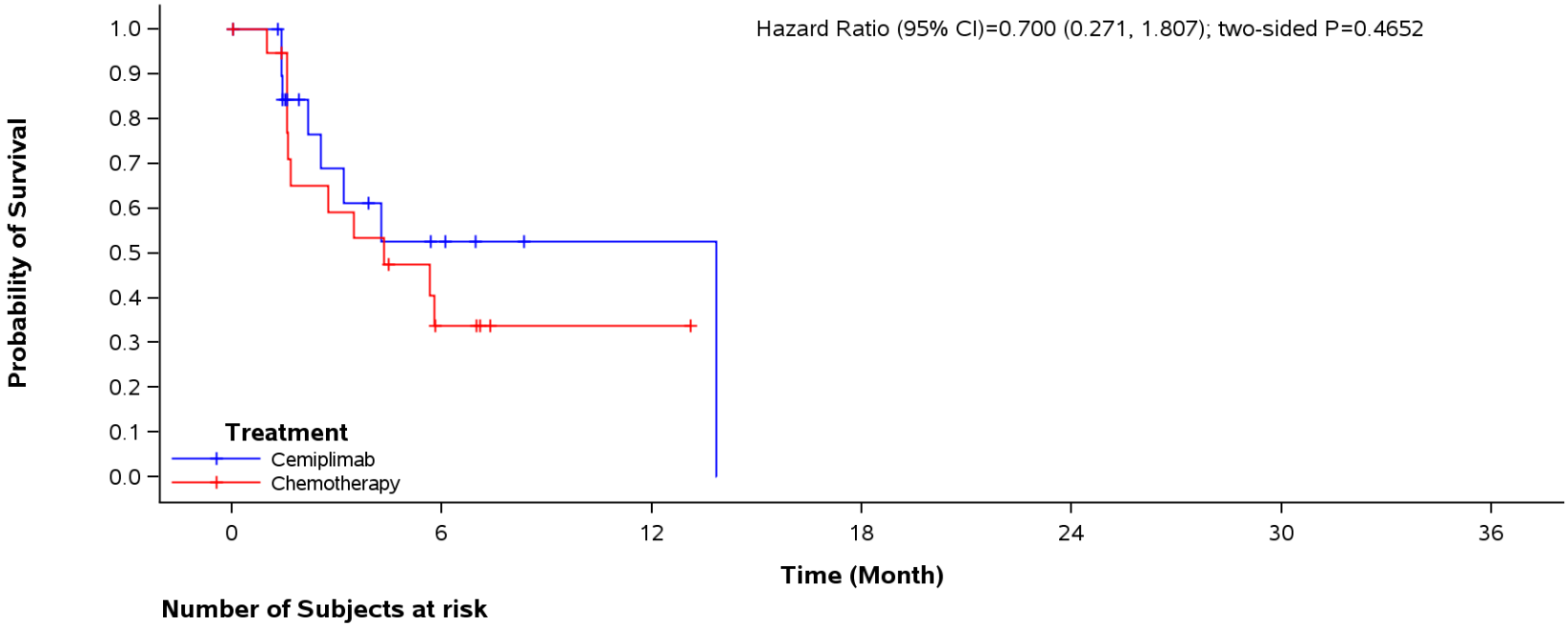

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Emotional Functioning - 10 pts deterioration



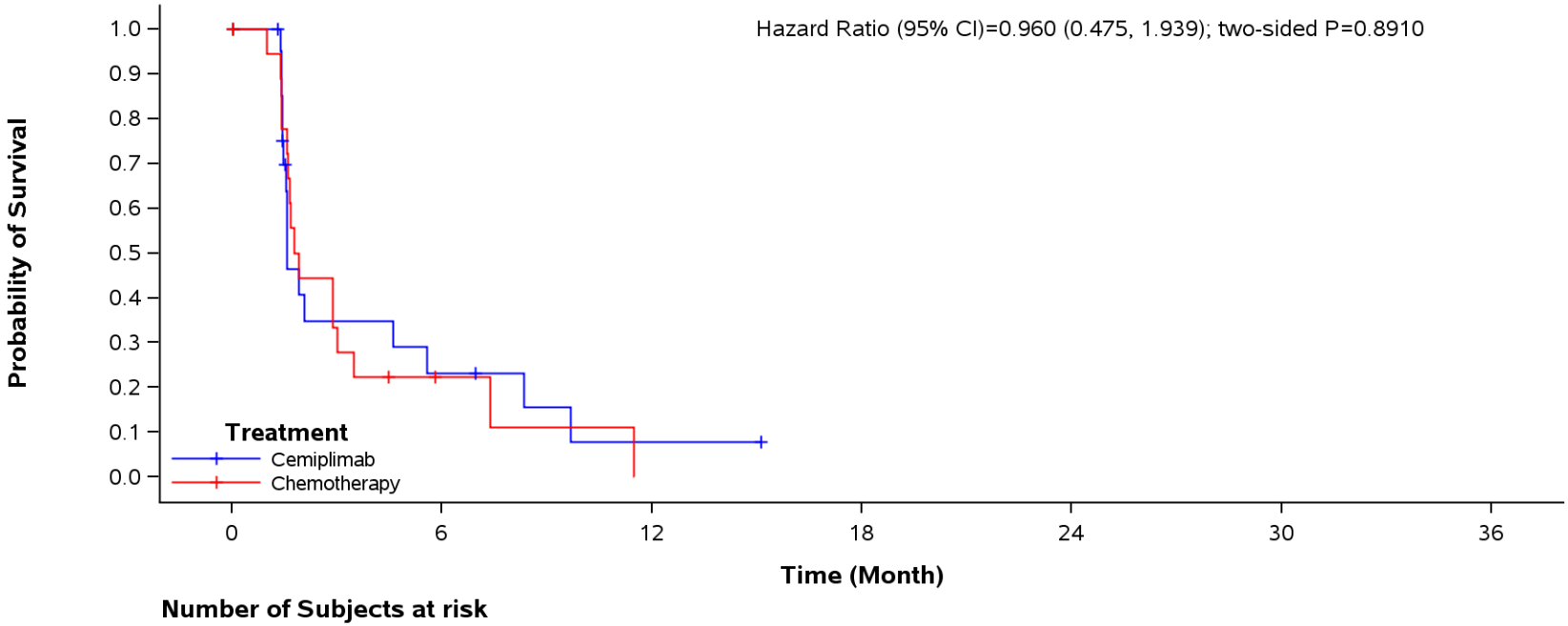

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Fatigue - 10 pts deterioration



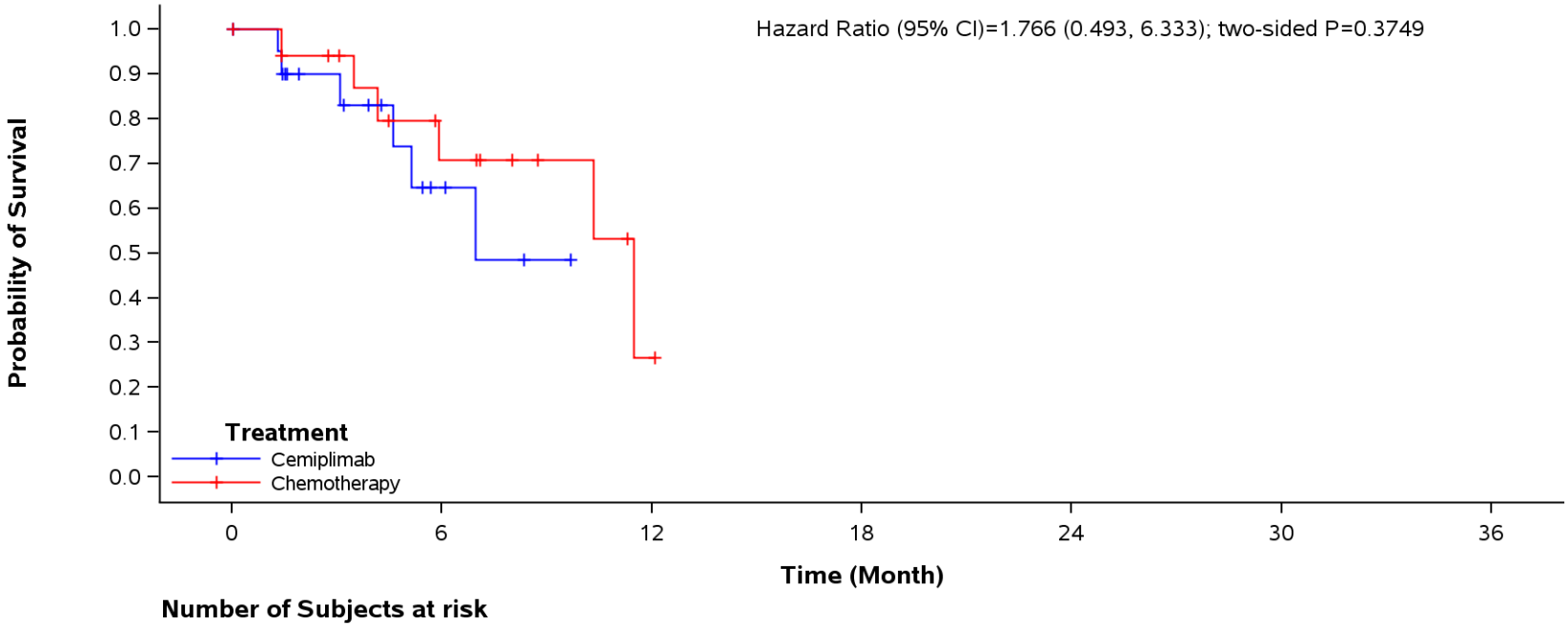

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Financial Problems - 10 pts deterioration



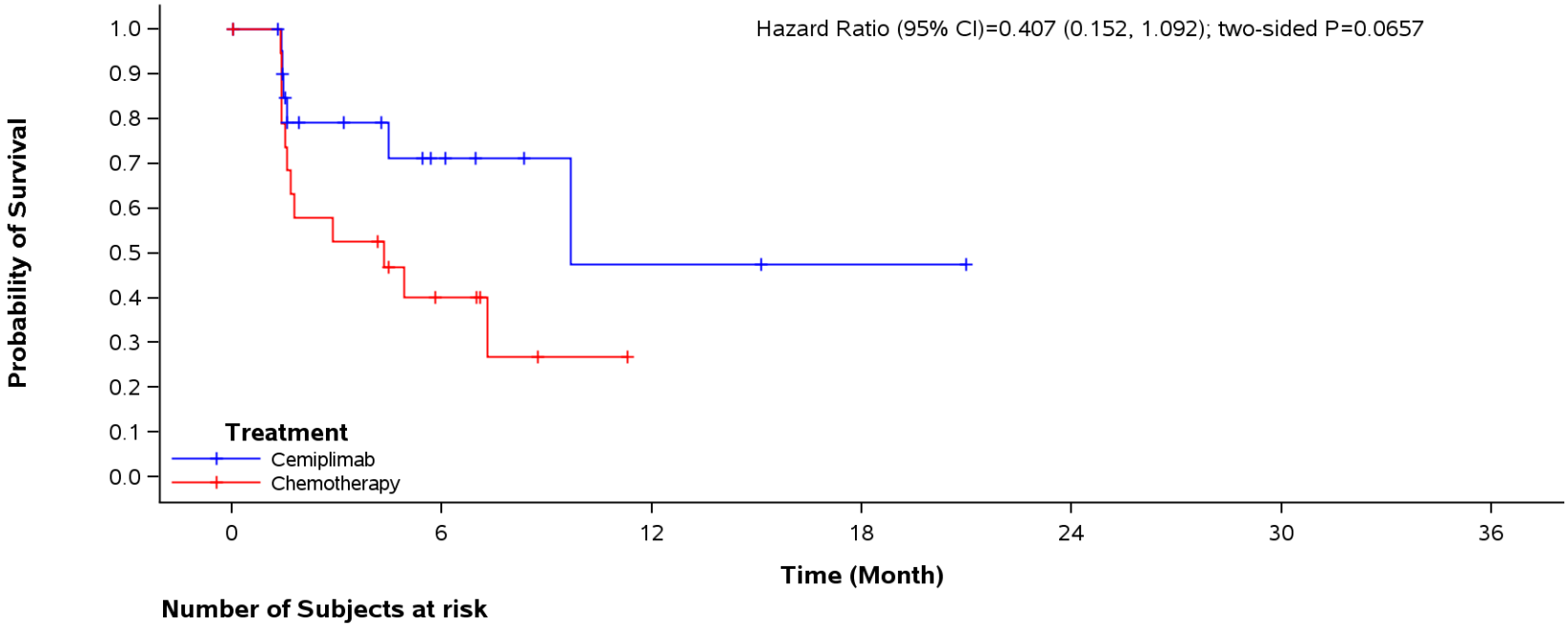

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Nausea / Vomiting - 10 pts deterioration



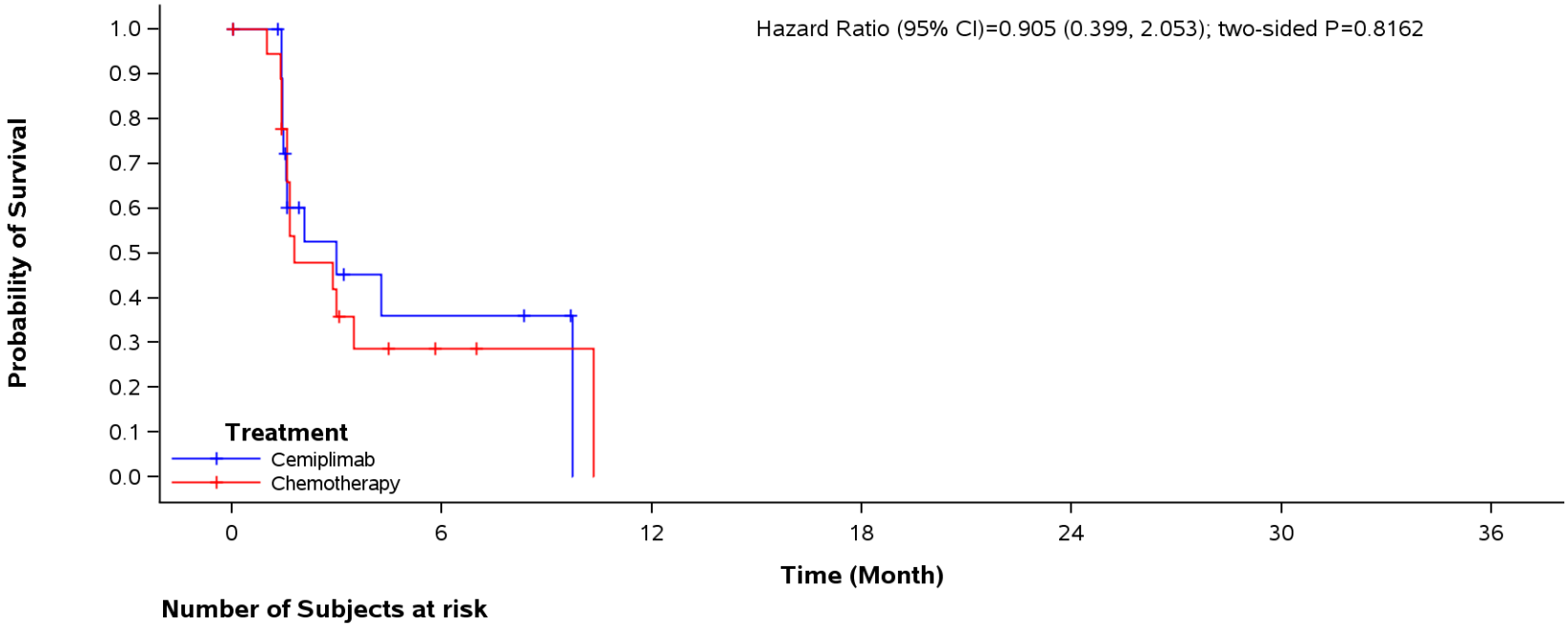

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Pain - 10 pts deterioration



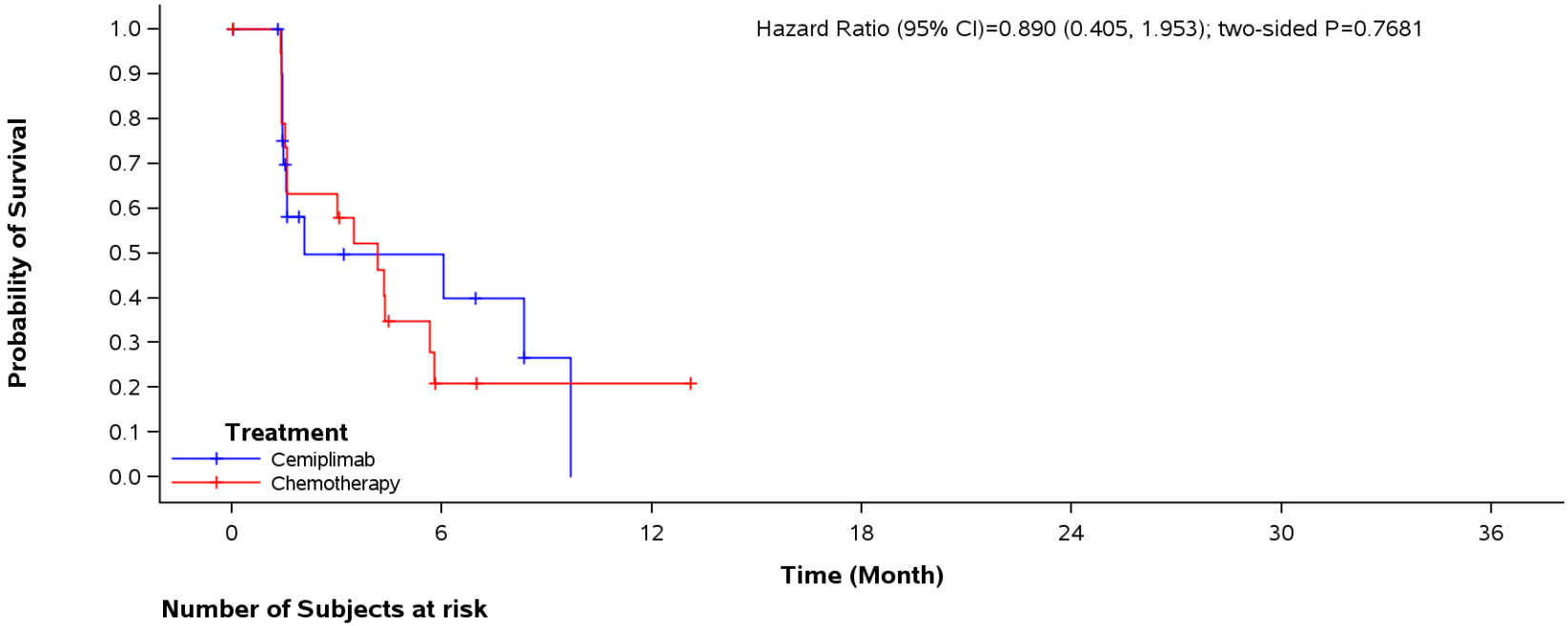

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Physical Functioning - 10 pts deterioration




Number of Subjects at risk

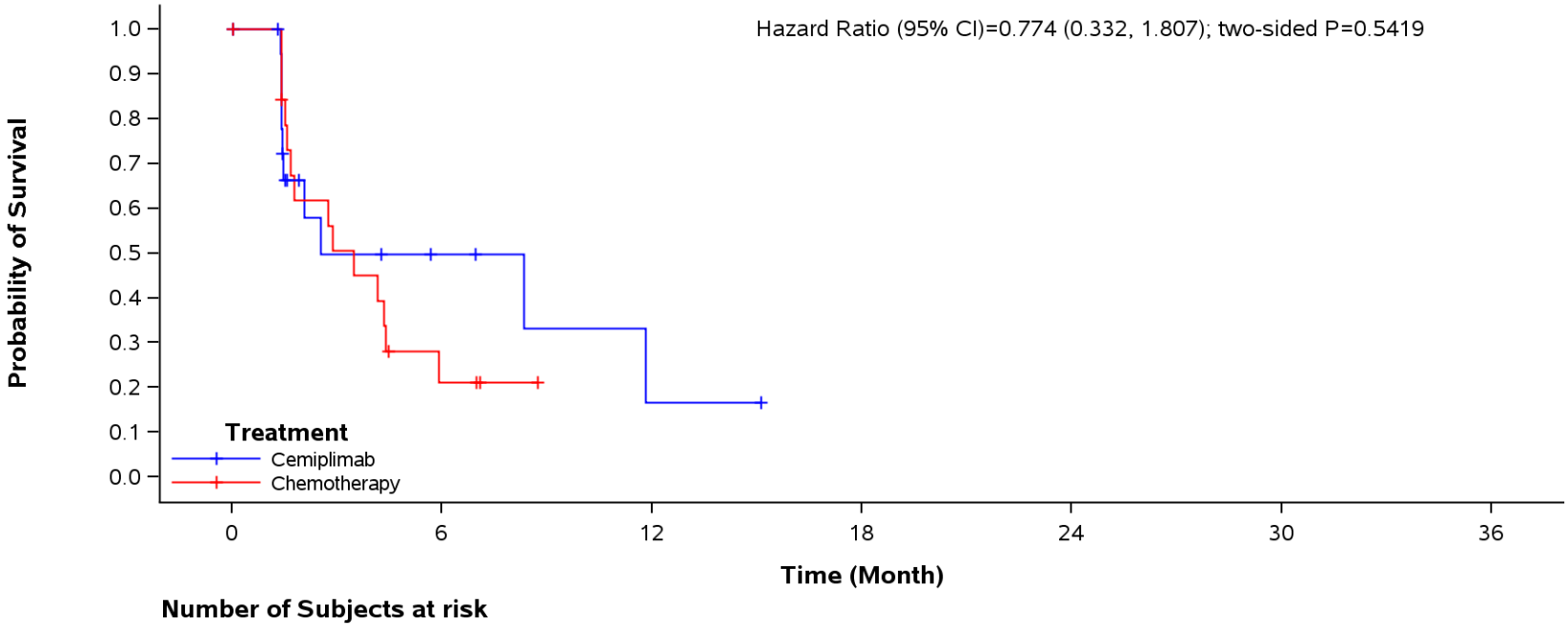
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:23, yingyuan.lin)

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Global health status / QoL - 10 pts deterioration




Number of Subjects at risk

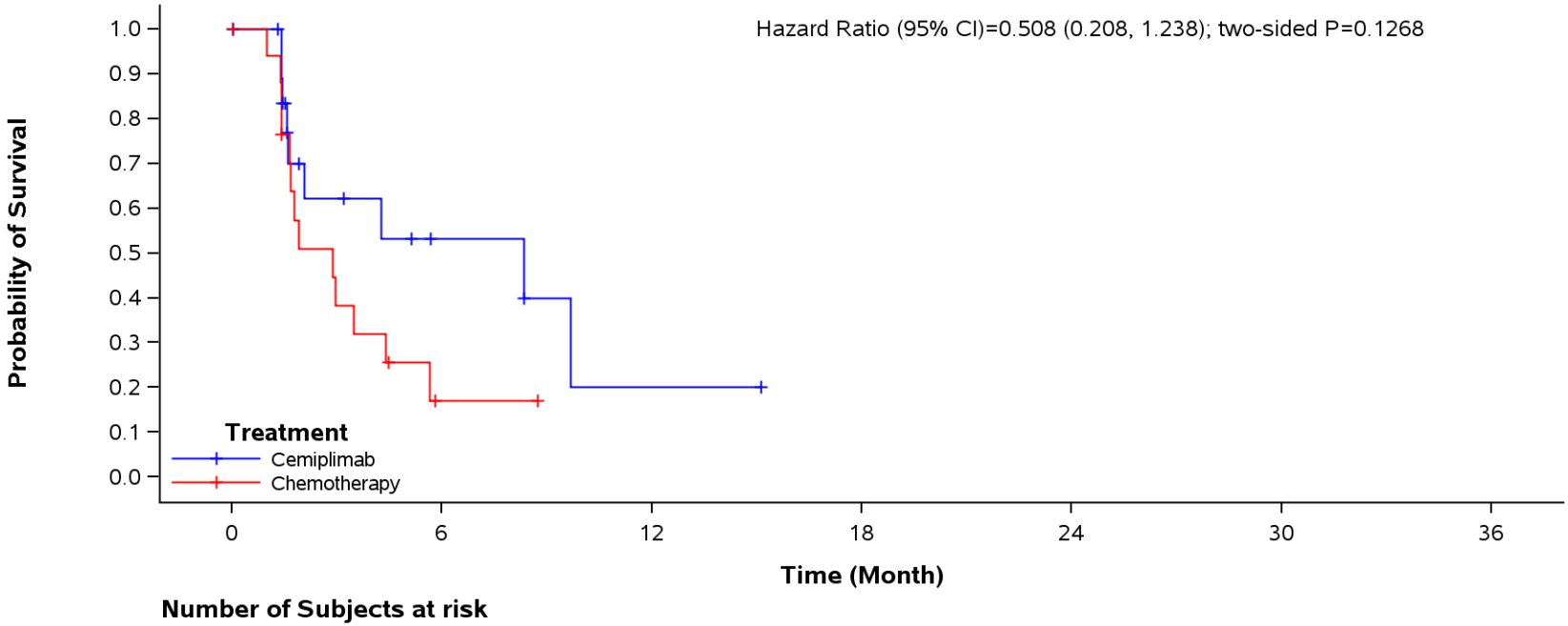
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:23, yingyuan.lin)

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Role Functioning - 10 pts deterioration



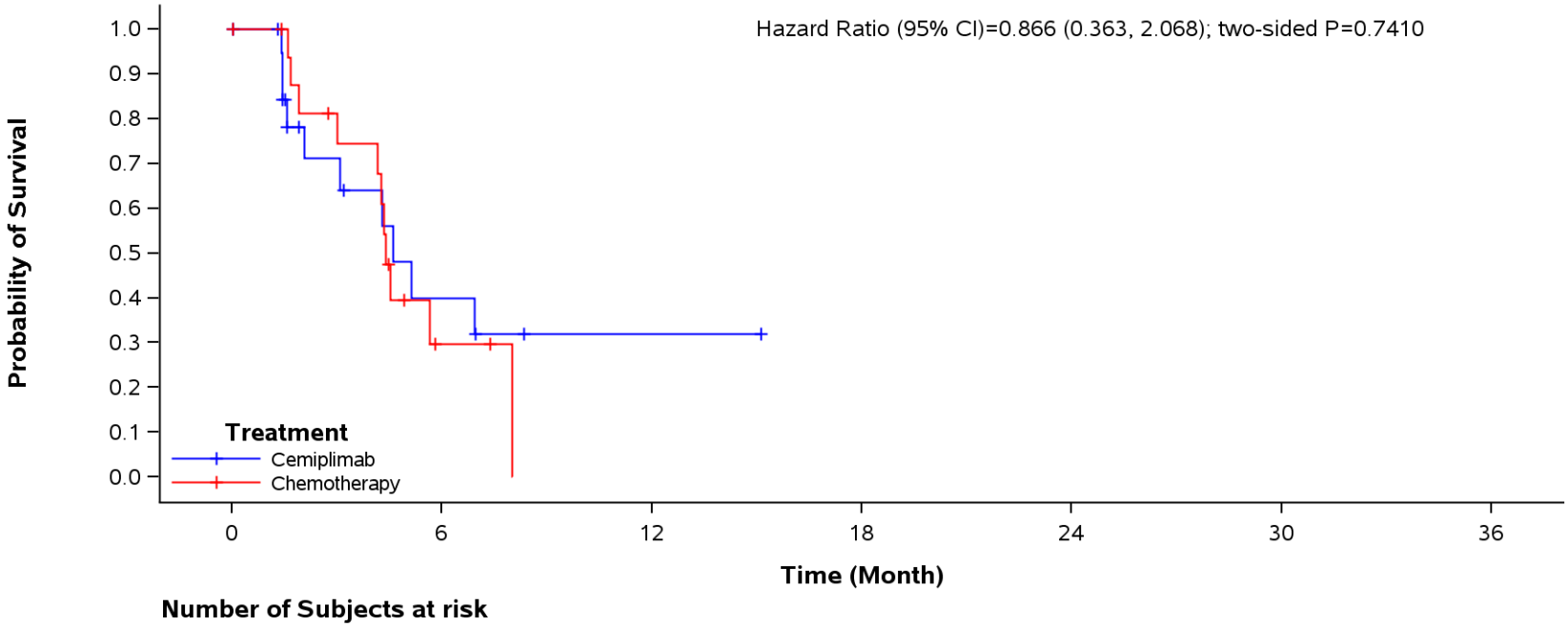

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 4 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Social Functioning - 10 pts deterioration



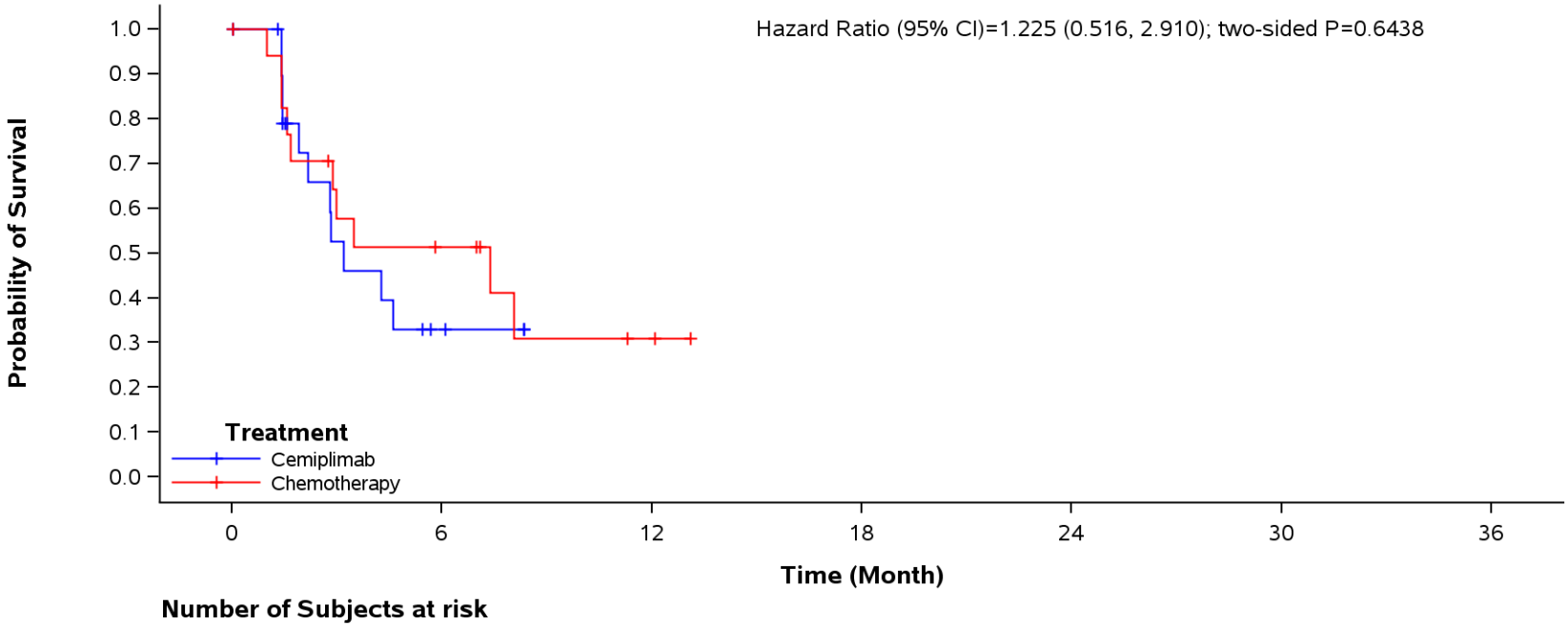

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Insomnia - 10 pts deterioration



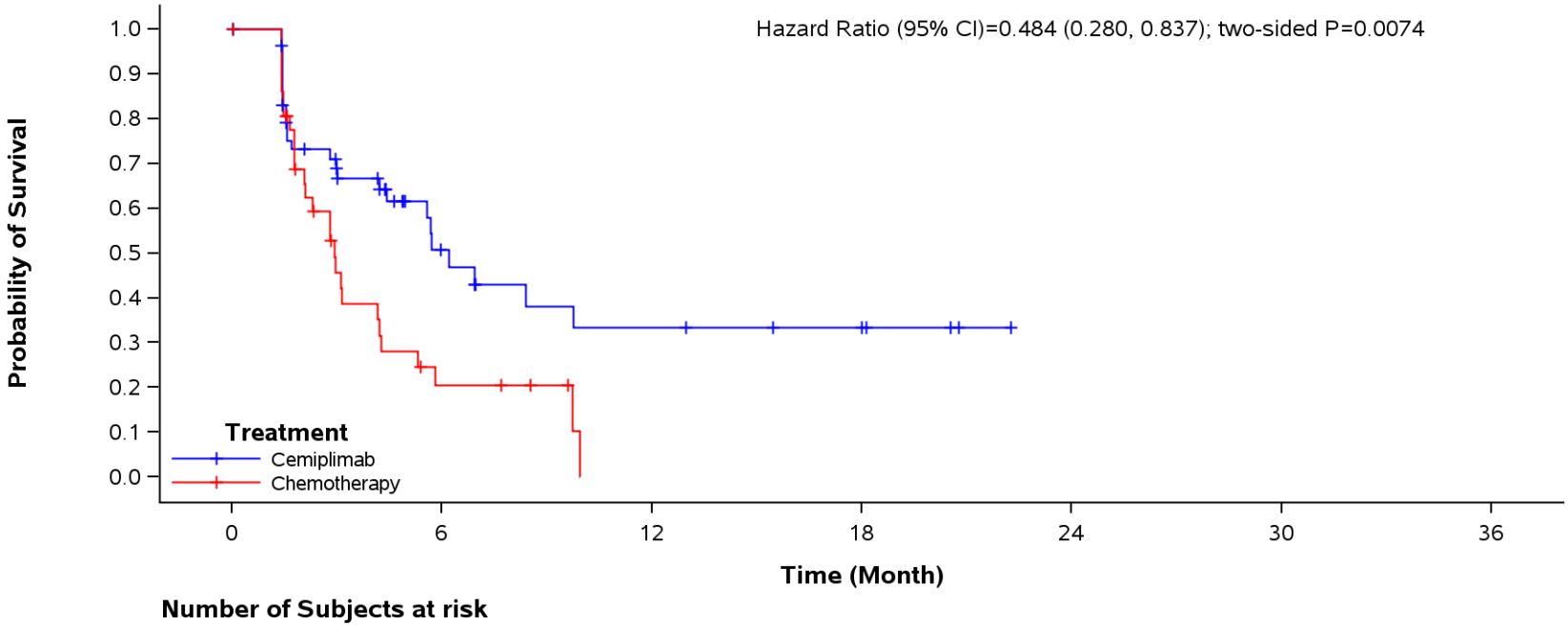

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 3 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 7 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Appetite loss - 10 pts deterioration



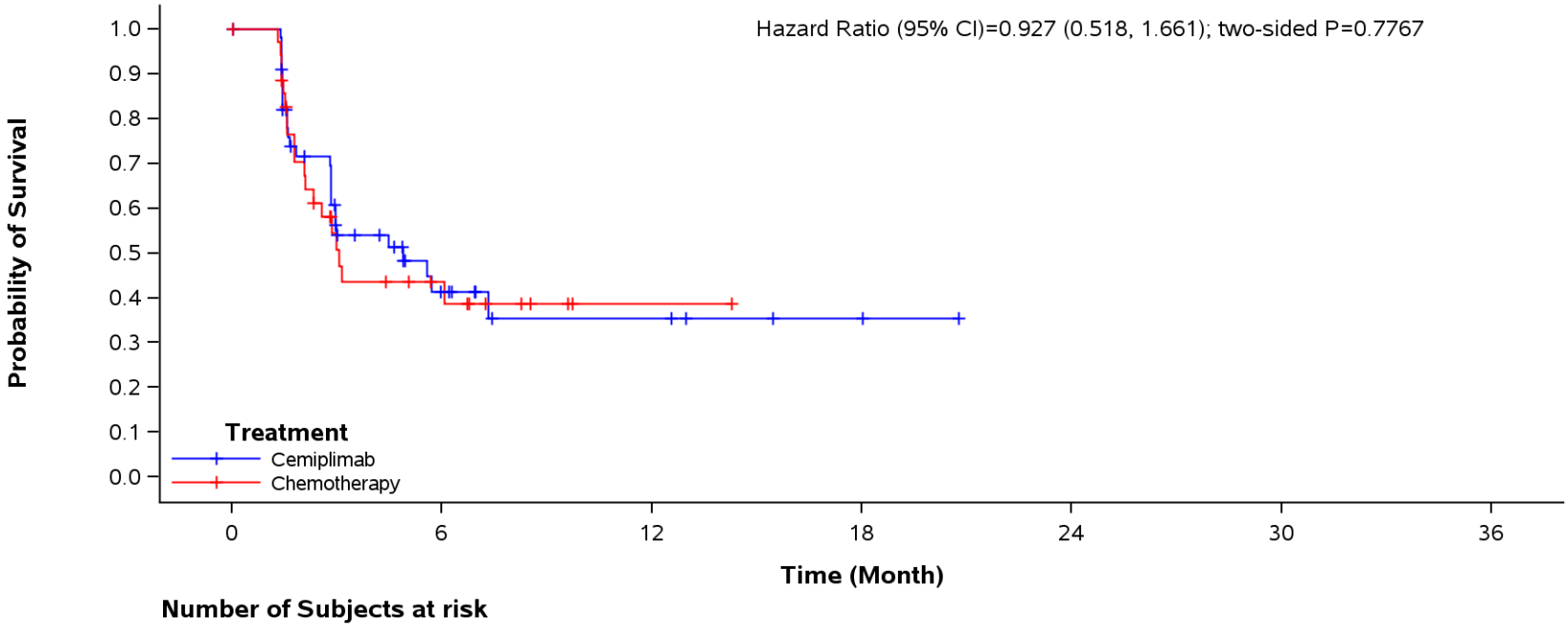

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 13 | 7 | 5 | 0 | 0 | 0 |
| Chemotherapy | 50 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Cognitive Functioning - 10 pts deterioration



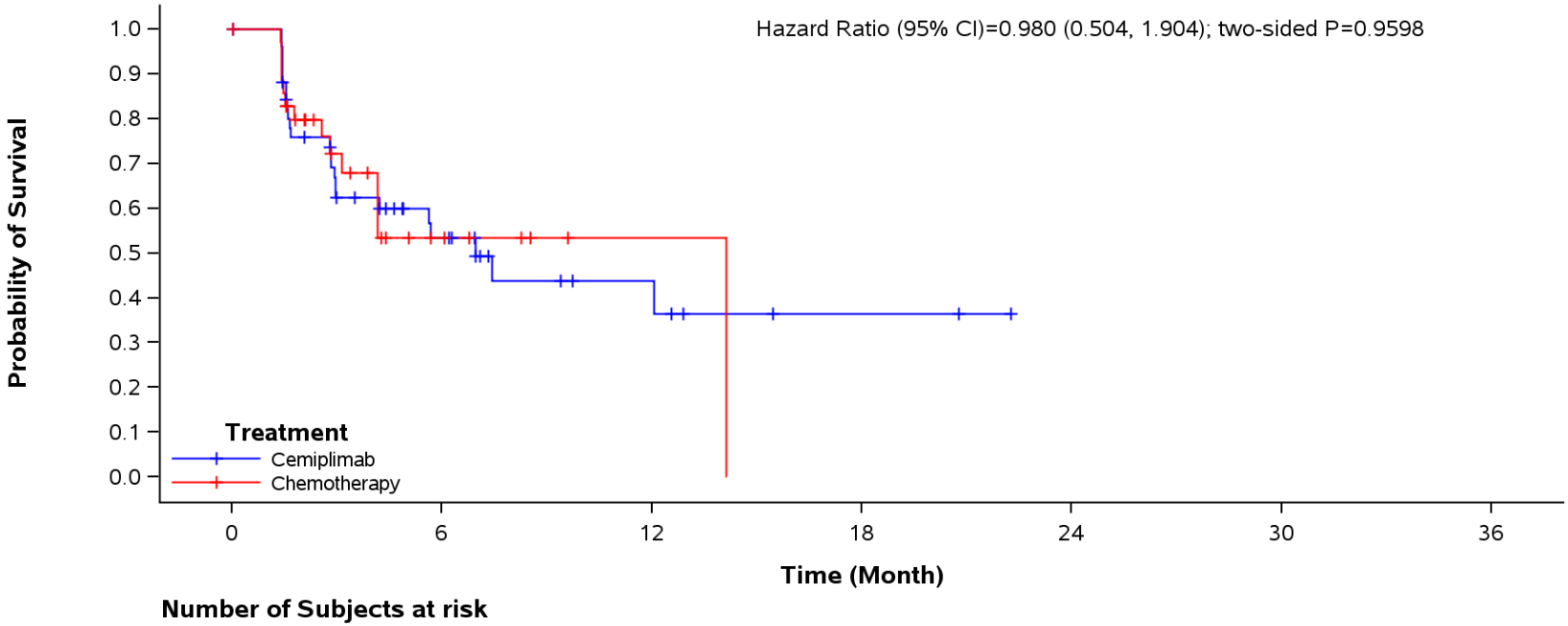

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 11 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Constipation - 10 pts deterioration



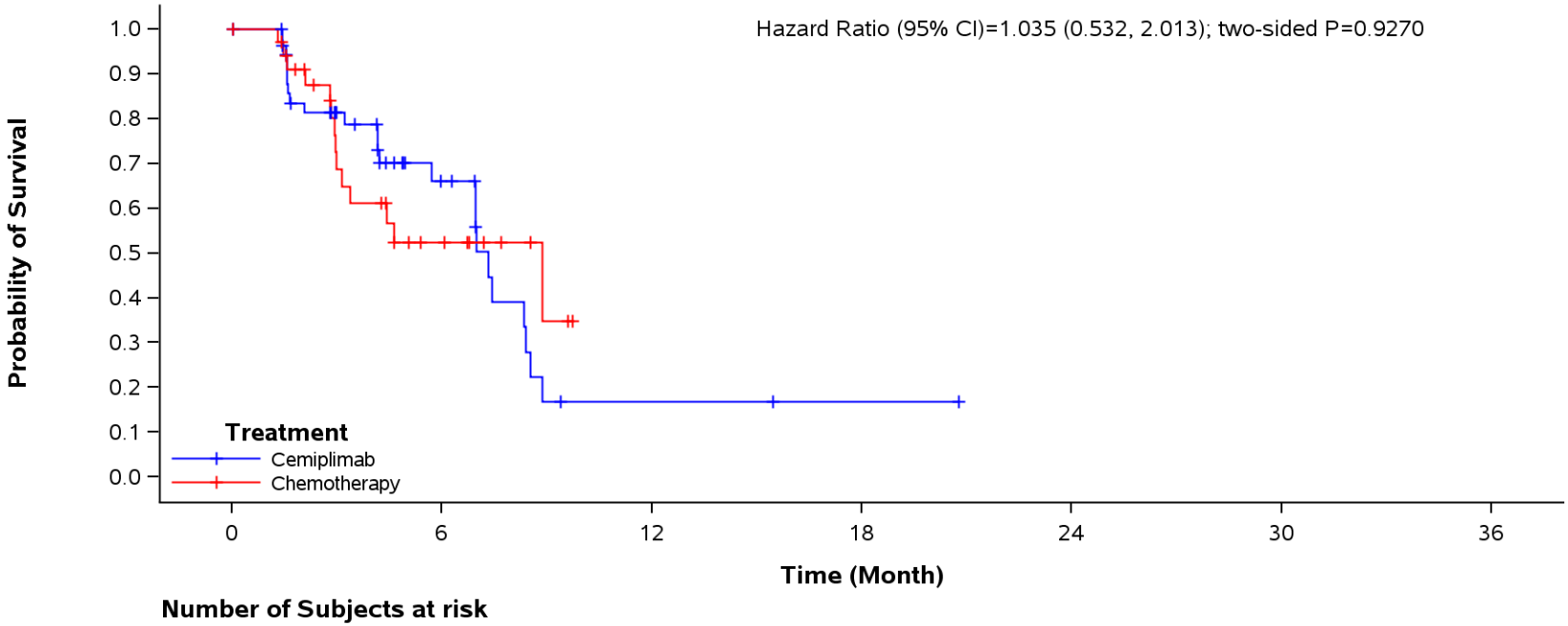

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 16 | 6 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Diarhoea - 10 pts deterioration



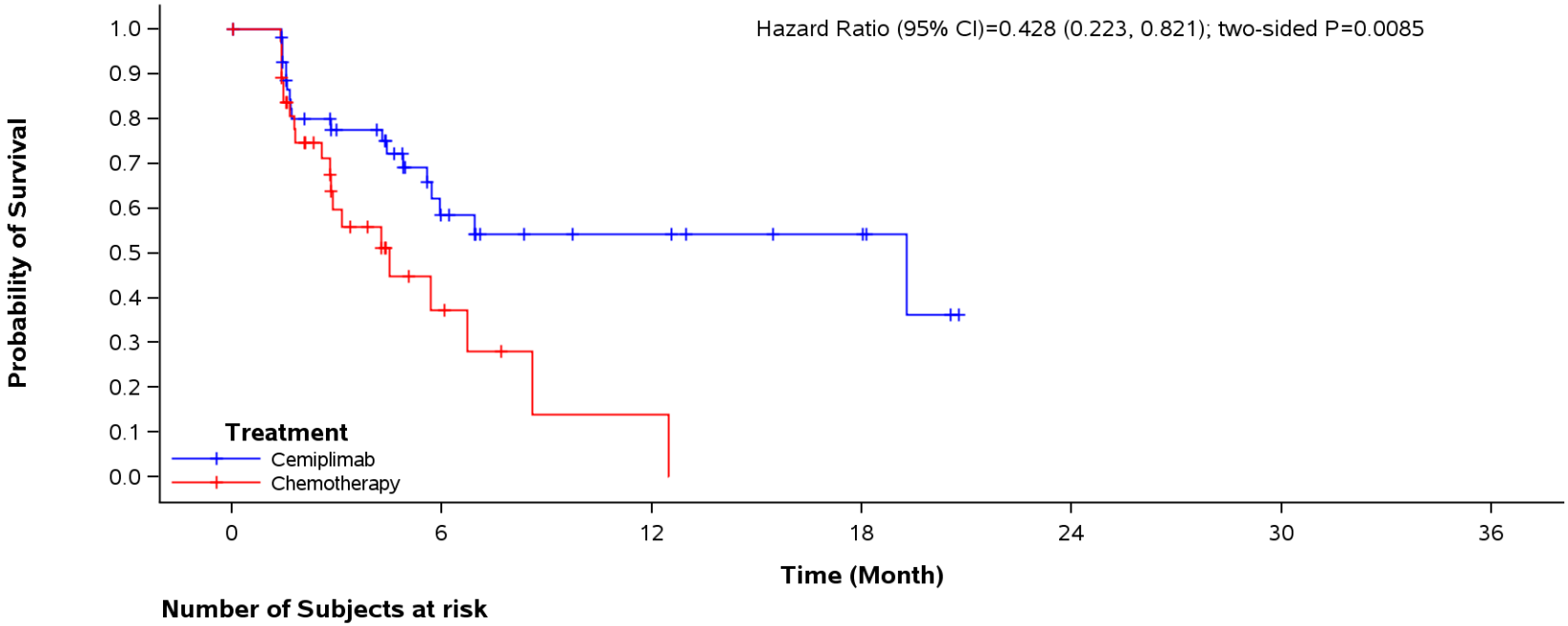

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 15 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Dyspnoea - 10 pts deterioration



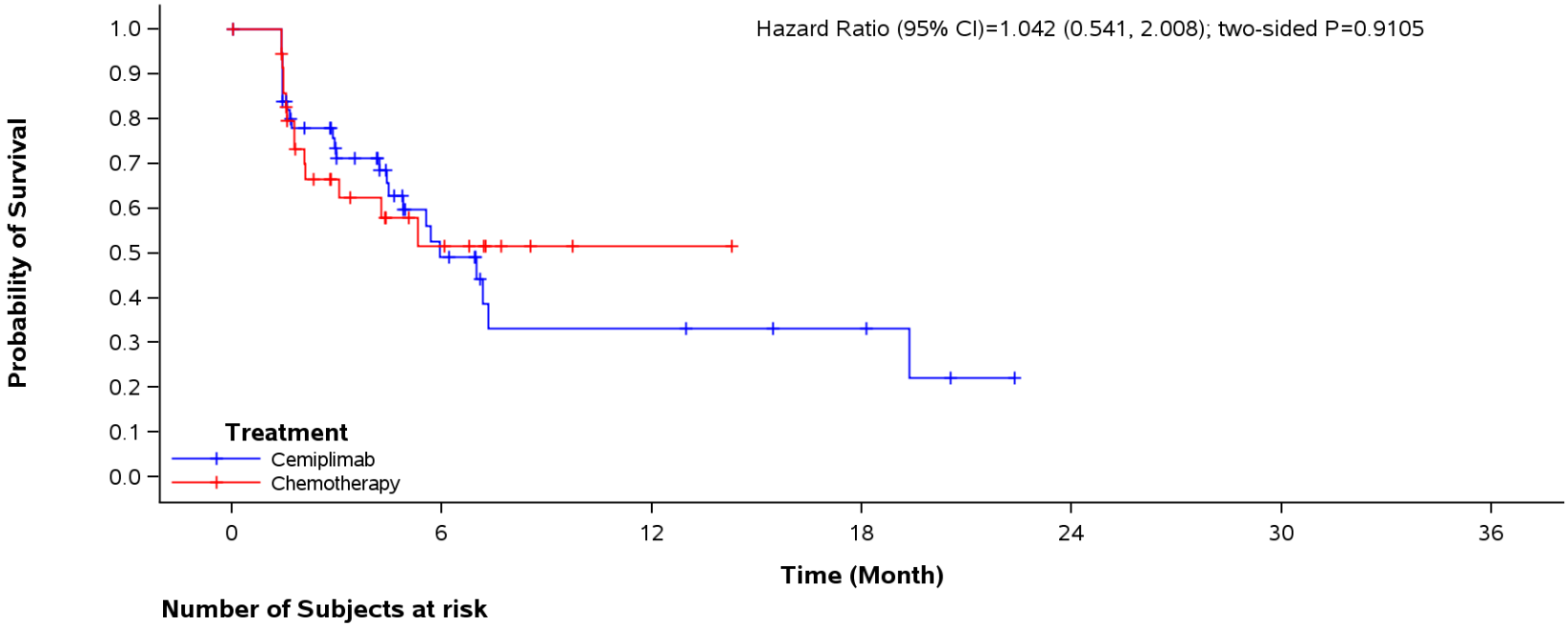

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 15 | 8 | 5 | 0 | 0 | 0 |
| Chemotherapy | 50 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Emotional Functioning - 10 pts deterioration



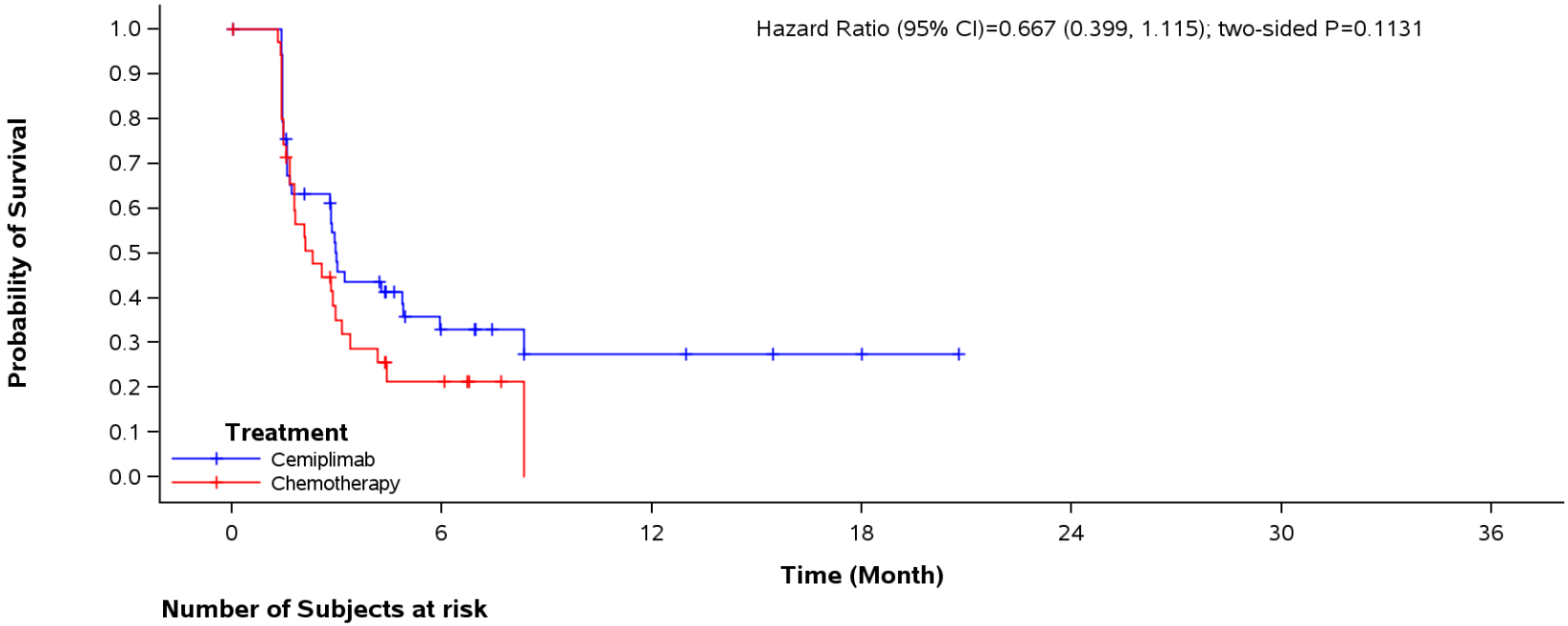

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 14 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 50 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Fatigue - 10 pts deterioration



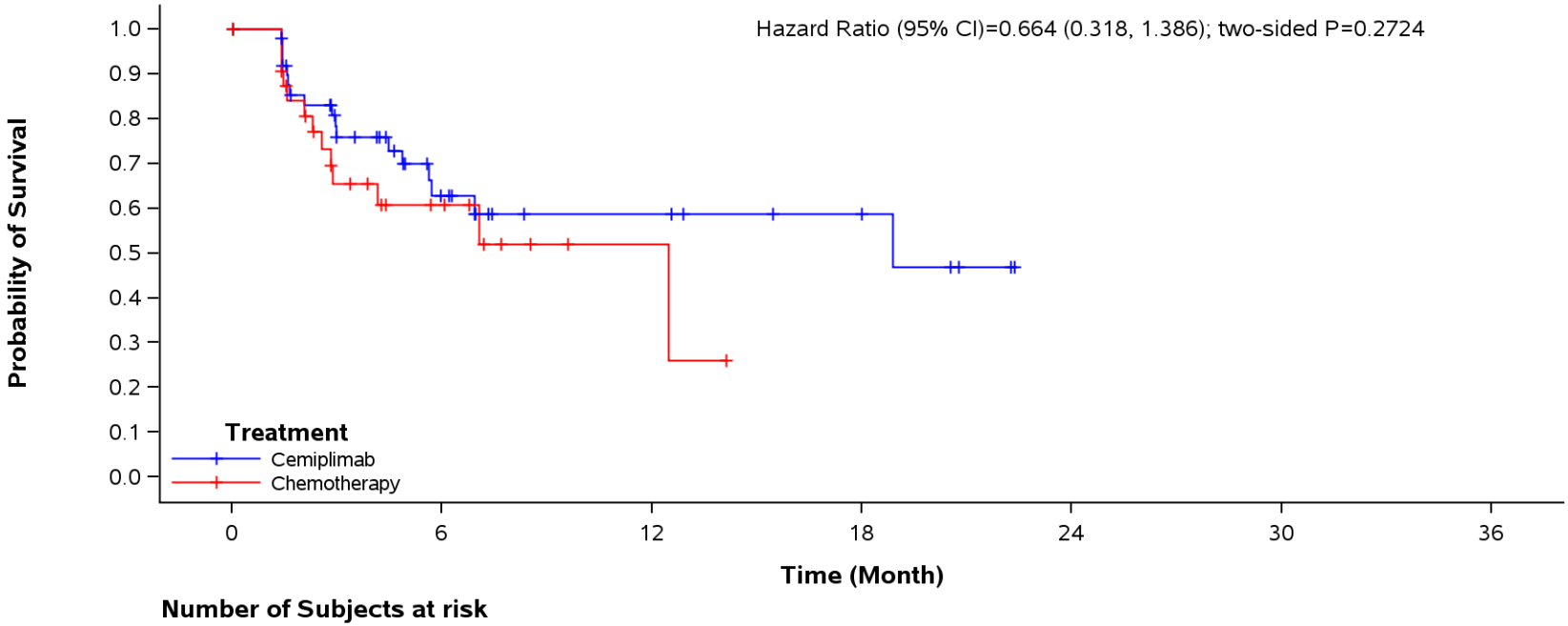

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 10 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Financial Problems - 10 pts deterioration




**Number of Subjects at risk**

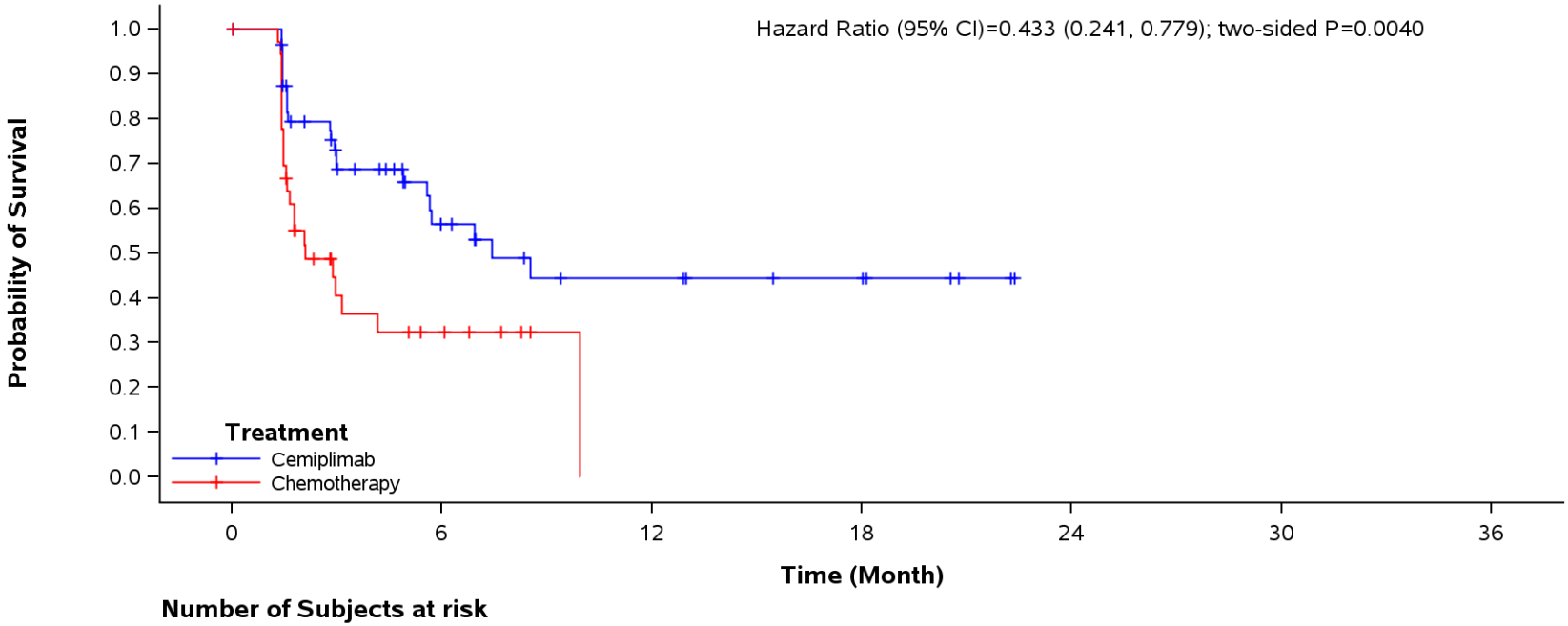
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 17 | 9 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:23, yingyuan.lin)

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Nausea / Vomiting - 10 pts deterioration



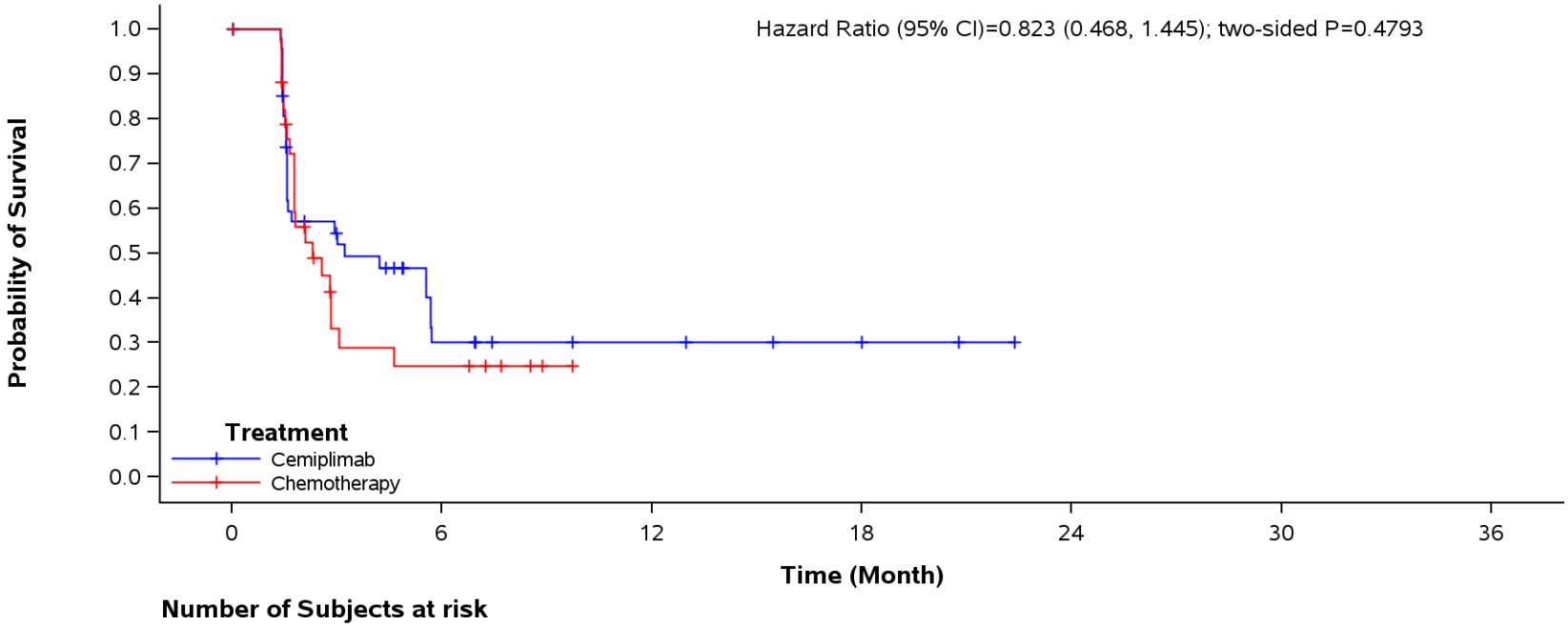

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 17 | 9 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Pain - 10 pts deterioration



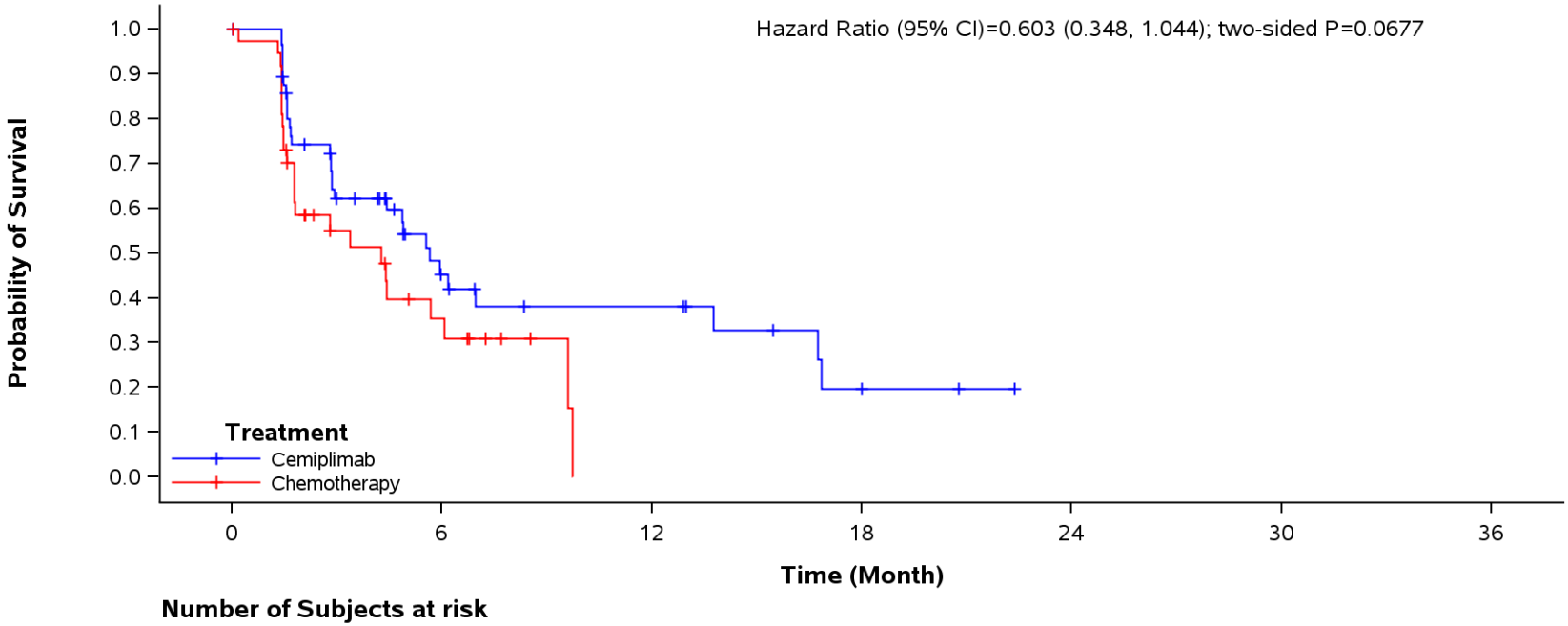

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 9 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Physical Functioning - 10 pts deterioration




Number of Subjects at risk

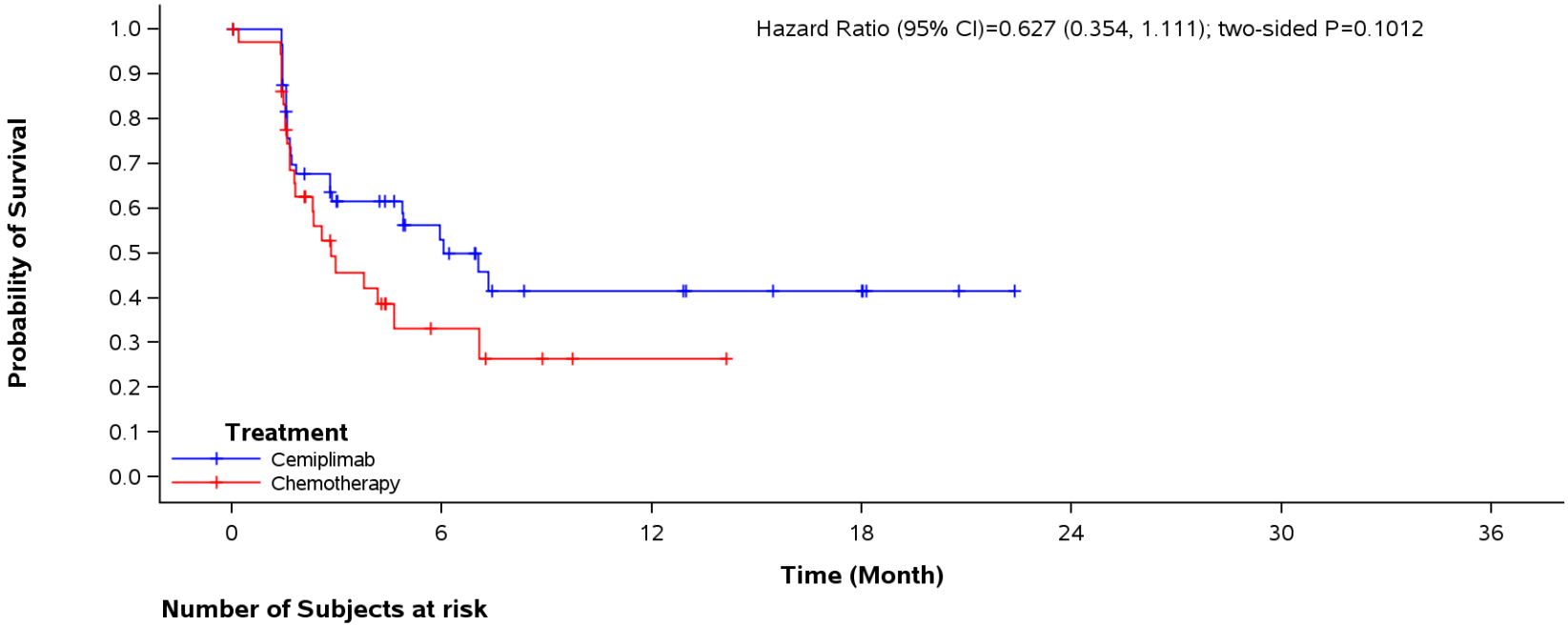
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 14 | 9 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:23, yingyuan.lin)

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Global health status / QoL - 10 pts deterioration



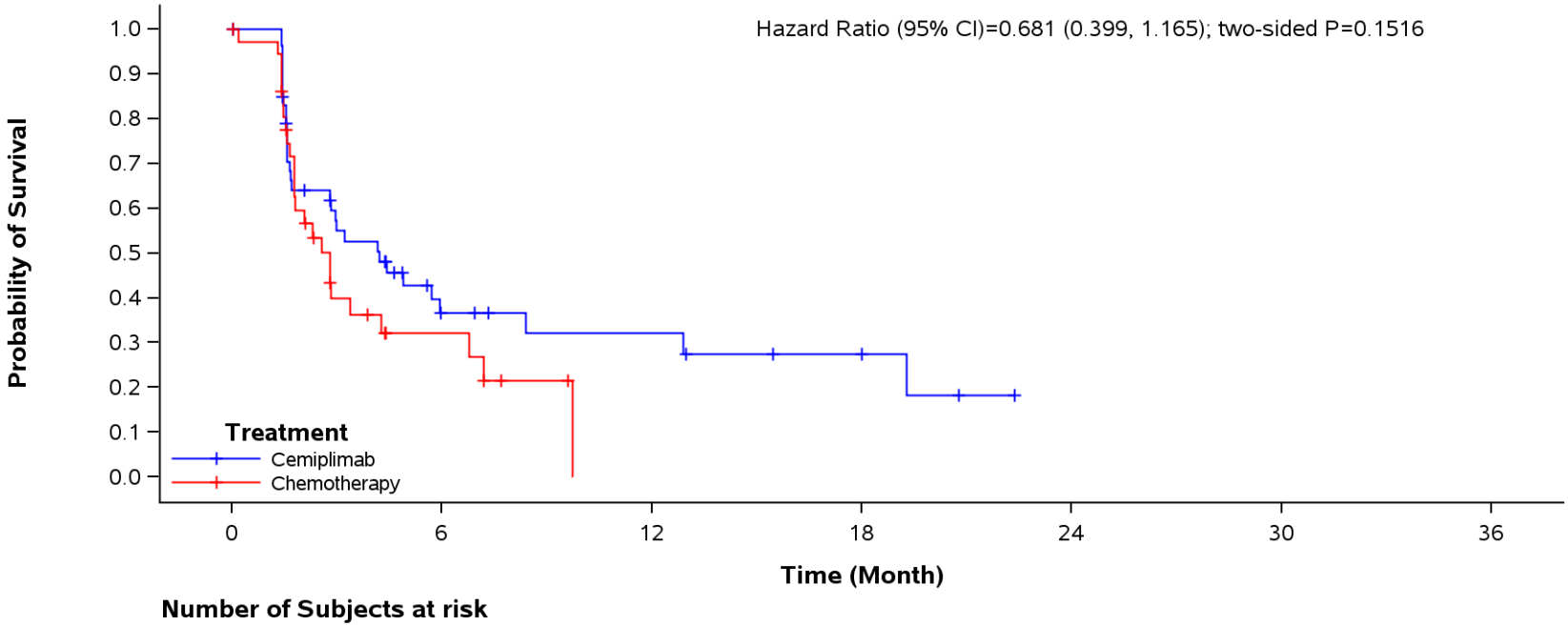

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 17 | 8 | 5 | 0 | 0 | 0 |
| Chemotherapy | 50 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Role Functioning - 10 pts deterioration



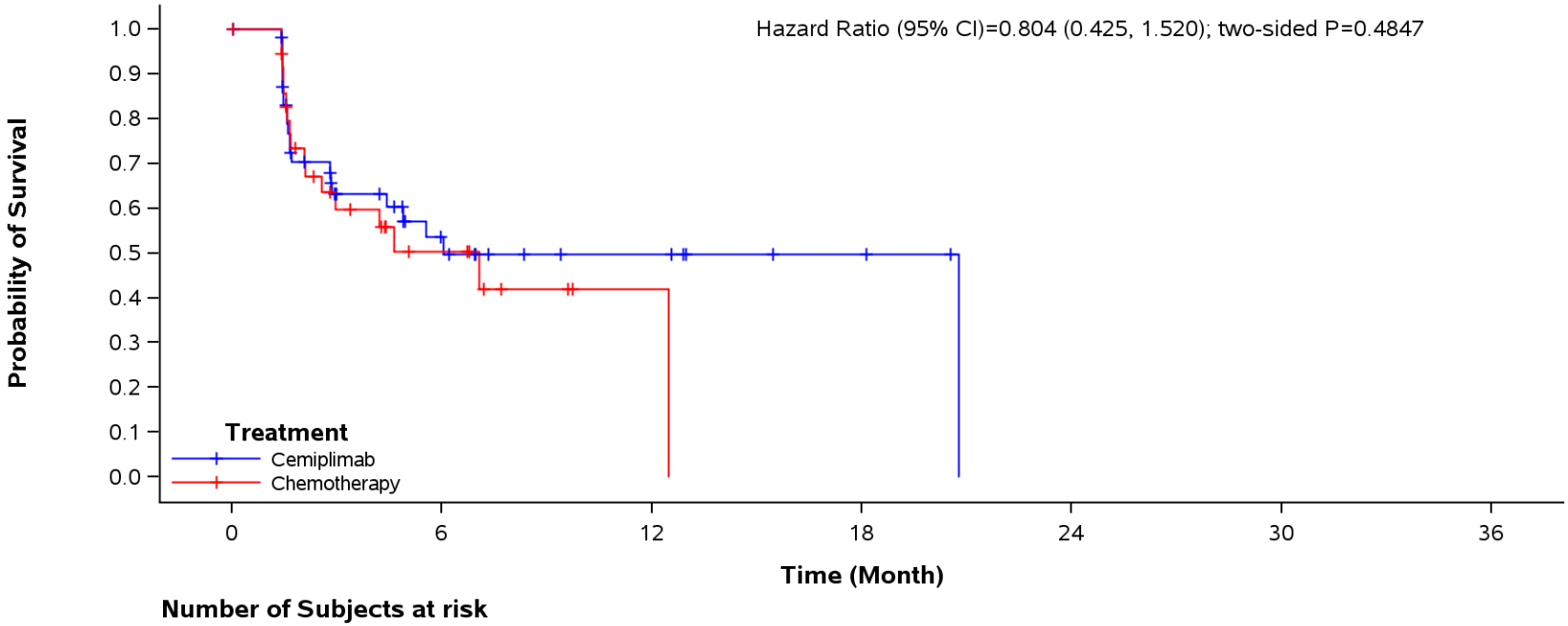

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 11 | 7 | 4 | 0 | 0 | 0 |
| Chemotherapy | 50 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Social Functioning - 10 pts deterioration




Number of Subjects at risk

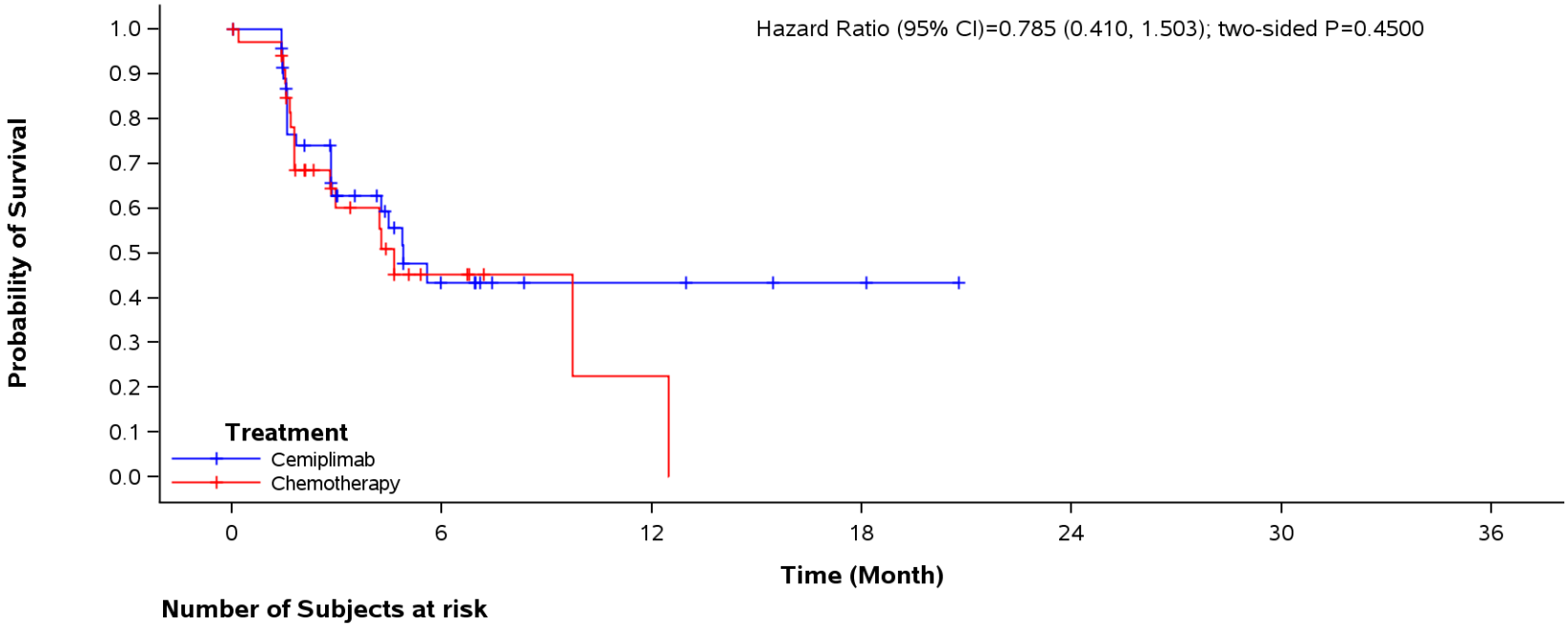
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 14 | 7 | 3 | 0 | 0 | 0 |
| Chemotherapy | 50 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Program: /home/yingyuan.lin/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-sub-no-pdl1.sas (23JAN23:14:29:23, yingyuan.lin)

Figure 2.3.4a. Time to First Deterioration with C30 10-points Threshold by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Insomnia - 10 pts deterioration



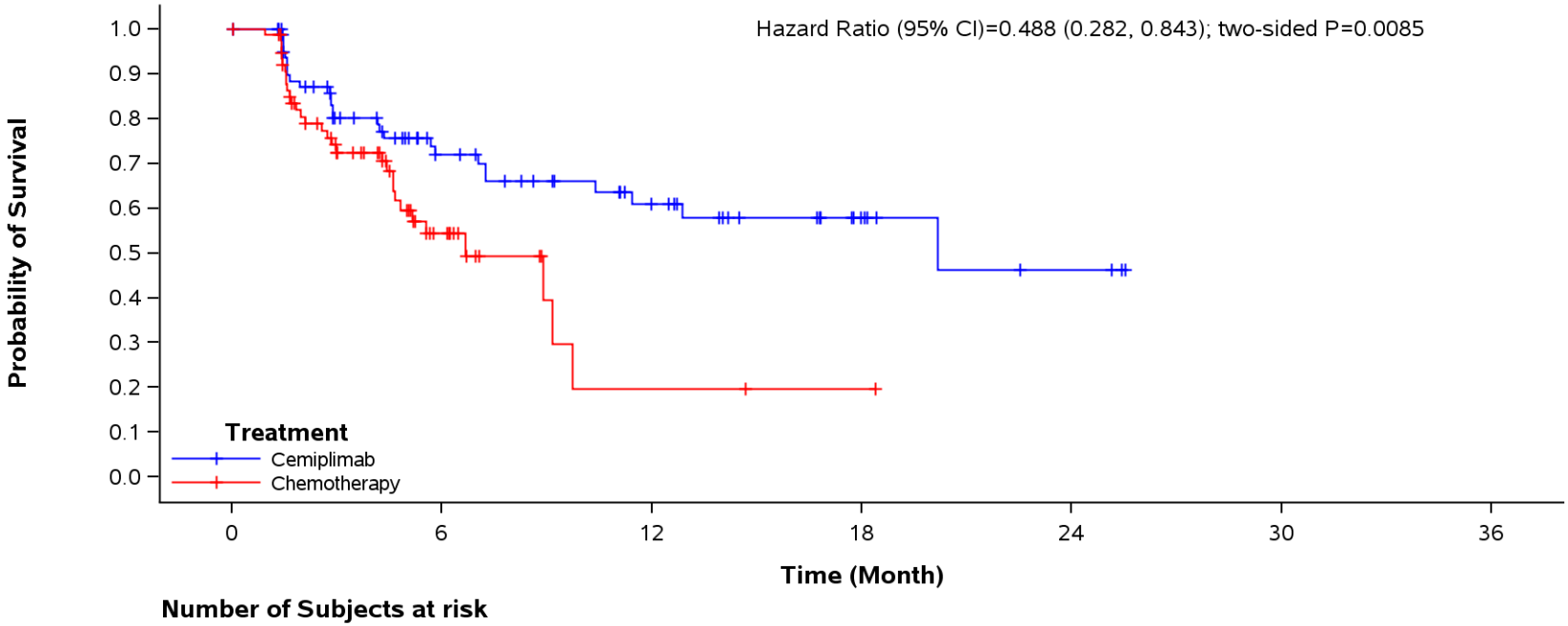

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 9 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 50 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Time is defined as (date of achieving 10 points deterioration first time - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Appetite loss - 10 pts sustained deterioration



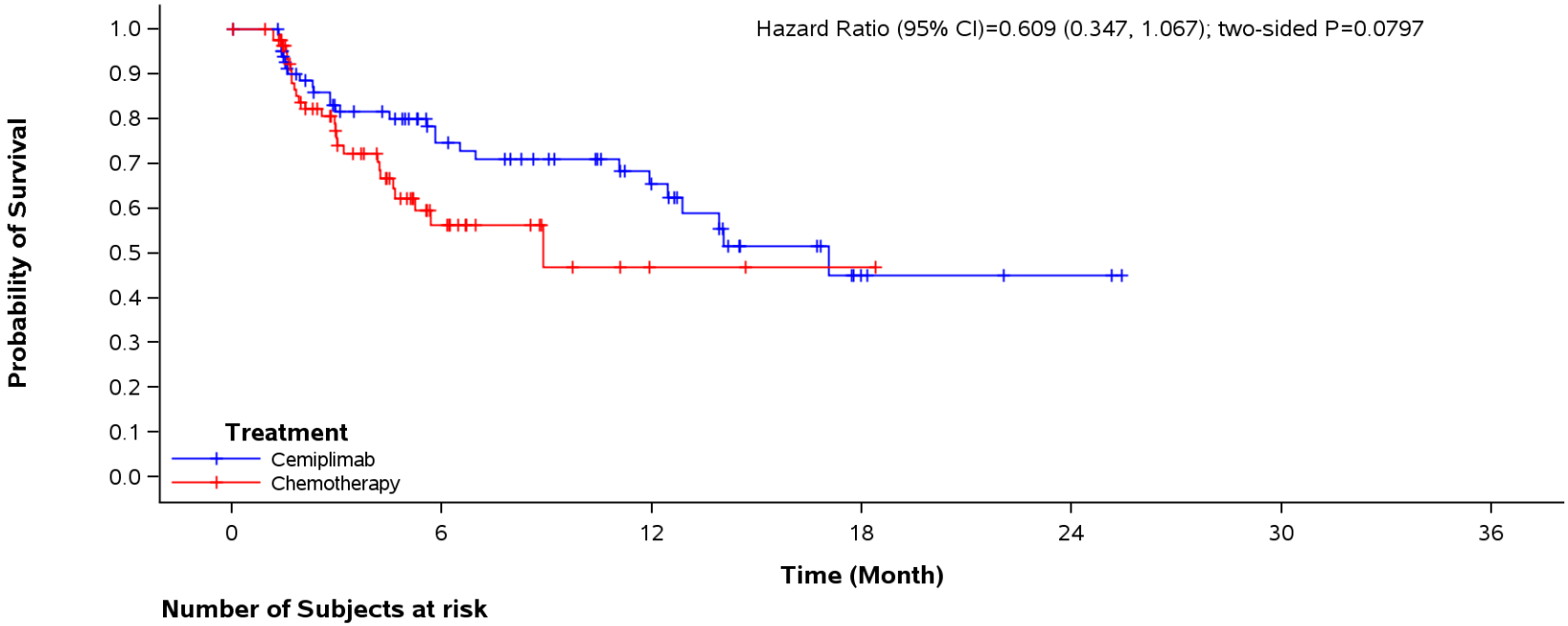

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 39 | 22 | 8 | 3 | 0 | 0 |
| Chemotherapy | 103 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Cognitive Functioning - 10 pts sustained deterioration



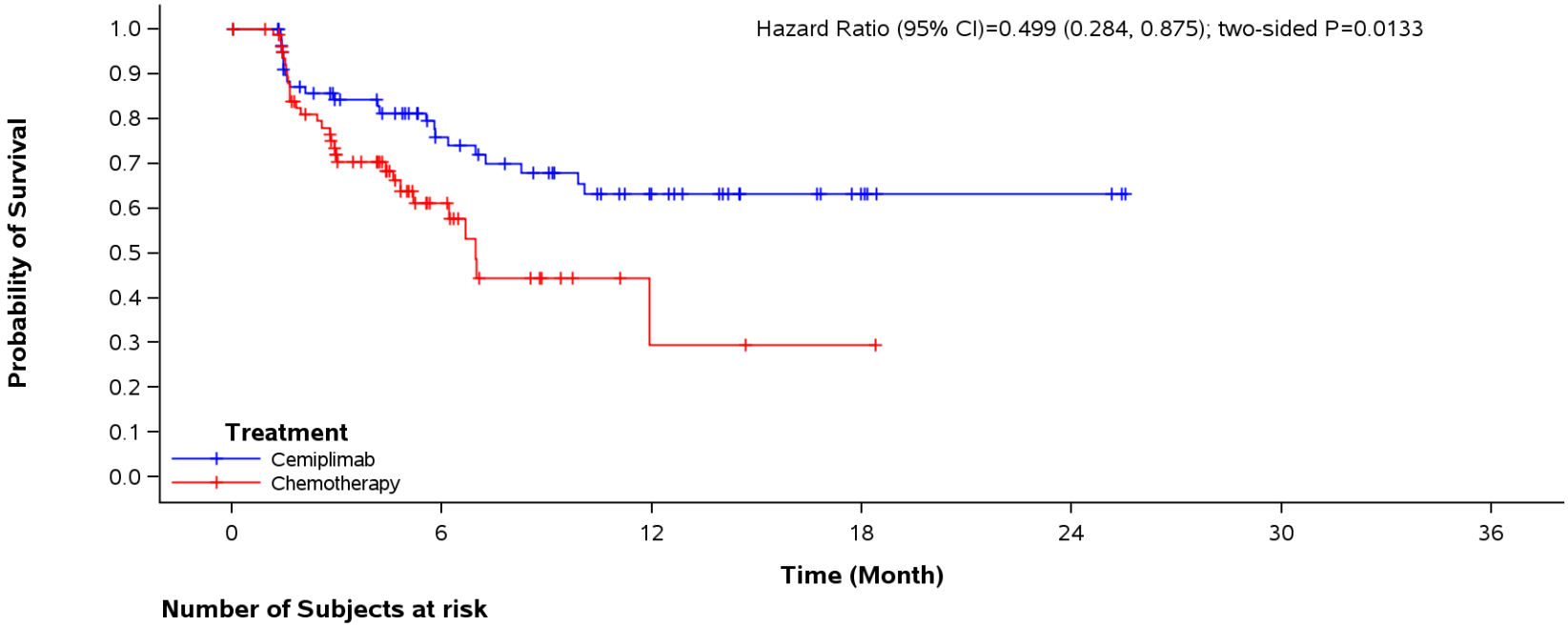

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 41 | 22 | 4 | 2 | 0 | 0 |
| Chemotherapy | 103 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Constipation - 10 pts sustained deterioration



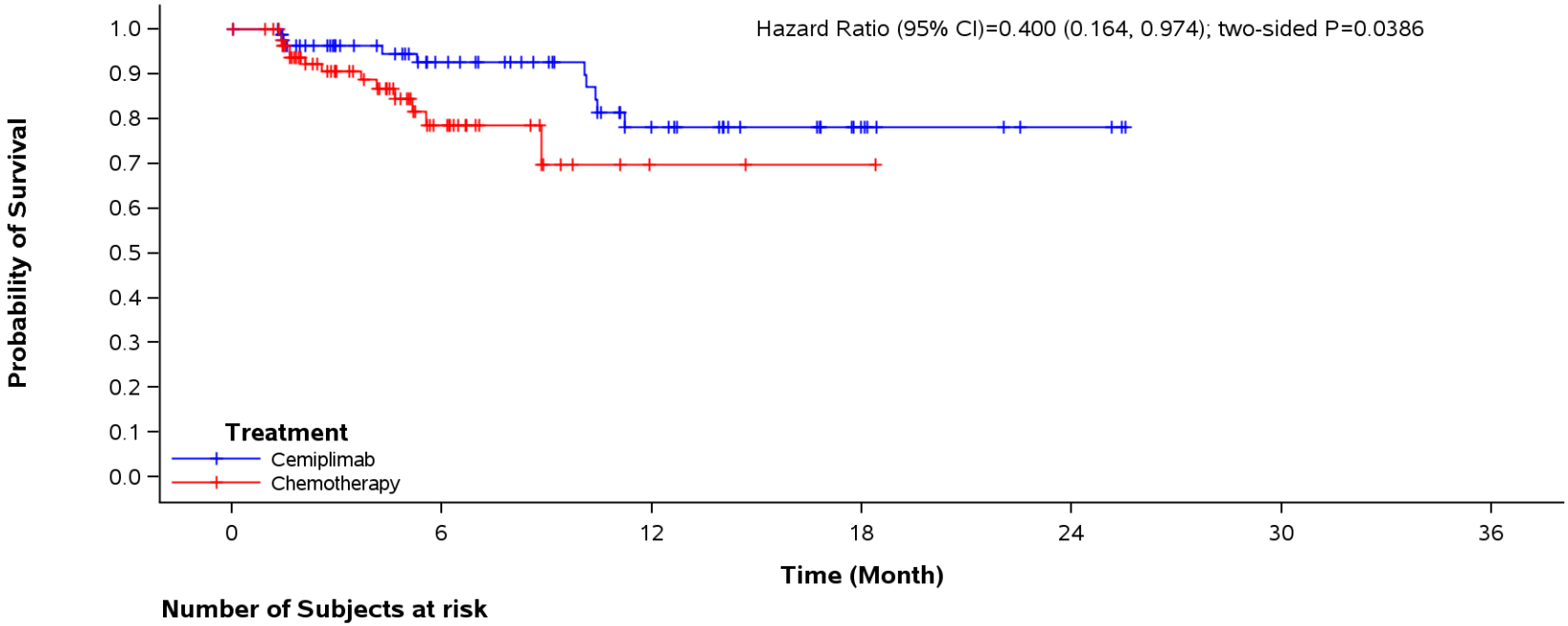

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 40 | 19 | 6 | 3 | 0 | 0 |
| Chemotherapy | 103 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Diarhoea - 10 pts sustained deterioration



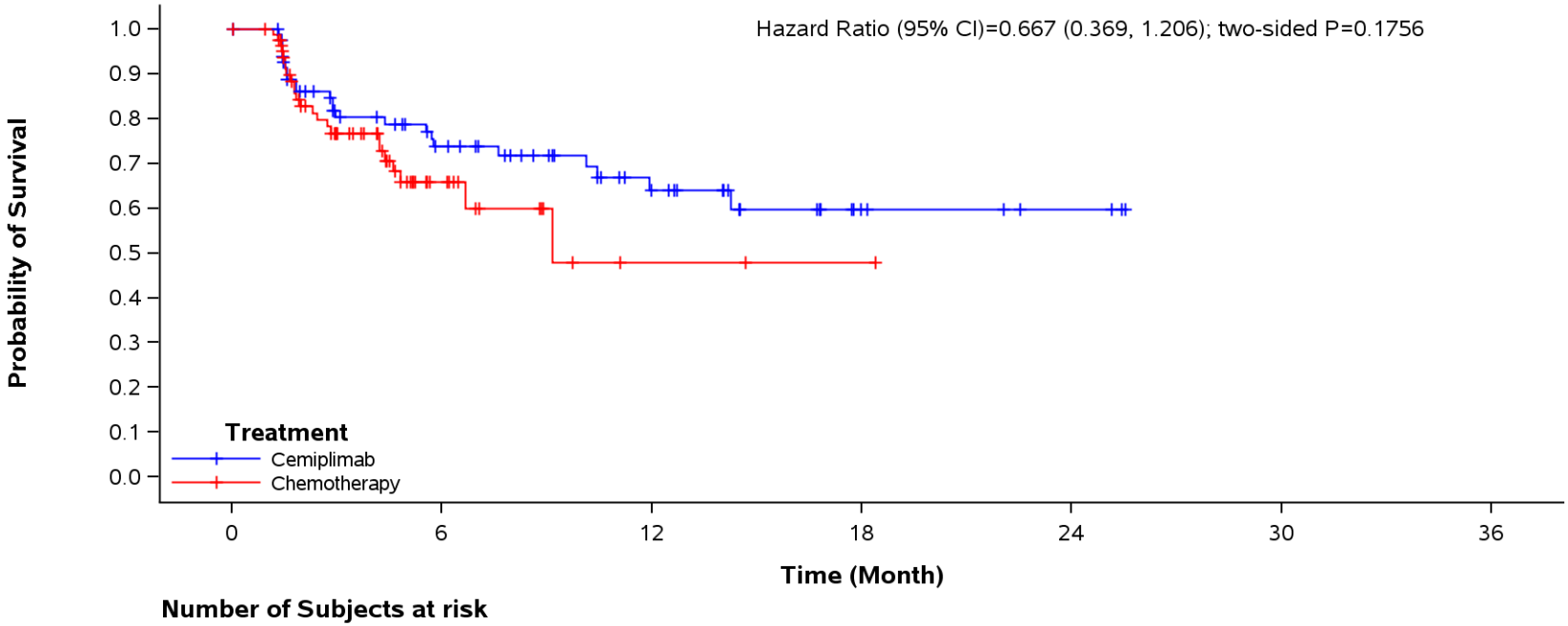

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 46 | 22 | 8 | 3 | 0 | 0 |
| Chemotherapy | 103 | 21 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Dyspnoea - 10 pts sustained deterioration



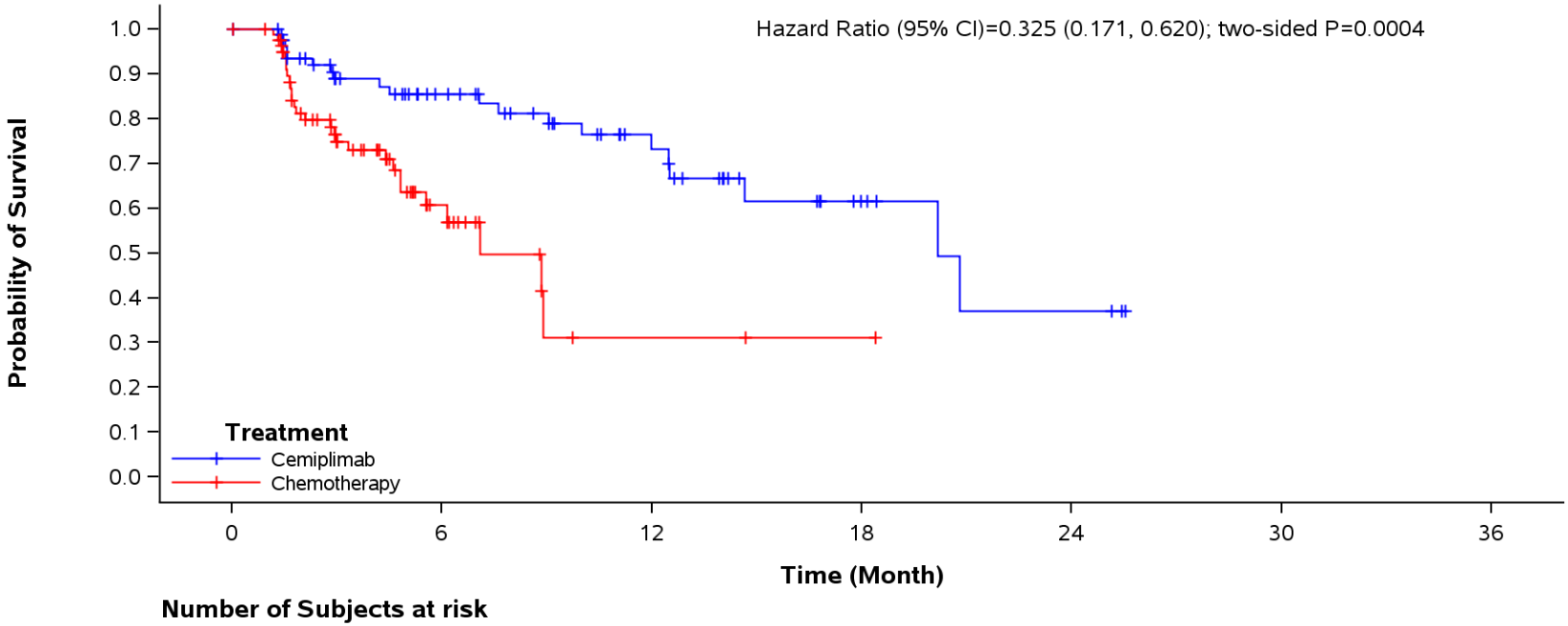

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 42 | 21 | 6 | 3 | 0 | 0 |
| Chemotherapy | 103 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Emotional Functioning - 10 pts sustained deterioration



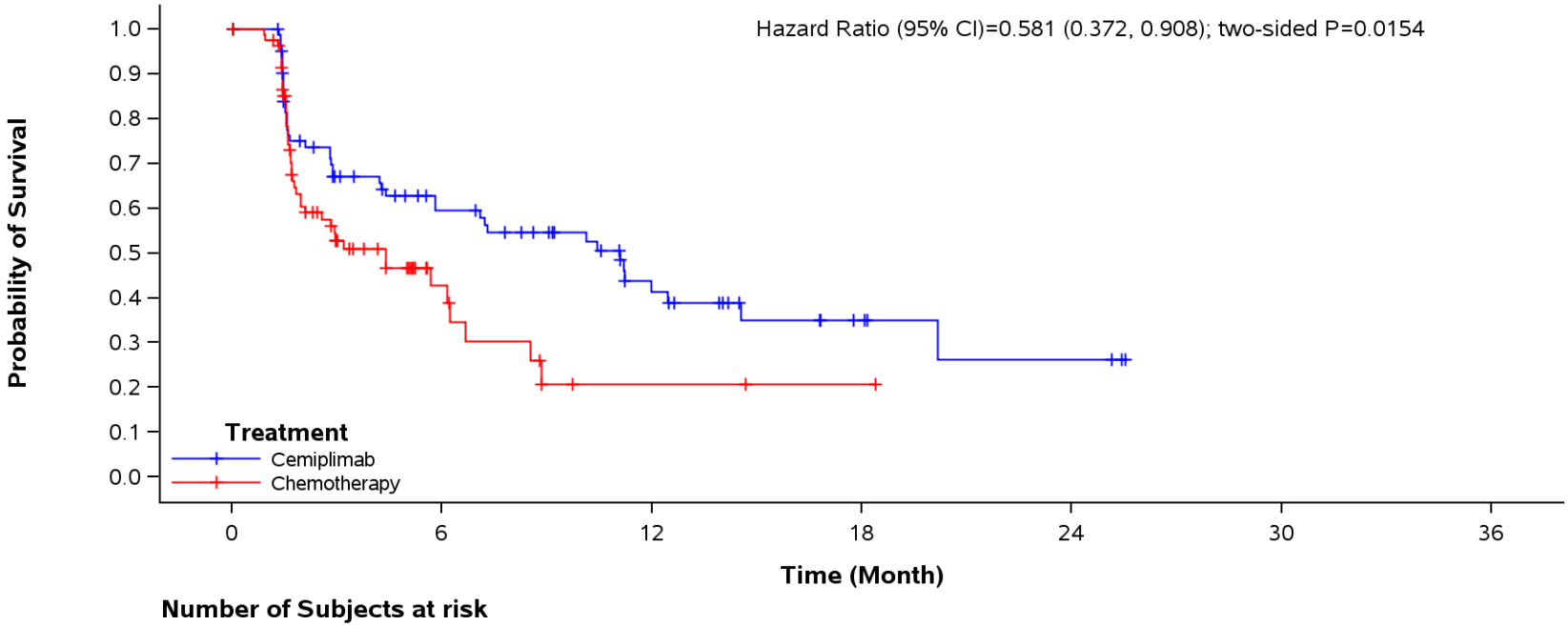

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 44 | 23 | 7 | 3 | 0 | 0 |
| Chemotherapy | 103 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Fatigue - 10 pts sustained deterioration



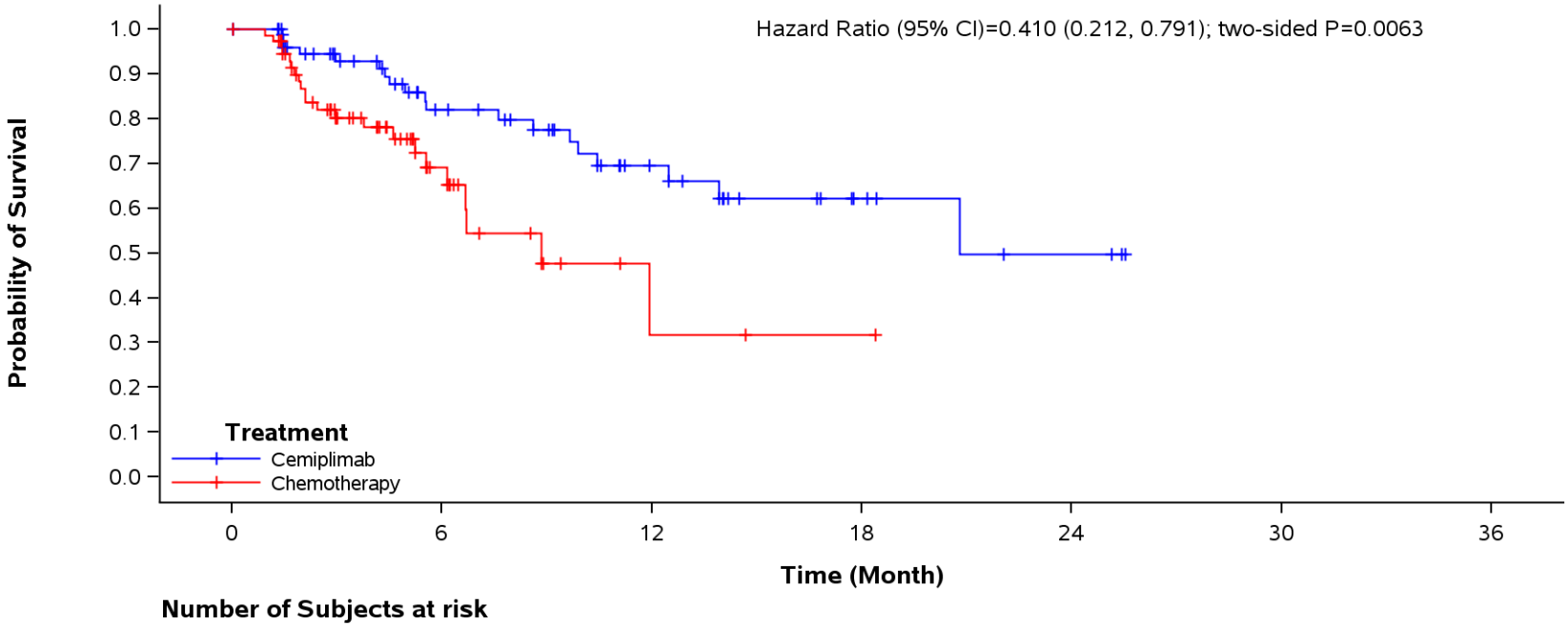

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 37 | 17 | 6 | 3 | 0 | 0 |
| Chemotherapy | 103 | 11 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Financial Problems - 10 pts sustained deterioration



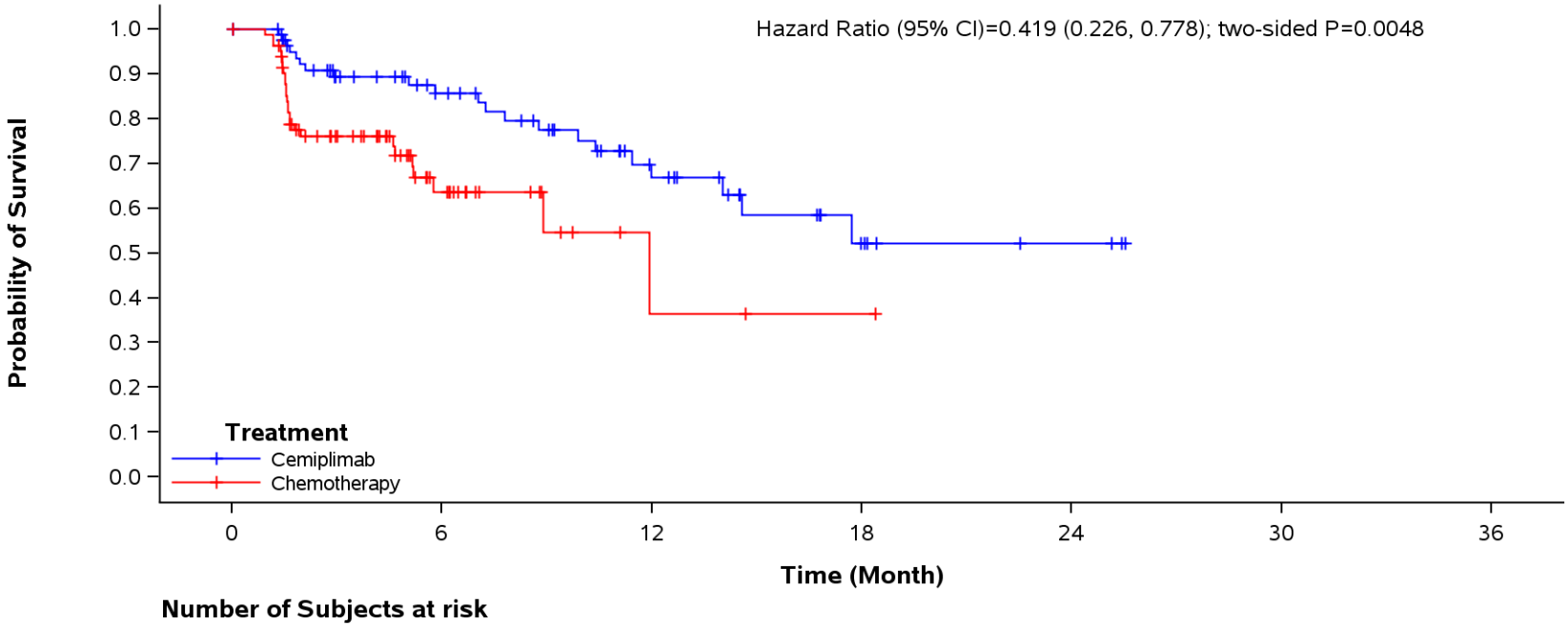

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 40 | 20 | 7 | 3 | 0 | 0 |
| Chemotherapy | 103 | 18 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Nausea / Vomiting - 10 pts sustained deterioration



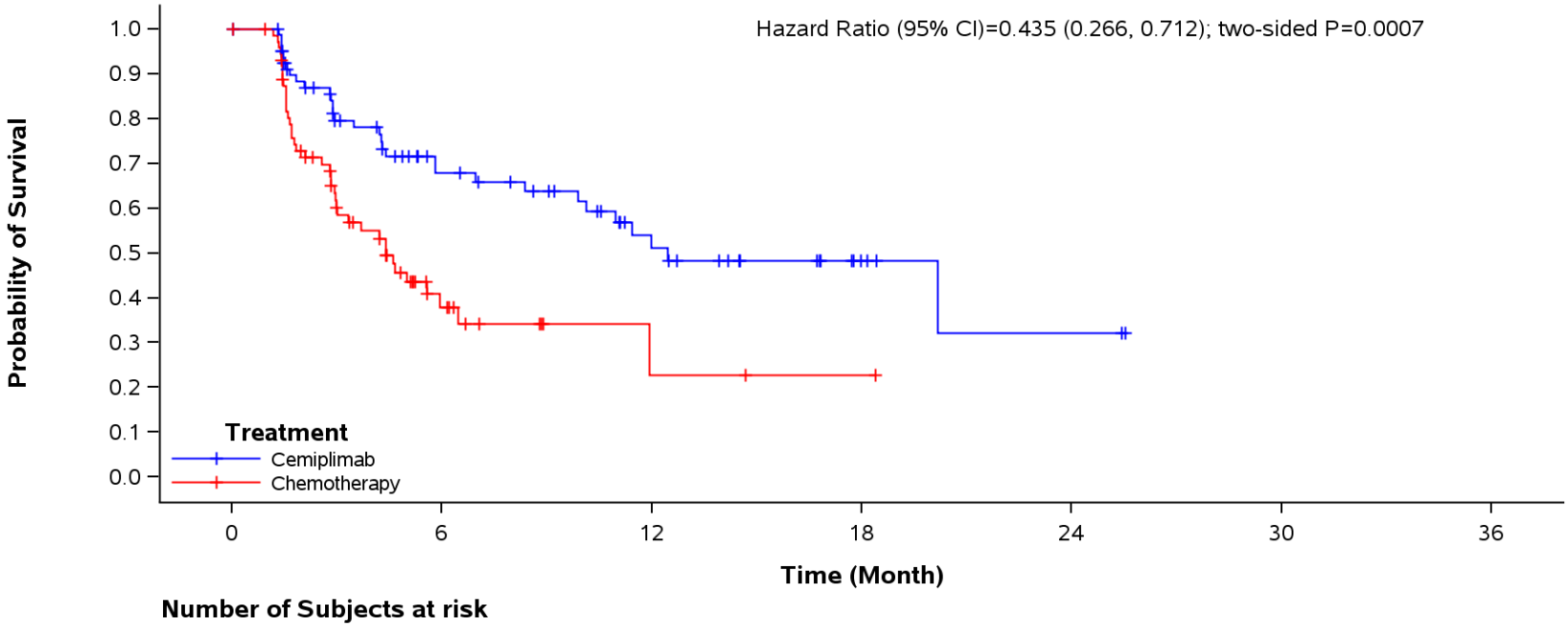

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 46 | 22 | 7 | 3 | 0 | 0 |
| Chemotherapy | 103 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Pain - 10 pts sustained deterioration



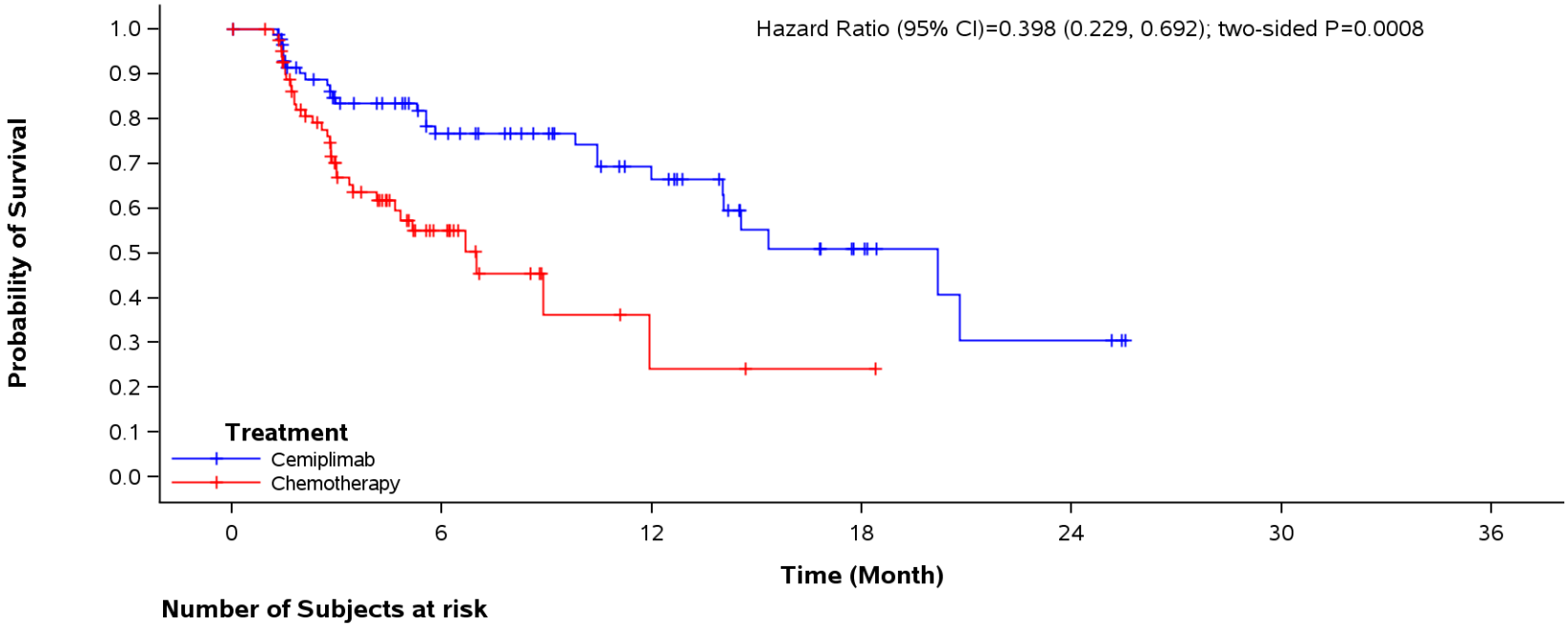

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 36 | 18 | 5 | 2 | 0 | 0 |
| Chemotherapy | 103 | 13 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Physical Functioning - 10 pts sustained deterioration



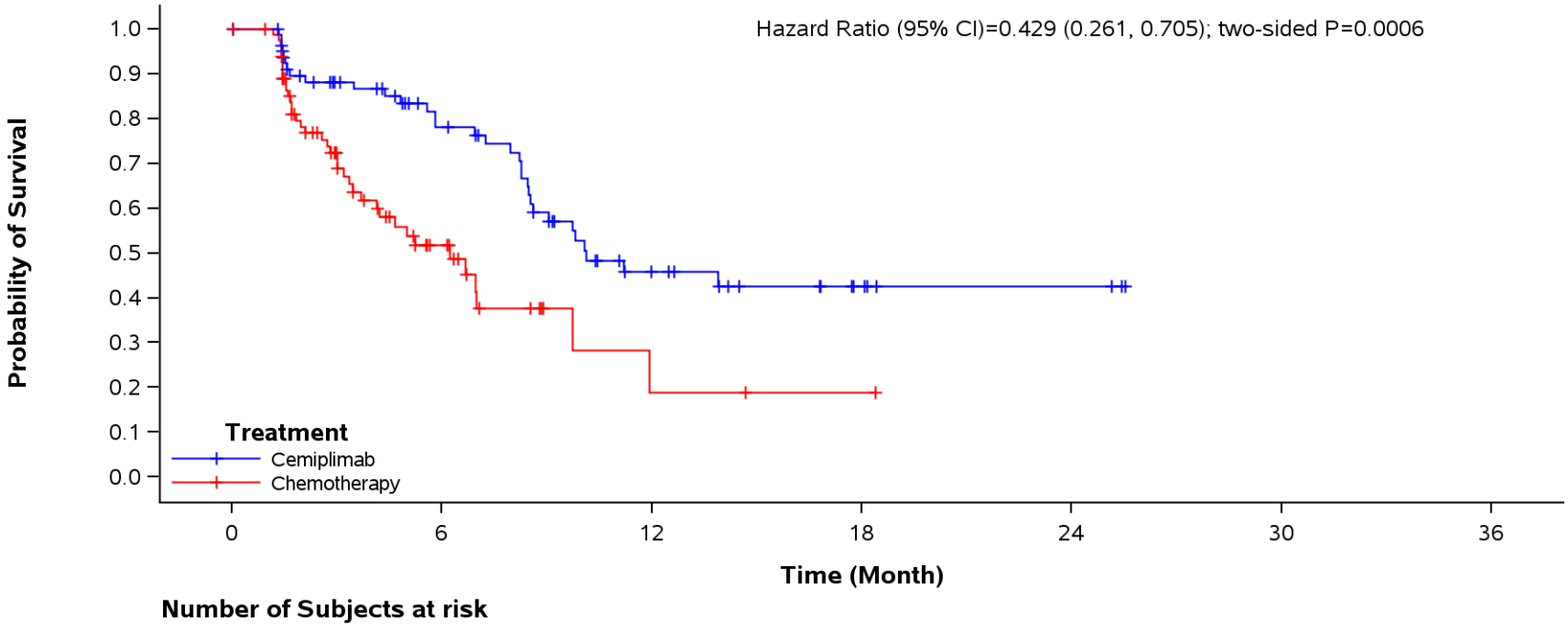

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 44 | 24 | 8 | 3 | 0 | 0 |
| Chemotherapy | 103 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Global health status / QoL - 10 pts sustained deterioration



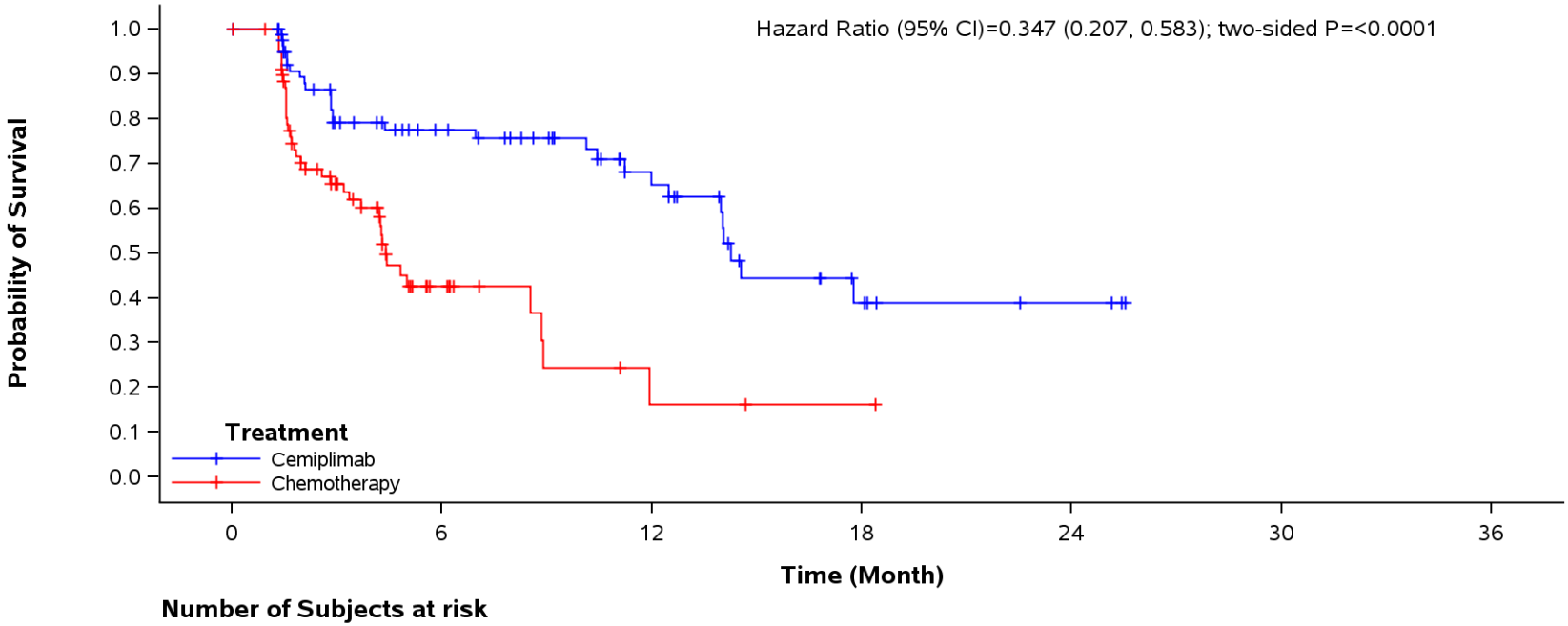

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 44 | 16 | 6 | 3 | 0 | 0 |
| Chemotherapy | 103 | 19 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Role Functioning - 10 pts sustained deterioration



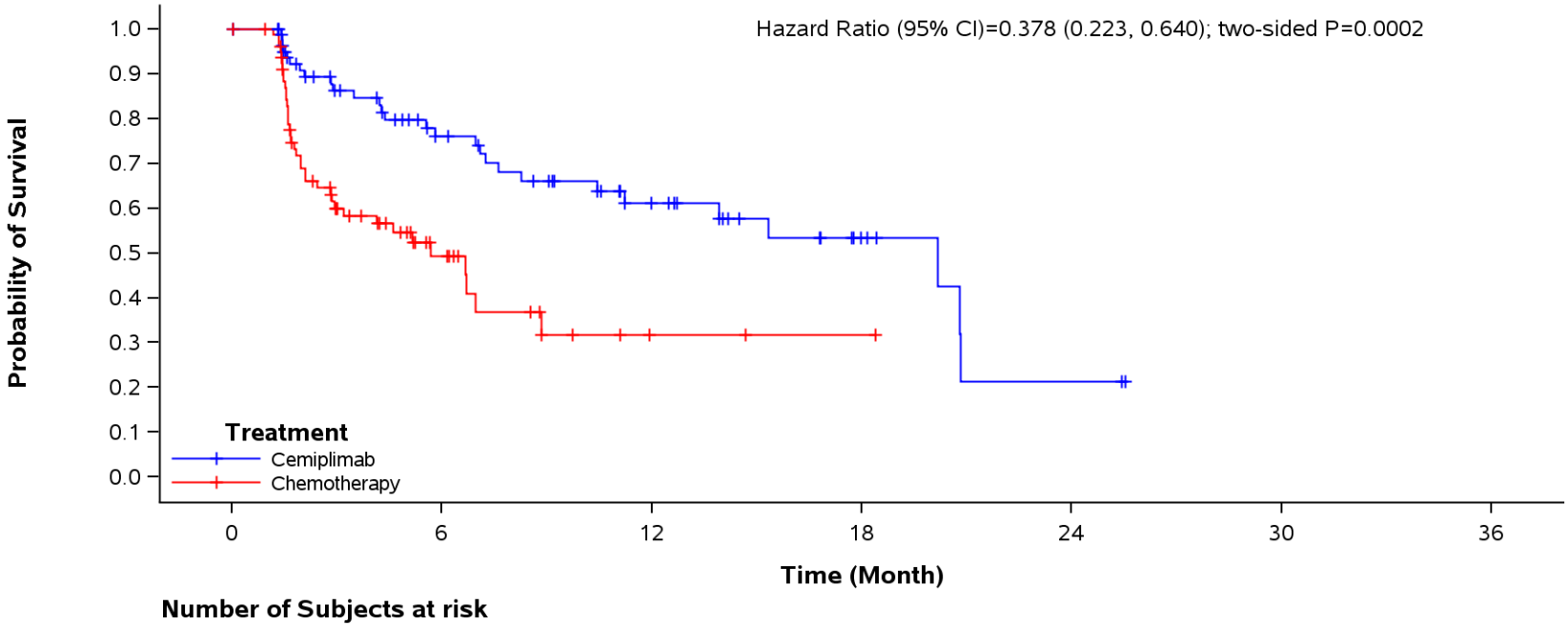

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 42 | 23 | 7 | 3 | 0 | 0 |
| Chemotherapy | 103 | 12 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Social Functioning - 10 pts sustained deterioration



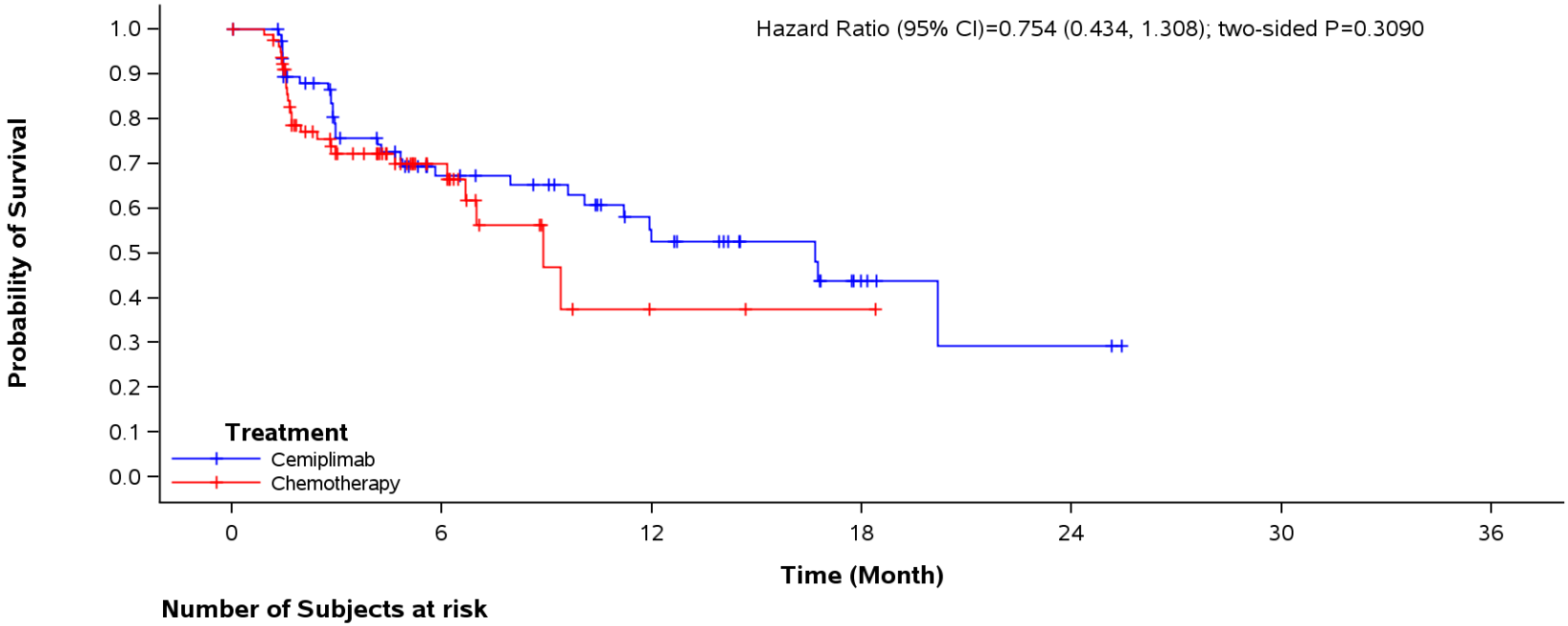

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 40 | 21 | 7 | 2 | 0 | 0 |
| Chemotherapy | 103 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1 (unkown status)
Insomnia - 10 pts sustained deterioration



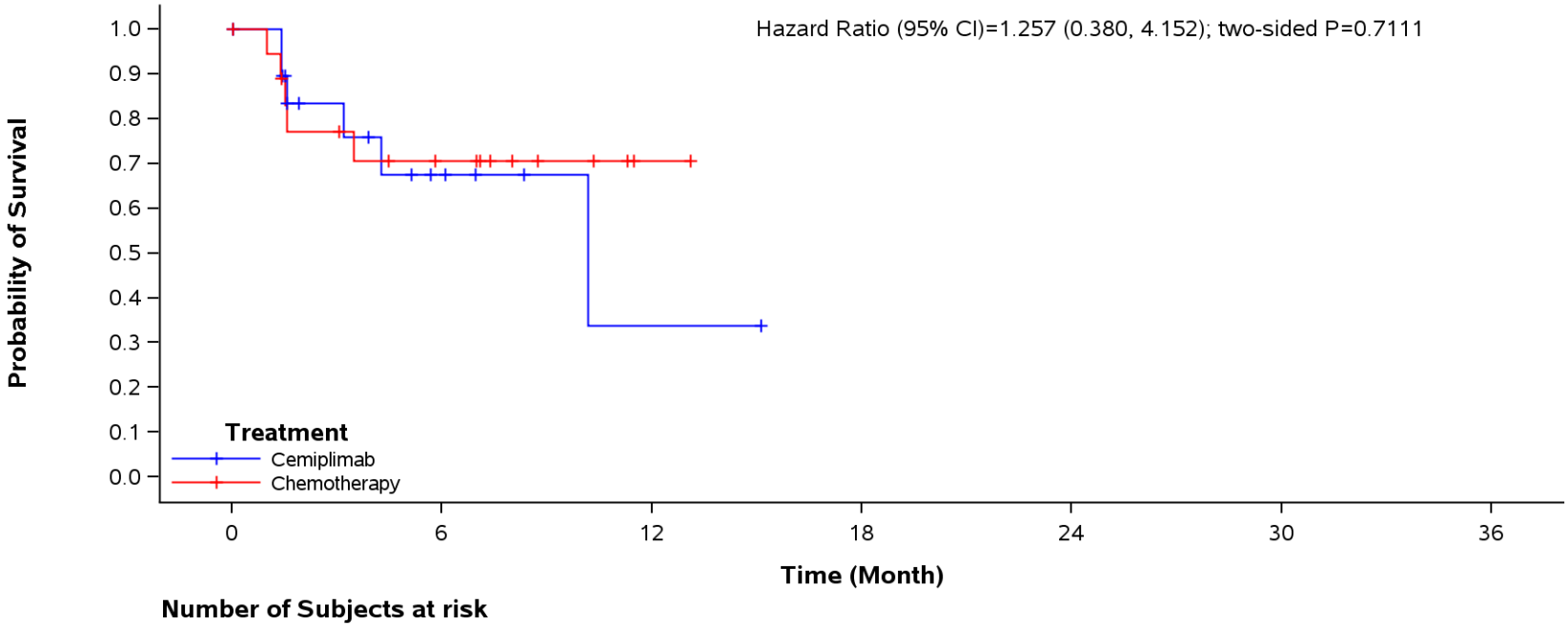

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 105 | 36 | 19 | 5 | 2 | 0 | 0 |
| Chemotherapy | 103 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Appetite loss - 10 pts sustained deterioration



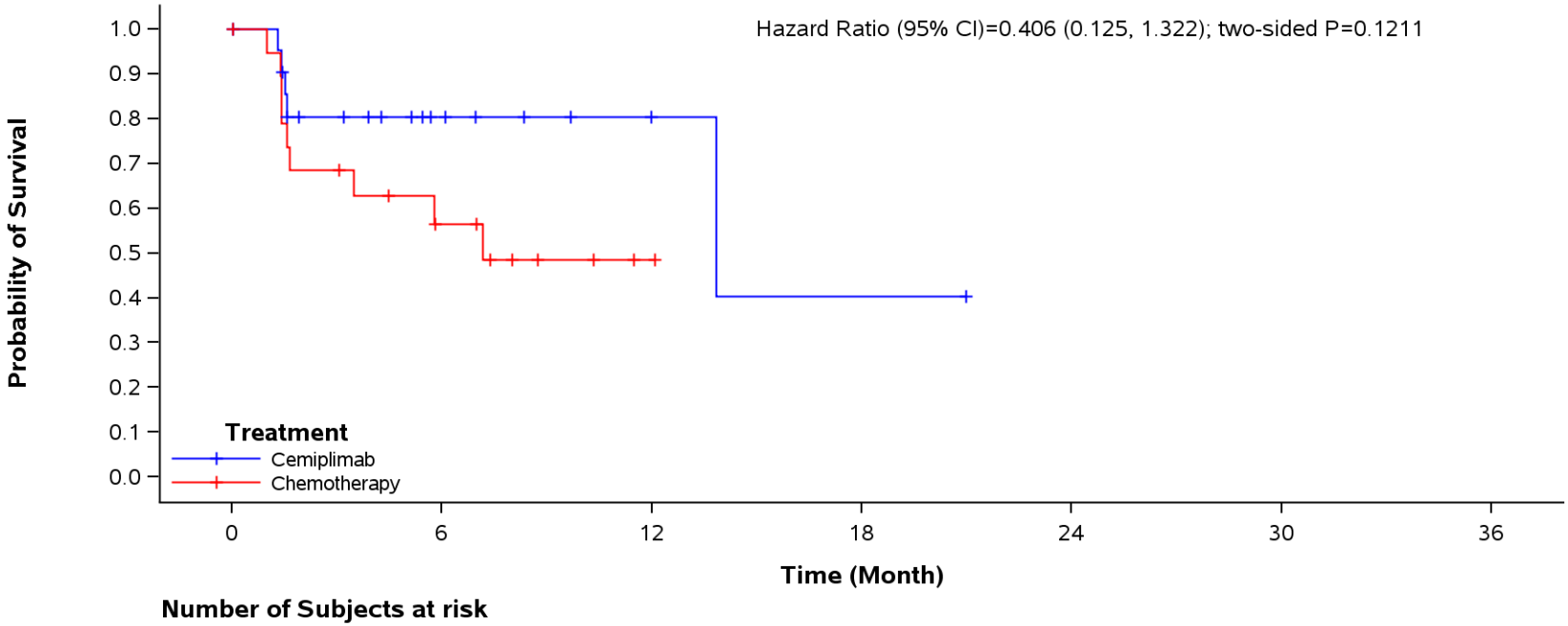

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Cognitive Functioning - 10 pts sustained deterioration



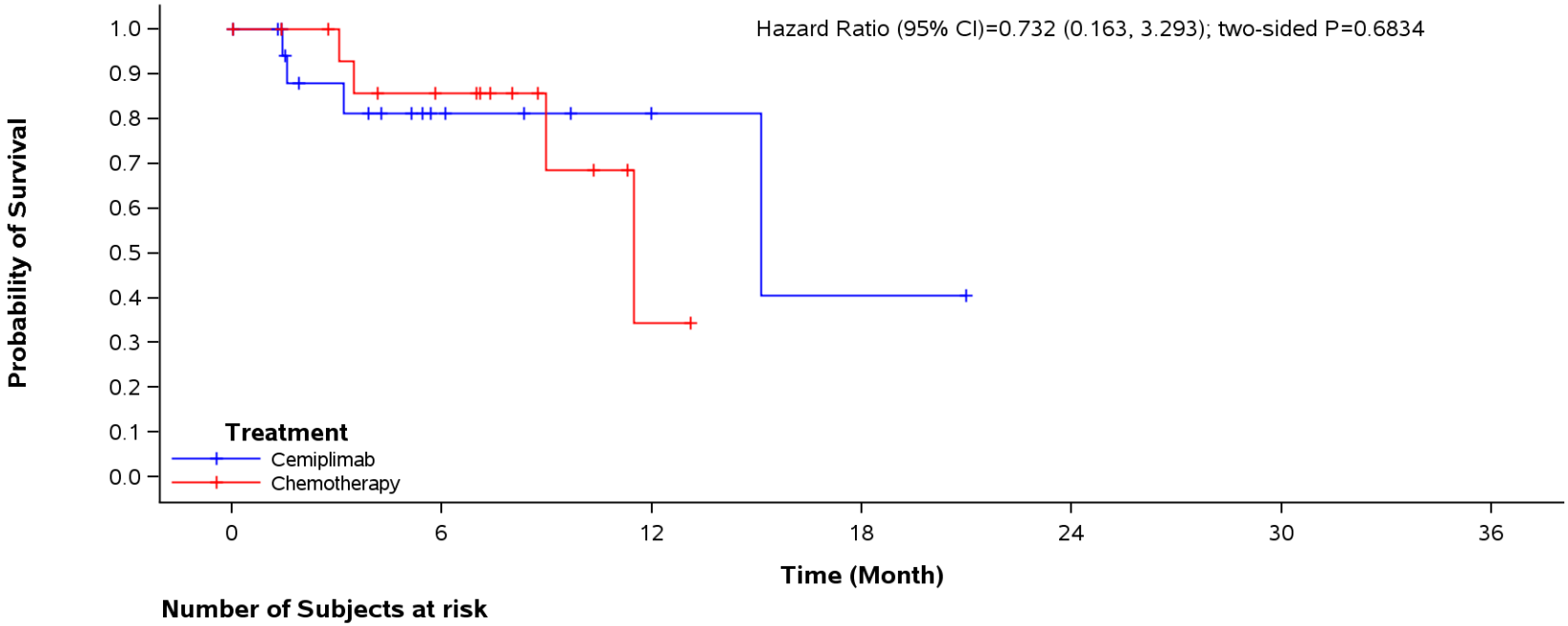

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Constipation - 10 pts sustained deterioration



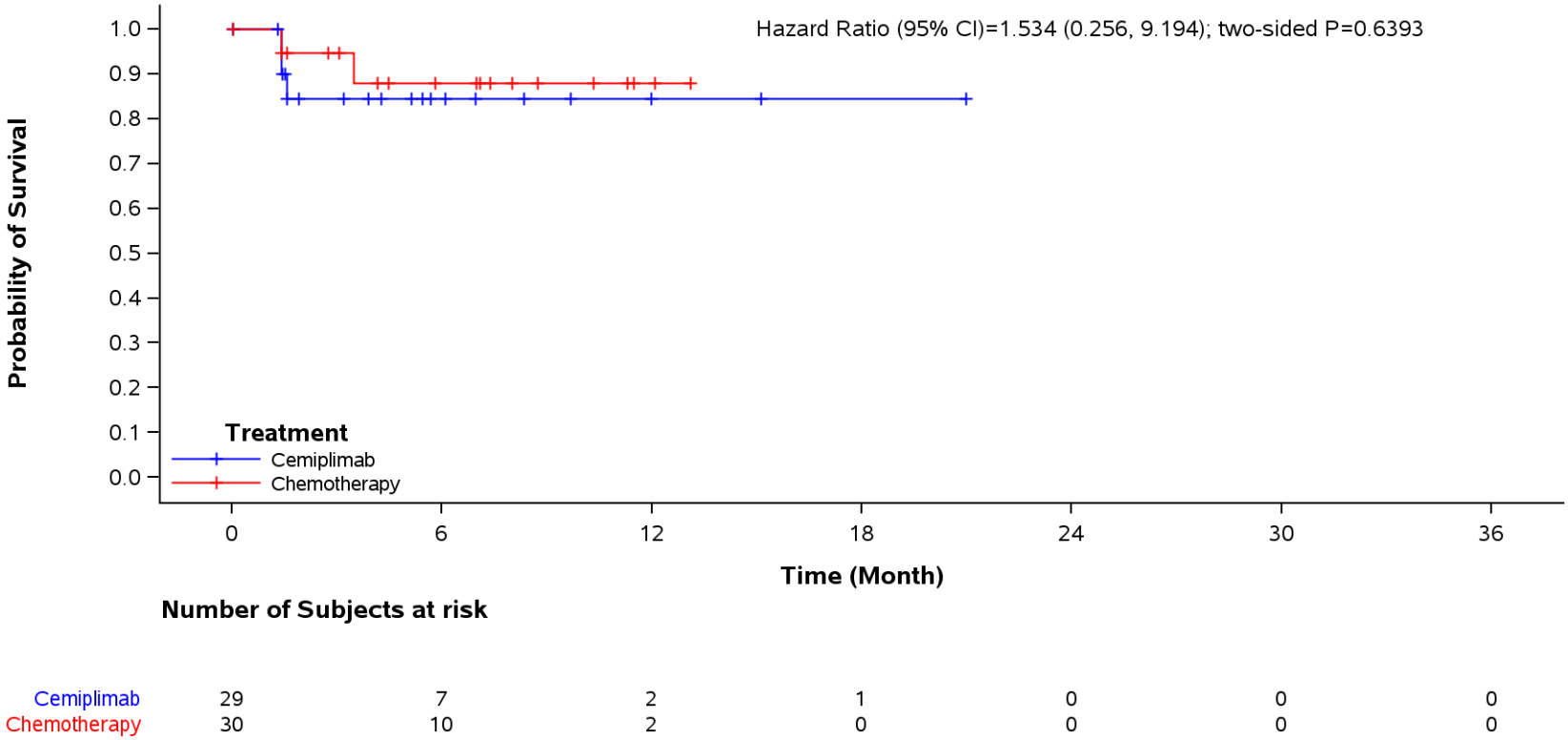

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Diarhoea - 10 pts sustained deterioration



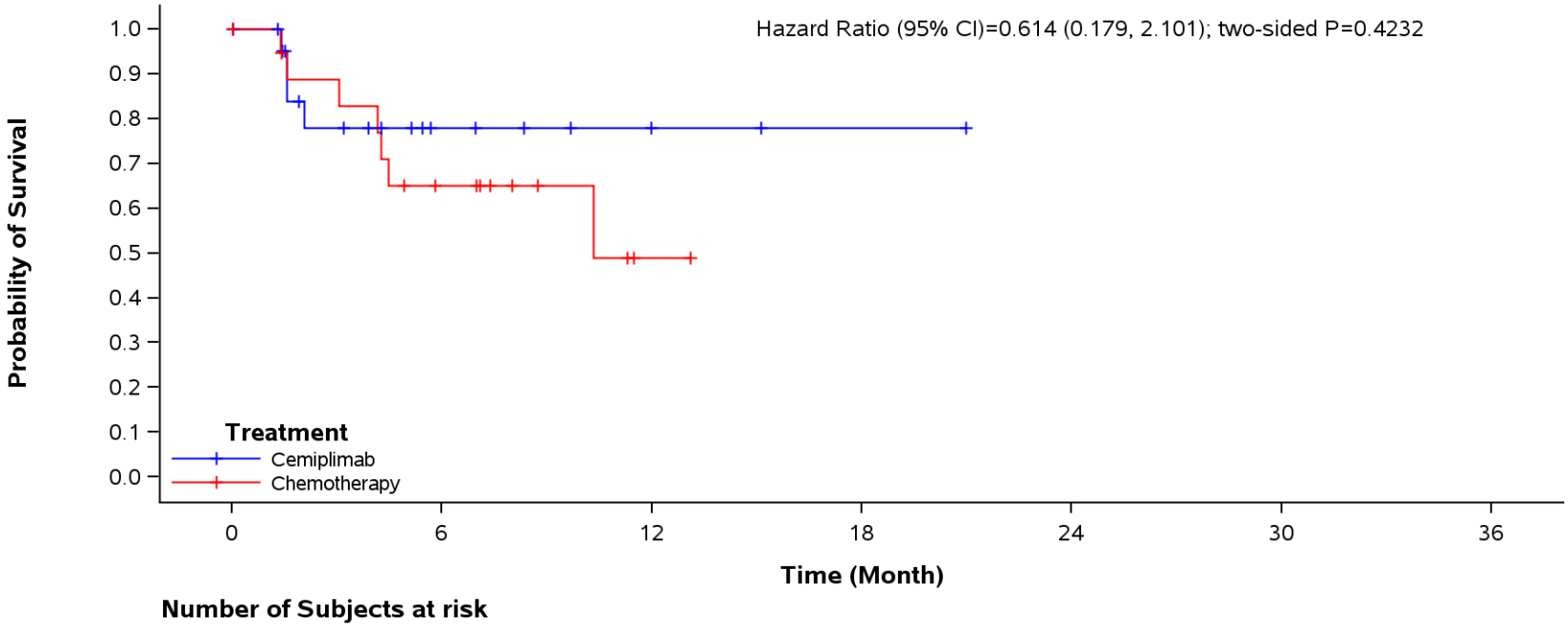

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Dyspnoea - 10 pts sustained deterioration



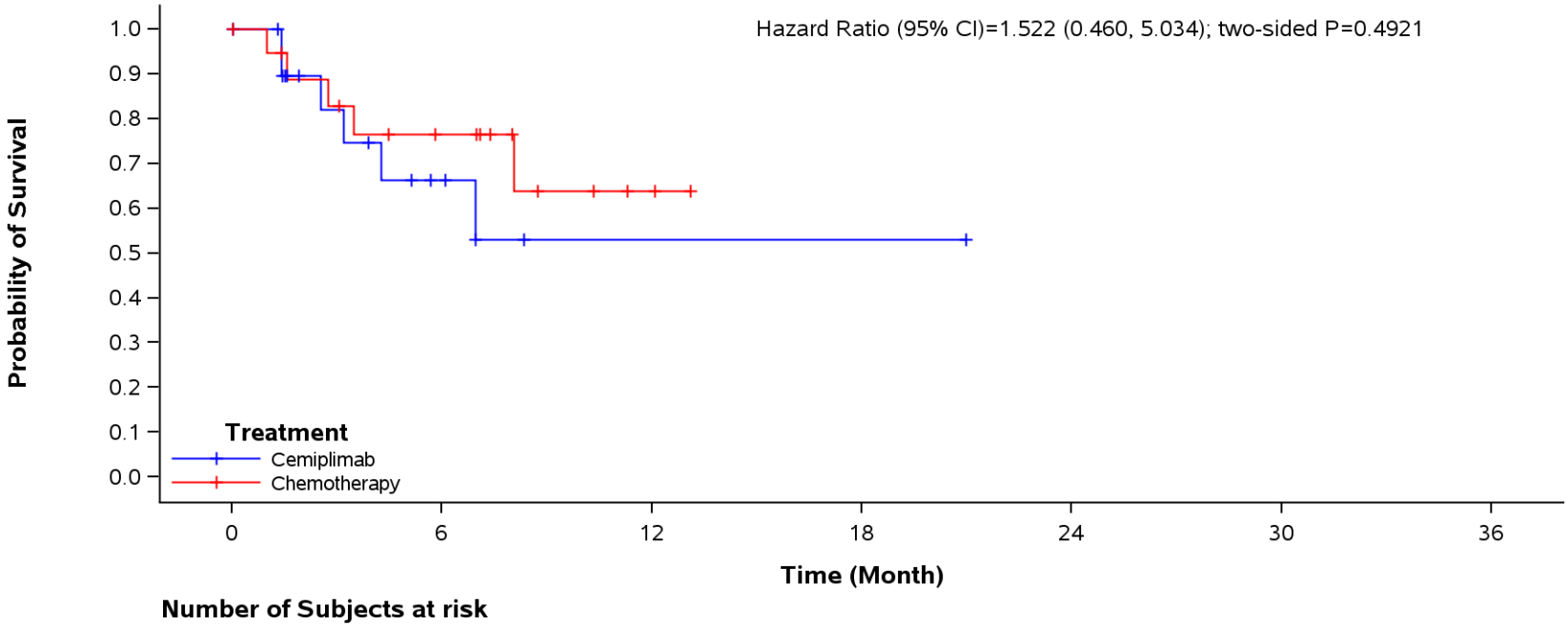

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Emotional Functioning - 10 pts sustained deterioration



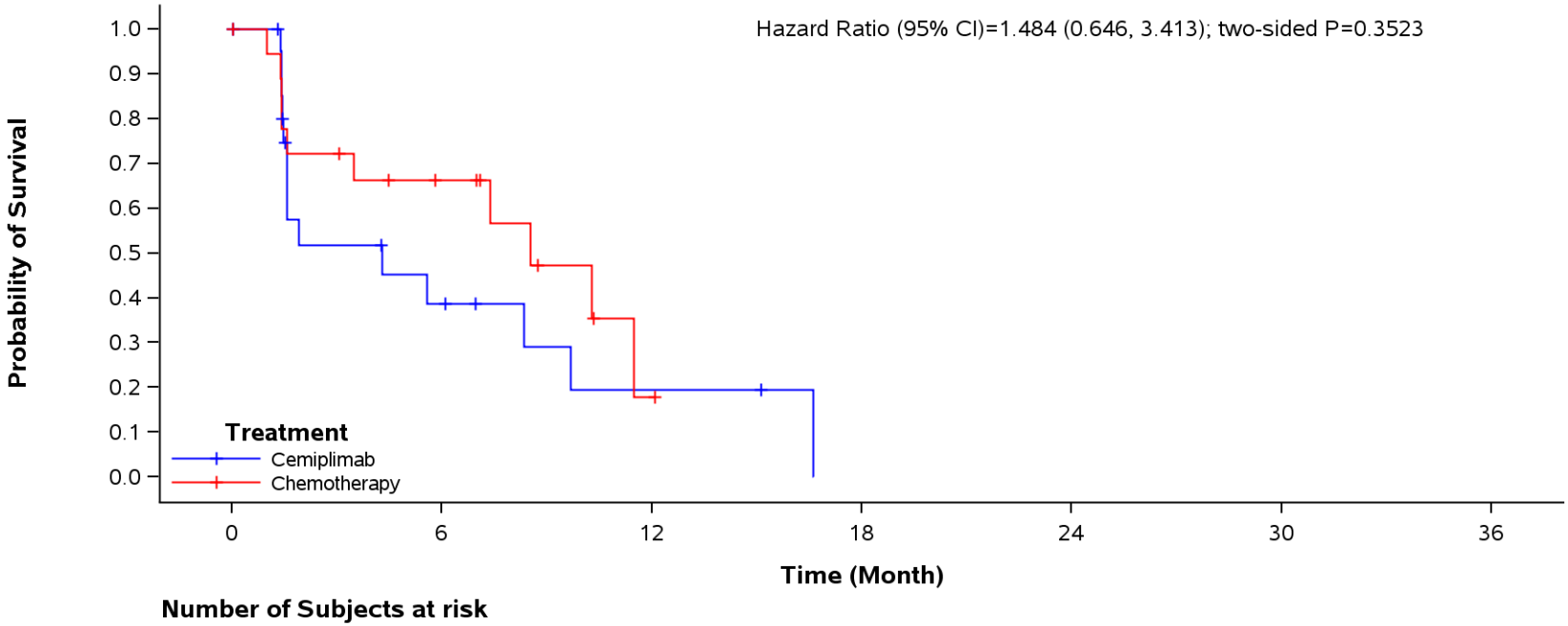

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Fatigue - 10 pts sustained deterioration



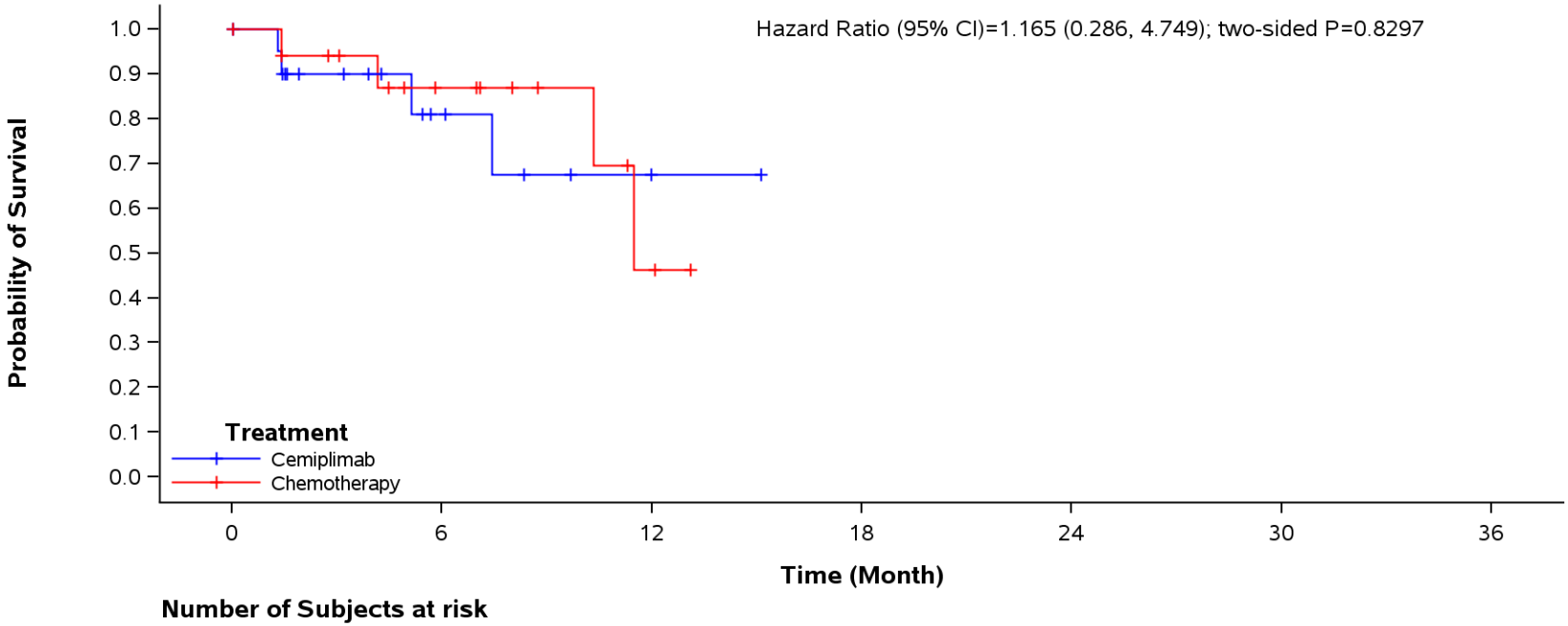

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Financial Problems - 10 pts sustained deterioration



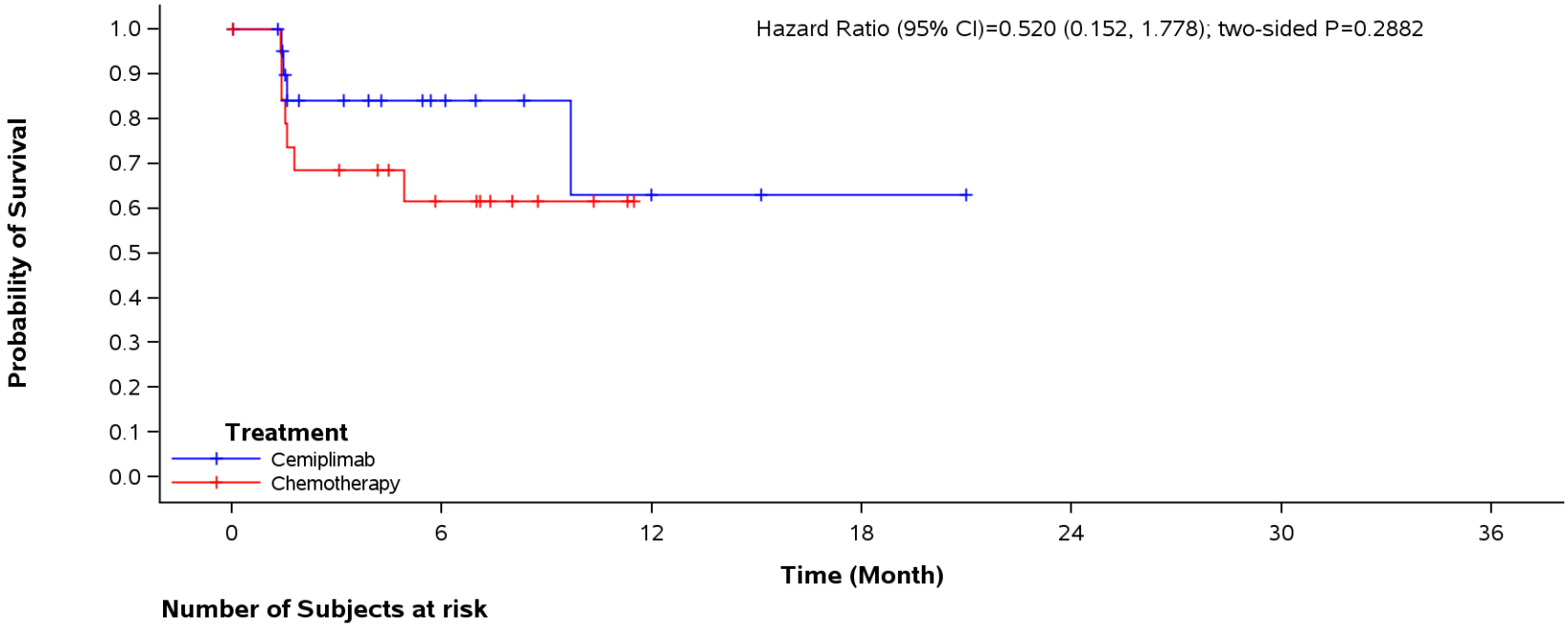

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Nausea / Vomiting - 10 pts sustained deterioration



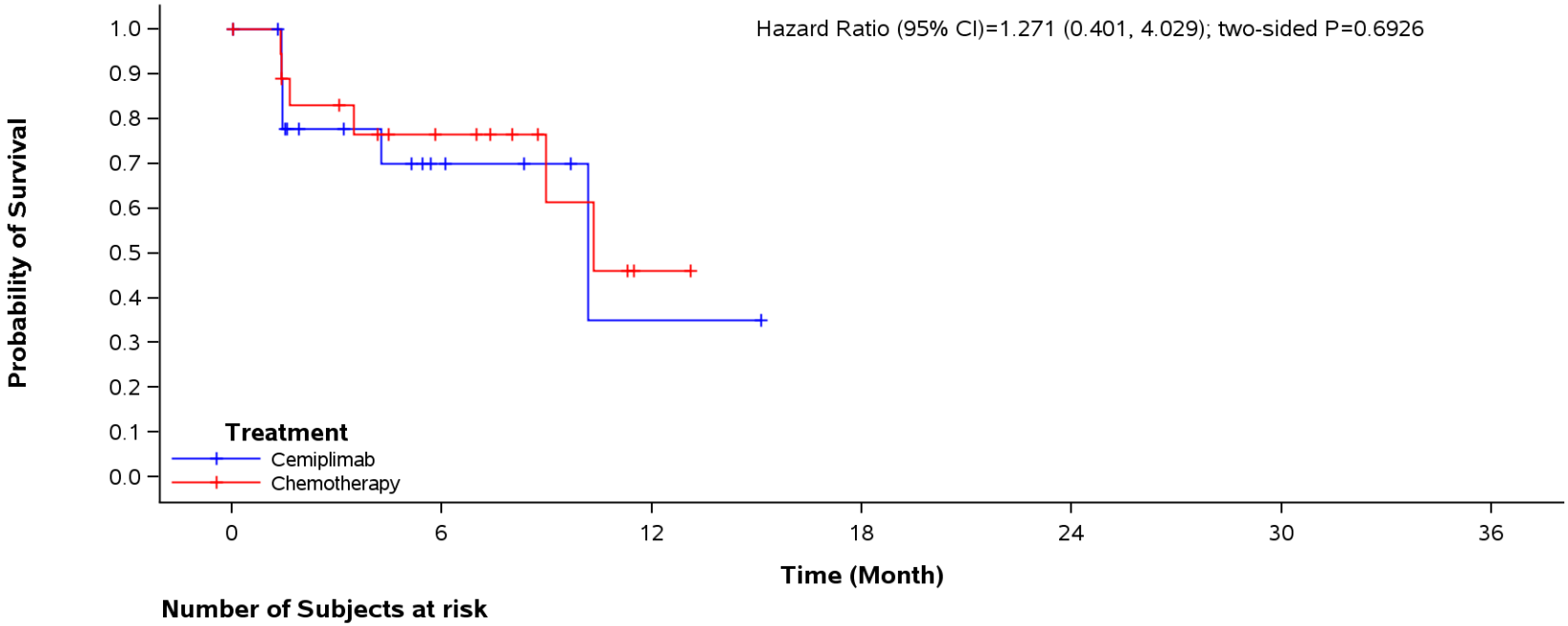

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 8 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Pain - 10 pts sustained deterioration



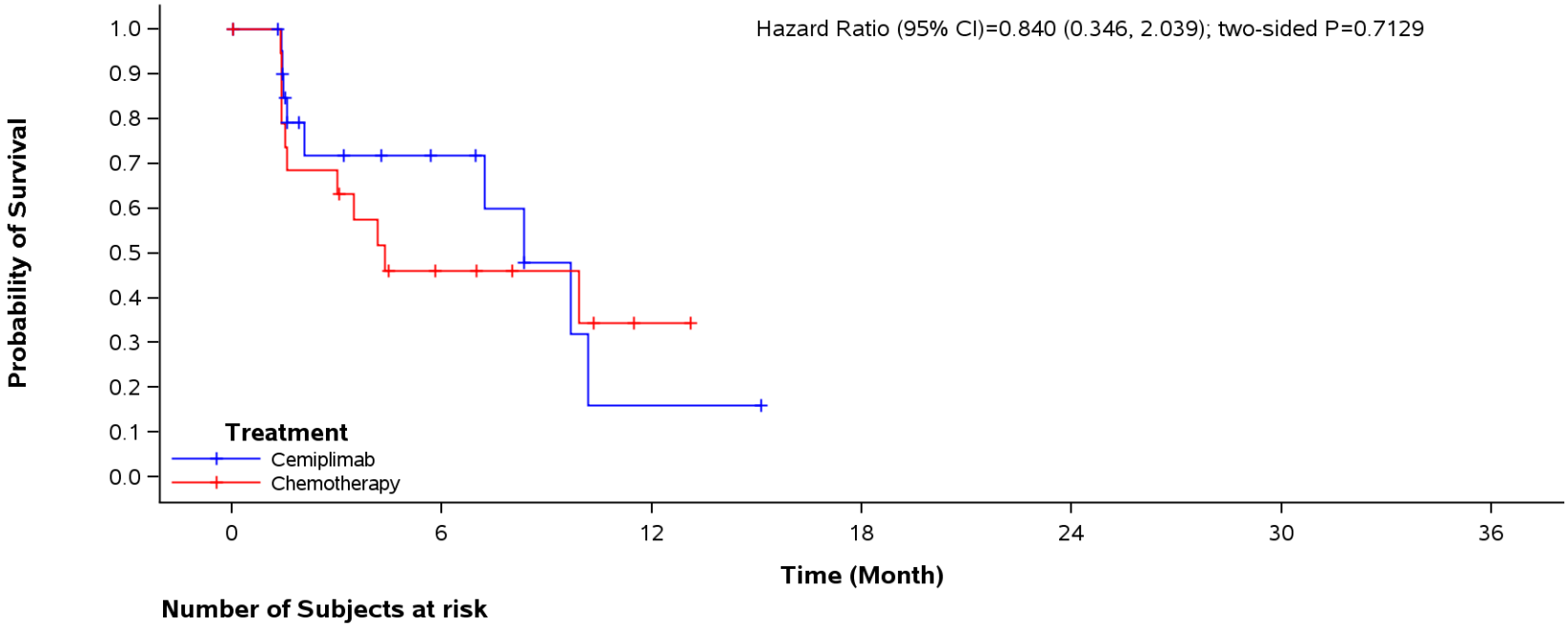

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Physical Functioning - 10 pts sustained deterioration



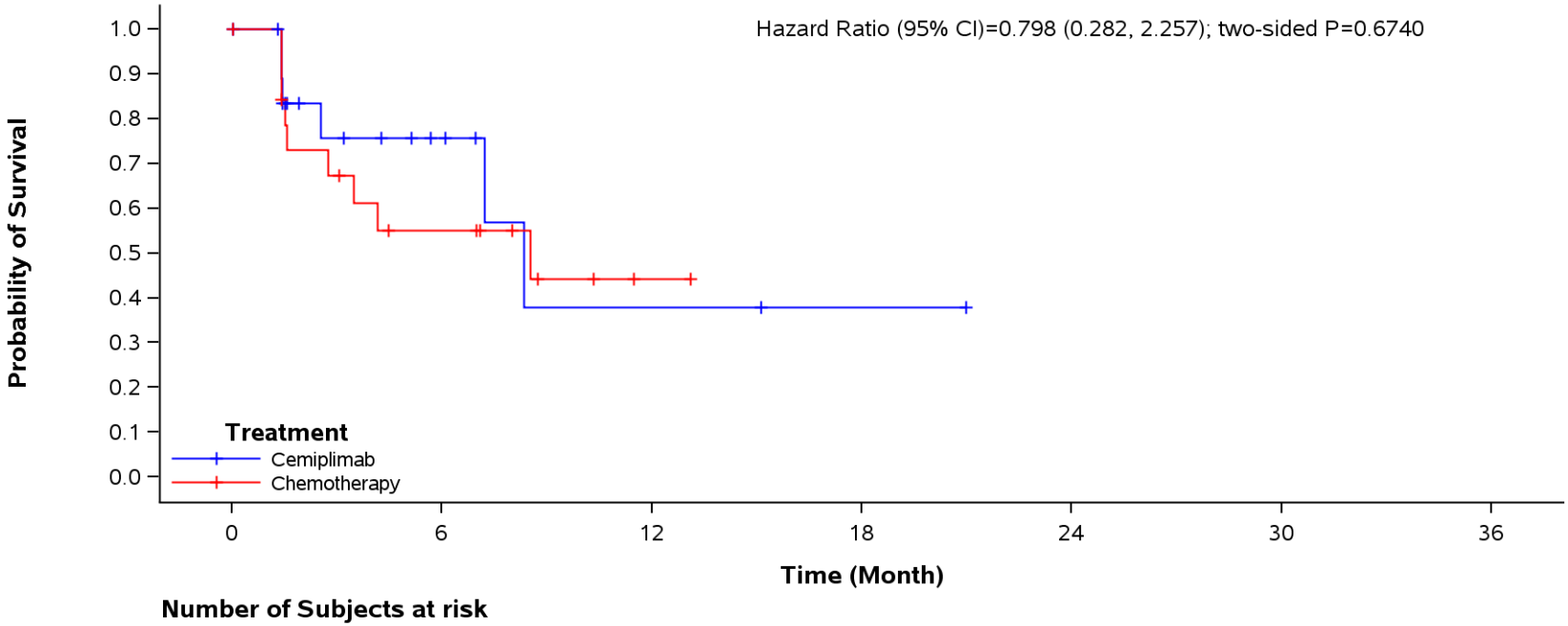

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 7 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Global health status / QoL - 10 pts sustained deterioration



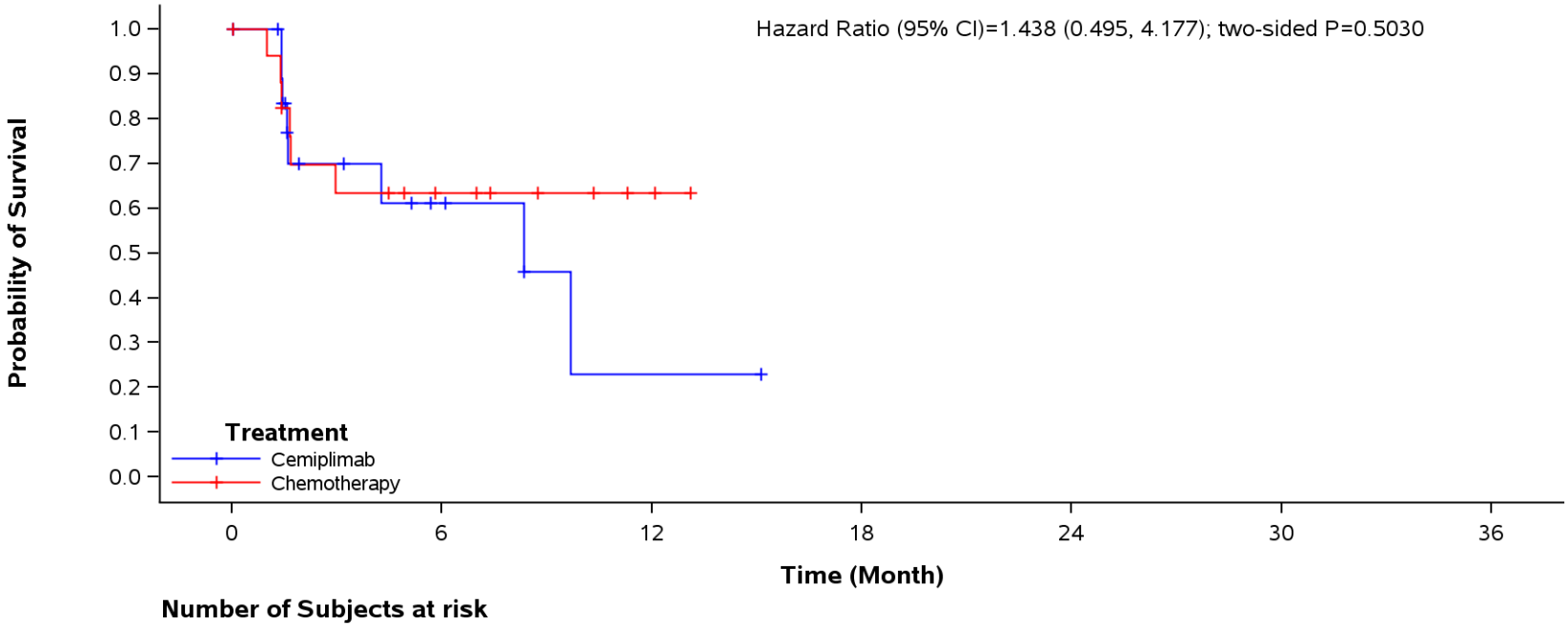

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Role Functioning - 10 pts sustained deterioration



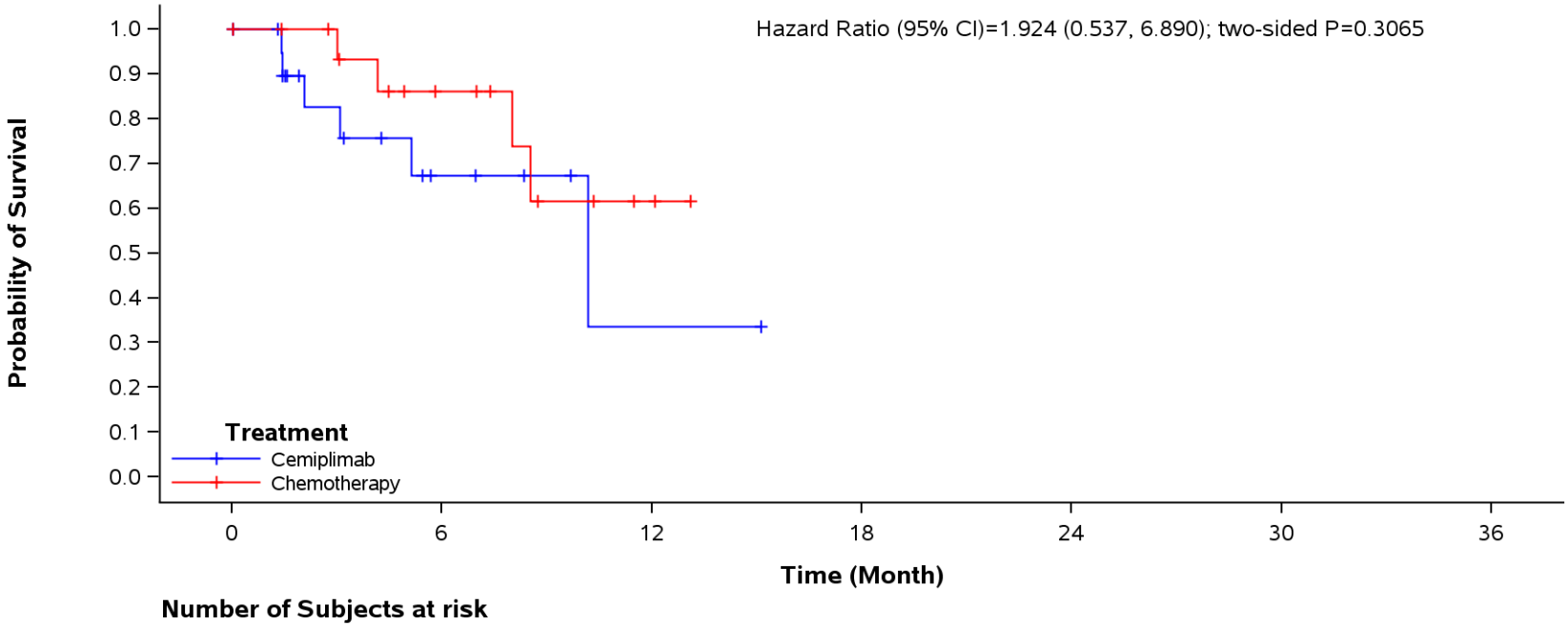

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 7 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Social Functioning - 10 pts sustained deterioration



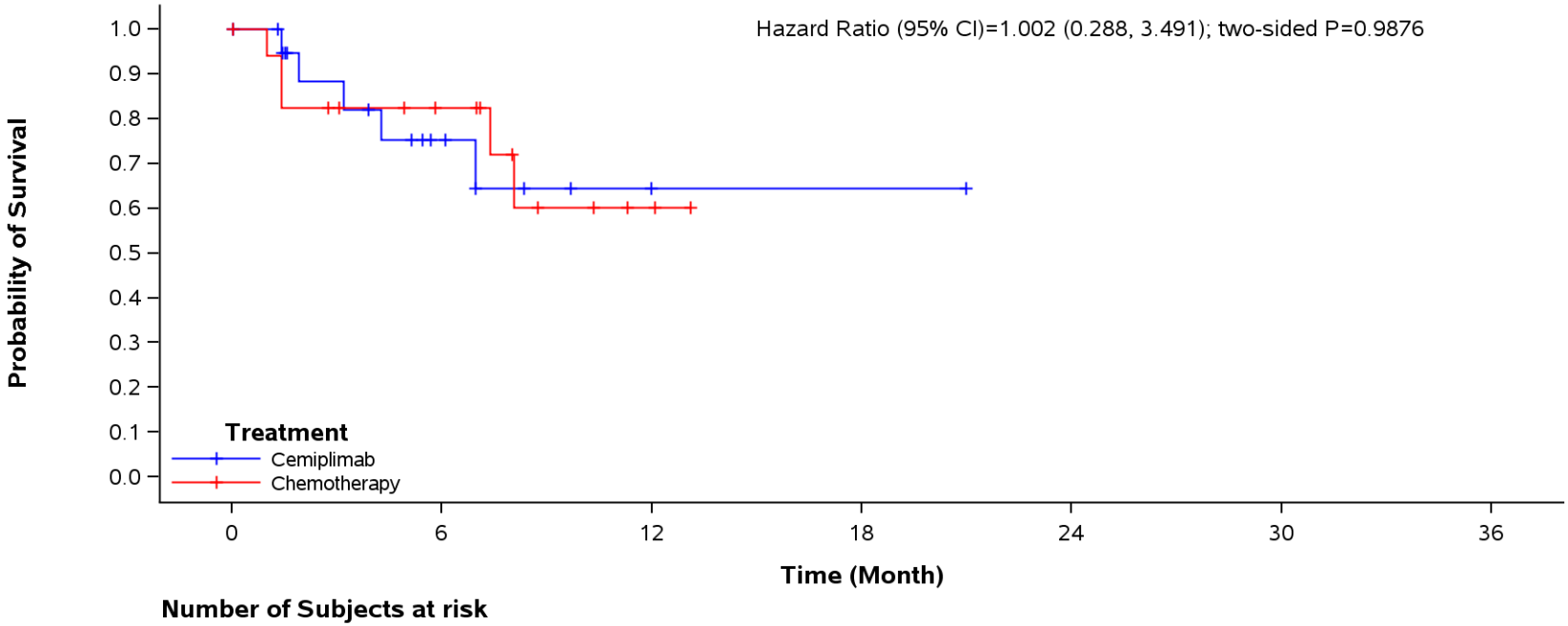

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 30 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC <1%
Insomnia - 10 pts sustained deterioration



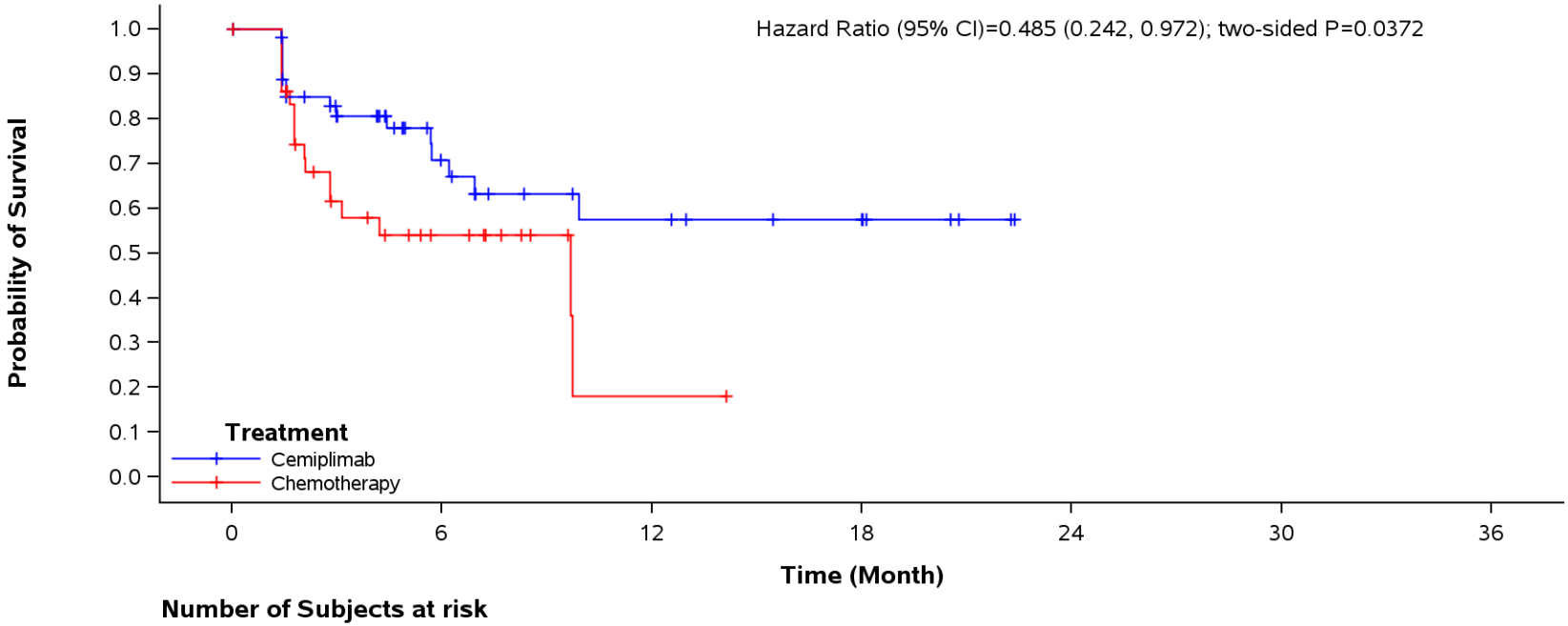

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 29 | 8 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 30 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Appetite loss - 10 pts sustained deterioration




**Number of Subjects at risk**

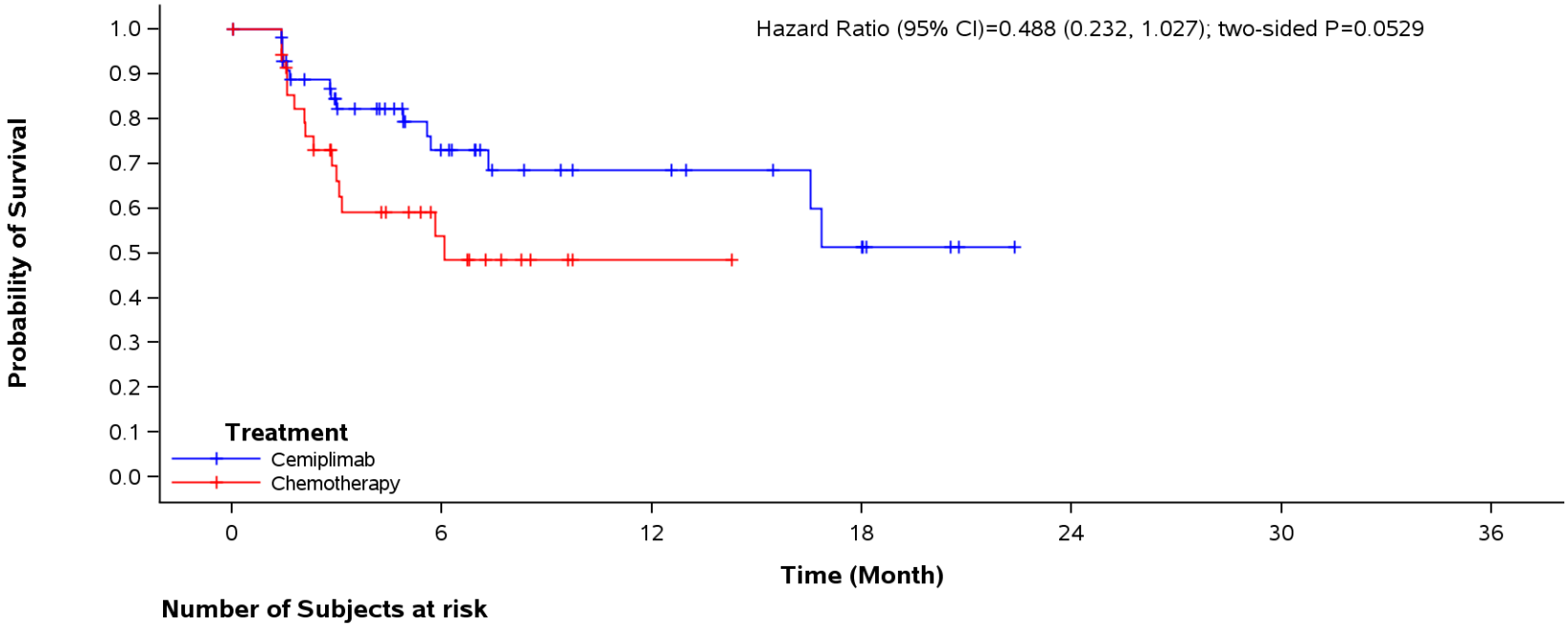
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 19 | 10 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%

Cognitive Functioning - 10 pts sustained deterioration




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 11 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 1 | 0 | 0 | 0 | 0 |

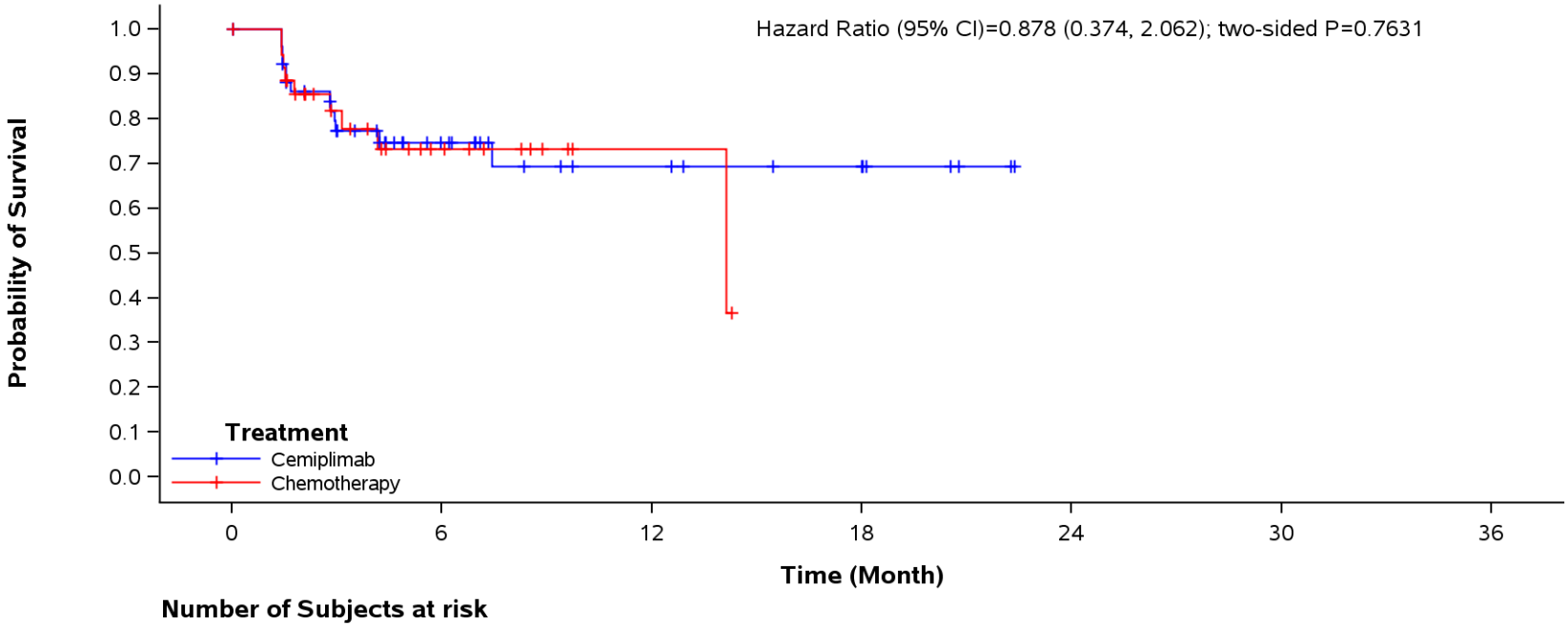
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Constipation - 10 pts sustained deterioration



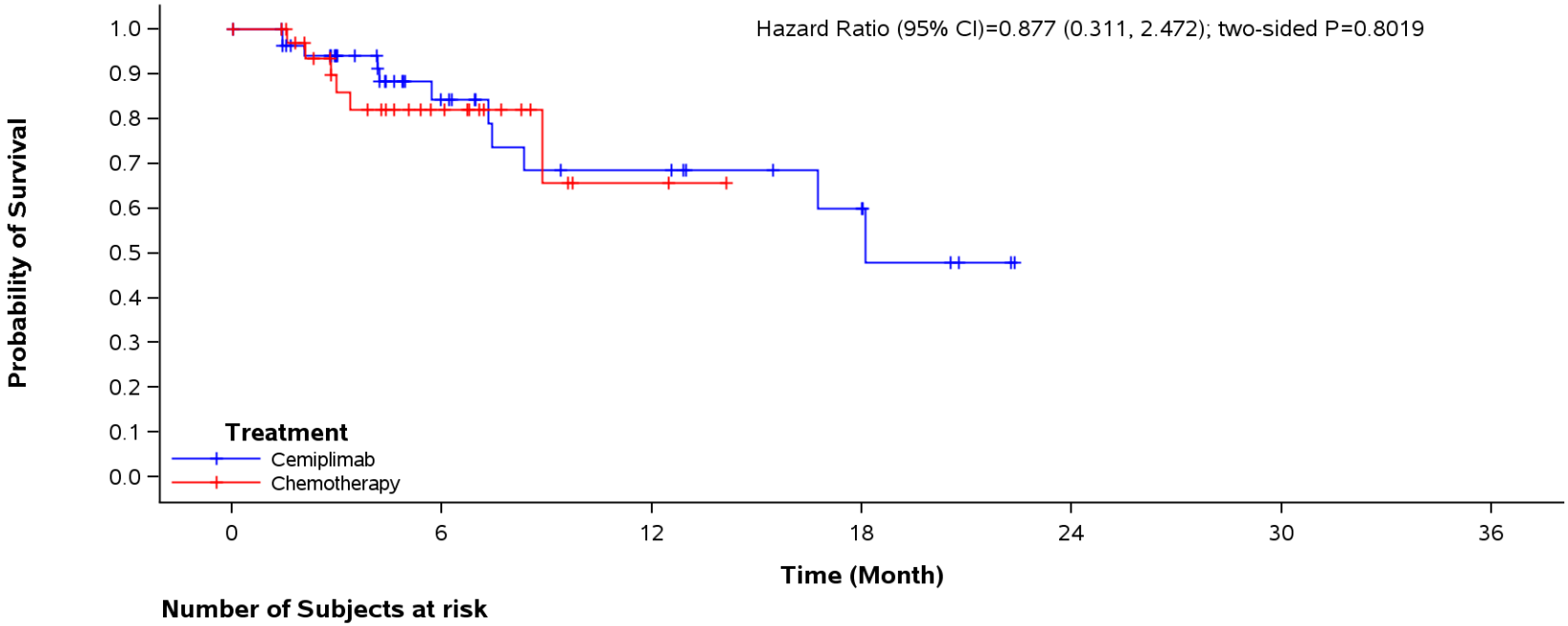

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 20 | 10 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Diarhoea - 10 pts sustained deterioration



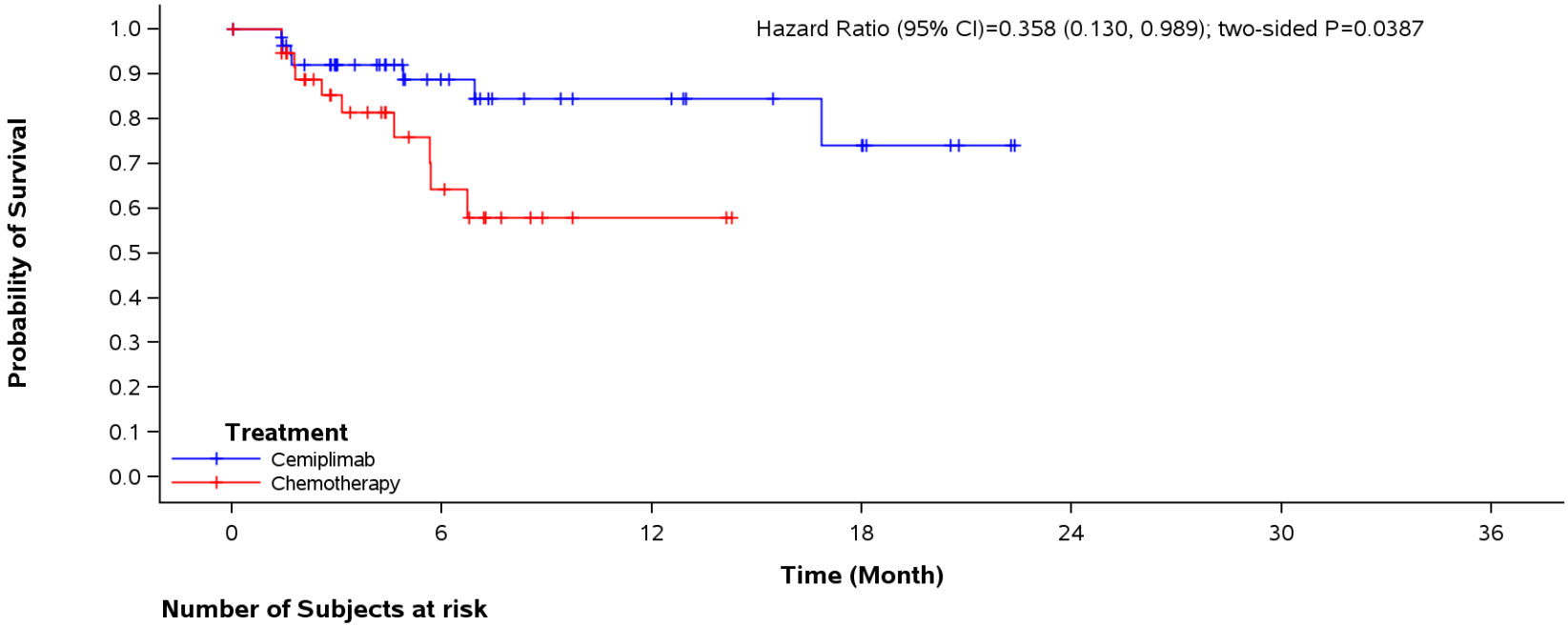

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 20 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Dyspnoea - 10 pts sustained deterioration



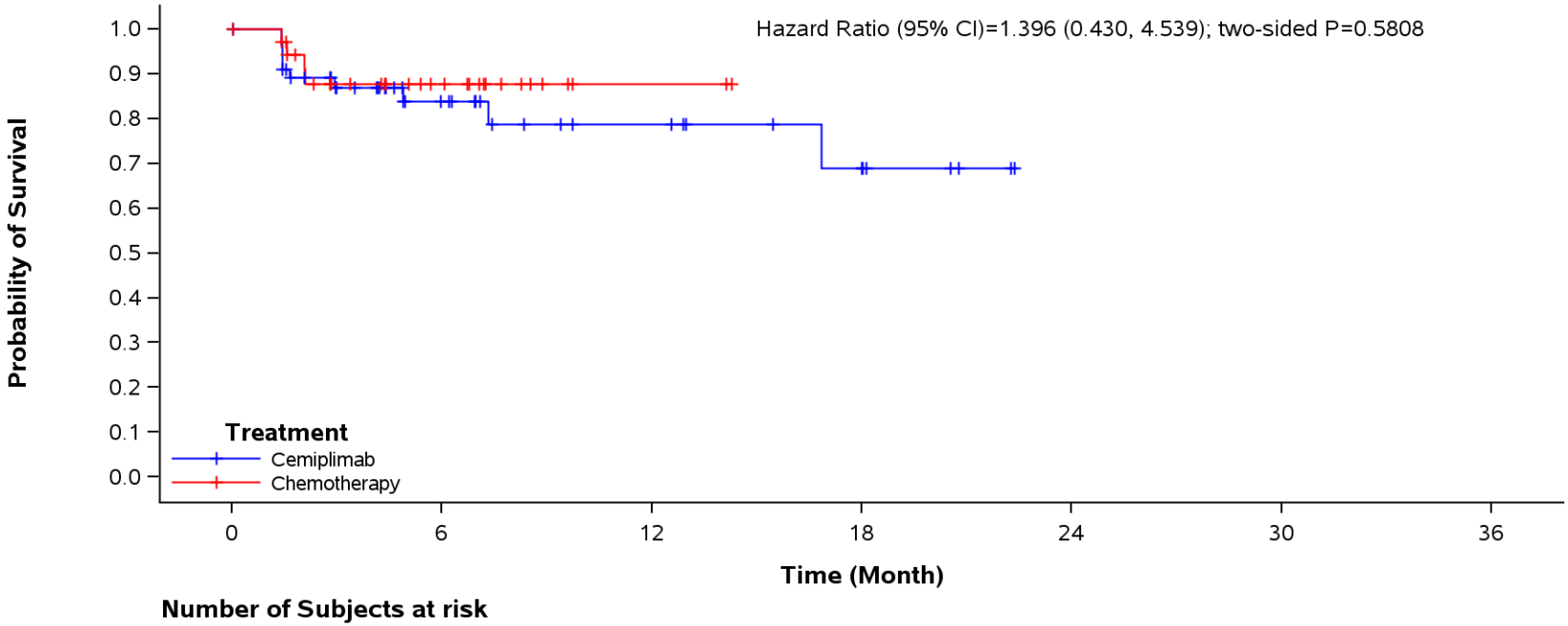

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Emotional Functioning - 10 pts sustained deterioration



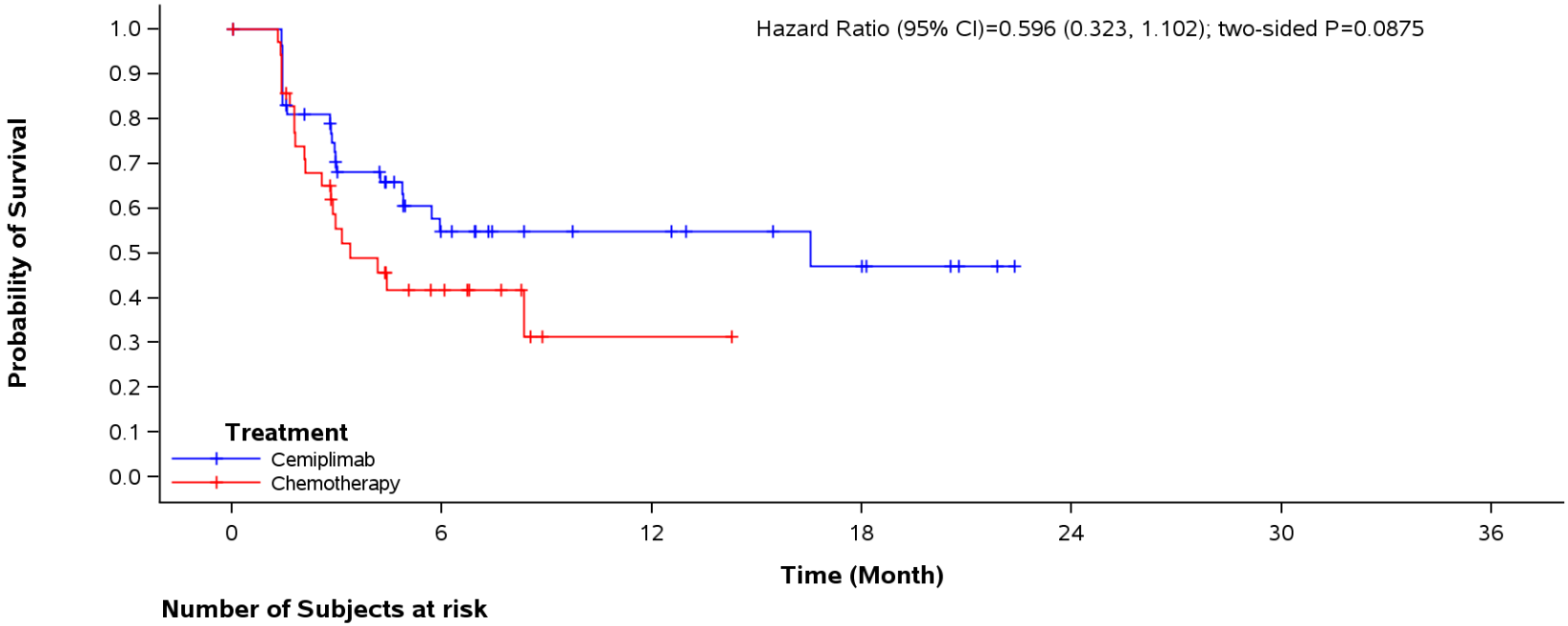

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 23 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Fatigue - 10 pts sustained deterioration



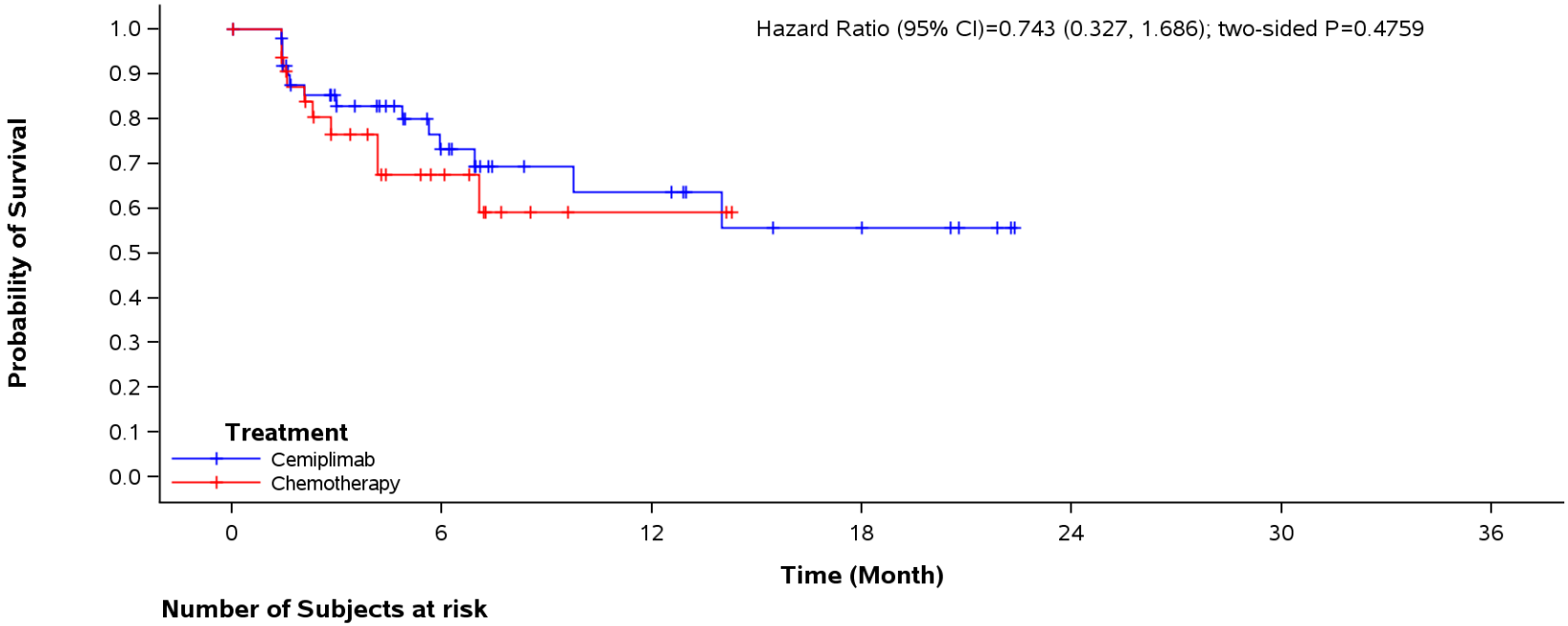

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 18 | 10 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Financial Problems - 10 pts sustained deterioration



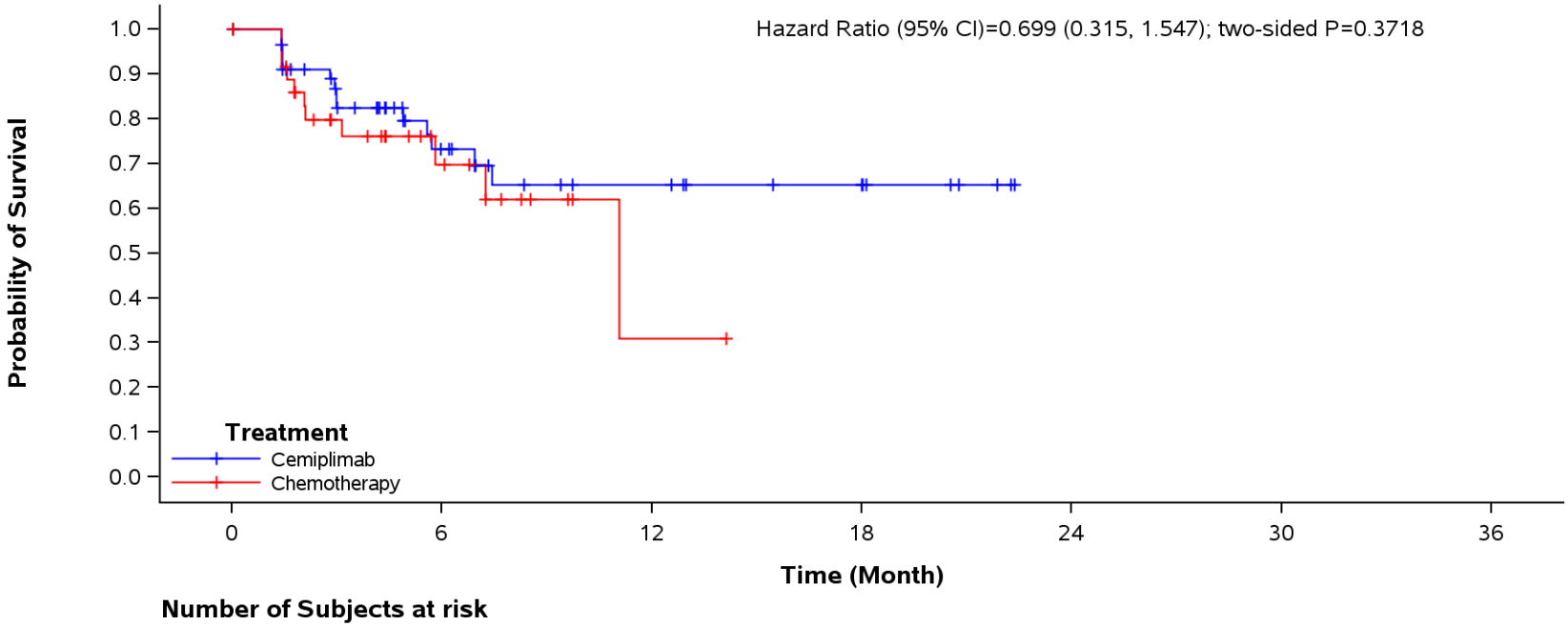

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 21 | 11 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Nausea / Vomiting - 10 pts sustained deterioration



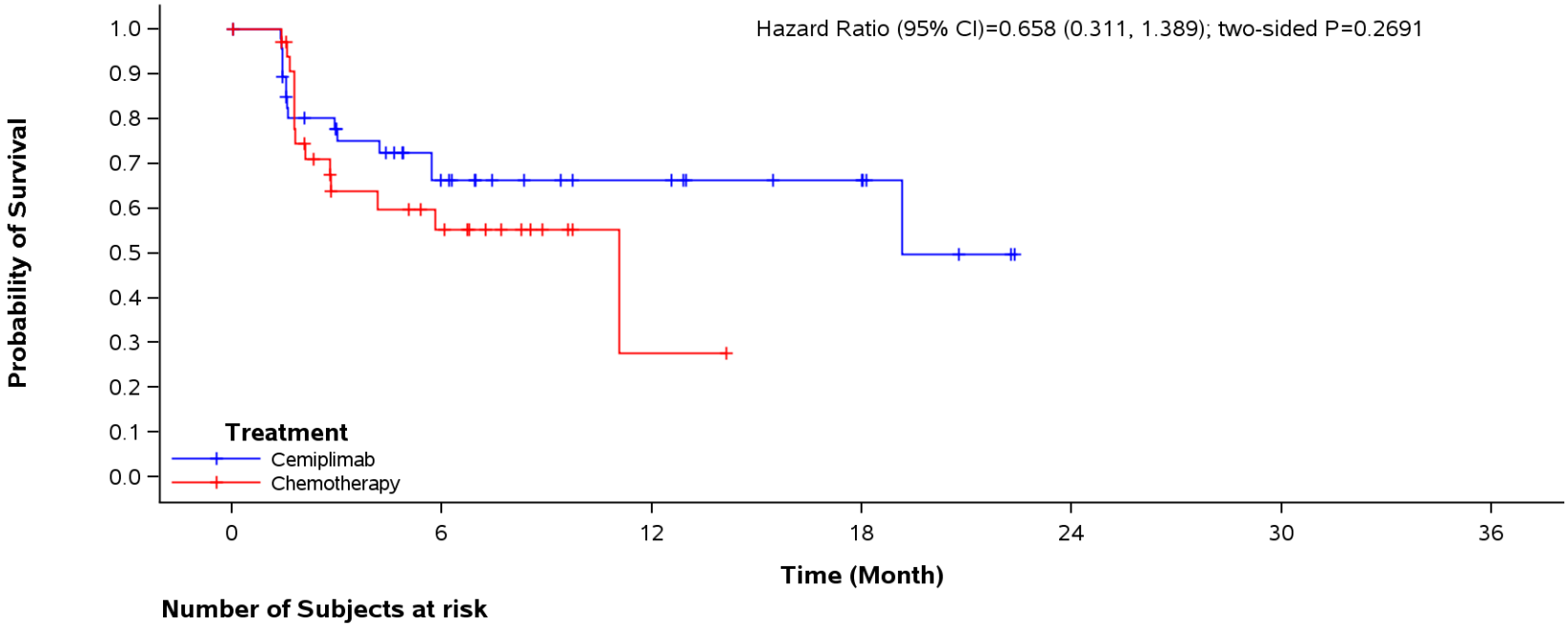

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 12 | 8 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Pain - 10 pts sustained deterioration



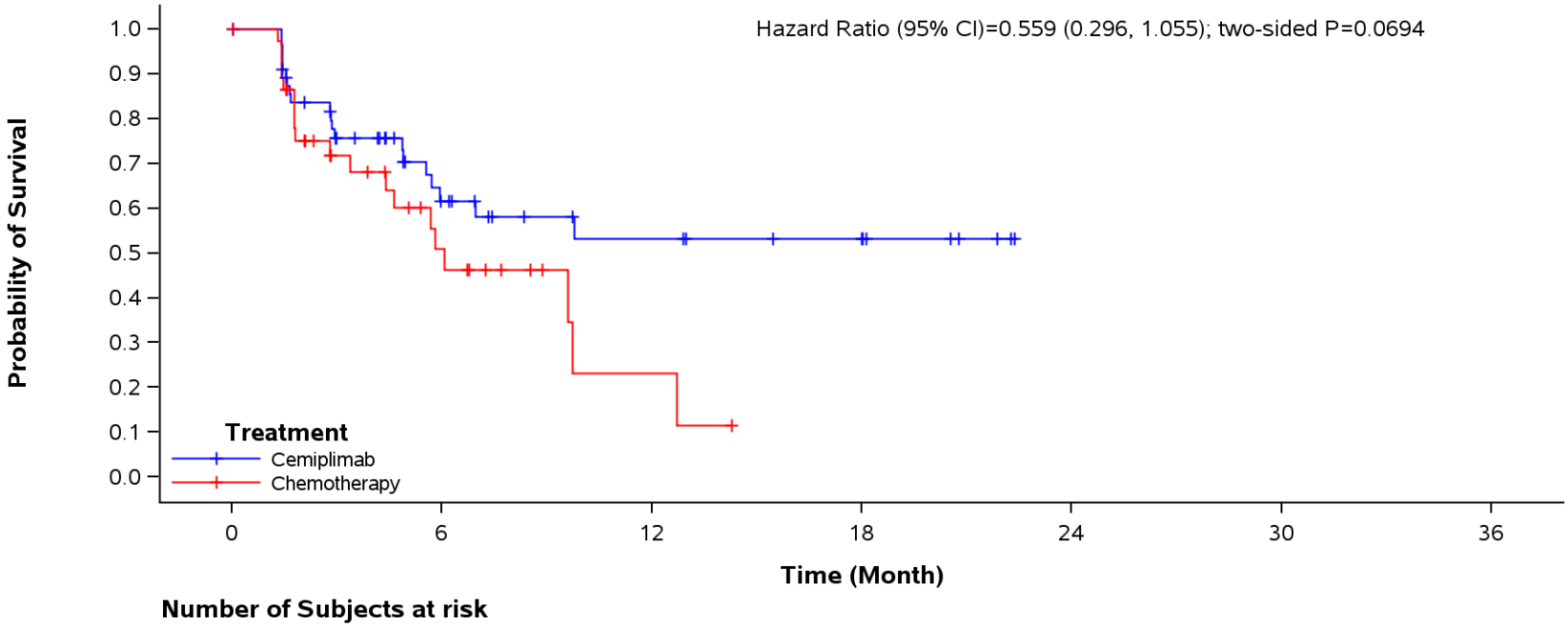

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 20 | 11 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Physical Functioning - 10 pts sustained deterioration



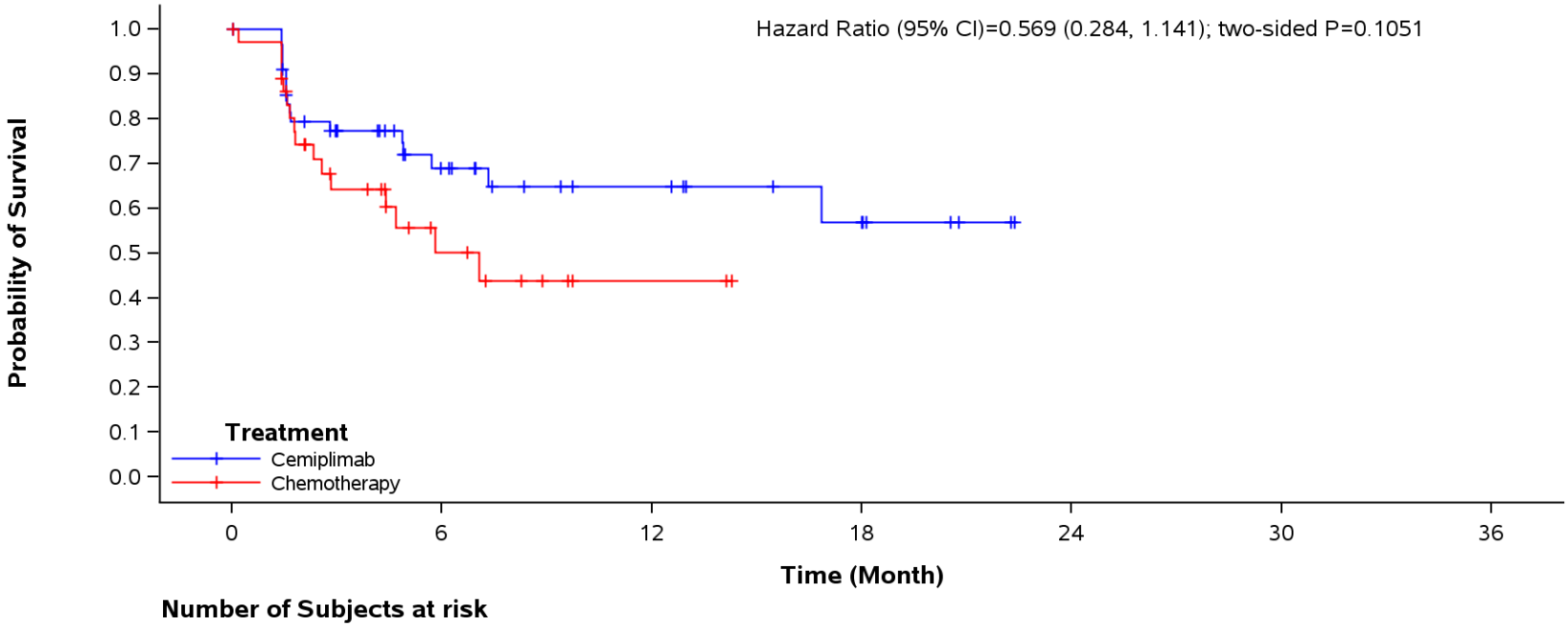

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 20 | 11 | 8 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Global health status / QoL - 10 pts sustained deterioration



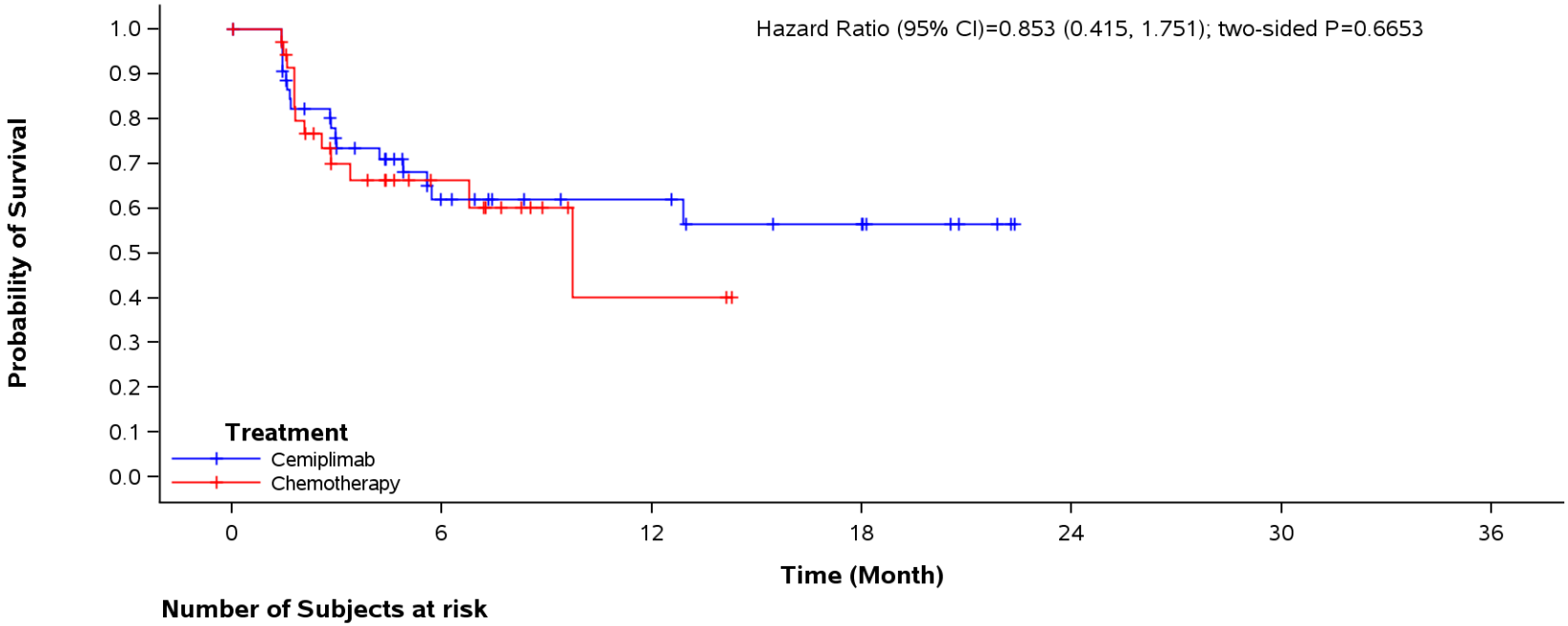

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Role Functioning - 10 pts sustained deterioration



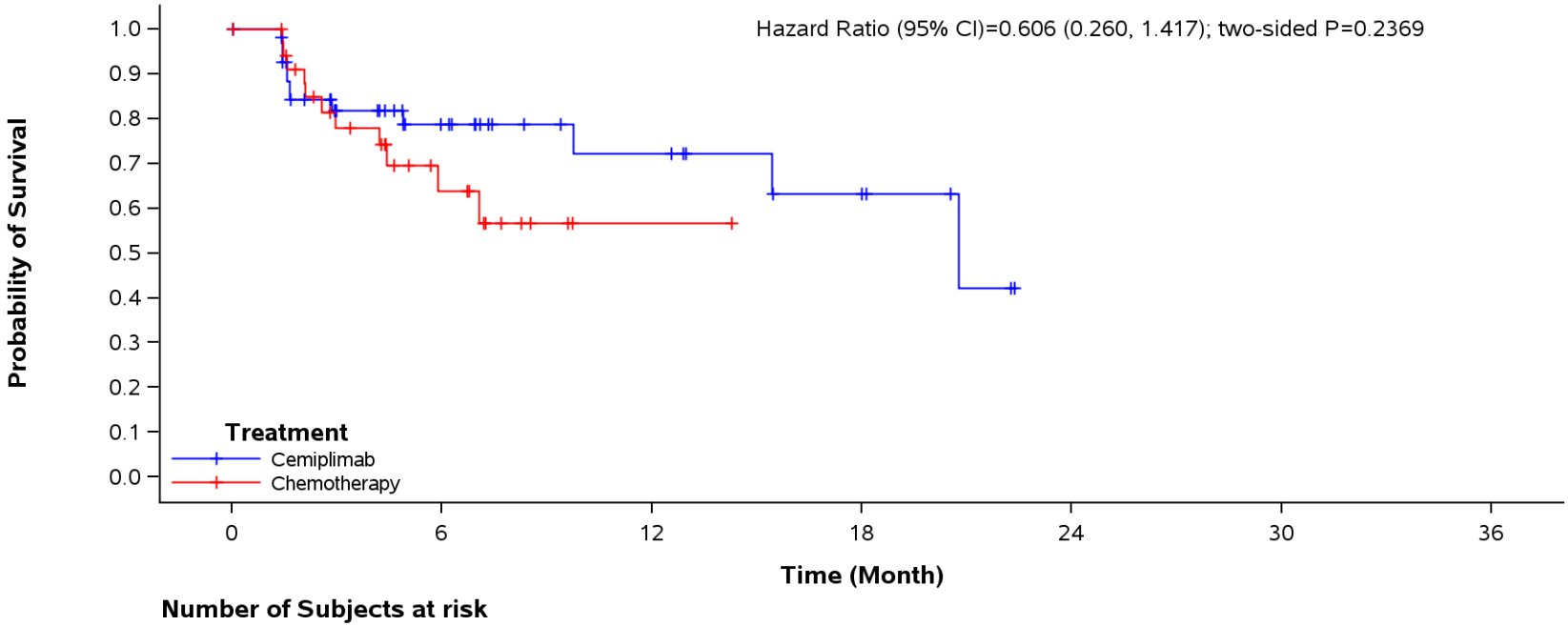

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 19 | 12 | 8 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Social Functioning - 10 pts sustained deterioration



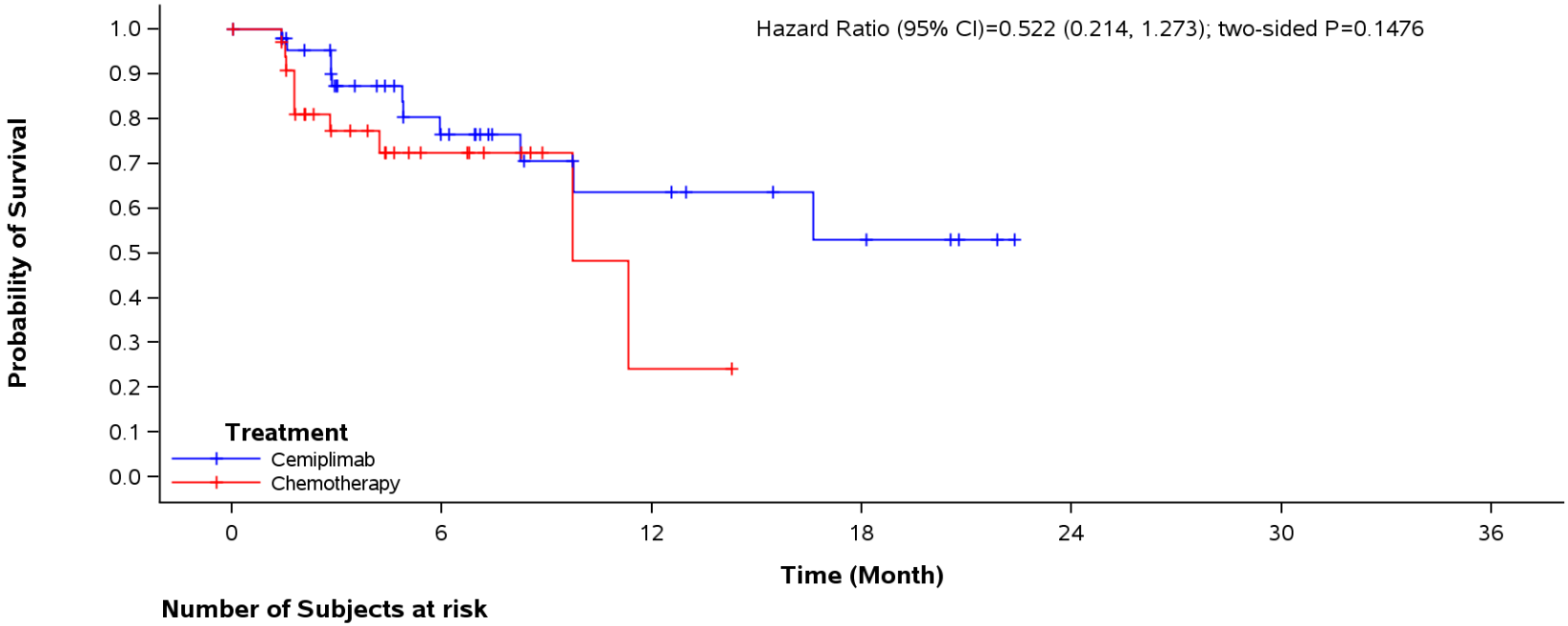

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 22 | 11 | 6 | 0 | 0 | 0 |
| Chemotherapy | 50 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 2.3.6a. Time to First Sustained Deterioration with C30 10-points Threshold, Last Observation Carried Forward by Subgroup for PD-L1 (Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: TC >=1%
Insomnia - 10 pts sustained deterioration

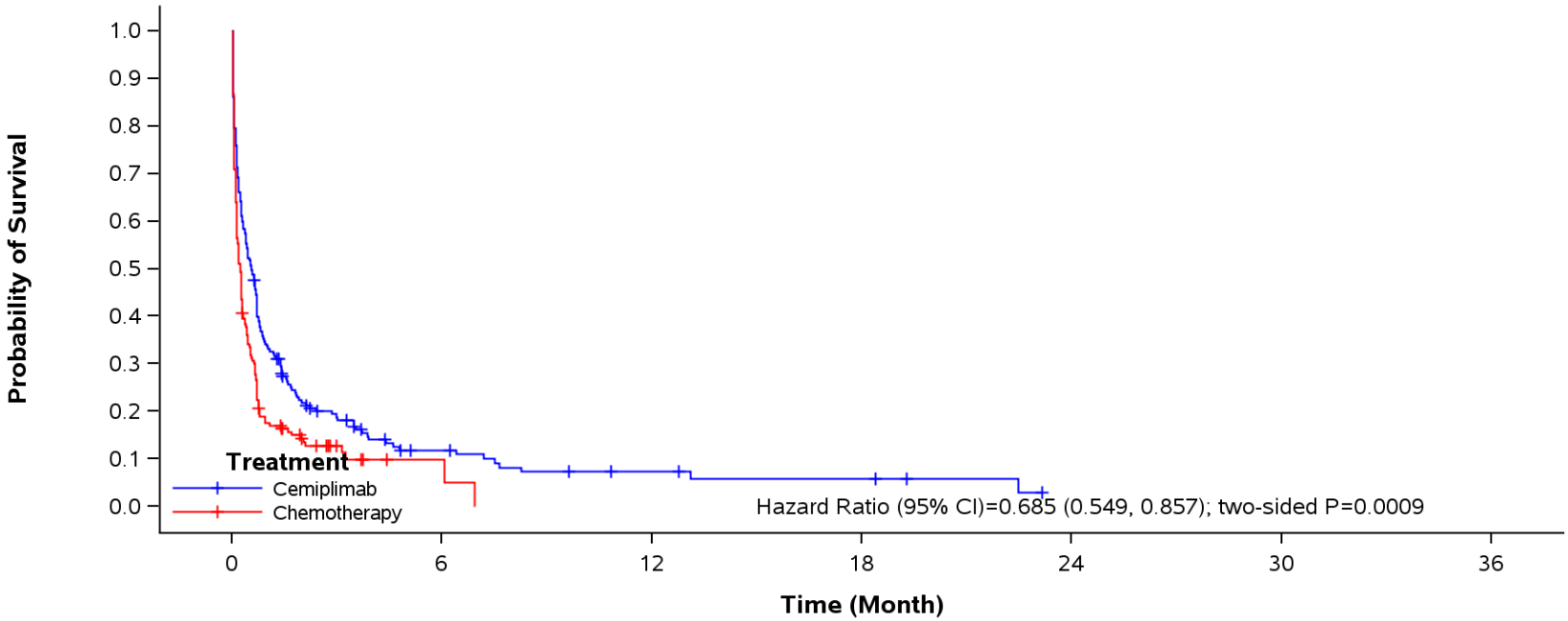



Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 62 | 19 | 9 | 5 | 0 | 0 | 0 |
| Chemotherapy | 50 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Post baseline score is imputed using LOCF, then sustained deterioration means those with consecutive achievement of 10 points deterioration till the last assessment. For all 10 points deterioration included in sustained deterioration, the date of first 10 points deterioration is used in the calculation of time. Time is defined as (date of first 10 points sustained deterioration - Date of Randomization +1)/ 365.25*12

Figure 3.1.1. Time to First Any Treatment-Emergent Adverse Events
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

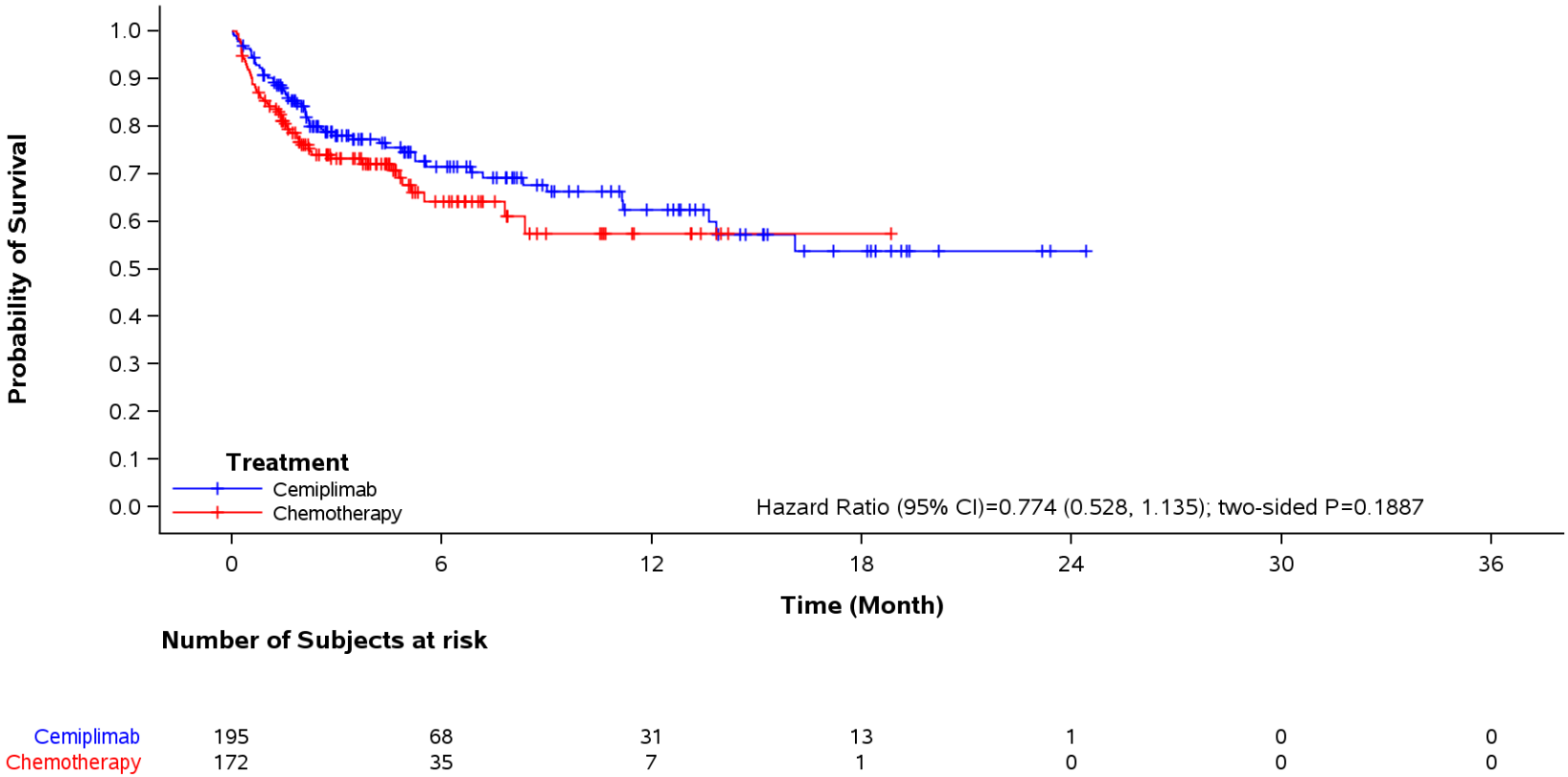



**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 14 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 172 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.1.2. Time to First Any Serious Treatment-Emergent Adverse Events
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

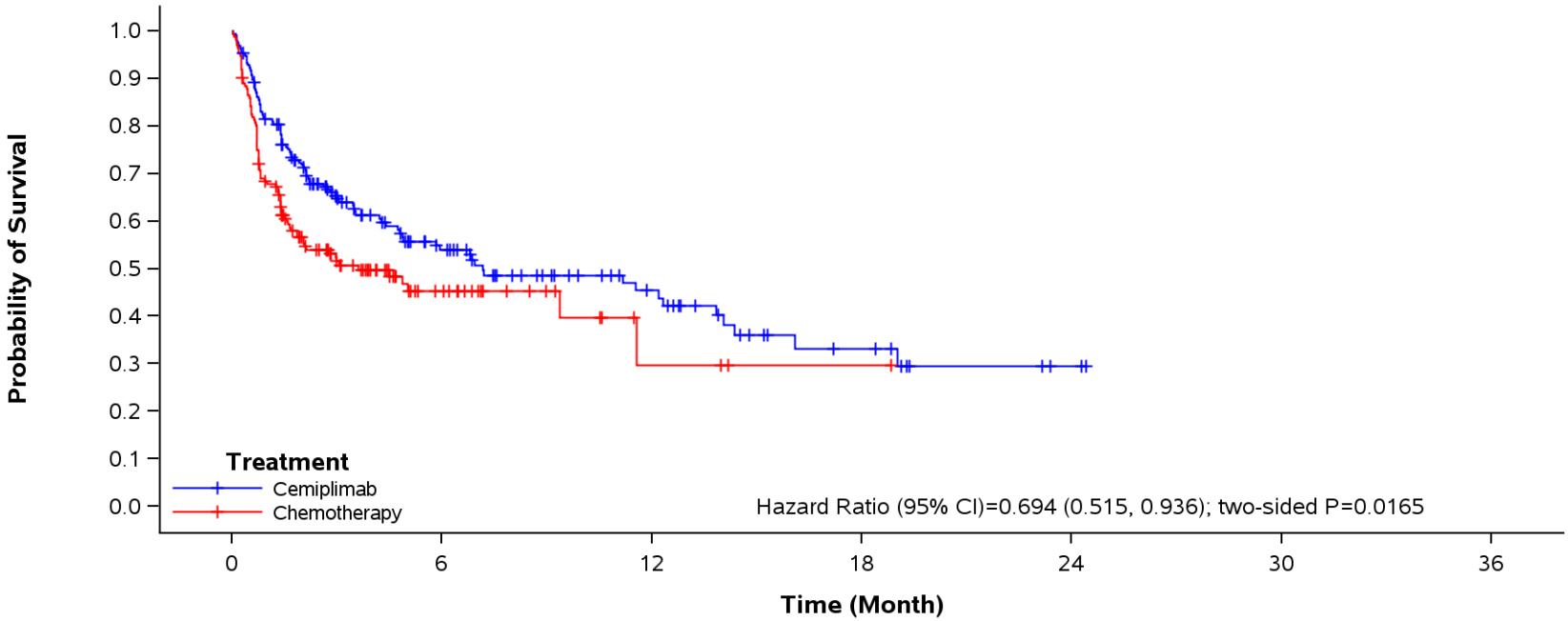



**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 68 | 31 | 13 | 1 | 0 | 0 |
| Chemotherapy | 172 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.1.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

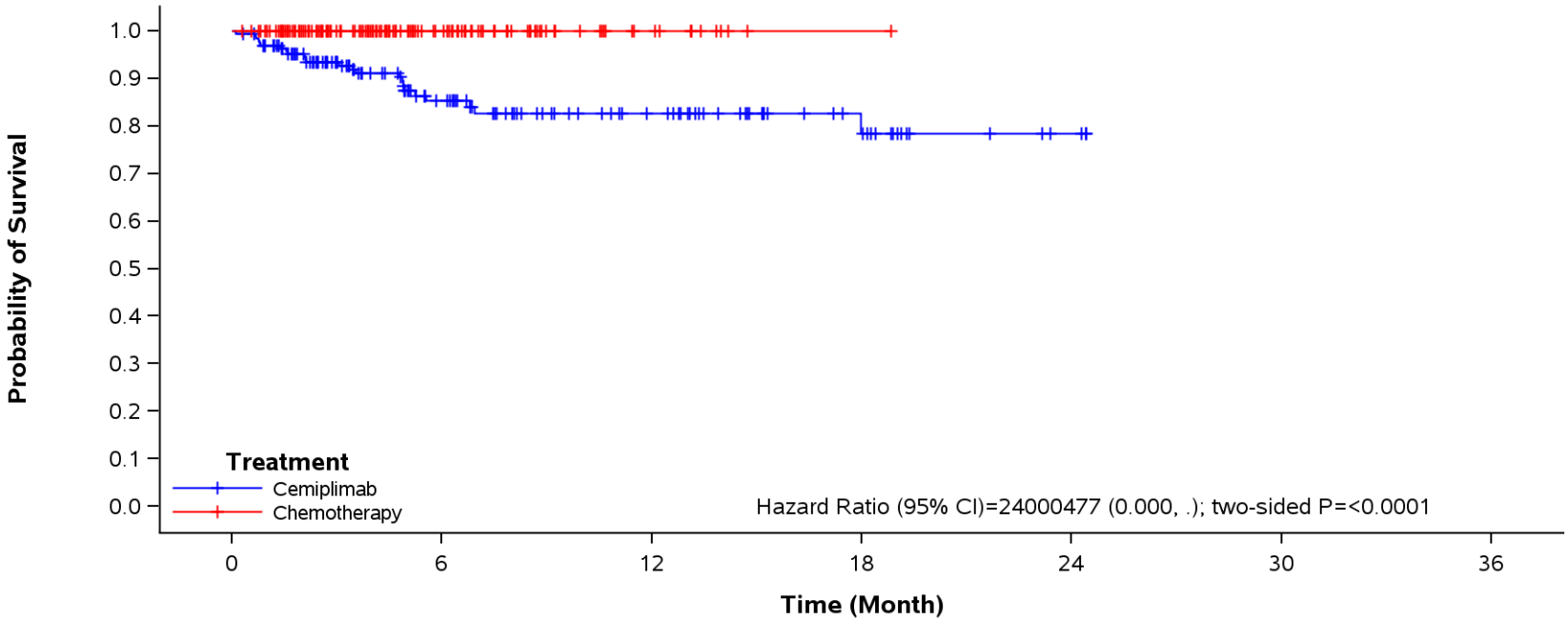



**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 58 | 28 | 11 | 2 | 0 | 0 |
| Chemotherapy | 172 | 24 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.1.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3)
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

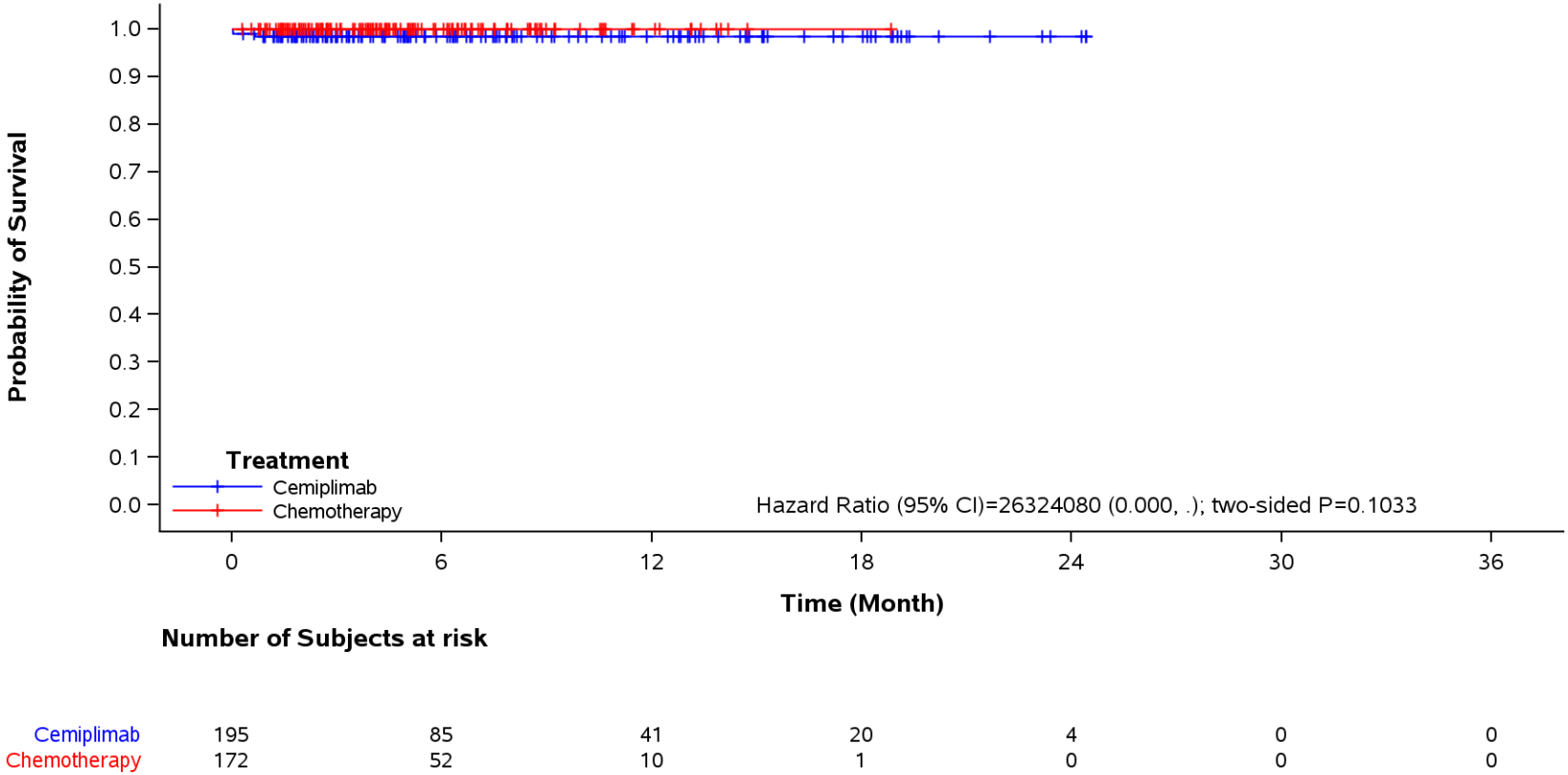



**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 76 | 41 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

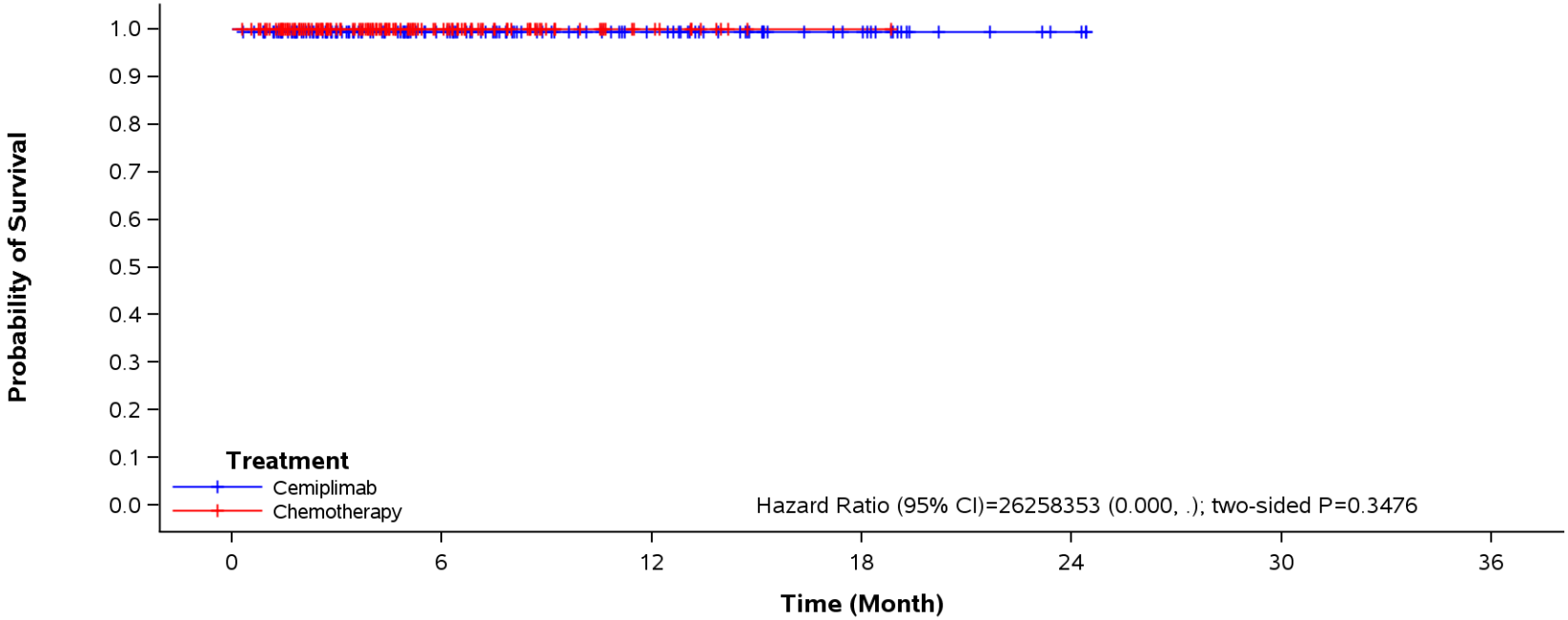
Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.1.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2)
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.1.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2)
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

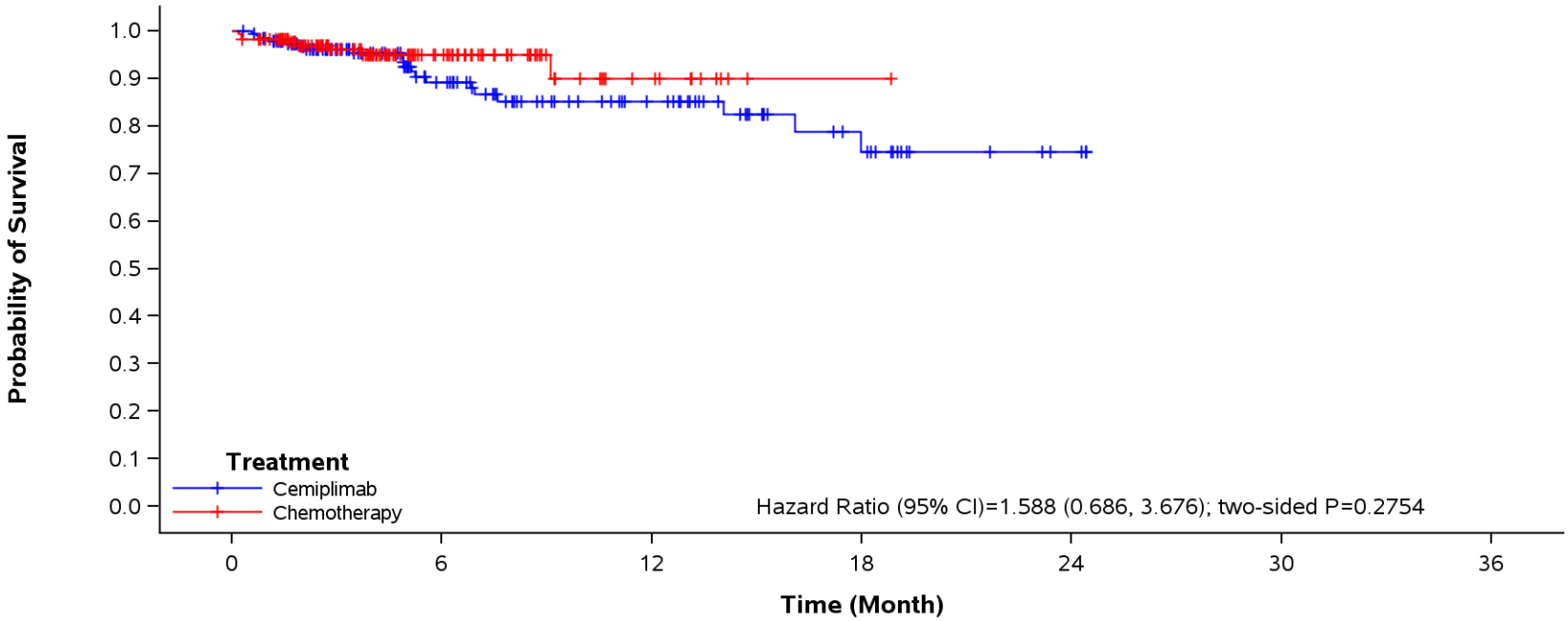



**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.1.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)



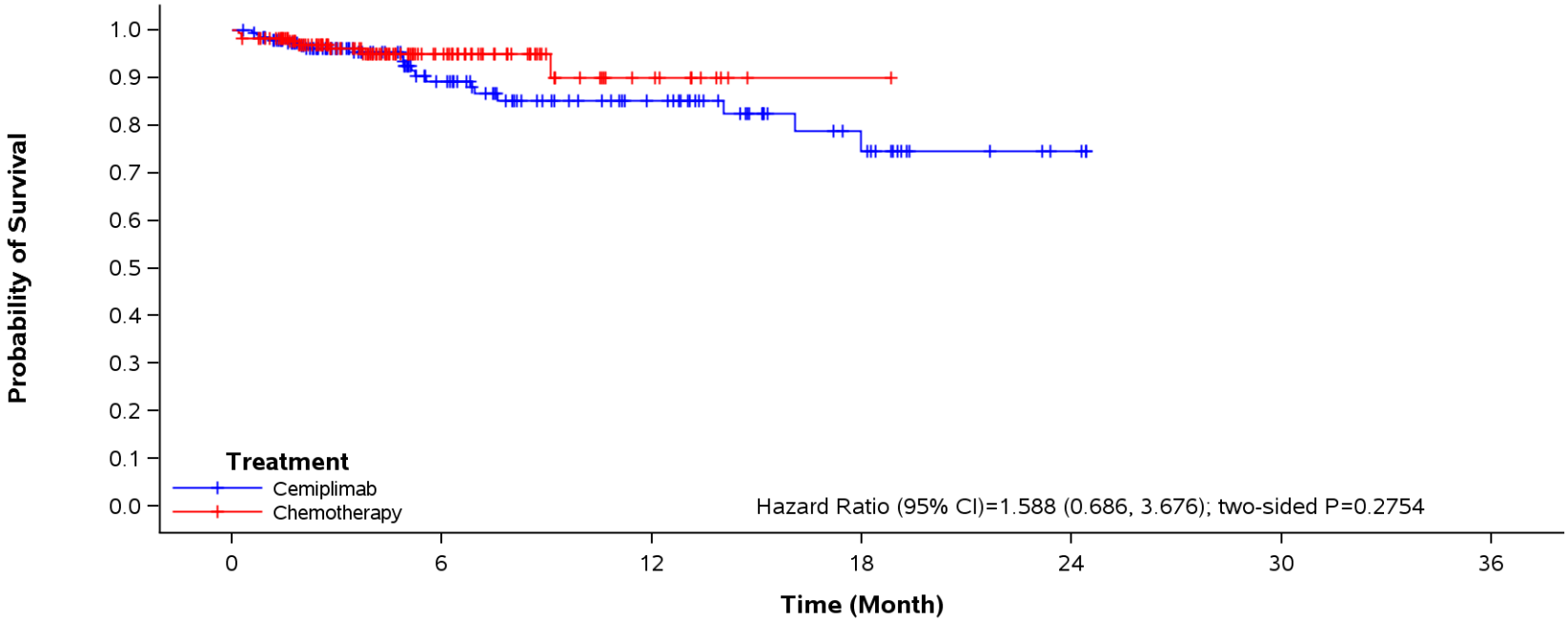

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 78 | 41 | 18 | 4 | 0 | 0 |
| Chemotherapy | 172 | 50 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any TEAE leading to discontinuation



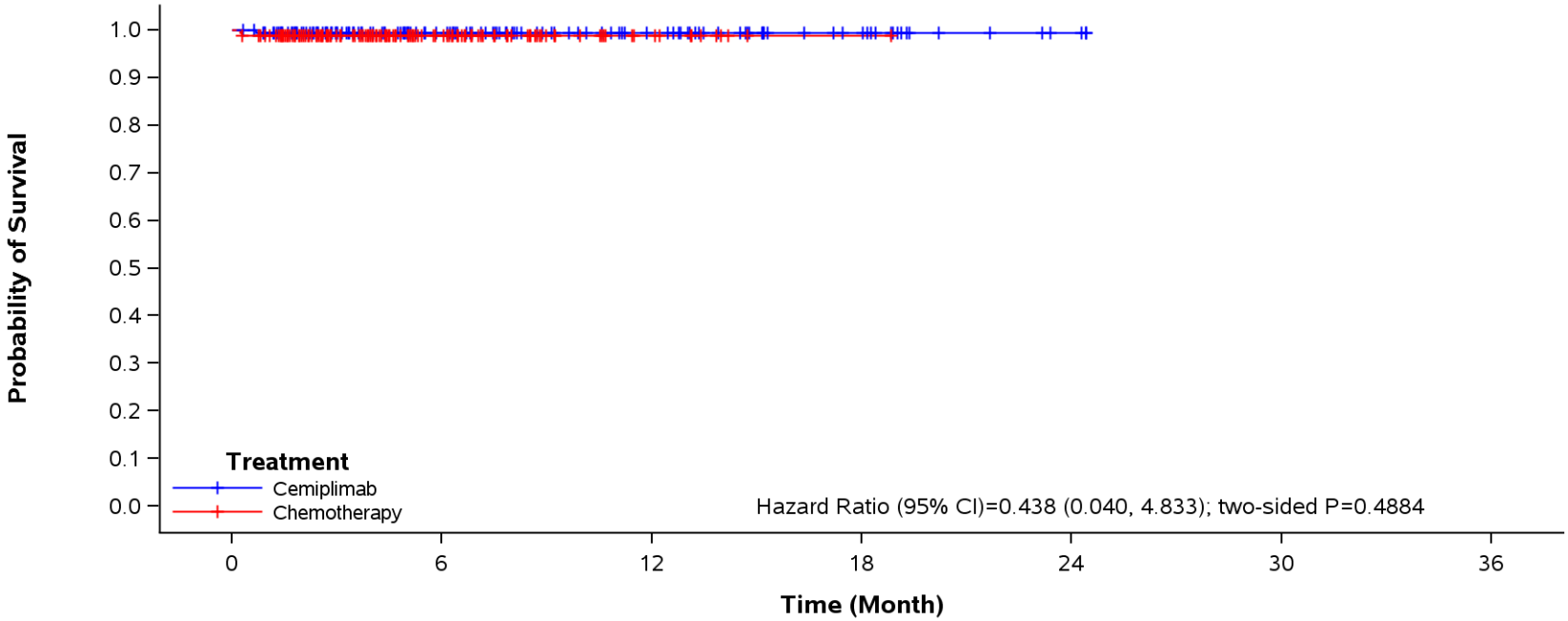

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 78 | 41 | 18 | 4 | 0 | 0 |
| Chemotherapy | 172 | 50 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders



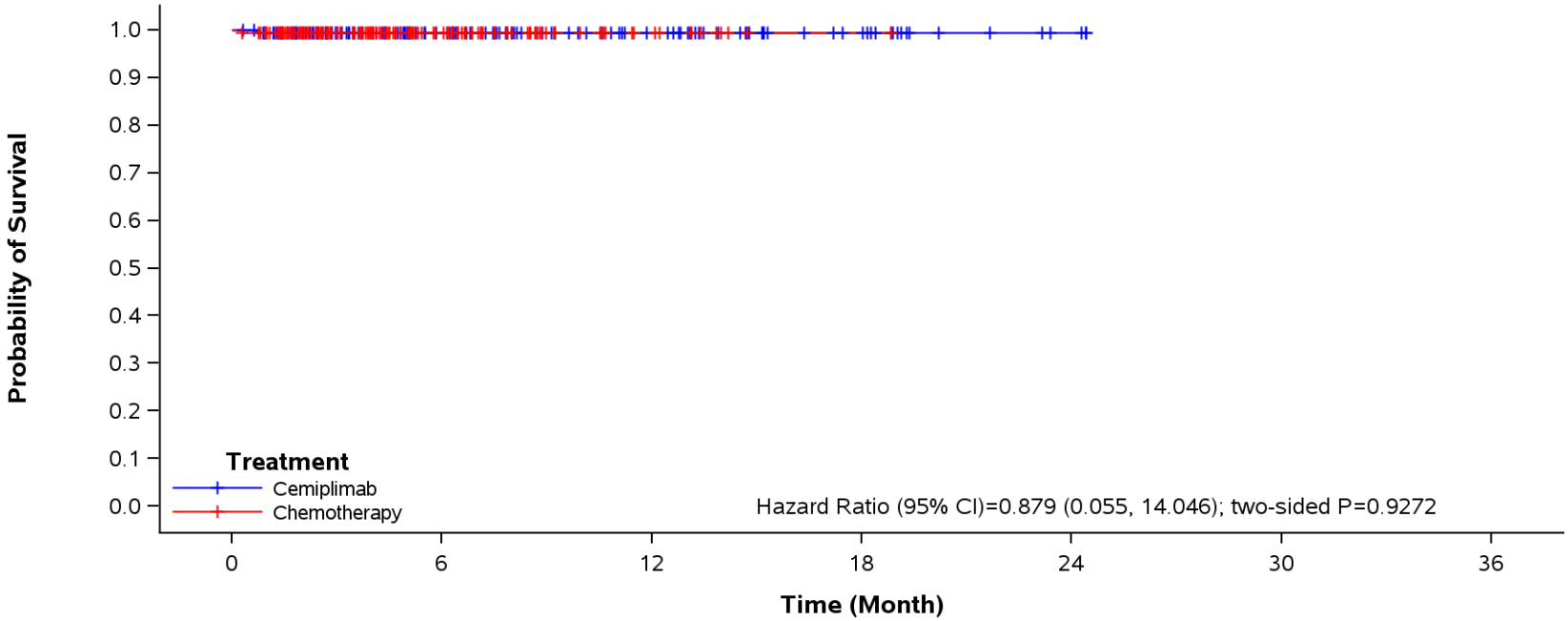

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia



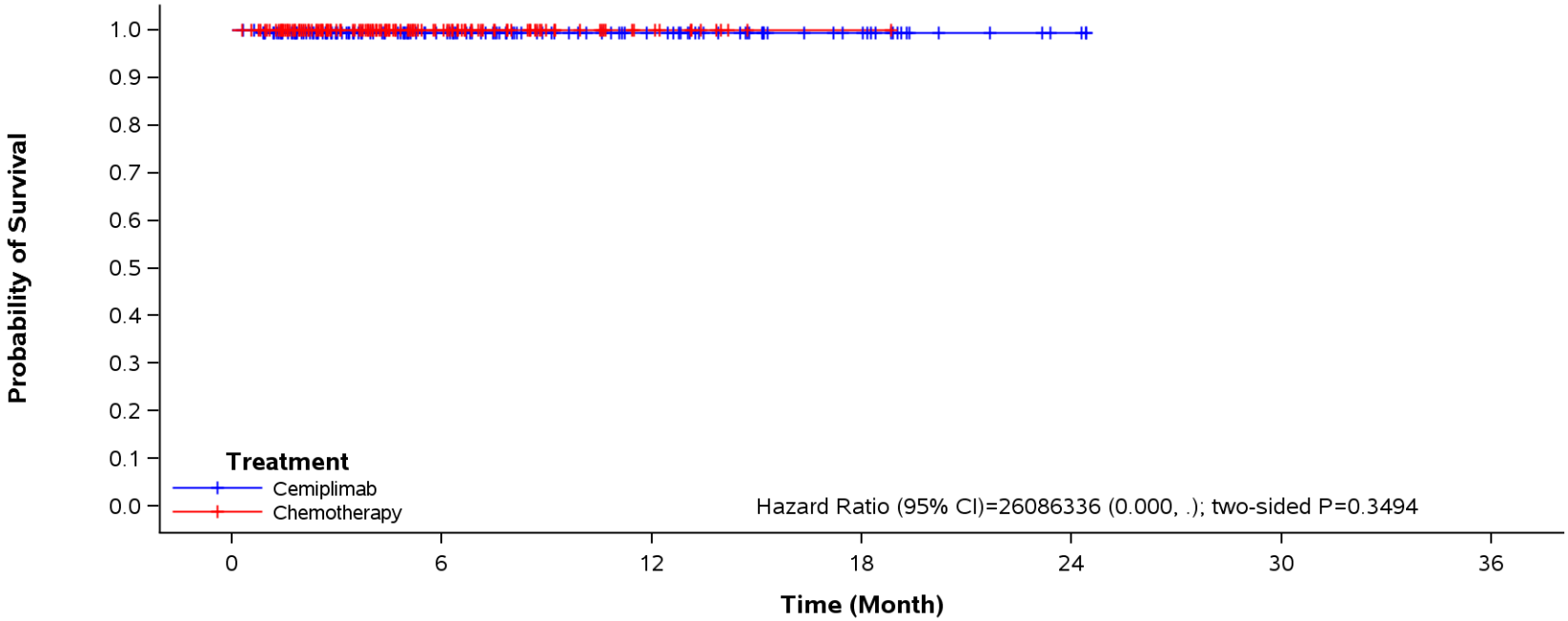

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



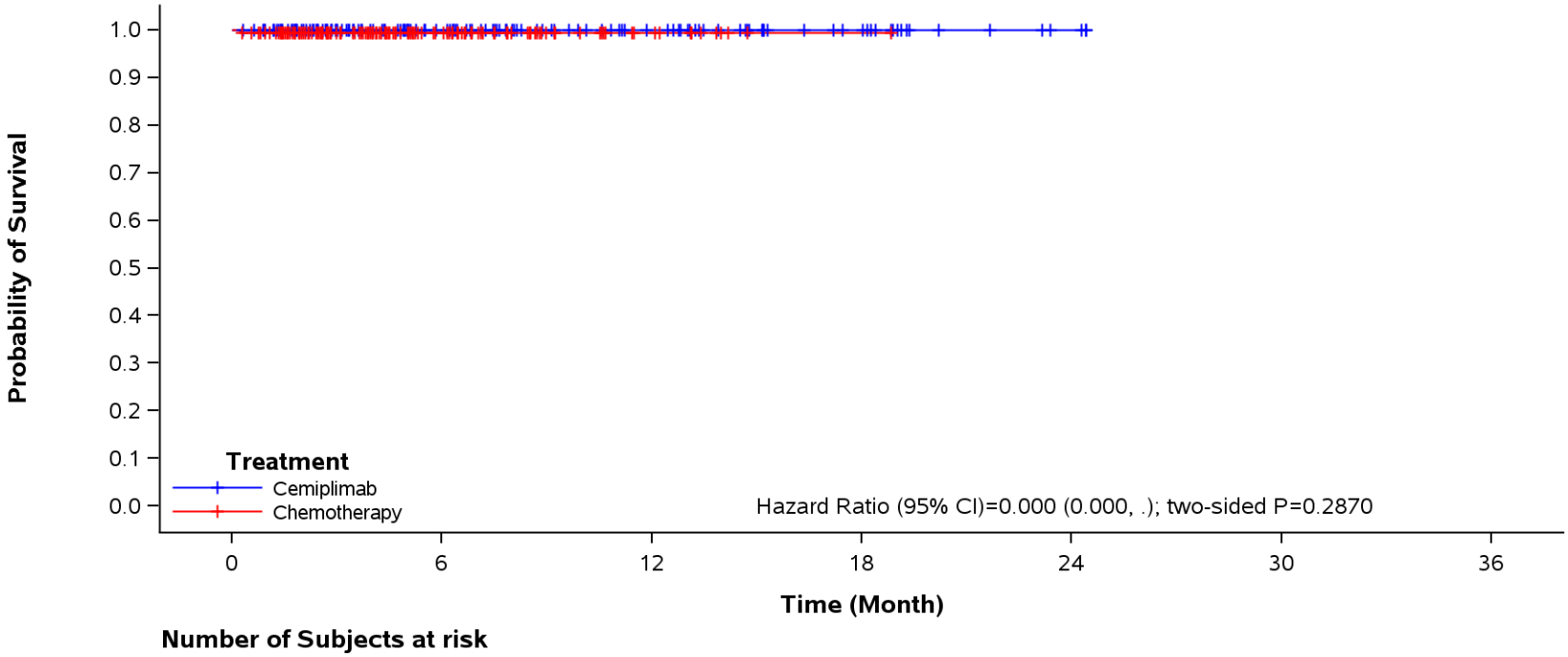

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Neutropenia



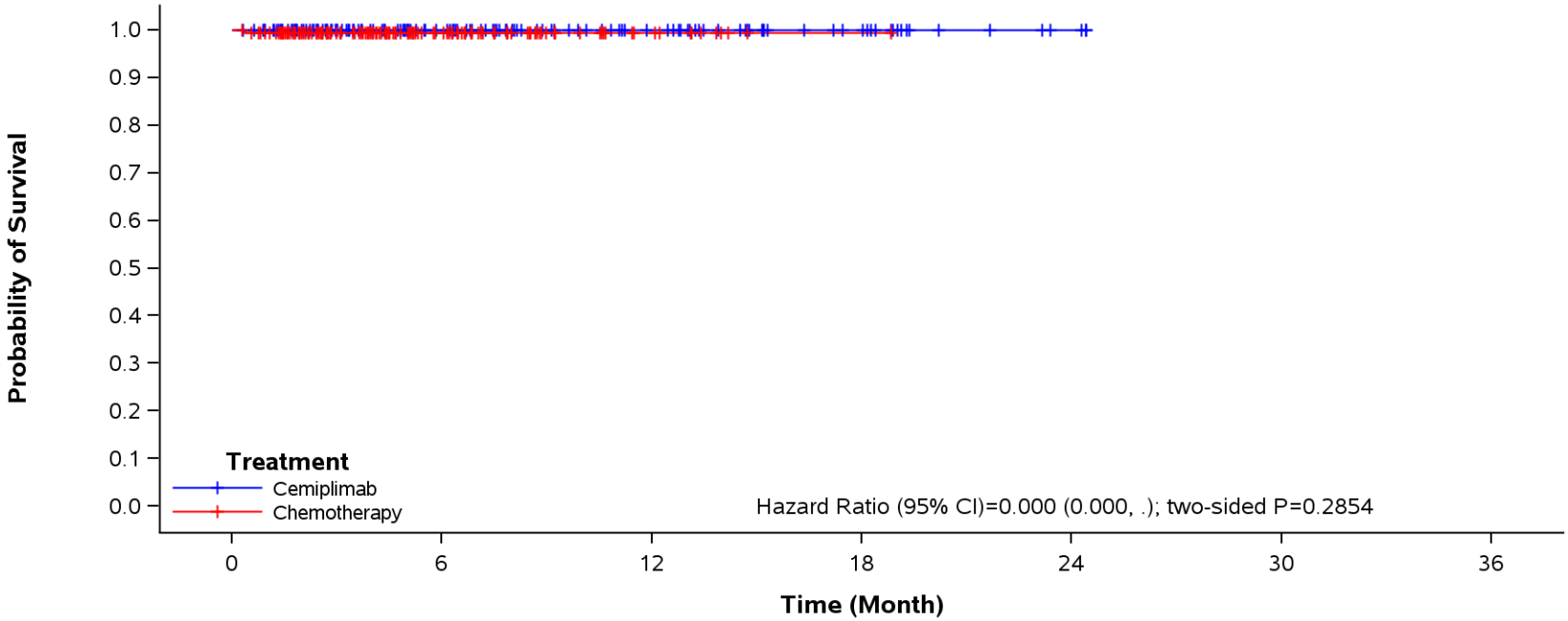

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



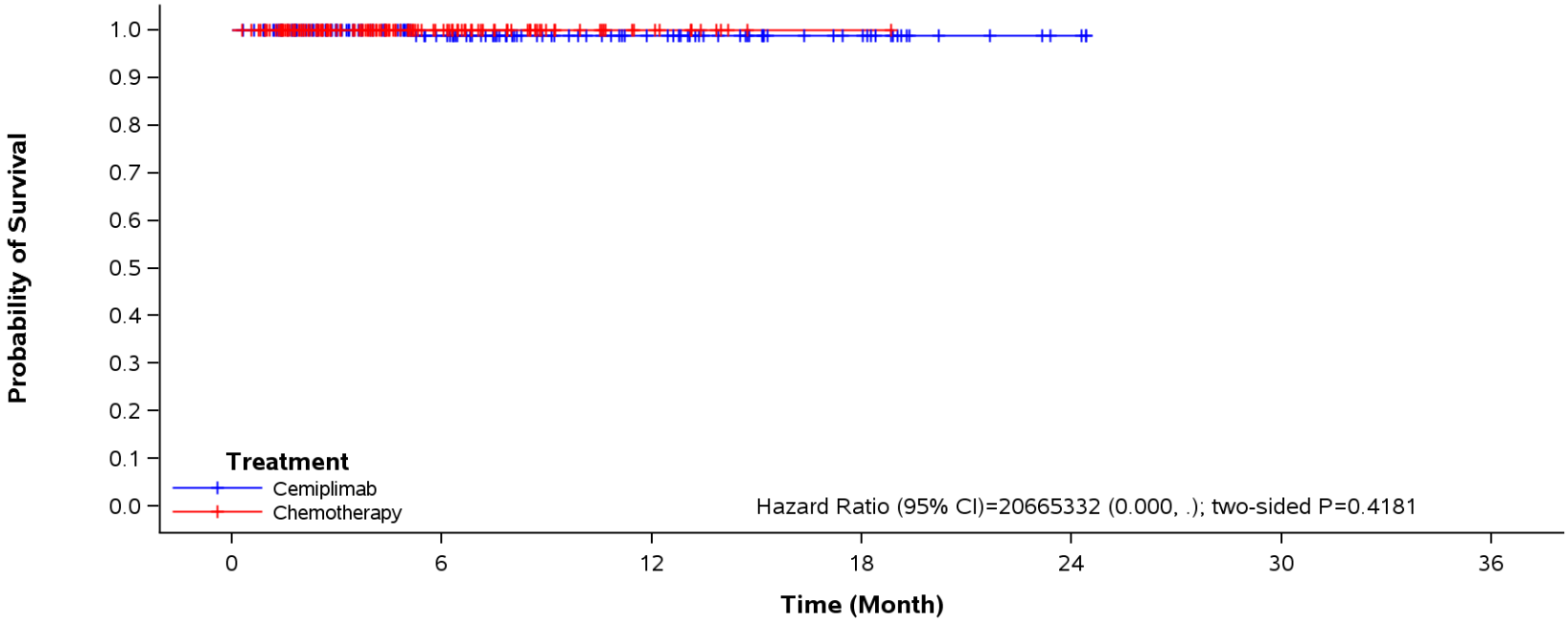

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Cardiac disorders



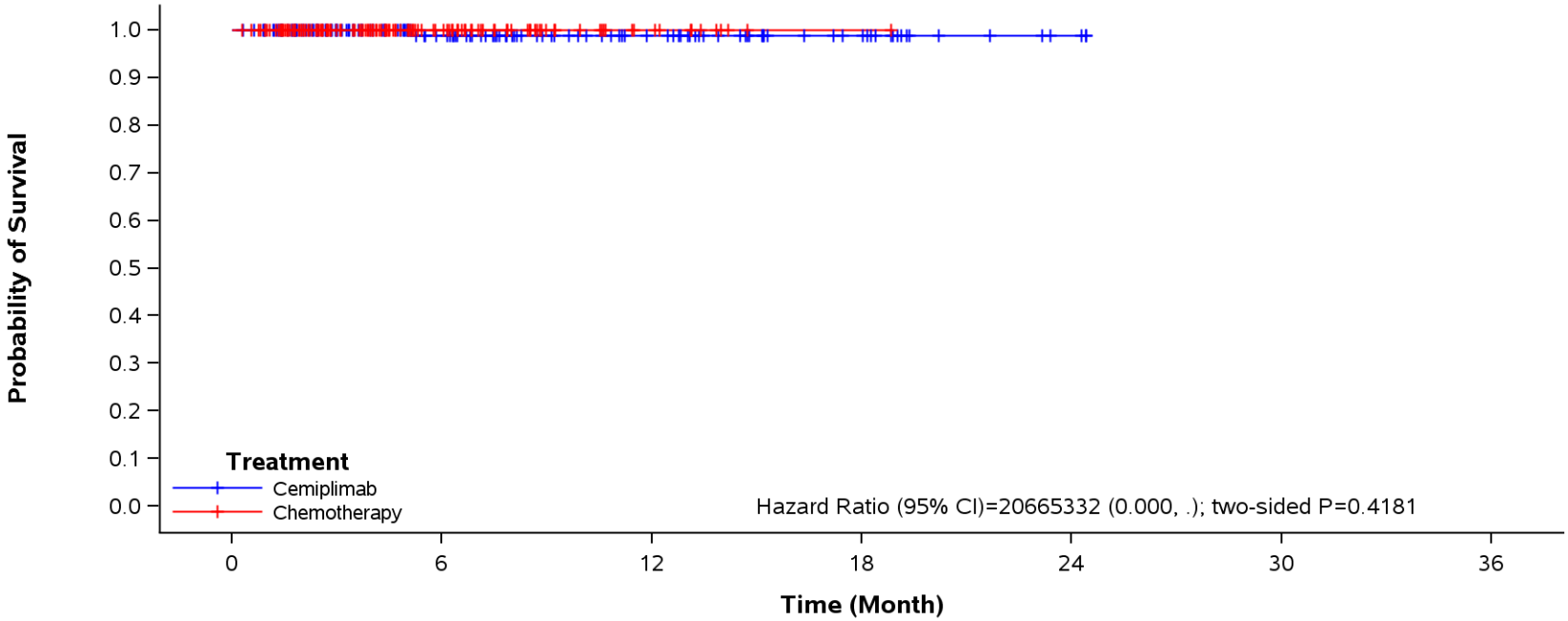

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Cardiac disorders
PT: Autoimmune pericarditis



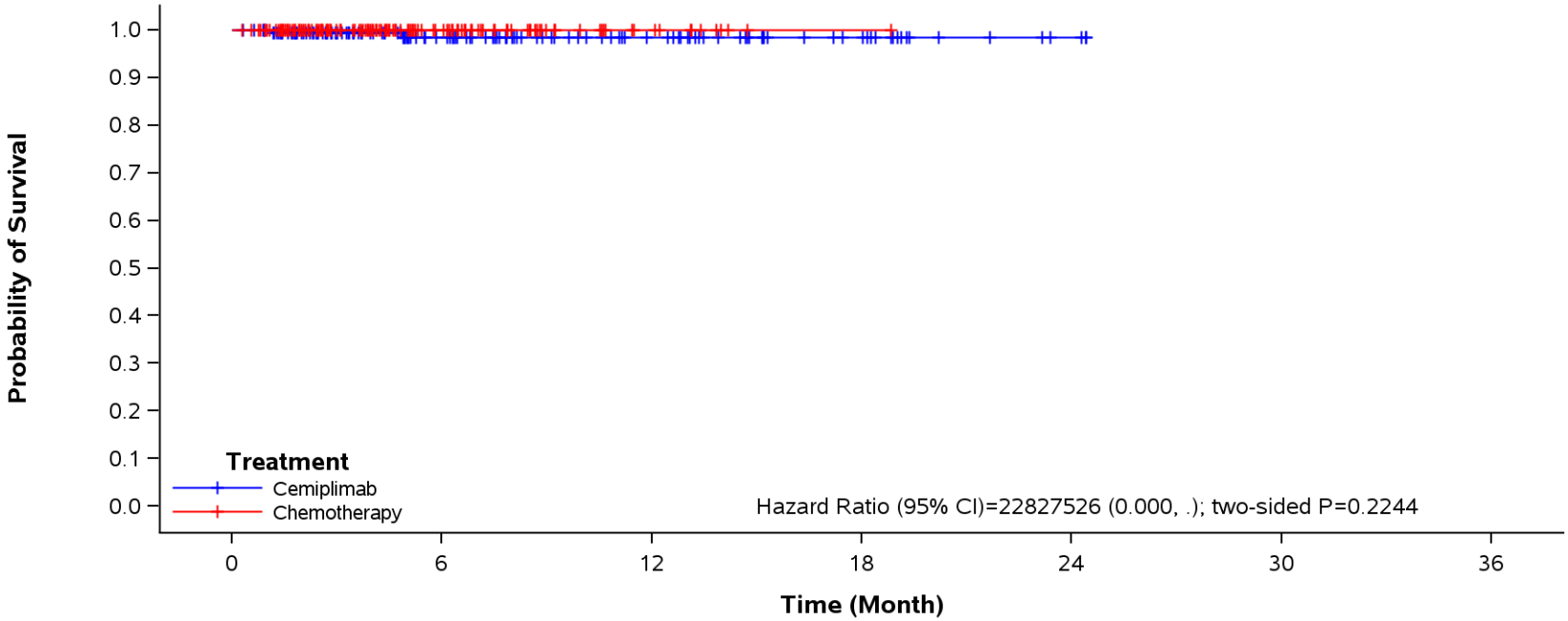

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Endocrine disorders



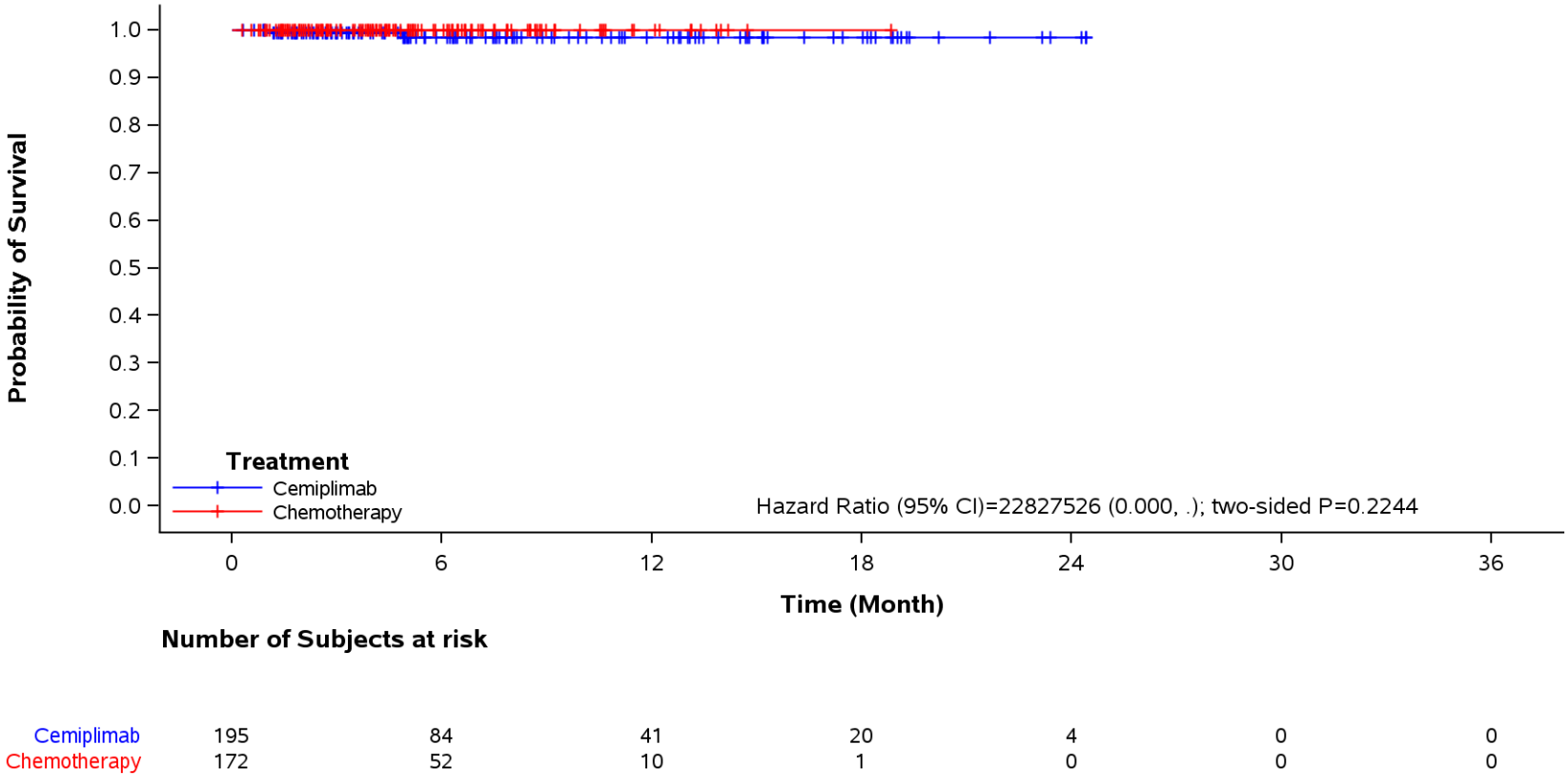

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

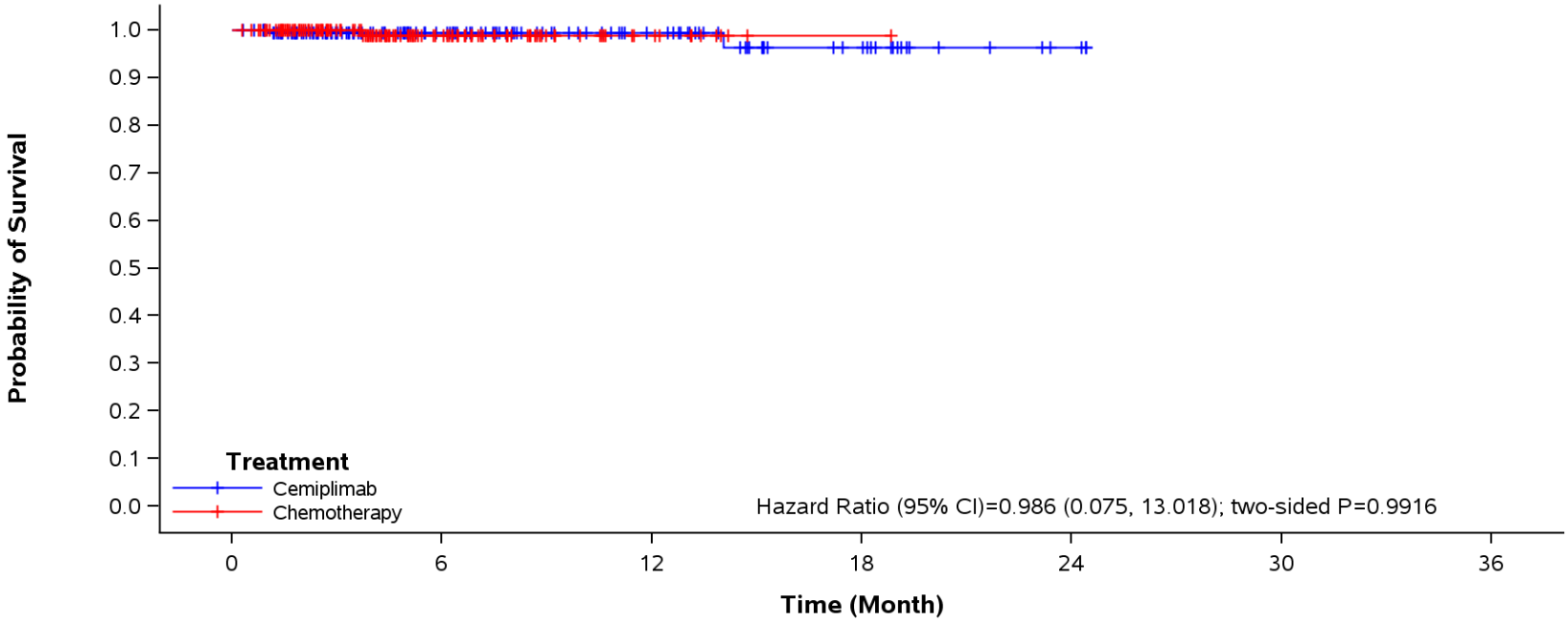
SOC: Endocrine disorders
PT: Hypothyroidism




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders



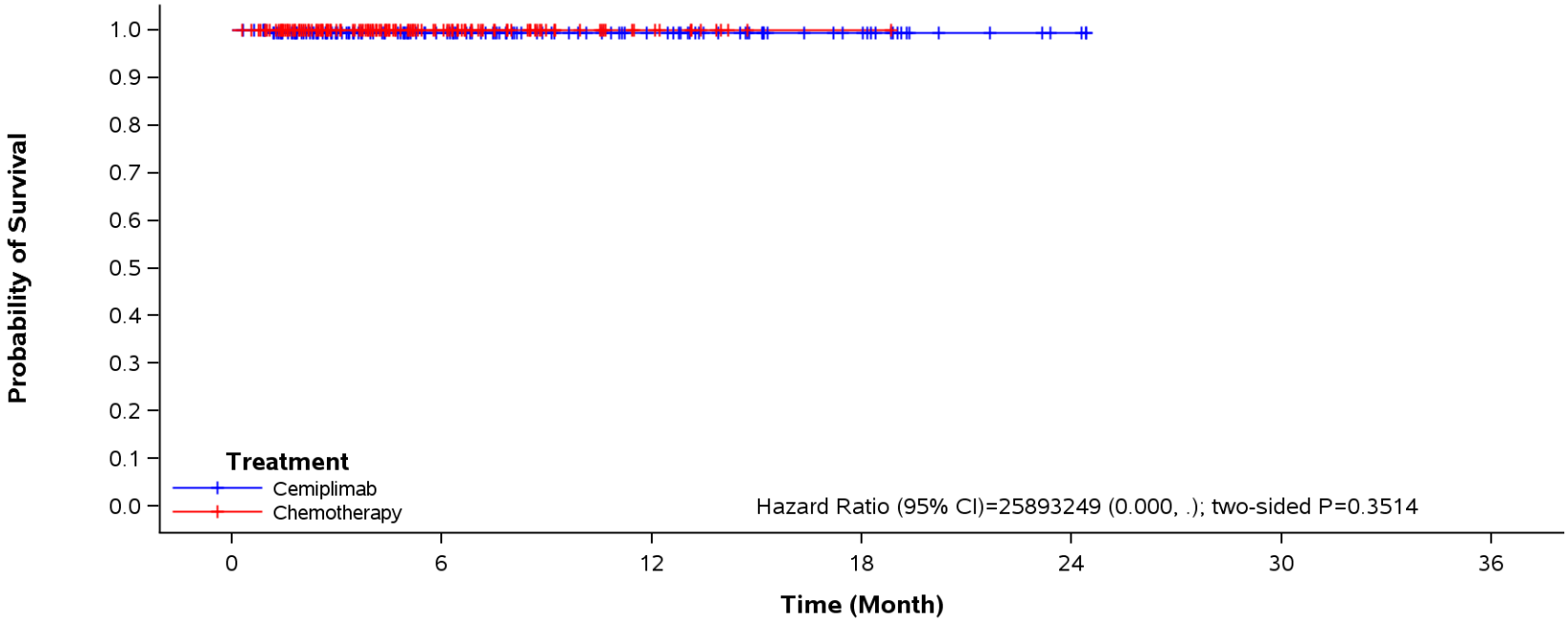

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 51 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Colitis



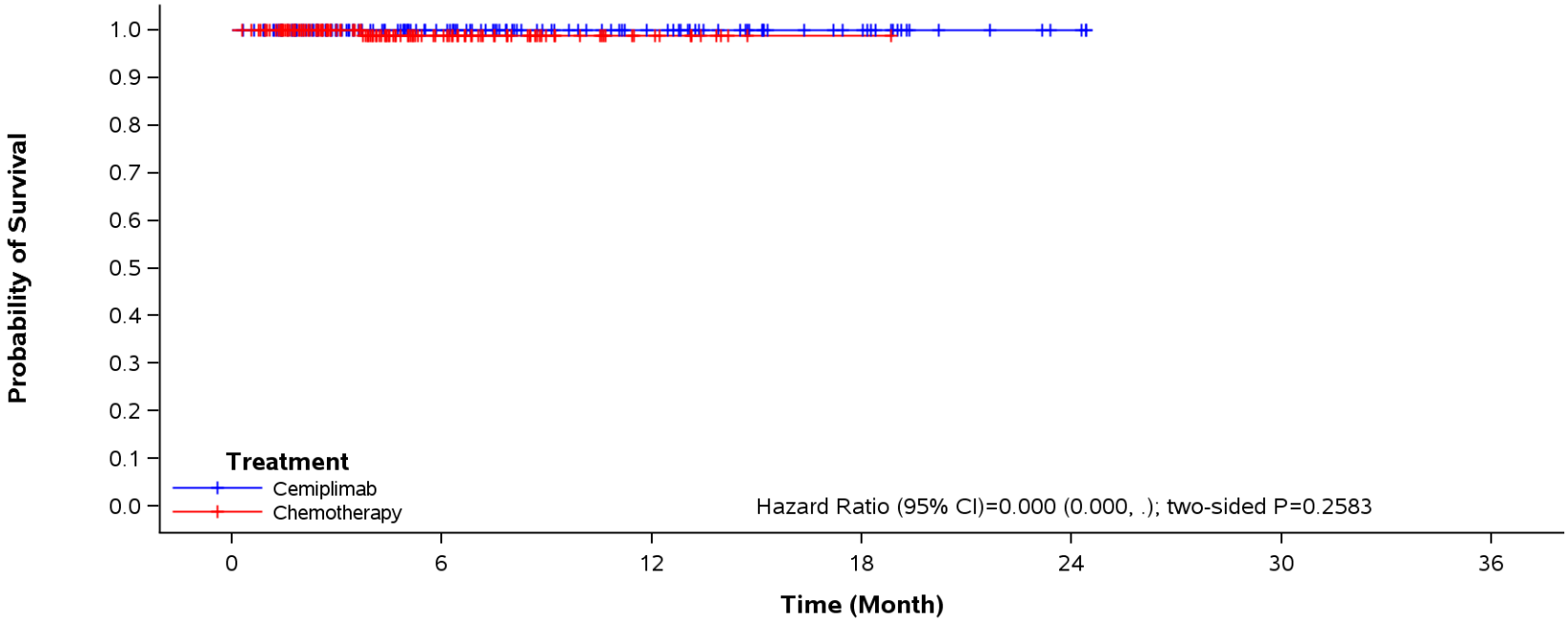

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Diverticular perforation



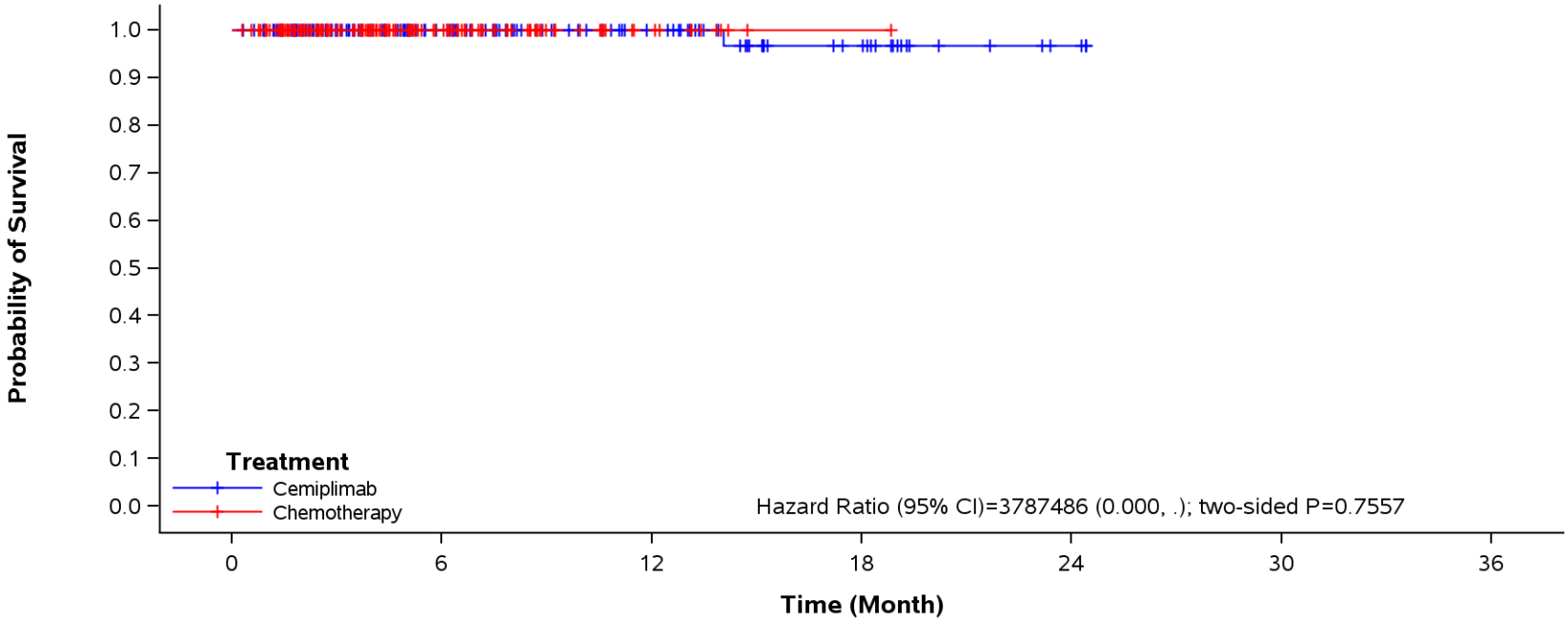

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 51 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Pancreatic mass



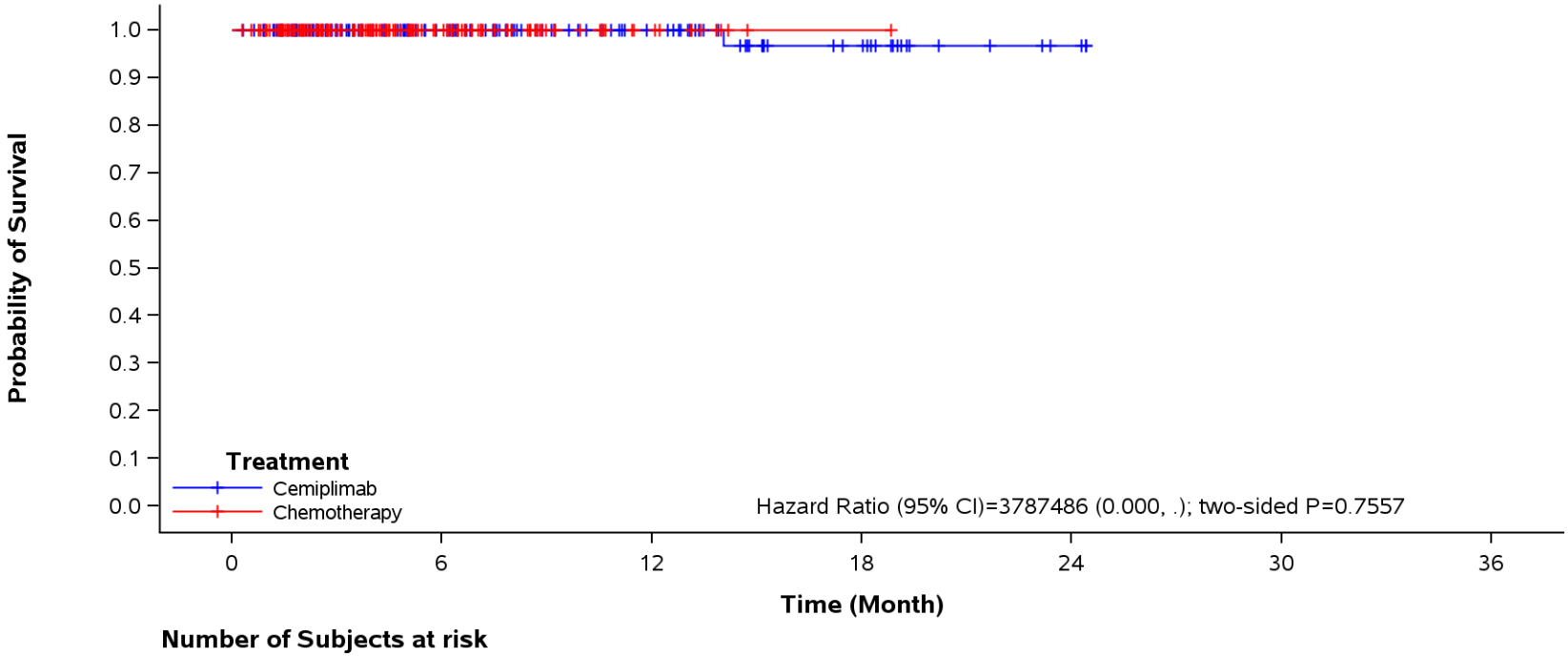

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



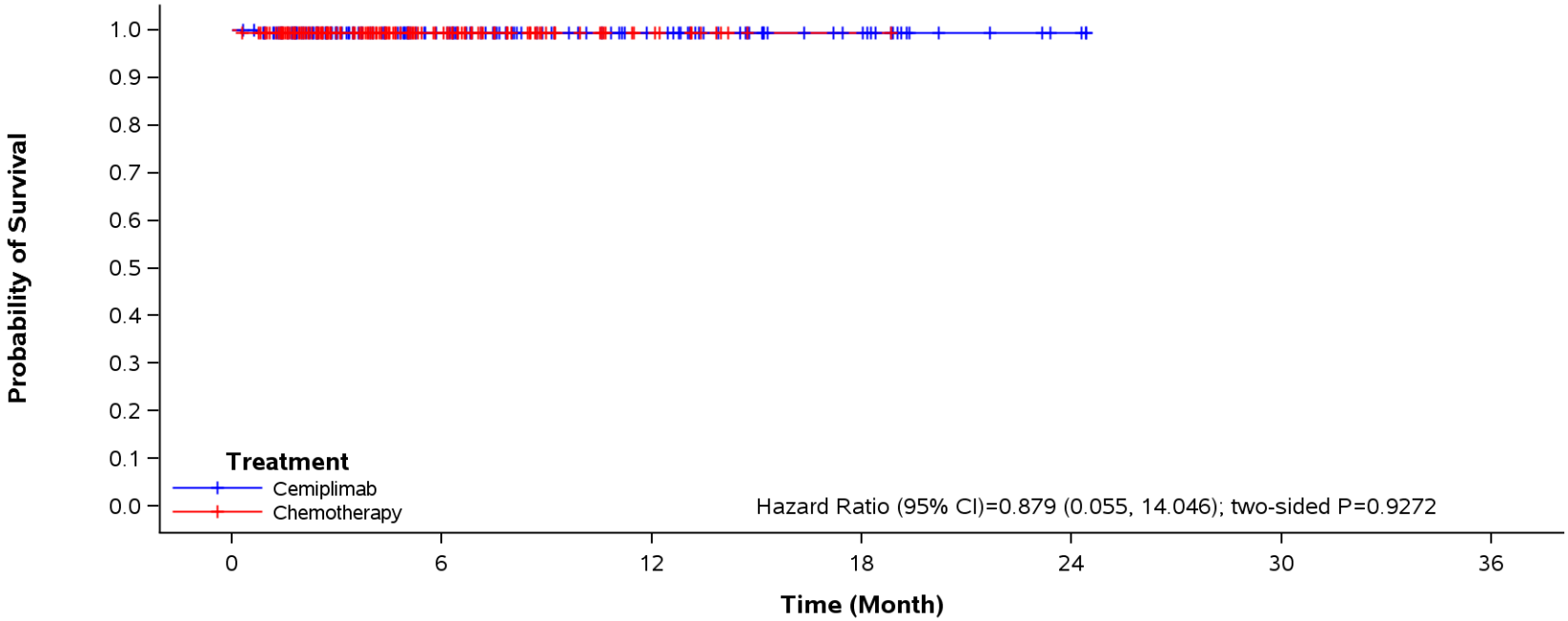

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions



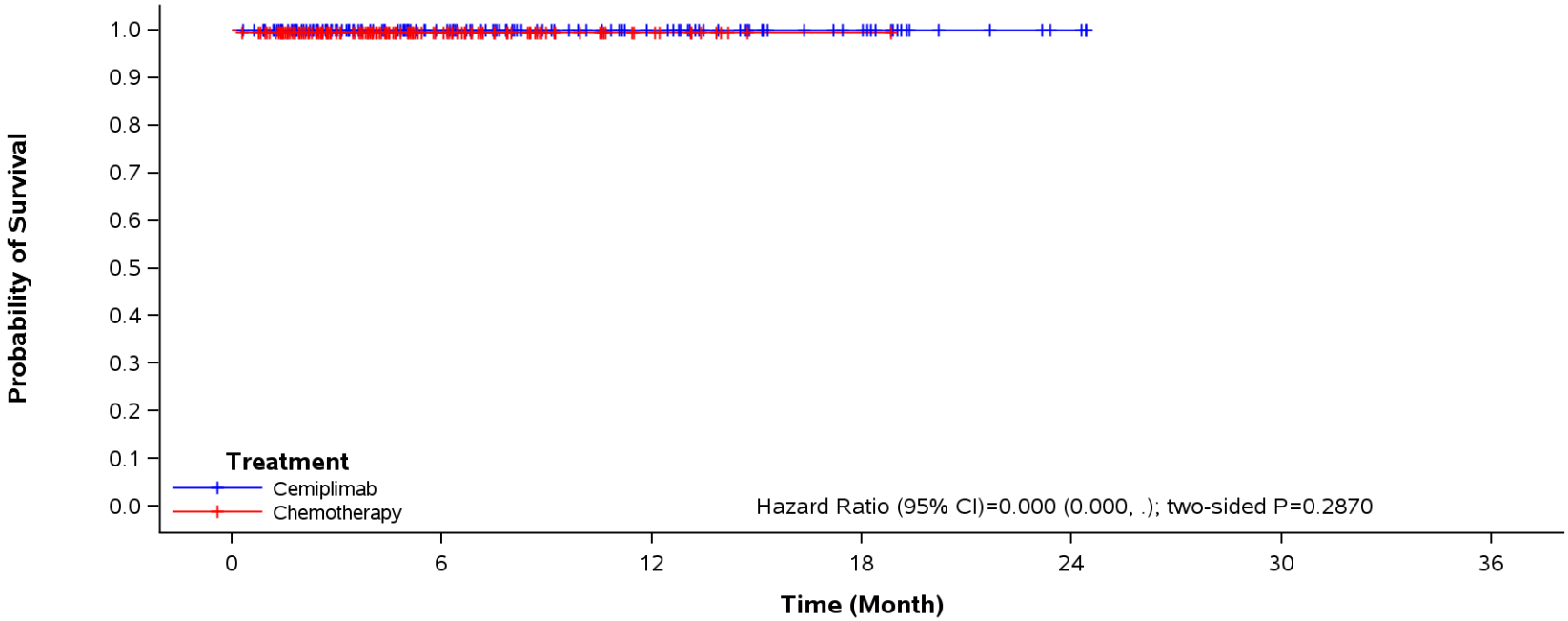

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Malaise



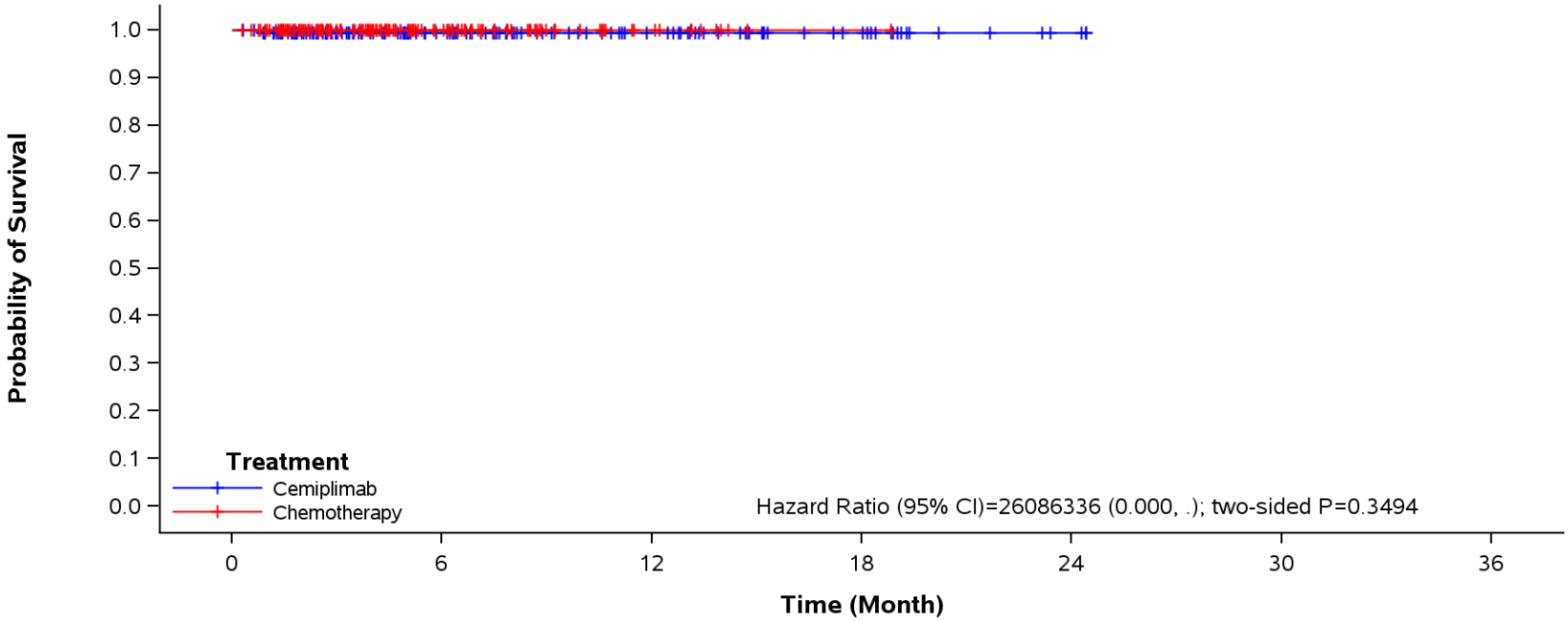

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



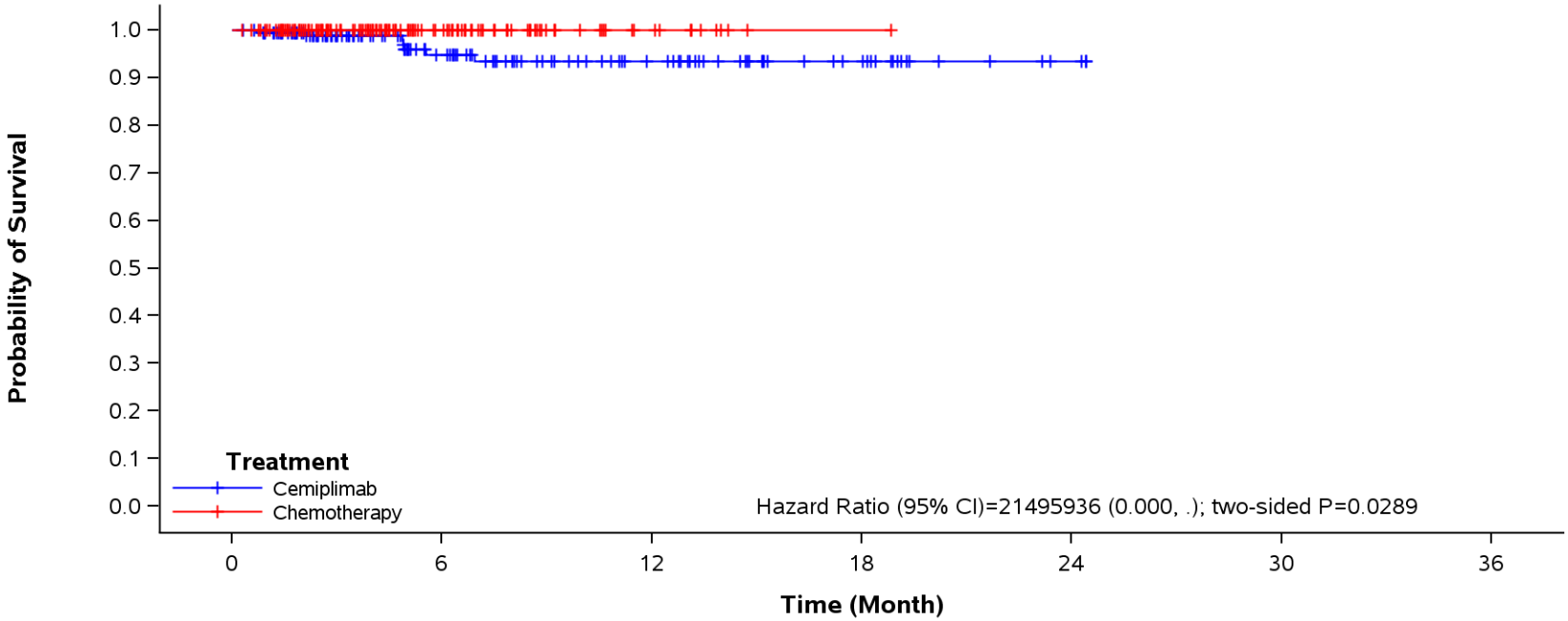

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders



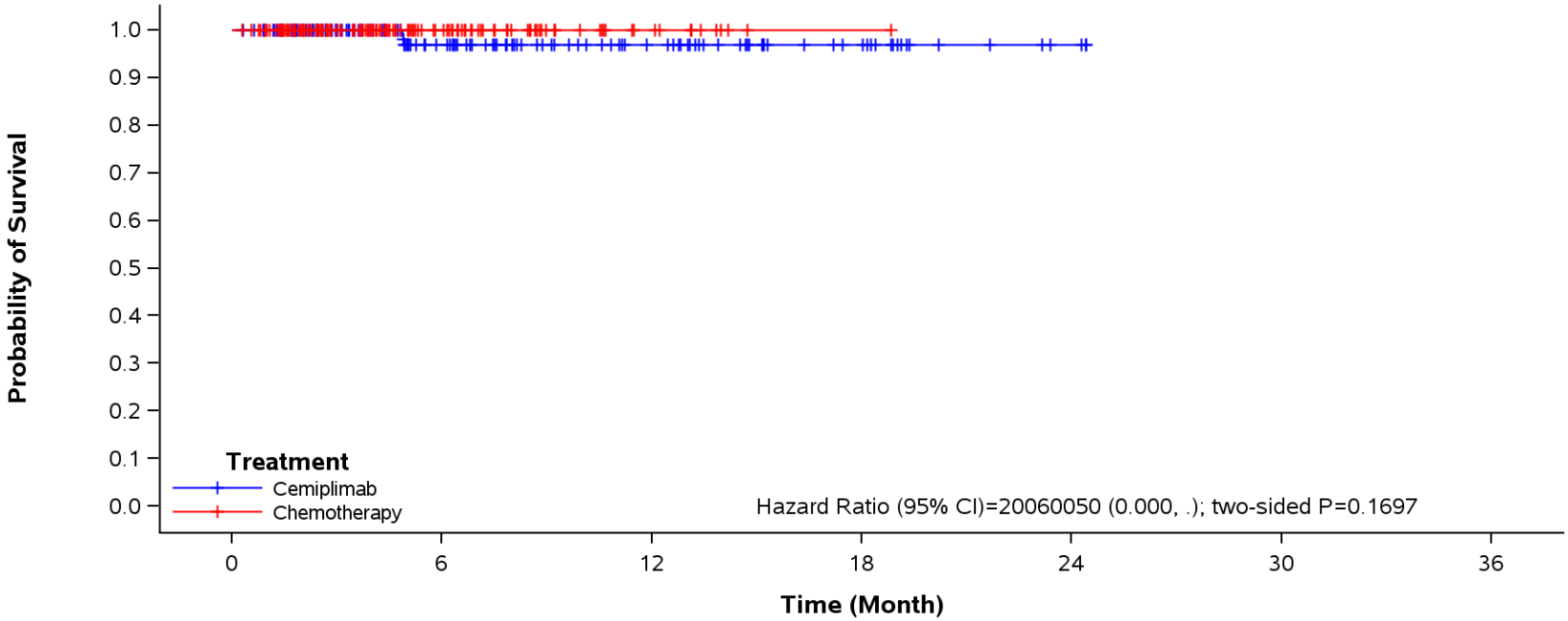

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 81 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



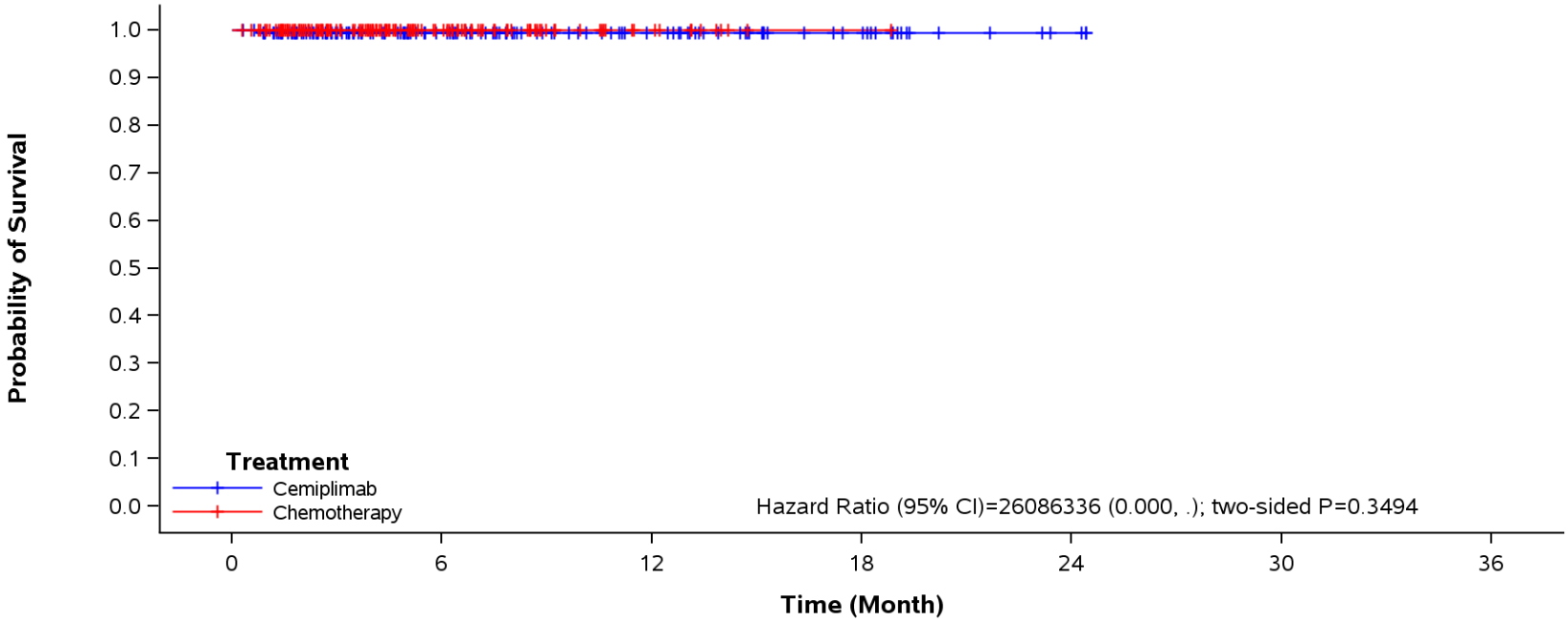

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



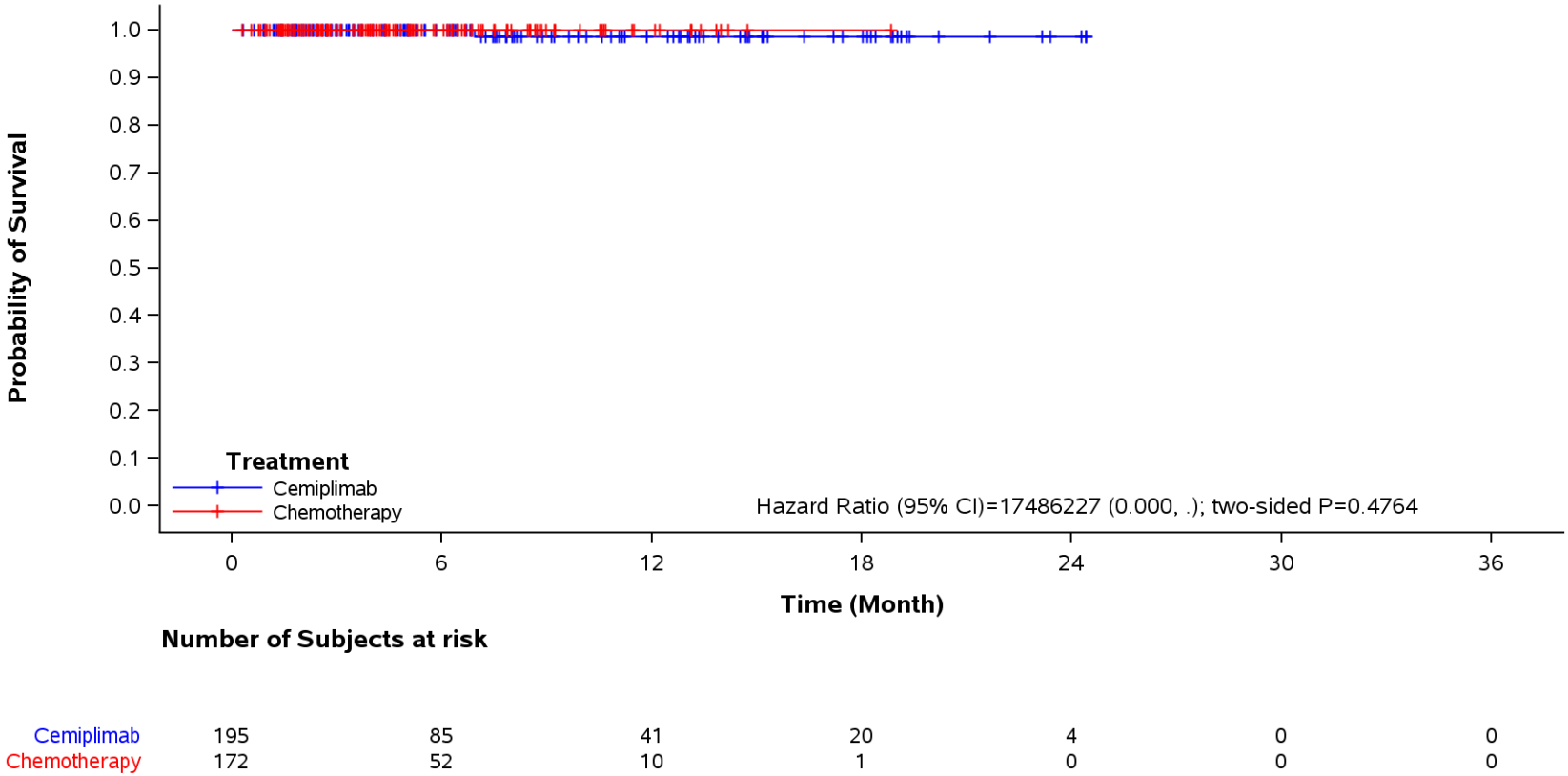

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

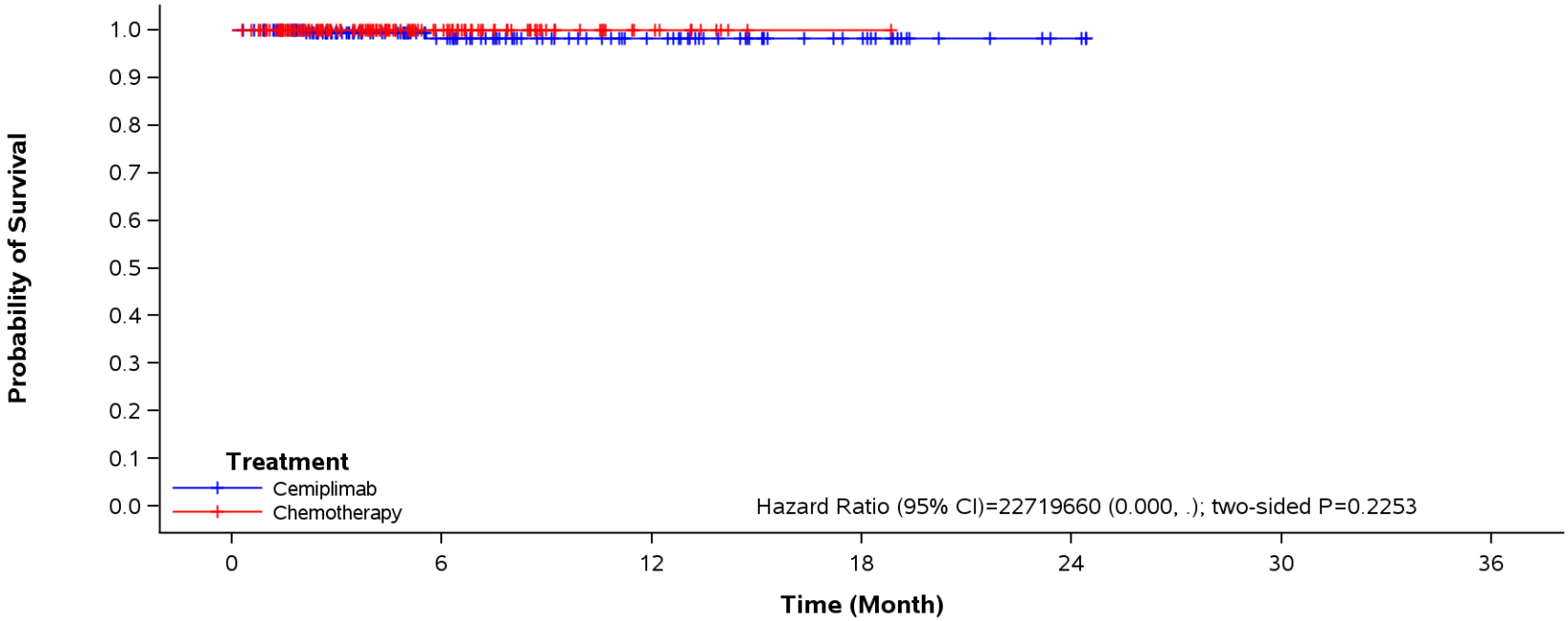
SOC: Hepatobiliary disorders
PT: Hepatitis




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



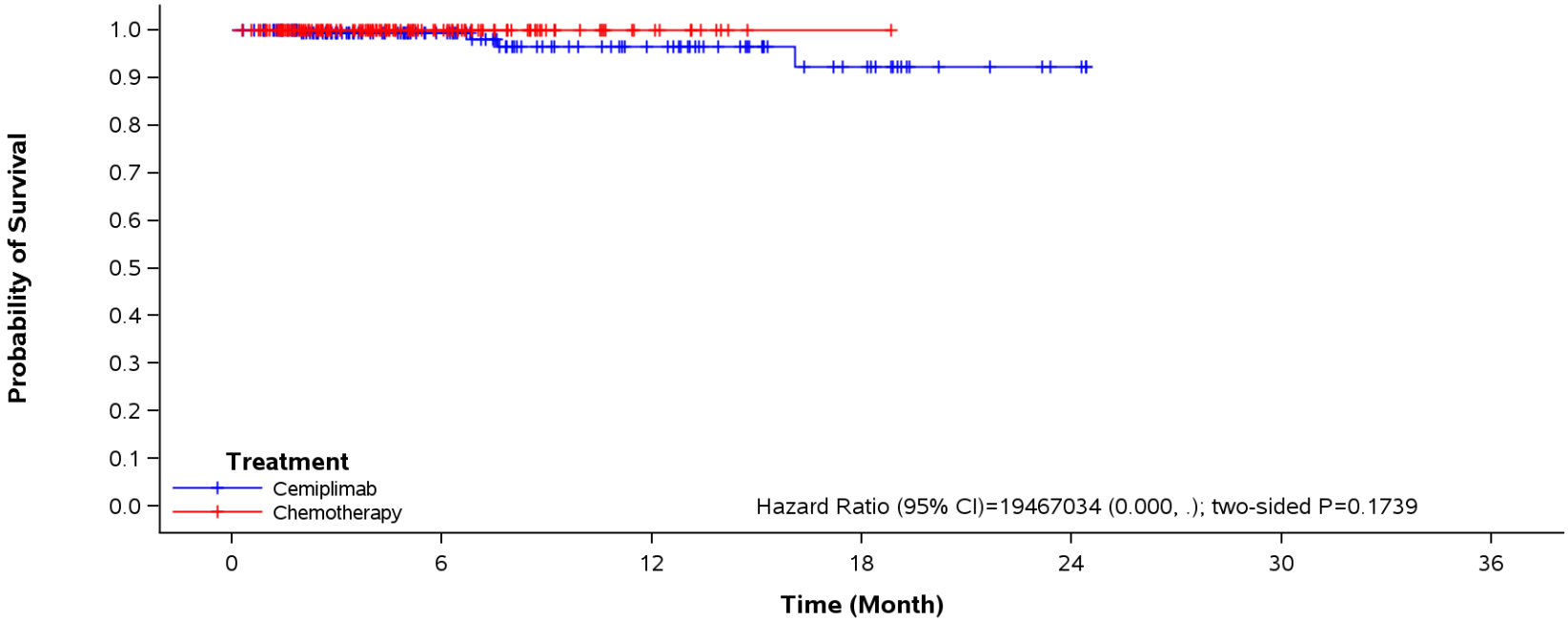

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations



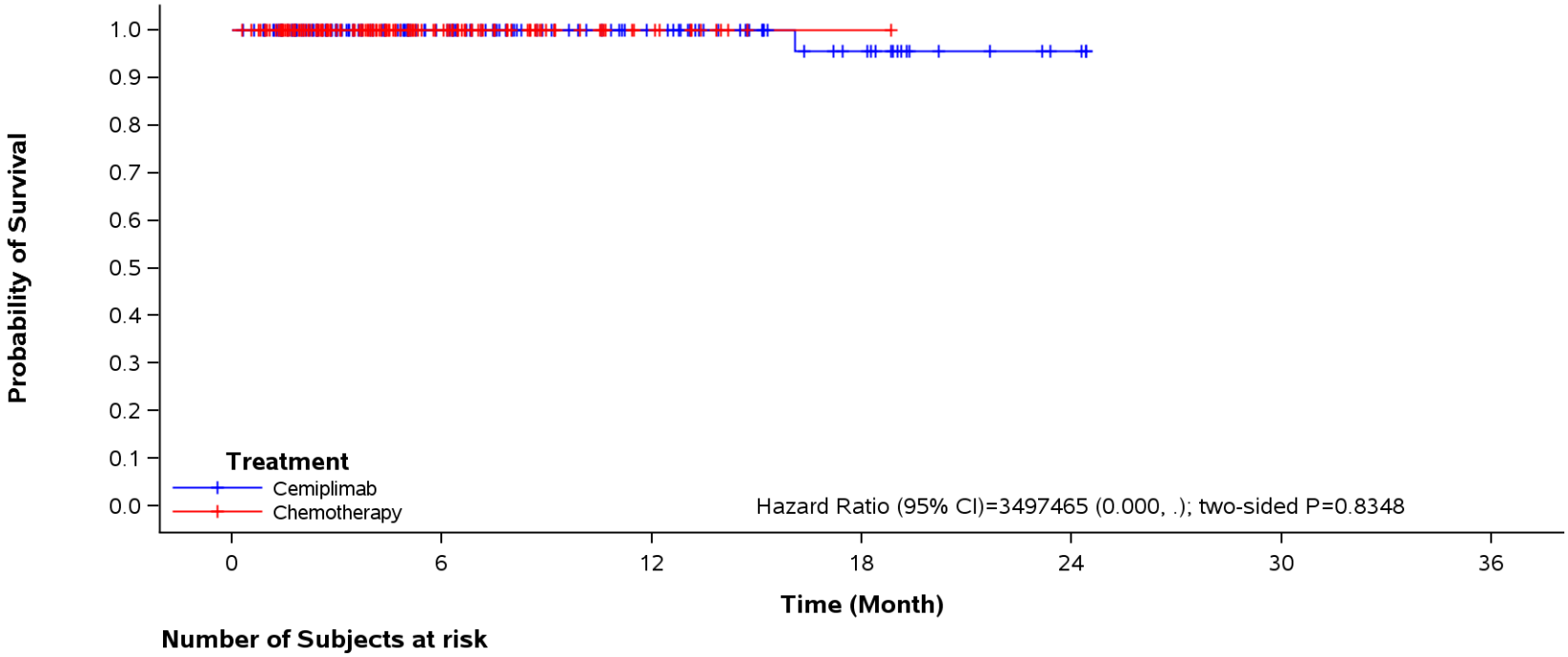

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: COVID-19 pneumonia



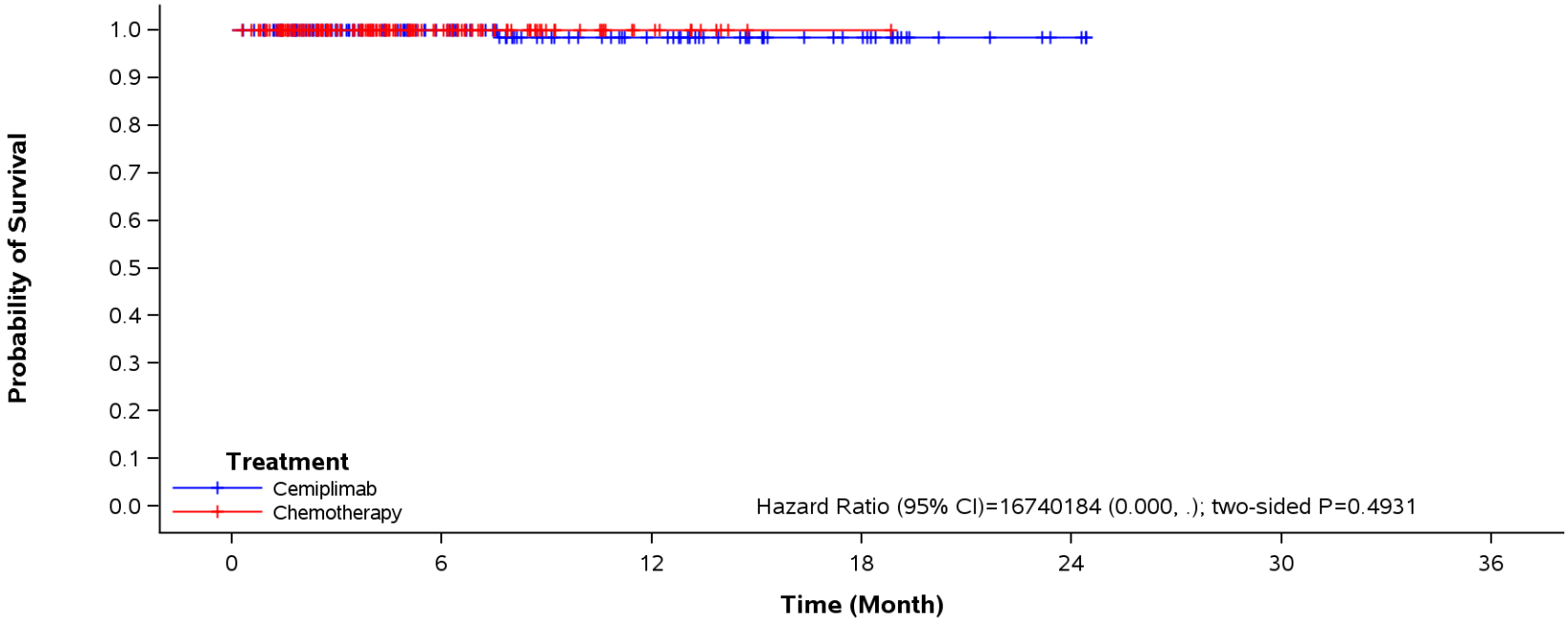

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Gastroenteritis



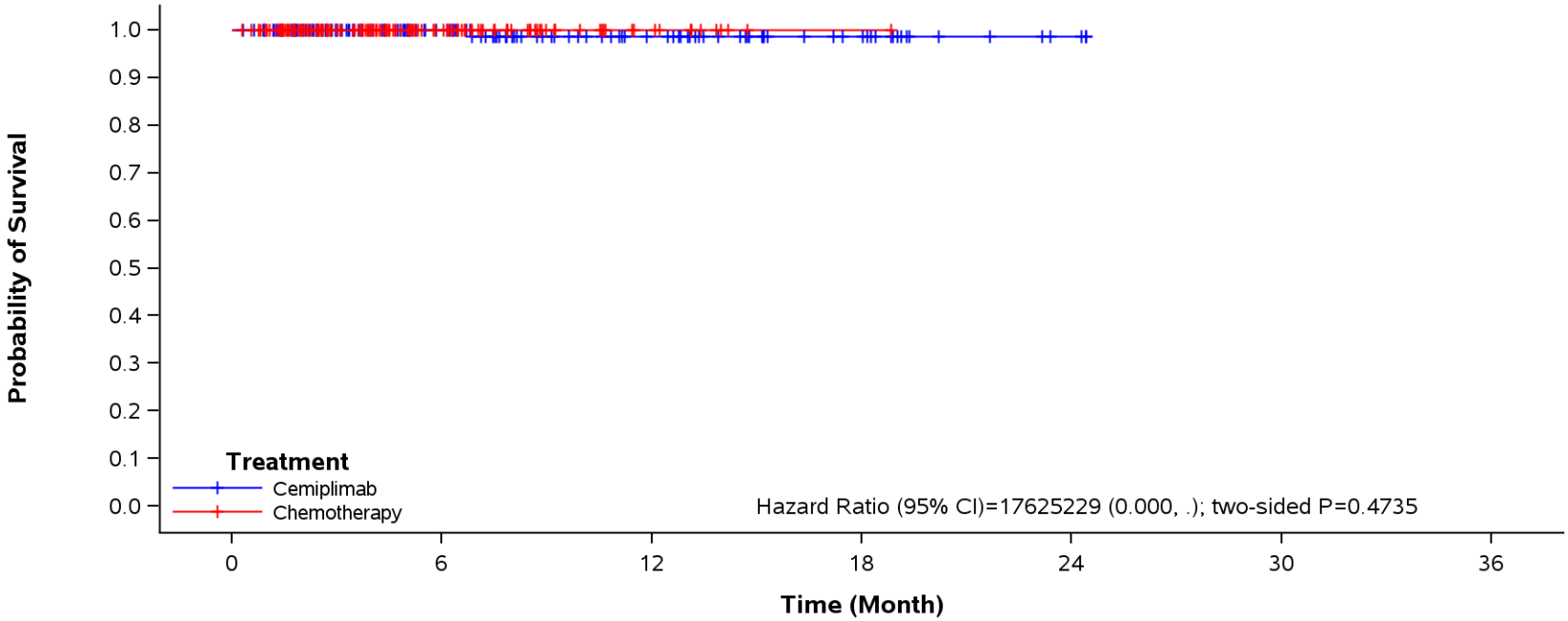

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Pelvic abscess



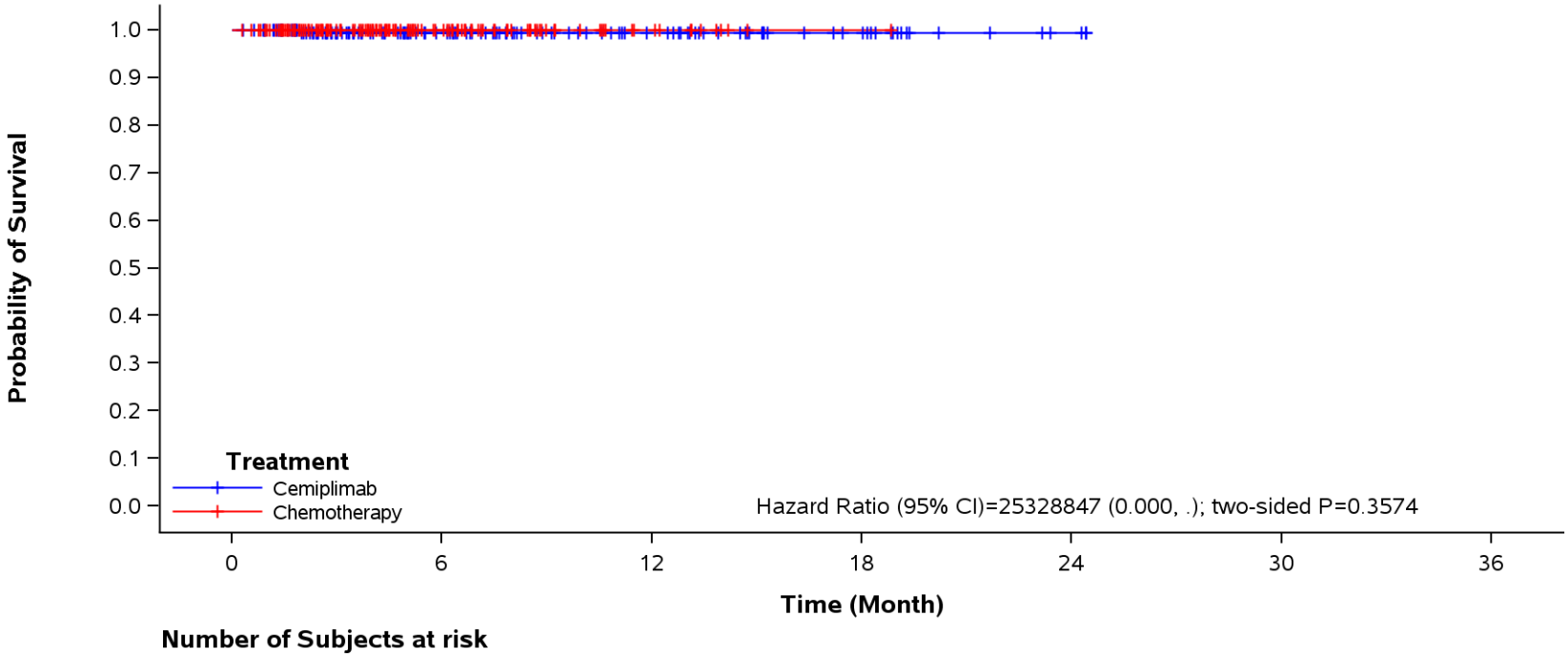

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Peritonitis



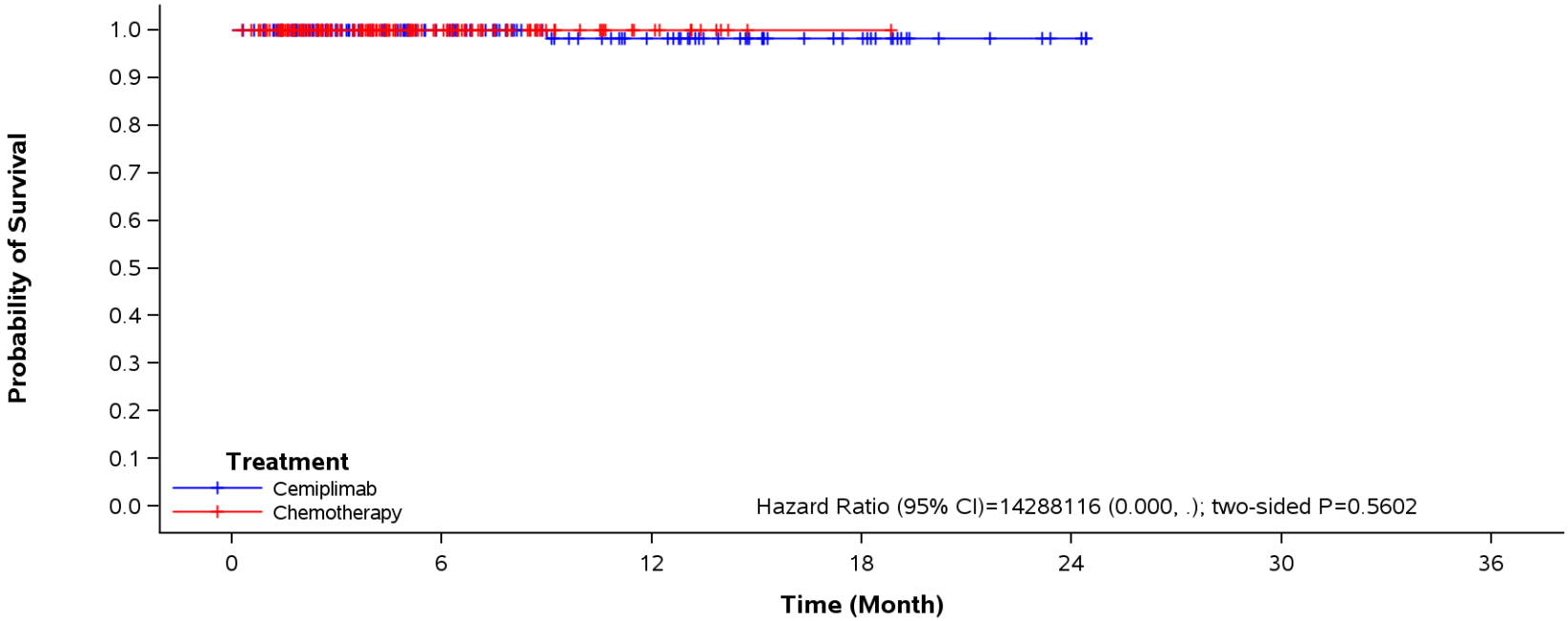

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Pneumonia



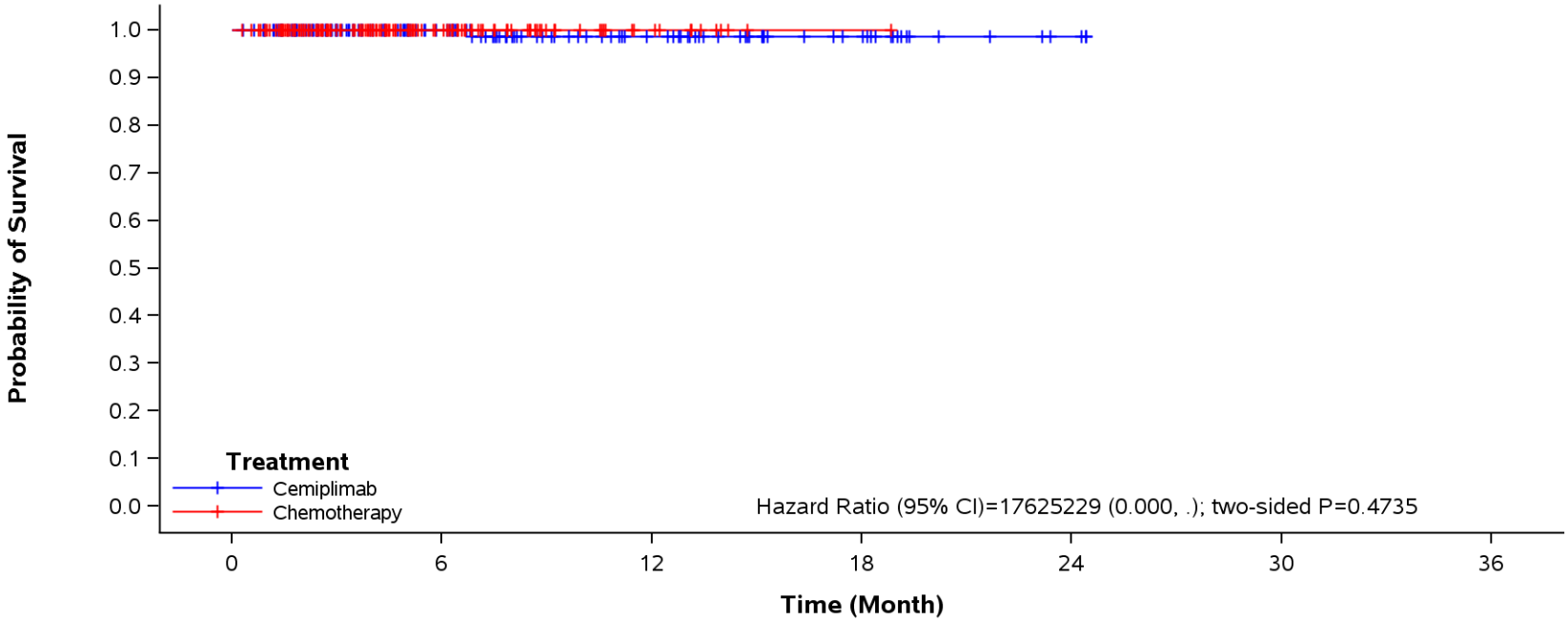

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Pyomyositis



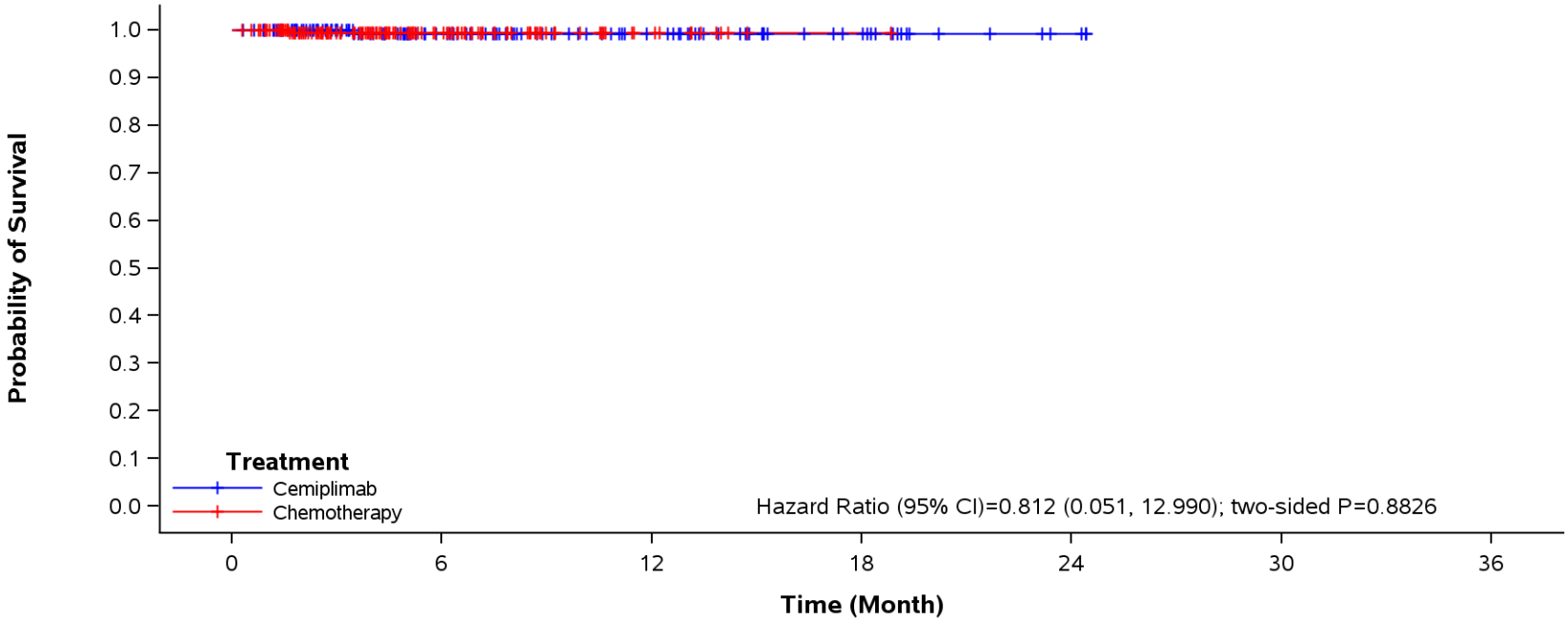

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Injury, poisoning and procedural complications



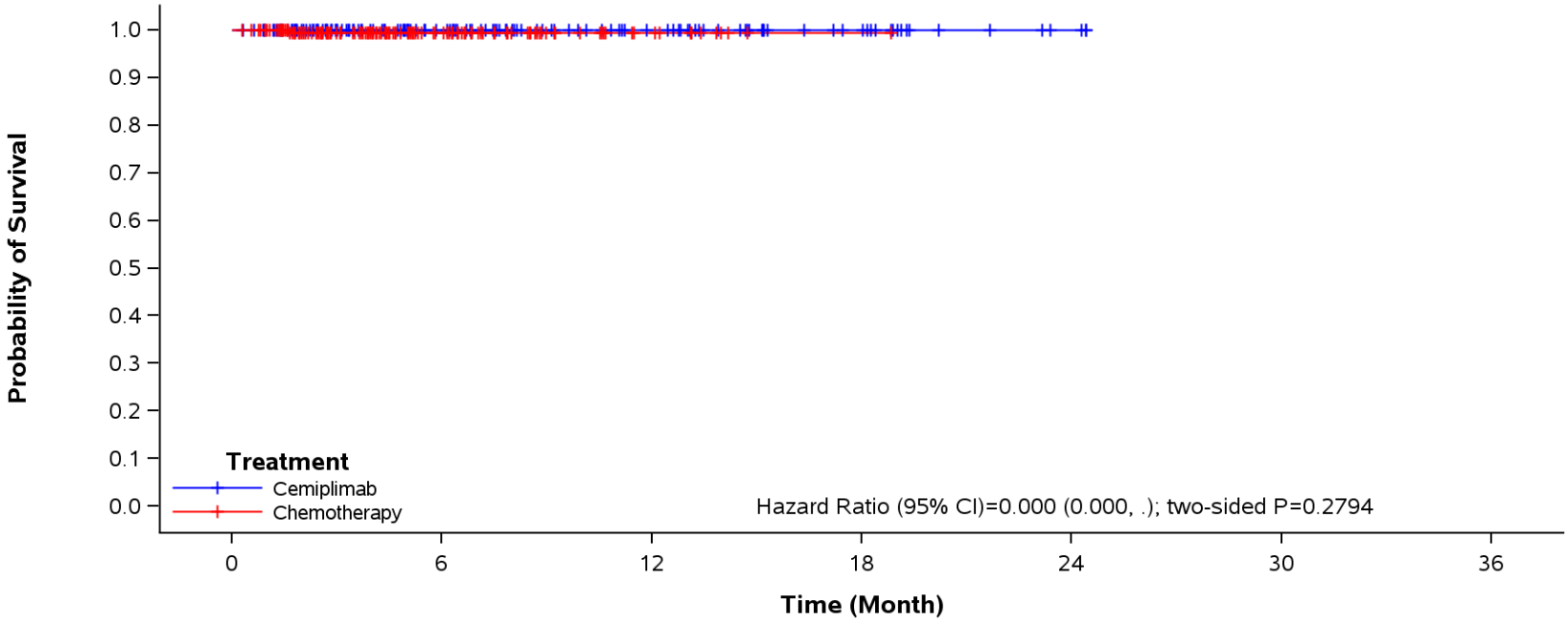

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



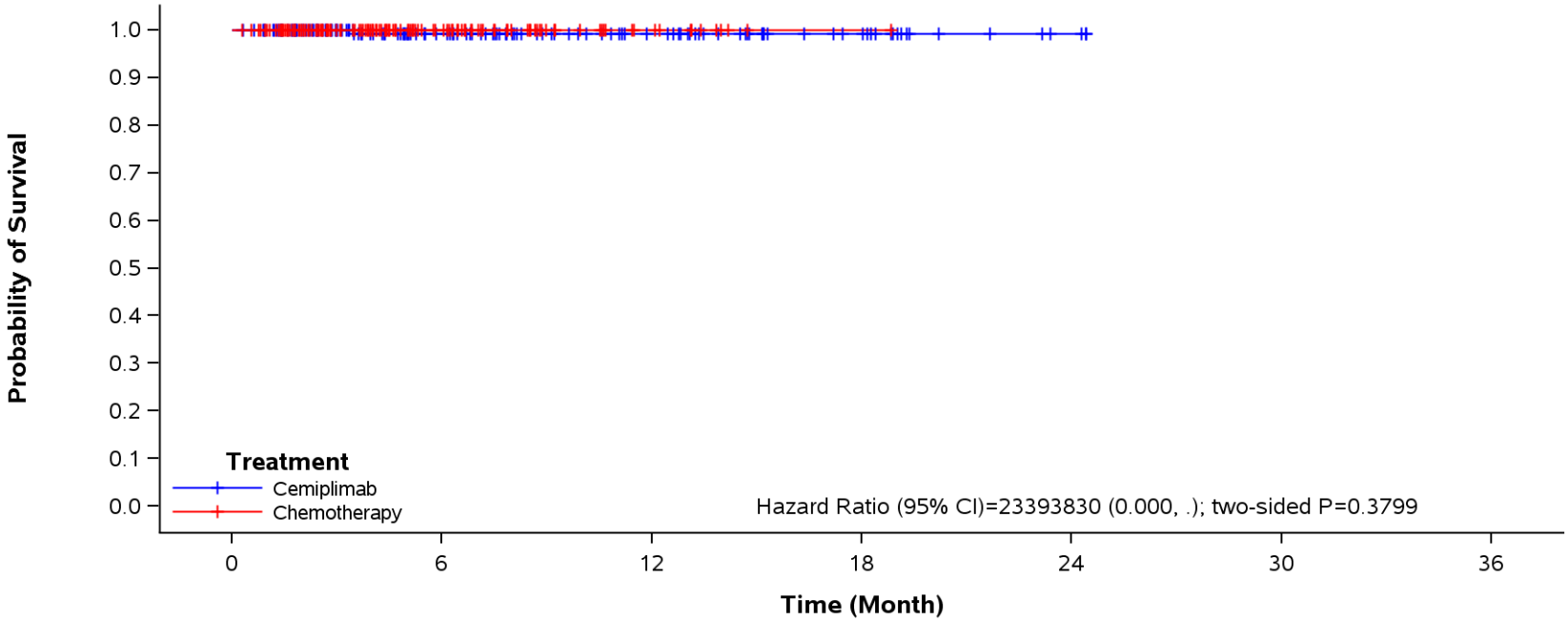

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



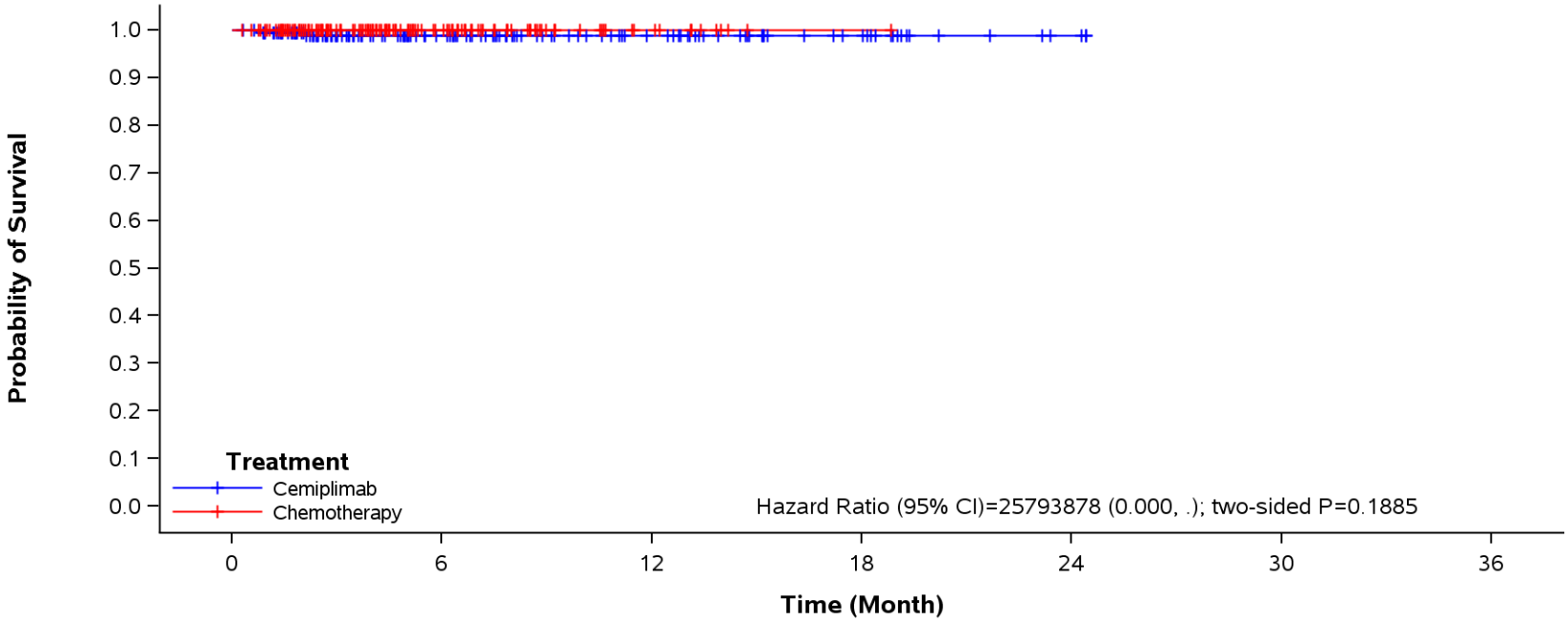

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations



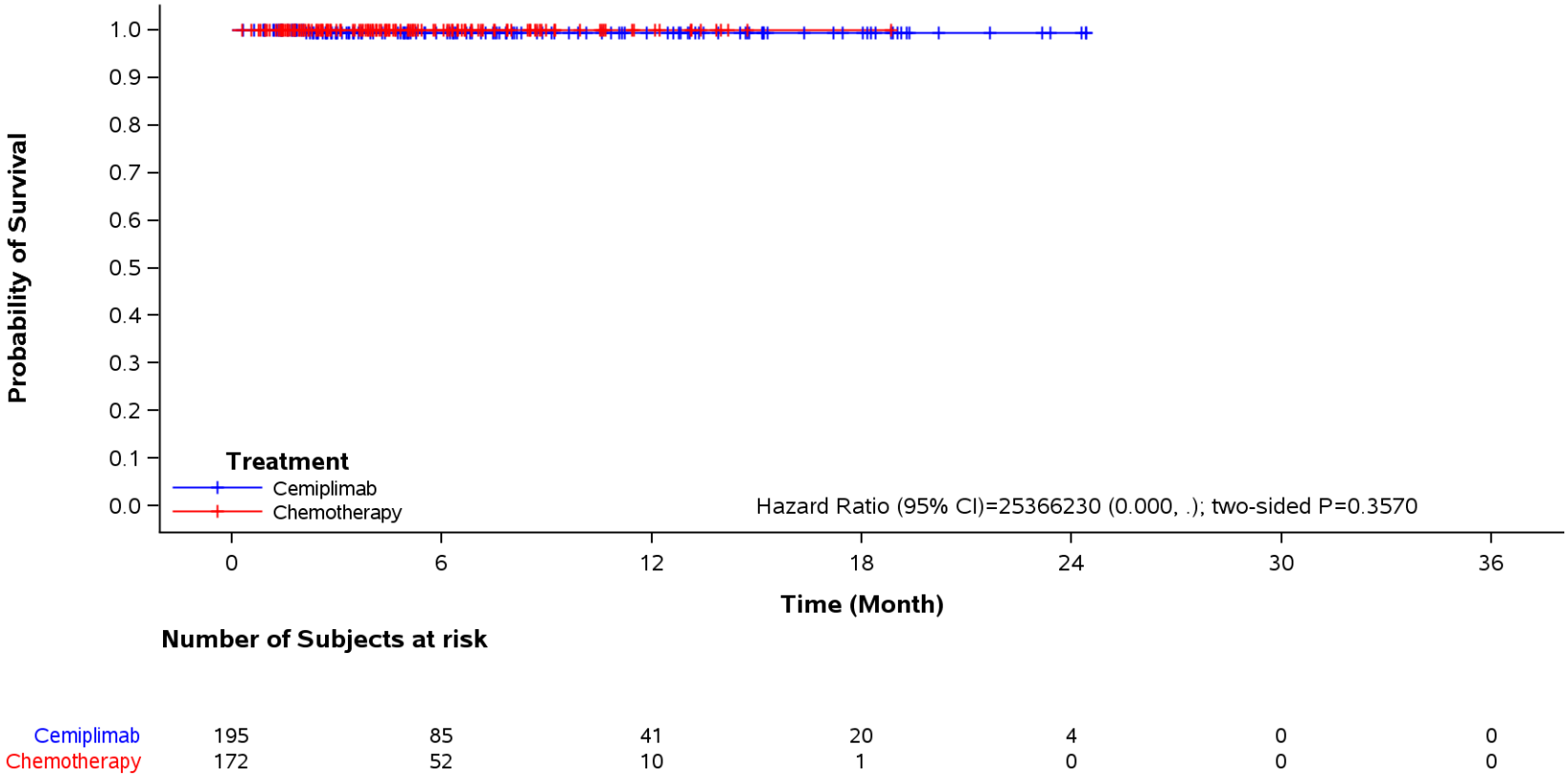

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

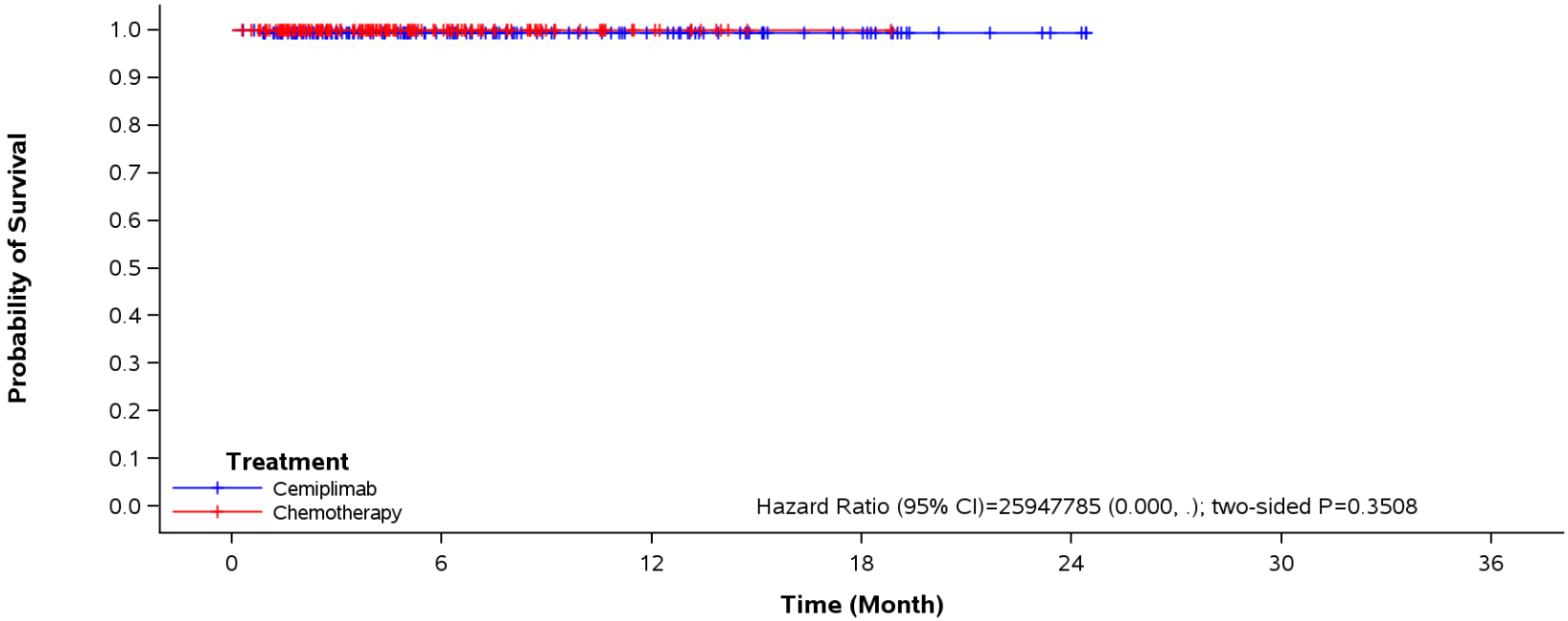
SOC: Investigations
PT: Alanine aminotransferase increased




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Amylase increased



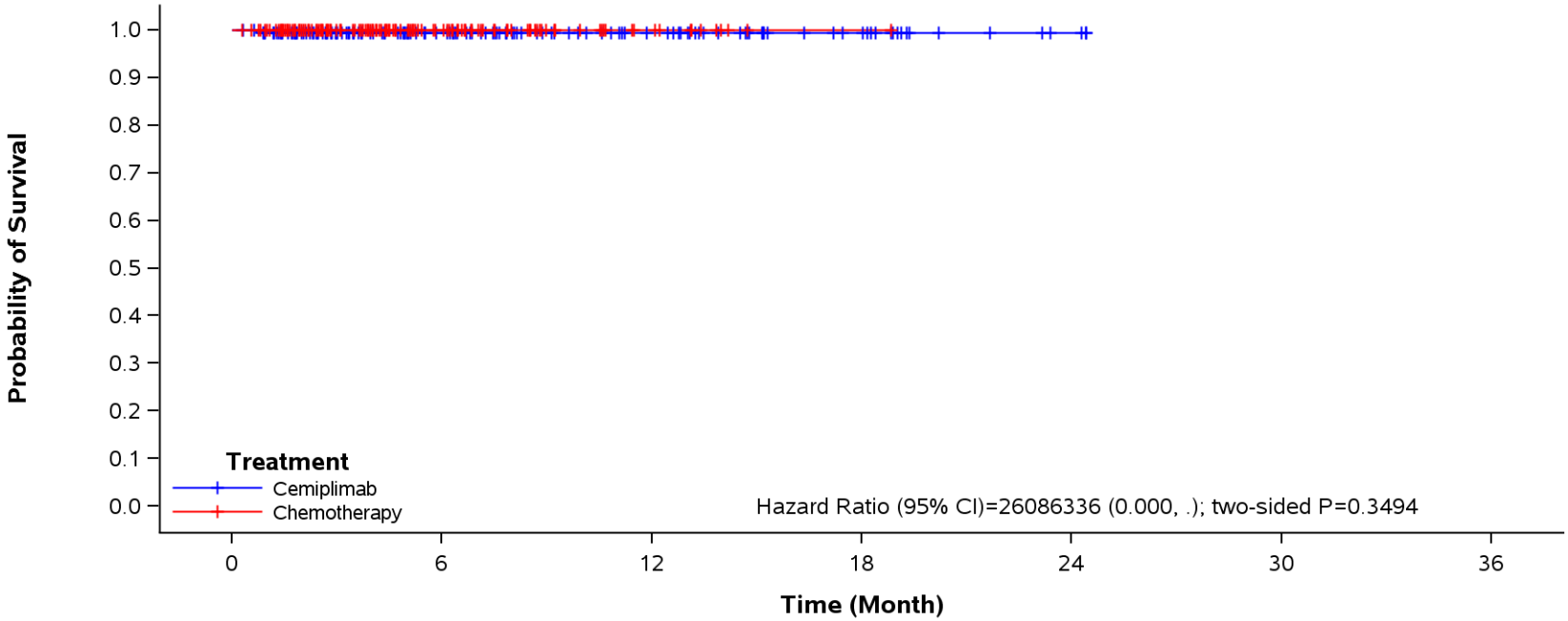

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Platelet count decreased



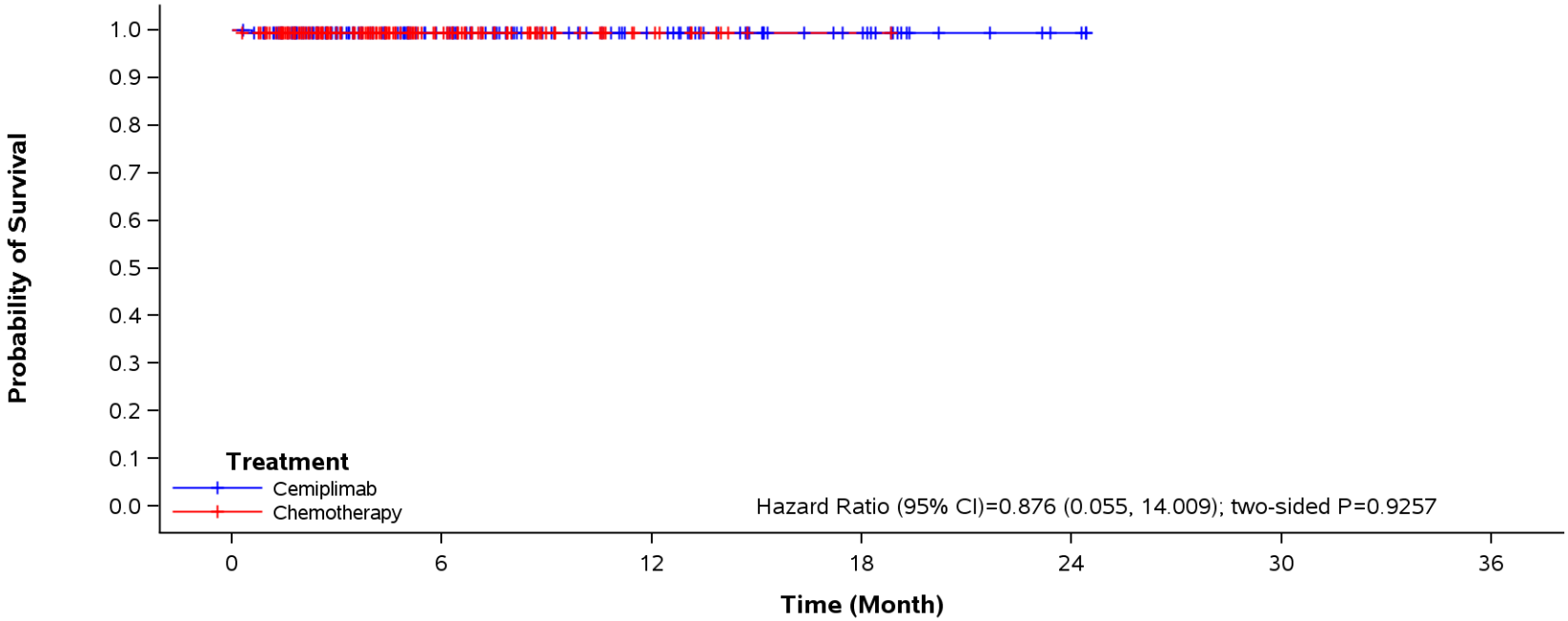

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders



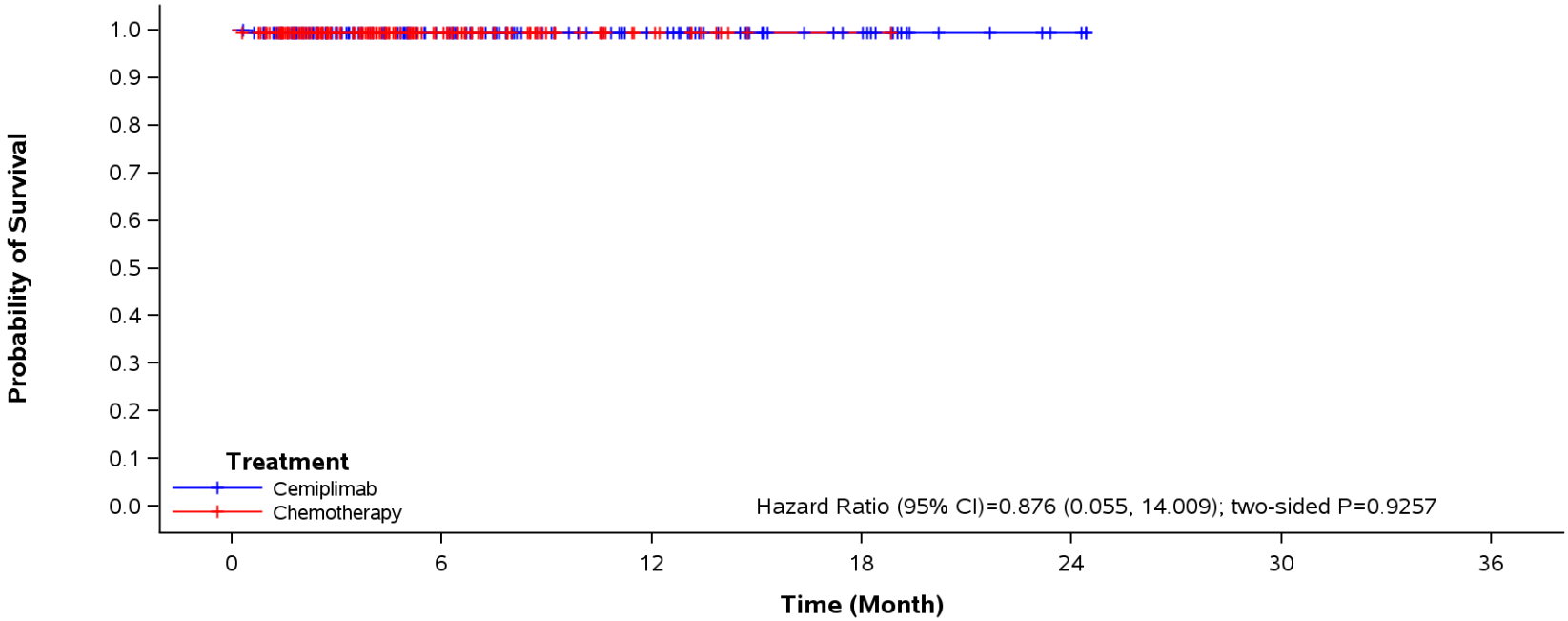

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Decreased appetite



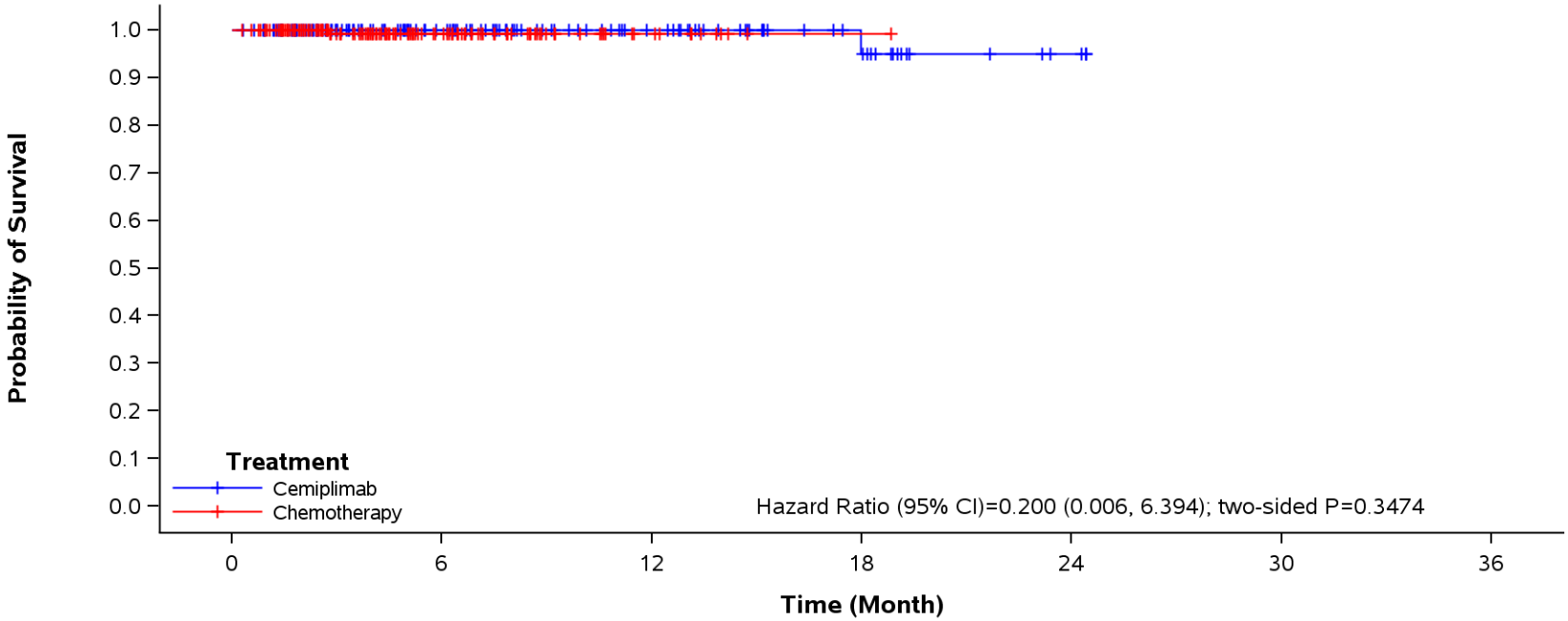

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders



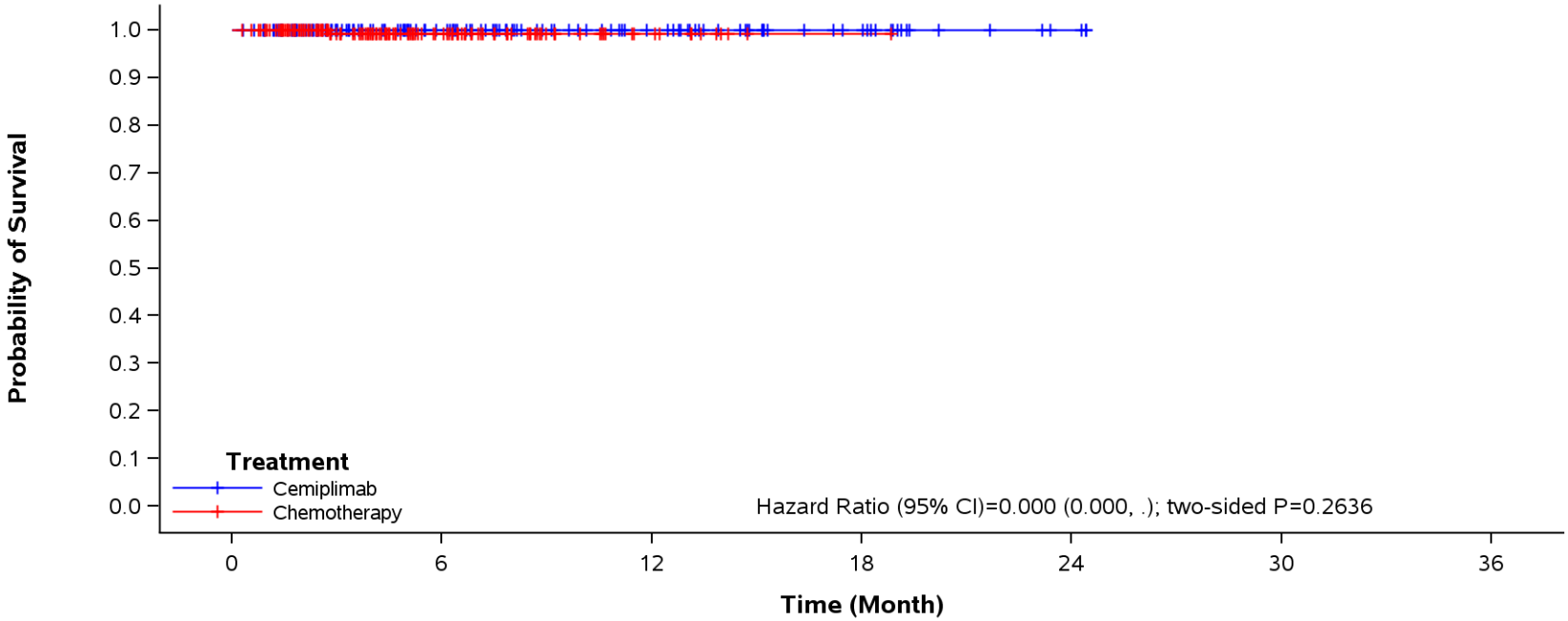

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 51 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



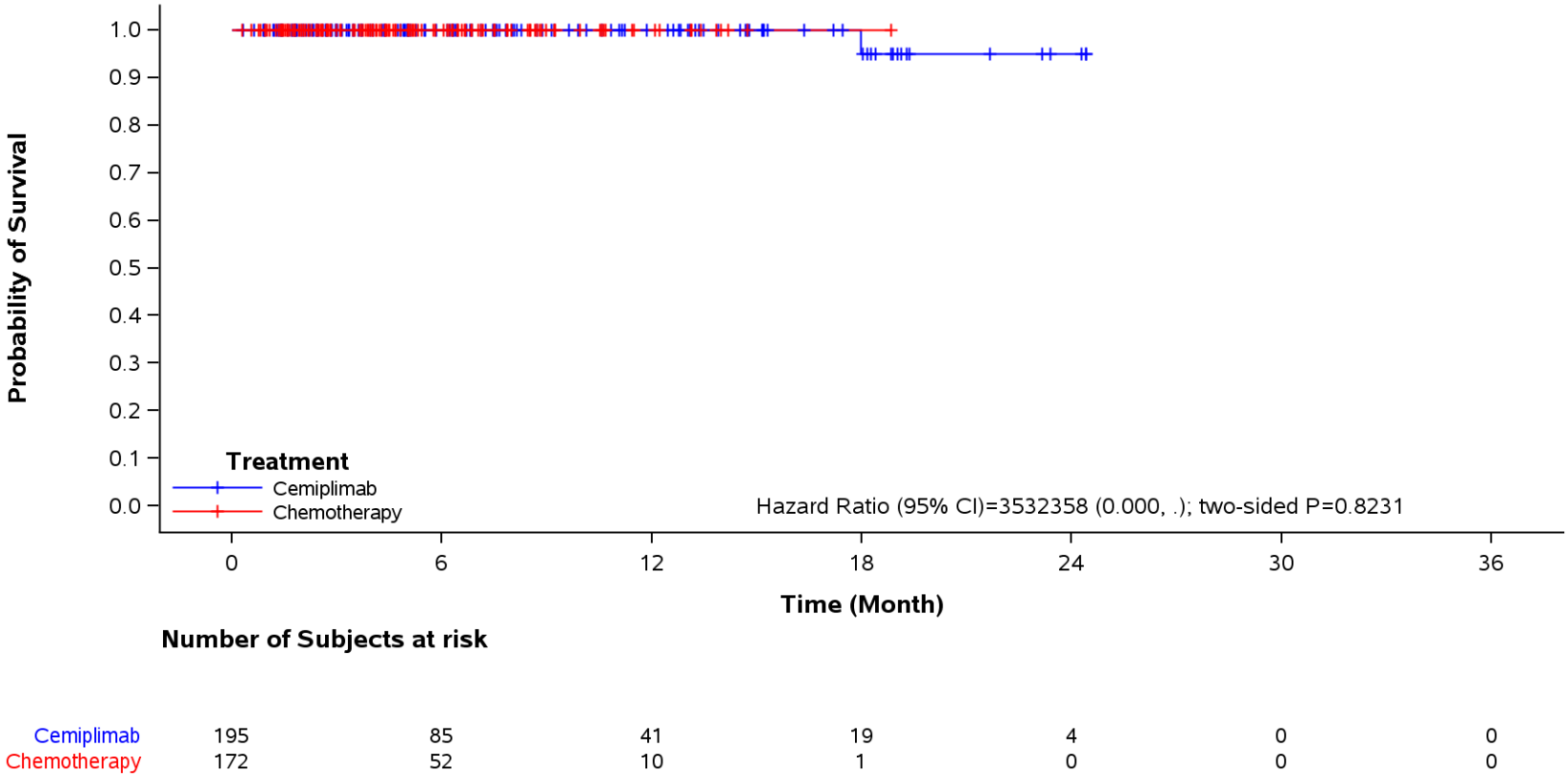

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 51 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

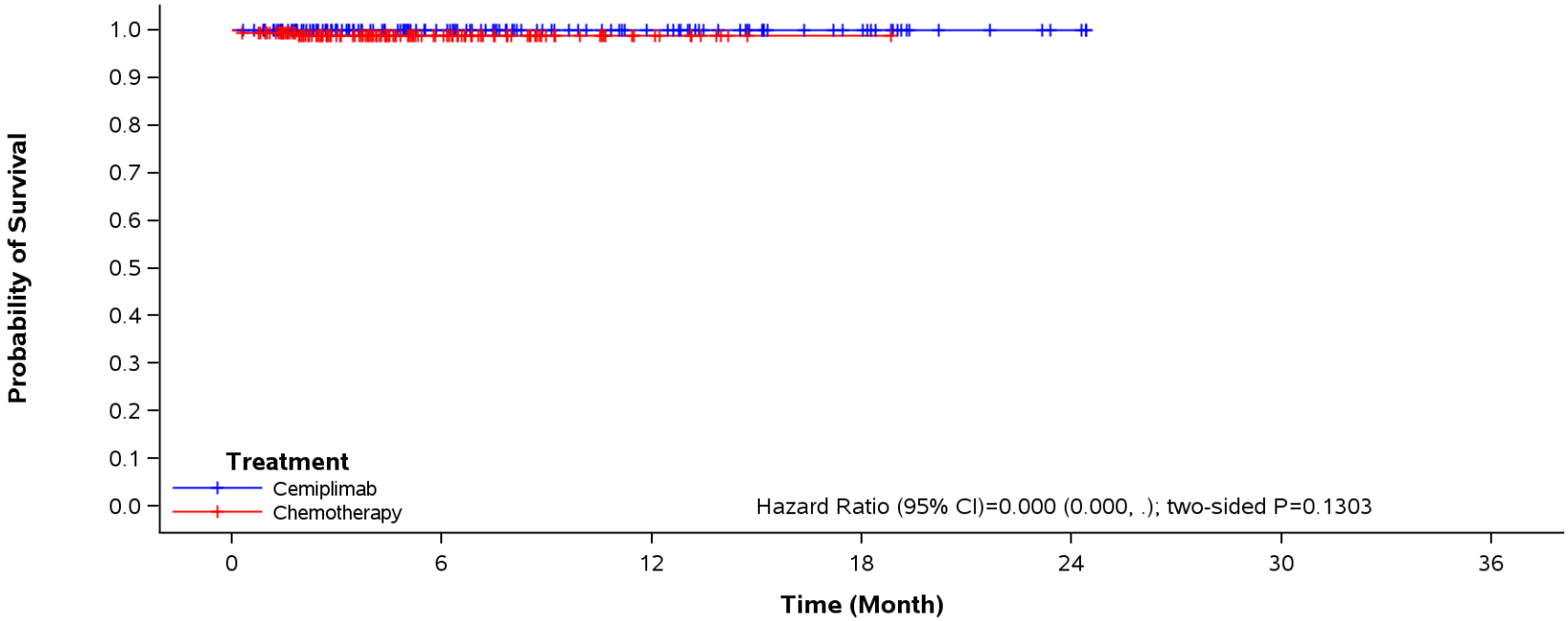
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders



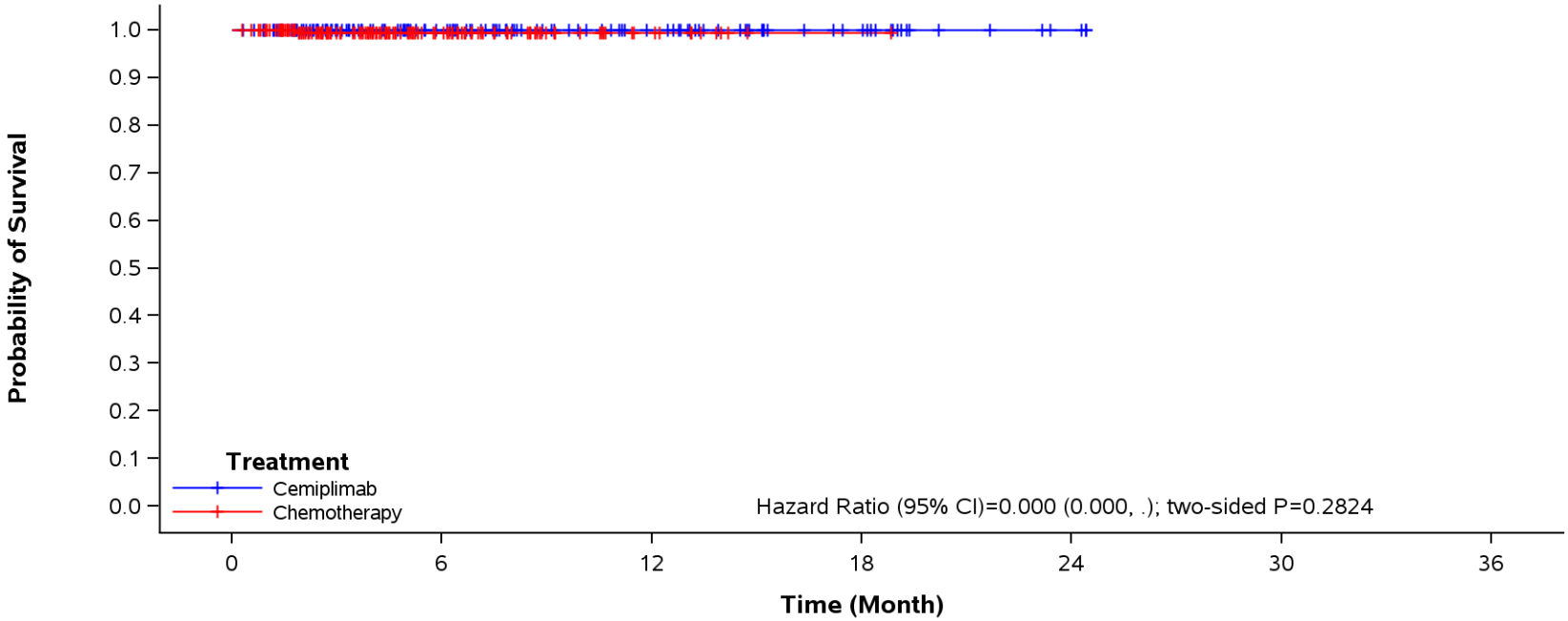

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders
PT: Neurotoxicity



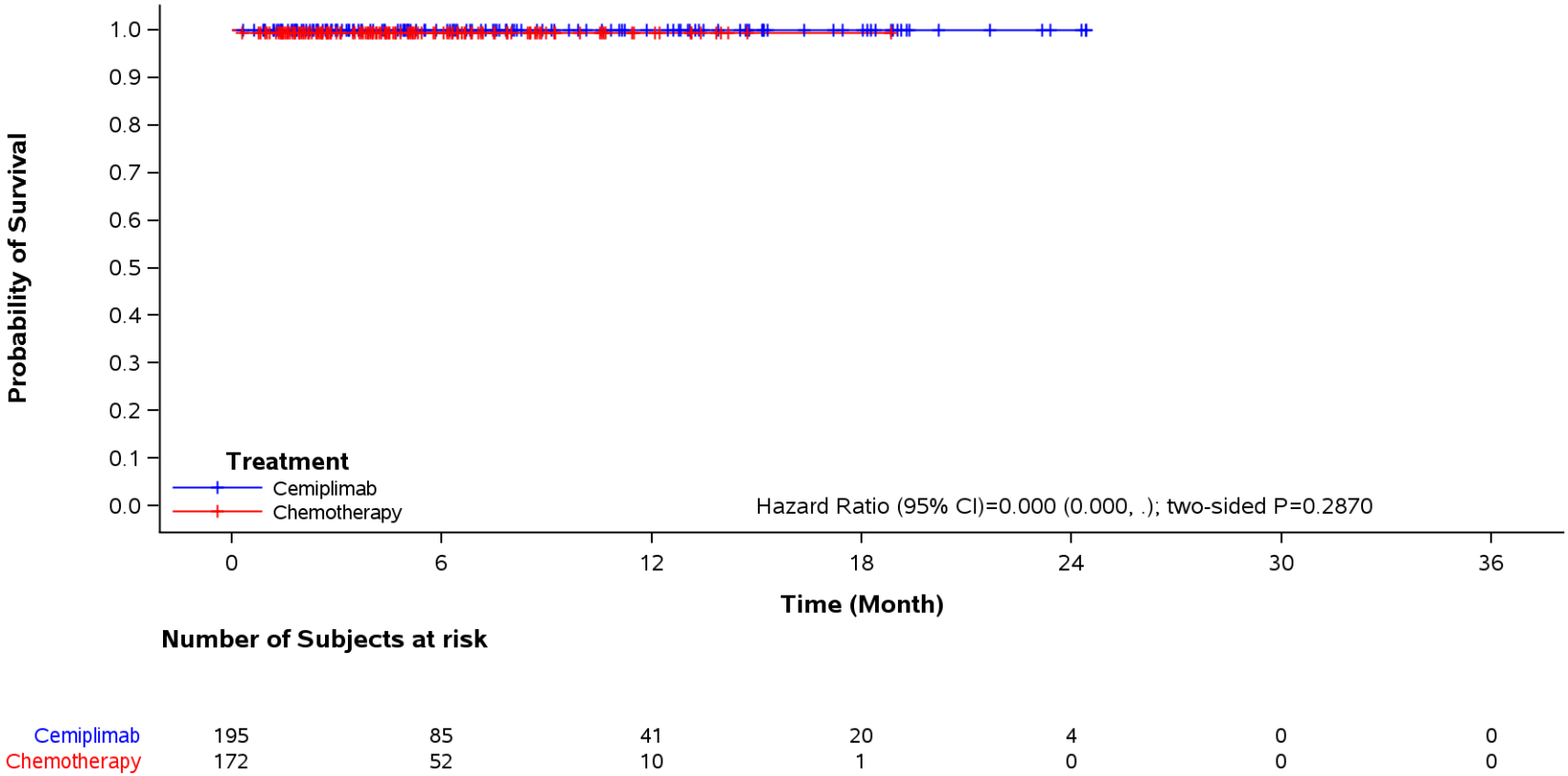

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

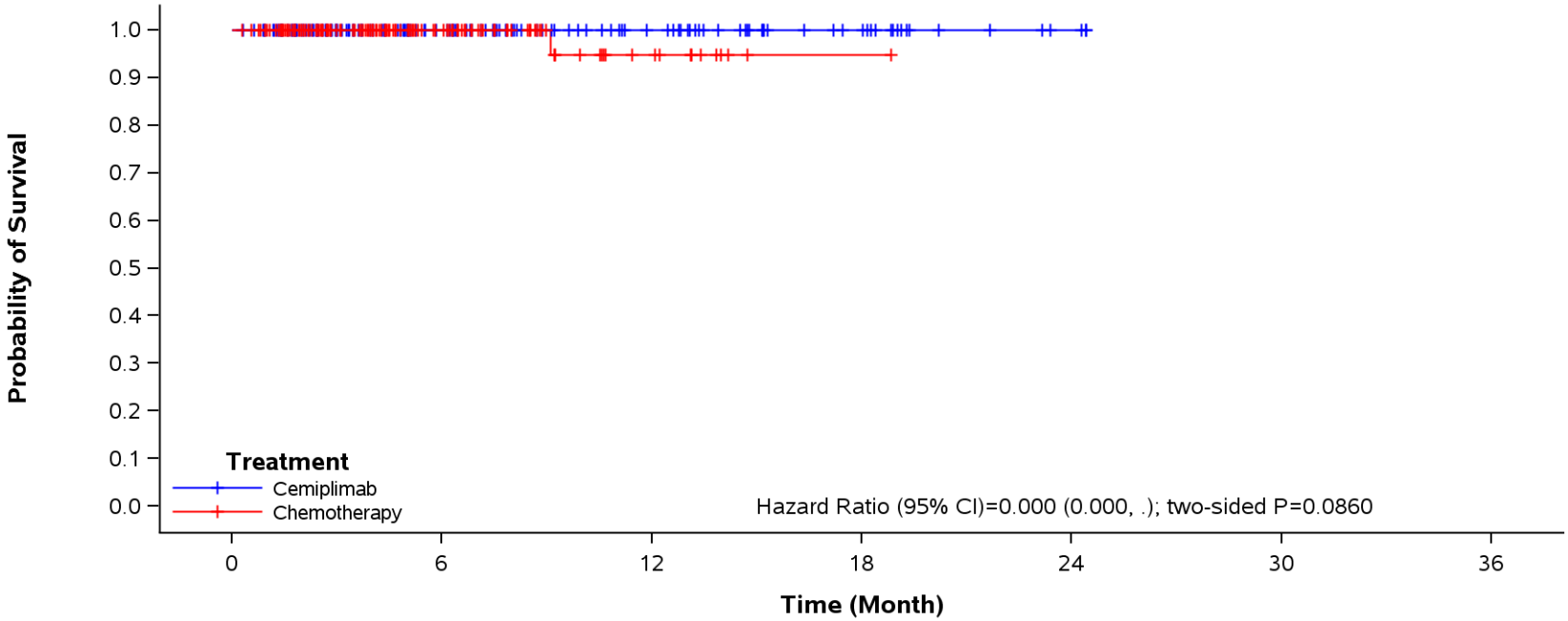
SOC: Nervous system disorders
PT: Transient ischaemic attack




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Psychiatric disorders



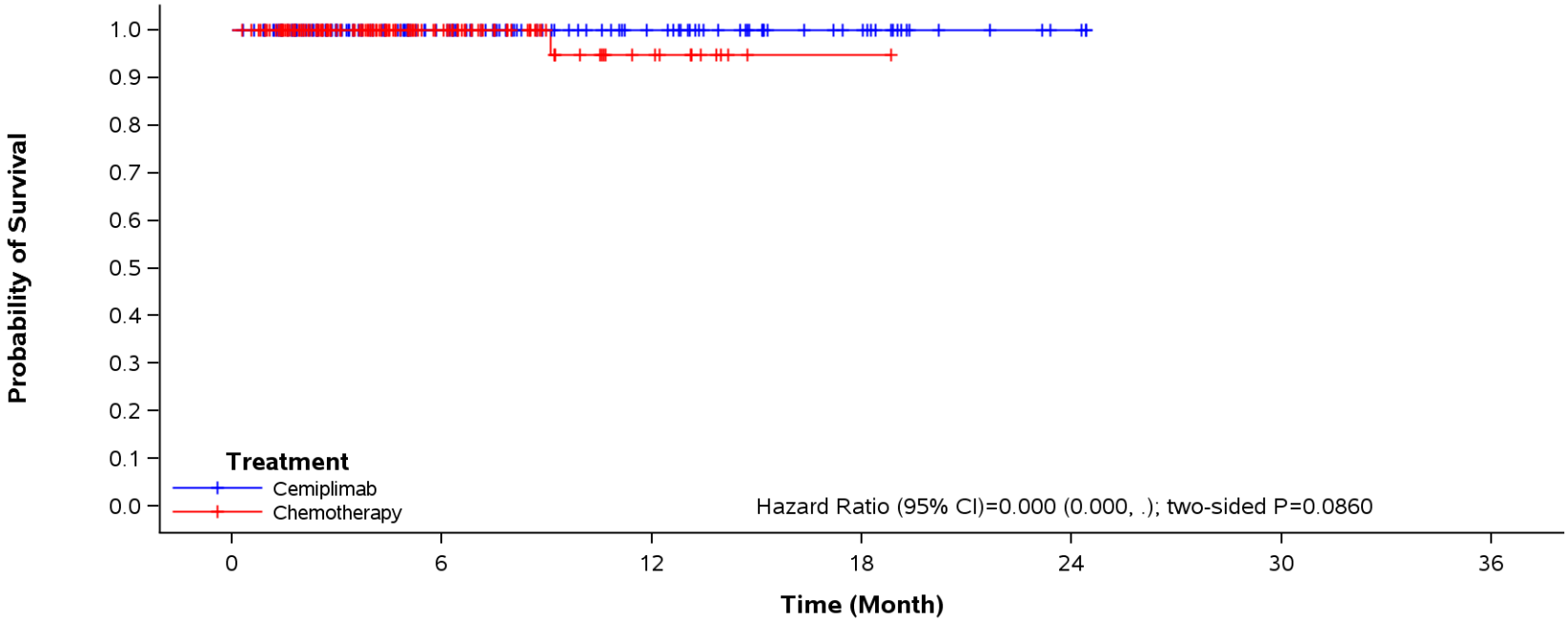

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Psychiatric disorders
PT: Agoraphobia



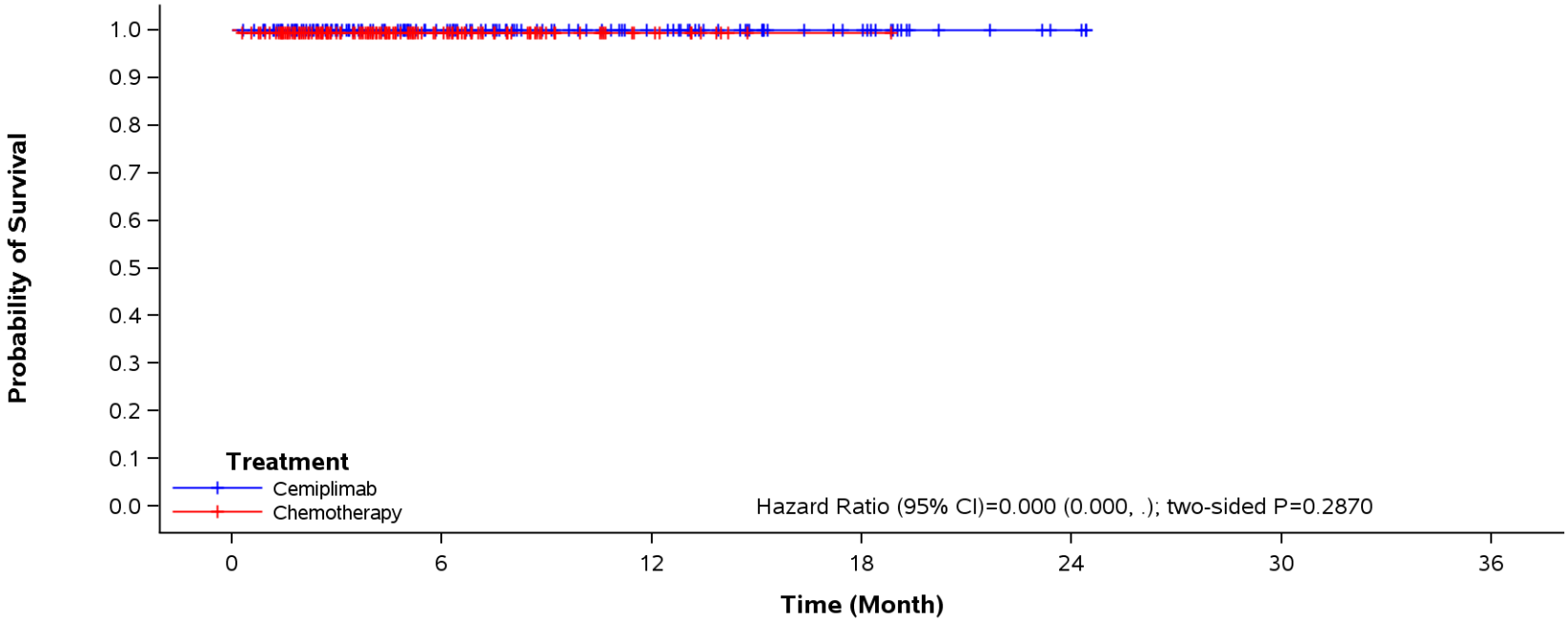

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders



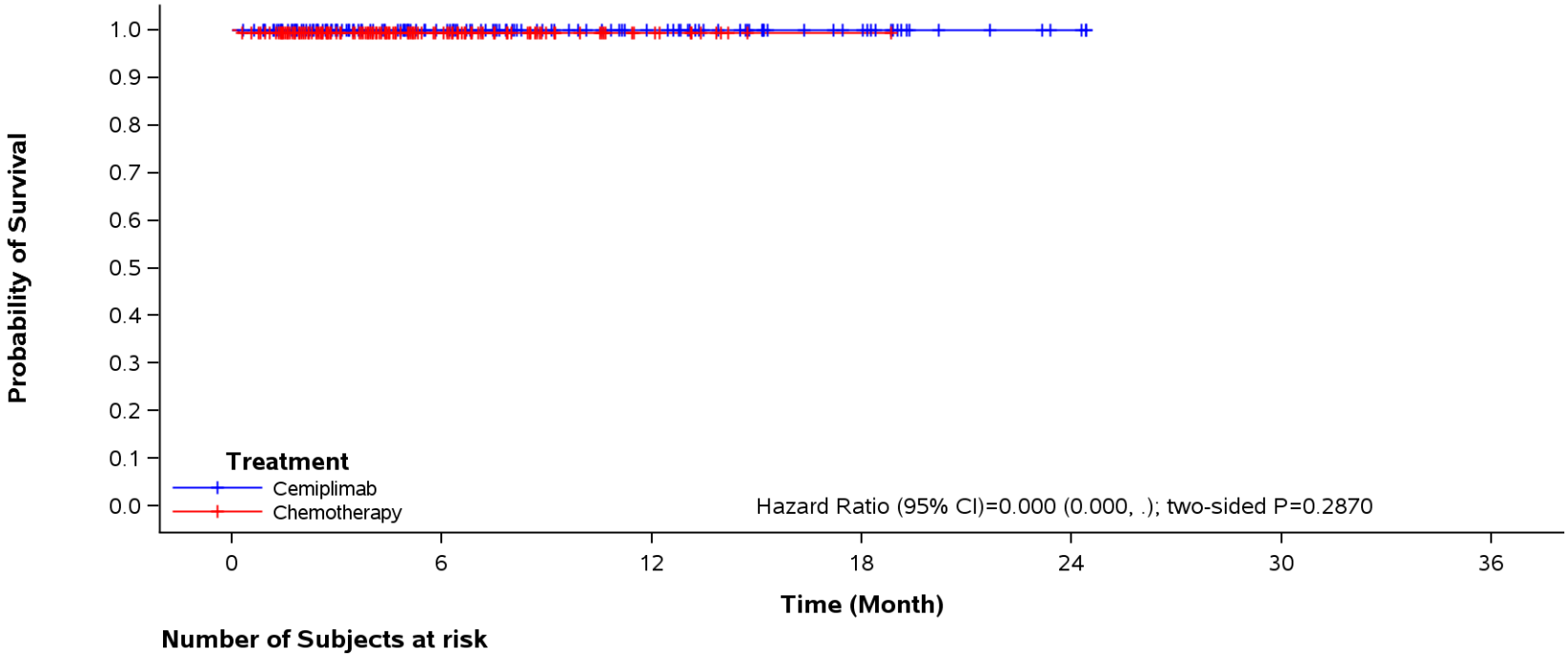

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders
PT: Renal failure



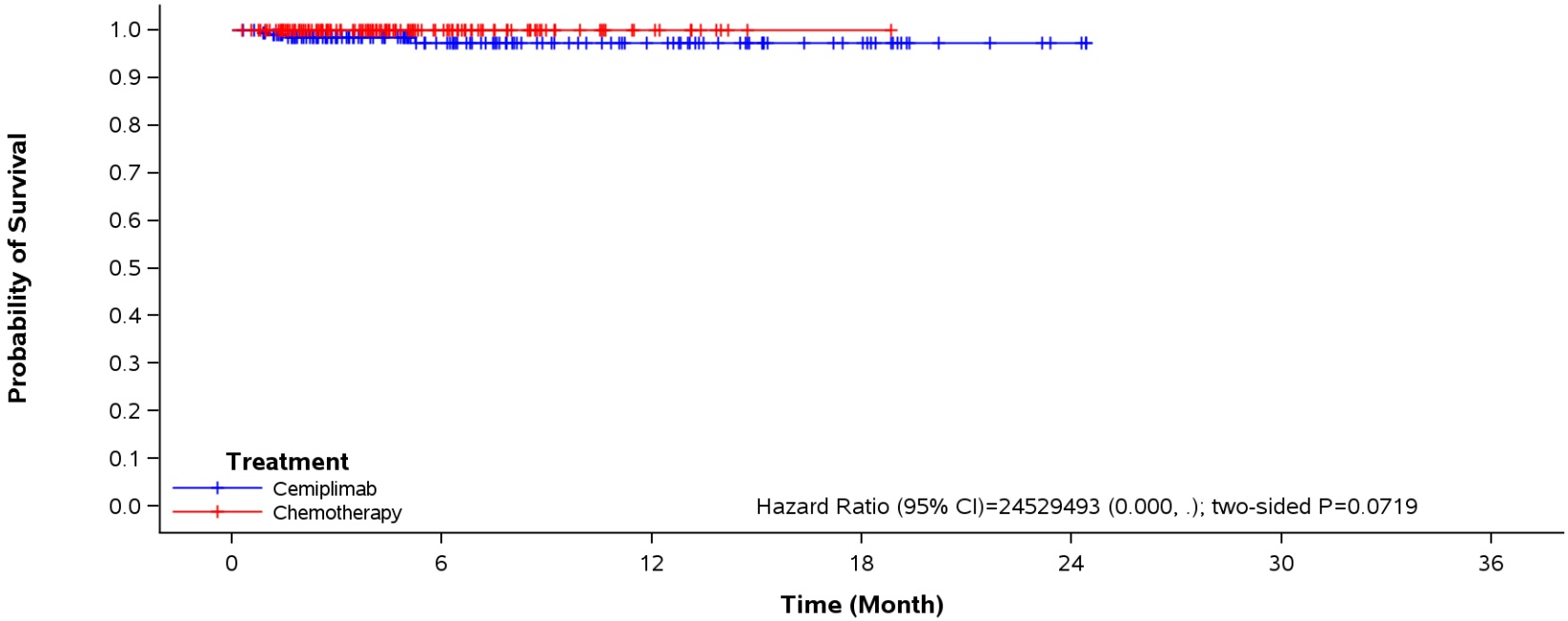

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders



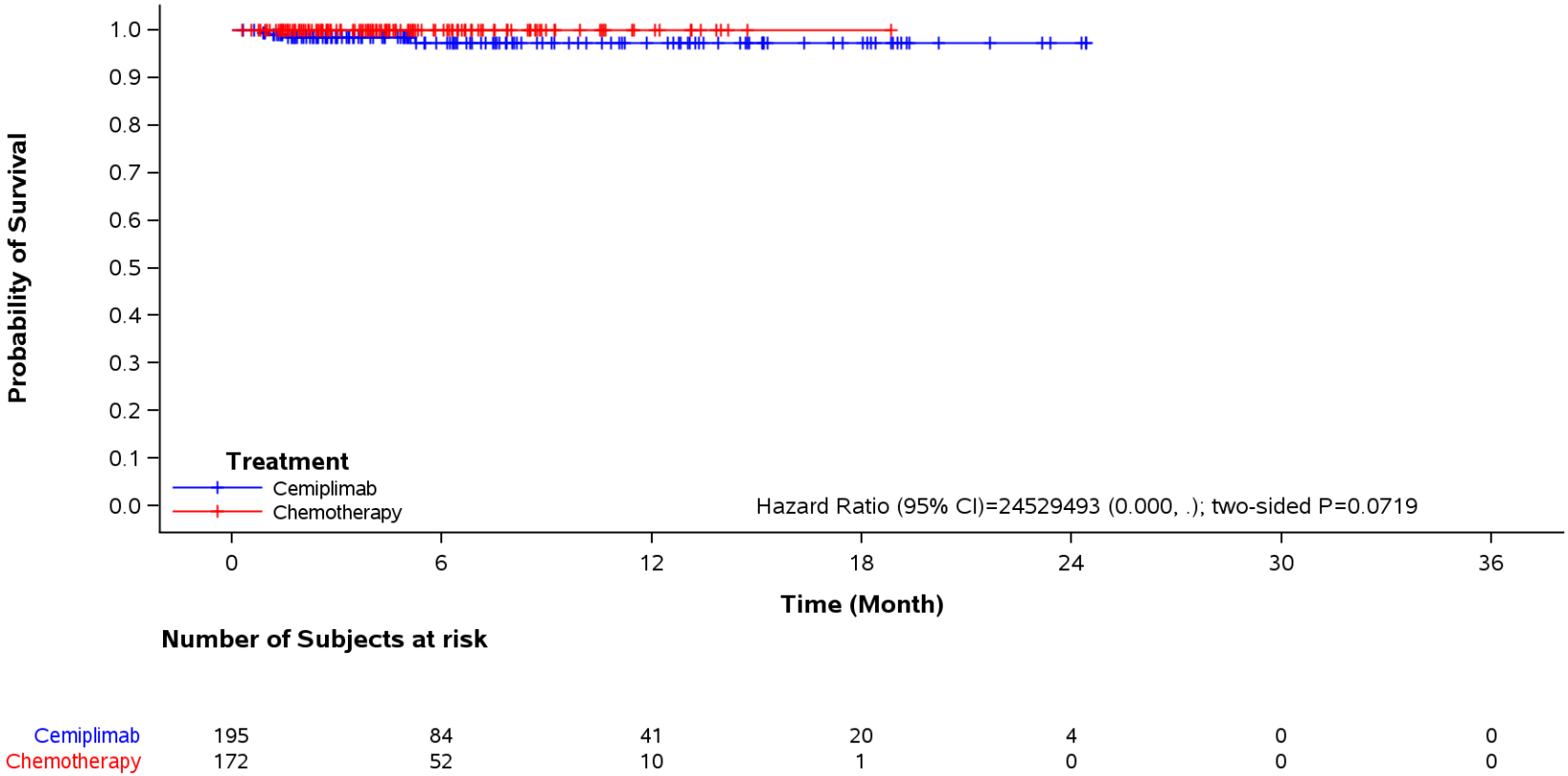

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

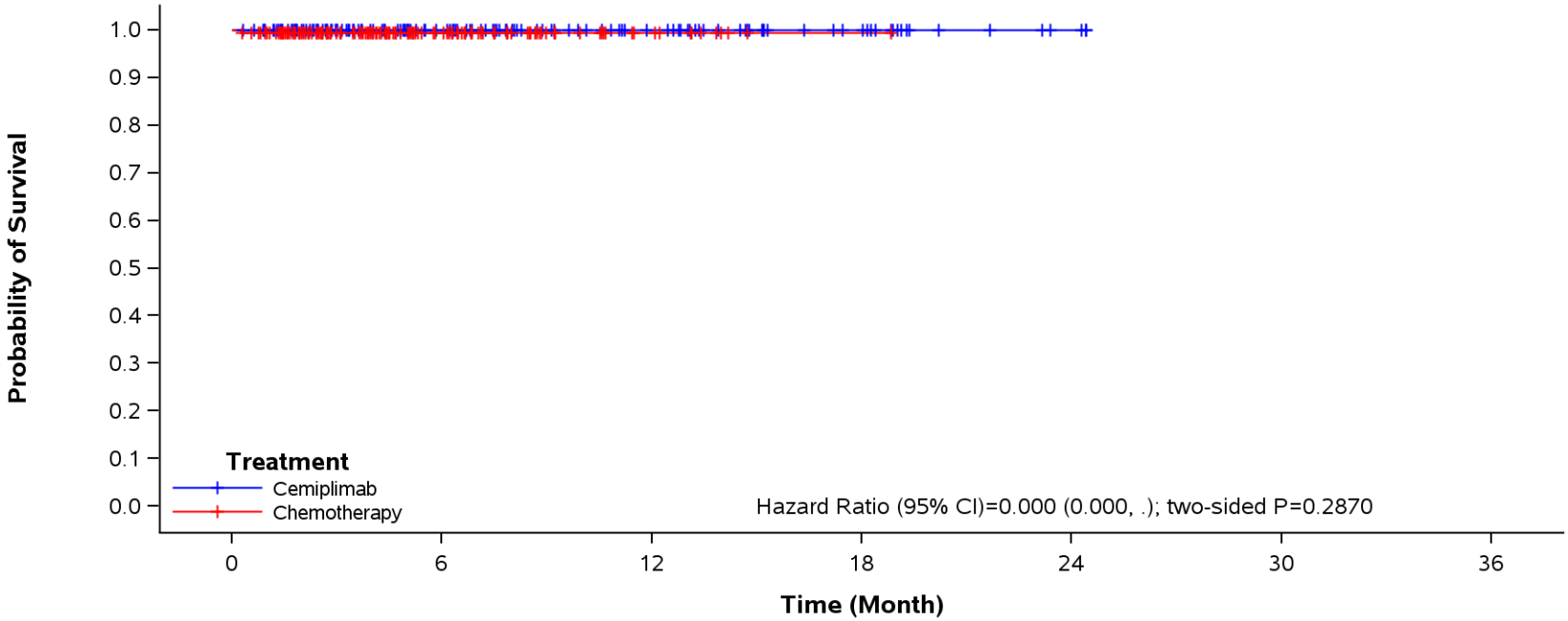
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Vascular disorders



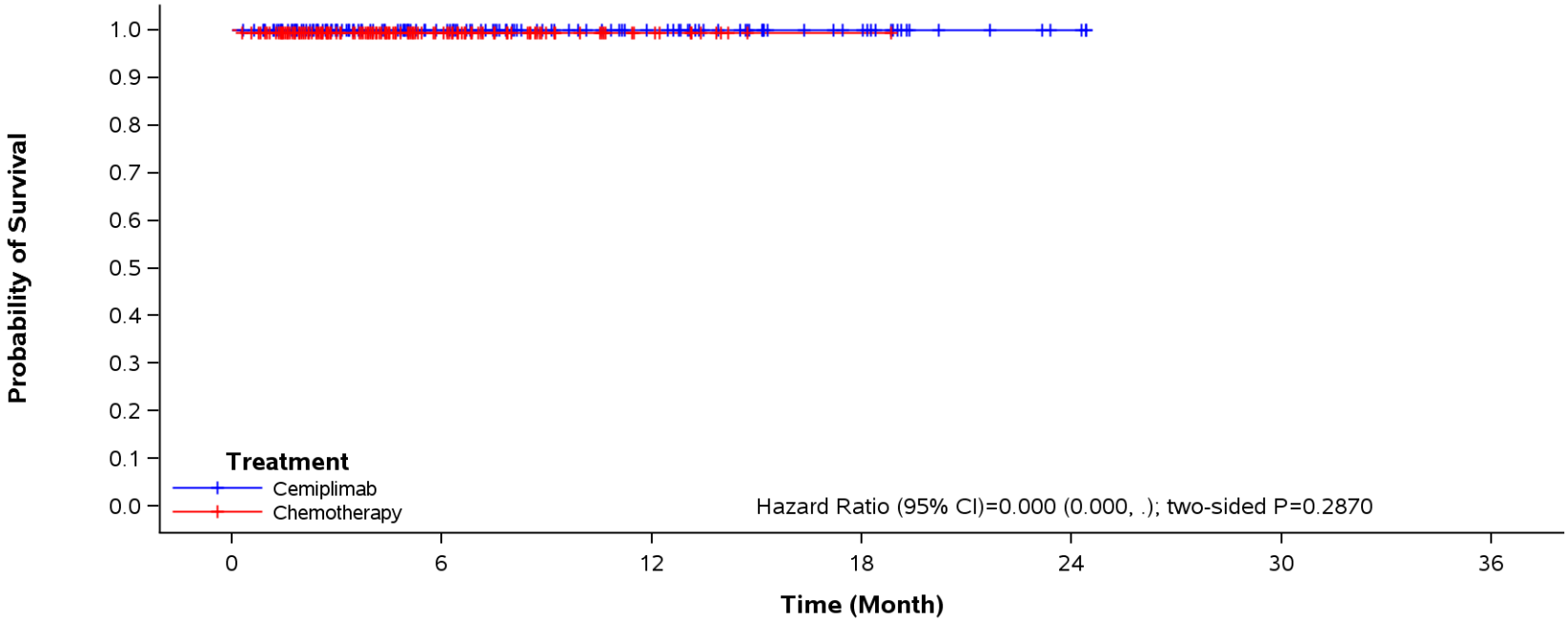

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Vascular disorders
PT: Deep vein thrombosis



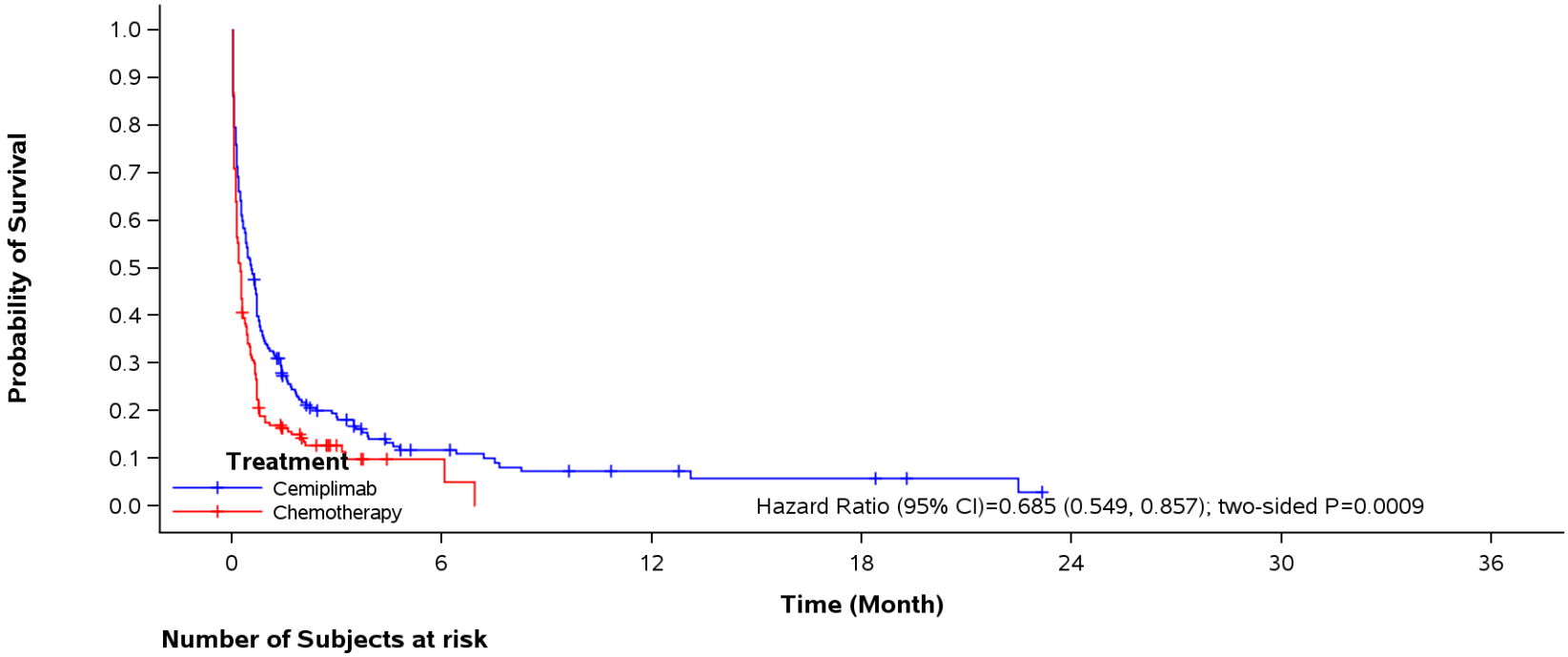

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any TEAE



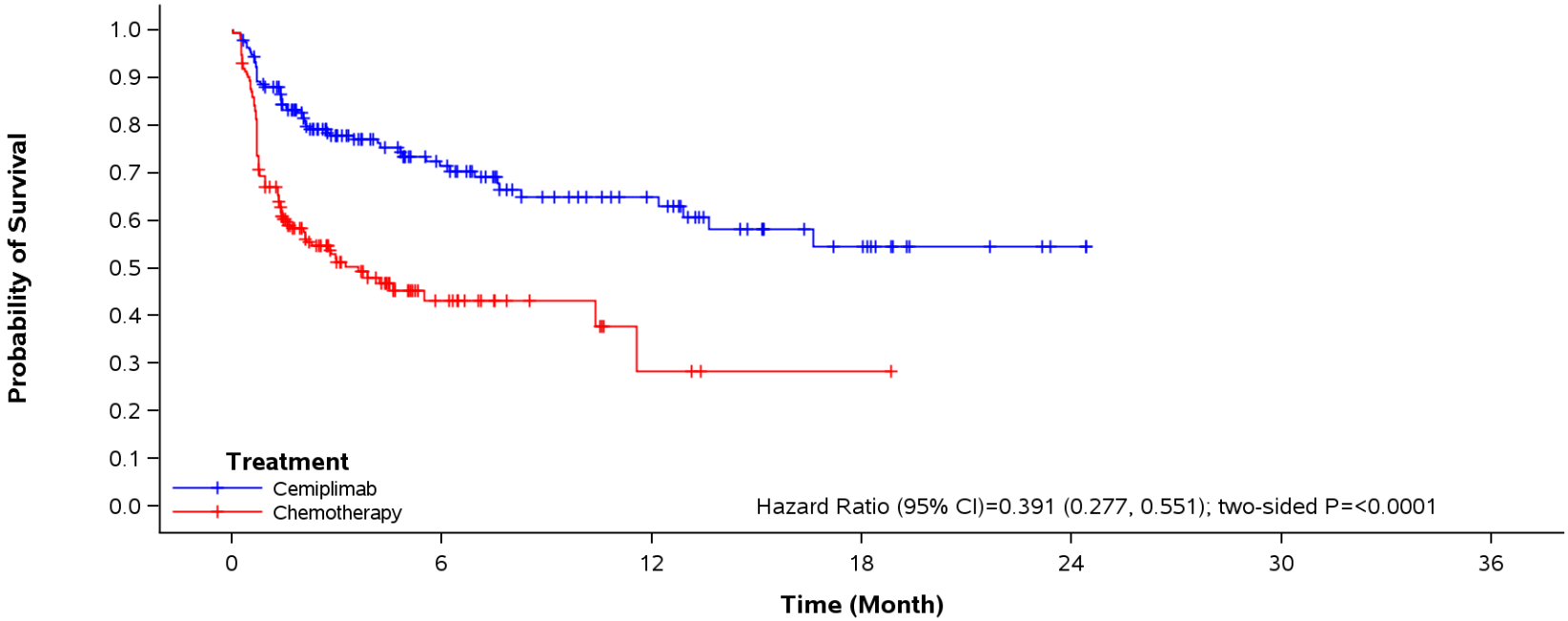

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 14 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 172 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders



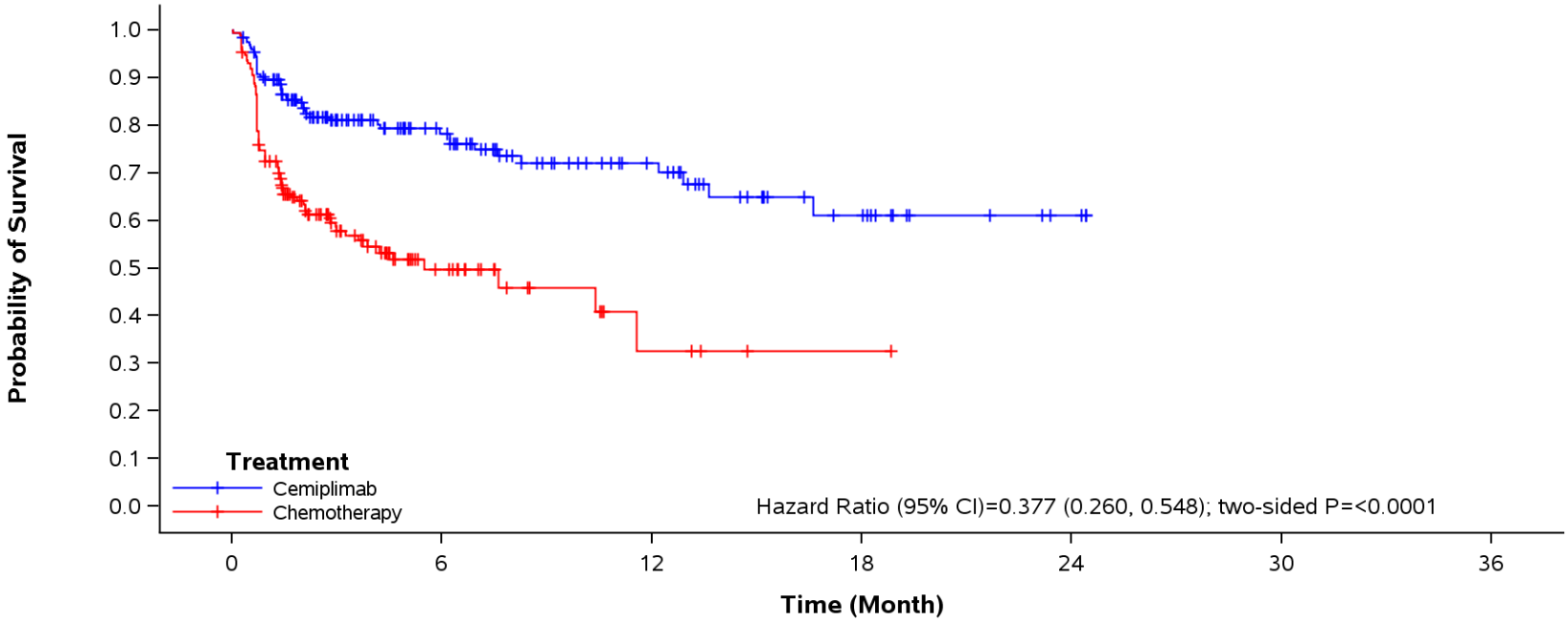

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 68 | 33 | 14 | 3 | 0 | 0 |
| Chemotherapy | 172 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia



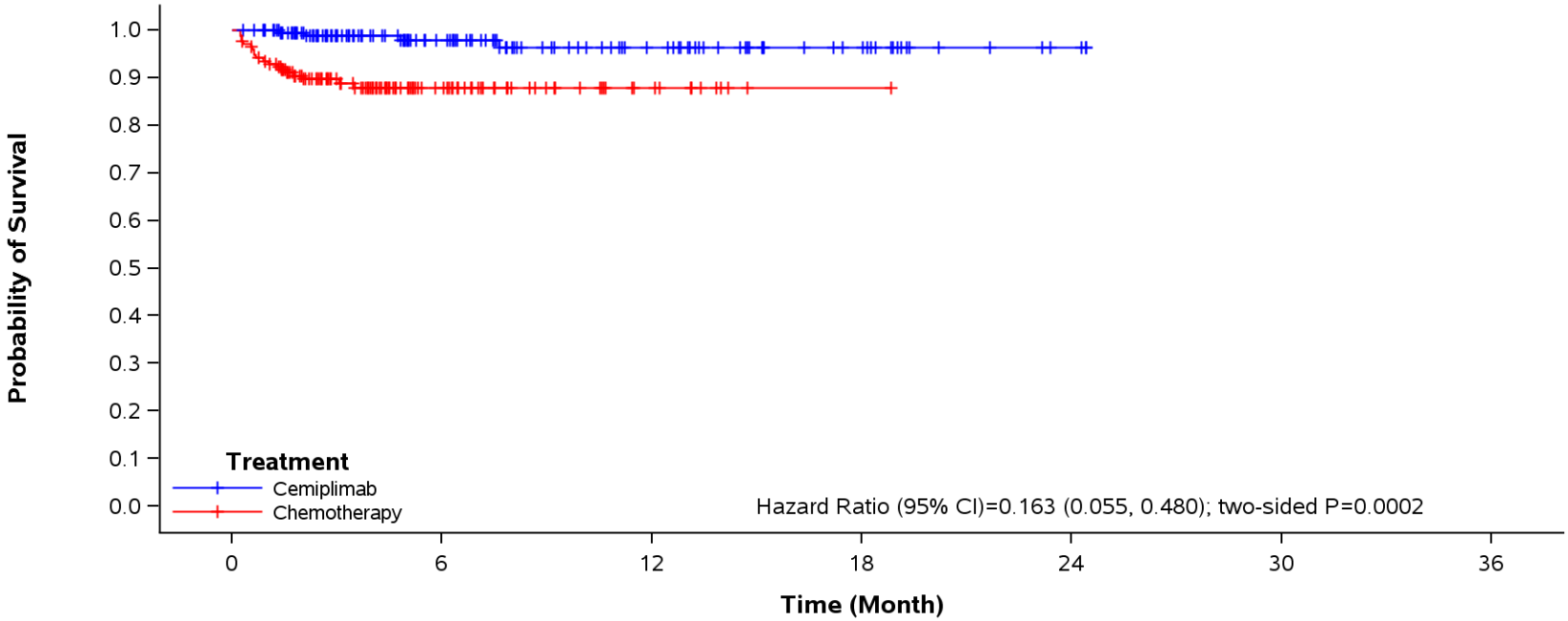

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 74 | 35 | 15 | 4 | 0 | 0 |
| Chemotherapy | 172 | 24 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Neutropenia



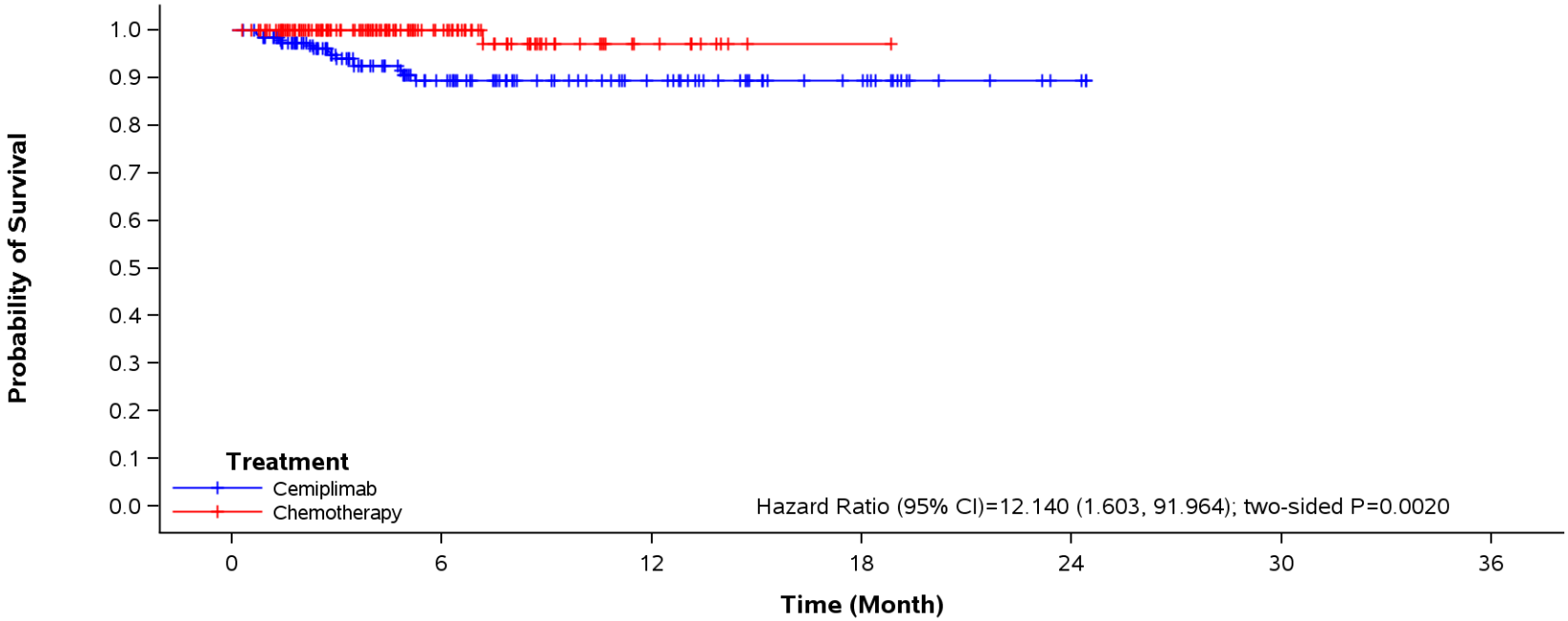

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 40 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 45 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Endocrine disorders



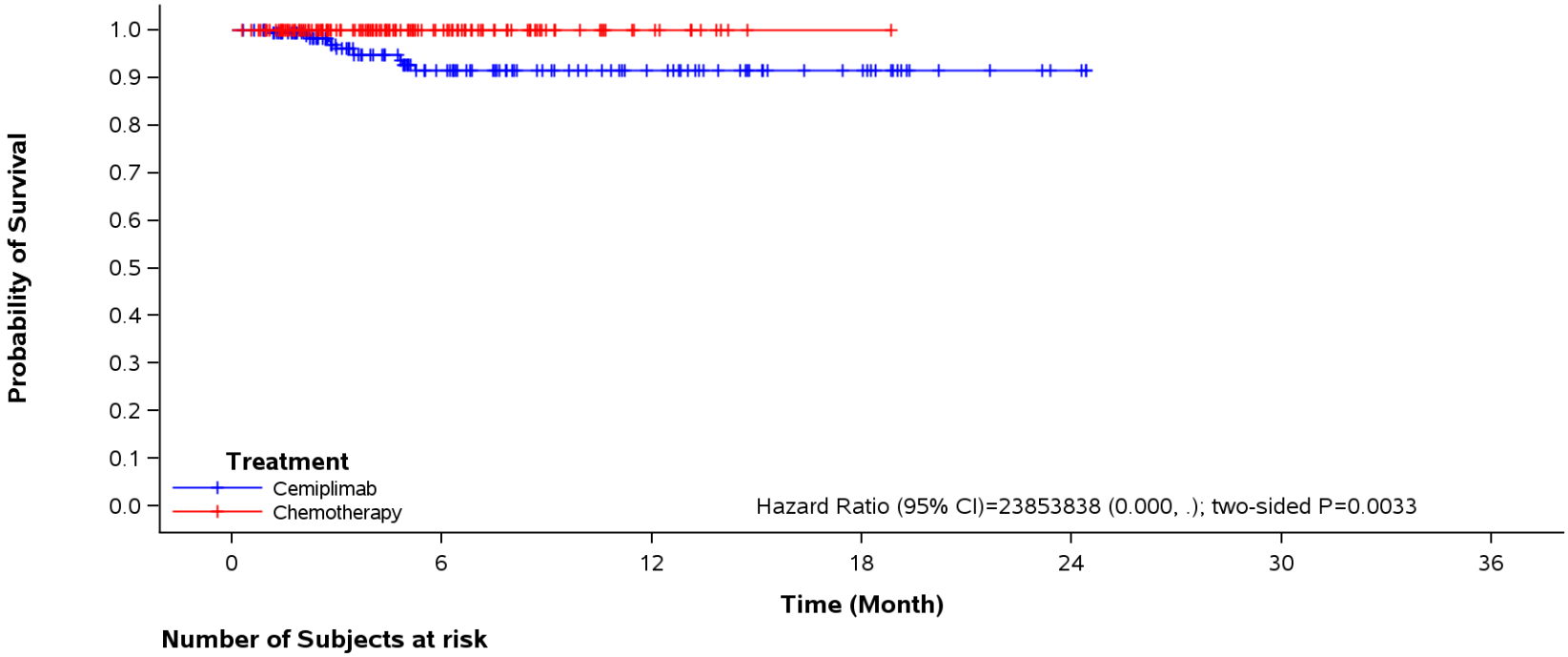

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 38 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Endocrine disorders
PT: Hypothyroidism



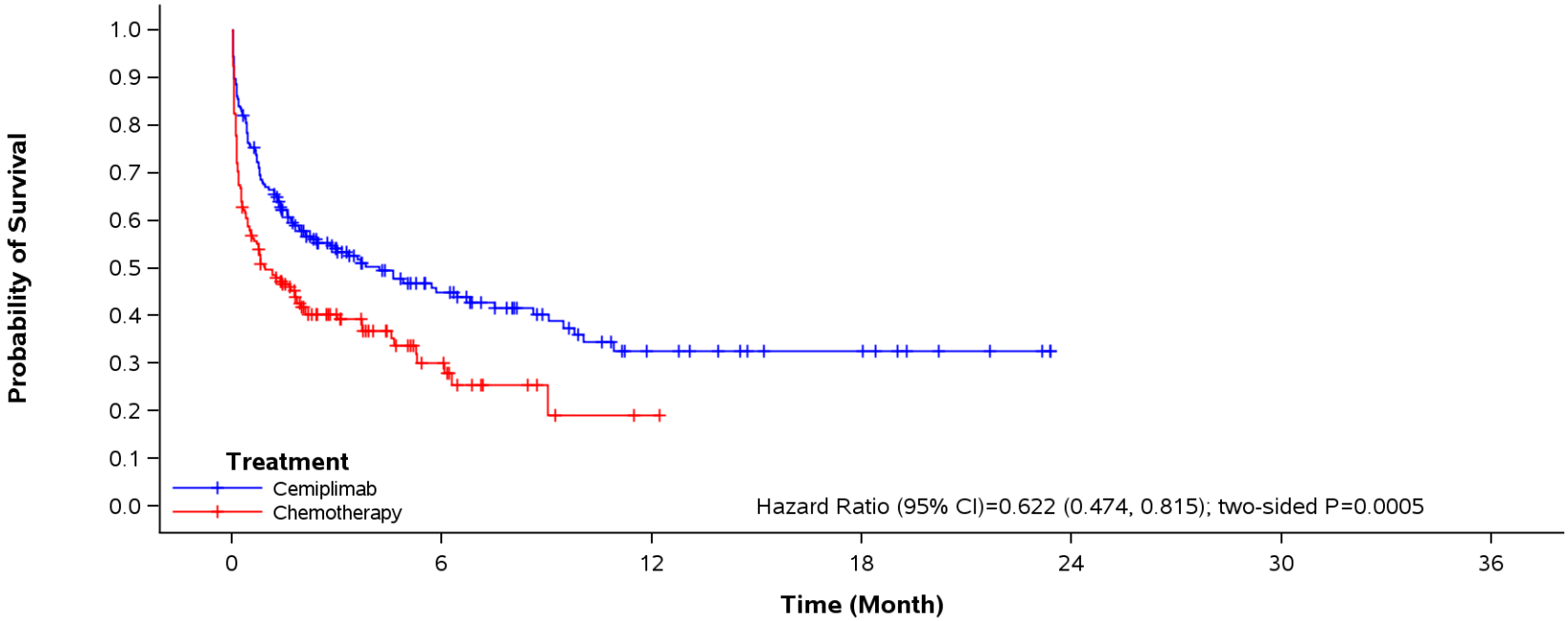

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 78 | 38 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders



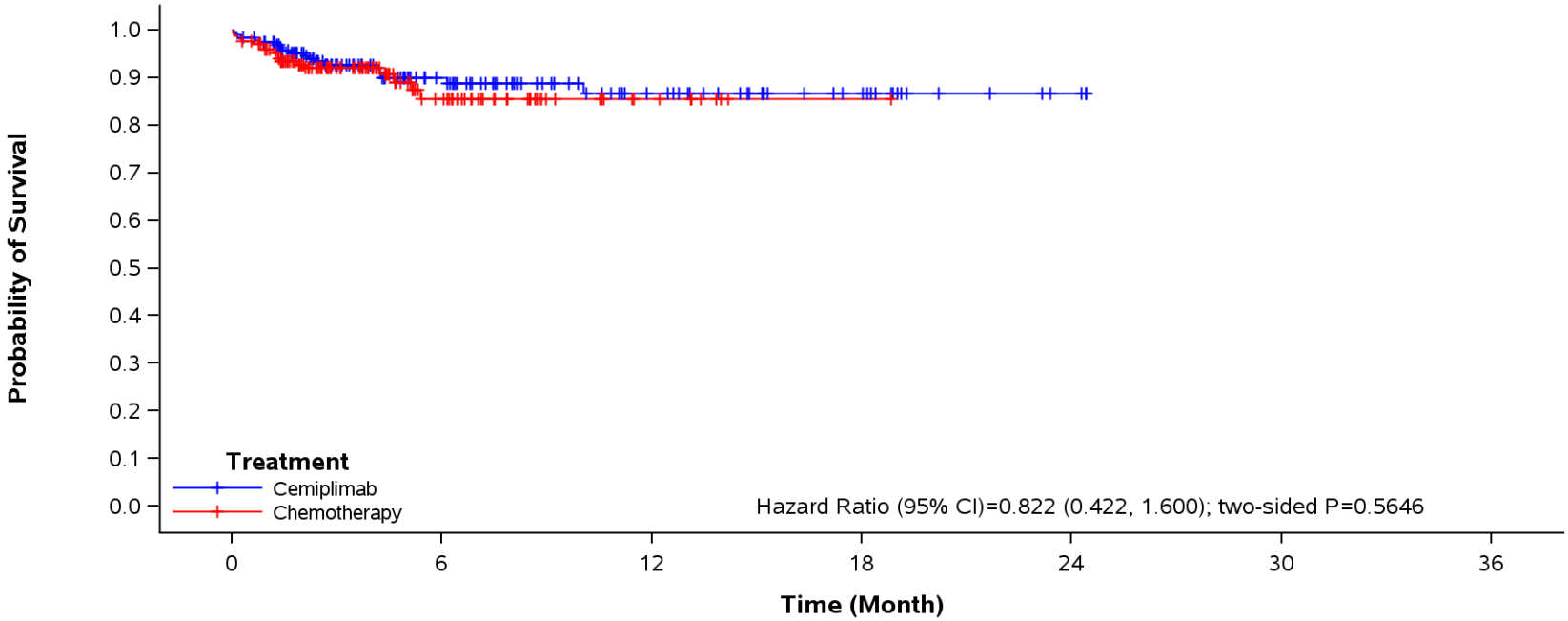

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 46 | 15 | 9 | 0 | 0 | 0 |
| Chemotherapy | 172 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Abdominal pain



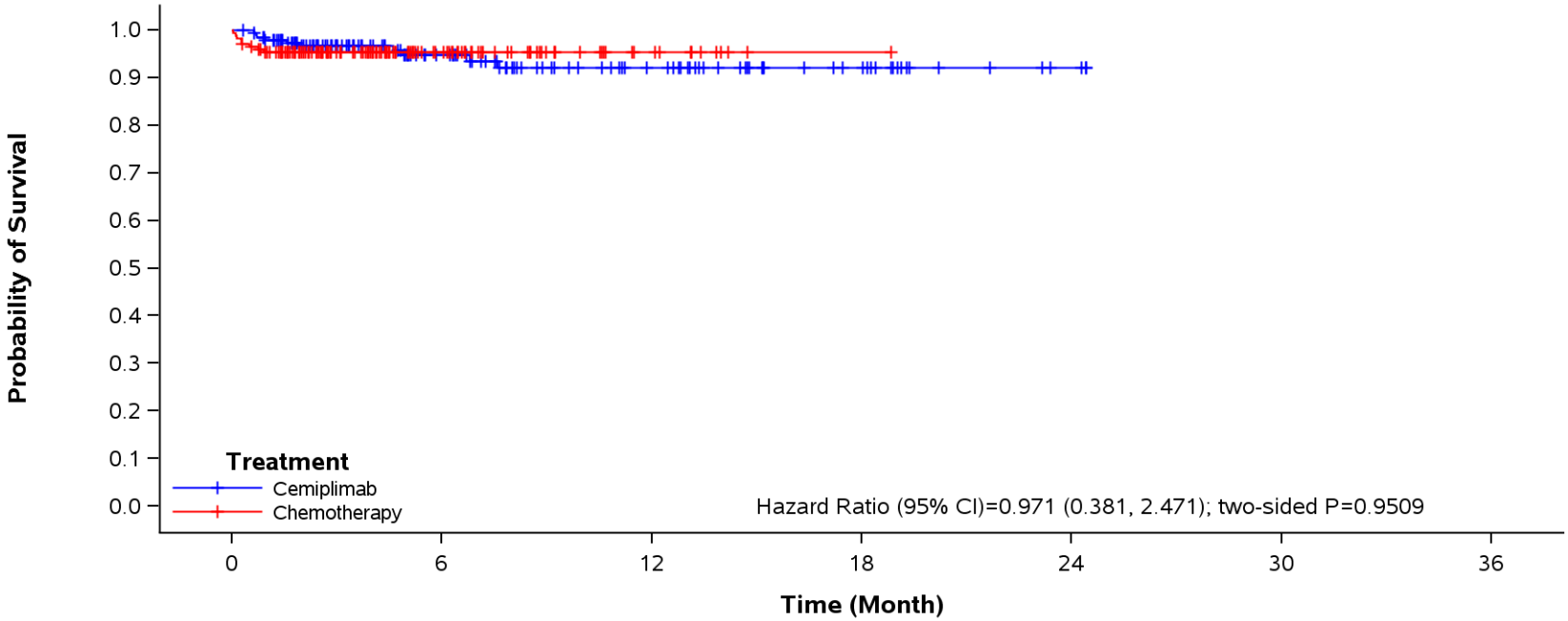

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 35 | 18 | 3 | 0 | 0 |
| Chemotherapy | 172 | 44 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Abdominal pain upper



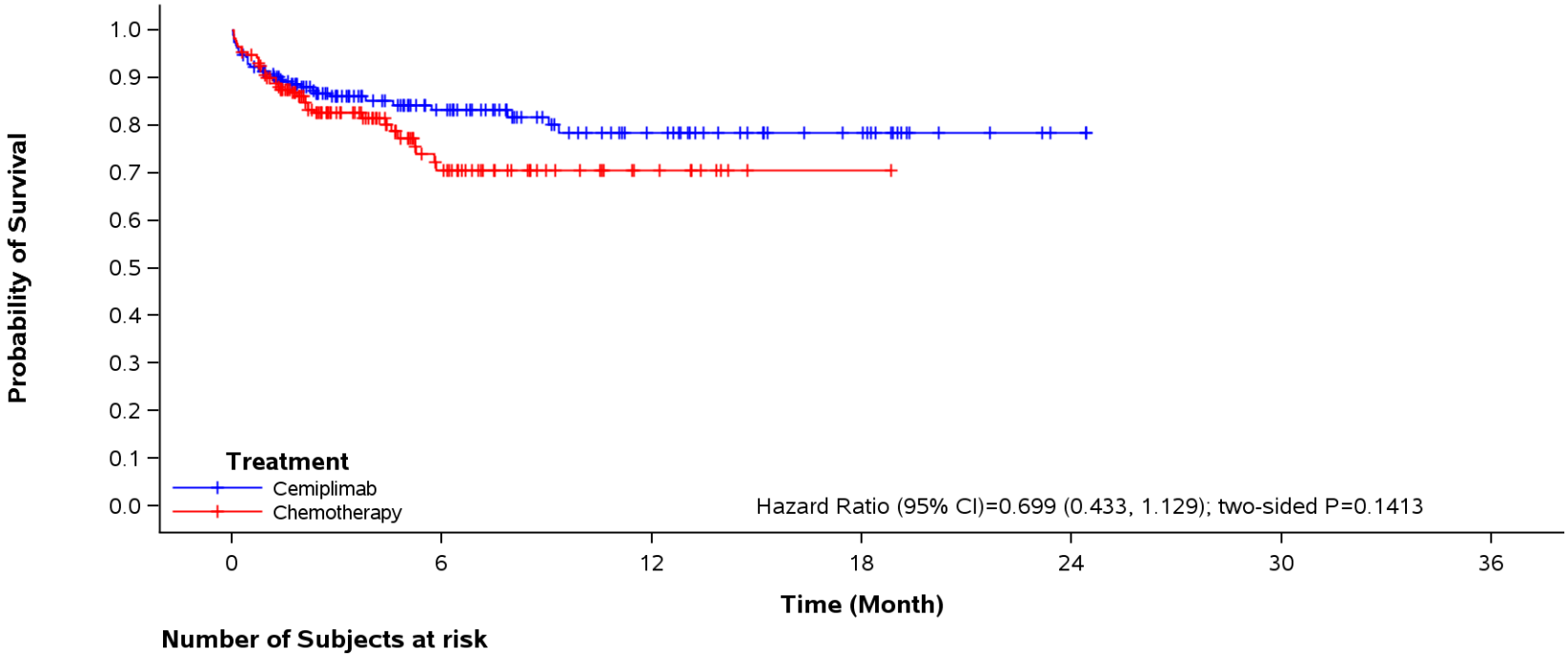

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 40 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 49 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Constipation



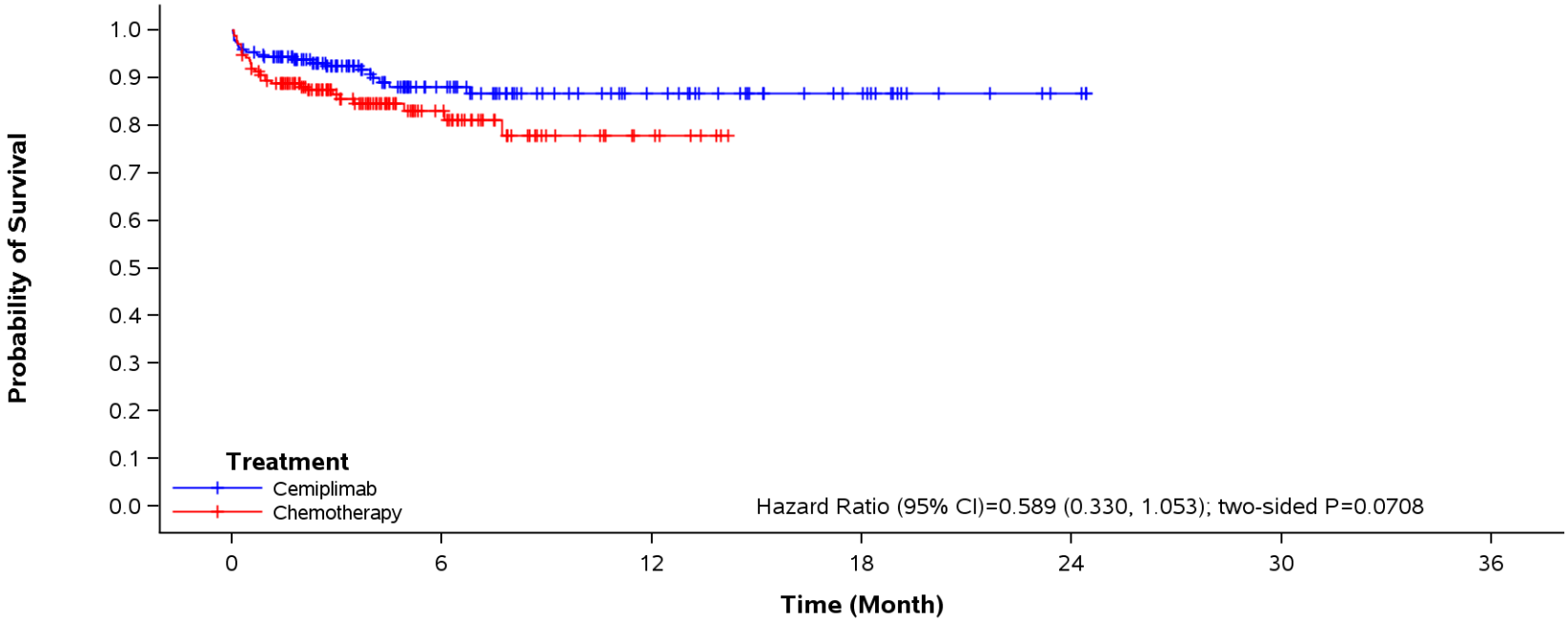

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 76 | 35 | 19 | 3 | 0 | 0 |
| Chemotherapy | 172 | 40 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Diarrhoea



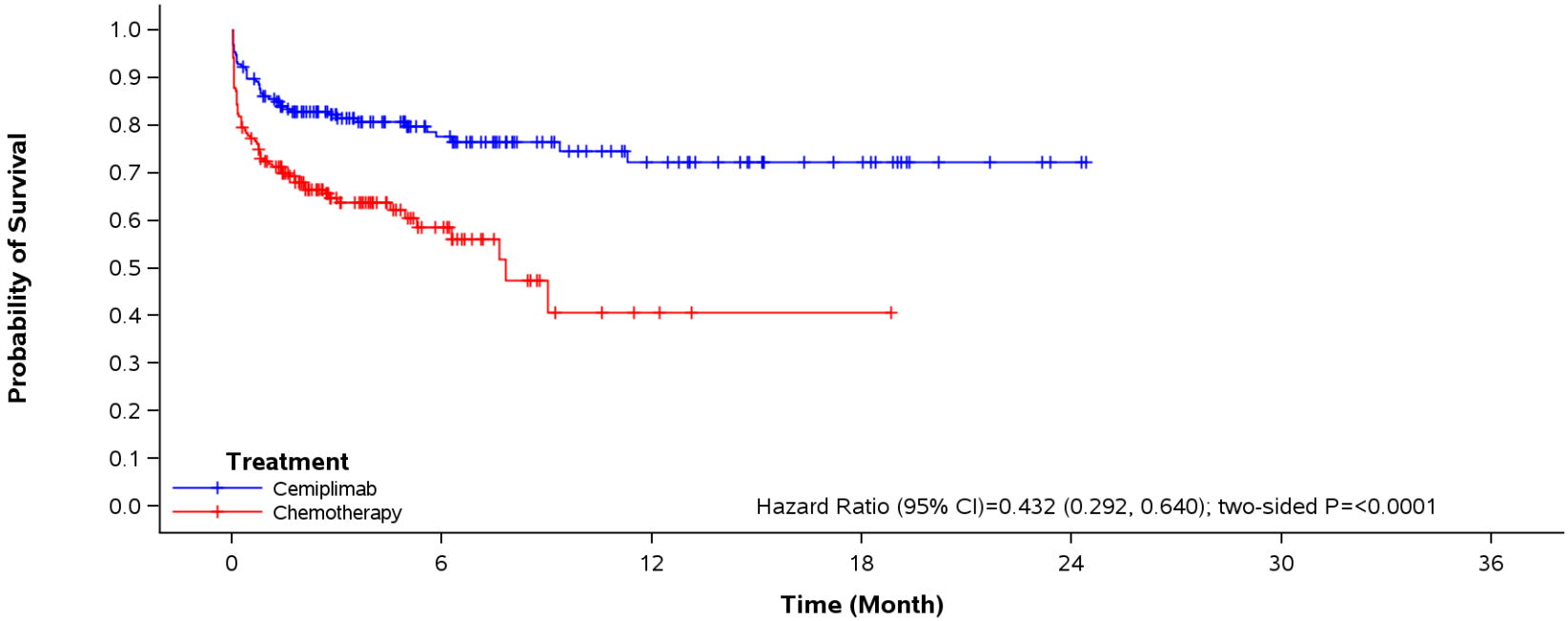

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 73 | 35 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 45 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Nausea



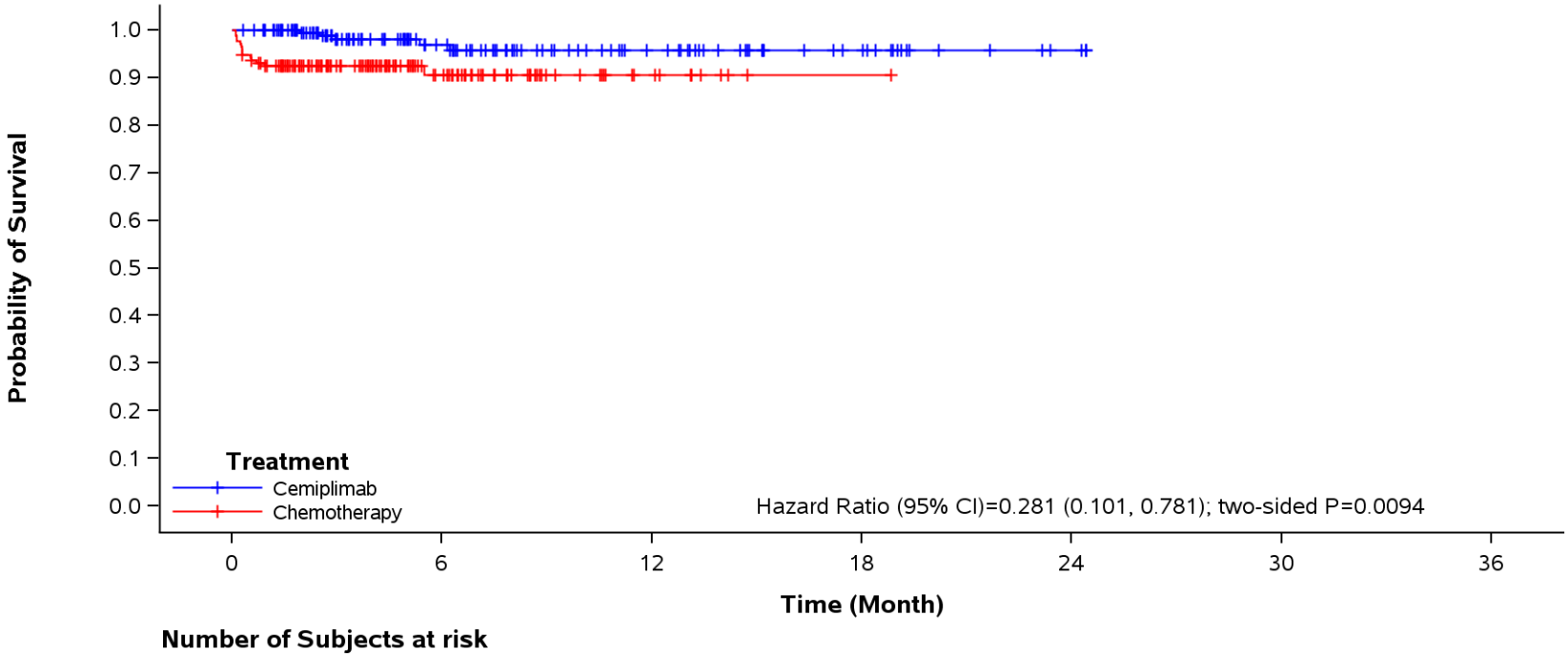

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 71 | 30 | 16 | 2 | 0 | 0 |
| Chemotherapy | 172 | 28 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Stomatitis



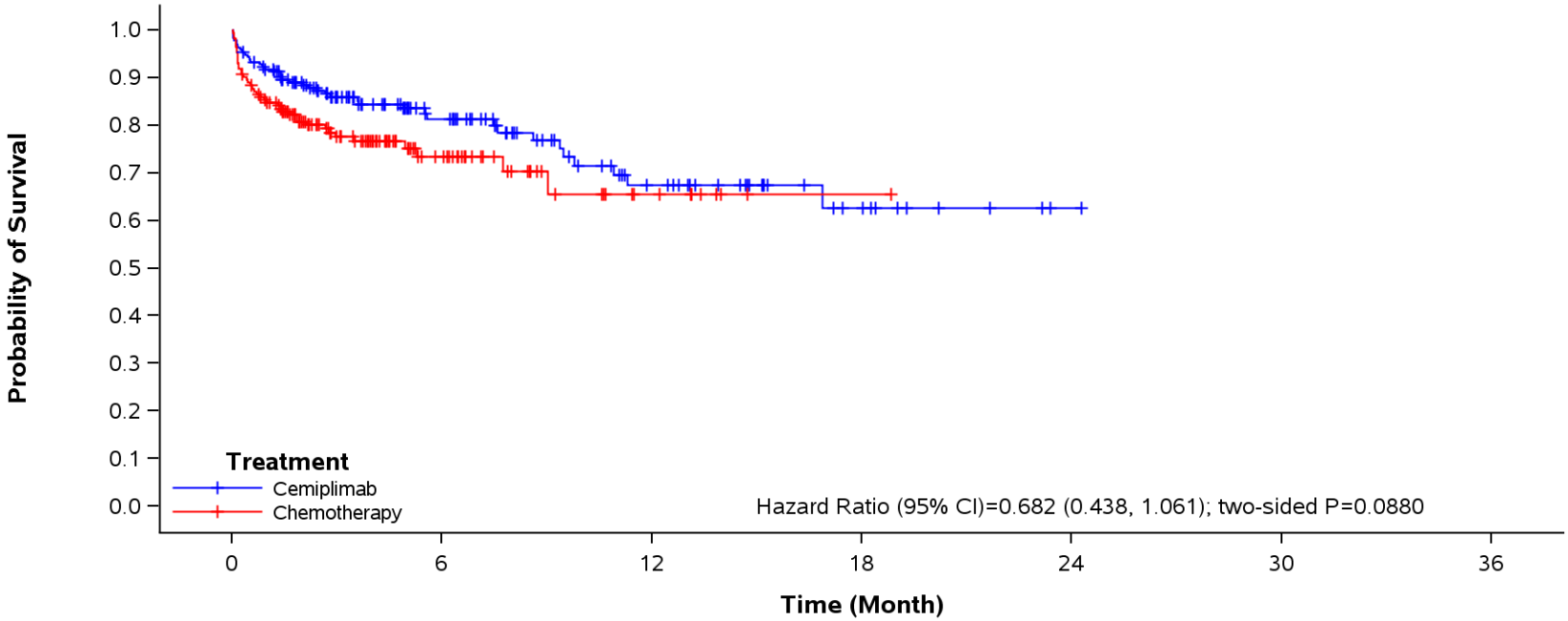

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 38 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 48 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Vomiting



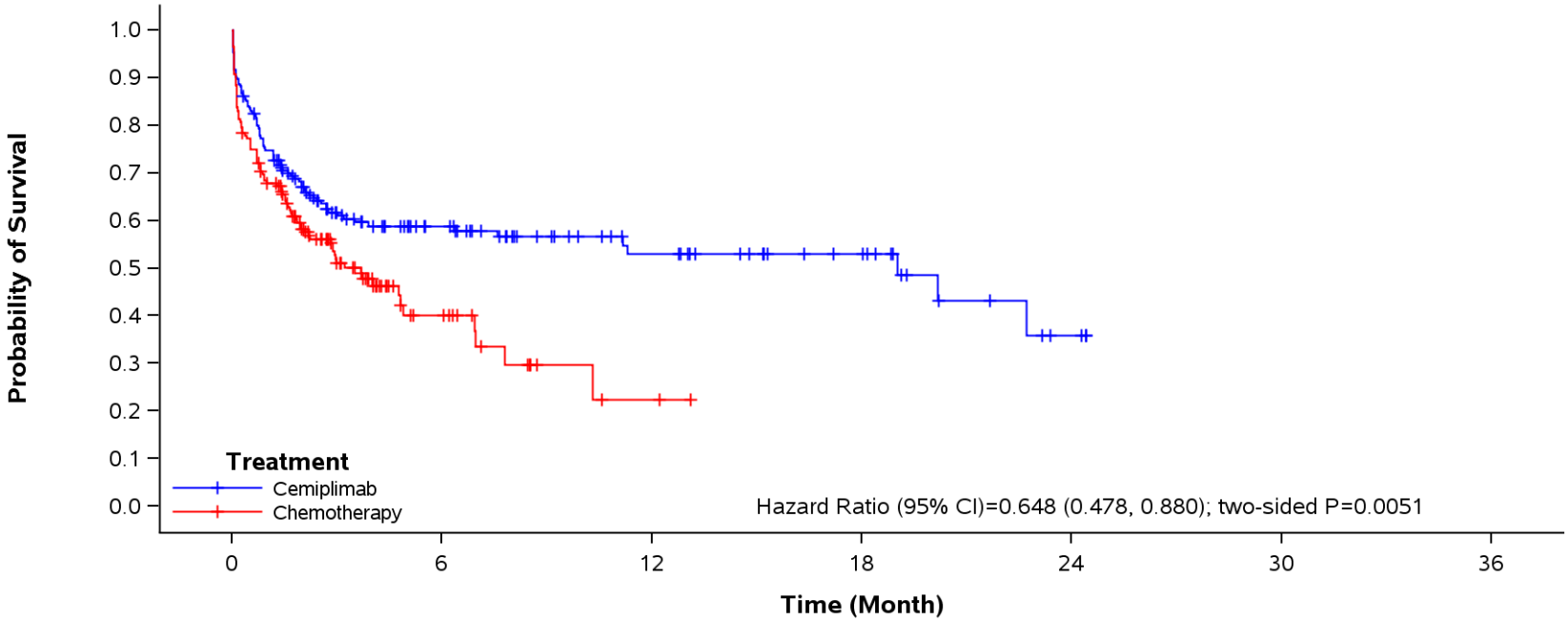

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 72 | 30 | 11 | 1 | 0 | 0 |
| Chemotherapy | 172 | 39 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions



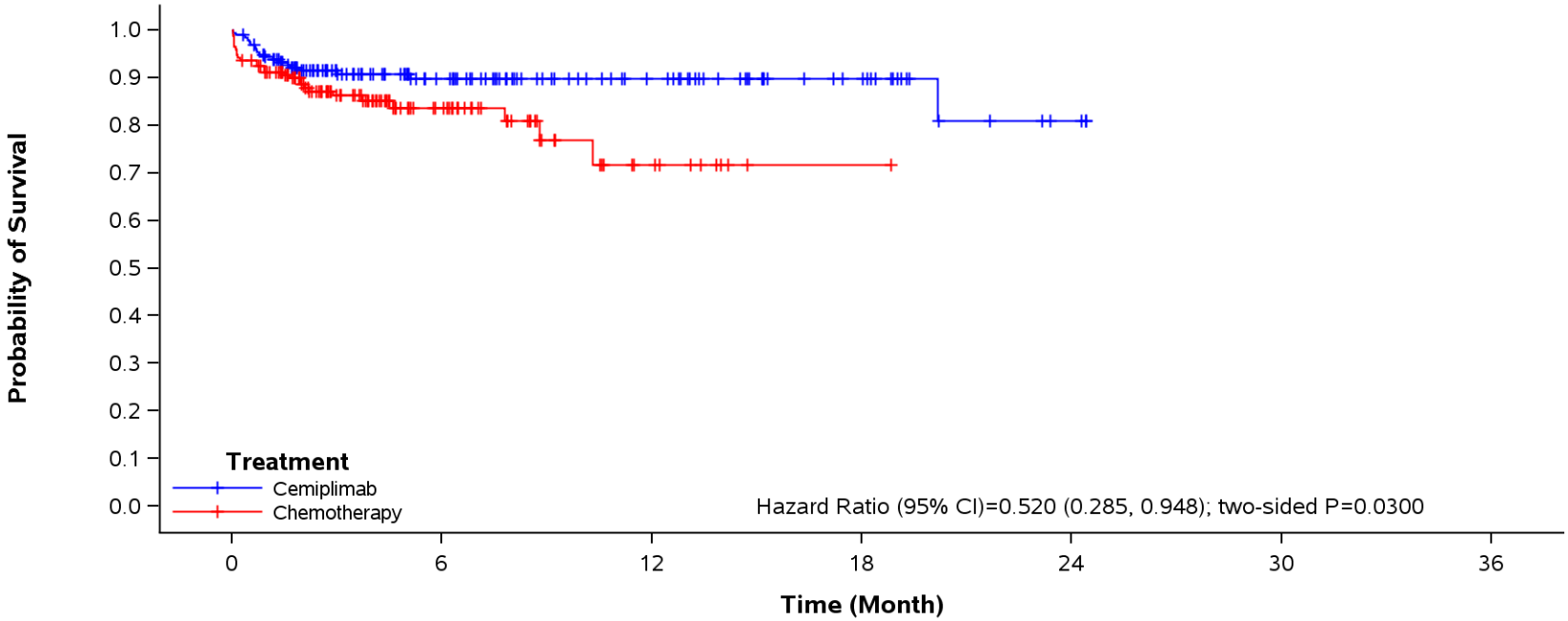

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 59 | 29 | 17 | 3 | 0 | 0 |
| Chemotherapy | 172 | 17 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Asthenia



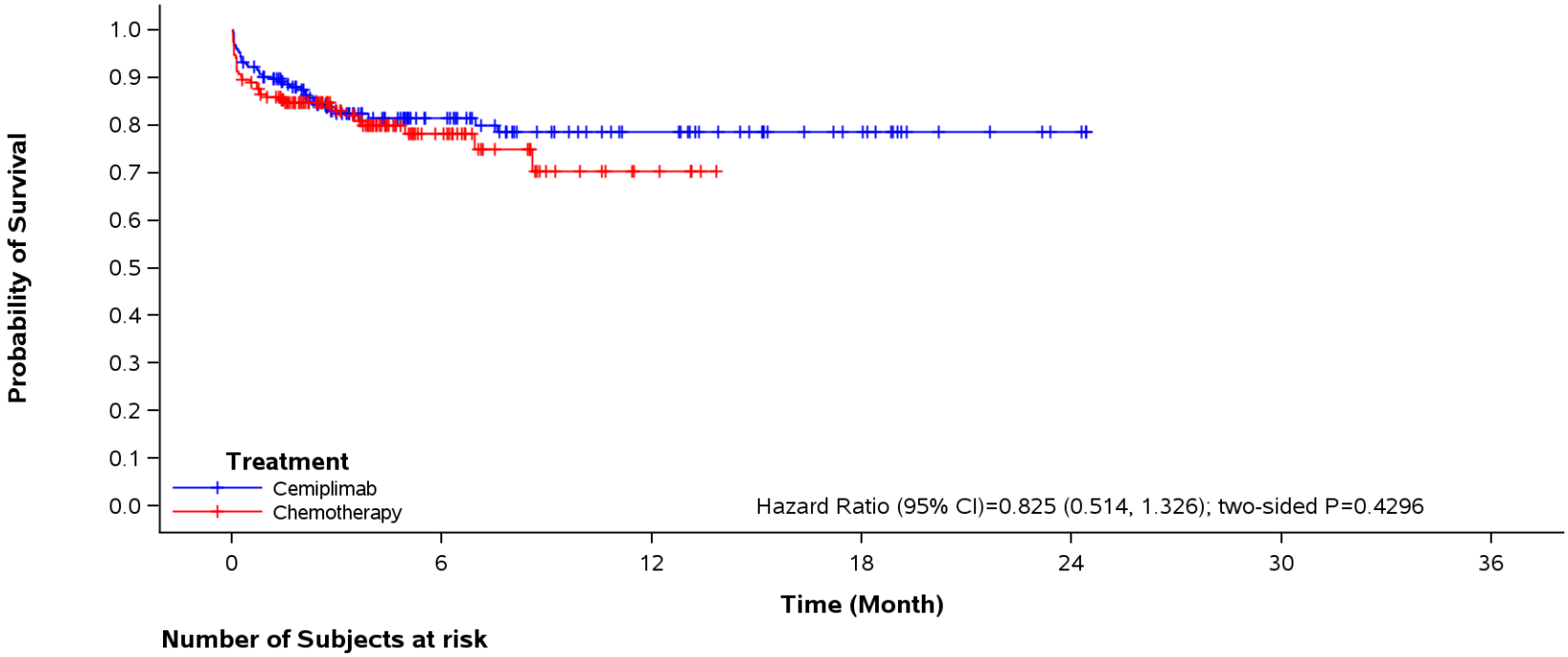

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 45 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Fatigue



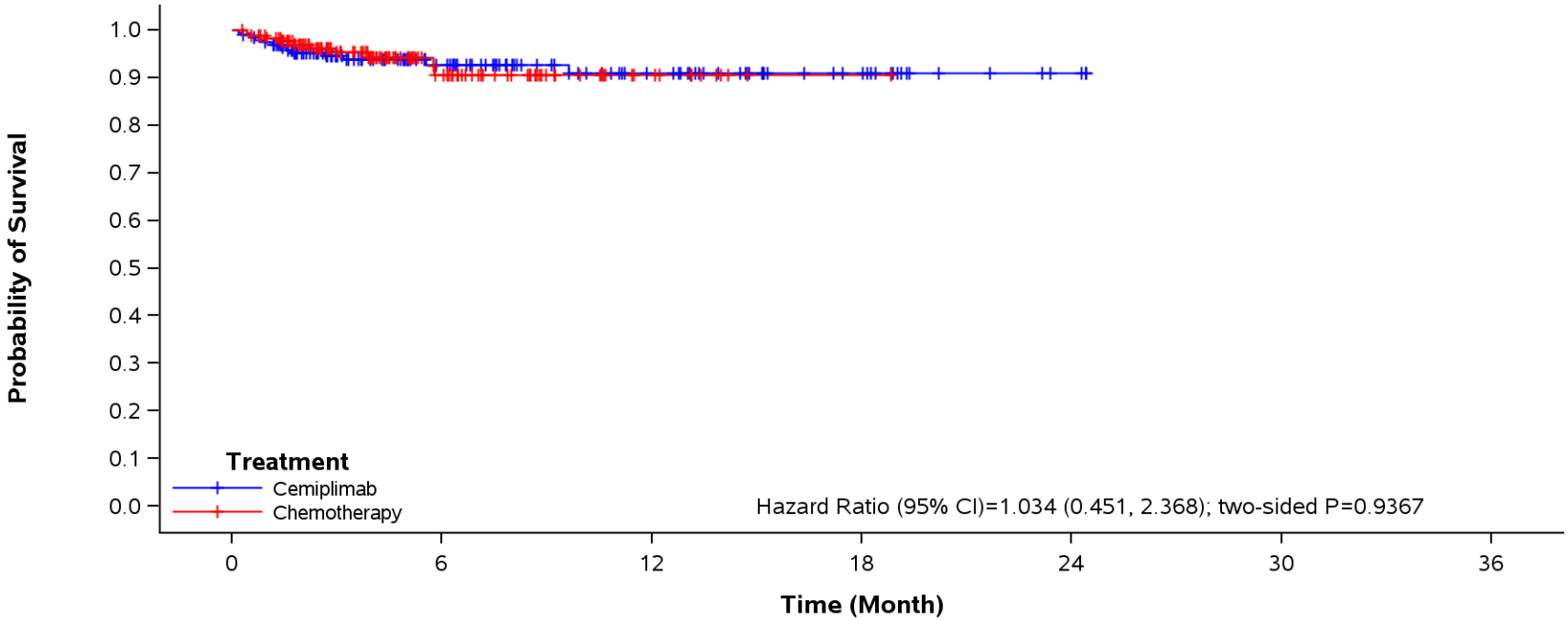

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 68 | 33 | 17 | 3 | 0 | 0 |
| Chemotherapy | 172 | 37 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Oedema peripheral



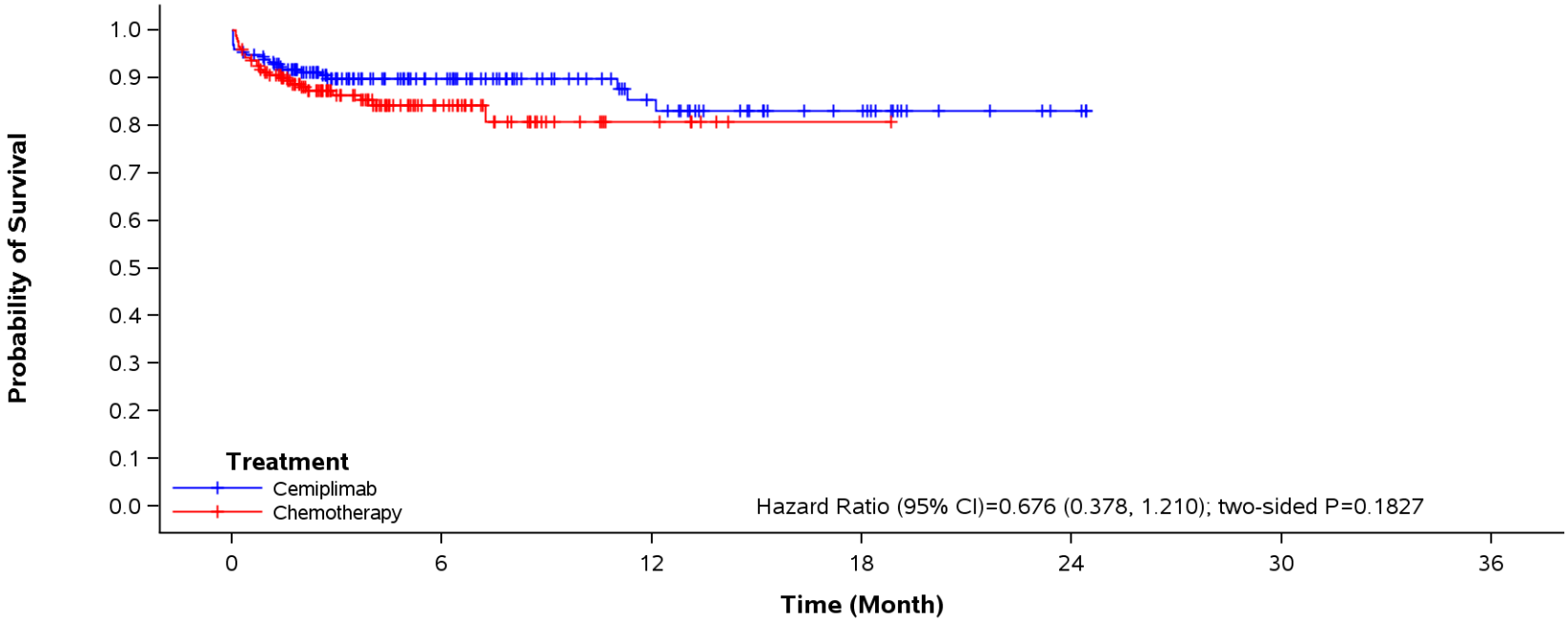

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 40 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 48 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Pyrexia



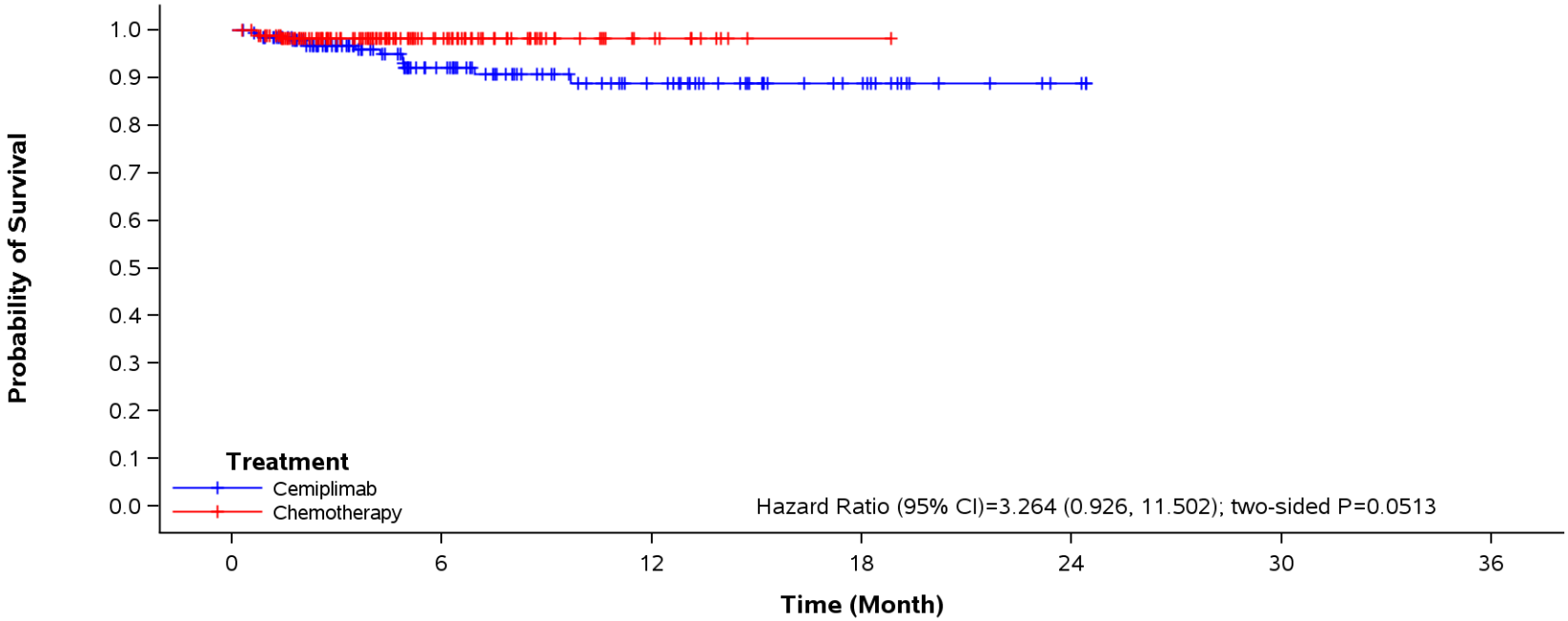

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 78 | 36 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 41 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders



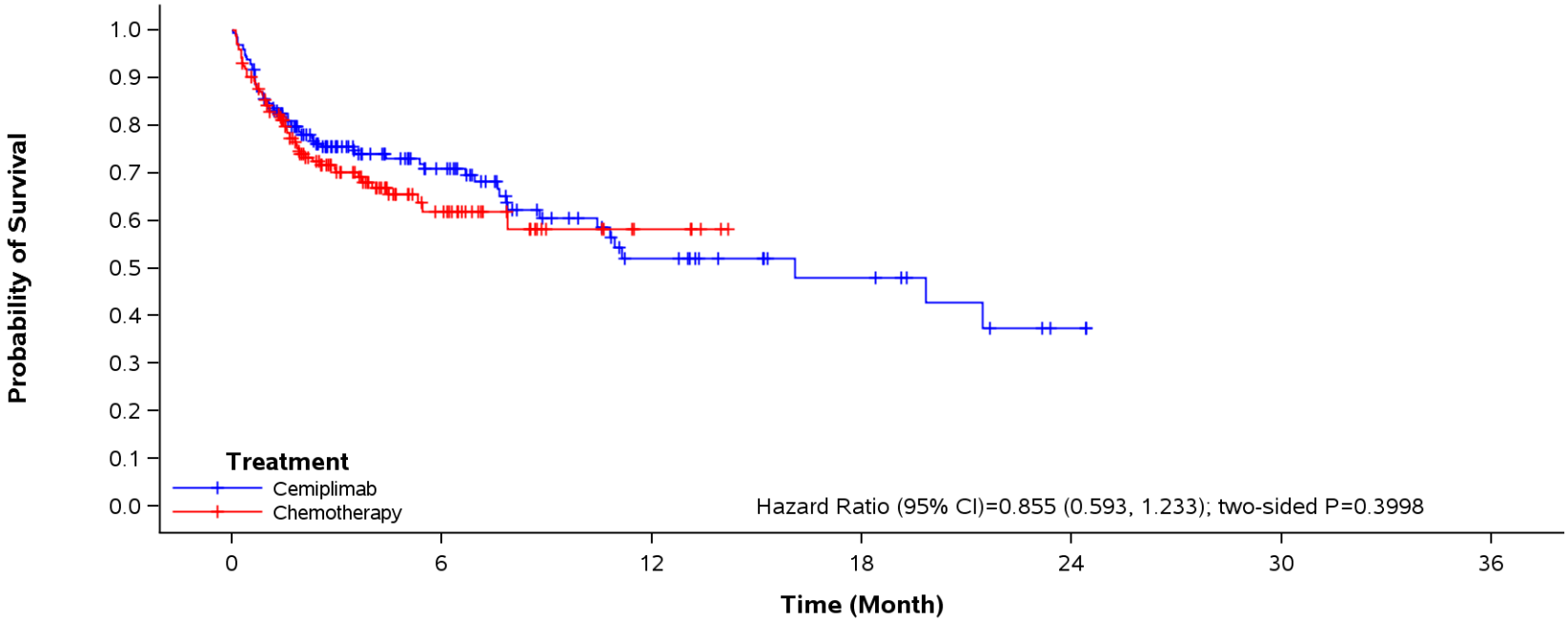

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 79 | 39 | 18 | 3 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations



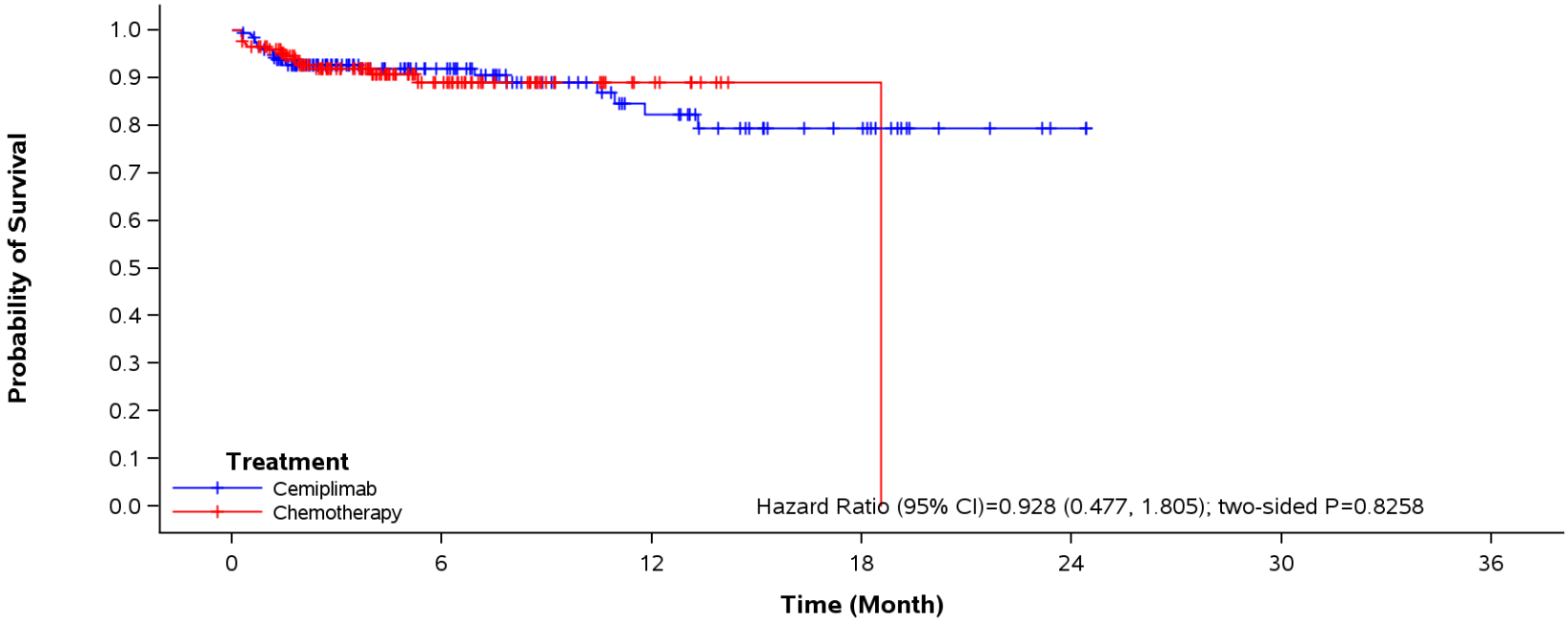

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 62 | 22 | 12 | 3 | 0 | 0 |
| Chemotherapy | 172 | 33 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Urinary tract infection



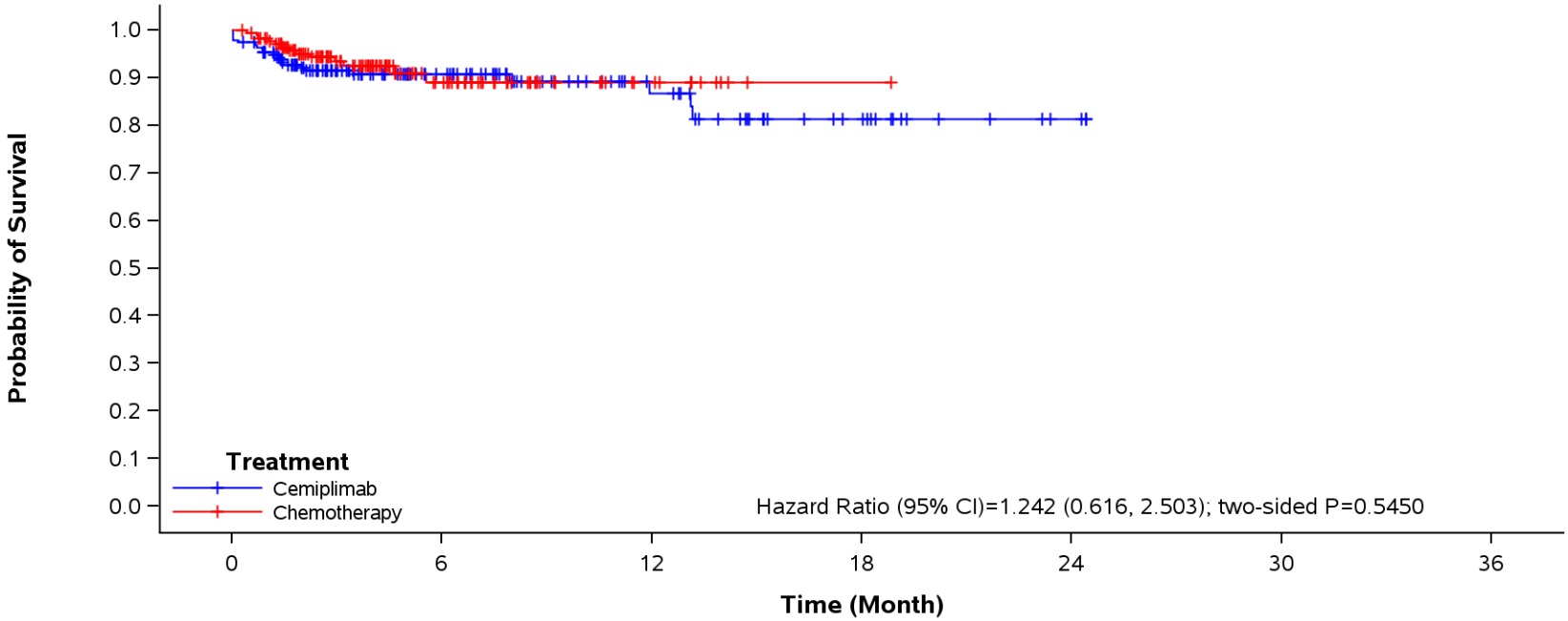

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 78 | 34 | 18 | 3 | 0 | 0 |
| Chemotherapy | 172 | 47 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Injury, poisoning and procedural complications



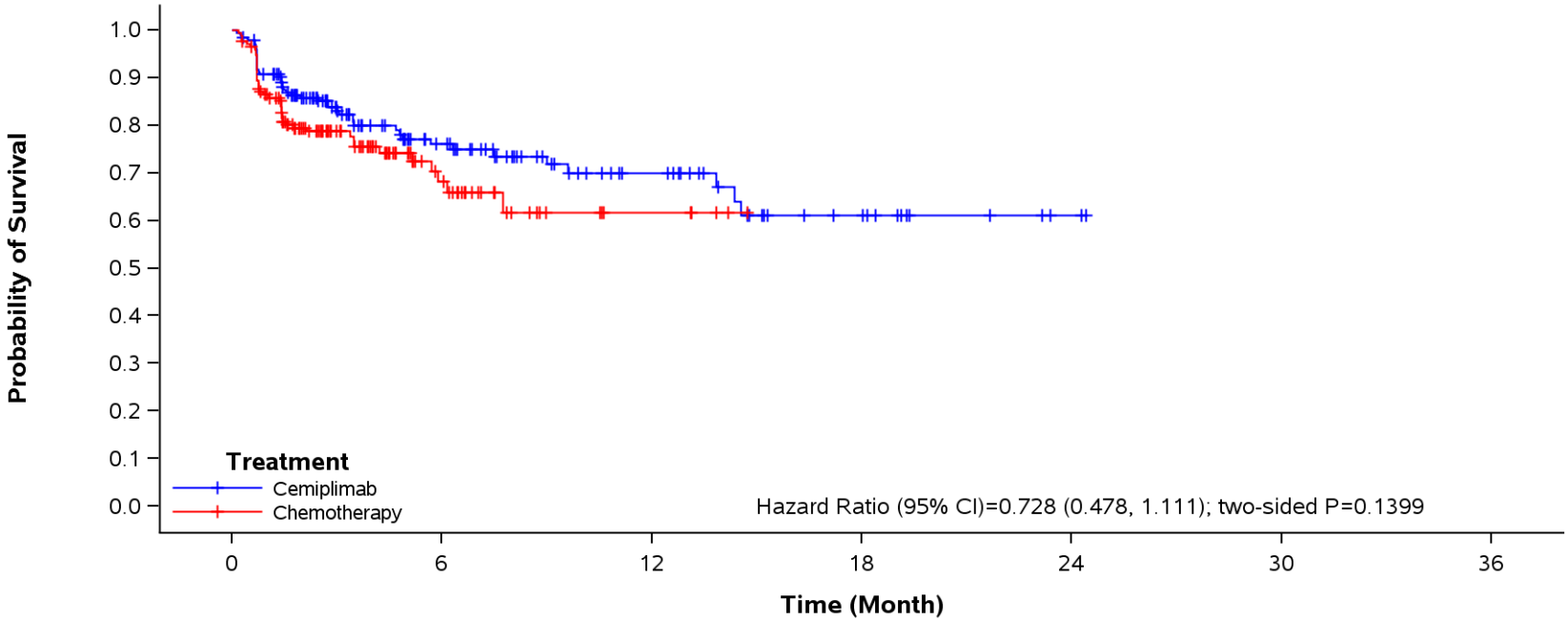

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 36 | 17 | 3 | 0 | 0 |
| Chemotherapy | 172 | 46 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations



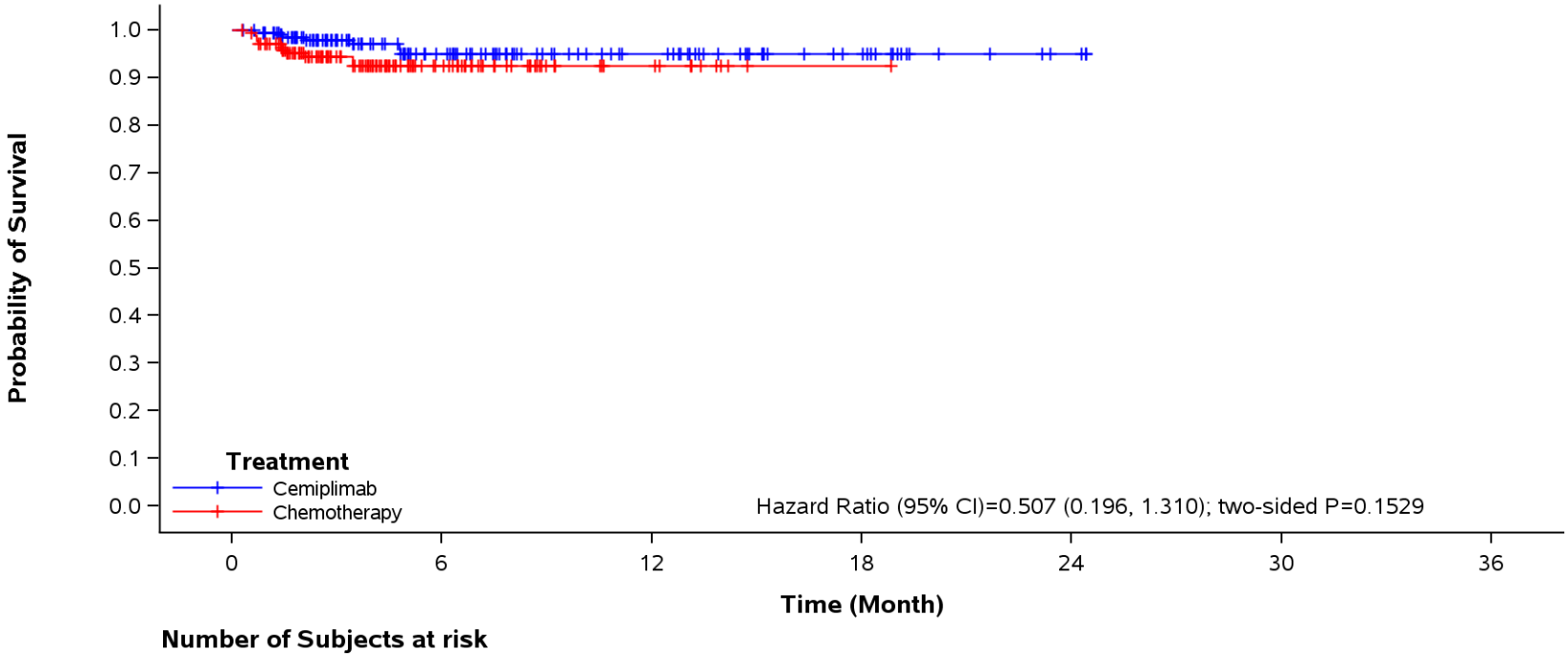

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 68 | 31 | 13 | 2 | 0 | 0 |
| Chemotherapy | 172 | 32 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Aspartate aminotransferase increased



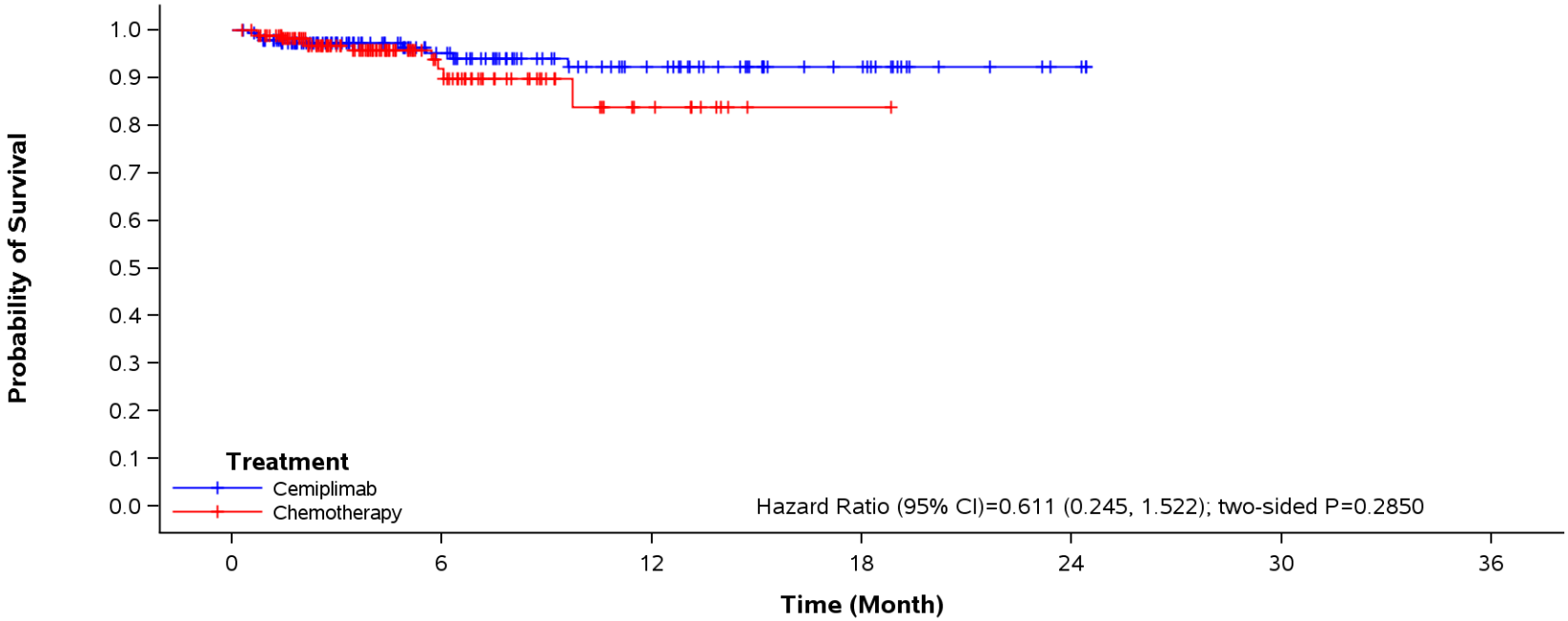

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 40 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 45 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Blood alkaline phosphatase increased



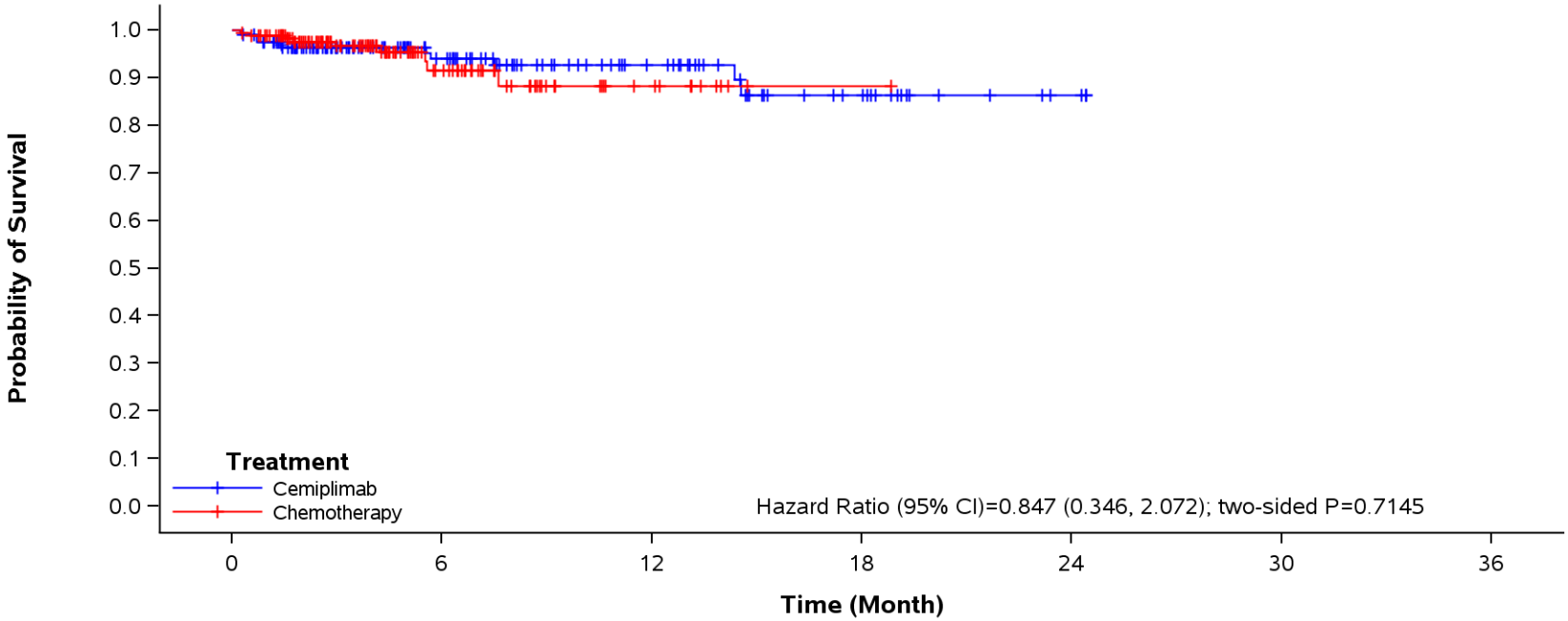

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 39 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Blood creatinine increased



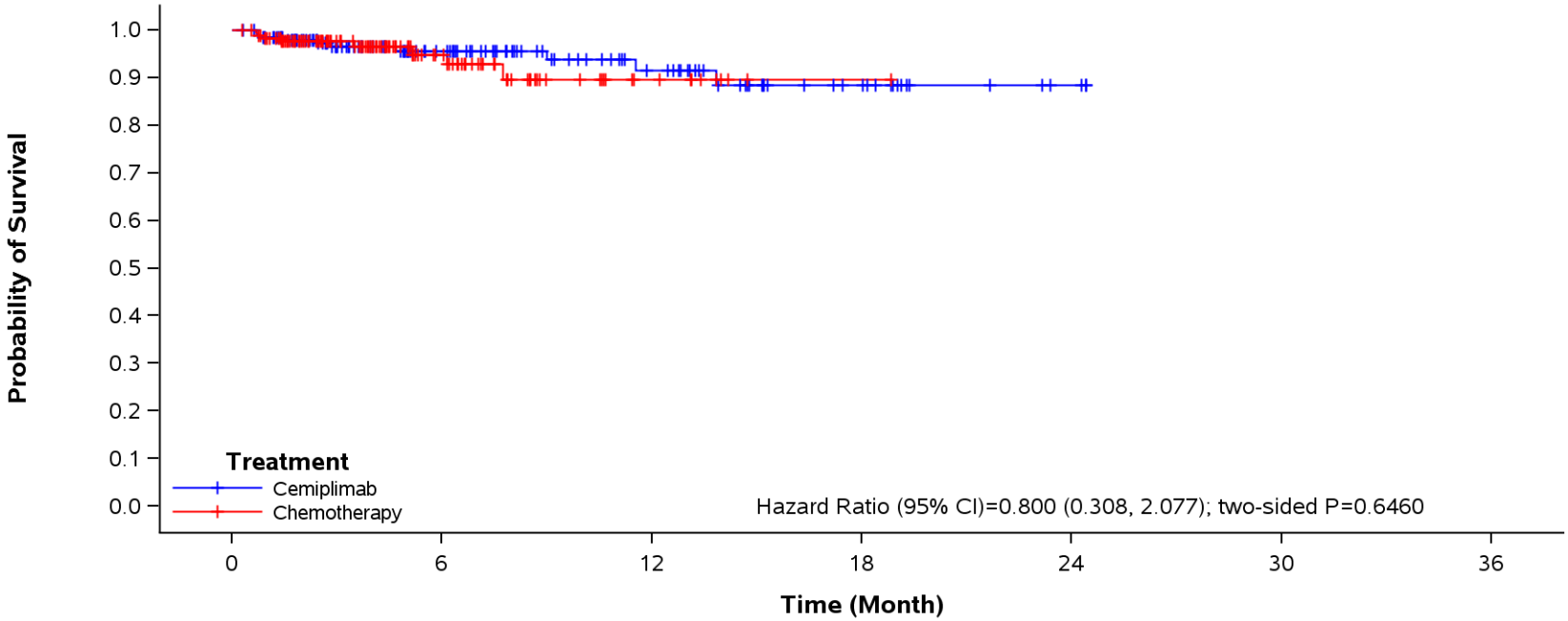

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 40 | 18 | 3 | 0 | 0 |
| Chemotherapy | 172 | 46 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Weight decreased



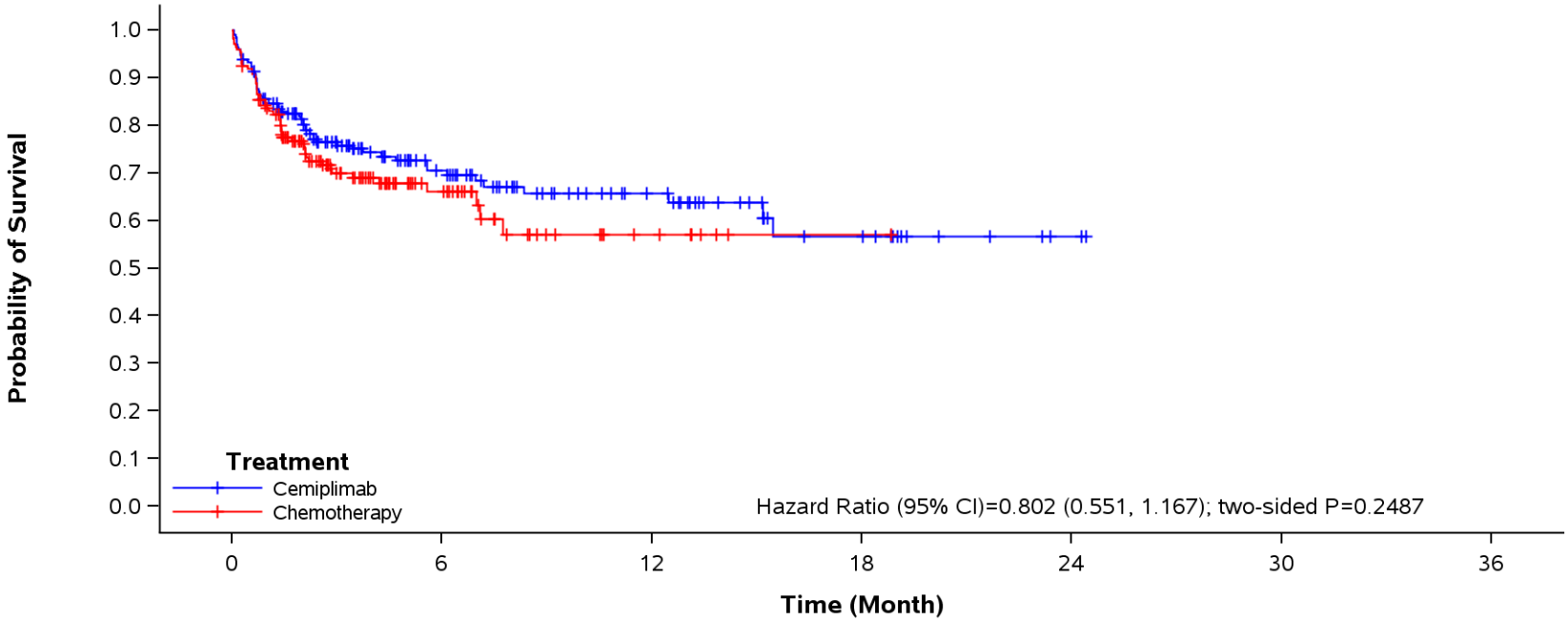

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 38 | 16 | 3 | 0 | 0 |
| Chemotherapy | 172 | 48 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders



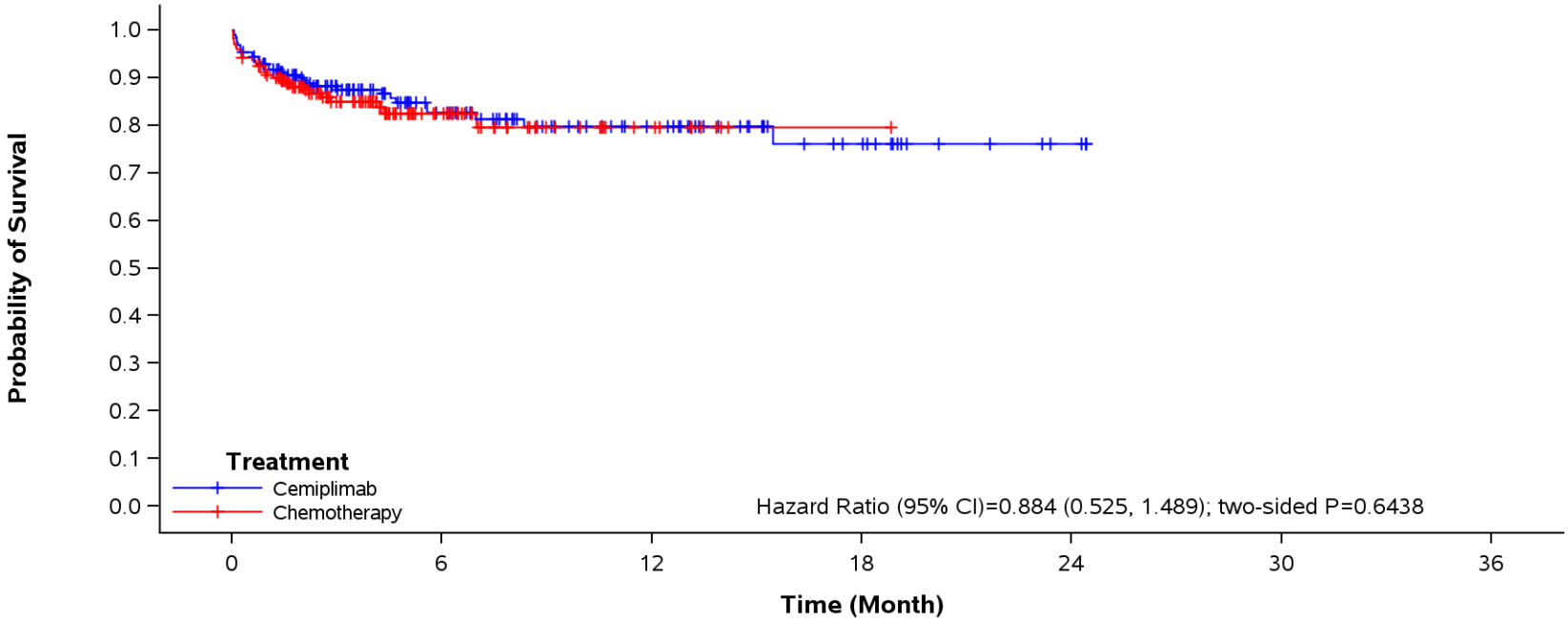

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 69 | 34 | 14 | 2 | 0 | 0 |
| Chemotherapy | 172 | 37 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Decreased appetite



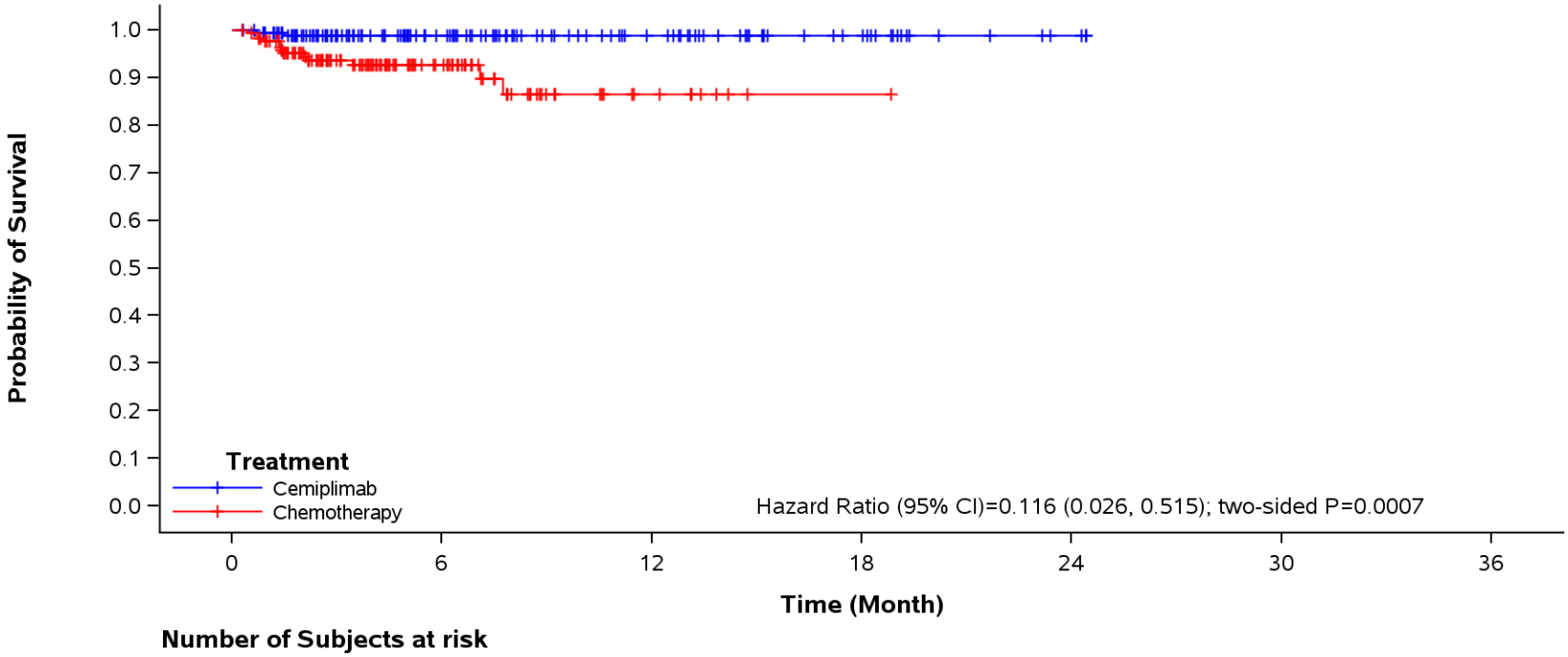

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 76 | 38 | 17 | 3 | 0 | 0 |
| Chemotherapy | 172 | 43 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



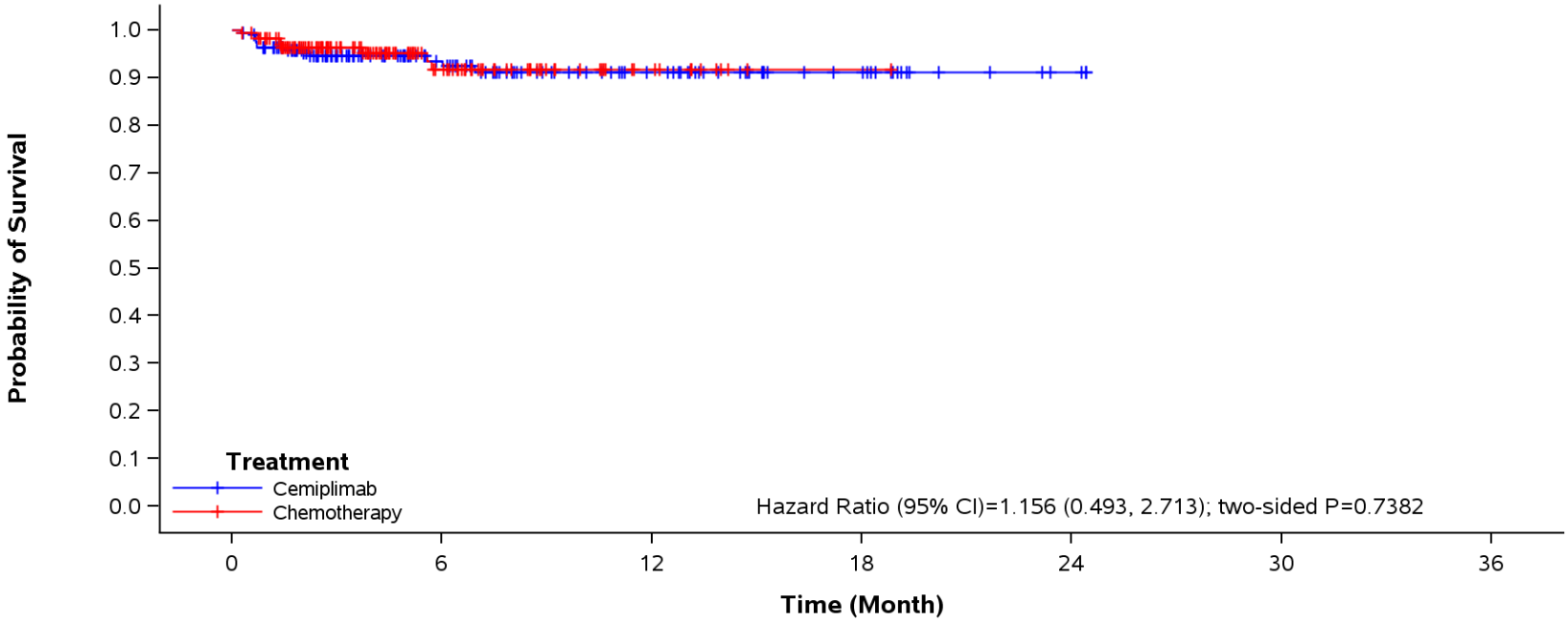

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 48 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Hypoalbuminaemia



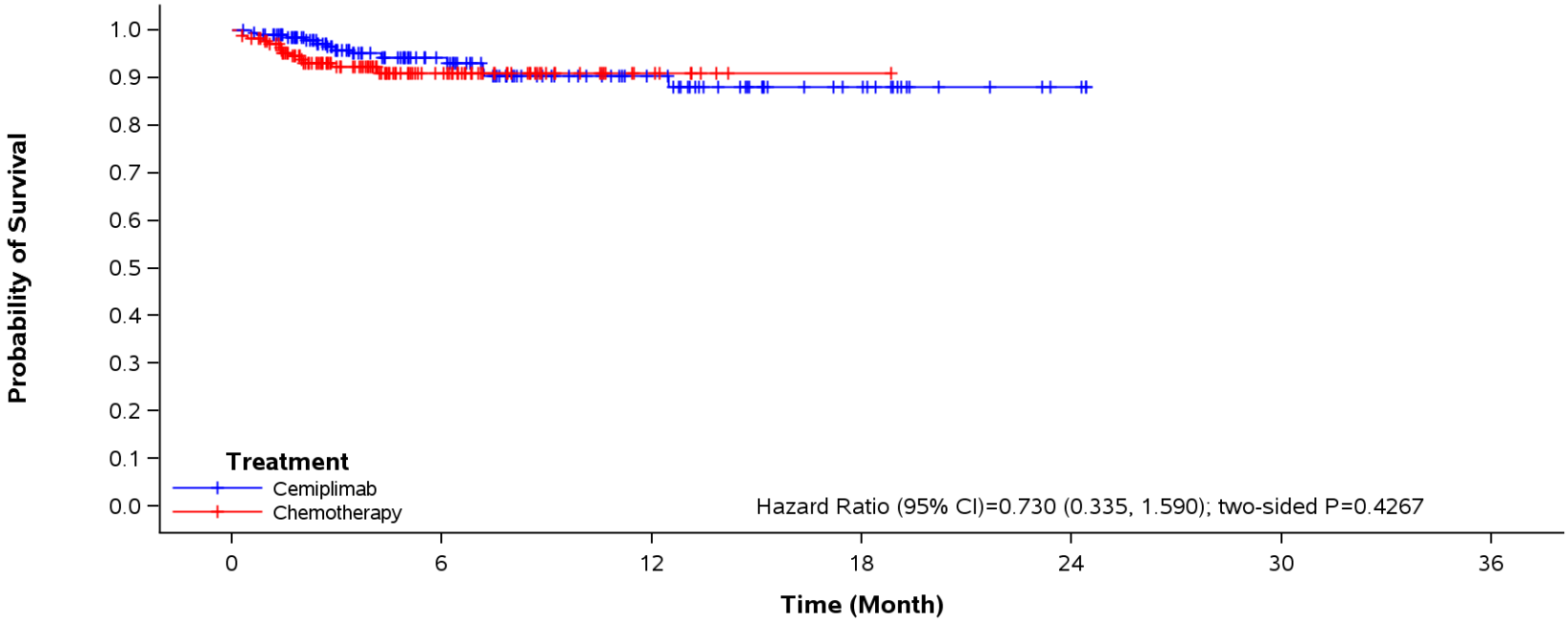

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 40 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 49 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Hypokalaemia



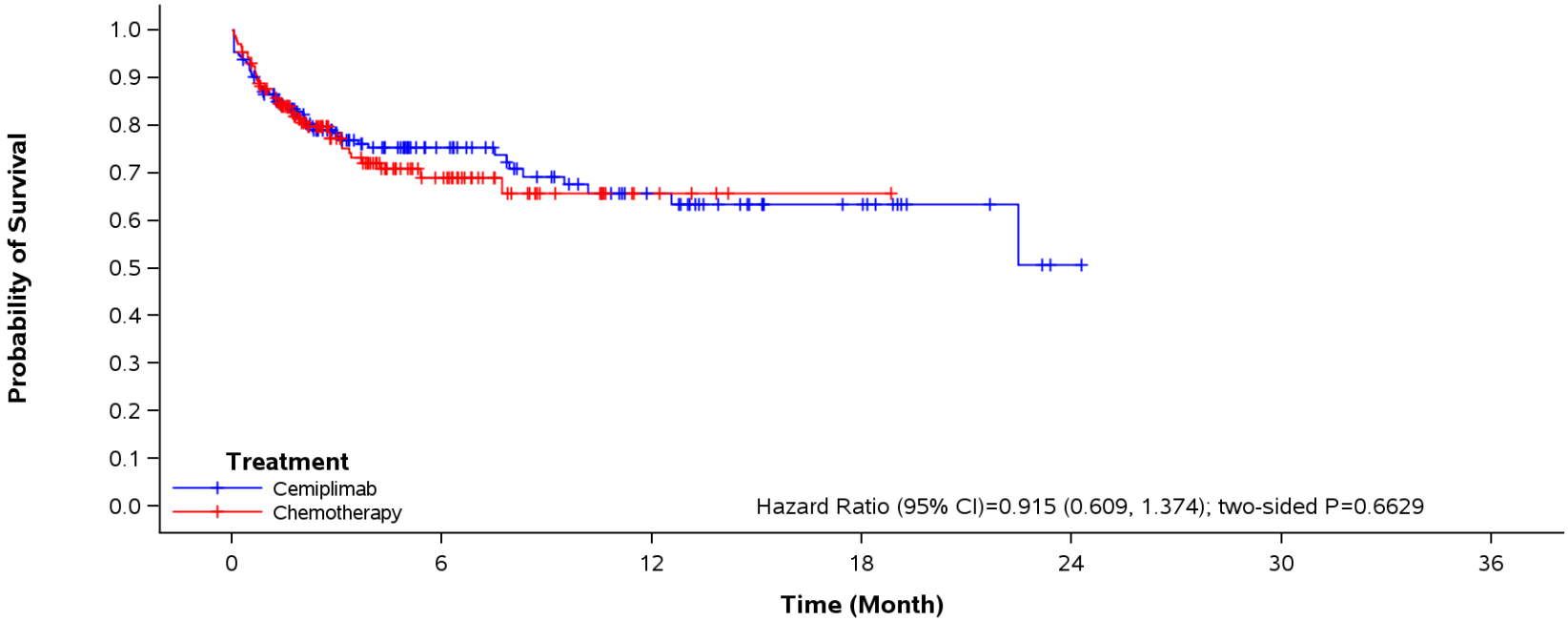

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 40 | 18 | 3 | 0 | 0 |
| Chemotherapy | 172 | 50 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders



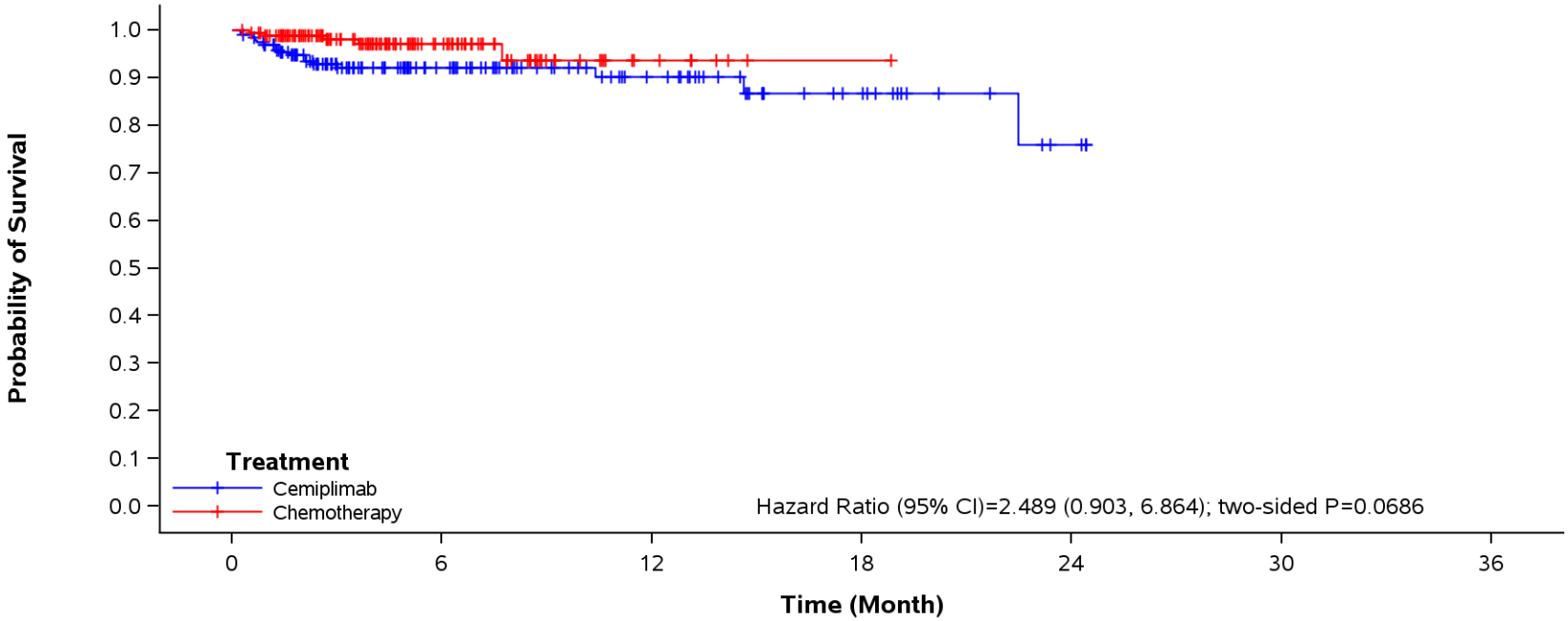

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 61 | 29 | 13 | 1 | 0 | 0 |
| Chemotherapy | 172 | 37 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia



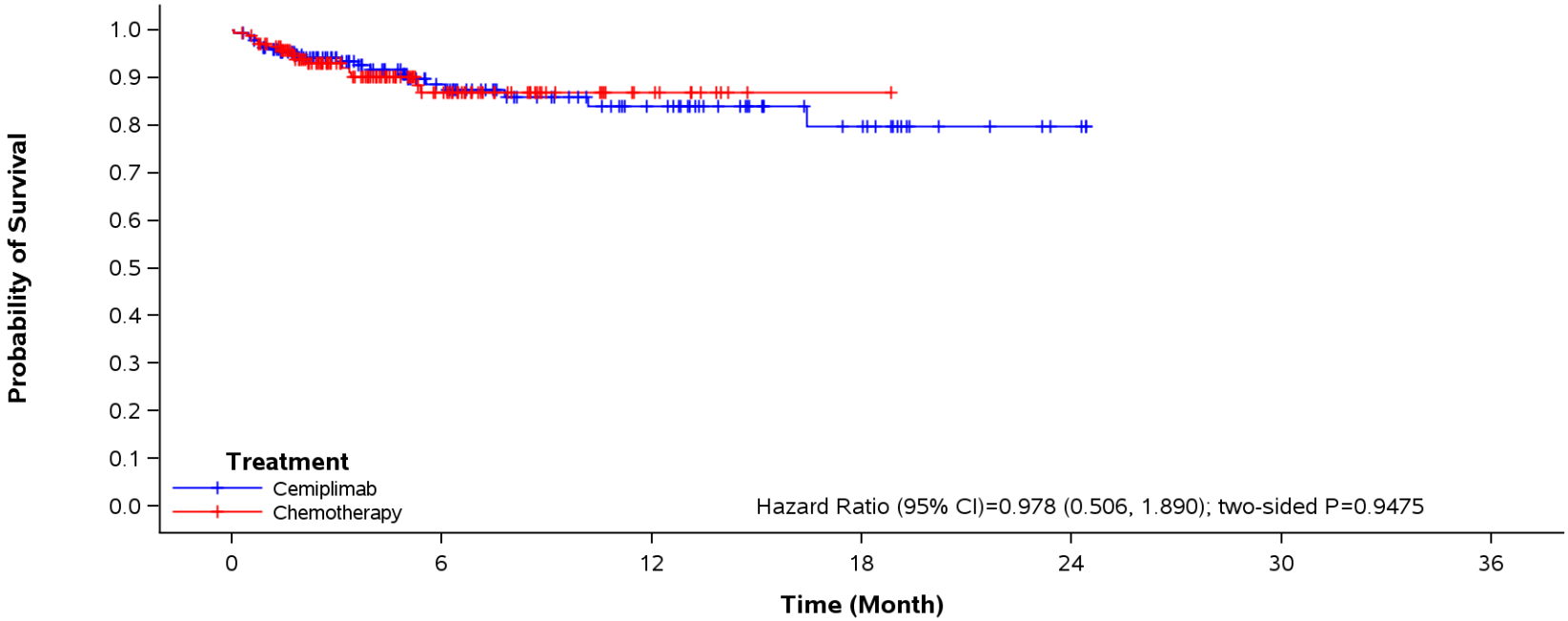

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 75 | 37 | 17 | 4 | 0 | 0 |
| Chemotherapy | 172 | 49 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Back pain



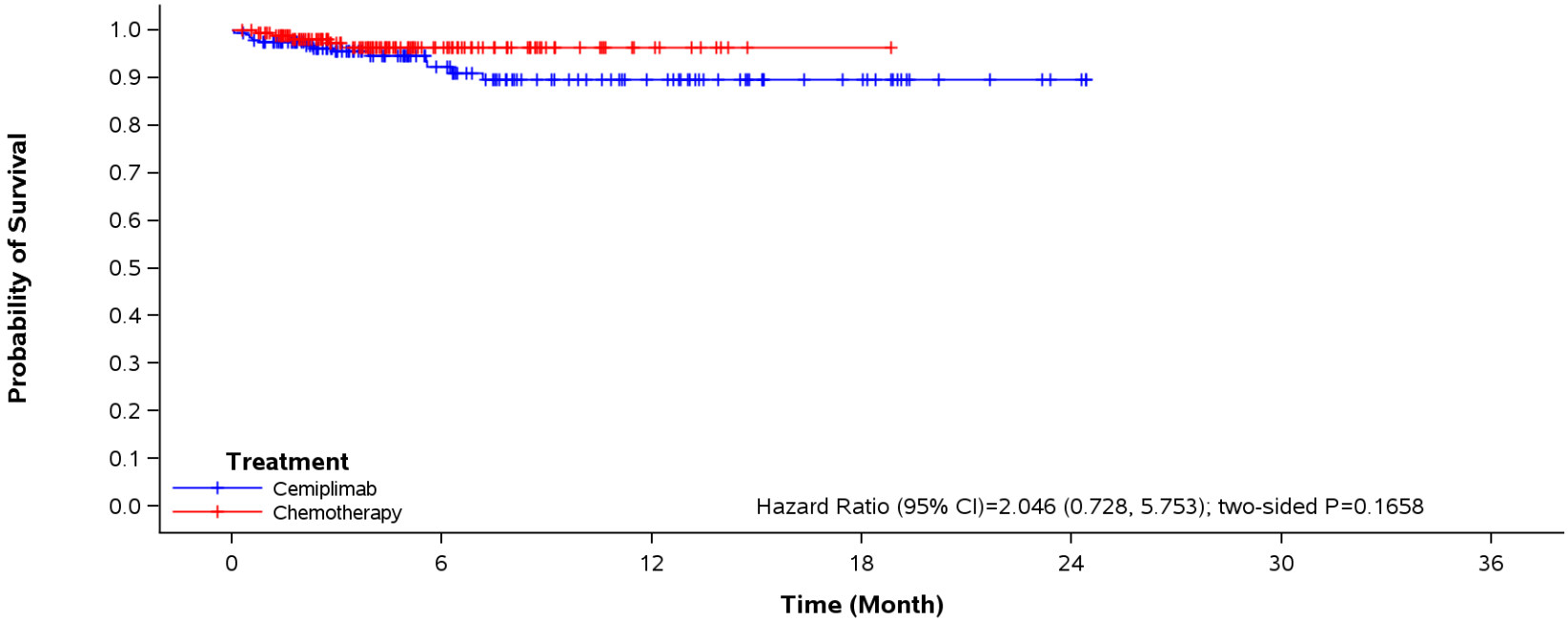

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 75 | 38 | 18 | 3 | 0 | 0 |
| Chemotherapy | 172 | 48 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Pain in extremity



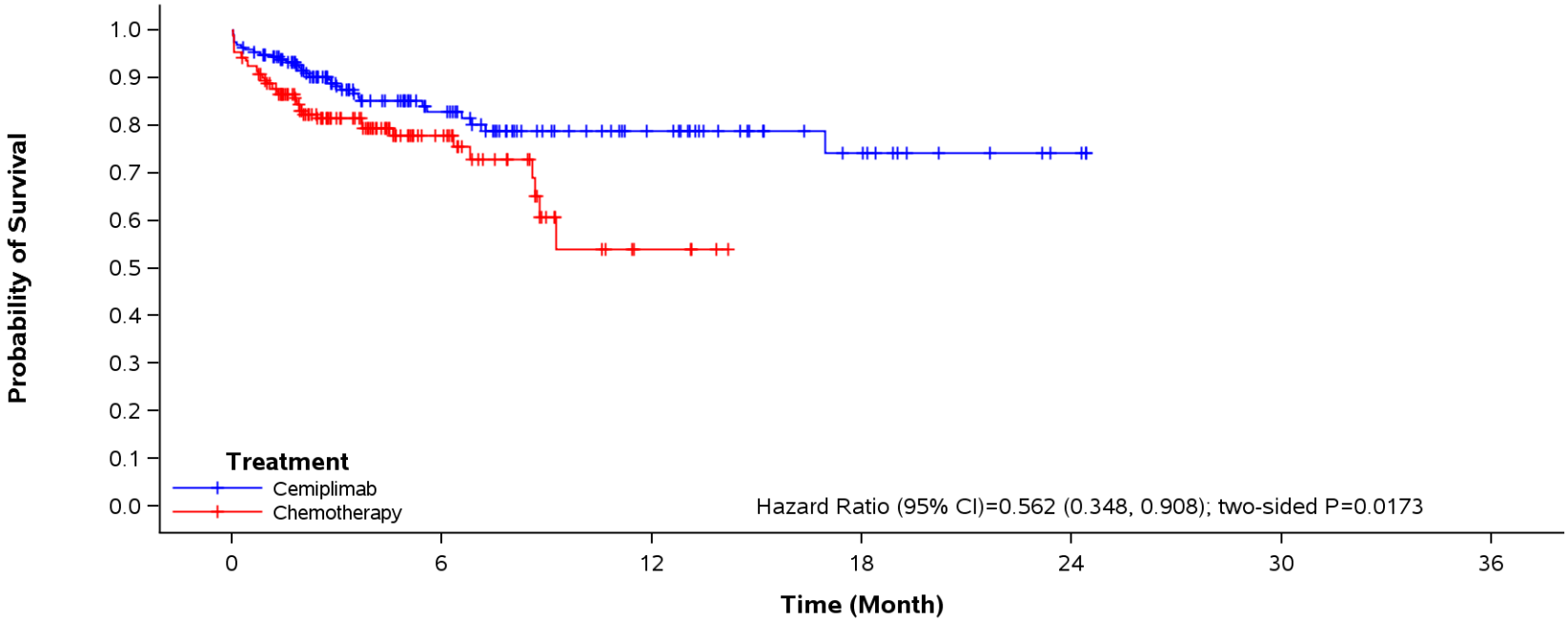

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 38 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 49 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders



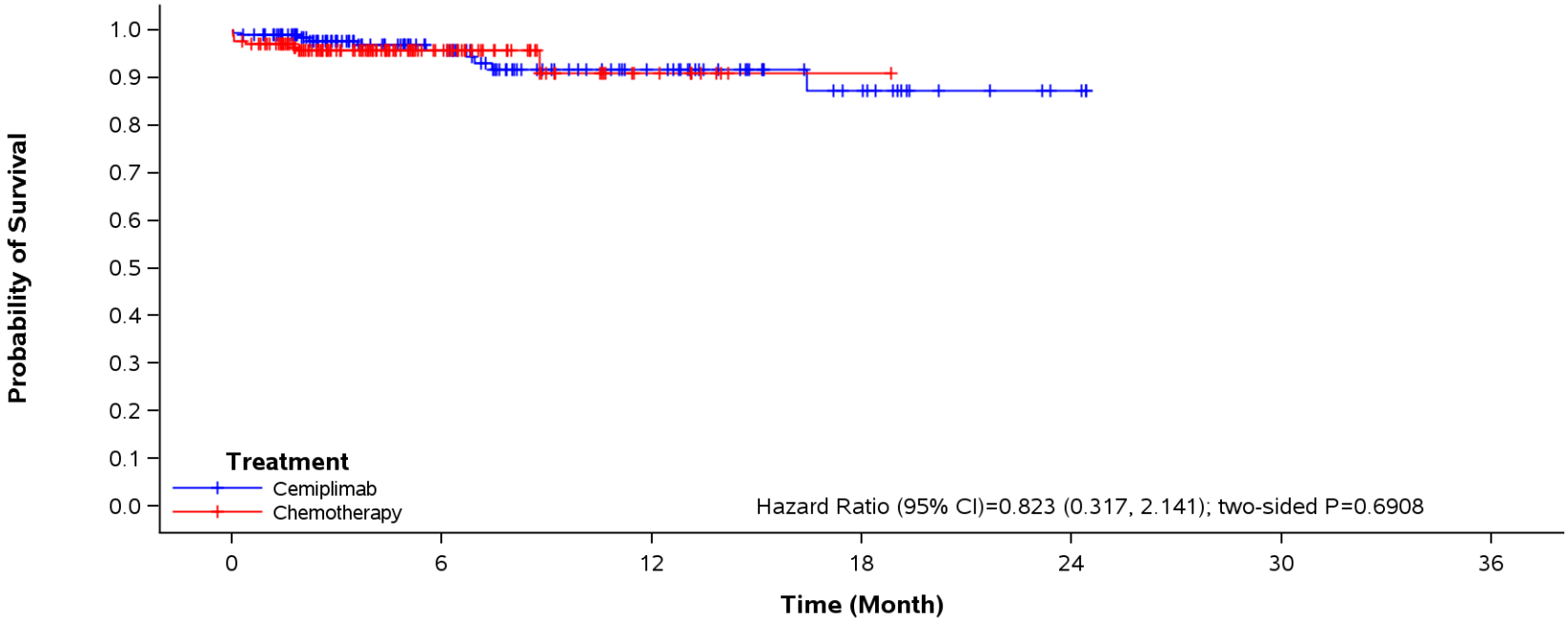

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 71 | 32 | 15 | 3 | 0 | 0 |
| Chemotherapy | 172 | 39 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders
PT: Dizziness



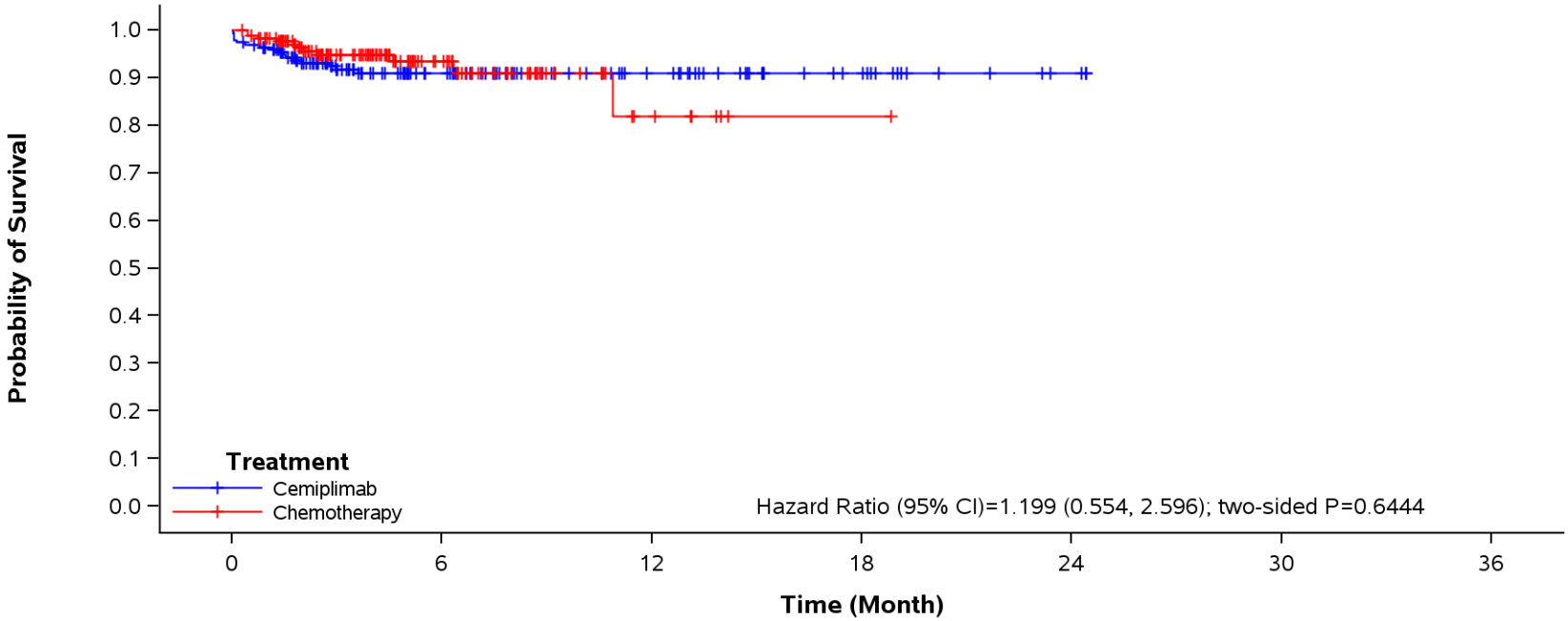

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 39 | 18 | 4 | 0 | 0 |
| Chemotherapy | 172 | 49 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders
PT: Headache



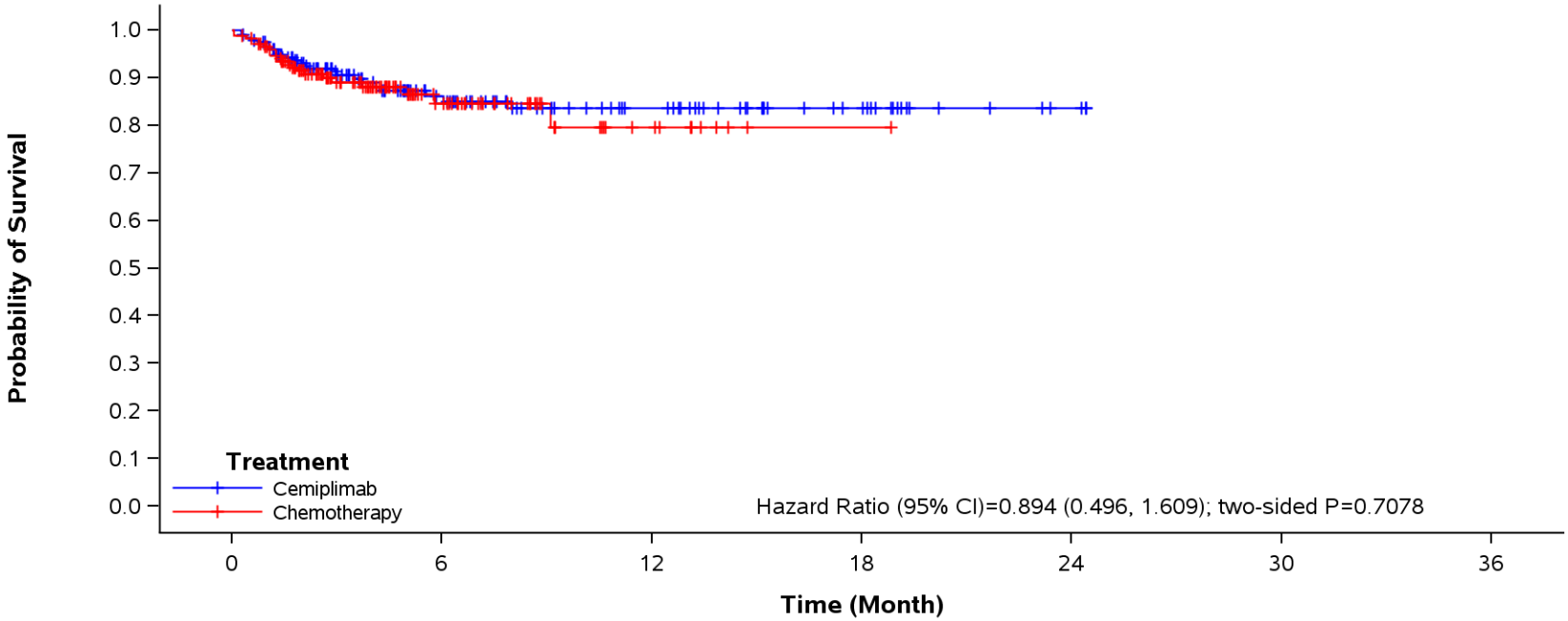

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 36 | 17 | 3 | 0 | 0 |
| Chemotherapy | 172 | 47 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Psychiatric disorders



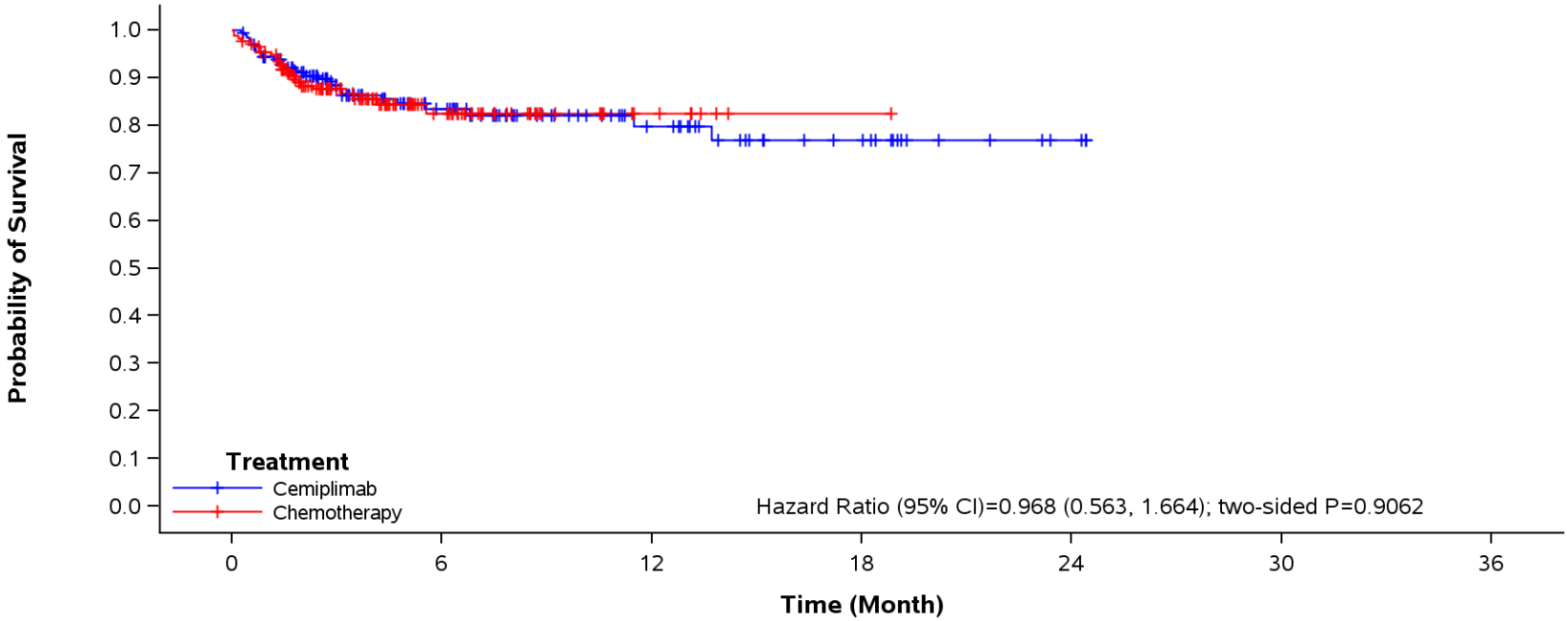

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 38 | 19 | 3 | 0 | 0 |
| Chemotherapy | 172 | 44 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders



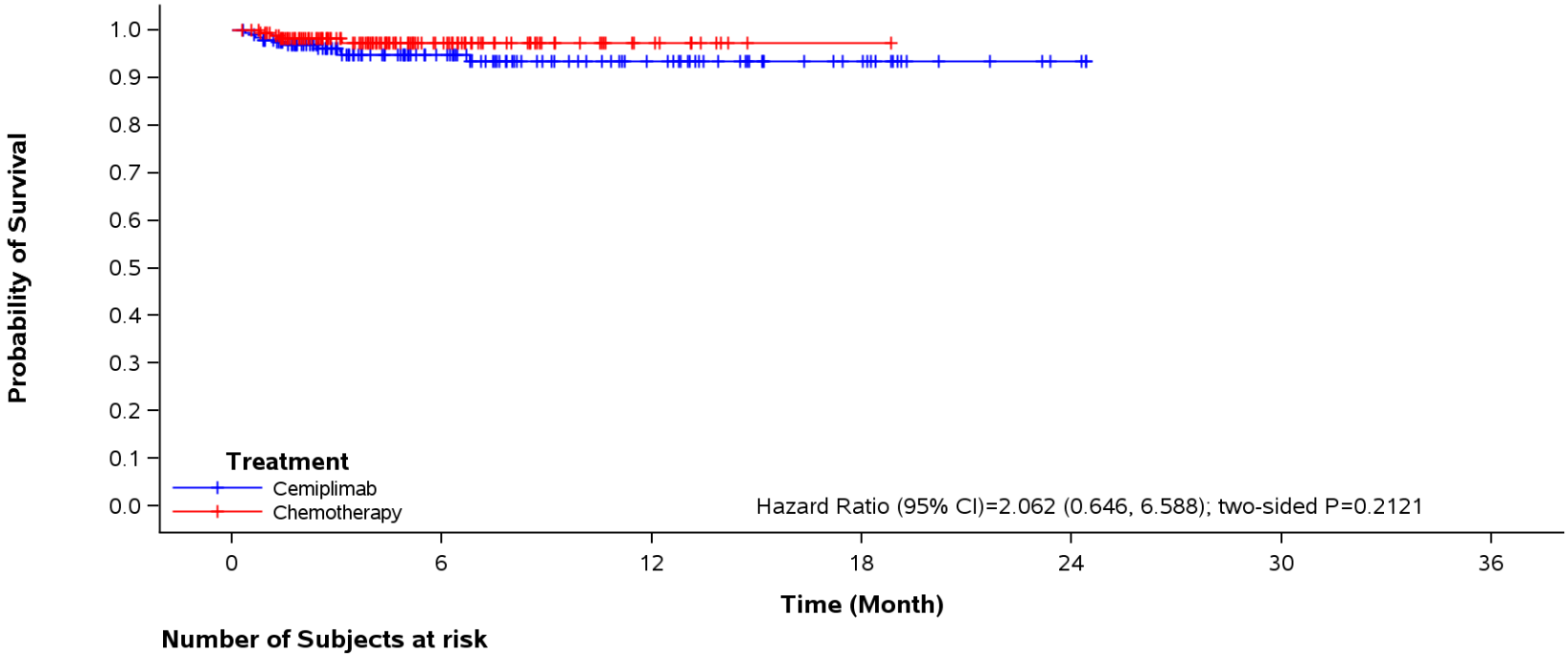

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 74 | 34 | 18 | 4 | 0 | 0 |
| Chemotherapy | 172 | 42 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders
PT: Haematuria



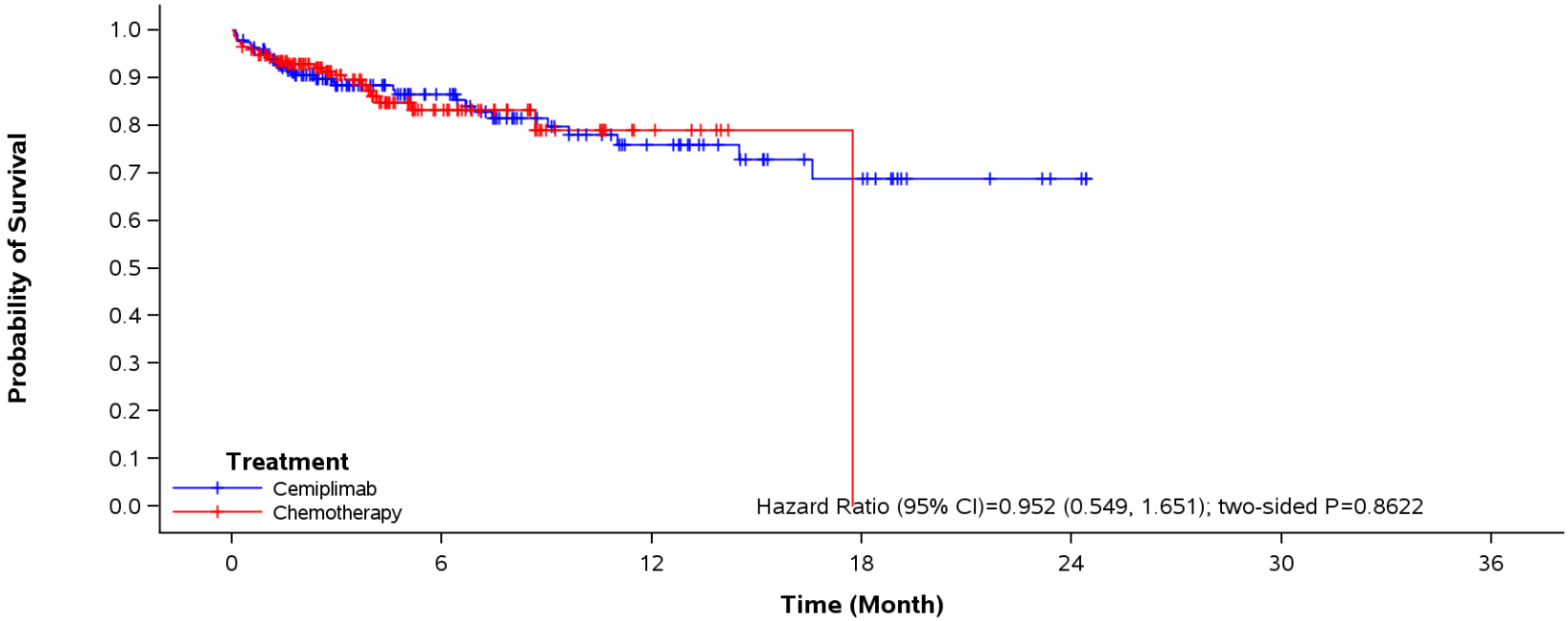

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 39 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 50 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Reproductive system and breast disorders



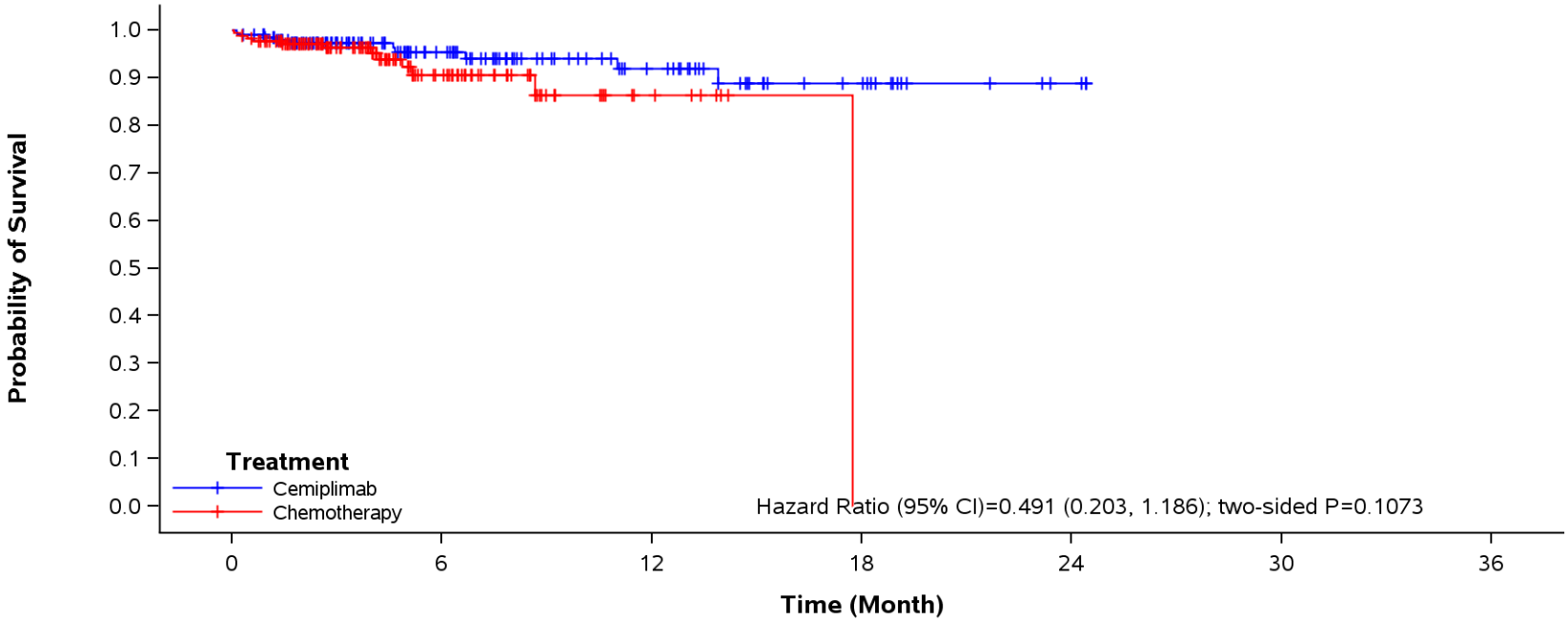

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 33 | 17 | 4 | 0 | 0 |
| Chemotherapy | 172 | 43 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Reproductive system and breast disorders
PT: Pelvic pain



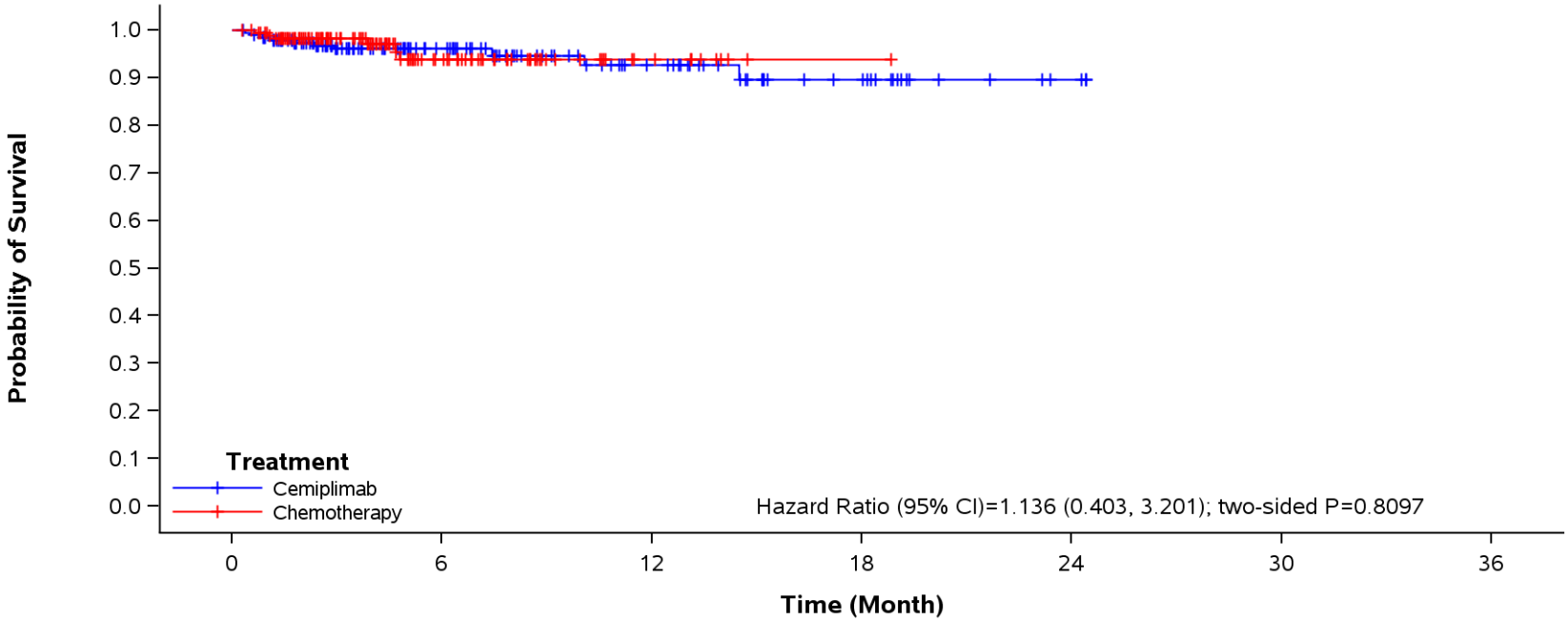

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 38 | 18 | 4 | 0 | 0 |
| Chemotherapy | 172 | 48 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Reproductive system and breast disorders
PT: Vaginal haemorrhage



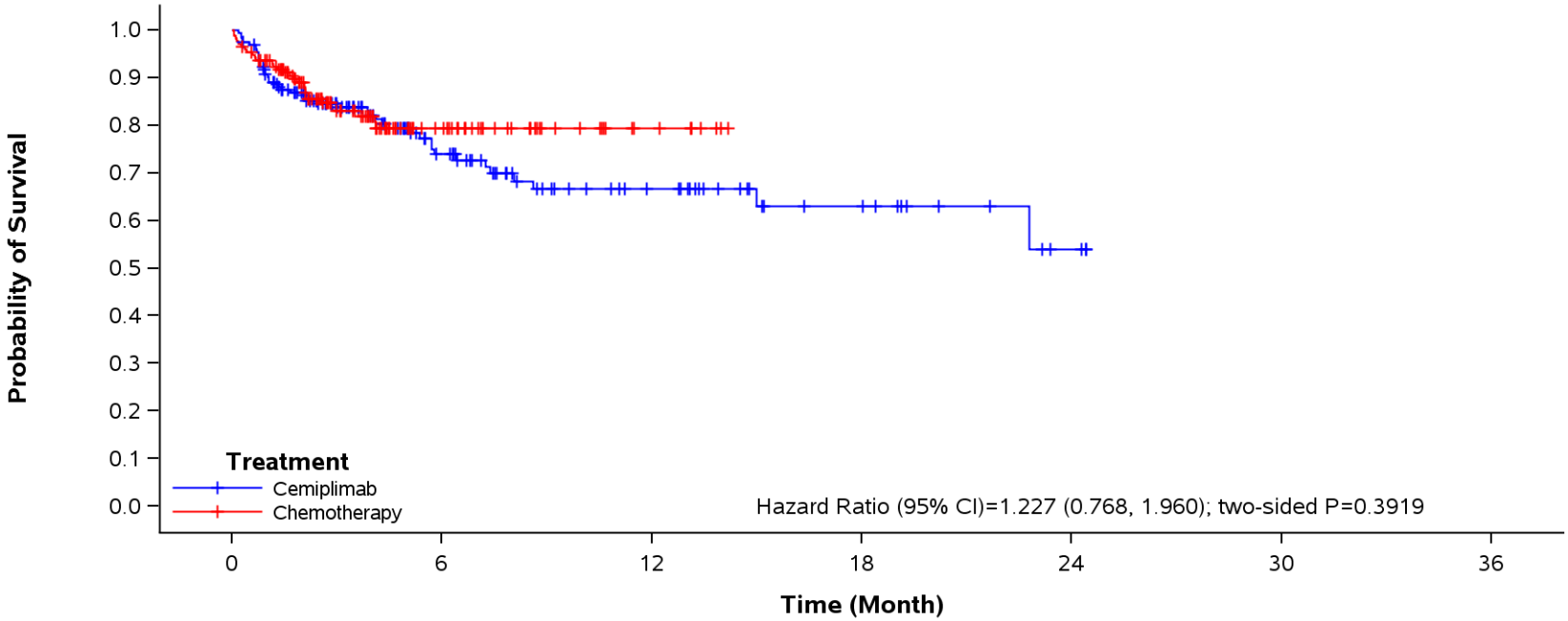

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 39 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 47 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders



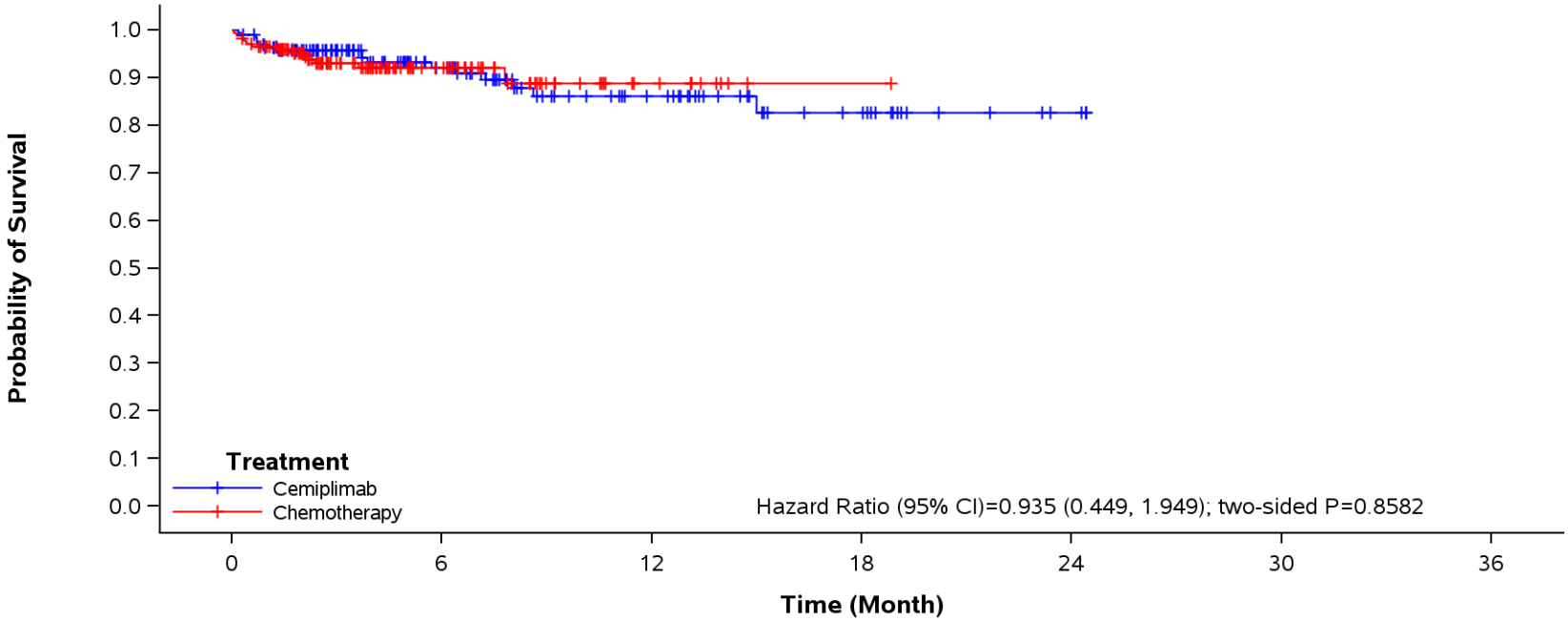

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 65 | 29 | 14 | 3 | 0 | 0 |
| Chemotherapy | 172 | 39 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough



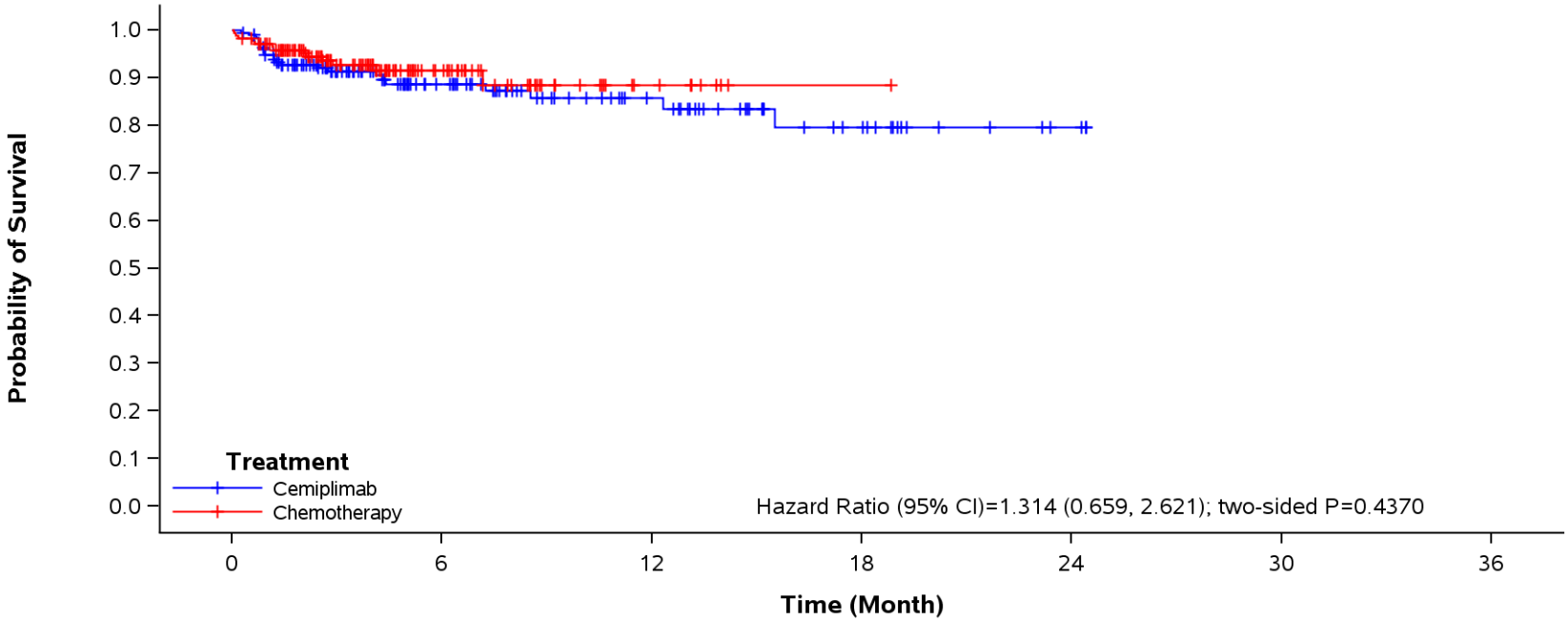

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 81 | 37 | 18 | 3 | 0 | 0 |
| Chemotherapy | 172 | 49 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea



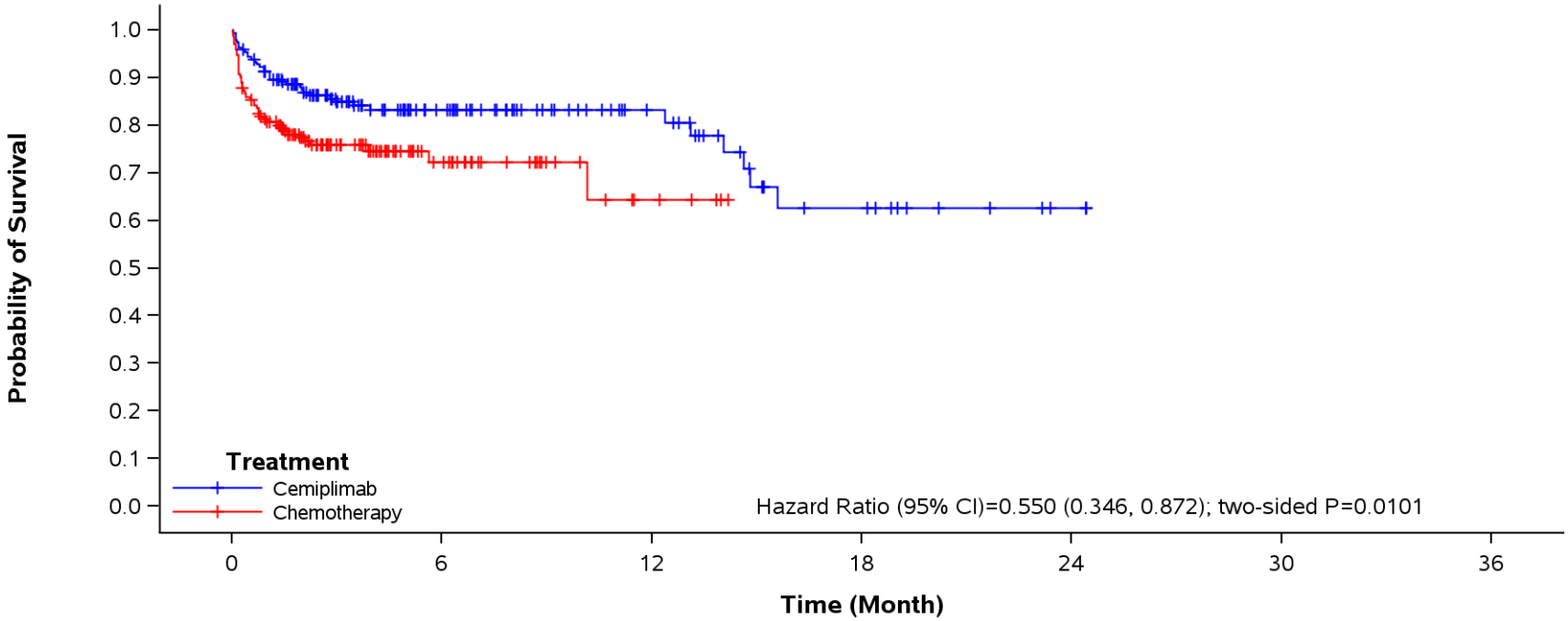

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 79 | 38 | 17 | 3 | 0 | 0 |
| Chemotherapy | 172 | 45 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Skin and subcutaneous tissue disorders



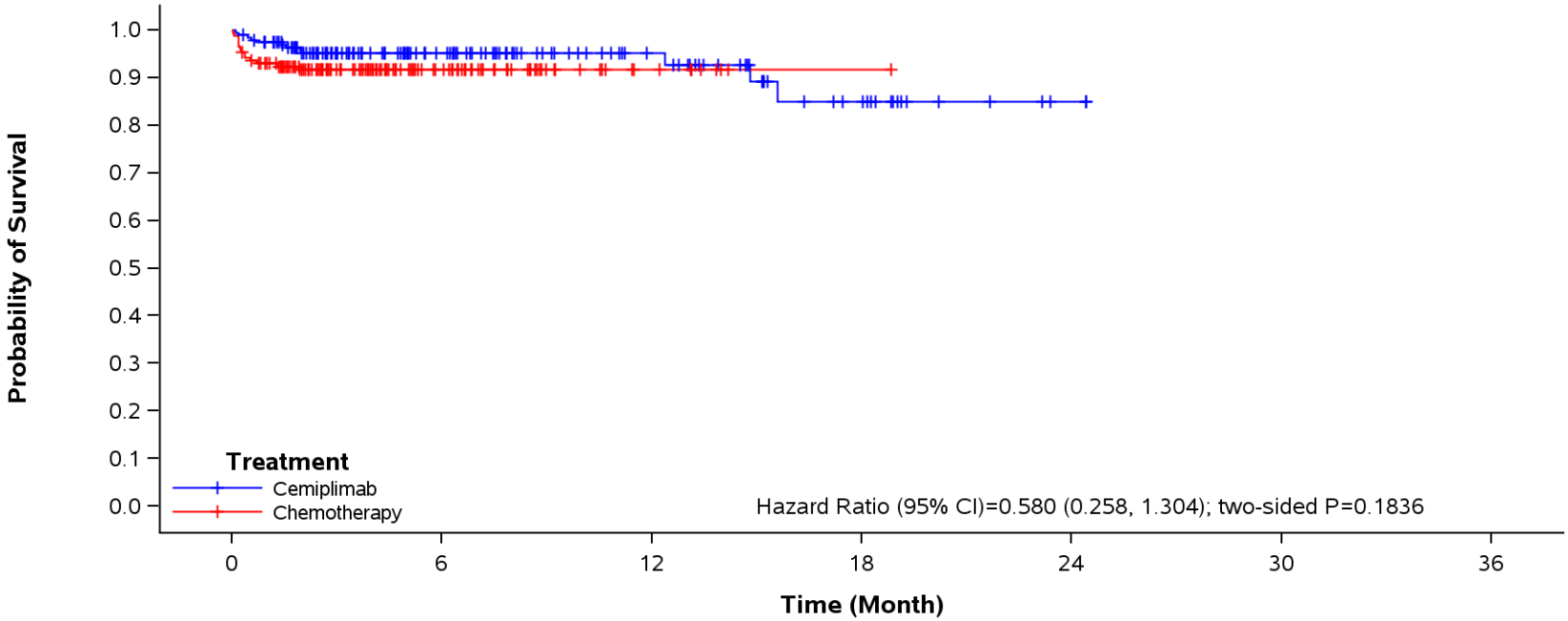

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 70 | 32 | 13 | 2 | 0 | 0 |
| Chemotherapy | 172 | 31 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Skin and subcutaneous tissue disorders
PT: Rash



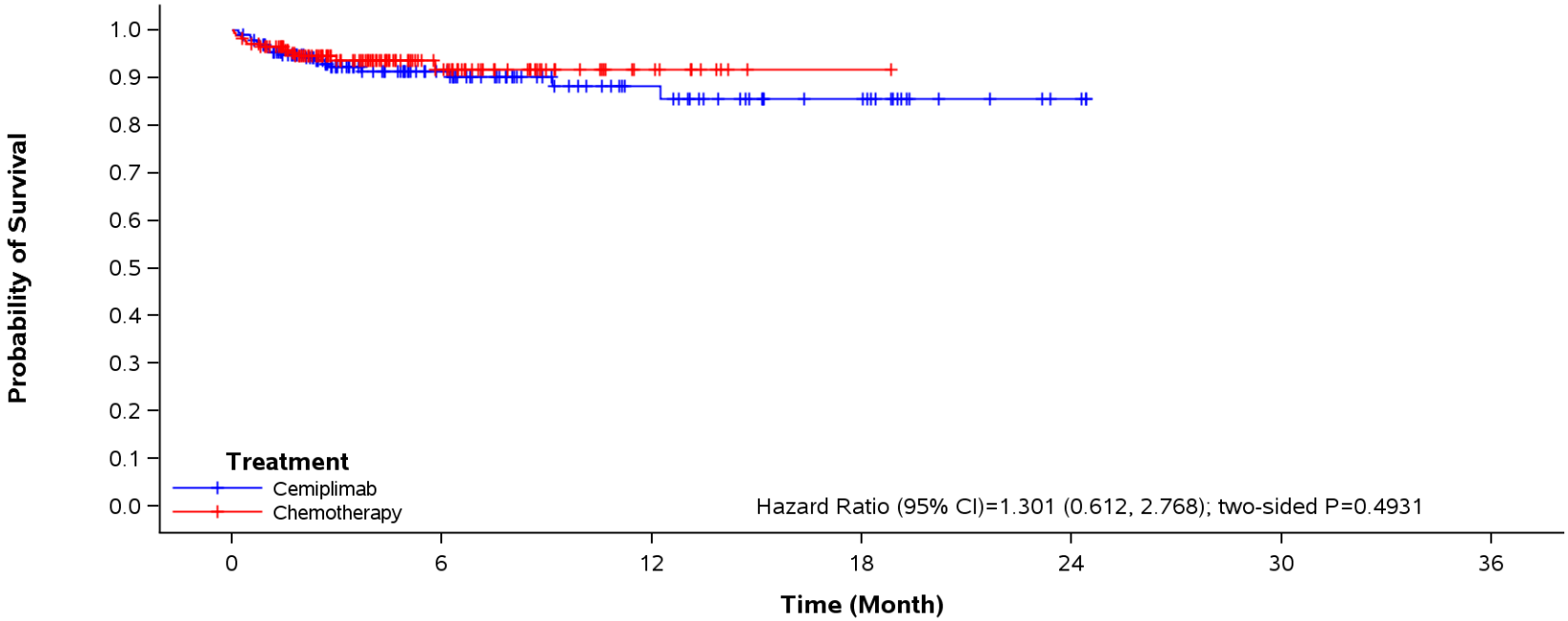

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 39 | 17 | 2 | 0 | 0 |
| Chemotherapy | 172 | 47 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Vascular disorders



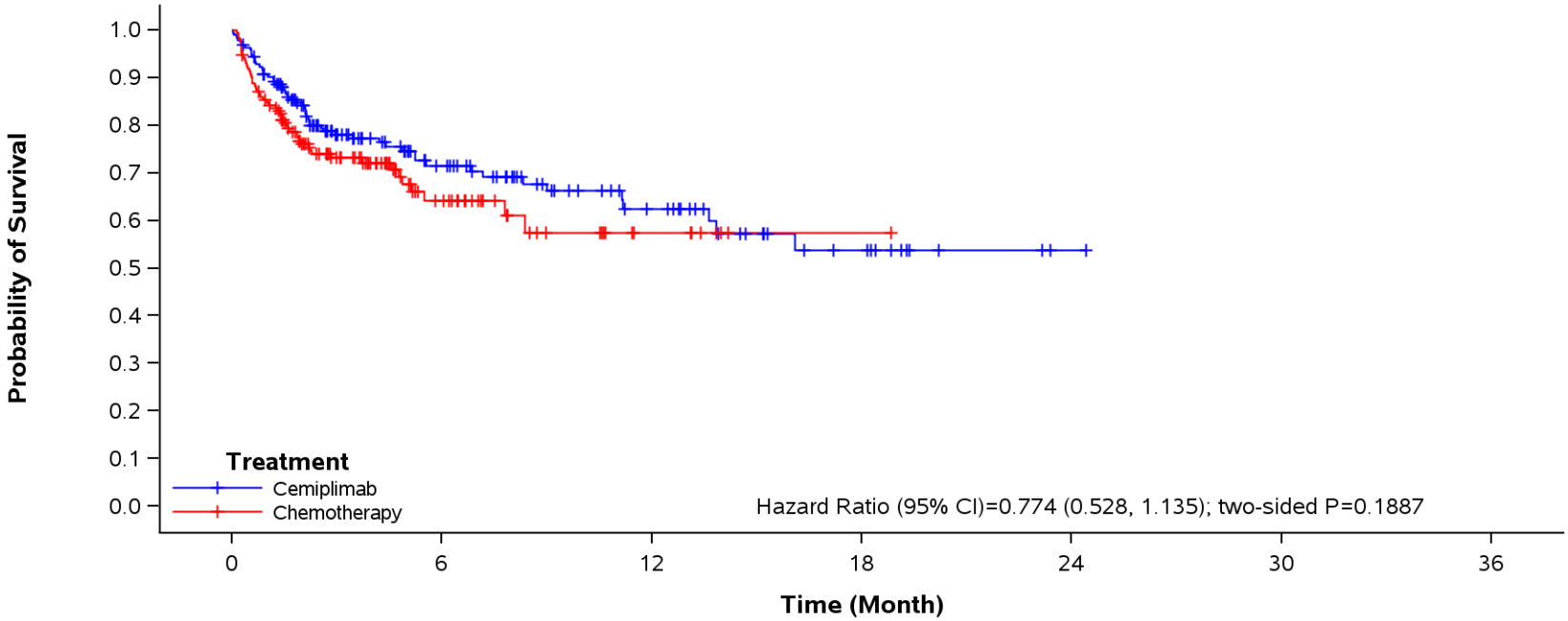

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 75 | 34 | 19 | 3 | 0 | 0 |
| Chemotherapy | 172 | 48 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any treatment-emergent SAE



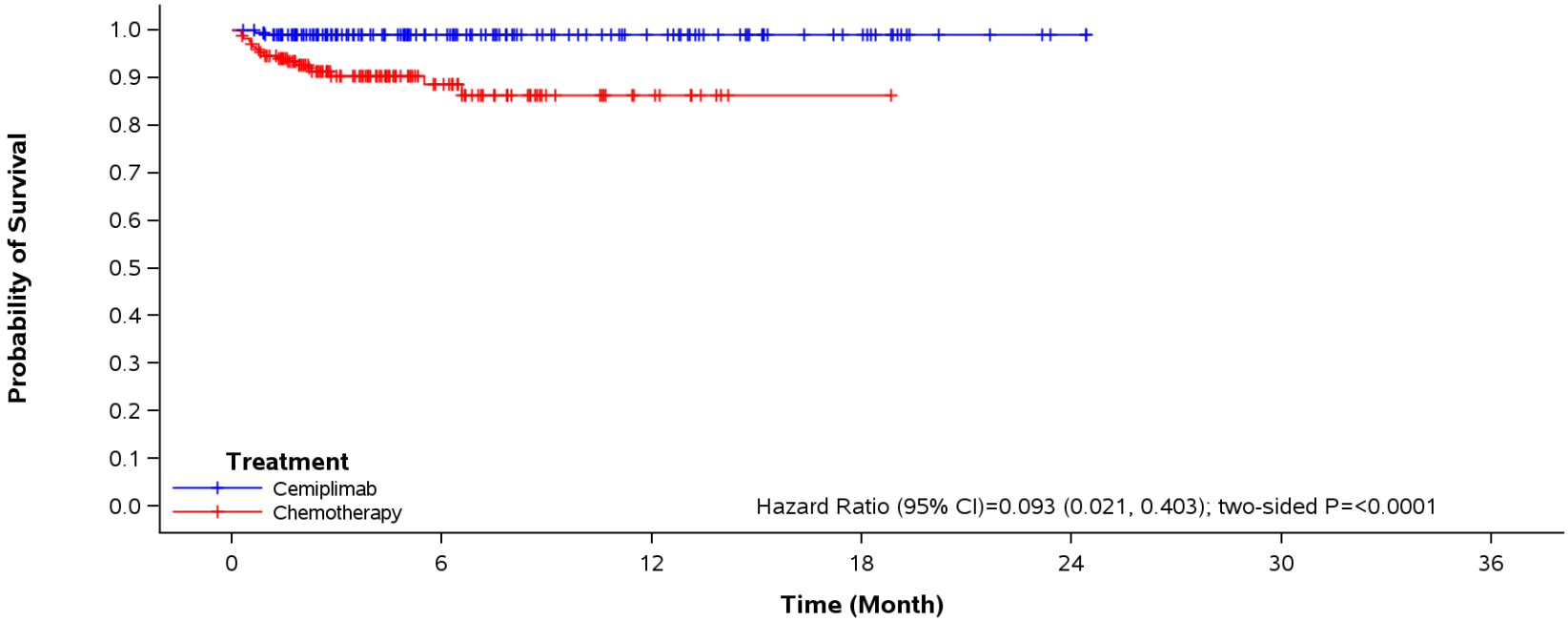

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 68 | 31 | 13 | 1 | 0 | 0 |
| Chemotherapy | 172 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders



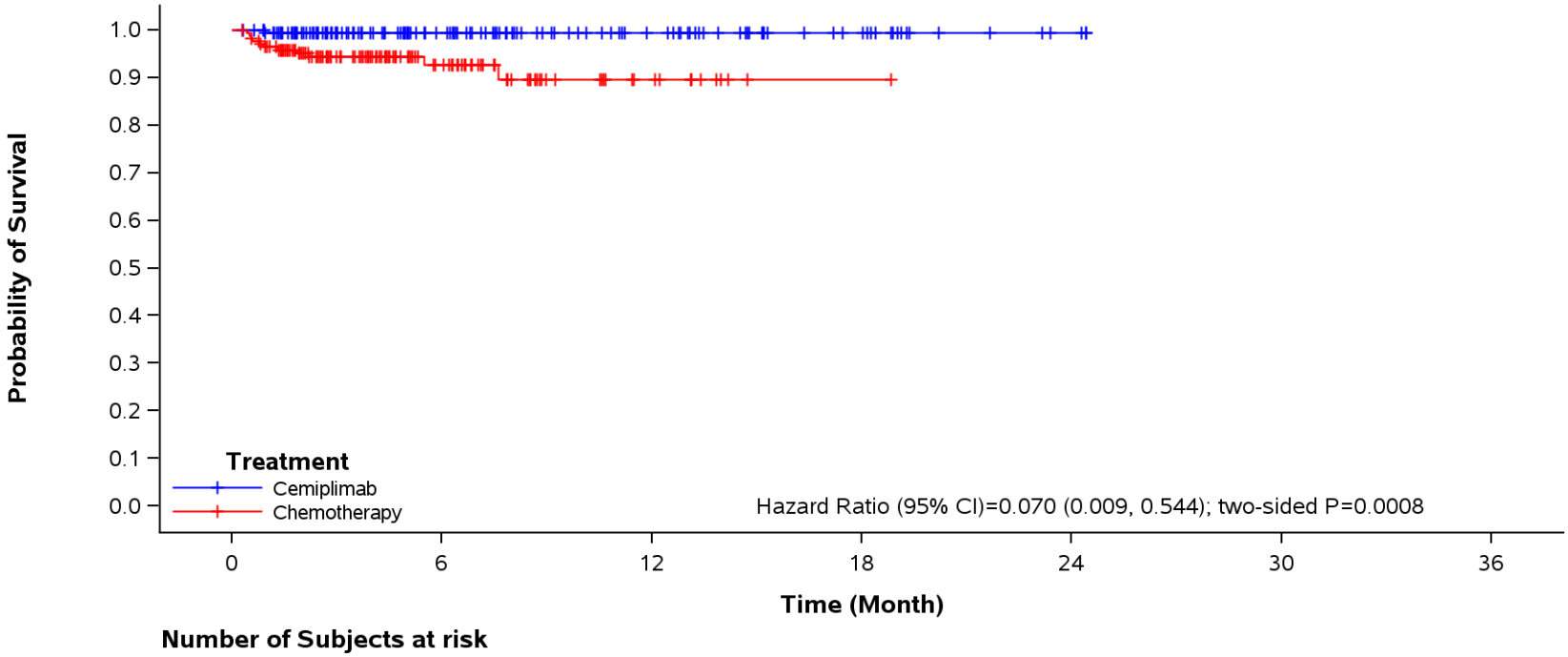

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 40 | 19 | 3 | 0 | 0 |
| Chemotherapy | 172 | 48 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia



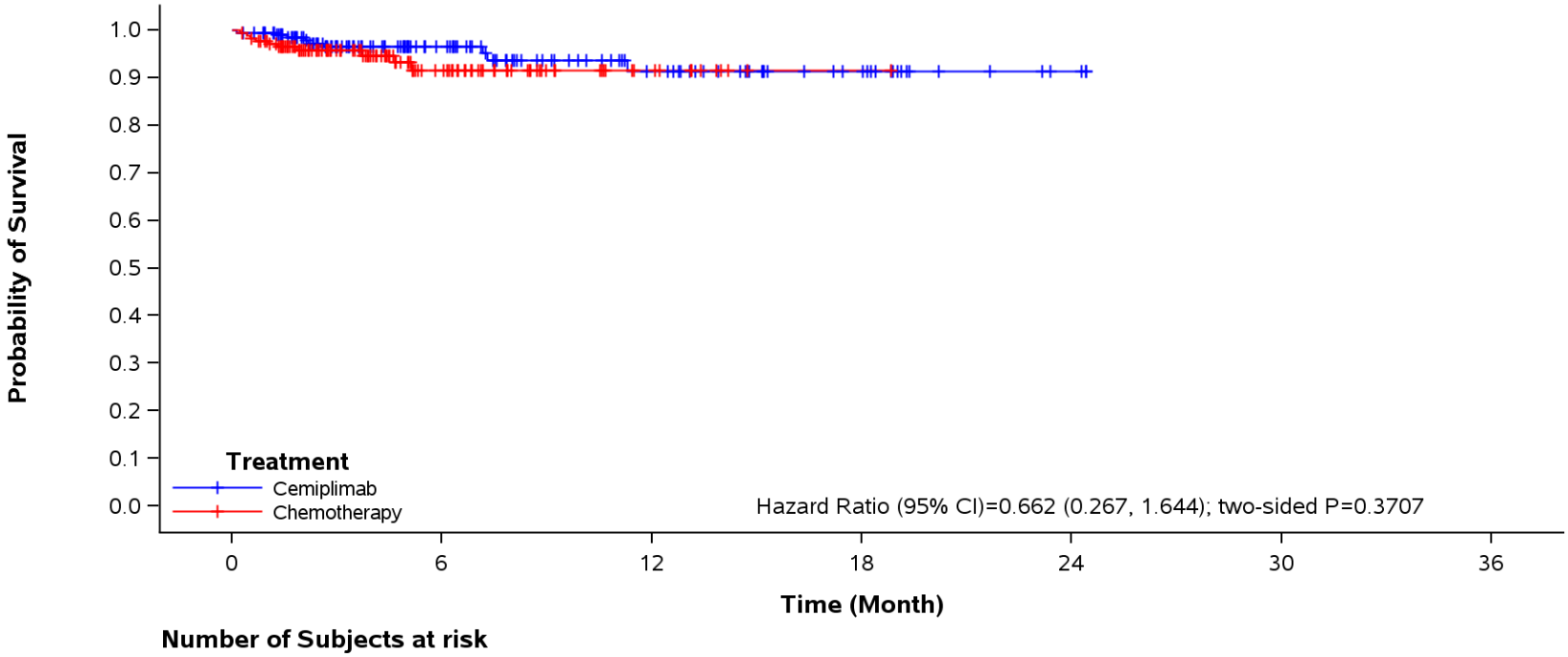

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 50 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders



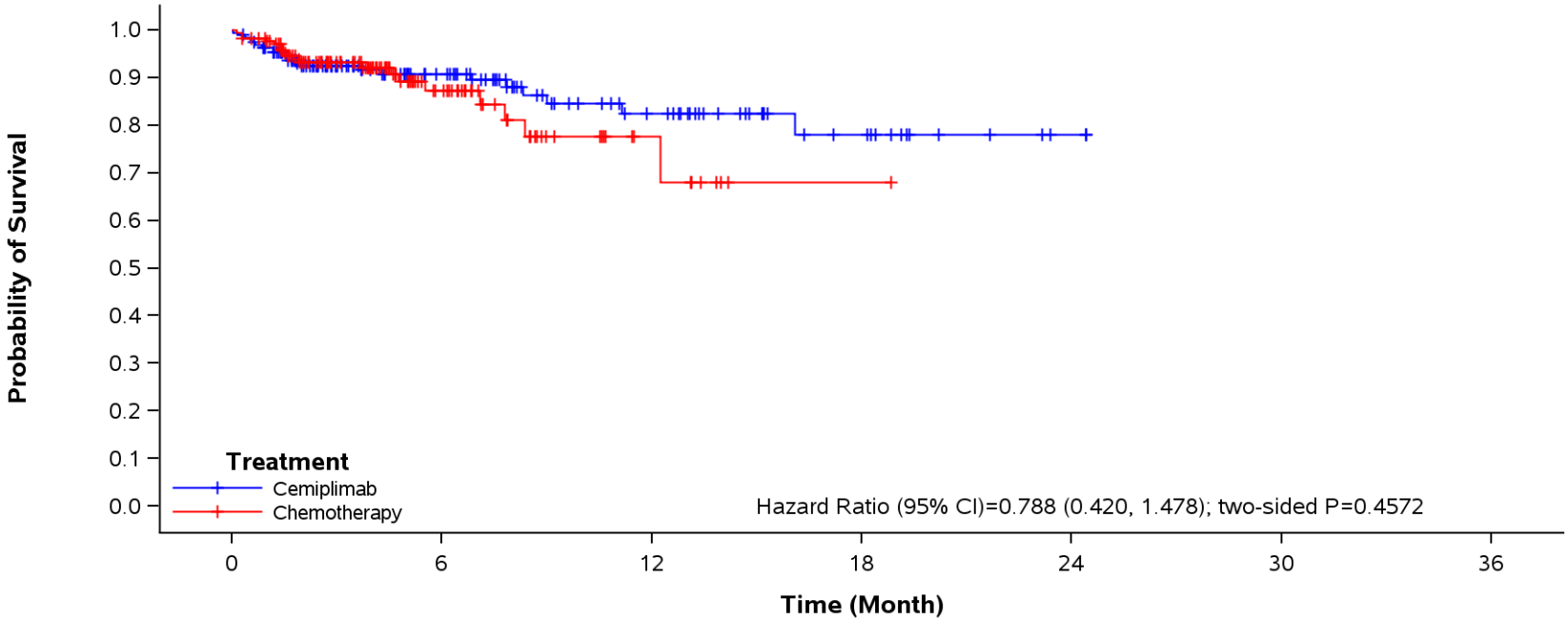

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 38 | 19 | 3 | 0 | 0 |
| Chemotherapy | 172 | 49 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations



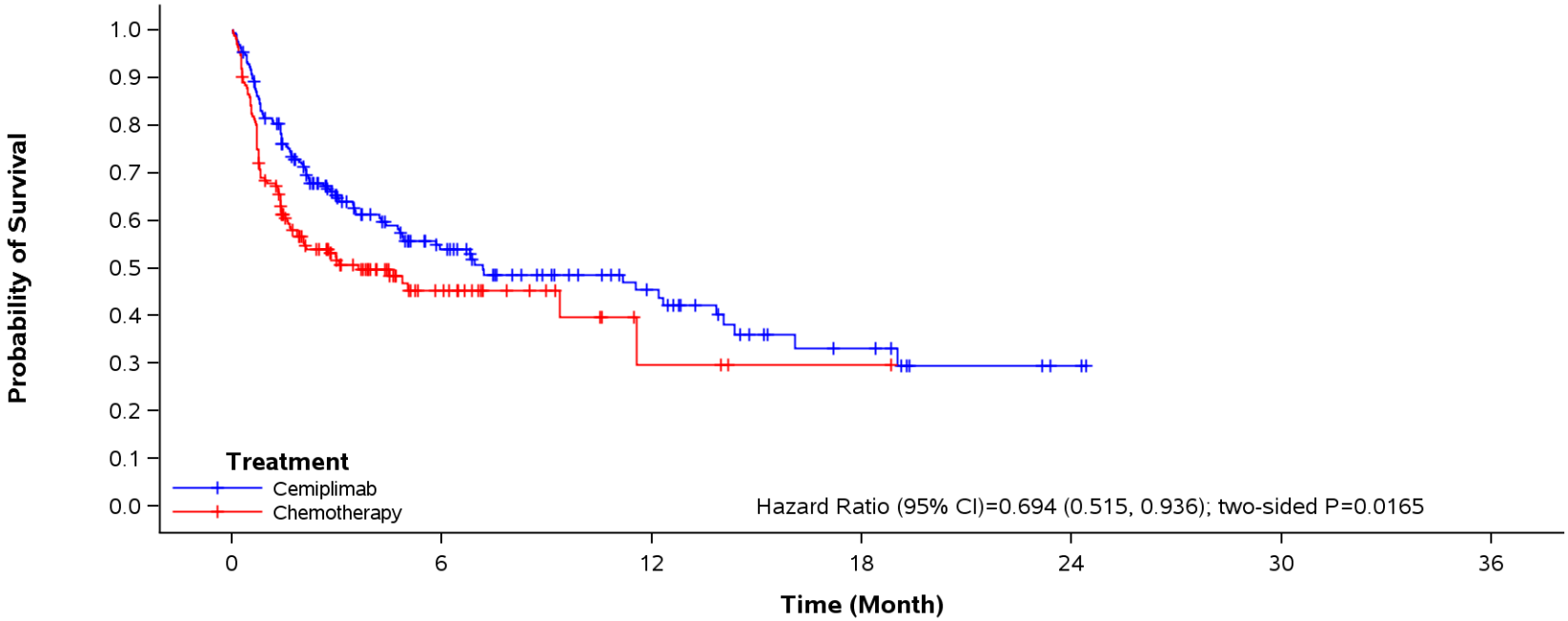

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 36 | 16 | 3 | 0 | 0 |
| Chemotherapy | 172 | 46 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any TEAE CTCAE Grade >= 3



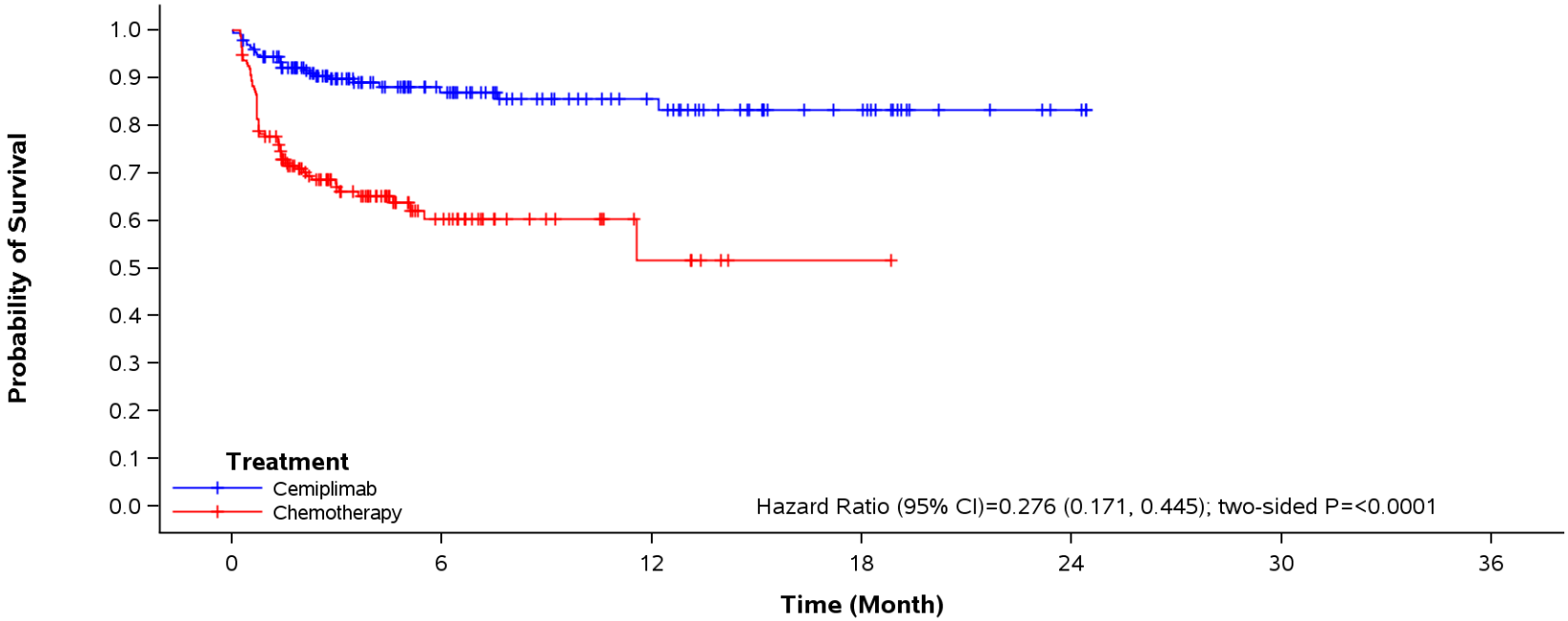

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 58 | 28 | 11 | 2 | 0 | 0 |
| Chemotherapy | 172 | 24 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders



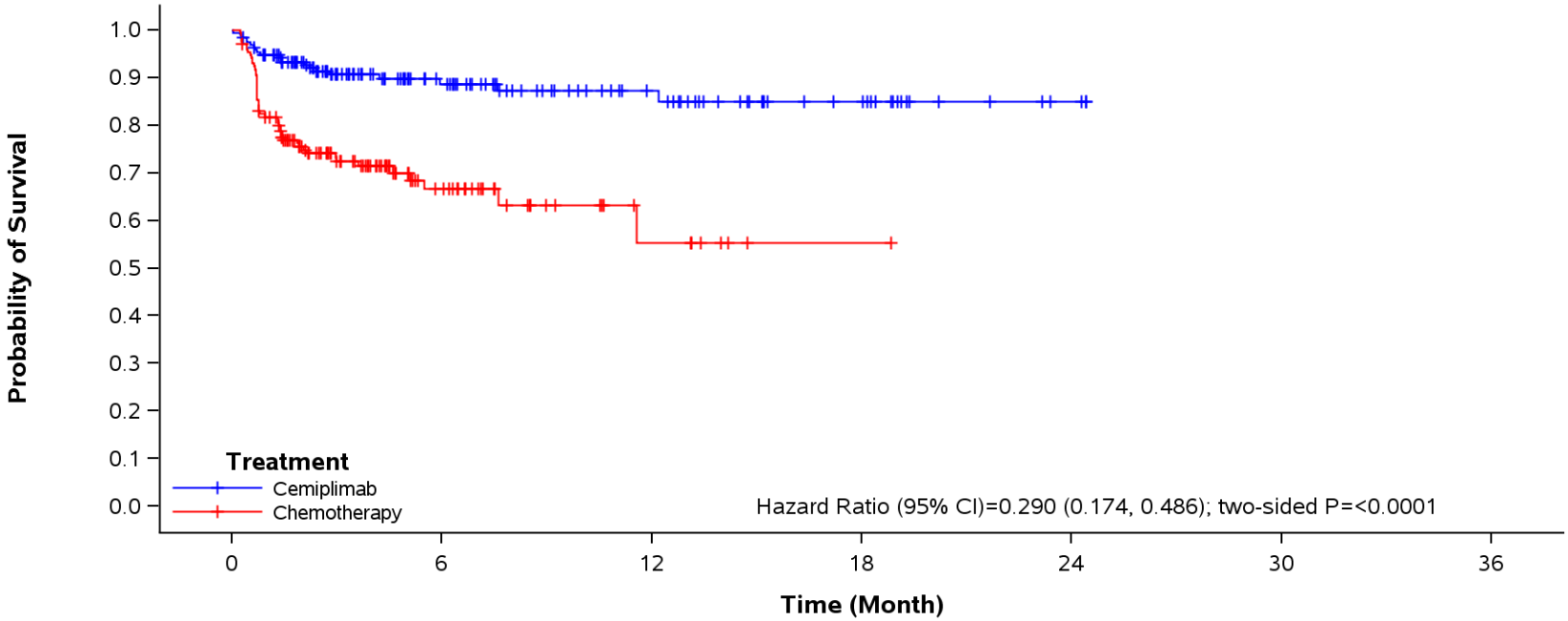

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 79 | 39 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 32 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia



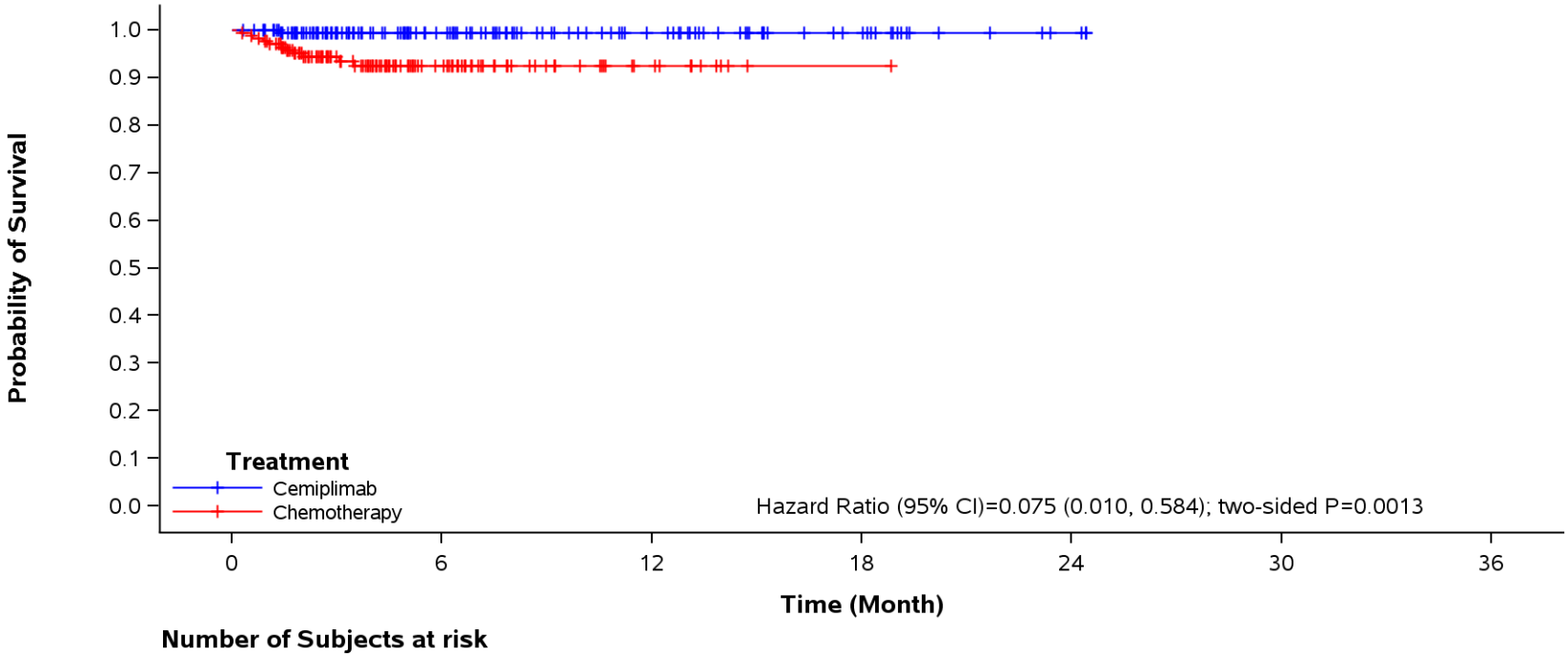

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 39 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Neutropenia



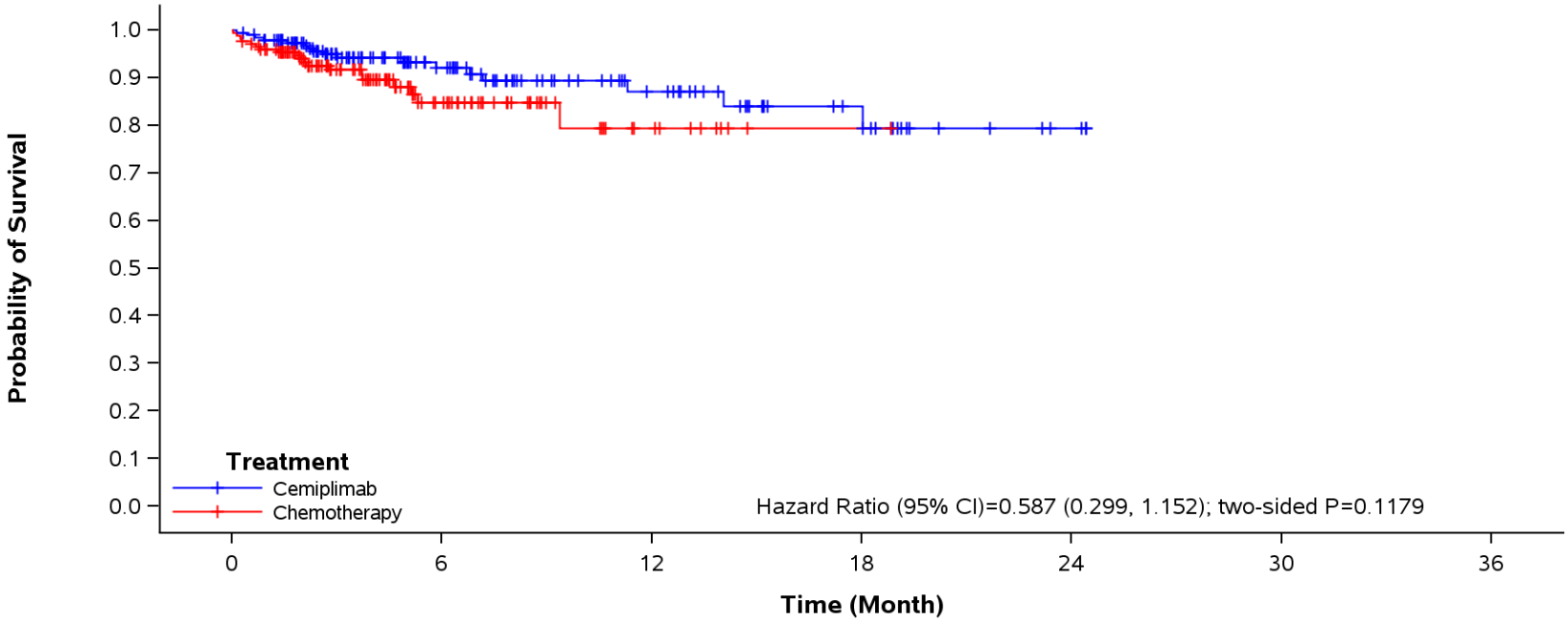

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 41 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 47 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders



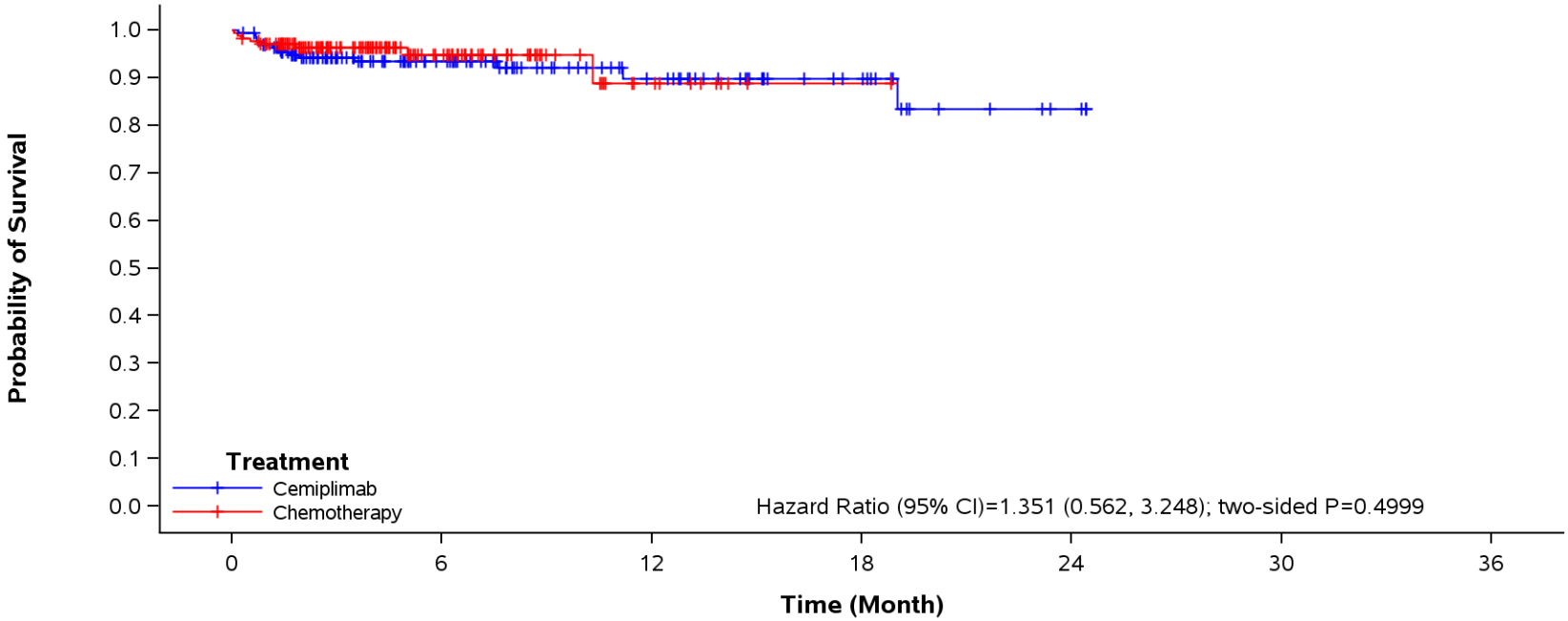

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 37 | 18 | 3 | 0 | 0 |
| Chemotherapy | 172 | 45 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions



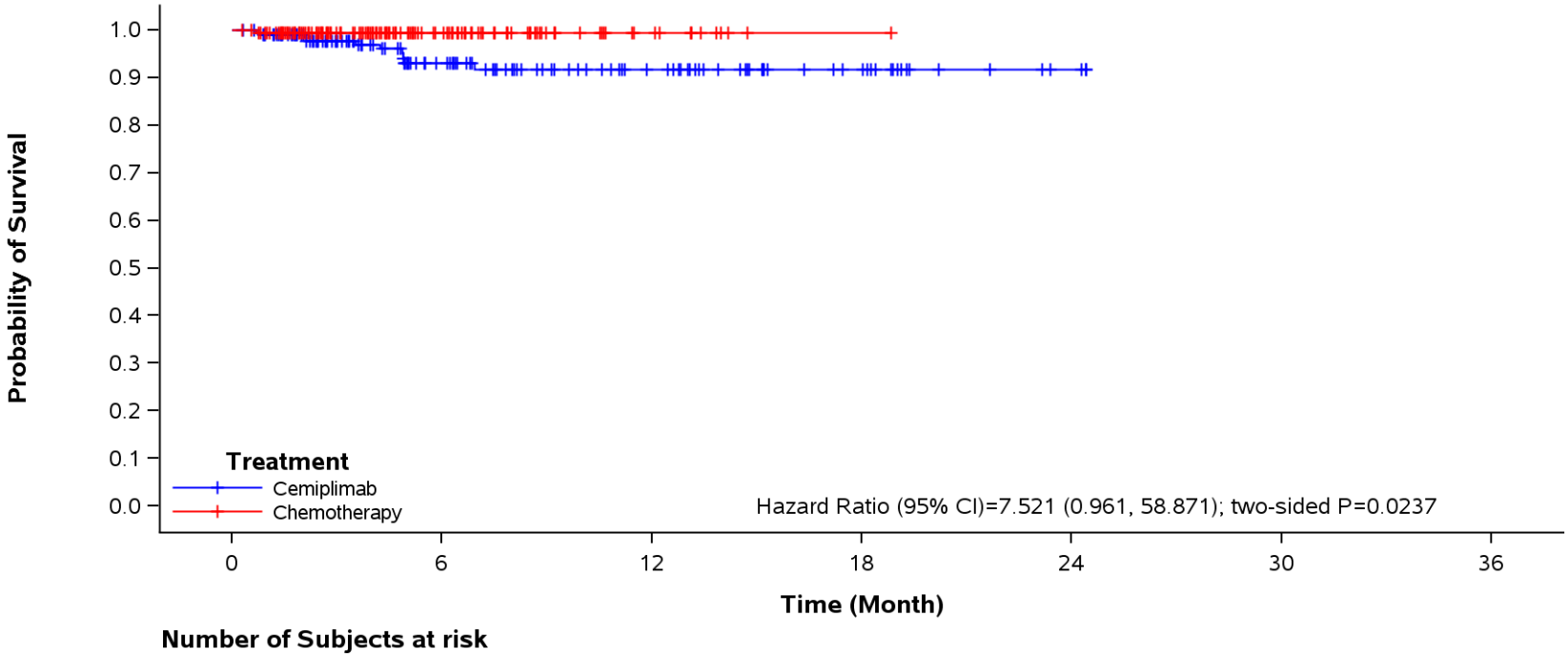

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 40 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 51 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders



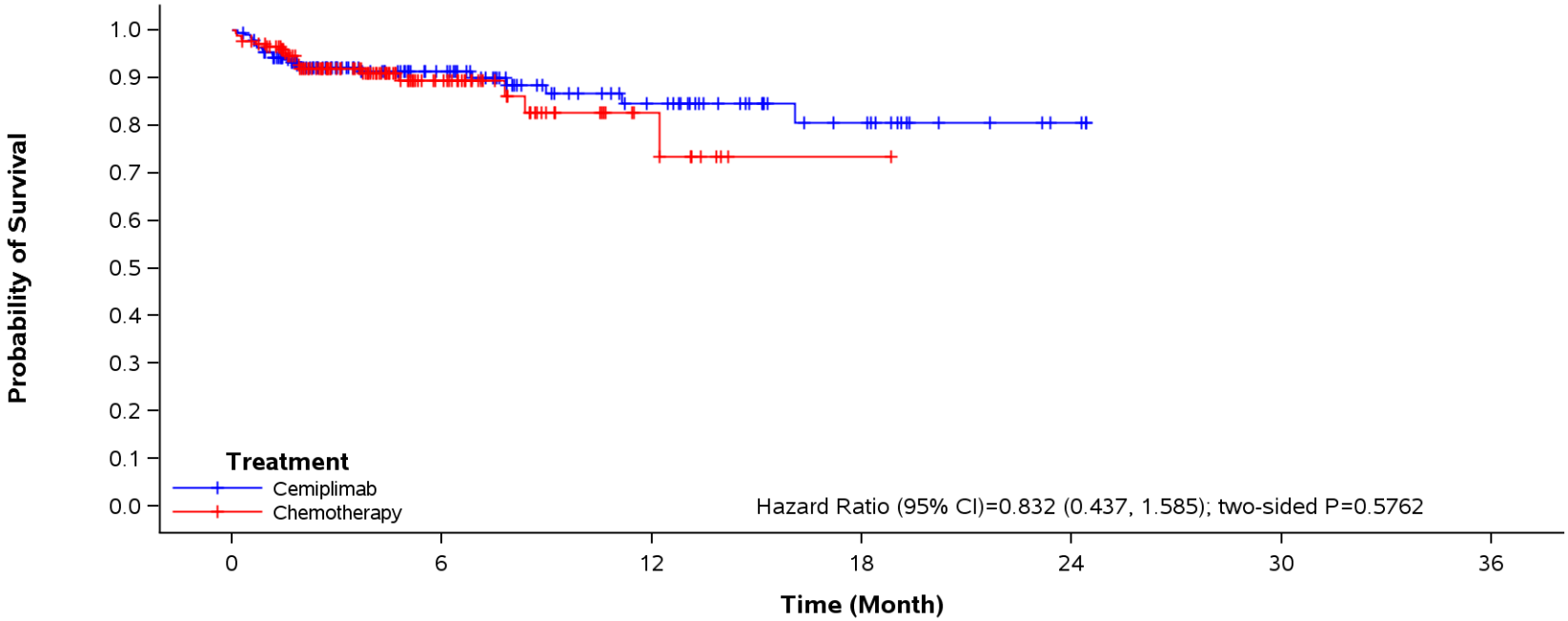

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 40 | 19 | 3 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations



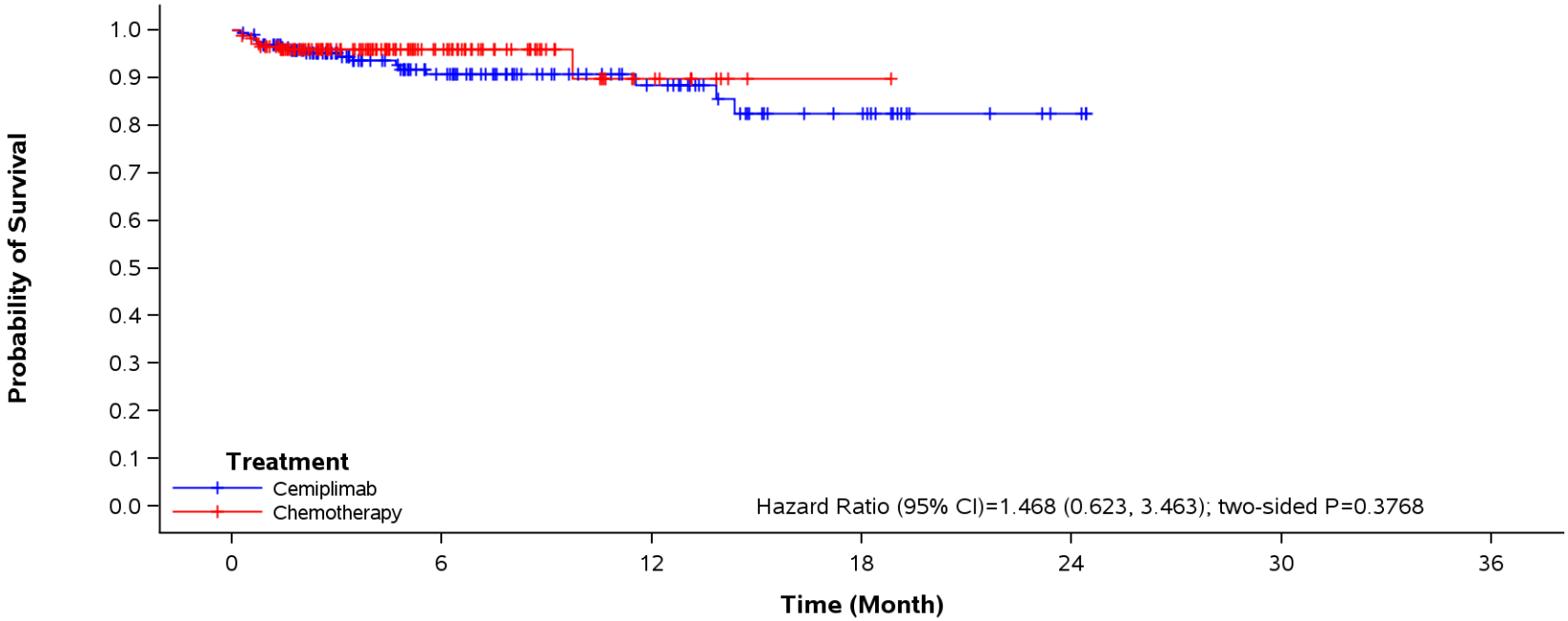

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 81 | 38 | 18 | 4 | 0 | 0 |
| Chemotherapy | 172 | 47 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations



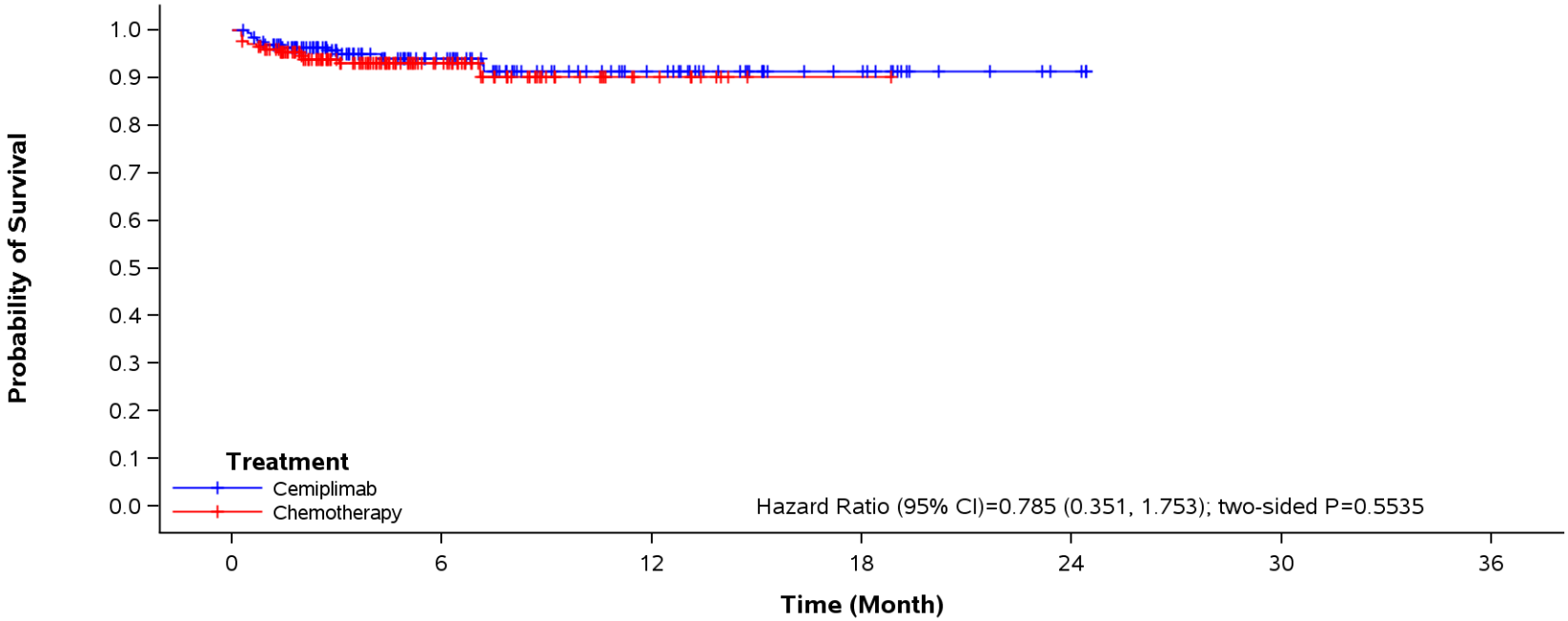

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 79 | 39 | 18 | 4 | 0 | 0 |
| Chemotherapy | 172 | 49 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders



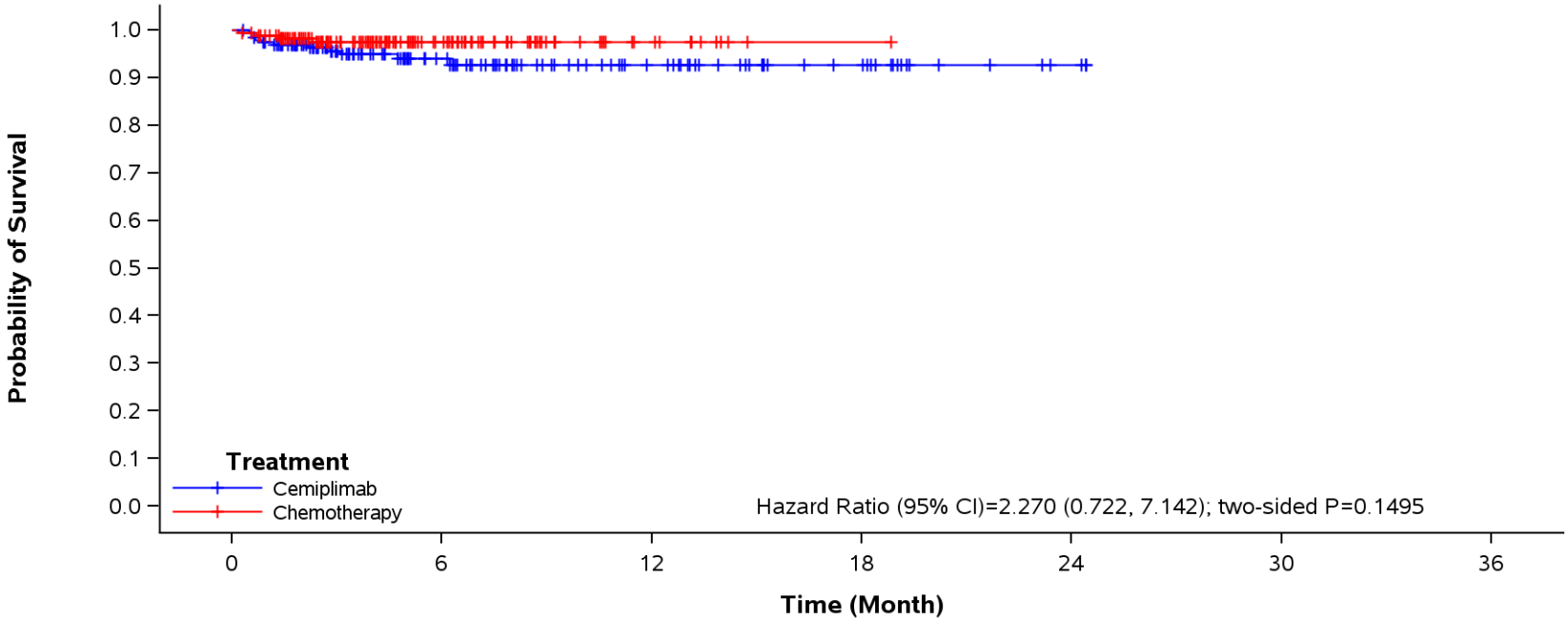

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 39 | 19 | 4 | 0 | 0 |
| Chemotherapy | 172 | 51 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders



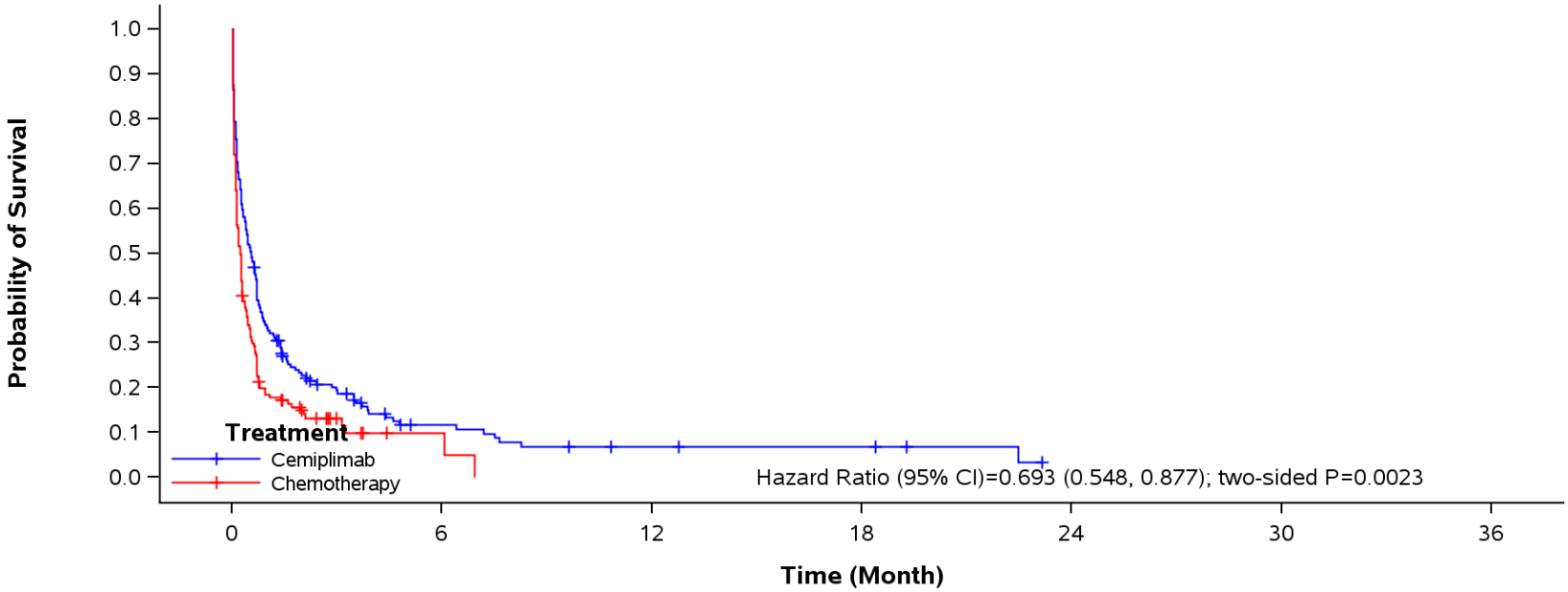

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 81 | 38 | 20 | 4 | 0 | 0 |
| Chemotherapy | 172 | 51 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Number of patients with any TEAE



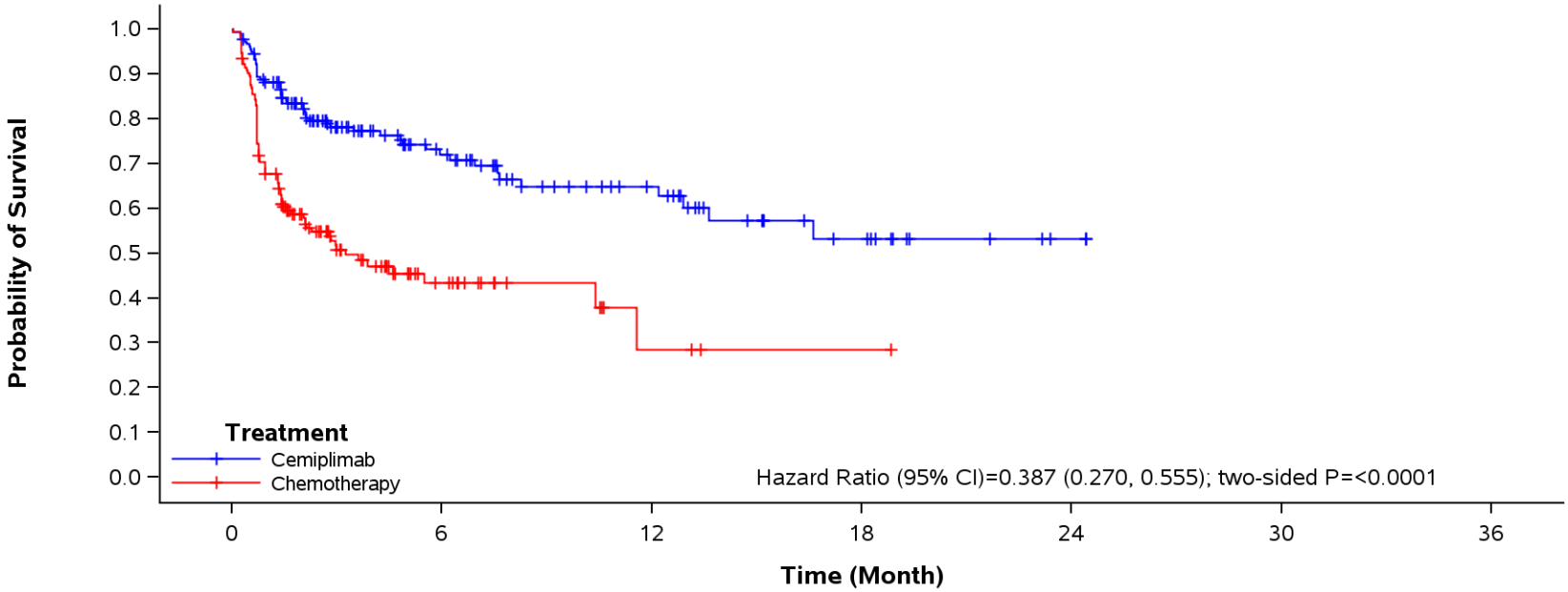

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 12 | 5 | 4 | 0 | 0 | 0 |
| Chemotherapy | 153 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders



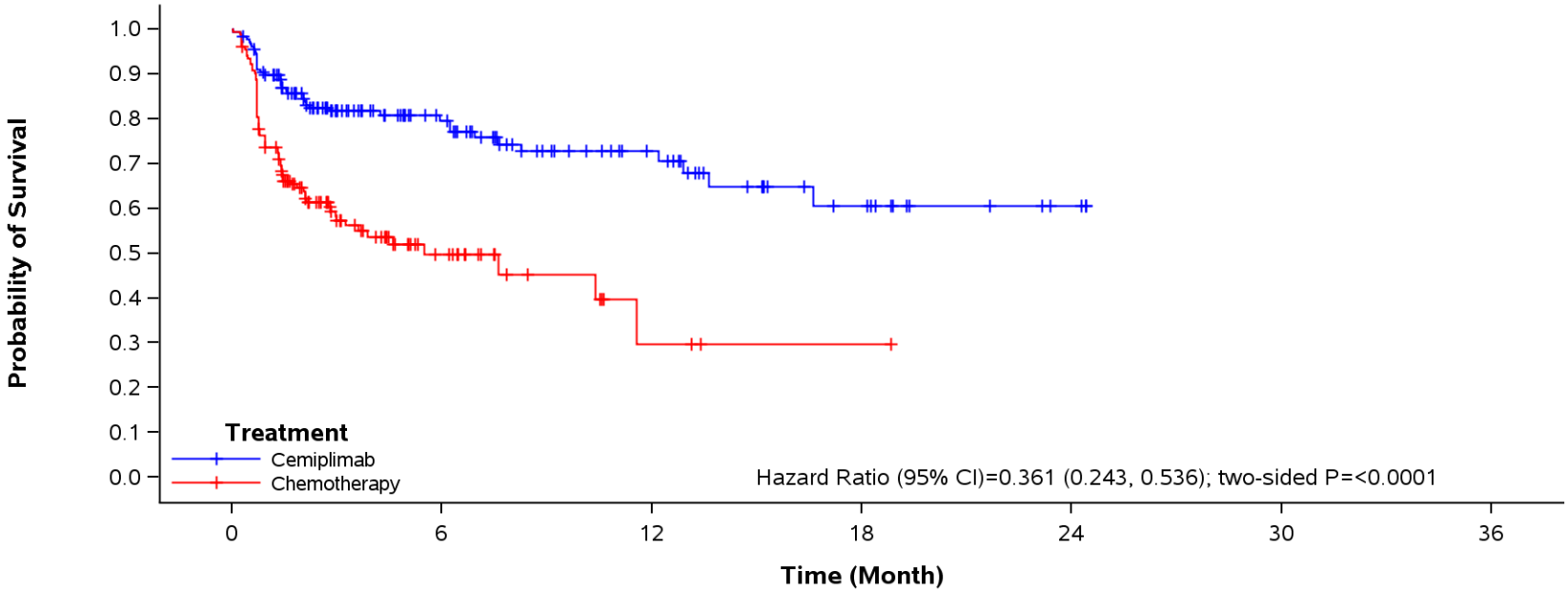

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 62 | 30 | 12 | 2 | 0 | 0 |
| Chemotherapy | 153 | 19 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Anaemia



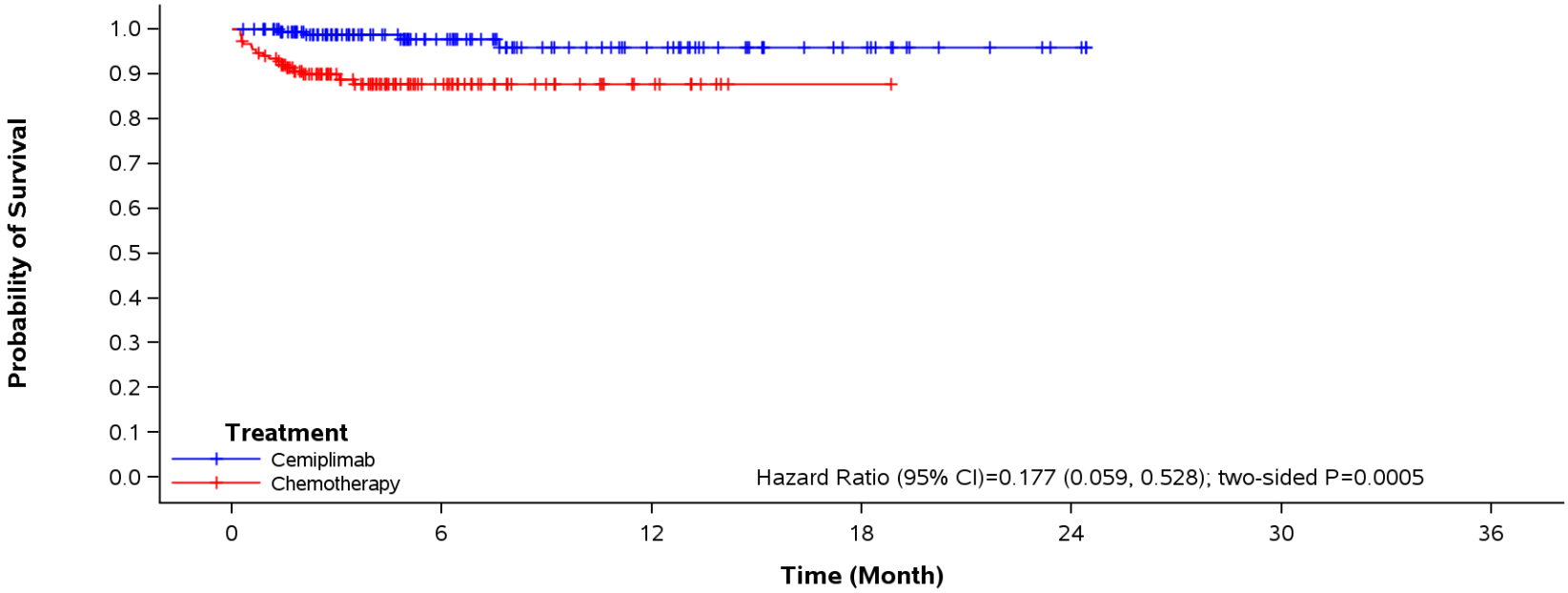

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 68 | 32 | 13 | 3 | 0 | 0 |
| Chemotherapy | 153 | 22 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



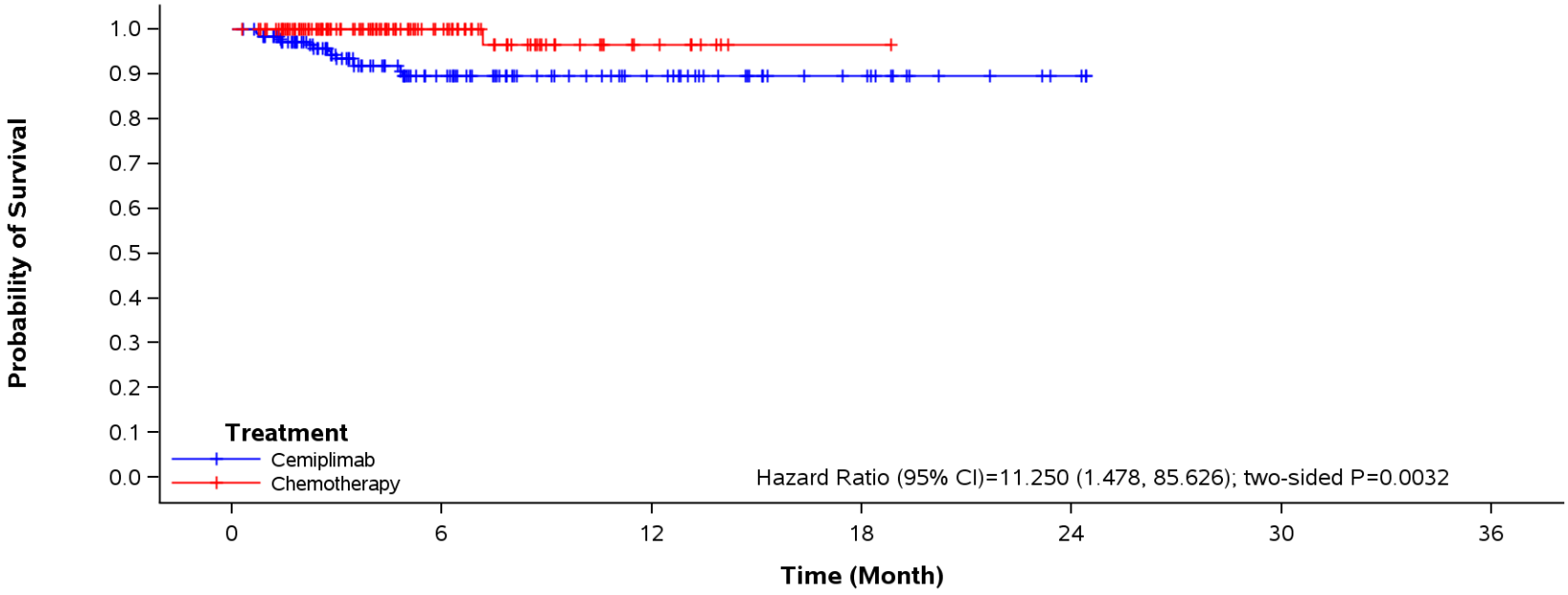

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 34 | 15 | 3 | 0 | 0 |
| Chemotherapy | 153 | 40 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Endocrine disorders



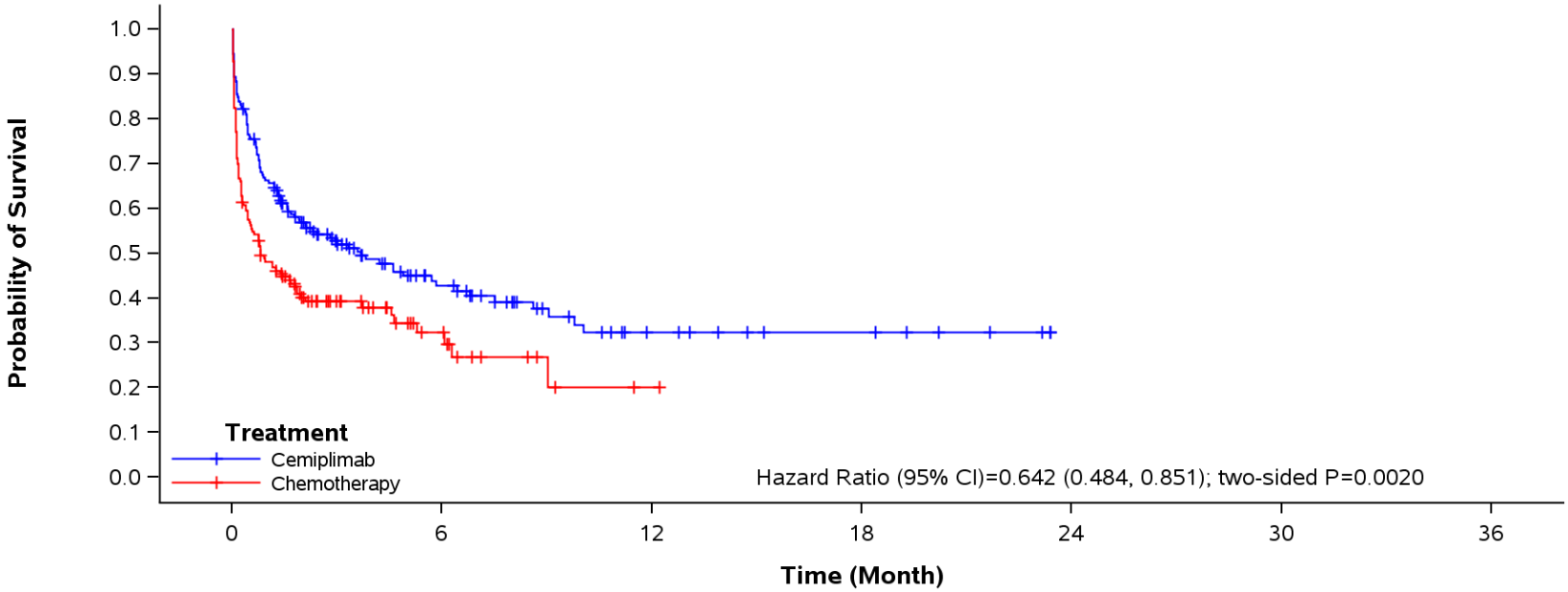

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 69 | 32 | 15 | 3 | 0 | 0 |
| Chemotherapy | 153 | 46 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders



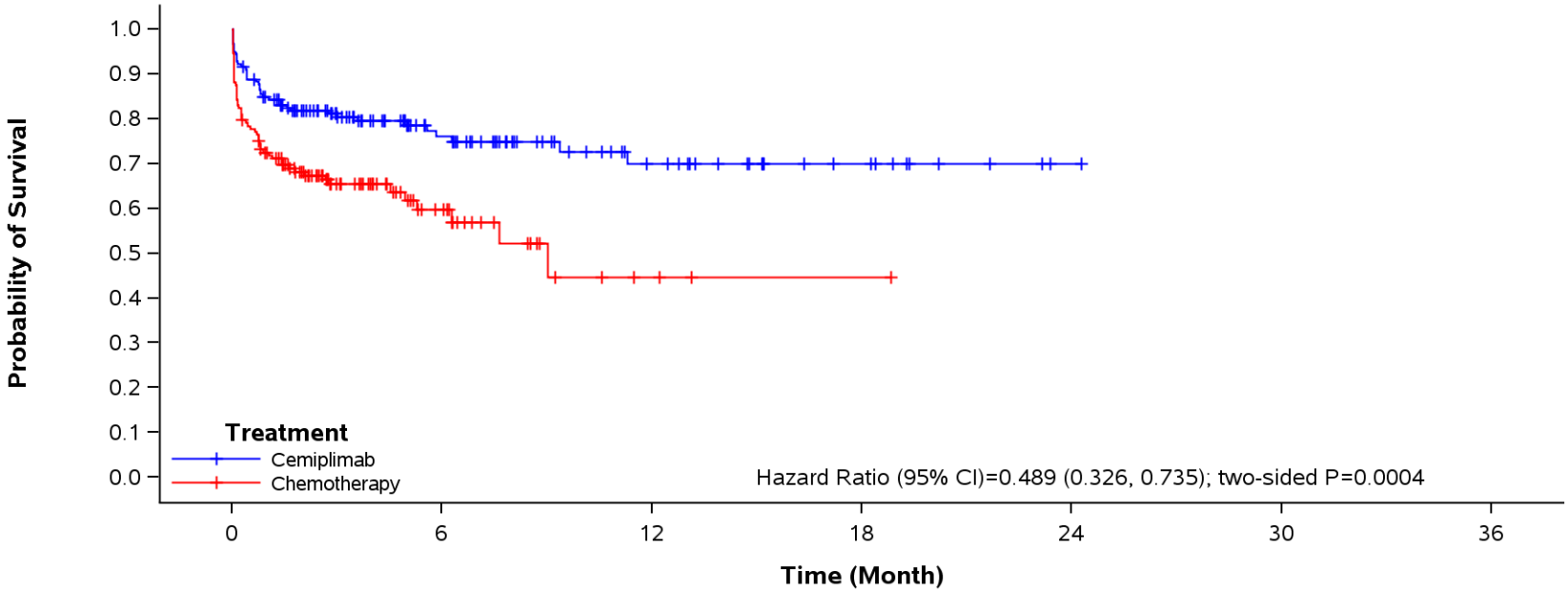

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 39 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 153 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders
PT: Nausea



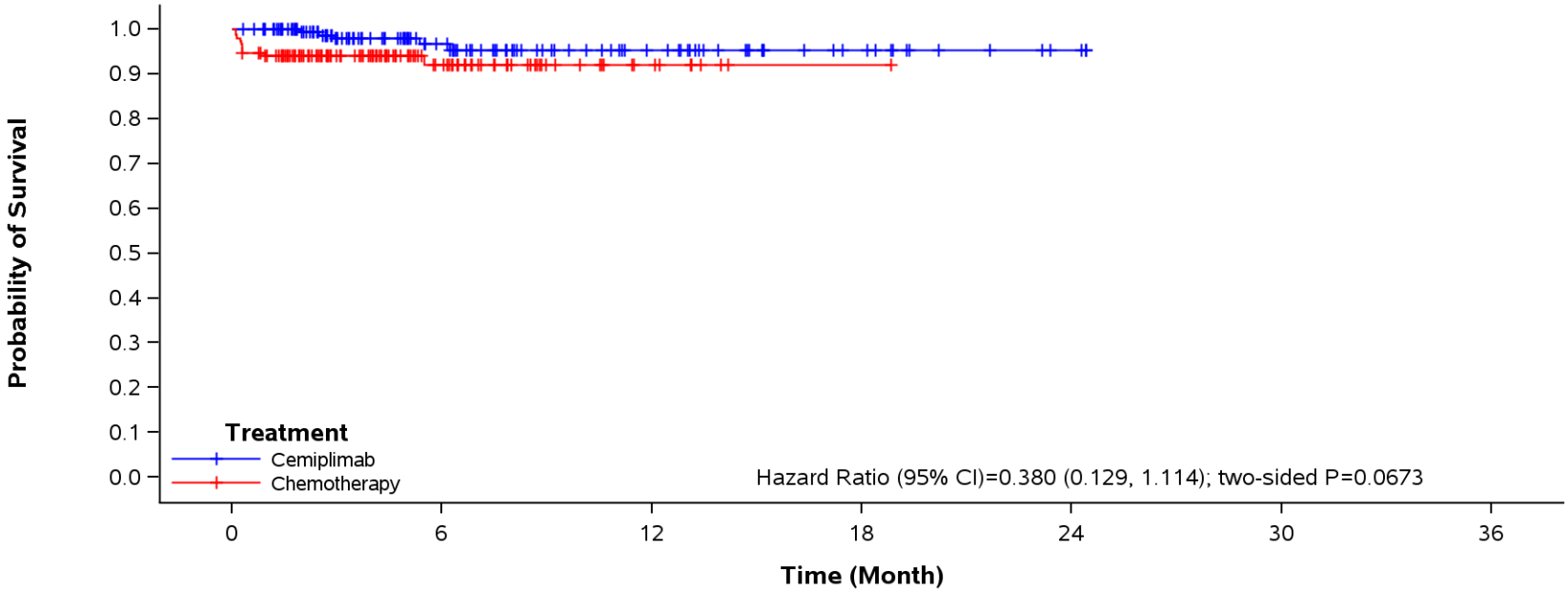

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 62 | 24 | 11 | 1 | 0 | 0 |
| Chemotherapy | 153 | 25 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders
PT: Stomatitis



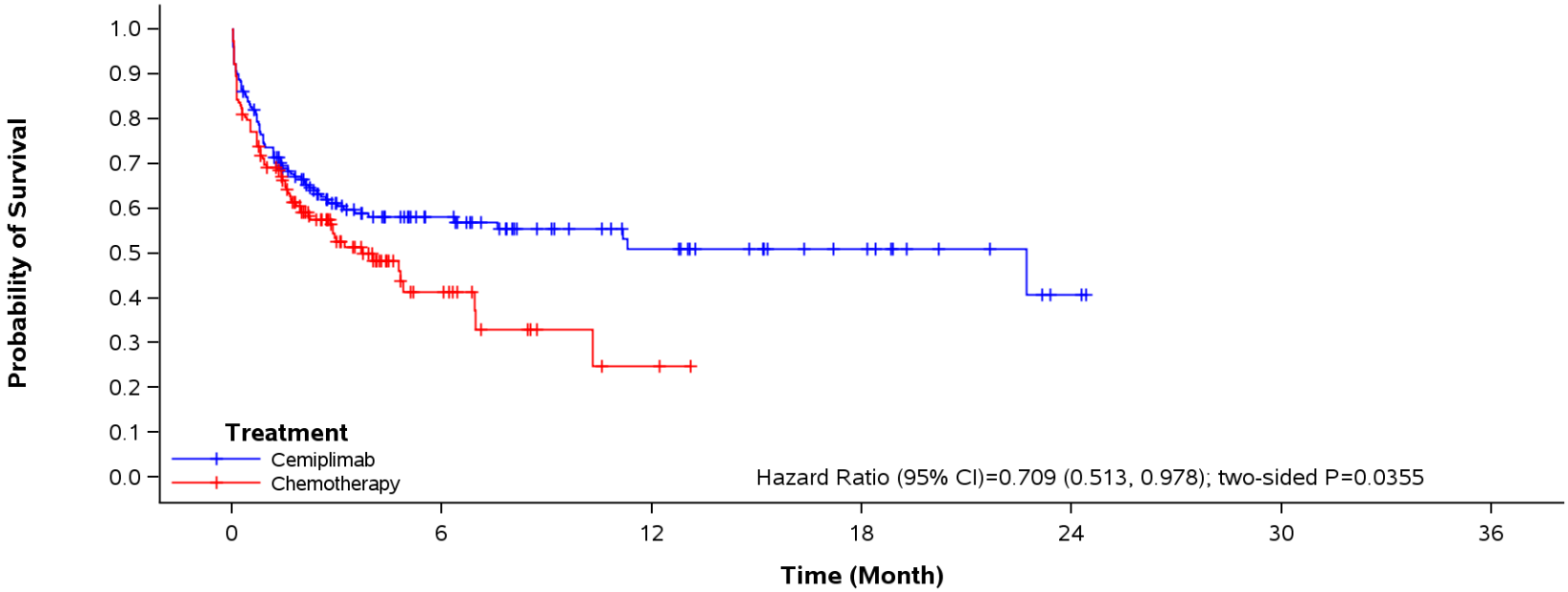

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 73 | 32 | 14 | 3 | 0 | 0 |
| Chemotherapy | 153 | 43 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: General disorders and administration site conditions



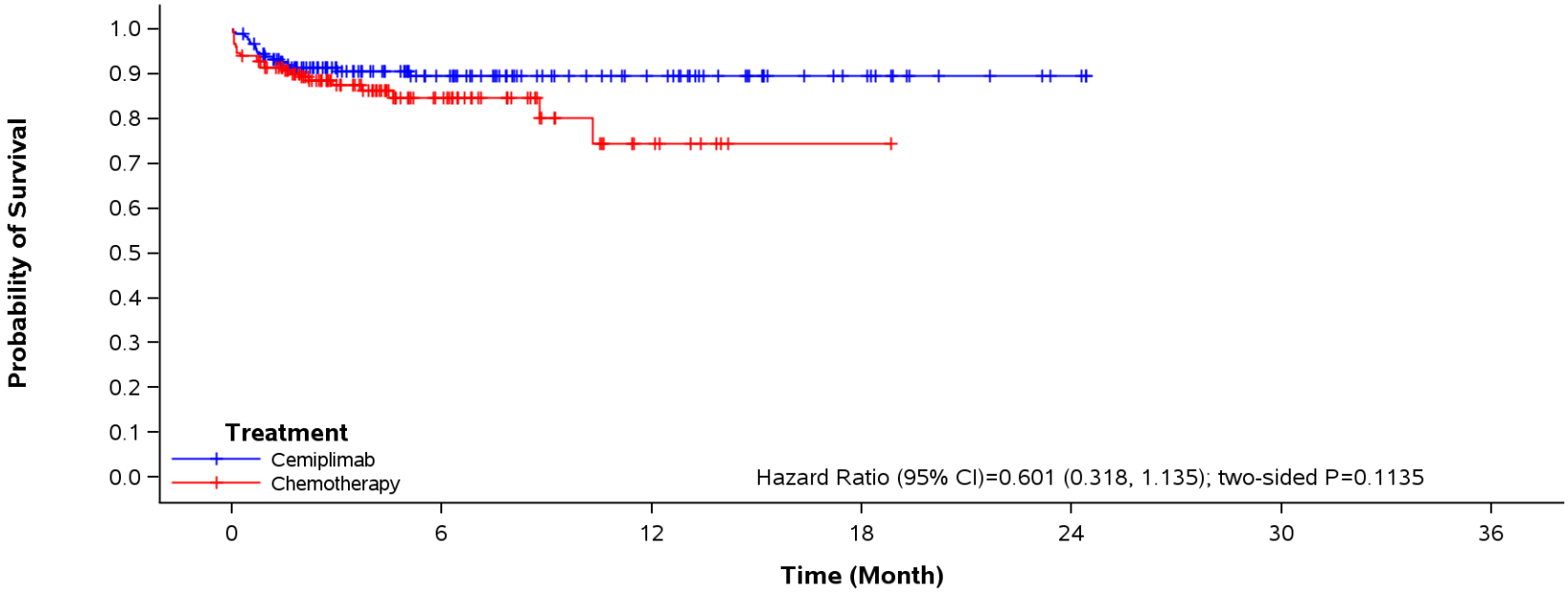

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 51 | 23 | 12 | 2 | 0 | 0 |
| Chemotherapy | 153 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: General disorders and administration site conditions
PT: Asthenia



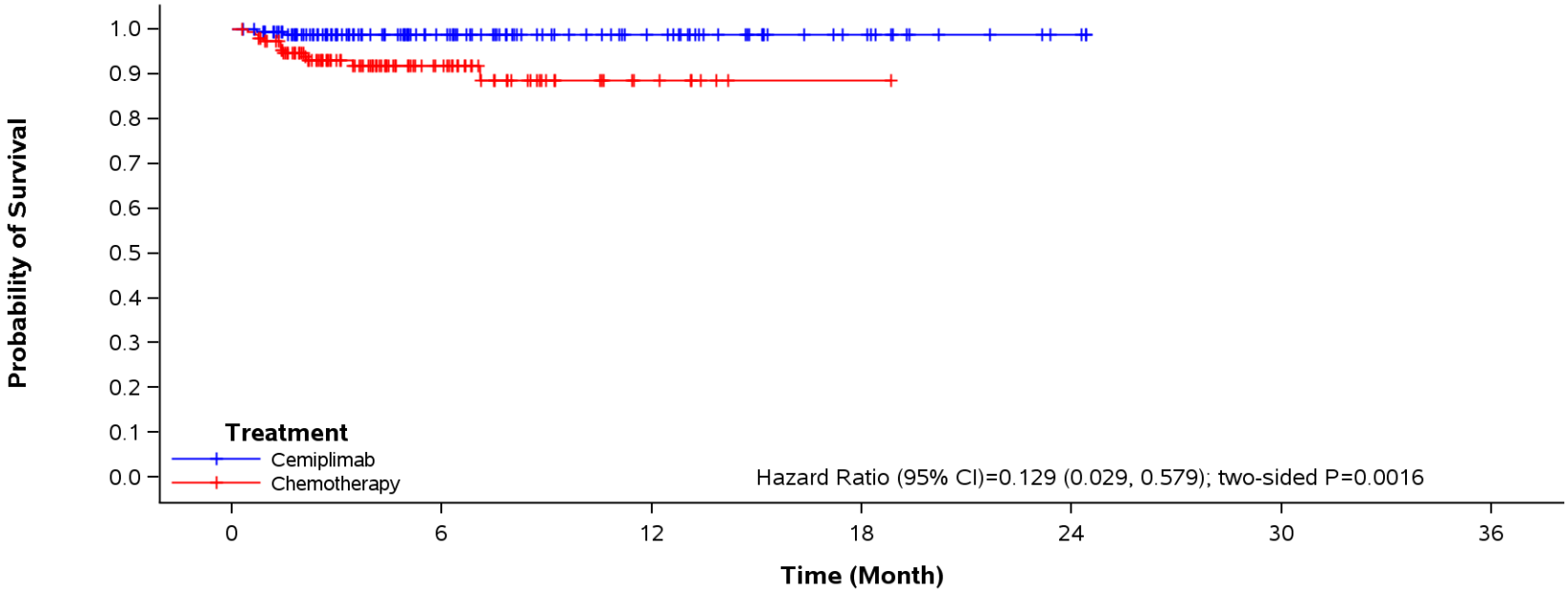

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 74 | 35 | 15 | 3 | 0 | 0 |
| Chemotherapy | 153 | 41 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



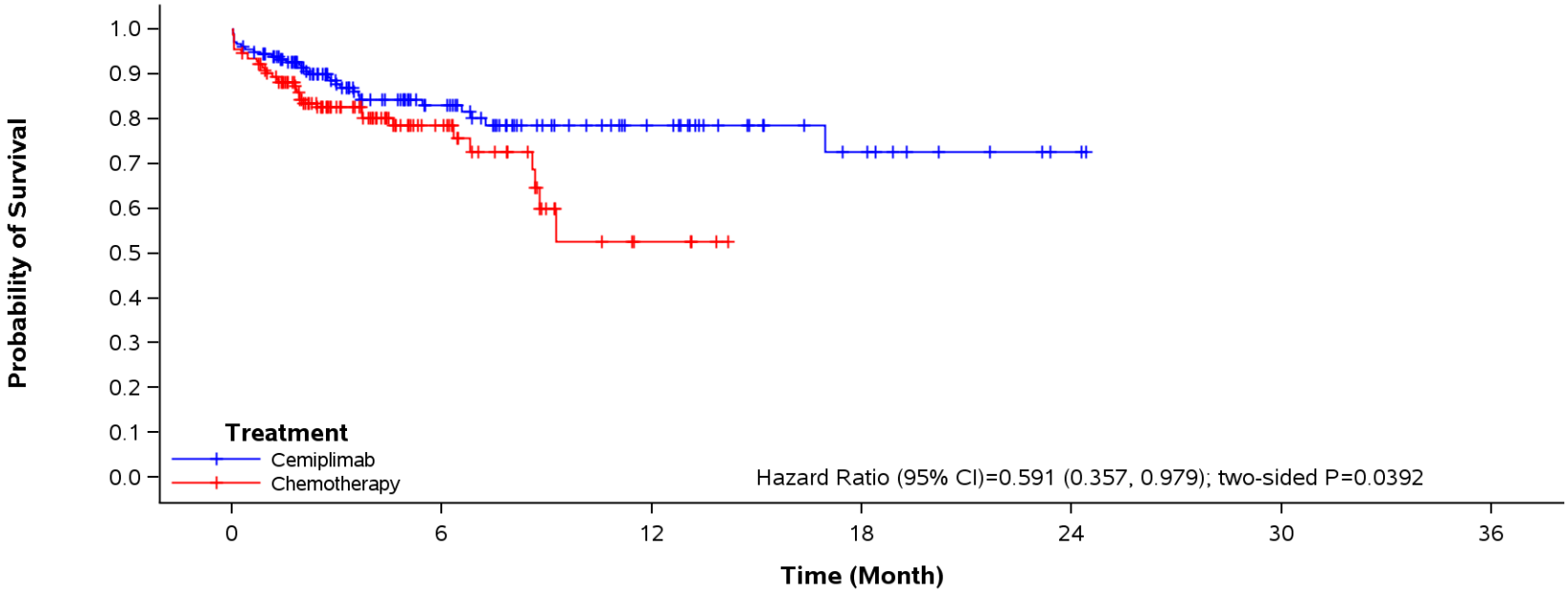

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 35 | 15 | 3 | 0 | 0 |
| Chemotherapy | 153 | 42 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Nervous system disorders



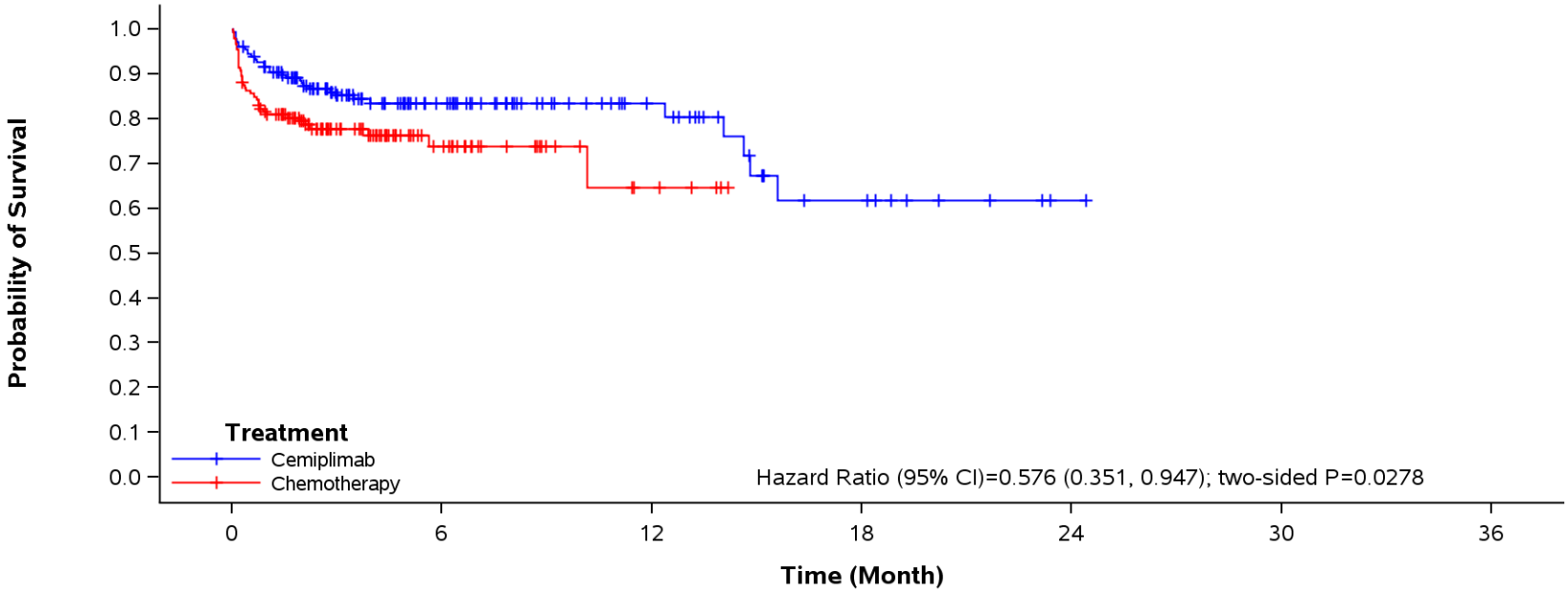

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 64 | 27 | 11 | 2 | 0 | 0 |
| Chemotherapy | 153 | 35 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Skin and subcutaneous tissue disorders



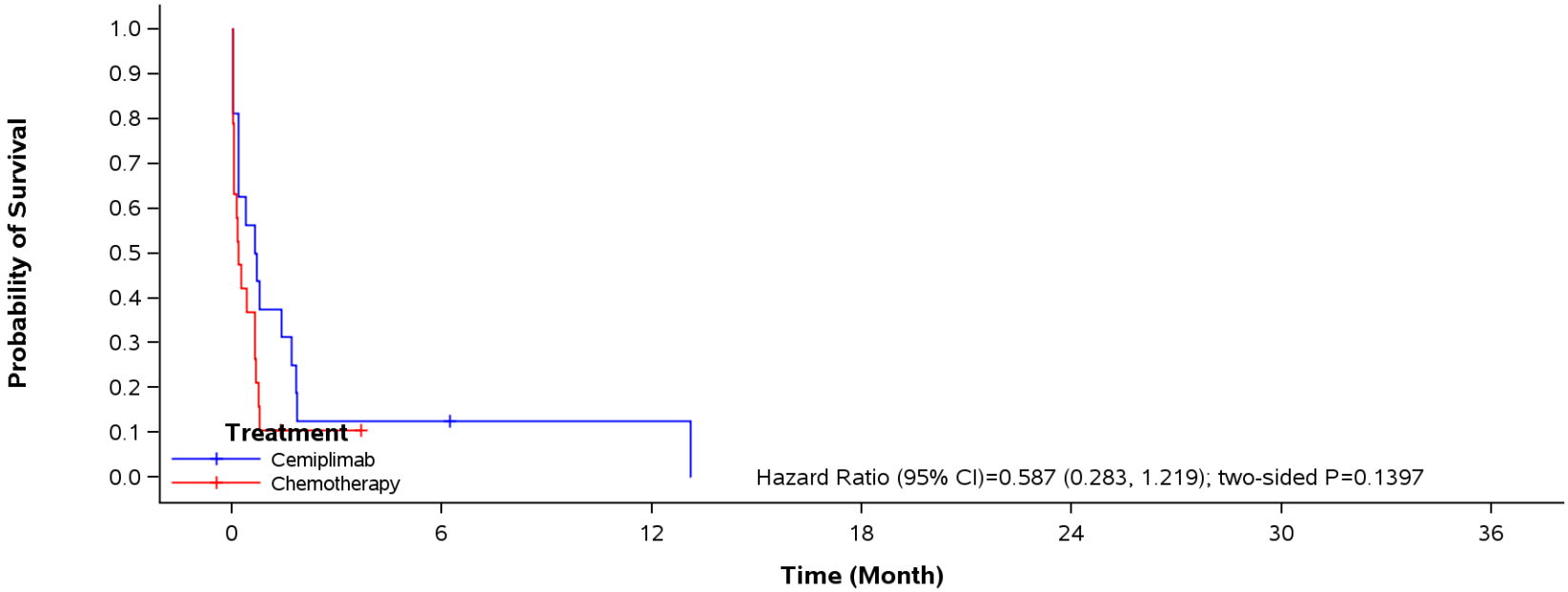

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 63 | 27 | 10 | 1 | 0 | 0 |
| Chemotherapy | 153 | 28 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Number of patients with any TEAE



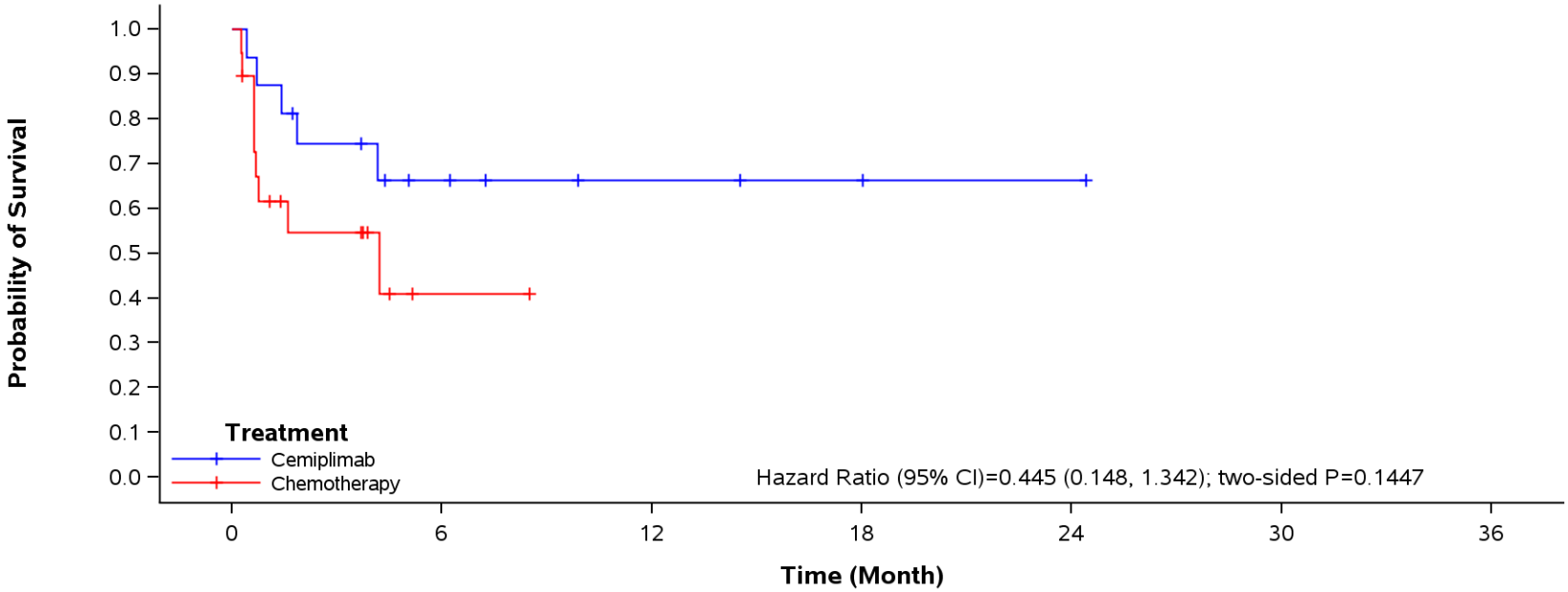

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders



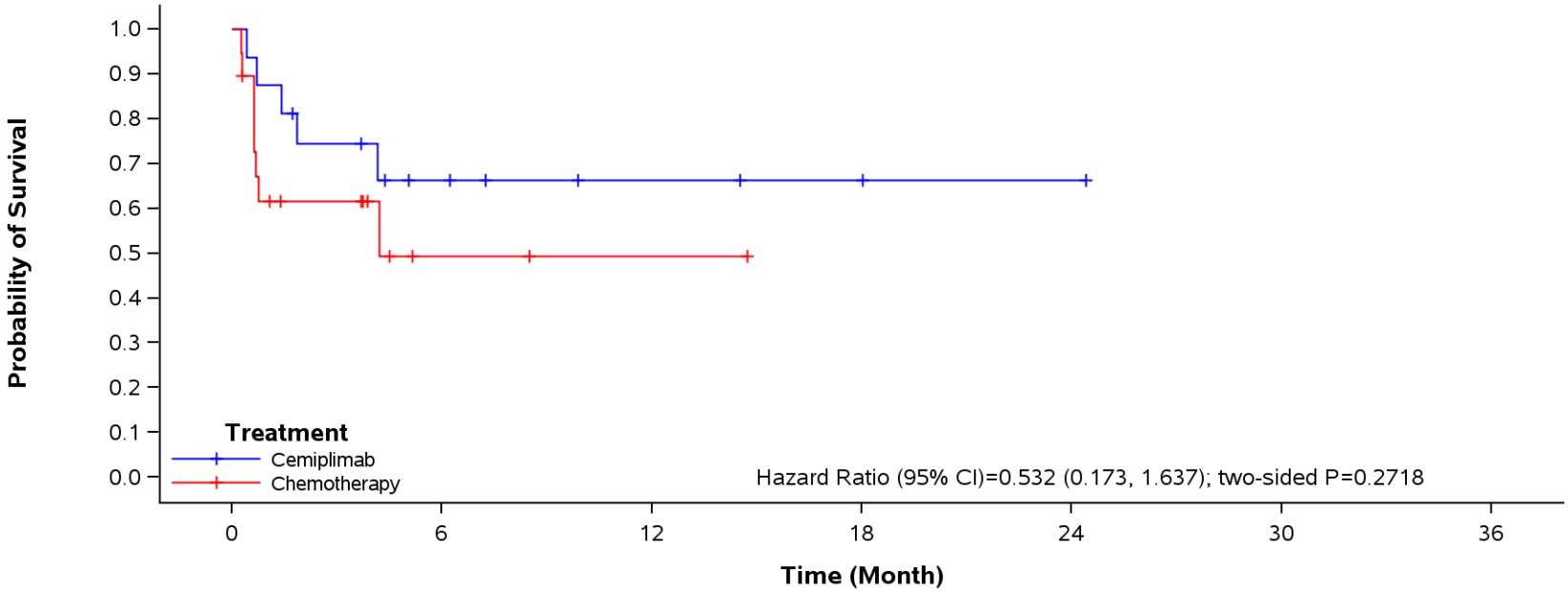

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Anaemia



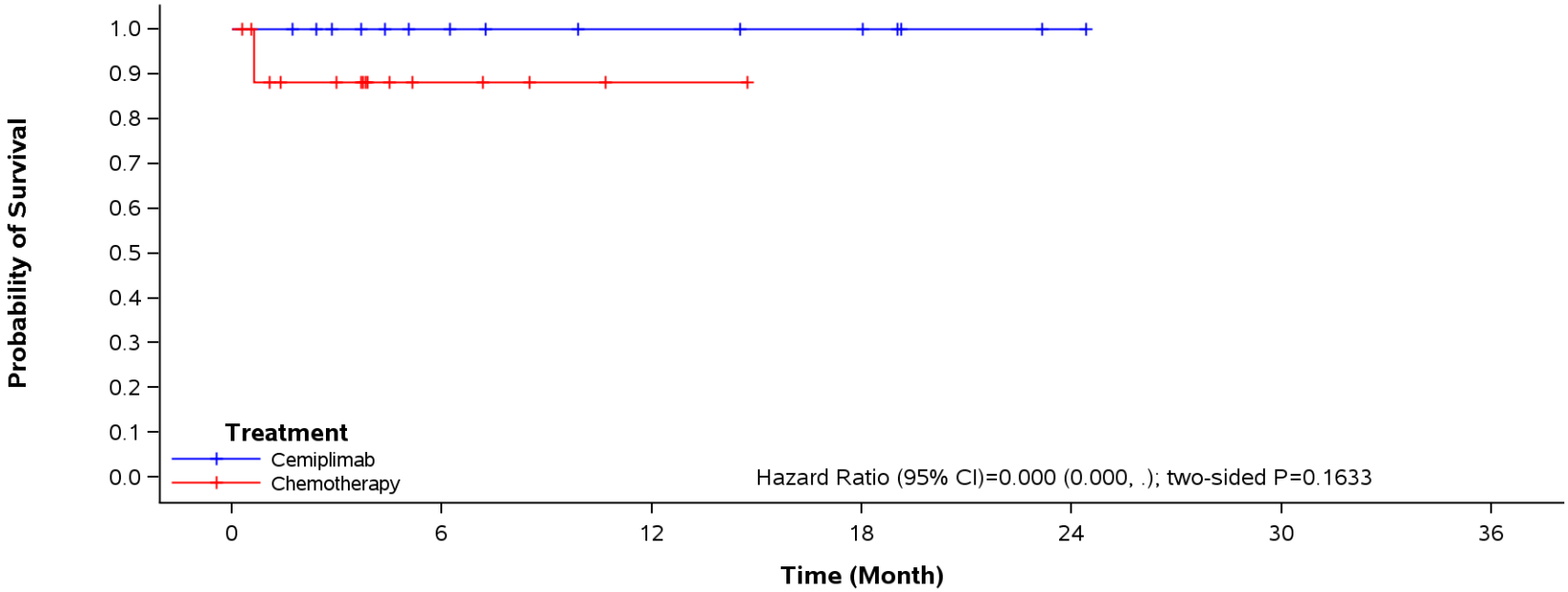

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 19 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



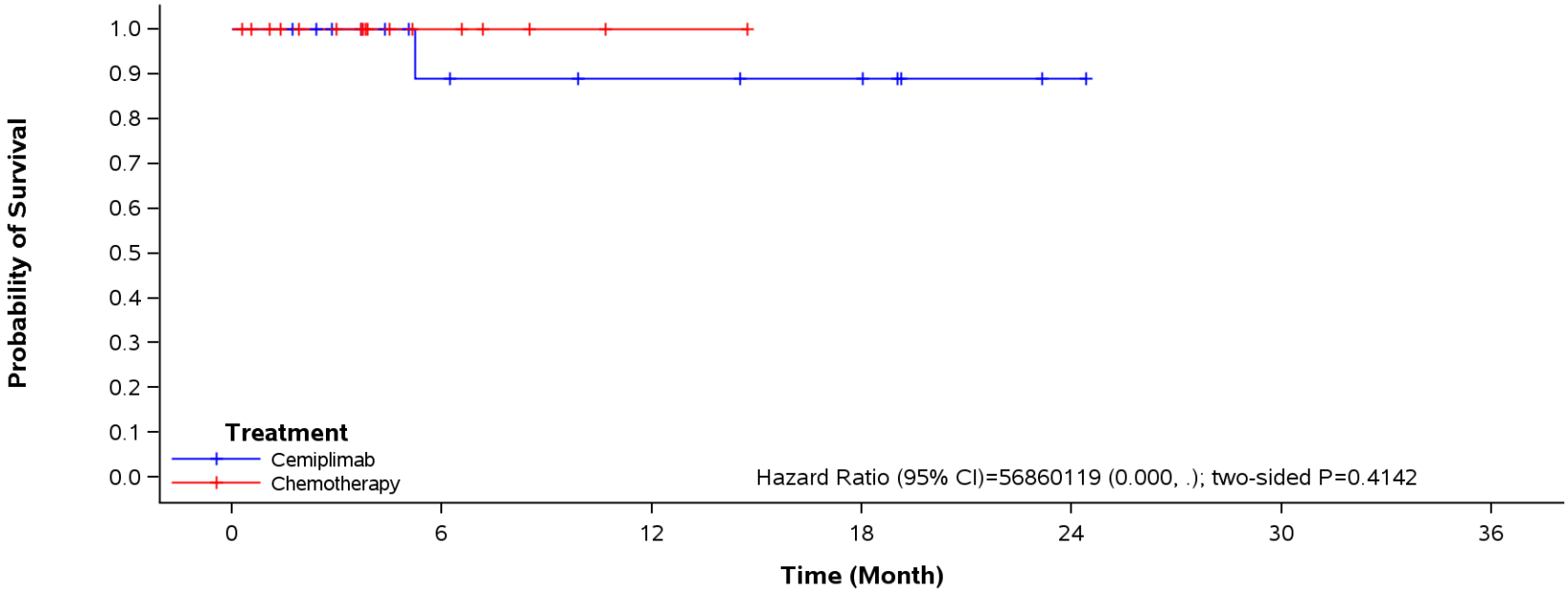

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Endocrine disorders



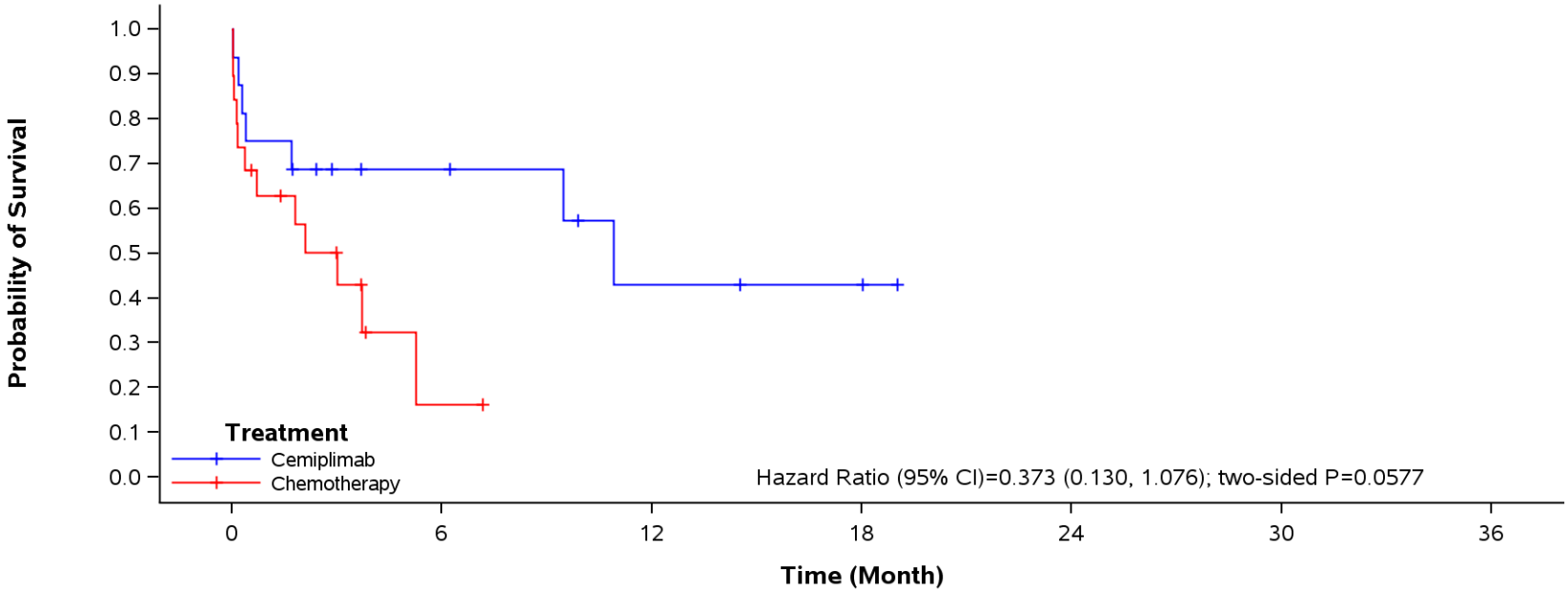

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders



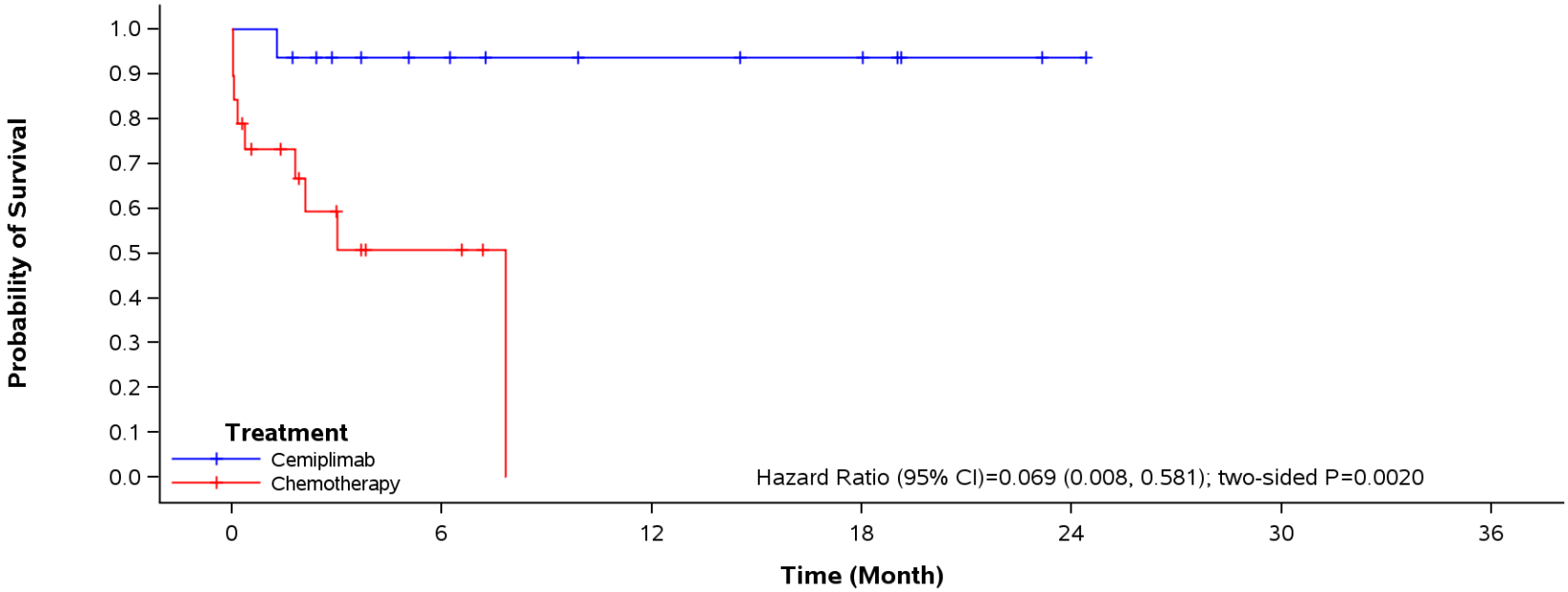

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders
PT: Nausea



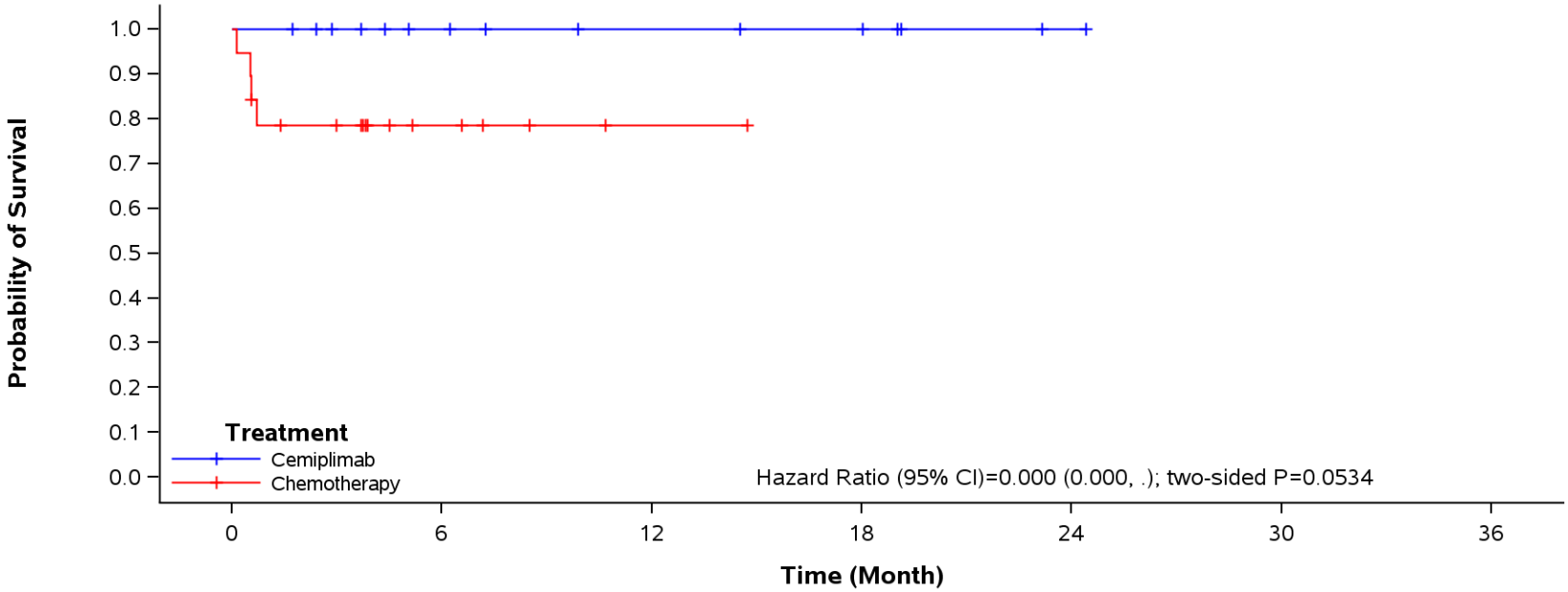

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders
PT: Stomatitis



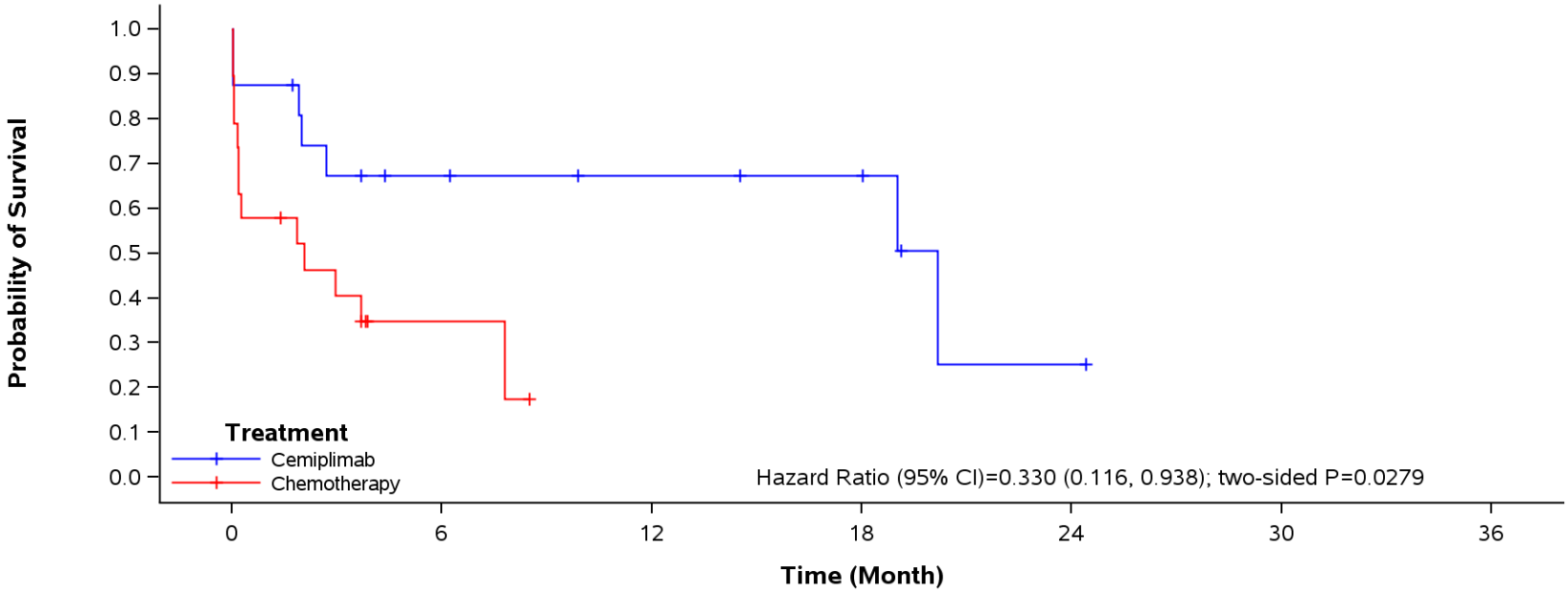

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: General disorders and administration site conditions



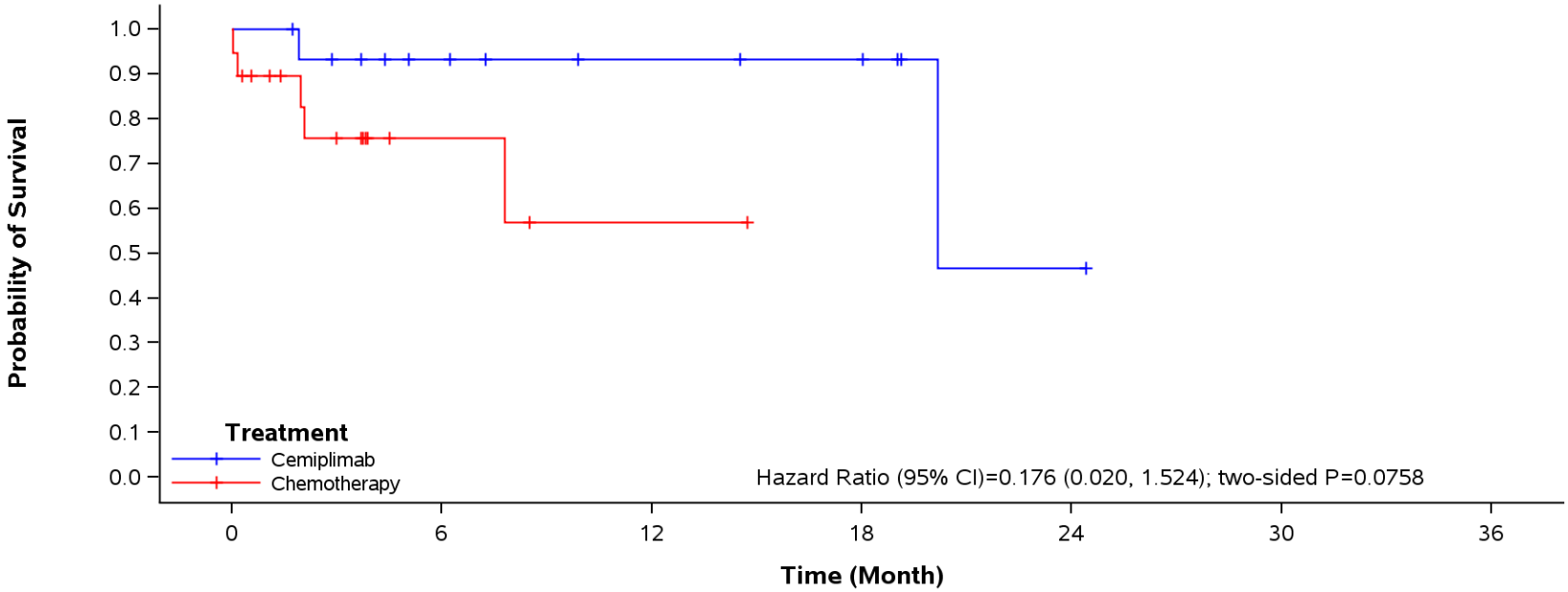

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: General disorders and administration site conditions
PT: Asthenia



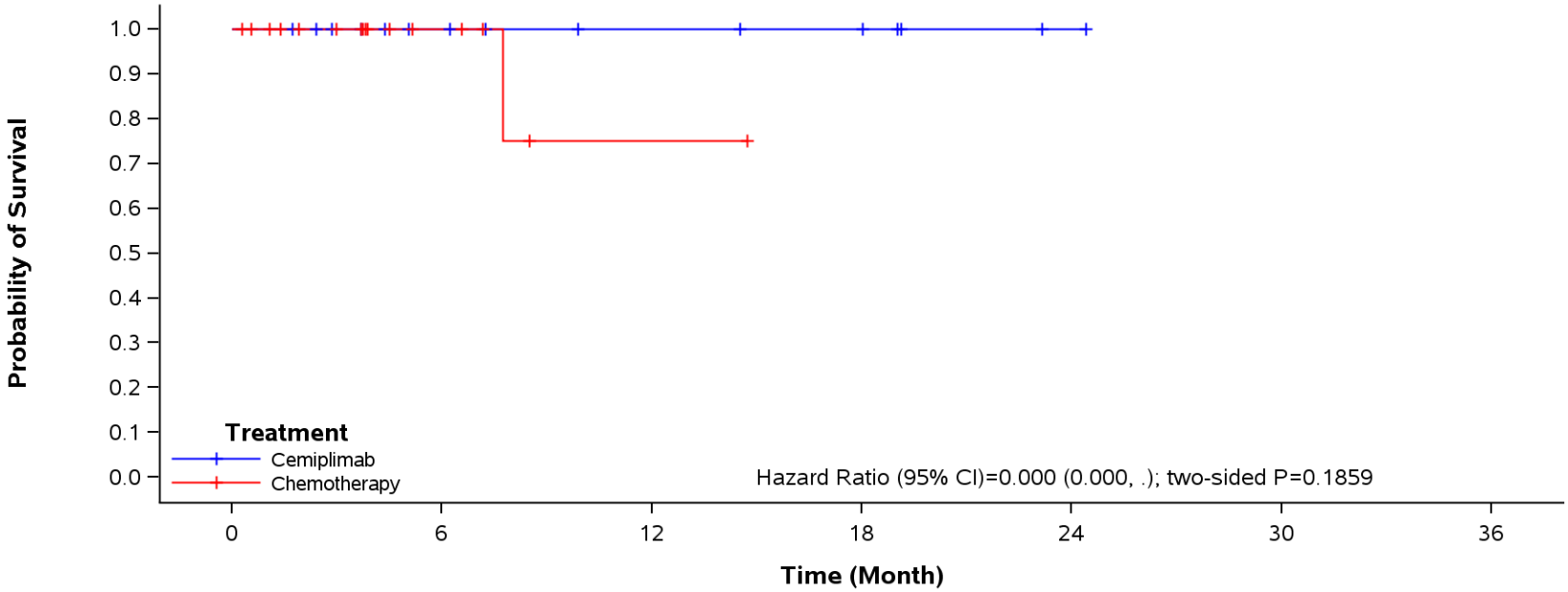

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



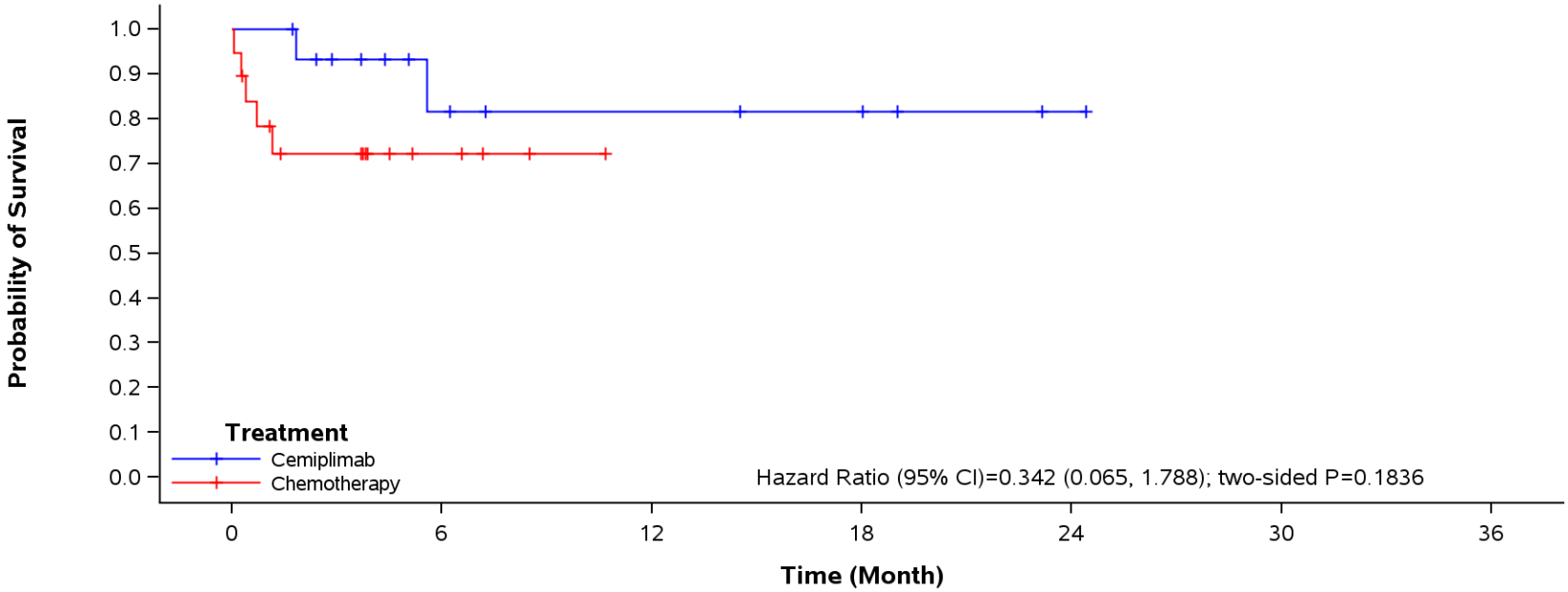

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Nervous system disorders



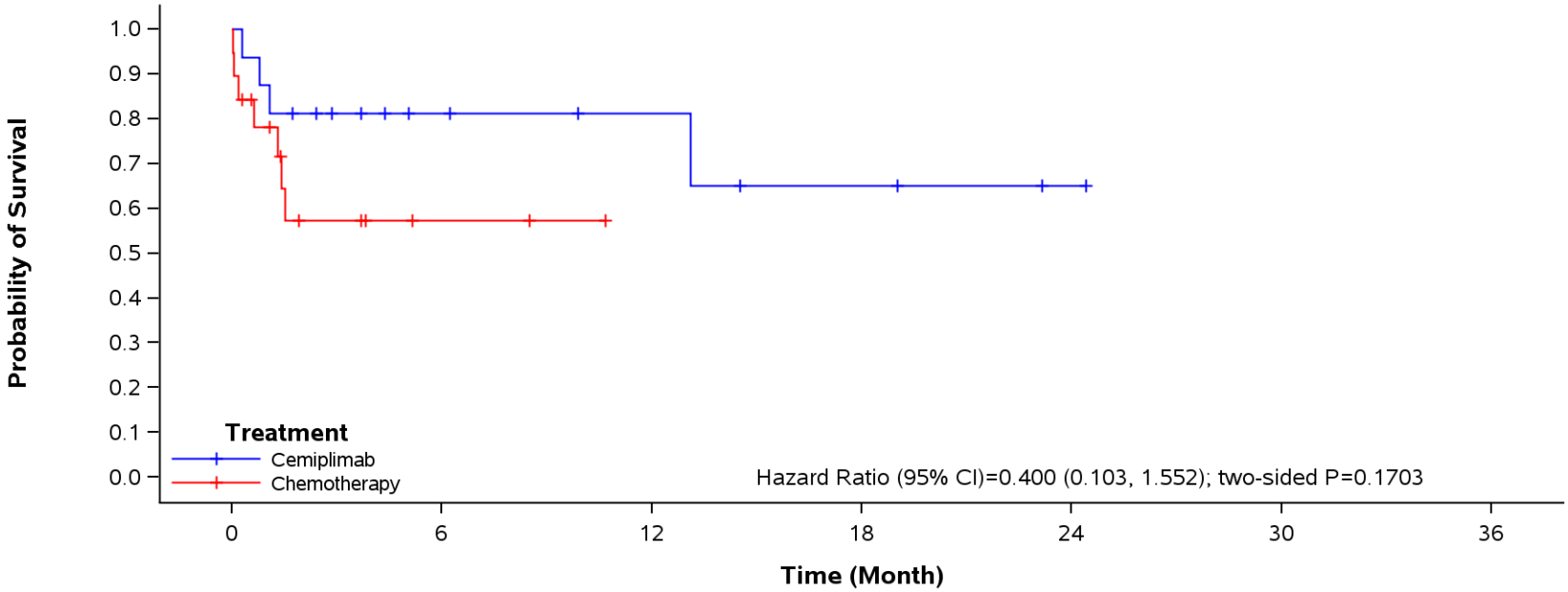

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Skin and subcutaneous tissue disorders



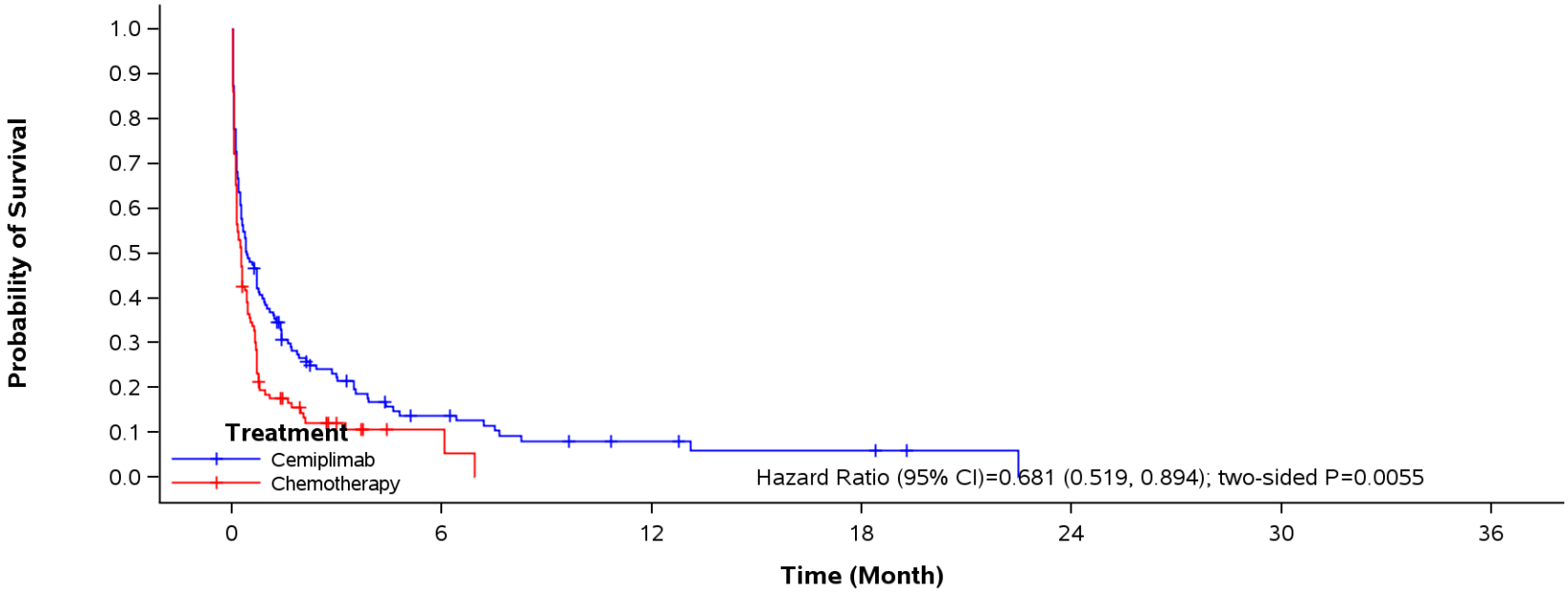

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Number of patients with any TEAE



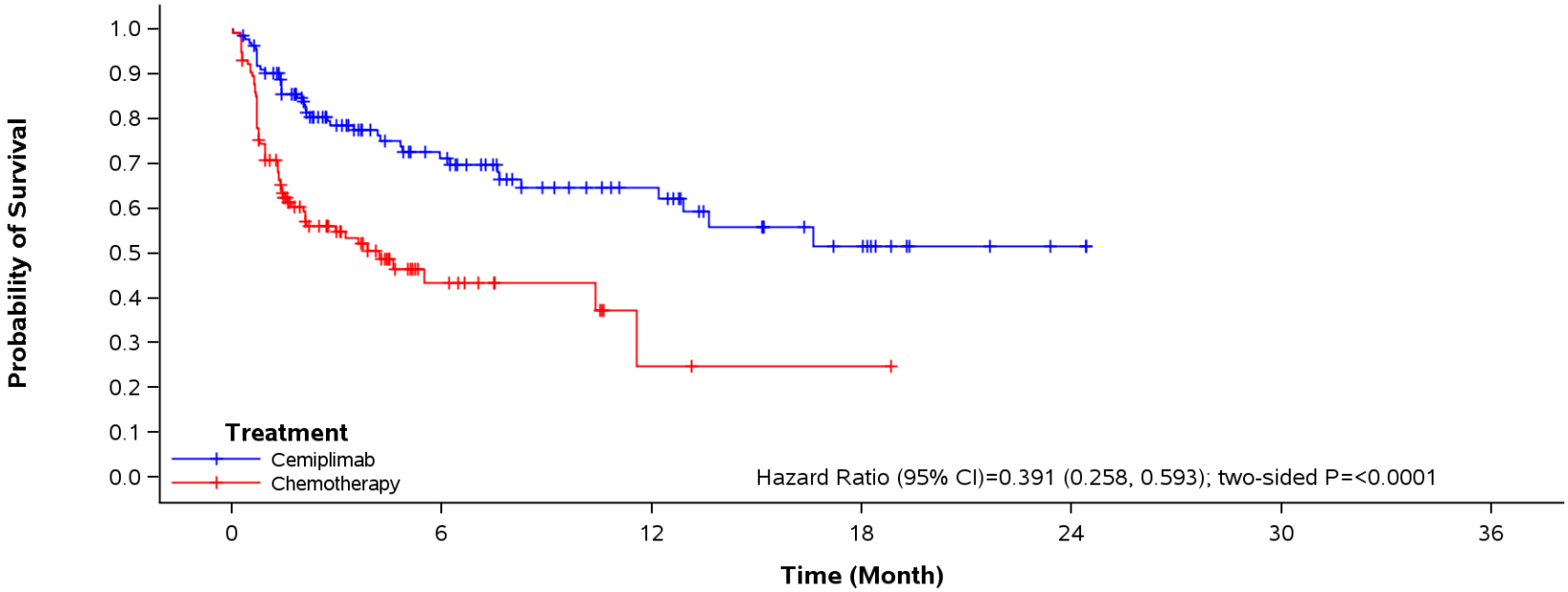

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 13 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 115 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders



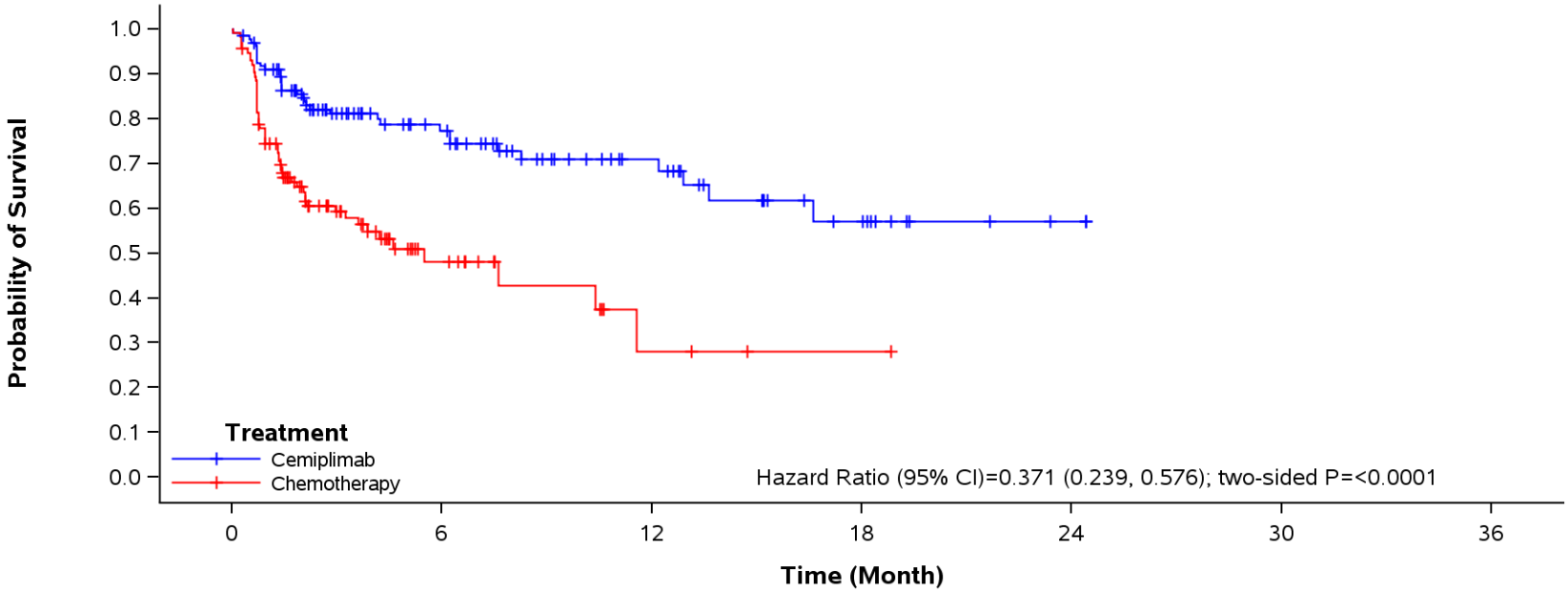

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 52 | 26 | 11 | 2 | 0 | 0 |
| Chemotherapy | 115 | 14 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Anaemia



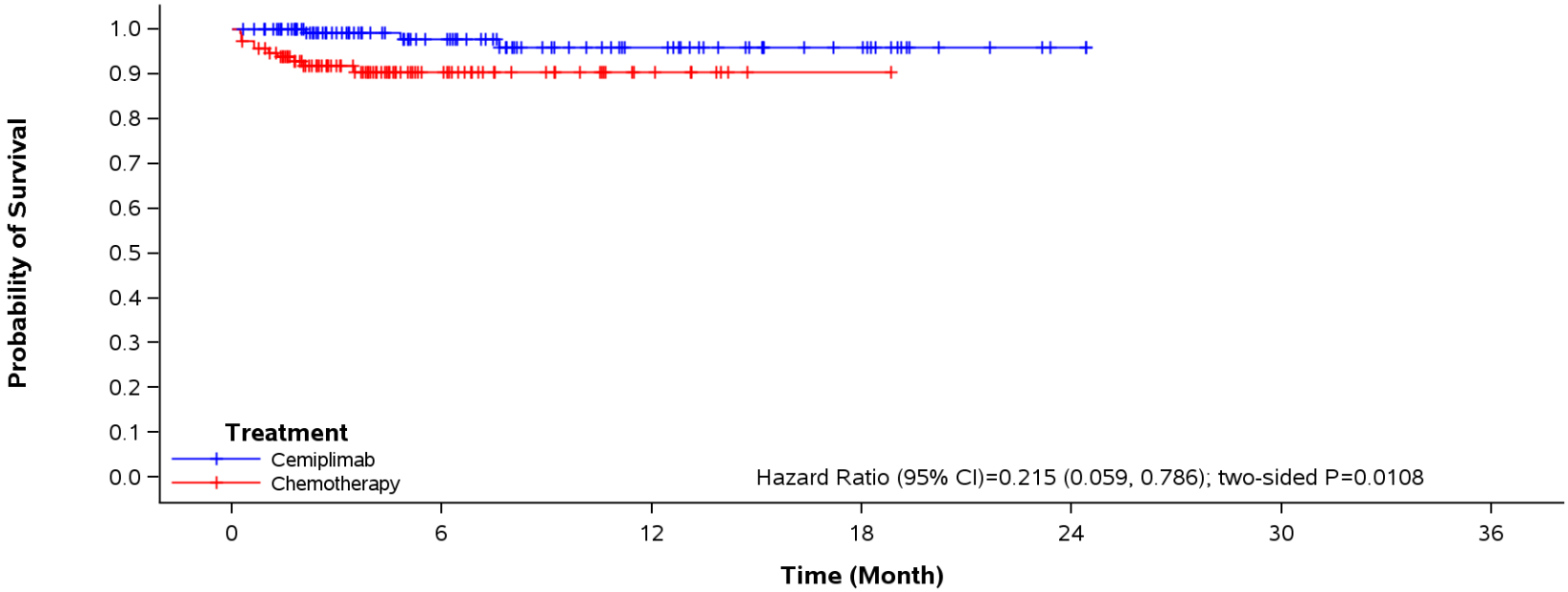

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 56 | 27 | 11 | 2 | 0 | 0 |
| Chemotherapy | 115 | 17 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



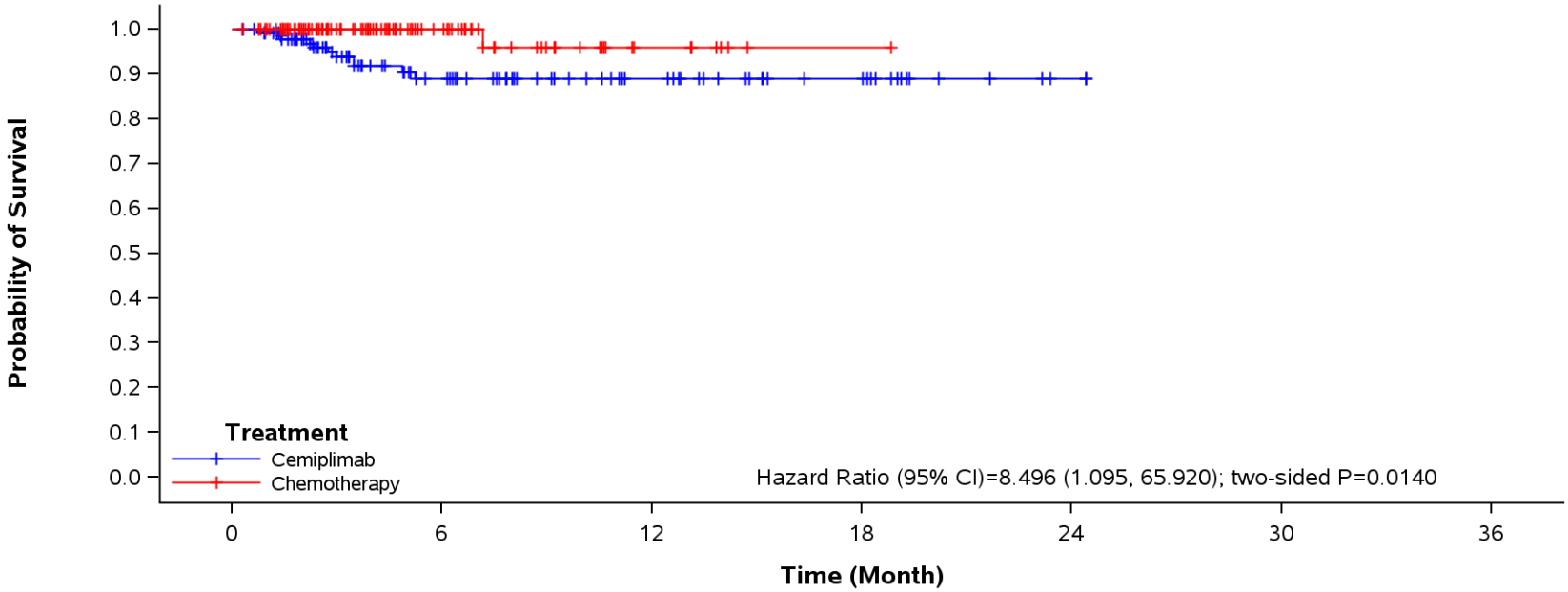

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 65 | 31 | 16 | 2 | 0 | 0 |
| Chemotherapy | 115 | 33 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Endocrine disorders



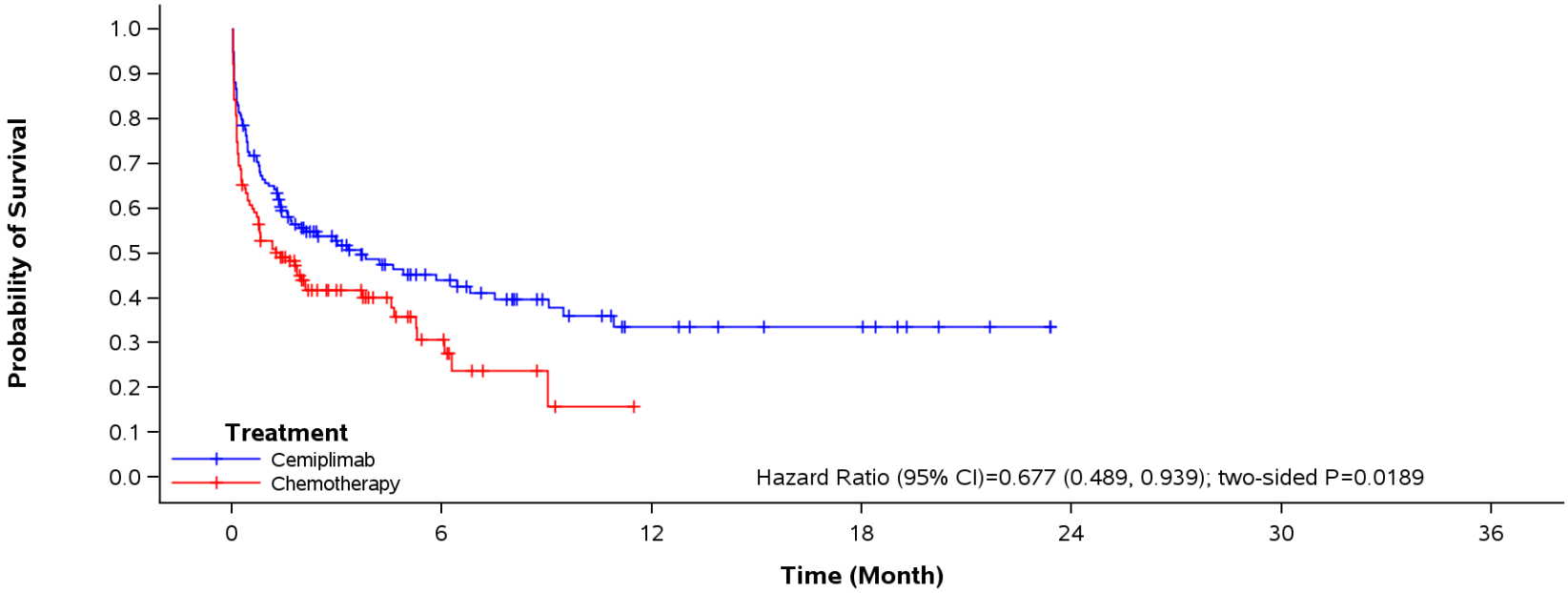

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 59 | 29 | 16 | 2 | 0 | 0 |
| Chemotherapy | 115 | 37 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders



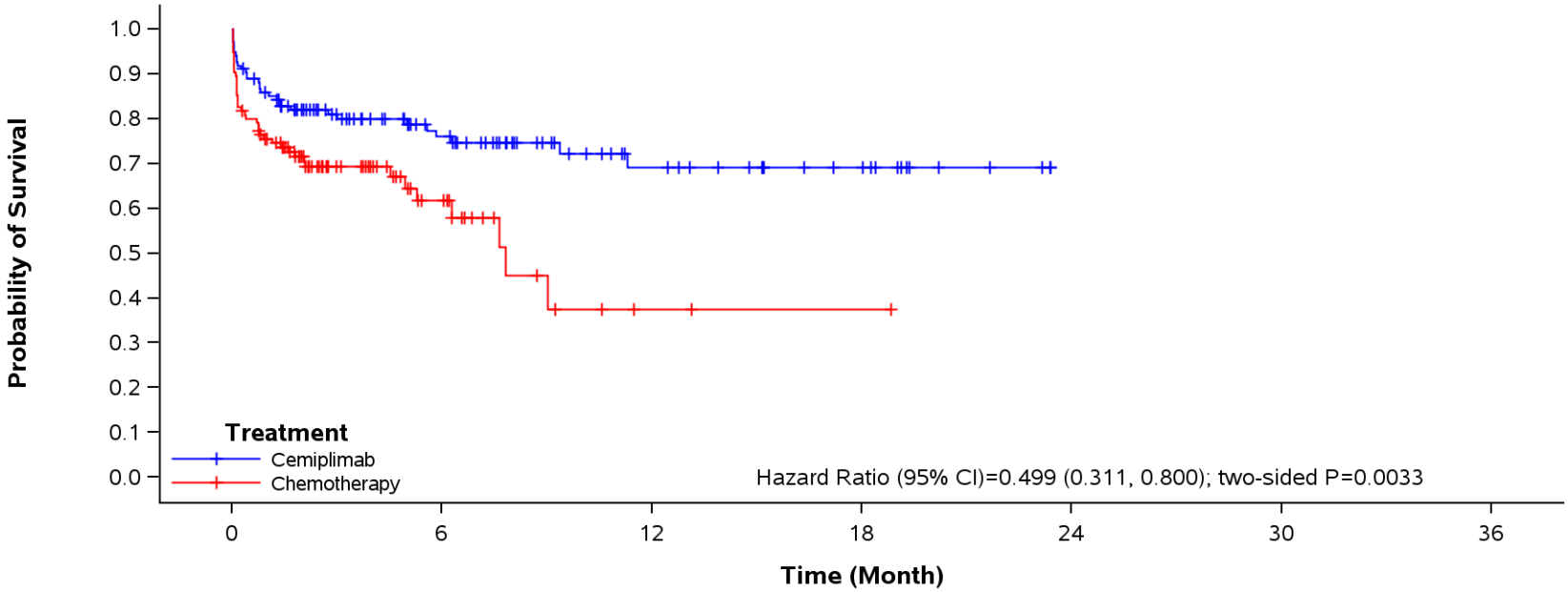

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 34 | 12 | 8 | 0 | 0 | 0 |
| Chemotherapy | 115 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders
PT: Nausea



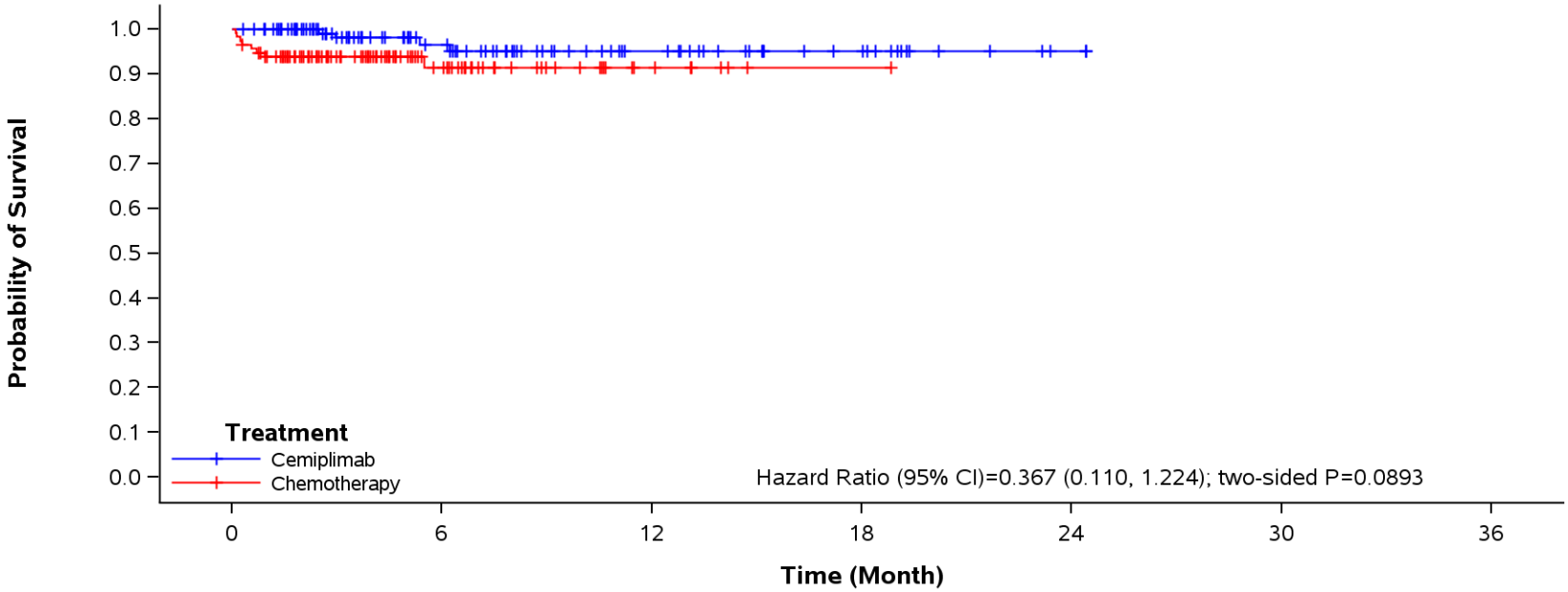

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 54 | 22 | 12 | 0 | 0 | 0 |
| Chemotherapy | 115 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders
PT: Stomatitis



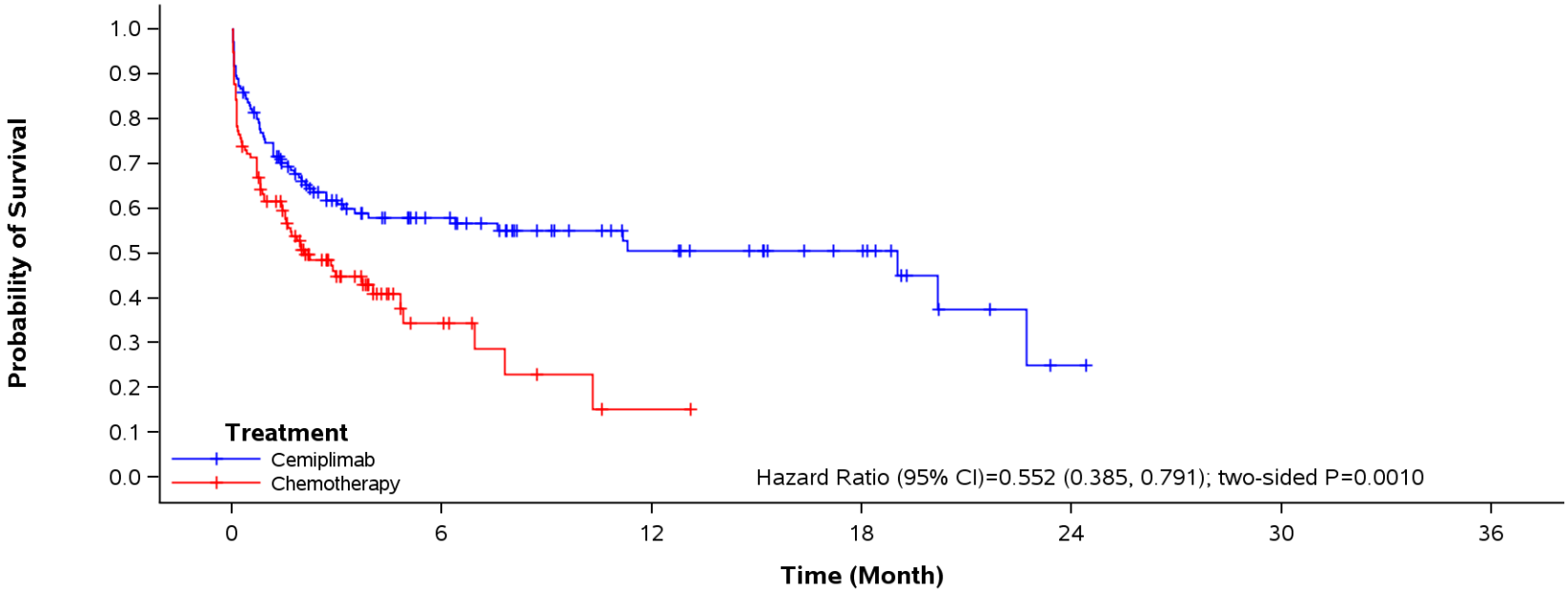

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 63 | 29 | 15 | 2 | 0 | 0 |
| Chemotherapy | 115 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: General disorders and administration site conditions



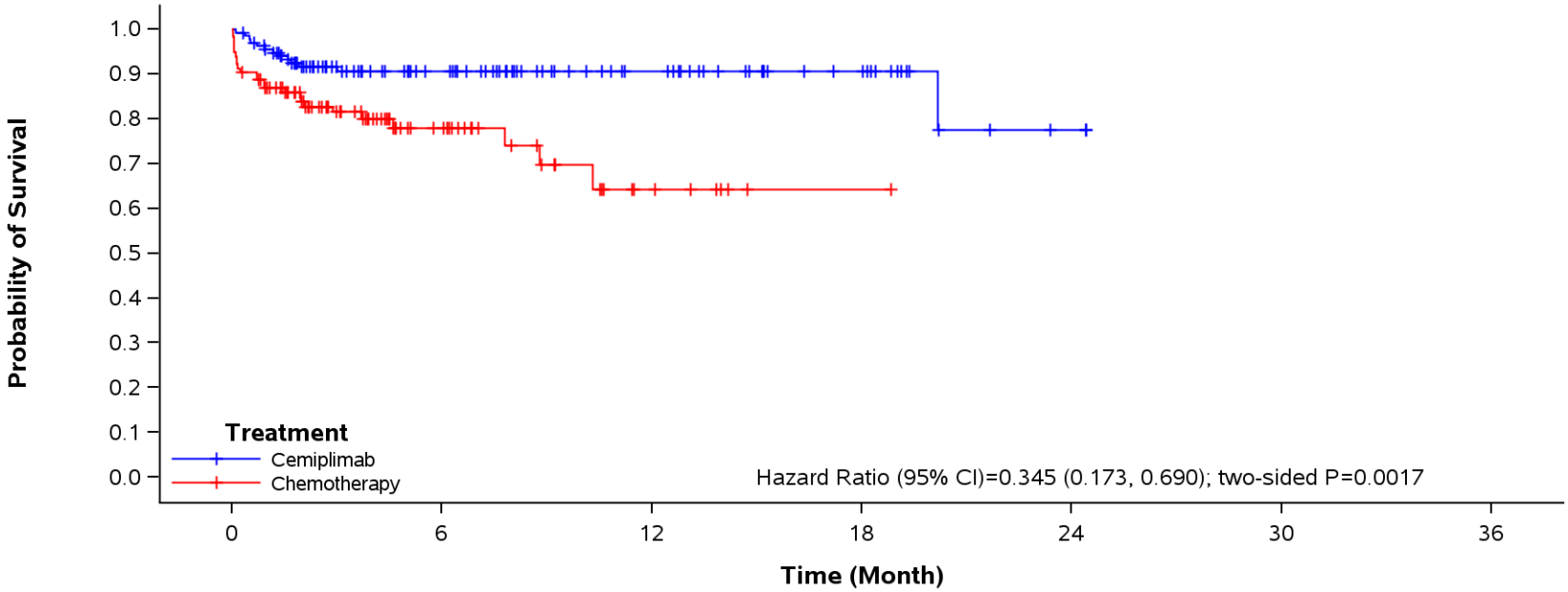

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 45 | 22 | 13 | 1 | 0 | 0 |
| Chemotherapy | 115 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: General disorders and administration site conditions
PT: Asthenia



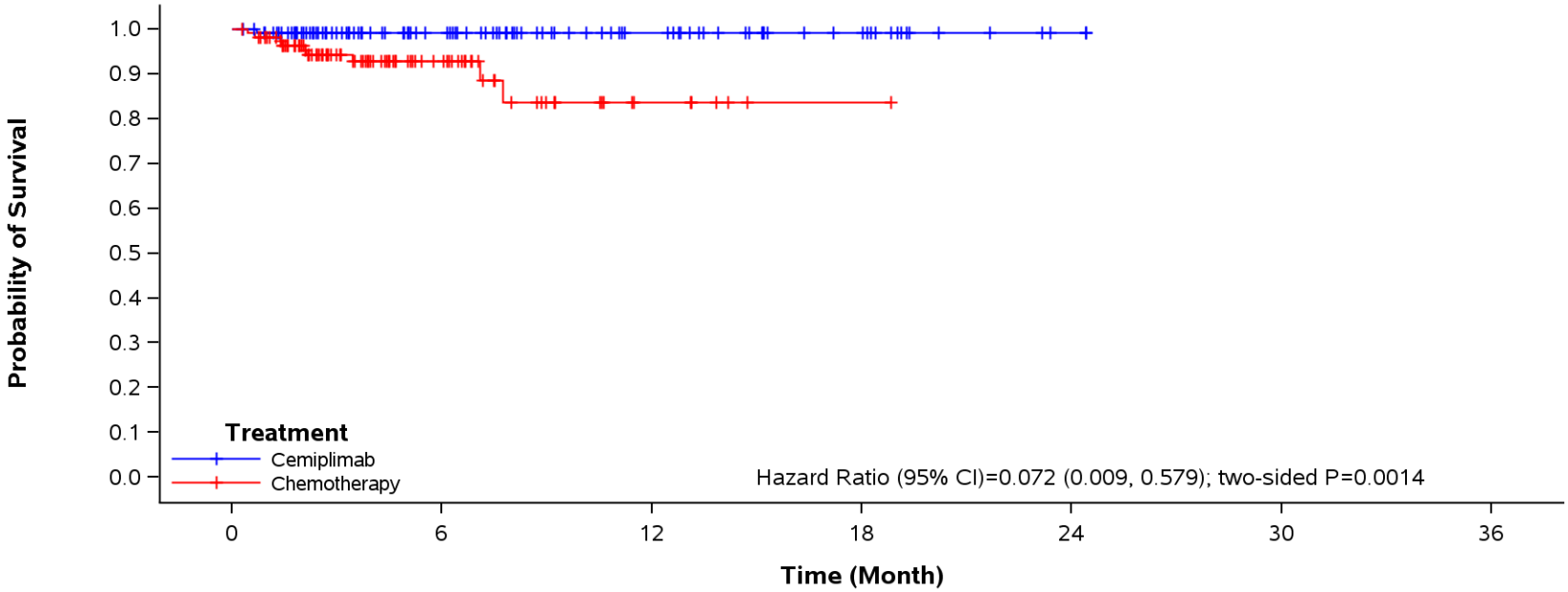

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 64 | 32 | 16 | 2 | 0 | 0 |
| Chemotherapy | 115 | 30 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



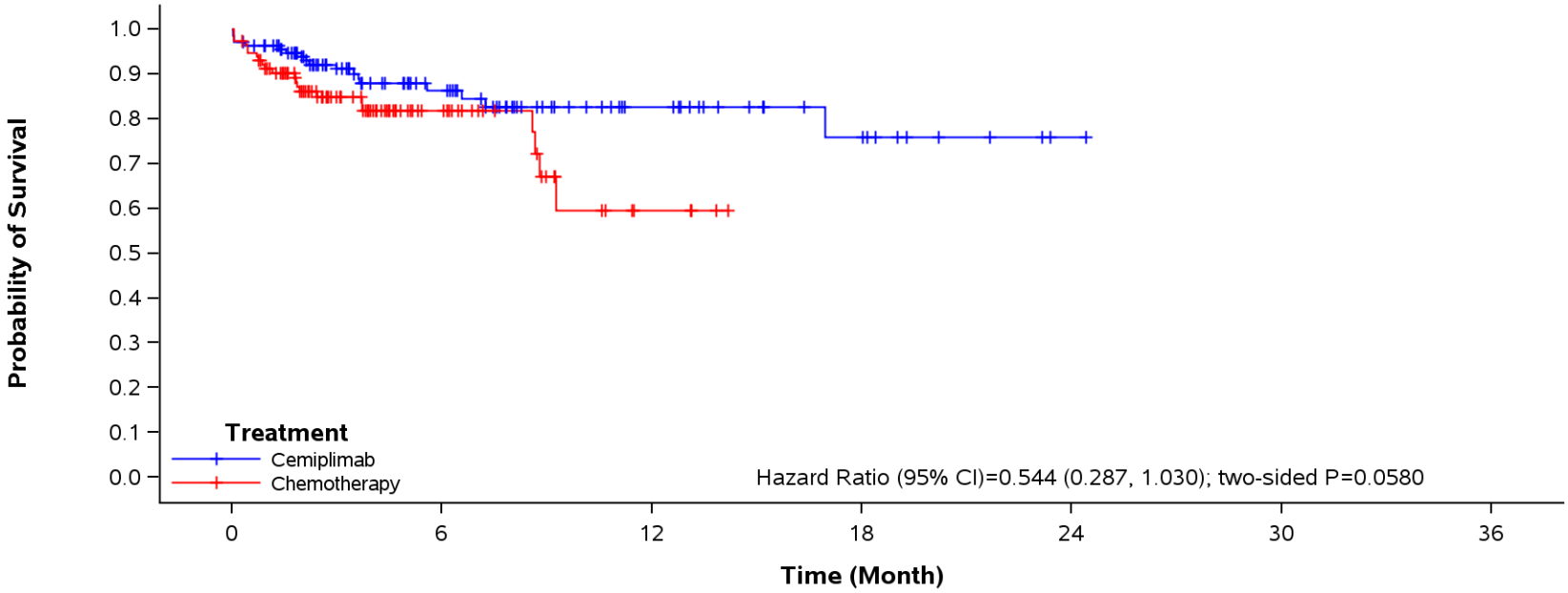

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 32 | 16 | 2 | 0 | 0 |
| Chemotherapy | 115 | 35 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Nervous system disorders



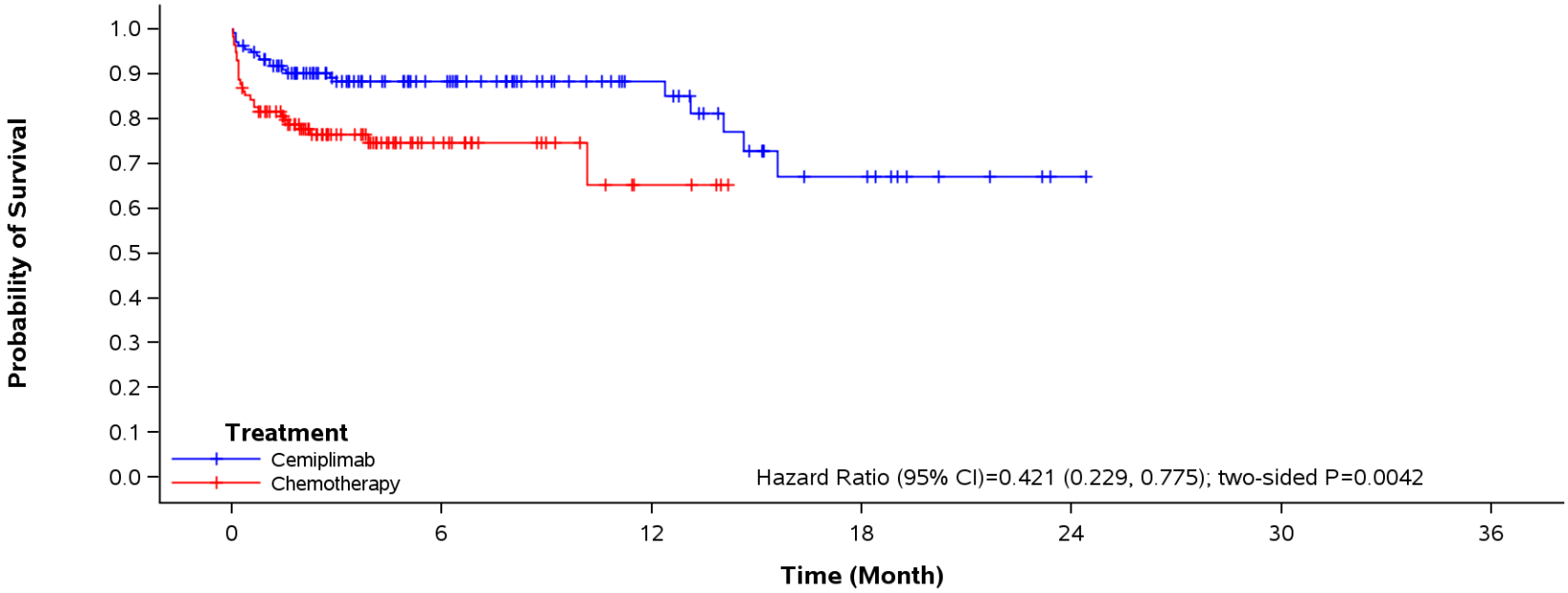

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 55 | 23 | 11 | 1 | 0 | 0 |
| Chemotherapy | 115 | 29 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Skin and subcutaneous tissue disorders



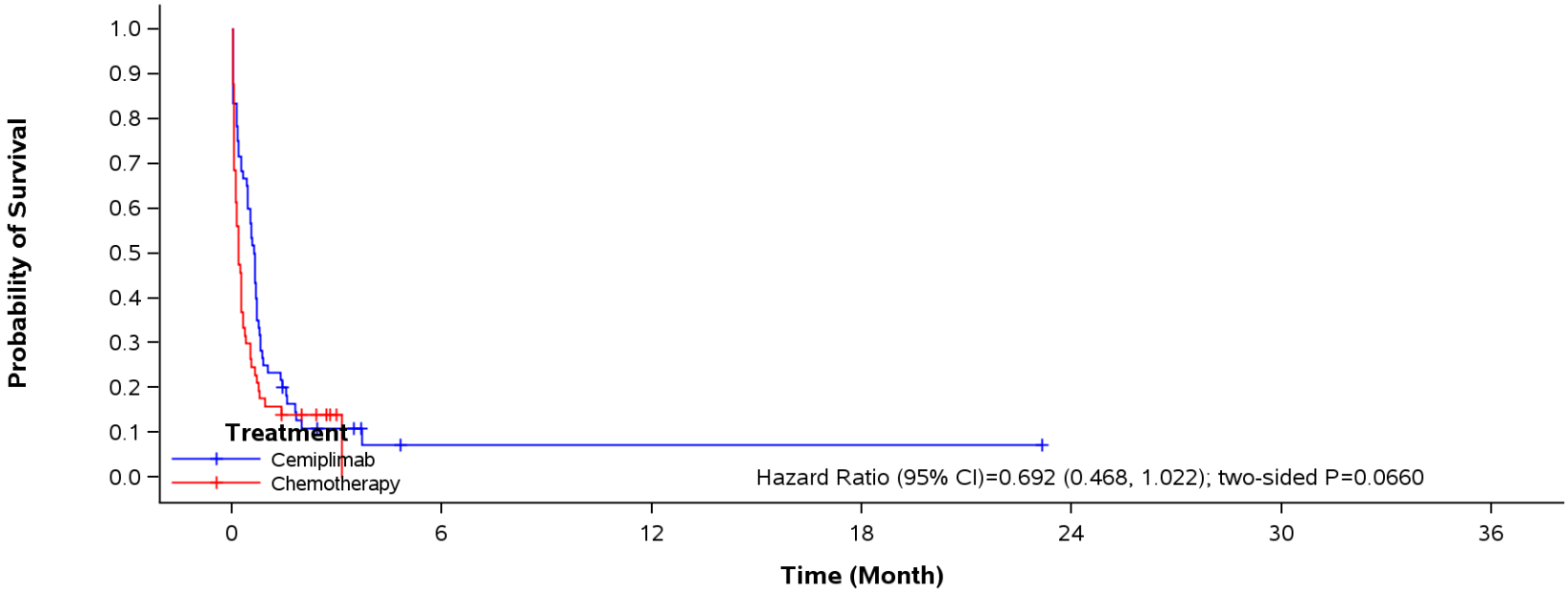

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 57 | 27 | 11 | 1 | 0 | 0 |
| Chemotherapy | 115 | 22 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Number of patients with any TEAE



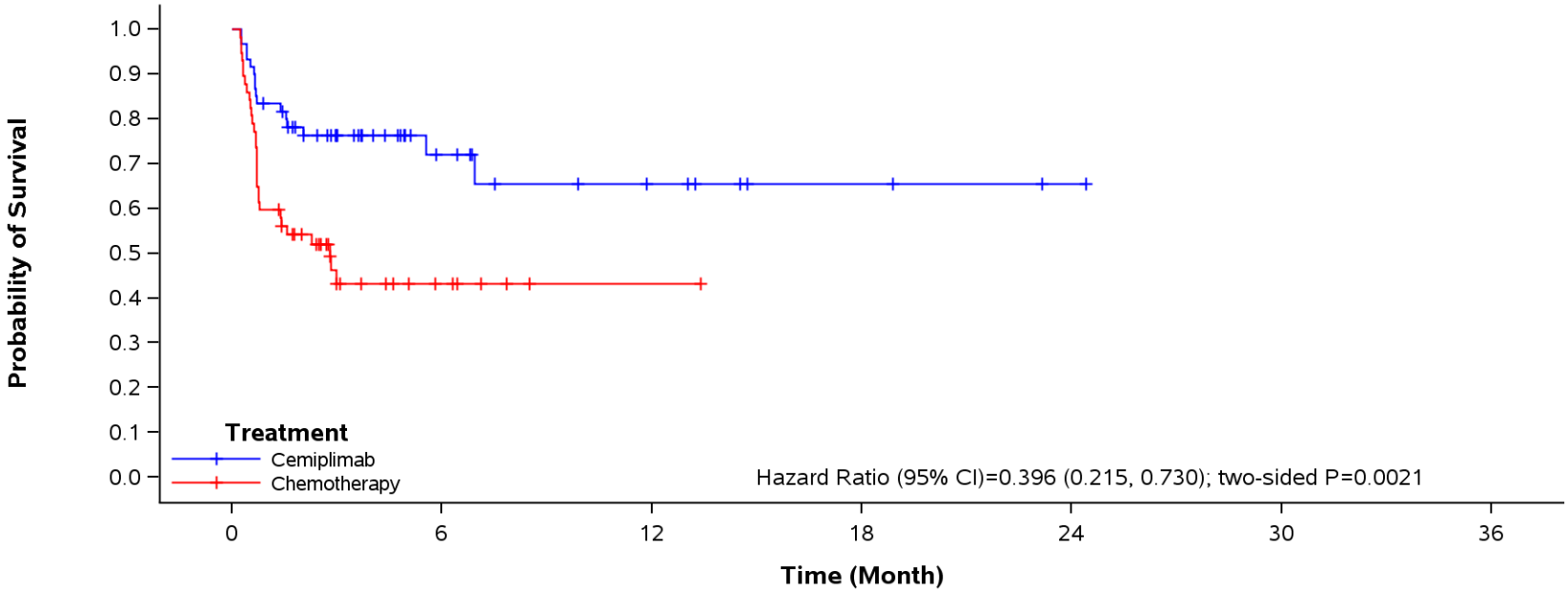

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 1 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 57 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders



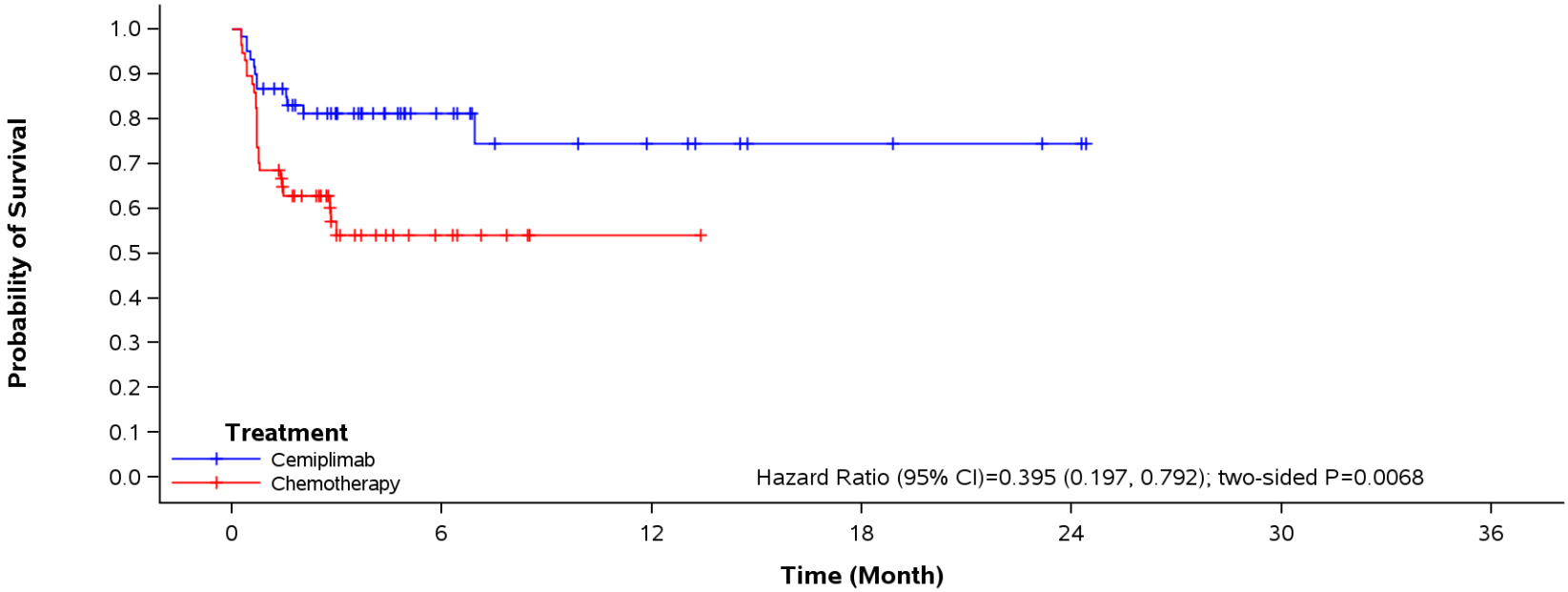

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 7 | 3 | 1 | 0 | 0 |
| Chemotherapy | 57 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Anaemia



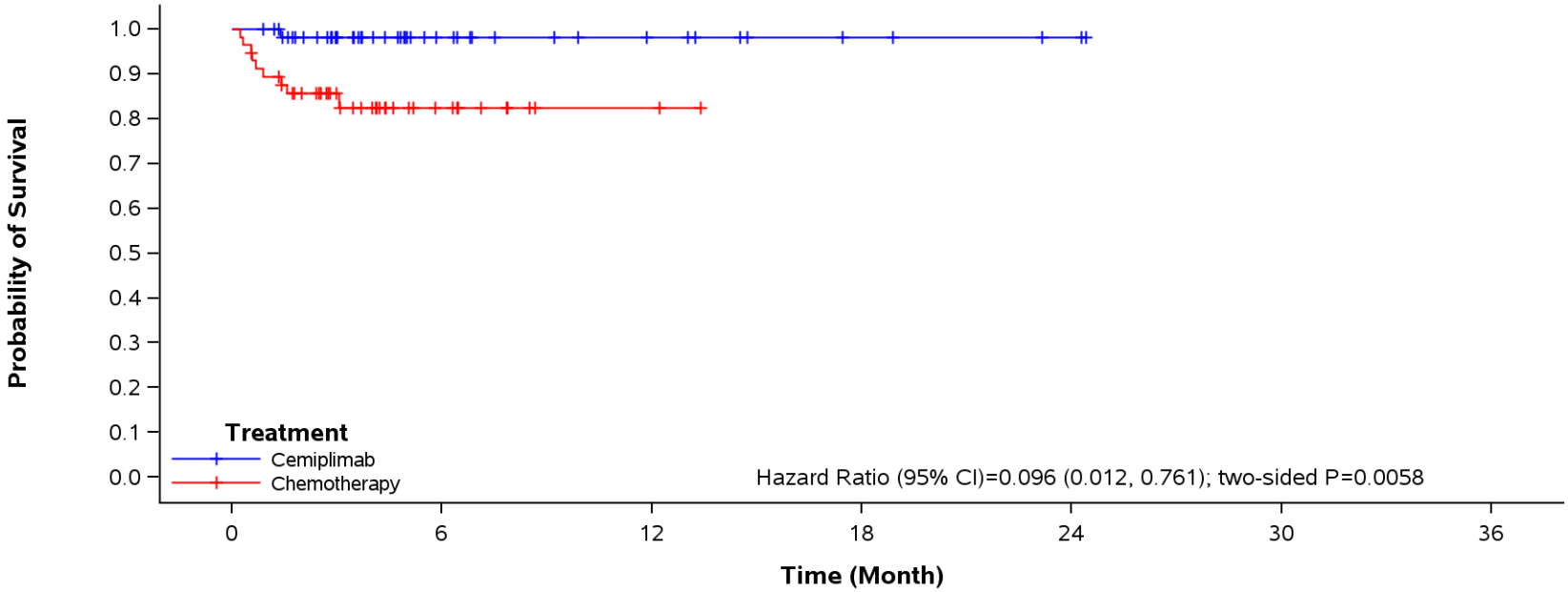

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 8 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



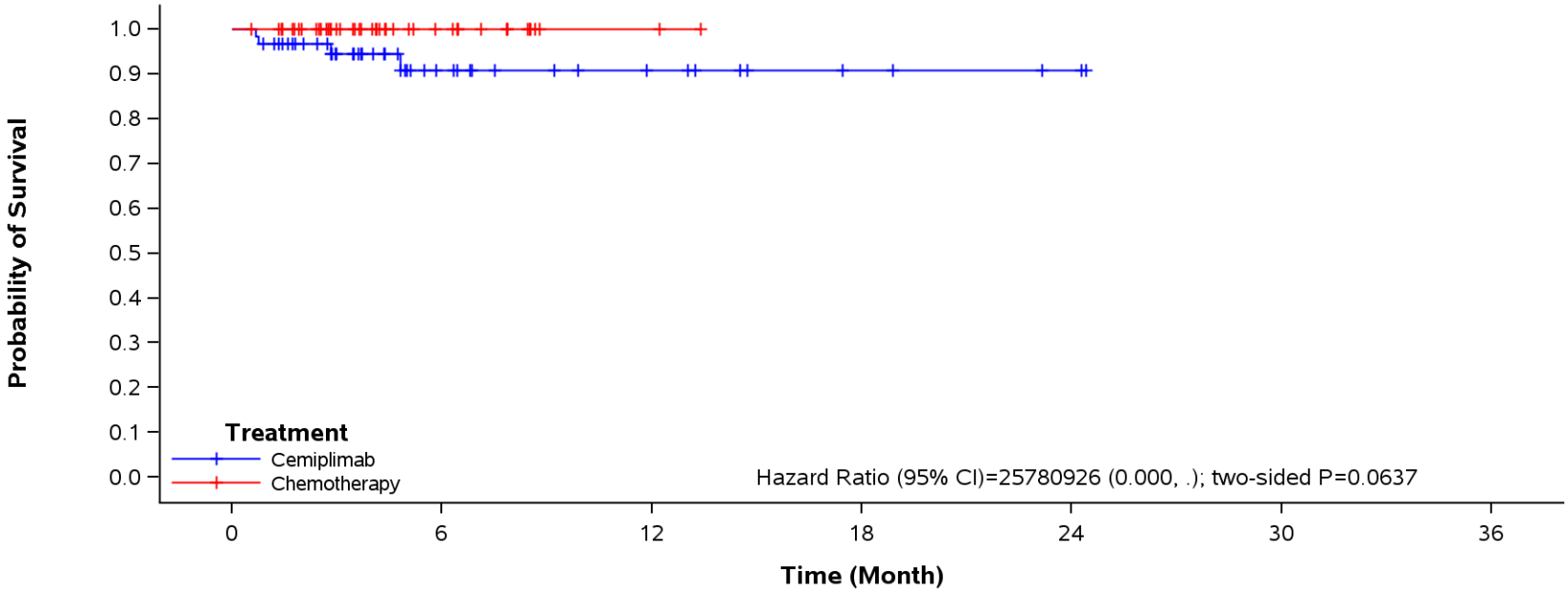

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Endocrine disorders



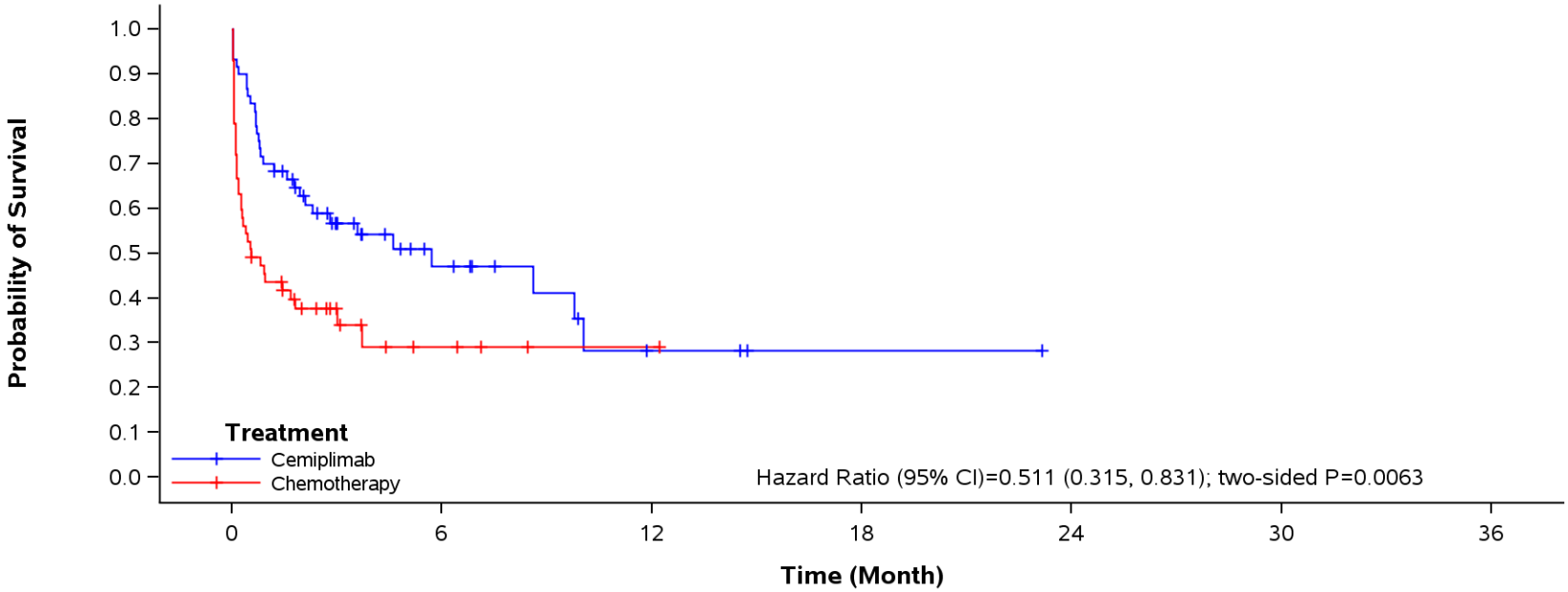

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders



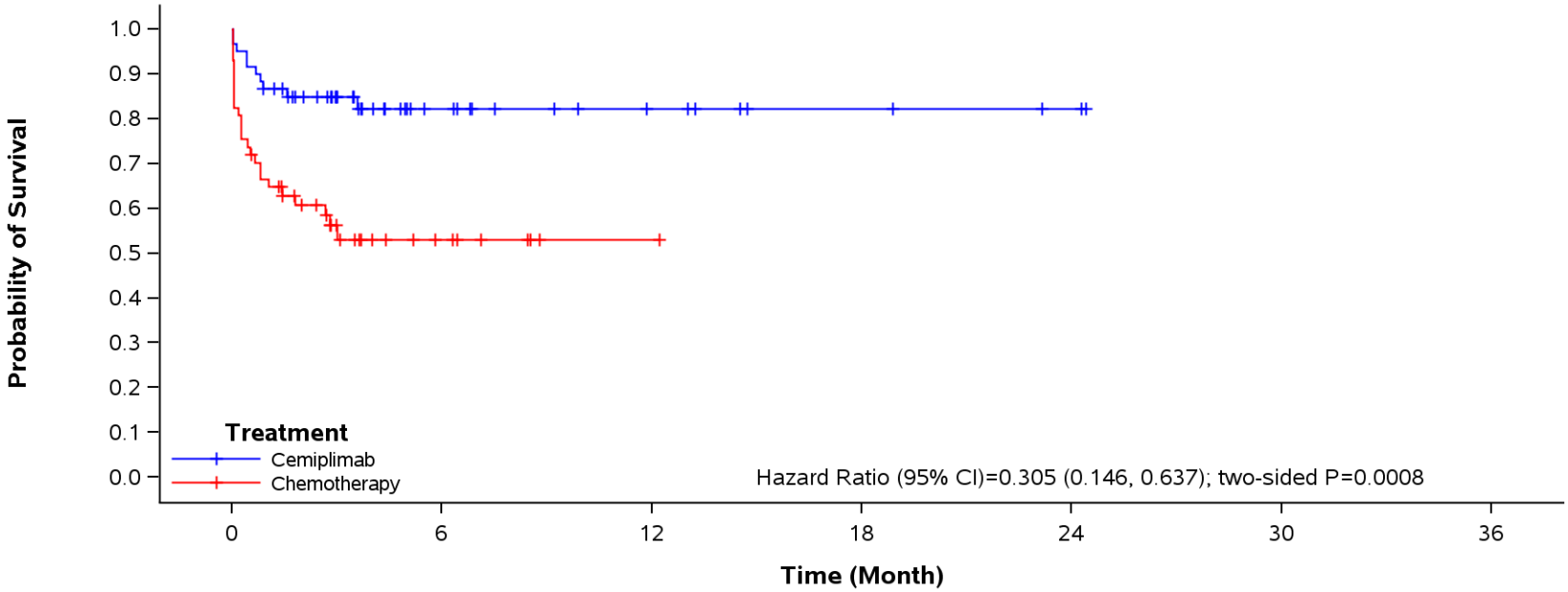

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 12 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 57 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders
PT: Nausea



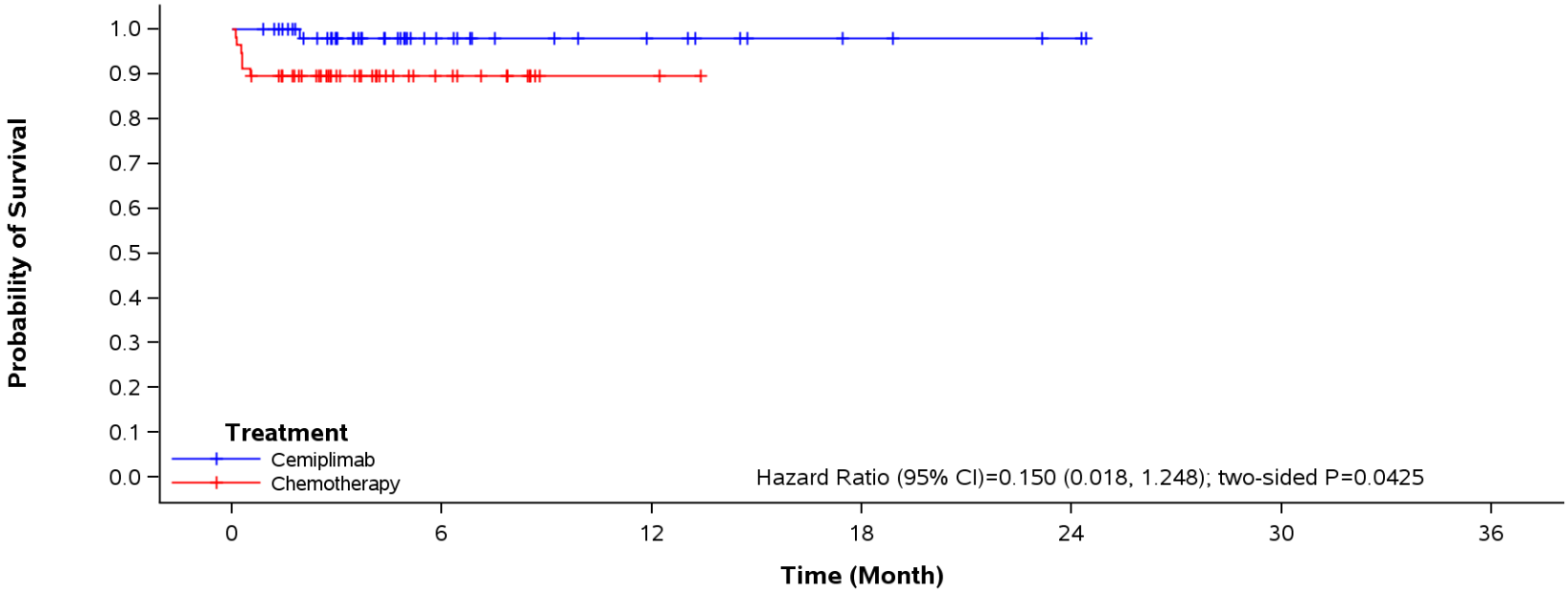

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 17 | 8 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders
PT: Stomatitis



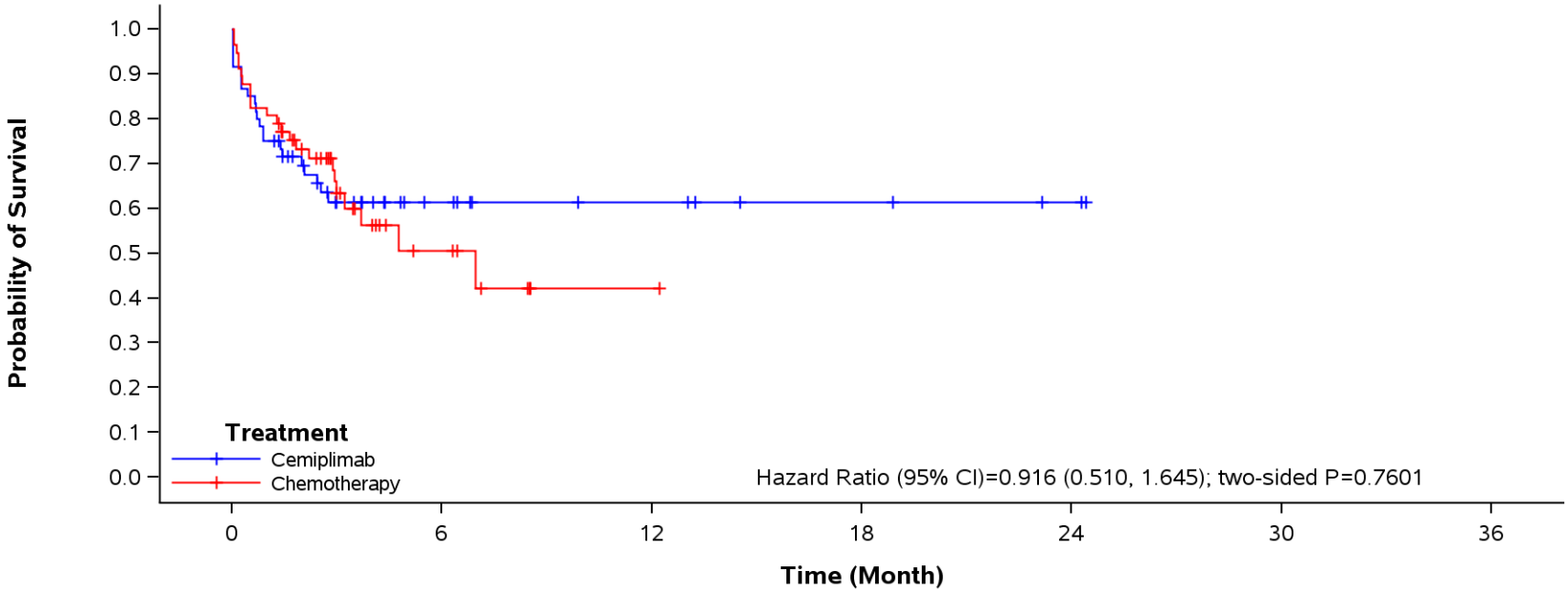

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: General disorders and administration site conditions



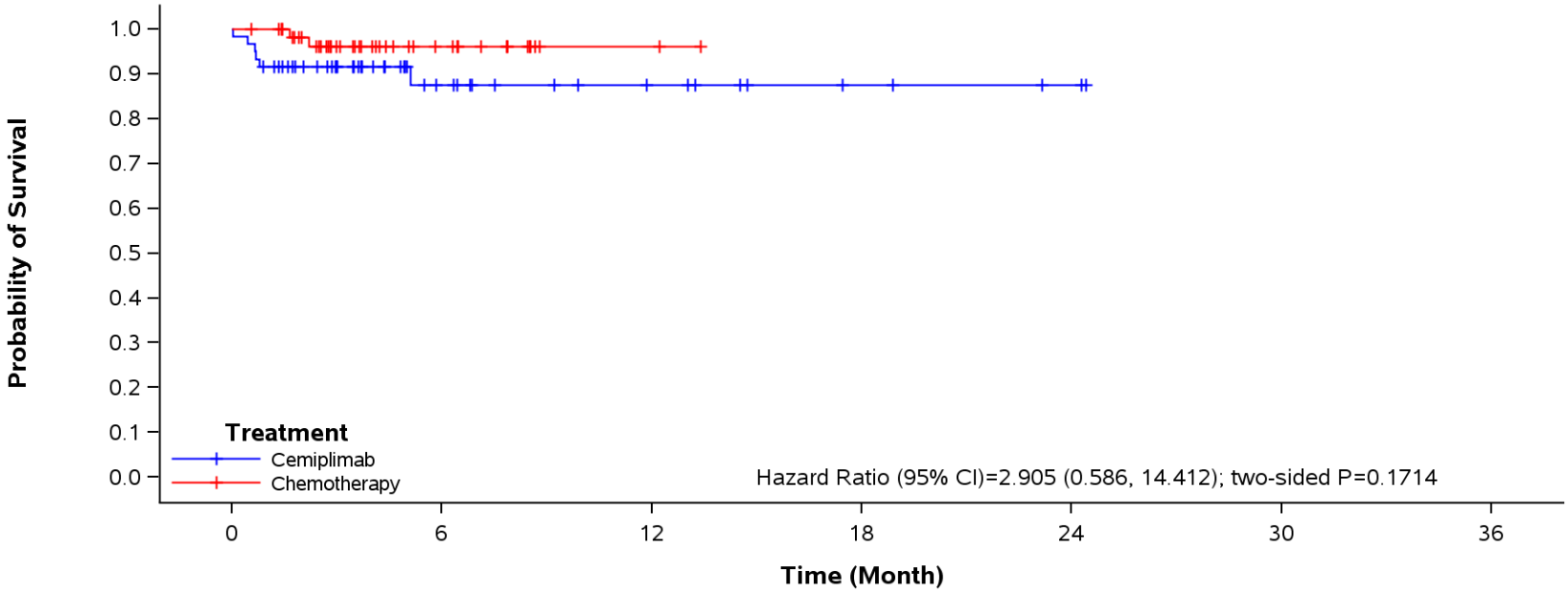

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 14 | 7 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: General disorders and administration site conditions
PT: Asthenia



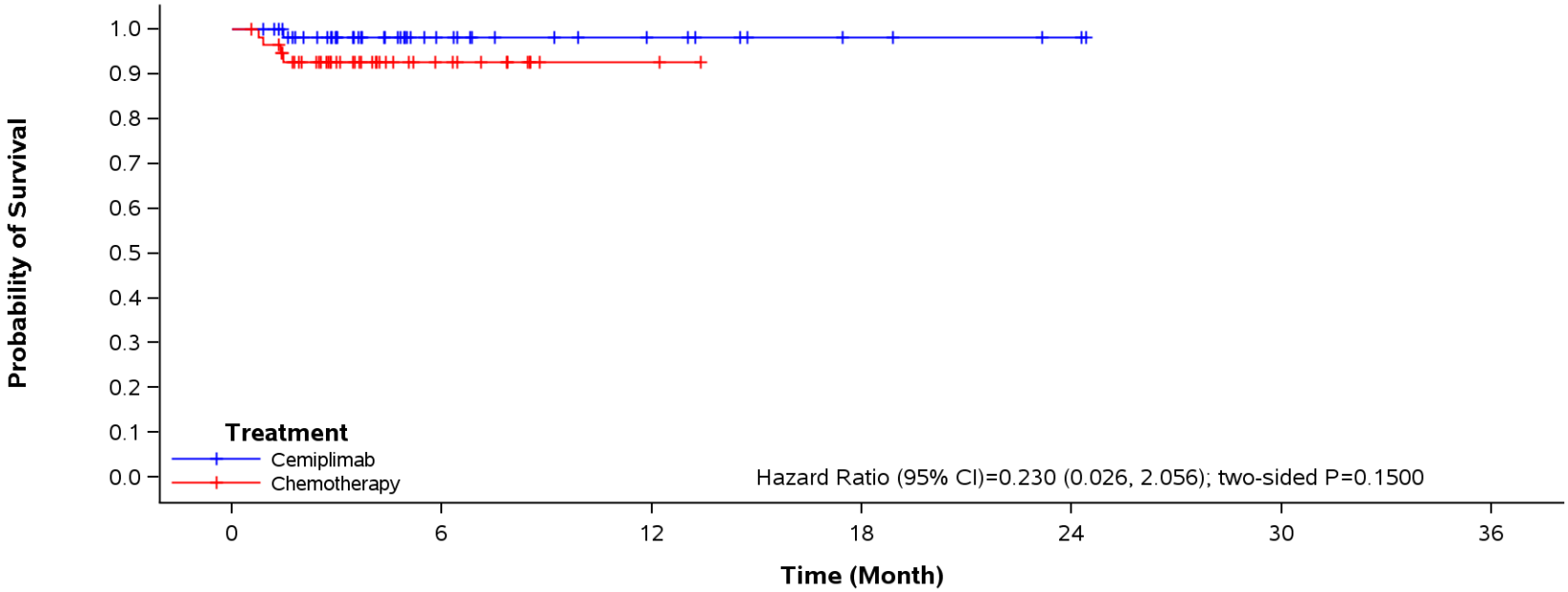

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



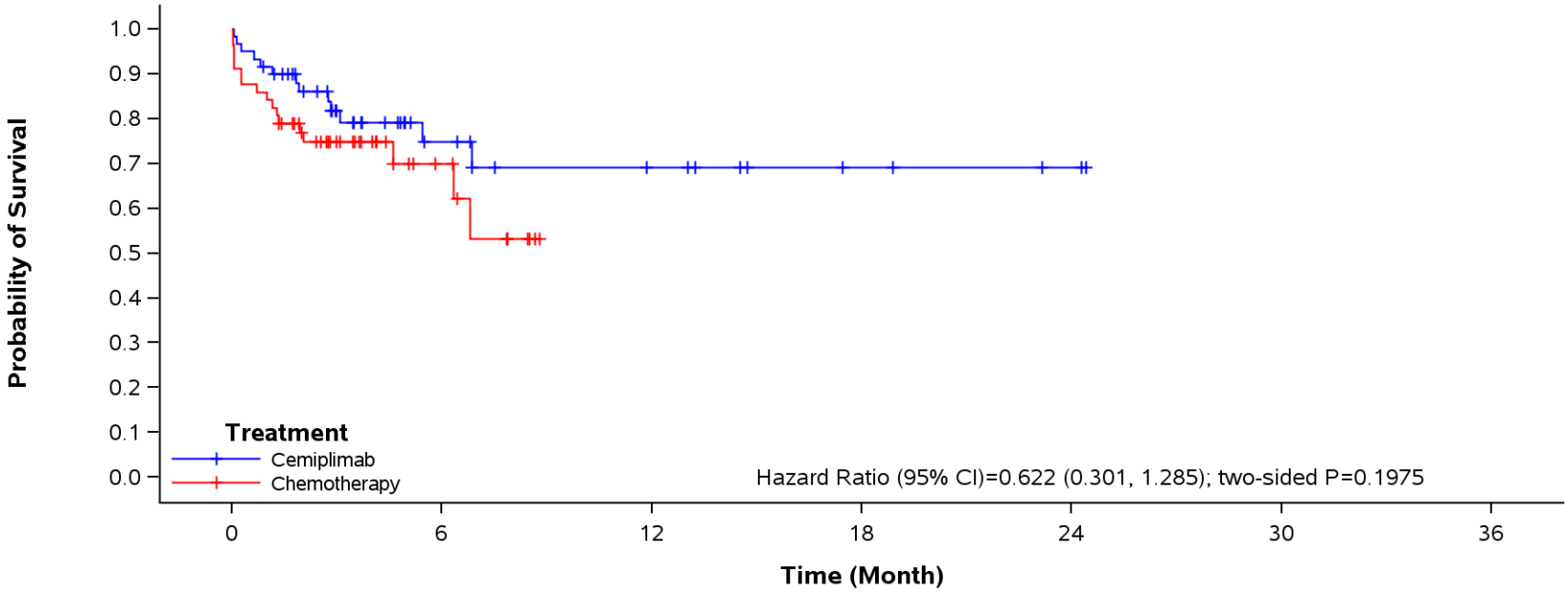

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Nervous system disorders



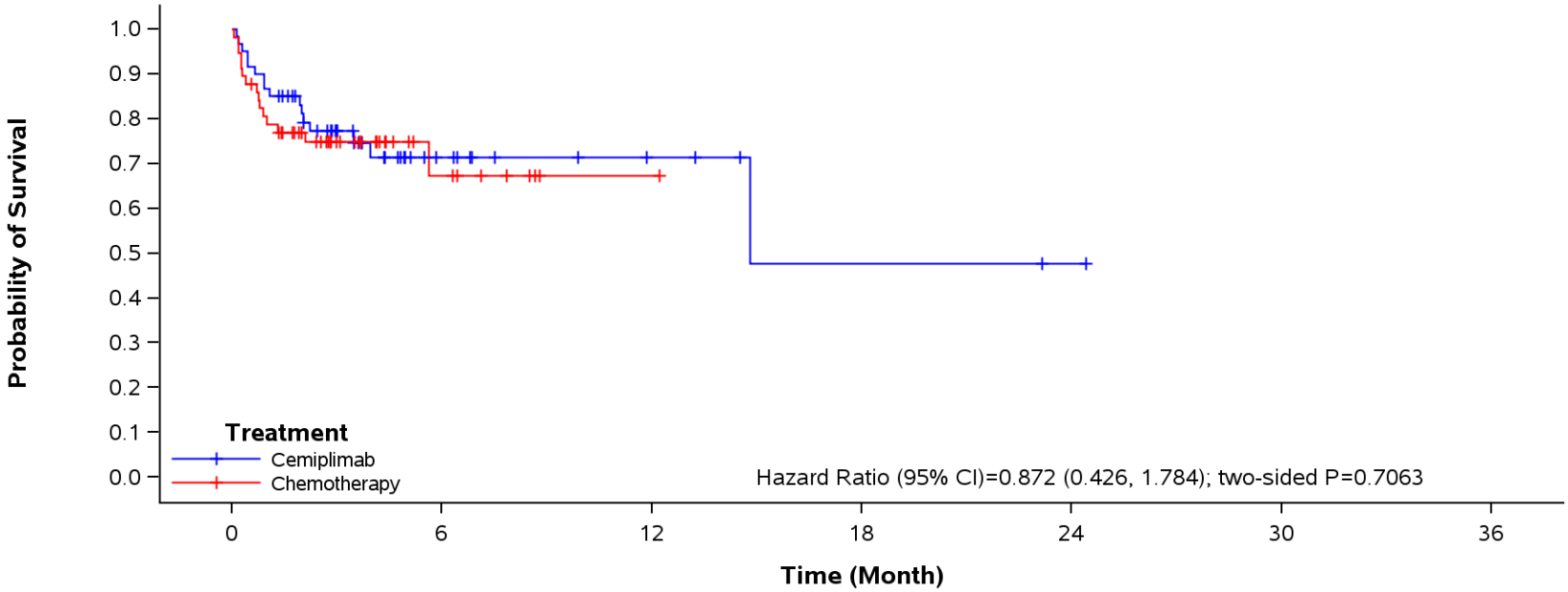

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Skin and subcutaneous tissue disorders



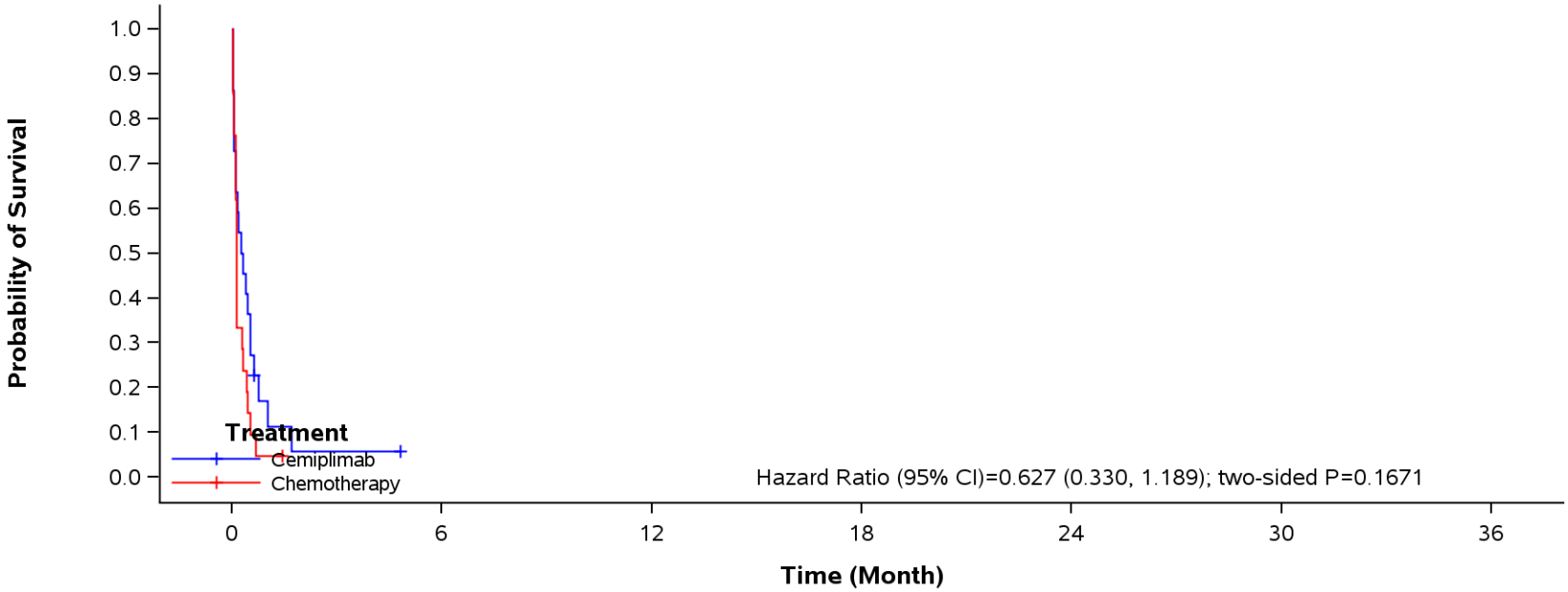

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 5 | 2 | 1 | 0 | 0 |
| Chemotherapy | 57 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Number of patients with any TEAE



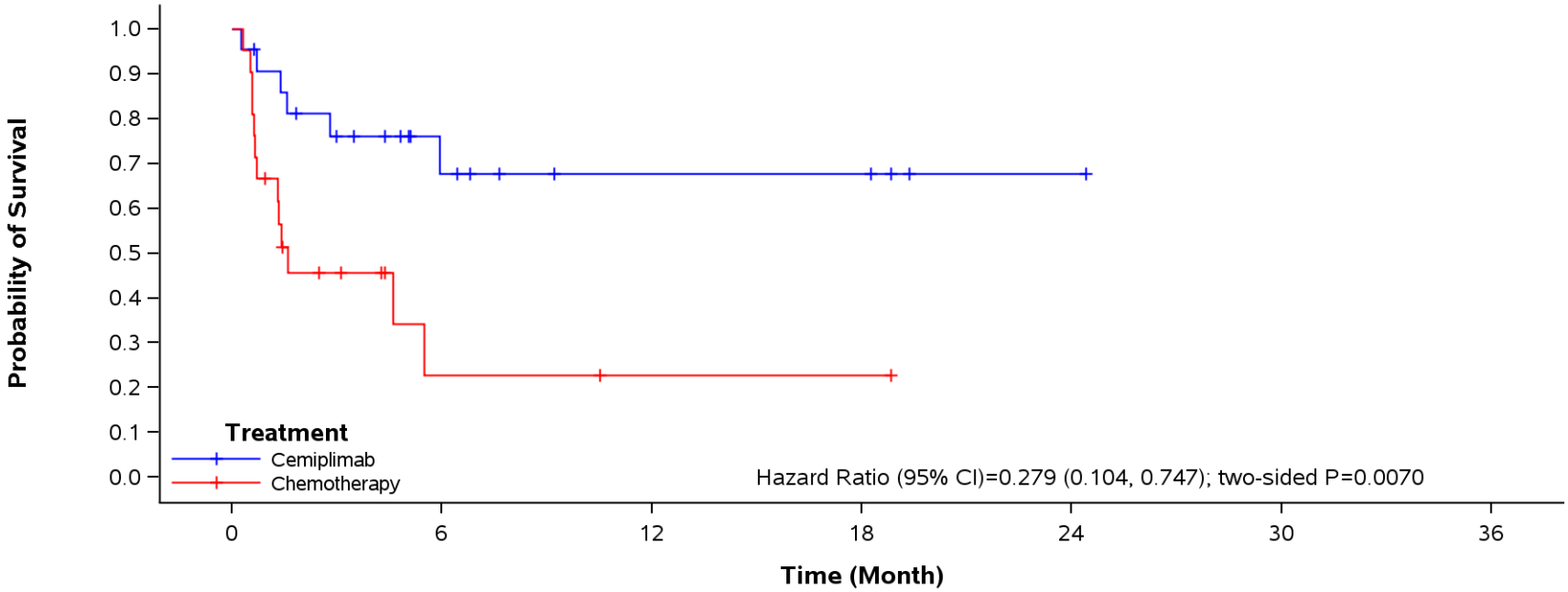

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders



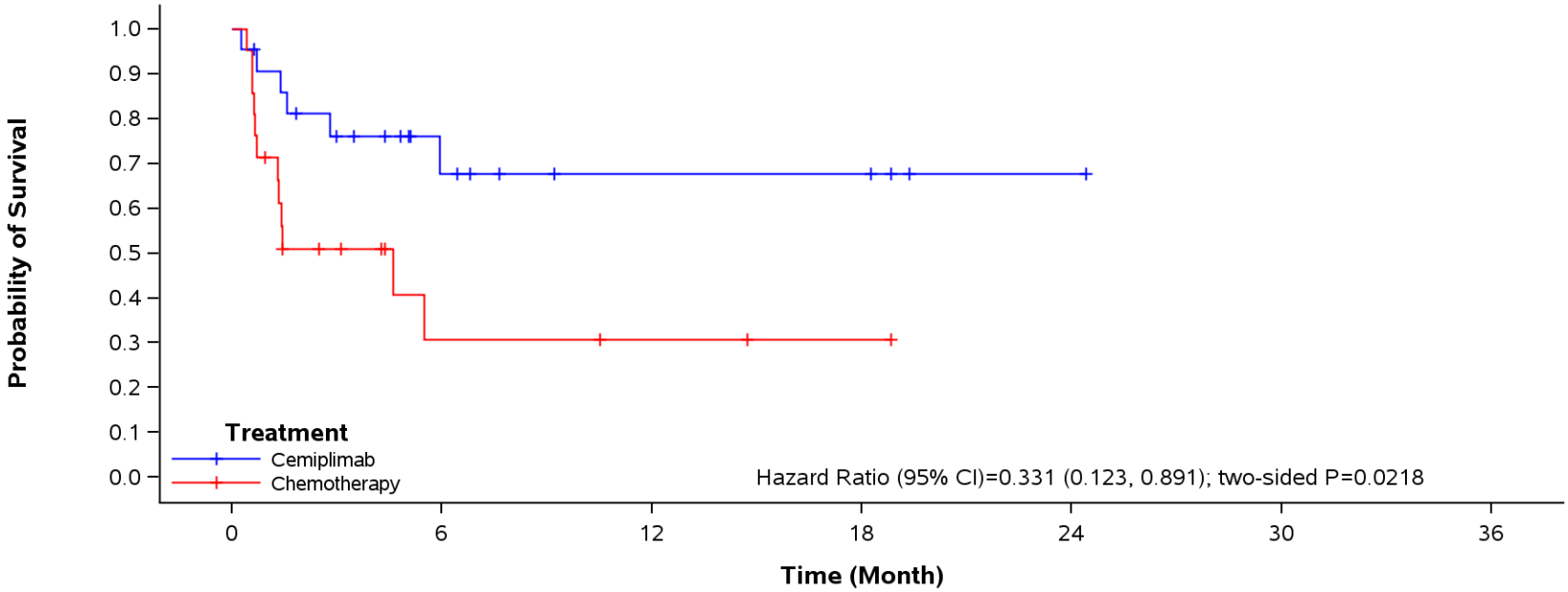

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Anaemia



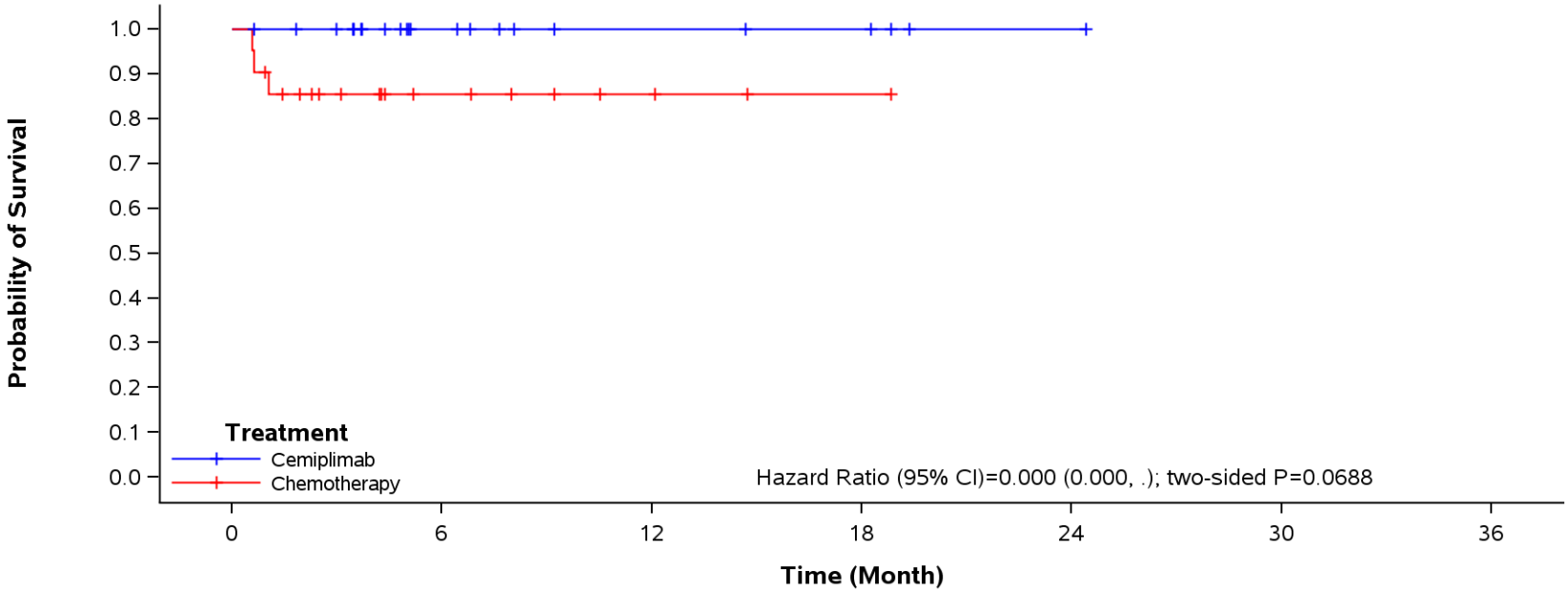

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 3 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Neutropenia



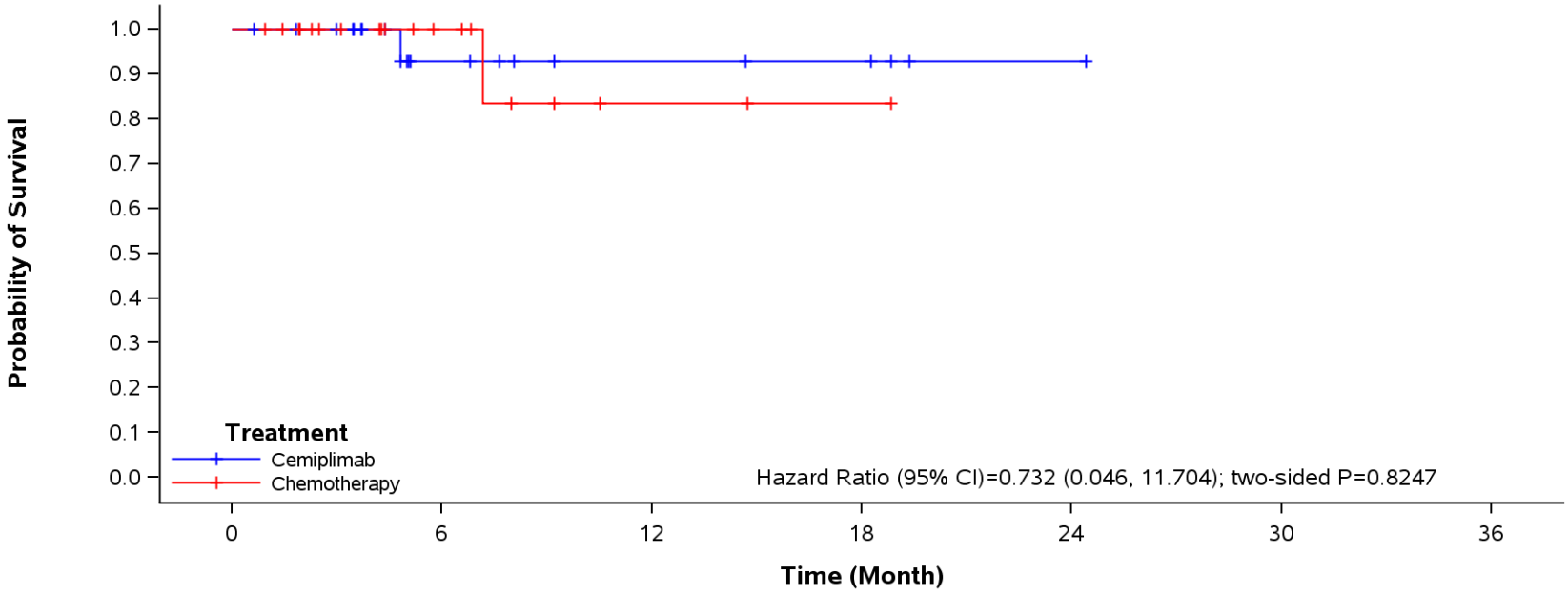

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Endocrine disorders



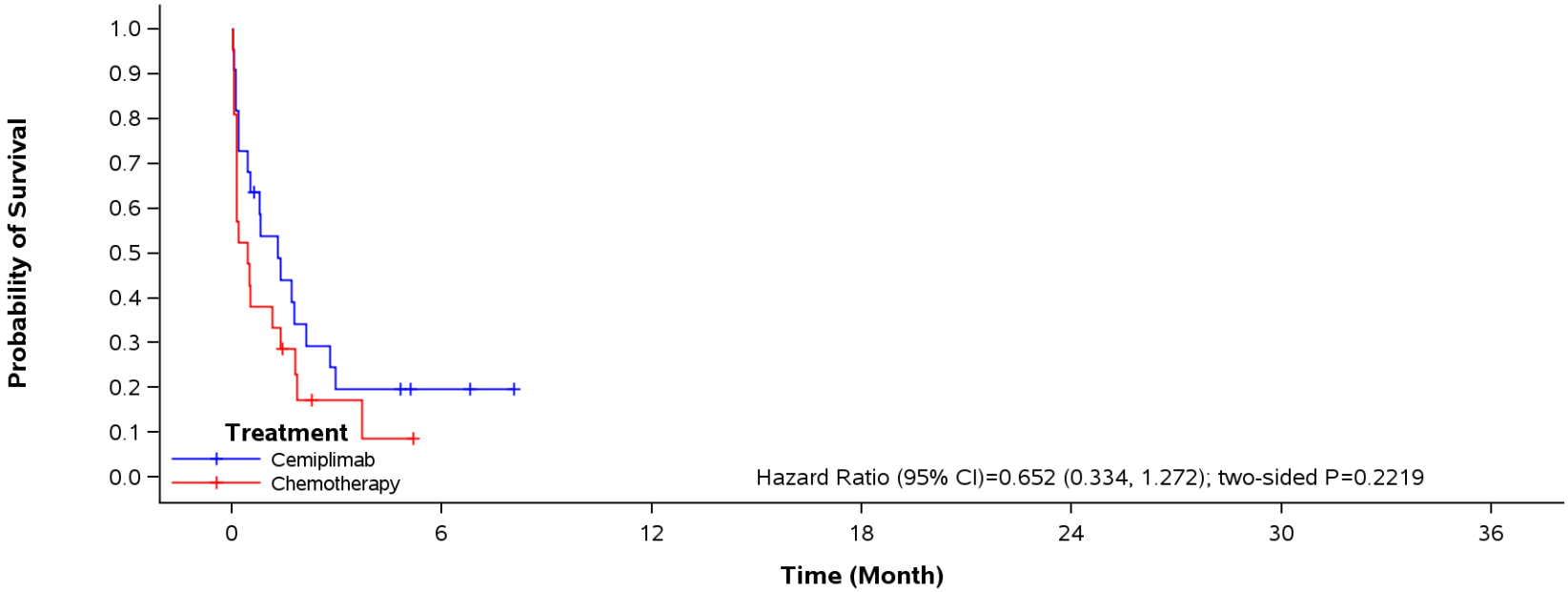

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 9 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders



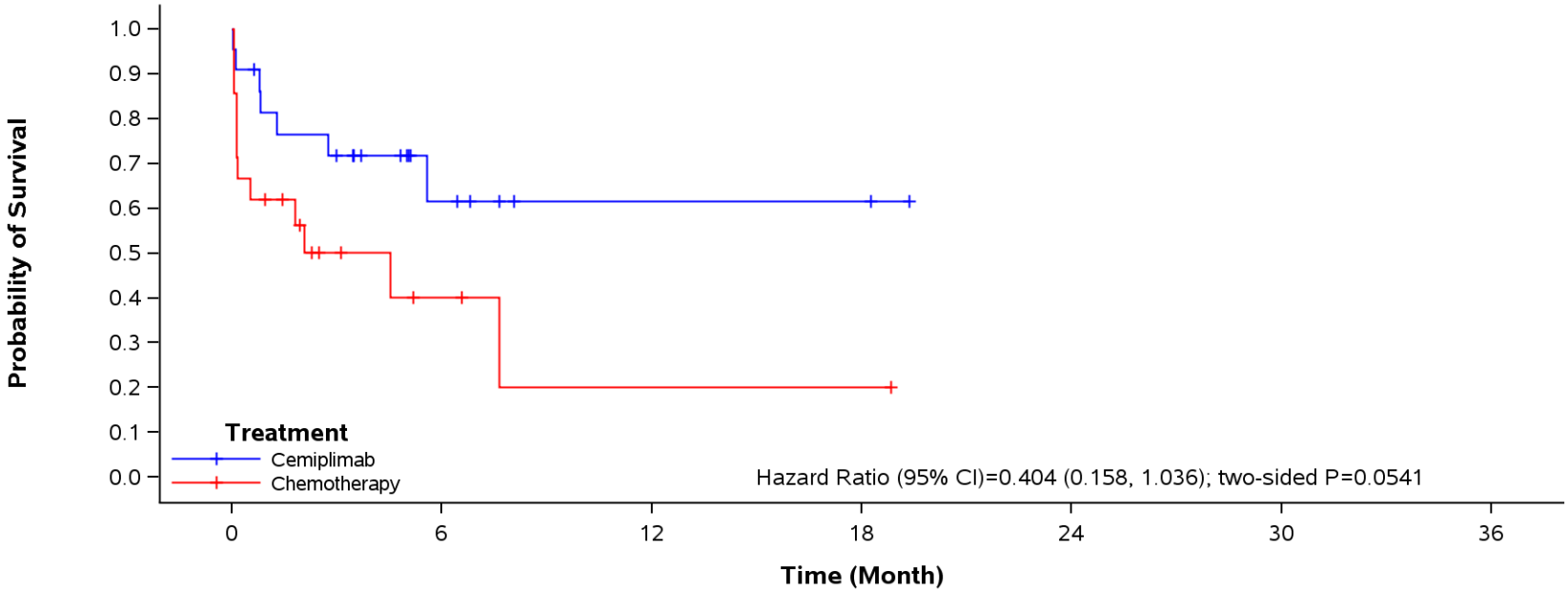

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders
PT: Nausea



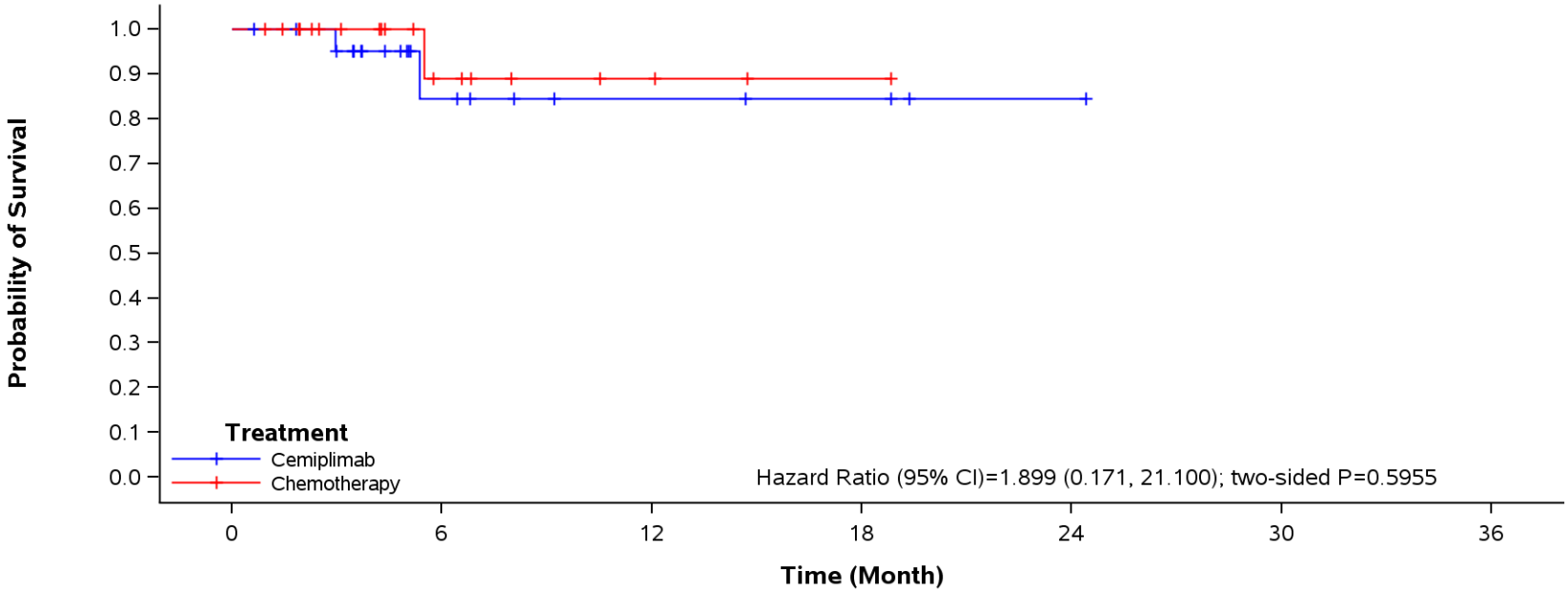

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 2 | 2 | 0 | 0 | 0 |
| Chemotherapy | 21 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders
PT: Stomatitis



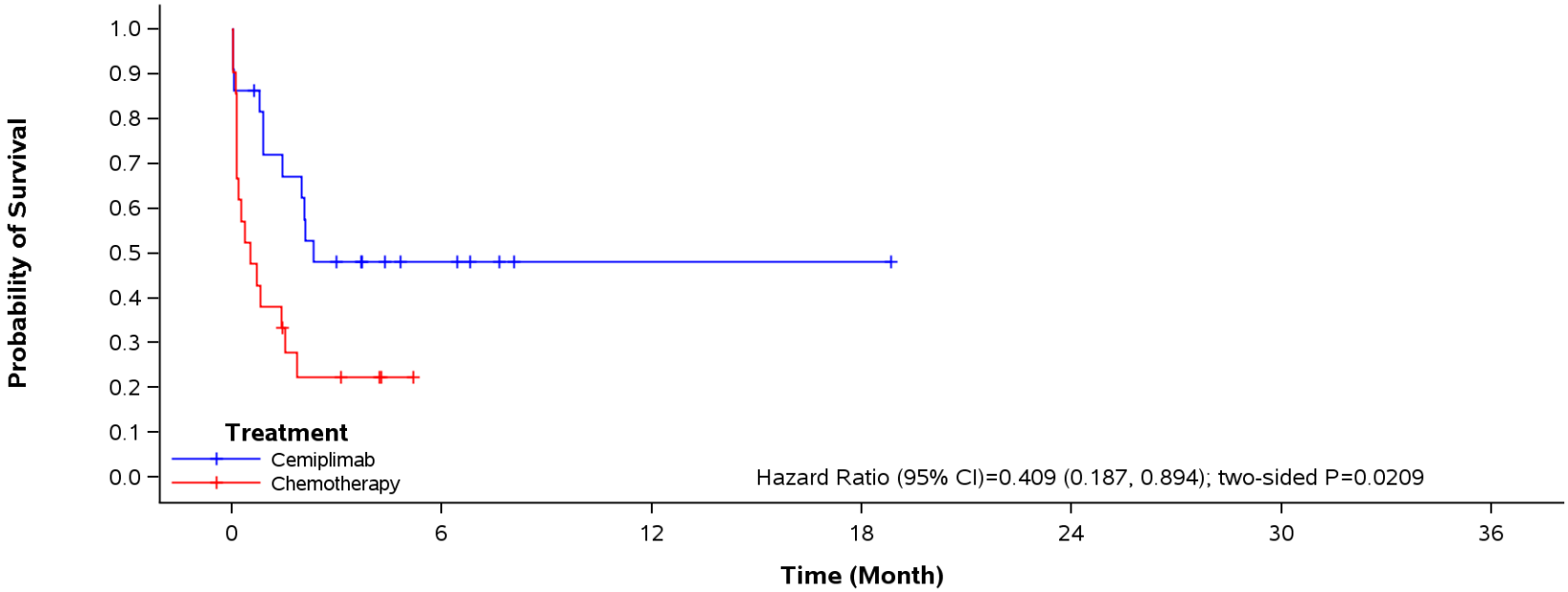

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: General disorders and administration site conditions



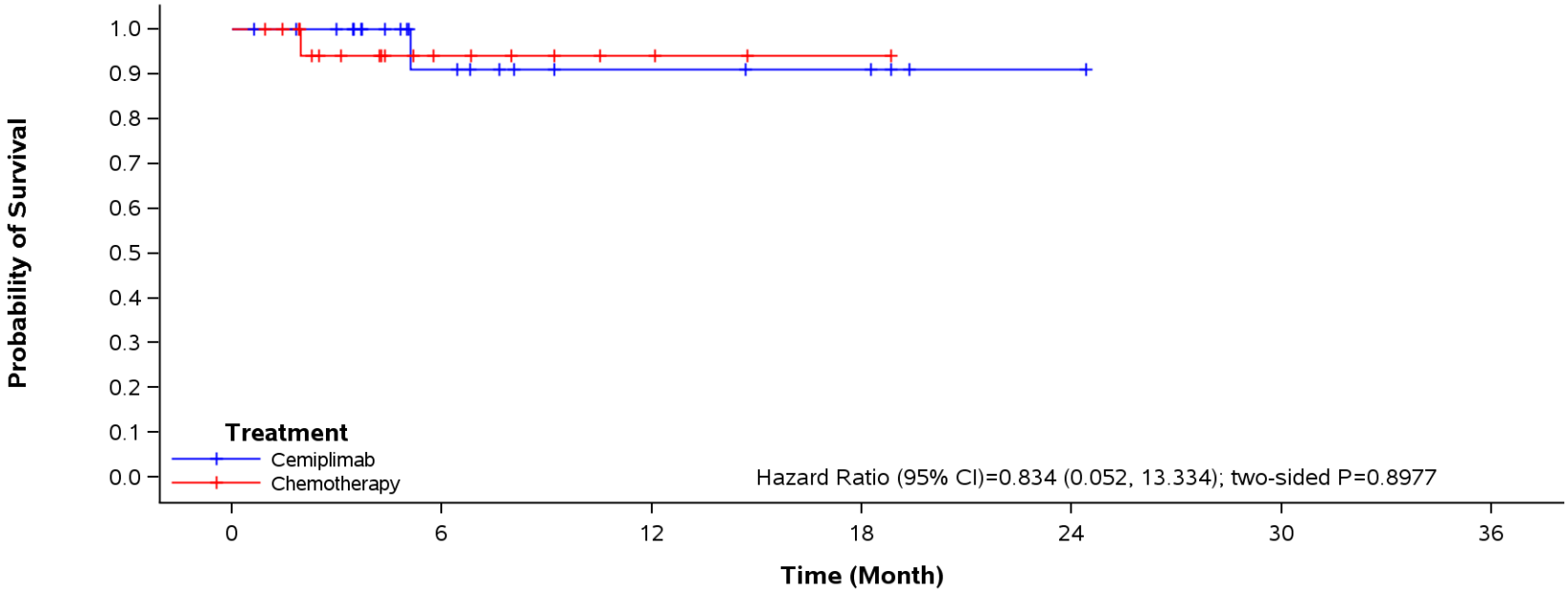

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: General disorders and administration site conditions
PT: Asthenia



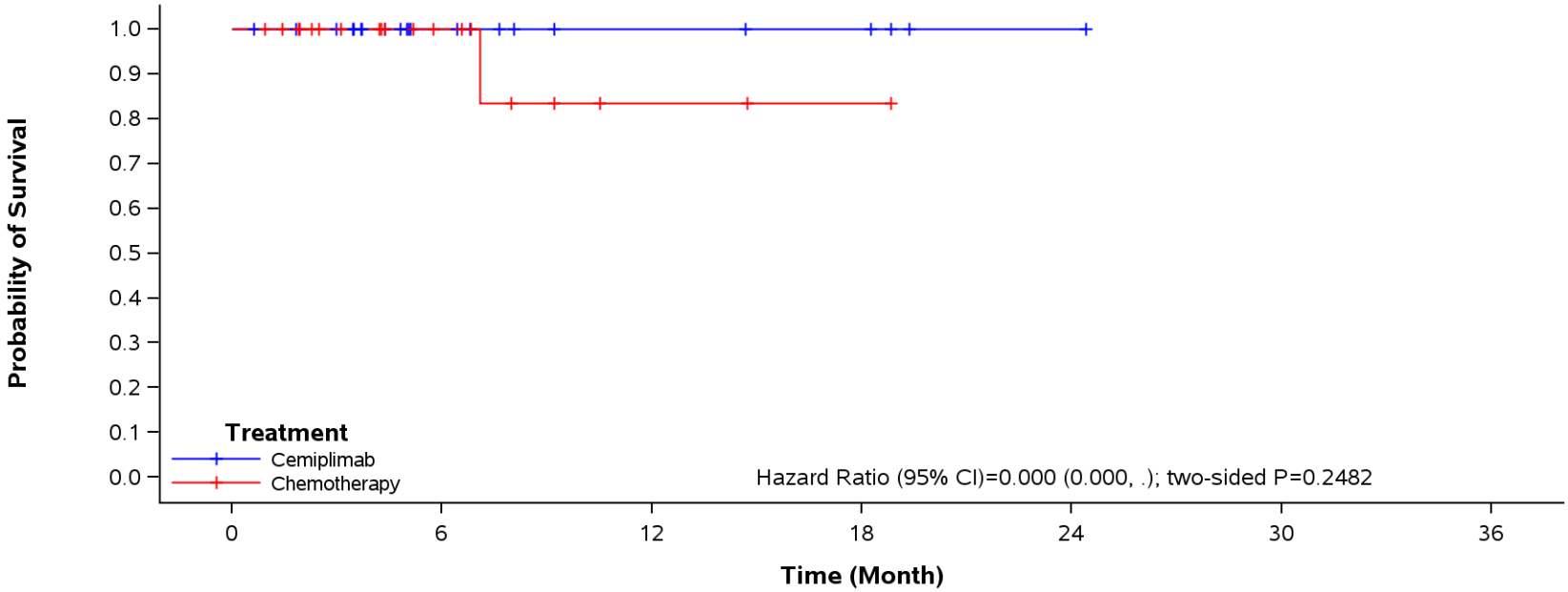

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



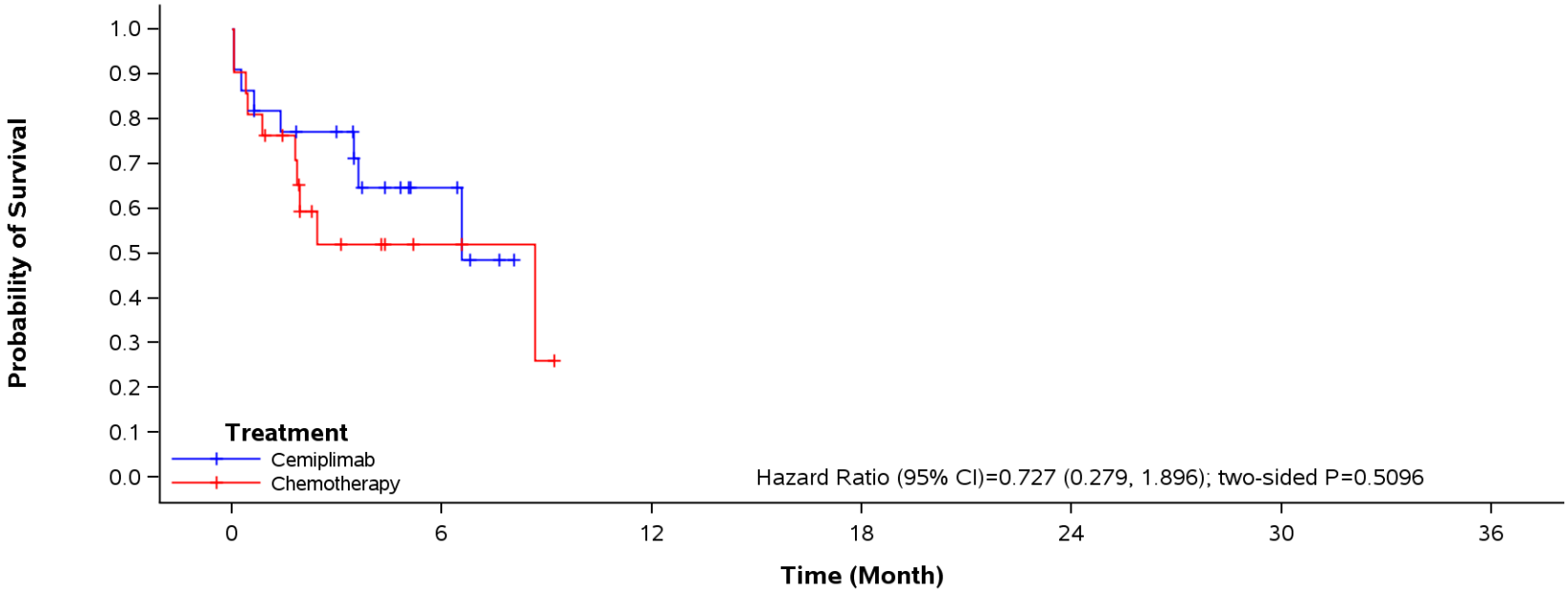

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Nervous system disorders



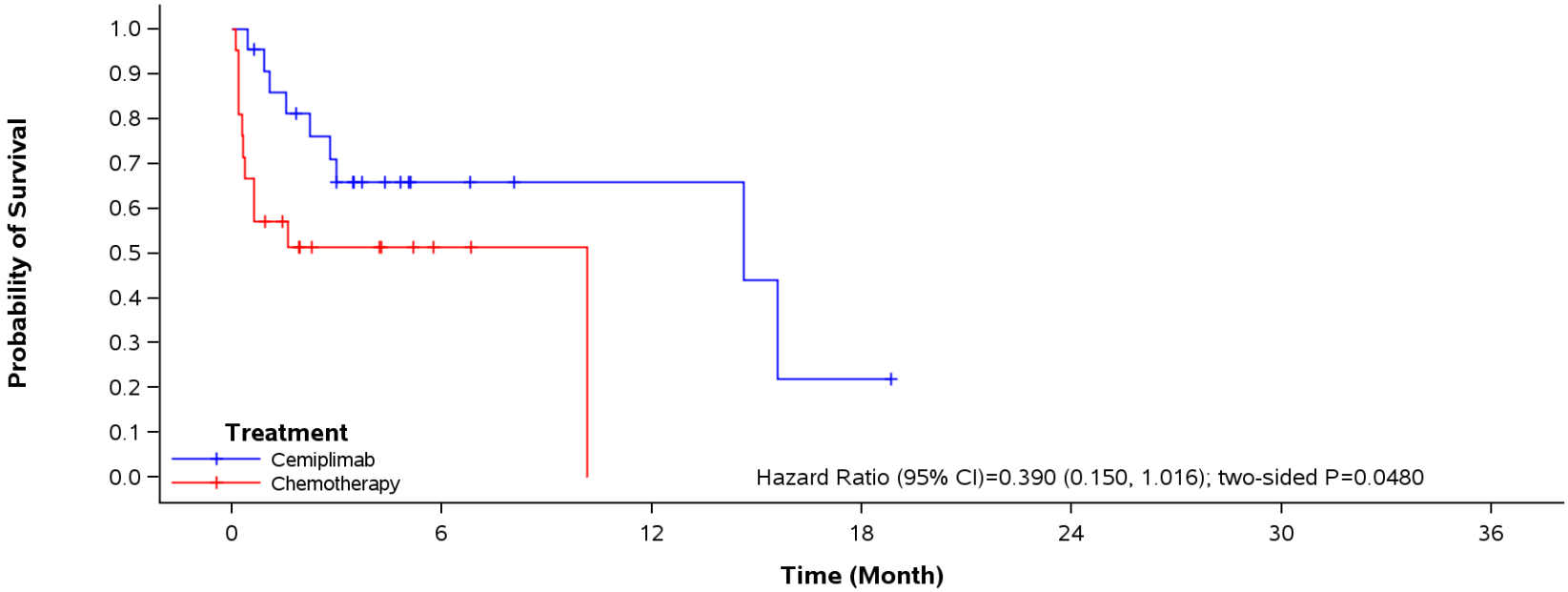

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Skin and subcutaneous tissue disorders



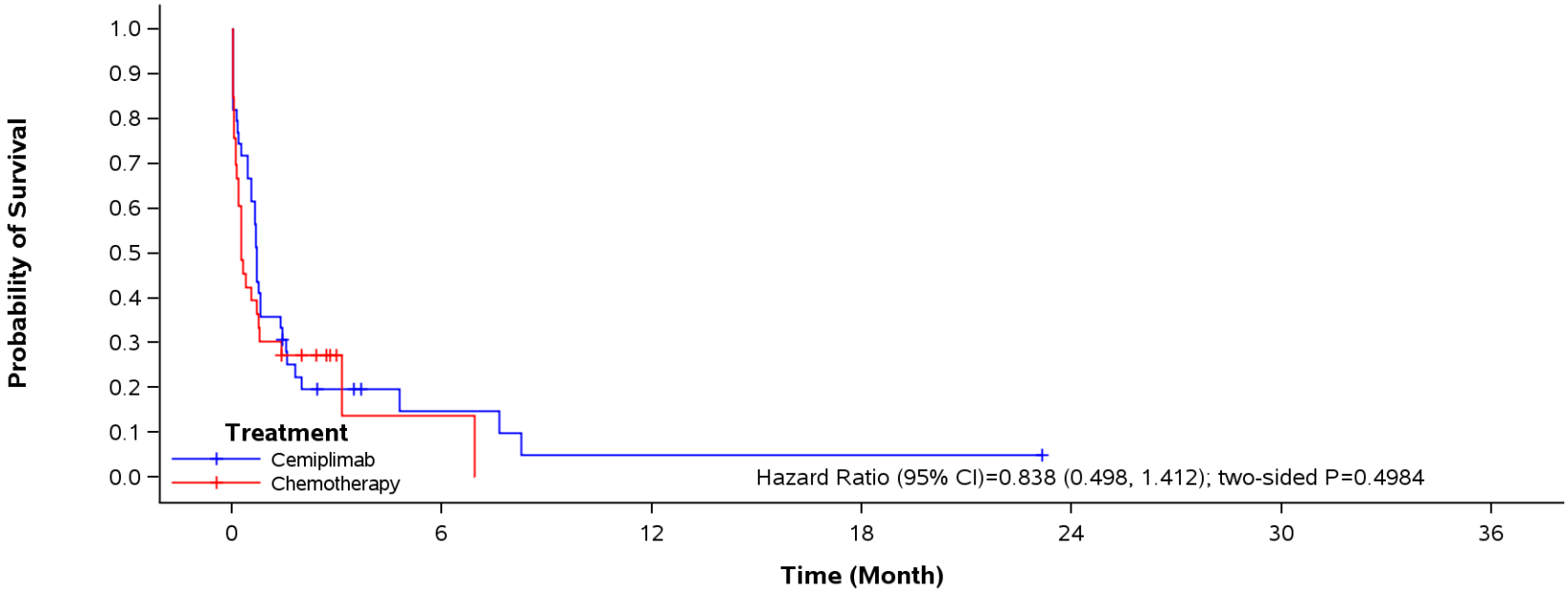

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Number of patients with any TEAE



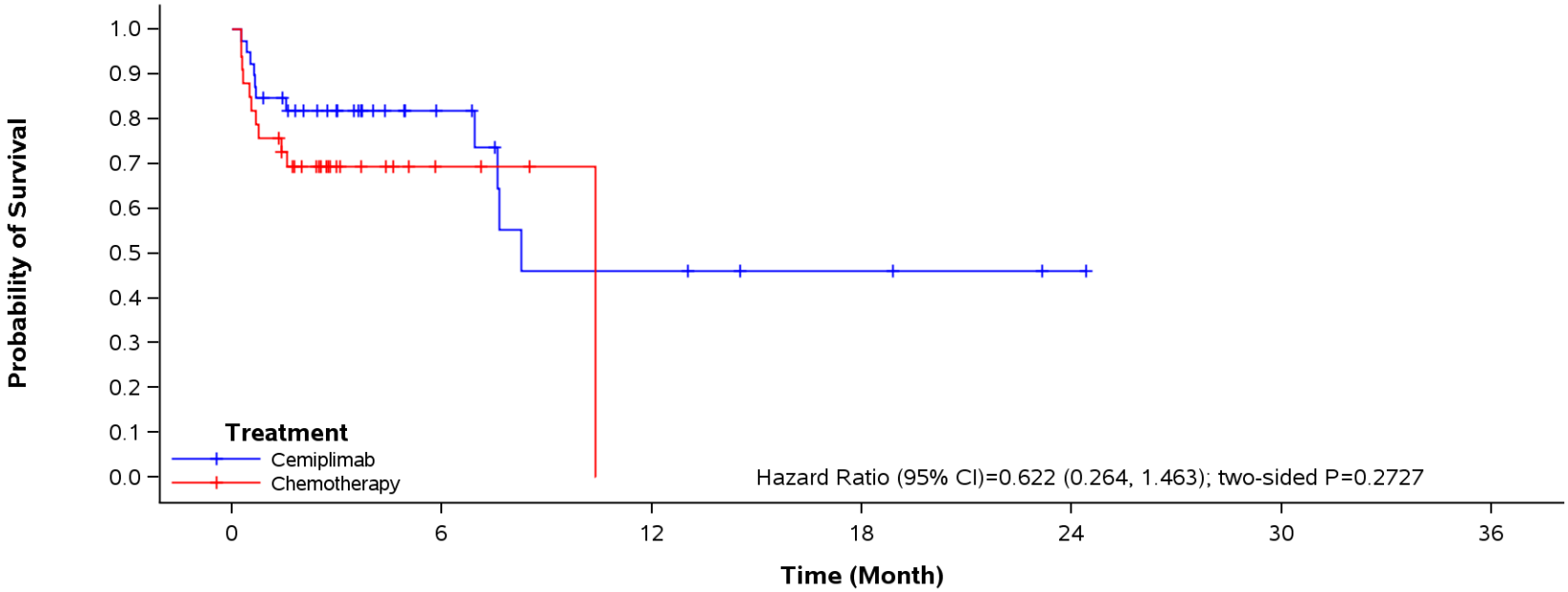

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 33 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders



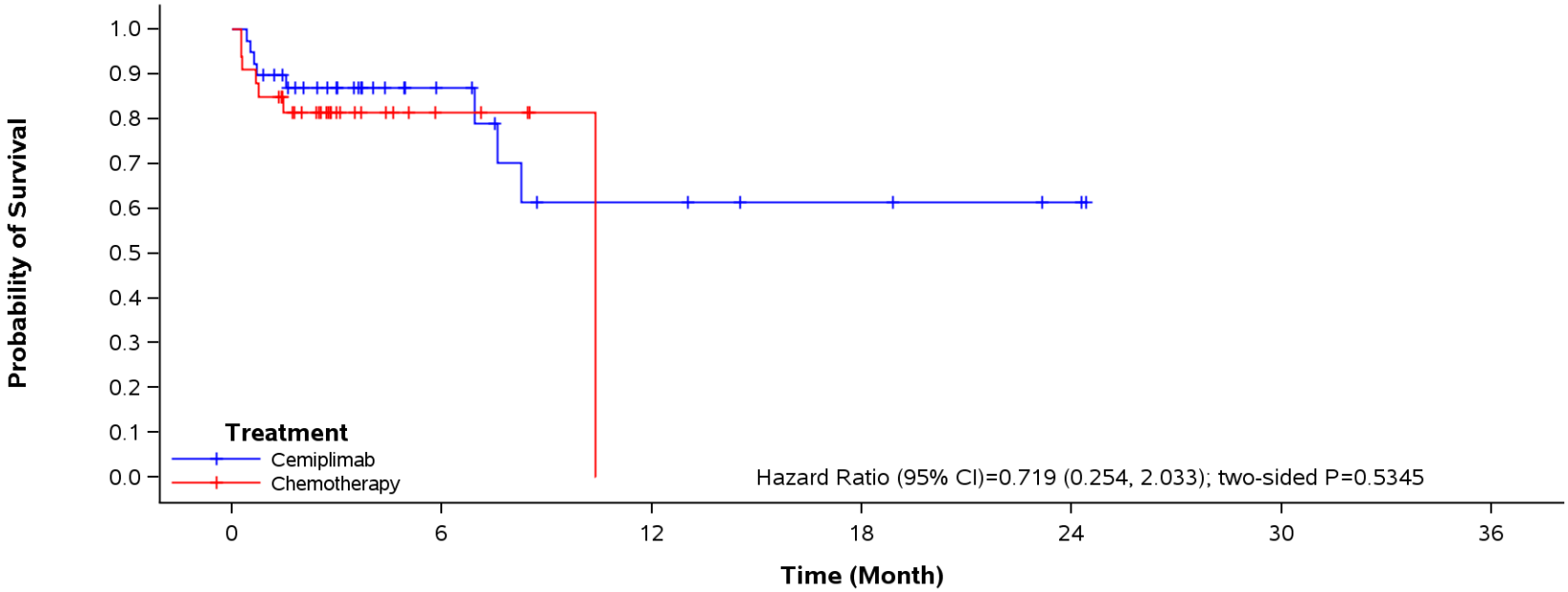

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 11 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 33 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Anaemia



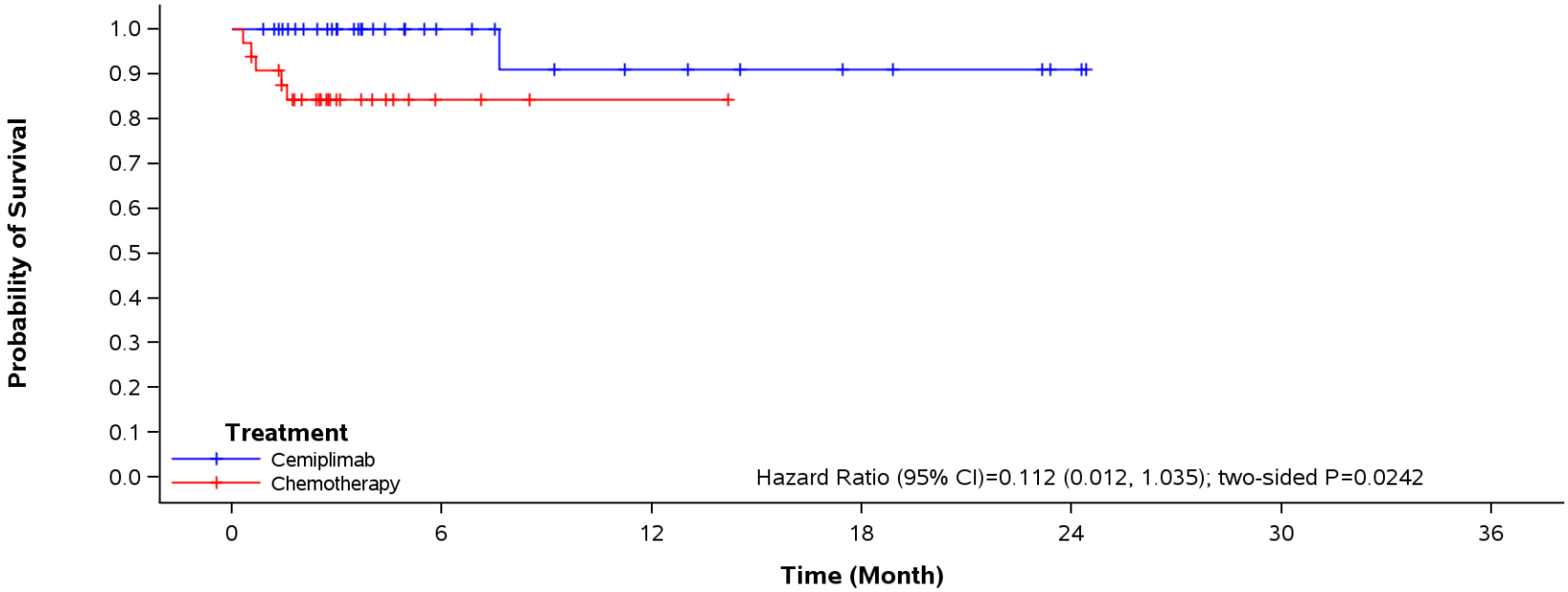

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 33 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Neutropenia



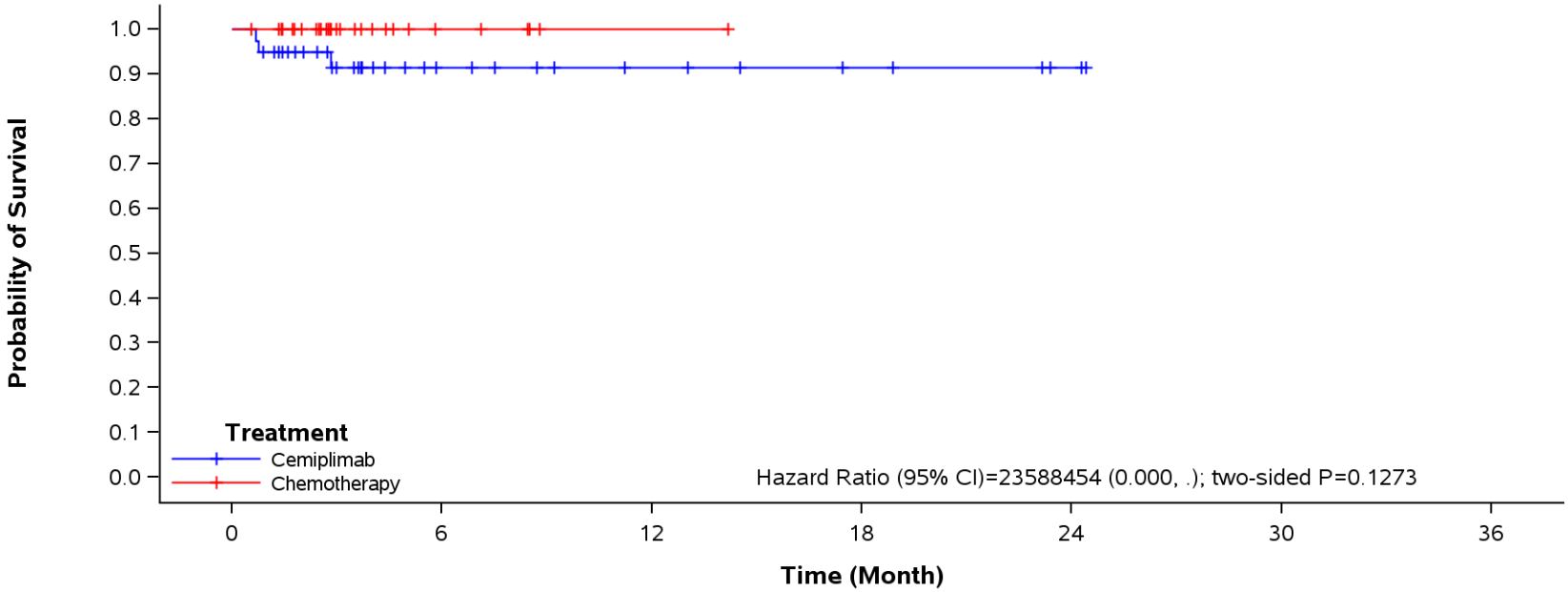

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Endocrine disorders



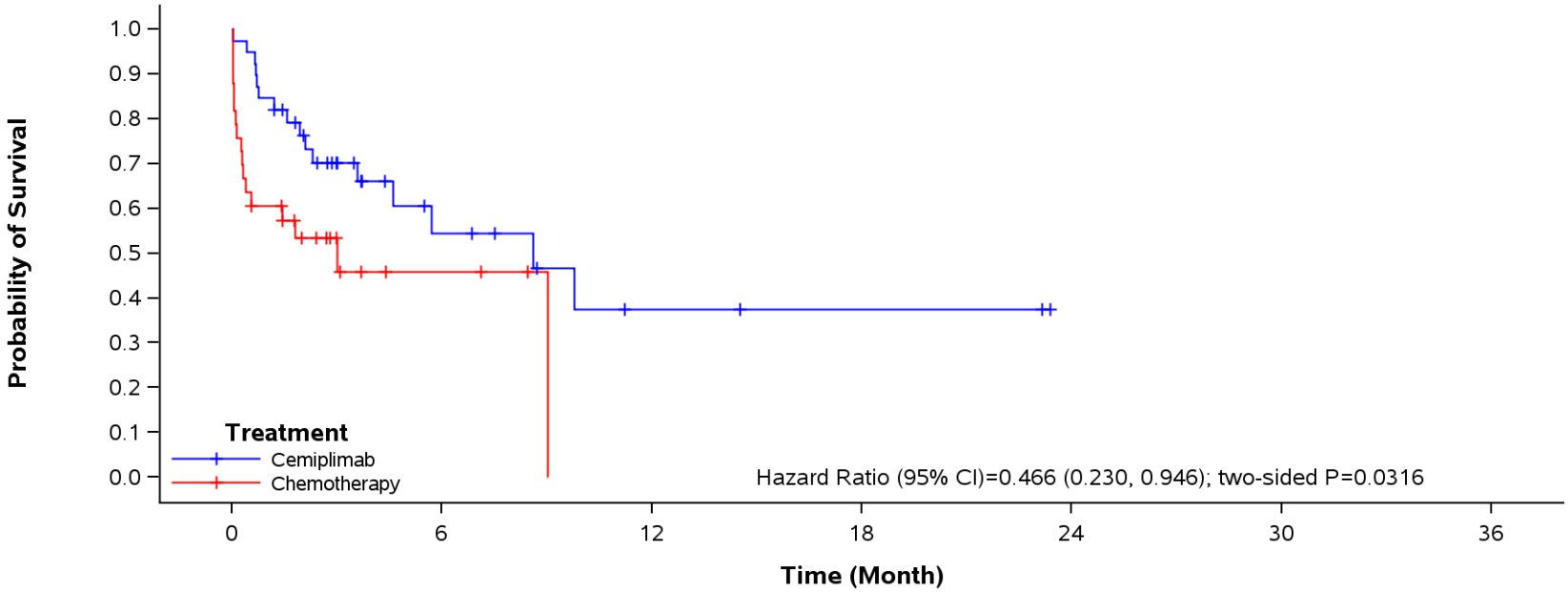

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders



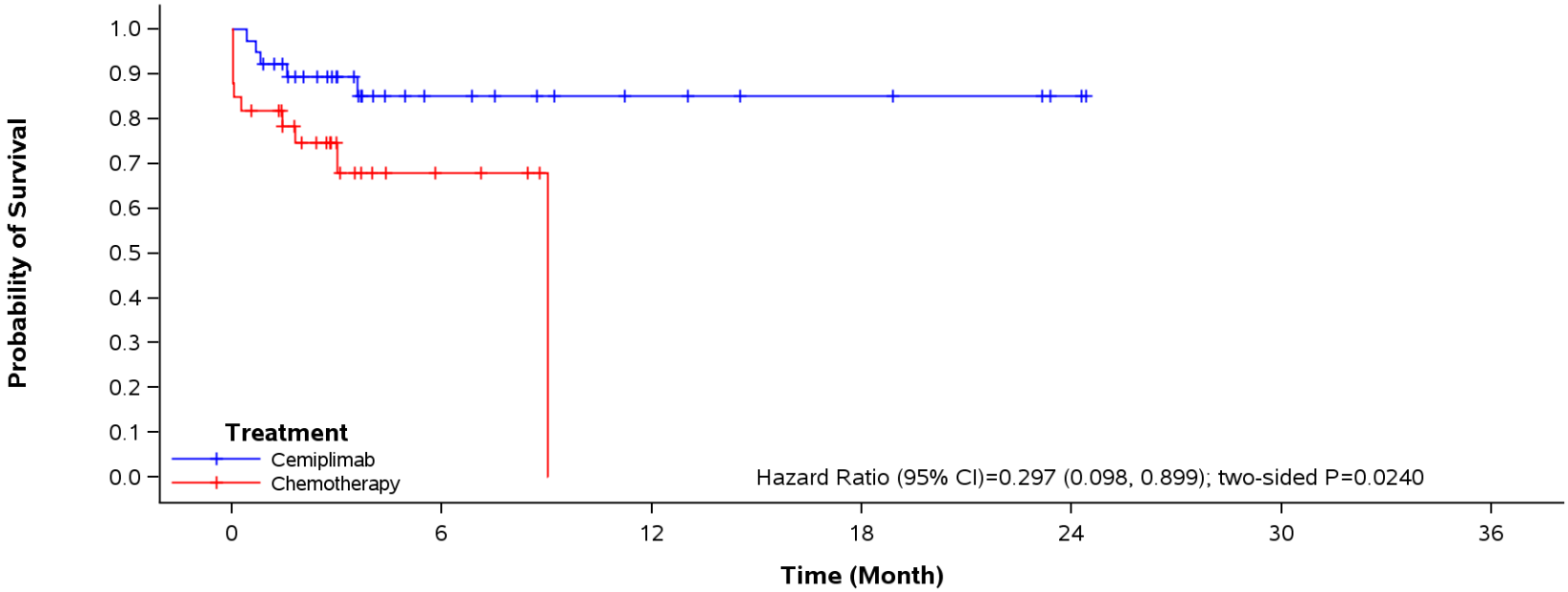

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 33 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders
PT: Nausea



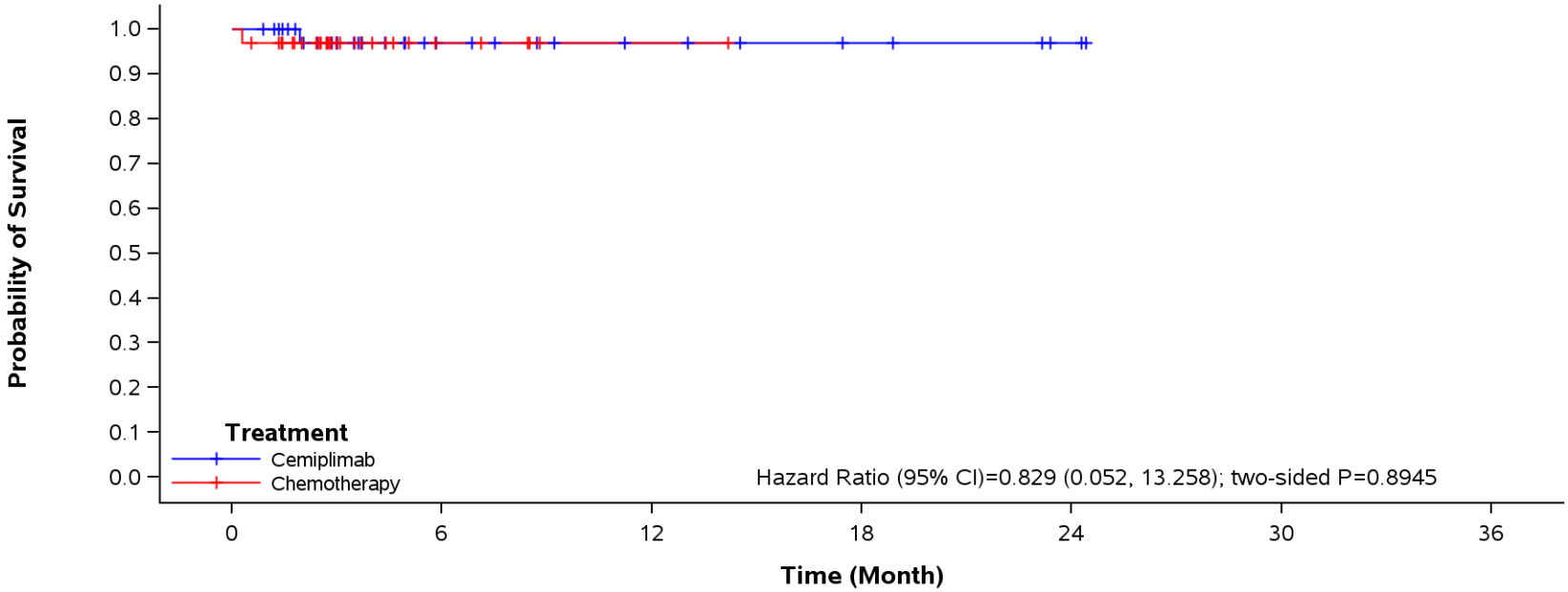

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders
PT: Stomatitis



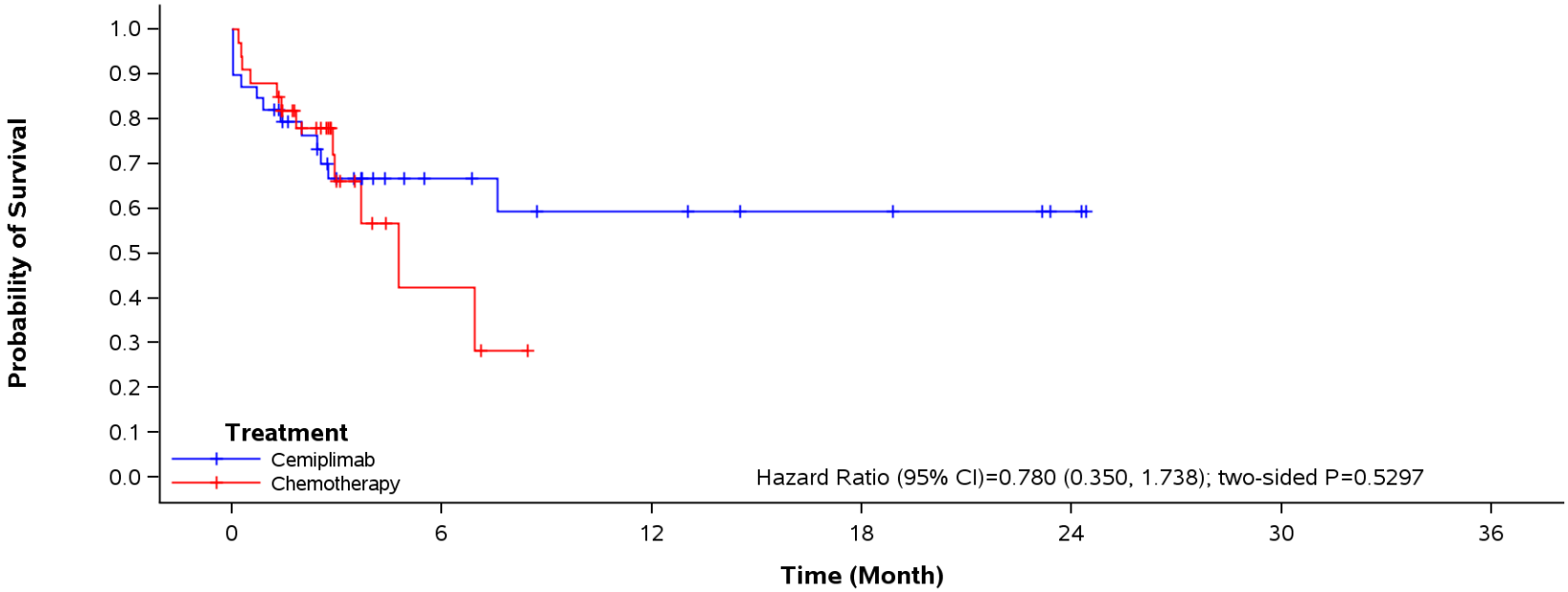

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: General disorders and administration site conditions



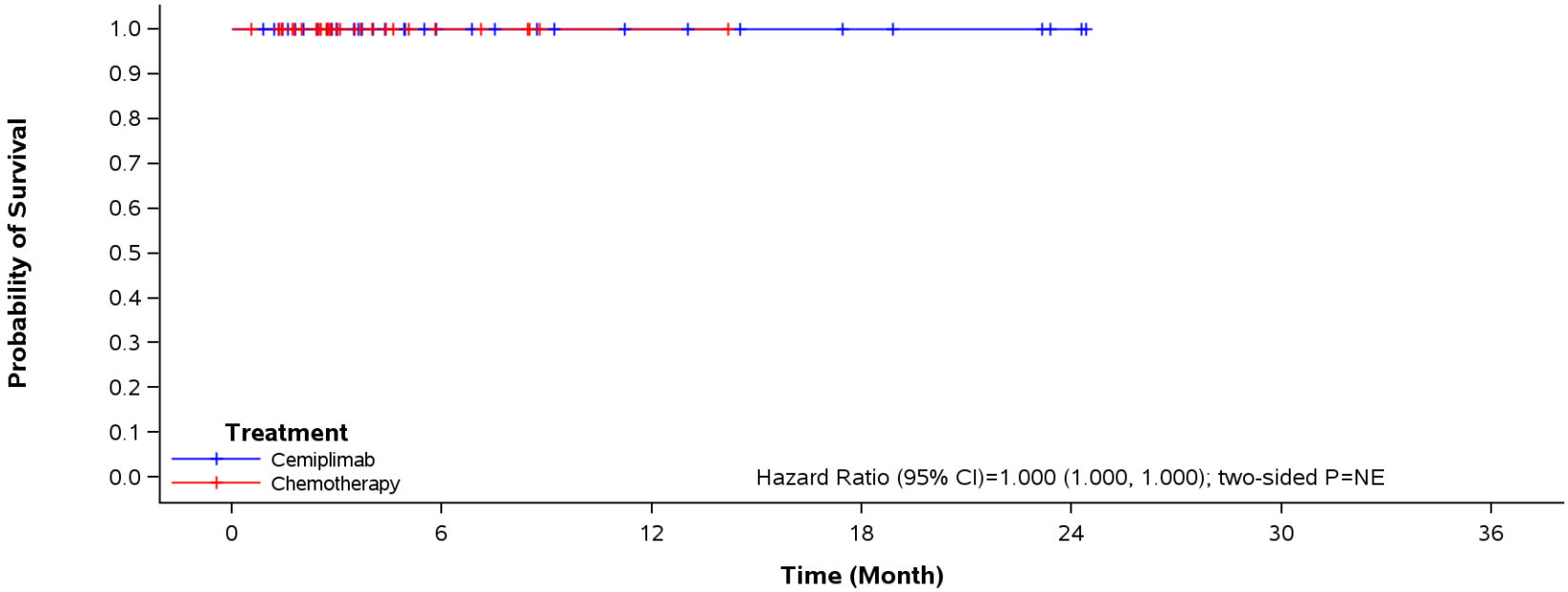

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 7 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: General disorders and administration site conditions
PT: Asthenia



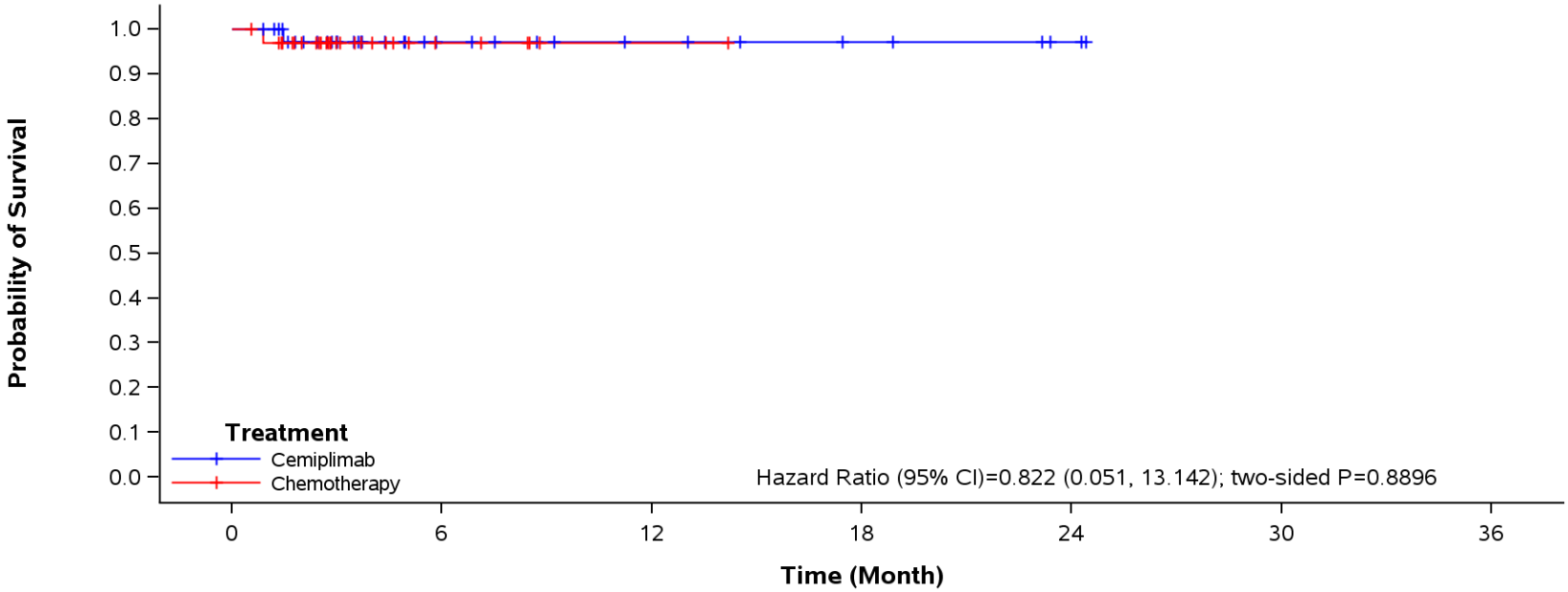

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



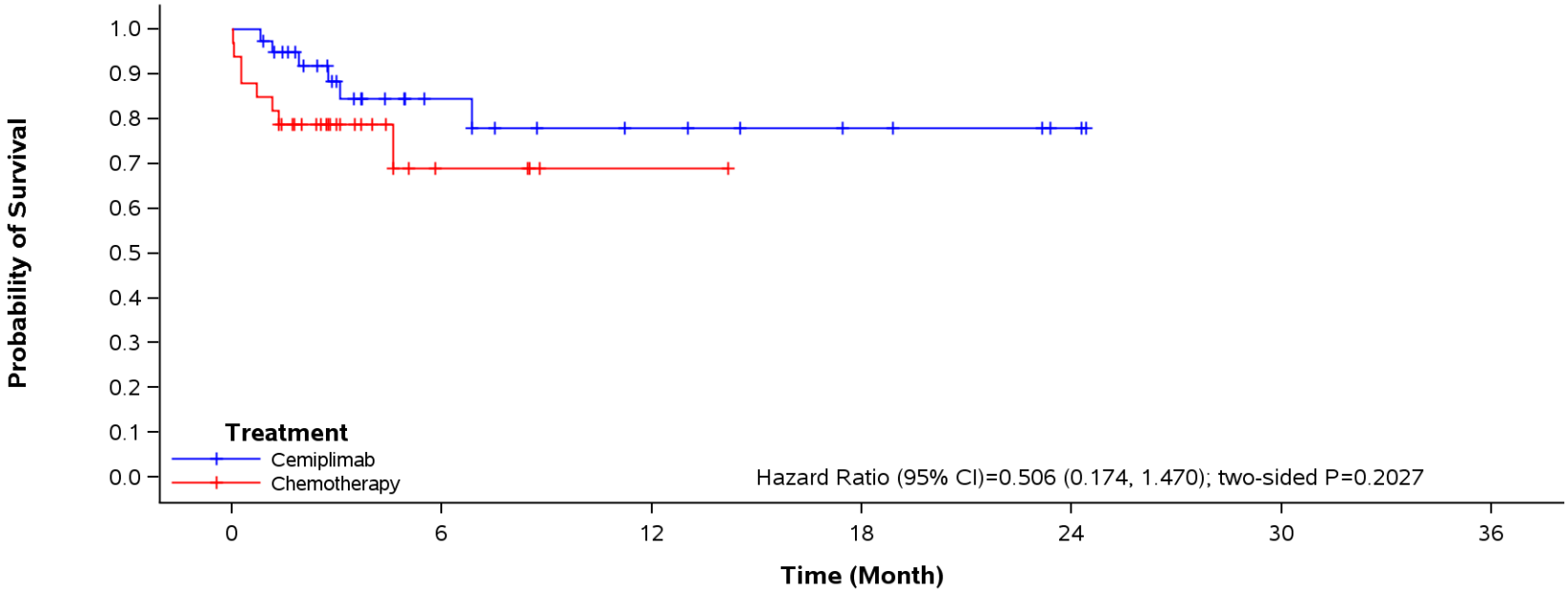

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Nervous system disorders



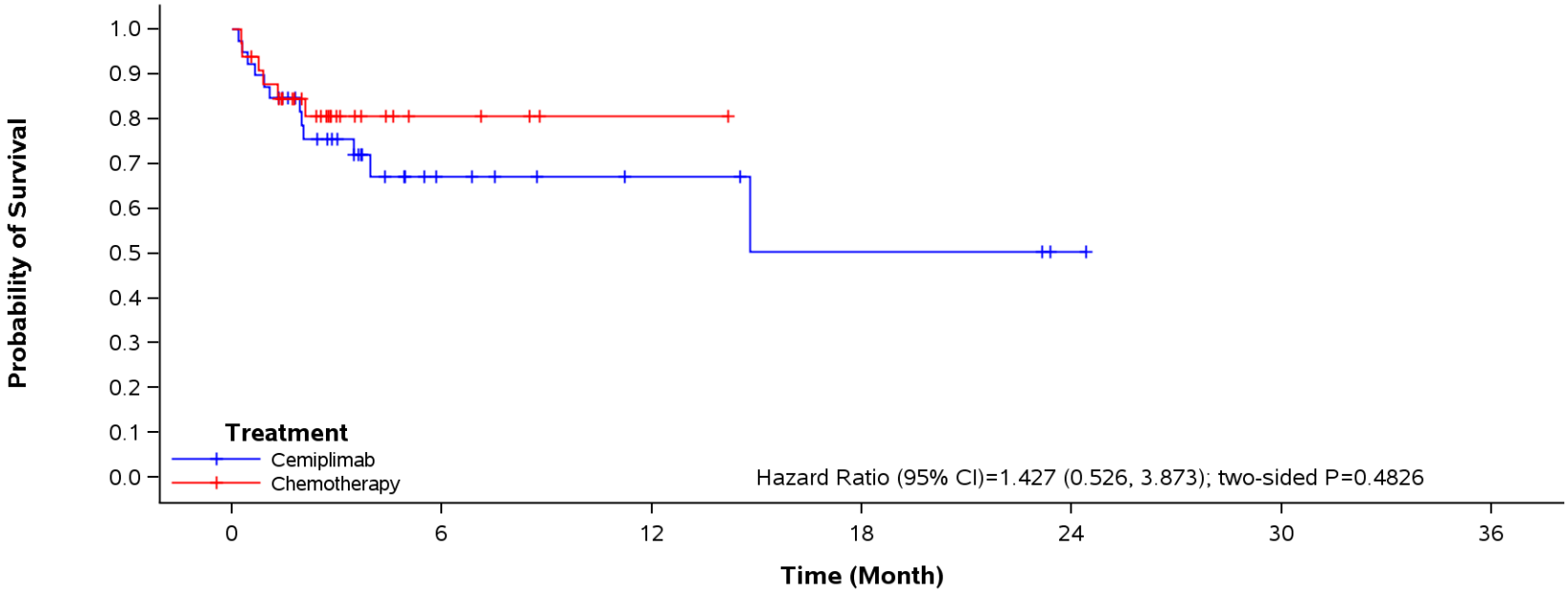

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Skin and subcutaneous tissue disorders



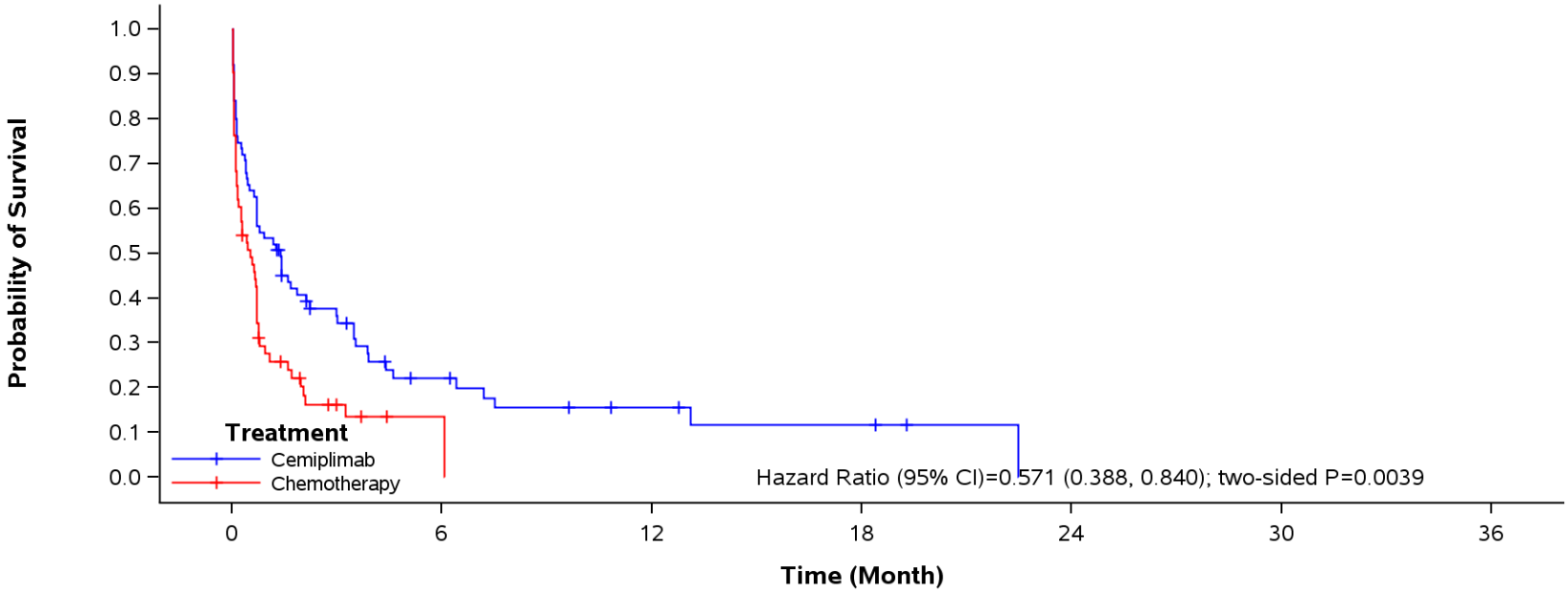

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 33 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Number of patients with any TEAE



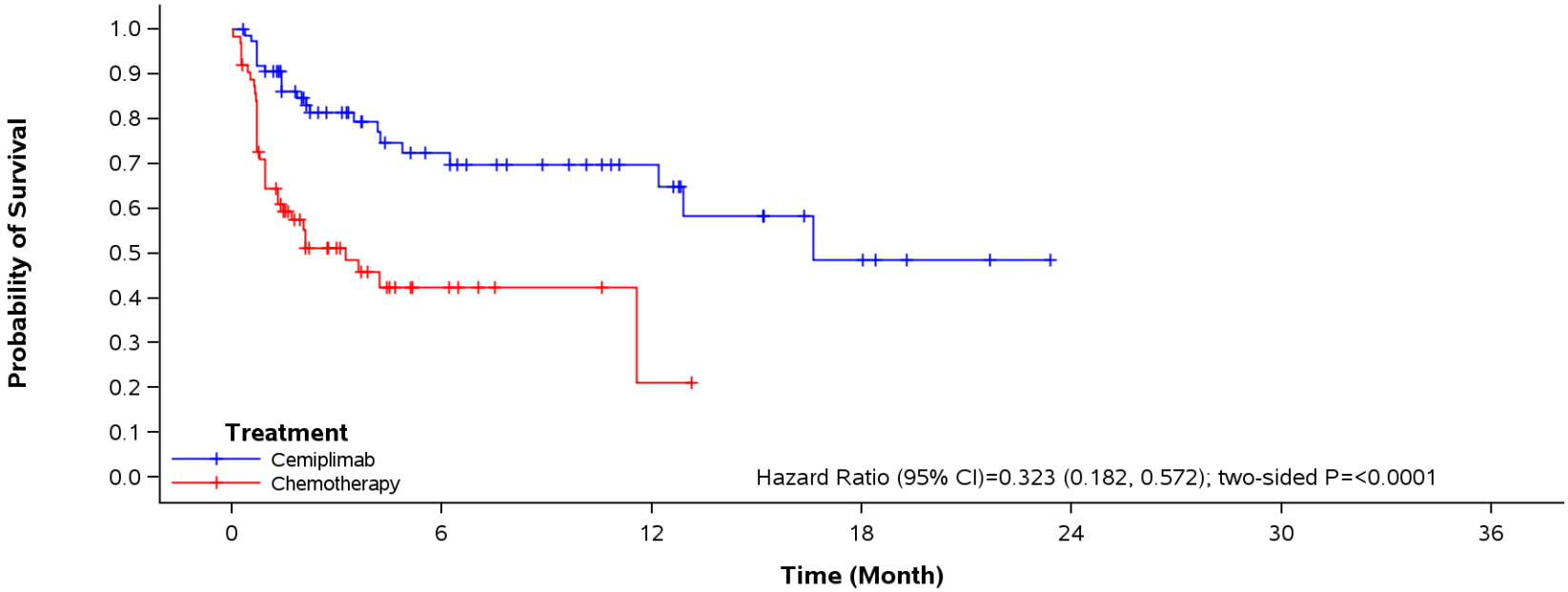

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 11 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 63 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders



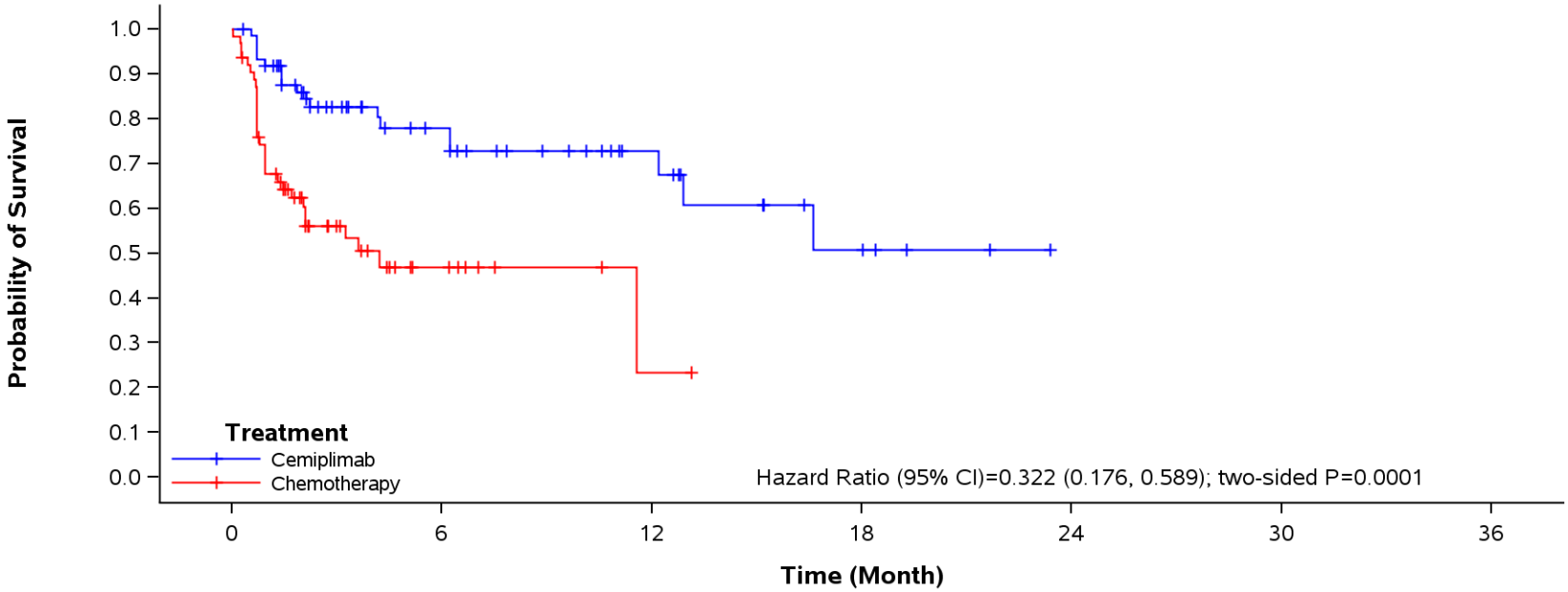

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 28 | 14 | 5 | 0 | 0 | 0 |
| Chemotherapy | 63 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Anaemia



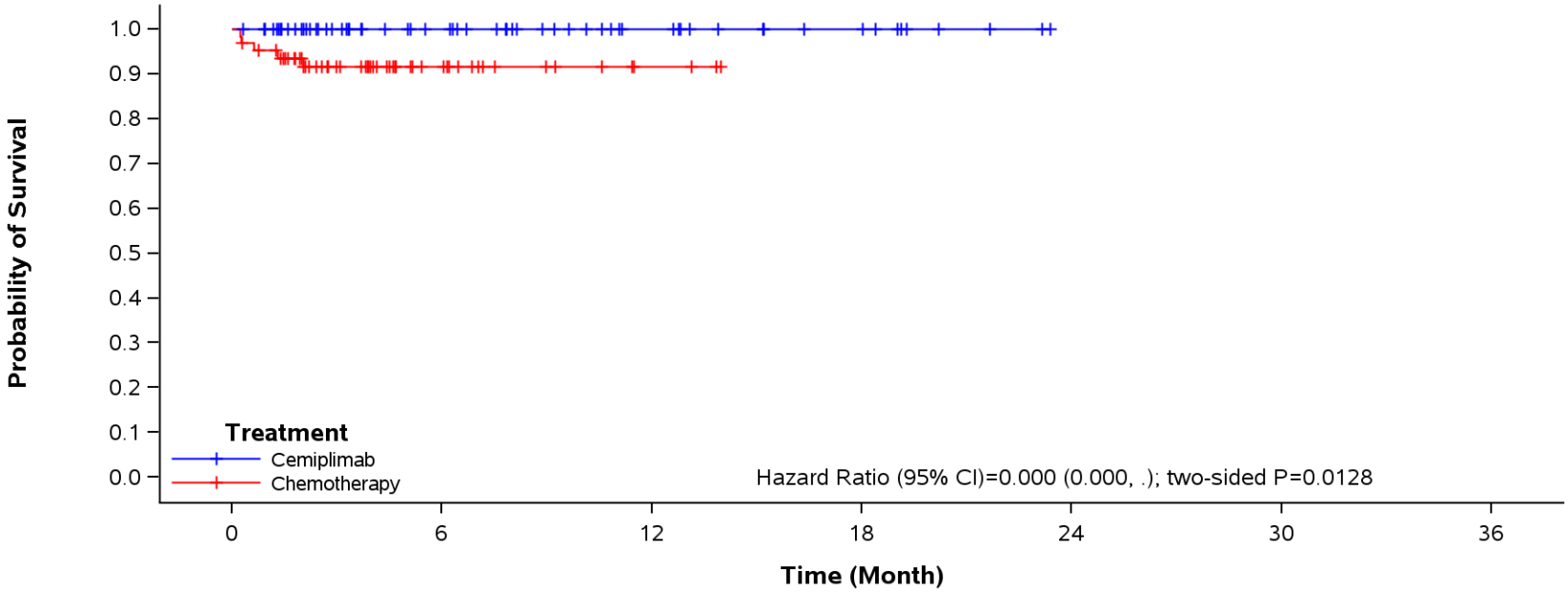

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 30 | 14 | 5 | 0 | 0 | 0 |
| Chemotherapy | 63 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Neutropenia



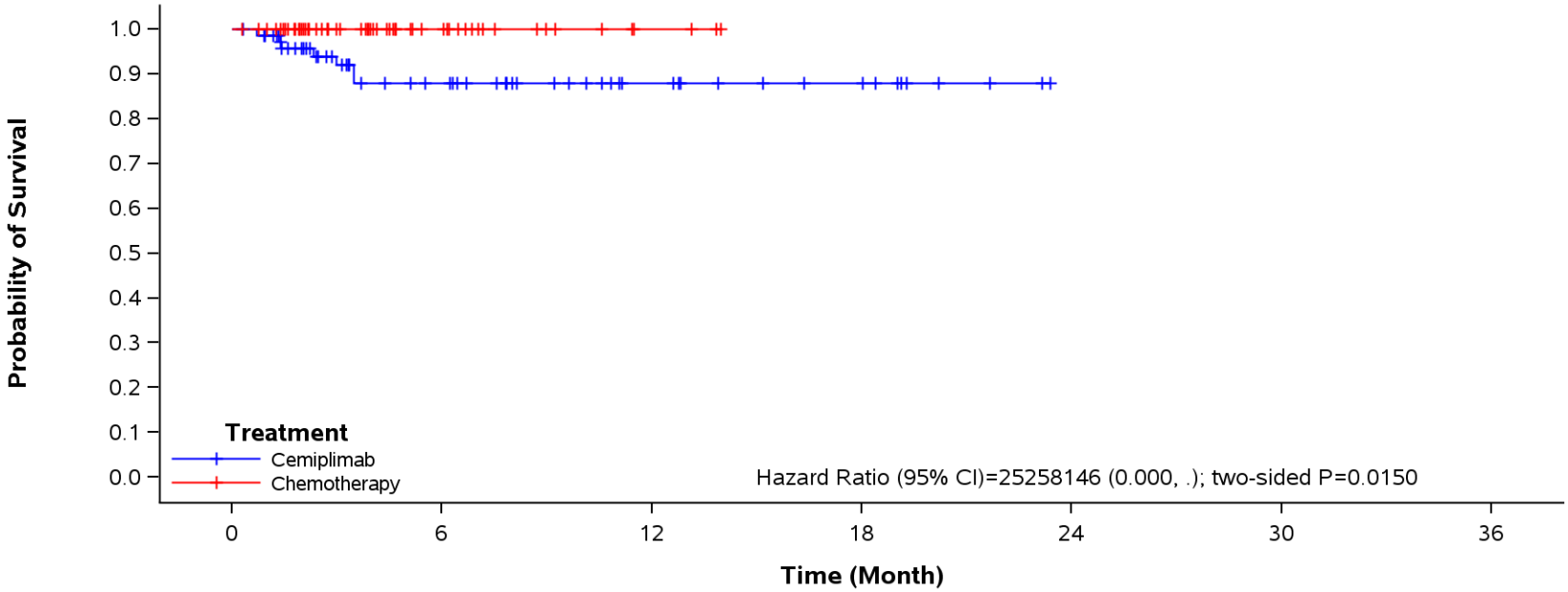

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 17 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Endocrine disorders



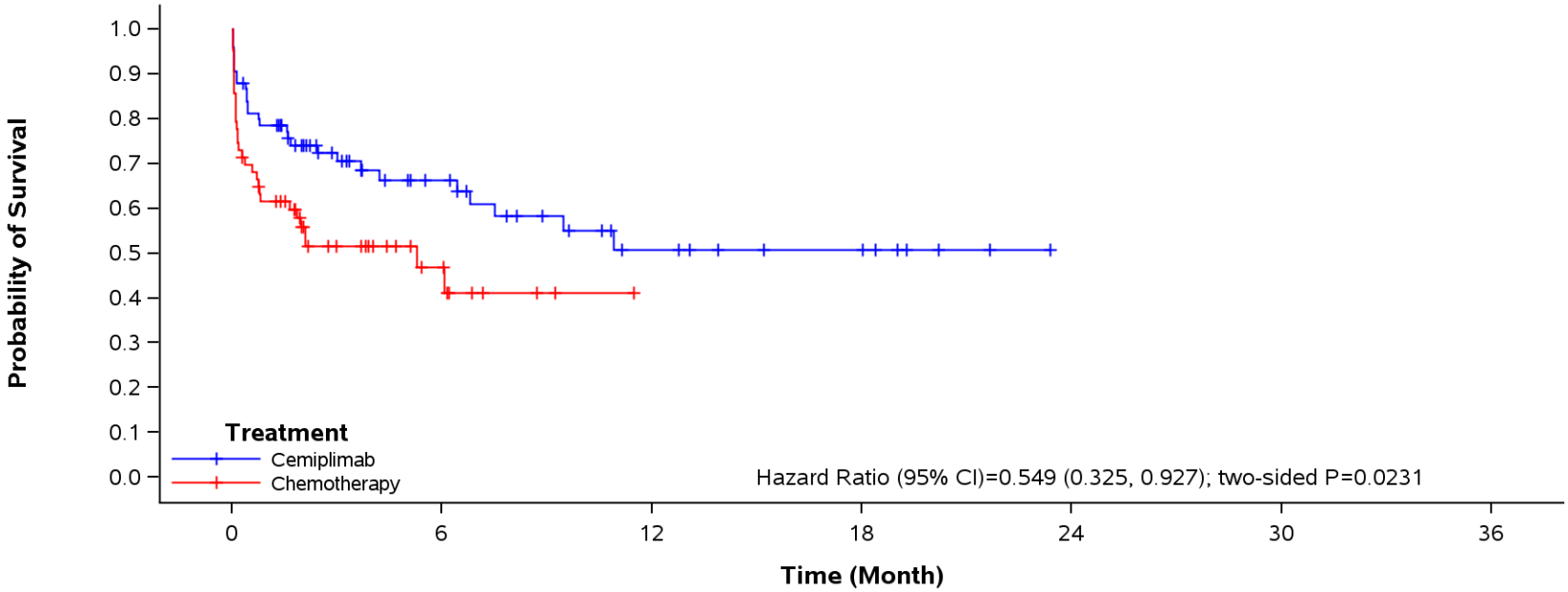

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 33 | 15 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders



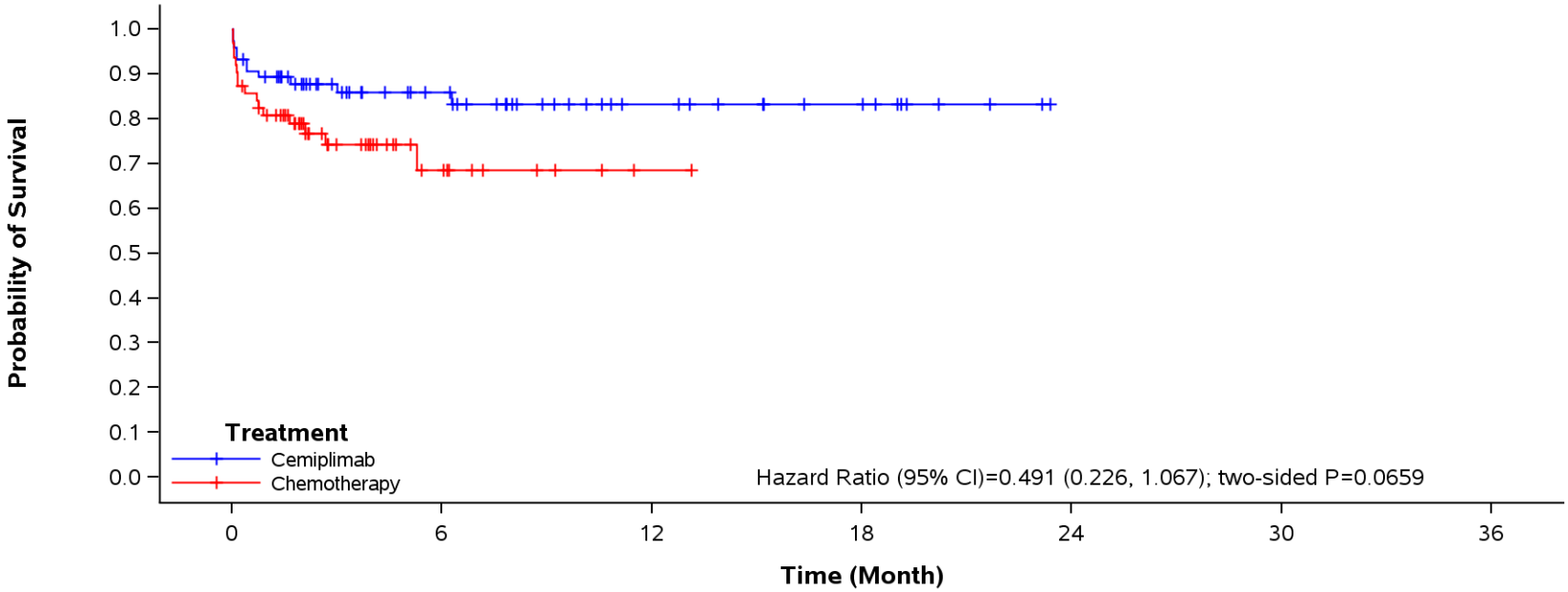

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 27 | 11 | 7 | 0 | 0 | 0 |
| Chemotherapy | 63 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders
PT: Nausea



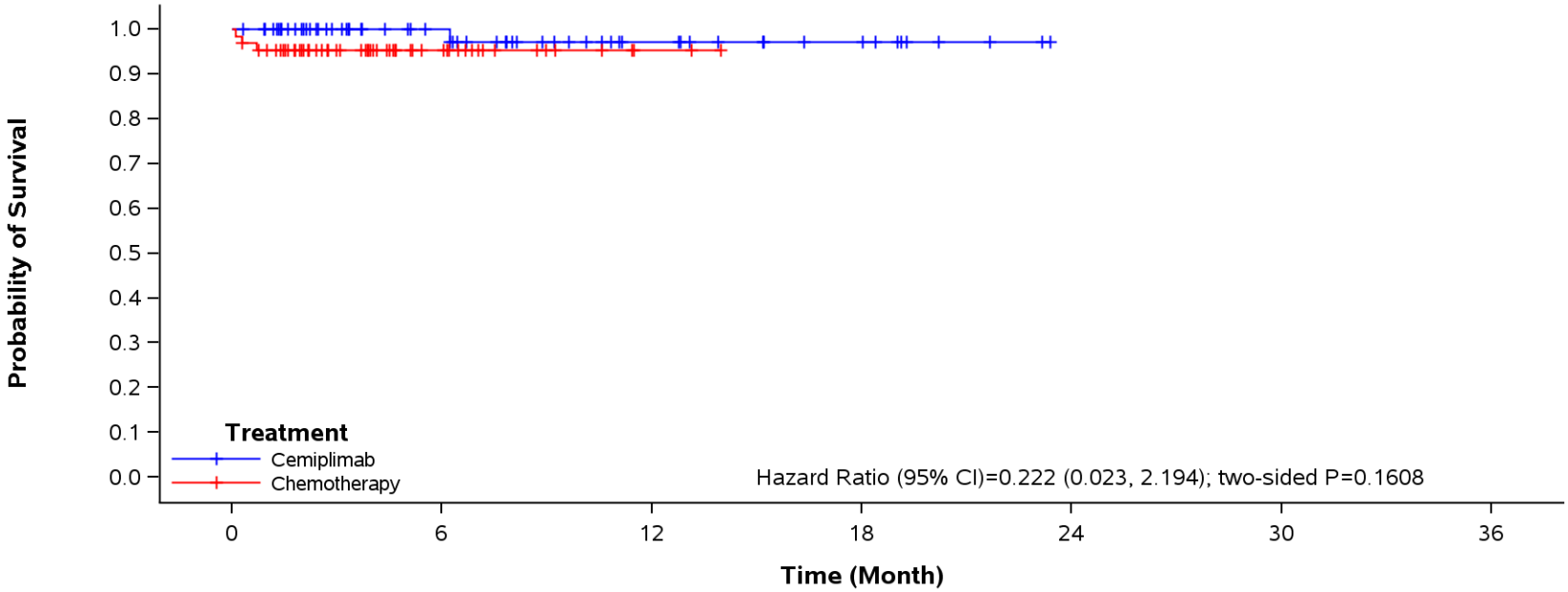

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 34 | 15 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders
PT: Stomatitis



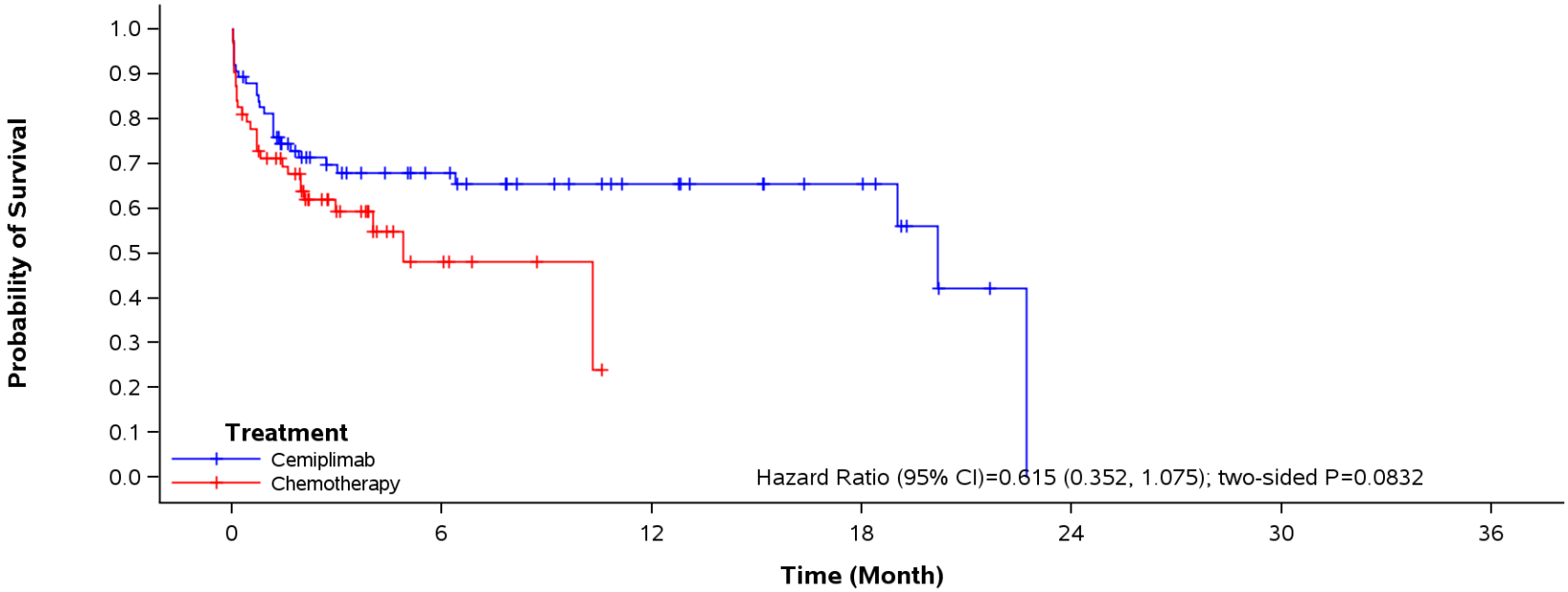

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 16 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: General disorders and administration site conditions



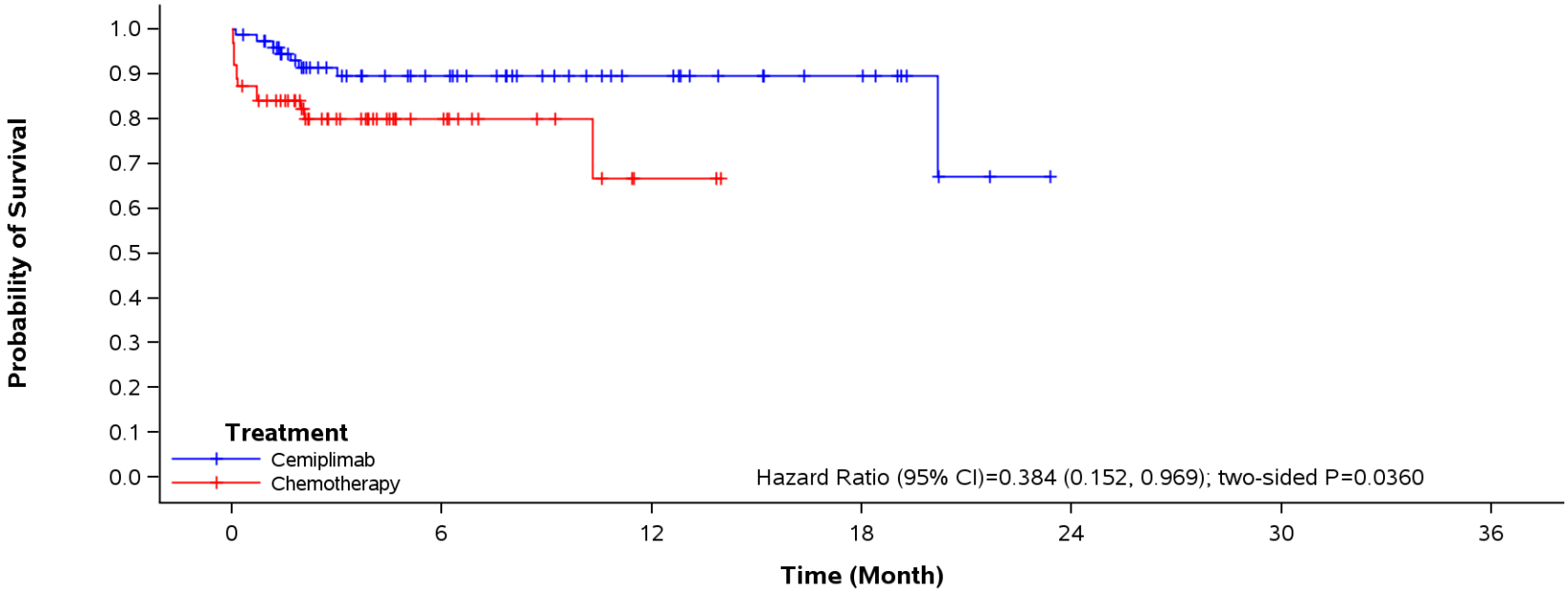

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 28 | 15 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: General disorders and administration site conditions
PT: Asthenia



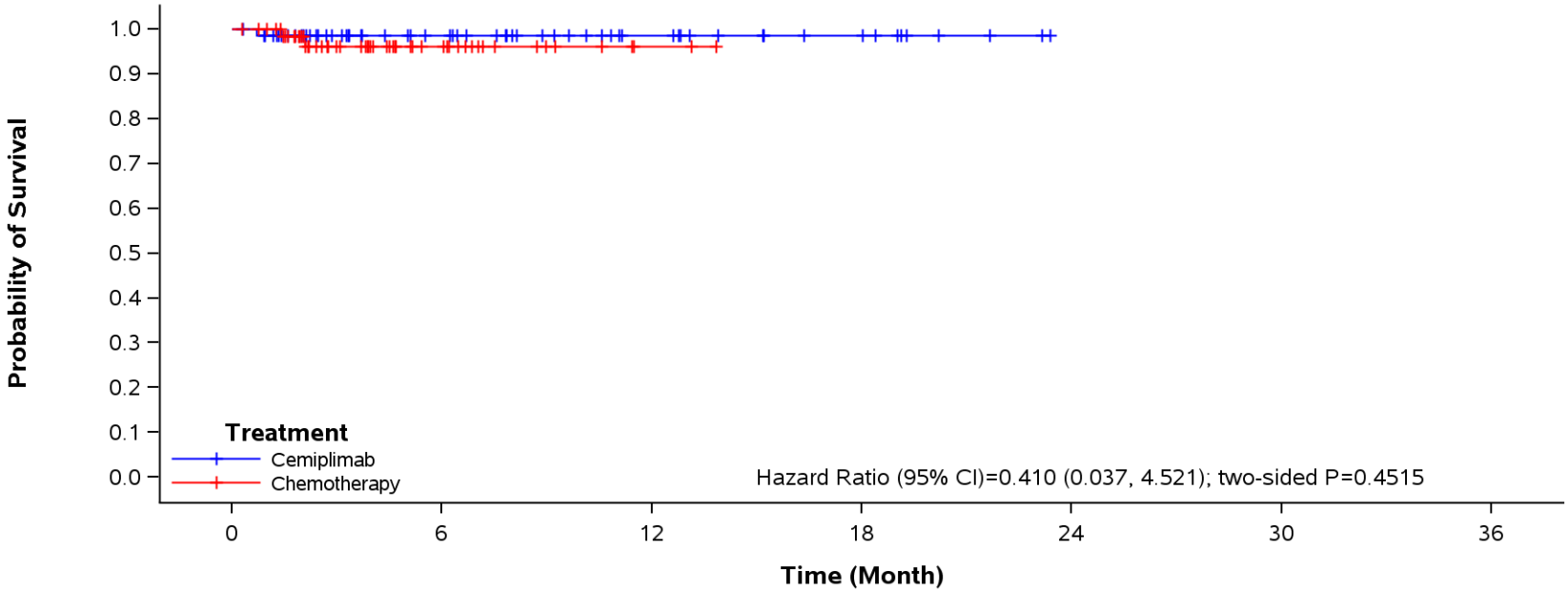

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 35 | 17 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



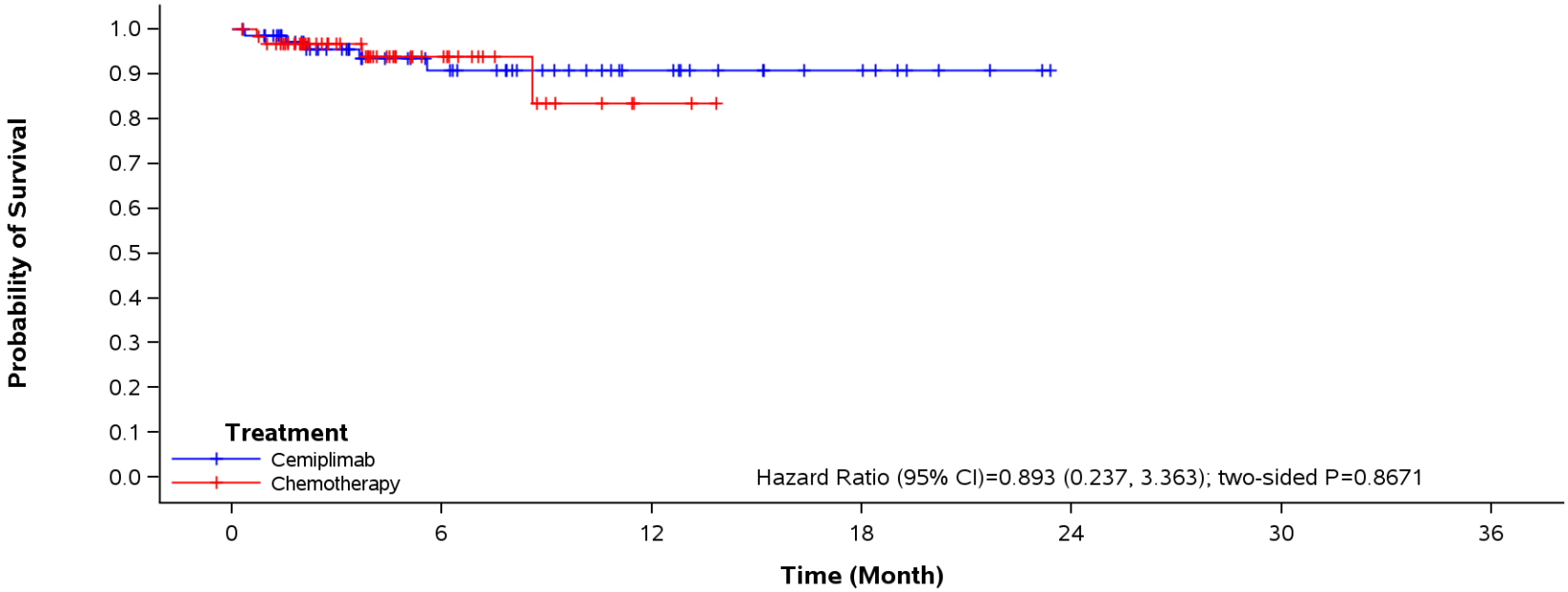

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 17 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Nervous system disorders



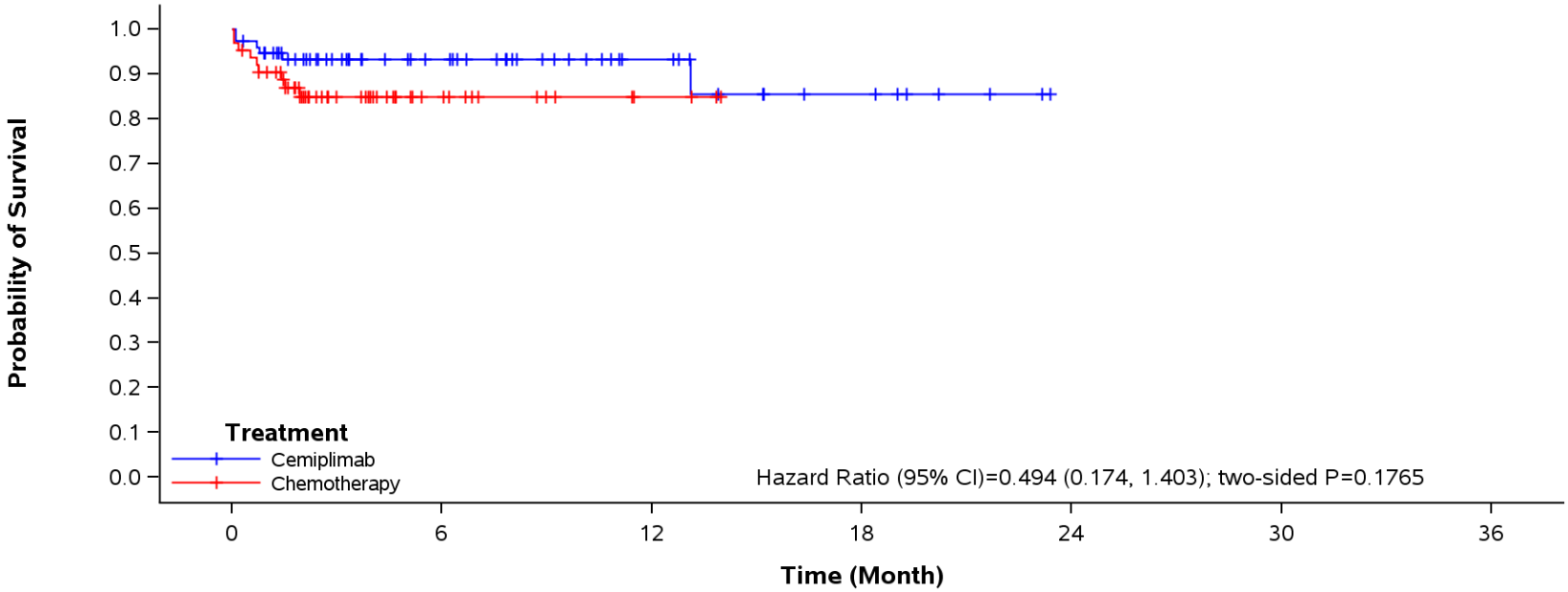

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 33 | 16 | 8 | 0 | 0 | 0 |
| Chemotherapy | 63 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Skin and subcutaneous tissue disorders



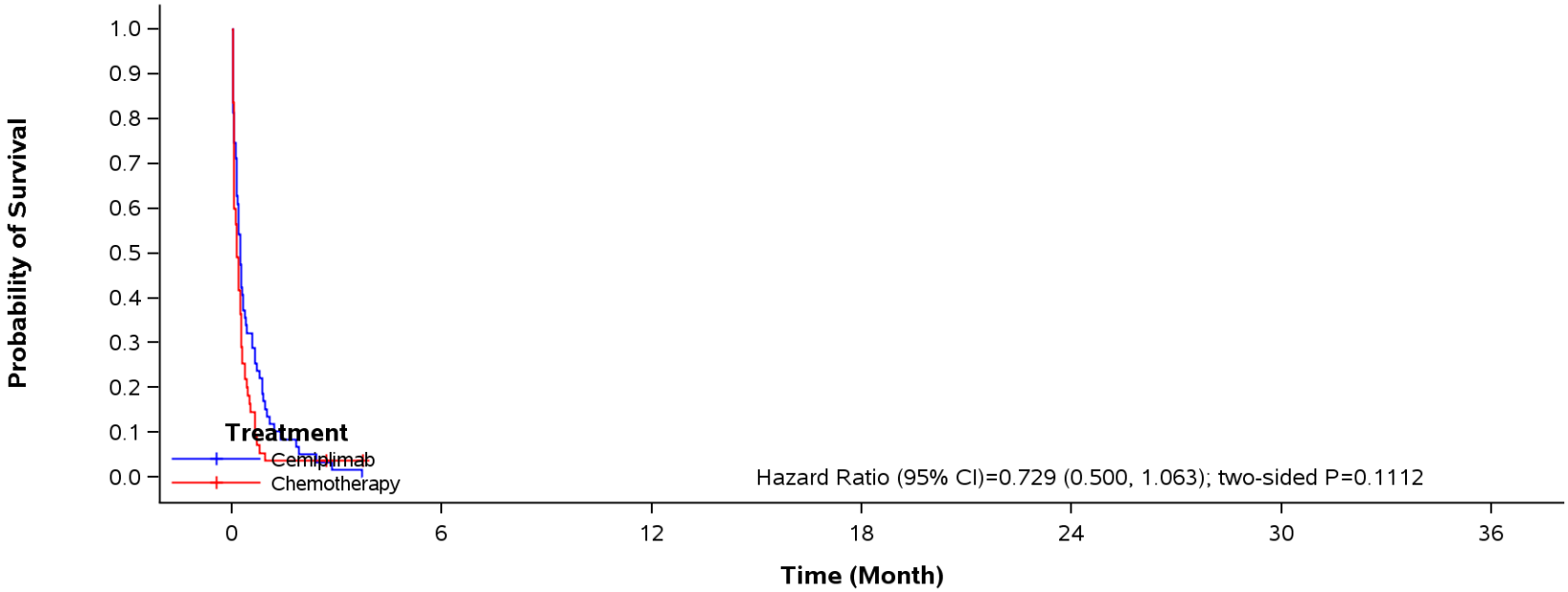

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 34 | 15 | 7 | 0 | 0 | 0 |
| Chemotherapy | 63 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Number of patients with any TEAE



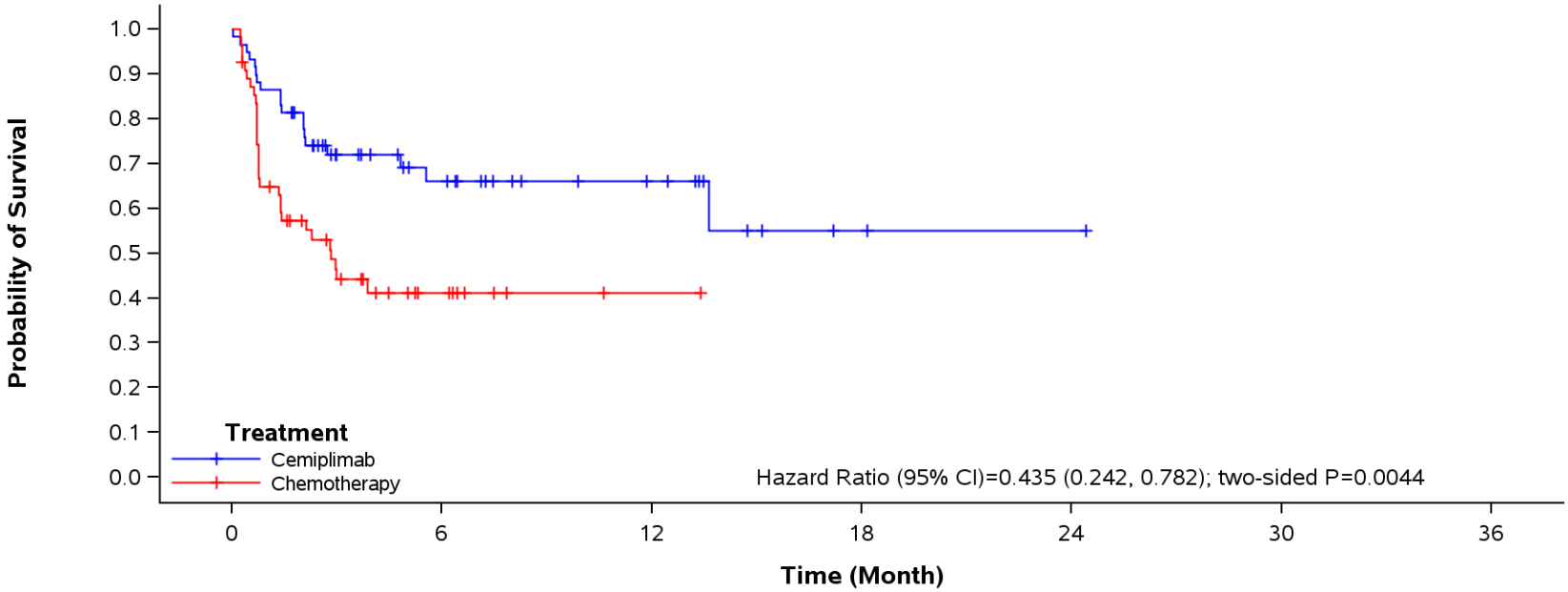

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 55 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders



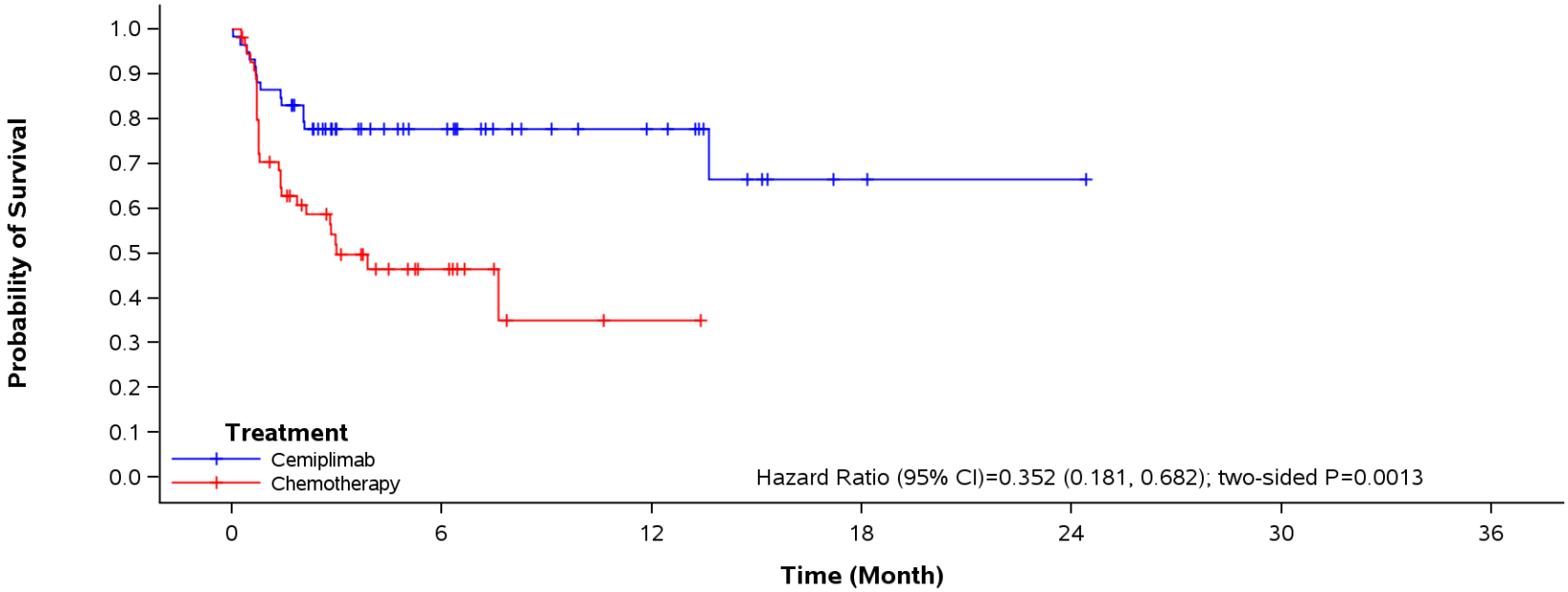

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 21 | 10 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Anaemia



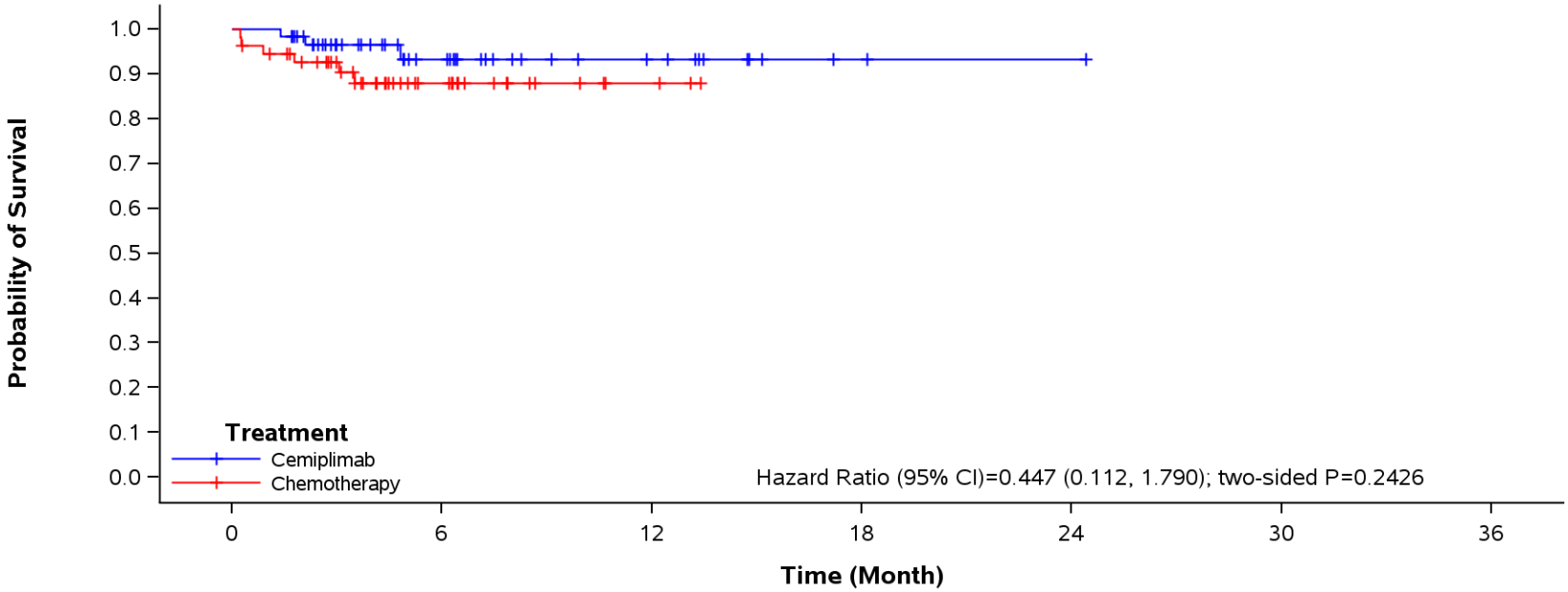

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 24 | 11 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Neutropenia



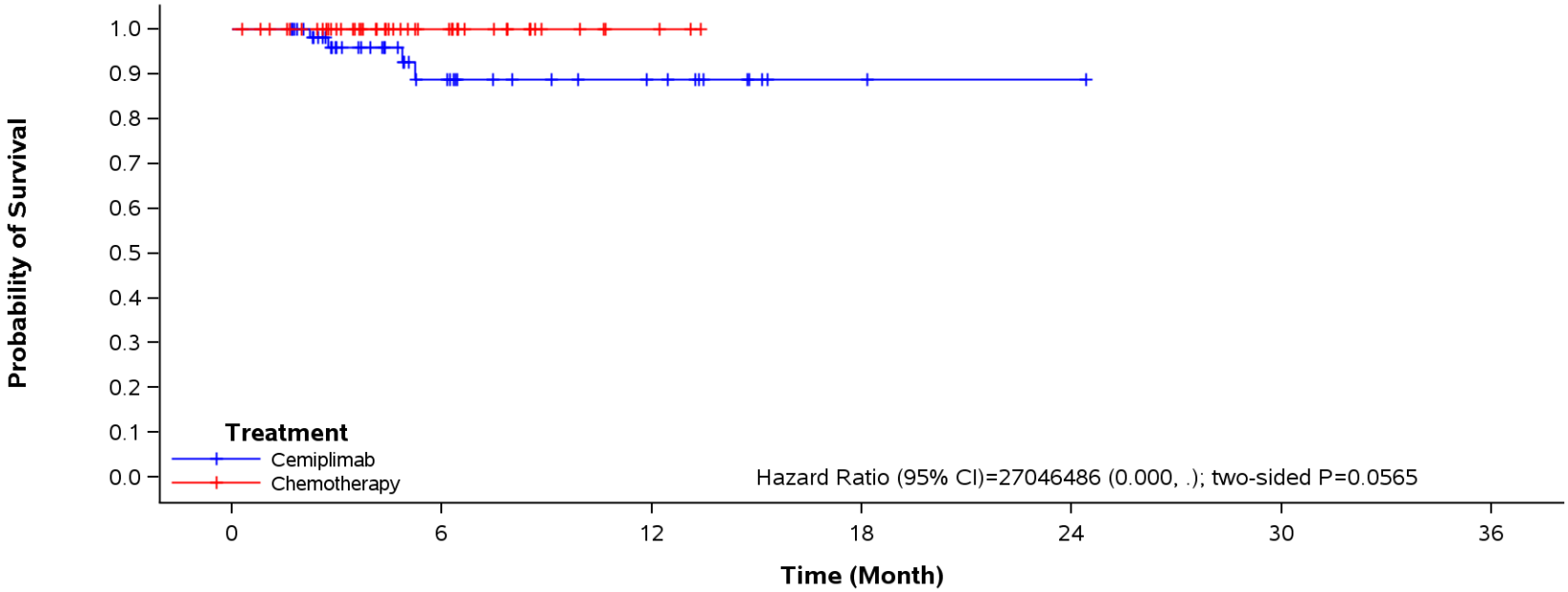

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 10 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Endocrine disorders



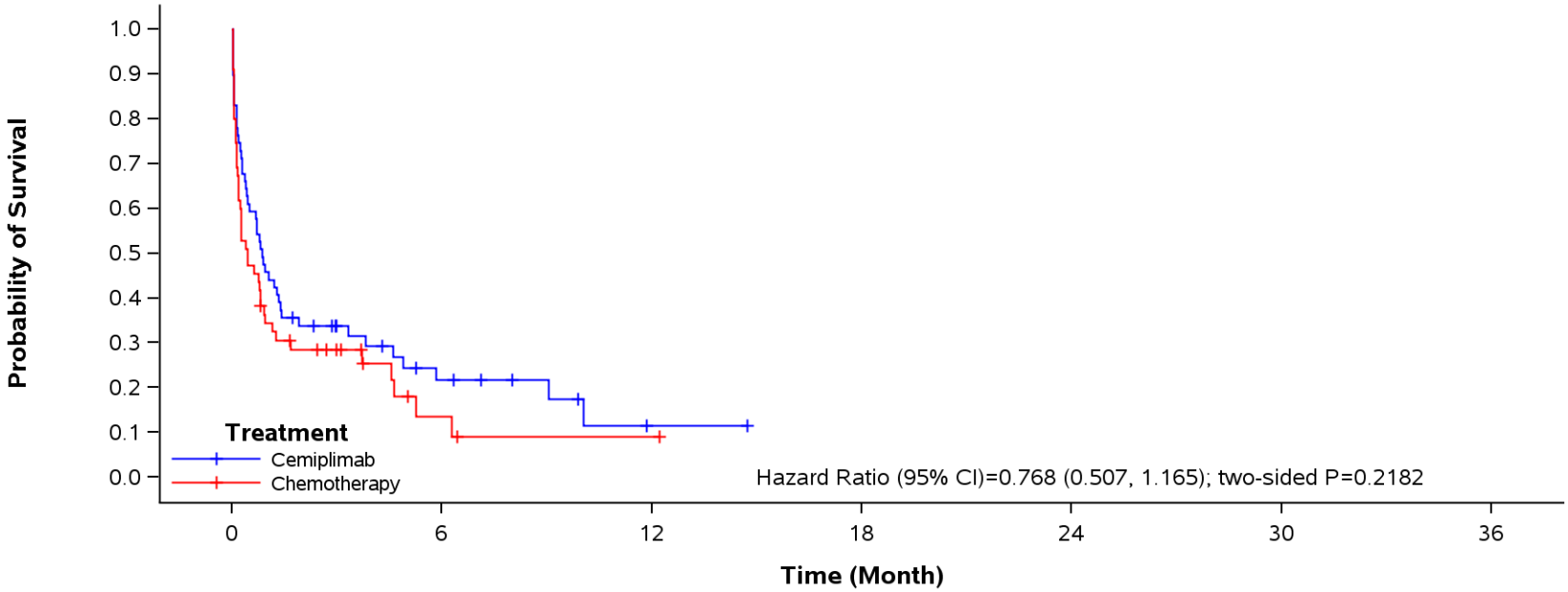

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 22 | 10 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders



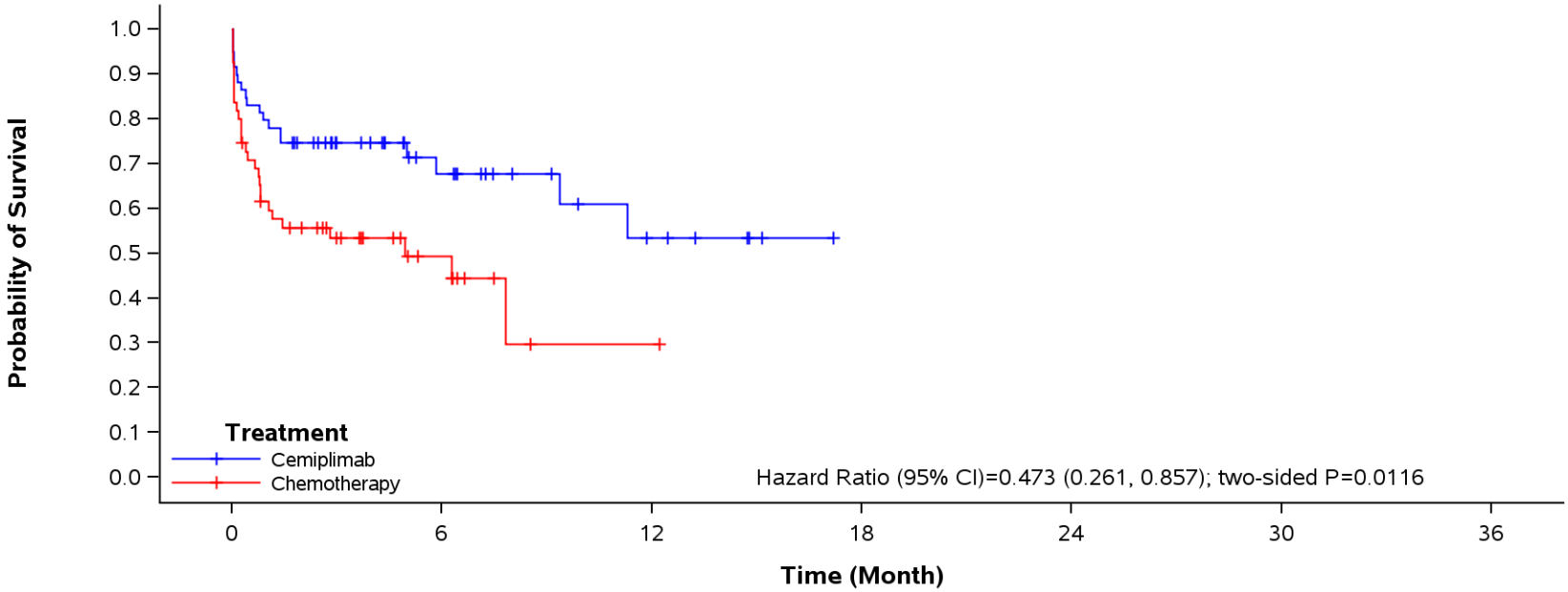

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 8 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 55 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders
PT: Nausea



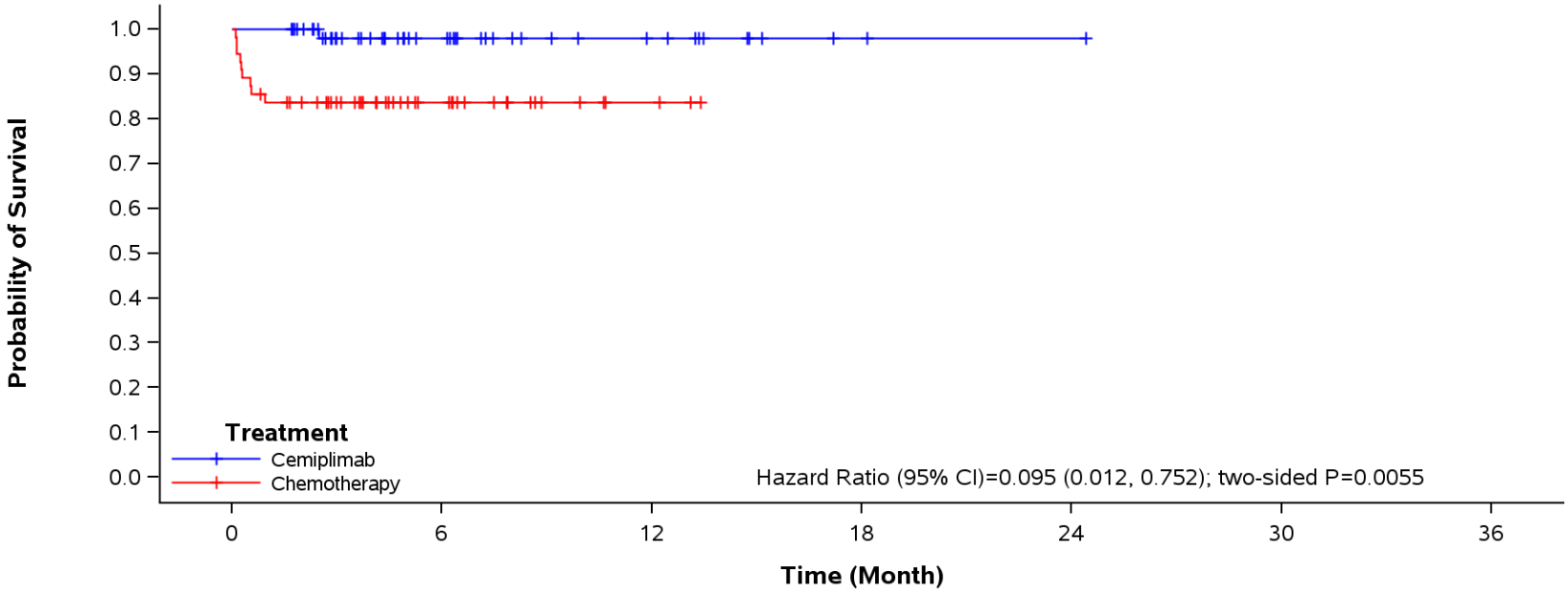

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 6 | 0 | 0 | 0 | 0 |
| Chemotherapy | 55 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders
PT: Stomatitis



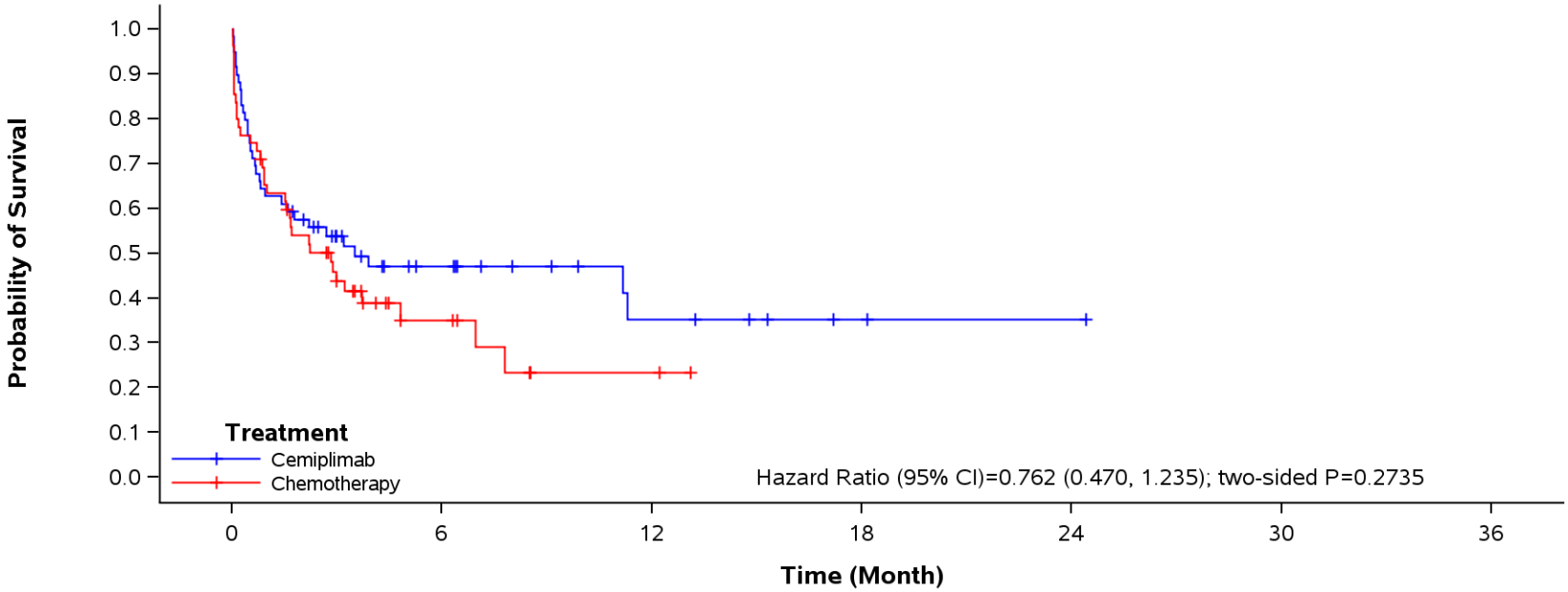

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 10 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: General disorders and administration site conditions



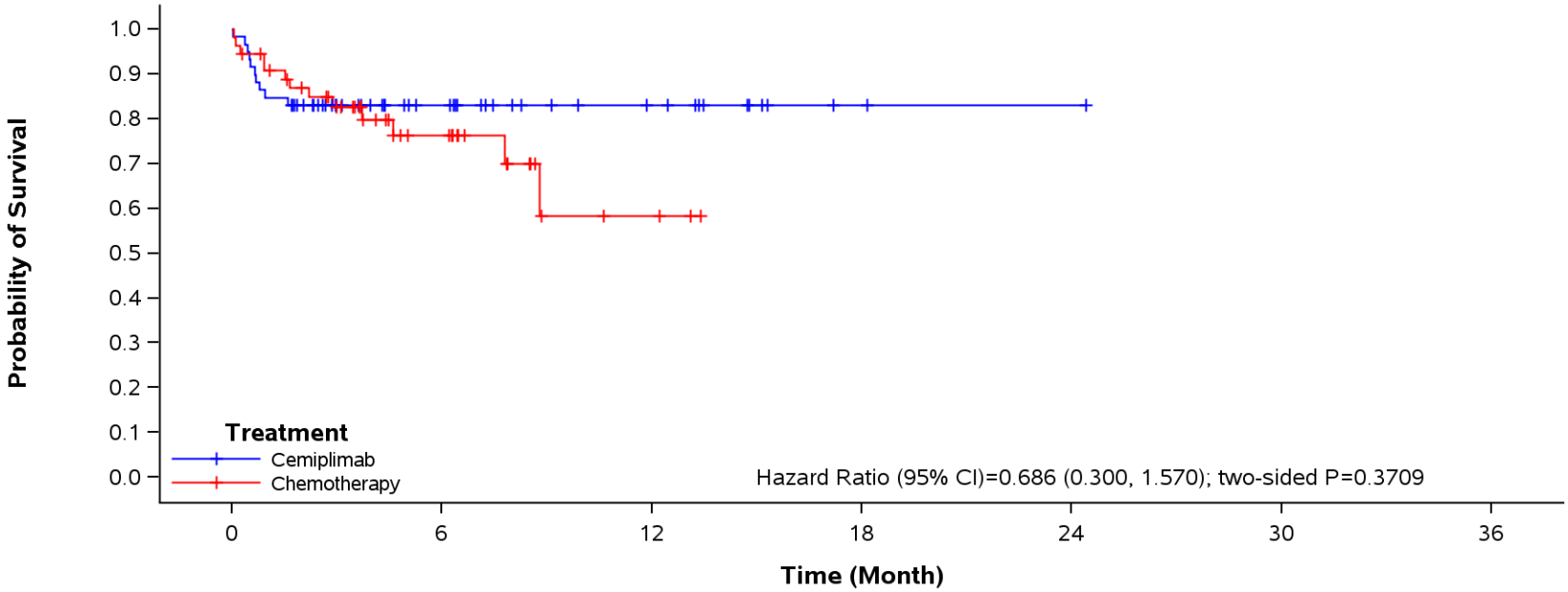

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 16 | 6 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: General disorders and administration site conditions
PT: Asthenia



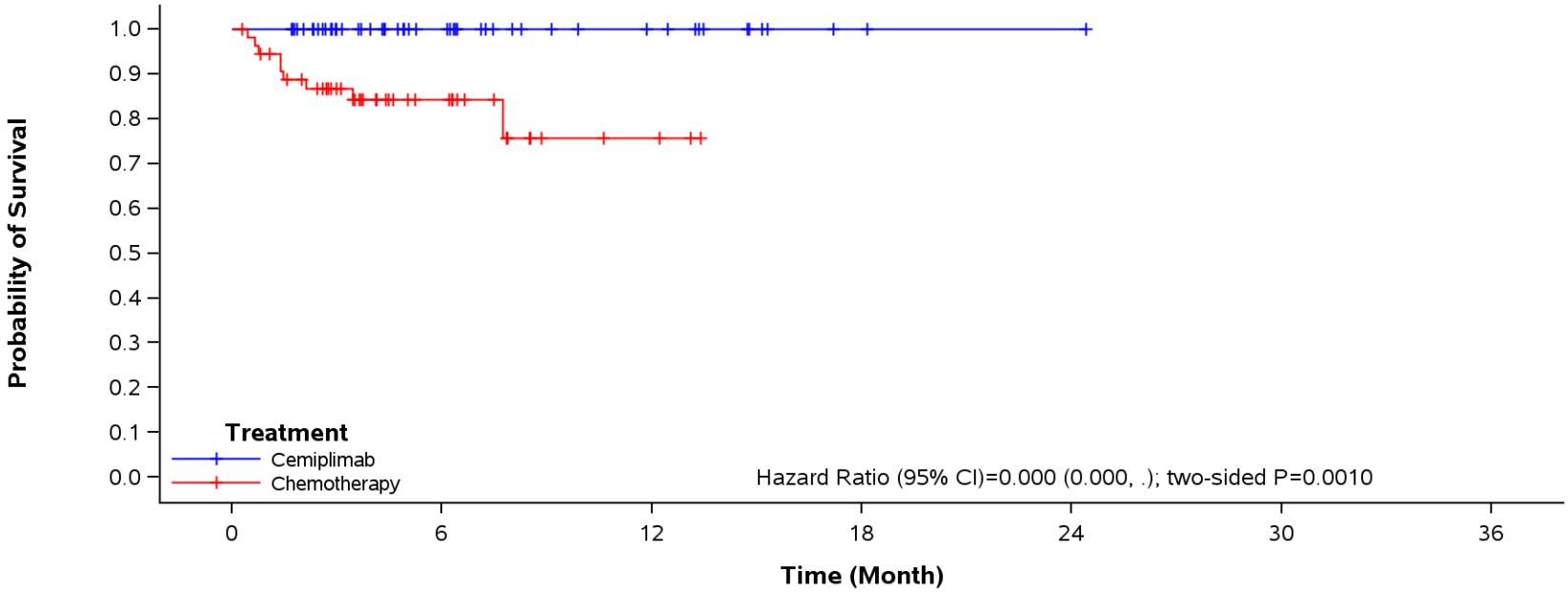

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 11 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



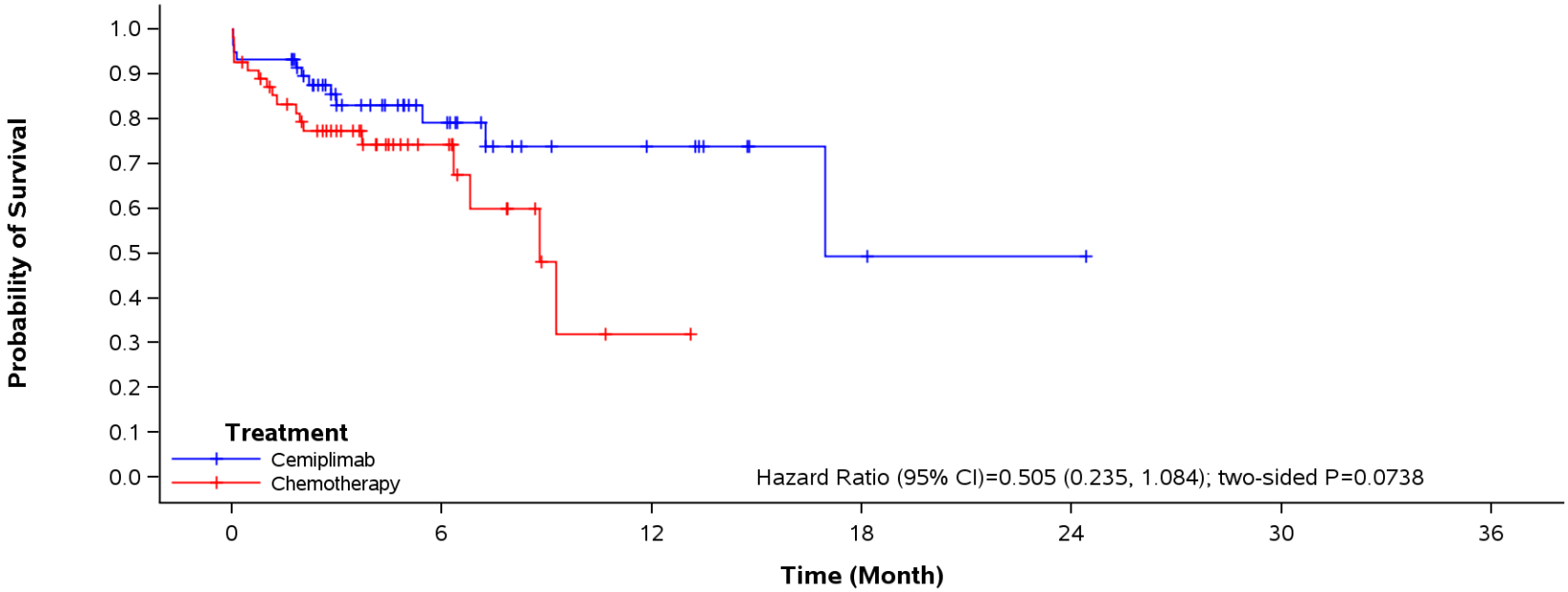

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 11 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Nervous system disorders



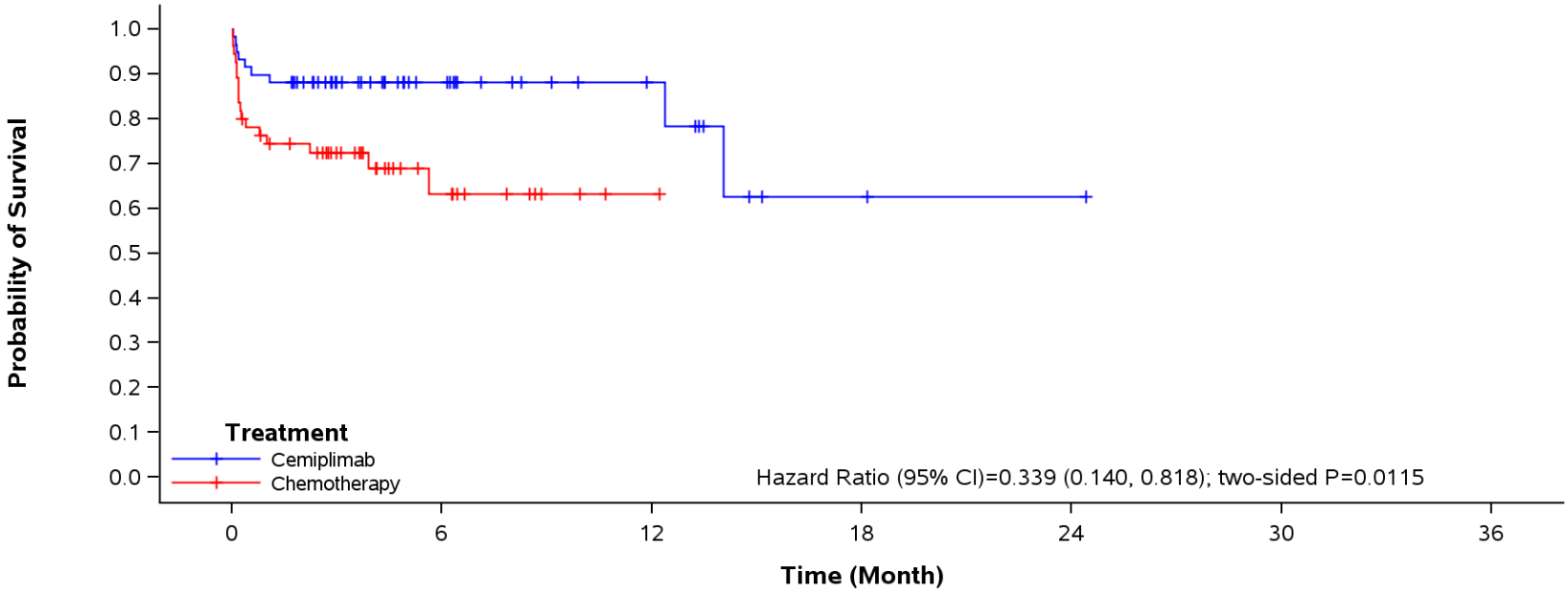

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 8 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Skin and subcutaneous tissue disorders



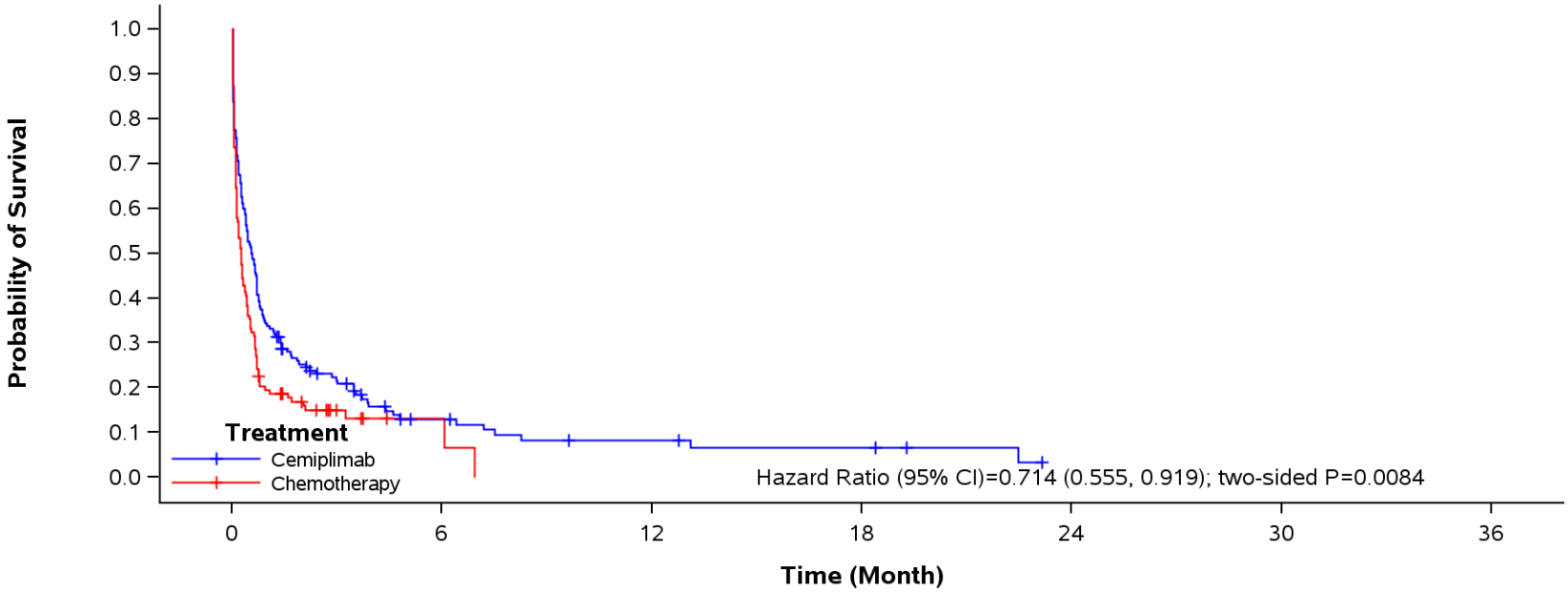

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 22 | 9 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Number of patients with any TEAE



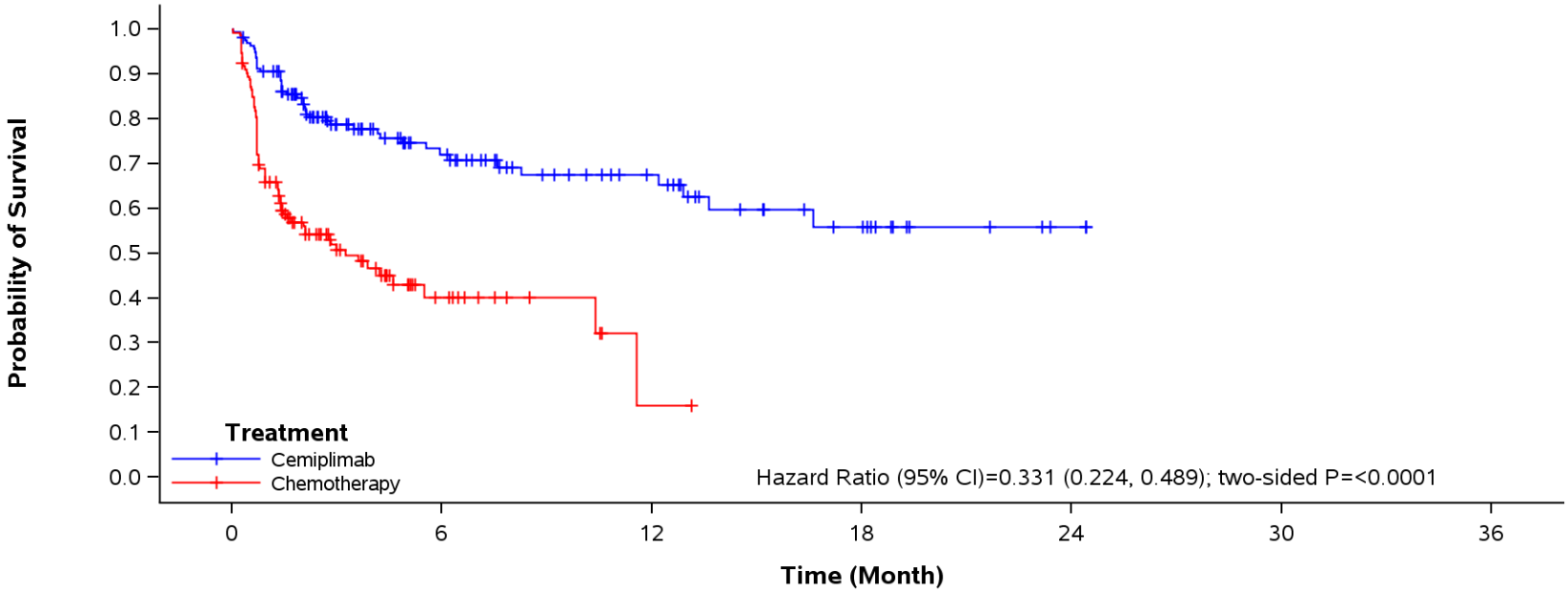

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 12 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 133 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders



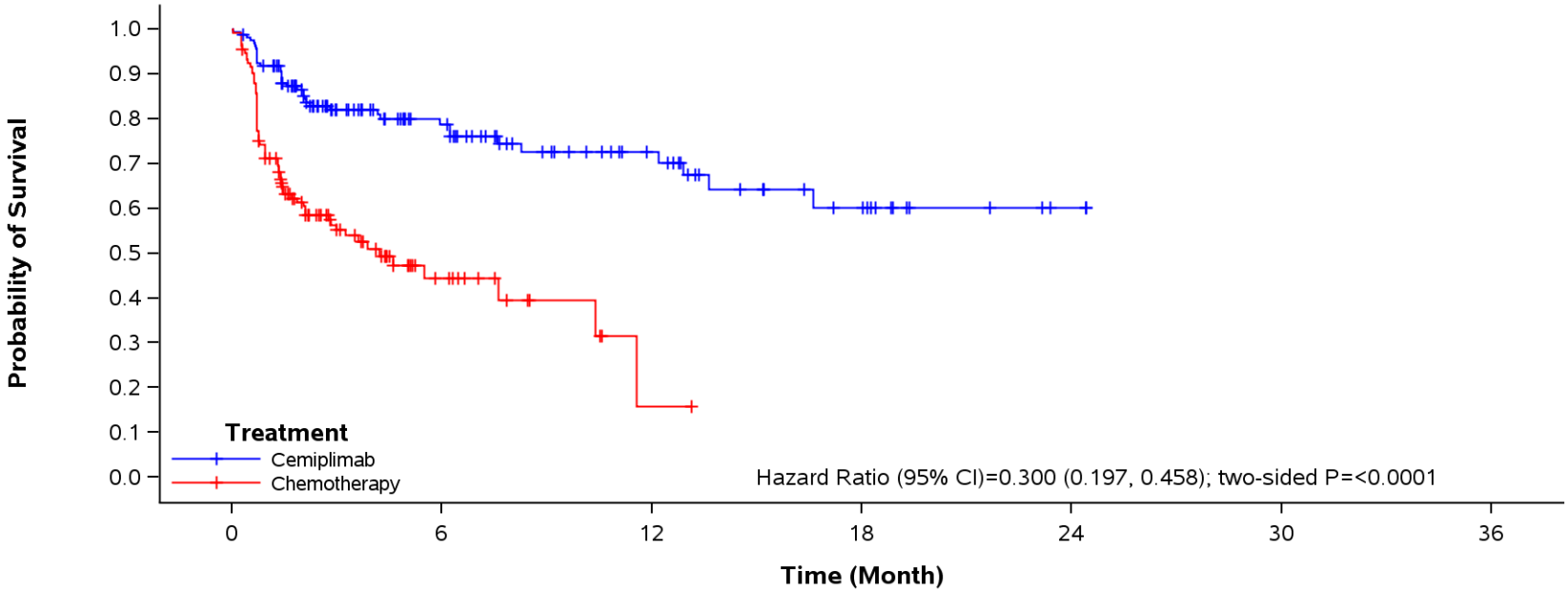

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 58 | 30 | 14 | 3 | 0 | 0 |
| Chemotherapy | 133 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



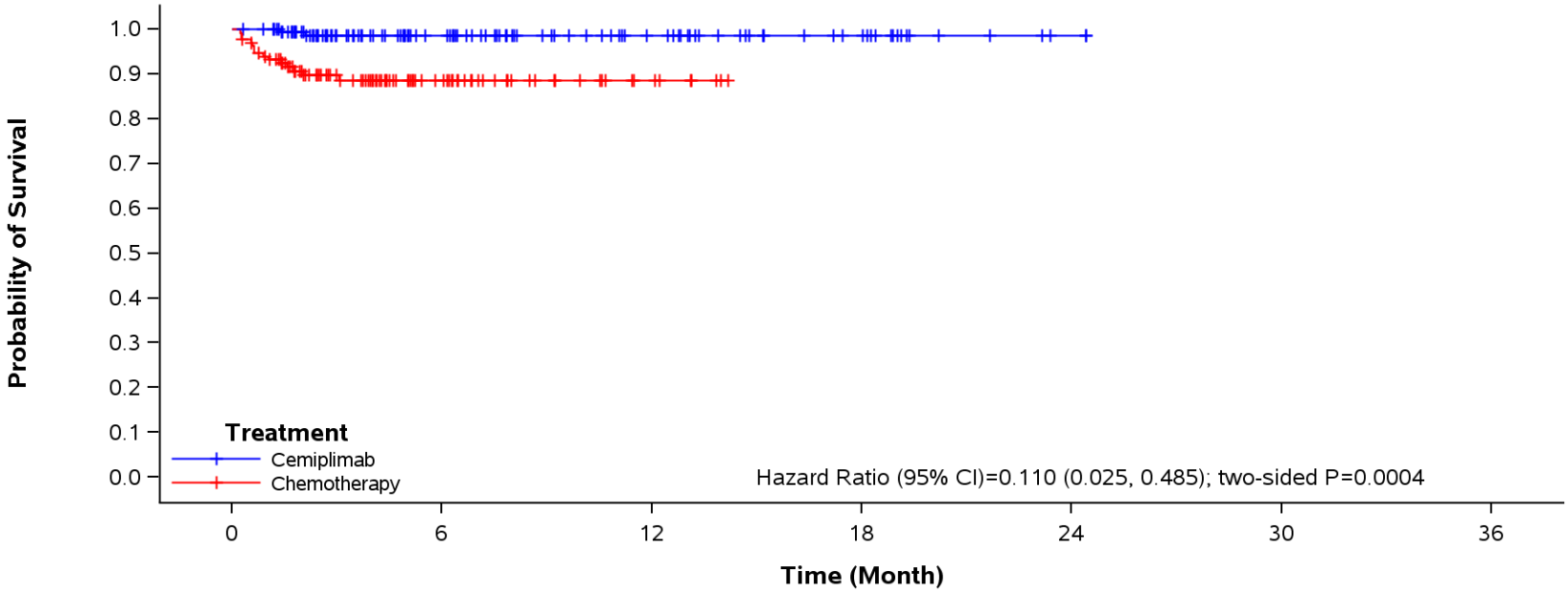

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 62 | 30 | 14 | 3 | 0 | 0 |
| Chemotherapy | 133 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



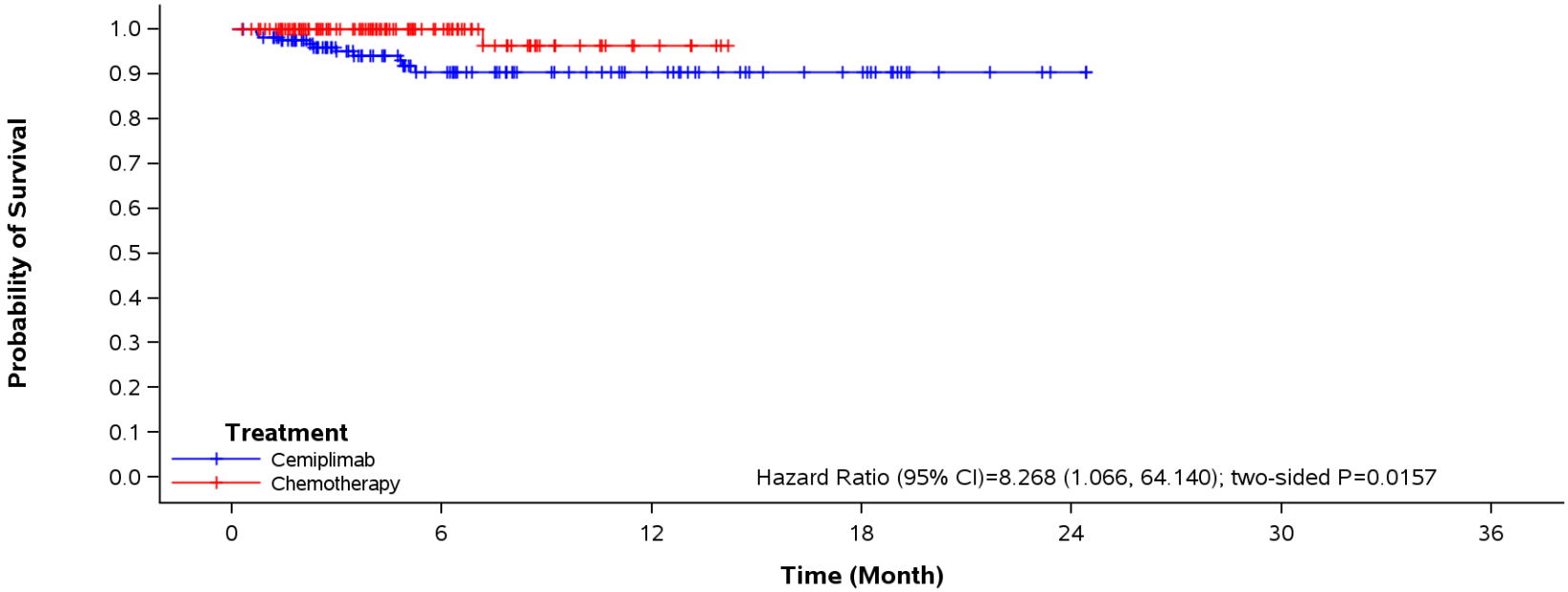

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 36 | 19 | 3 | 0 | 0 |
| Chemotherapy | 133 | 36 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Endocrine disorders



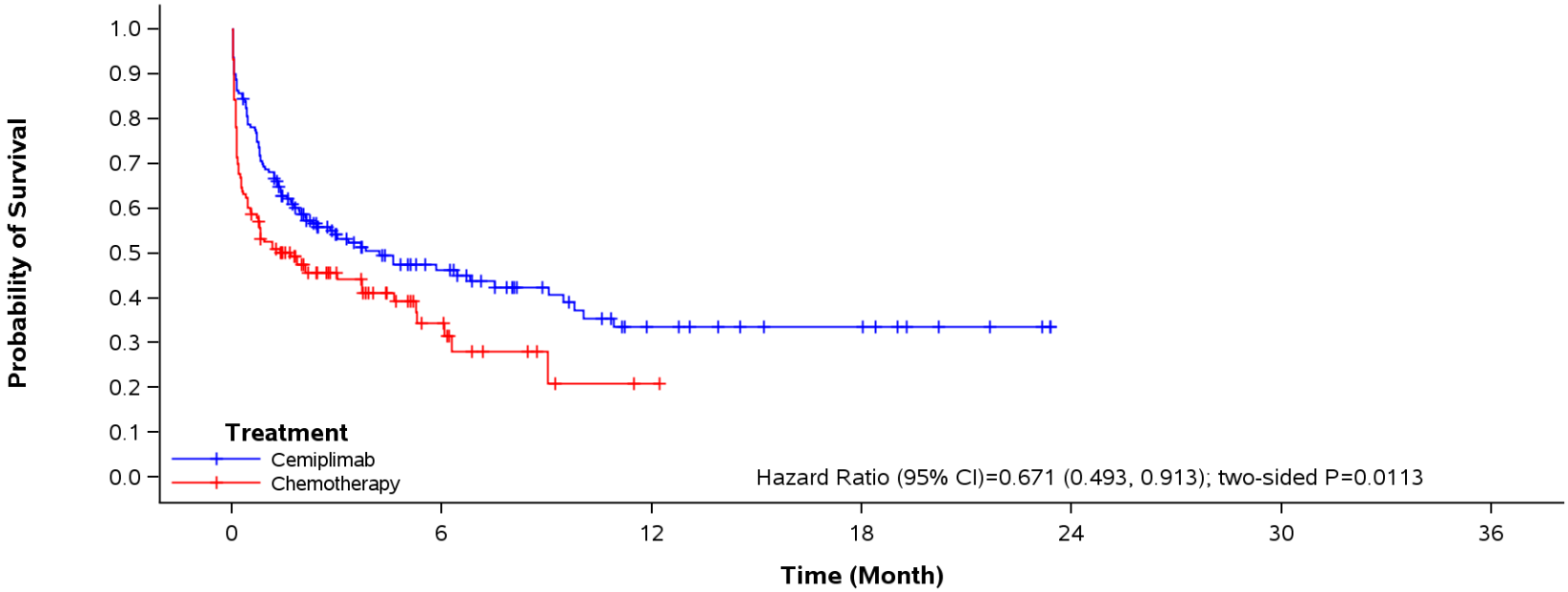

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 66 | 33 | 19 | 3 | 0 | 0 |
| Chemotherapy | 133 | 41 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders



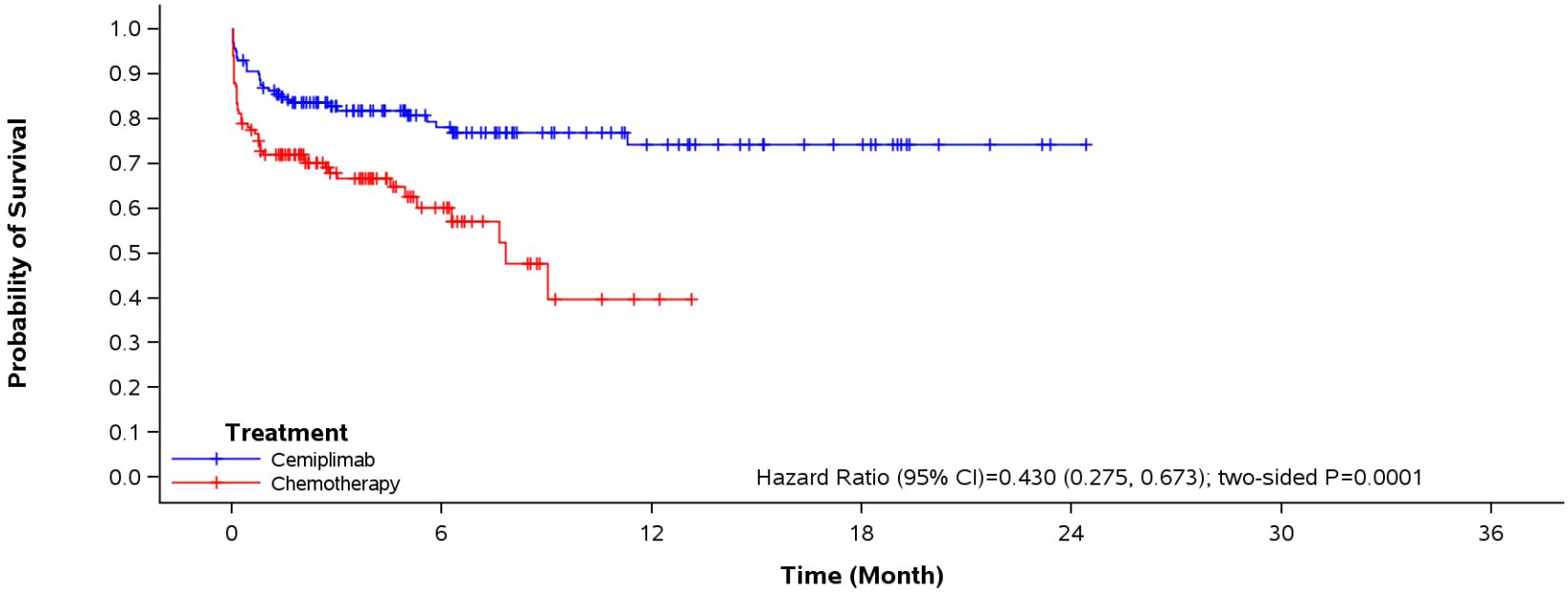

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 40 | 14 | 9 | 0 | 0 | 0 |
| Chemotherapy | 133 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders
PT: Nausea



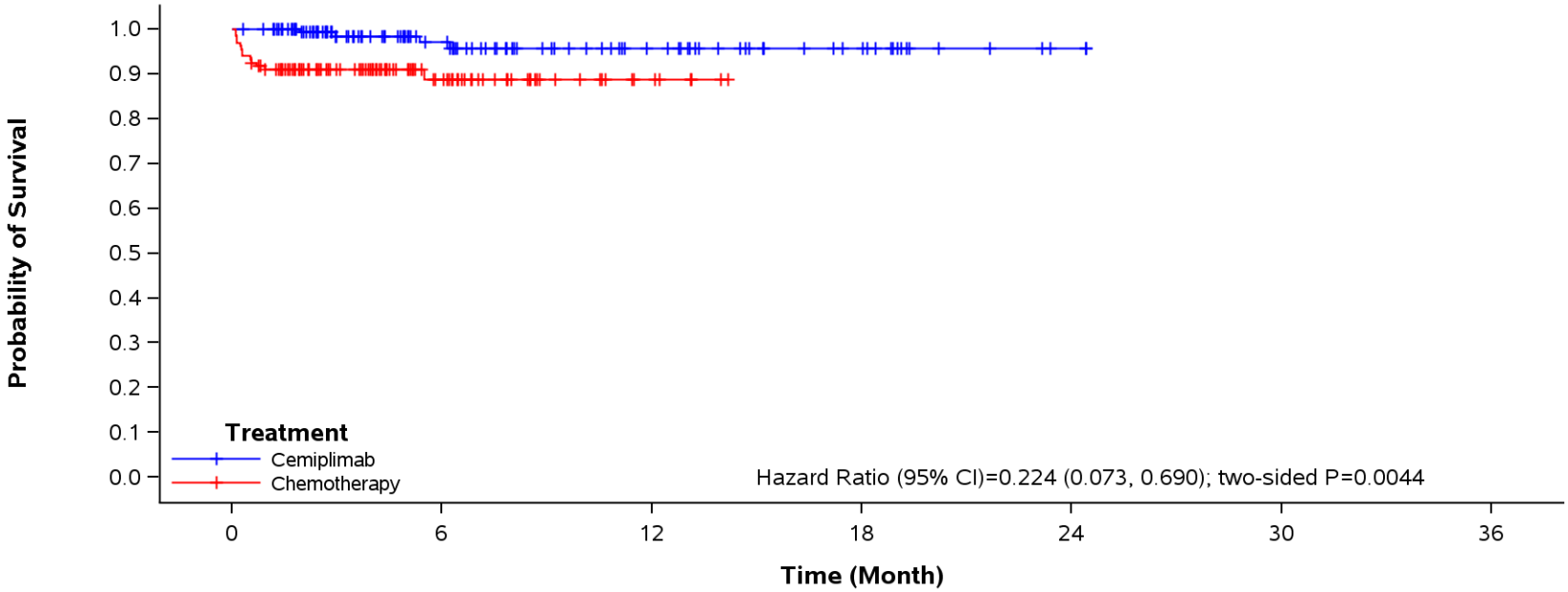

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 61 | 27 | 15 | 1 | 0 | 0 |
| Chemotherapy | 133 | 23 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders
PT: Stomatitis



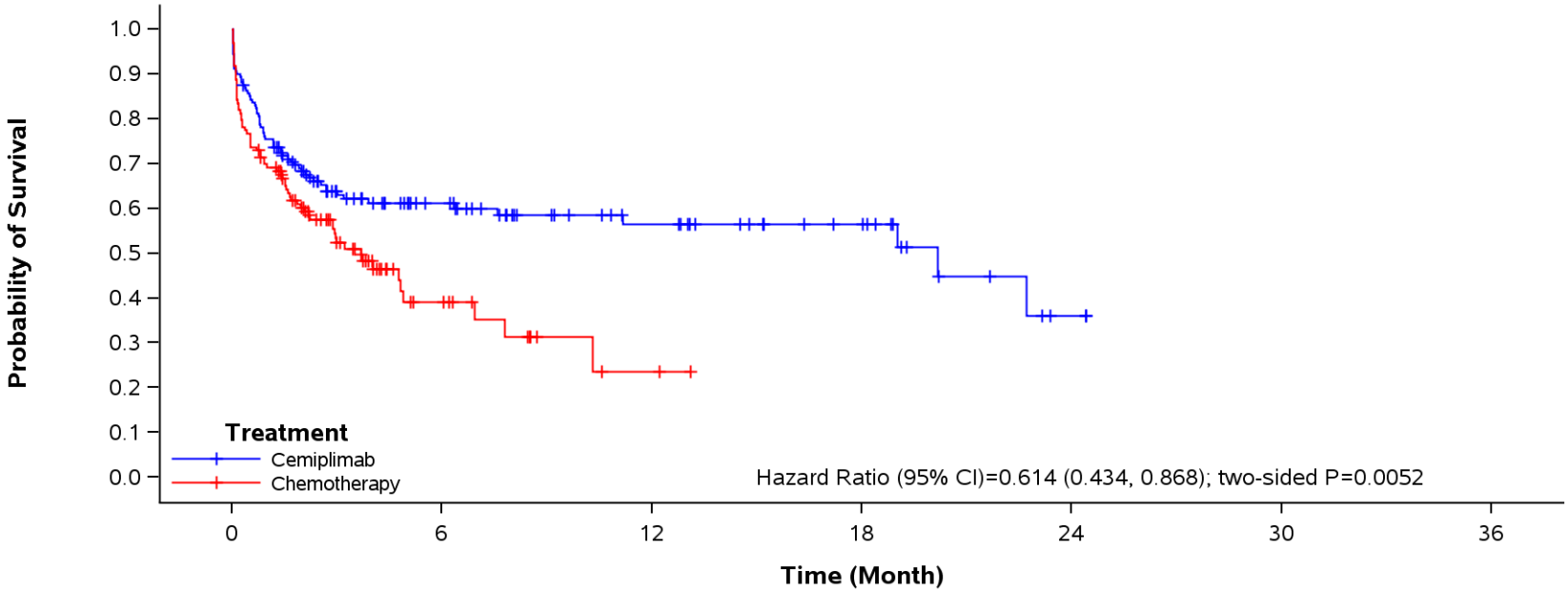

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 71 | 34 | 18 | 3 | 0 | 0 |
| Chemotherapy | 133 | 37 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: General disorders and administration site conditions



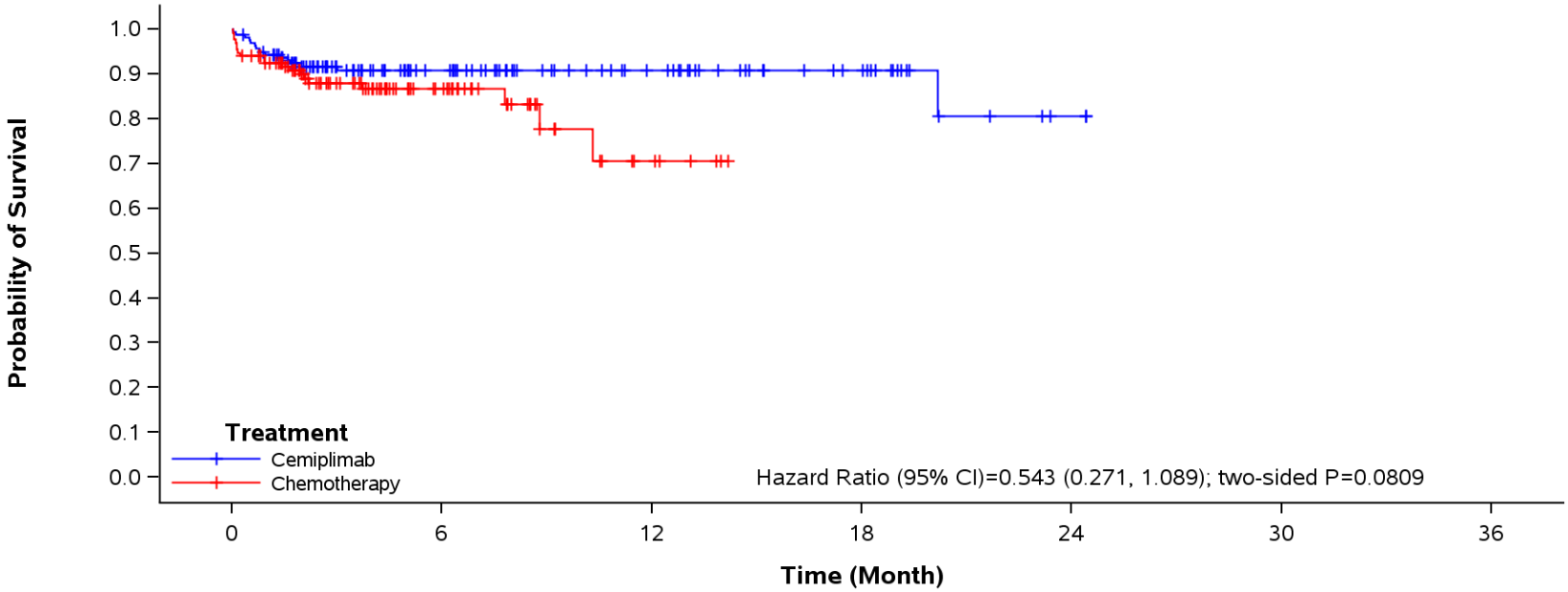

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 52 | 27 | 16 | 2 | 0 | 0 |
| Chemotherapy | 133 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: General disorders and administration site conditions
PT: Asthenia



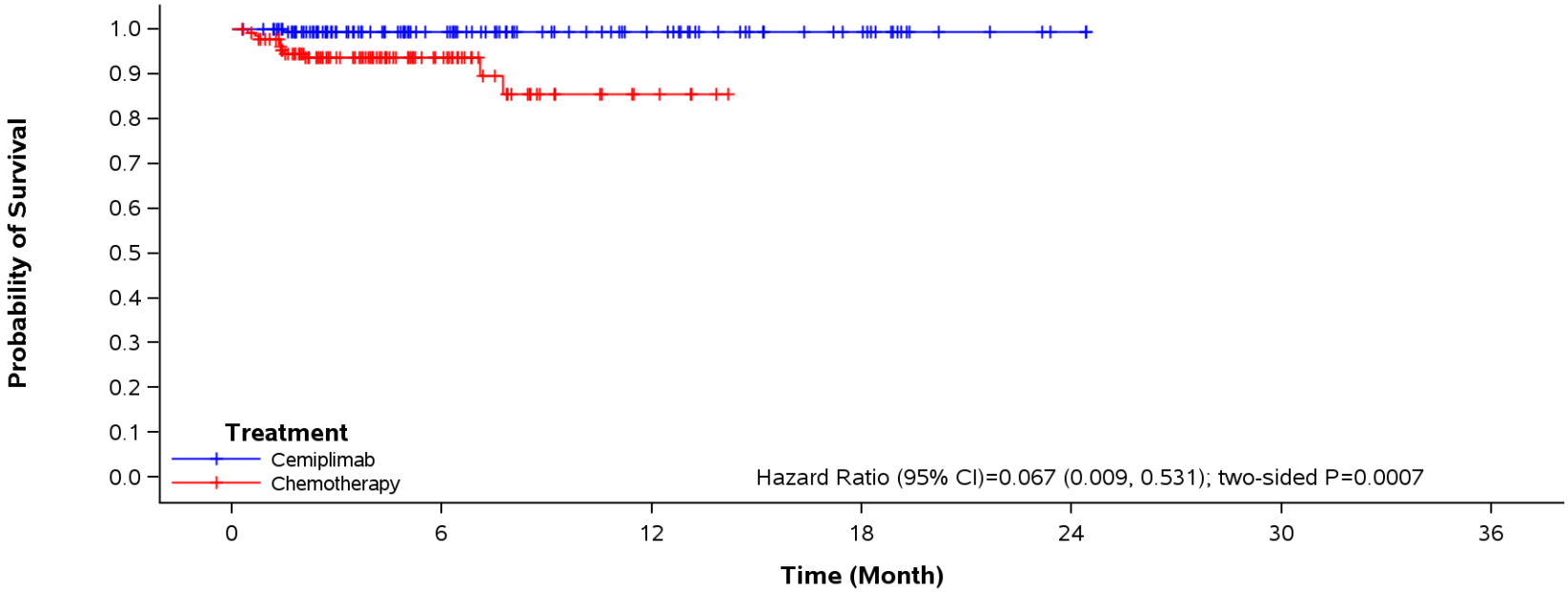

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 71 | 36 | 19 | 3 | 0 | 0 |
| Chemotherapy | 133 | 38 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



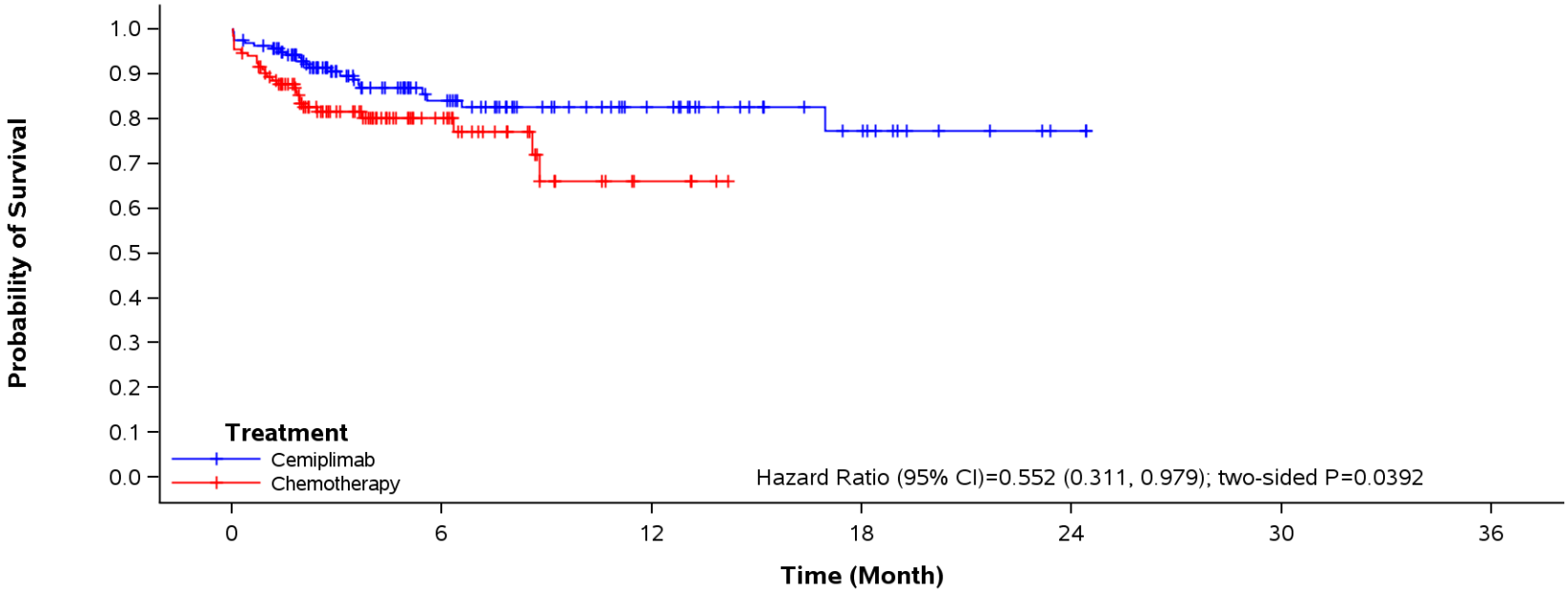

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 36 | 19 | 3 | 0 | 0 |
| Chemotherapy | 133 | 37 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Nervous system disorders



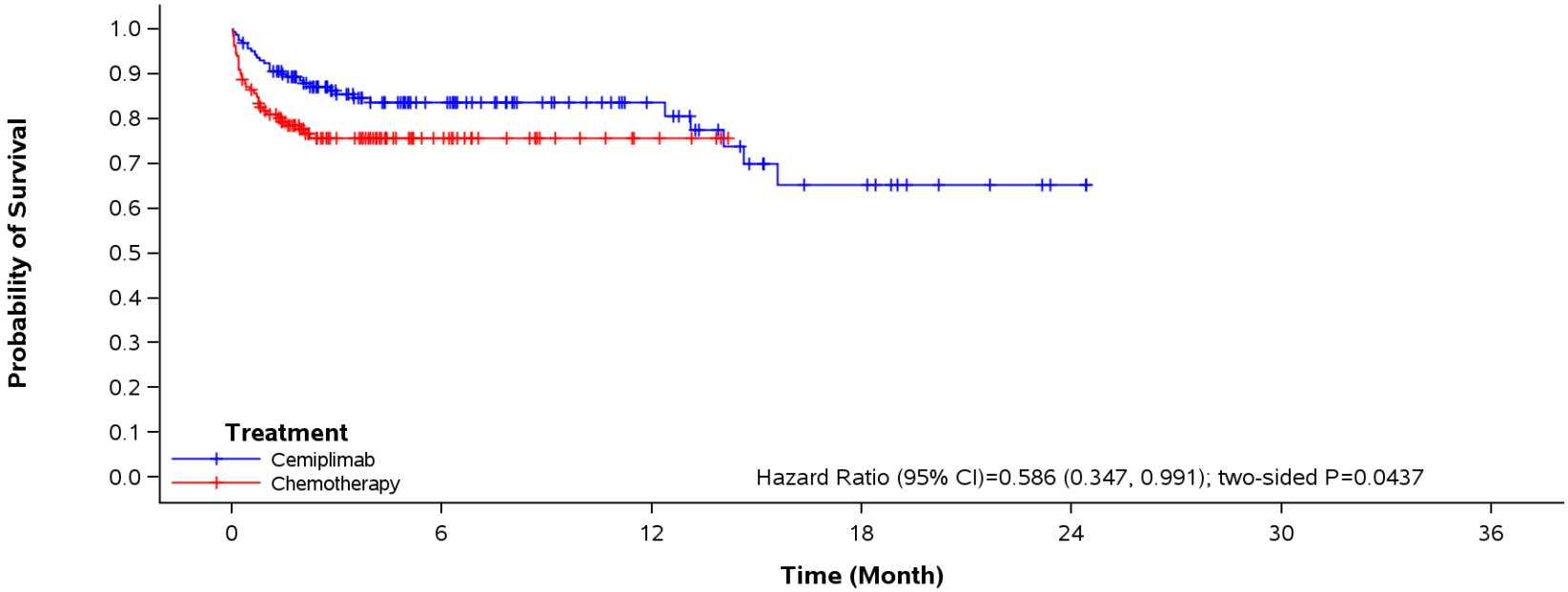

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 61 | 29 | 14 | 2 | 0 | 0 |
| Chemotherapy | 133 | 32 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Skin and subcutaneous tissue disorders



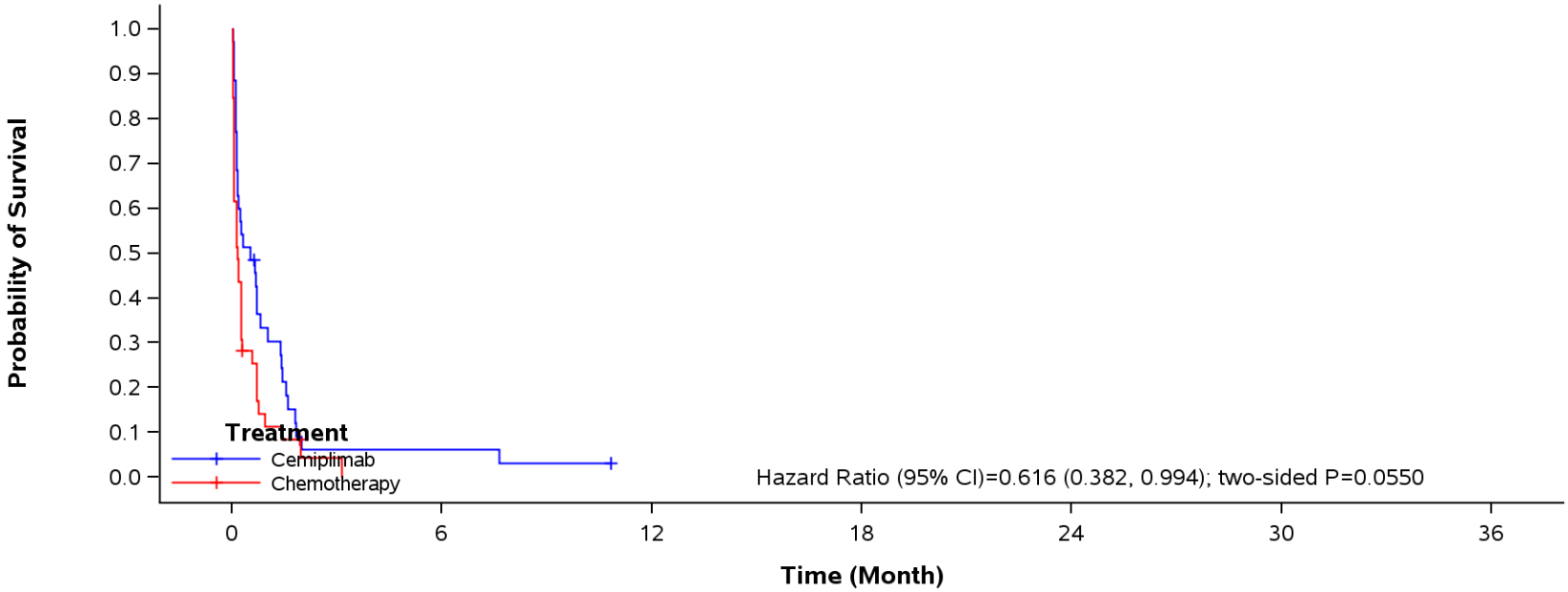

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 62 | 29 | 13 | 2 | 0 | 0 |
| Chemotherapy | 133 | 25 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Number of patients with any TEAE



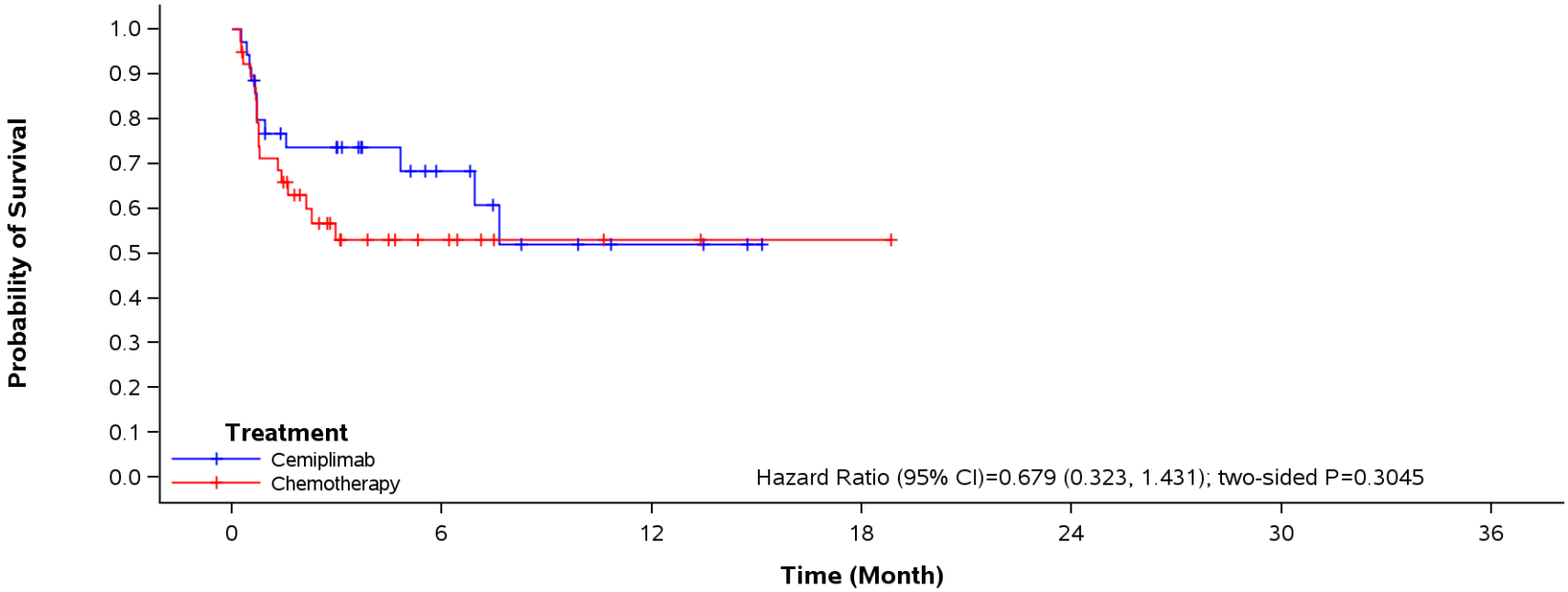

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 39 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders



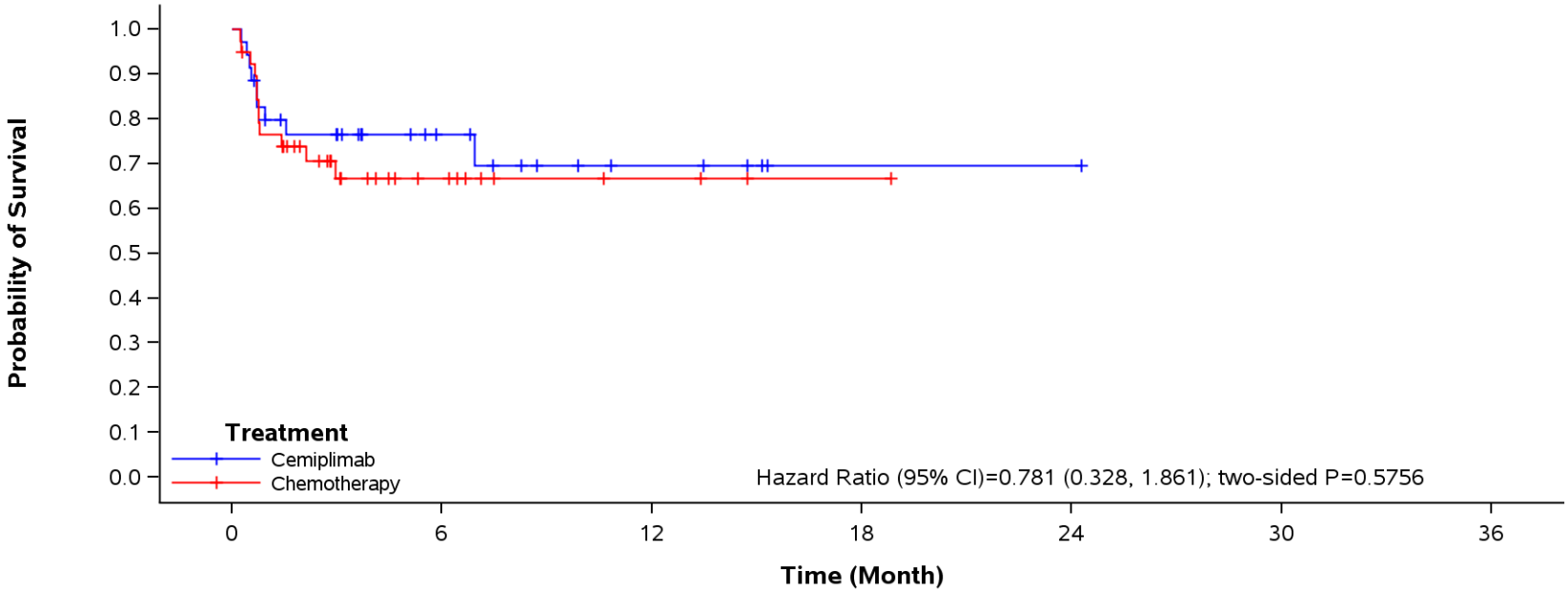

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 39 | 7 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



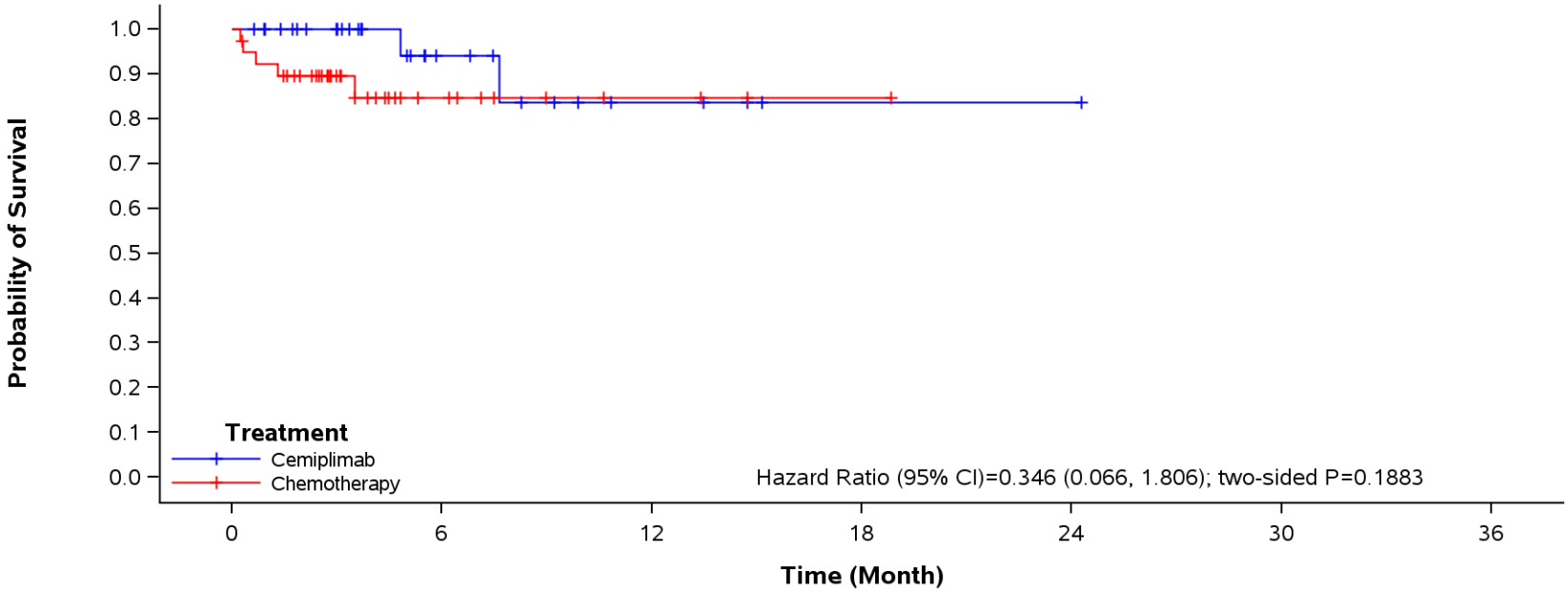

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 9 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



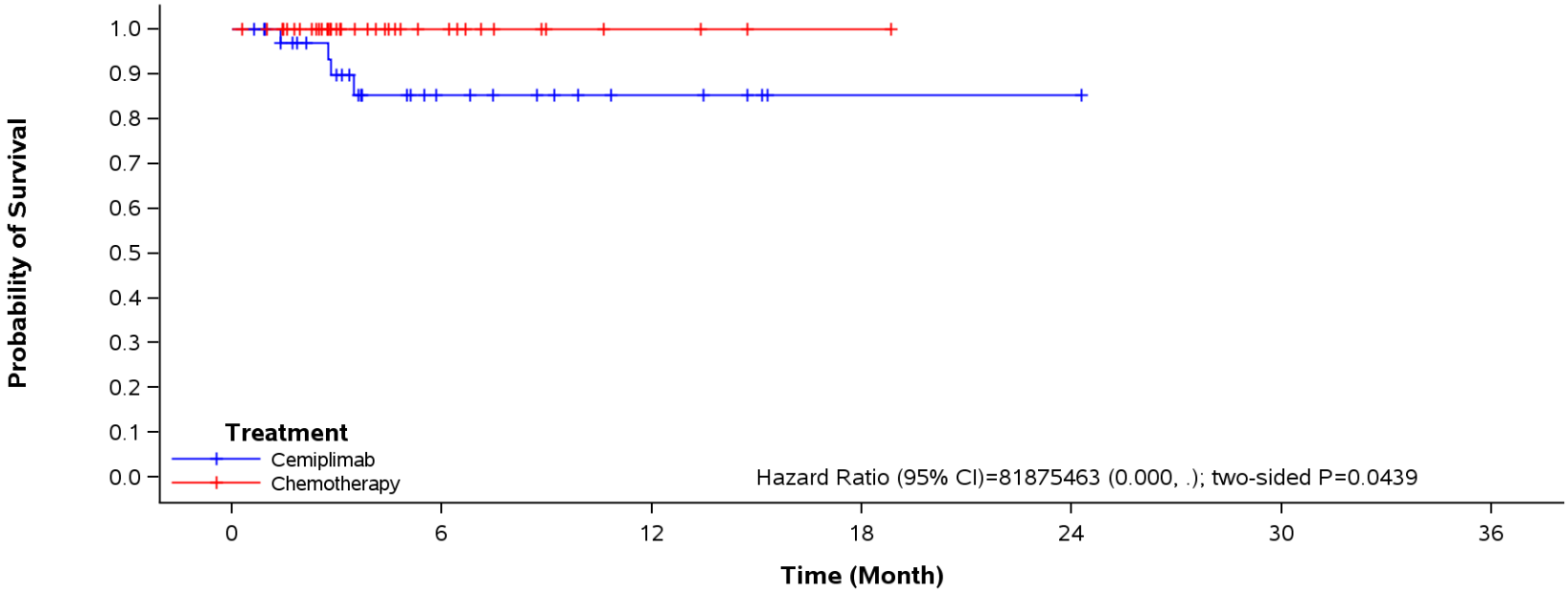

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 9 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Endocrine disorders



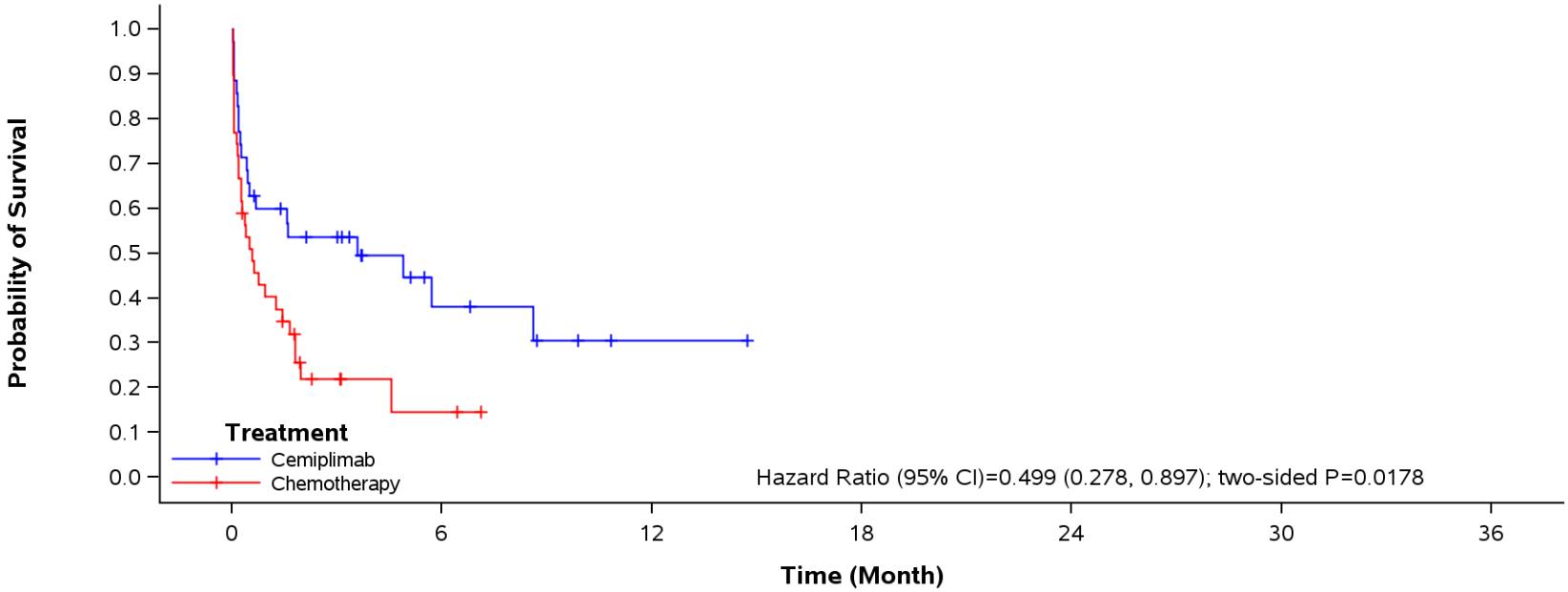

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders



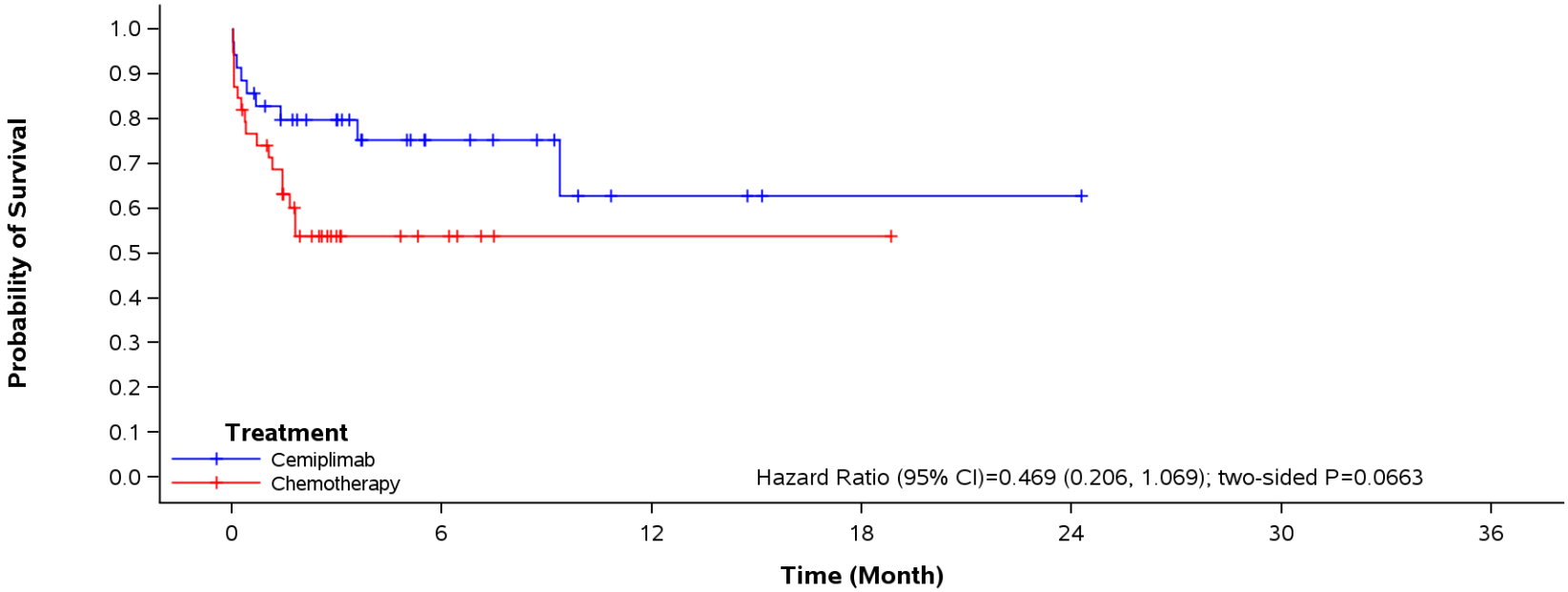

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 39 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders
PT: Nausea



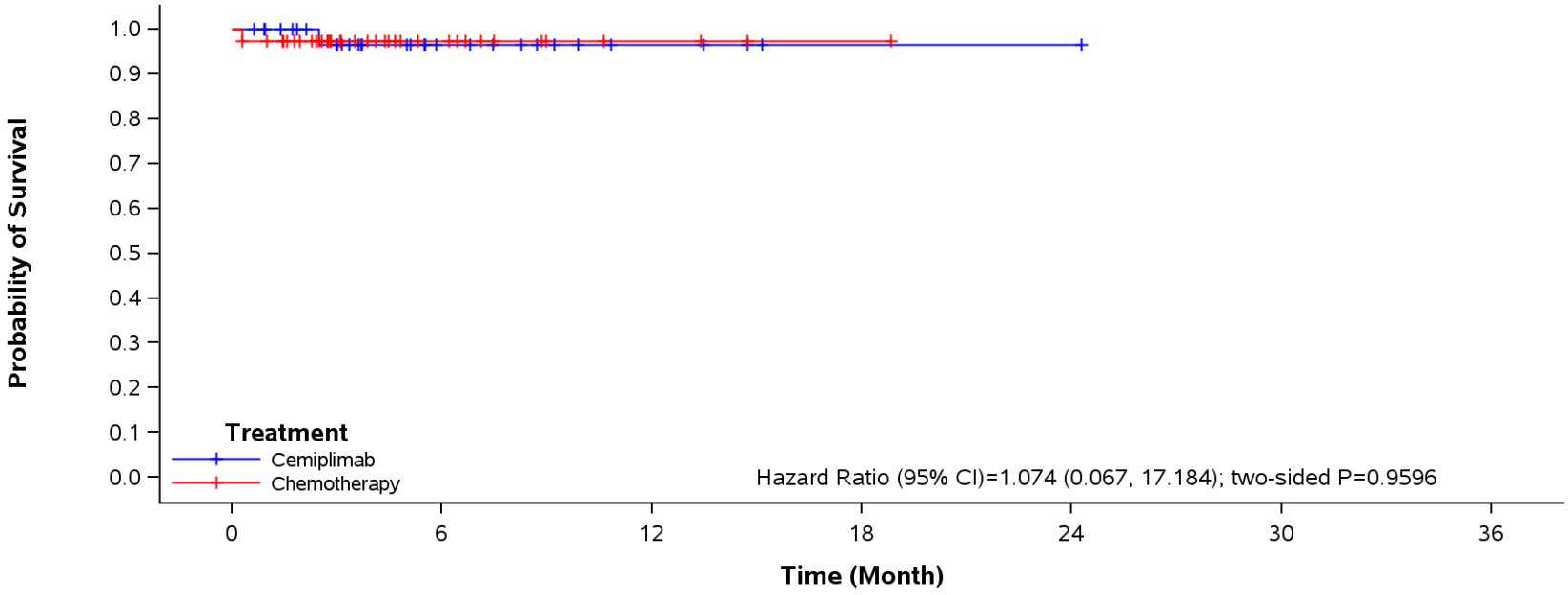

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders
PT: Stomatitis



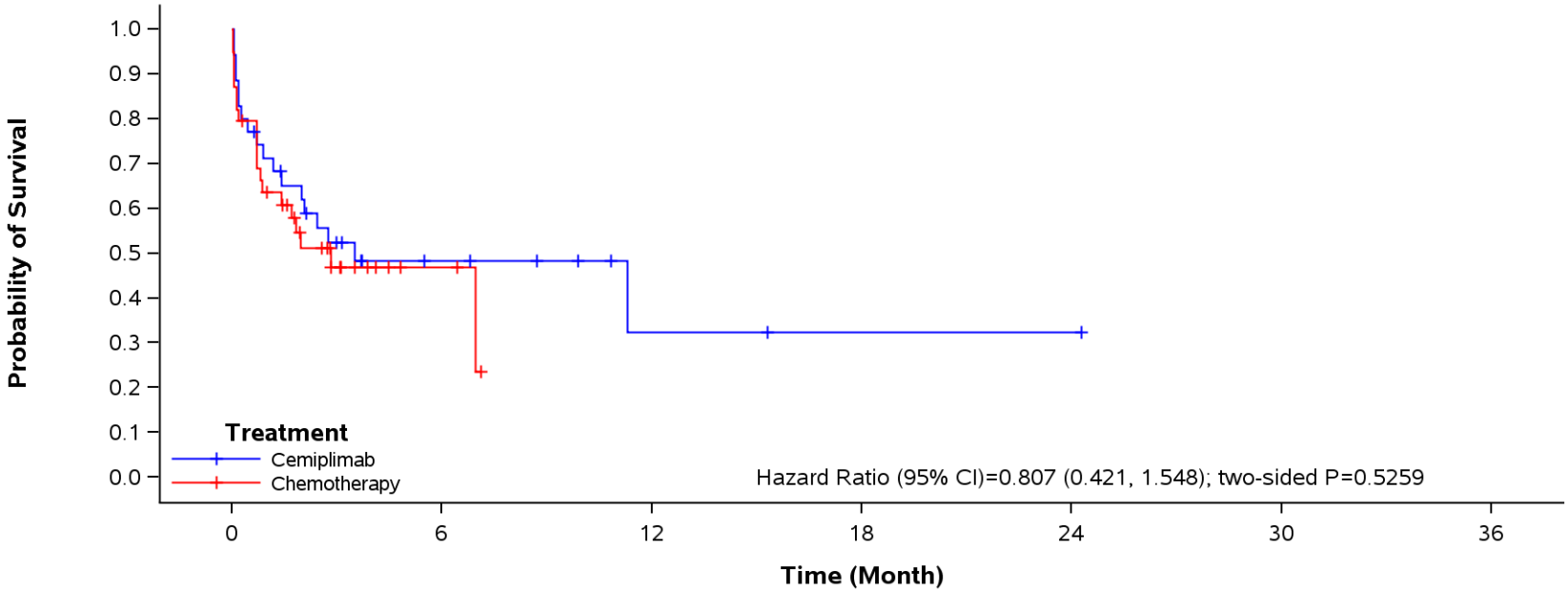

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: General disorders and administration site conditions



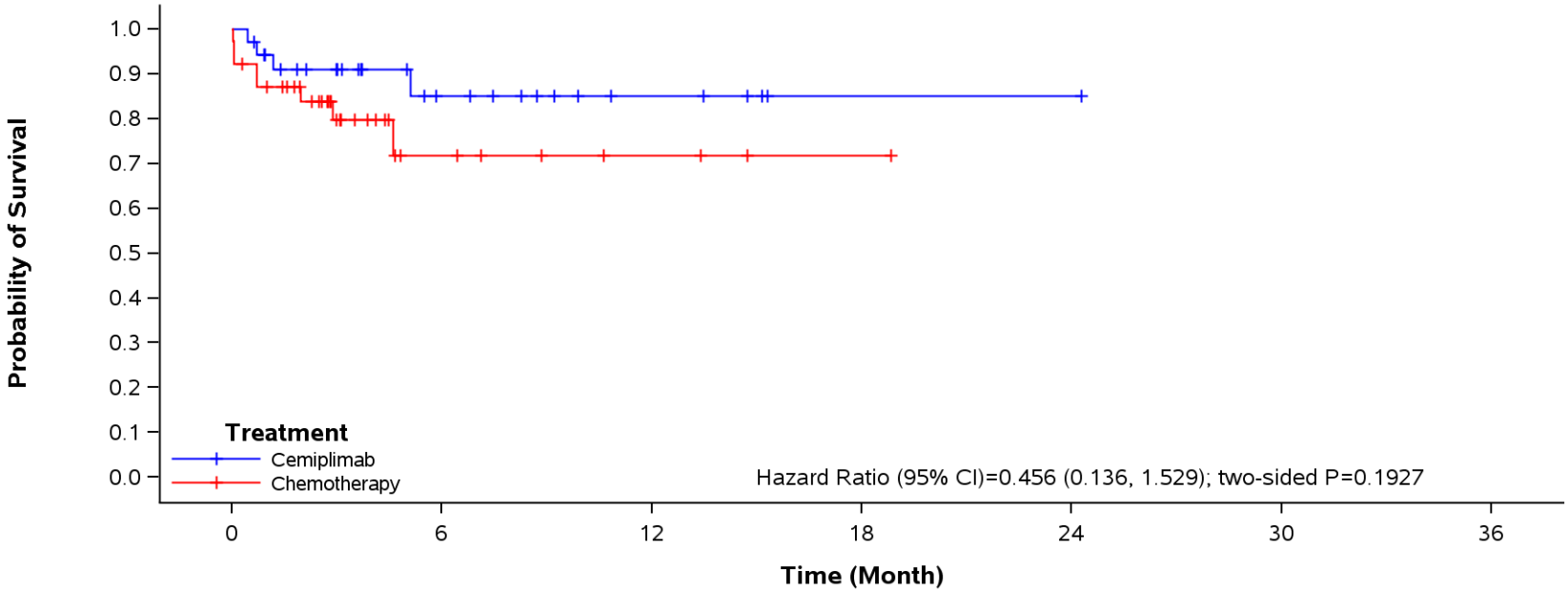

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 7 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: General disorders and administration site conditions
PT: Asthenia



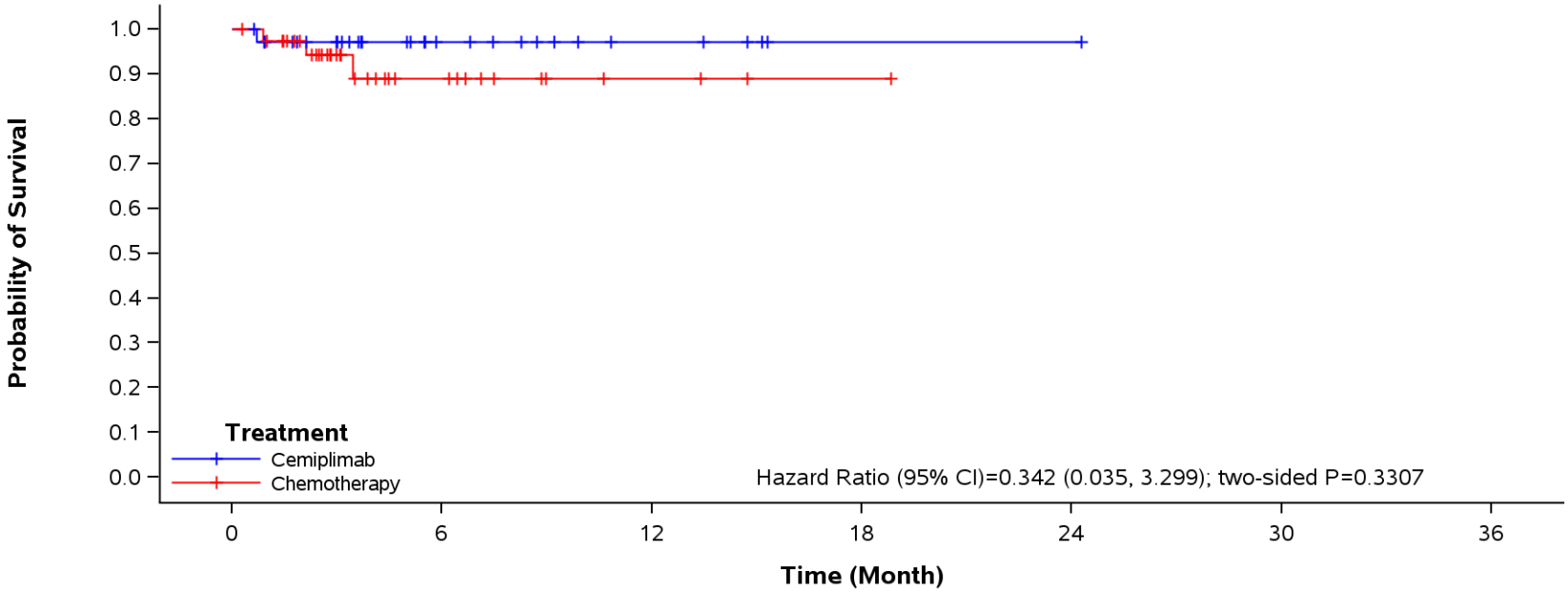

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



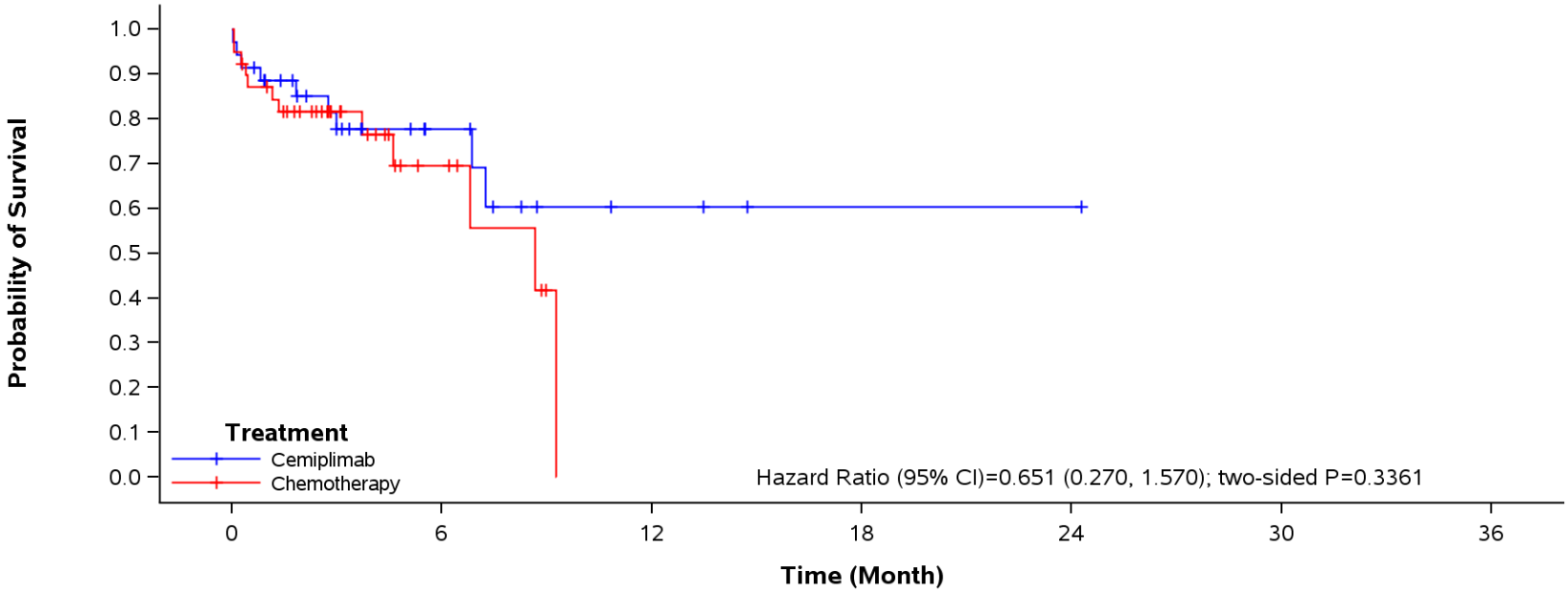

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Nervous system disorders



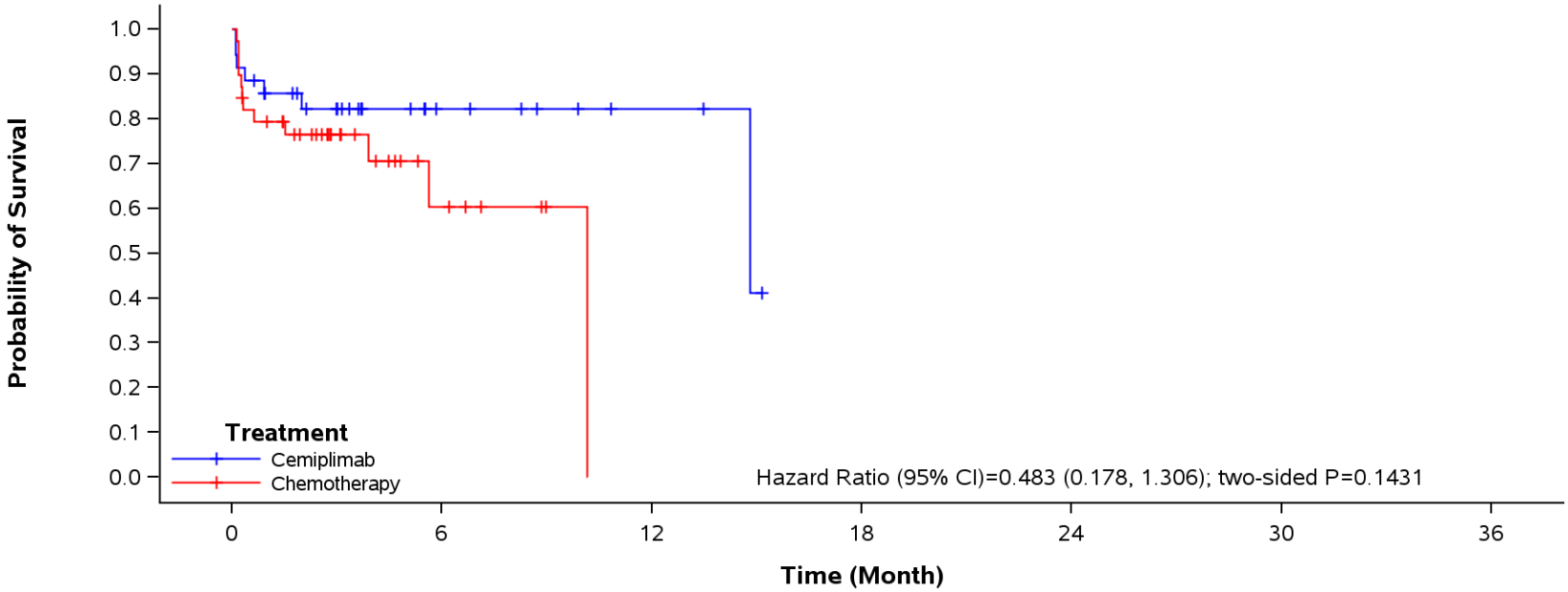

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Skin and subcutaneous tissue disorders



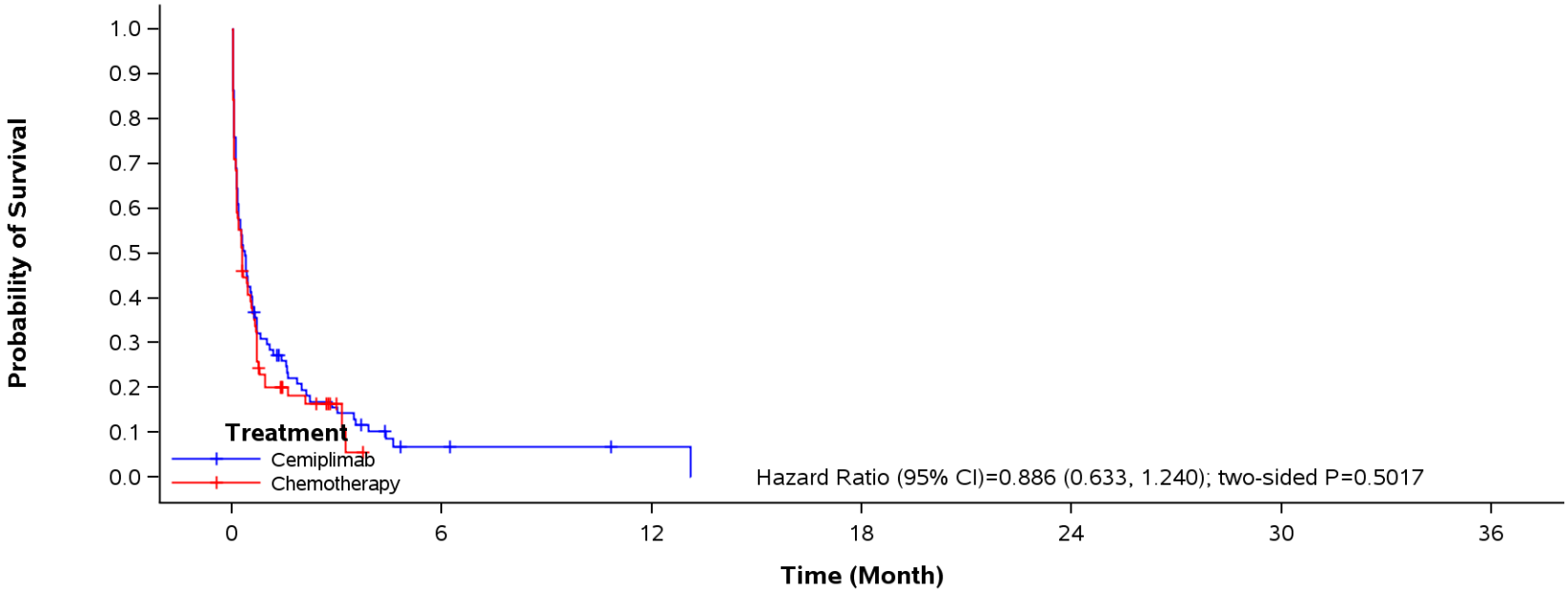

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 3 | 0 | 0 | 0 | 0 |
| Chemotherapy | 39 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Number of patients with any TEAE



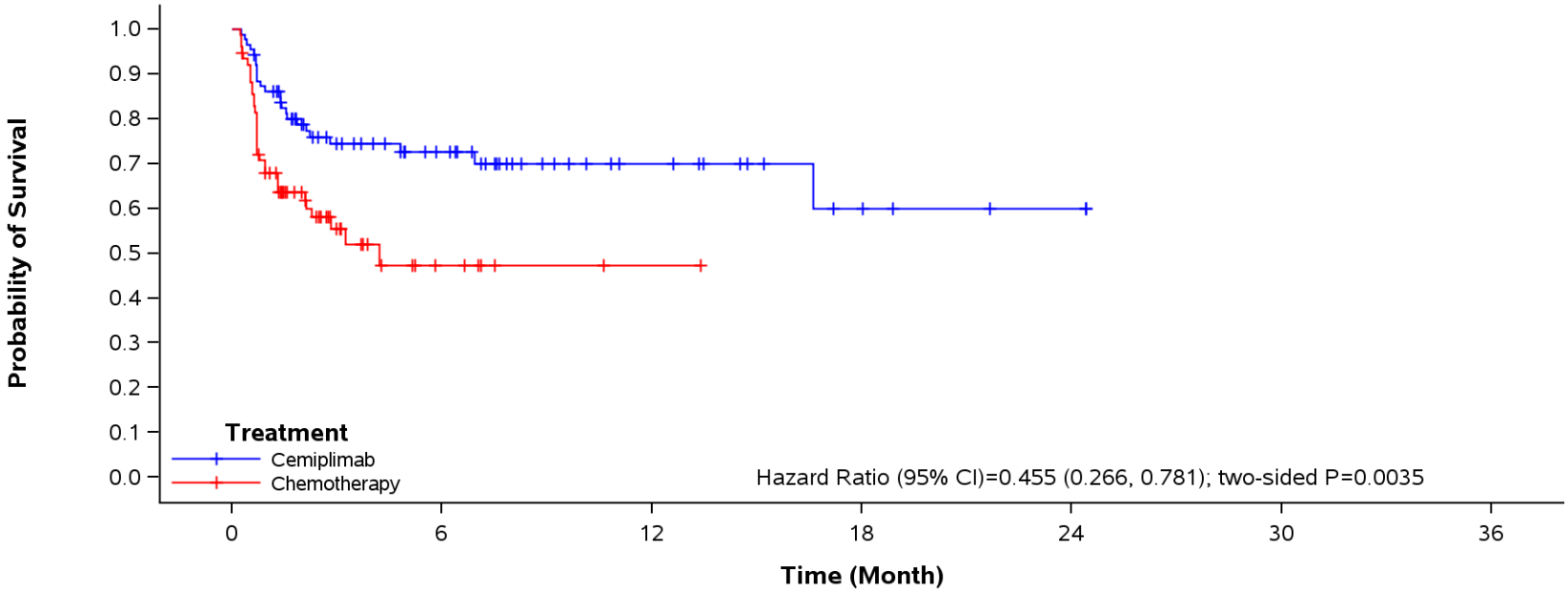

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 76 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders



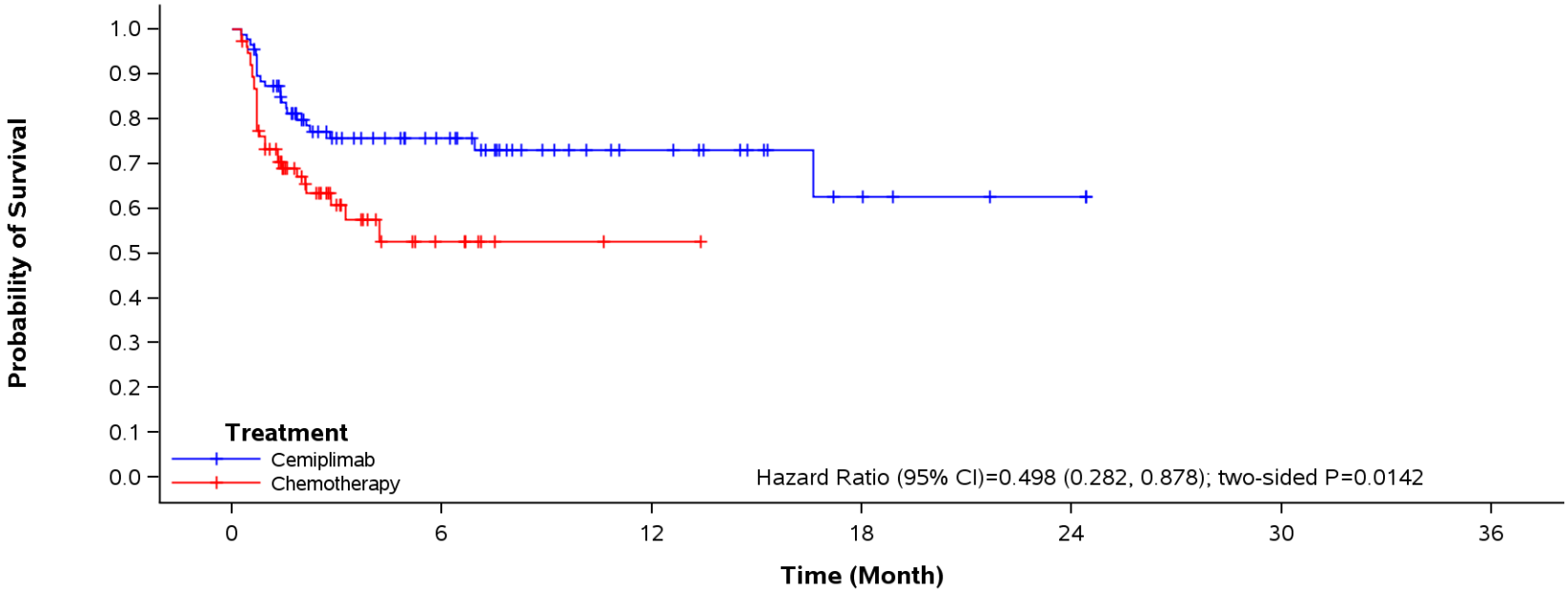

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 34 | 13 | 5 | 2 | 0 | 0 |
| Chemotherapy | 76 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Anaemia



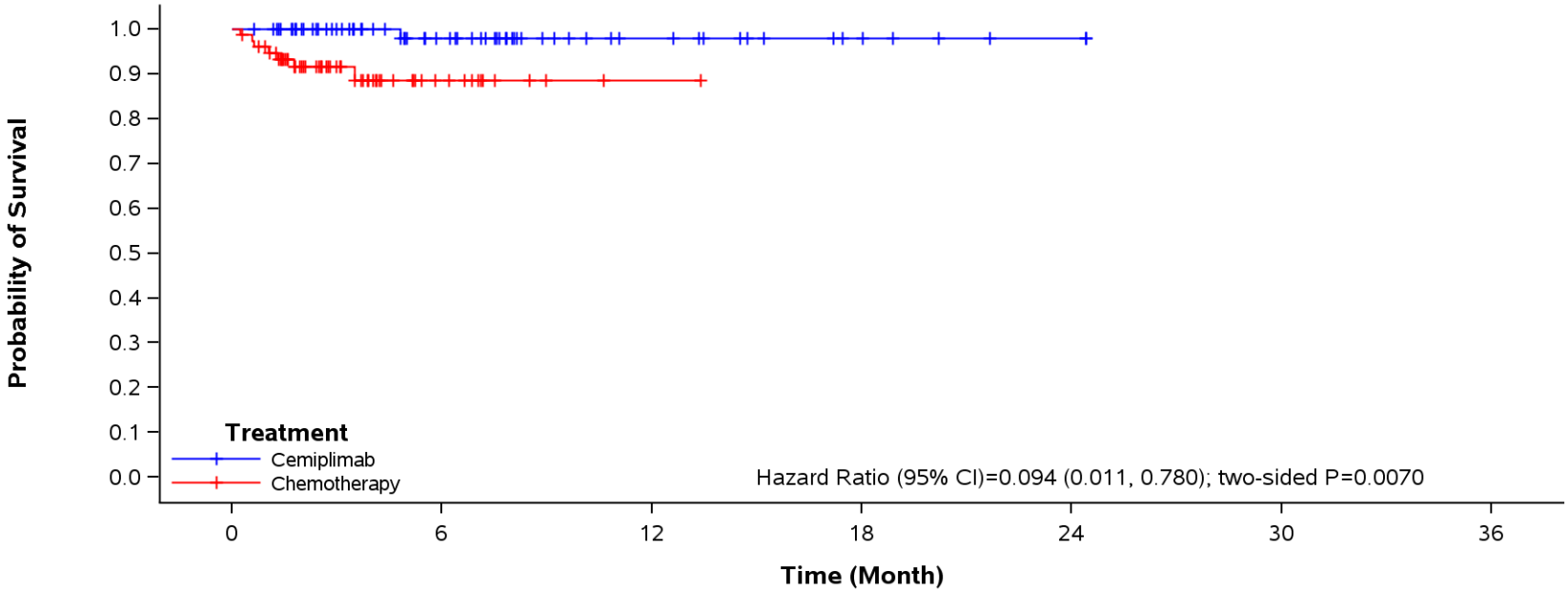

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 35 | 14 | 5 | 2 | 0 | 0 |
| Chemotherapy | 76 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Neutropenia



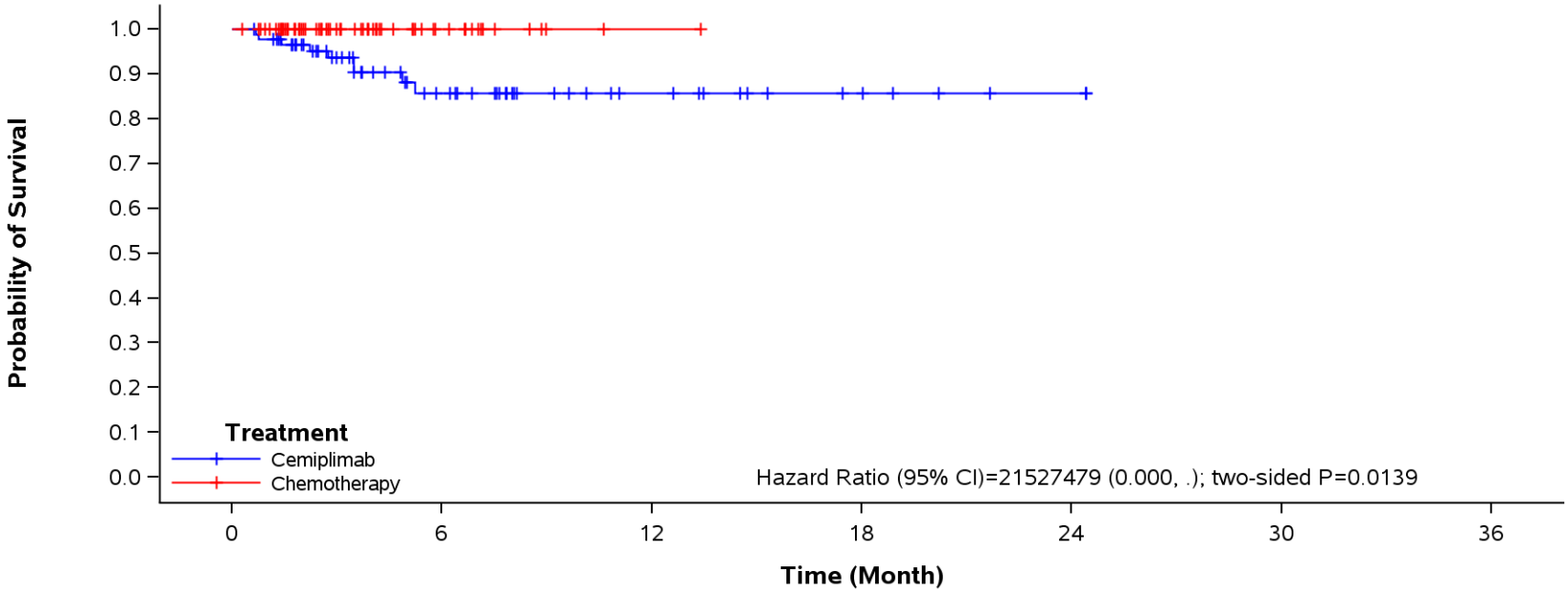

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 14 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Endocrine disorders



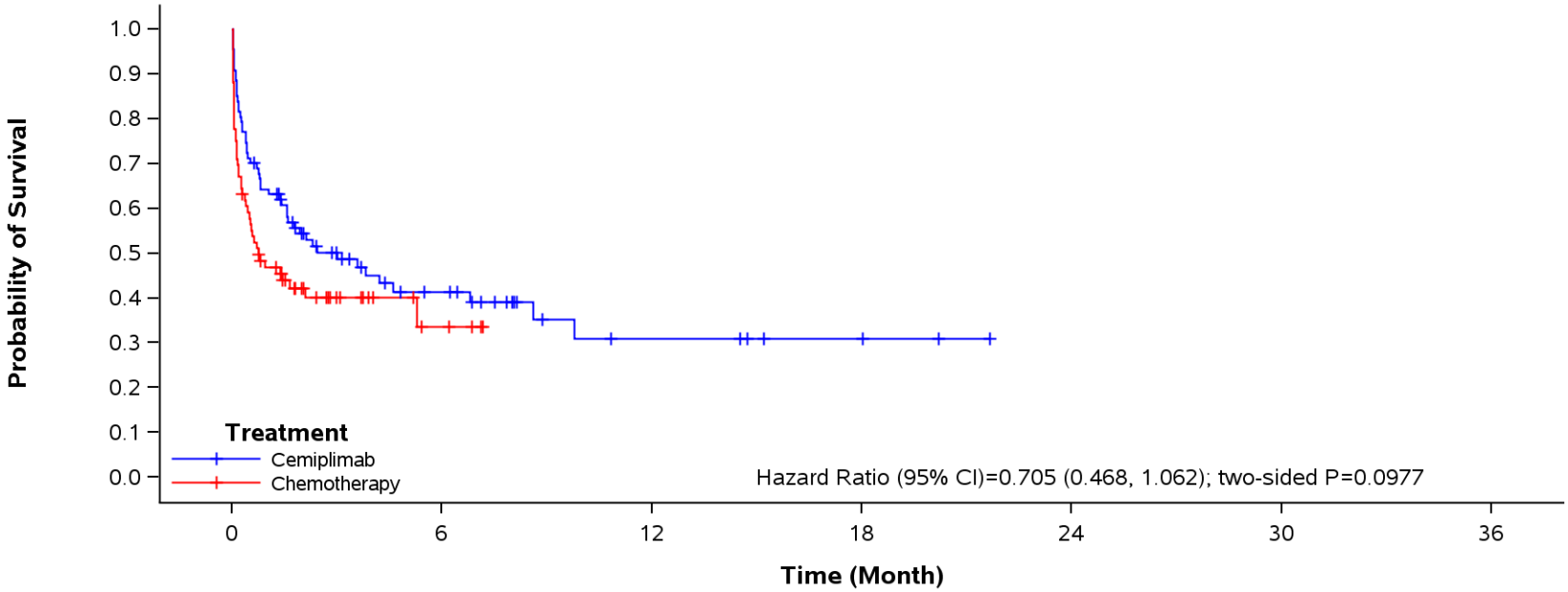

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 35 | 13 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders



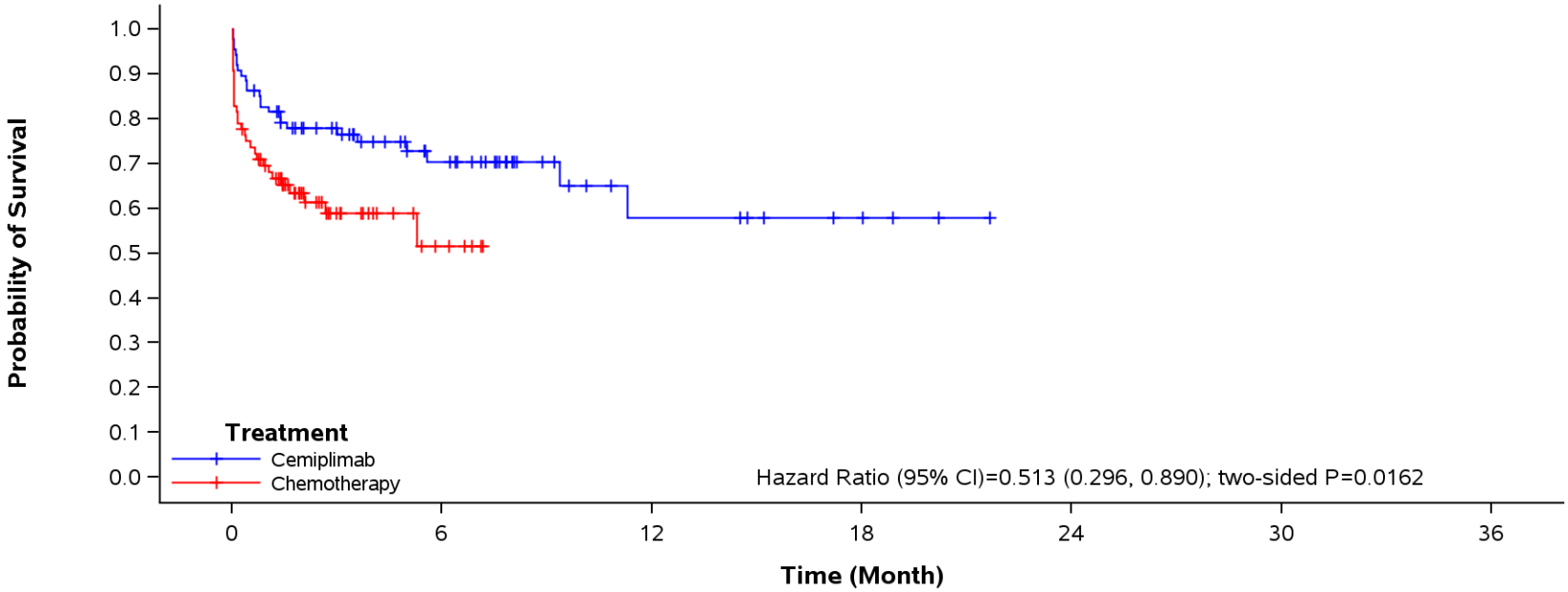

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 20 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 76 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders
PT: Nausea



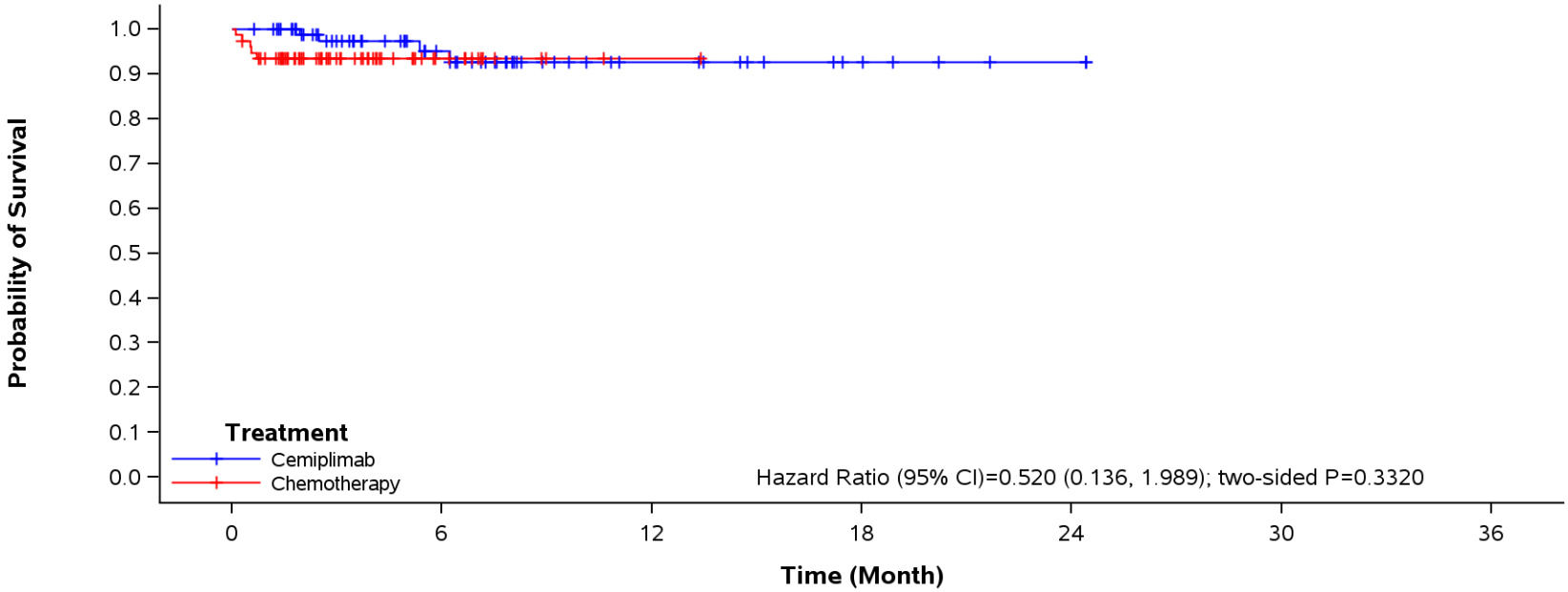

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 31 | 8 | 4 | 0 | 0 | 0 |
| Chemotherapy | 76 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders
PT: Stomatitis



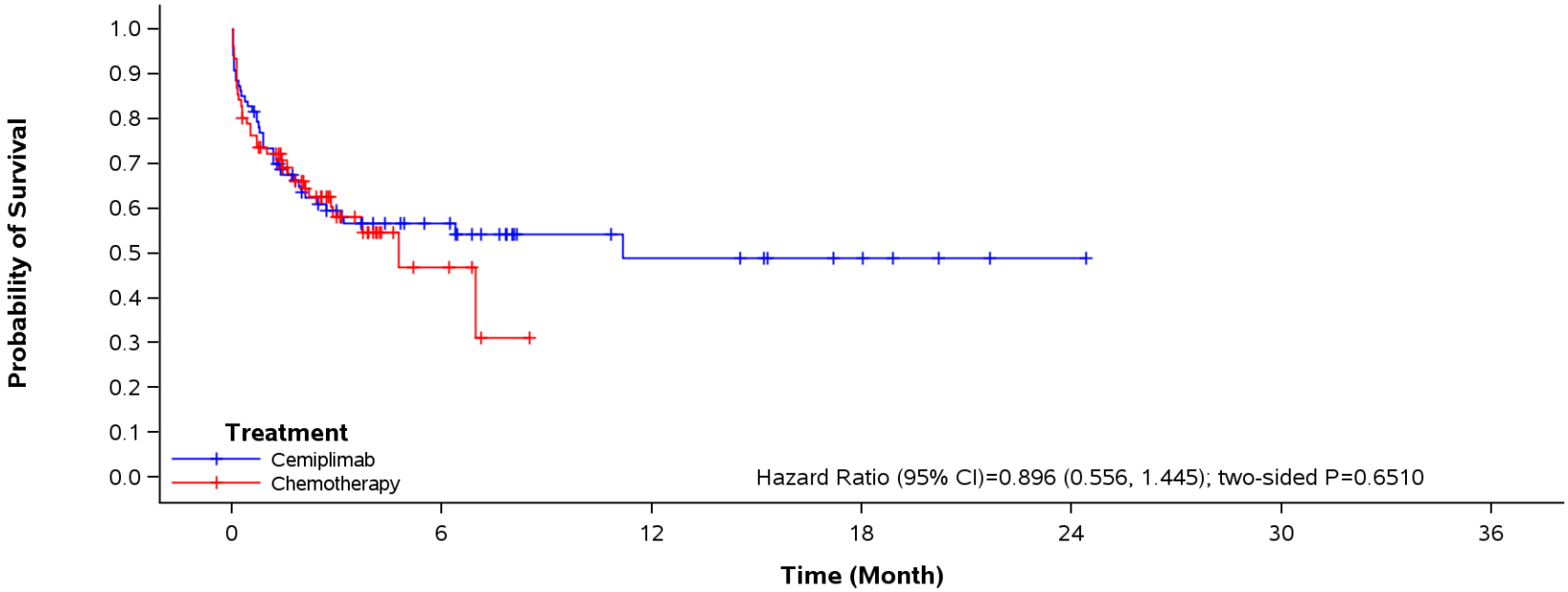

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 39 | 13 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: General disorders and administration site conditions



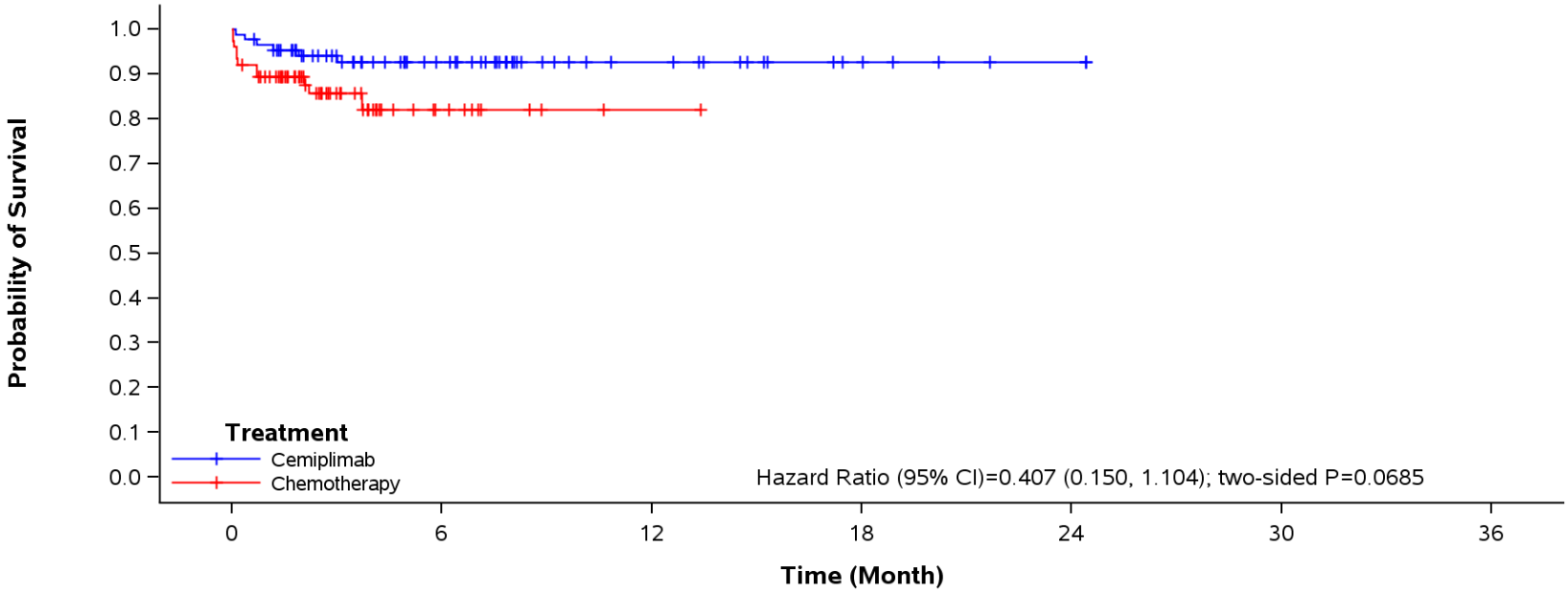

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 25 | 9 | 5 | 1 | 0 | 0 |
| Chemotherapy | 76 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: General disorders and administration site conditions
PT: Asthenia



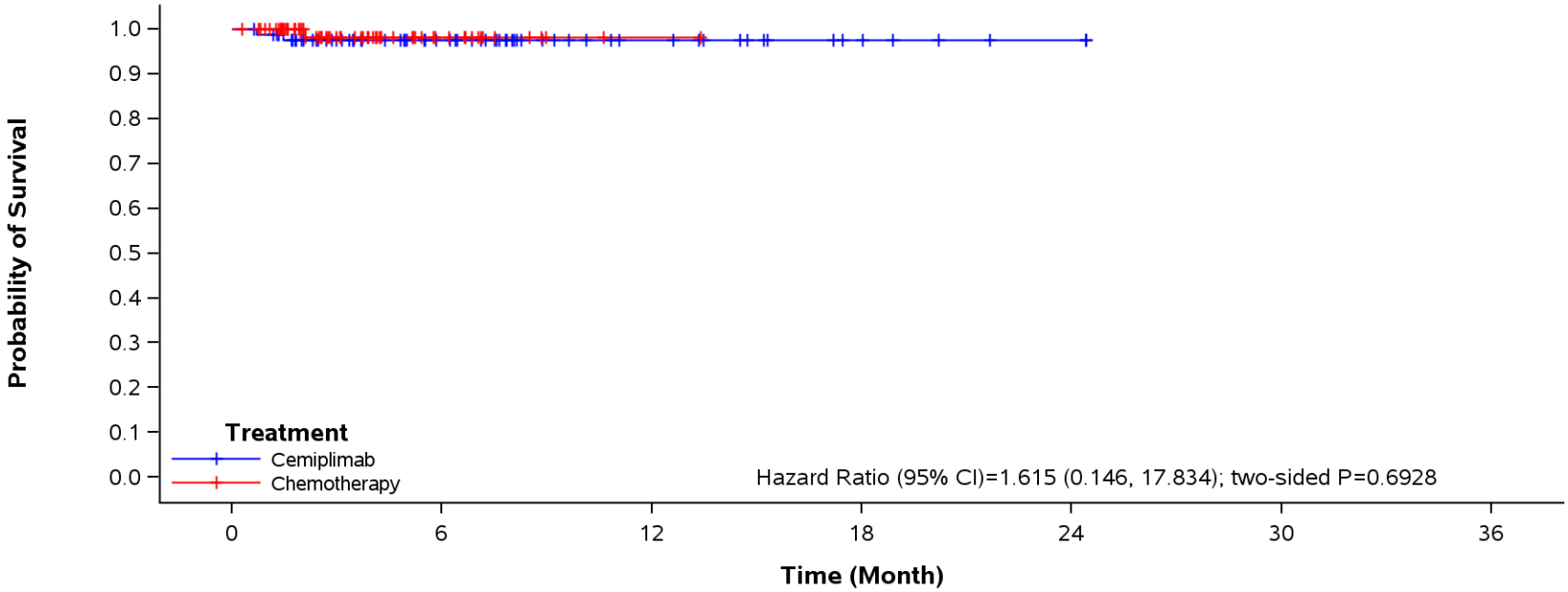

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 15 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



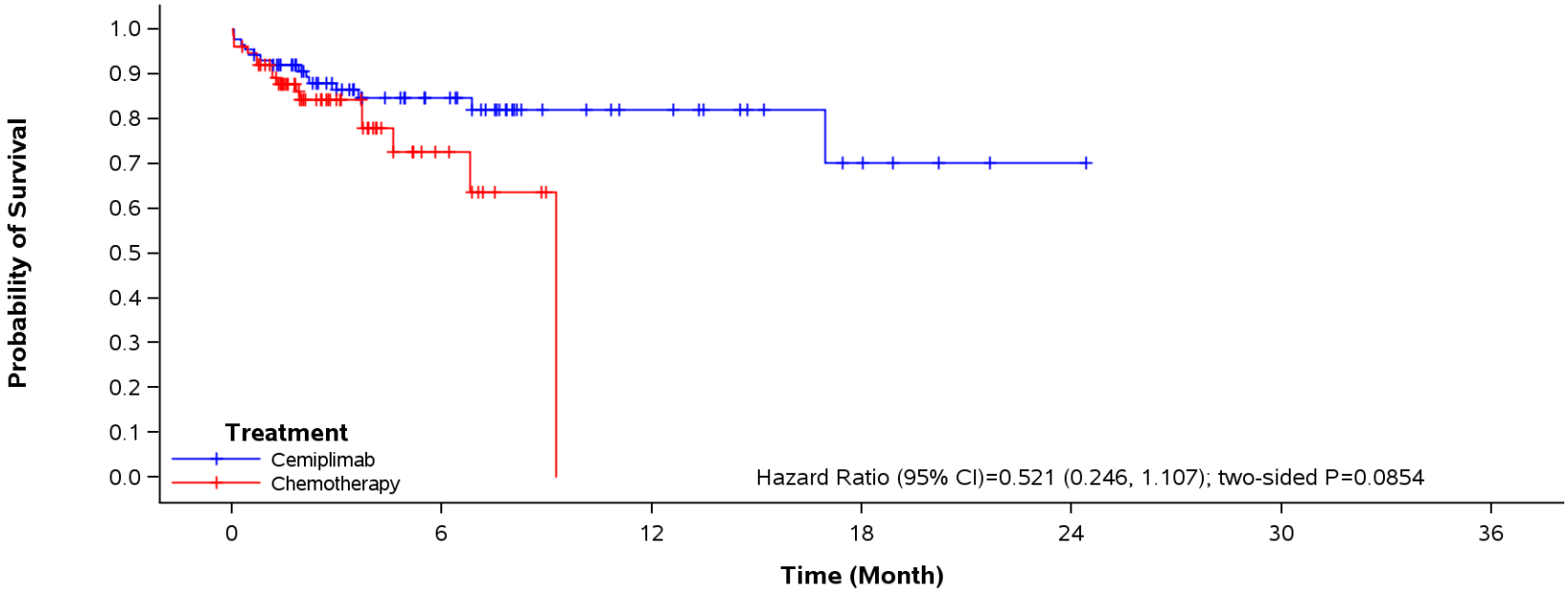

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 15 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Nervous system disorders



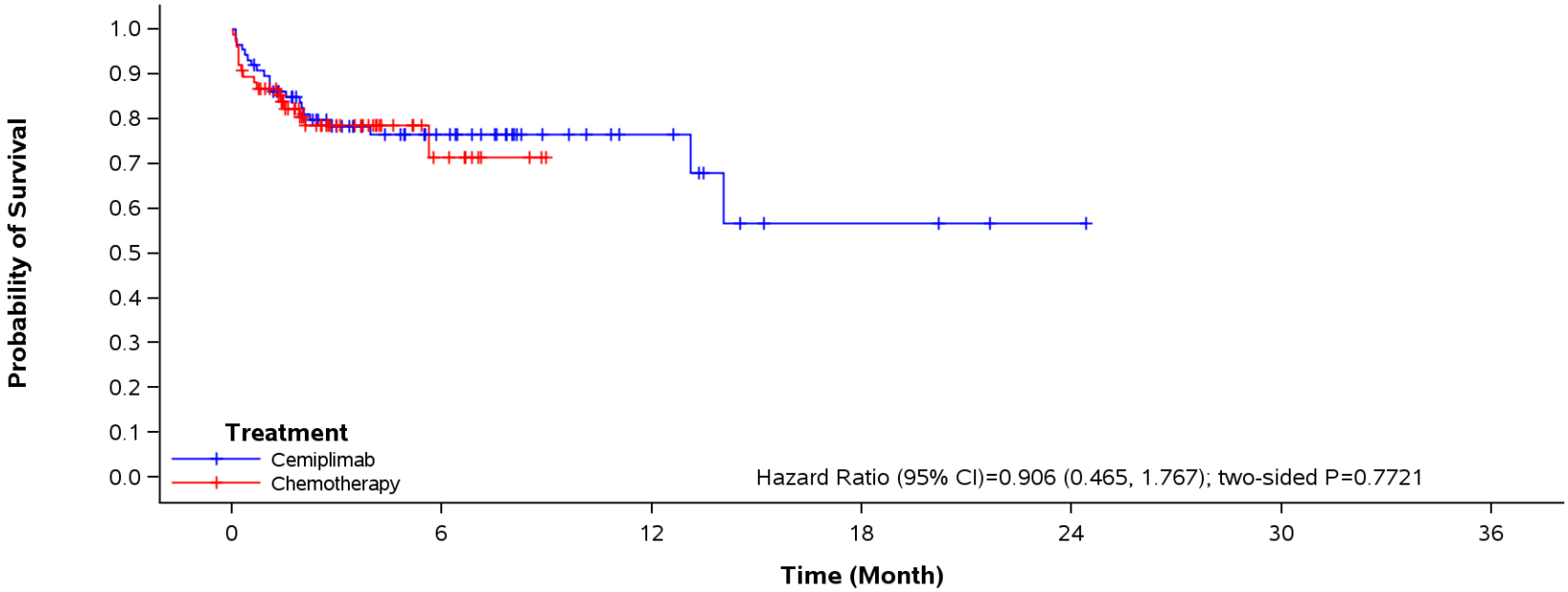

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 35 | 13 | 5 | 1 | 0 | 0 |
| Chemotherapy | 76 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Skin and subcutaneous tissue disorders



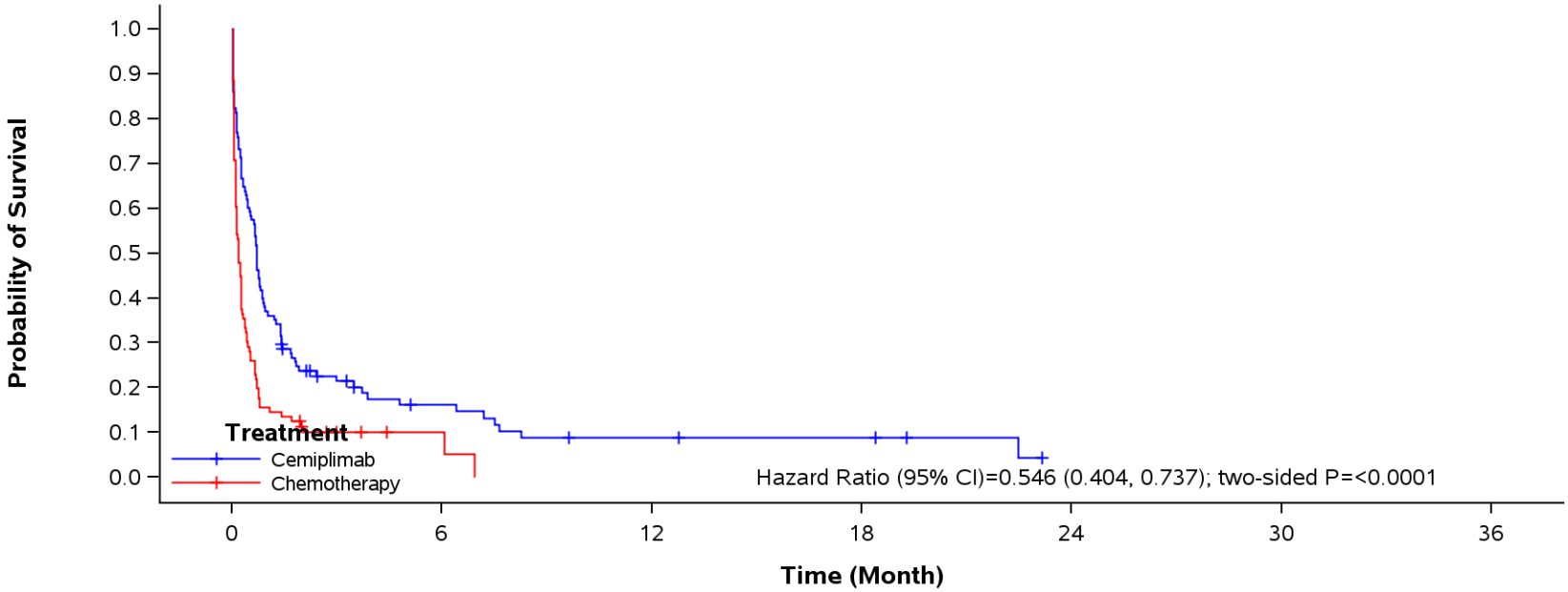

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 32 | 10 | 3 | 1 | 0 | 0 |
| Chemotherapy | 76 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Number of patients with any TEAE



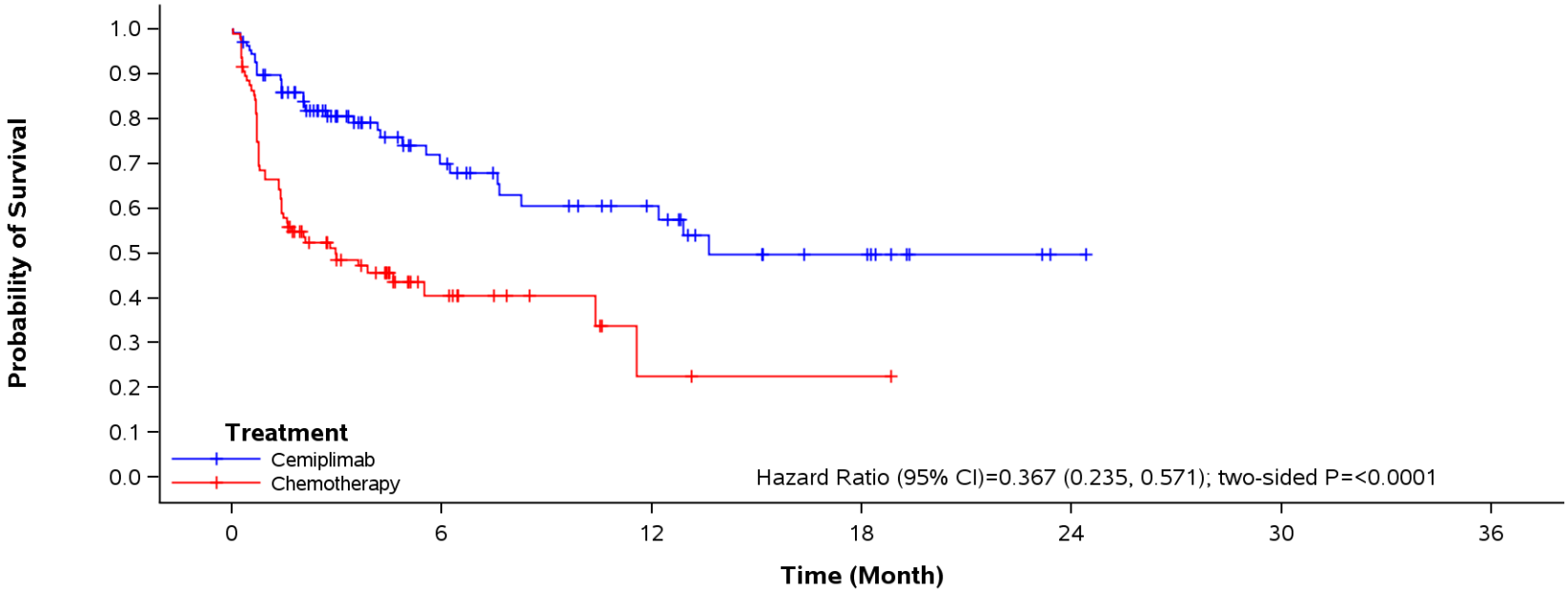

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 11 | 5 | 4 | 0 | 0 | 0 |
| Chemotherapy | 96 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders



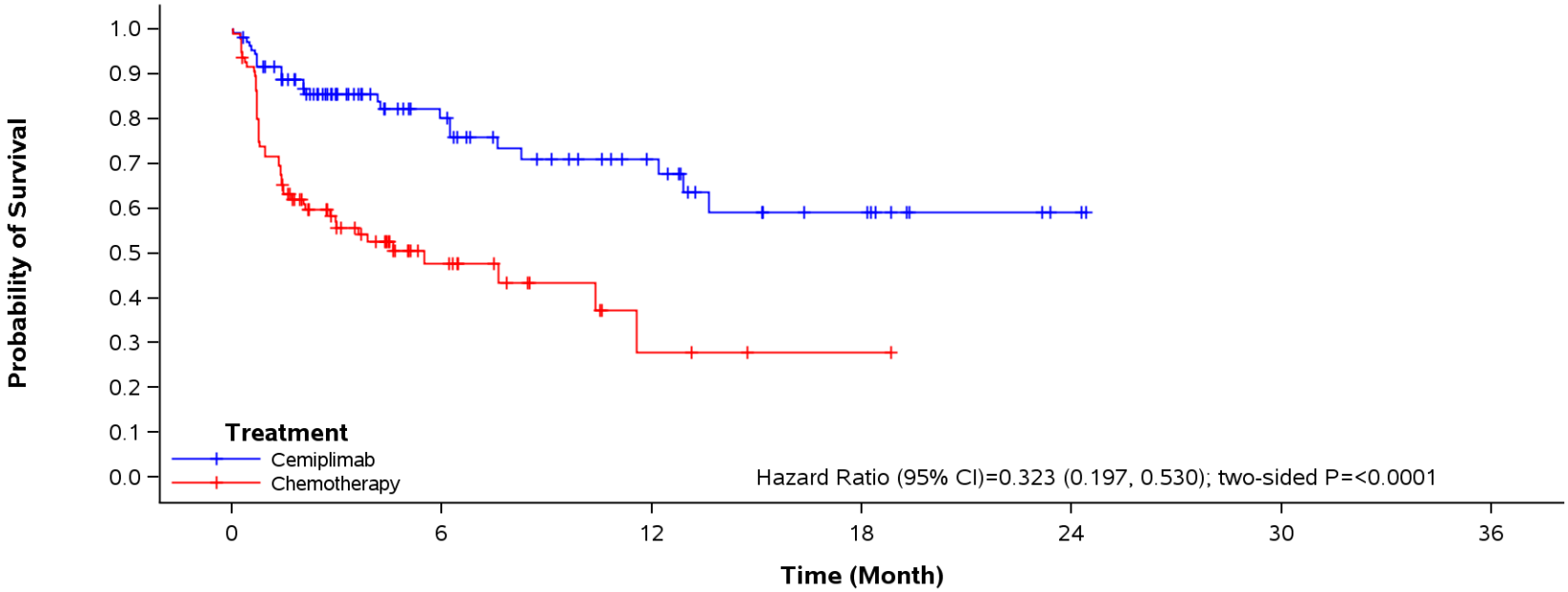

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 34 | 20 | 9 | 1 | 0 | 0 |
| Chemotherapy | 96 | 14 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Anaemia



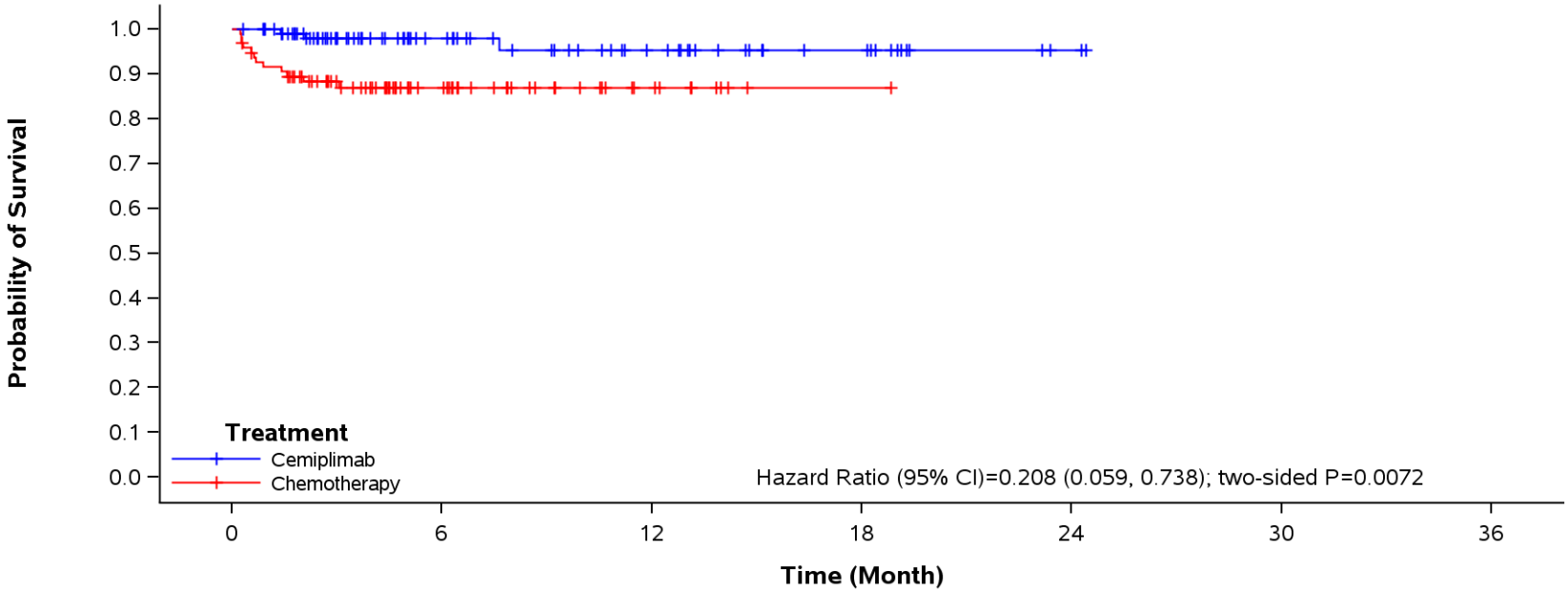

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 39 | 21 | 10 | 2 | 0 | 0 |
| Chemotherapy | 96 | 17 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Neutropenia



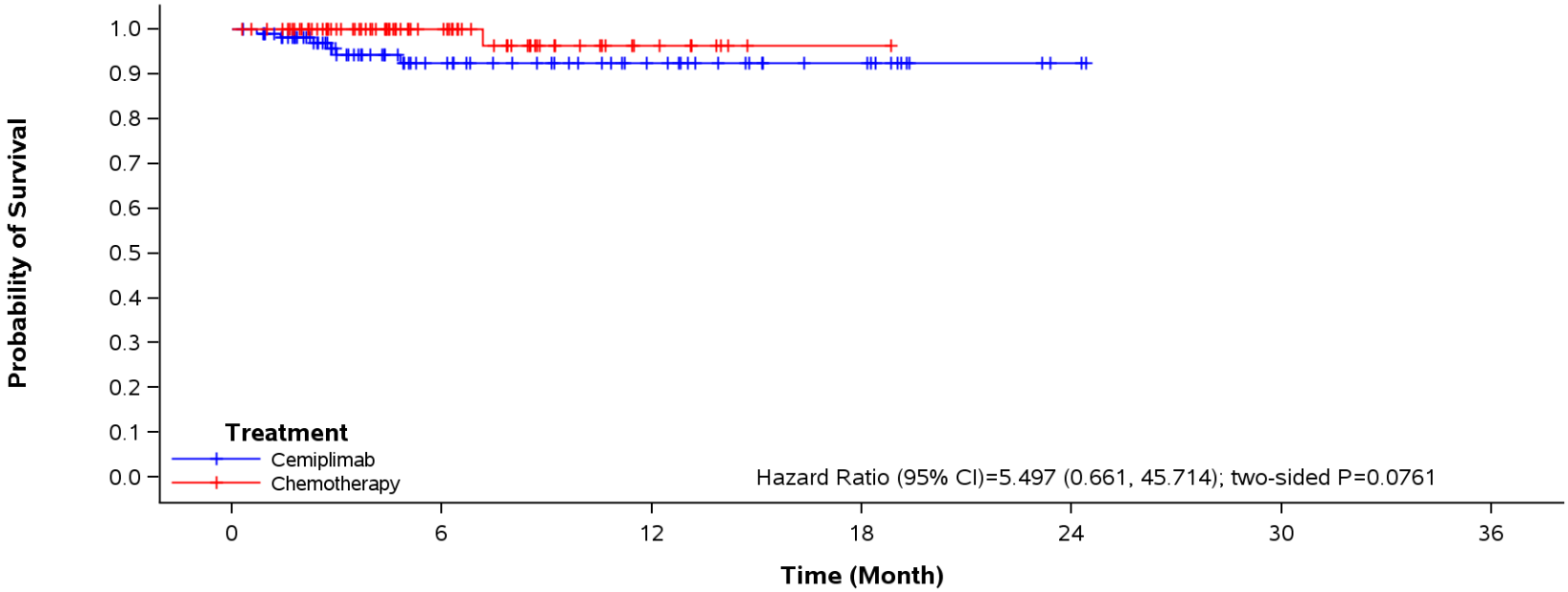

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 26 | 14 | 2 | 0 | 0 |
| Chemotherapy | 96 | 34 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Endocrine disorders



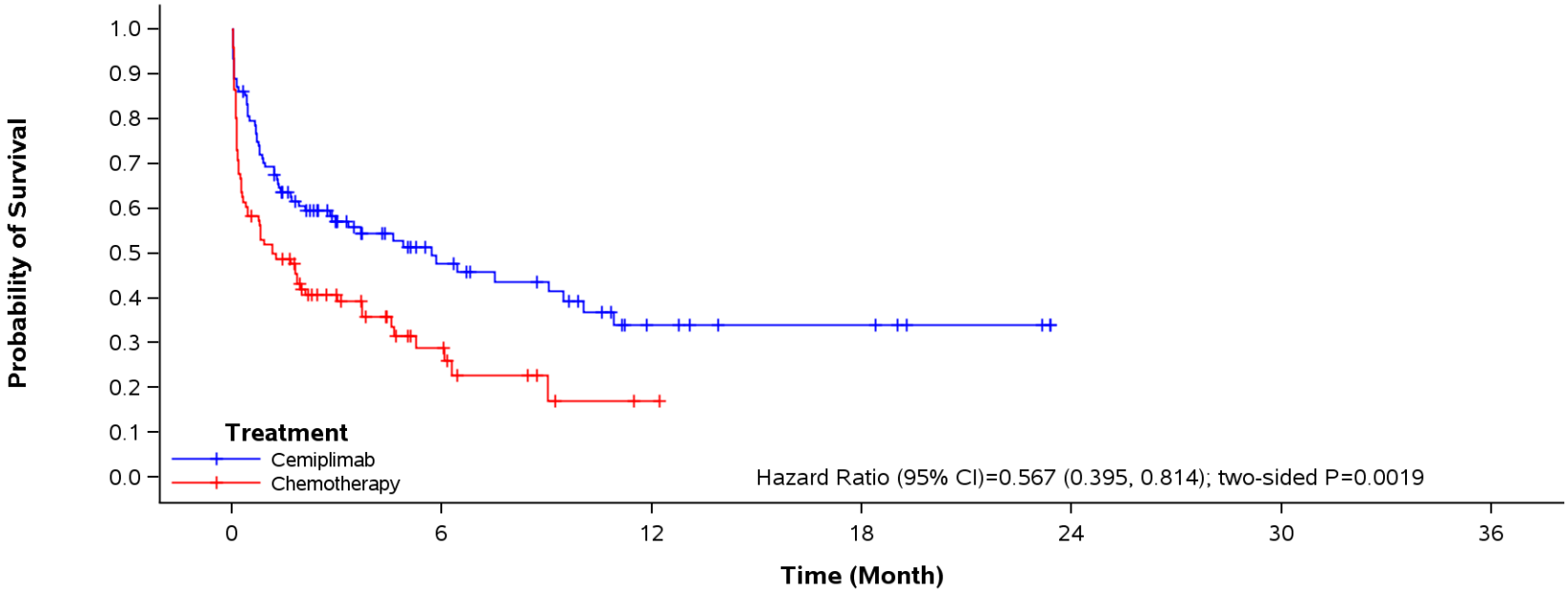

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 42 | 25 | 14 | 2 | 0 | 0 |
| Chemotherapy | 96 | 39 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders



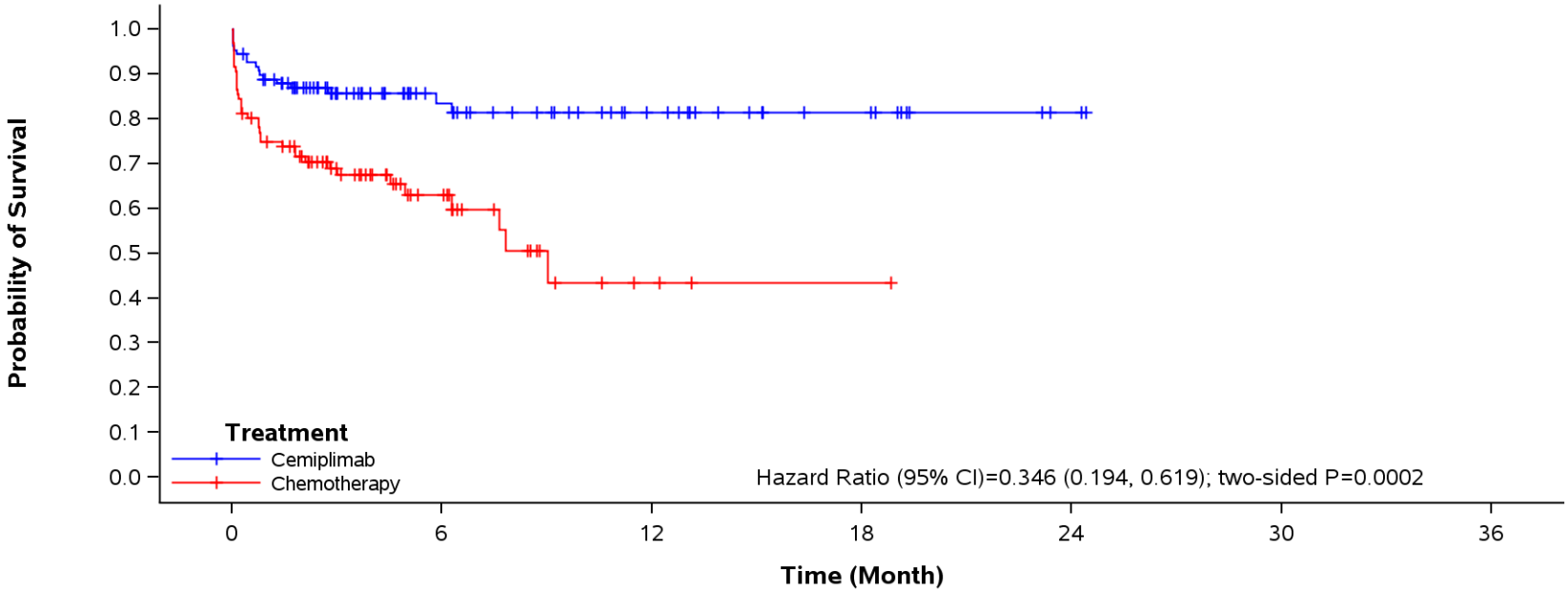

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 26 | 9 | 6 | 0 | 0 | 0 |
| Chemotherapy | 96 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders
PT: Nausea



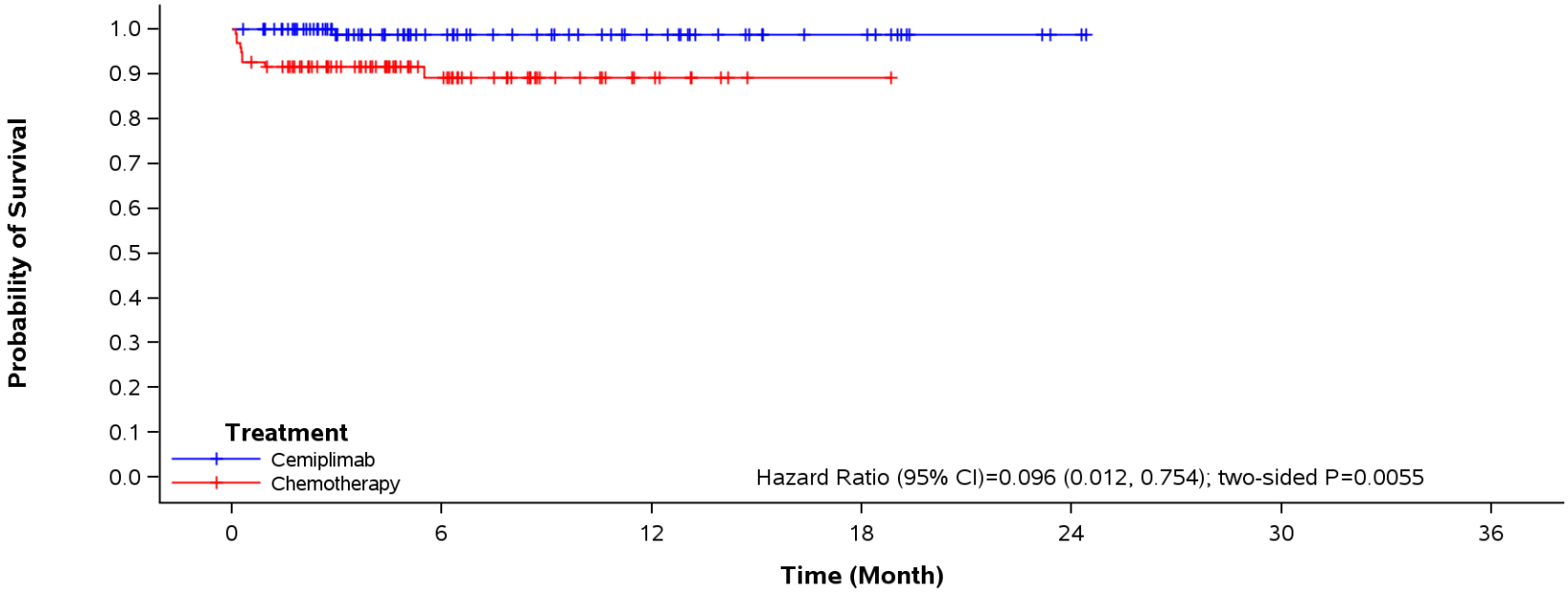

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 40 | 22 | 12 | 2 | 0 | 0 |
| Chemotherapy | 96 | 23 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders
PT: Stomatitis



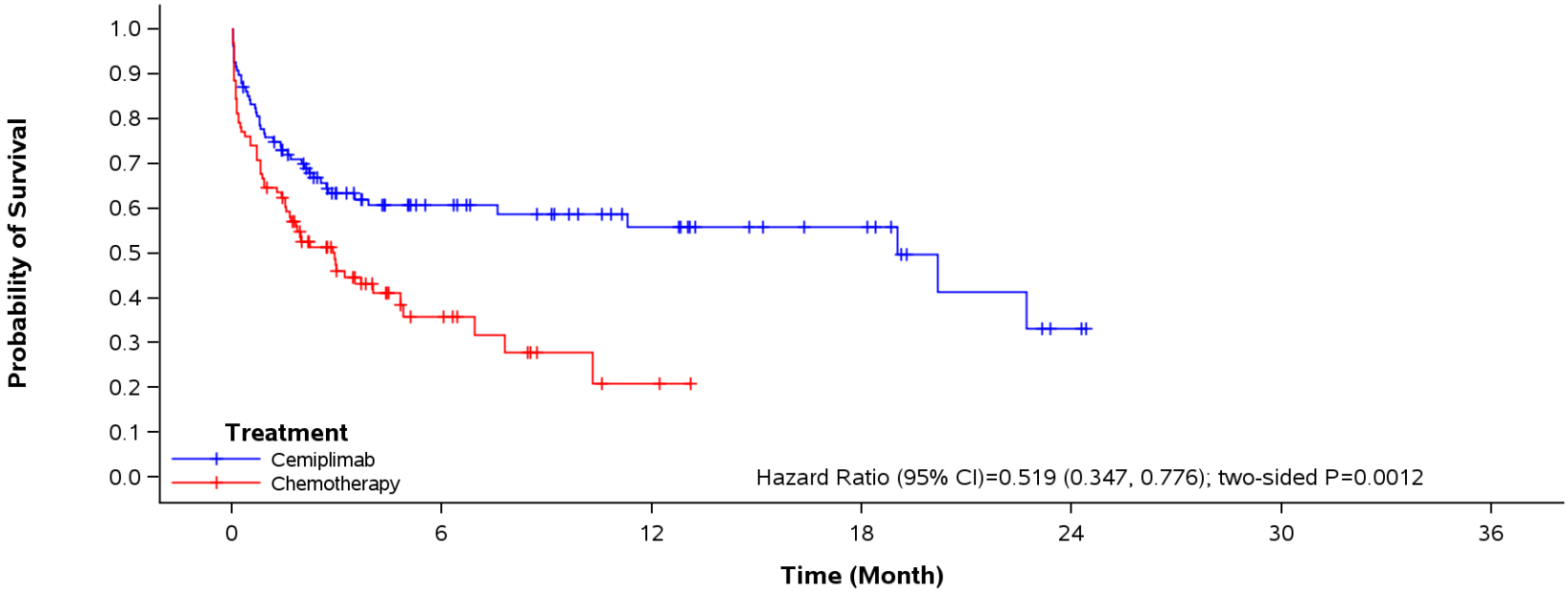

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 25 | 13 | 2 | 0 | 0 |
| Chemotherapy | 96 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: General disorders and administration site conditions



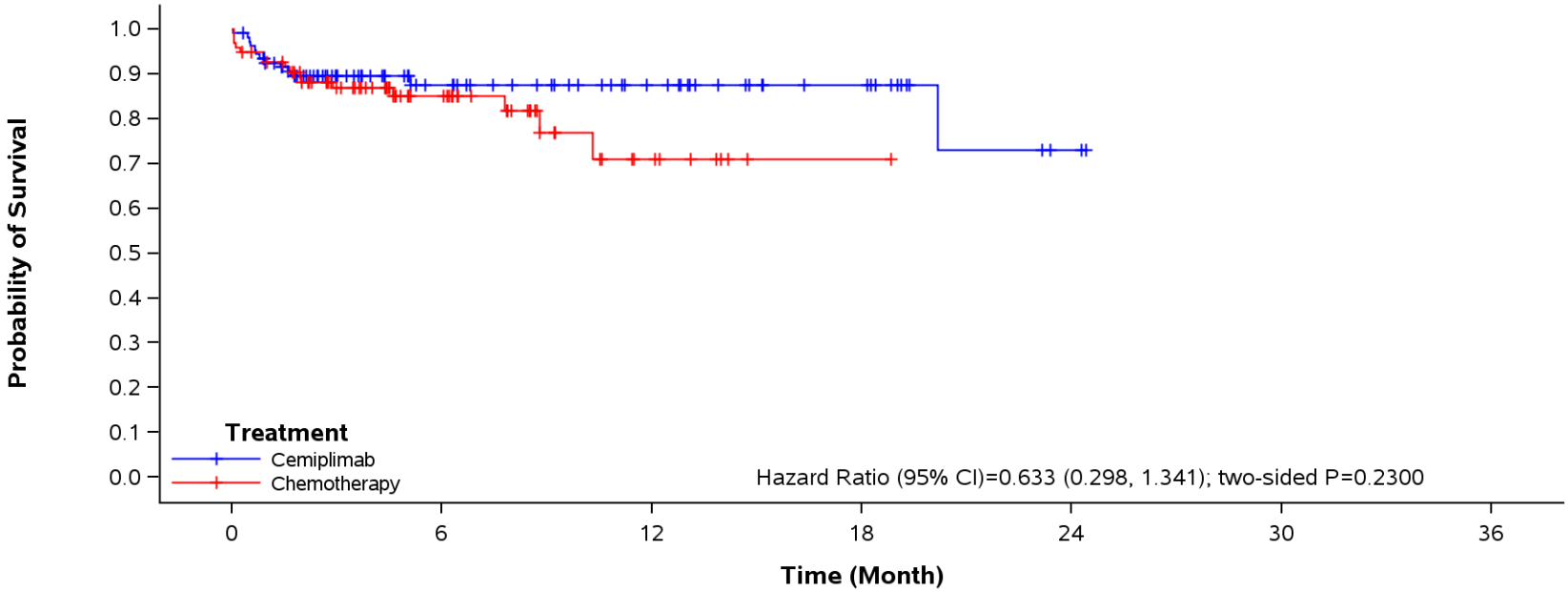

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 34 | 20 | 12 | 2 | 0 | 0 |
| Chemotherapy | 96 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: General disorders and administration site conditions
PT: Asthenia



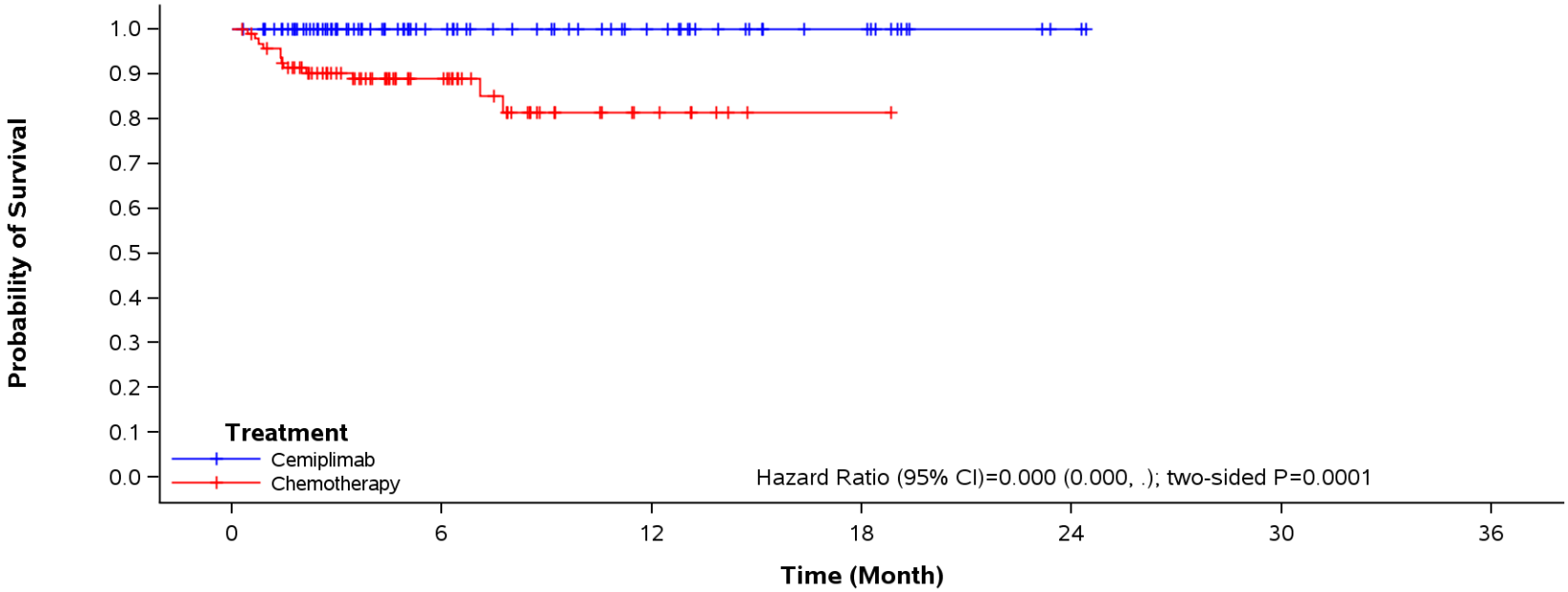

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 26 | 14 | 2 | 0 | 0 |
| Chemotherapy | 96 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



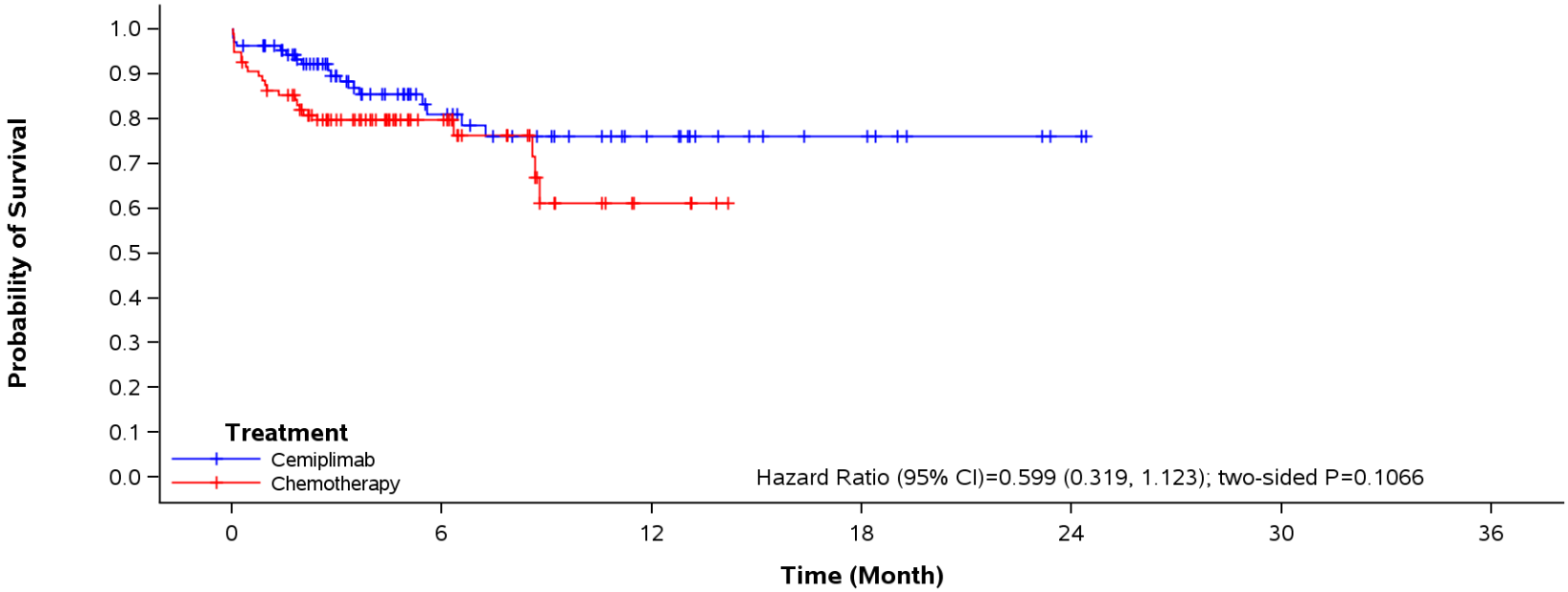

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 26 | 14 | 2 | 0 | 0 |
| Chemotherapy | 96 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Nervous system disorders



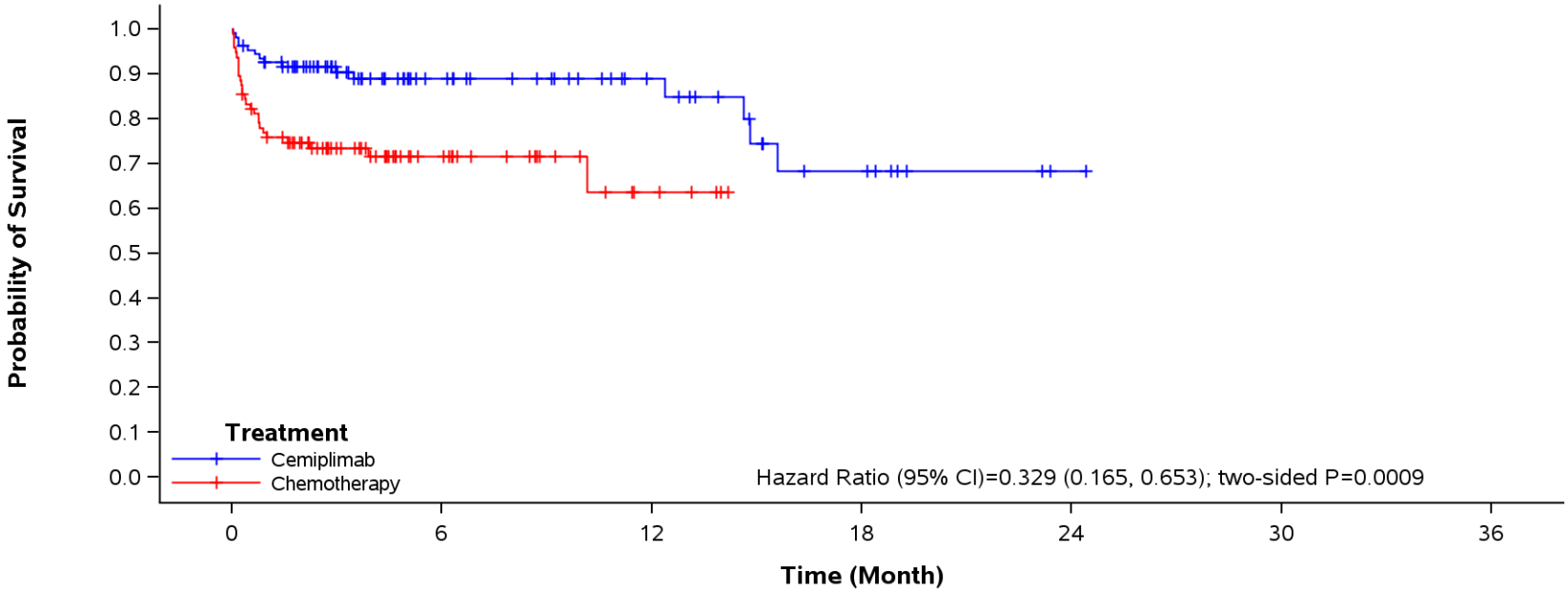

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 36 | 19 | 10 | 2 | 0 | 0 |
| Chemotherapy | 96 | 30 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Skin and subcutaneous tissue disorders



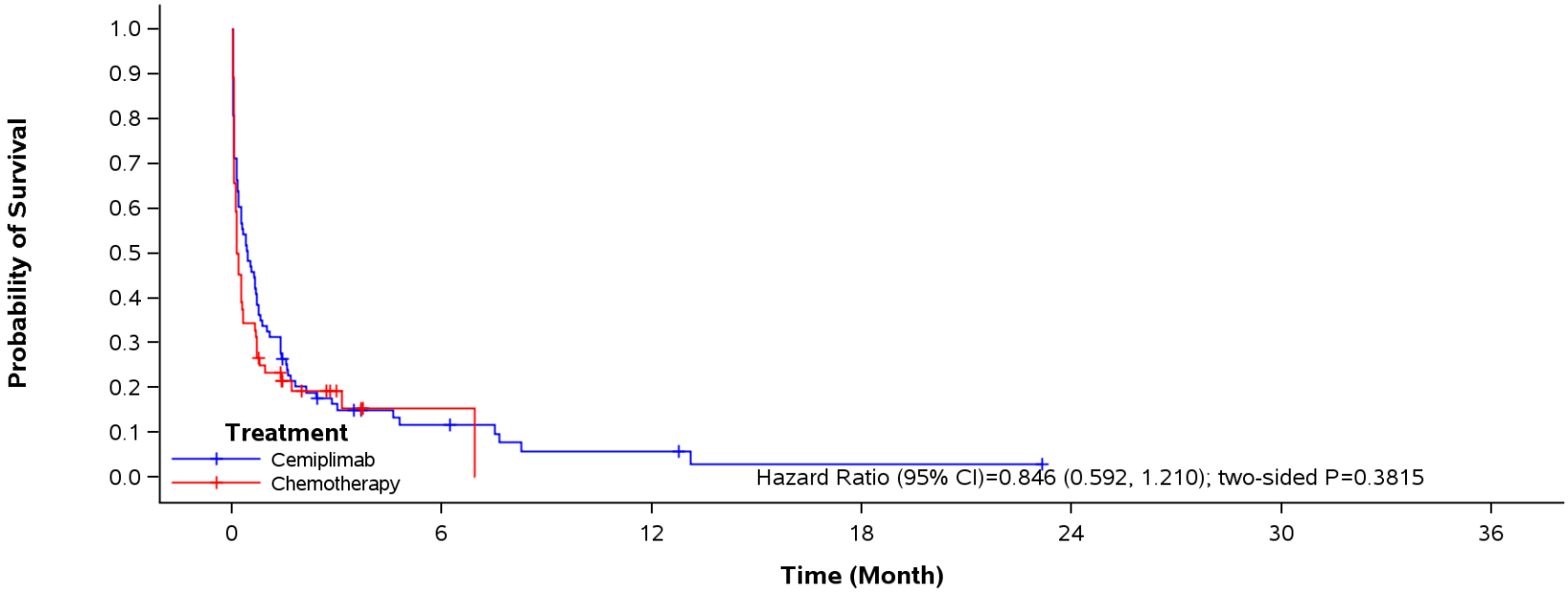

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 38 | 22 | 10 | 1 | 0 | 0 |
| Chemotherapy | 96 | 22 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Number of patients with any TEAE



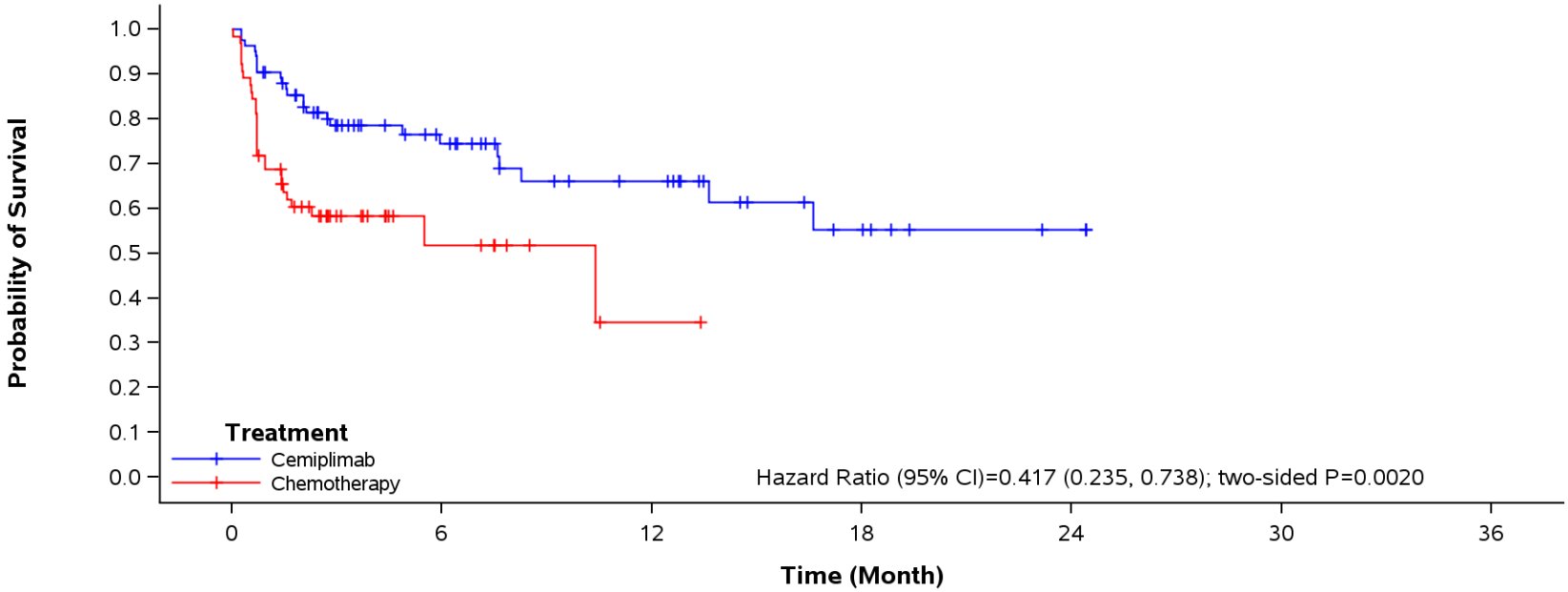

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 7 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 64 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders



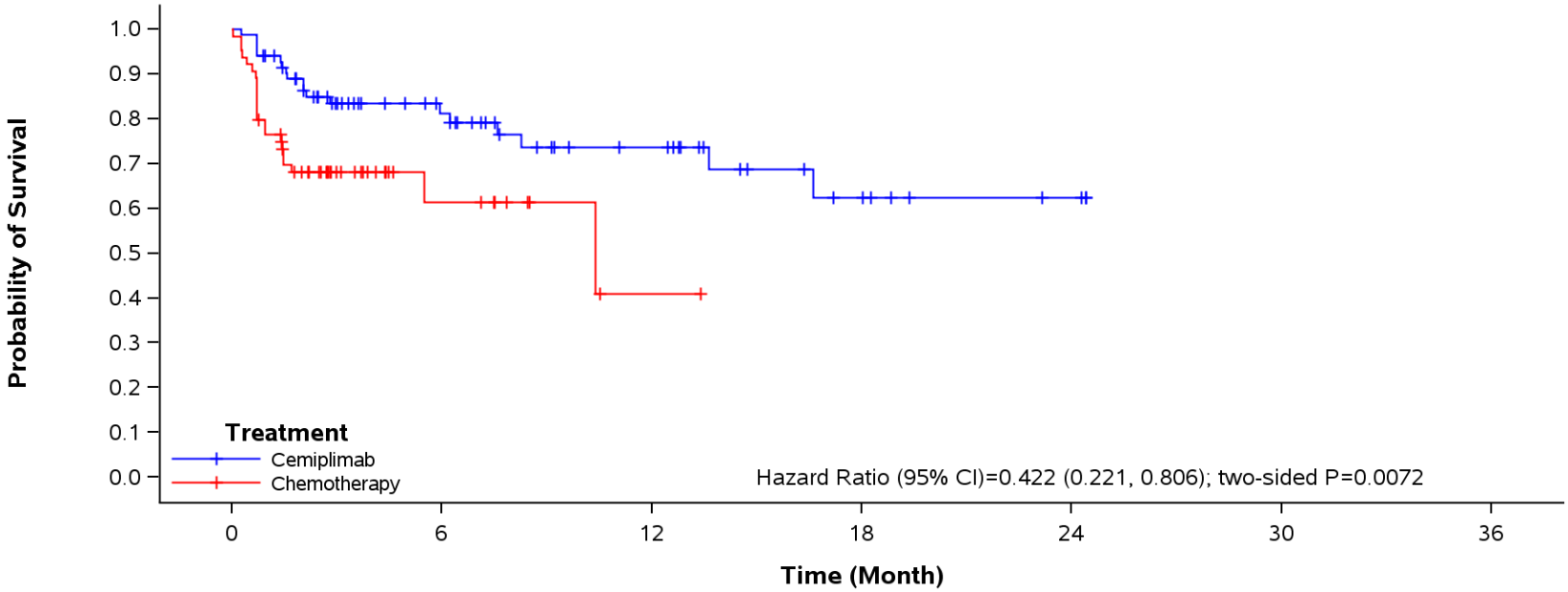

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 20 | 8 | 3 | 0 | 0 |
| Chemotherapy | 64 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Anaemia



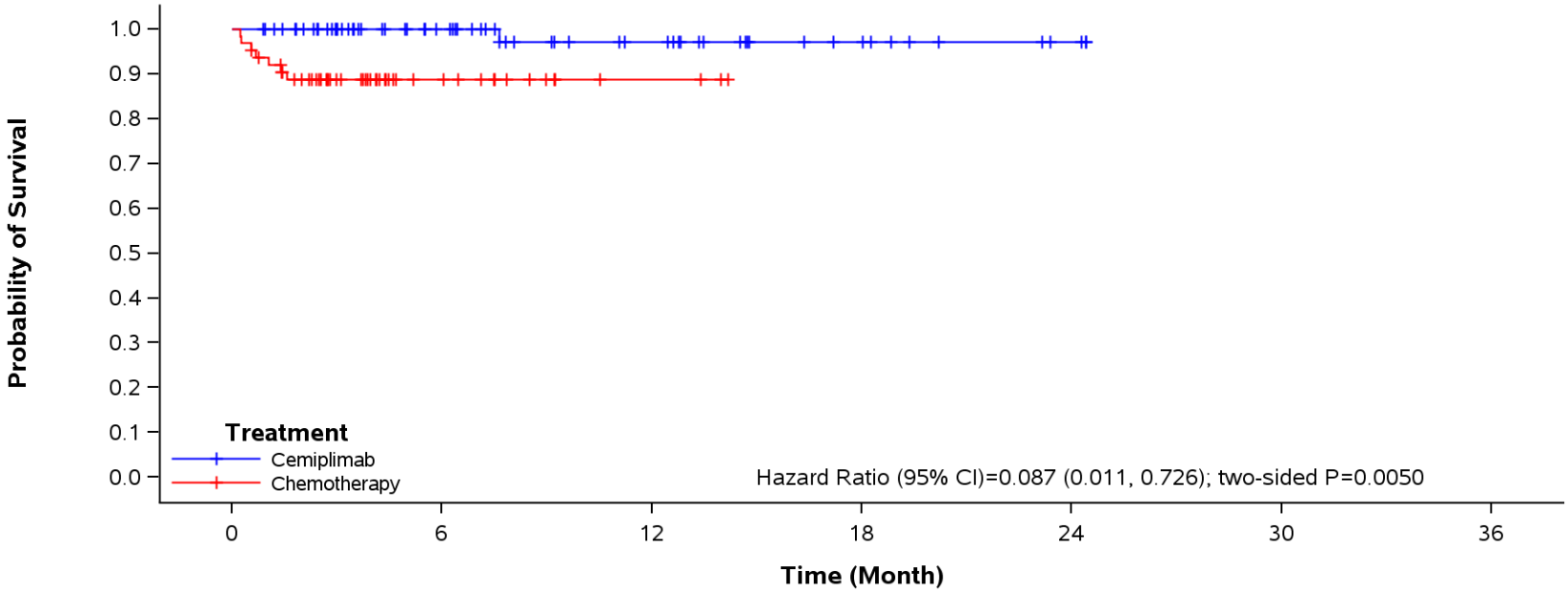

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 38 | 21 | 9 | 4 | 0 | 0 |
| Chemotherapy | 64 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Neutropenia



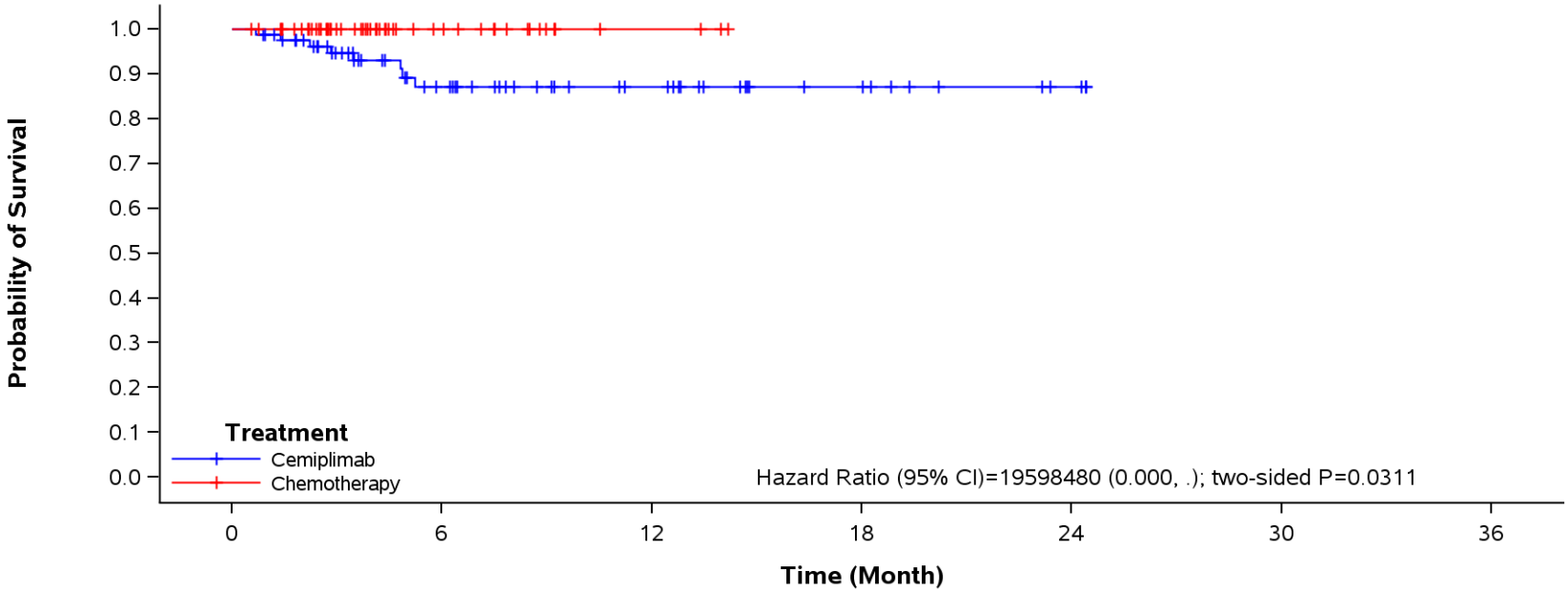

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 24 | 12 | 4 | 0 | 0 |
| Chemotherapy | 64 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Endocrine disorders



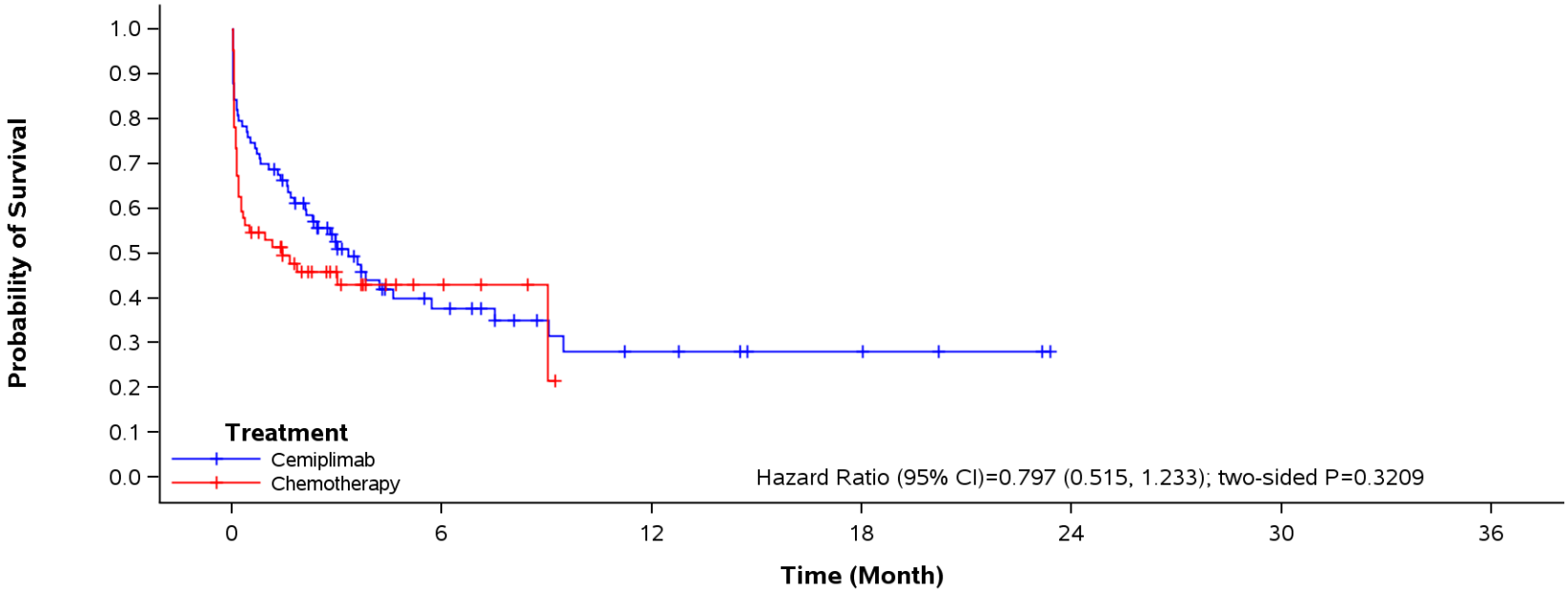

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 40 | 23 | 12 | 4 | 0 | 0 |
| Chemotherapy | 64 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders



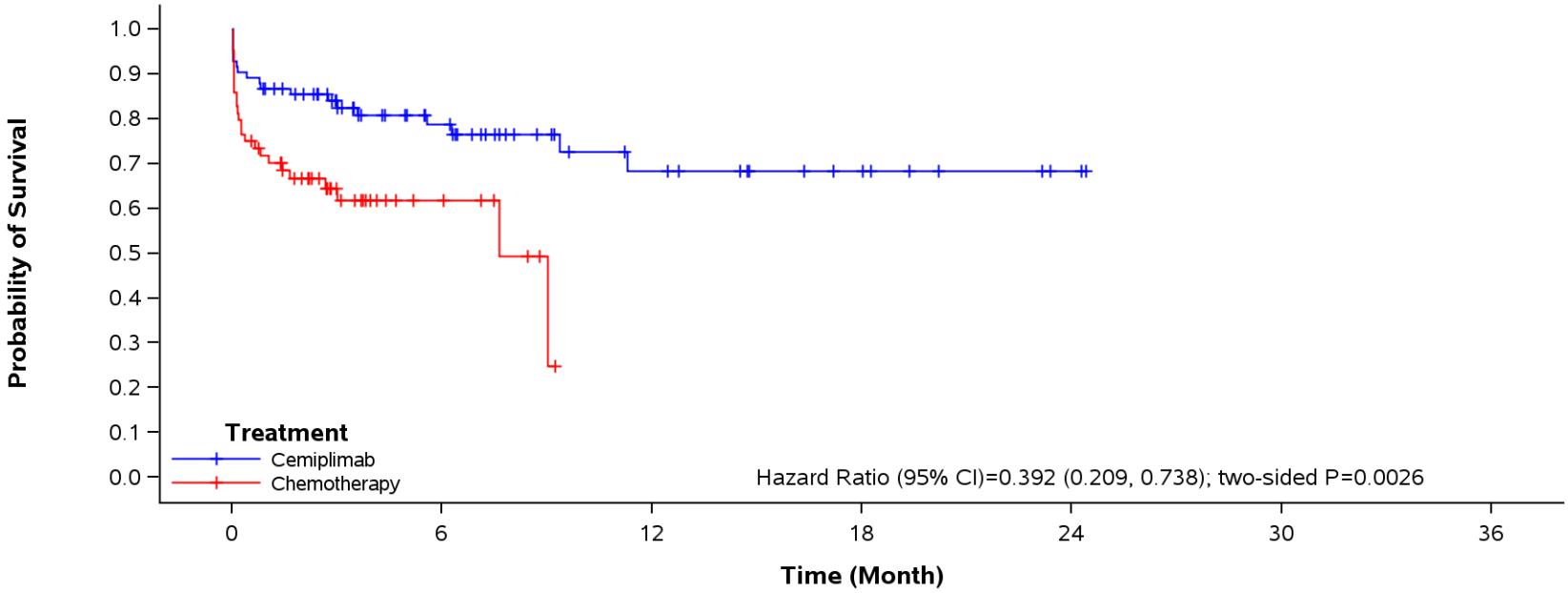

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 17 | 7 | 4 | 0 | 0 | 0 |
| Chemotherapy | 64 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders
PT: Nausea



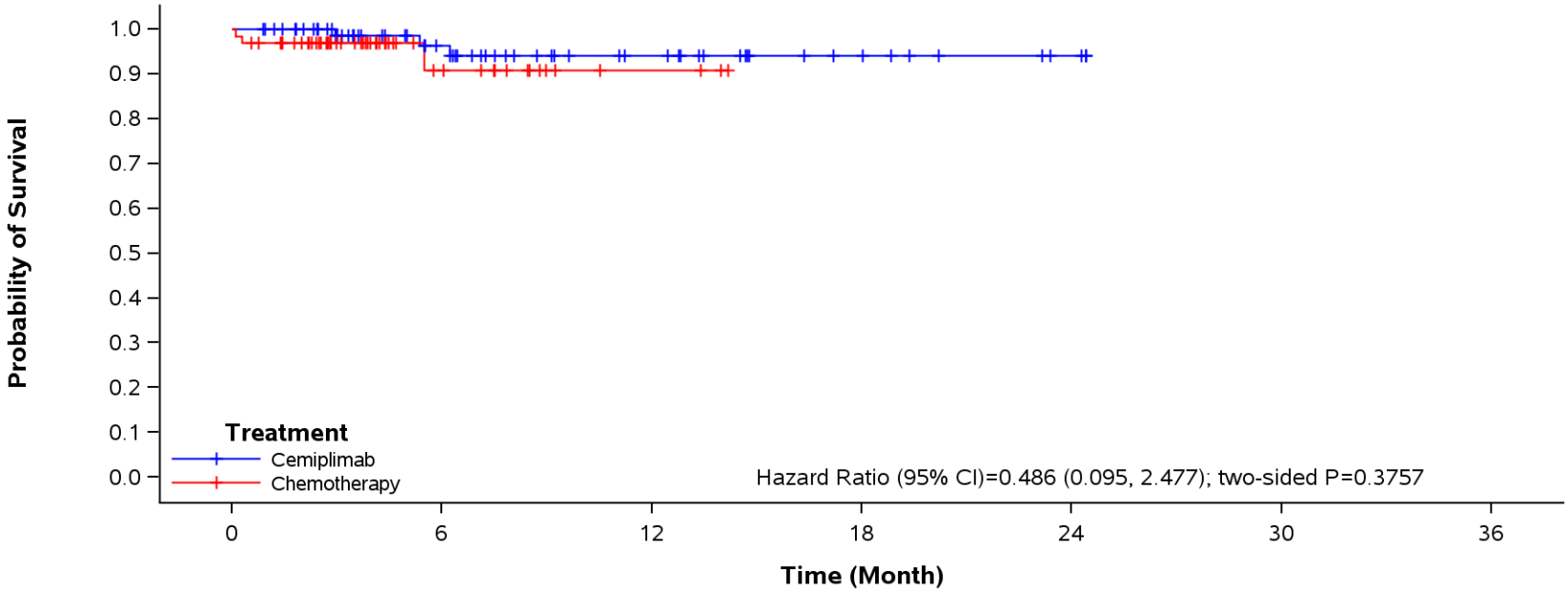

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 16 | 9 | 2 | 0 | 0 |
| Chemotherapy | 64 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders
PT: Stomatitis



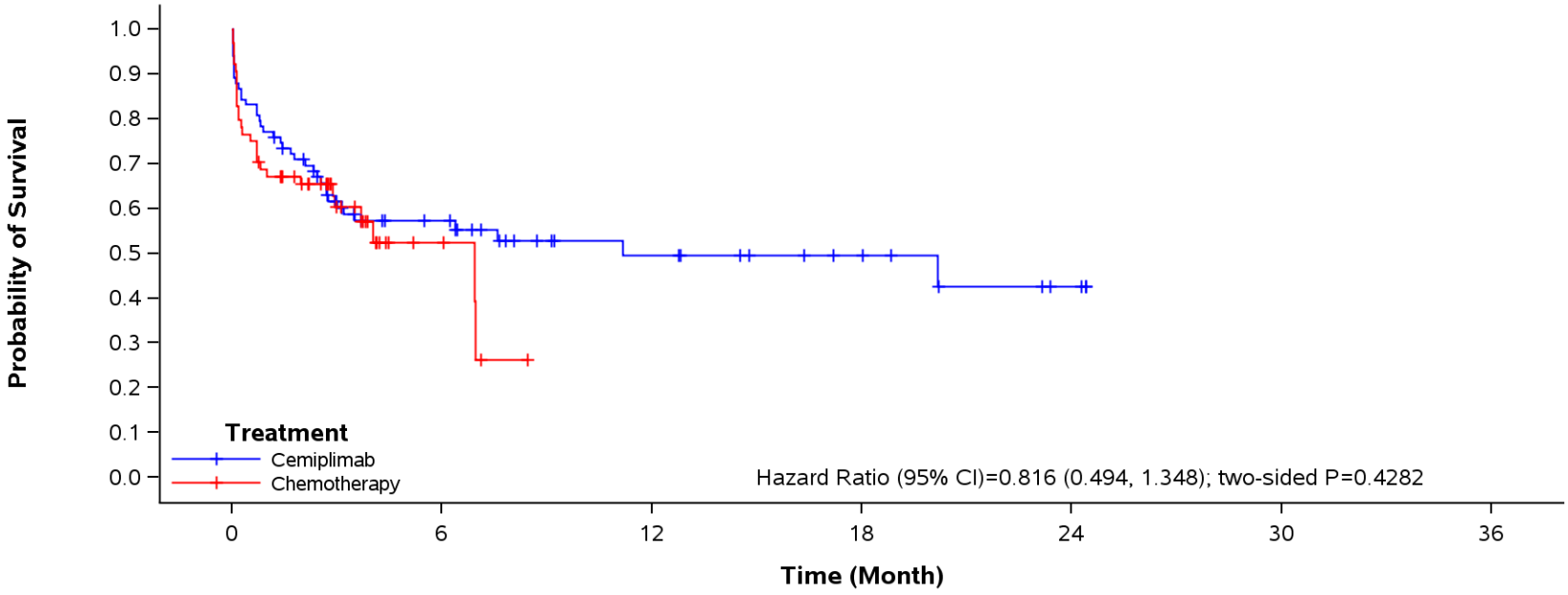

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 42 | 22 | 11 | 4 | 0 | 0 |
| Chemotherapy | 64 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: General disorders and administration site conditions



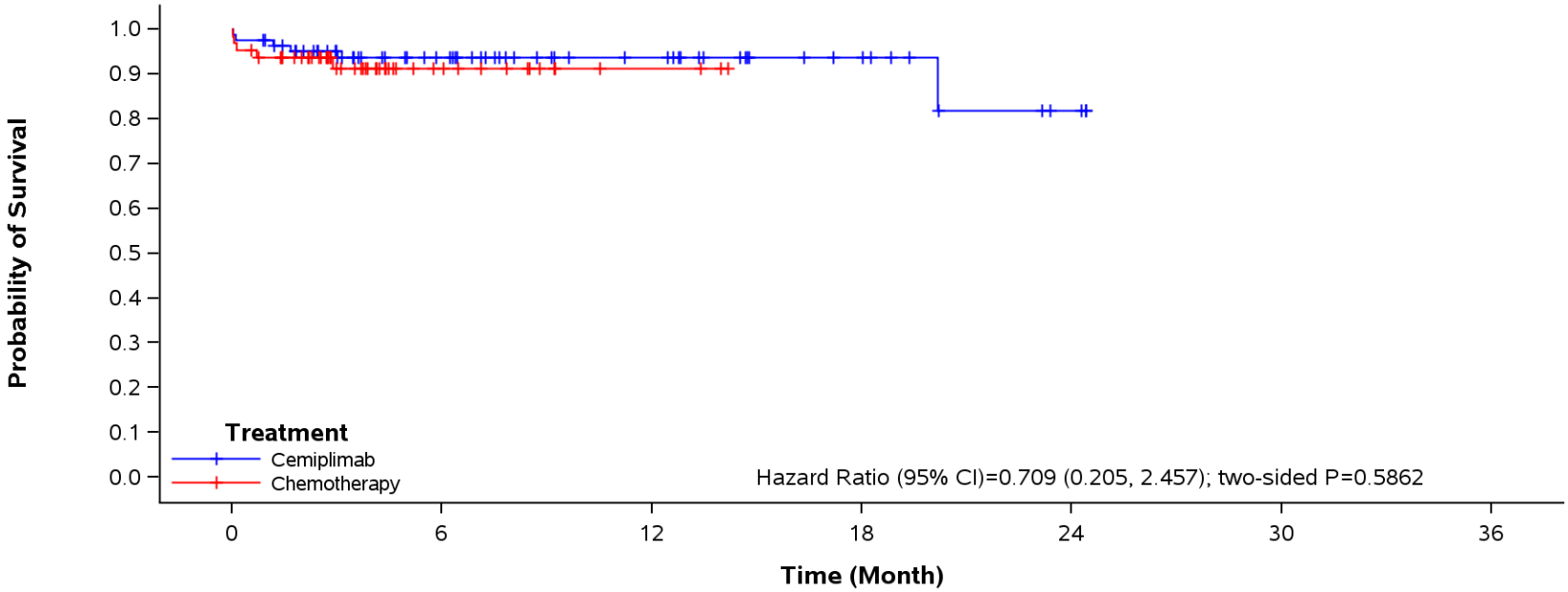

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 30 | 15 | 9 | 3 | 0 | 0 |
| Chemotherapy | 64 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: General disorders and administration site conditions
PT: Asthenia



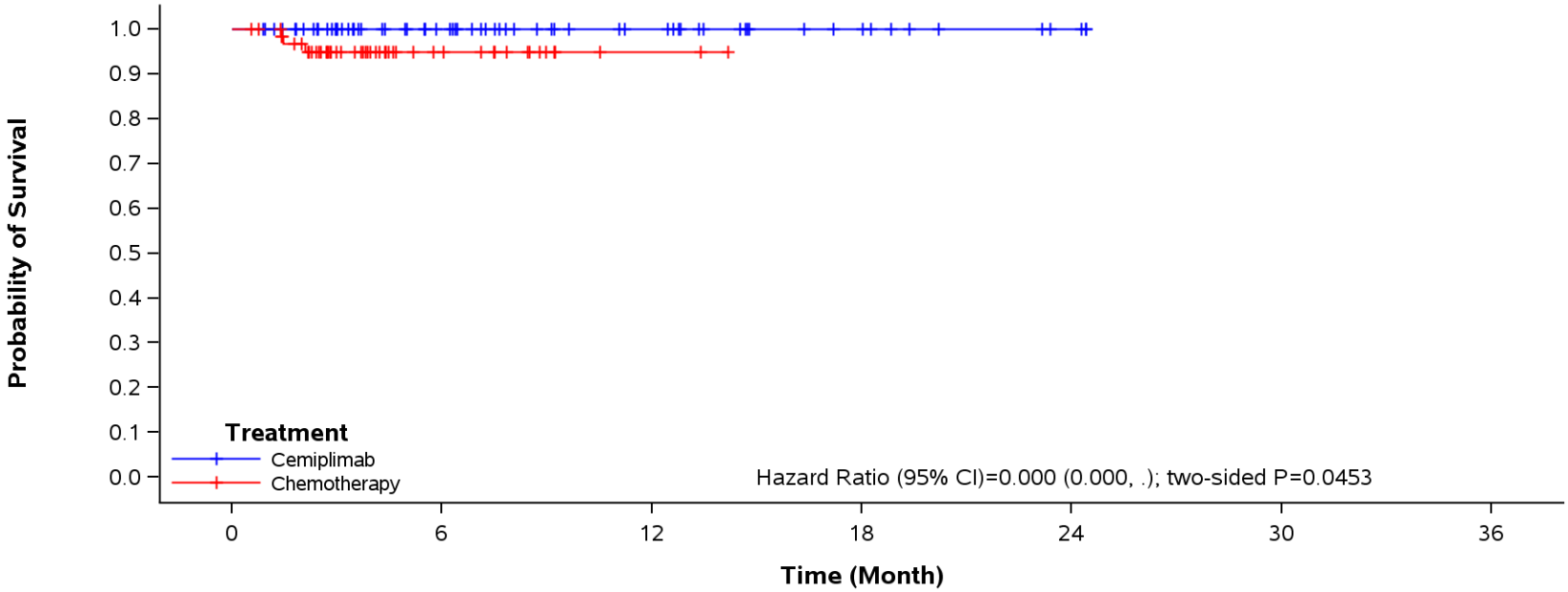

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 43 | 24 | 12 | 4 | 0 | 0 |
| Chemotherapy | 64 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



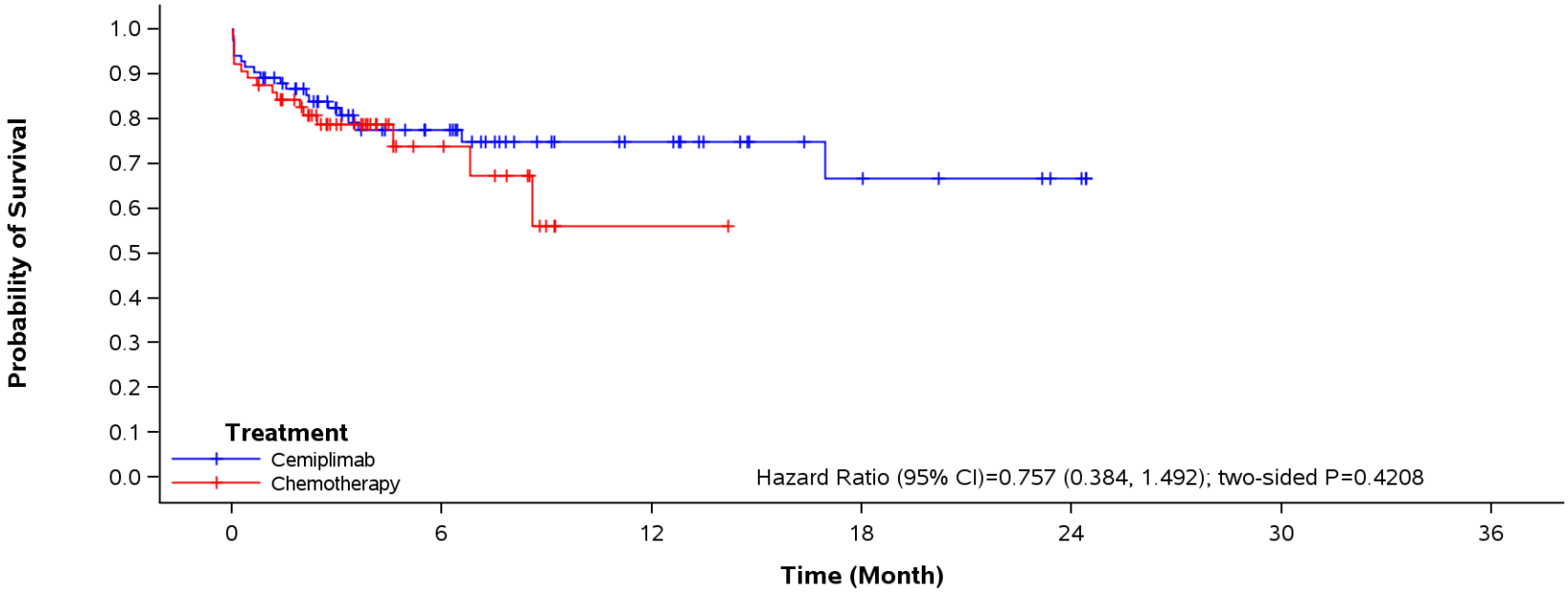

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 24 | 12 | 4 | 0 | 0 |
| Chemotherapy | 64 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Nervous system disorders



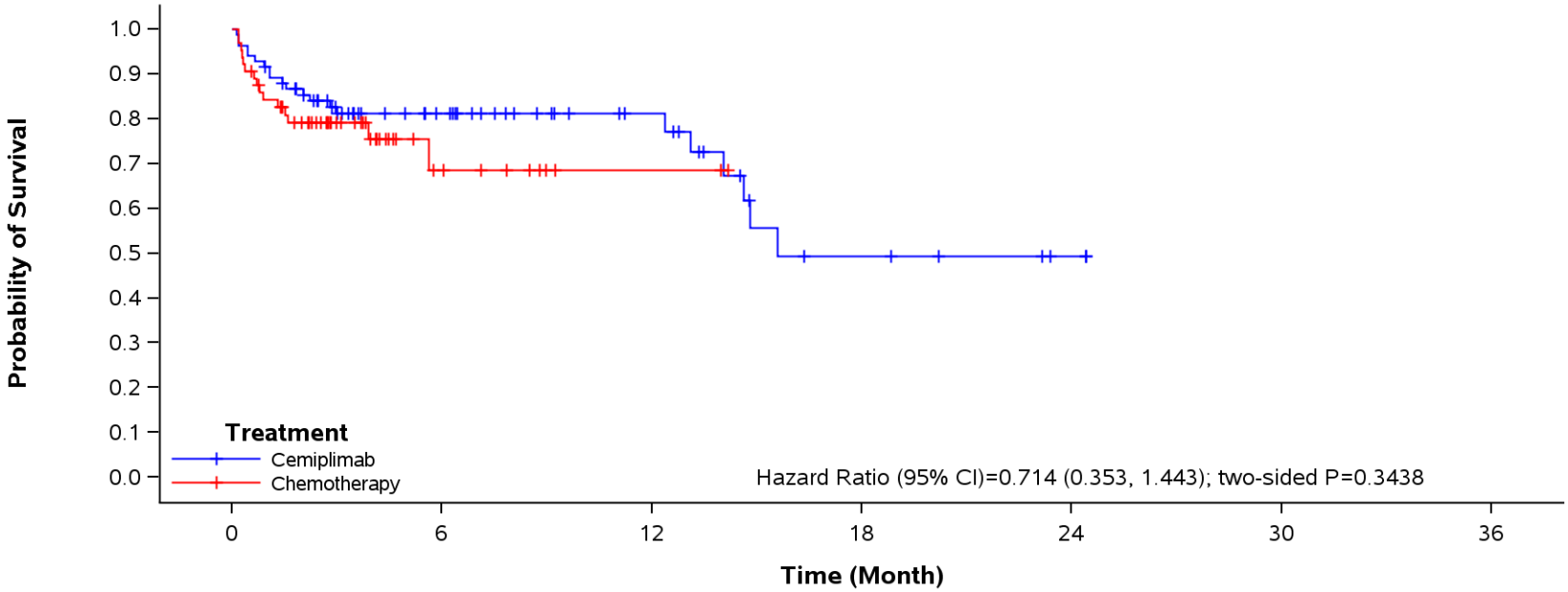

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 18 | 8 | 3 | 0 | 0 |
| Chemotherapy | 64 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Skin and subcutaneous tissue disorders



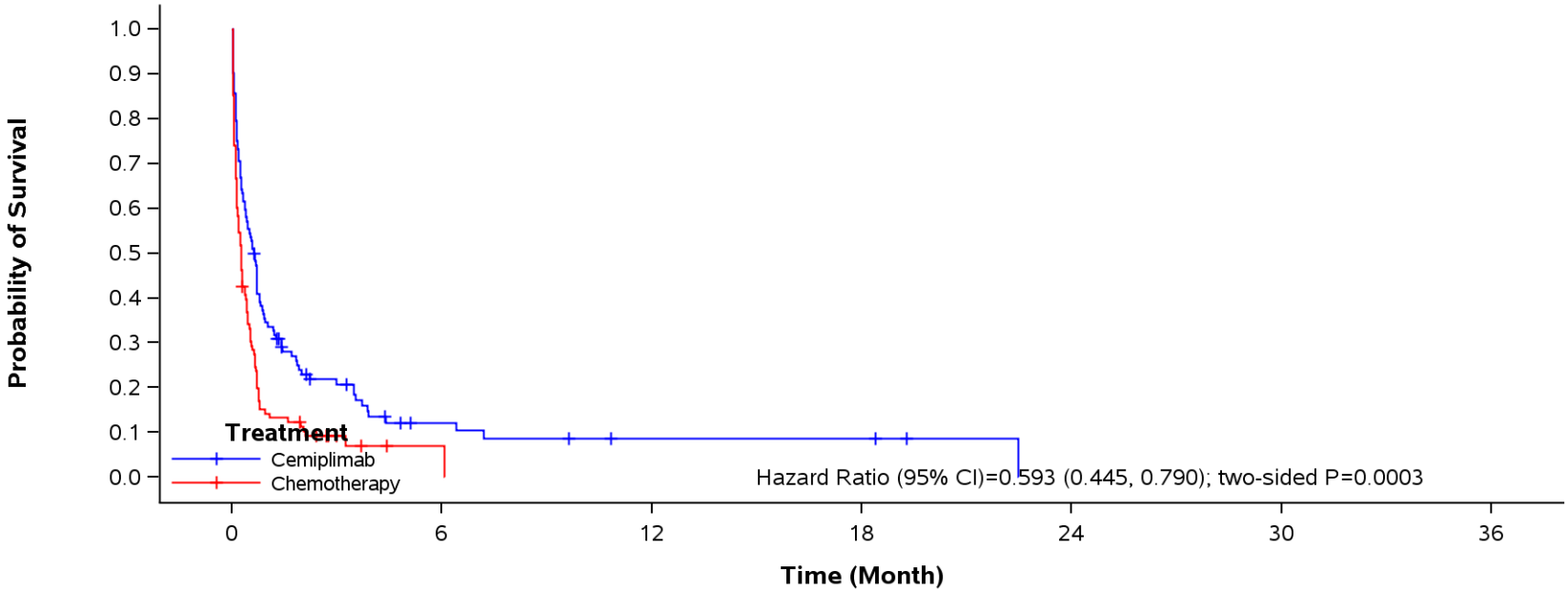

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 20 | 7 | 2 | 0 | 0 |
| Chemotherapy | 64 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Number of patients with any TEAE



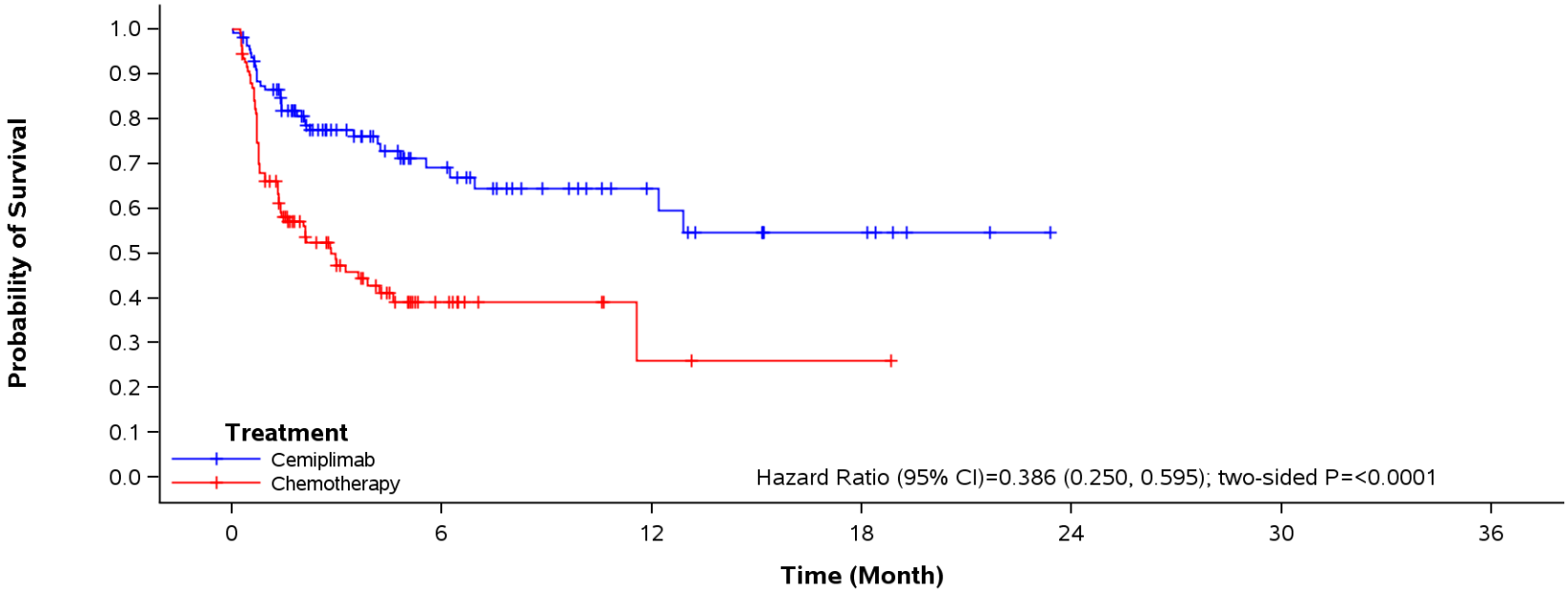

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 7 | 3 | 3 | 0 | 0 | 0 |
| Chemotherapy | 108 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders



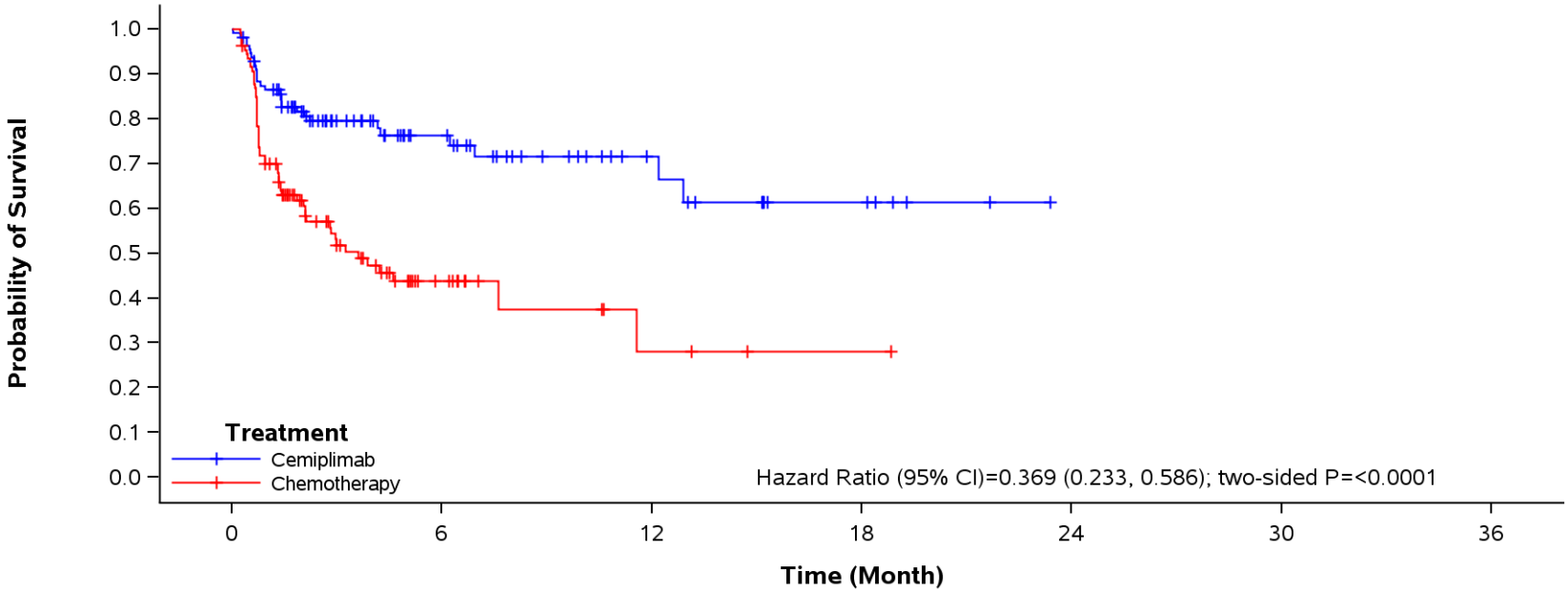

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 33 | 13 | 6 | 0 | 0 | 0 |
| Chemotherapy | 108 | 12 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Anaemia



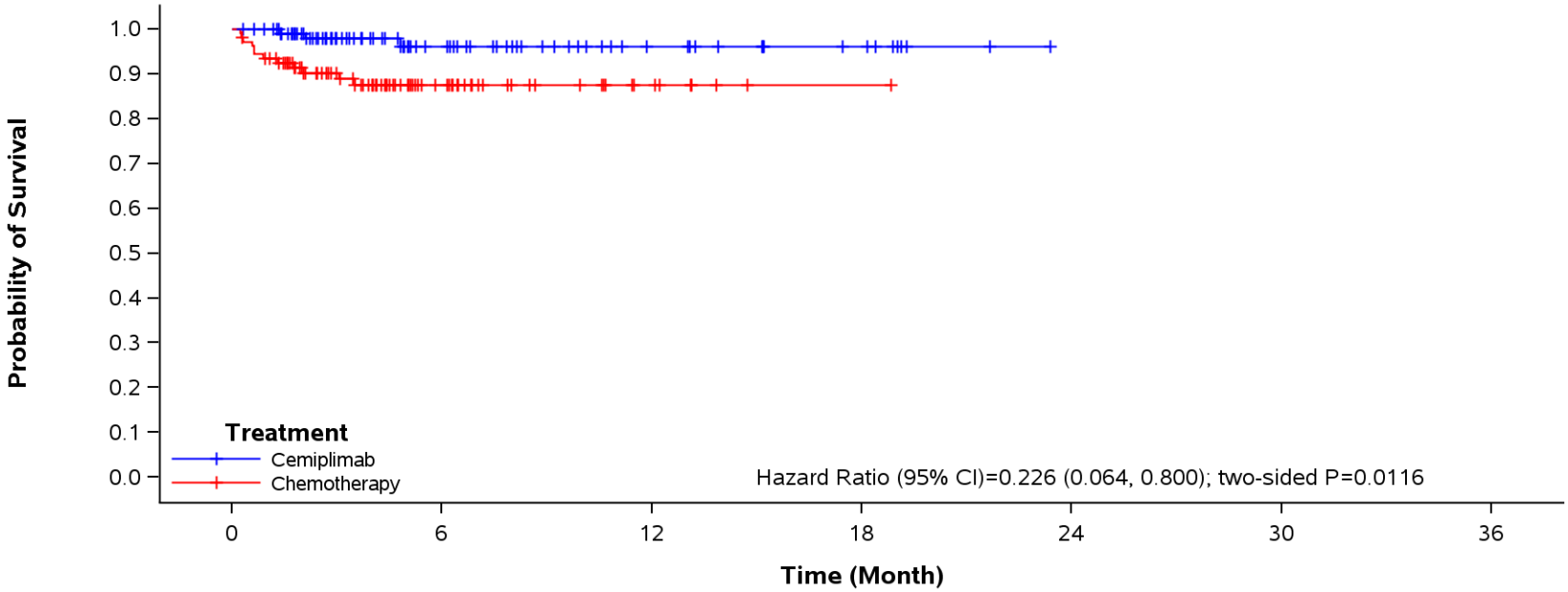

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 36 | 14 | 6 | 0 | 0 | 0 |
| Chemotherapy | 108 | 15 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Neutropenia



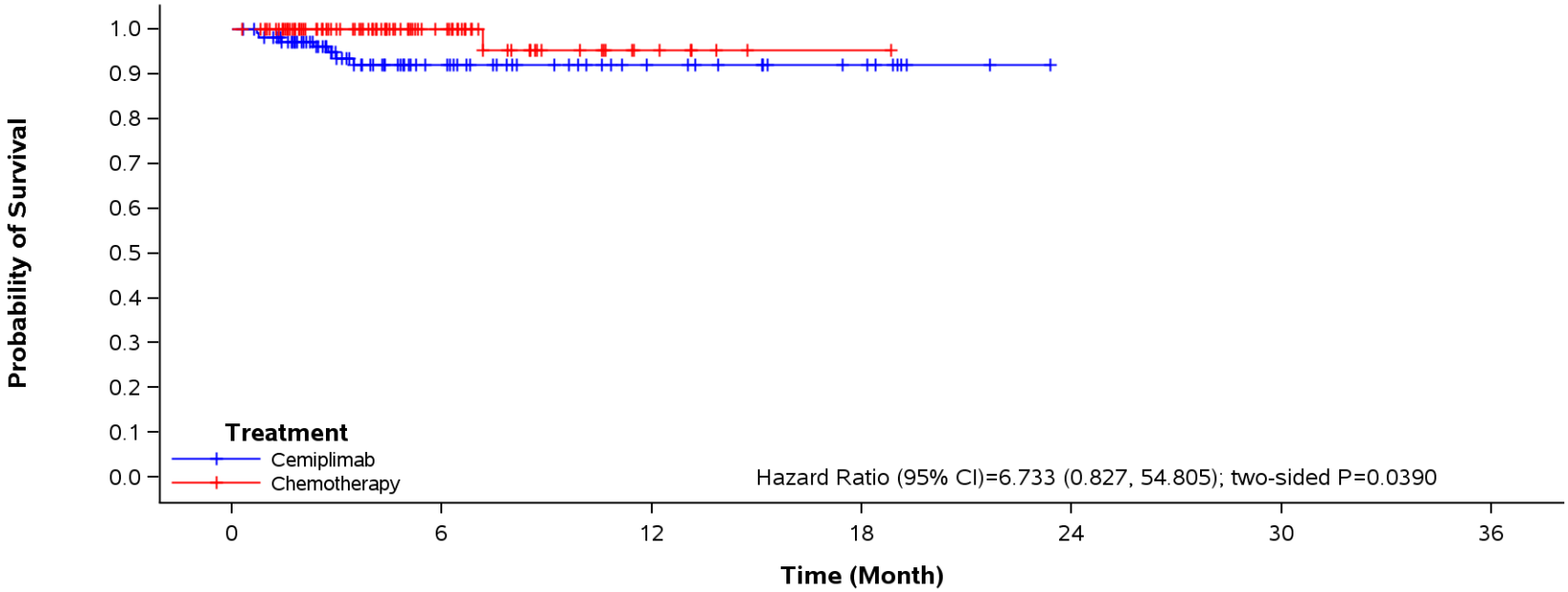

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 16 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 31 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Endocrine disorders



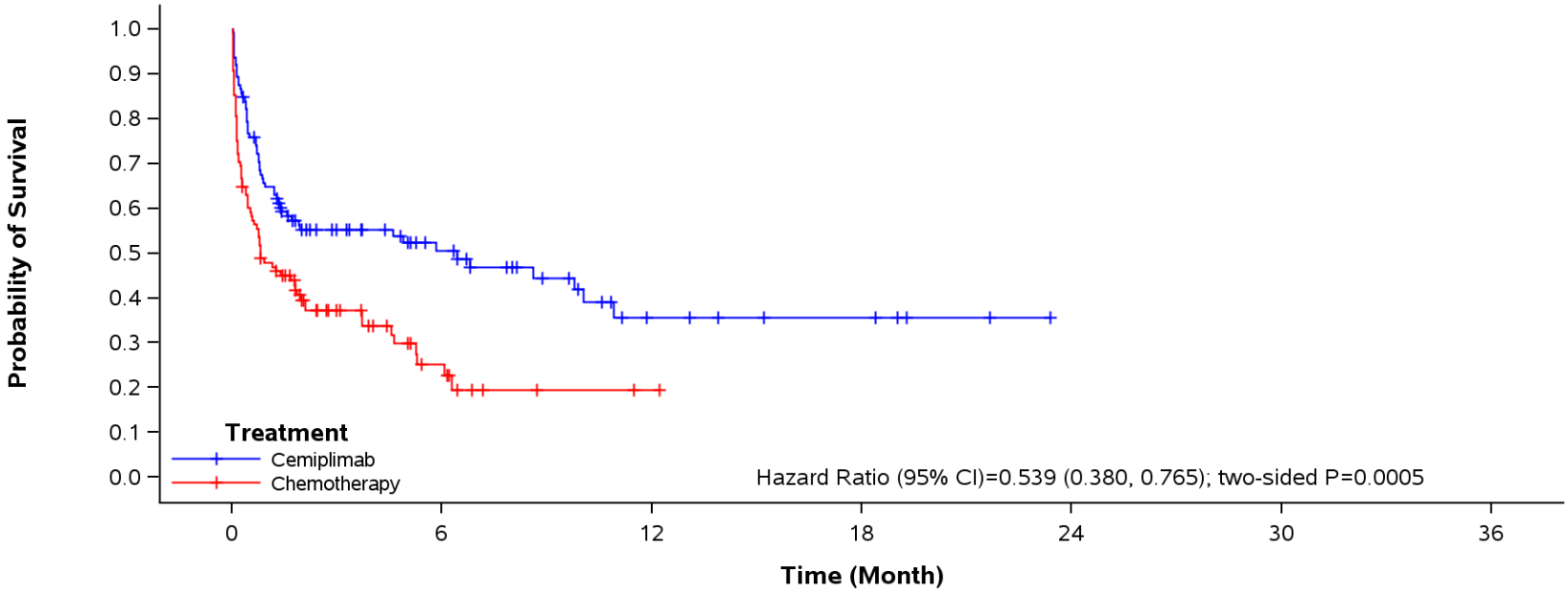

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 37 | 15 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 36 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders



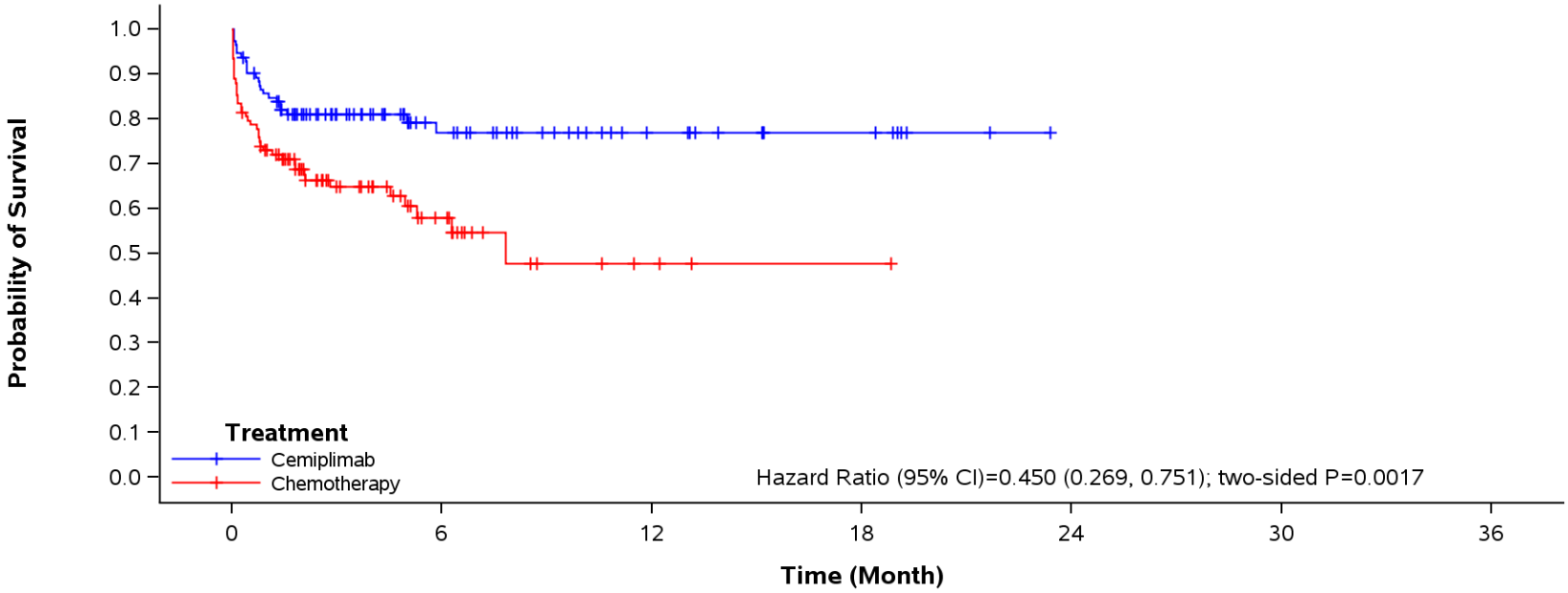

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 29 | 8 | 5 | 0 | 0 | 0 |
| Chemotherapy | 108 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders
PT: Nausea



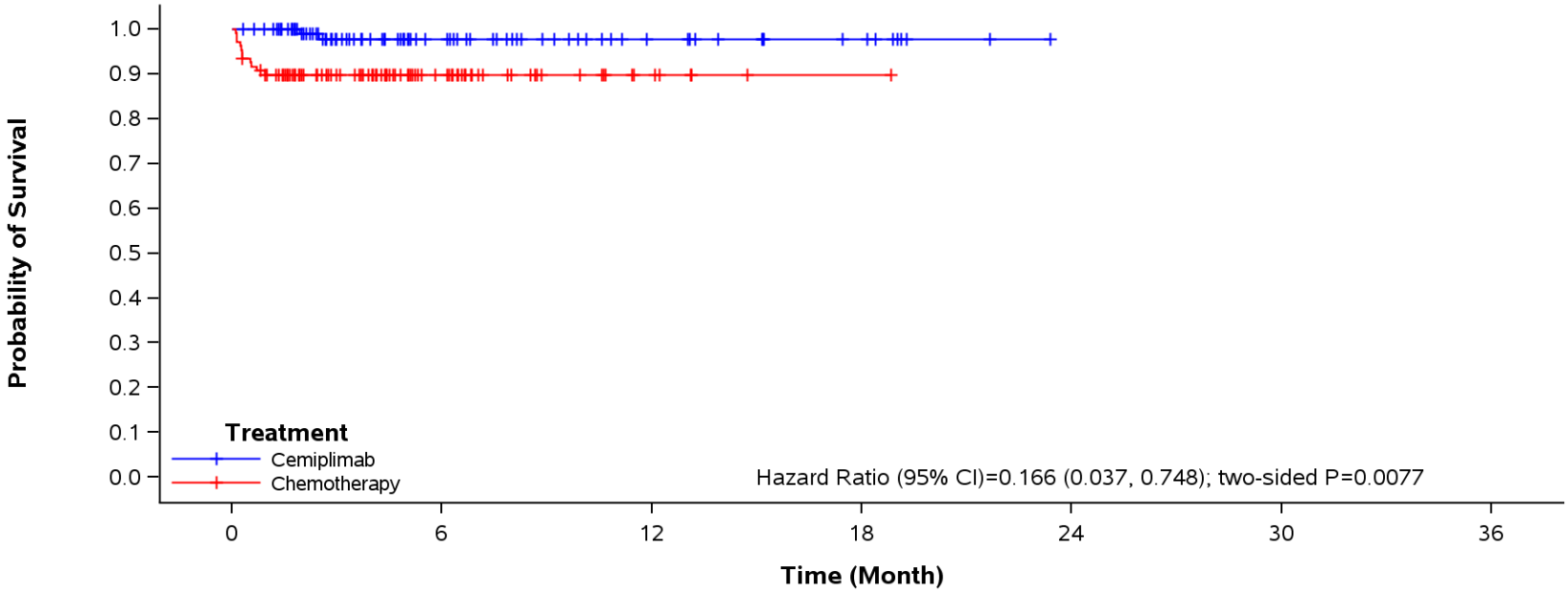

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 35 | 14 | 7 | 0 | 0 | 0 |
| Chemotherapy | 108 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders
PT: Stomatitis



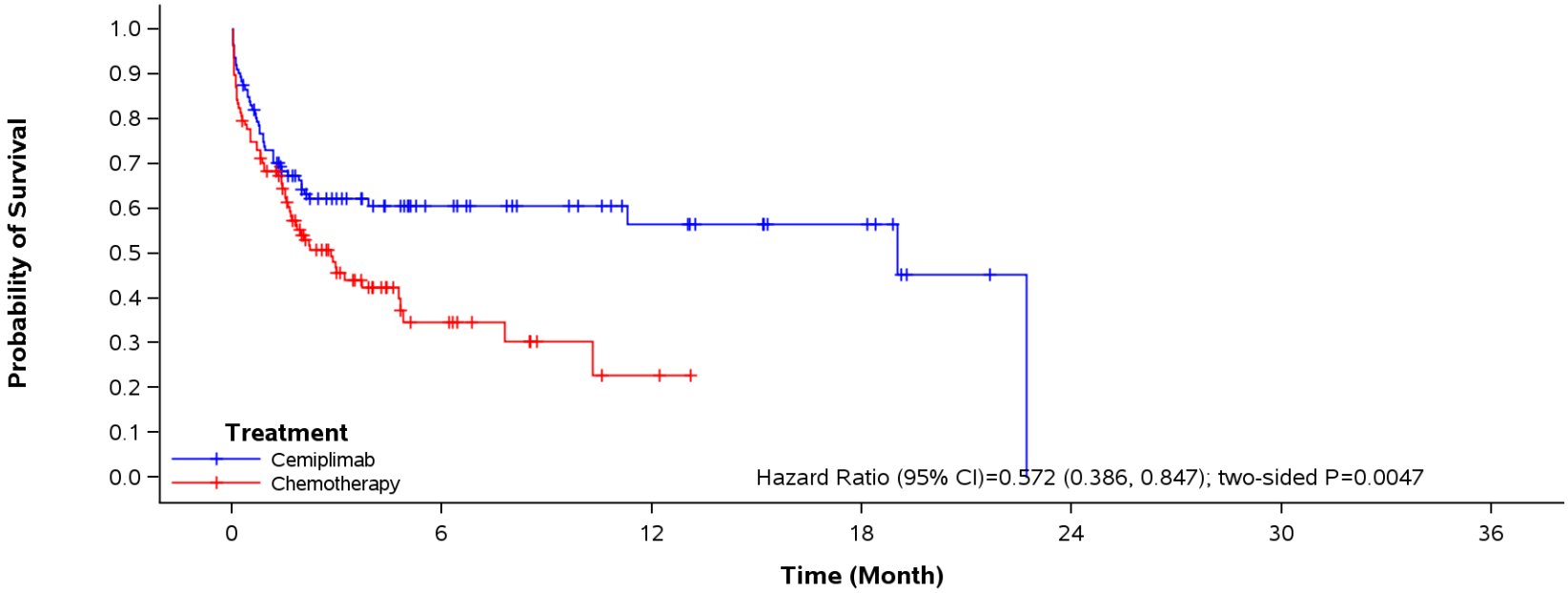

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 16 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 34 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: General disorders and administration site conditions



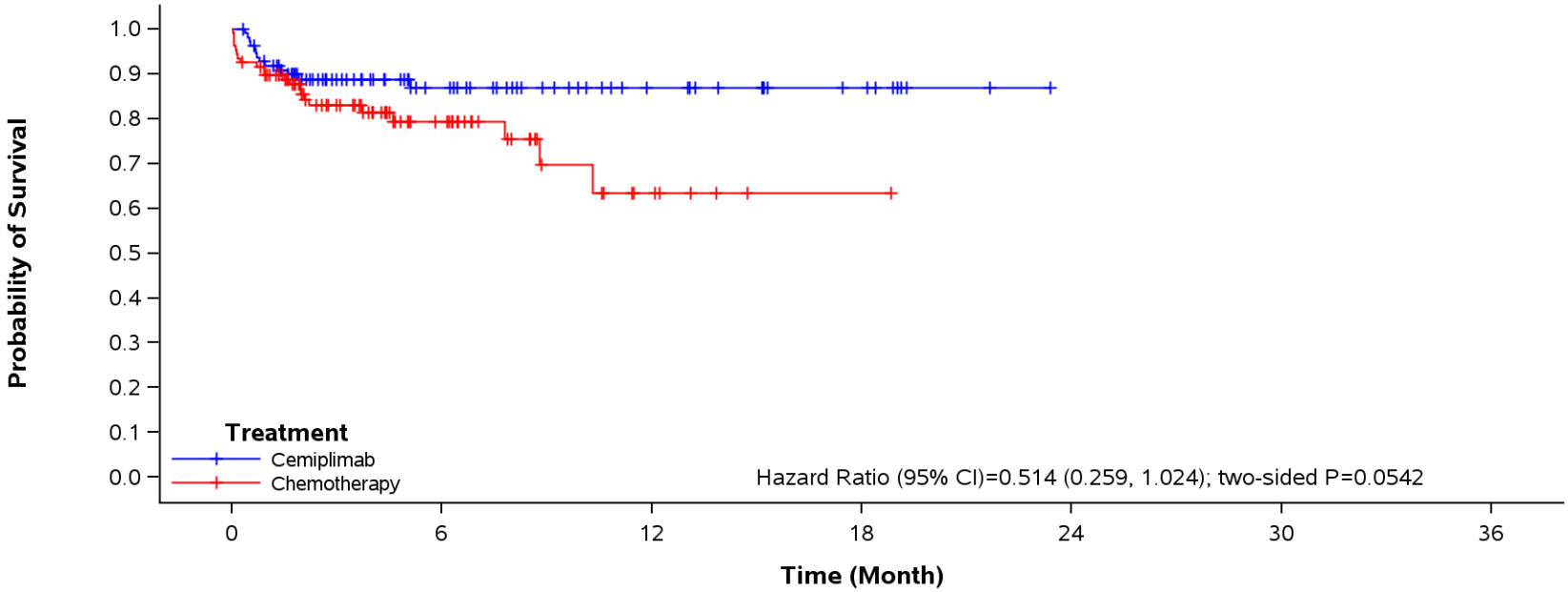

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 29 | 14 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: General disorders and administration site conditions
PT: Asthenia



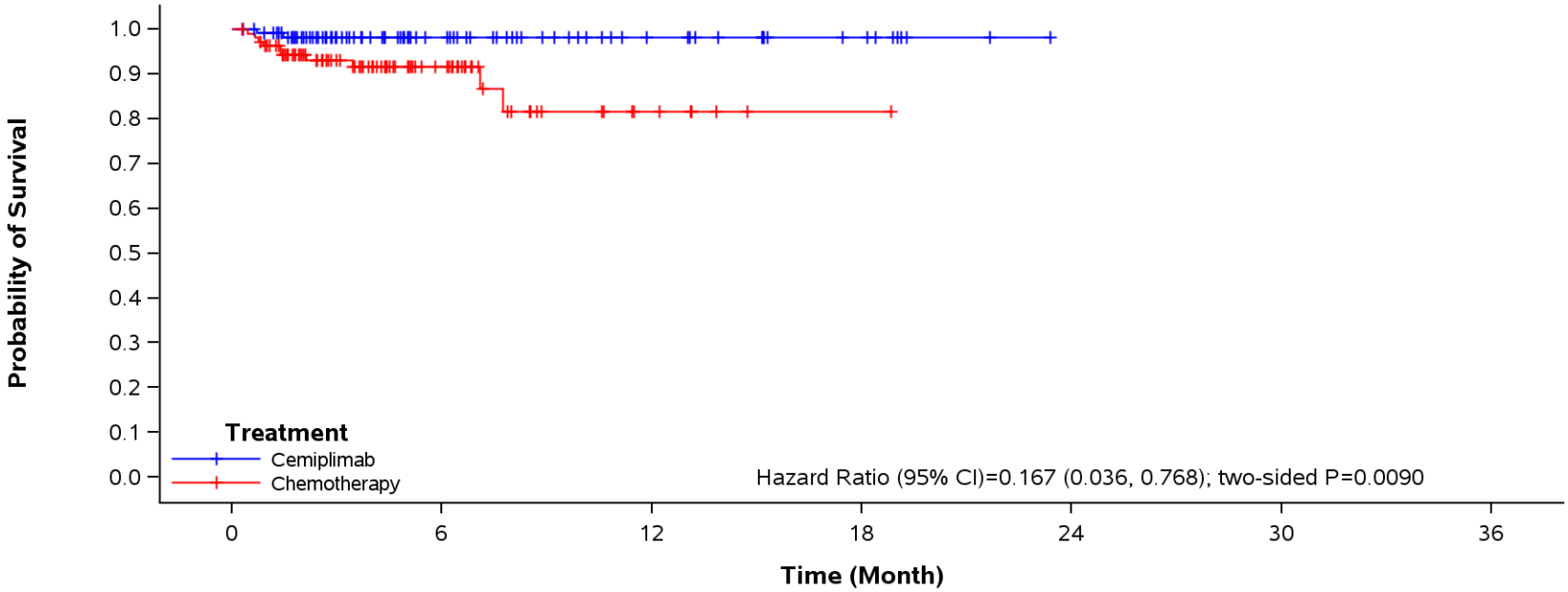

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 17 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 32 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



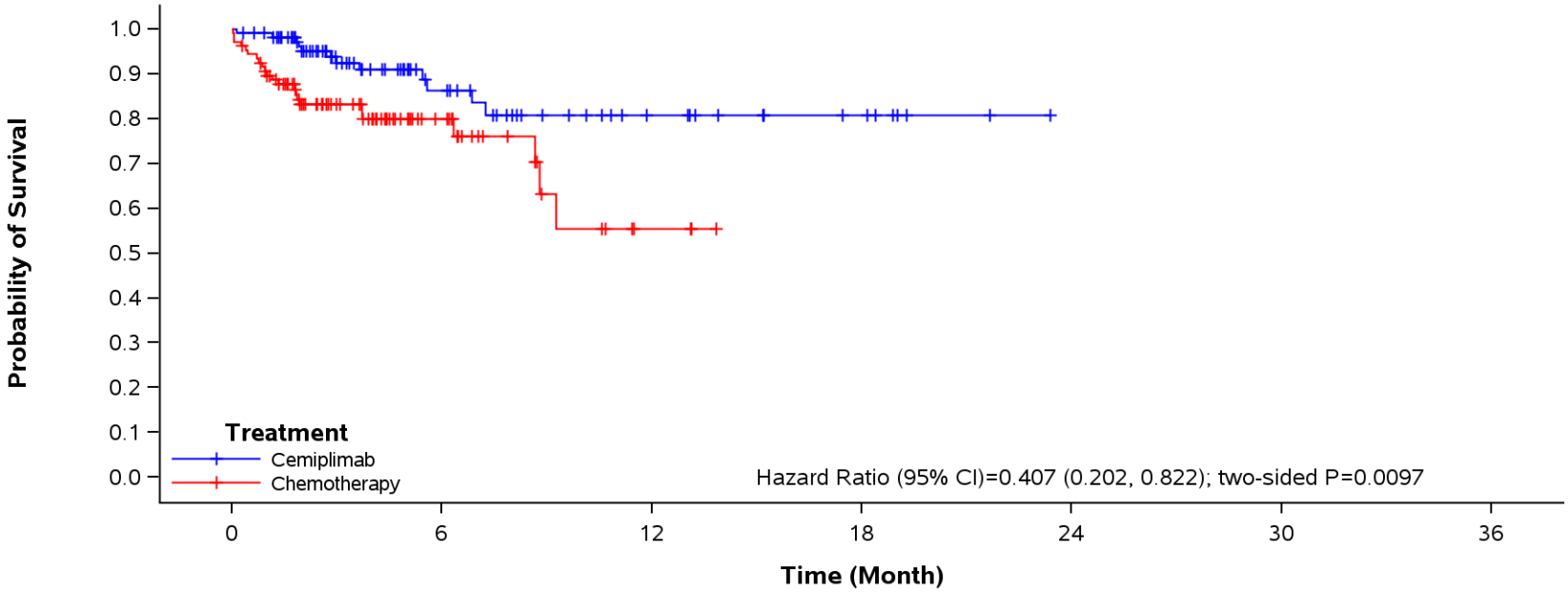

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 17 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 34 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Nervous system disorders



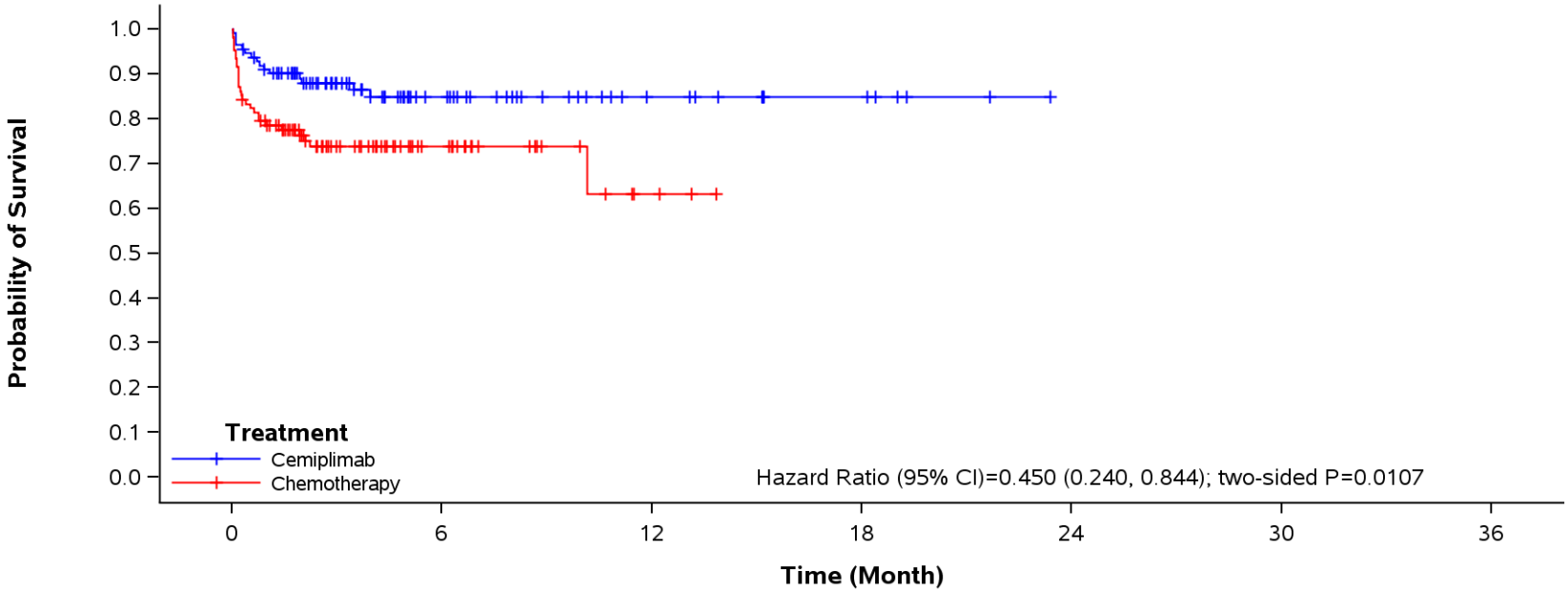

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 36 | 14 | 7 | 0 | 0 | 0 |
| Chemotherapy | 108 | 27 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Skin and subcutaneous tissue disorders



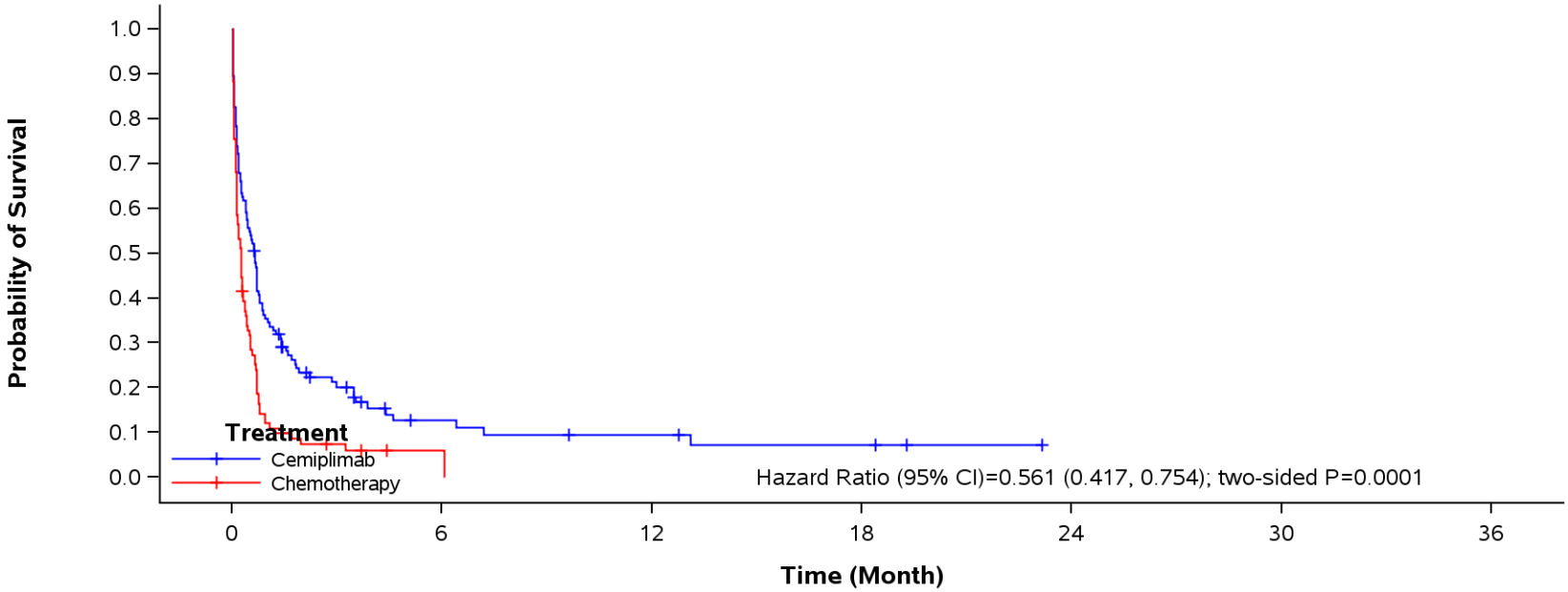

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 34 | 12 | 6 | 0 | 0 | 0 |
| Chemotherapy | 108 | 22 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Number of patients with any TEAE



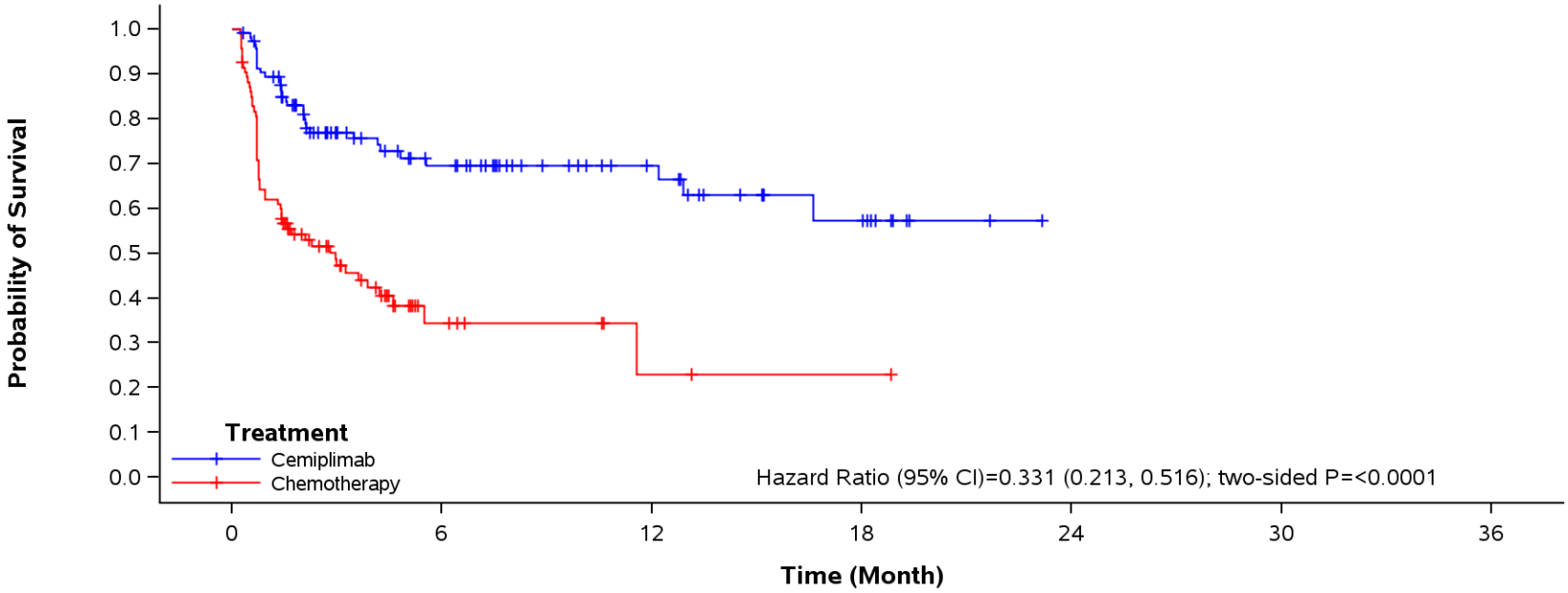

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 8 | 5 | 3 | 0 | 0 | 0 |
| Chemotherapy | 94 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders



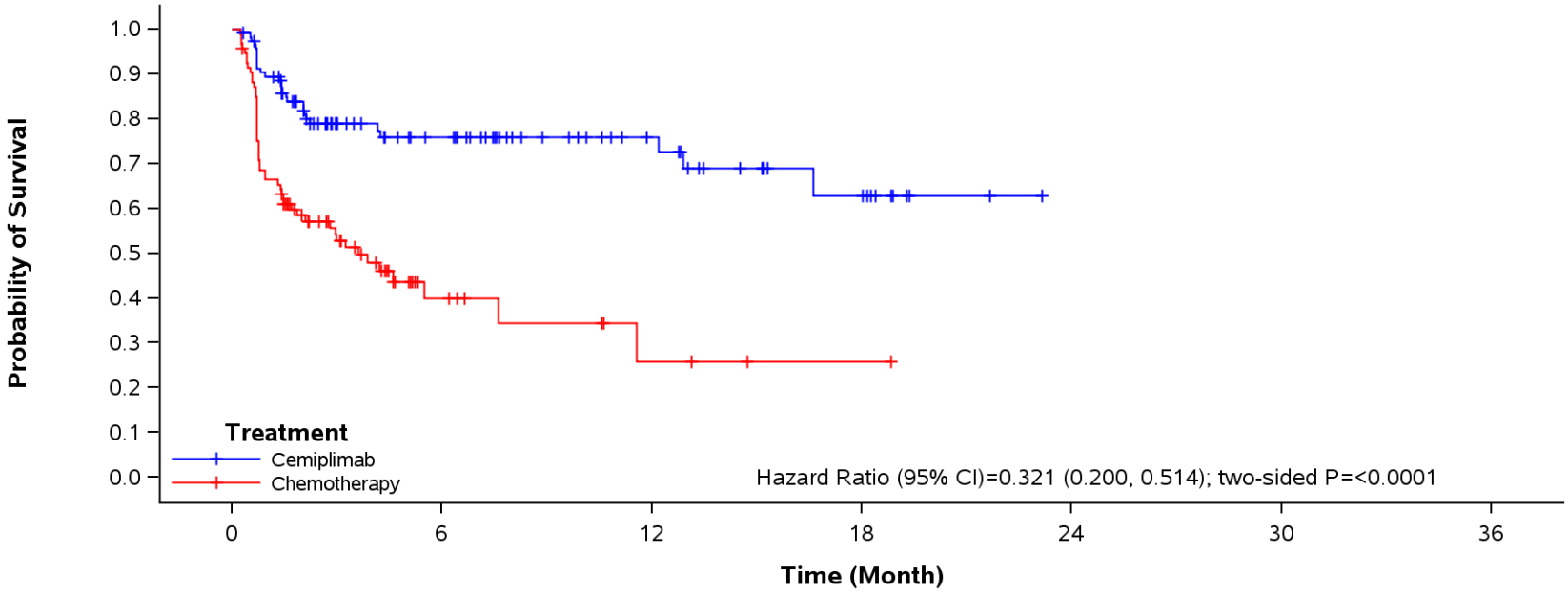

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 42 | 22 | 10 | 0 | 0 | 0 |
| Chemotherapy | 94 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



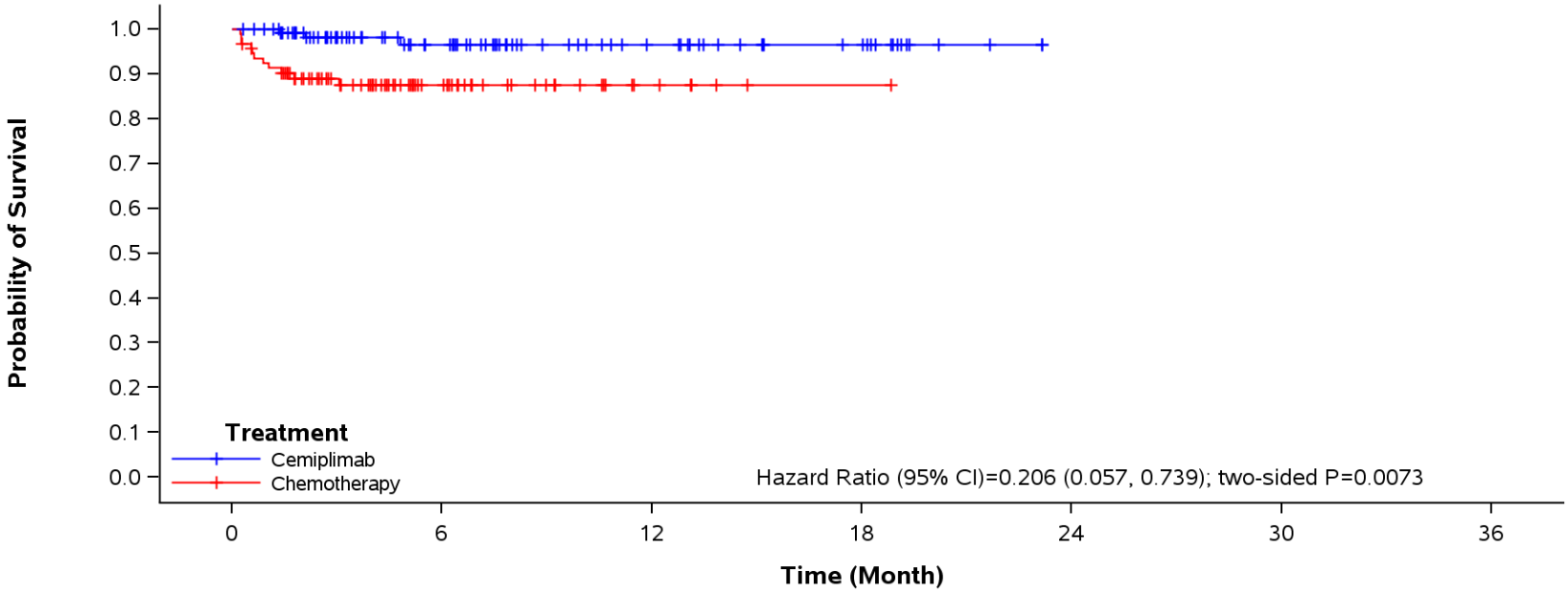

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 45 | 23 | 10 | 0 | 0 | 0 |
| Chemotherapy | 94 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia



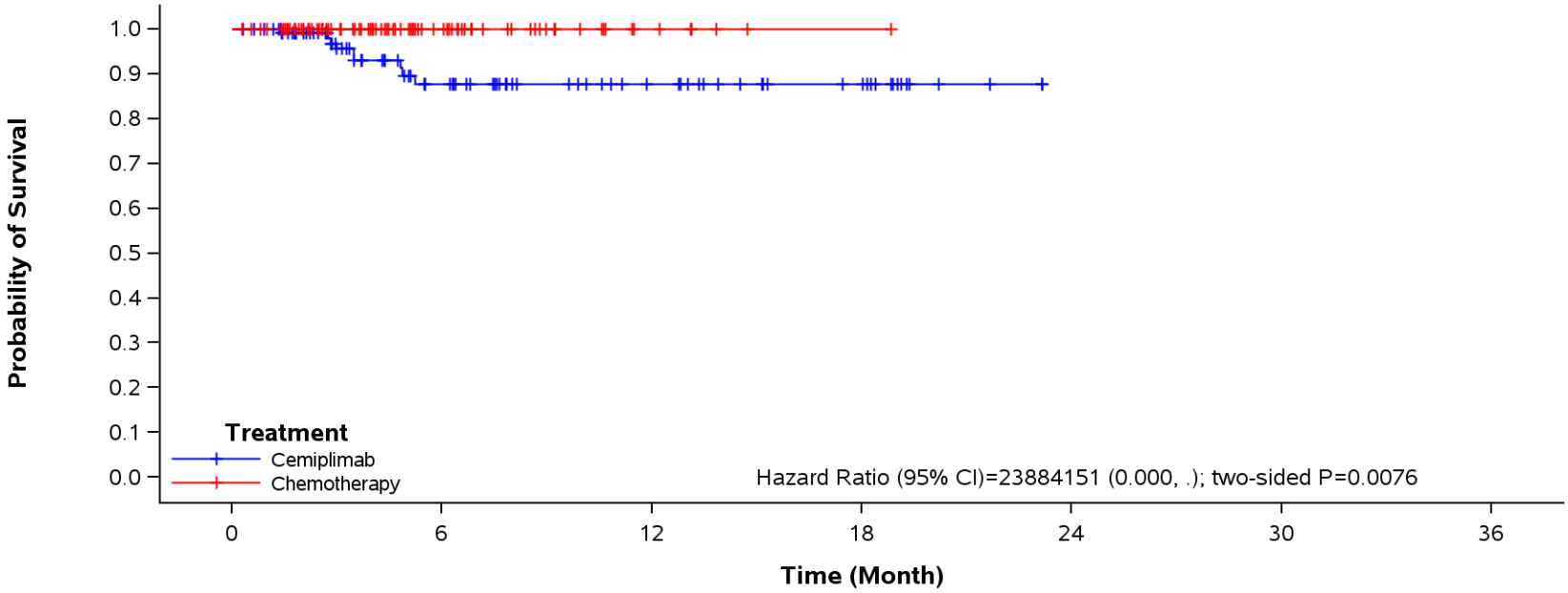

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 52 | 26 | 14 | 0 | 0 | 0 |
| Chemotherapy | 94 | 30 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Endocrine disorders



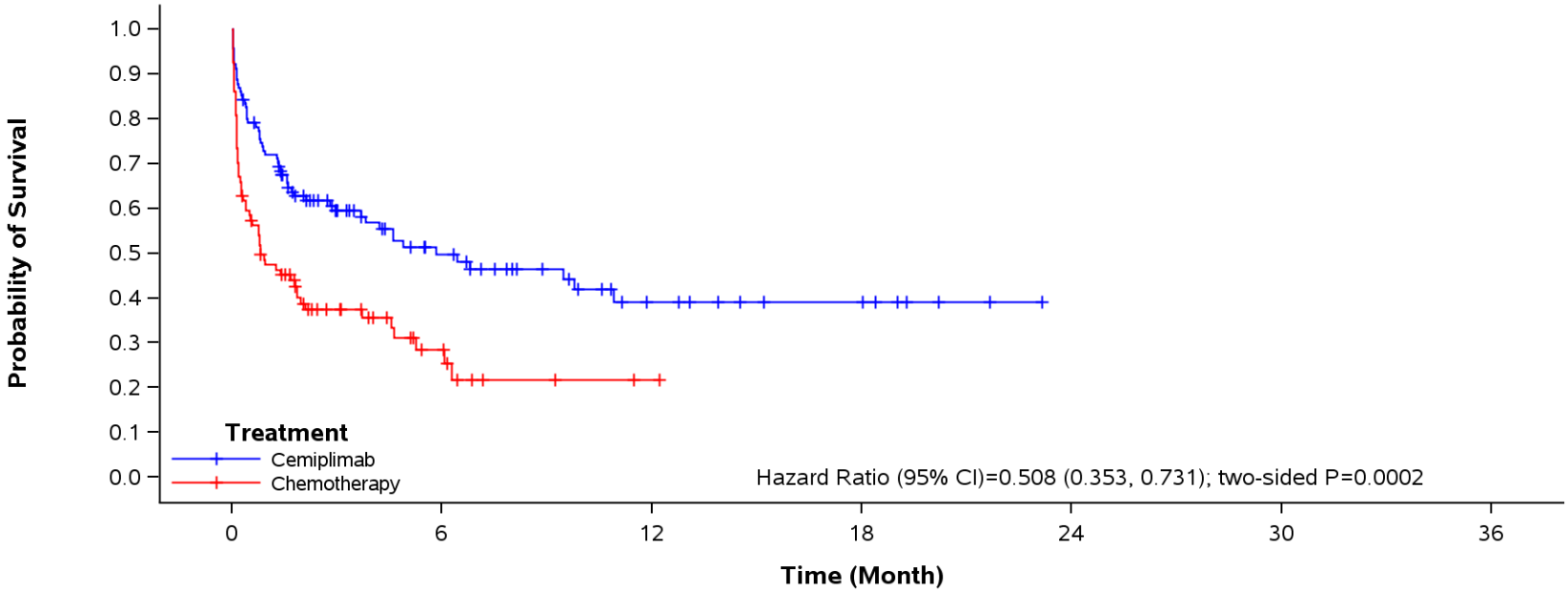

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 46 | 25 | 14 | 0 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders



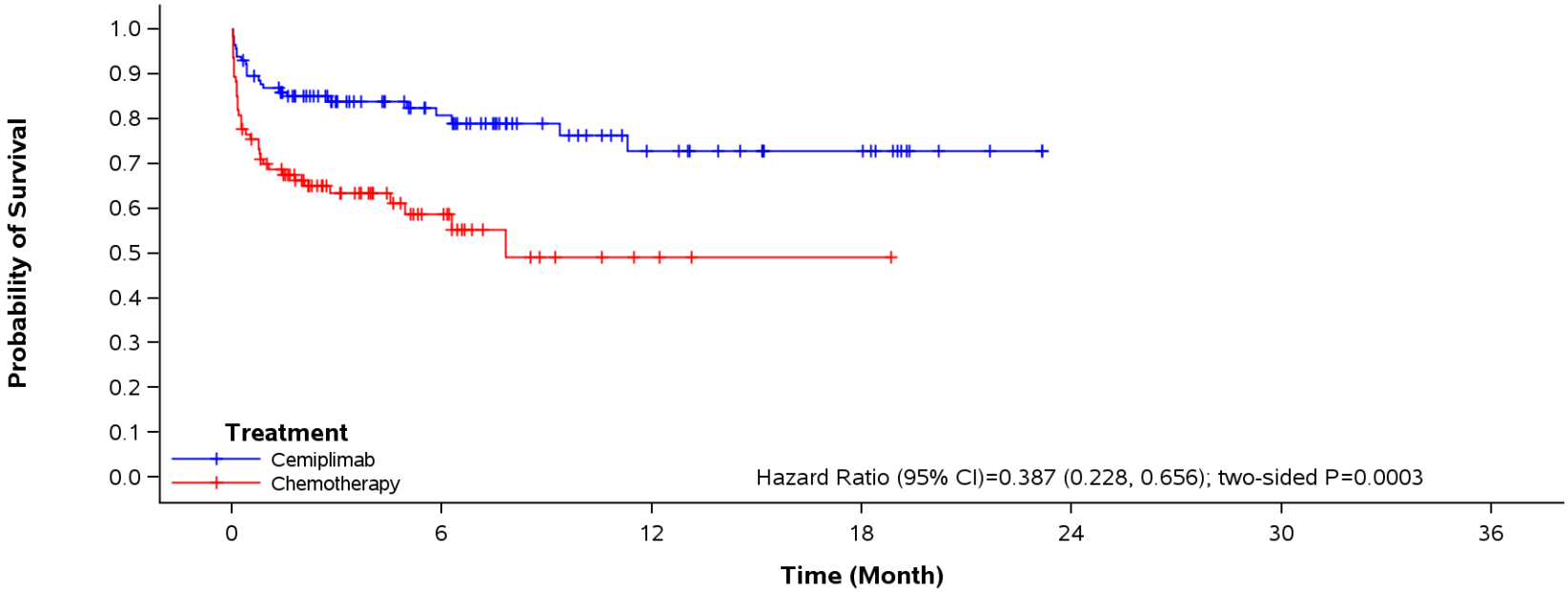

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 32 | 12 | 7 | 0 | 0 | 0 |
| Chemotherapy | 94 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders
PT: Nausea



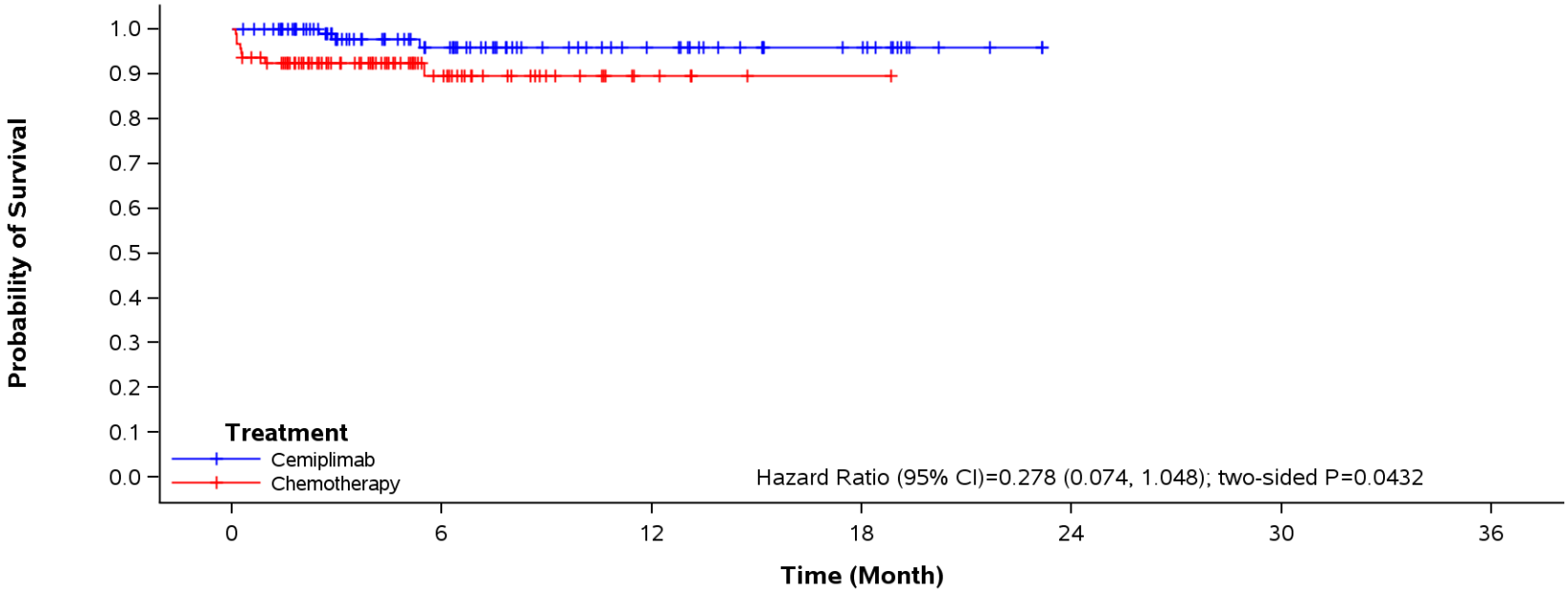

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 47 | 20 | 12 | 0 | 0 | 0 |
| Chemotherapy | 94 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders
PT: Stomatitis



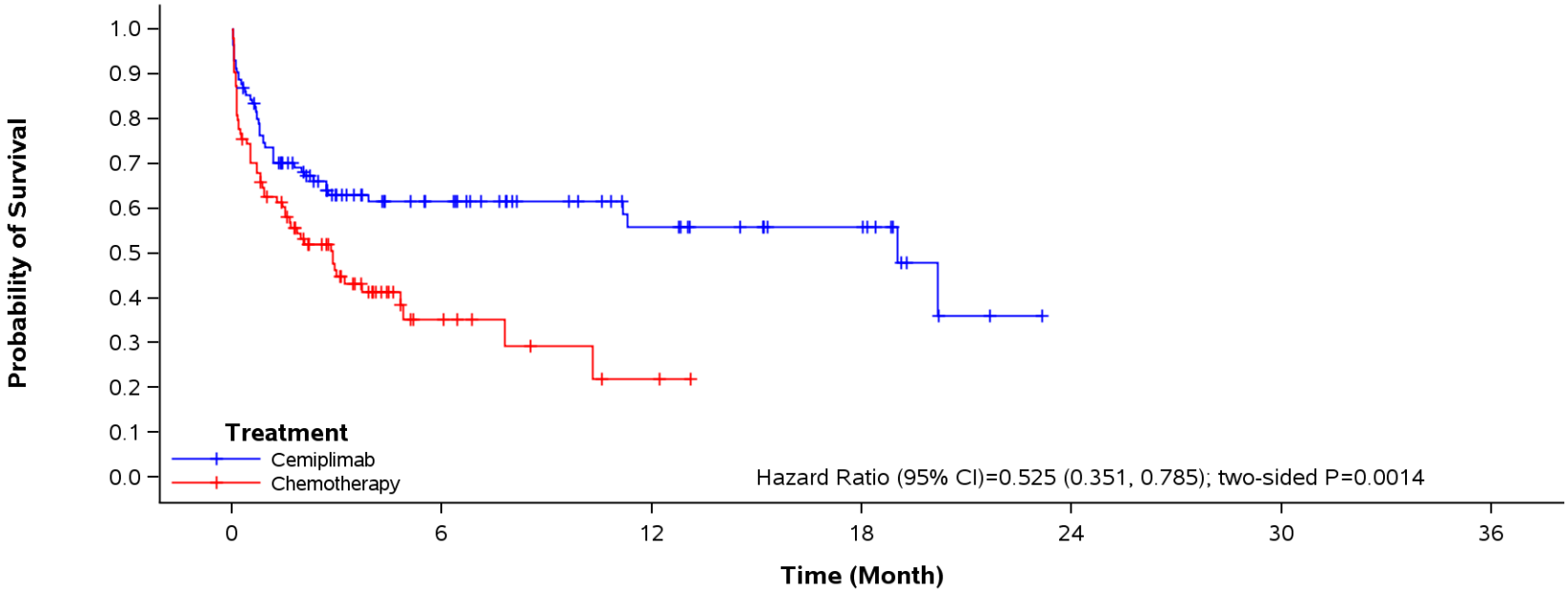

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 50 | 25 | 13 | 0 | 0 | 0 |
| Chemotherapy | 94 | 30 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: General disorders and administration site conditions



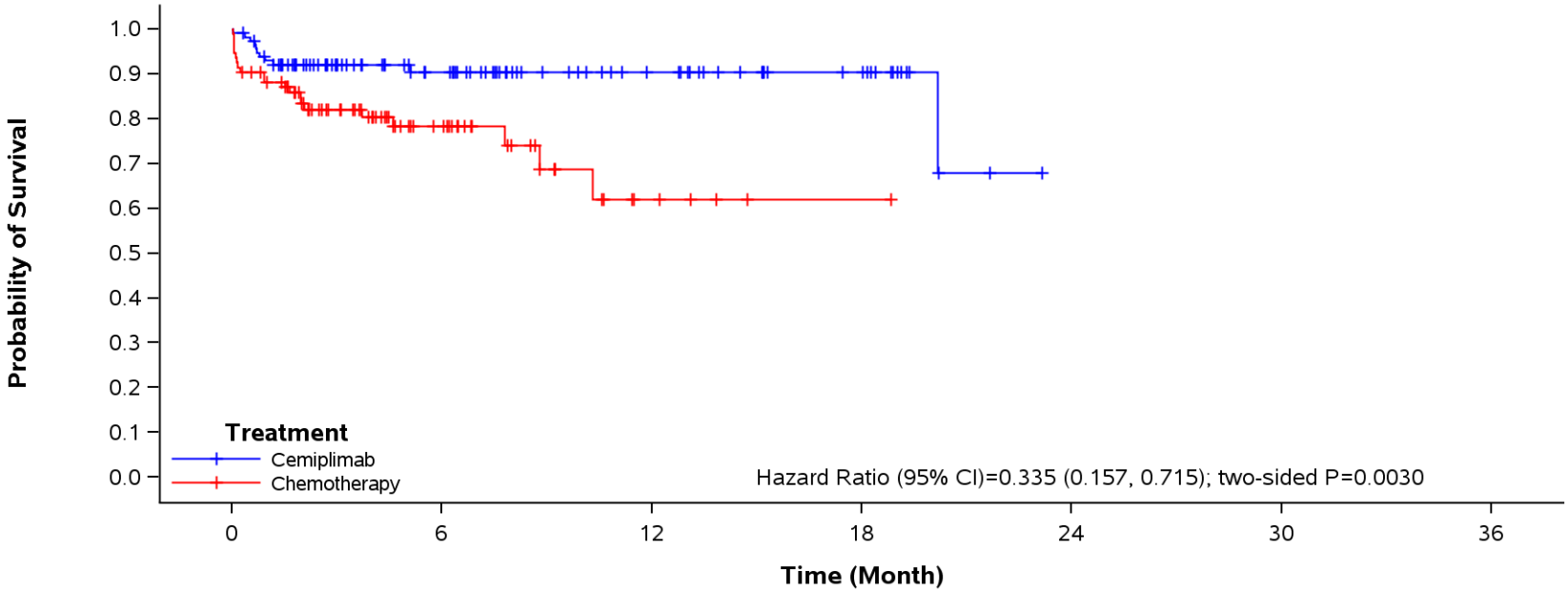

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 38 | 20 | 12 | 0 | 0 | 0 |
| Chemotherapy | 94 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: General disorders and administration site conditions
PT: Asthenia



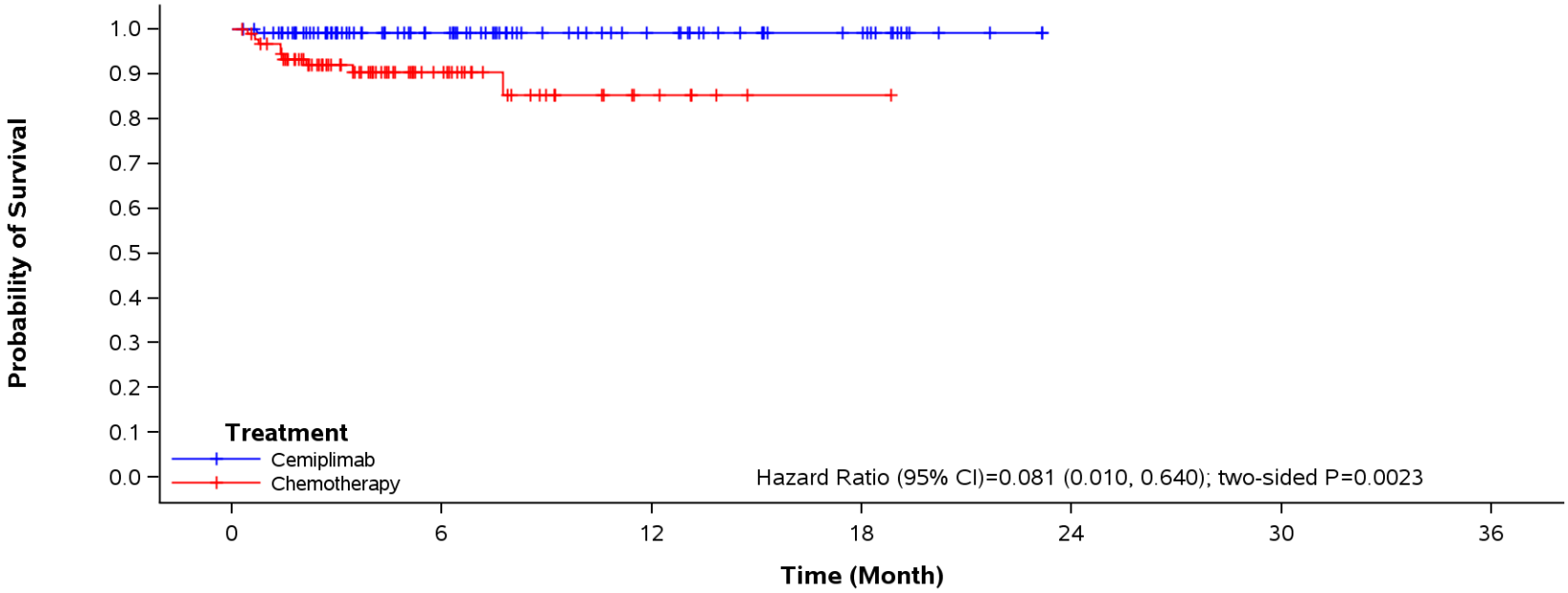

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 27 | 14 | 0 | 0 | 0 |
| Chemotherapy | 94 | 29 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



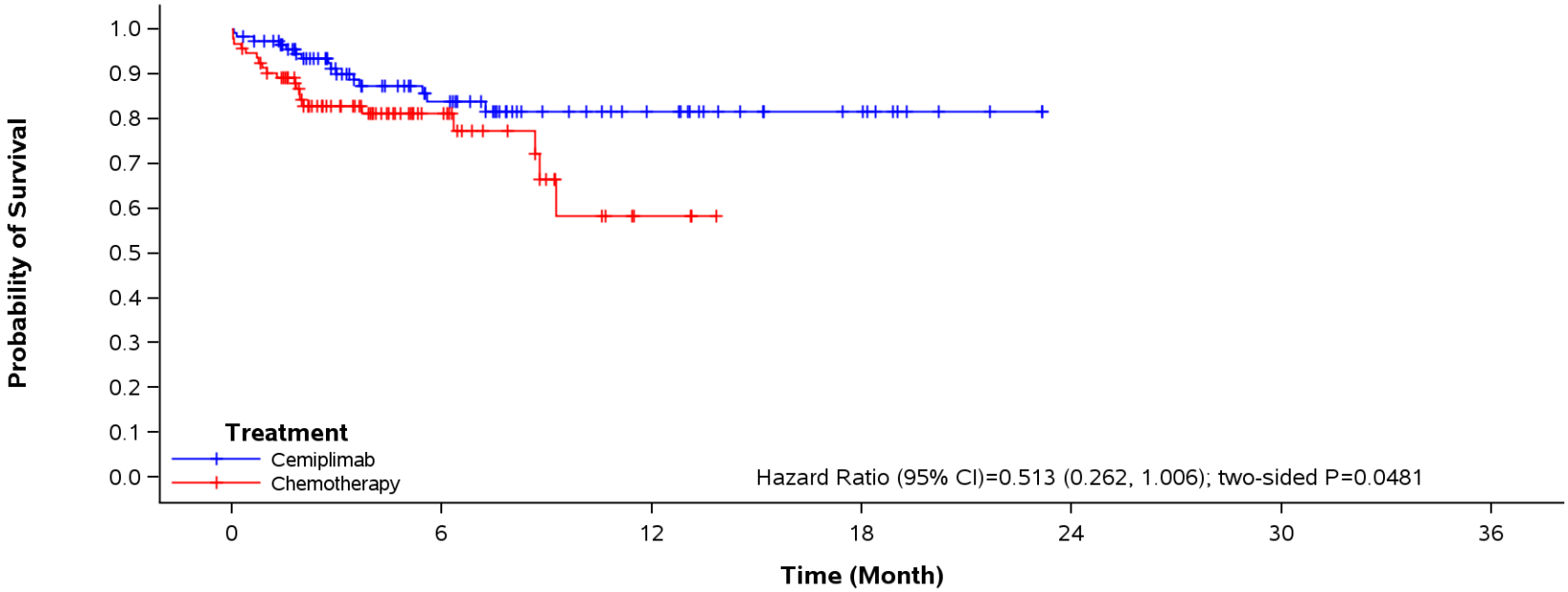

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 27 | 14 | 0 | 0 | 0 |
| Chemotherapy | 94 | 30 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Nervous system disorders



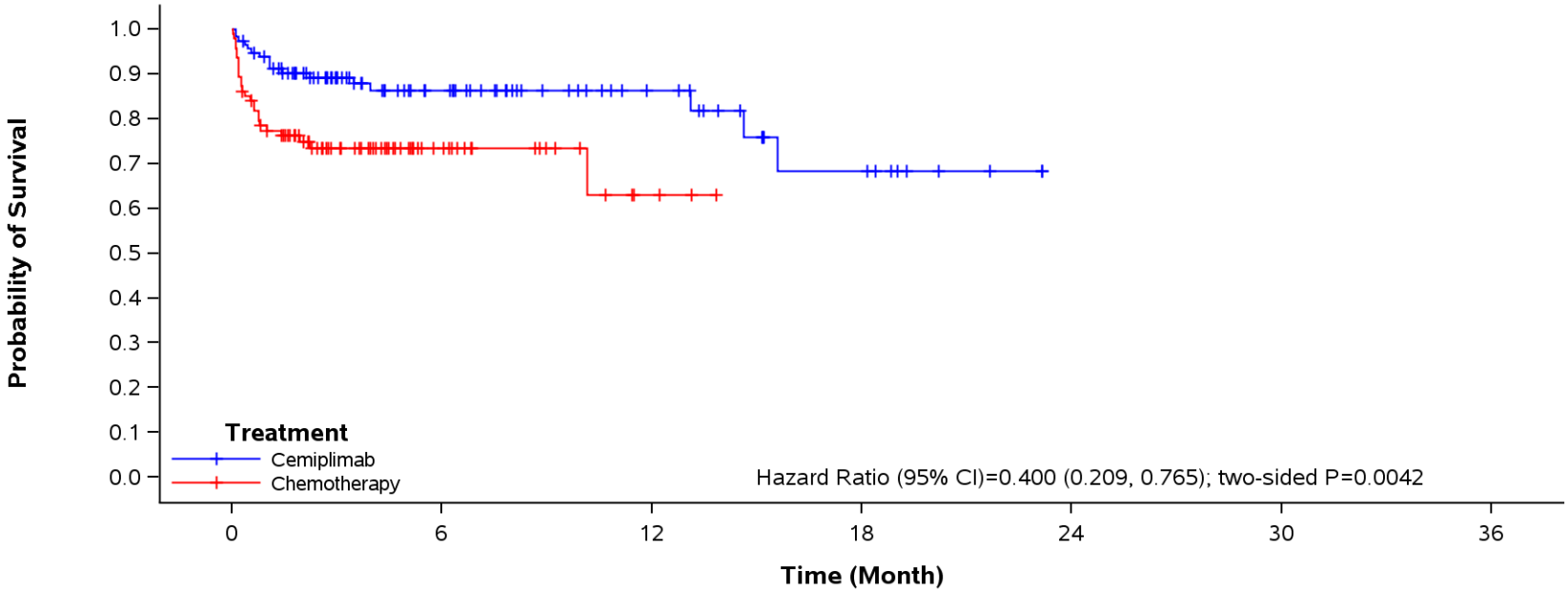

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 45 | 21 | 10 | 0 | 0 | 0 |
| Chemotherapy | 94 | 26 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Skin and subcutaneous tissue disorders



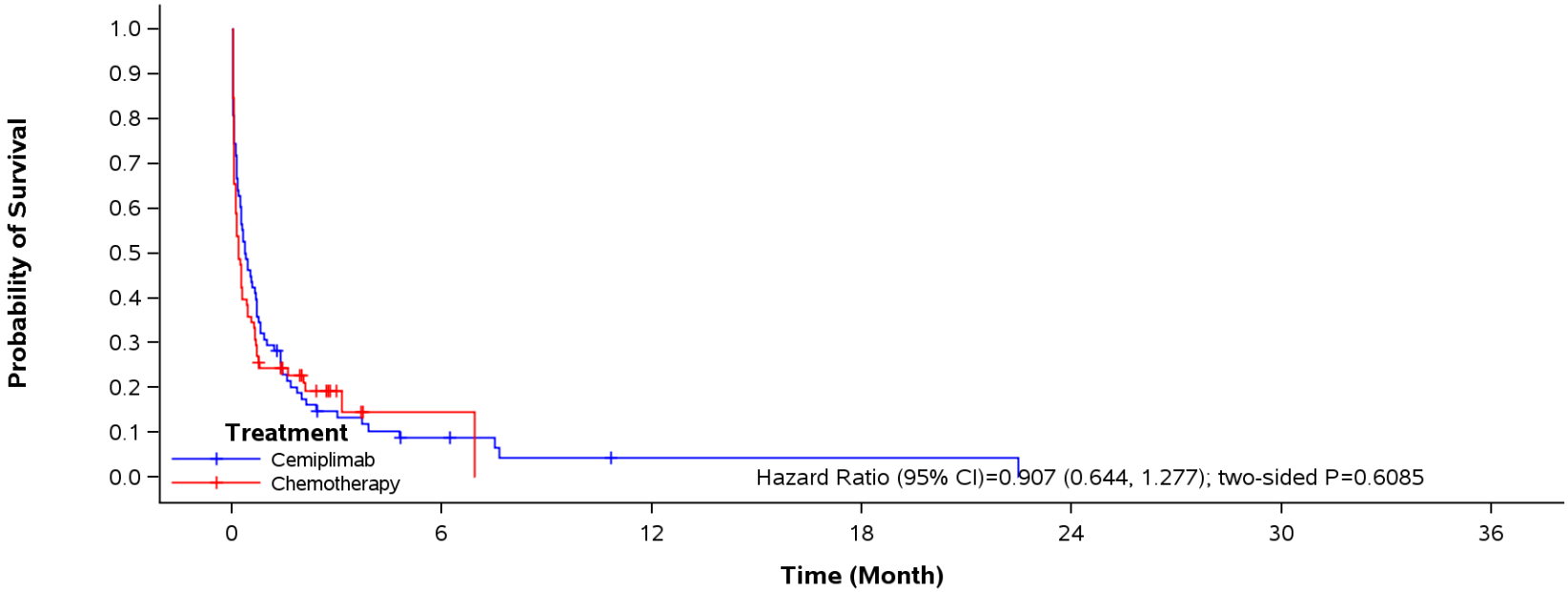

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 43 | 21 | 9 | 0 | 0 | 0 |
| Chemotherapy | 94 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Number of patients with any TEAE



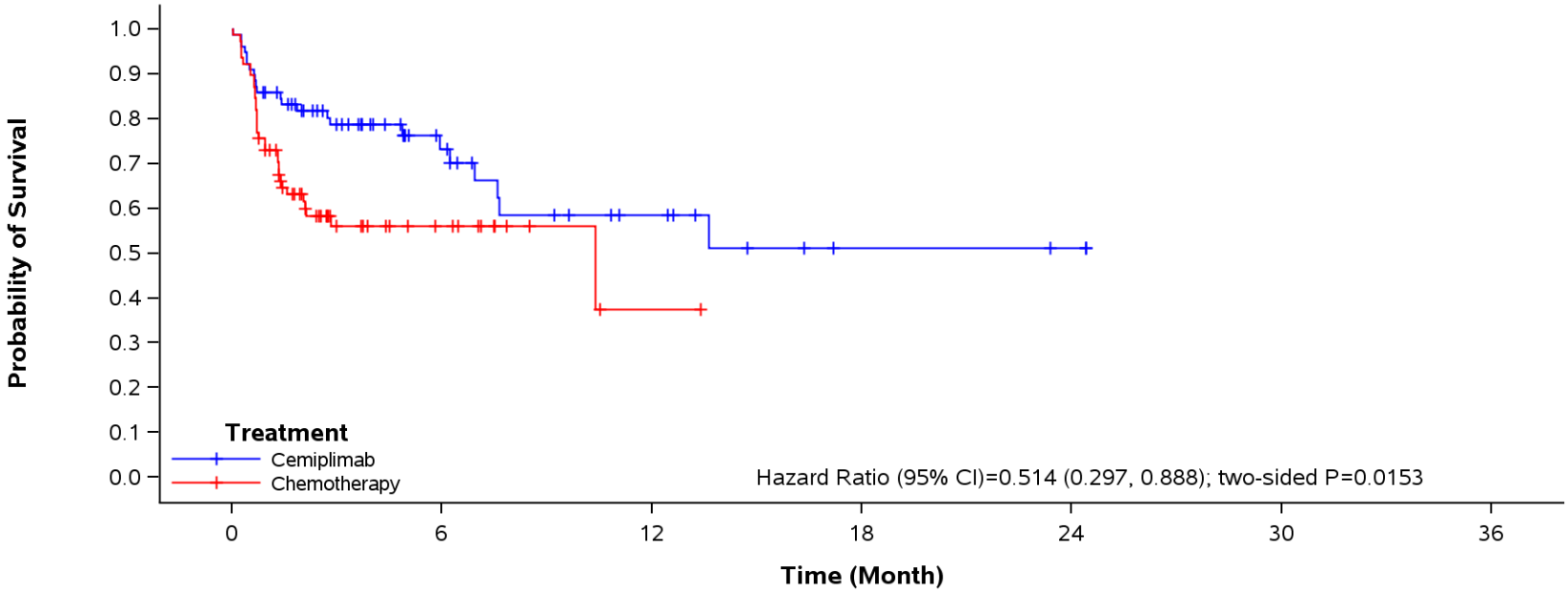

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 78 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders



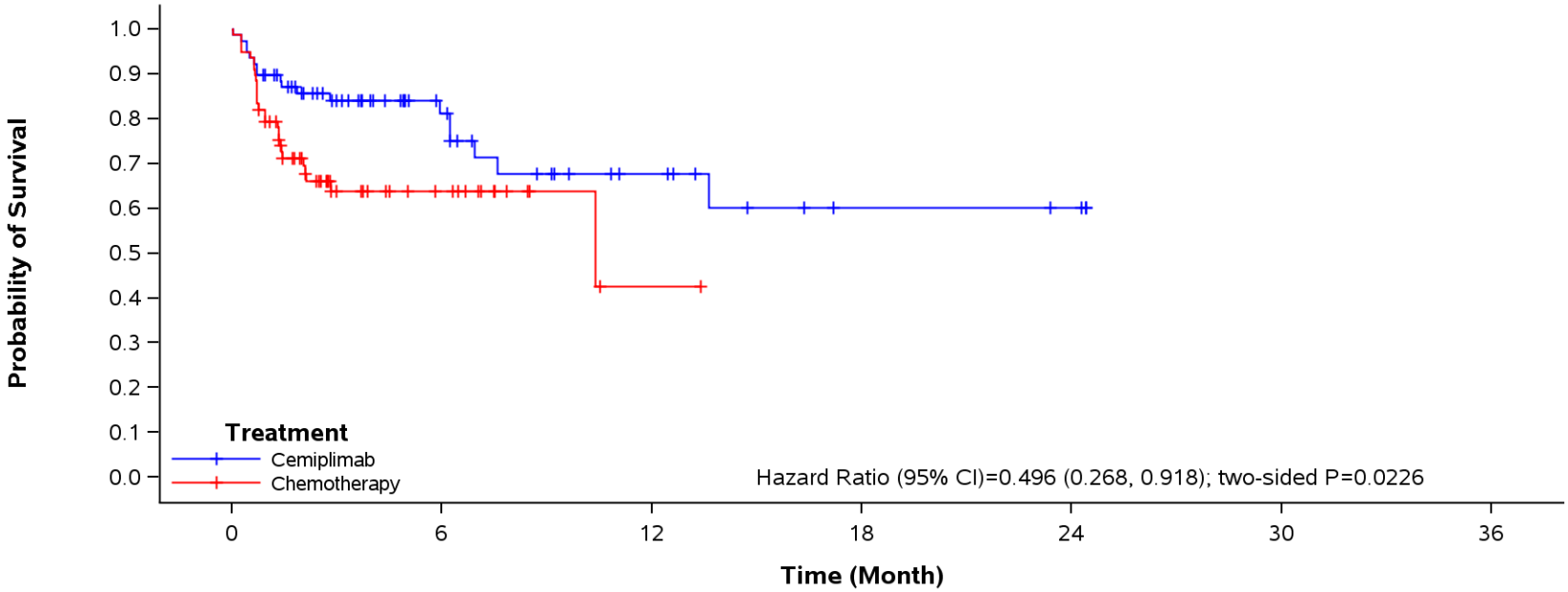

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 25 | 11 | 4 | 3 | 0 | 0 |
| Chemotherapy | 78 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



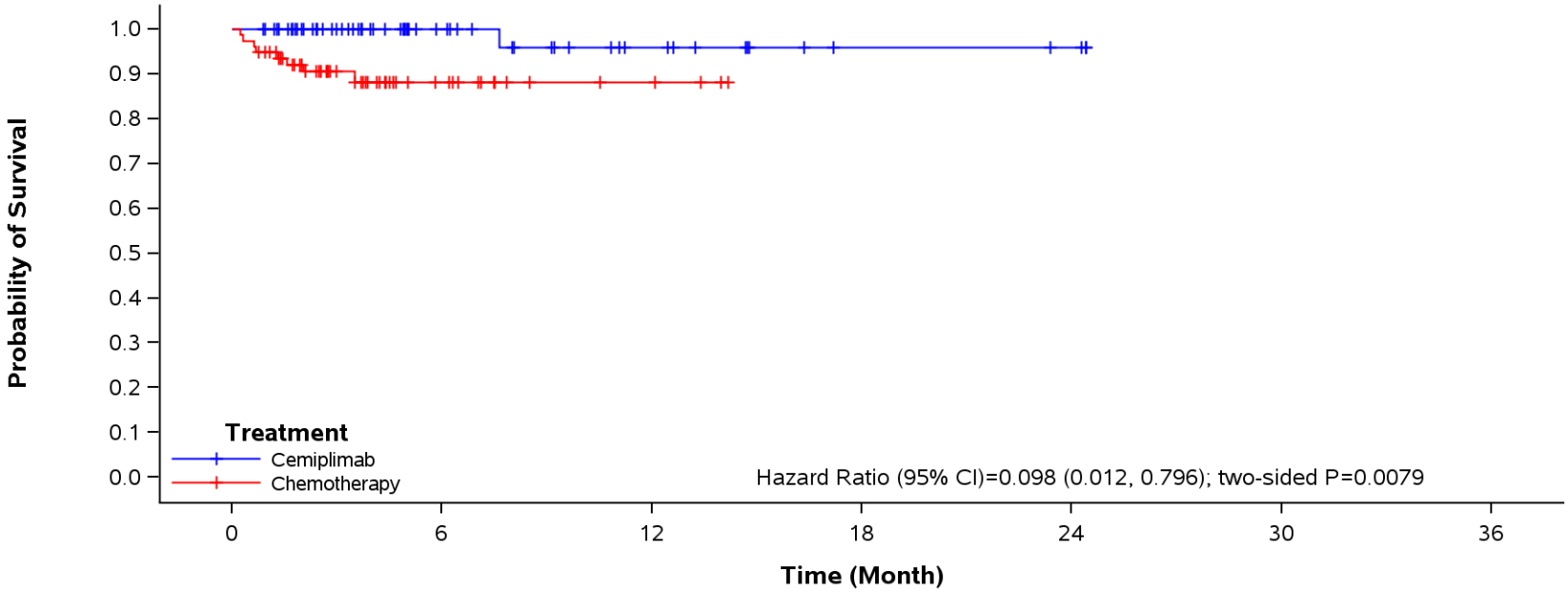

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 28 | 12 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia



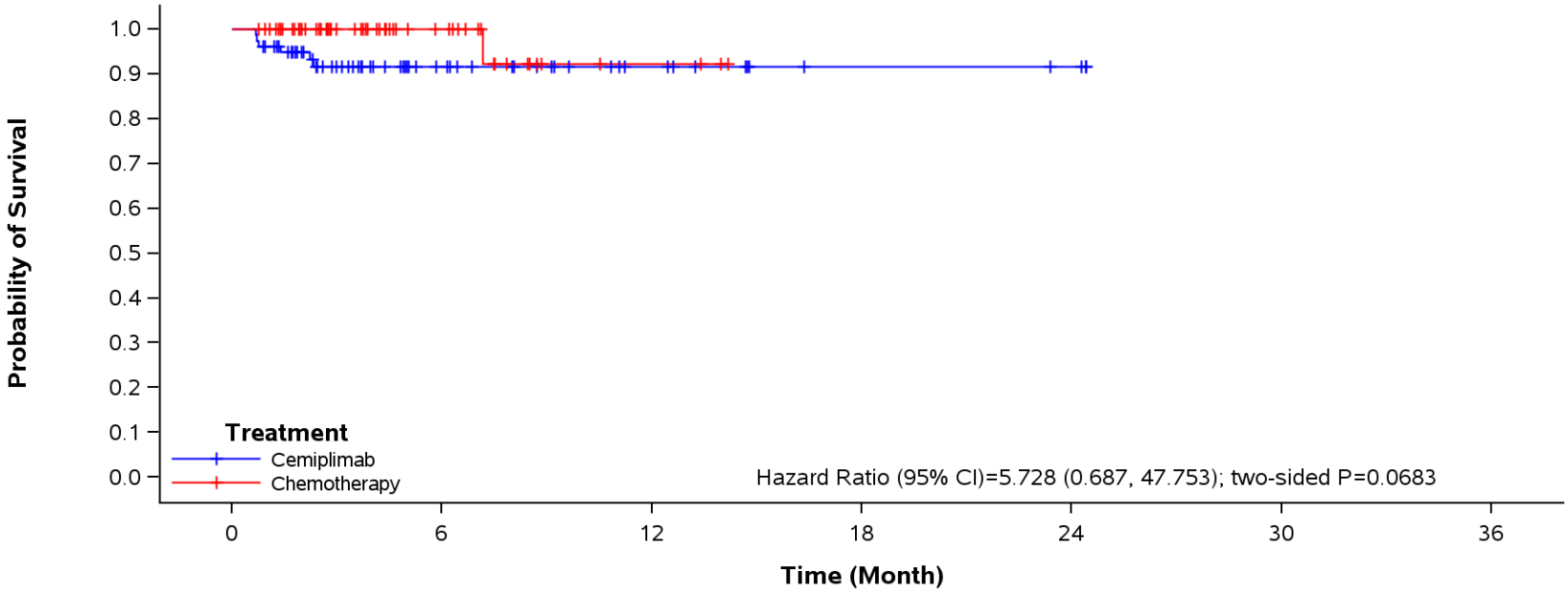

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 13 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Endocrine disorders



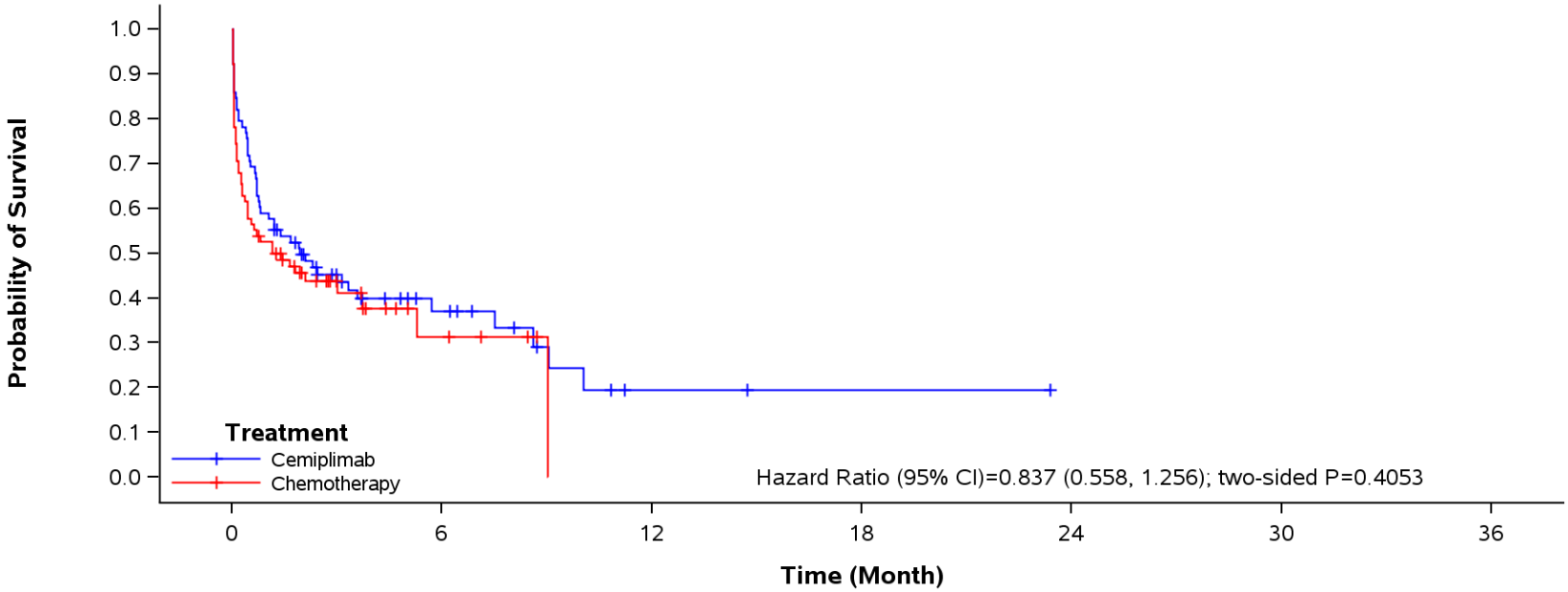

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 30 | 12 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders




**Number of Subjects at risk**

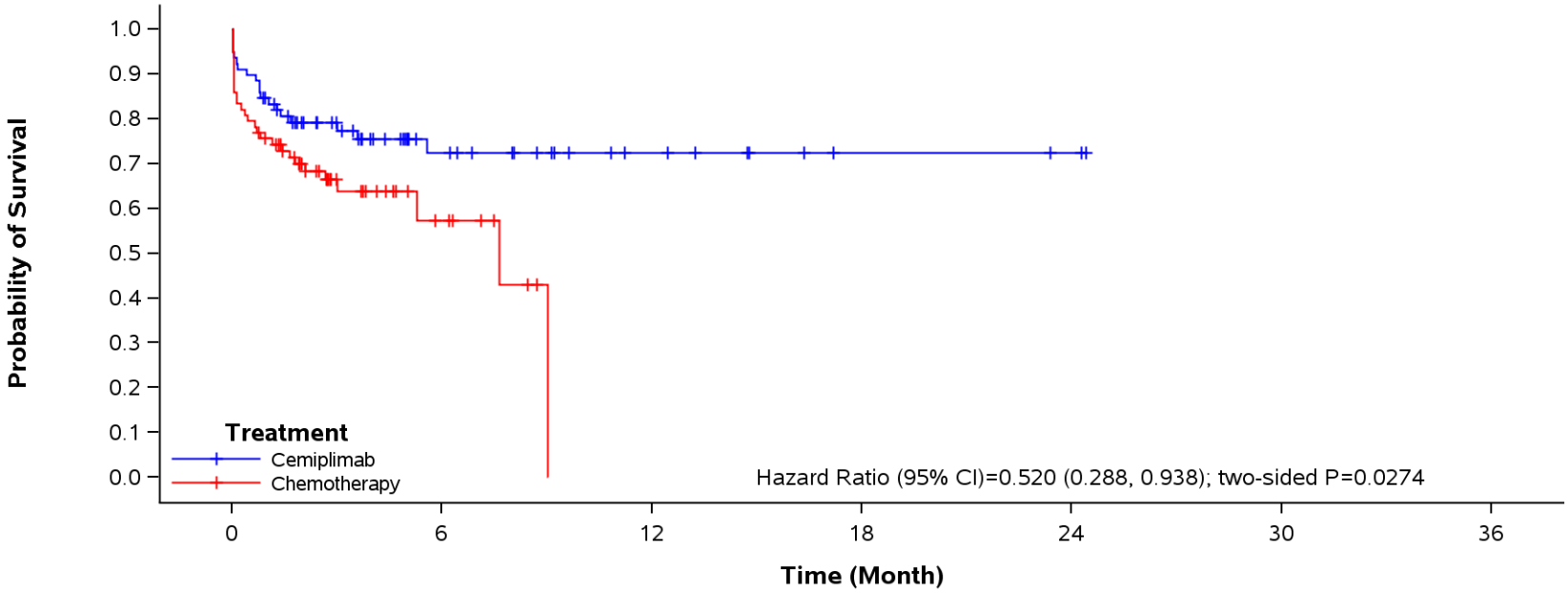
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 13 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 78 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (04NOV22:11:07:08, qiuyue.chen1)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders
PT: Nausea



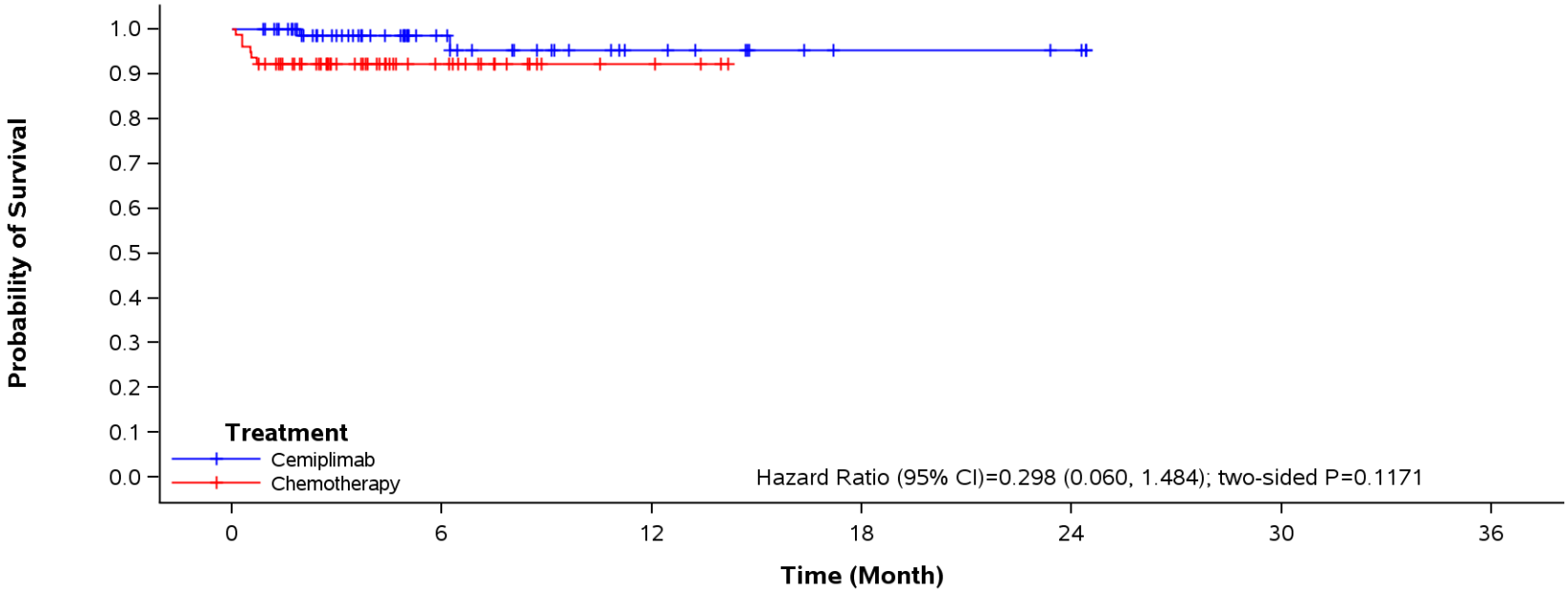

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 23 | 9 | 3 | 2 | 0 | 0 |
| Chemotherapy | 78 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders
PT: Stomatitis



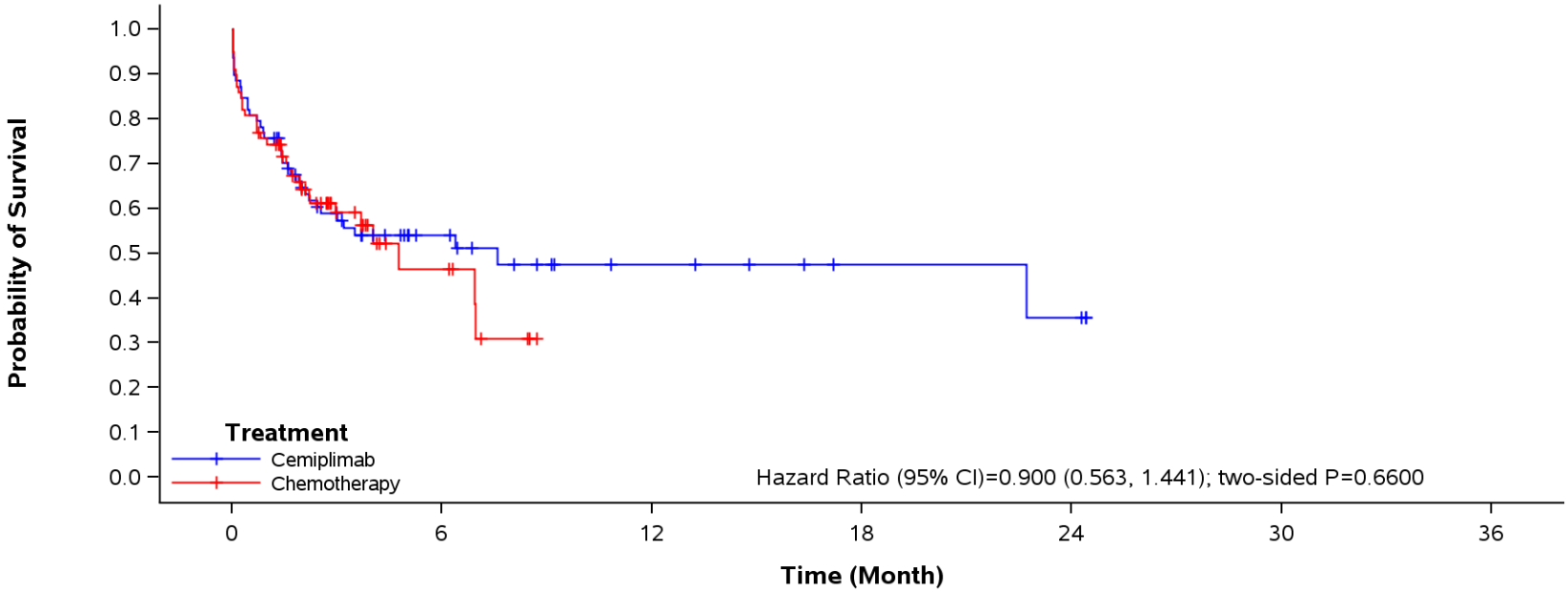

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 12 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 18 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: General disorders and administration site conditions




**Number of Subjects at risk**

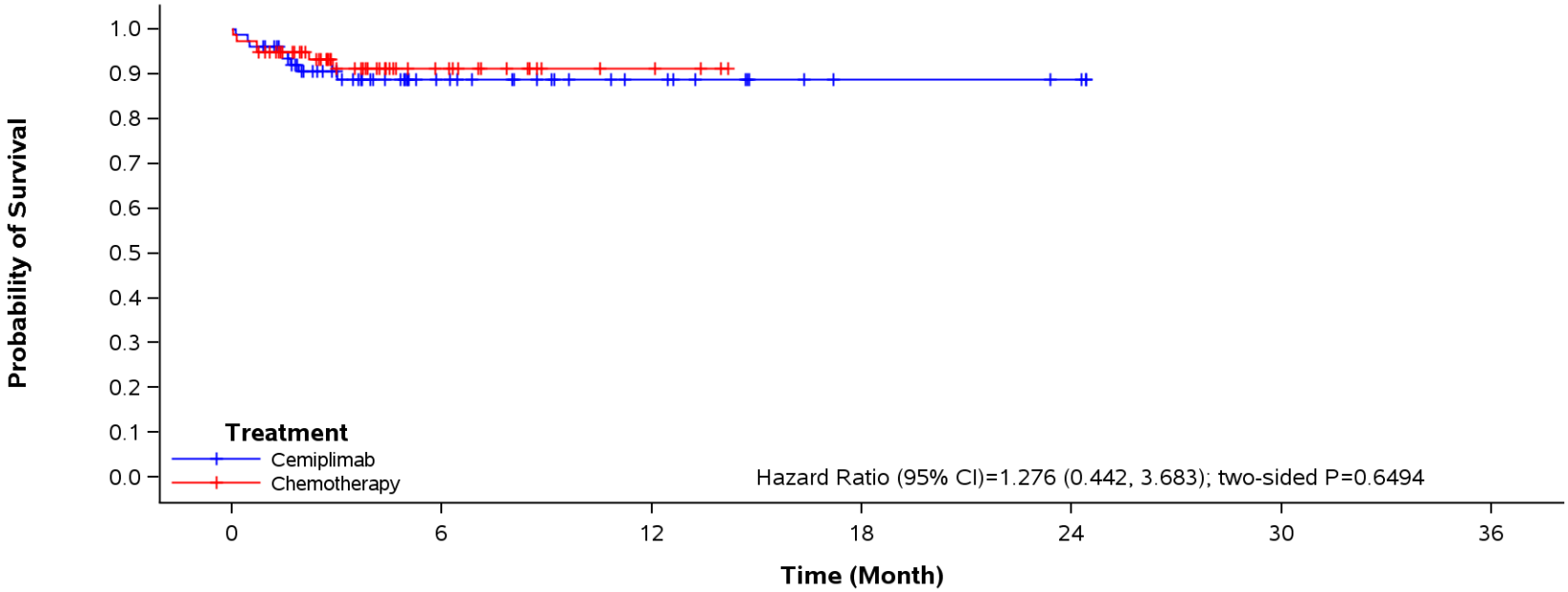
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 20 | 8 | 4 | 3 | 0 | 0 |
| Chemotherapy | 78 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/qiuyue.chen1/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (04NOV22:11:07:08, qiuyue.chen1)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: General disorders and administration site conditions
PT: Asthenia



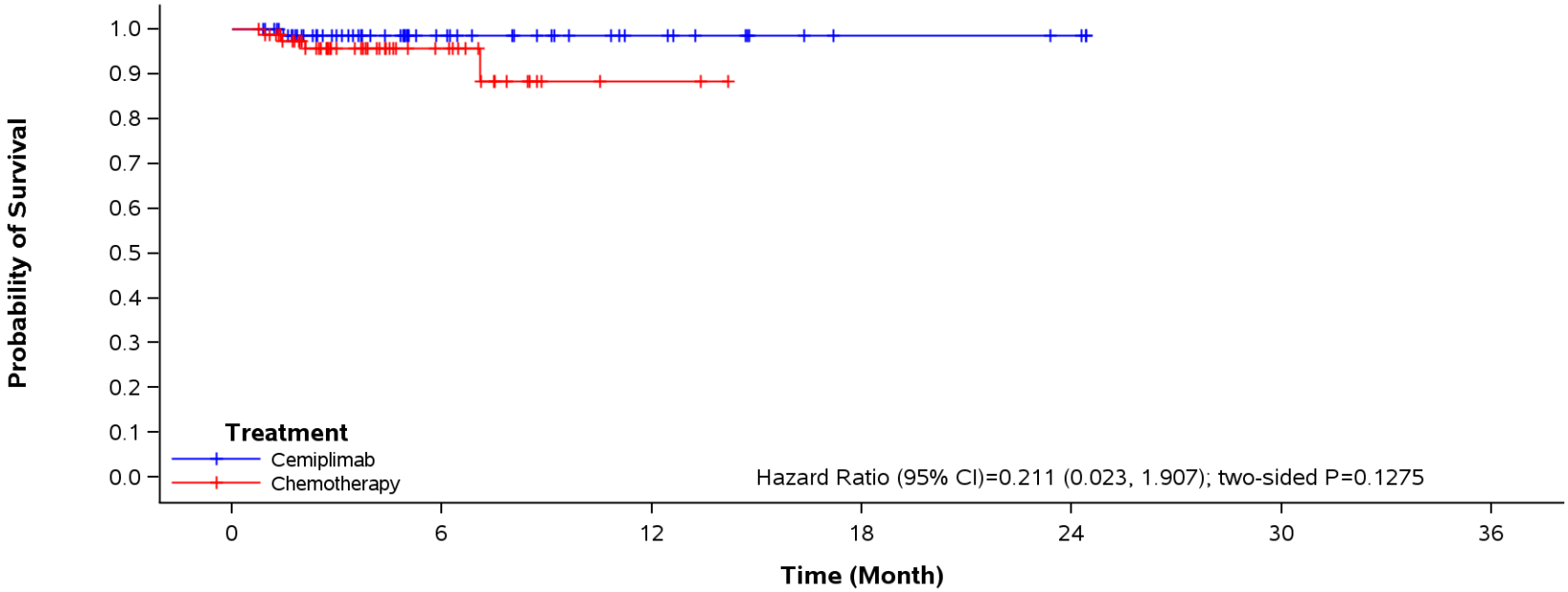

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 29 | 13 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



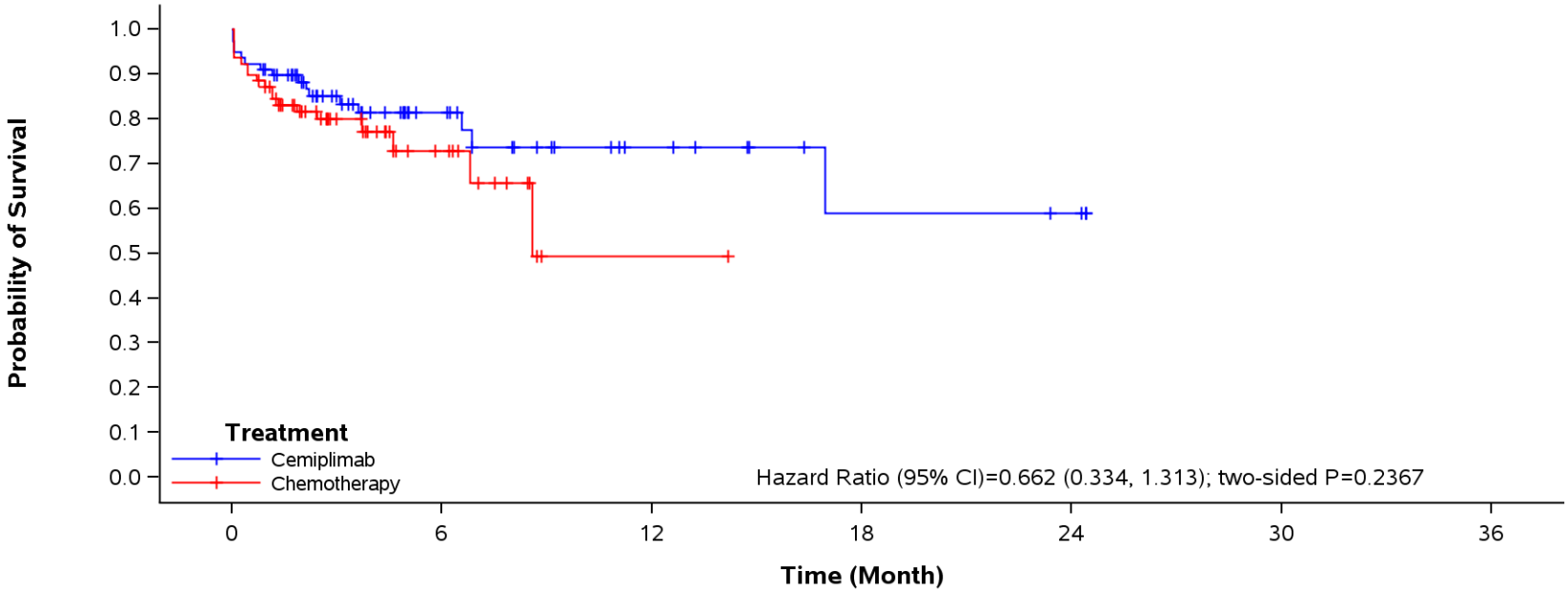

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 13 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Nervous system disorders



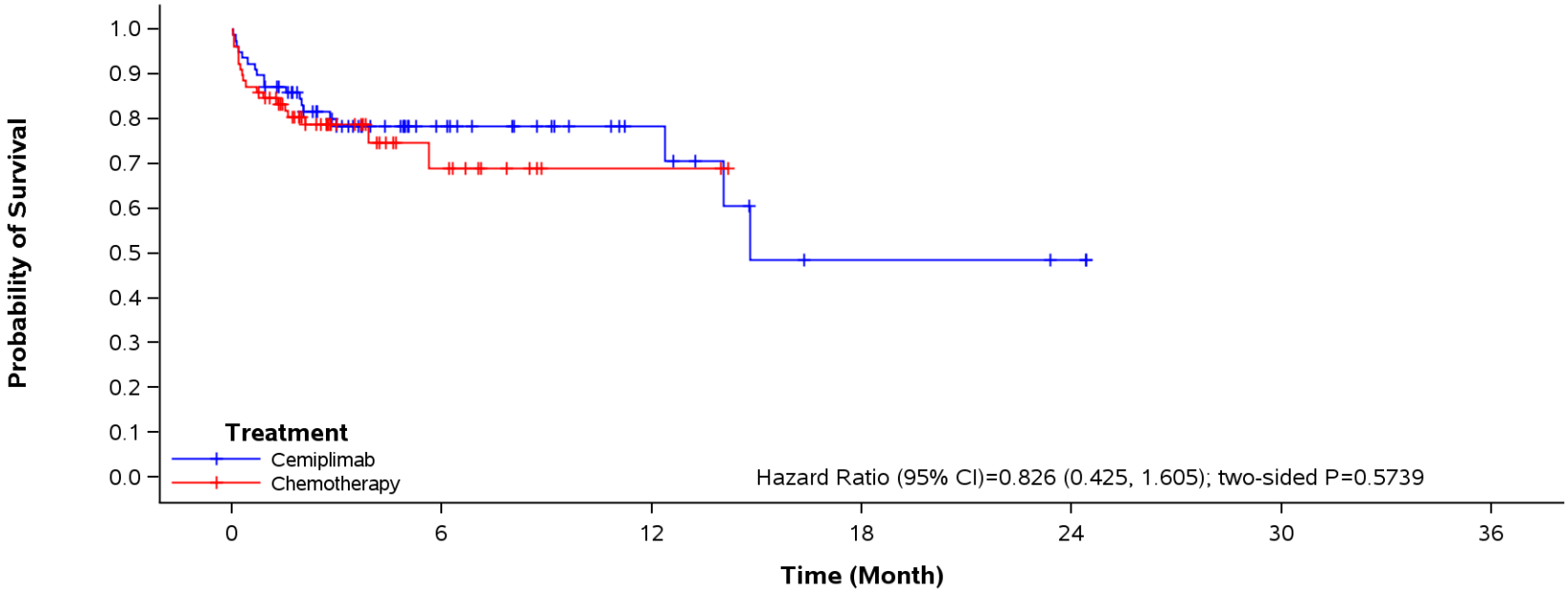

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 25 | 10 | 4 | 3 | 0 | 0 |
| Chemotherapy | 78 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Skin and subcutaneous tissue disorders



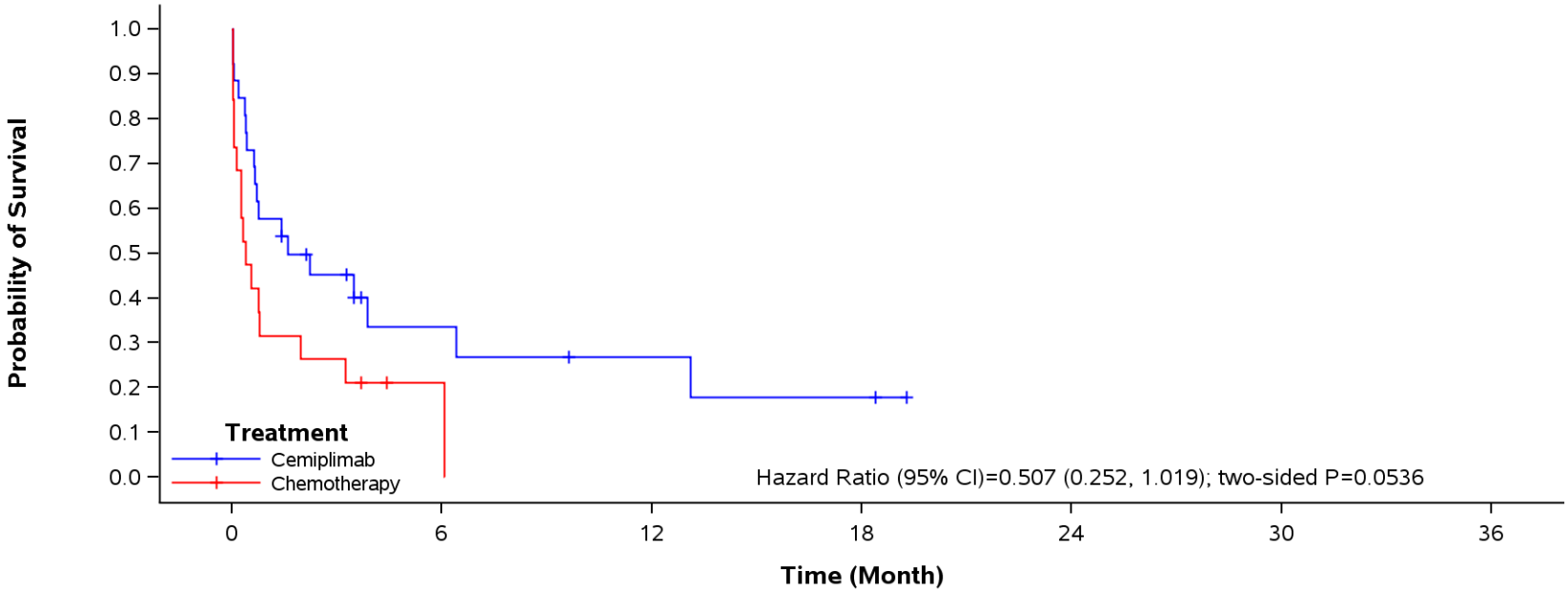

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 26 | 10 | 3 | 2 | 0 | 0 |
| Chemotherapy | 78 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Number of patients with any TEAE



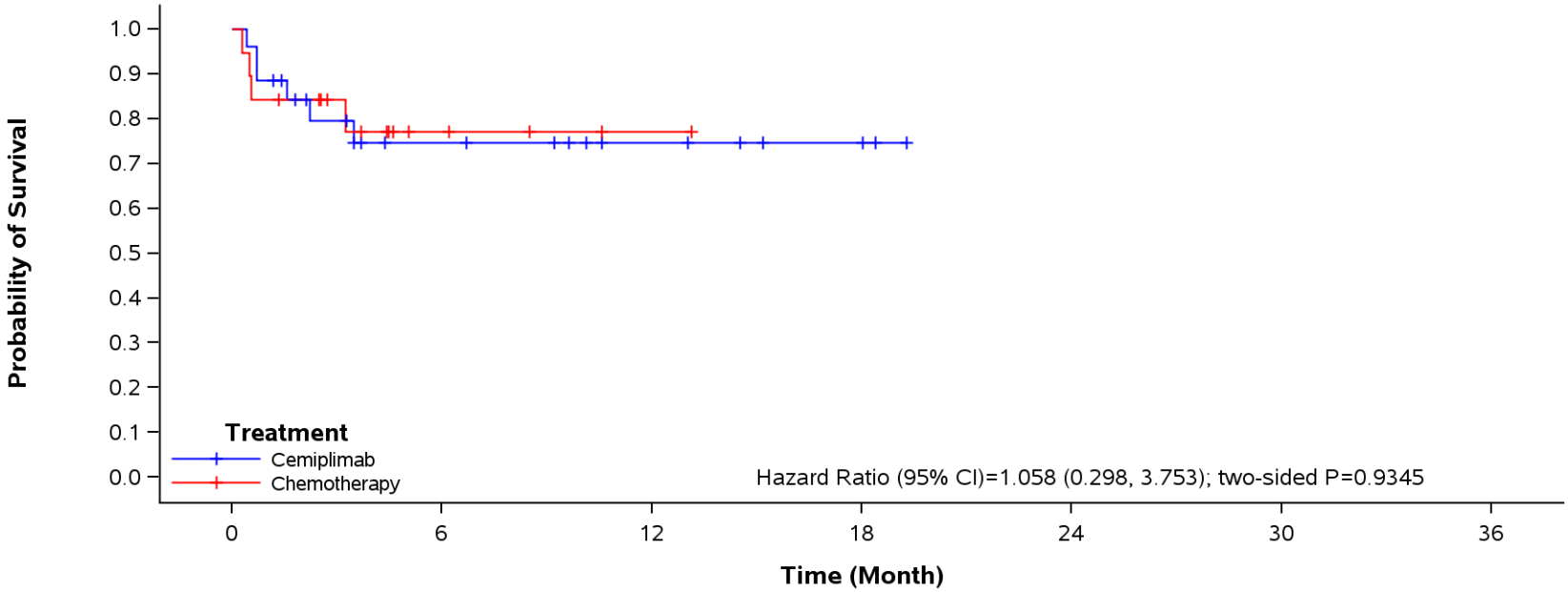

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 5 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders



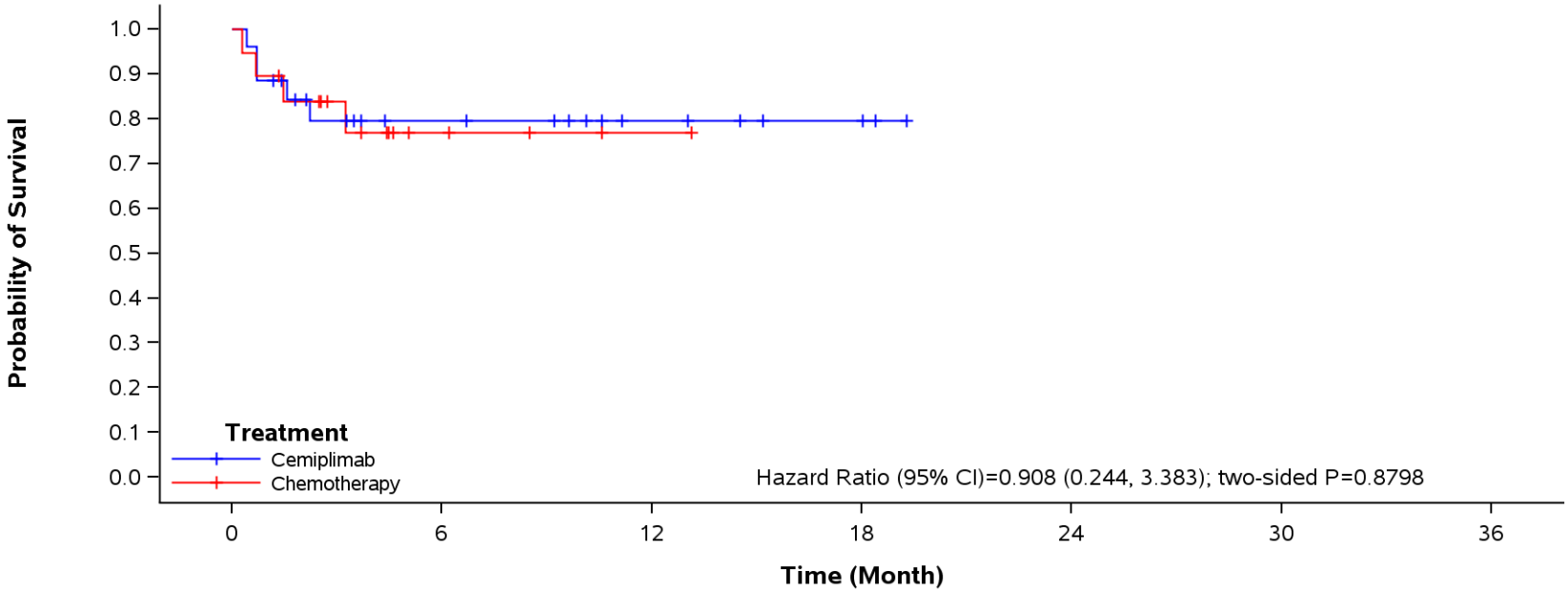

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



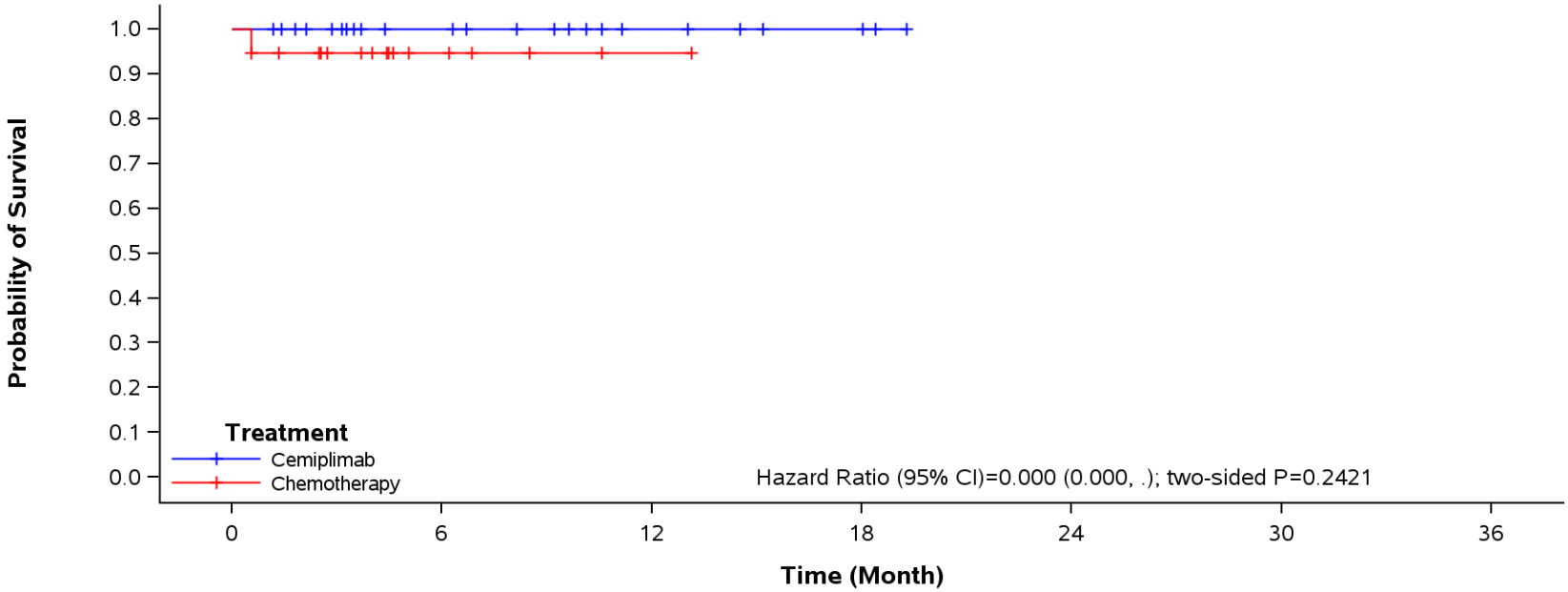

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



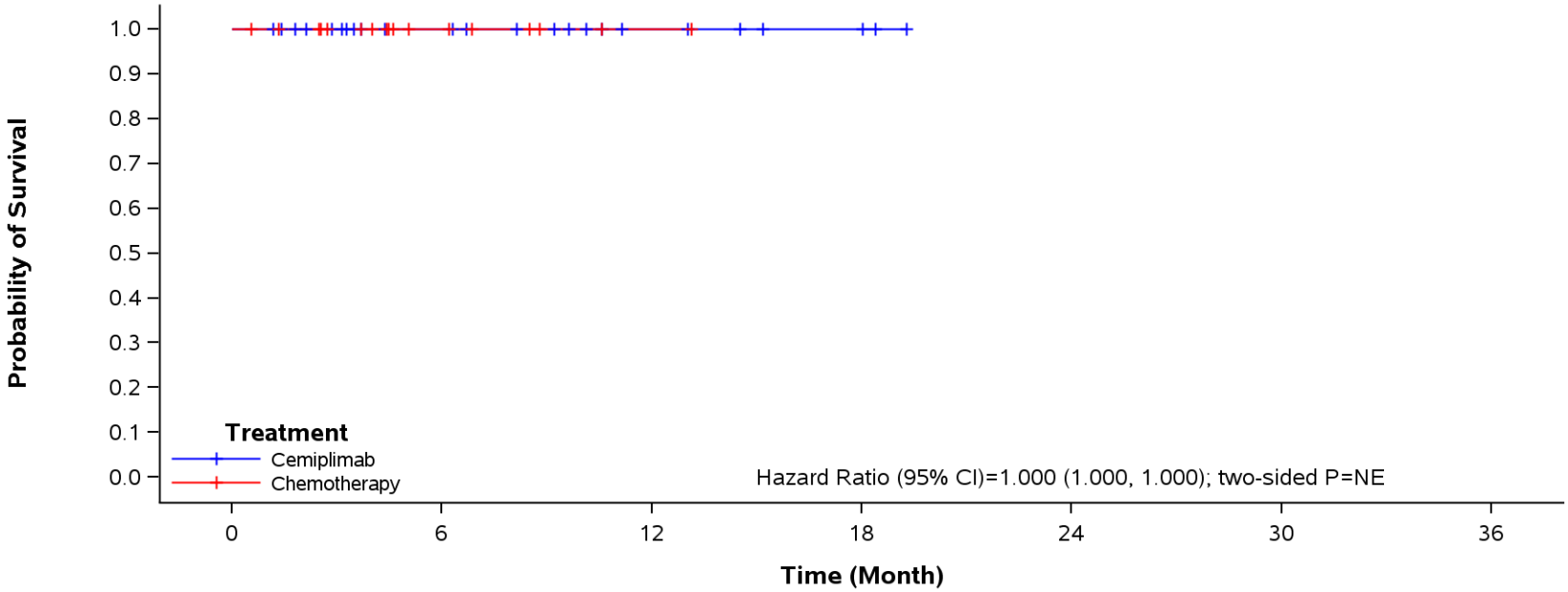

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Endocrine disorders



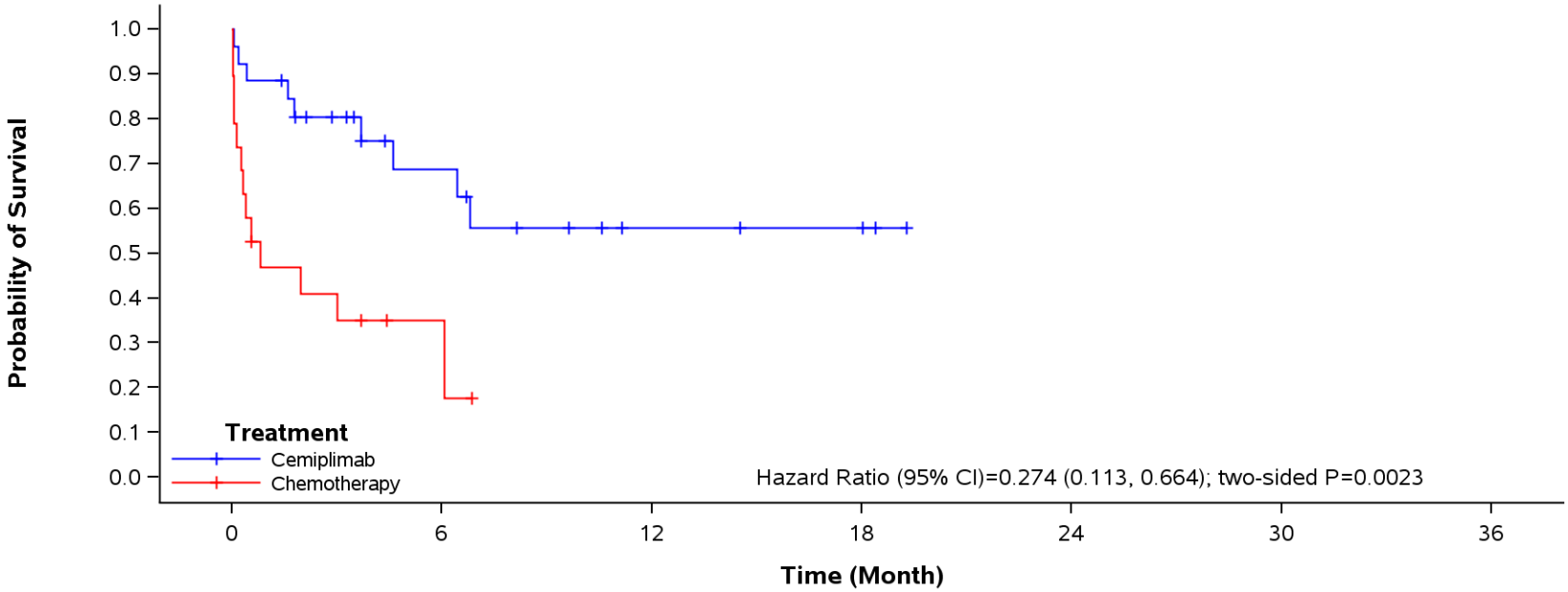

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders



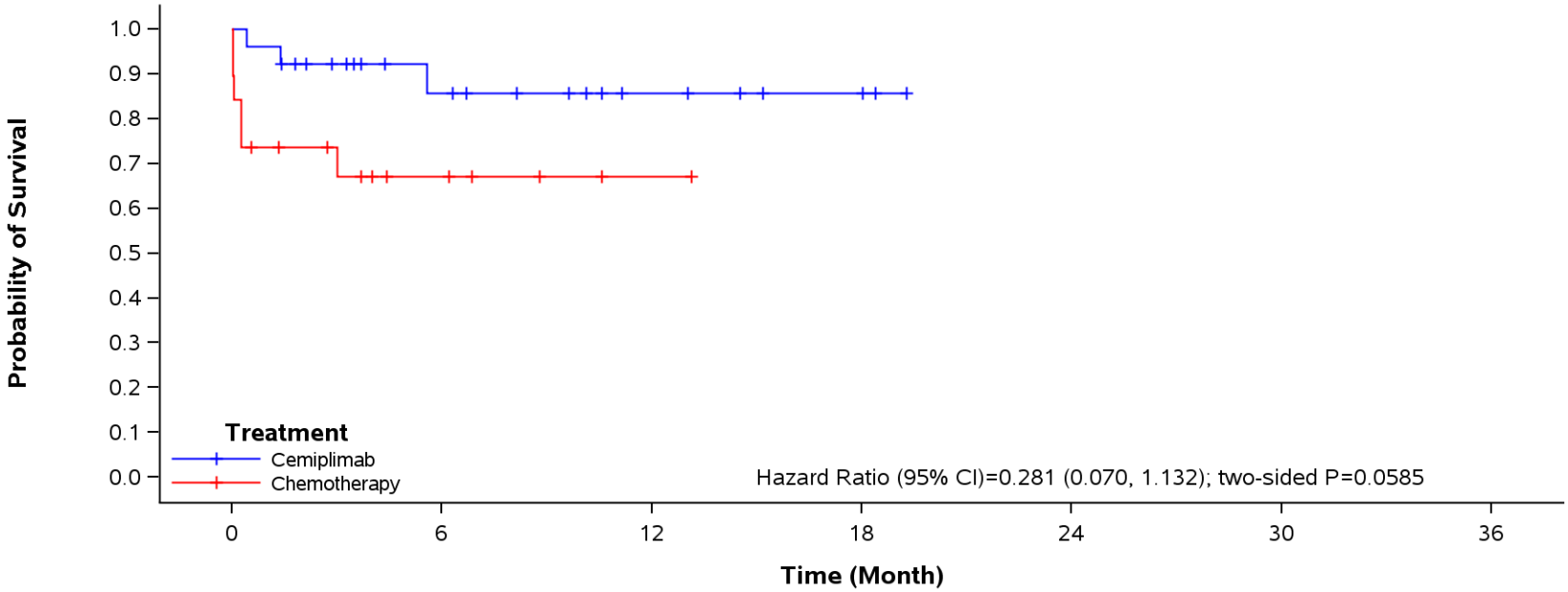

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 4 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders
PT: Nausea



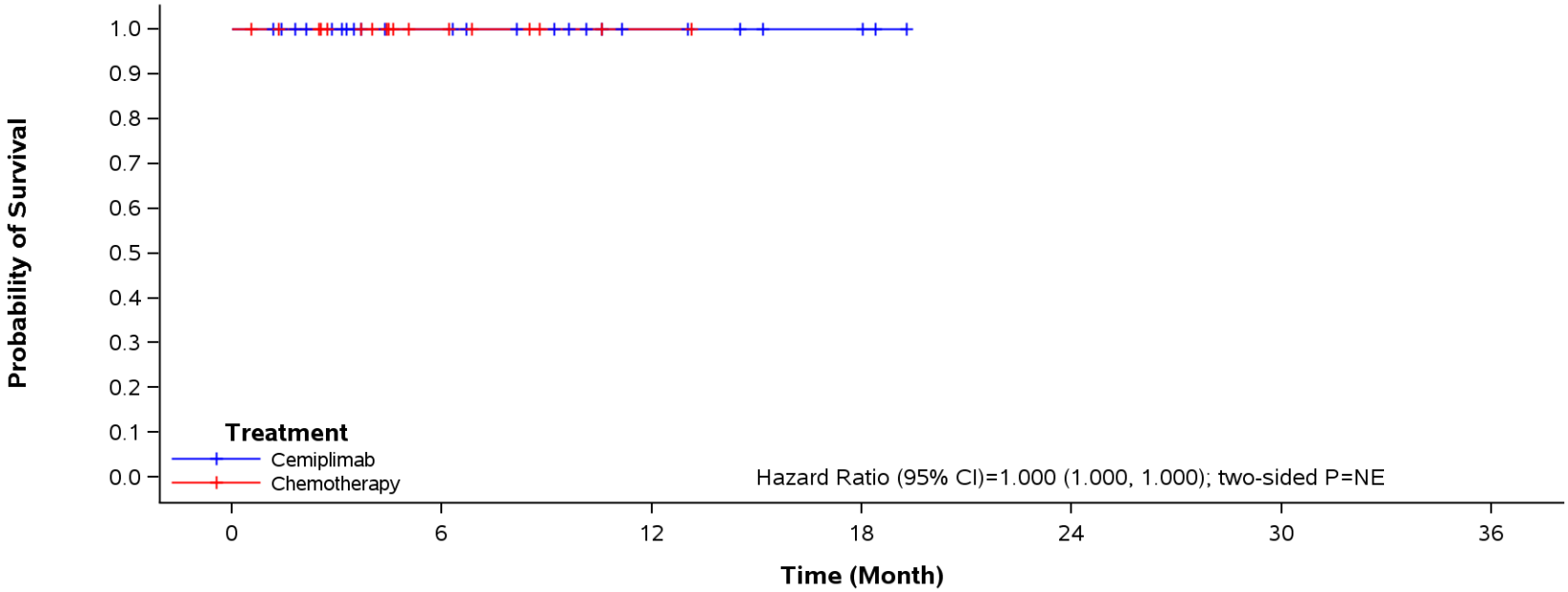

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 13 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders
PT: Stomatitis



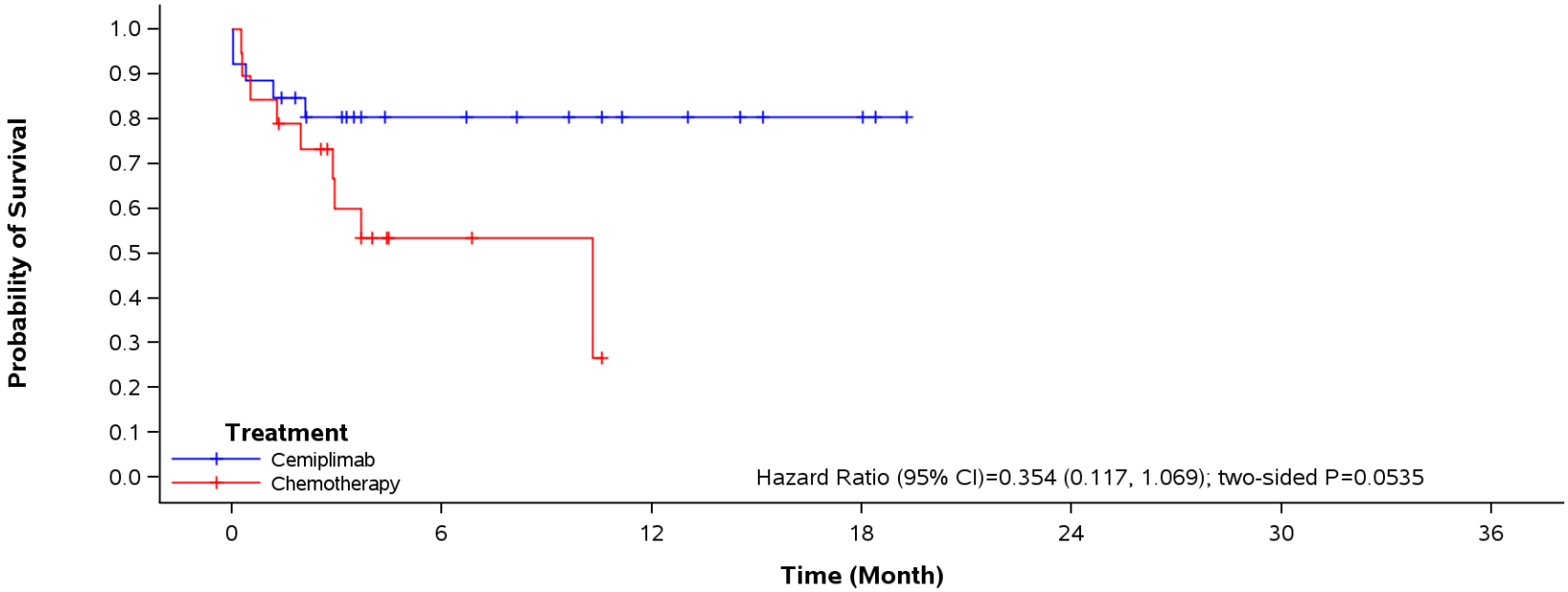

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: General disorders and administration site conditions



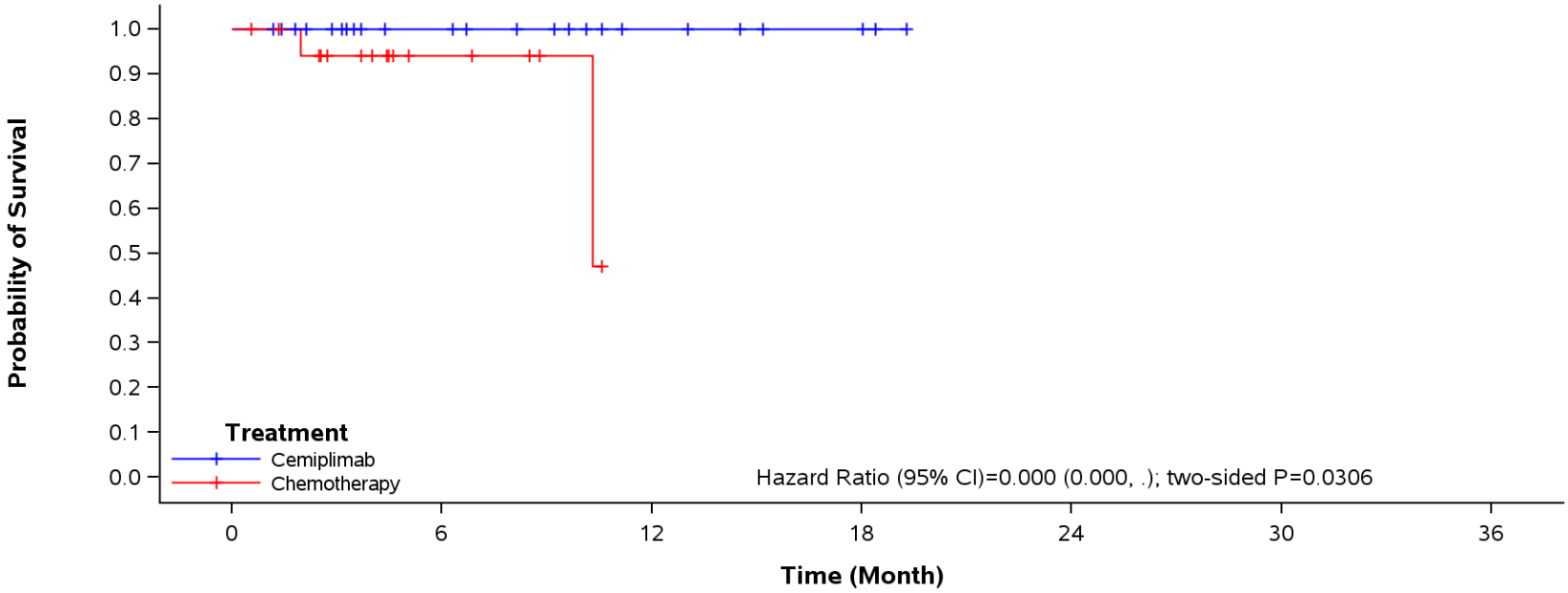

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: General disorders and administration site conditions
PT: Asthenia



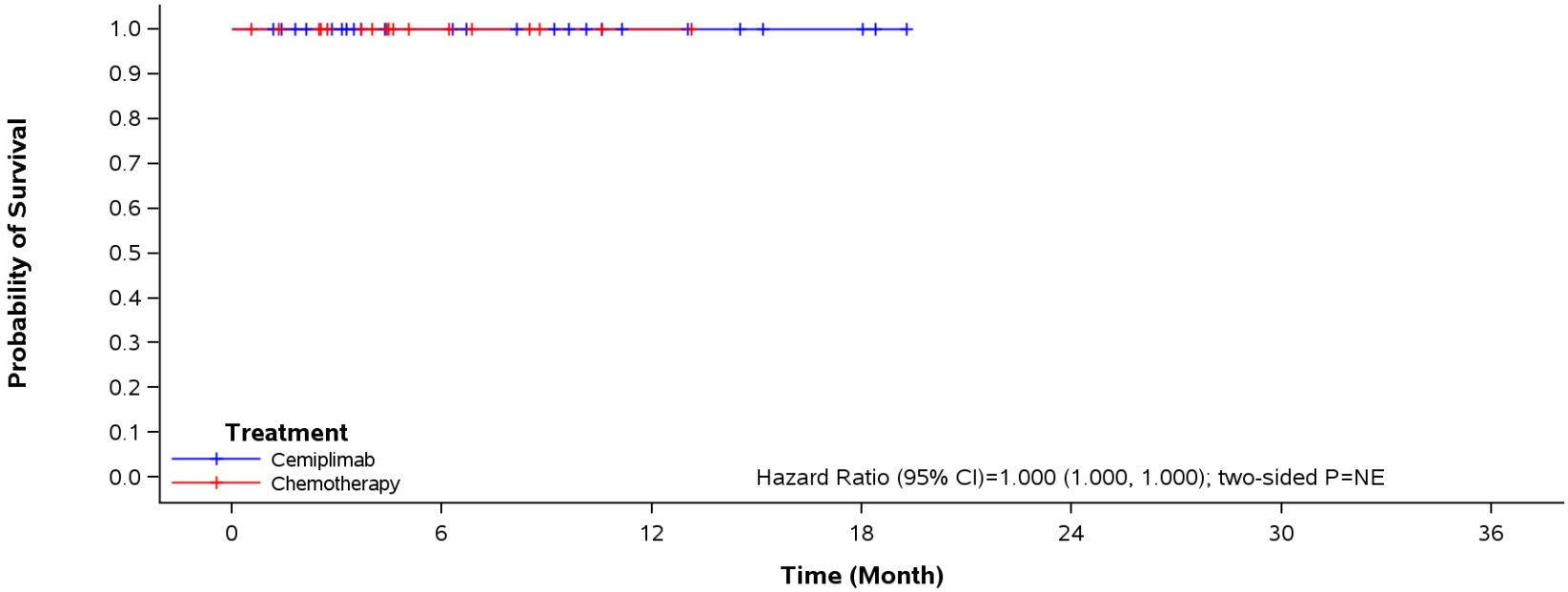

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



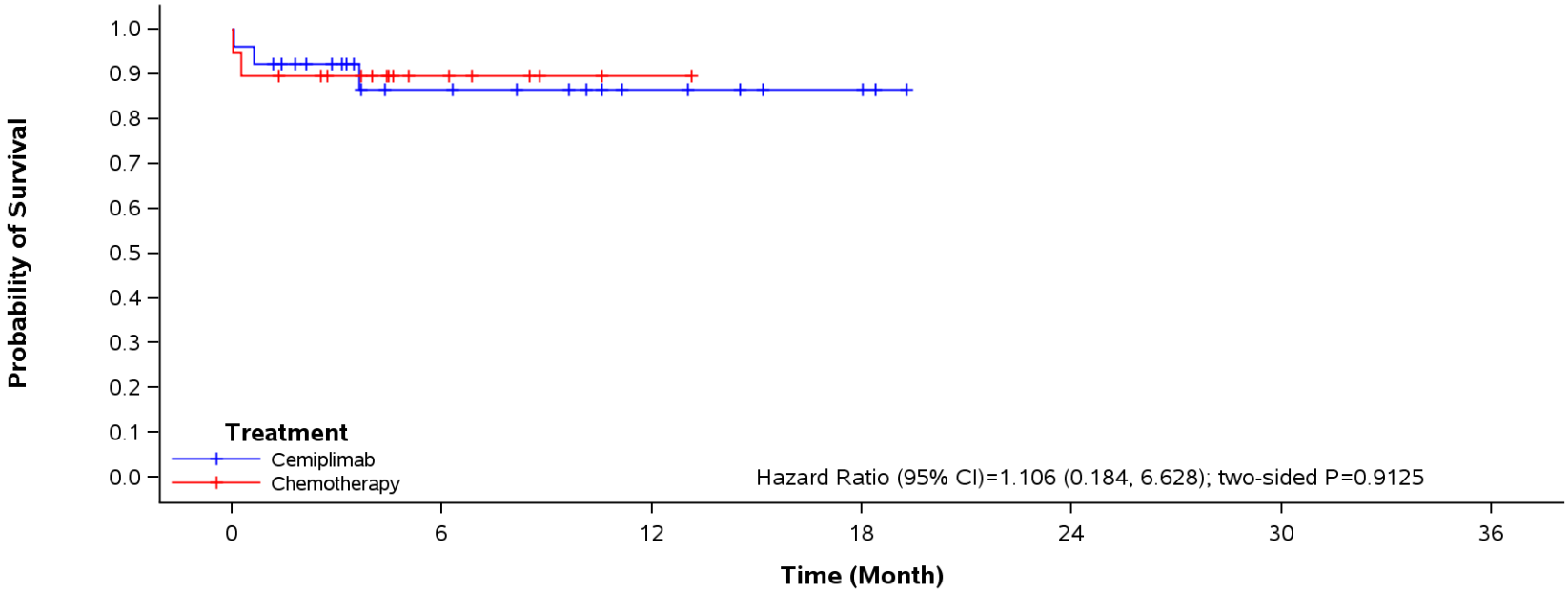

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Nervous system disorders



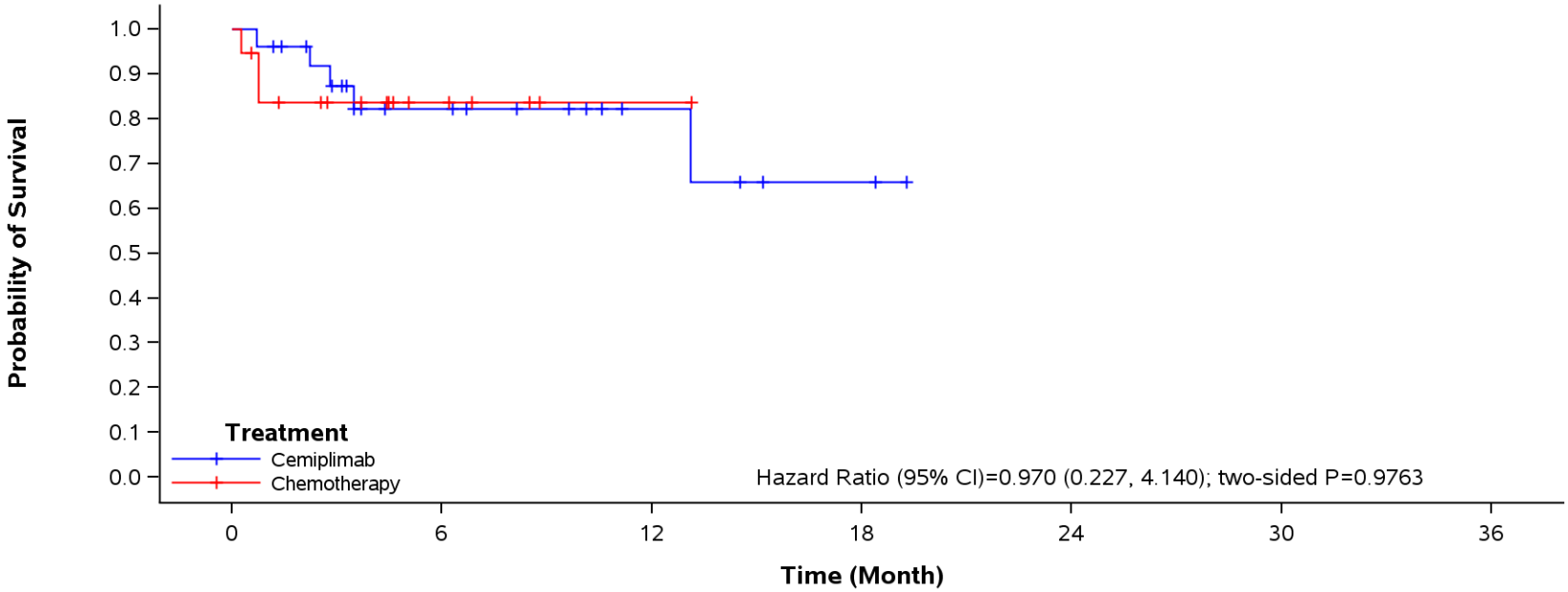

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Skin and subcutaneous tissue disorders



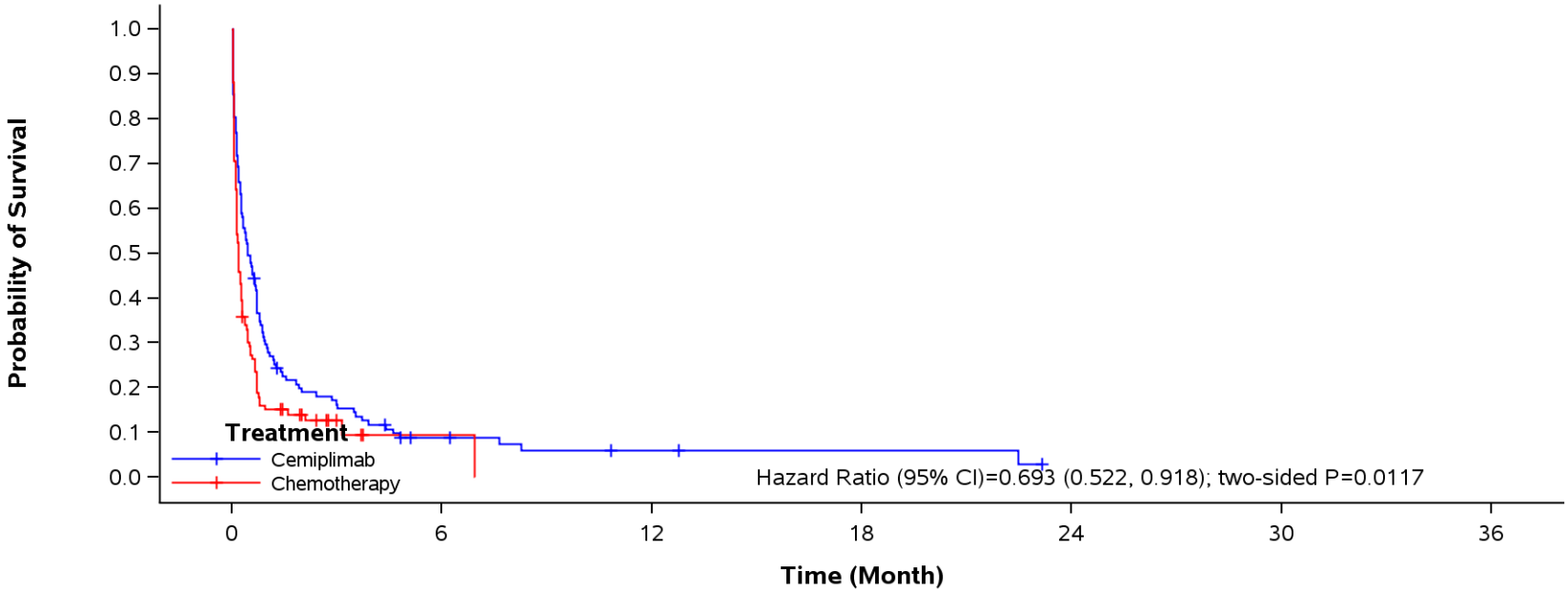

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Number of patients with any TEAE



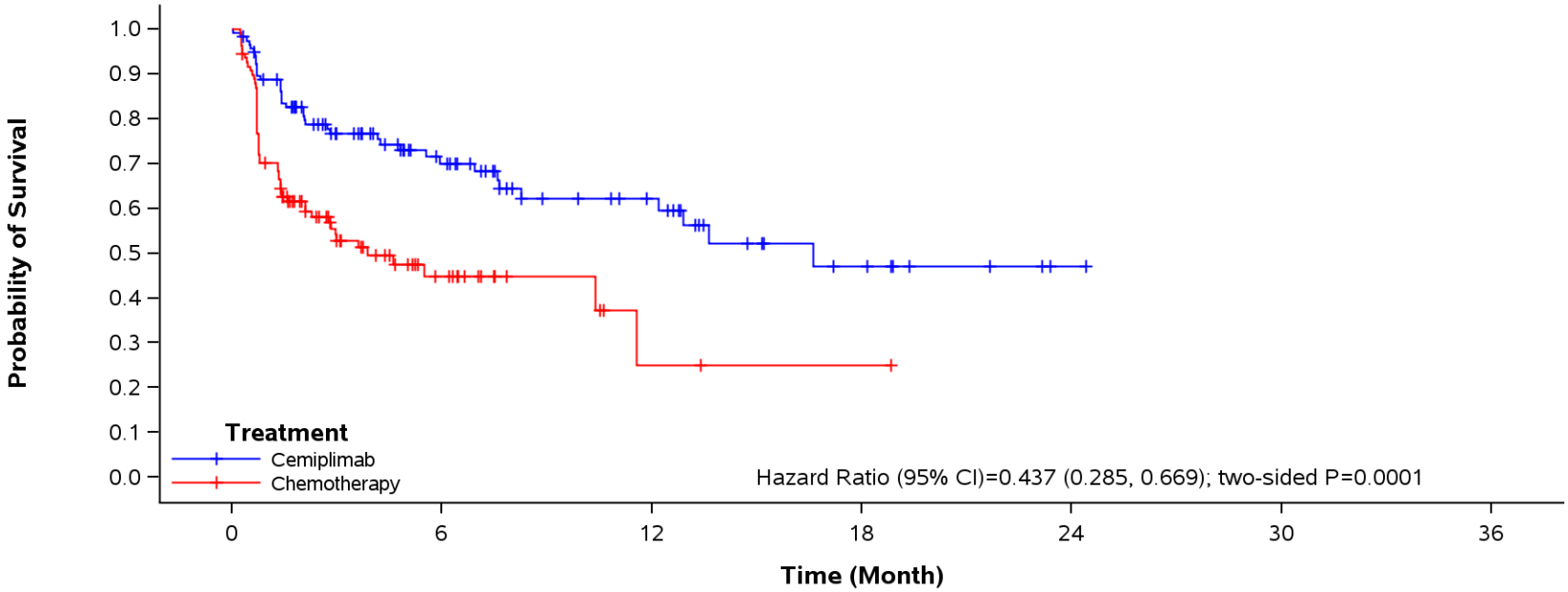

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 7 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 109 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders



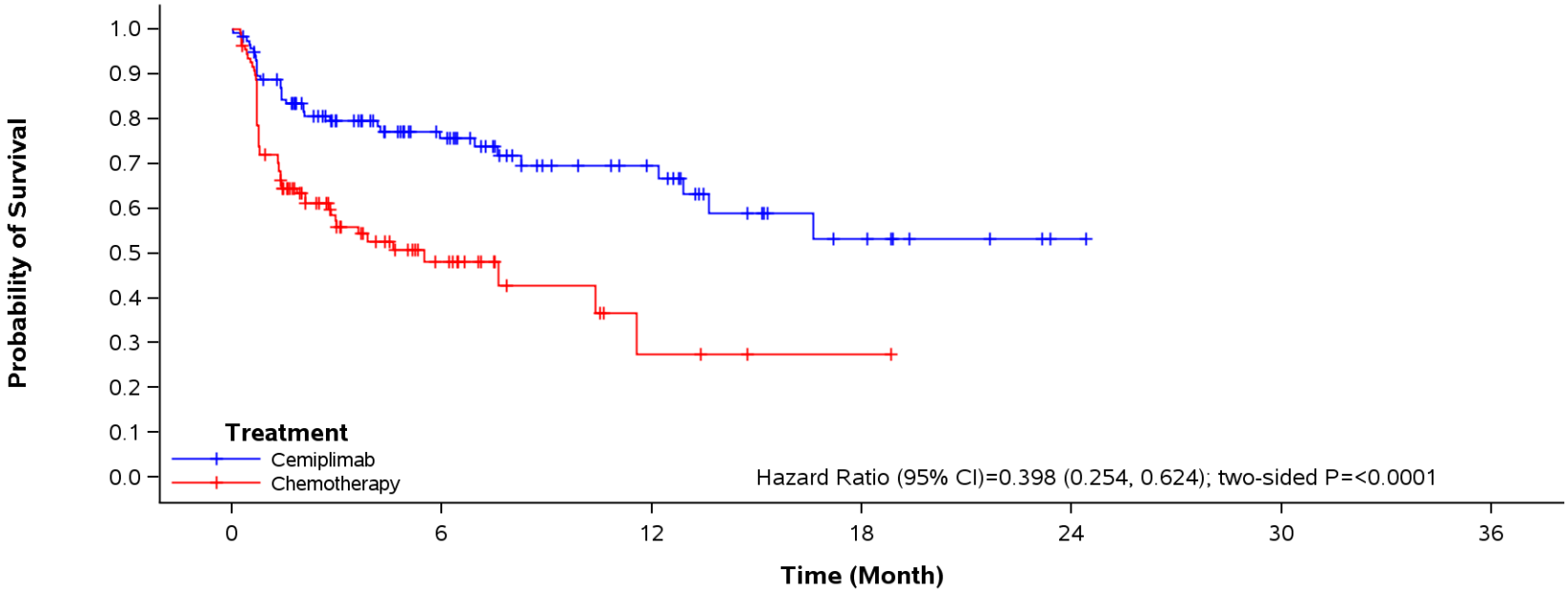

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 47 | 23 | 8 | 1 | 0 | 0 |
| Chemotherapy | 109 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Anaemia



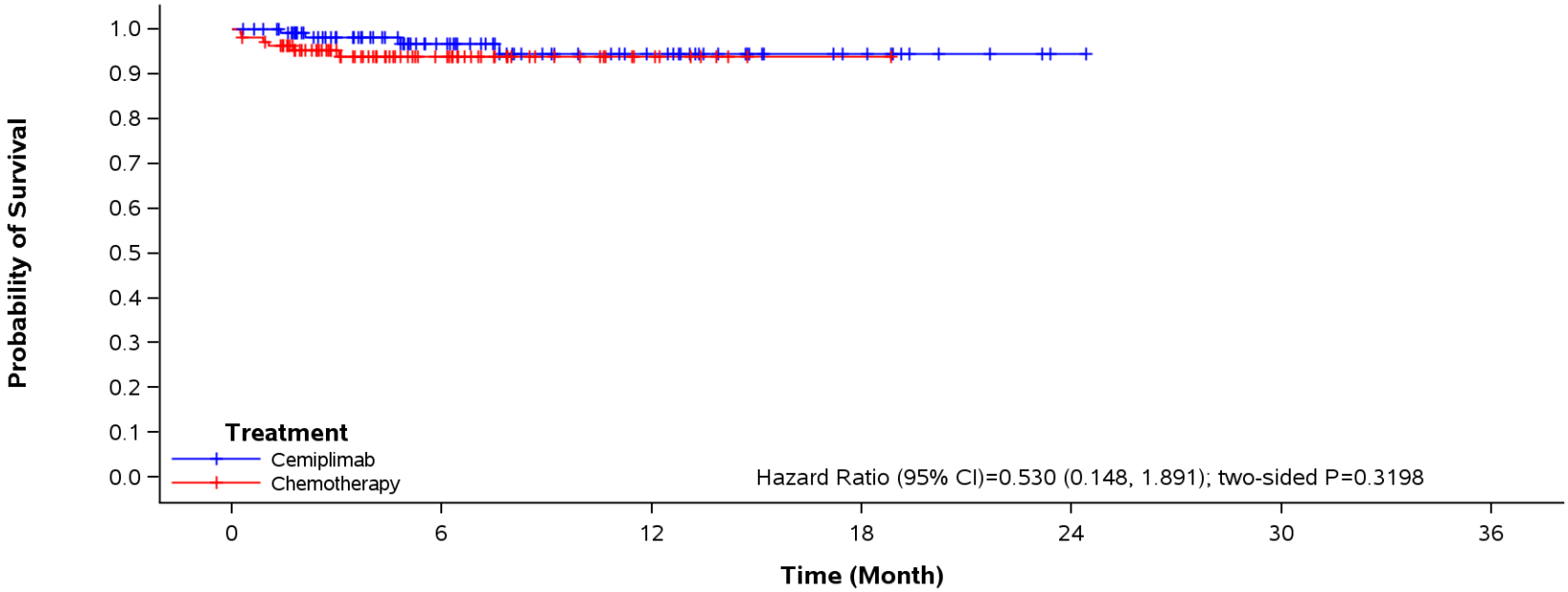

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 50 | 24 | 8 | 1 | 0 | 0 |
| Chemotherapy | 109 | 18 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Neutropenia



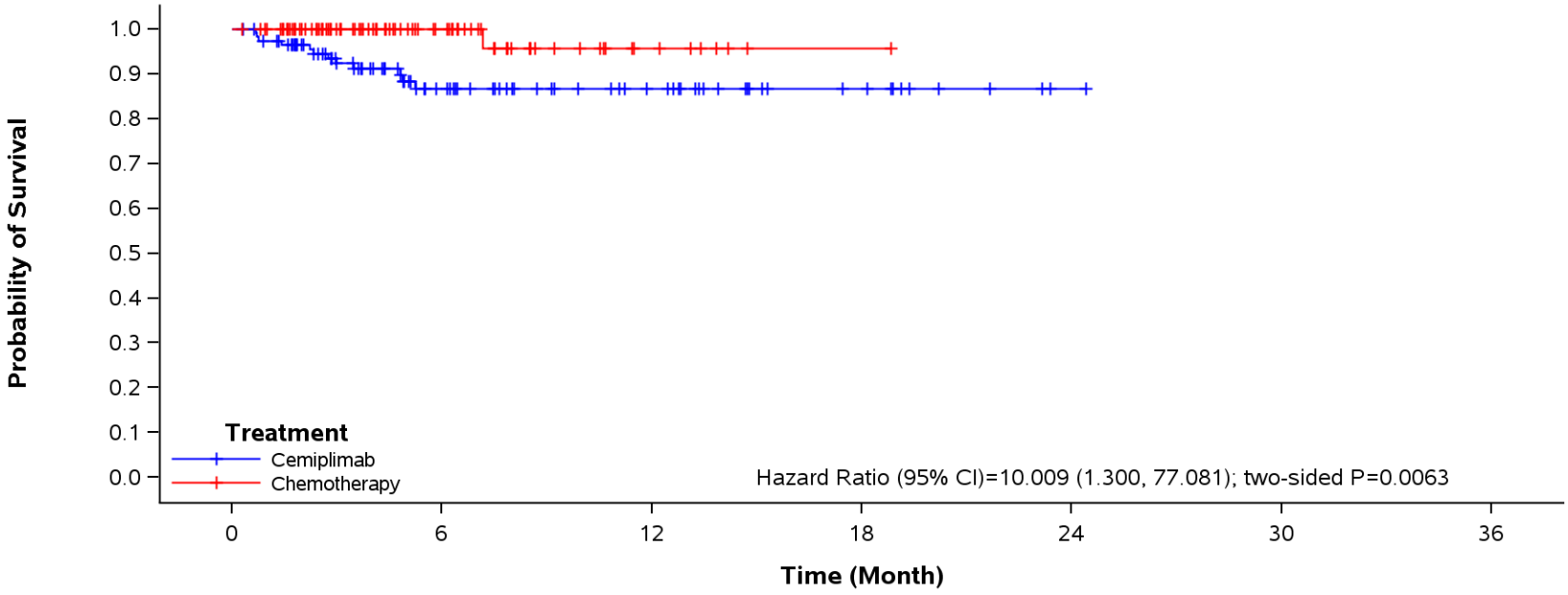

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 28 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Endocrine disorders



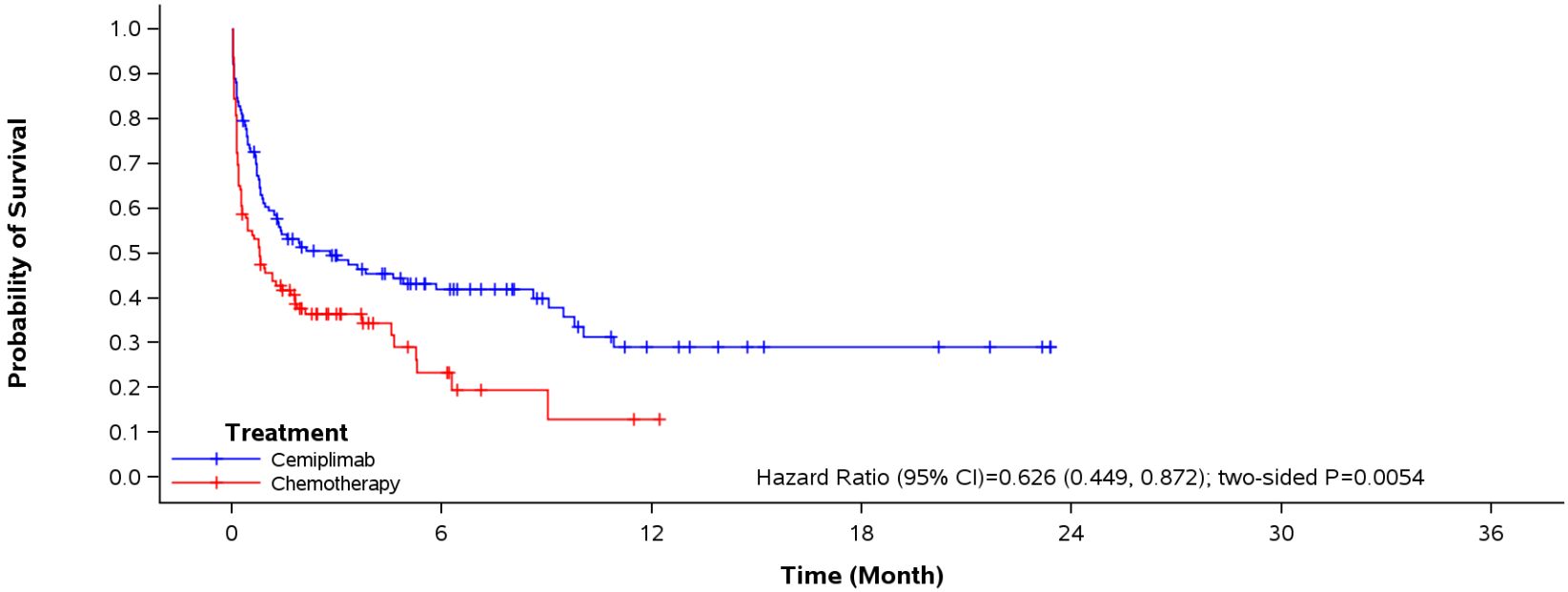

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 49 | 26 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders



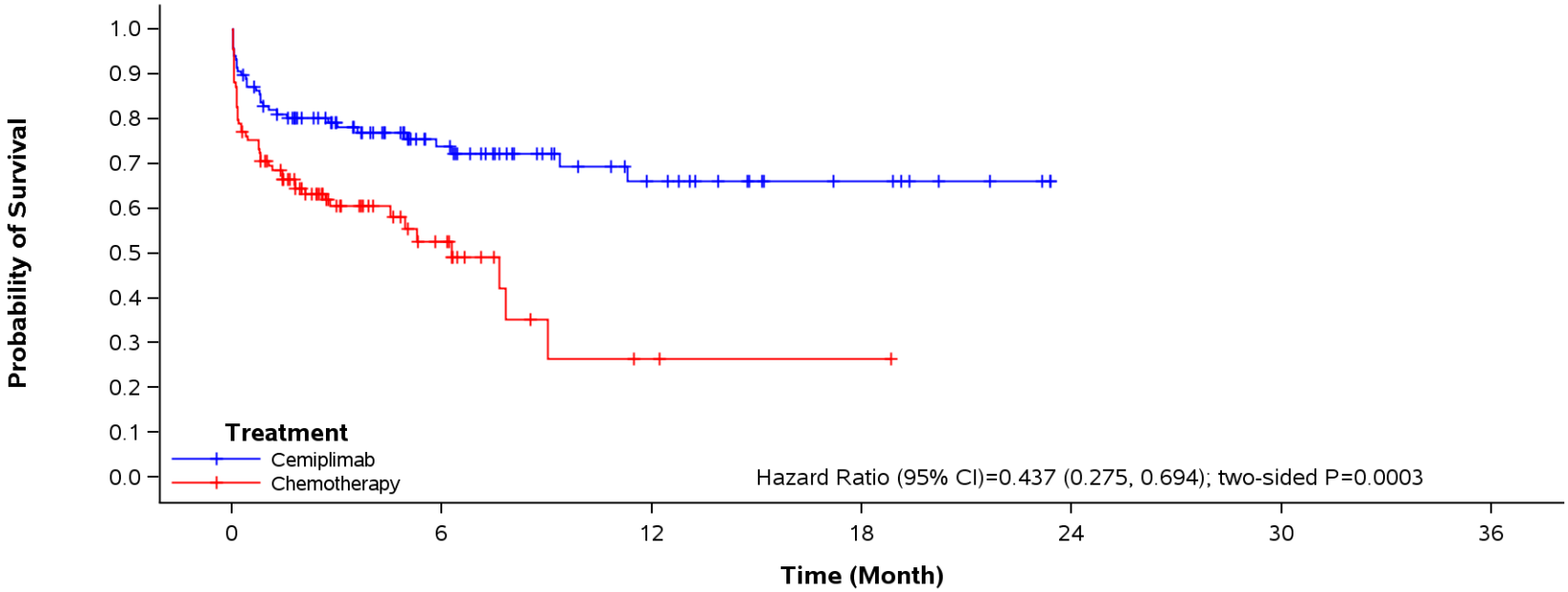

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 31 | 10 | 5 | 0 | 0 | 0 |
| Chemotherapy | 109 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders
PT: Nausea



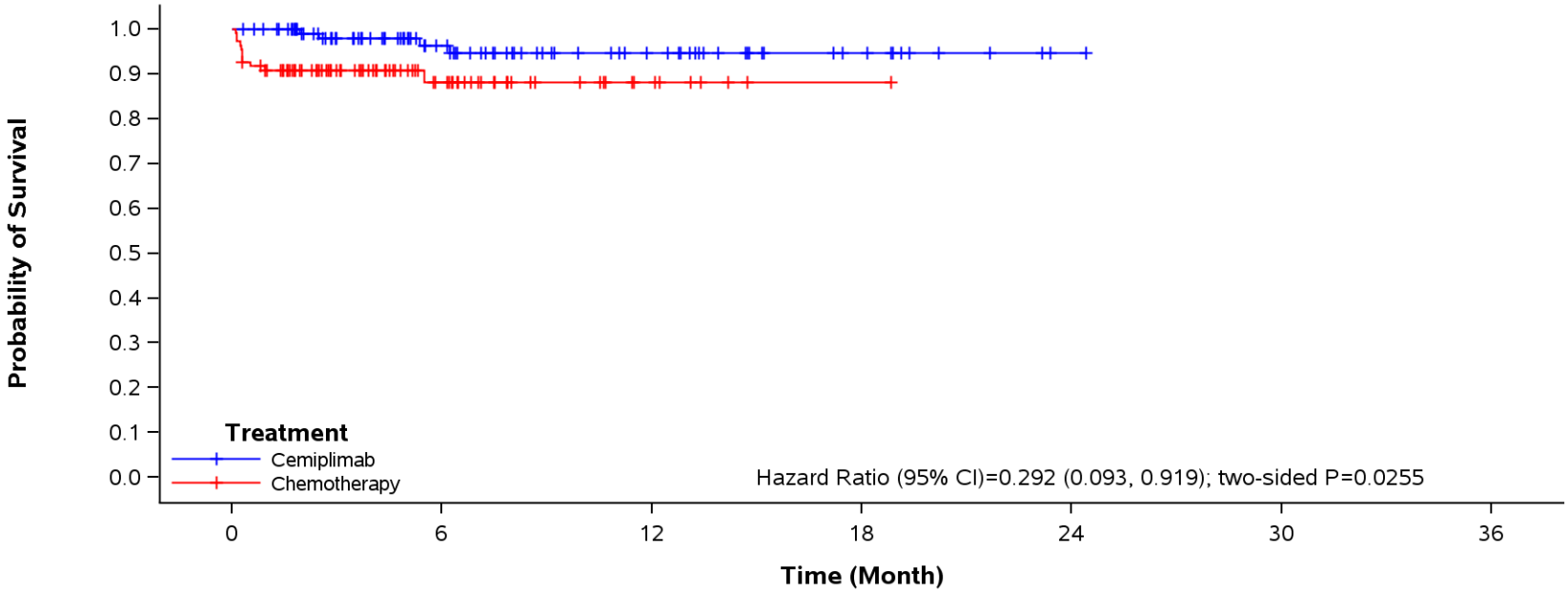

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 46 | 19 | 9 | 0 | 0 | 0 |
| Chemotherapy | 109 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders
PT: Stomatitis



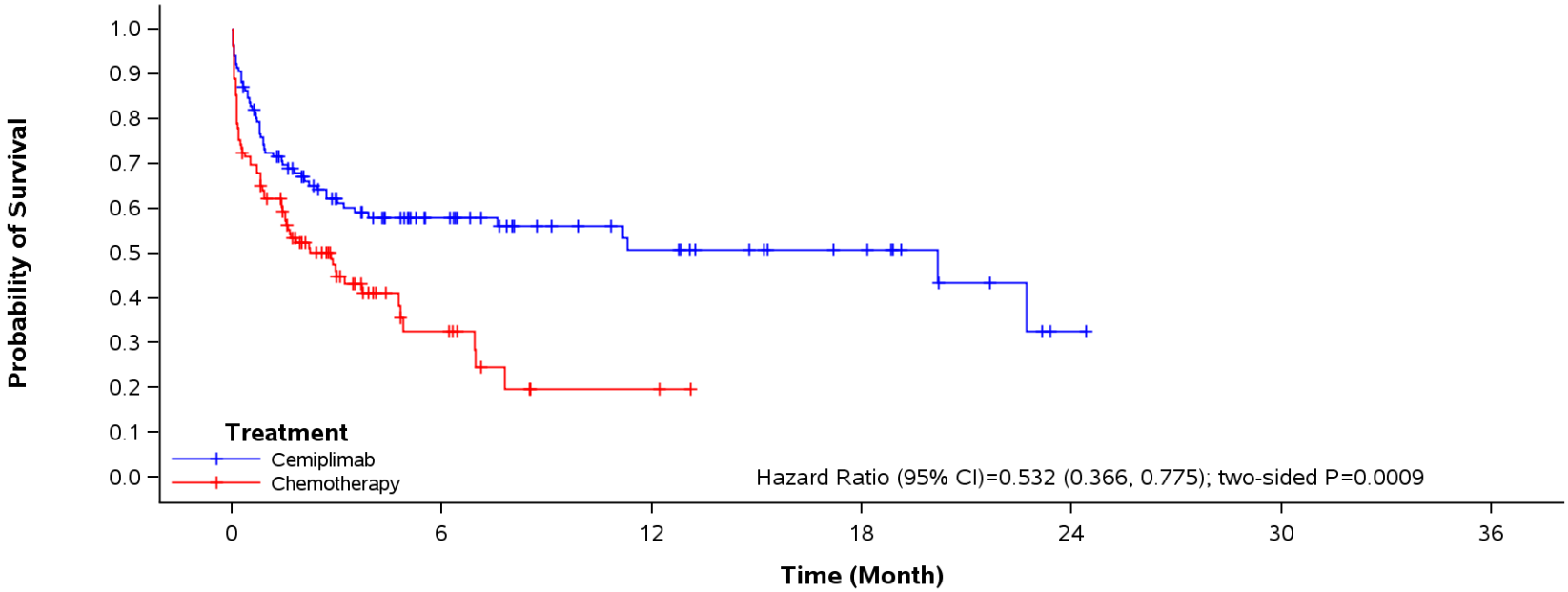

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 55 | 27 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 32 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: General disorders and administration site conditions



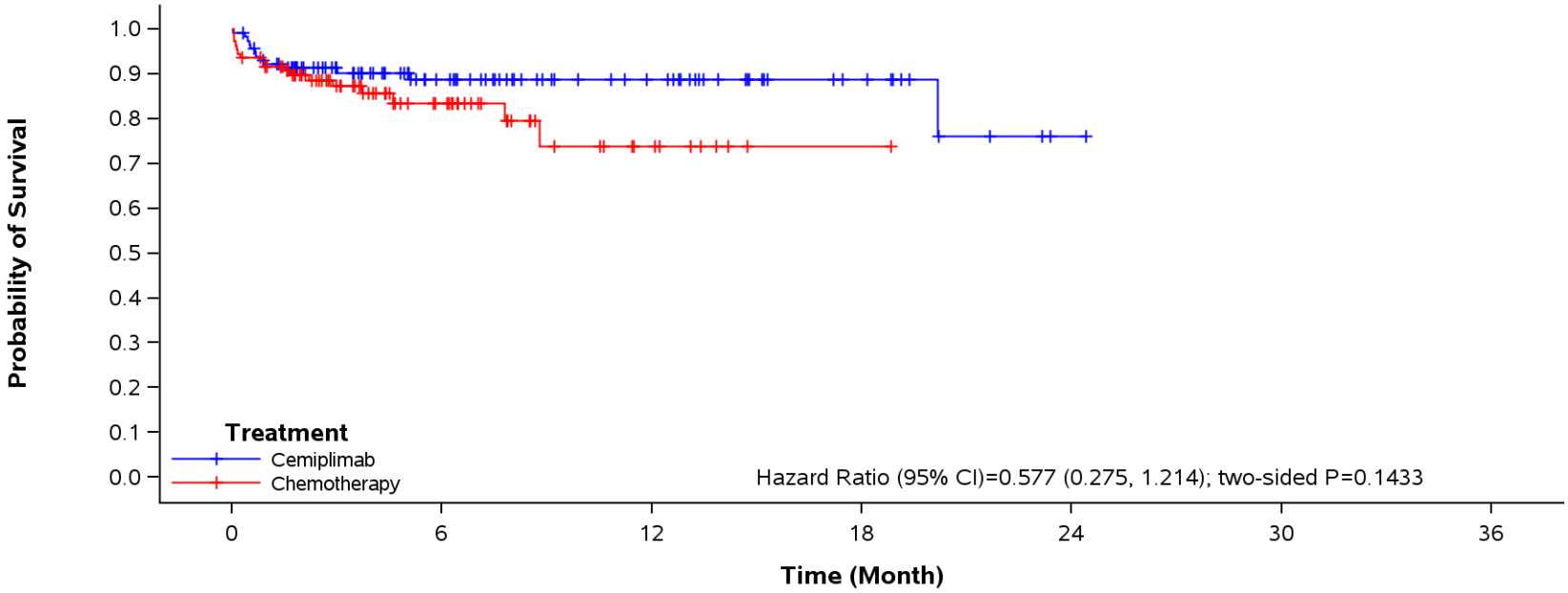

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 38 | 19 | 11 | 1 | 0 | 0 |
| Chemotherapy | 109 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: General disorders and administration site conditions
PT: Asthenia



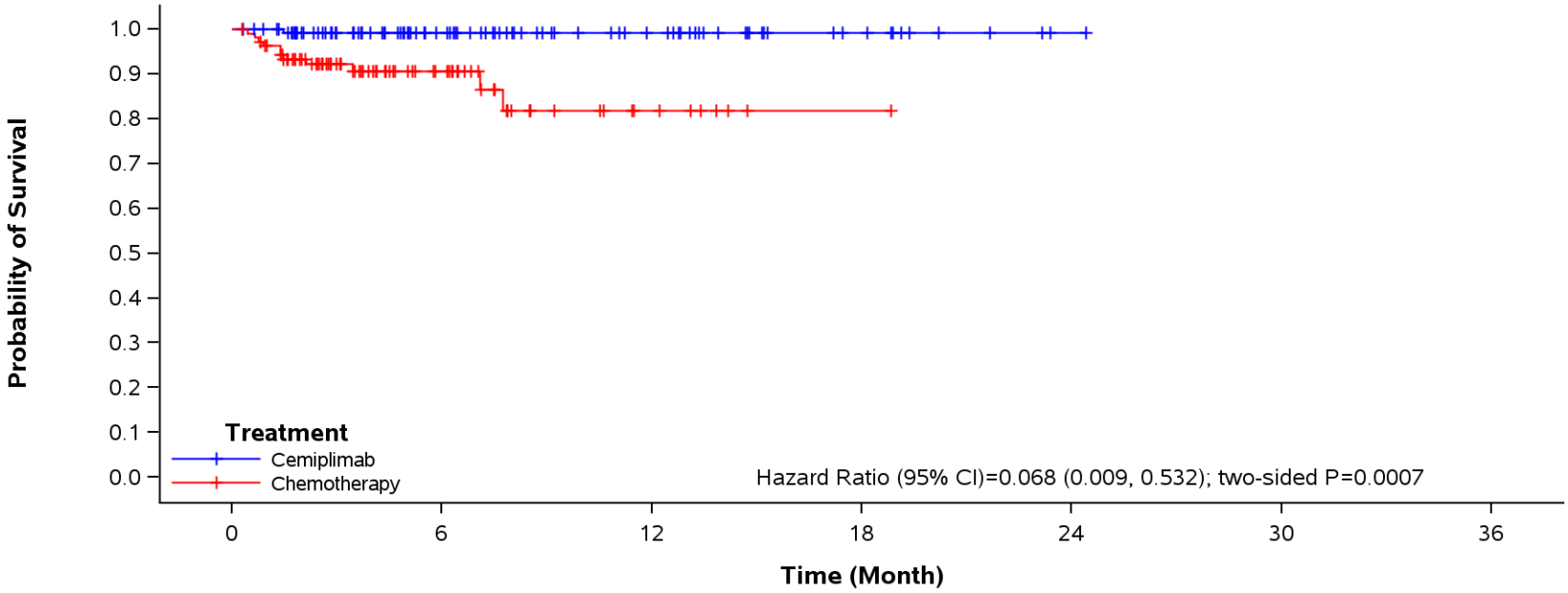

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 55 | 29 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 34 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



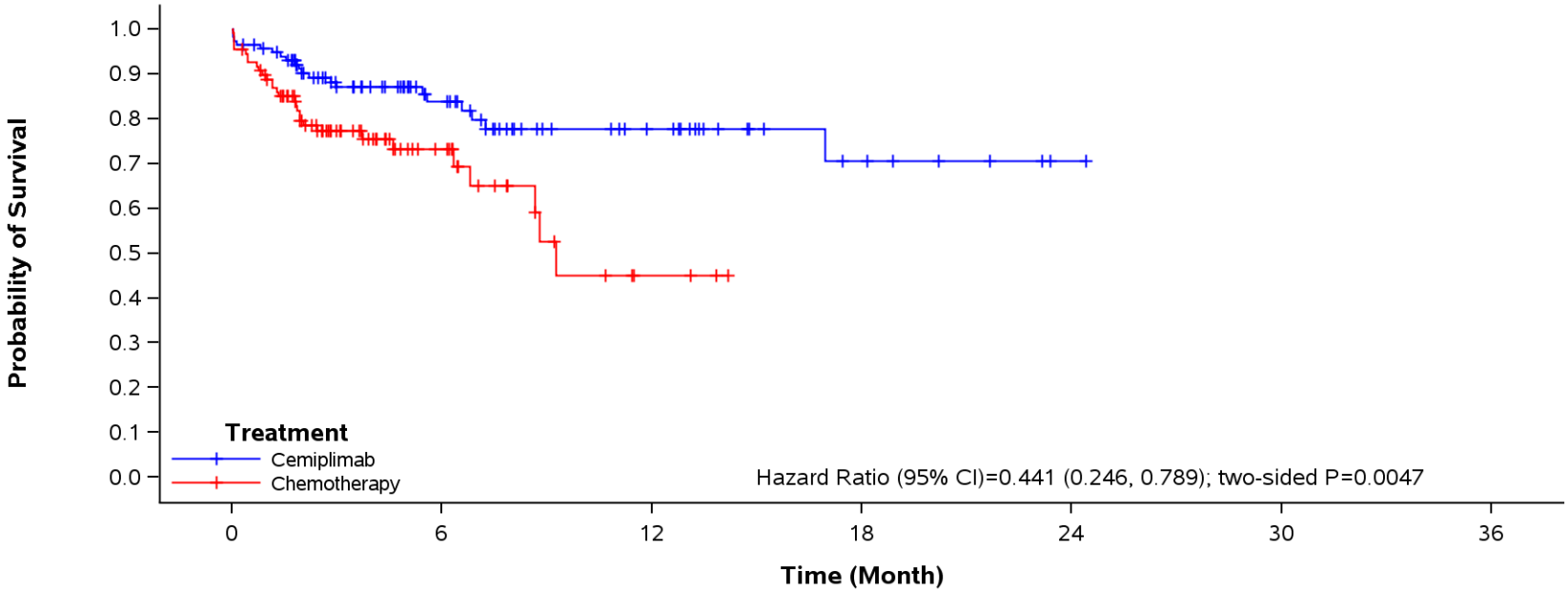

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 29 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 33 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Nervous system disorders



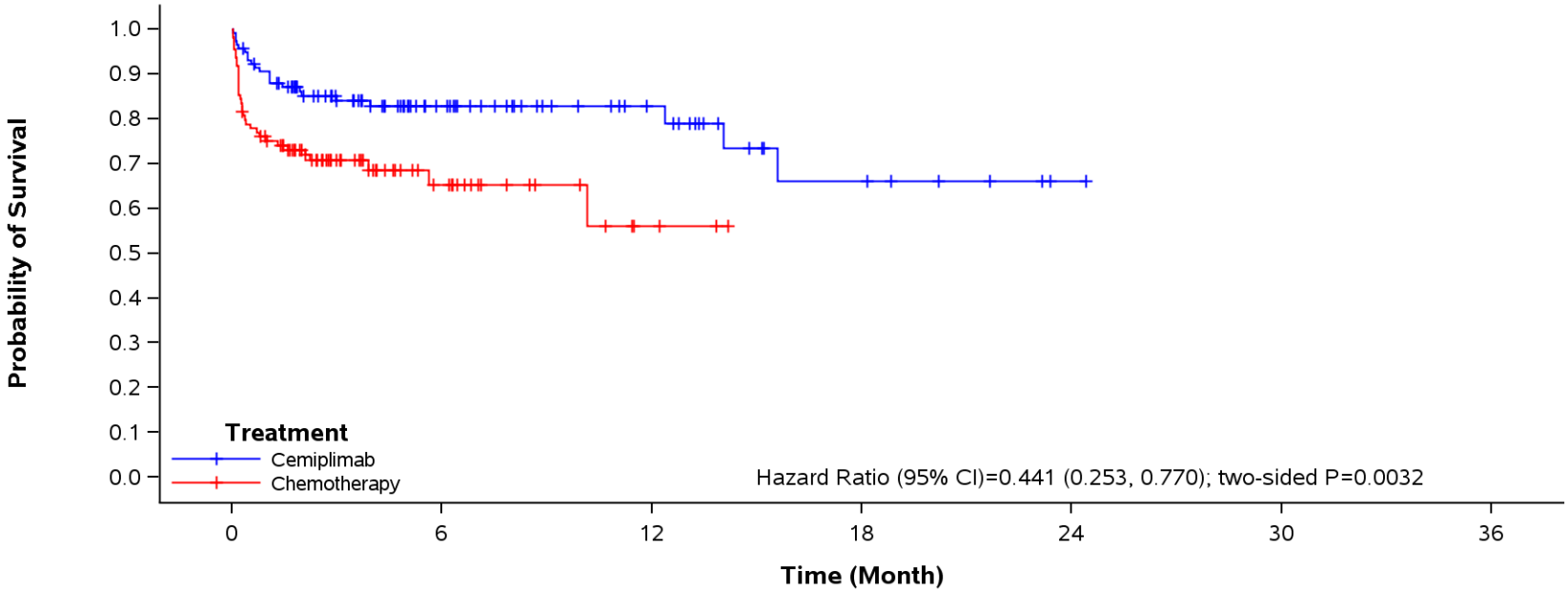

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 49 | 22 | 9 | 1 | 0 | 0 |
| Chemotherapy | 109 | 24 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Skin and subcutaneous tissue disorders



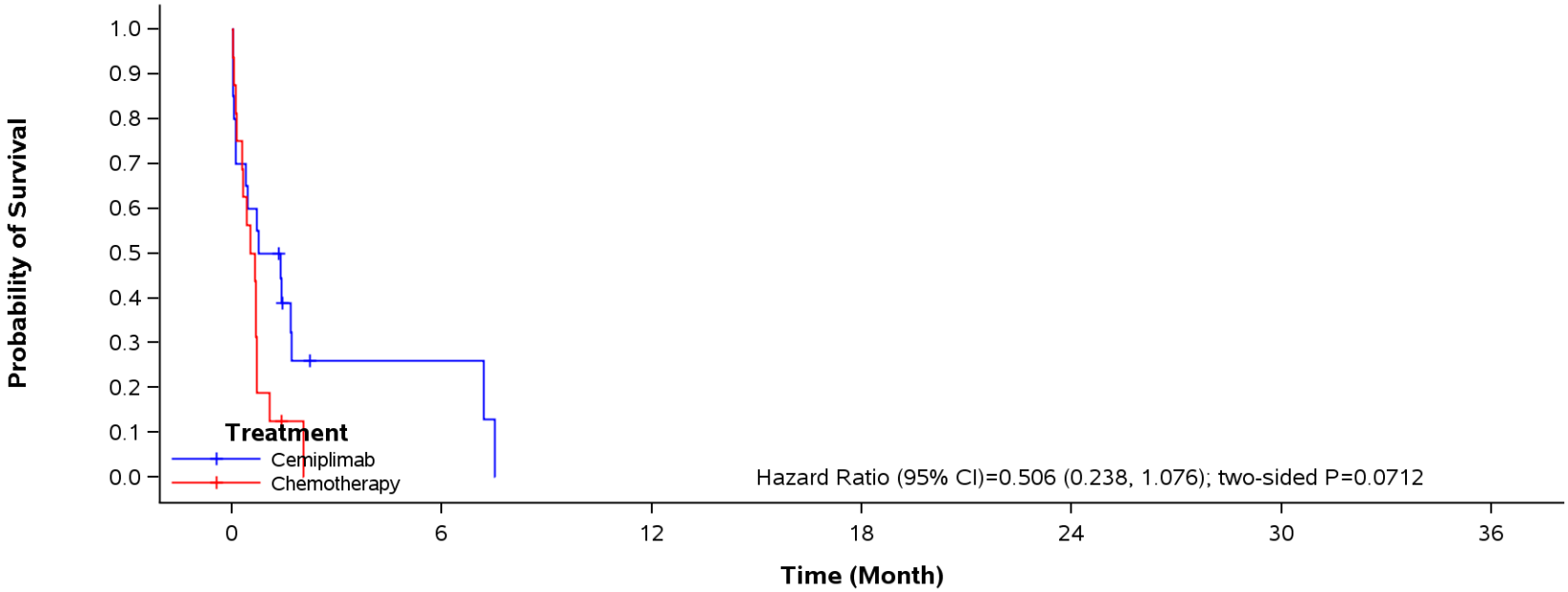

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 45 | 22 | 9 | 1 | 0 | 0 |
| Chemotherapy | 109 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Number of patients with any TEAE



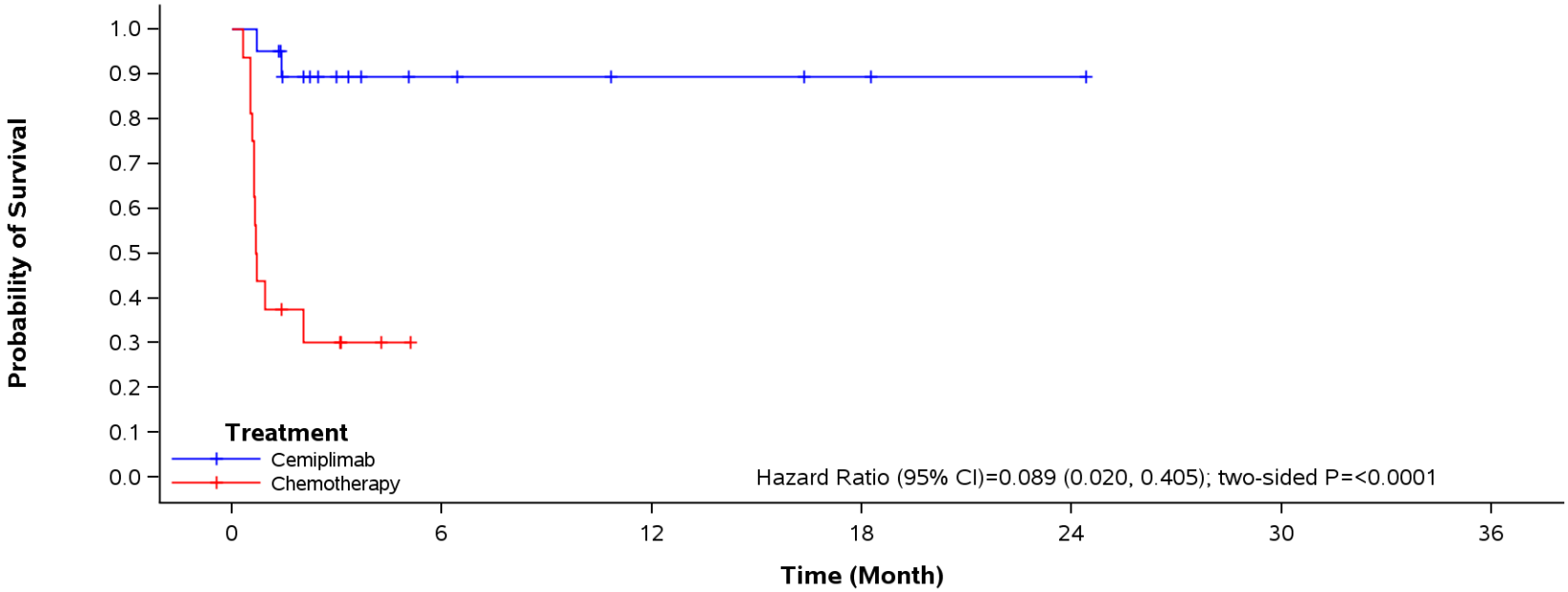

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 16 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders



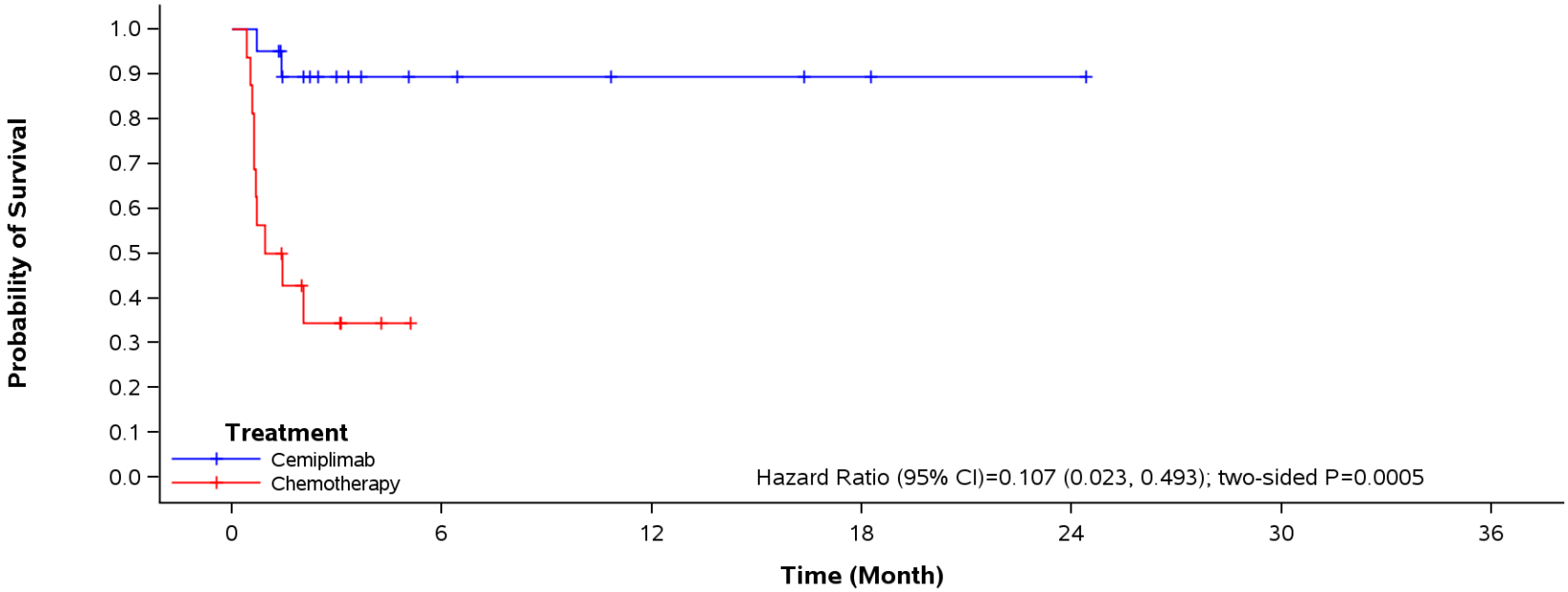

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 16 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



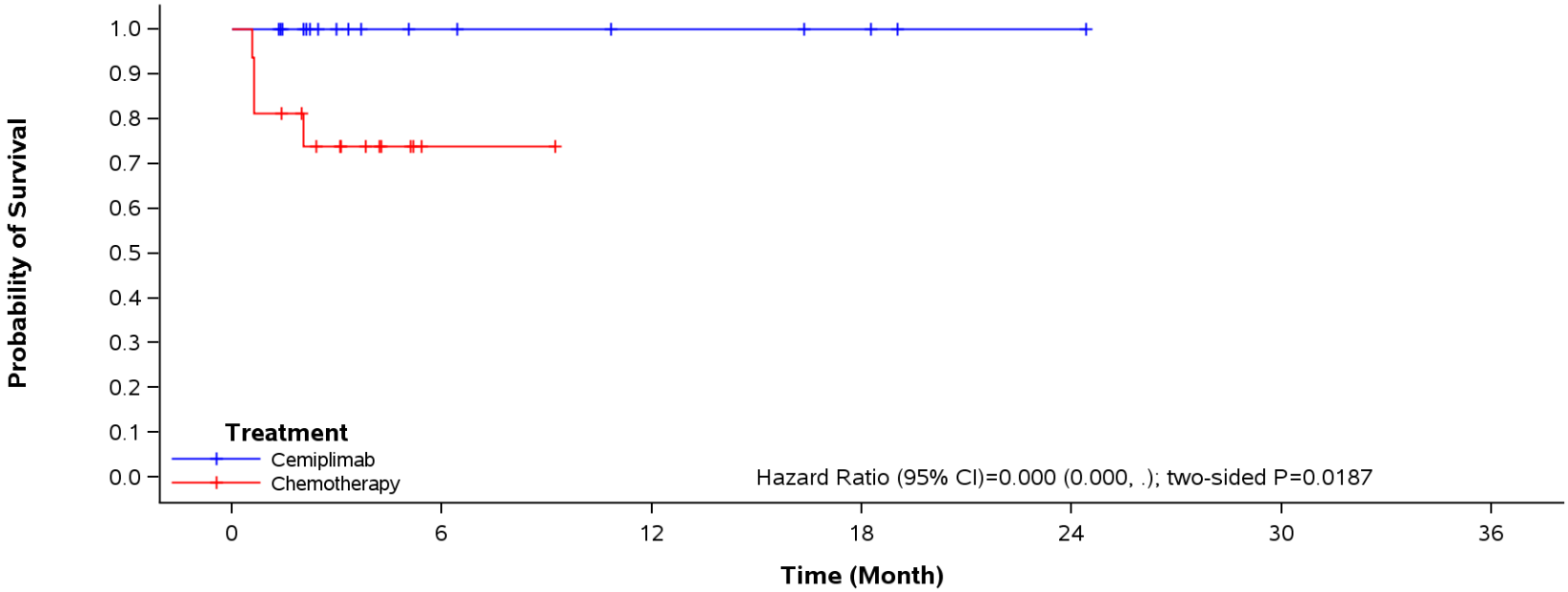

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 16 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



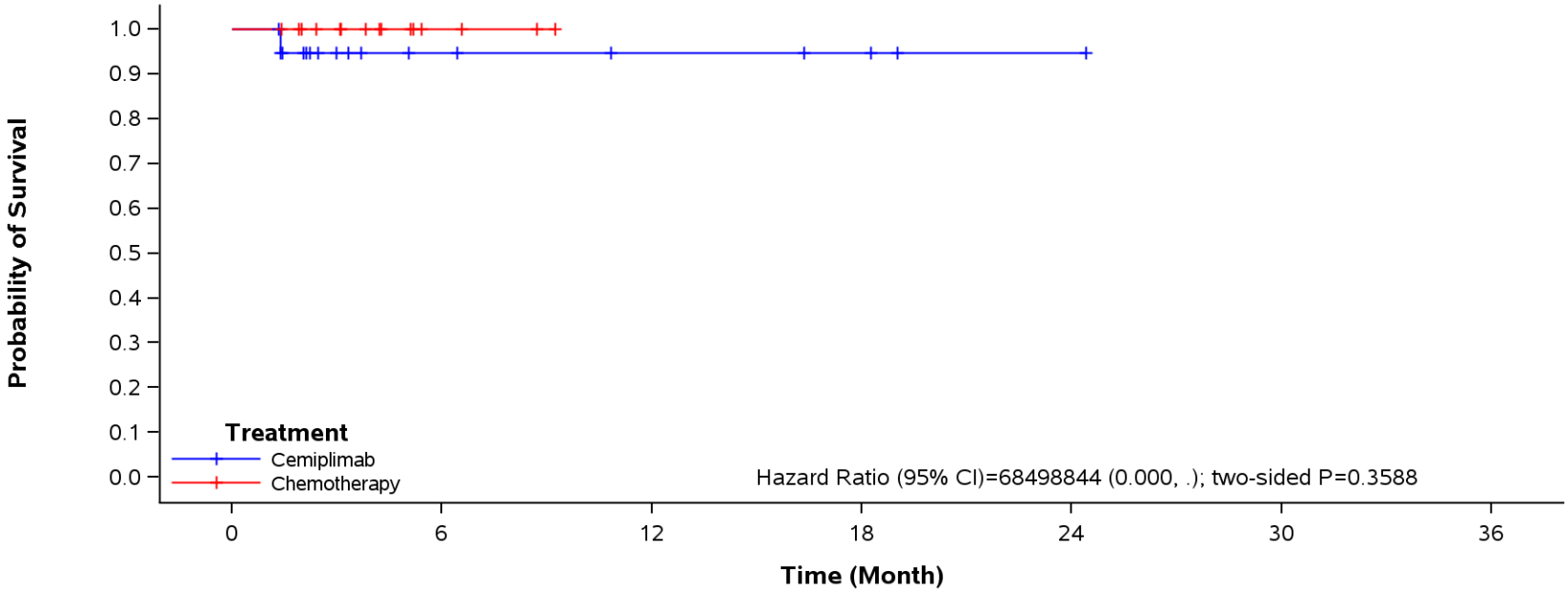

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Endocrine disorders



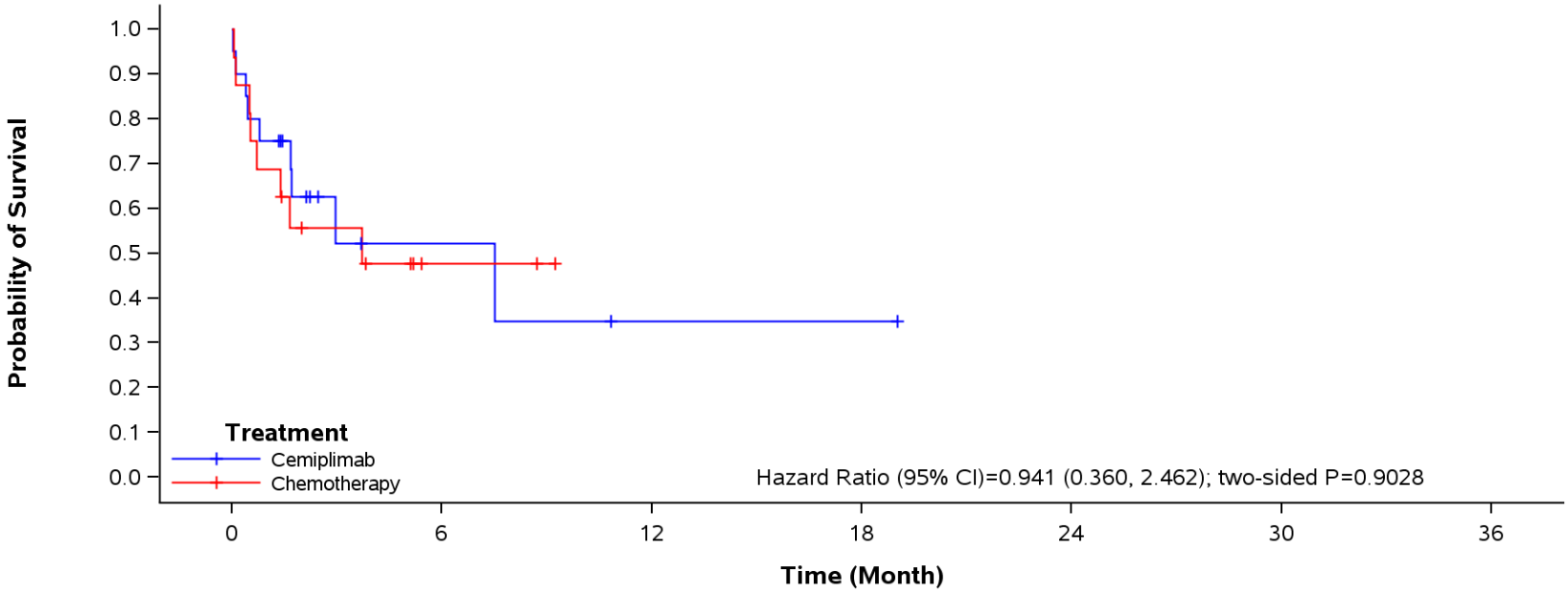

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders



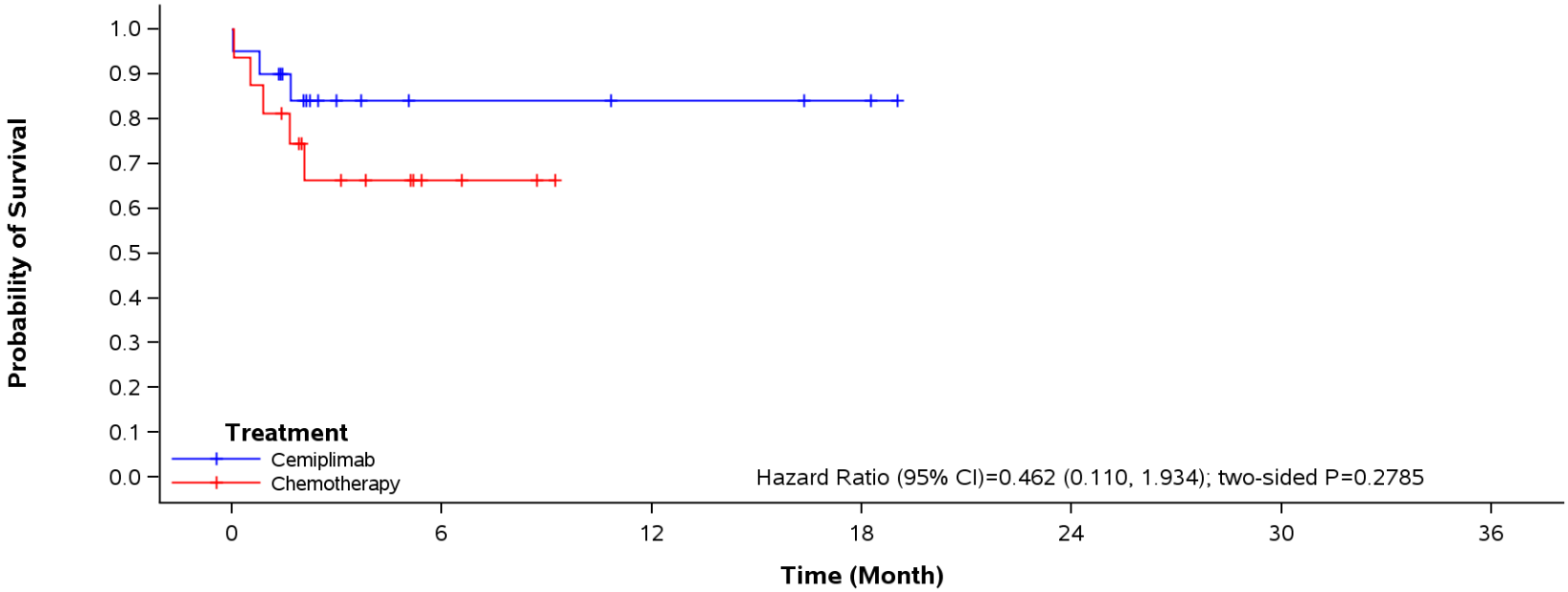

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders
PT: Nausea



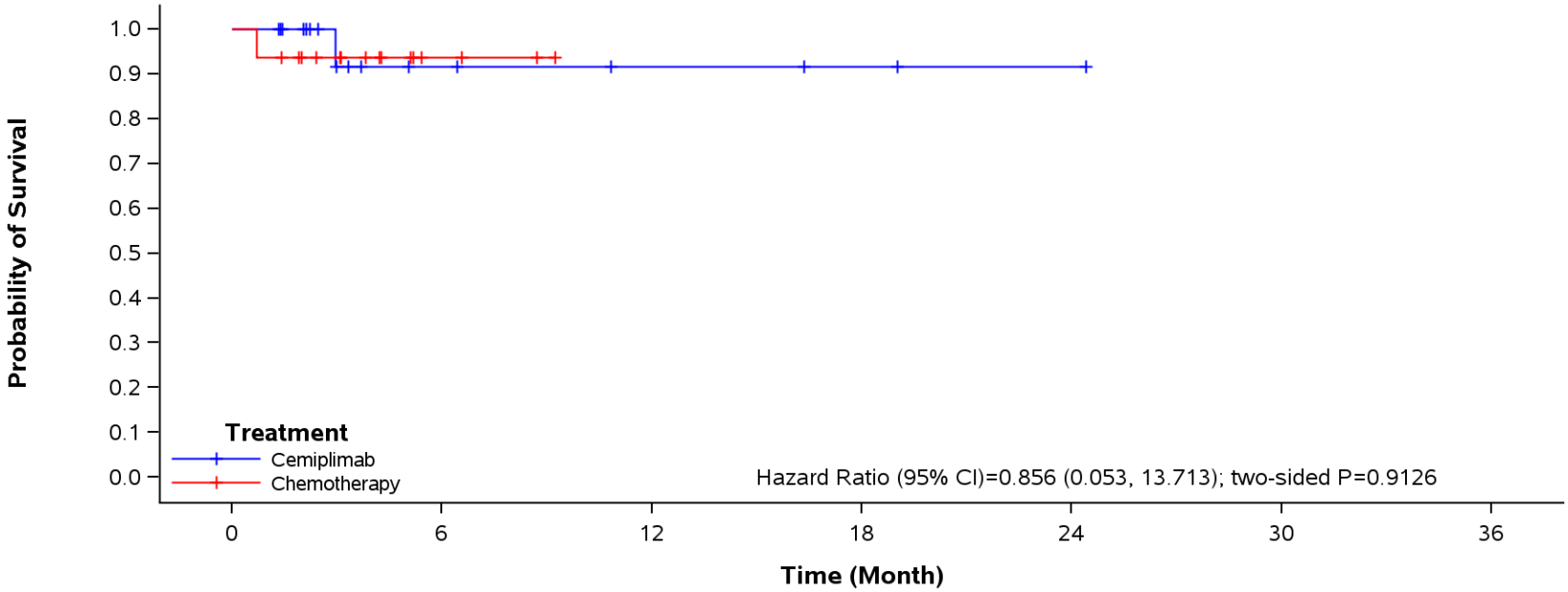

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders
PT: Stomatitis



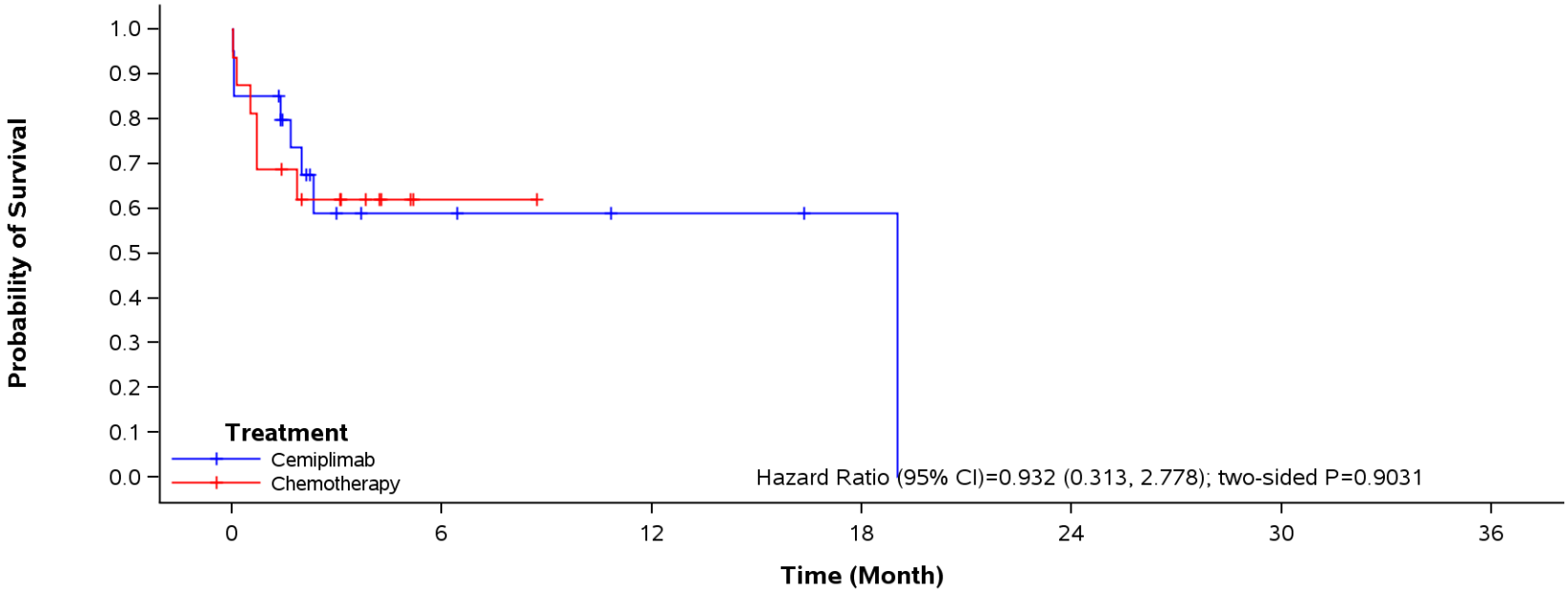

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: General disorders and administration site conditions



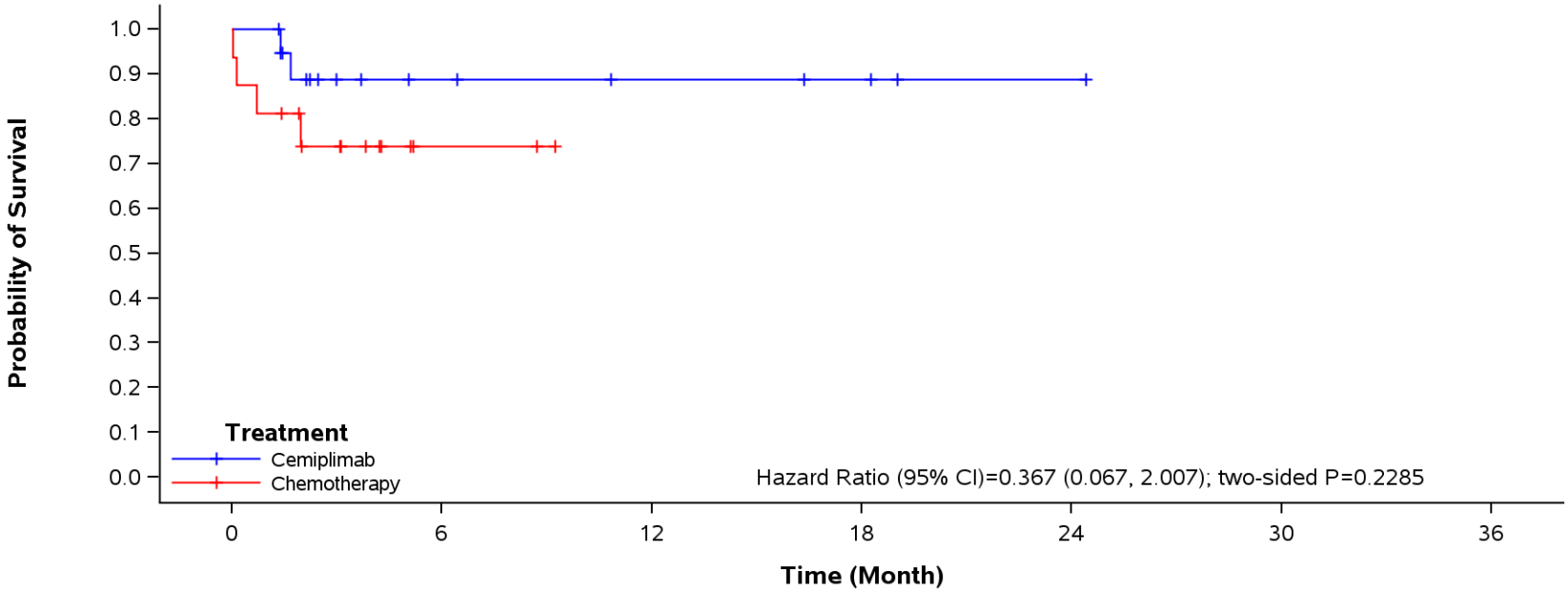

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: General disorders and administration site conditions
PT: Asthenia



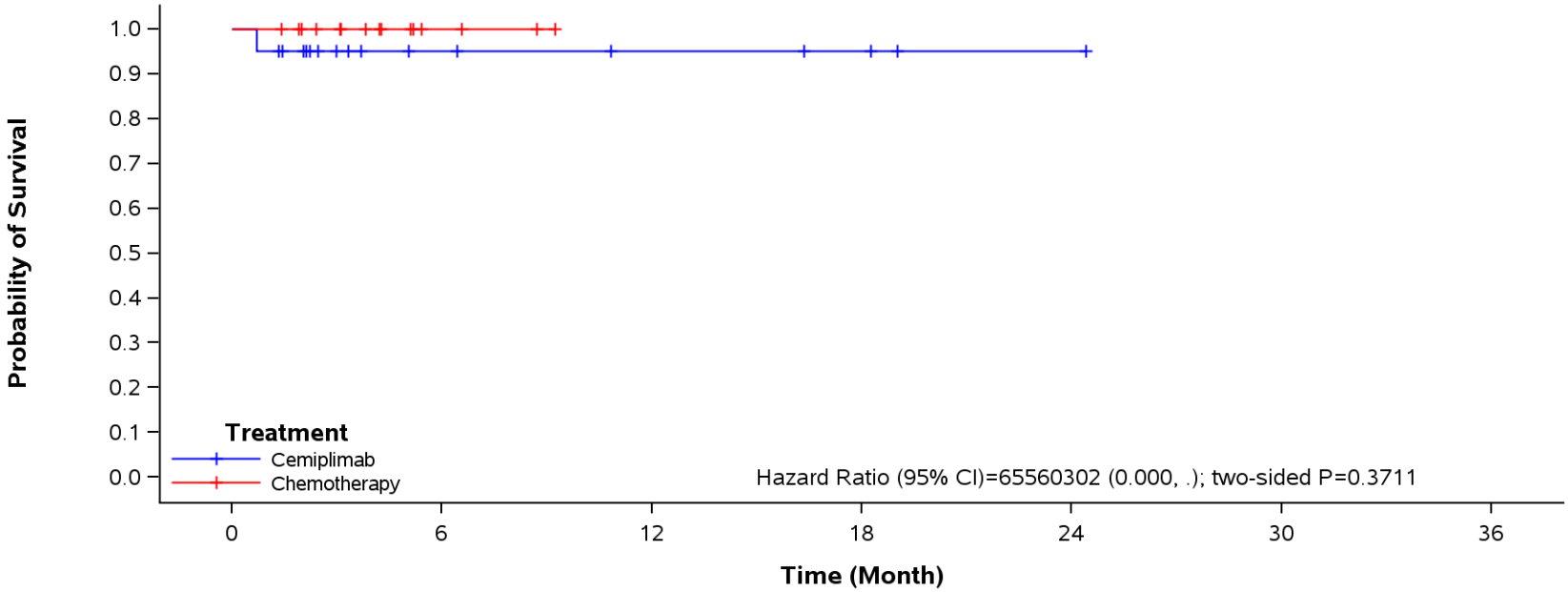

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



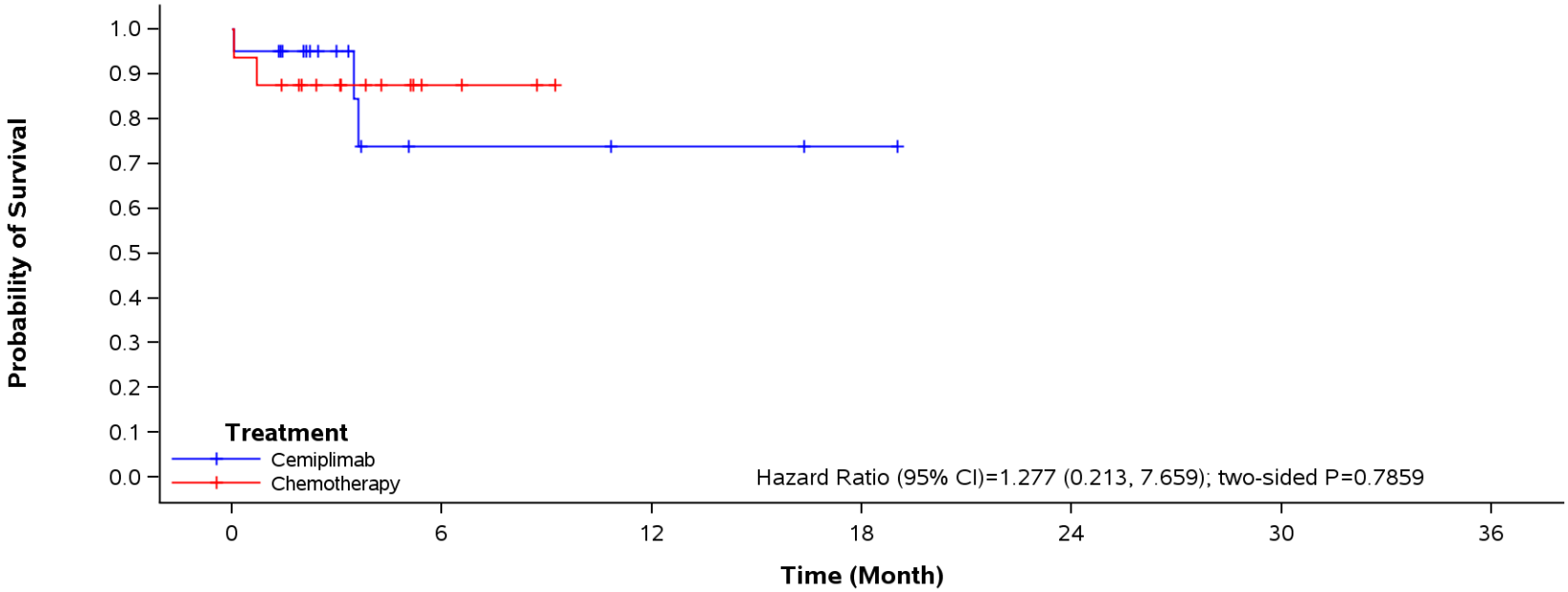

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Nervous system disorders



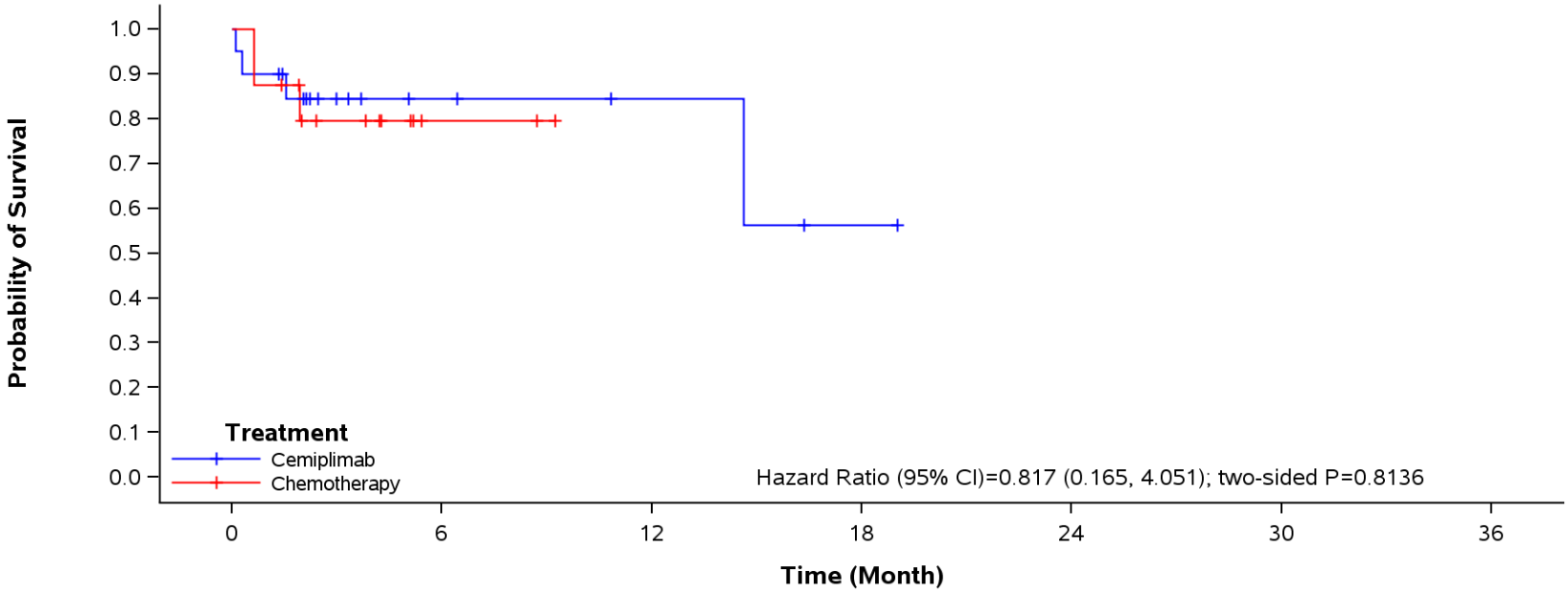

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Skin and subcutaneous tissue disorders



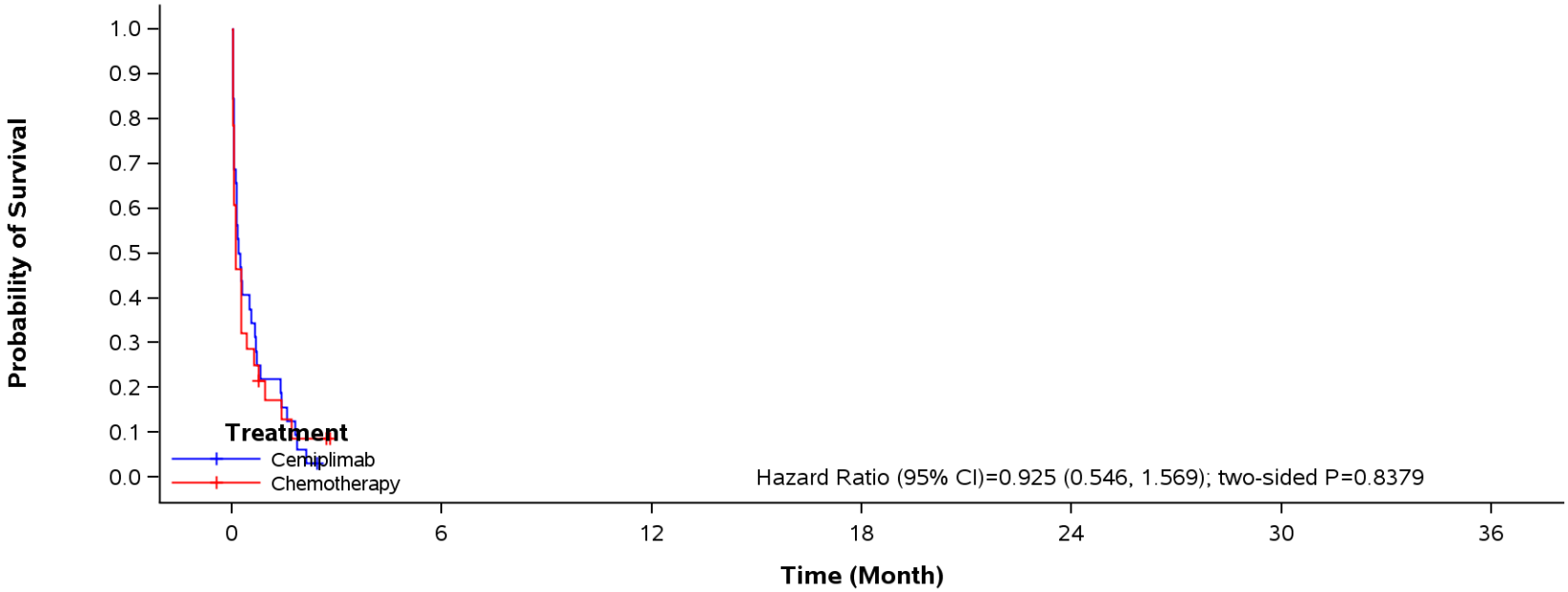

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Number of patients with any TEAE



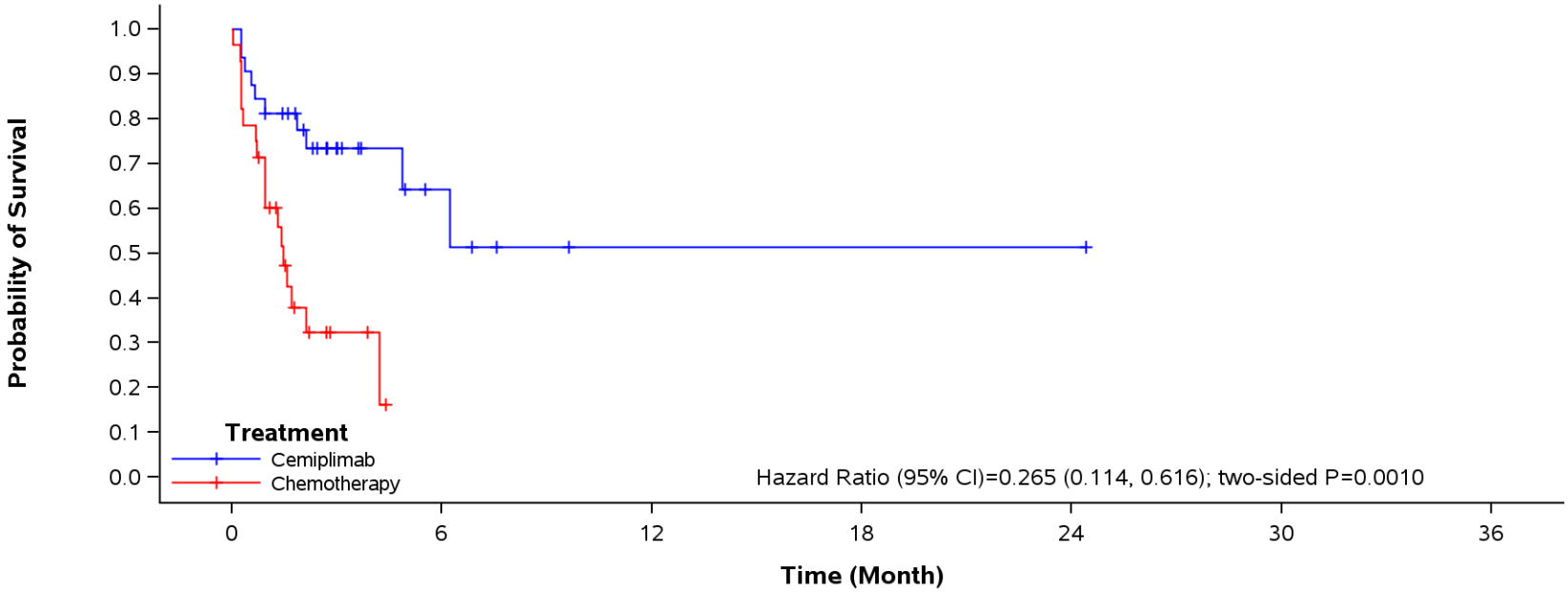

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 28 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders



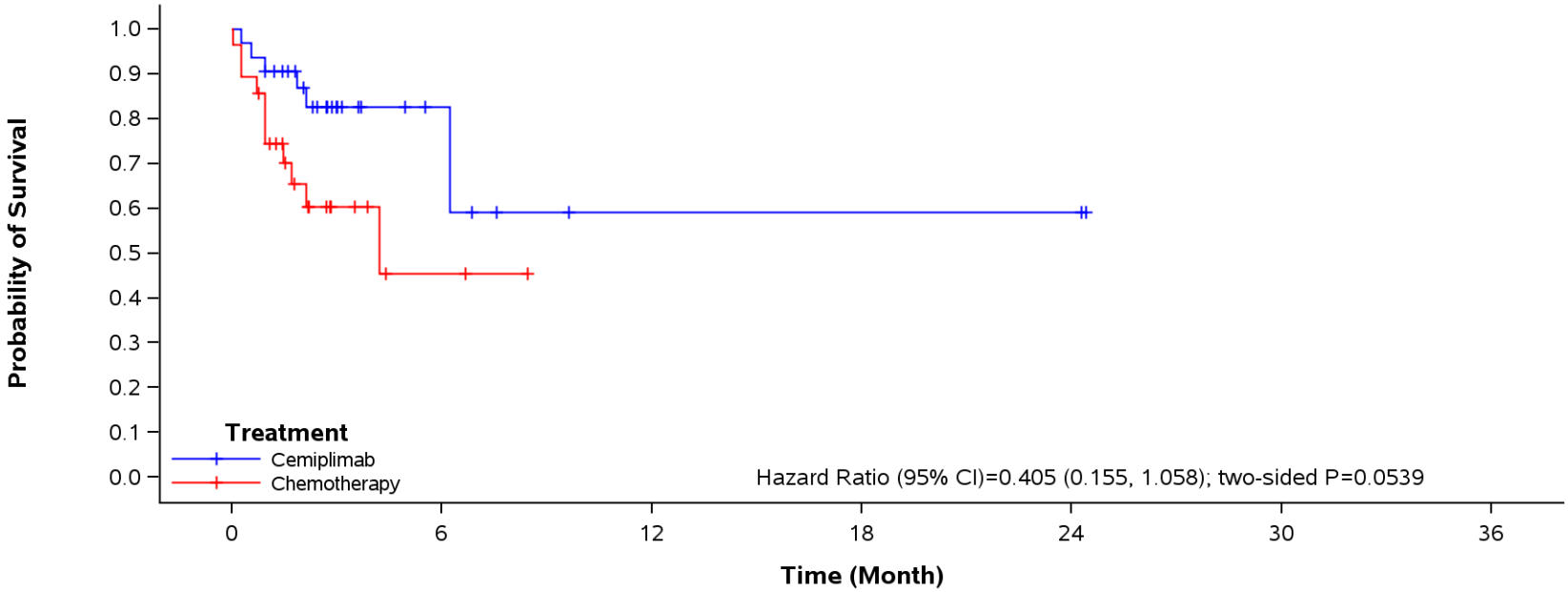

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 5 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 28 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Anaemia



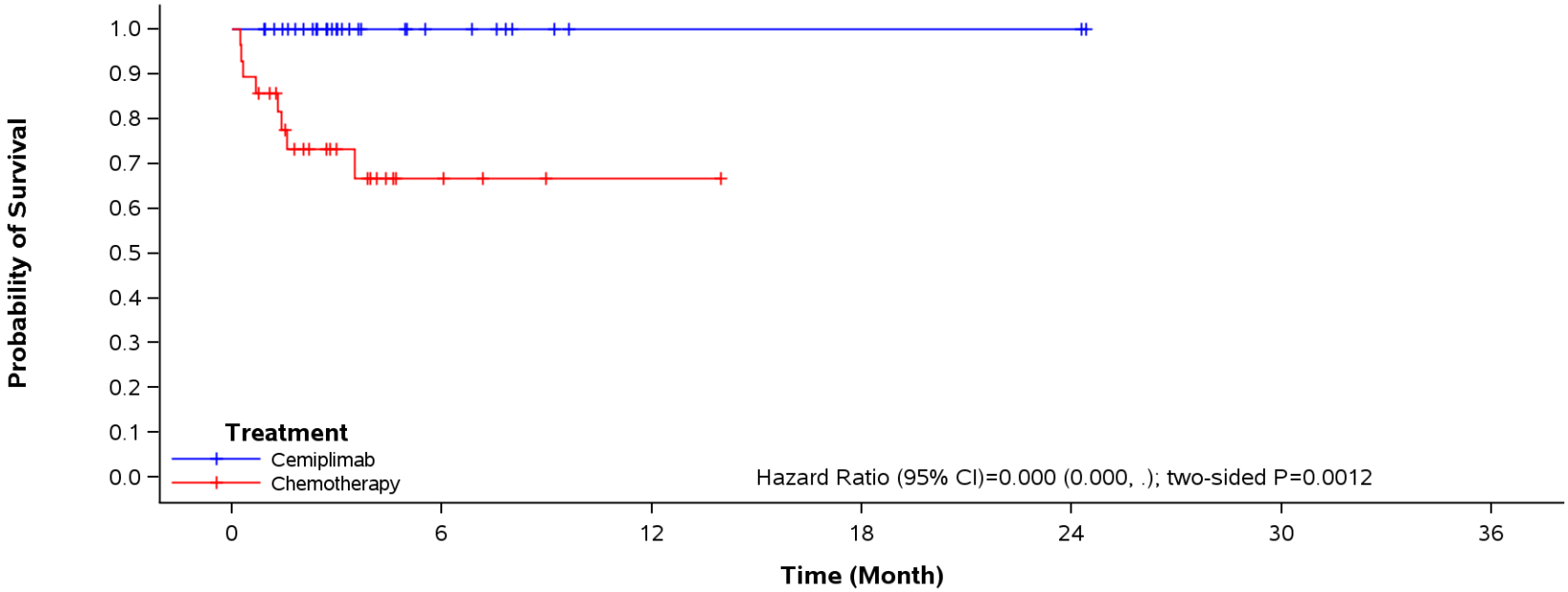

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 7 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Neutropenia



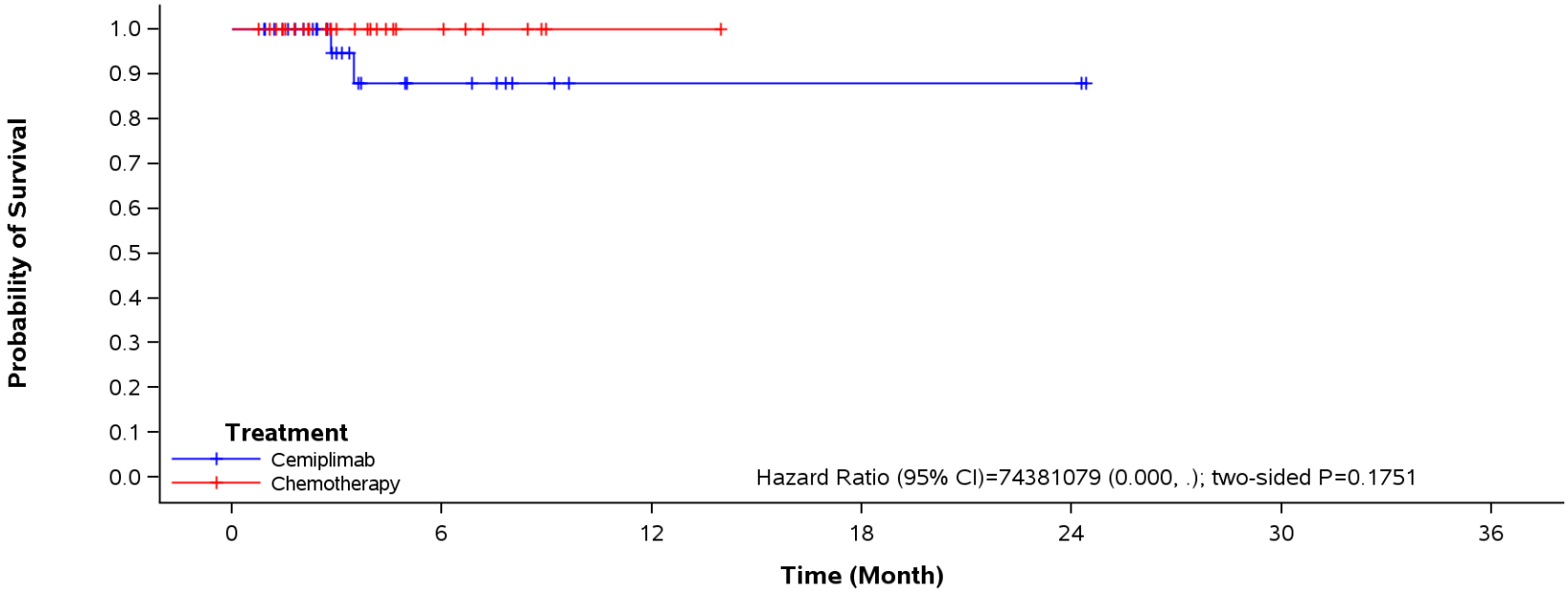

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Endocrine disorders



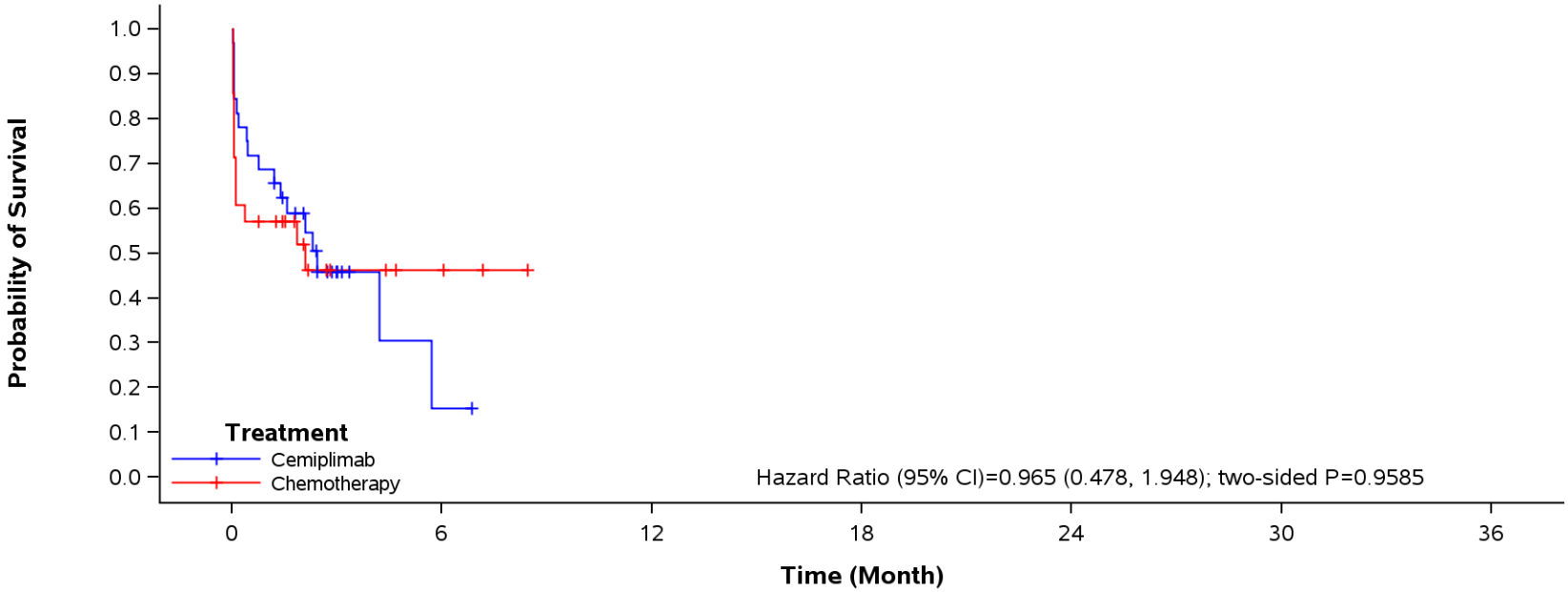

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders



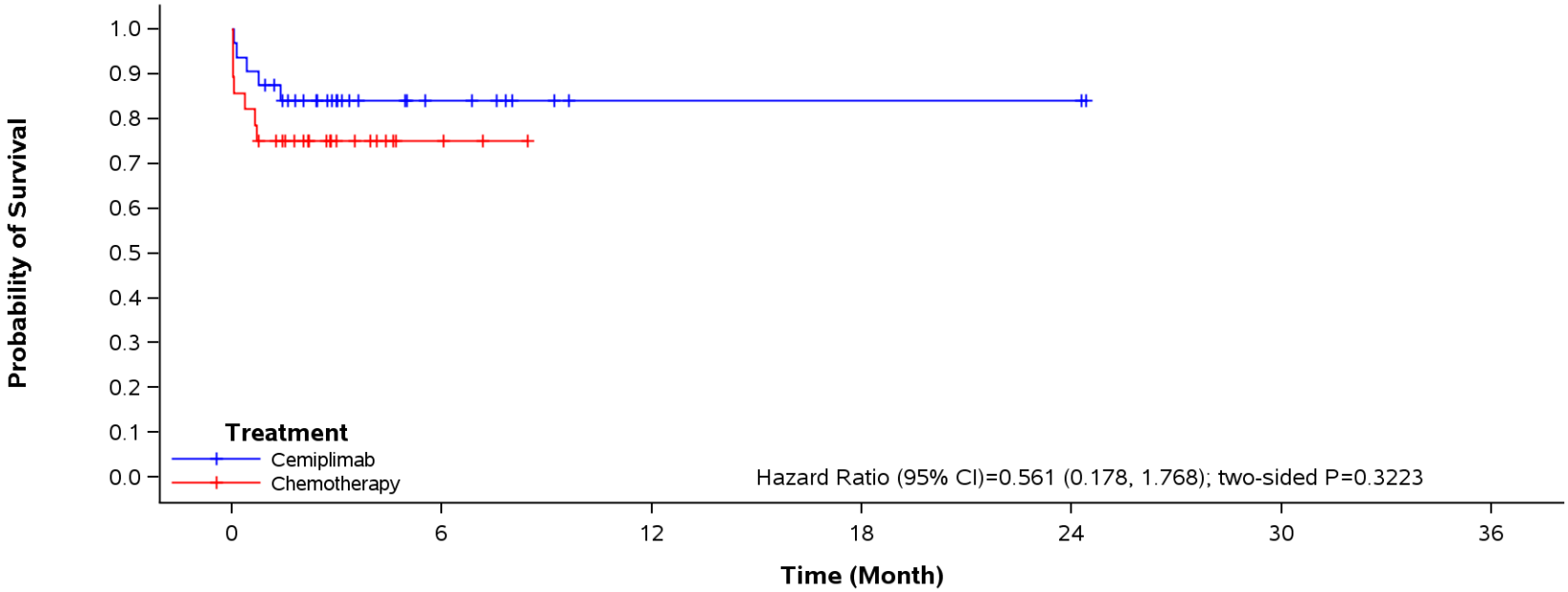

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 28 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders
PT: Nausea



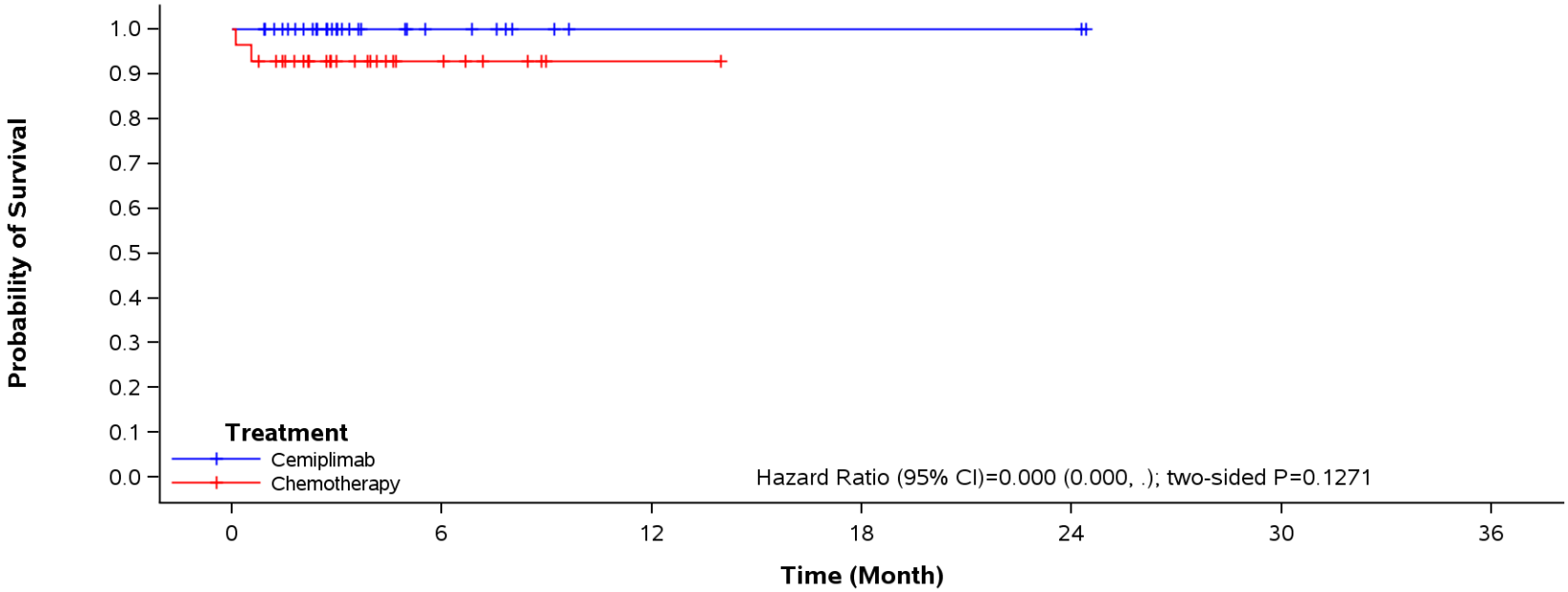

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders
PT: Stomatitis



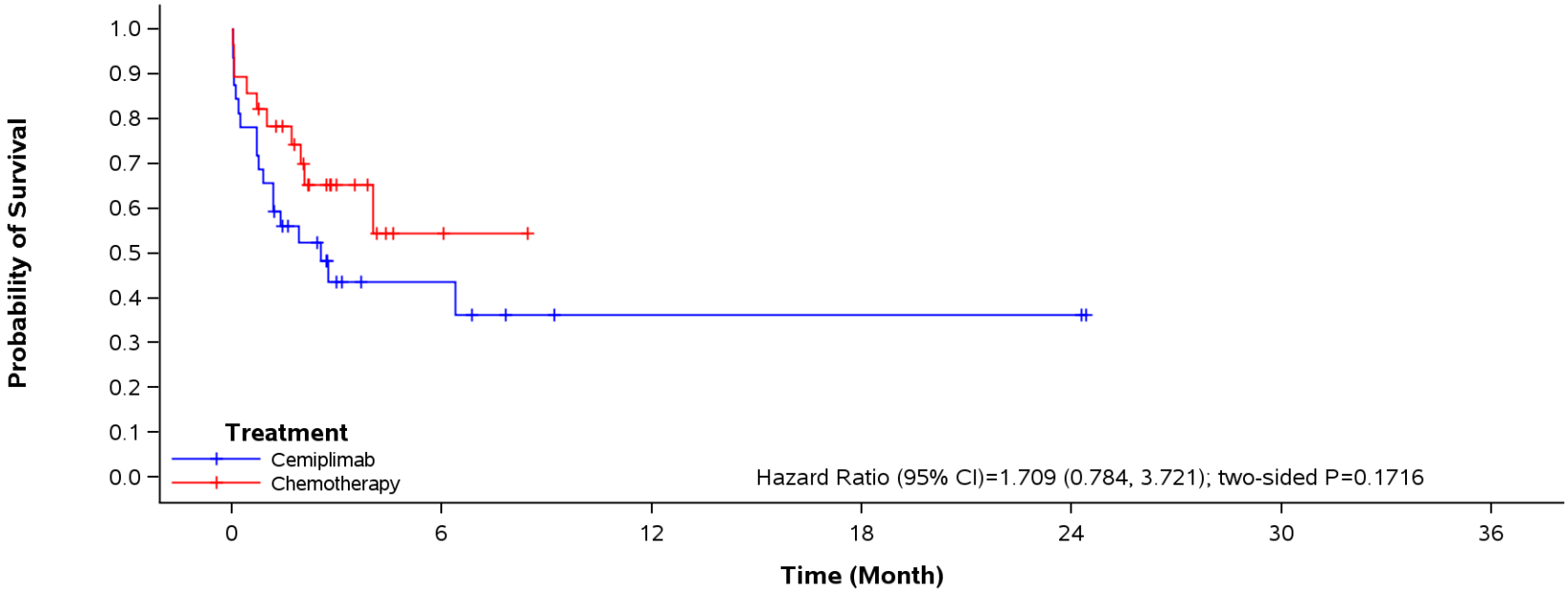

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: General disorders and administration site conditions



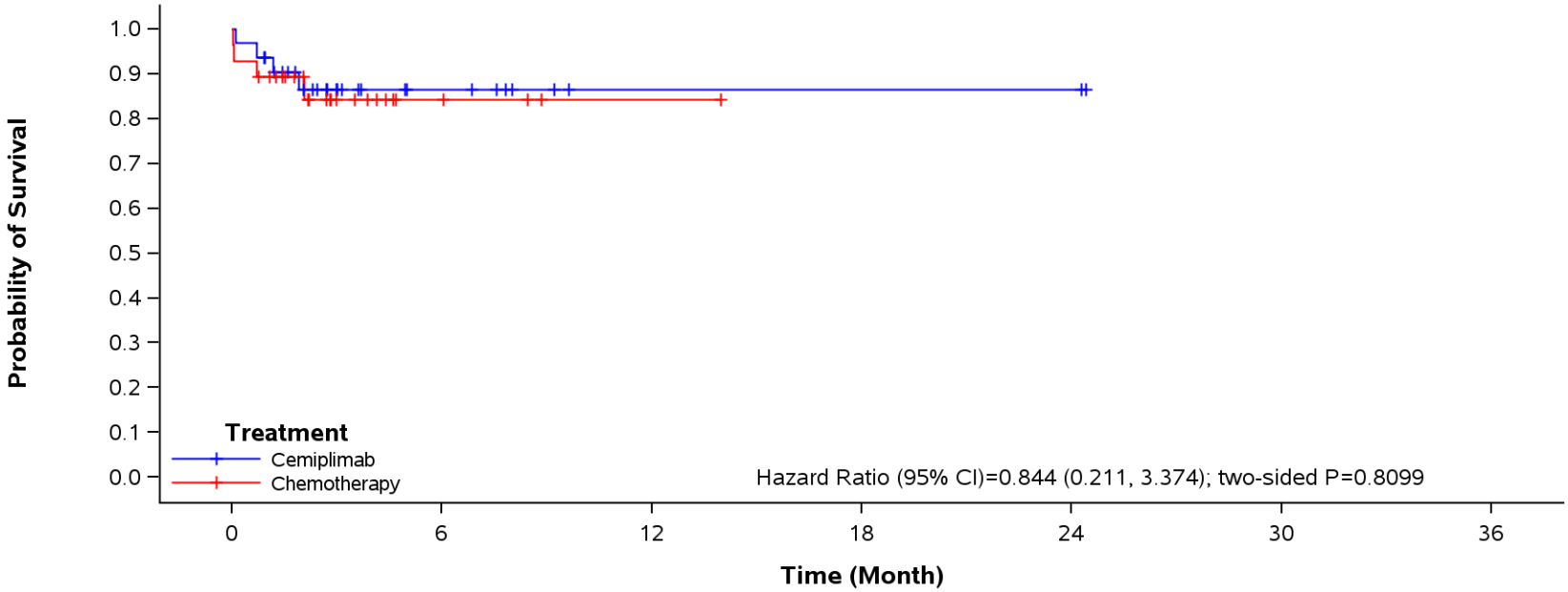

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 6 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: General disorders and administration site conditions
PT: Asthenia



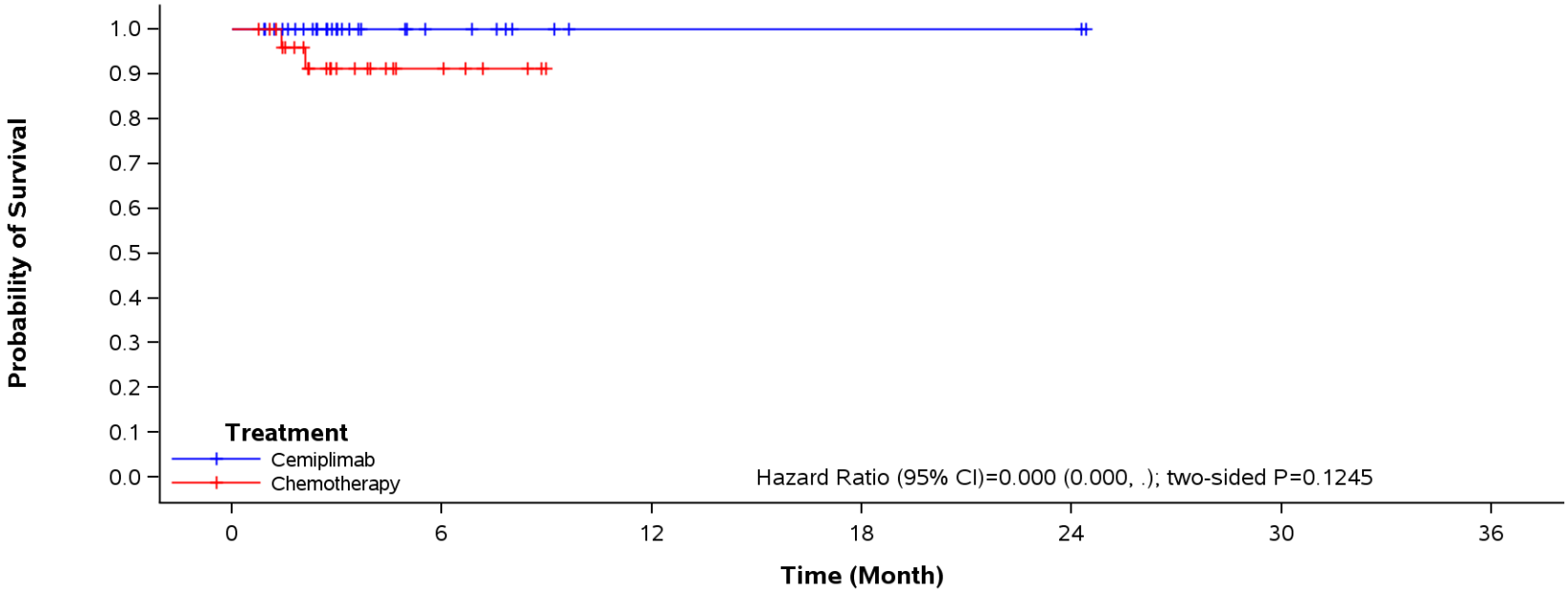

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



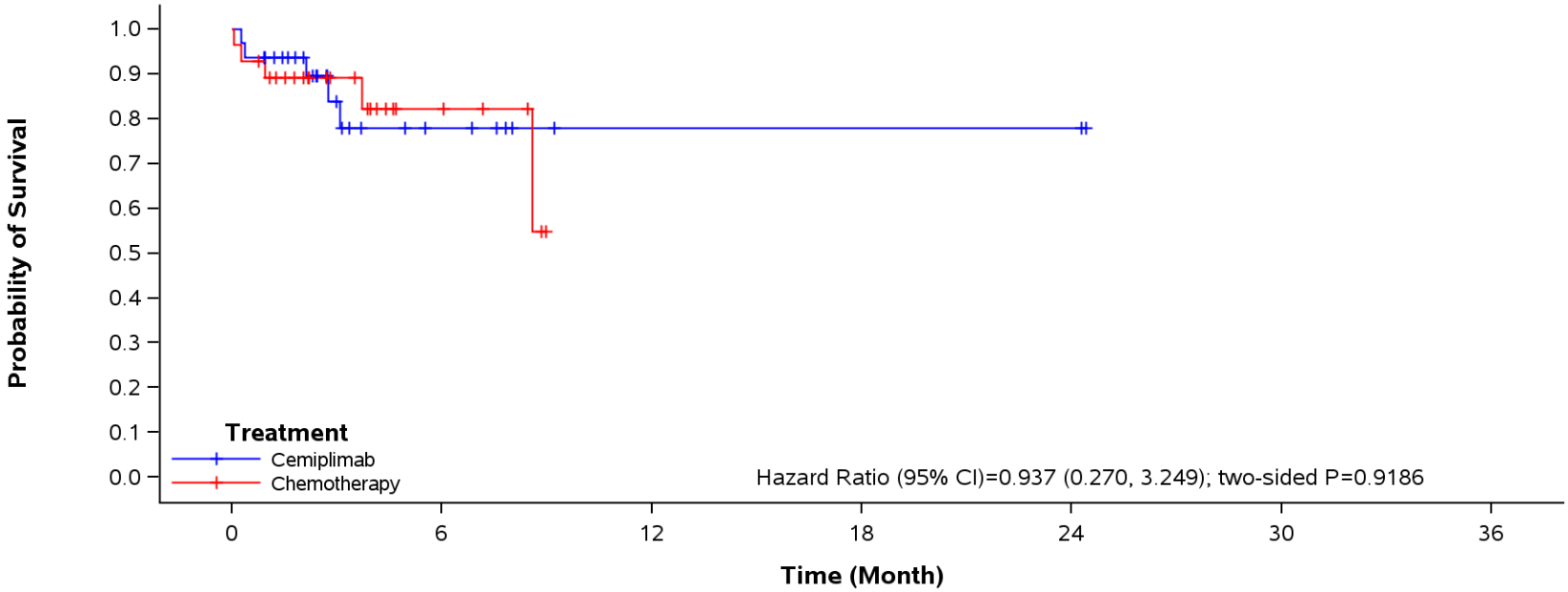

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Nervous system disorders



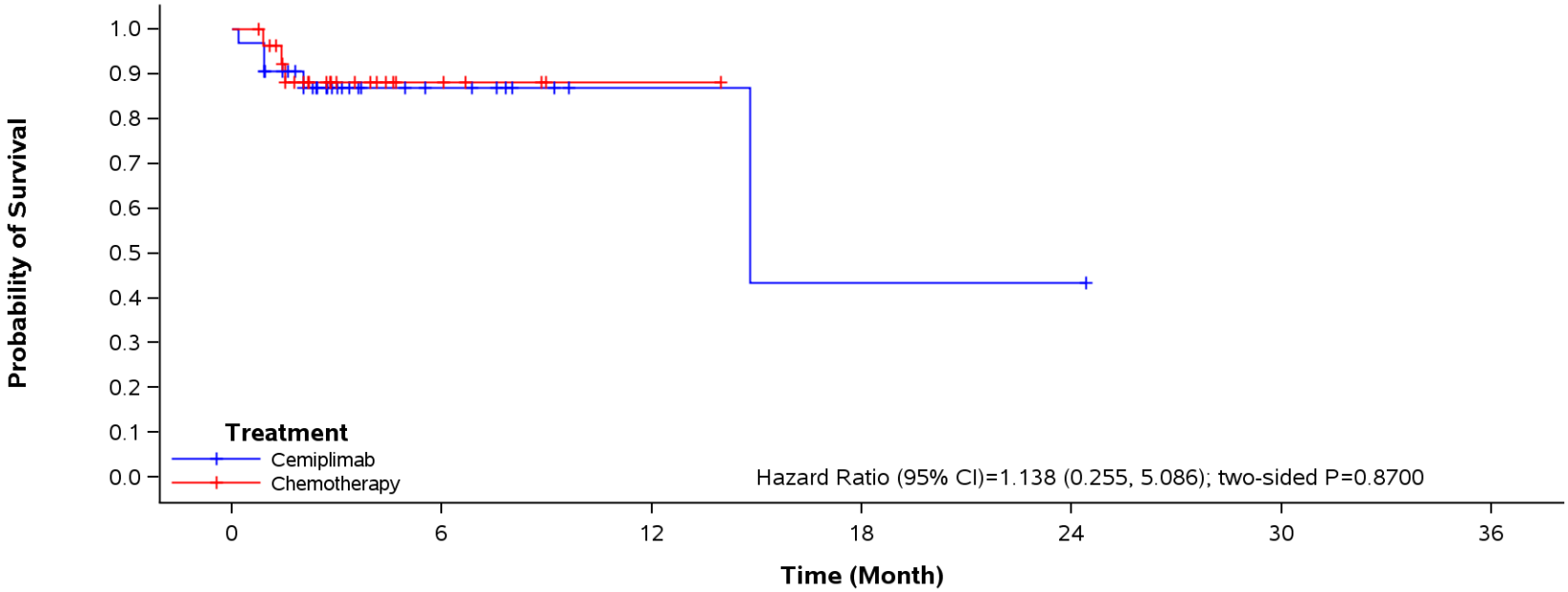

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 7 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Skin and subcutaneous tissue disorders



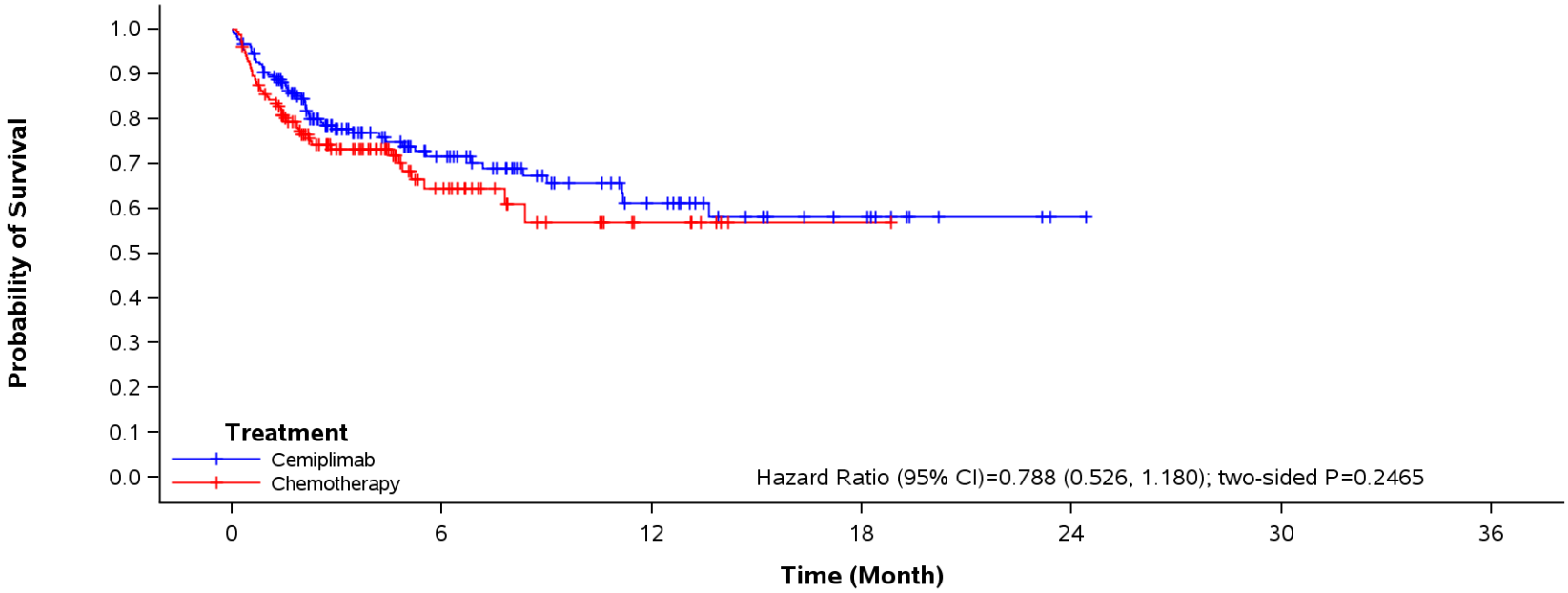

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 28 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Number of patients with any treatment-emergent SAE



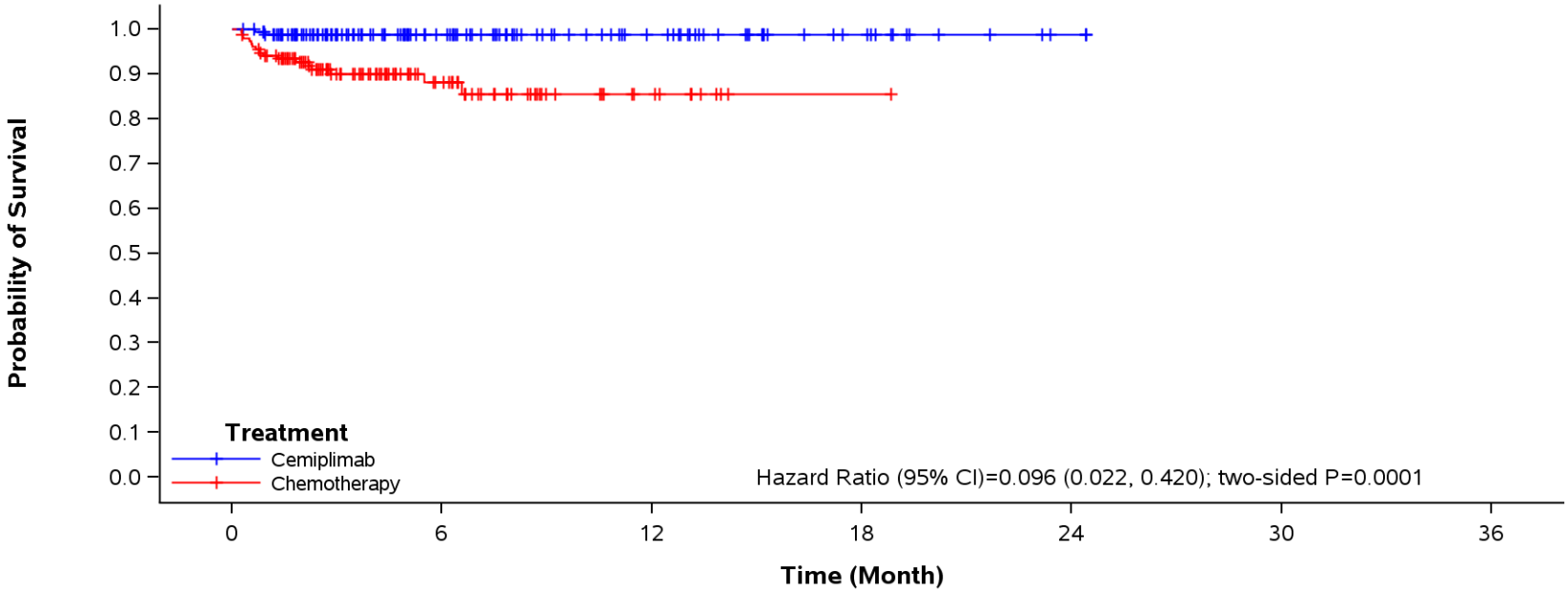

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 61 | 26 | 11 | 1 | 0 | 0 |
| Chemotherapy | 153 | 32 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders



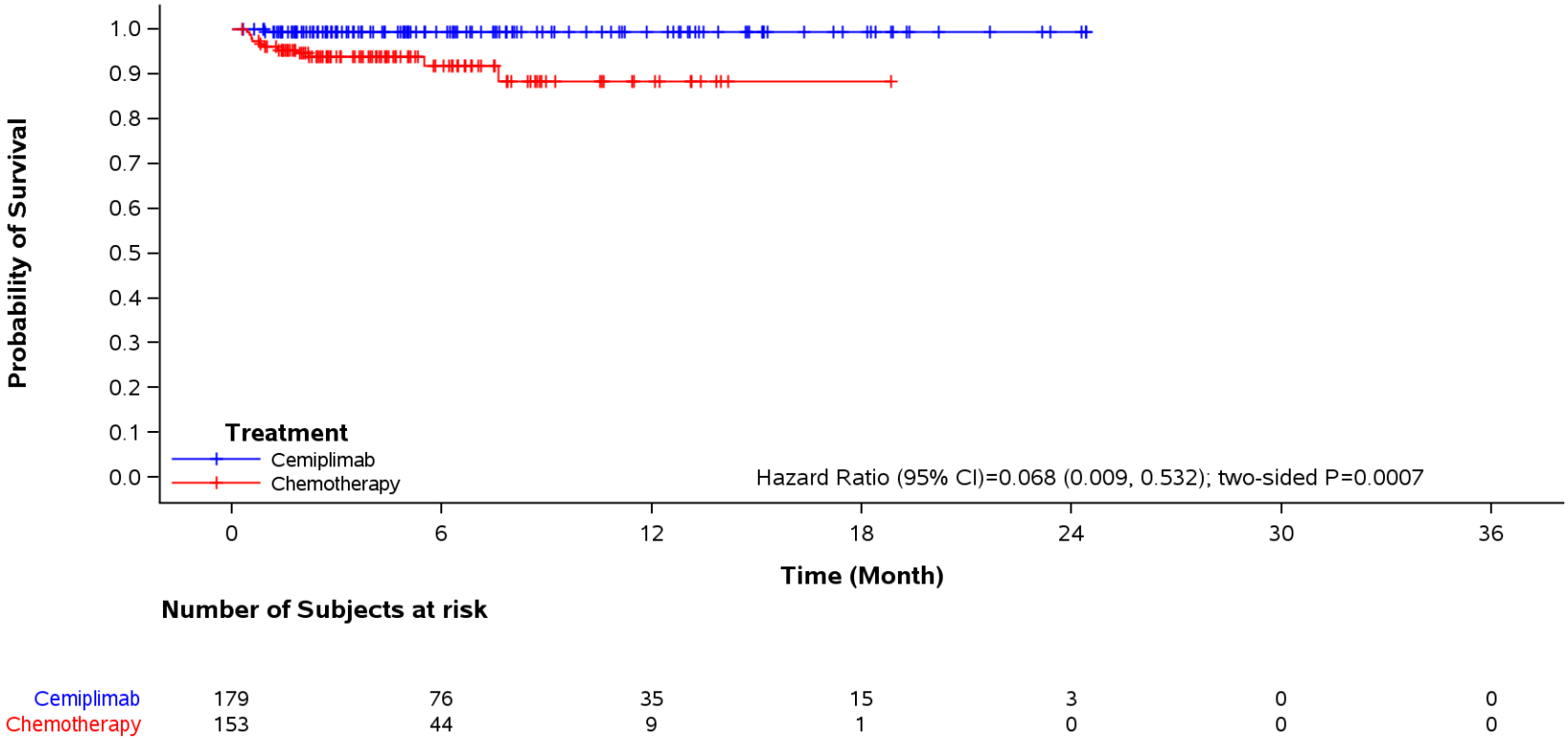

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 34 | 14 | 2 | 0 | 0 |
| Chemotherapy | 153 | 43 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Anaemia

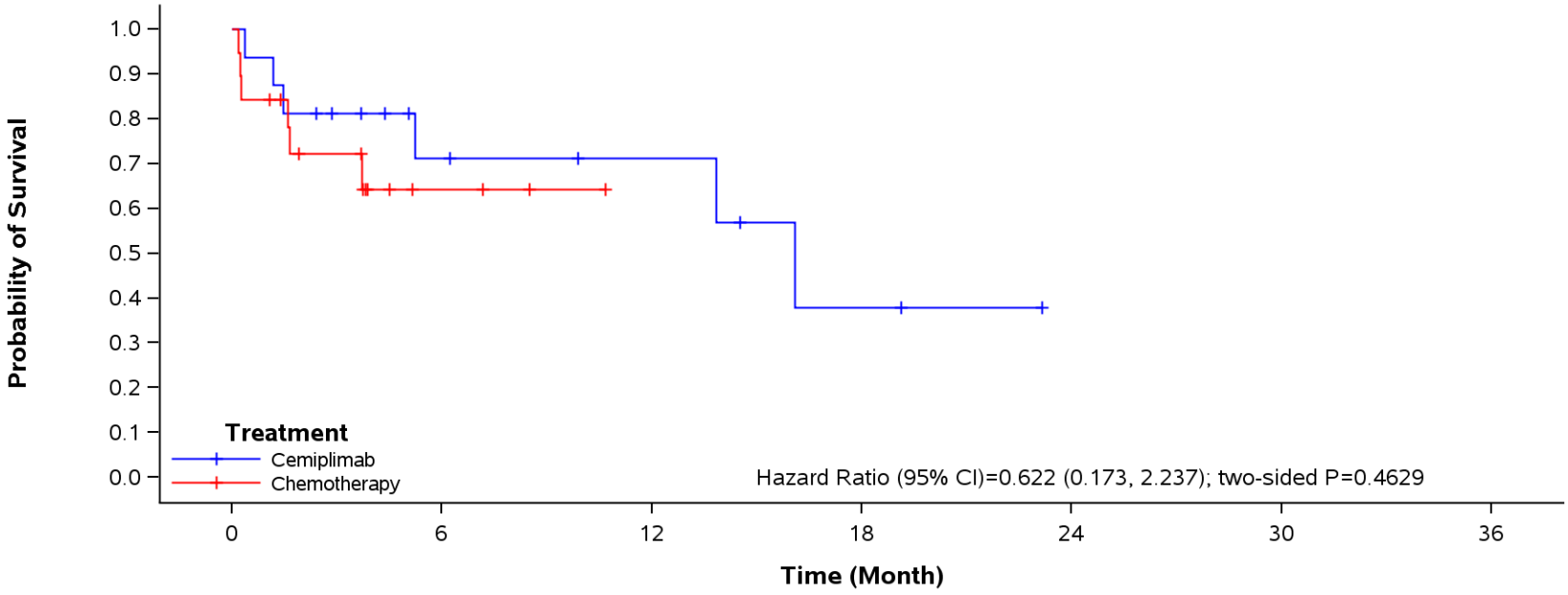



Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

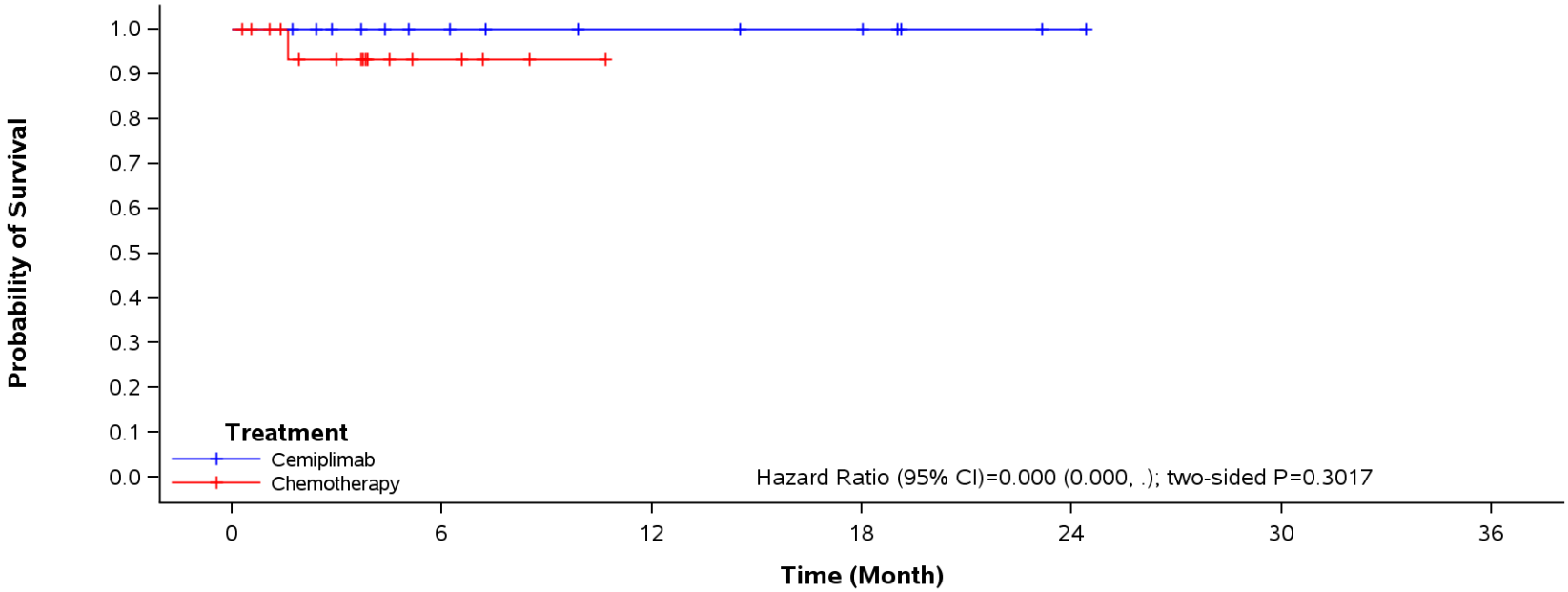
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders



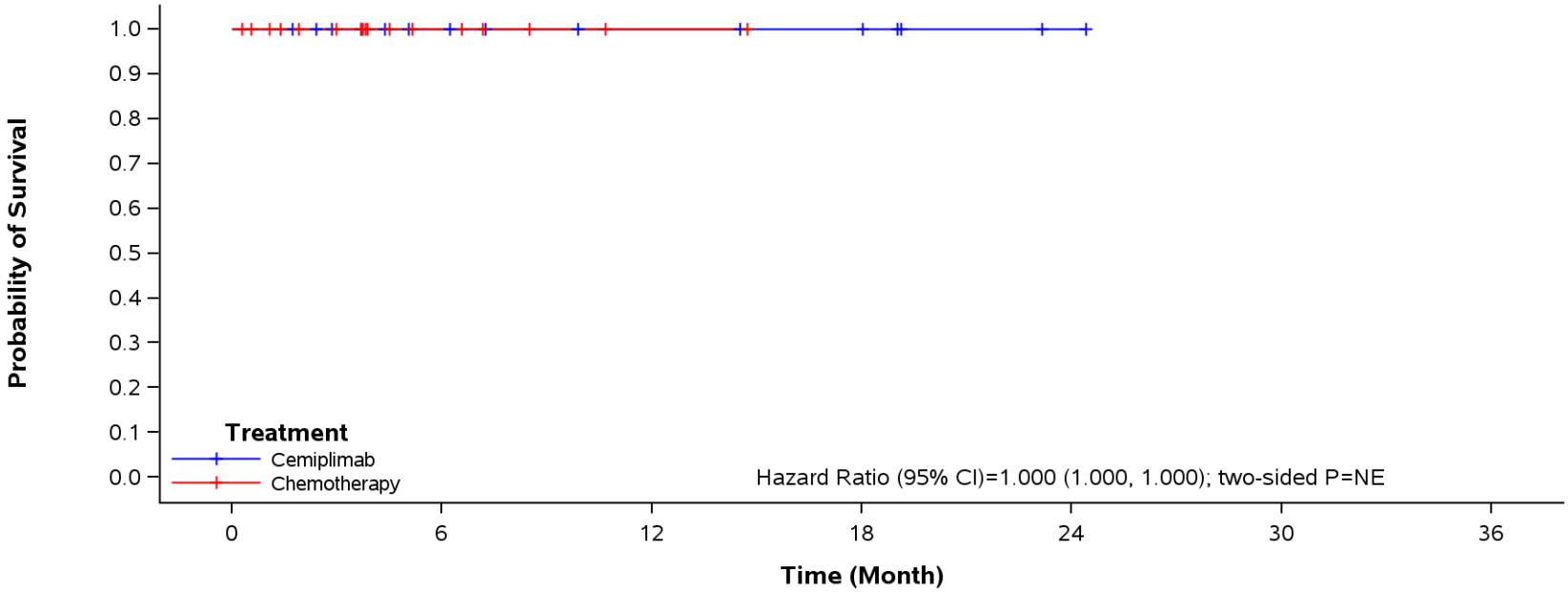

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Anaemia



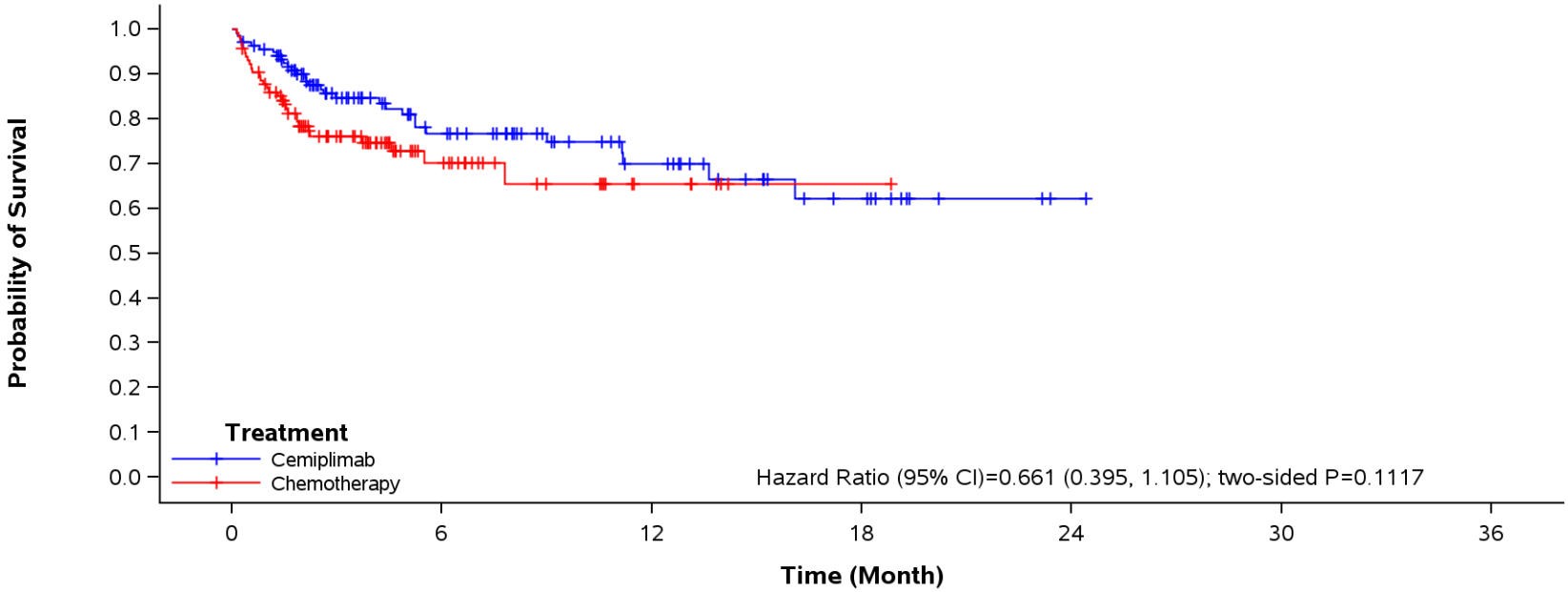

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Number of patients with any treatment-emergent SAE



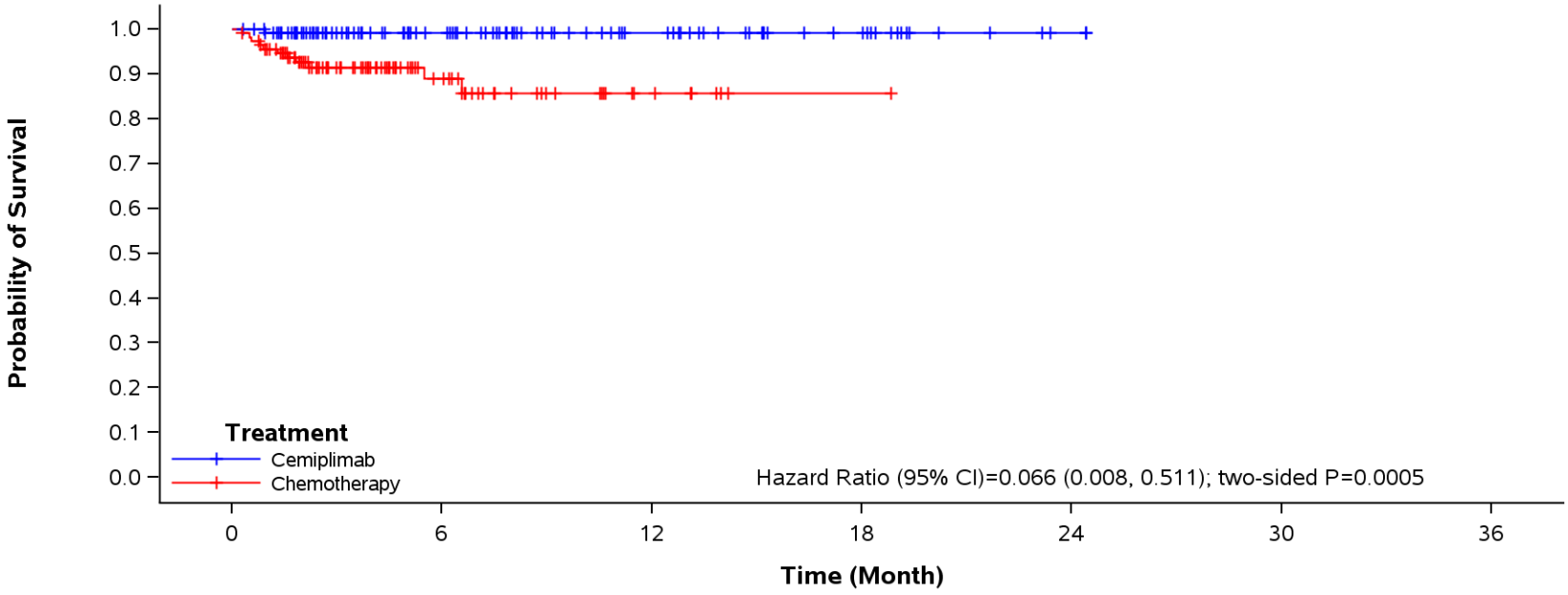

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 55 | 27 | 12 | 1 | 0 | 0 |
| Chemotherapy | 115 | 27 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders



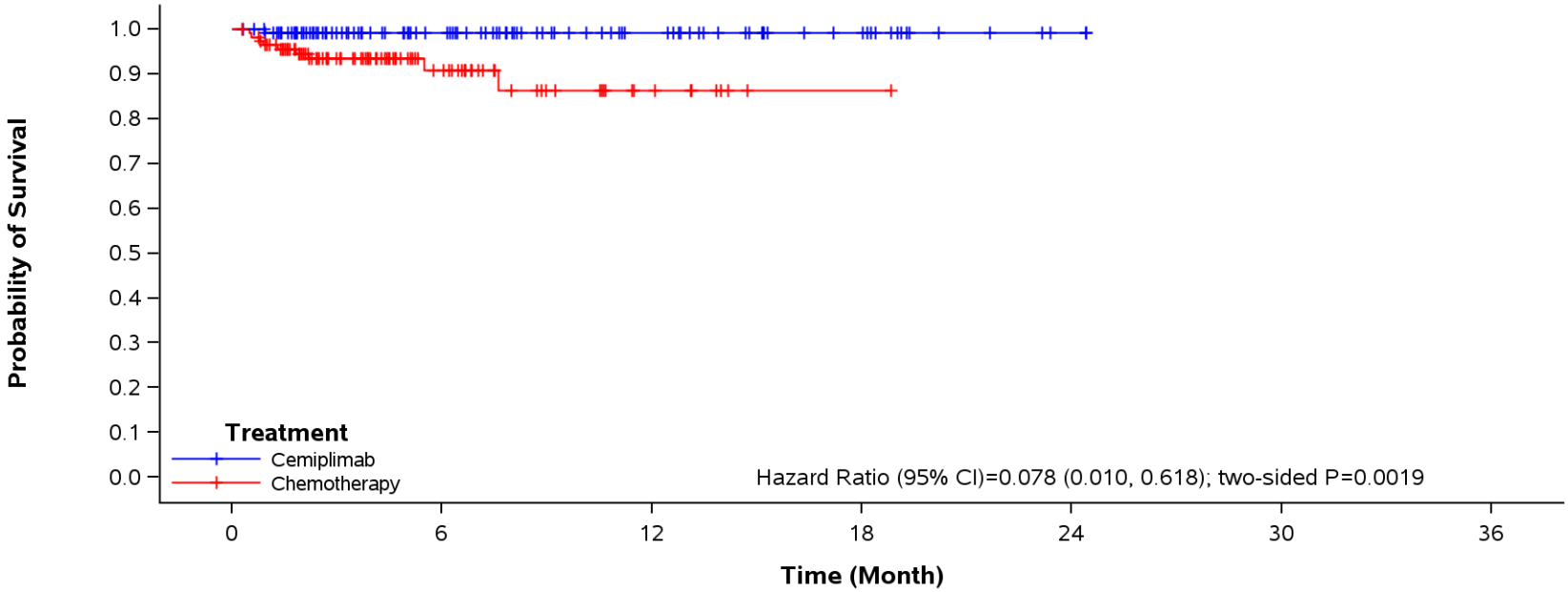

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 32 | 16 | 2 | 0 | 0 |
| Chemotherapy | 115 | 33 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Anaemia



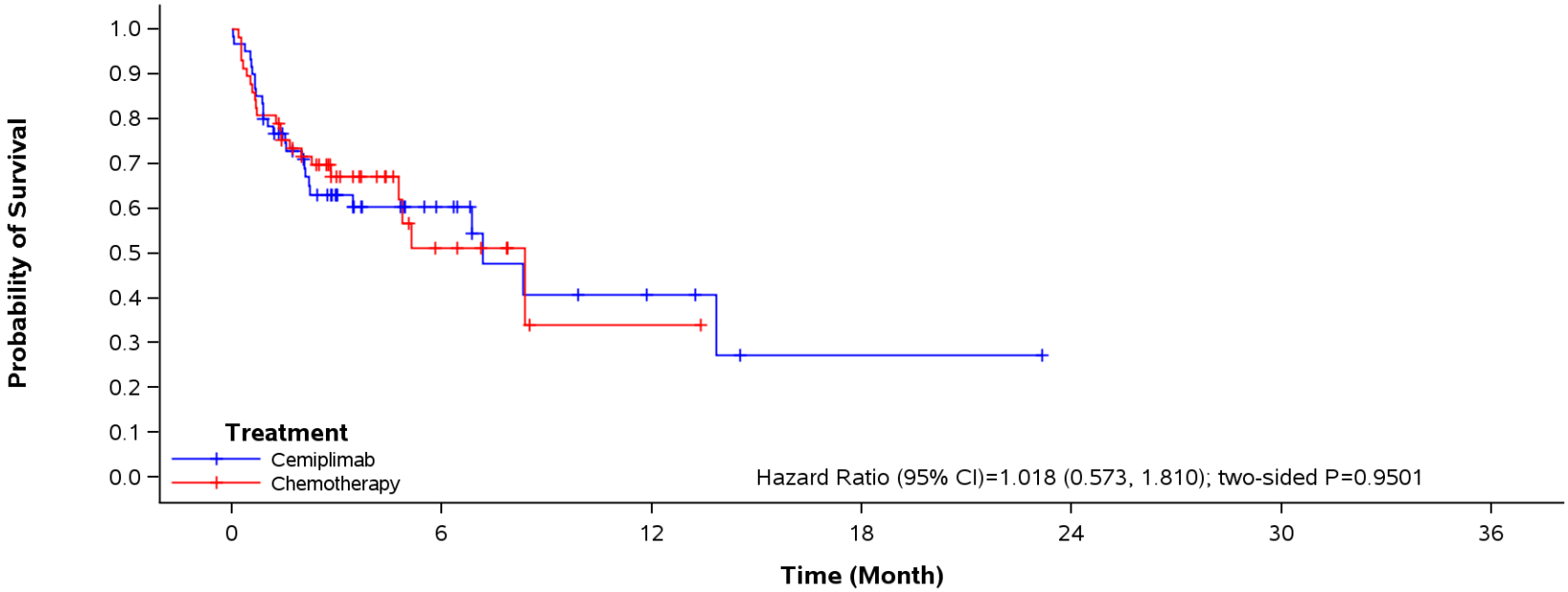

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 32 | 16 | 2 | 0 | 0 |
| Chemotherapy | 115 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Number of patients with any treatment-emergent SAE



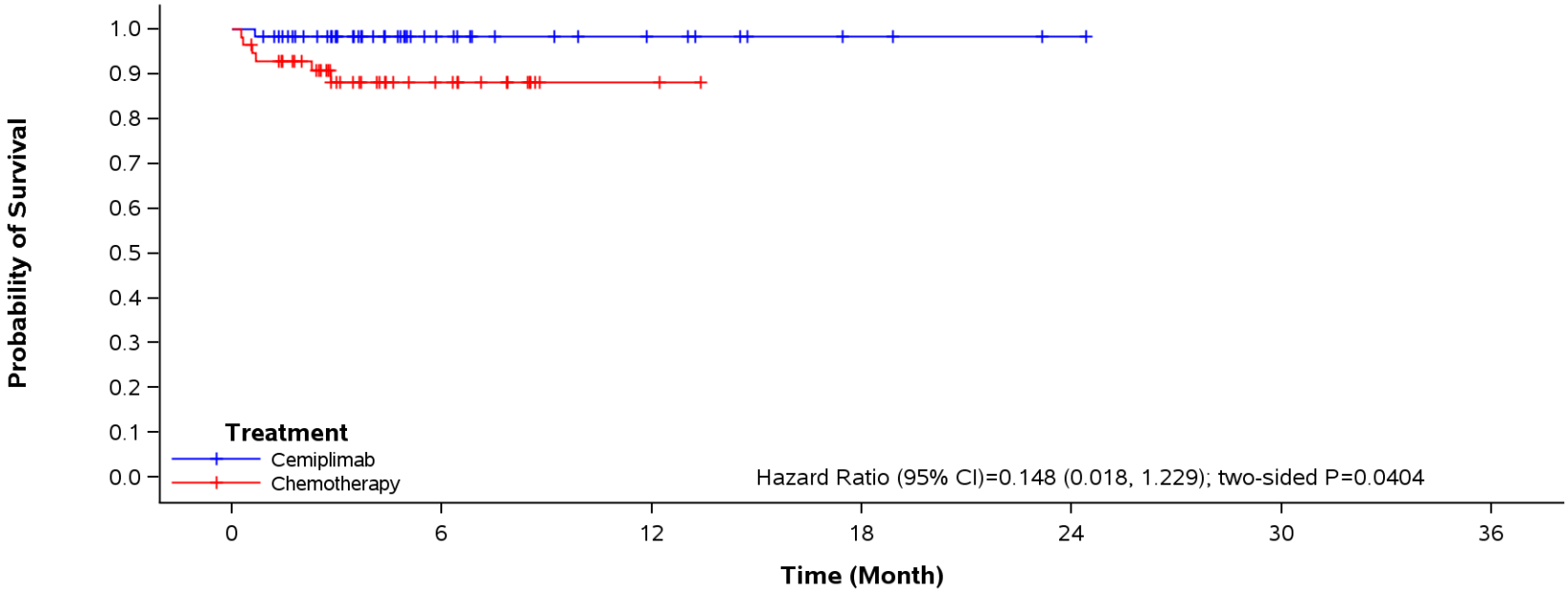

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 57 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders



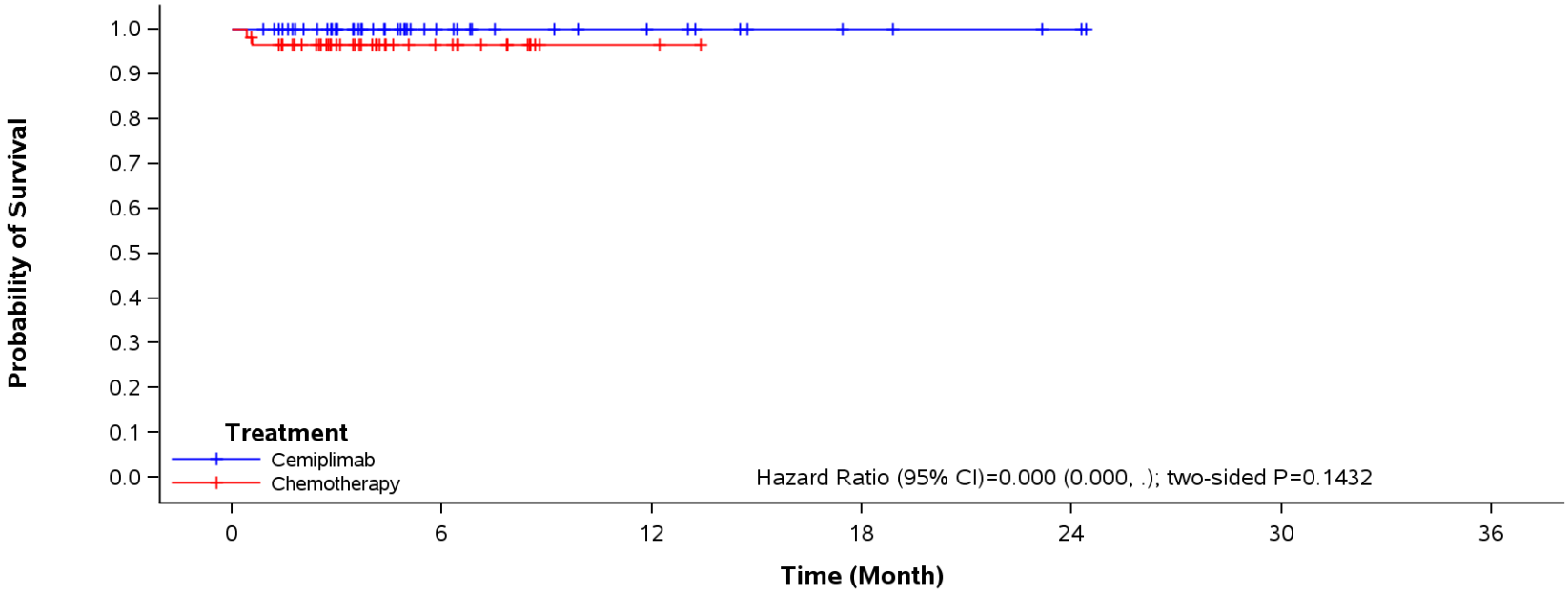

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 8 | 3 | 1 | 0 | 0 |
| Chemotherapy | 57 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Anaemia



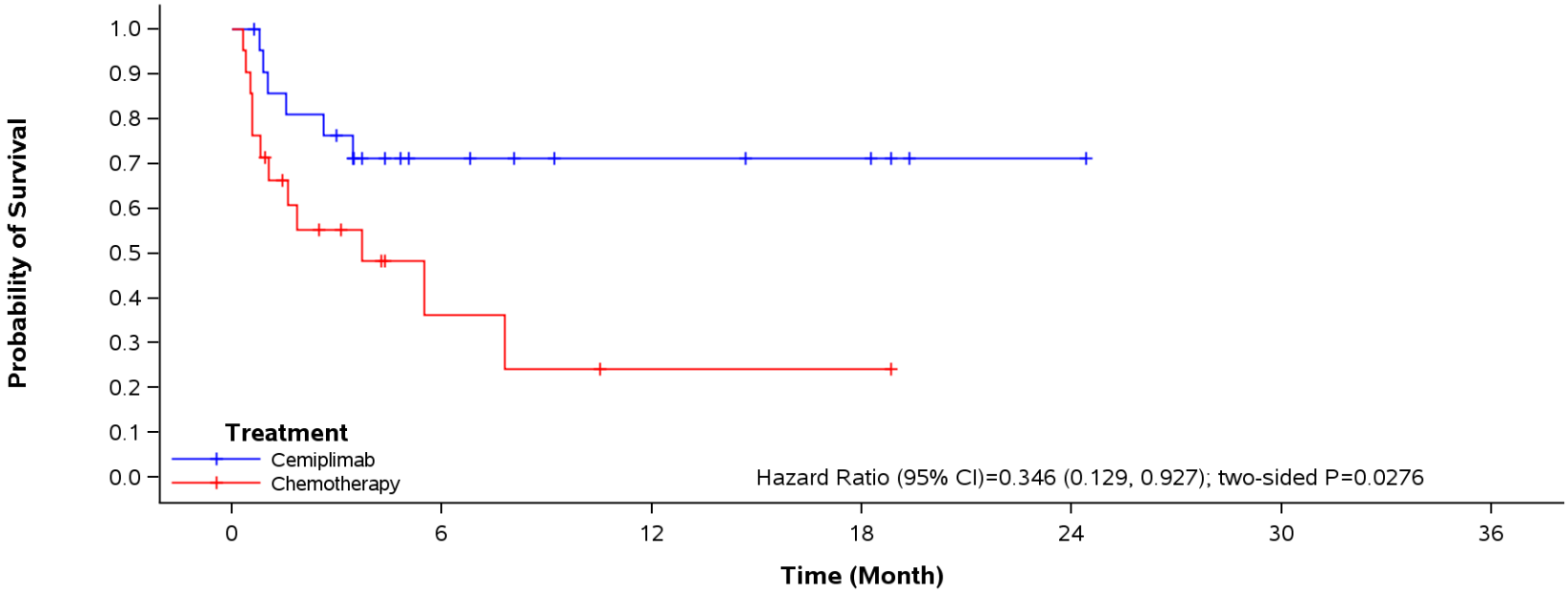

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Number of patients with any treatment-emergent SAE



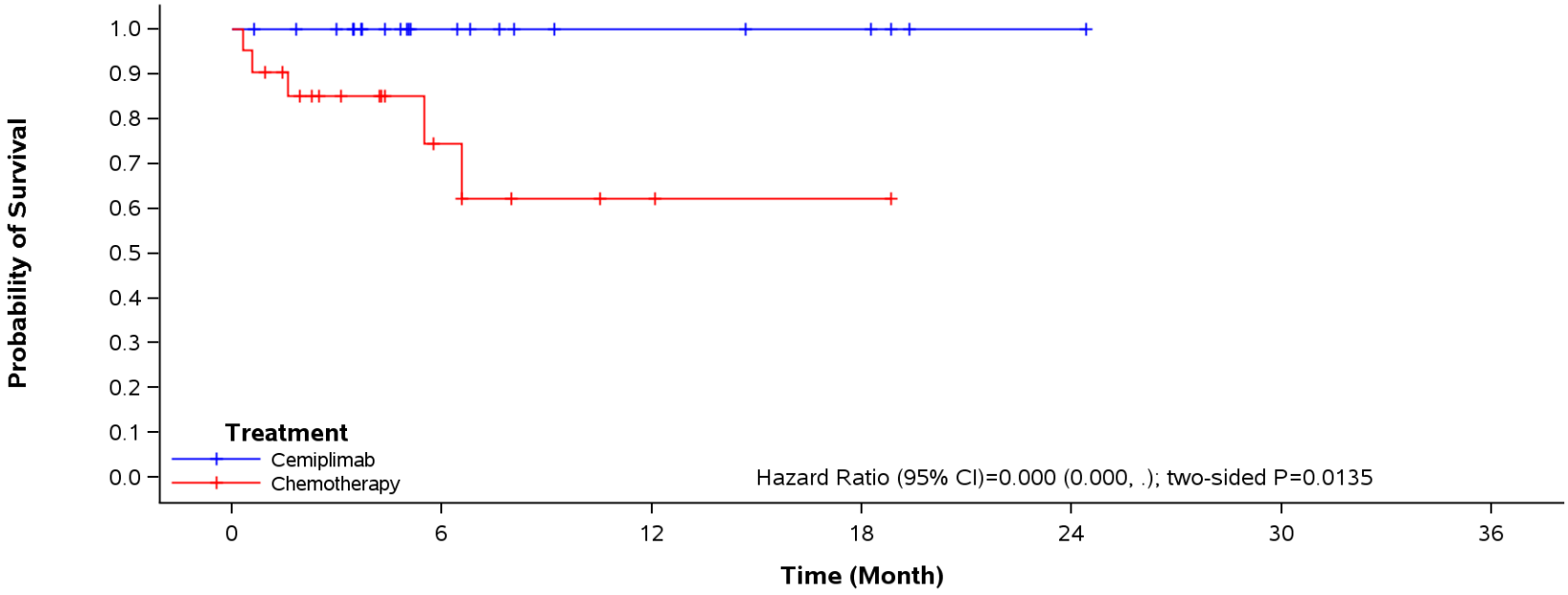

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders



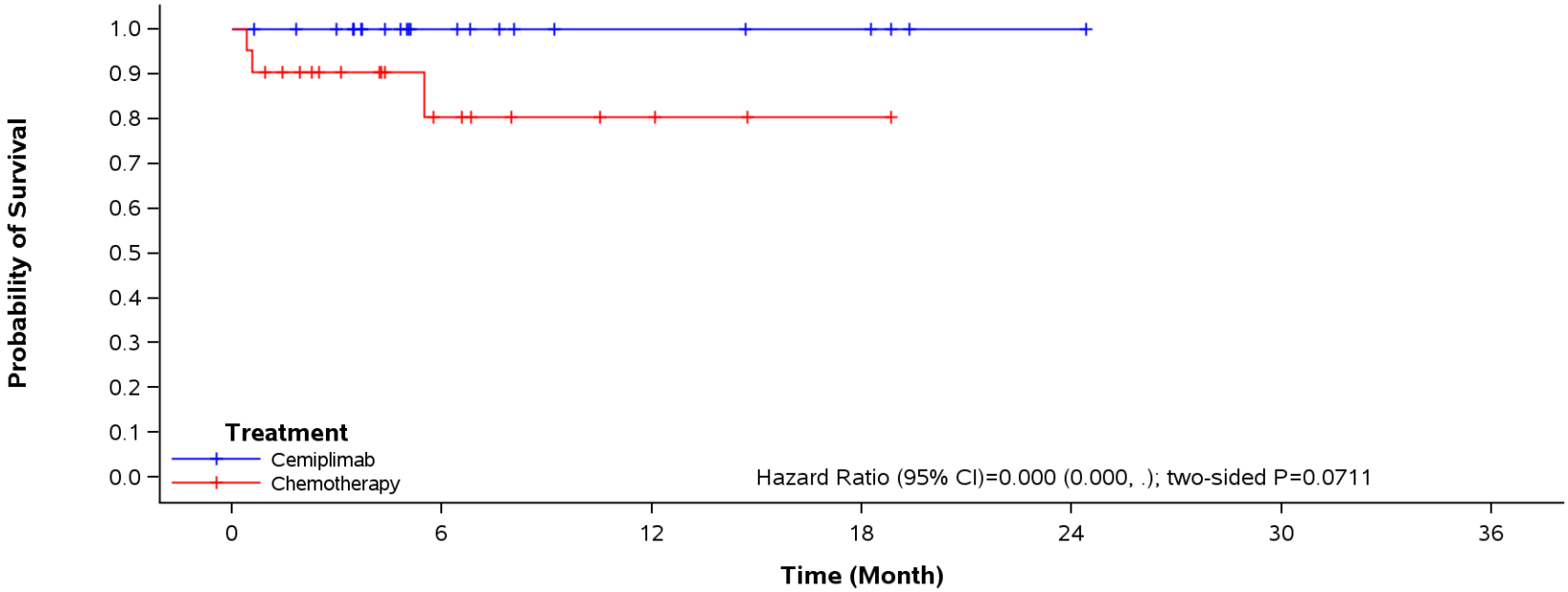

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Anaemia



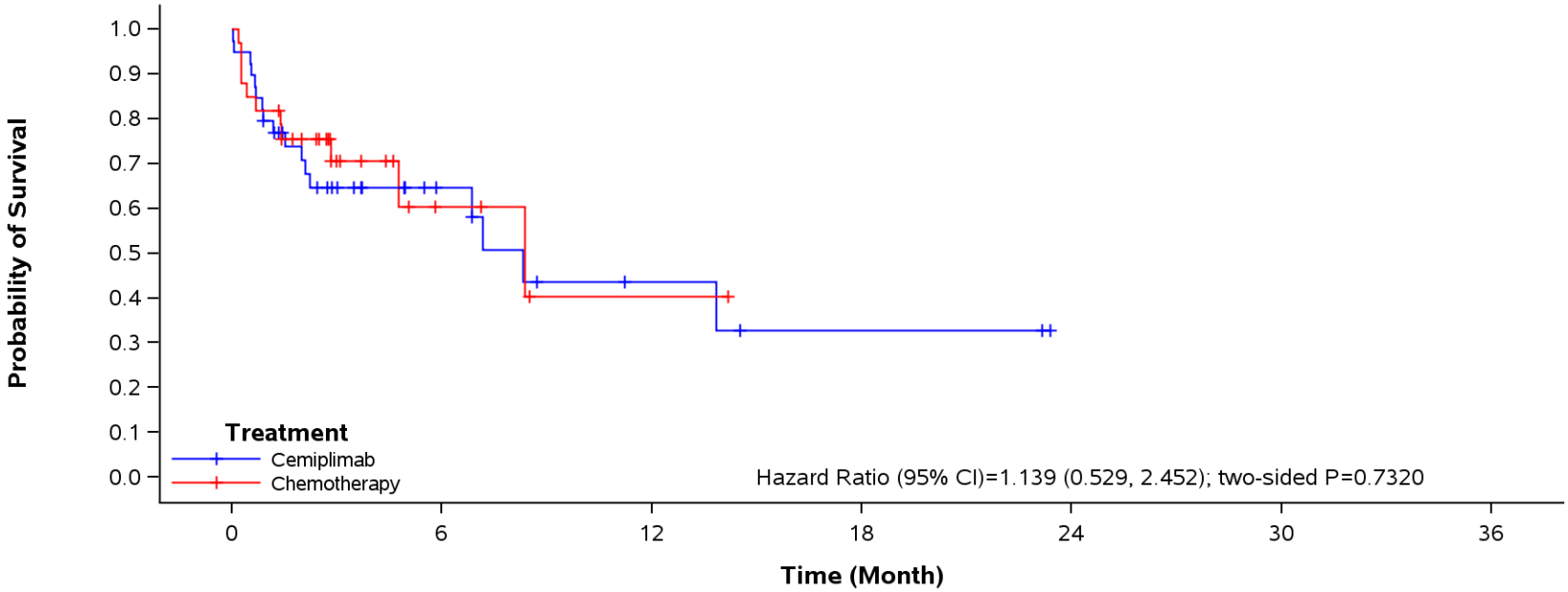

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Number of patients with any treatment-emergent SAE



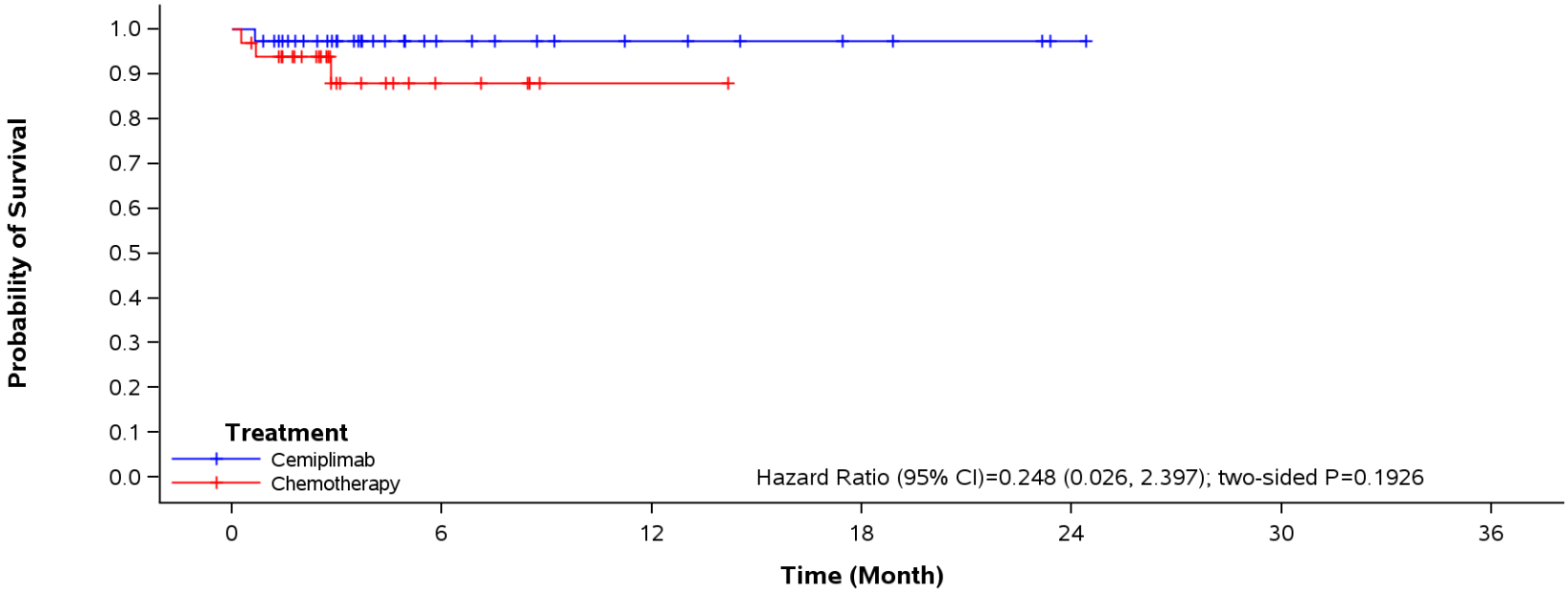

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 33 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders



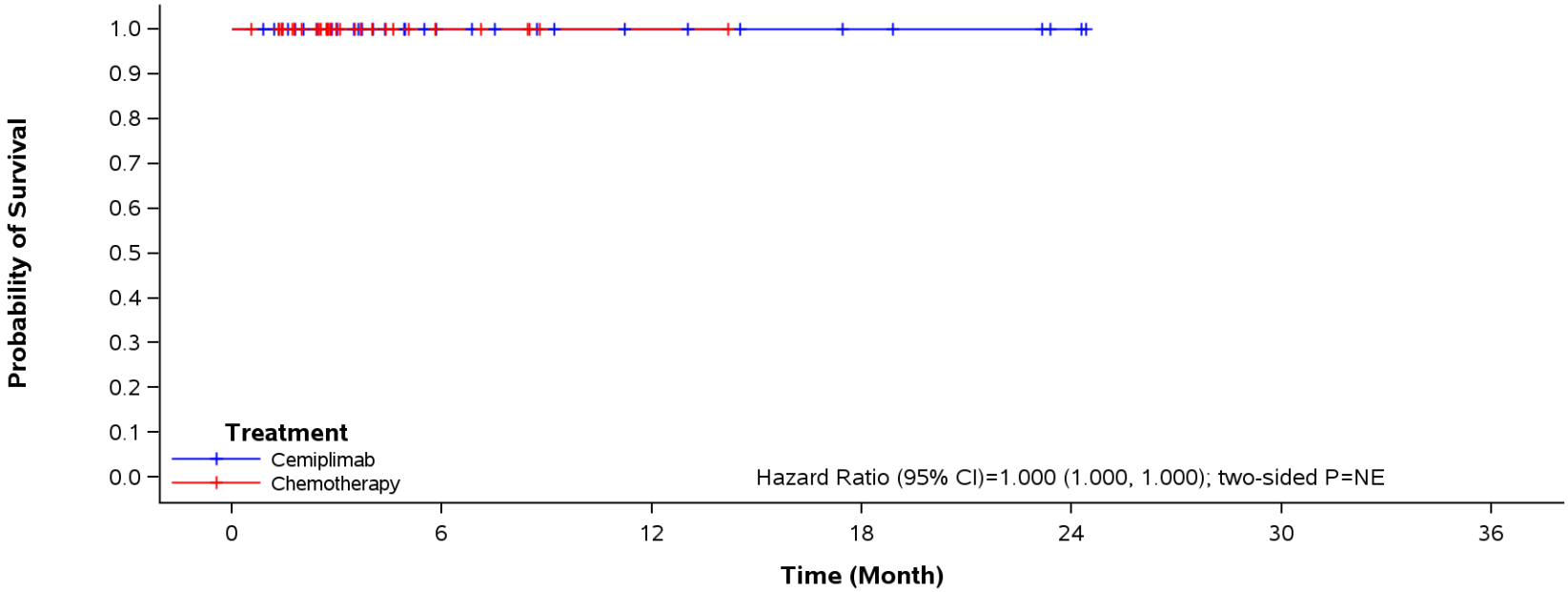

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 4 | 1 | 0 | 0 |
| Chemotherapy | 33 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Anaemia



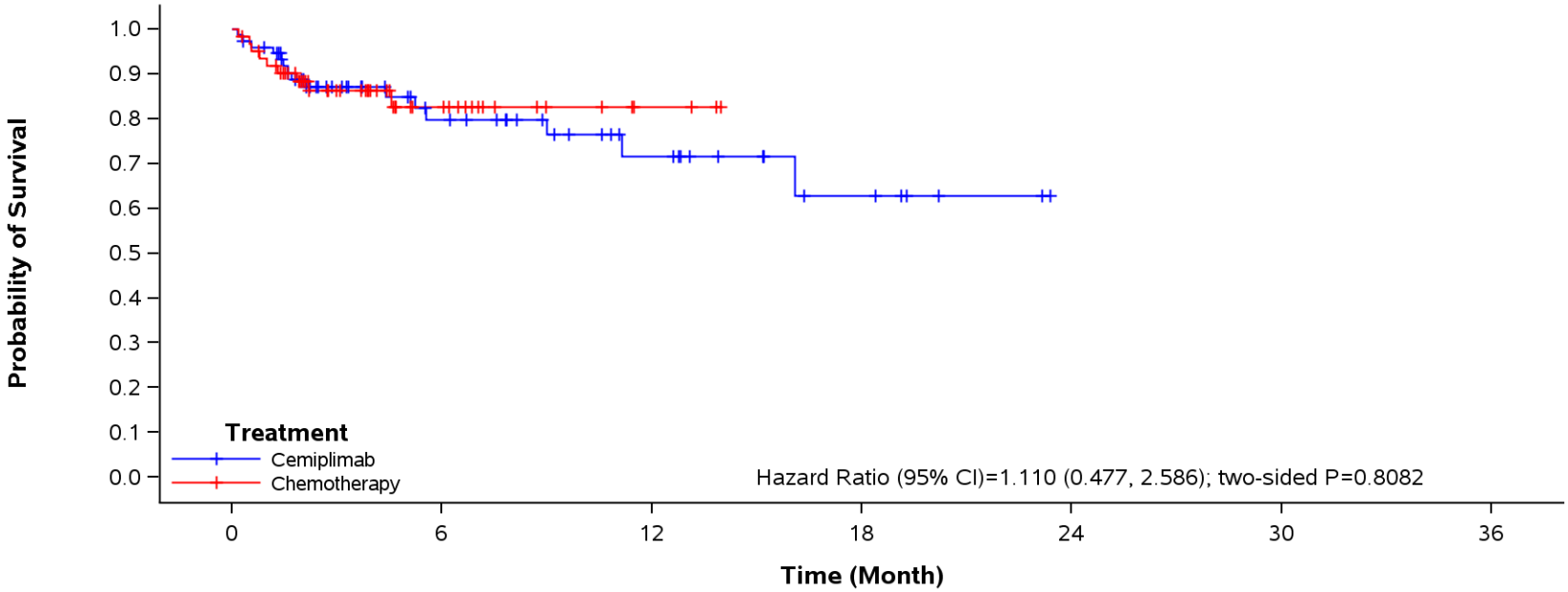

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Number of patients with any treatment-emergent SAE



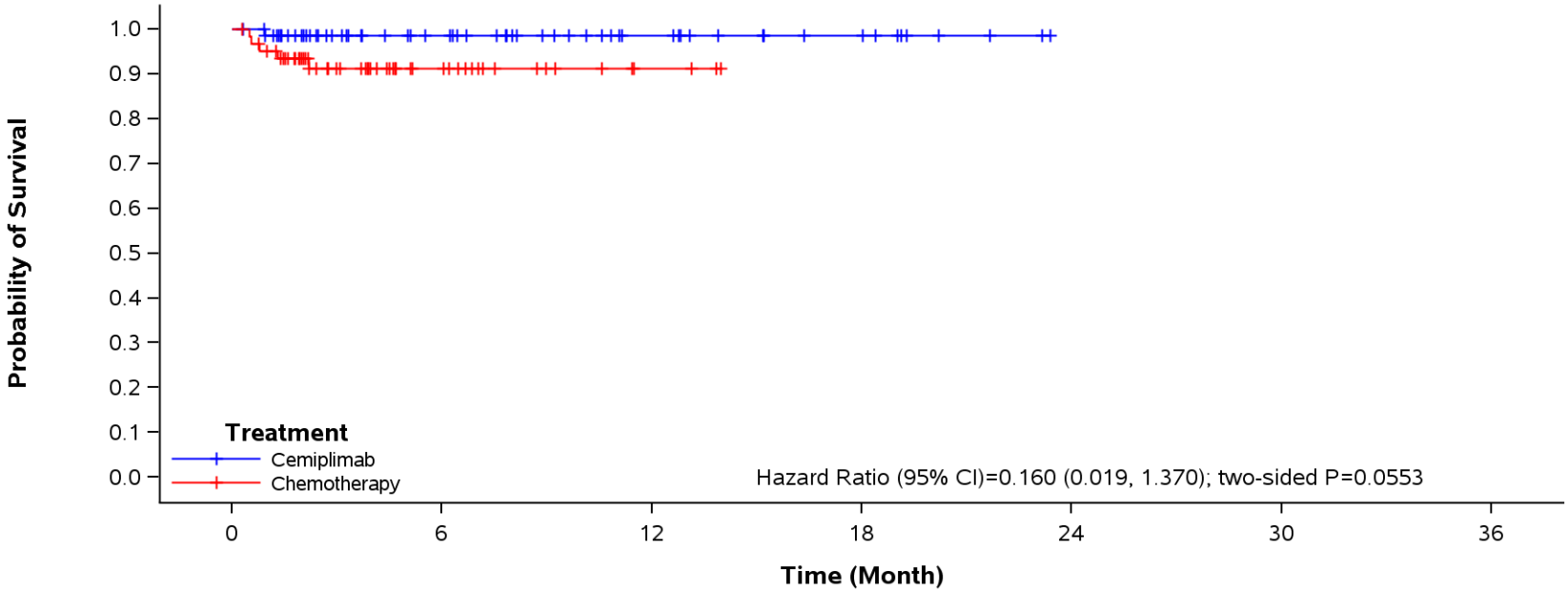

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 31 | 15 | 6 | 0 | 0 | 0 |
| Chemotherapy | 63 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders



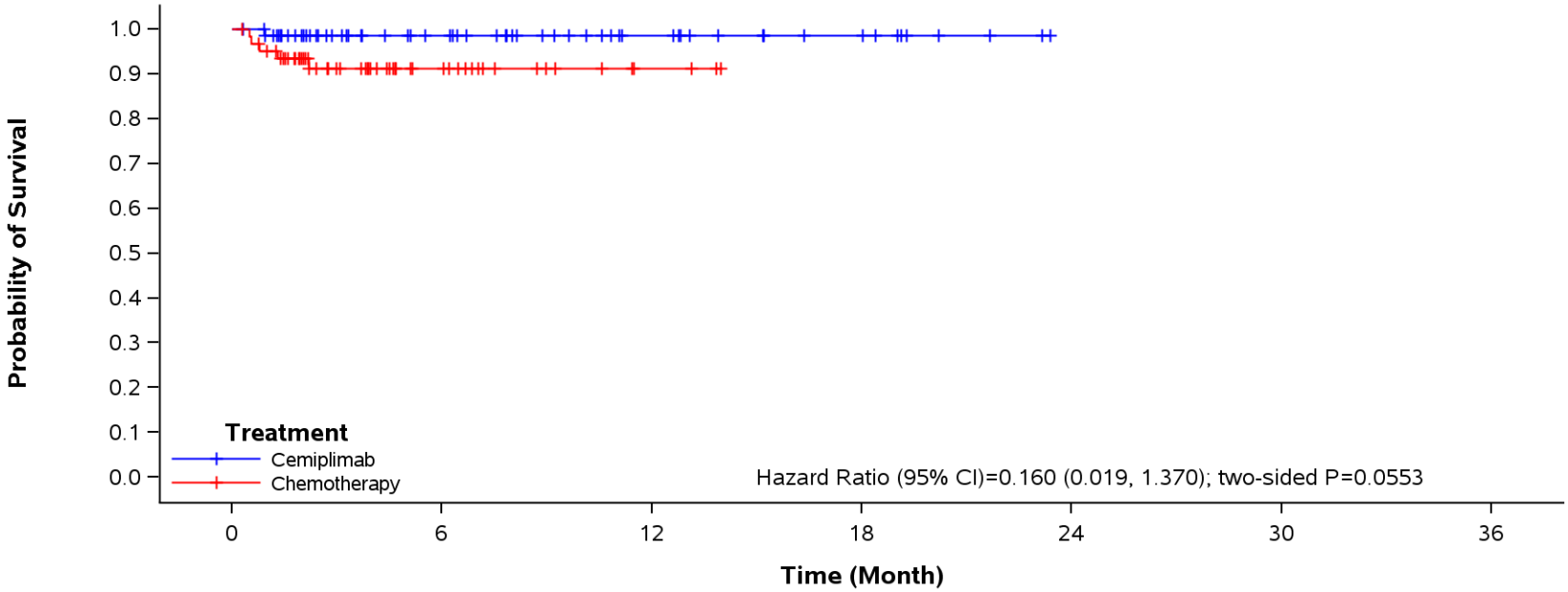

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 17 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Anaemia



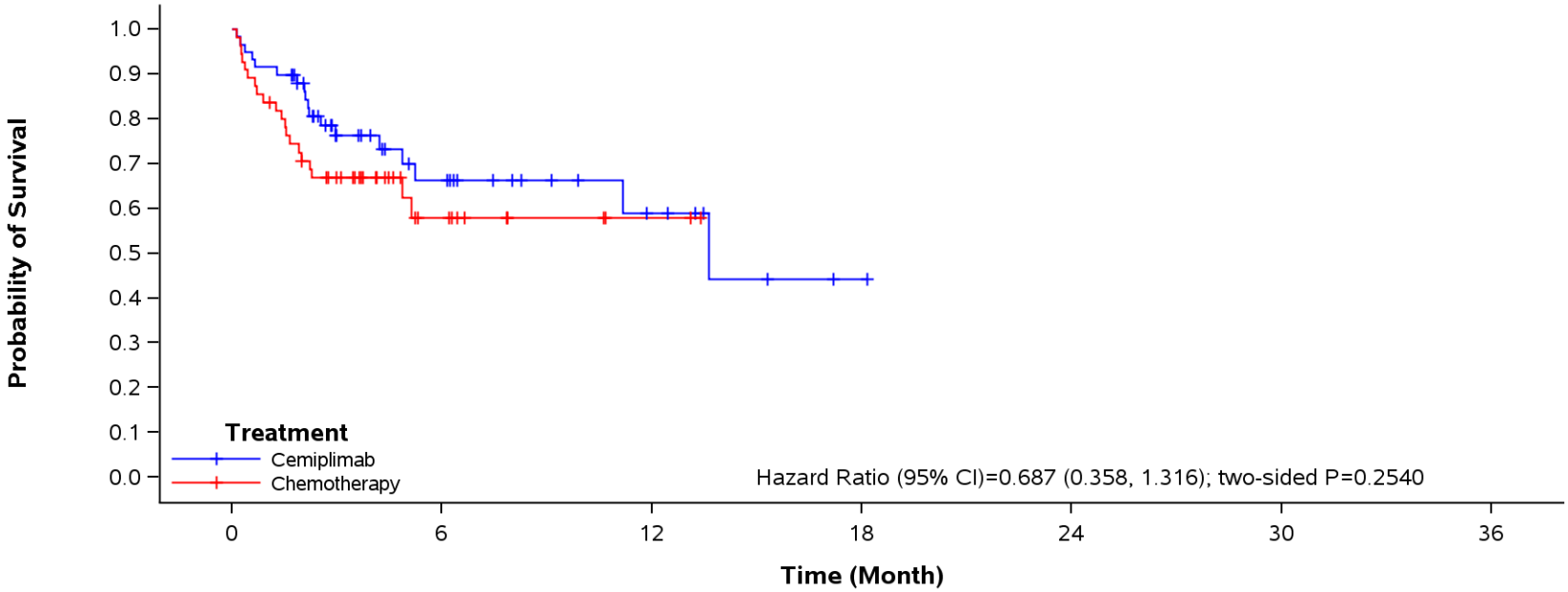

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 17 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Number of patients with any treatment-emergent SAE



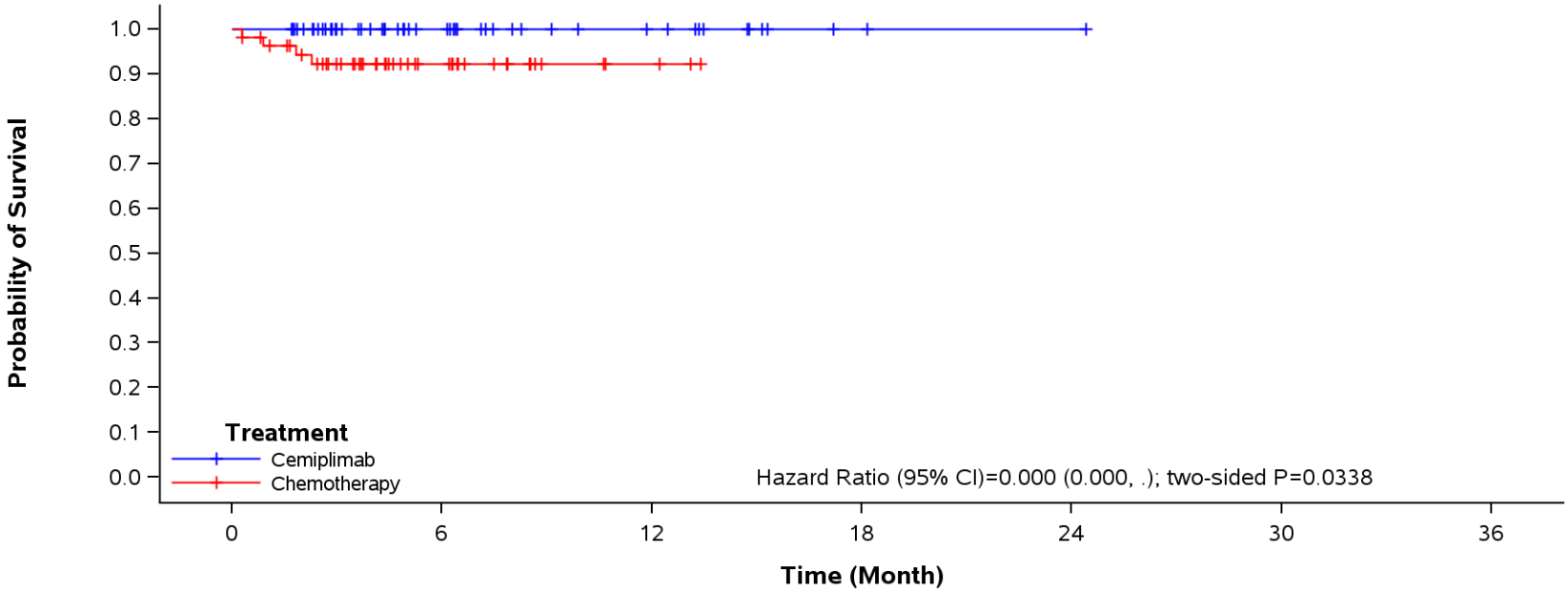

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 7 | 1 | 0 | 0 | 0 |
| Chemotherapy | 55 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders



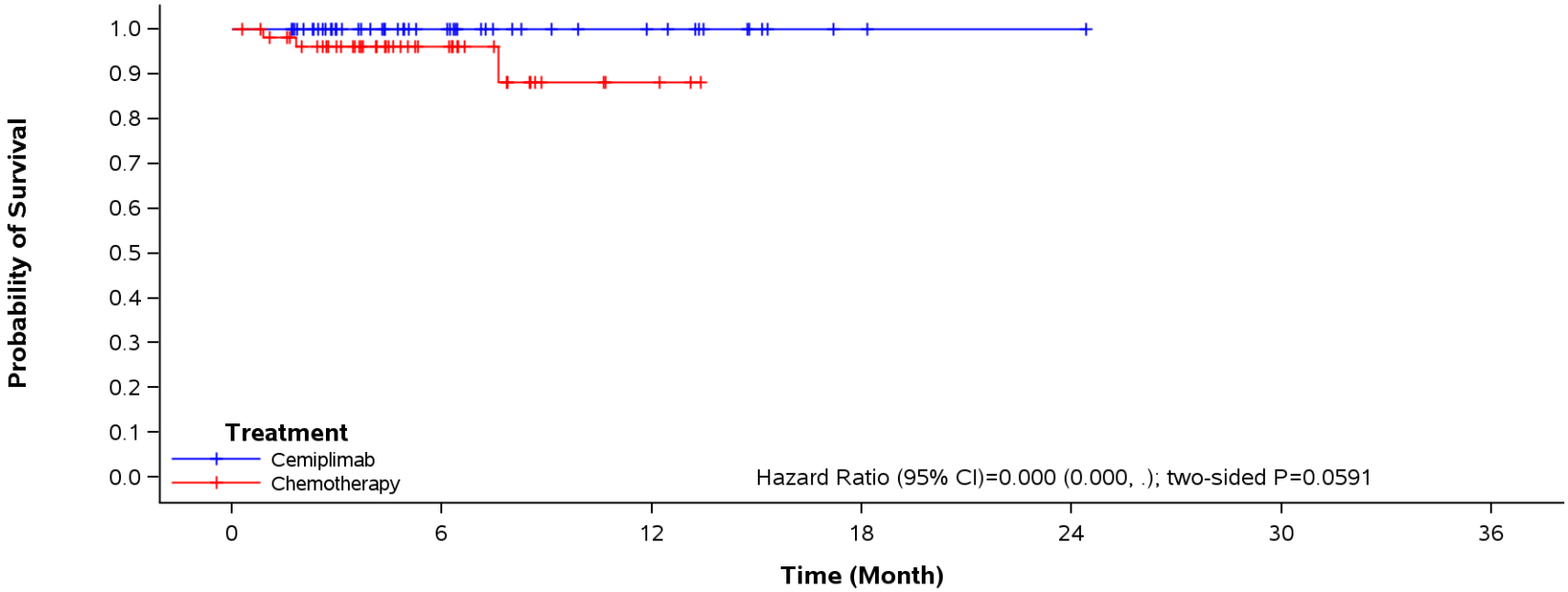

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 11 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Anaemia



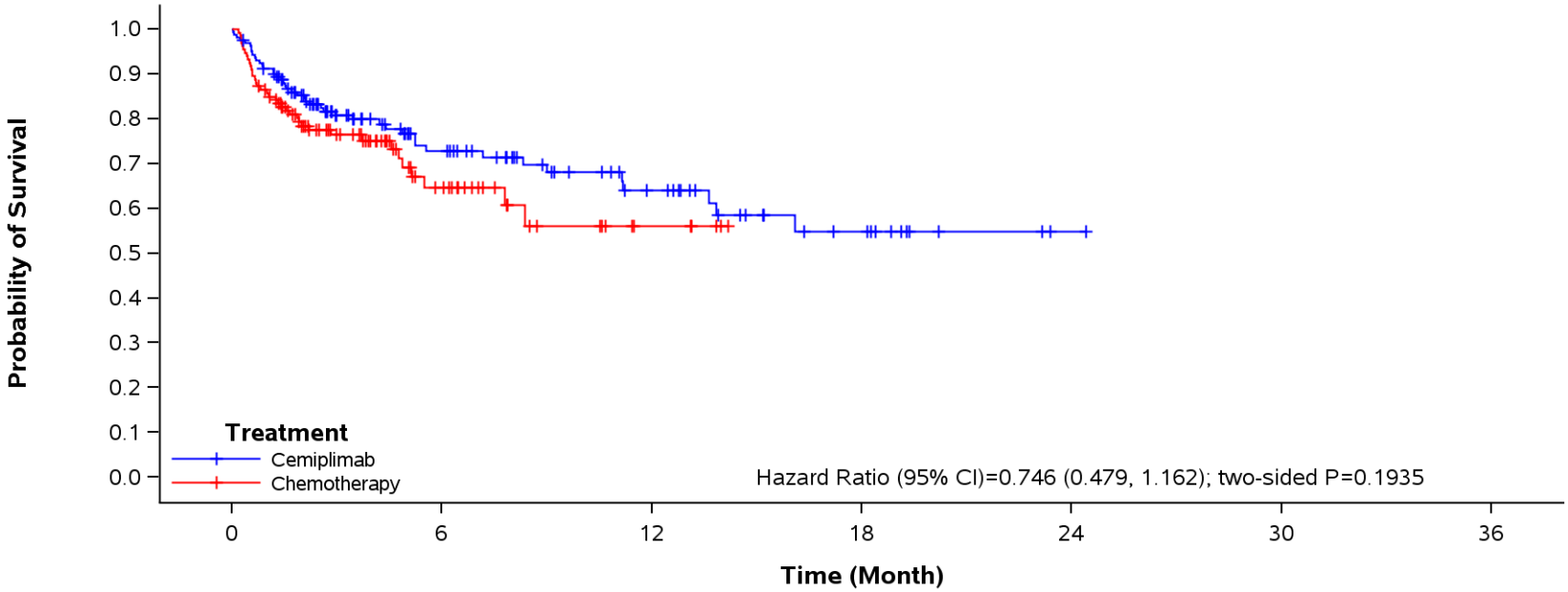

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 11 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Number of patients with any treatment-emergent SAE



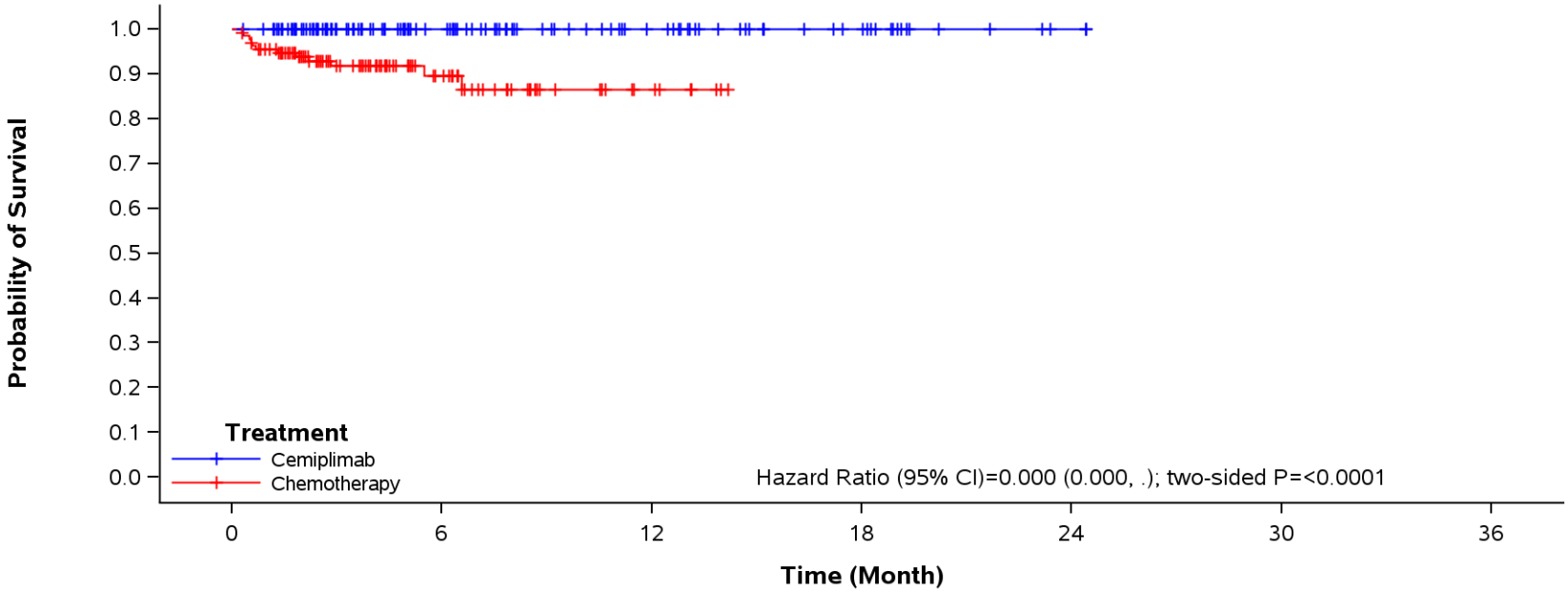

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 59 | 29 | 13 | 1 | 0 | 0 |
| Chemotherapy | 133 | 27 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders



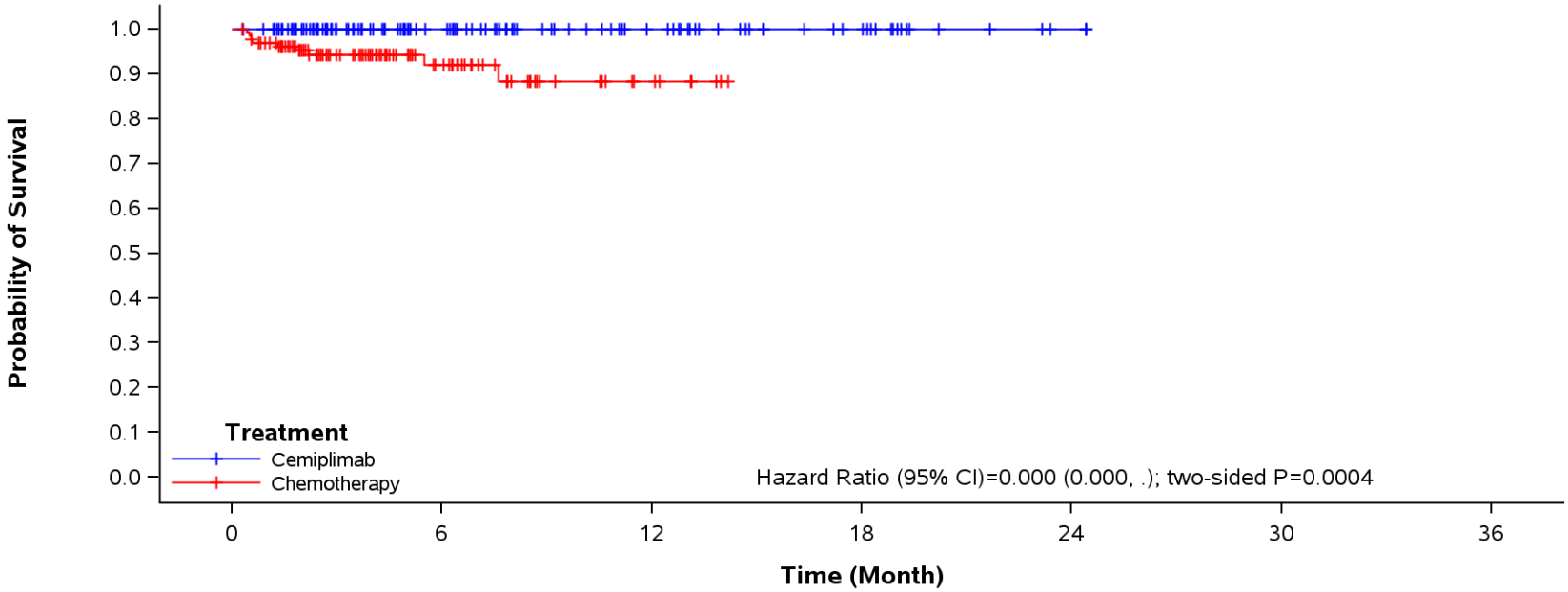

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 36 | 19 | 3 | 0 | 0 |
| Chemotherapy | 133 | 38 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



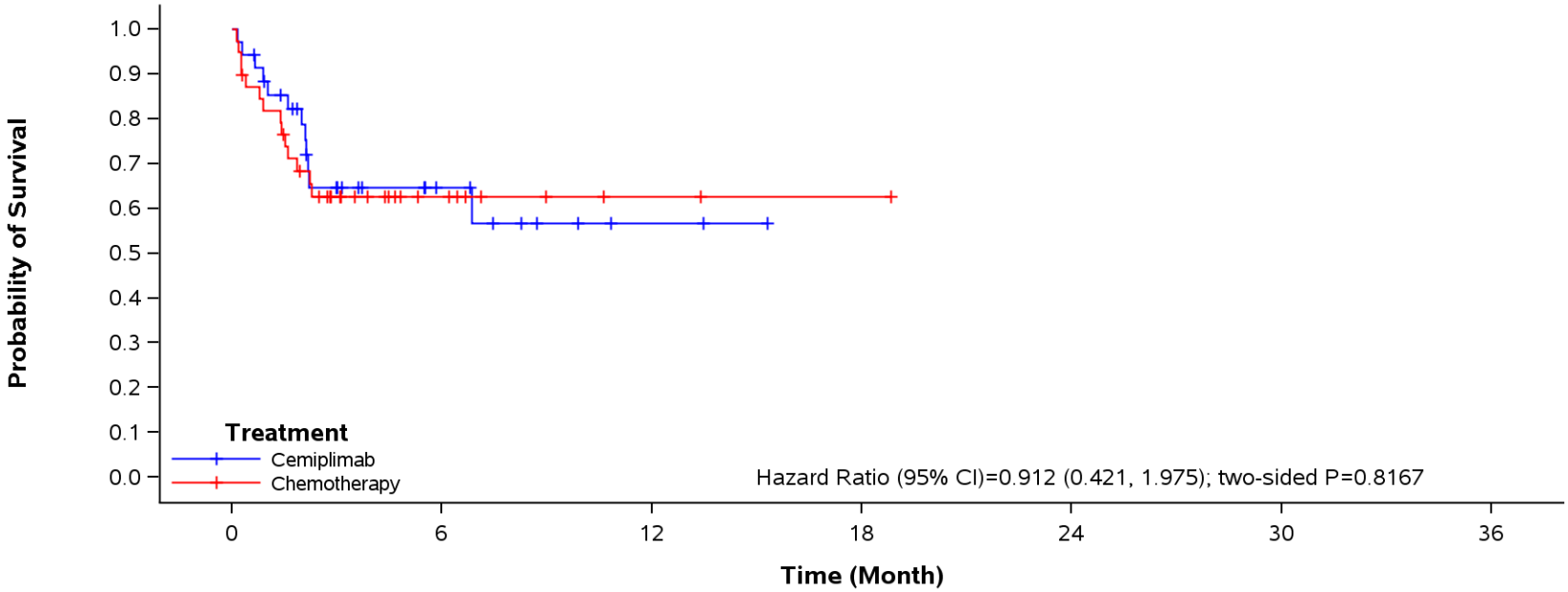

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 36 | 19 | 3 | 0 | 0 |
| Chemotherapy | 133 | 39 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Number of patients with any treatment-emergent SAE



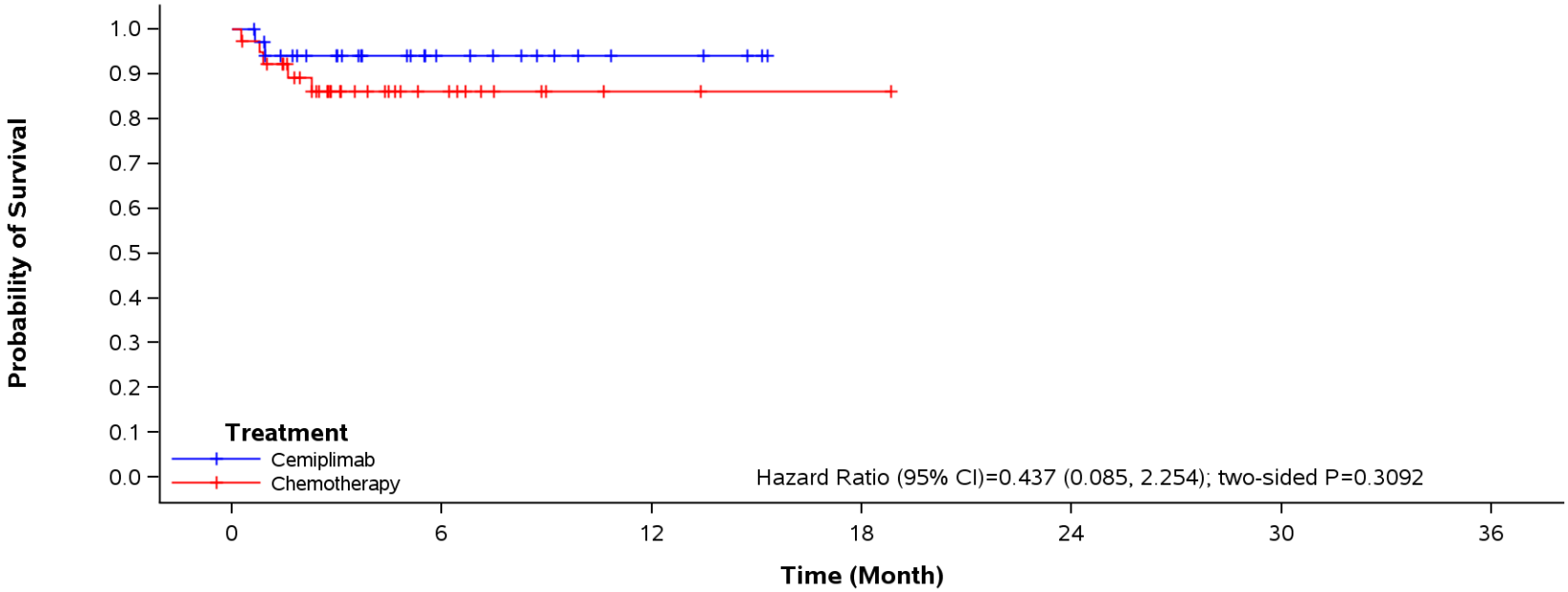

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 39 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders



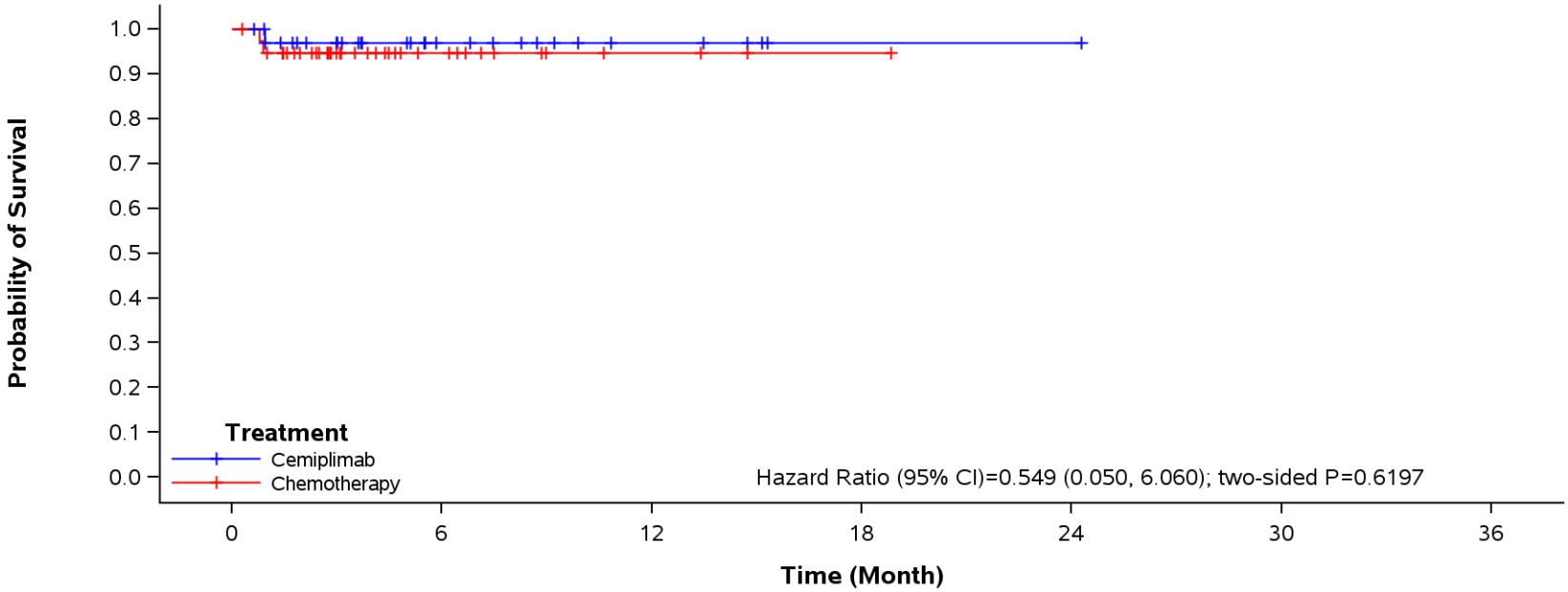

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 4 | 0 | 0 | 0 | 0 |
| Chemotherapy | 39 | 10 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



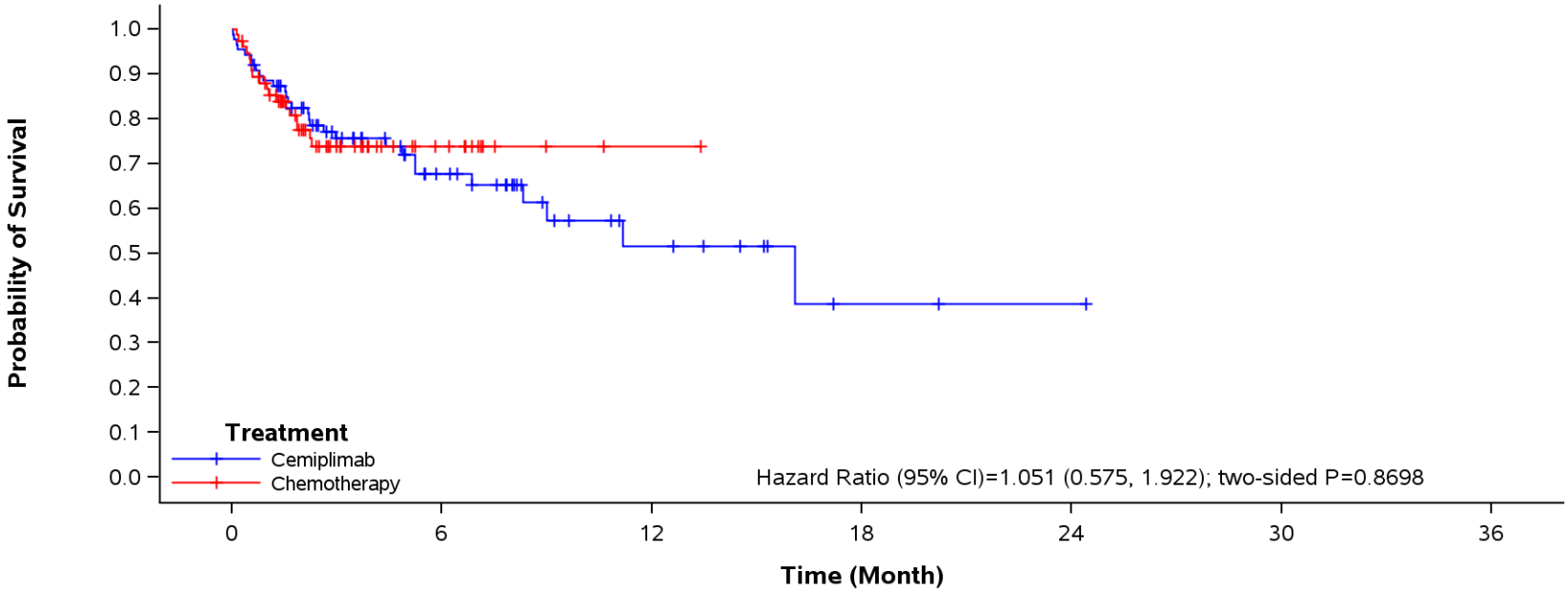

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Number of patients with any treatment-emergent SAE



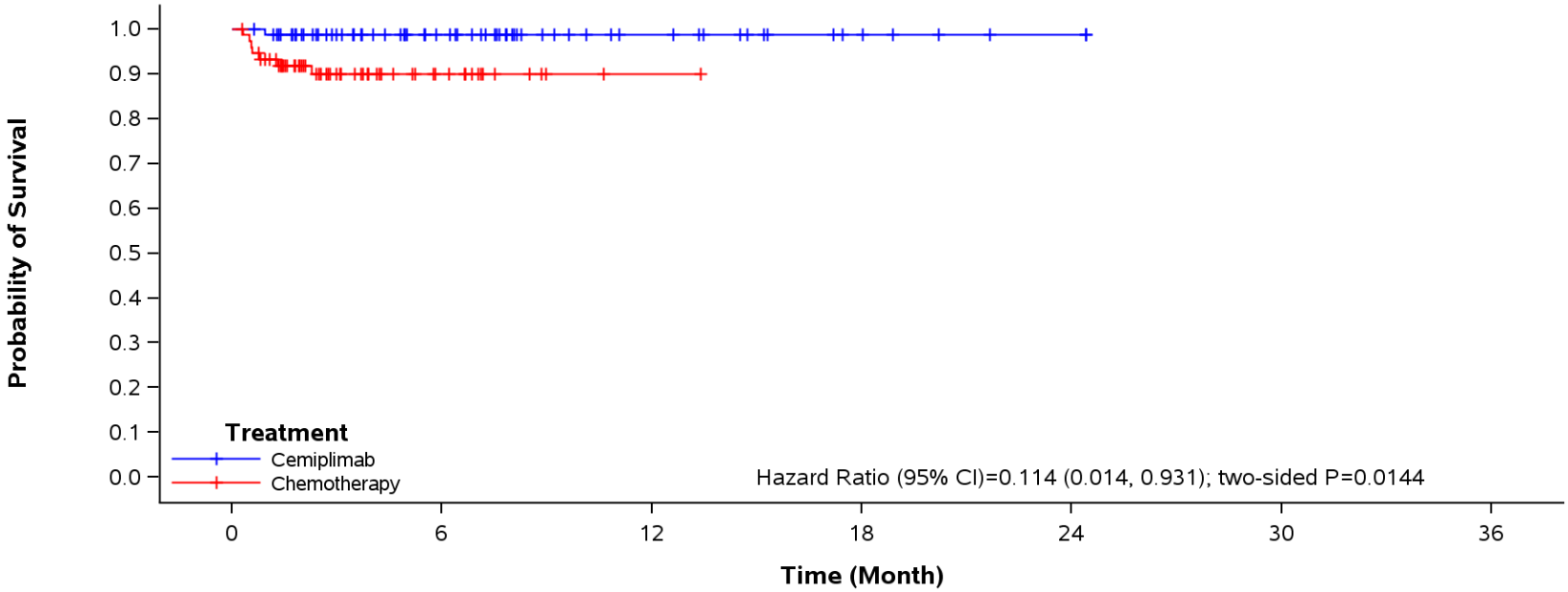

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 30 | 9 | 2 | 1 | 0 | 0 |
| Chemotherapy | 76 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders



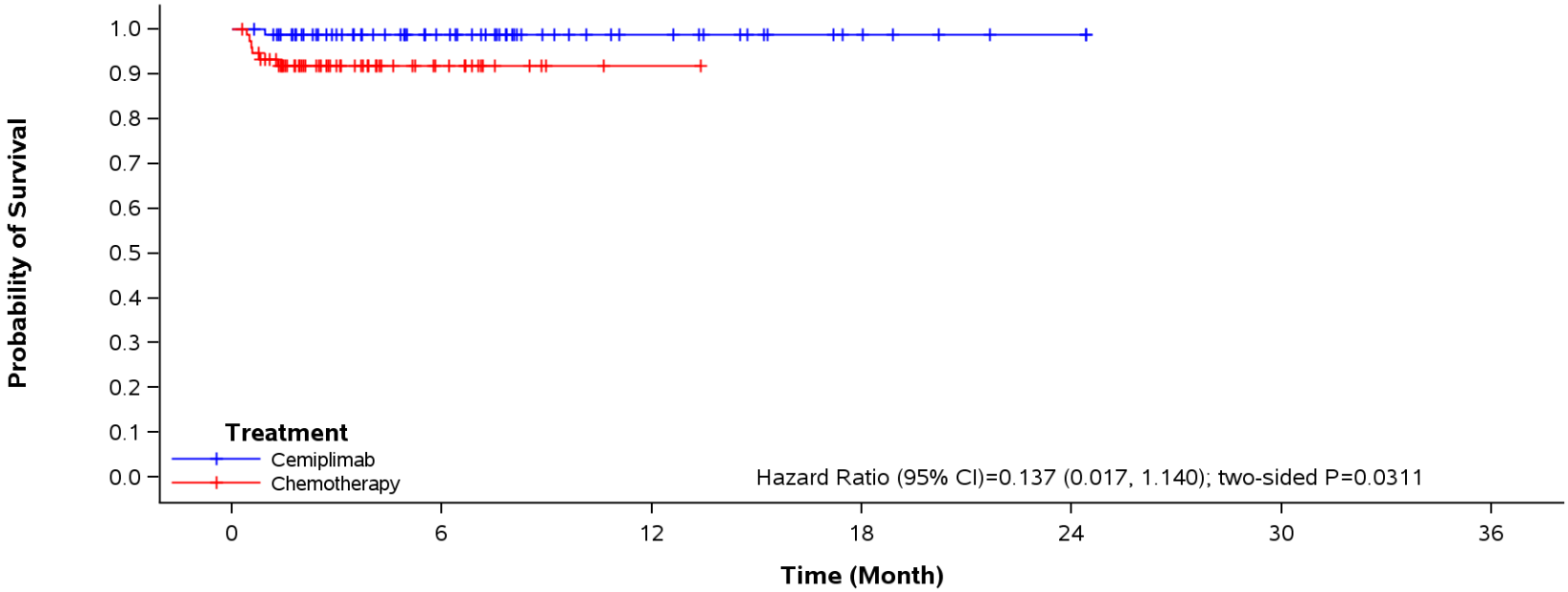

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 15 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Anaemia



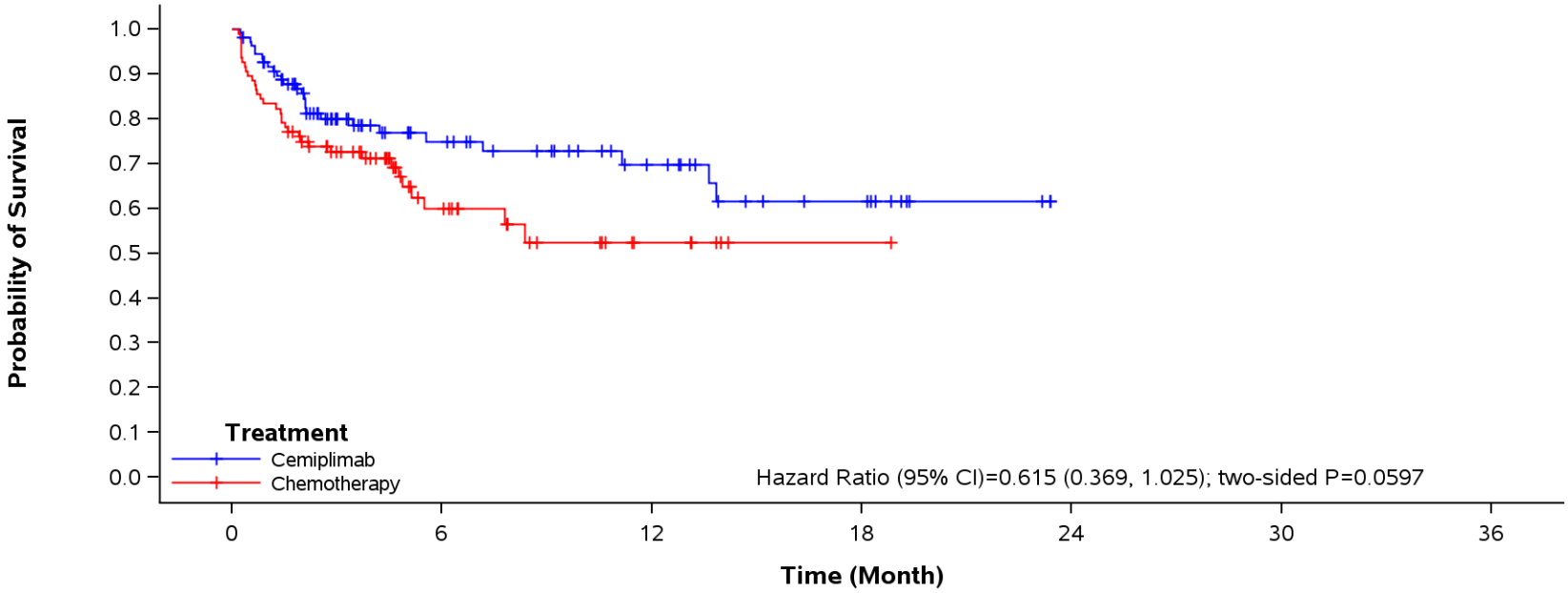

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 15 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Number of patients with any treatment-emergent SAE



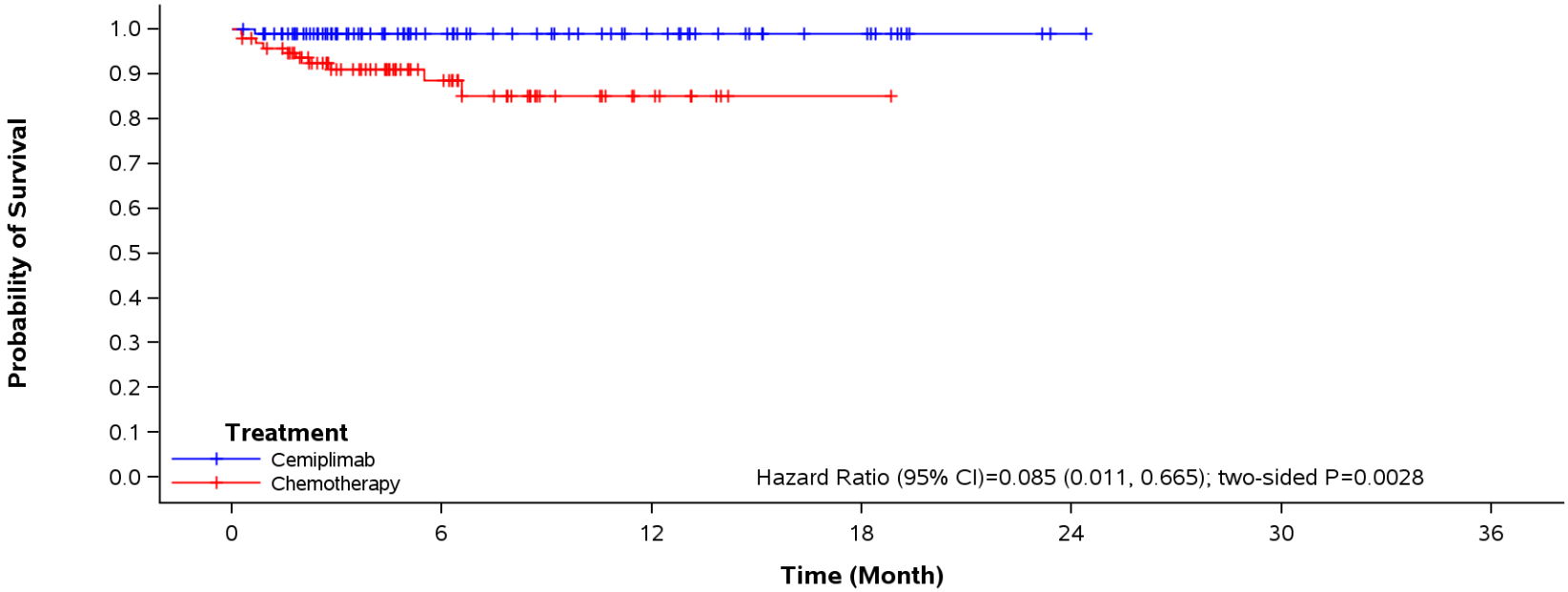

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 38 | 22 | 11 | 0 | 0 | 0 |
| Chemotherapy | 96 | 24 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders



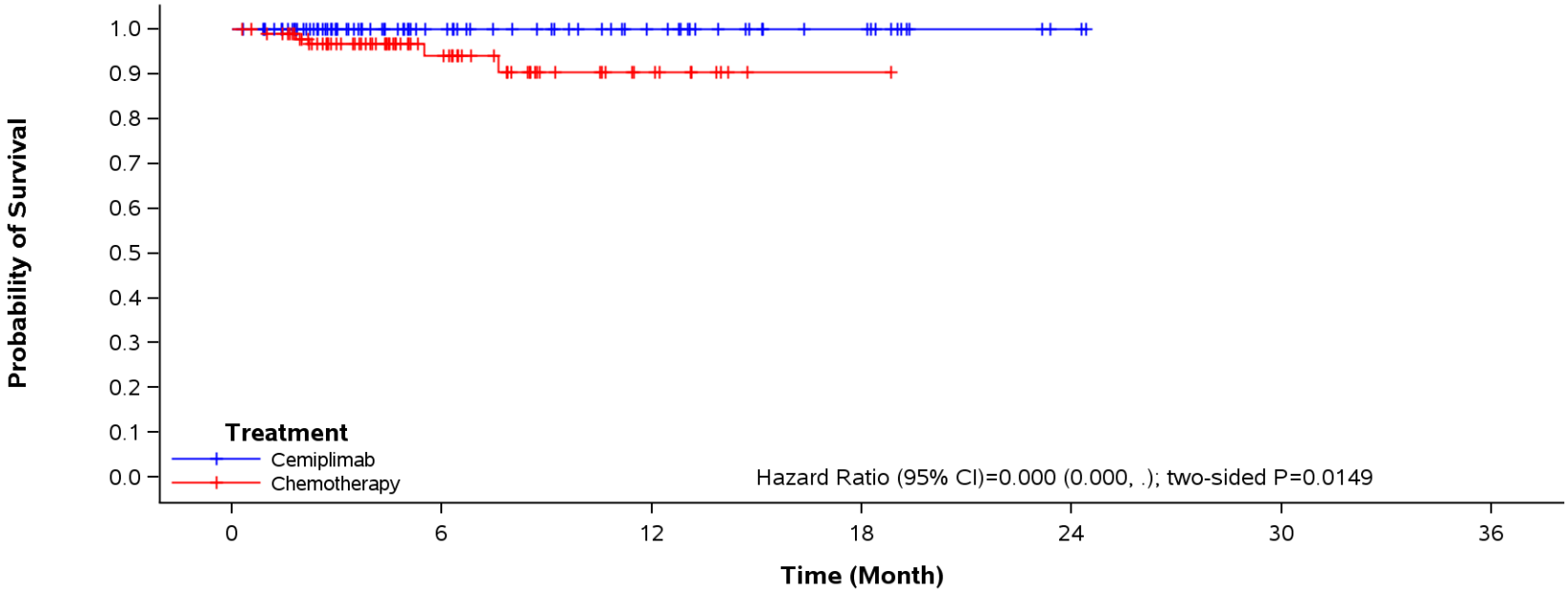

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 25 | 13 | 1 | 0 | 0 |
| Chemotherapy | 96 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

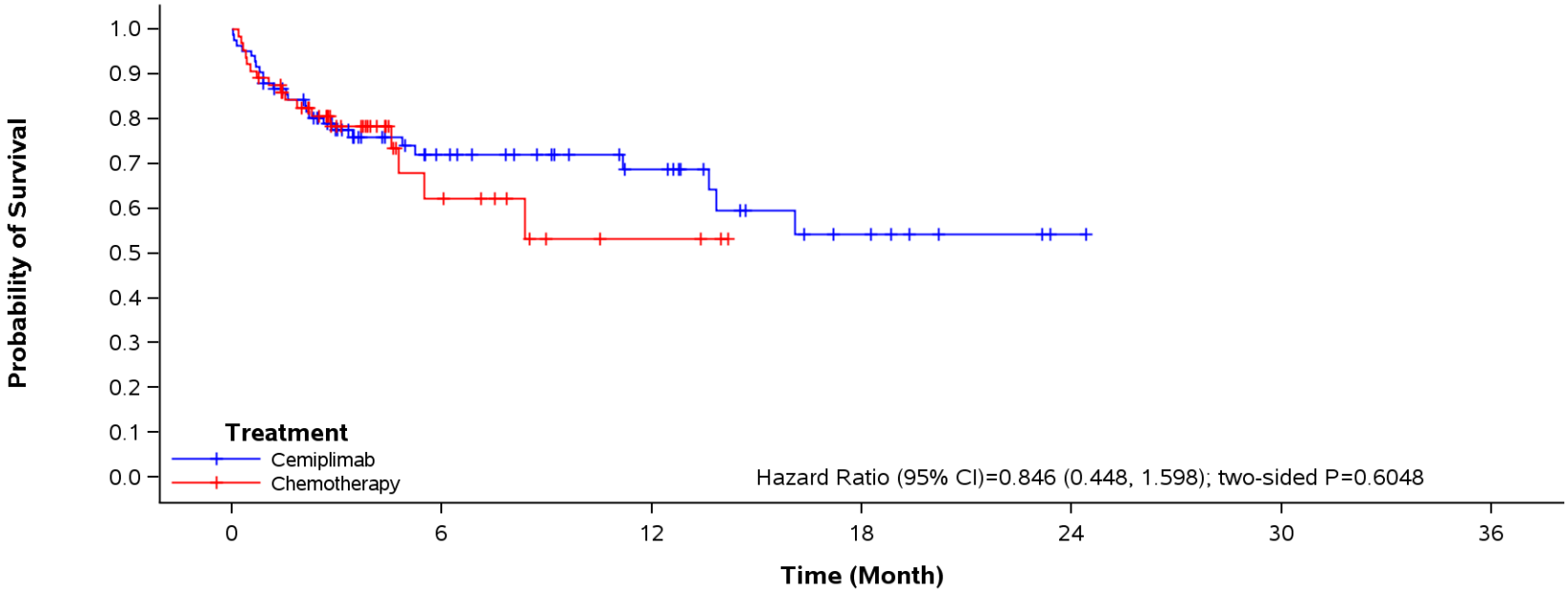
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 26 | 14 | 2 | 0 | 0 |
| Chemotherapy | 96 | 37 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 34 | 20 | 8 | 1 | 0 | 0 |
| Chemotherapy | 64 | 11 | 3 | 0 | 0 | 0 | 0 |

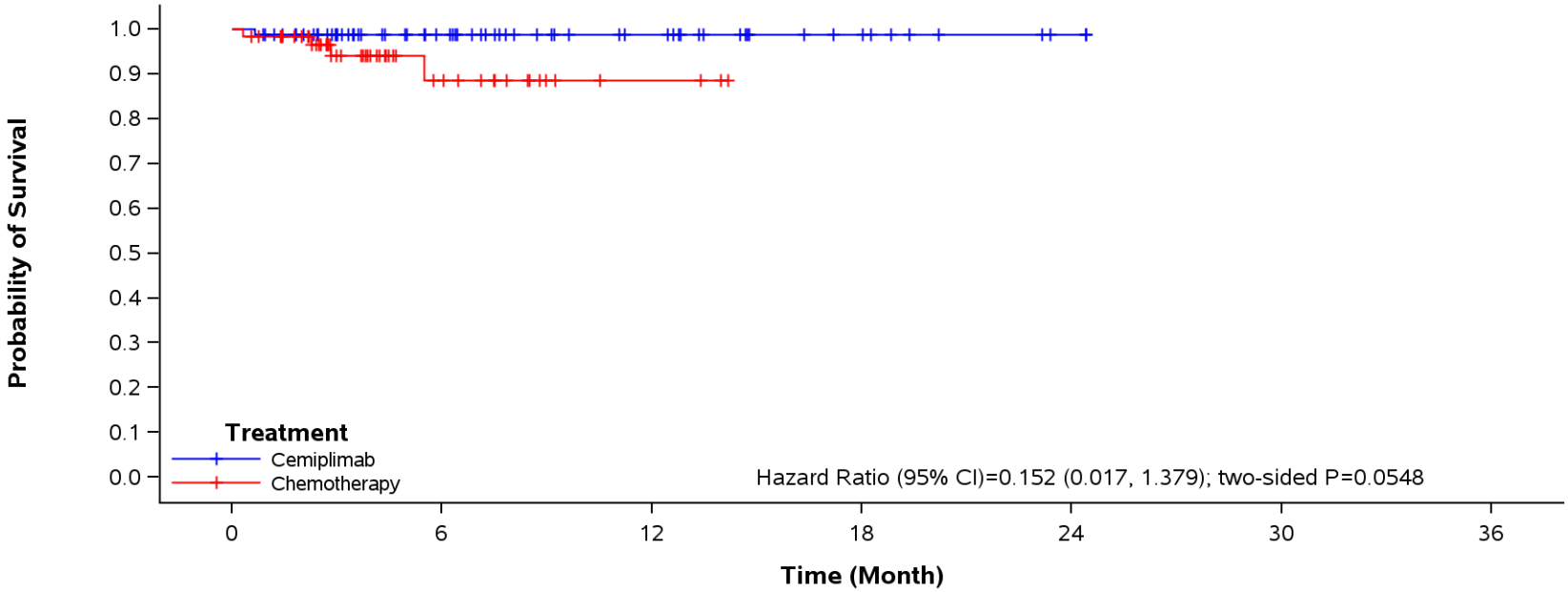
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders



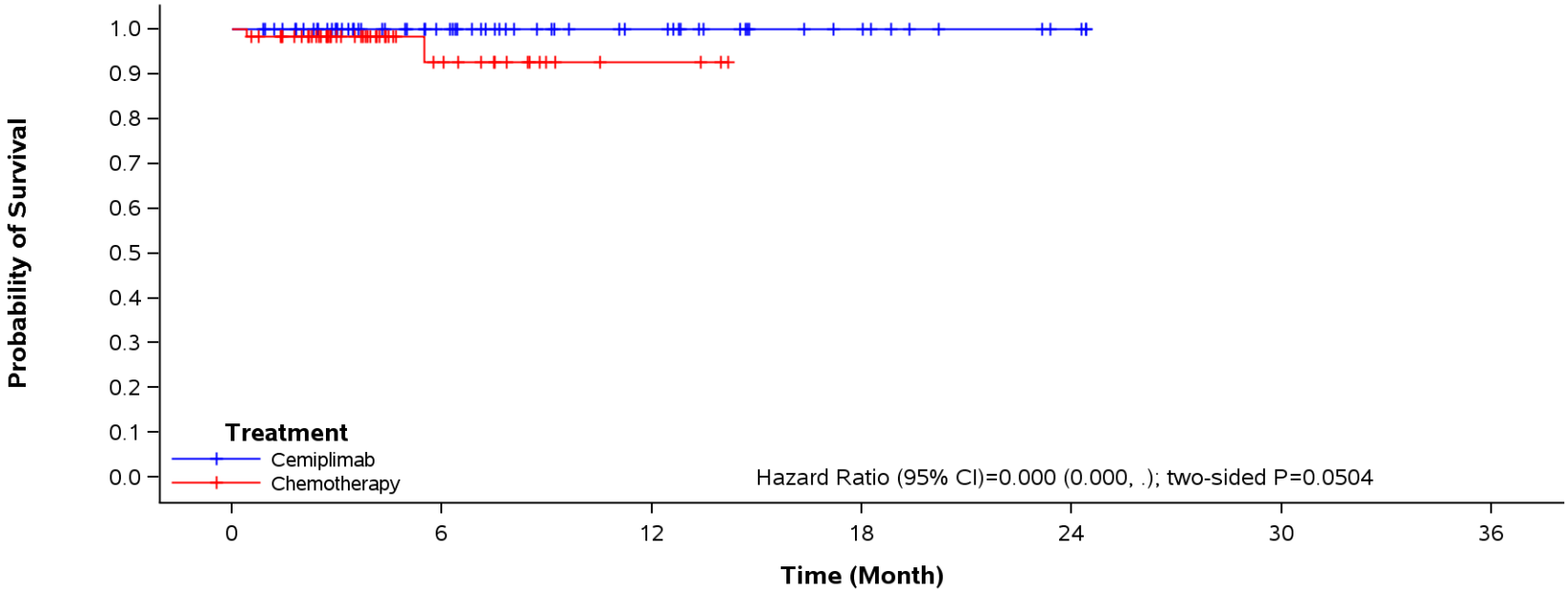

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 43 | 23 | 11 | 3 | 0 | 0 |
| Chemotherapy | 64 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

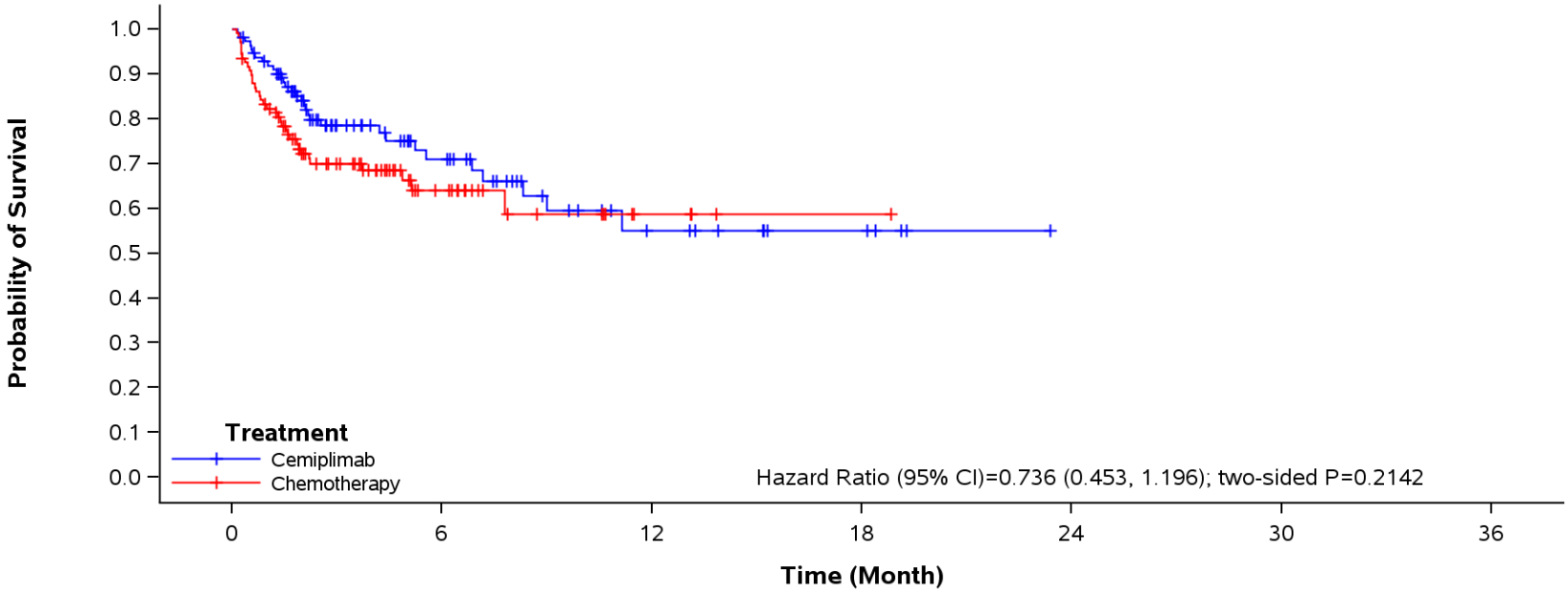
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 24 | 12 | 4 | 0 | 0 |
| Chemotherapy | 64 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 34 | 11 | 5 | 0 | 0 | 0 |
| Chemotherapy | 108 | 24 | 4 | 1 | 0 | 0 | 0 |

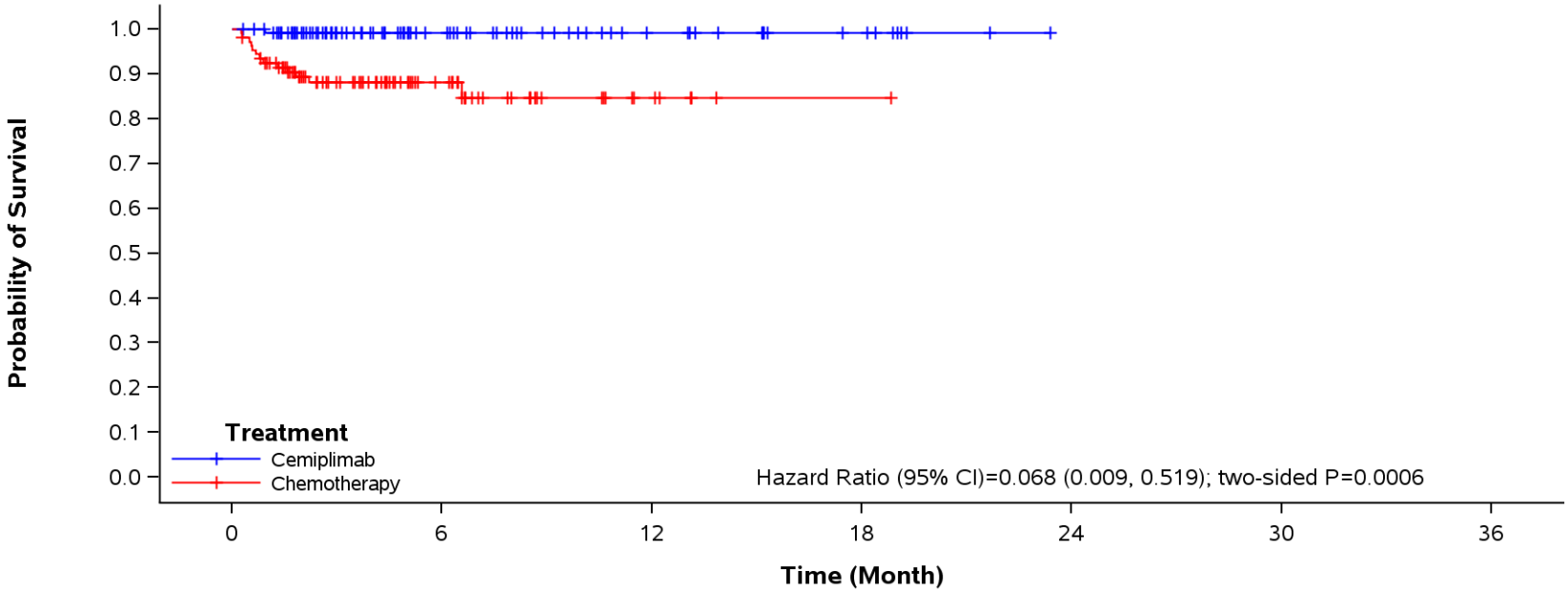
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders



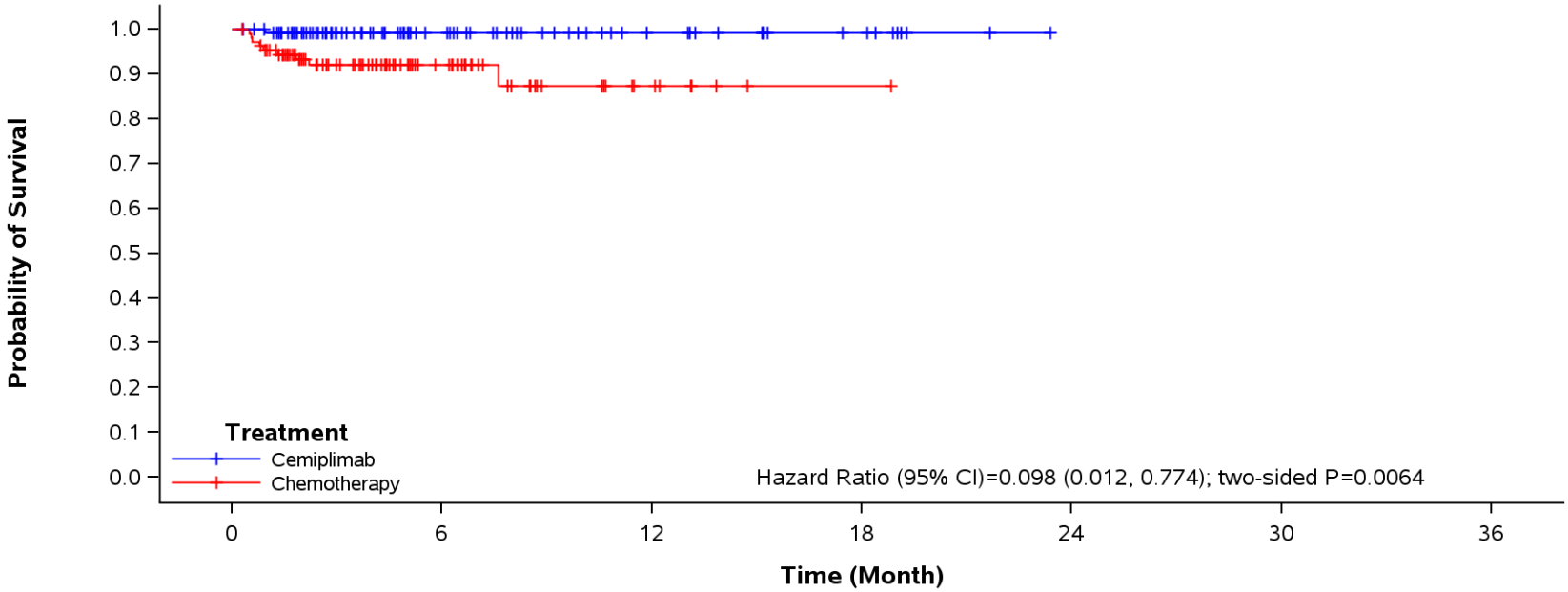

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 17 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

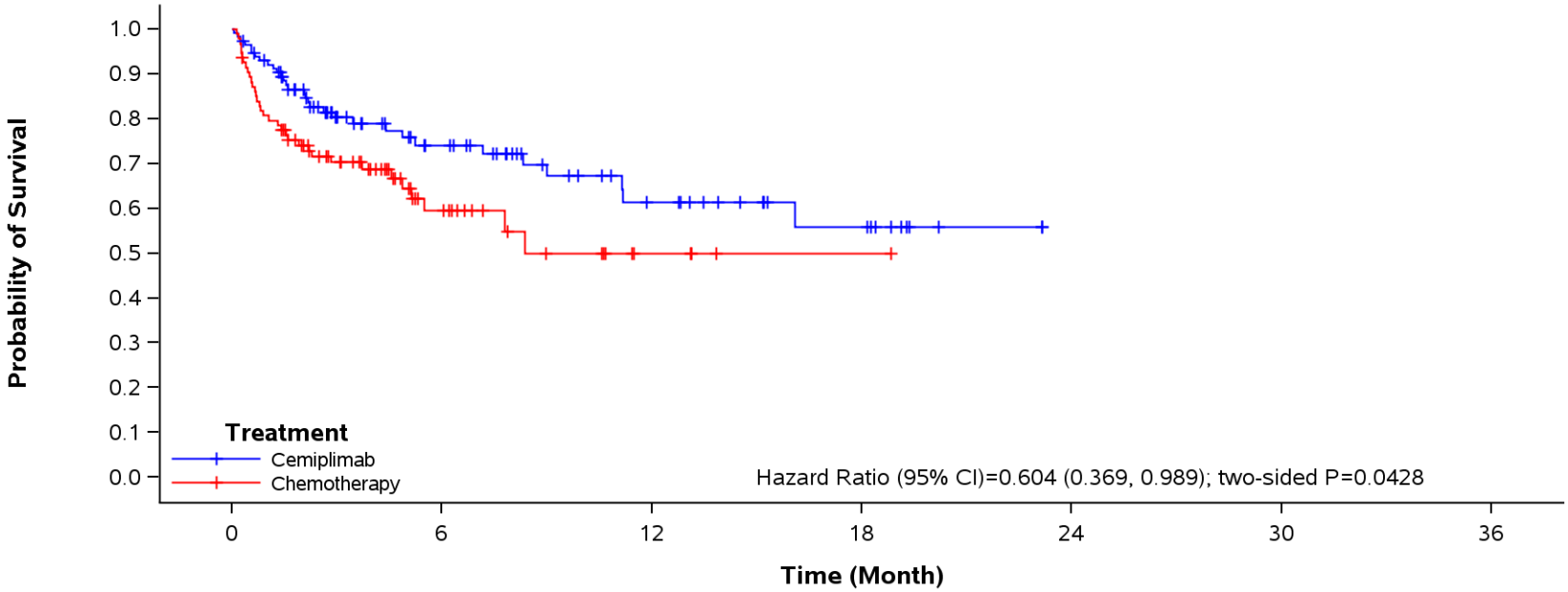
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 17 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 42 | 20 | 10 | 0 | 0 | 0 |
| Chemotherapy | 94 | 22 | 4 | 1 | 0 | 0 | 0 |

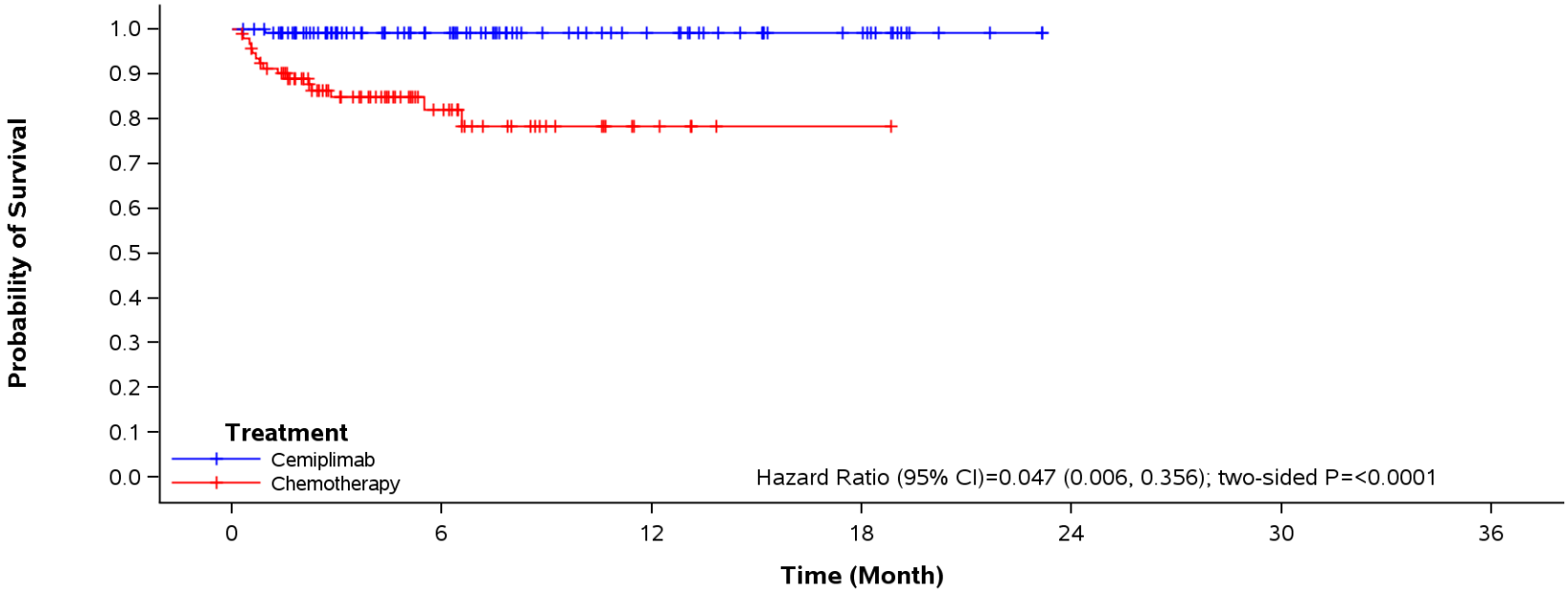
Data cut-off as of Jan 4th, 2021.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders



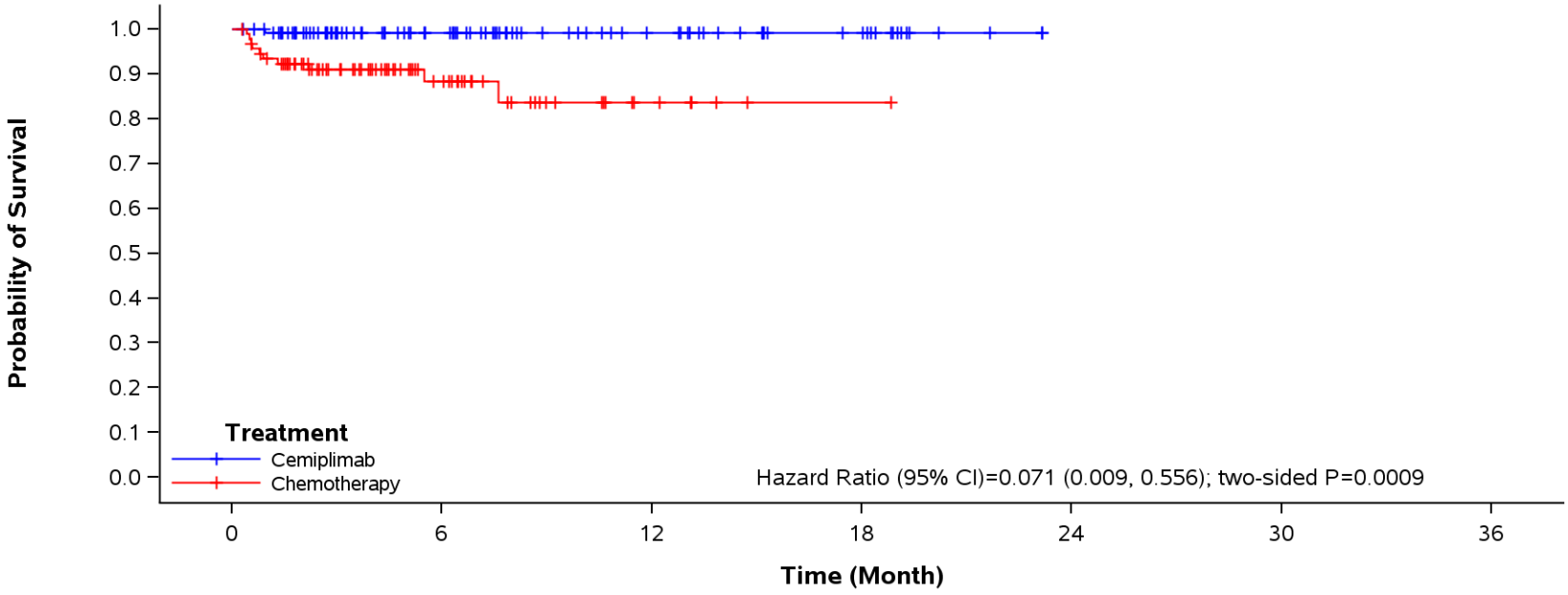

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 27 | 14 | 0 | 0 | 0 |
| Chemotherapy | 94 | 29 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



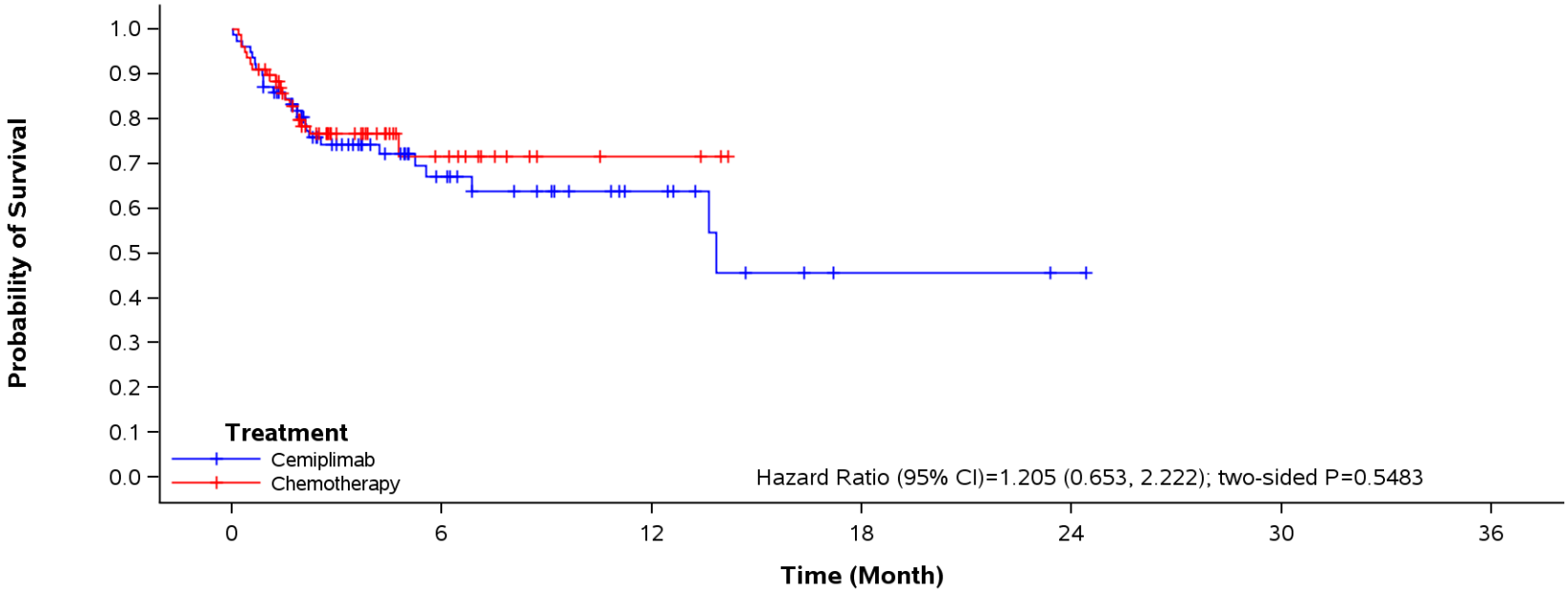

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 27 | 14 | 0 | 0 | 0 |
| Chemotherapy | 94 | 31 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Number of patients with any treatment-emergent SAE



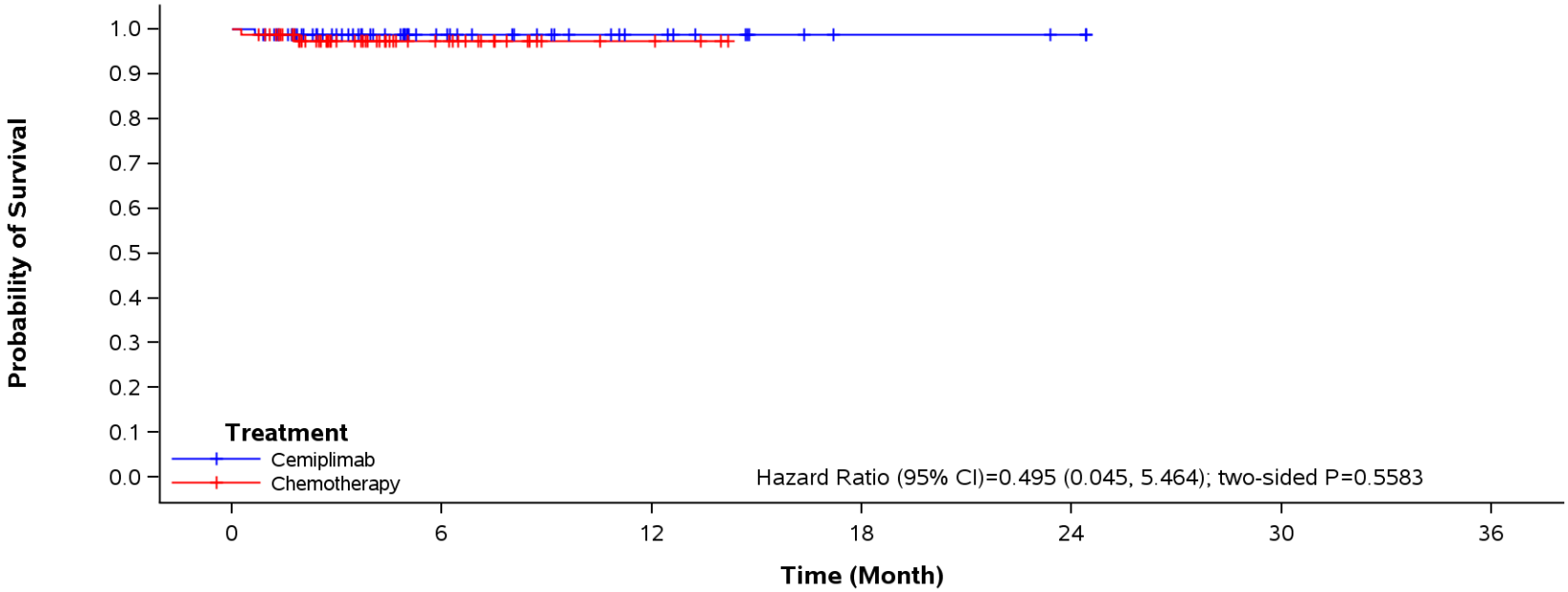

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 25 | 10 | 2 | 1 | 0 | 0 |
| Chemotherapy | 78 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders



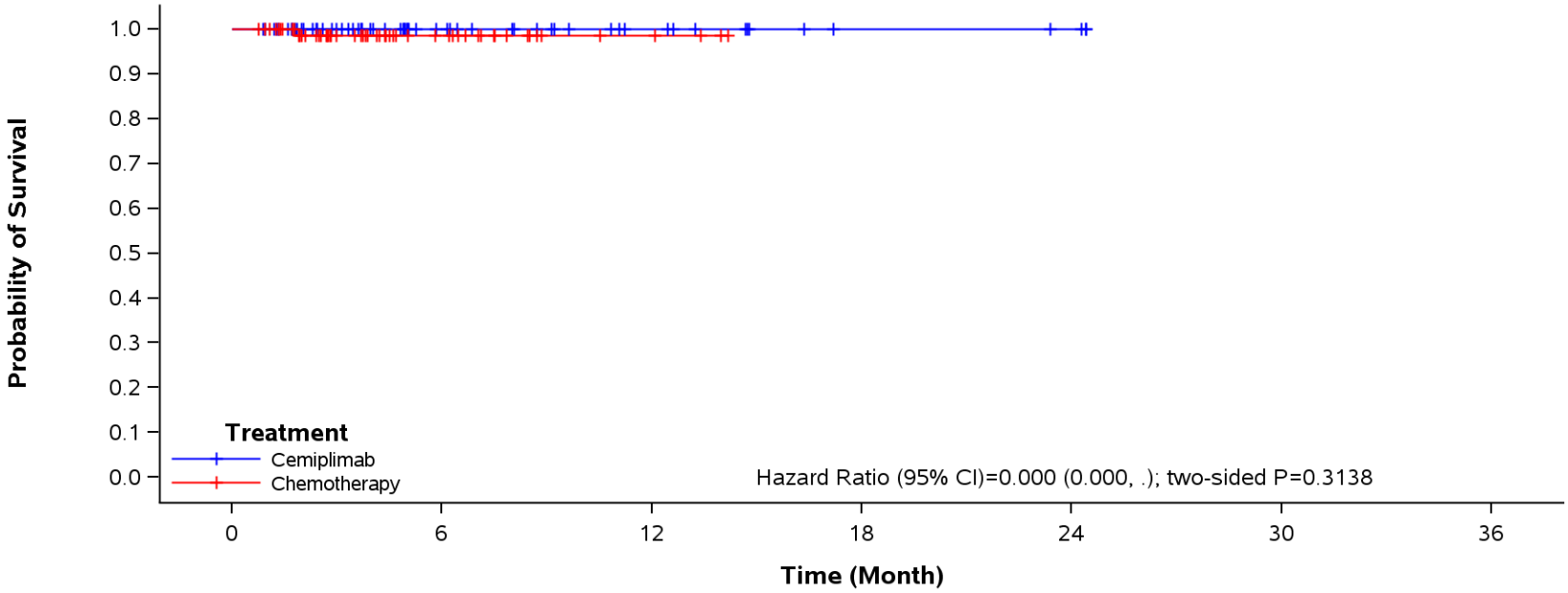

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 30 | 12 | 4 | 3 | 0 | 0 |
| Chemotherapy | 78 | 19 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



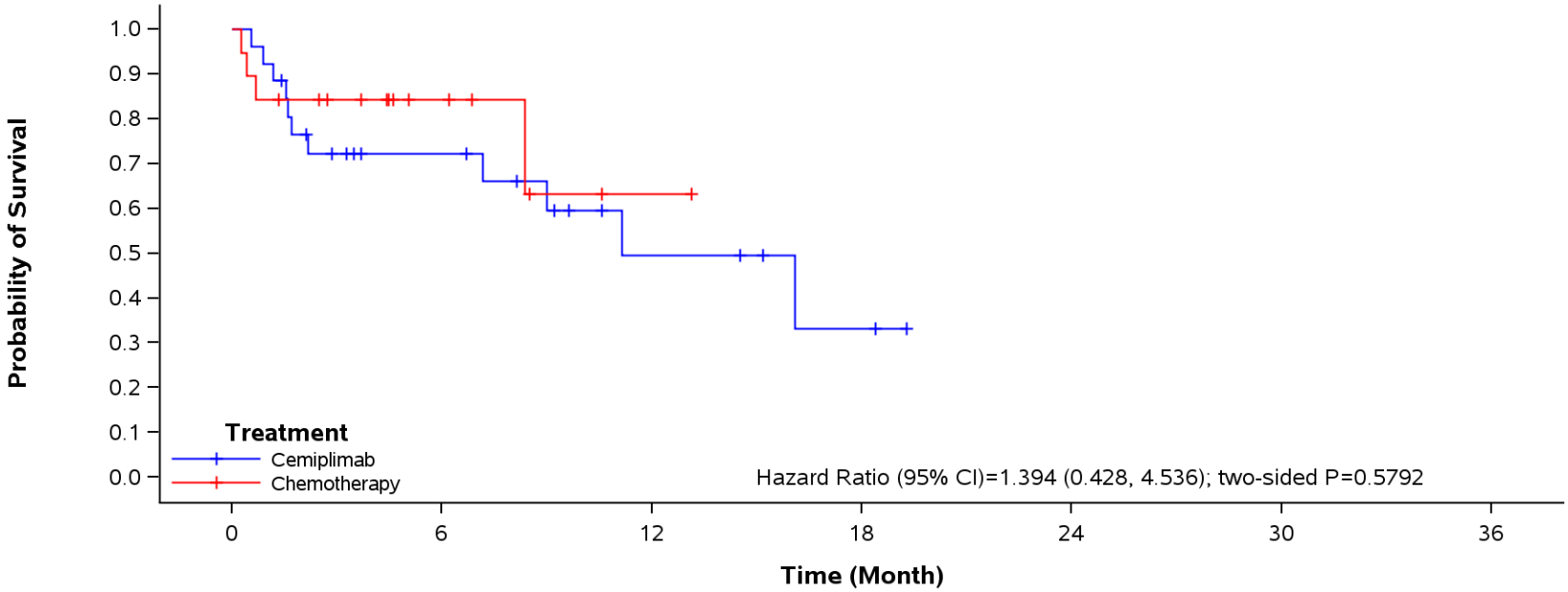

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 13 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 19 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Number of patients with any treatment-emergent SAE



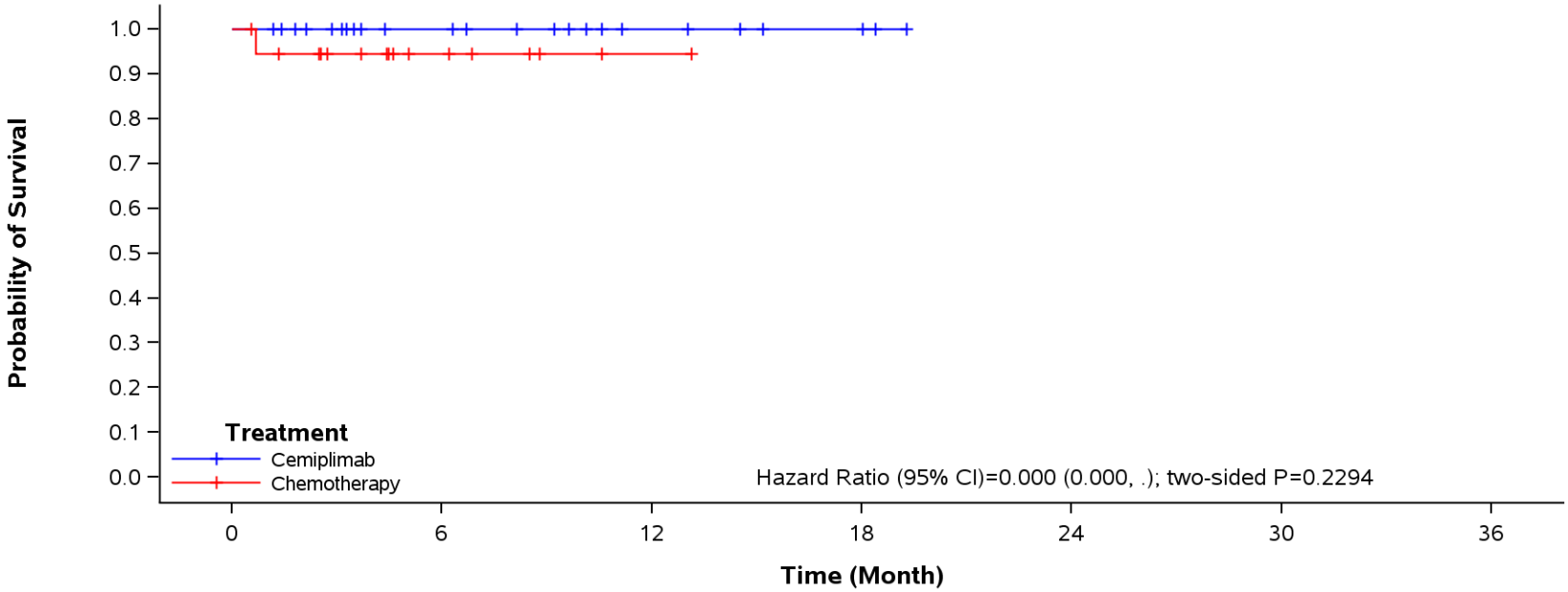

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 13 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders



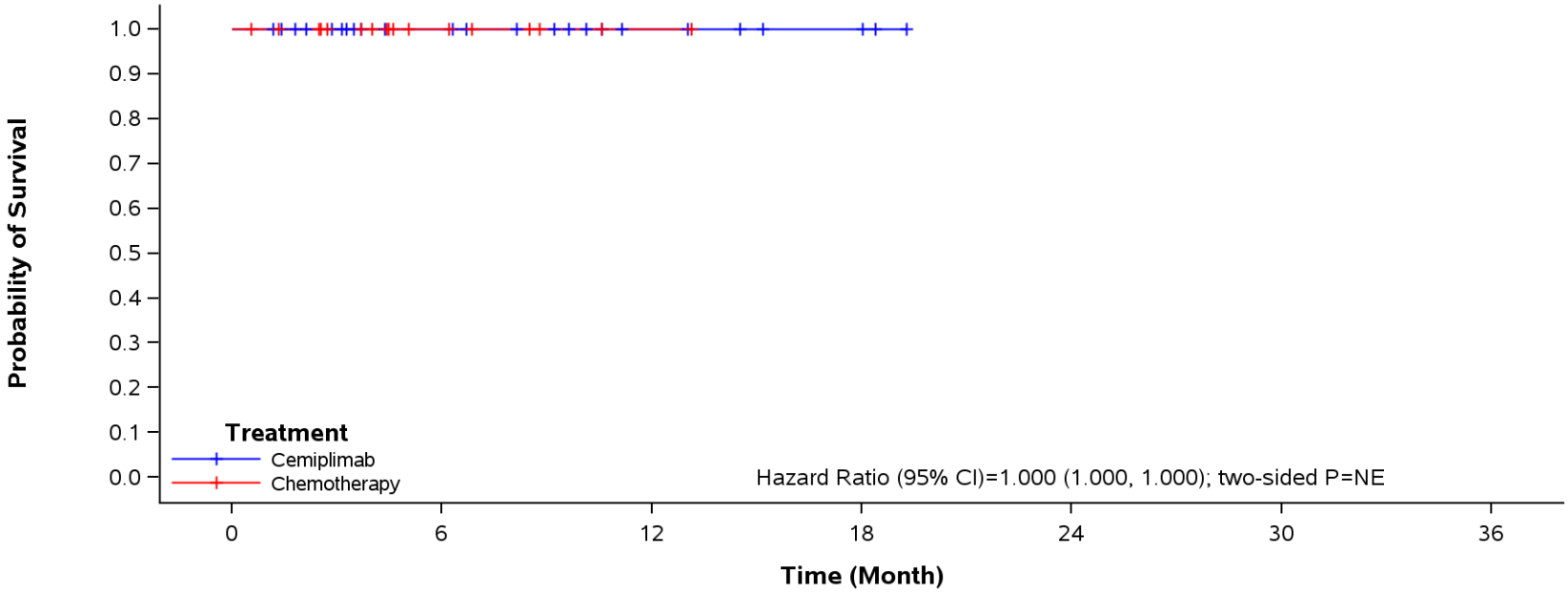

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



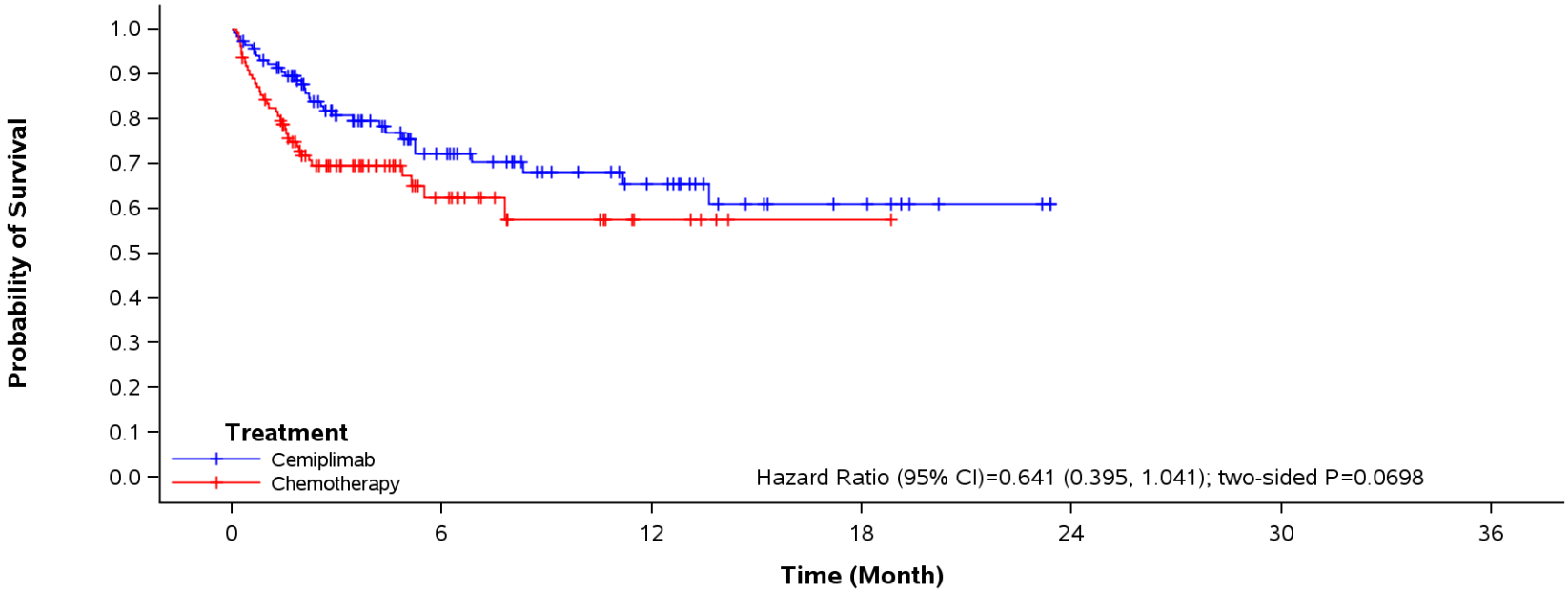

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Number of patients with any treatment-emergent SAE



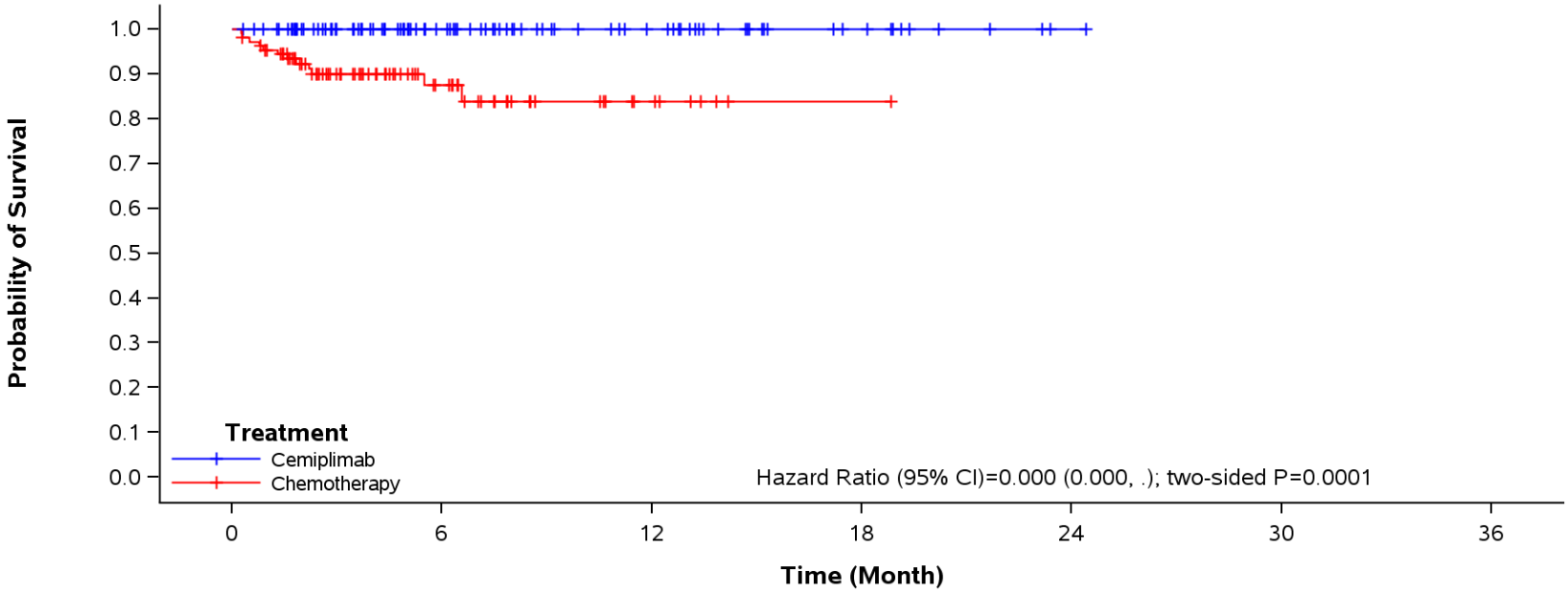

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 44 | 22 | 9 | 0 | 0 | 0 |
| Chemotherapy | 109 | 23 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders



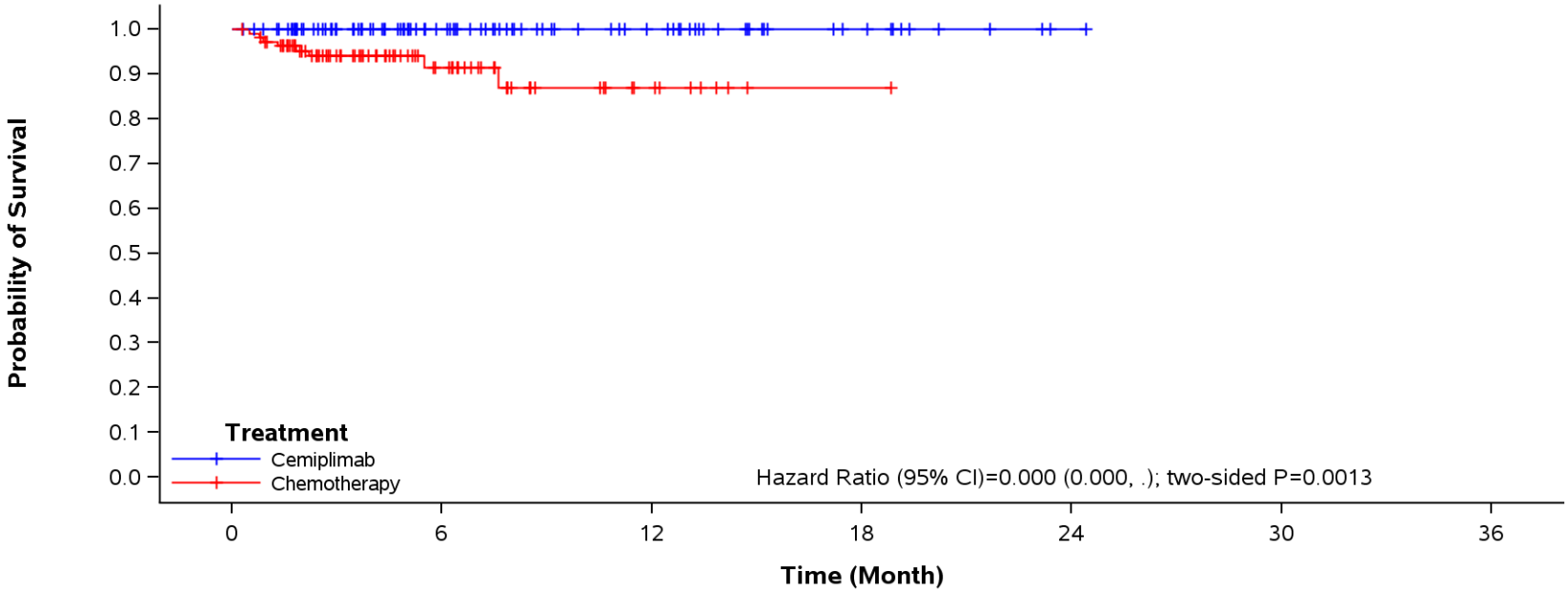

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 29 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 32 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Anaemia



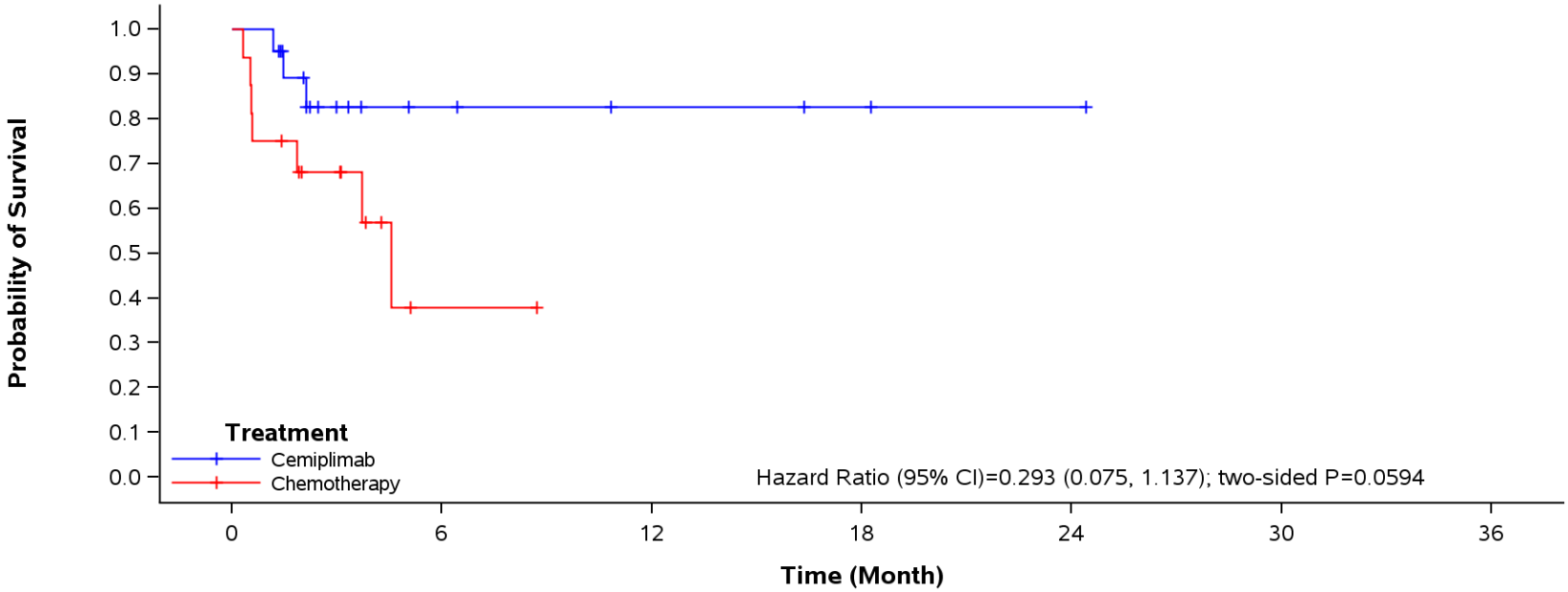

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 29 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 34 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Number of patients with any treatment-emergent SAE



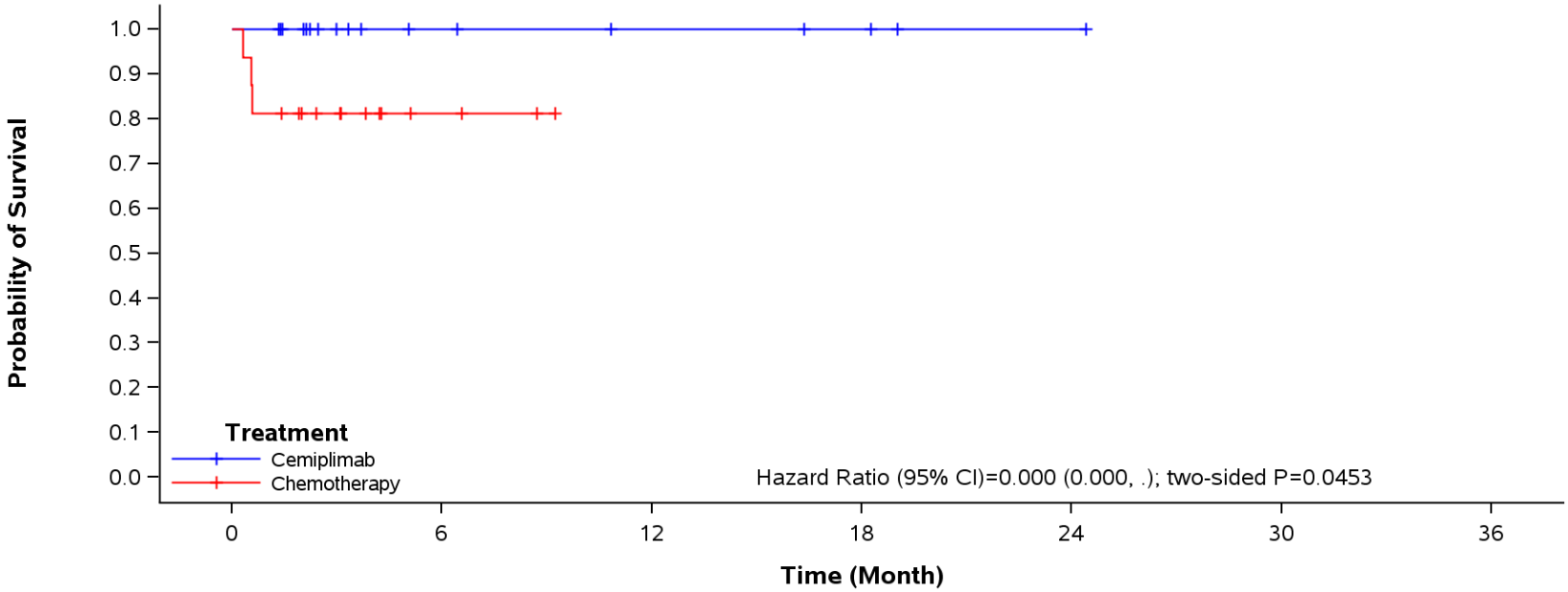

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders



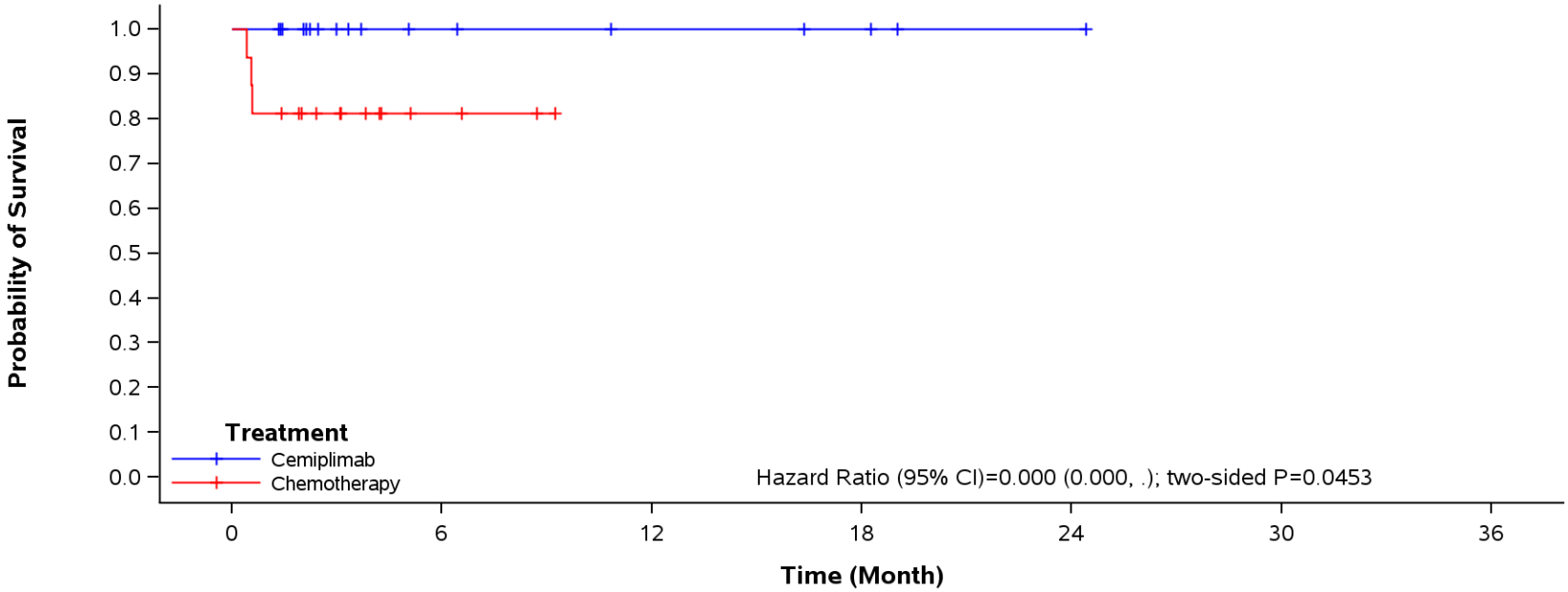

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



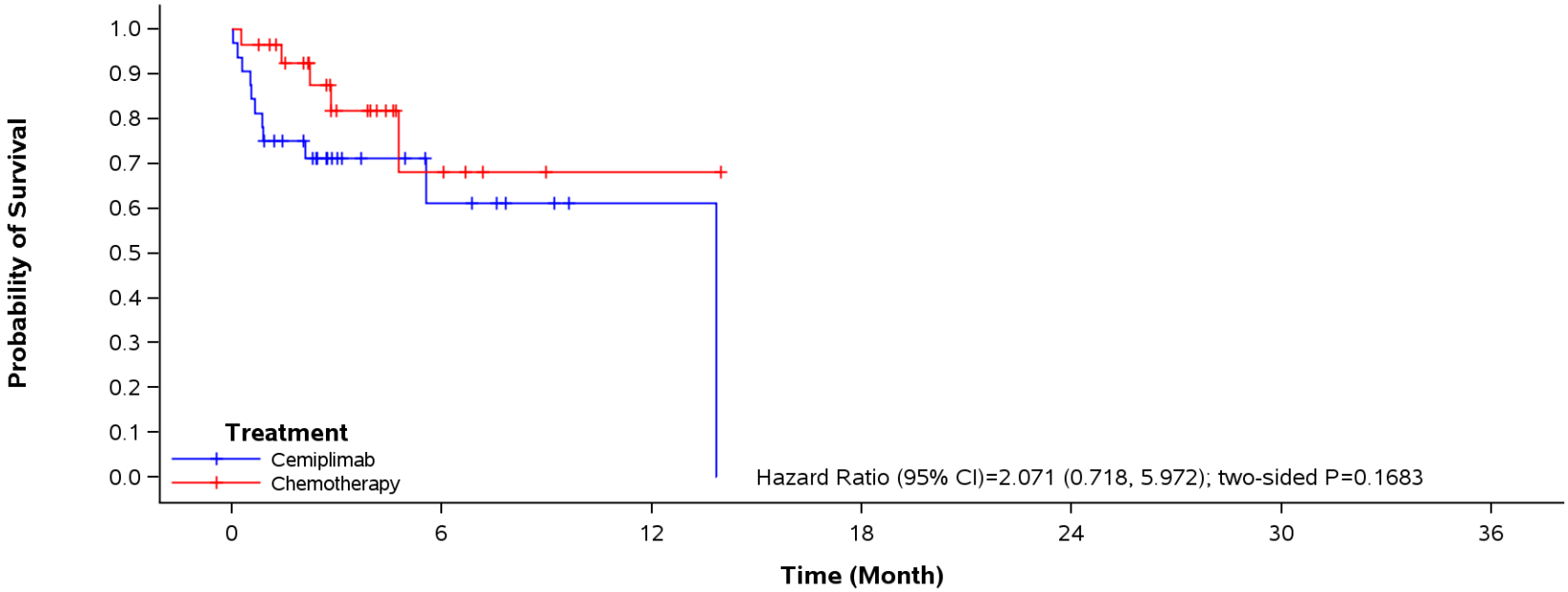

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Number of patients with any treatment-emergent SAE



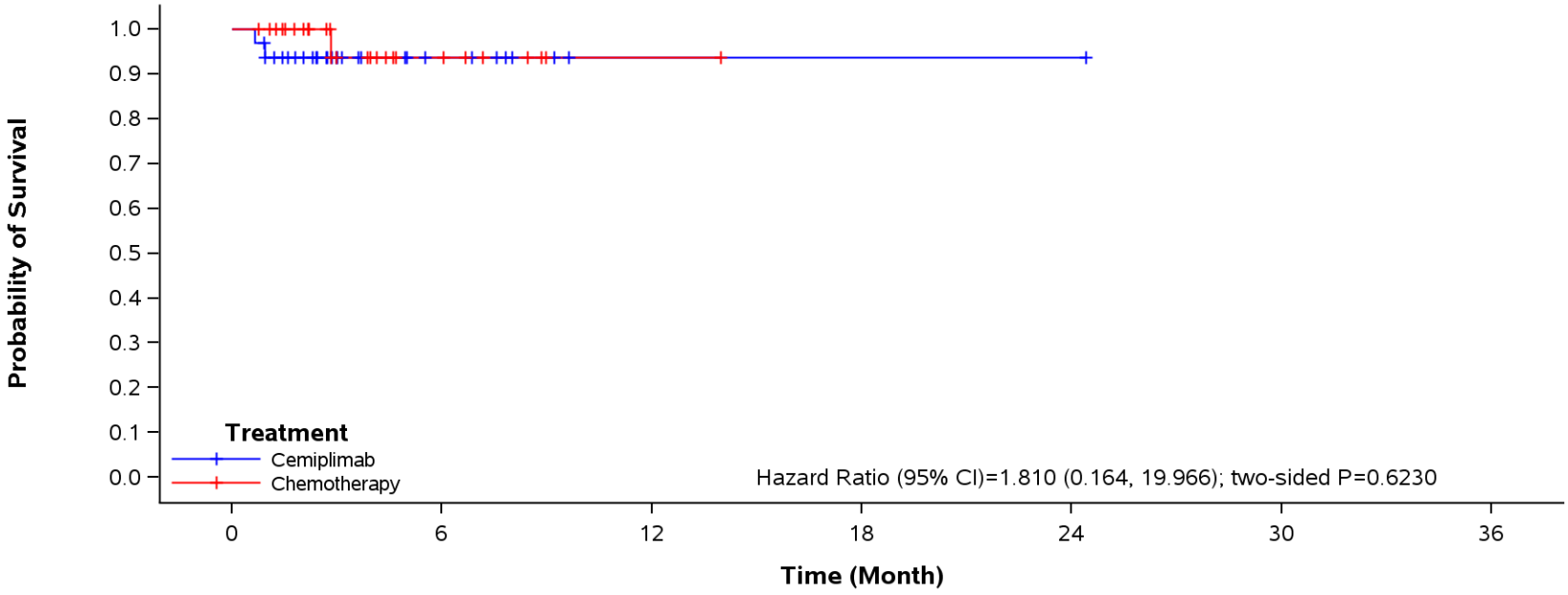

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 6 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 28 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

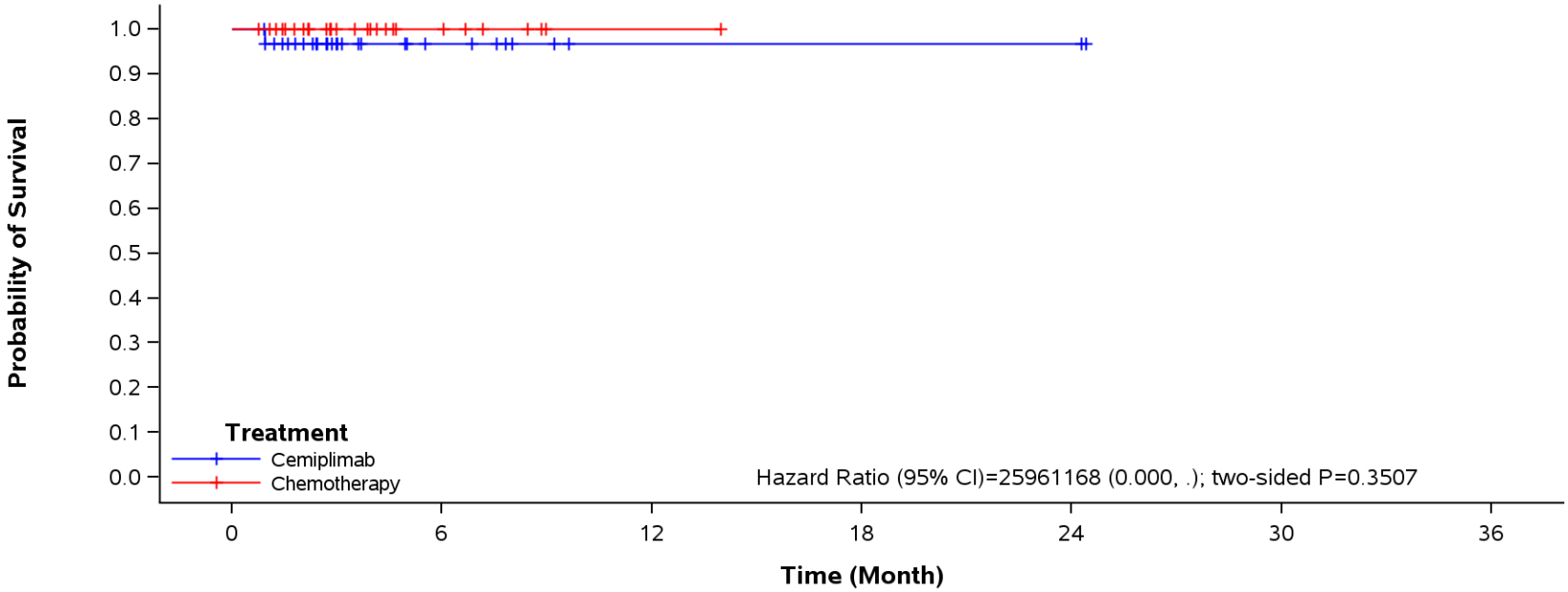
Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders




Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Anaemia



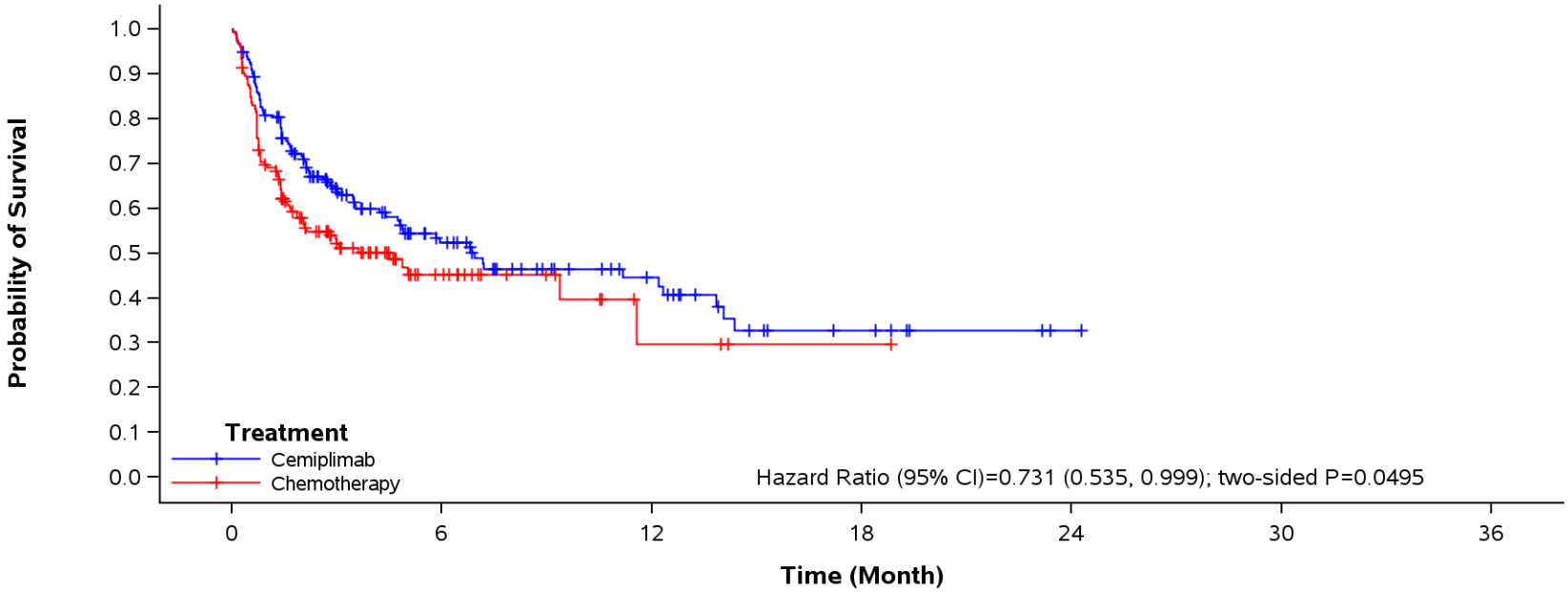

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Number of patients with any TEAE CTCAE Grade >= 3



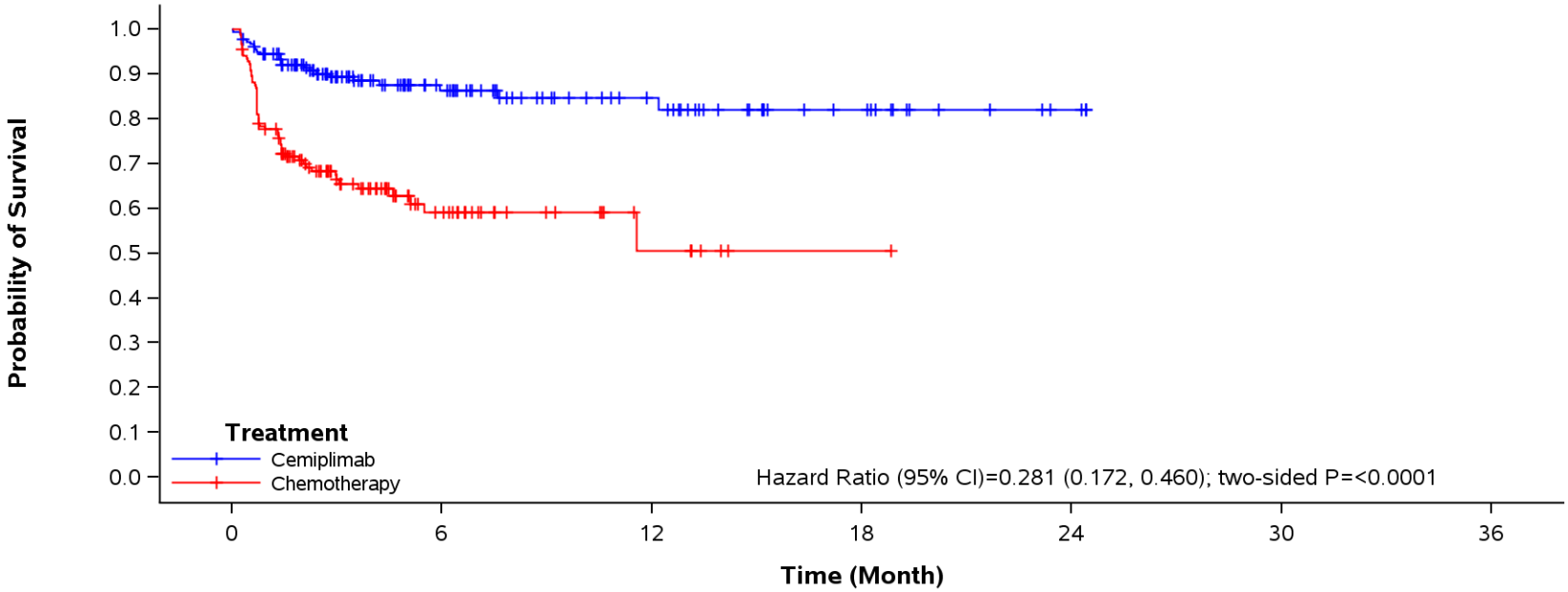

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 50 | 23 | 8 | 1 | 0 | 0 |
| Chemotherapy | 153 | 22 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders



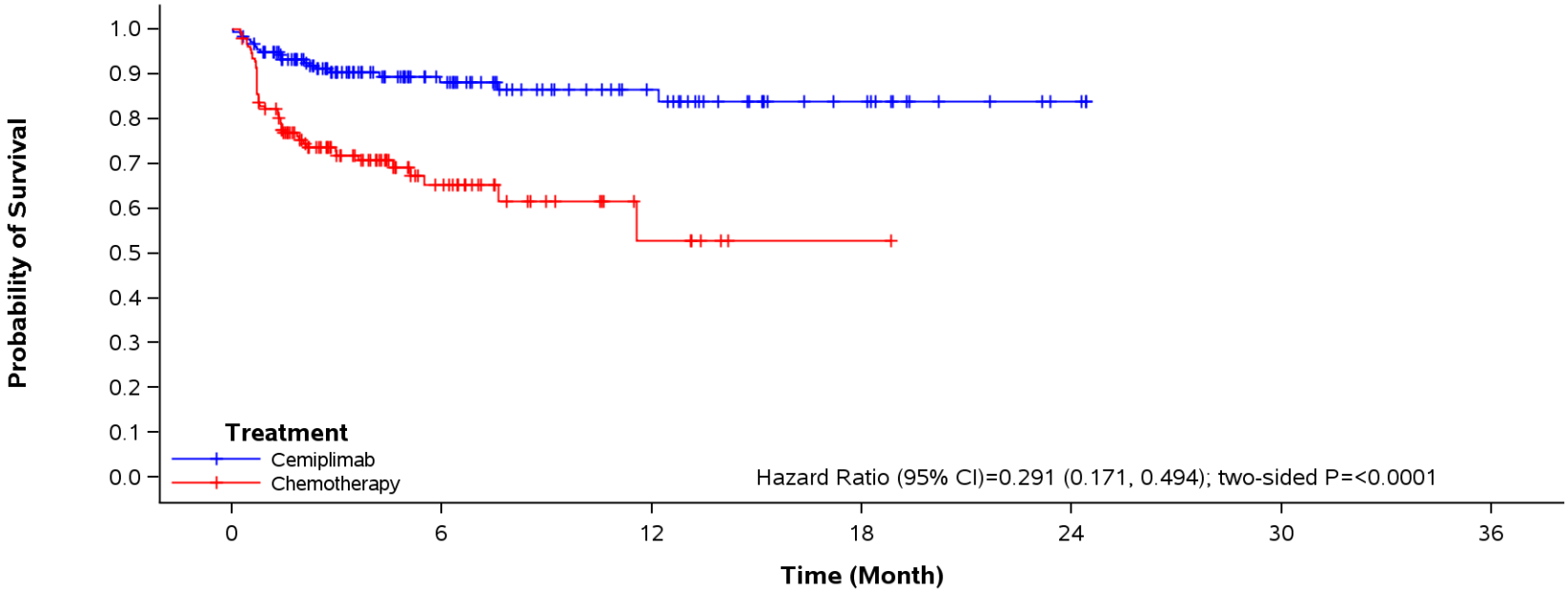

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 70 | 33 | 15 | 3 | 0 | 0 |
| Chemotherapy | 153 | 29 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Anaemia



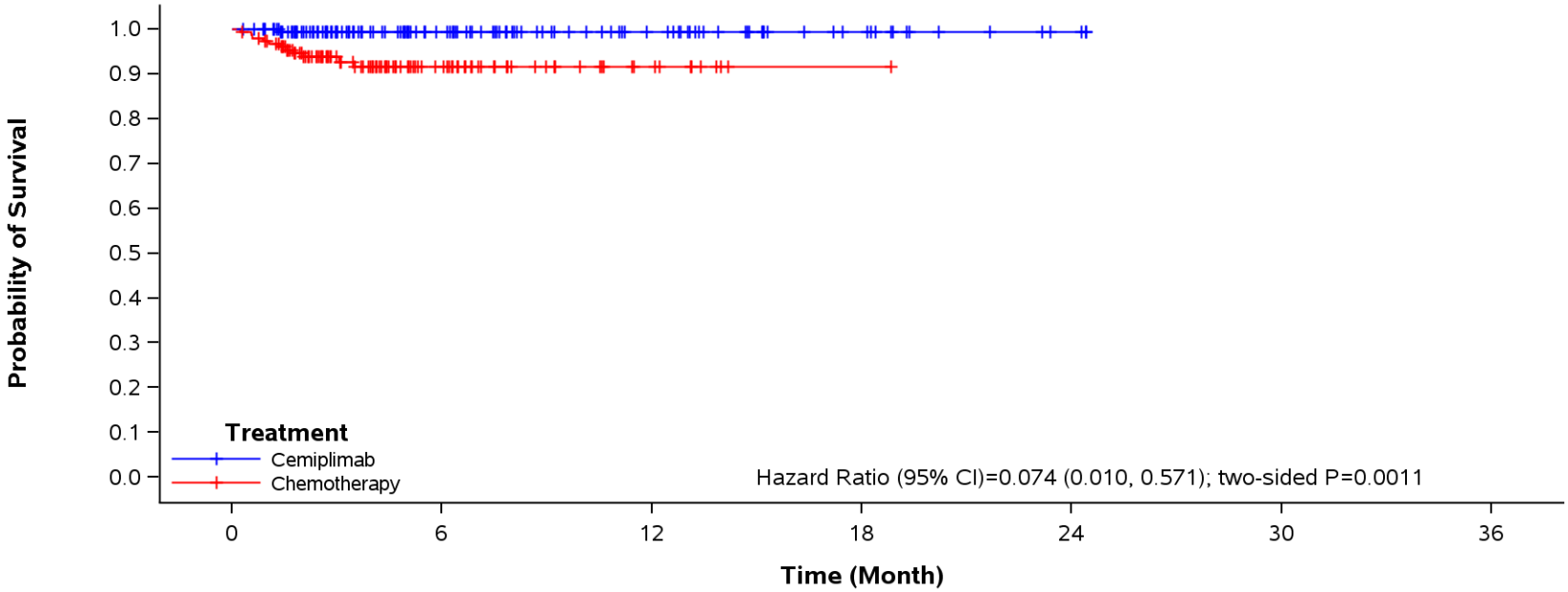

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 71 | 33 | 15 | 3 | 0 | 0 |
| Chemotherapy | 153 | 32 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



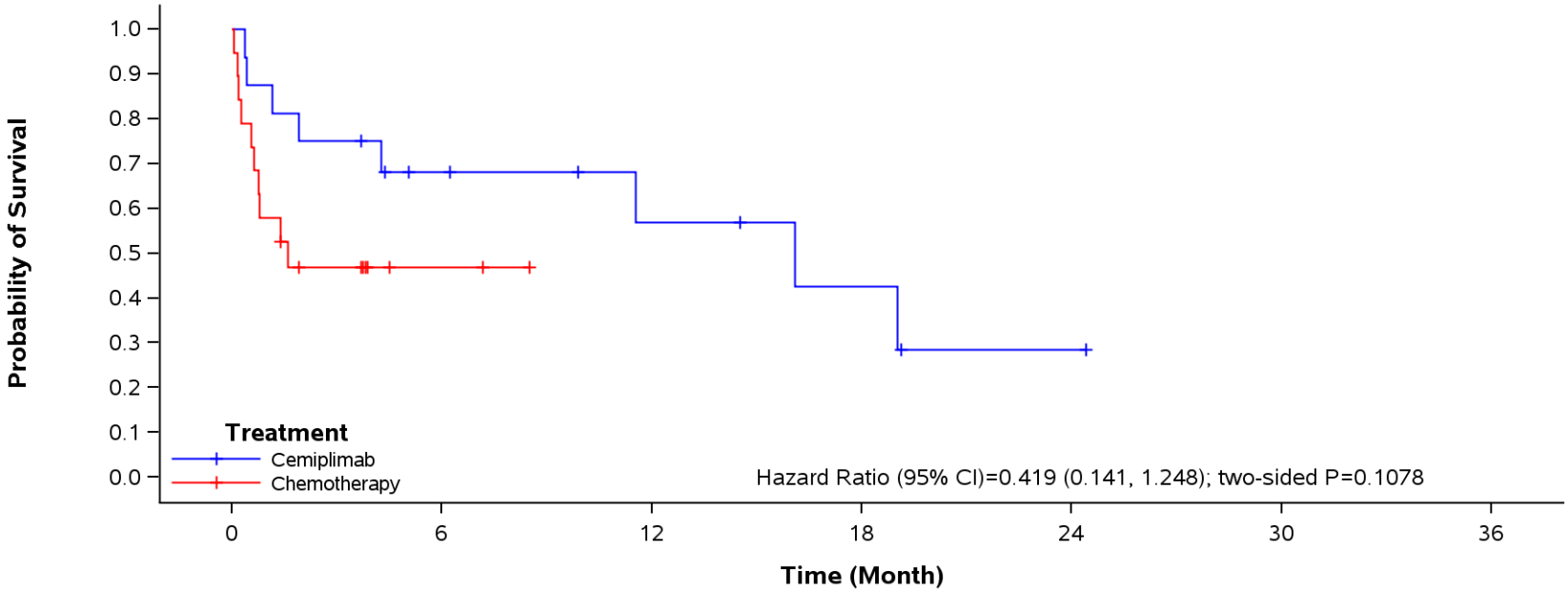

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 35 | 15 | 3 | 0 | 0 |
| Chemotherapy | 153 | 41 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Number of patients with any TEAE CTCAE Grade >= 3



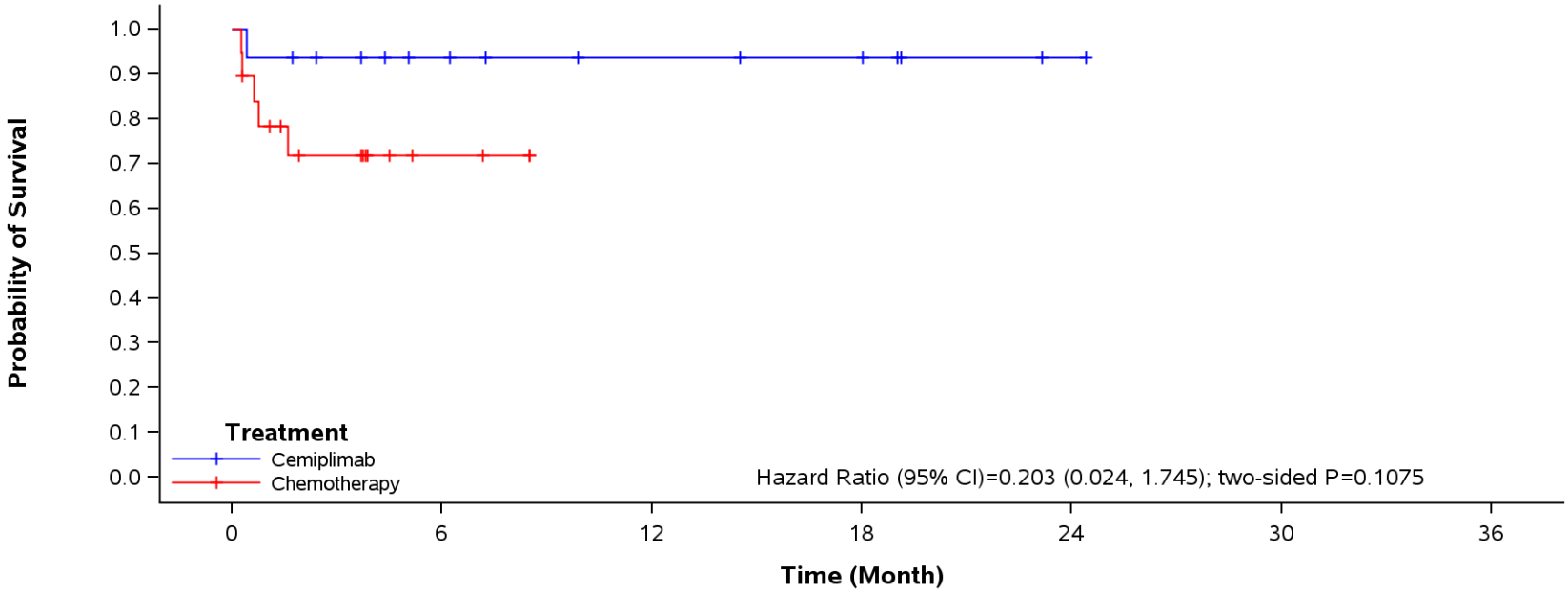

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 5 | 3 | 1 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders



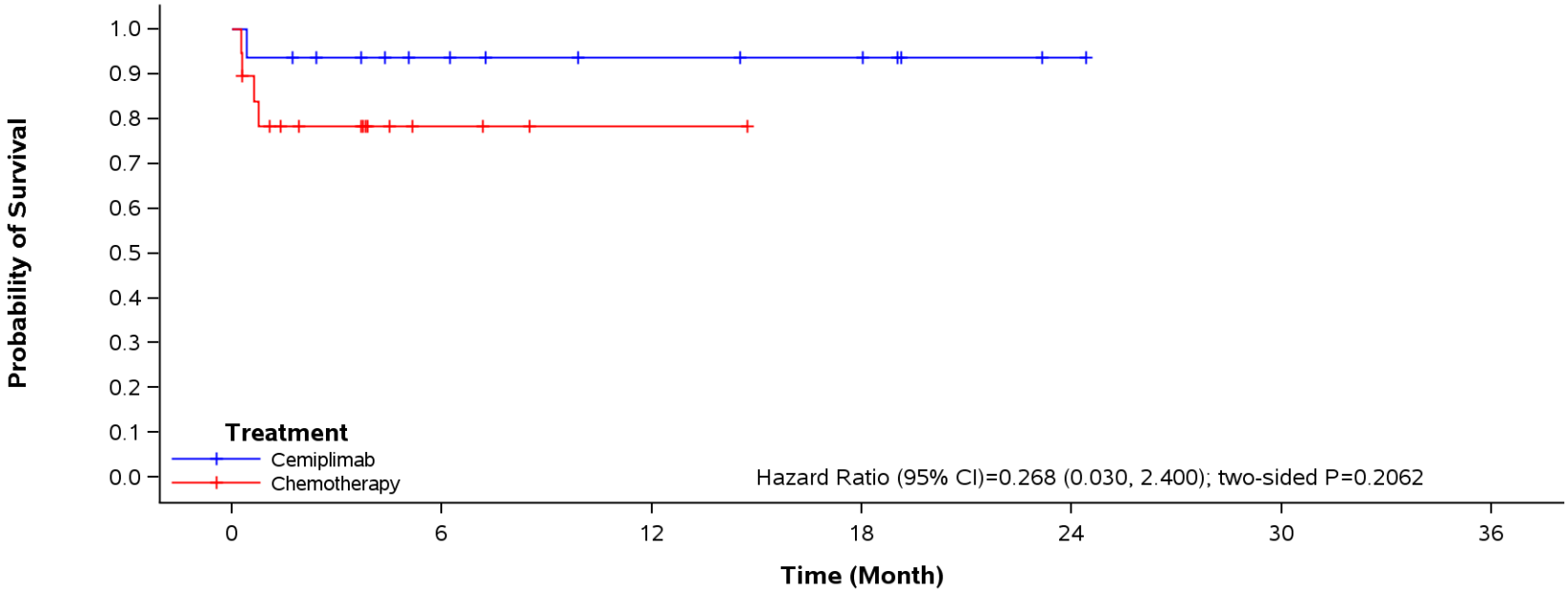

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Anaemia



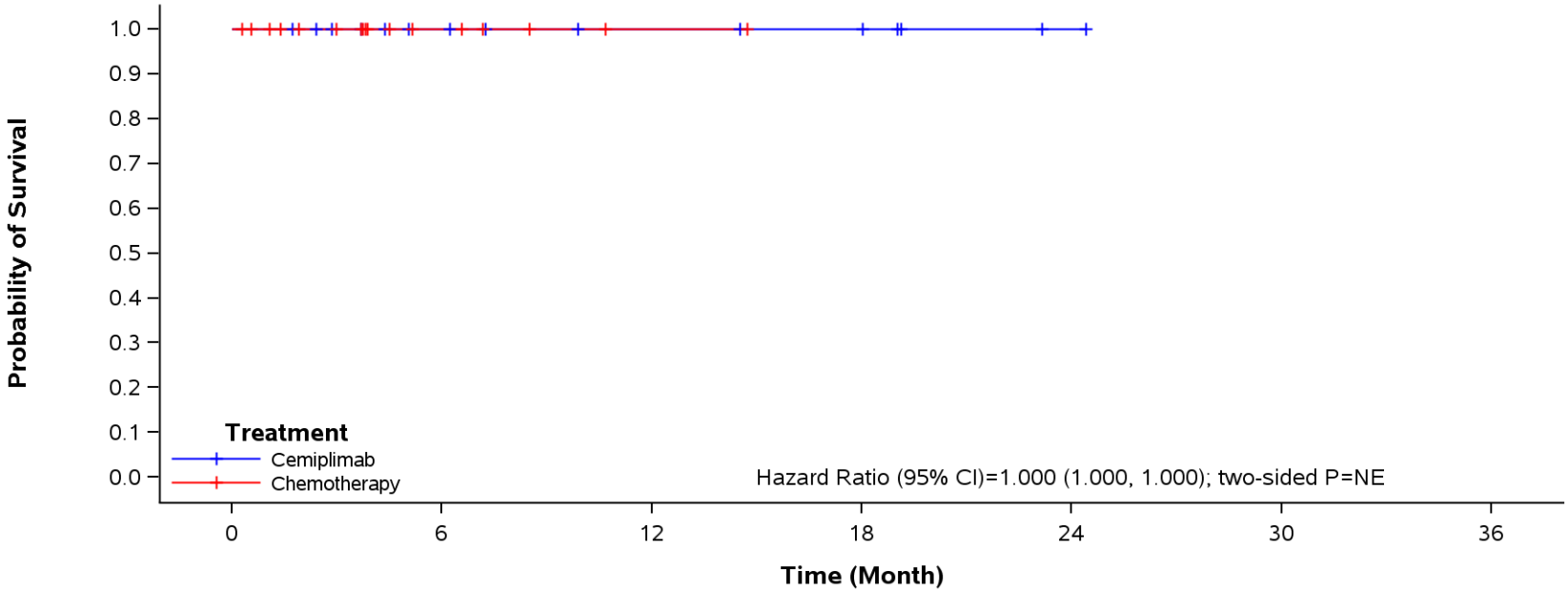

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



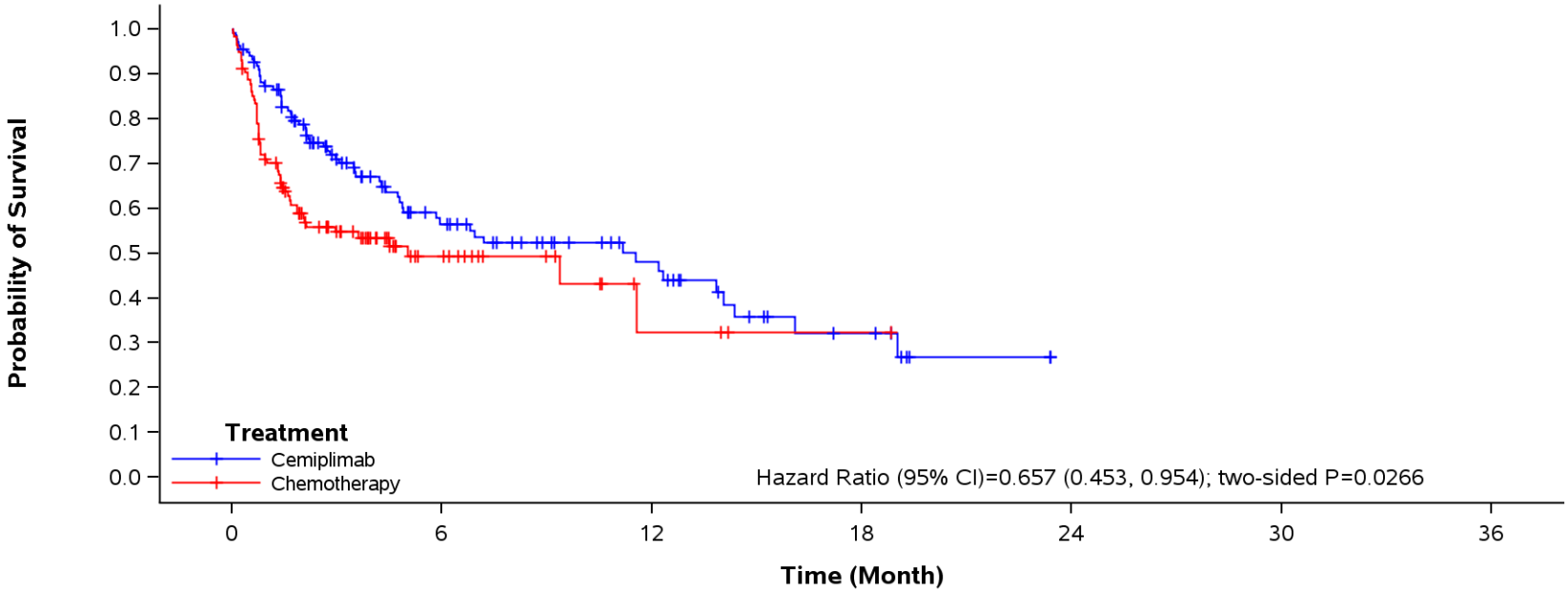

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Number of patients with any TEAE CTCAE Grade >= 3



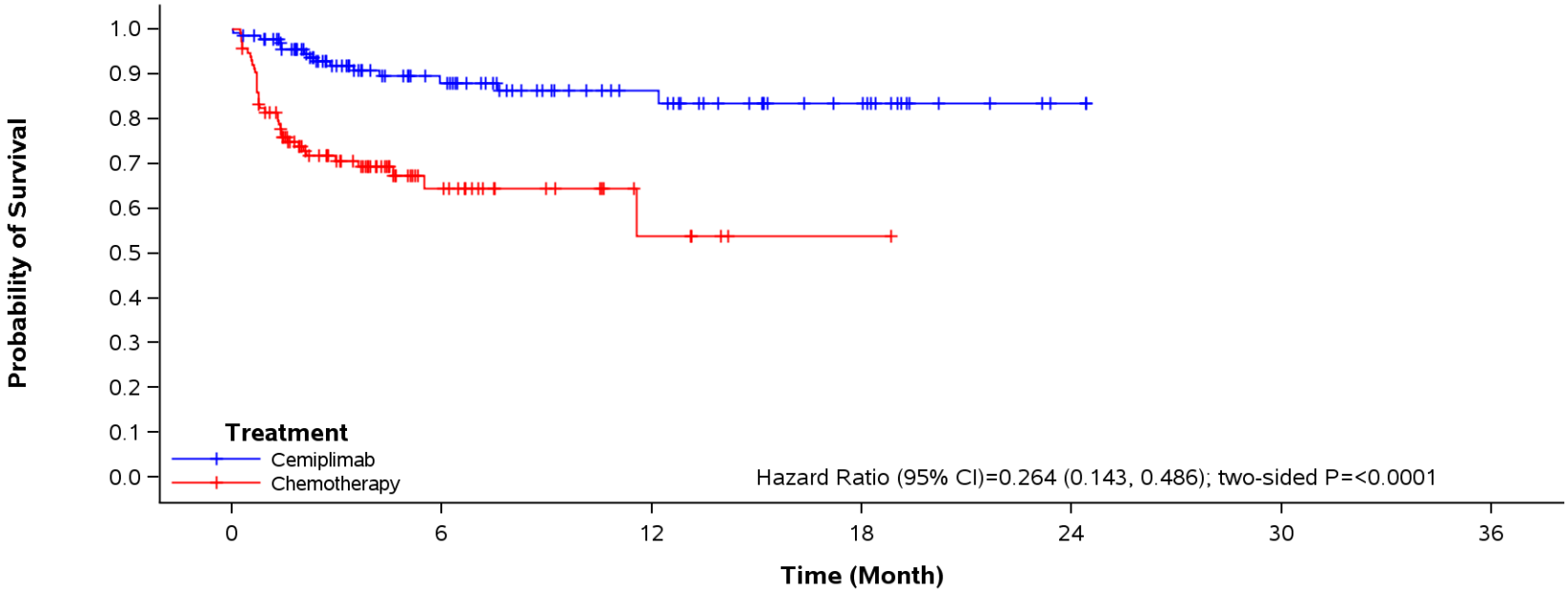

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 44 | 23 | 8 | 0 | 0 | 0 |
| Chemotherapy | 115 | 19 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders



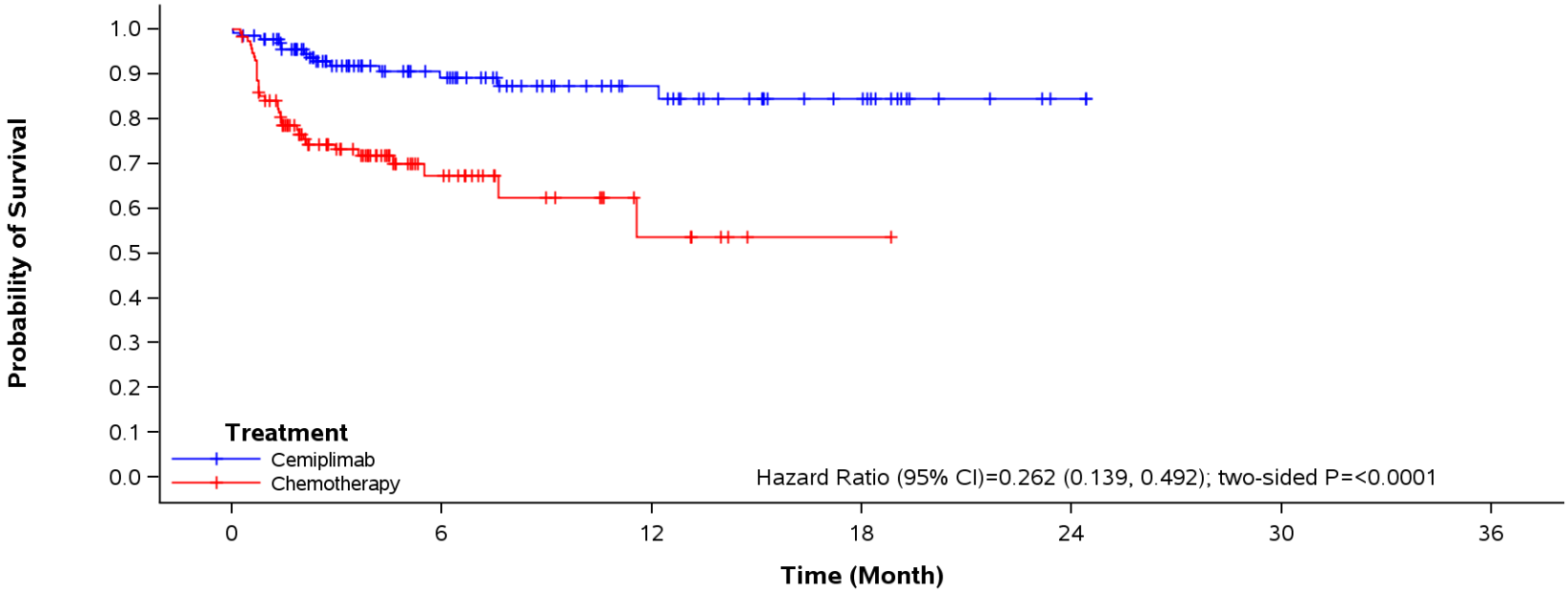

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 61 | 31 | 16 | 2 | 0 | 0 |
| Chemotherapy | 115 | 24 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Anaemia



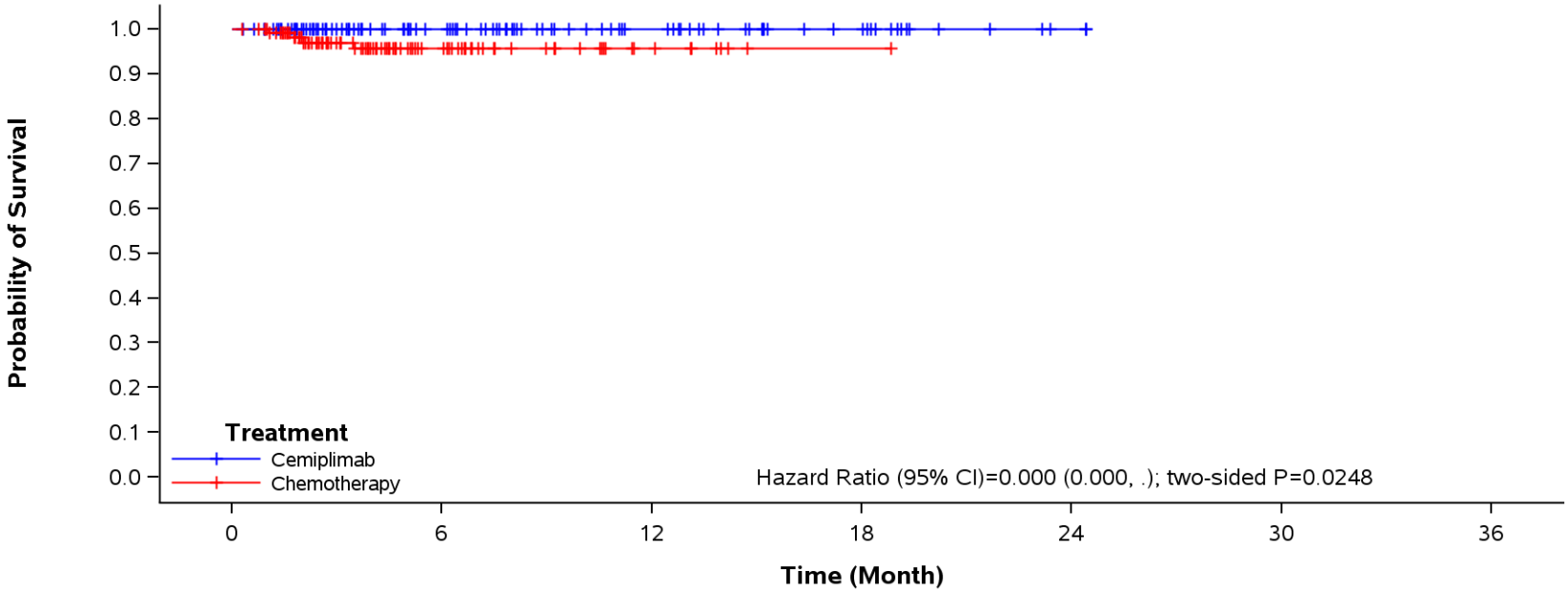

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 62 | 31 | 16 | 2 | 0 | 0 |
| Chemotherapy | 115 | 26 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



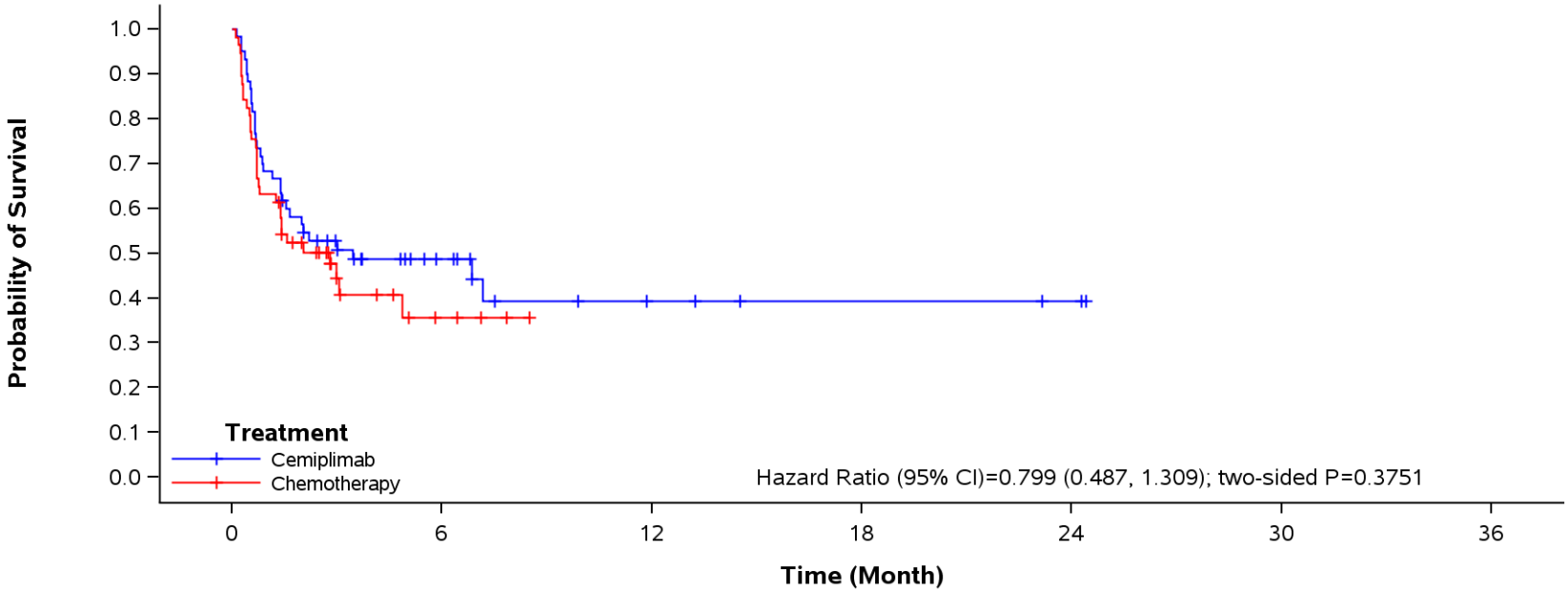

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 32 | 16 | 2 | 0 | 0 |
| Chemotherapy | 115 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Number of patients with any TEAE CTCAE Grade >= 3



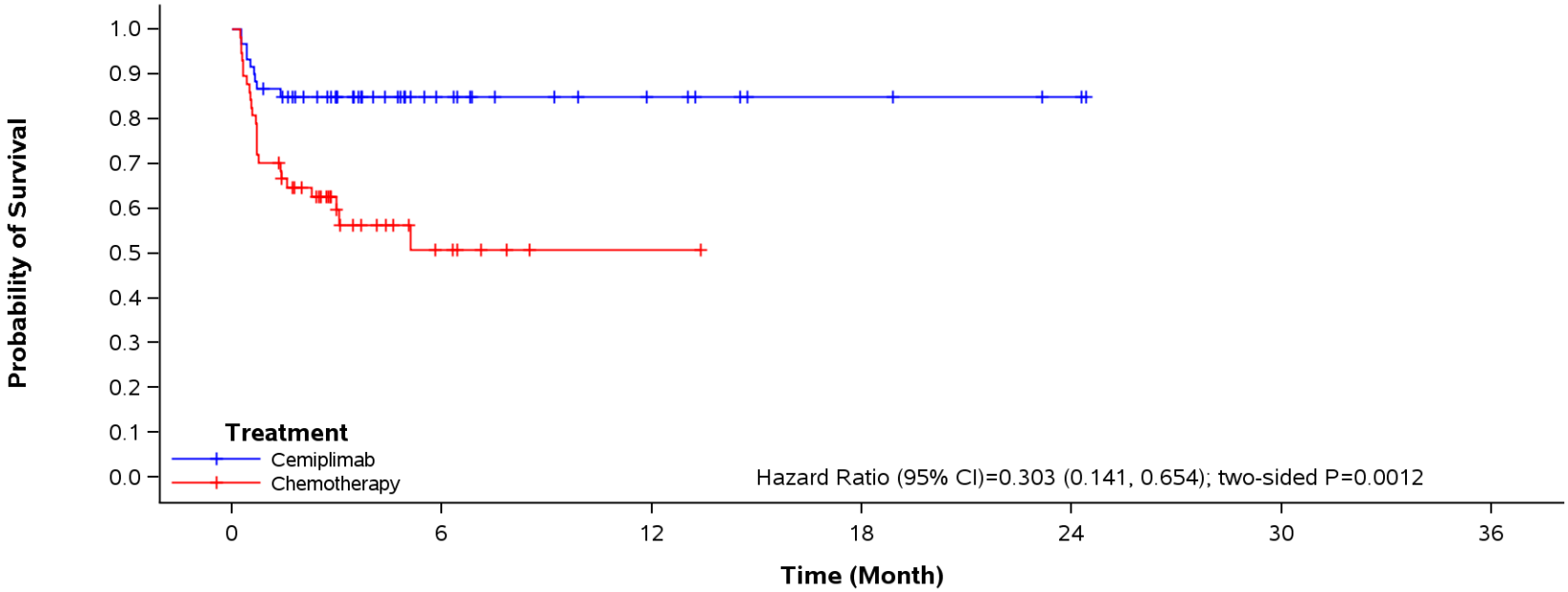

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 14 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 57 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders



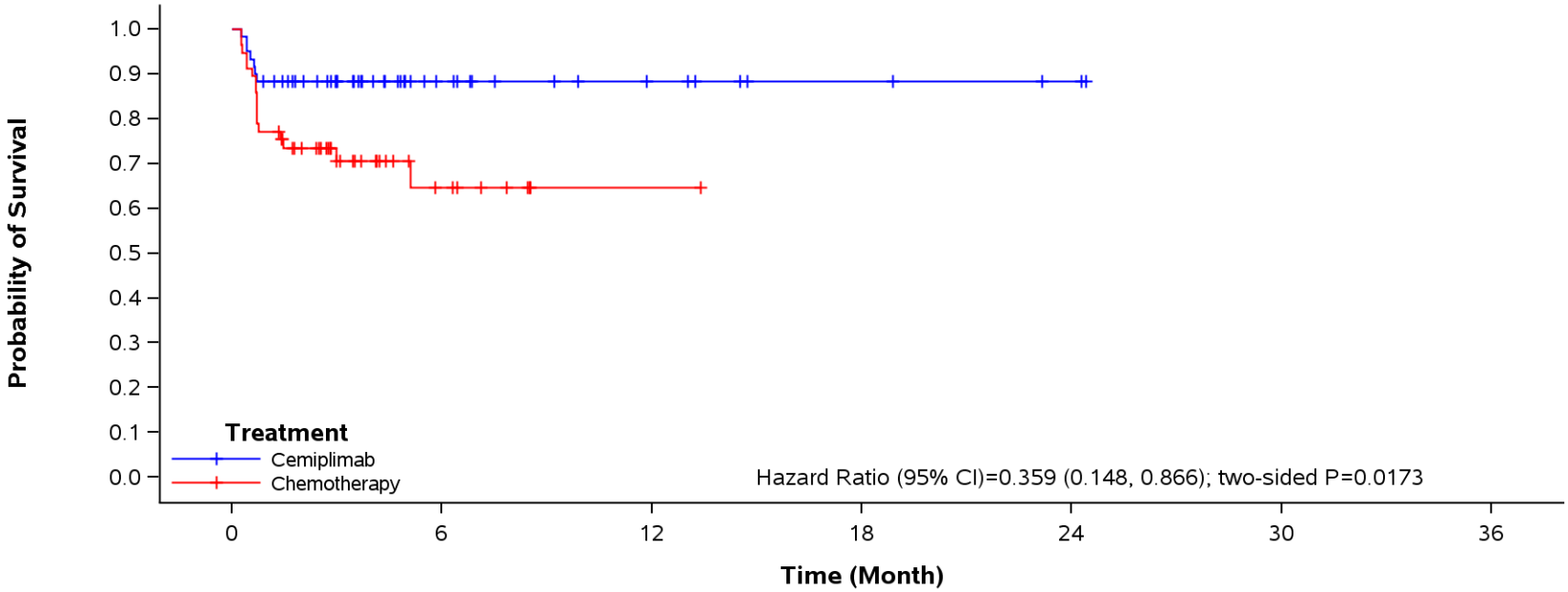

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 8 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Anaemia



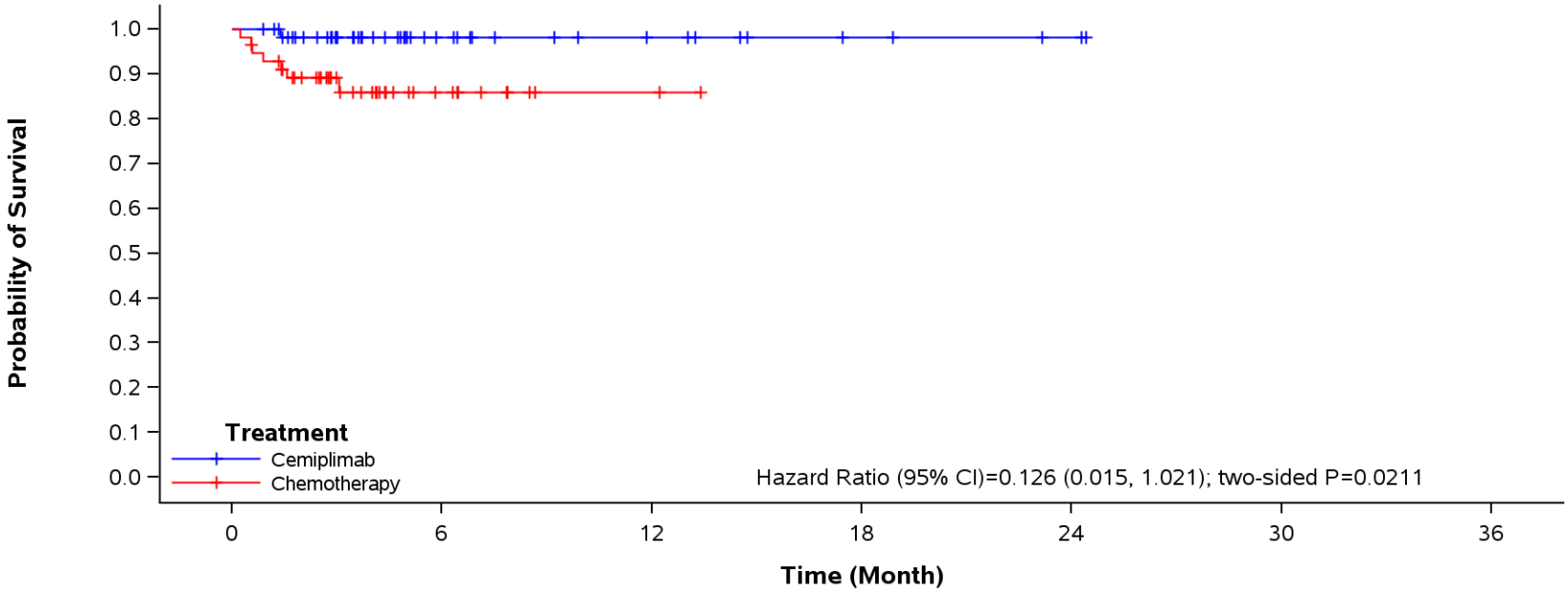

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 8 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



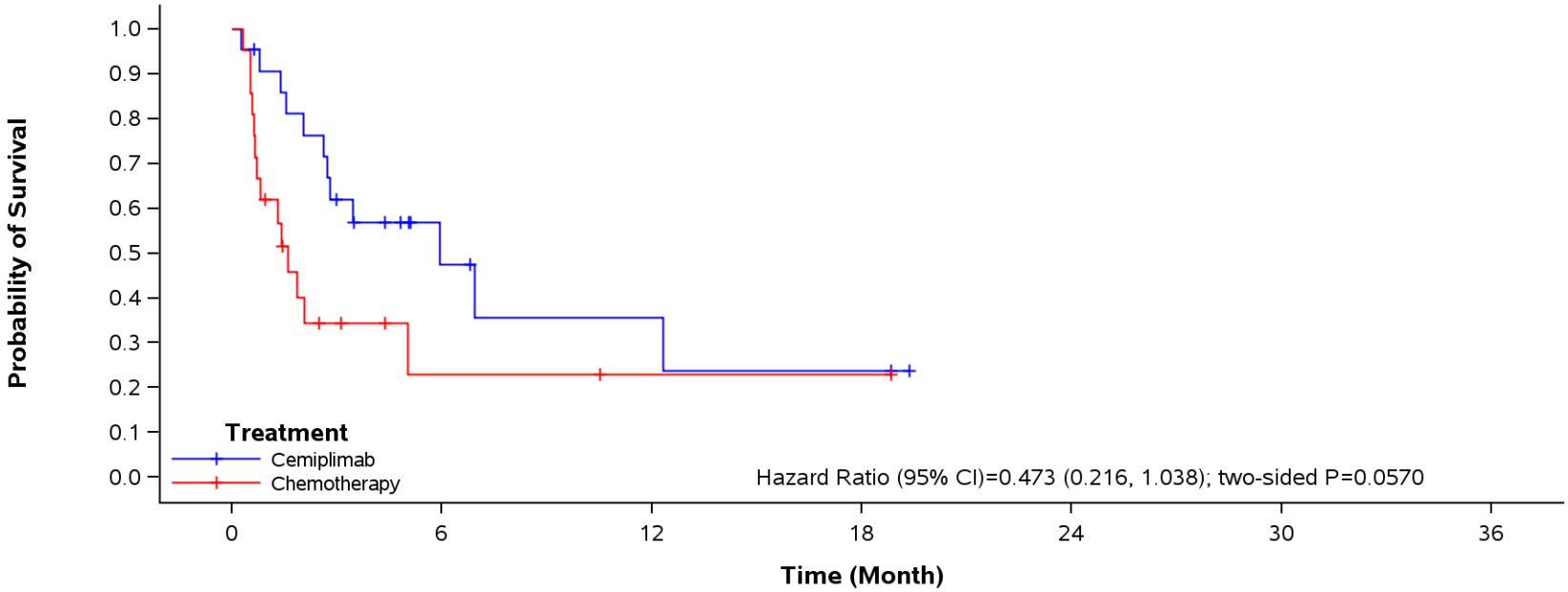

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 9 | 4 | 2 | 0 | 0 |
| Chemotherapy | 57 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Number of patients with any TEAE CTCAE Grade >= 3



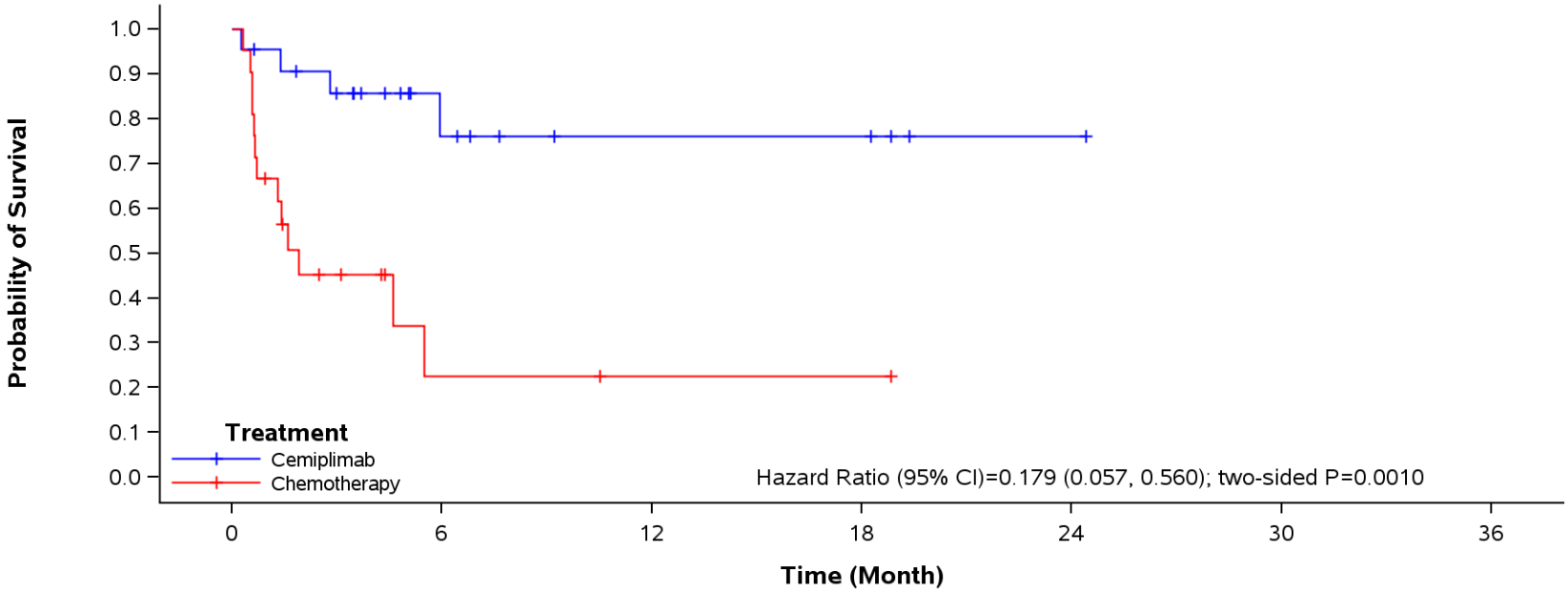

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 21 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders



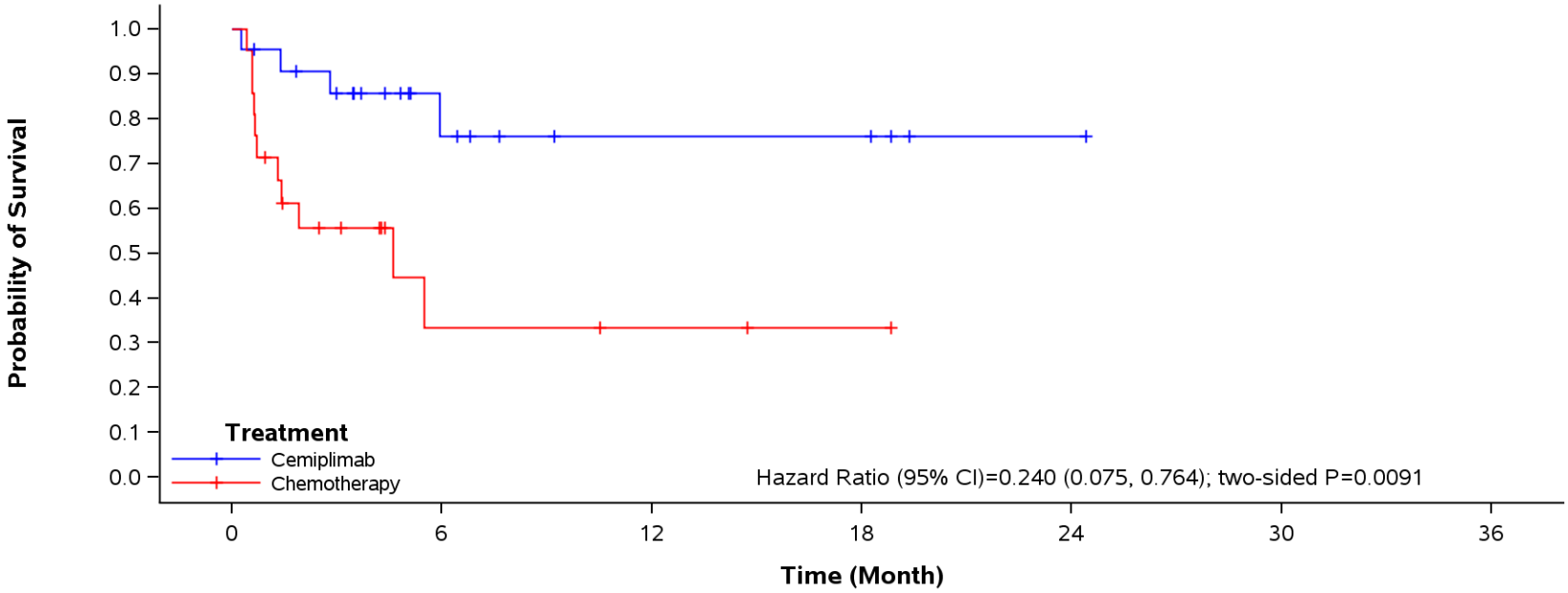

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Anaemia



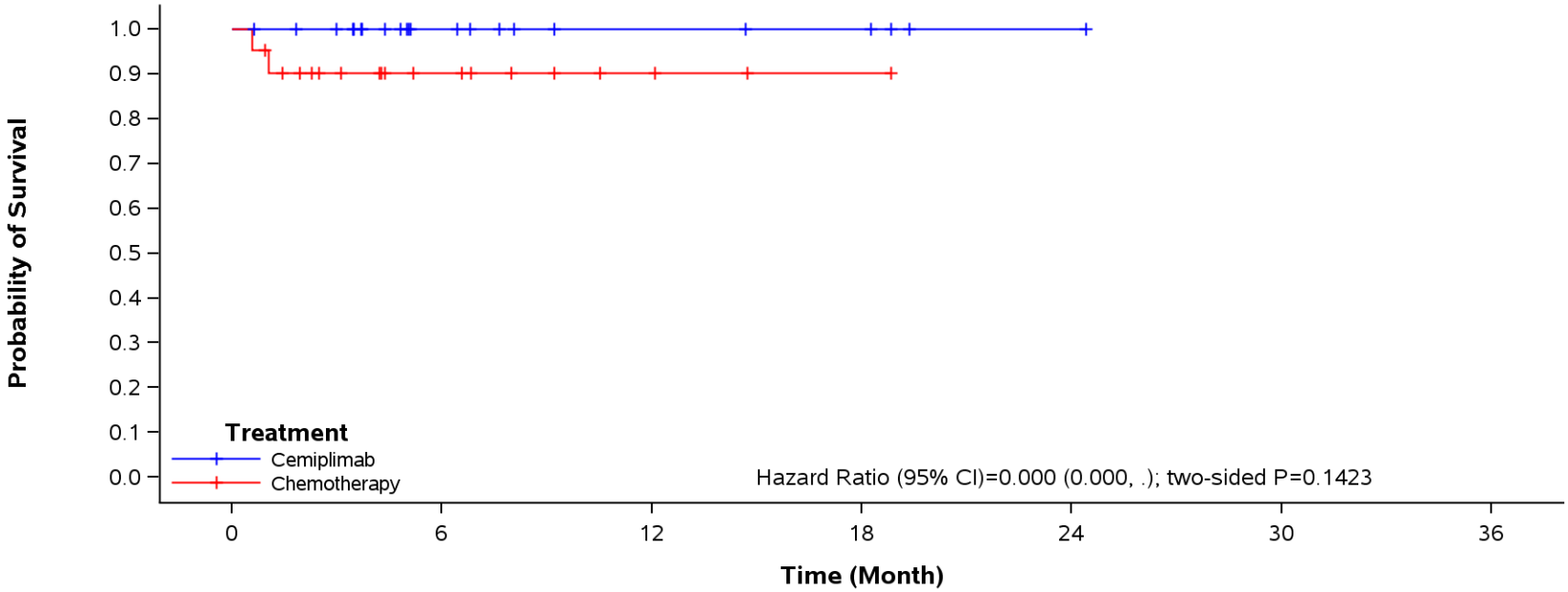

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 4 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 3 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Neutropenia



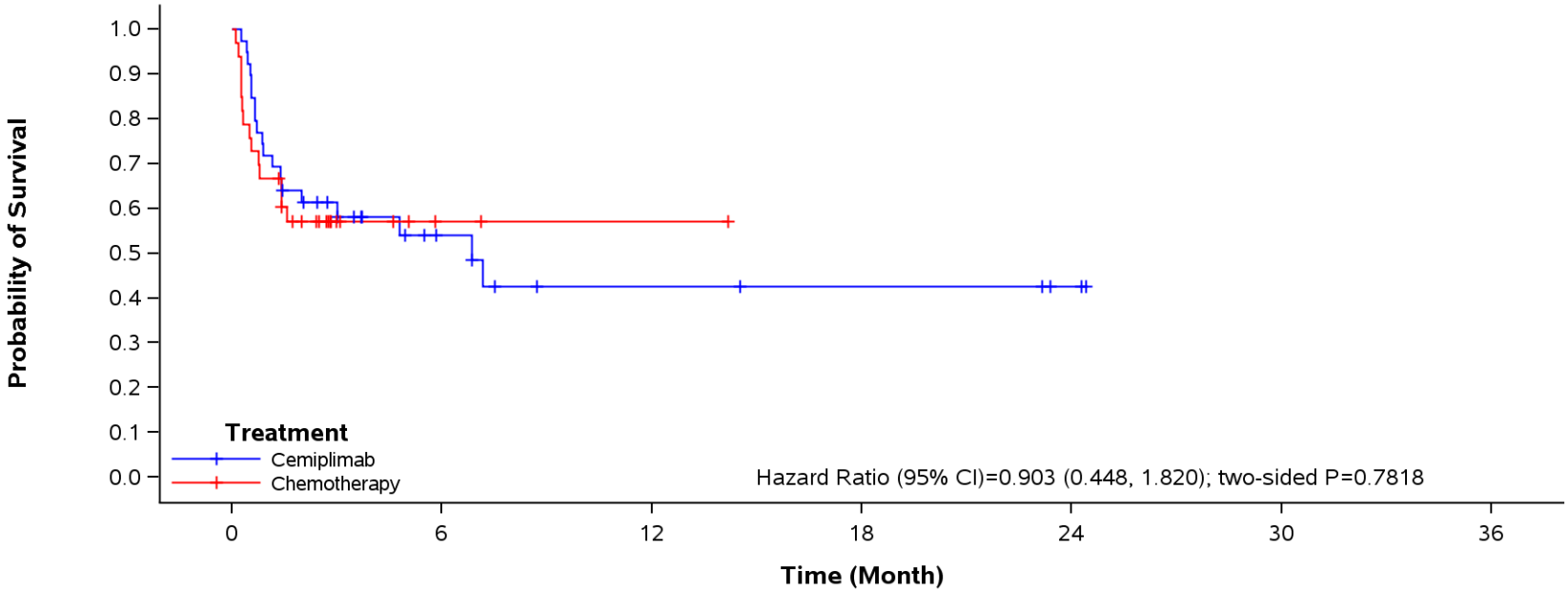

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 5 | 4 | 1 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Number of patients with any TEAE CTCAE Grade >= 3



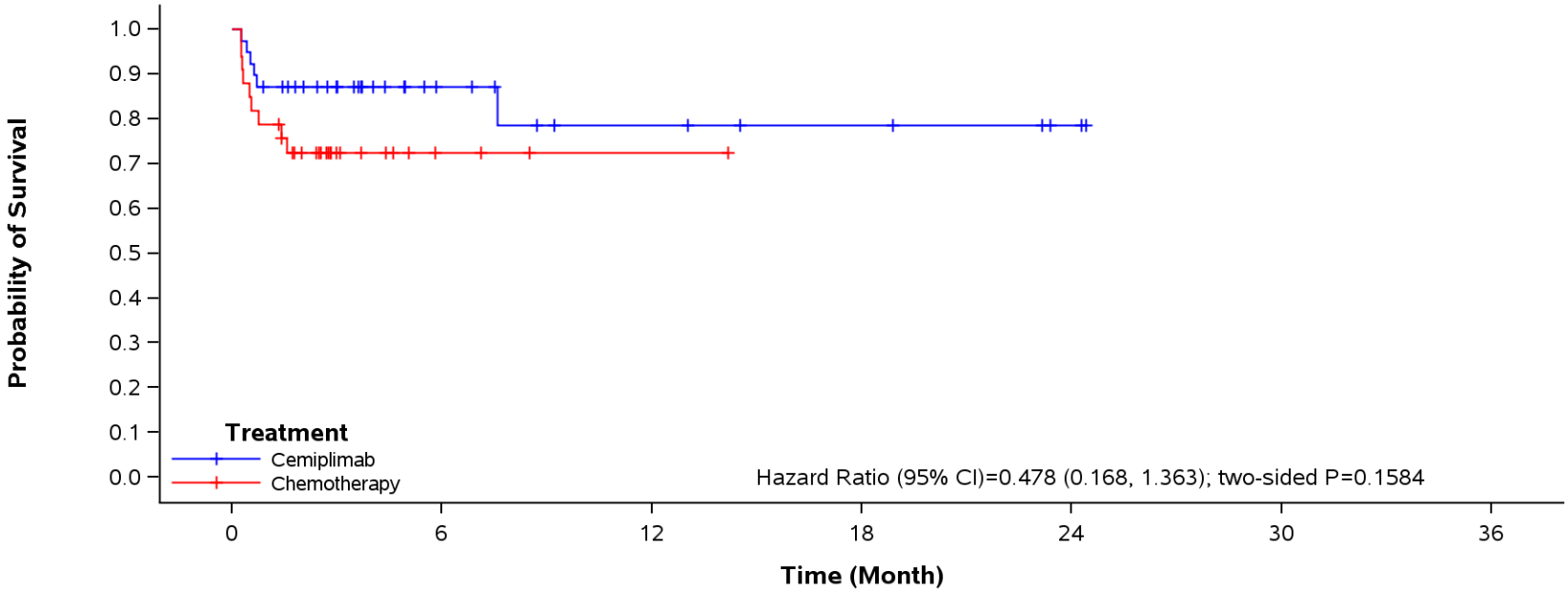

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 5 | 4 | 2 | 0 | 0 |
| Chemotherapy | 33 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders



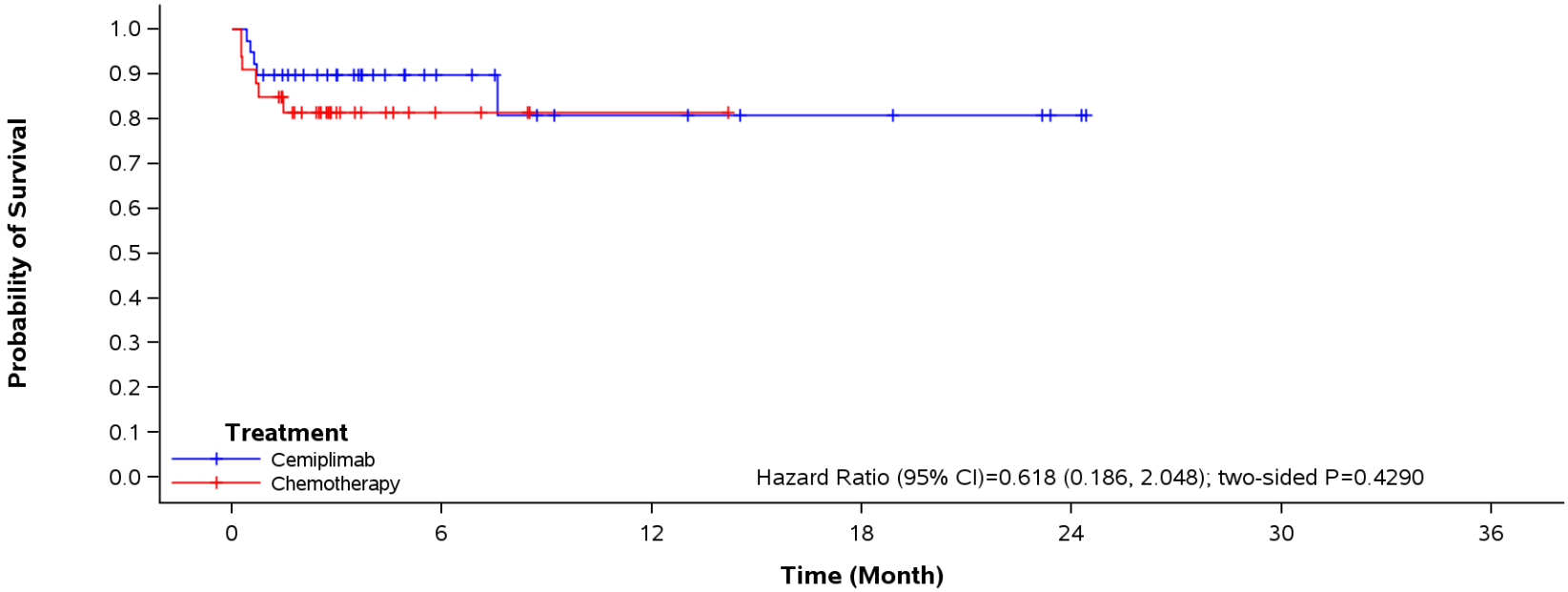

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Anaemia



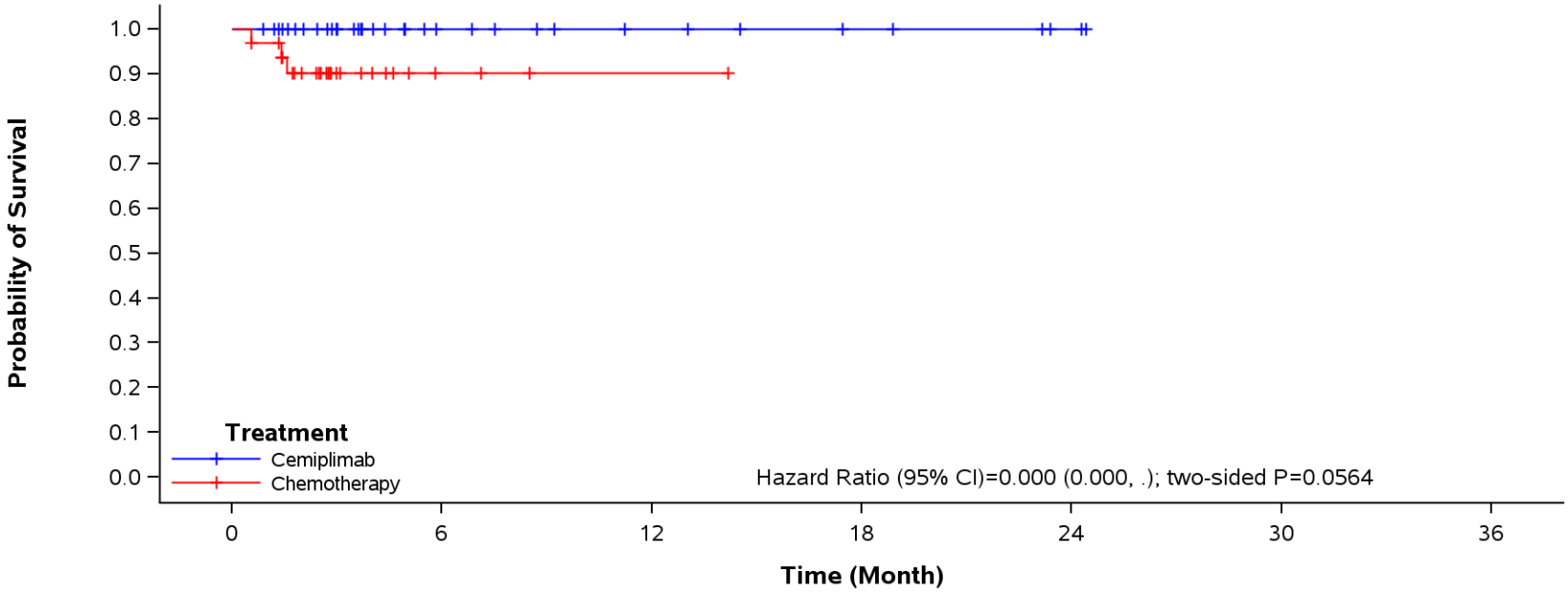

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Neutropenia



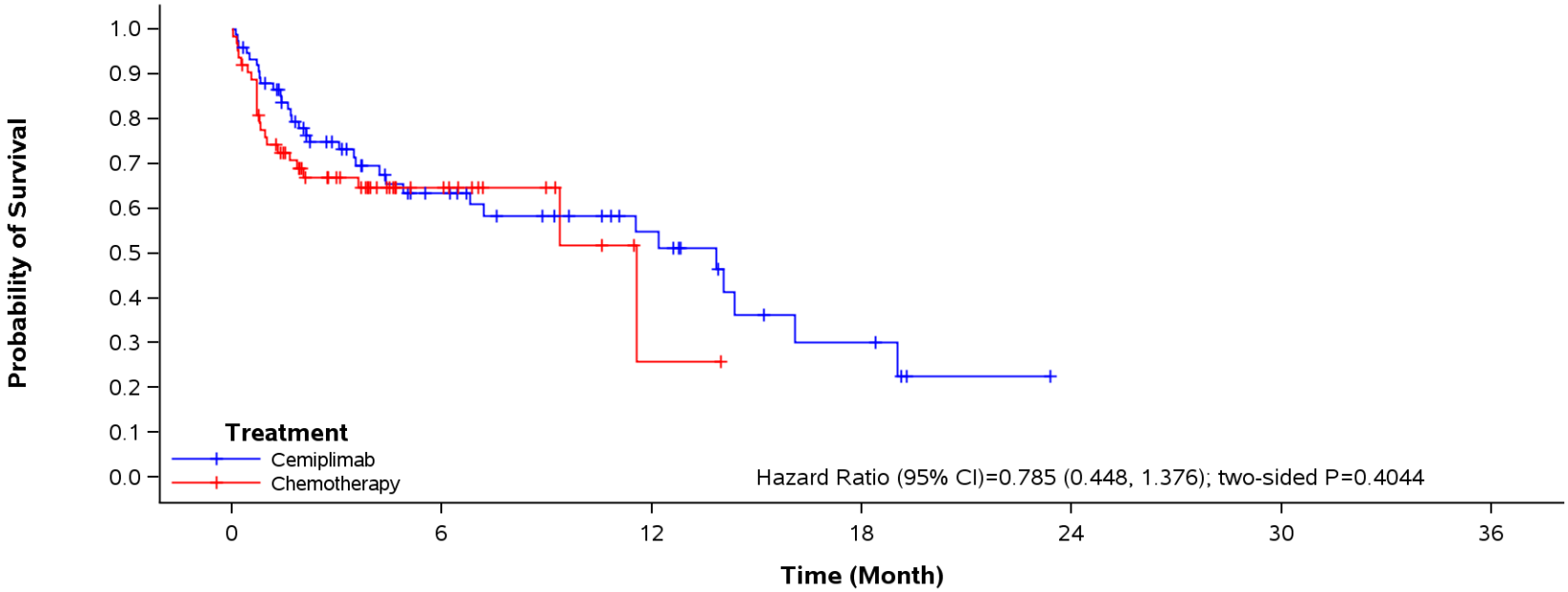

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 5 | 2 | 0 | 0 |
| Chemotherapy | 33 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Number of patients with any TEAE CTCAE Grade >= 3



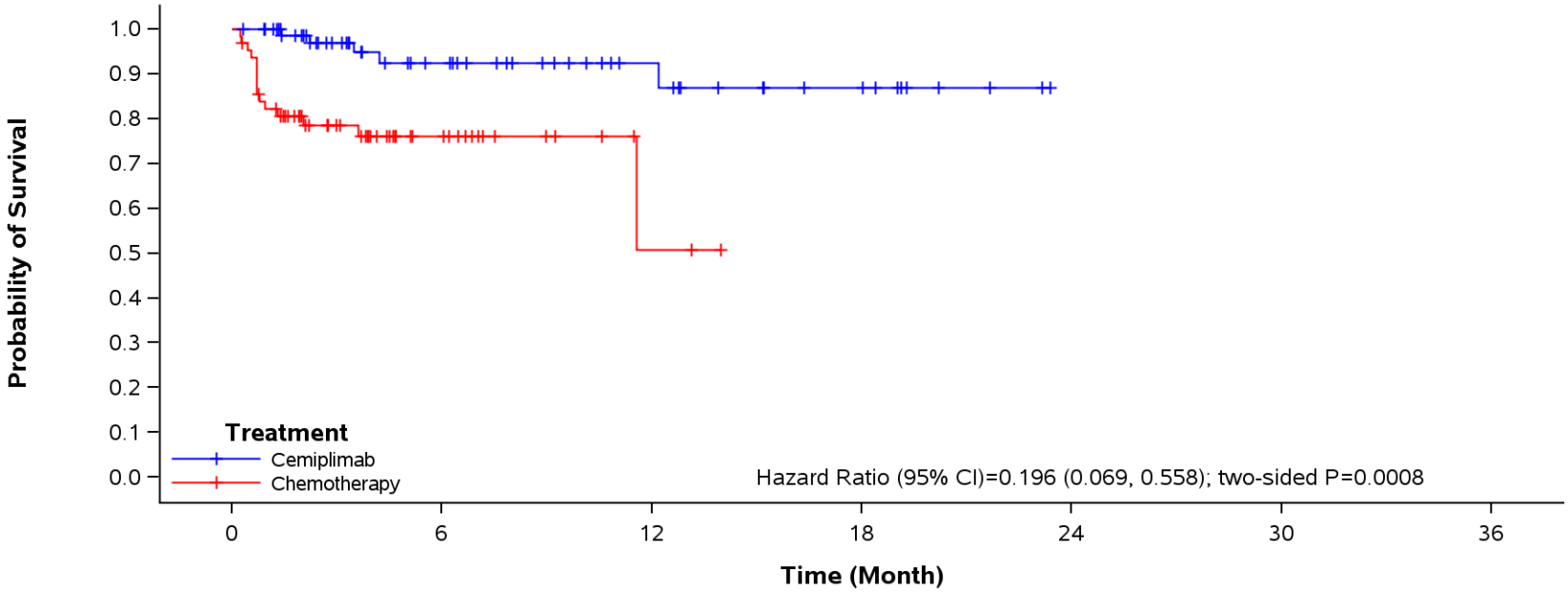

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 28 | 15 | 5 | 0 | 0 | 0 |
| Chemotherapy | 63 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders



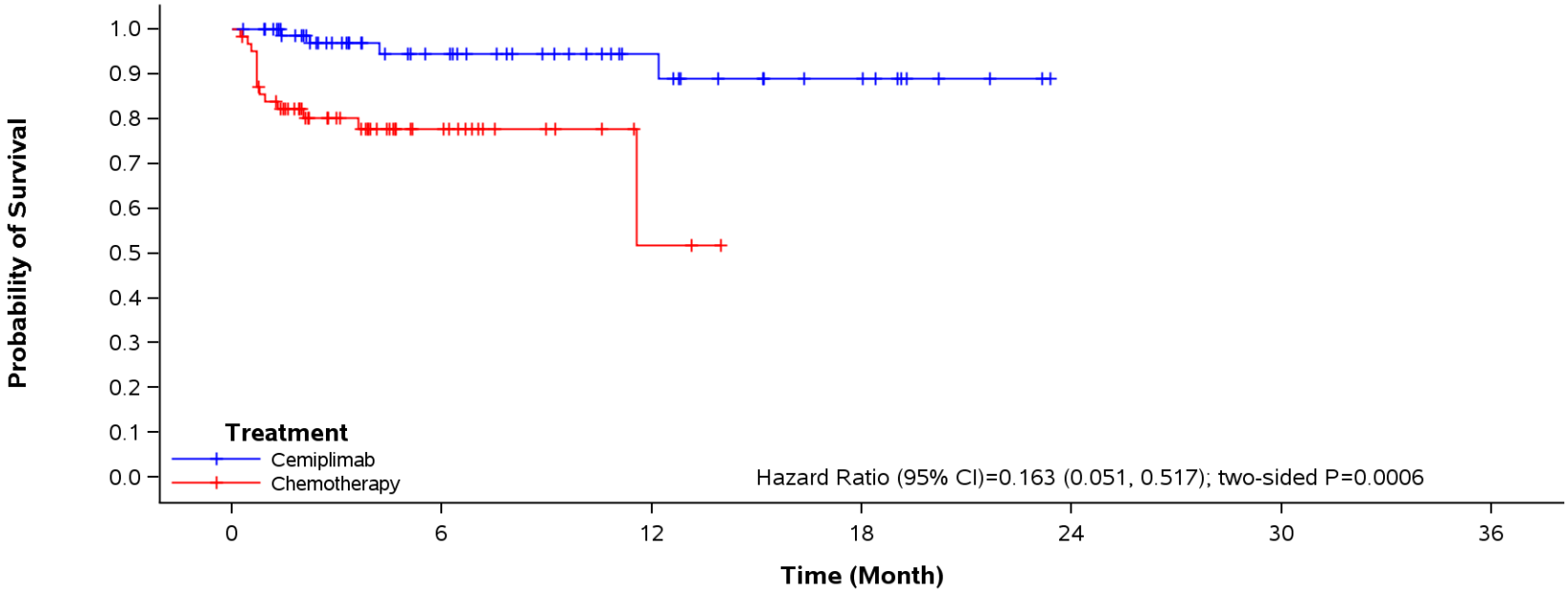

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 33 | 17 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Anaemia



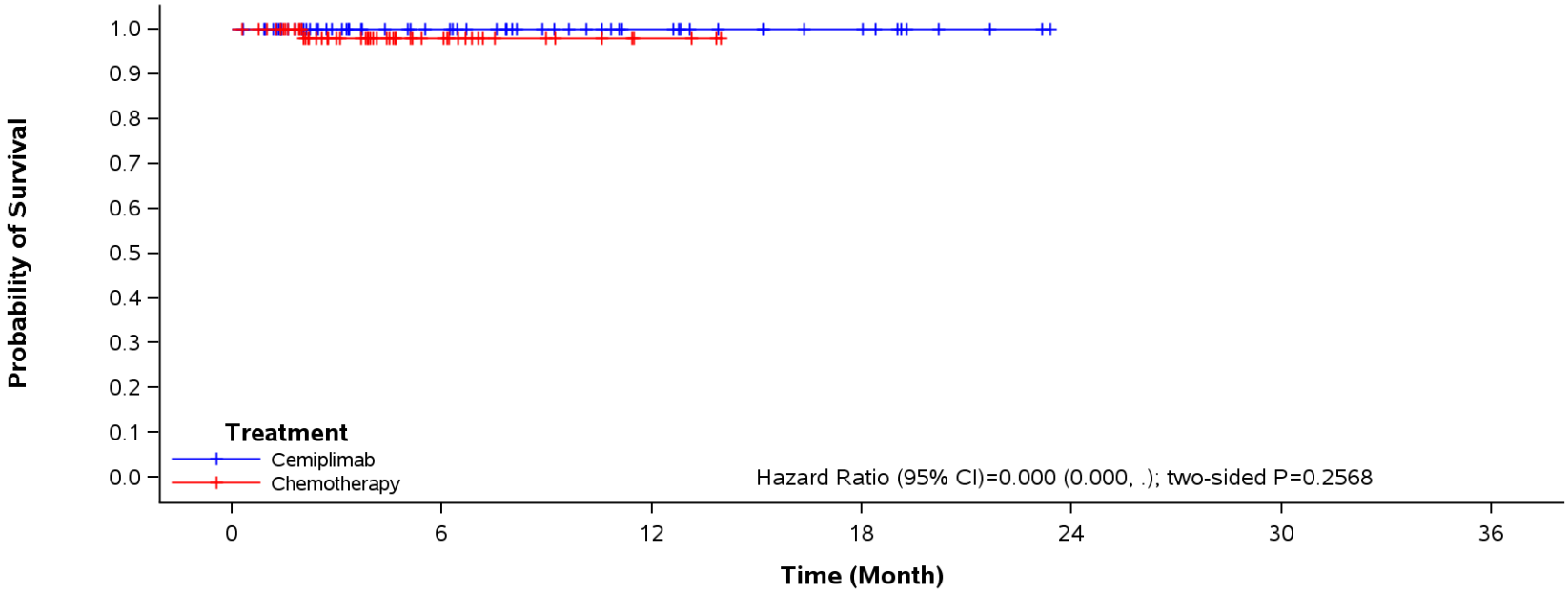

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 34 | 17 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Neutropenia



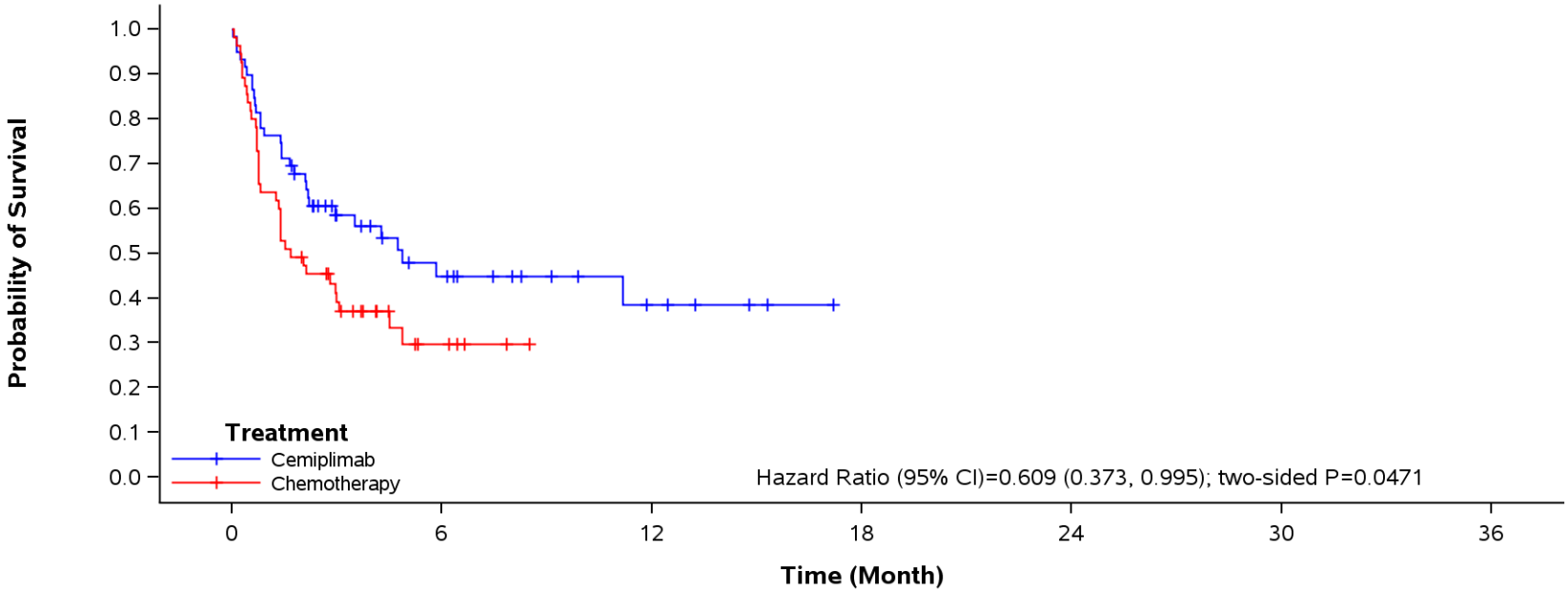

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 17 | 9 | 0 | 0 | 0 |
| Chemotherapy | 63 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Number of patients with any TEAE CTCAE Grade >= 3



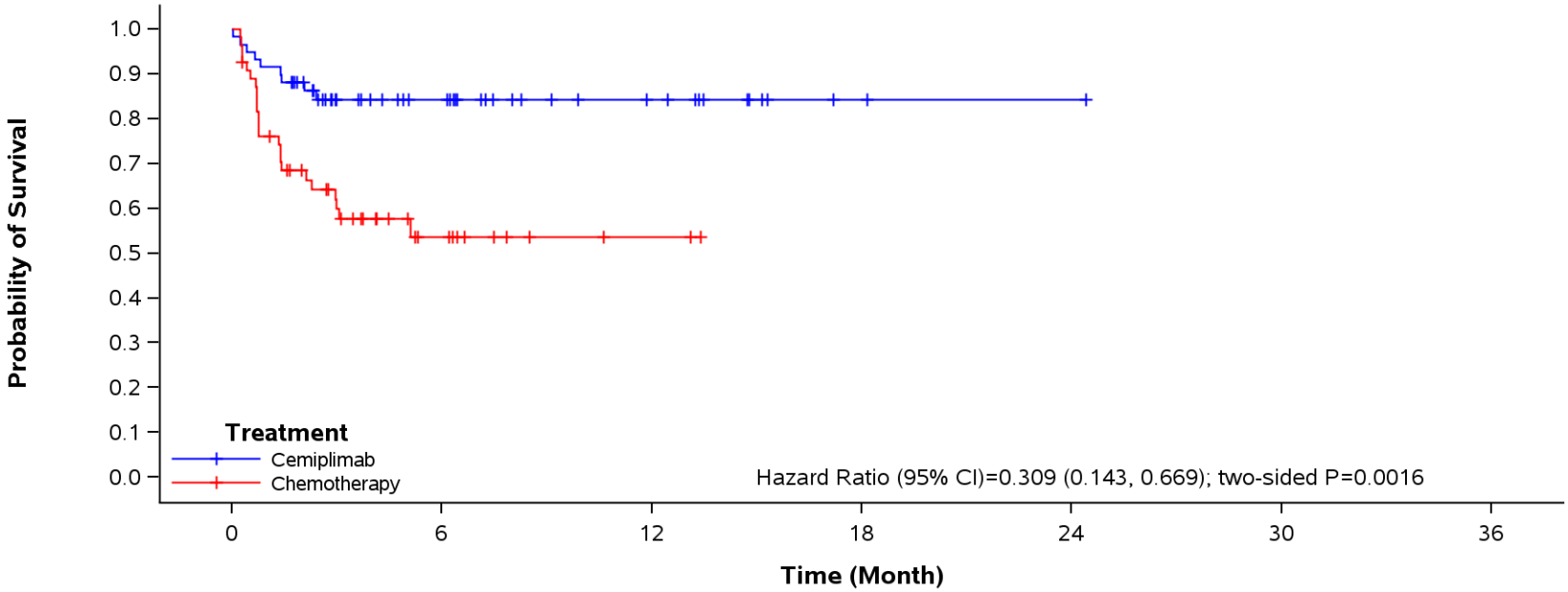

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 15 | 5 | 0 | 0 | 0 | 0 |
| Chemotherapy | 55 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders



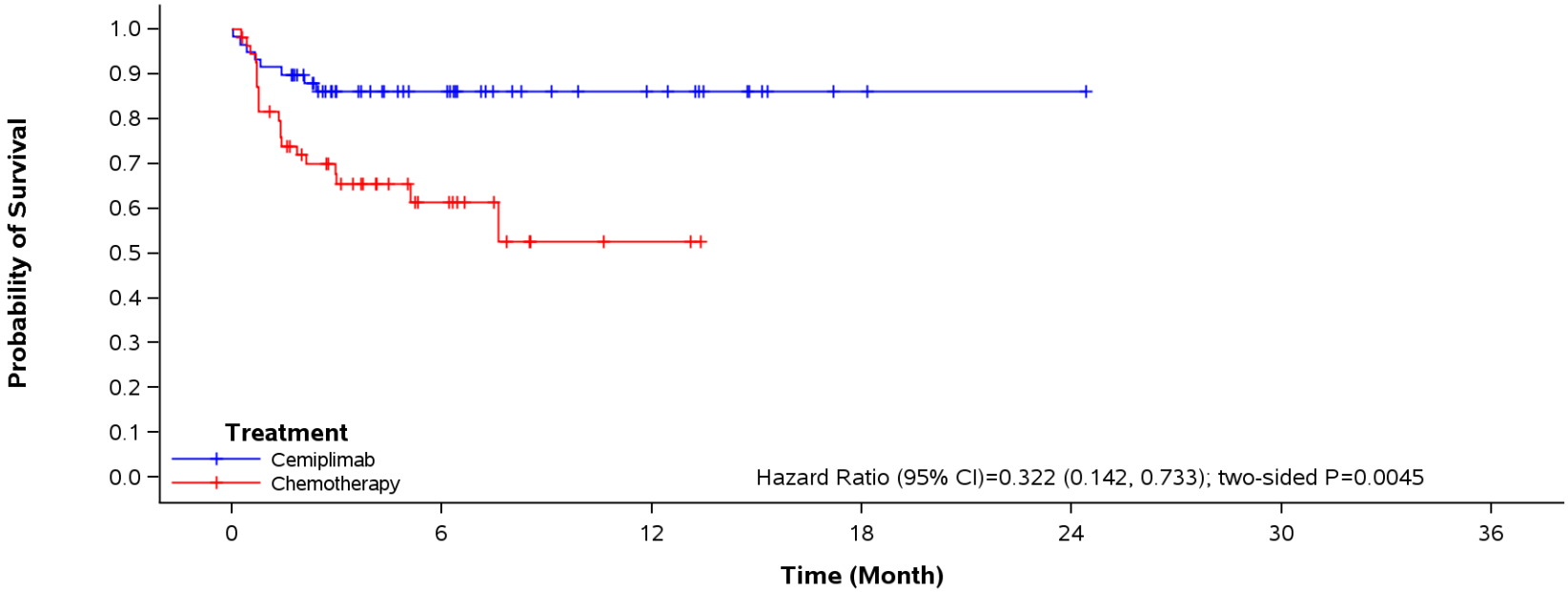

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 11 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Anaemia



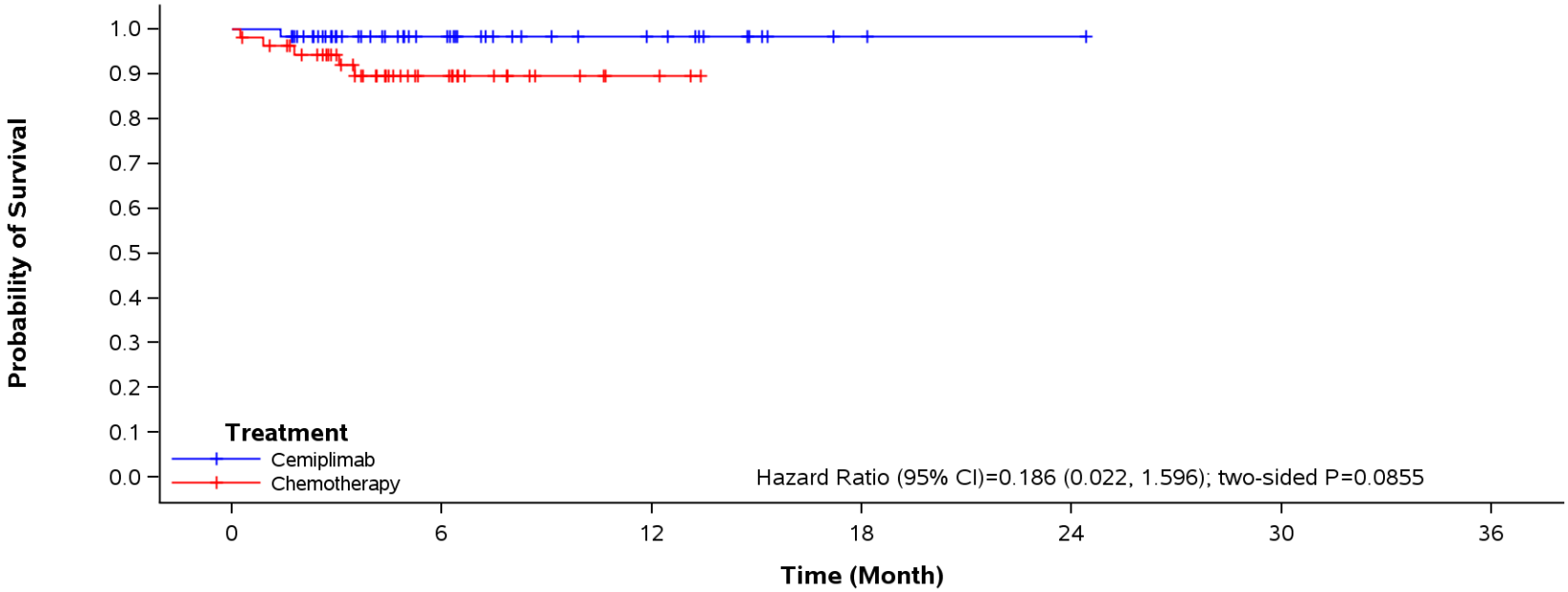

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 11 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Neutropenia



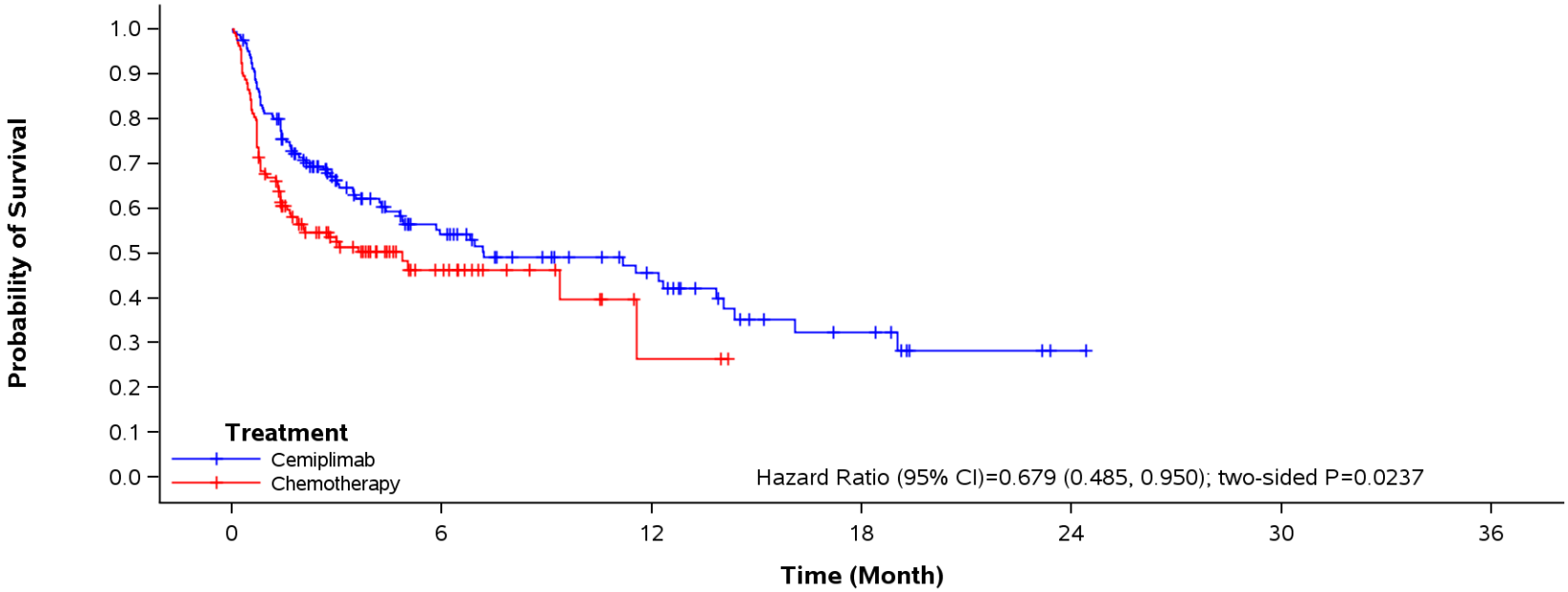

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 11 | 2 | 1 | 0 | 0 |
| Chemotherapy | 55 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Number of patients with any TEAE CTCAE Grade >= 3



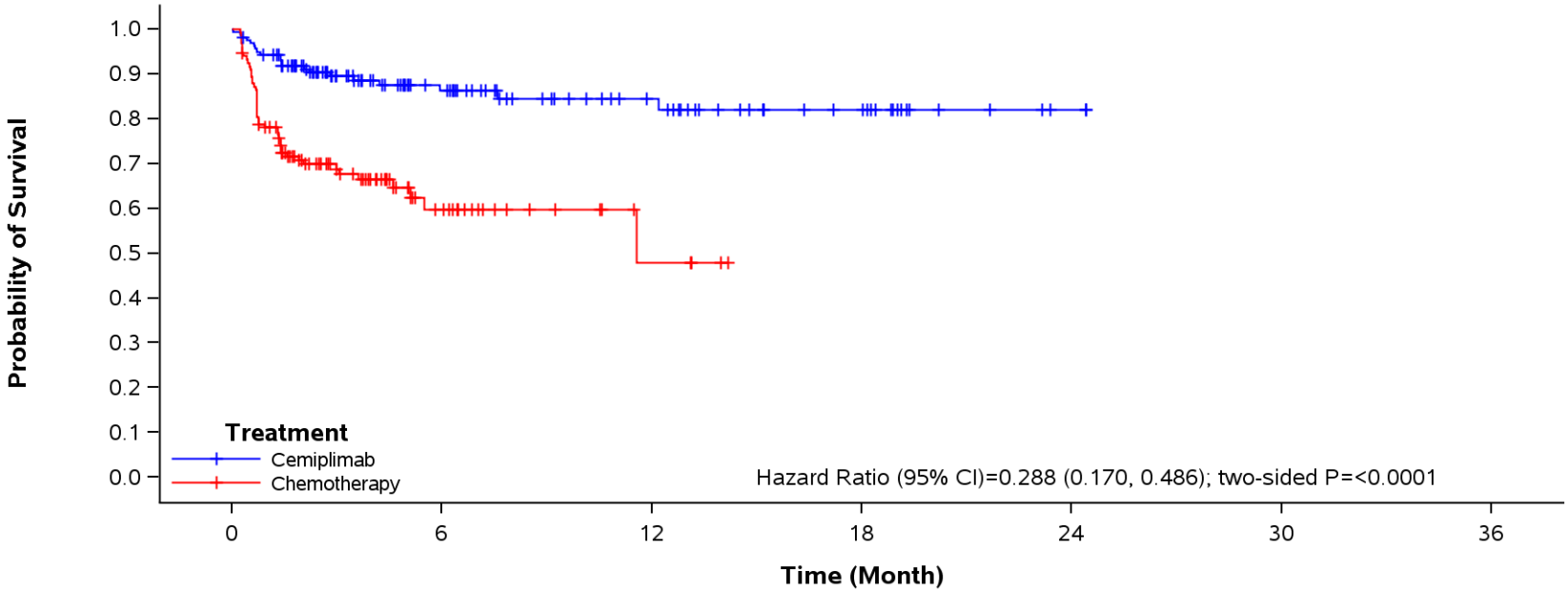

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 49 | 26 | 10 | 1 | 0 | 0 |
| Chemotherapy | 133 | 19 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders



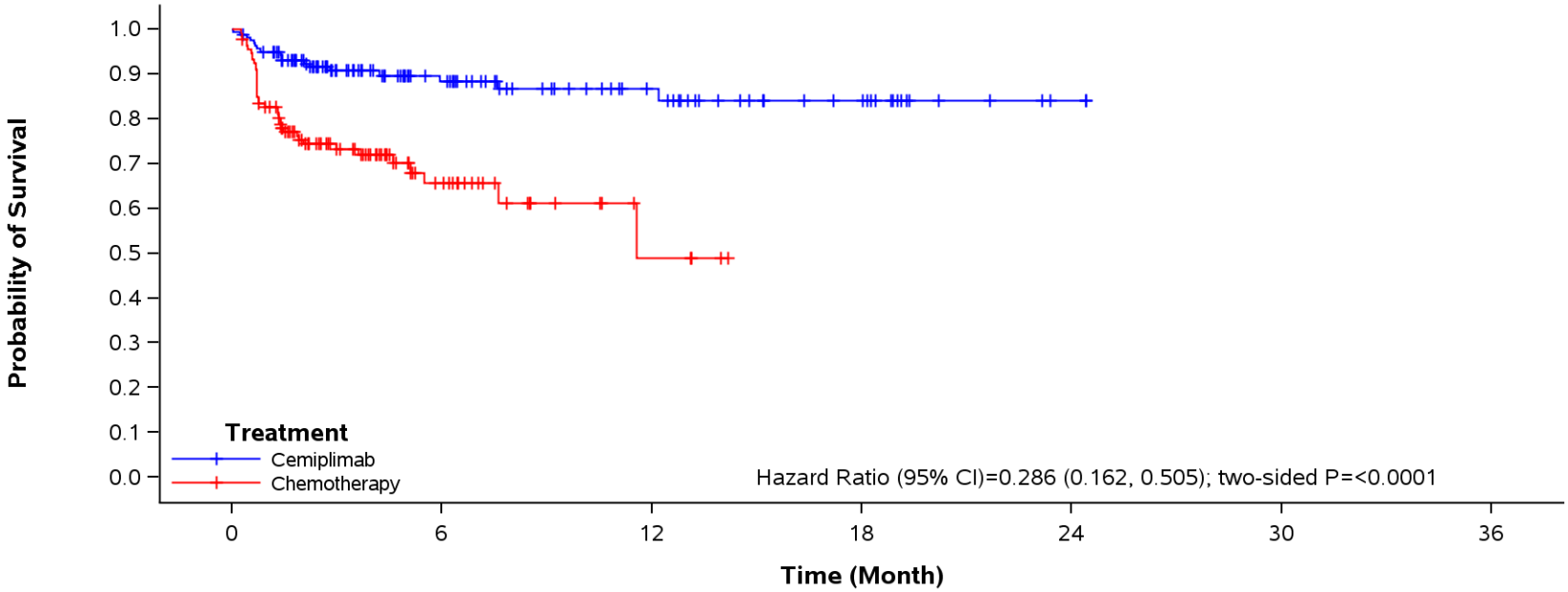

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 67 | 34 | 19 | 3 | 0 | 0 |
| Chemotherapy | 133 | 23 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



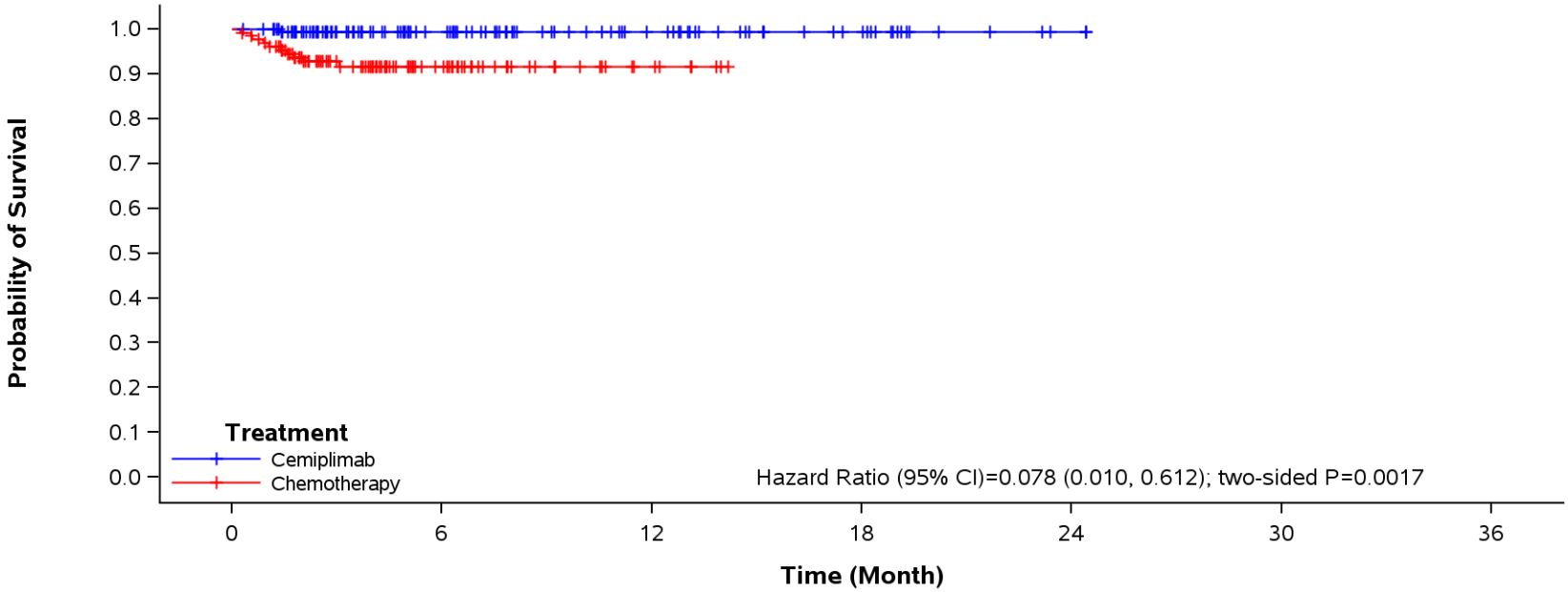

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 68 | 34 | 19 | 3 | 0 | 0 |
| Chemotherapy | 133 | 26 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



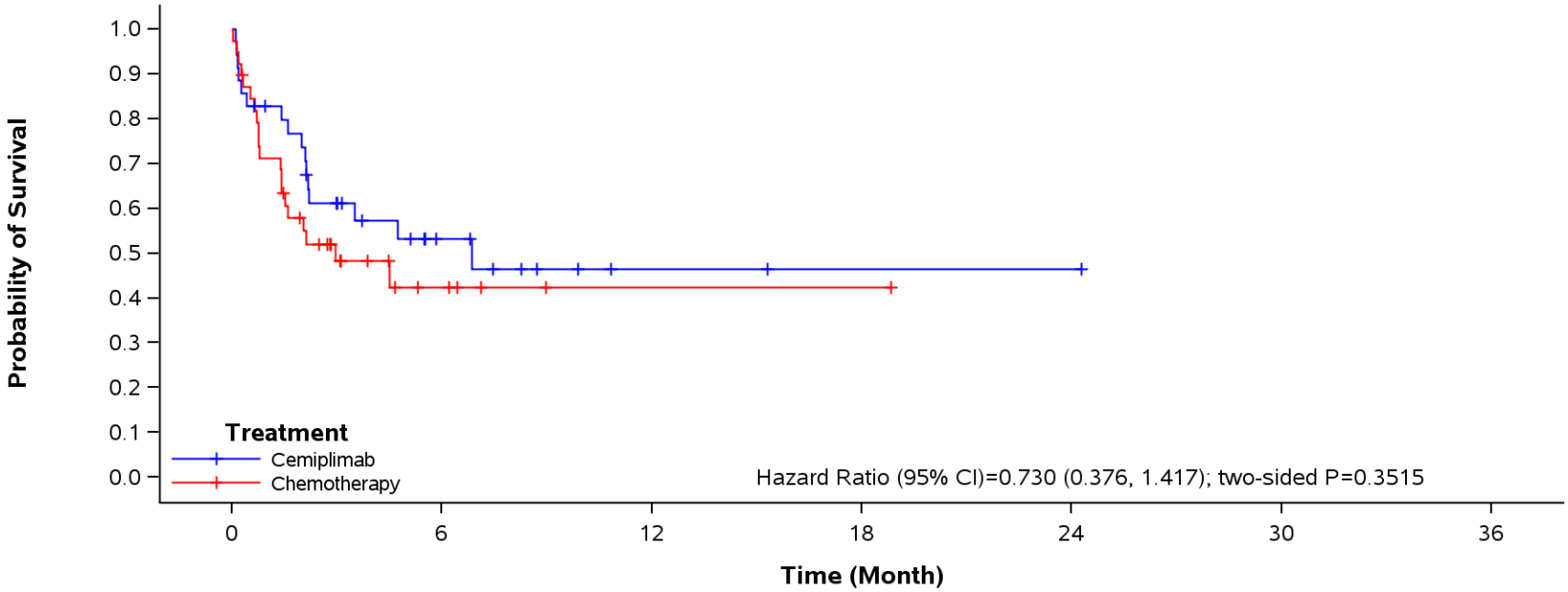

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 36 | 19 | 3 | 0 | 0 |
| Chemotherapy | 133 | 37 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Number of patients with any TEAE CTCAE Grade >= 3



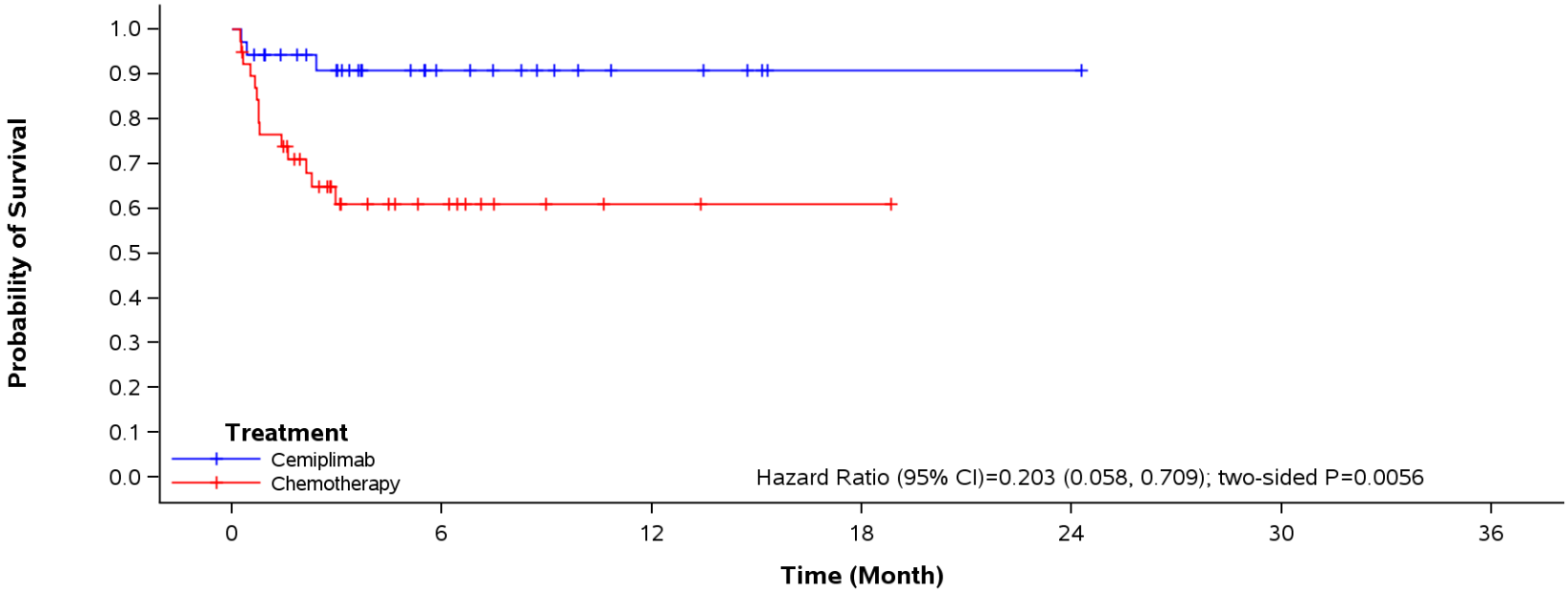

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders



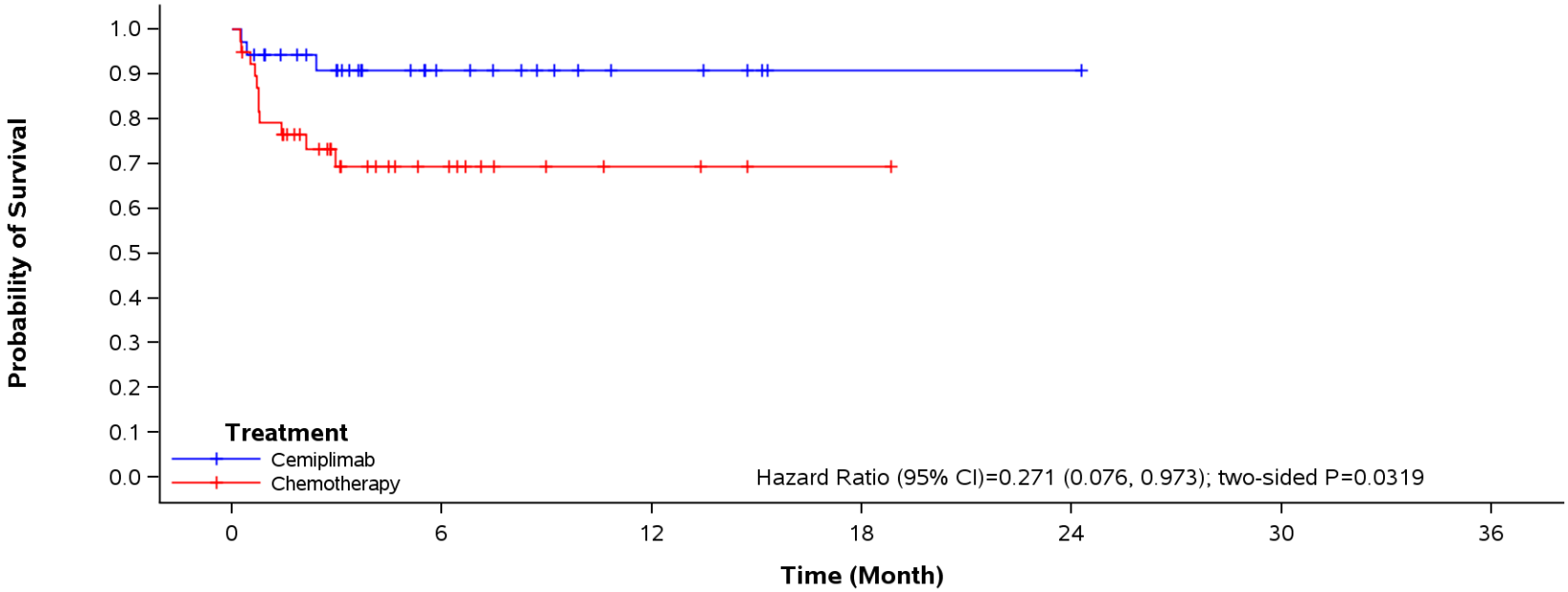

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



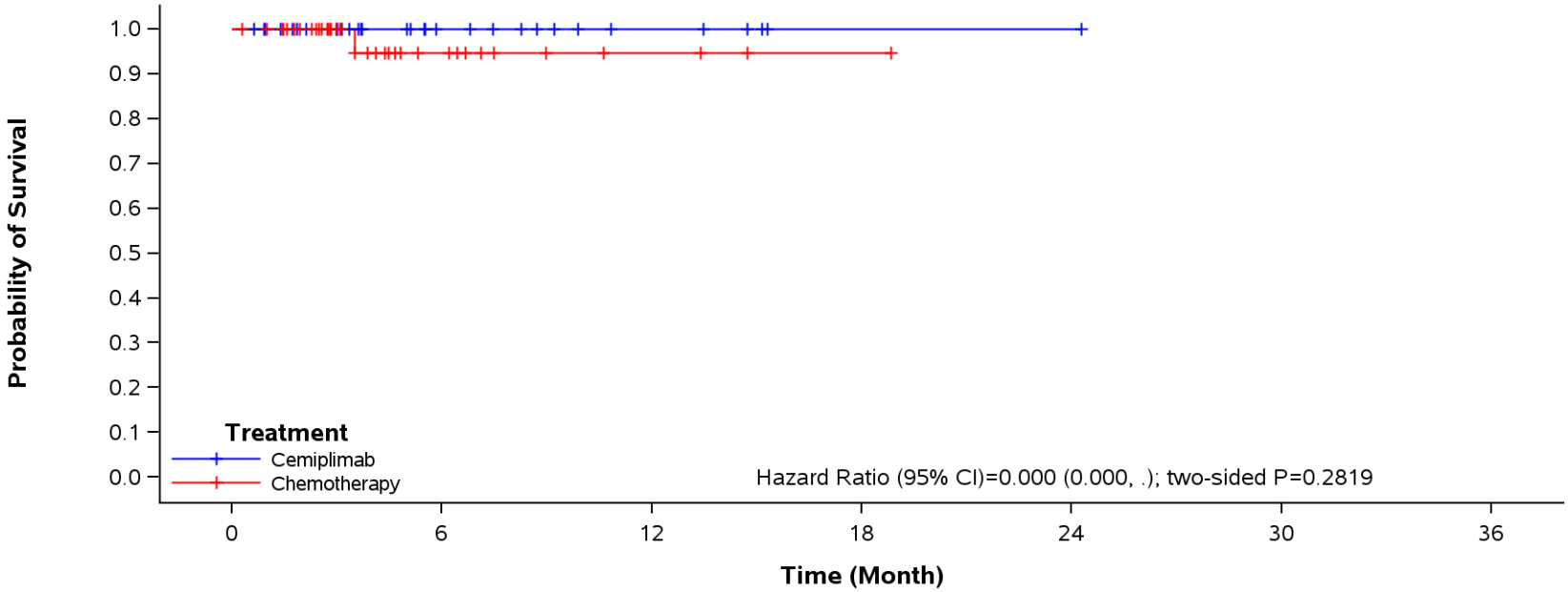

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



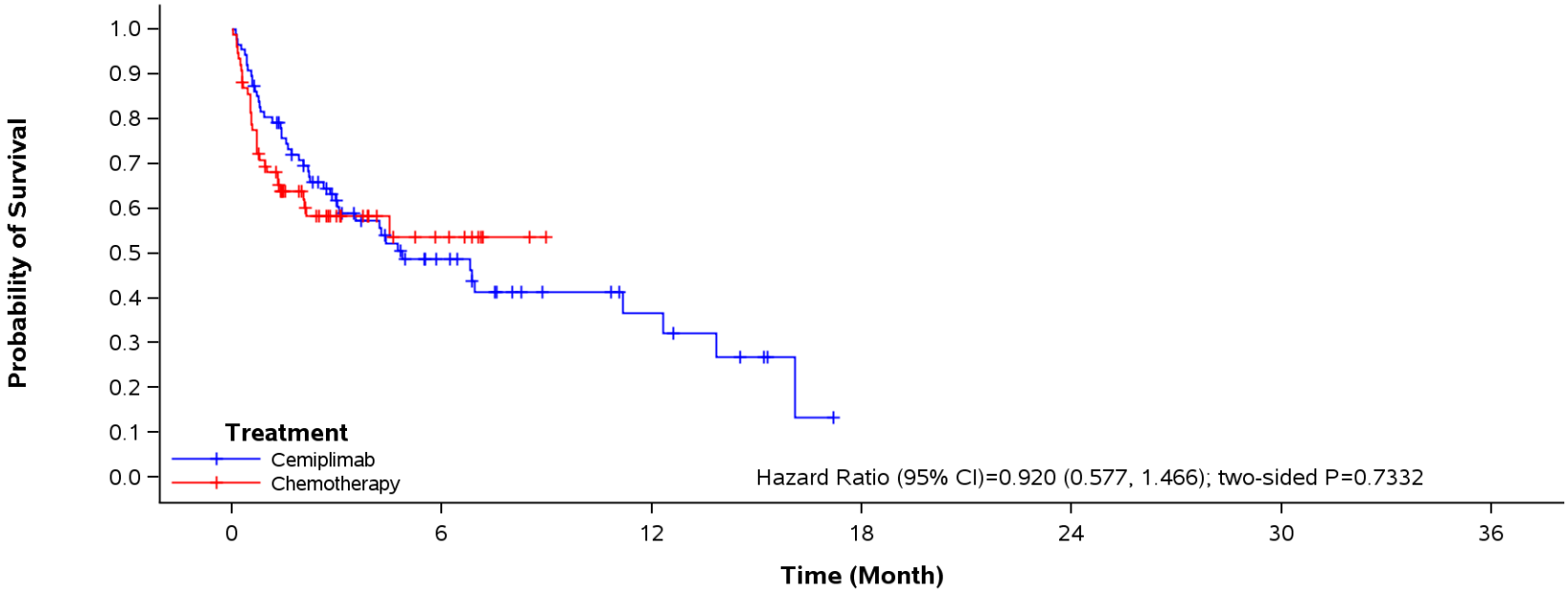

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 5 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Number of patients with any TEAE CTCAE Grade >= 3



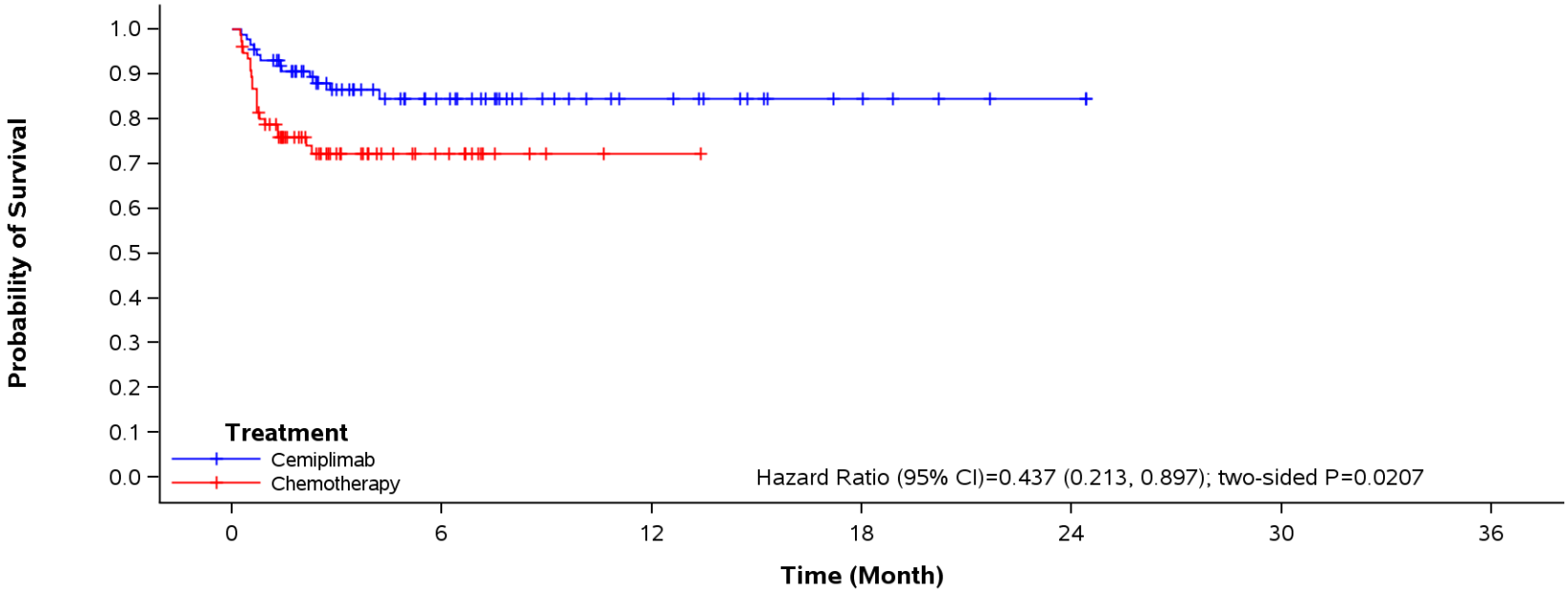

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 23 | 8 | 0 | 0 | 0 | 0 |
| Chemotherapy | 76 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders



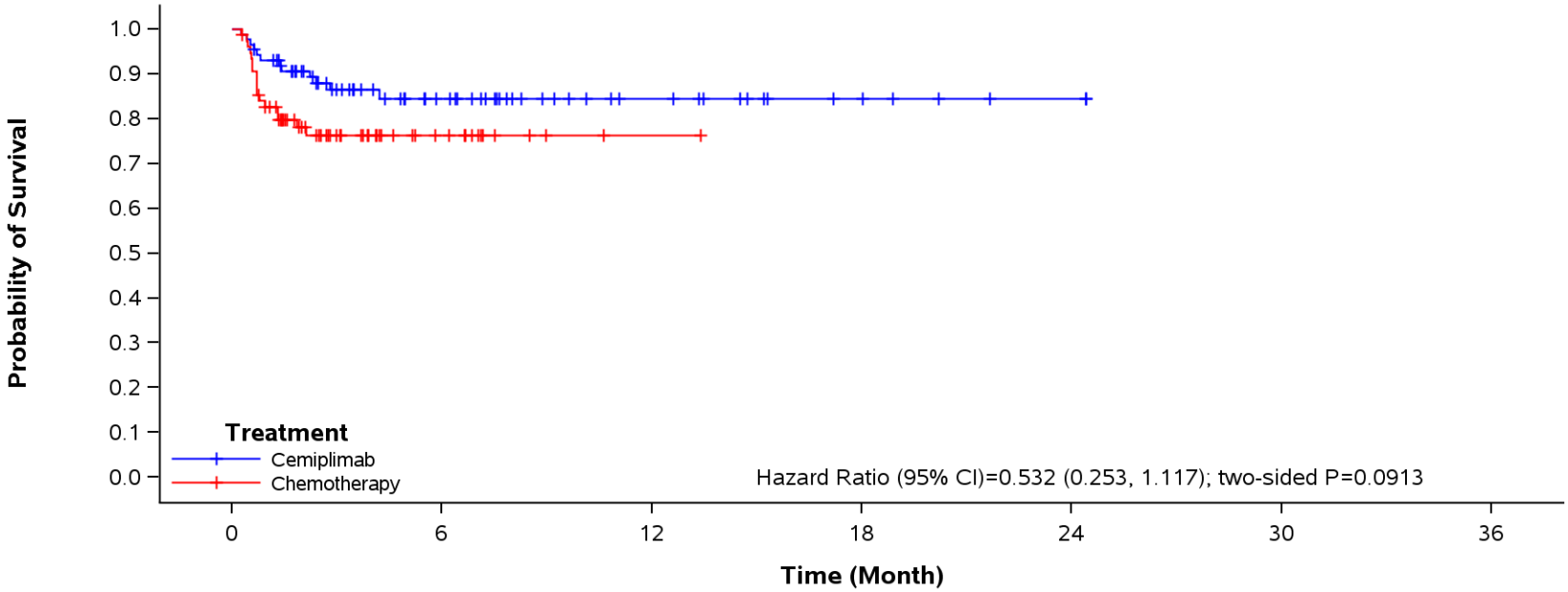

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 37 | 14 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Anaemia



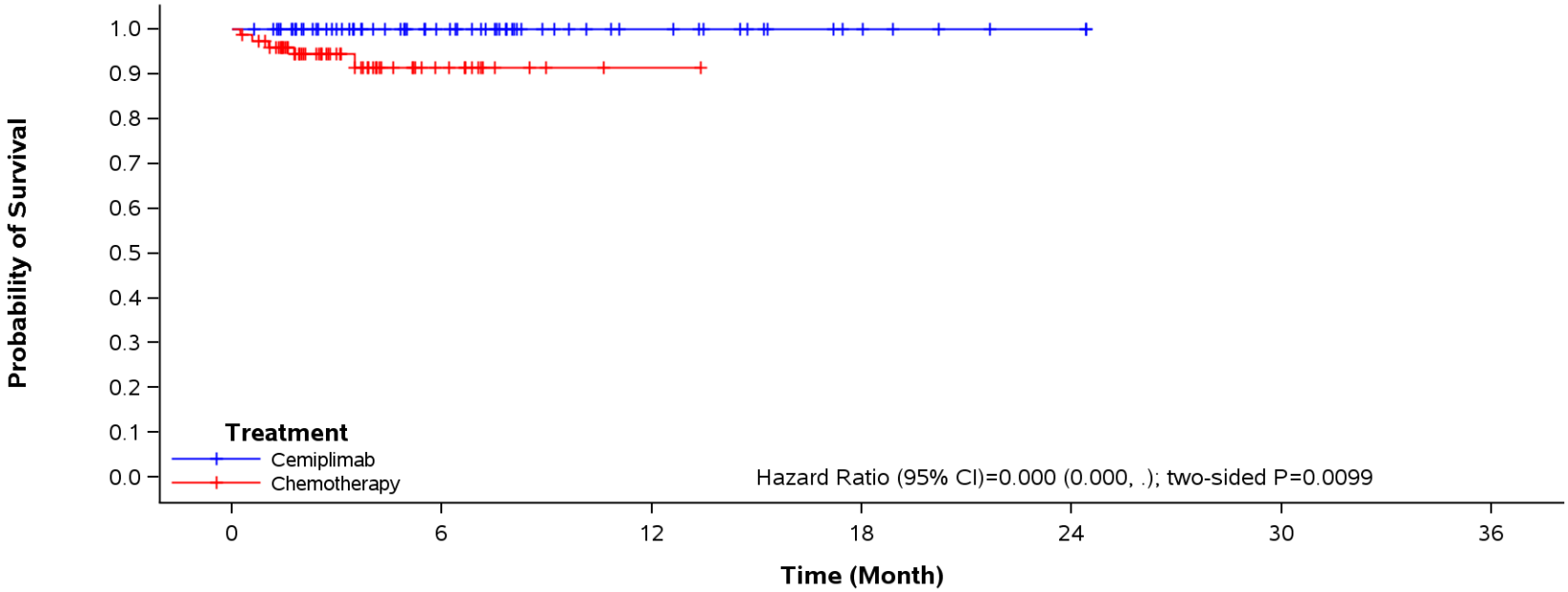

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 37 | 14 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Neutropenia



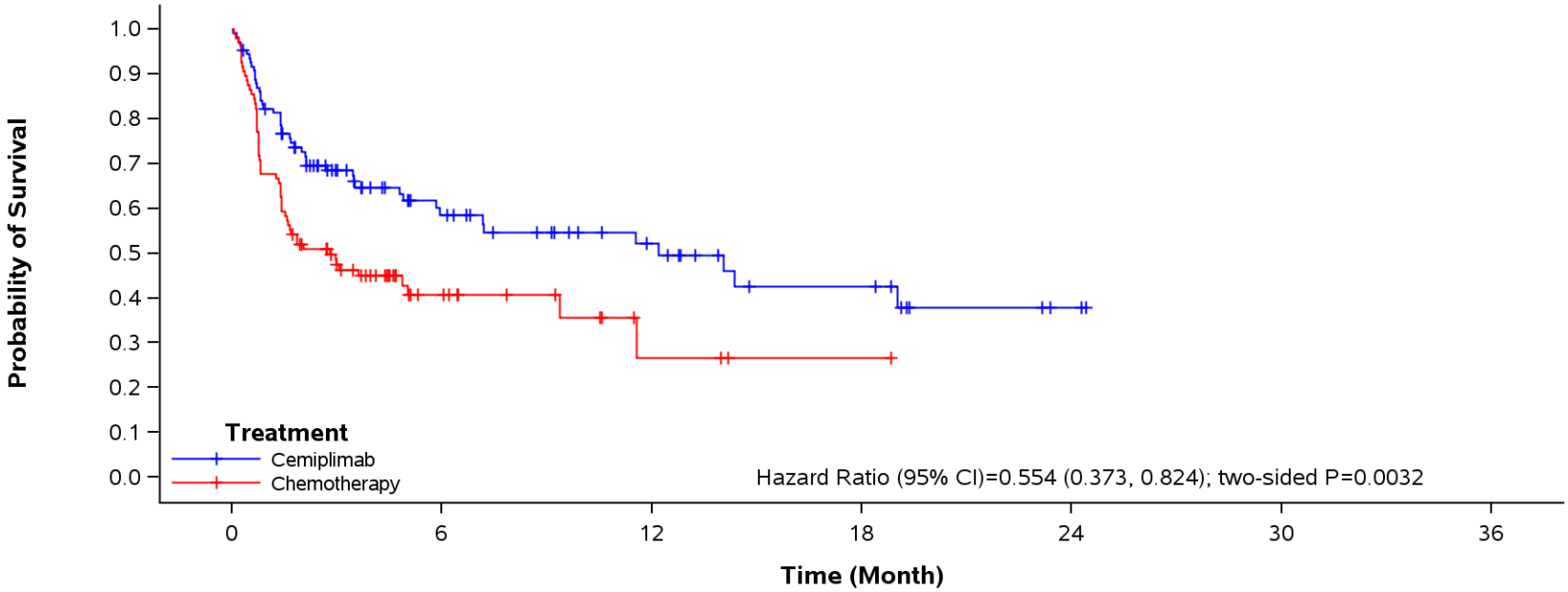

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 15 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Number of patients with any TEAE CTCAE Grade >= 3



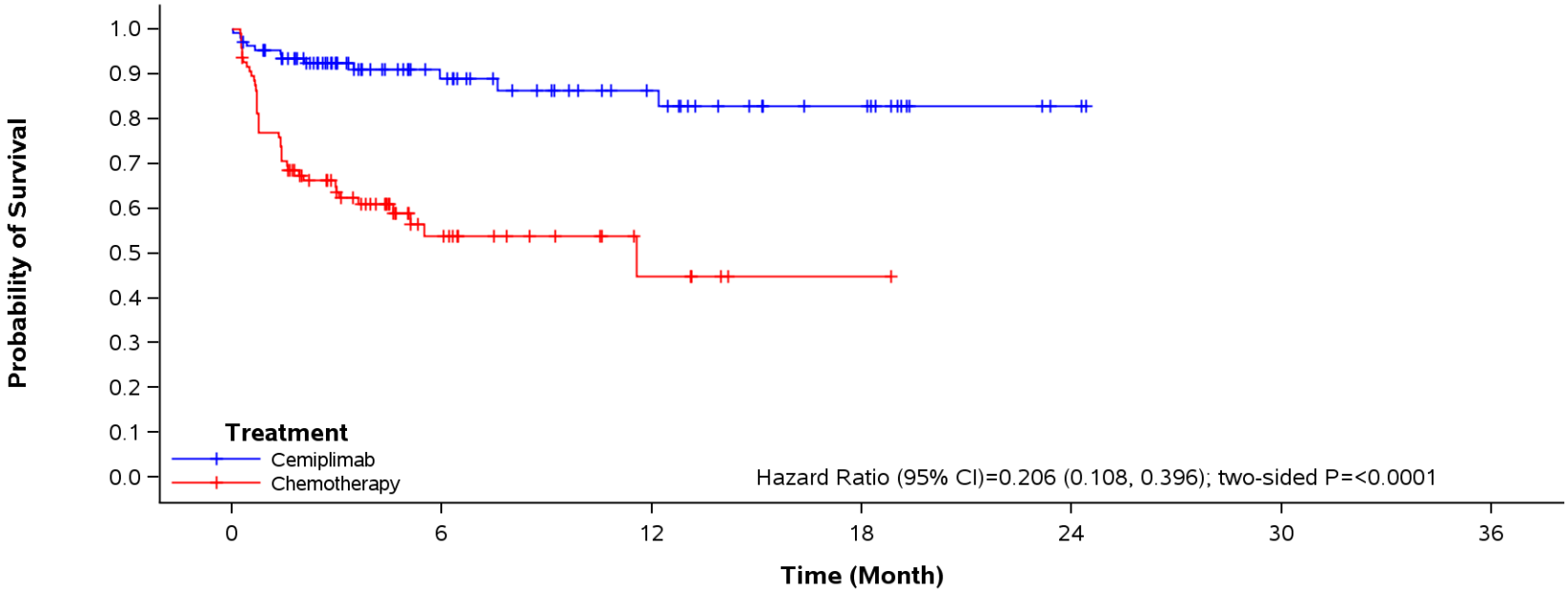

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 35 | 20 | 11 | 2 | 0 | 0 |
| Chemotherapy | 96 | 16 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders



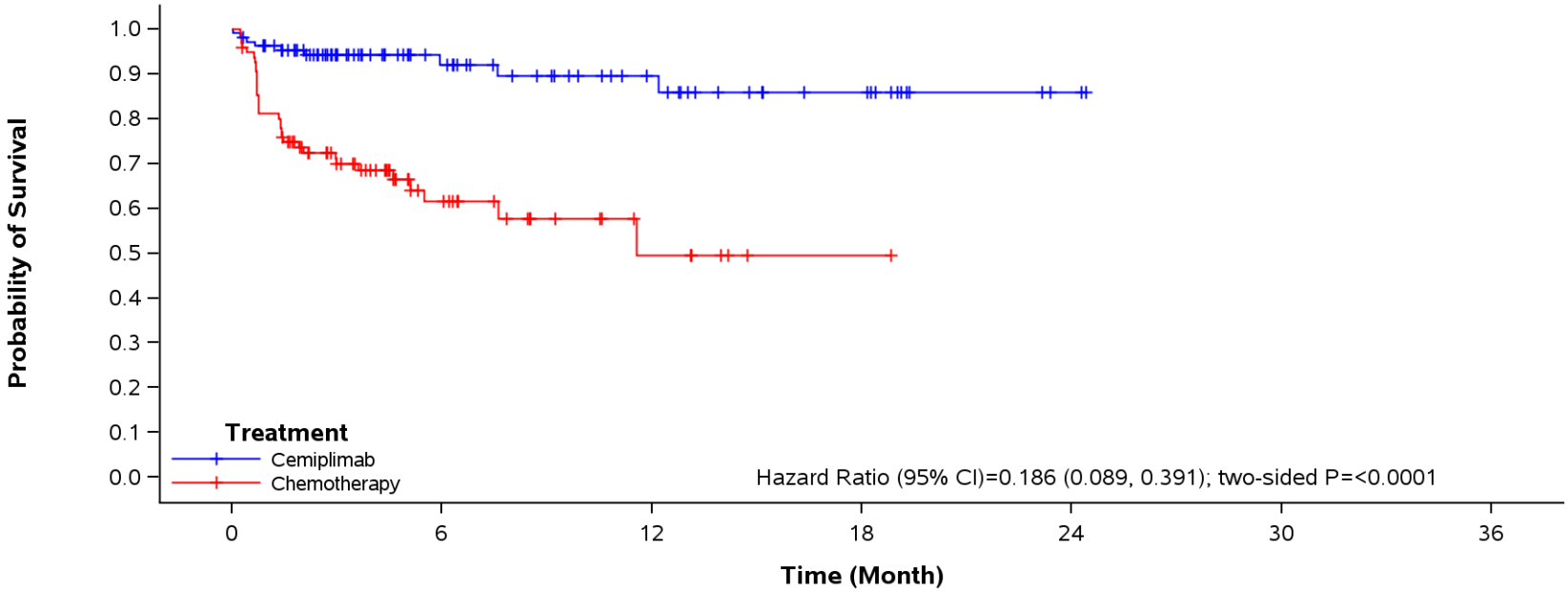

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 42 | 25 | 14 | 2 | 0 | 0 |
| Chemotherapy | 96 | 20 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Anaemia



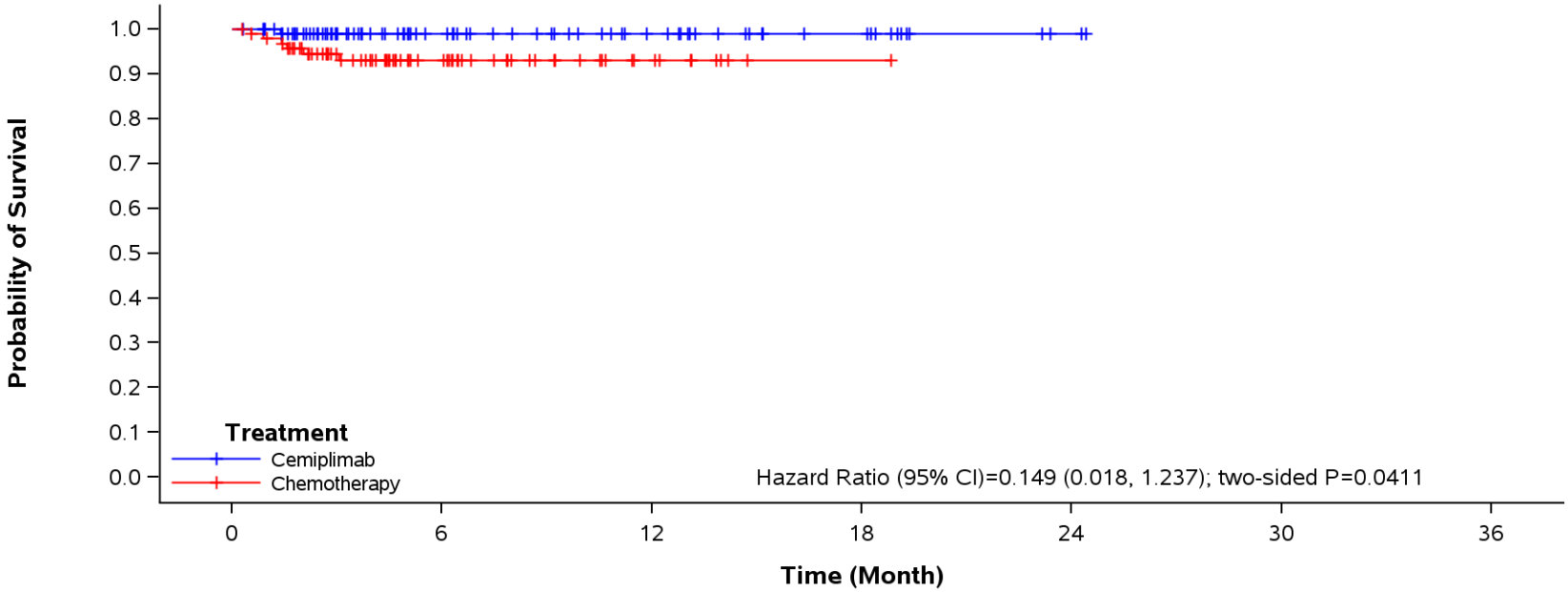

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 25 | 14 | 2 | 0 | 0 |
| Chemotherapy | 96 | 24 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Neutropenia



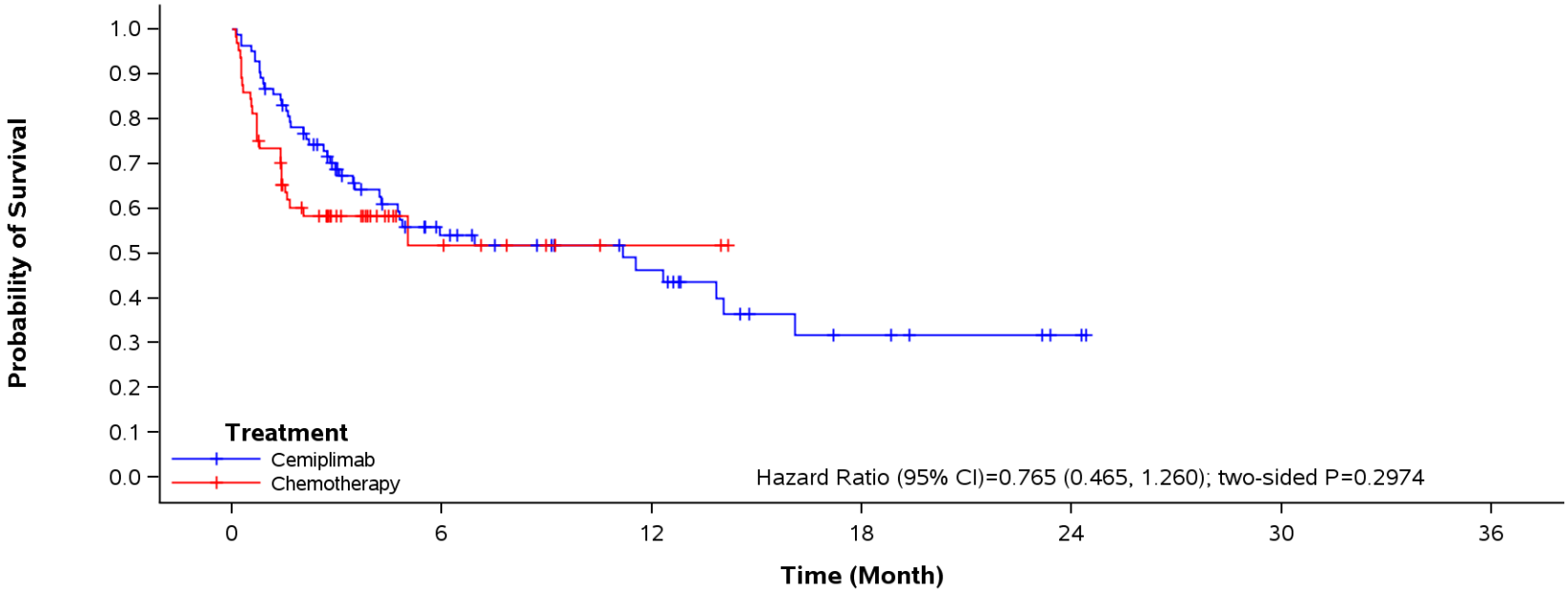

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 26 | 14 | 2 | 0 | 0 |
| Chemotherapy | 96 | 35 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Number of patients with any TEAE CTCAE Grade >= 3



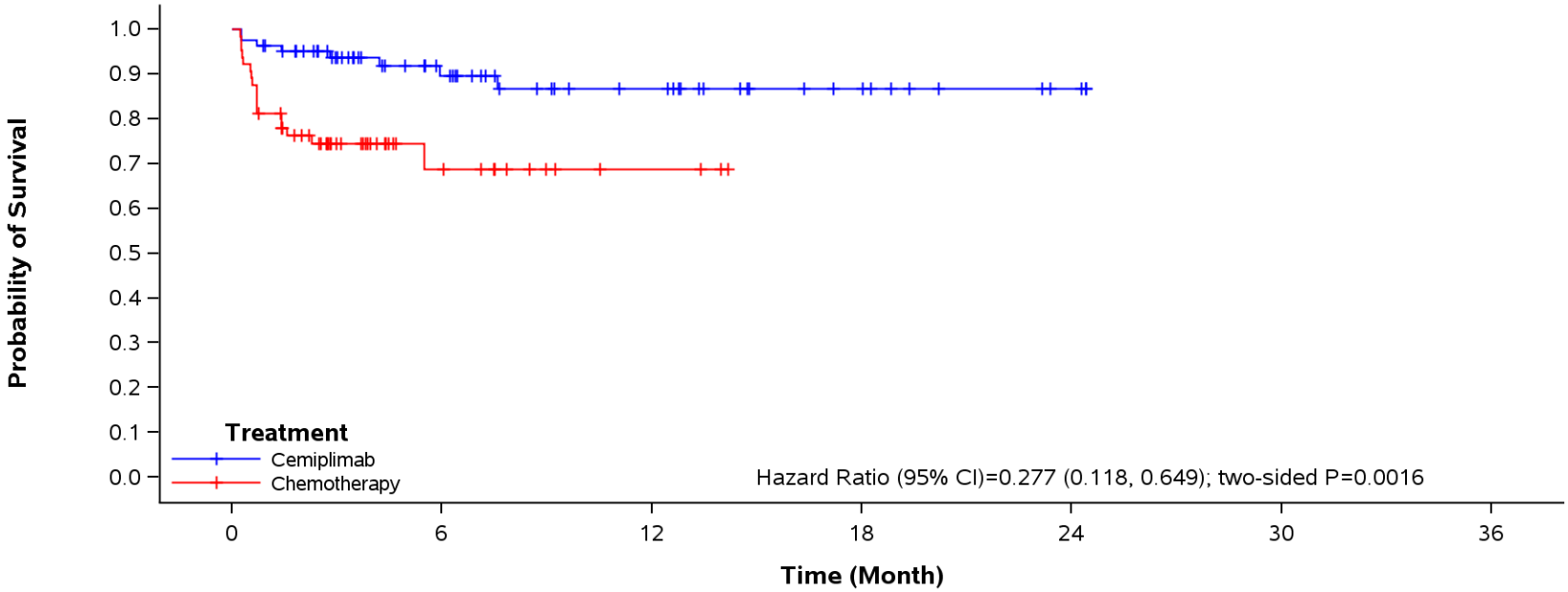

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 28 | 17 | 6 | 2 | 0 | 0 |
| Chemotherapy | 64 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders



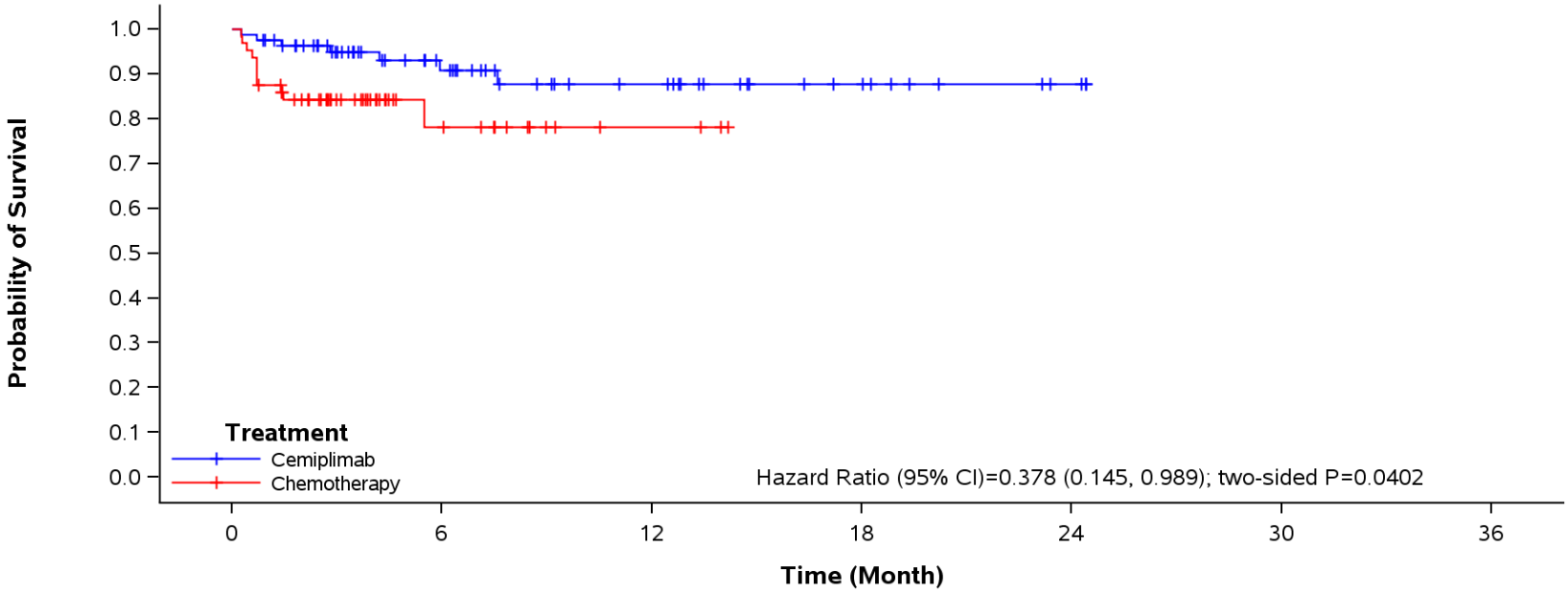

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 41 | 23 | 12 | 4 | 0 | 0 |
| Chemotherapy | 64 | 12 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Anaemia



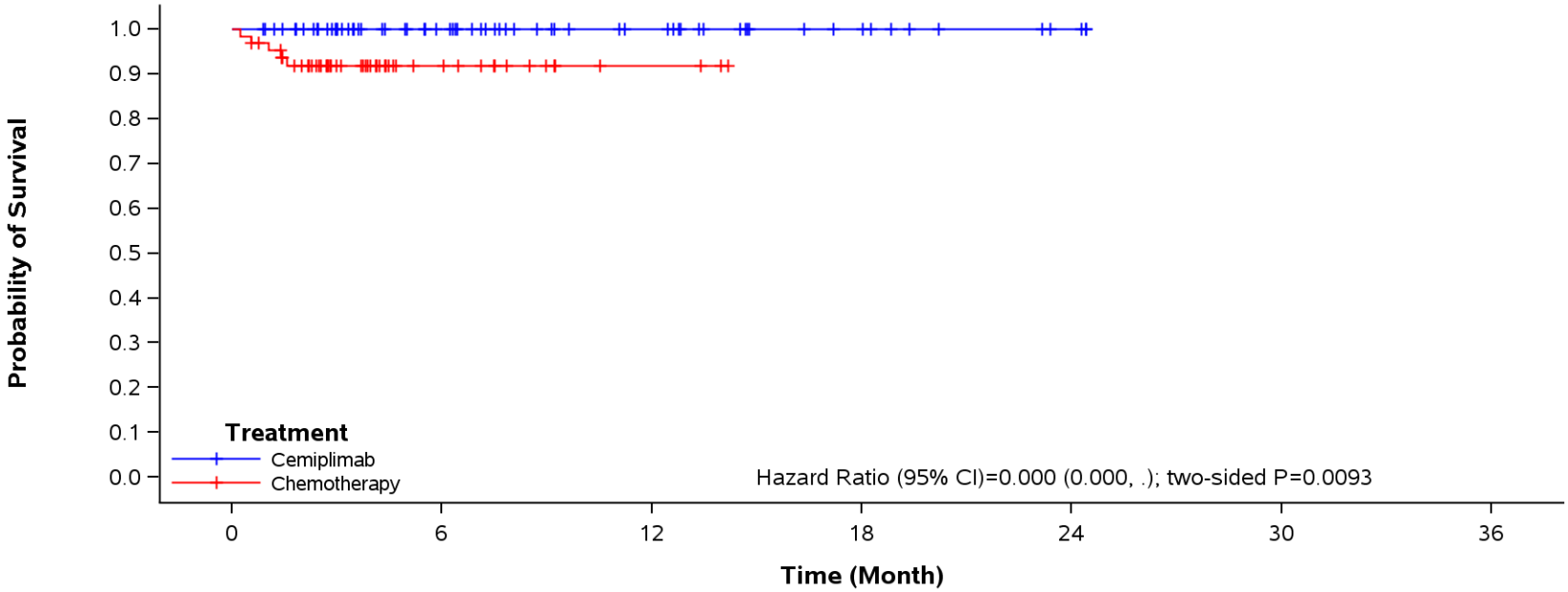

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 41 | 23 | 12 | 4 | 0 | 0 |
| Chemotherapy | 64 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Neutropenia



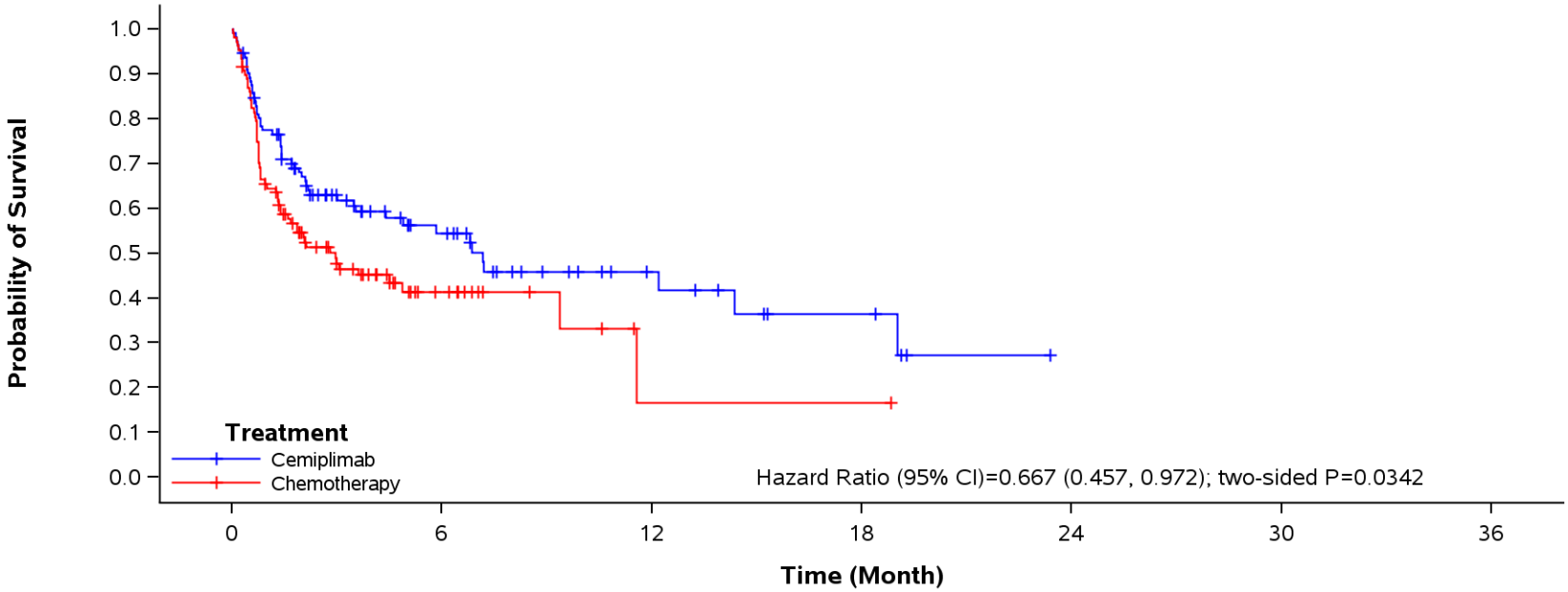

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 24 | 12 | 4 | 0 | 0 |
| Chemotherapy | 64 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Number of patients with any TEAE CTCAE Grade >= 3



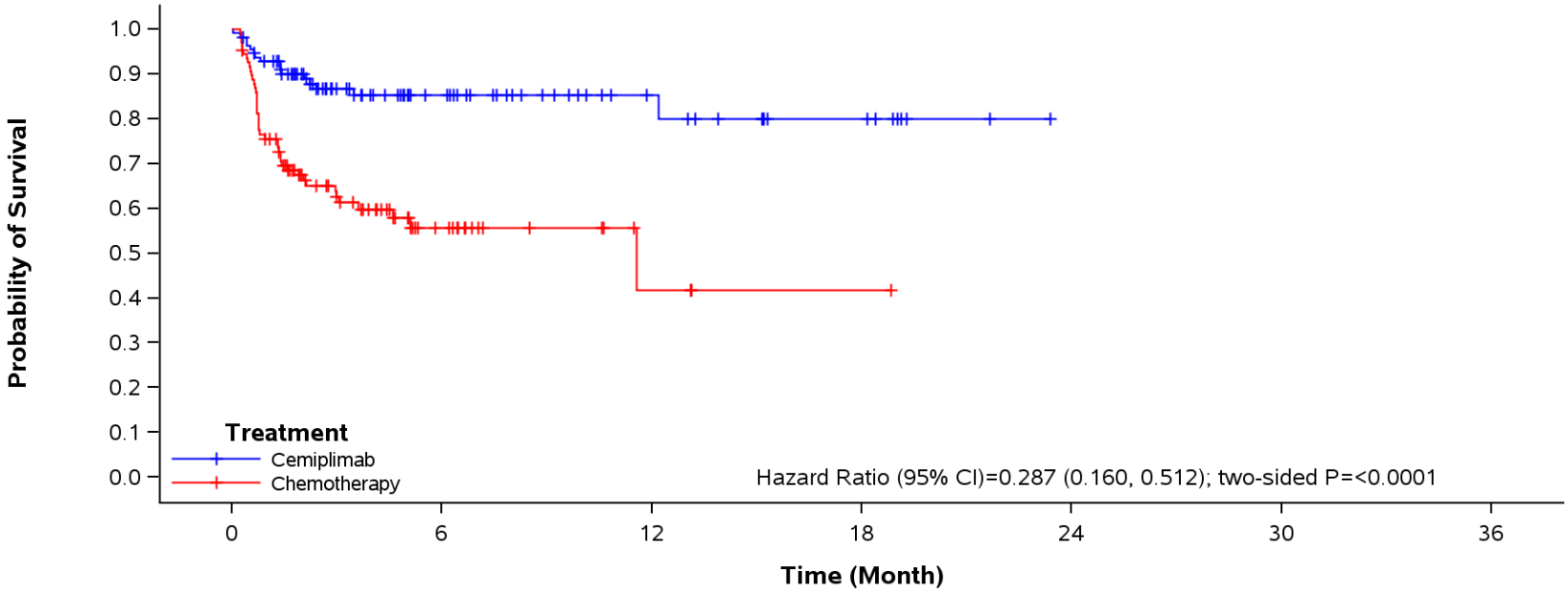

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 30 | 11 | 5 | 0 | 0 | 0 |
| Chemotherapy | 108 | 16 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders



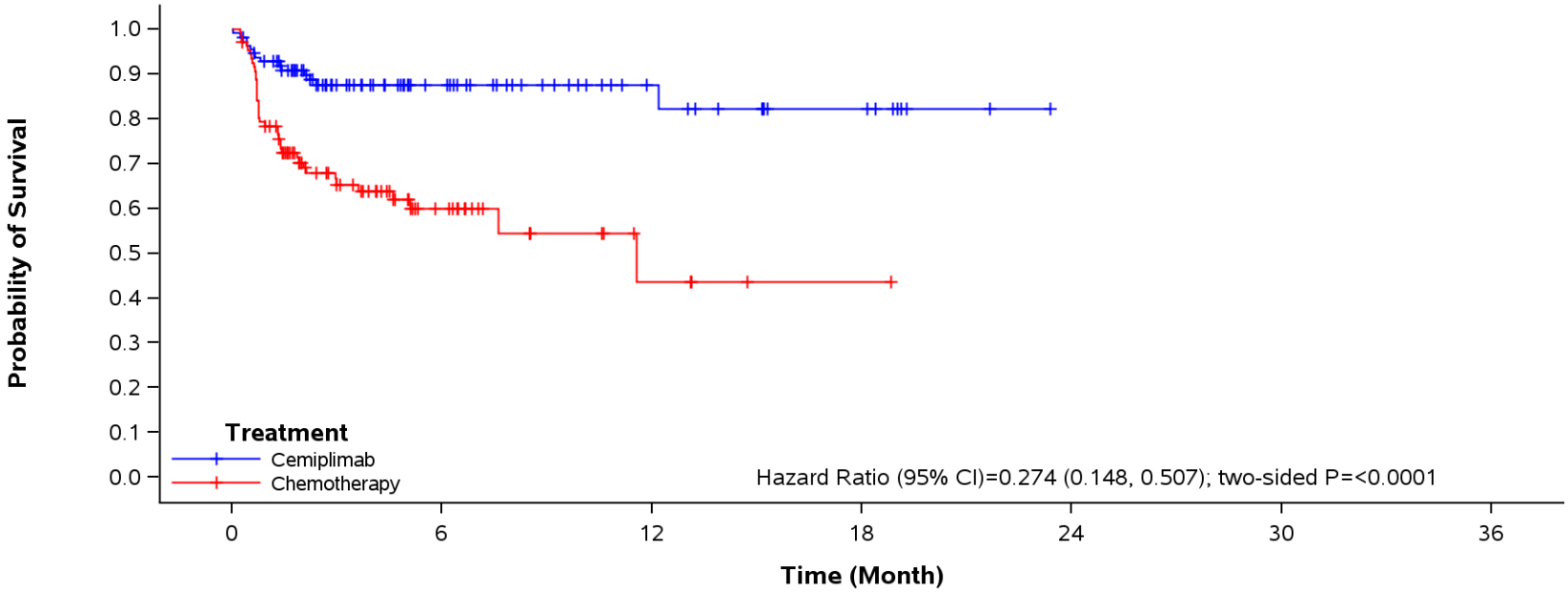

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 38 | 16 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Anaemia



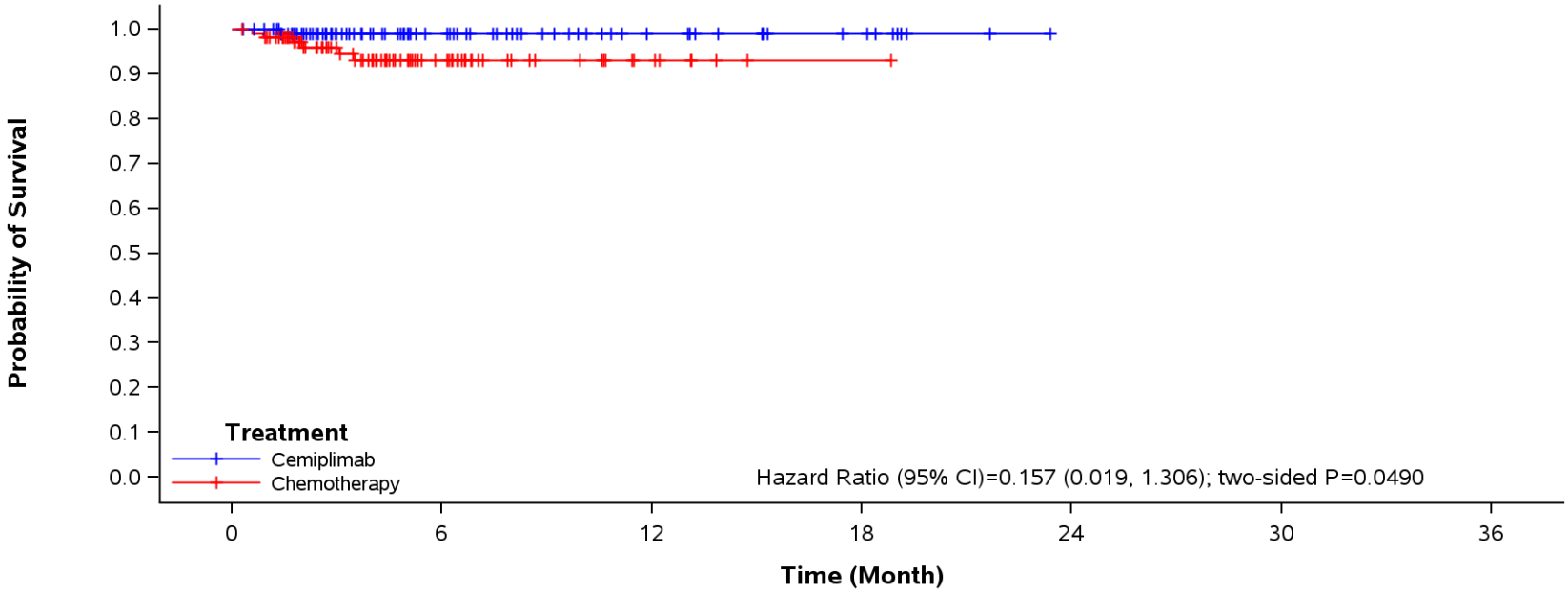

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 39 | 16 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 23 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Neutropenia



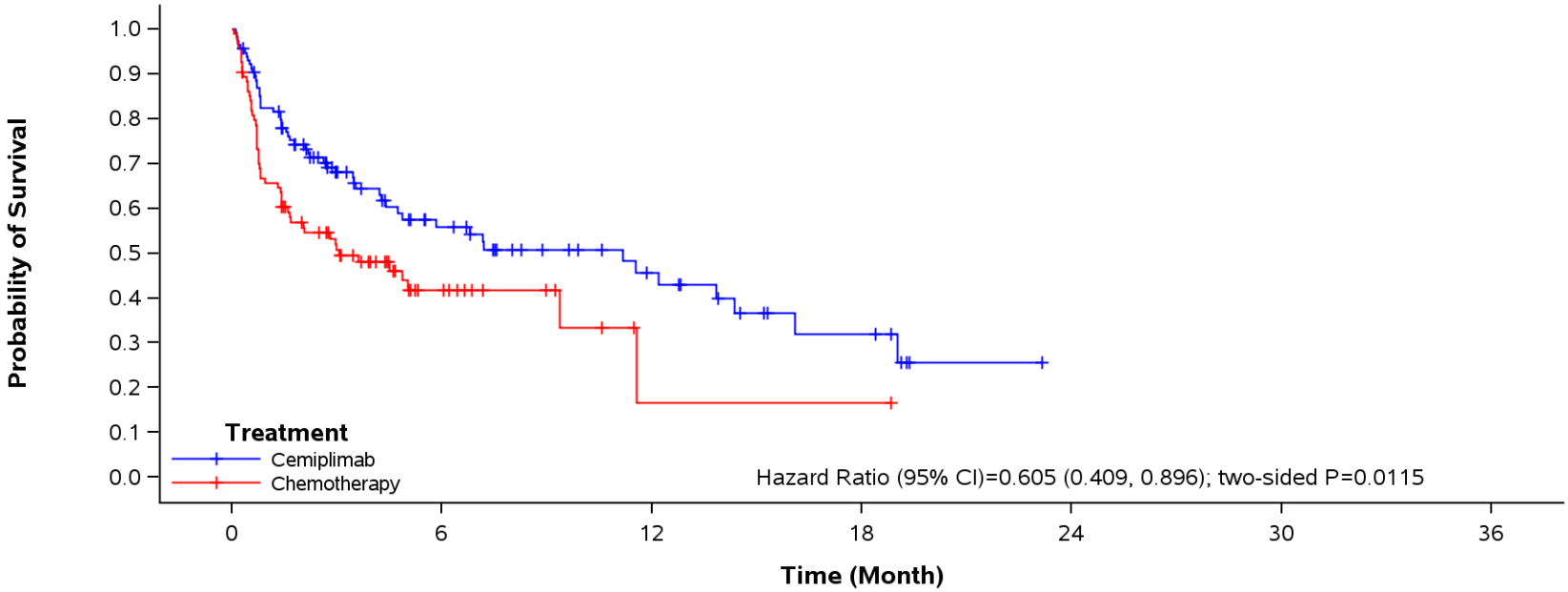

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 17 | 8 | 0 | 0 | 0 |
| Chemotherapy | 108 | 33 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Number of patients with any TEAE CTCAE Grade >= 3



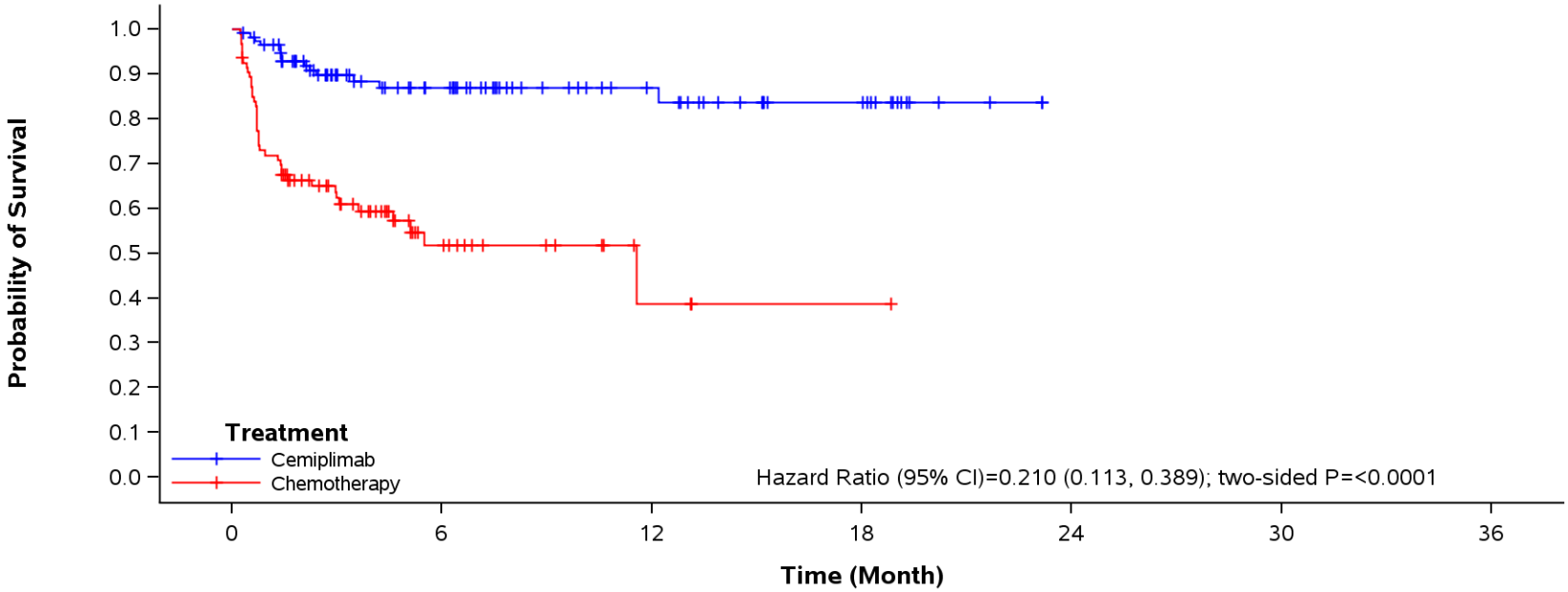

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 35 | 17 | 7 | 0 | 0 | 0 |
| Chemotherapy | 94 | 15 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders



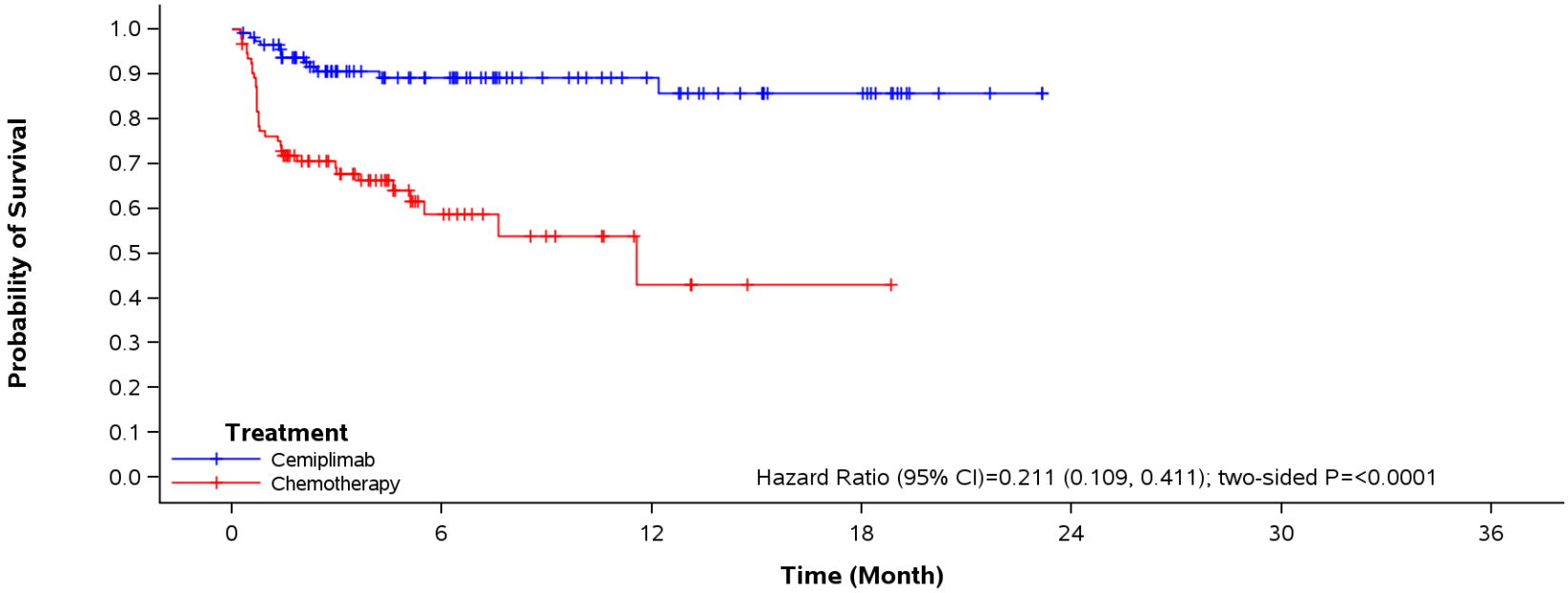

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 49 | 26 | 14 | 0 | 0 | 0 |
| Chemotherapy | 94 | 17 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



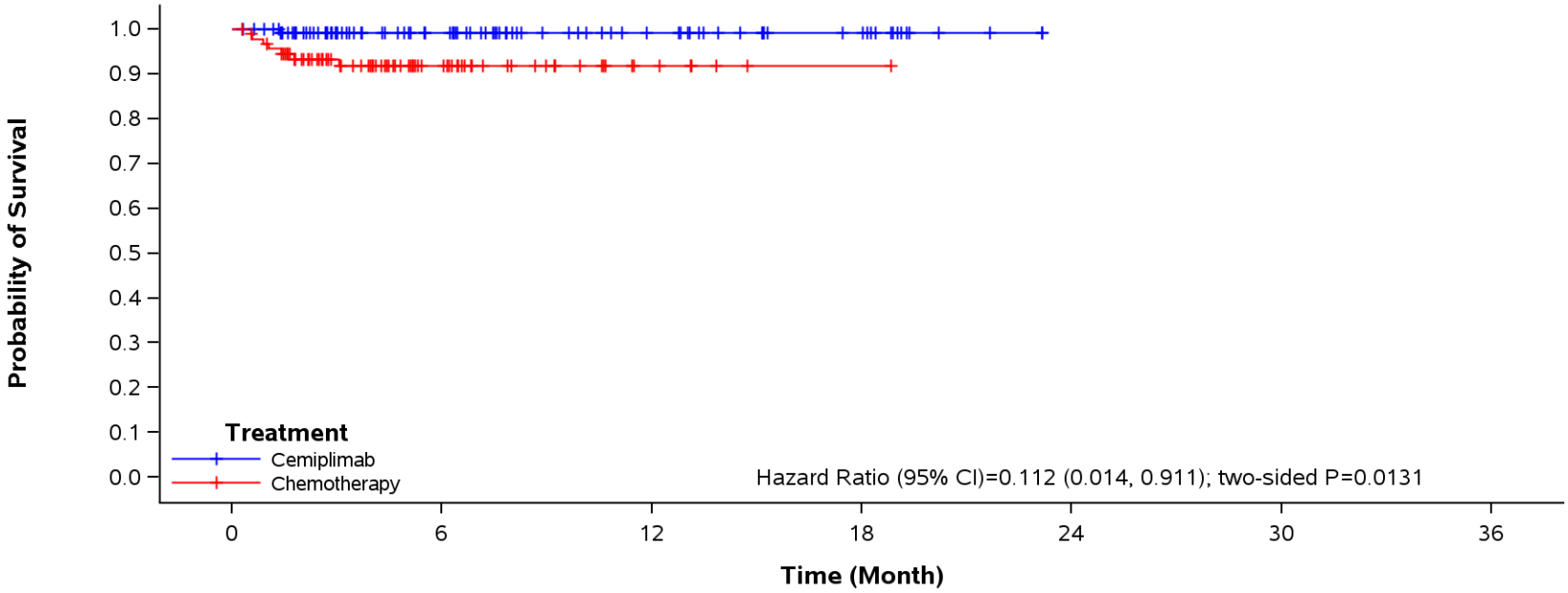

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 50 | 26 | 14 | 0 | 0 | 0 |
| Chemotherapy | 94 | 20 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia



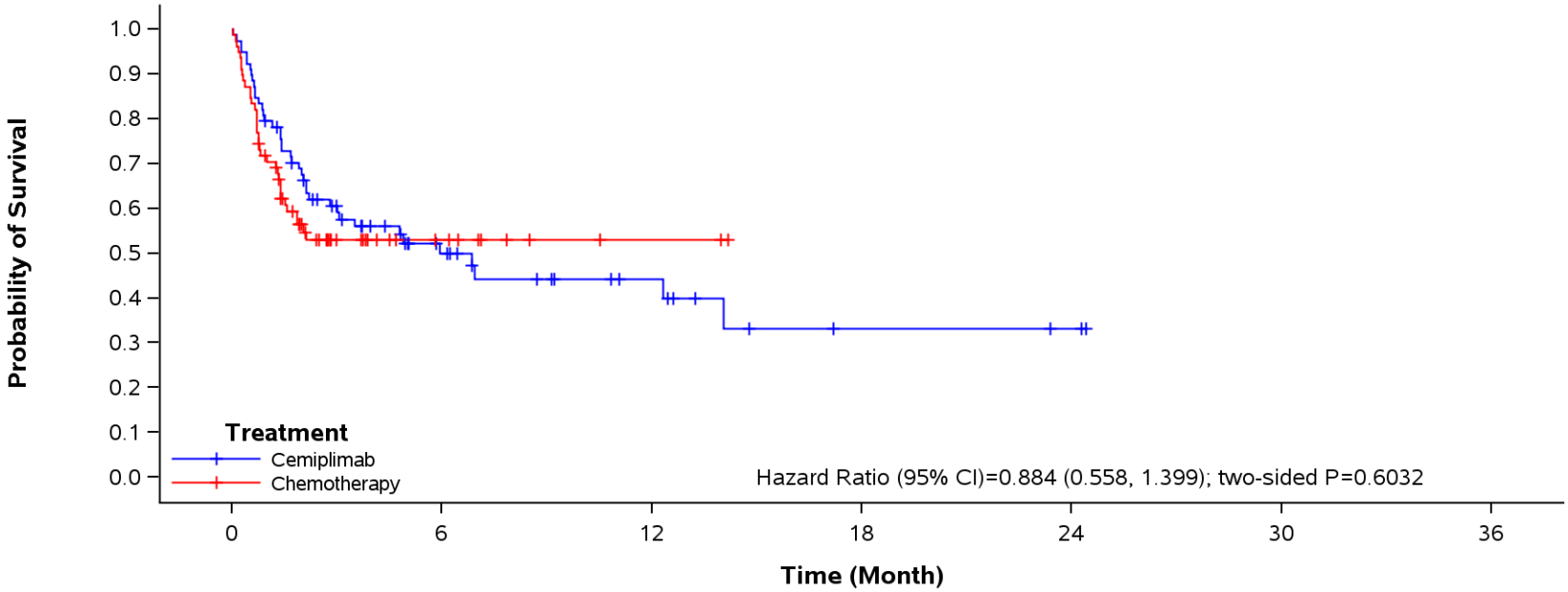

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 27 | 14 | 0 | 0 | 0 |
| Chemotherapy | 94 | 31 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Number of patients with any TEAE CTCAE Grade >= 3



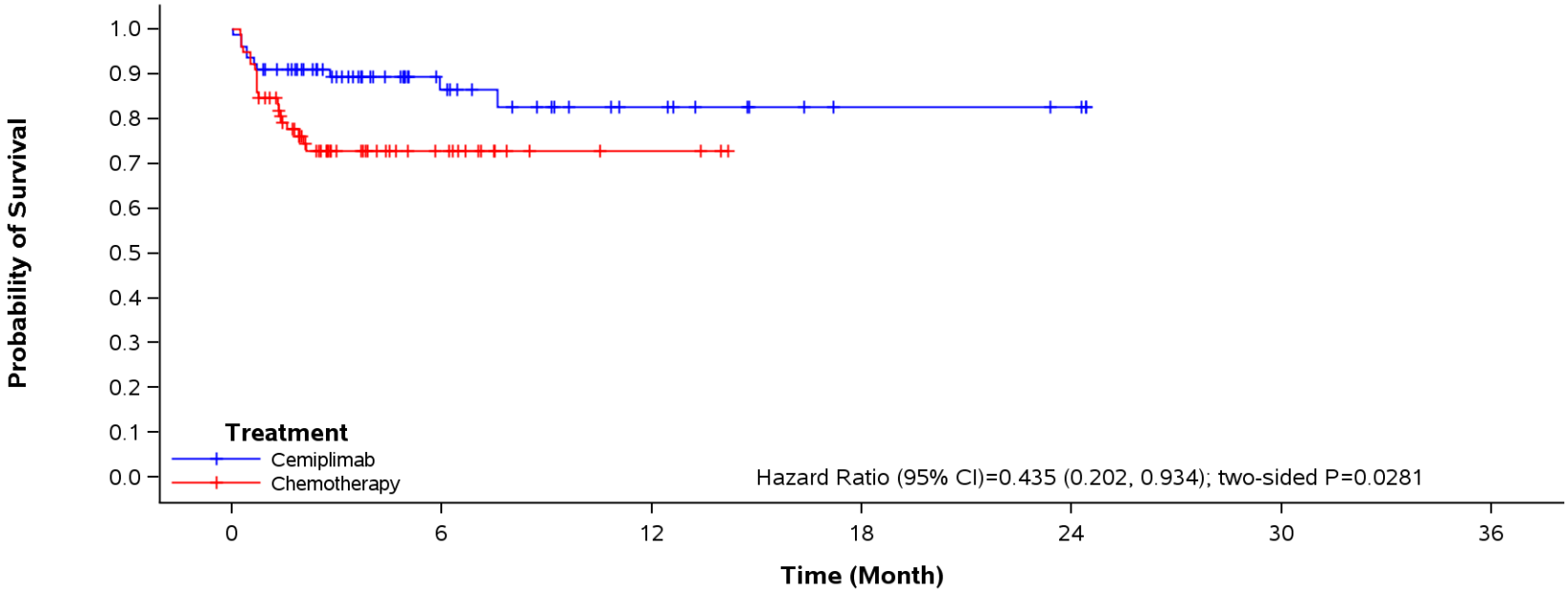

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 22 | 10 | 3 | 2 | 0 | 0 |
| Chemotherapy | 78 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders



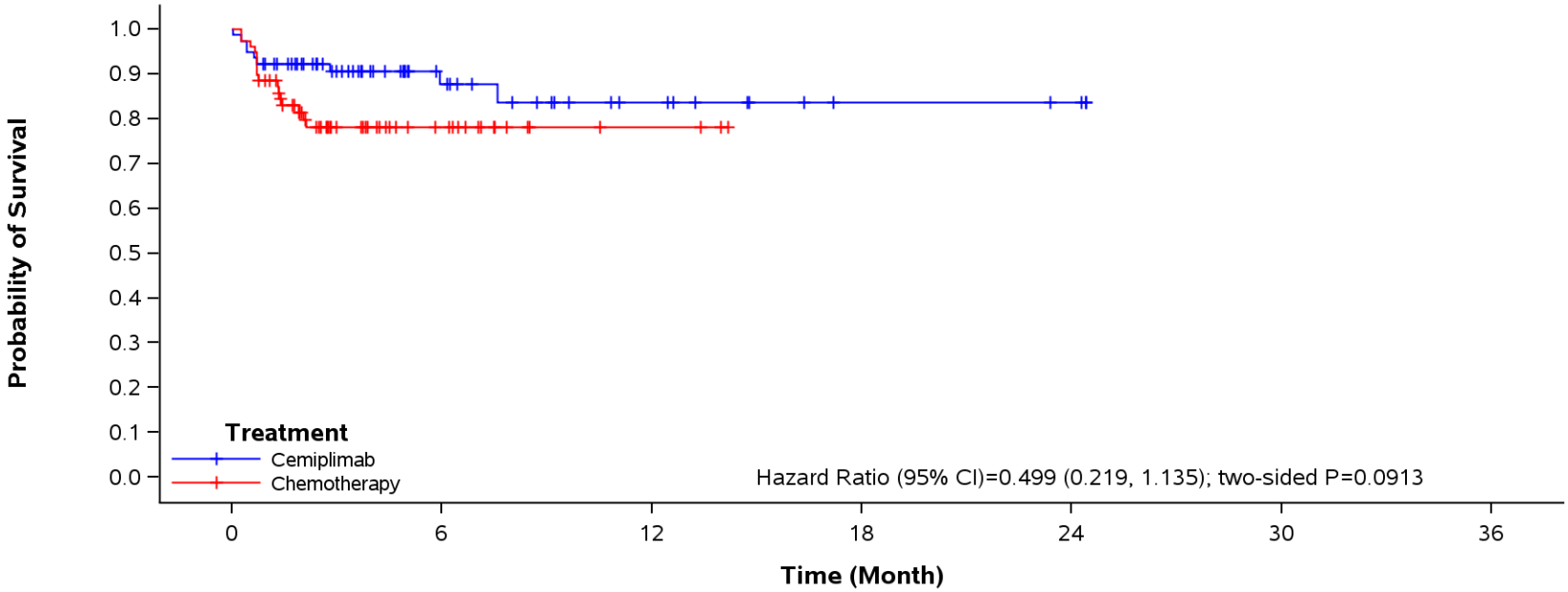

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 29 | 12 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



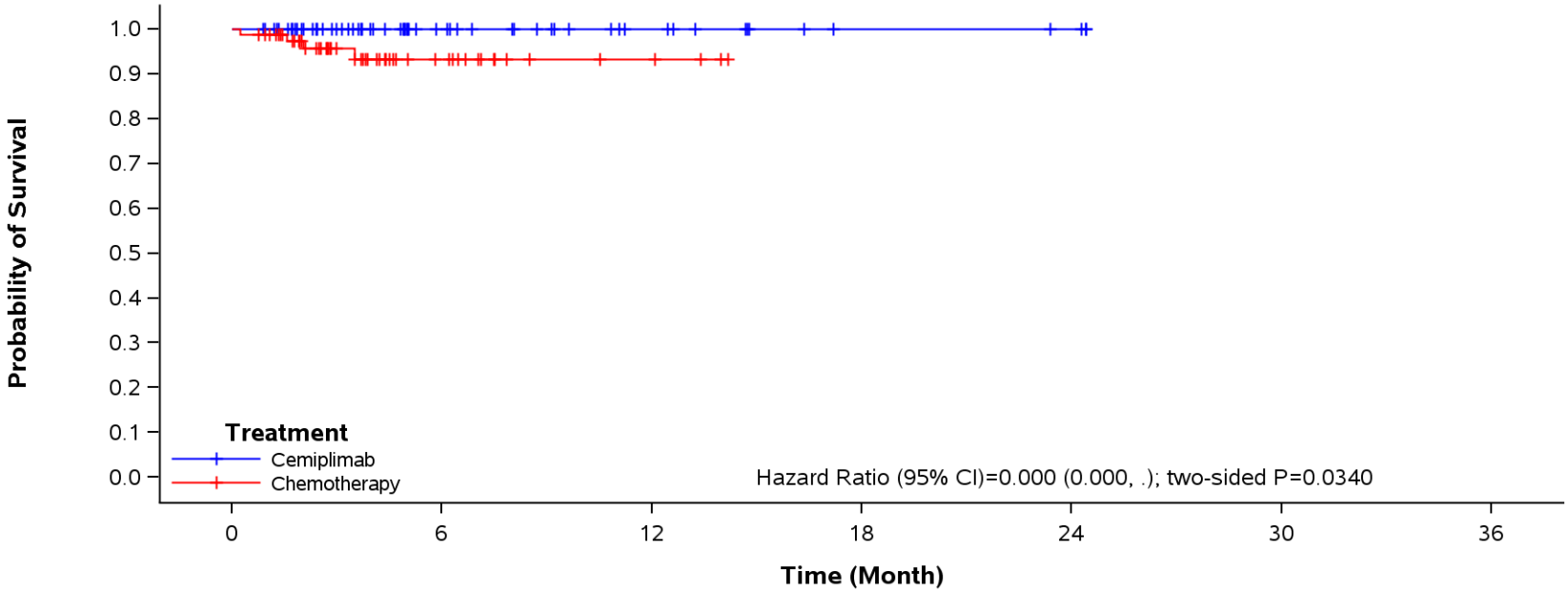

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 29 | 12 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 16 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia



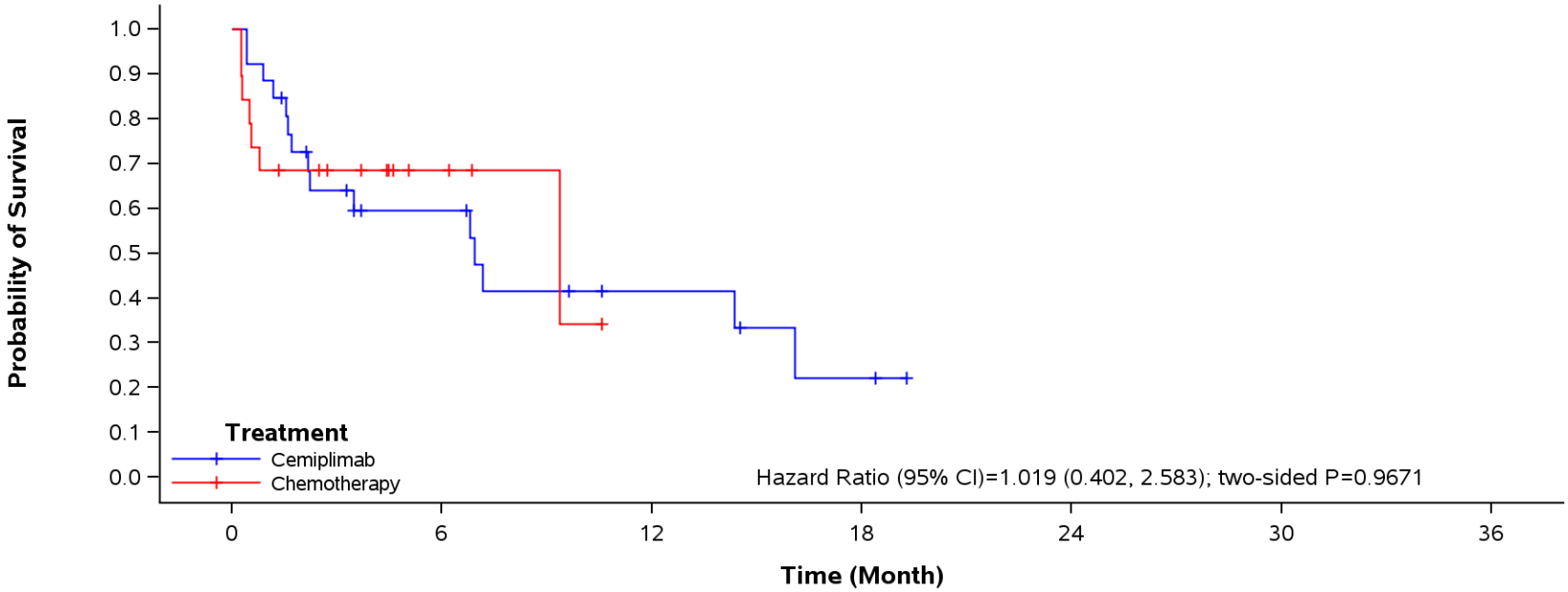

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 13 | 5 | 4 | 0 | 0 |
| Chemotherapy | 78 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Number of patients with any TEAE CTCAE Grade >= 3



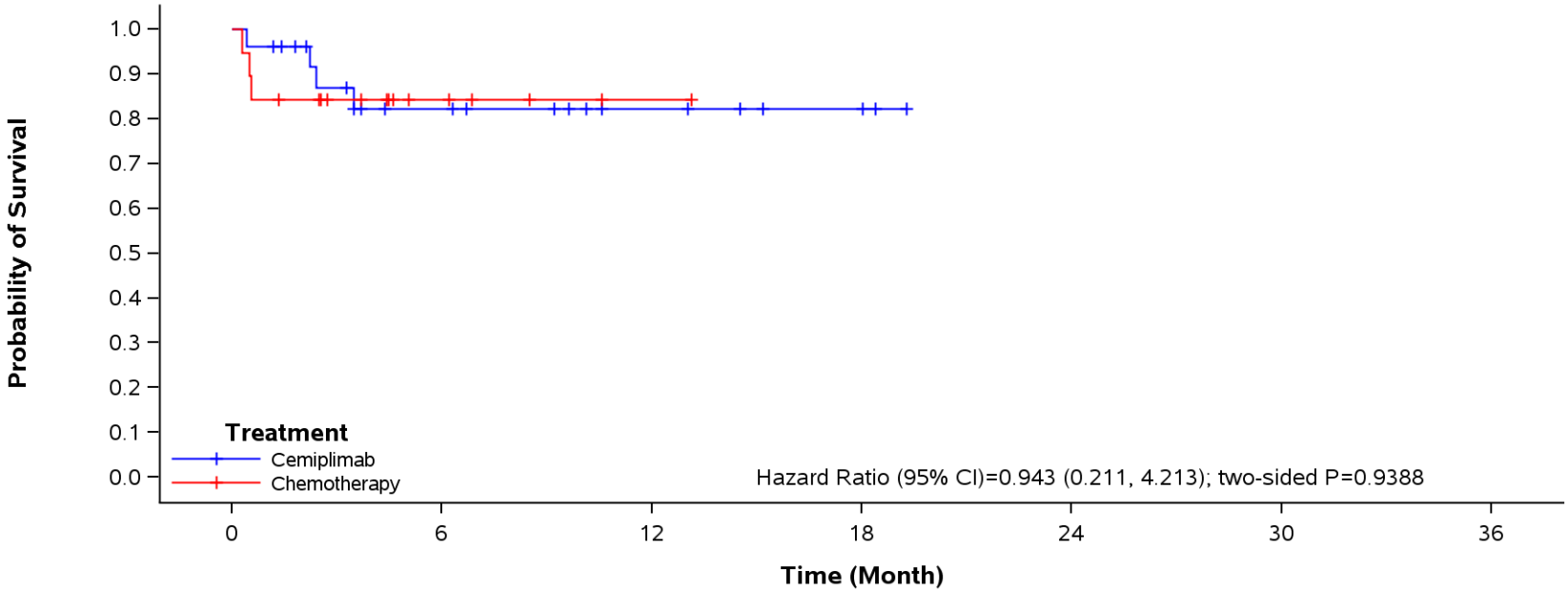

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 5 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders



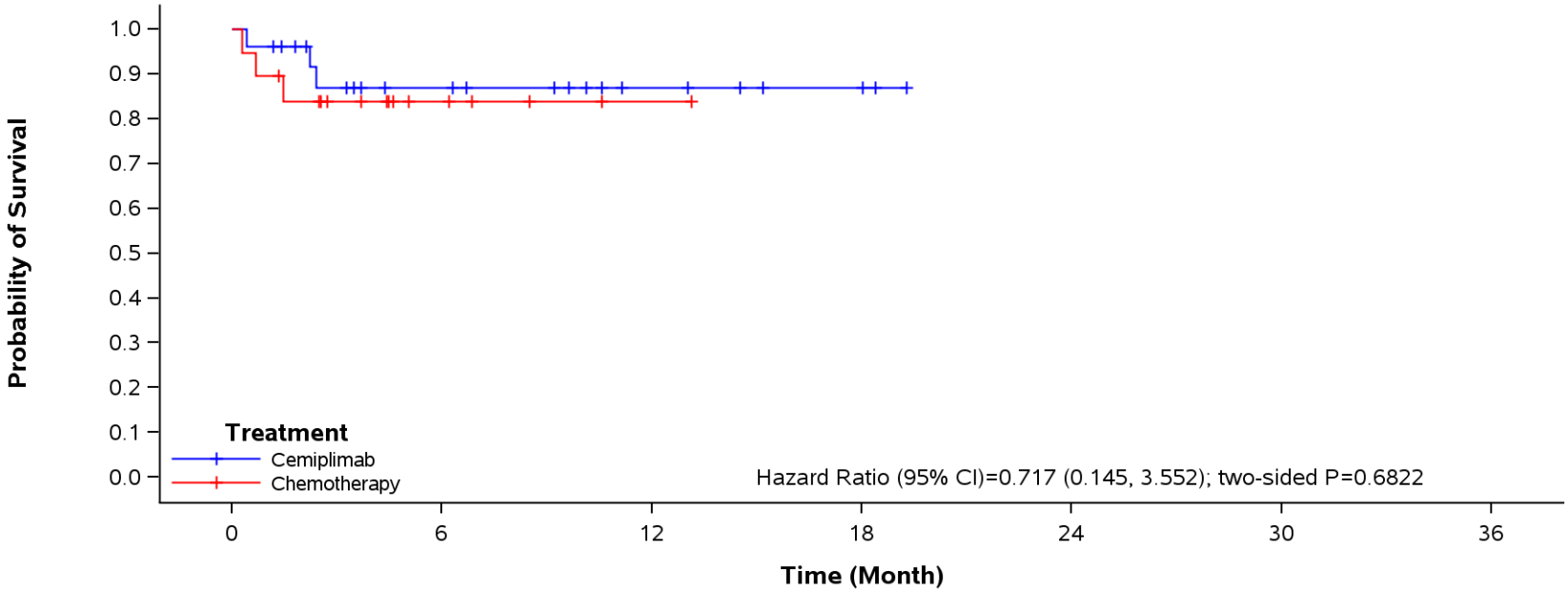

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



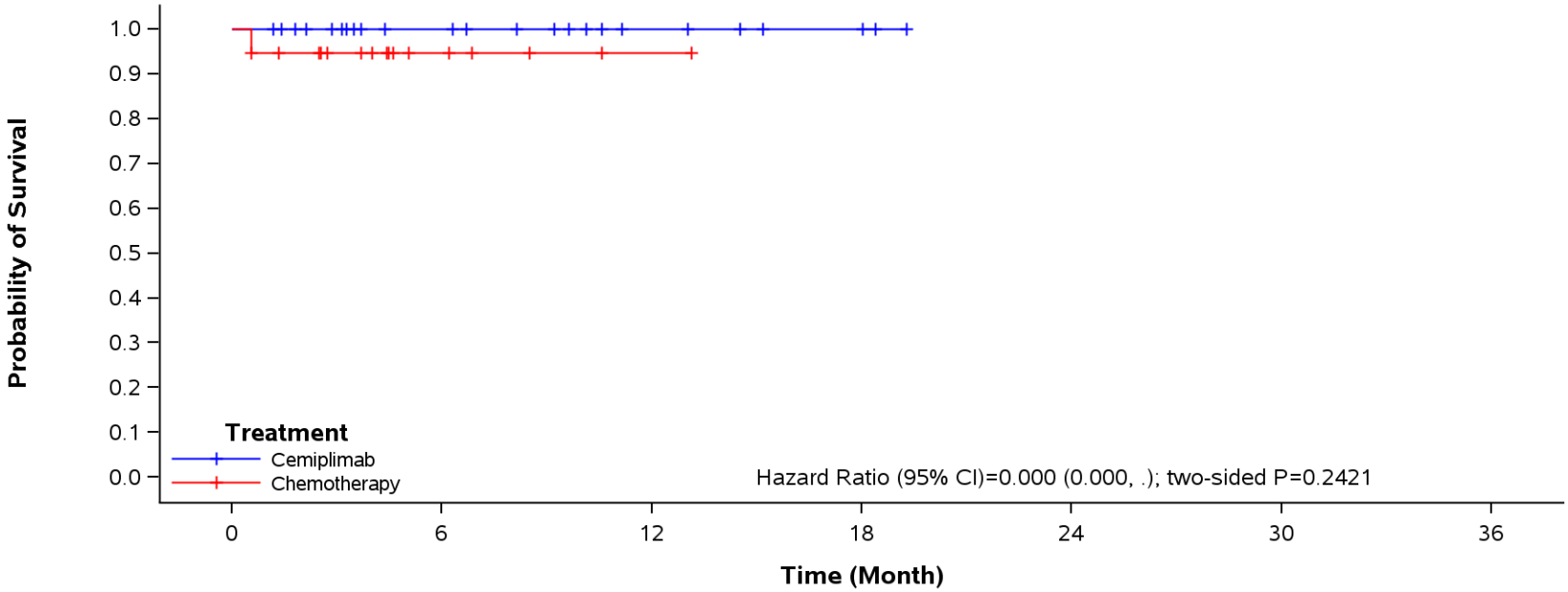

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 13 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



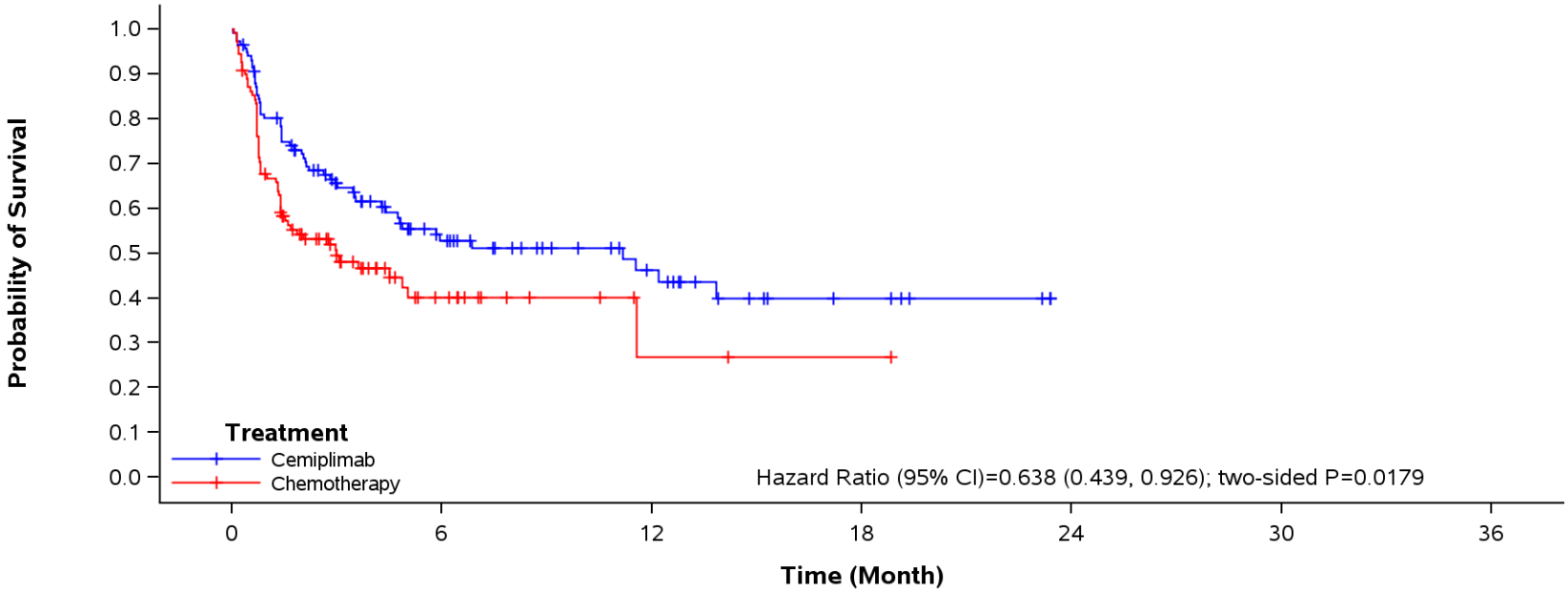

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 6 | 3 | 0 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Number of patients with any TEAE CTCAE Grade >= 3



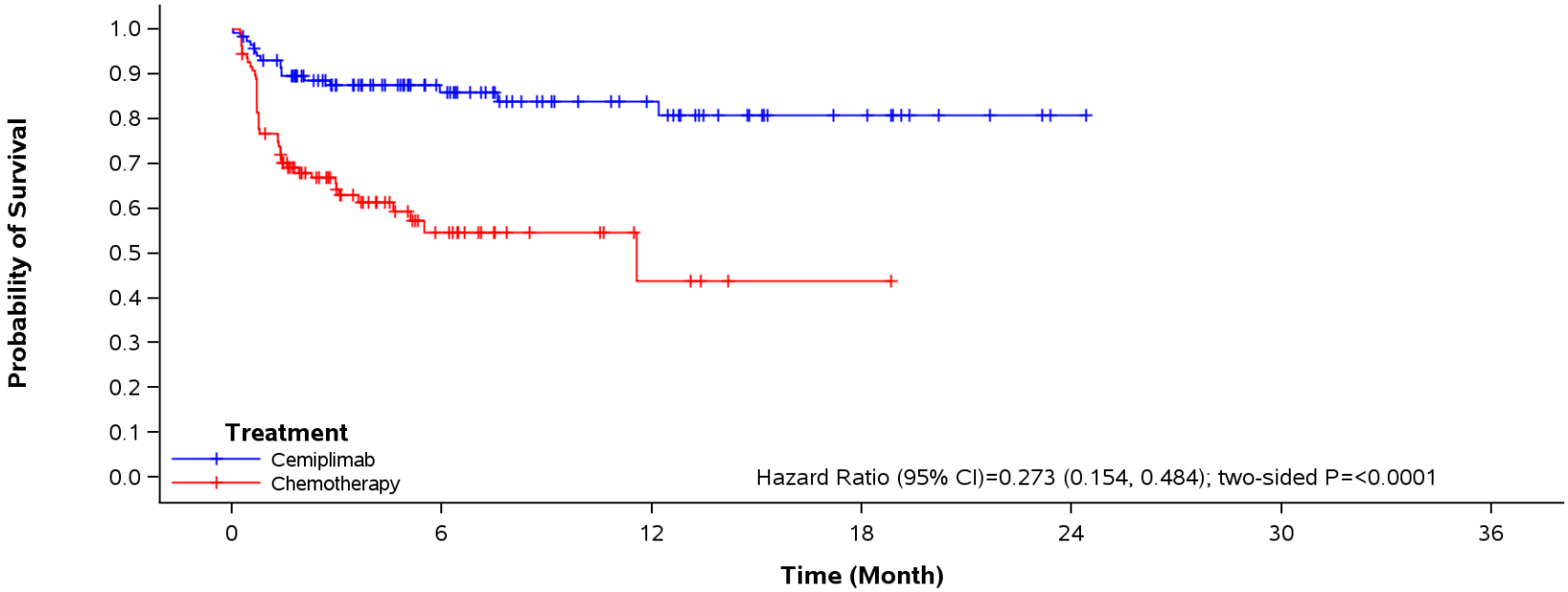

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 37 | 18 | 6 | 0 | 0 | 0 |
| Chemotherapy | 109 | 15 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders



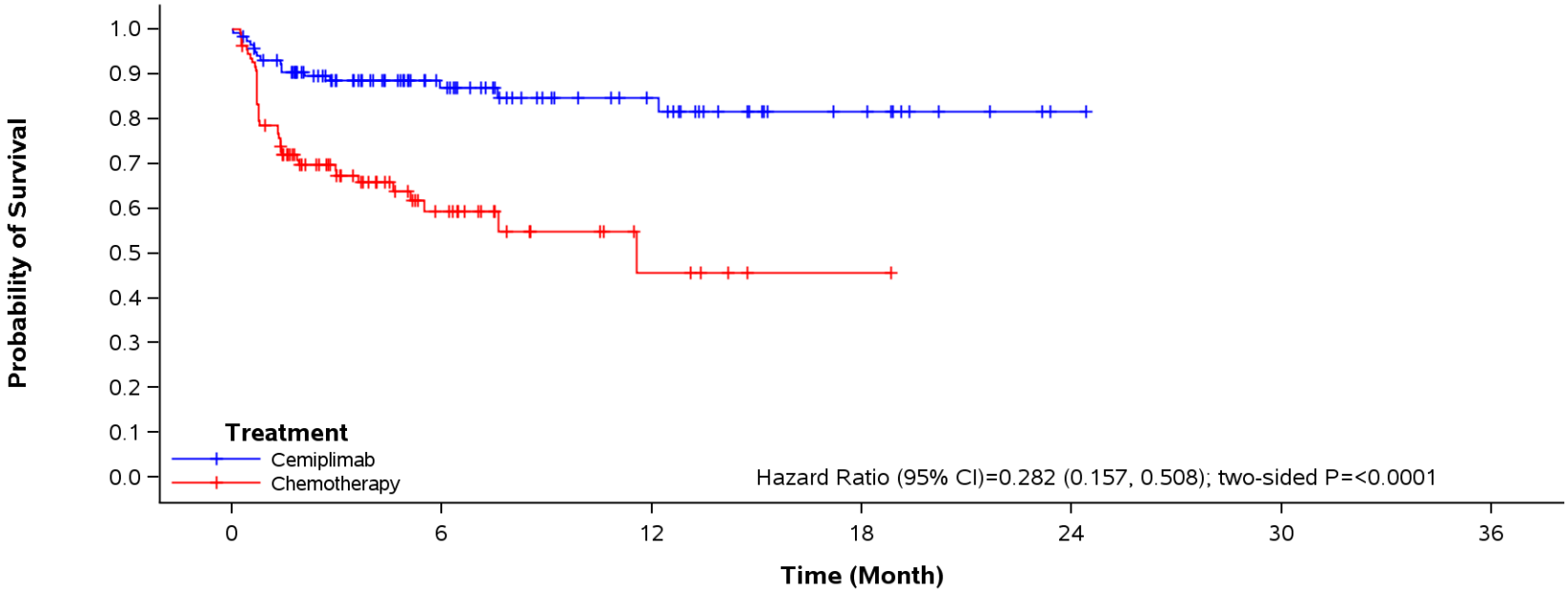

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 54 | 27 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 21 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Anaemia



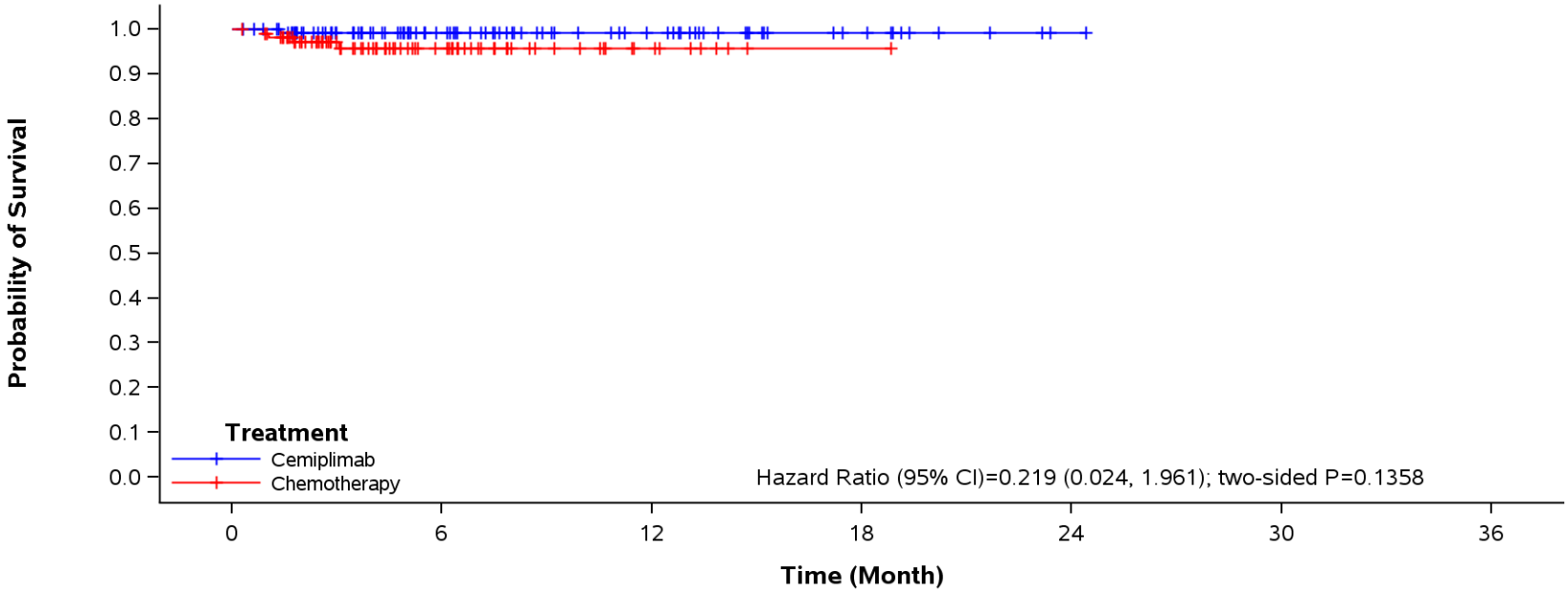

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 54 | 27 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 24 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Neutropenia



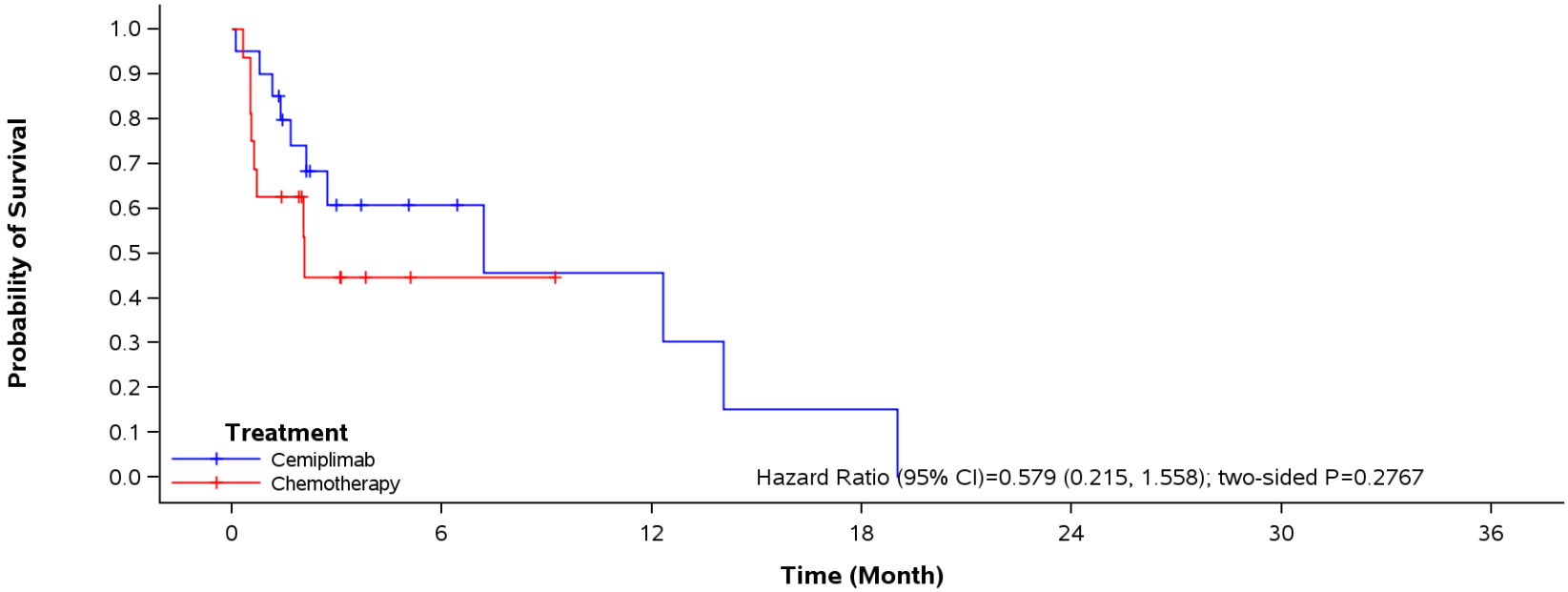

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 29 | 12 | 1 | 0 | 0 |
| Chemotherapy | 109 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Number of patients with any TEAE CTCAE Grade >= 3



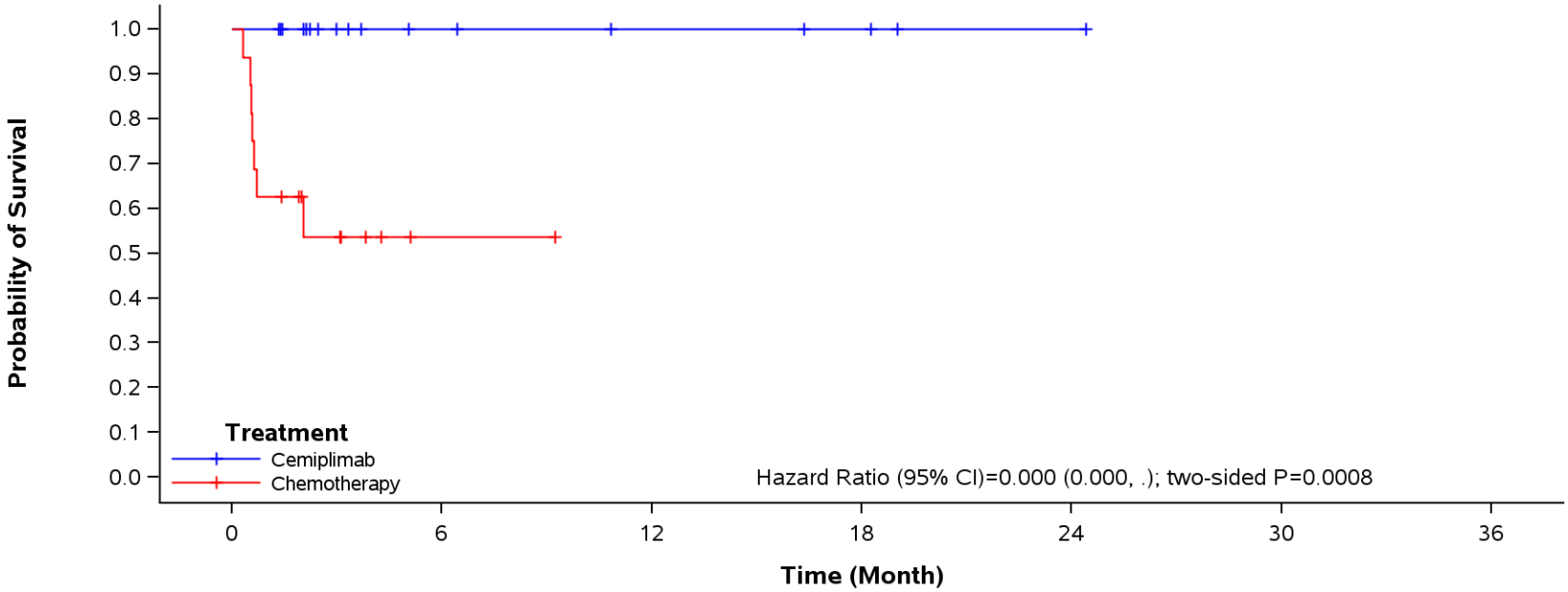

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders



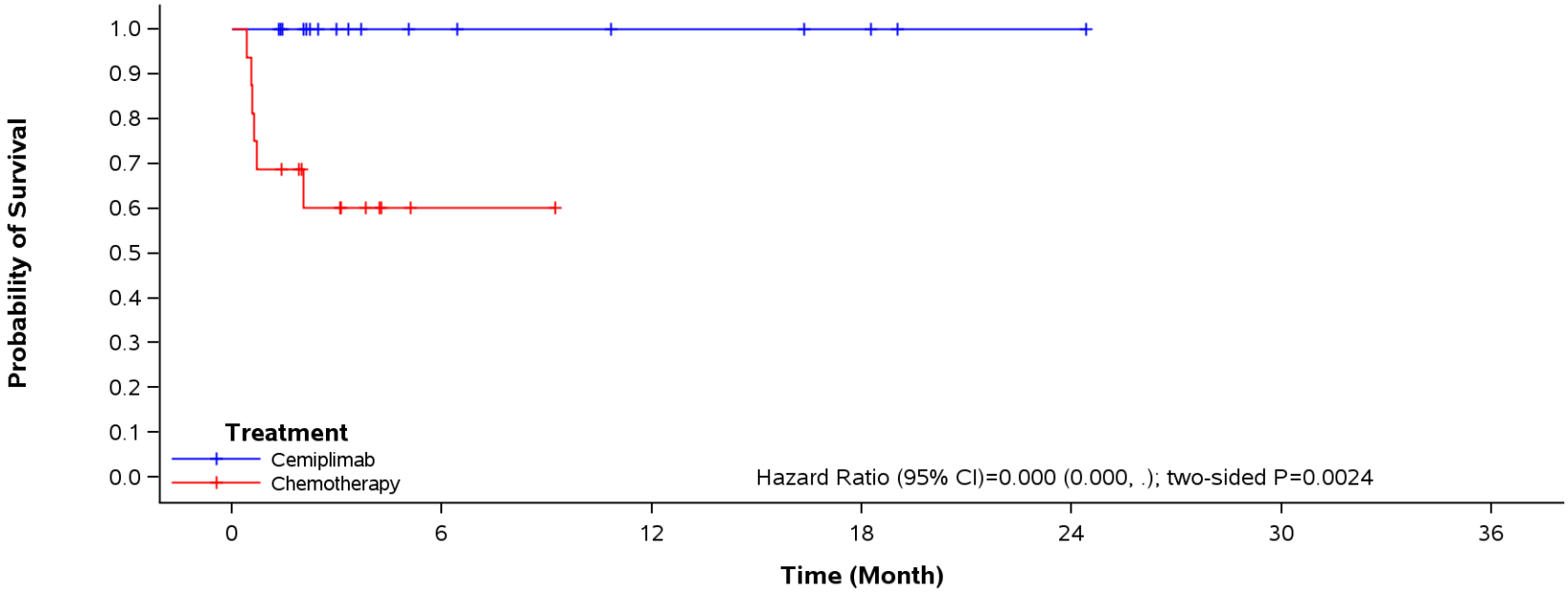

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



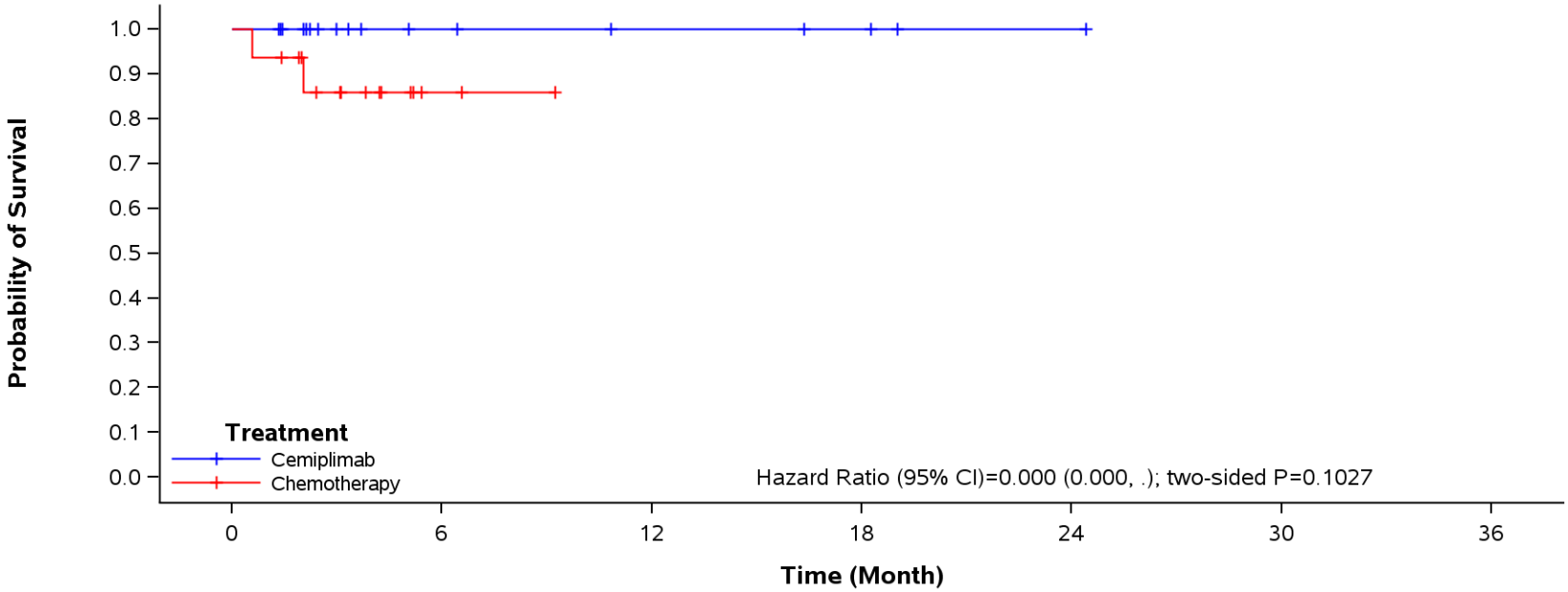

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



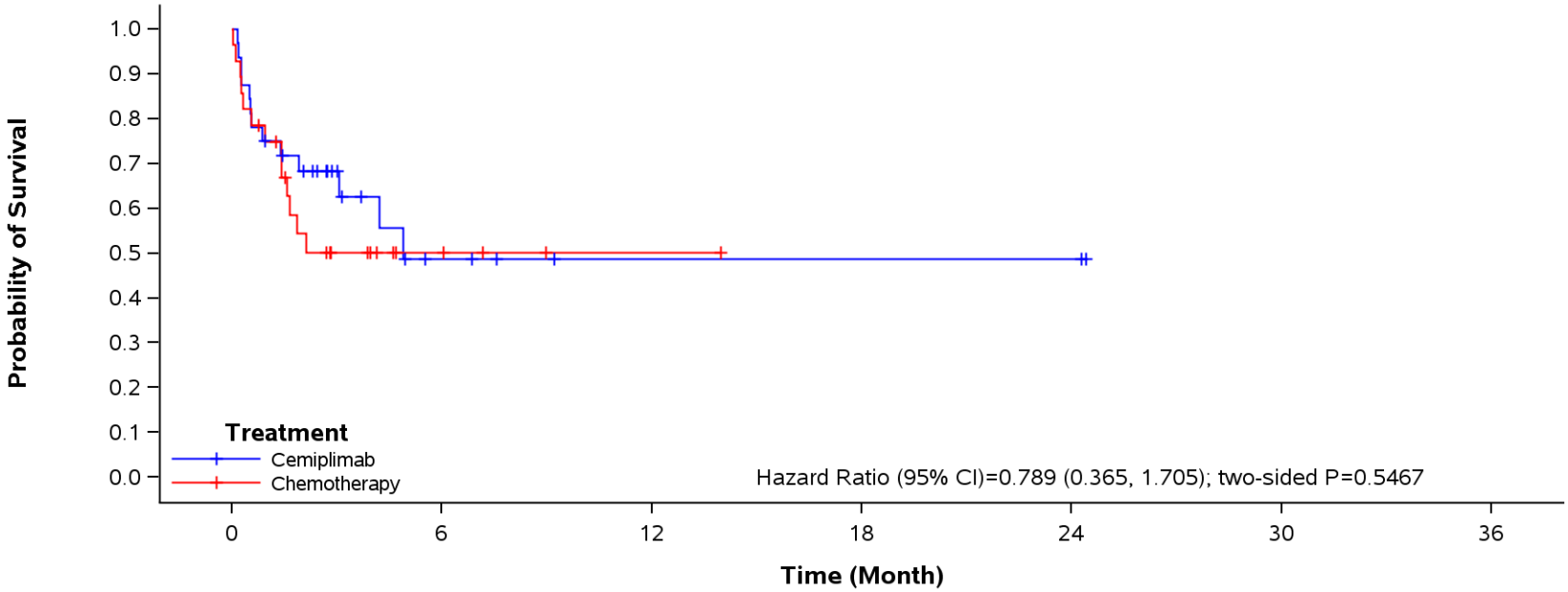

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Number of patients with any TEAE CTCAE Grade >= 3



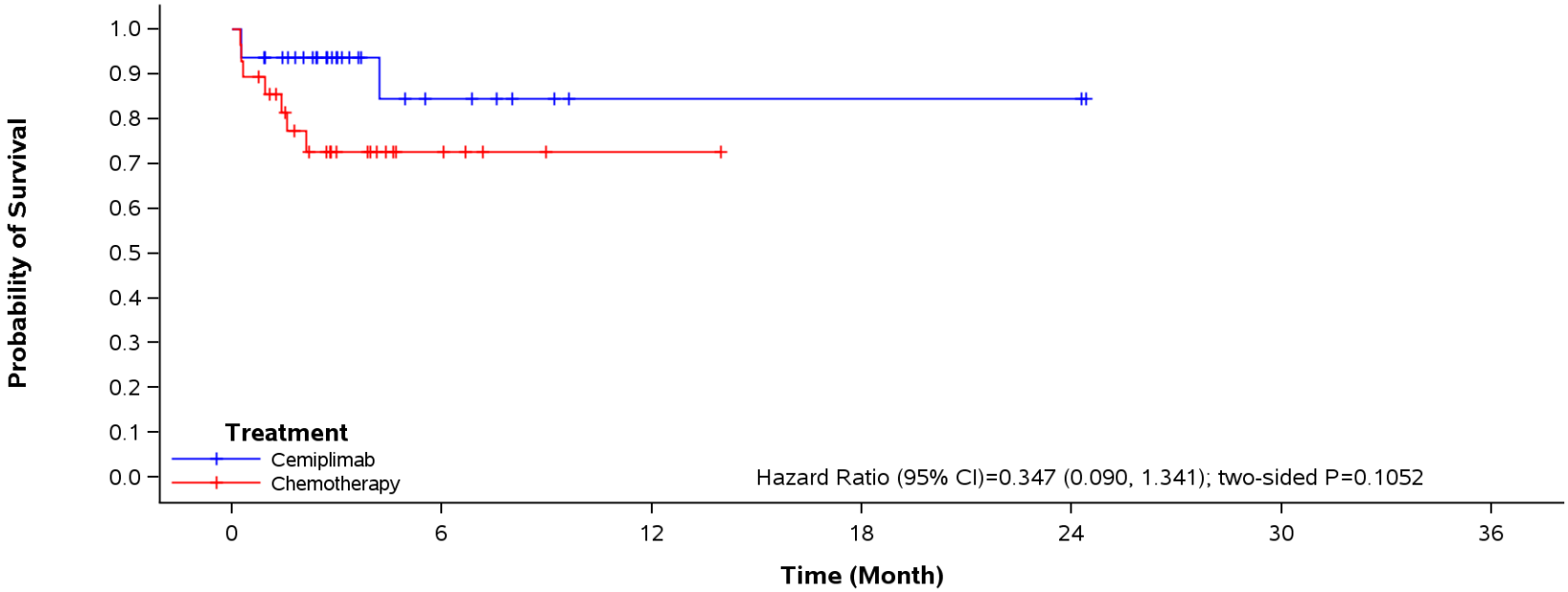

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 5 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders



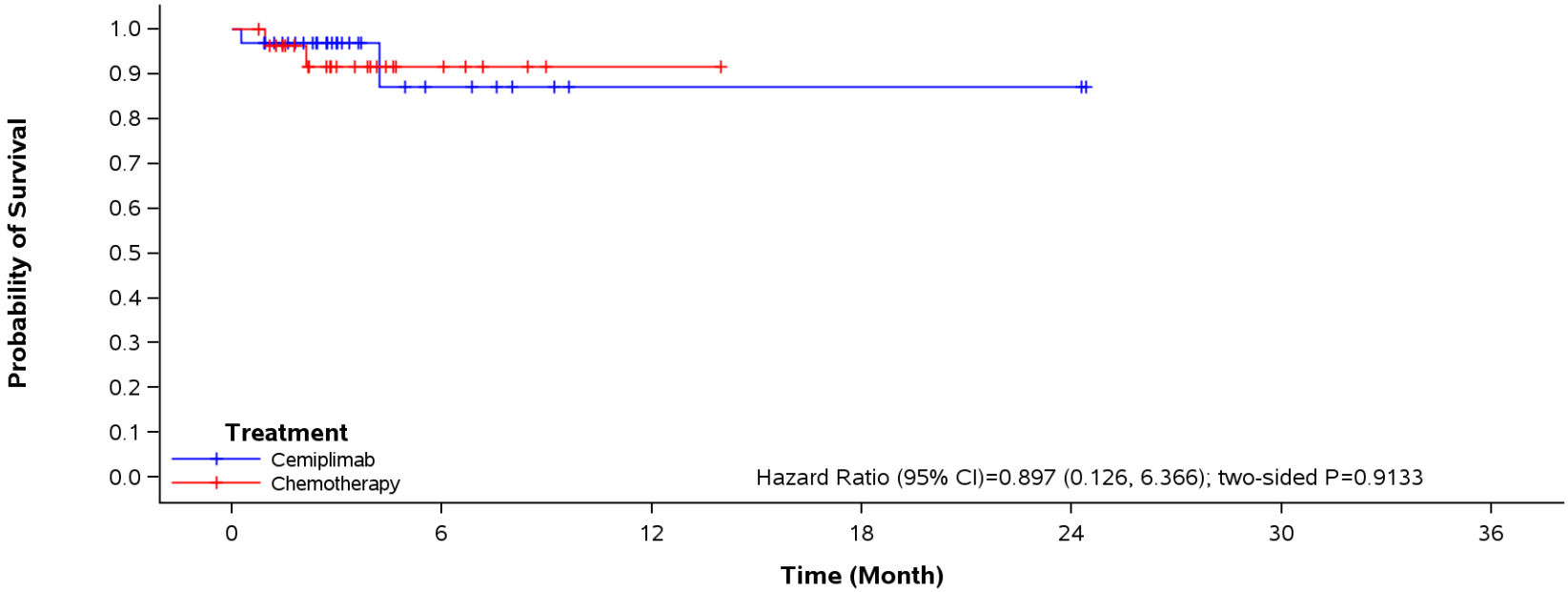

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 7 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Anaemia



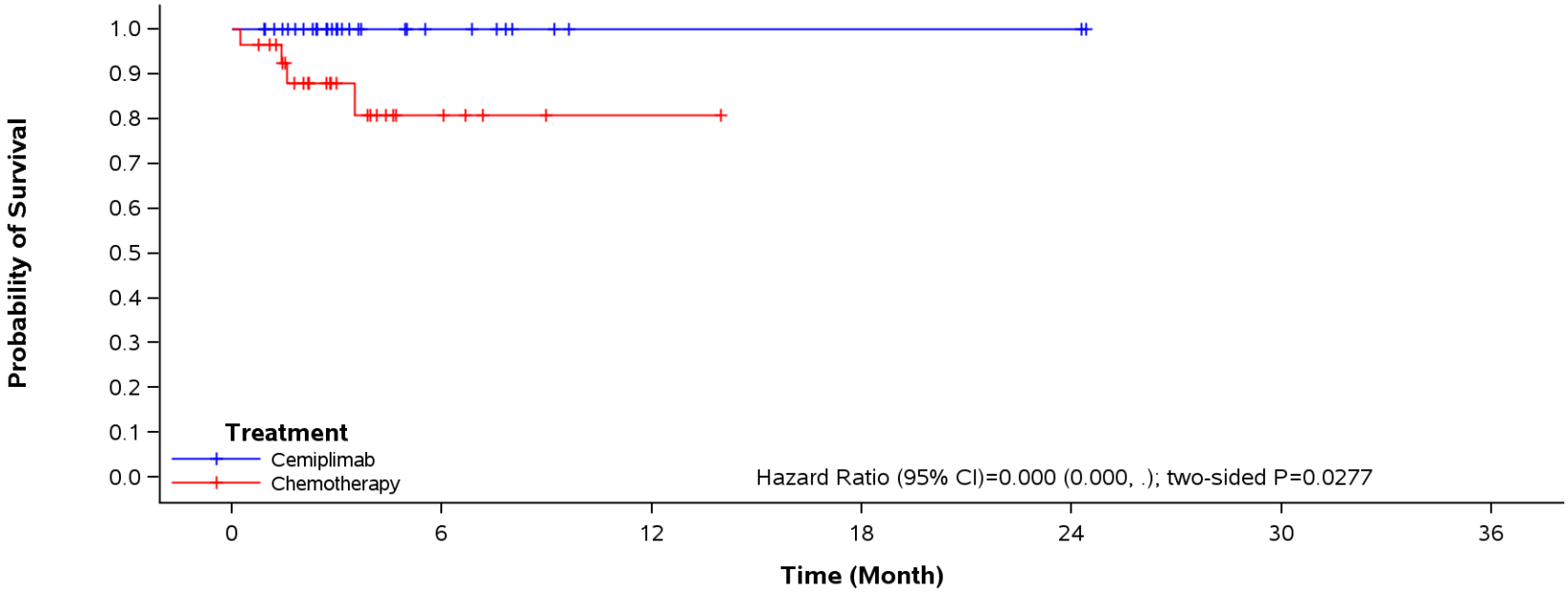

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 7 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Neutropenia




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2021.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Table 1.1.1. Demographics and Baseline Characteristics
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Age (years) | | | |
| n | 196 | 183 | 379 |
| Mean (SD) | 49.6 (10.96) | 50.4 (11.45) | 50.0 (11.19) |
| Median | 50.0 | 50.0 | 50.0 |
| Q1 : Q3 | 41.0 : 58.5 | 43.0 : 56.0 | 42.0 : 57.0 |
| Min : Max | 22 : 75 | 28 : 87 | 22 : 87 |
| Age Groups (years), n (%) | | | |
| <65 | 180 (91.8%) | 163 (89.1%) | 343 (90.5%) |
| >=65 | 16 (8.2%) | 20 (10.9%) | 36 (9.5%) |
| Age Groups (years), n (%) | | | |
| <65 | 180 (91.8%) | 163 (89.1%) | 343 (90.5%) |
| >=65 and <75 | 15 (7.7%) | 14 (7.7%) | 29 (7.7%) |
| >=75 | 1 (0.5%) | 6 (3.3%) | 7 (1.8%) |

Data cut-off as of Jan 4th, 2022.
ECOG, Geographic Region are based on clinical database.

Table 1.1.1. Demographics and Baseline Characteristics
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Race, n (%) | | | |
| White | 136 (69.4%) | 123 (67.2%) | 259 (68.3%) |
| Black or African American | 9 (4.6%) | 12 (6.6%) | 21 (5.5%) |
| Asian | 41 (20.9%) | 38 (20.8%) | 79 (20.8%) |
| American Indian or Alaska Native | 0 | 1 (0.5%) | 1 (0.3%) |
| Other | 6 (3.1%) | 3 (1.6%) | 9 (2.4%) |
| Unknown | 1 (0.5%) | 1 (0.5%) | 2 (0.5%) |
| Not Reported | 3 (1.5%) | 5 (2.7%) | 8 (2.1%) |
| Ethnicity, n (%) | | | |
| Not Hispanic or Latino | 150 (76.5%) | 138 (75.4%) | 288 (76.0%) |
| Hispanic or Latino | 40 (20.4%) | 38 (20.8%) | 78 (20.6%) |
| Not Reported | 6 (3.1%) | 7 (3.8%) | 13 (3.4%) |
| Geographic region, n (%) | | | |
| North America | 22 (11.2%) | 25 (13.7%) | 47 (12.4%) |
| Asia | 36 (18.4%) | 35 (19.1%) | 71 (18.7%) |
| Rest of World | 138 (70.4%) | 123 (67.2%) | 261 (68.9%) |

Data cut-off as of Jan 4th, 2022.
ECOG, Geographic Region are based on clinical database.

Table 1.1.1. Demographics and Baseline Characteristics
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| Height (cm) | | | |
| n | 196 | 183 | 379 |
| Mean (SD) | 160.81 (6.582) | 160.54 (6.879) | 160.68 (6.719) |
| Median | 160.40 | 160.00 | 160.00 |
| Q1 : Q3 | 156.00 : 165.00 | 156.00 : 165.00 | 156.00 : 165.00 |
| Min : Max | 147.0 : 178.0 | 137.0 : 181.0 | 137.0 : 181.0 |
| Body Weight (kg) | | | |
| n | 196 | 183 | 379 |
| Mean (SD) | 67.00 (17.283) | 64.64 (16.326) | 65.86 (16.847) |
| Median | 65.00 | 62.00 | 63.50 |
| Q1 : Q3 | 53.00 : 77.80 | 52.50 : 75.00 | 52.70 : 76.00 |
| Min : Max | 36.6 : 128.7 | 35.0 : 120.0 | 35.0 : 128.7 |
| BMI (kg/m2) | | | |
| n | 196 | 183 | 379 |
| Mean (SD) | 25.868 (6.3681) | 25.010 (5.7981) | 25.454 (6.1066) |
| Median | 24.890 | 24.090 | 24.570 |
| Q1 : Q3 | 21.330 : 29.060 | 20.500 : 28.520 | 21.090 : 28.880 |
| Min : Max | 14.17 : 49.00 | 15.43 : 43.73 | 14.17 : 49.00 |

Data cut-off as of Jan 4th, 2022.
ECOG, Geographic Region are based on clinical database.

Table 1.1.1. Demographics and Baseline Characteristics
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) | Total (N=379) |
|---|---|---|---|
| ECOG performance status, n (%) | | | |
| 0 | 83 (42.3%) | 69 (37.7%) | 152 (40.1%) |
| 1 | 113 (57.7%) | 114 (62.3%) | 227 (59.9%) |

Data cut-off as of Jan 4th, 2022.
ECOG, Geographic Region are based on clinical database.

Table 1.2.1. Demographics and Baseline Characteristics
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) | Total (N=367) |
|---|---|---|---|
| Age (years) | | | |
| n | 195 | 172 | 367 |
| Mean (SD) | 49.8 (10.92) | 50.1 (11.58) | 50.0 (11.22) |
| Median | 50.0 | 49.5 | 50.0 |
| Q1 : Q3 | 41.0 : 59.0 | 42.0 : 56.0 | 42.0 : 57.0 |
| Min : Max | 22 : 75 | 28 : 87 | 22 : 87 |
| Age Groups (years), n (%) | | | |
| <65 | 179 (91.8%) | 153 (89.0%) | 332 (90.5%) |
| >=65 | 16 (8.2%) | 19 (11.0%) | 35 (9.5%) |
| Age Groups (years), n (%) | | | |
| <65 | 179 (91.8%) | 153 (89.0%) | 332 (90.5%) |
| >=65 and <75 | 15 (7.7%) | 13 (7.6%) | 28 (7.6%) |
| >=75 | 1 (0.5%) | 6 (3.5%) | 7 (1.9%) |

Data cut-off as of Jan 4th, 2022.
ECOG, Geographic Region are based on clinical database.

Table 1.2.1. Demographics and Baseline Characteristics
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) | Total (N=367) |
|---|---|---|---|
| Race, n (%) | | | |
| White | 135 (69.2%) | 115 (66.9%) | 250 (68.1%) |
| Black or African American | 9 (4.6%) | 12 (7.0%) | 21 (5.7%) |
| Asian | 41 (21.0%) | 35 (20.3%) | 76 (20.7%) |
| American Indian or Alaska Native | 0 | 1 (0.6%) | 1 (0.3%) |
| Other | 6 (3.1%) | 3 (1.7%) | 9 (2.5%) |
| Unknown | 1 (0.5%) | 1 (0.6%) | 2 (0.5%) |
| Not Reported | 3 (1.5%) | 5 (2.9%) | 8 (2.2%) |
| Ethnicity, n (%) | | | |
| Not Hispanic or Latino | 149 (76.4%) | 128 (74.4%) | 277 (75.5%) |
| Hispanic or Latino | 40 (20.5%) | 37 (21.5%) | 77 (21.0%) |
| Not Reported | 6 (3.1%) | 7 (4.1%) | 13 (3.5%) |
| Geographic region, n (%) | | | |
| North America | 22 (11.3%) | 21 (12.2%) | 43 (11.7%) |
| Asia | 36 (18.5%) | 32 (18.6%) | 68 (18.5%) |
| Rest of World | 137 (70.3%) | 119 (69.2%) | 256 (69.8%) |

Data cut-off as of Jan 4th, 2022.
ECOG, Geographic Region are based on clinical database.

Table 1.2.1. Demographics and Baseline Characteristics
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) | Total (N=367) |
|---|---|---|---|
| Height (cm) | | | |
| n | 195 | 172 | 367 |
| Mean (SD) | 160.72 (6.513) | 160.48 (6.858) | 160.61 (6.669) |
| Median | 160.30 | 160.00 | 160.00 |
| Q1 : Q3 | 156.00 : 165.00 | 156.00 : 165.30 | 156.00 : 165.00 |
| Min : Max | 147.0 : 178.0 | 137.0 : 177.0 | 137.0 : 178.0 |
| Body Weight (kg) | | | |
| n | 195 | 172 | 367 |
| Mean (SD) | 67.20 (17.264) | 64.77 (16.500) | 66.06 (16.931) |
| Median | 65.00 | 62.20 | 63.70 |
| Q1 : Q3 | 53.00 : 78.30 | 52.60 : 75.15 | 52.80 : 77.00 |
| Min : Max | 36.6 : 128.7 | 35.0 : 120.0 | 35.0 : 128.7 |
| BMI (kg/m2) | | | |
| n | 195 | 172 | 367 |
| Mean (SD) | 25.968 (6.3403) | 25.086 (5.8917) | 25.555 (6.1417) |
| Median | 24.970 | 23.910 | 24.680 |
| Q1 : Q3 | 21.340 : 29.120 | 20.475 : 28.705 | 21.250 : 29.050 |
| Min : Max | 15.88 : 49.00 | 15.43 : 43.73 | 15.43 : 49.00 |

Data cut-off as of Jan 4th, 2022.
ECOG, Geographic Region are based on clinical database.

Table 1.2.1. Demographics and Baseline Characteristics
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) | Total (N=367) |
|---|---|---|---|
| ECOG performance status, n (%) | | | |
| 0 | 83 (42.6%) | 64 (37.2%) | 147 (40.1%) |
| 1 | 112 (57.4%) | 108 (62.8%) | 220 (59.9%) |

Data cut-off as of Jan 4th, 2022.
ECOG, Geographic Region are based on clinical database.

Table 4.1.1. Best Overall Tumor Response Rate per RECIST 1.1 - CMH Test
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Best Overall Tumor Response, n(%) | | |
| Complete Response (CR) [a] | 7 (3.6%) | 2 (1.1%) |
| Partial Response (PR) [a] | 26 (13.3%) | 11 (6.0%) |
| Stable Disease (SD) [b] | 77 (39.3%) | 87 (47.5%) |
| Progressive Disease (PD) | 70 (35.7%) | 52 (28.4%) |
| Not Evaluable (NE) | 16 (8.2%) | 31 (16.9%) |
| Response | | |
| Objective Response Rate (ORR:CR+PR) | 33 (16.8%) | 13 (7.1%) |
| 95% CI for ORR [c] | (11.9%, 22.8%) | (3.8%, 11.8%) |
| Stratified CMH test One-sided p-value [d] | 0.00361 | |
| Odds ratio (95% CI) [d] | 2.512 (1.267, 4.977) | |

Data cut-off as of Jan 4th, 2022.
[a] CR/PR must be confirmed by repeated assessments no less than 4 weeks apart
[b] SD criteria must be met at least once for a minimum duration of 4 weeks after first dose date
[c] Clopper-Person exact confidence interval.
[d] One-sided p-value and odds ratio using geographic region and histology stratified Cochran-Mantel-Haenszel test. Due to the low response rate in the Chemotherapy arm, the results from CMH test should be interpreted with caution.

Table 5.1.1. Overall Survival
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=196) | Chemotherapy (N=183) |
|---|---|---|
| Number of deaths, n (%) | 140 (71.4%) | 151 (82.5%) |
| Number of censored patients, n (%) | 56 (28.6%) | 32 (17.5%) |
| | | |
| Median (95% CI), (Months) [a] | 12.4 (8.3, 14.9) | 8.0 (7.0, 9.7) |
| Stratified log-rank test 2-sided p-value [b][c] | <0.0001 | |
| HR (95% CI) [b][d] | 0.626 (0.495, 0.793) | |
| HR P-Value [b][d] | 0.0001 | |
| | | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 66.6 (59.5, 72.7) | 63.4 (55.7, 70.2) |
| 12 months | 52.4 (45.1, 59.2) | 34.4 (27.2, 41.7) |
| 18 months | 35.3 (28.5, 42.2) | 18.1 (12.6, 24.4) |
| 24 months | 29.7 (23.2, 36.4) | 10.4 (6.1, 16.1) |
| 30 months | 24.0 (17.5, 31.1) | 6.4 (2.9, 11.7) |
| 36 months | 22.6 (16.1, 29.9) | 5.1 (2.0, 10.4) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 5.1.3. Kaplan-Meier Estimation of Duration of Response
(Full Analysis Set Exclude Patients Assigned to Gemcitabine - Patients with Confirmed CR or PR)

| | Cemiplimab (N=33) | Chemotherapy (N=13) |
|---|---|---|
| KM Estimation of Duration of Response (CR or PR) [a] | | |
| n | 33 | 13 |
| Number of events, n (%) | 13 (39.4%) | 11 (84.6%) |
| Number of censored patients, n (%) | 20 (60.6%) | 2 (15.4%) |
| Median (95% CI), (months) [a] | 28.9 (17.3, NE) | 7.7 (5.1, 10.1) |
| Stratified log-rank test 2-sided p-value [b][c] | <0.0001 | |
| HR (95% CI) [b][d] | 0.155 (0.061, 0.397) | |
| HR P-Value [b][d] | 0.0001 | |
| Estimated Event-Free Probability, % (95% CI) [a] | | |
| 6 months | 90.9 (74.4, 97.0) | 76.9 (44.2, 91.9) |
| 12 months | 87.8 (70.6, 95.2) | 9.2 (0.6, 33.4) |
| 18 months | 69.7 (49.6, 83.1) | 9.2 (0.6, 33.4) |
| 24 months | 61.5 (40.9, 76.8) | NE (NE, NE) |
| 30 months | 34.2 (7.9, 63.5) | NE (NE, NE) |
| 36 months | 34.2 (7.9, 63.5) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on patients with confirmed CR or PR.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] Two-sided p-value is from stratified log-rank test.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 6.1.1. Observed Duration of Response
(Full Analysis Set Exclude Patients Assigned to Gemcitabine - Patients with Confirmed CR or PR)

| | Cemiplimab (N=33) | Chemotherapy (N=13) |
|---|---|---|
| Observed Duration of Response (CR or PR) (months) [a] | | |
| n | 33 | 13 |
| Mean (SD) | 18.55 (8.356) | 8.40 (4.044) |
| Median | 18.07 | 7.69 |
| Q1 : Q3 | 15.74 : 22.31 | 6.93 : 9.89 |
| Min : Max | 3.9 : 44.5 | 2.7 : 18.8 |
| Observed Duration of Response (CR or PR), n (%) [a] | | |
| <6 months | 3 (9.1%) | 3 (23.1%) |
| >=6 months | 30 (90.9%) | 10 (76.9%) |
| >=12 months | 26 (78.8%) | 1 (7.7%) |
| >=18 months | 18 (54.5%) | 1 (7.7%) |
| >=24 months | 7 (21.2%) | 0 |
| >=30 months | 2 (6.1%) | 0 |
| >=36 months | 1 (3.0%) | 0 |

Data cut-off as of Jan 4th, 2022.
[a] Based on patients with confirmed CR or PR.

Table 12.2.1. Time to First Any Treatment-Emergent Adverse Events
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 175 (89.7%) | 153 (89.0%) |
| Censored Patients, n (%) | 20 (10.3%) | 19 (11.0%) |
| Median (95% CI), (Months) [a] | 0.56 (0.39, 0.72) | 0.23 (0.13, 0.30) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0009 | |
| HR (95% CI) [c] | 0.685 (0.549, 0.856) | |
| HR P-Value [c] | 0.0009 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 11.8 (7.5, 17.3) | 9.6 (5.2, 15.5) |
| 12 months | 7.3 (3.7, 12.5) | 0.0 (NE, NE) |
| 18 months | 6.2 (2.9, 11.3) | 0.0 (NE, NE) |
| 24 months | 1.6 (0.2, 6.8) | 0.0 (NE, NE) |
| 30 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.2. Time to First Any Serious Treatment-Emergent Adverse Events
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 61 (31.3%) | 52 (30.2%) |
| Censored Patients, n (%) | 134 (68.7%) | 120 (69.8%) |
| Median (95% CI), (Months) [a] | 20.57 (13.83, NE) | NE (7.79, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2021 | |
| HR (95% CI) [c] | 0.781 (0.533, 1.143) | |
| HR P-Value [c] | 0.2030 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 71.5 (63.5, 78.1) | 64.2 (54.3, 72.5) |
| 12 months | 63.2 (53.5, 71.5) | 57.4 (44.5, 68.4) |
| 18 months | 56.1 (45.1, 65.7) | 57.4 (44.5, 68.4) |
| 24 months | 46.1 (33.5, 57.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 98 (50.3%) | 88 (51.2%) |
| Censored Patients, n (%) | 97 (49.7%) | 84 (48.8%) |
| Median (95% CI), (Months) [a] | 7.16 (4.73, 13.83) | 3.61 (1.87, 11.56) |
| Unstratified log-rank test 2-sided p-value [b] | 0.0157 | |
| HR (95% CI) [c] | 0.694 (0.516, 0.933) | |
| HR P-Value [c] | 0.0157 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 53.2 (45.1, 60.7) | 44.6 (35.9, 53.0) |
| 12 months | 45.3 (36.5, 53.6) | 29.3 (12.4, 48.6) |
| 18 months | 36.6 (27.3, 45.9) | 29.3 (12.4, 48.6) |
| 24 months | 29.0 (19.4, 39.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 21 (10.8%) | 8 (4.7%) |
| Censored Patients, n (%) | 174 (89.2%) | 164 (95.3%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.2774 | |
| HR (95% CI) [c] | 1.586 (0.685, 3.673) | |
| HR P-Value [c] | 0.2818 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 89.3 (82.1, 93.7) | 95.0 (89.6, 97.7) |
| 12 months | 85.4 (77.0, 91.0) | 90.3 (74.6, 96.5) |
| 18 months | 79.1 (67.7, 86.8) | 90.3 (74.6, 96.5) |
| 24 months | 76.5 (64.2, 85.1) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65

| | Cemiplimab (N=180) | Chemotherapy (N=163) |
|---|---|---|
| Number of deaths, n (%) | 131 (72.8%) | 133 (81.6%) |
| Number of censored patients, n (%) | 49 (27.2%) | 30 (18.4%) |
| Median (95% CI), (Months) [a] | 12.1 (8.0, 14.5) | 7.9 (6.9, 9.5) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.00062 | |
| HR (95% CI) [b][d] | 0.667 (0.521, 0.854) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 65.3 (57.8, 71.8) | 64.1 (55.8, 71.2) |
| 12 months | 51.5 (43.9, 58.6) | 34.0 (26.4, 41.8) |
| 18 months | 32.8 (25.9, 39.9) | 18.4 (12.6, 25.2) |
| 24 months | 27.3 (20.7, 34.2) | 9.8 (5.3, 15.8) |
| 30 months | 21.8 (15.2, 29.1) | 7.4 (3.5, 13.3) |
| 36 months | 21.8 (15.2, 29.1) | 5.9 (2.4, 11.9) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65

| | Cemiplimab (N=16) | Chemotherapy (N=20) |
|---|---|---|
| Number of deaths, n (%) | 9 (56.3%) | 18 (90.0%) |
| Number of censored patients, n (%) | 7 (43.8%) | 2 (10.0%) |
| Median (95% CI), (Months) [a] | 24.8 (7.0, NE) | 11.2 (3.2, 13.8) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.00606 | |
| HR (95% CI) [b][d] | 0.316 (0.123, 0.808) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 81.3 (52.5, 93.5) | 58.4 (33.8, 76.7) |
| 12 months | 62.5 (34.9, 81.1) | 37.2 (16.7, 57.8) |
| 18 months | 62.5 (34.9, 81.1) | 15.9 (4.0, 35.2) |
| 24 months | 55.6 (28.6, 75.9) | 15.9 (4.0, 35.2) |
| 30 months | 46.3 (19.9, 69.3) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

| | Cemiplimab (N=136) | Chemotherapy (N=123) |
|---|---|---|
| Number of deaths, n (%) | 97 (71.3%) | 105 (85.4%) |
| Number of censored patients, n (%) | 39 (28.7%) | 18 (14.6%) |
| Median (95% CI), (Months) [a] | 12.7 (9.1, 15.2) | 7.9 (6.5, 10.0) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.00027 | |
| HR (95% CI) [b][d] | 0.607 (0.456, 0.808) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 66.9 (58.3, 74.1) | 61.9 (52.4, 70.1) |
| 12 months | 53.5 (44.7, 61.5) | 33.3 (24.8, 42.0) |
| 18 months | 34.8 (26.7, 42.9) | 18.0 (11.5, 25.6) |
| 24 months | 30.6 (22.9, 38.7) | 11.5 (6.3, 18.5) |
| 30 months | 25.2 (17.4, 33.6) | 6.6 (2.7, 13.0) |
| 36 months | 25.2 (17.4, 33.6) | 4.9 (1.6, 11.3) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white

| | Cemiplimab (N=60) | Chemotherapy (N=60) |
|---|---|---|
| Number of deaths, n (%) | 43 (71.7%) | 46 (76.7%) |
| Number of censored patients, n (%) | 17 (28.3%) | 14 (23.3%) |
| Median (95% CI), (Months) [a] | 10.5 (7.0, 17.9) | 8.8 (6.4, 11.4) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.09313 | |
| HR (95% CI) [b][d] | 0.737 (0.467, 1.161) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 65.6 (51.9, 76.3) | 66.7 (52.4, 77.5) |
| 12 months | 49.6 (36.1, 61.7) | 36.8 (23.9, 49.8) |
| 18 months | 36.5 (24.1, 49.0) | 18.4 (9.1, 30.2) |
| 24 months | 26.9 (15.5, 39.6) | 7.8 (1.9, 19.3) |
| 30 months | 21.5 (11.0, 34.2) | 7.8 (1.9, 19.3) |
| 36 months | 16.1 (6.0, 30.7) | 7.8 (1.9, 19.3) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America

| | Cemiplimab (N=22) | Chemotherapy (N=25) |
|---|---|---|
| Number of deaths, n (%) | 13 (59.1%) | 17 (68.0%) |
| Number of censored patients, n (%) | 9 (40.9%) | 8 (32.0%) |
| Median (95% CI), (Months) [a] | 16.7 (3.9, NE) | 7.0 (4.5, 17.3) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.11327 | |
| HR (95% CI) [b][d] | 0.639 (0.307, 1.328) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (44.6, 83.4) | 62.6 (38.8, 79.3) |
| 12 months | 63.3 (39.8, 79.7) | 36.1 (16.0, 56.7) |
| 18 months | 40.9 (19.5, 61.4) | 24.1 (7.9, 45.0) |
| 24 months | 40.9 (19.5, 61.4) | 24.1 (7.9, 45.0) |
| 30 months | 30.7 (10.1, 54.4) | 18.0 (4.7, 38.5) |
| 36 months | 30.7 (10.1, 54.4) | 18.0 (4.7, 38.5) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia

| | Cemiplimab (N=39) | Chemotherapy (N=36) |
|---|---|---|
| Number of deaths, n (%) | 30 (76.9%) | 26 (72.2%) |
| Number of censored patients, n (%) | 9 (23.1%) | 10 (27.8%) |
| Median (95% CI), (Months) [a] | 12.4 (7.0, 16.0) | 9.4 (5.8, 14.5) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.07535 | |
| HR (95% CI) [b][d] | 0.659 (0.371, 1.169) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 71.1 (53.9, 82.8) | 67.6 (48.1, 81.1) |
| 12 months | 50.0 (33.4, 64.6) | 43.3 (25.3, 60.0) |
| 18 months | 34.2 (19.8, 49.1) | 21.6 (8.9, 38.0) |
| 24 months | 24.9 (12.3, 39.7) | 13.0 (3.6, 28.6) |
| 30 months | 21.8 (10.0, 36.4) | 13.0 (3.6, 28.6) |
| 36 months | 17.4 (6.7, 32.4) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe

| | Cemiplimab (N=76) | Chemotherapy (N=66) |
|---|---|---|
| Number of deaths, n (%) | 55 (72.4%) | 57 (86.4%) |
| Number of censored patients, n (%) | 21 (27.6%) | 9 (13.6%) |
| Median (95% CI), (Months) [a] | 13.8 (8.9, 15.2) | 8.0 (5.7, 11.3) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.00108 | |
| HR (95% CI) [b][d] | 0.554 (0.377, 0.812) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 69.7 (58.1, 78.7) | 63.1 (49.9, 73.8) |
| 12 months | 56.6 (44.7, 66.8) | 34.9 (23.2, 46.8) |
| 18 months | 33.7 (23.3, 44.4) | 15.0 (7.4, 25.0) |
| 24 months | 31.0 (21.0, 41.6) | 10.0 (3.7, 20.0) |
| 30 months | 26.2 (16.1, 37.4) | 0.0 (NE, NE) |
| 36 months | 26.2 (16.1, 37.4) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW

| | Cemiplimab (N=59) | Chemotherapy (N=56) |
|---|---|---|
| Number of deaths, n (%) | 42 (71.2%) | 51 (91.1%) |
| Number of censored patients, n (%) | 17 (28.8%) | 5 (8.9%) |
| Median (95% CI), (Months) [a] | 7.5 (5.3, 17.3) | 7.7 (5.4, 10.5) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.05601 | |
| HR (95% CI) [b][d] | 0.717 (0.475, 1.083) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 58.9 (45.2, 70.3) | 62.0 (47.9, 73.3) |
| 12 months | 44.4 (31.3, 56.7) | 29.2 (17.9, 41.4) |
| 18 months | 36.3 (23.8, 48.9) | 18.2 (9.4, 29.4) |
| 24 months | 27.3 (15.9, 40.0) | 6.6 (1.8, 15.6) |
| 30 months | 20.2 (9.5, 33.8) | 6.6 (1.8, 15.6) |
| 36 months | 20.2 (9.5, 33.8) | 6.6 (1.8, 15.6) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

| | Cemiplimab (N=161) | Chemotherapy (N=137) |
|---|---|---|
| Number of deaths, n (%) | 111 (68.9%) | 114 (83.2%) |
| Number of censored patients, n (%) | 50 (31.1%) | 23 (16.8%) |
| Median (95% CI), (Months) [a] | 12.5 (8.3, 15.0) | 8.2 (7.4, 10.3) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.00030 | |
| HR (95% CI) [b][d] | 0.629 (0.481, 0.821) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 68.2 (60.4, 74.8) | 67.2 (58.3, 74.6) |
| 12 months | 52.9 (44.9, 60.3) | 35.8 (27.5, 44.1) |
| 18 months | 36.7 (29.1, 44.2) | 18.7 (12.4, 26.0) |
| 24 months | 31.2 (23.9, 38.8) | 11.3 (6.1, 18.2) |
| 30 months | 26.4 (19.0, 34.4) | 6.6 (2.5, 13.4) |
| 36 months | 24.8 (17.3, 33.0) | 4.9 (1.5, 11.5) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous

| | Cemiplimab (N=35) | Chemotherapy (N=46) |
|---|---|---|
| Number of deaths, n (%) | 29 (82.9%) | 37 (80.4%) |
| Number of censored patients, n (%) | 6 (17.1%) | 9 (19.6%) |
| Median (95% CI), (Months) [a] | 12.1 (4.7, 17.4) | 6.2 (4.3, 11.4) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.04529 | |
| HR (95% CI) [b][d] | 0.639 (0.379, 1.078) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 59.0 (40.8, 73.3) | 51.6 (35.5, 65.6) |
| 12 months | 50.1 (32.6, 65.4) | 30.1 (16.6, 44.7) |
| 18 months | 29.5 (15.4, 45.0) | 16.4 (6.7, 29.8) |
| 24 months | 22.9 (10.5, 38.2) | 8.2 (2.1, 19.7) |
| 30 months | 14.7 (4.7, 30.2) | 5.5 (1.0, 16.0) |
| 36 months | 14.7 (4.7, 30.2) | 5.5 (1.0, 16.0) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

| | Cemiplimab (N=89) | Chemotherapy (N=85) |
|---|---|---|
| Number of deaths, n (%) | 59 (66.3%) | 69 (81.2%) |
| Number of censored patients, n (%) | 30 (33.7%) | 16 (18.8%) |
| Median (95% CI), (Months) [a] | 12.4 (8.3, 17.9) | 6.7 (4.5, 8.5) |
| Stratified log-rank test 1-sided p-value [b][c] | <0.0001 | |
| HR (95% CI) [b][d] | 0.488 (0.339, 0.702) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 70.8 (60.1, 79.0) | 52.7 (40.9, 63.2) |
| 12 months | 52.1 (41.2, 62.0) | 25.9 (16.5, 36.4) |
| 18 months | 38.6 (28.3, 48.8) | 11.5 (5.4, 20.2) |
| 24 months | 32.8 (22.9, 43.1) | 7.9 (2.9, 16.1) |
| 30 months | 30.8 (20.8, 41.3) | 5.3 (1.3, 13.7) |
| 36 months | 30.8 (20.8, 41.3) | 5.3 (1.3, 13.7) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

| | Cemiplimab (N=107) | Chemotherapy (N=98) |
|---|---|---|
| Number of deaths, n (%) | 81 (75.7%) | 82 (83.7%) |
| Number of censored patients, n (%) | 26 (24.3%) | 16 (16.3%) |
| Median (95% CI), (Months) [a] | 12.3 (6.6, 14.5) | 9.8 (7.7, 12.0) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.07164 | |
| HR (95% CI) [b][d] | 0.790 (0.575, 1.084) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 63.1 (53.1, 71.5) | 72.1 (61.8, 80.1) |
| 12 months | 52.5 (42.6, 61.6) | 41.1 (31.0, 51.0) |
| 18 months | 32.6 (23.7, 41.7) | 23.3 (15.2, 32.4) |
| 24 months | 27.0 (18.7, 36.0) | 12.8 (6.6, 21.0) |
| 30 months | 20.0 (12.4, 29.0) | 7.5 (2.7, 15.3) |
| 36 months | 18.4 (10.9, 27.3) | 5.0 (1.2, 13.0) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

| | Cemiplimab (N=83) | Chemotherapy (N=69) |
|---|---|---|
| Number of deaths, n (%) | 50 (60.2%) | 54 (78.3%) |
| Number of censored patients, n (%) | 33 (39.8%) | 15 (21.7%) |
| Median (95% CI), (Months) [a] | 17.3 (12.5, 27.8) | 11.2 (8.2, 13.5) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.00061 | |
| HR (95% CI) [b][d] | 0.517 (0.344, 0.776) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 78.2 (67.6, 85.6) | 76.4 (63.9, 85.0) |
| 12 months | 64.4 (52.9, 73.7) | 44.5 (31.7, 56.5) |
| 18 months | 46.3 (35.1, 56.8) | 22.2 (12.7, 33.5) |
| 24 months | 41.8 (30.7, 52.5) | 17.1 (8.8, 27.7) |
| 30 months | 37.6 (26.4, 48.8) | 11.4 (4.4, 22.2) |
| 36 months | 34.7 (23.2, 46.5) | 7.6 (1.8, 19.0) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

| | Cemiplimab (N=113) | Chemotherapy (N=114) |
|---|---|---|
| Number of deaths, n (%) | 90 (79.6%) | 97 (85.1%) |
| Number of censored patients, n (%) | 23 (20.4%) | 17 (14.9%) |
| Median (95% CI), (Months) [a] | 8.0 (5.5, 12.1) | 7.0 (5.4, 8.5) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.01608 | |
| HR (95% CI) [b][d] | 0.724 (0.539, 0.974) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 58.1 (48.4, 66.6) | 55.7 (45.7, 64.5) |
| 12 months | 43.7 (34.4, 52.6) | 28.3 (20.0, 37.2) |
| 18 months | 27.2 (19.2, 35.9) | 15.6 (9.4, 23.3) |
| 24 months | 20.8 (13.5, 29.1) | 7.5 (3.3, 14.1) |
| 30 months | 13.7 (7.1, 22.5) | 4.5 (1.4, 10.7) |
| 36 months | 13.7 (7.1, 22.5) | 4.5 (1.4, 10.7) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line

| | Cemiplimab (N=117) | Chemotherapy (N=97) |
|---|---|---|
| Number of deaths, n (%) | 82 (70.1%) | 84 (86.6%) |
| Number of censored patients, n (%) | 35 (29.9%) | 13 (13.4%) |
| Median (95% CI), (Months) [a] | 12.3 (8.9, 16.0) | 7.7 (6.2, 9.8) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.00012 | |
| HR (95% CI) [b][d] | 0.556 (0.405, 0.764) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 68.3 (59.0, 75.9) | 61.8 (51.0, 70.8) |
| 12 months | 52.6 (43.1, 61.2) | 31.5 (22.2, 41.2) |
| 18 months | 37.8 (28.9, 46.7) | 16.9 (10.0, 25.3) |
| 24 months | 32.6 (24.0, 41.5) | 8.3 (3.4, 15.9) |
| 30 months | 25.3 (16.9, 34.7) | 2.1 (0.2, 9.0) |
| 36 months | 25.3 (16.9, 34.7) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line

| | Cemiplimab (N=77) | Chemotherapy (N=86) |
|---|---|---|
| Number of deaths, n (%) | 57 (74.0%) | 67 (77.9%) |
| Number of censored patients, n (%) | 20 (26.0%) | 19 (22.1%) |
| Median (95% CI), (Months) [a] | 12.1 (6.2, 15.2) | 8.8 (6.9, 11.8) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.11039 | |
| HR (95% CI) [b][d] | 0.796 (0.551, 1.150) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 63.1 (51.2, 72.8) | 65.5 (53.8, 74.9) |
| 12 months | 50.9 (39.1, 61.5) | 37.9 (26.9, 48.7) |
| 18 months | 31.0 (20.8, 41.8) | 19.6 (11.4, 29.5) |
| 24 months | 24.5 (15.1, 35.1) | 13.1 (6.3, 22.3) |
| 30 months | 21.0 (11.4, 32.5) | 11.2 (5.0, 20.3) |
| 36 months | 17.5 (8.2, 29.6) | 9.0 (3.4, 18.0) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan

| | Cemiplimab (N=26) | Chemotherapy (N=19) |
|---|---|---|
| Number of deaths, n (%) | 17 (65.4%) | 14 (73.7%) |
| Number of censored patients, n (%) | 9 (34.6%) | 5 (26.3%) |
| Median (95% CI), (Months) [a] | 15.2 (11.2, NE) | 12.4 (6.9, 20.2) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.23772 | |
| HR (95% CI) [b][d] | 0.751 (0.341, 1.653) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 88.5 (68.4, 96.1) | 82.6 (55.2, 94.1) |
| 12 months | 64.6 (42.9, 79.8) | 53.1 (27.8, 73.2) |
| 18 months | 36.3 (18.4, 54.6) | 29.5 (10.8, 51.3) |
| 24 months | 36.3 (18.4, 54.6) | 19.7 (4.2, 43.5) |
| 30 months | 31.8 (14.9, 50.2) | 0.0 (NE, NE) |
| 36 months | NE (NE, NE) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed

| | Cemiplimab (N=119) | Chemotherapy (N=111) |
|---|---|---|
| Number of deaths, n (%) | 82 (68.9%) | 96 (86.5%) |
| Number of censored patients, n (%) | 37 (31.1%) | 15 (13.5%) |
| Median (95% CI), (Months) [a] | 12.5 (7.5, 16.7) | 7.7 (6.4, 10.0) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.00039 | |
| HR (95% CI) [b][d] | 0.596 (0.440, 0.809) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 65.2 (55.8, 73.0) | 62.5 (52.6, 71.0) |
| 12 months | 52.2 (42.8, 60.8) | 31.0 (22.3, 40.0) |
| 18 months | 39.4 (30.4, 48.2) | 17.0 (10.4, 24.9) |
| 24 months | 32.0 (23.5, 40.9) | 9.4 (4.6, 16.3) |
| 30 months | 23.6 (15.0, 33.2) | 8.1 (3.6, 14.8) |
| 36 months | 23.6 (15.0, 33.2) | 6.5 (2.5, 13.1) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan

| | Cemiplimab (N=20) | Chemotherapy (N=21) |
|---|---|---|
| Number of deaths, n (%) | 14 (70.0%) | 13 (61.9%) |
| Number of censored patients, n (%) | 6 (30.0%) | 8 (38.1%) |
| Median (95% CI), (Months) [a] | 7.0 (3.9, 19.1) | 6.5 (4.4, 8.8) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.11854 | |
| HR (95% CI) [b][d] | 0.593 (0.247, 1.421) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 59.2 (34.7, 77.2) | 51.8 (24.3, 73.7) |
| 12 months | 48.5 (25.4, 68.2) | 17.8 (3.0, 42.7) |
| 18 months | 30.3 (11.5, 51.7) | 8.9 (0.6, 32.4) |
| 24 months | 24.2 (7.8, 45.5) | 8.9 (0.6, 32.4) |
| 30 months | 24.2 (7.8, 45.5) | 0.0 (NE, NE) |
| 36 months | 24.2 (7.8, 45.5) | 0.0 (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.1.1. Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine

| | Cemiplimab (N=31) | Chemotherapy (N=32) |
|---|---|---|
| Number of deaths, n (%) | 27 (87.1%) | 28 (87.5%) |
| Number of censored patients, n (%) | 4 (12.9%) | 4 (12.5%) |
| Median (95% CI), (Months) [a] | 9.1 (3.4, 14.5) | 7.6 (5.2, 13.8) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.41201 | |
| HR (95% CI) [b][d] | 0.935 (0.516, 1.693) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 58.1 (39.0, 73.1) | 61.3 (42.0, 75.8) |
| 12 months | 45.2 (27.4, 61.4) | 41.9 (24.7, 58.3) |
| 18 months | 22.6 (10.0, 38.3) | 19.4 (7.9, 34.6) |
| 24 months | 16.9 (5.6, 33.5) | 10.8 (2.5, 26.1) |
| 30 months | 16.9 (5.6, 33.5) | NE (NE, NE) |
| 36 months | 11.3 (2.4, 28.0) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.2.1. Overall Survival by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: <1%

| | Cemiplimab (N=42) | Chemotherapy (N=45) |
|---|---|---|
| Number of deaths, n (%) | 31 (73.8%) | 39 (86.7%) |
| Number of censored patients, n (%) | 11 (26.2%) | 6 (13.3%) |
| Median (95% CI), (Months) [a] | 9.3 (4.7, 15.0) | 6.7 (4.1, 11.8) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.10334 | |
| HR (95% CI) [b][d] | 0.724 (0.438, 1.196) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 57.1 (40.9, 70.4) | 58.2 (42.1, 71.2) |
| 12 months | 44.9 (29.5, 59.1) | 34.2 (20.5, 48.4) |
| 18 months | 27.4 (14.9, 41.5) | 14.7 (6.0, 27.0) |
| 24 months | 27.4 (14.9, 41.5) | 12.2 (4.5, 24.1) |
| 30 months | 22.9 (10.7, 37.8) | 7.3 (1.9, 17.8) |
| 36 months | NE (NE, NE) | 7.3 (1.9, 17.8) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.2.1. Overall Survival by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: >=1%

| | Cemiplimab (N=84) | Chemotherapy (N=78) |
|---|---|---|
| Number of deaths, n (%) | 54 (64.3%) | 65 (83.3%) |
| Number of censored patients, n (%) | 30 (35.7%) | 13 (16.7%) |
| Median (95% CI), (Months) [a] | 14.0 (10.3, 17.9) | 8.0 (6.4, 11.2) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.00244 | |
| HR (95% CI) [b][d] | 0.589 (0.406, 0.855) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 67.7 (56.5, 76.6) | 63.0 (50.8, 73.0) |
| 12 months | 57.7 (46.3, 67.5) | 34.4 (23.7, 45.5) |
| 18 months | 38.5 (27.7, 49.2) | 23.0 (14.0, 33.3) |
| 24 months | 36.9 (26.2, 47.6) | 10.8 (4.5, 20.1) |
| 30 months | 29.6 (18.7, 41.3) | 7.2 (1.9, 17.5) |
| 36 months | 29.6 (18.7, 41.3) | 3.6 (0.4, 14.1) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 17.2.1. Overall Survival by Subgroup for PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

PD-L1 Status group: Without PD-L1

| | Cemiplimab (N=70) | Chemotherapy (N=60) |
|---|---|---|
| Number of deaths, n (%) | 55 (78.6%) | 47 (78.3%) |
| Number of censored patients, n (%) | 15 (21.4%) | 13 (21.7%) |
| Median (95% CI), (Months) [a] | 12.4 (7.6, 15.8) | 8.7 (6.9, 11.4) |
| Stratified log-rank test 1-sided p-value [b][c] | 0.02735 | |
| HR (95% CI) [b][d] | 0.665 (0.438, 1.010) | |
| Estimated Survival Probability, %(95% CI)[a] | | |
| 6 months | 71.1 (58.8, 80.3) | 68.2 (53.9, 78.9) |
| 12 months | 50.8 (38.5, 61.8) | 34.3 (21.7, 47.3) |
| 18 months | 36.3 (25.1, 47.5) | 14.1 (6.2, 25.2) |
| 24 months | 24.5 (15.1, 35.1) | 7.9 (1.9, 19.3) |
| 30 months | 20.7 (11.8, 31.2) | 3.9 (0.4, 15.4) |
| 36 months | 18.1 (9.5, 28.9) | 3.9 (0.4, 15.4) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Stratified by geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.
[c] One-sided p-value converted from stratified log-rank test two-sided p-value.
[d] Based on stratified proportional hazards model (cemiplimab vs chemotherapy).

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any TEAE | 688 | 532 | 200 | 14 | 3 | 723 | 489 | 221 | 12 | 1 |
| Number of Patients with Any TEAE | 14 (7.2) | 63 (32.3) | 85 (43.6) | 10 (5.1) | 3 (1.5) | 14 (8.1) | 51 (29.7) | 76 (44.2) | 11 (6.4) | 1 (0.6) |
| Blood and lymphatic system disorders | 7 (3.6) | 28 (14.4) | 24 (12.3) | 0 | 0 | 6 (3.5) | 19 (11.0) | 55 (32.0) | 6 (3.5) | 0 |
| Anaemia | 4 (2.1) | 23 (11.8) | 21 (10.8) | 0 | 0 | 6 (3.5) | 18 (10.5) | 51 (29.7) | 1 (0.6) | 0 |
| Disseminated intravascular coagulation | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Eosinophilia | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Febrile neutropenia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 5 (2.9) | 0 | 0 |
| Hyperchromasia | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Leukopenia | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 5 (2.9) | 1 (0.6) | 0 |
| Lymph node pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lymphopenia | 1 (0.5) | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Neutropenia | 0 | 3 (1.5) | 1 (0.5) | 0 | 0 | 2 (1.2) | 6 (3.5) | 9 (5.2) | 3 (1.7) | 0 |
| Pancytopenia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Thrombocytopenia | 0 | 0 | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 5 (2.9) | 2 (1.2) | 0 |
| Thrombocytosis | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Cardiac disorders | 7 (3.6) | 2 (1.0) | 0 | 1 (0.5) | 0 | 5 (2.9) | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Angina pectoris | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Arteriosclerosis coronary artery | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Autoimmune pericarditis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Left ventricular dysfunction | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Myocardial ischaemia | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Palpitations | 0 | 0 | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 | 0 |
| Pericardial effusion | 0 | 1 (0.5) | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Sinus tachycardia | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tachycardia | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Ear and labyrinth disorders | 8 (4.1) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Ear discomfort | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ear pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ear pruritus | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Tinnitus | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vertigo | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Endocrine disorders | 2 (1.0) | 14 (7.2) | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Adrenal insufficiency | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Autoimmune thyroiditis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hyperthyroidism | 2 (1.0) | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypothyroidism | 1 (0.5) | 10 (5.1) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Thyroiditis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Eye disorders | 4 (2.1) | 1 (0.5) | 0 | 0 | 0 | 7 (4.1) | 2 (1.2) | 0 | 0 | 0 |
| Corneal perforation | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Dry eye | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Eye pruritus | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Eyelid oedema | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Lacrimation increased | 1 (0.5) | 0 | 0 | 0 | 0 | 5 (2.9) | 1 (0.6) | 0 | 0 | 0 |
| Vision blurred | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vitreous floaters | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Gastrointestinal disorders | 38 (19.5) | 53 (27.2) | 18 (9.2) | 0 | 0 | 42 (24.4) | 49 (28.5) | 19 (11.0) | 0 | 0 |
| Abdominal discomfort | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Abdominal distension | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Abdominal pain | 7 (3.6) | 10 (5.1) | 2 (1.0) | 0 | 0 | 6 (3.5) | 10 (5.8) | 1 (0.6) | 0 | 0 |
| Abdominal pain lower | 2 (1.0) | 3 (1.5) | 1 (0.5) | 0 | 0 | 2 (1.2) | 3 (1.7) | 1 (0.6) | 0 | 0 |
| Abdominal pain upper | 8 (4.1) | 2 (1.0) | 0 | 0 | 0 | 5 (2.9) | 3 (1.7) | 0 | 0 | 0 |
| Anal fissure | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Anal fistula | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Anal haemorrhage | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Anal incontinence | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Anal inflammation | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Anal stenosis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Anorectal discomfort | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Aphthous ulcer | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Ascites | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Change of bowel habit | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Colitis | 1 (0.5) | 3 (1.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Constipation | 16 (8.2) | 16 (8.2) | 0 | 0 | 0 | 17 (9.9) | 18 (10.5) | 1 (0.6) | 0 | 0 |
| Diarrhoea | 11 (5.6) | 7 (3.6) | 3 (1.5) | 0 | 0 | 16 (9.3) | 8 (4.7) | 3 (1.7) | 0 | 0 |
| Diverticular perforation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Dry mouth | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Duodenal ulcer | 0 | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dyspepsia | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 4 (2.3) | 0 | 0 | 0 | 0 |
| Dysphagia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Faeces soft | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Flatulence | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Gastric mucosa erythema | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastric ulcer | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastritis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastritis erosive | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastrointestinal oedema | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | 2 (1.0) | 3 (1.5) | 0 | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 |
| Gingival bleeding | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Gingival pain | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Glossitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Haematochezia | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 1 (0.6) | 0 | 0 |
| Haemoperitoneum | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Haemorrhoids | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ileus | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Inguinal hernia | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Intestinal obstruction | 0 | 0 | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 1 (0.6) | 0 | 0 |
| Large intestinal obstruction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lip blister | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lip dry | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lip swelling | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Melaena | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Mouth haemorrhage | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Mouth ulceration | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Nausea | 17 (8.7) | 24 (12.3) | 2 (1.0) | 0 | 0 | 35 (20.3) | 26 (15.1) | 5 (2.9) | 0 | 0 |
| Odynophagia | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Oesophageal obstruction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oesophagitis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Oral papule | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pancreatic mass | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pancreatitis chronic | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Proctalgia | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Proctitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rectal haemorrhage | 4 (2.1) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Rectal tenesmus | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Salivary hypersecretion | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 | 0 |
| Stomatitis | 2 (1.0) | 3 (1.5) | 0 | 0 | 0 | 8 (4.7) | 4 (2.3) | 2 (1.2) | 0 | 0 |
| Toothache | 3 (1.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vomiting | 25 (12.8) | 14 (7.2) | 3 (1.5) | 0 | 0 | 24 (14.0) | 11 (6.4) | 6 (3.5) | 0 | 0 |
| General disorders and administration site conditions | 34 (17.4) | 37 (19.0) | 13 (6.7) | 0 | 2 (1.0) | 31 (18.0) | 52 (30.2) | 7 (4.1) | 0 | 1 (0.6) |
| Asthenia | 9 (4.6) | 6 (3.1) | 6 (3.1) | 0 | 0 | 9 (5.2) | 15 (8.7) | 3 (1.7) | 0 | 0 |
| Catheter site thrombosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Chest pain | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Chills | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Death | 0 | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 |
| Discomfort | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Drug intolerance | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Early satiety | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Face oedema | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Fatigue | 14 (7.2) | 20 (10.3) | 2 (1.0) | 0 | 0 | 10 (5.8) | 22 (12.8) | 2 (1.2) | 0 | 0 |
| Feeling cold | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Gait disturbance | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Generalised oedema | 0 | 1 (0.5) | 0 | 0 | 0 | 2 (1.2) | 0 | 1 (0.6) | 0 | 0 |
| Hyperpyrexia | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hyperthermia | 2 (1.0) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Influenza like illness | 3 (1.5) | 1 (0.5) | 1 (0.5) | 0 | 0 | 4 (2.3) | 1 (0.6) | 0 | 0 | 0 |
| Localised oedema | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Malaise | 2 (1.0) | 0 | 0 | 0 | 0 | 4 (2.3) | 3 (1.7) | 1 (0.6) | 0 | 0 |
| Mucosal dryness | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Non-cardiac chest pain | 1 (0.5) | 1 (0.5) | 2 (1.0) | 0 | 0 | 1 (0.6) | 4 (2.3) | 0 | 0 | 0 |
| Oedema | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Oedema peripheral | 9 (4.6) | 4 (2.1) | 1 (0.5) | 0 | 0 | 6 (3.5) | 4 (2.3) | 0 | 0 | 0 |
| Pain | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Performance status decreased | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) |
| Puncture site erythema | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Pyrexia | 15 (7.7) | 9 (4.6) | 1 (0.5) | 0 | 0 | 16 (9.3) | 10 (5.8) | 0 | 0 | 0 |
| Sudden death | 0 | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 |
| Swelling | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hepatobiliary disorders | 1 (0.5) | 2 (1.0) | 8 (4.1) | 2 (1.0) | 0 | 2 (1.2) | 0 | 1 (0.6) | 0 | 0 |
| Autoimmune hepatitis | 0 | 1 (0.5) | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cholecystitis acute | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cholestasis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Hepatic cytolysis | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hepatic function abnormal | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatic pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatic steatosis | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hepatitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatotoxicity | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypertransaminasaemia | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Immune-mediated hepatitis | 0 | 0 | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Immune system disorders | 3 (1.5) | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Contrast media allergy | 1 (0.5) | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypersensitivity | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Seasonal allergy | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Infections and infestations | 16 (8.2) | 29 (14.9) | 20 (10.3) | 2 (1.0) | 1 (0.5) | 18 (10.5) | 19 (11.0) | 17 (9.9) | 1 (0.6) | 0 |
| Acute sinusitis | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Aspergillus infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Bacteraemia | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Bronchitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| COVID-19 | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| COVID-19 pneumonia | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Candida infection | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Cellulitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Clostridium difficile infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Conjunctivitis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Cystitis | 1 (0.5) | 5 (2.6) | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Cytomegalovirus infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device related infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Empyema | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Enterobacter bacteraemia | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Enterobacter infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Escherichia urinary tract infection | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Fungal infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Fungal skin infection | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastroenteritis | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastroenteritis viral | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Herpes virus infection | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Herpes zoster | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Infection | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Influenza | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Kidney infection | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Lower respiratory tract infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lymphangitis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |

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(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Nasopharyngitis | 6 (3.1) | 2 (1.0) | 0 | 0 | 0 | 5 (2.9) | 0 | 0 | 0 | 0 |
| Ophthalmic herpes zoster | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oral candidiasis | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oral herpes | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Otitis externa | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pelvic abscess | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Peritonitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pharyngitis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pneumonia | 1 (0.5) | 3 (1.5) | 2 (1.0) | 0 | 1 (0.5) | 1 (0.6) | 0 | 3 (1.7) | 0 | 0 |
| Pneumonia viral | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Postoperative wound infection | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pulmonary tuberculosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pyelonephritis | 0 | 1 (0.5) | 3 (1.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Pyelonephritis acute | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pyomyositis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rash pustular | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Respiratory tract infection | 0 | 0 | 0 | 0 | 0 | 3 (1.7) | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Respiratory tract infection viral | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Rhinitis | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Sepsis | 0 | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 |
| Serratia infection | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Sinusitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Staphylococcal bacteraemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Staphylococcal infection | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Staphylococcal sepsis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Stoma site infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Streptococcal sepsis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 |
| Tonsillitis | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Tonsillitis bacterial | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Tooth abscess | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Toxic shock syndrome streptococcal | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Upper respiratory tract infection | 4 (2.1) | 4 (2.1) | 0 | 0 | 0 | 2 (1.2) | 1 (0.6) | 0 | 0 | 0 |
| Urinary tract infection | 3 (1.5) | 9 (4.6) | 9 (4.6) | 0 | 0 | 4 (2.3) | 7 (4.1) | 5 (2.9) | 0 | 0 |
| Urinary tract infection bacterial | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Urosepsis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vaginal infection | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Viral infection | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Viral rash | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Viral rhinitis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vulvitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vulvovaginitis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Injury, poisoning and procedural complications | 7 (3.6) | 10 (5.1) | 5 (2.6) | 0 | 0 | 5 (2.9) | 4 (2.3) | 4 (2.3) | 0 | 0 |
| Allergic transfusion reaction | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Animal bite | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chillblains | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Contusion | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Cystitis radiation | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device use error | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Fall | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Febrile nonhaemolytic transfusion reaction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Foot fracture | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastrointestinal stoma complication | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Hand fracture | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Infusion related reaction | 3 (1.5) | 3 (1.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Muscle strain | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Overdose | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Peroneal nerve injury | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Post procedural urine leak | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Procedural nausea | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Procedural pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Skin injury | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Spinal compression fracture | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Spinal fracture | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tooth fracture | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transfusion reaction | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Upper limb fracture | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Urinary tract stoma complication | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vascular access complication | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Investigations | 14 (7.2) | 16 (8.2) | 14 (7.2) | 4 (2.1) | 0 | 14 (8.1) | 22 (12.8) | 7 (4.1) | 1 (0.6) | 0 |
| Alanine aminotransferase decreased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Alanine aminotransferase increased | 6 (3.1) | 3 (1.5) | 1 (0.5) | 0 | 0 | 4 (2.3) | 3 (1.7) | 2 (1.2) | 0 | 0 |
| Amylase increased | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Aspartate aminotransferase increased | 2 (1.0) | 4 (2.1) | 2 (1.0) | 0 | 0 | 7 (4.1) | 4 (2.3) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | 3 (1.5) | 2 (1.0) | 4 (2.1) | 0 | 0 | 6 (3.5) | 3 (1.7) | 1 (0.6) | 0 | 0 |
| Blood bilirubin increased | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Blood chloride decreased | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Blood creatine phosphokinase MB increased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Blood creatine phosphokinase increased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood creatinine increased | 6 (3.1) | 4 (2.1) | 3 (1.5) | 1 (0.5) | 0 | 3 (1.7) | 6 (3.5) | 0 | 0 | 0 |
| Blood iron decreased | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Blood thyroid stimulating hormone increased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood triglycerides increased | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Blood urea increased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Breath sounds absent | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| C-reactive protein increased | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gamma-glutamyltransferase increased | 4 (2.1) | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Glomerular filtration rate decreased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Haemoglobin decreased | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| International normalised ratio increased | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Lymphocyte count decreased | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Neutrophil count decreased | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 6 (3.5) | 2 (1.2) | 0 | 0 |
| Platelet count decreased | 1 (0.5) | 0 | 0 | 2 (1.0) | 0 | 0 | 1 (0.6) | 1 (0.6) | 1 (0.6) | 0 |
| SARS-CoV-2 test positive | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Thyroid function test abnormal | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transaminases abnormal | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |

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Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Tri-iodothyronine decreased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Troponin increased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Urine output decreased | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Weight decreased | 3 (1.5) | 4 (2.1) | 3 (1.5) | 0 | 0 | 3 (1.7) | 5 (2.9) | 0 | 0 | 0 |
| Weight increased | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| White blood cell count decreased | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 4 (2.3) | 1 (0.6) | 0 | 0 |
| Metabolism and nutrition disorders | 20 (10.3) | 28 (14.4) | 11 (5.6) | 2 (1.0) | 0 | 25 (14.5) | 17 (9.9) | 9 (5.2) | 3 (1.7) | 0 |
| Decreased appetite | 18 (9.2) | 13 (6.7) | 1 (0.5) | 0 | 0 | 15 (8.7) | 10 (5.8) | 2 (1.2) | 0 | 0 |
| Dehydration | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 | 0 |
| Electrolyte imbalance | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Glucose tolerance impaired | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Hypercalcaemia | 2 (1.0) | 1 (0.5) | 0 | 1 (0.5) | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hyperglycaemia | 1 (0.5) | 0 | 0 | 1 (0.5) | 0 | 7 (4.1) | 3 (1.7) | 3 (1.7) | 0 | 0 |
| Hyperkalaemia | 1 (0.5) | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypernatraemia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypertriglyceridaemia | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hyperuricaemia | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypoalbuminaemia | 1 (0.5) | 11 (5.6) | 3 (1.5) | 0 | 0 | 3 (1.7) | 3 (1.7) | 3 (1.7) | 0 | 0 |
| Hypocalcaemia | 0 | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Hypochloraemia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypokalaemia | 5 (2.6) | 4 (2.1) | 6 (3.1) | 0 | 0 | 7 (4.1) | 0 | 4 (2.3) | 2 (1.2) | 0 |

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(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Hypomagnesaemia | 5 (2.6) | 1 (0.5) | 0 | 0 | 0 | 5 (2.9) | 1 (0.6) | 0 | 1 (0.6) | 0 |
| Hyponatraemia | 3 (1.5) | 1 (0.5) | 1 (0.5) | 1 (0.5) | 0 | 1 (0.6) | 0 | 1 (0.6) | 0 | 0 |
| Hypophagia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypophosphataemia | 0 | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Hypoproteinaemia | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Iron deficiency | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vitamin D deficiency | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 23 (11.8) | 23 (11.8) | 8 (4.1) | 0 | 0 | 13 (7.6) | 27 (15.7) | 5 (2.9) | 0 | 0 |
| Arthralgia | 14 (7.2) | 4 (2.1) | 1 (0.5) | 0 | 0 | 2 (1.2) | 3 (1.7) | 0 | 0 | 0 |
| Arthritis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Back pain | 11 (5.6) | 7 (3.6) | 3 (1.5) | 0 | 0 | 5 (2.9) | 10 (5.8) | 2 (1.2) | 0 | 0 |
| Bone pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 |
| Bursitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Coccydynia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Fistula | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Flank pain | 3 (1.5) | 2 (1.0) | 0 | 0 | 0 | 2 (1.2) | 1 (0.6) | 0 | 0 | 0 |
| Groin pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Intervertebral disc degeneration | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Joint stiffness | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Muscle spasms | 3 (1.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |

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| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Muscular weakness | 1 (0.5) | 0 | 1 (0.5) | 0 | 0 | 2 (1.2) | 3 (1.7) | 1 (0.6) | 0 | 0 |
| Musculoskeletal chest pain | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Musculoskeletal pain | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Myalgia | 7 (3.6) | 0 | 0 | 0 | 0 | 2 (1.2) | 7 (4.1) | 0 | 0 | 0 |
| Neck pain | 2 (1.0) | 3 (1.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pain in extremity | 7 (3.6) | 4 (2.1) | 2 (1.0) | 0 | 0 | 2 (1.2) | 1 (0.6) | 2 (1.2) | 0 | 0 |
| Pain in jaw | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pathological fracture | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Polyarthritis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rheumatoid arthritis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Spinal pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Spondylolisthesis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Torticollis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (1.0) | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Cancer pain | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tumour associated fever | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tumour pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Nervous system disorders | 20 (10.3) | 11 (5.6) | 1 (0.5) | 0 | 0 | 30 (17.4) | 8 (4.7) | 2 (1.2) | 0 | 0 |
| Altered state of consciousness | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Balance disorder | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Brain oedema | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cerebrovascular disorder | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cognitive disorder | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Diabetic neuropathy | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dizziness | 8 (4.1) | 2 (1.0) | 0 | 0 | 0 | 7 (4.1) | 1 (0.6) | 0 | 0 | 0 |
| Dysgeusia | 0 | 0 | 0 | 0 | 0 | 4 (2.3) | 0 | 0 | 0 | 0 |
| Extrapyramidal disorder | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Gait spastic | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Headache | 11 (5.6) | 4 (2.1) | 1 (0.5) | 0 | 0 | 9 (5.2) | 3 (1.7) | 0 | 0 | 0 |
| Hypersomnia | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Hypoaesthesia | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Lethargy | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Mental impairment | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Migraine | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Neuropathy peripheral | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Neurotoxicity | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 1 (0.6) | 0 | 0 |
| Paraesthesia | 2 (1.0) | 0 | 0 | 0 | 0 | 2 (1.2) | 1 (0.6) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Sciatica | 0 | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Seizure | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Somnolence | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Syncope | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Taste disorder | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Tension headache | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transient ischaemic attack | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Tremor | 1 (0.5) | 0 | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 | 0 |
| Vocal cord paresis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Product issues | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Device occlusion | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Psychiatric disorders | 8 (4.1) | 14 (7.2) | 2 (1.0) | 0 | 0 | 11 (6.4) | 9 (5.2) | 1 (0.6) | 0 | 0 |
| Adjustment disorder with depressed mood | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Affect lability | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Agitation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Agoraphobia | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Anorexia nervosa | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Anxiety | 2 (1.0) | 5 (2.6) | 1 (0.5) | 0 | 0 | 2 (1.2) | 4 (2.3) | 1 (0.6) | 0 | 0 |
| Attention deficit hyperactivity disorder | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Confusional state | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Delirium | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Depressed mood | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Depression | 4 (2.1) | 3 (1.5) | 0 | 0 | 0 | 4 (2.3) | 1 (0.6) | 0 | 0 | 0 |
| Insomnia | 2 (1.0) | 7 (3.6) | 0 | 0 | 0 | 6 (3.5) | 2 (1.2) | 1 (0.6) | 0 | 0 |
| Mental disorder | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Mood disorder due to a general medical condition | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Personality change | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Suicide attempt | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Renal and urinary disorders | 13 (6.7) | 9 (4.6) | 11 (5.6) | 0 | 0 | 11 (6.4) | 10 (5.8) | 4 (2.3) | 0 | 0 |
| Acute kidney injury | 2 (1.0) | 1 (0.5) | 2 (1.0) | 0 | 0 | 4 (2.3) | 1 (0.6) | 0 | 0 | 0 |
| Azotaemia | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Calculus urinary | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chronic kidney disease | 1 (0.5) | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Cystitis haemorrhagic | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dysuria | 5 (2.6) | 3 (1.5) | 0 | 0 | 0 | 3 (1.7) | 2 (1.2) | 0 | 0 | 0 |
| Haematuria | 4 (2.1) | 2 (1.0) | 4 (2.1) | 0 | 0 | 3 (1.7) | 0 | 1 (0.6) | 0 | 0 |
| Haemorrhage urinary tract | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hydronephrosis | 1 (0.5) | 0 | 2 (1.0) | 0 | 0 | 1 (0.6) | 0 | 2 (1.2) | 0 | 0 |
| Micturition urgency | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Nephritis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pollakiuria | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Polyuria | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Proteinuria | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Renal artery stenosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Renal colic | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Renal failure | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Renal impairment | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Renal injury | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ureteric obstruction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Ureteric stenosis | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Urinary incontinence | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Urinary retention | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Urinary tract obstruction | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Urine flow decreased | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Urogenital fistula | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Reproductive system and breast disorders | 15 (7.7) | 16 (8.2) | 3 (1.5) | 0 | 0 | 9 (5.2) | 10 (5.8) | 4 (2.3) | 0 | 0 |
| Atrophic vulvovaginitis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Breast oedema | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Breast pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Female genital tract fistula | 0 | 2 (1.0) | 1 (0.5) | 0 | 0 | 1 (0.6) | 2 (1.2) | 1 (0.6) | 0 | 0 |
| Genital haemorrhage | 3 (1.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Genital rash | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Intermenstrual bleeding | 1 (0.5) | 1 (0.5) | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Ovarian cyst | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pelvic discomfort | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Pelvic pain | 4 (2.1) | 6 (3.1) | 0 | 0 | 0 | 4 (2.3) | 5 (2.9) | 3 (1.7) | 0 | 0 |
| Perineal pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Uterine pain | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vaginal discharge | 3 (1.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Vaginal disorder | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Vaginal fistula | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Vaginal haemorrhage | 4 (2.1) | 5 (2.6) | 1 (0.5) | 0 | 0 | 3 (1.7) | 2 (1.2) | 1 (0.6) | 0 | 0 |
| Vaginal obstruction | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Vaginal odour | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Vulval ulceration | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Vulvovaginal pain | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Vulvovaginal pruritus | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 19 (9.7) | 23 (11.8) | 5 (2.6) | 0 | 0 | 16 (9.3) | 10 (5.8) | 3 (1.7) | 0 | 0 |
| Asthma | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Bronchospasm | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Cough | 6 (3.1) | 10 (5.1) | 1 (0.5) | 0 | 0 | 5 (2.9) | 7 (4.1) | 1 (0.6) | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Dysphonia | 3 (1.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Dyspnoea | 13 (6.7) | 7 (3.6) | 4 (2.1) | 0 | 0 | 7 (4.1) | 6 (3.5) | 0 | 0 | 0 |
| Dyspnoea exertional | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Epistaxis | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Haemoptysis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hiccups | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hydrothorax | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypoventilation | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Increased upper airway secretion | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Interstitial lung disease | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Laryngeal inflammation | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lung opacity | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Nasal congestion | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oropharyngeal pain | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Pleural effusion | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pneumonitis | 0 | 2 (1.0) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pneumothorax | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Productive cough | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Pulmonary embolism | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| Respiratory alkalosis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Respiratory distress | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Rhinitis allergic | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Rhinorrhoea | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 23 (11.8) | 10 (5.1) | 3 (1.5) | 0 | 0 | 30 (17.4) | 12 (7.0) | 1 (0.6) | 0 | 0 |
| Alopecia | 0 | 0 | 0 | 0 | 0 | 5 (2.9) | 3 (1.7) | 0 | 0 | 0 |
| Blister | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Cold sweat | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Decubitus ulcer | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dermal cyst | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dermatitis | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Dermatitis acneiform | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Dermatitis allergic | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dry skin | 4 (2.1) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Eczema | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Erythema | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Erythema multiforme | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Erythema nodosum | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Nail discolouration | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Onychoclasis | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Papule | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Pruritus | 8 (4.1) | 1 (0.5) | 0 | 0 | 0 | 7 (4.1) | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Rash | 8 (4.1) | 2 (1.0) | 2 (1.0) | 0 | 0 | 10 (5.8) | 4 (2.3) | 0 | 0 | 0 |
| Rash erythematous | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Rash maculo-papular | 4 (2.1) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rash papular | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rash pruritic | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Sensitive skin | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin burning sensation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin discolouration | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 | 0 | 0 |
| Skin hyperpigmentation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin hypopigmentation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin irritation | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |
| Skin toxicity | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Stasis dermatitis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Urticaria | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Vascular disorders | 6 (3.1) | 10 (5.1) | 3 (1.5) | 0 | 0 | 3 (1.7) | 4 (2.3) | 4 (2.3) | 0 | 0 |
| Arterial haemorrhage | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Brachiocephalic vein thrombosis | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Deep vein thrombosis | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Embolism | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Flushing | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.1. Number of patients with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Hot flush | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypertension | 1 (0.5) | 2 (1.0) | 2 (1.0) | 0 | 0 | 2 (1.2) | 1 (0.6) | 0 | 0 | 0 |
| Hypotension | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Hypovolaemic shock | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Jugular vein thrombosis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lymphoedema | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Peripheral vascular disorder | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Thrombophlebitis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Varicose ulceration | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Venous thrombosis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any Serious TEAE | 2 | 22 | 66 | 9 | 3 | 1 | 25 | 62 | 3 | 1 |
| Number of Patients with Any Serious TEAE | 1 (0.5) | 9 (4.6) | 41 (21.0) | 7 (3.6) | 3 (1.5) | 0 | 10 (5.8) | 38 (22.1) | 3 (1.7) | 1 (0.6) |
| Blood and lymphatic system disorders | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 16 (9.3) | 0 | 0 |
| Anaemia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 10 (5.8) | 0 | 0 |
| Febrile neutropenia | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 5 (2.9) | 0 | 0 |
| Neutropenia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Pancytopenia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Thrombocytopenia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Cardiac disorders | 0 | 1 (0.5) | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Autoimmune pericarditis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pericardial effusion | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Endocrine disorders | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypothyroidism | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastrointestinal disorders | 0 | 1 (0.5) | 10 (5.1) | 0 | 0 | 0 | 2 (1.2) | 8 (4.7) | 0 | 0 |
| Abdominal pain | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Colitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Diarrhoea | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| Diverticular perforation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Duodenal ulcer | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Haematochezia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Intestinal obstruction | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Nausea | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oral papule | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Proctalgia | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Proctitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rectal haemorrhage | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Stomatitis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Vomiting | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| General disorders and administration site conditions | 0 | 1 (0.5) | 2 (1.0) | 0 | 2 (1.0) | 0 | 4 (2.3) | 0 | 0 | 1 (0.6) |
| Catheter site thrombosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Death | 0 | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 |
| Influenza like illness | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Performance status decreased | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) |
| Pyrexia | 0 | 1 (0.5) | 1 (0.5) | 0 | 0 | 0 | 3 (1.7) | 0 | 0 | 0 |
| Sudden death | 0 | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Hepatobiliary disorders | 0 | 1 (0.5) | 6 (3.1) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Autoimmune hepatitis | 0 | 1 (0.5) | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cholecystitis acute | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatic function abnormal | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Immune-mediated hepatitis | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Immune system disorders | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Contrast media allergy | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Infections and infestations | 0 | 4 (2.1) | 17 (8.7) | 2 (1.0) | 1 (0.5) | 0 | 5 (2.9) | 13 (7.6) | 1 (0.6) | 0 |
| COVID-19 pneumonia | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Cellulitis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Clostridium difficile infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device related infection | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Empyema | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastroenteritis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Gastroenteritis viral | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Infection | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Kidney infection | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Ophthalmic herpes zoster | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pelvic abscess | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Peritonitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pneumonia | 0 | 0 | 2 (1.0) | 0 | 1 (0.5) | 0 | 0 | 3 (1.7) | 0 | 0 |
| Pyelonephritis | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Pyelonephritis acute | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Pyomyositis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Respiratory tract infection | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Sepsis | 0 | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 |
| Staphylococcal bacteraemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Staphylococcal infection | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Staphylococcal sepsis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Stoma site infection | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Streptococcal sepsis | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 |
| Toxic shock syndrome streptococcal | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Urinary tract infection | 0 | 2 (1.0) | 6 (3.1) | 0 | 0 | 0 | 1 (0.6) | 3 (1.7) | 0 | 0 |
| Urinary tract infection bacterial | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Viral rash | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 0 | 0 | 4 (2.1) | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 |
| Cystitis radiation | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Device use error | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Overdose | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Procedural nausea | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Spinal compression fracture | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Transfusion reaction | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Investigations | 0 | 0 | 0 | 3 (1.5) | 0 | 0 | 2 (1.2) | 0 | 0 | 0 |
| Blood creatine phosphokinase MB increased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood creatinine increased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Neutrophil count decreased | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Platelet count decreased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Metabolism and nutrition disorders | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 |
| Hyperglycaemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Hypocalcaemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Hypokalaemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 |
| Hypomagnesaemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 |
| Hyponatraemia | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 0 | 2 (1.0) | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Arthritis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Muscular weakness | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Pathological fracture | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Spondylolisthesis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Tumour associated fever | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Nervous system disorders | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Seizure | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Transient ischaemic attack | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Product issues | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Device occlusion | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Psychiatric disorders | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Anxiety | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Personality change | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Renal and urinary disorders | 0 | 1 (0.5) | 6 (3.1) | 0 | 0 | 1 (0.6) | 3 (1.7) | 2 (1.2) | 0 | 0 |
| Acute kidney injury | 0 | 0 | 2 (1.0) | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 | 0 |
| Cystitis haemorrhagic | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Haematuria | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Renal failure | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 1 (0.6) | 1 (0.6) | 0 | 0 |
| Renal impairment | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Urinary tract obstruction | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Reproductive system and breast disorders | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| Female genital tract fistula | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Pelvic pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Vaginal haemorrhage | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 1 (0.5) | 2 (1.0) | 2 (1.0) | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 |
| Cough | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Dyspnoea | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Haemoptysis | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pneumonitis | 0 | 1 (0.5) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pneumothorax | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pulmonary embolism | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 (1.2) | 0 | 0 |
| Vascular disorders | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 2 (1.2) | 0 | 0 |
| Arterial haemorrhage | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.2. Number of patients with Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Deep vein thrombosis | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 | 0 |
| Hypotension | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |
| Hypovolaemic shock | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.6) | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.4. Number of patients with treatment-emergent adverse events of interest - immune-related AE (Grade 3) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any immune-related AE (Grade 3 or Greater) | 0 | 0 | 24 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of Patients with Any immune-related AE (Grade 3 or Greater) | 0 | 0 | 21 (10.8) | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Endocrine disorders | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypothyroidism | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Gastrointestinal disorders | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Colitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Diarrhoea | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Oral papule | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatobiliary disorders | 0 | 0 | 7 (3.6) | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 |
| Autoimmune hepatitis | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatic function abnormal | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatitis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hepatotoxicity | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Immune-mediated hepatitis | 0 | 0 | 2 (1.0) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.4. Number of patients with treatment-emergent adverse events of interest - immune-related AE (Grade 3) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Investigations | 0 | 0 | 5 (2.6) | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Aspartate aminotransferase increased | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood creatine phosphokinase MB increased | 0 | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 |
| Blood creatine phosphokinase increased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Glomerular filtration rate decreased | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Polyarthritis | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pneumonitis | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.4. Number of patients with treatment-emergent adverse events of interest - immune-related AE (Grade 3) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Skin and subcutaneous tissue disorders | 0 | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Rash | 0 | 0 | 2 (1.0) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Skin toxicity | 0 | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.5. Number of patients with treatment-emergent adverse events of interest - Infusion-related reactions (Grade >=2) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any Infusion-related reactions (Grade >=2) | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of Patients with Any Infusion-related reactions (Grade >=2) | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Infusion related reaction | 0 | 3 (1.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

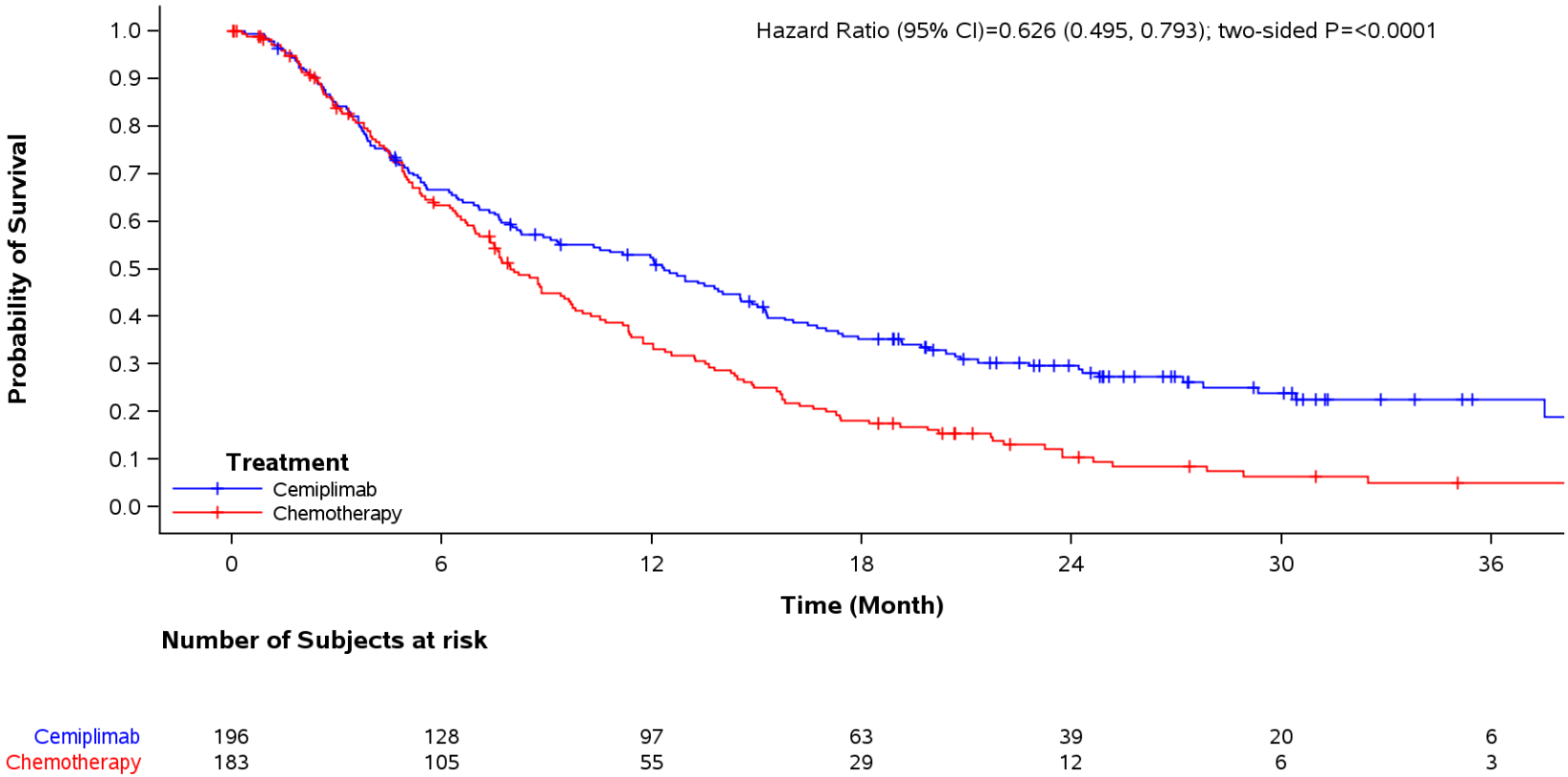
Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Table 26.1.6. Number of patients with treatment-emergent adverse events of interest - allergic/hypersensitivity reactions (Grade >=2) by primary system organ class and preferred term and toxicity grade
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | | | | | Chemotherapy (N=172) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Primary System Organ Class<br>Preferred Term | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) | Grade 1<br>n (%) | Grade 2<br>n (%) | Grade 3<br>n (%) | Grade 4<br>n (%) | Grade 5<br>n (%) |
| Number of Any allergic/hypersensitivity reactions (Grade >=2) | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of Patients with Any allergic/hypersensitivity reactions (Grade >=2) | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Laryngeal inflammation | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dermatitis | 0 | 1 (0.5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

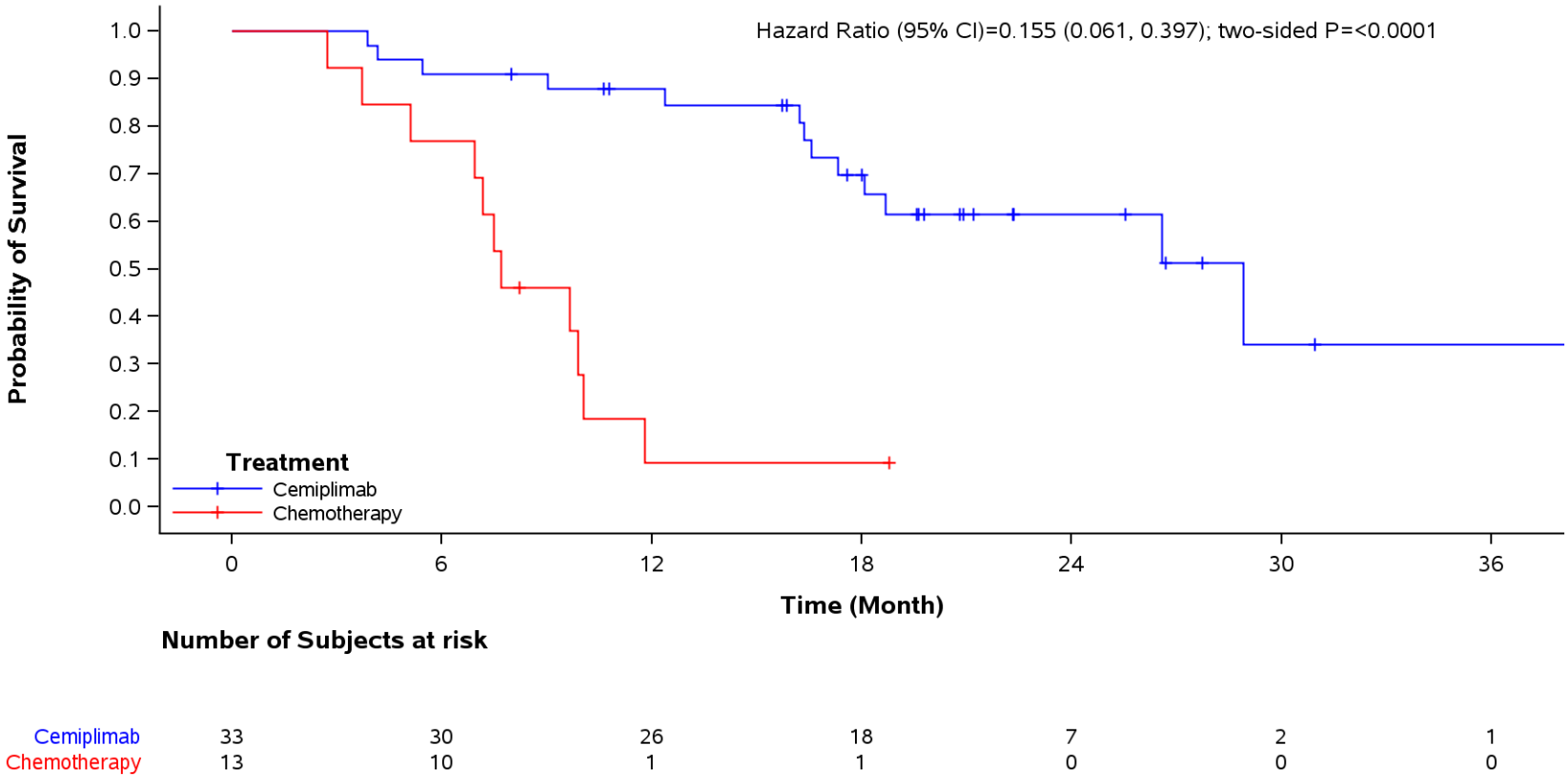
Data cut-off as of Jan 4th, 2022.
If a patient experienced multiple AEs in the same category, the patient is only counted once in the highest grade.

Figure 2.1.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

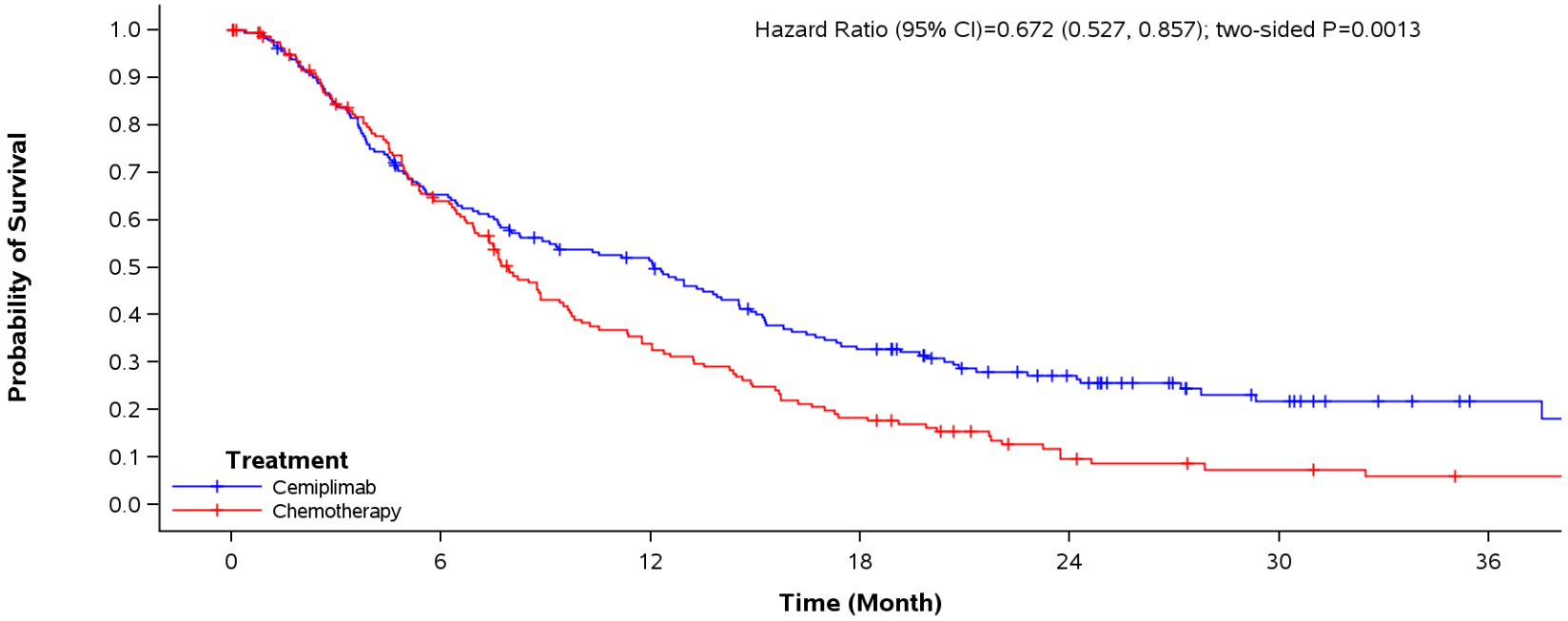
Figure 2.1.3. Kaplan Meier Cumulative Incidence Curve for Estimation of Duration of Response
(Full Analysis Set Exclude Patients Assigned to Gemcitabine - Patients with Confirmed CR or PR)




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on stratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from stratified log-rank test. Stratification factors are geographic region (North America versus Asia versus ROW) and Histology (SCC versus adenocarcinoma) according to IWRS.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



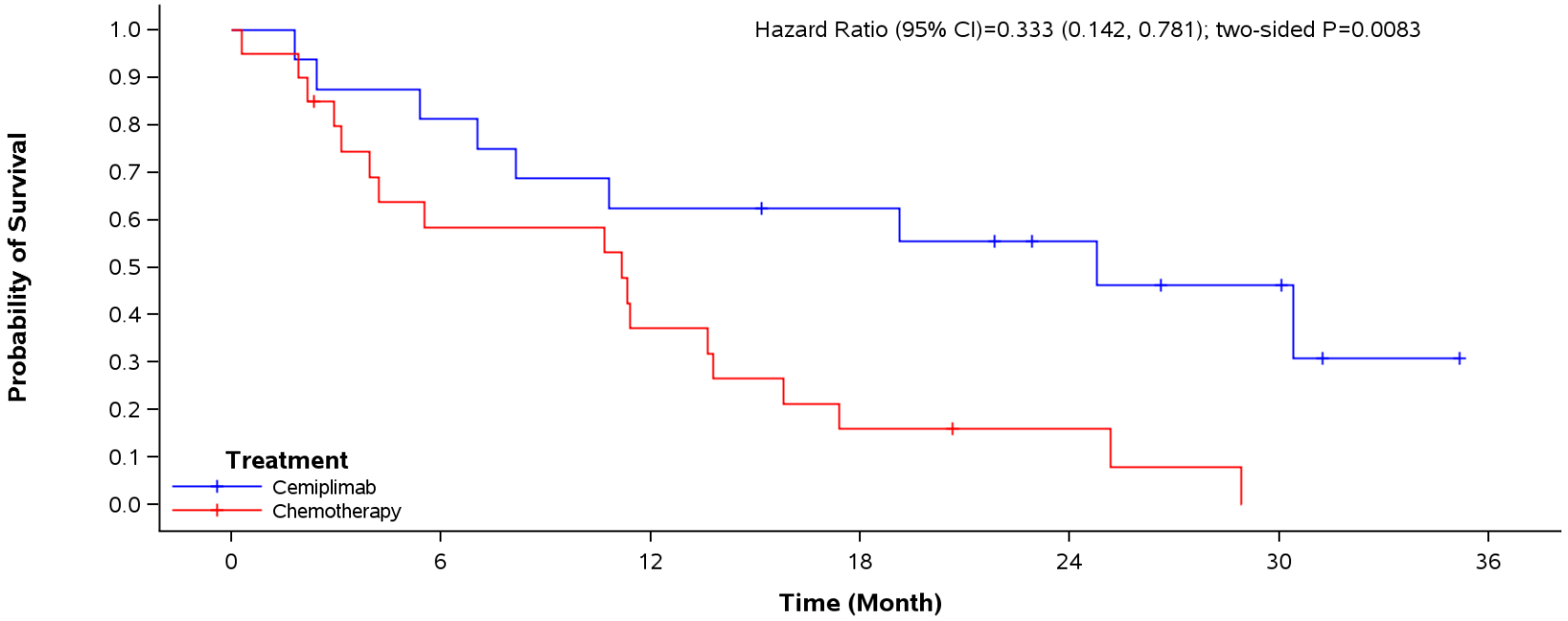

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 180 | 115 | 87 | 54 | 33 | 16 | 6 |
| Chemotherapy | 163 | 94 | 48 | 26 | 10 | 6 | 3 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



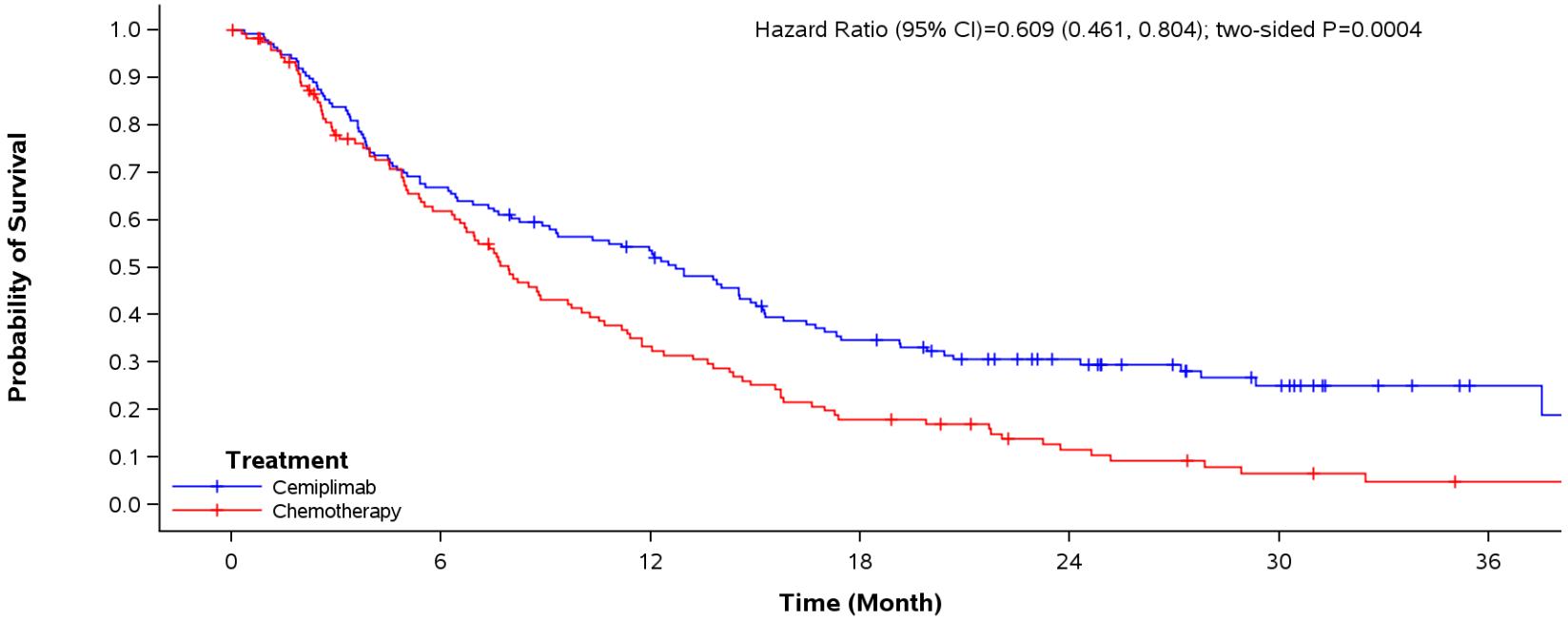

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 13 | 10 | 9 | 6 | 4 | 0 |
| Chemotherapy | 20 | 11 | 7 | 3 | 2 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



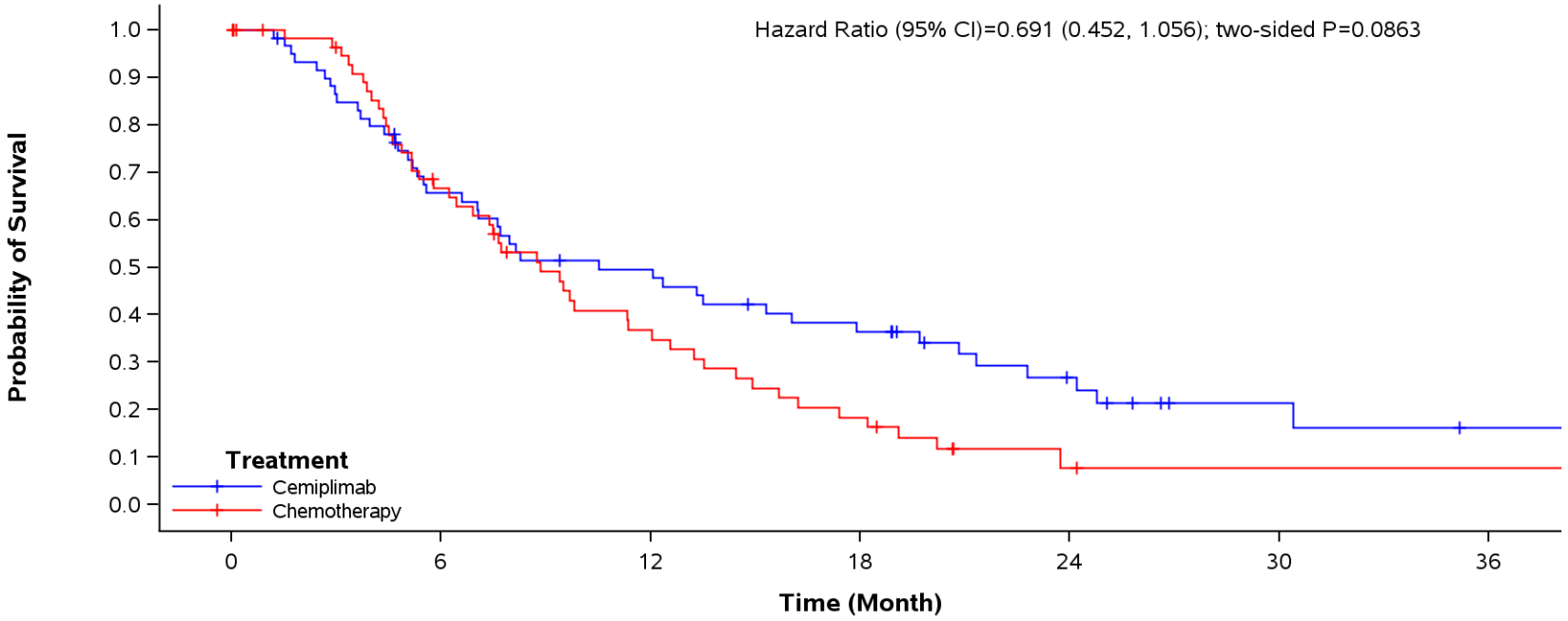

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 136 | 91 | 70 | 44 | 29 | 16 | 4 |
| Chemotherapy | 123 | 70 | 37 | 20 | 10 | 5 | 2 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



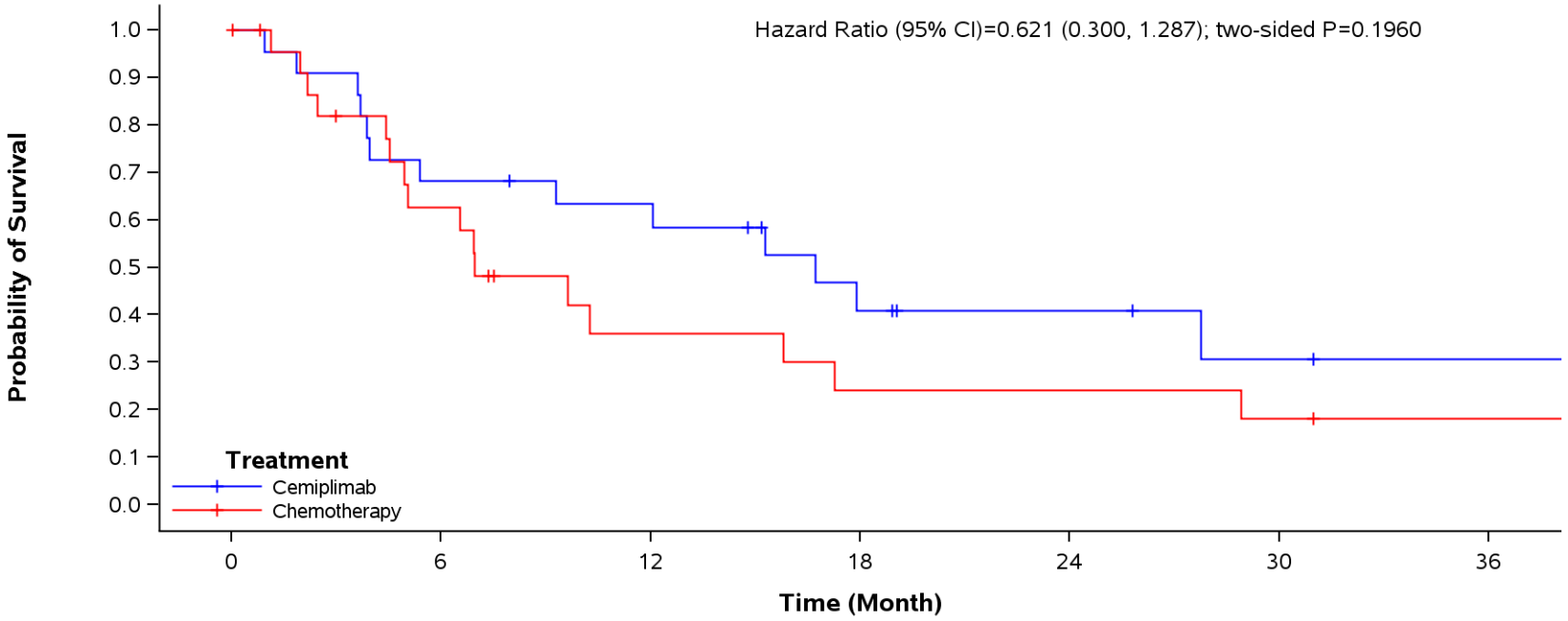

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 37 | 27 | 19 | 10 | 4 | 2 |
| Chemotherapy | 60 | 35 | 18 | 9 | 2 | 1 | 1 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America



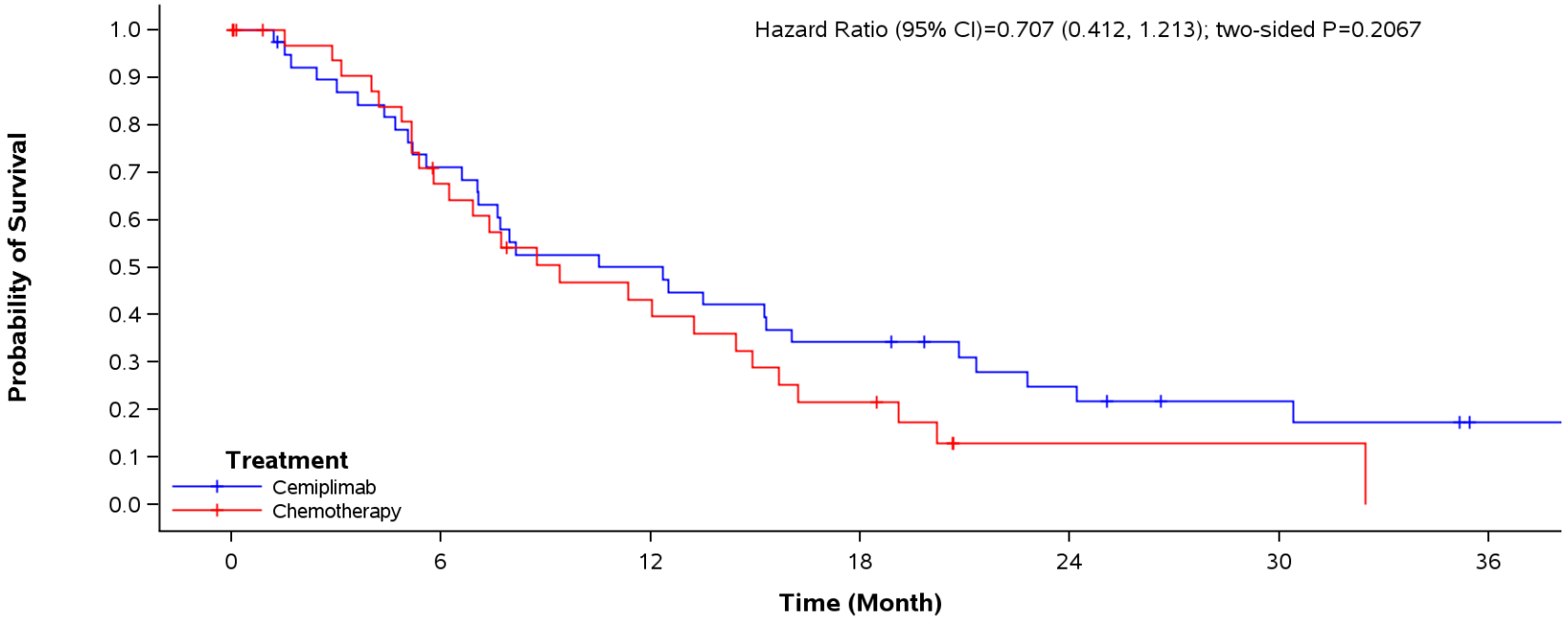

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 15 | 13 | 7 | 5 | 3 | 2 |
| Chemotherapy | 25 | 13 | 6 | 4 | 4 | 3 | 2 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia



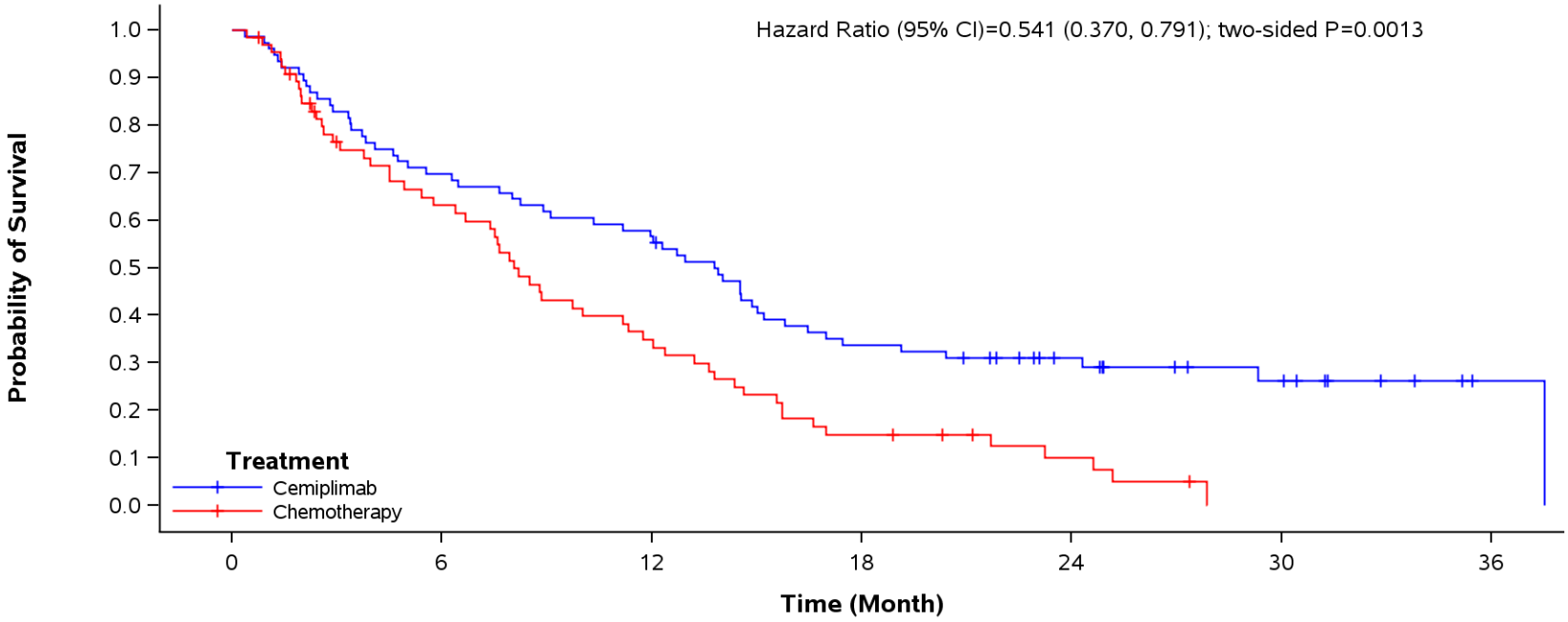

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 27 | 19 | 13 | 8 | 5 | 2 |
| Chemotherapy | 36 | 20 | 12 | 6 | 1 | 1 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



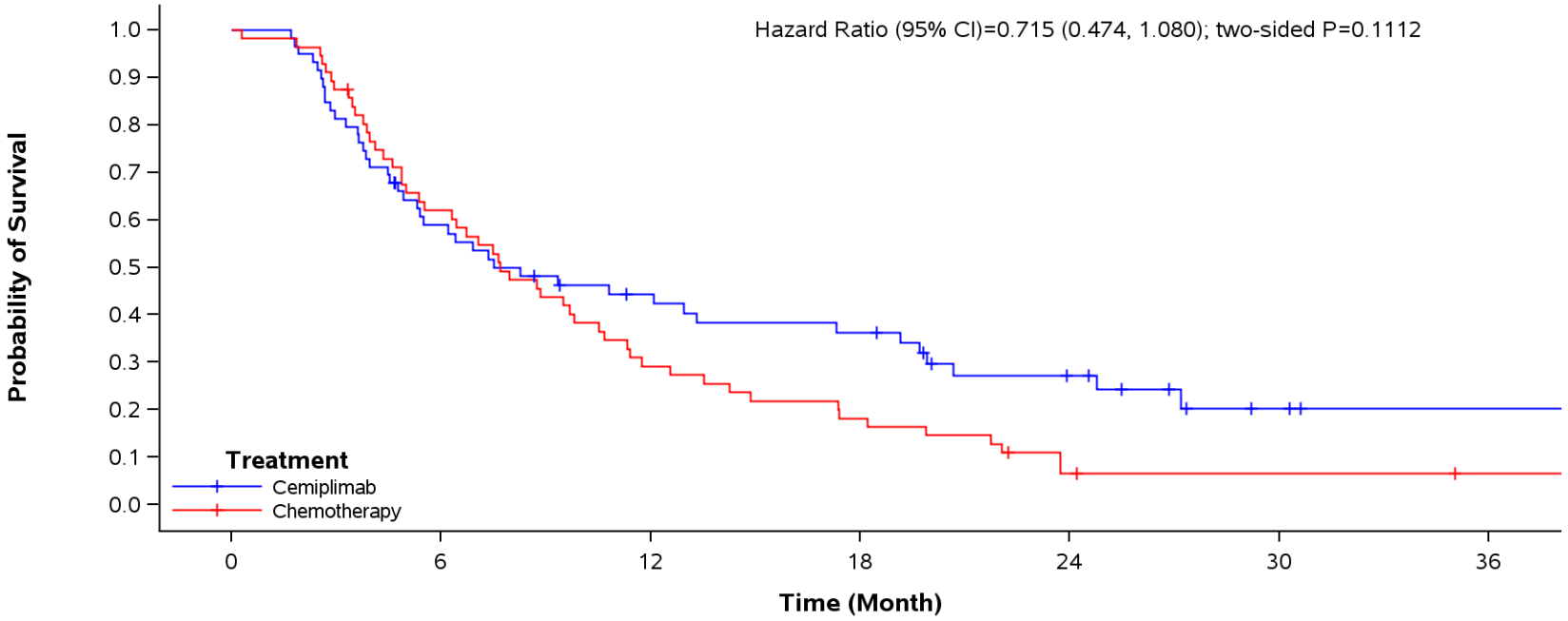

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 76 | 53 | 43 | 25 | 16 | 9 | 1 |
| Chemotherapy | 66 | 38 | 21 | 9 | 4 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW



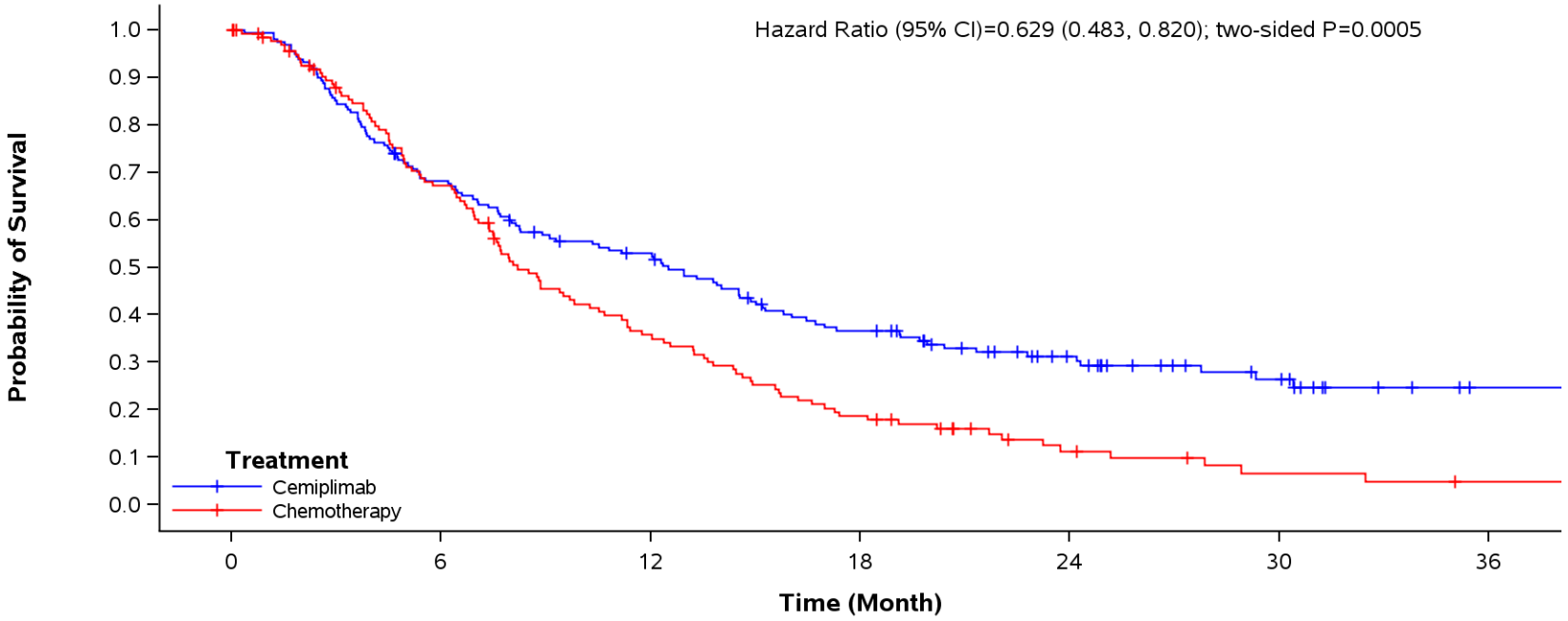

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 33 | 22 | 18 | 10 | 3 | 1 |
| Chemotherapy | 56 | 34 | 16 | 10 | 3 | 2 | 1 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous



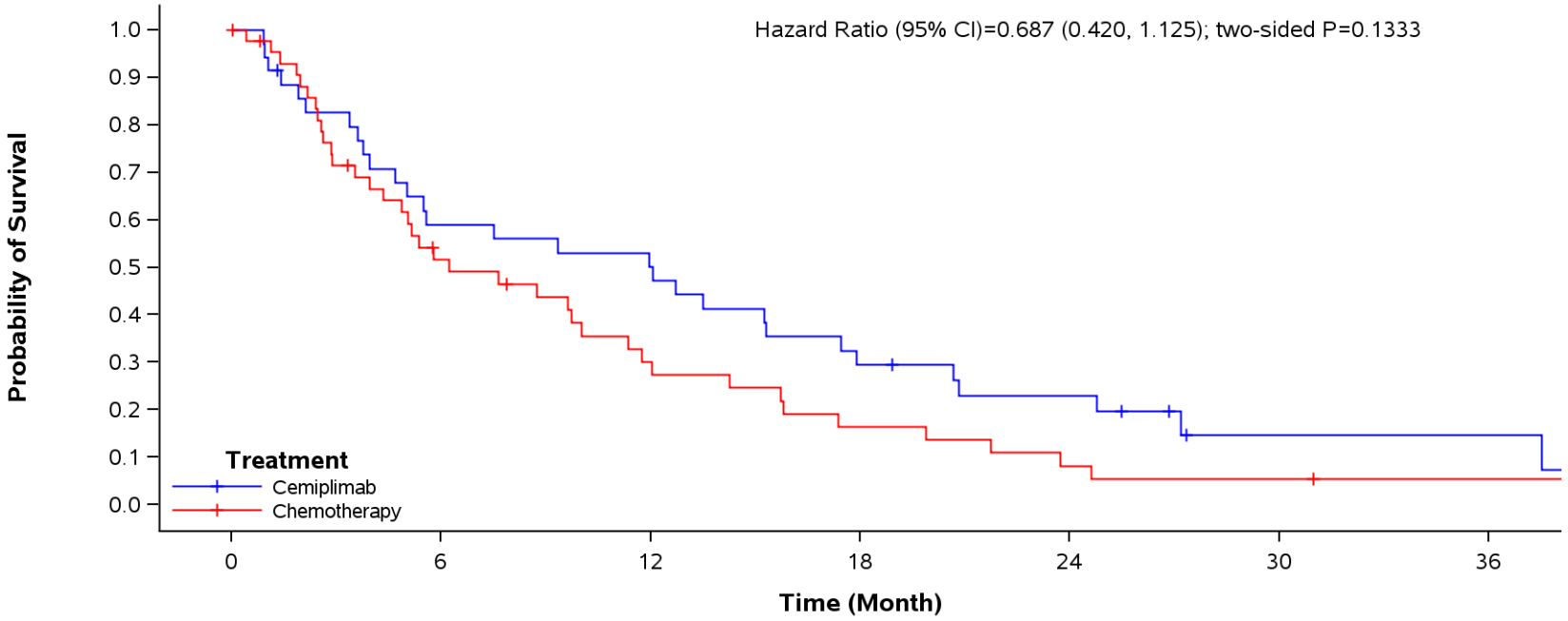

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 161 | 108 | 80 | 53 | 32 | 18 | 4 |
| Chemotherapy | 137 | 85 | 44 | 23 | 9 | 4 | 2 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



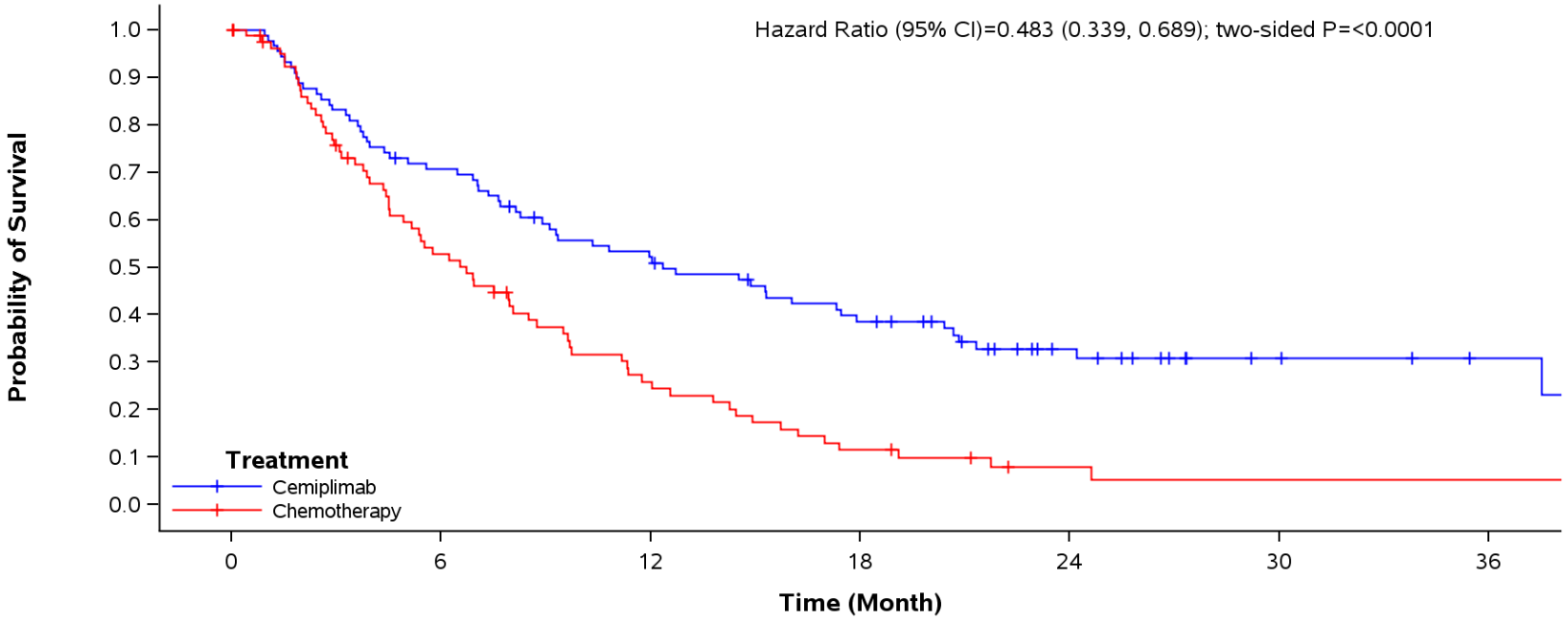

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 20 | 17 | 10 | 7 | 2 | 2 |
| Chemotherapy | 46 | 20 | 11 | 6 | 3 | 2 | 1 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes



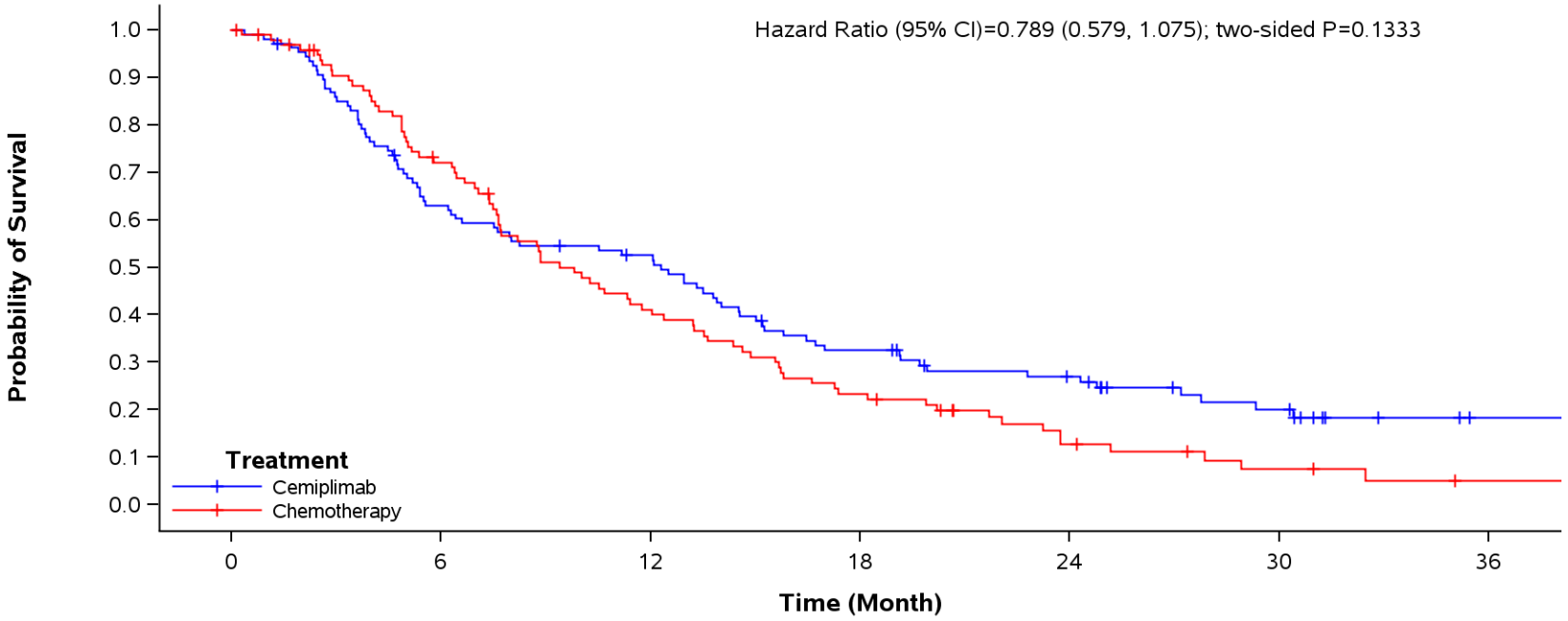

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 89 | 62 | 44 | 31 | 16 | 7 | 4 |
| Chemotherapy | 85 | 39 | 18 | 8 | 3 | 2 | 2 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No



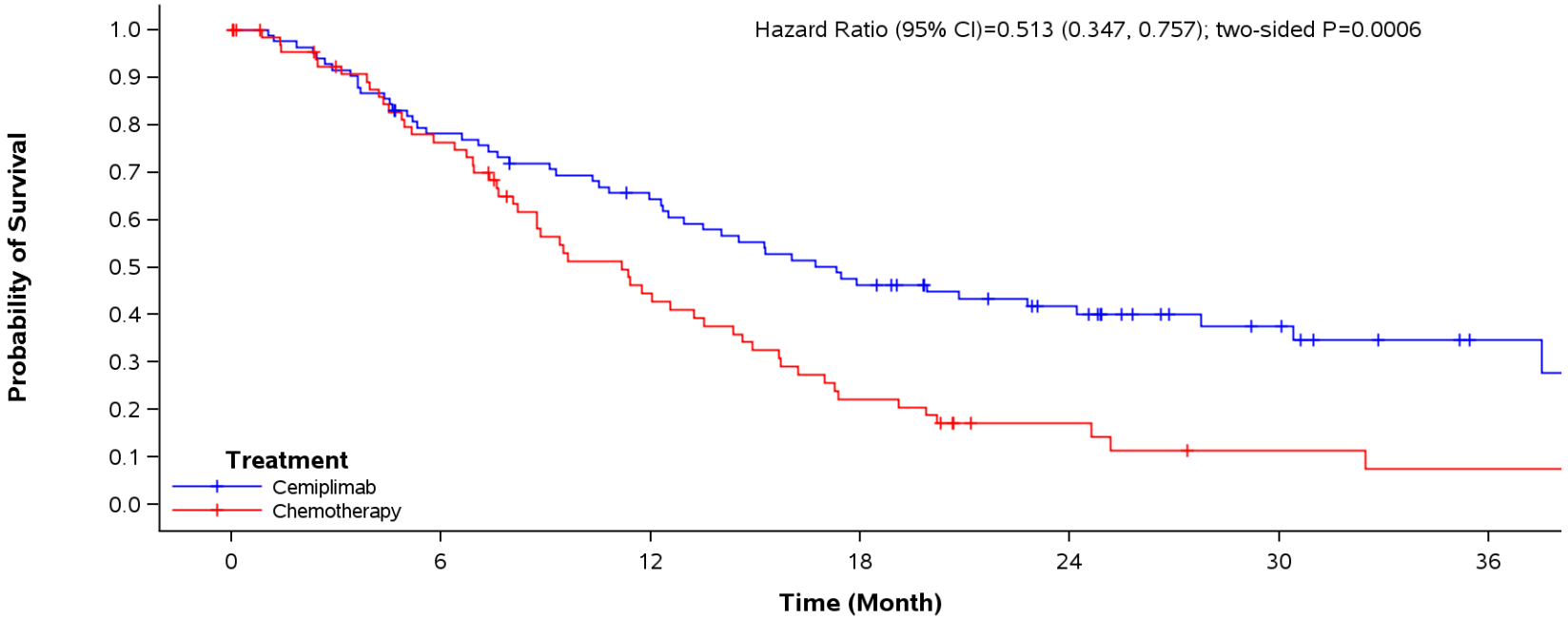

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 107 | 66 | 53 | 32 | 23 | 13 | 2 |
| Chemotherapy | 98 | 66 | 37 | 21 | 9 | 4 | 1 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0



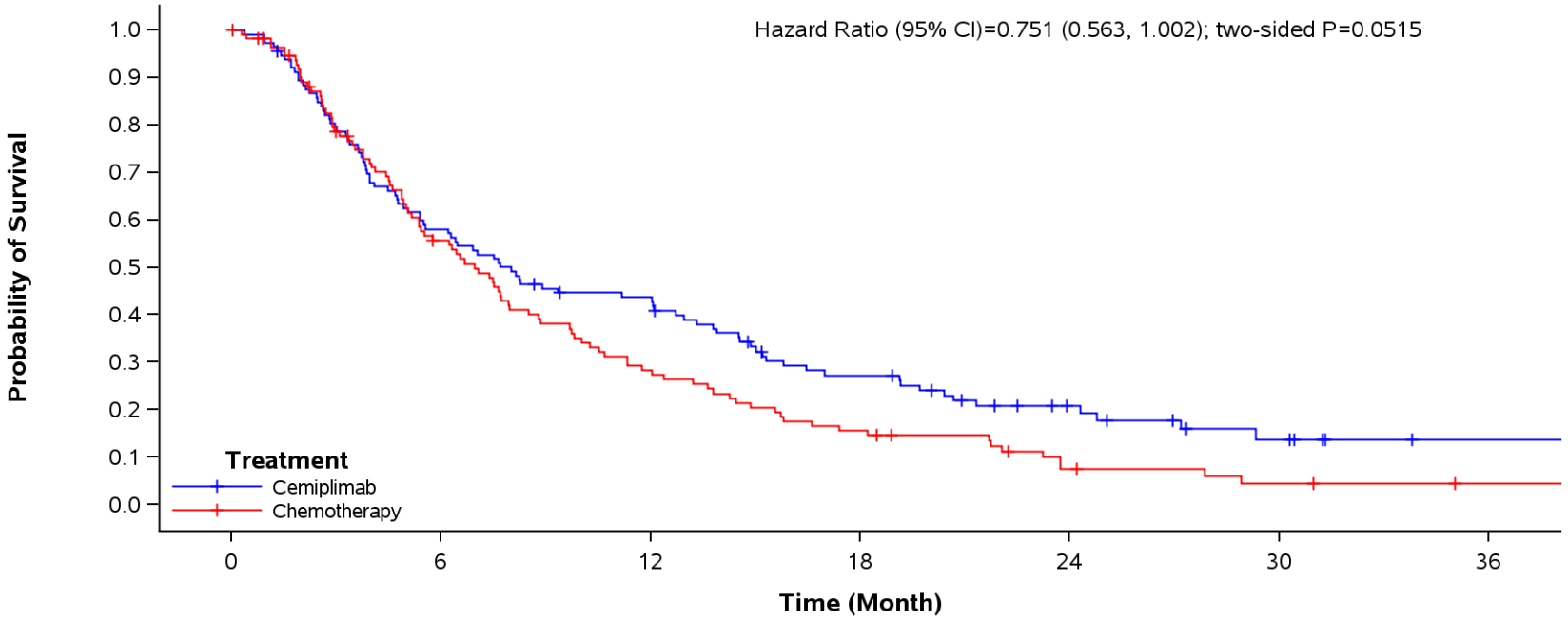

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 63 | 50 | 36 | 25 | 14 | 5 |
| Chemotherapy | 69 | 48 | 26 | 13 | 6 | 3 | 2 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1



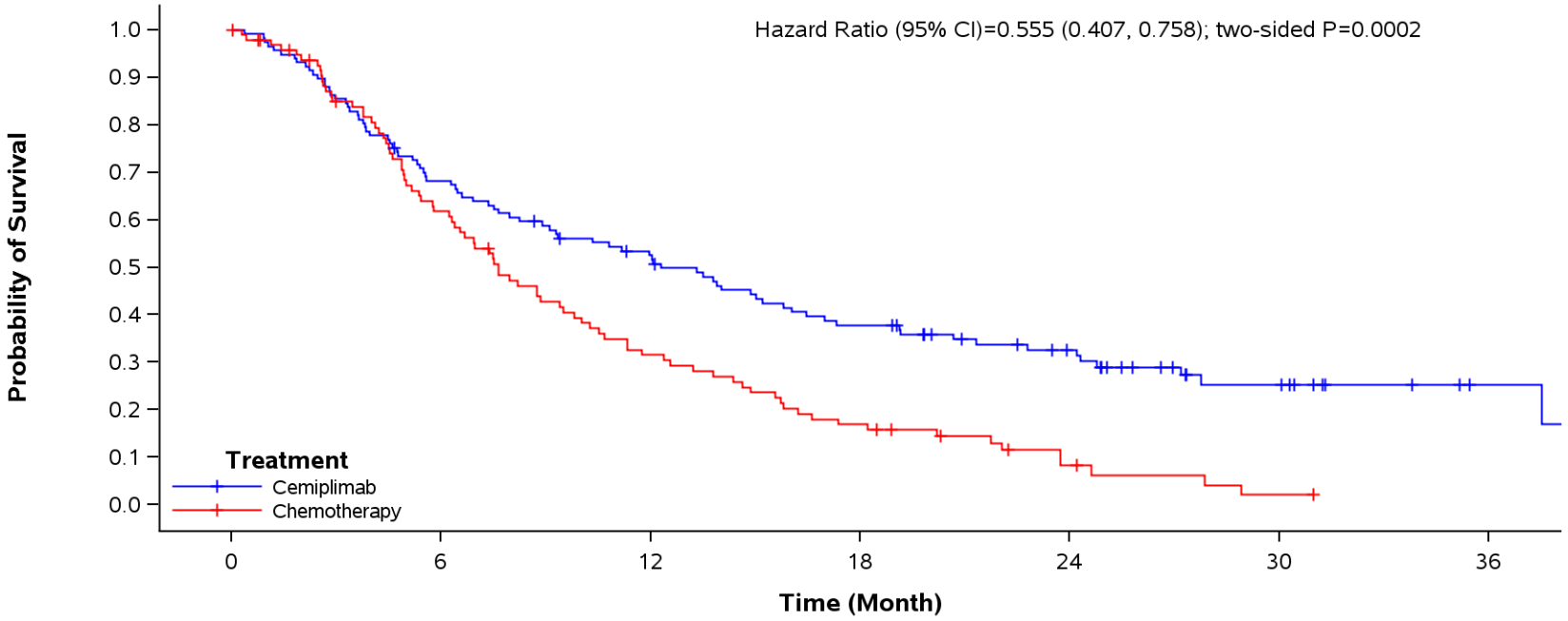

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 113 | 65 | 47 | 27 | 14 | 6 | 1 |
| Chemotherapy | 114 | 57 | 29 | 16 | 6 | 3 | 1 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line



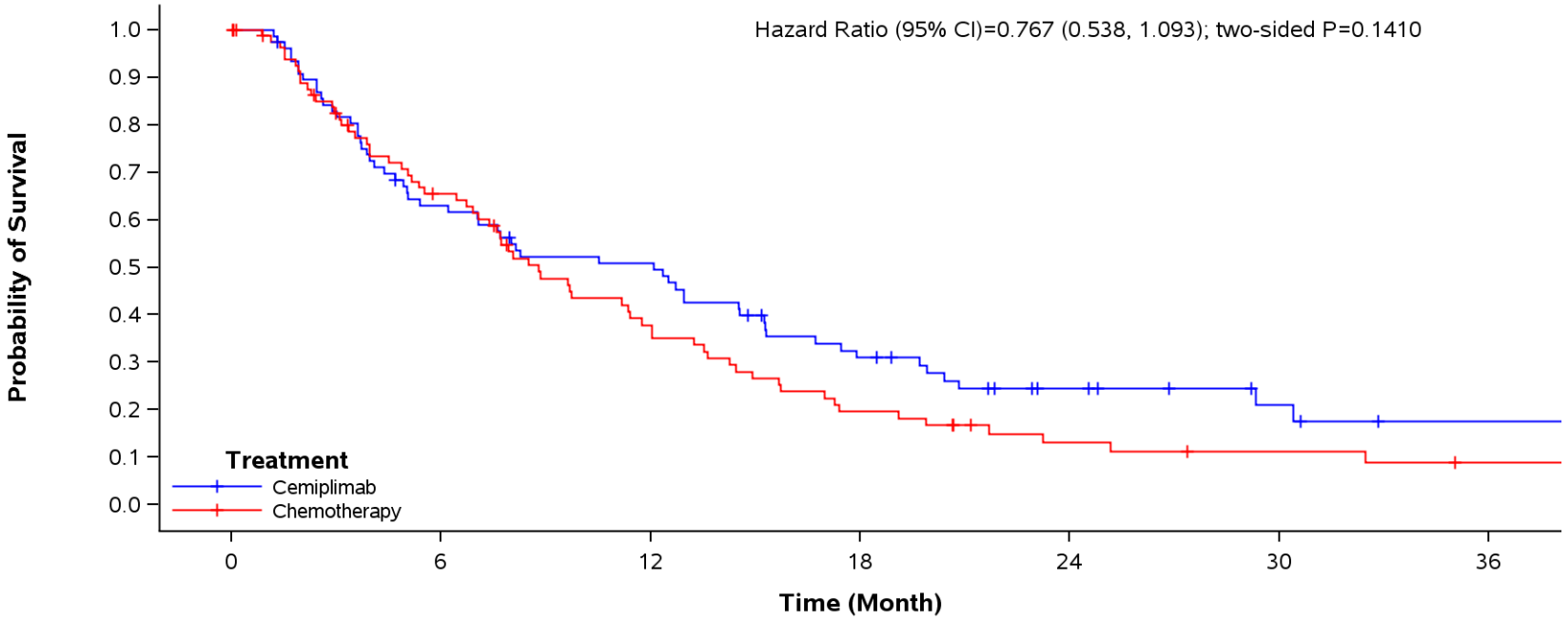

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 79 | 58 | 41 | 27 | 13 | 3 |
| Chemotherapy | 97 | 56 | 28 | 15 | 5 | 1 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line



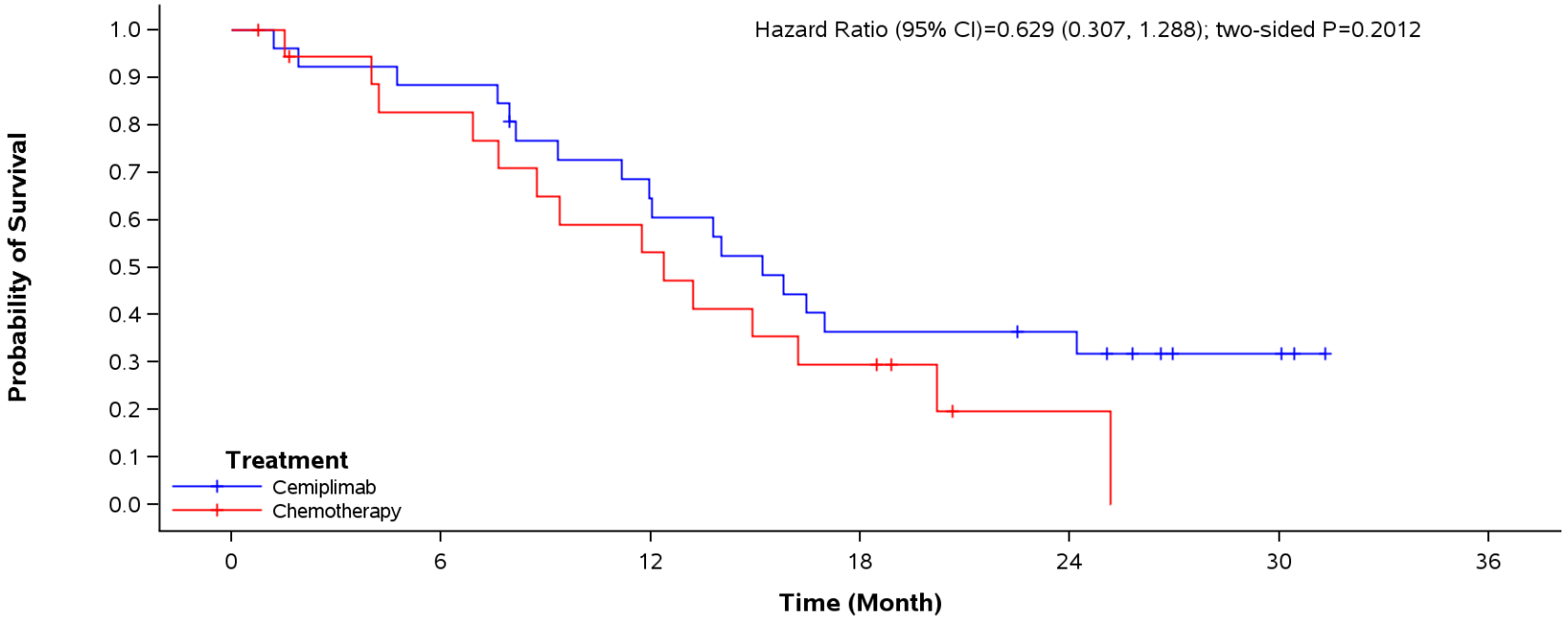

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 77 | 47 | 37 | 21 | 11 | 6 | 3 |
| Chemotherapy | 86 | 49 | 27 | 14 | 7 | 5 | 3 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



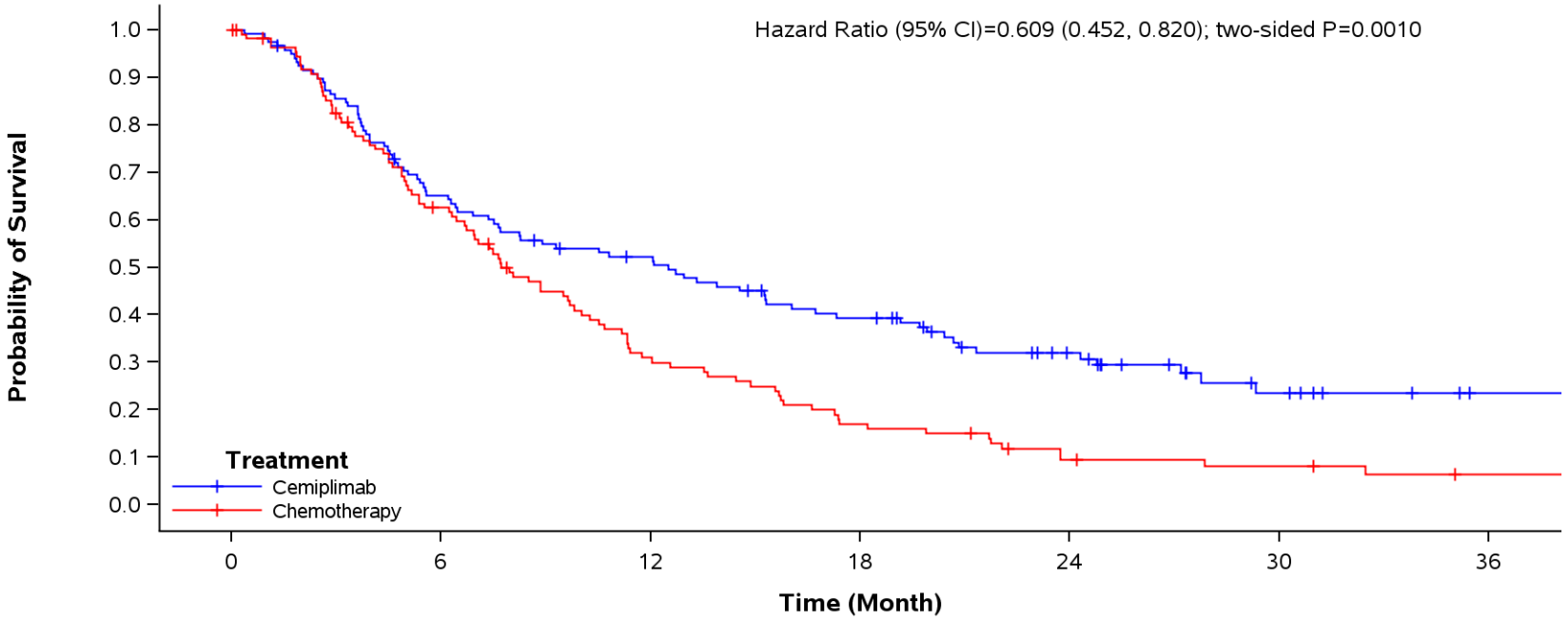

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 23 | 16 | 9 | 8 | 3 | 0 |
| Chemotherapy | 19 | 14 | 9 | 5 | 1 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed



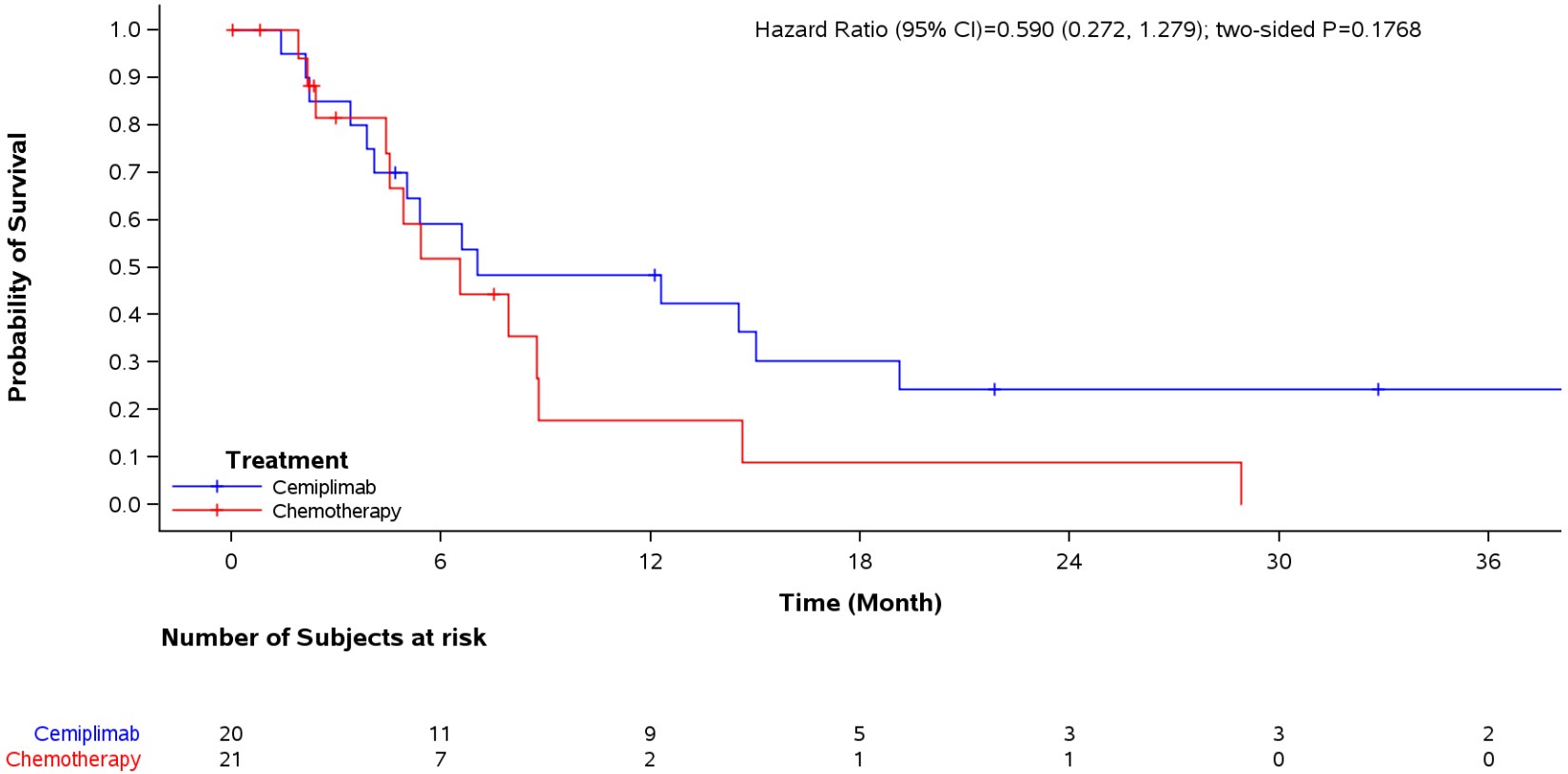

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 119 | 76 | 58 | 42 | 25 | 11 | 2 |
| Chemotherapy | 111 | 65 | 31 | 17 | 8 | 6 | 3 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

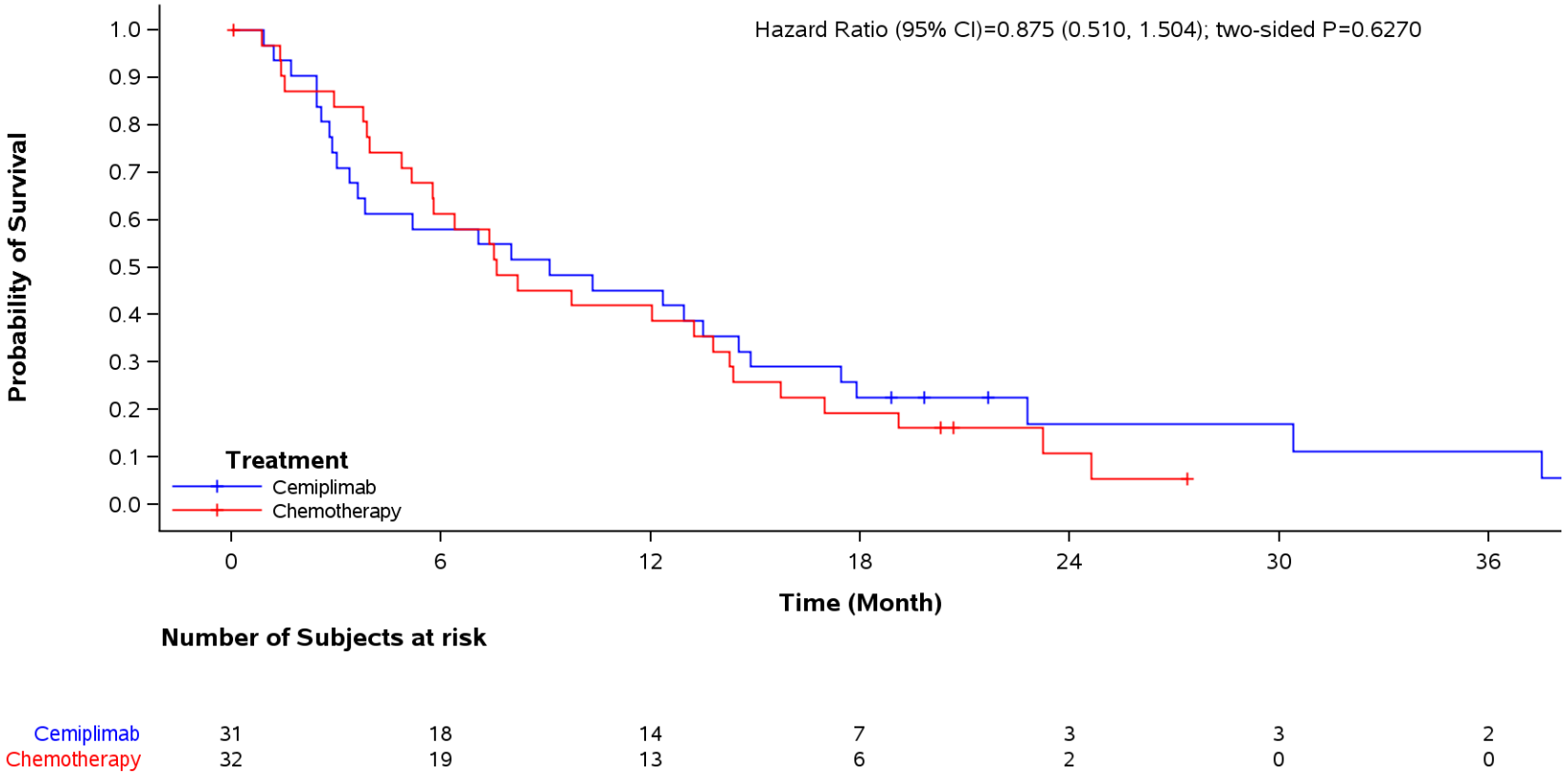
Choice of IC chemotherapy: Topotecan




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 2.2.1. Kaplan Meier Cumulative Incidence Curve for Overall Survival by Subgroup without PD-L1
(Full Analysis Set Exclude Patients Assigned to Gemcitabine)

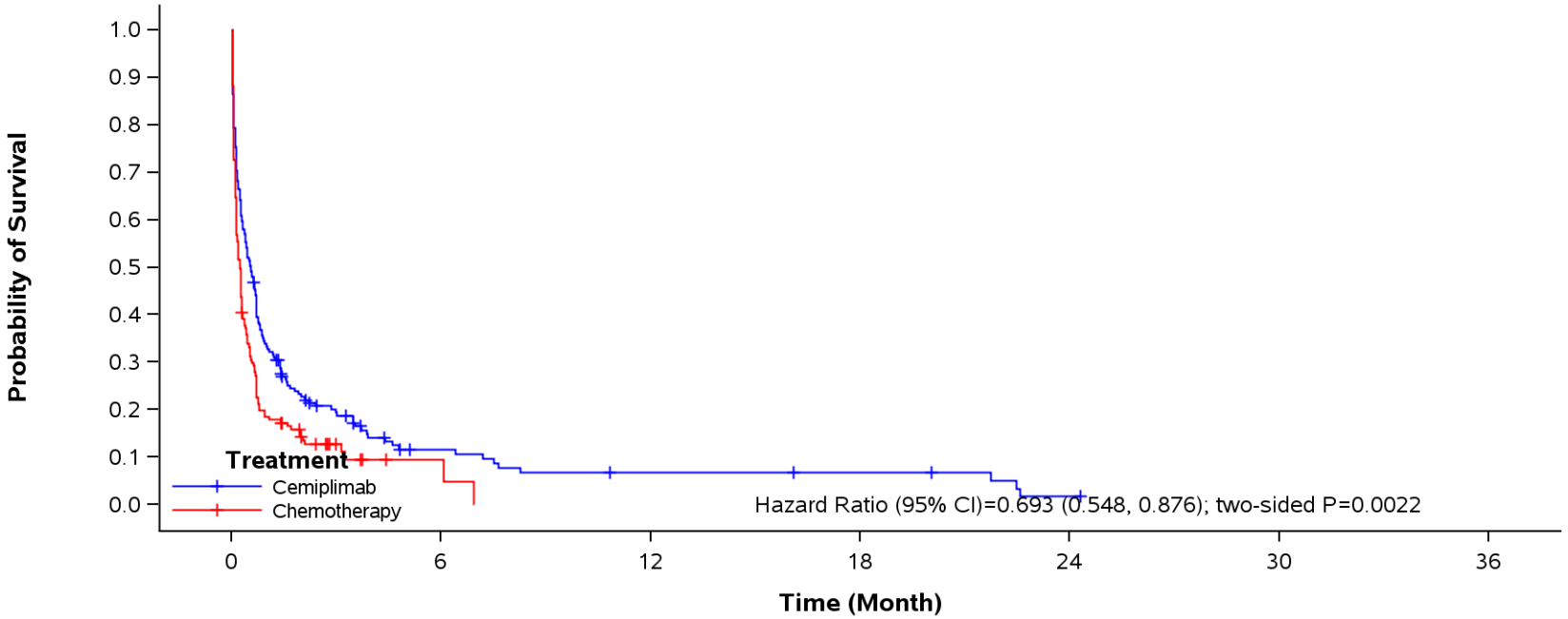
Choice of IC chemotherapy: Vinorelbine




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



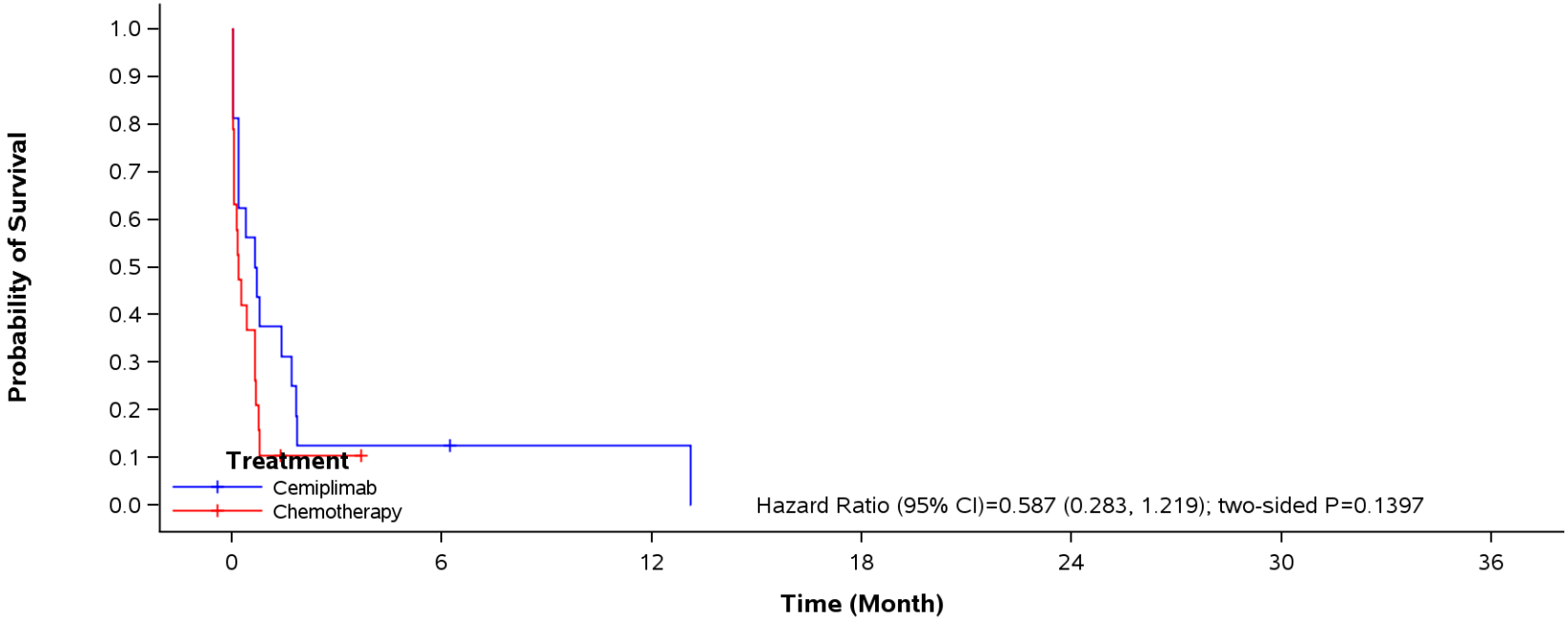

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 12 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 153 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



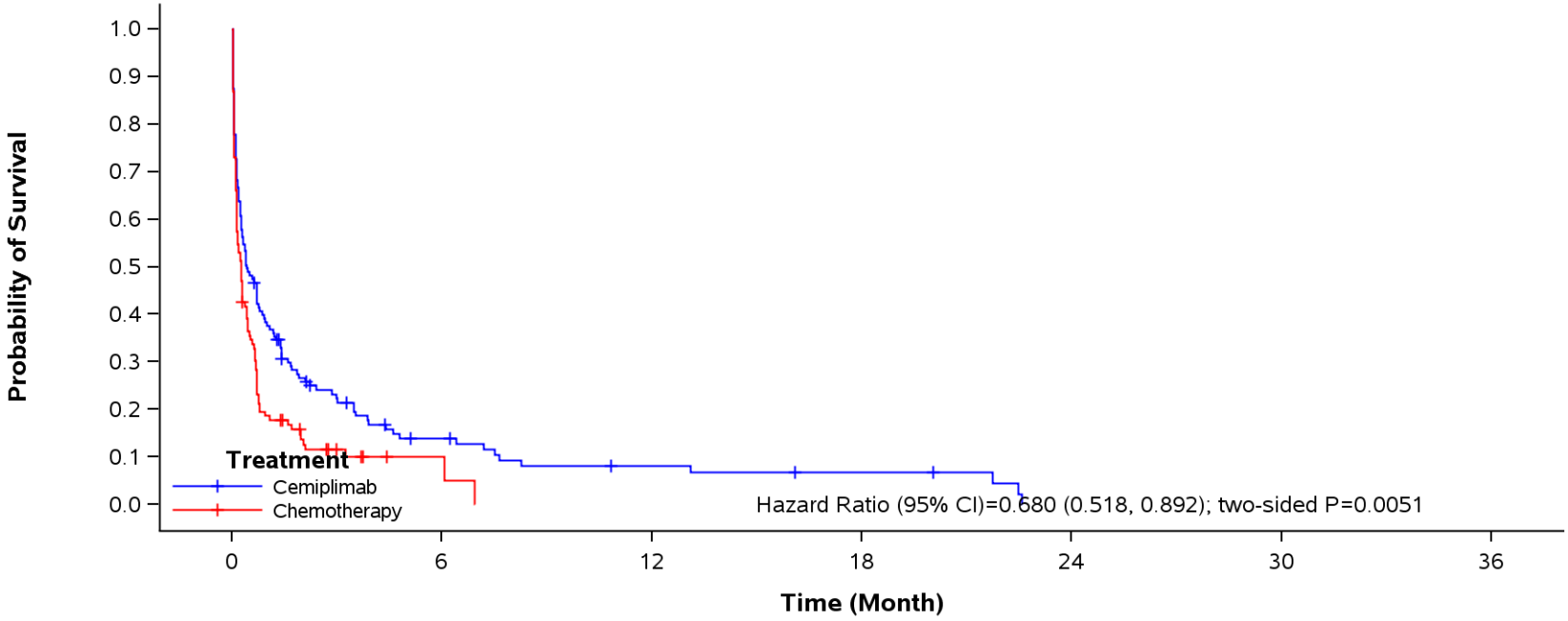

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



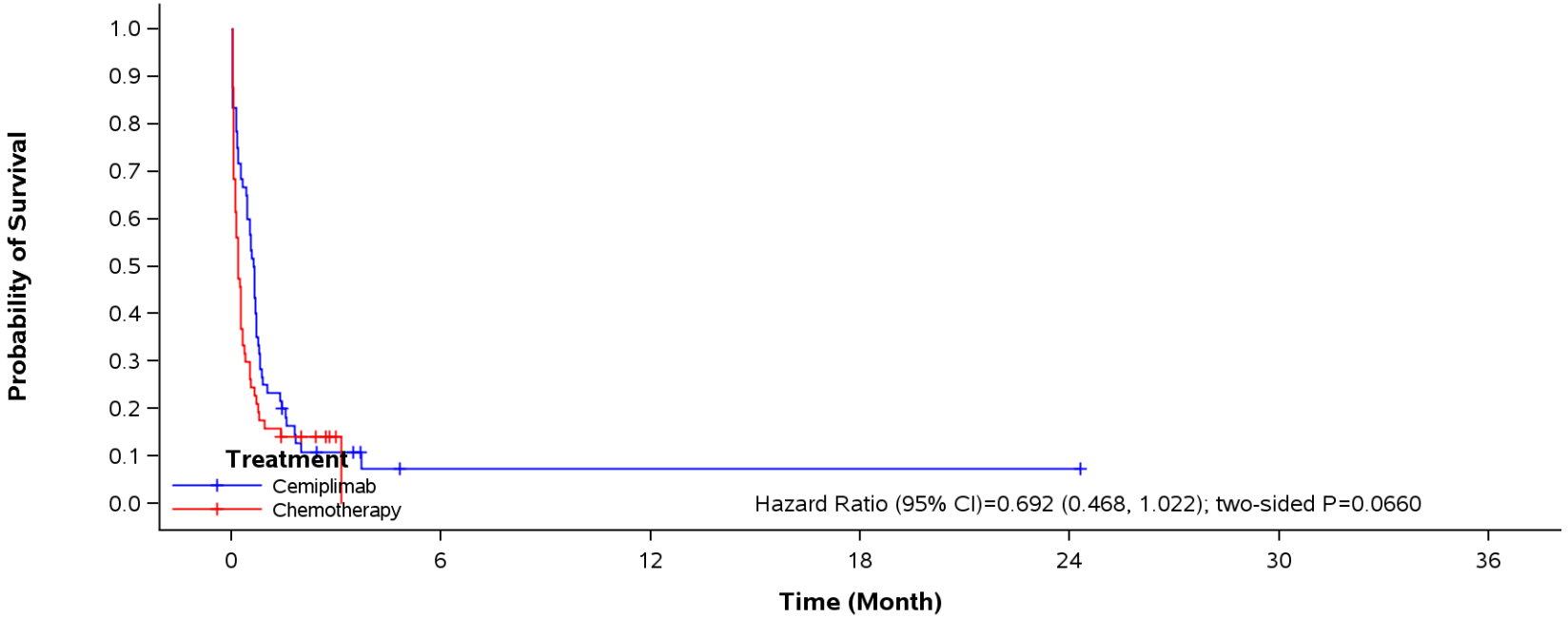

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 13 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 115 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



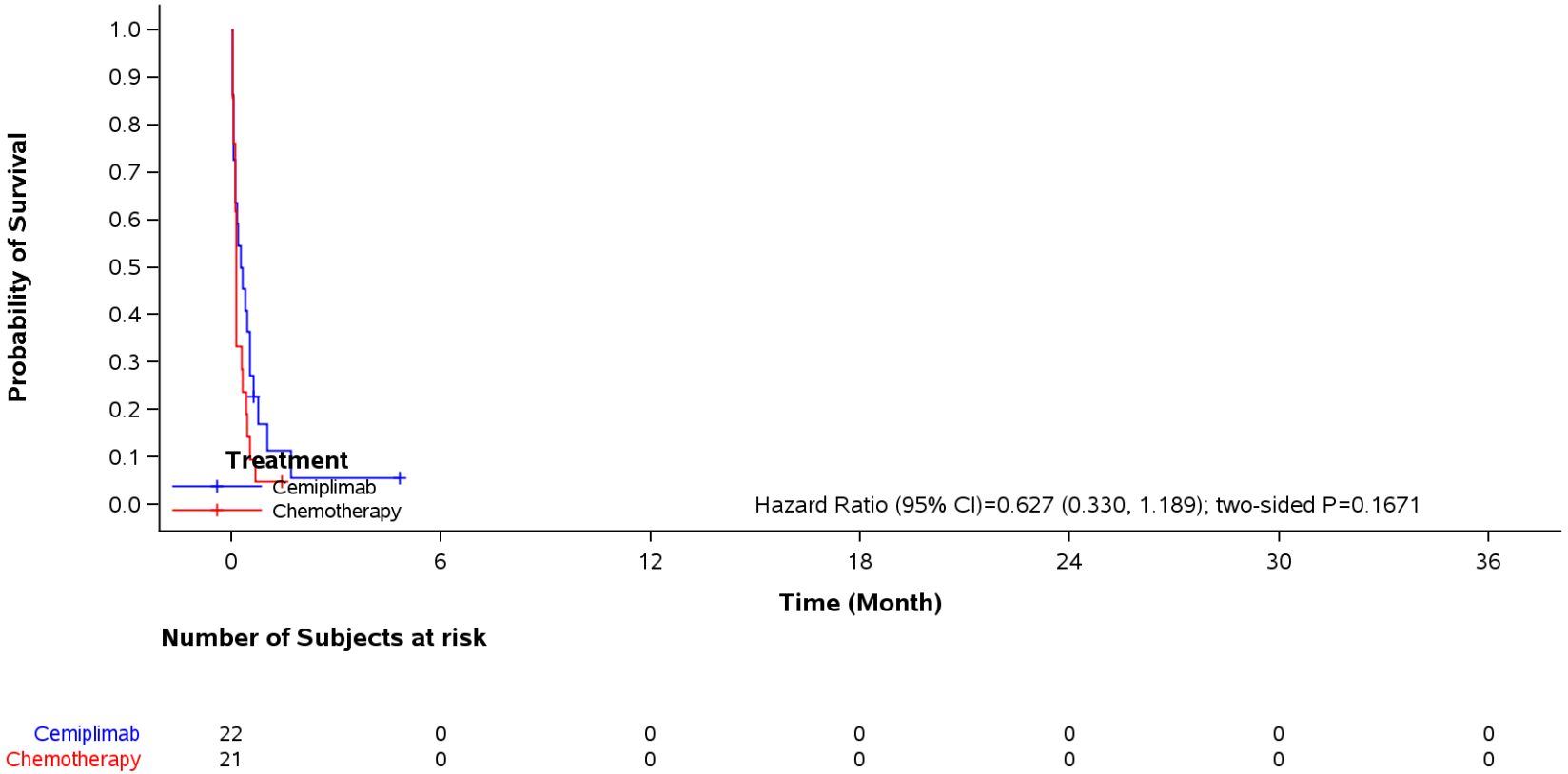

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 1 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 57 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

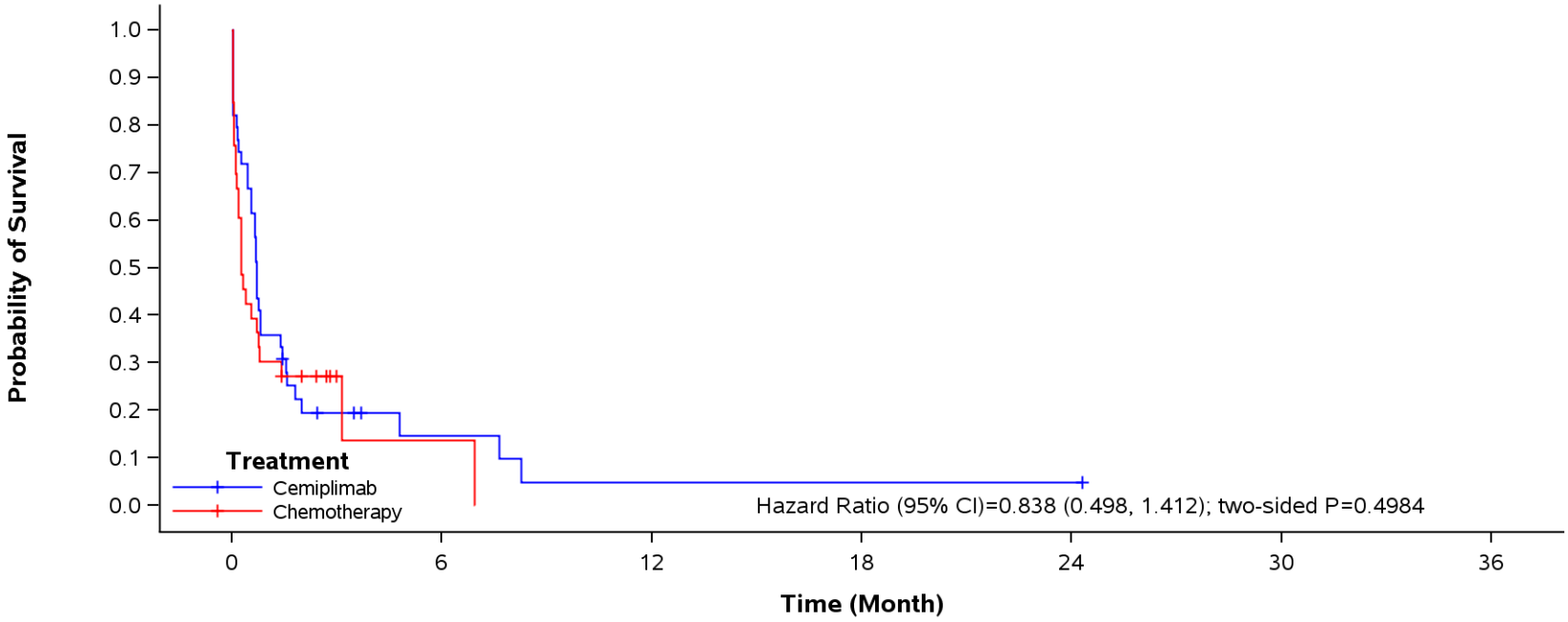
Geographic region: North America




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia



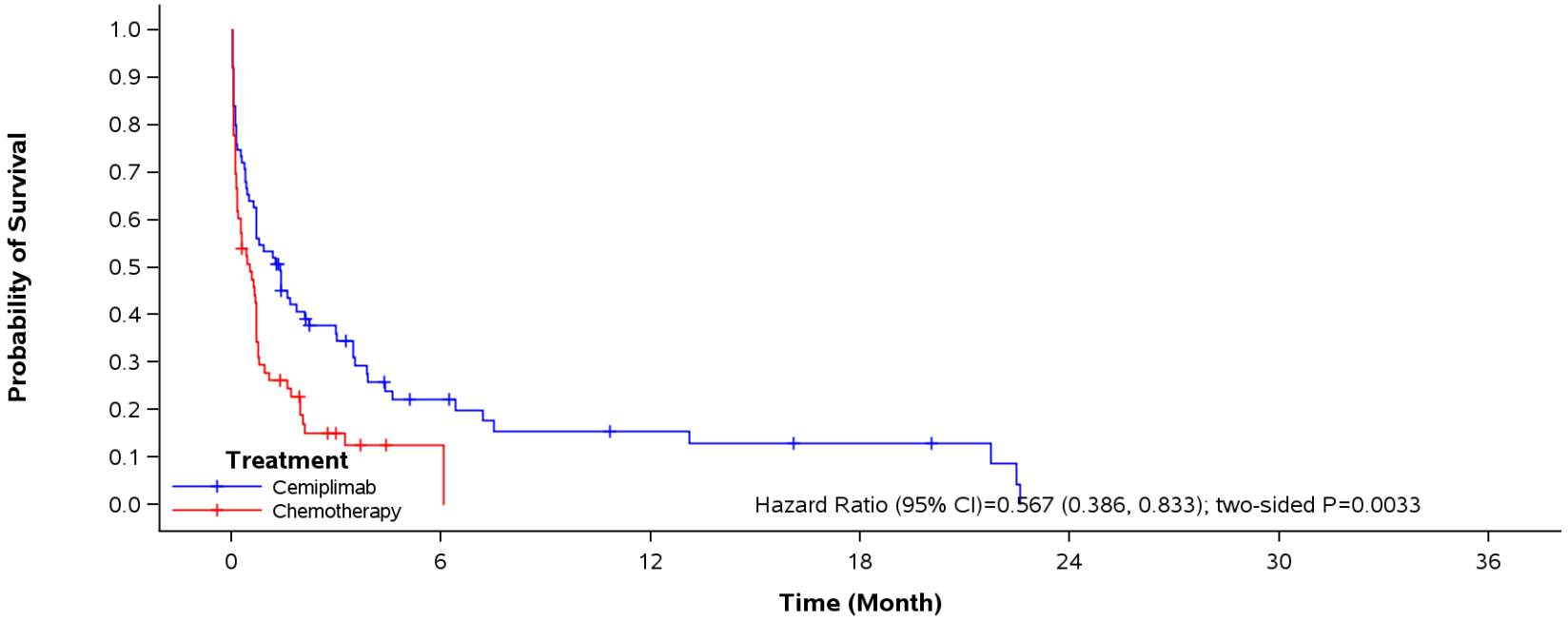

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 33 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



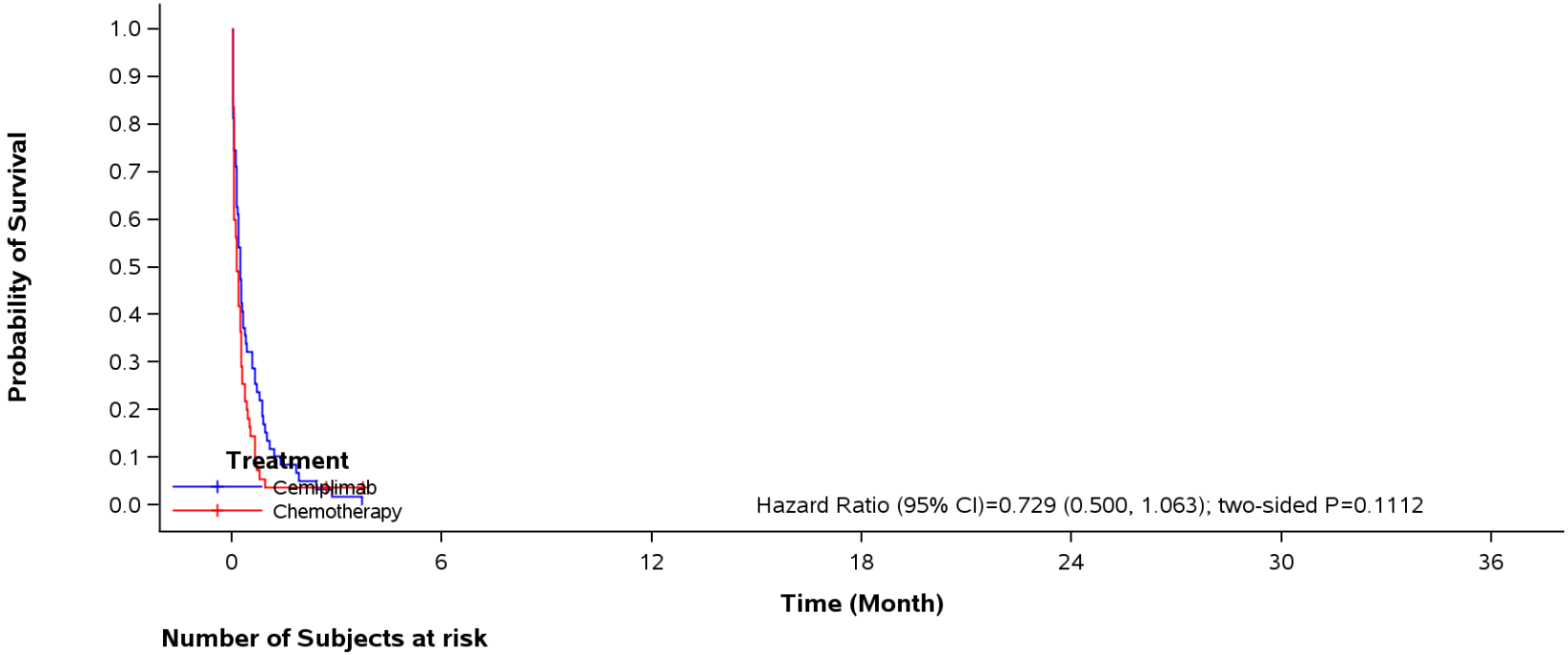

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 11 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 63 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW



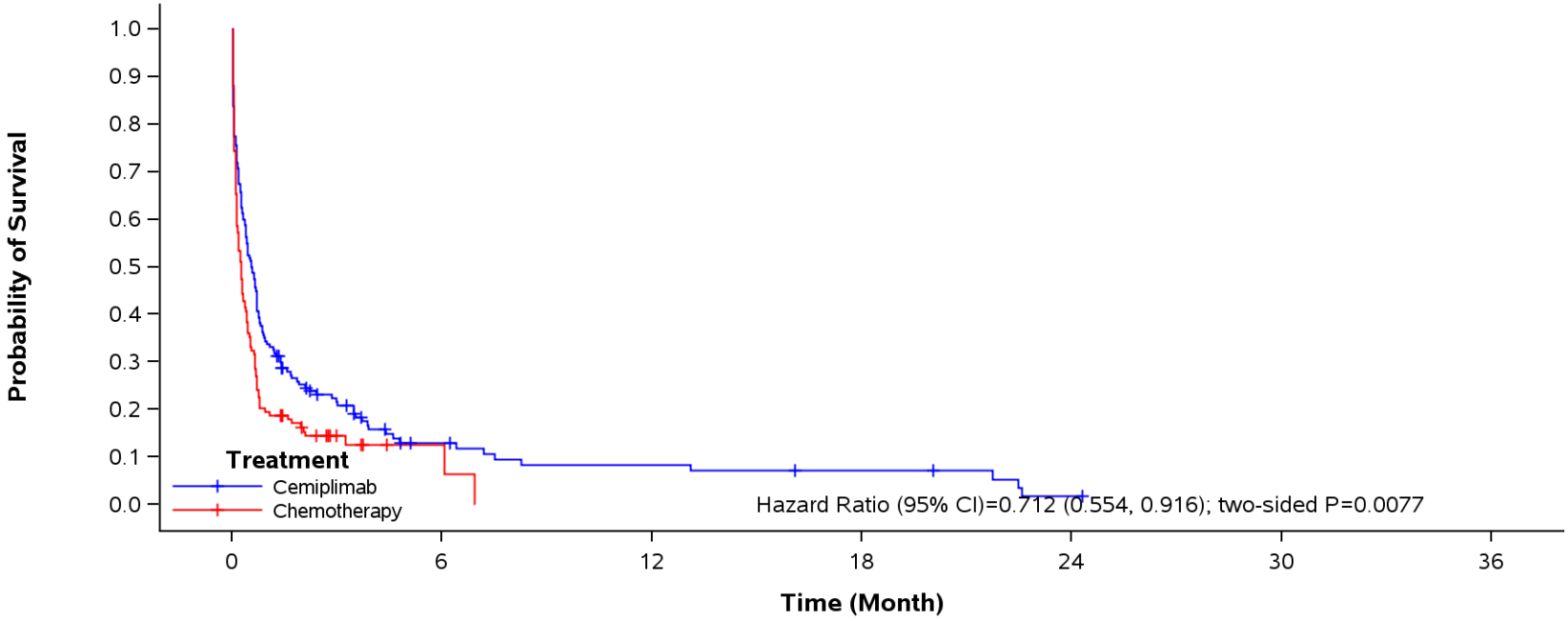

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 55 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous



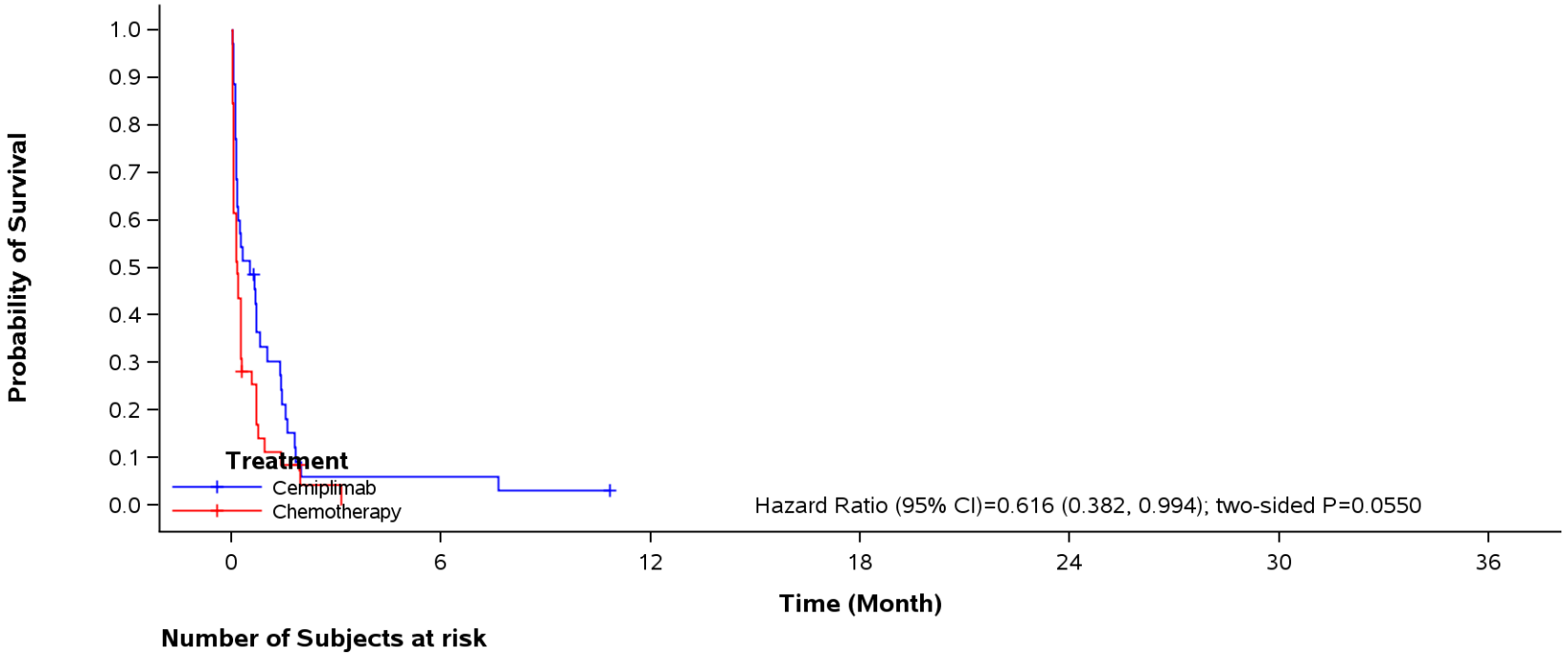

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 12 | 7 | 5 | 1 | 0 | 0 |
| Chemotherapy | 133 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



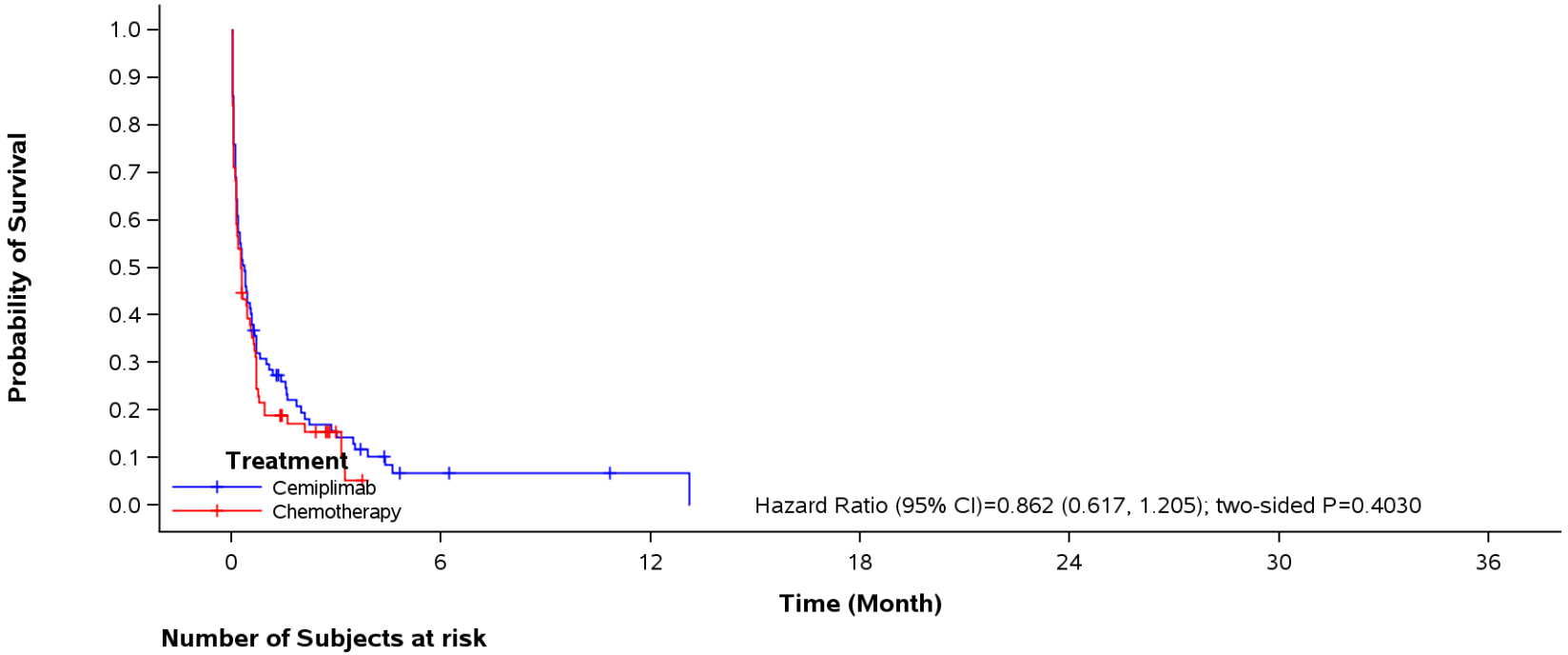

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 39 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes



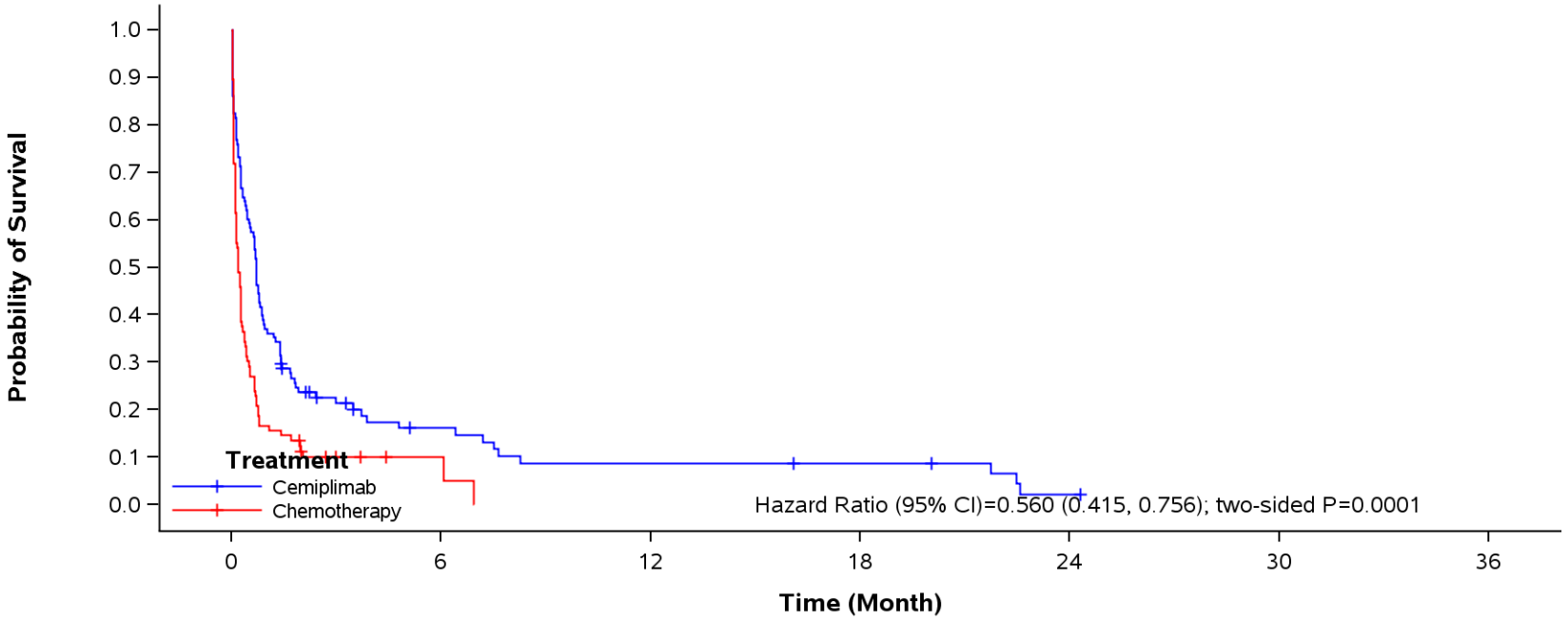

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 76 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No



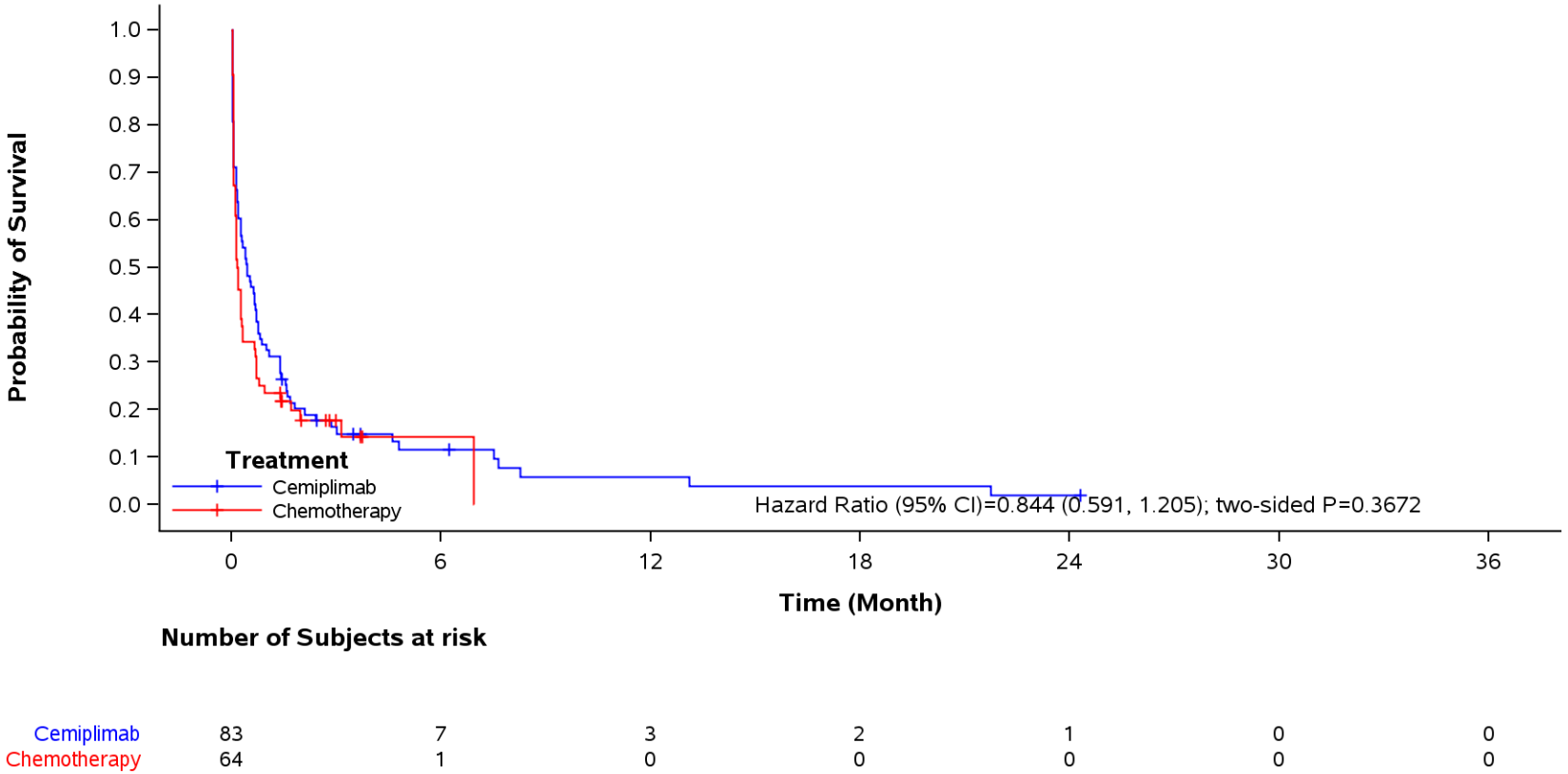

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 11 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 96 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

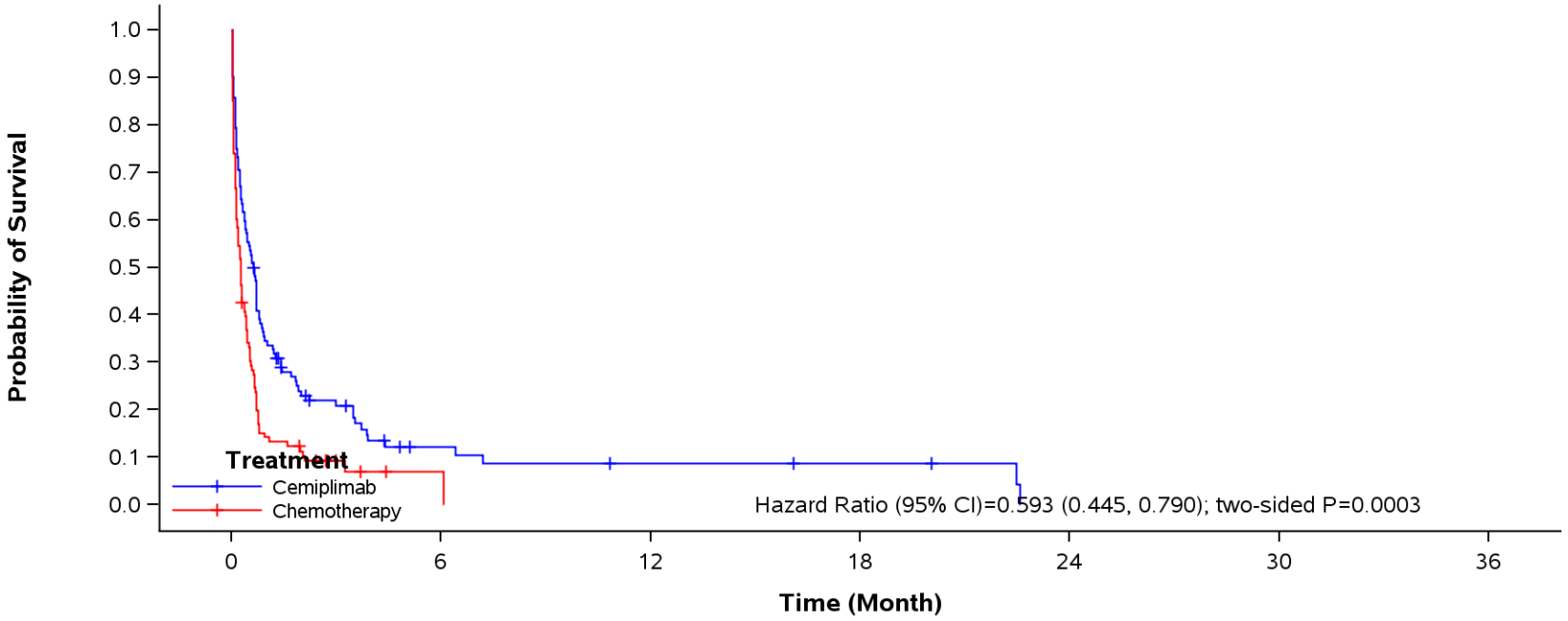
Baseline ECOG Status: 0




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1



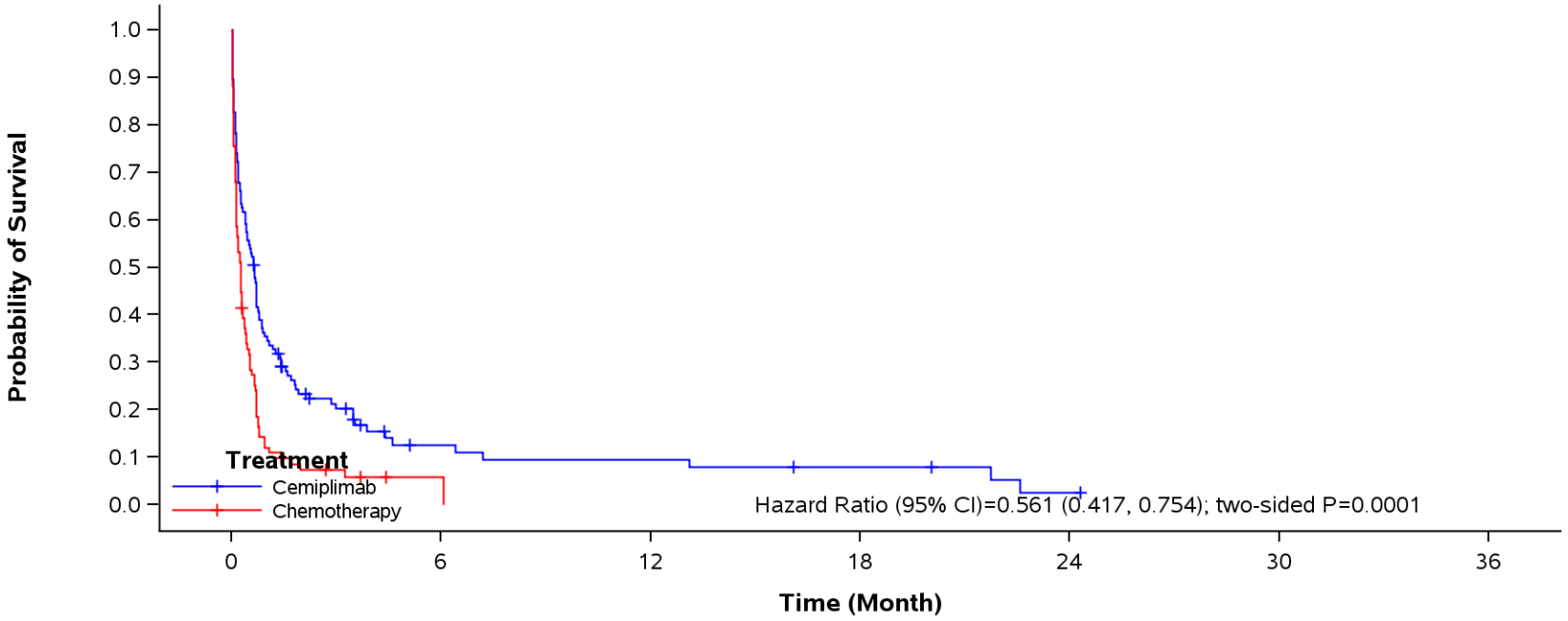

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 7 | 4 | 3 | 0 | 0 | 0 |
| Chemotherapy | 108 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line



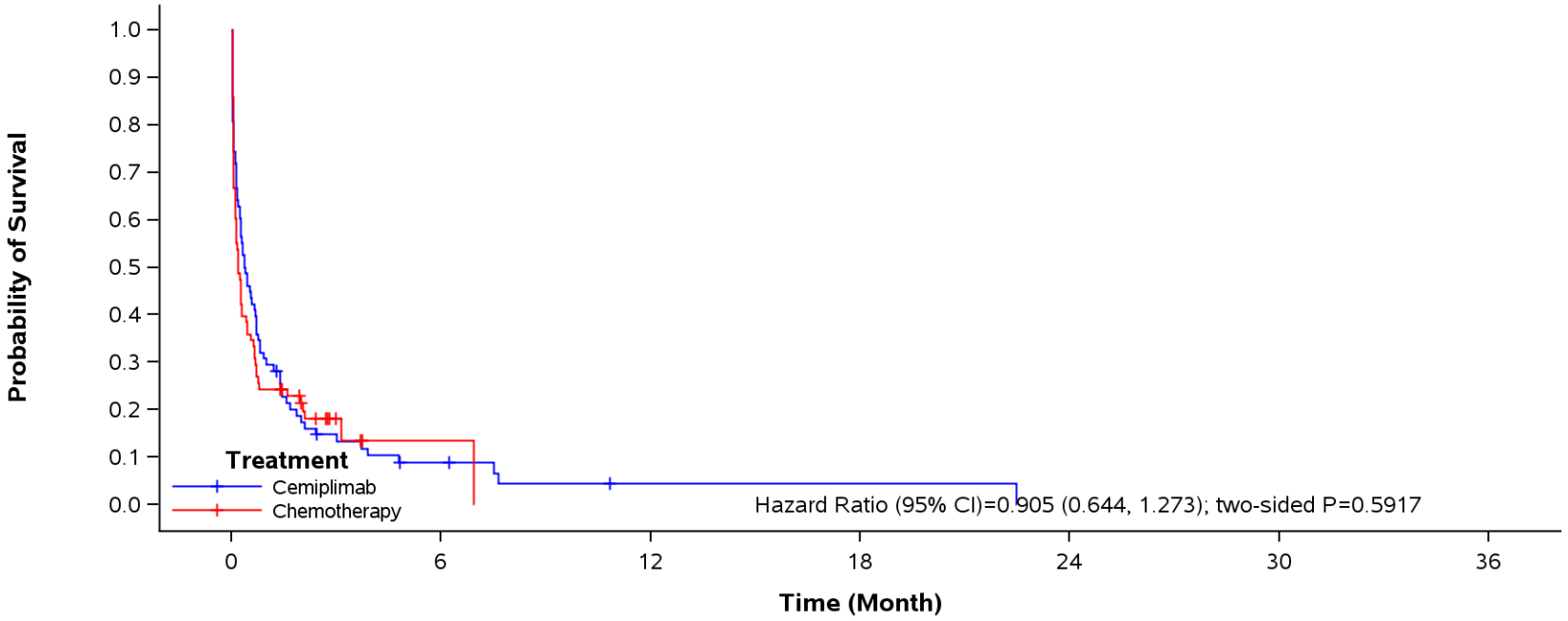

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 8 | 6 | 4 | 1 | 0 | 0 |
| Chemotherapy | 94 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line



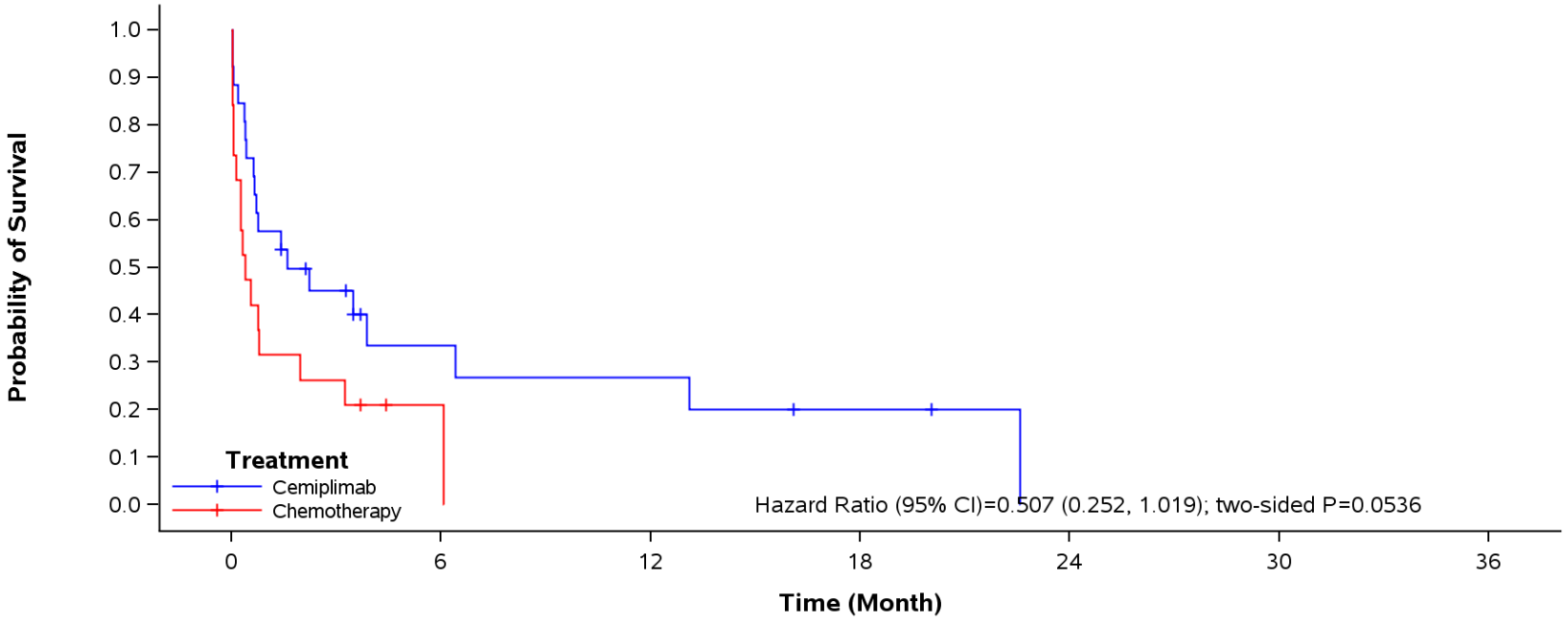

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 78 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



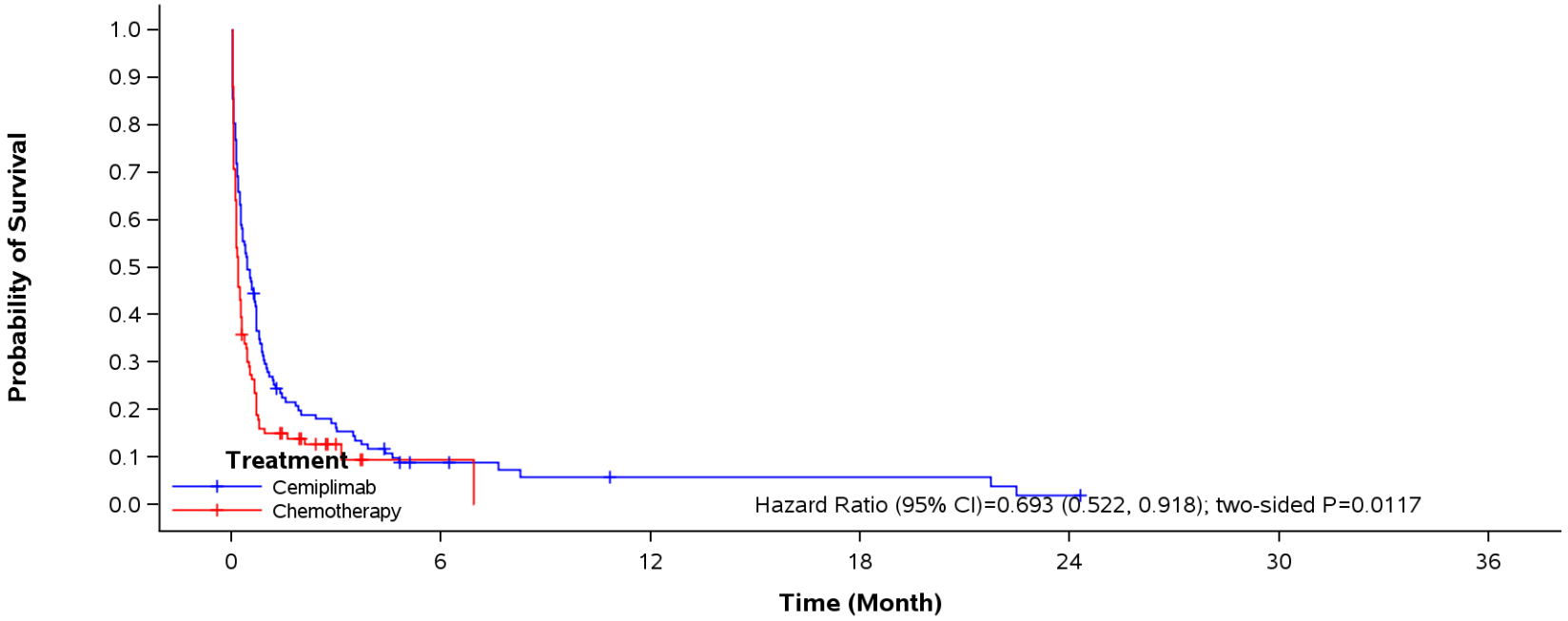

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 5 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed



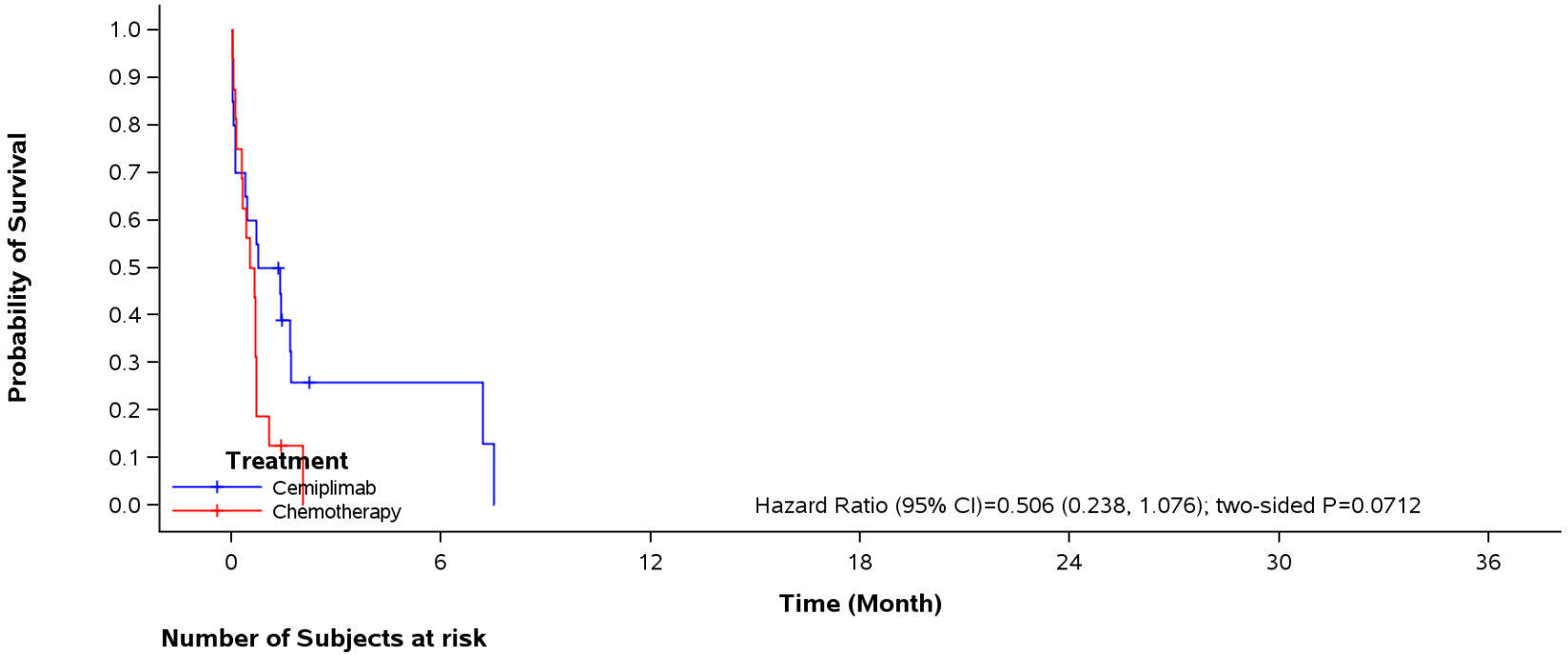

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 7 | 3 | 3 | 1 | 0 | 0 |
| Chemotherapy | 109 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan



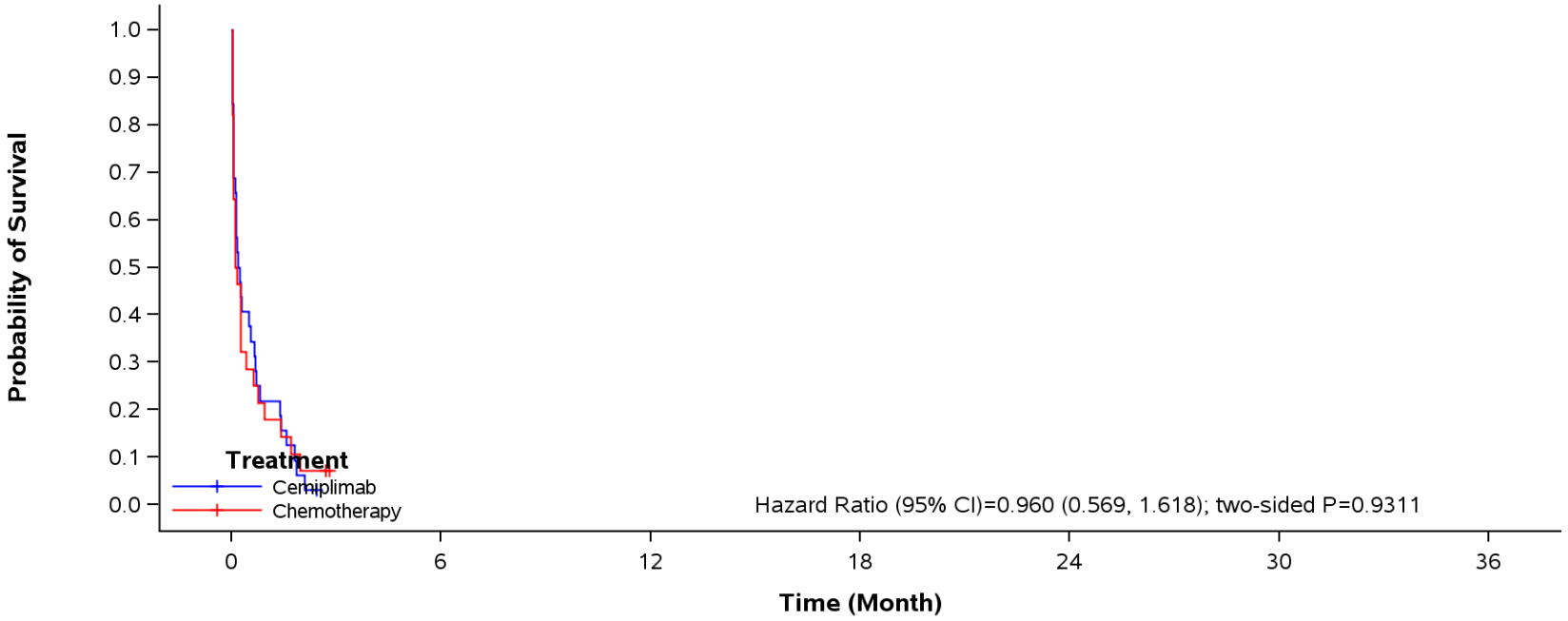

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 16 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.1. Time to First Any Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine



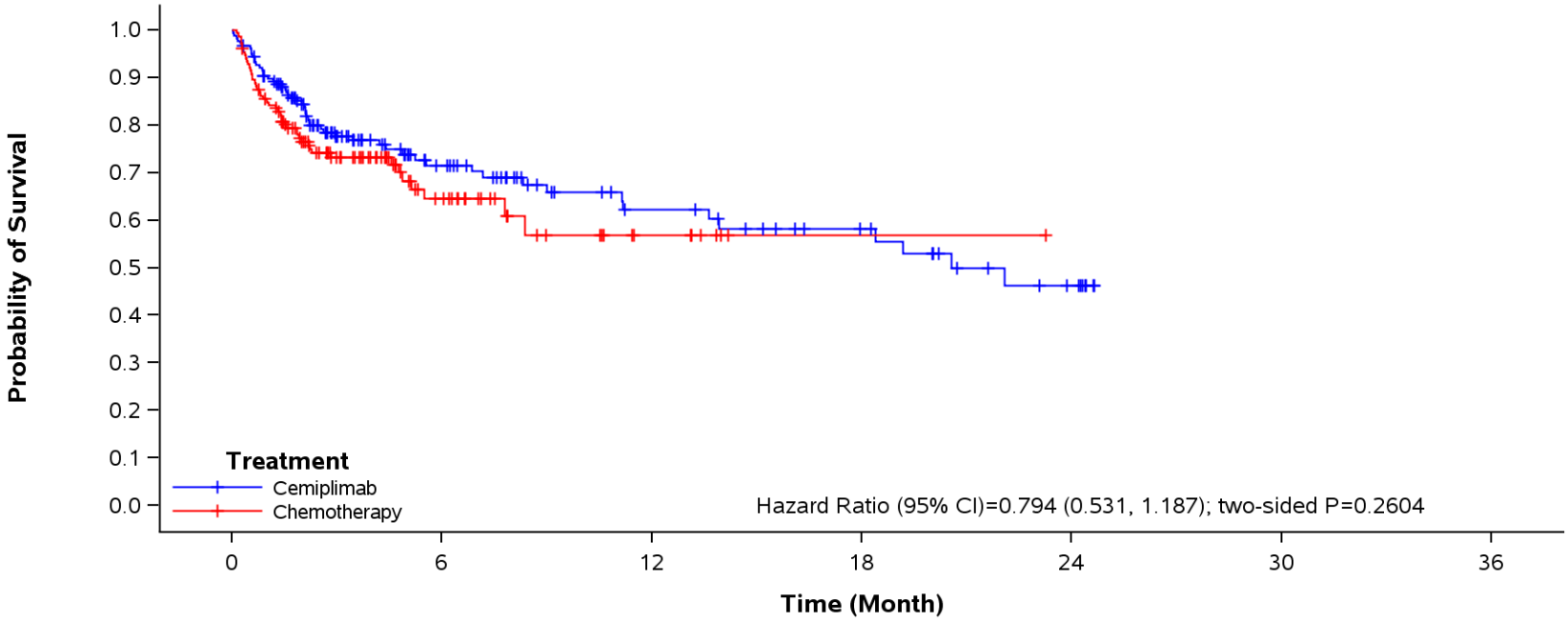

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 28 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



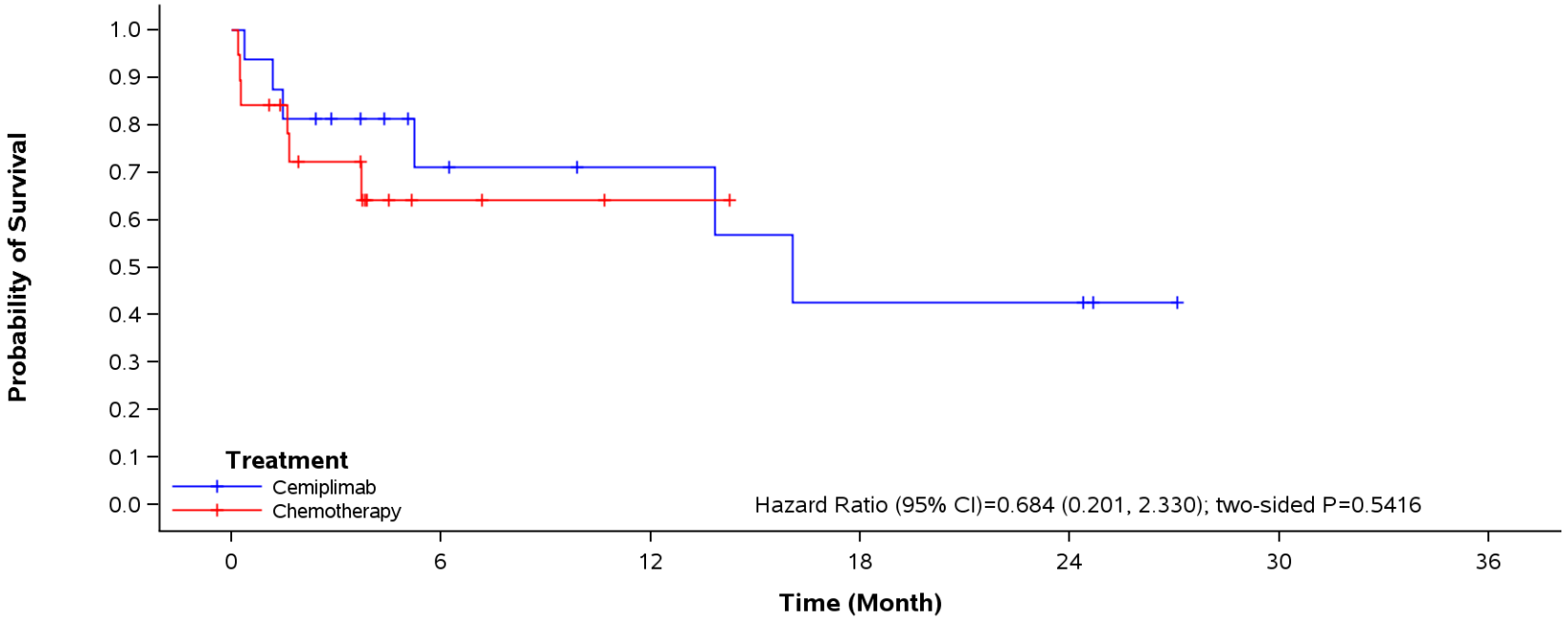

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 61 | 33 | 23 | 11 | 0 | 0 |
| Chemotherapy | 153 | 32 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



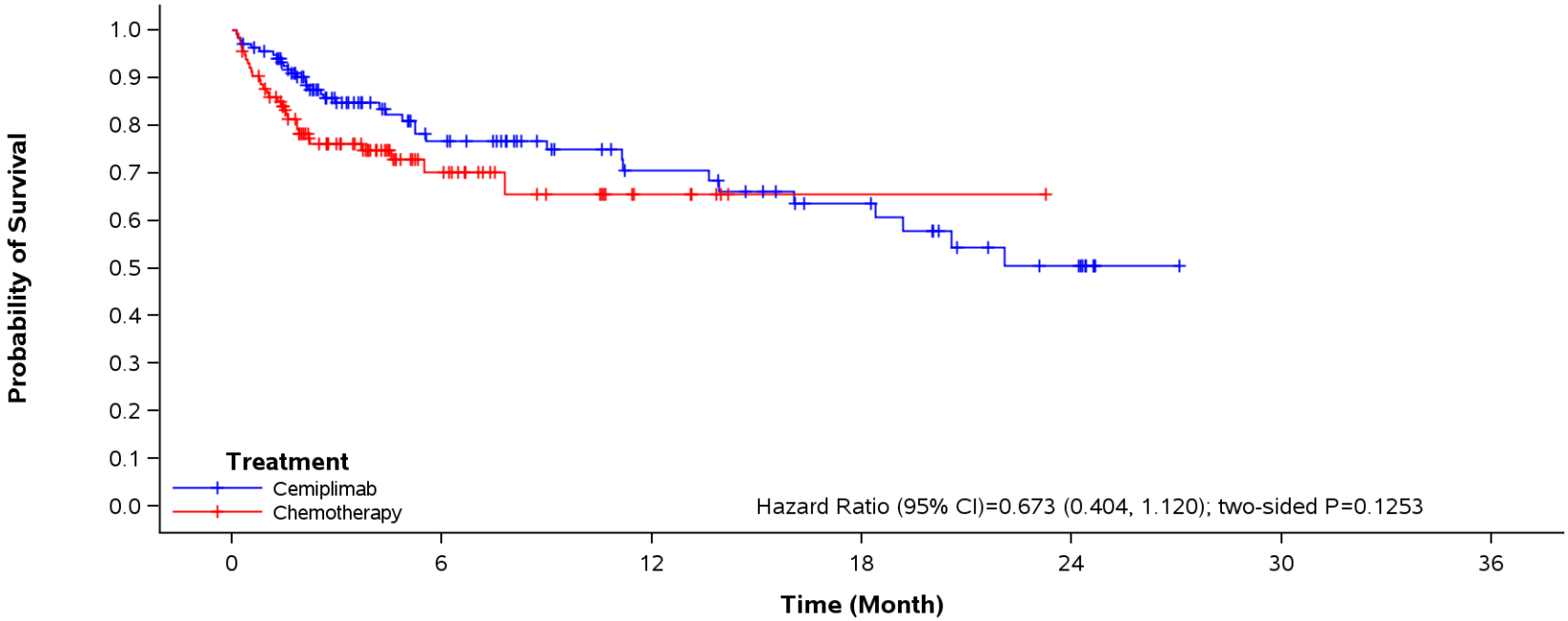

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 3 | 3 | 0 | 0 |
| Chemotherapy | 19 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



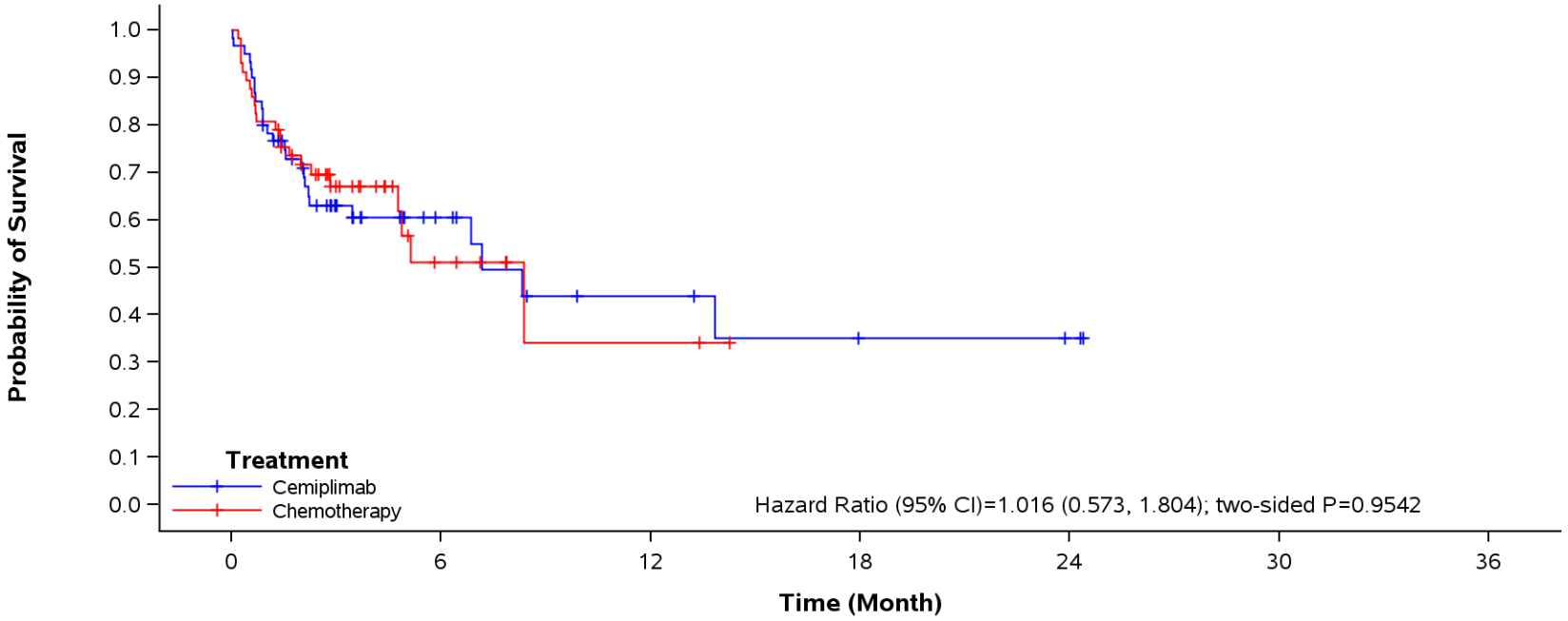

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 55 | 32 | 23 | 12 | 0 | 0 |
| Chemotherapy | 115 | 27 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



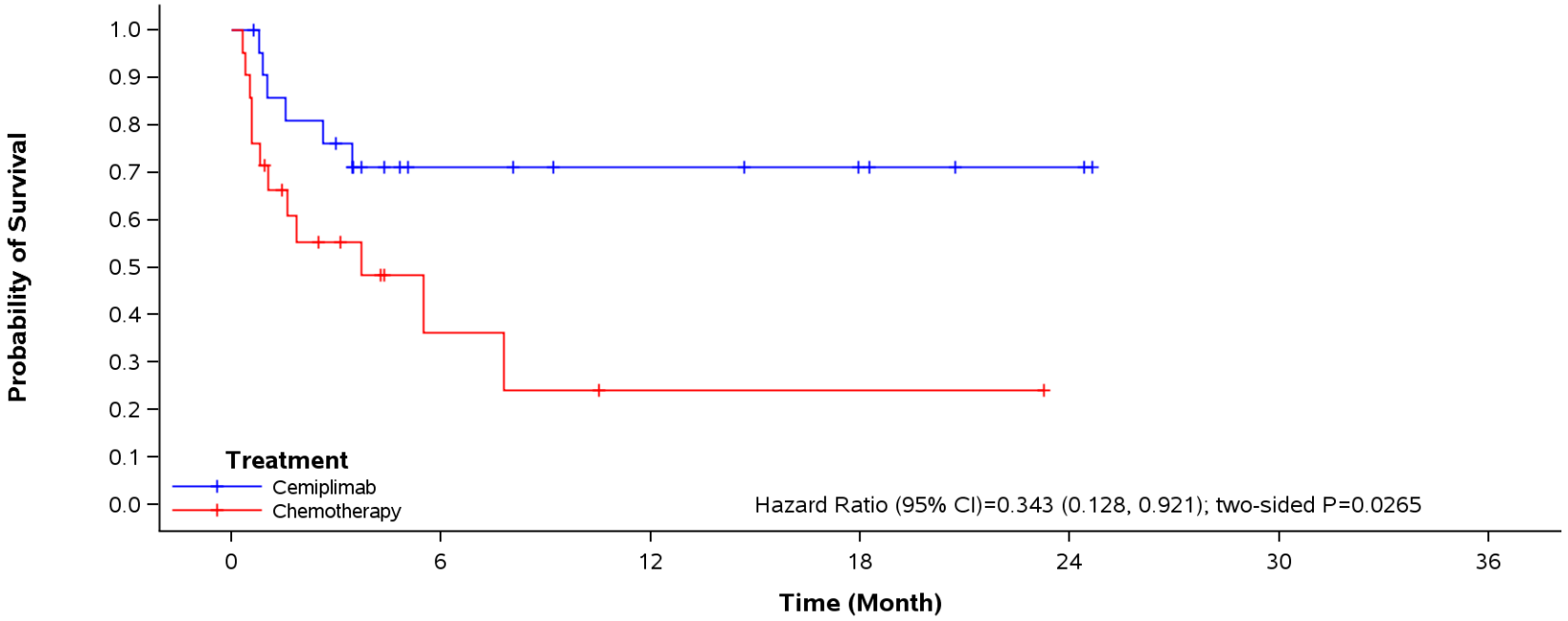

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 6 | 3 | 2 | 0 | 0 |
| Chemotherapy | 57 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America



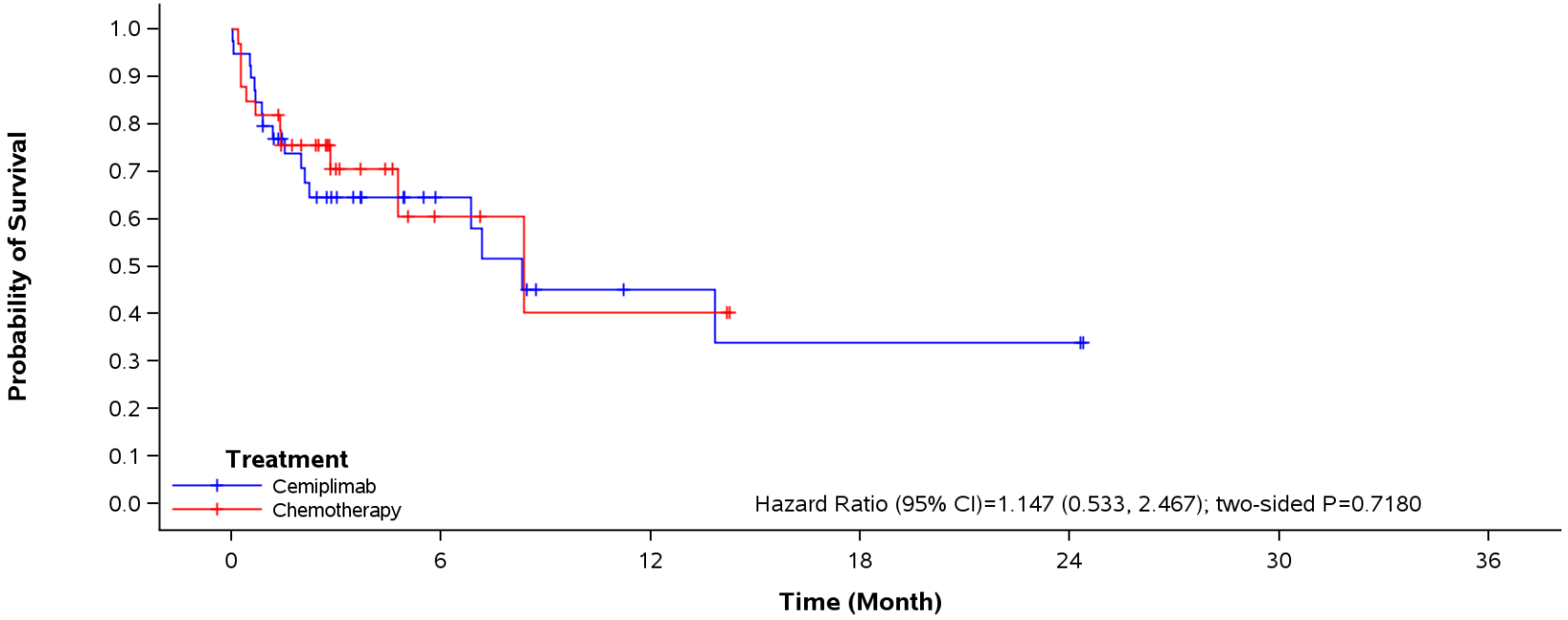

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia



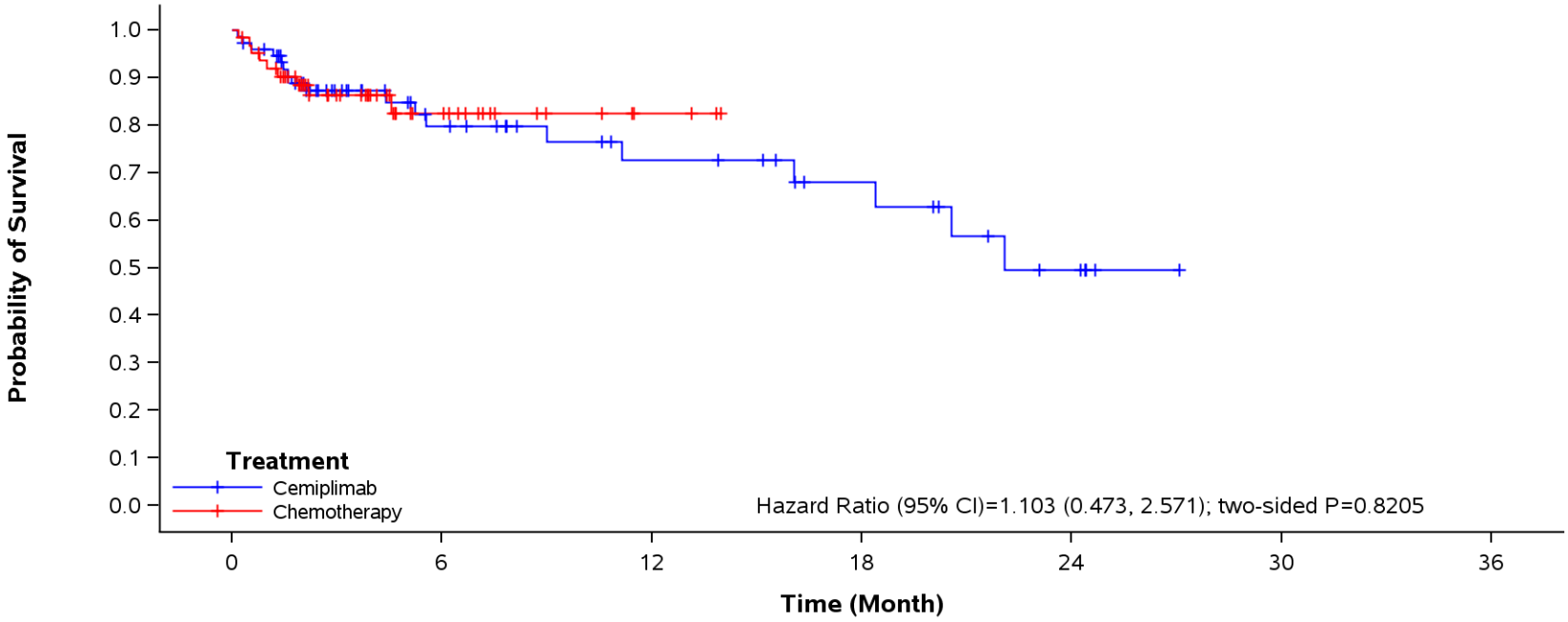

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 4 | 3 | 3 | 0 | 0 |
| Chemotherapy | 33 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



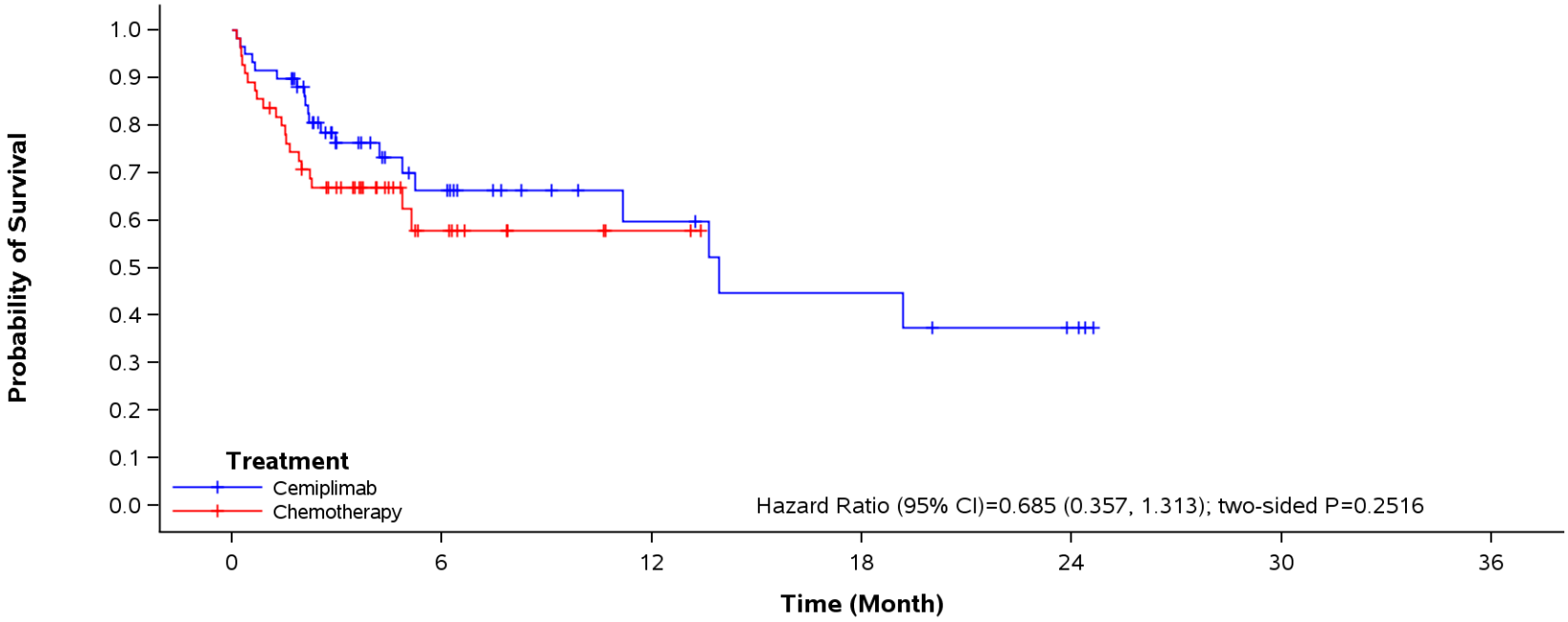

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 31 | 19 | 13 | 6 | 0 | 0 |
| Chemotherapy | 63 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW



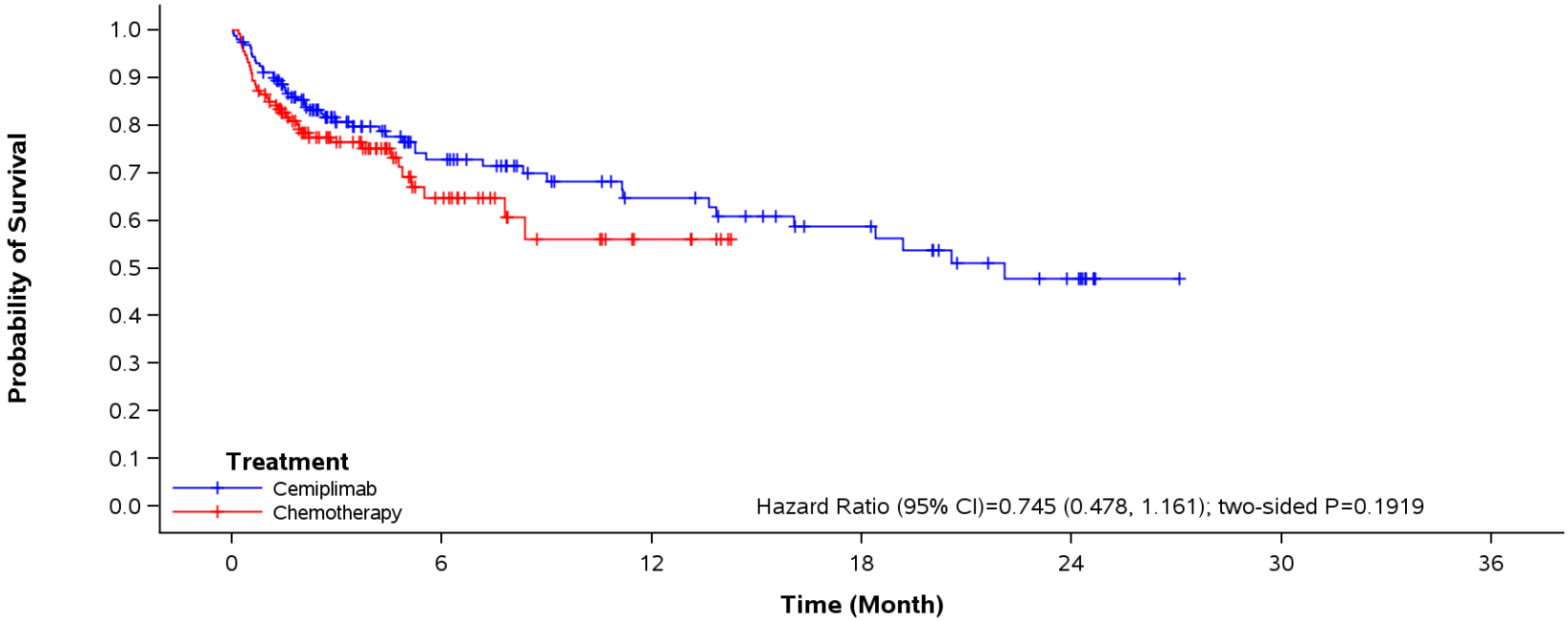

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 9 | 6 | 3 | 0 | 0 |
| Chemotherapy | 55 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous



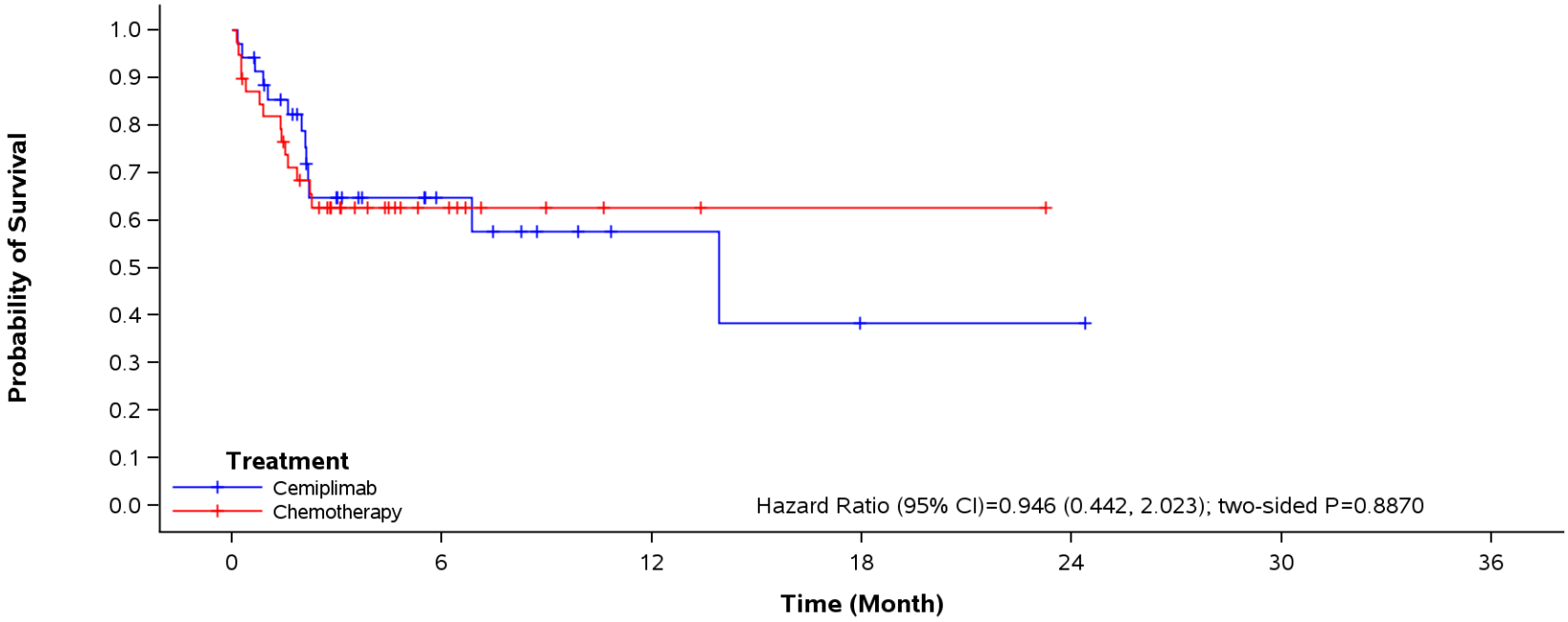

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 59 | 35 | 25 | 13 | 0 | 0 |
| Chemotherapy | 133 | 27 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



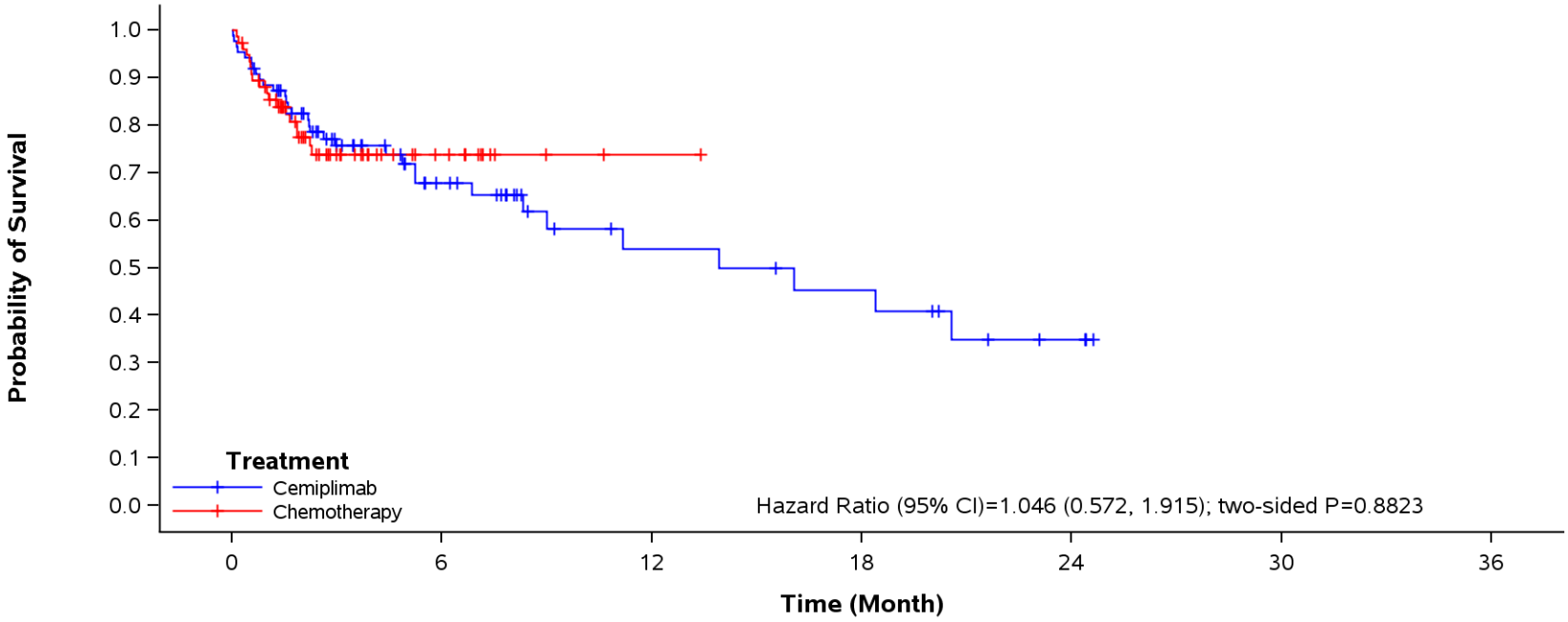

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes



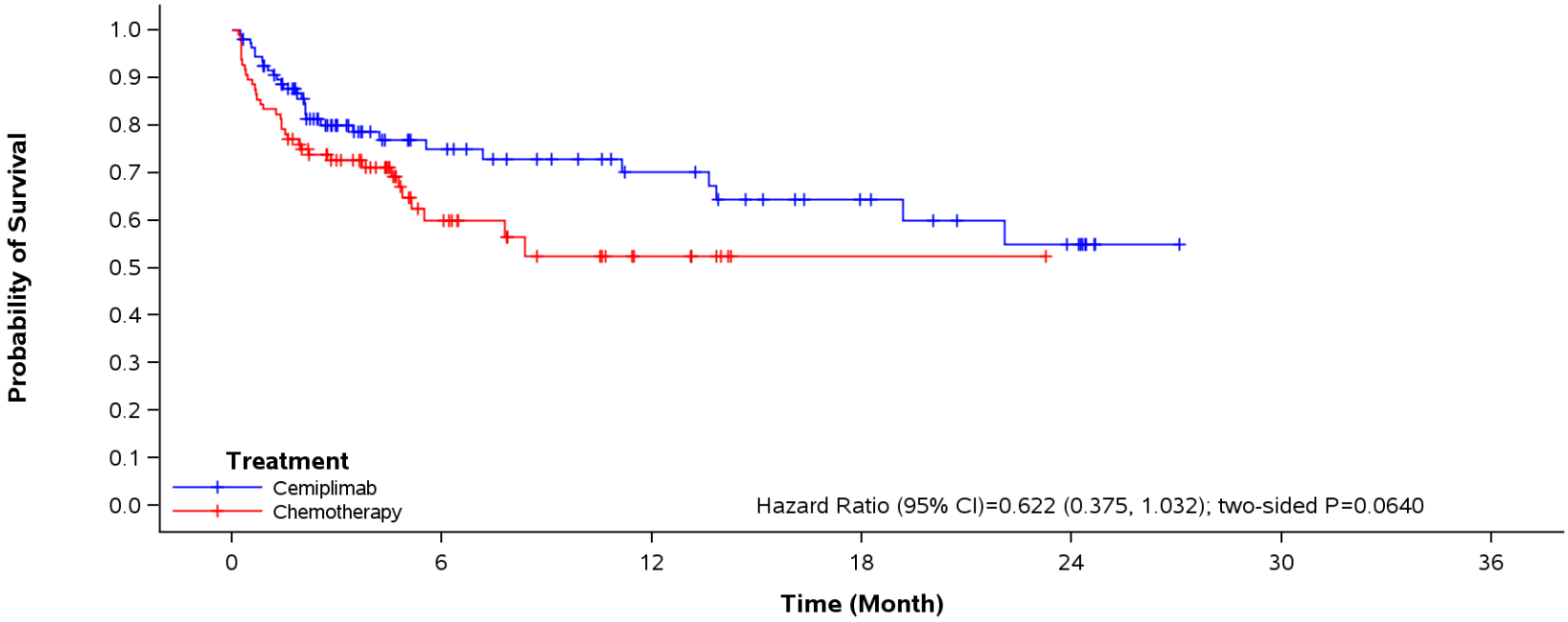

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 30 | 13 | 10 | 4 | 0 | 0 |
| Chemotherapy | 76 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No



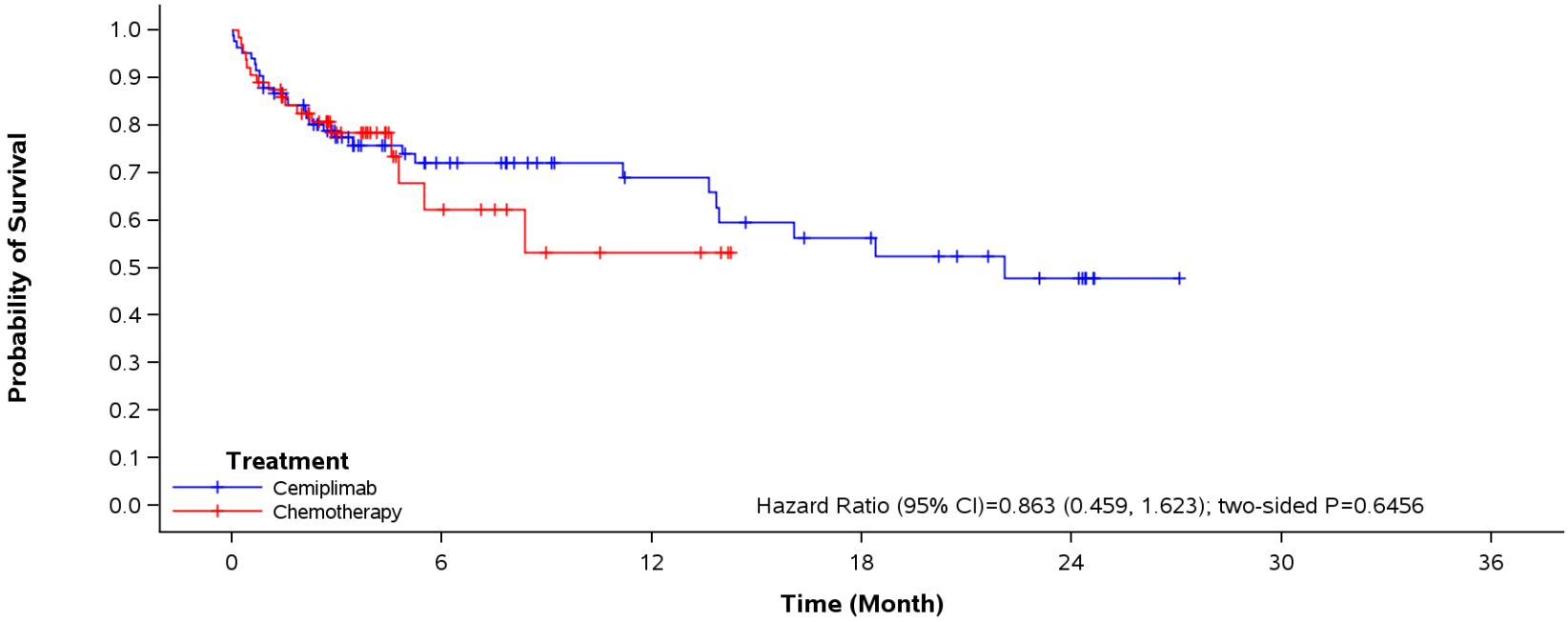

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 38 | 25 | 16 | 10 | 0 | 0 |
| Chemotherapy | 96 | 24 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0



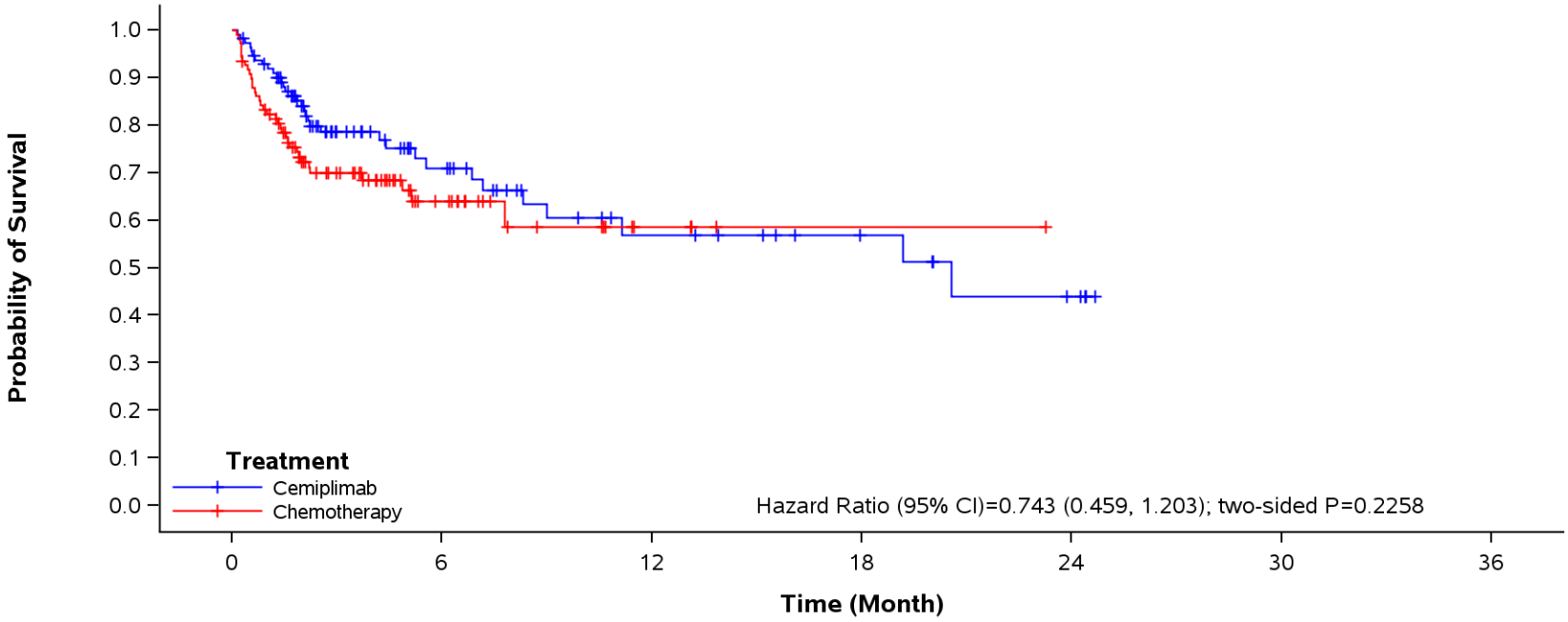

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 34 | 22 | 16 | 9 | 0 | 0 |
| Chemotherapy | 64 | 11 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1



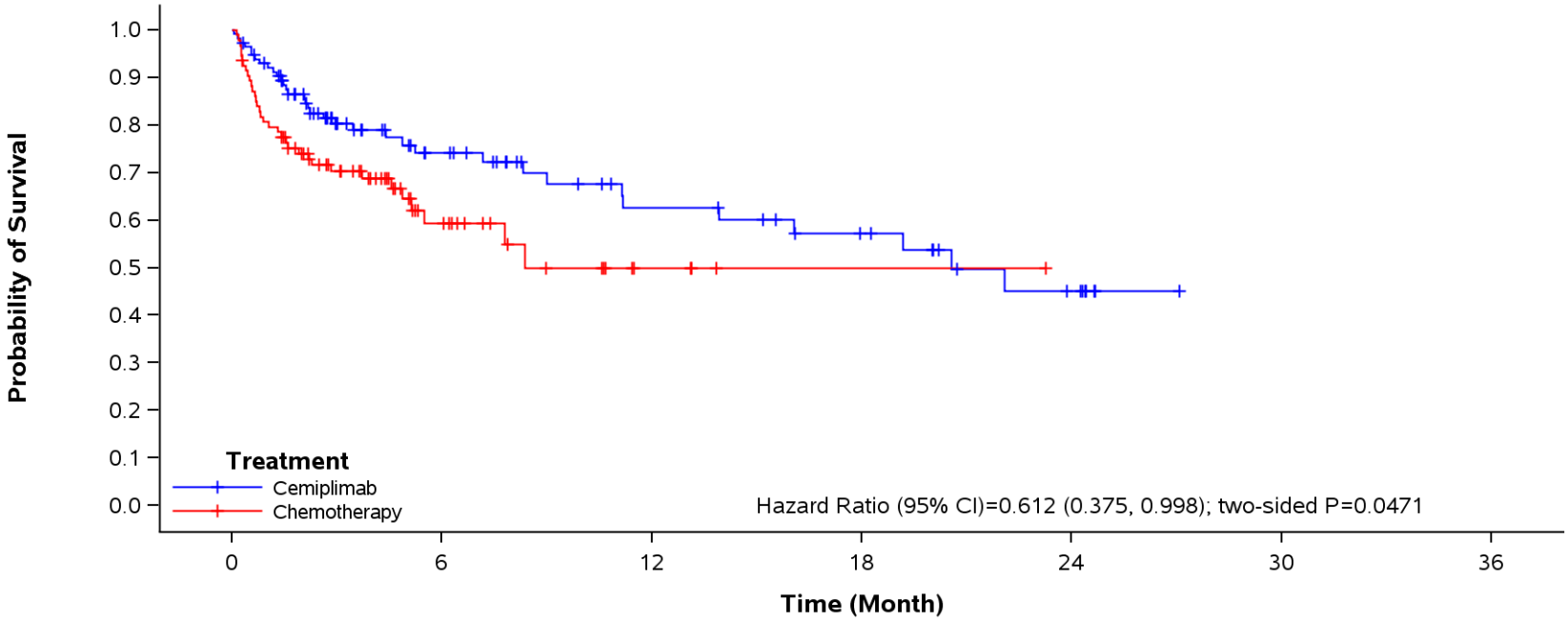

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 34 | 16 | 10 | 5 | 0 | 0 |
| Chemotherapy | 108 | 24 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line



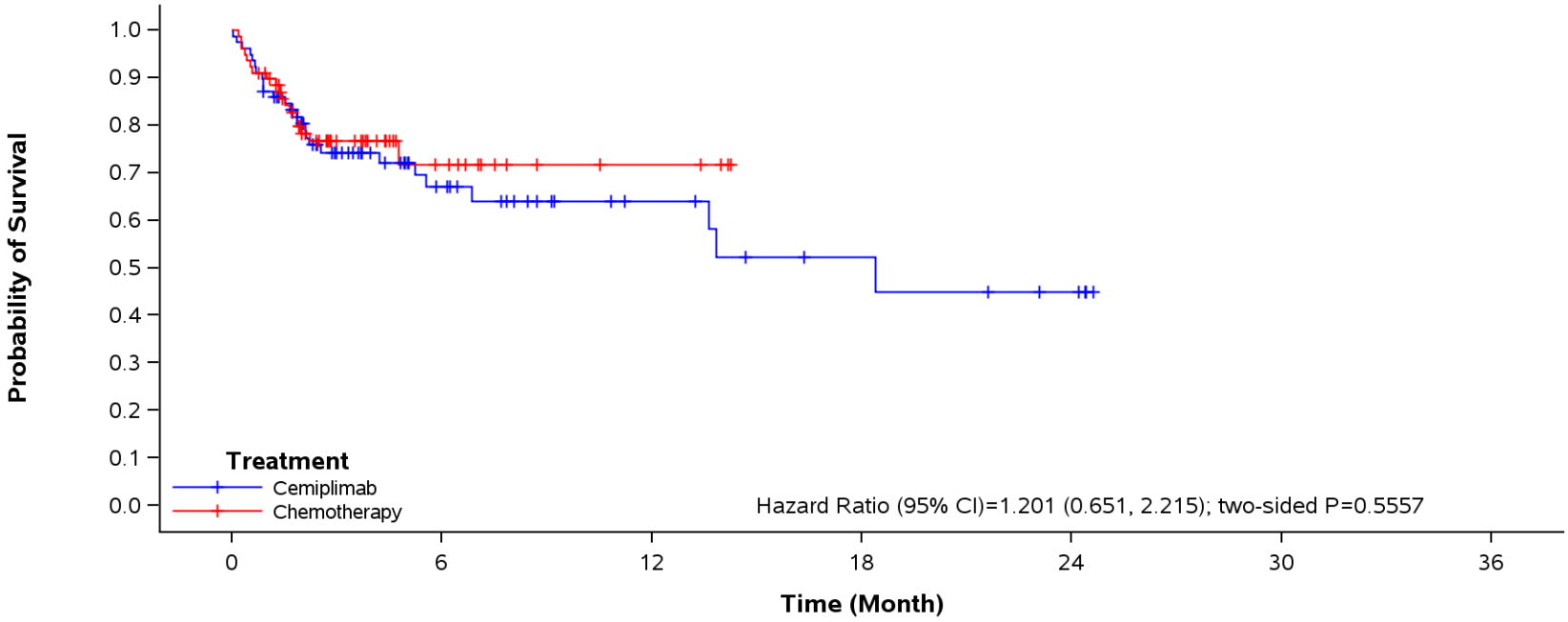

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 42 | 25 | 18 | 9 | 0 | 0 |
| Chemotherapy | 94 | 22 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line



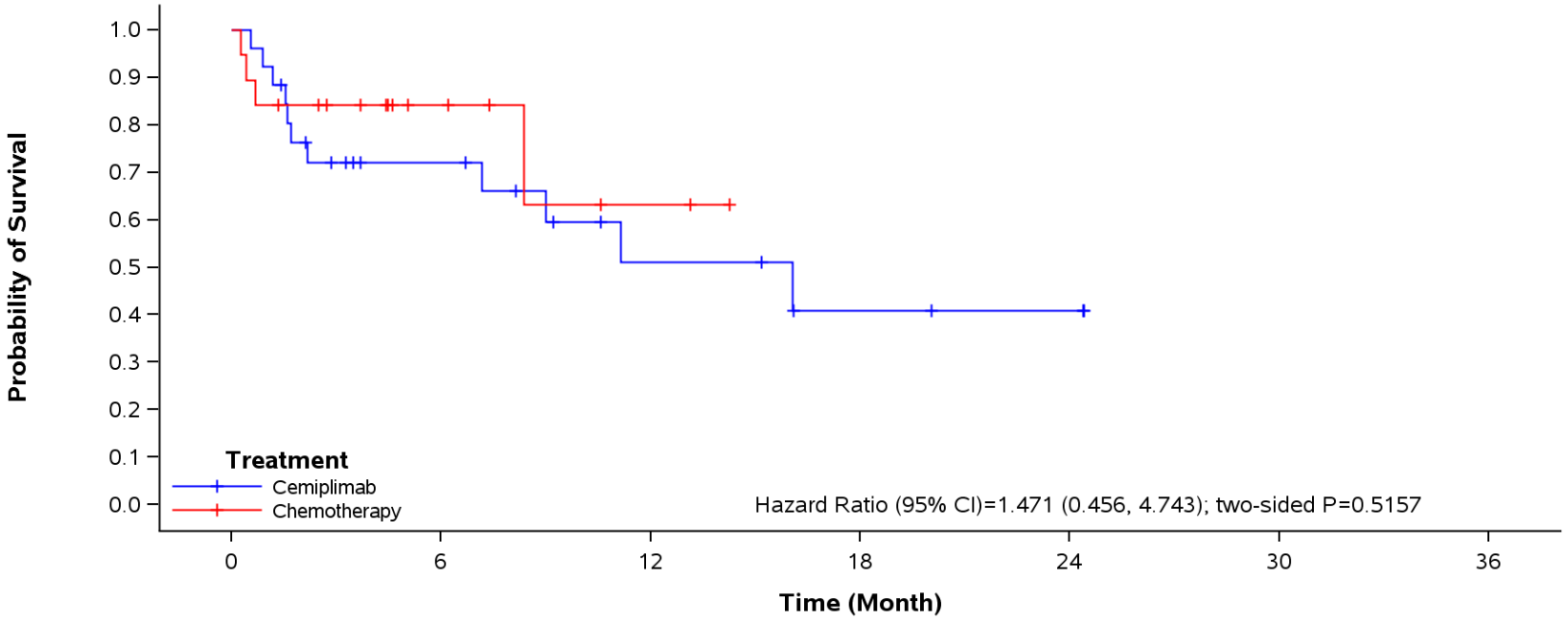

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 25 | 12 | 7 | 4 | 0 | 0 |
| Chemotherapy | 78 | 13 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



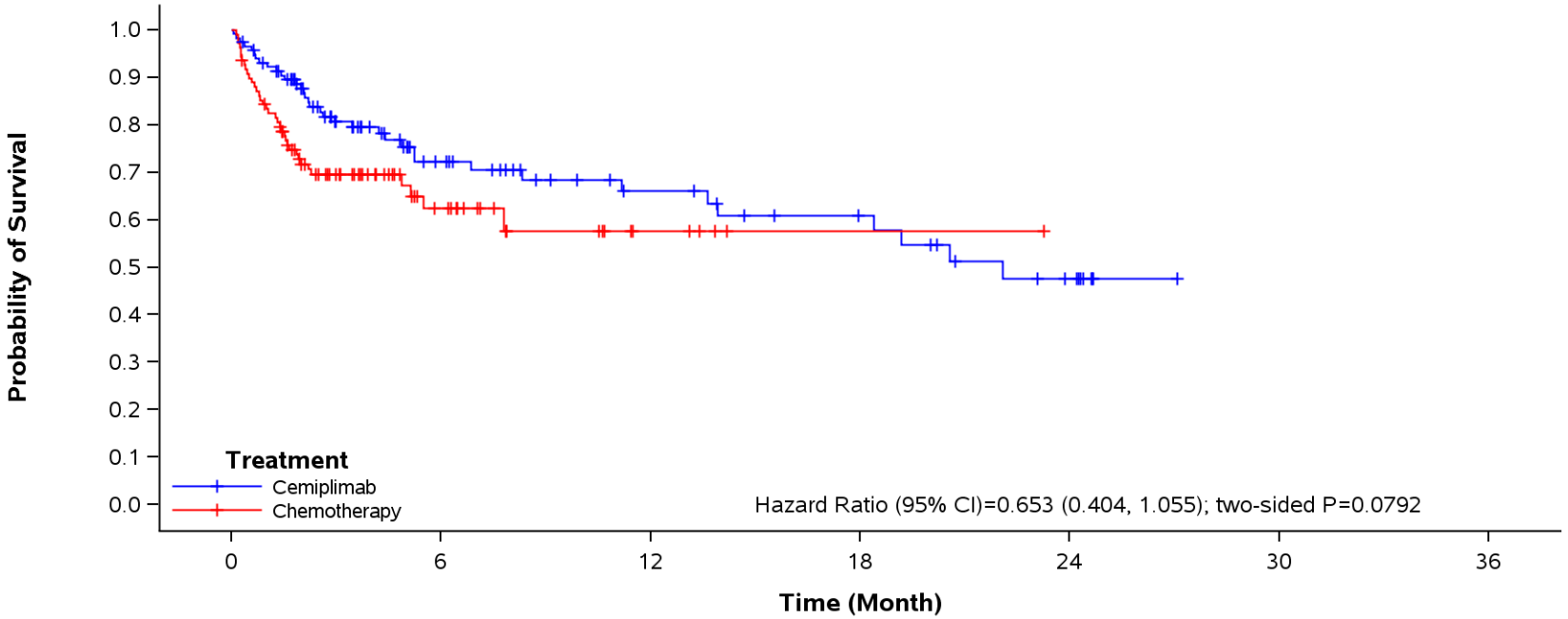

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 13 | 6 | 3 | 2 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed



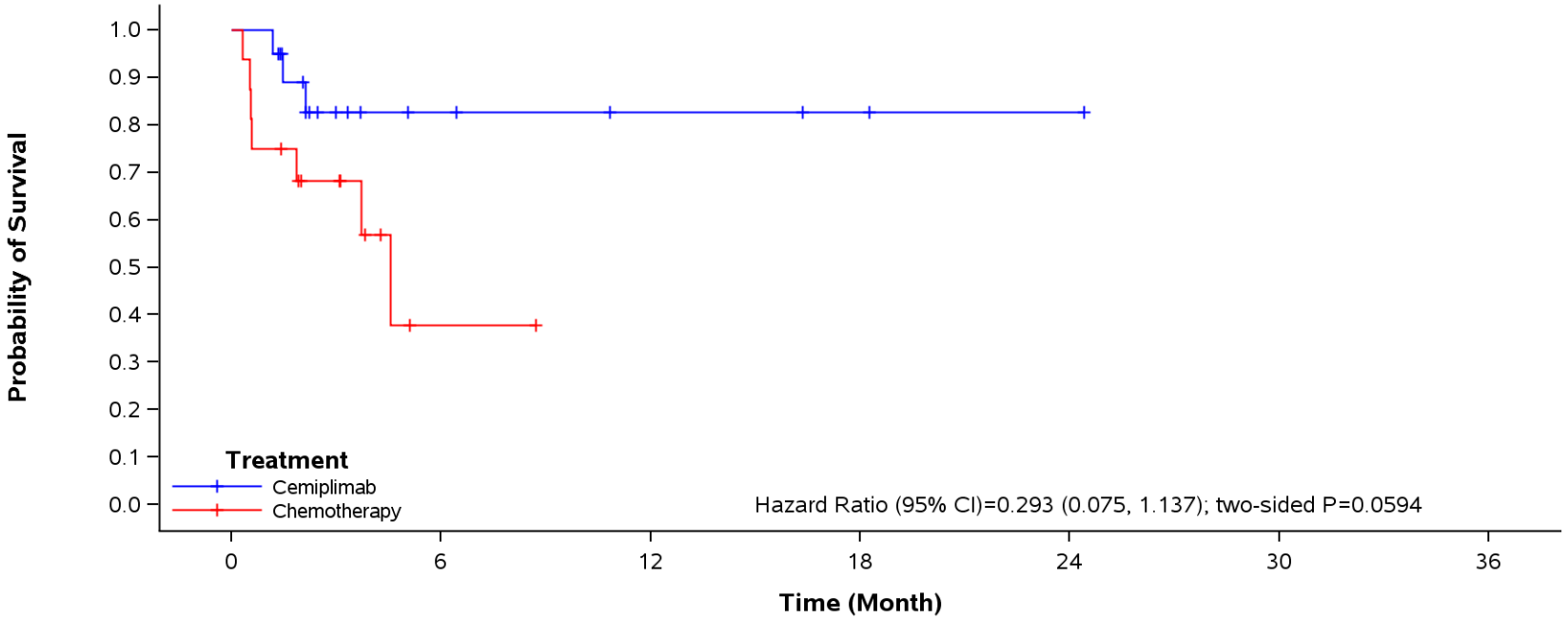

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 44 | 27 | 20 | 11 | 0 | 0 |
| Chemotherapy | 109 | 23 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan



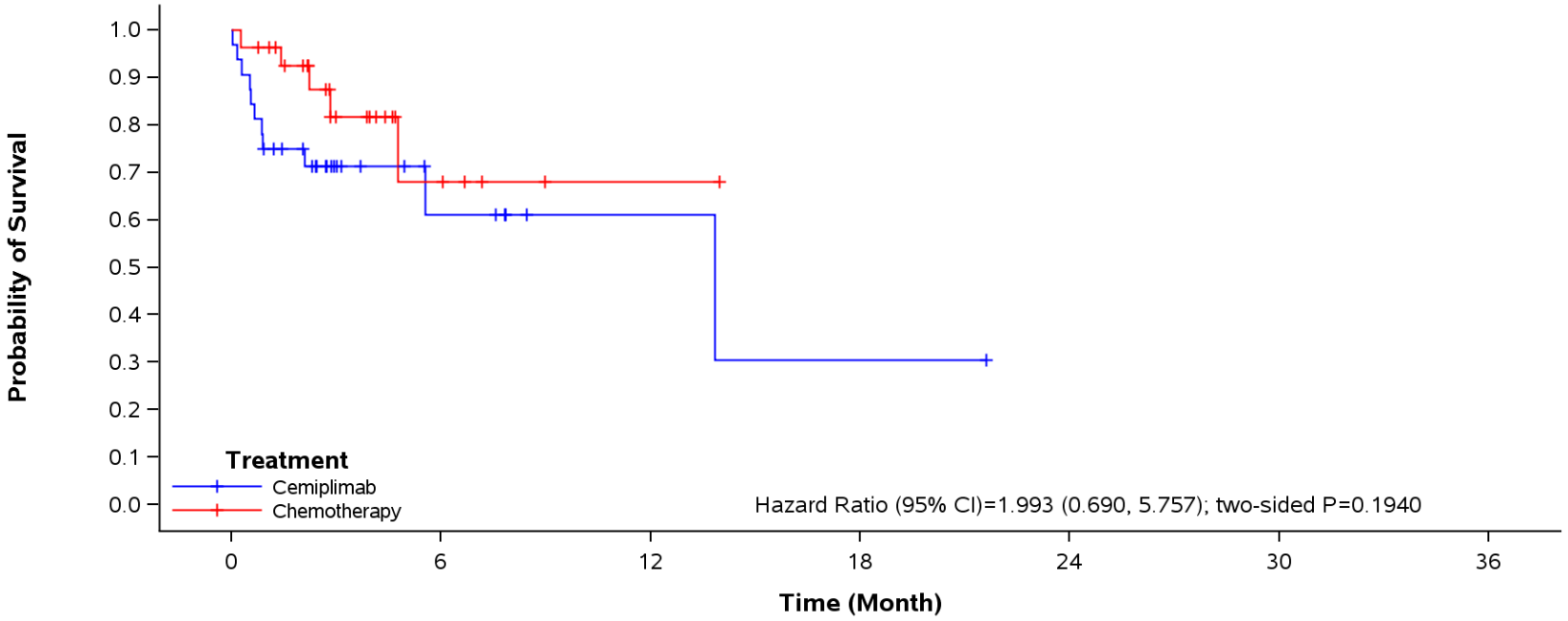

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.2. Time to First Any Serious Treatment-Emergent Adverse Events by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine



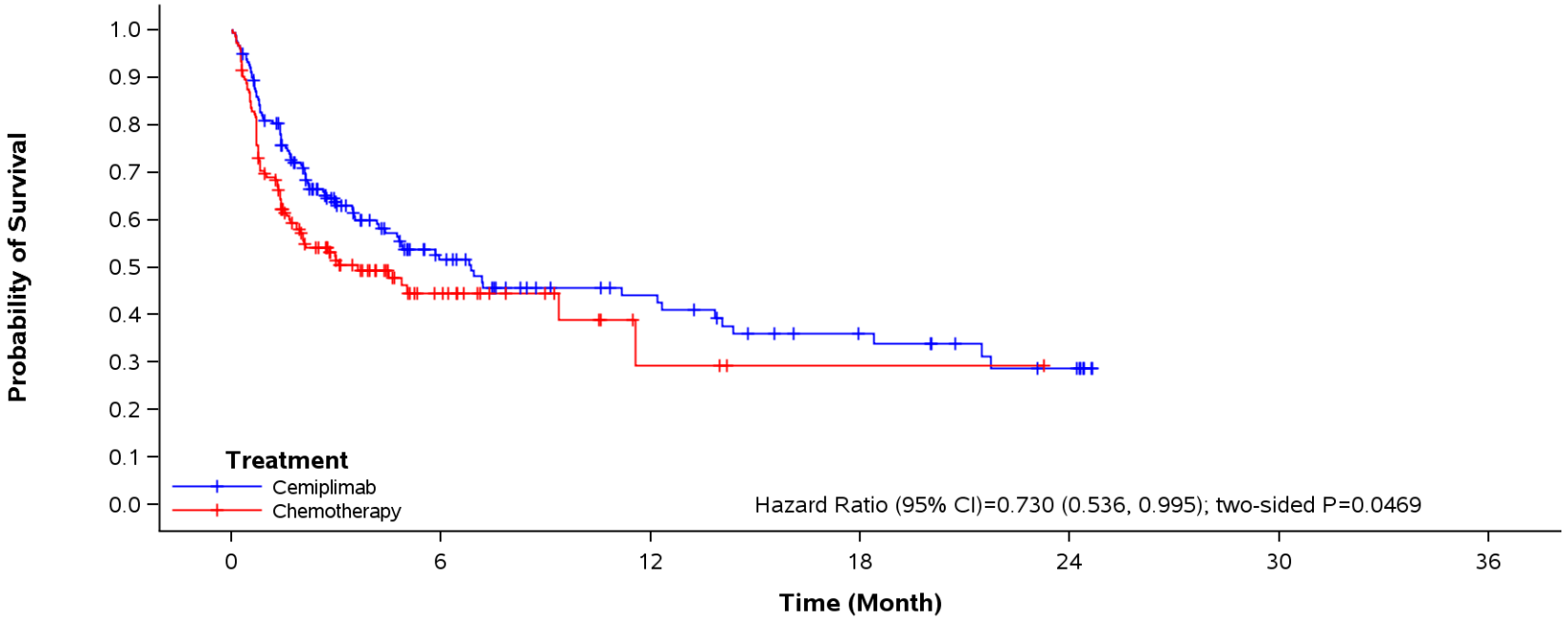

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 28 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



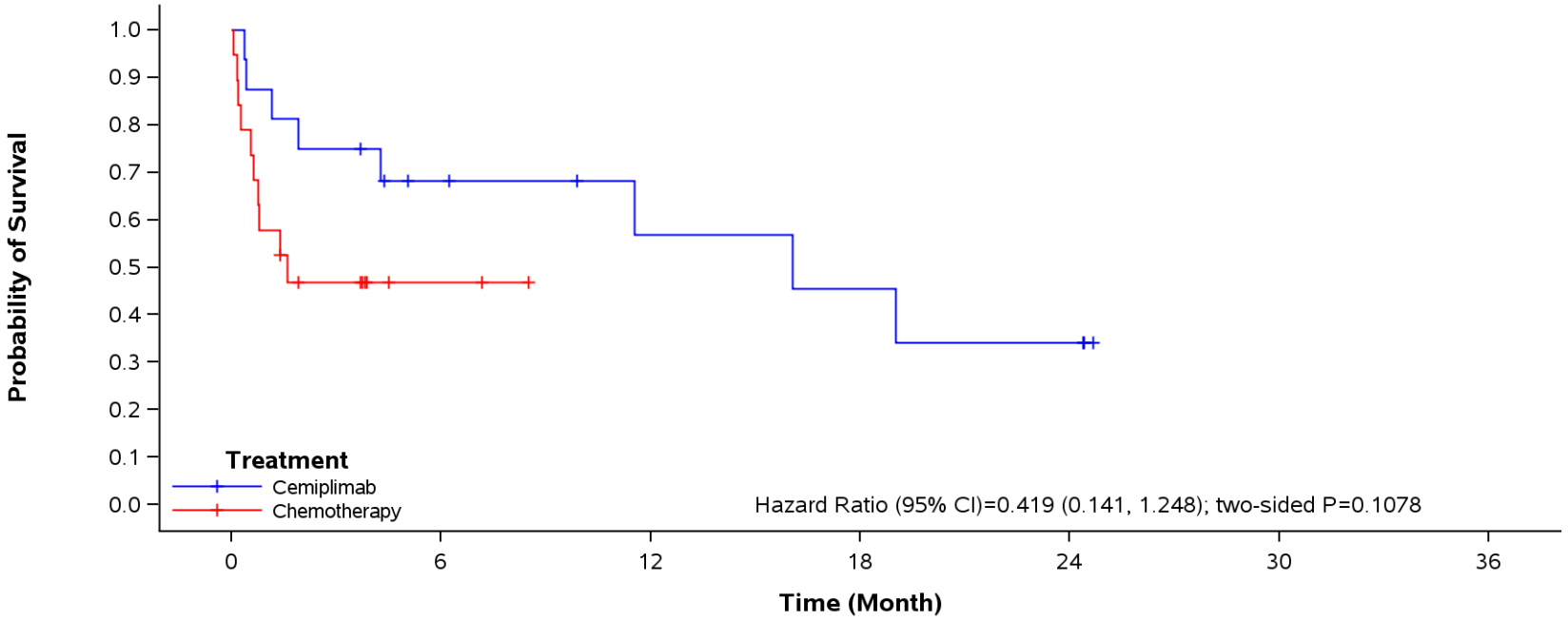

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 49 | 28 | 17 | 10 | 0 | 0 |
| Chemotherapy | 153 | 22 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



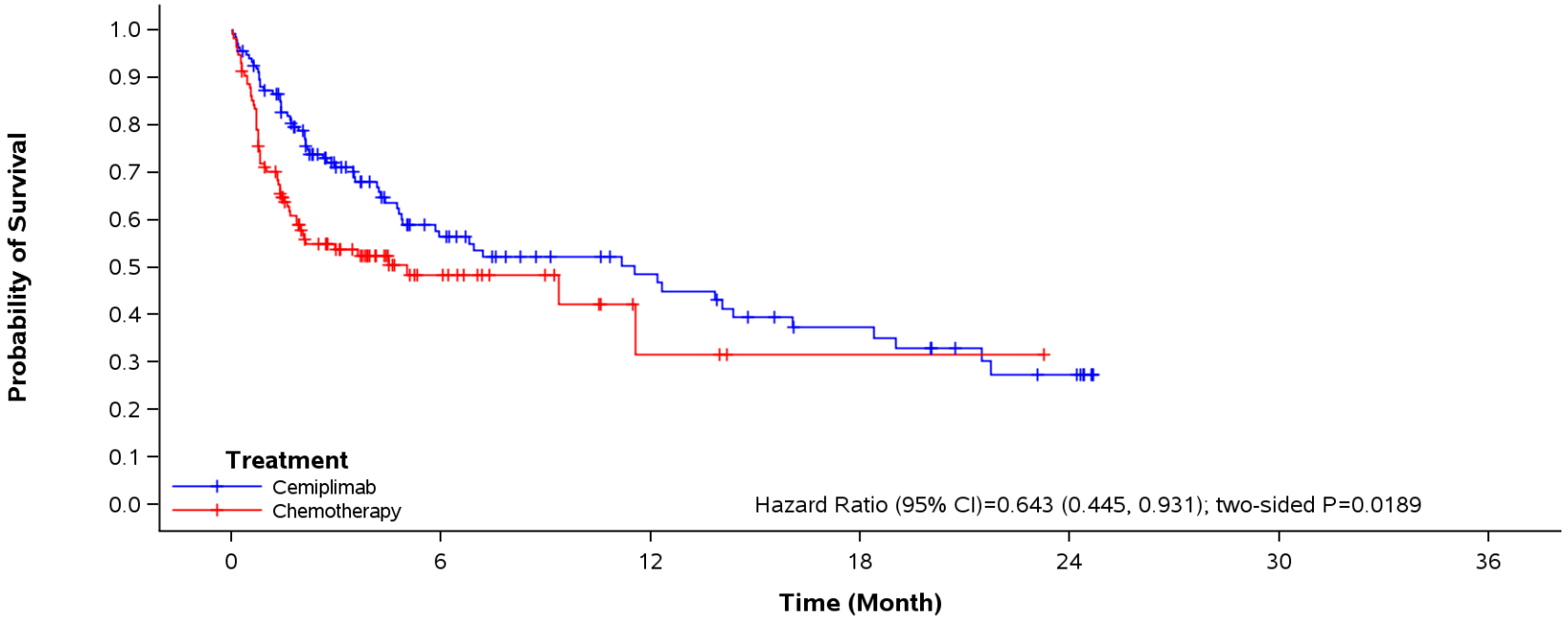

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 5 | 4 | 3 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



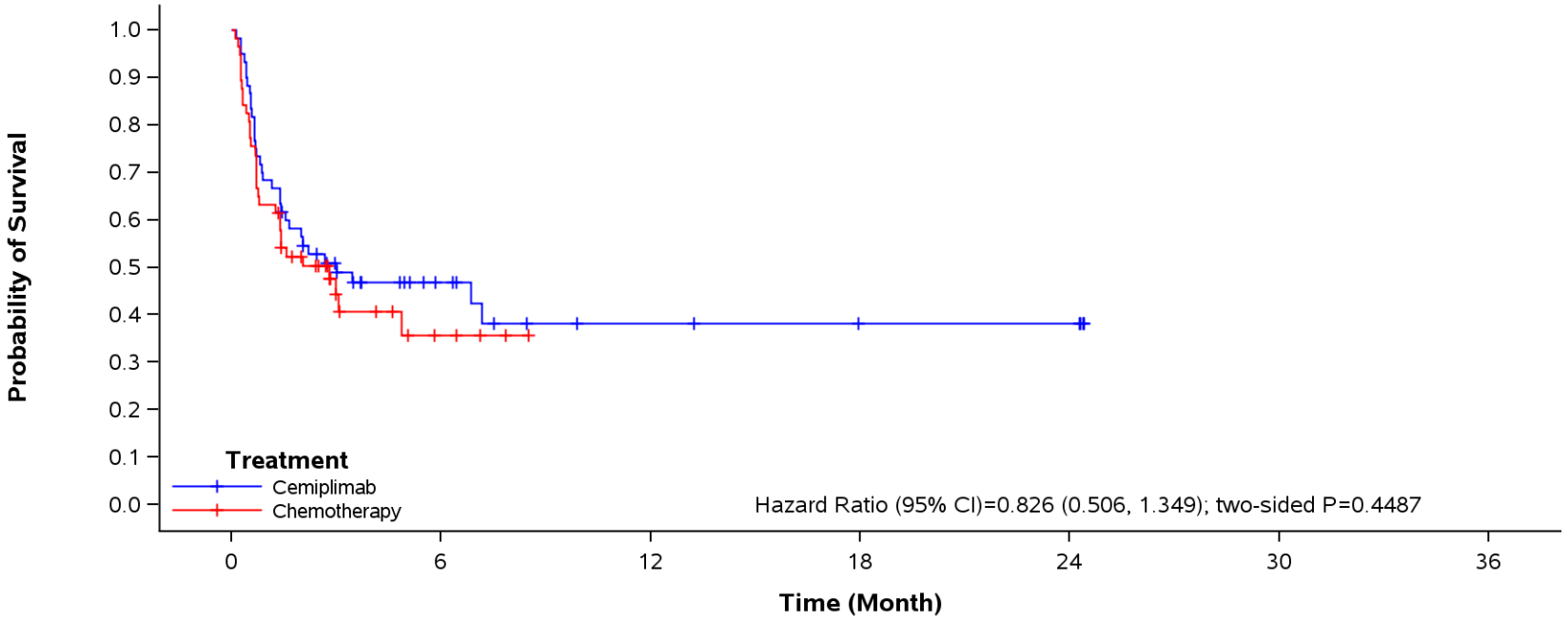

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 44 | 27 | 17 | 9 | 0 | 0 |
| Chemotherapy | 115 | 19 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



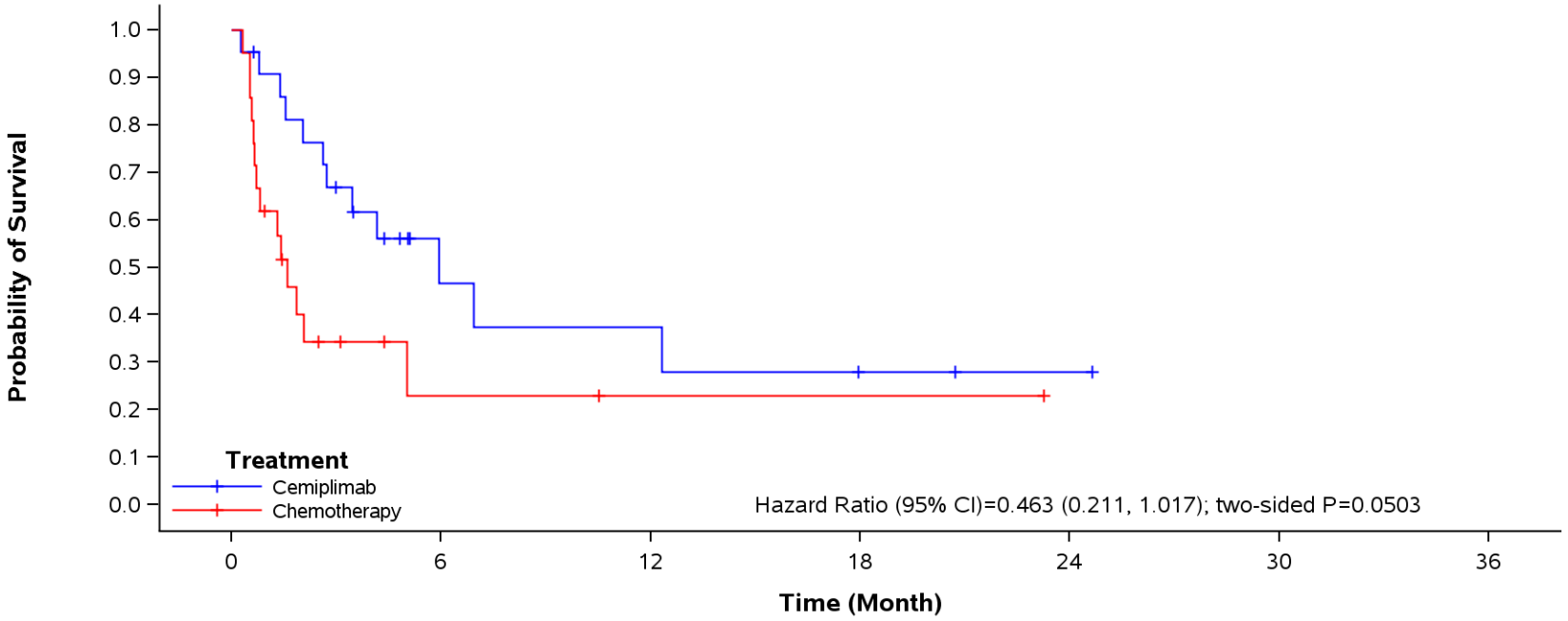

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 6 | 4 | 4 | 0 | 0 |
| Chemotherapy | 57 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America



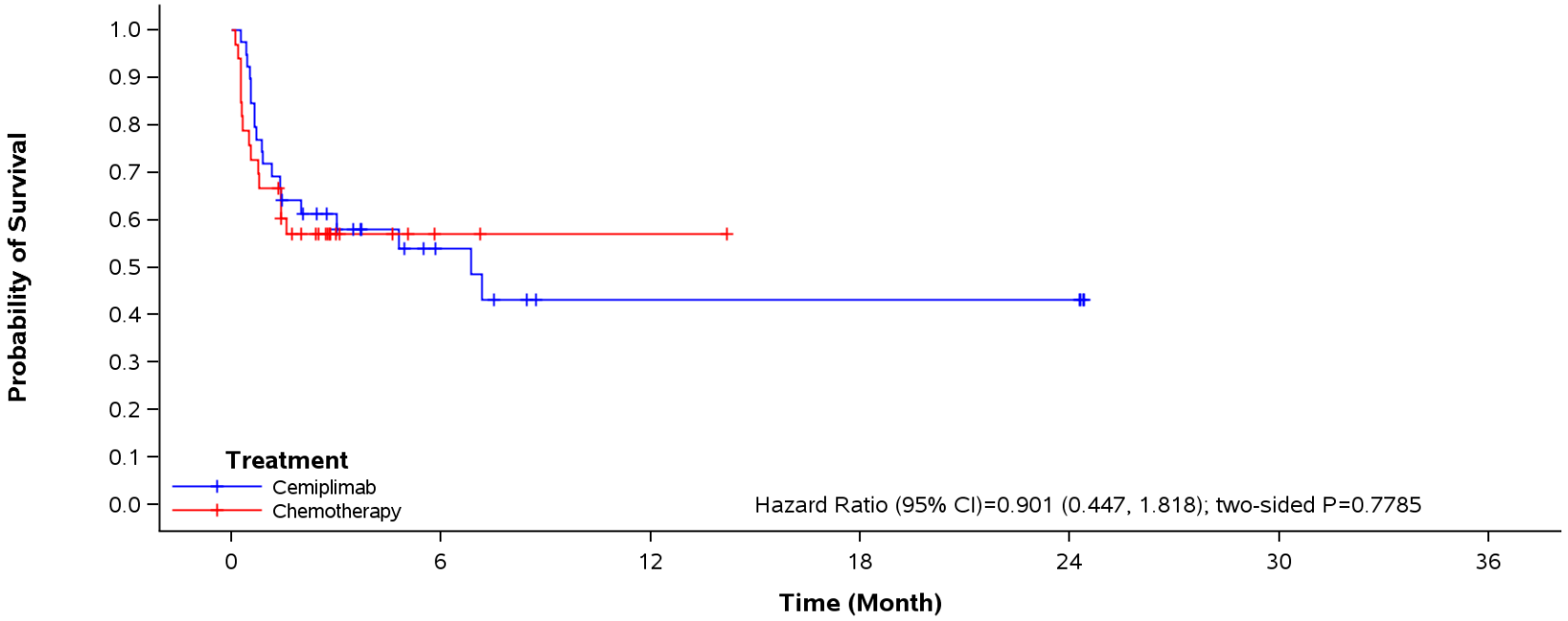

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia



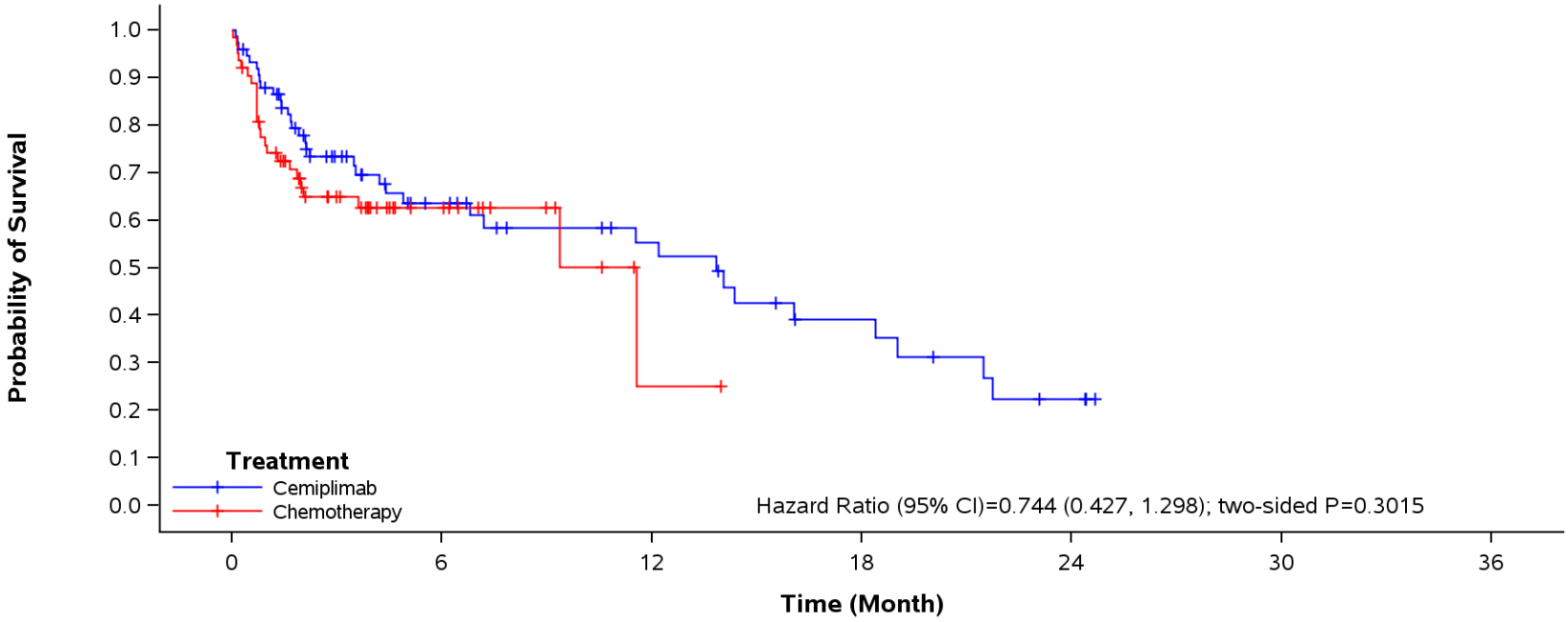

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 5 | 5 | 5 | 0 | 0 |
| Chemotherapy | 33 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



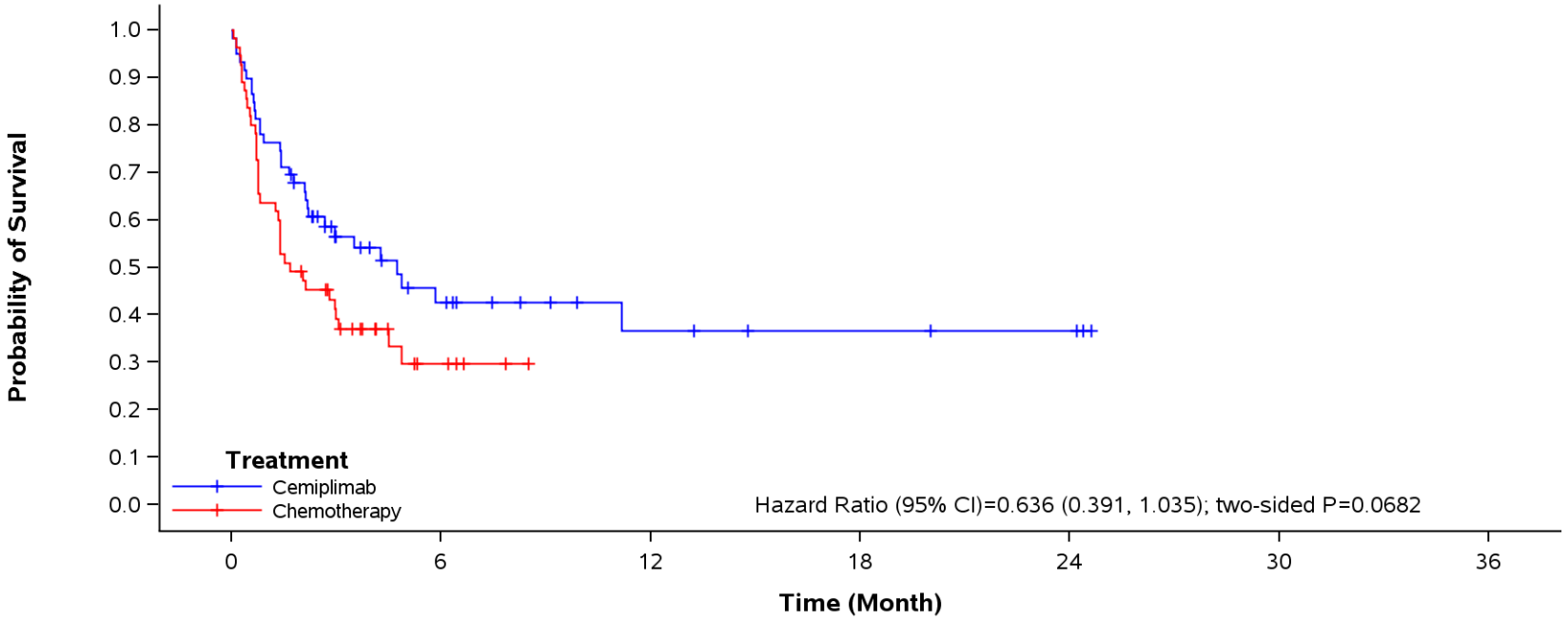

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 28 | 18 | 10 | 4 | 0 | 0 |
| Chemotherapy | 63 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW



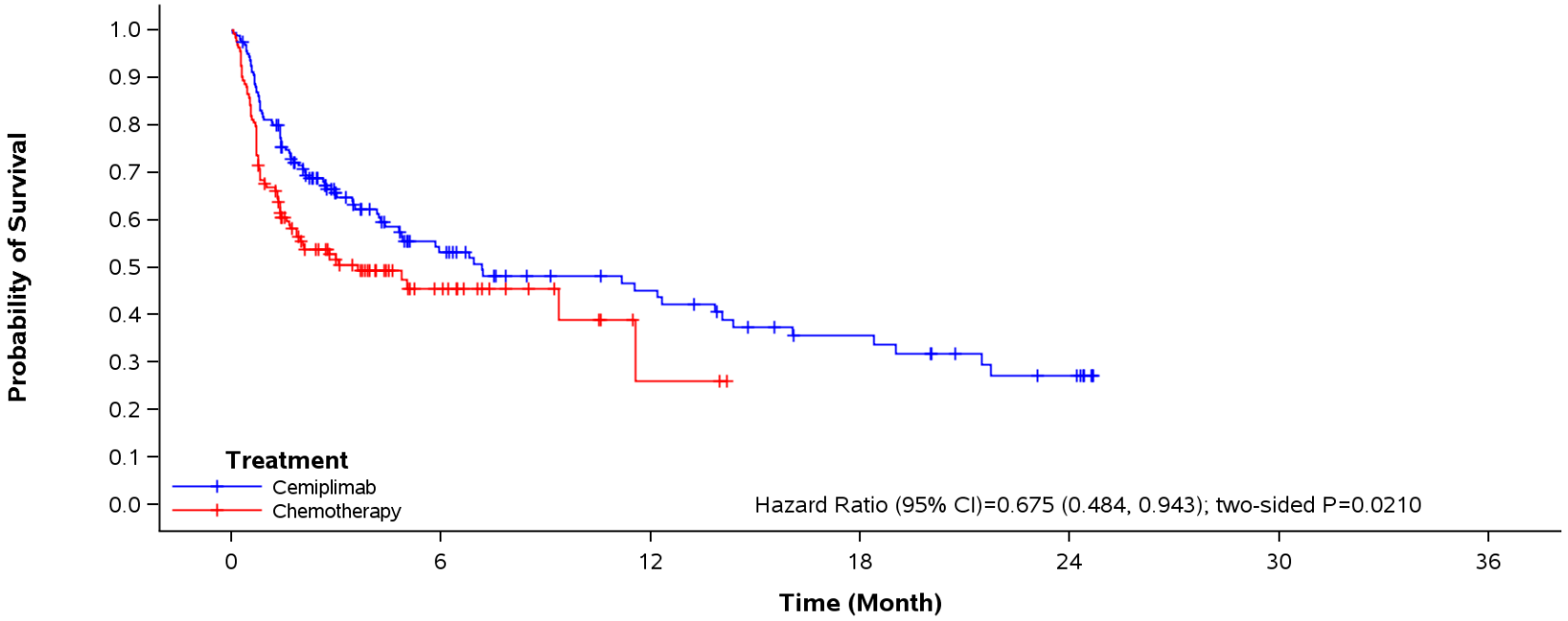

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 14 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 55 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous



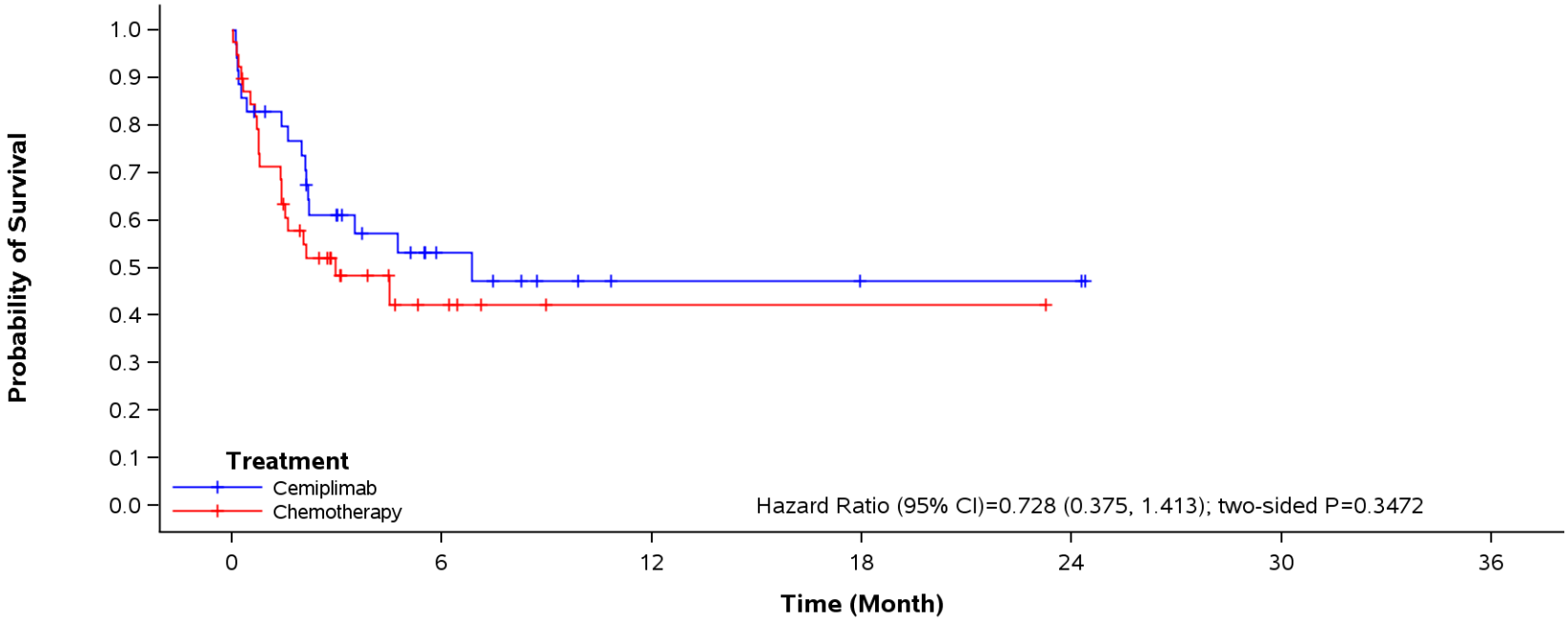

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 48 | 30 | 19 | 11 | 0 | 0 |
| Chemotherapy | 133 | 19 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



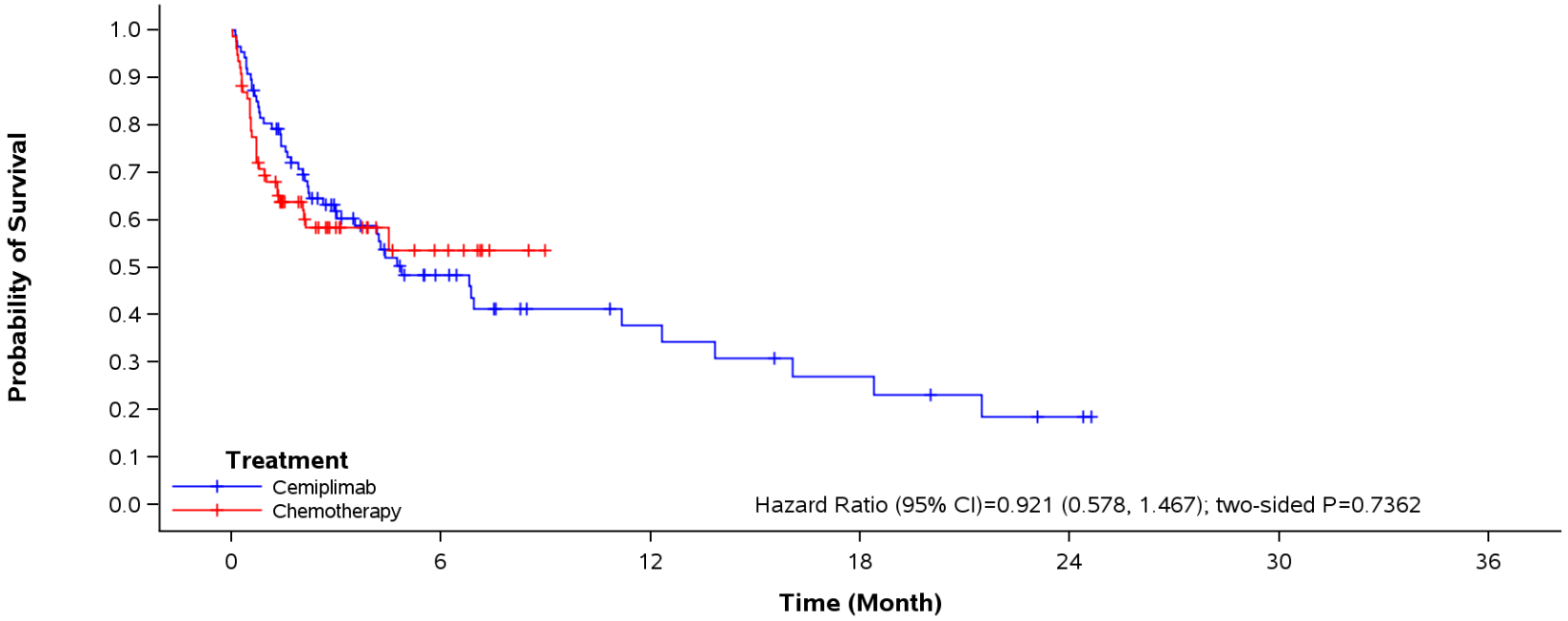

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 3 | 2 | 2 | 0 | 0 |
| Chemotherapy | 39 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes



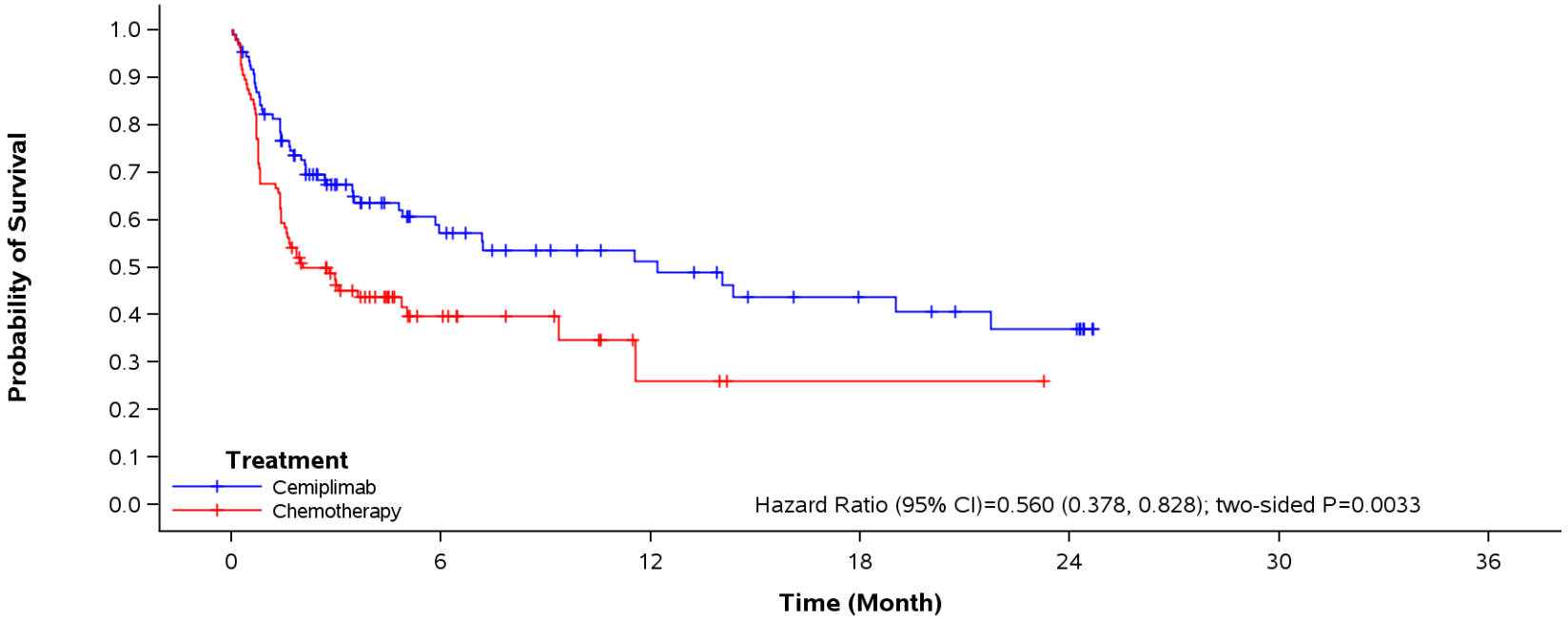

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 23 | 11 | 7 | 3 | 0 | 0 |
| Chemotherapy | 76 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No



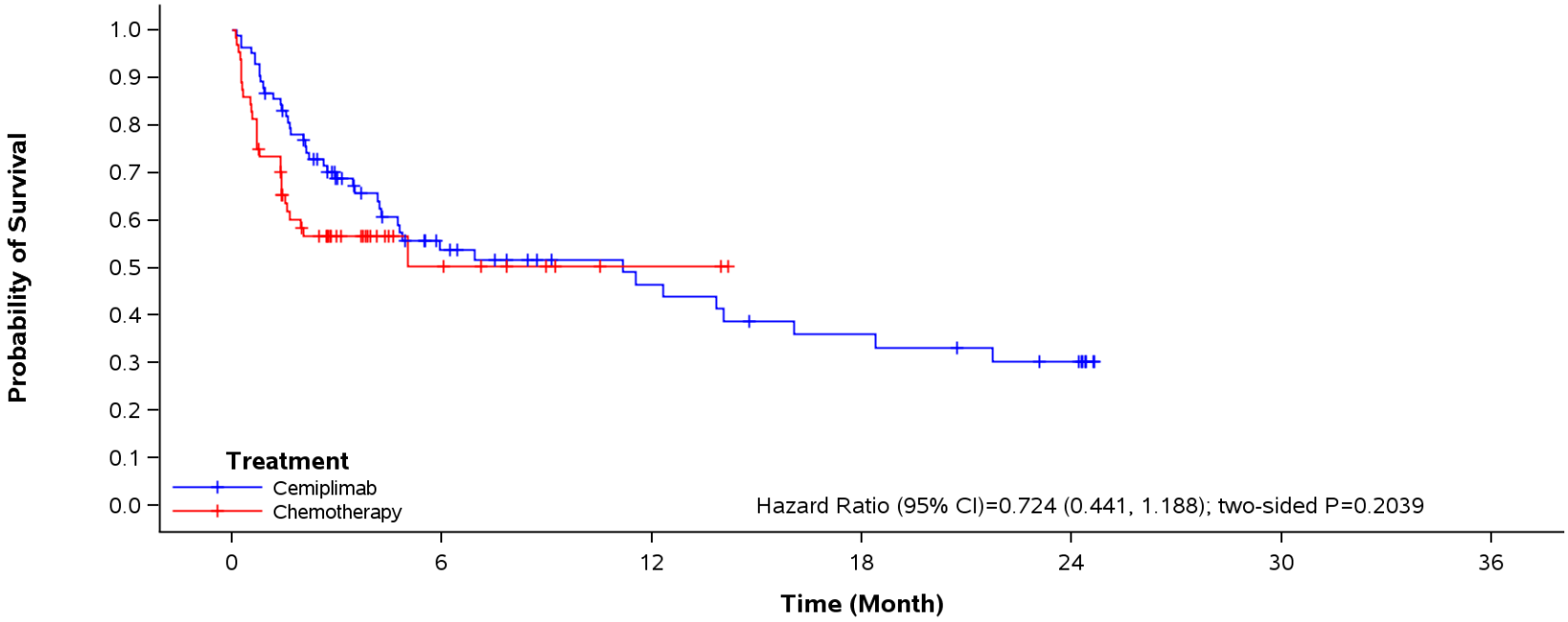

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 34 | 22 | 14 | 10 | 0 | 0 |
| Chemotherapy | 96 | 16 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0



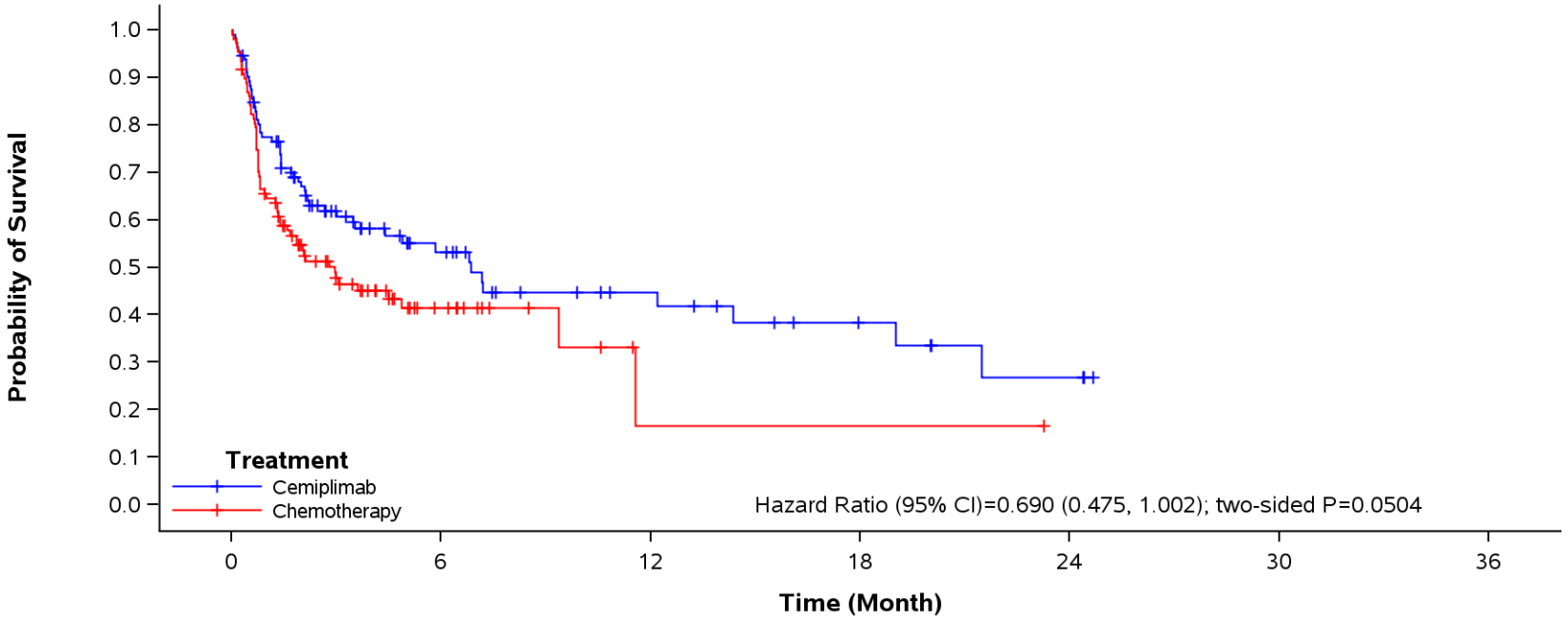

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 28 | 18 | 13 | 9 | 0 | 0 |
| Chemotherapy | 64 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1



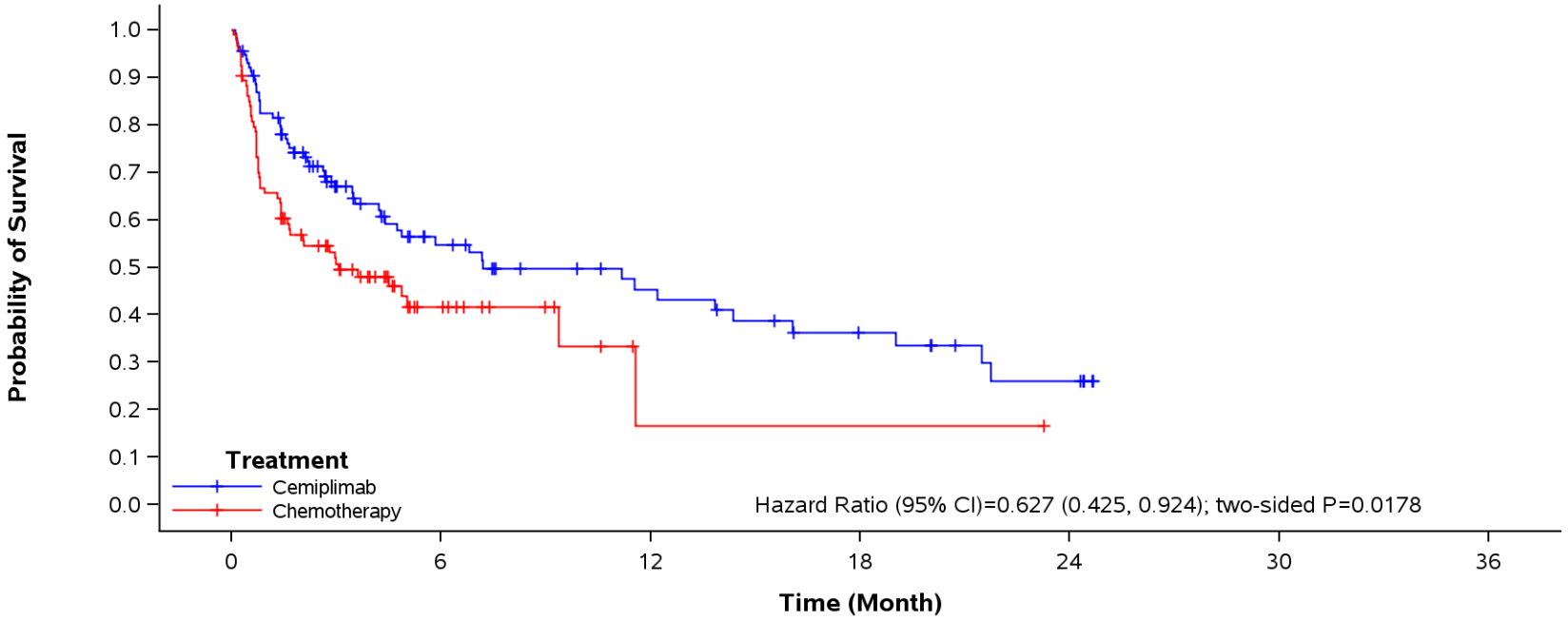

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 29 | 15 | 8 | 4 | 0 | 0 |
| Chemotherapy | 108 | 16 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line



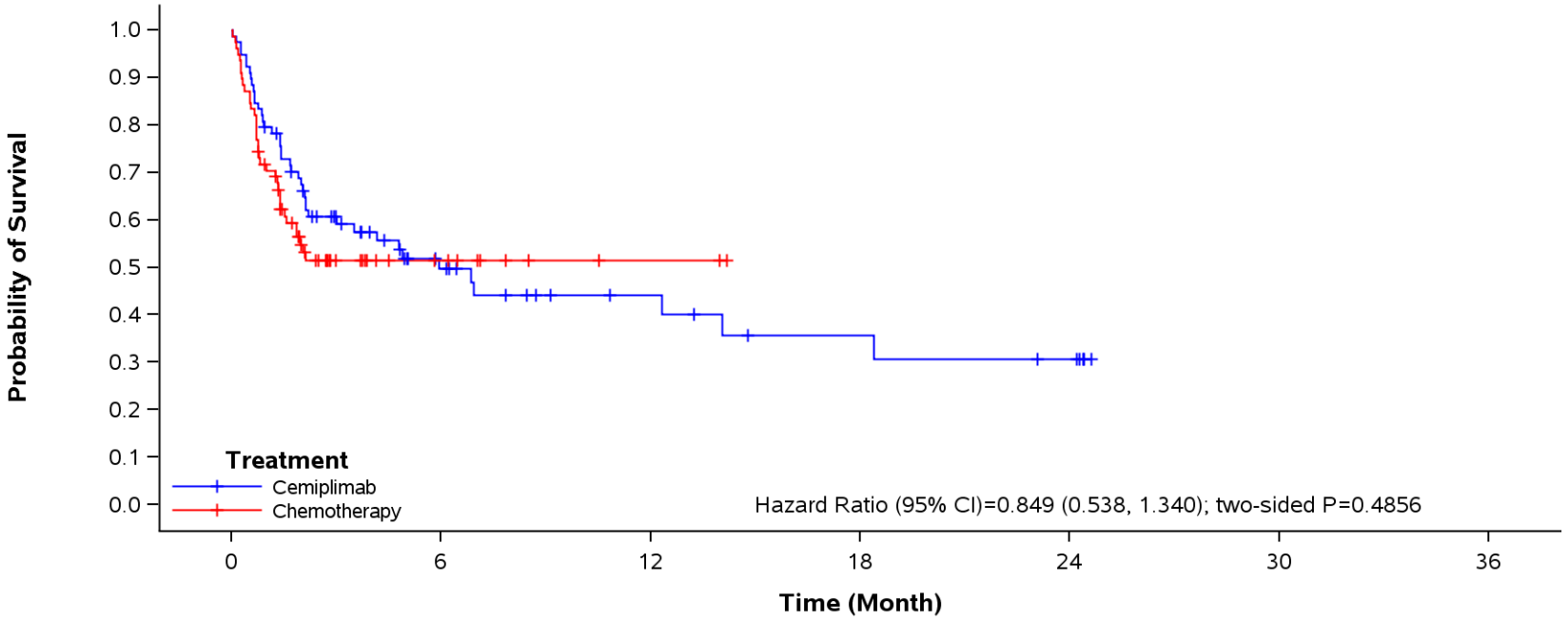

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 34 | 21 | 13 | 7 | 0 | 0 |
| Chemotherapy | 94 | 15 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line



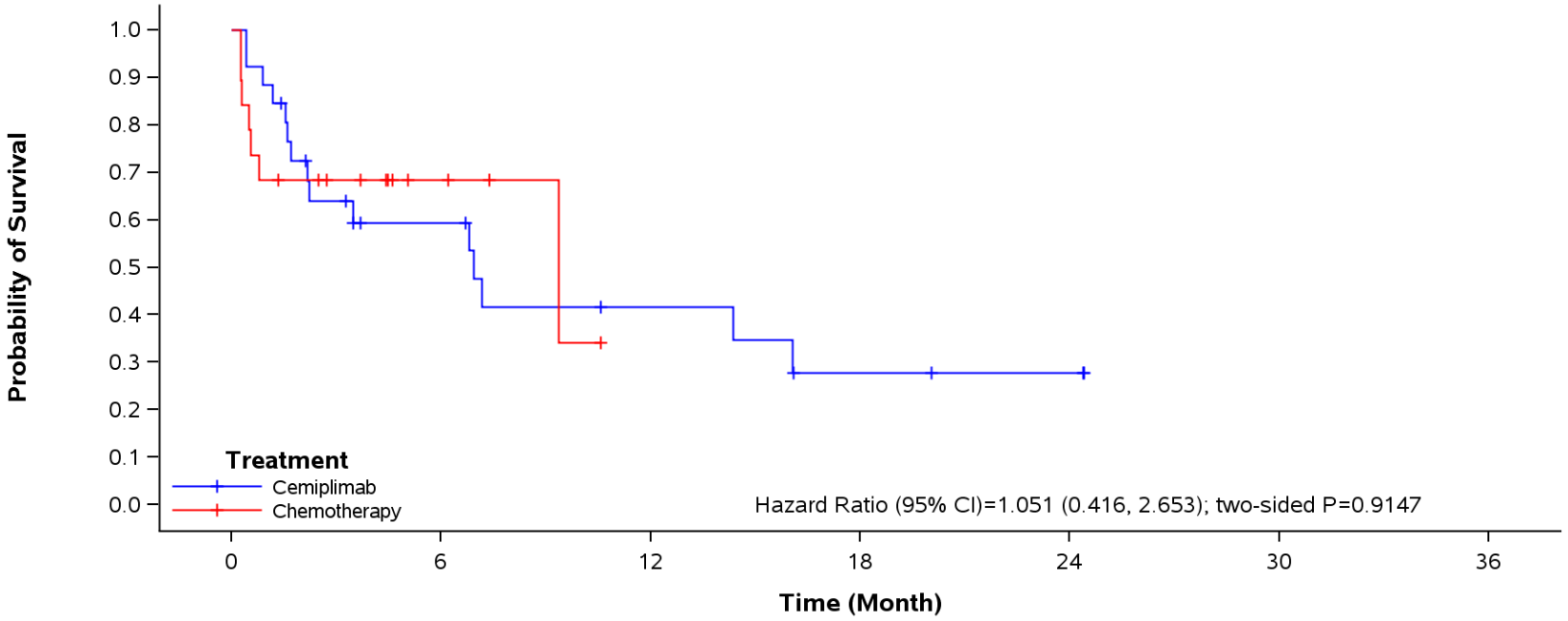

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 22 | 11 | 7 | 5 | 0 | 0 |
| Chemotherapy | 78 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



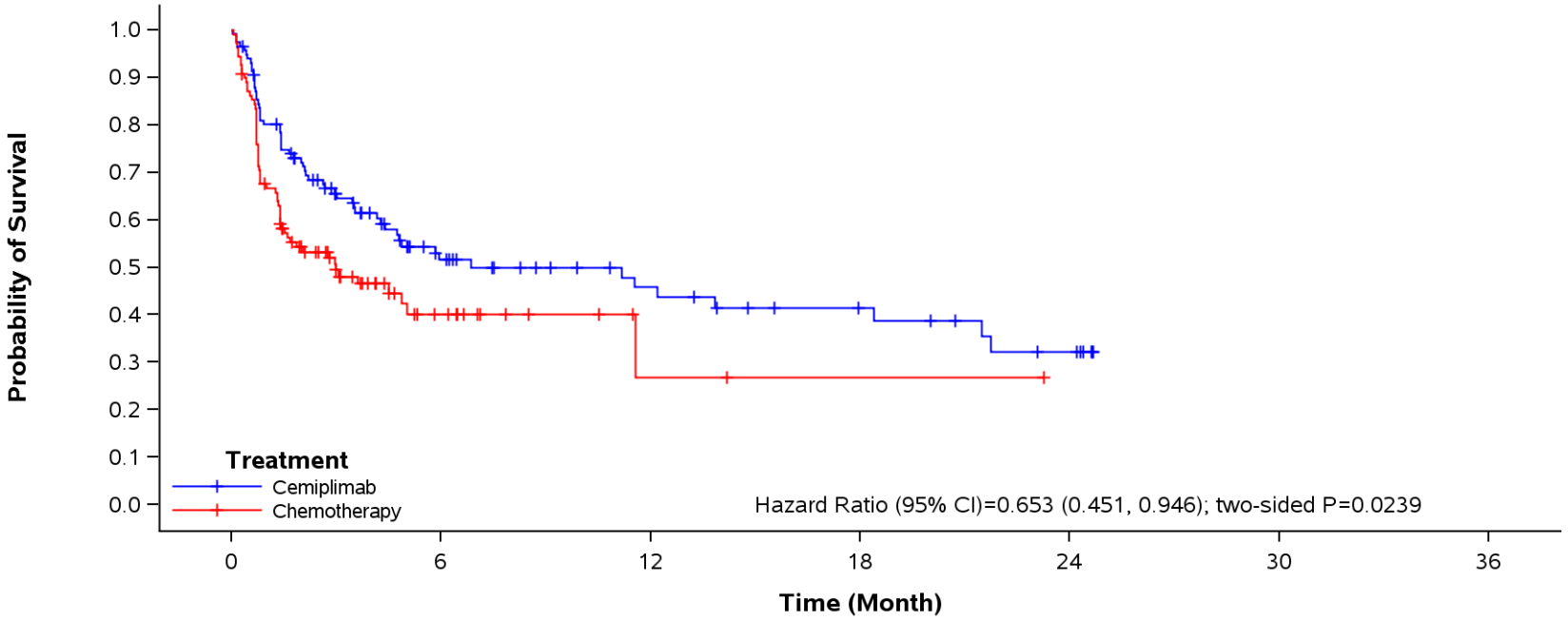

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 6 | 3 | 2 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed



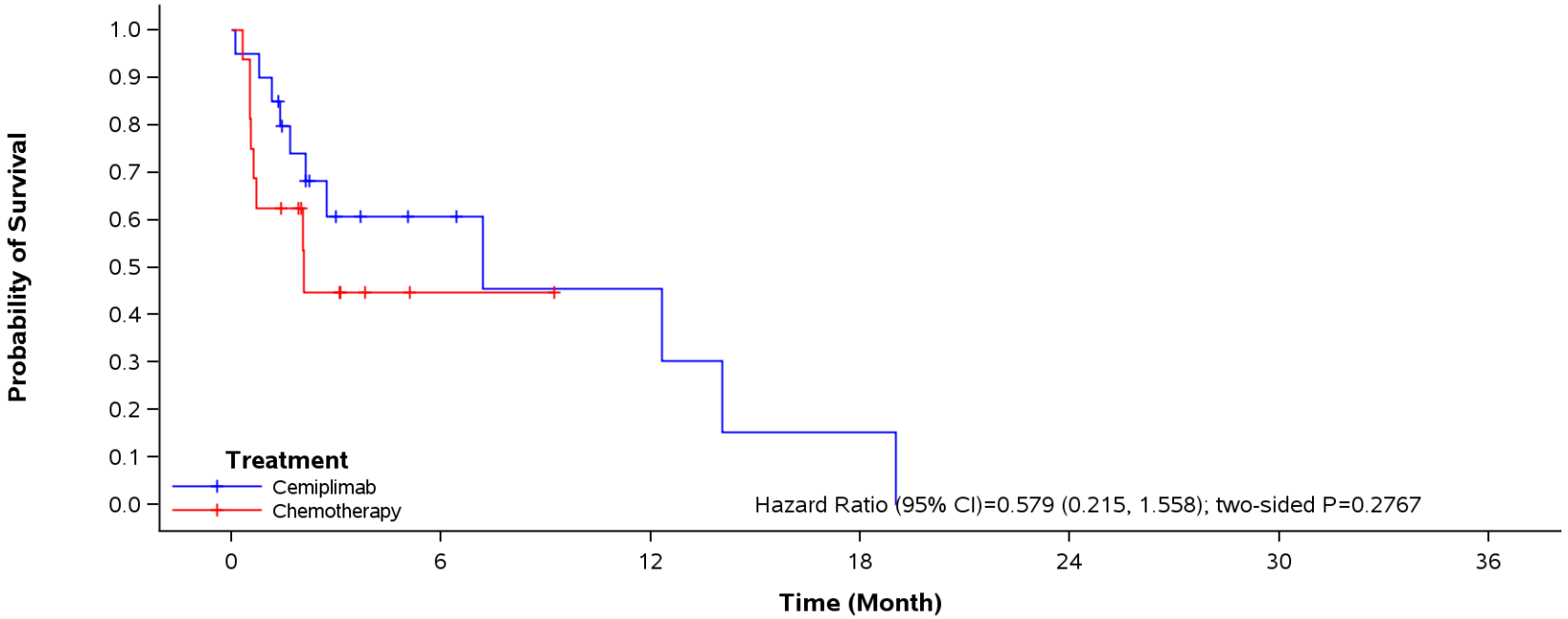

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 36 | 22 | 15 | 9 | 0 | 0 |
| Chemotherapy | 109 | 15 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan



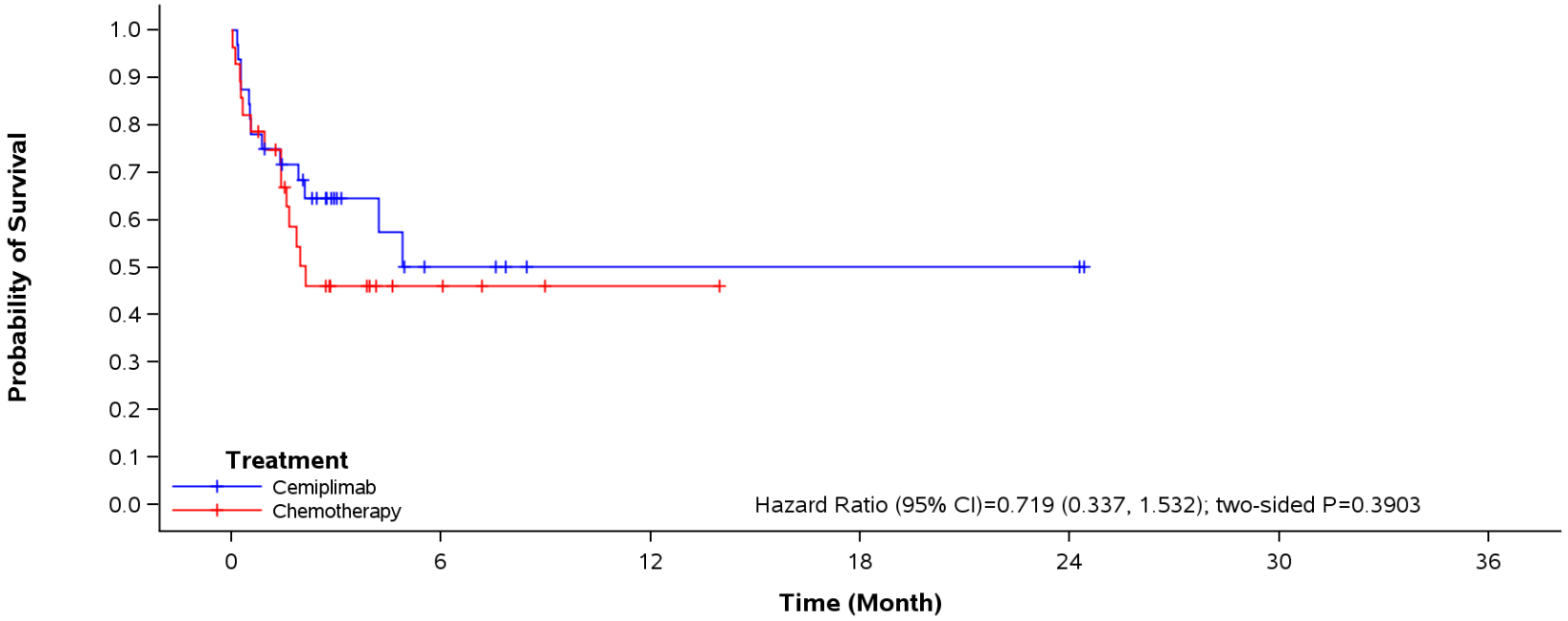

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.3. Time to First Any Treatment-Emergent Adverse Events with CTCAE Grade >= 3 by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine



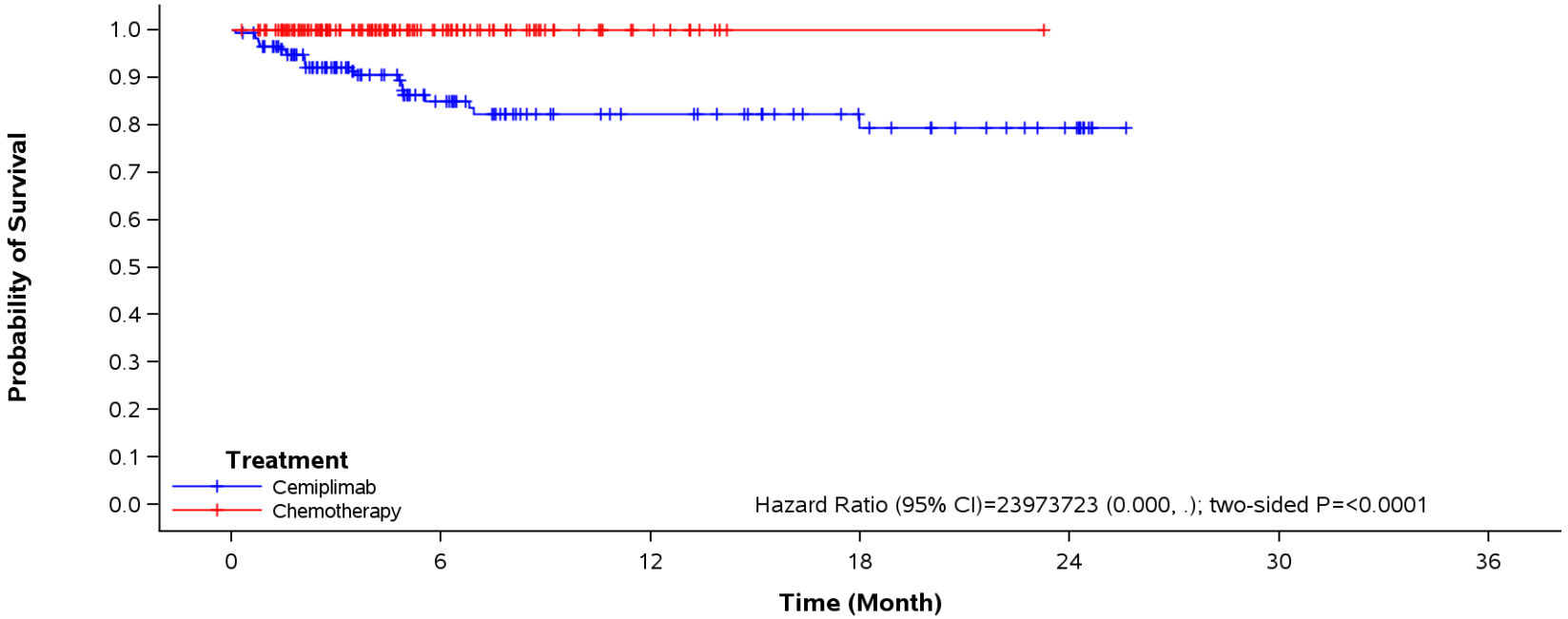

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 5 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



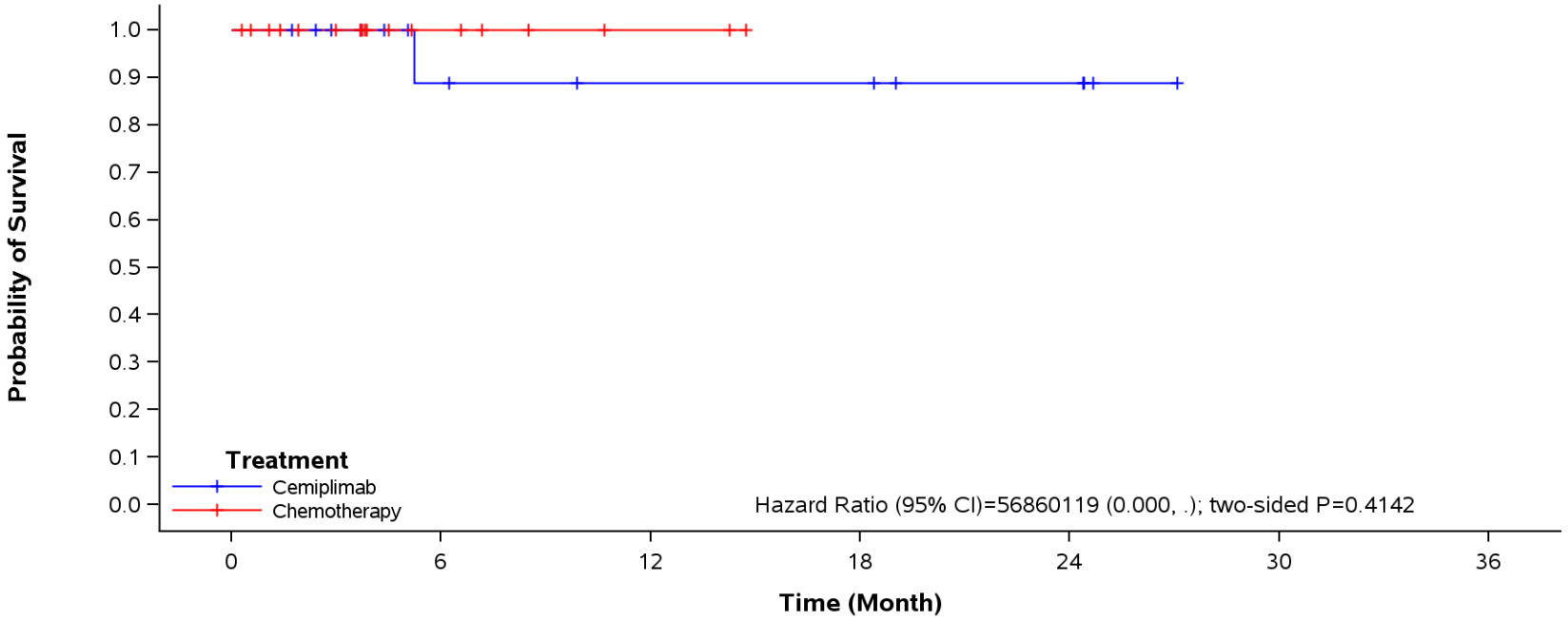

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 68 | 41 | 28 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



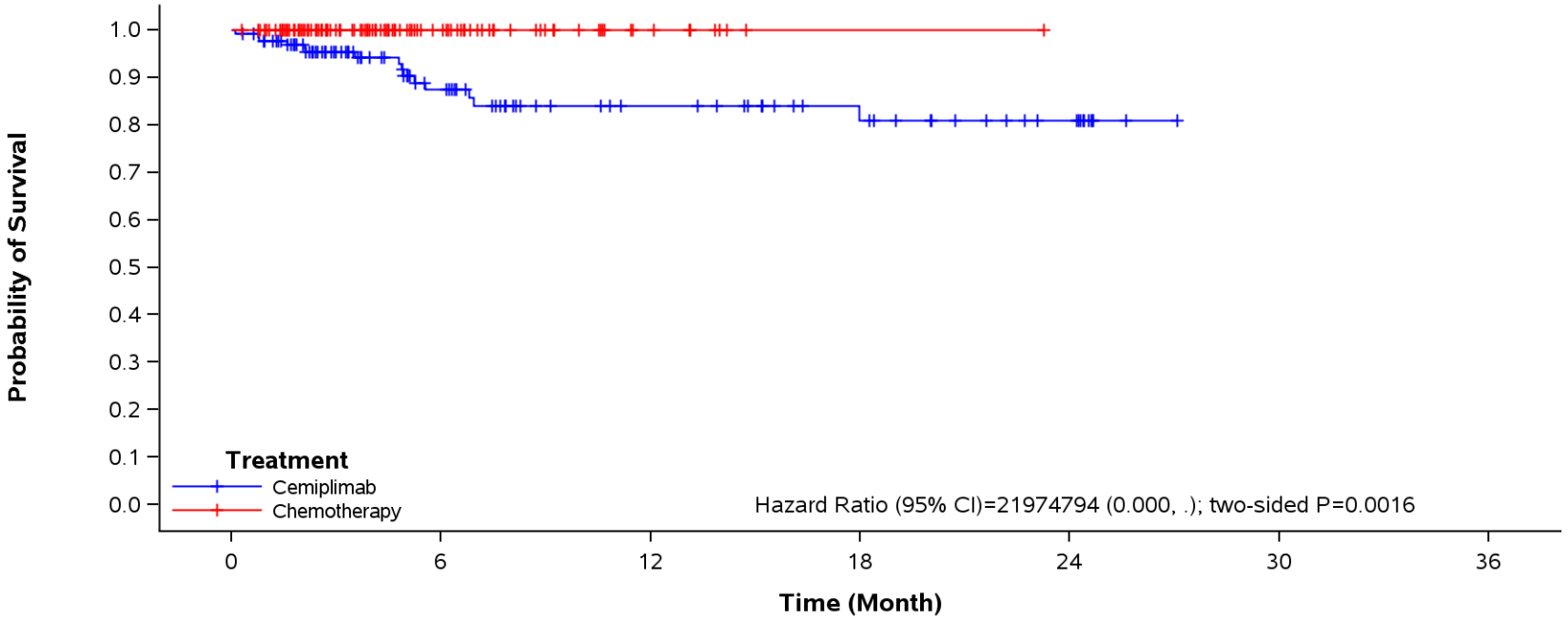

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



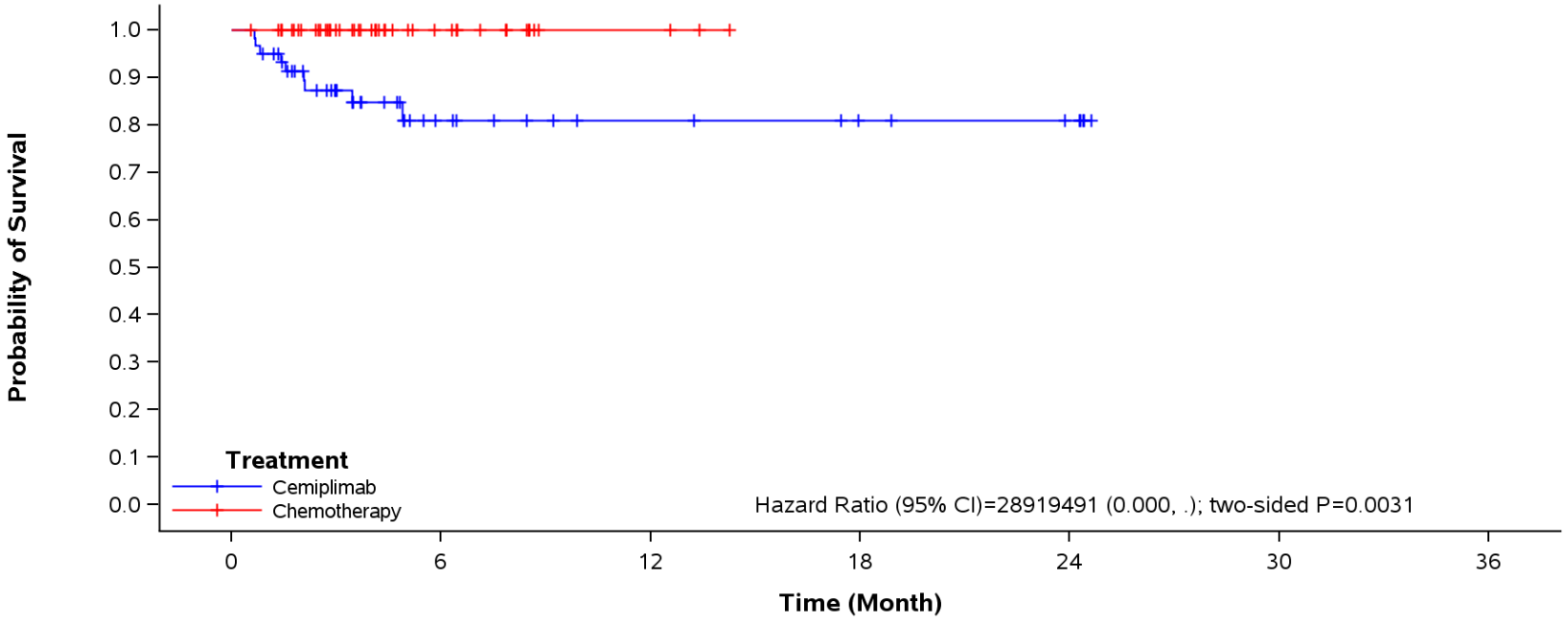

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 59 | 36 | 26 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



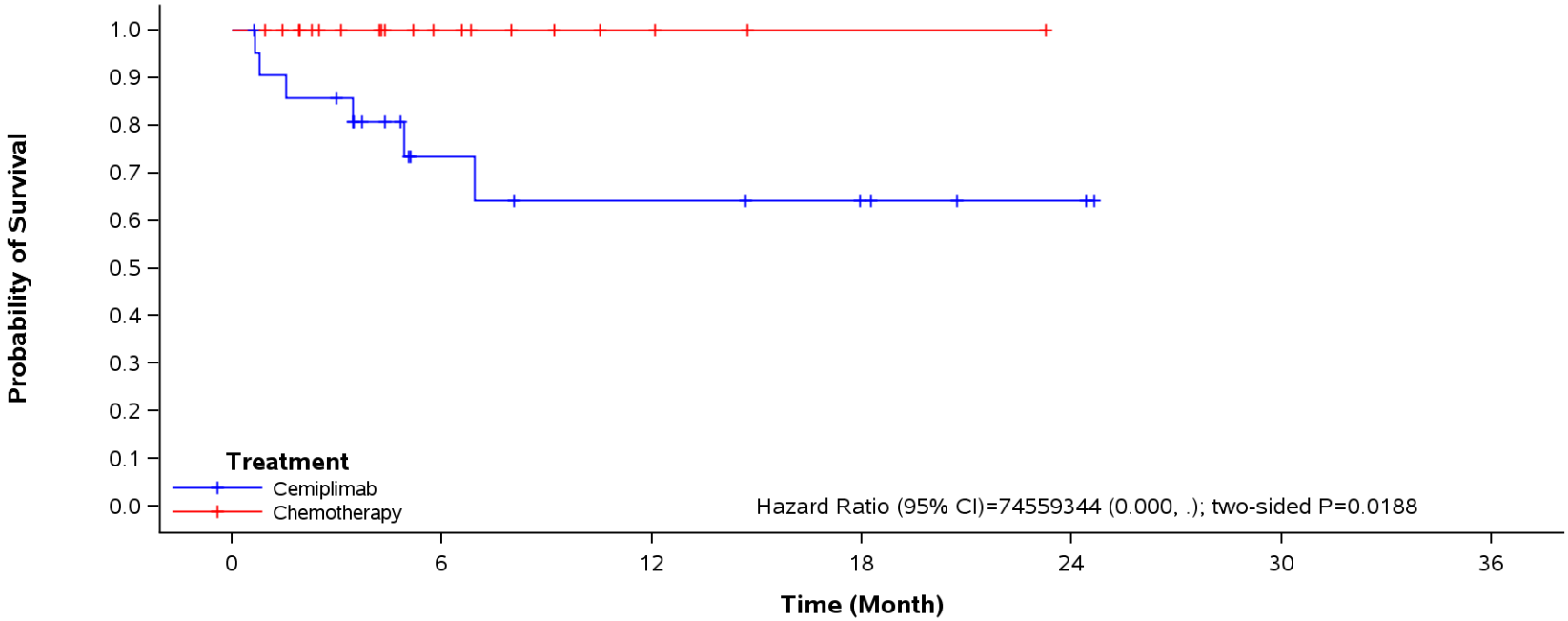

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 17 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America



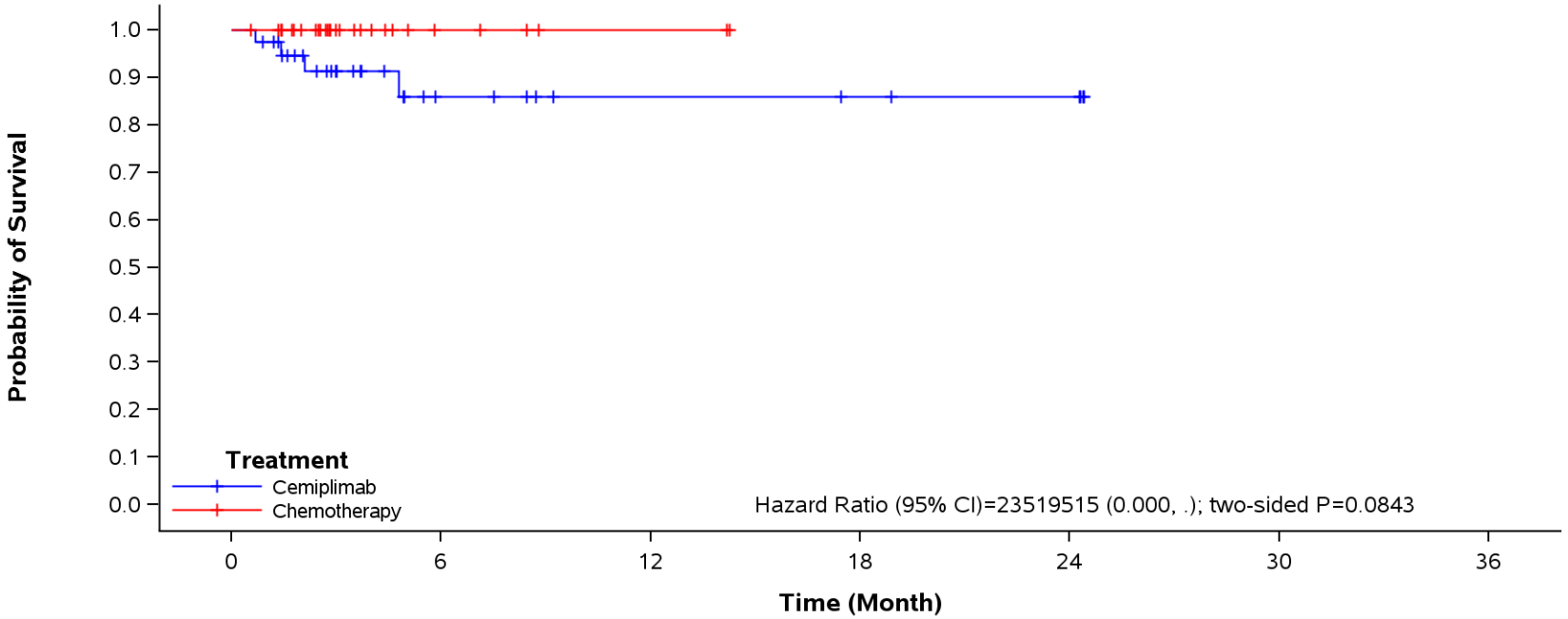

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia



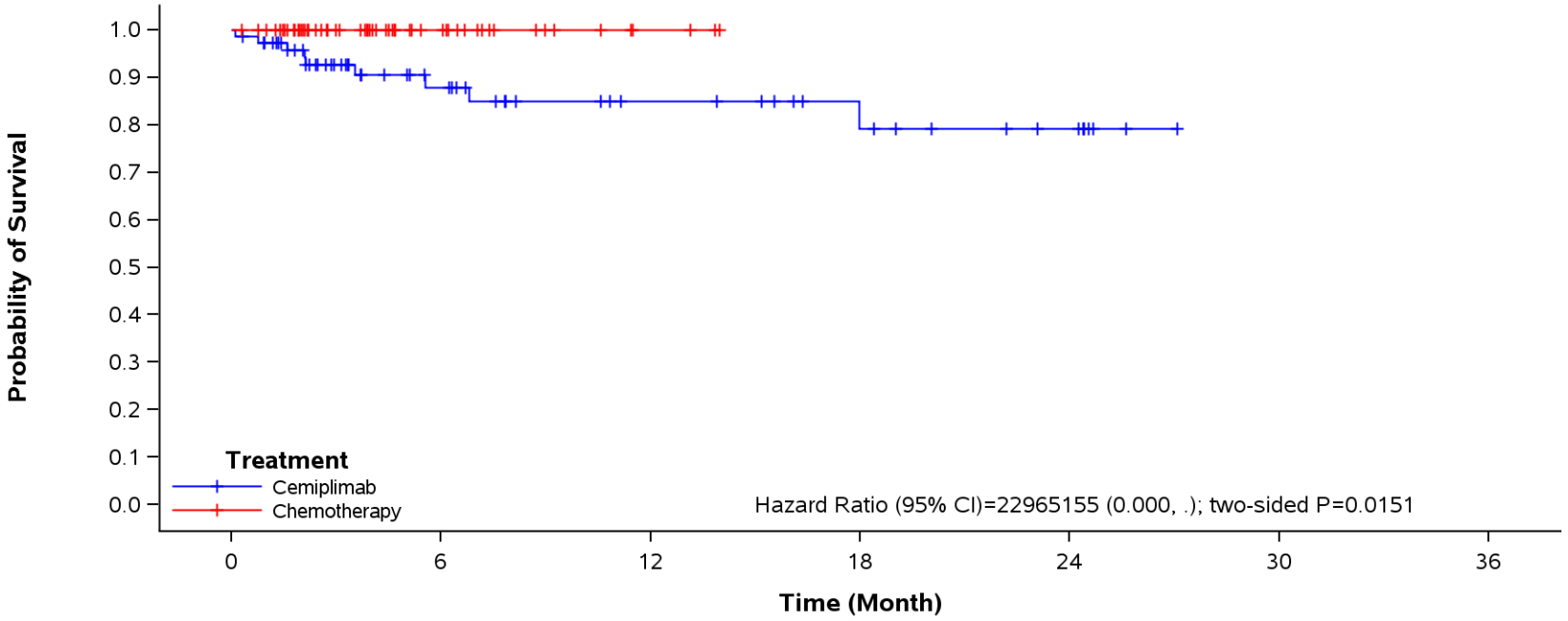

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



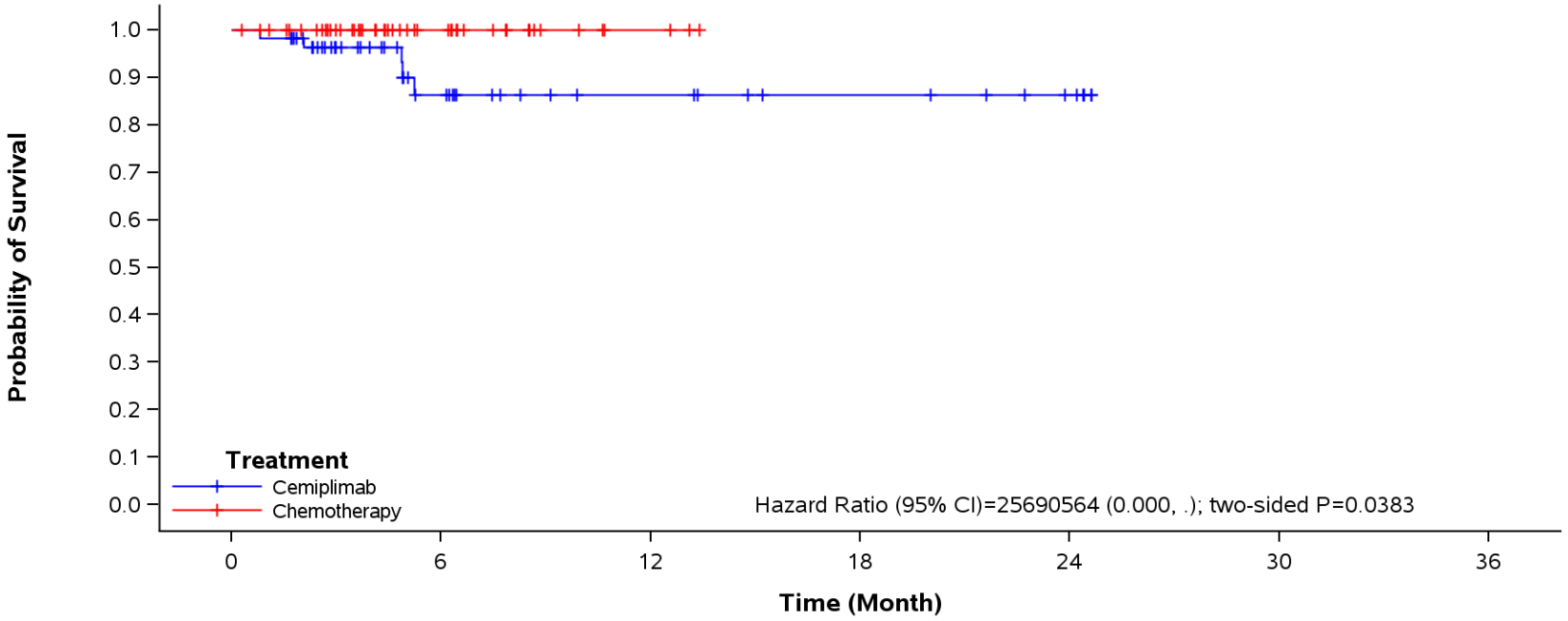

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 33 | 20 | 14 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW



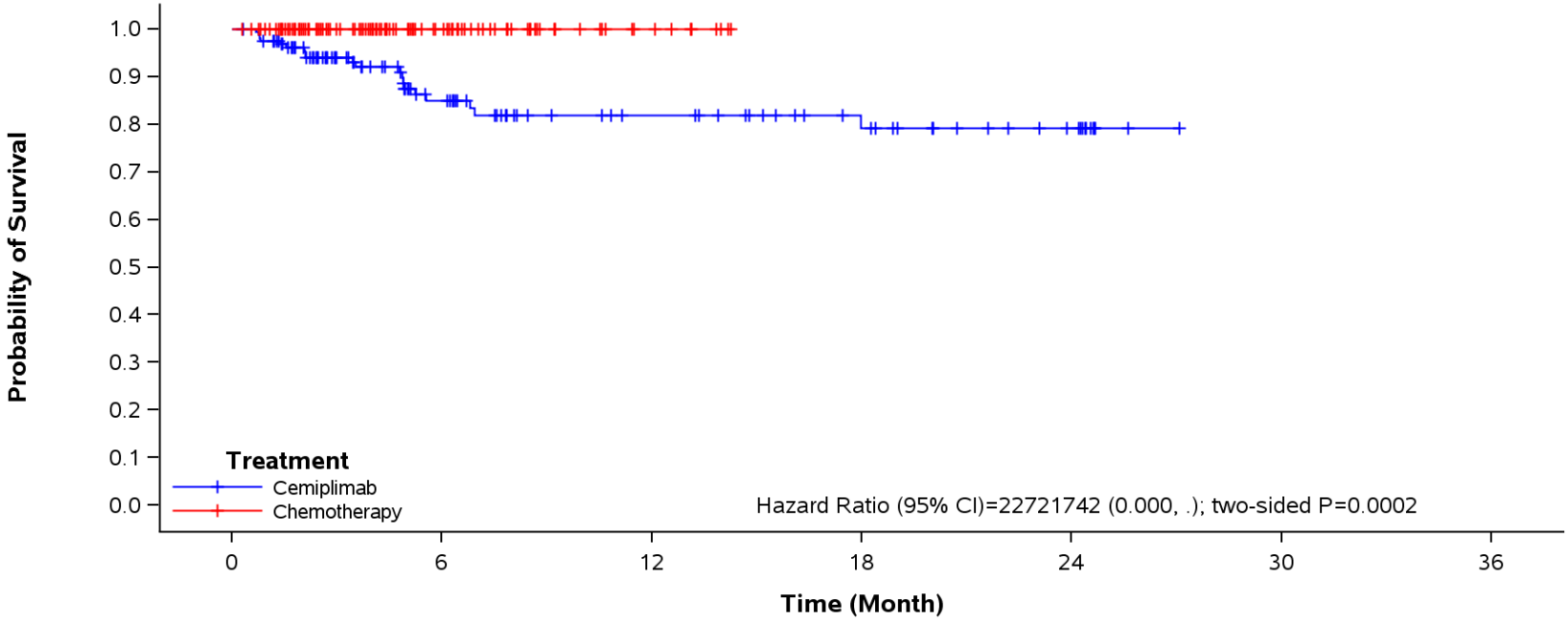

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 23 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous



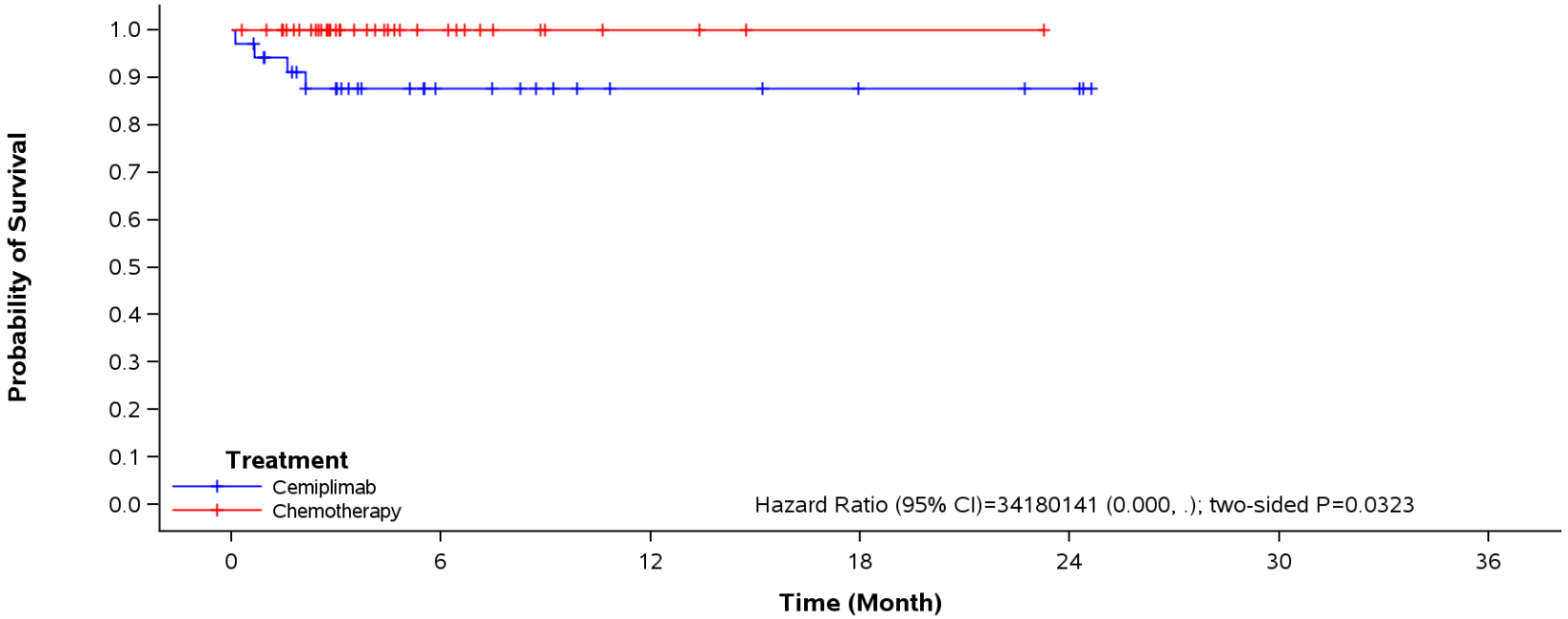

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 64 | 41 | 30 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



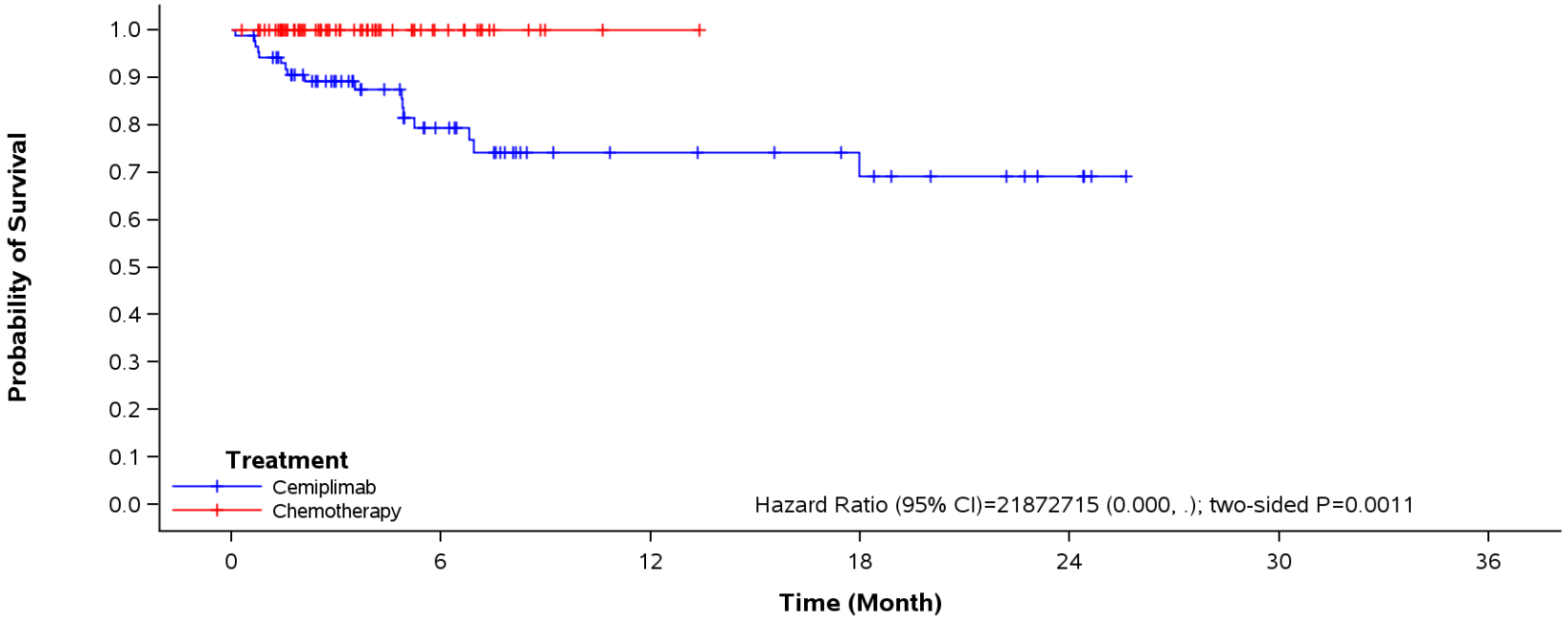

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes



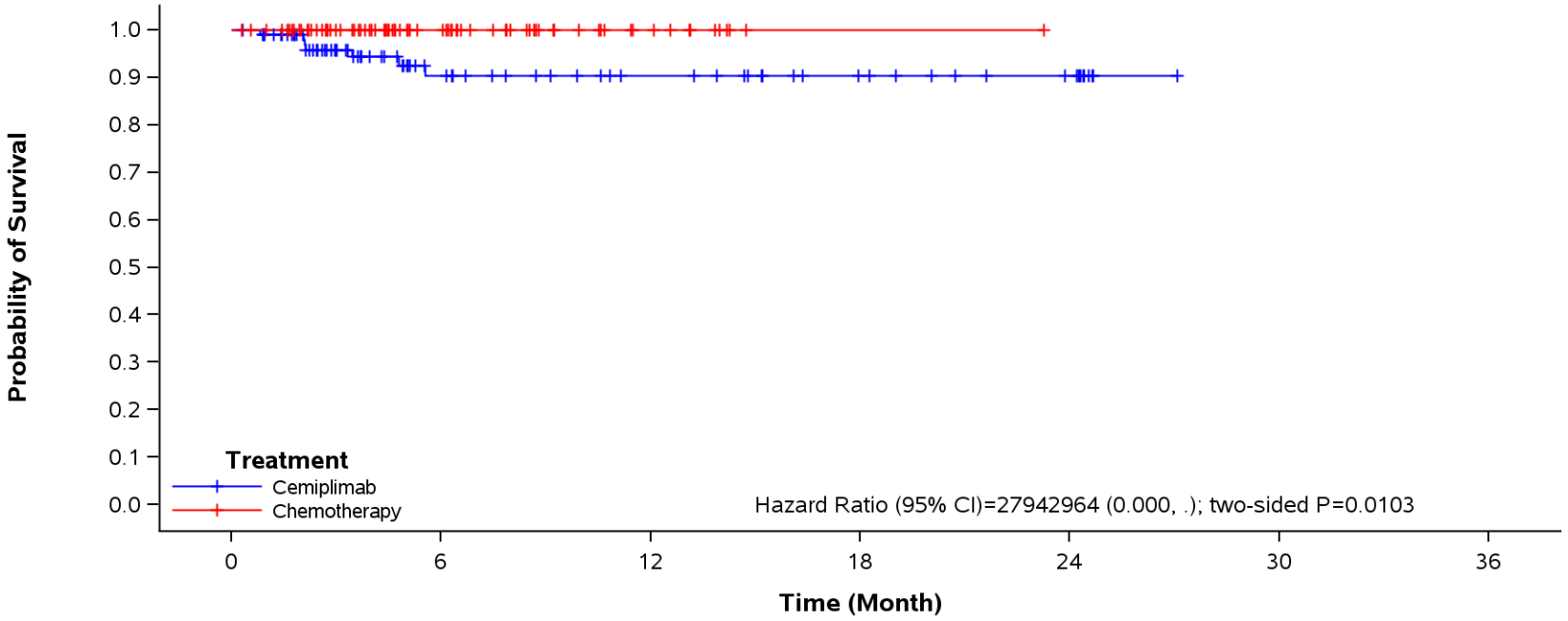

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 35 | 18 | 14 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No



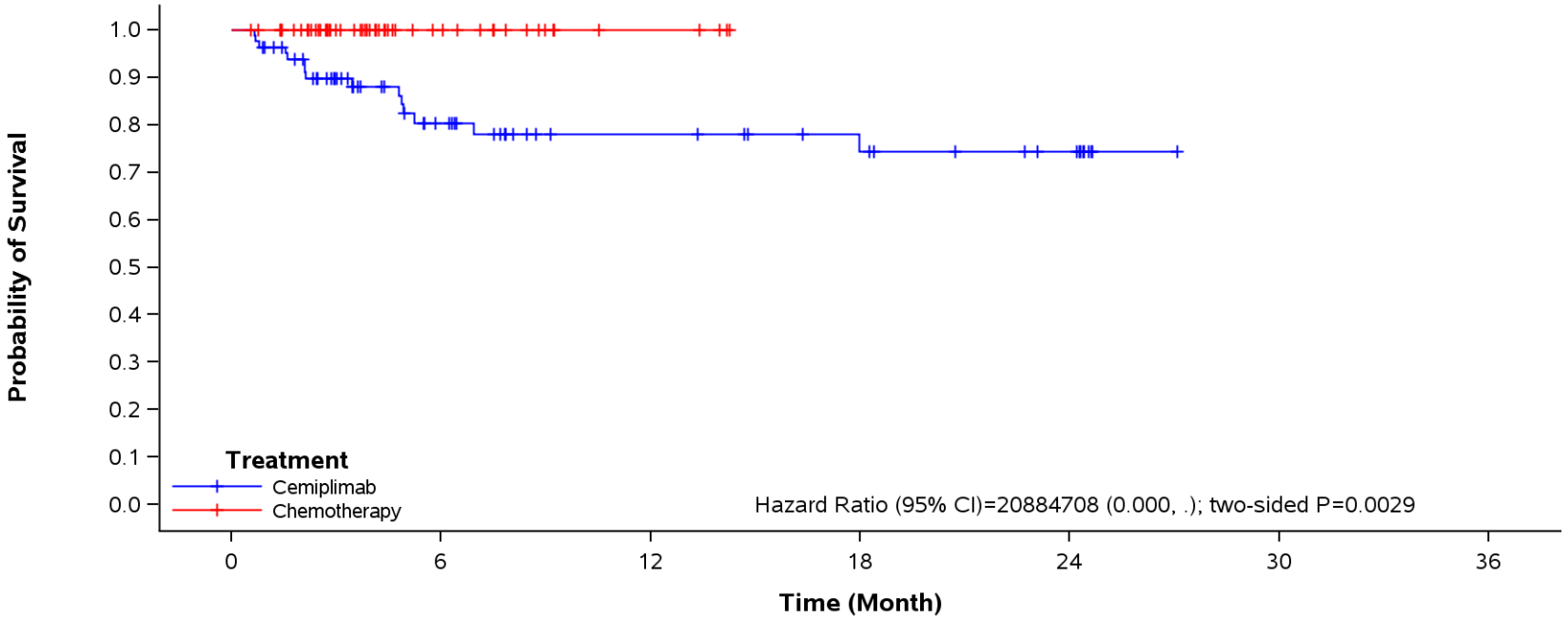

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 41 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0



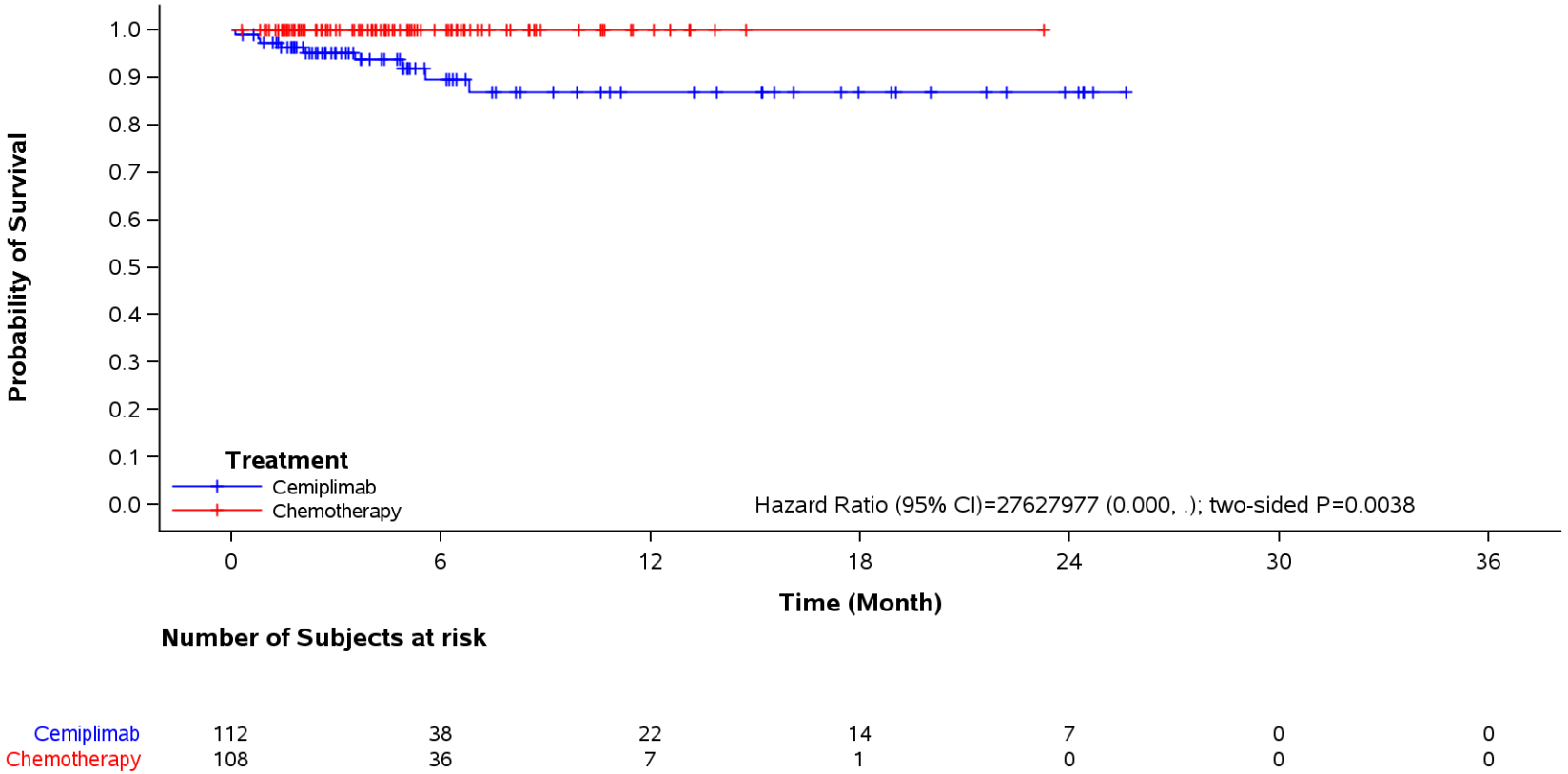

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 38 | 25 | 20 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1



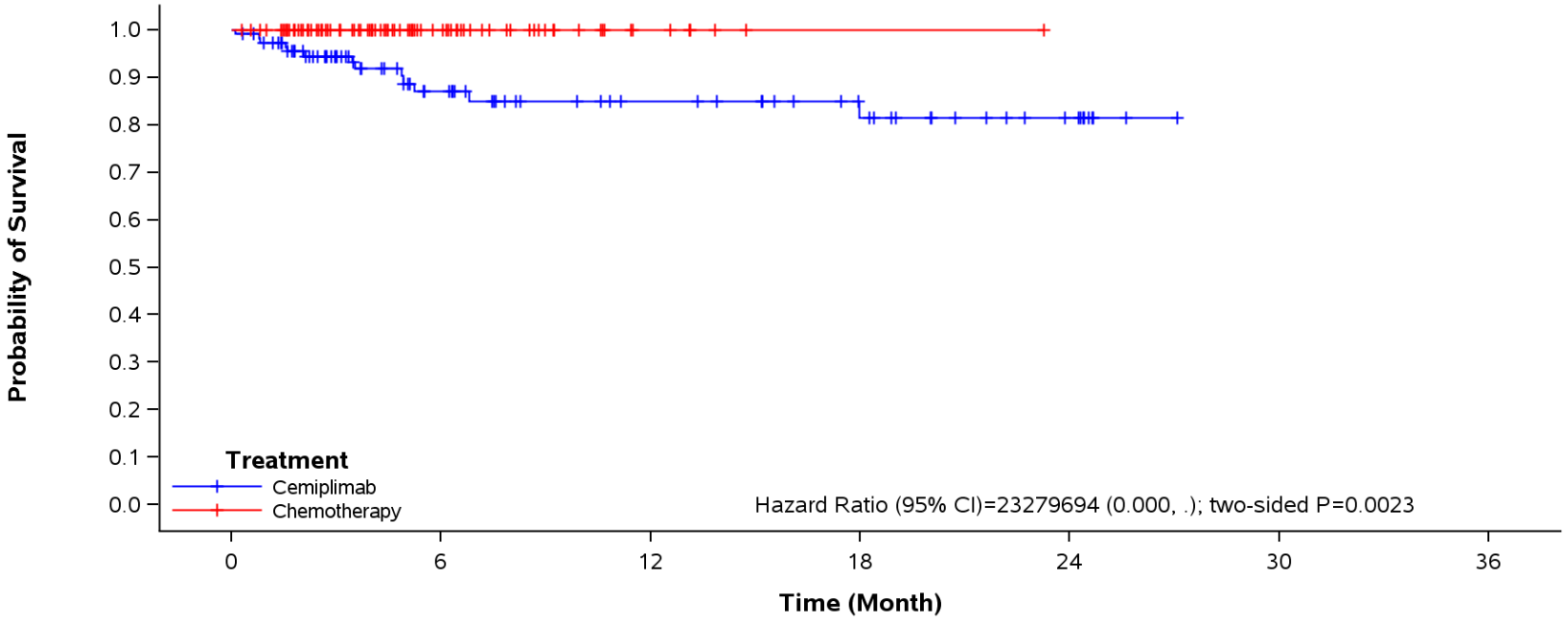

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 38 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line



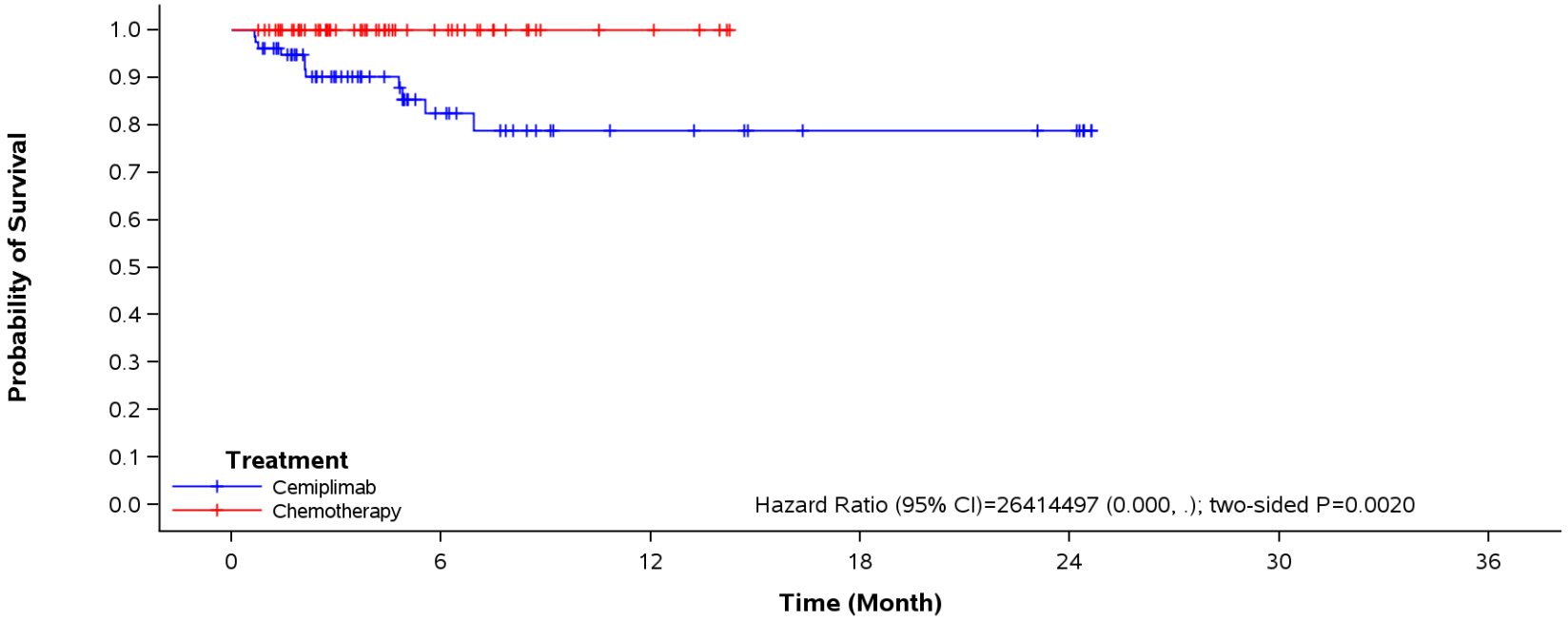

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 48 | 32 | 23 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line



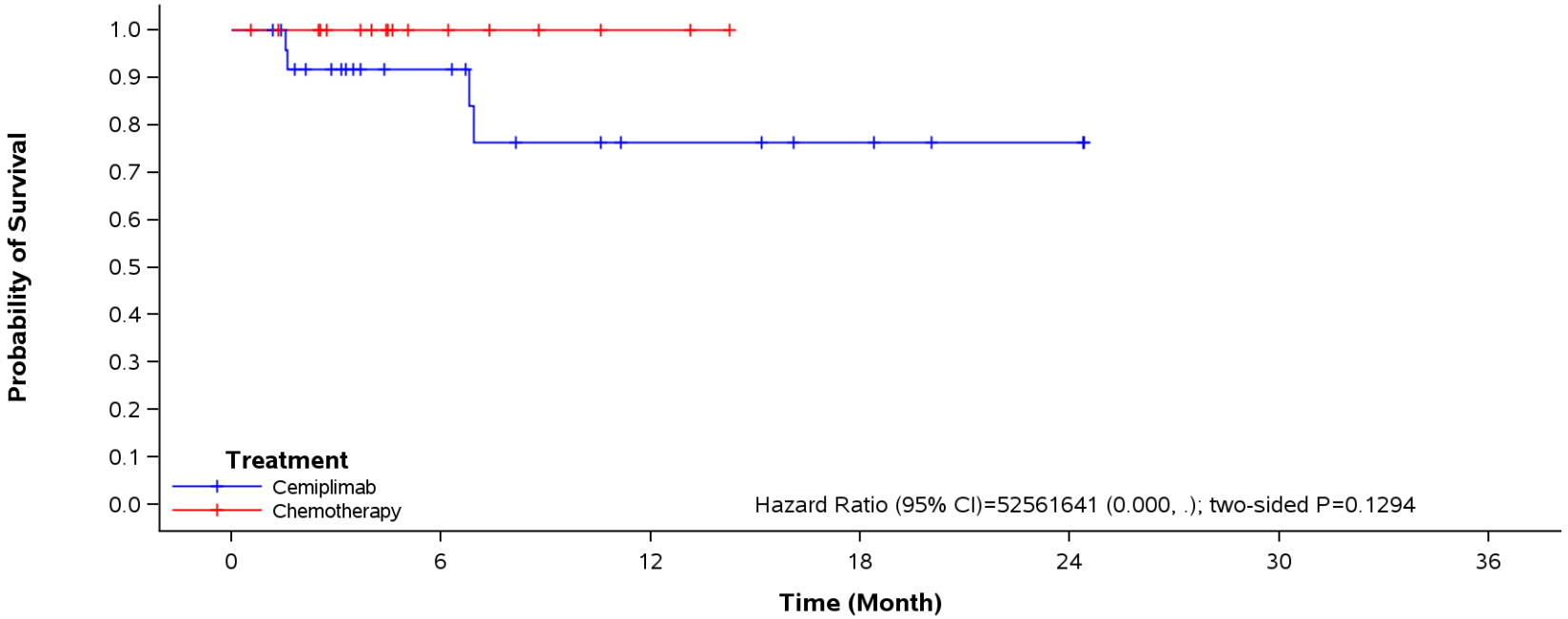

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 27 | 14 | 10 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



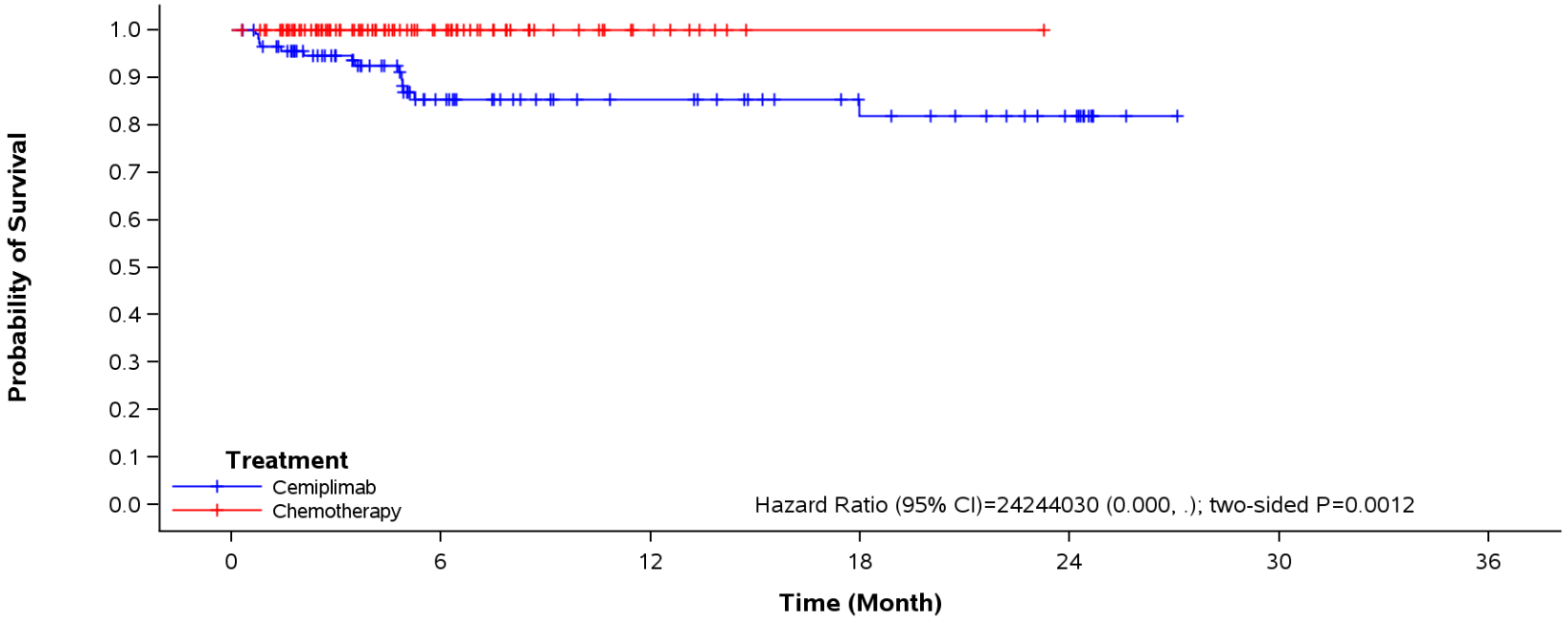

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed



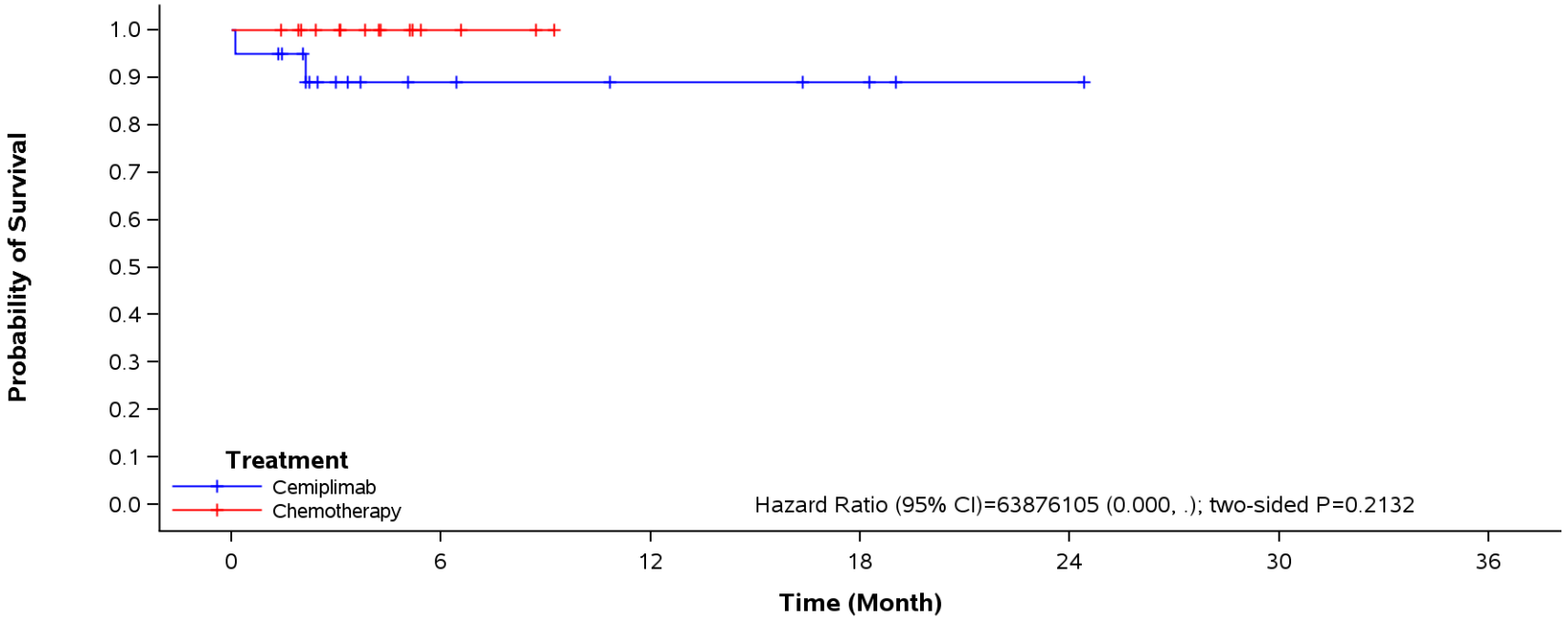

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 50 | 34 | 24 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan



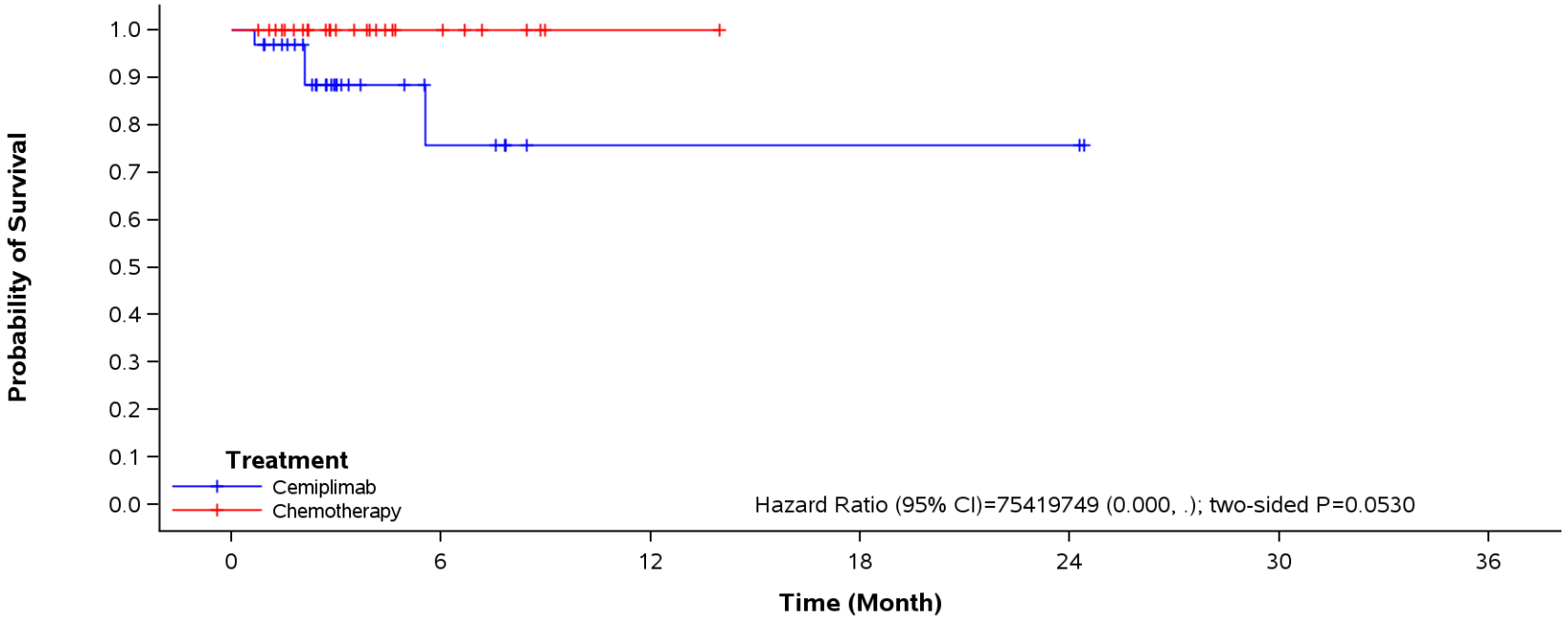

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine



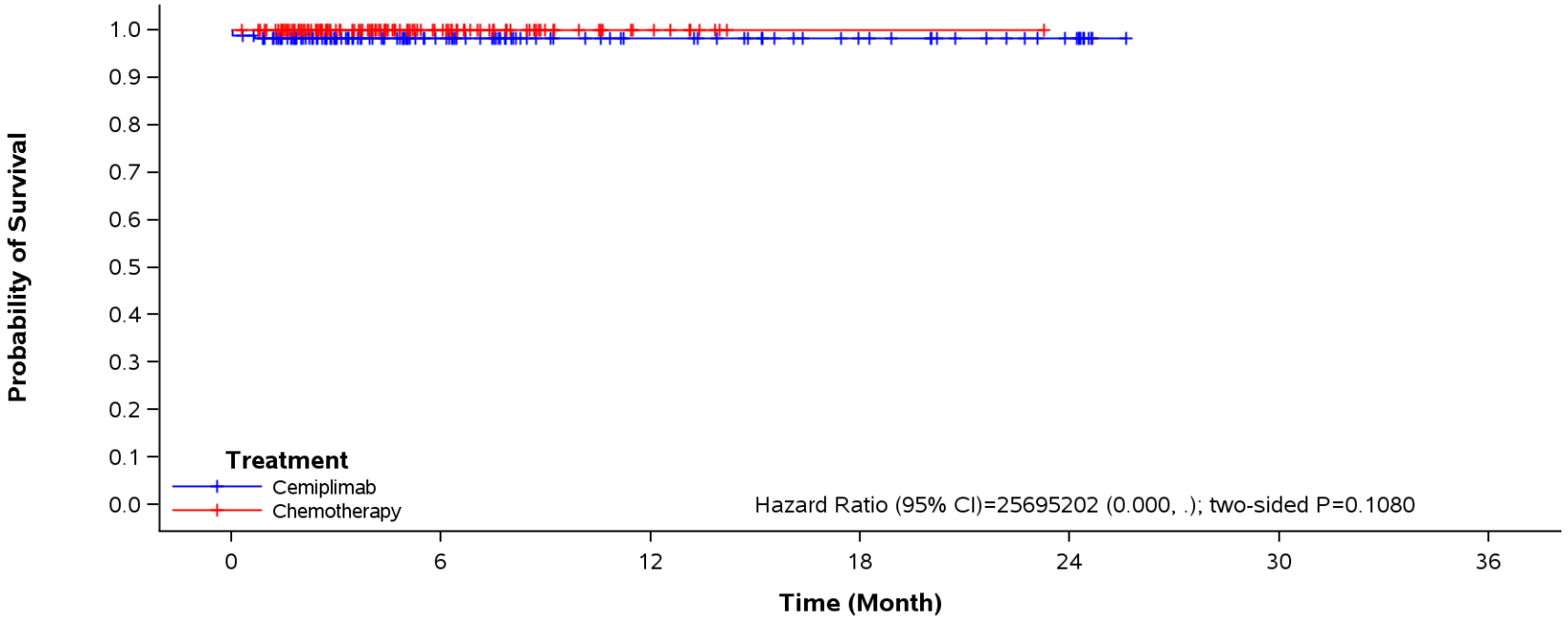

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 6 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



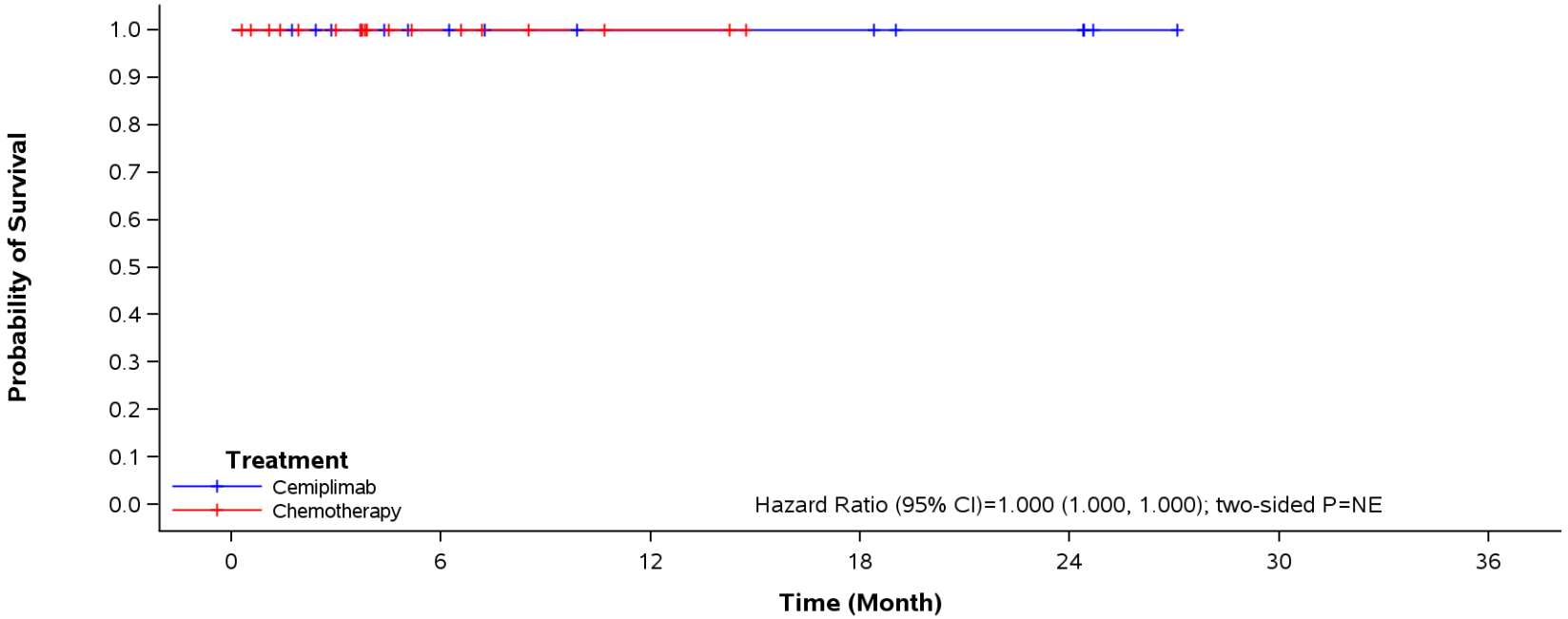

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



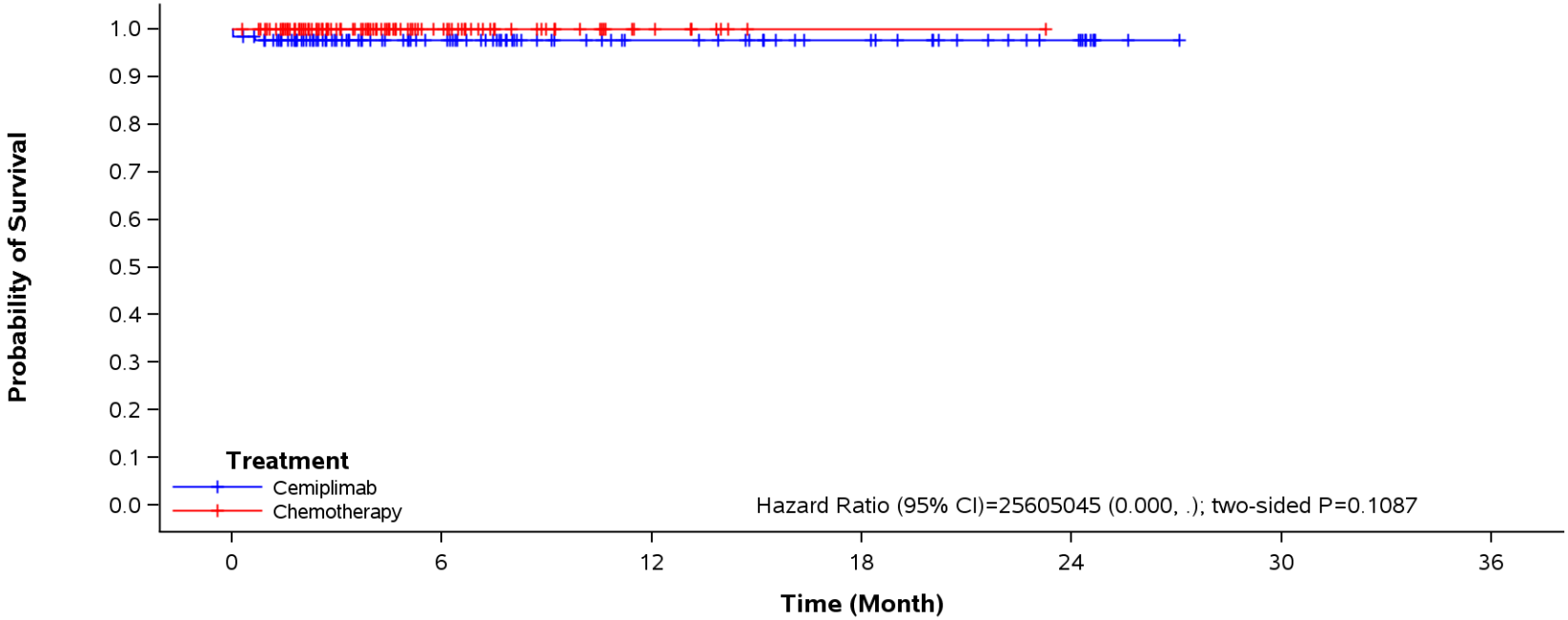

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



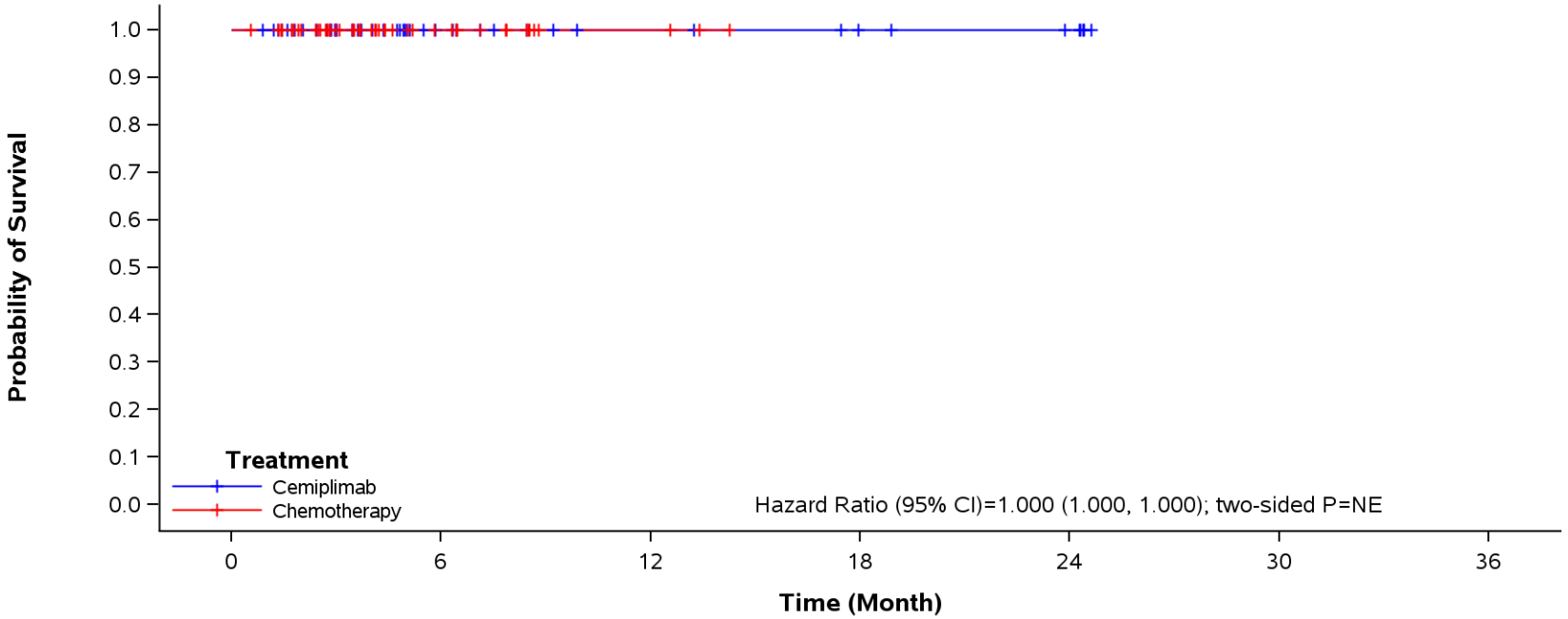

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



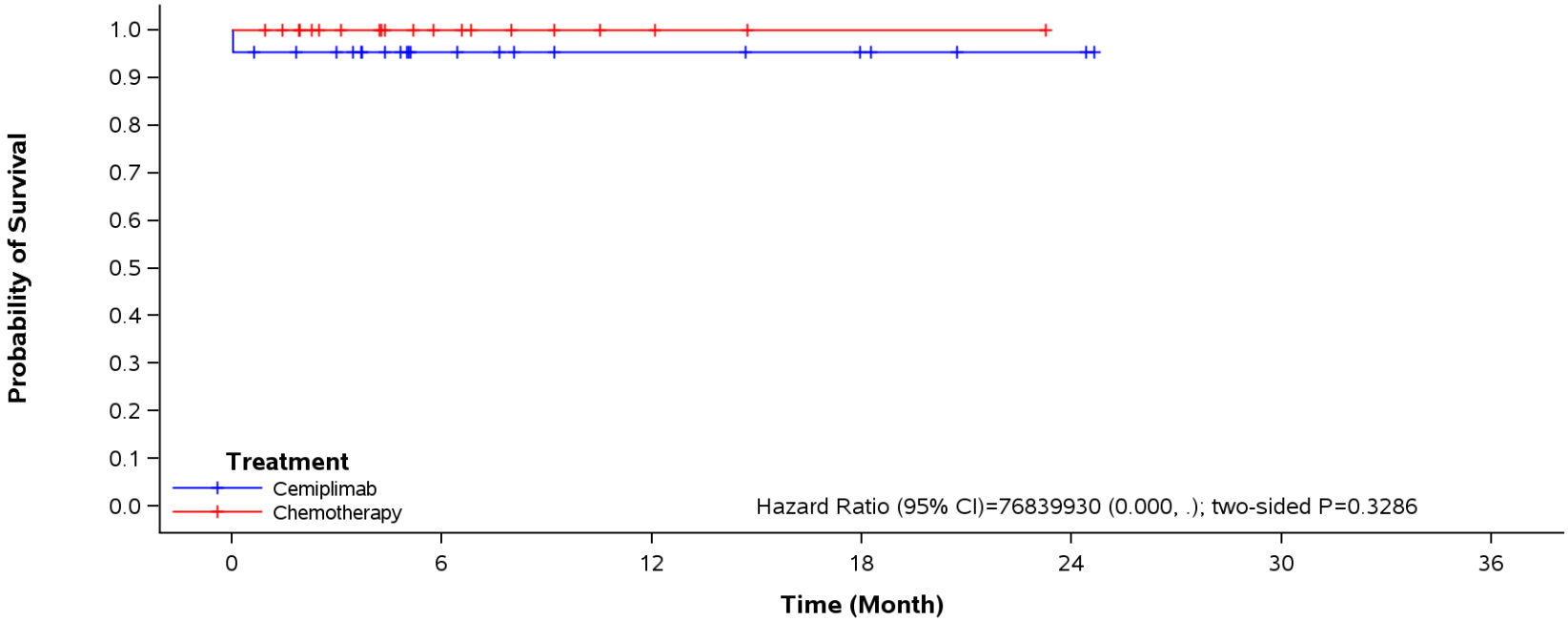

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America



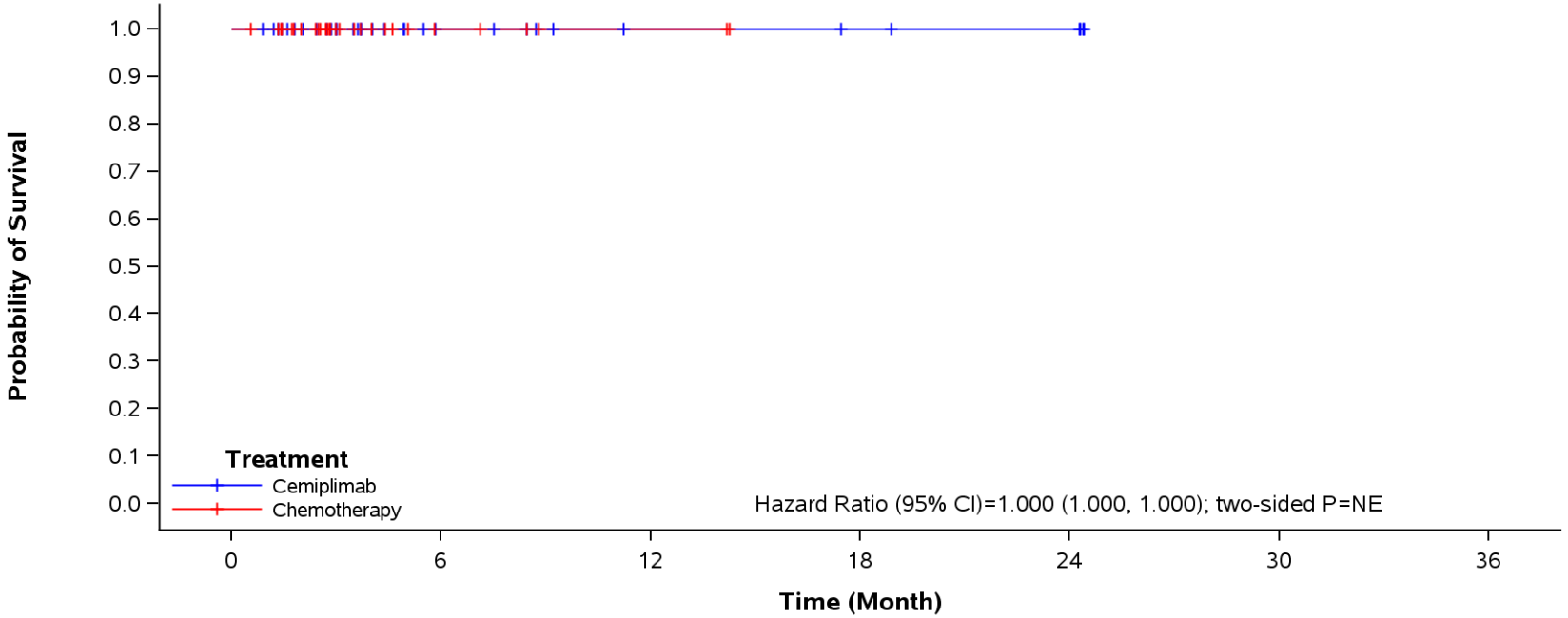

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

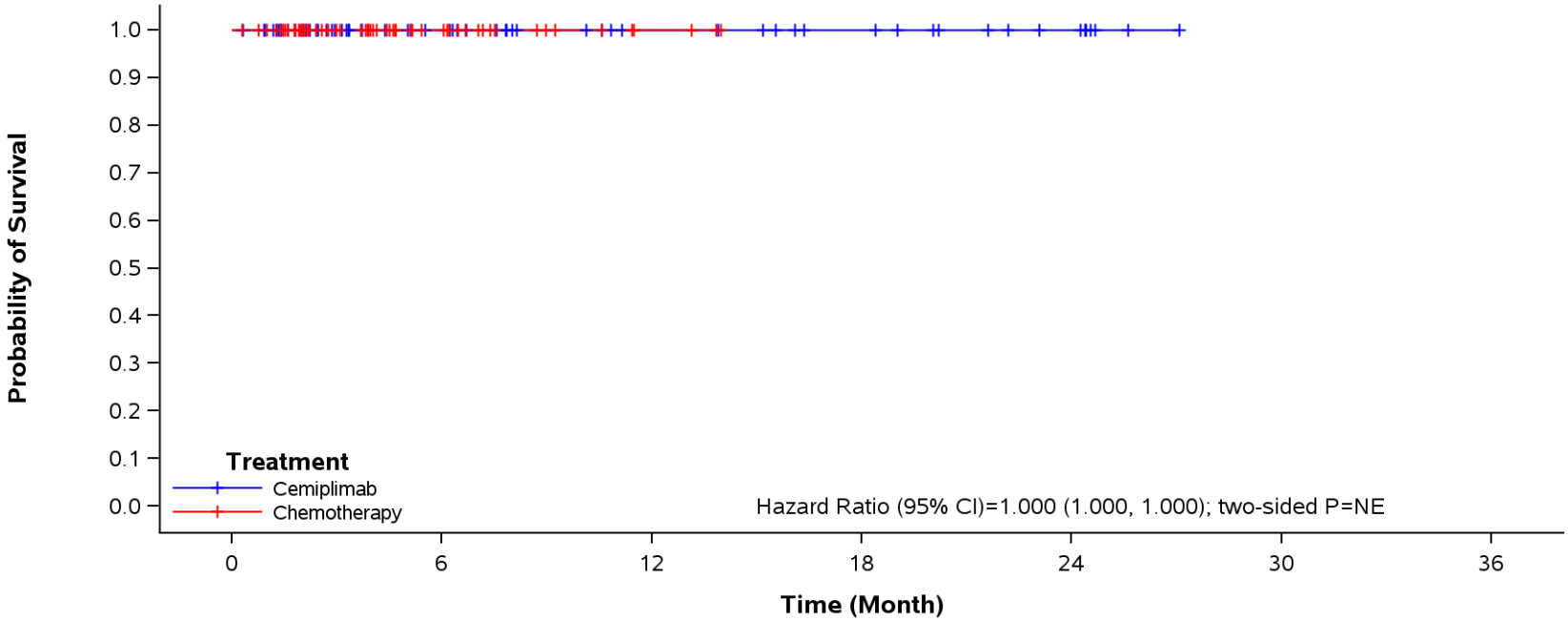
Geographic region: Asia




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



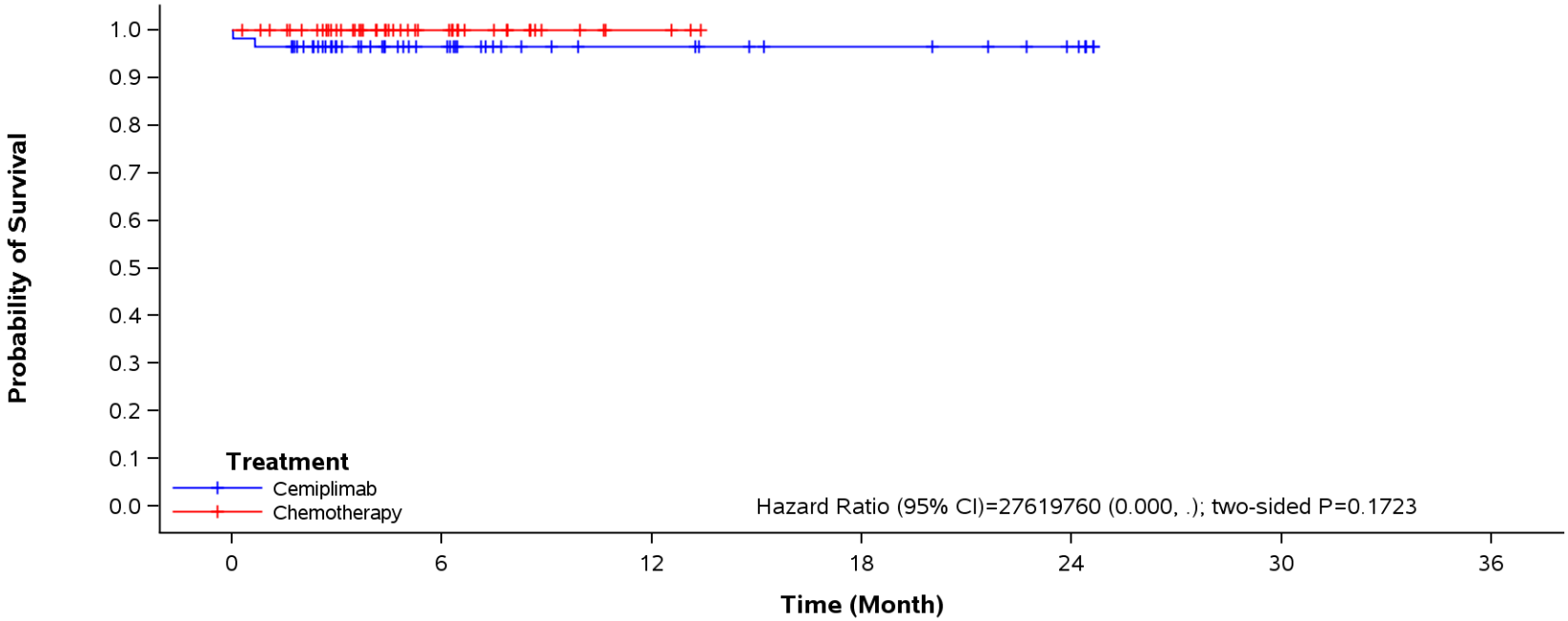

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW



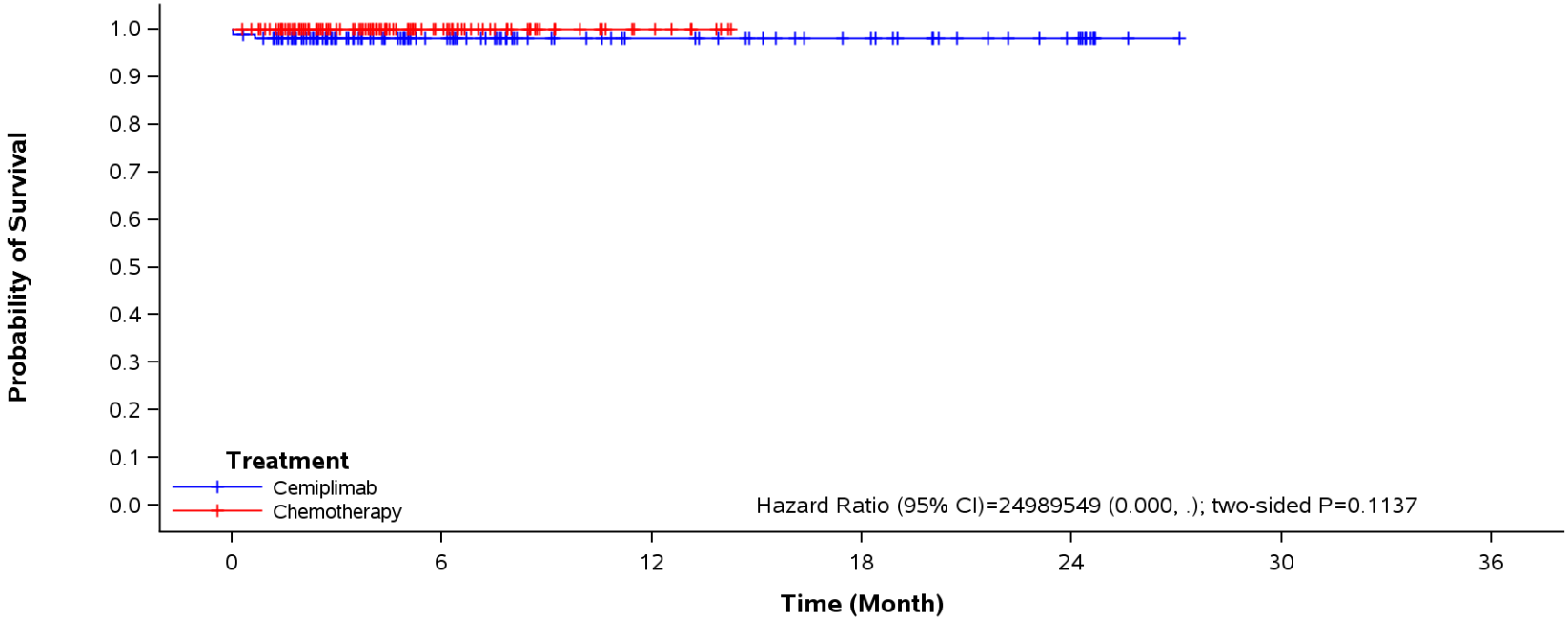

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous



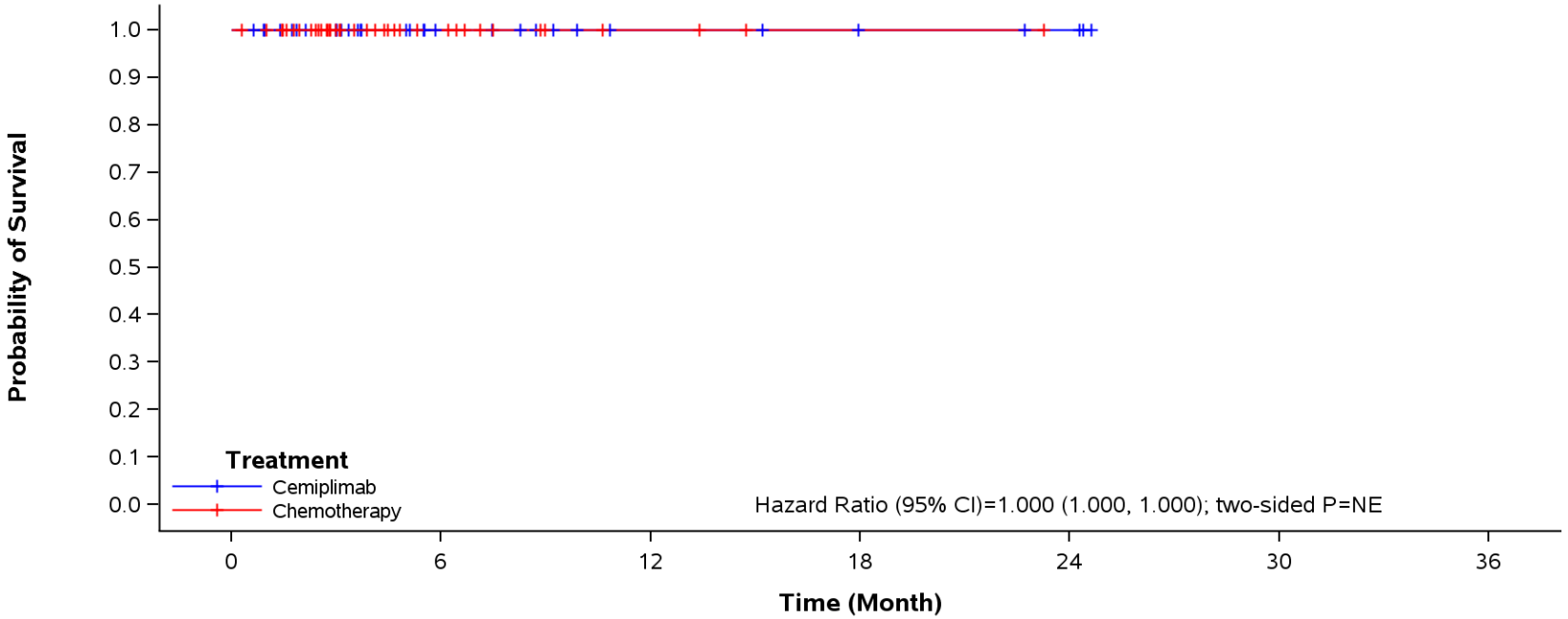

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



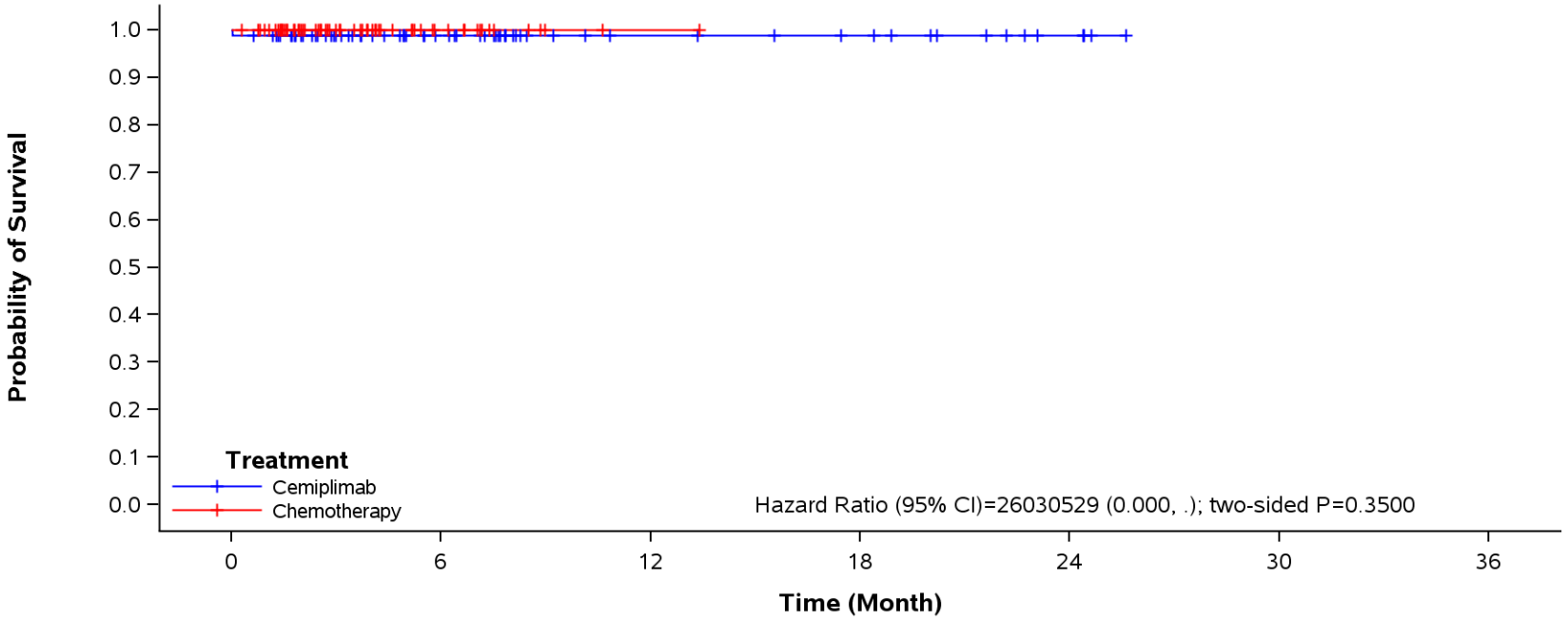

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes



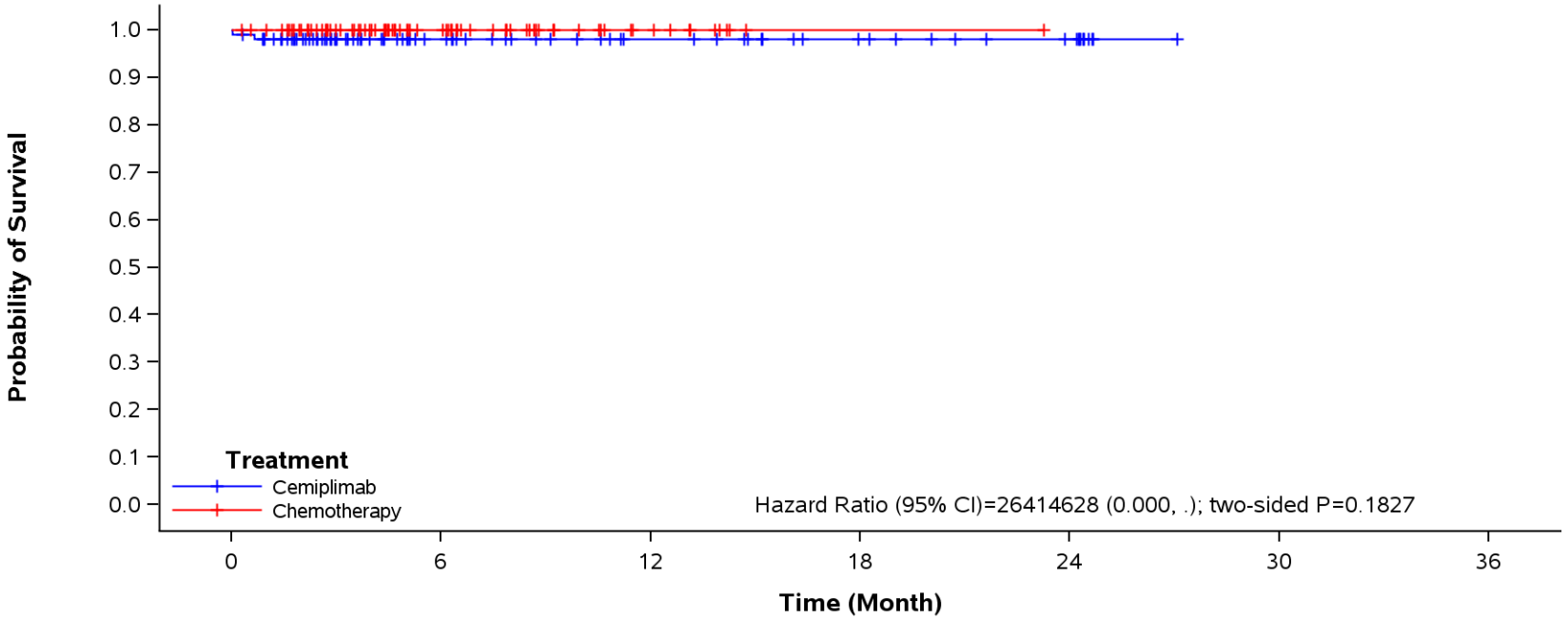

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No



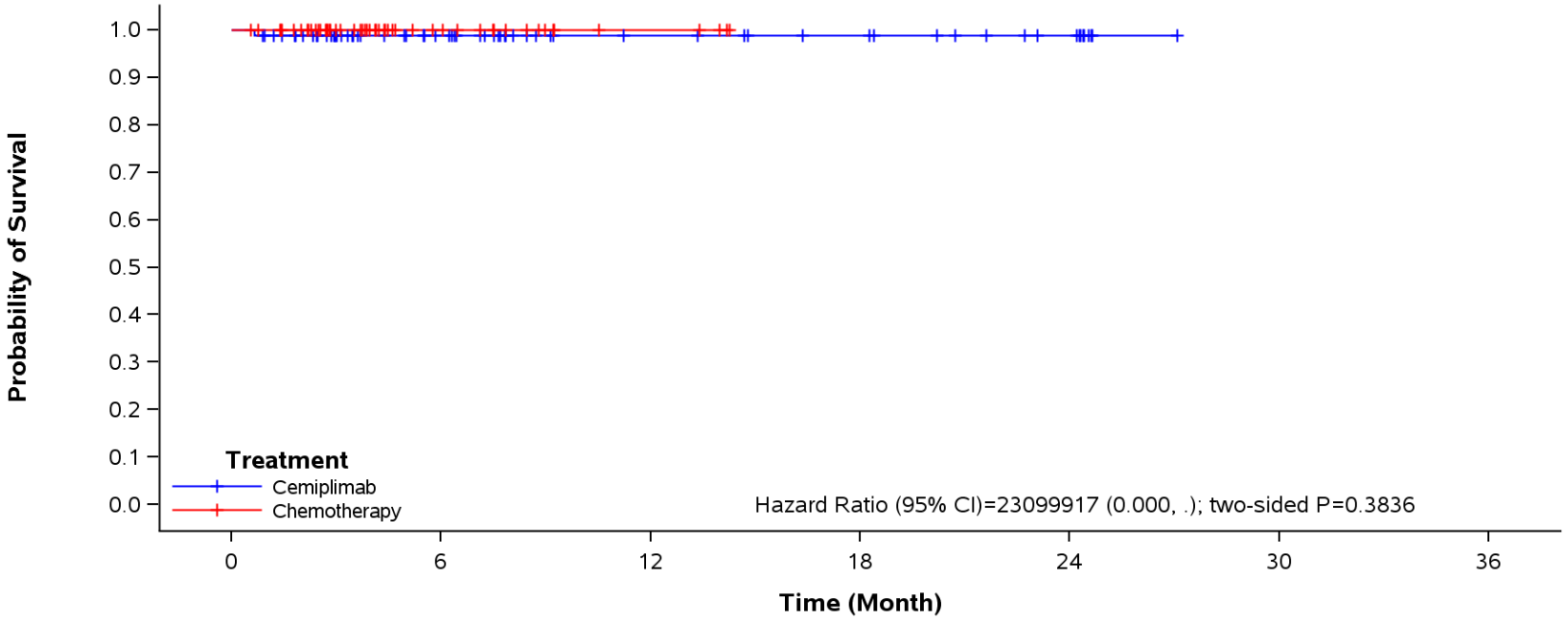

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0



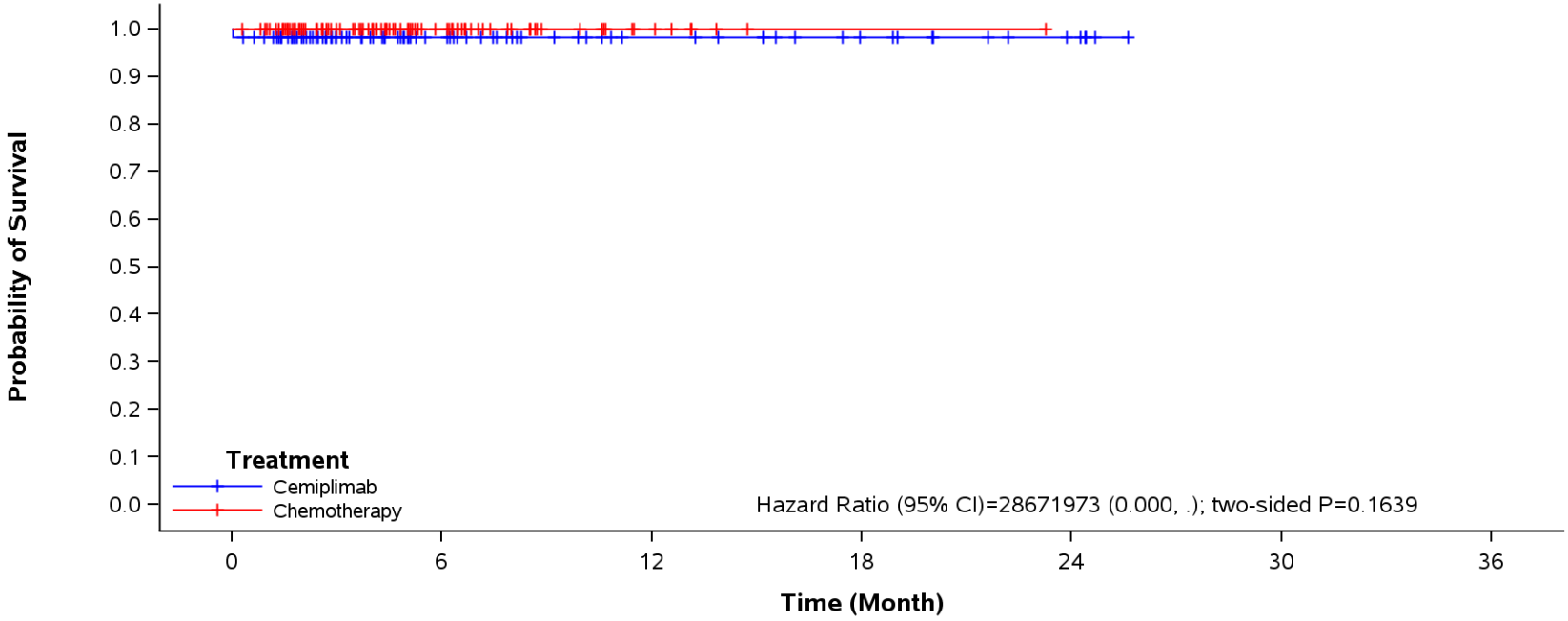

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1



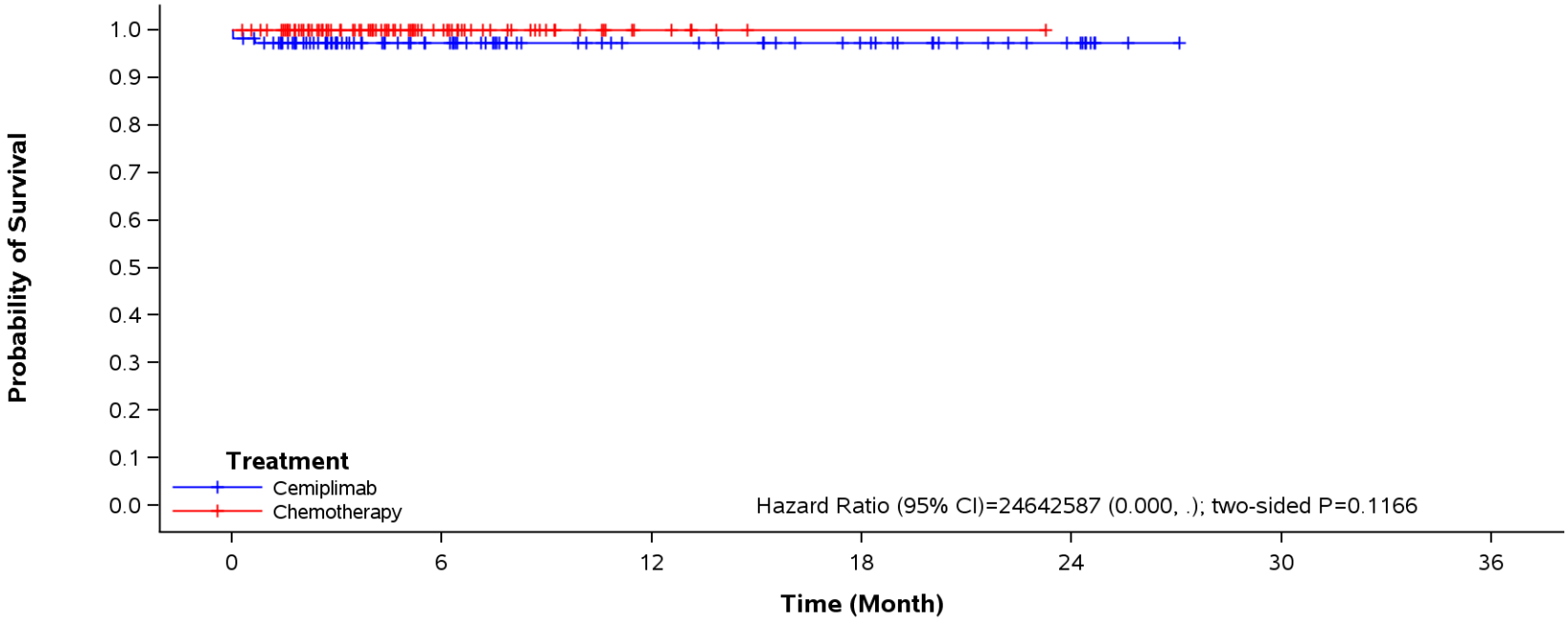

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line




**Number of Subjects at risk**

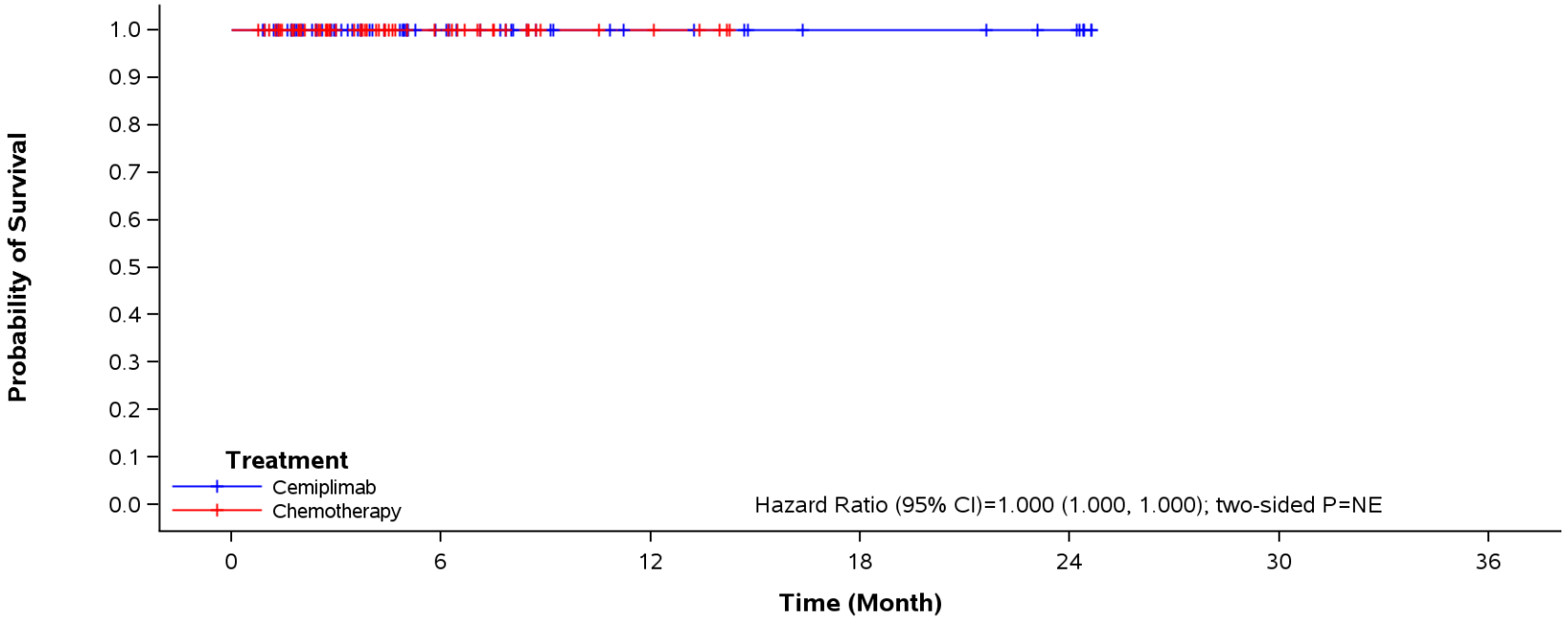
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line



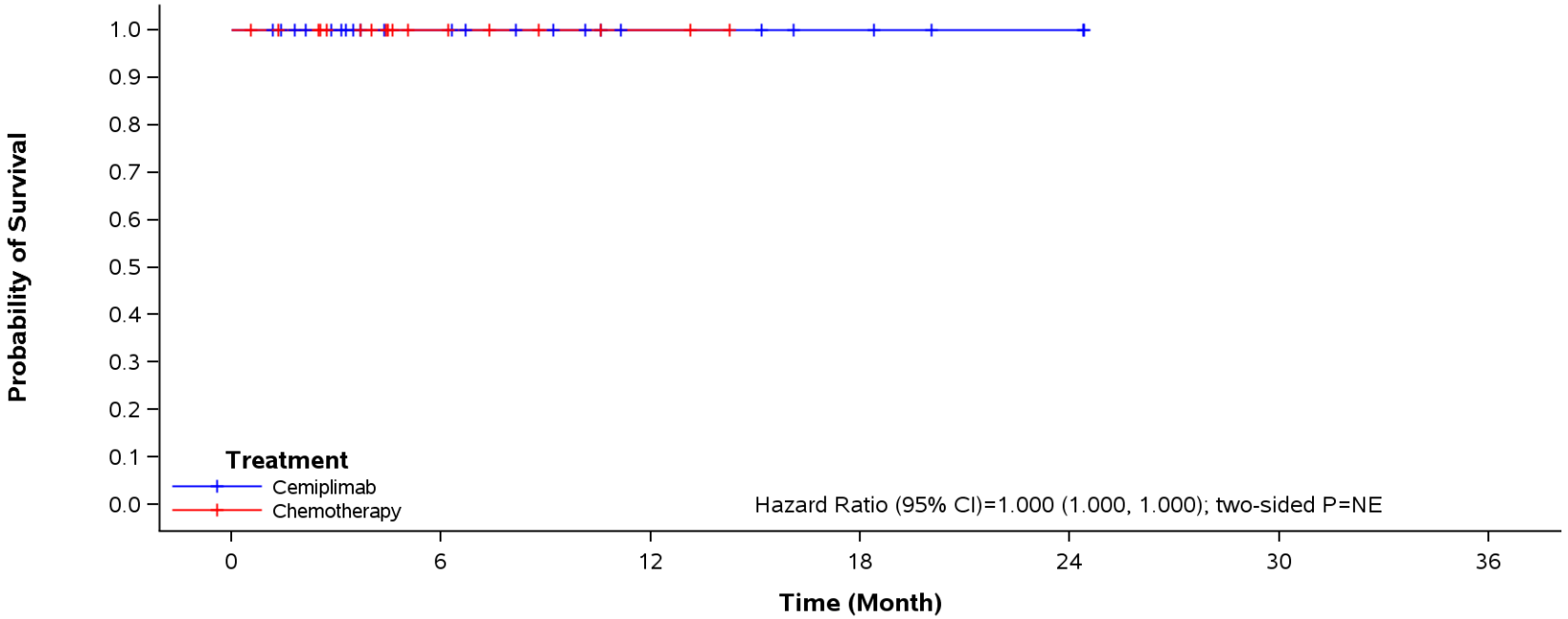

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



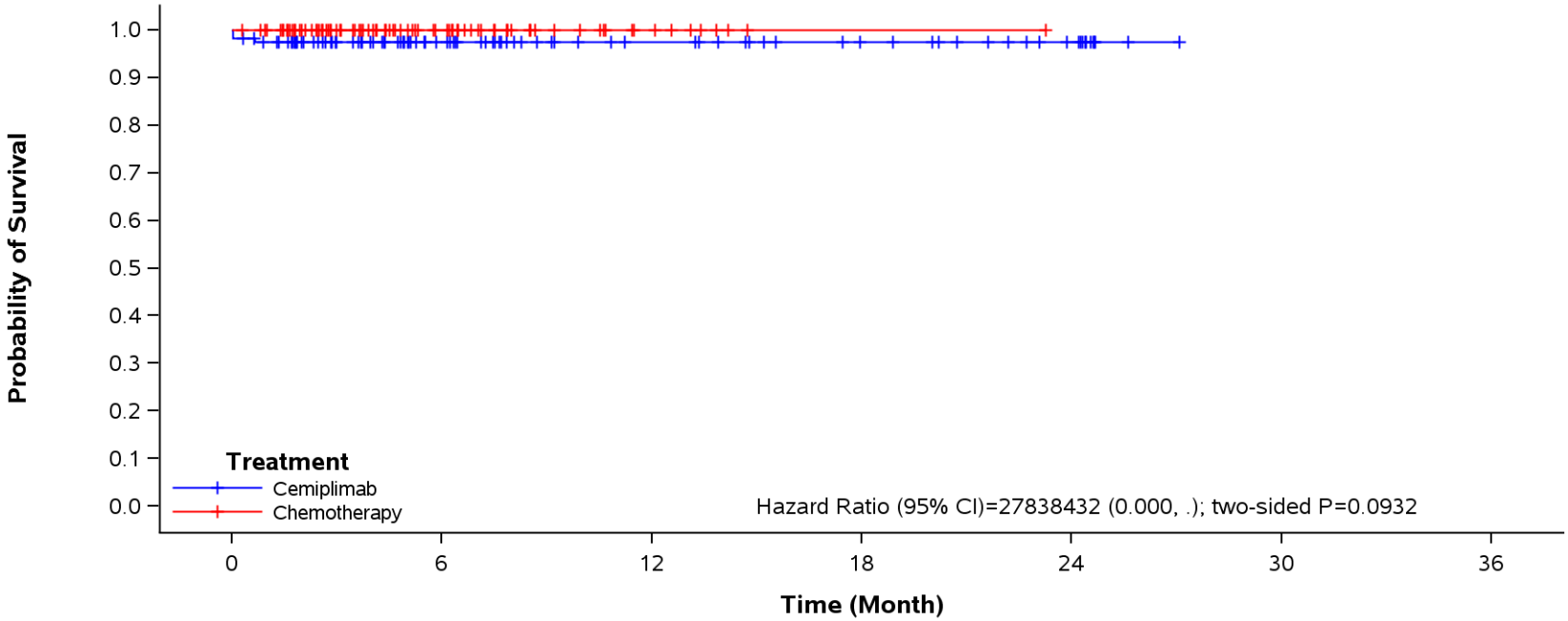

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed



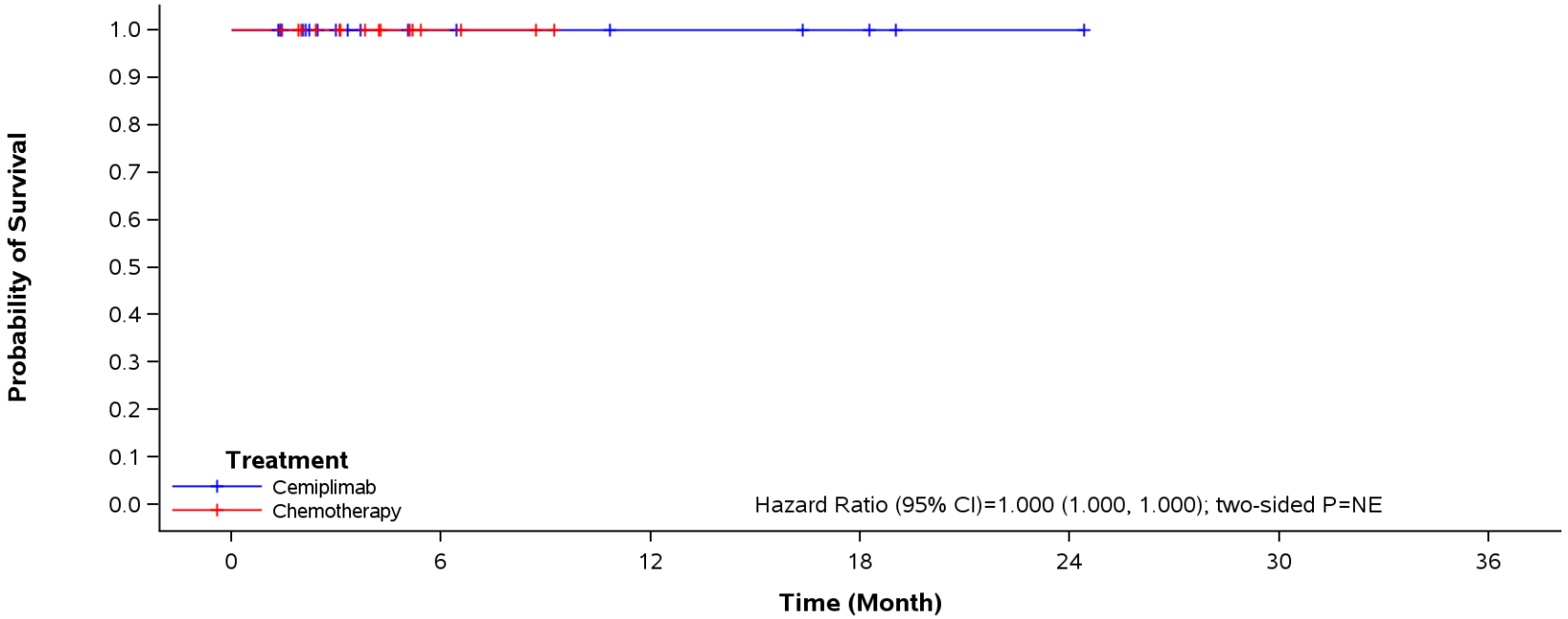

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan



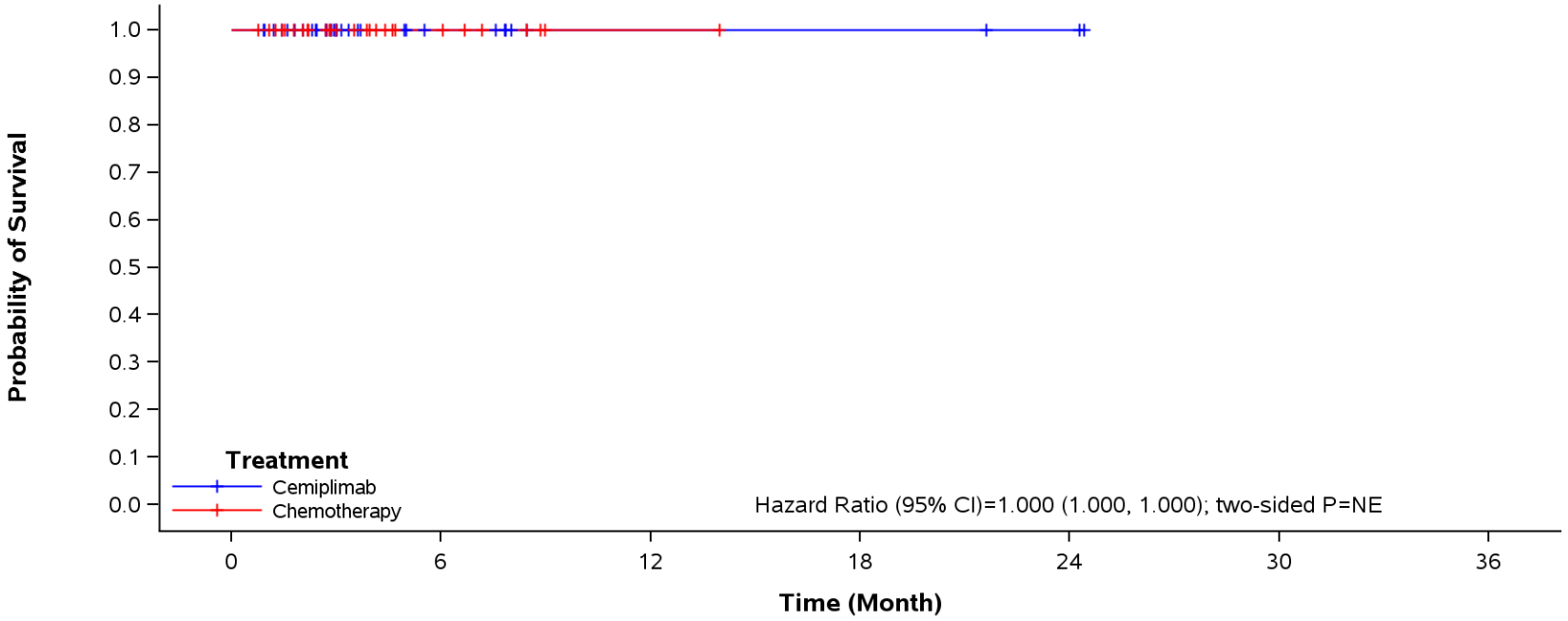

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine




**Number of Subjects at risk**

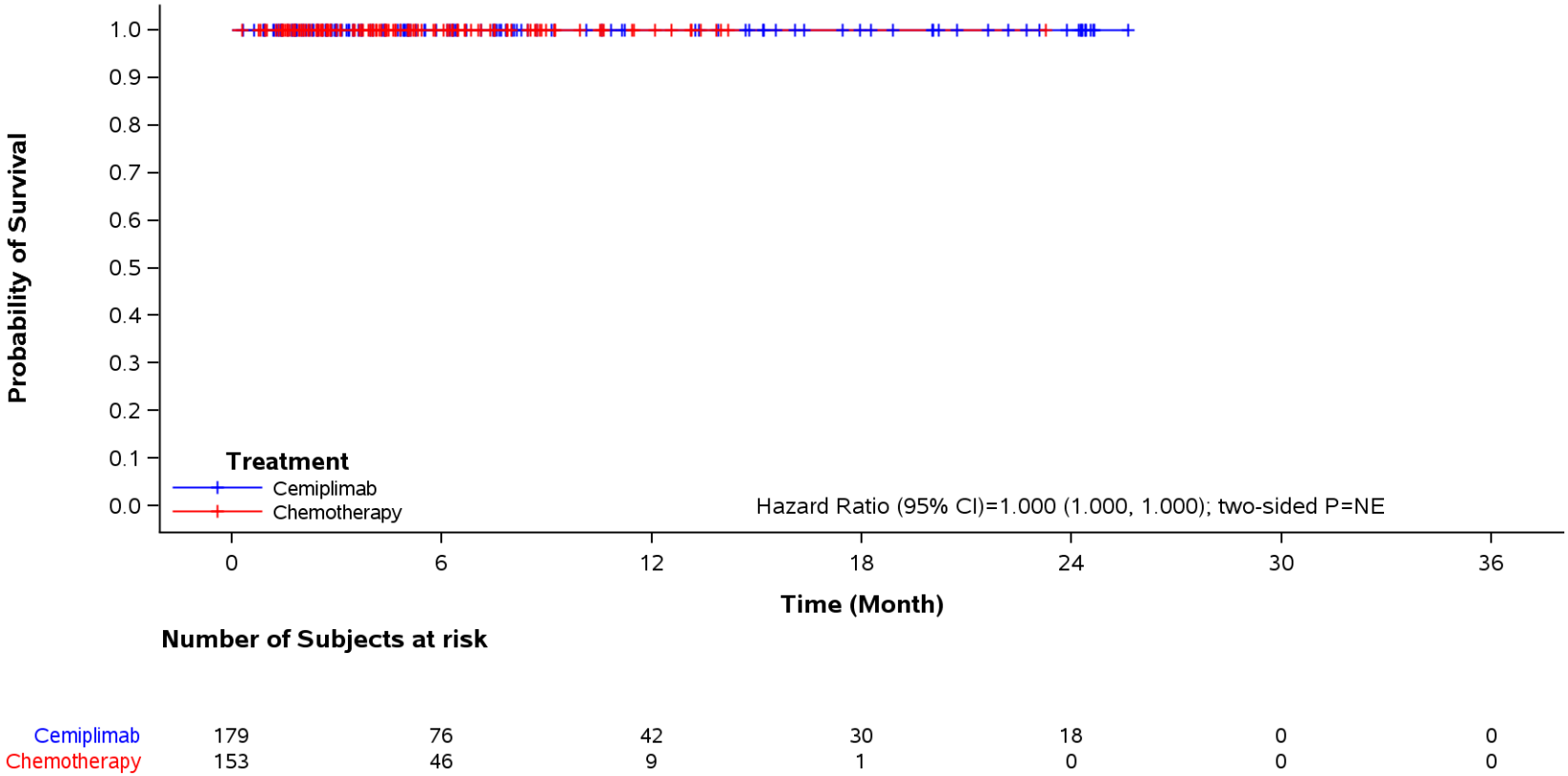
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



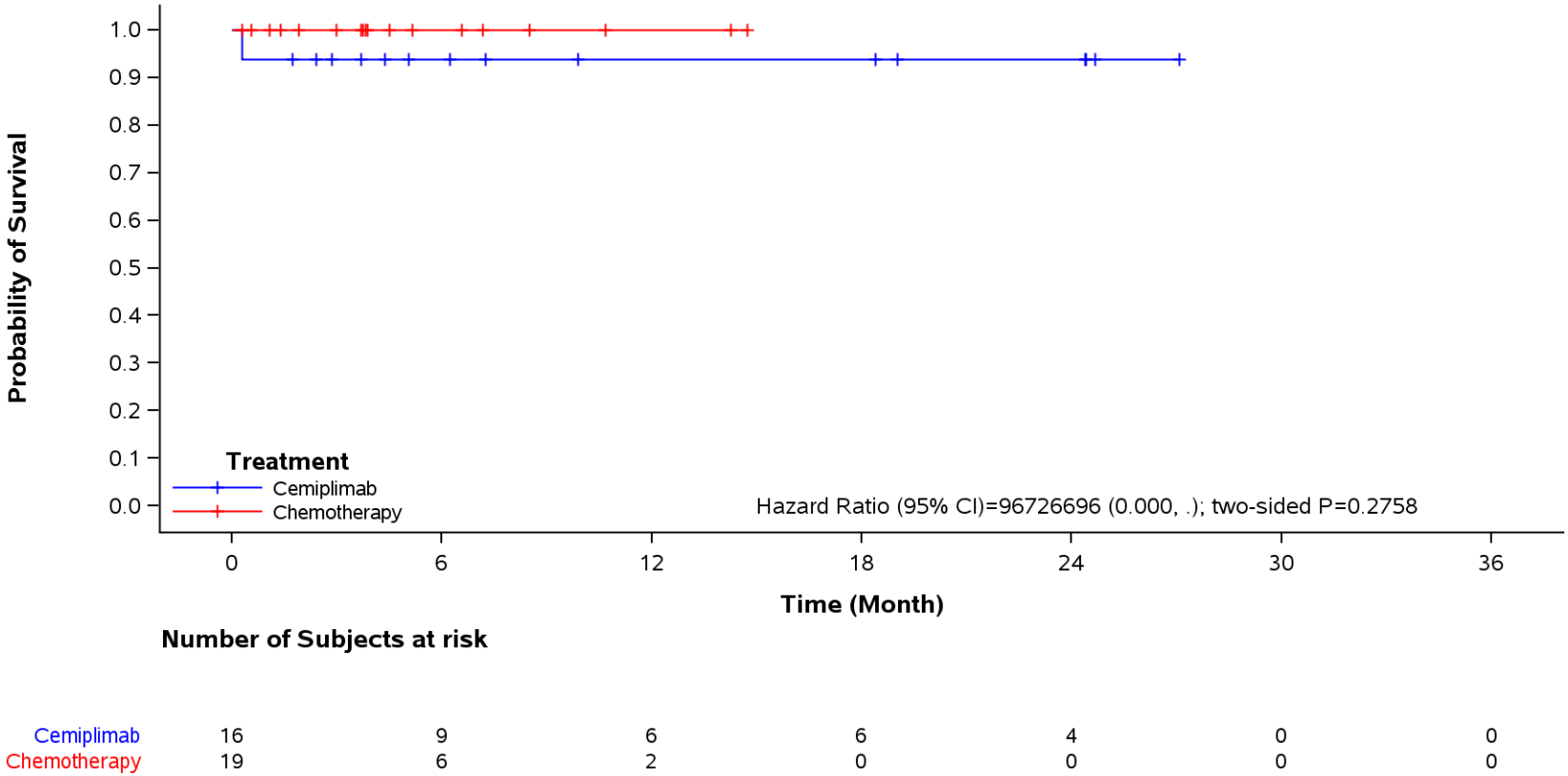

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



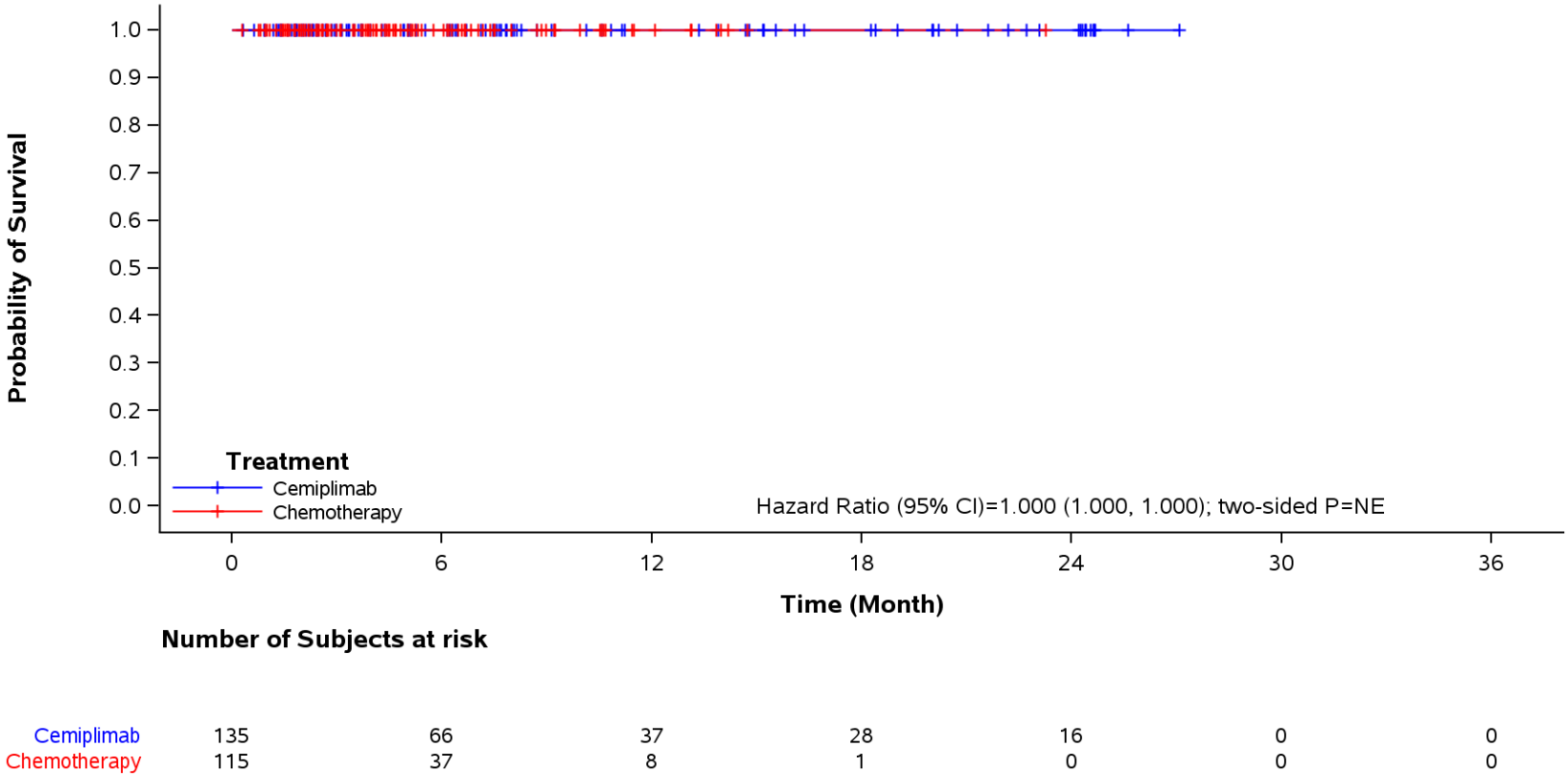

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



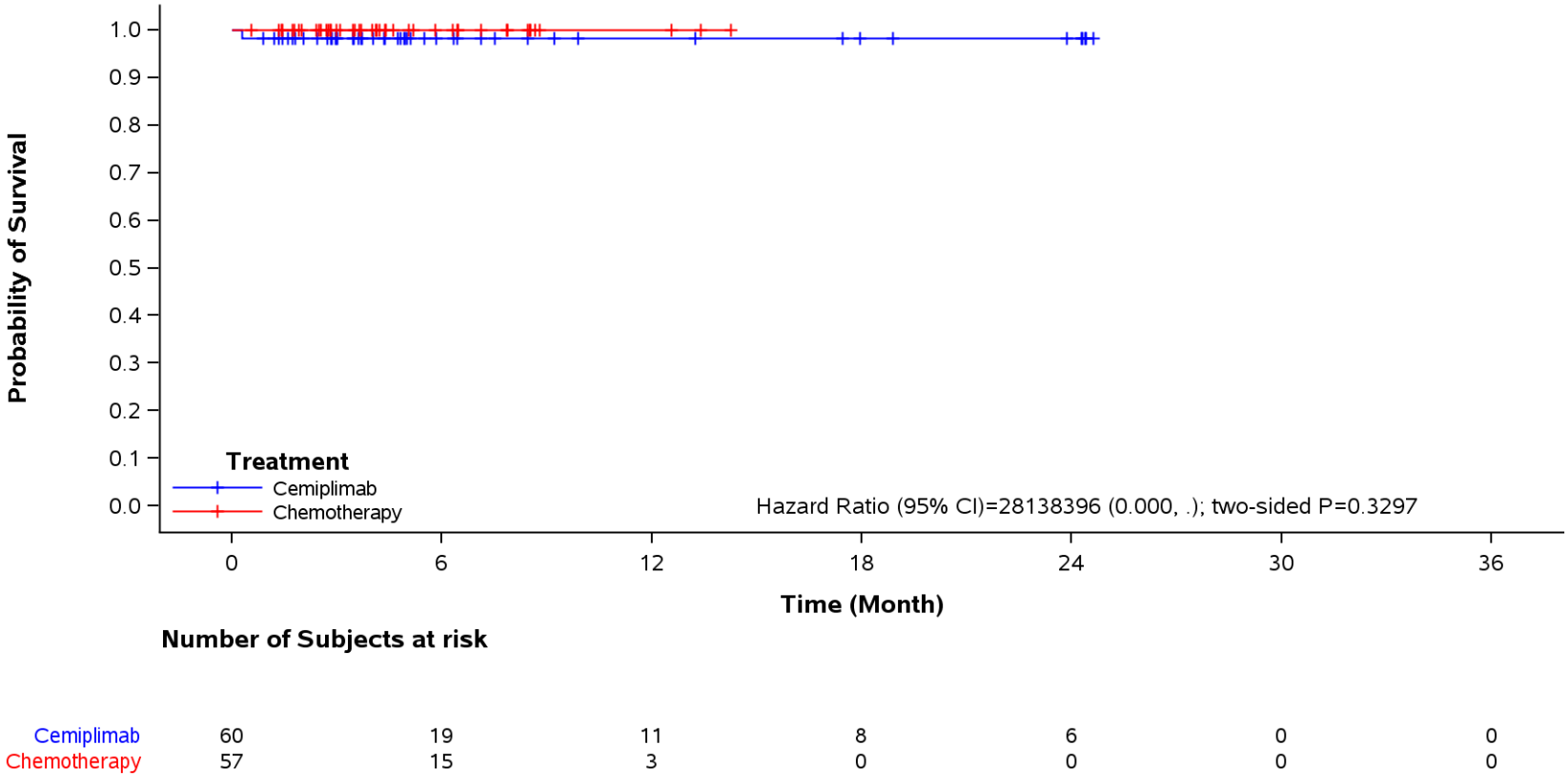

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



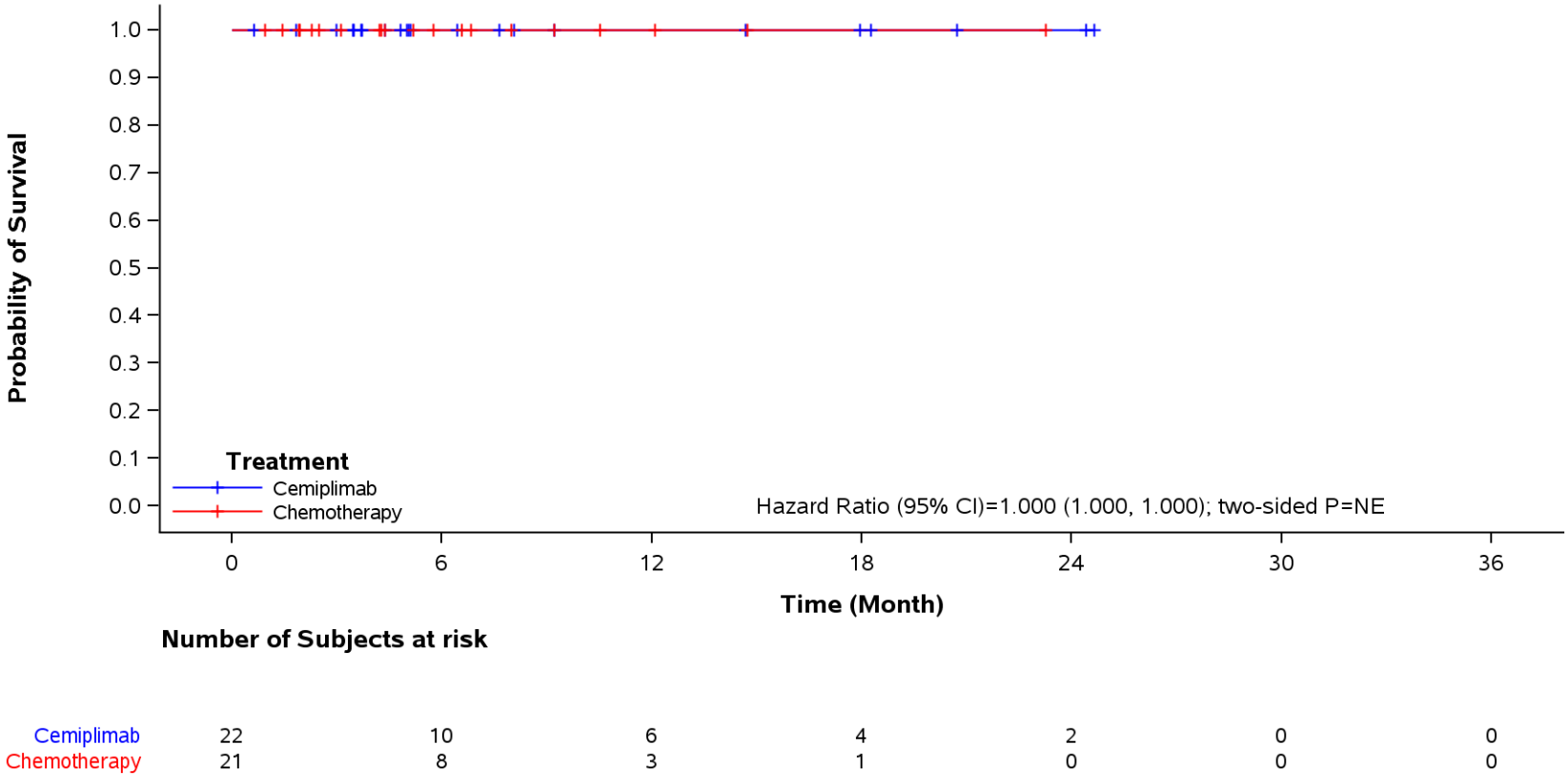

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America



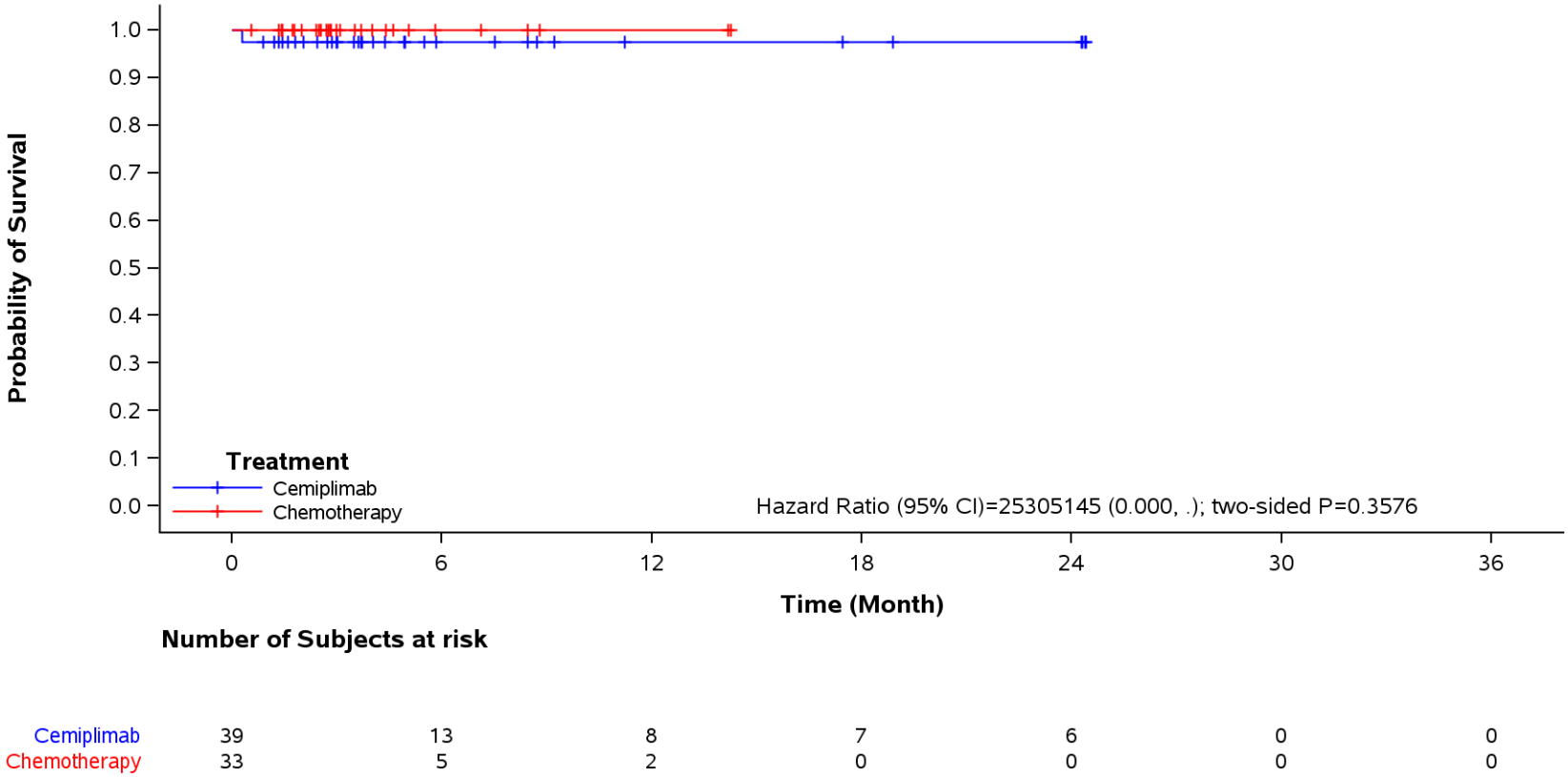

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia



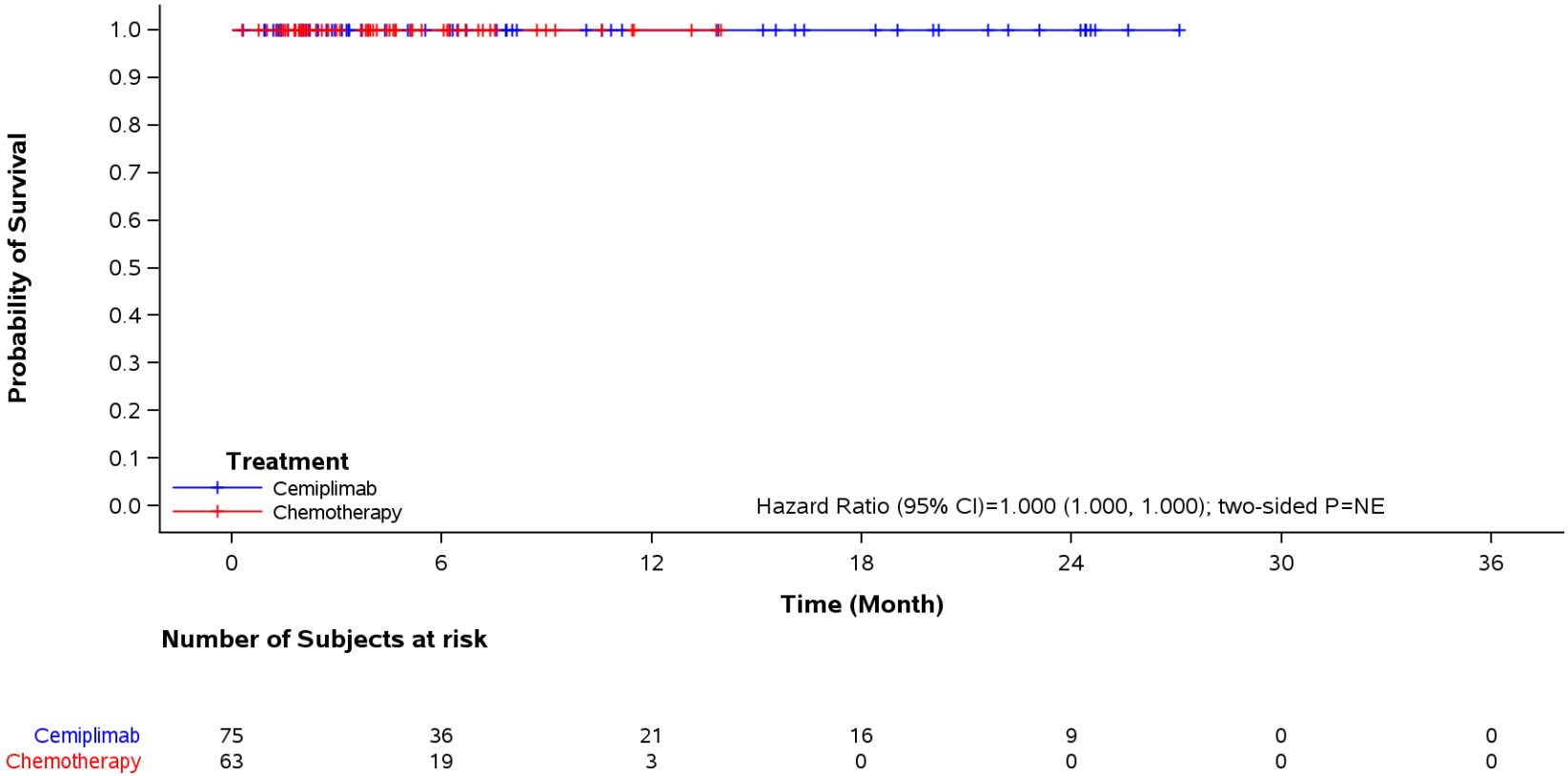

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



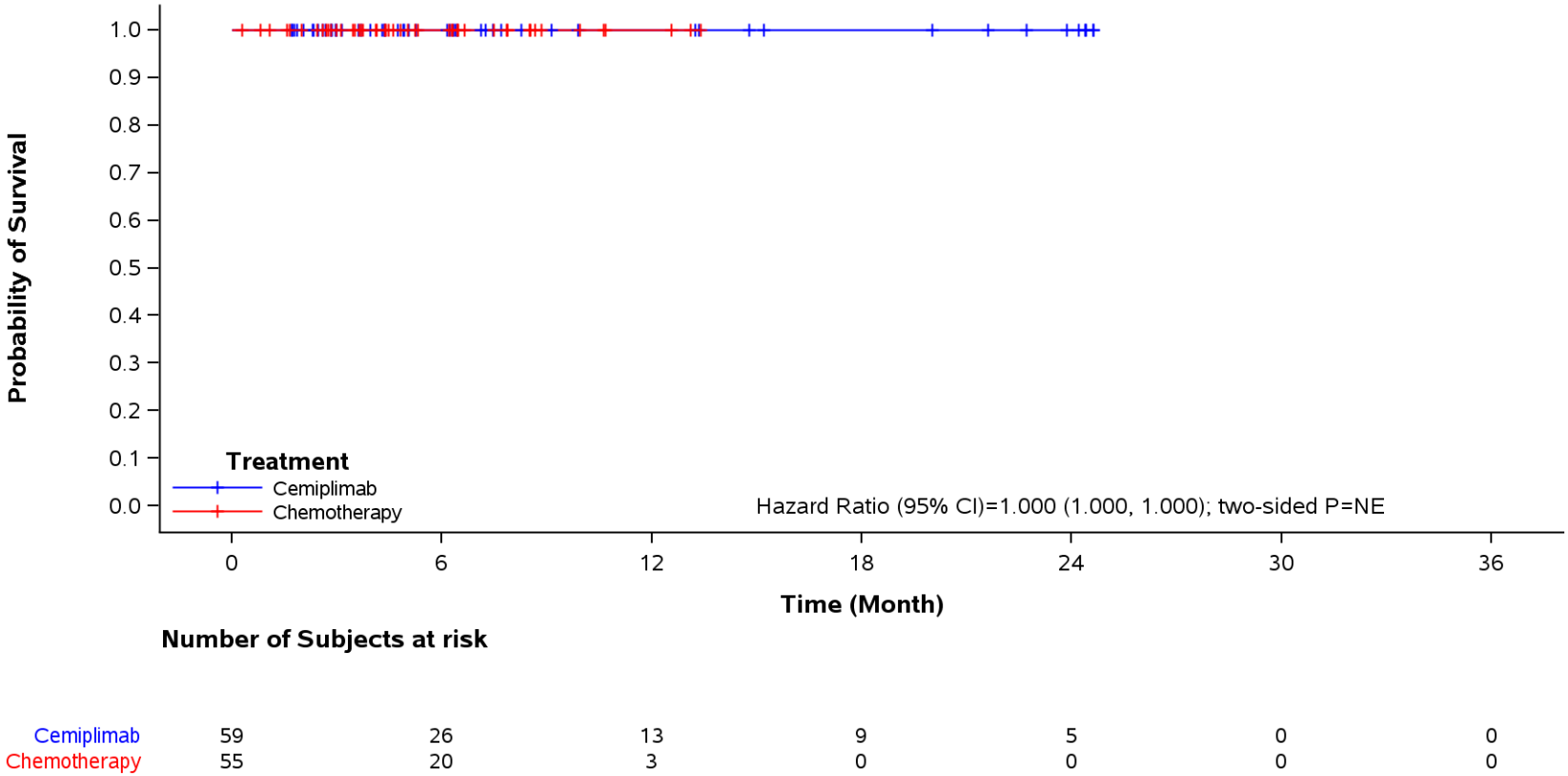

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW

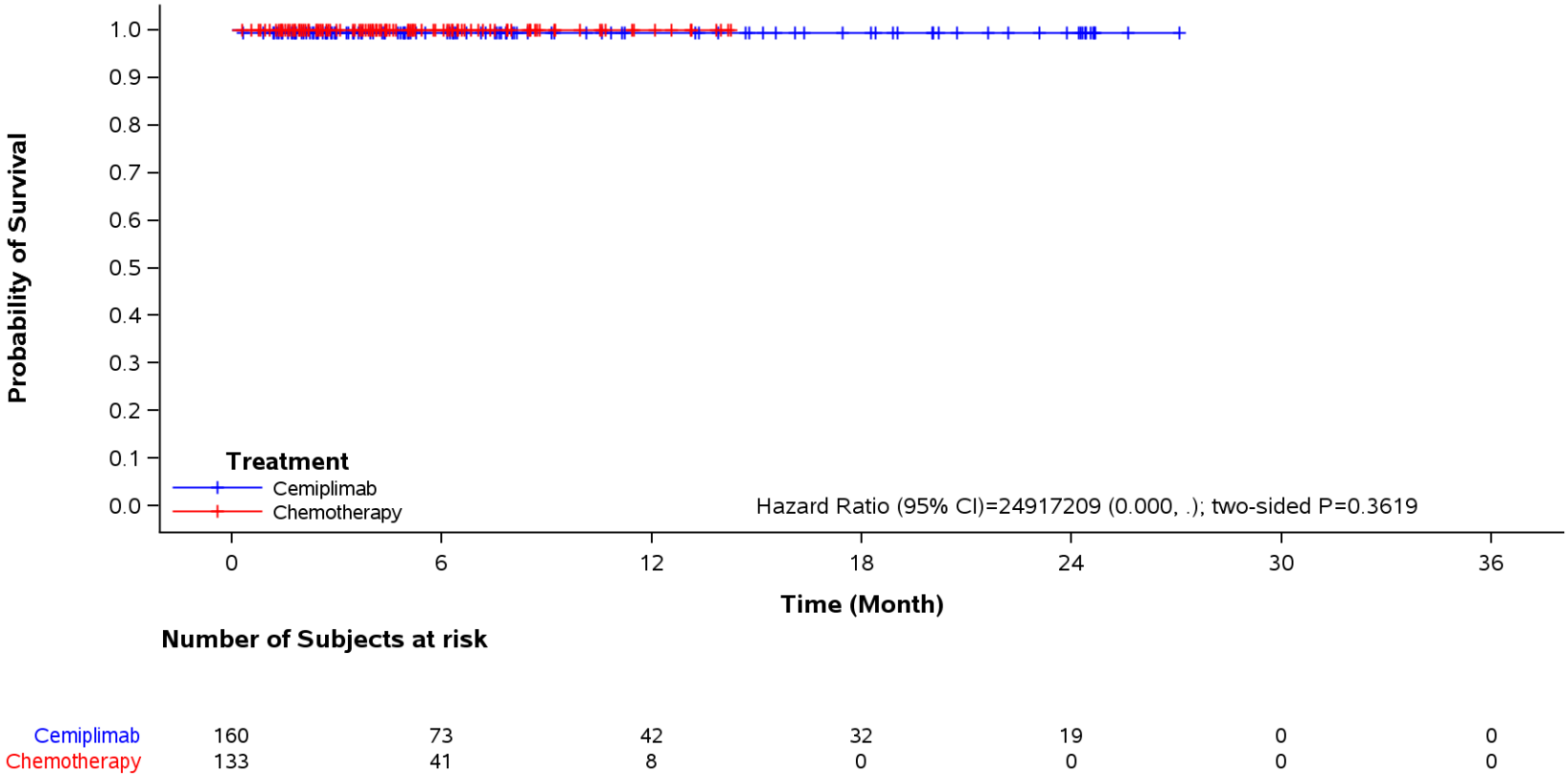



Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous

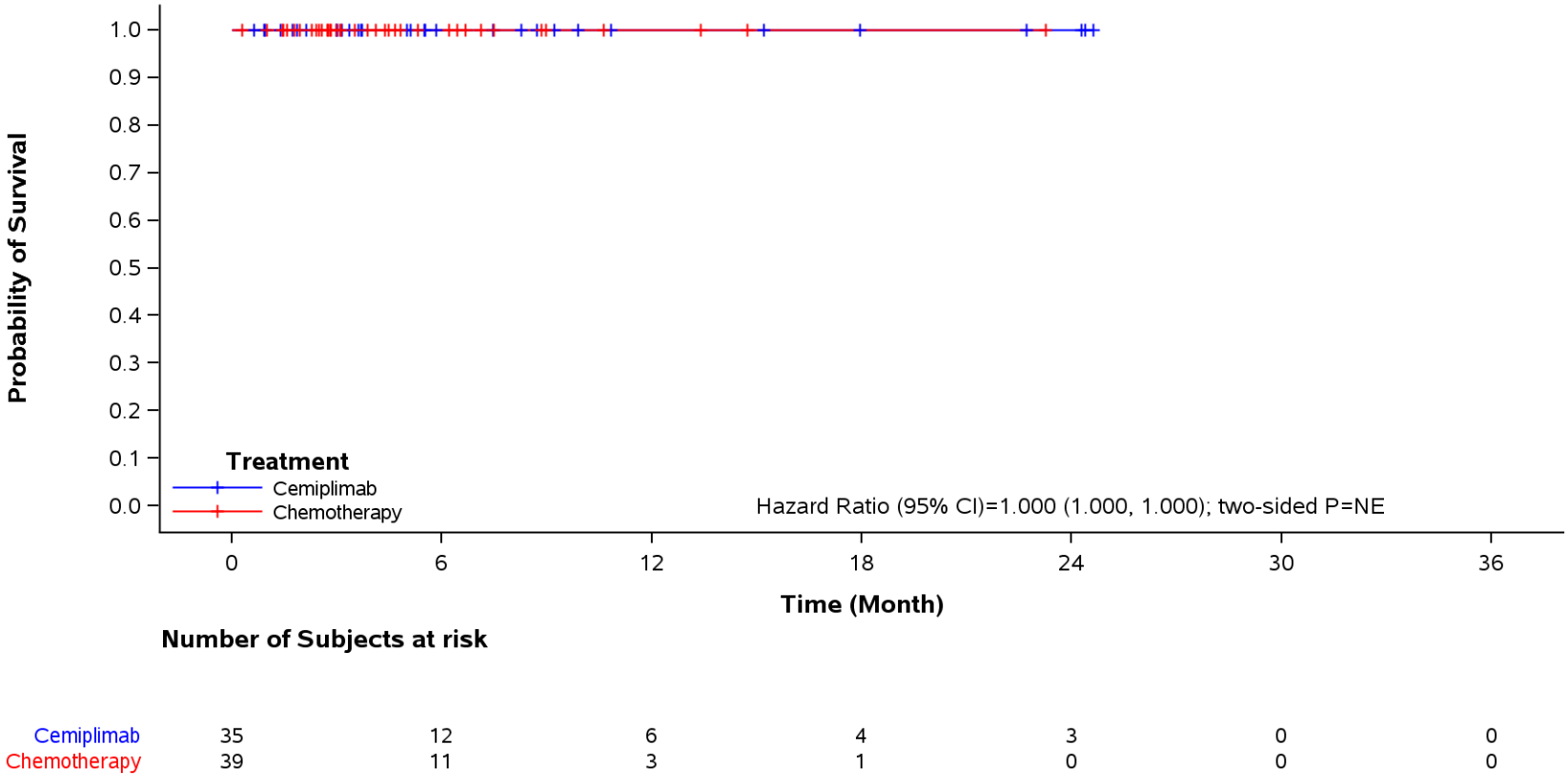



Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



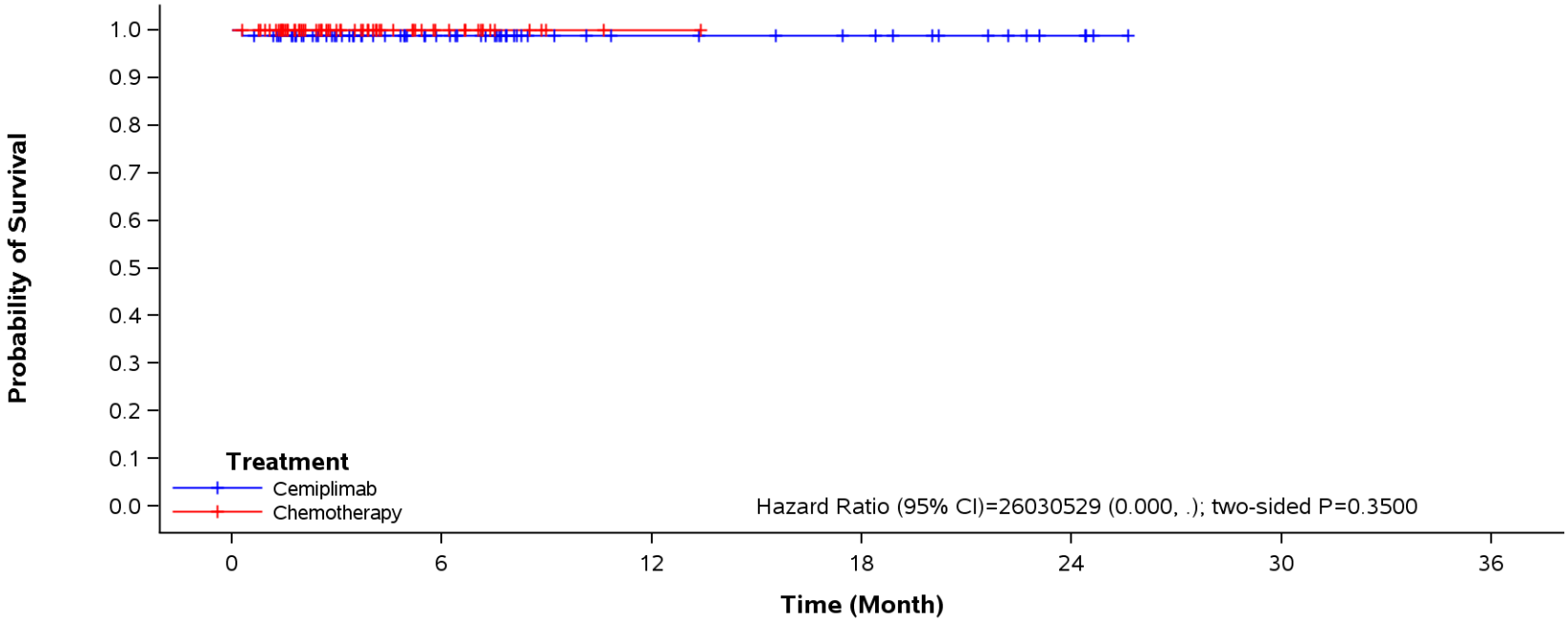

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

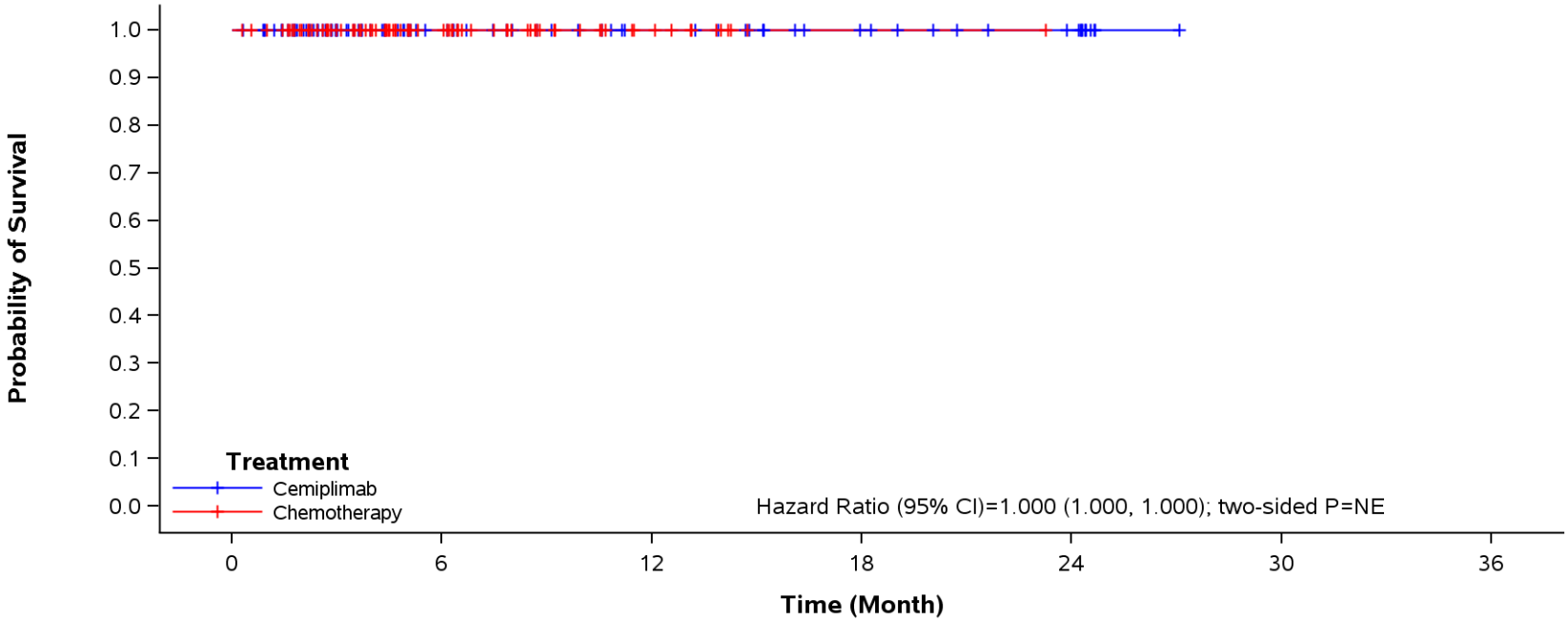
Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

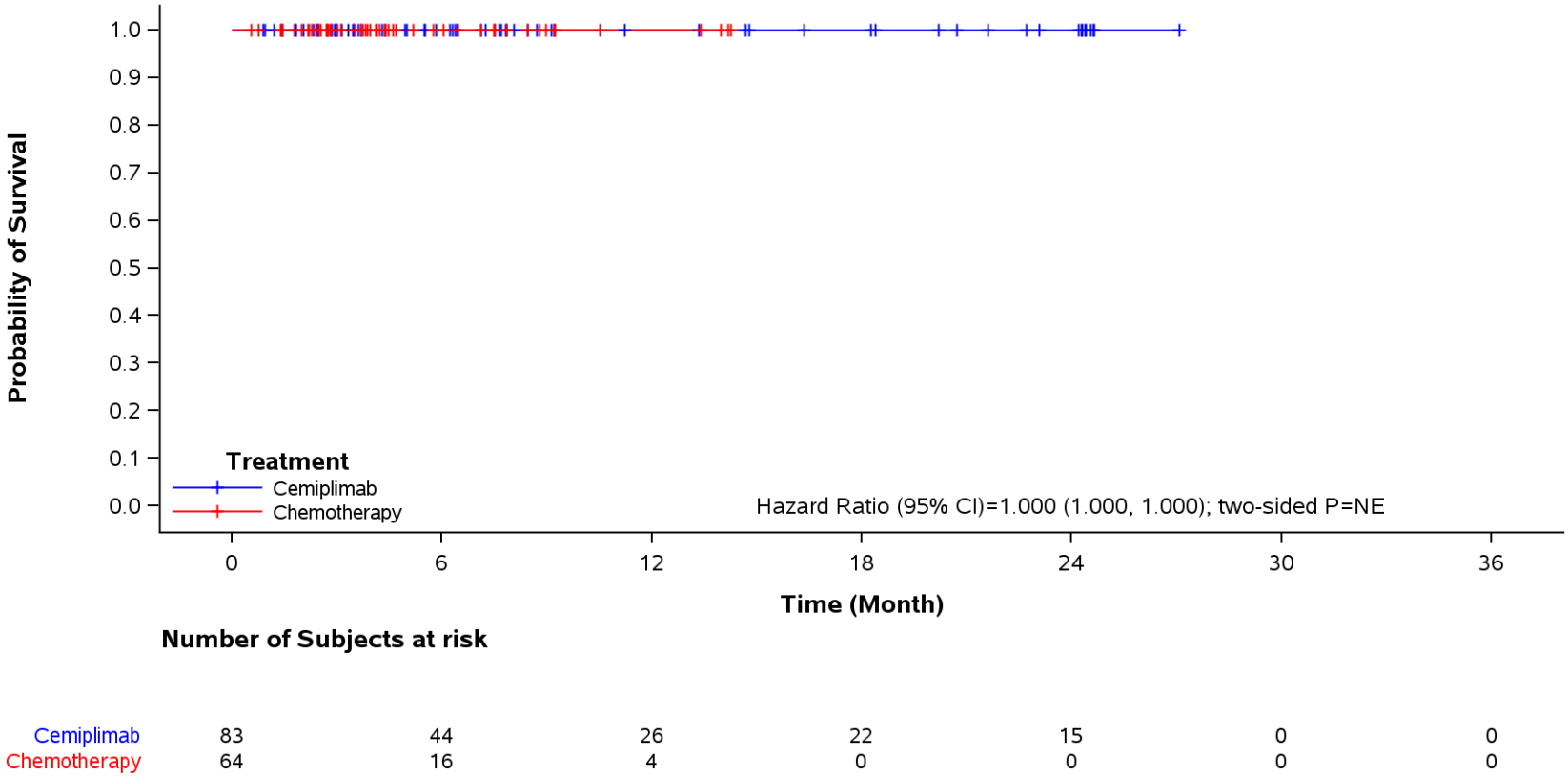
Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

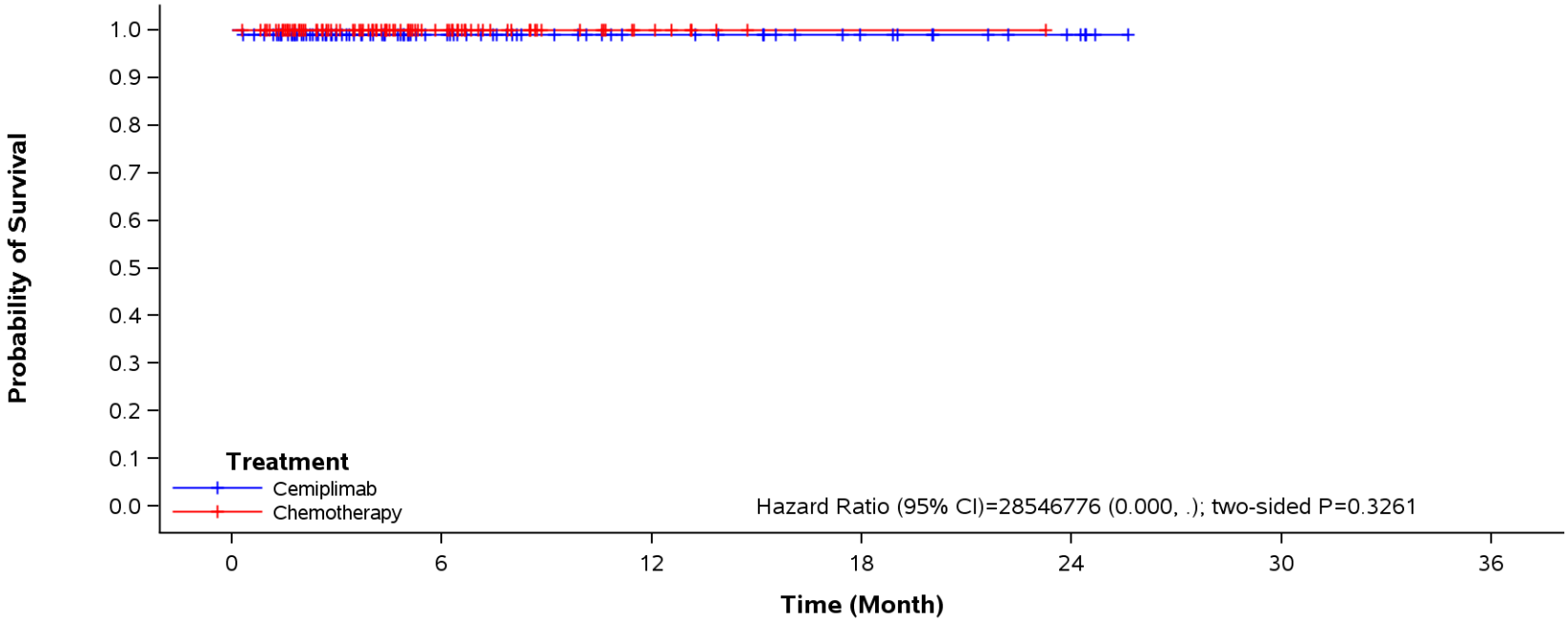



Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1




Number of Subjects at risk

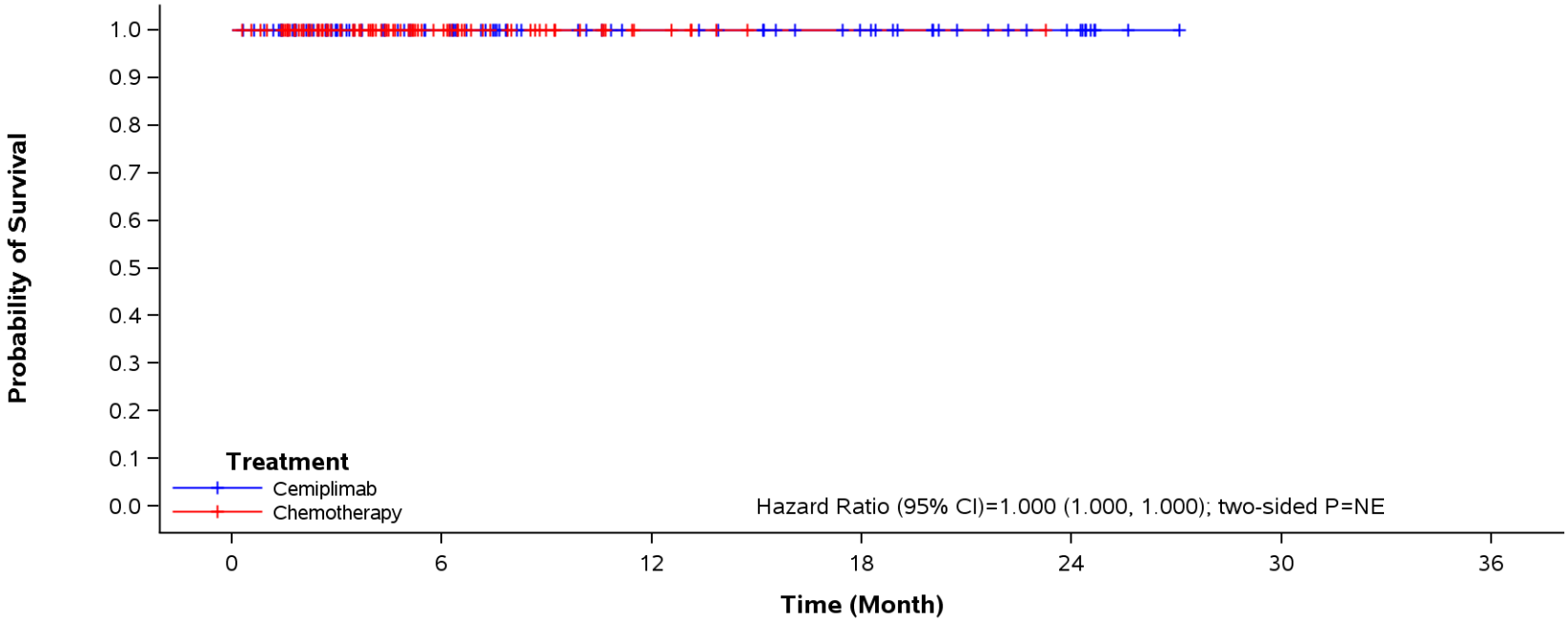
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

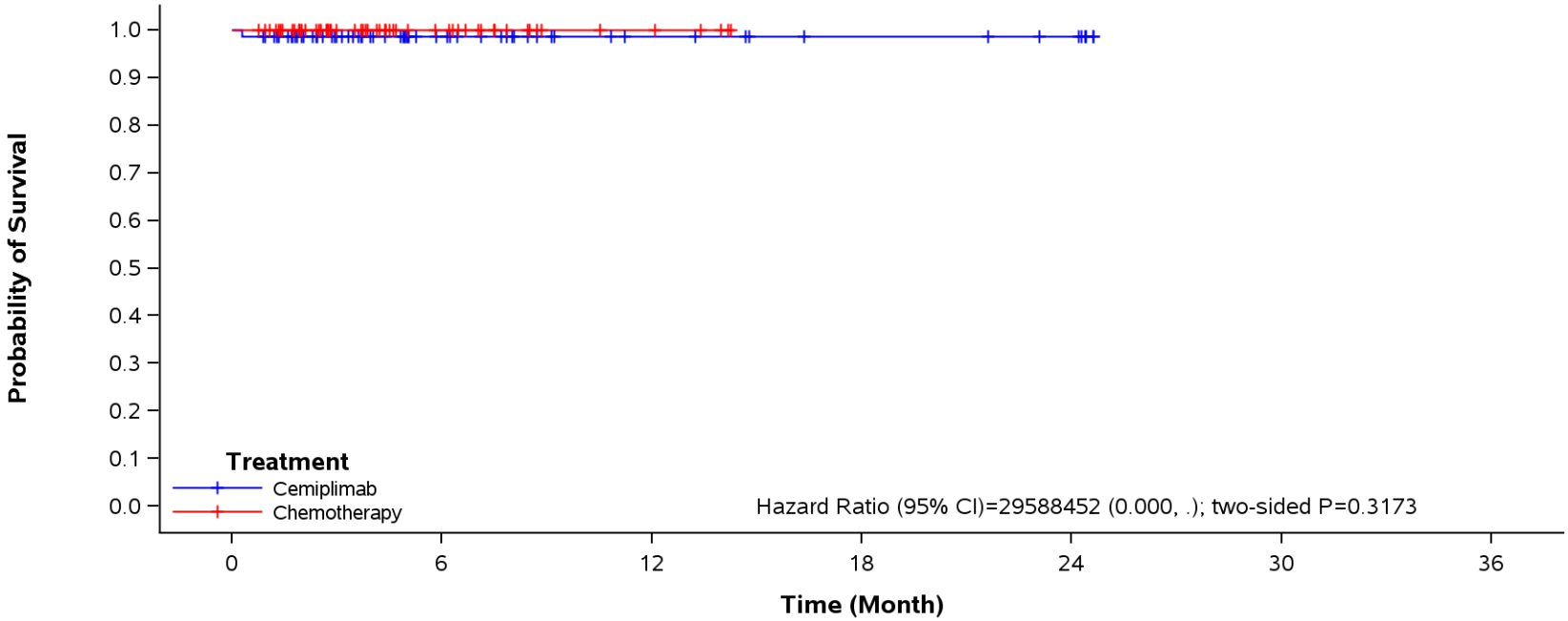
Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

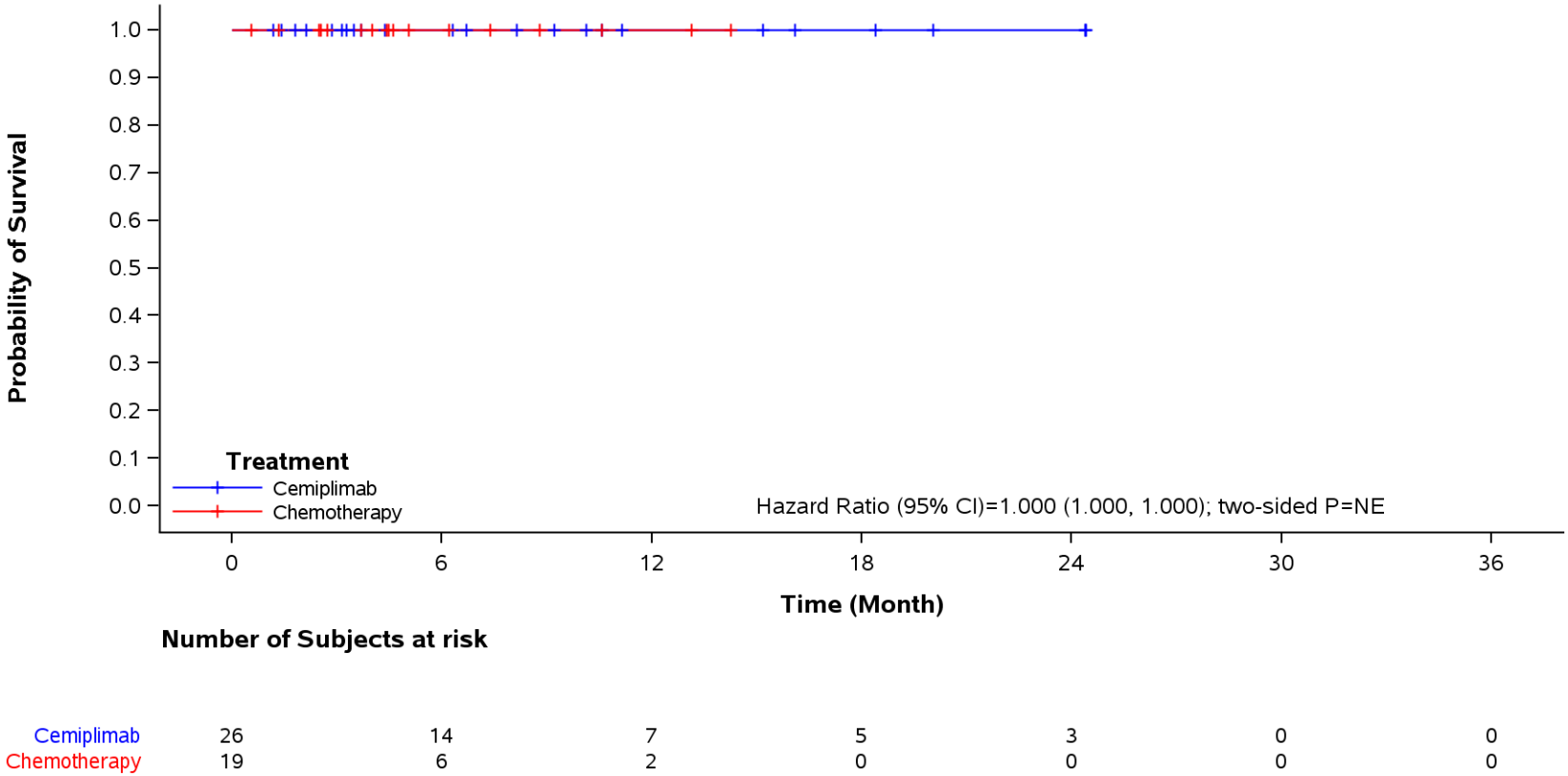
Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



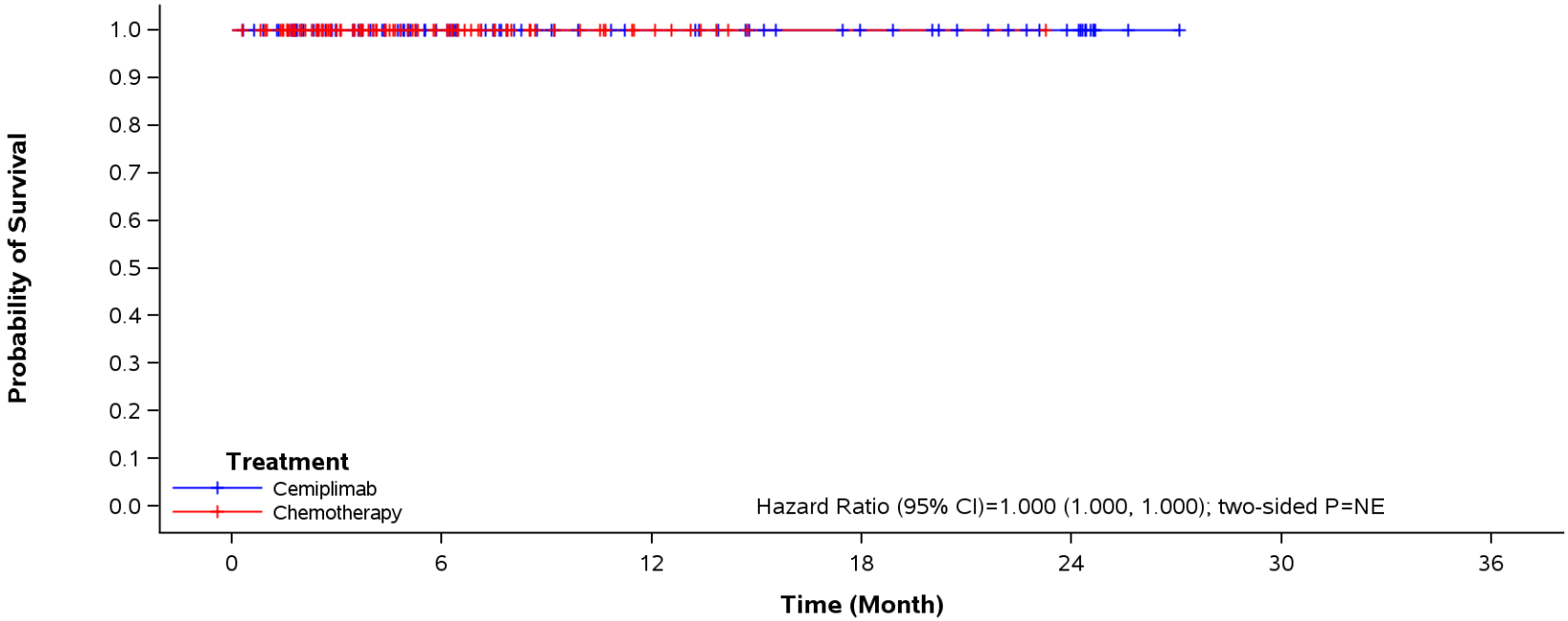

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

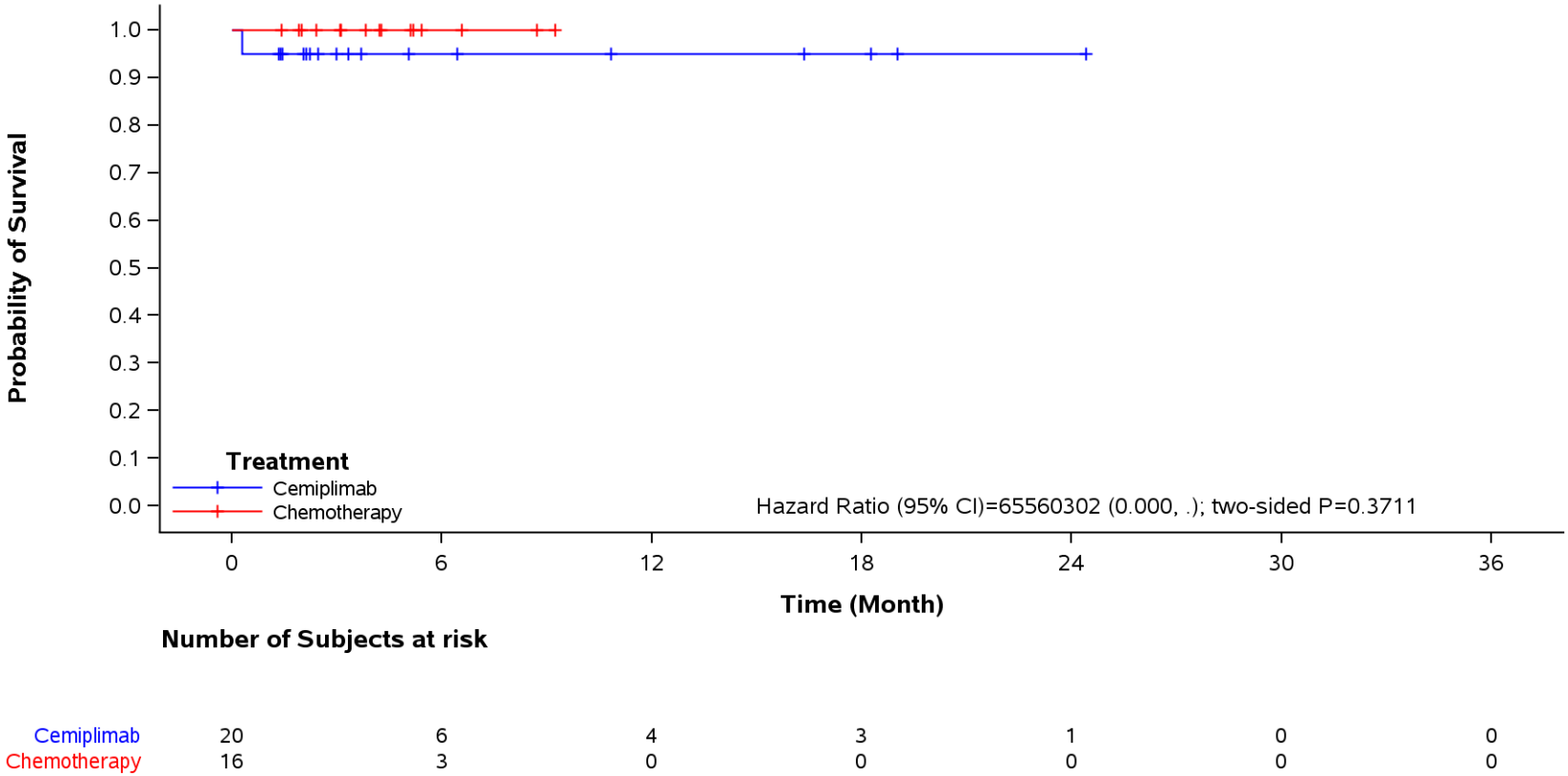
Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan



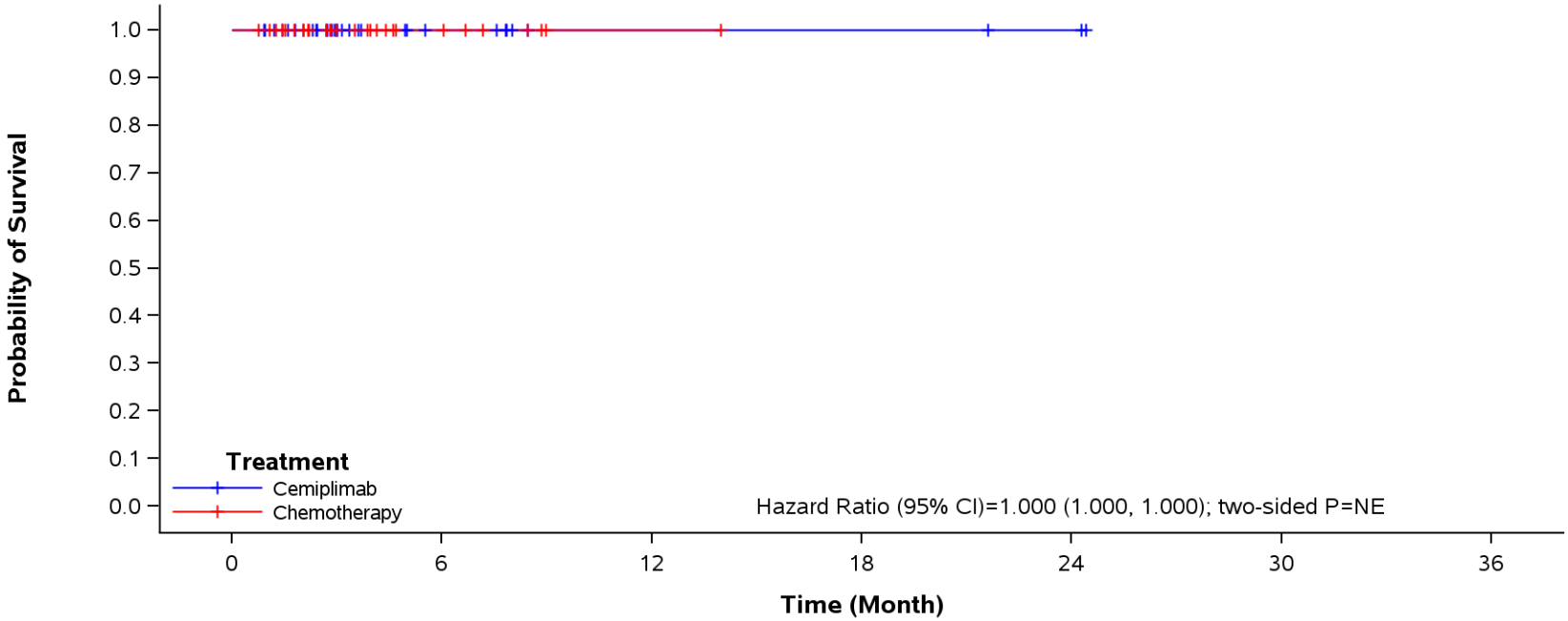

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2) by Subgroup without PD-L1

(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine




**Number of Subjects at risk**

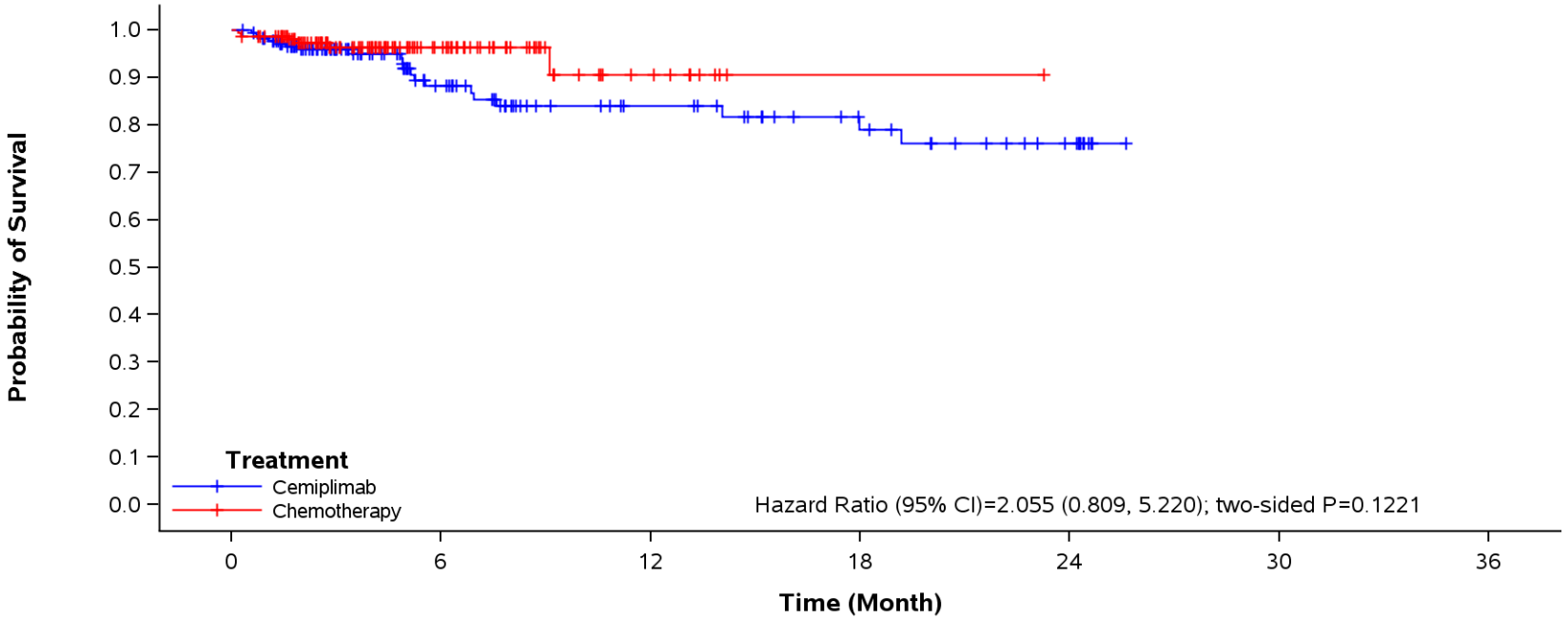
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: <65



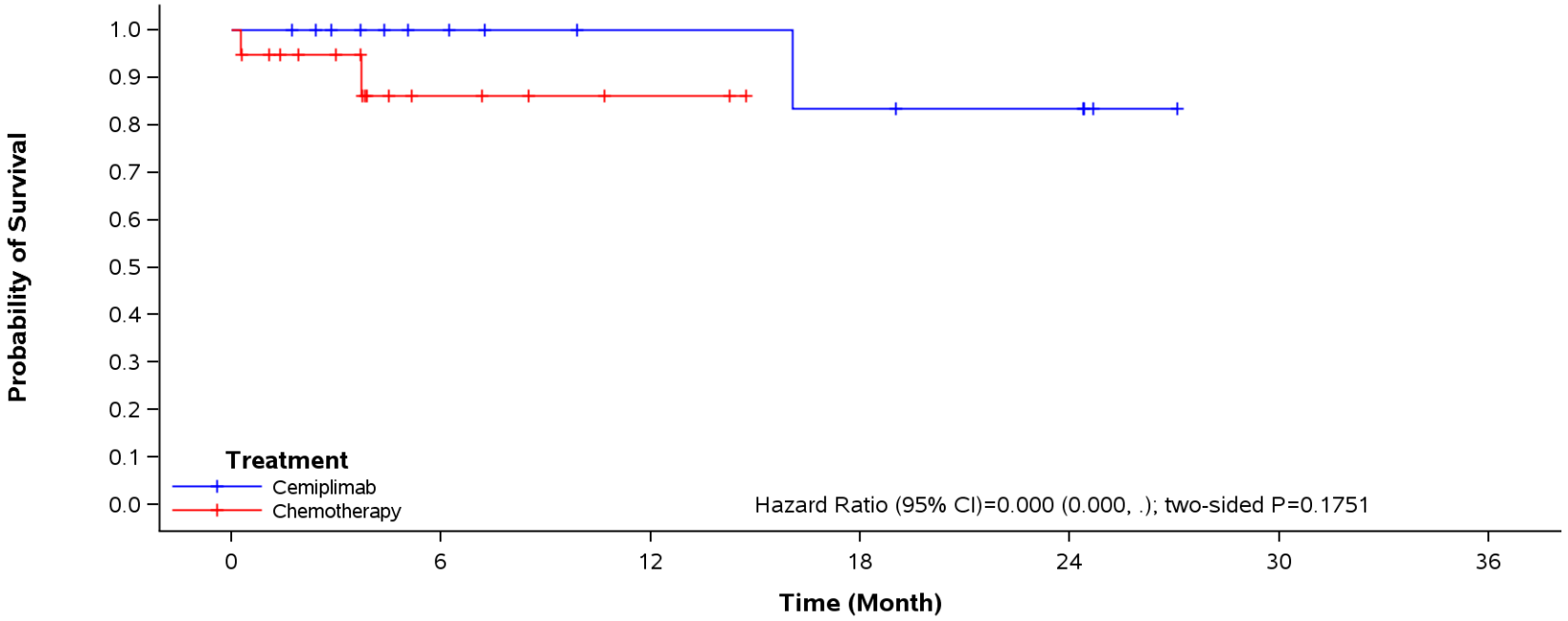

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 69 | 42 | 29 | 18 | 0 | 0 |
| Chemotherapy | 153 | 45 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age group: >=65



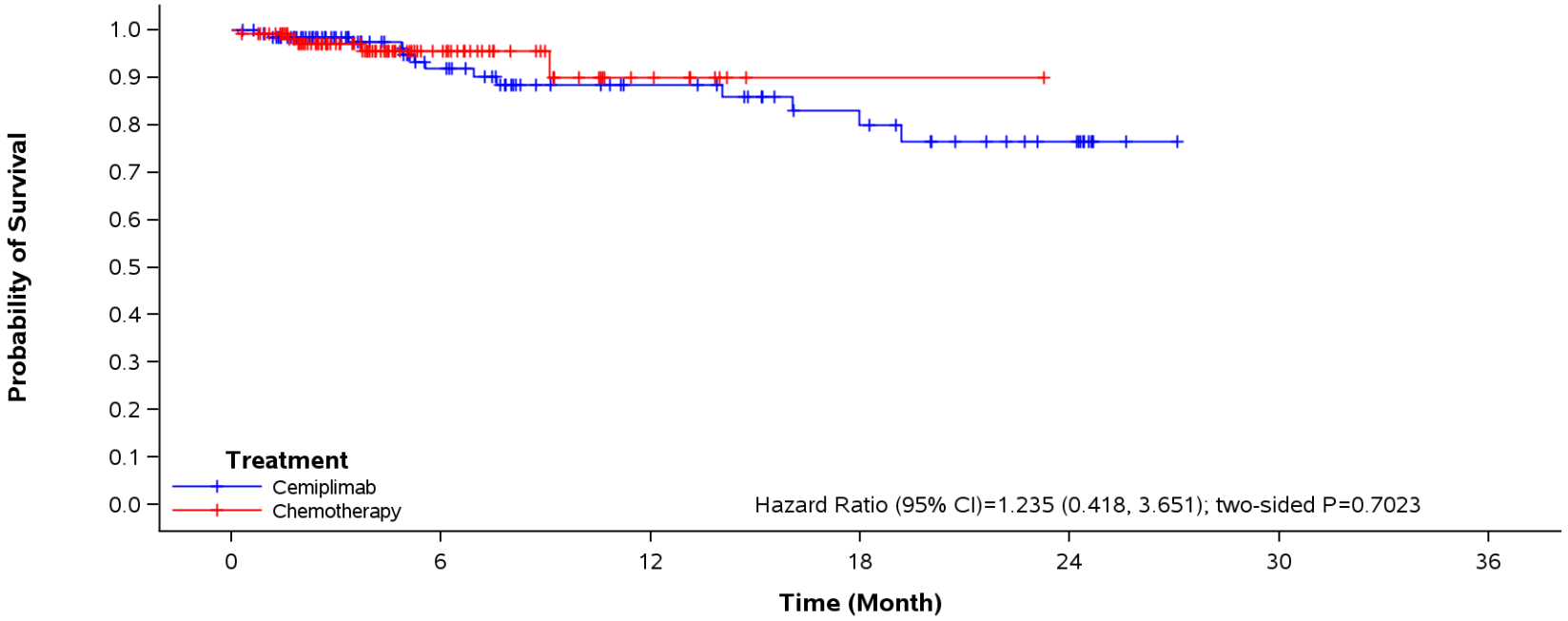

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 4 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White



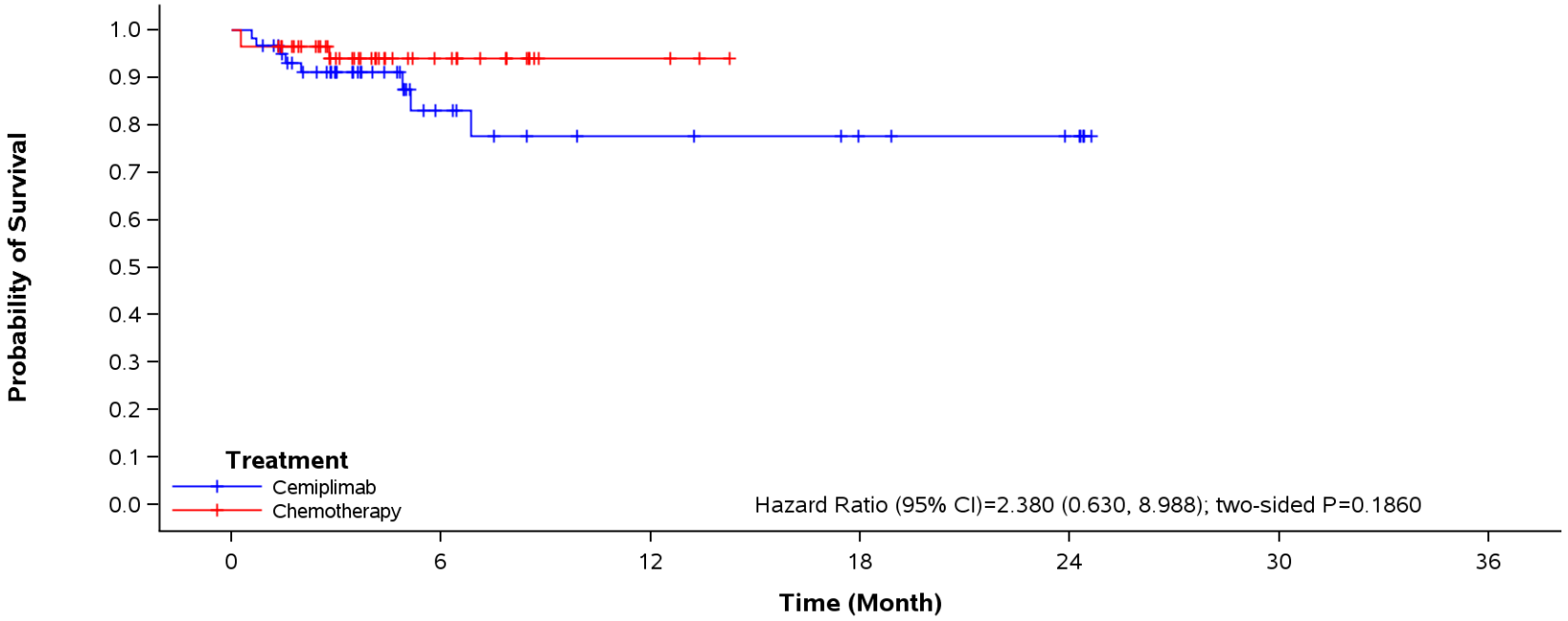

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 61 | 37 | 26 | 16 | 0 | 0 |
| Chemotherapy | 115 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-white



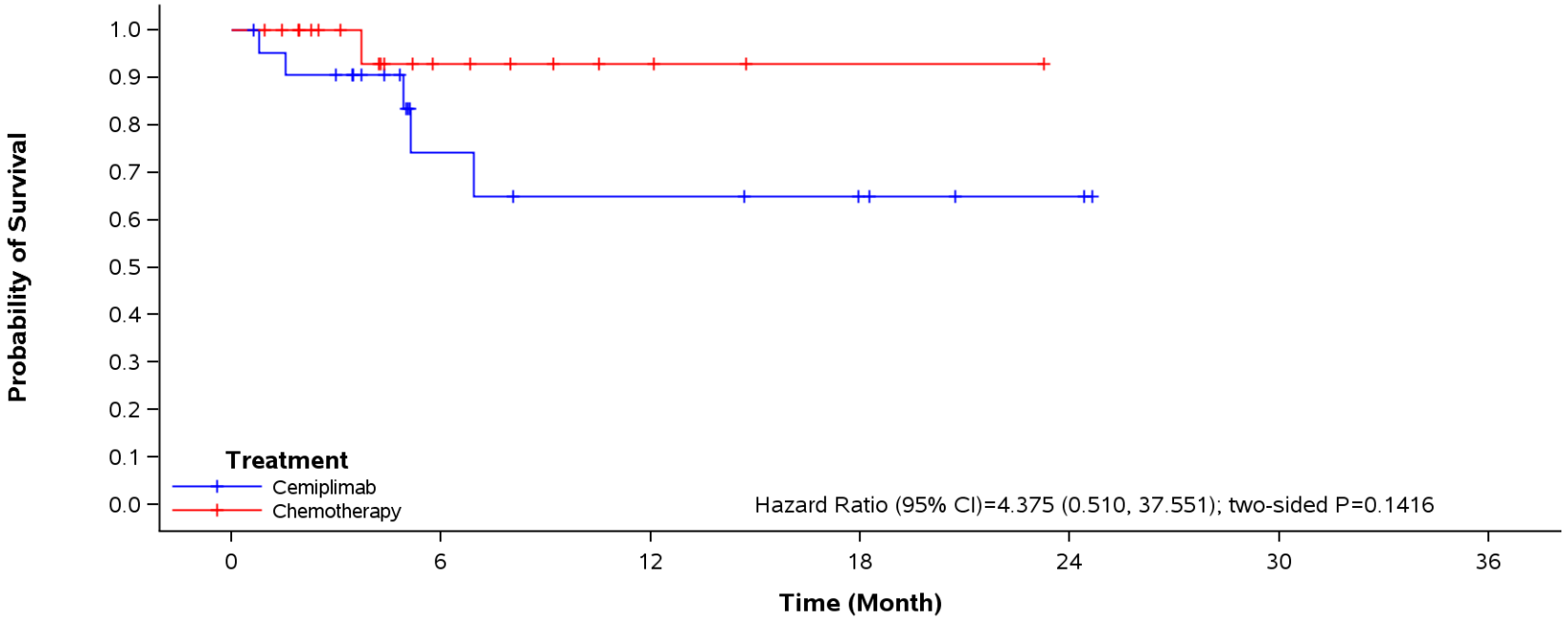

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 17 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America



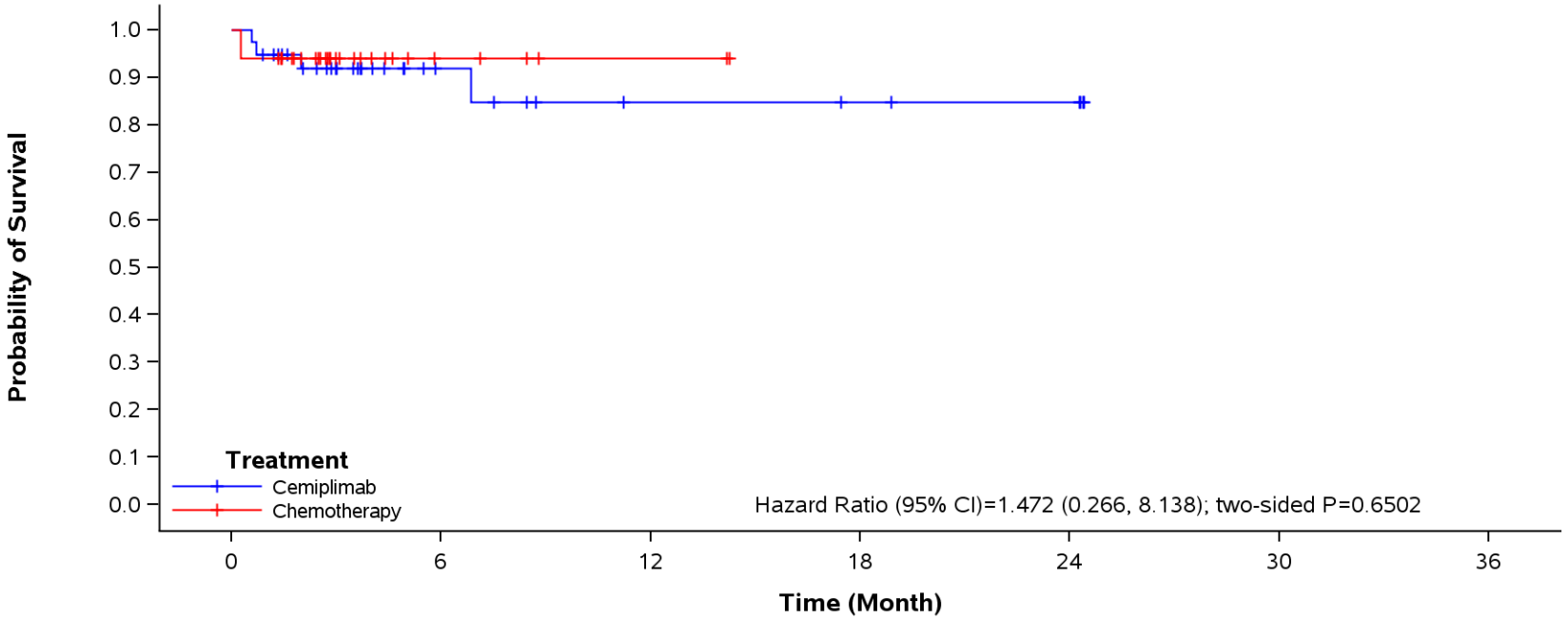

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia



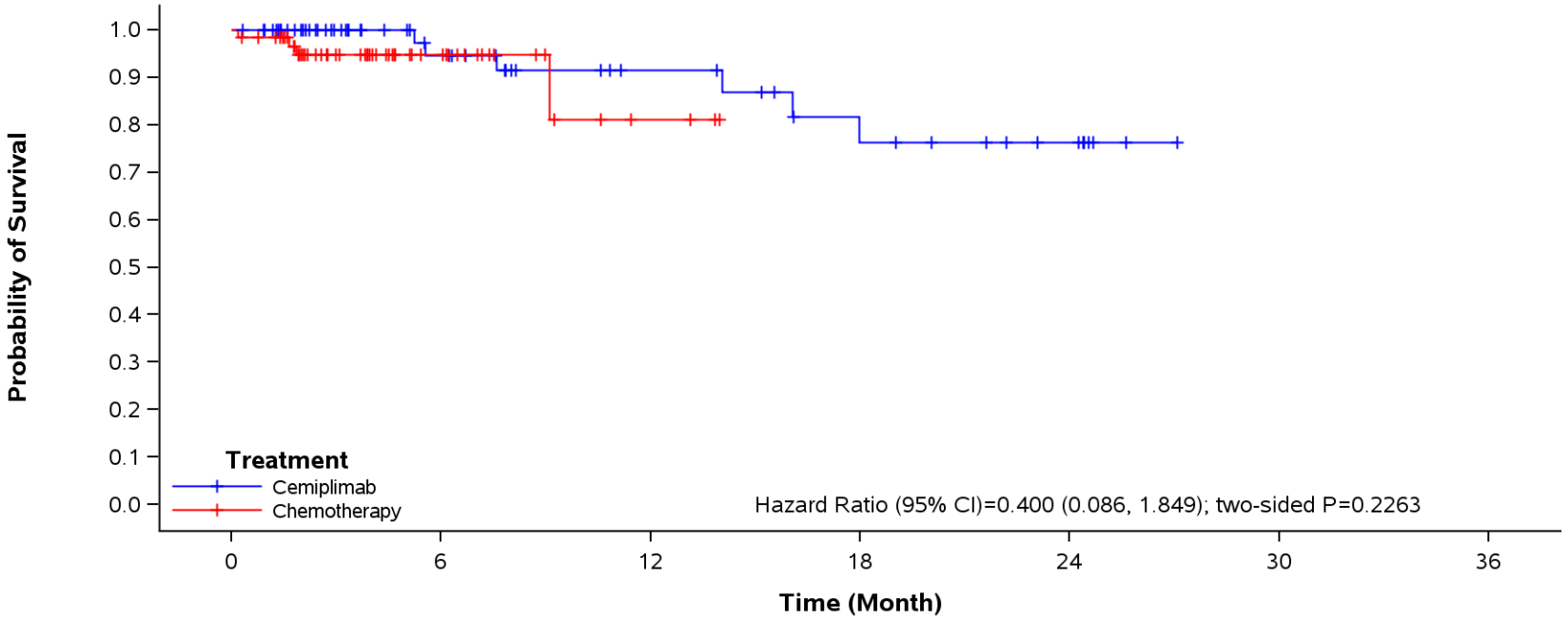

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe



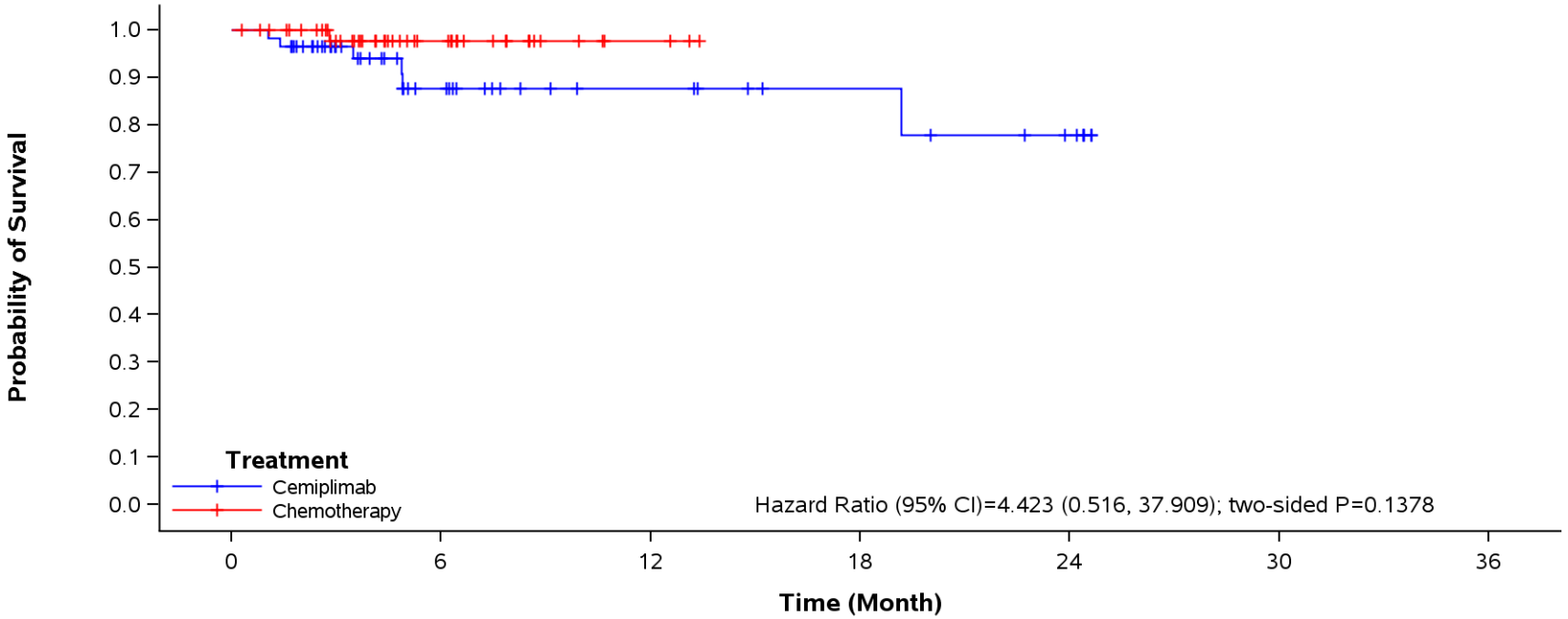

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 34 | 21 | 14 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW



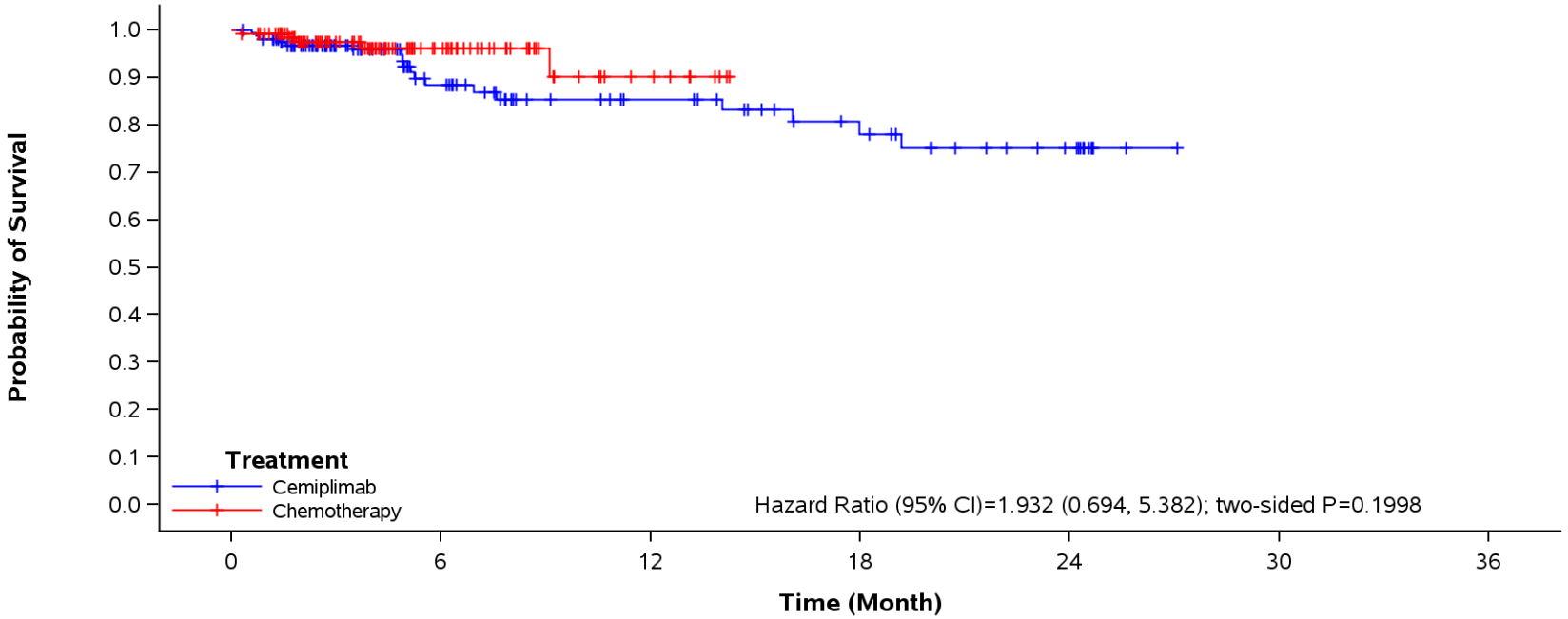

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 23 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous



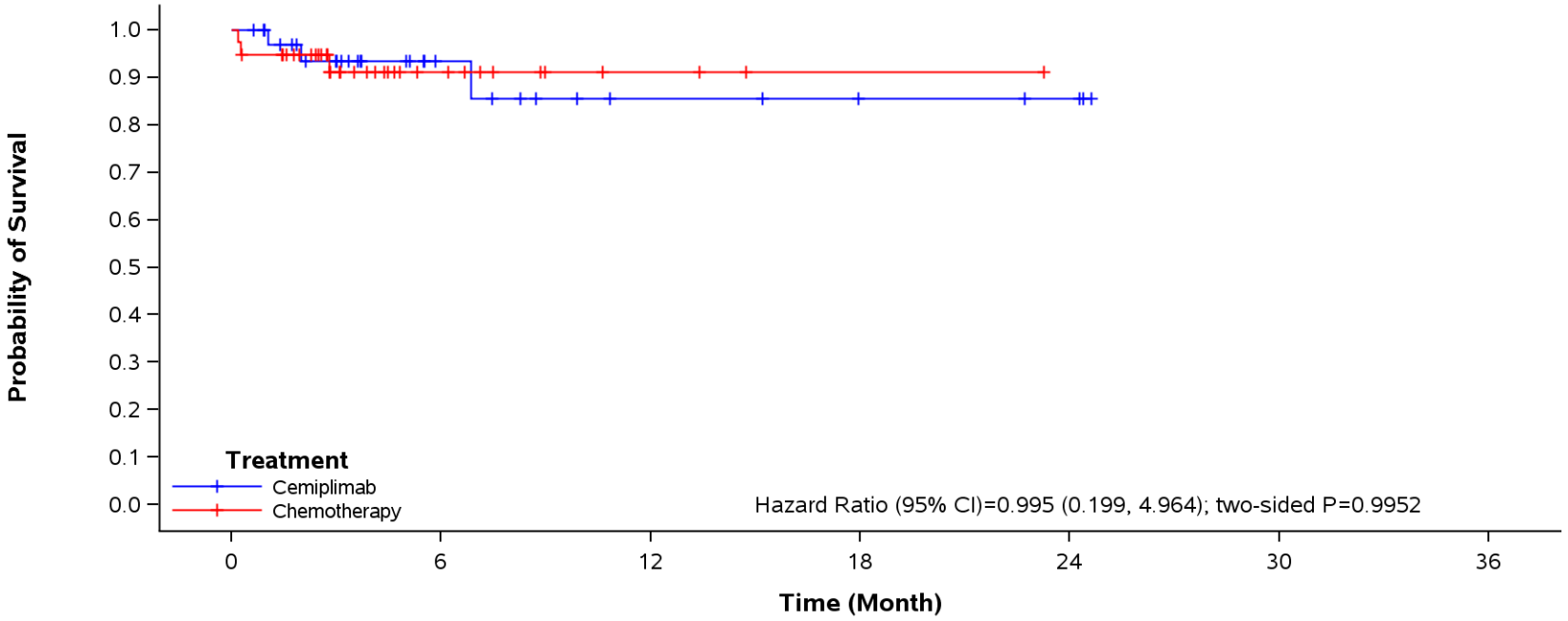

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 66 | 42 | 30 | 19 | 0 | 0 |
| Chemotherapy | 133 | 40 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous



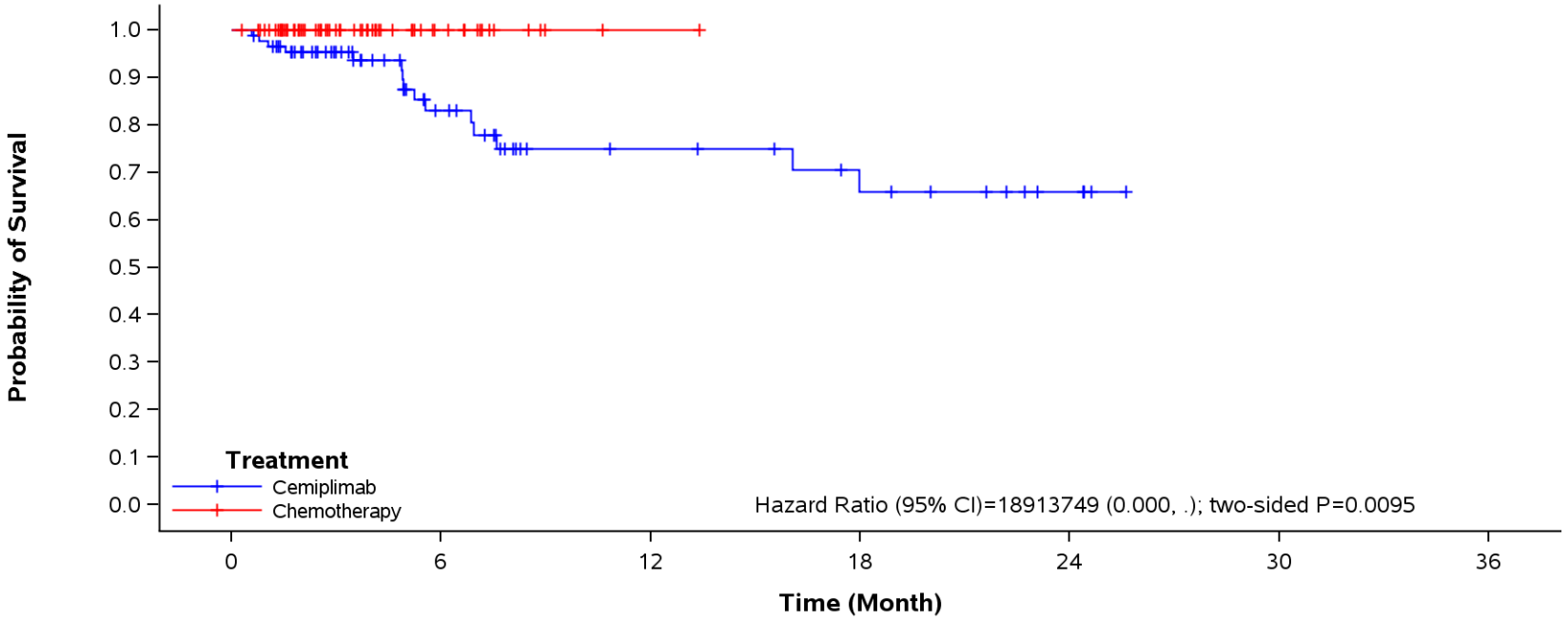

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes



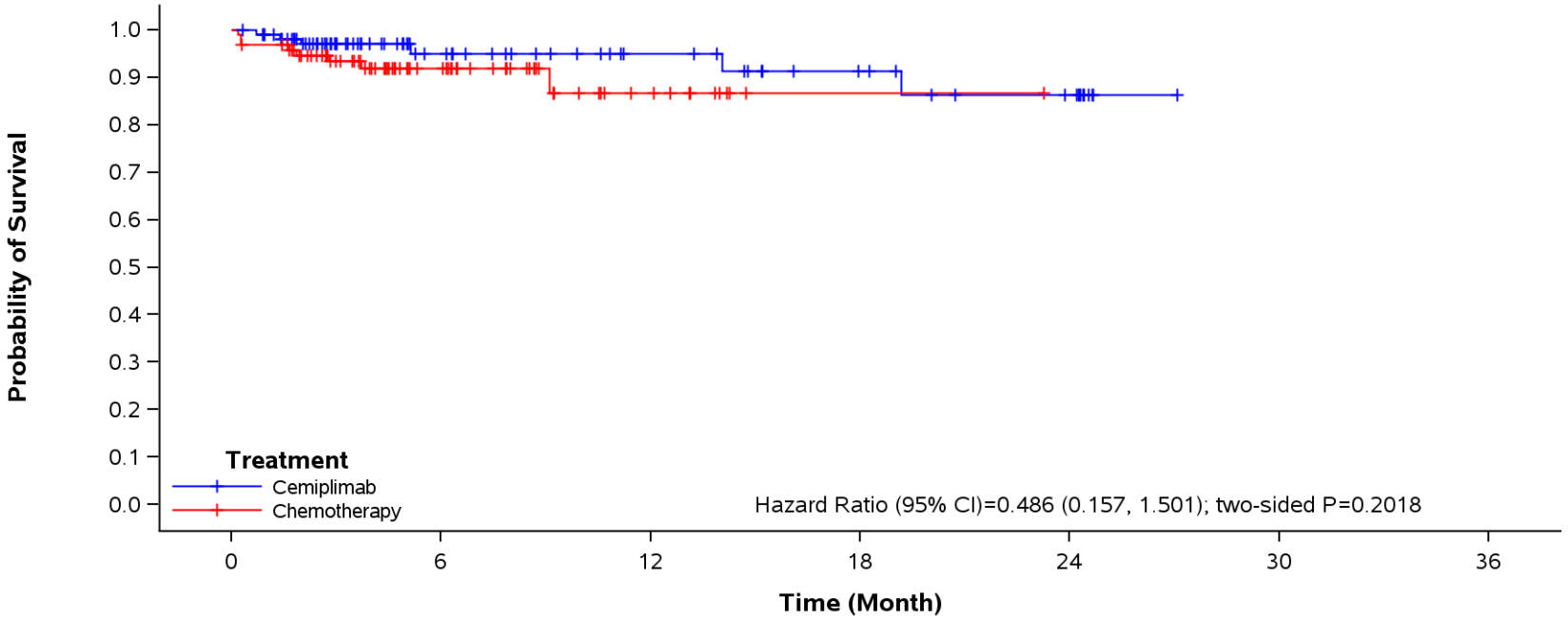

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 35 | 19 | 14 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No



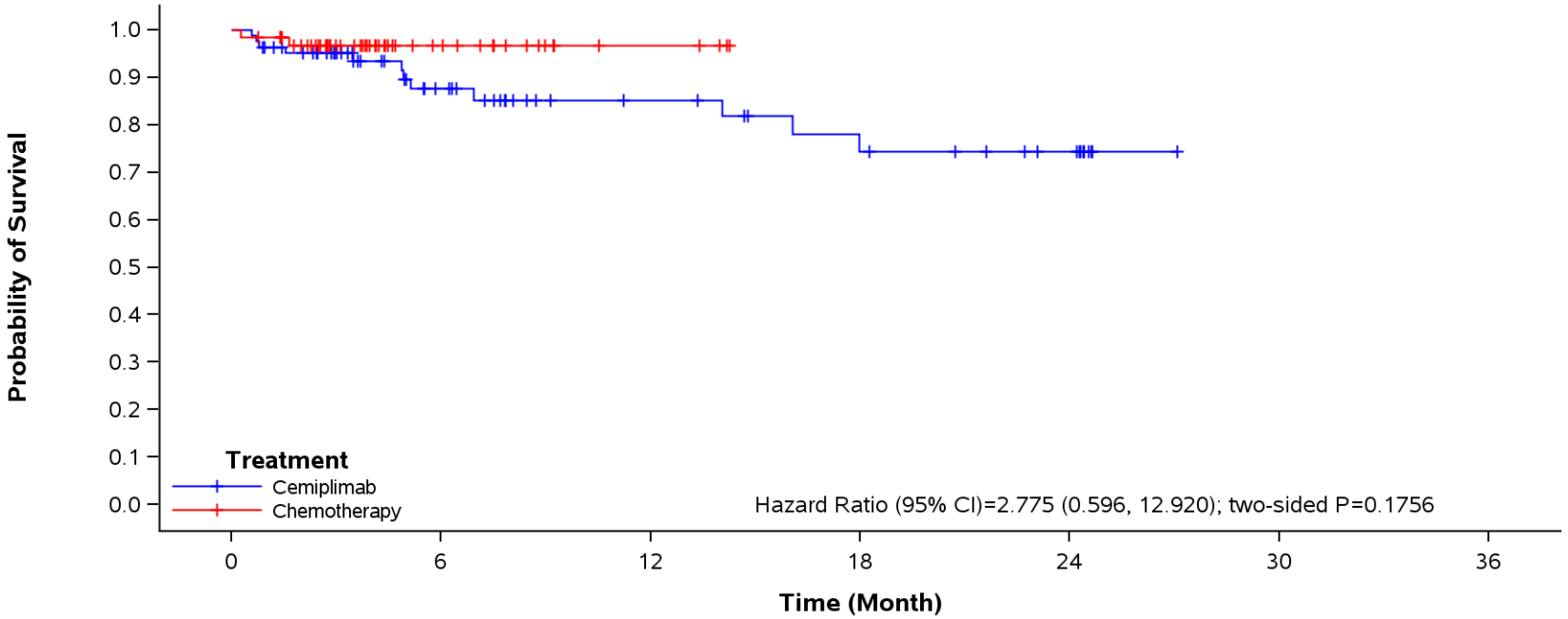

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 37 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0



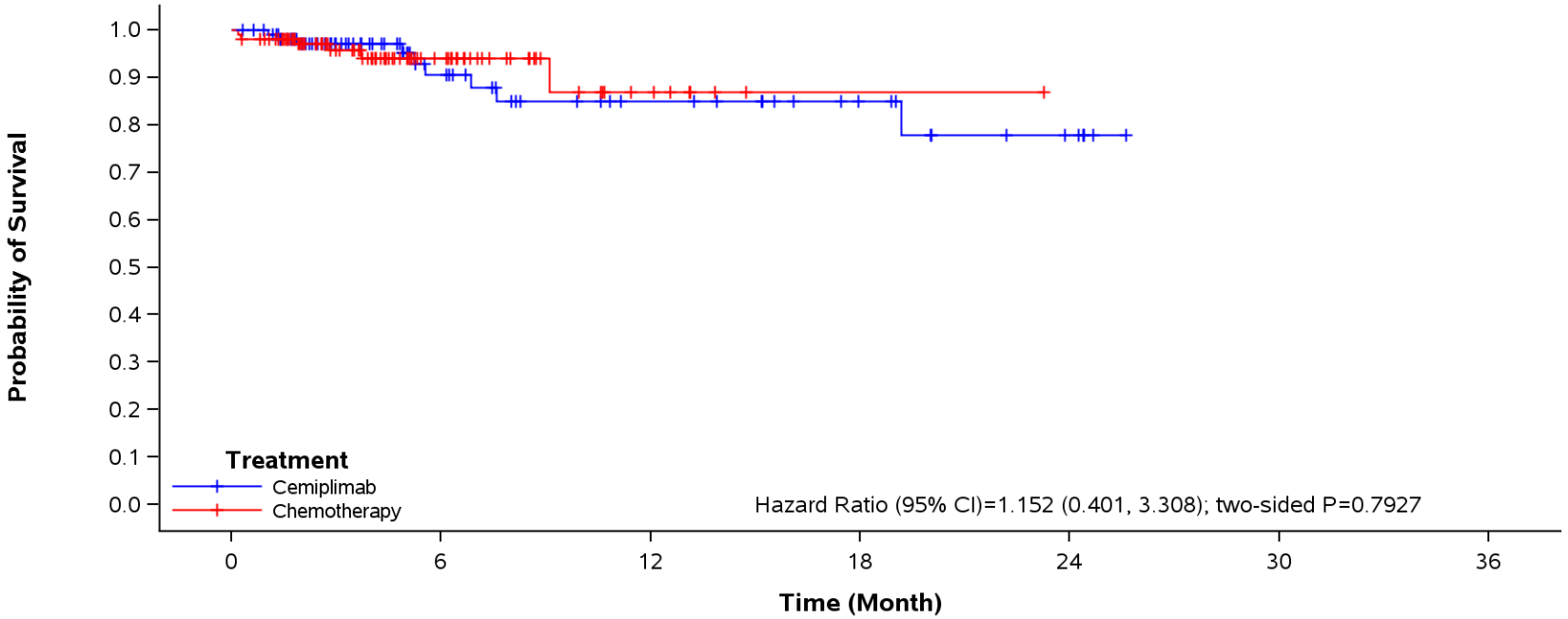

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 40 | 26 | 20 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1



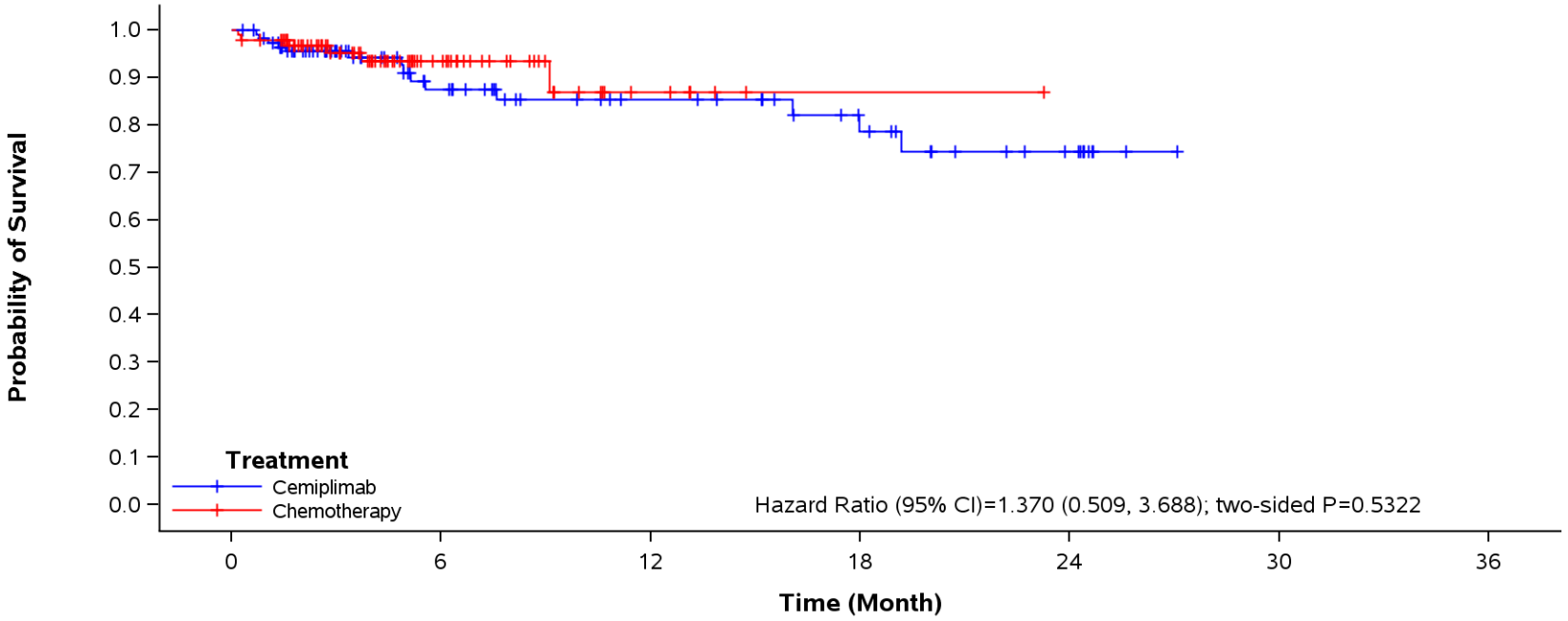

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 38 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 34 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line



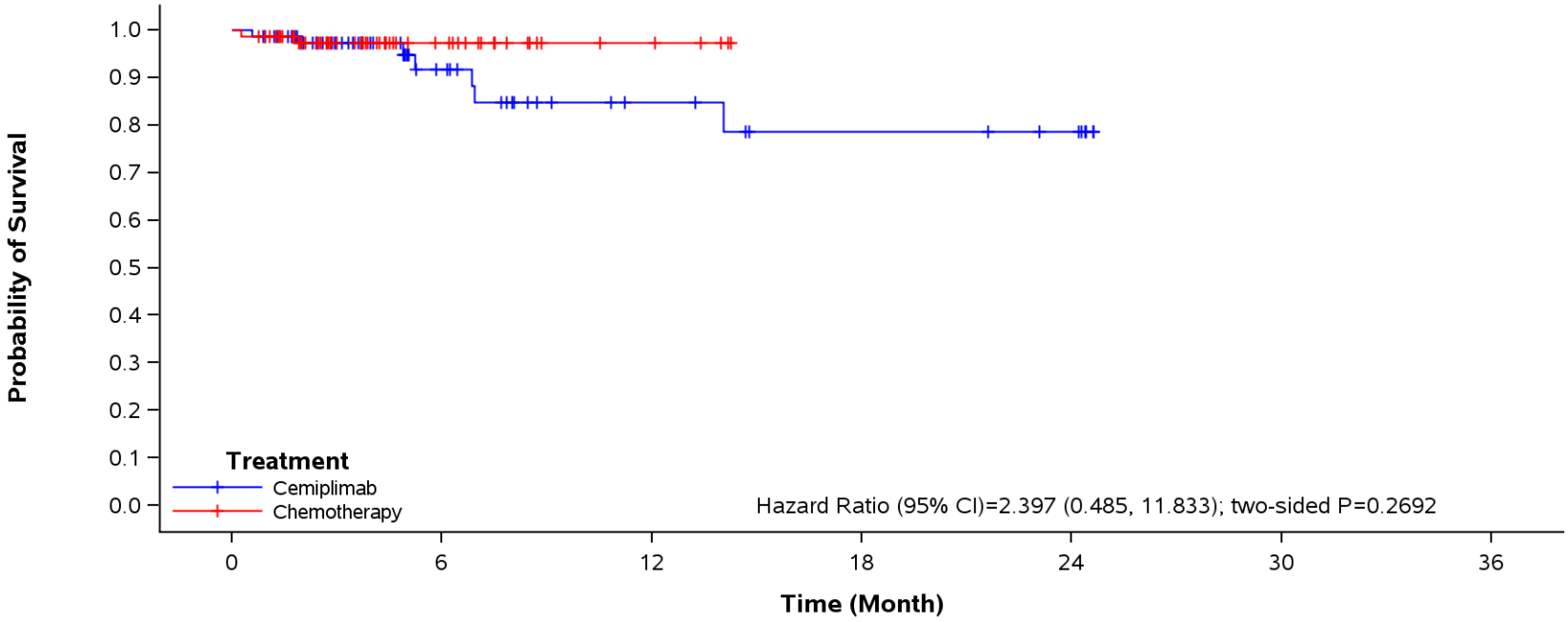

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 48 | 32 | 22 | 12 | 0 | 0 |
| Chemotherapy | 94 | 31 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line



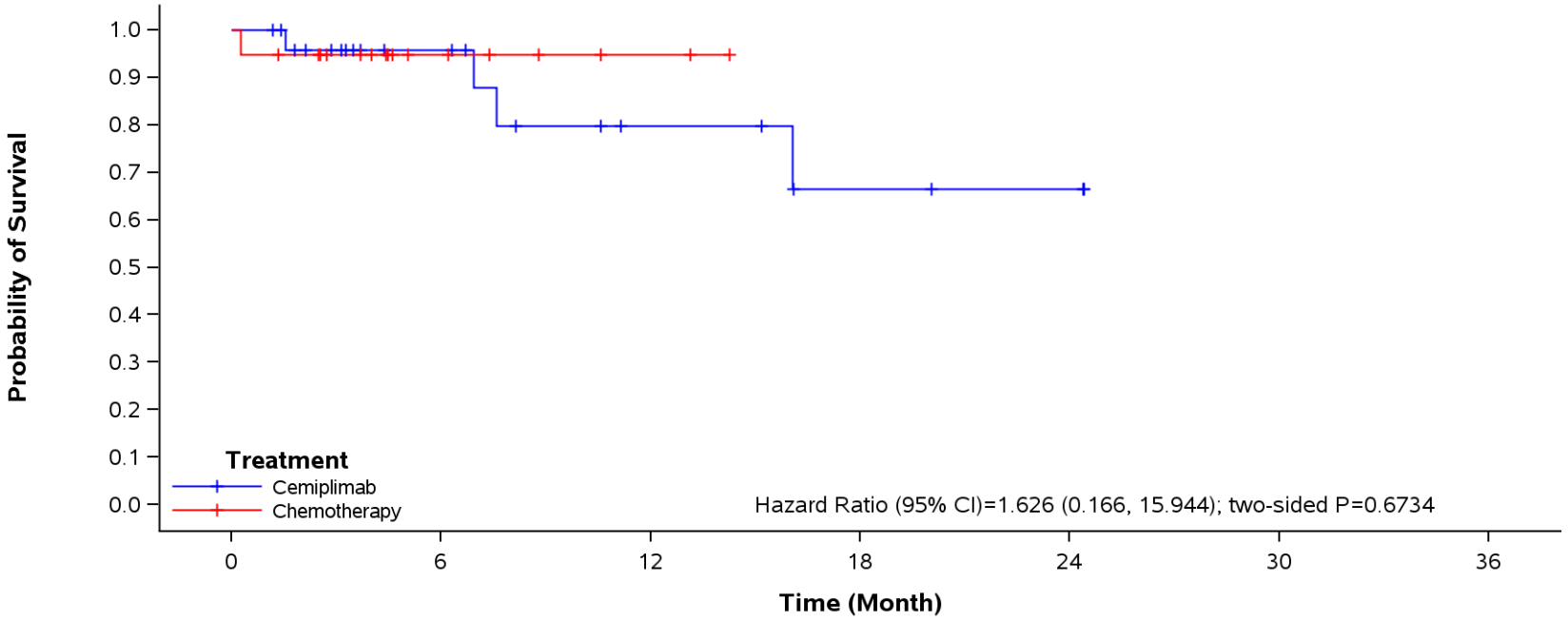

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 29 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan



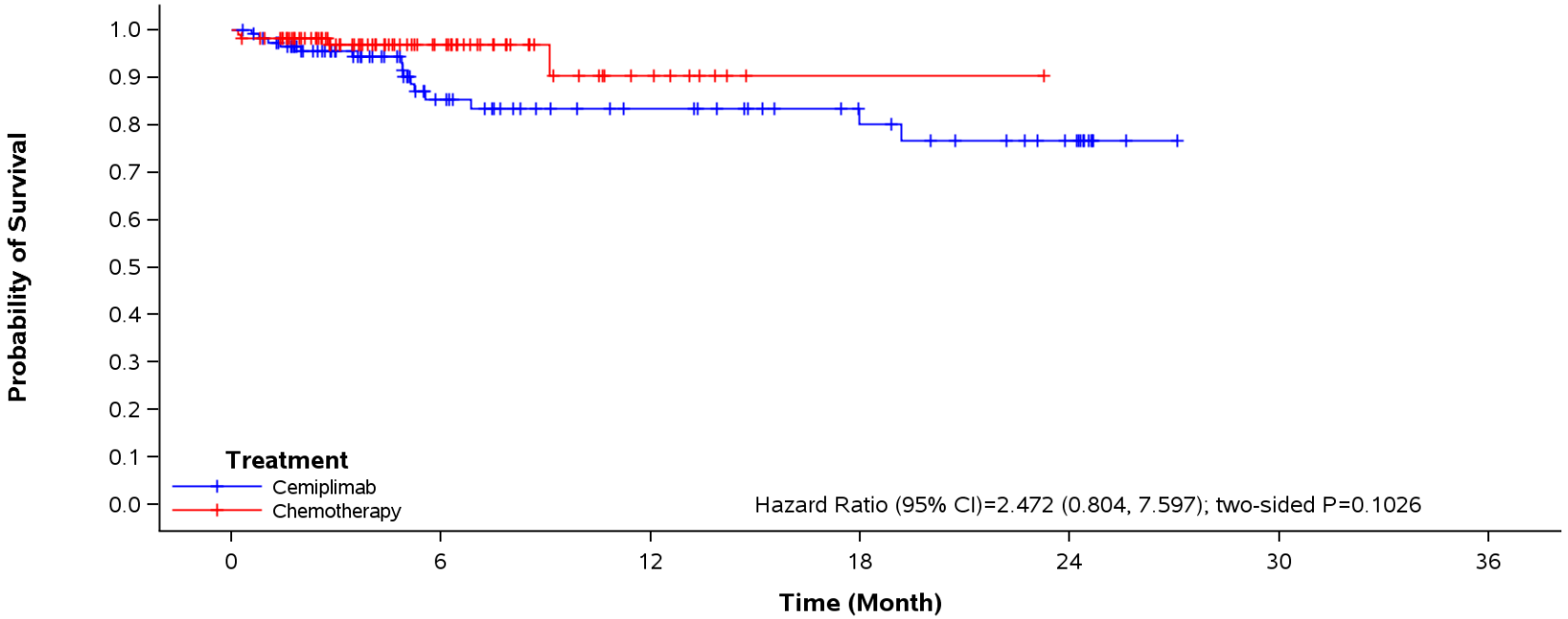

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 4 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed



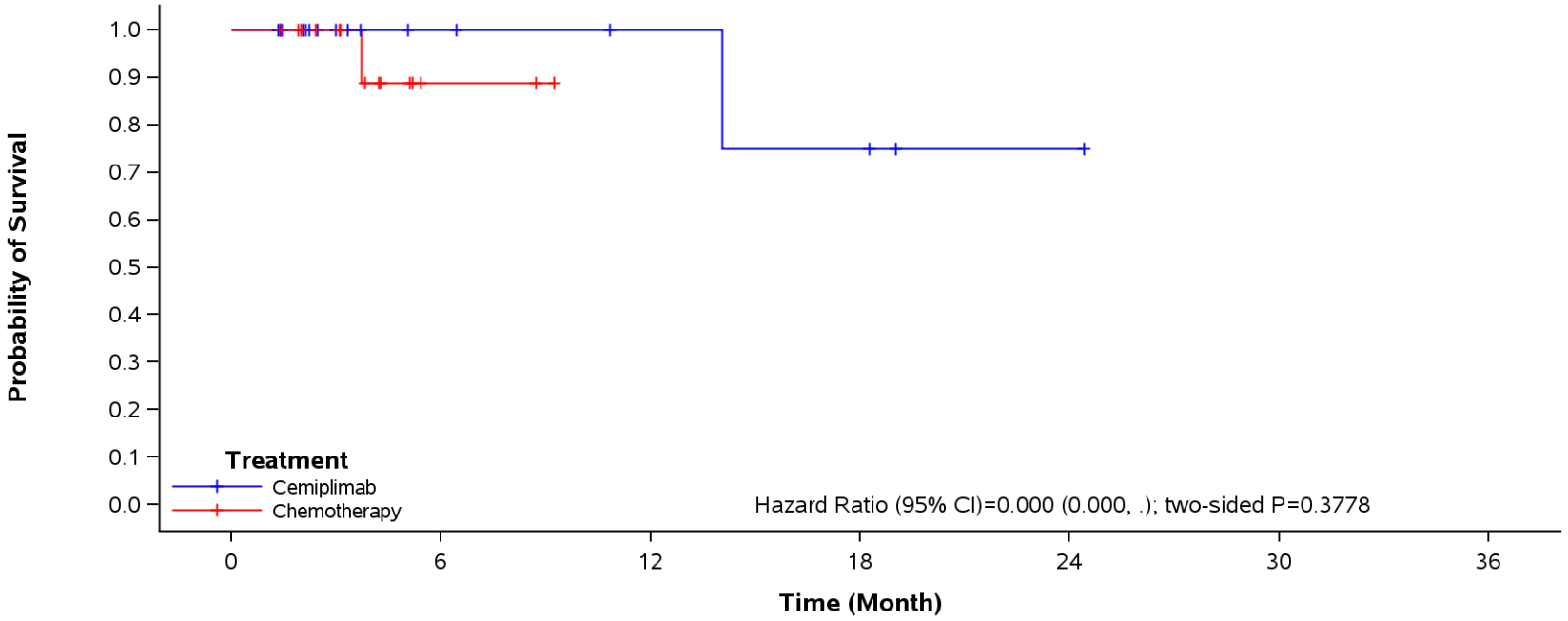

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 50 | 34 | 24 | 16 | 0 | 0 |
| Chemotherapy | 109 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan



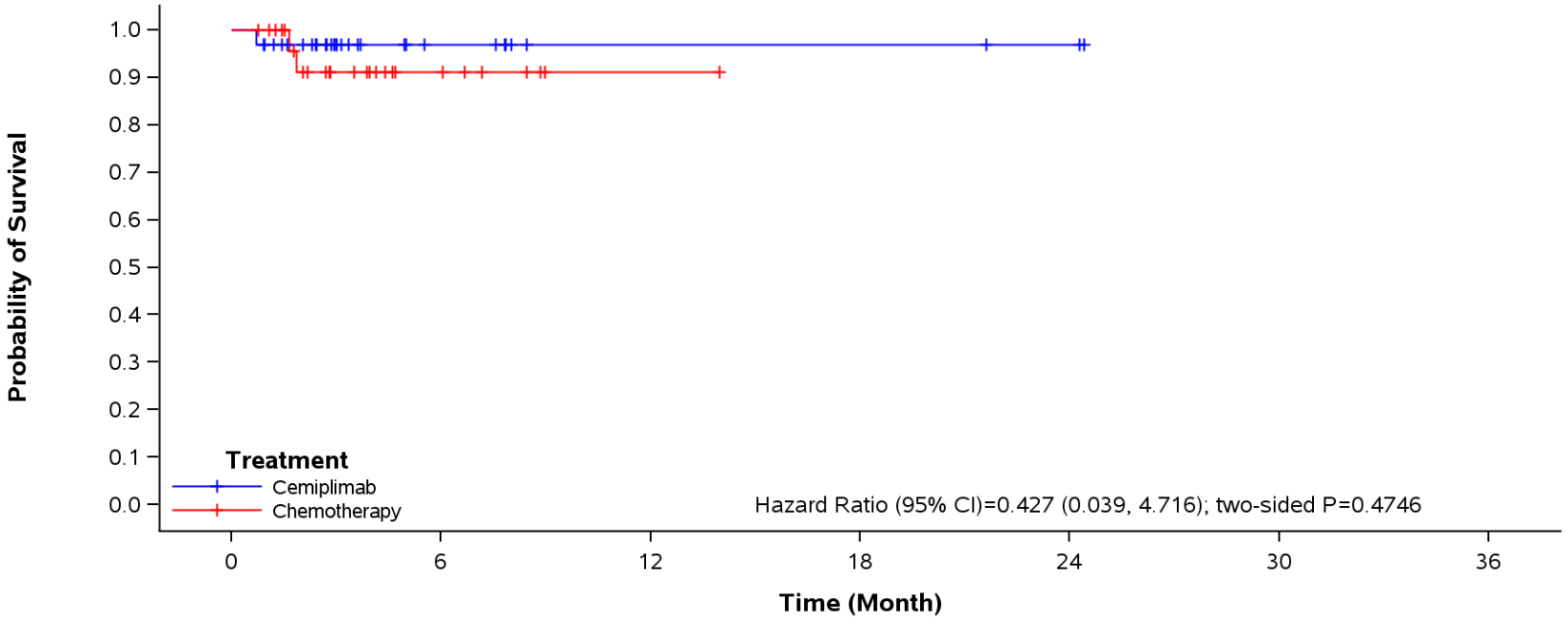

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 3.2.8. Time to First Any Treatment-Emergent Adverse Events Resulting in Treatment Discontinuation by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine



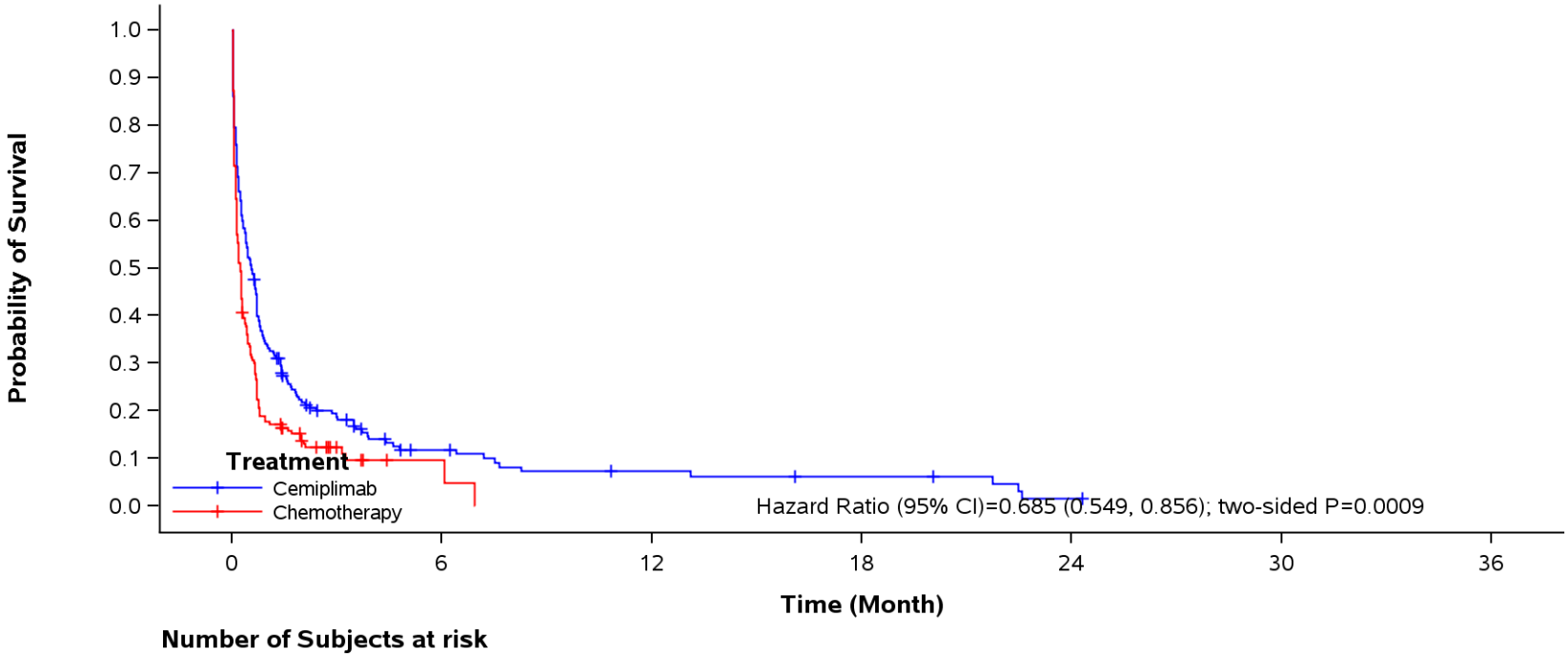

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any TEAE



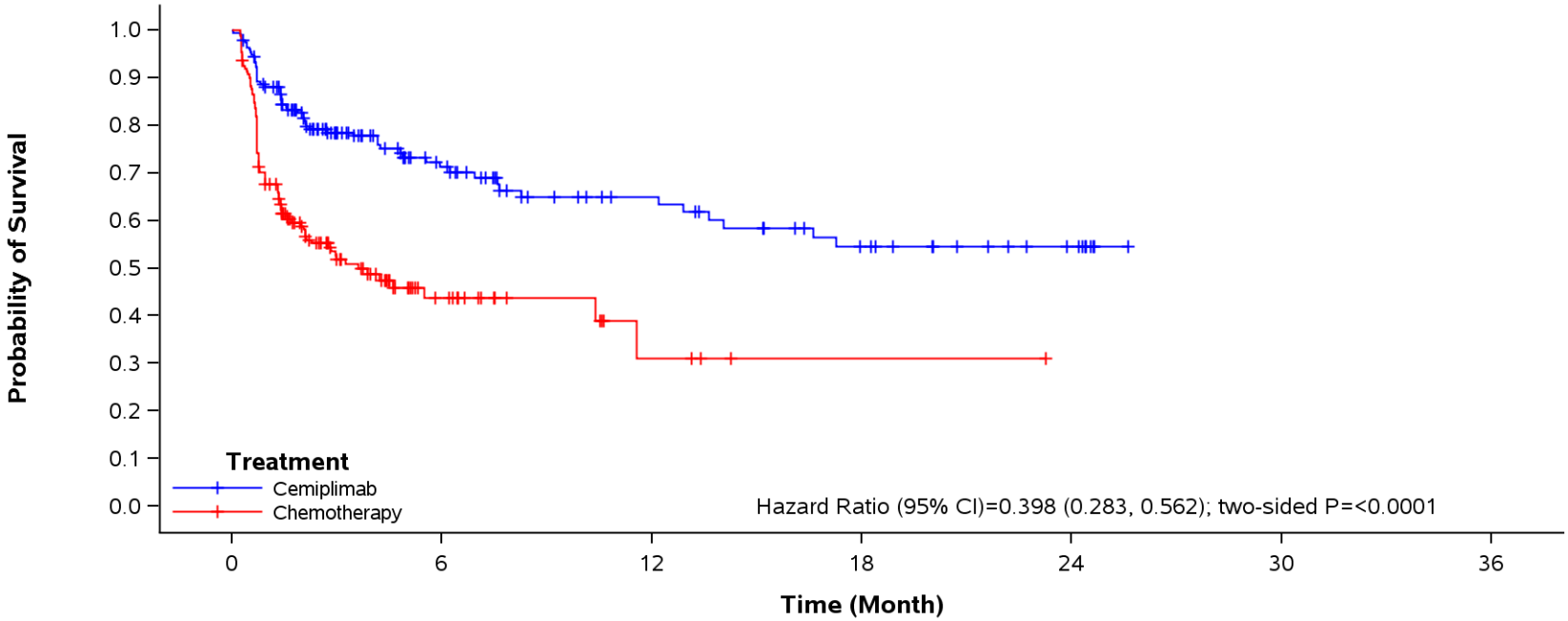

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 14 | 7 | 5 | 1 | 0 | 0 |
| Chemotherapy | 172 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders



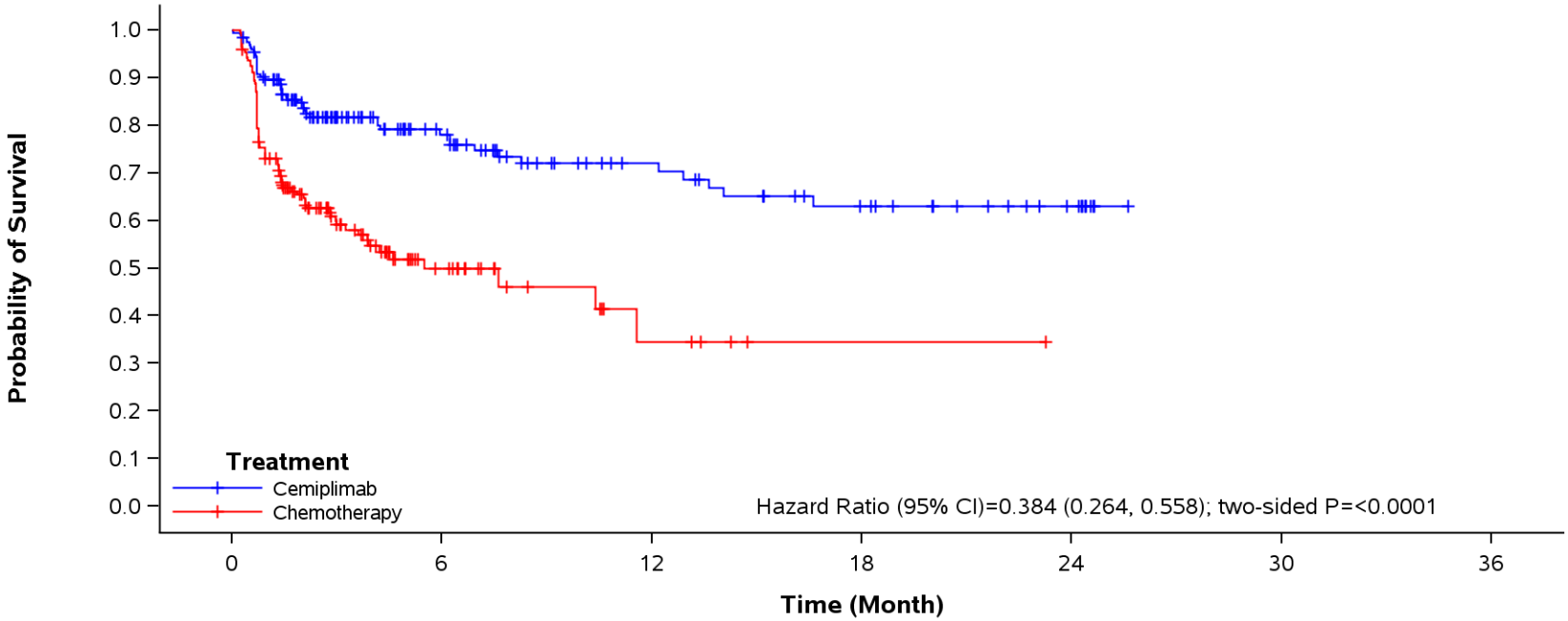

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 68 | 40 | 27 | 16 | 0 | 0 |
| Chemotherapy | 172 | 20 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia



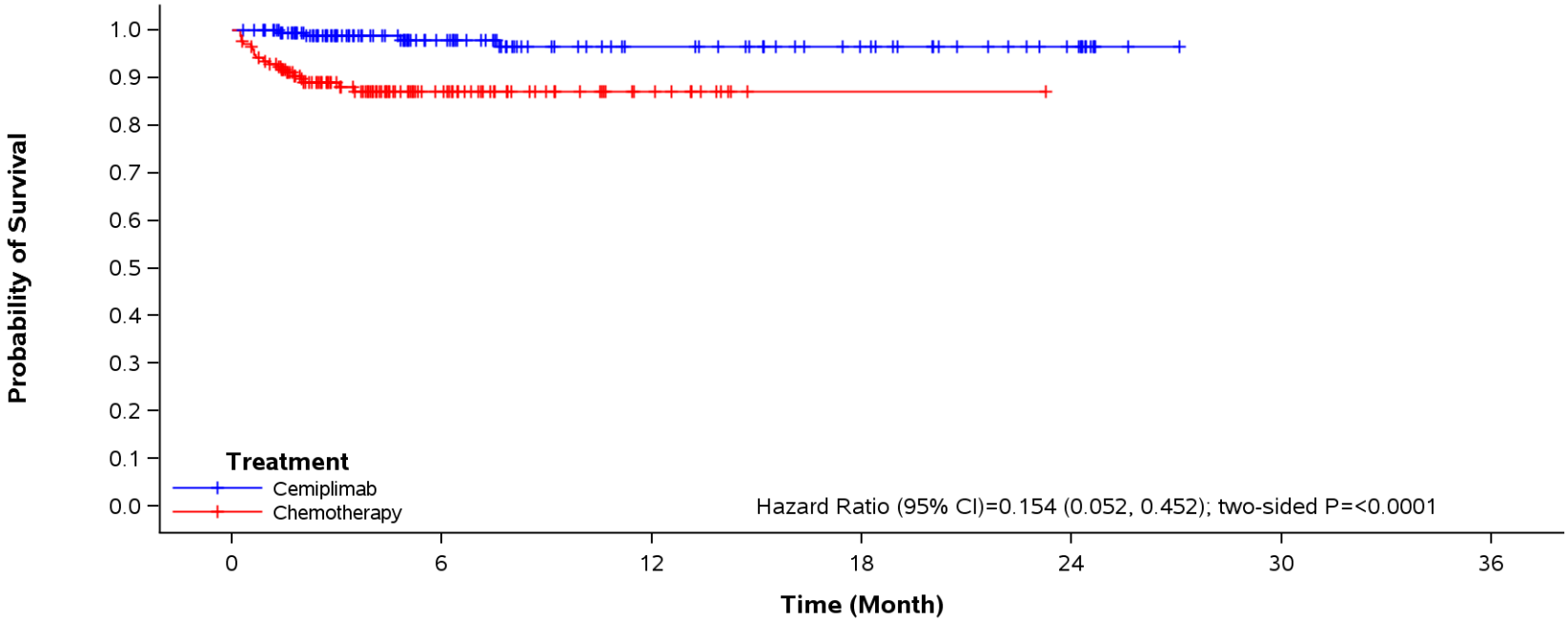

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 74 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 172 | 24 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Neutropenia



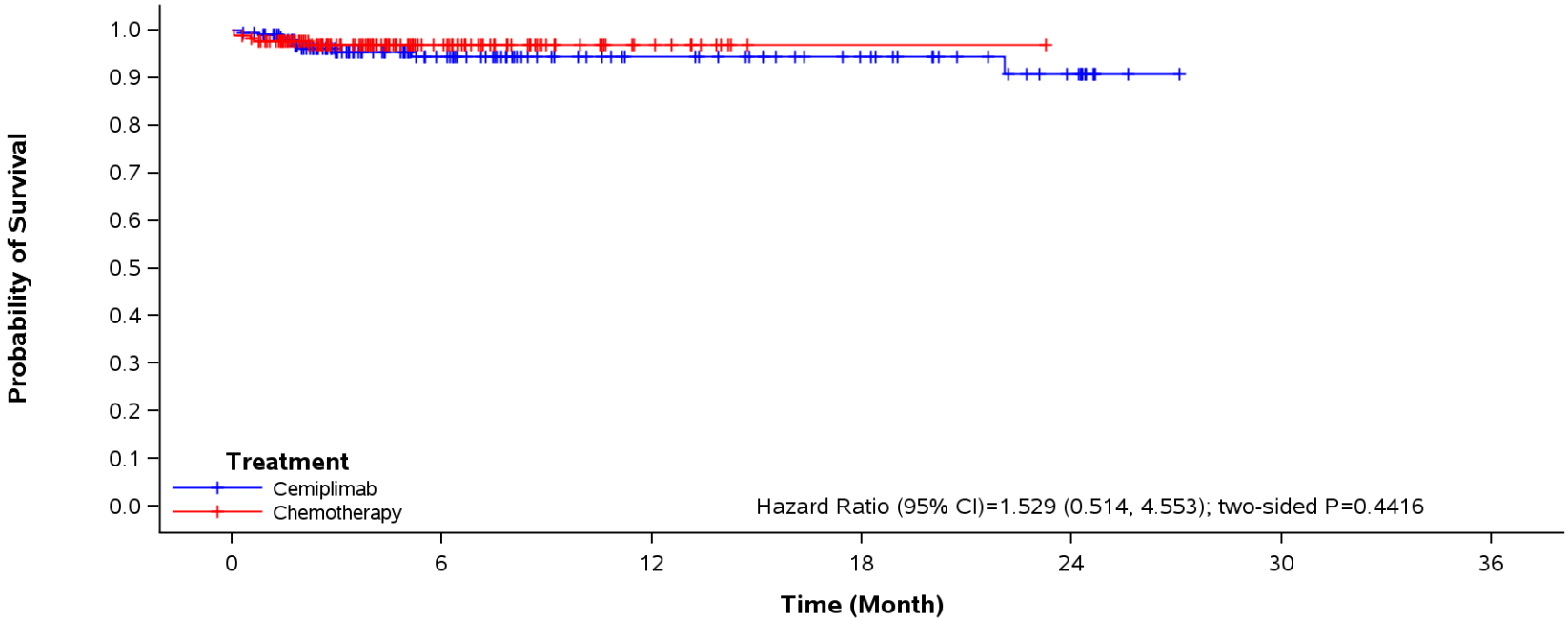

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 47 | 35 | 21 | 0 | 0 |
| Chemotherapy | 172 | 45 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Cardiac disorders



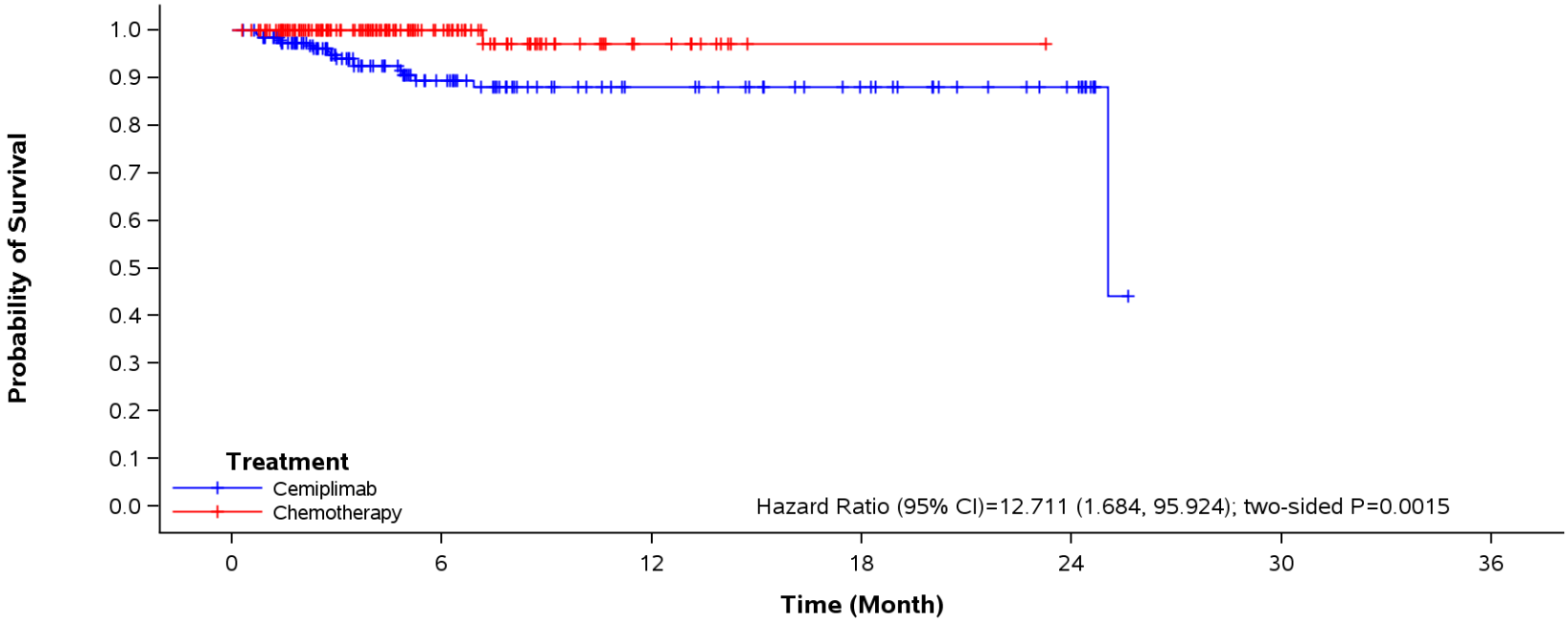

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 48 | 36 | 21 | 0 | 0 |
| Chemotherapy | 172 | 52 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Endocrine disorders



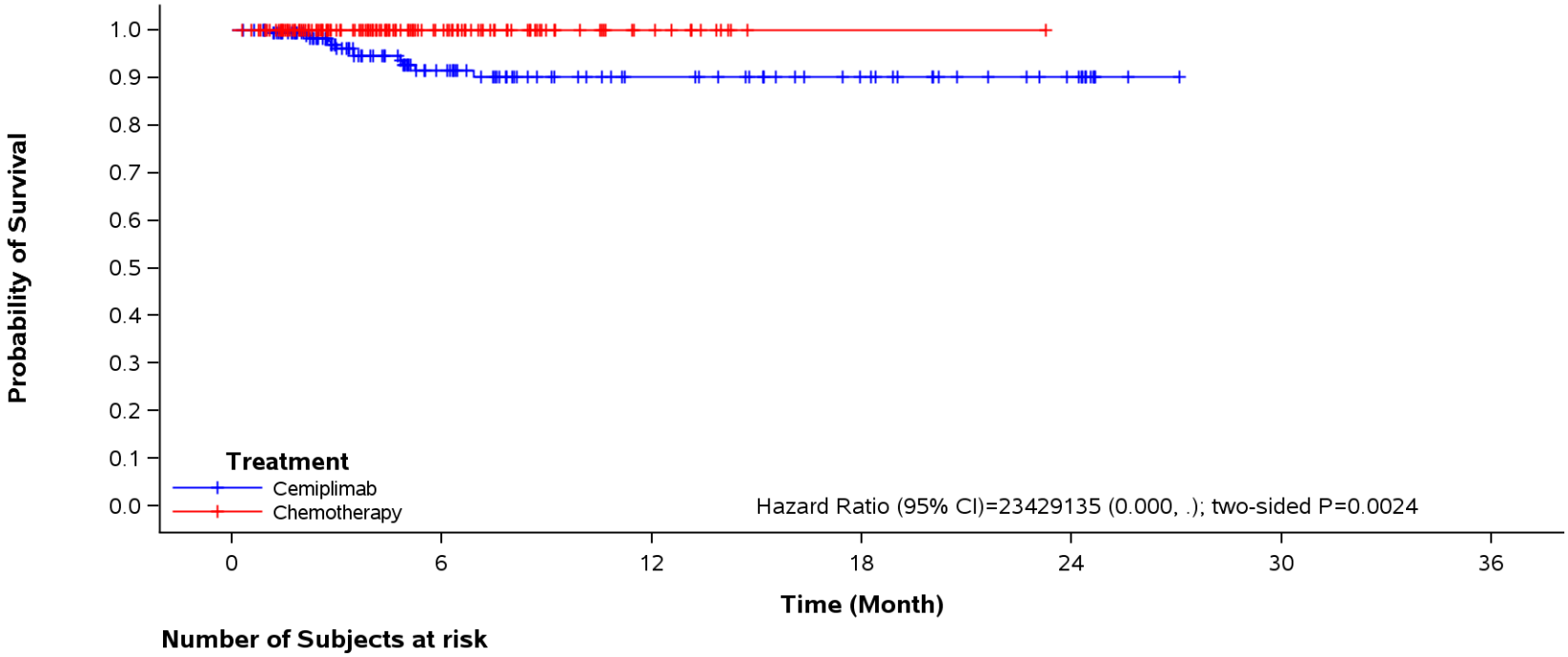

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 44 | 33 | 20 | 0 | 0 |
| Chemotherapy | 172 | 52 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Endocrine disorders
PT: Hypothyroidism



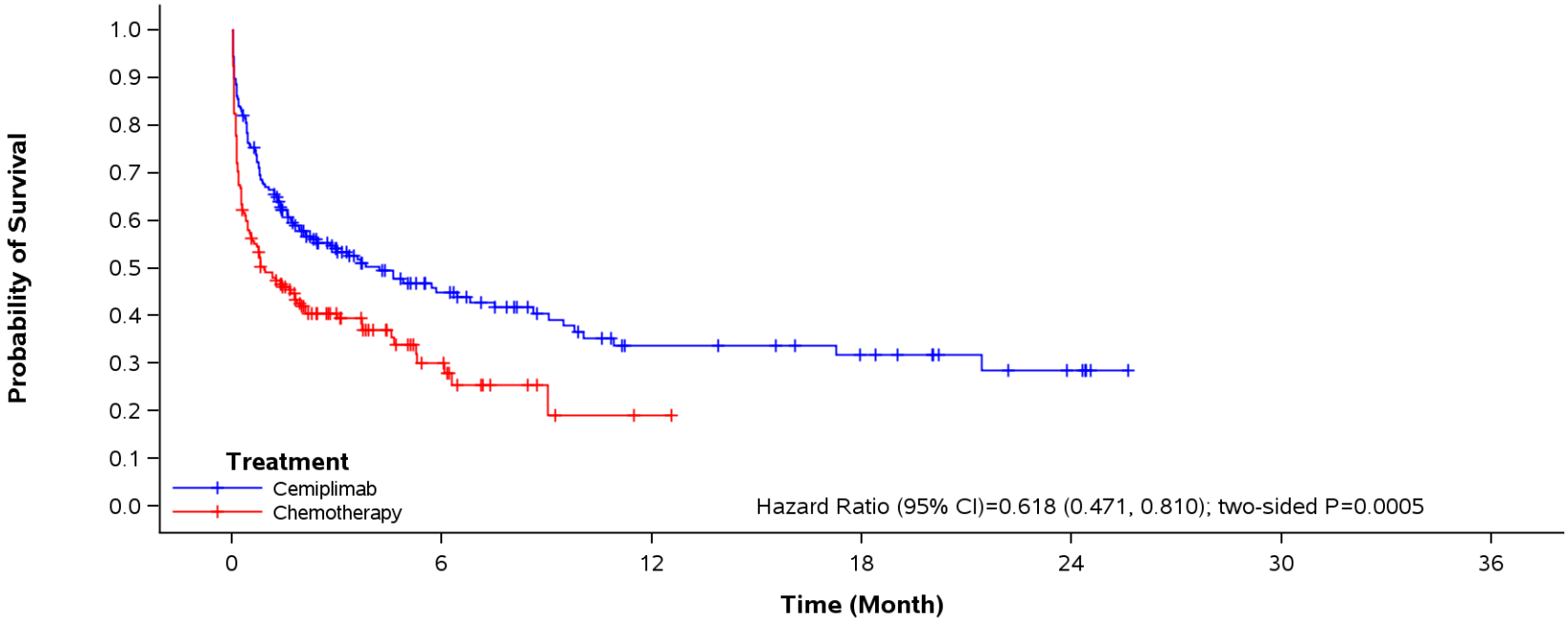

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 78 | 45 | 33 | 20 | 0 | 0 |
| Chemotherapy | 172 | 52 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders



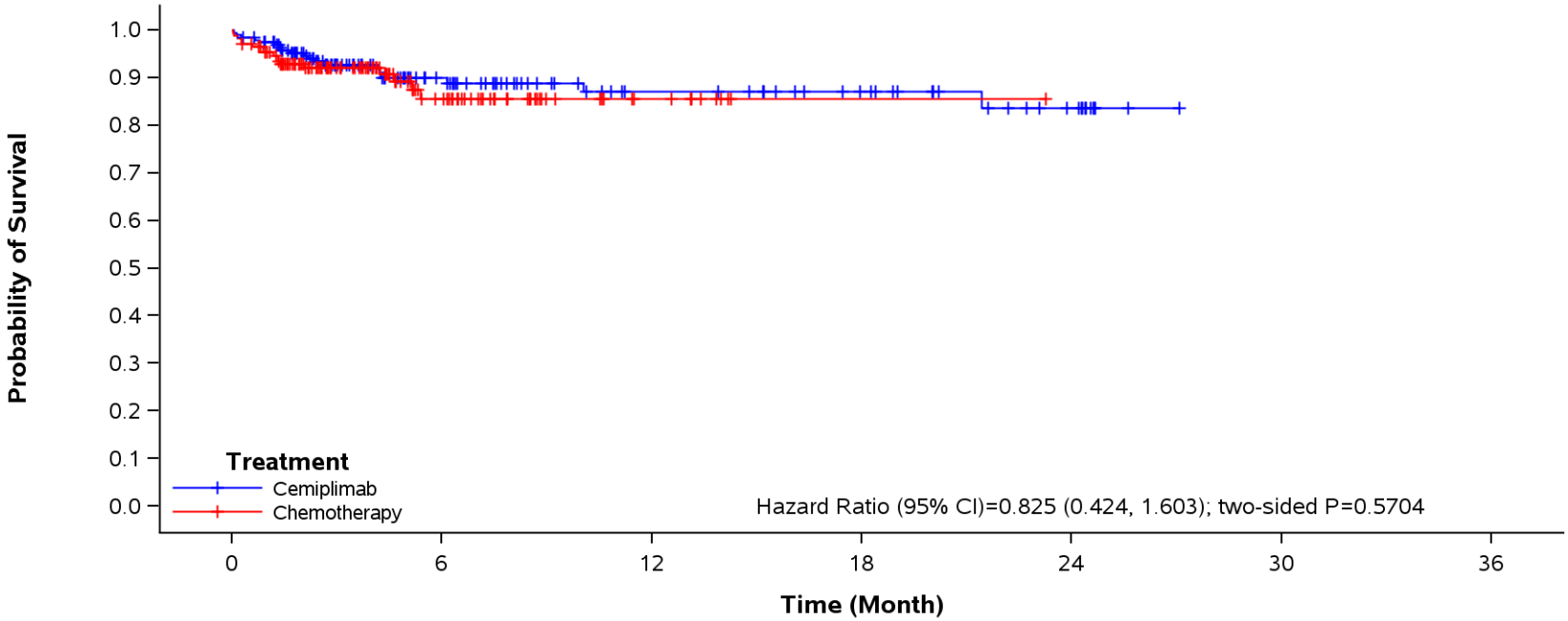

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 46 | 20 | 15 | 7 | 0 | 0 |
| Chemotherapy | 172 | 15 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Abdominal pain



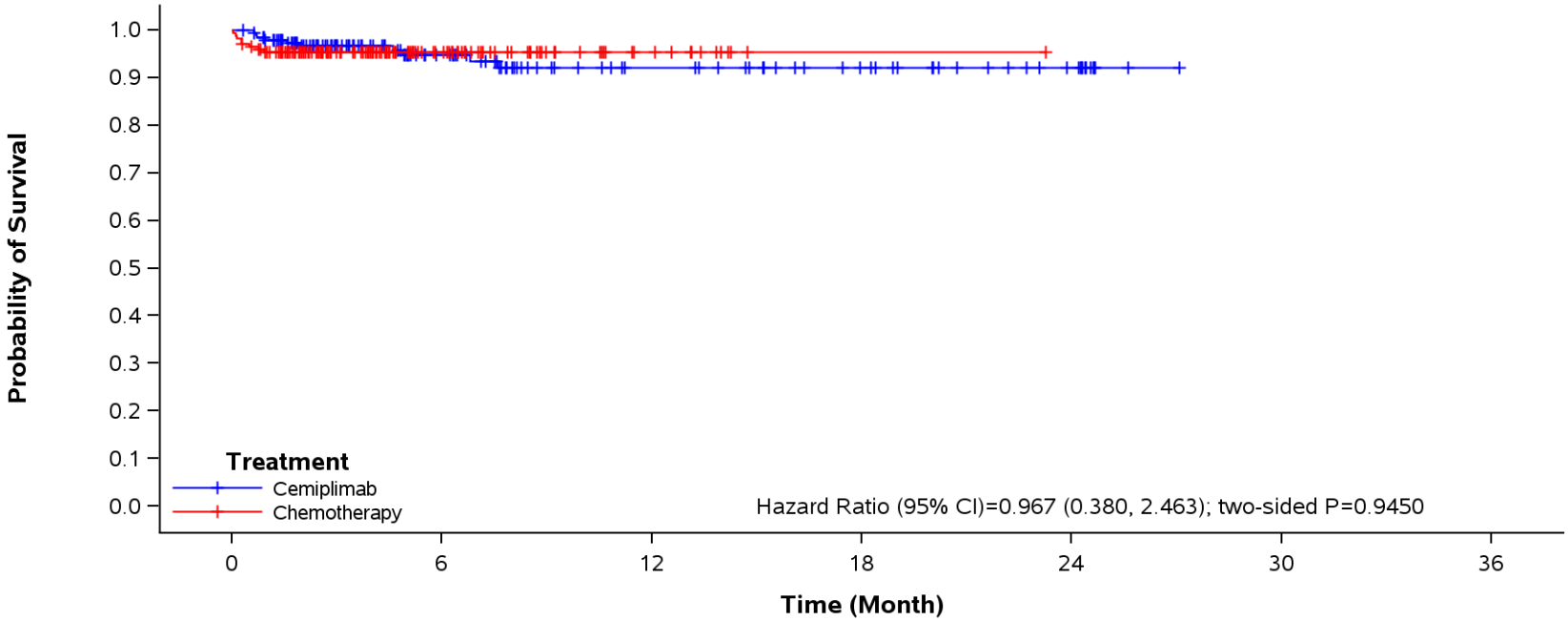

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 42 | 33 | 19 | 0 | 0 |
| Chemotherapy | 172 | 44 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Abdominal pain upper



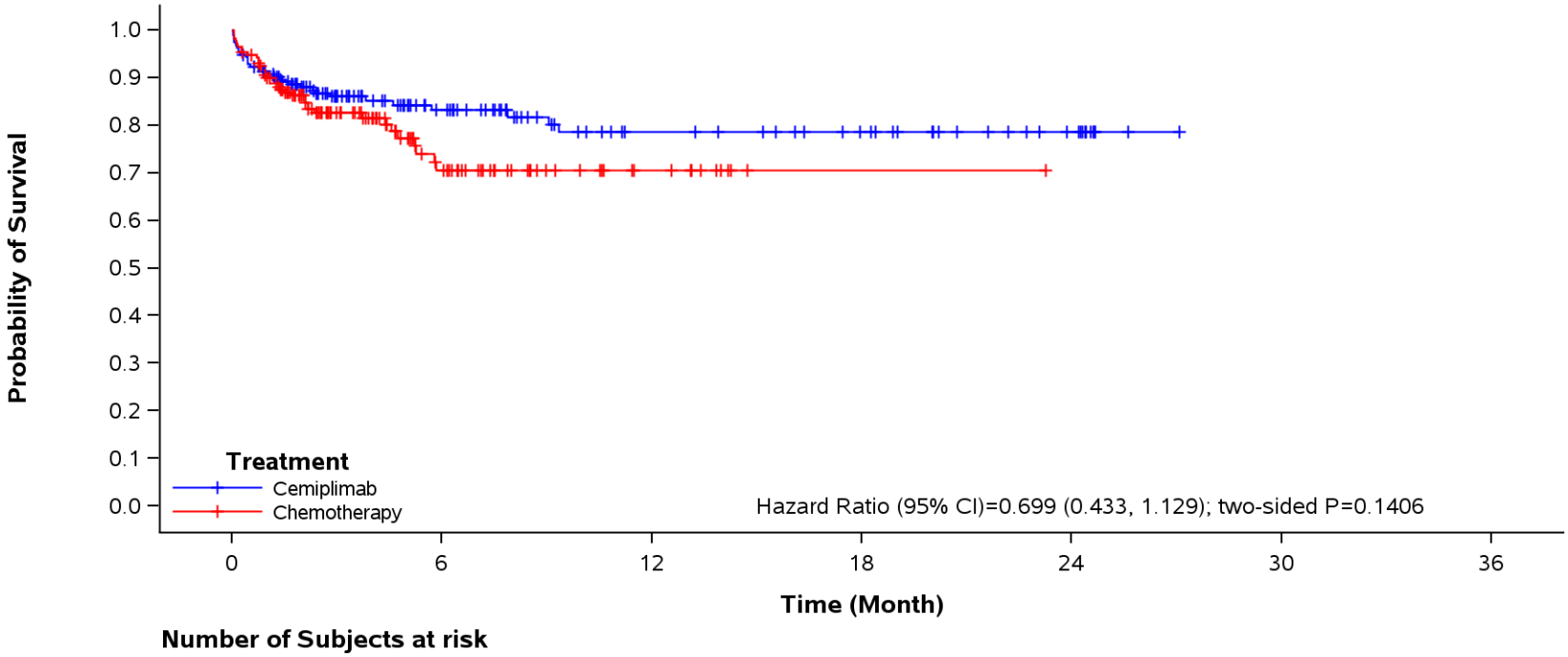

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 47 | 35 | 21 | 0 | 0 |
| Chemotherapy | 172 | 49 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Constipation



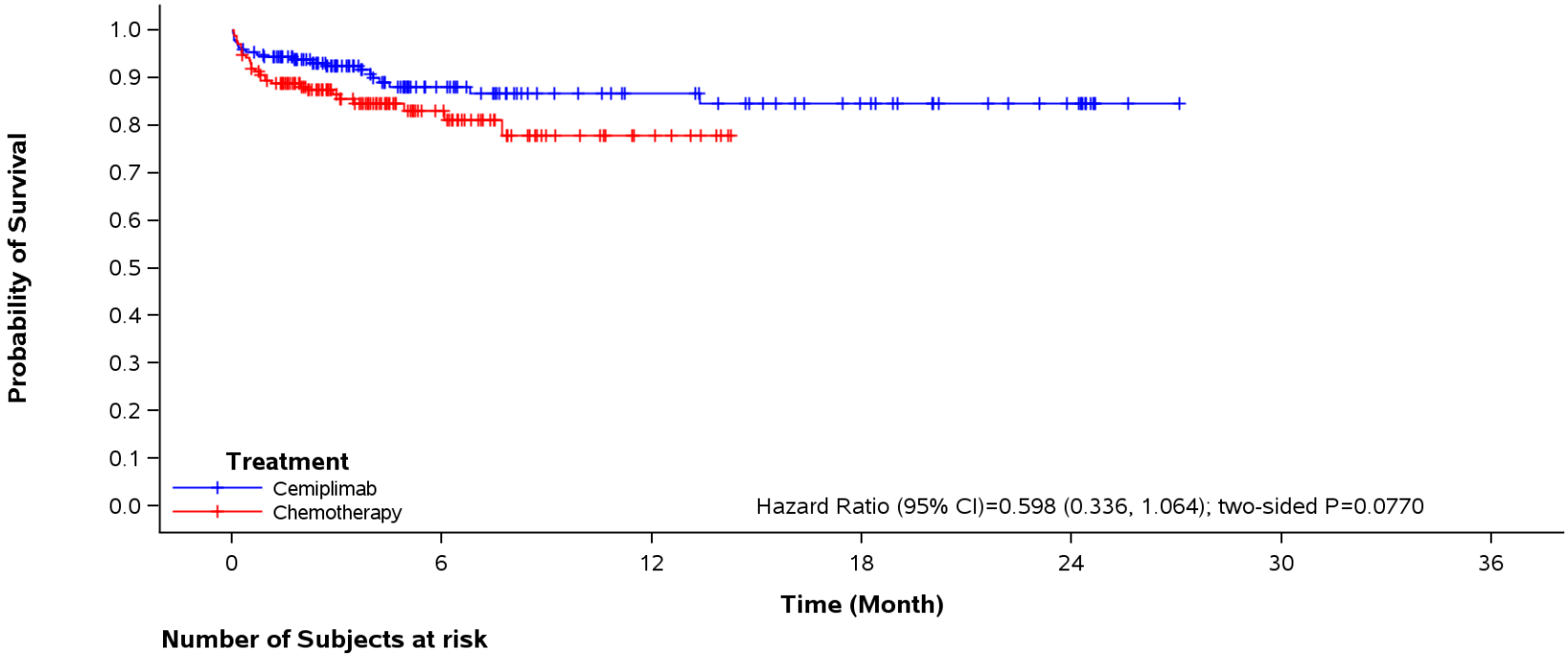

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 76 | 42 | 34 | 20 | 0 | 0 |
| Chemotherapy | 172 | 40 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Diarrhoea



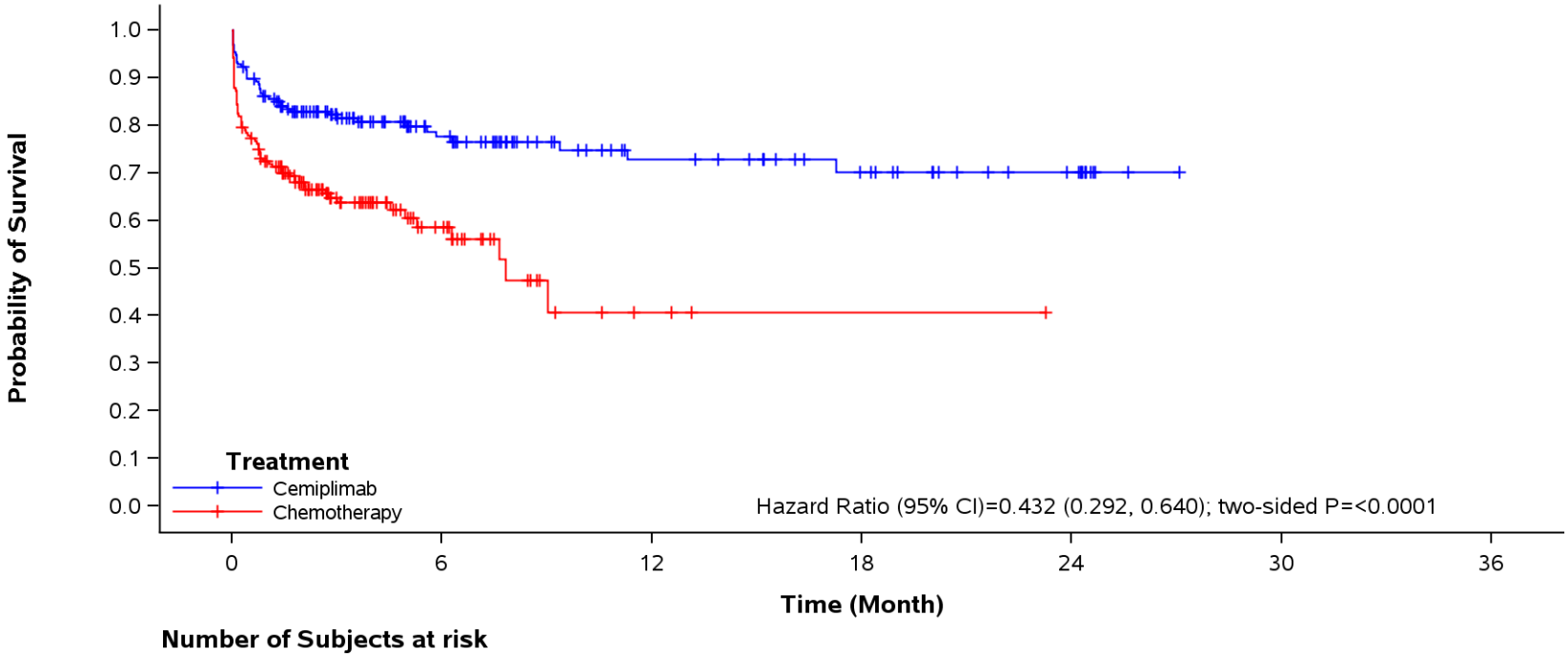

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 73 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 172 | 45 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Nausea



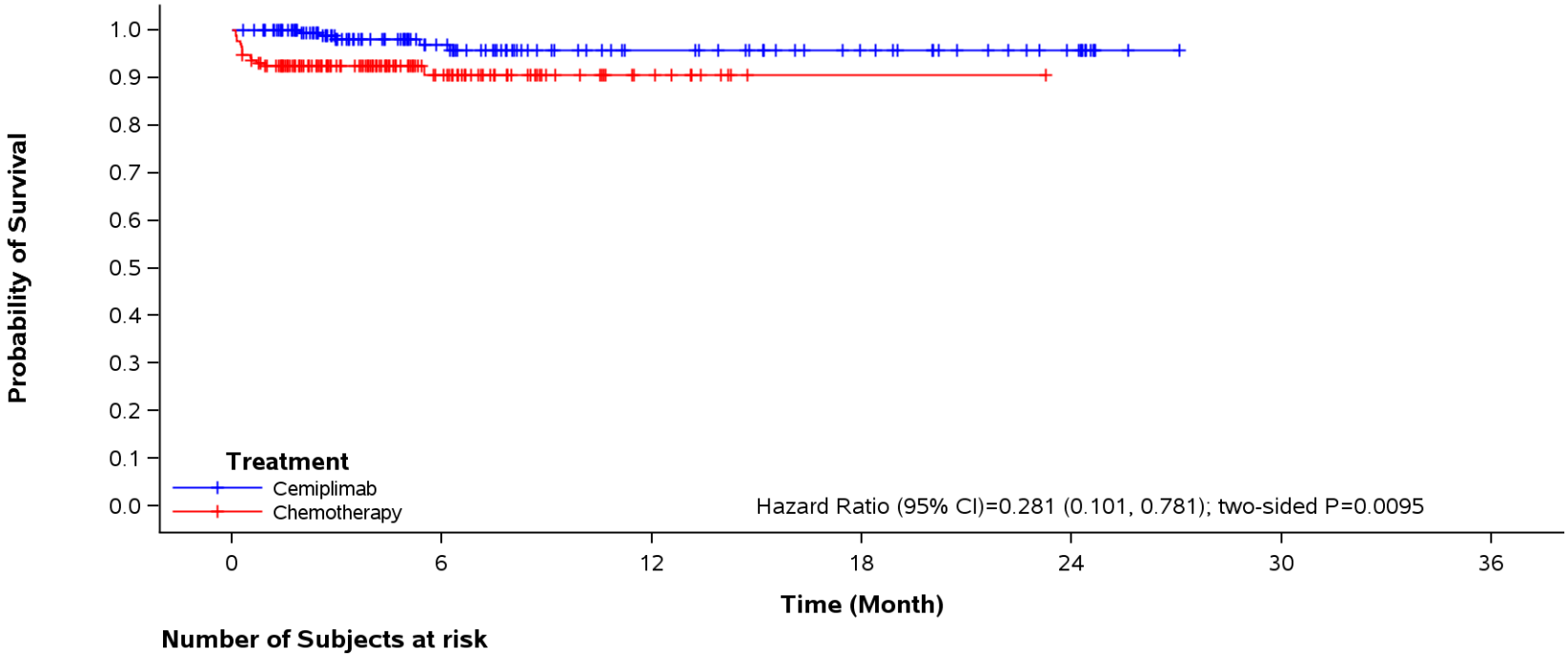

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 71 | 36 | 26 | 15 | 0 | 0 |
| Chemotherapy | 172 | 28 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Stomatitis



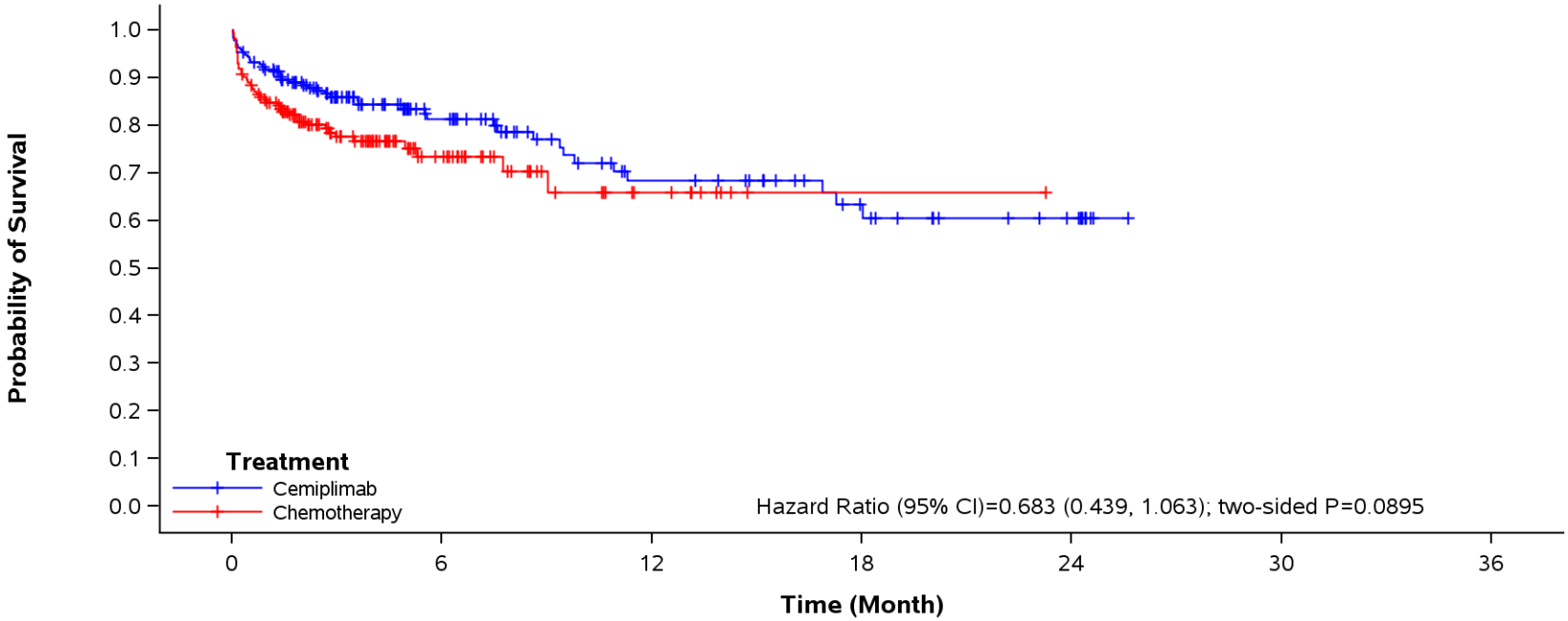

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 45 | 33 | 20 | 0 | 0 |
| Chemotherapy | 172 | 48 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders
PT: Vomiting



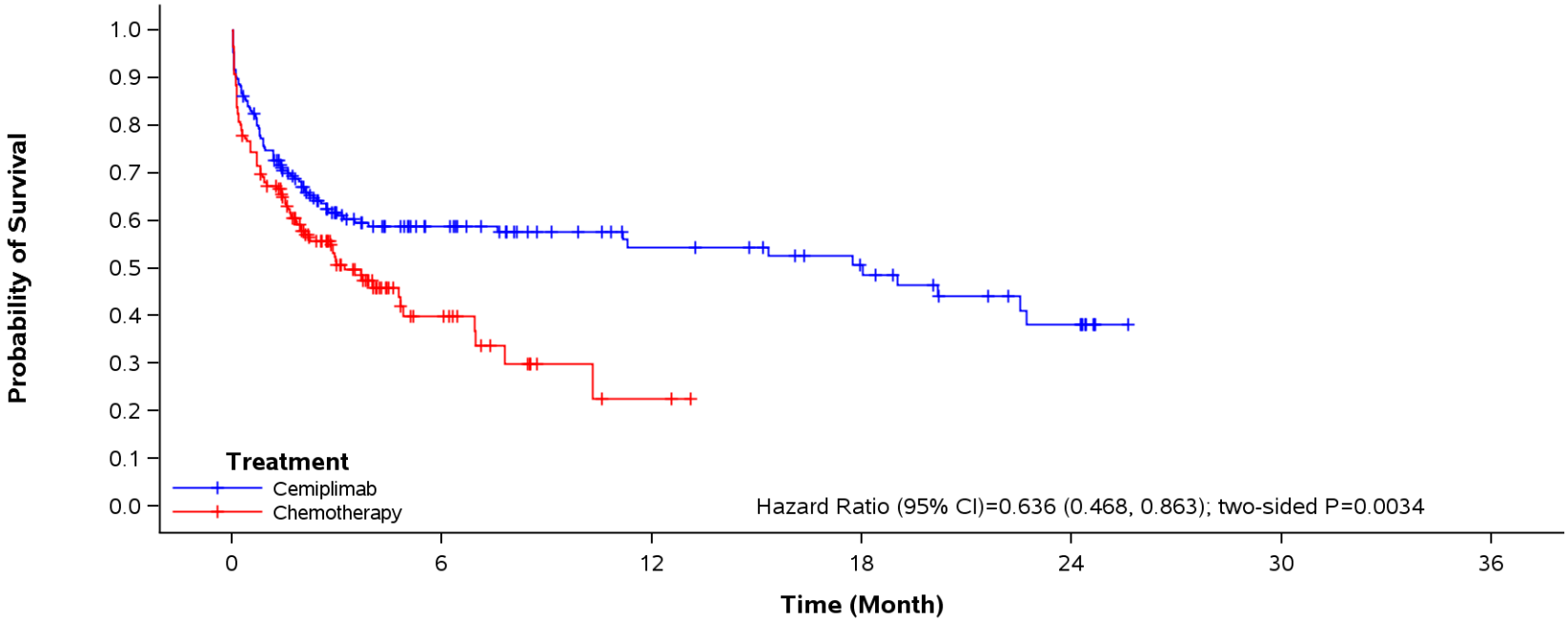

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 72 | 36 | 23 | 13 | 0 | 0 |
| Chemotherapy | 172 | 39 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions



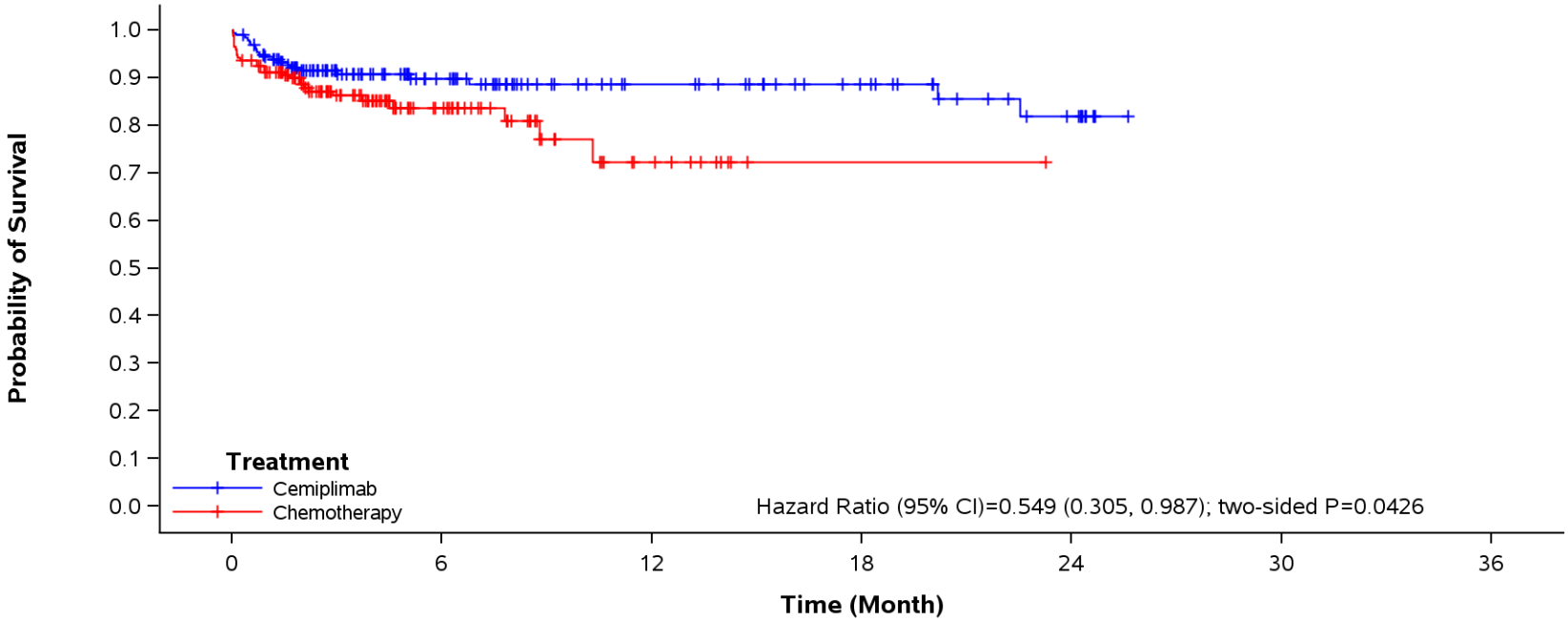

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 59 | 33 | 25 | 13 | 0 | 0 |
| Chemotherapy | 172 | 17 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Asthenia



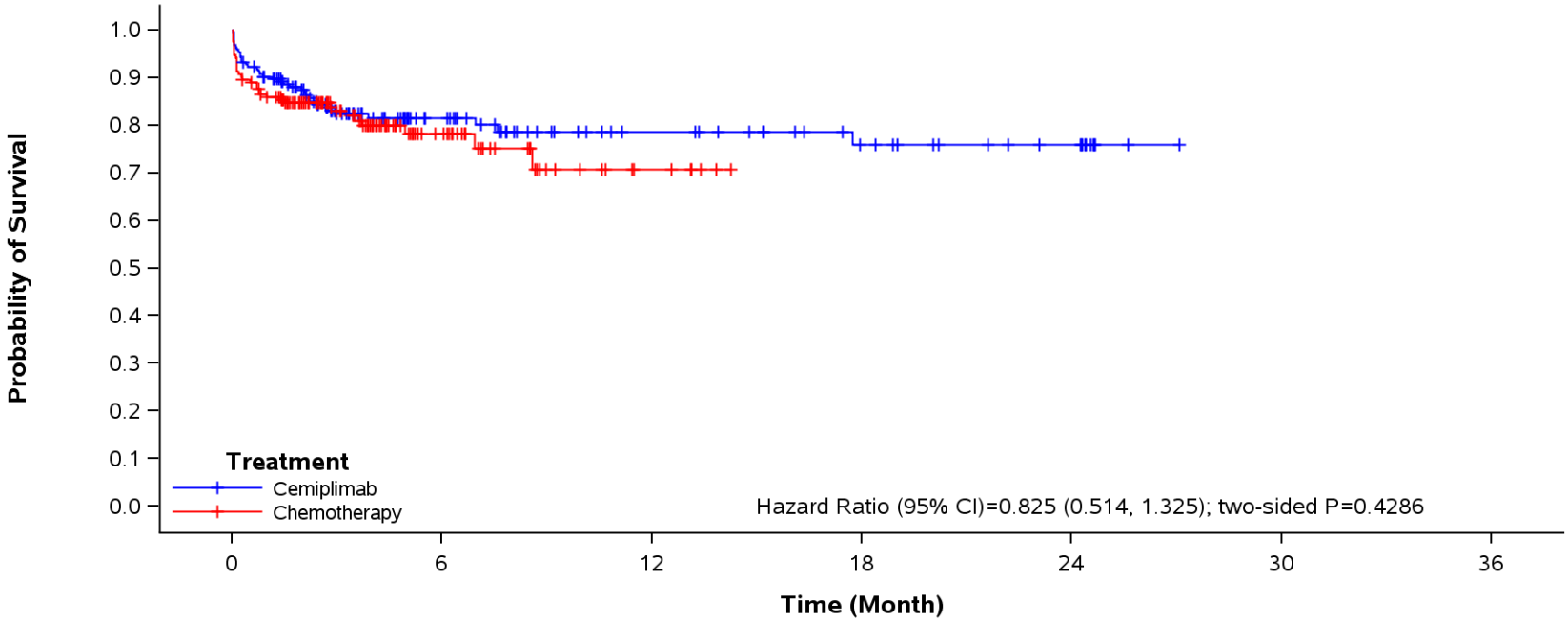

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 47 | 35 | 20 | 0 | 0 |
| Chemotherapy | 172 | 45 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Fatigue



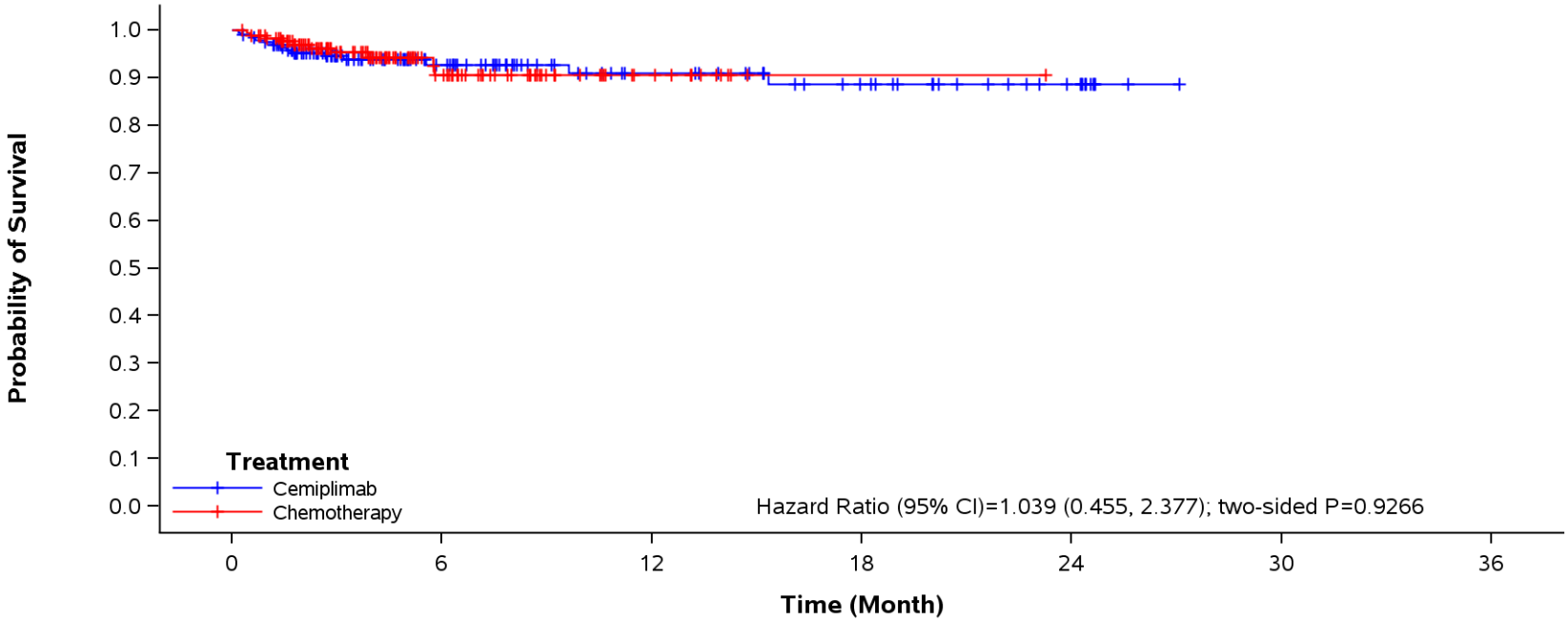

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 68 | 38 | 27 | 18 | 0 | 0 |
| Chemotherapy | 172 | 37 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Oedema peripheral



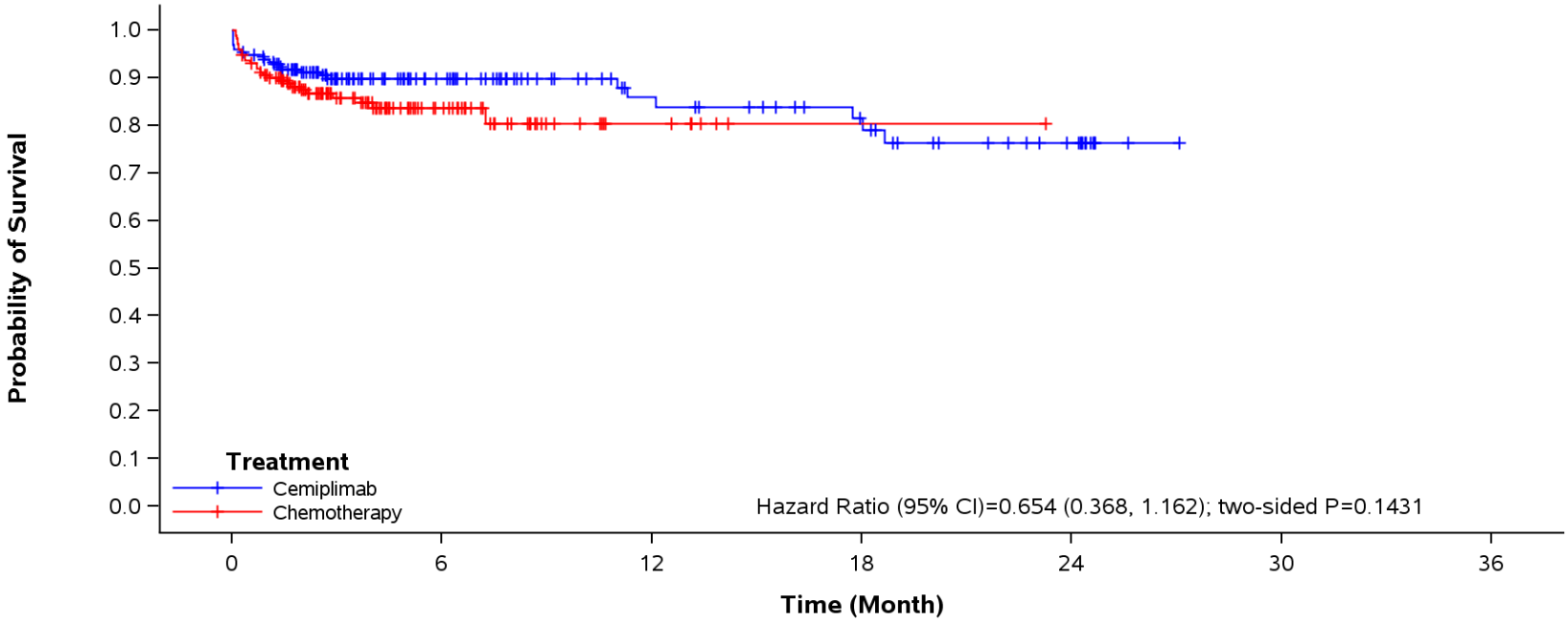

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 46 | 34 | 20 | 0 | 0 |
| Chemotherapy | 172 | 48 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions
PT: Pyrexia



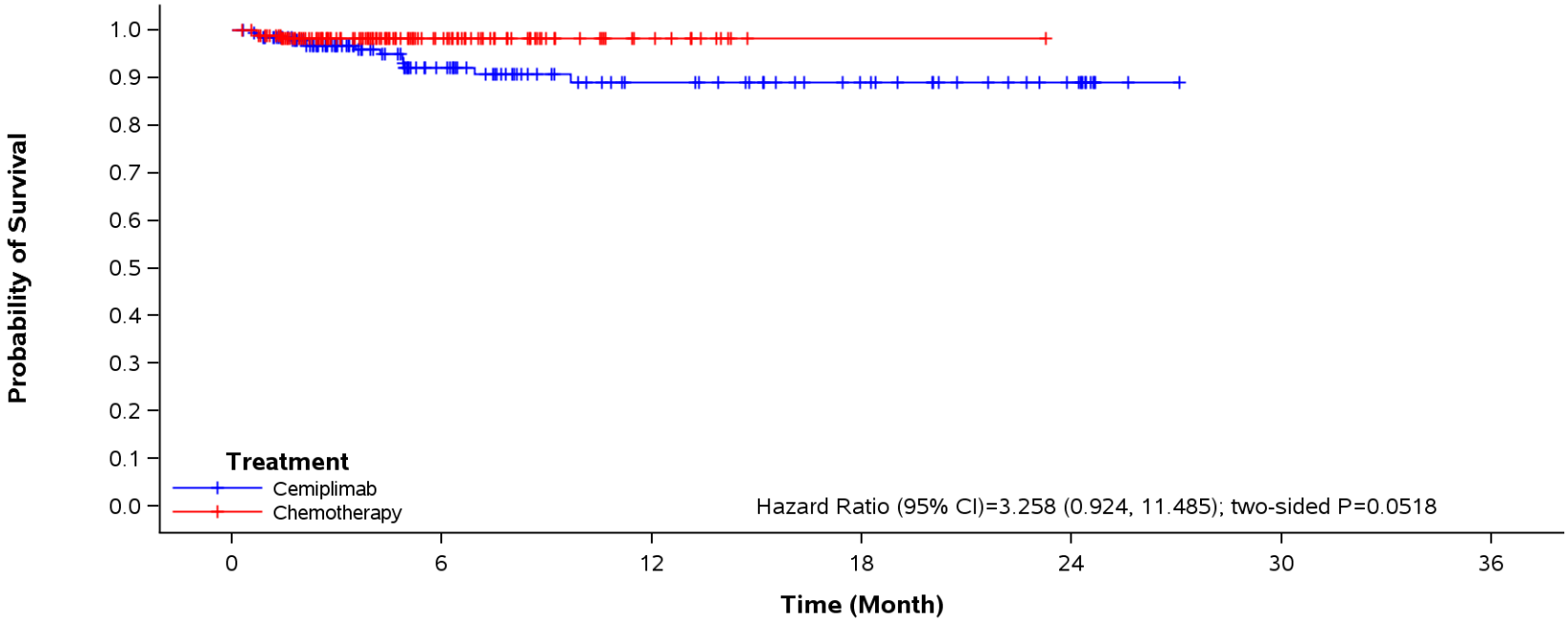

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 78 | 43 | 33 | 19 | 0 | 0 |
| Chemotherapy | 172 | 41 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders



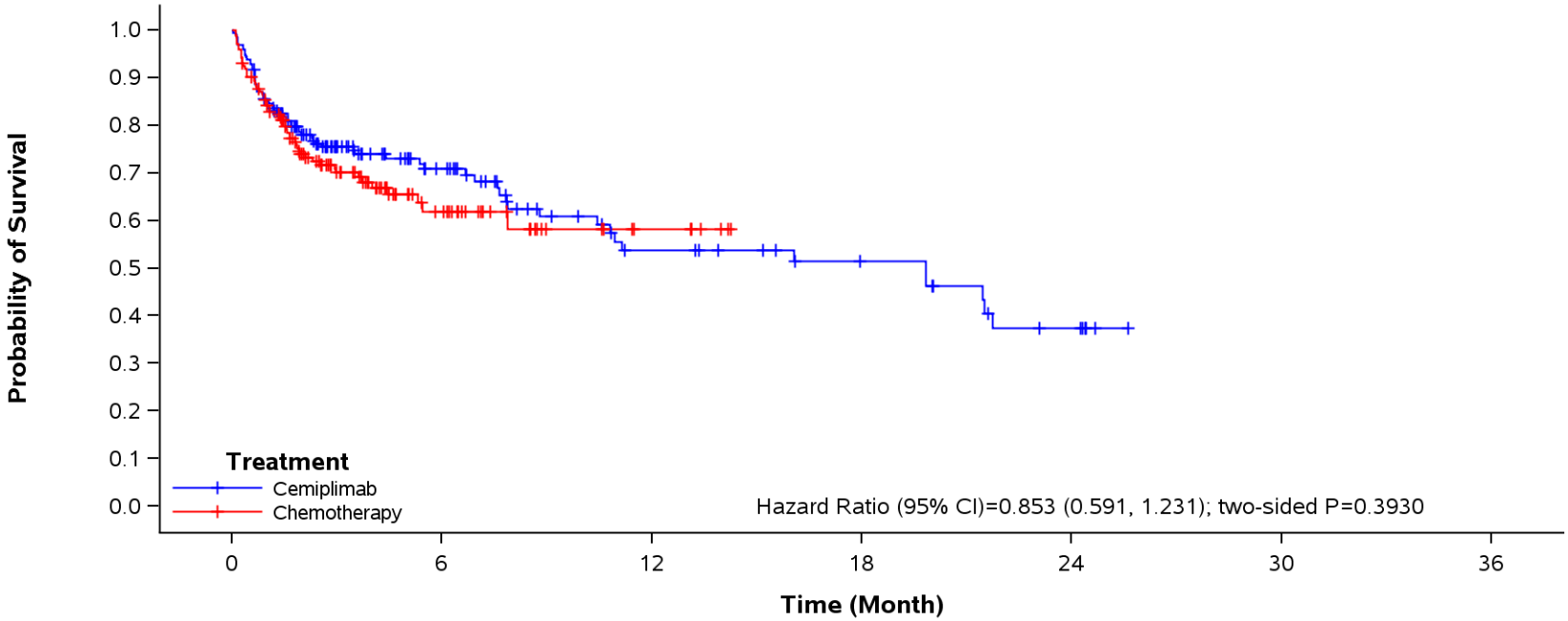

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 79 | 46 | 34 | 21 | 0 | 0 |
| Chemotherapy | 172 | 52 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations



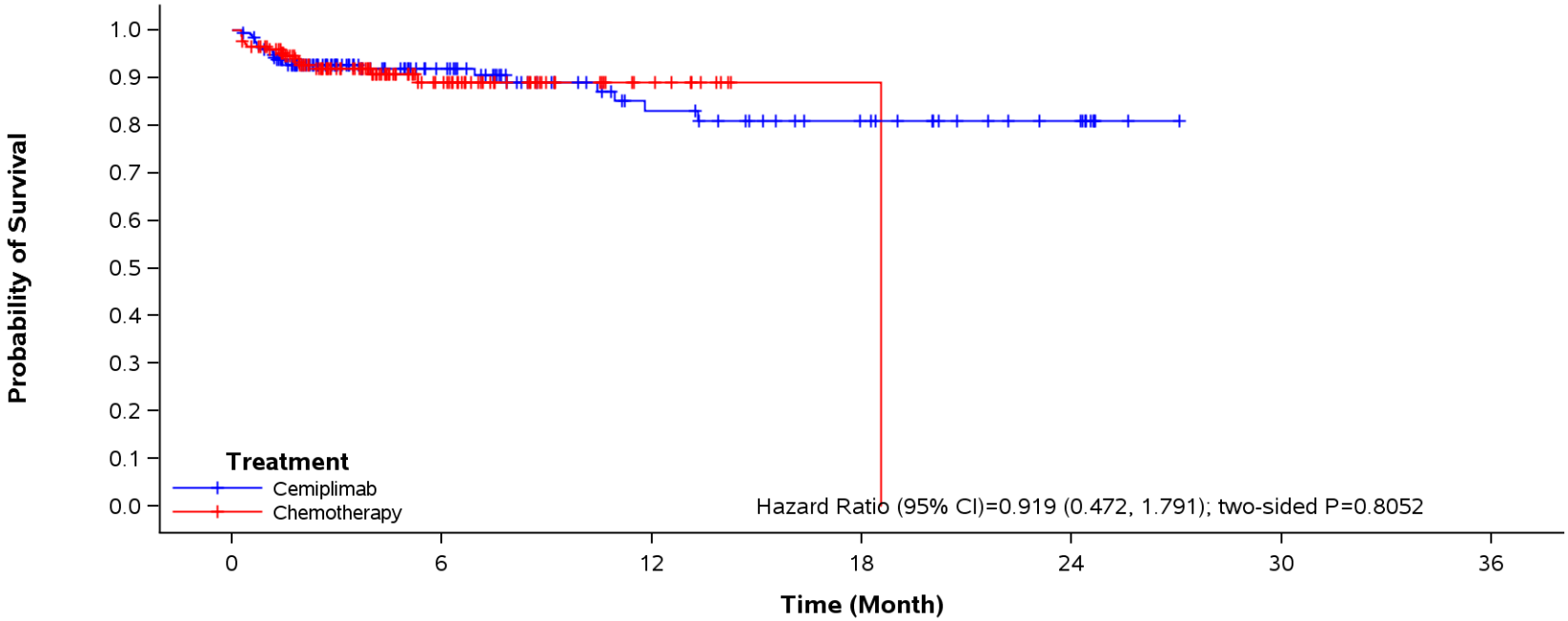

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 62 | 28 | 20 | 11 | 0 | 0 |
| Chemotherapy | 172 | 33 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations
PT: Urinary tract infection



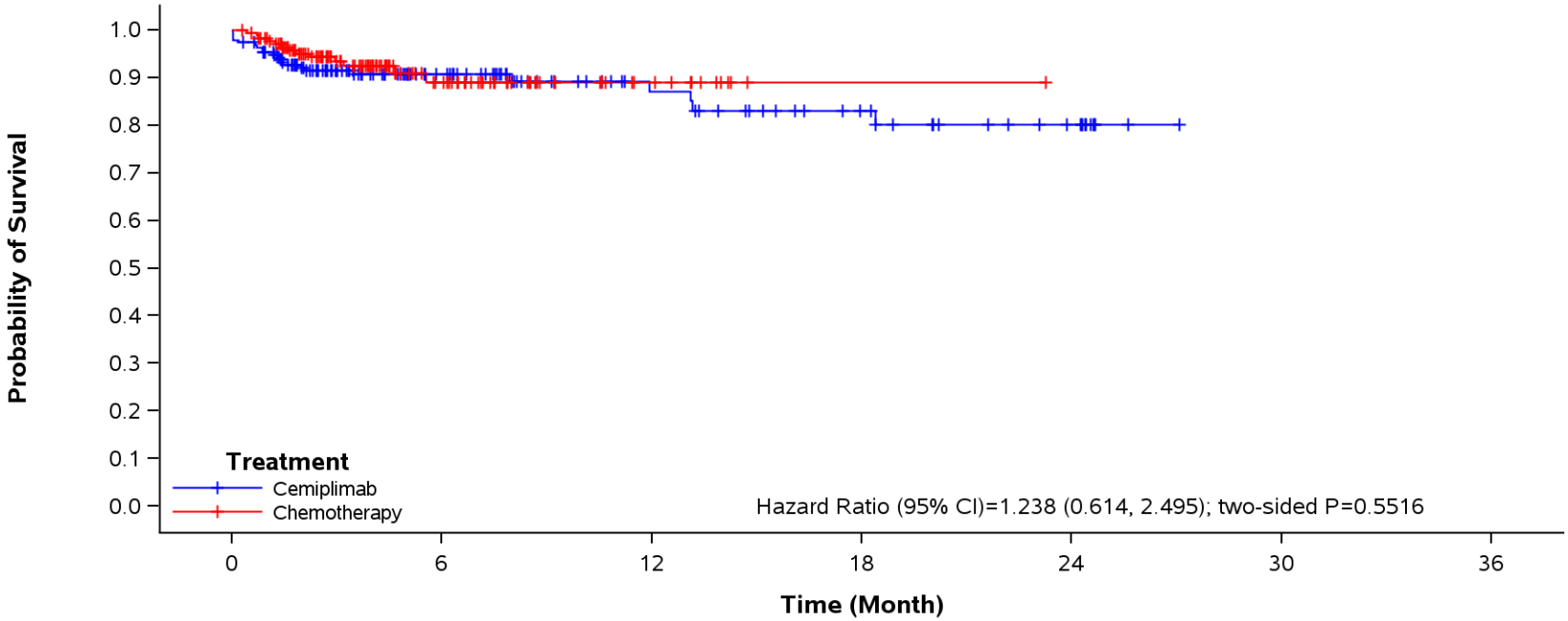

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 78 | 40 | 29 | 18 | 0 | 0 |
| Chemotherapy | 172 | 47 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Injury, poisoning and procedural complications



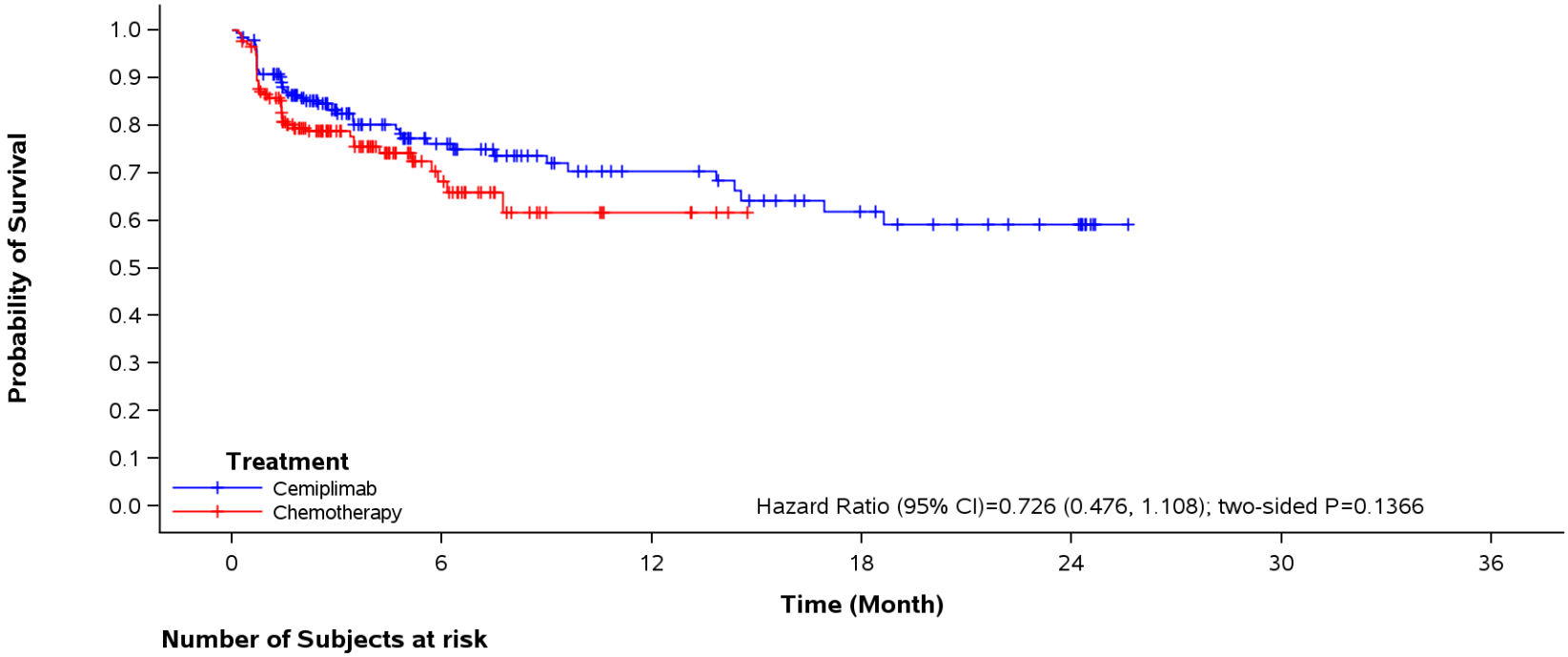

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 43 | 30 | 18 | 0 | 0 |
| Chemotherapy | 172 | 46 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations



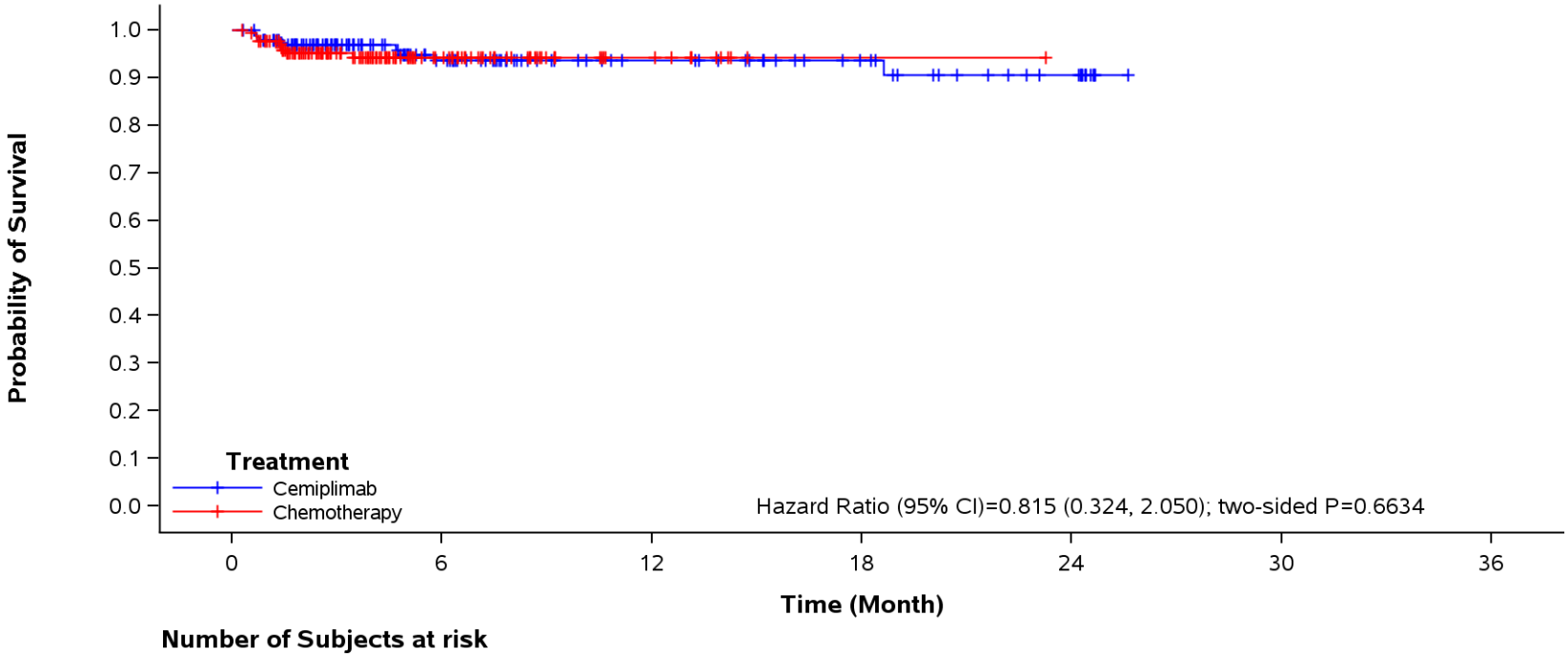

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 68 | 36 | 24 | 16 | 0 | 0 |
| Chemotherapy | 172 | 32 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Alanine aminotransferase increased



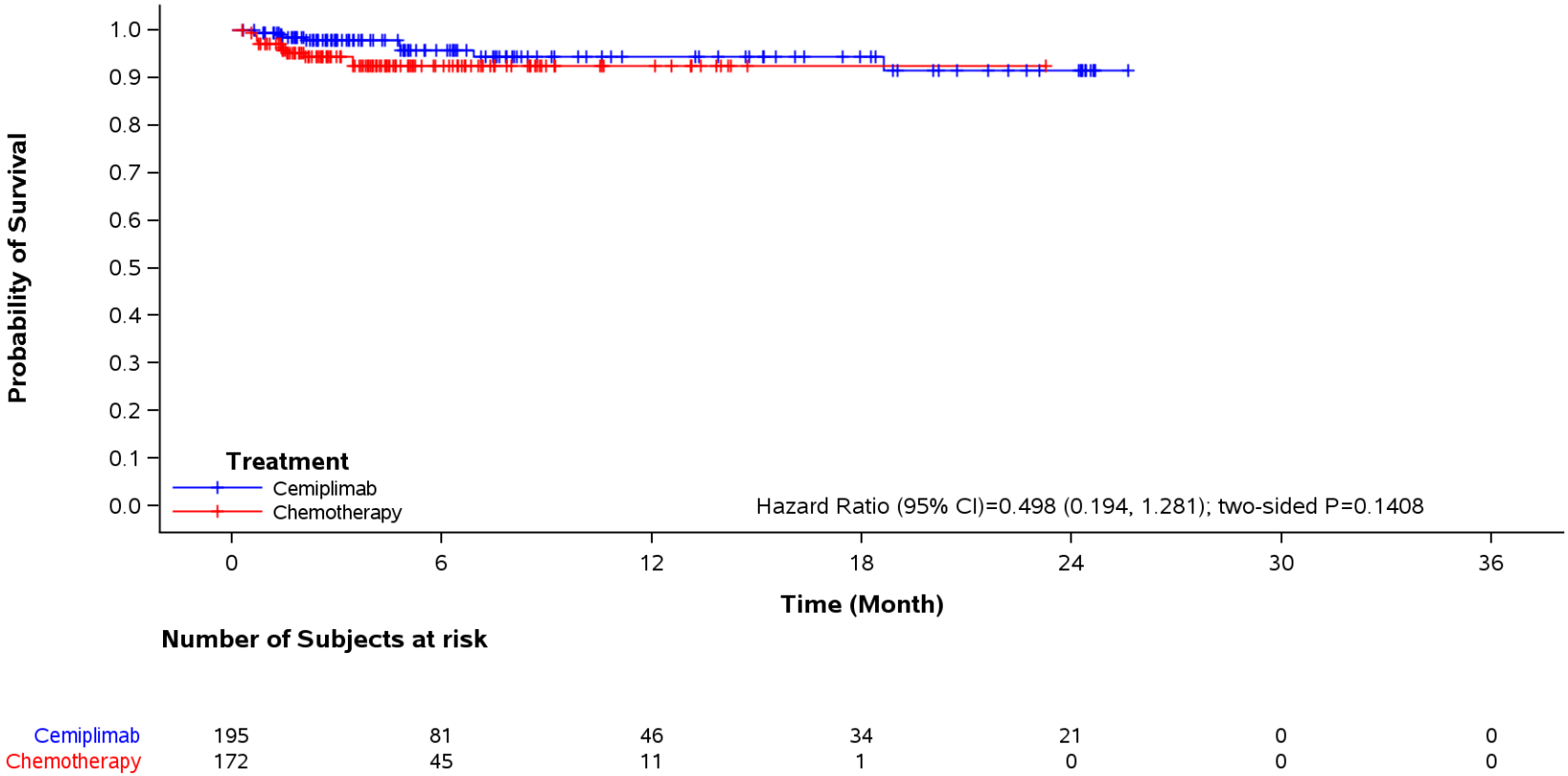

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 78 | 44 | 32 | 19 | 0 | 0 |
| Chemotherapy | 172 | 46 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Aspartate aminotransferase increased



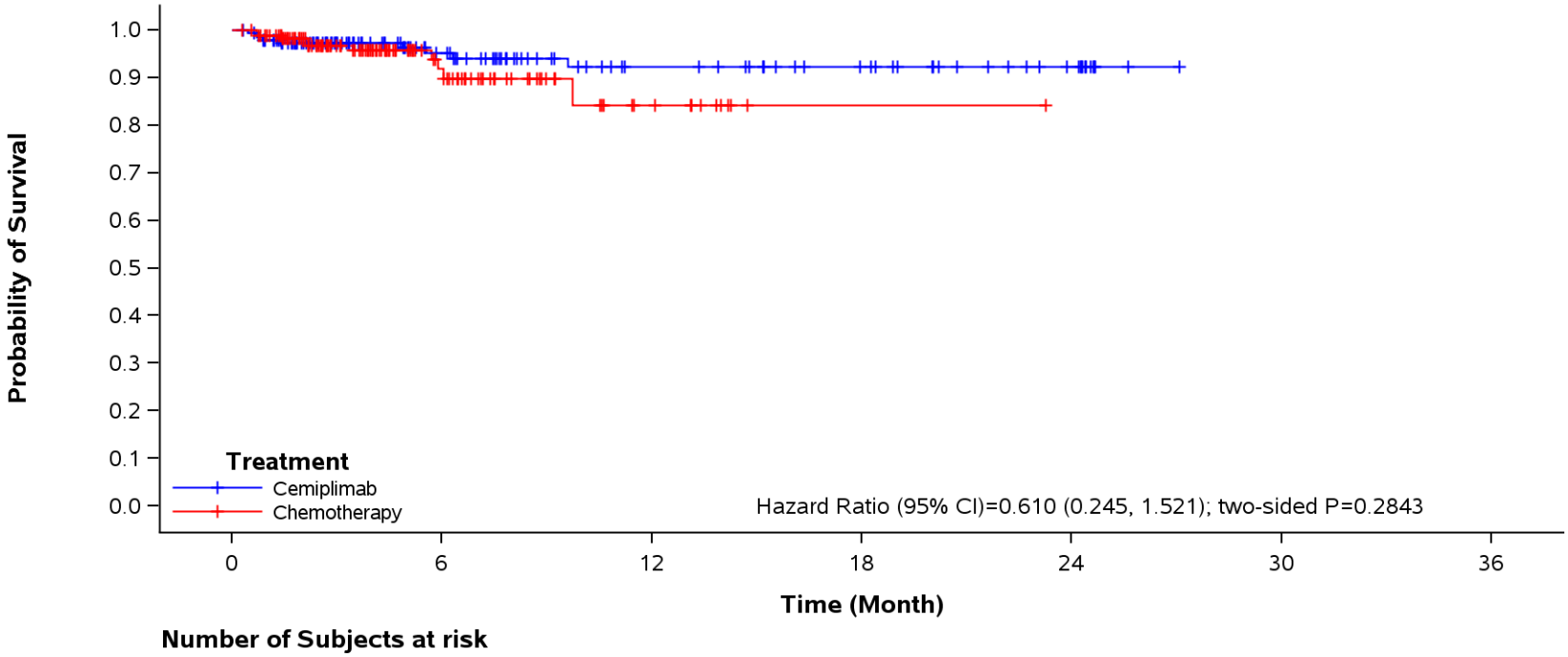

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 81 | 46 | 34 | 21 | 0 | 0 |
| Chemotherapy | 172 | 45 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Blood alkaline phosphatase increased



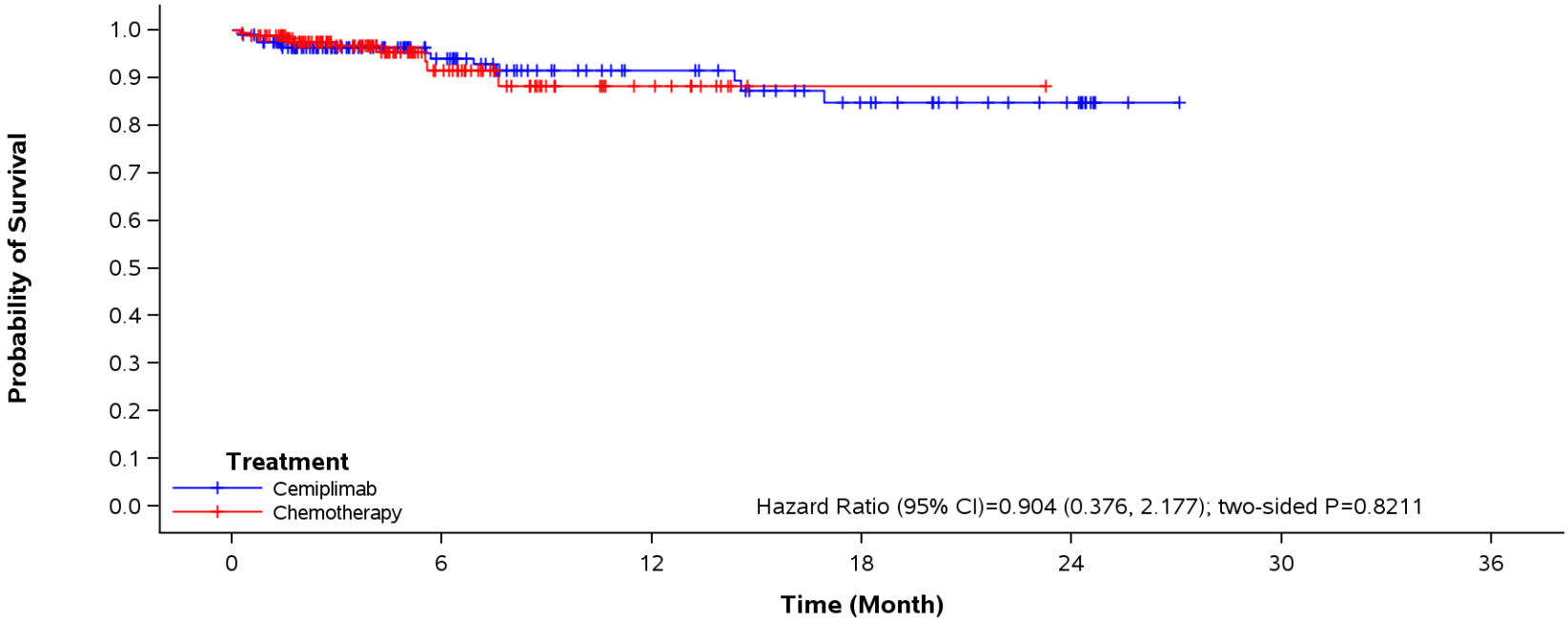

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 46 | 36 | 22 | 0 | 0 |
| Chemotherapy | 172 | 46 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Blood creatinine increased



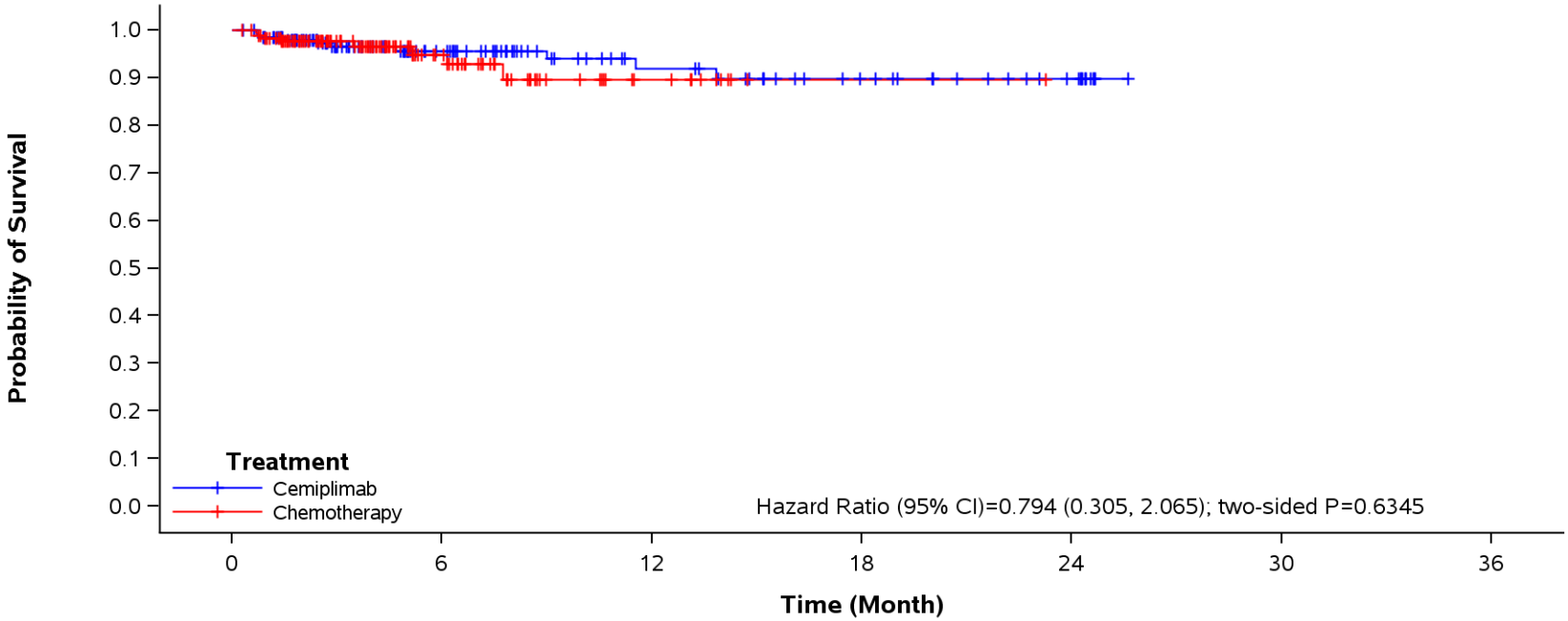

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 47 | 33 | 21 | 0 | 0 |
| Chemotherapy | 172 | 46 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations
PT: Weight decreased



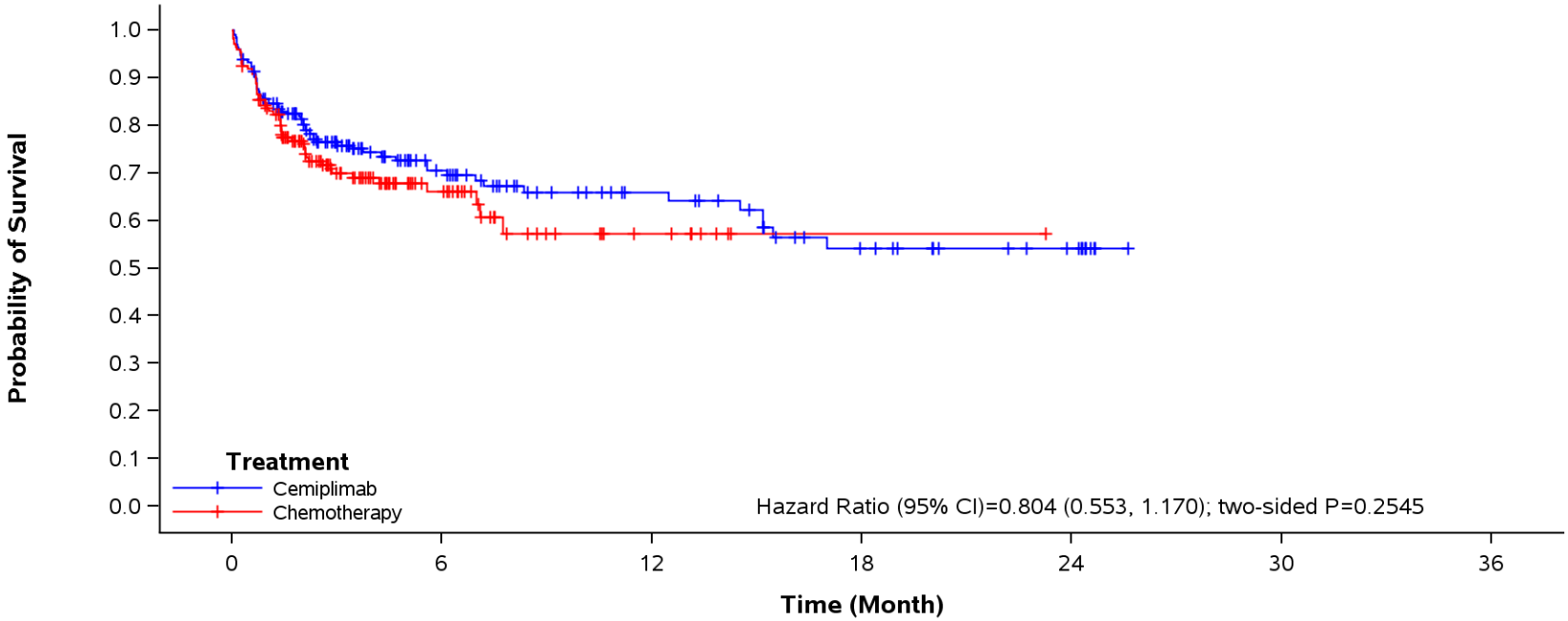

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 45 | 32 | 20 | 0 | 0 |
| Chemotherapy | 172 | 48 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders



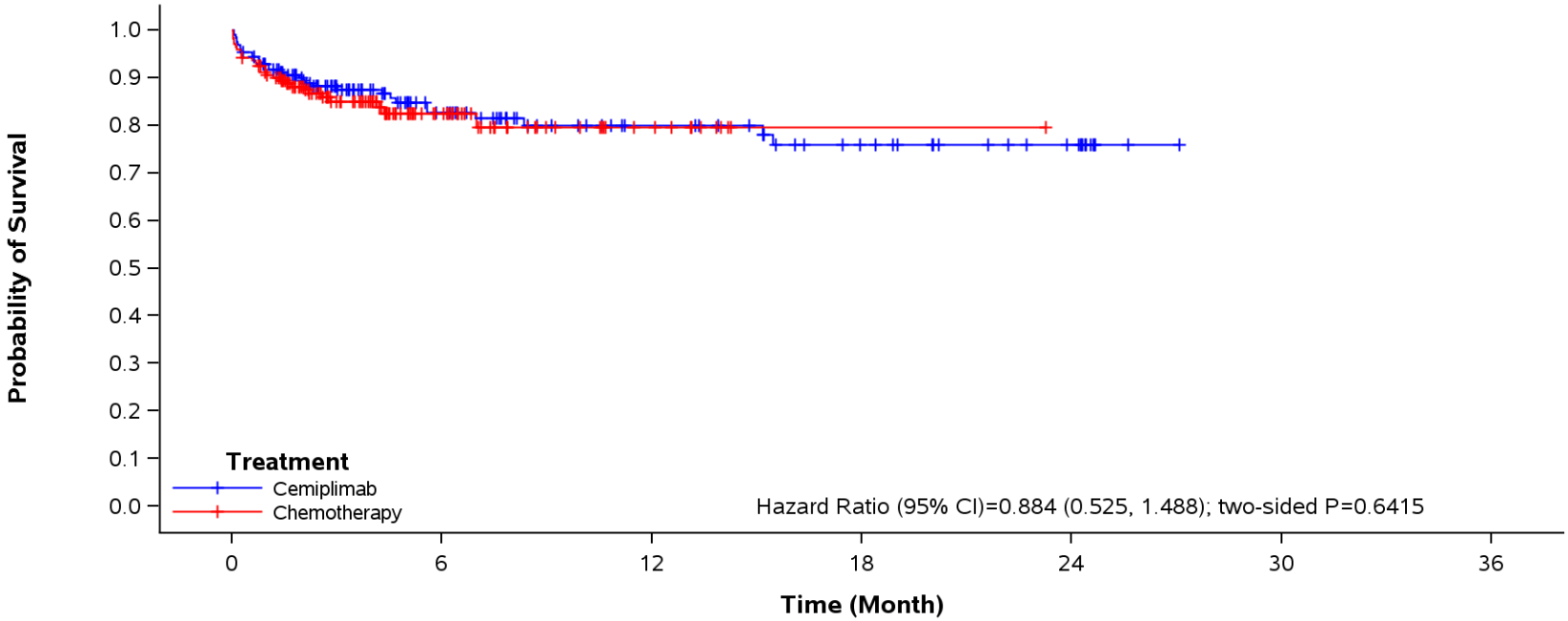

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 69 | 39 | 23 | 14 | 0 | 0 |
| Chemotherapy | 172 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Decreased appetite



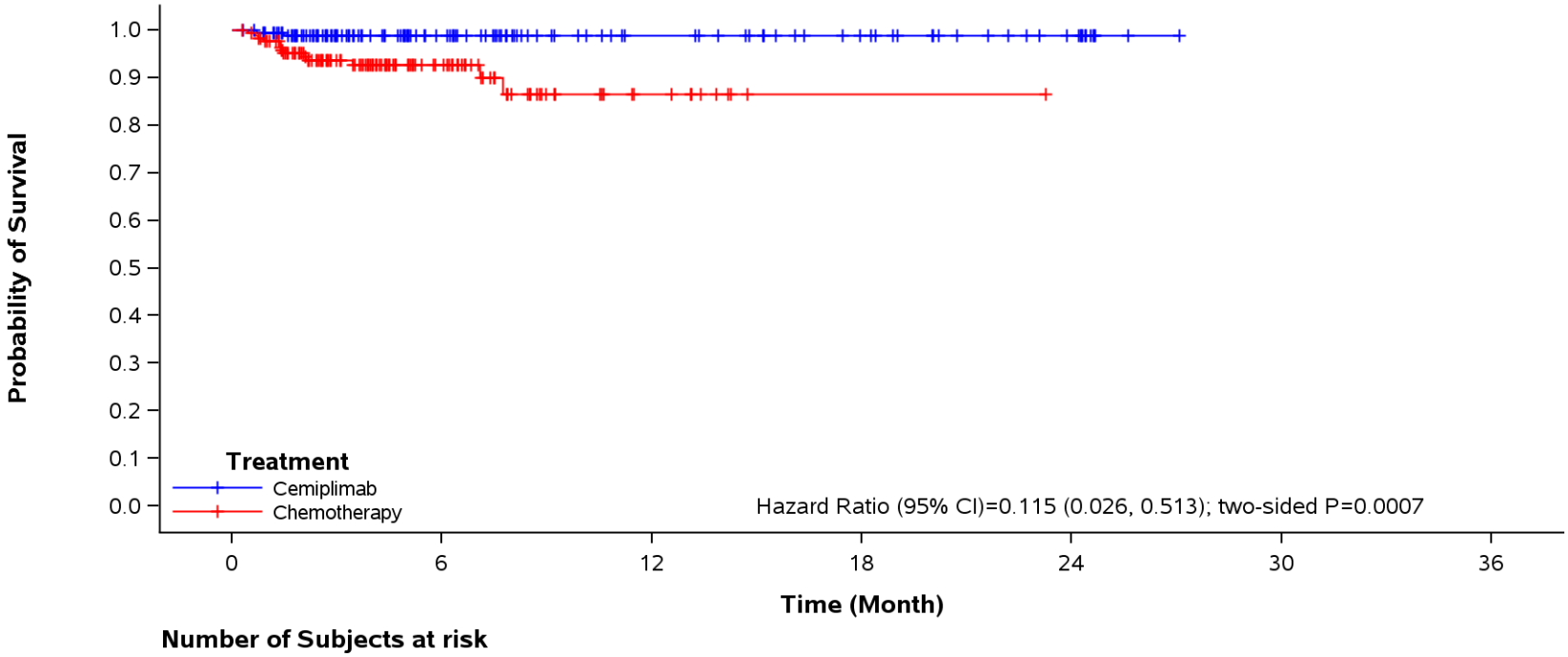

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 76 | 44 | 31 | 20 | 0 | 0 |
| Chemotherapy | 172 | 43 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



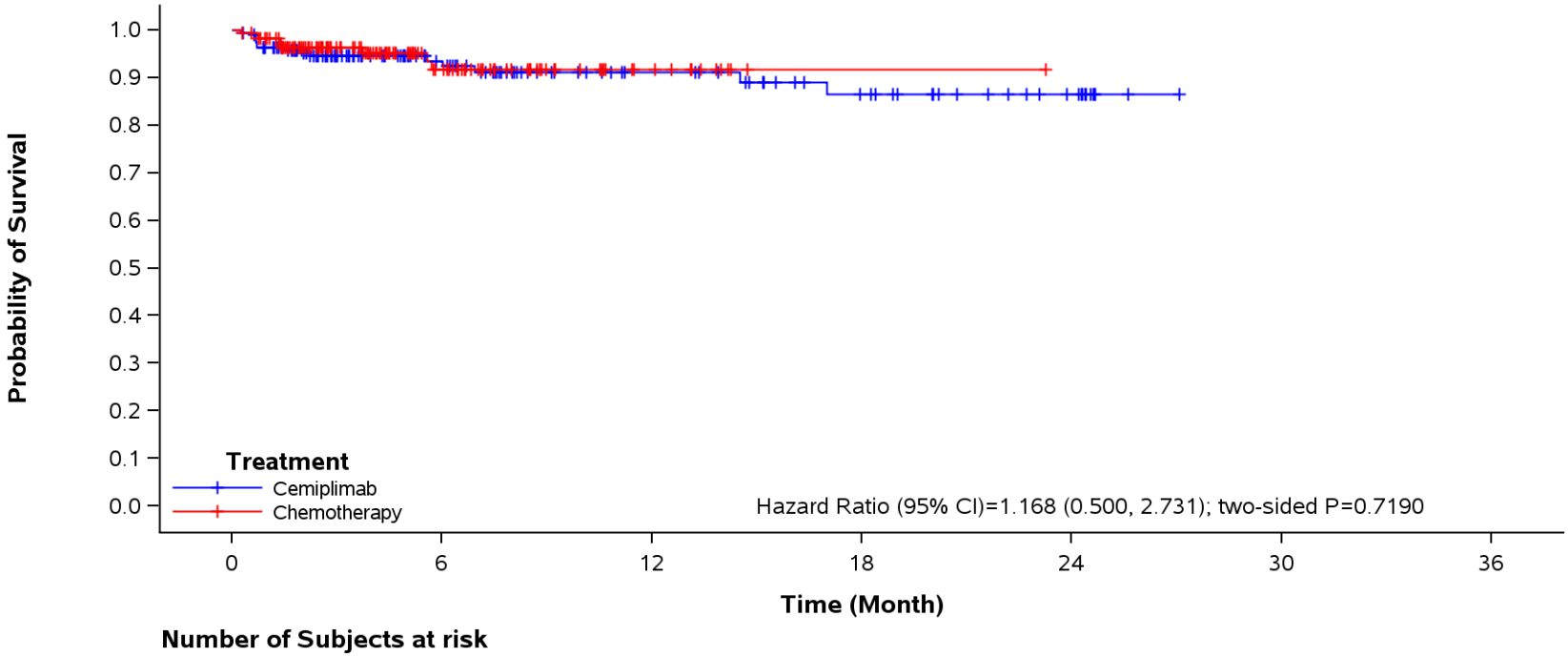

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 48 | 36 | 22 | 0 | 0 |
| Chemotherapy | 172 | 48 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Hypoalbuminaemia



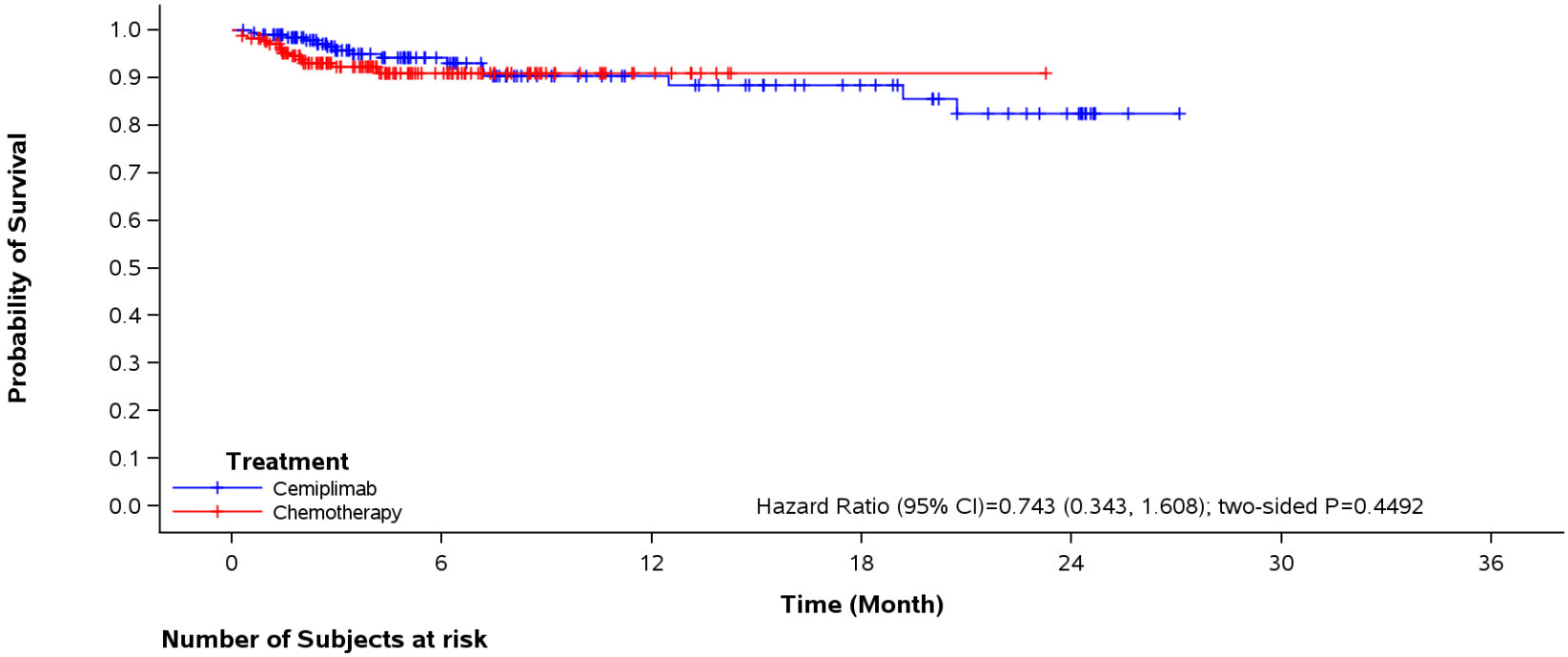

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 47 | 34 | 20 | 0 | 0 |
| Chemotherapy | 172 | 49 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders
PT: Hypokalaemia



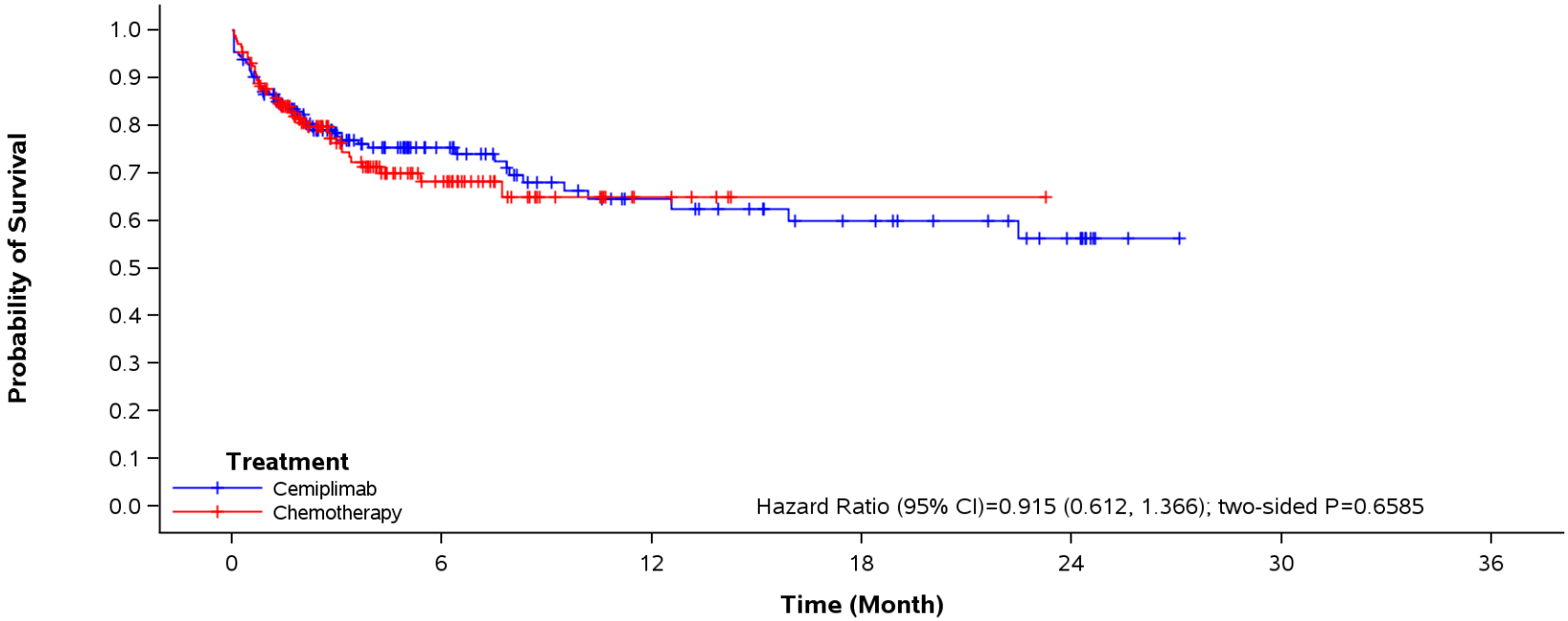

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 47 | 34 | 20 | 0 | 0 |
| Chemotherapy | 172 | 50 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders



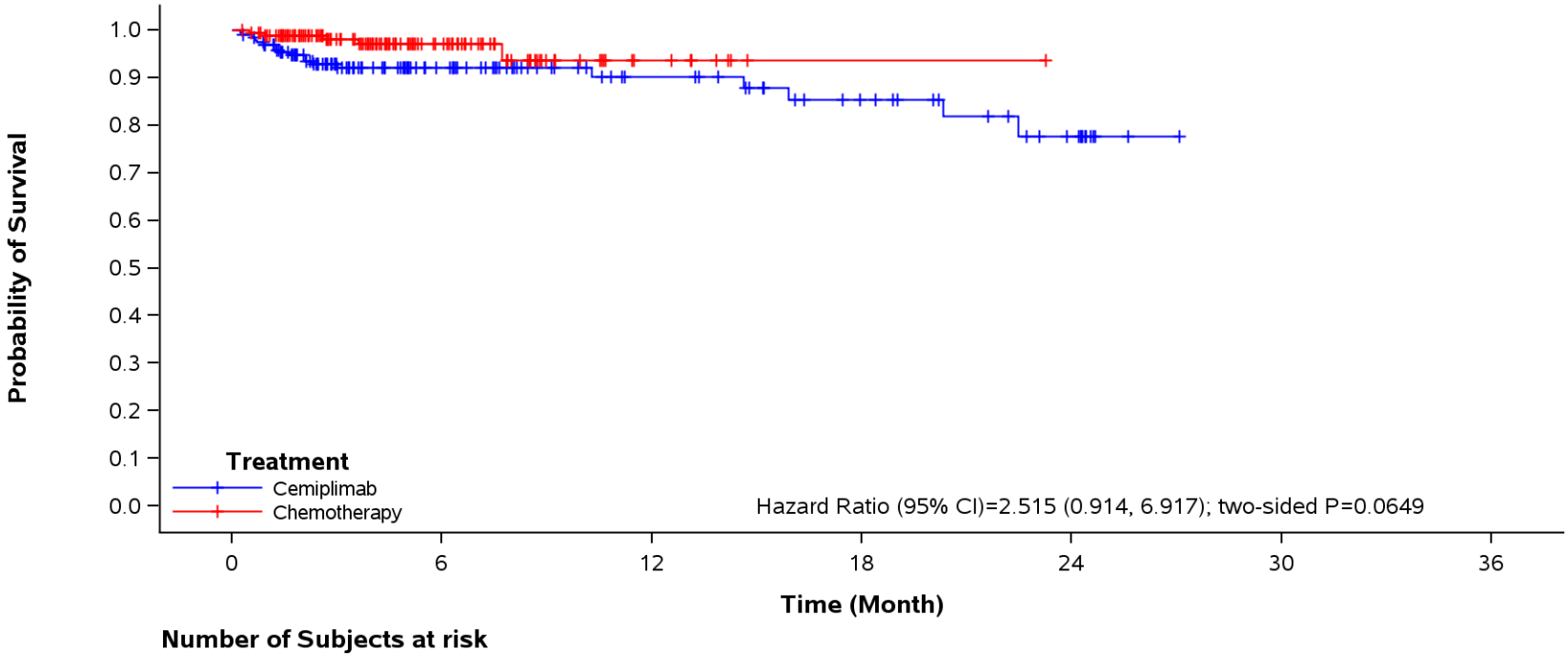

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 61 | 32 | 22 | 12 | 0 | 0 |
| Chemotherapy | 172 | 37 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia



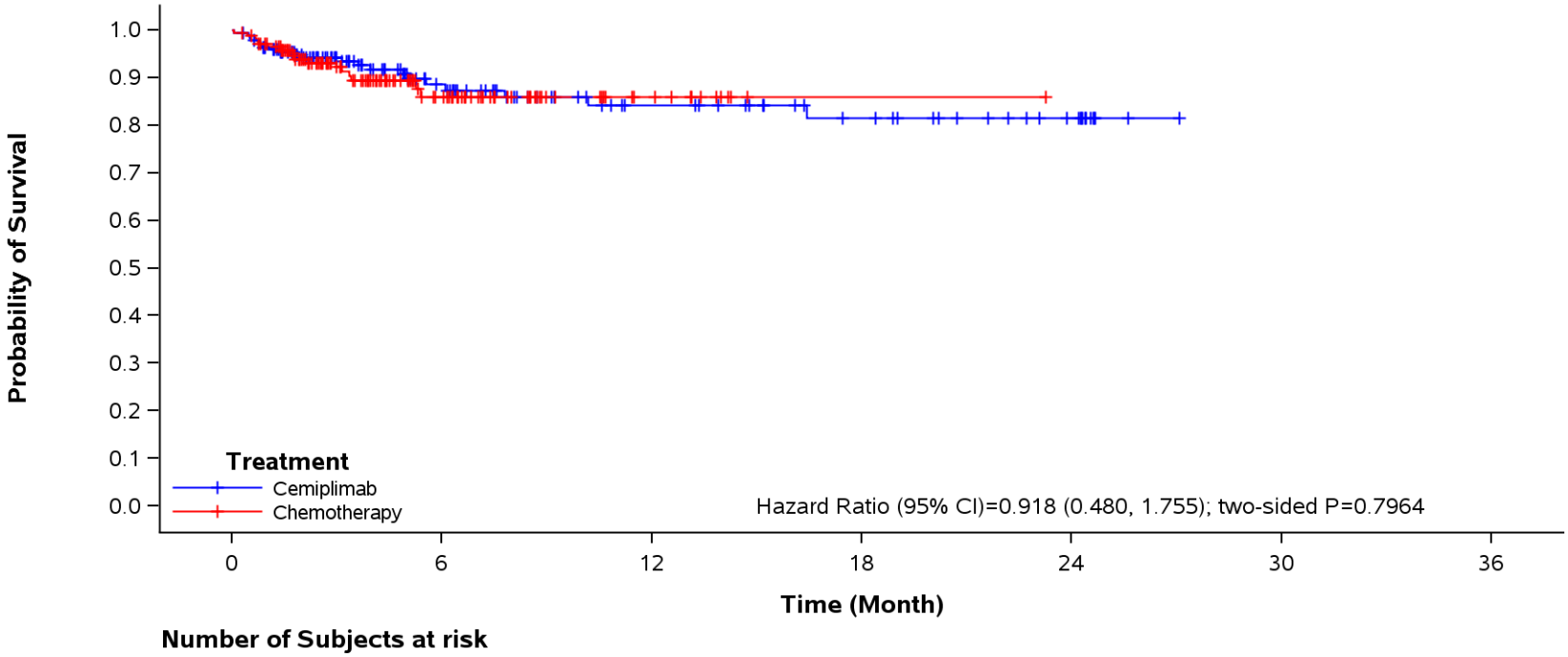

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 75 | 42 | 29 | 16 | 0 | 0 |
| Chemotherapy | 172 | 49 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Back pain



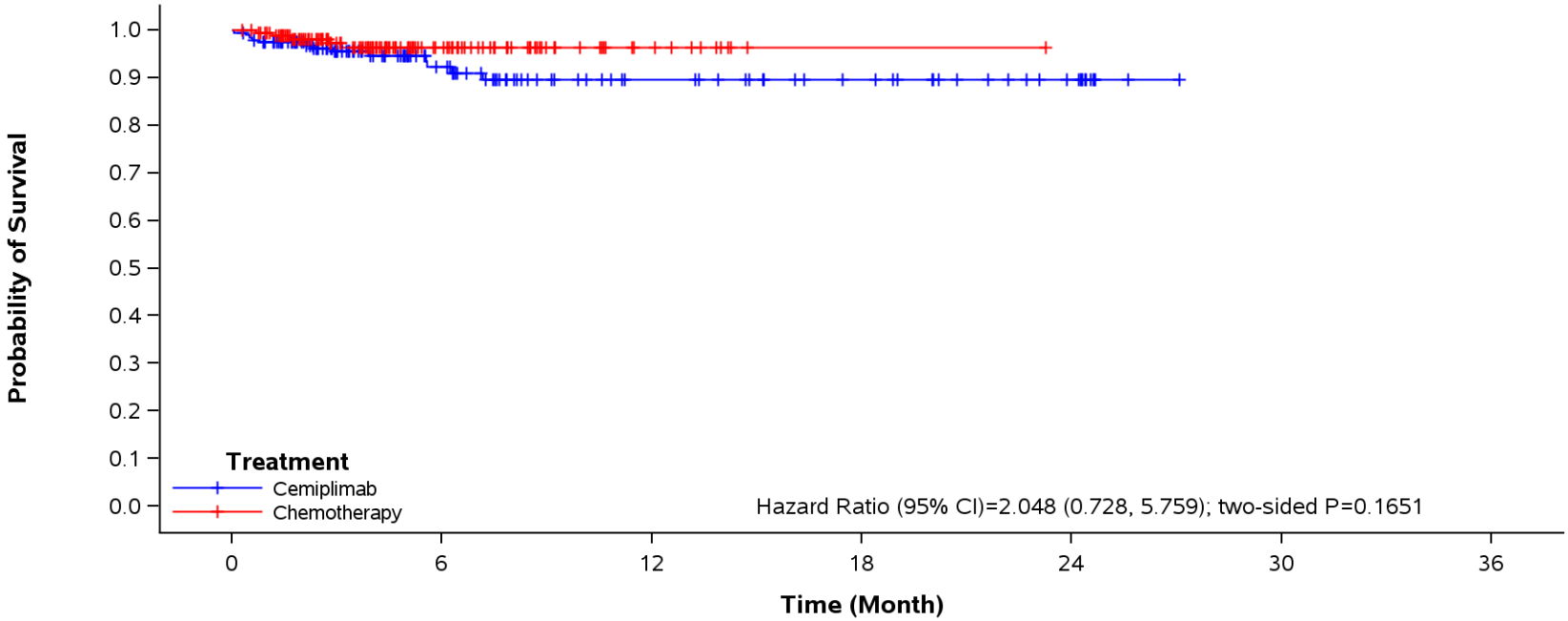

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 75 | 42 | 31 | 19 | 0 | 0 |
| Chemotherapy | 172 | 48 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Musculoskeletal and connective tissue disorders
PT: Pain in extremity



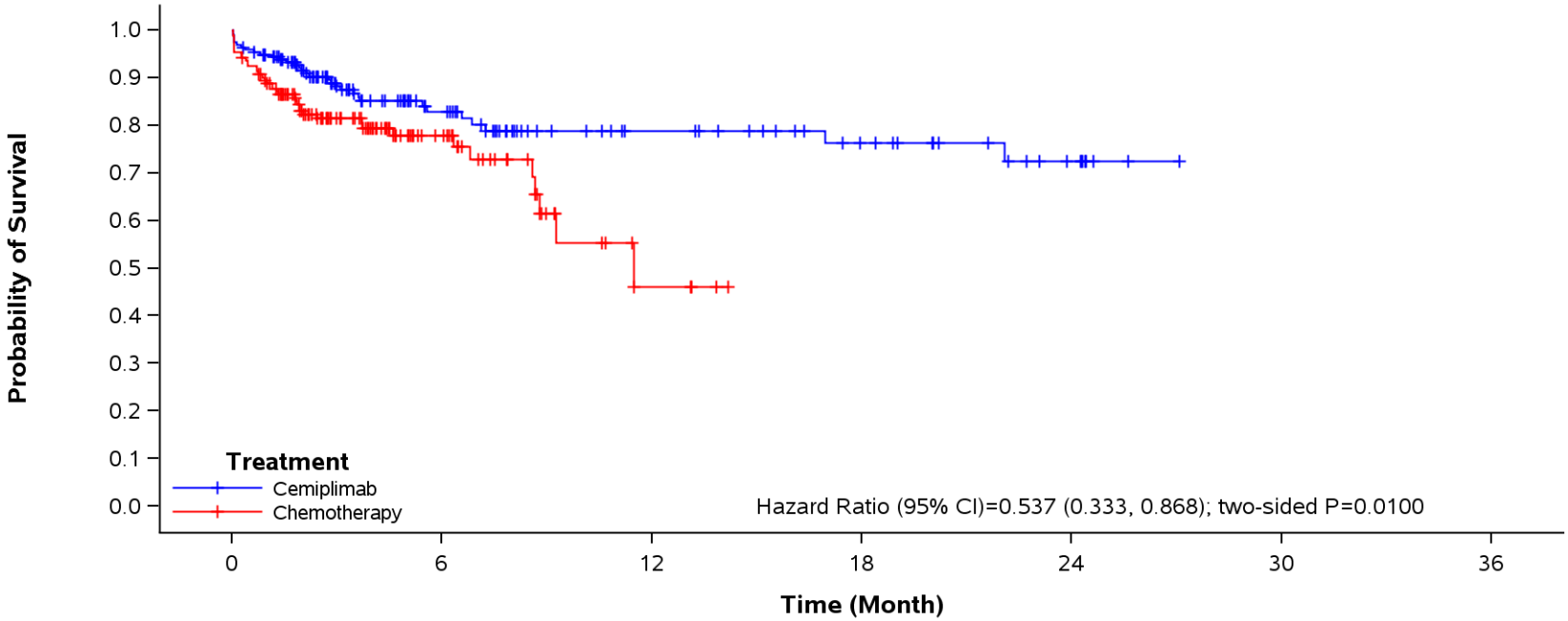

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 43 | 33 | 20 | 0 | 0 |
| Chemotherapy | 172 | 49 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders



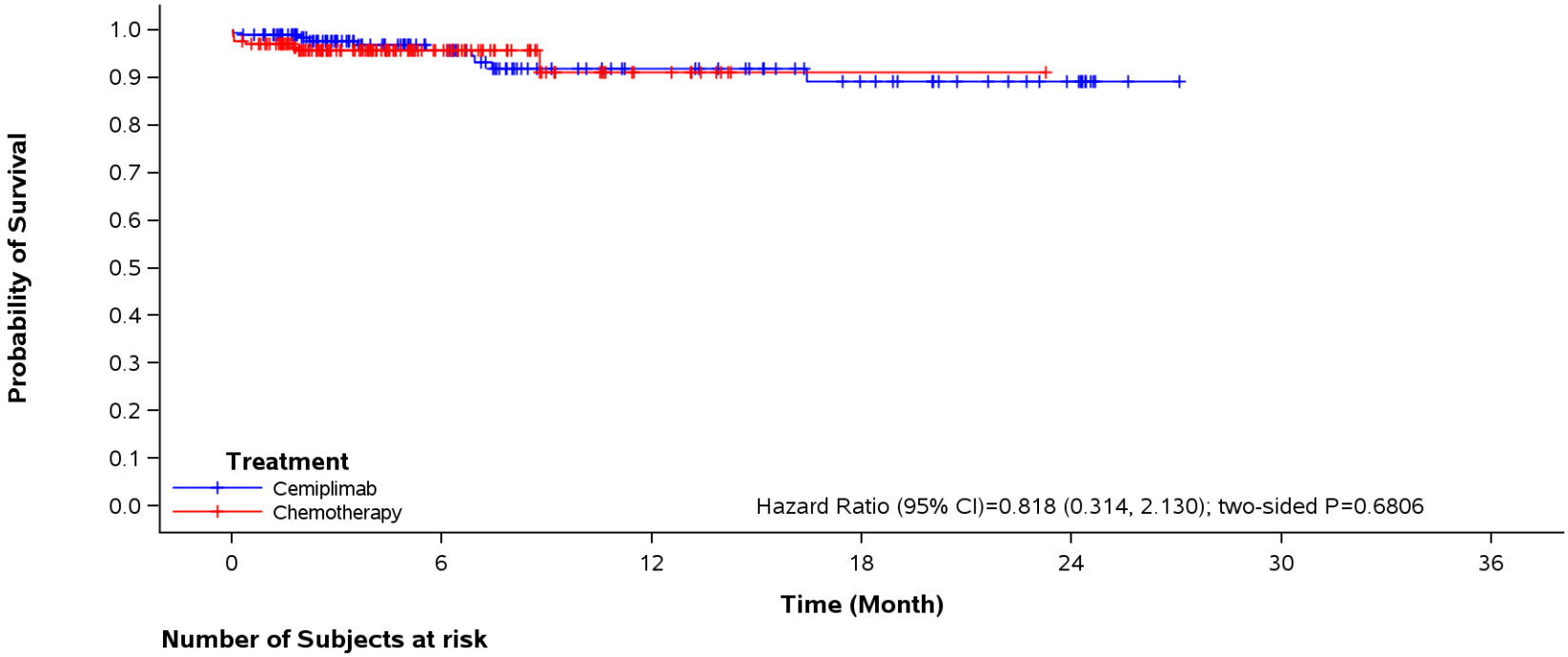

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 71 | 38 | 27 | 15 | 0 | 0 |
| Chemotherapy | 172 | 39 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders
PT: Dizziness



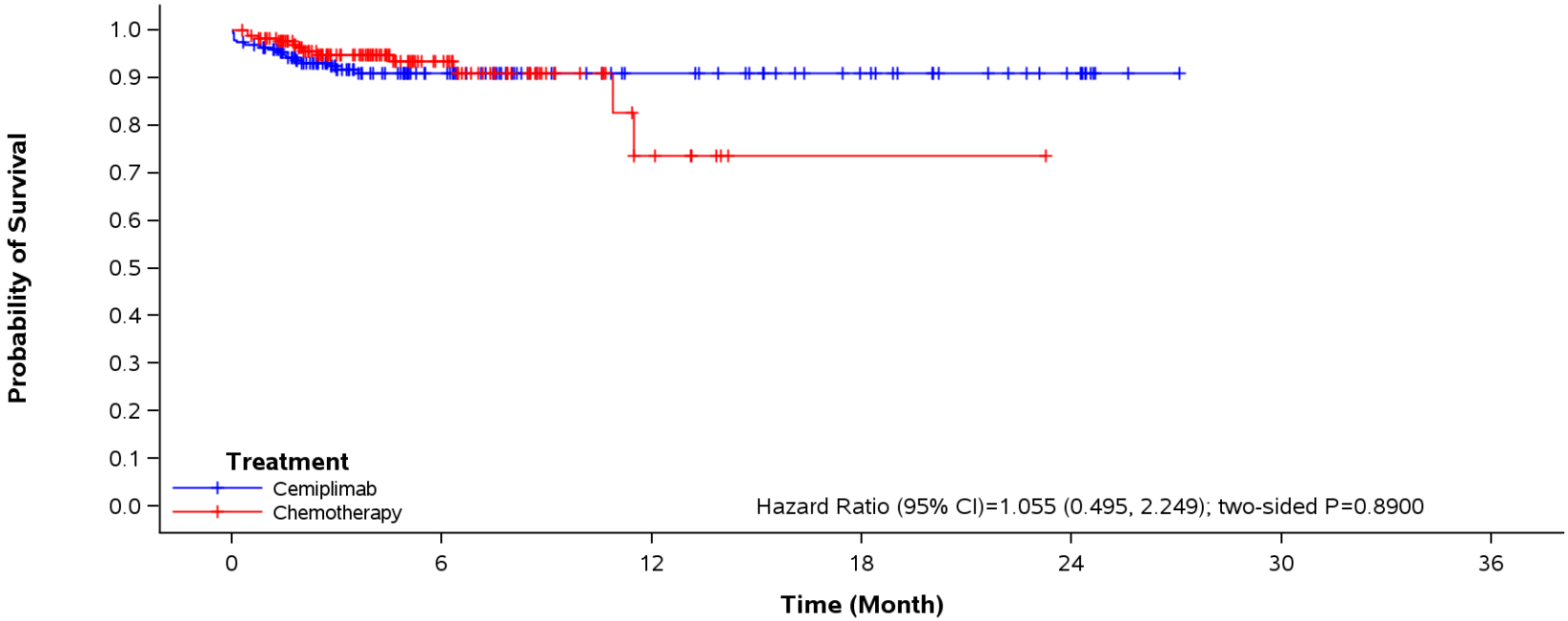

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 46 | 33 | 20 | 0 | 0 |
| Chemotherapy | 172 | 49 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Nervous system disorders
PT: Headache



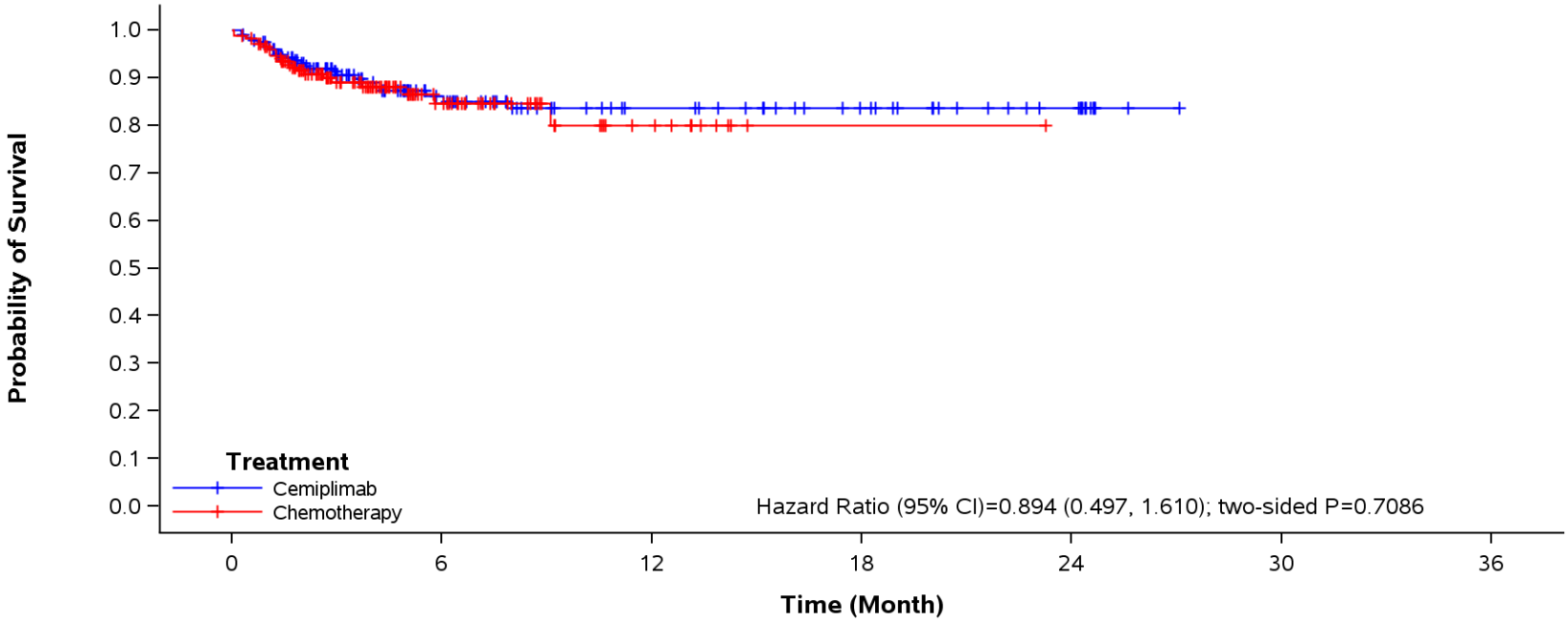

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 43 | 31 | 18 | 0 | 0 |
| Chemotherapy | 172 | 47 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Psychiatric disorders



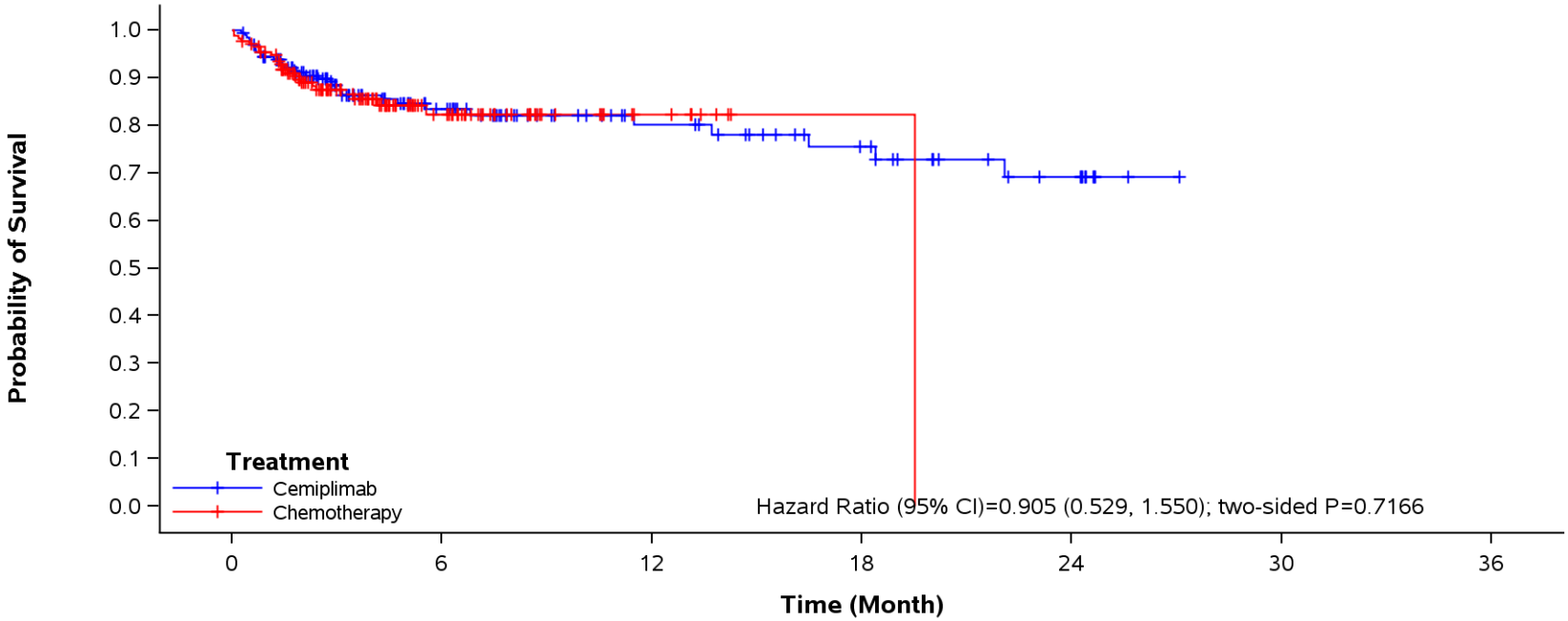

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 44 | 33 | 20 | 0 | 0 |
| Chemotherapy | 172 | 44 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders



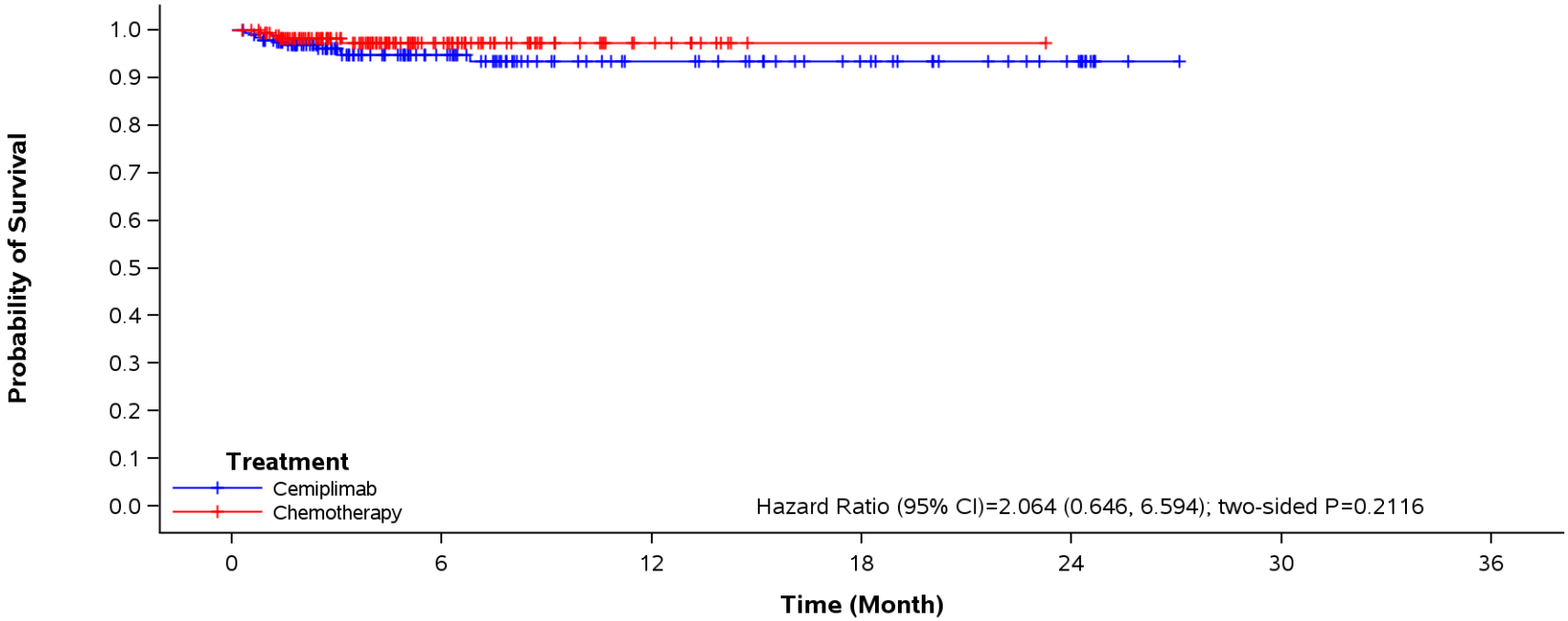

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 74 | 41 | 29 | 17 | 0 | 0 |
| Chemotherapy | 172 | 42 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders
PT: Haematuria



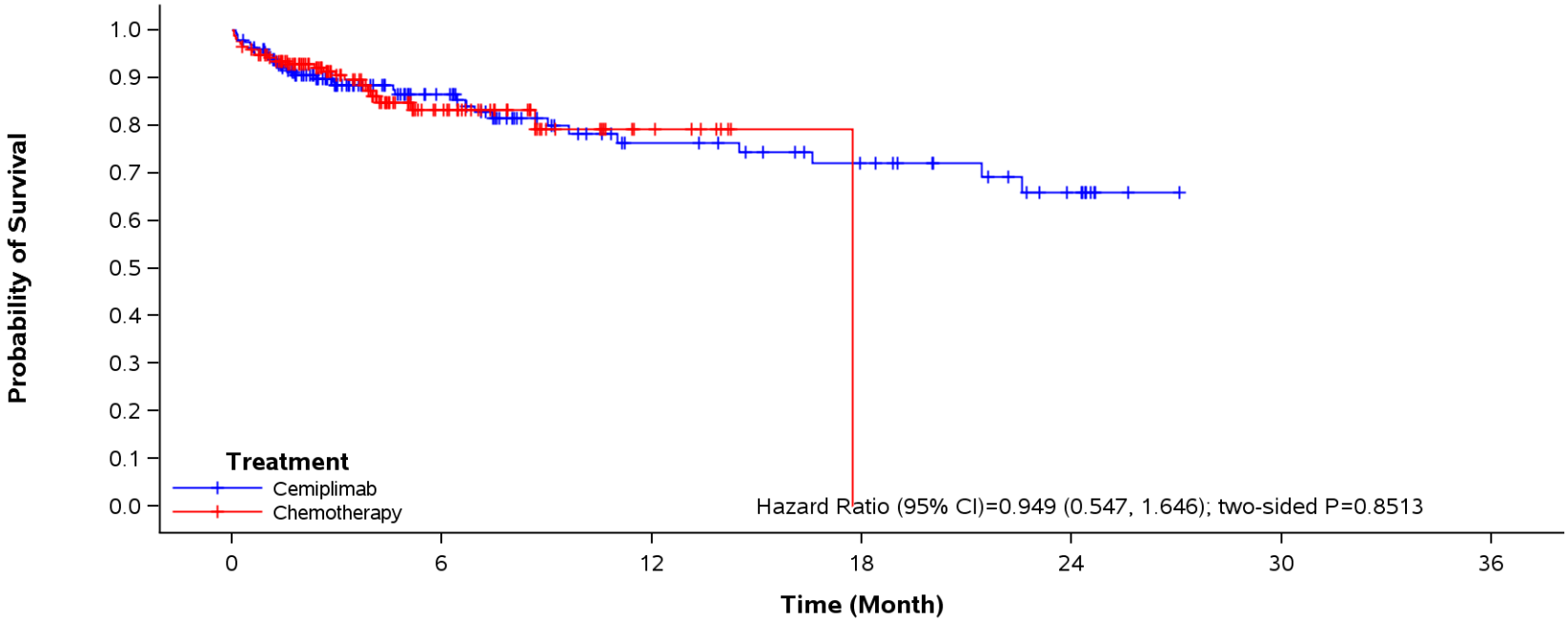

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 46 | 34 | 21 | 0 | 0 |
| Chemotherapy | 172 | 50 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Reproductive system and breast disorders



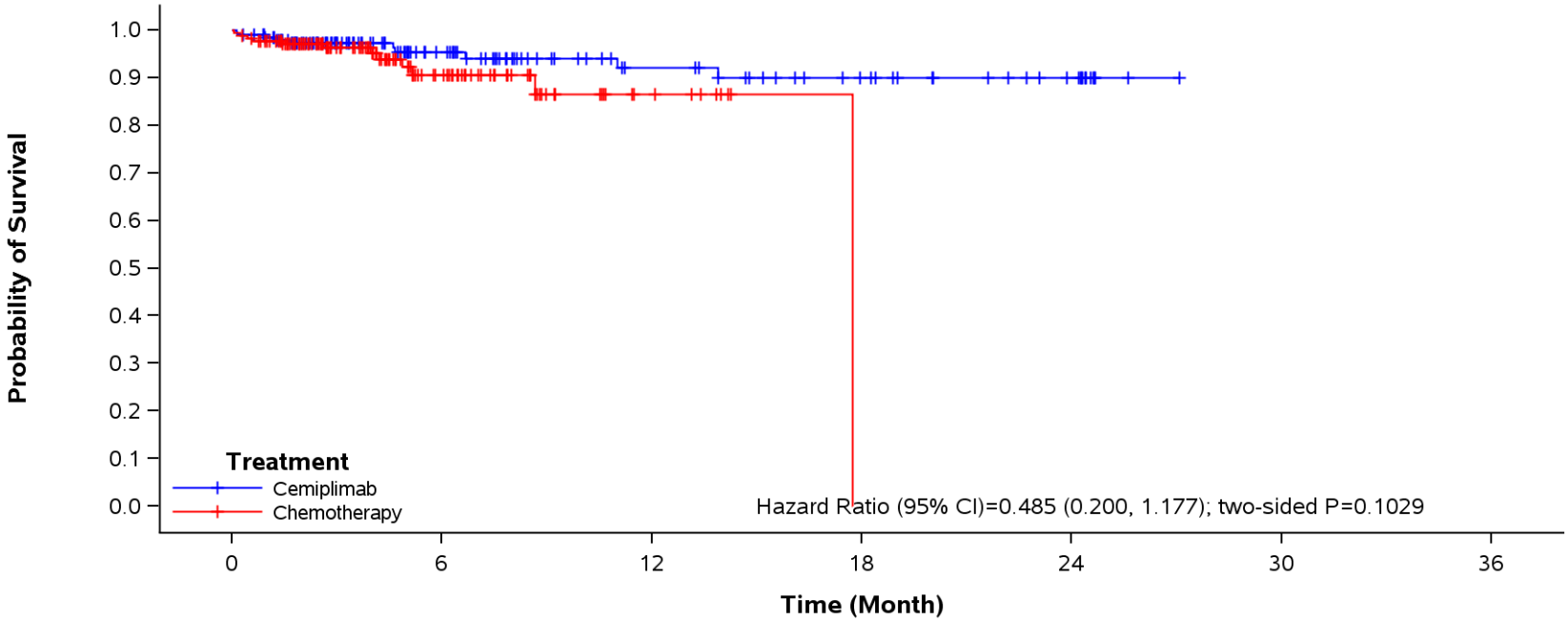

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 77 | 39 | 30 | 17 | 0 | 0 |
| Chemotherapy | 172 | 43 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Reproductive system and breast disorders
PT: Pelvic pain



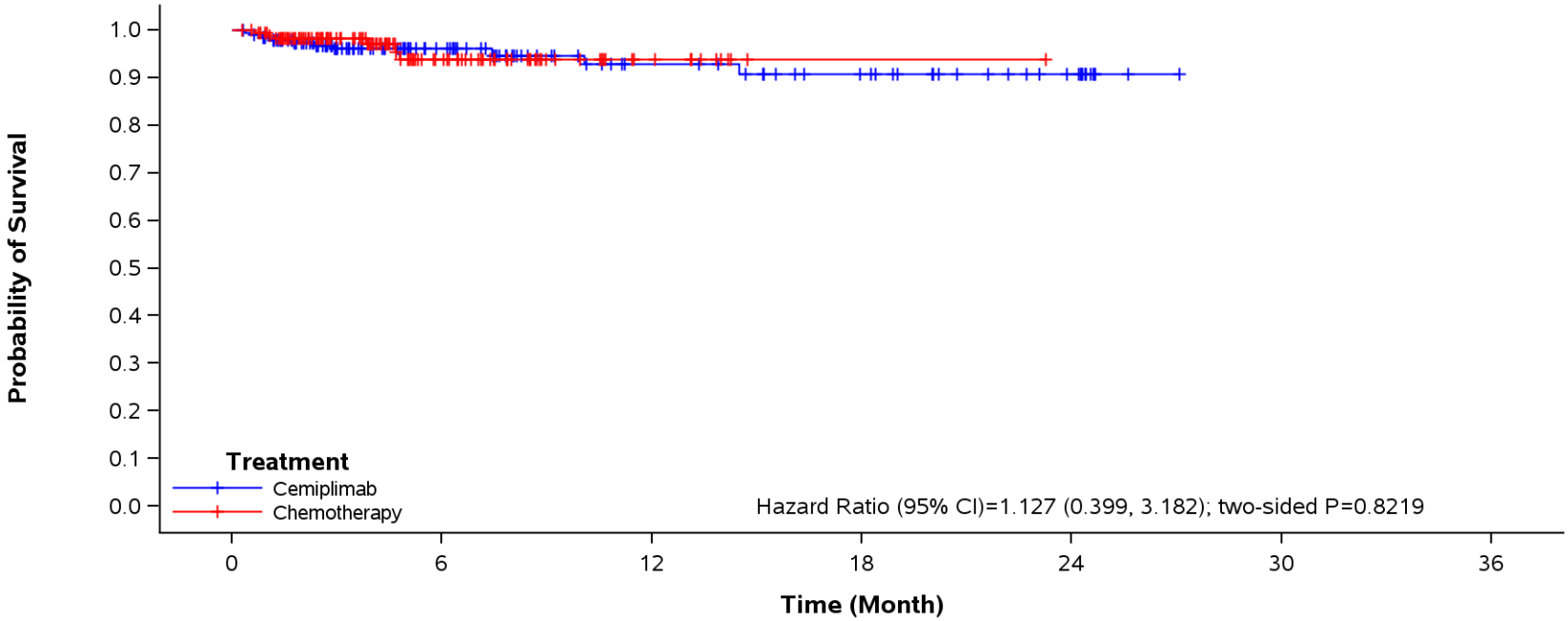

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 45 | 33 | 21 | 0 | 0 |
| Chemotherapy | 172 | 48 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Reproductive system and breast disorders
PT: Vaginal haemorrhage



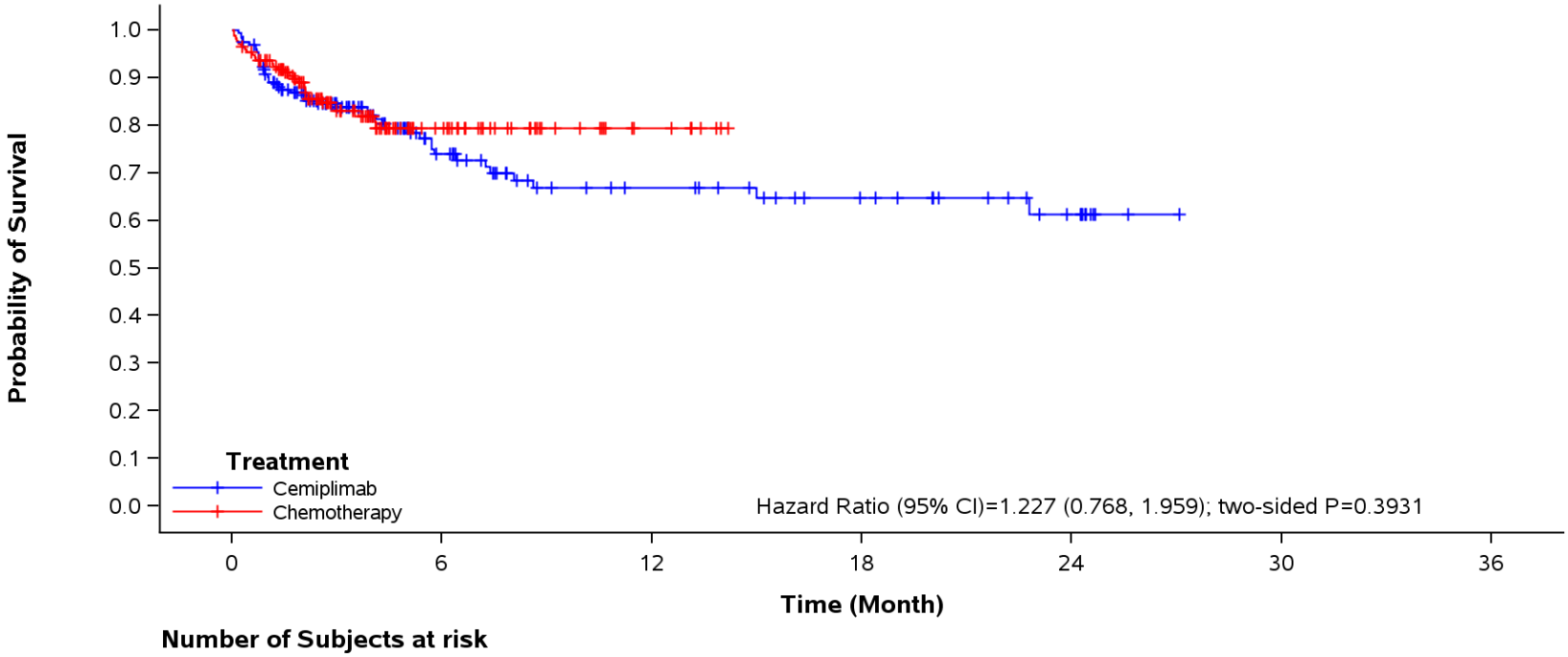

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 46 | 36 | 22 | 0 | 0 |
| Chemotherapy | 172 | 47 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders



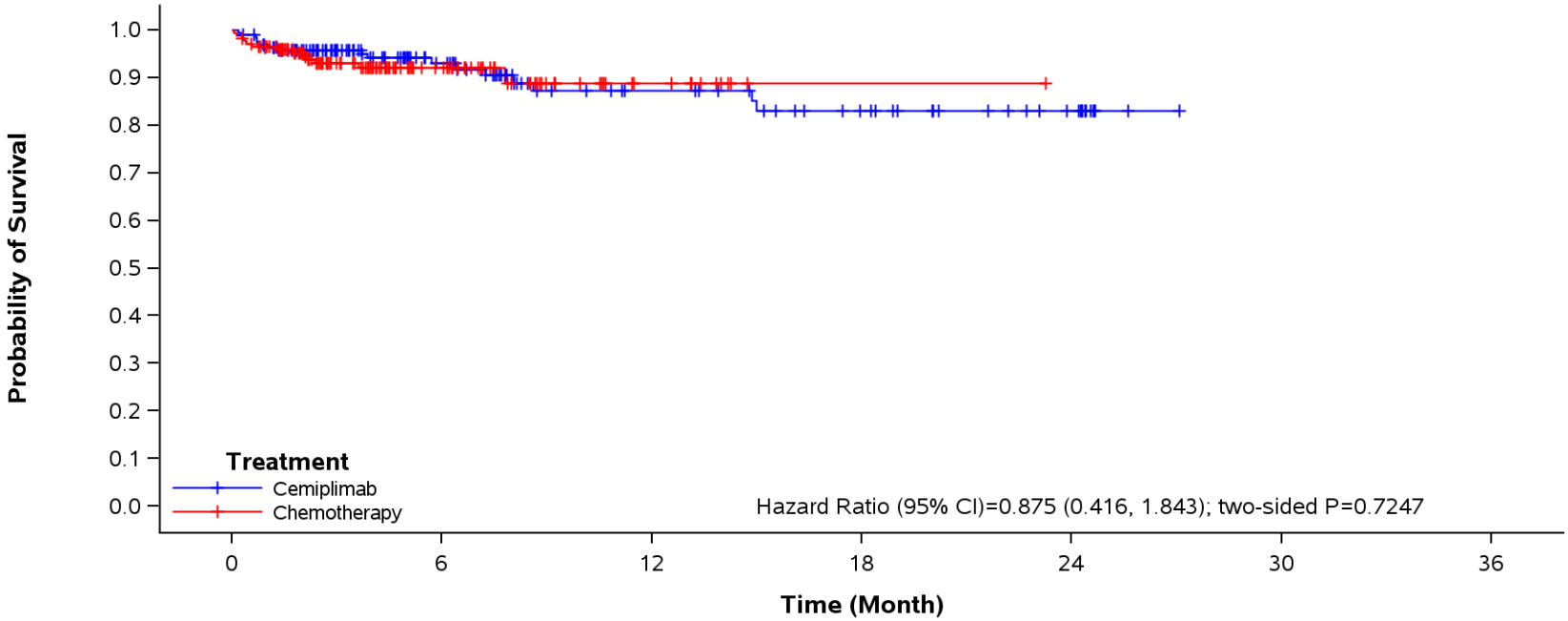

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 65 | 36 | 26 | 15 | 0 | 0 |
| Chemotherapy | 172 | 39 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough



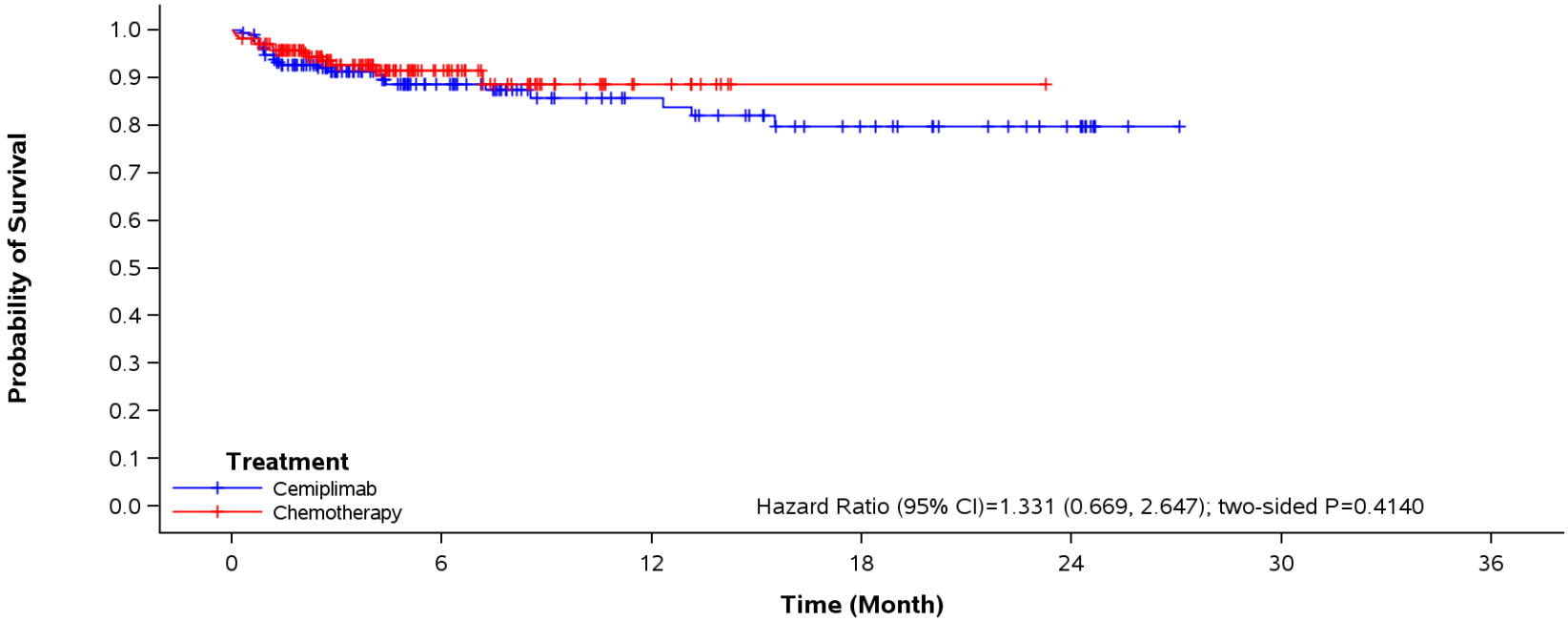

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 45 | 33 | 20 | 0 | 0 |
| Chemotherapy | 172 | 49 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea




**Number of Subjects at risk**

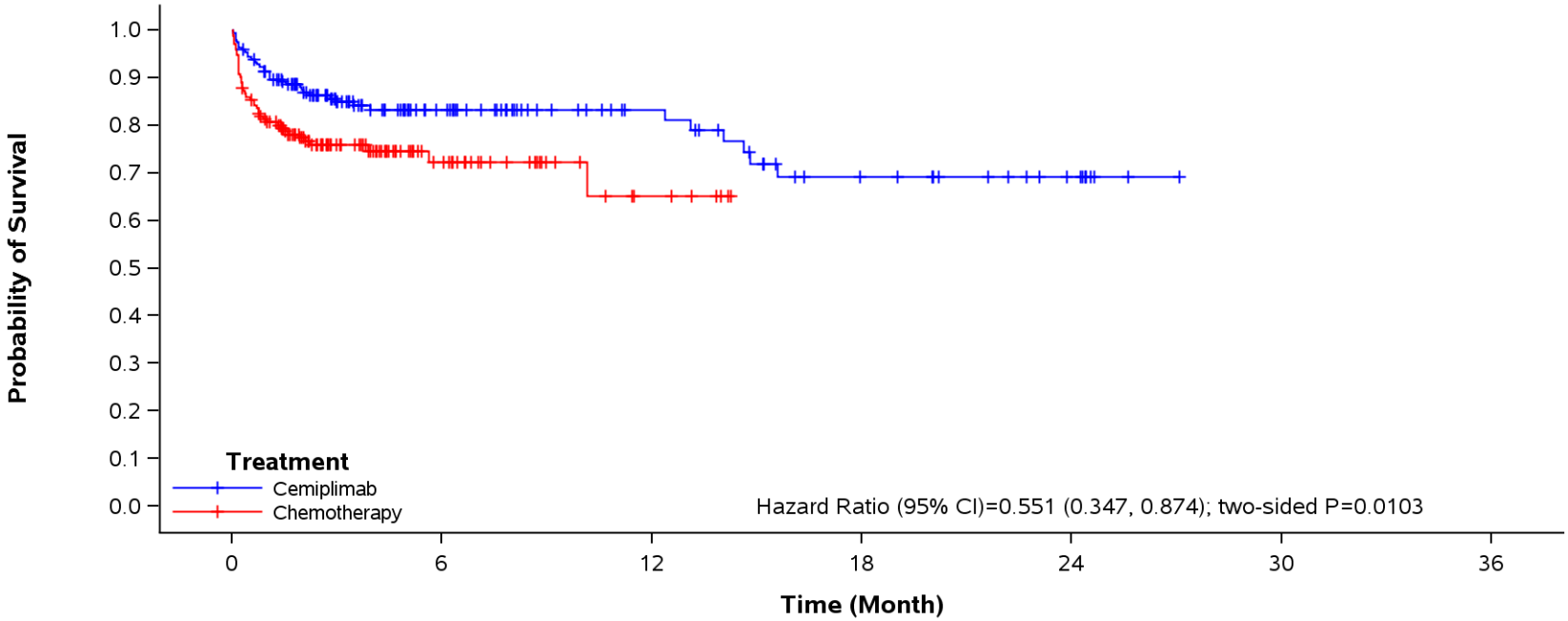
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 79 | 45 | 30 | 18 | 0 | 0 |
| Chemotherapy | 172 | 45 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt.sas
(14NOV22:04:27:55, haijin.tang)

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Skin and subcutaneous tissue disorders



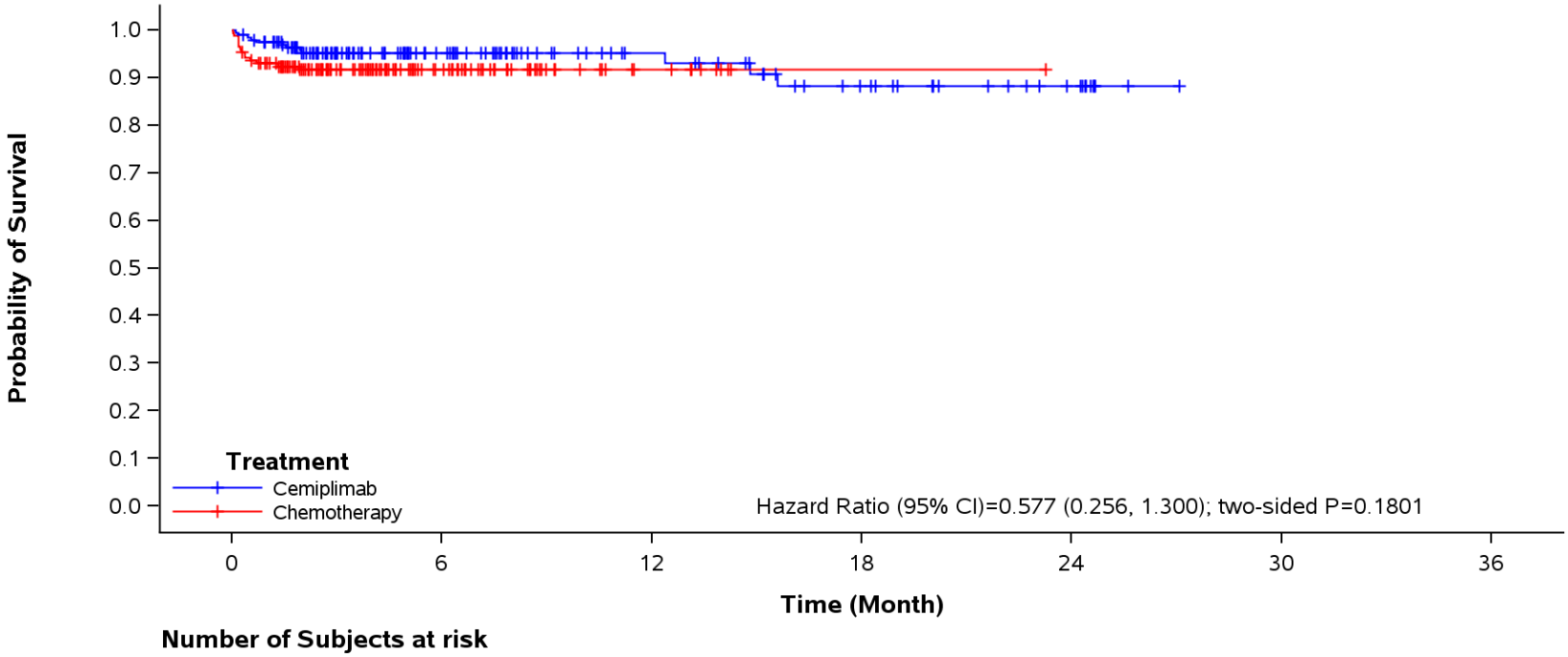

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 70 | 39 | 23 | 13 | 0 | 0 |
| Chemotherapy | 172 | 31 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Skin and subcutaneous tissue disorders
PT: Rash




Number of Subjects at risk

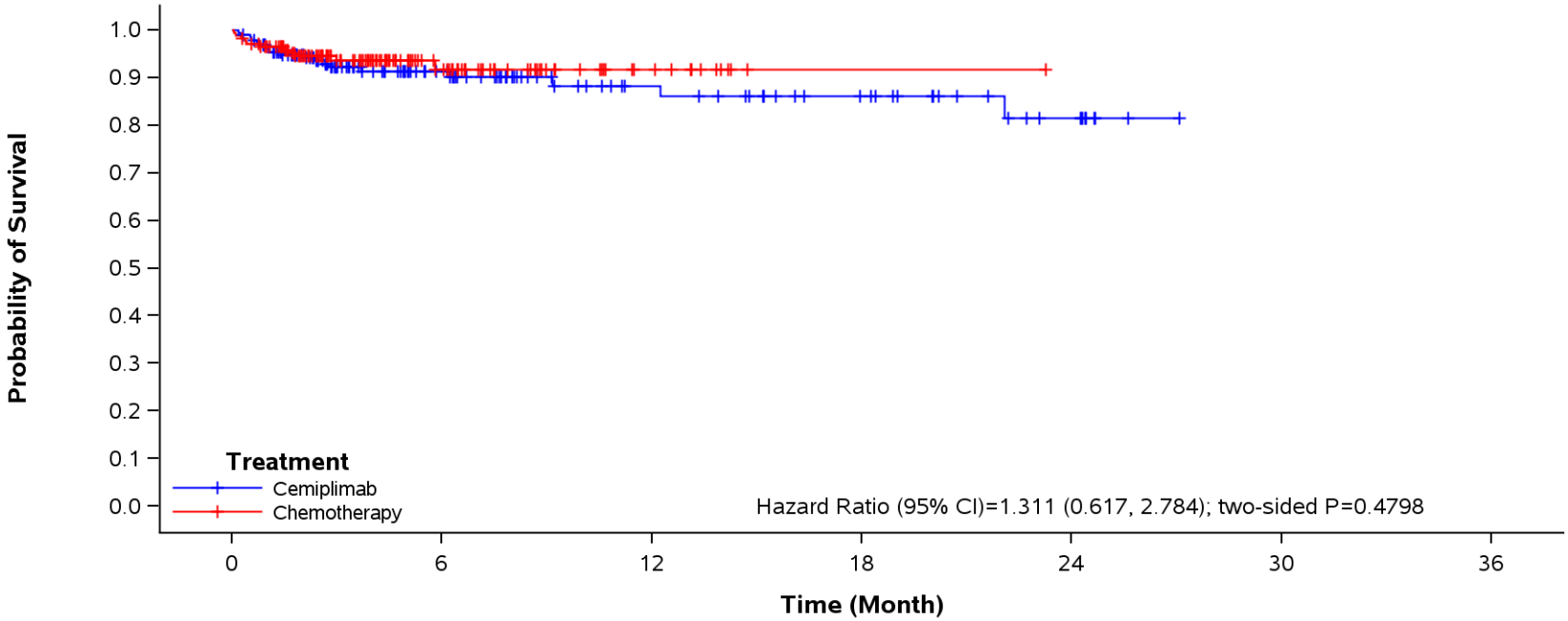
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 46 | 31 | 18 | 0 | 0 |
| Chemotherapy | 172 | 47 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt.sas
(14NOV22:04:27:55, haijin.tang)

Figure 4.1.1. Time to First Any TEAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Vascular disorders



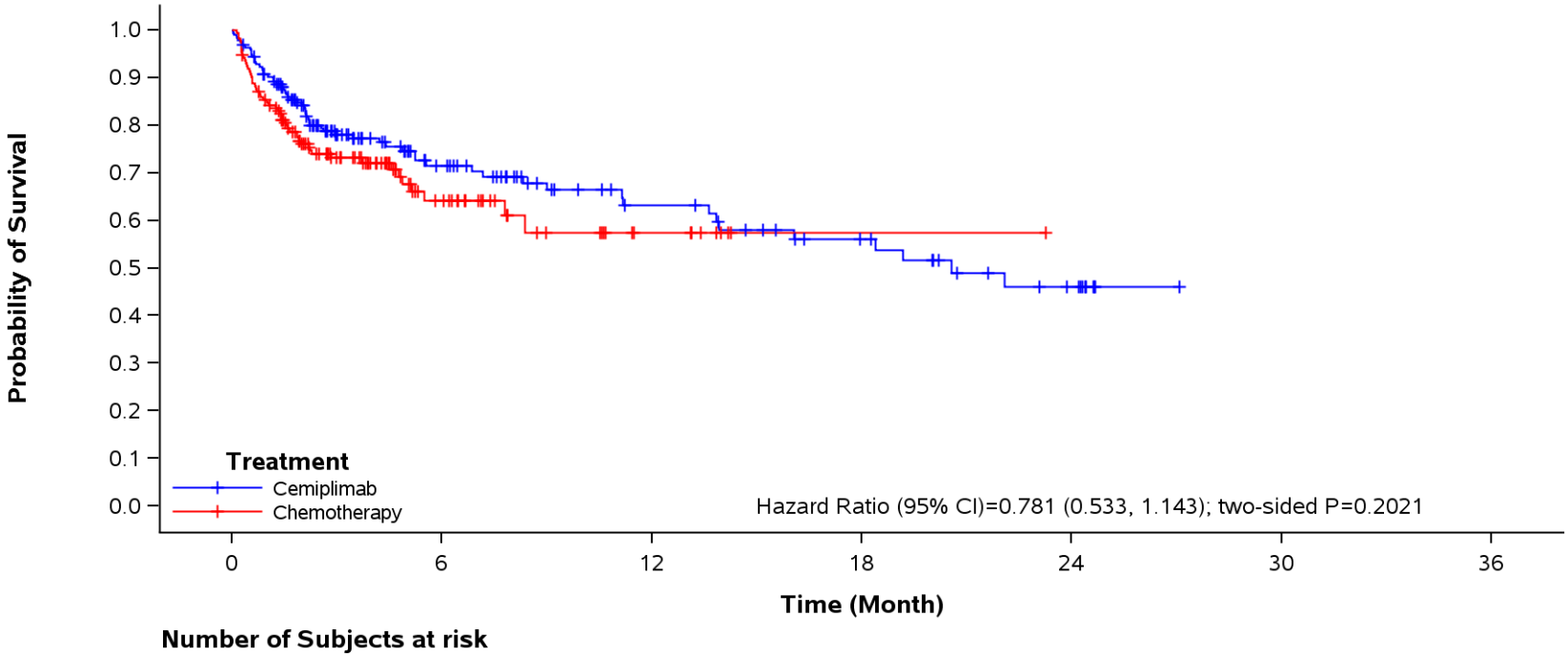

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 75 | 40 | 29 | 15 | 0 | 0 |
| Chemotherapy | 172 | 48 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any treatment-emergent SAE



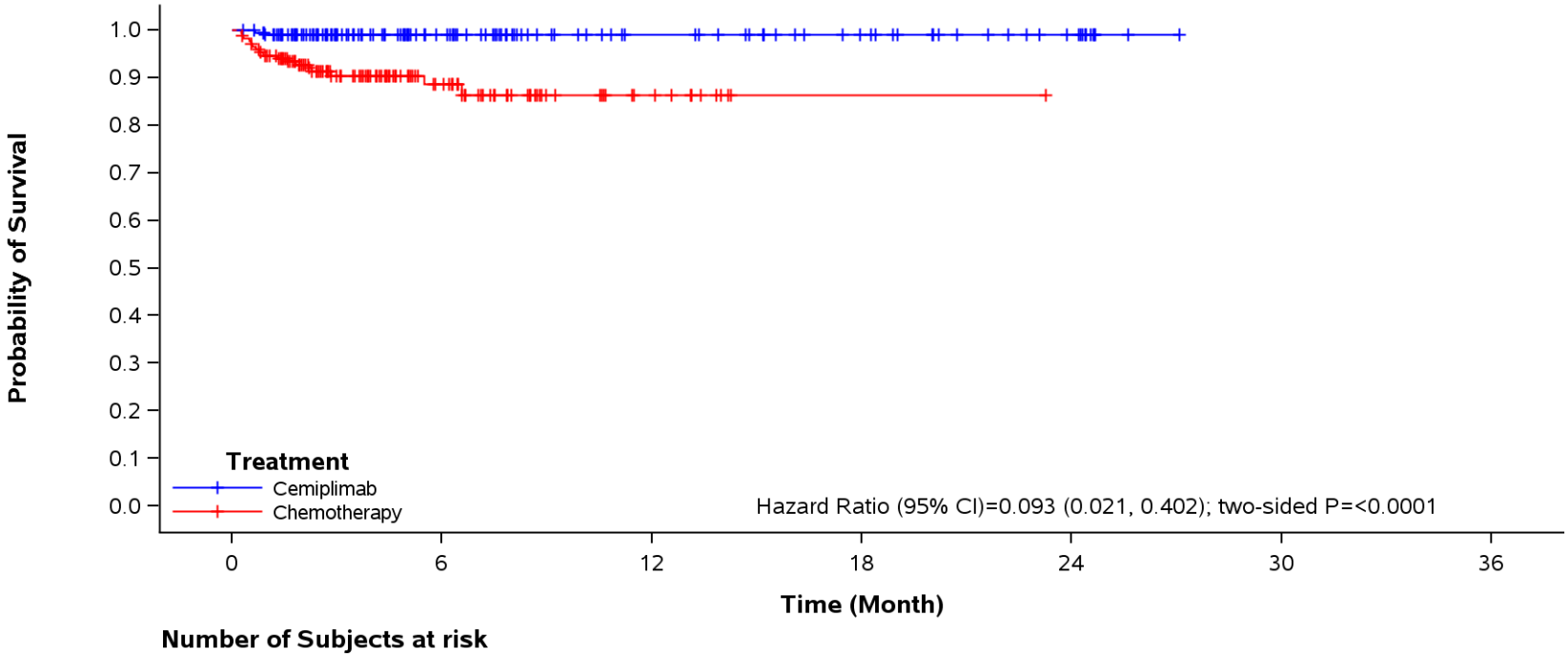

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 68 | 38 | 26 | 14 | 0 | 0 |
| Chemotherapy | 172 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders



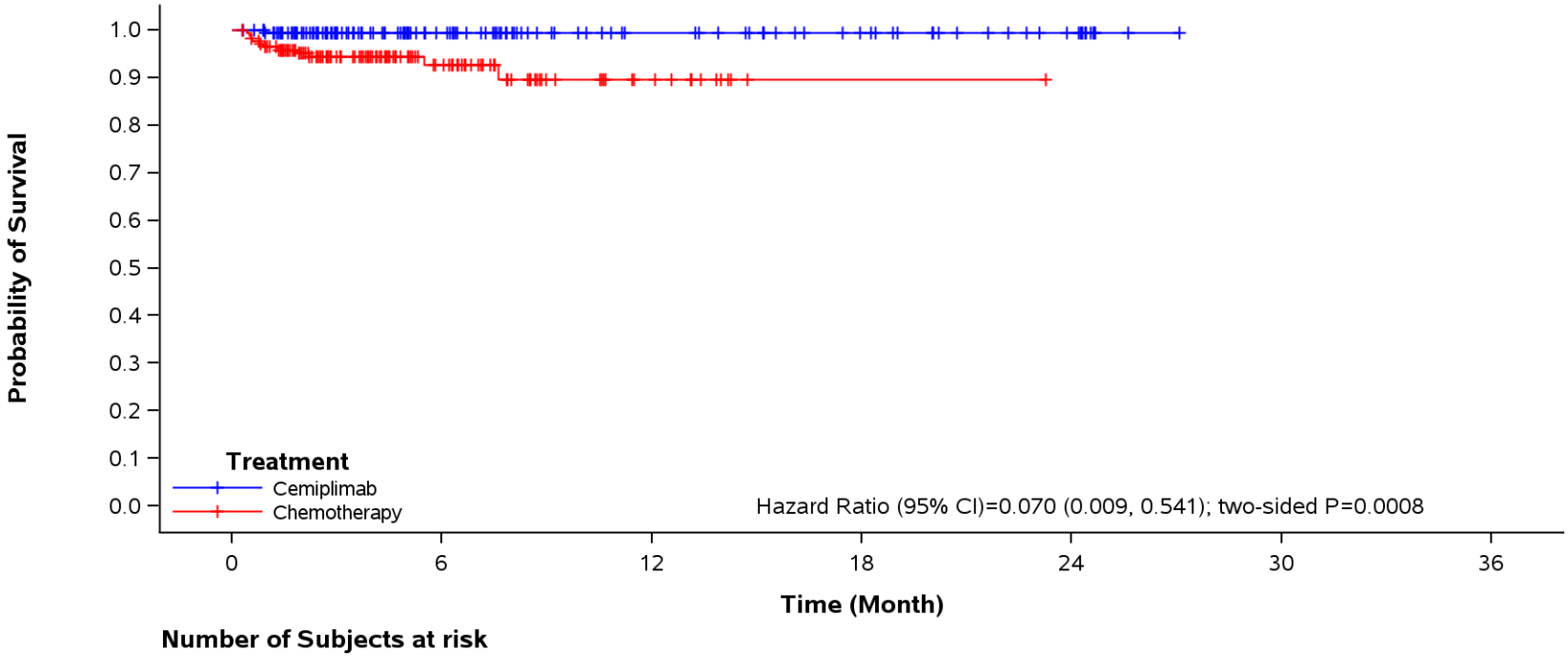

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 84 | 47 | 35 | 21 | 0 | 0 |
| Chemotherapy | 172 | 48 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia



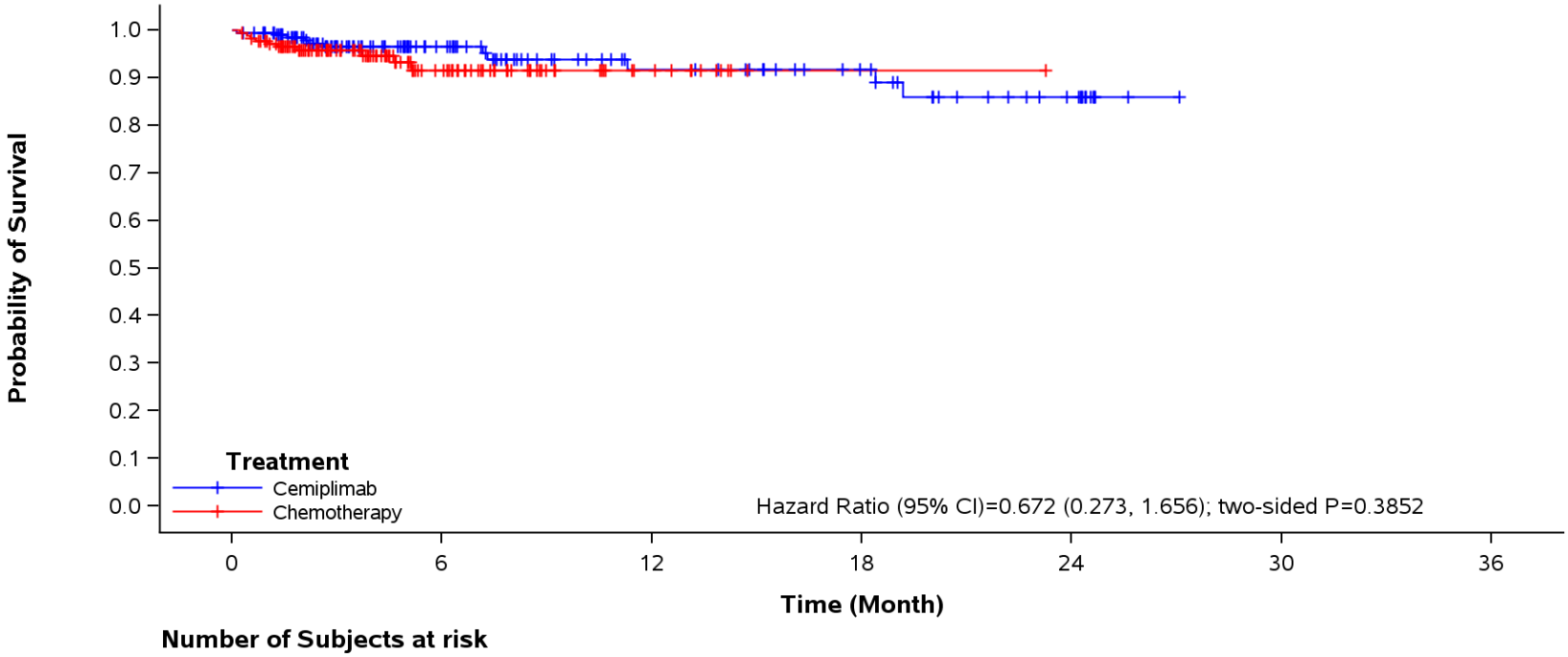

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 48 | 36 | 22 | 0 | 0 |
| Chemotherapy | 172 | 50 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders



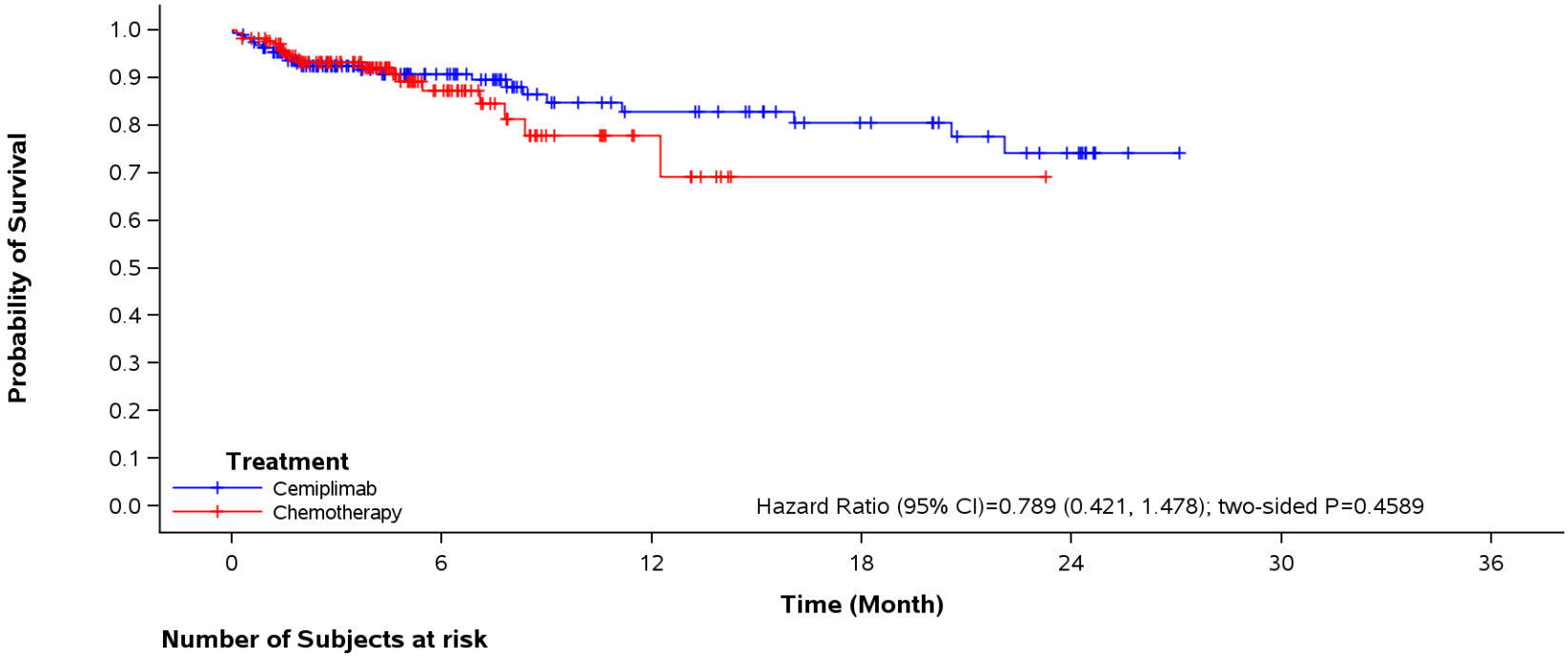

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 83 | 45 | 34 | 19 | 0 | 0 |
| Chemotherapy | 172 | 49 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations



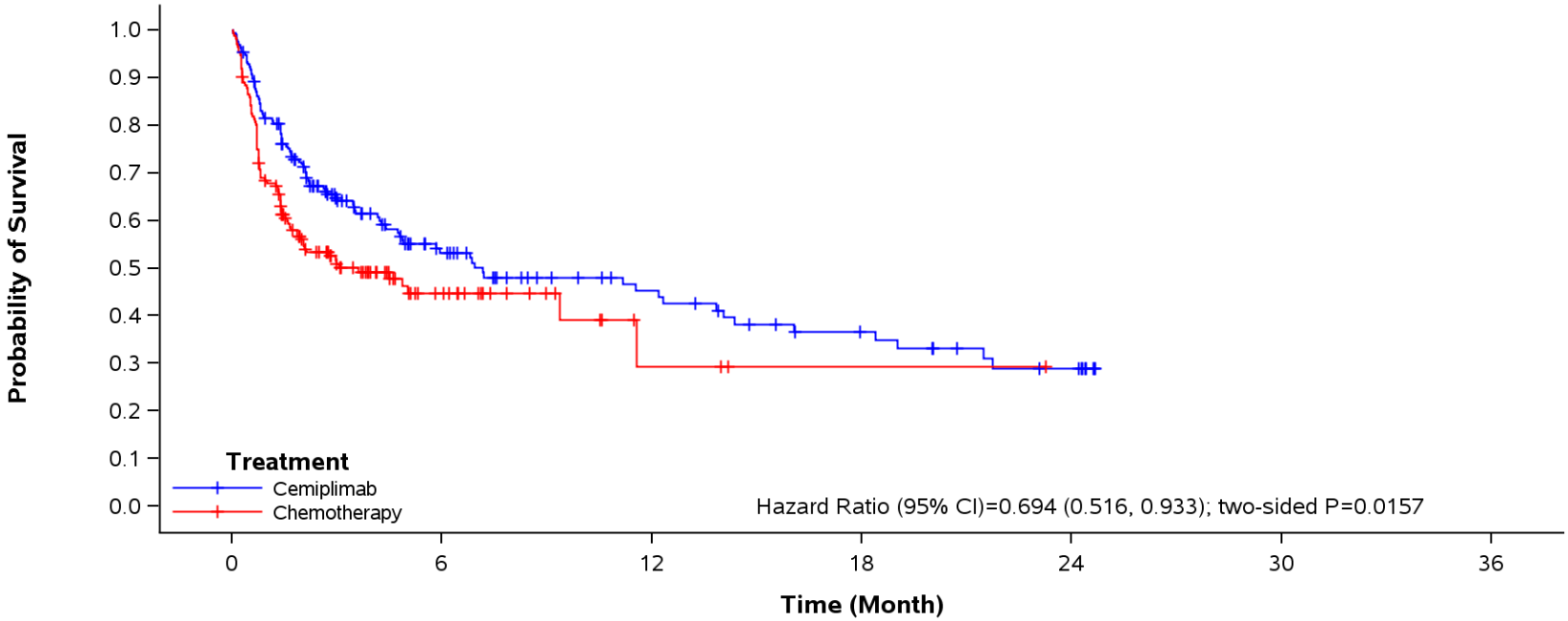

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 43 | 31 | 19 | 0 | 0 |
| Chemotherapy | 172 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of patients with any TEAE CTCAE Grade >= 3



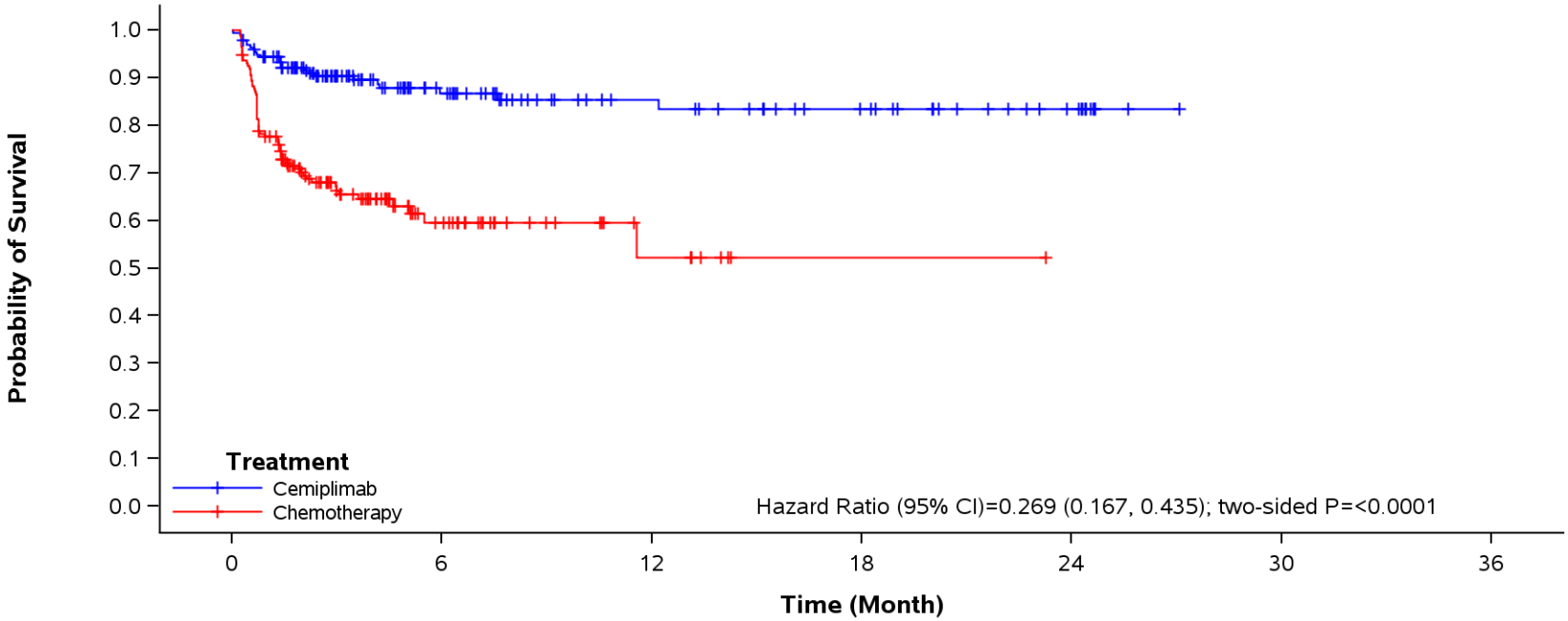

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 57 | 33 | 21 | 13 | 0 | 0 |
| Chemotherapy | 172 | 24 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders



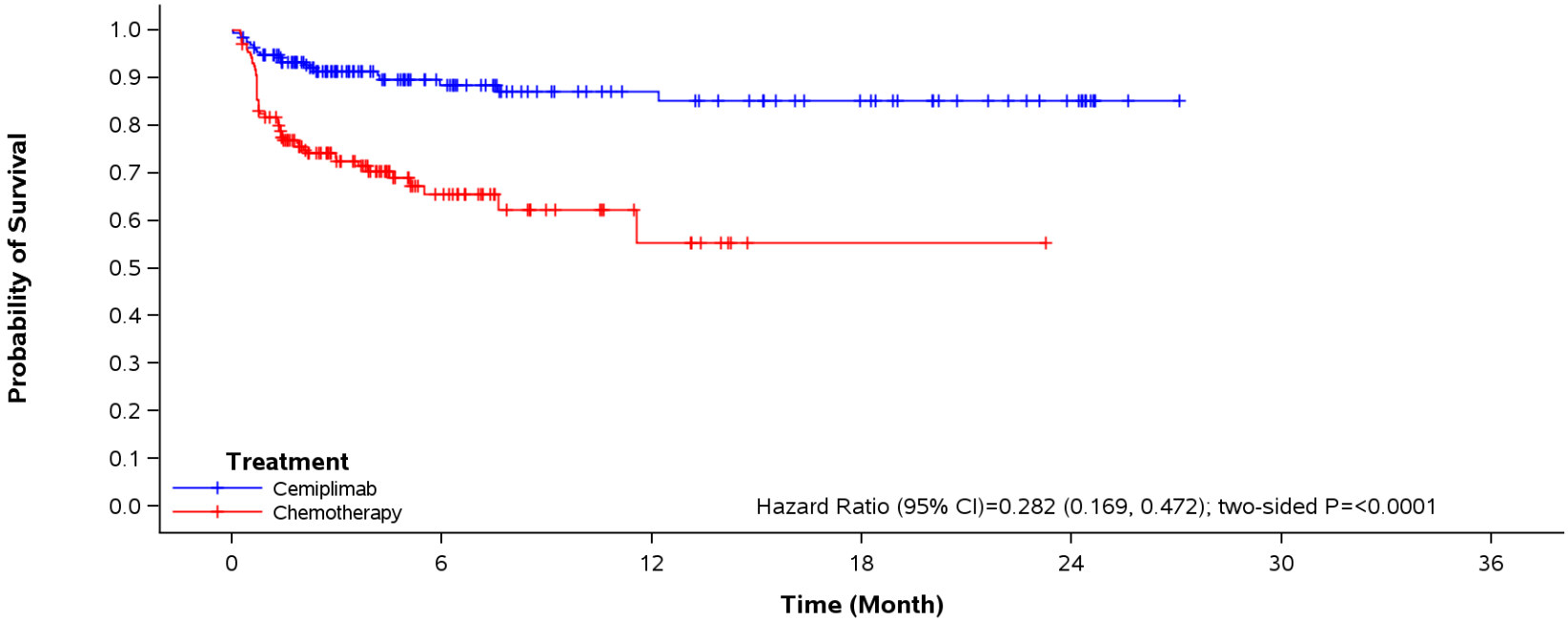

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 79 | 46 | 35 | 21 | 0 | 0 |
| Chemotherapy | 172 | 32 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Anaemia



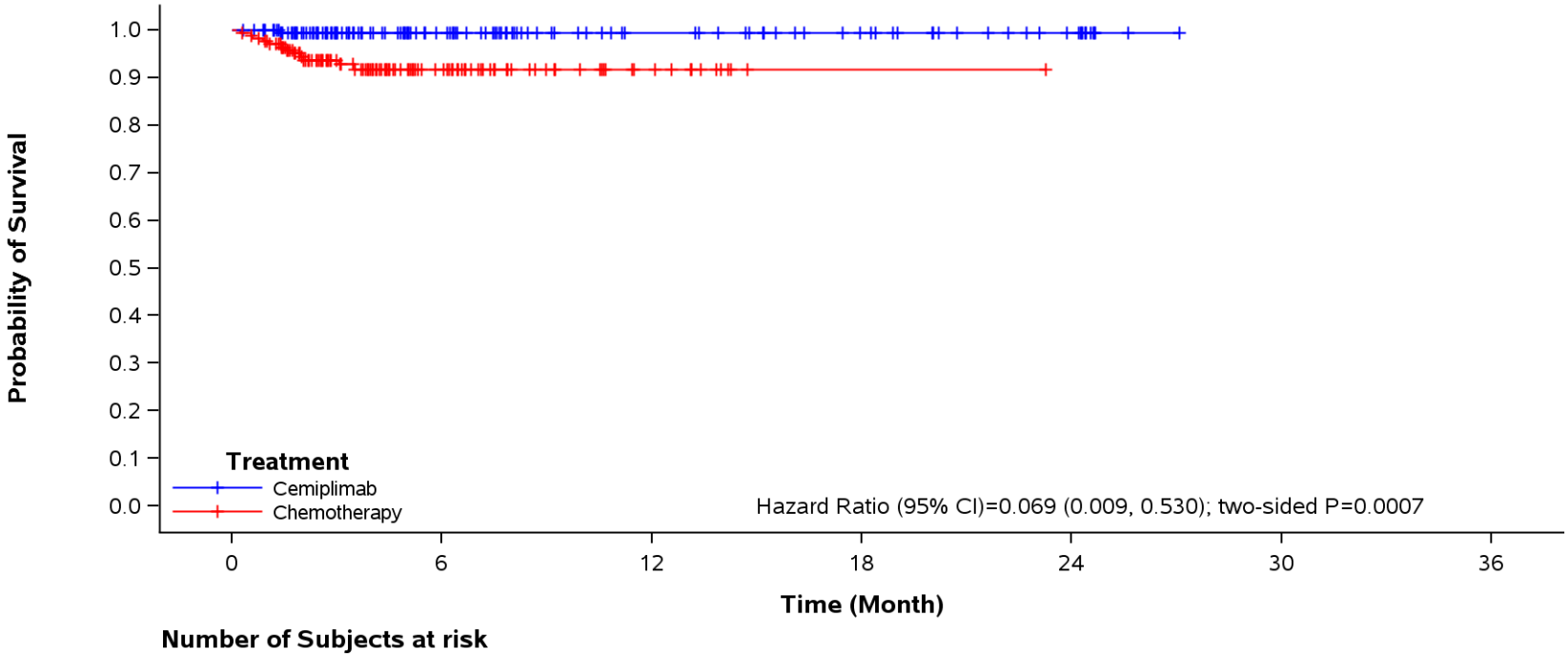

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 46 | 35 | 21 | 0 | 0 |
| Chemotherapy | 172 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Blood and lymphatic system disorders
PT: Neutropenia



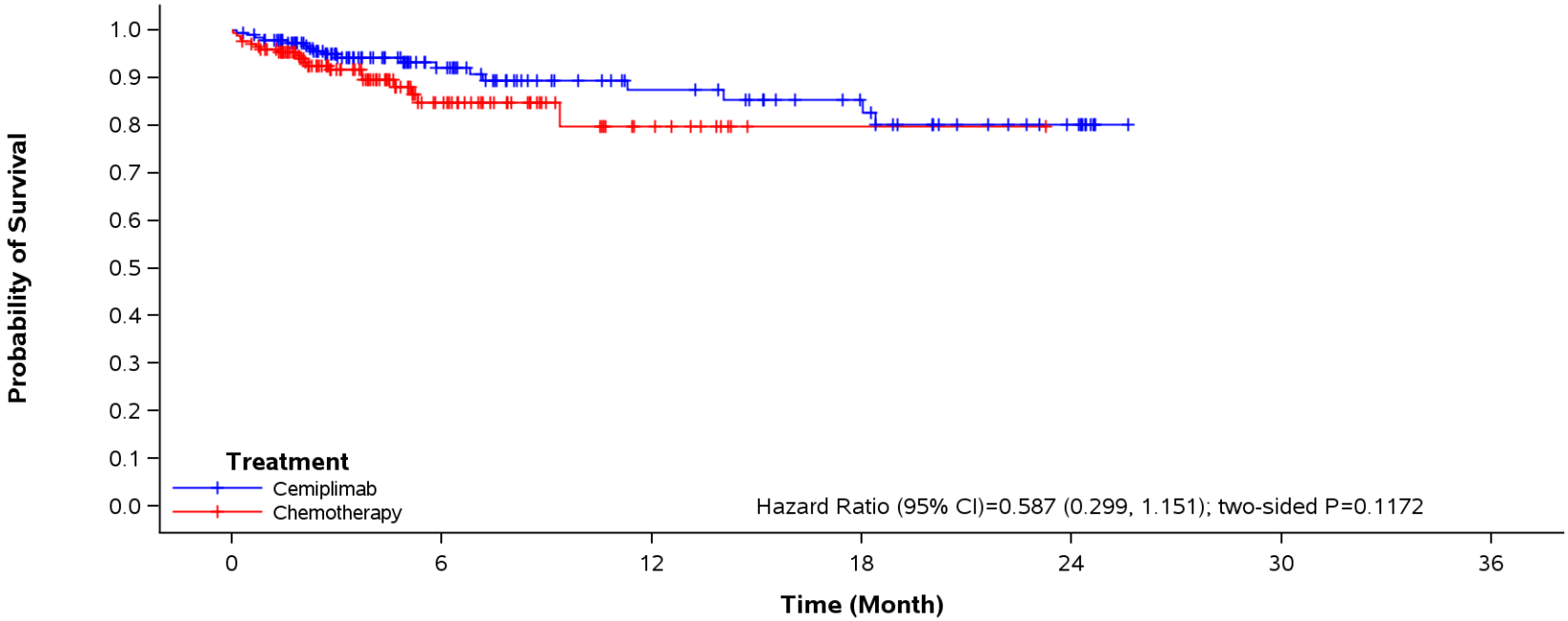

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 48 | 36 | 22 | 0 | 0 |
| Chemotherapy | 172 | 47 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Gastrointestinal disorders



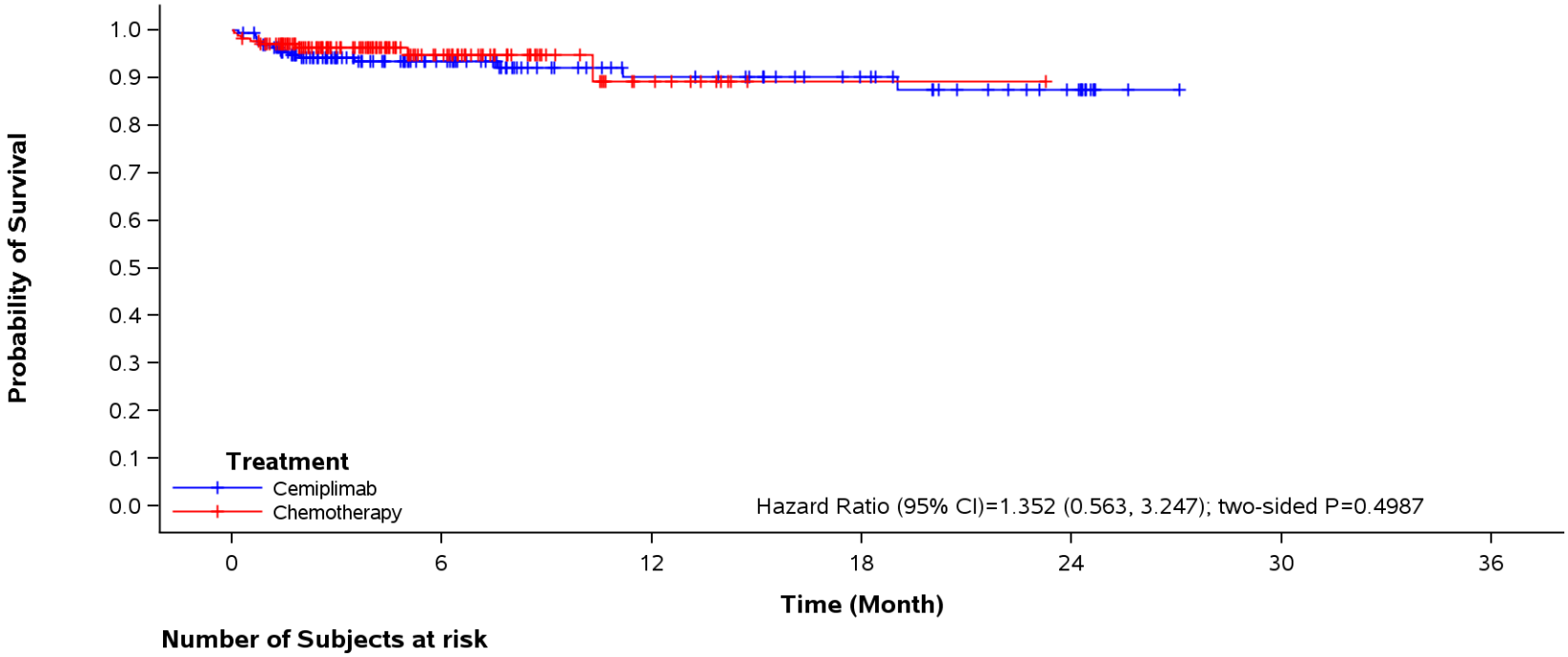

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 44 | 33 | 18 | 0 | 0 |
| Chemotherapy | 172 | 45 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: General disorders and administration site conditions



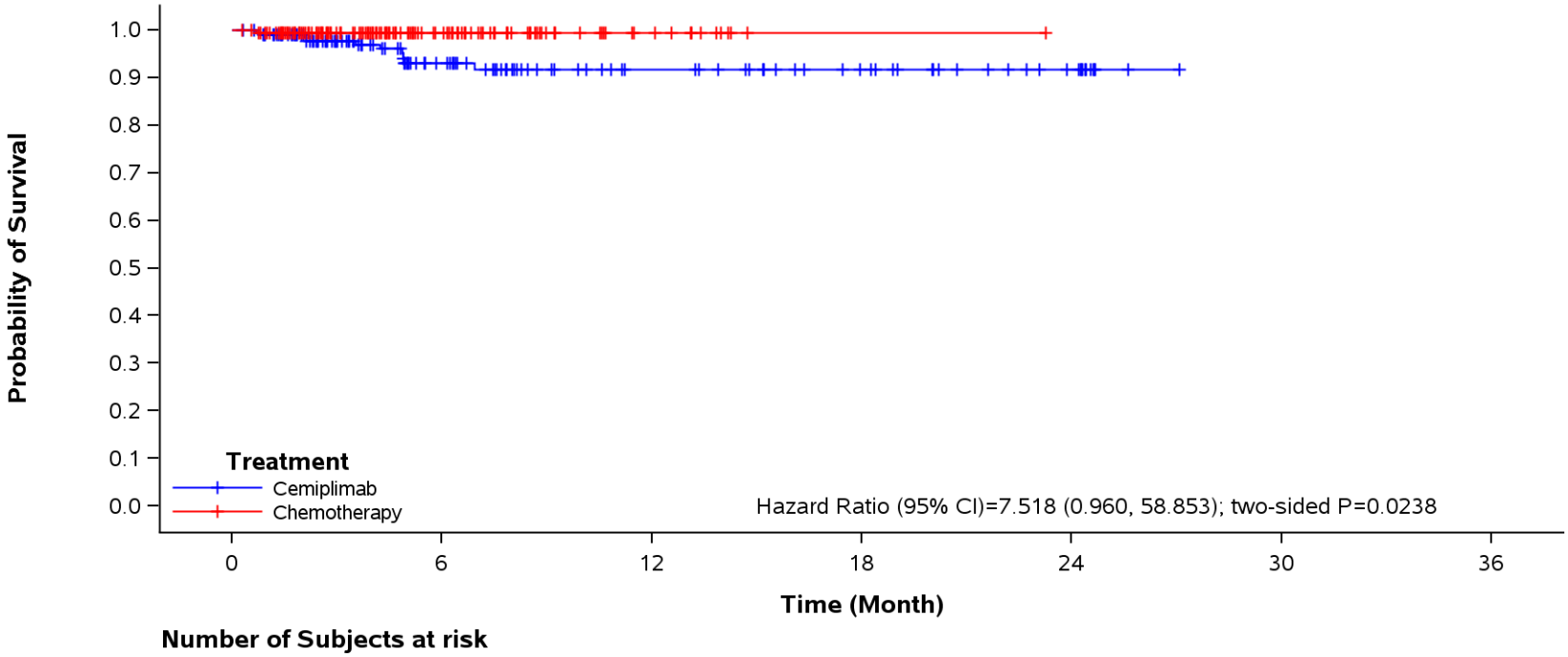

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 85 | 47 | 36 | 22 | 0 | 0 |
| Chemotherapy | 172 | 51 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Hepatobiliary disorders



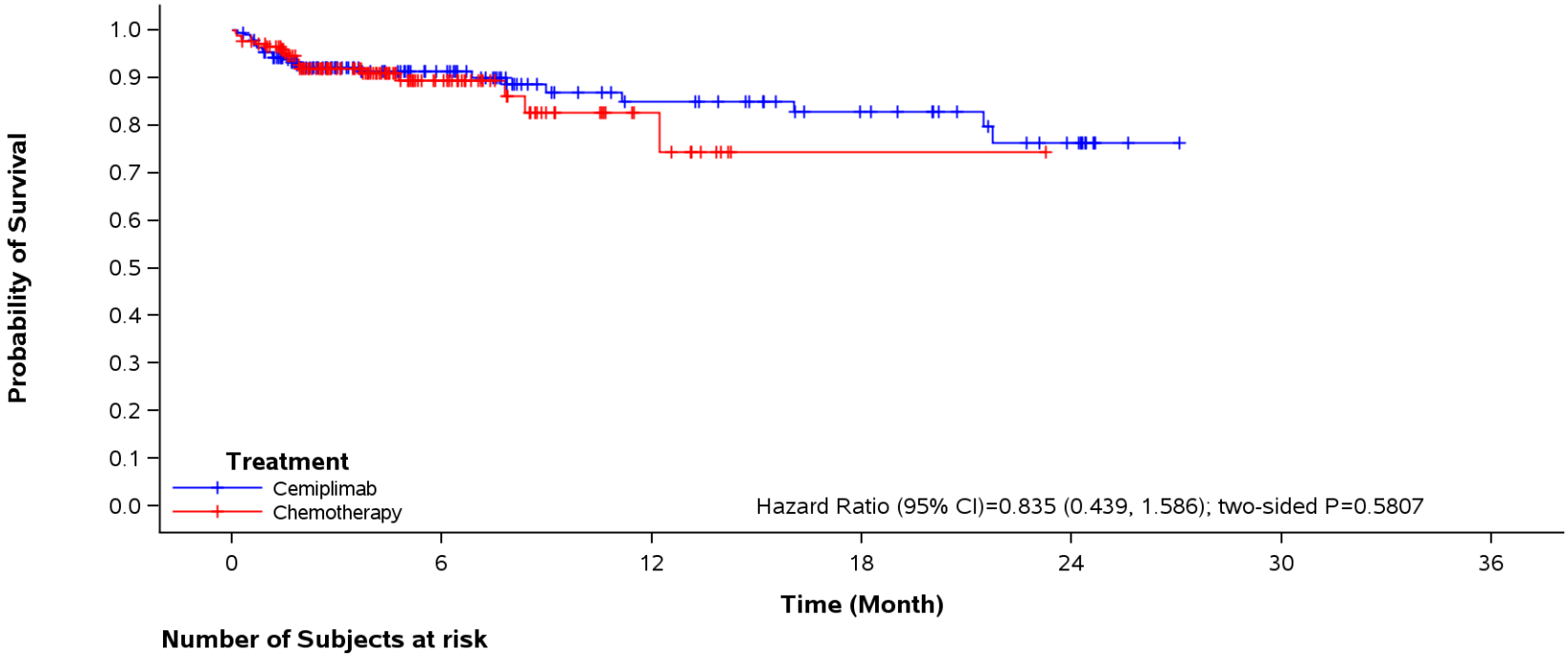

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 80 | 47 | 35 | 21 | 0 | 0 |
| Chemotherapy | 172 | 52 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Infections and infestations



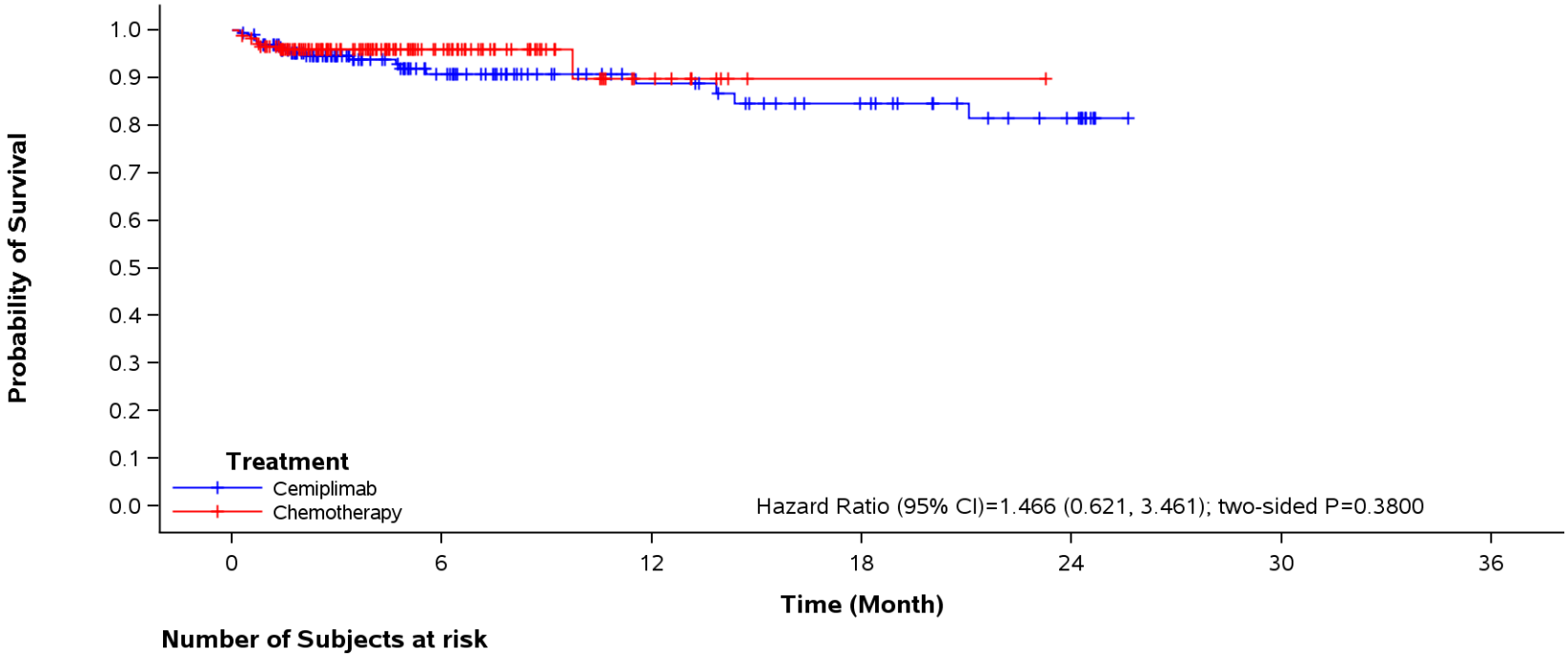

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 81 | 45 | 33 | 20 | 0 | 0 |
| Chemotherapy | 172 | 47 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Investigations



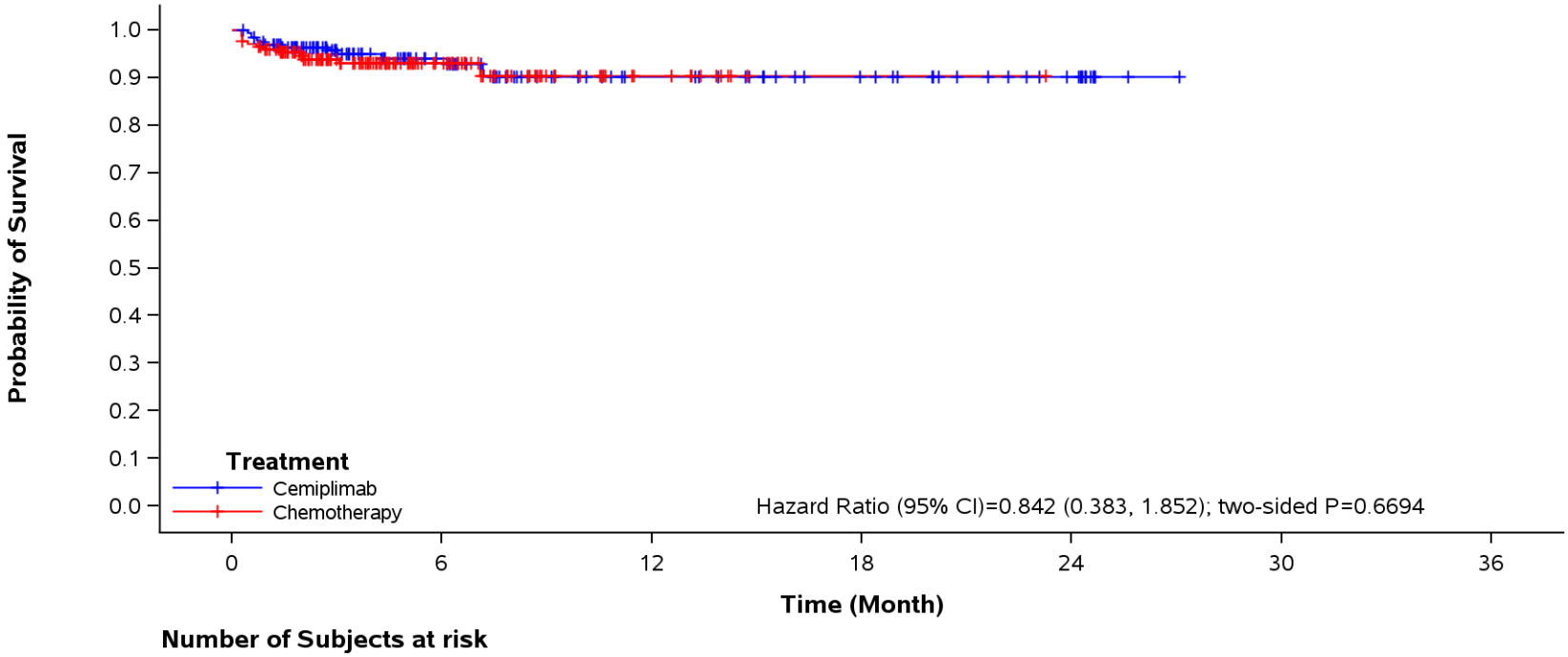

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 79 | 45 | 33 | 21 | 0 | 0 |
| Chemotherapy | 172 | 49 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Metabolism and nutrition disorders



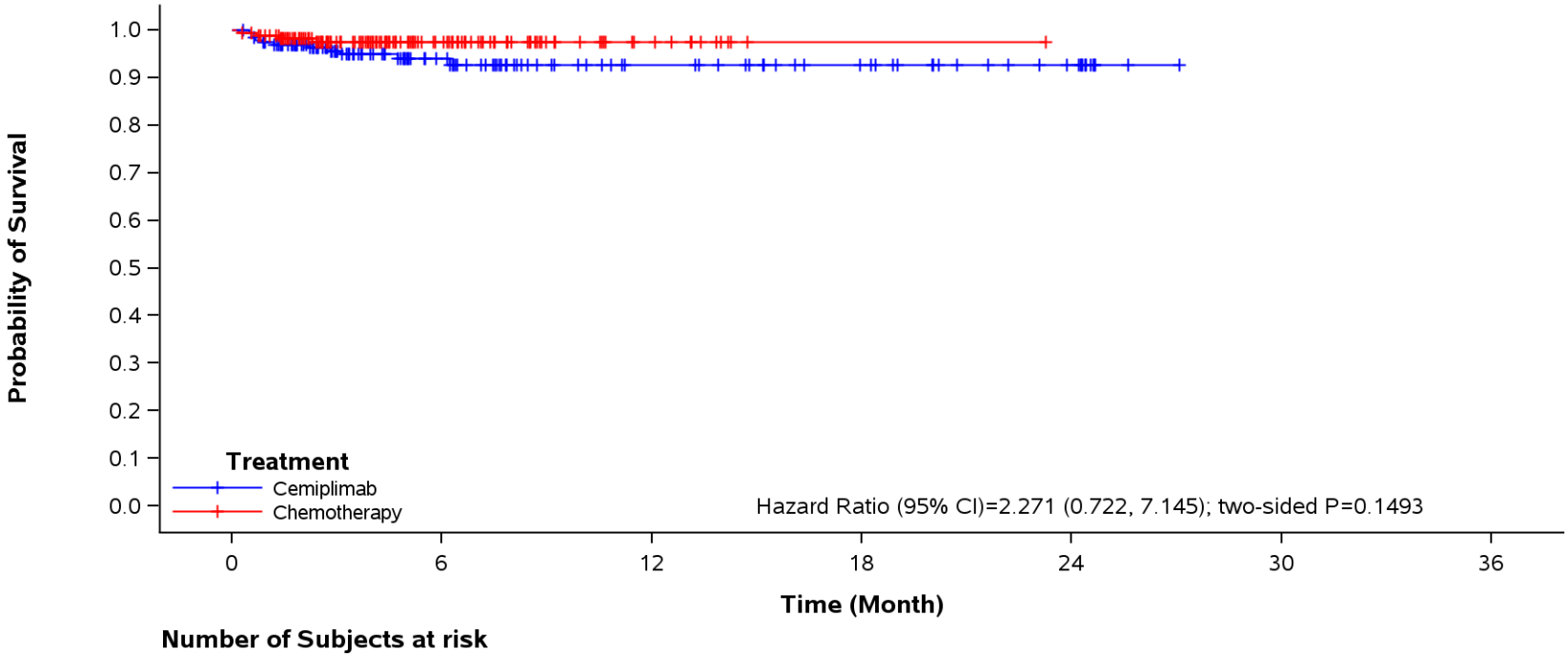

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 82 | 46 | 35 | 22 | 0 | 0 |
| Chemotherapy | 172 | 51 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.1.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

SOC: Renal and urinary disorders



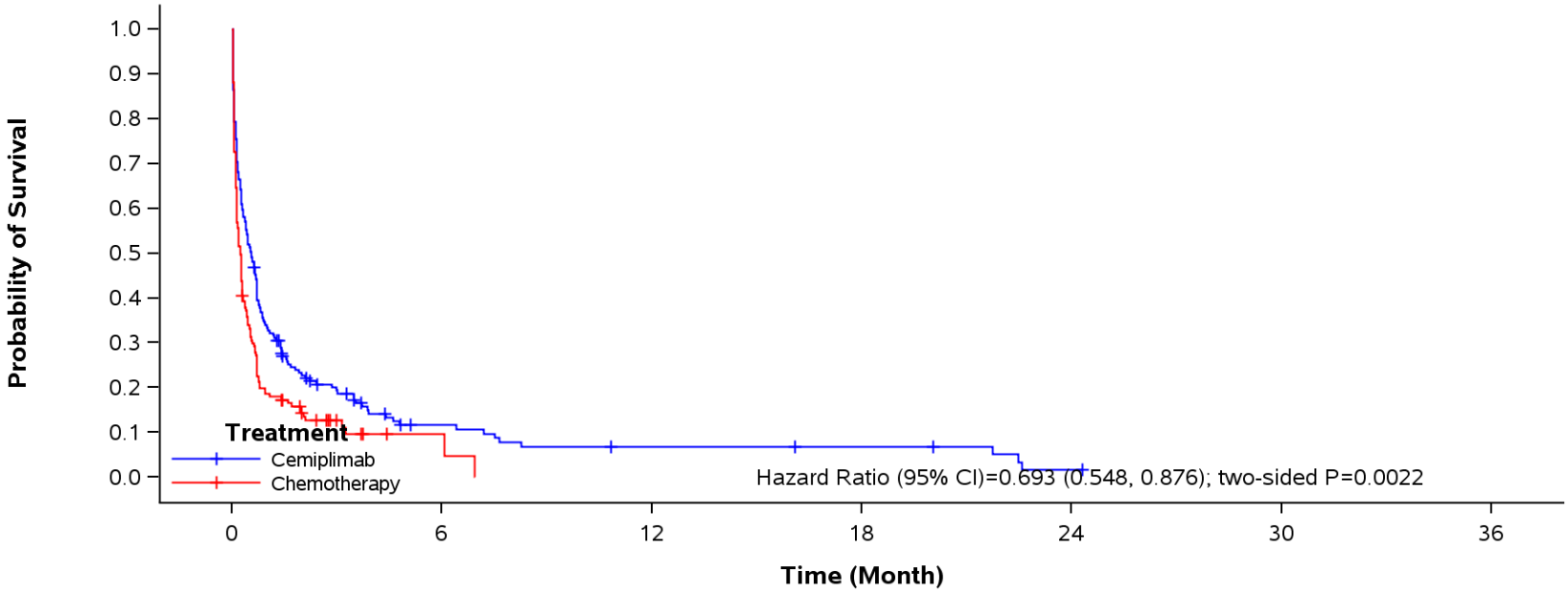

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 195 | 81 | 45 | 34 | 21 | 0 | 0 |
| Chemotherapy | 172 | 51 | 11 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Number of patients with any TEAE



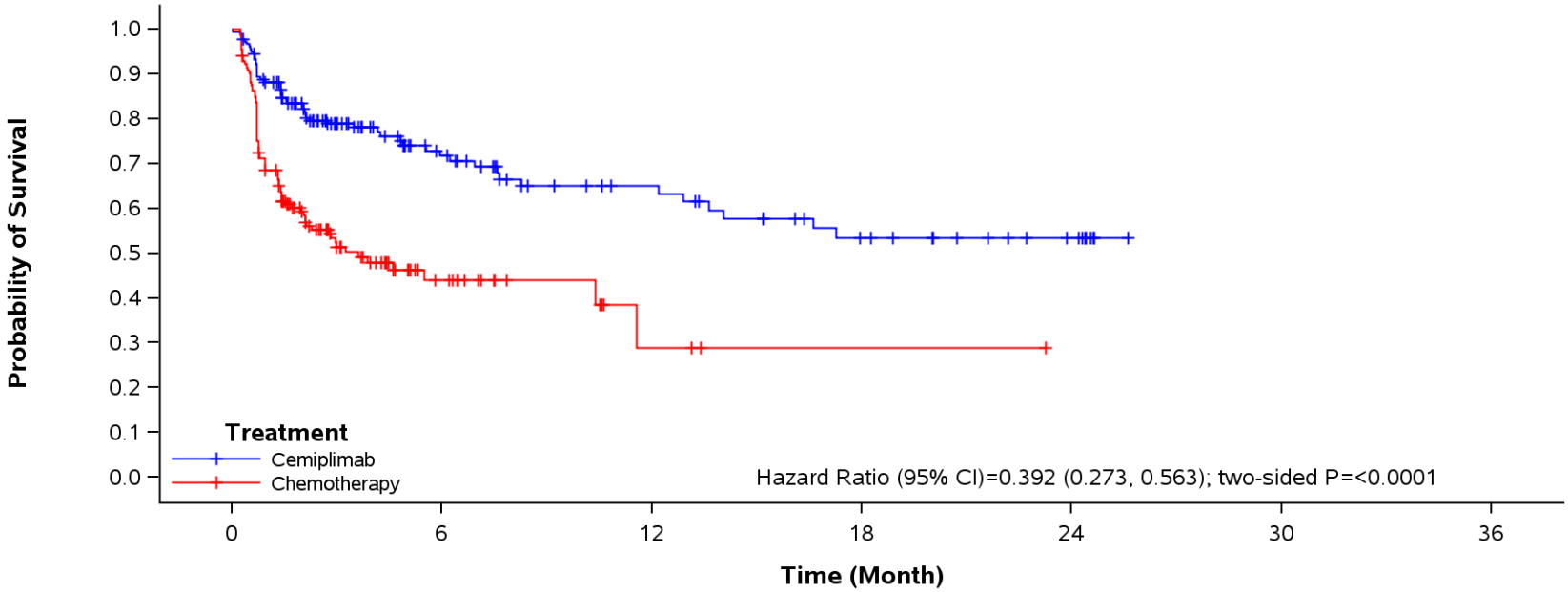

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 12 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 153 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders



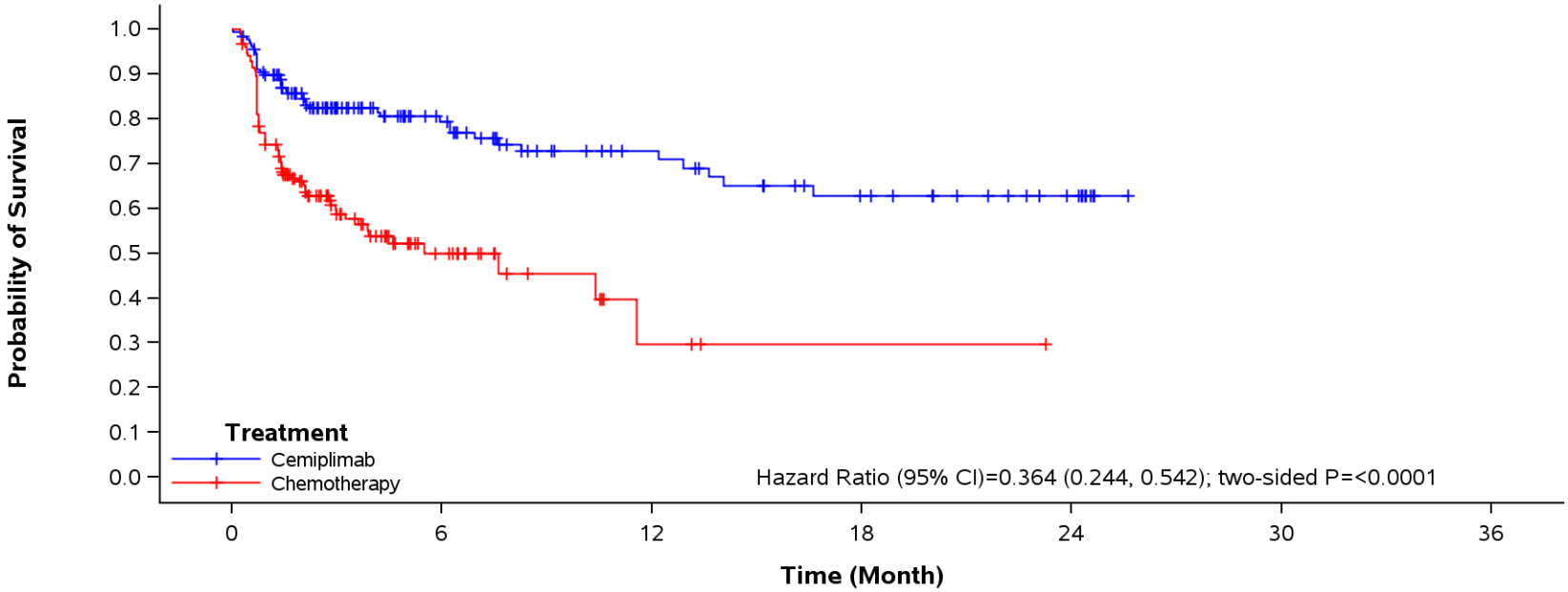

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 62 | 37 | 24 | 14 | 0 | 0 |
| Chemotherapy | 153 | 19 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Anaemia



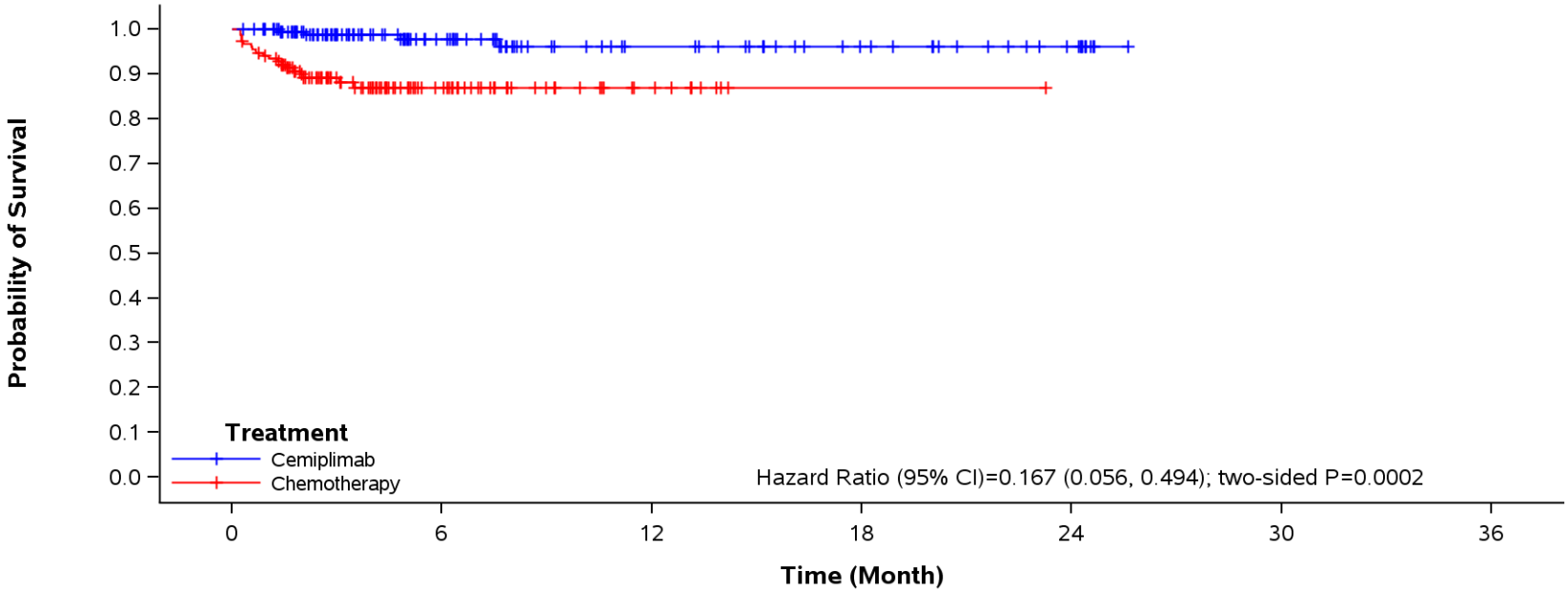

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 68 | 39 | 27 | 16 | 0 | 0 |
| Chemotherapy | 153 | 22 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



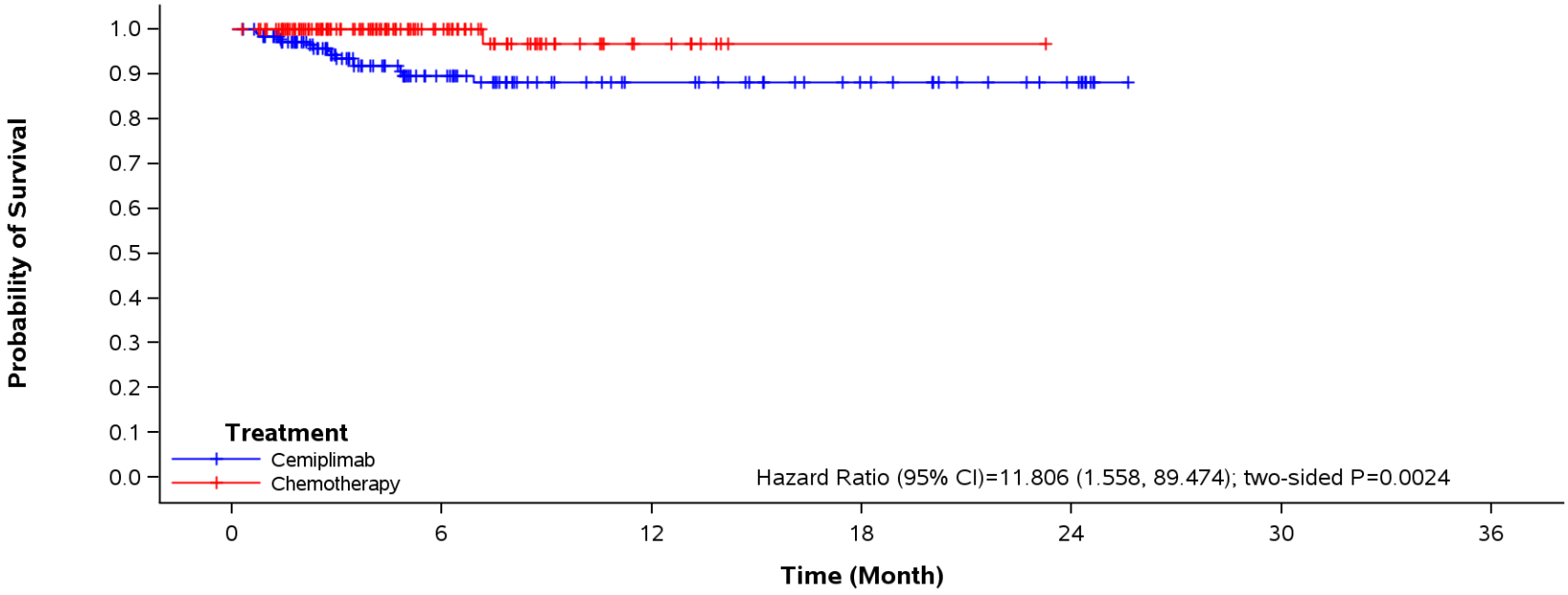

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 41 | 29 | 17 | 0 | 0 |
| Chemotherapy | 153 | 40 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Endocrine disorders



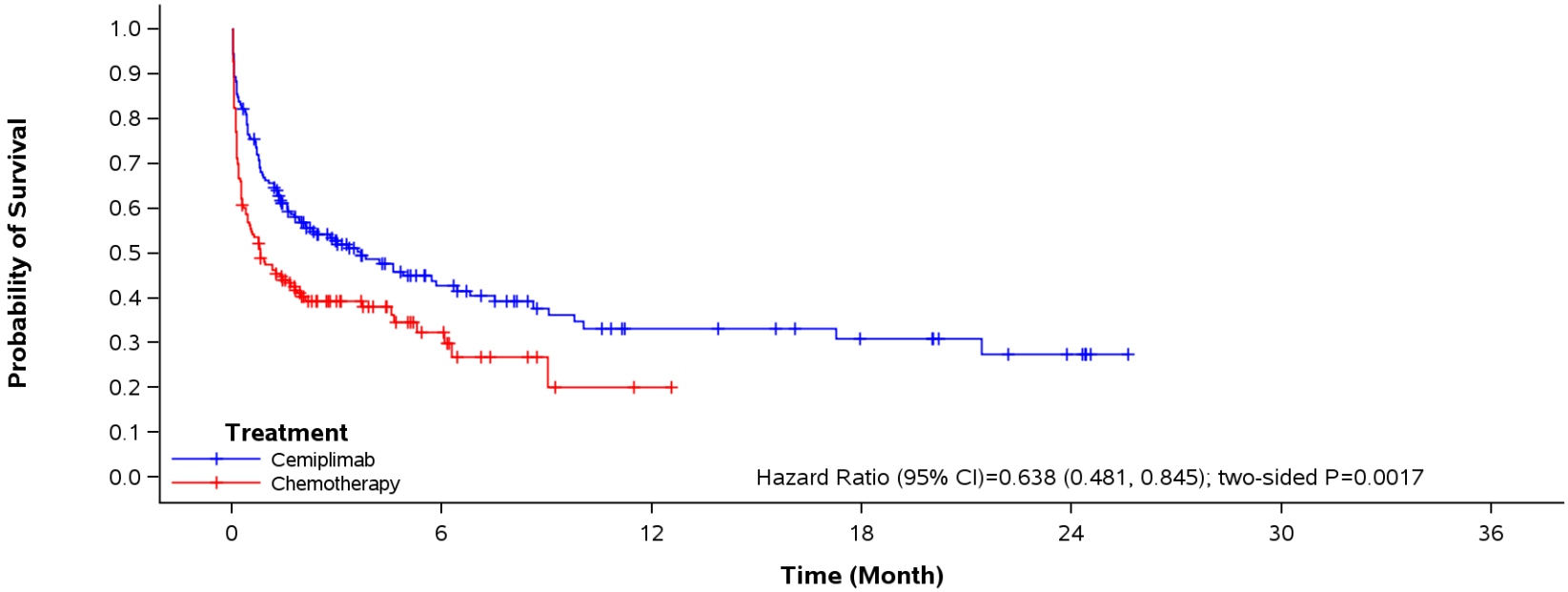

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 69 | 38 | 27 | 16 | 0 | 0 |
| Chemotherapy | 153 | 46 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders



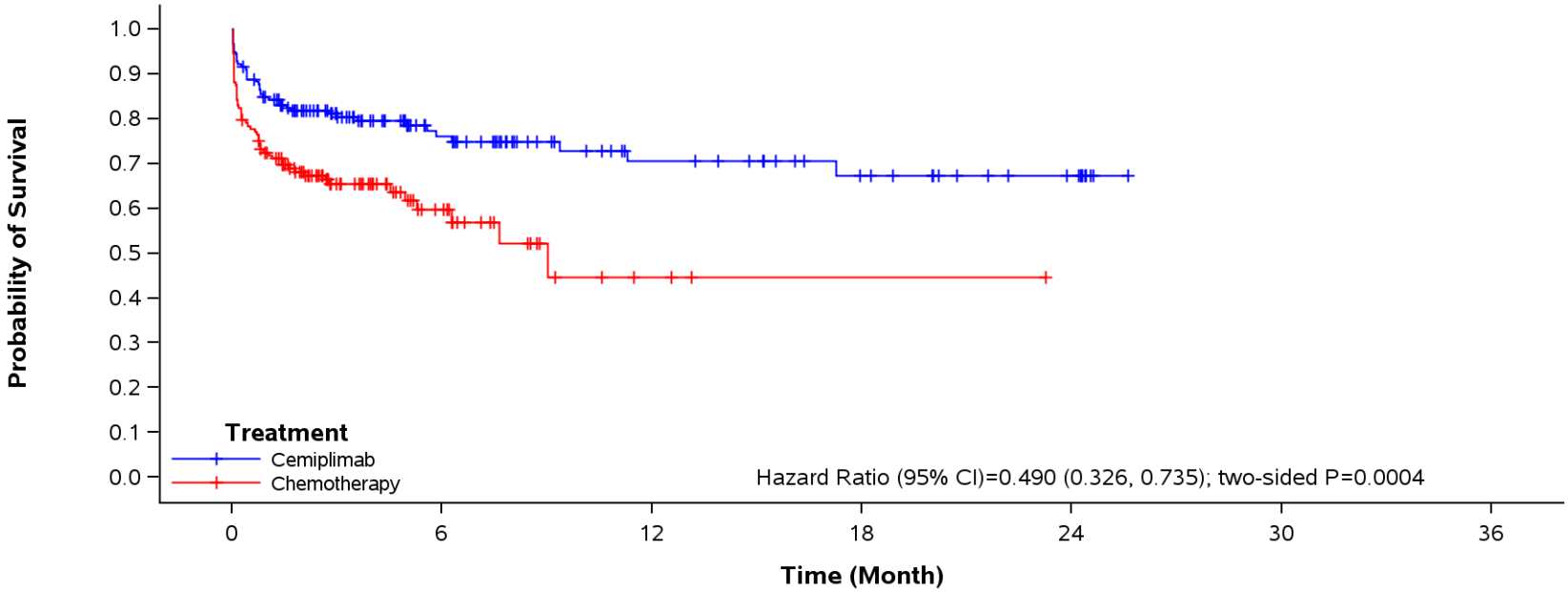

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 39 | 17 | 12 | 6 | 0 | 0 |
| Chemotherapy | 153 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders
PT: Nausea



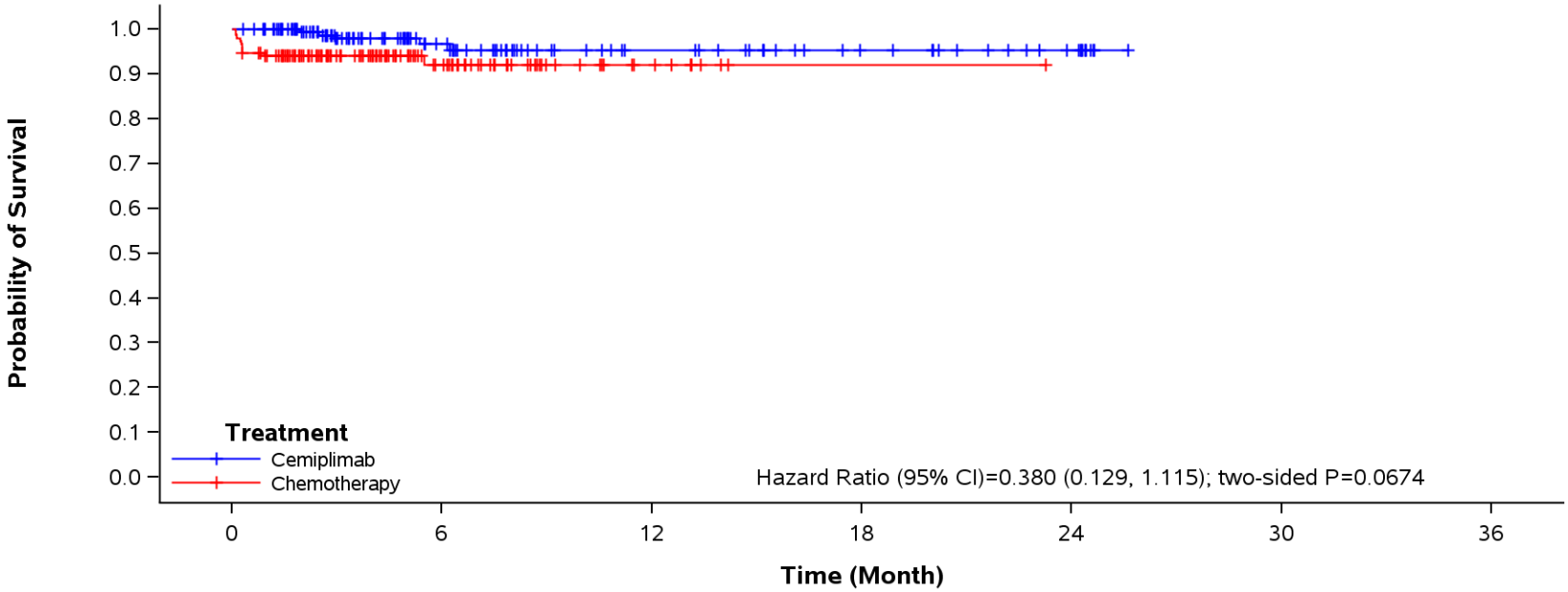

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 62 | 30 | 20 | 11 | 0 | 0 |
| Chemotherapy | 153 | 25 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders
PT: Stomatitis



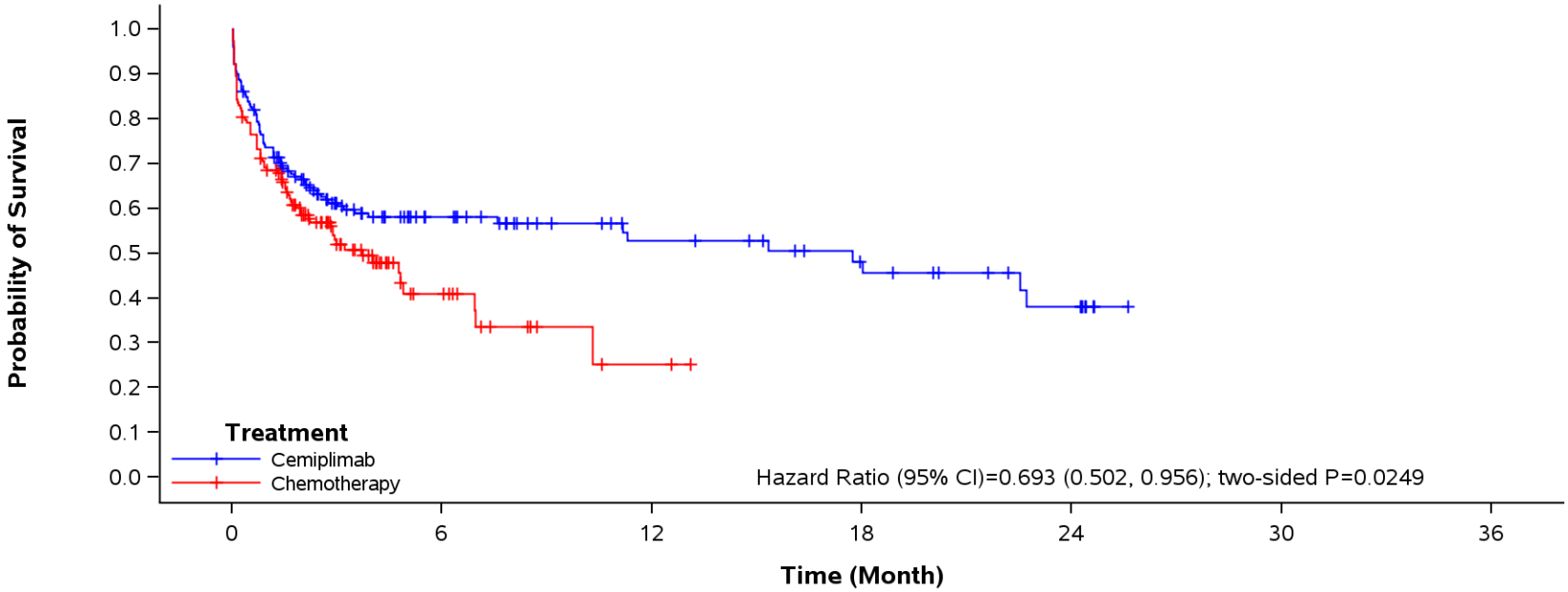

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 73 | 39 | 27 | 16 | 0 | 0 |
| Chemotherapy | 153 | 43 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: General disorders and administration site conditions



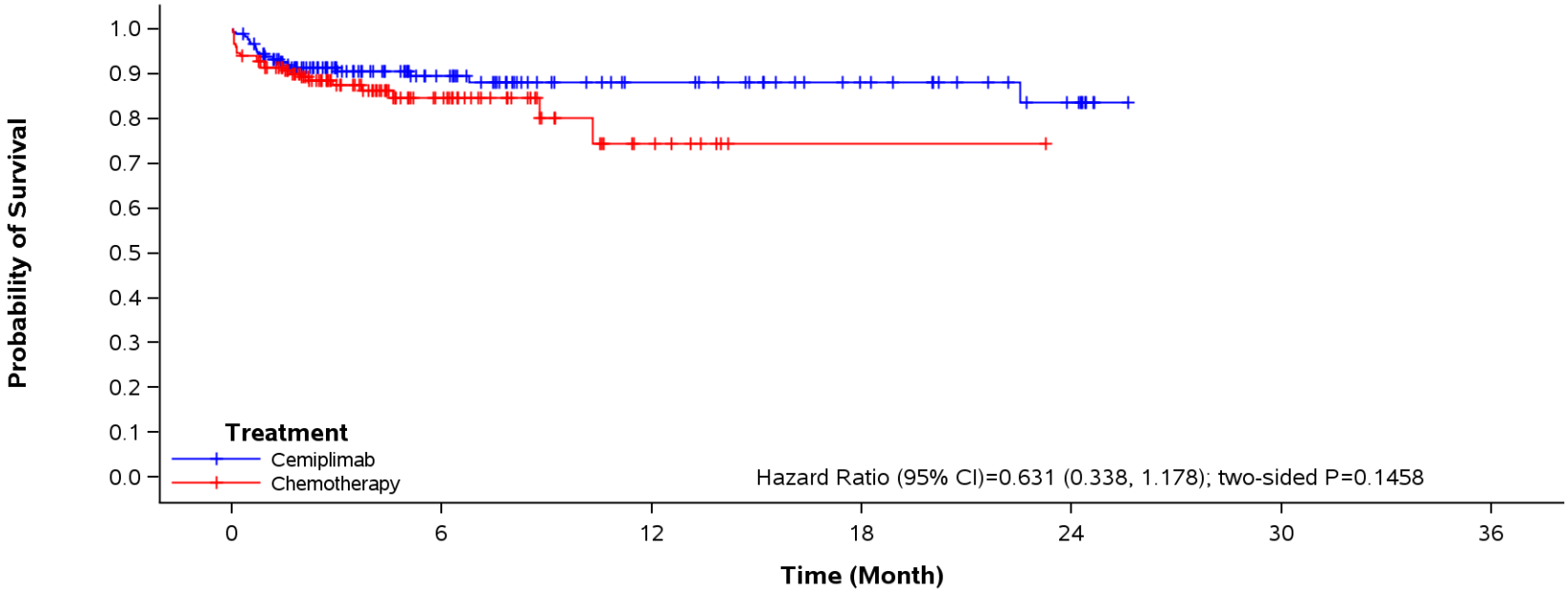

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 51 | 27 | 19 | 10 | 0 | 0 |
| Chemotherapy | 153 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: General disorders and administration site conditions
PT: Asthenia



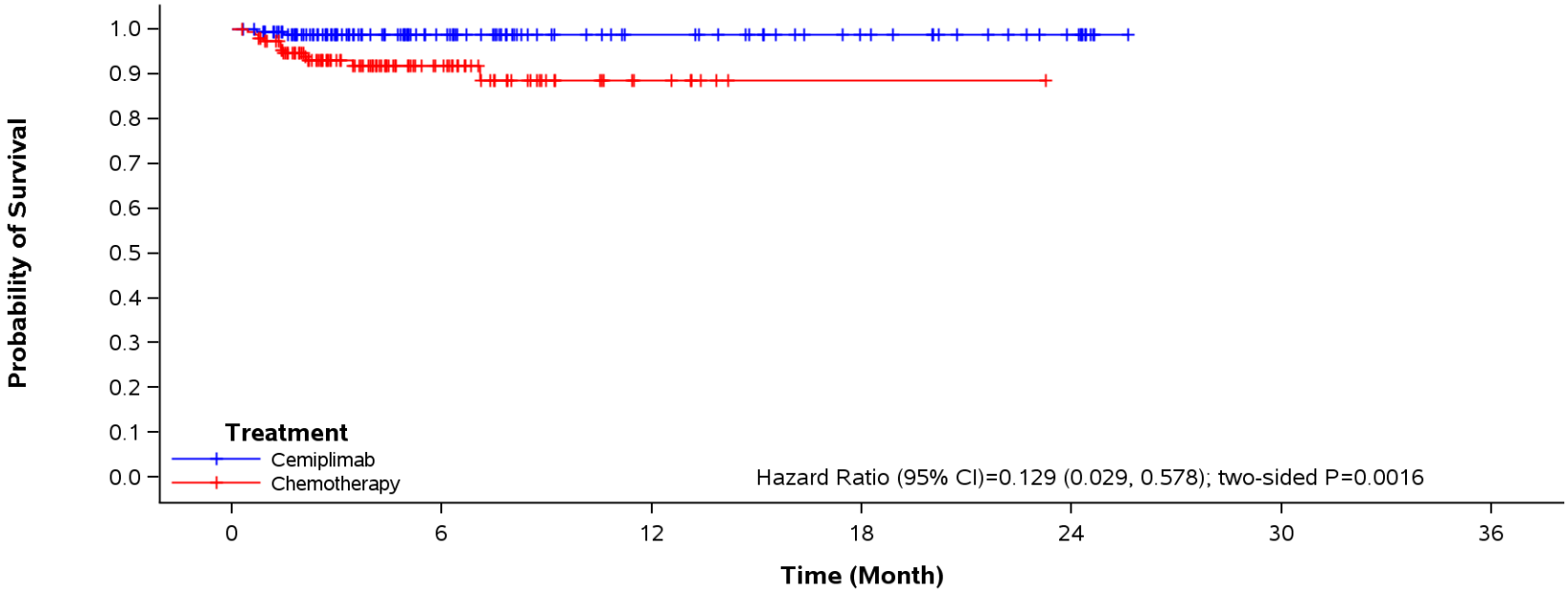

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 74 | 41 | 29 | 17 | 0 | 0 |
| Chemotherapy | 153 | 41 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



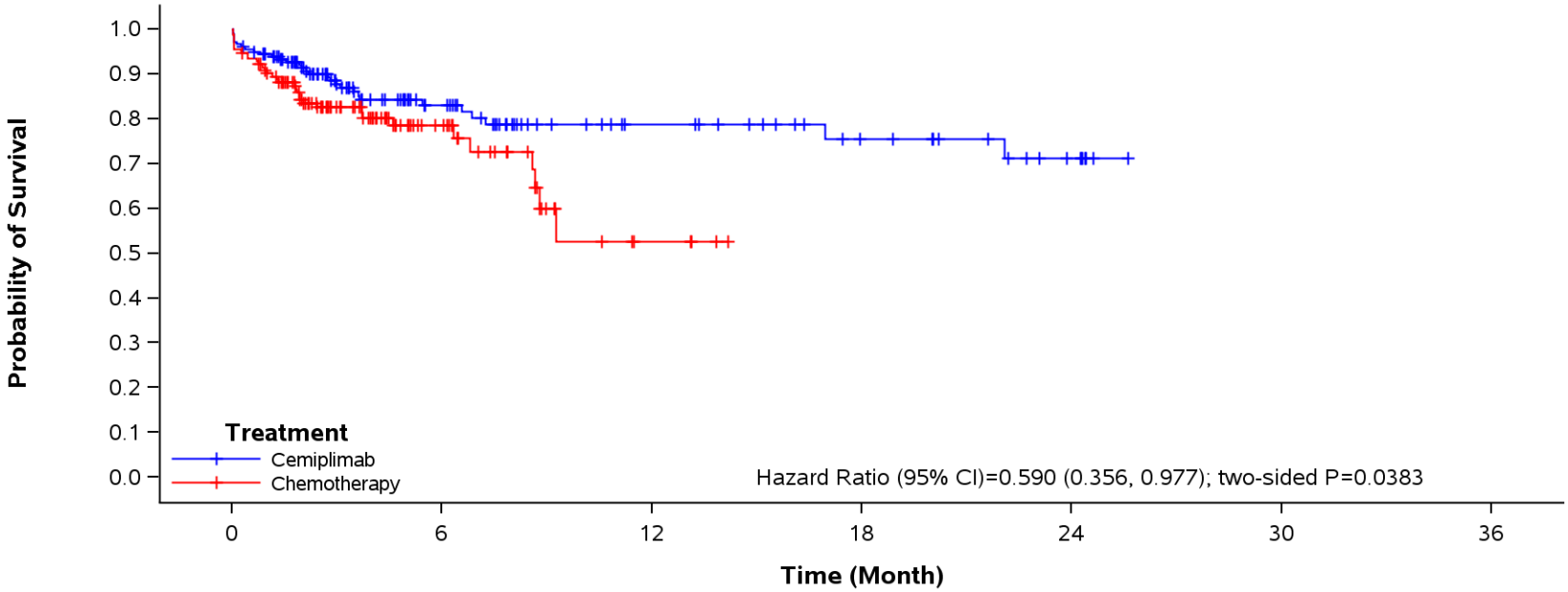

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 42 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Nervous system disorders



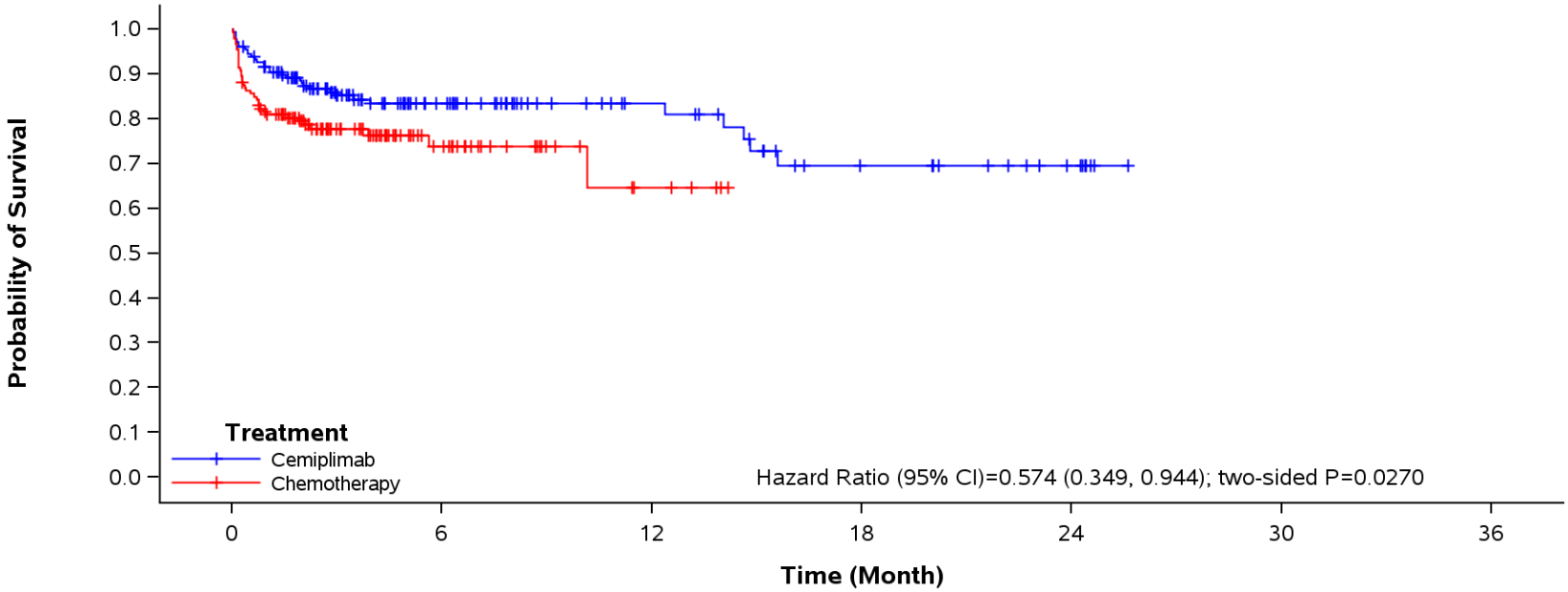

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 64 | 33 | 22 | 12 | 0 | 0 |
| Chemotherapy | 153 | 35 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Skin and subcutaneous tissue disorders



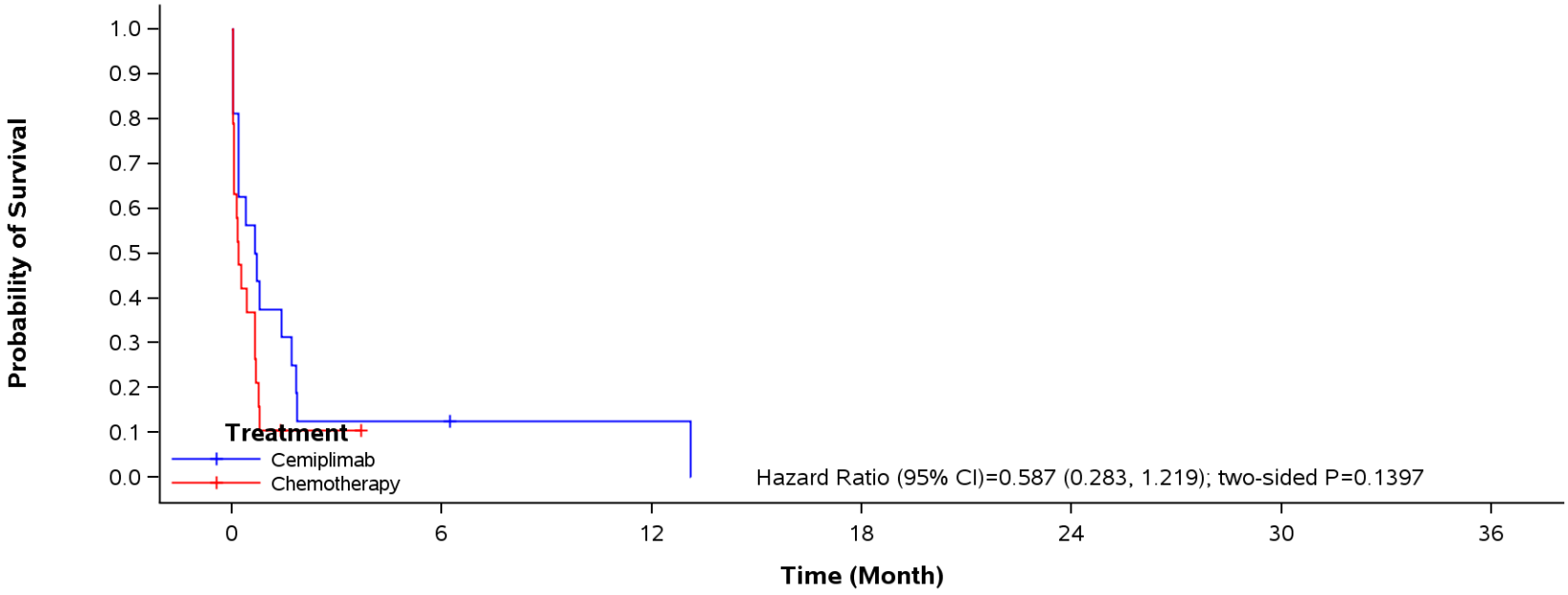

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 63 | 34 | 19 | 10 | 0 | 0 |
| Chemotherapy | 153 | 28 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Number of patients with any TEAE



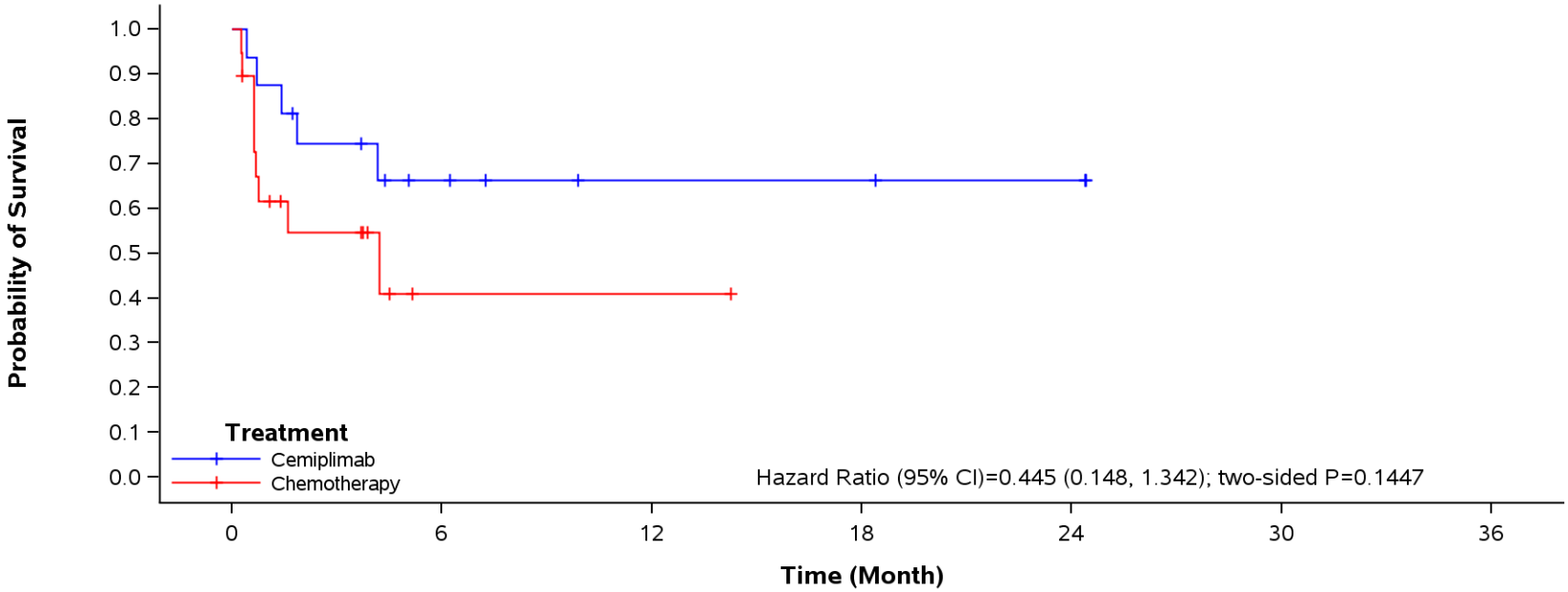

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 19 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders



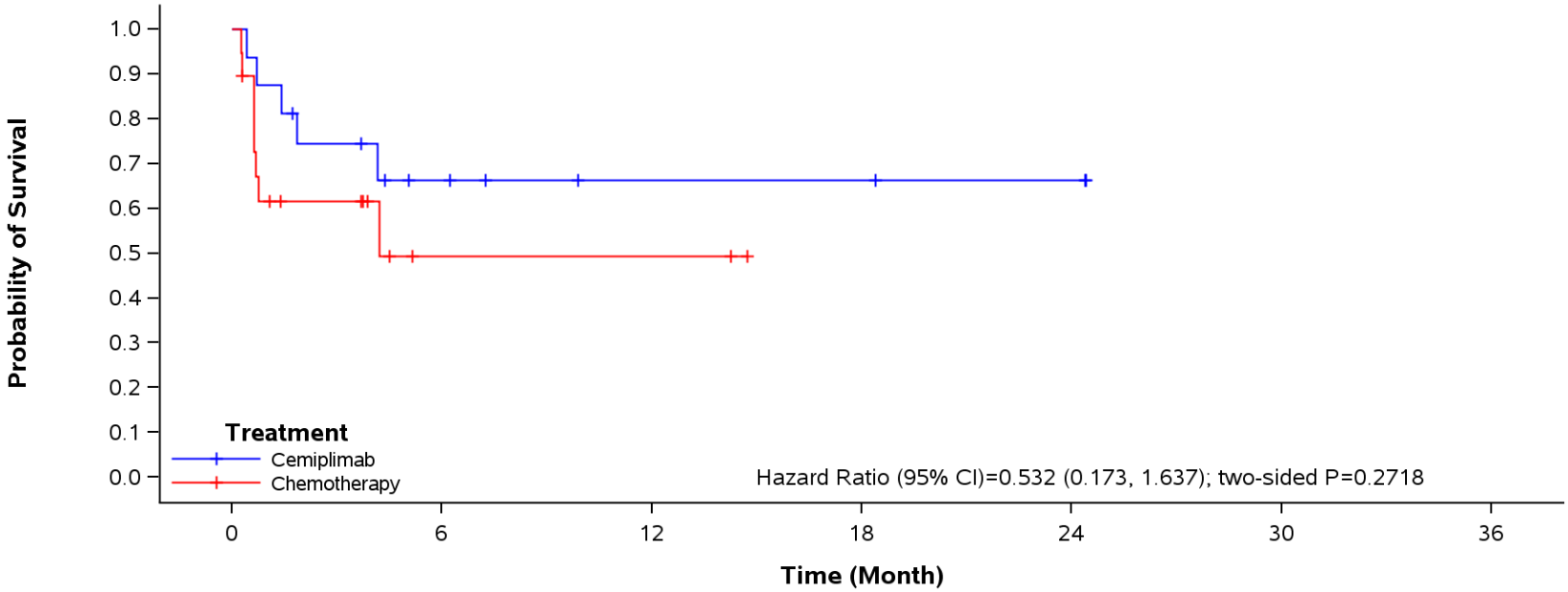

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 19 | 1 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Anaemia



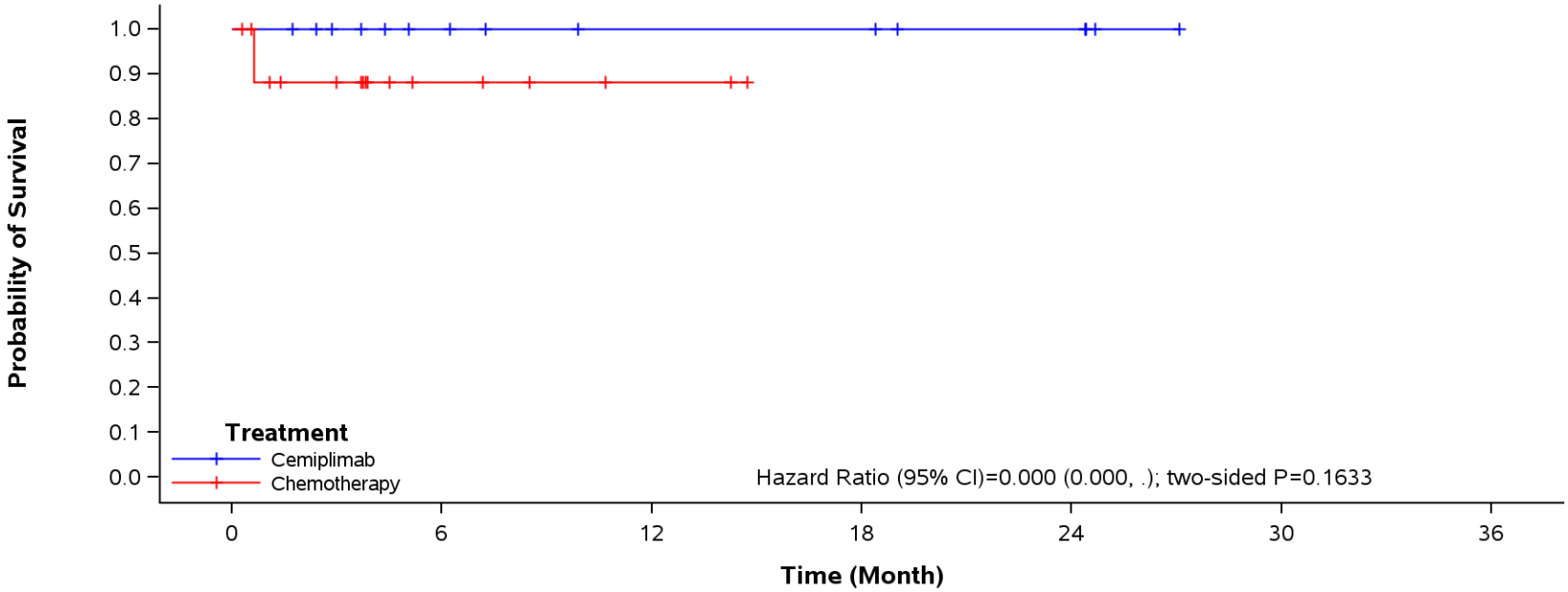

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 6 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 19 | 2 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



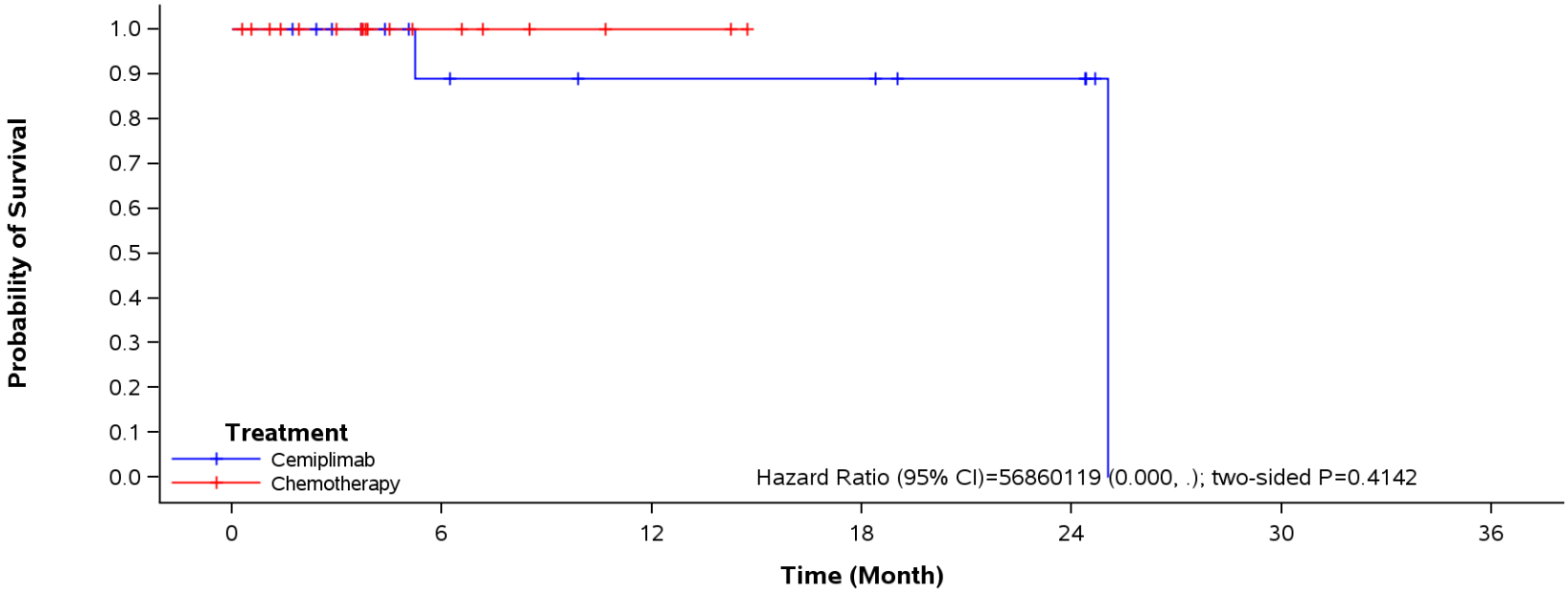

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Endocrine disorders



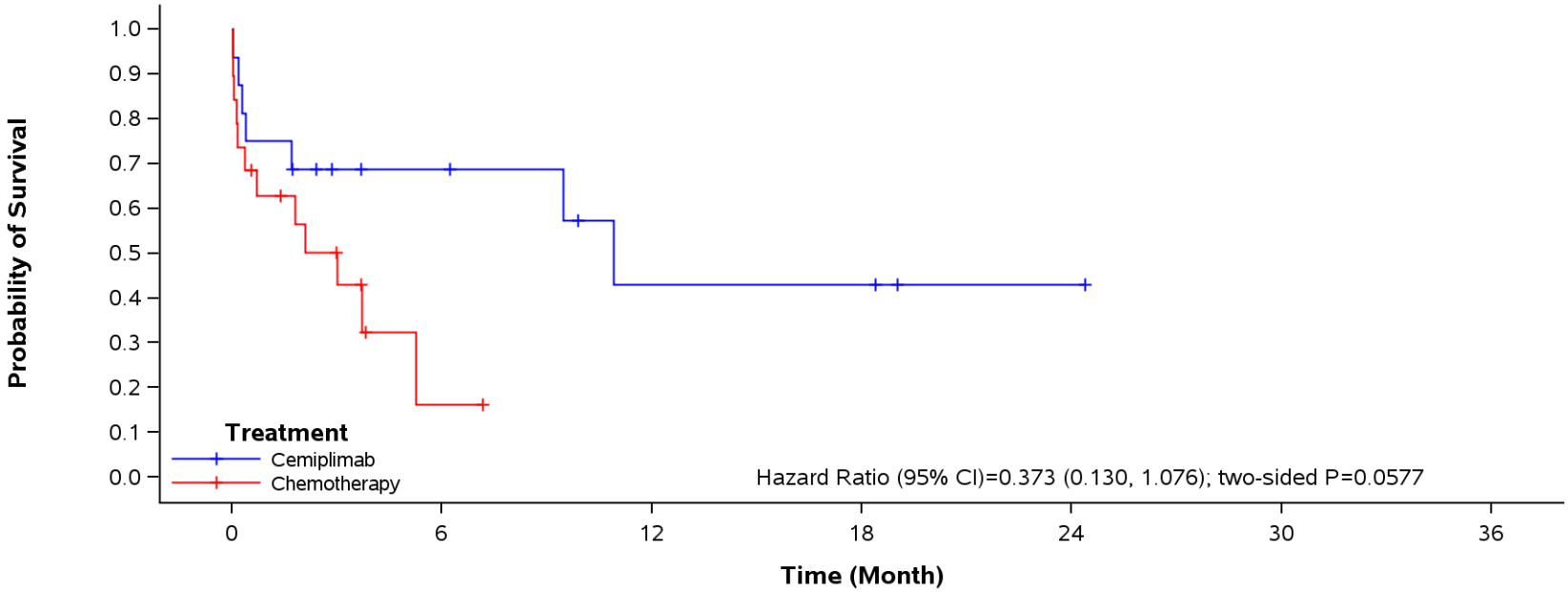

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders



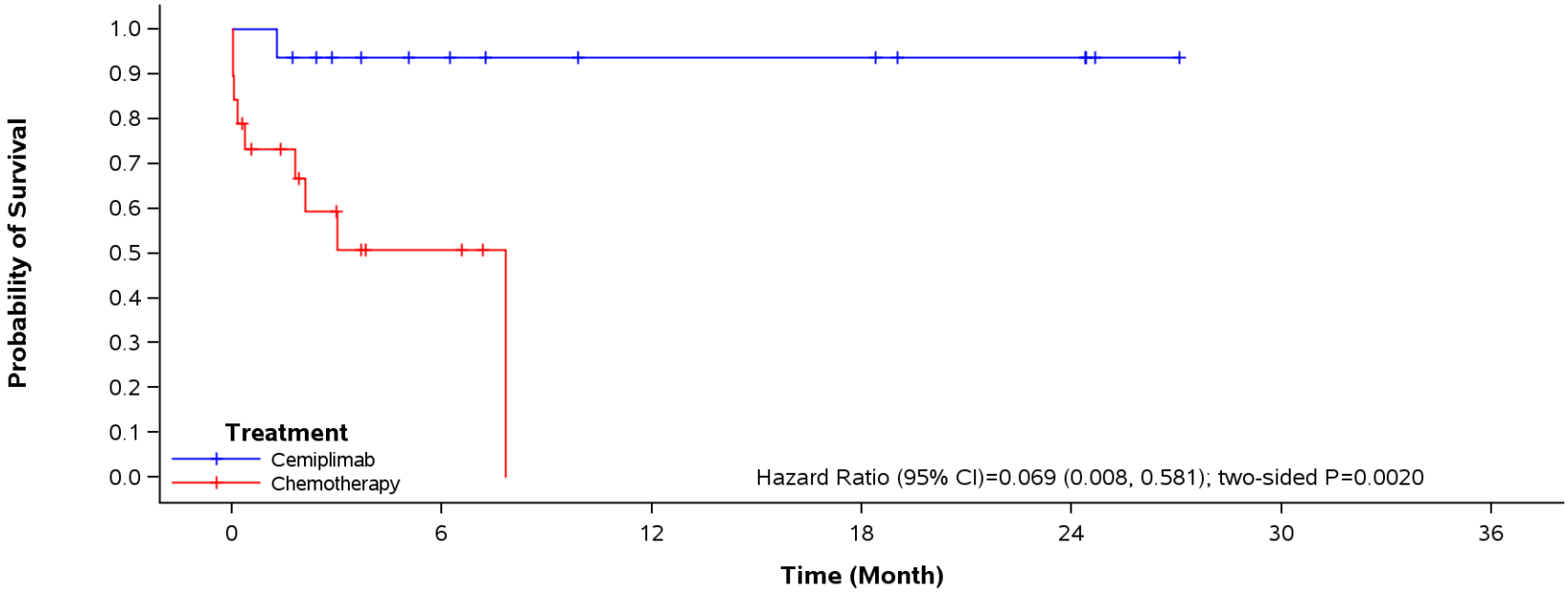

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 3 | 3 | 1 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders
PT: Nausea



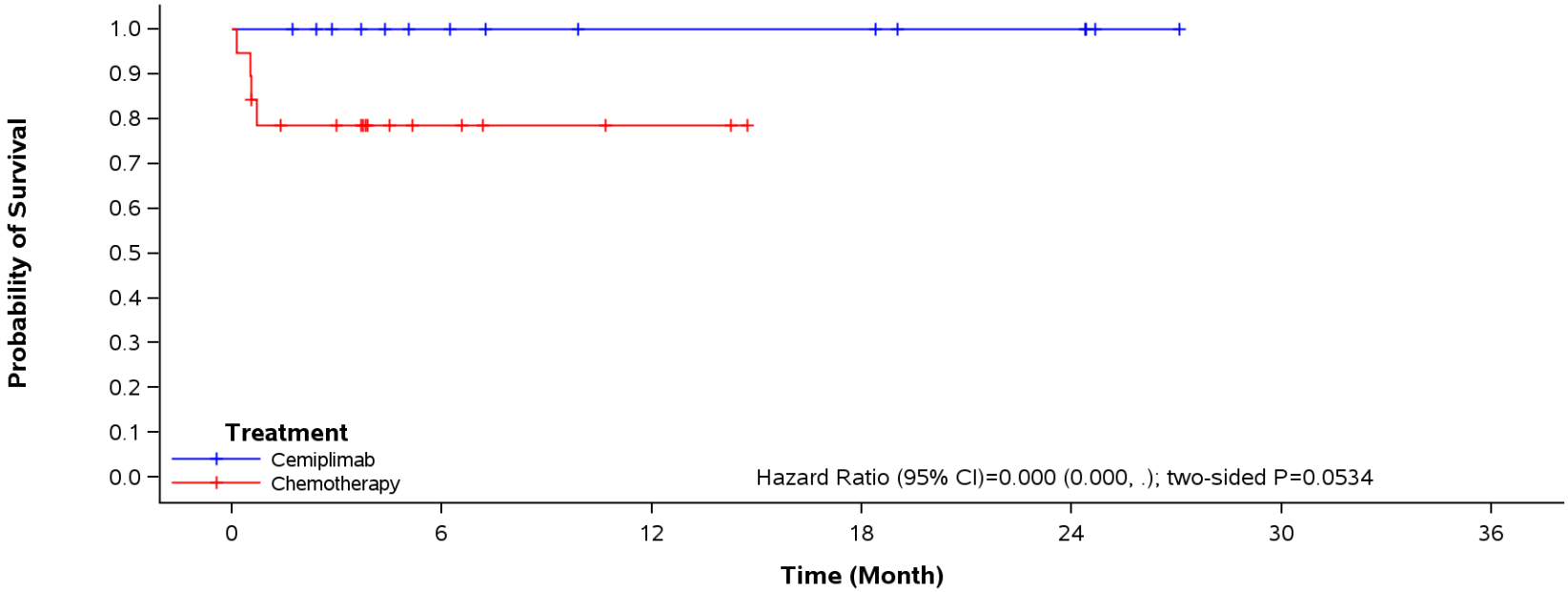

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders
PT: Stomatitis



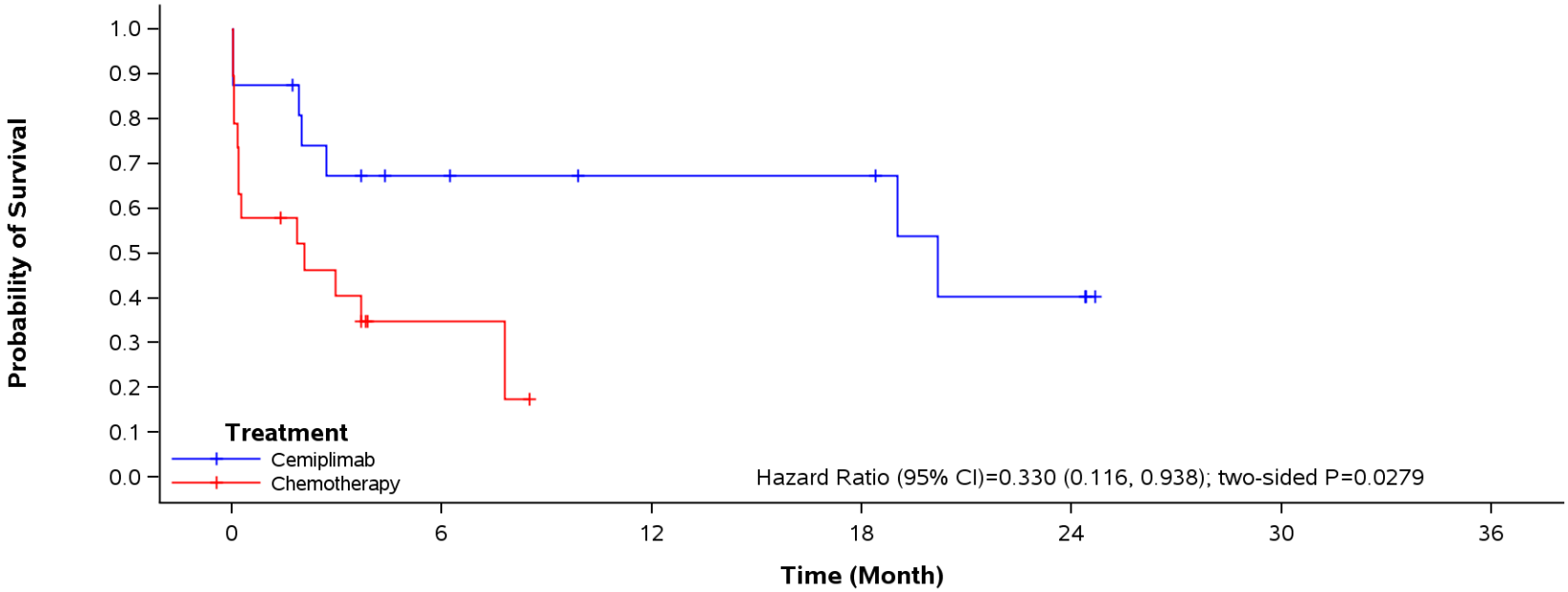

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: General disorders and administration site conditions



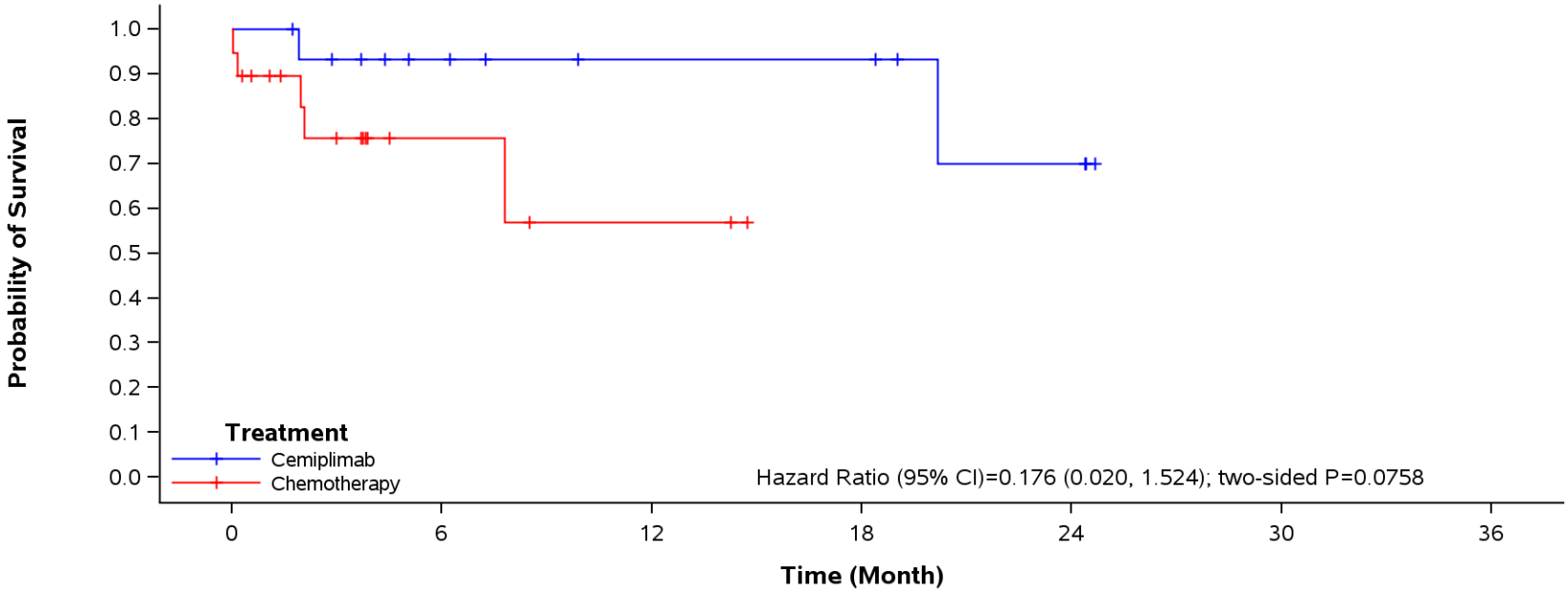

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 6 | 6 | 3 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: General disorders and administration site conditions
PT: Asthenia



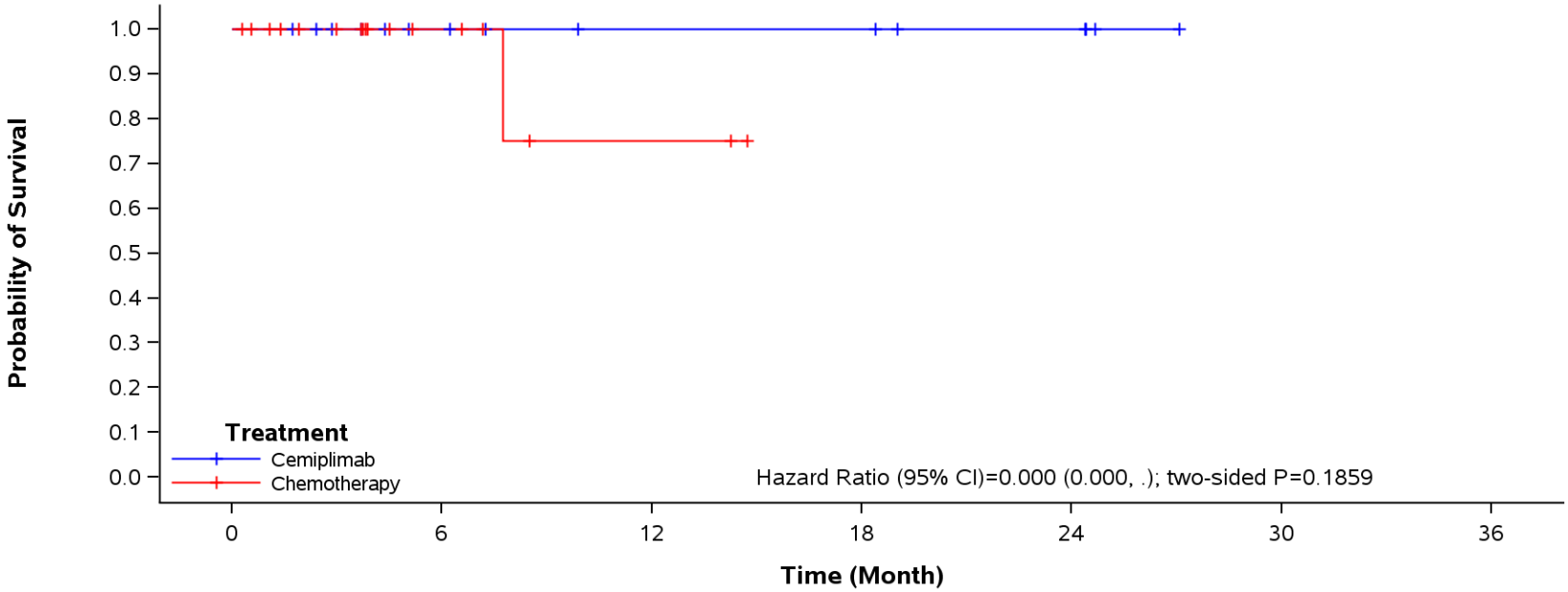

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 3 | 0 | 0 |
| Chemotherapy | 19 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



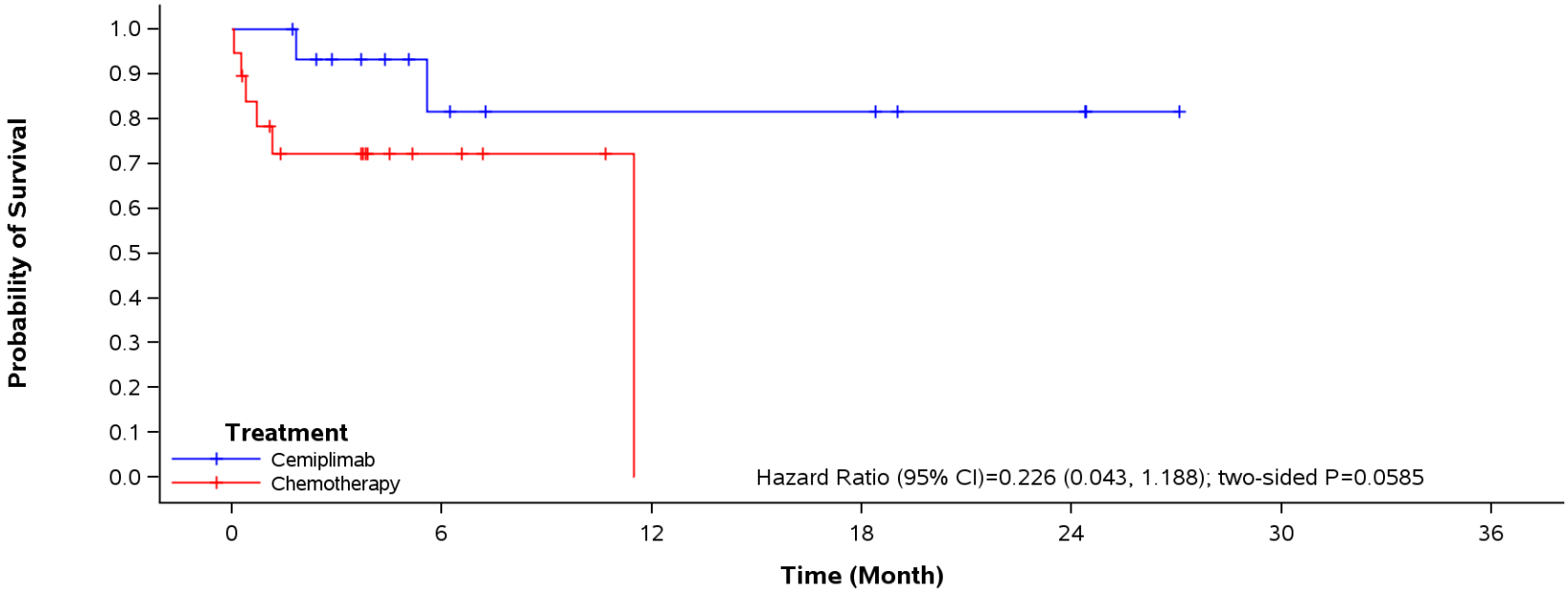

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Nervous system disorders



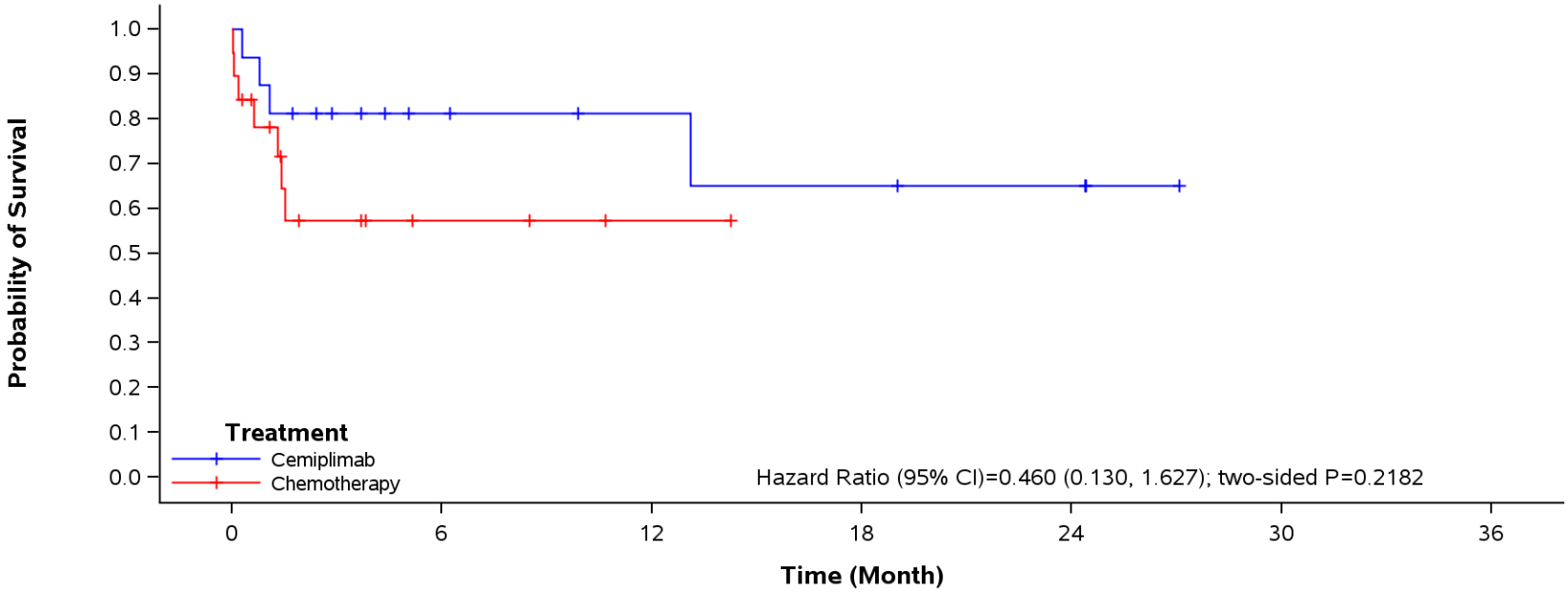

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Skin and subcutaneous tissue disorders



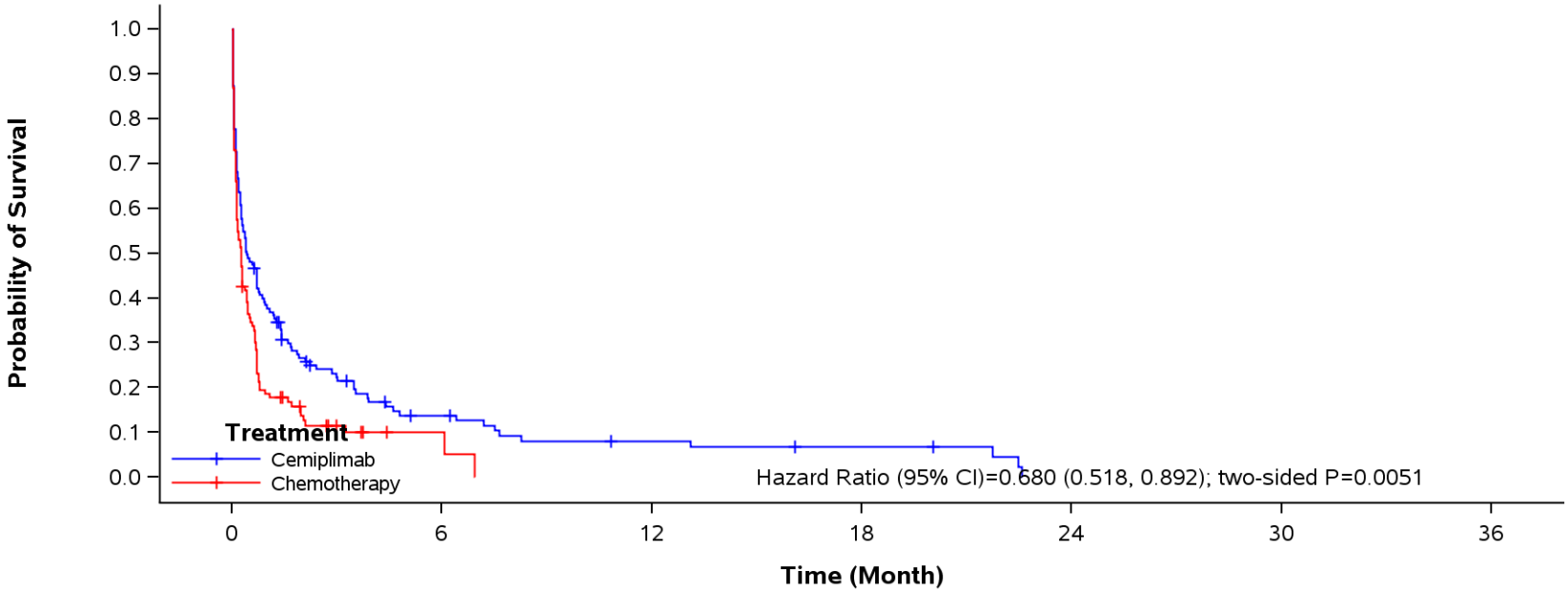

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 4 | 3 | 0 | 0 |
| Chemotherapy | 19 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Number of patients with any TEAE



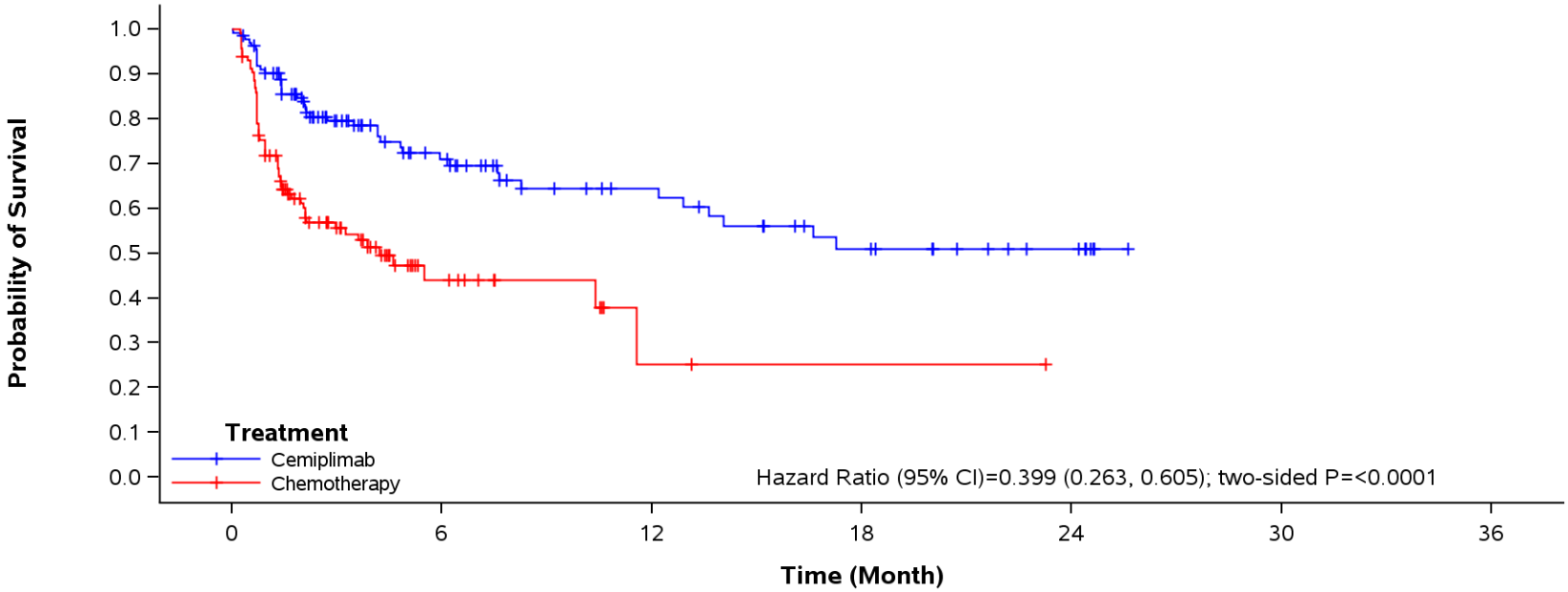

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 13 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 115 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders



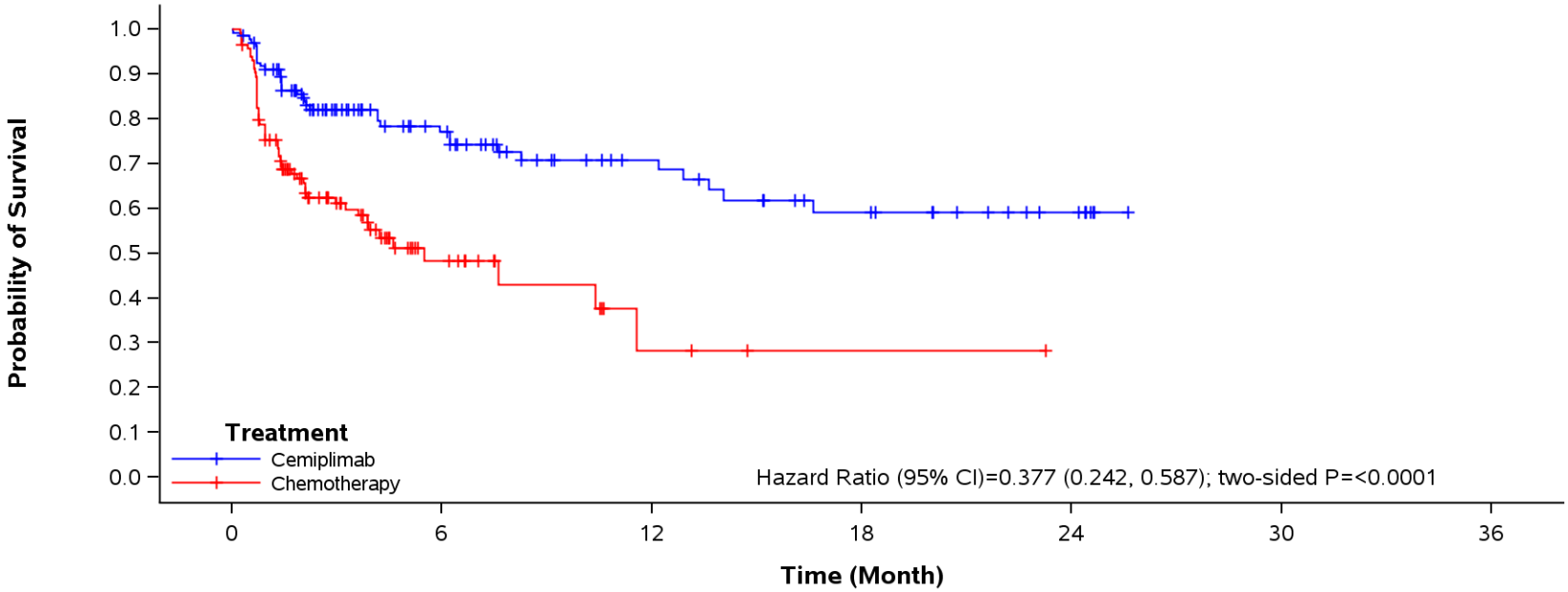

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 52 | 31 | 20 | 11 | 0 | 0 |
| Chemotherapy | 115 | 14 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Anaemia



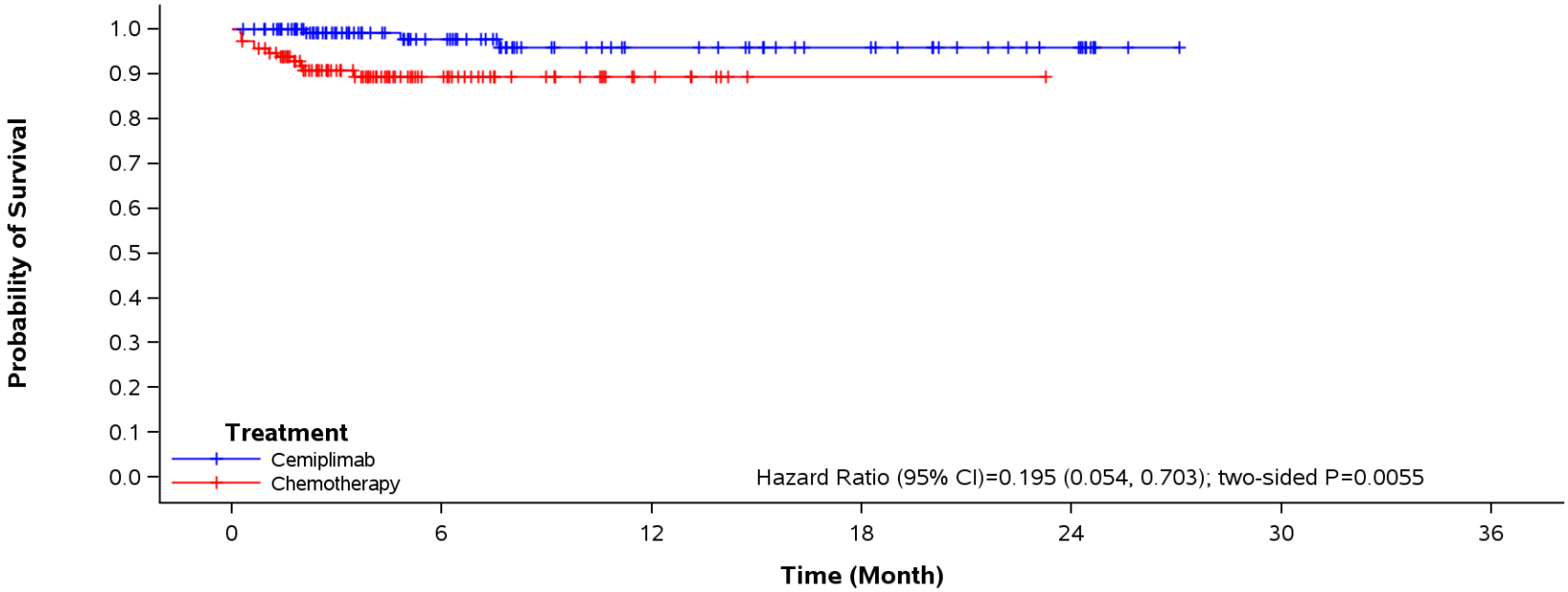

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 56 | 32 | 22 | 12 | 0 | 0 |
| Chemotherapy | 115 | 17 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



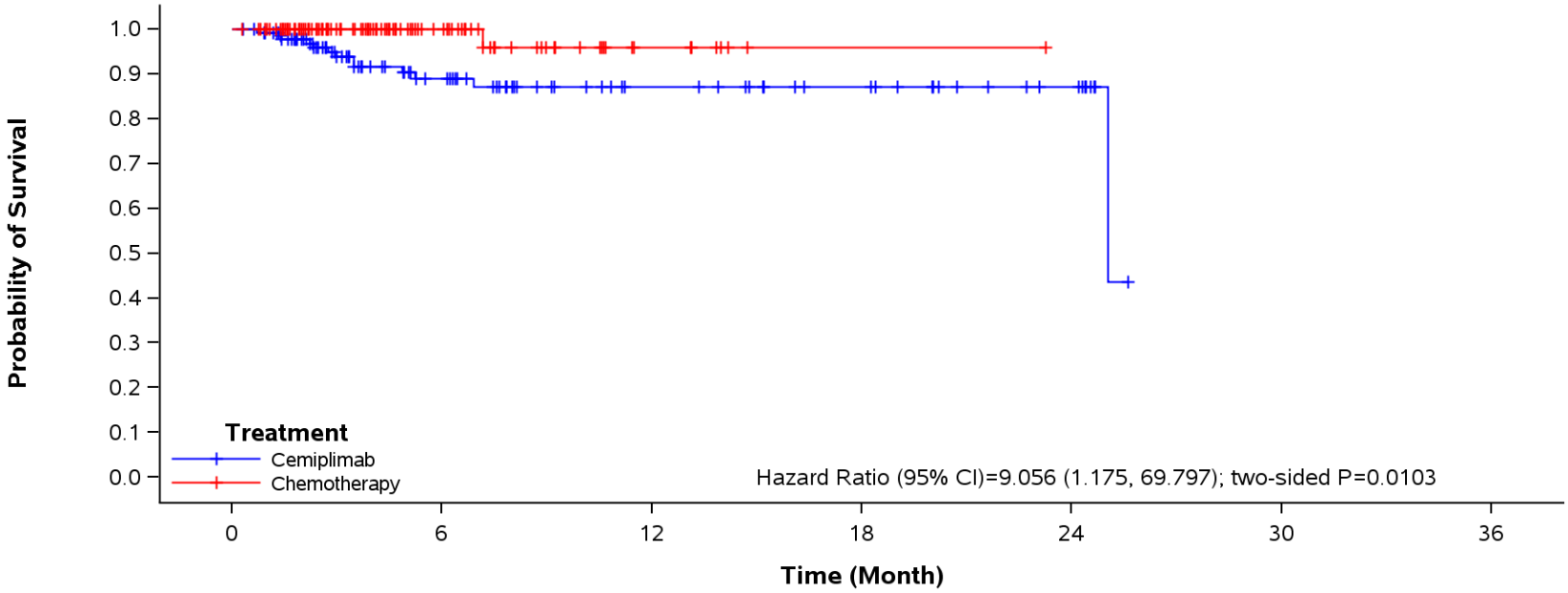

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 65 | 36 | 27 | 15 | 0 | 0 |
| Chemotherapy | 115 | 33 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Endocrine disorders



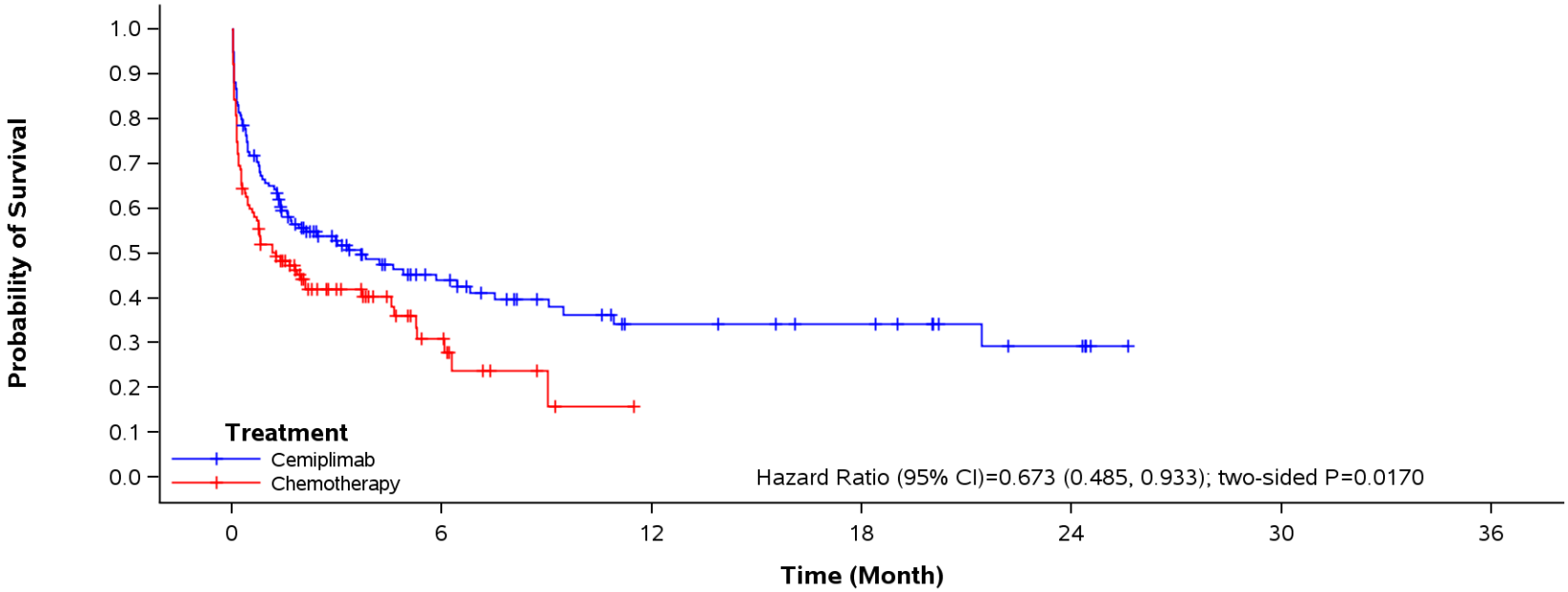

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 59 | 33 | 25 | 14 | 0 | 0 |
| Chemotherapy | 115 | 37 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders



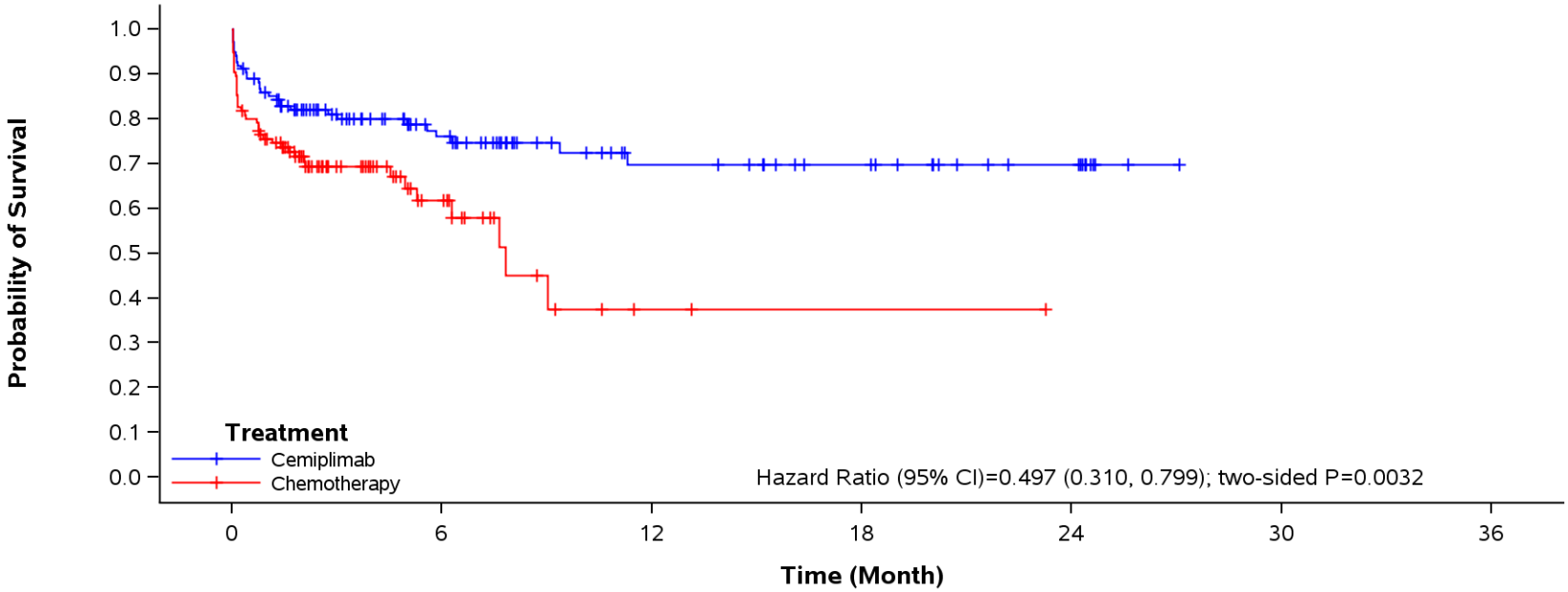

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 34 | 15 | 12 | 5 | 0 | 0 |
| Chemotherapy | 115 | 11 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders
PT: Nausea



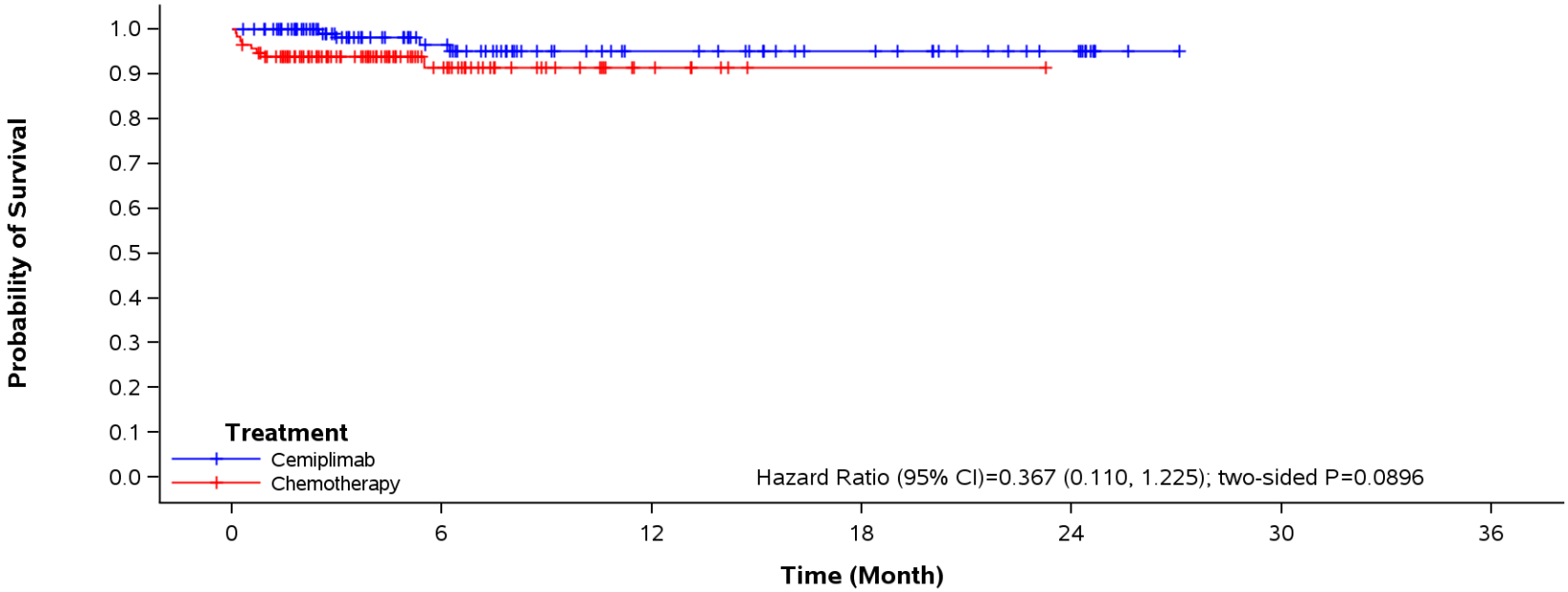

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 54 | 26 | 19 | 10 | 0 | 0 |
| Chemotherapy | 115 | 20 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders
PT: Stomatitis



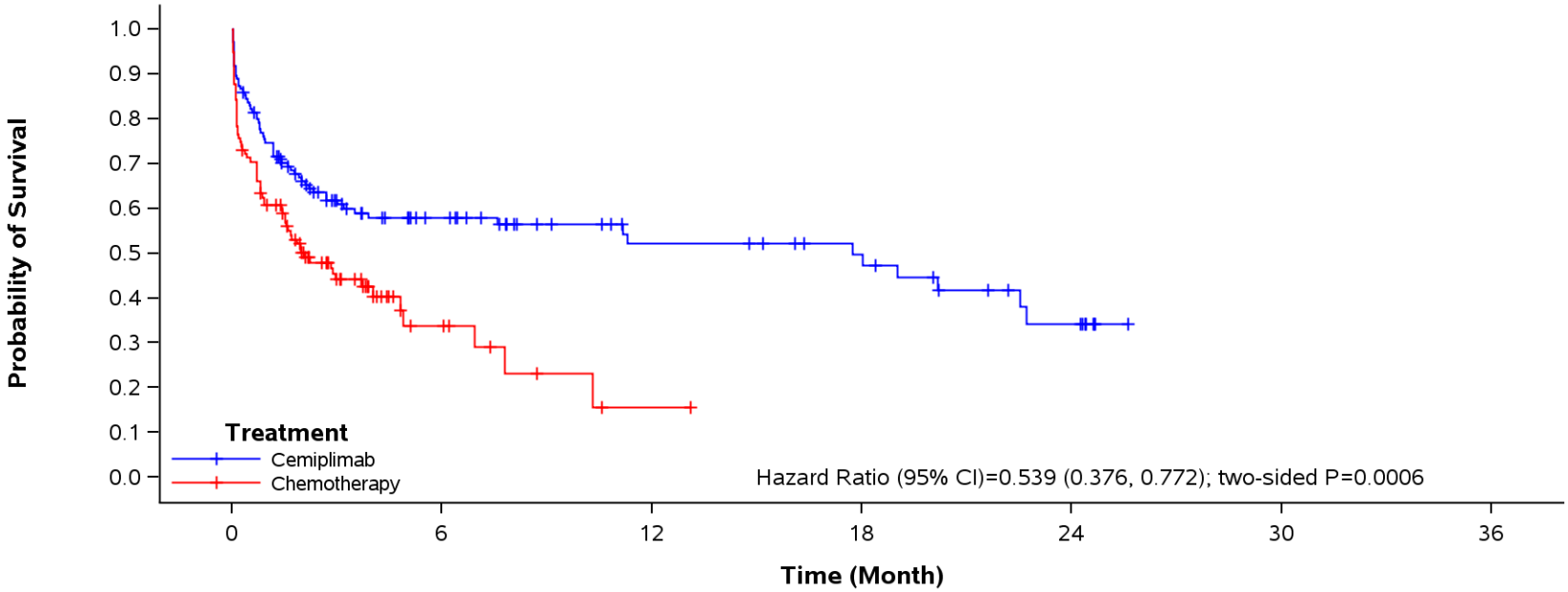

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 63 | 34 | 25 | 14 | 0 | 0 |
| Chemotherapy | 115 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: General disorders and administration site conditions



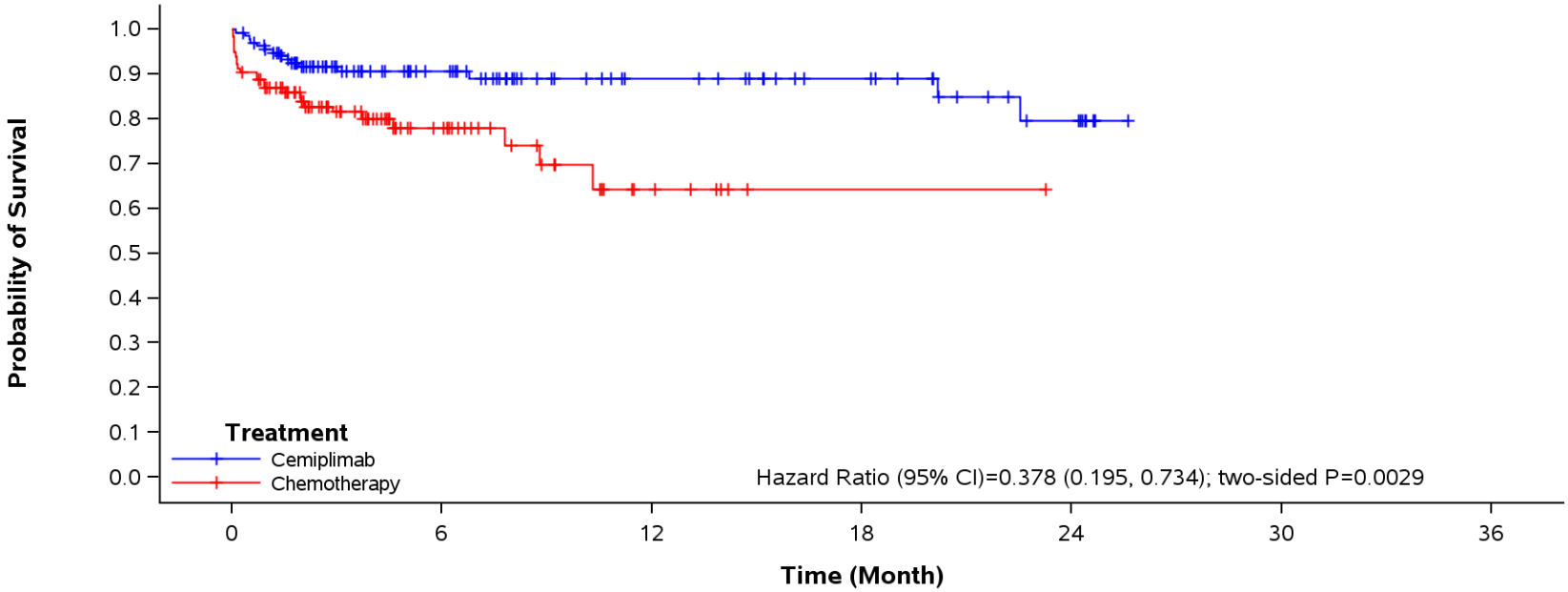

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 45 | 25 | 20 | 9 | 0 | 0 |
| Chemotherapy | 115 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: General disorders and administration site conditions
PT: Asthenia



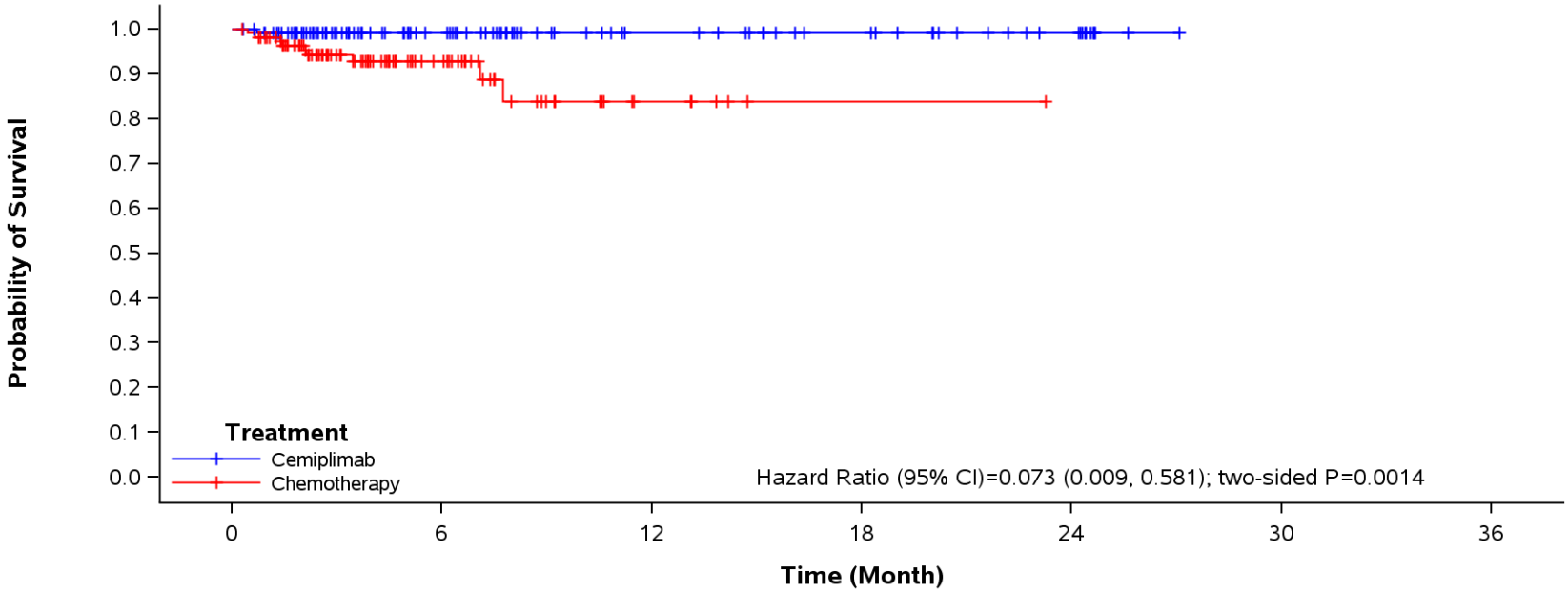

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 64 | 36 | 27 | 14 | 0 | 0 |
| Chemotherapy | 115 | 30 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



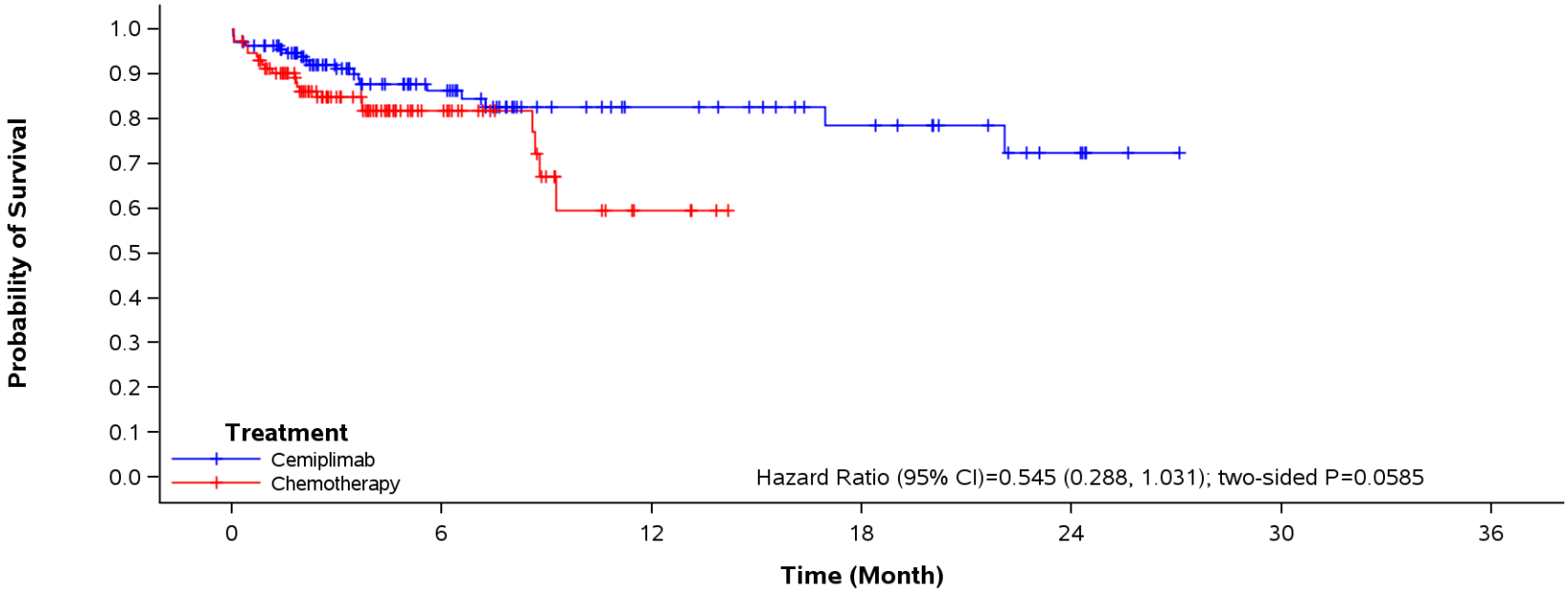

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 35 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Nervous system disorders



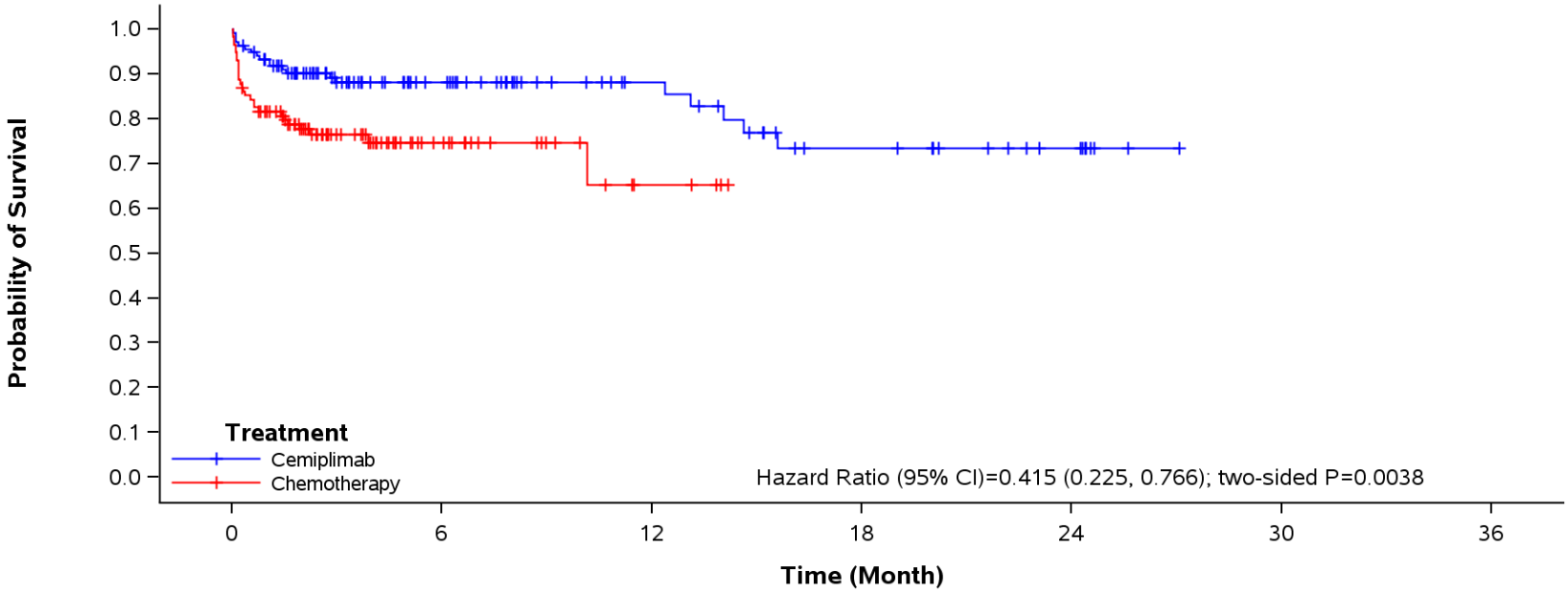

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 55 | 27 | 19 | 9 | 0 | 0 |
| Chemotherapy | 115 | 29 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Skin and subcutaneous tissue disorders



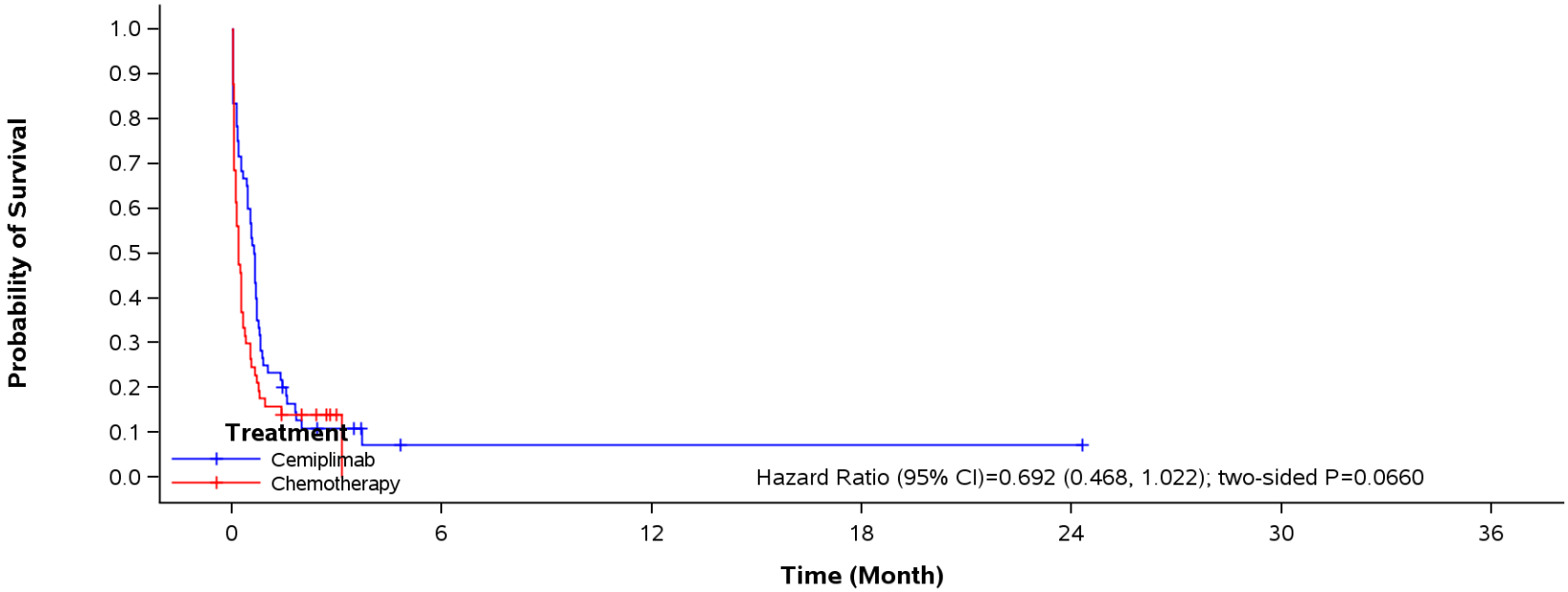

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 57 | 32 | 19 | 10 | 0 | 0 |
| Chemotherapy | 115 | 22 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Number of patients with any TEAE



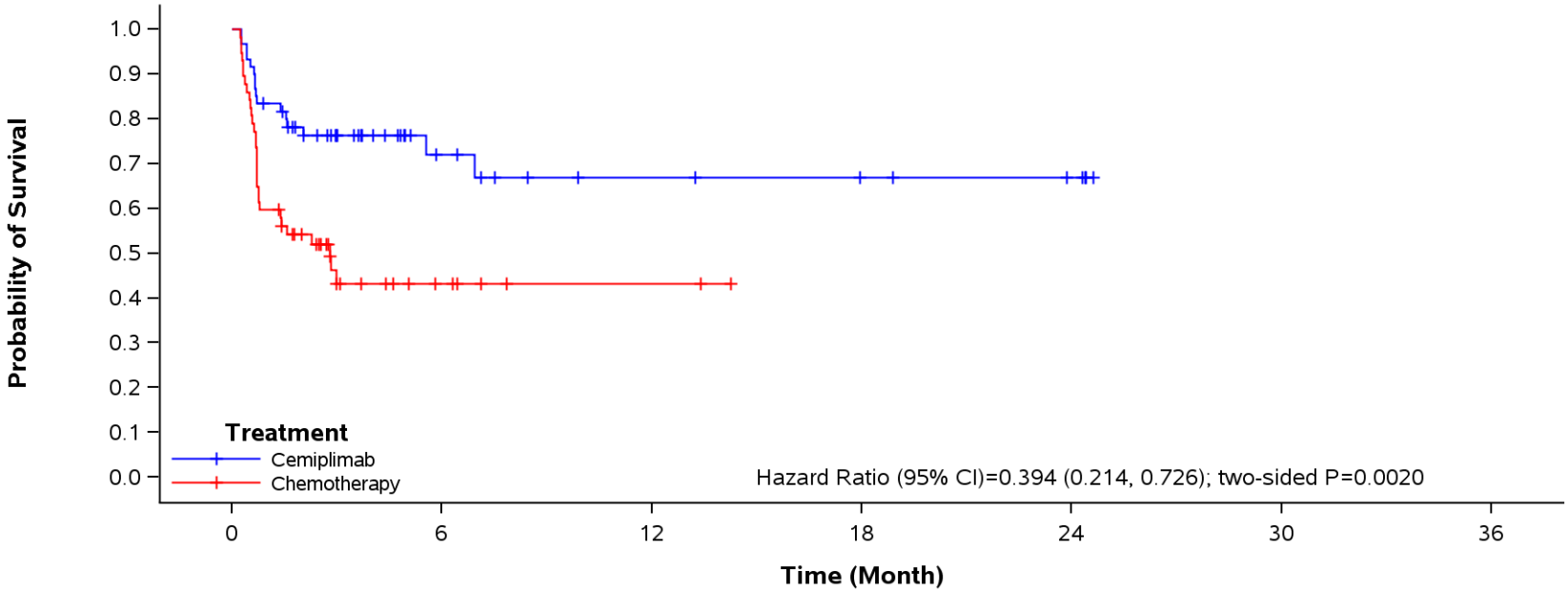

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 1 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 57 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders



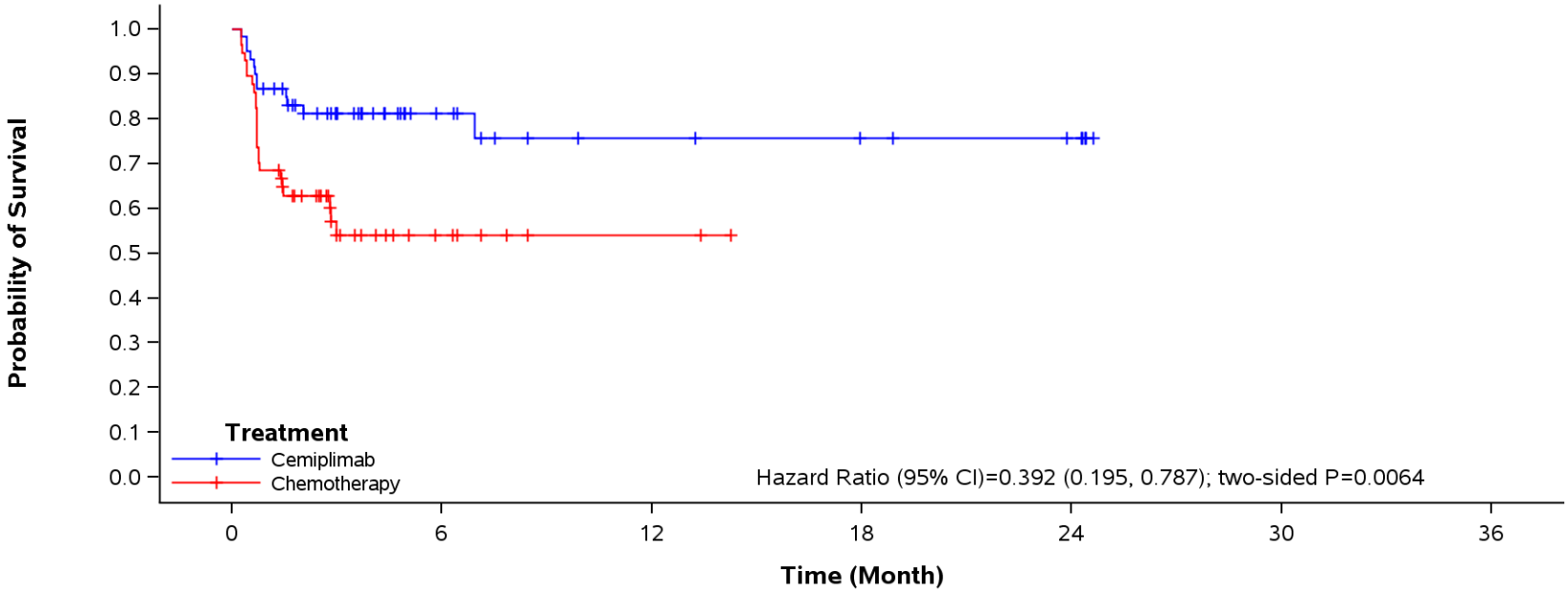

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 9 | 7 | 5 | 0 | 0 |
| Chemotherapy | 57 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Anaemia



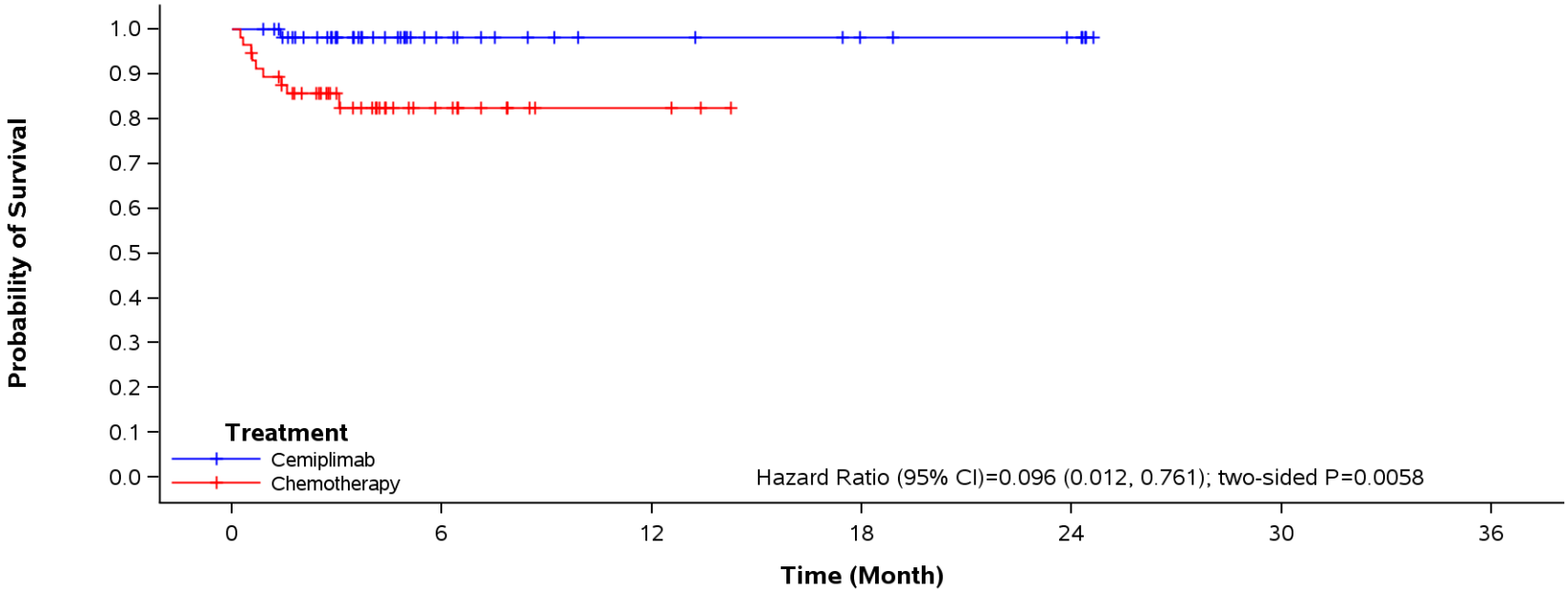

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 10 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 7 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



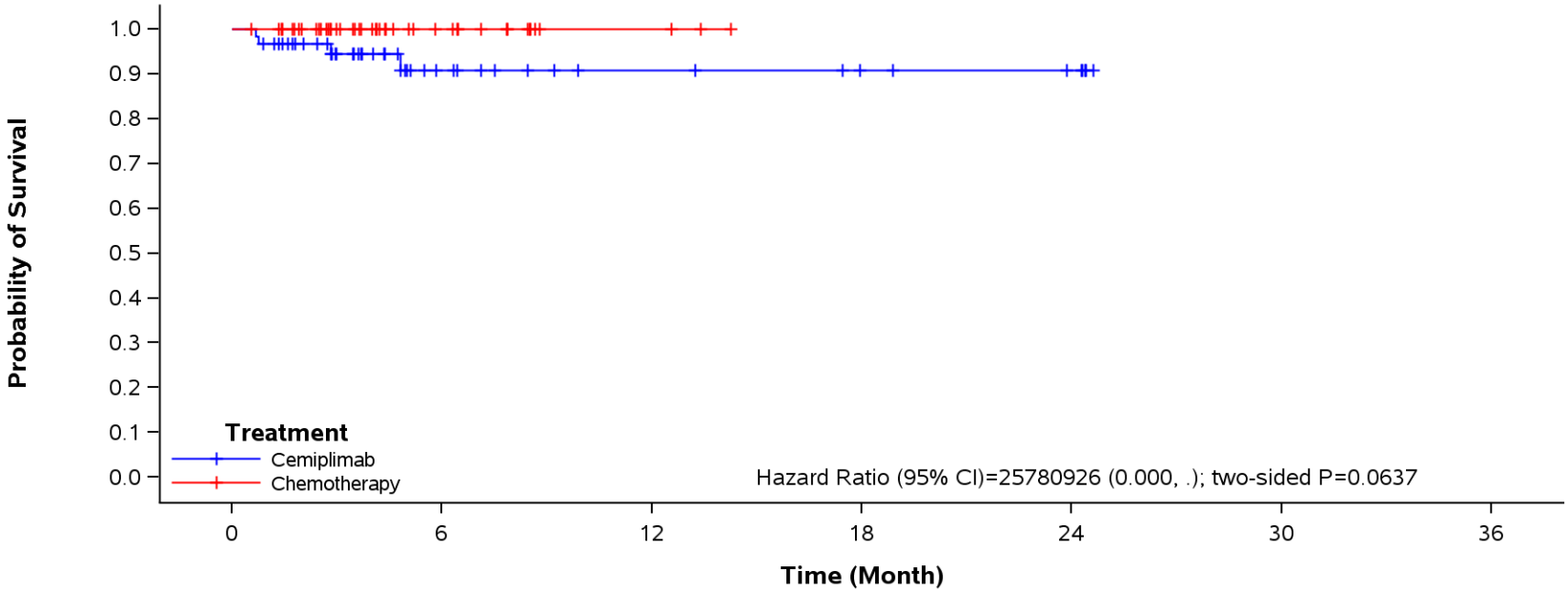

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 12 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Endocrine disorders



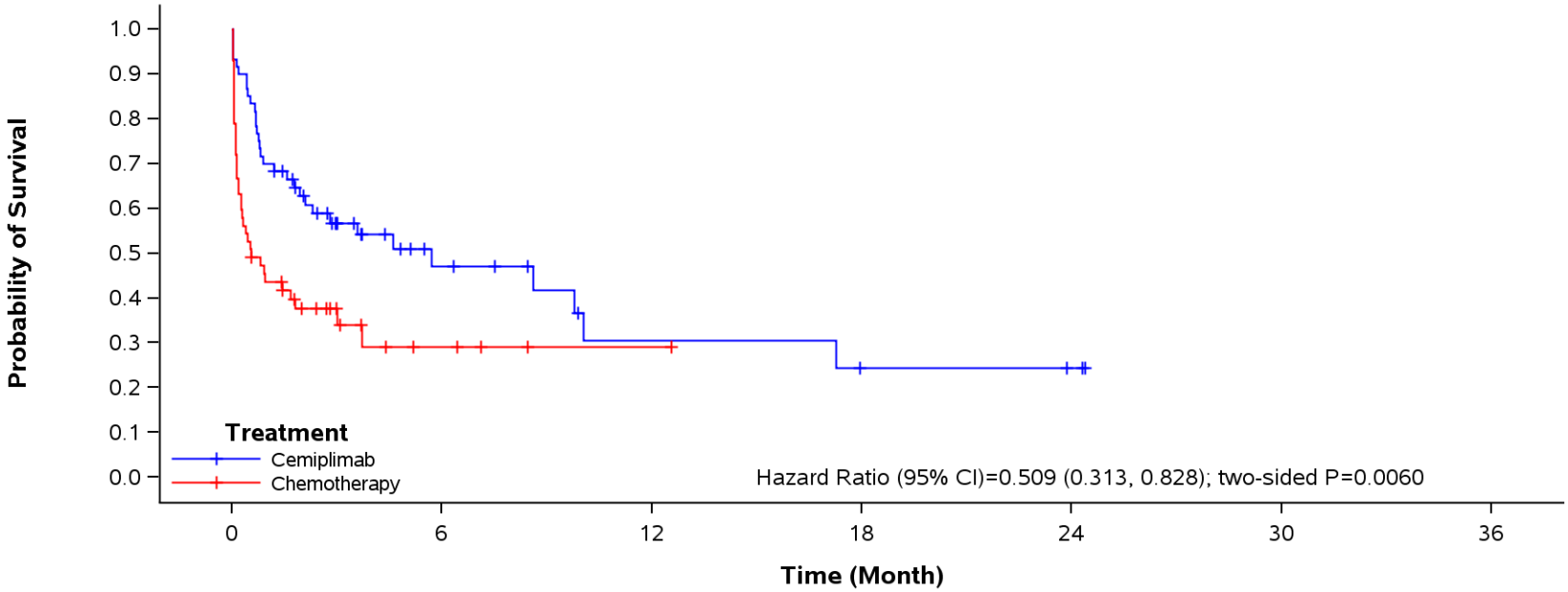

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders




**Number of Subjects at risk**

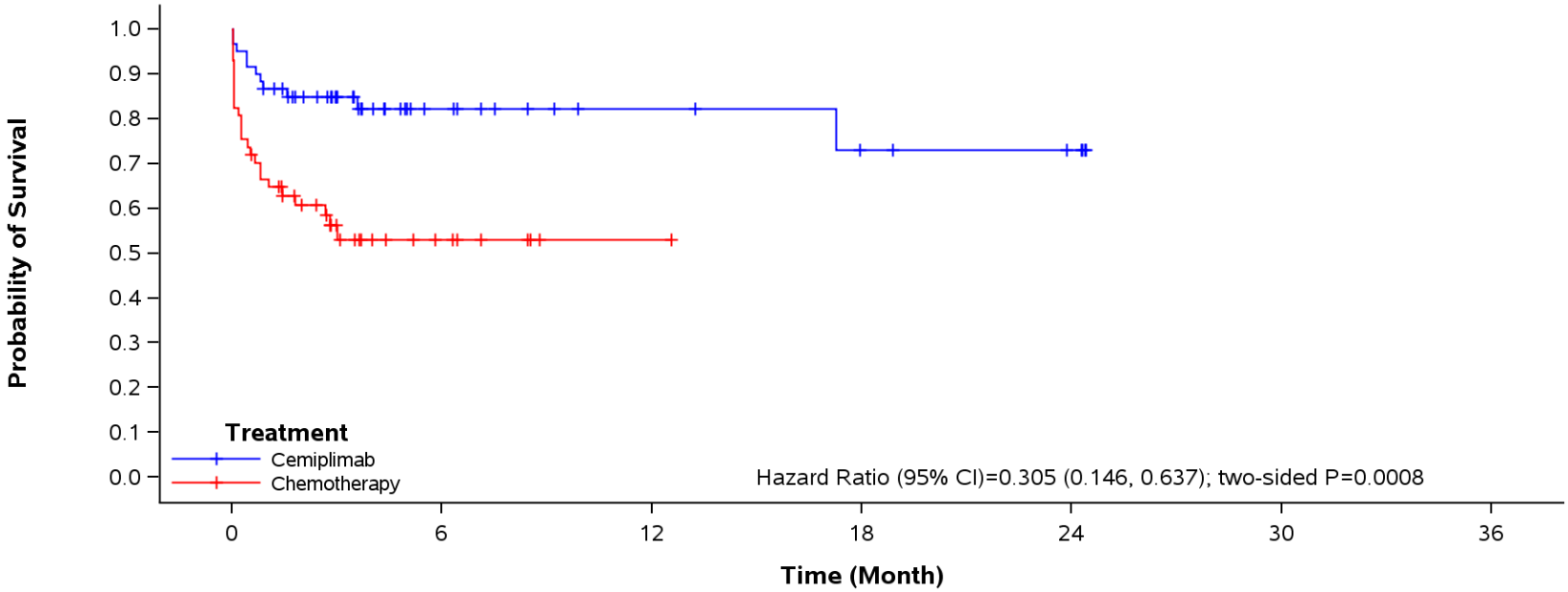
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 12 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 57 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders
PT: Nausea



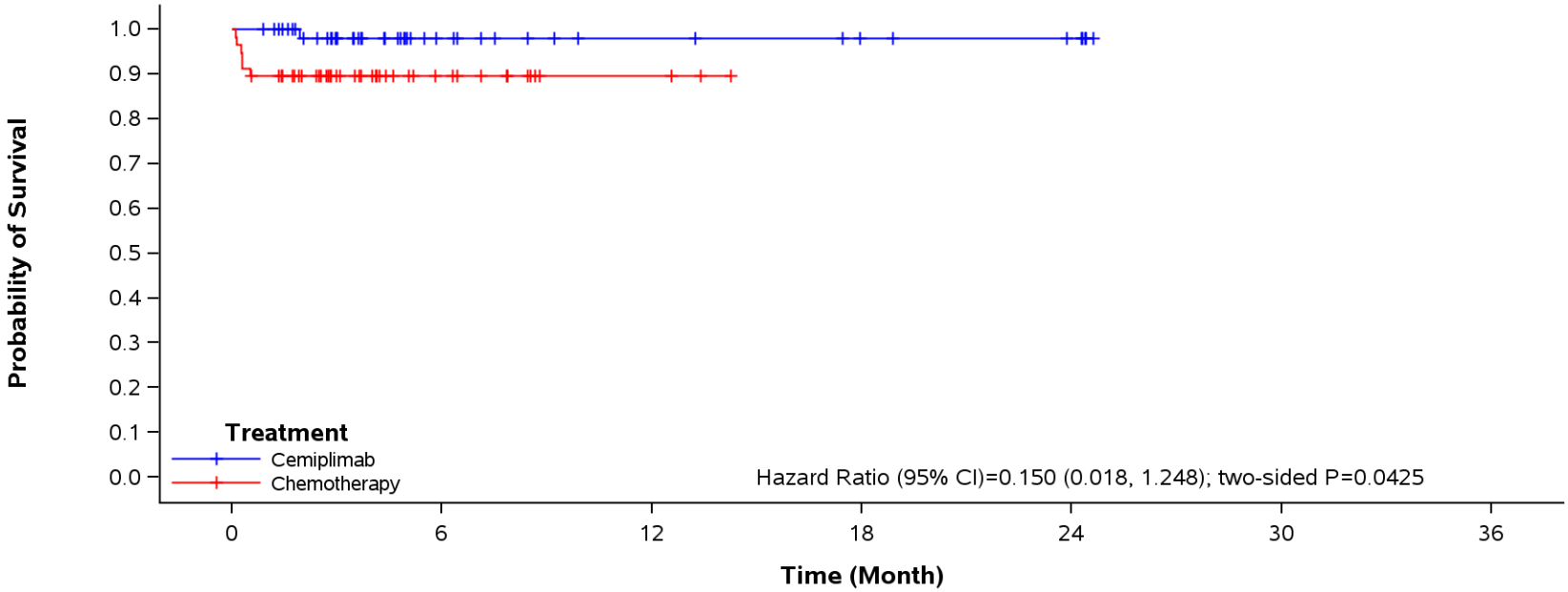

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 17 | 10 | 7 | 5 | 0 | 0 |
| Chemotherapy | 57 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders
PT: Stomatitis



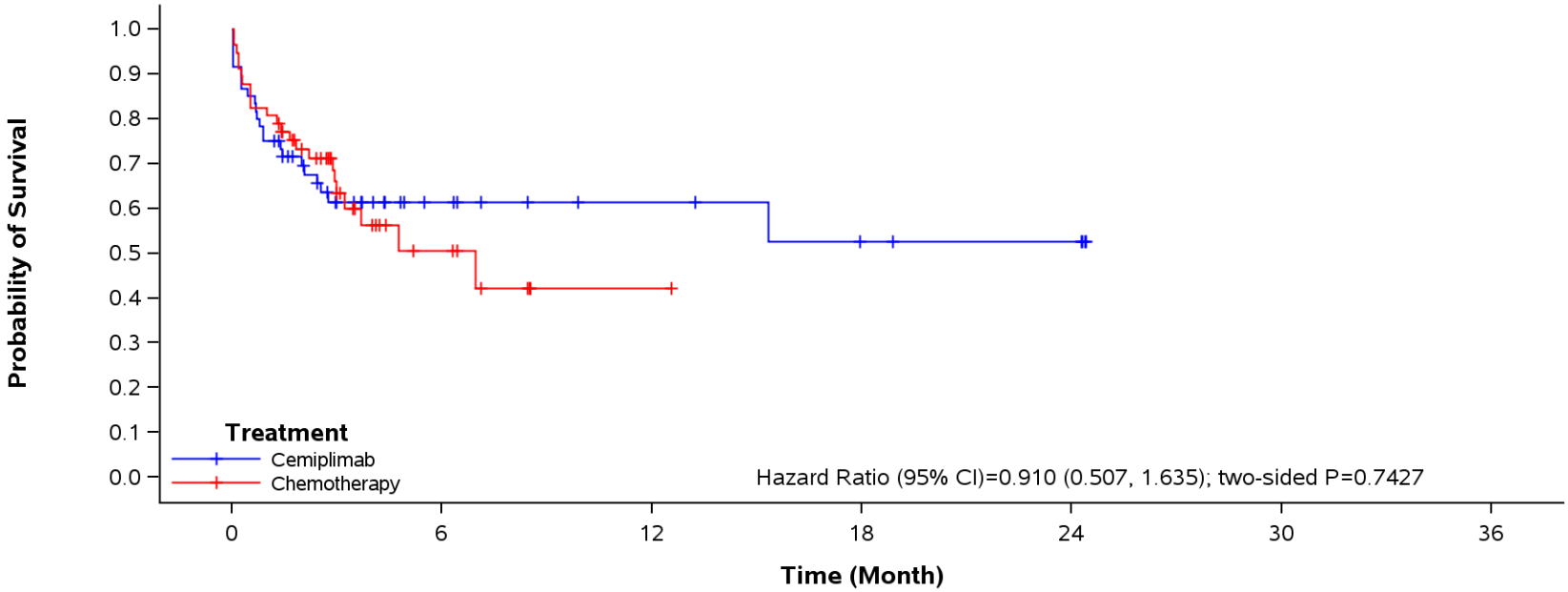

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: General disorders and administration site conditions



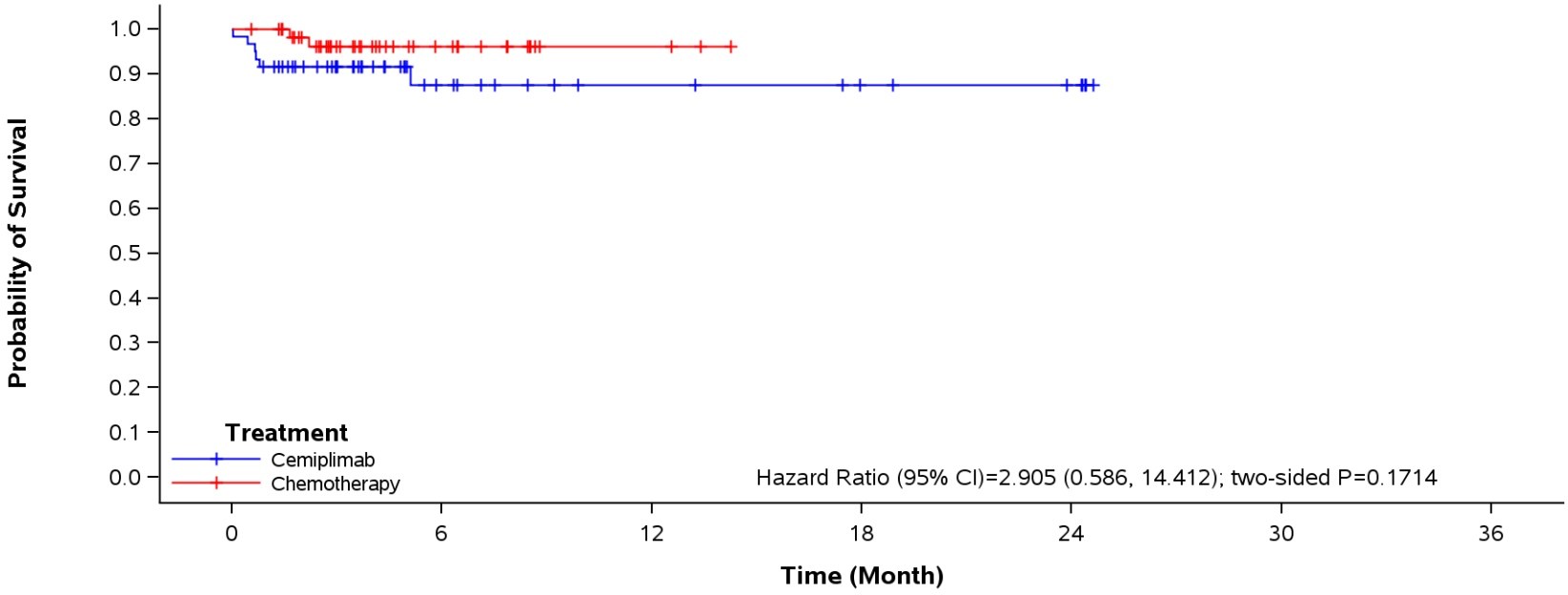

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 14 | 8 | 5 | 4 | 0 | 0 |
| Chemotherapy | 57 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: General disorders and administration site conditions
PT: Asthenia



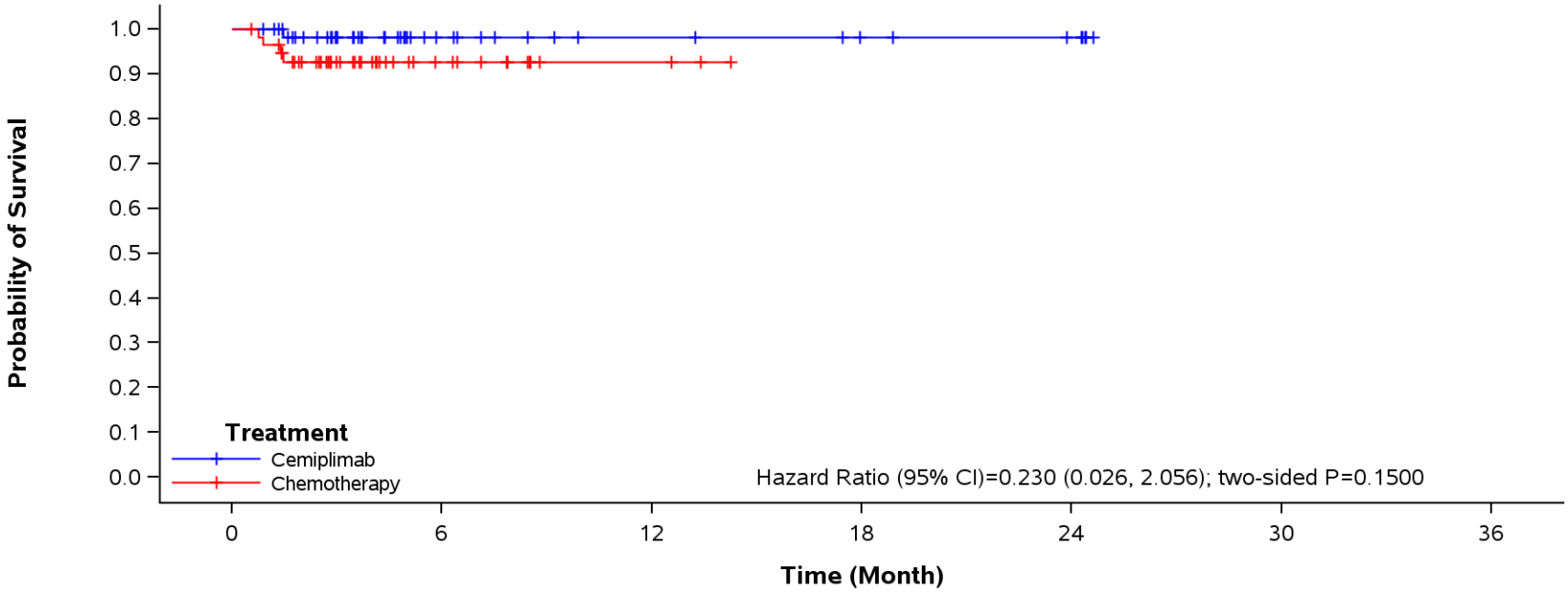

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



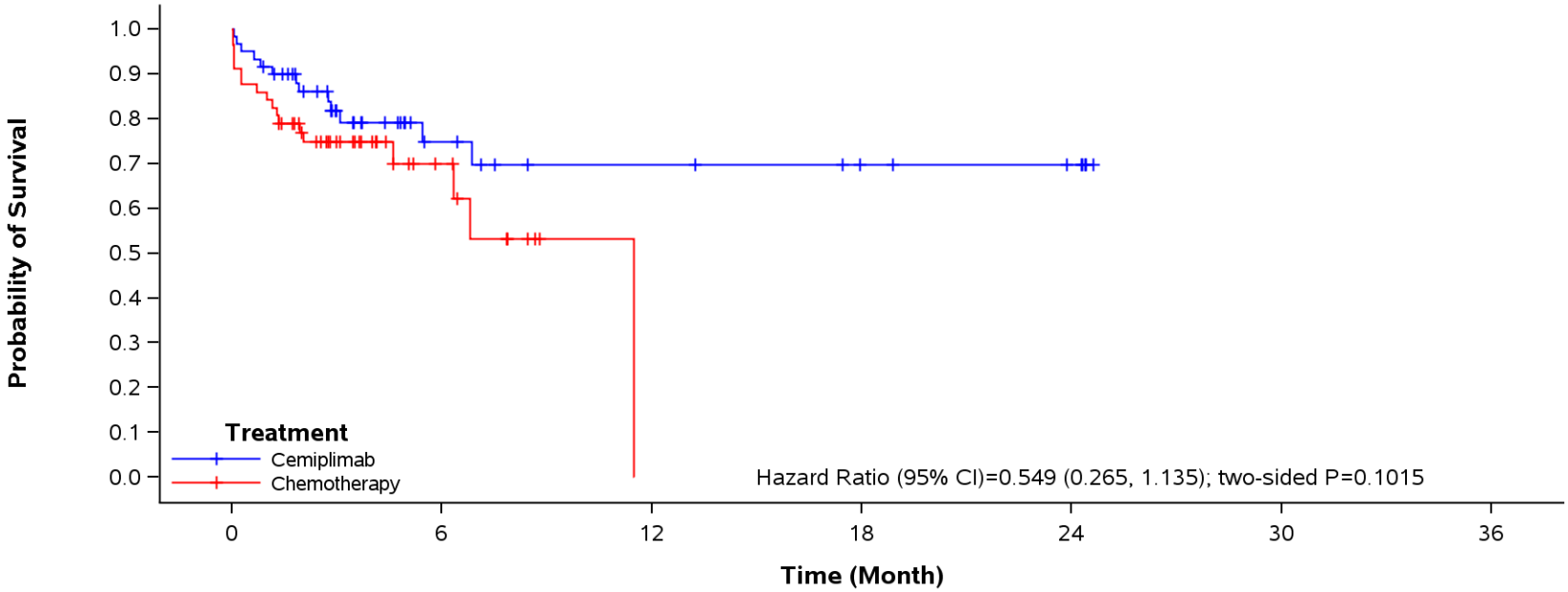

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 13 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Nervous system disorders



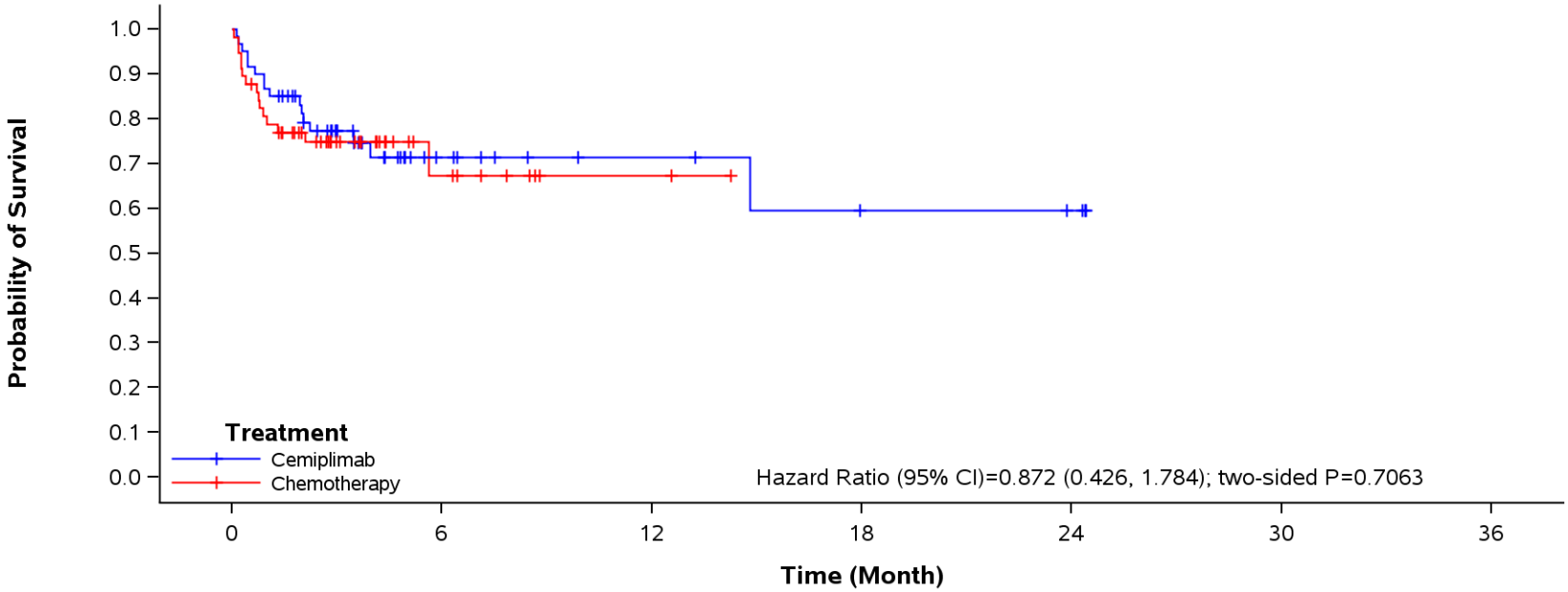

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 16 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 10 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Skin and subcutaneous tissue disorders



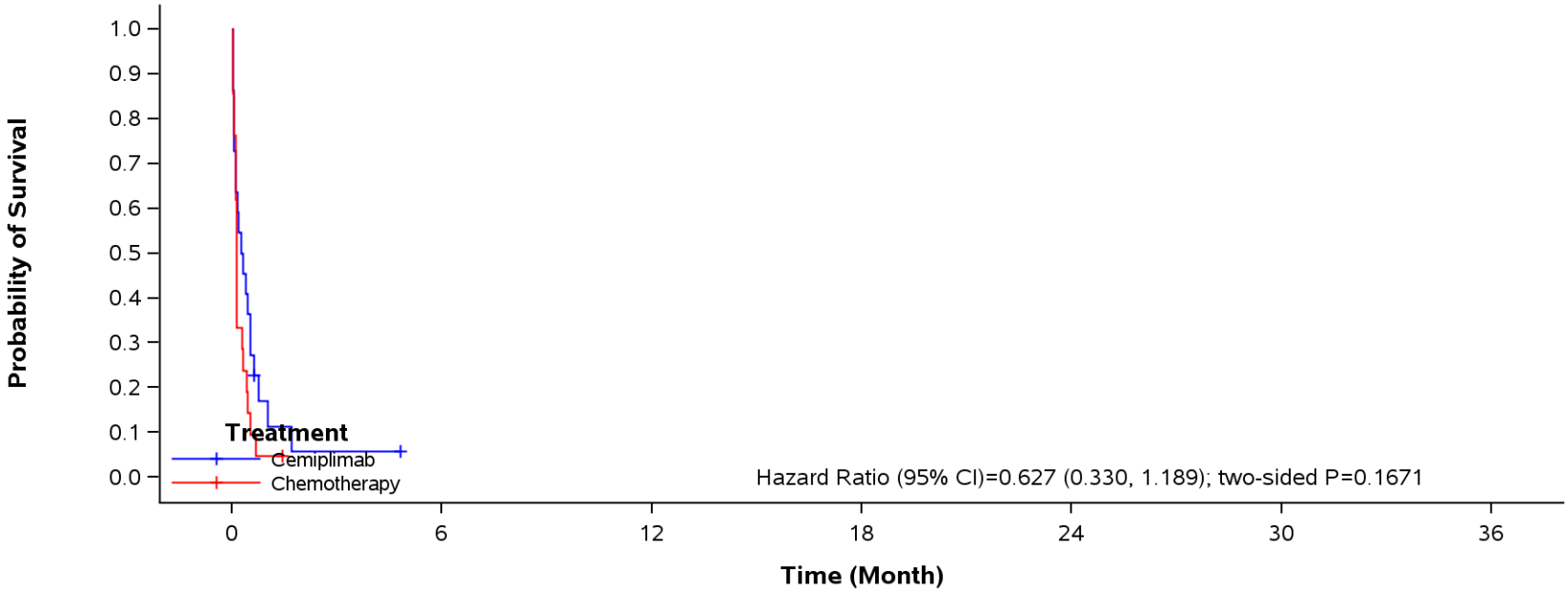

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 7 | 4 | 3 | 0 | 0 |
| Chemotherapy | 57 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Number of patients with any TEAE



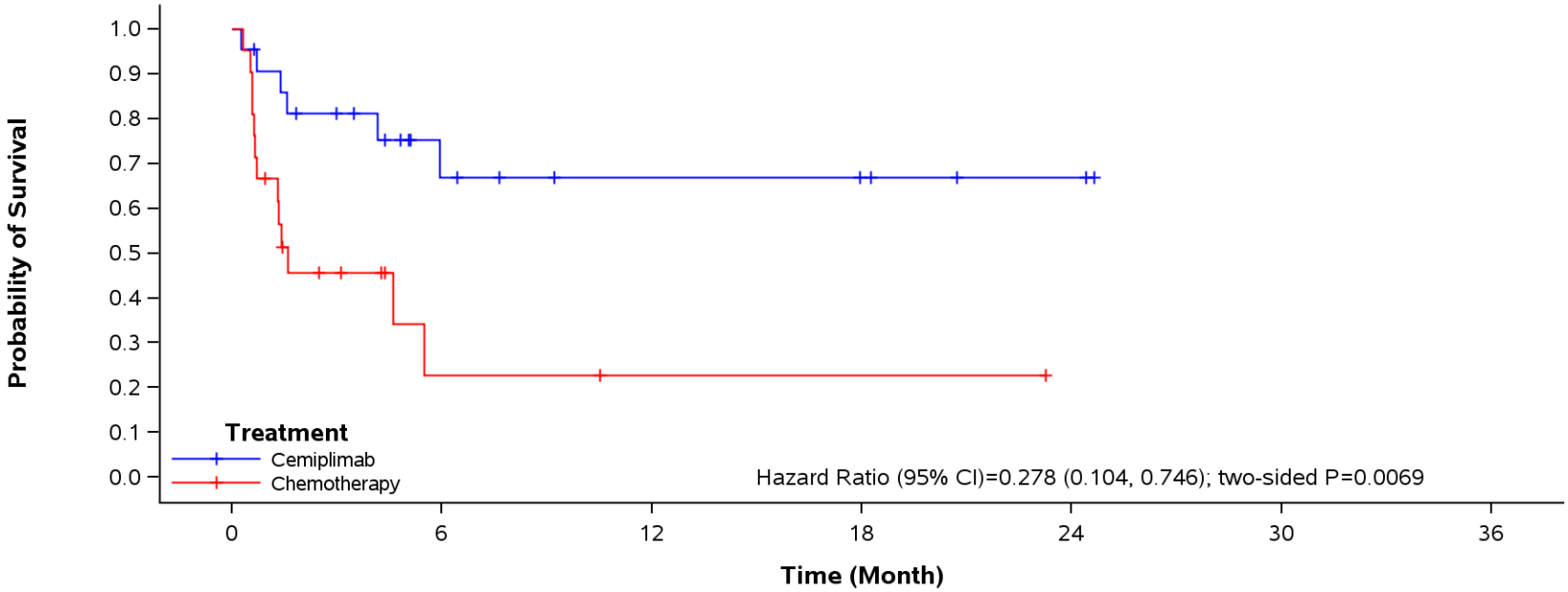

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders



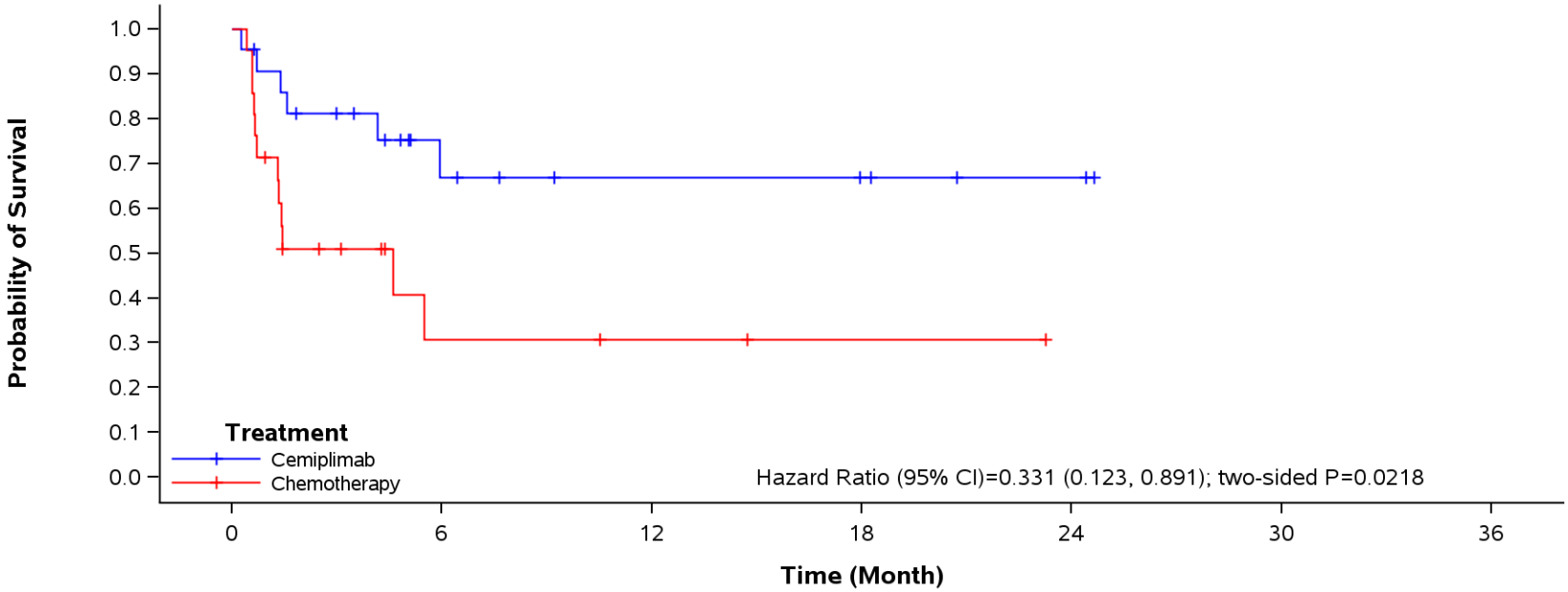

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 5 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Anaemia



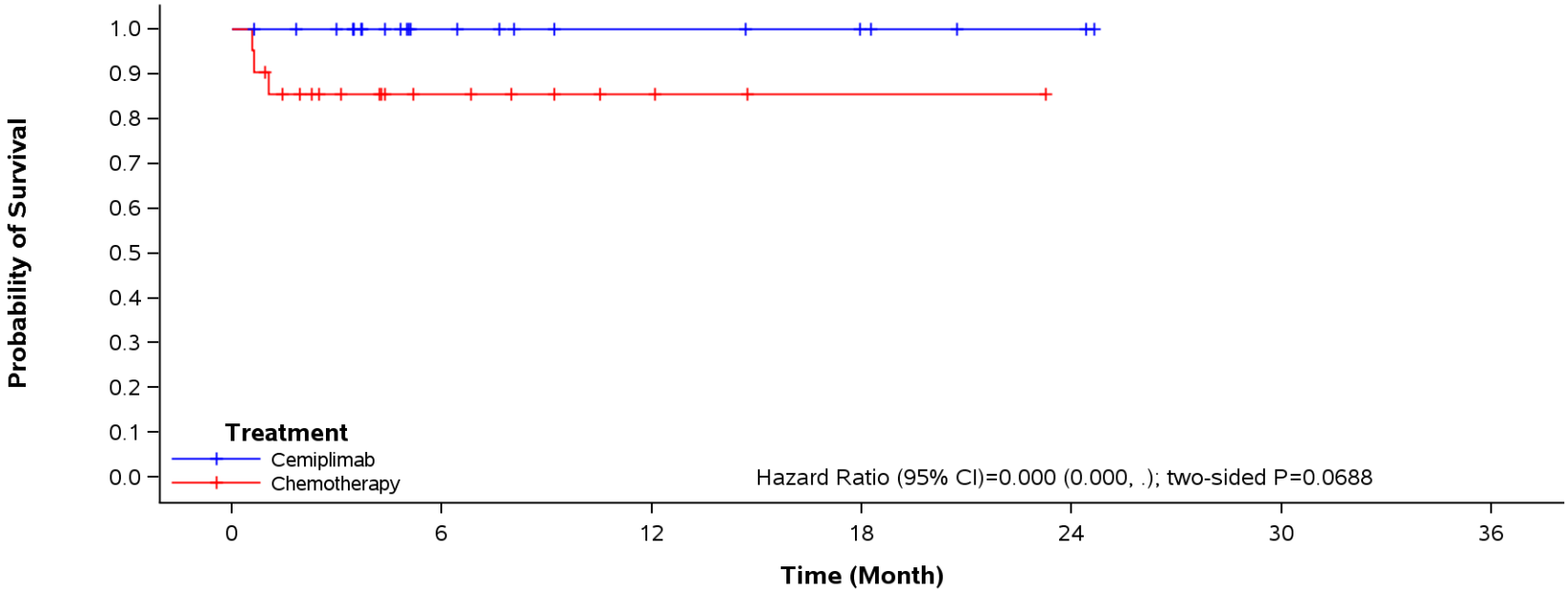

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 5 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 3 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Neutropenia



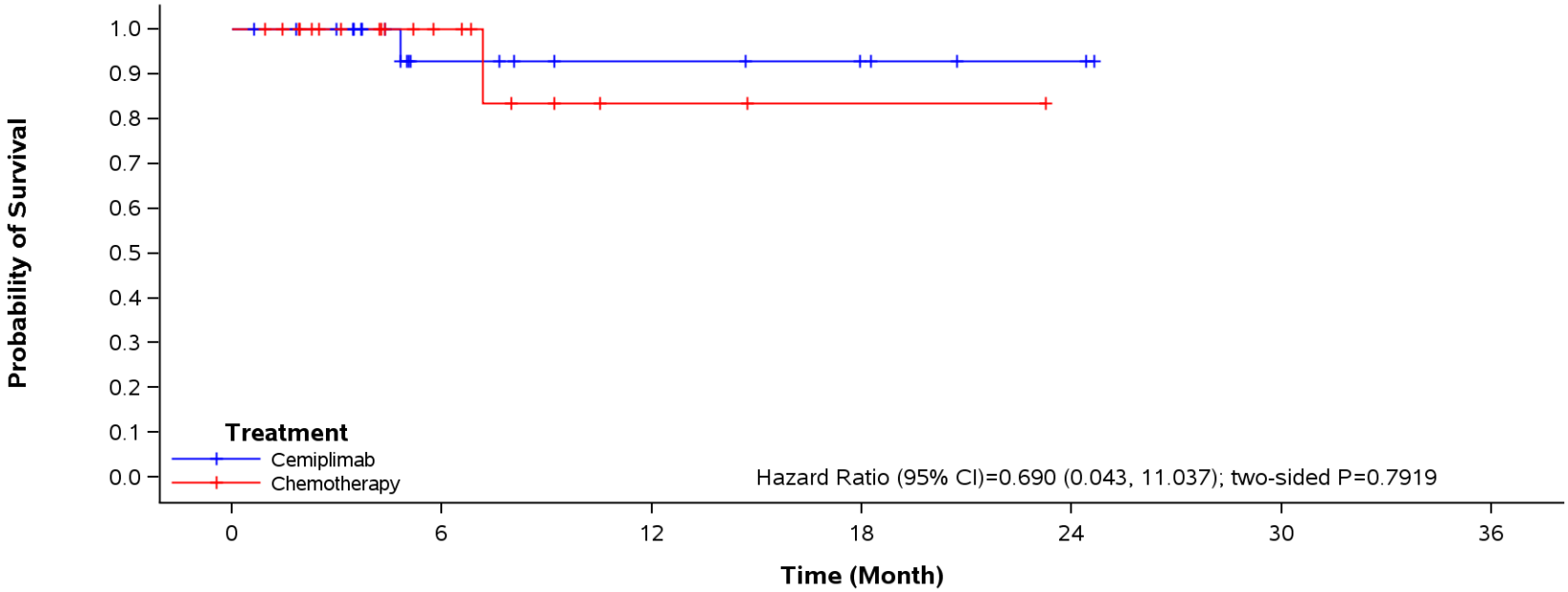

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Endocrine disorders



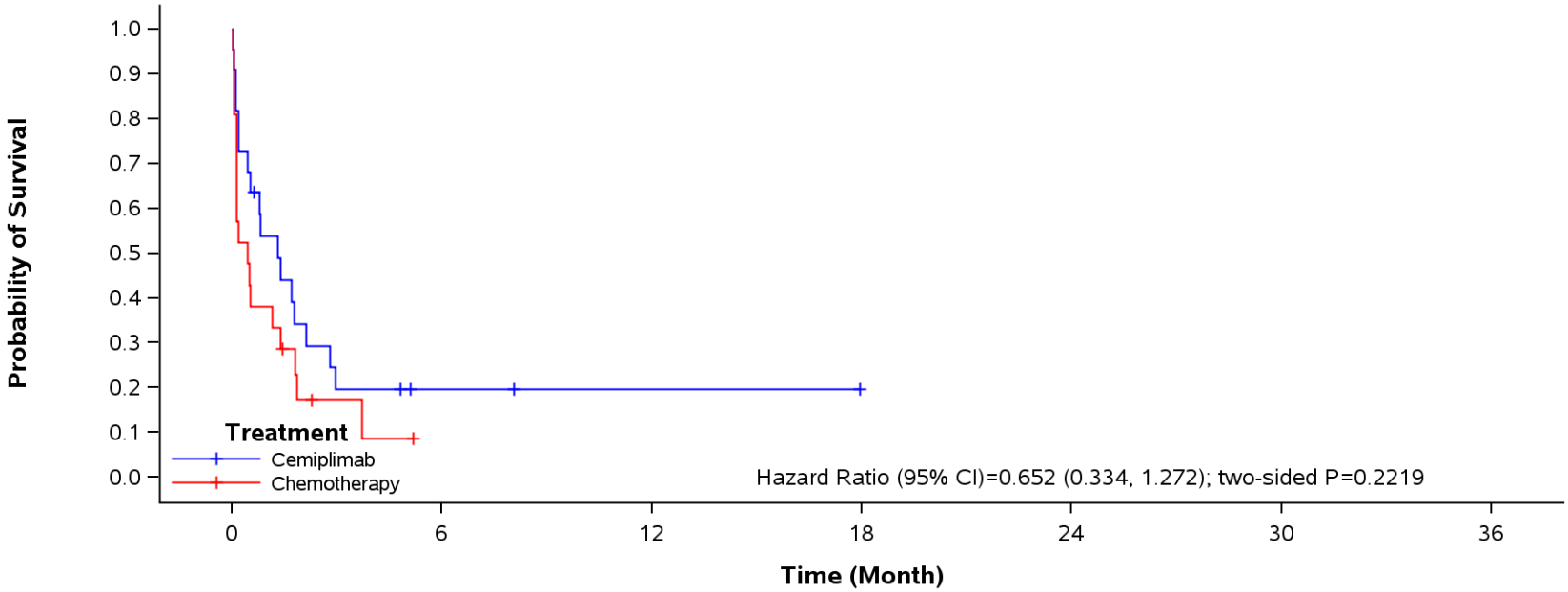

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 9 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders



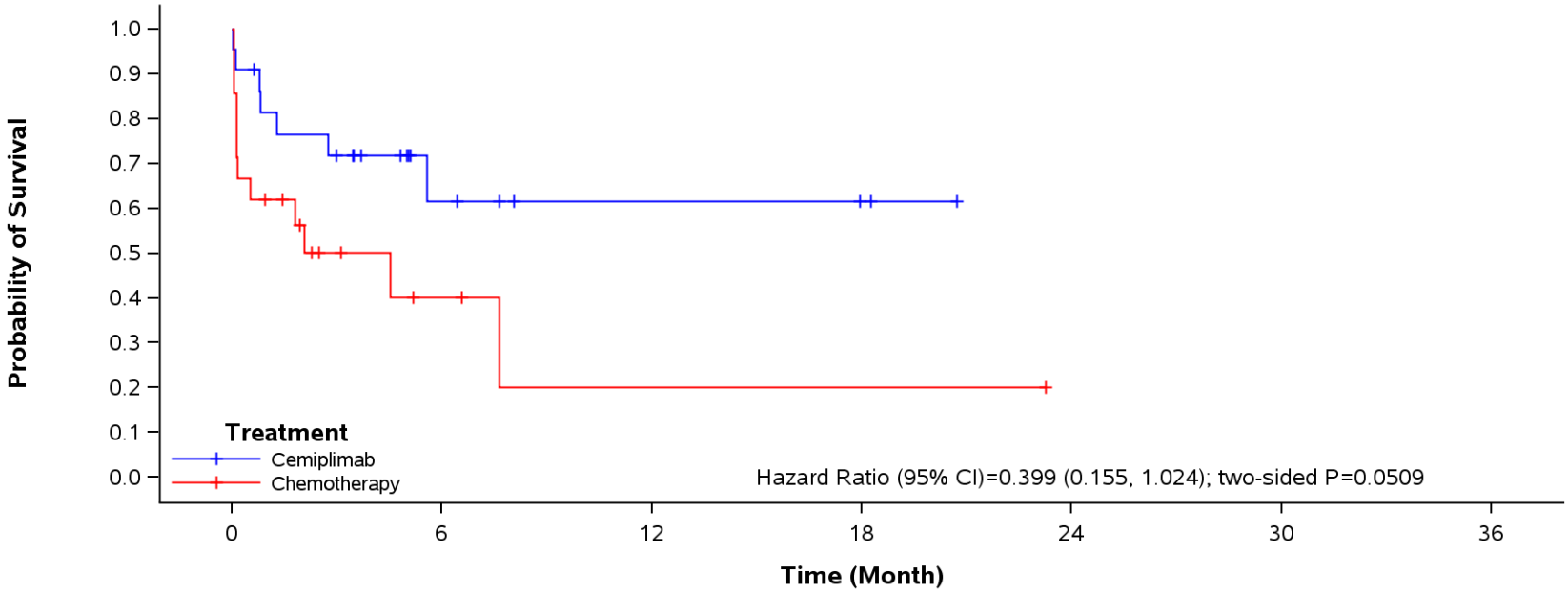

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 2 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders
PT: Nausea



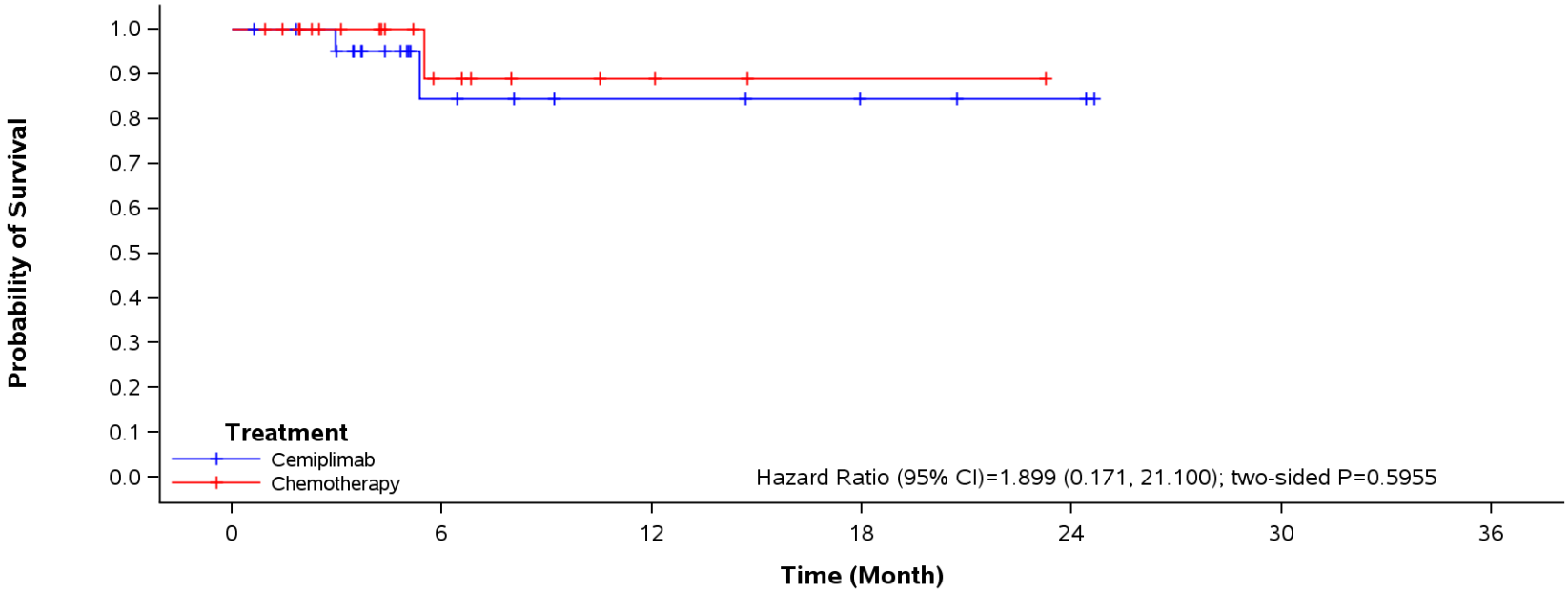

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 6 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 21 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders
PT: Stomatitis



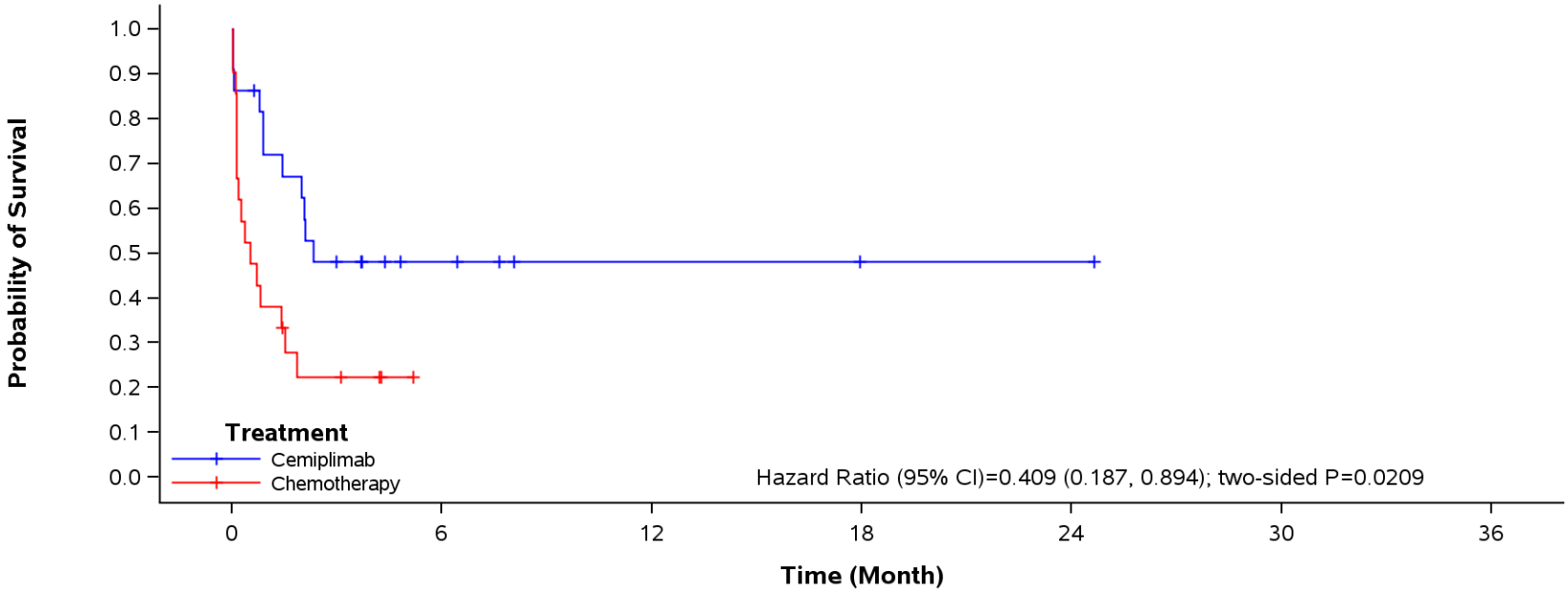

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: General disorders and administration site conditions



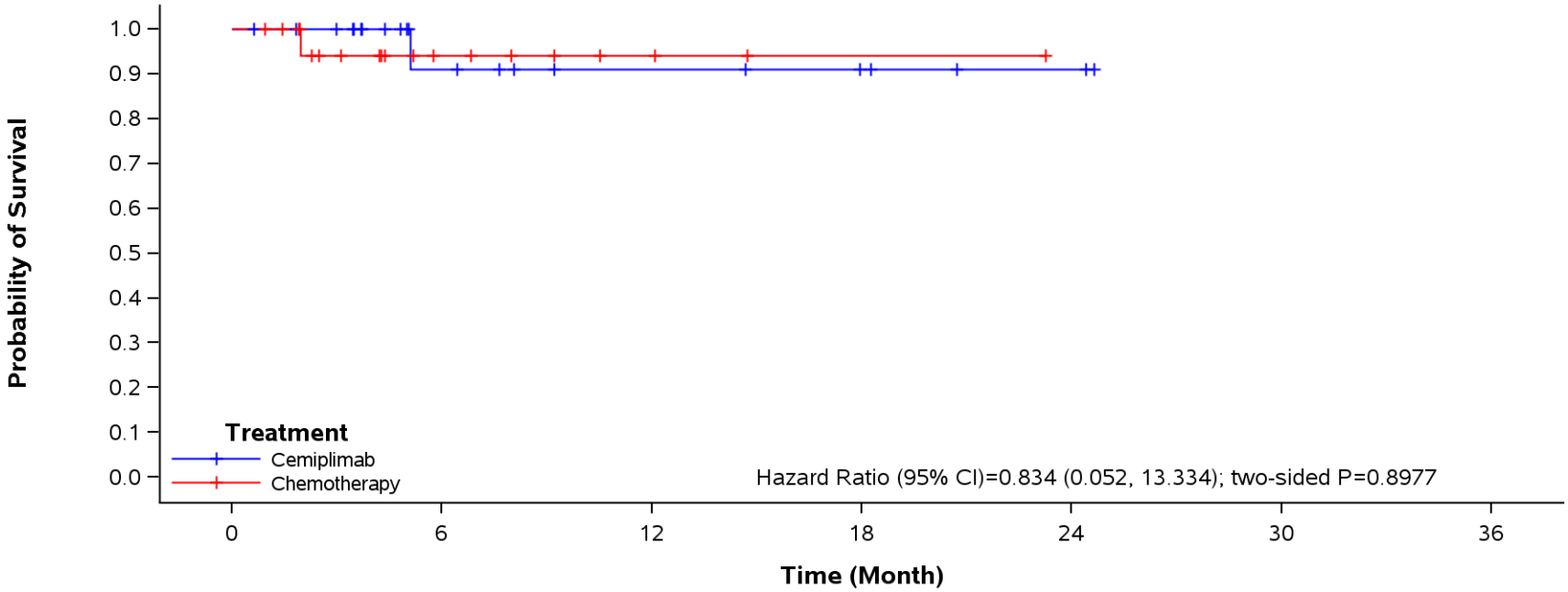

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: General disorders and administration site conditions
PT: Asthenia



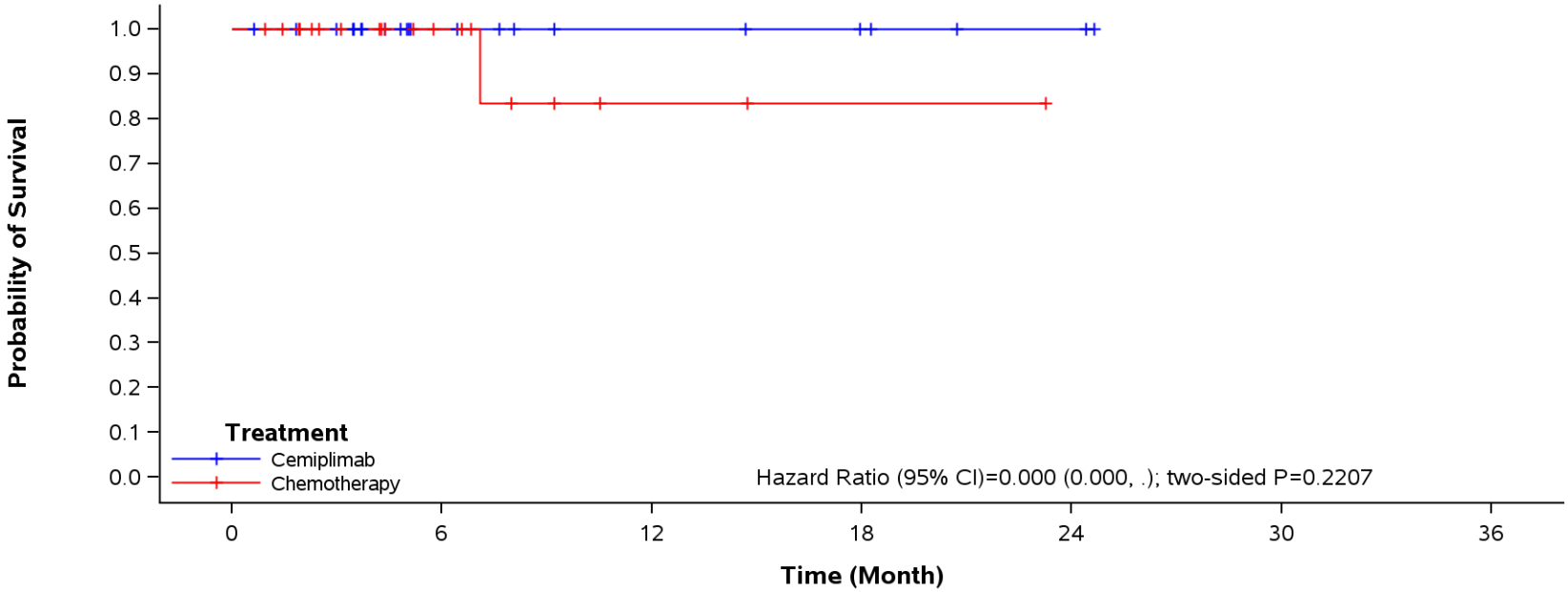

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



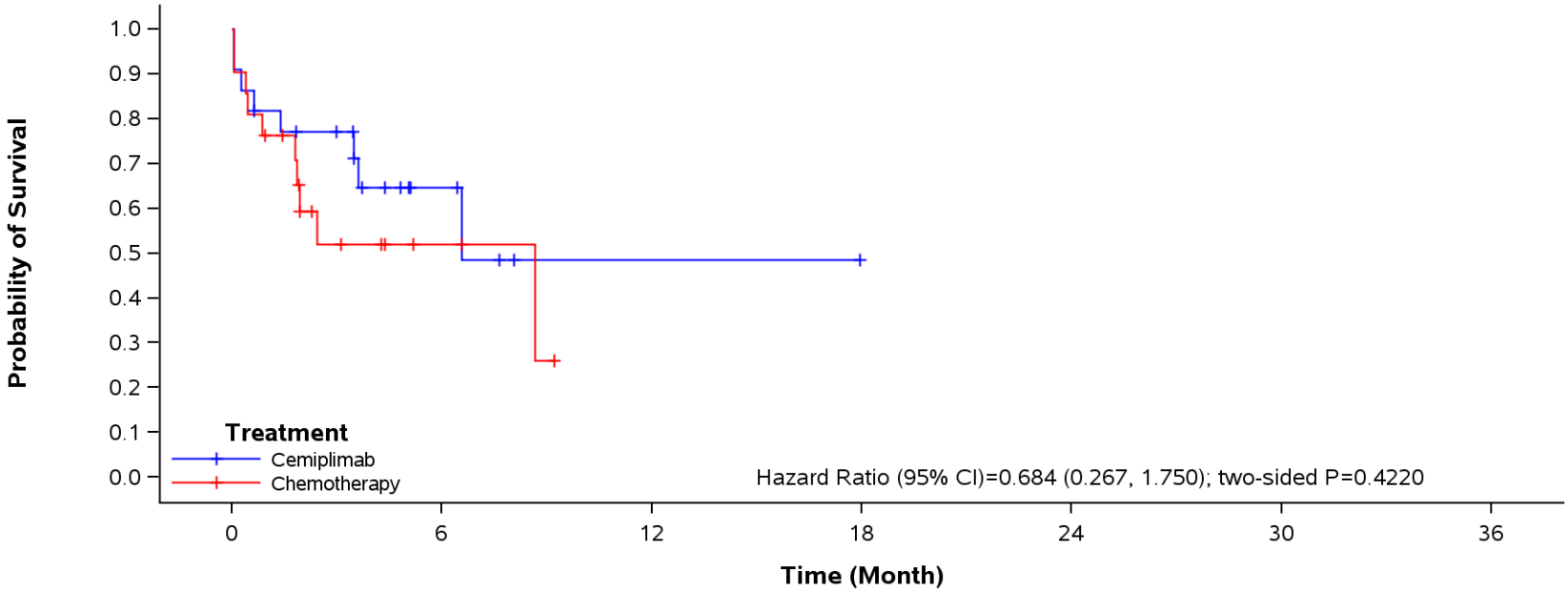

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Nervous system disorders



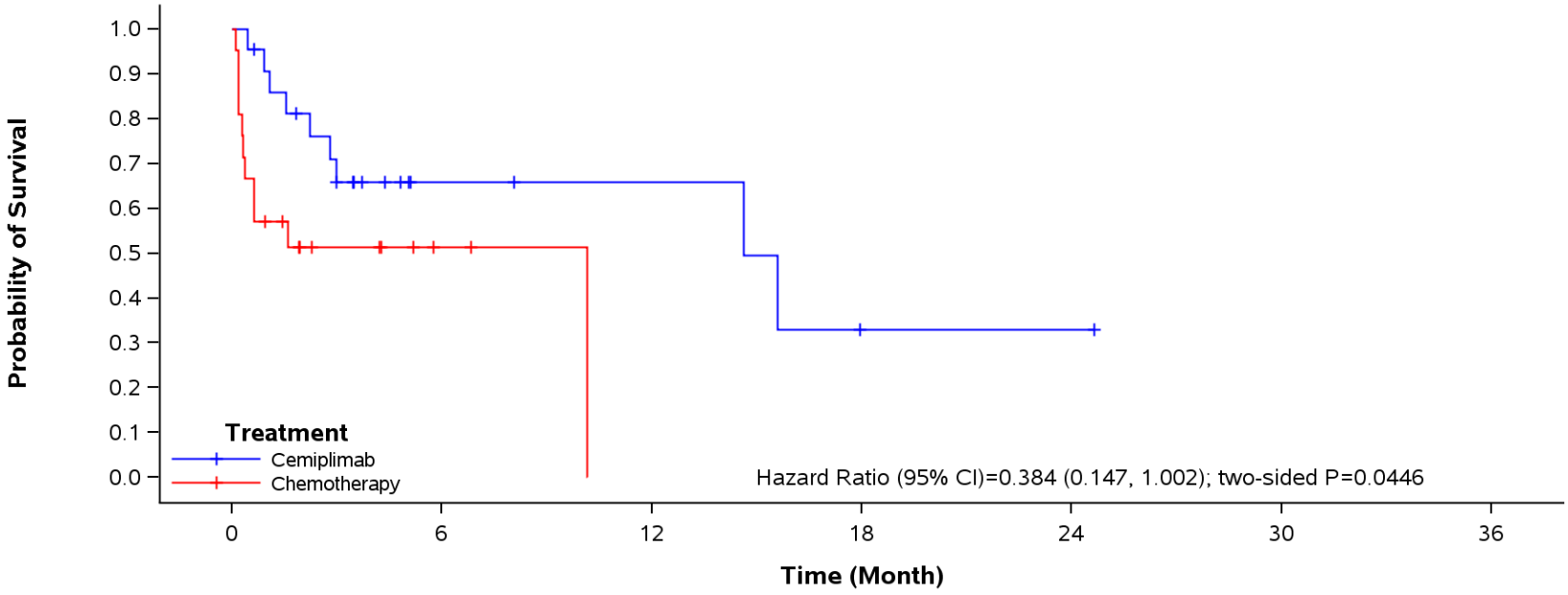

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 21 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Skin and subcutaneous tissue disorders



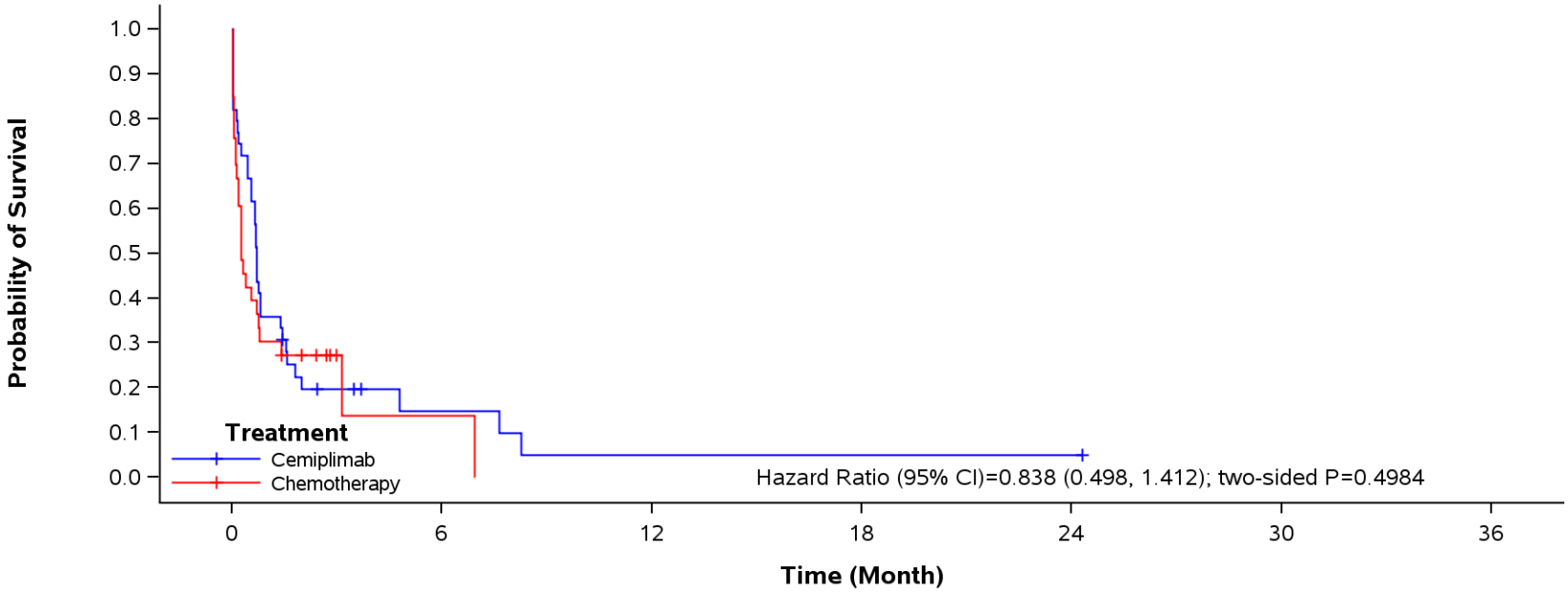

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Number of patients with any TEAE



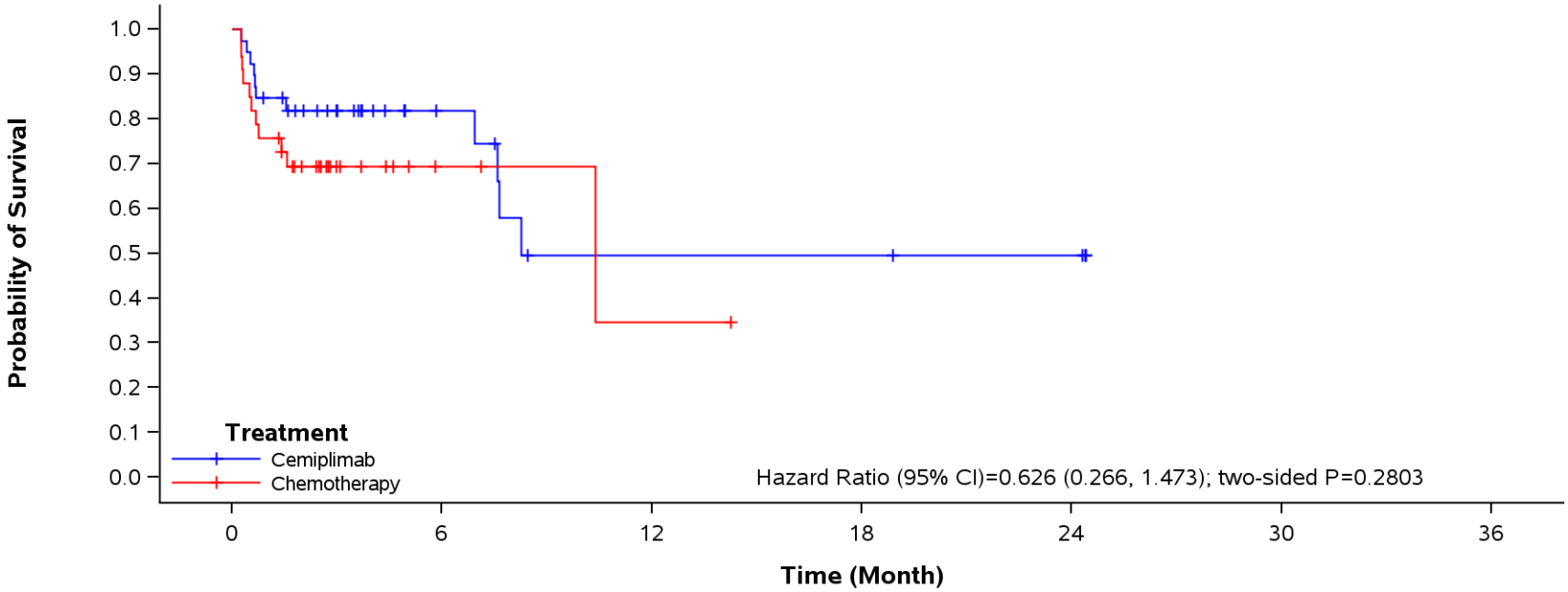

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 3 | 1 | 1 | 1 | 0 | 0 |
| Chemotherapy | 33 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders



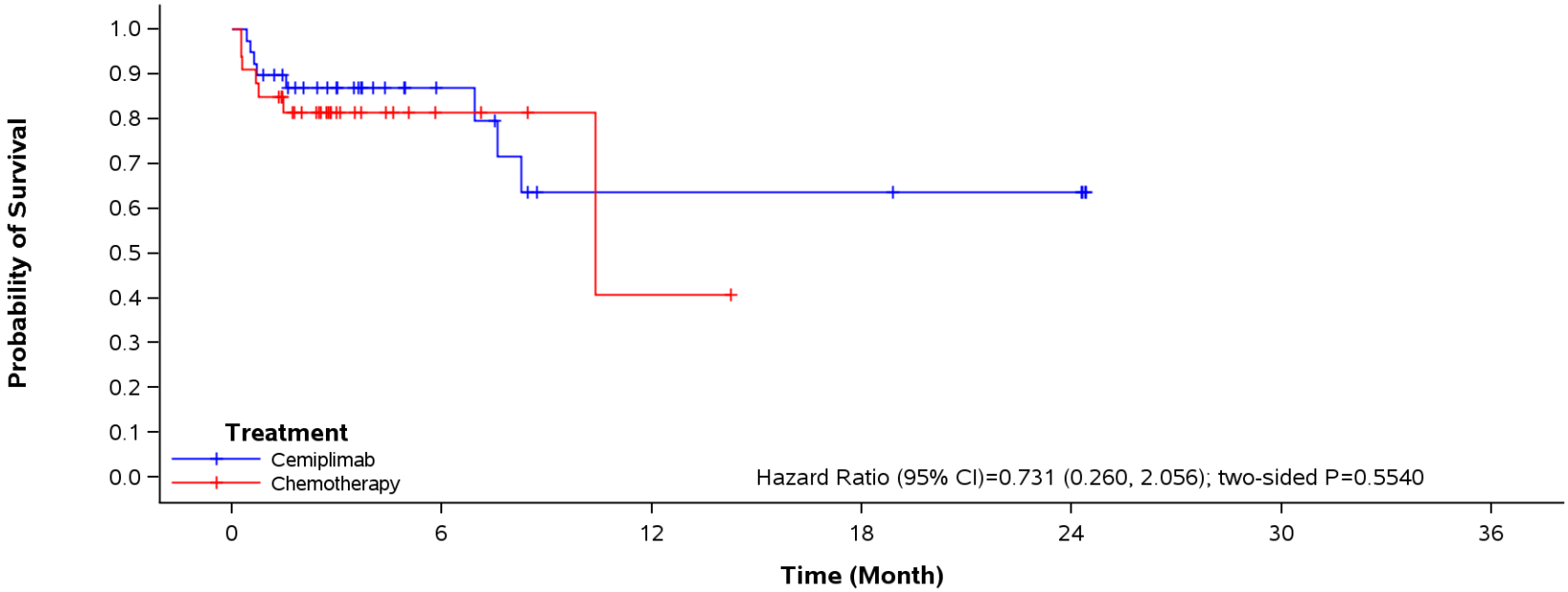

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 11 | 5 | 5 | 4 | 0 | 0 |
| Chemotherapy | 33 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Anaemia



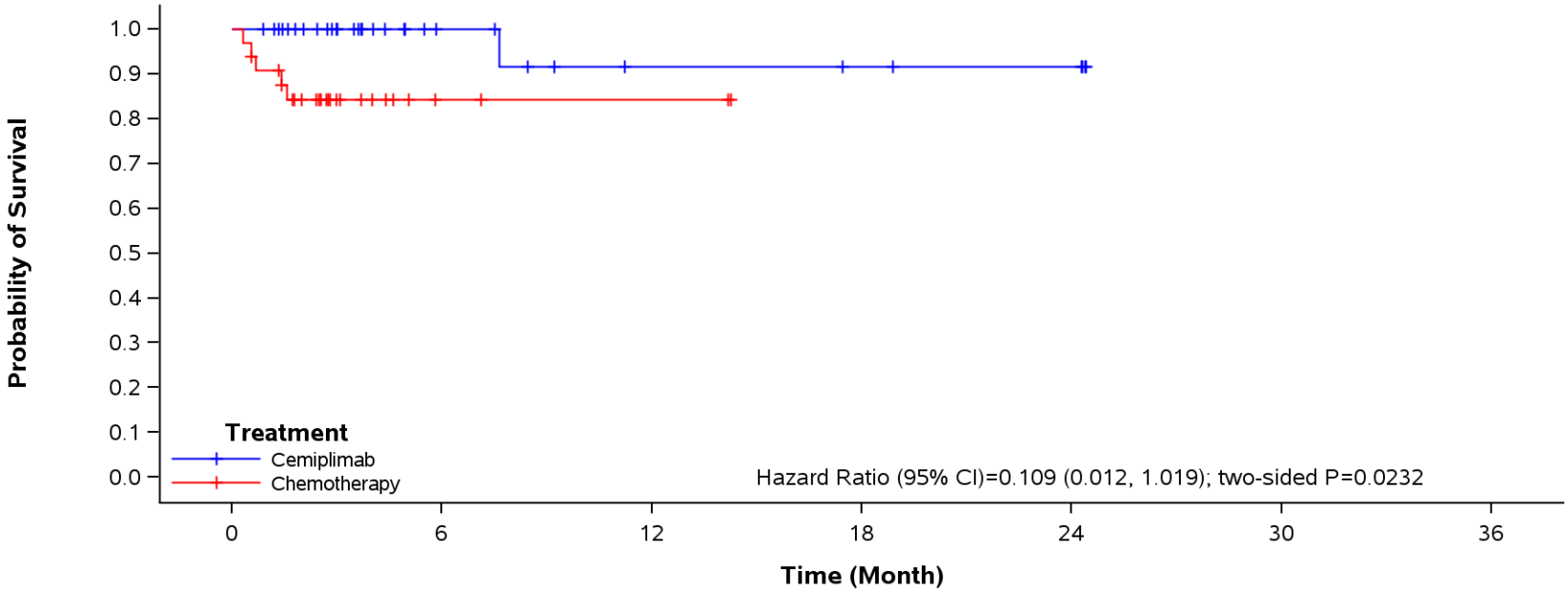

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 6 | 6 | 5 | 0 | 0 |
| Chemotherapy | 33 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Neutropenia



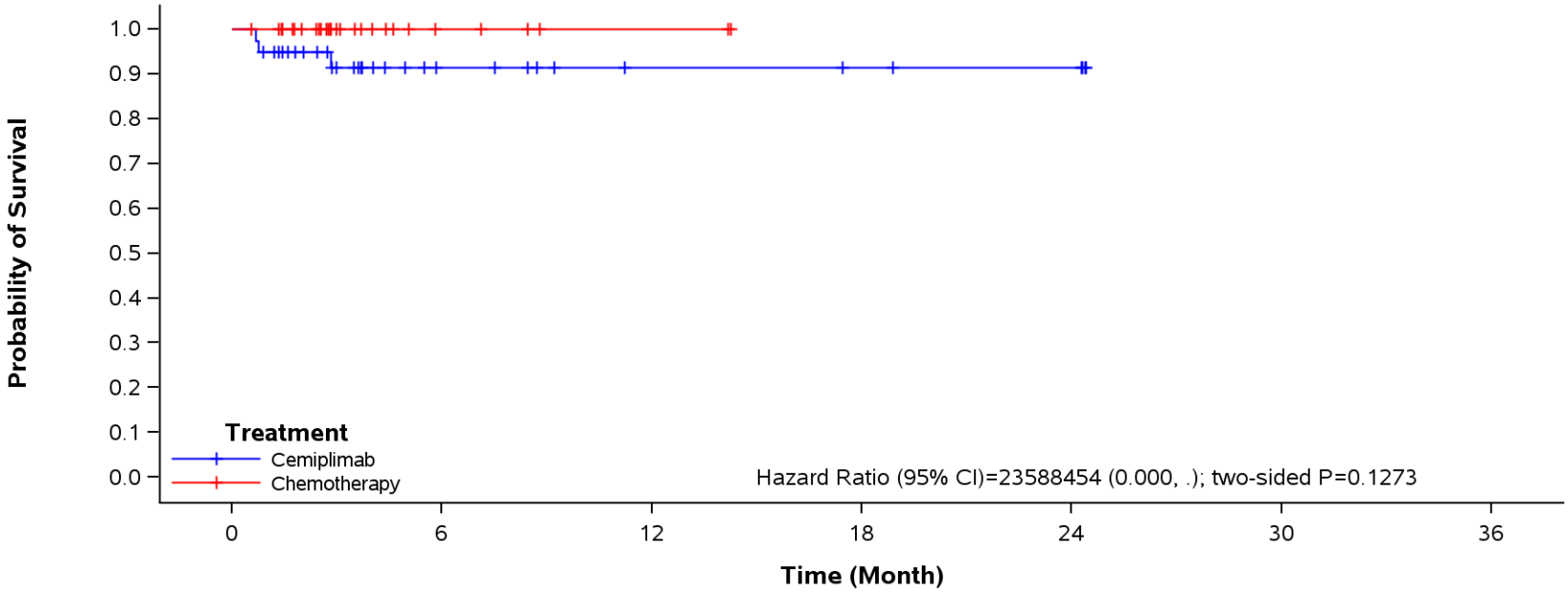

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 3 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Endocrine disorders



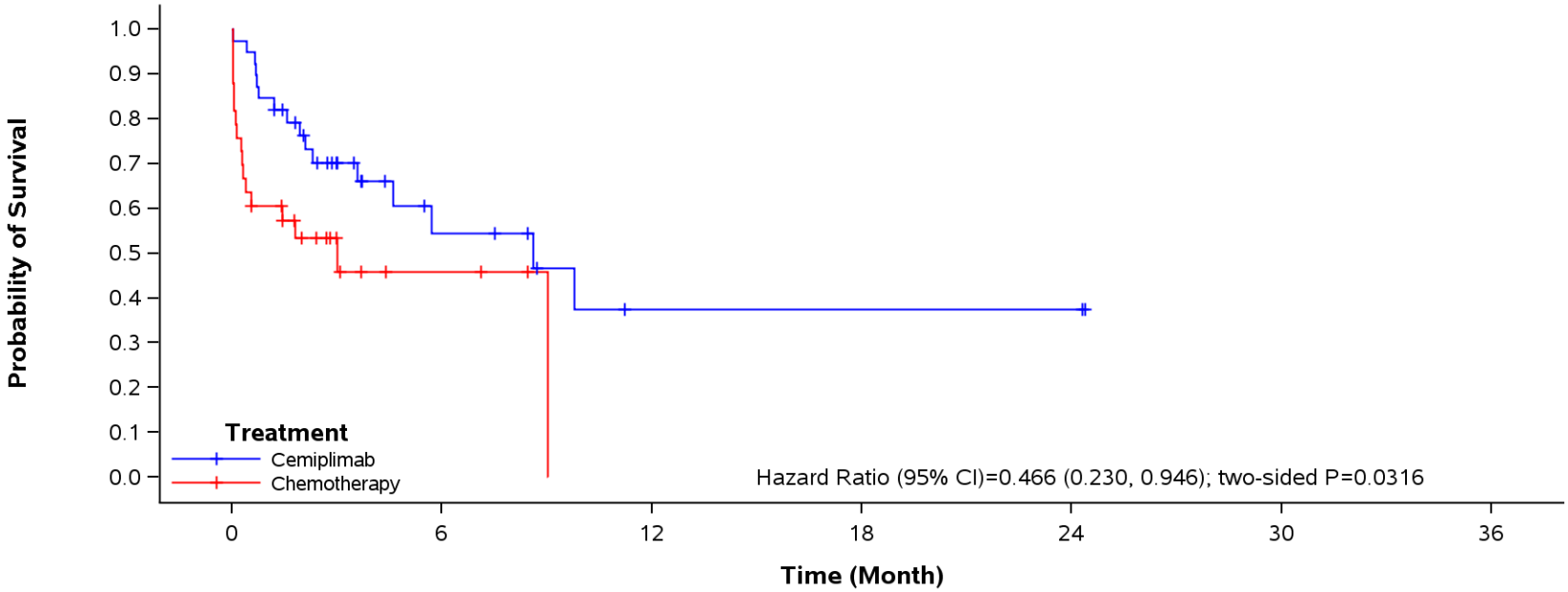

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders



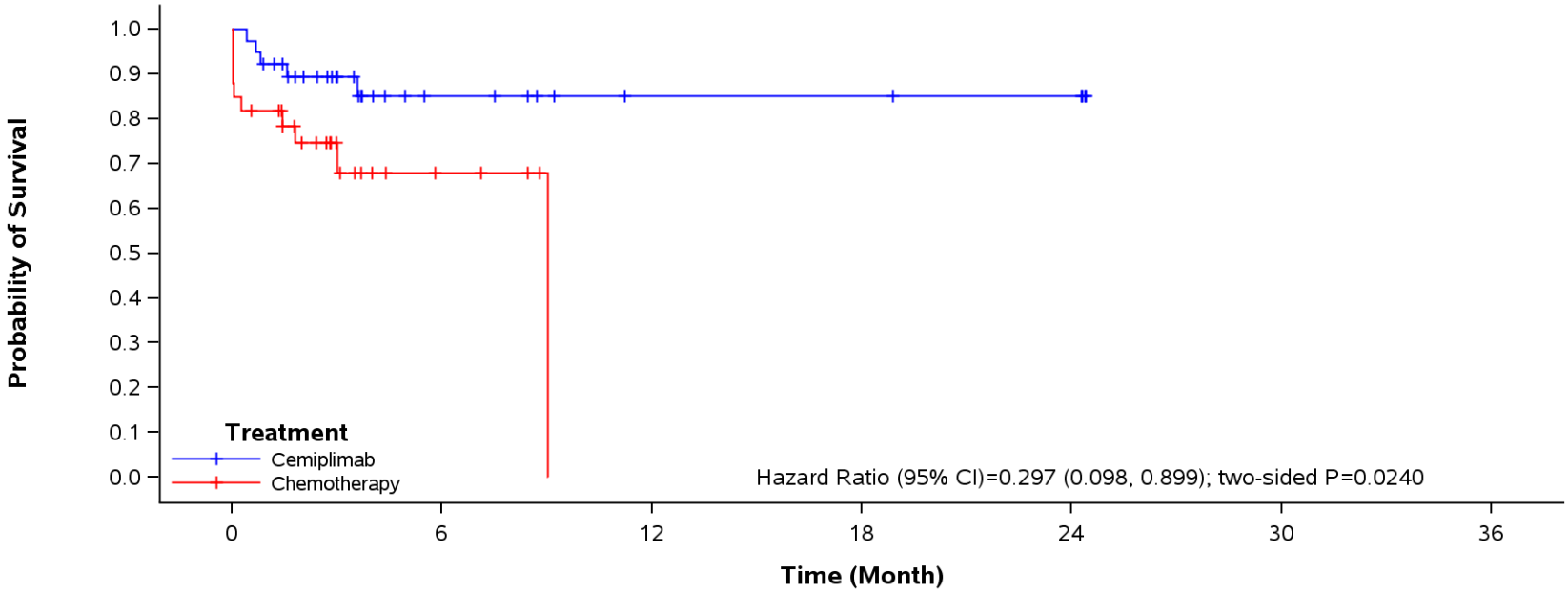

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 3 | 3 | 3 | 0 | 0 |
| Chemotherapy | 33 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders
PT: Nausea



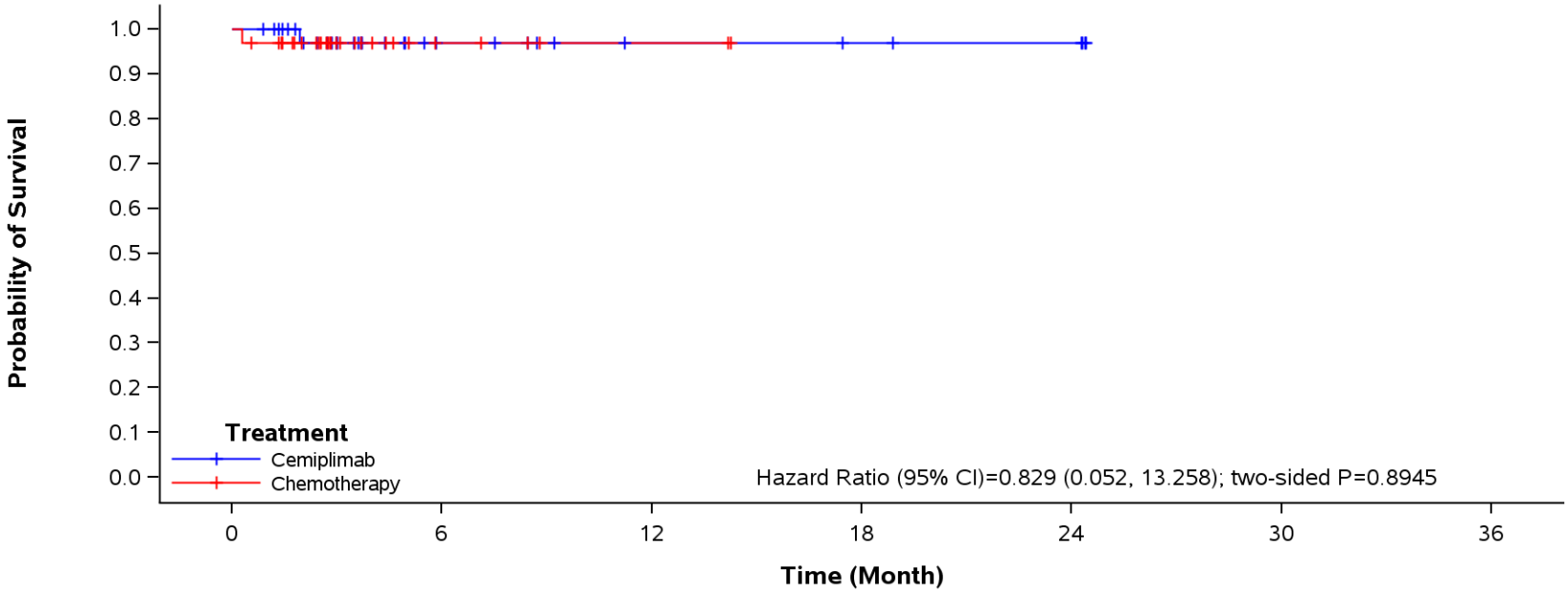

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders
PT: Stomatitis



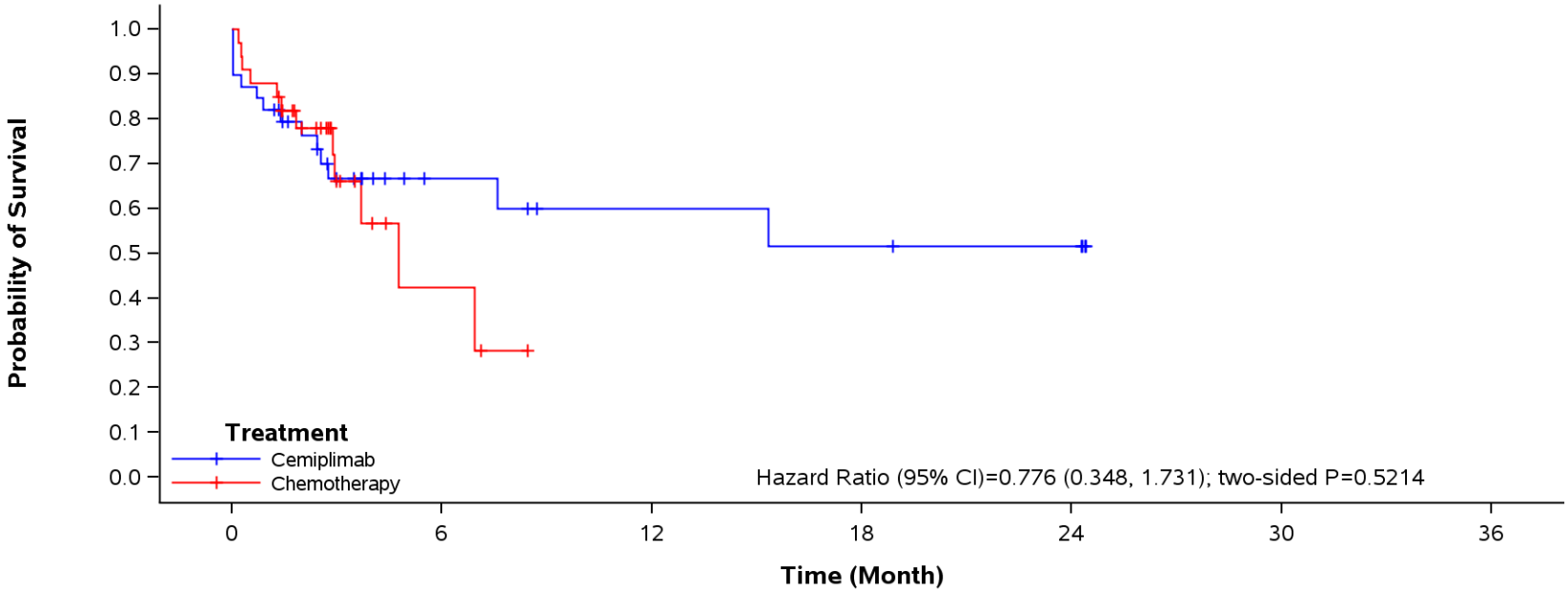

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: General disorders and administration site conditions



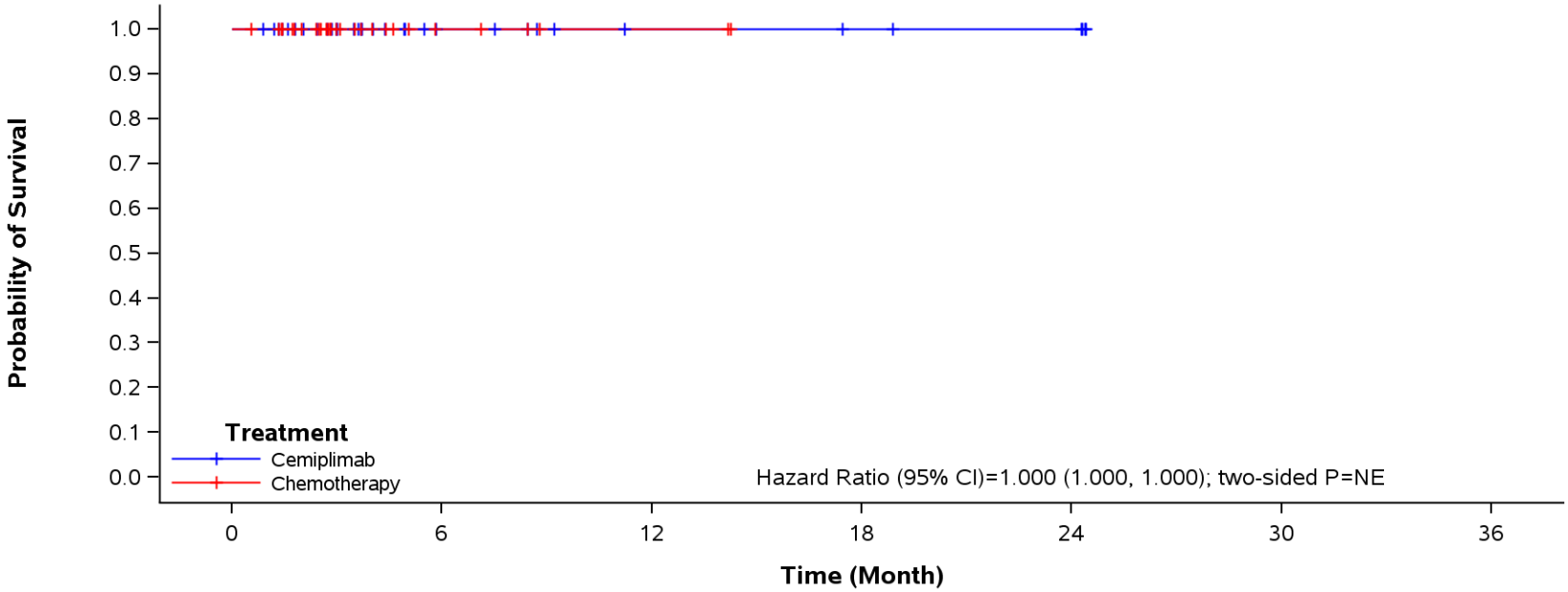

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 7 | 6 | 5 | 0 | 0 |
| Chemotherapy | 33 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: General disorders and administration site conditions
PT: Asthenia



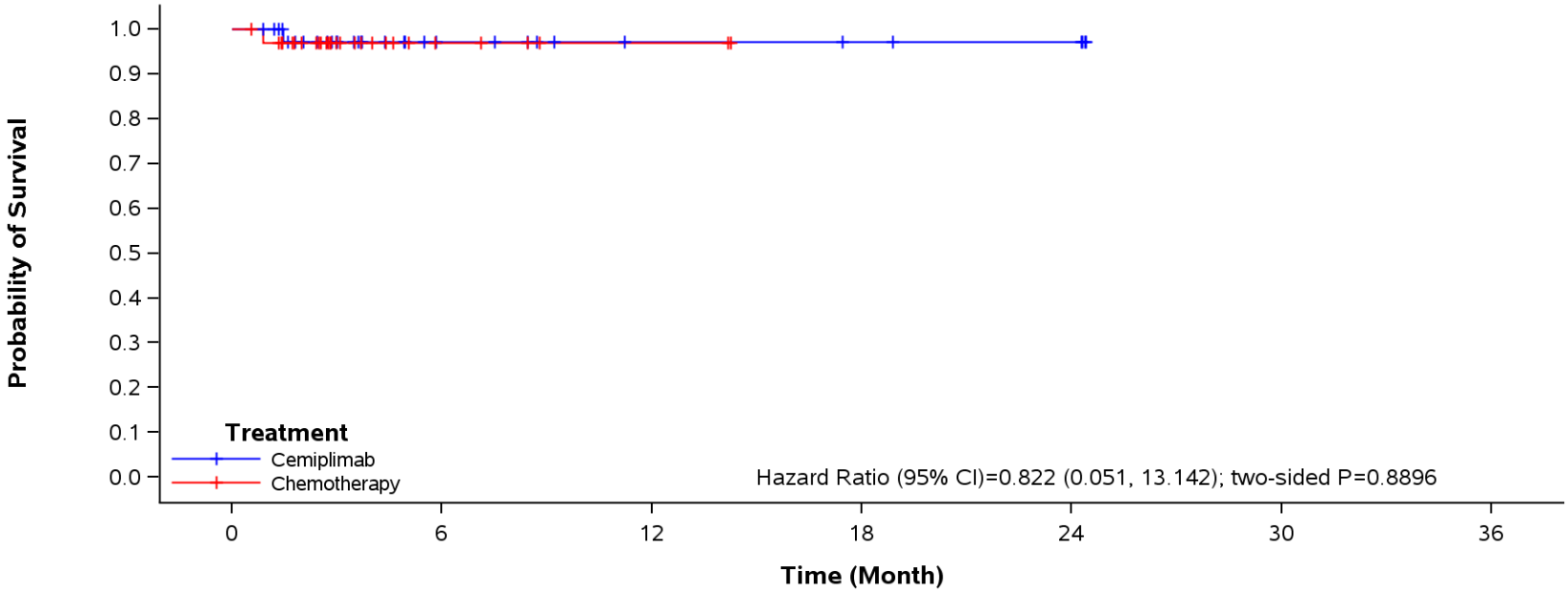

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



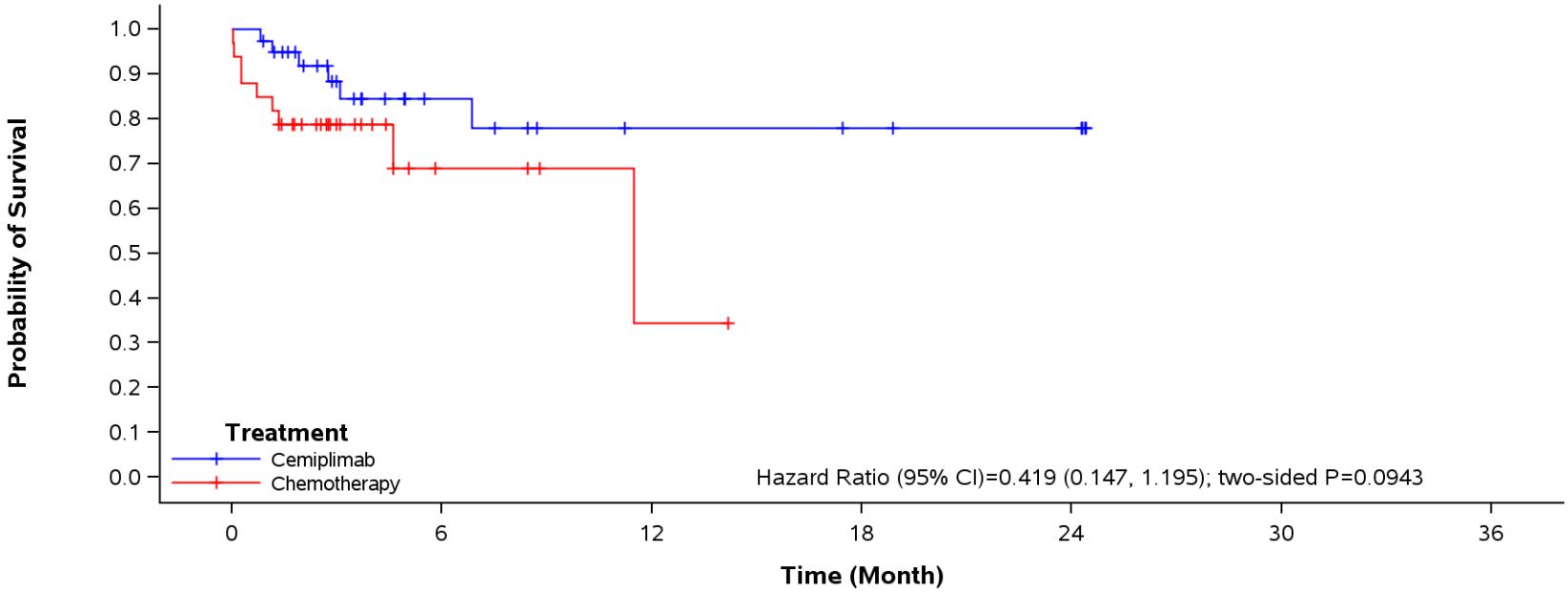

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Nervous system disorders



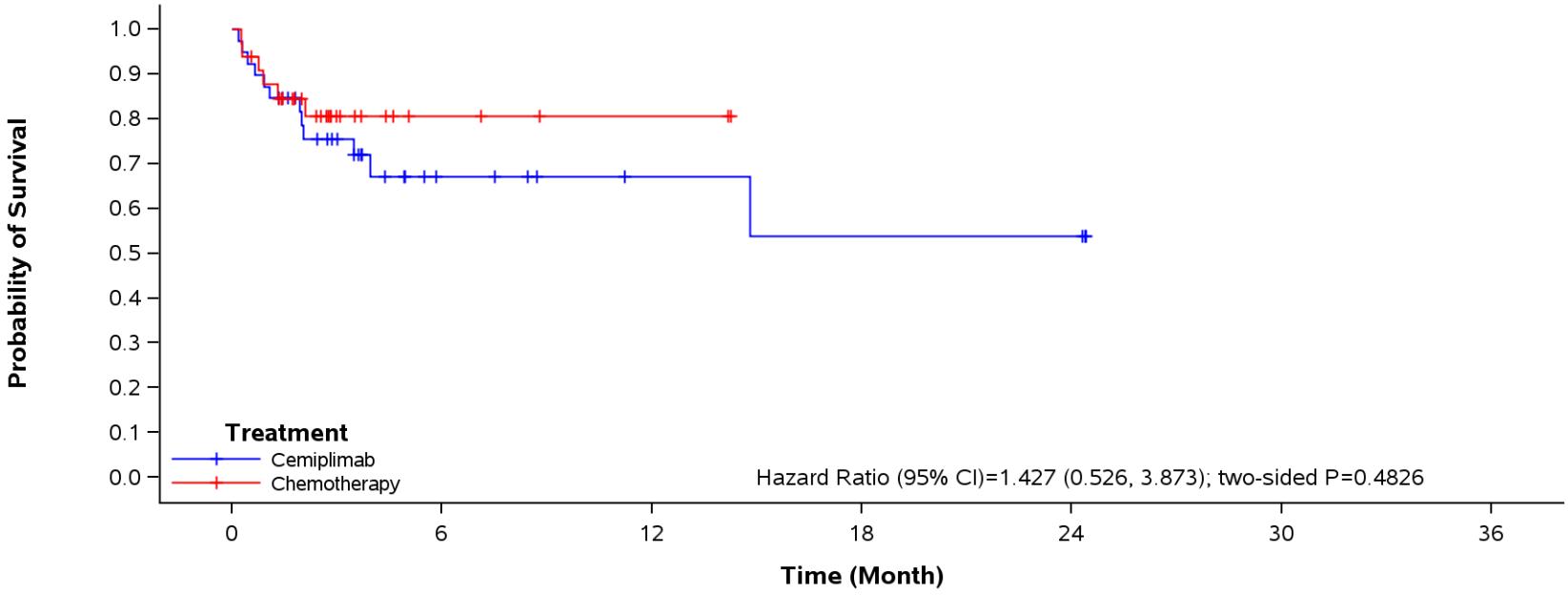

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Skin and subcutaneous tissue disorders



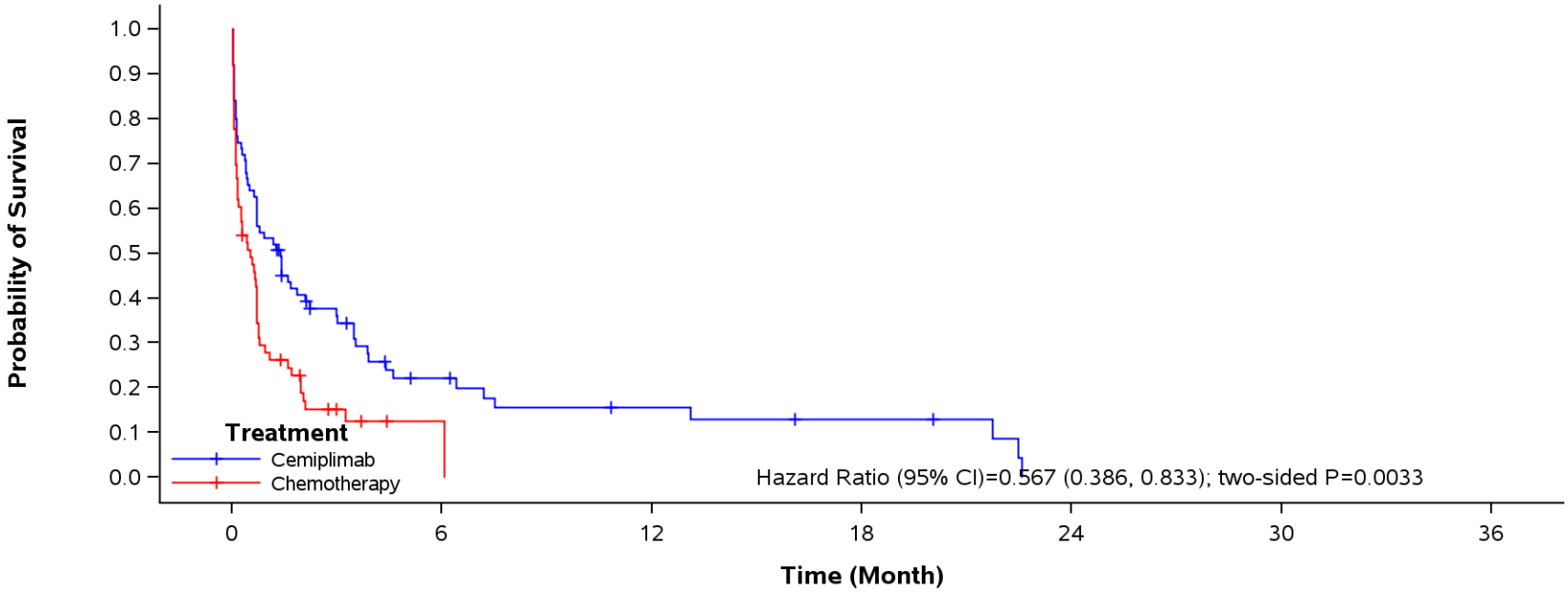

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 9 | 5 | 4 | 4 | 0 | 0 |
| Chemotherapy | 33 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Number of patients with any TEAE



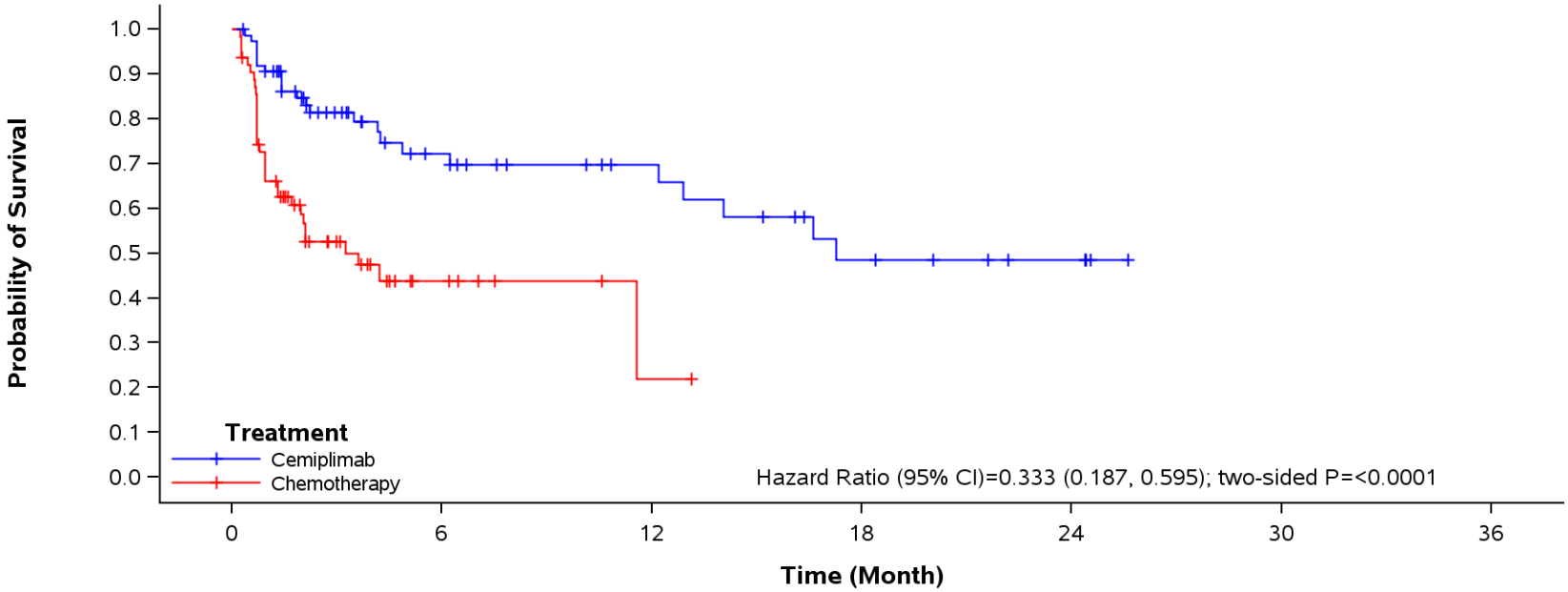

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 11 | 6 | 4 | 0 | 0 | 0 |
| Chemotherapy | 63 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders



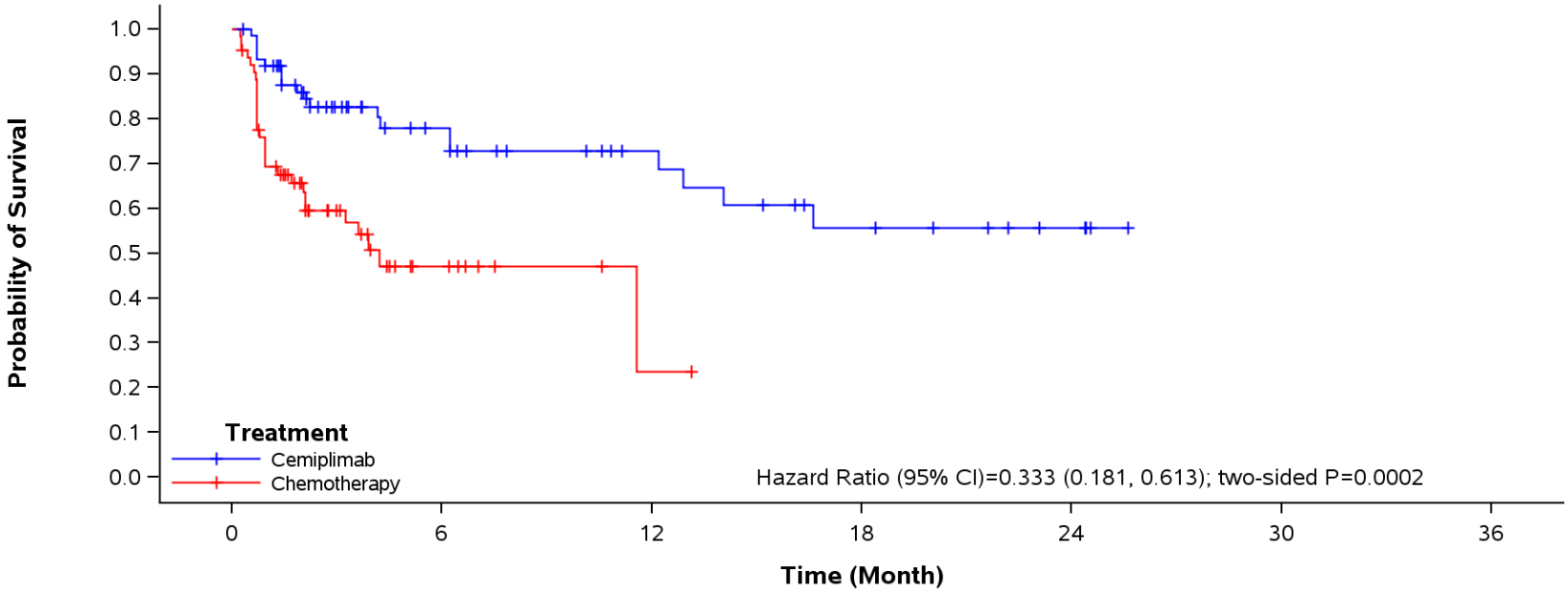

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 28 | 18 | 10 | 6 | 0 | 0 |
| Chemotherapy | 63 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Anaemia



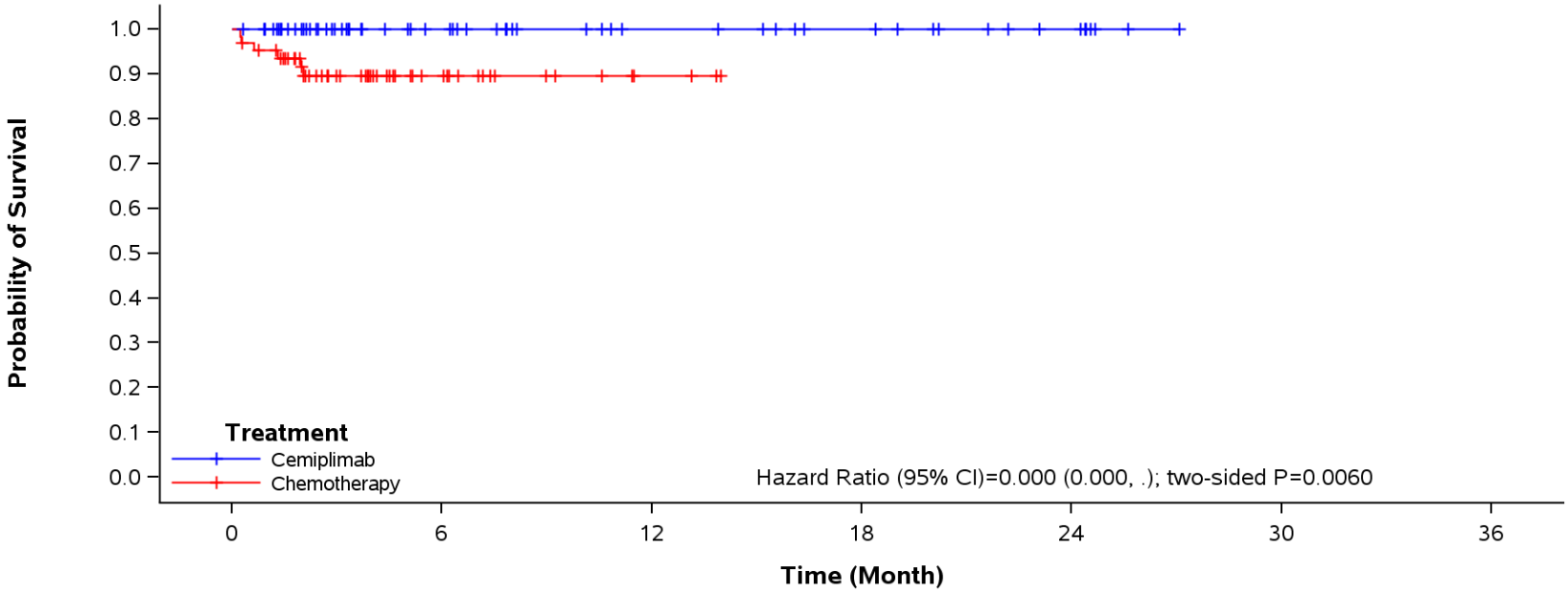

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 30 | 18 | 11 | 6 | 0 | 0 |
| Chemotherapy | 63 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Neutropenia



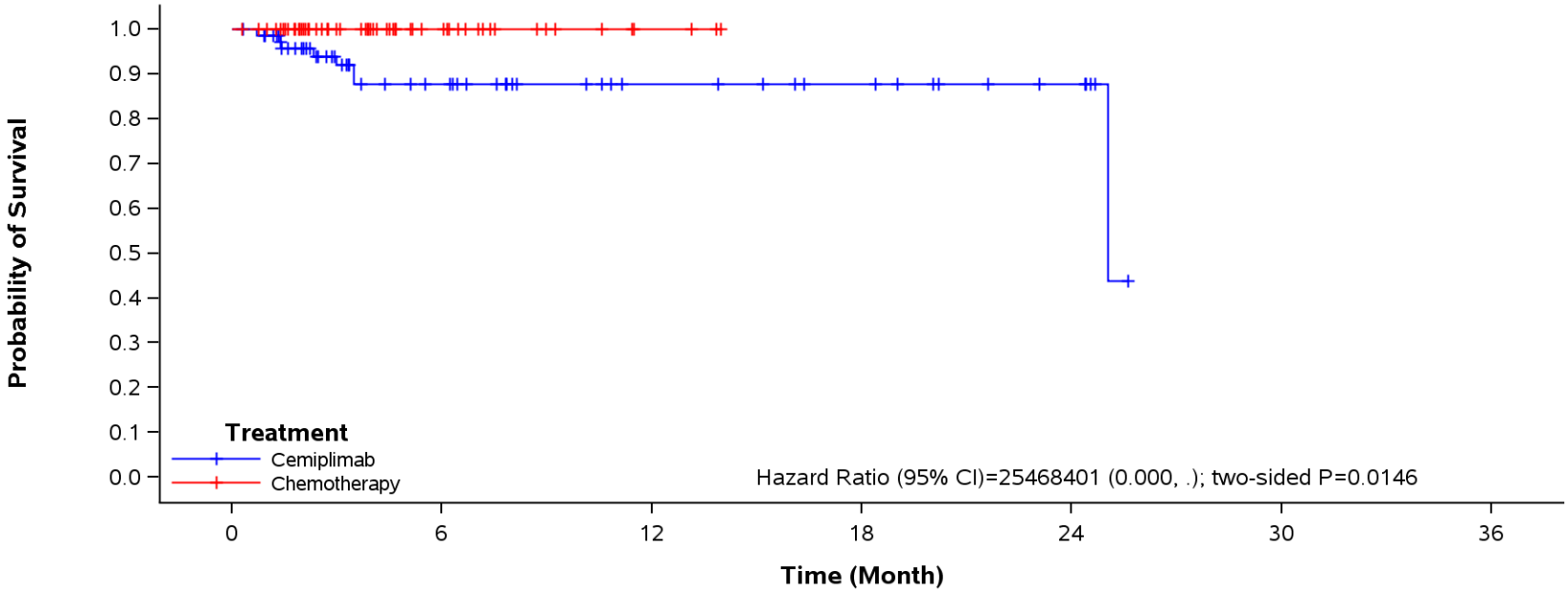

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Endocrine disorders



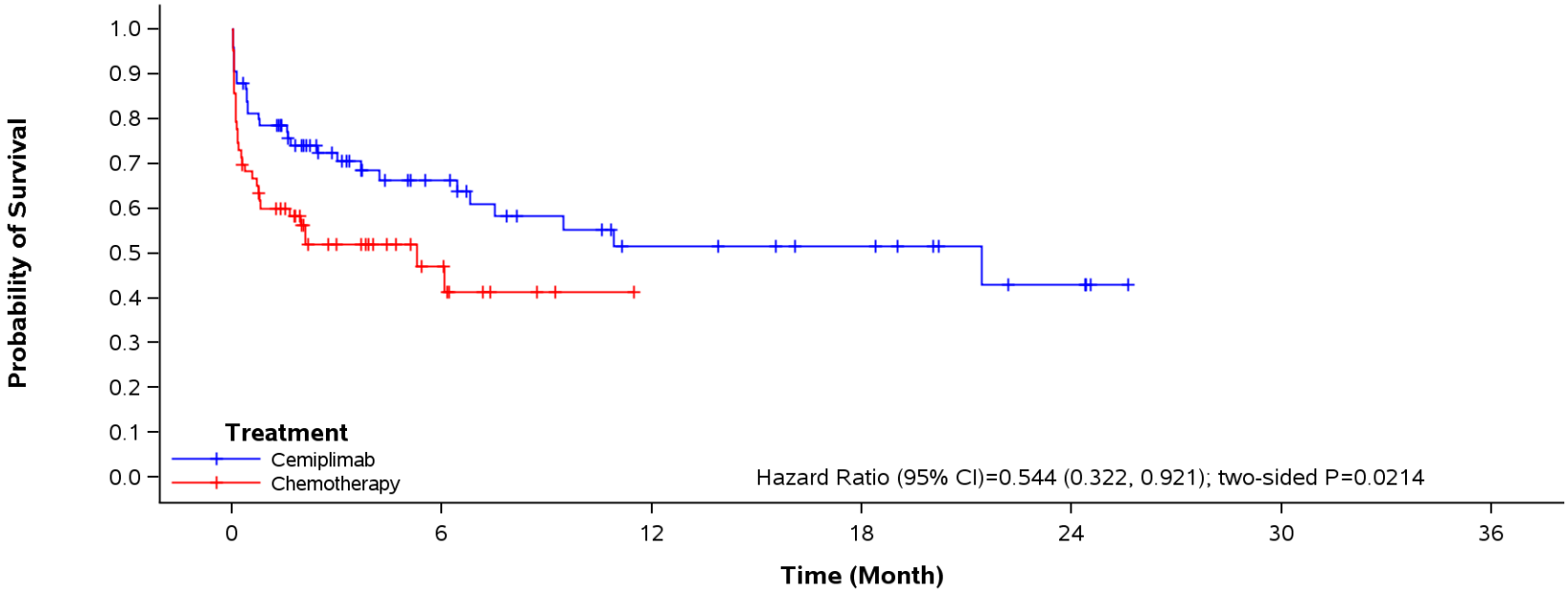

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 33 | 18 | 14 | 8 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders



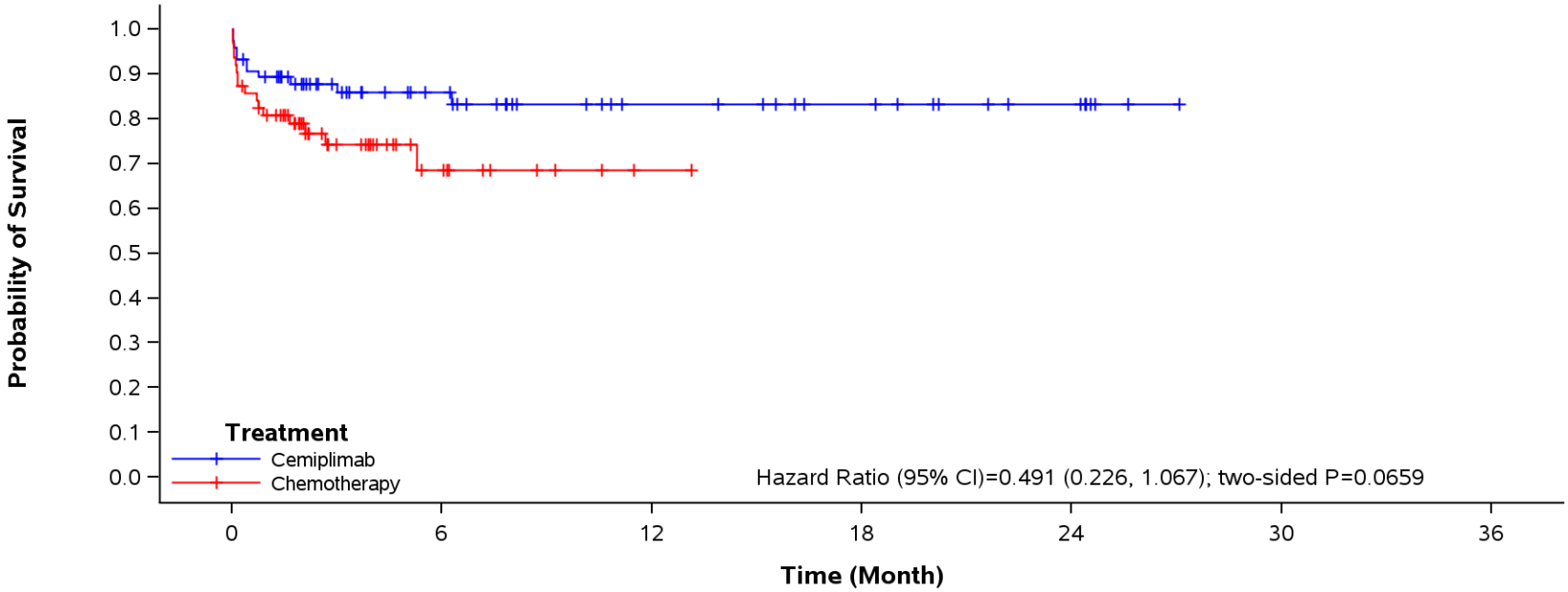

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 27 | 13 | 10 | 4 | 0 | 0 |
| Chemotherapy | 63 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders
PT: Nausea



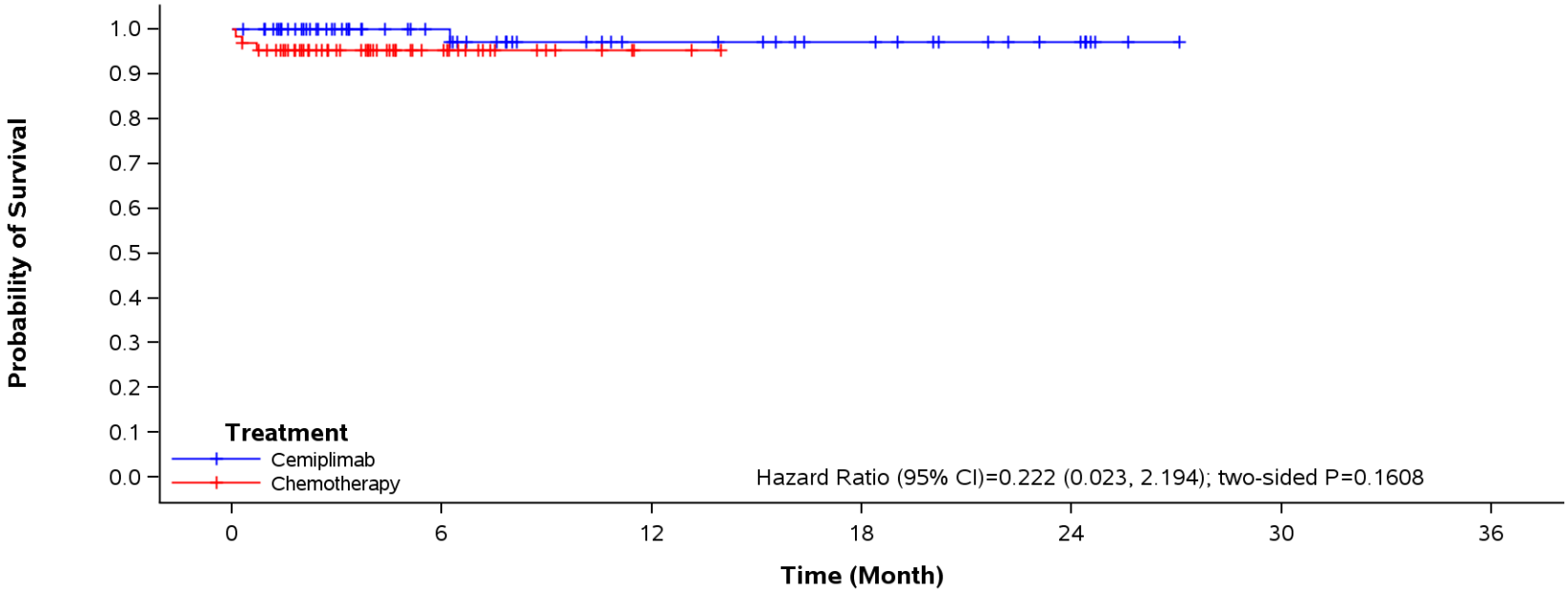

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 34 | 18 | 13 | 7 | 0 | 0 |
| Chemotherapy | 63 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders
PT: Stomatitis



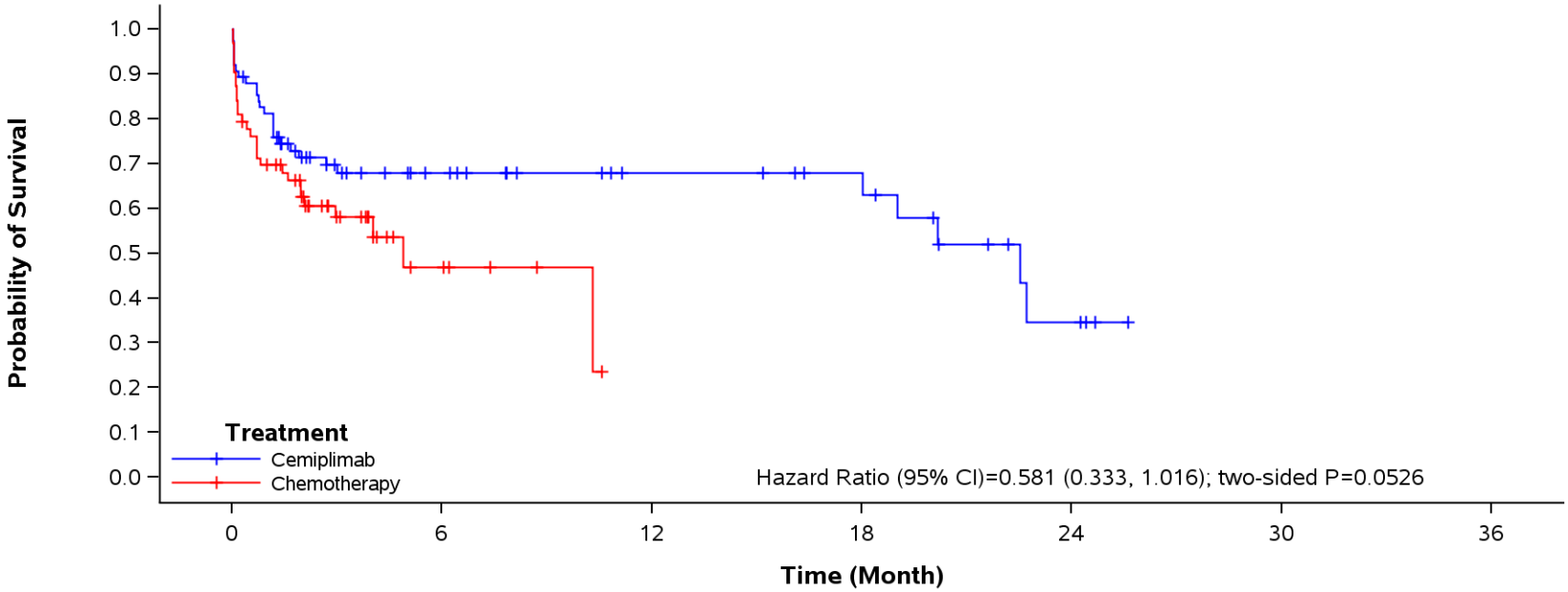

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 20 | 15 | 8 | 0 | 0 |
| Chemotherapy | 63 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: General disorders and administration site conditions



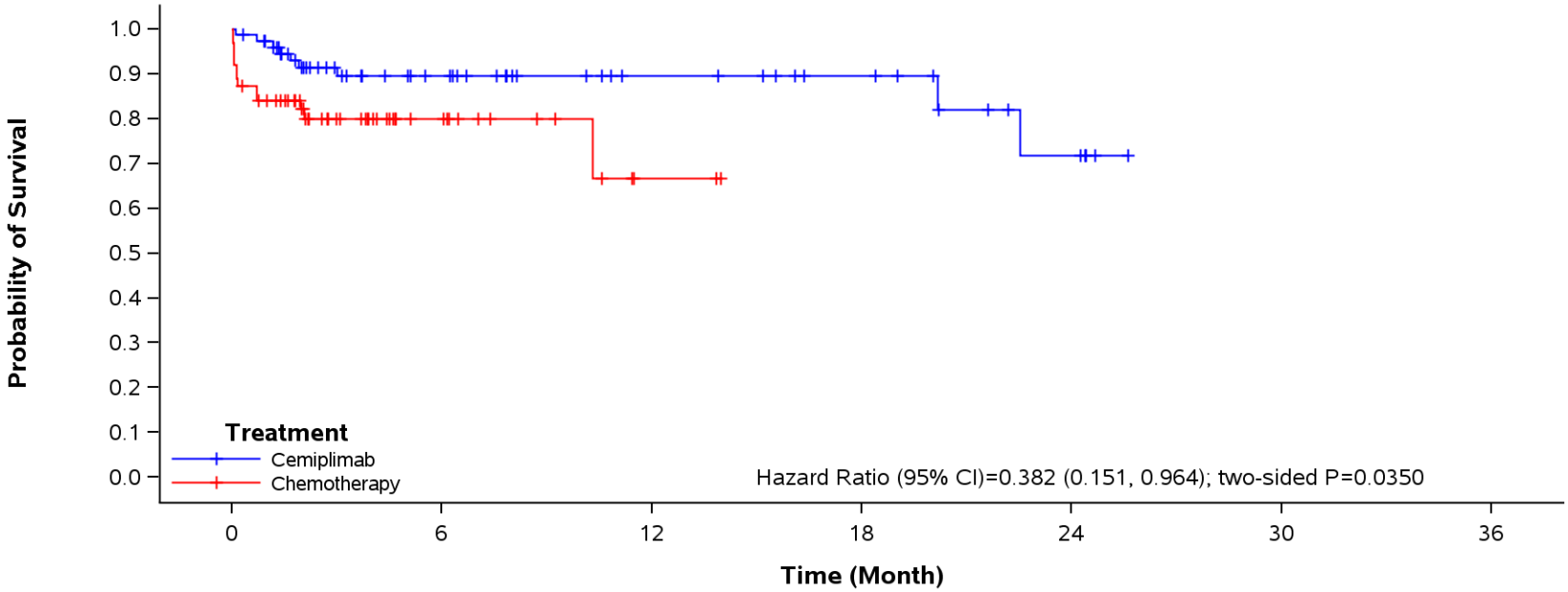

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 28 | 17 | 14 | 4 | 0 | 0 |
| Chemotherapy | 63 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: General disorders and administration site conditions
PT: Asthenia



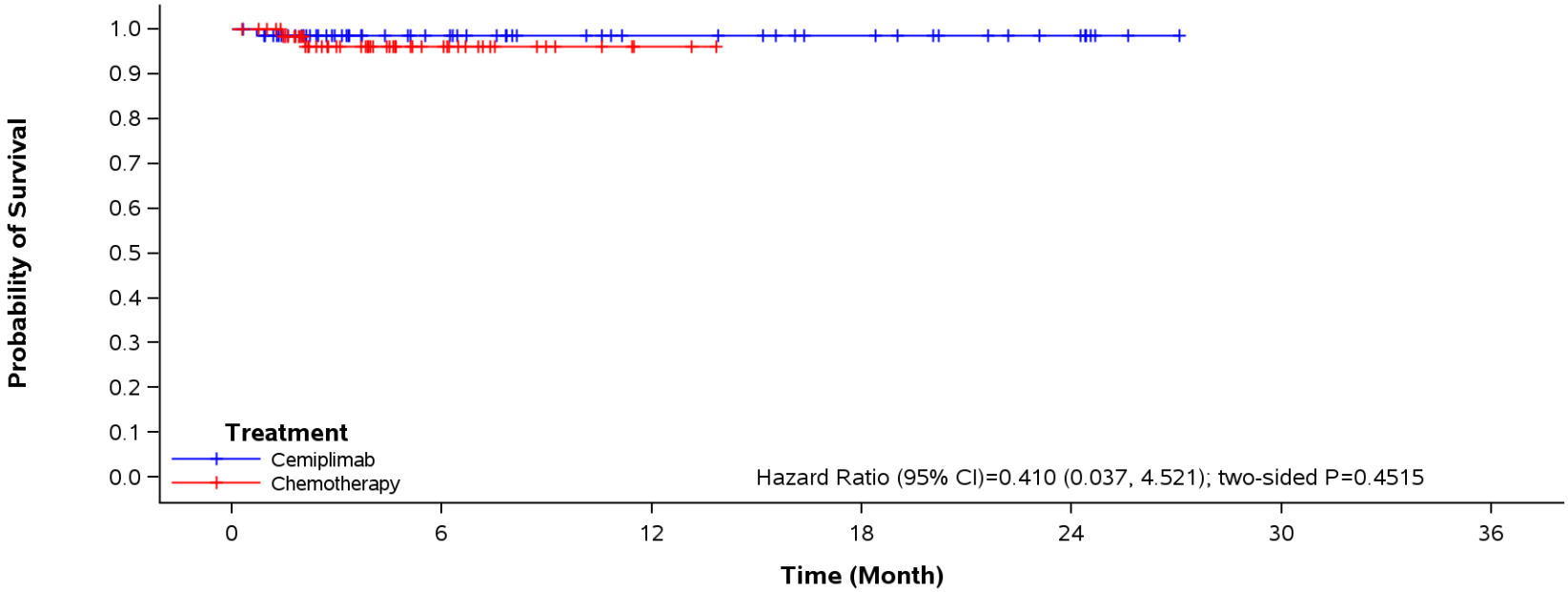

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 35 | 20 | 15 | 7 | 0 | 0 |
| Chemotherapy | 63 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



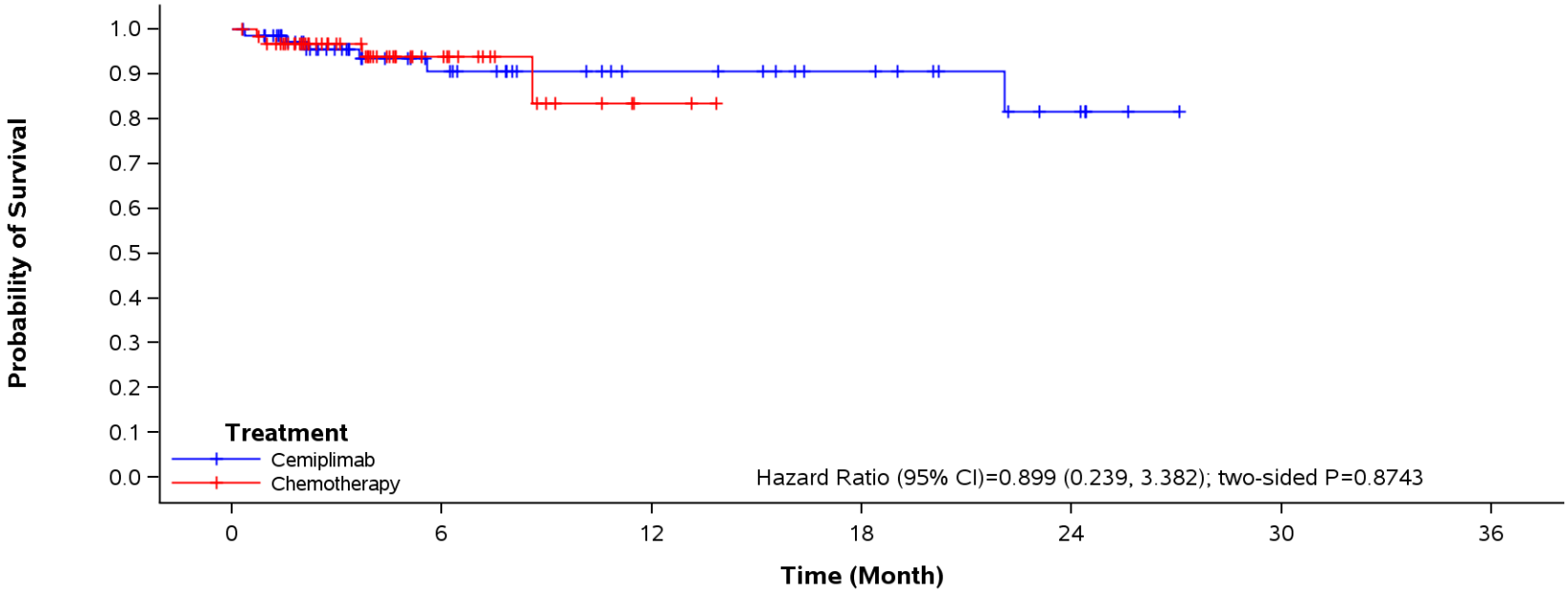

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Nervous system disorders



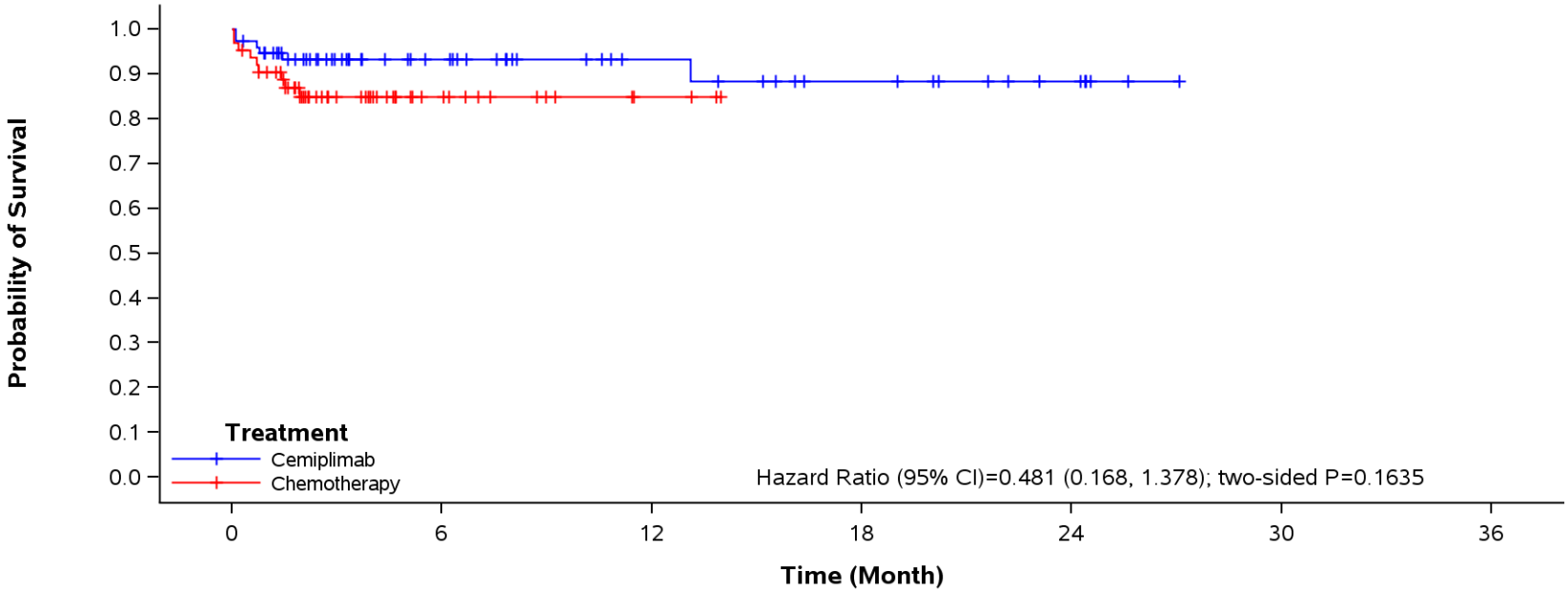

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 33 | 19 | 14 | 7 | 0 | 0 |
| Chemotherapy | 63 | 18 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Skin and subcutaneous tissue disorders



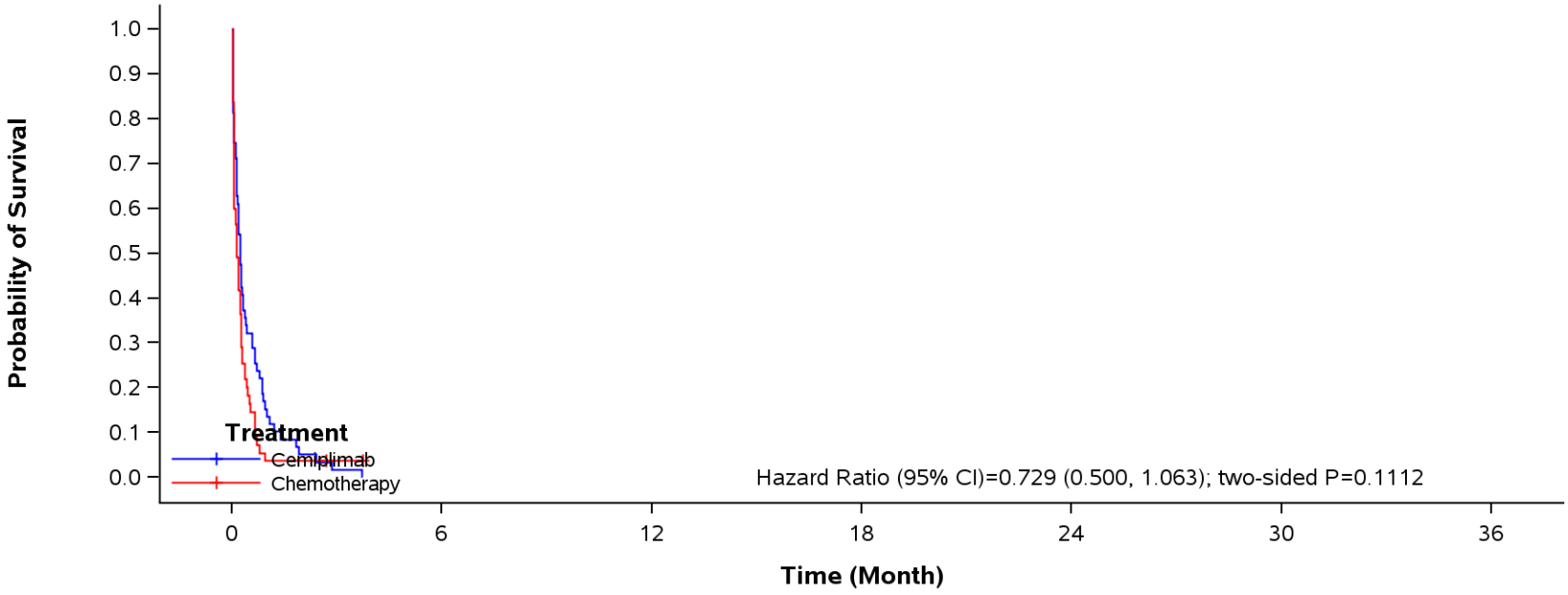

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 34 | 19 | 13 | 7 | 0 | 0 |
| Chemotherapy | 63 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Number of patients with any TEAE



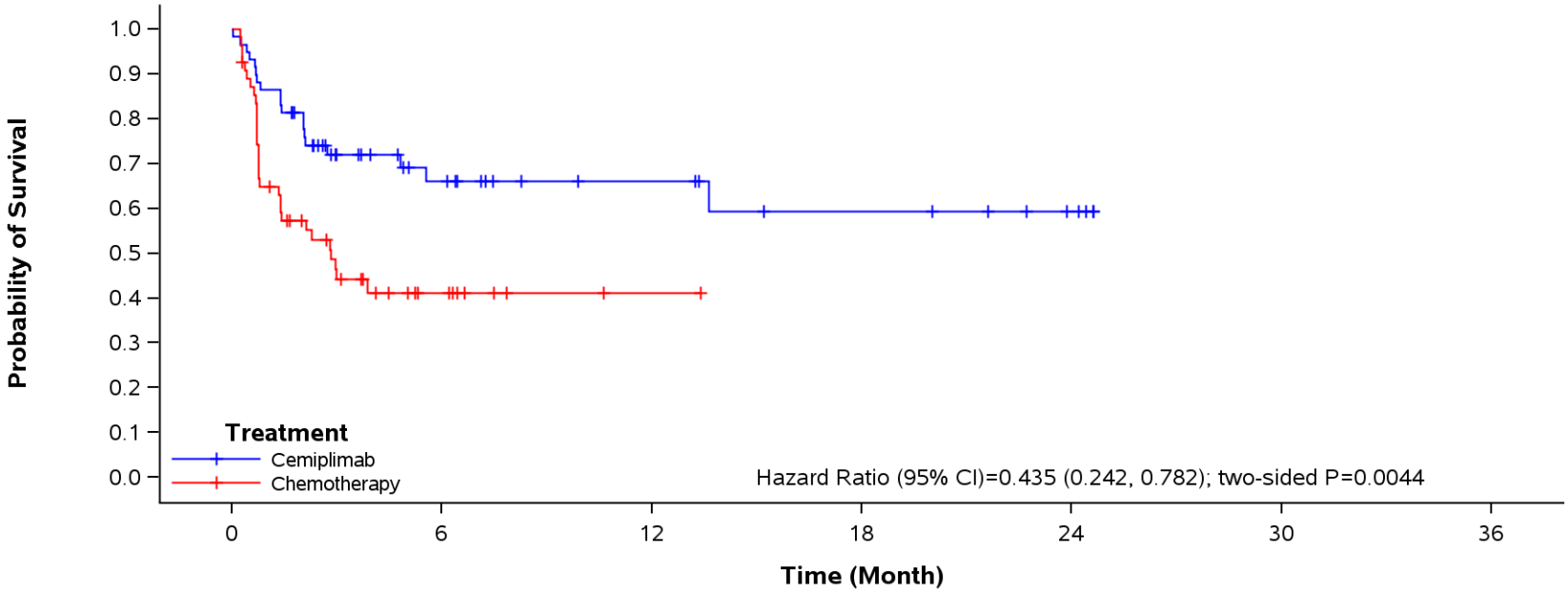

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 55 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders



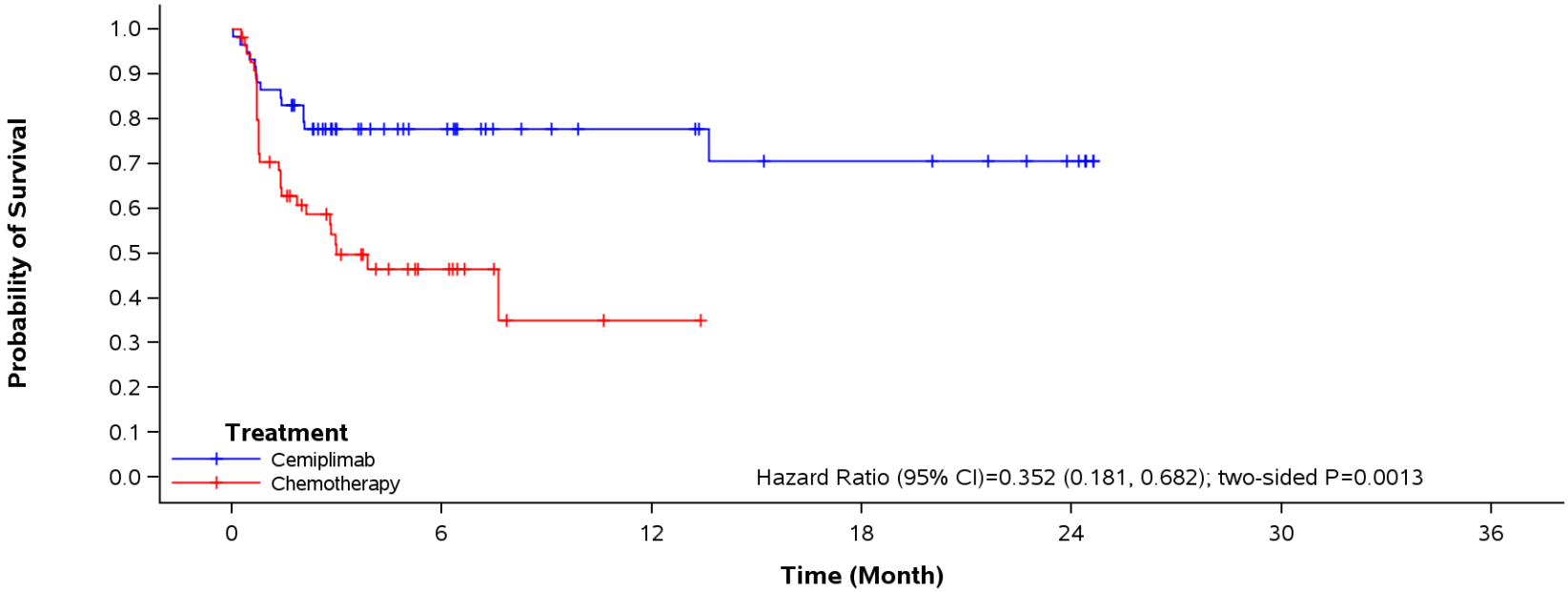

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 21 | 12 | 8 | 4 | 0 | 0 |
| Chemotherapy | 55 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Anaemia



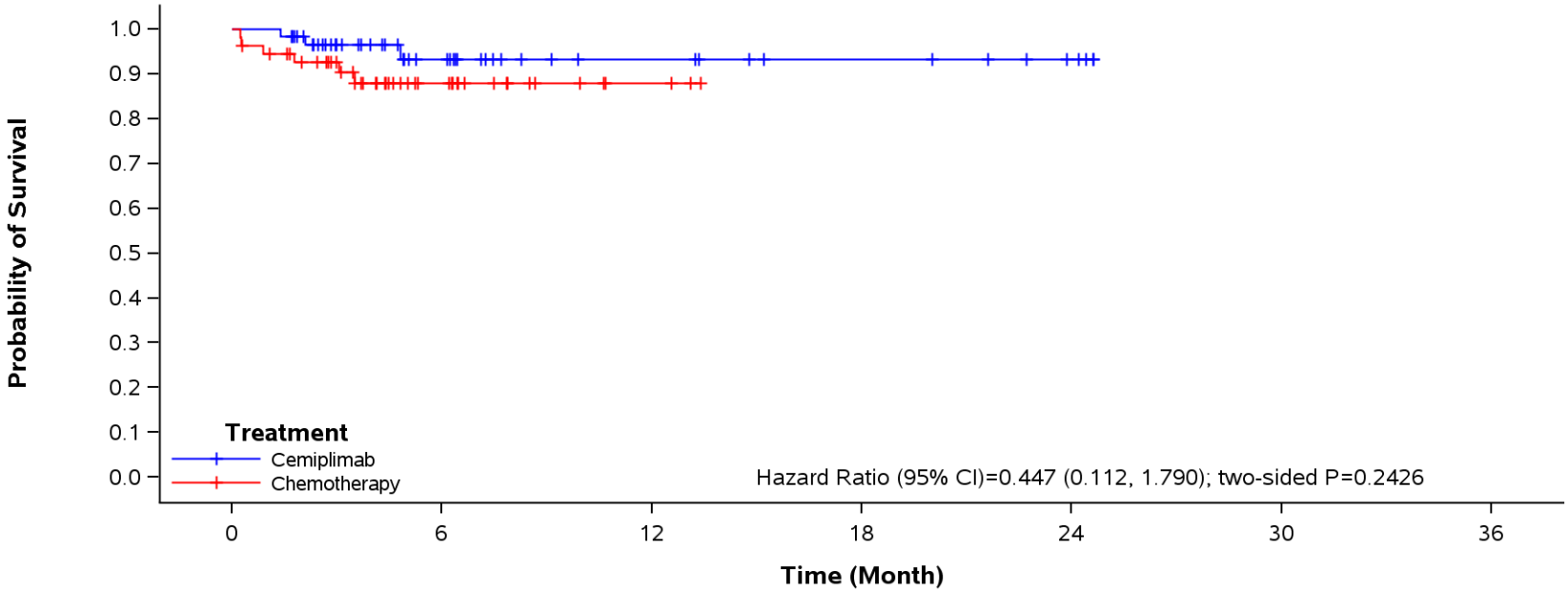

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 24 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Neutropenia



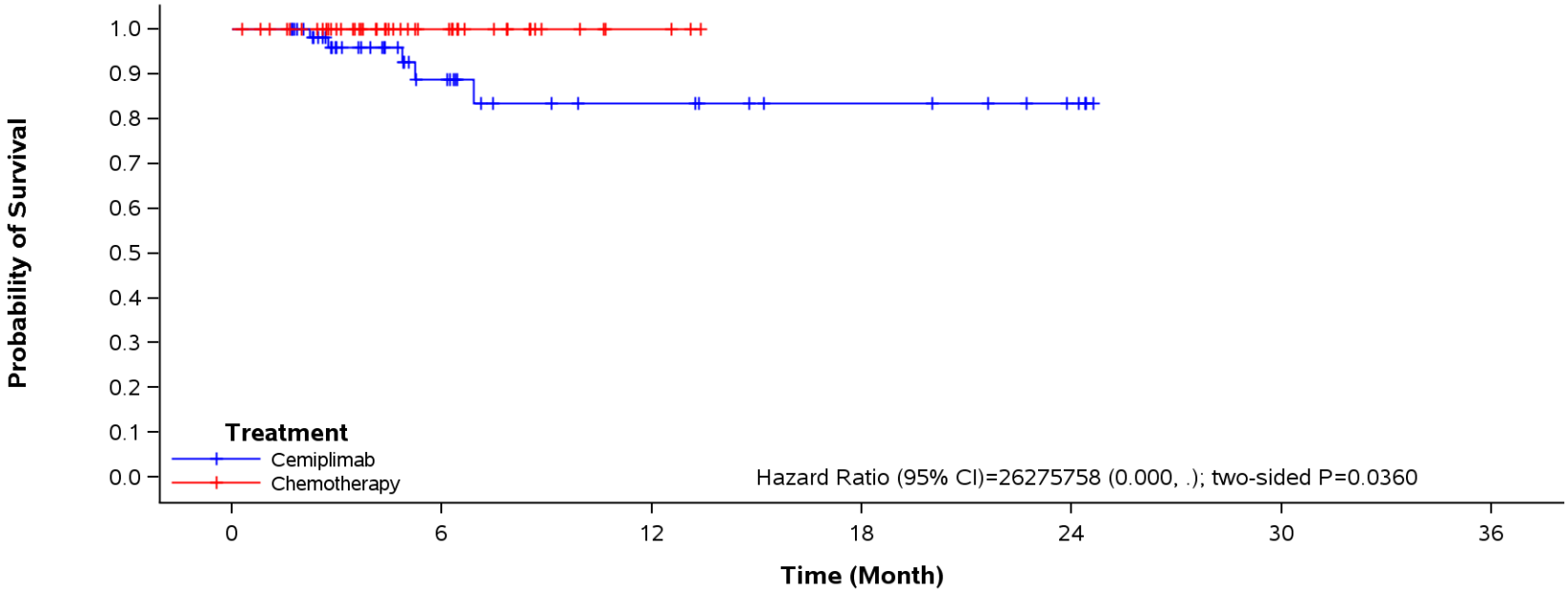

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 12 | 8 | 4 | 0 | 0 |
| Chemotherapy | 55 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Endocrine disorders



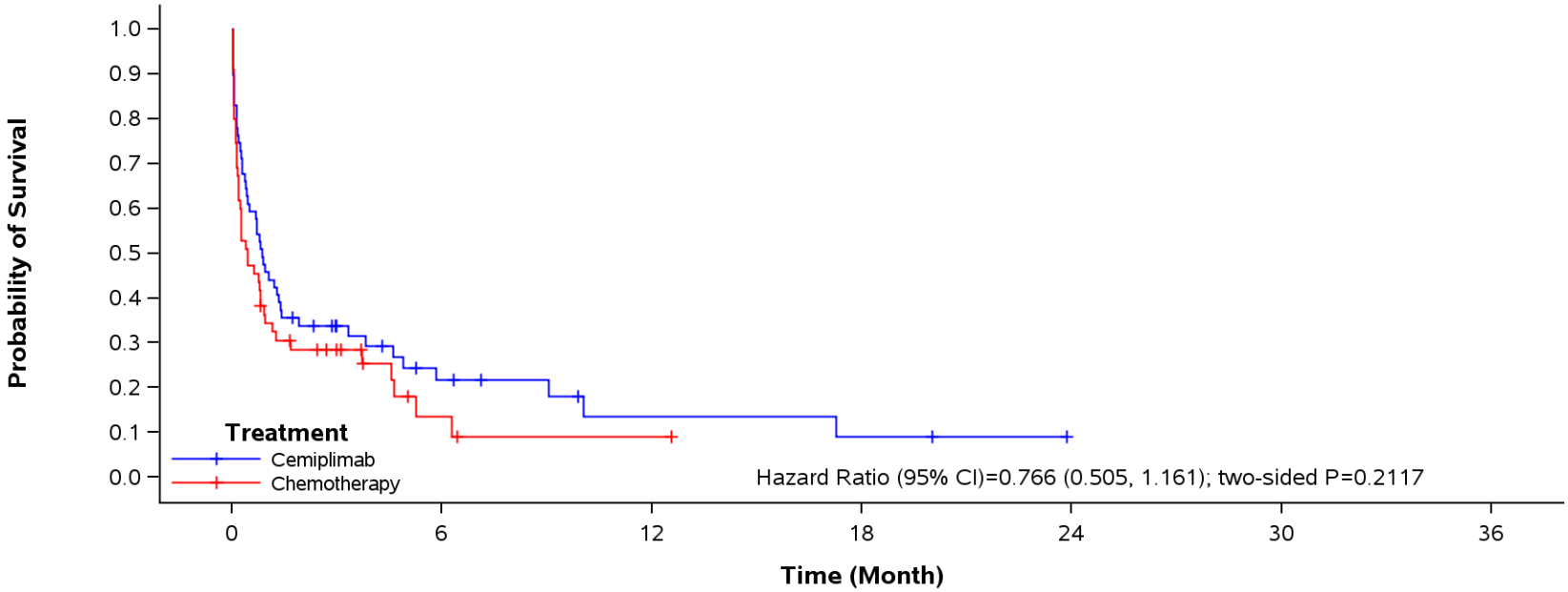

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 22 | 12 | 8 | 4 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 8 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 55 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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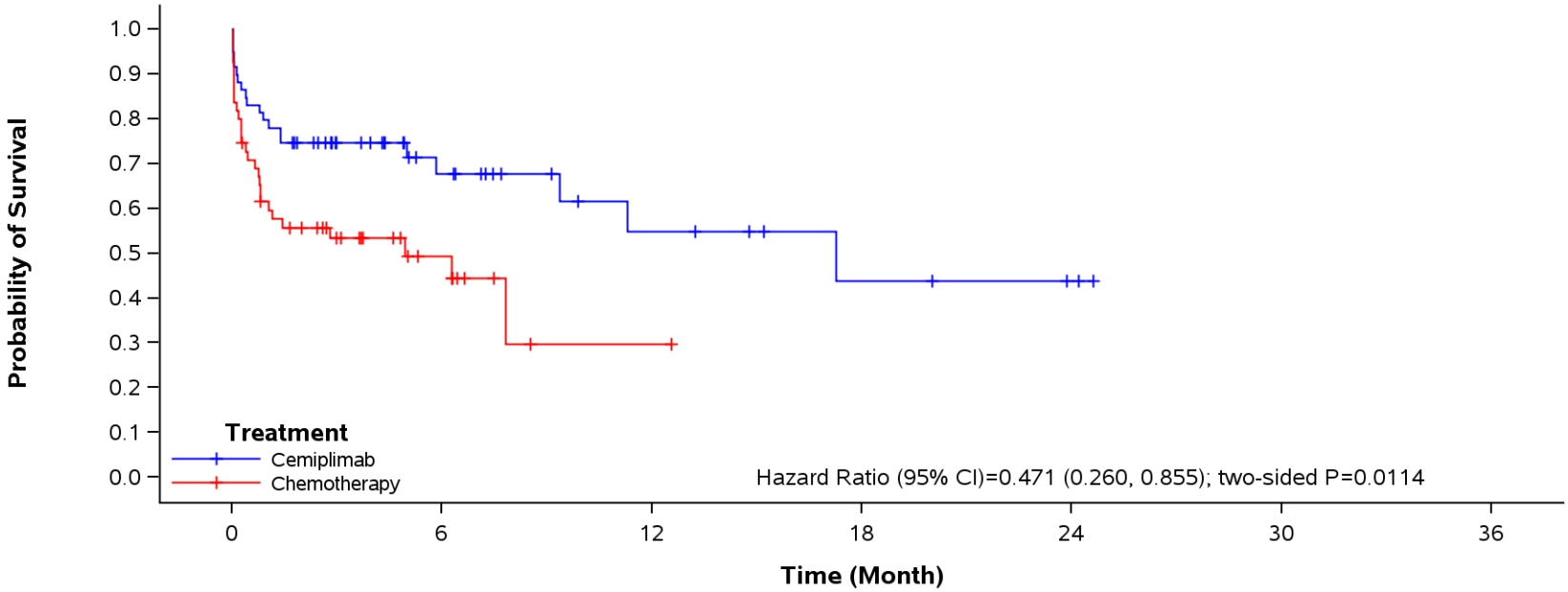
Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders
PT: Nausea



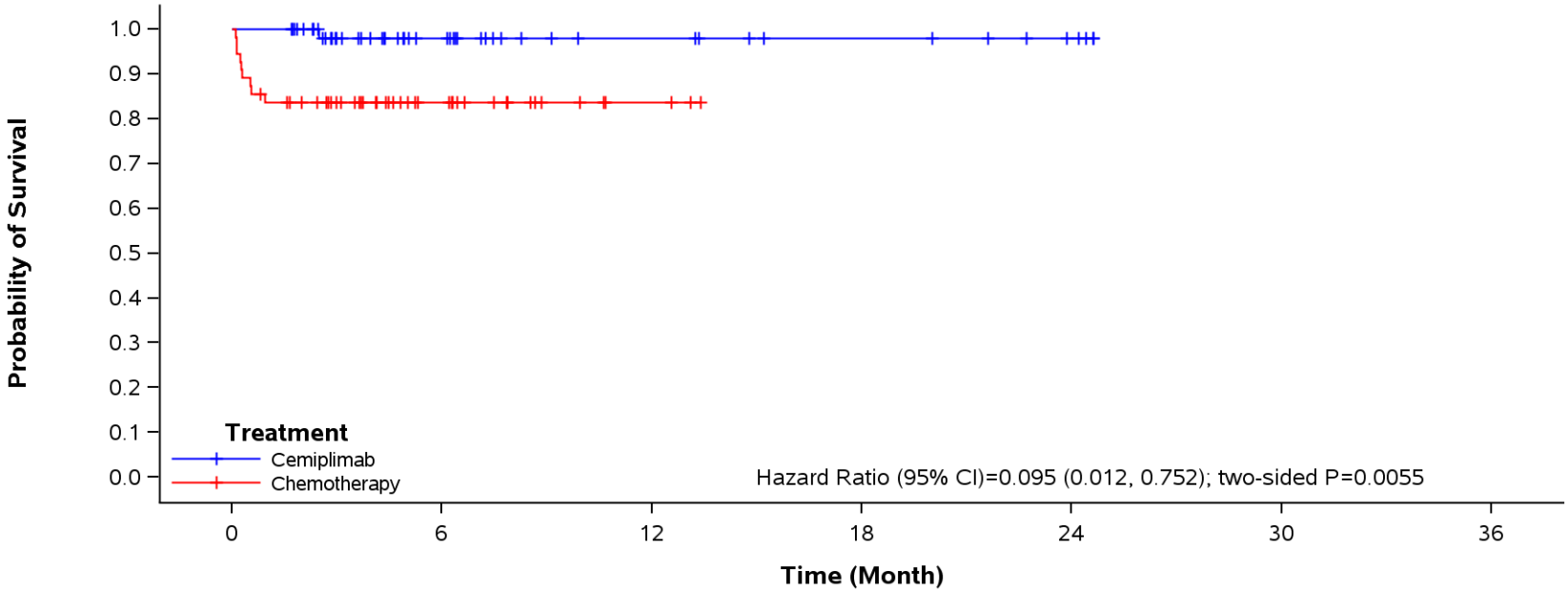

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 8 | 4 | 2 | 0 | 0 |
| Chemotherapy | 55 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders
PT: Stomatitis



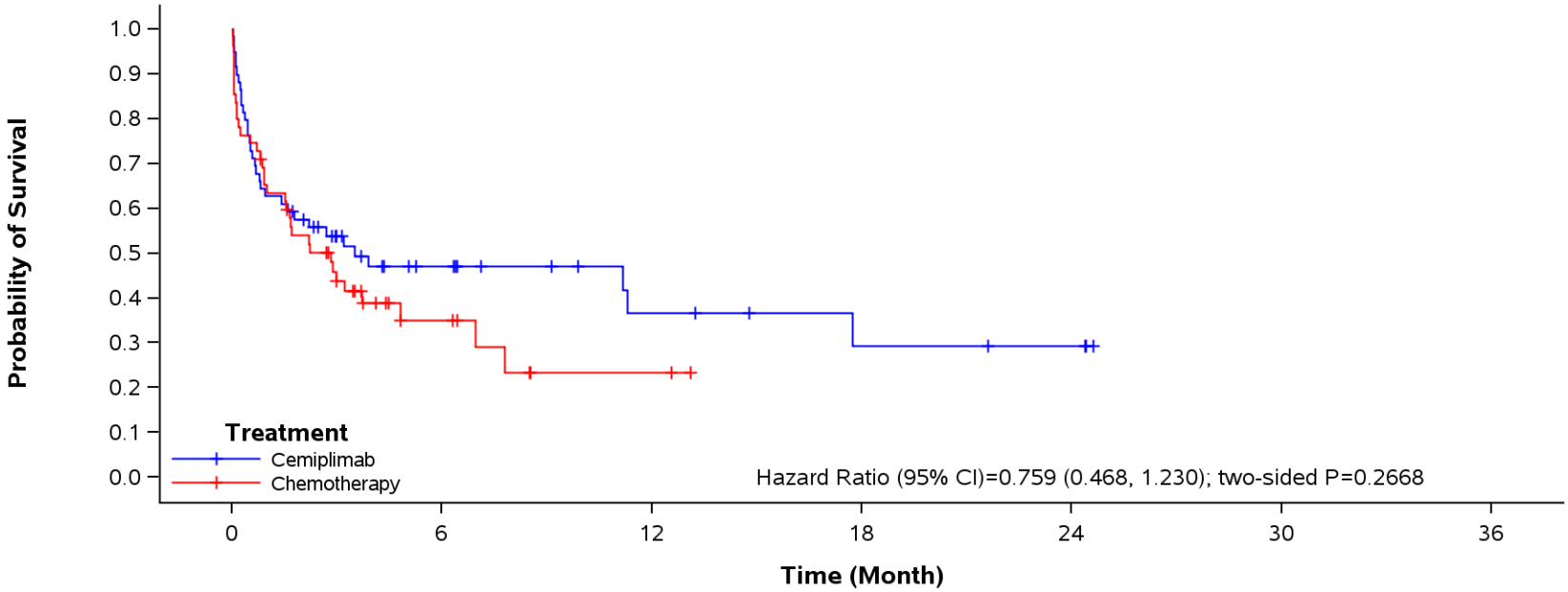

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 12 | 8 | 4 | 0 | 0 |
| Chemotherapy | 55 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: General disorders and administration site conditions




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 16 | 7 | 4 | 3 | 0 | 0 |
| Chemotherapy | 55 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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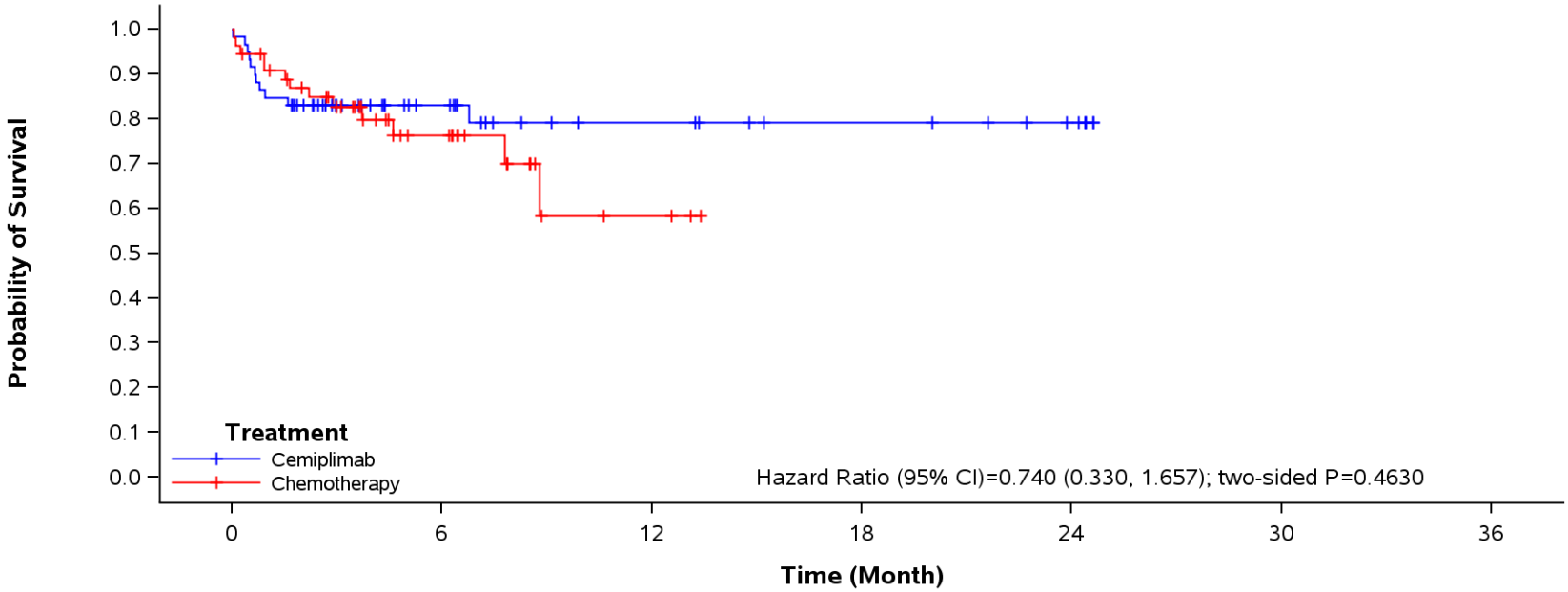
Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: General disorders and administration site conditions
PT: Asthenia



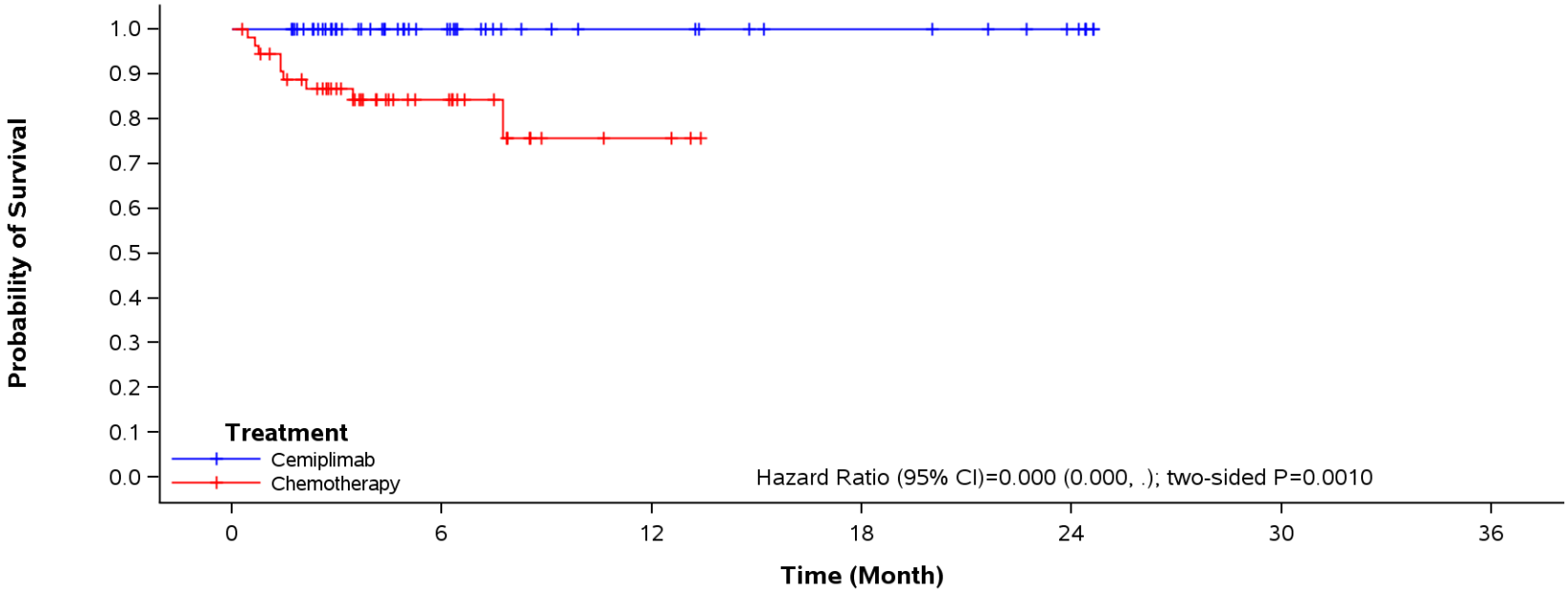

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



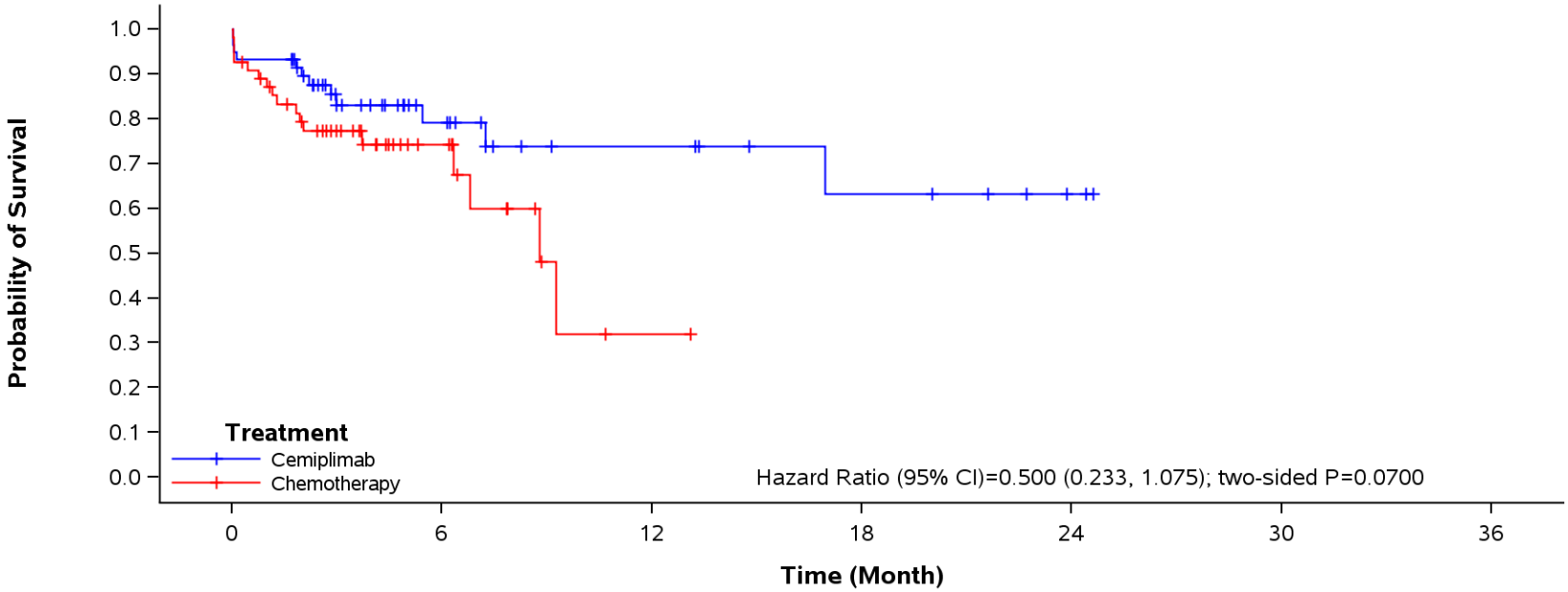

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Nervous system disorders




**Number of Subjects at risk**

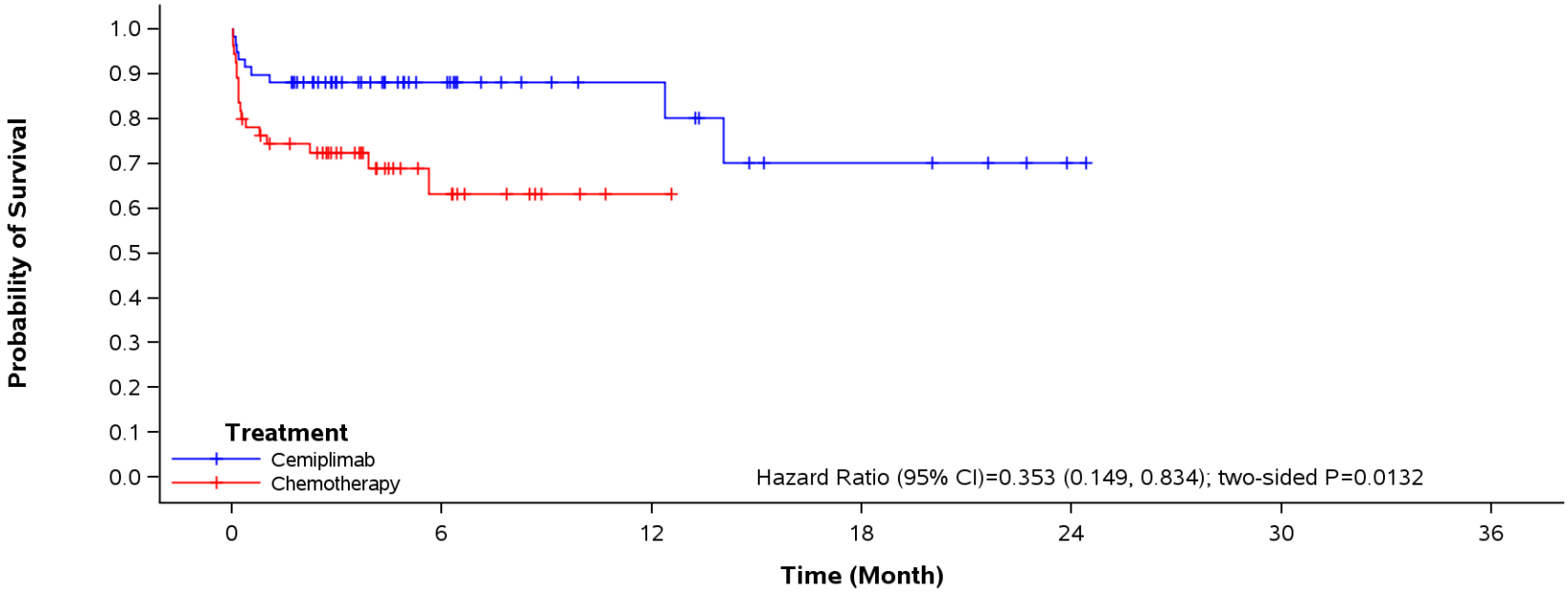
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 20 | 10 | 6 | 2 | 0 | 0 |
| Chemotherapy | 55 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Skin and subcutaneous tissue disorders



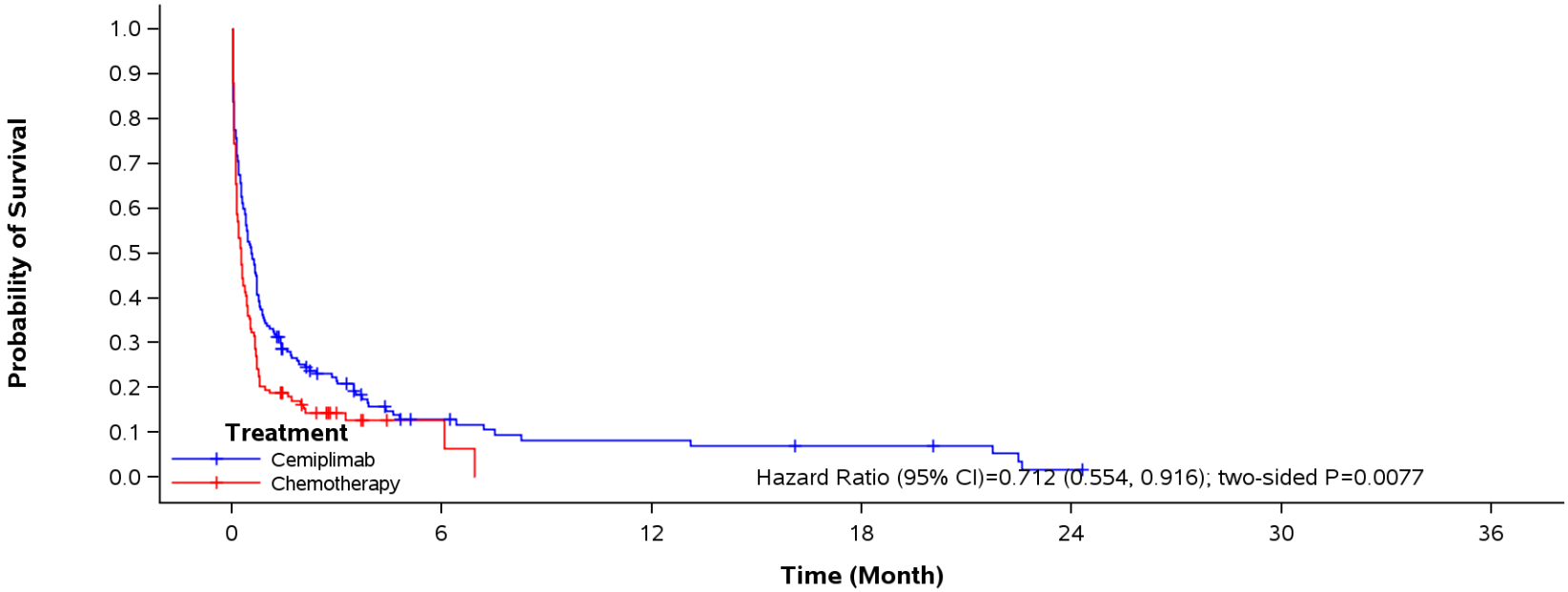

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 22 | 11 | 5 | 1 | 0 | 0 |
| Chemotherapy | 55 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Number of patients with any TEAE



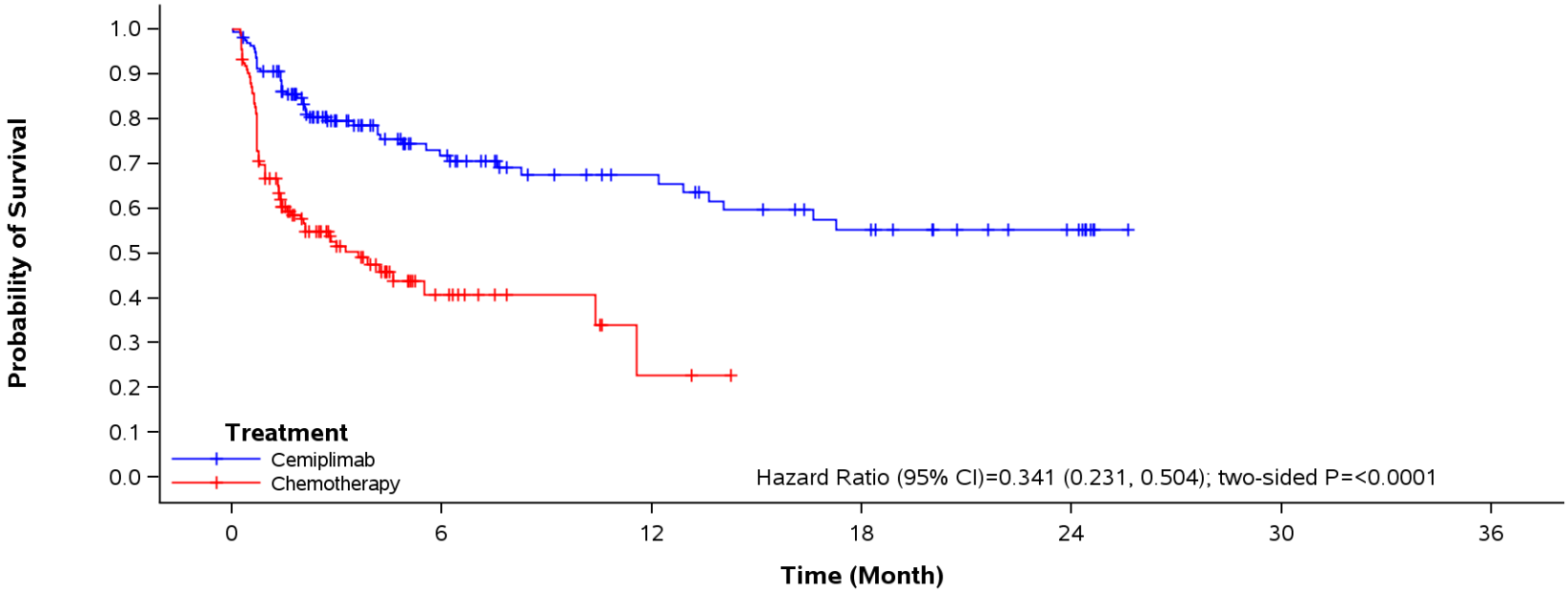

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 12 | 7 | 5 | 1 | 0 | 0 |
| Chemotherapy | 133 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders



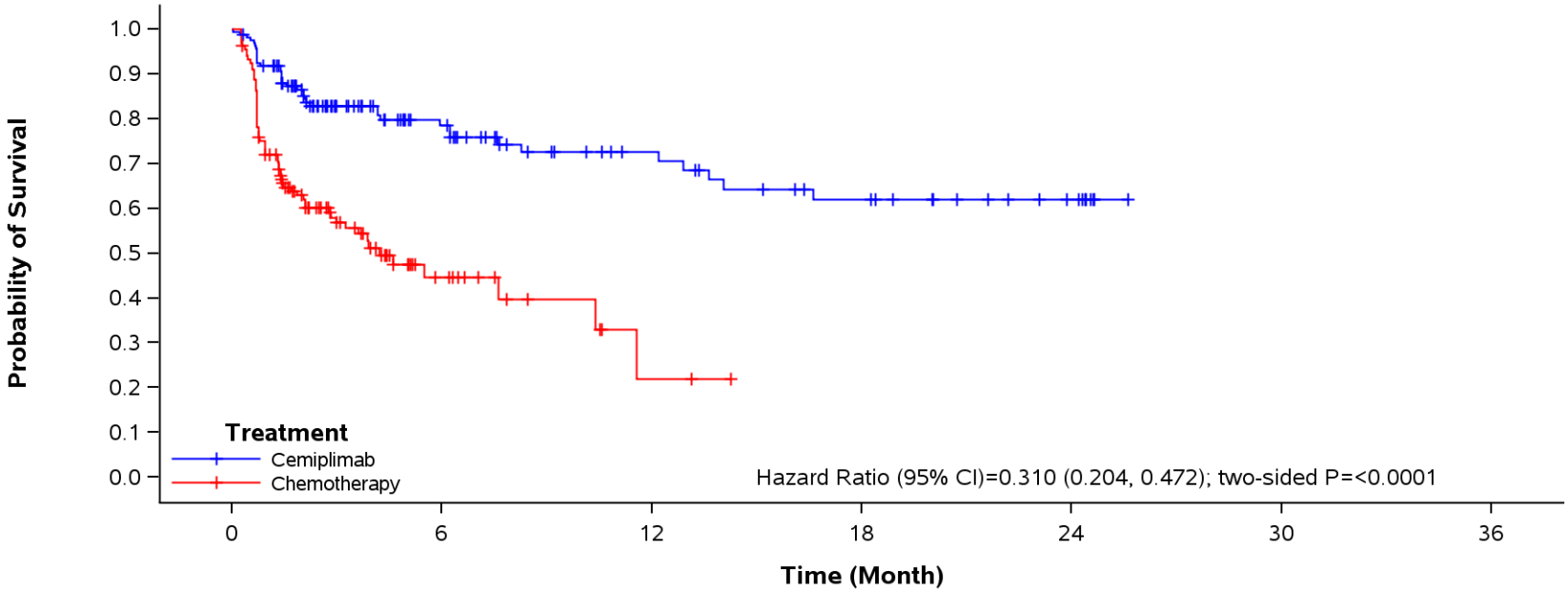

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 58 | 36 | 25 | 15 | 0 | 0 |
| Chemotherapy | 133 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



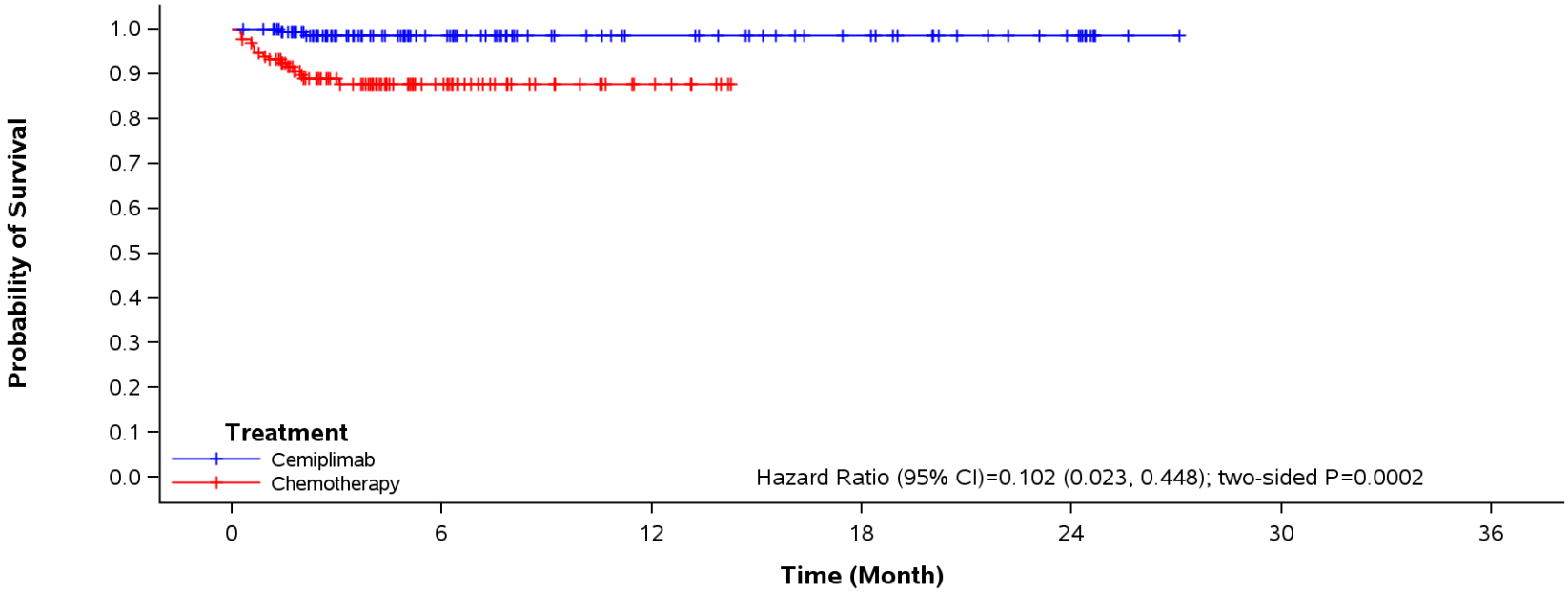

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 62 | 36 | 26 | 15 | 0 | 0 |
| Chemotherapy | 133 | 15 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



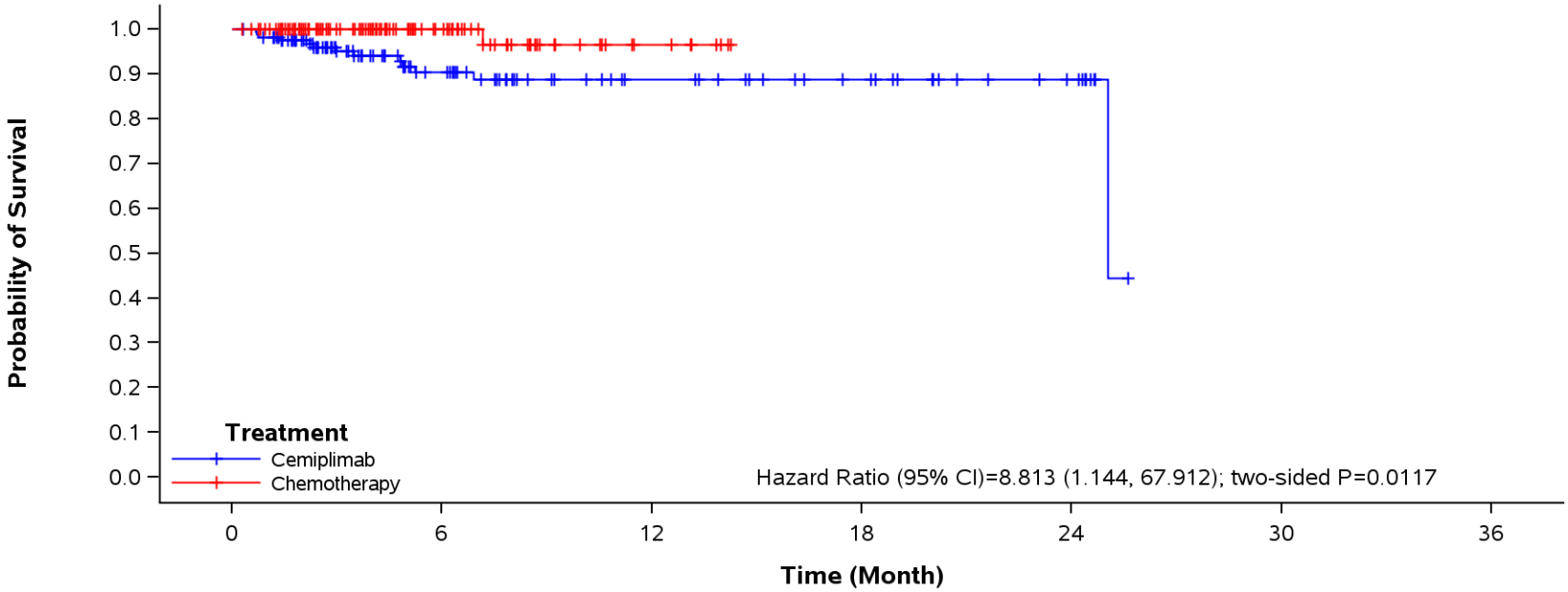

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 36 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Endocrine disorders



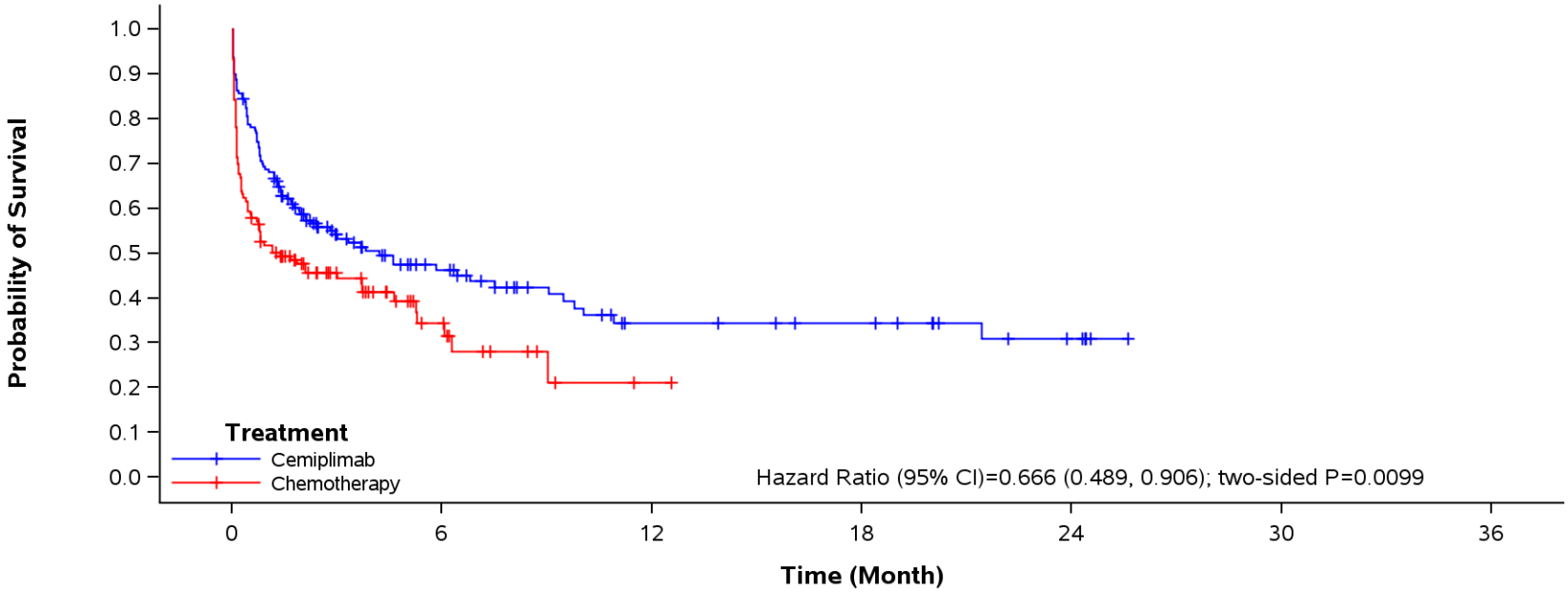

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 66 | 38 | 29 | 17 | 0 | 0 |
| Chemotherapy | 133 | 41 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders




**Number of Subjects at risk**

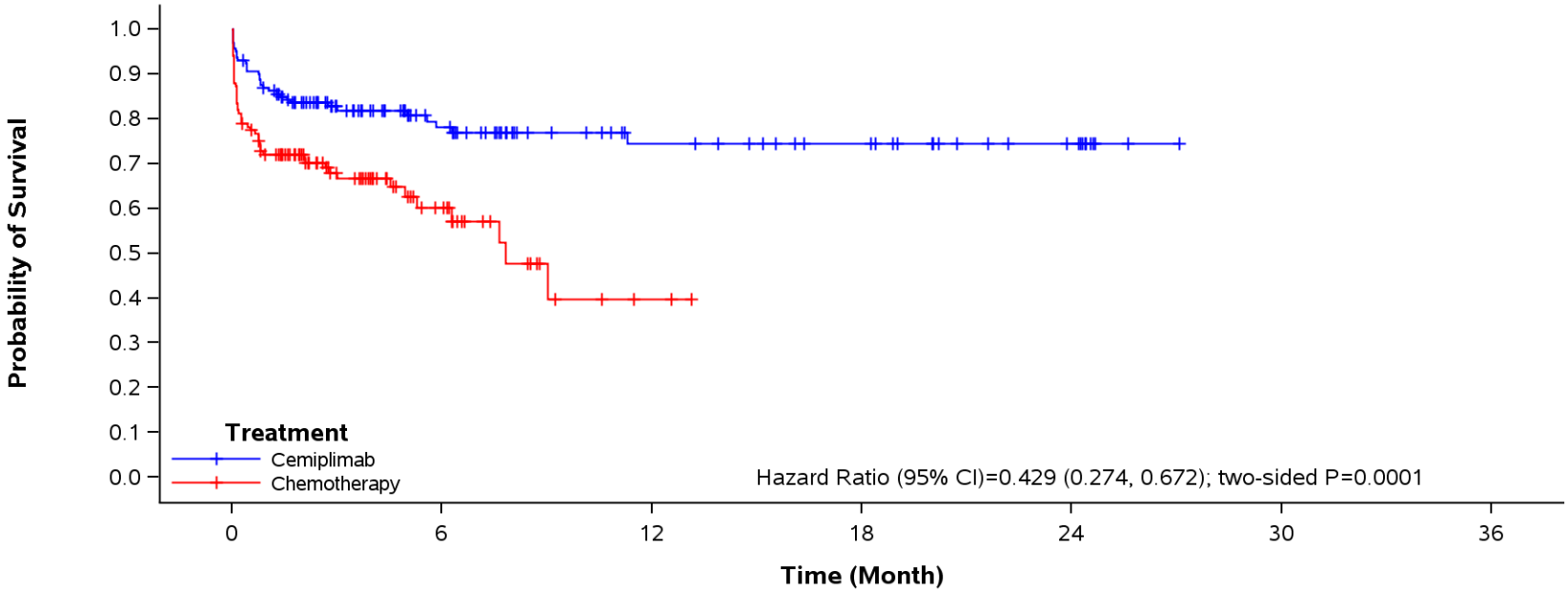
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 40 | 18 | 15 | 7 | 0 | 0 |
| Chemotherapy | 133 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders
PT: Nausea



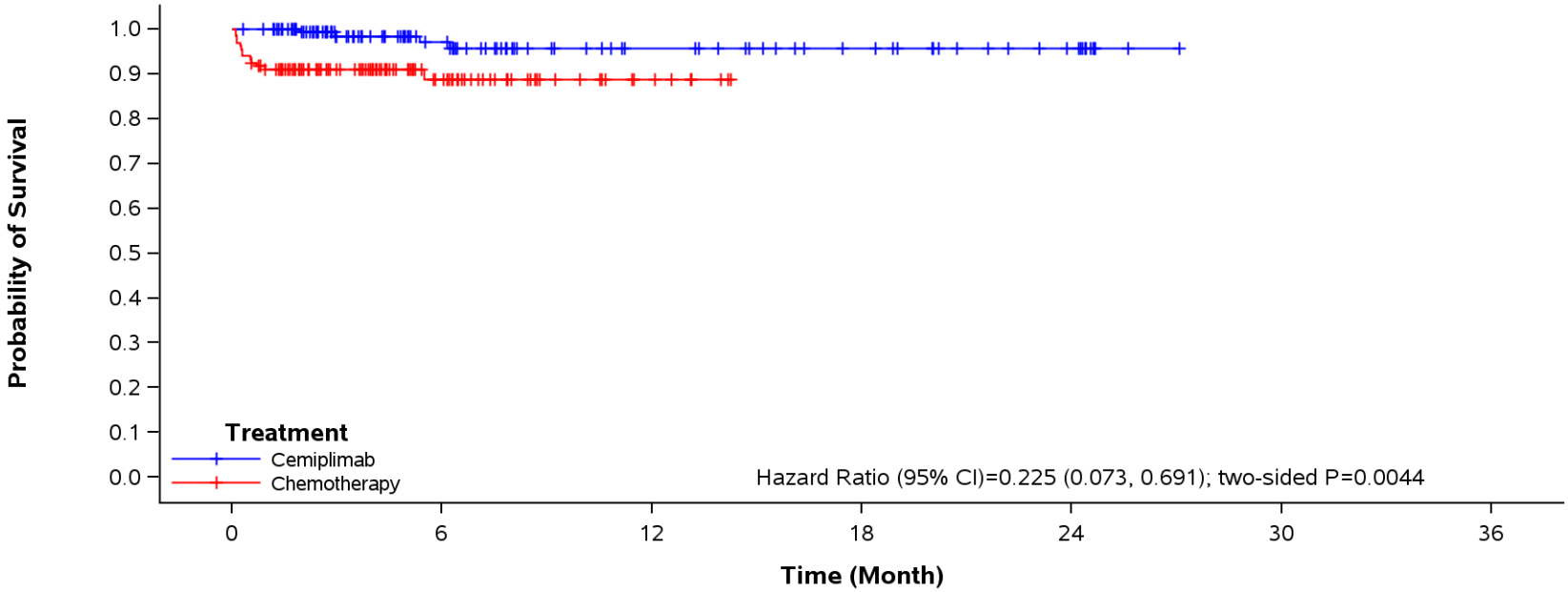

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 61 | 32 | 25 | 14 | 0 | 0 |
| Chemotherapy | 133 | 23 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders
PT: Stomatitis



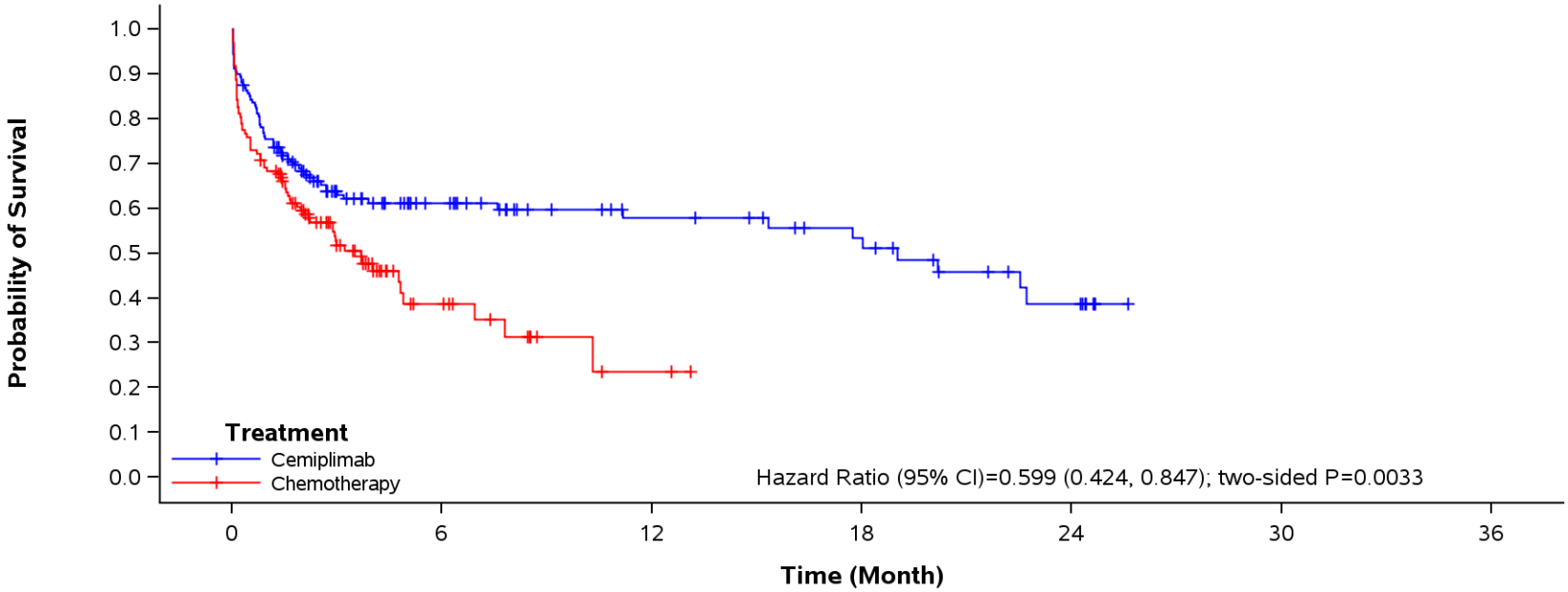

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 71 | 40 | 30 | 18 | 0 | 0 |
| Chemotherapy | 133 | 37 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: General disorders and administration site conditions



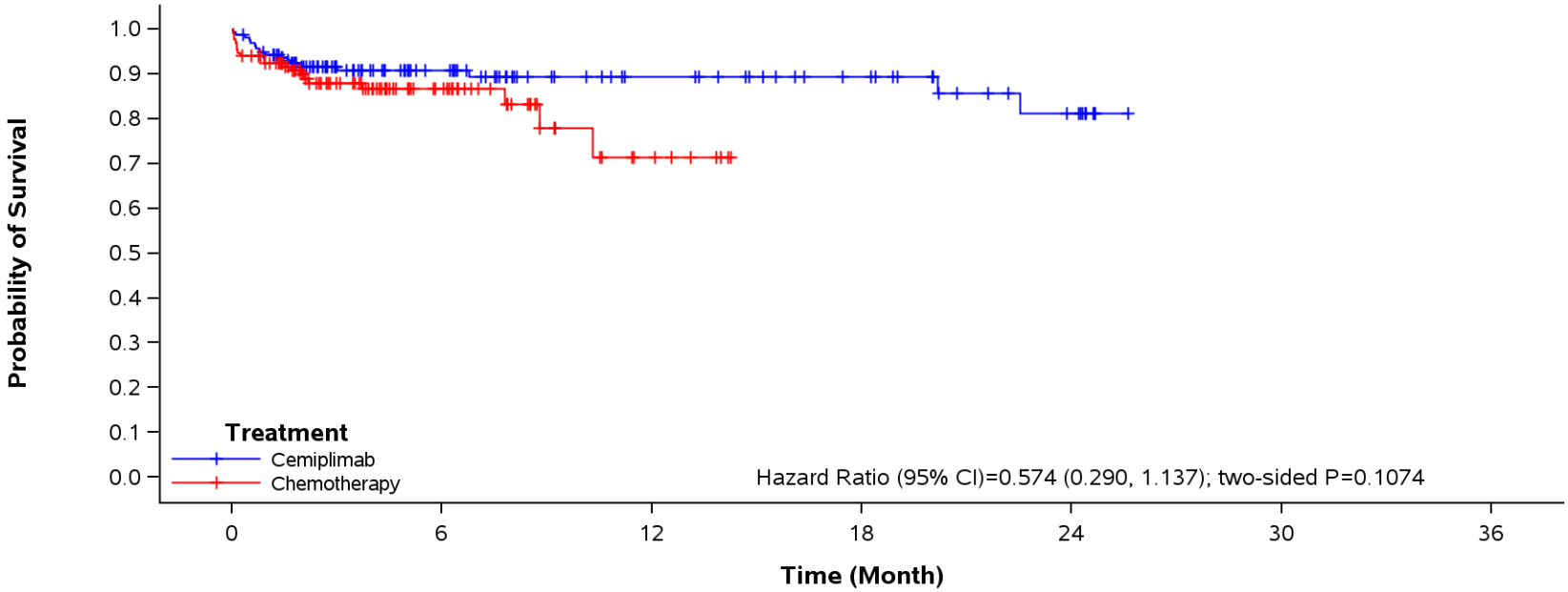

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 52 | 30 | 23 | 11 | 0 | 0 |
| Chemotherapy | 133 | 14 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: General disorders and administration site conditions
PT: Asthenia



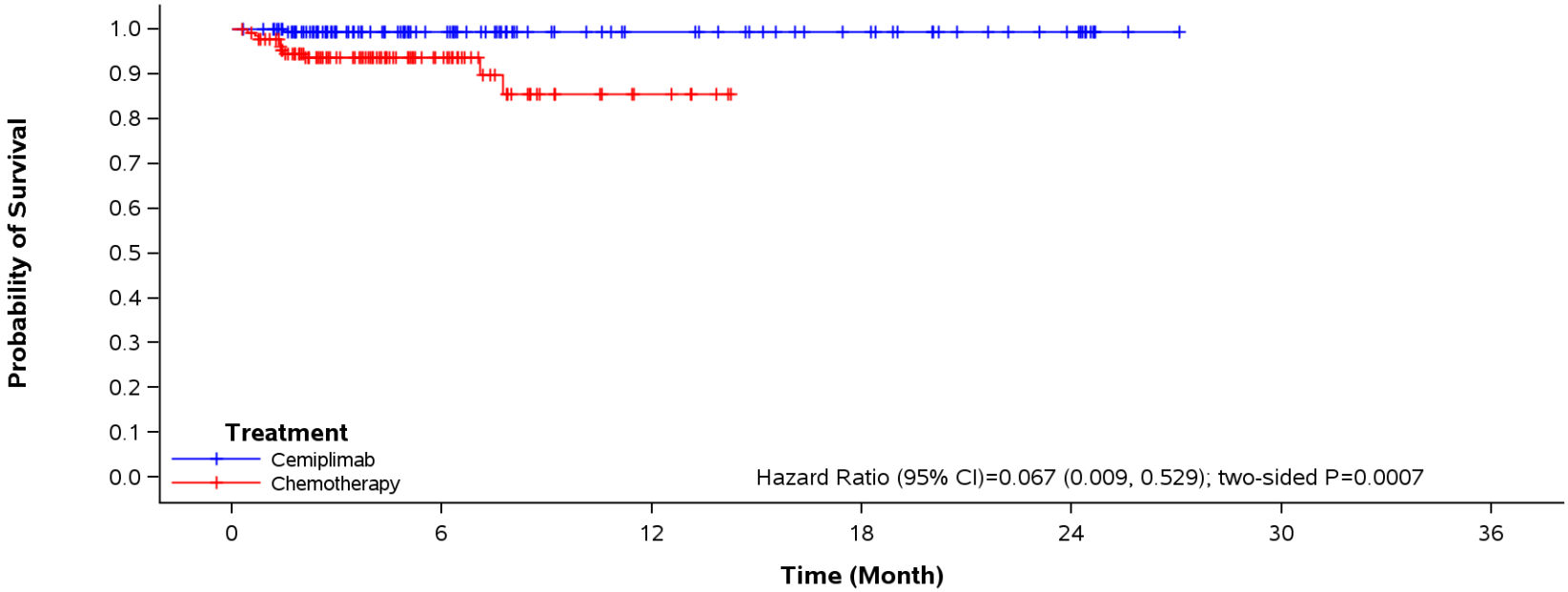

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 71 | 41 | 31 | 17 | 0 | 0 |
| Chemotherapy | 133 | 38 | 7 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



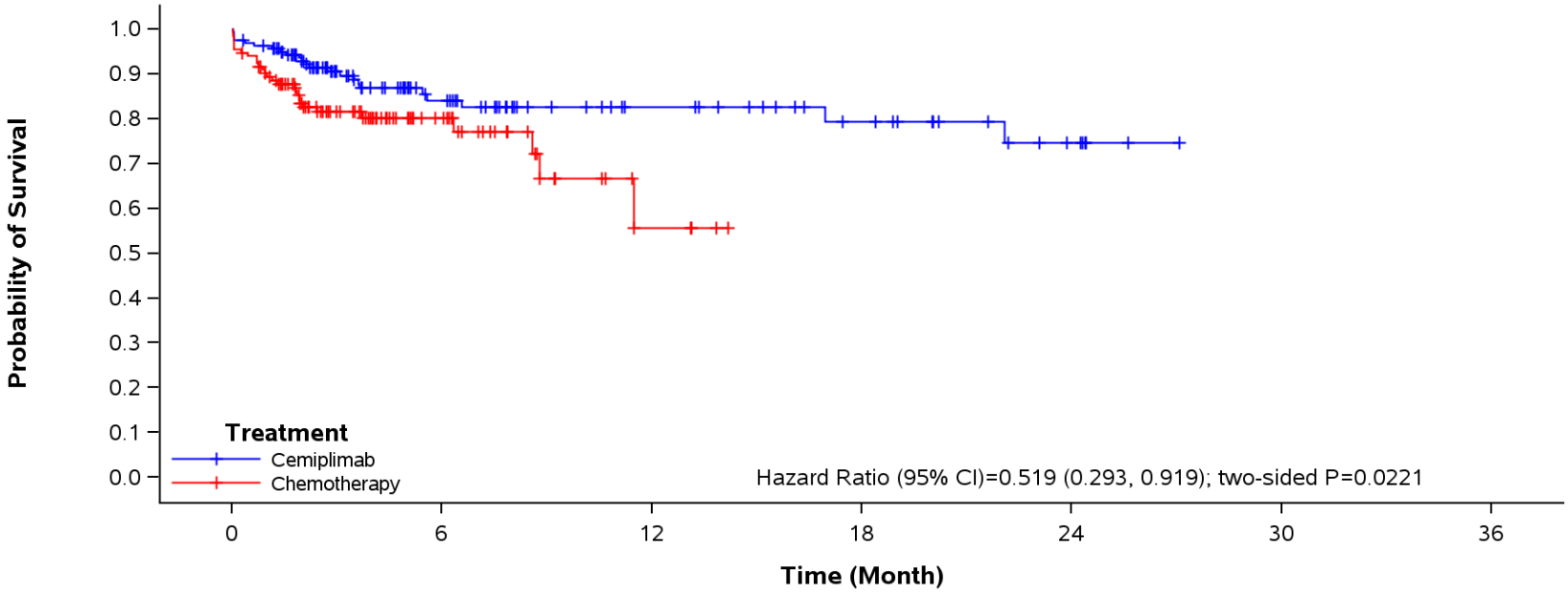

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 37 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Nervous system disorders



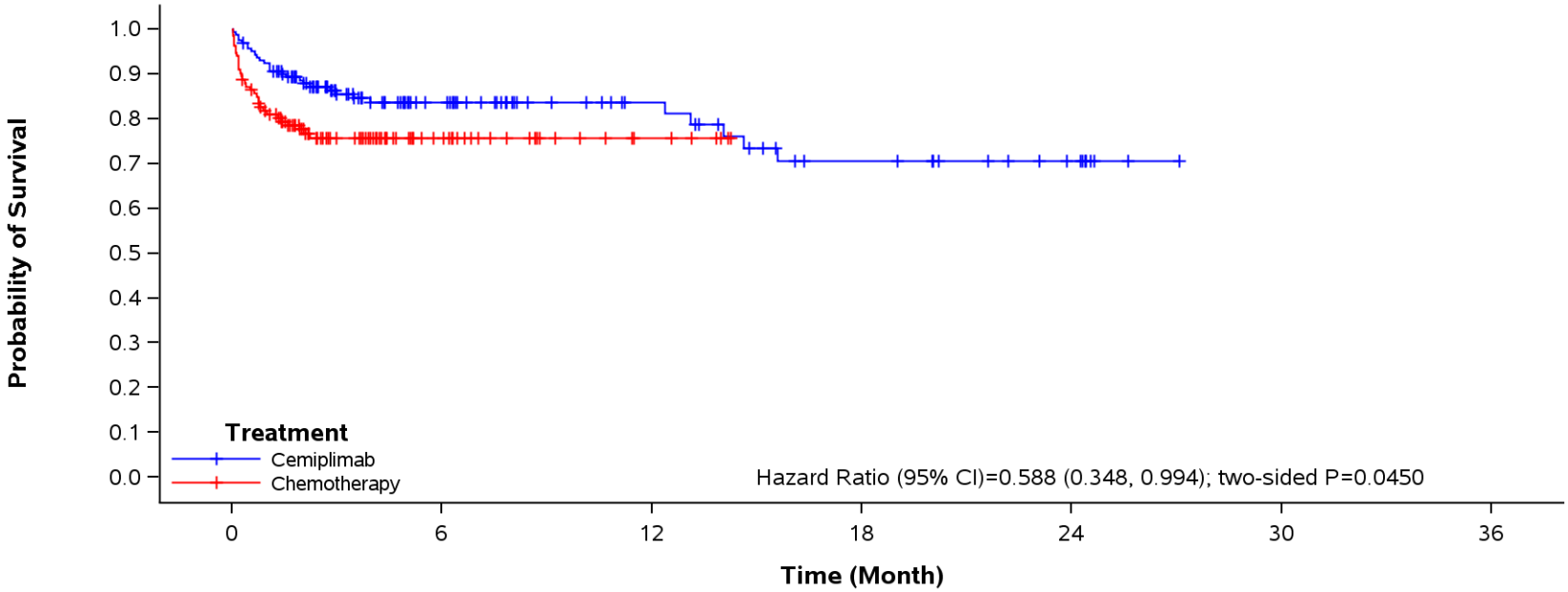

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 61 | 34 | 24 | 13 | 0 | 0 |
| Chemotherapy | 133 | 32 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Skin and subcutaneous tissue disorders



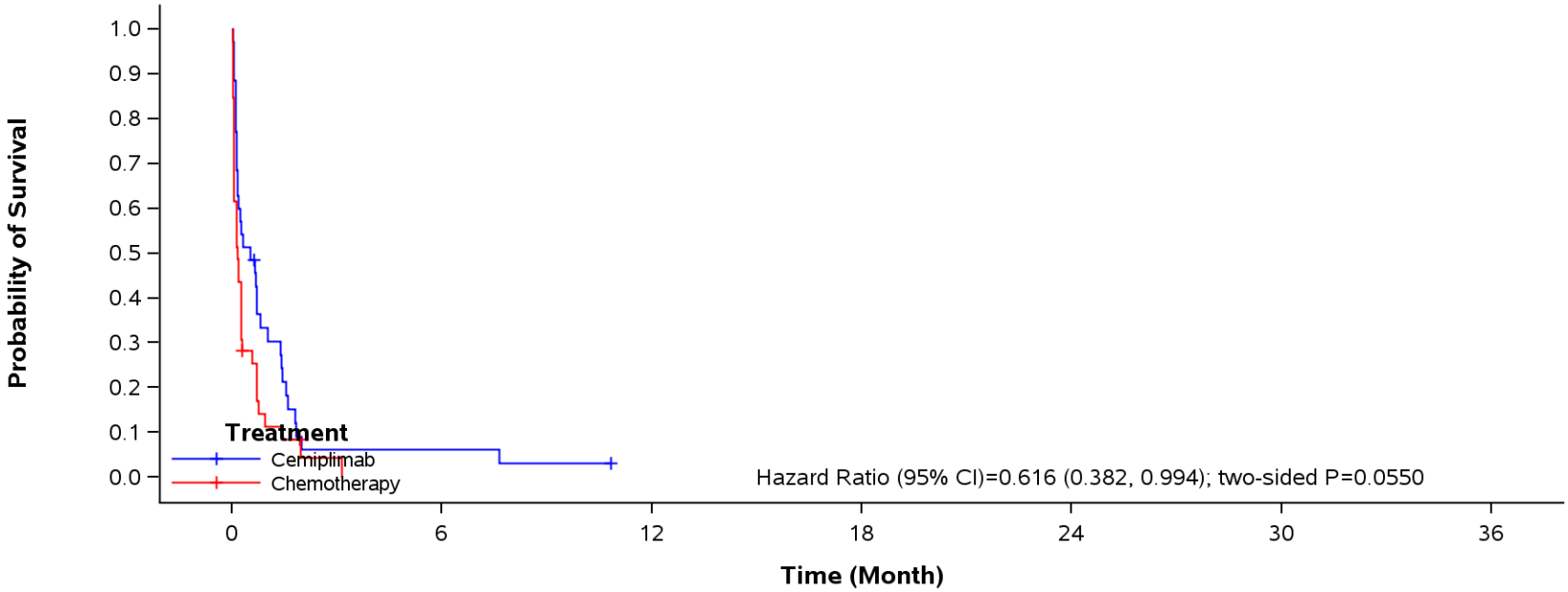

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 62 | 35 | 22 | 13 | 0 | 0 |
| Chemotherapy | 133 | 25 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Number of patients with any TEAE




**Number of Subjects at risk**

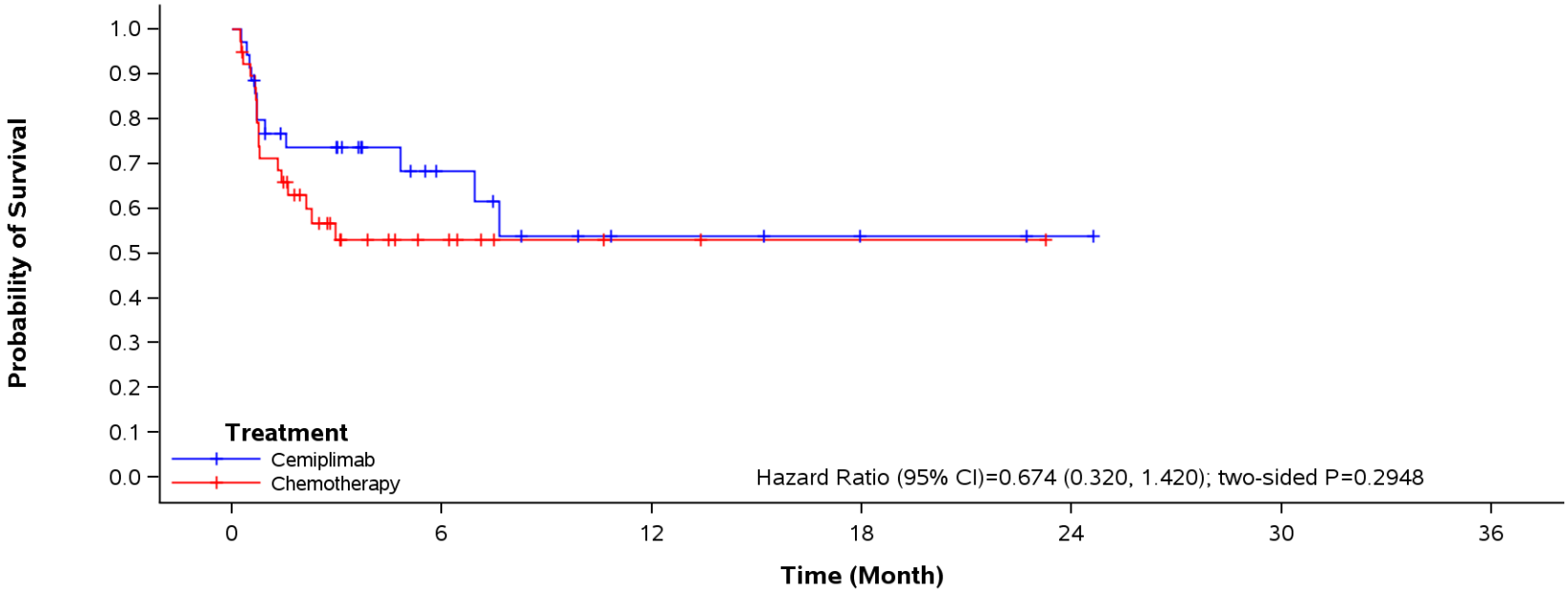
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 39 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders



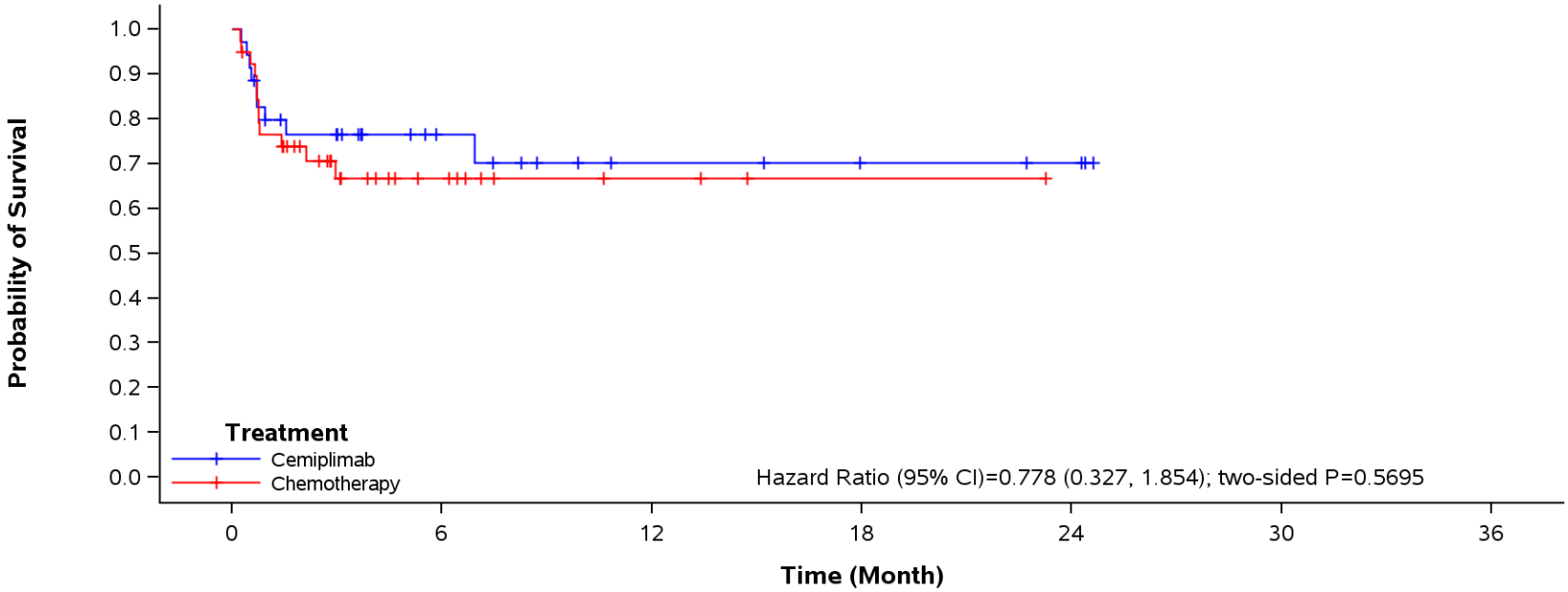

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 39 | 7 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



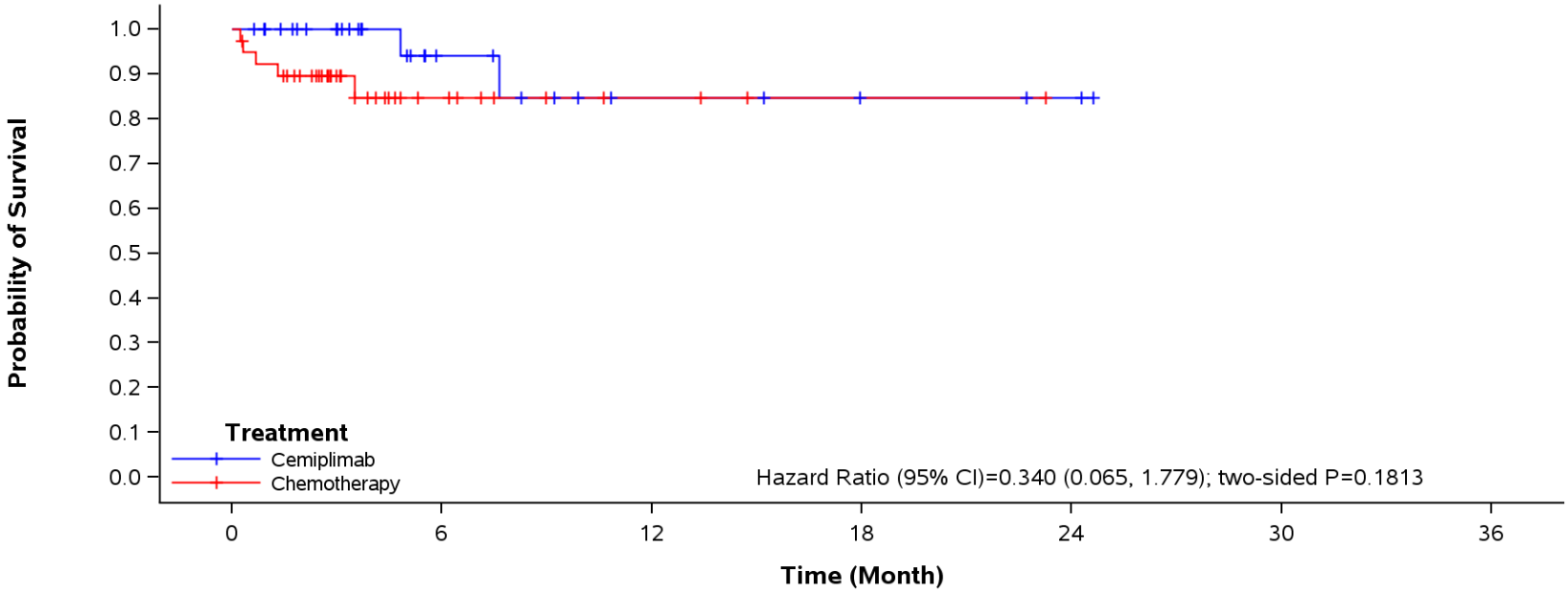

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 9 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



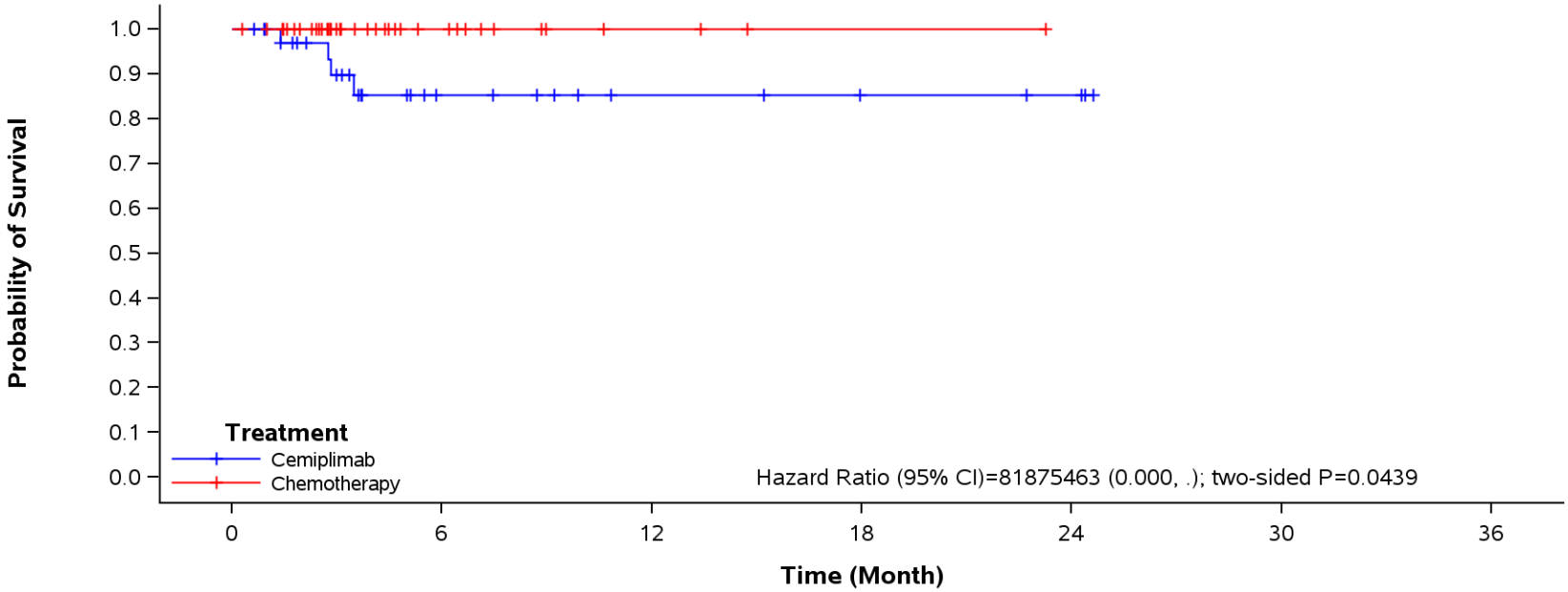

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 39 | 9 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Endocrine disorders



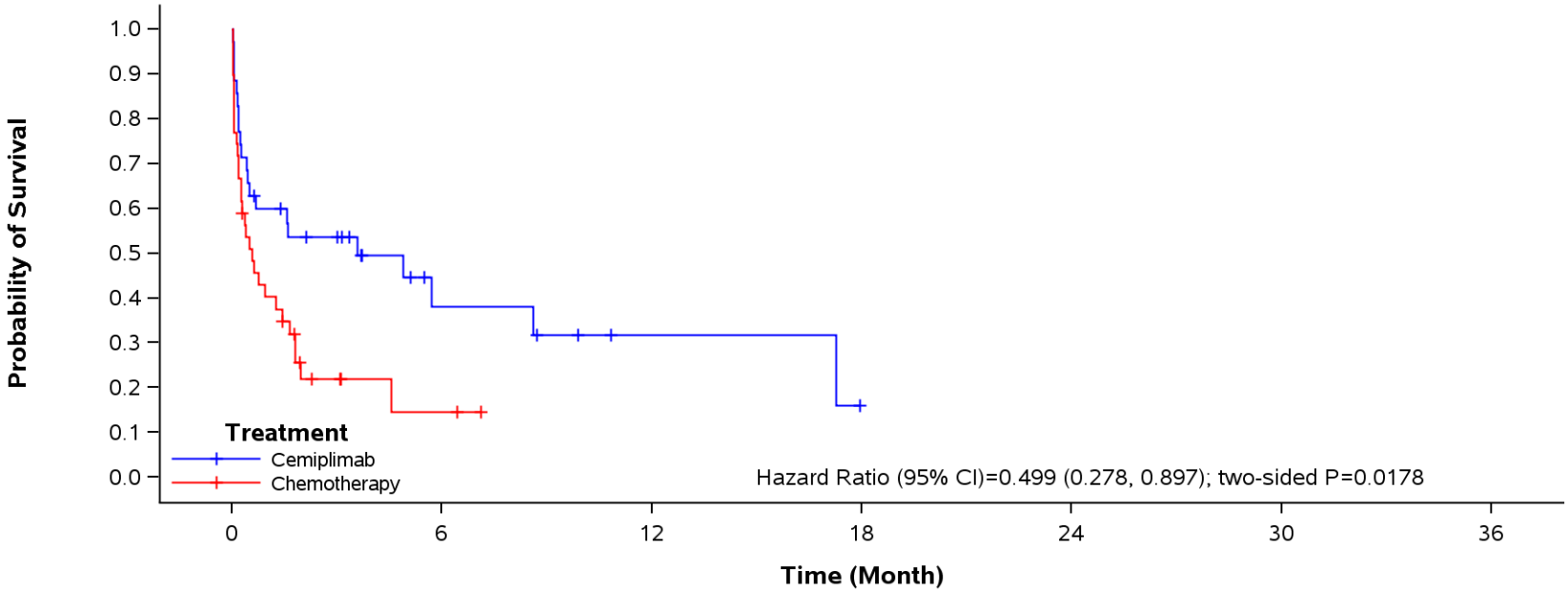

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders



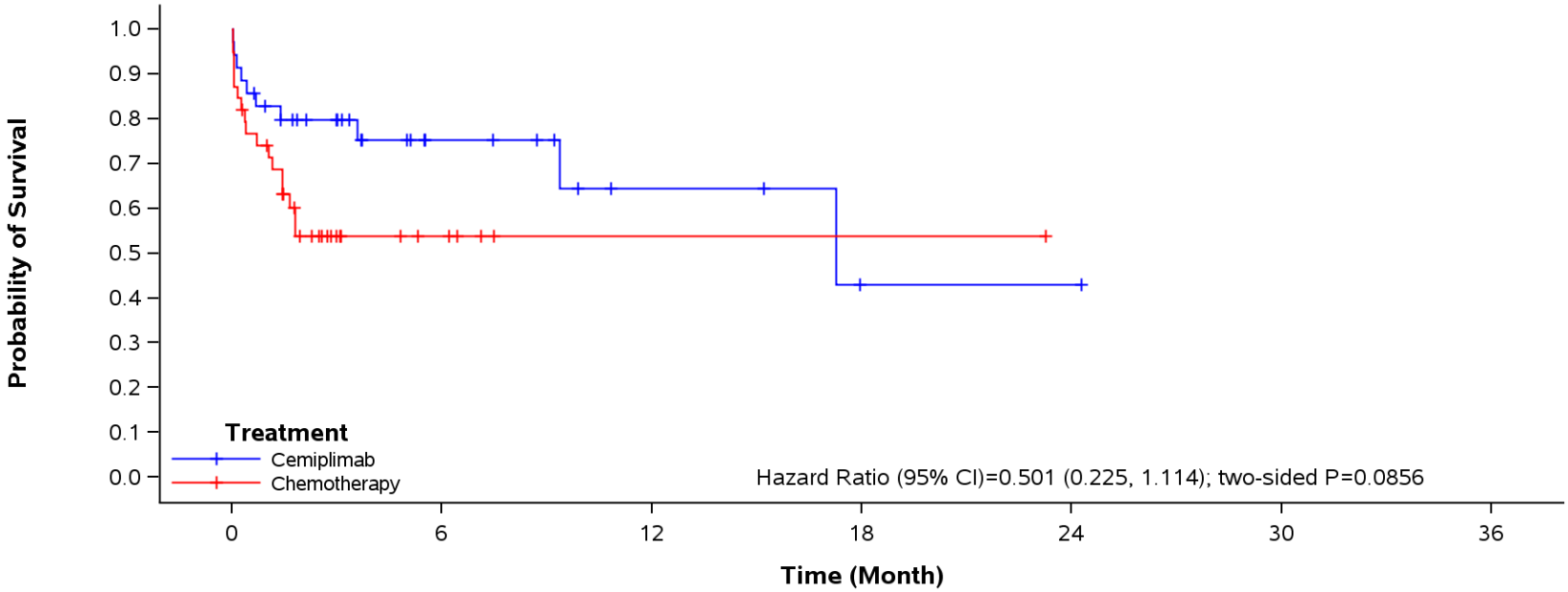

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 6 | 2 | 0 | 0 | 0 | 0 |
| Chemotherapy | 39 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders
PT: Nausea



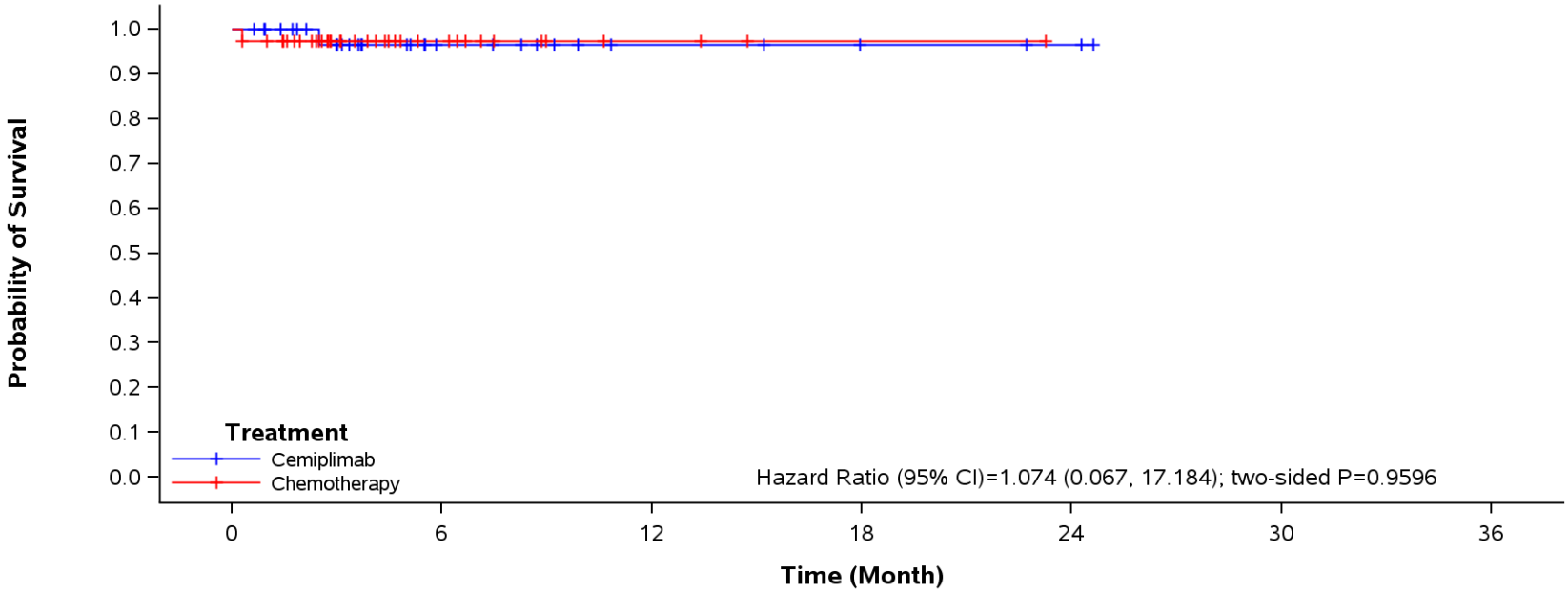

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 4 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders
PT: Stomatitis



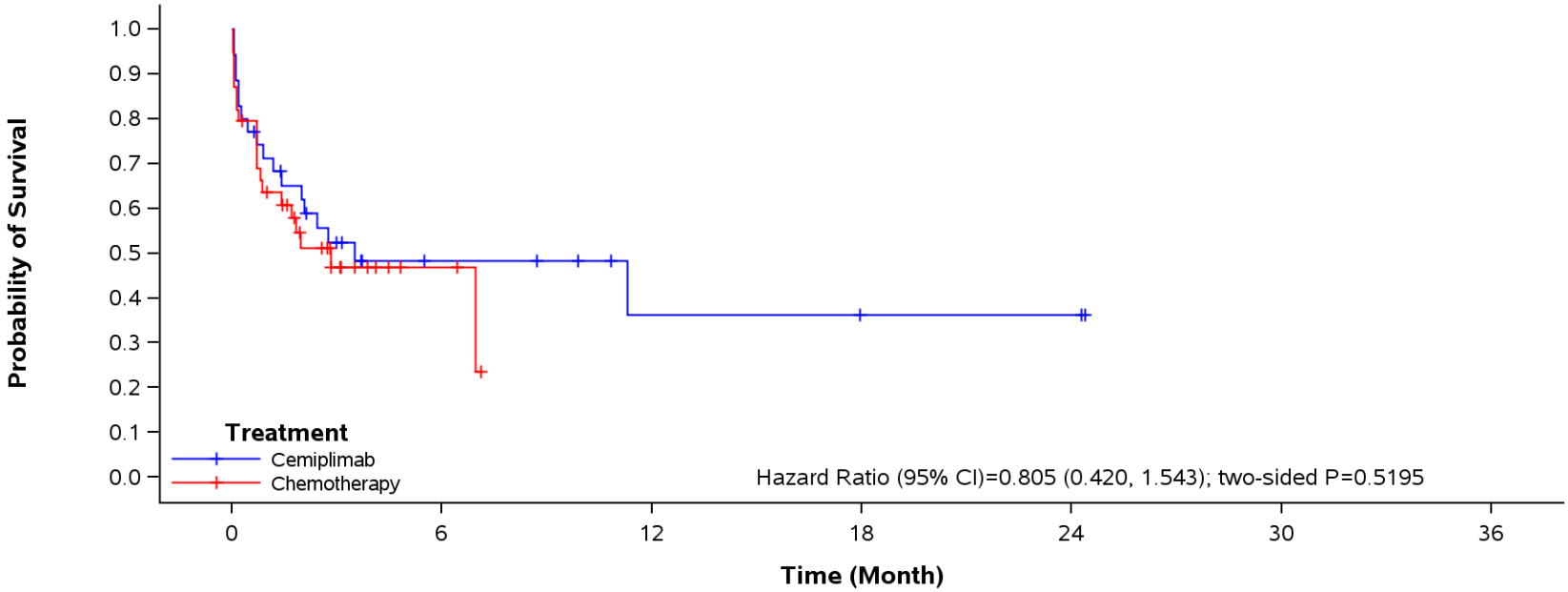

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: General disorders and administration site conditions



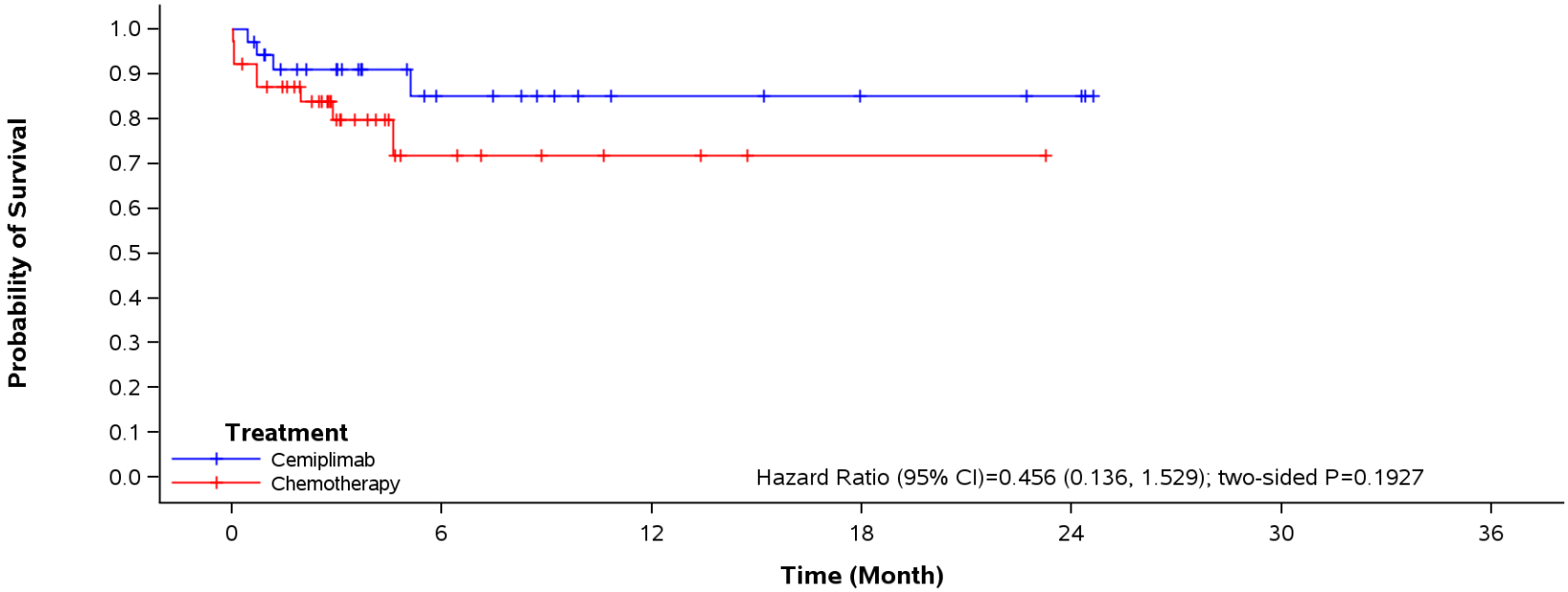

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 7 | 3 | 2 | 2 | 0 | 0 |
| Chemotherapy | 39 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: General disorders and administration site conditions
PT: Asthenia



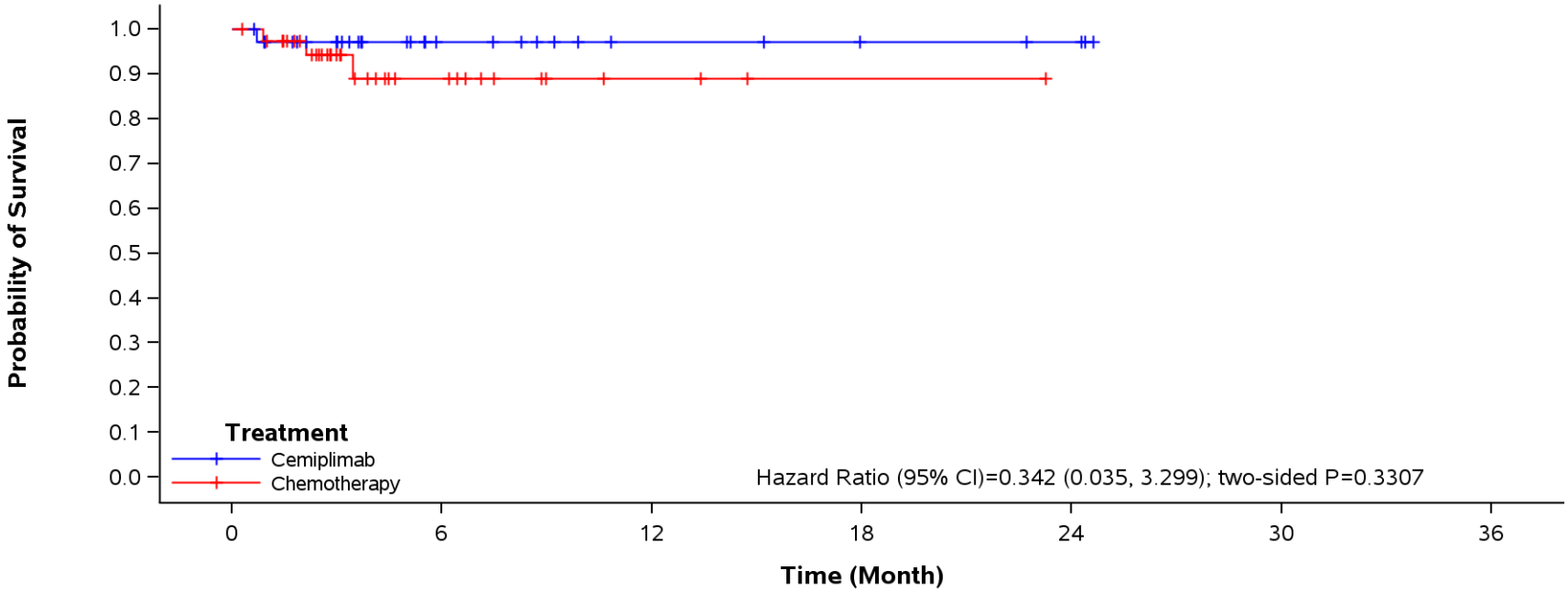

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



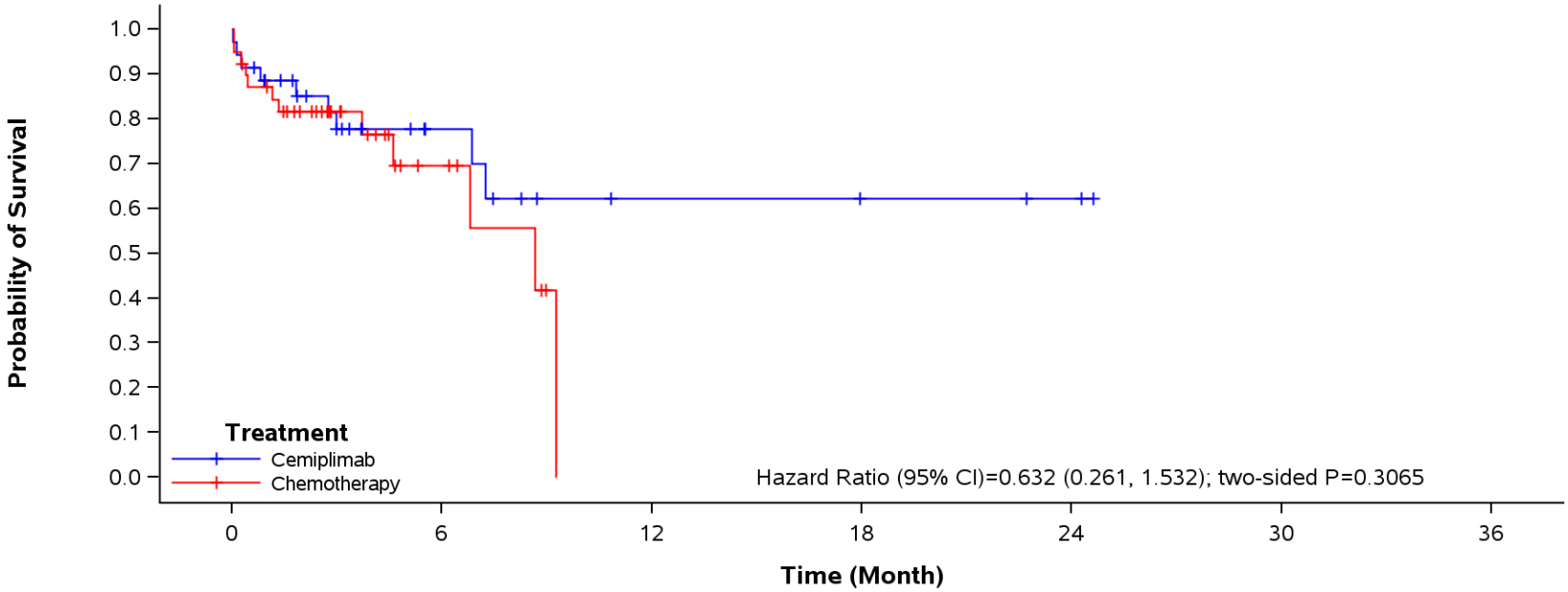

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Nervous system disorders



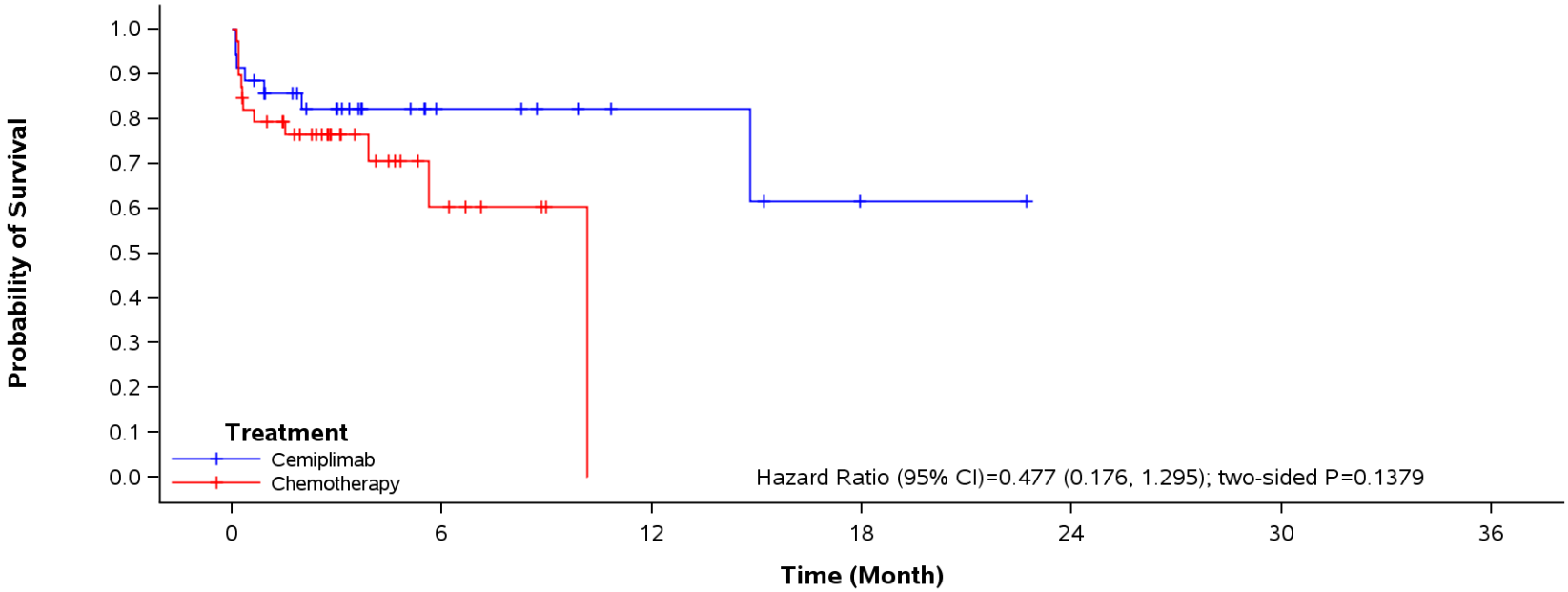

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 10 | 4 | 3 | 2 | 0 | 0 |
| Chemotherapy | 39 | 7 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Skin and subcutaneous tissue disorders



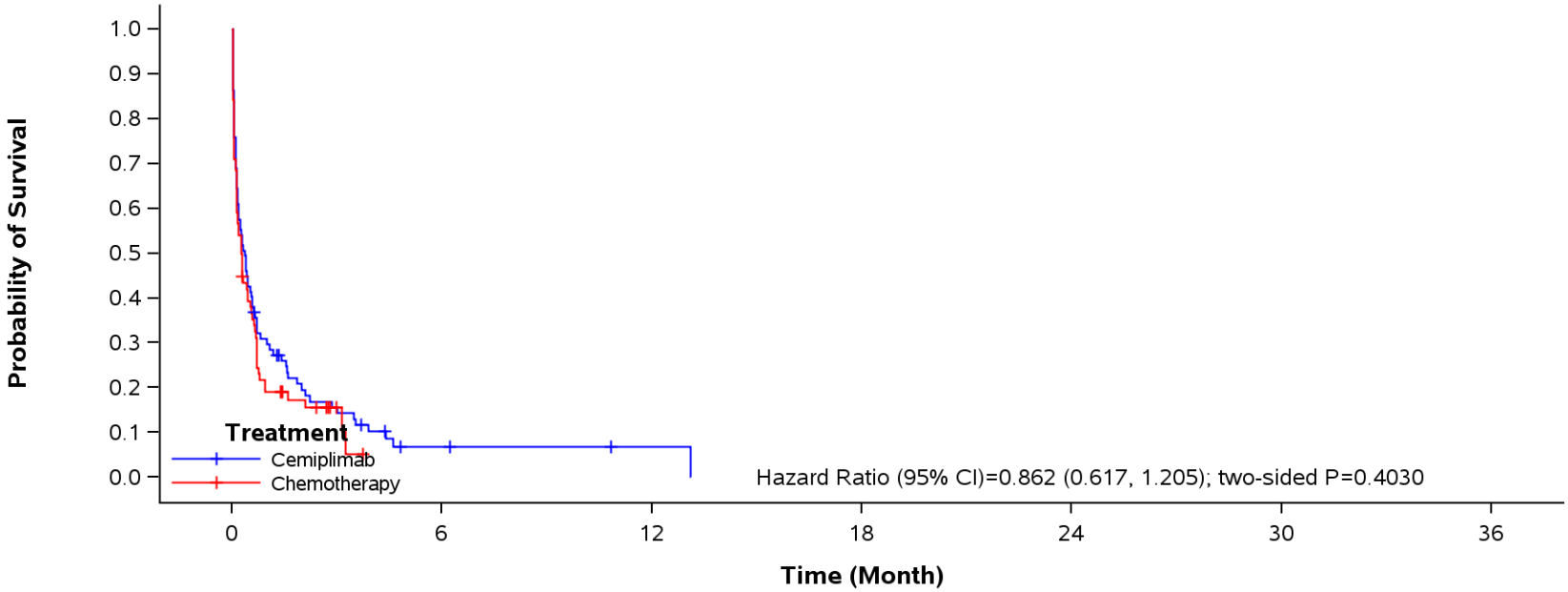

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 8 | 4 | 1 | 0 | 0 | 0 |
| Chemotherapy | 39 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Number of patients with any TEAE



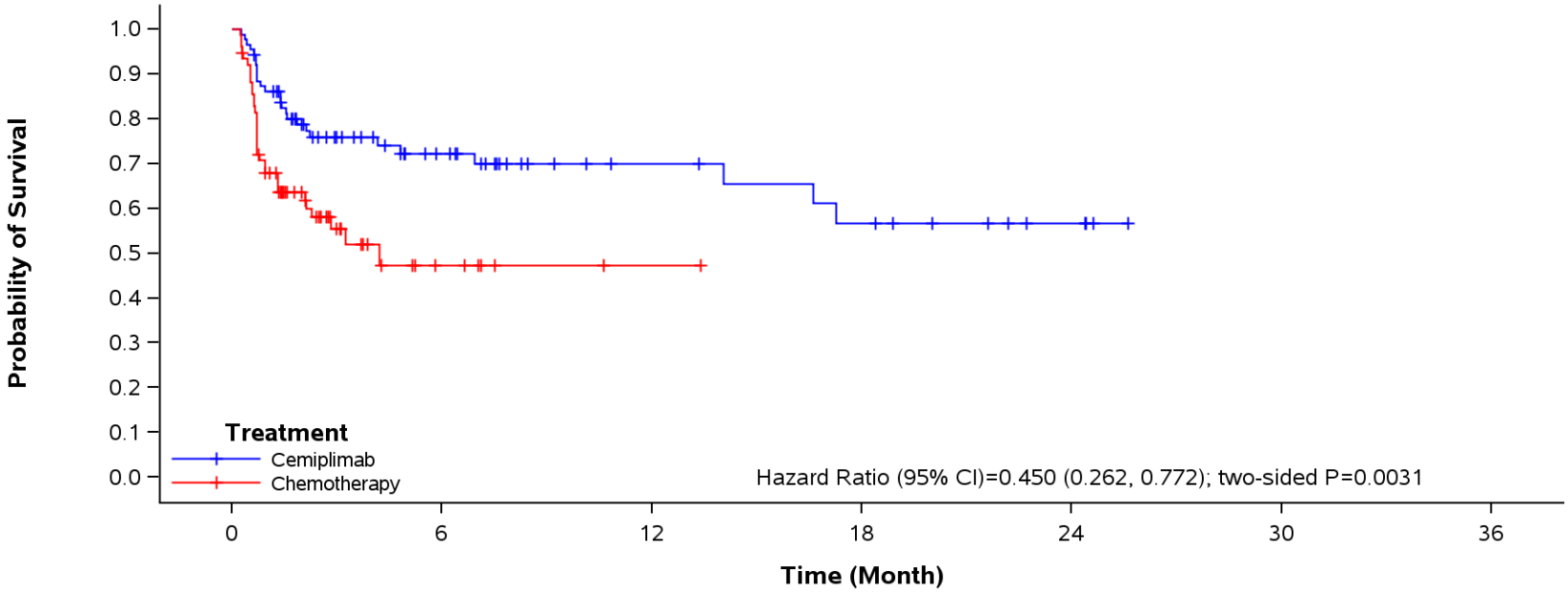

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 3 | 1 | 0 | 0 | 0 | 0 |
| Chemotherapy | 76 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders



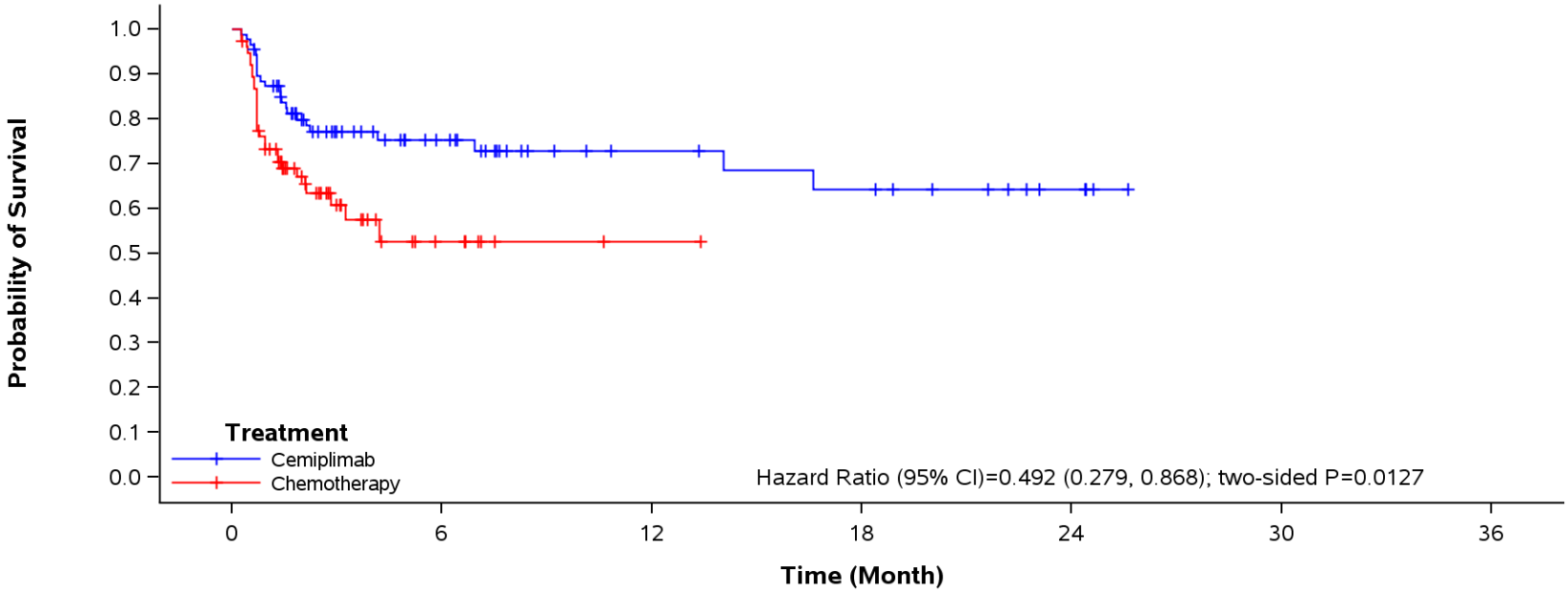

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 34 | 17 | 13 | 7 | 0 | 0 |
| Chemotherapy | 76 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Anaemia



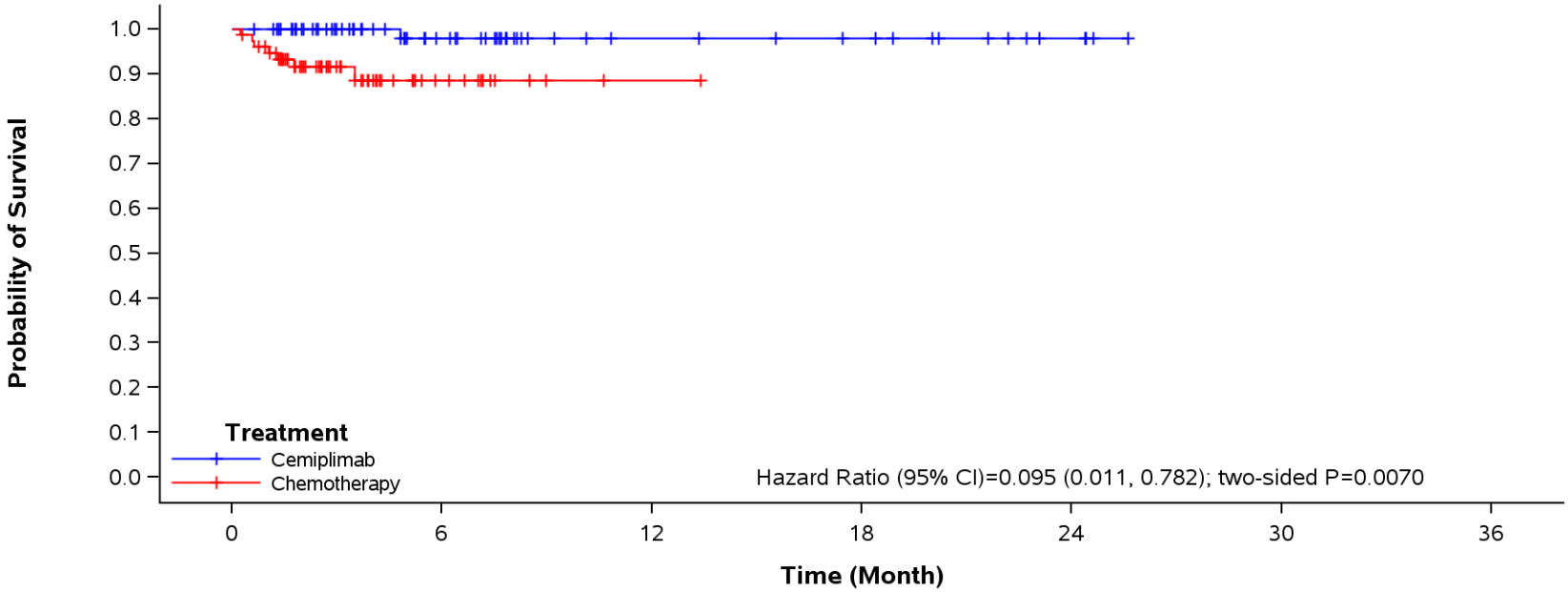

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 35 | 18 | 15 | 8 | 0 | 0 |
| Chemotherapy | 76 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Neutropenia



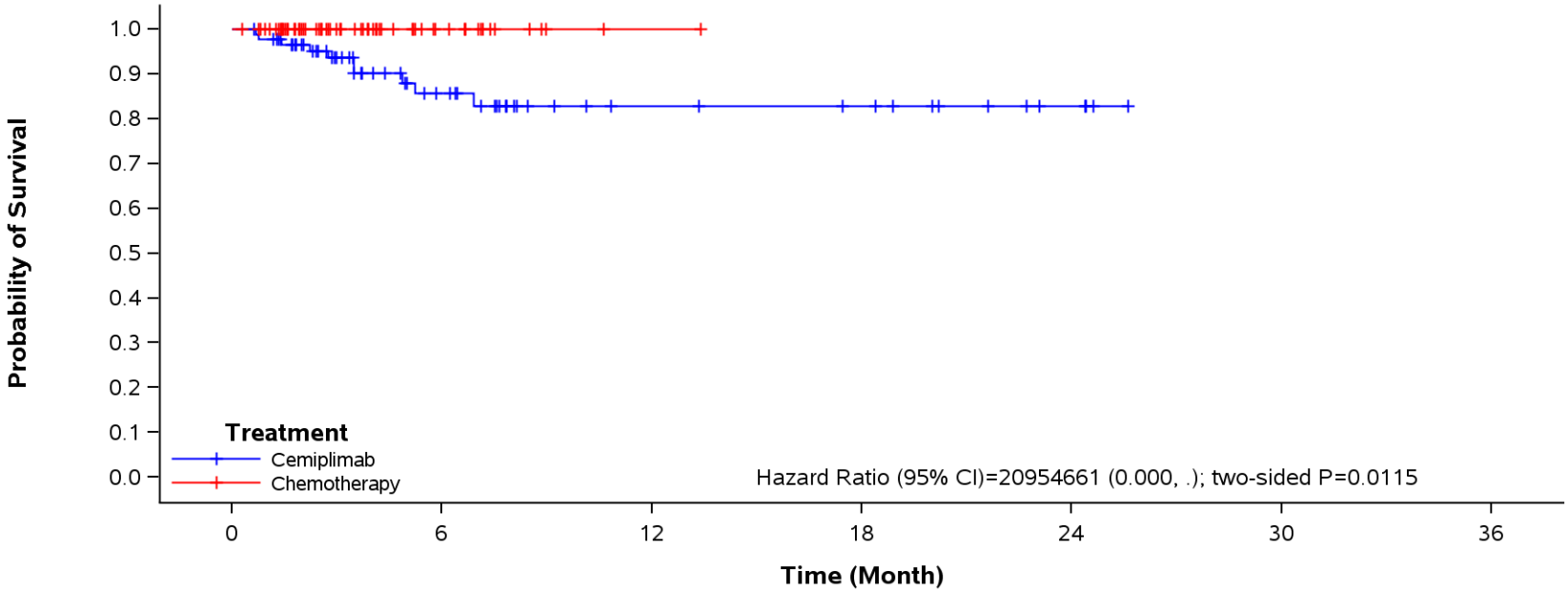

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 18 | 15 | 7 | 0 | 0 |
| Chemotherapy | 76 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Endocrine disorders



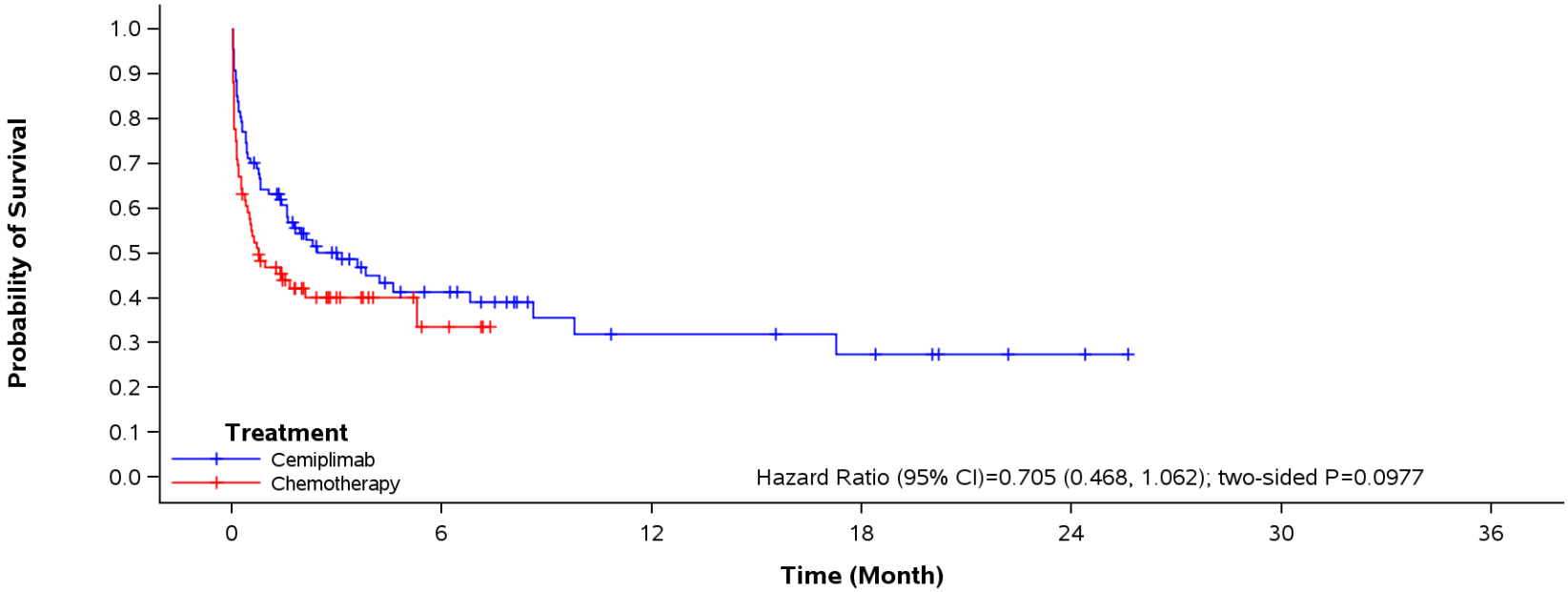

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 35 | 16 | 14 | 7 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders



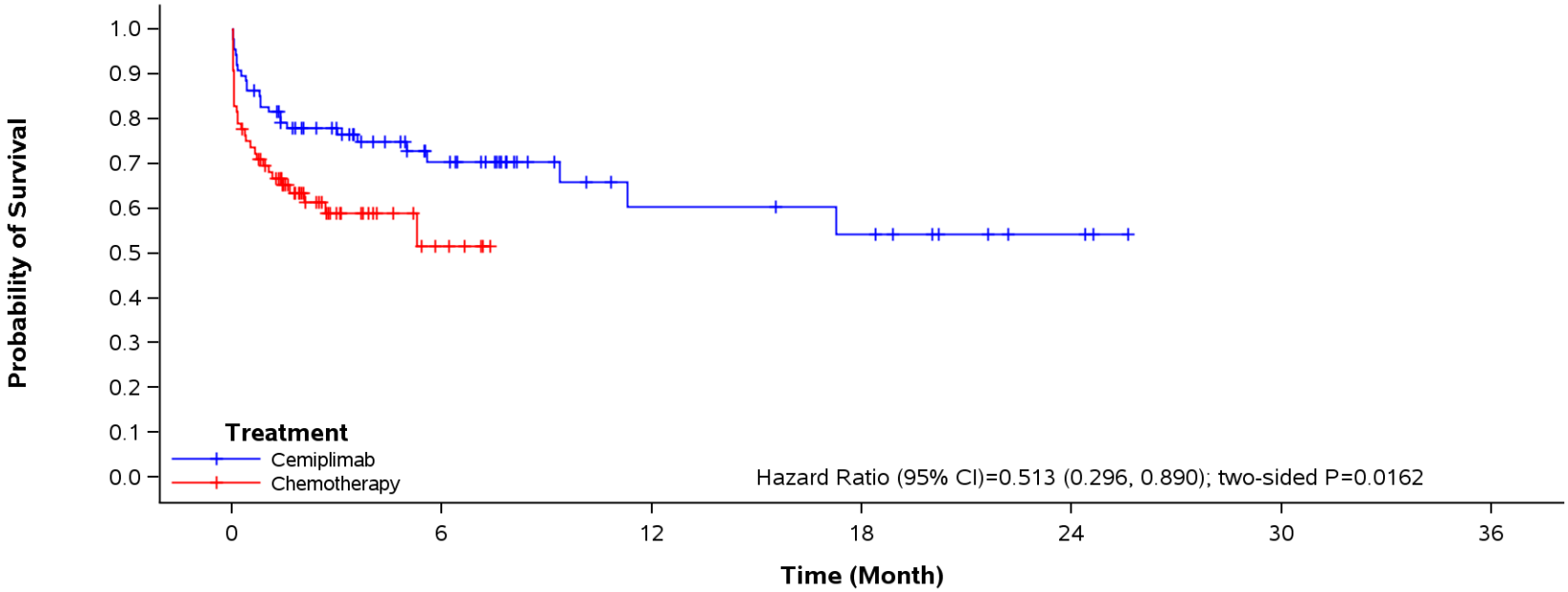

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 20 | 8 | 6 | 2 | 0 | 0 |
| Chemotherapy | 76 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders
PT: Nausea



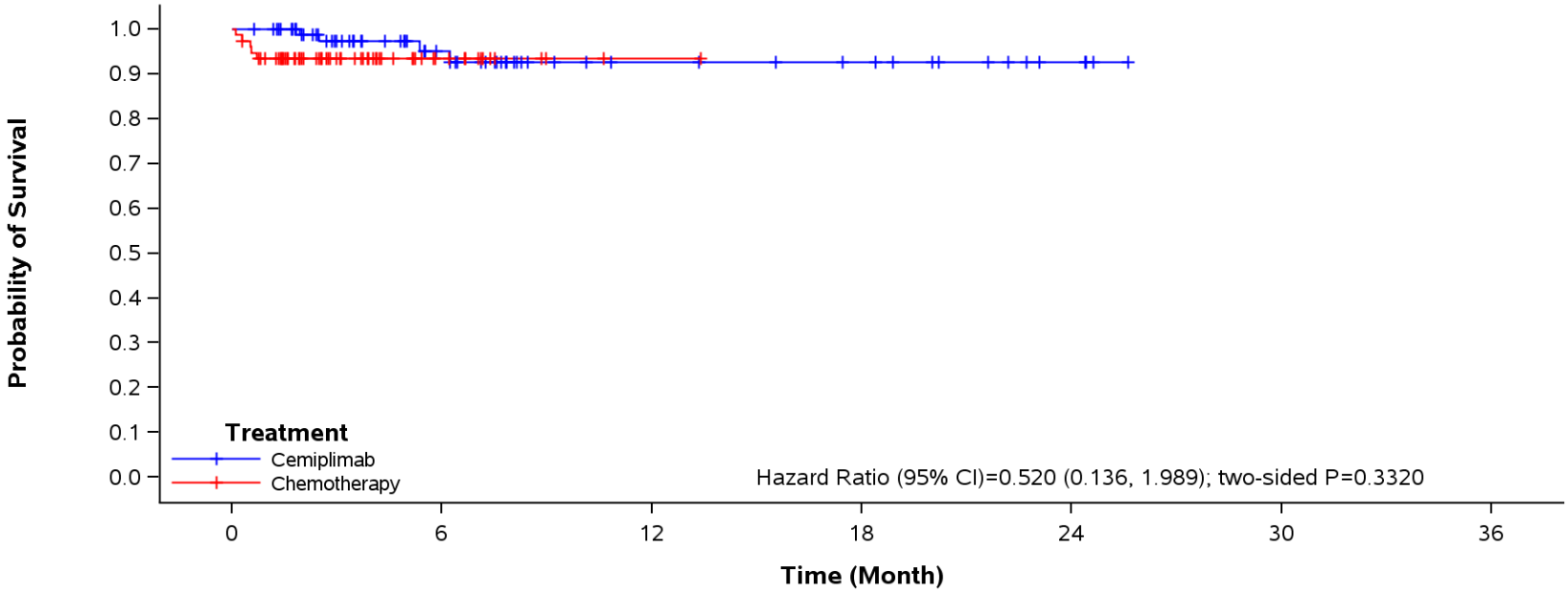

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 31 | 11 | 9 | 3 | 0 | 0 |
| Chemotherapy | 76 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders
PT: Stomatitis



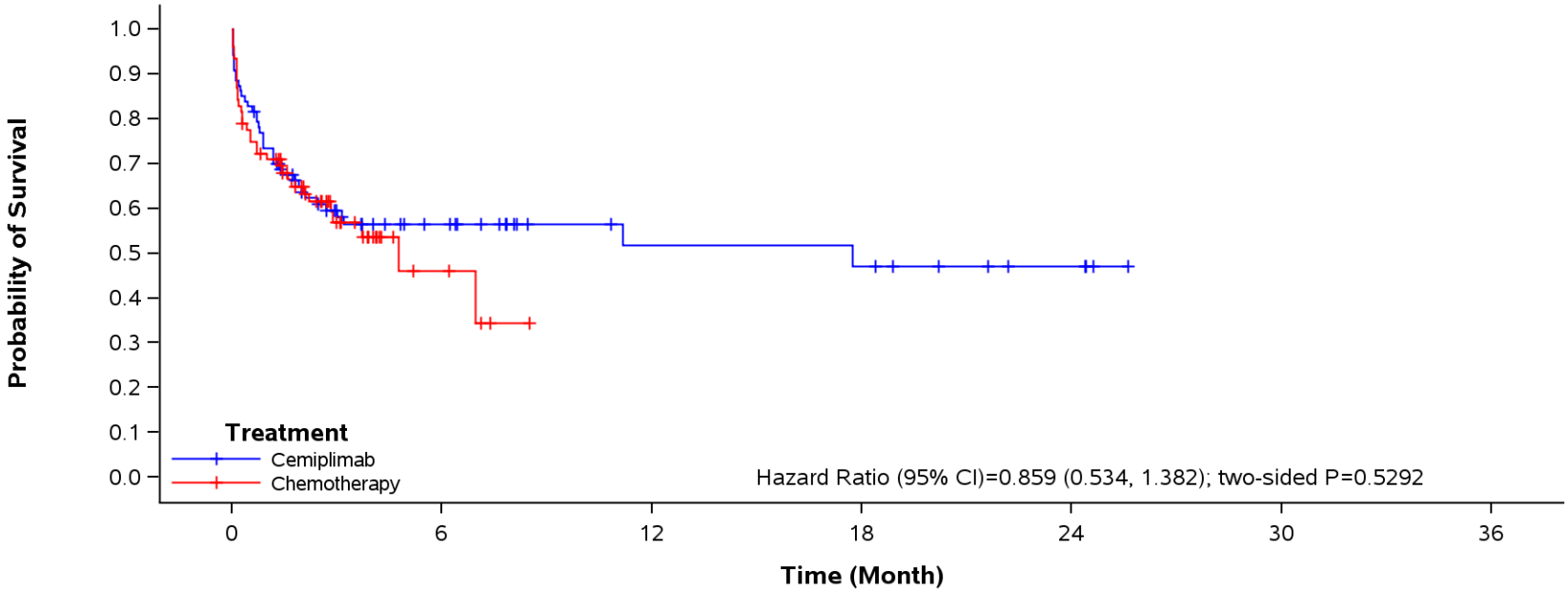

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 39 | 17 | 14 | 6 | 0 | 0 |
| Chemotherapy | 76 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: General disorders and administration site conditions




**Number of Subjects at risk**

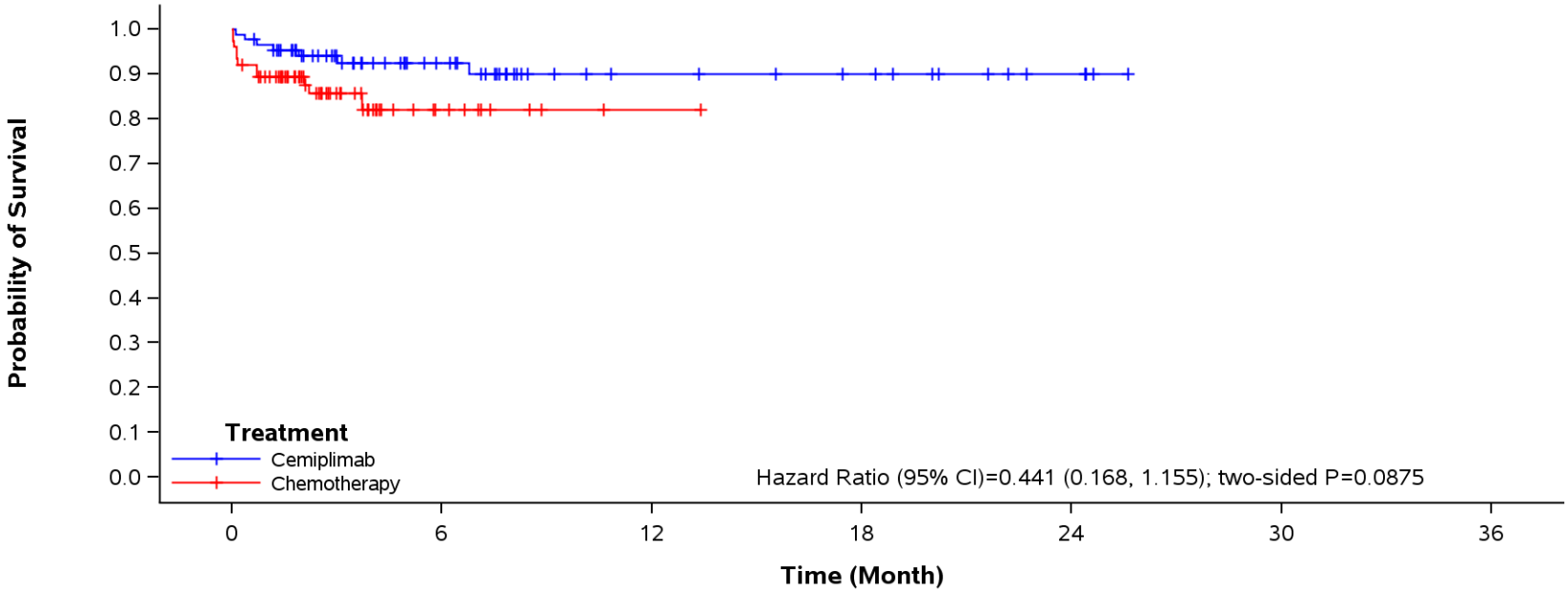
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 25 | 11 | 10 | 5 | 0 | 0 |
| Chemotherapy | 76 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: General disorders and administration site conditions
PT: Asthenia



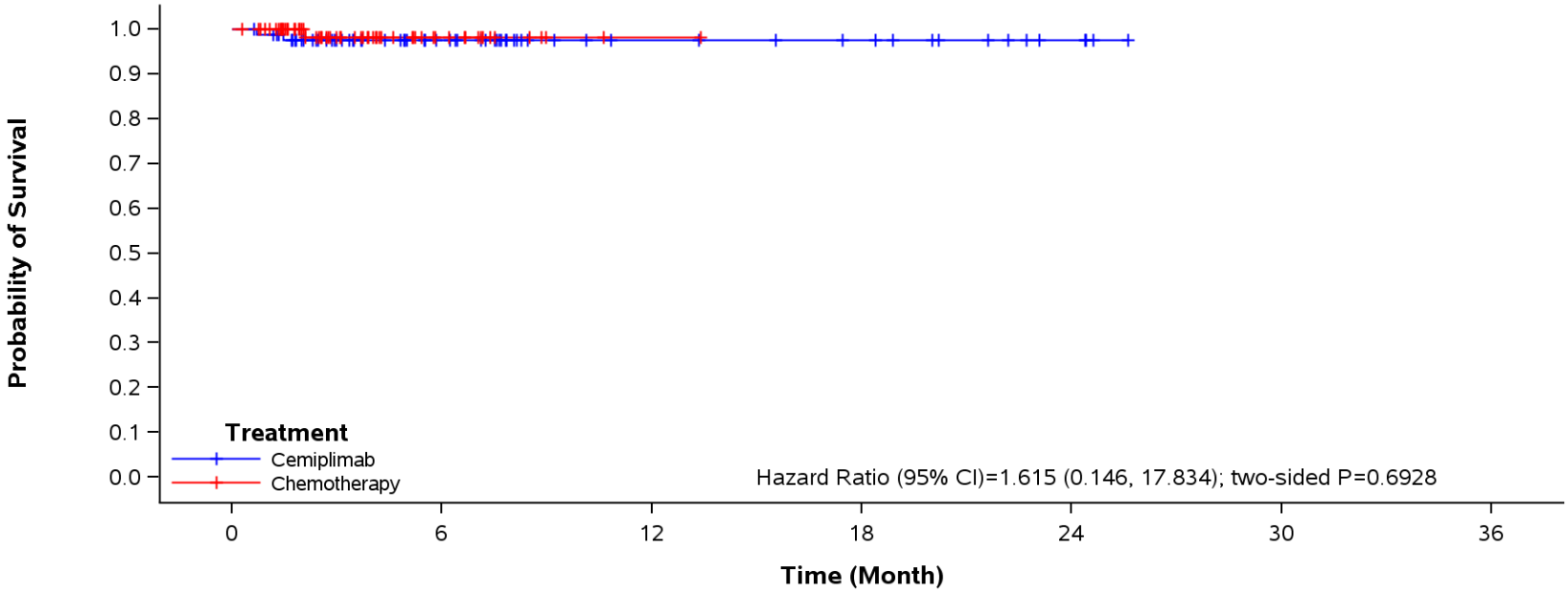

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 18 | 15 | 8 | 0 | 0 |
| Chemotherapy | 76 | 9 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



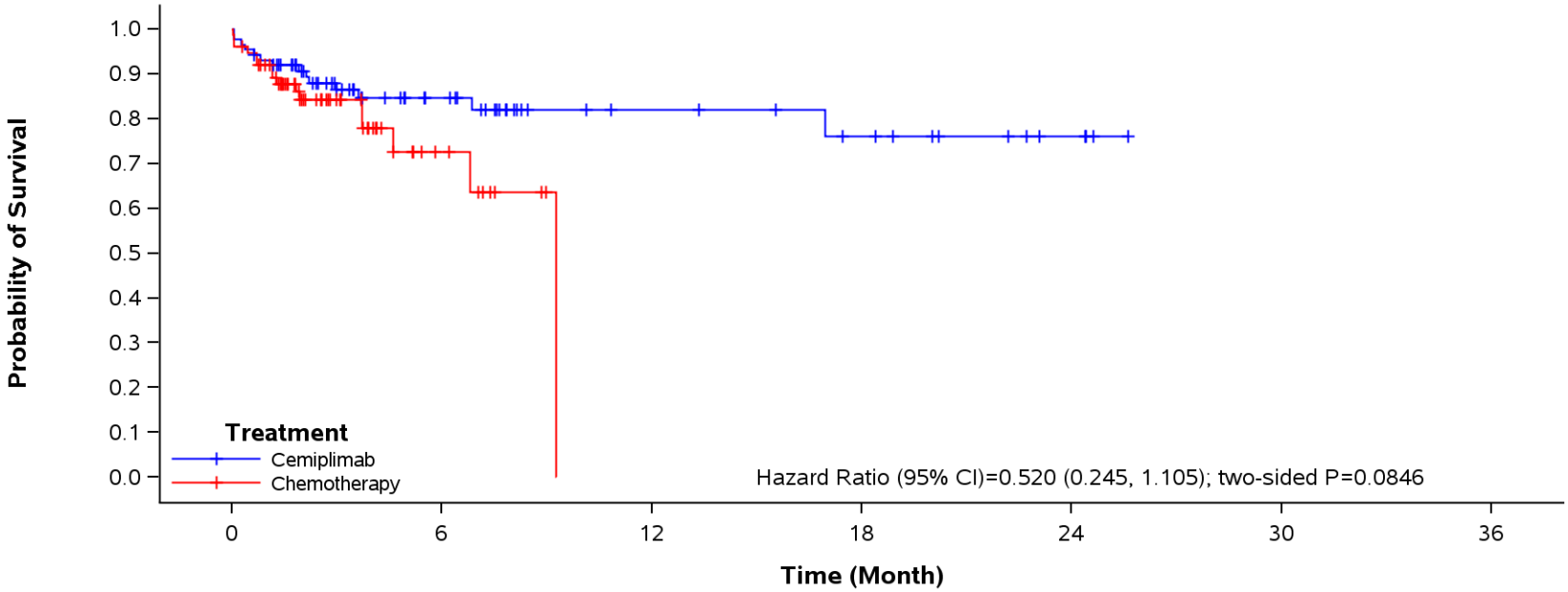

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Nervous system disorders



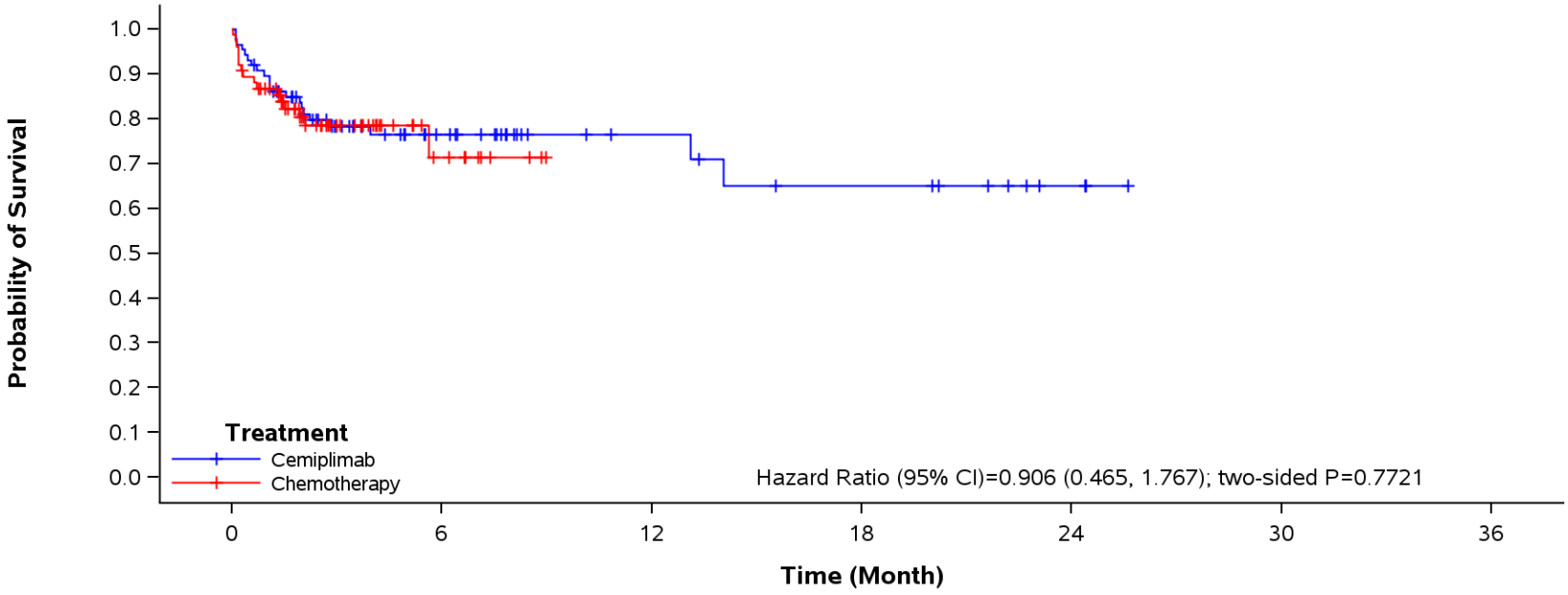

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 35 | 16 | 12 | 5 | 0 | 0 |
| Chemotherapy | 76 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Skin and subcutaneous tissue disorders



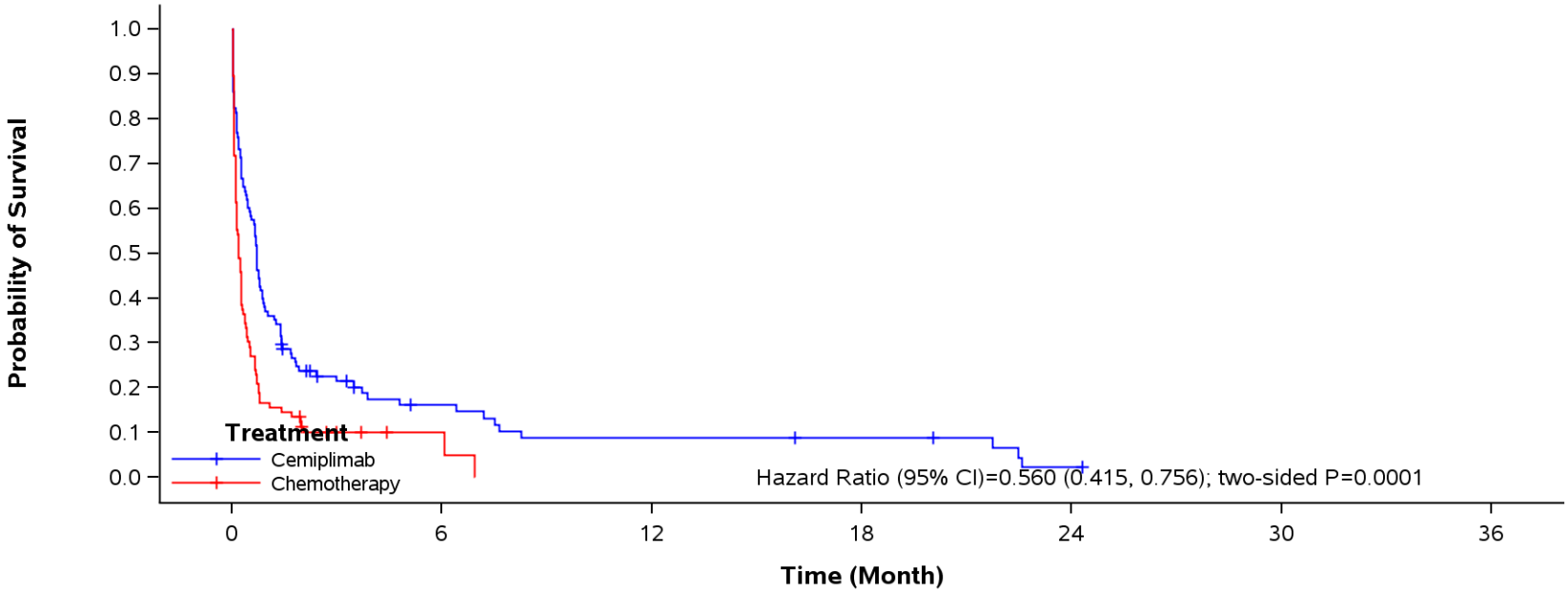

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 32 | 14 | 10 | 4 | 0 | 0 |
| Chemotherapy | 76 | 9 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Number of patients with any TEAE



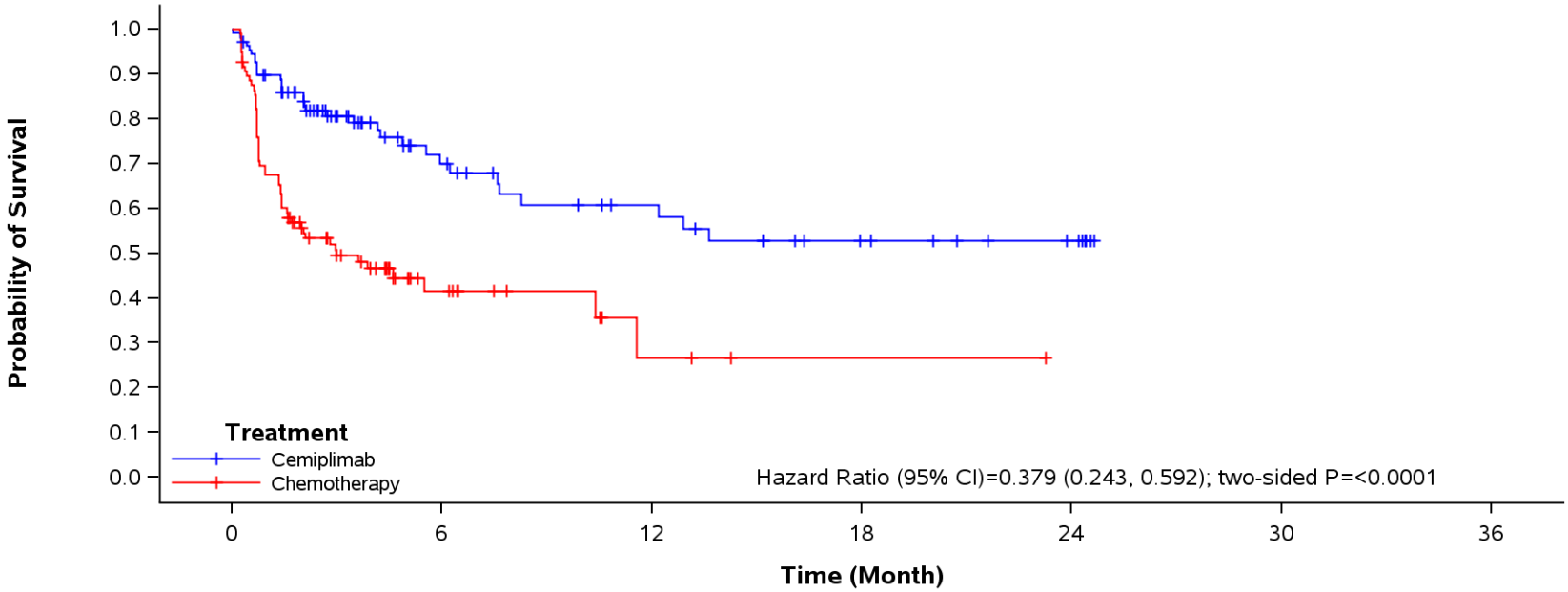

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 11 | 6 | 5 | 1 | 0 | 0 |
| Chemotherapy | 96 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders



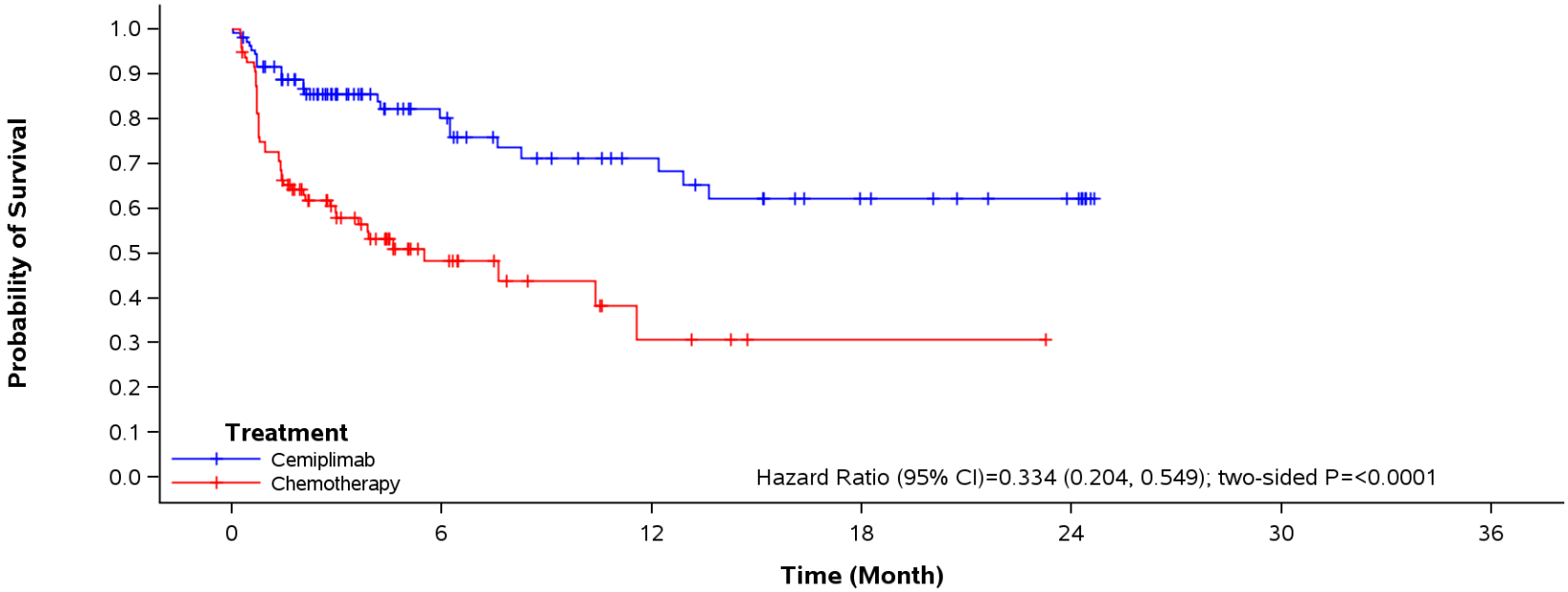

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 34 | 23 | 14 | 9 | 0 | 0 |
| Chemotherapy | 96 | 14 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Anaemia



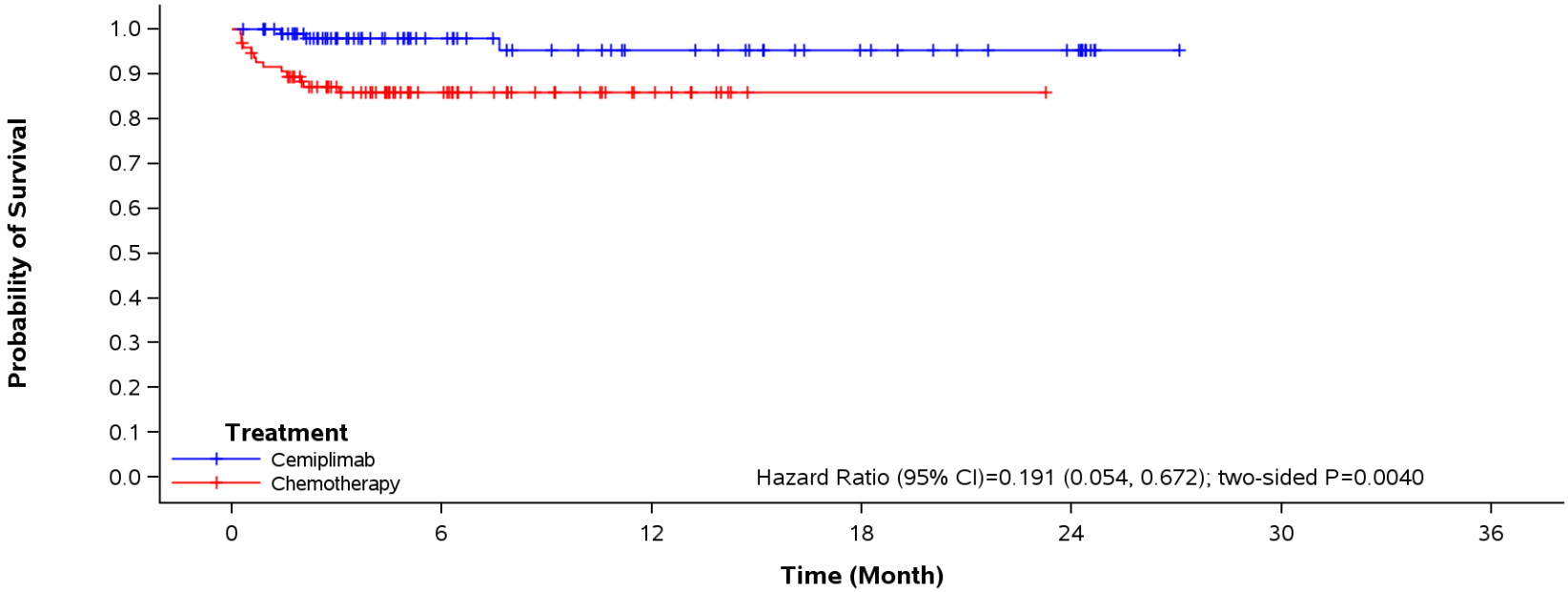

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 39 | 24 | 15 | 10 | 0 | 0 |
| Chemotherapy | 96 | 17 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Neutropenia



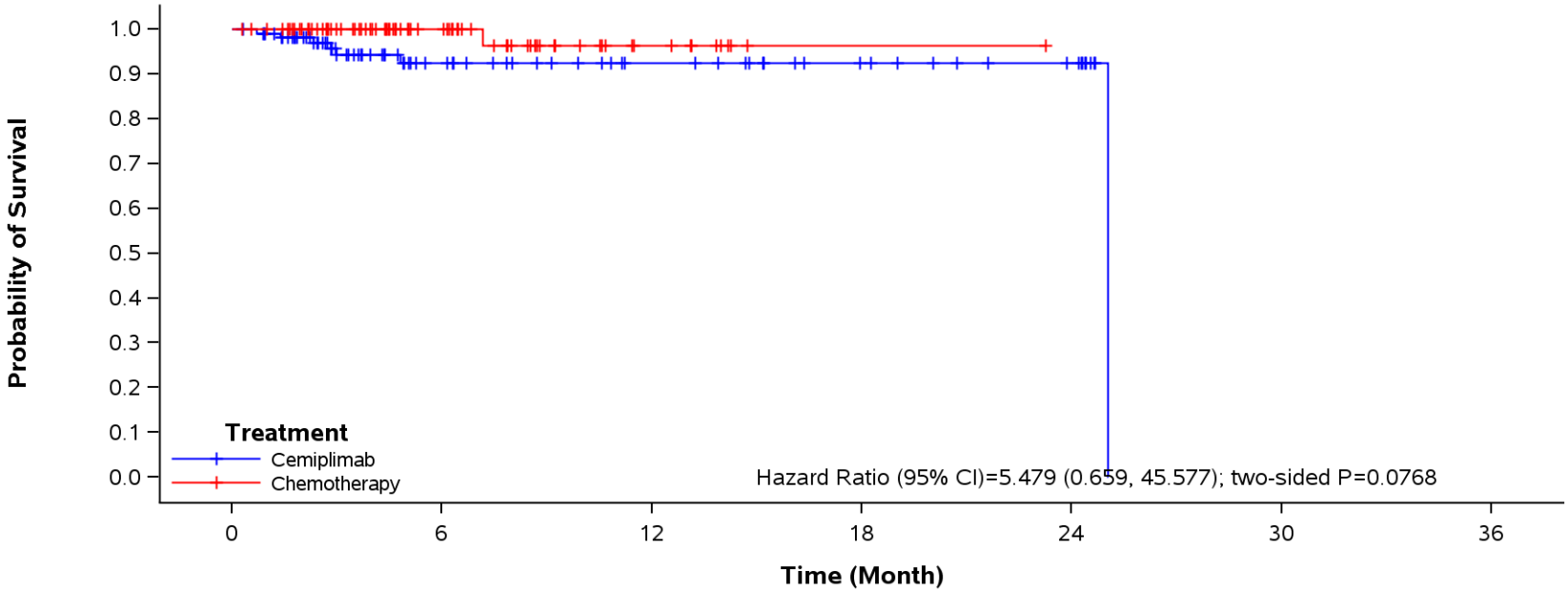

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 34 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Endocrine disorders



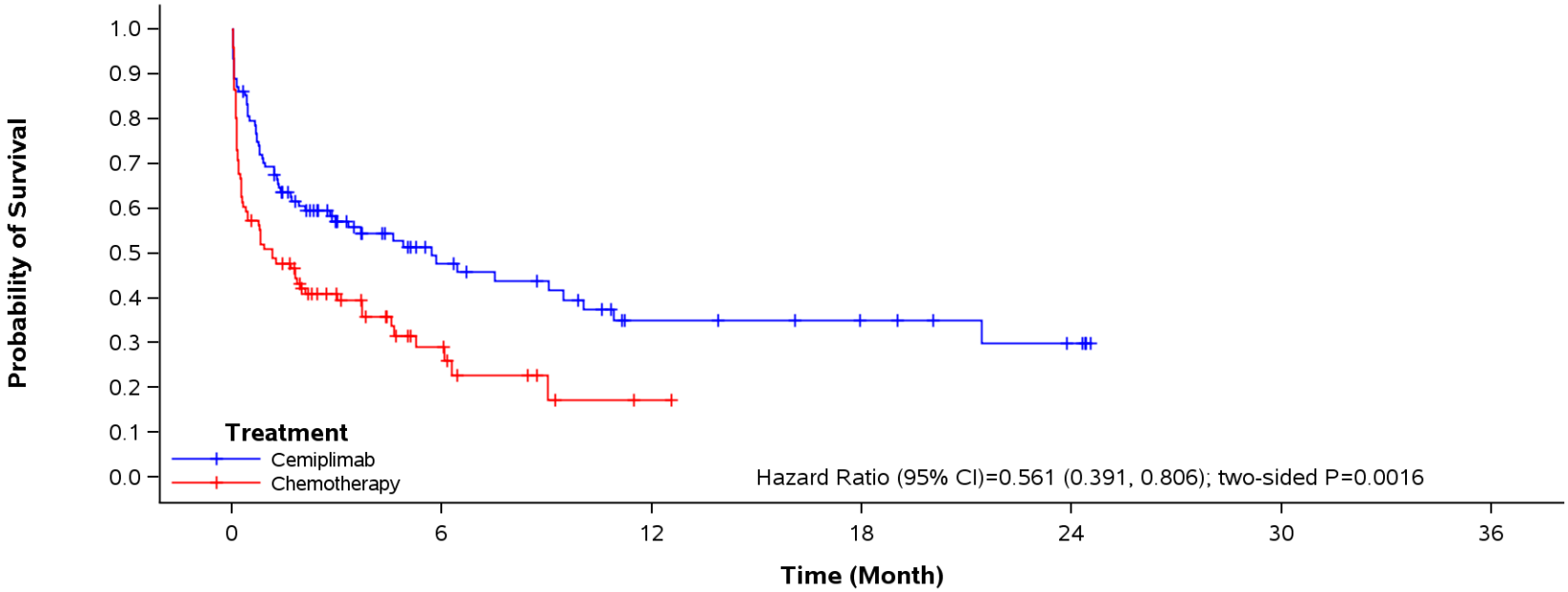

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 42 | 28 | 19 | 13 | 0 | 0 |
| Chemotherapy | 96 | 39 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders



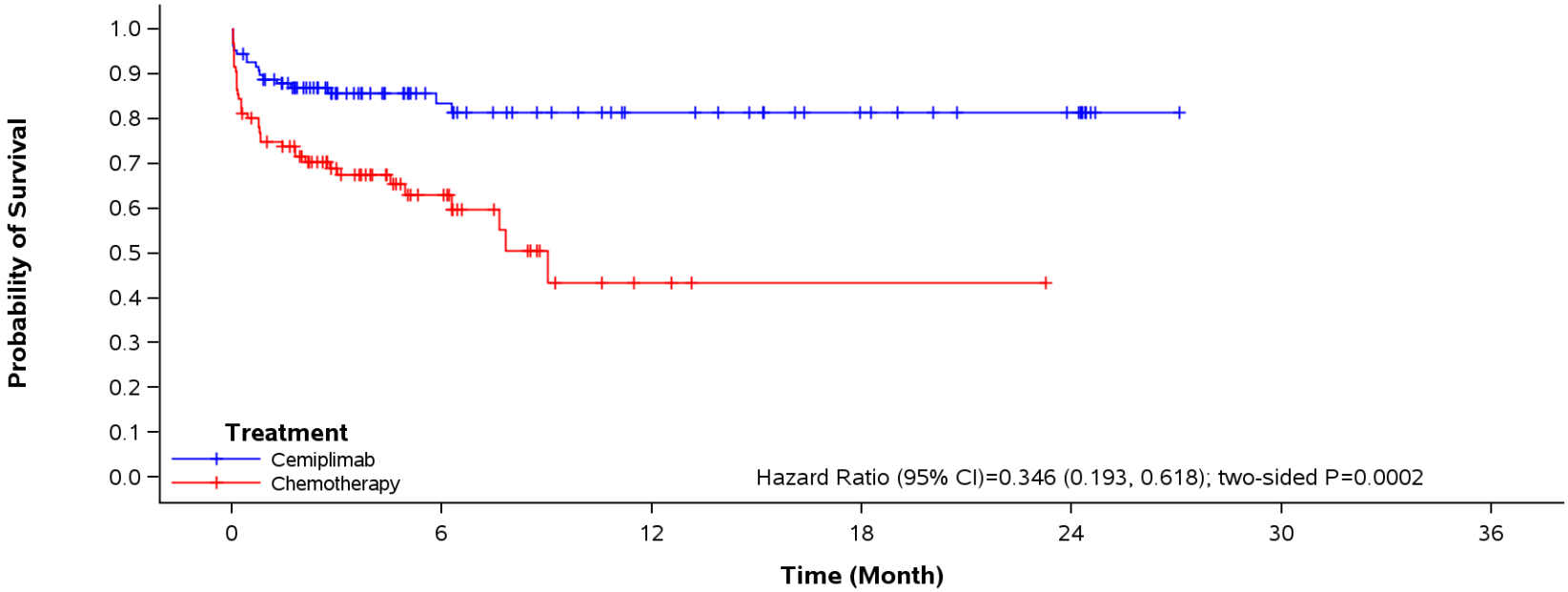

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 26 | 12 | 9 | 5 | 0 | 0 |
| Chemotherapy | 96 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders
PT: Nausea



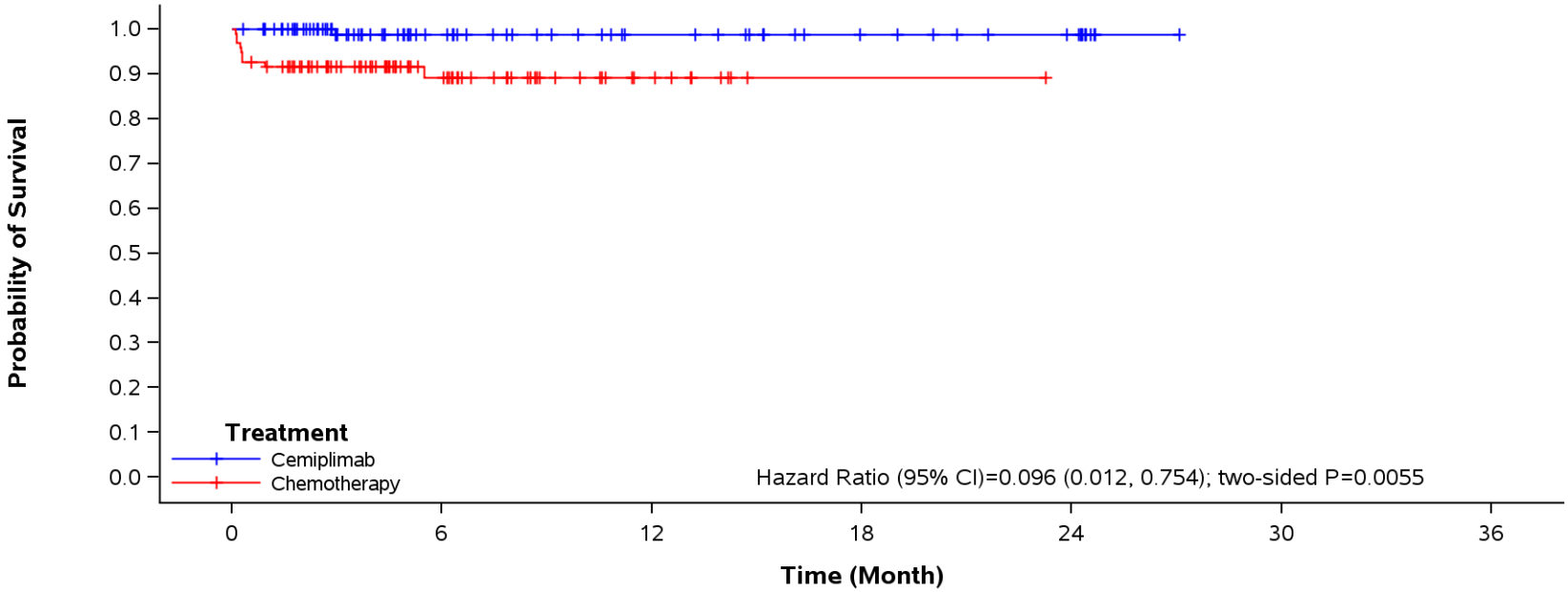

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 40 | 25 | 17 | 12 | 0 | 0 |
| Chemotherapy | 96 | 23 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders
PT: Stomatitis



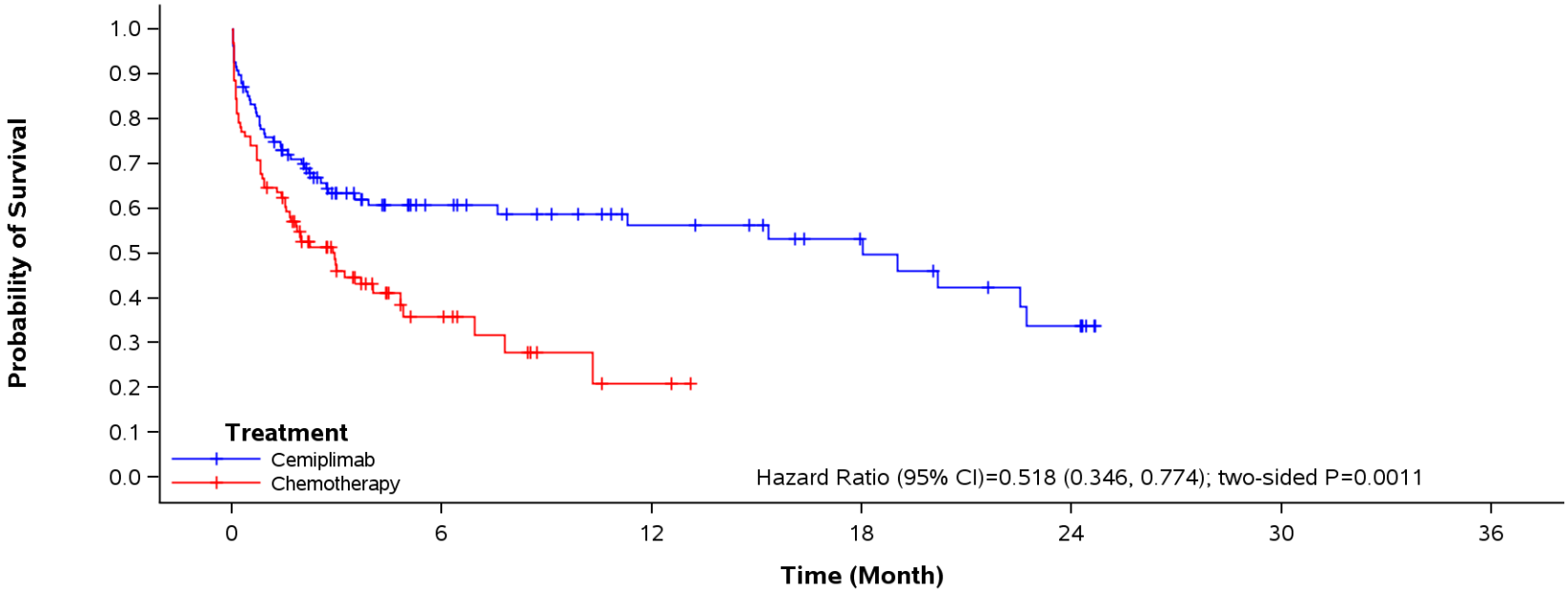

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 28 | 19 | 14 | 0 | 0 |
| Chemotherapy | 96 | 36 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: General disorders and administration site conditions



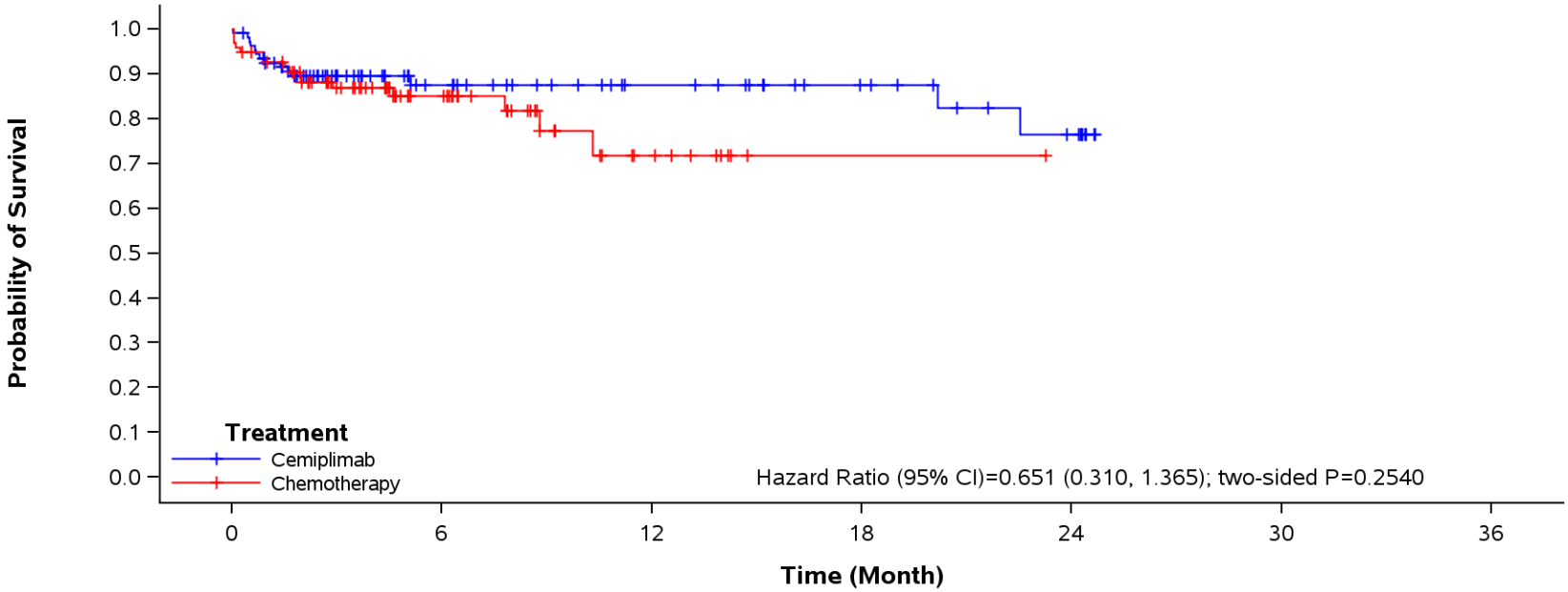

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 34 | 22 | 15 | 8 | 0 | 0 |
| Chemotherapy | 96 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: General disorders and administration site conditions
PT: Asthenia



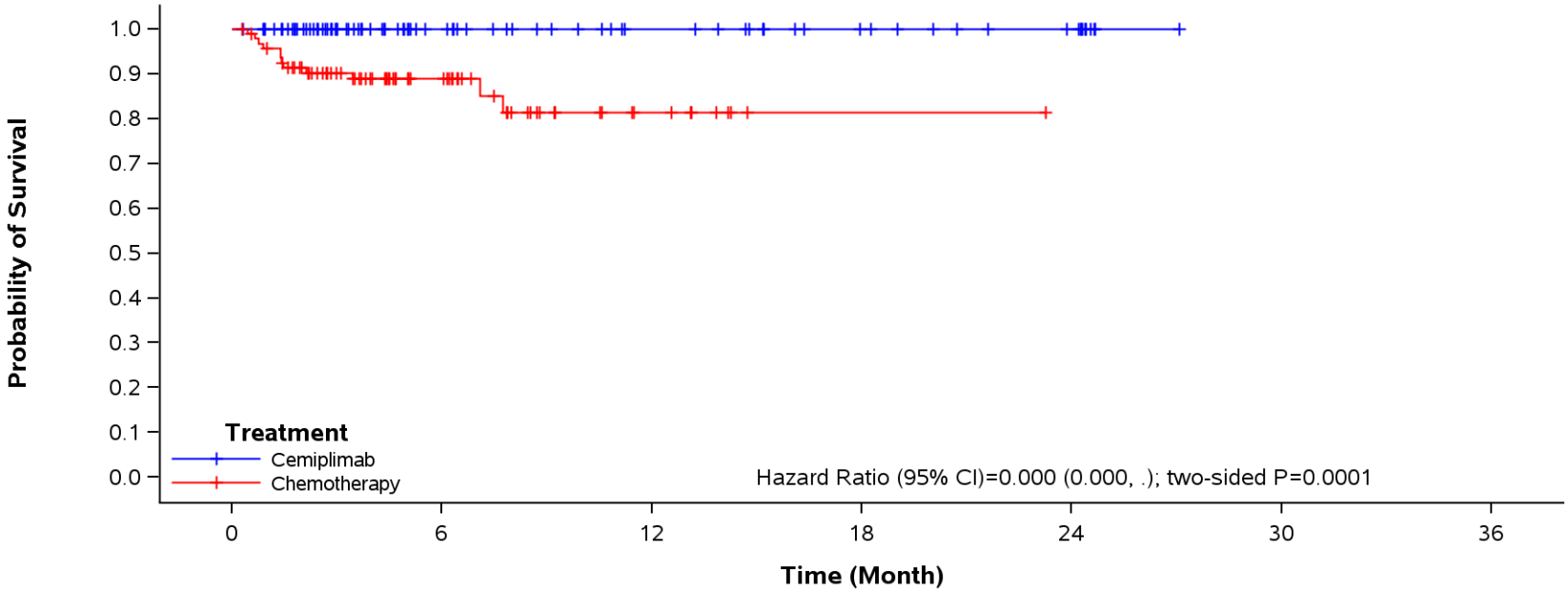

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 29 | 20 | 12 | 0 | 0 |
| Chemotherapy | 96 | 36 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



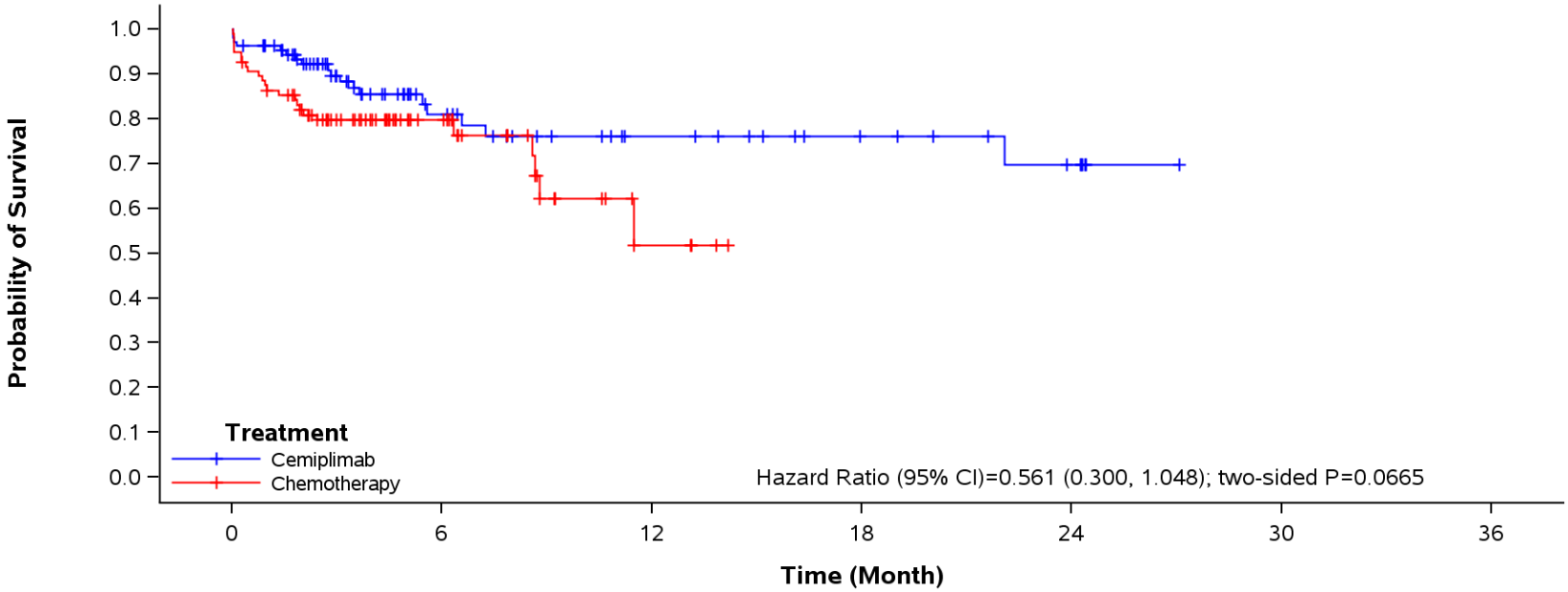

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Nervous system disorders



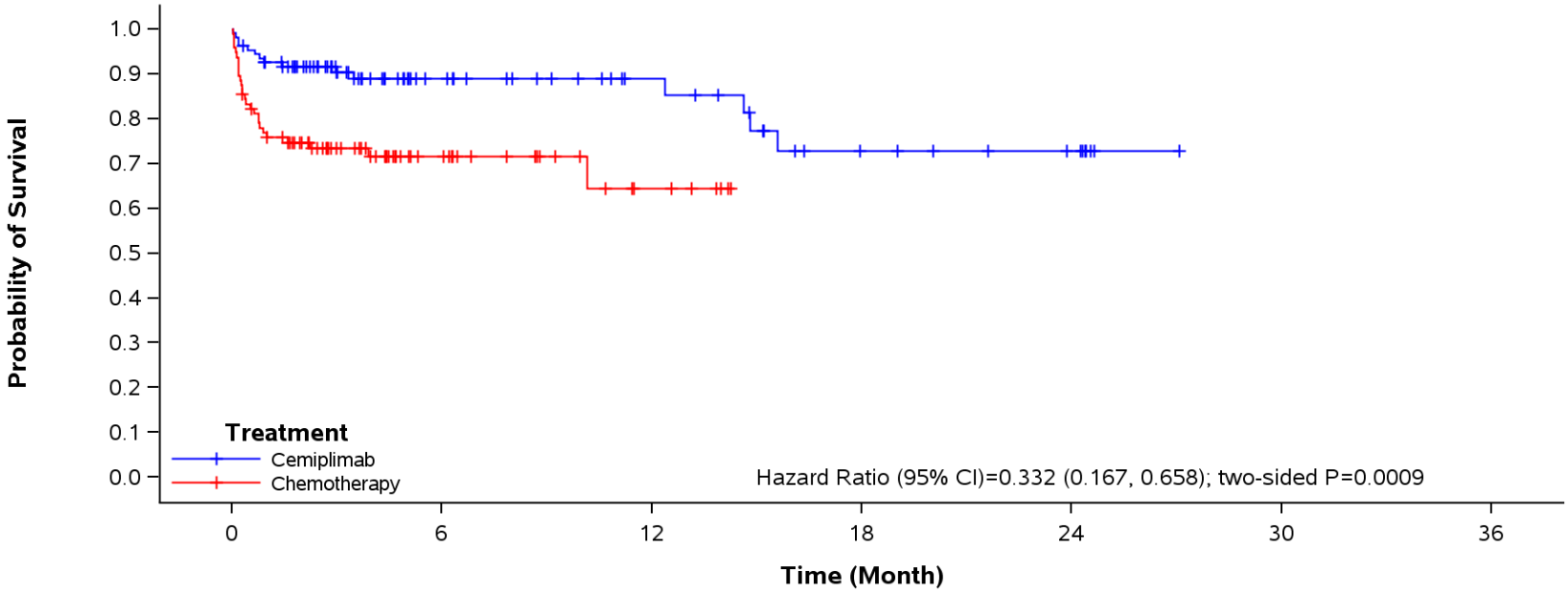

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 36 | 22 | 15 | 10 | 0 | 0 |
| Chemotherapy | 96 | 30 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Skin and subcutaneous tissue disorders



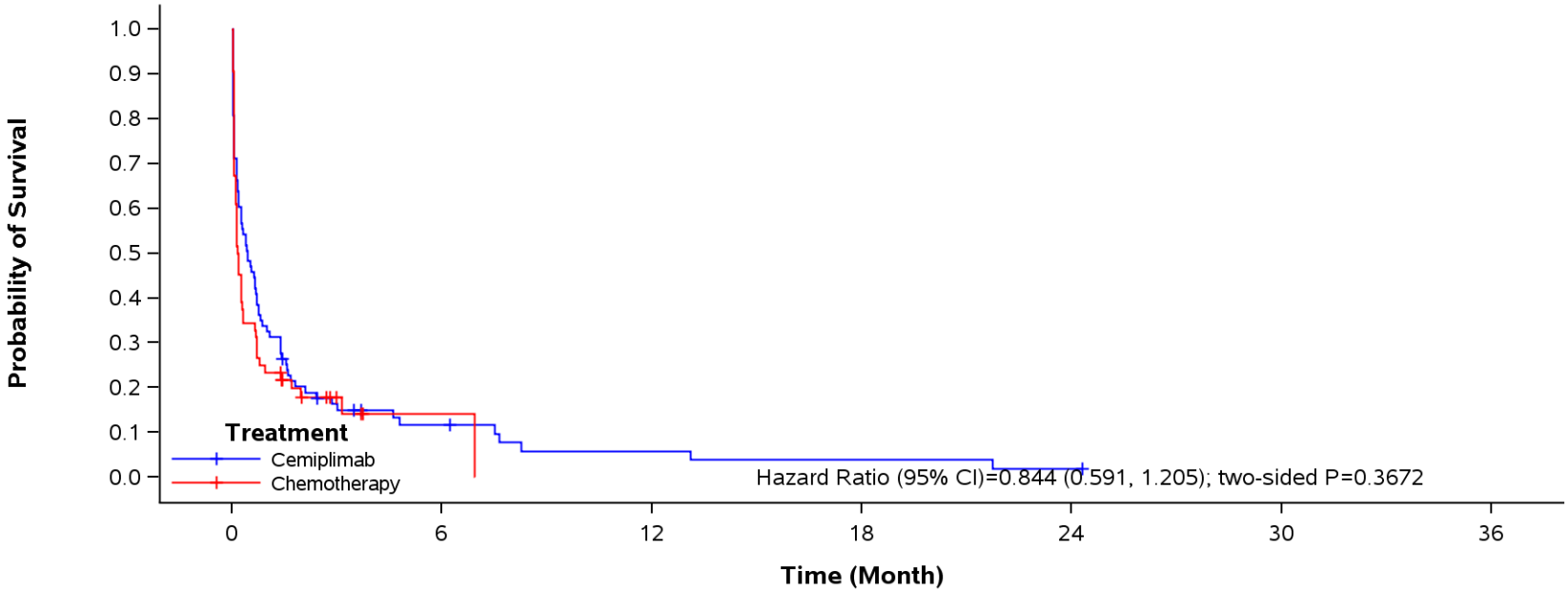

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 38 | 25 | 13 | 9 | 0 | 0 |
| Chemotherapy | 96 | 22 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Number of patients with any TEAE



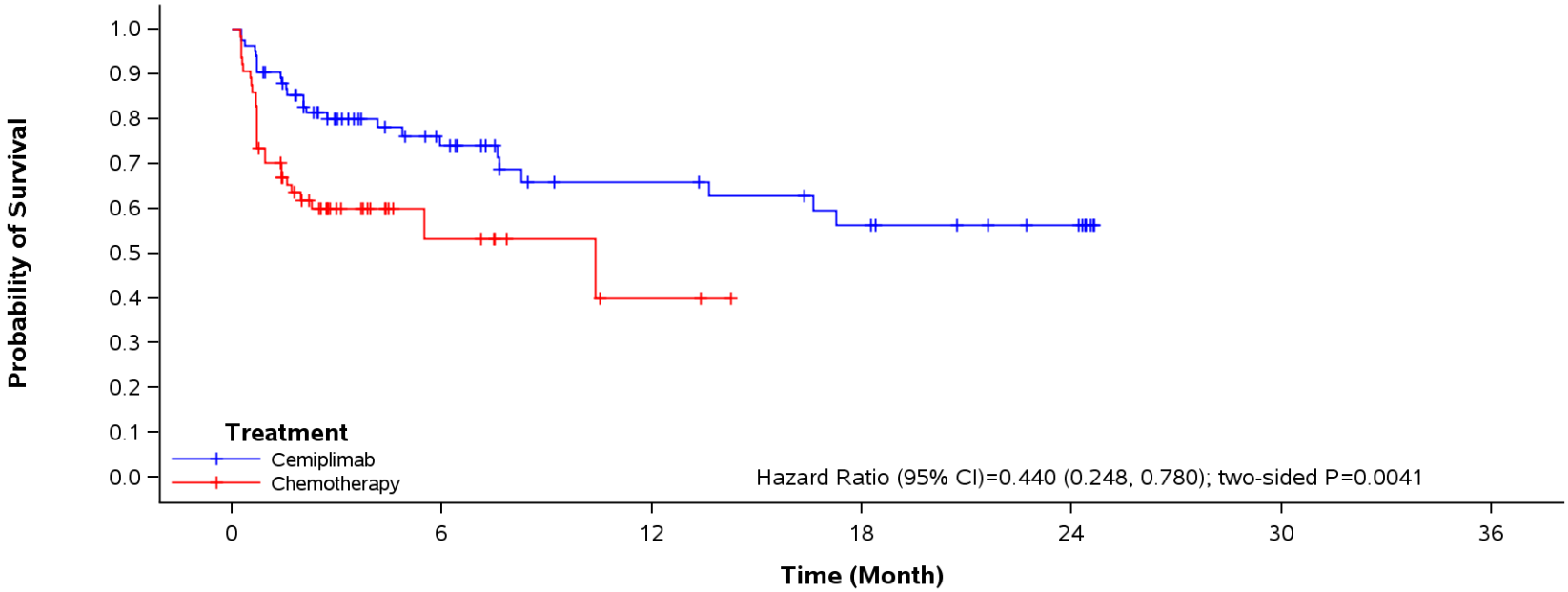

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 7 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 64 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders



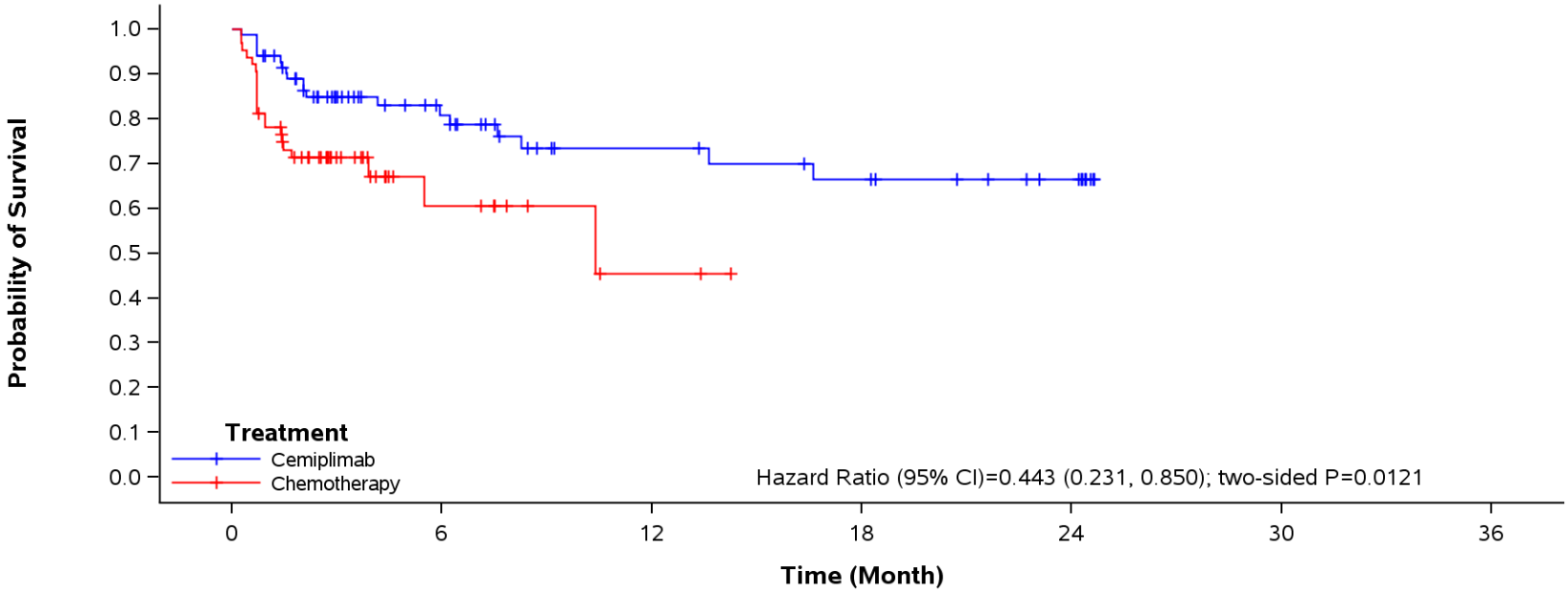

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 22 | 17 | 12 | 0 | 0 |
| Chemotherapy | 64 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Anaemia



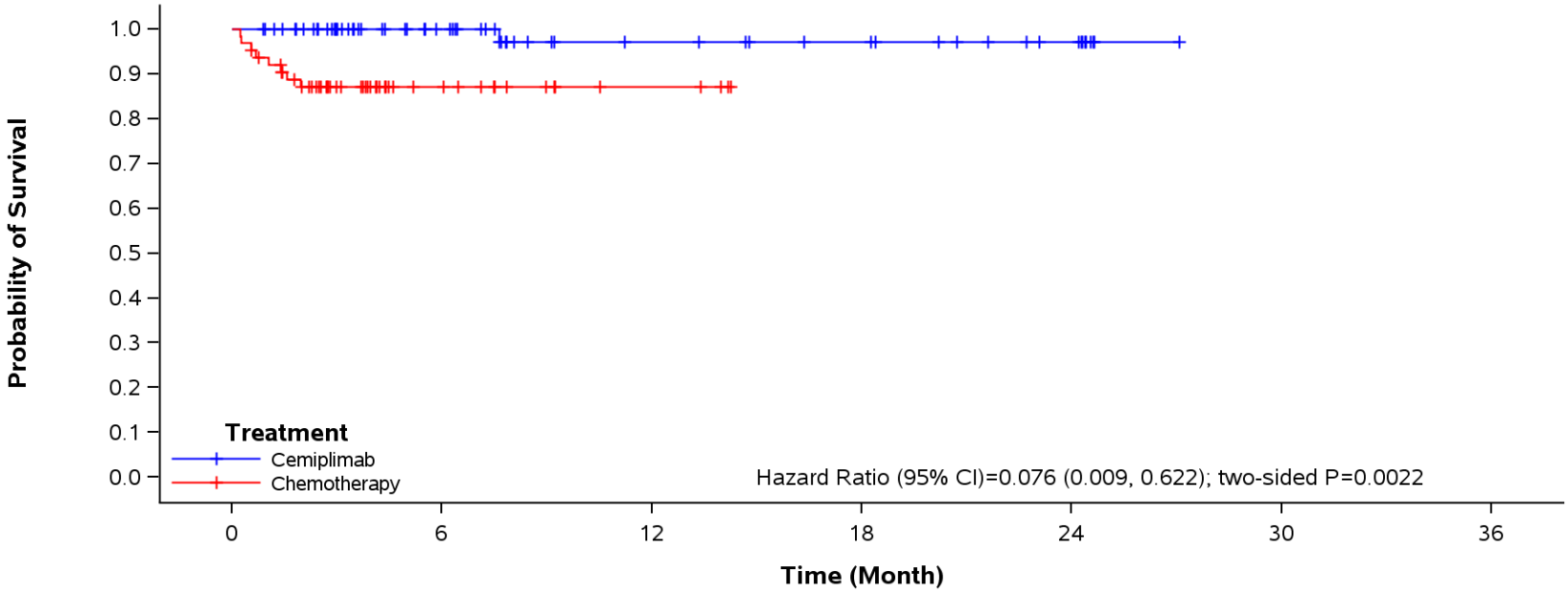

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 38 | 23 | 19 | 13 | 0 | 0 |
| Chemotherapy | 64 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Neutropenia



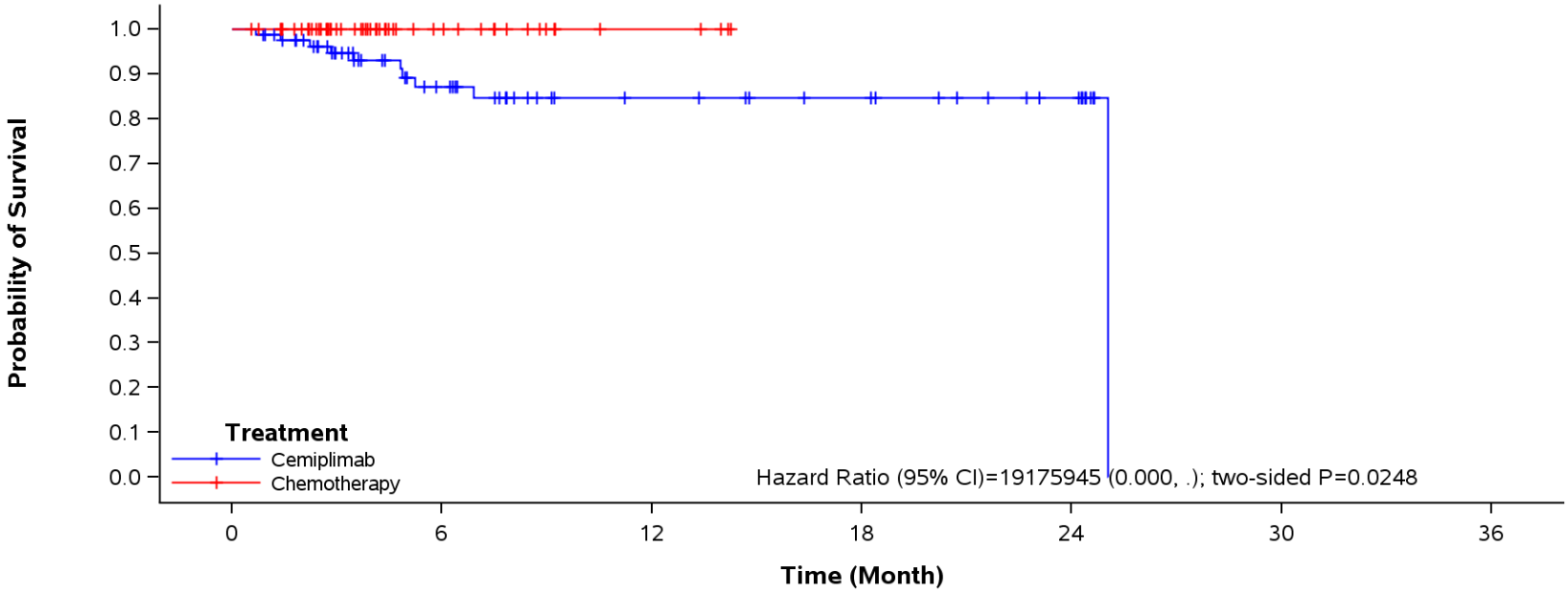

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 14 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Endocrine disorders



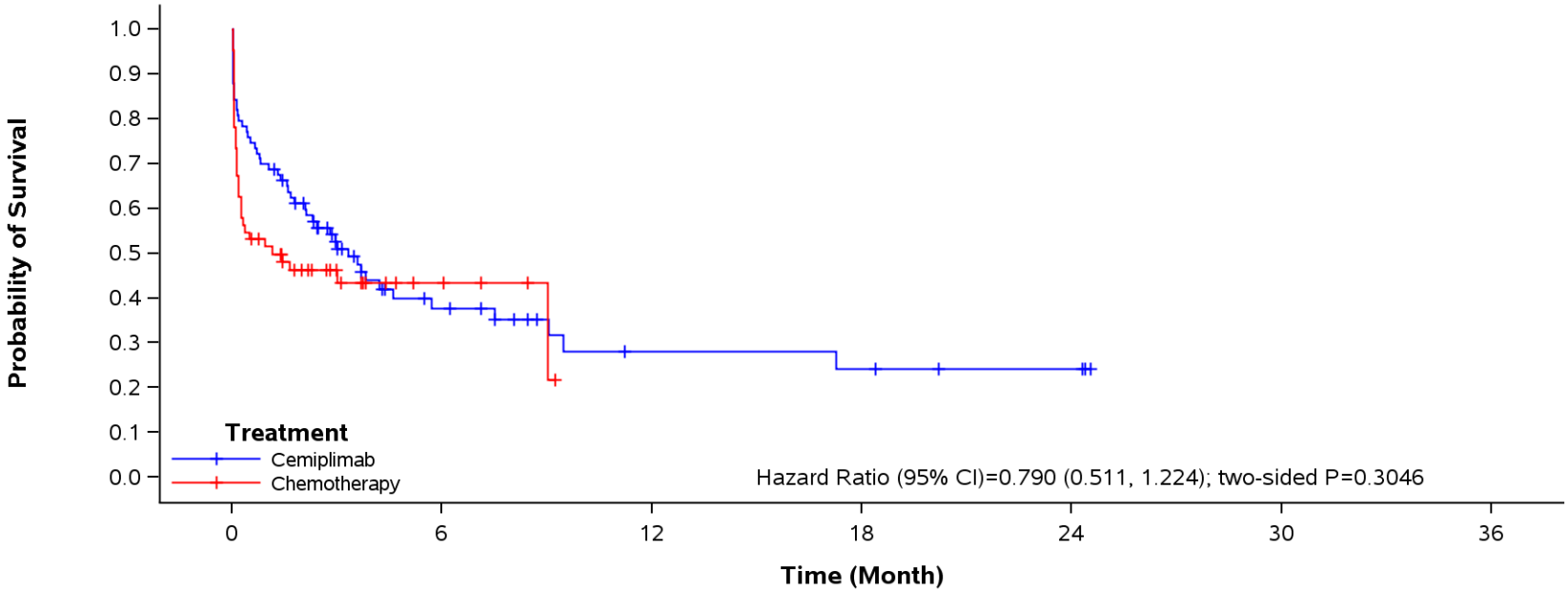

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 40 | 25 | 21 | 14 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders



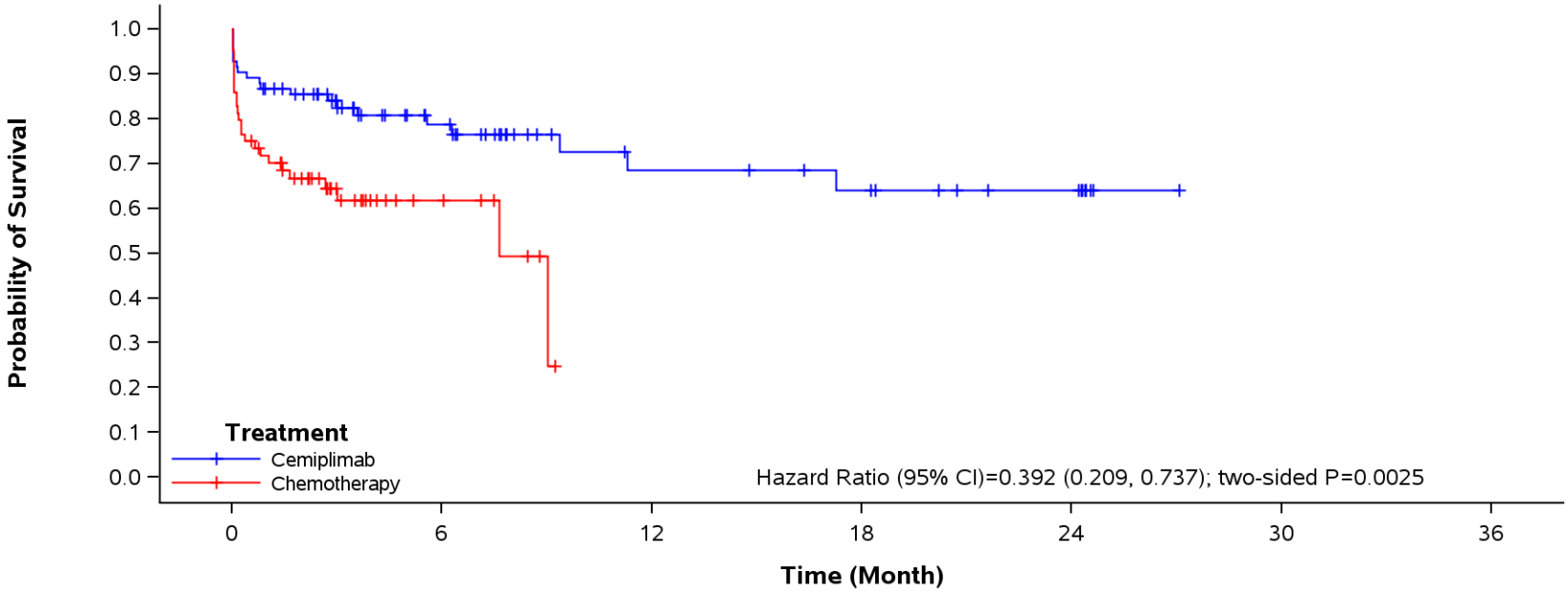

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 17 | 7 | 6 | 4 | 0 | 0 |
| Chemotherapy | 64 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders
PT: Nausea



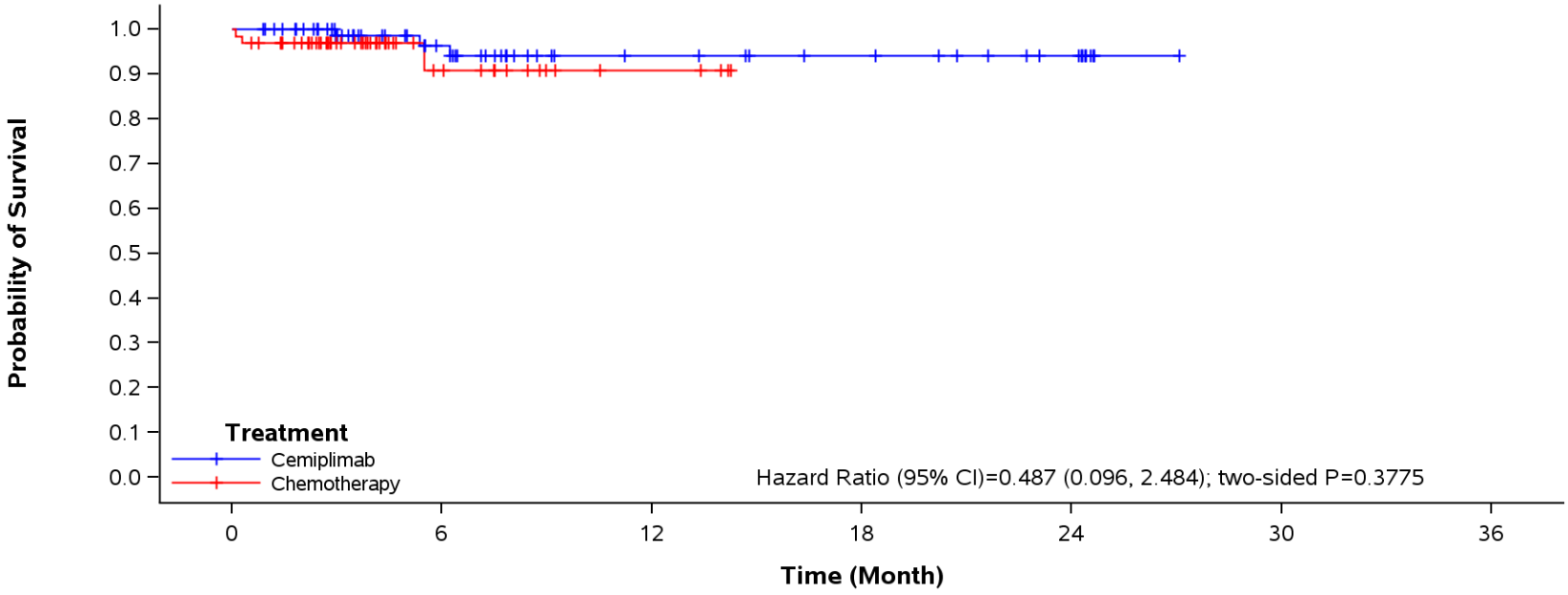

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 17 | 14 | 9 | 0 | 0 |
| Chemotherapy | 64 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders
PT: Stomatitis



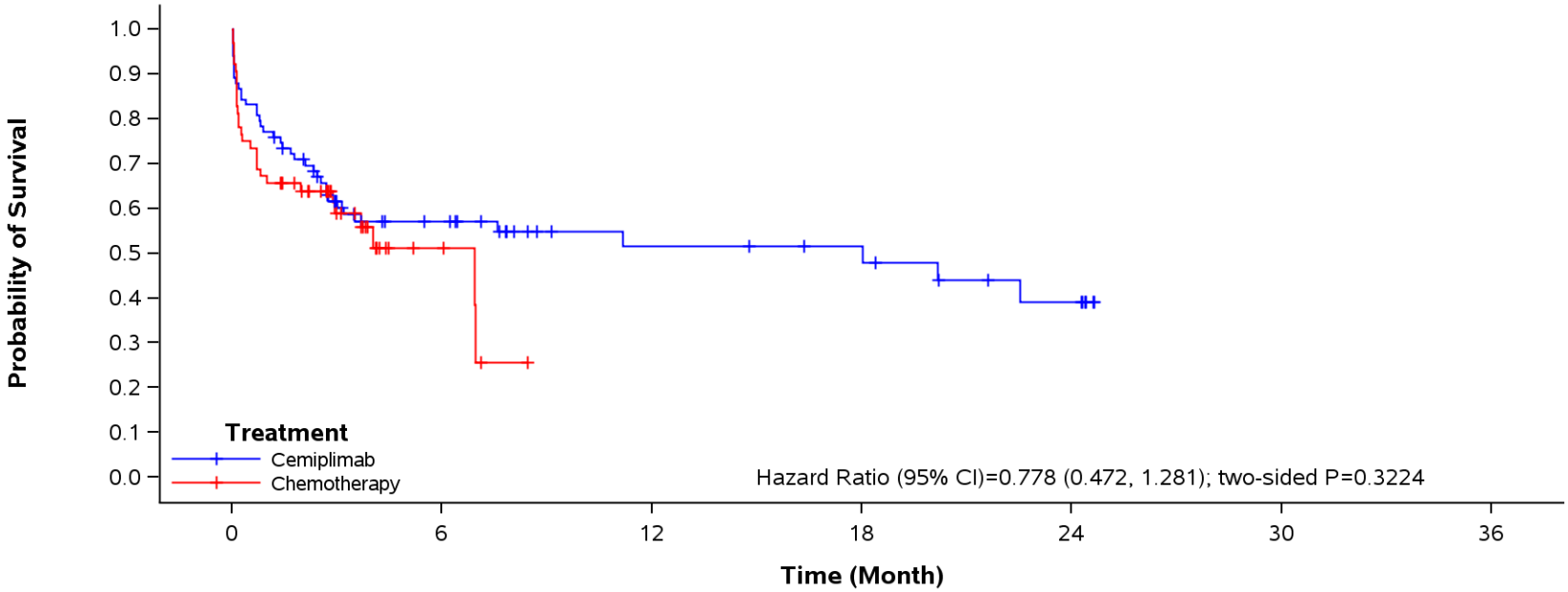

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 42 | 24 | 20 | 14 | 0 | 0 |
| Chemotherapy | 64 | 14 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: General disorders and administration site conditions




**Number of Subjects at risk**

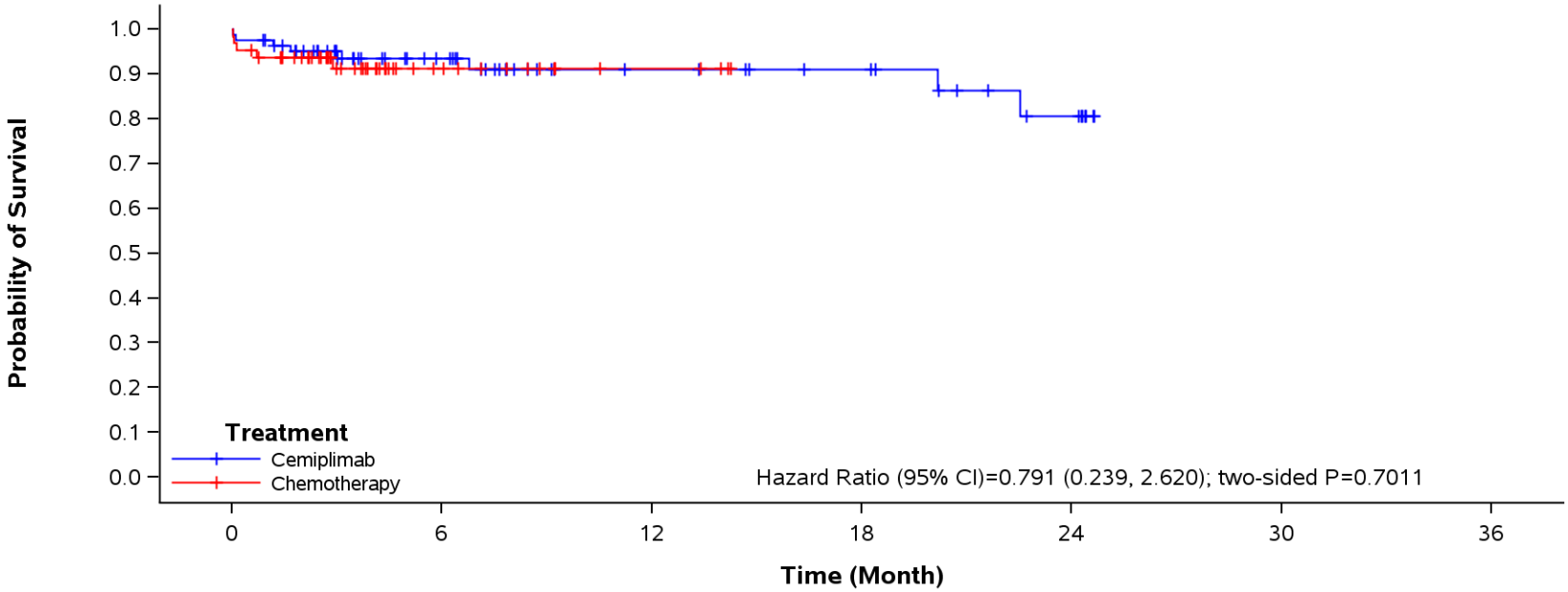
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 30 | 16 | 14 | 8 | 0 | 0 |
| Chemotherapy | 64 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: General disorders and administration site conditions
PT: Asthenia



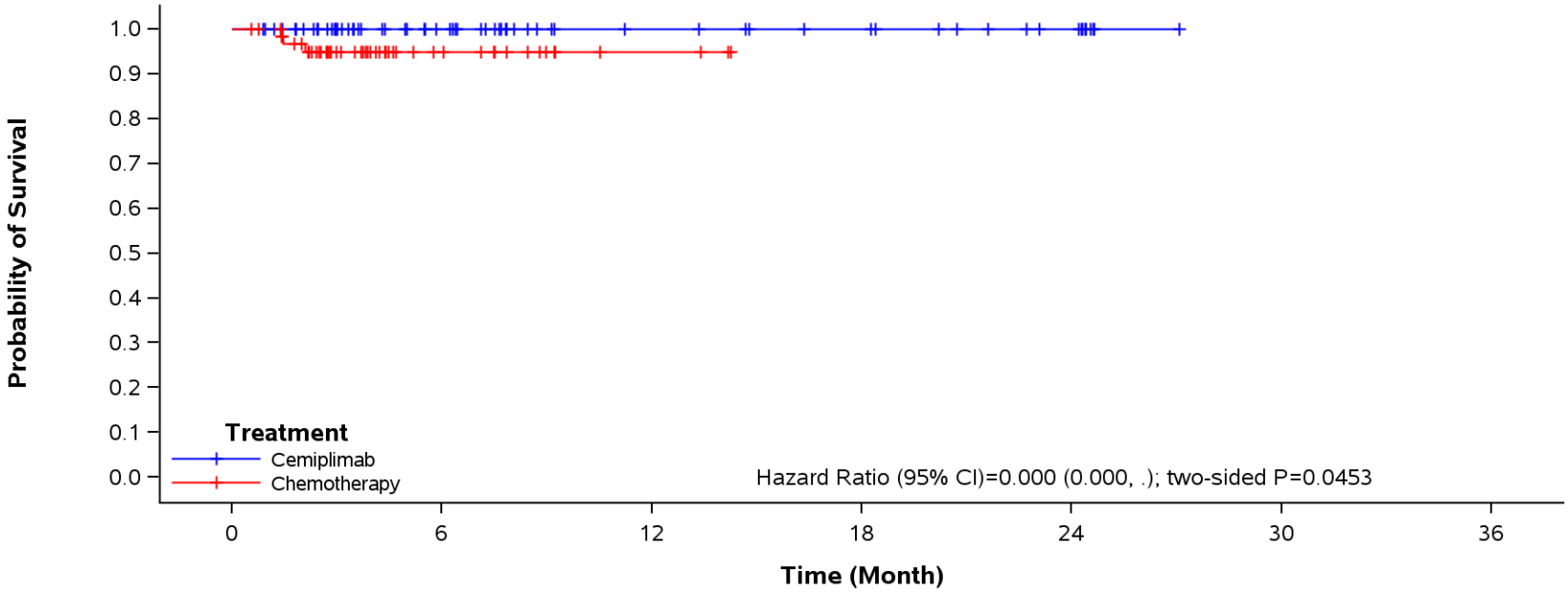

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 43 | 25 | 21 | 13 | 0 | 0 |
| Chemotherapy | 64 | 13 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



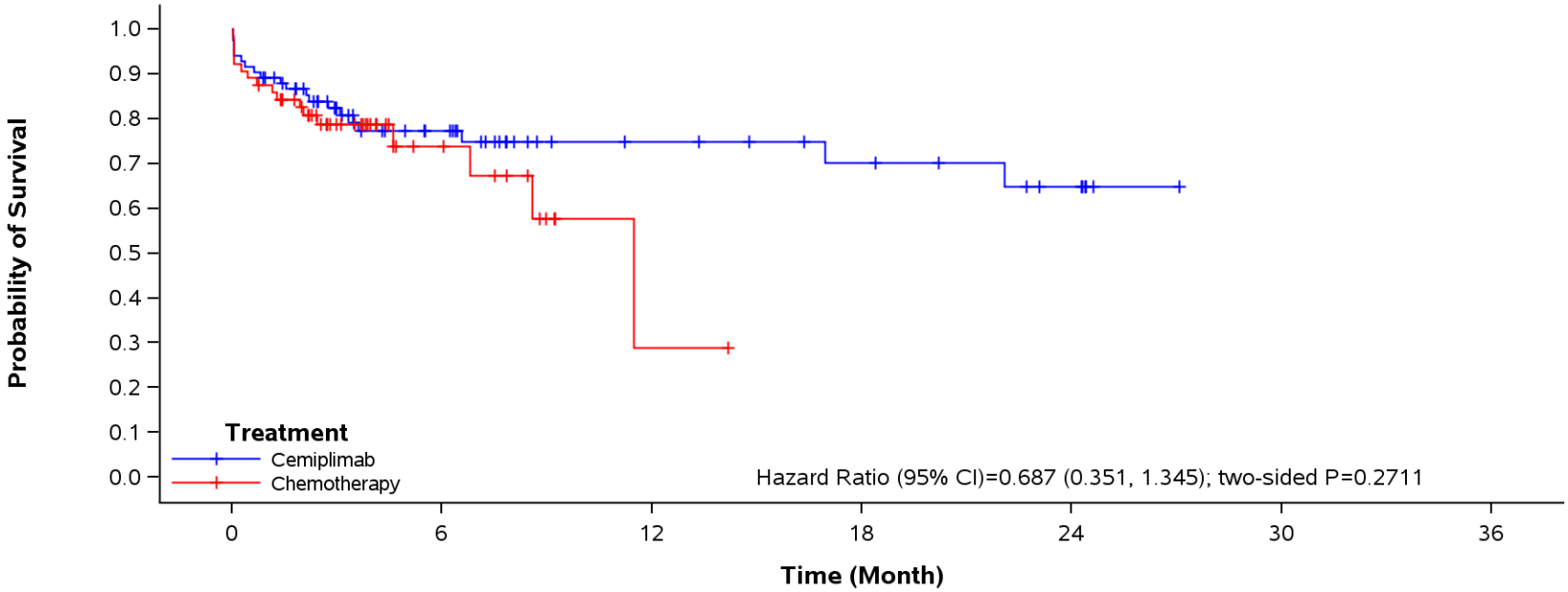

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Nervous system disorders



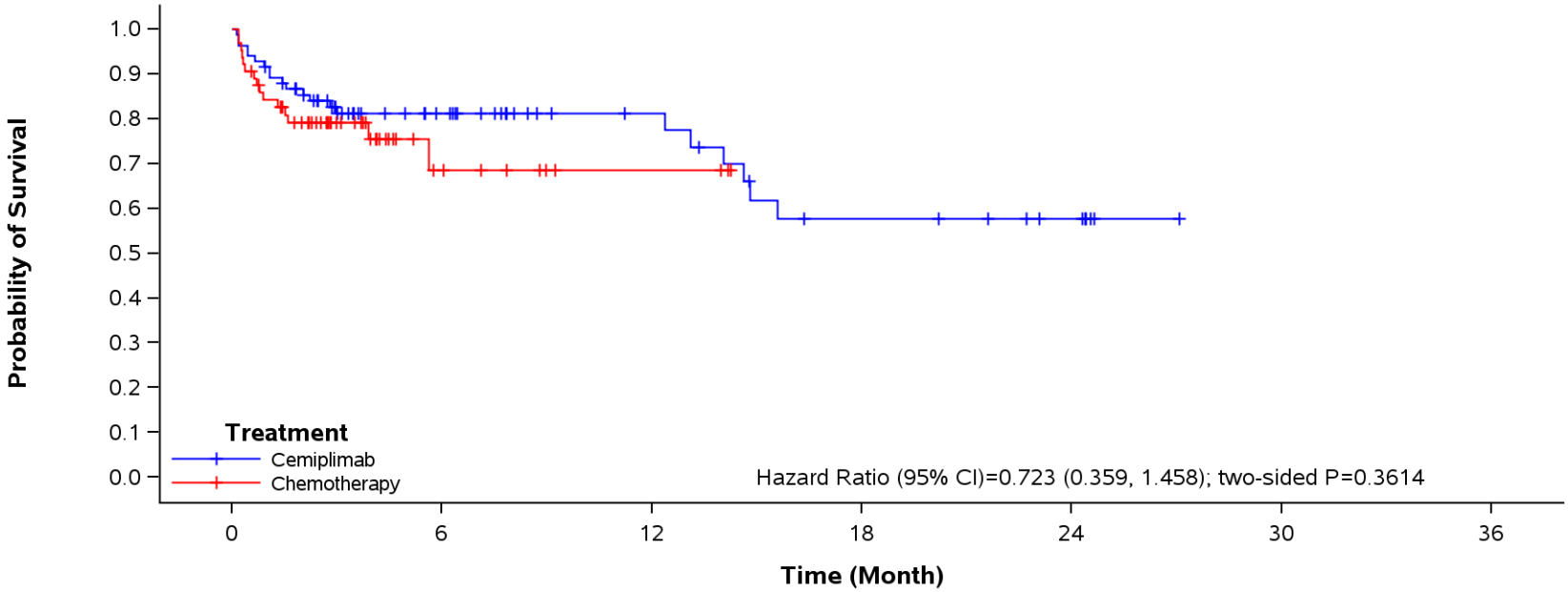

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 35 | 19 | 15 | 10 | 0 | 0 |
| Chemotherapy | 64 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Skin and subcutaneous tissue disorders



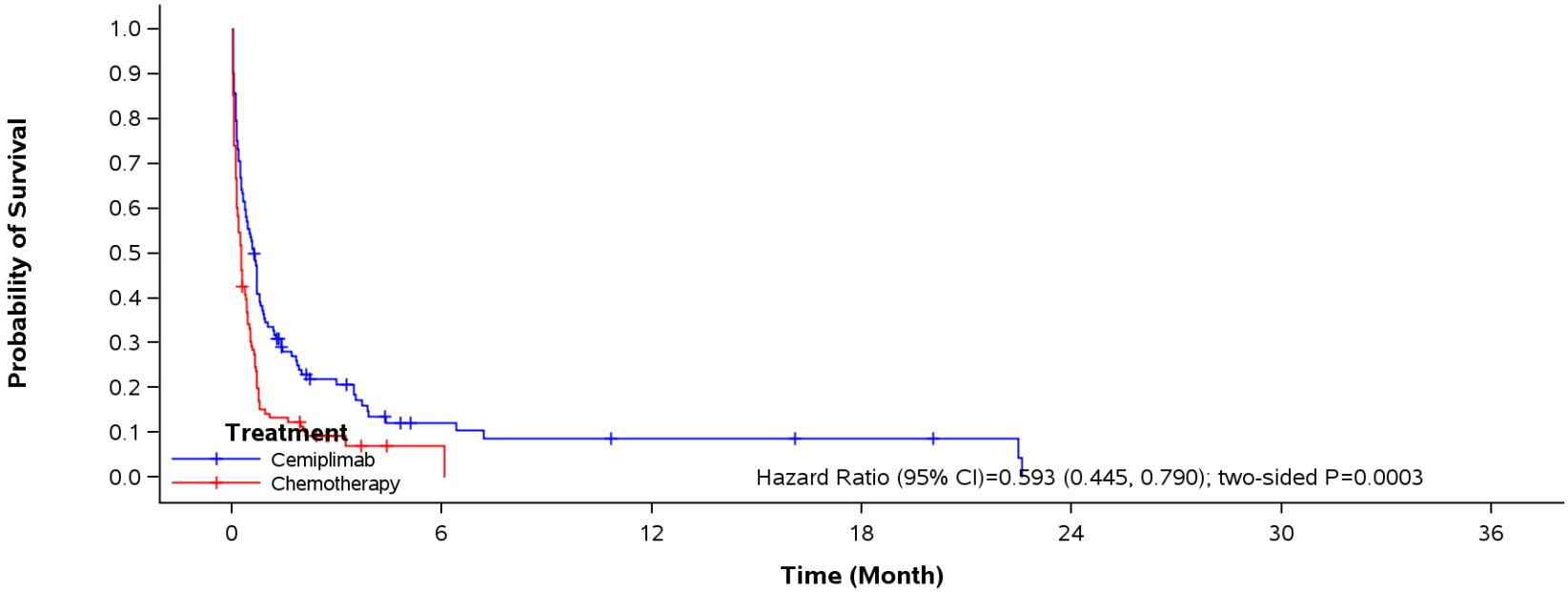

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 36 | 22 | 13 | 9 | 0 | 0 |
| Chemotherapy | 64 | 9 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Number of patients with any TEAE



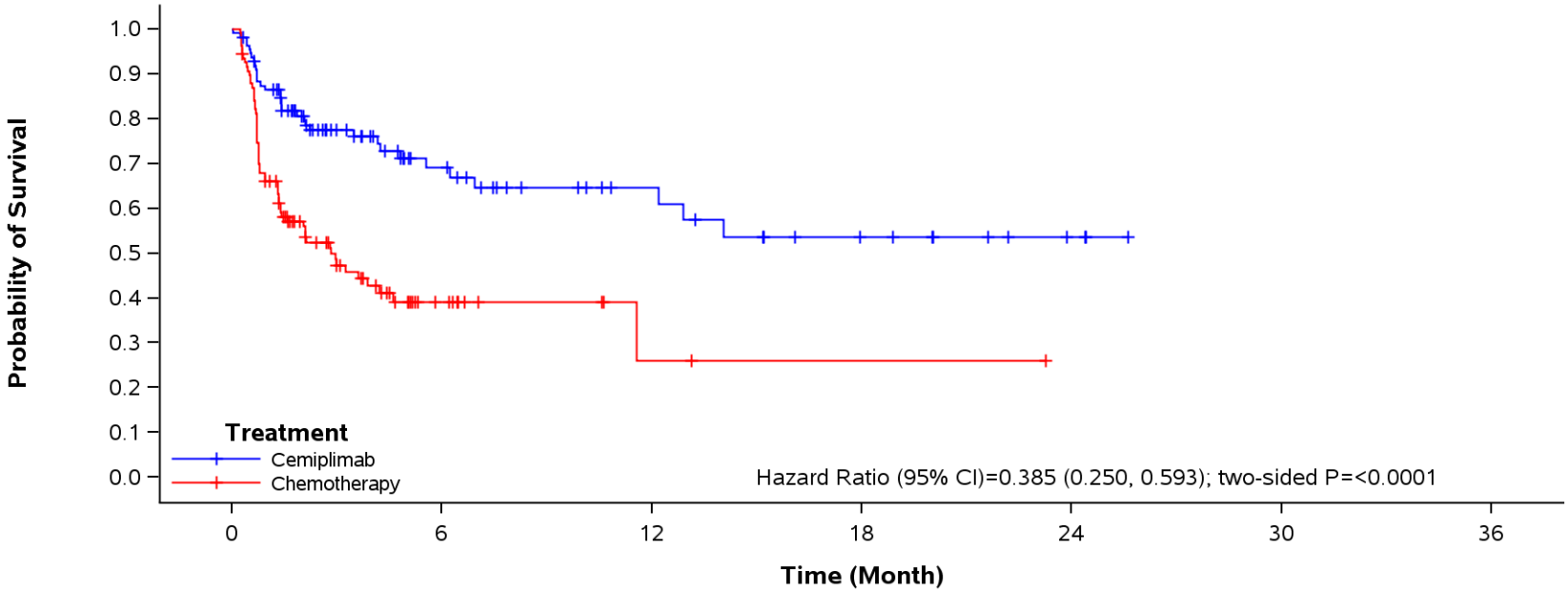

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 7 | 4 | 3 | 0 | 0 | 0 |
| Chemotherapy | 108 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders



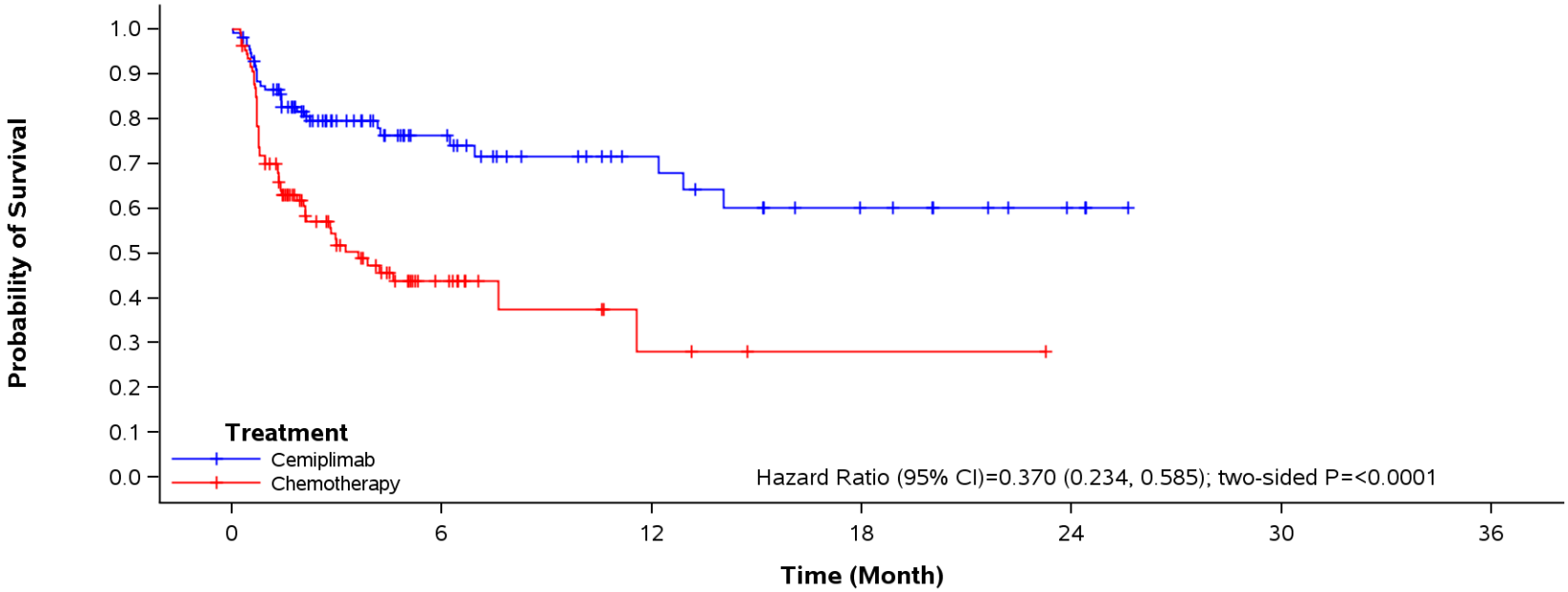

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 33 | 18 | 10 | 4 | 0 | 0 |
| Chemotherapy | 108 | 12 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Anaemia



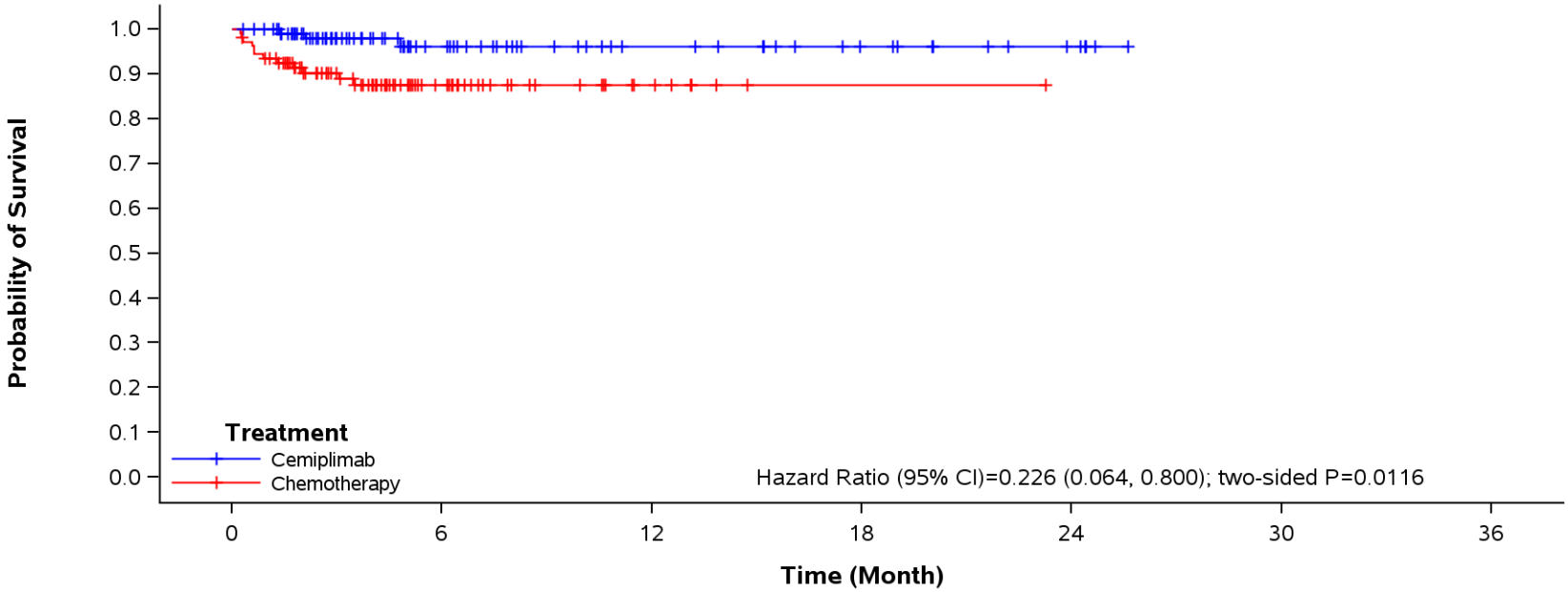

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 36 | 19 | 11 | 5 | 0 | 0 |
| Chemotherapy | 108 | 15 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Neutropenia



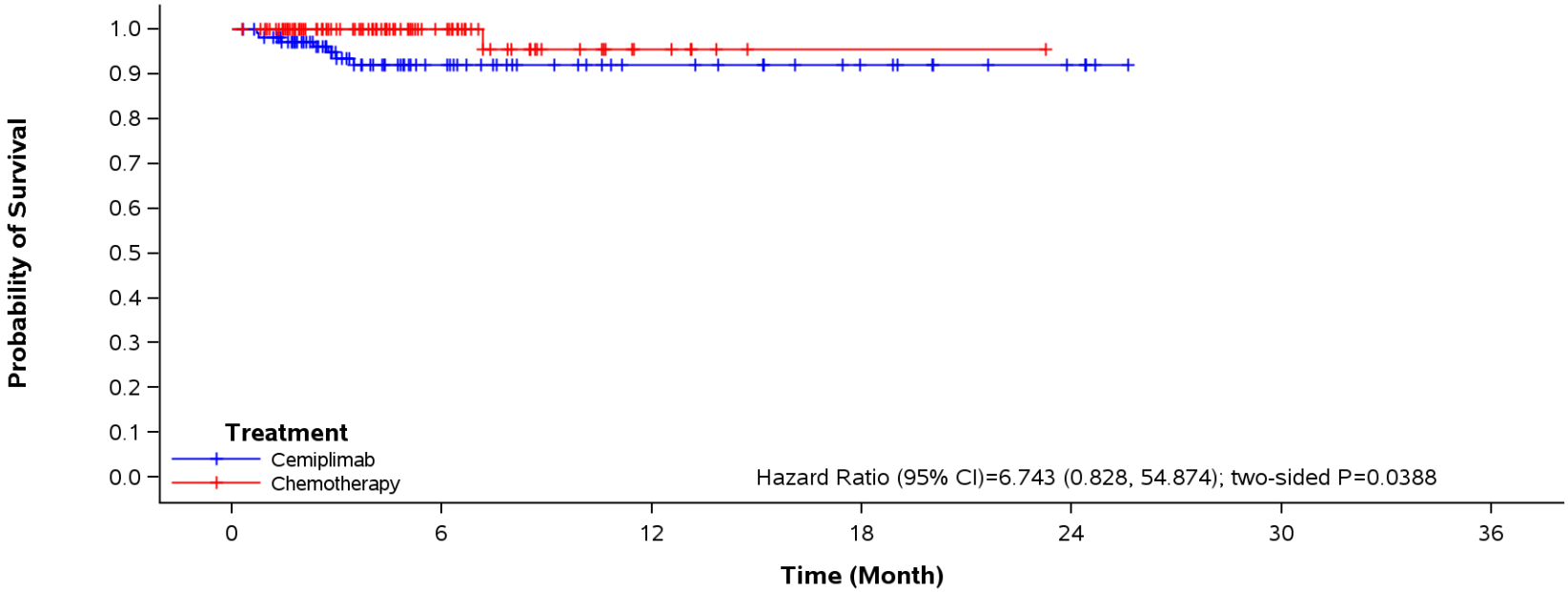

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 21 | 13 | 6 | 0 | 0 |
| Chemotherapy | 108 | 31 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Endocrine disorders



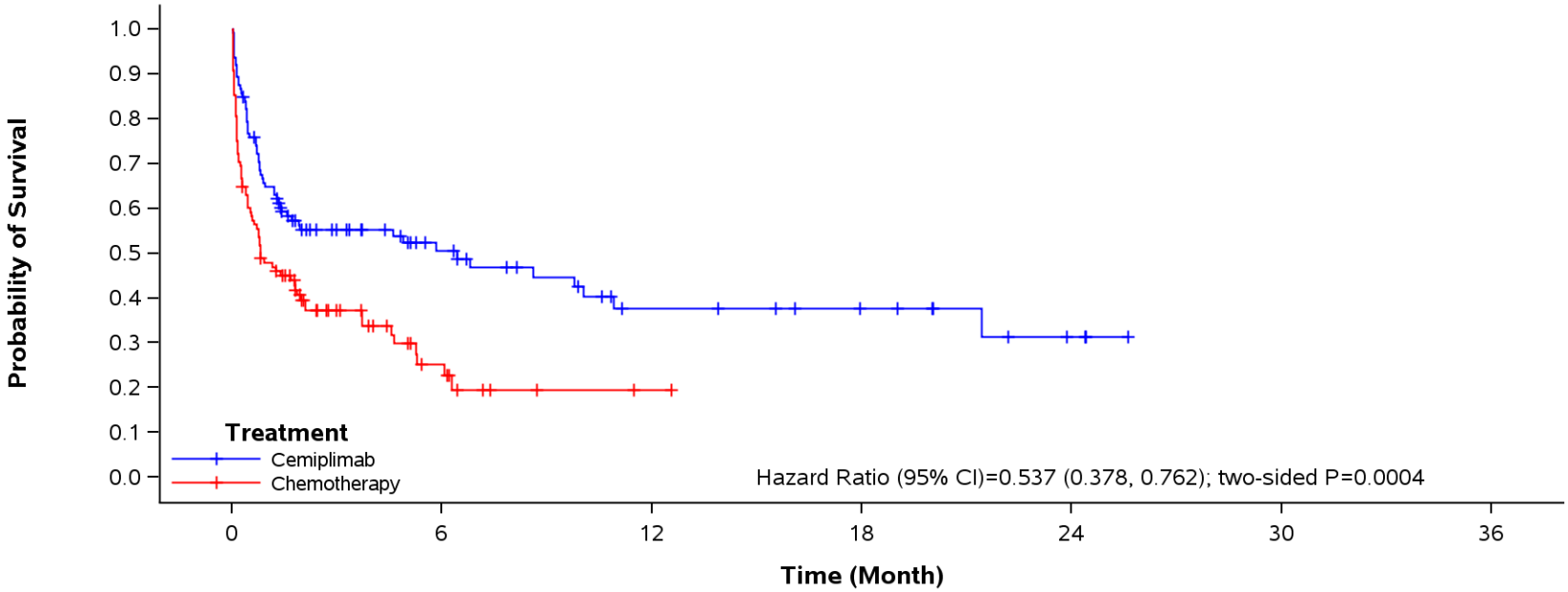

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 37 | 19 | 12 | 6 | 0 | 0 |
| Chemotherapy | 108 | 36 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders




**Number of Subjects at risk**

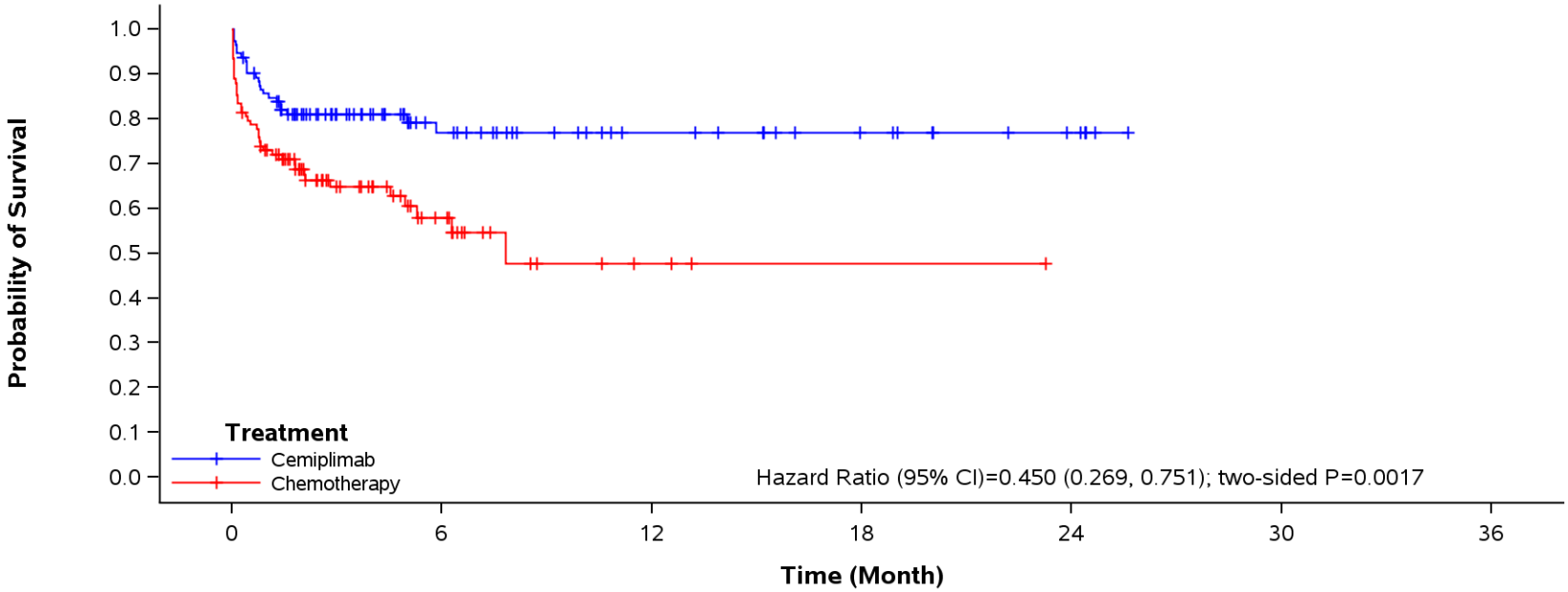
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 29 | 13 | 9 | 3 | 0 | 0 |
| Chemotherapy | 108 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders
PT: Nausea



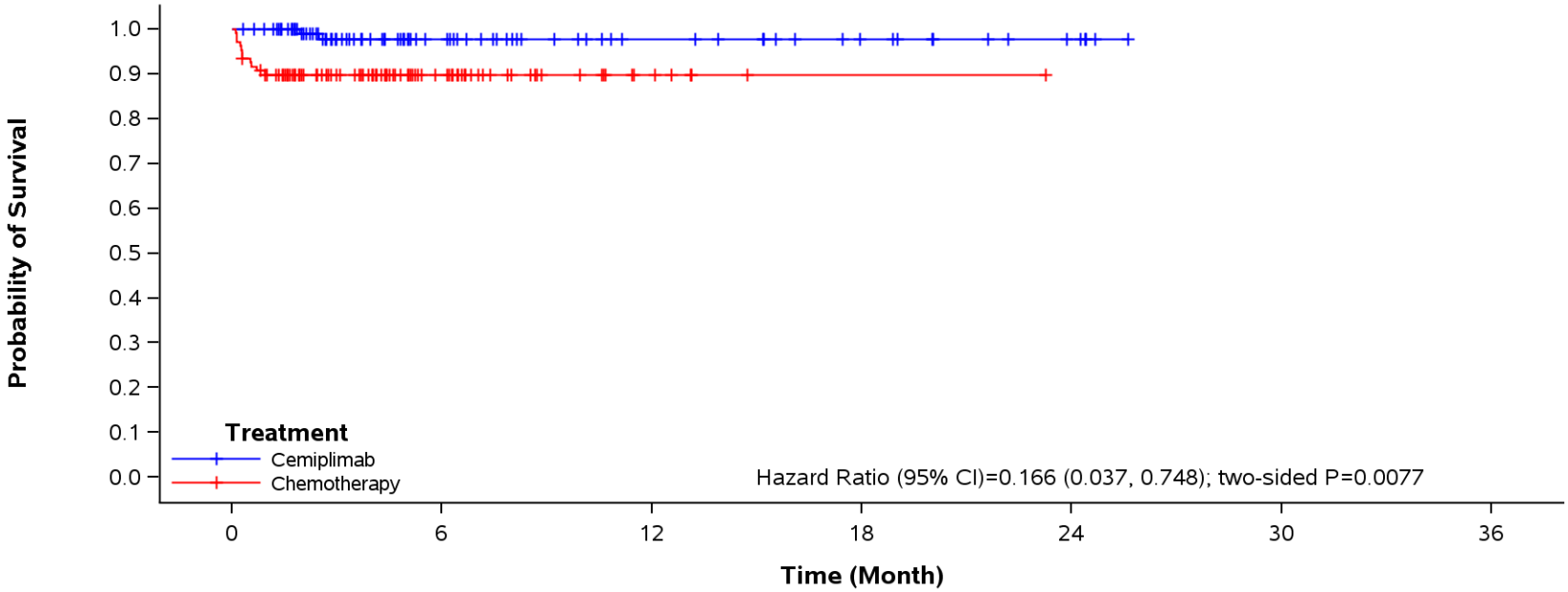

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 35 | 19 | 12 | 6 | 0 | 0 |
| Chemotherapy | 108 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders
PT: Stomatitis



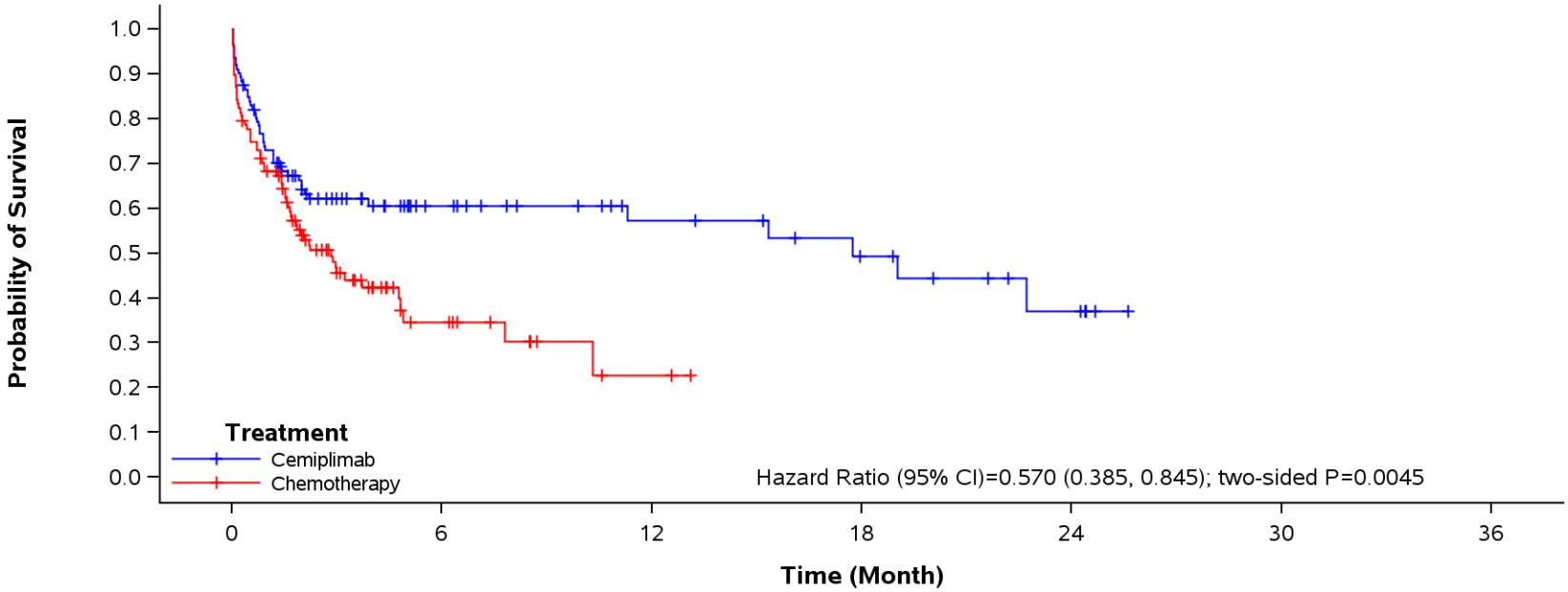

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 21 | 13 | 6 | 0 | 0 |
| Chemotherapy | 108 | 34 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: General disorders and administration site conditions



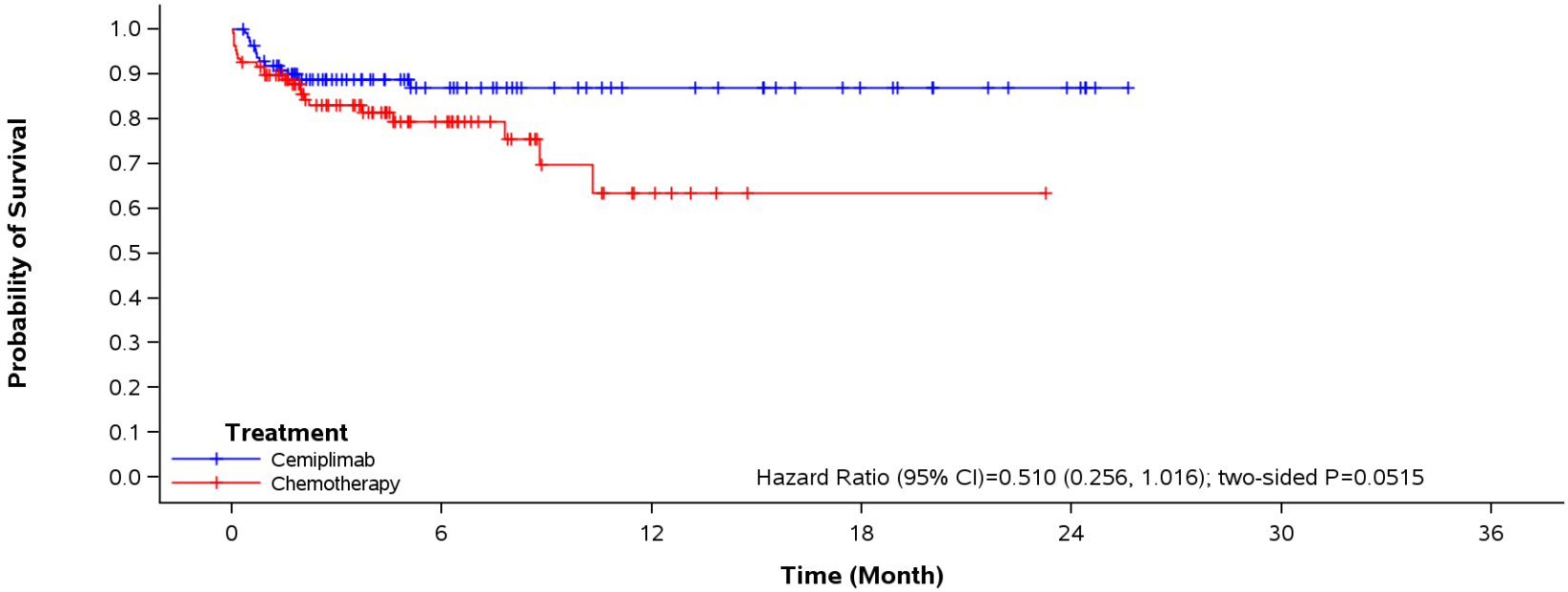

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 29 | 17 | 11 | 5 | 0 | 0 |
| Chemotherapy | 108 | 12 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: General disorders and administration site conditions
PT: Asthenia



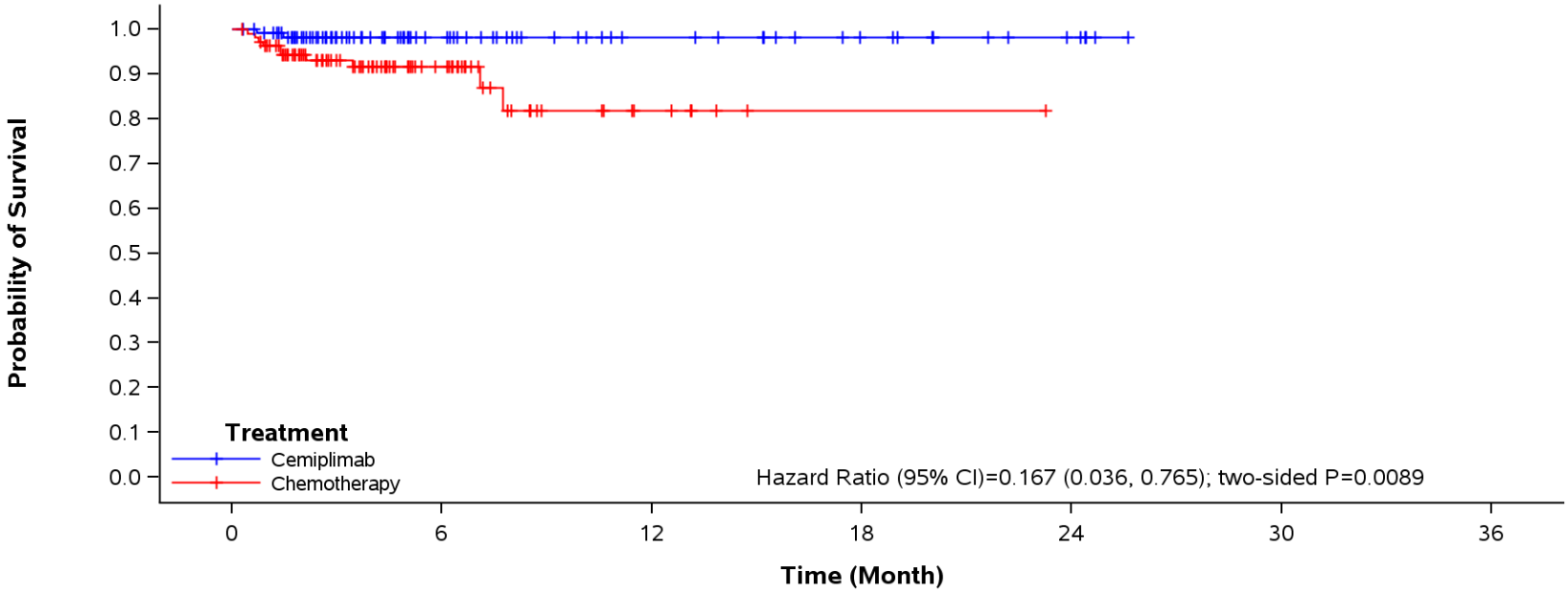

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 32 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



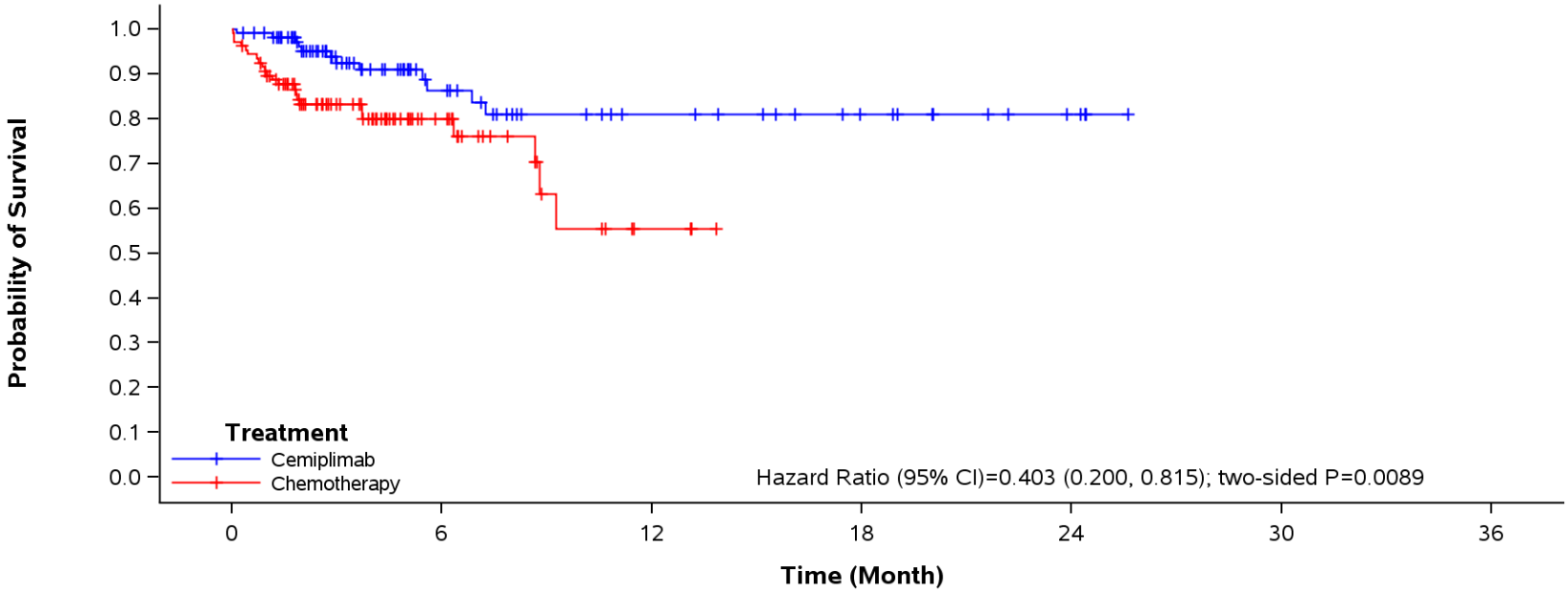

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 34 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Nervous system disorders



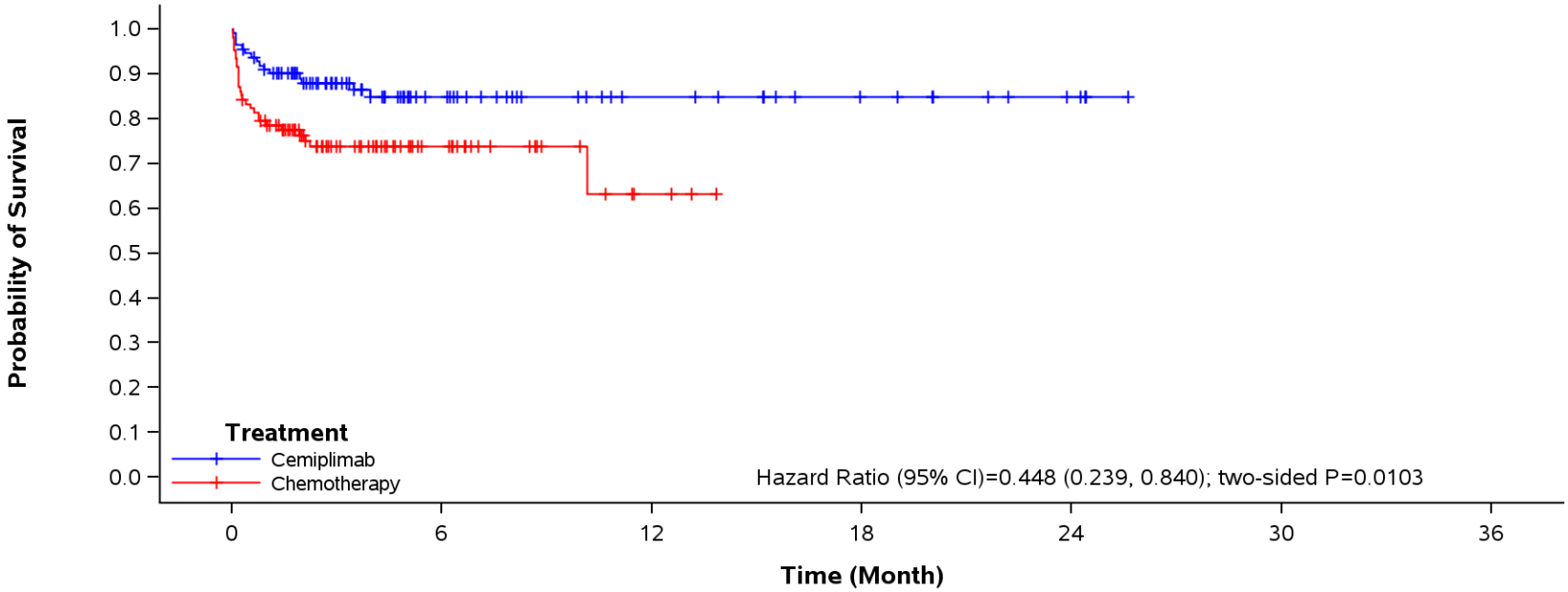

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 36 | 19 | 12 | 5 | 0 | 0 |
| Chemotherapy | 108 | 27 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Skin and subcutaneous tissue disorders



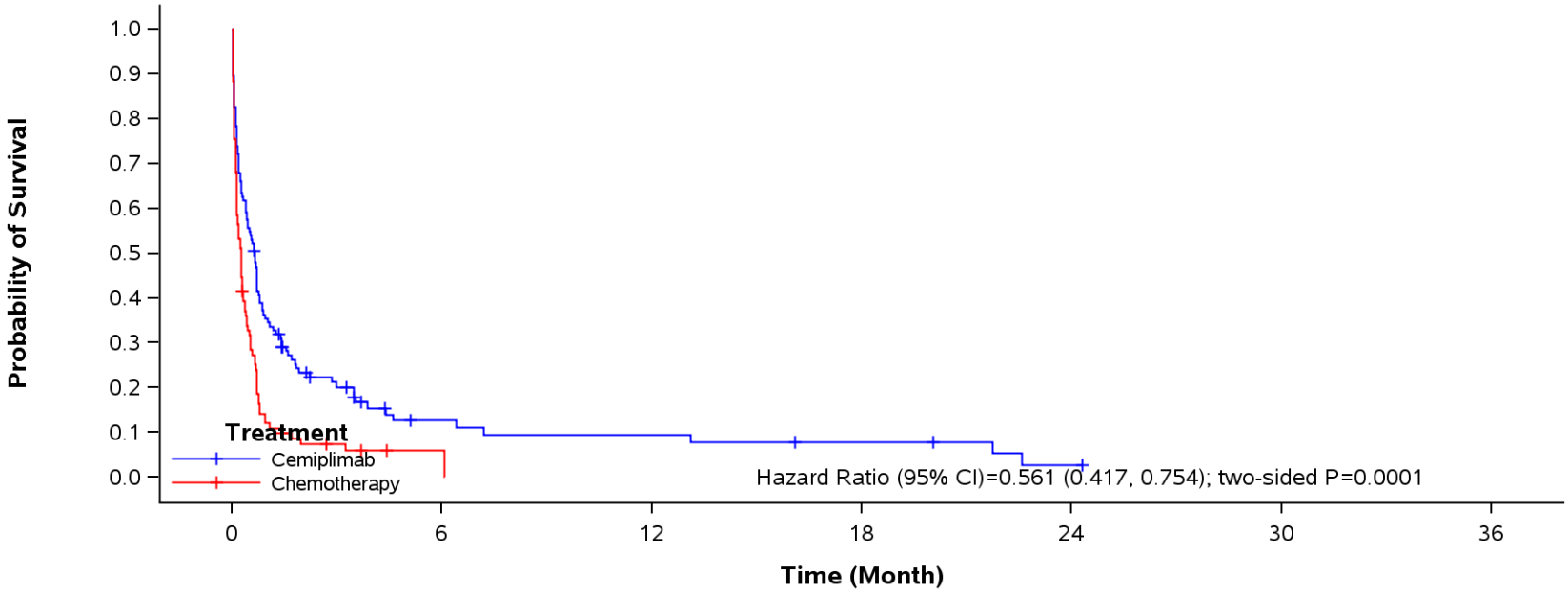

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 34 | 17 | 10 | 4 | 0 | 0 |
| Chemotherapy | 108 | 22 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Number of patients with any TEAE



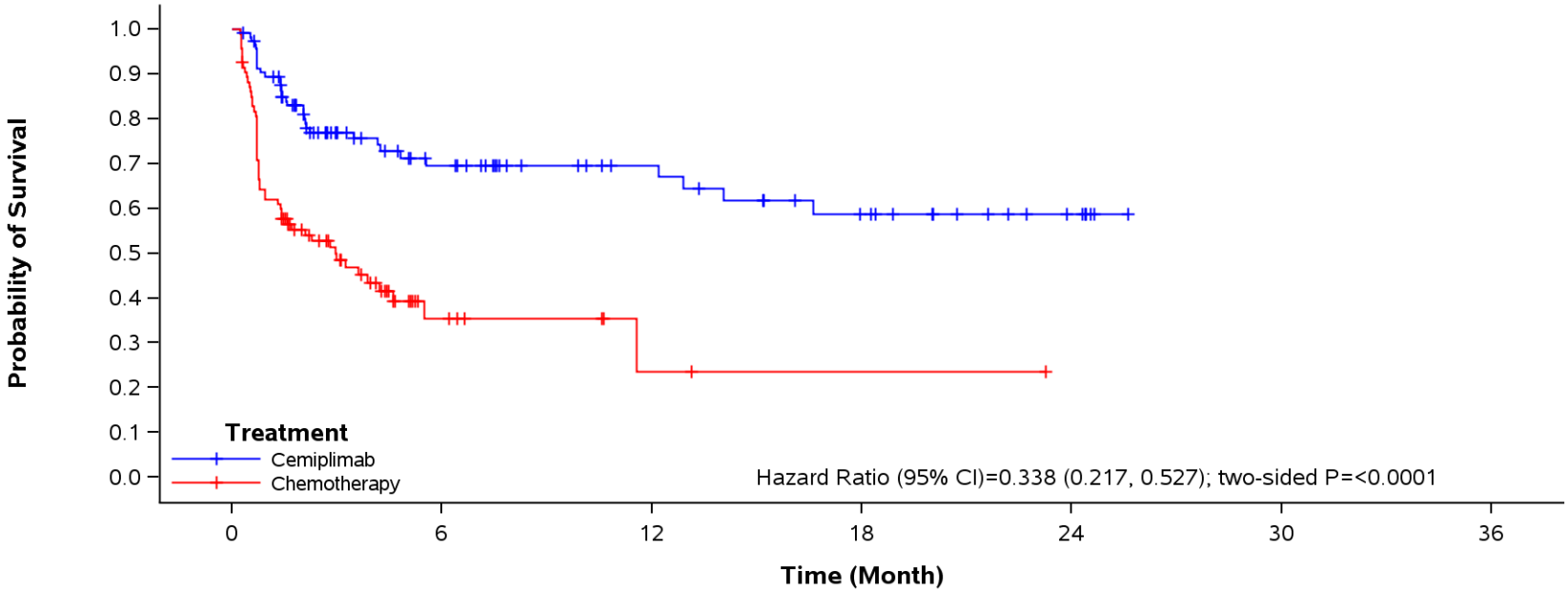

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 8 | 6 | 4 | 1 | 0 | 0 |
| Chemotherapy | 94 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders



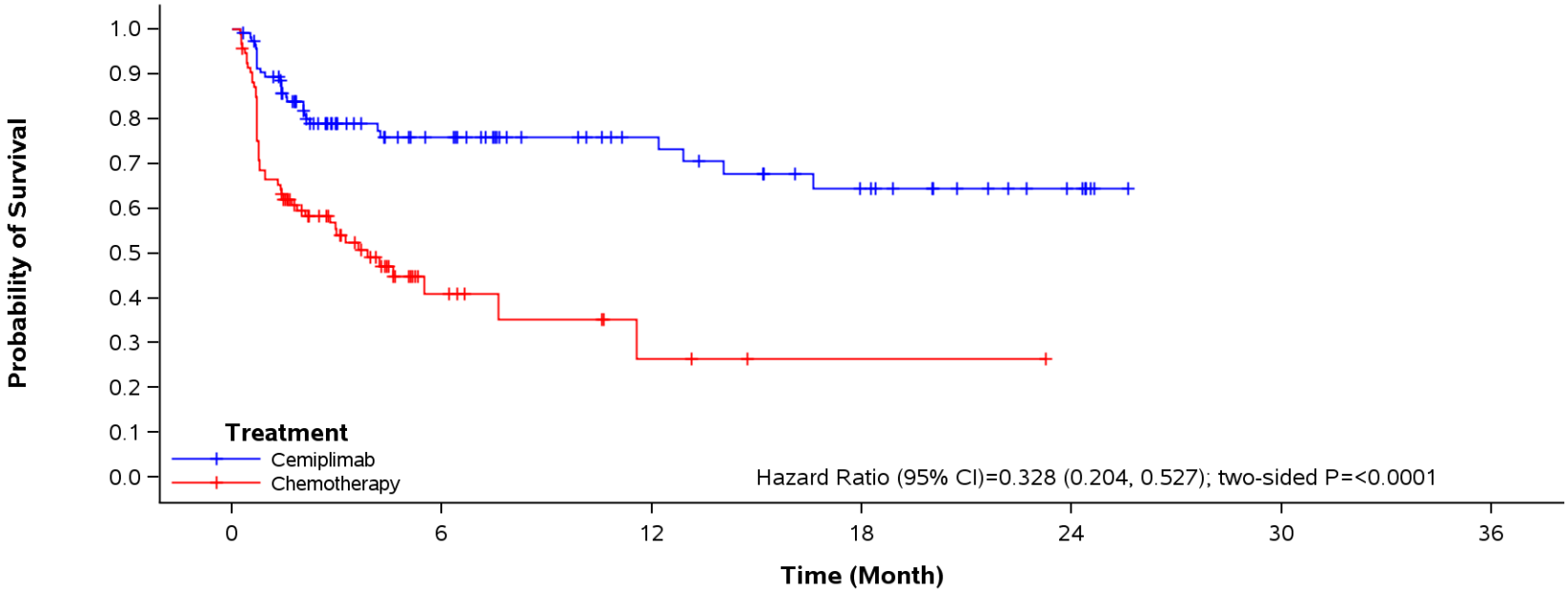

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 42 | 27 | 18 | 8 | 0 | 0 |
| Chemotherapy | 94 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



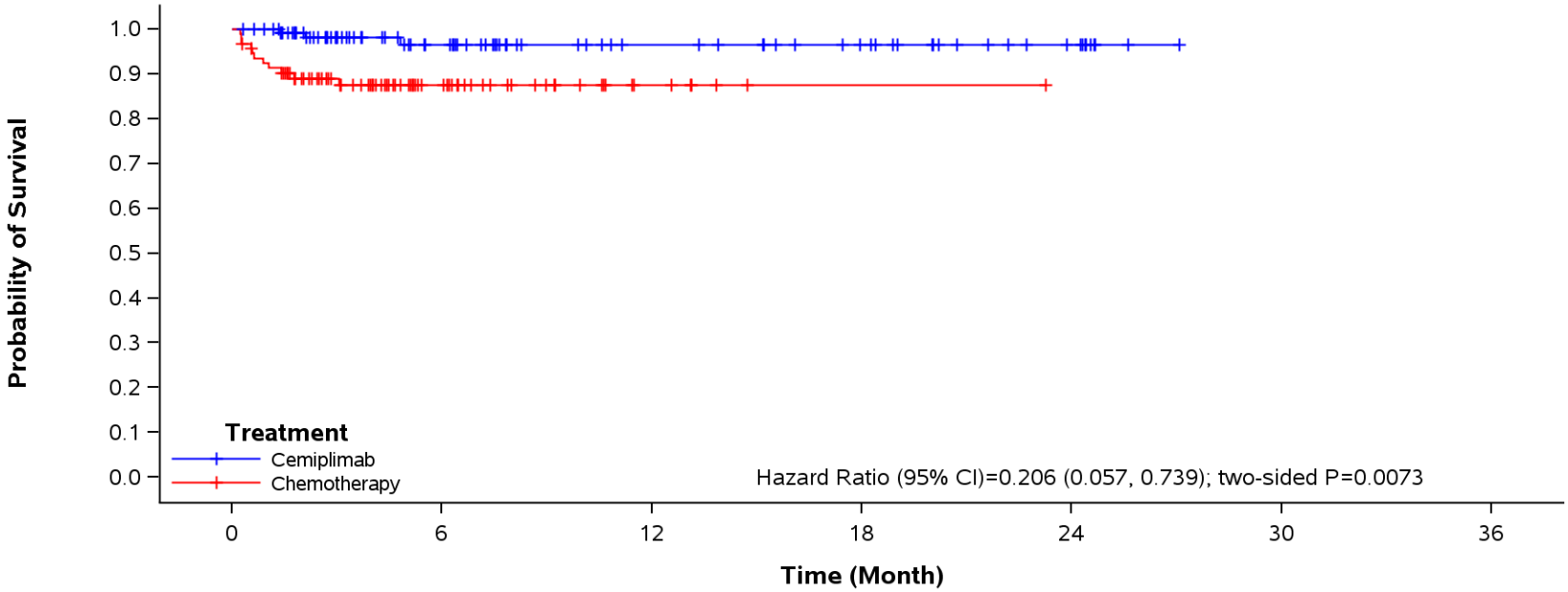

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 45 | 28 | 19 | 9 | 0 | 0 |
| Chemotherapy | 94 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia



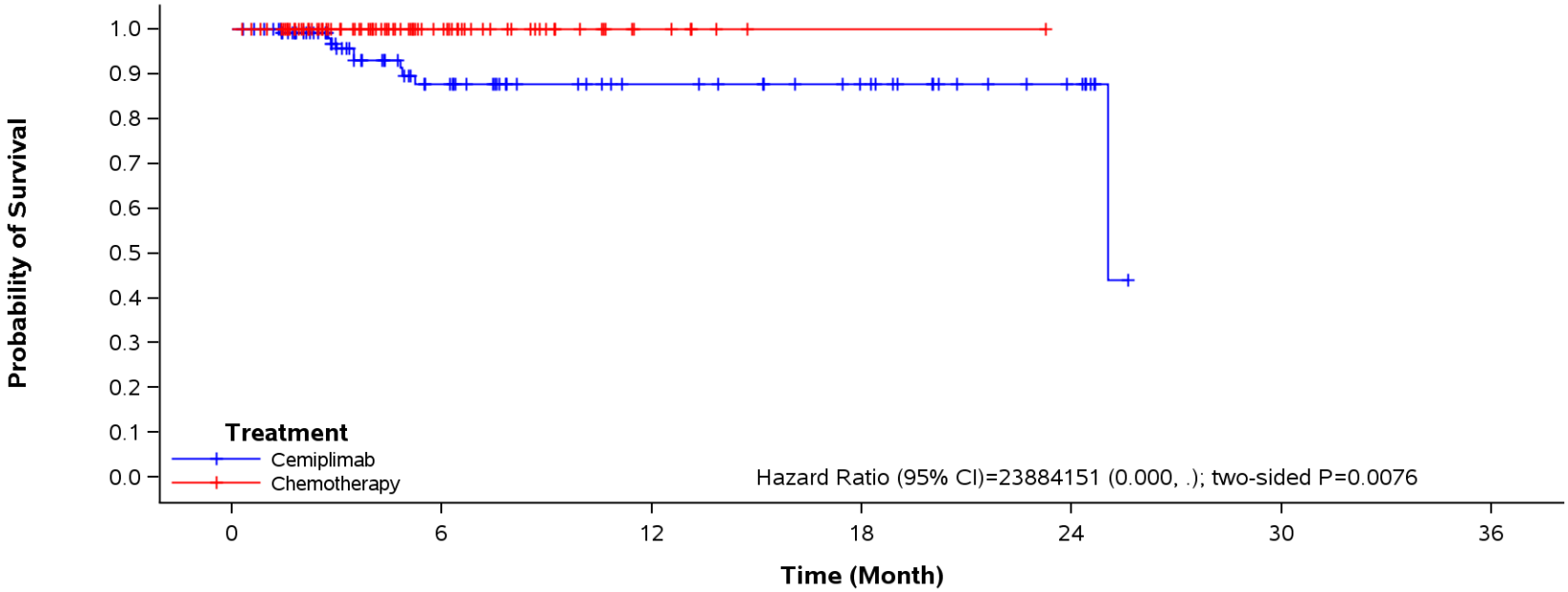

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 52 | 31 | 23 | 11 | 0 | 0 |
| Chemotherapy | 94 | 30 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Endocrine disorders



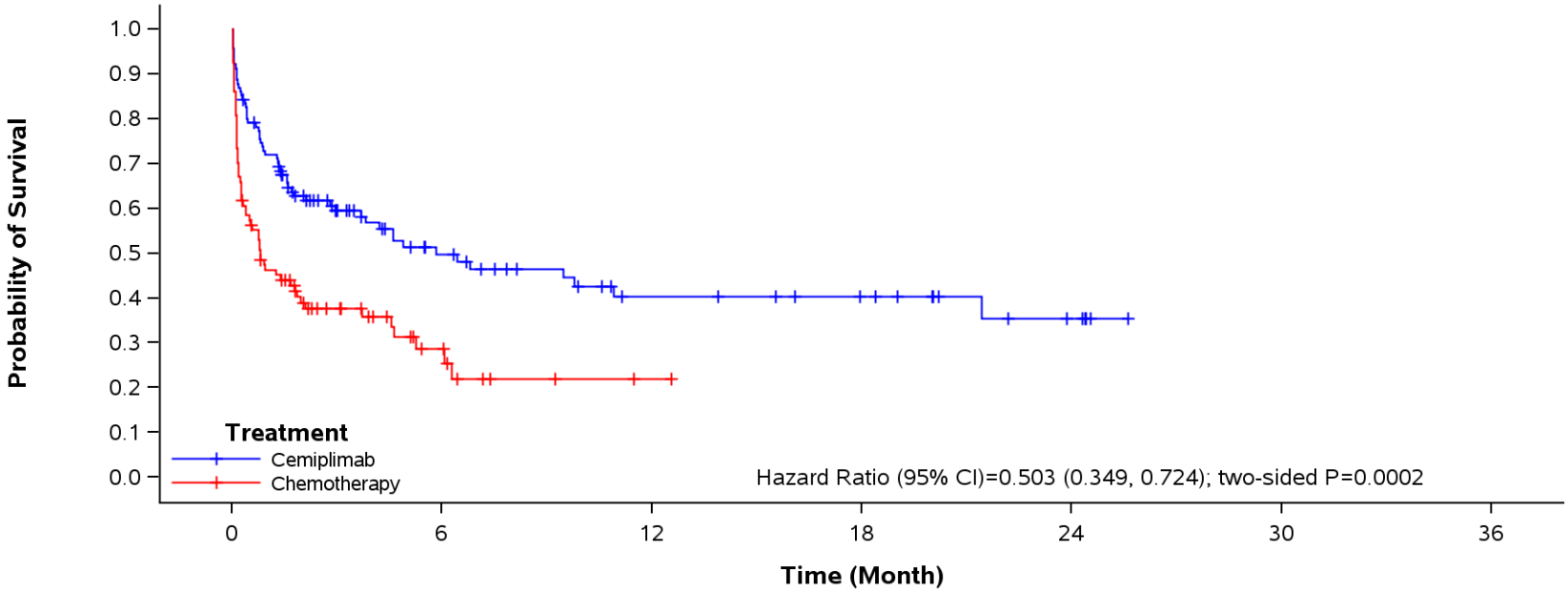

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 46 | 29 | 22 | 11 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders



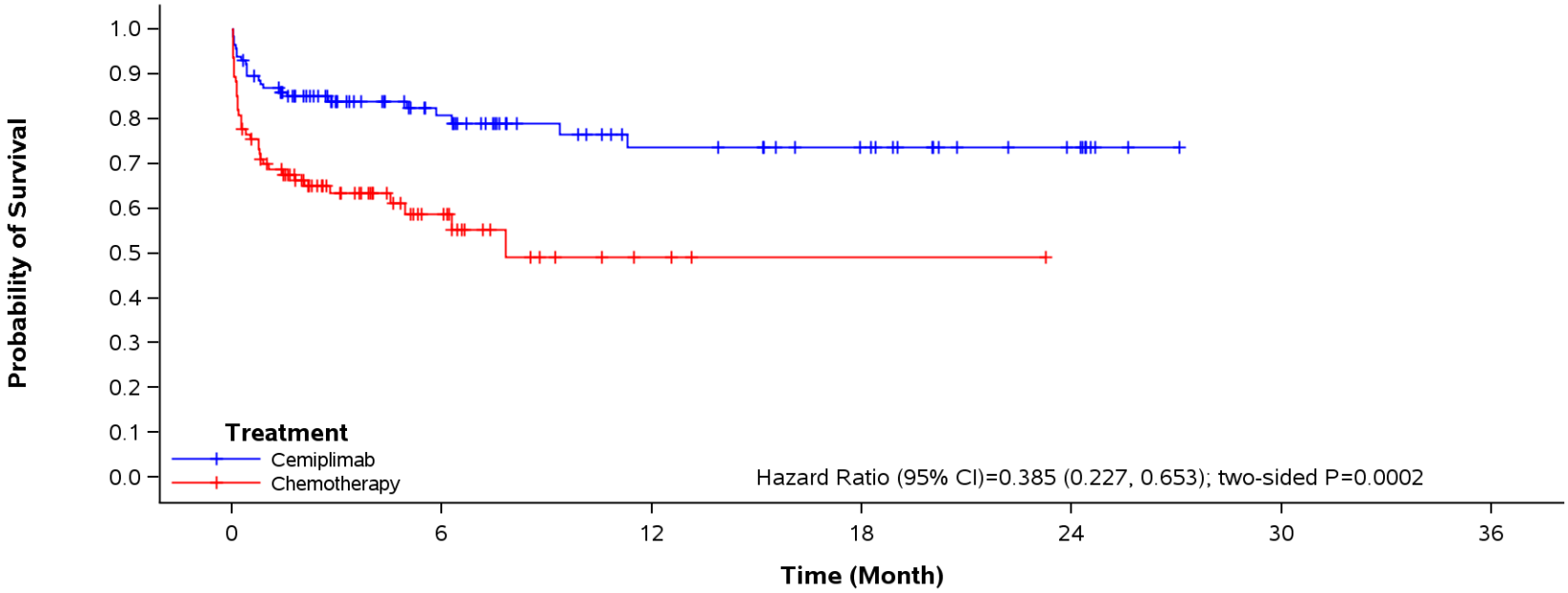

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 32 | 17 | 13 | 5 | 0 | 0 |
| Chemotherapy | 94 | 10 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders
PT: Nausea



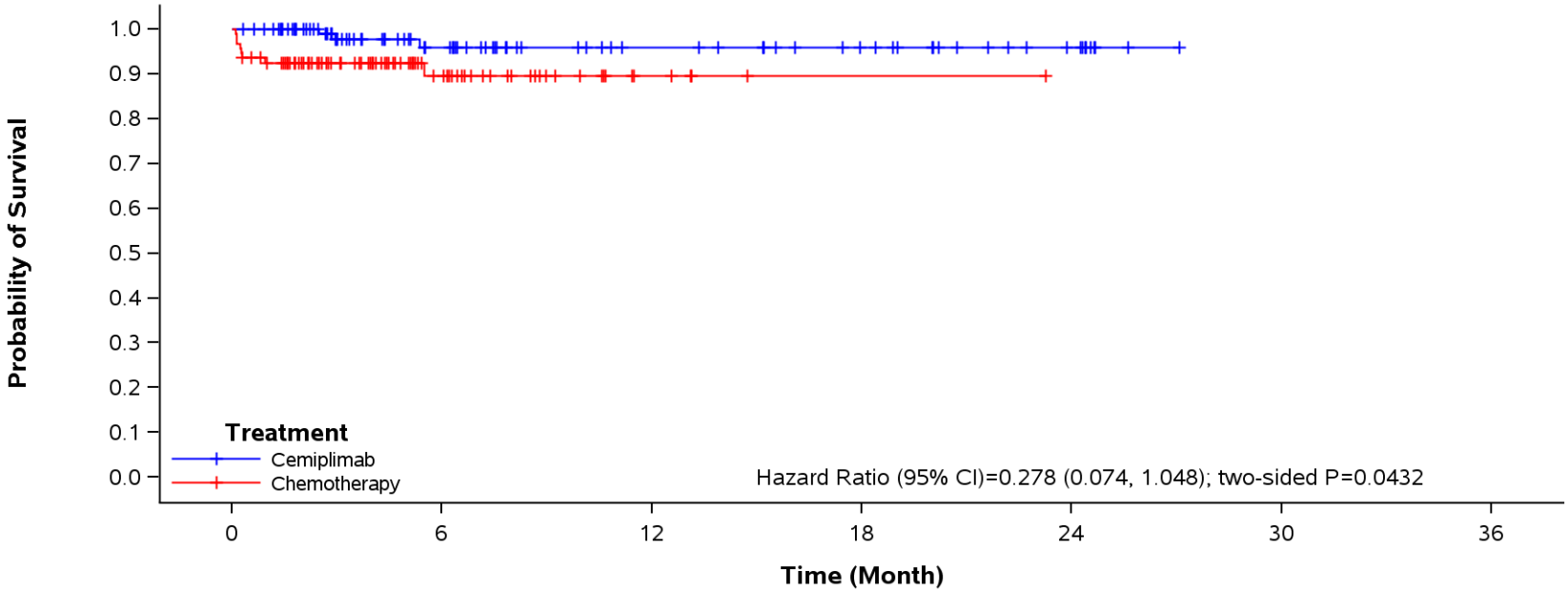

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 47 | 25 | 19 | 9 | 0 | 0 |
| Chemotherapy | 94 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders
PT: Stomatitis



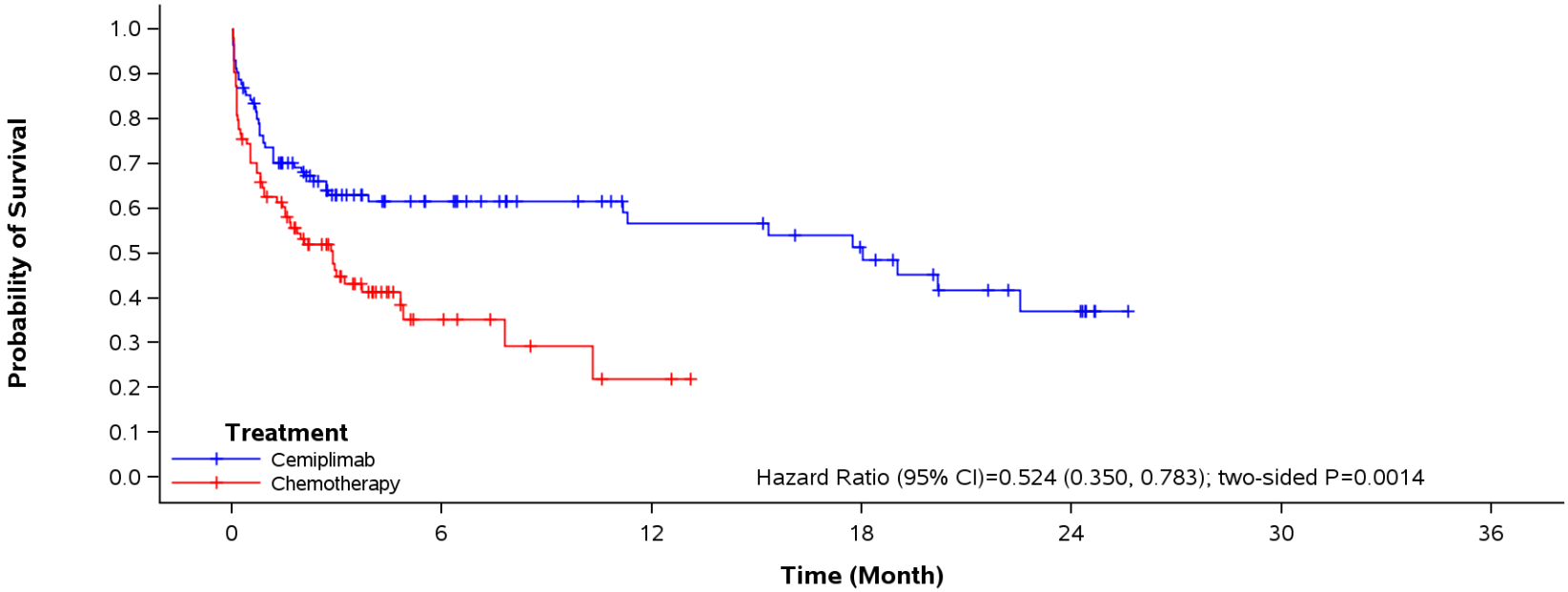

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 50 | 30 | 22 | 11 | 0 | 0 |
| Chemotherapy | 94 | 30 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: General disorders and administration site conditions



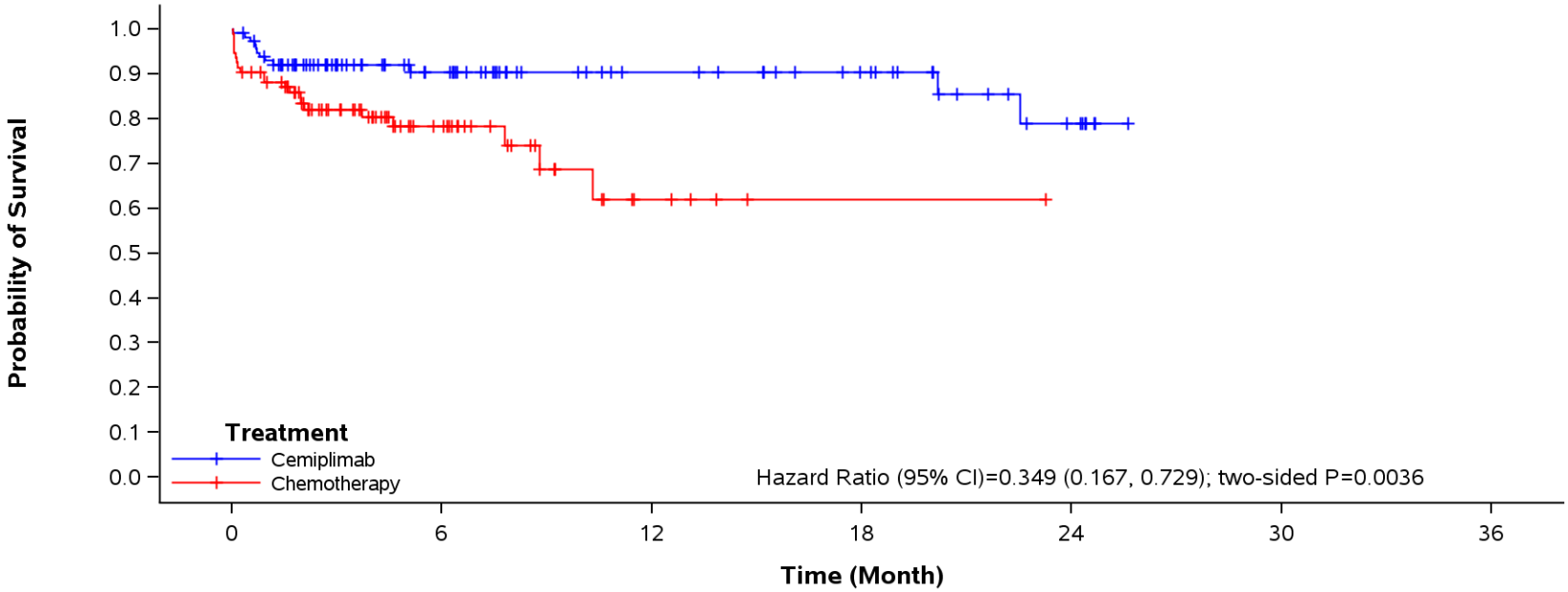

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 38 | 23 | 18 | 8 | 0 | 0 |
| Chemotherapy | 94 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: General disorders and administration site conditions
PT: Asthenia



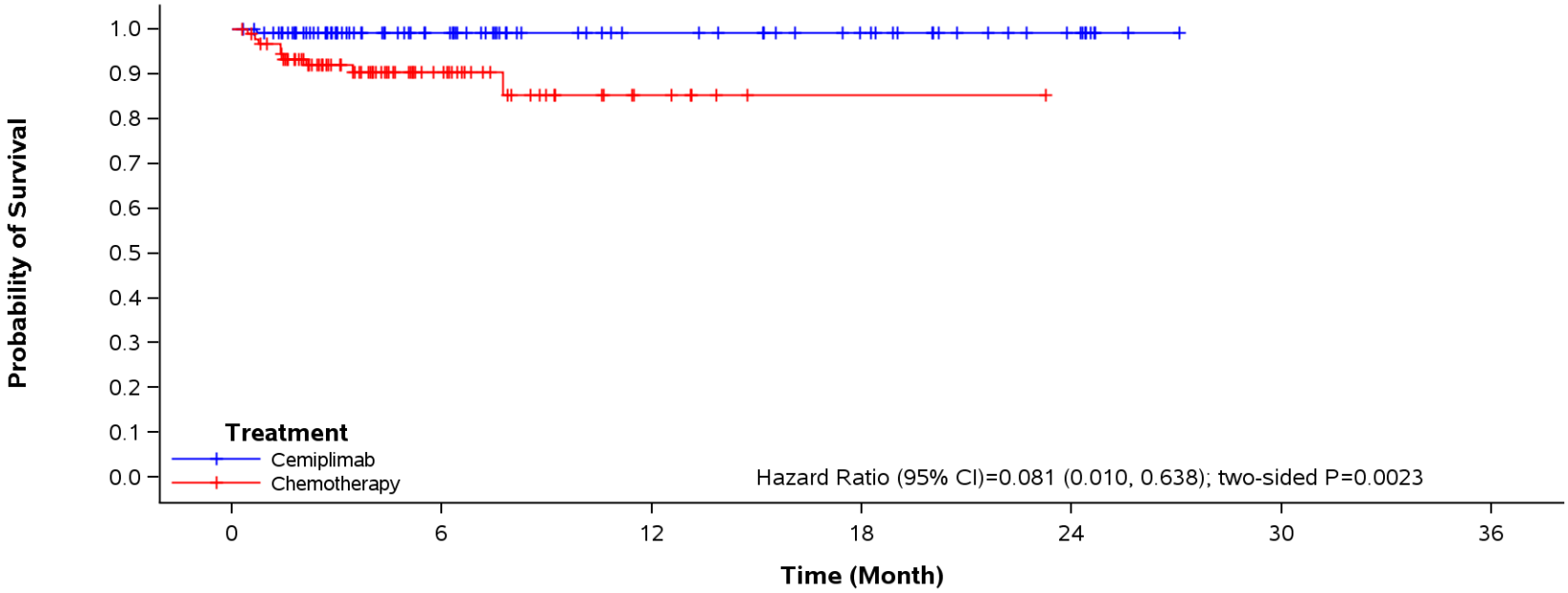

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 10 | 0 | 0 |
| Chemotherapy | 94 | 29 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



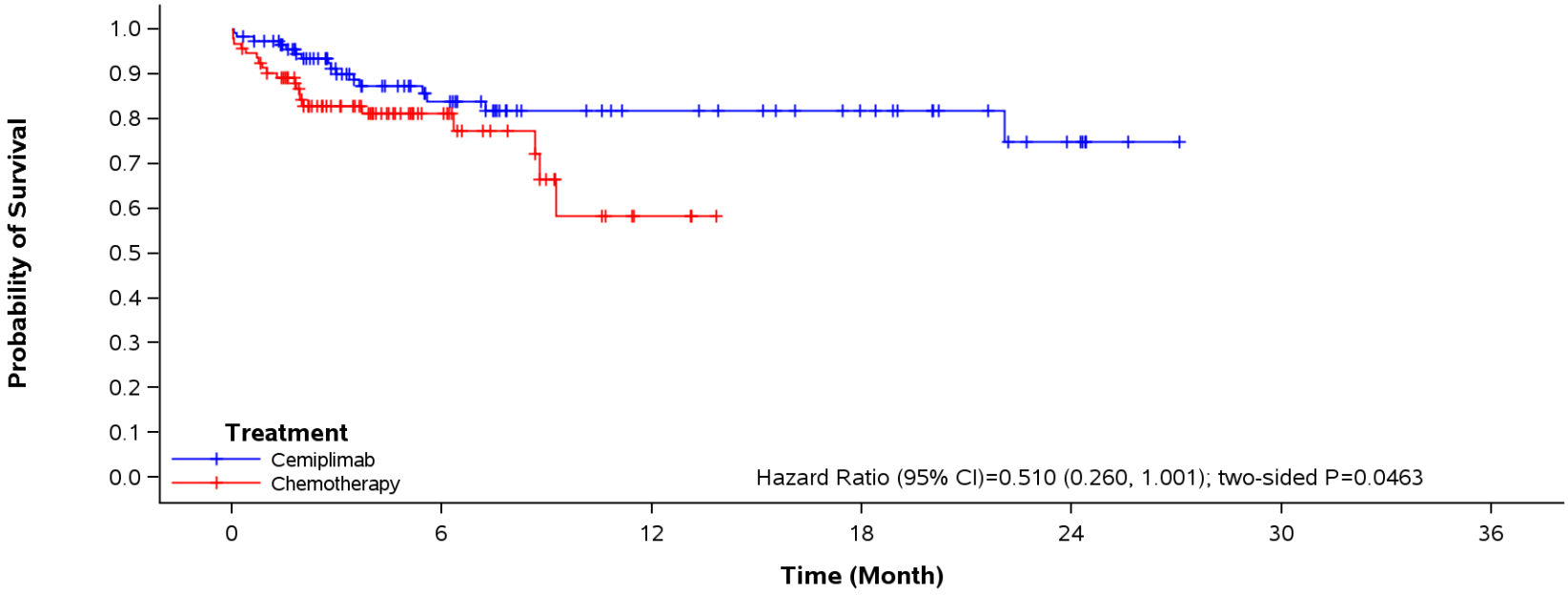

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 30 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Nervous system disorders




**Number of Subjects at risk**

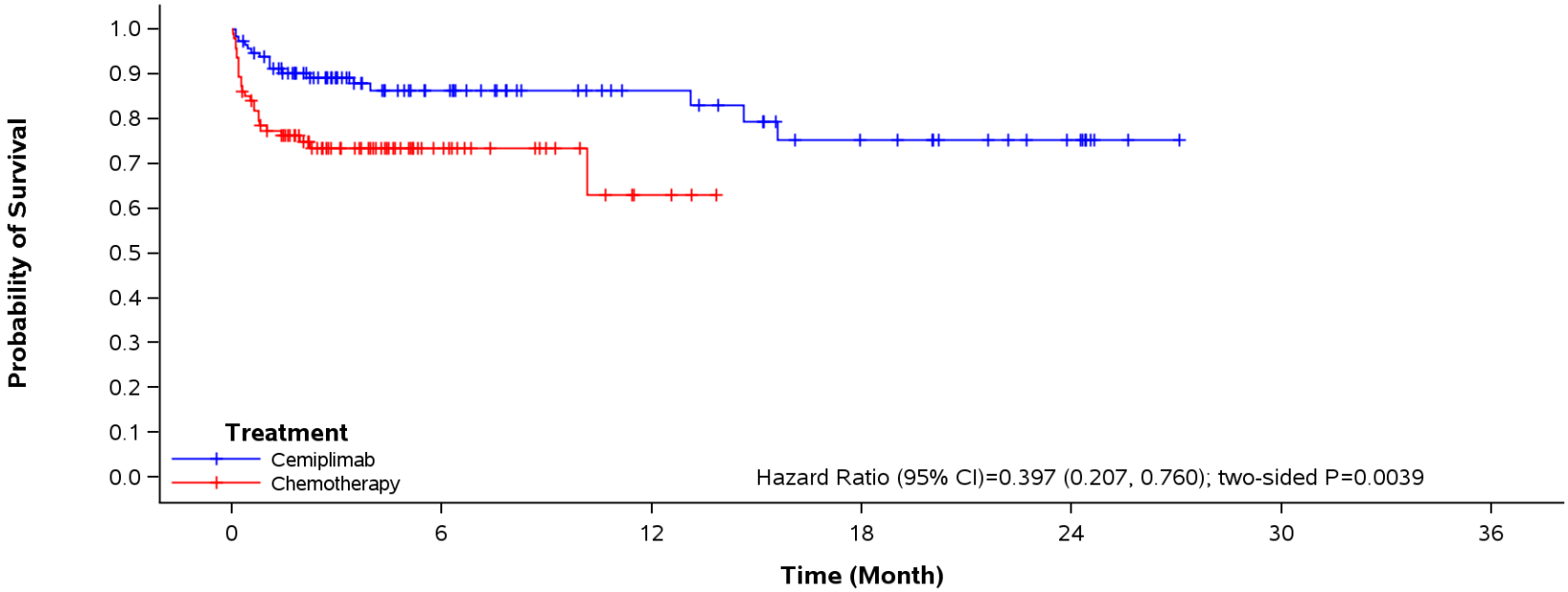
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 45 | 26 | 19 | 8 | 0 | 0 |
| Chemotherapy | 94 | 26 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Skin and subcutaneous tissue disorders



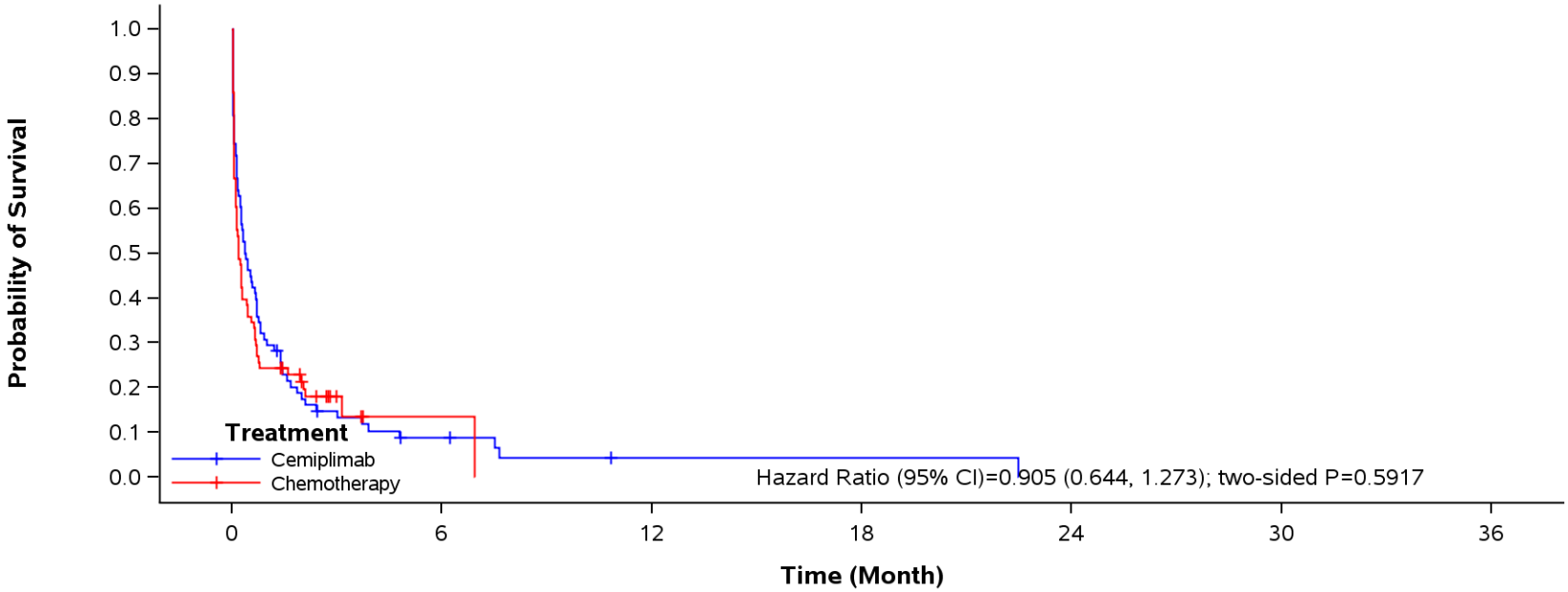

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 43 | 26 | 16 | 8 | 0 | 0 |
| Chemotherapy | 94 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Number of patients with any TEAE



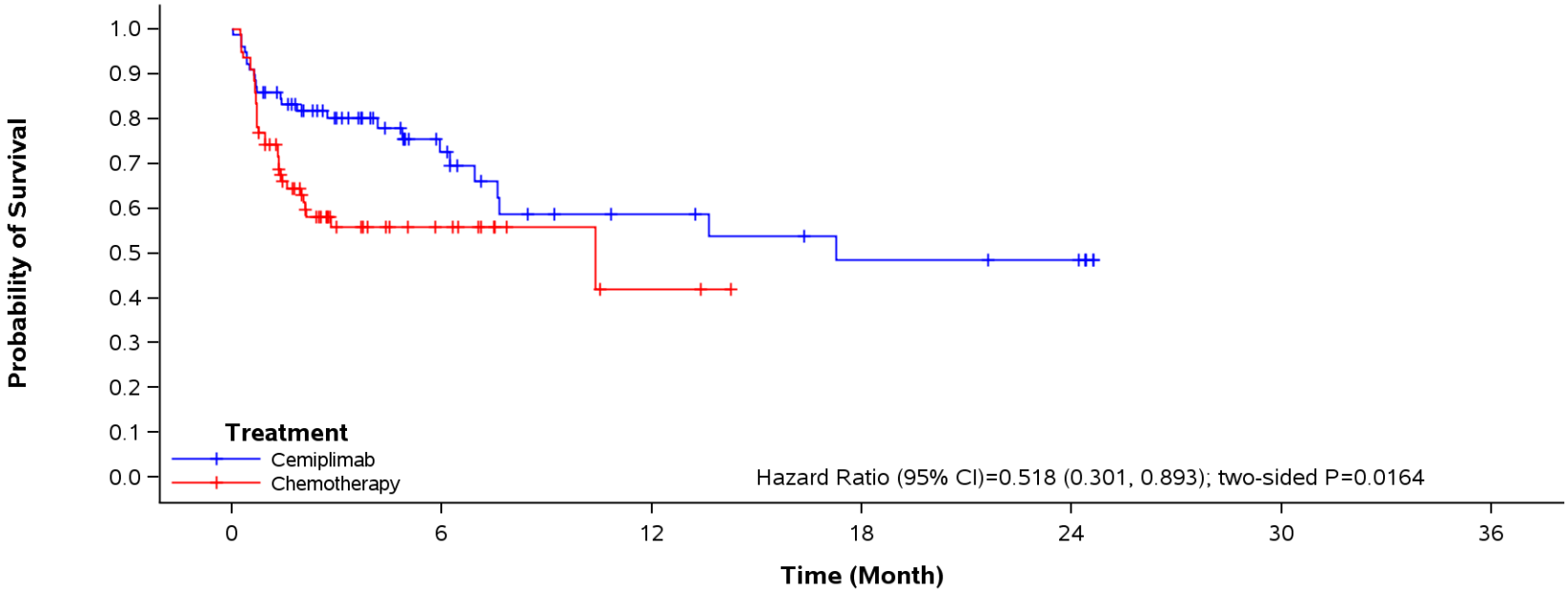

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 5 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 78 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders



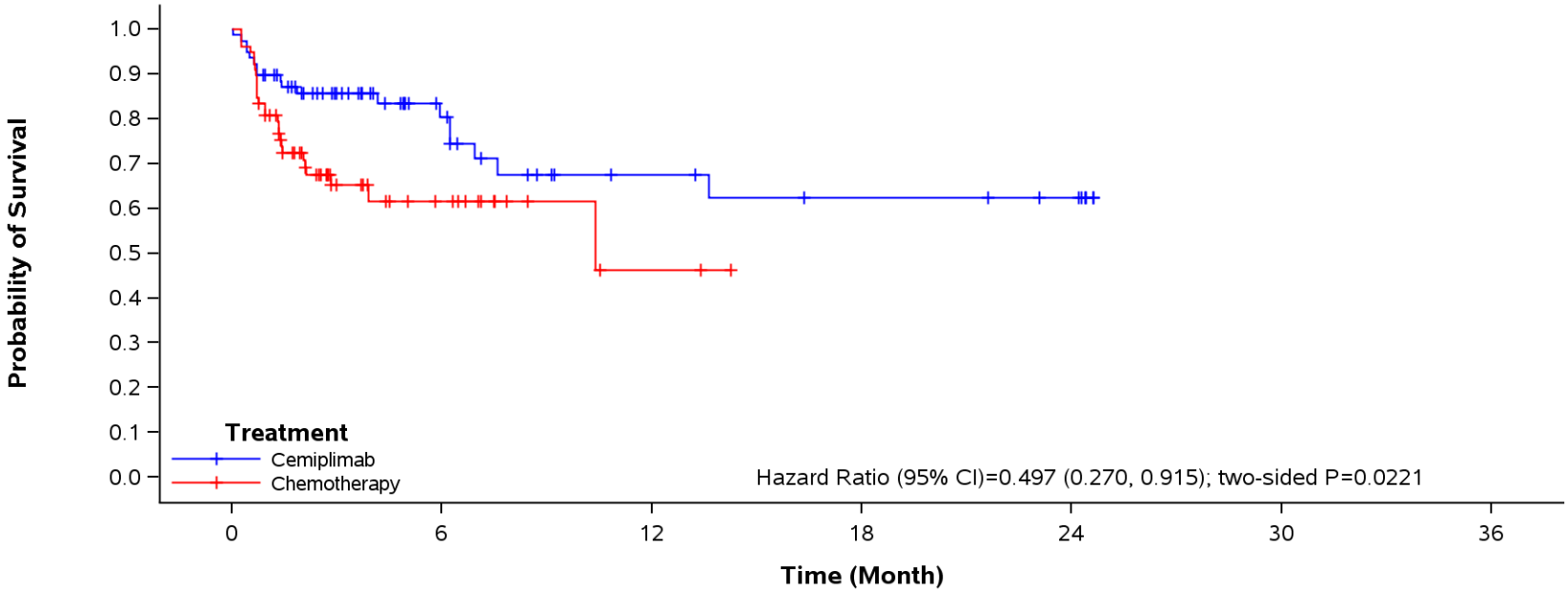

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 25 | 13 | 9 | 8 | 0 | 0 |
| Chemotherapy | 78 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



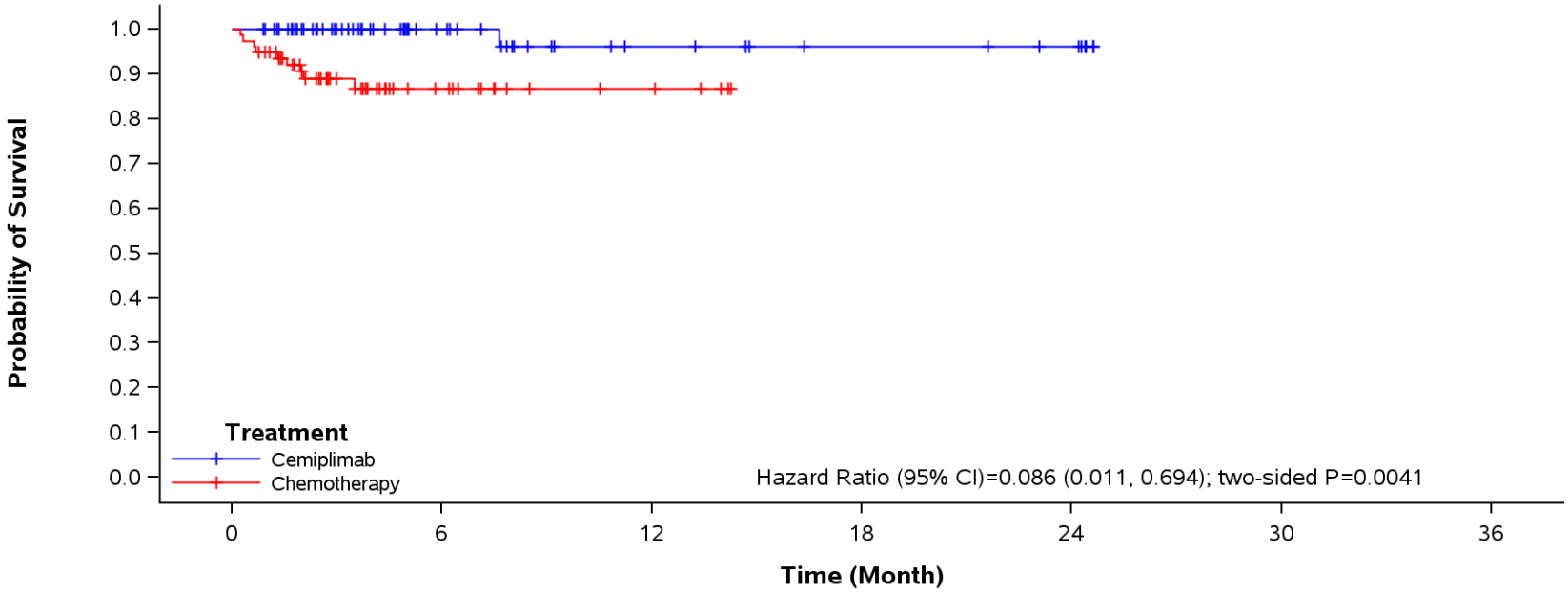

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 28 | 14 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia



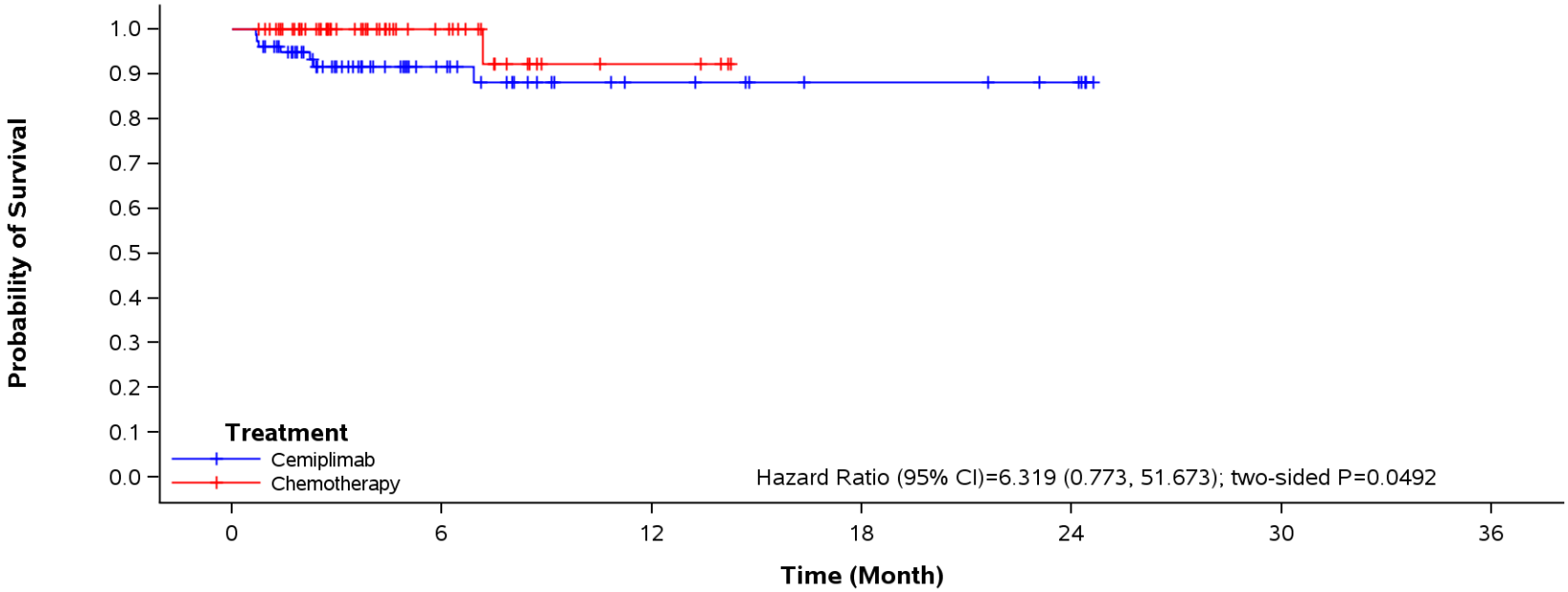

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 15 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Endocrine disorders



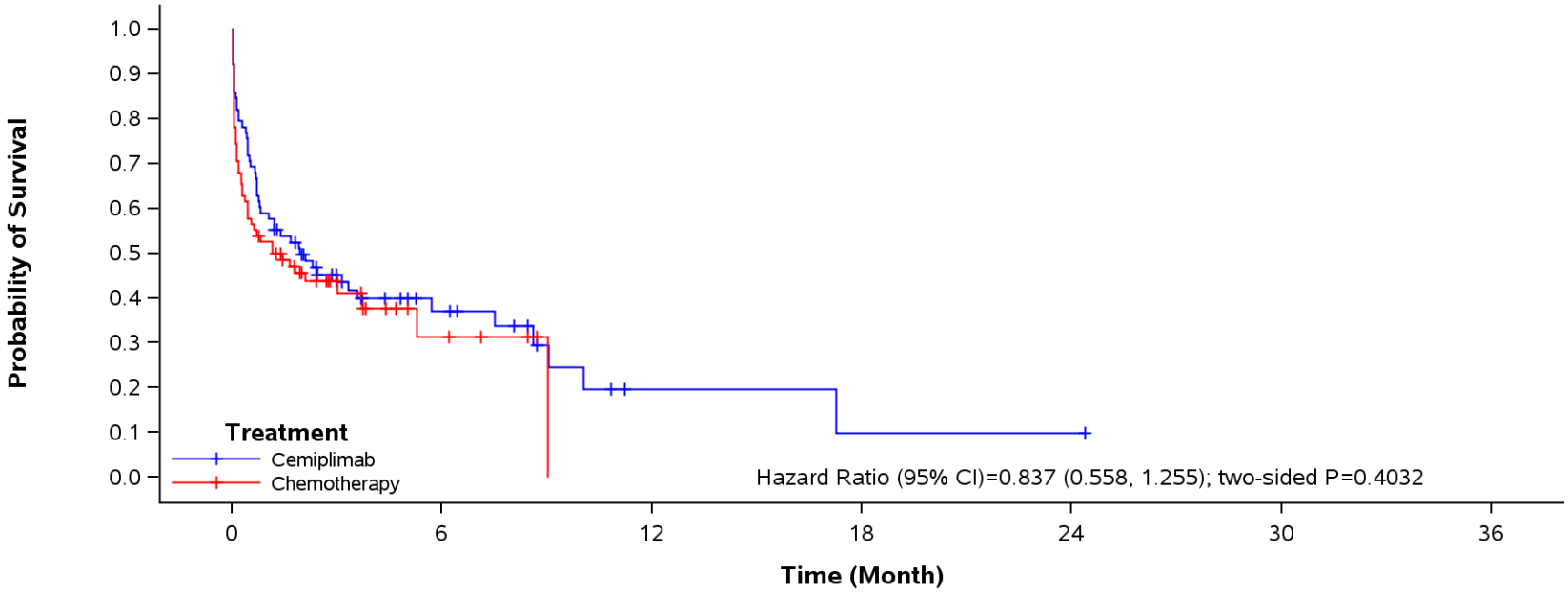

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 30 | 14 | 10 | 8 | 0 | 0 |
| Chemotherapy | 78 | 19 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders



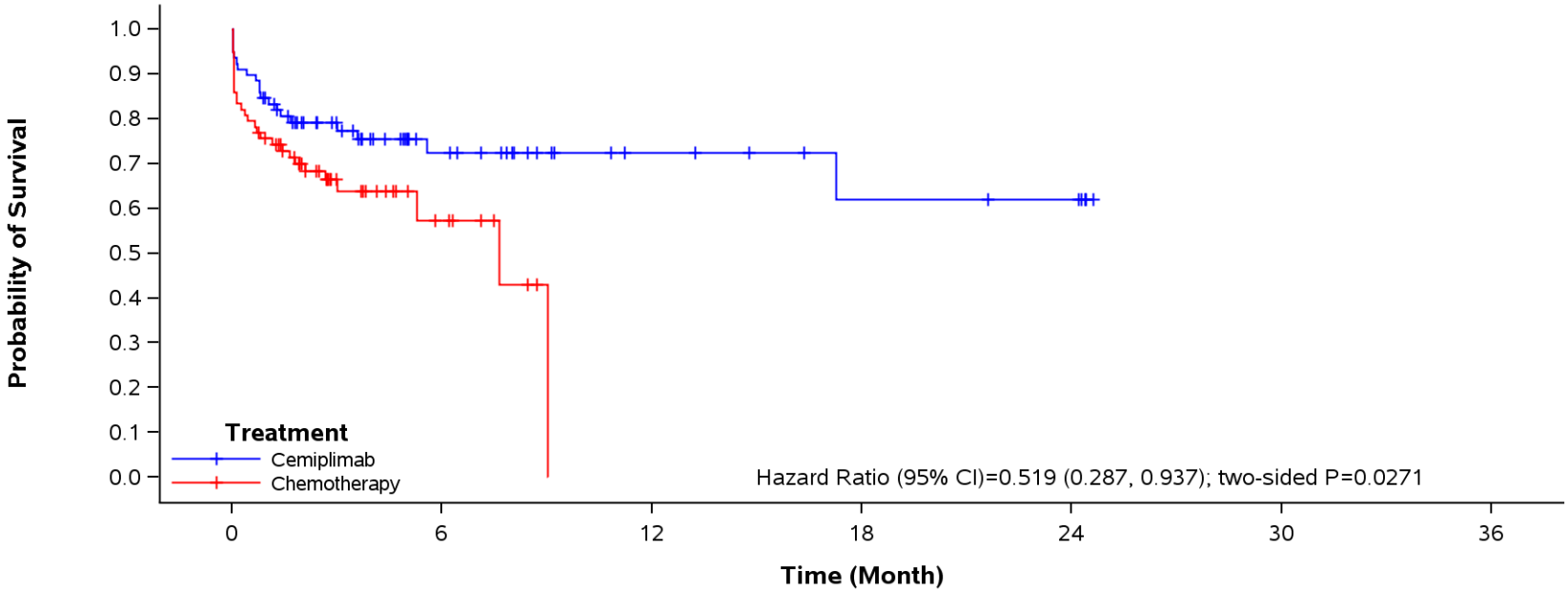

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 13 | 2 | 1 | 1 | 0 | 0 |
| Chemotherapy | 78 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders
PT: Nausea



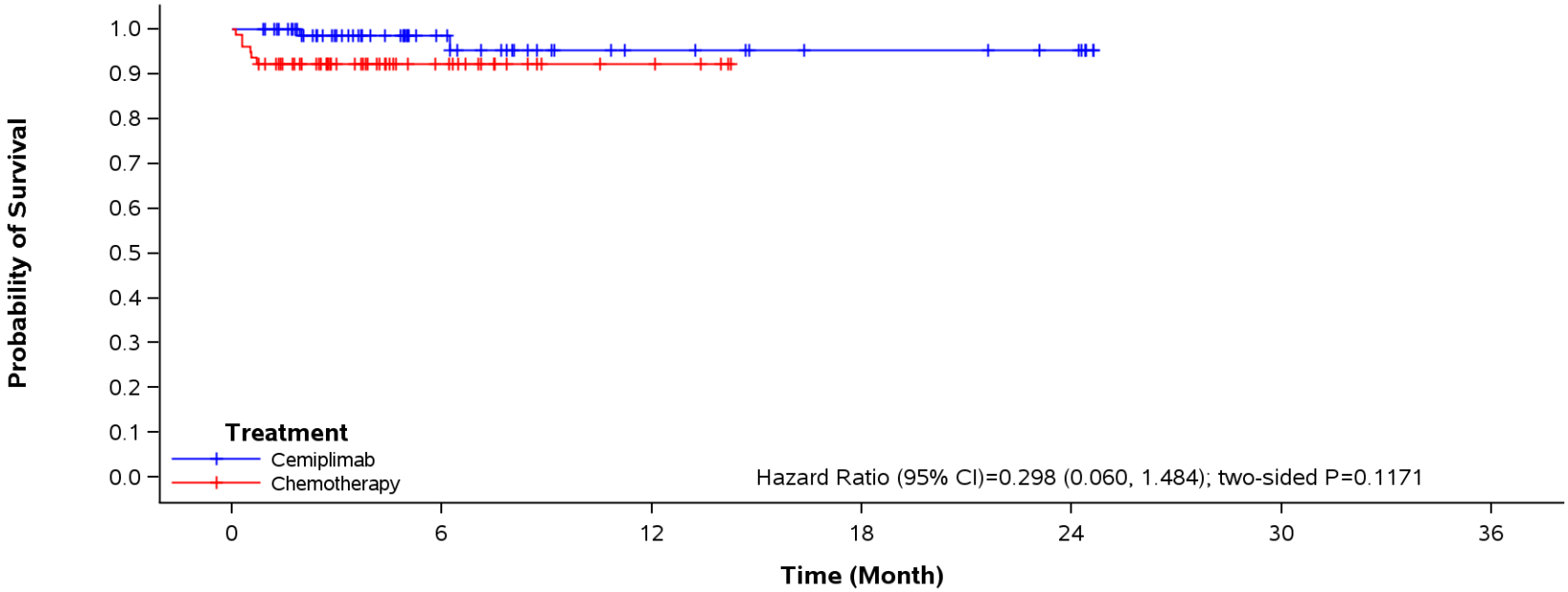

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 23 | 10 | 6 | 5 | 0 | 0 |
| Chemotherapy | 78 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders
PT: Stomatitis



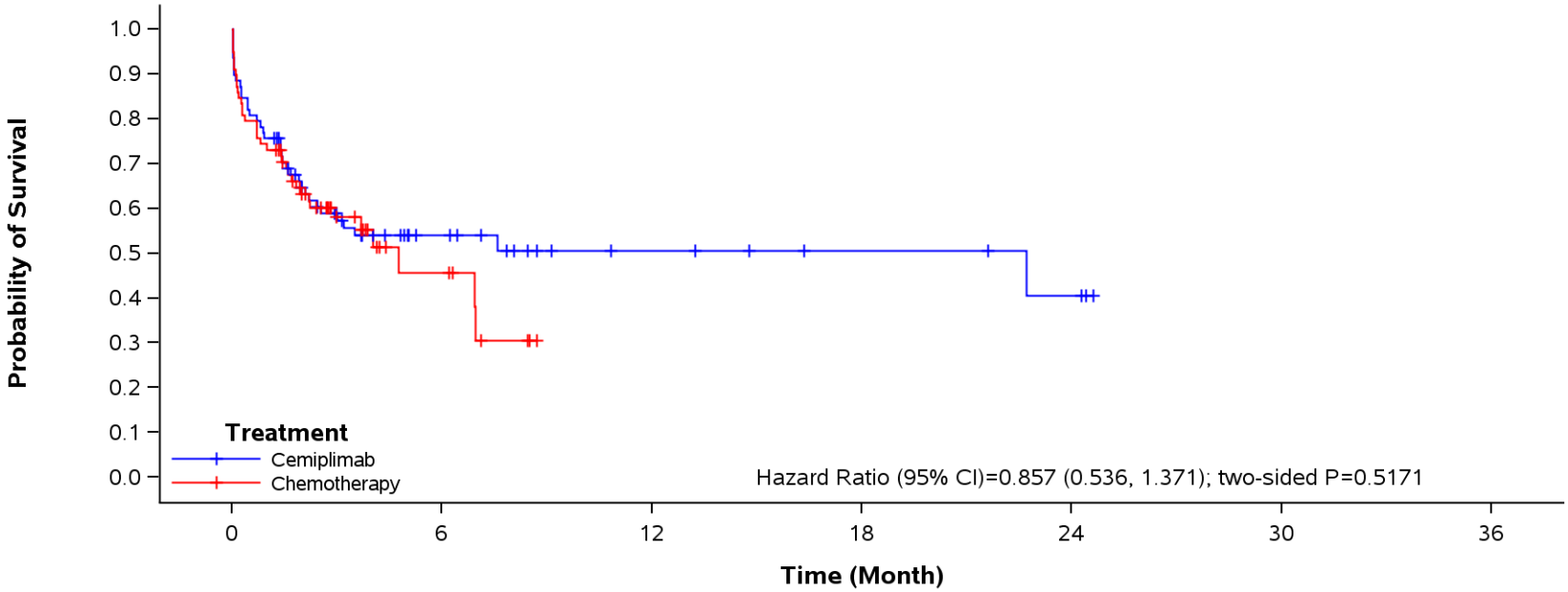

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 14 | 10 | 8 | 0 | 0 |
| Chemotherapy | 78 | 18 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: General disorders and administration site conditions



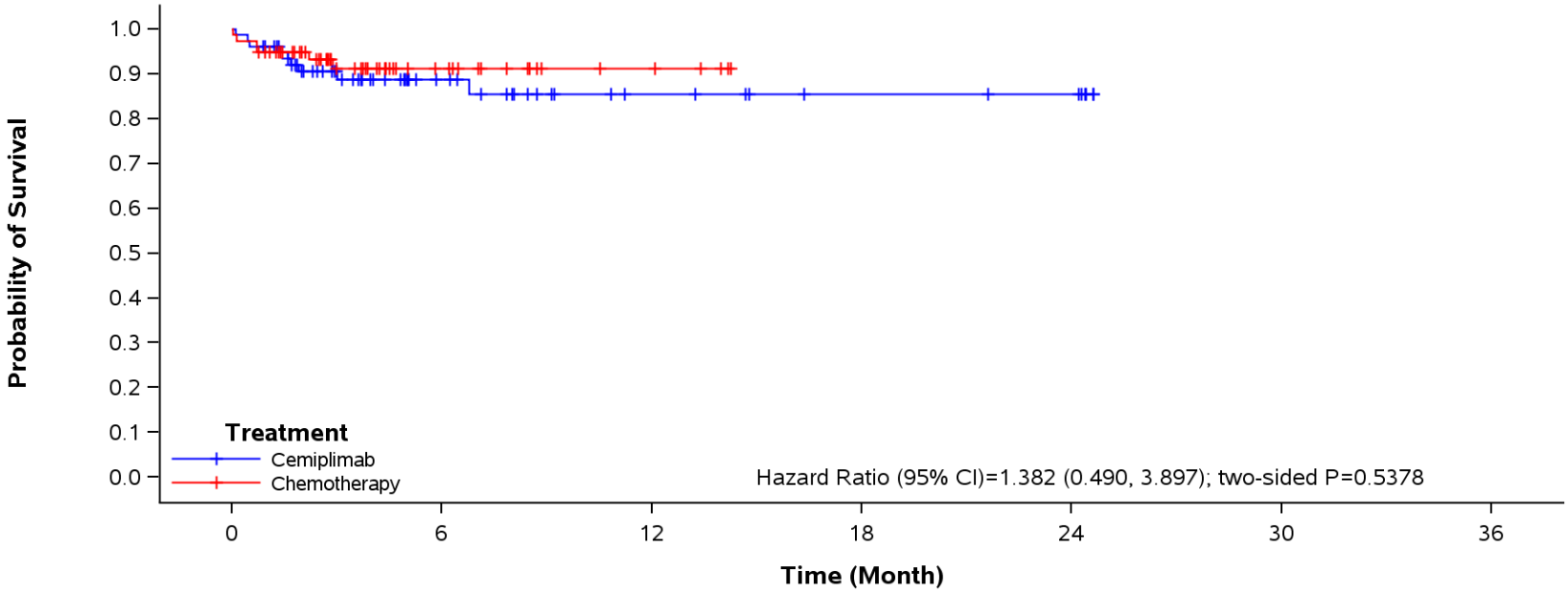

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 20 | 9 | 6 | 4 | 0 | 0 |
| Chemotherapy | 78 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: General disorders and administration site conditions
PT: Asthenia



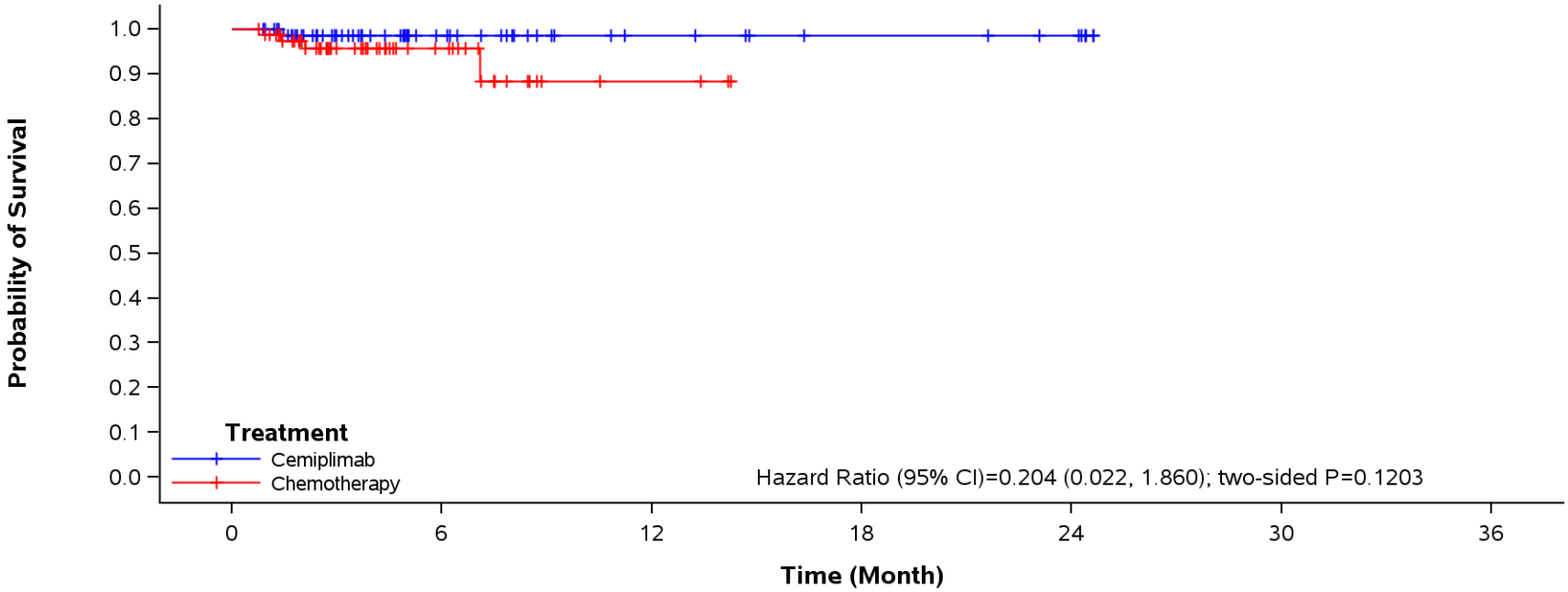

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 29 | 14 | 10 | 9 | 0 | 0 |
| Chemotherapy | 78 | 16 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



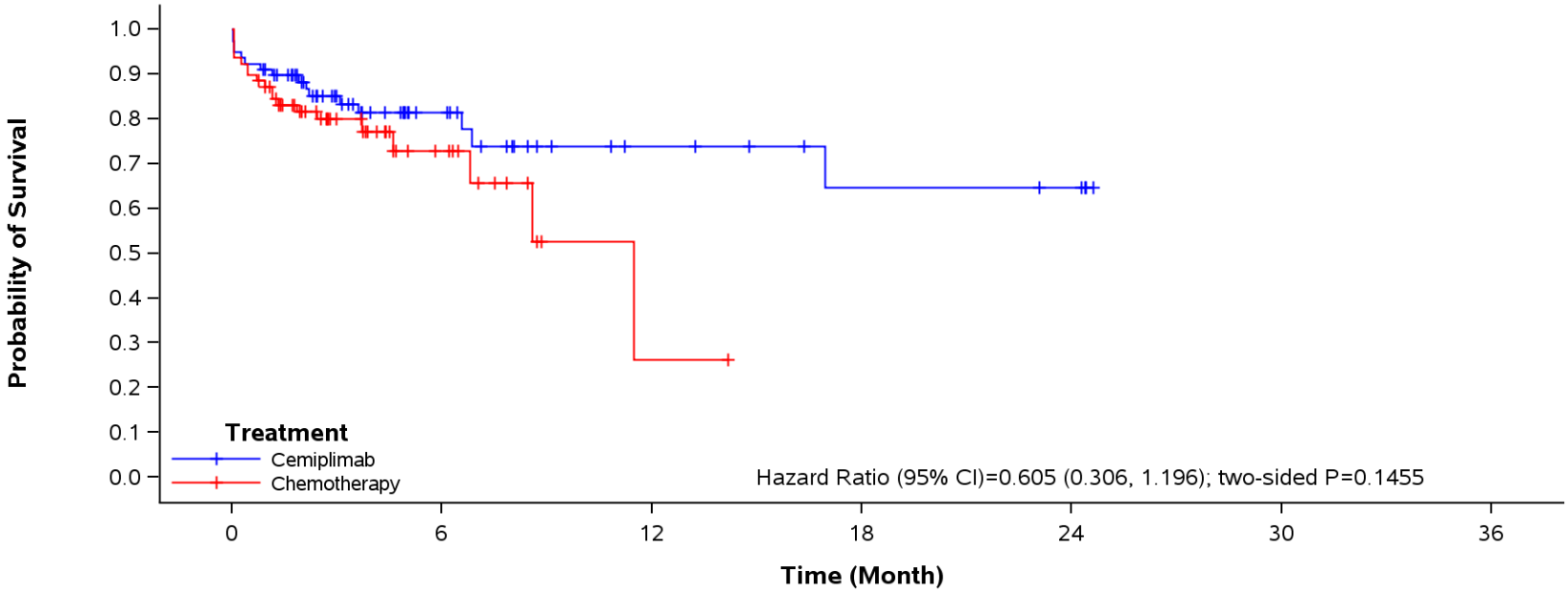

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Nervous system disorders



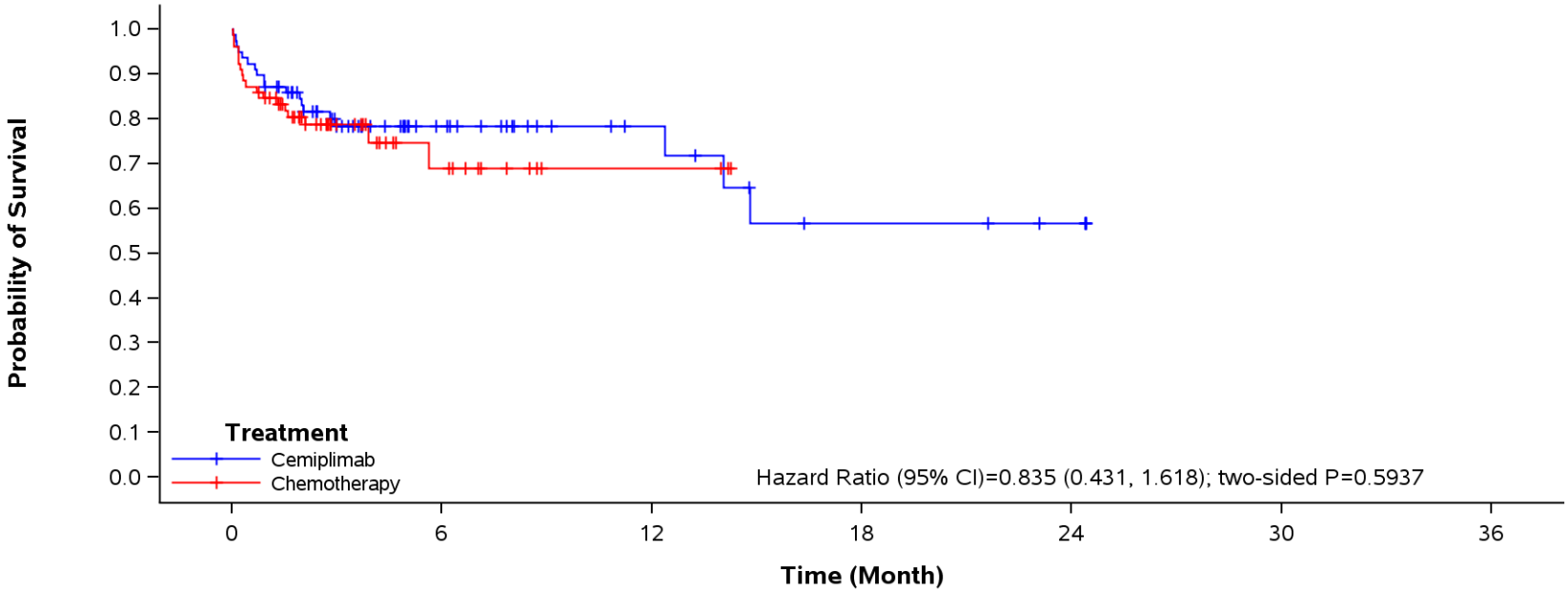

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 25 | 11 | 7 | 6 | 0 | 0 |
| Chemotherapy | 78 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Skin and subcutaneous tissue disorders



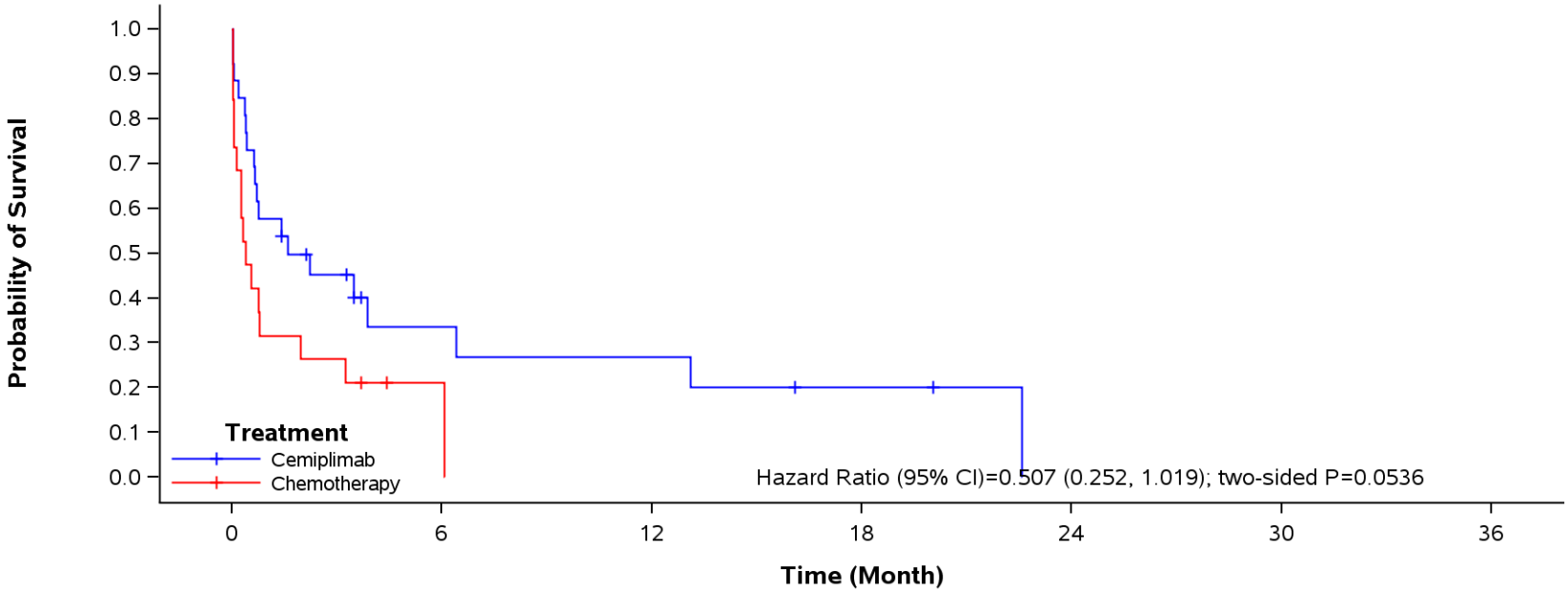

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 26 | 12 | 6 | 4 | 0 | 0 |
| Chemotherapy | 78 | 12 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Number of patients with any TEAE



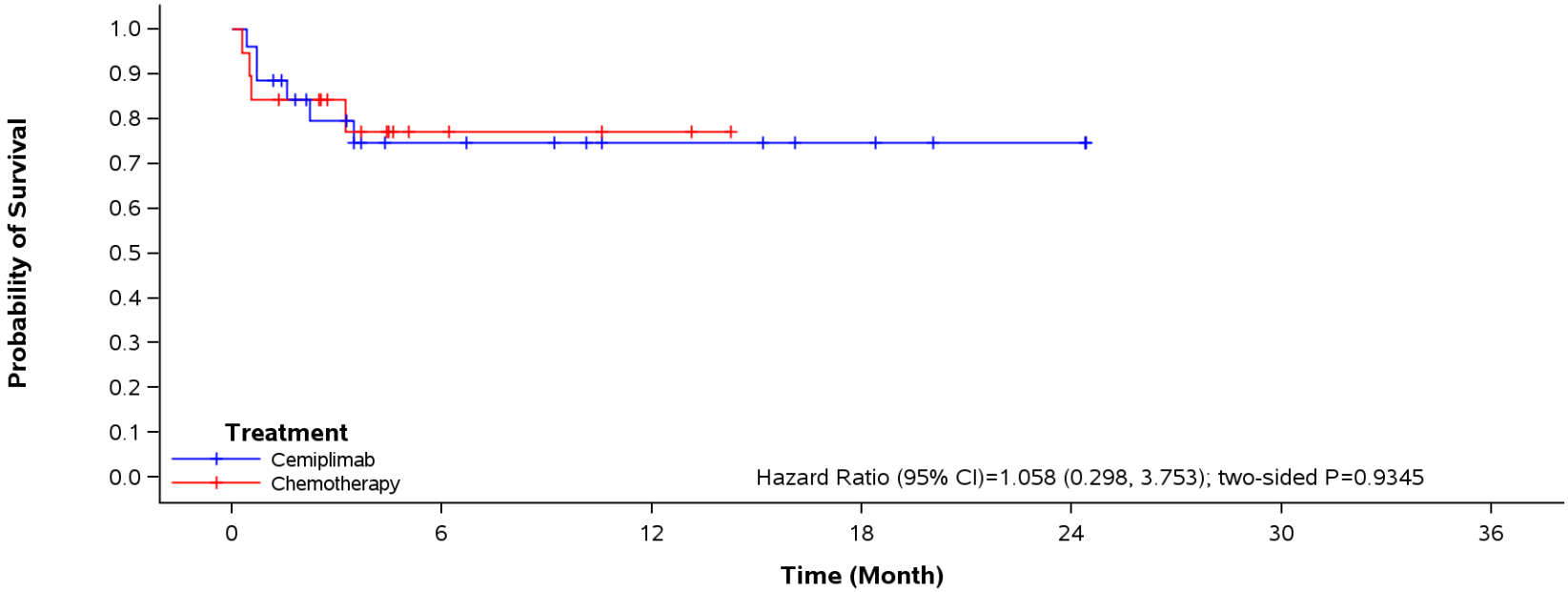

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 5 | 4 | 2 | 0 | 0 | 0 |
| Chemotherapy | 19 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders



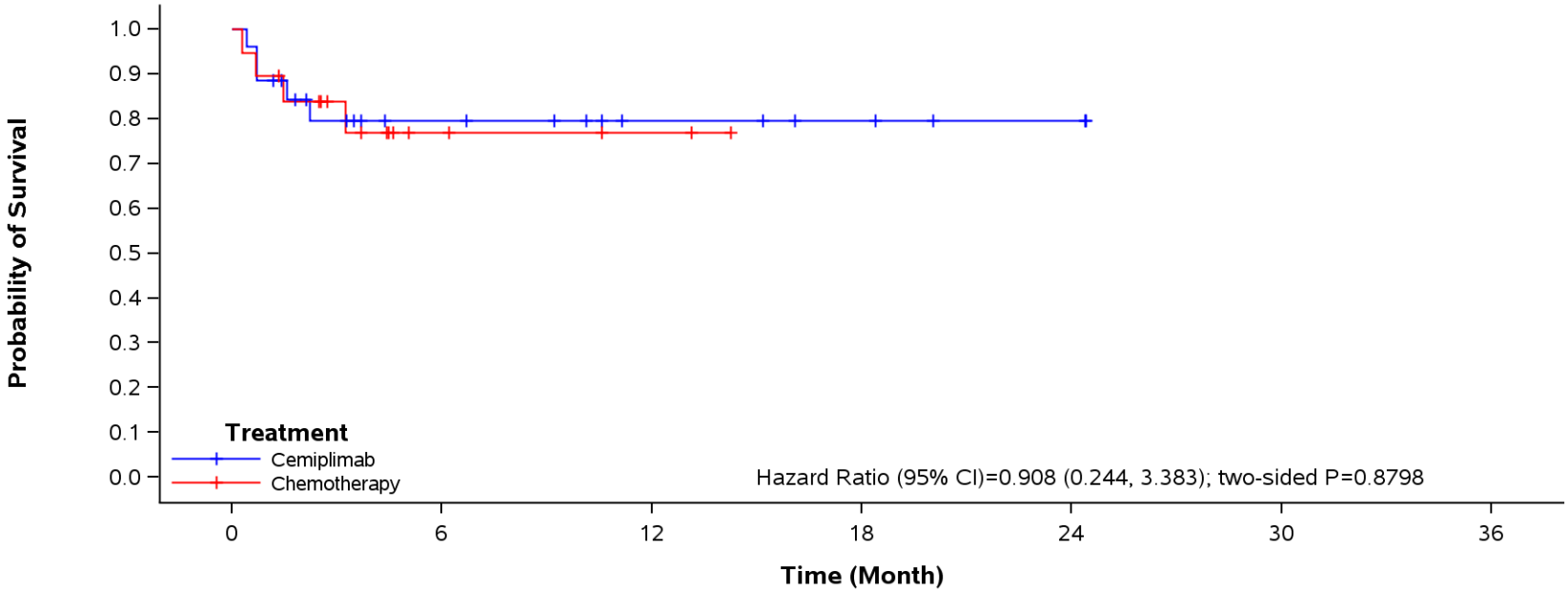

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



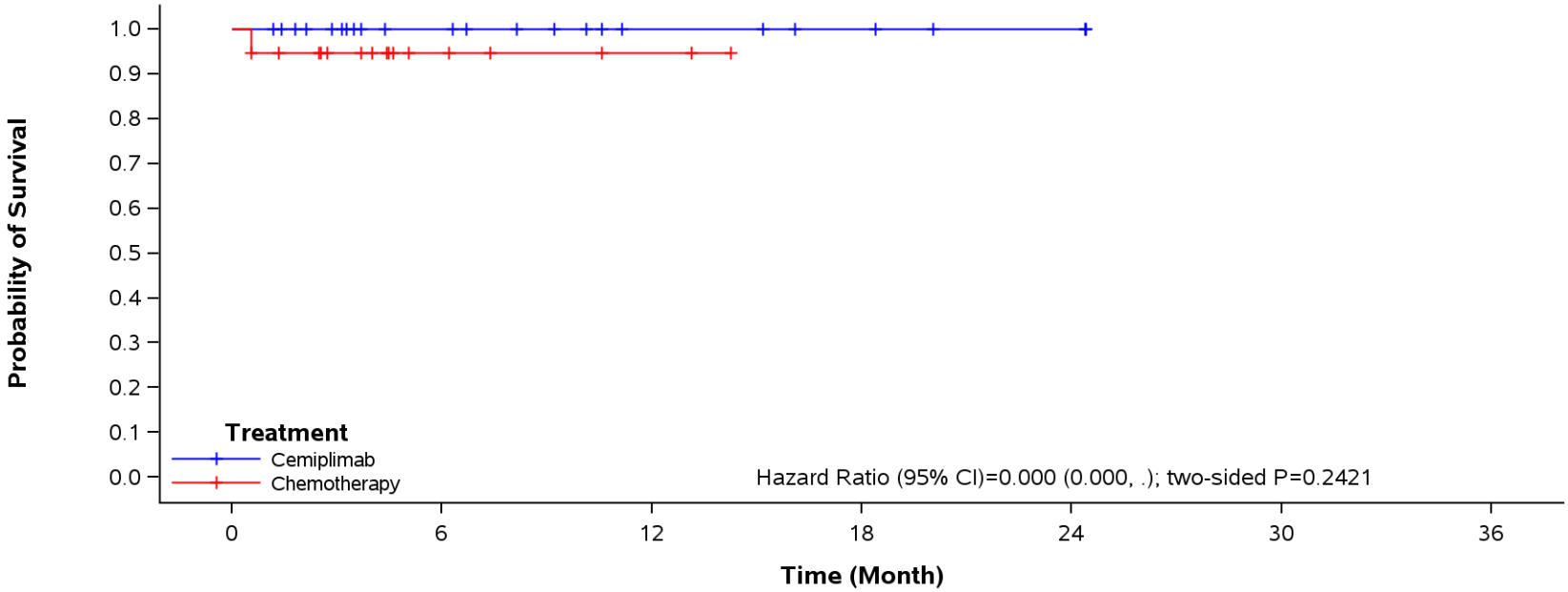

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



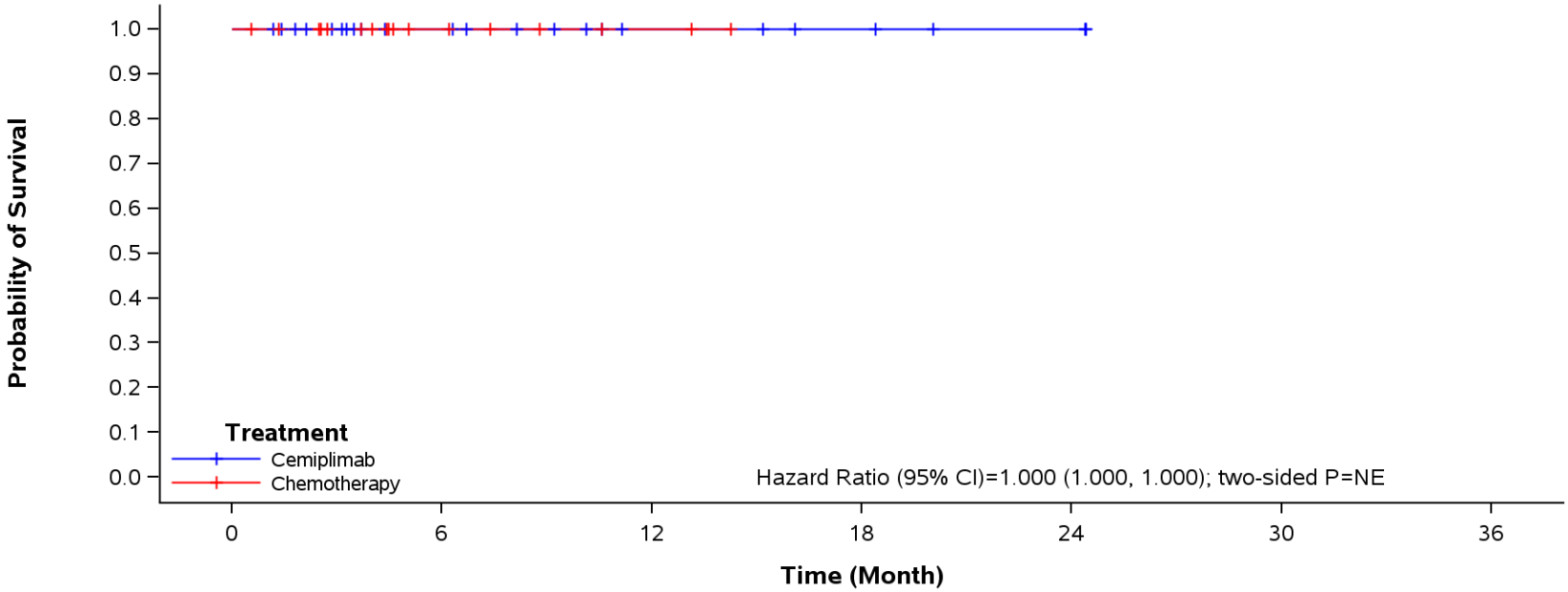

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Endocrine disorders



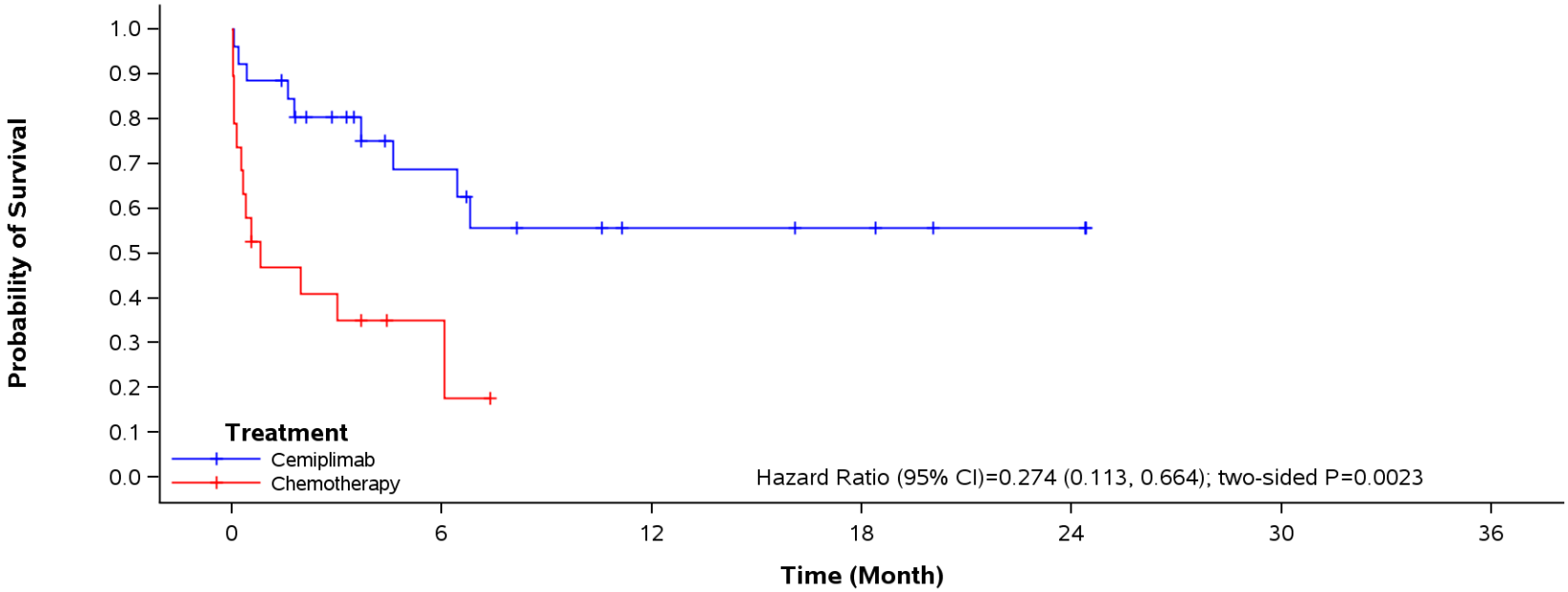

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders



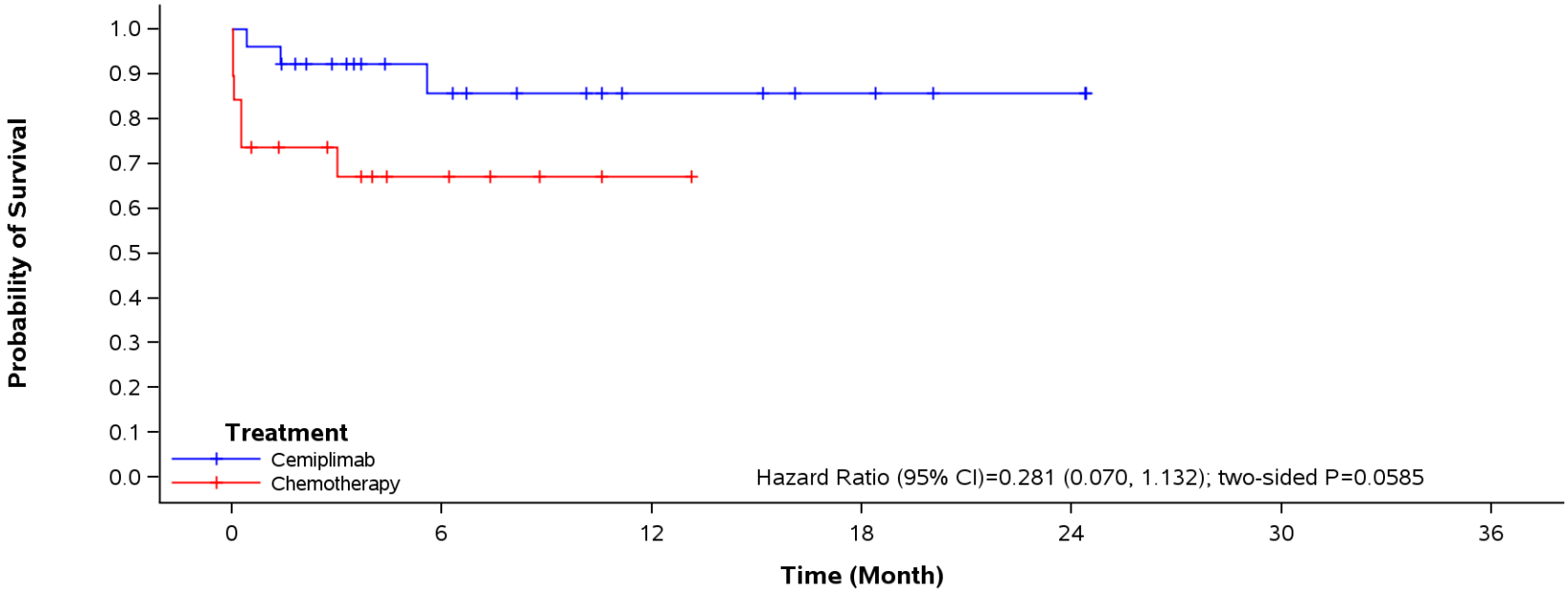

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 5 | 4 | 2 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders
PT: Nausea



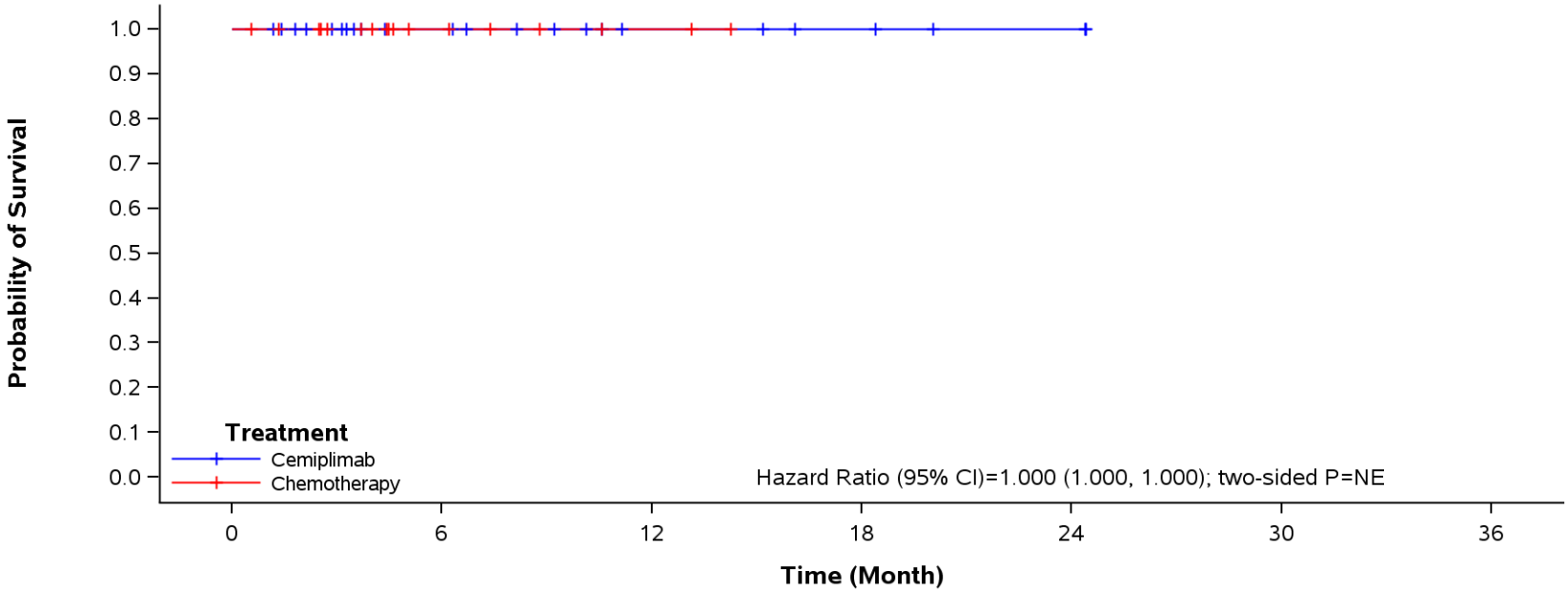

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 13 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders
PT: Stomatitis



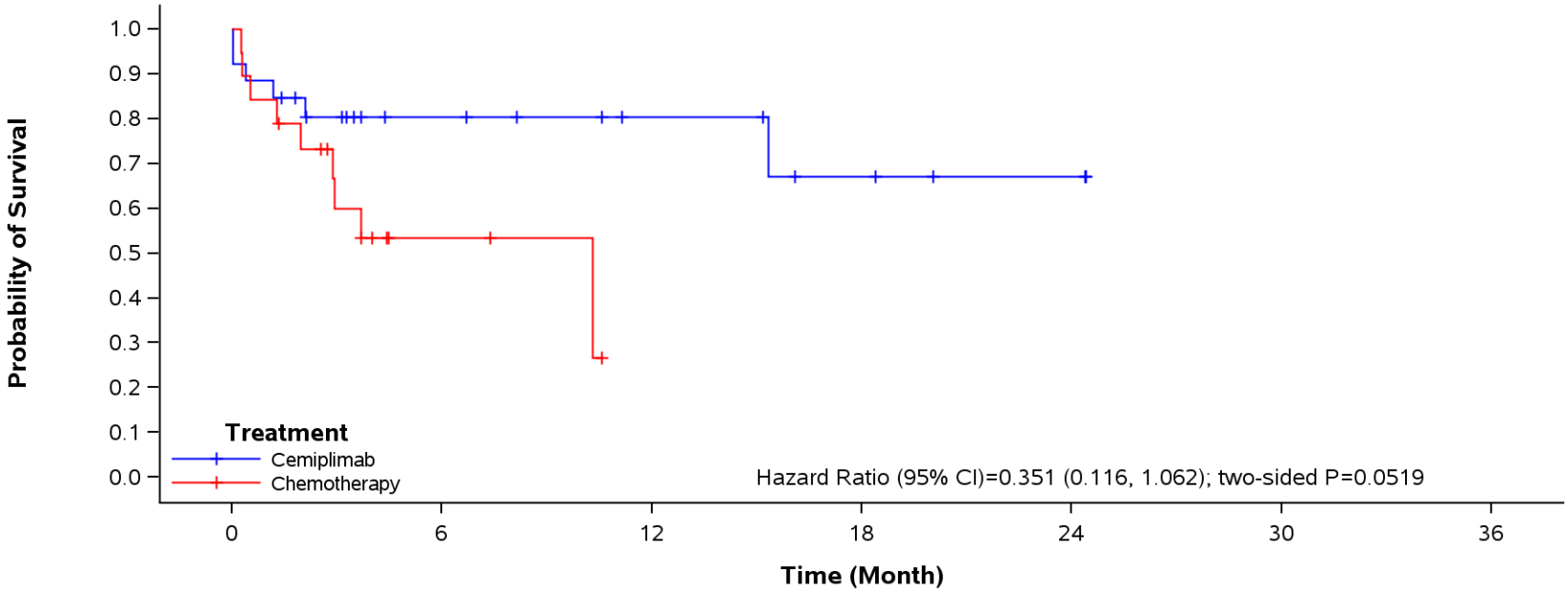

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: General disorders and administration site conditions



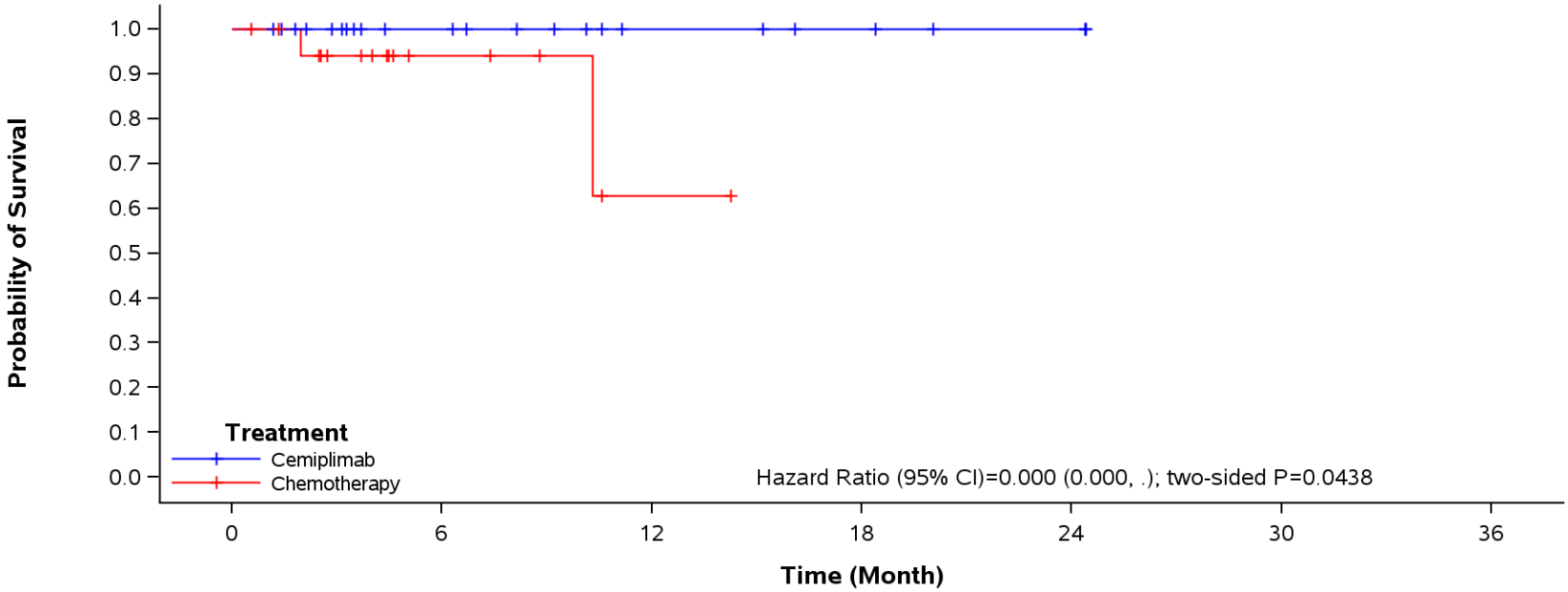

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 7 | 4 | 2 | 0 | 0 |
| Chemotherapy | 19 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: General disorders and administration site conditions
PT: Asthenia



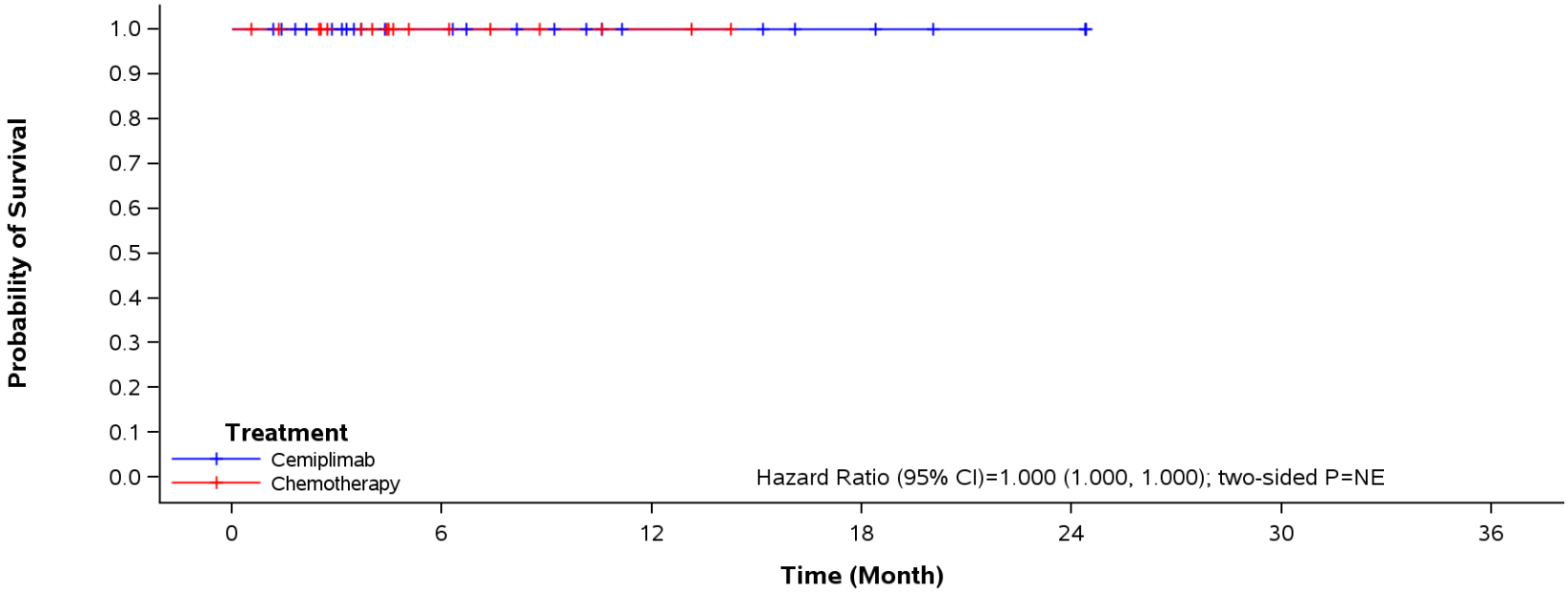

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



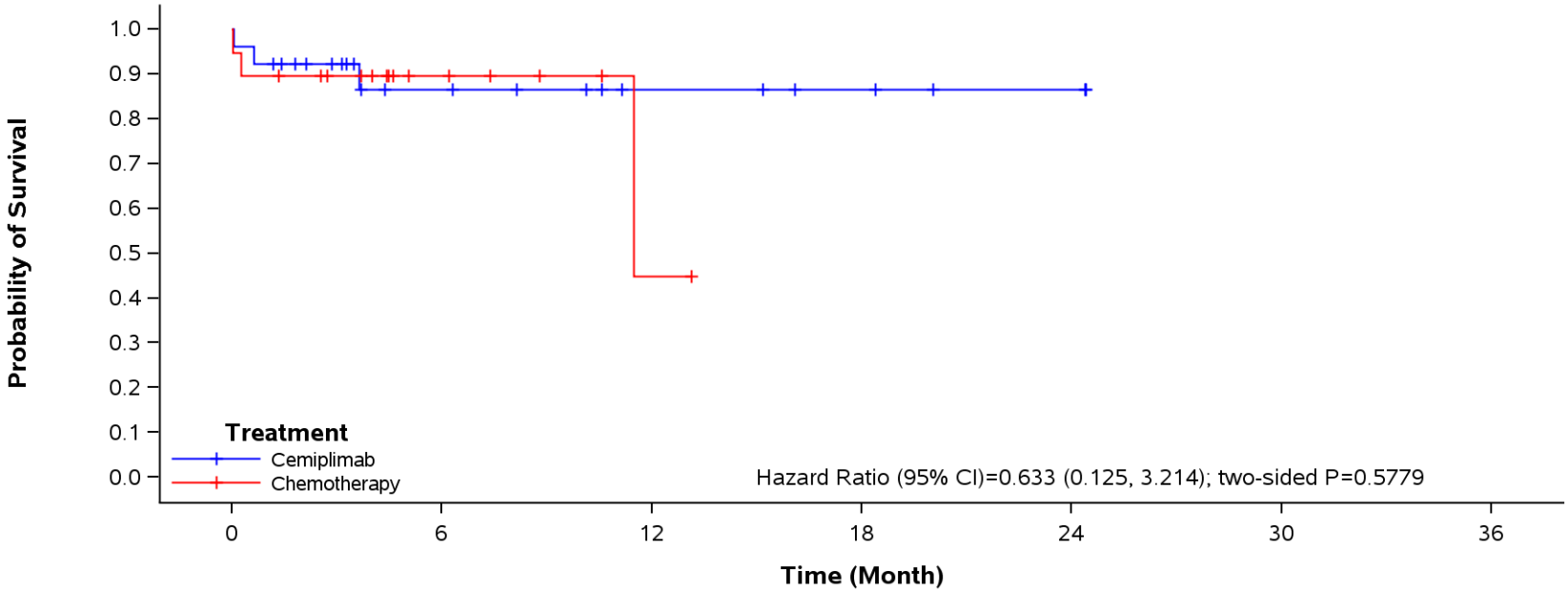

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Nervous system disorders



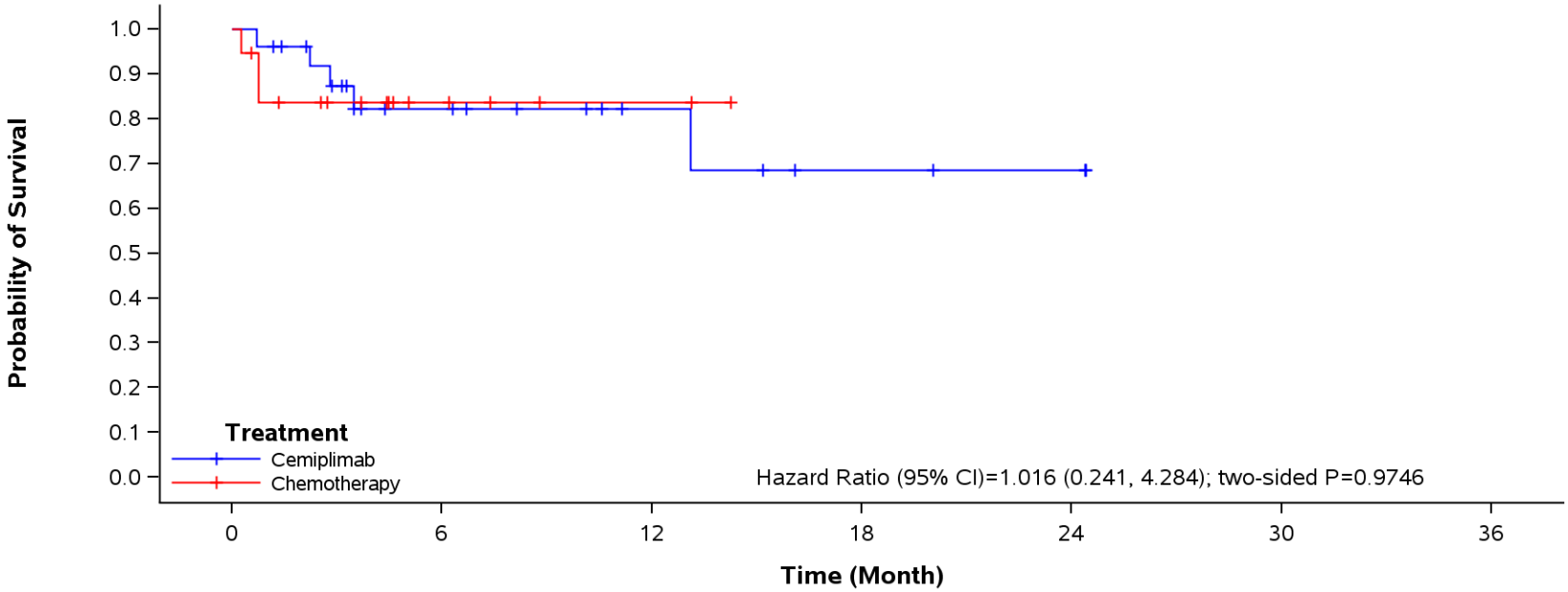

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Skin and subcutaneous tissue disorders



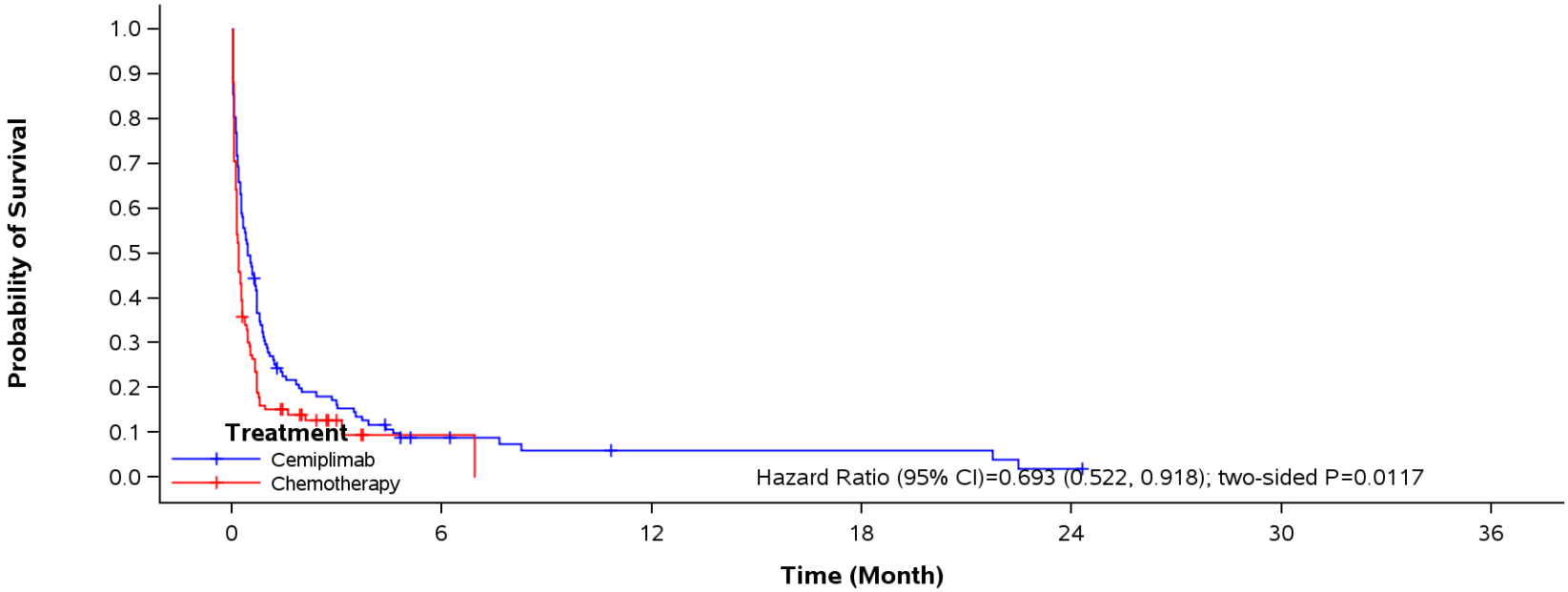

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 6 | 3 | 2 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Number of patients with any TEAE



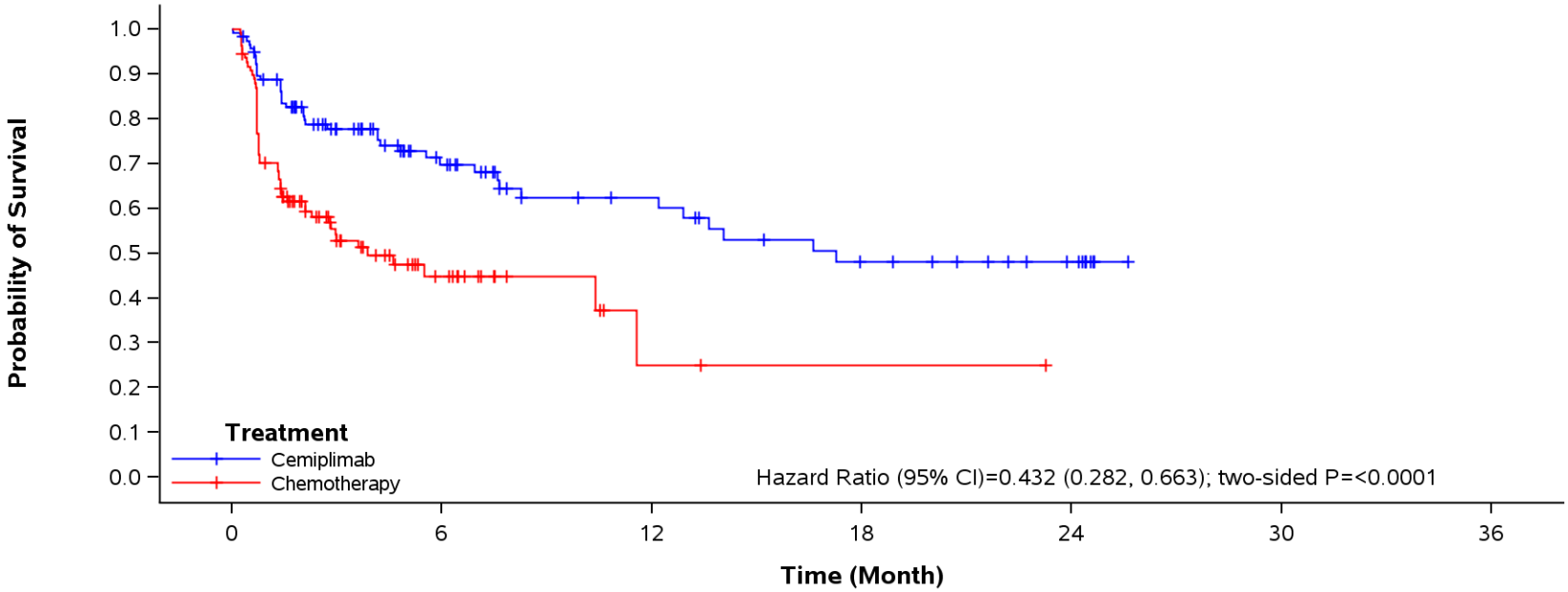

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 7 | 3 | 3 | 1 | 0 | 0 |
| Chemotherapy | 109 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders



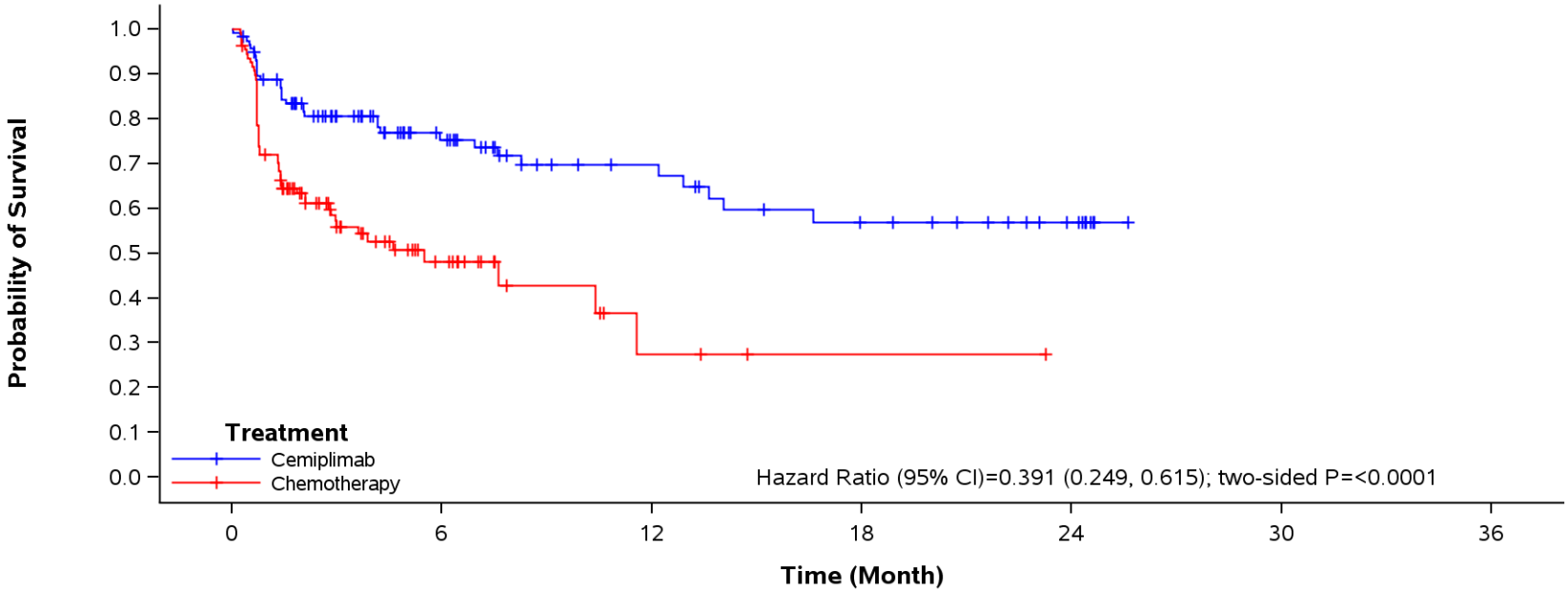

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 47 | 28 | 18 | 11 | 0 | 0 |
| Chemotherapy | 109 | 16 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Anaemia



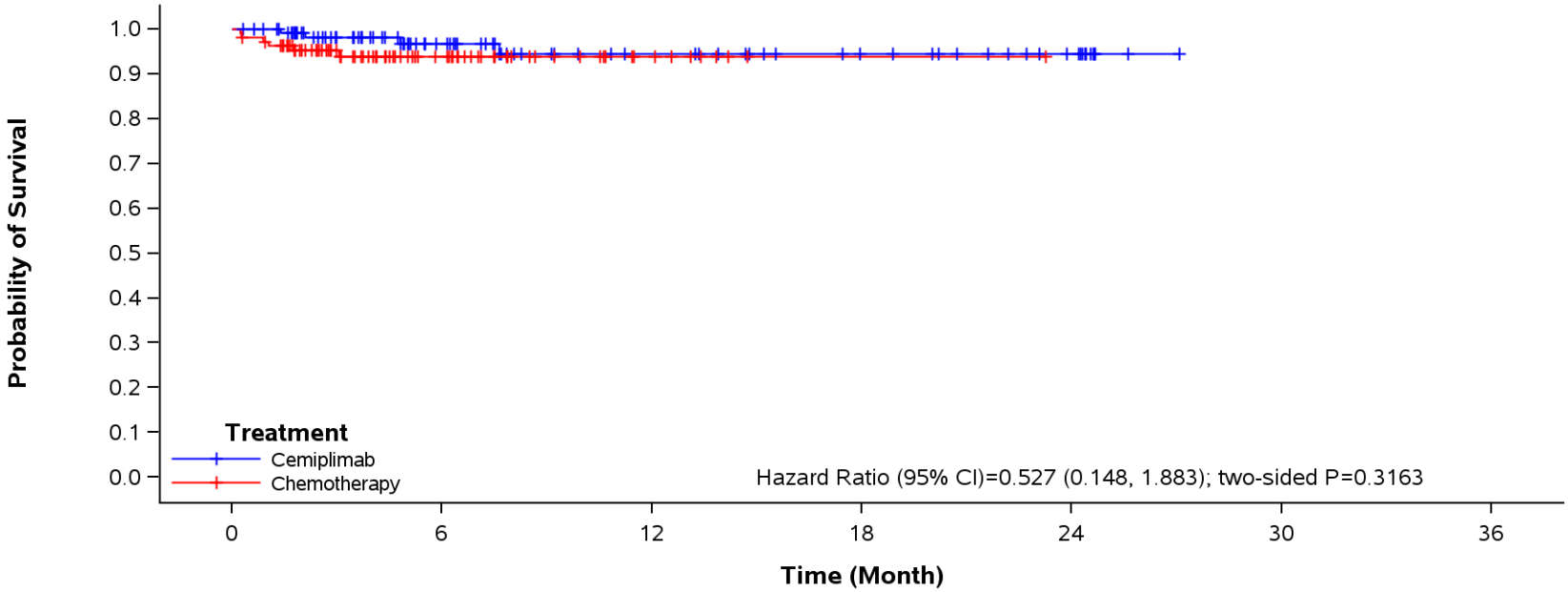

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 50 | 29 | 20 | 12 | 0 | 0 |
| Chemotherapy | 109 | 18 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Neutropenia



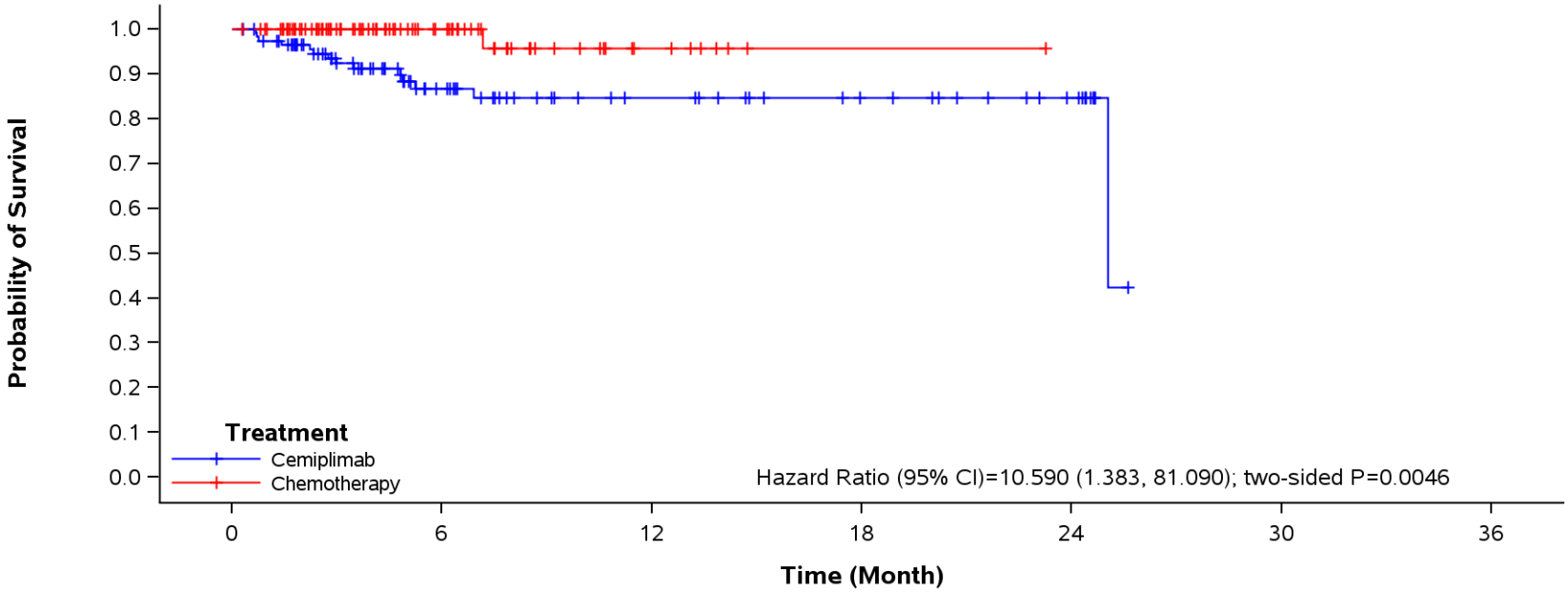

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 33 | 24 | 15 | 0 | 0 |
| Chemotherapy | 109 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Endocrine disorders



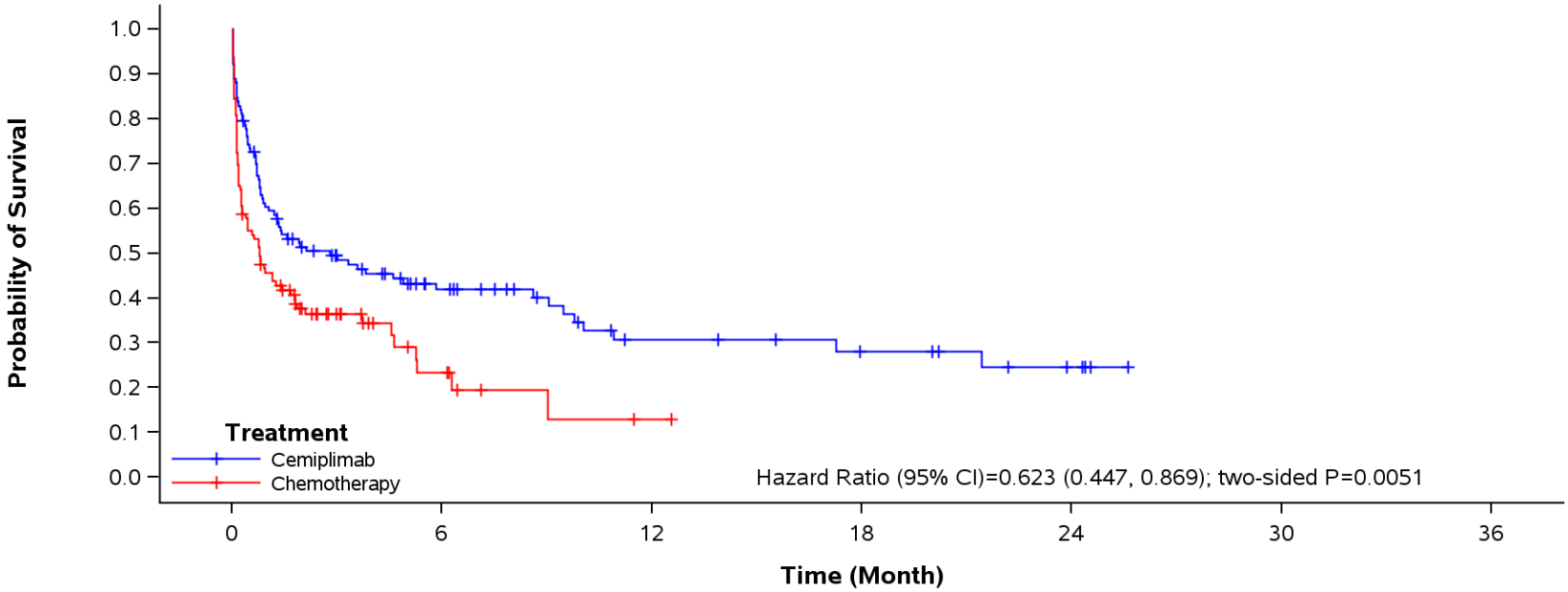

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 49 | 30 | 22 | 14 | 0 | 0 |
| Chemotherapy | 109 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders



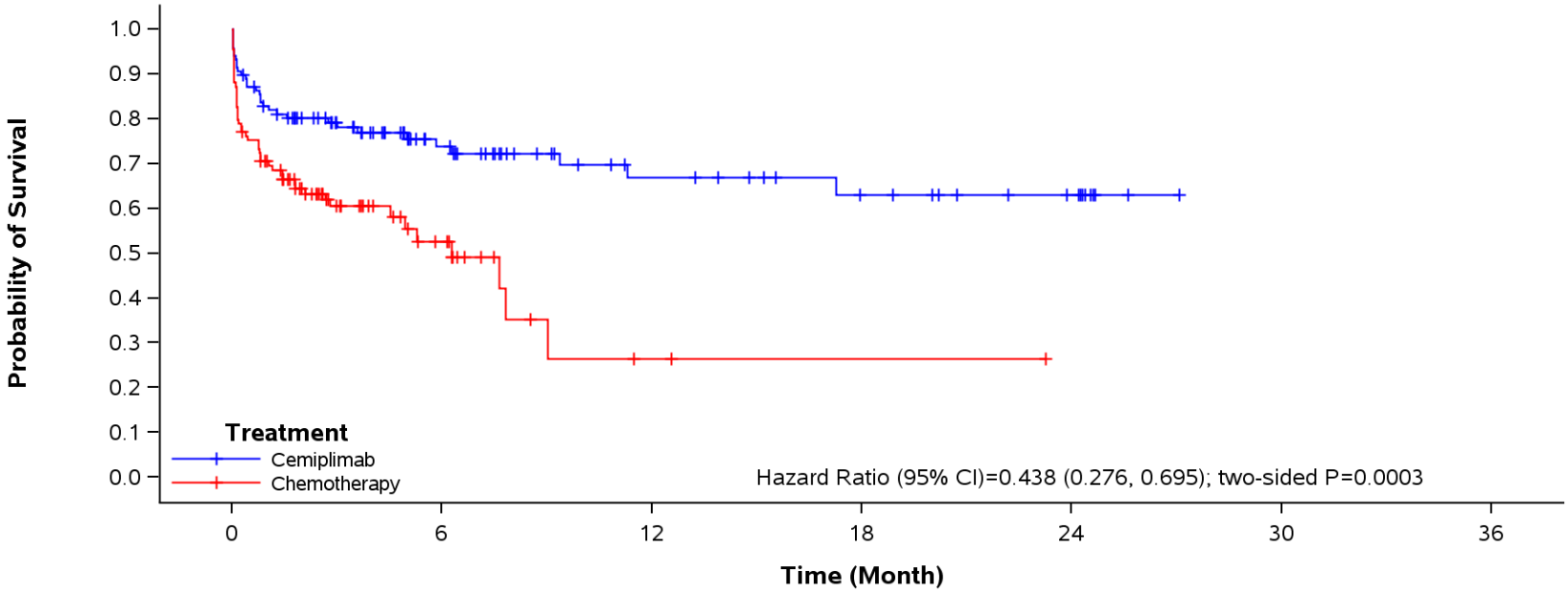

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 31 | 14 | 10 | 5 | 0 | 0 |
| Chemotherapy | 109 | 8 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders
PT: Nausea



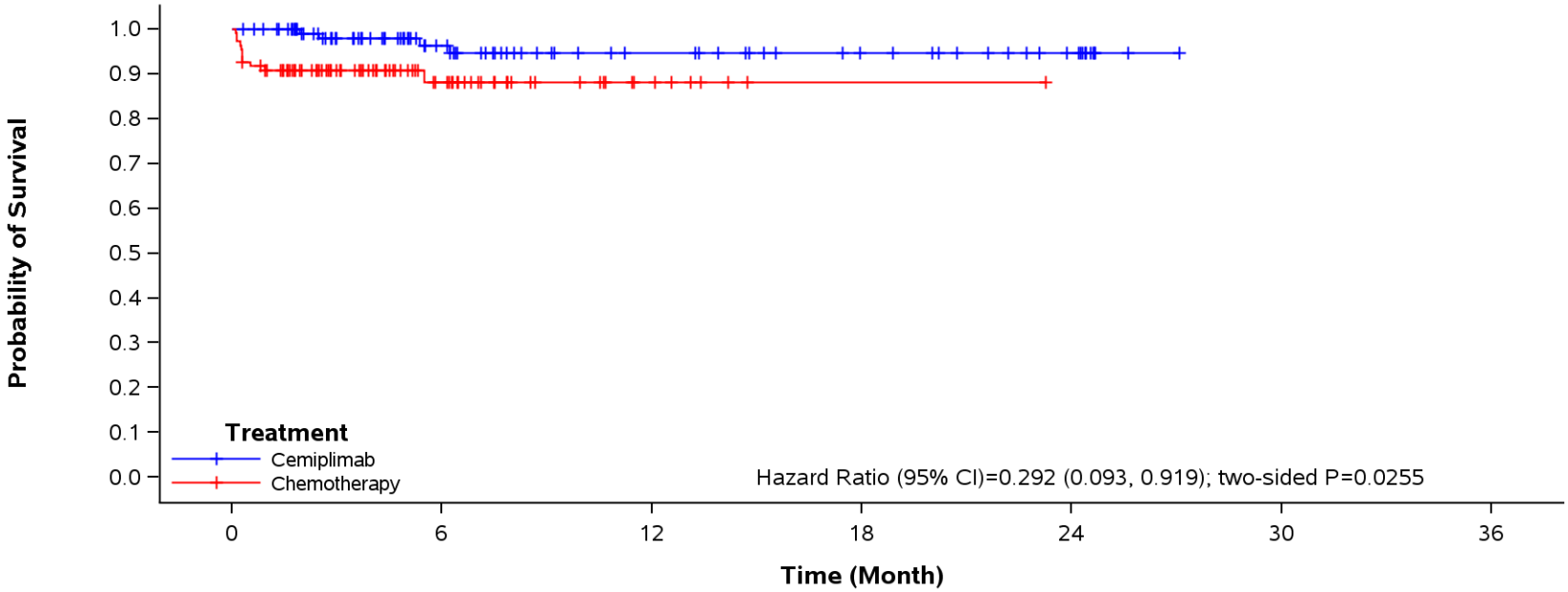

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 46 | 23 | 16 | 10 | 0 | 0 |
| Chemotherapy | 109 | 17 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders
PT: Stomatitis



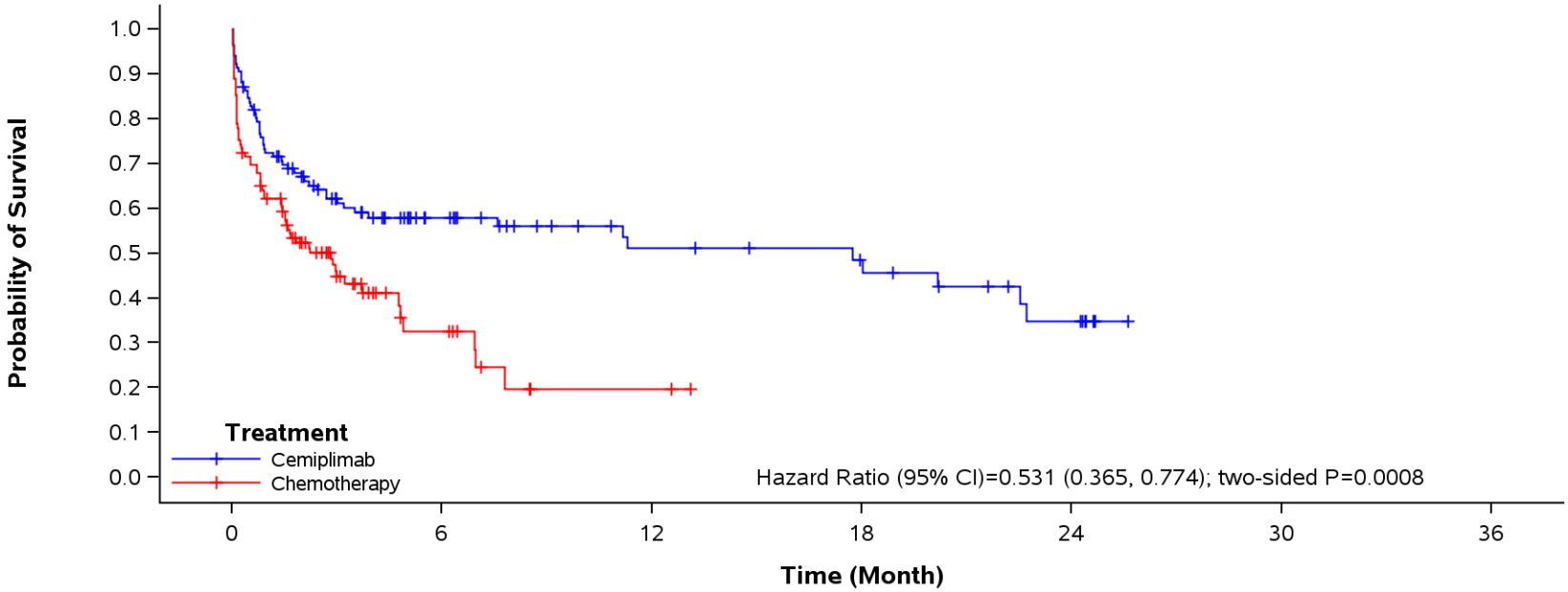

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 55 | 32 | 23 | 14 | 0 | 0 |
| Chemotherapy | 109 | 32 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: General disorders and administration site conditions



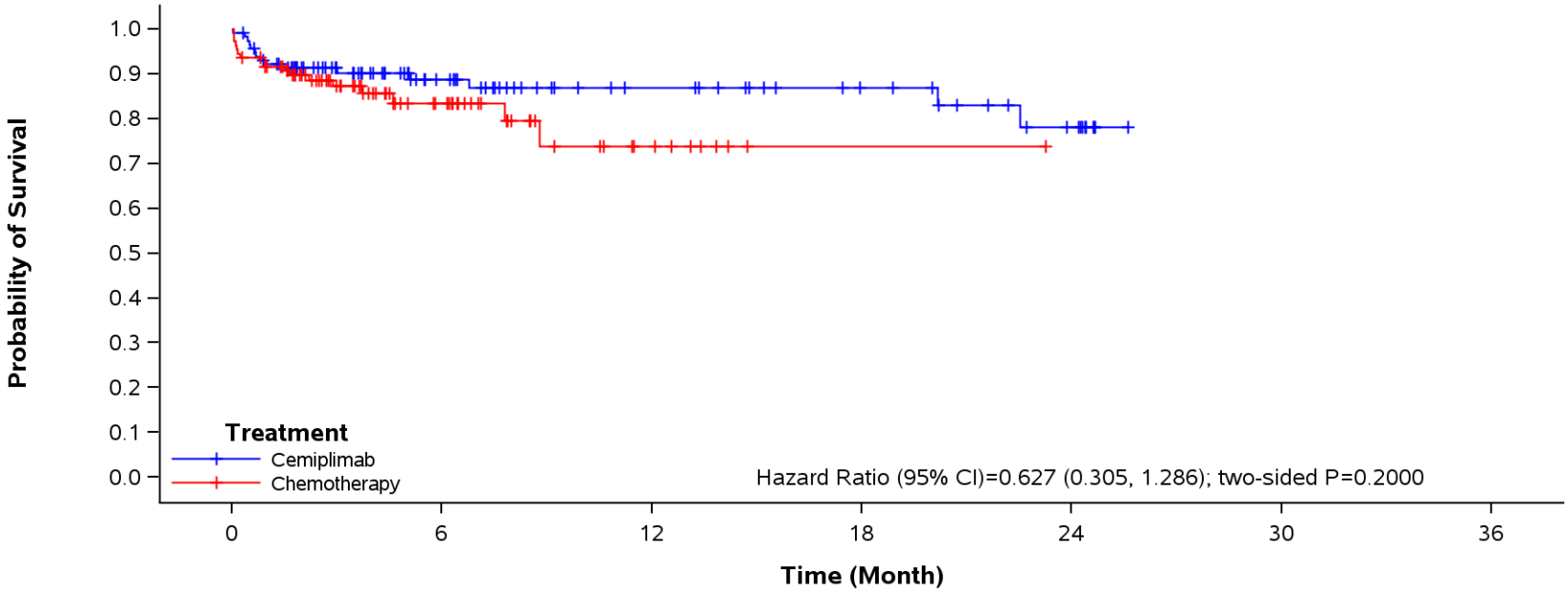

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 38 | 21 | 17 | 9 | 0 | 0 |
| Chemotherapy | 109 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: General disorders and administration site conditions
PT: Asthenia



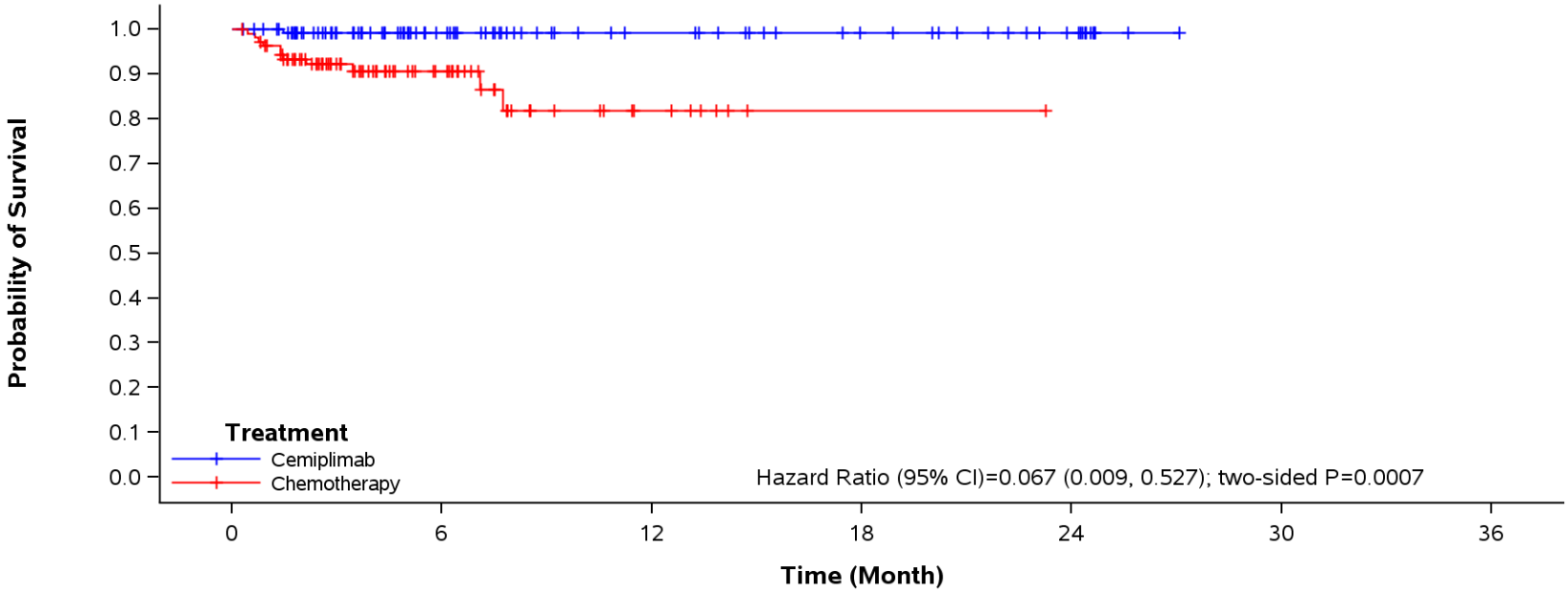

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 55 | 33 | 24 | 14 | 0 | 0 |
| Chemotherapy | 109 | 34 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



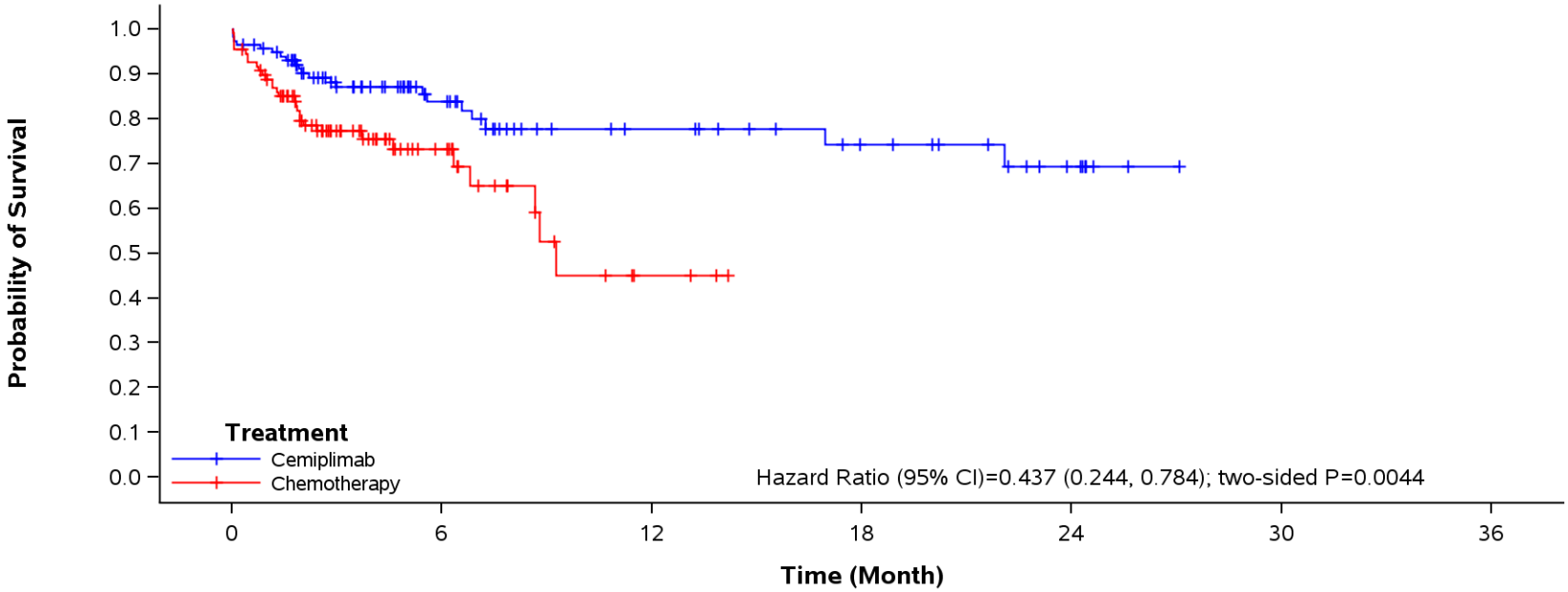

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 33 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Nervous system disorders




**Number of Subjects at risk**

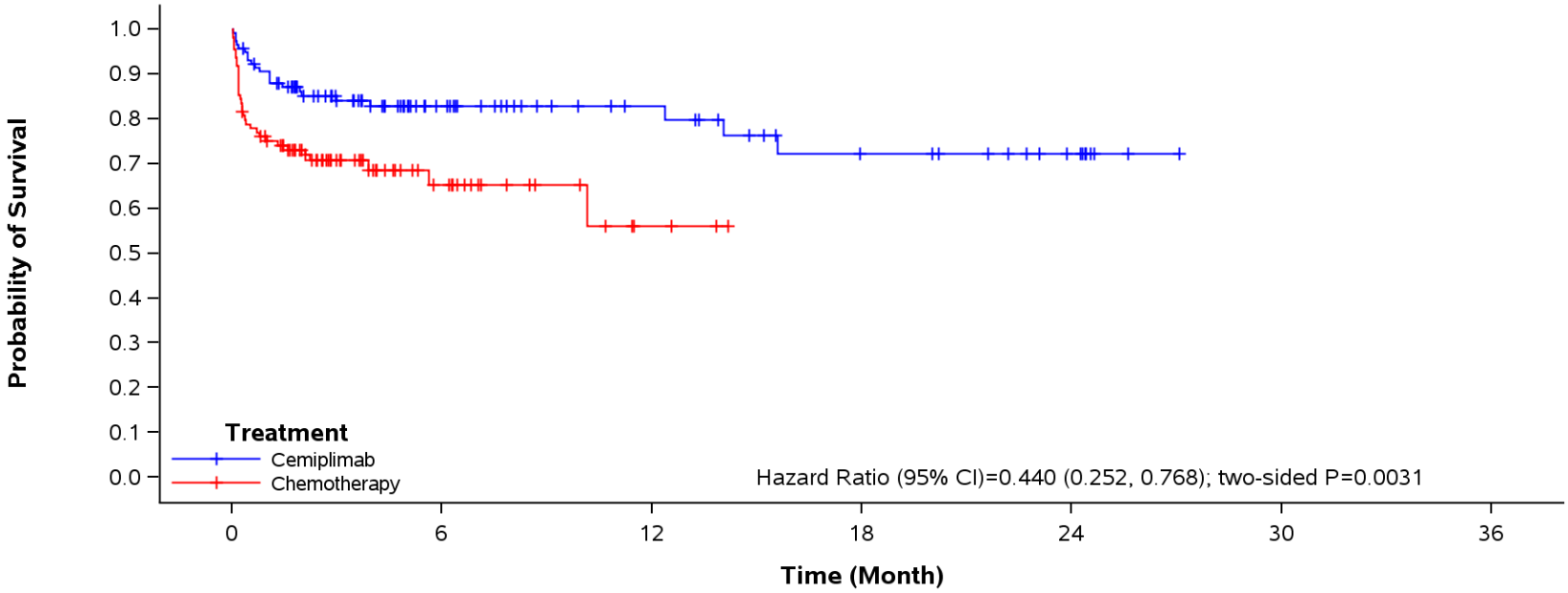
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 49 | 27 | 19 | 10 | 0 | 0 |
| Chemotherapy | 109 | 24 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Skin and subcutaneous tissue disorders



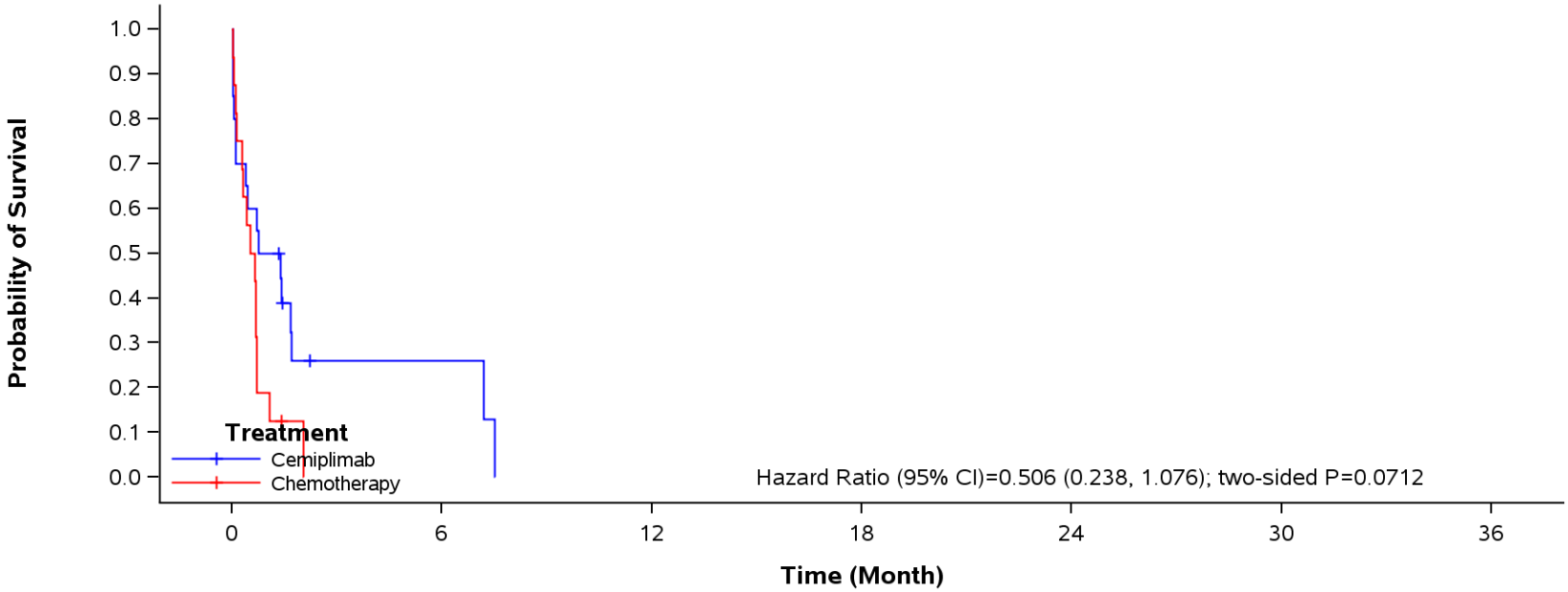

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 45 | 27 | 17 | 10 | 0 | 0 |
| Chemotherapy | 109 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Number of patients with any TEAE



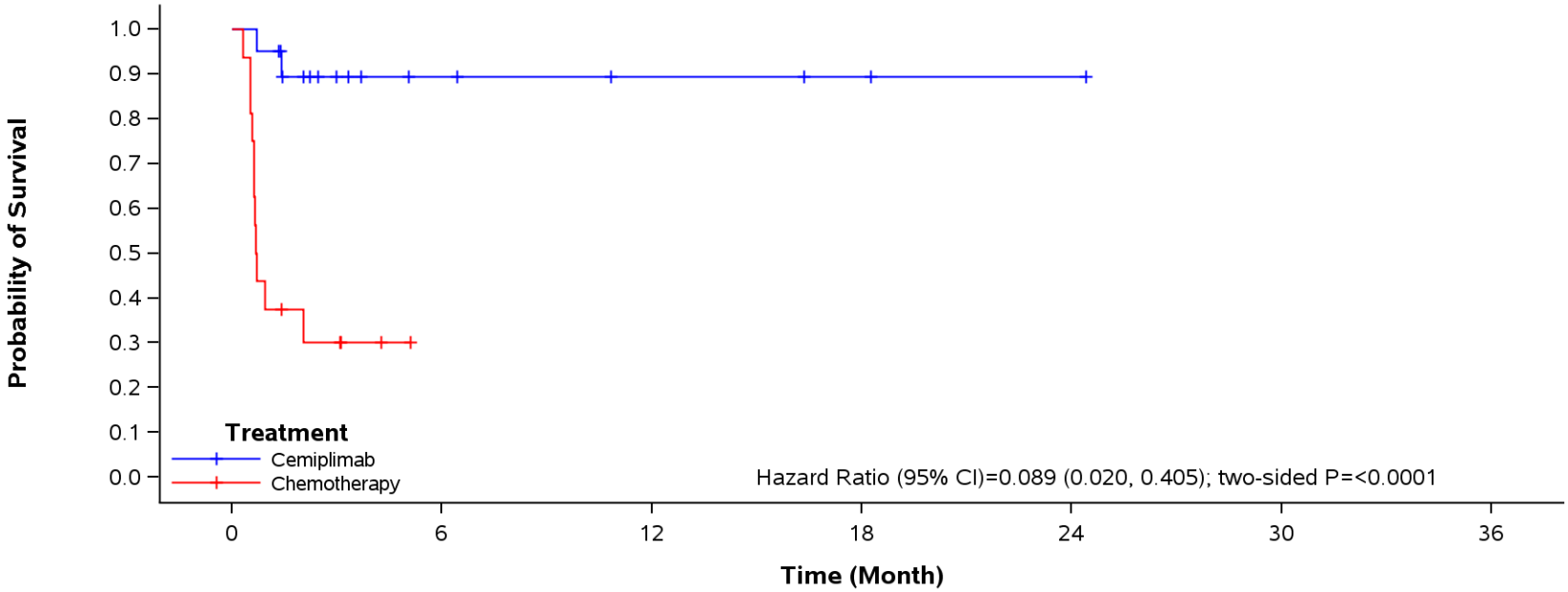

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 2 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 16 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders



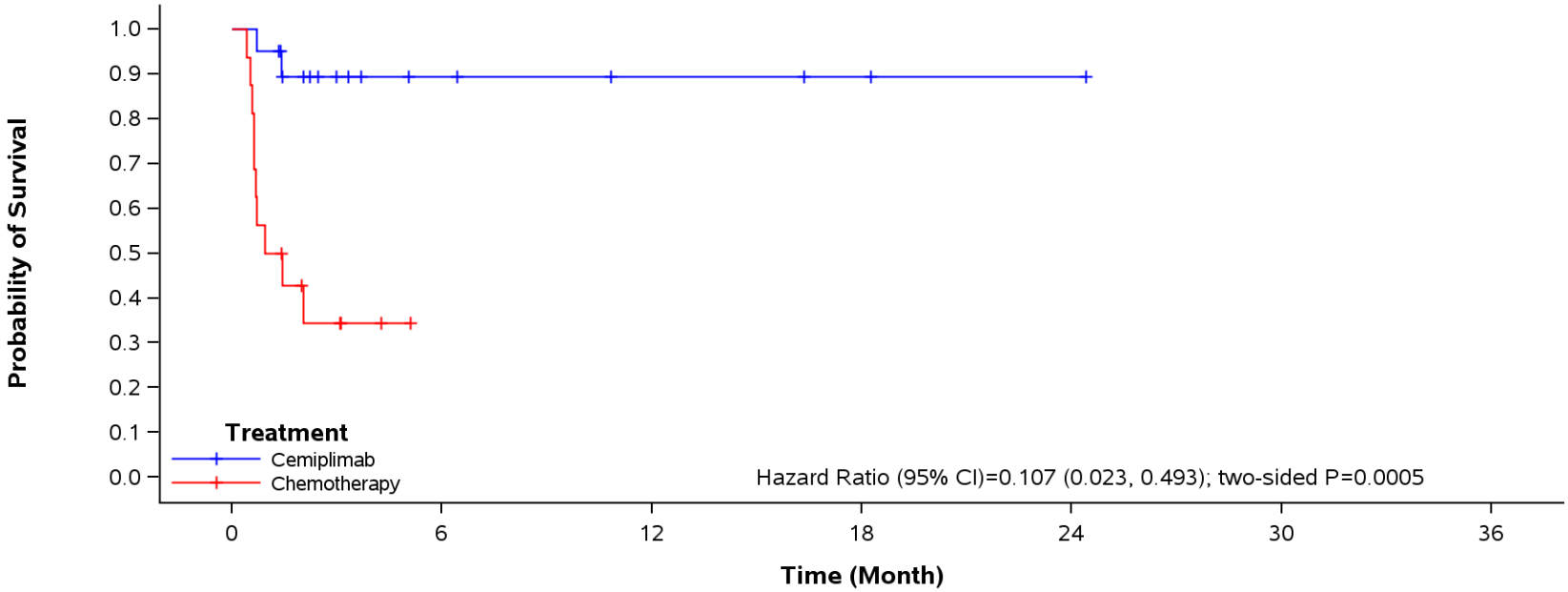

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 16 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



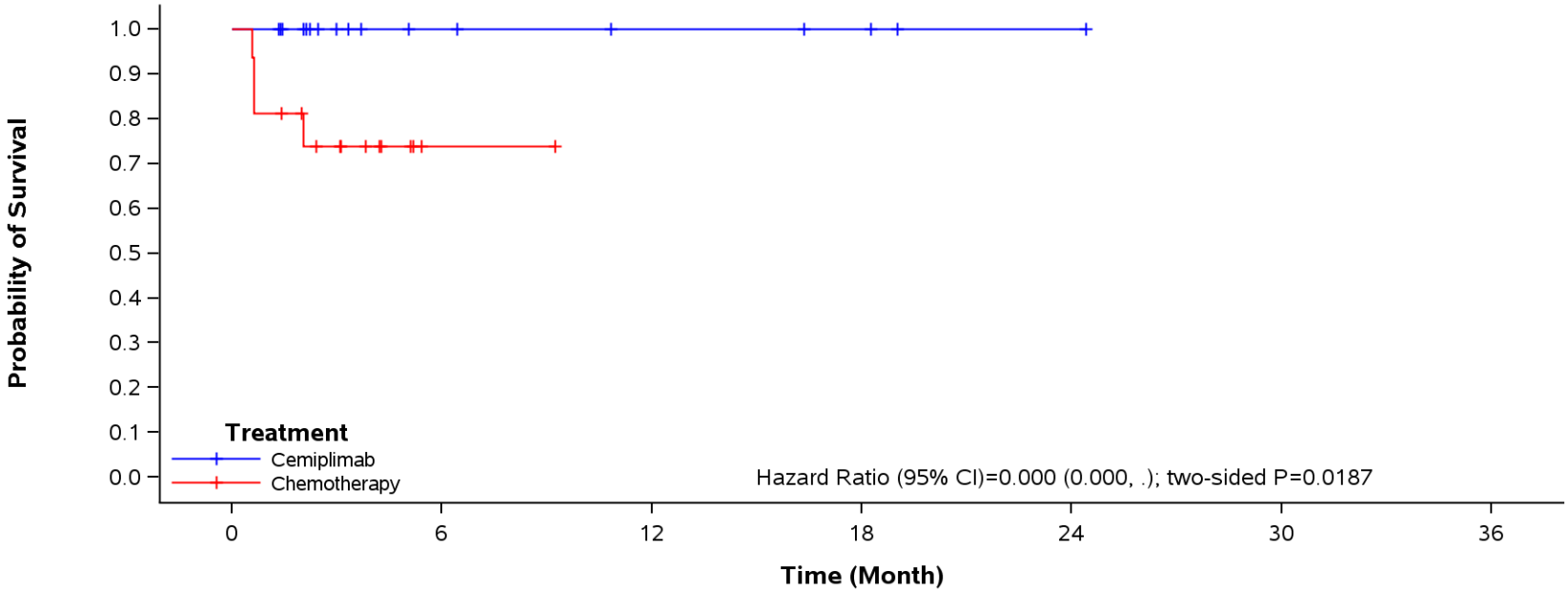

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 16 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



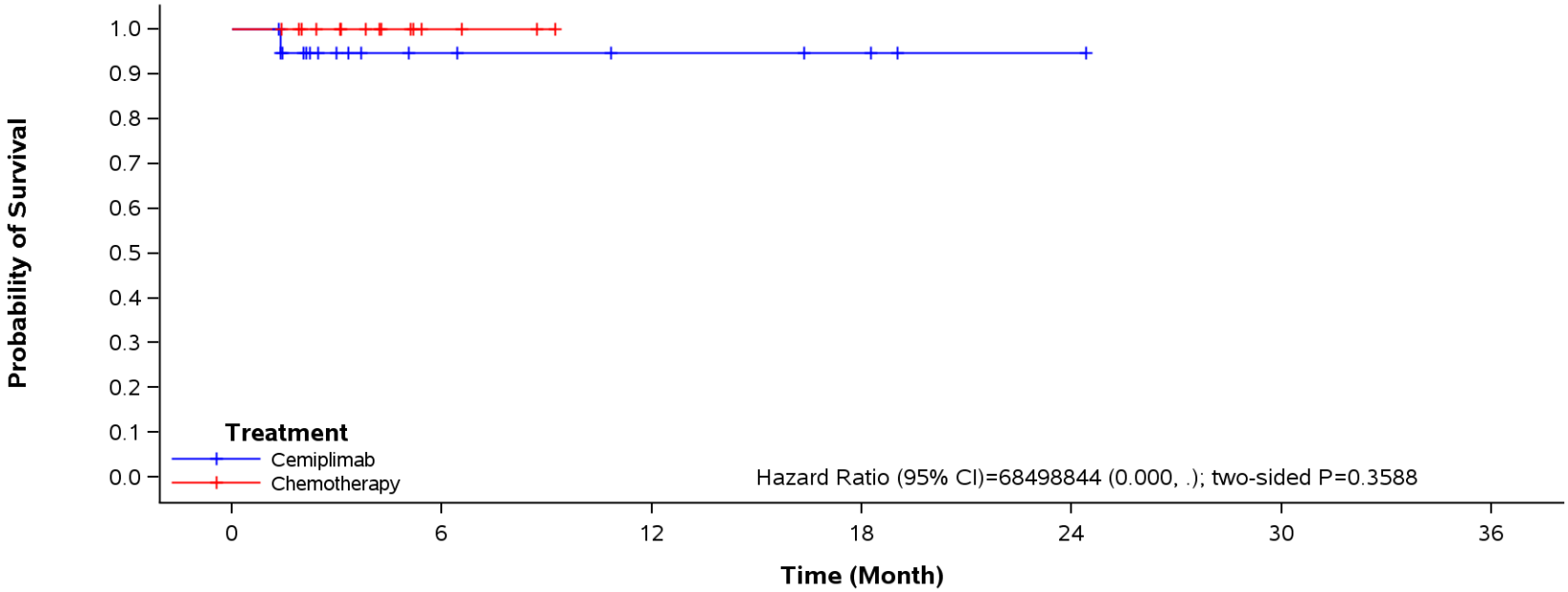

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Endocrine disorders



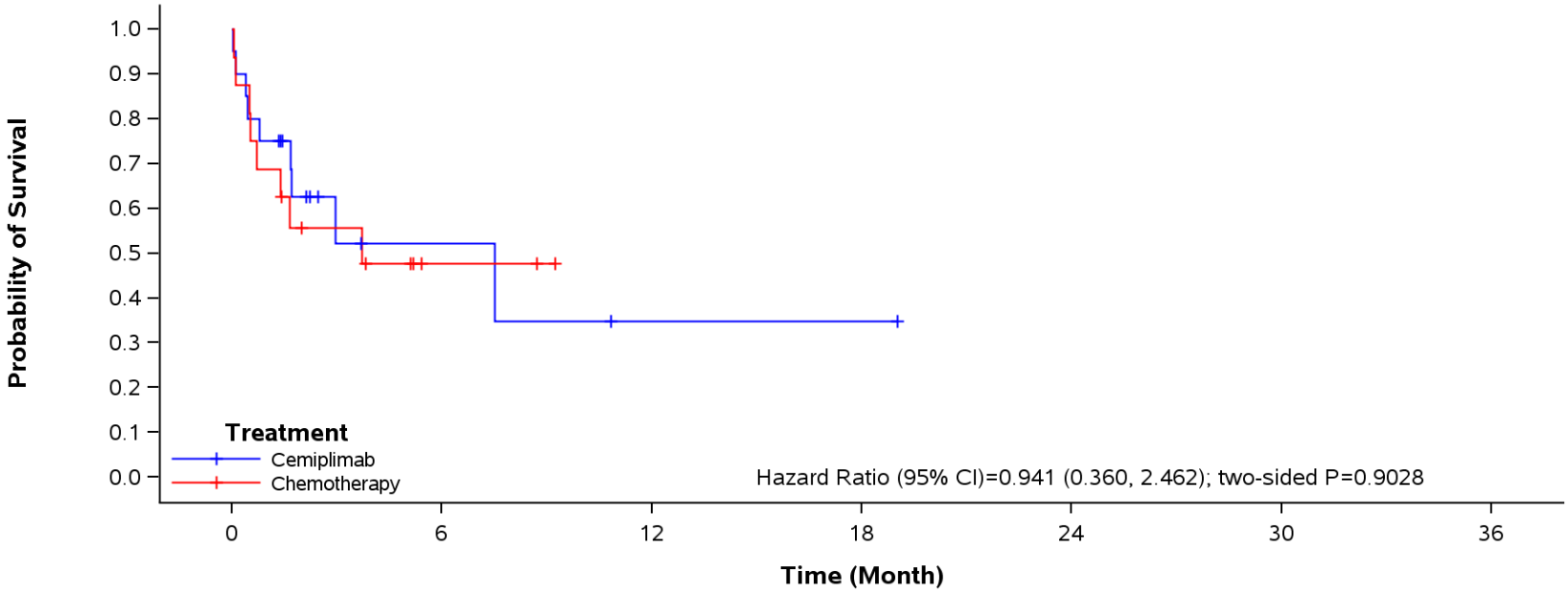

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders



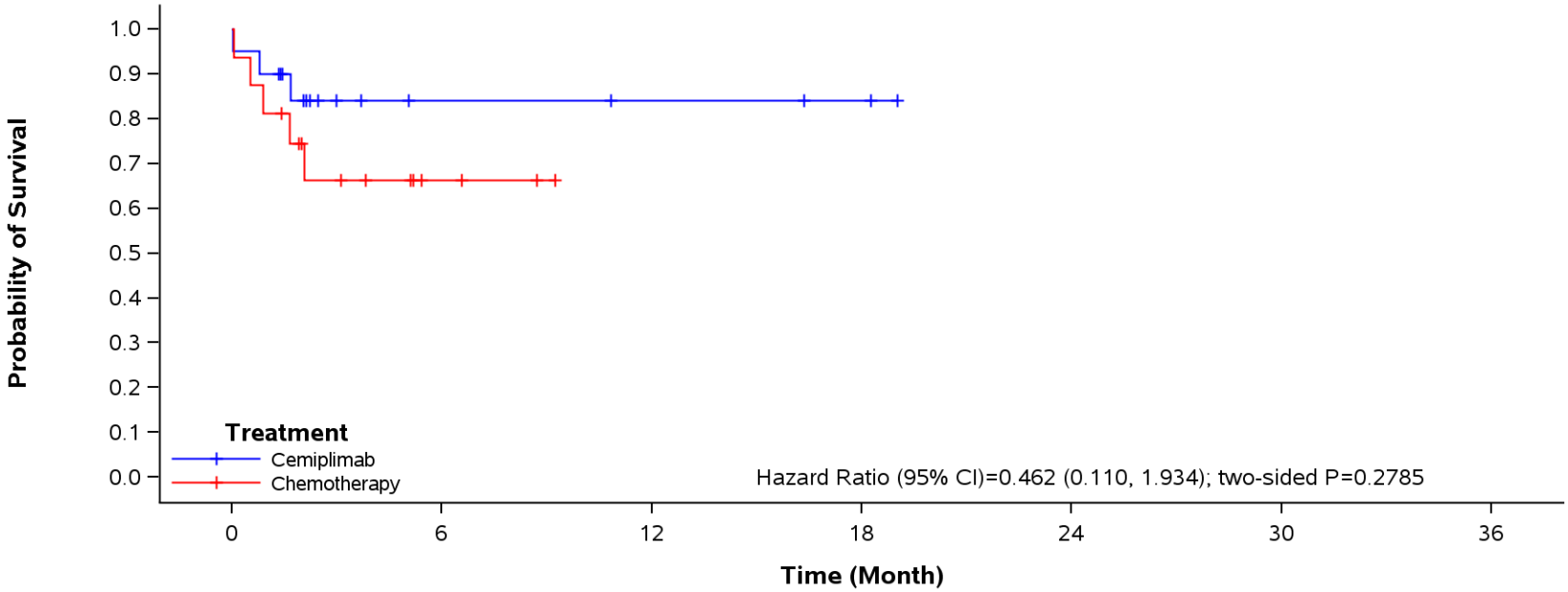

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 1 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders
PT: Nausea



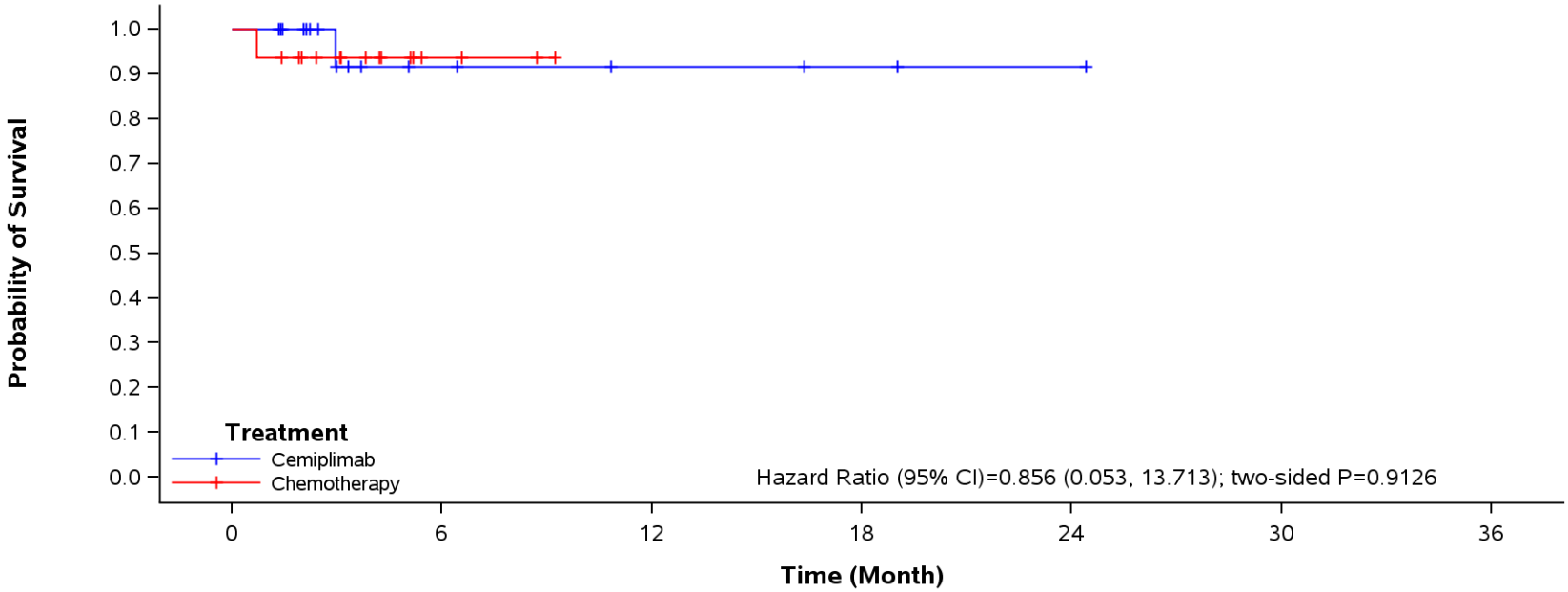

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 3 | 2 | 0 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders
PT: Stomatitis



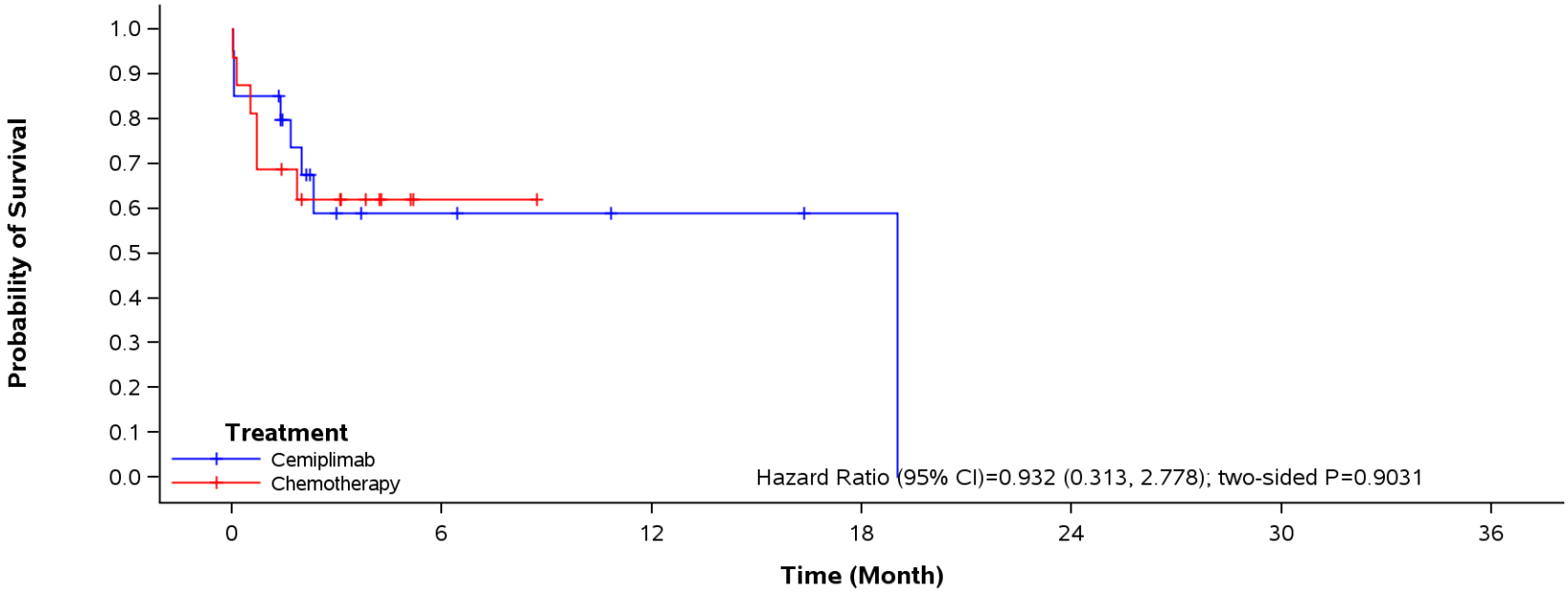

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: General disorders and administration site conditions



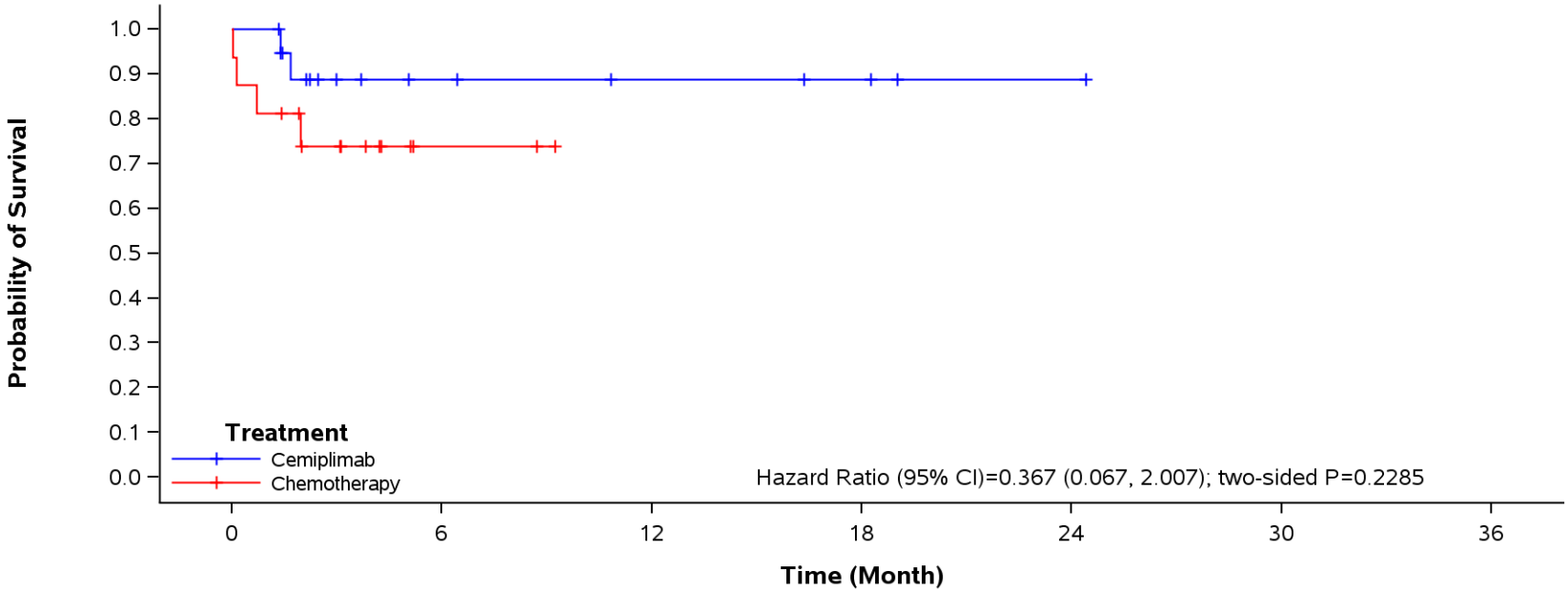

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 4 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: General disorders and administration site conditions
PT: Asthenia



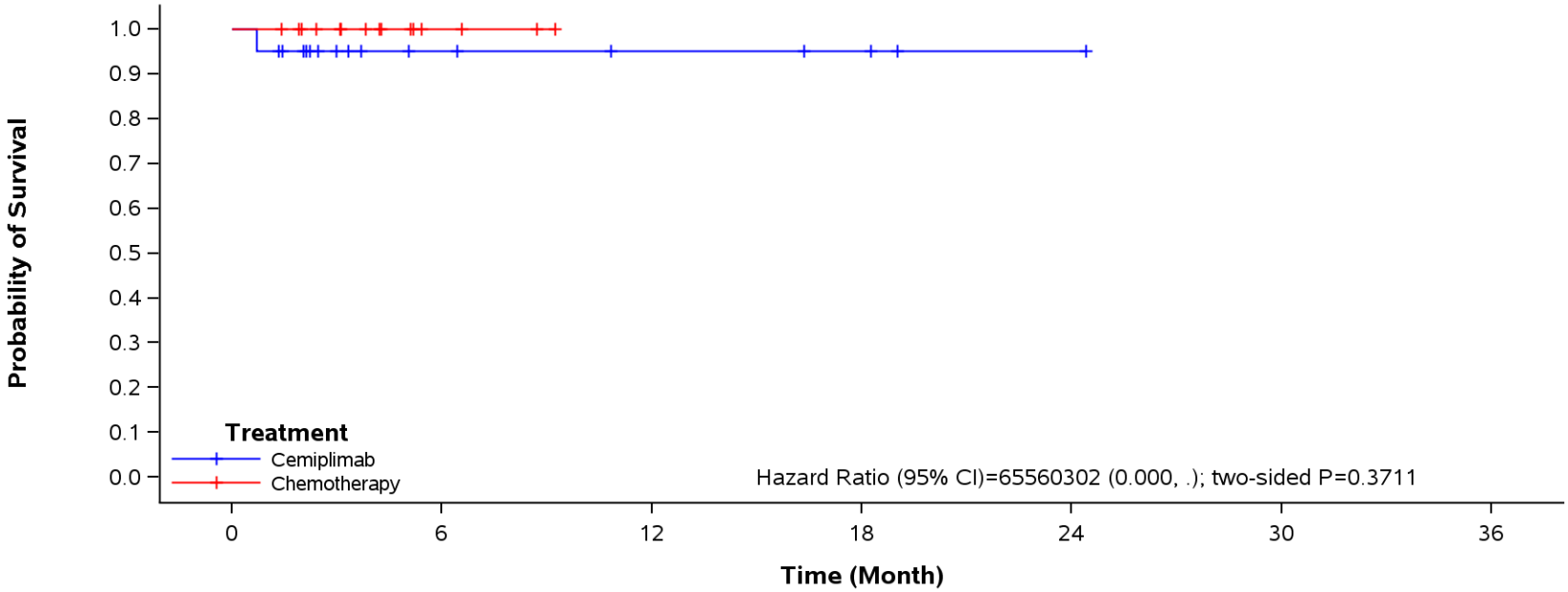

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



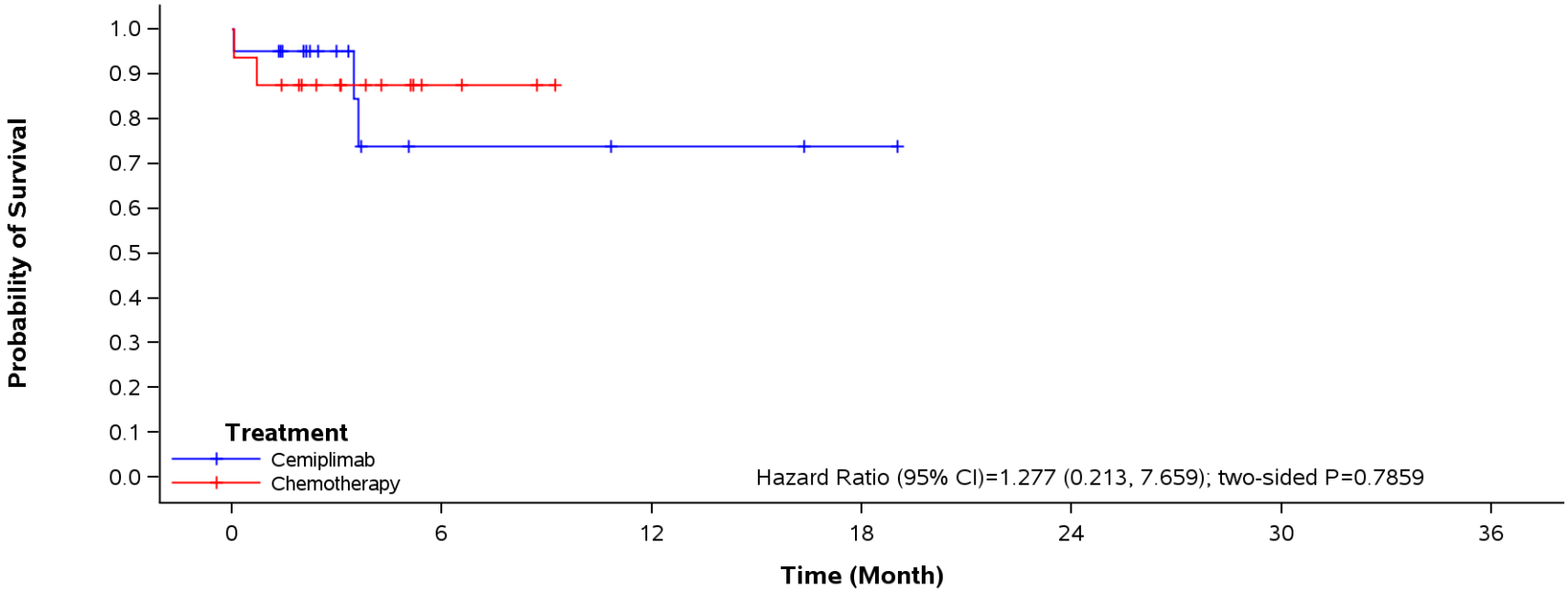

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Nervous system disorders



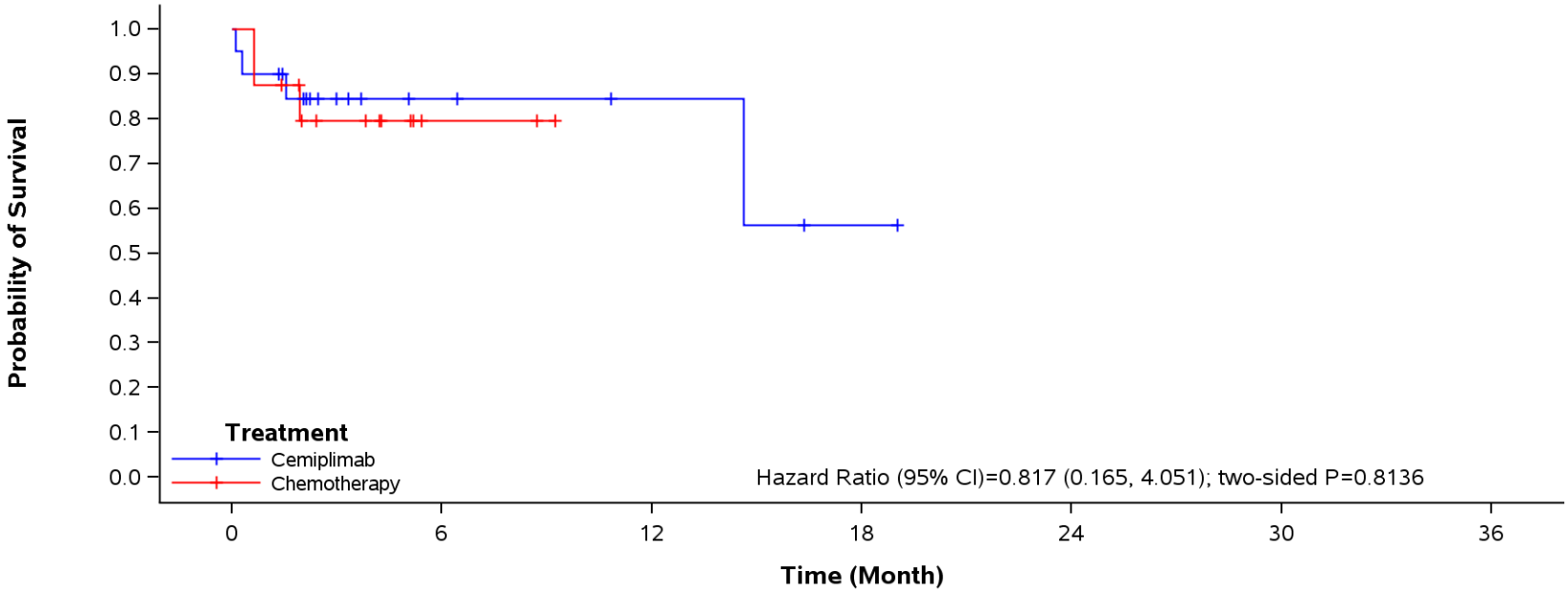

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 3 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Skin and subcutaneous tissue disorders



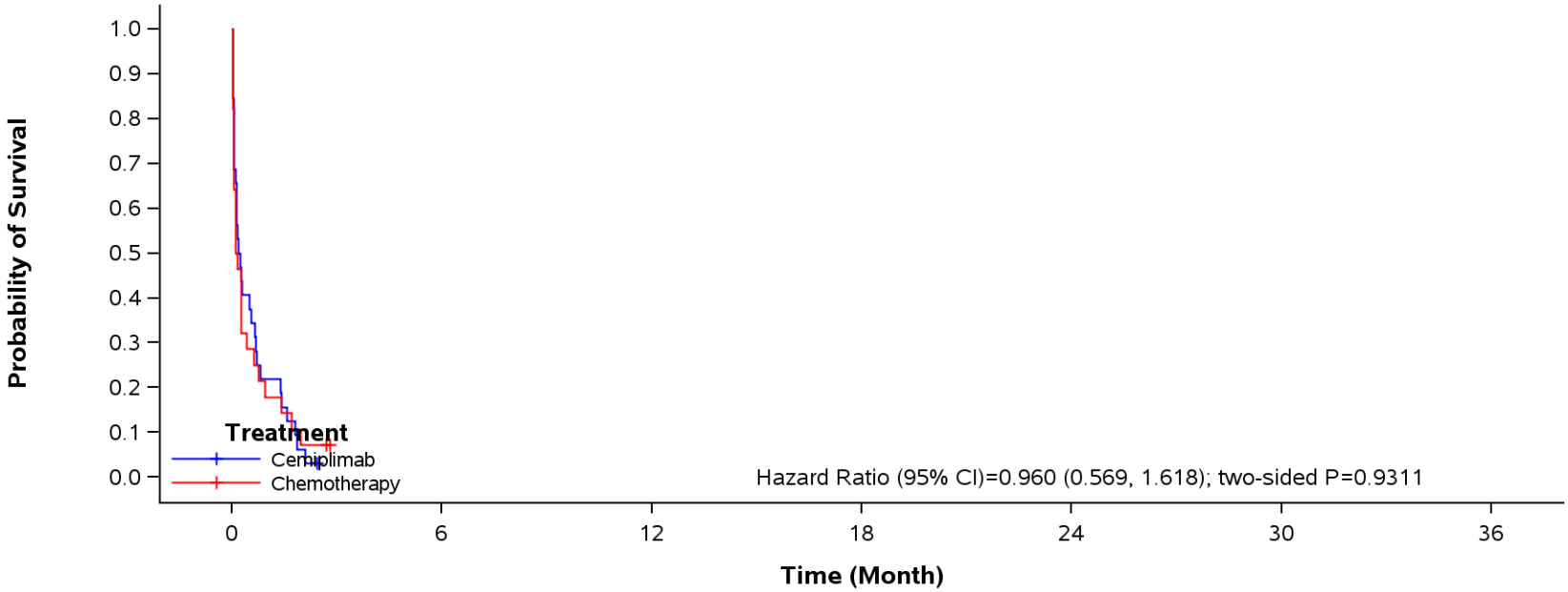

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Number of patients with any TEAE



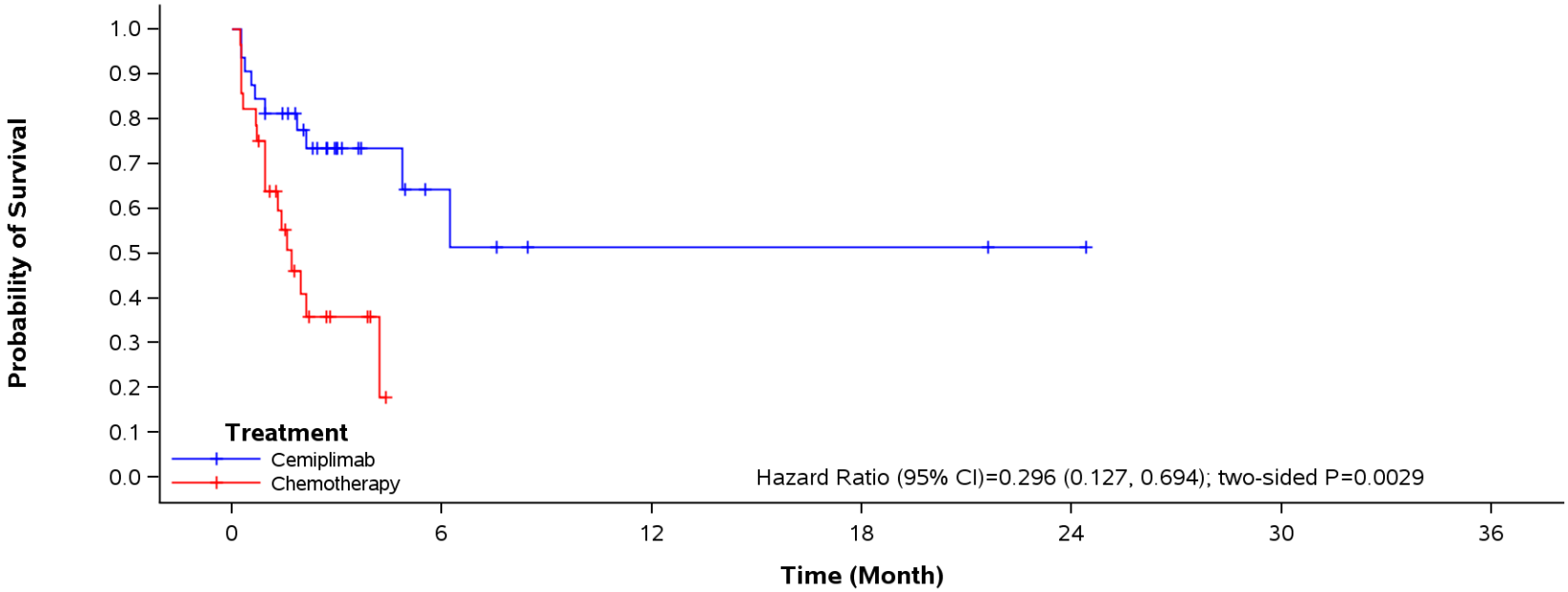

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 0 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 28 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders




**Number of Subjects at risk**

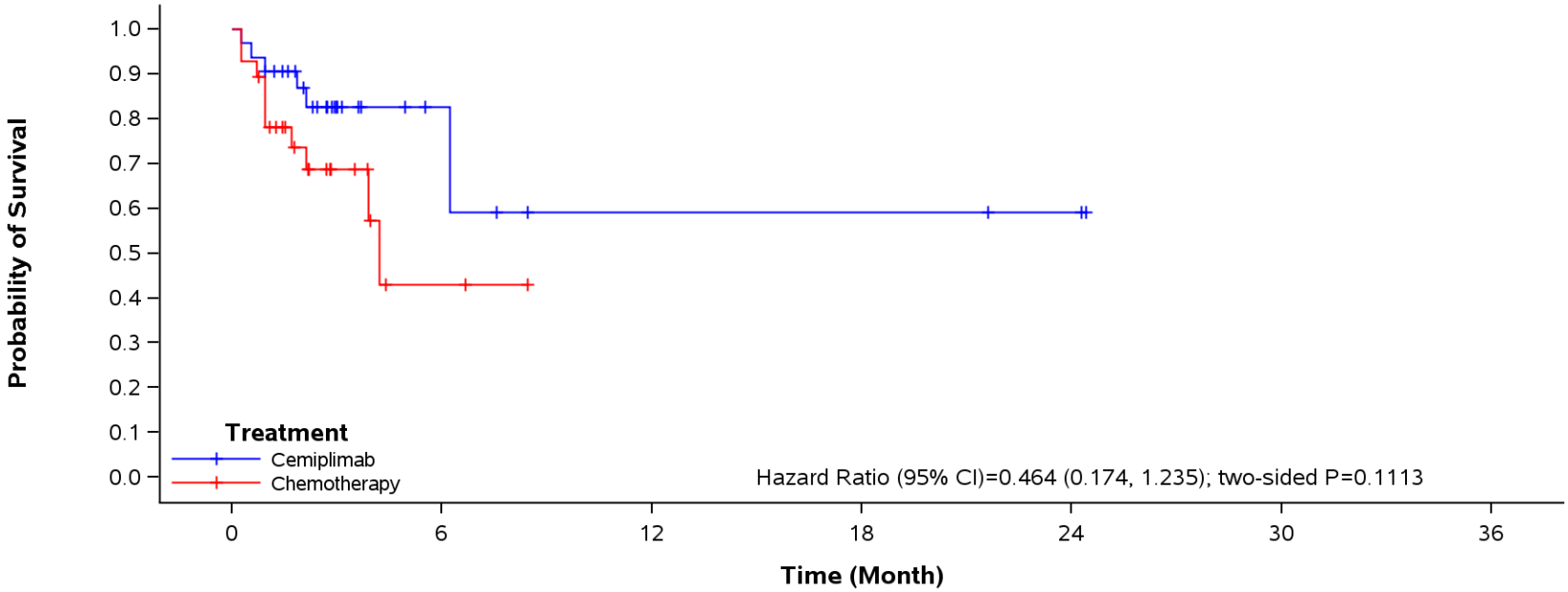
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 5 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 28 | 0 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:48:02, haijin.tang)

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Anaemia



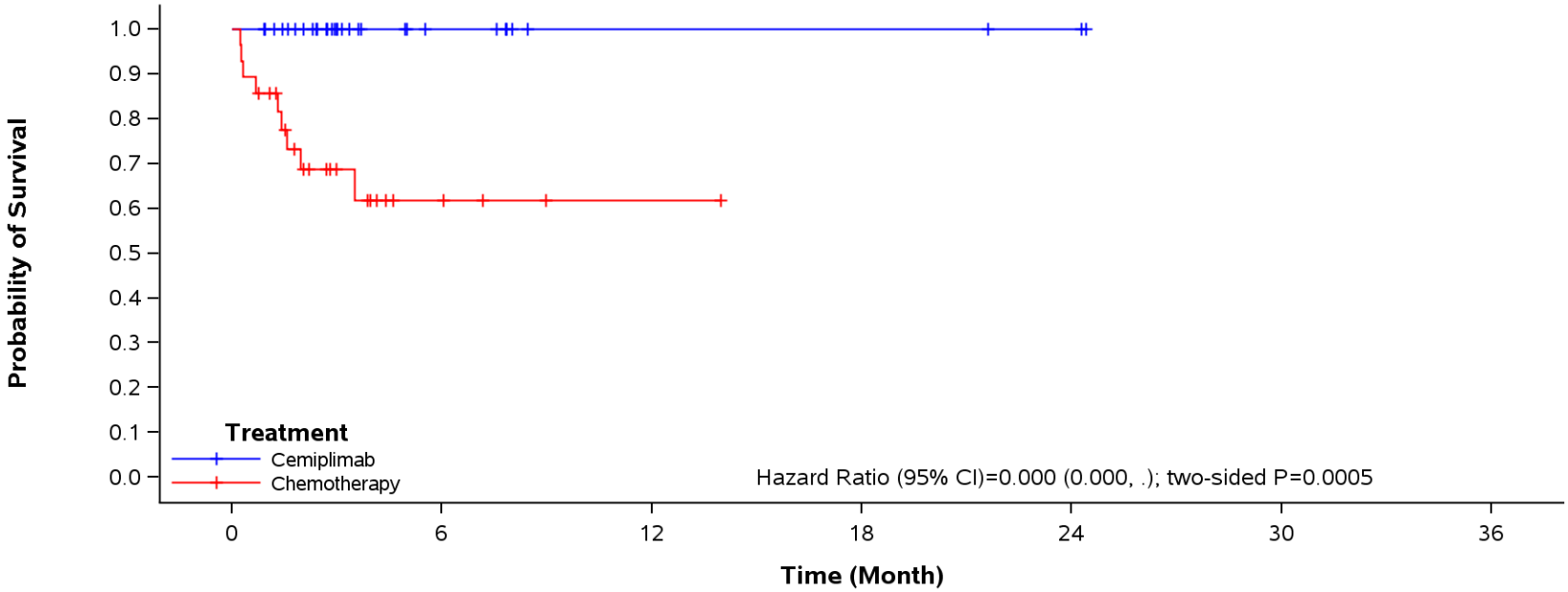

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 7 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Neutropenia



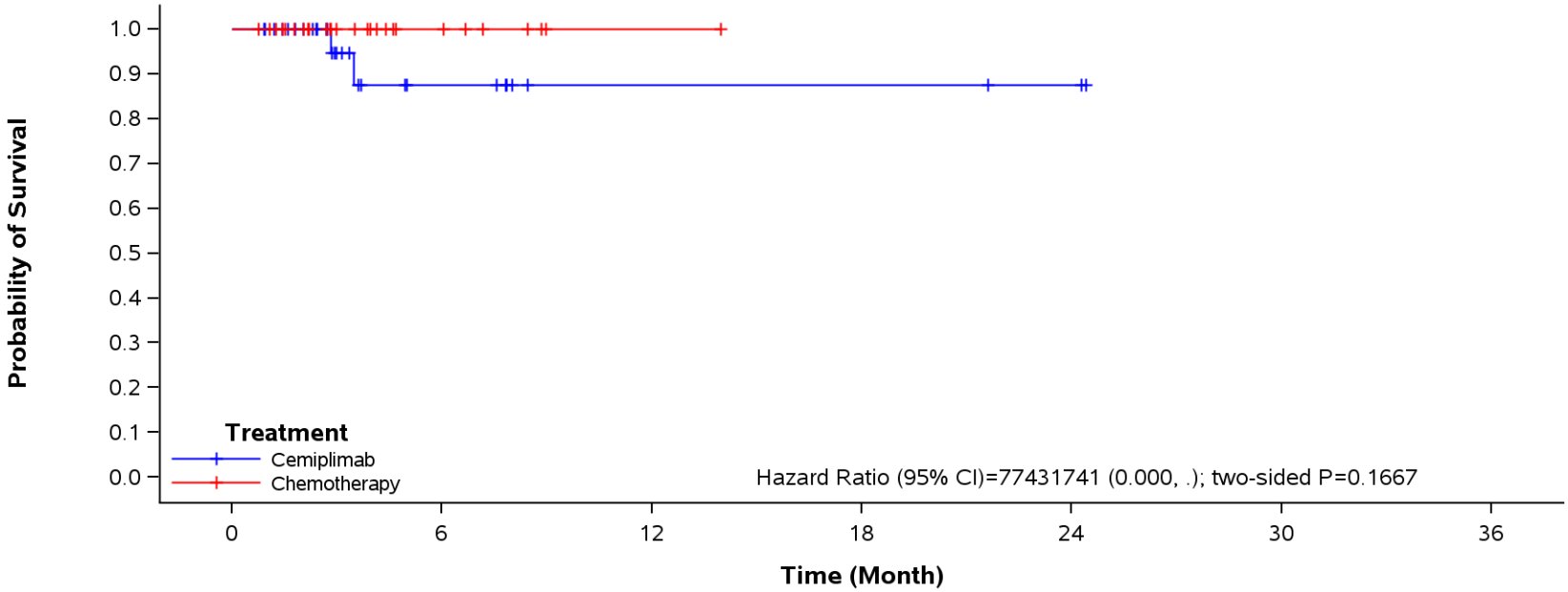

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Endocrine disorders



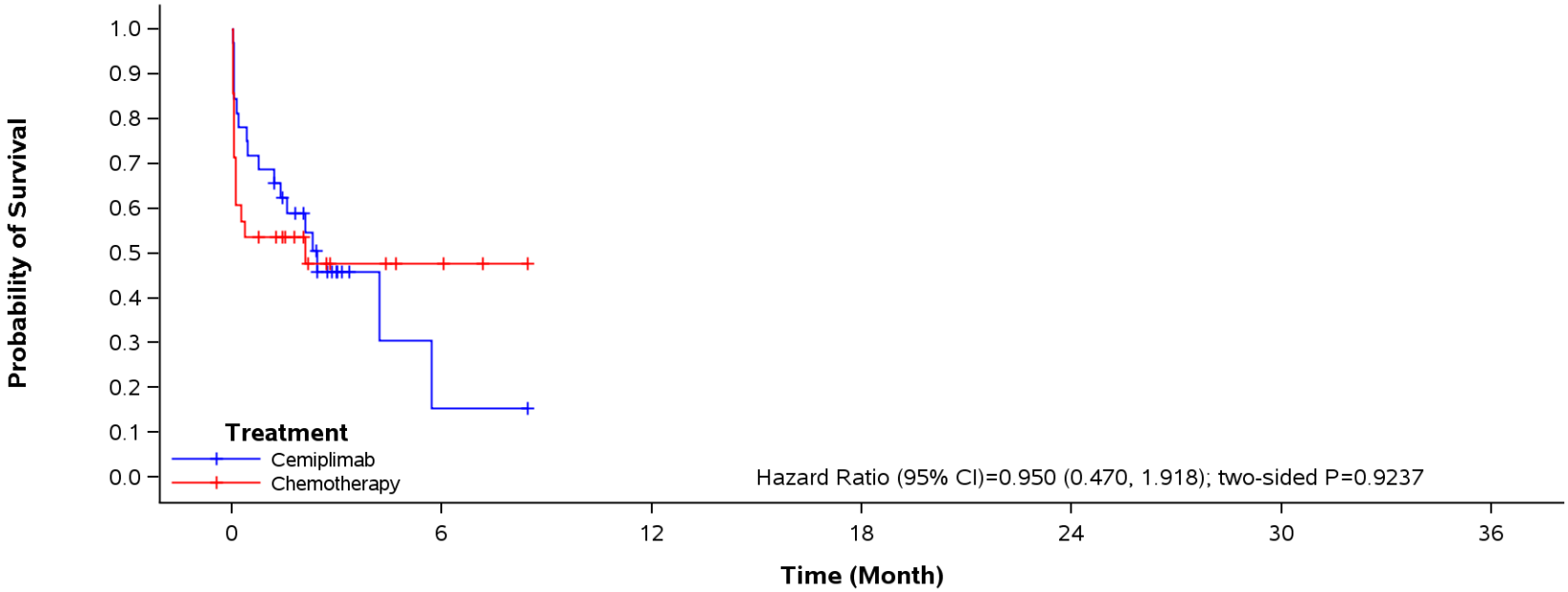

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders



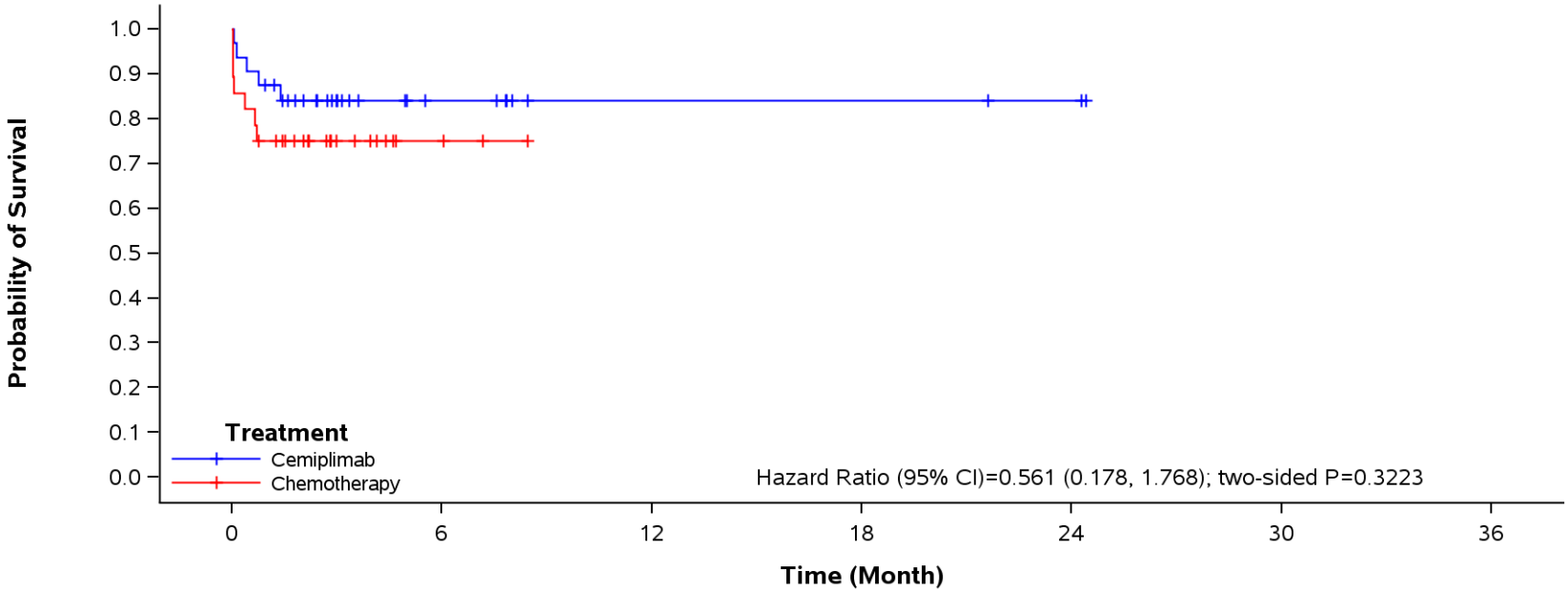

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 1 | 0 | 0 | 0 | 0 | 0 |
| Chemotherapy | 28 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders
PT: Nausea



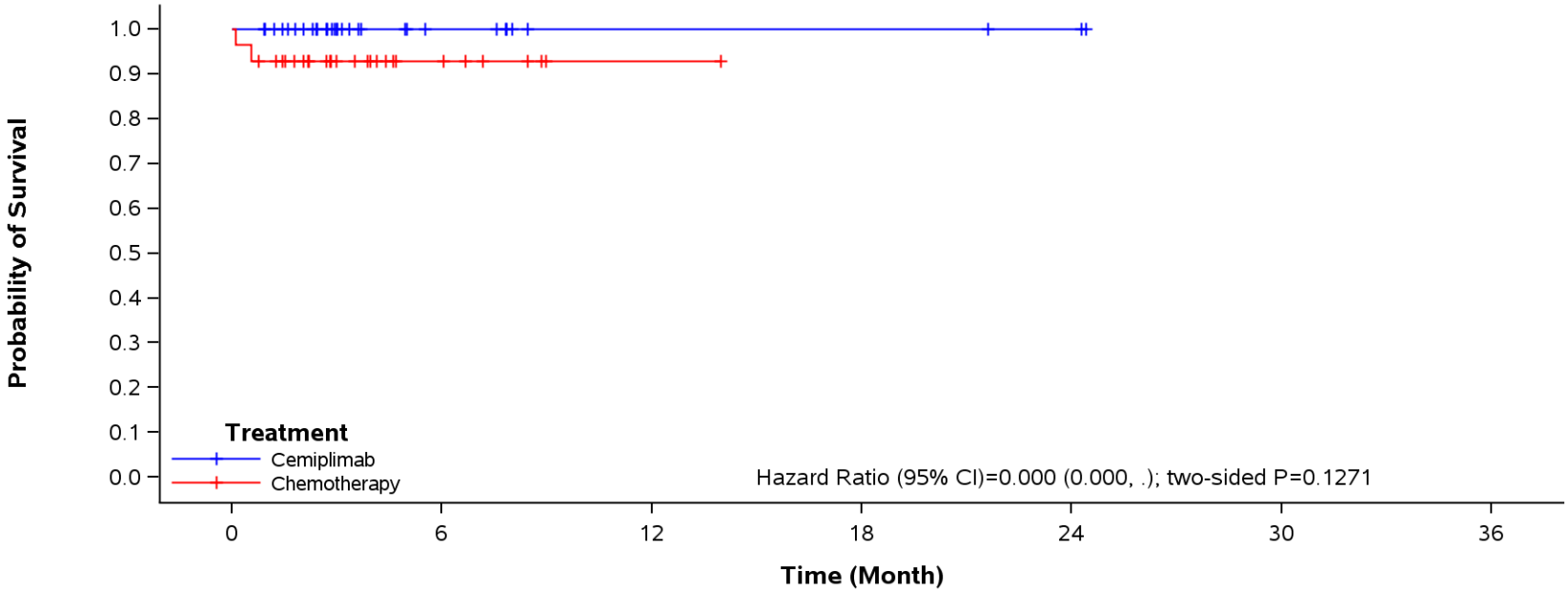

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders
PT: Stomatitis



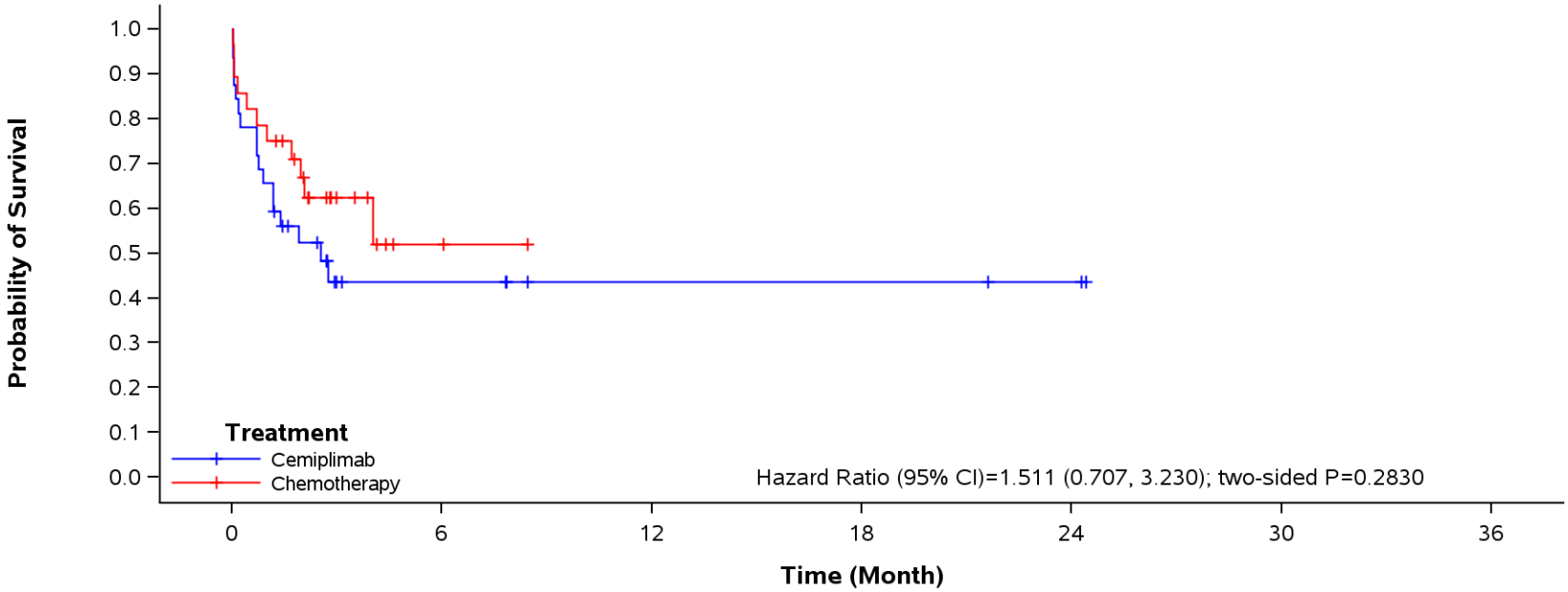

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: General disorders and administration site conditions



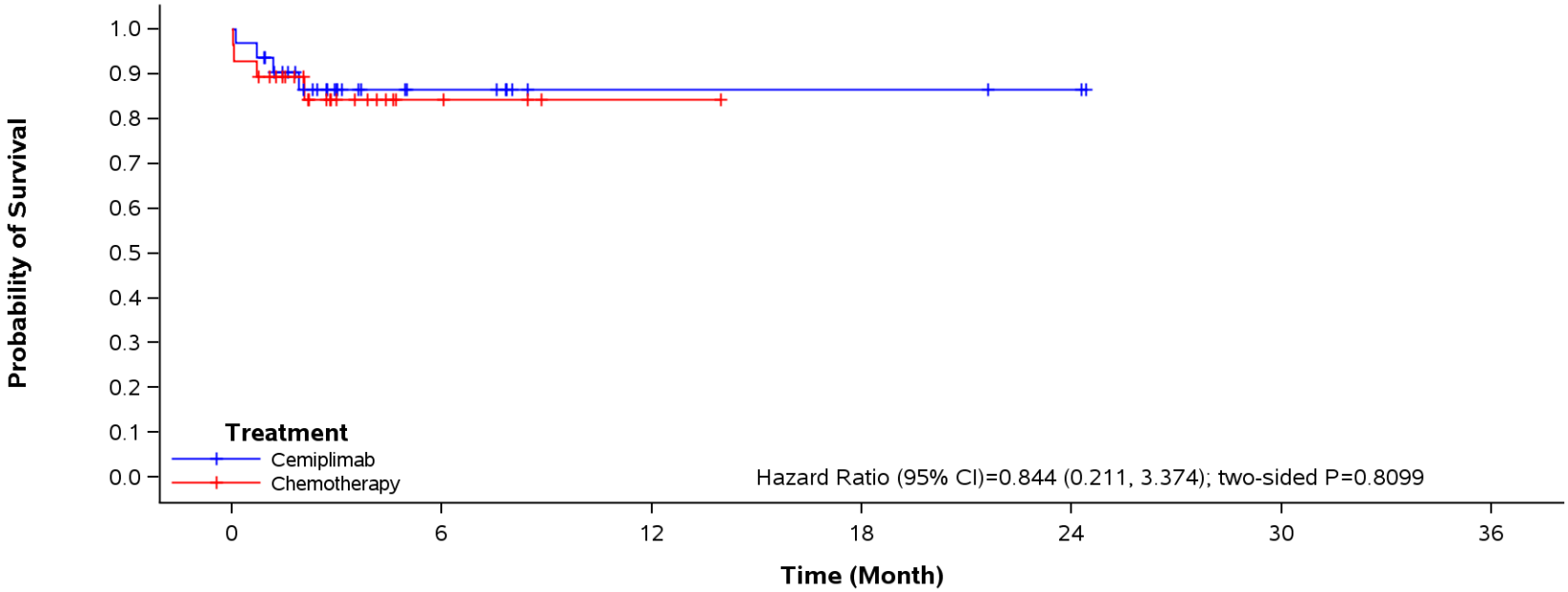

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 6 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: General disorders and administration site conditions
PT: Asthenia



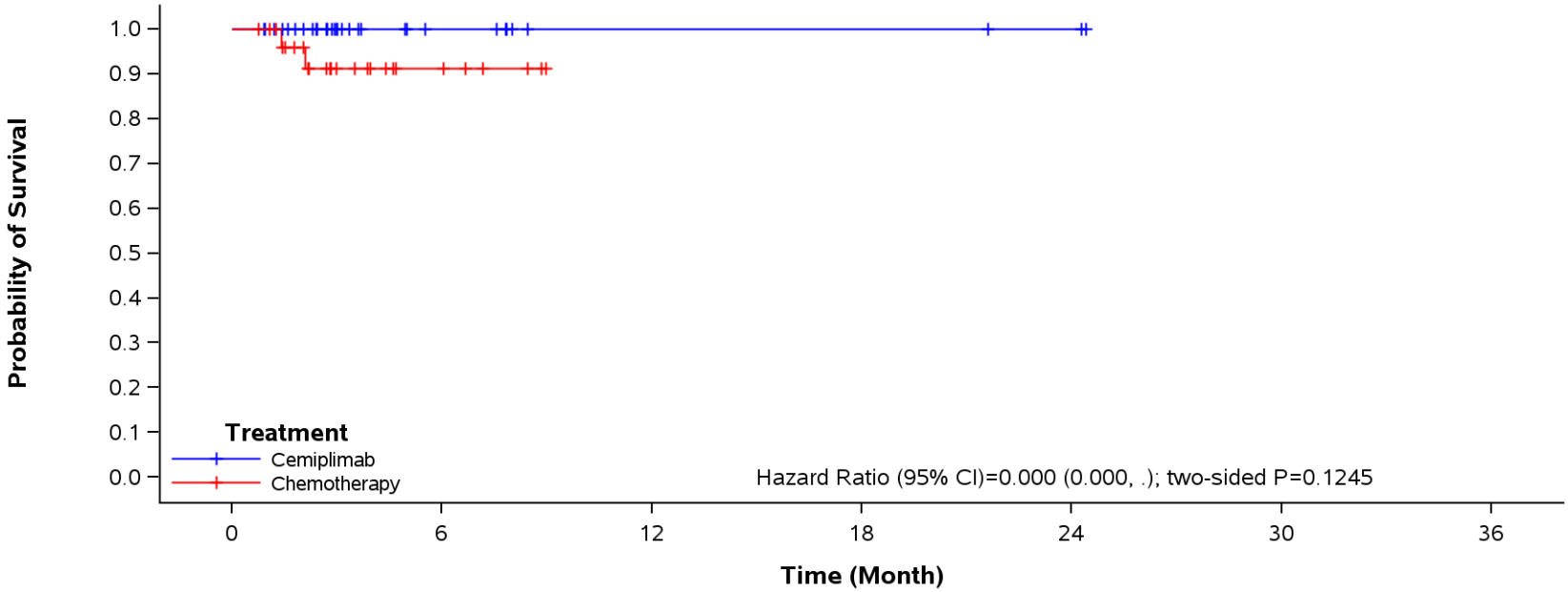

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia



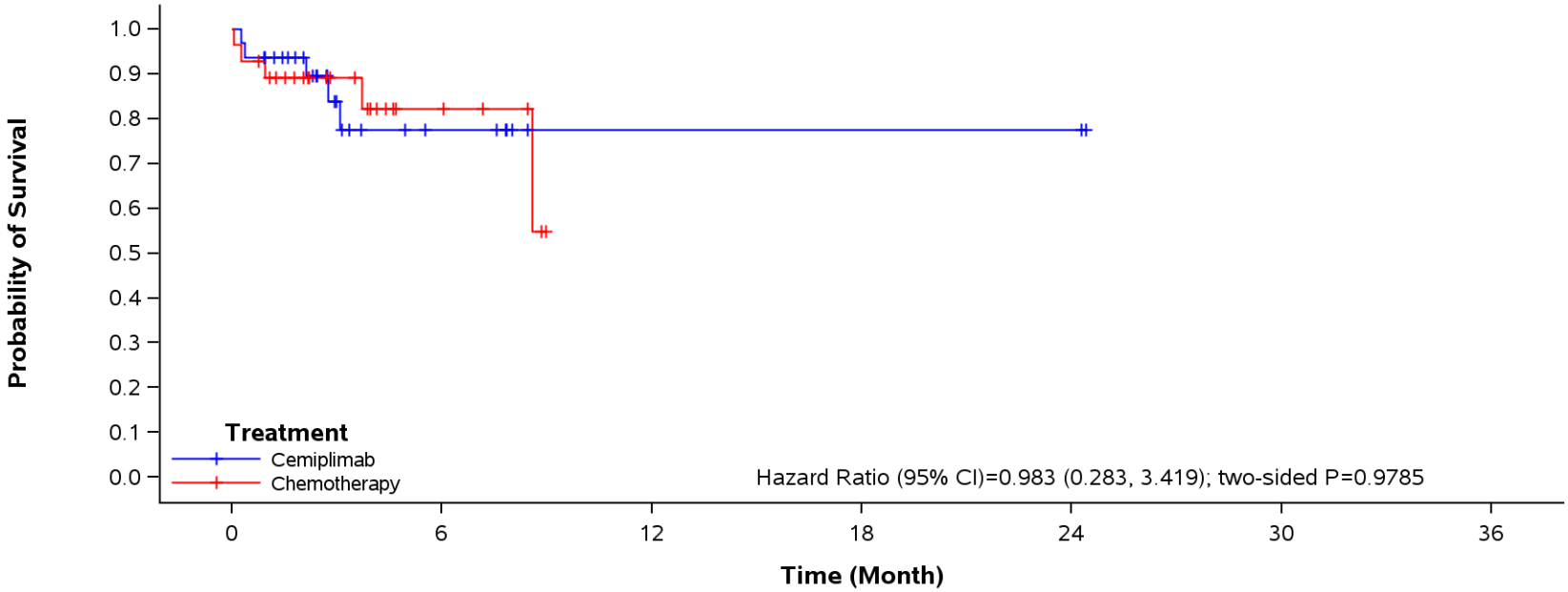

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Nervous system disorders



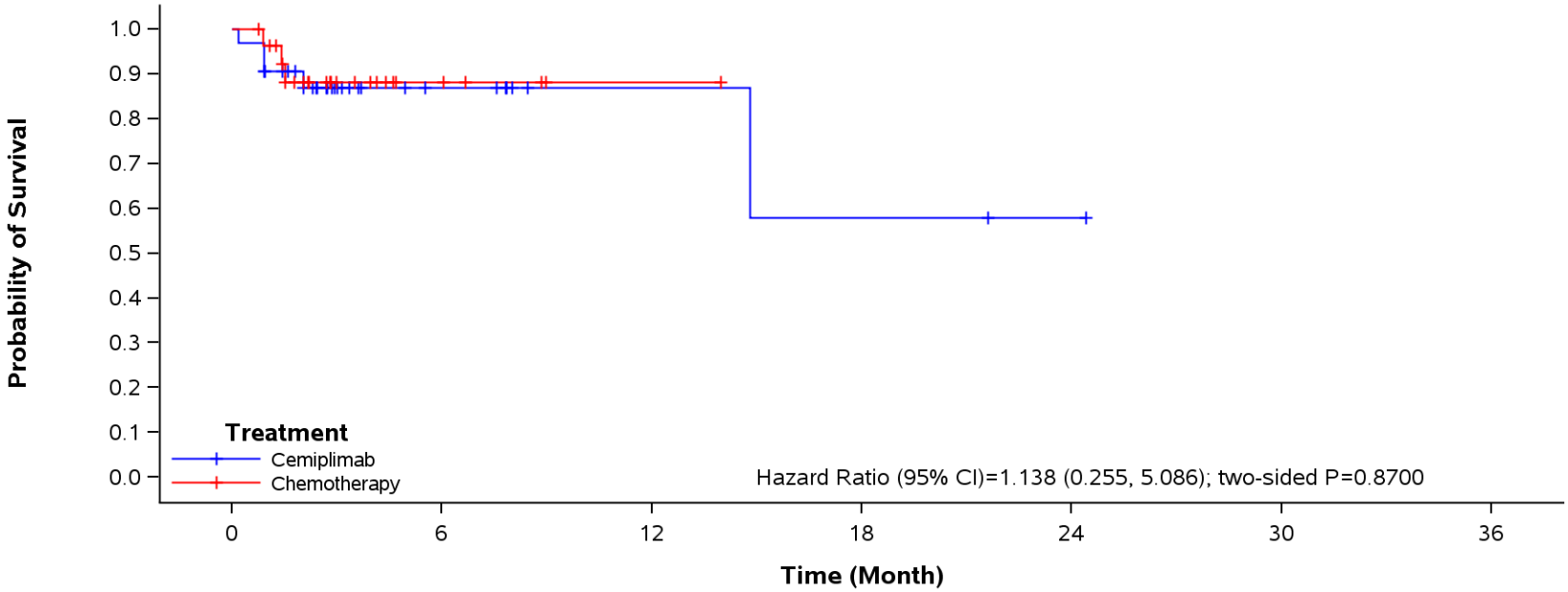

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 7 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.1. Time to First Any TEAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Skin and subcutaneous tissue disorders



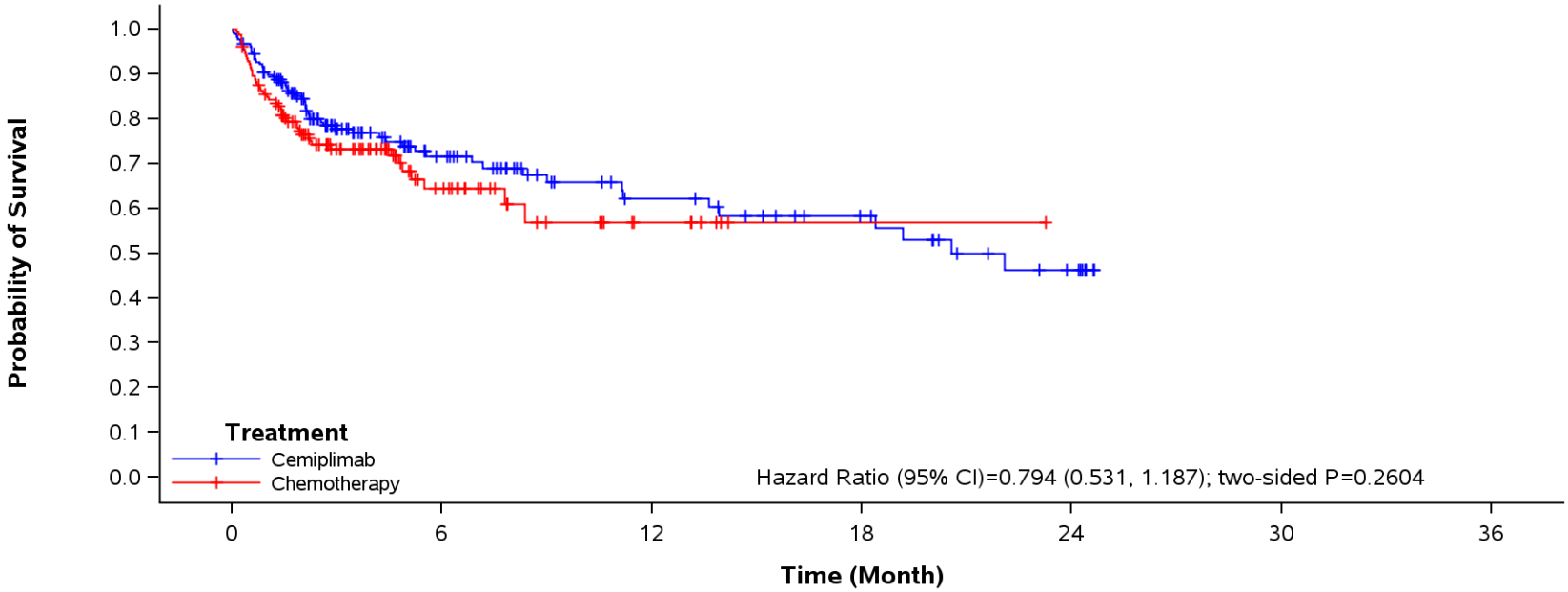

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 28 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 10 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 61 | 33 | 23 | 11 | 0 | 0 |
| Chemotherapy | 153 | 32 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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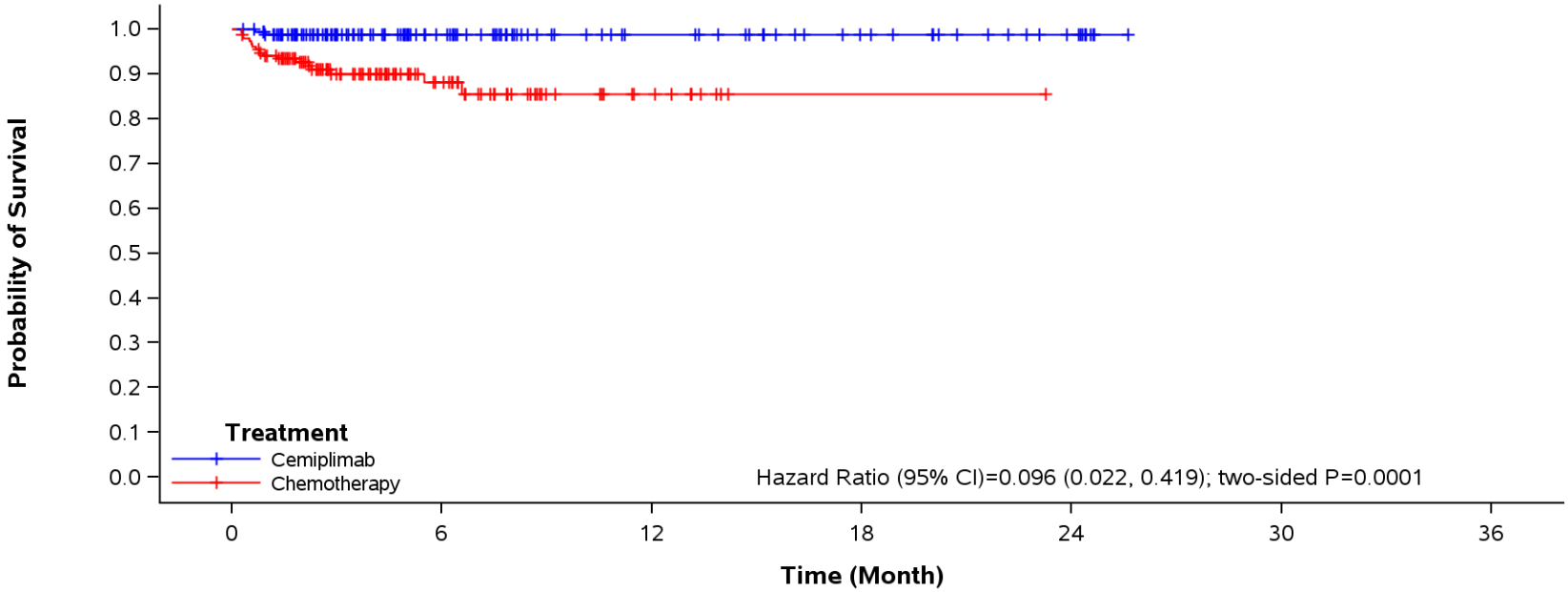
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders



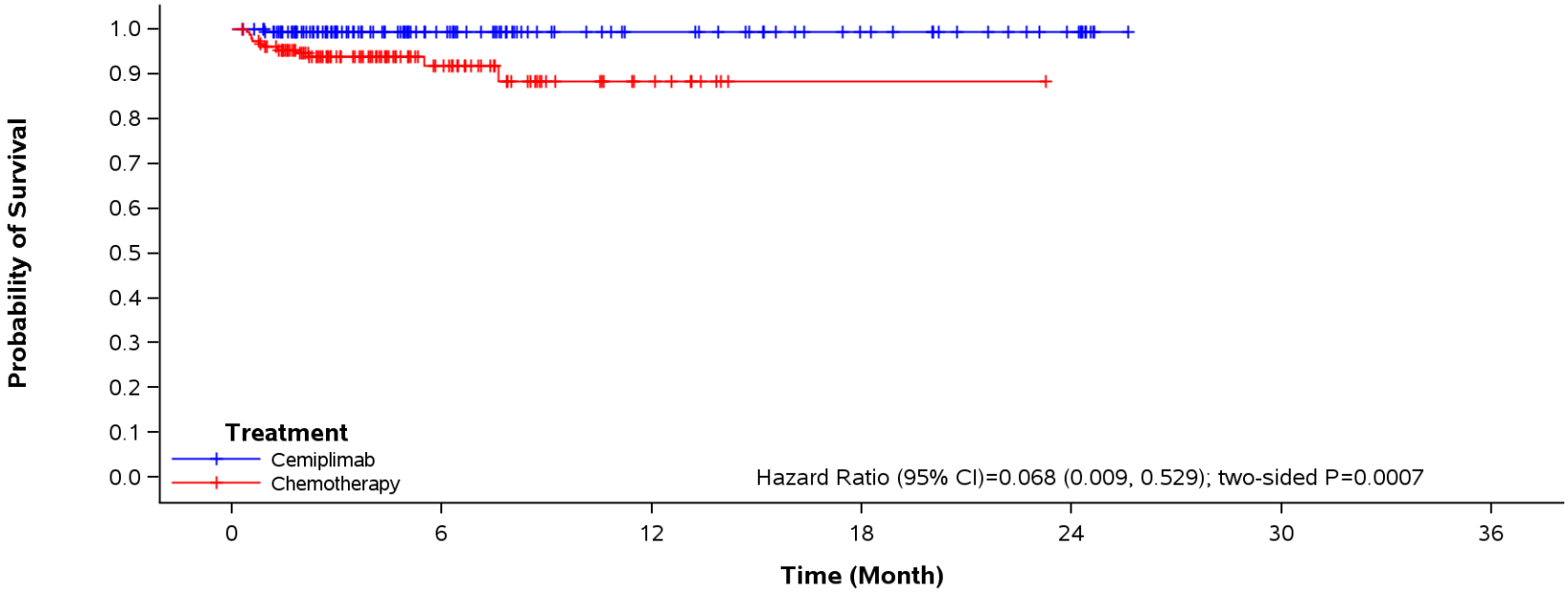

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 41 | 29 | 17 | 0 | 0 |
| Chemotherapy | 153 | 43 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Anaemia



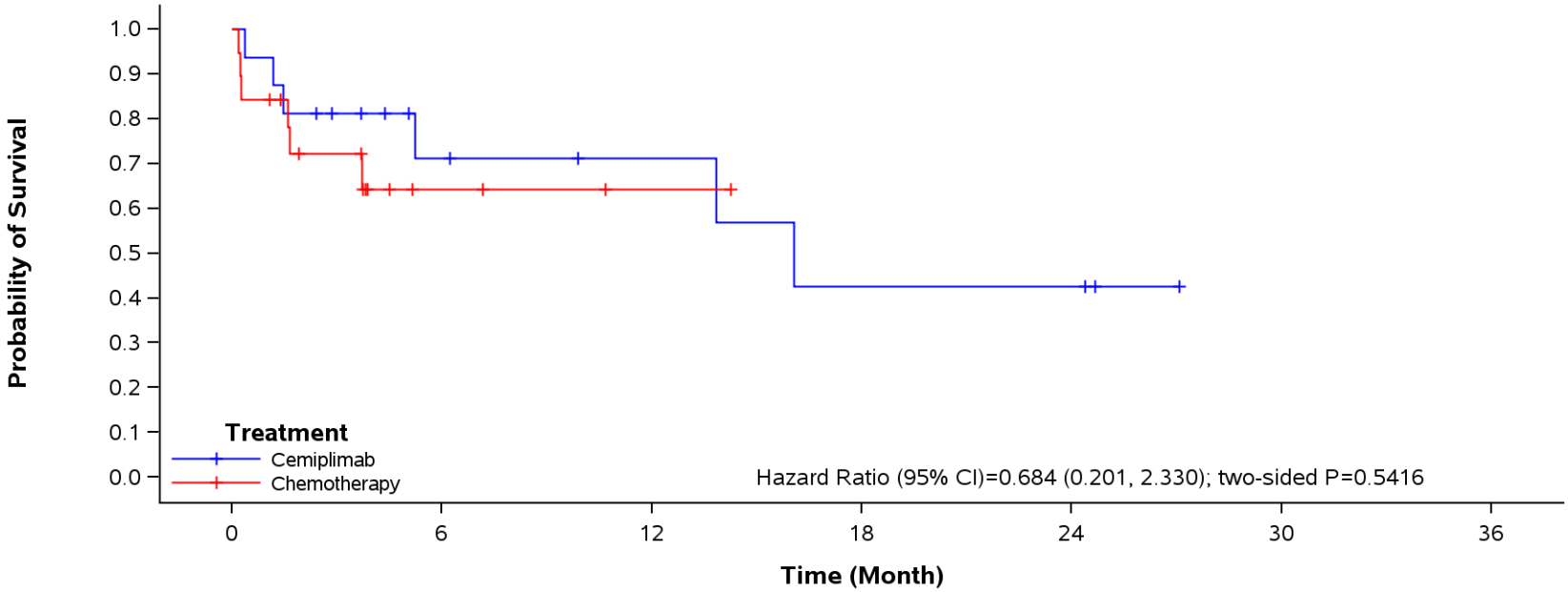

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 44 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Number of patients with any treatment-emergent SAE



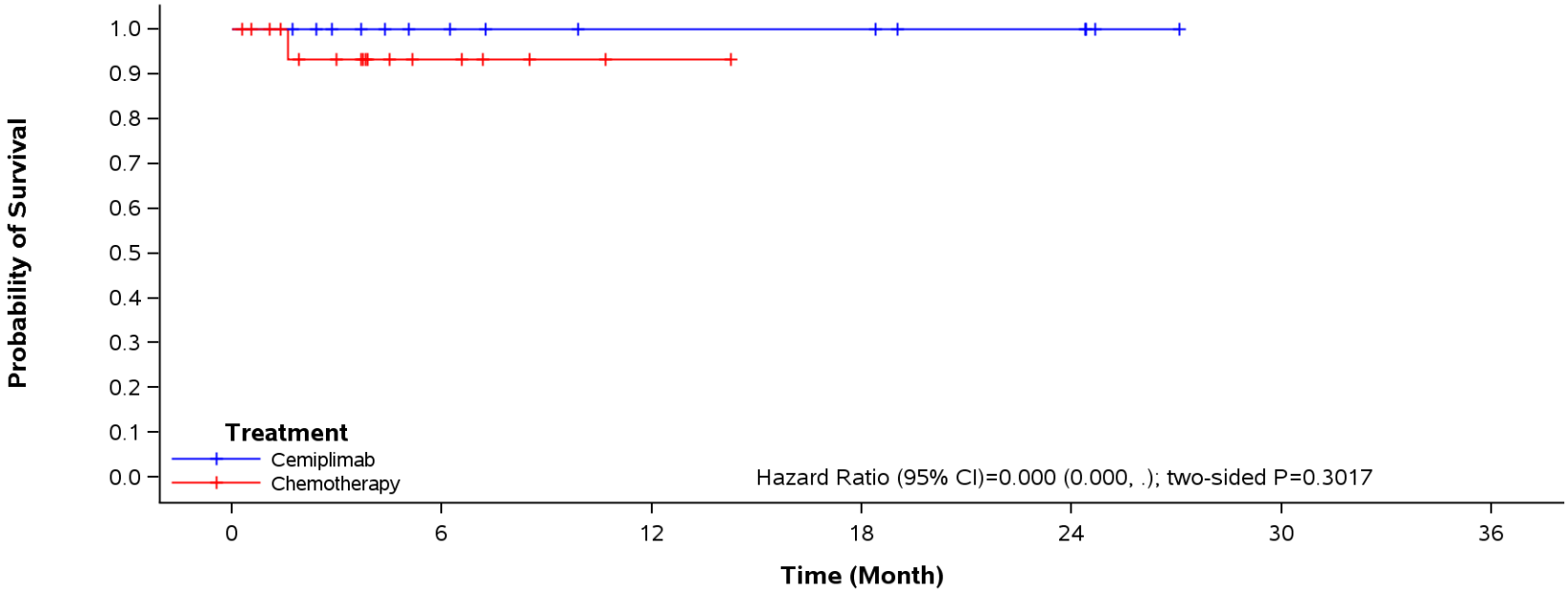

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 7 | 5 | 3 | 3 | 0 | 0 |
| Chemotherapy | 19 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders



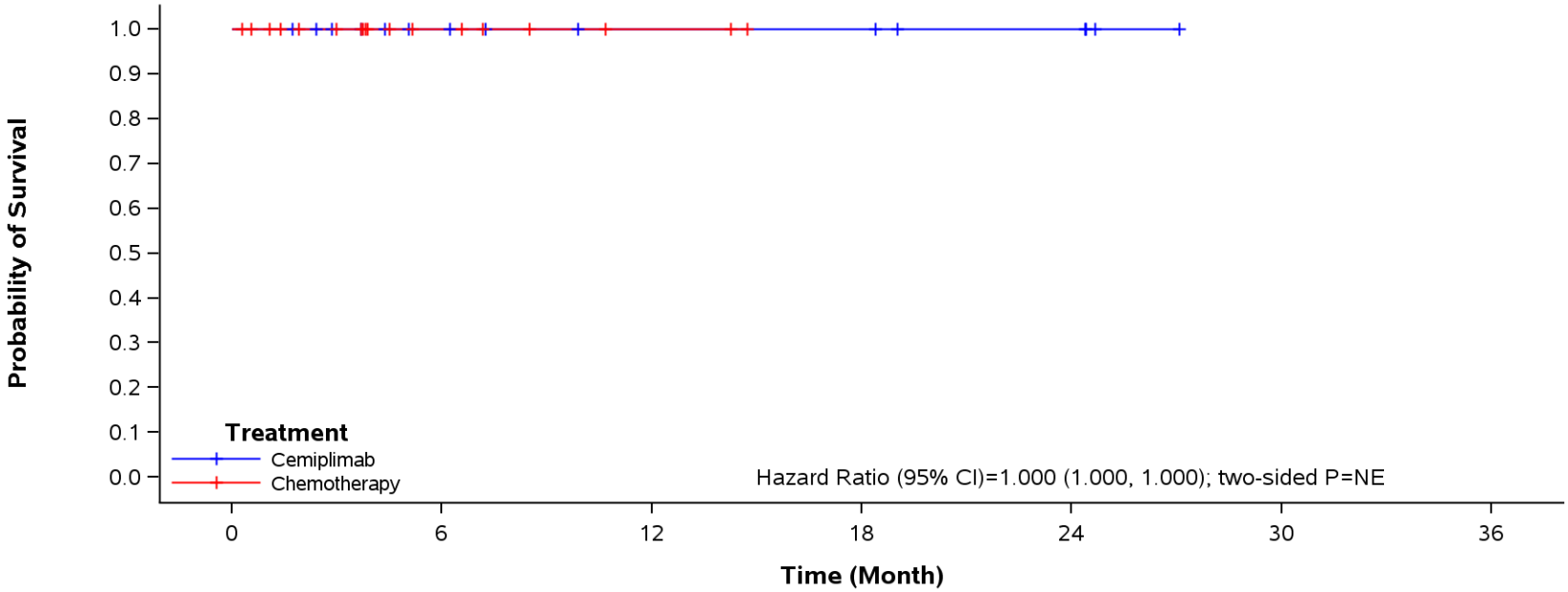

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Anaemia



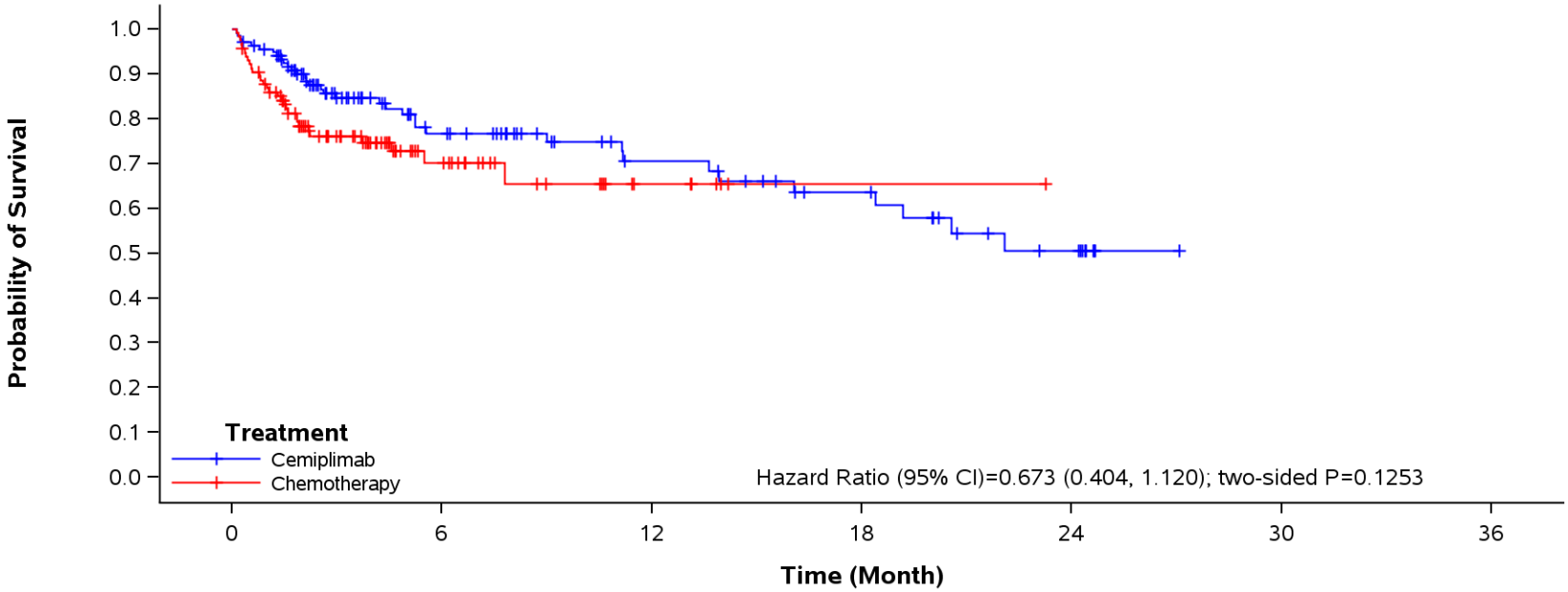

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 55 | 32 | 23 | 12 | 0 | 0 |
| Chemotherapy | 115 | 27 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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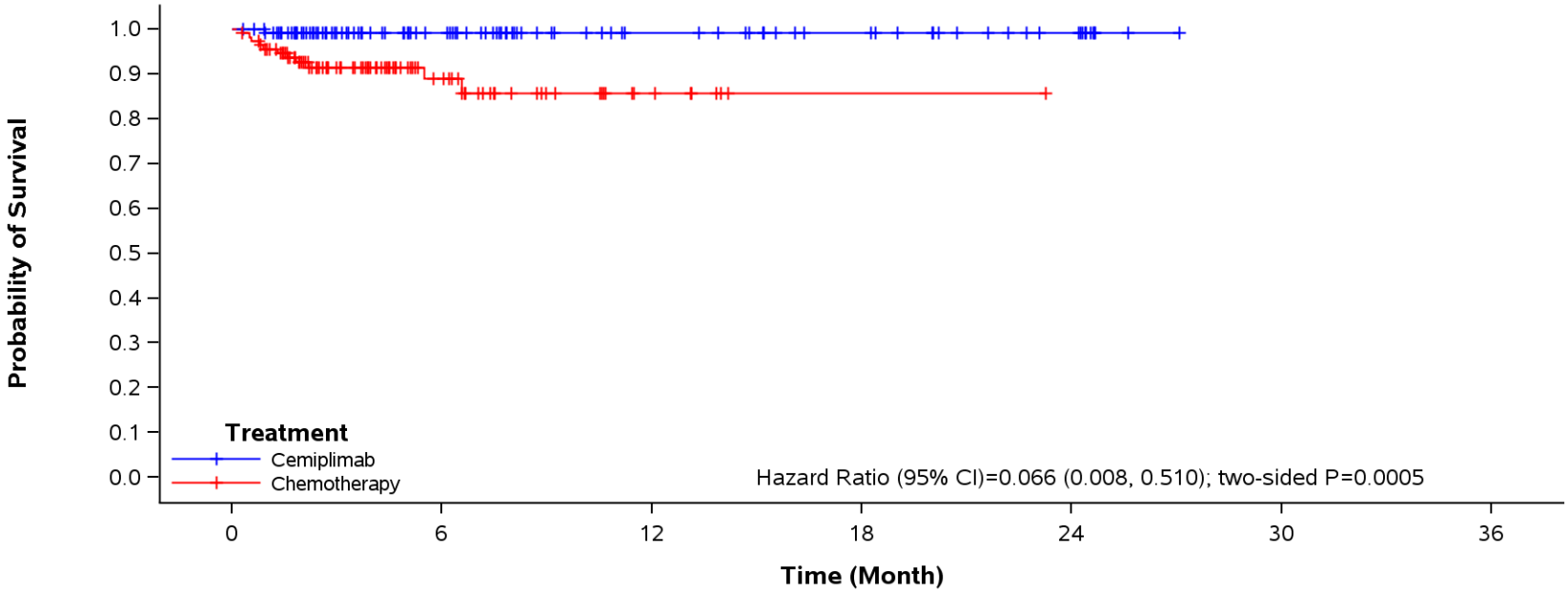
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders



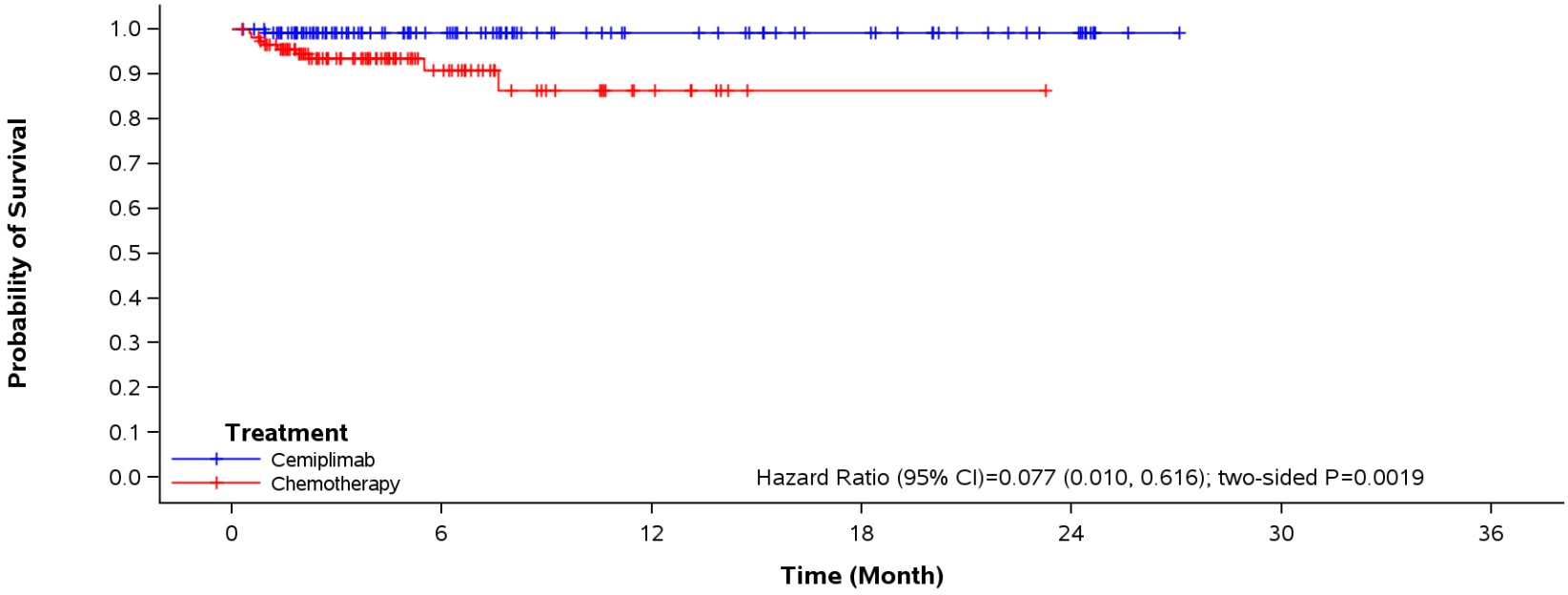

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 33 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Anaemia



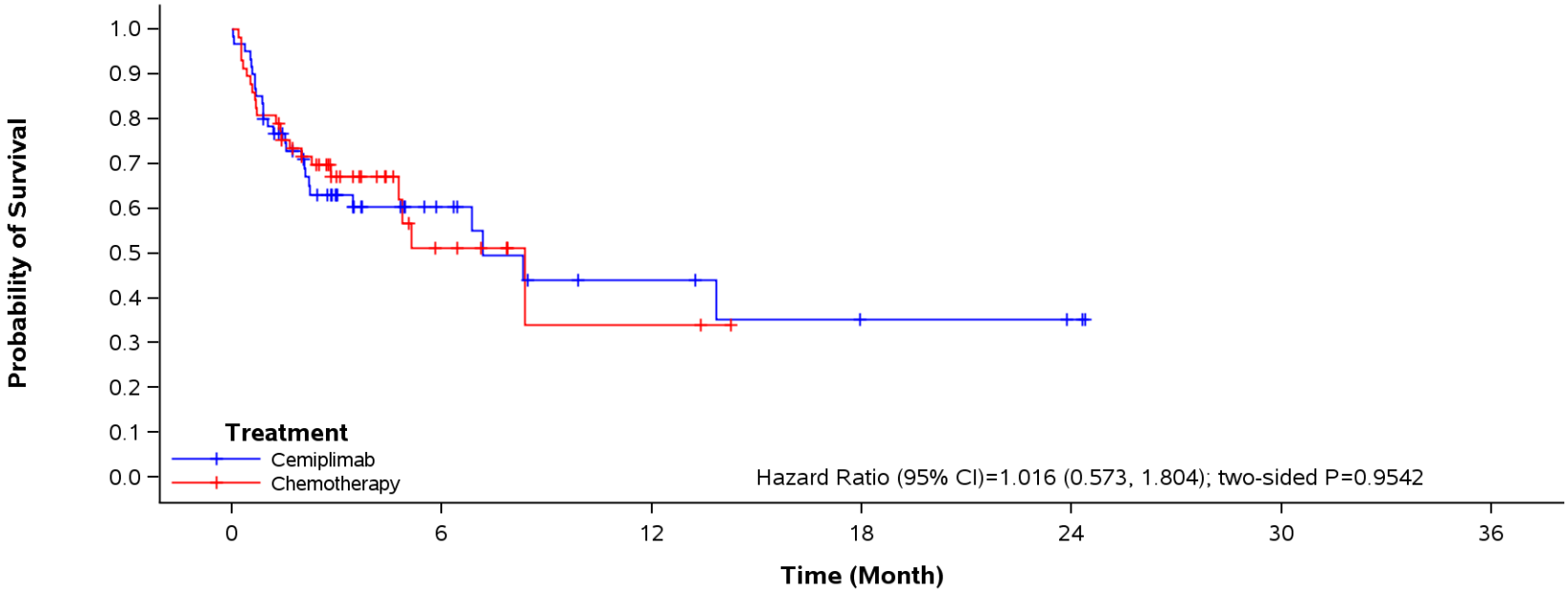

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

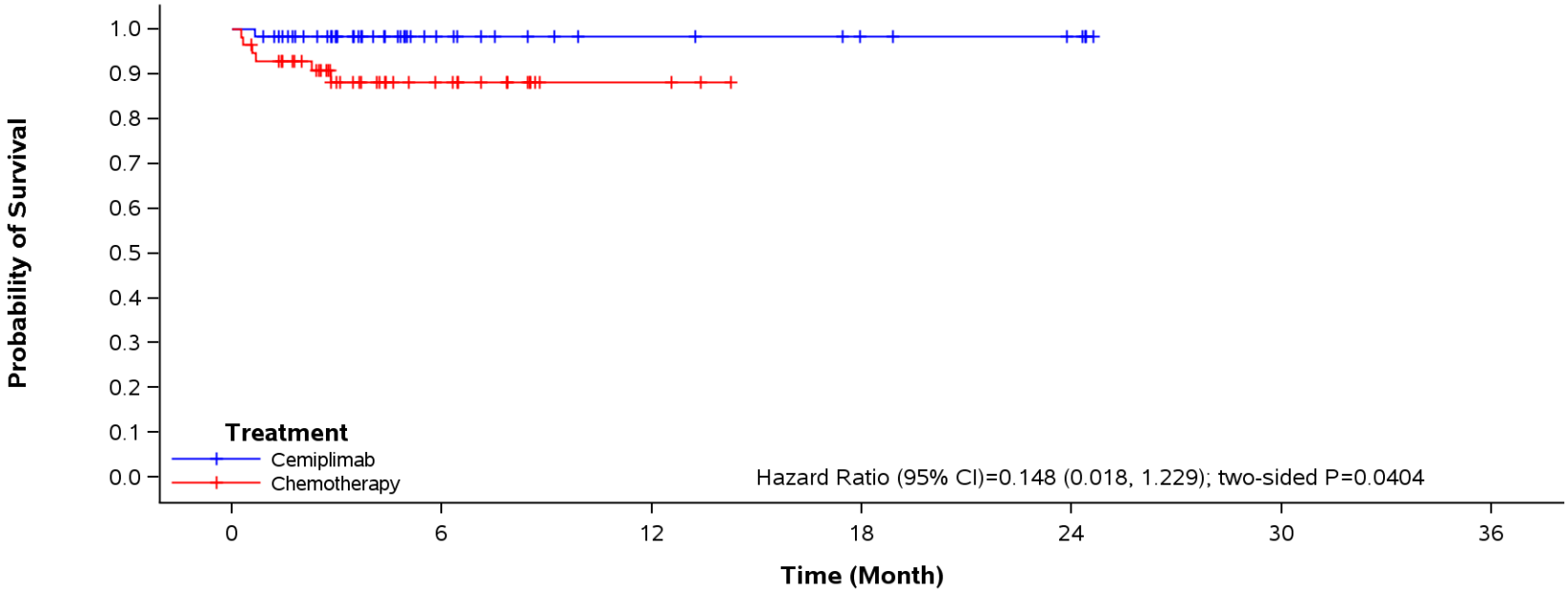
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 6 | 3 | 2 | 0 | 0 |
| Chemotherapy | 57 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders



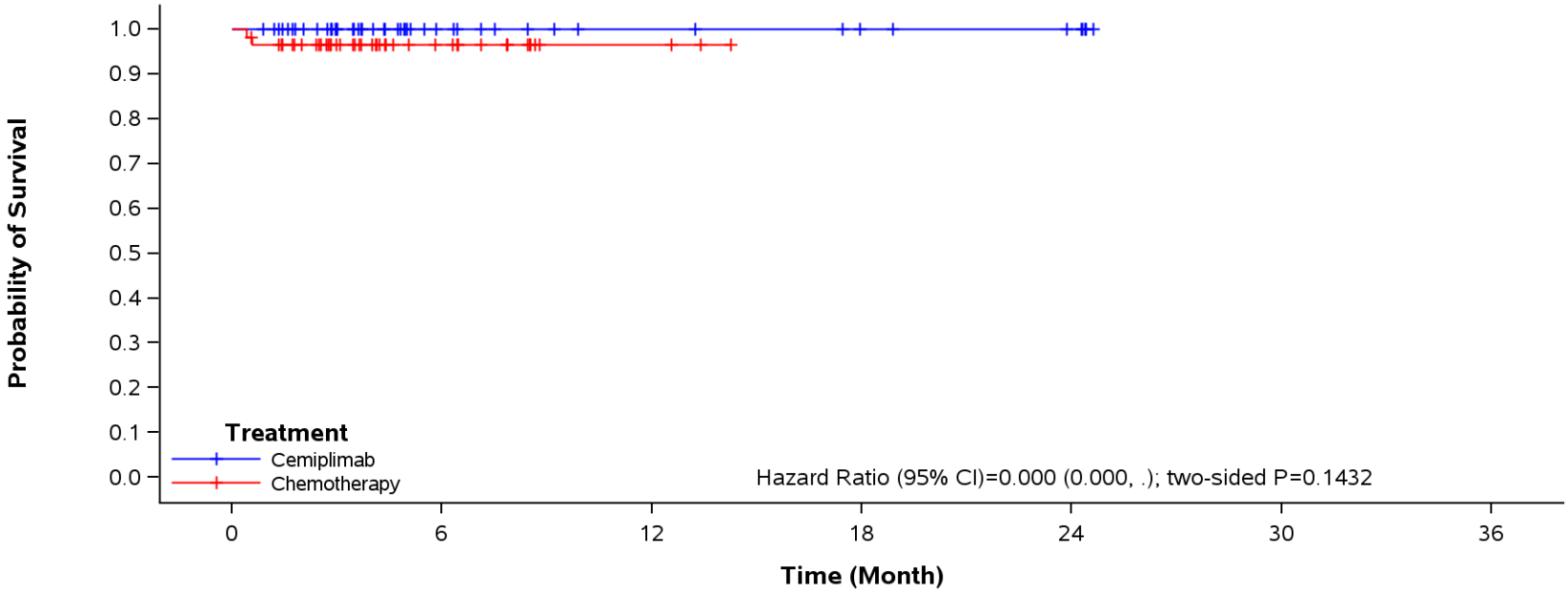

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 10 | 7 | 5 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

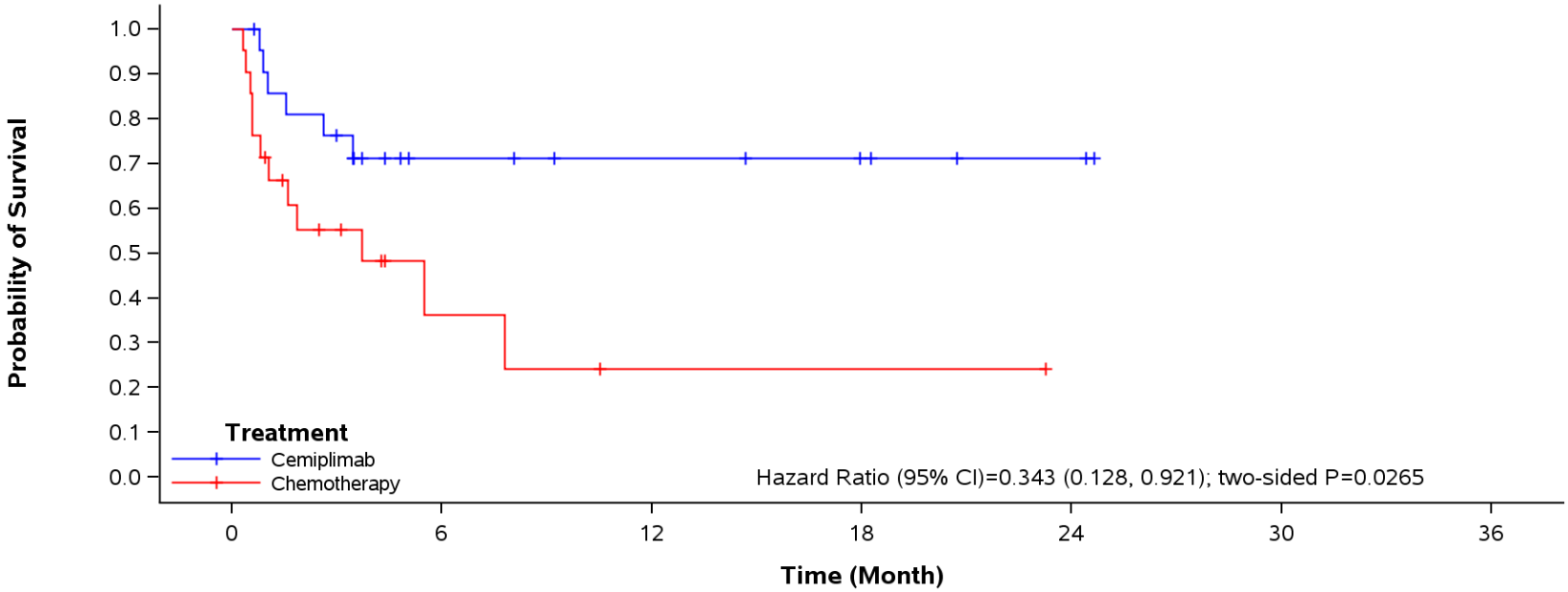
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

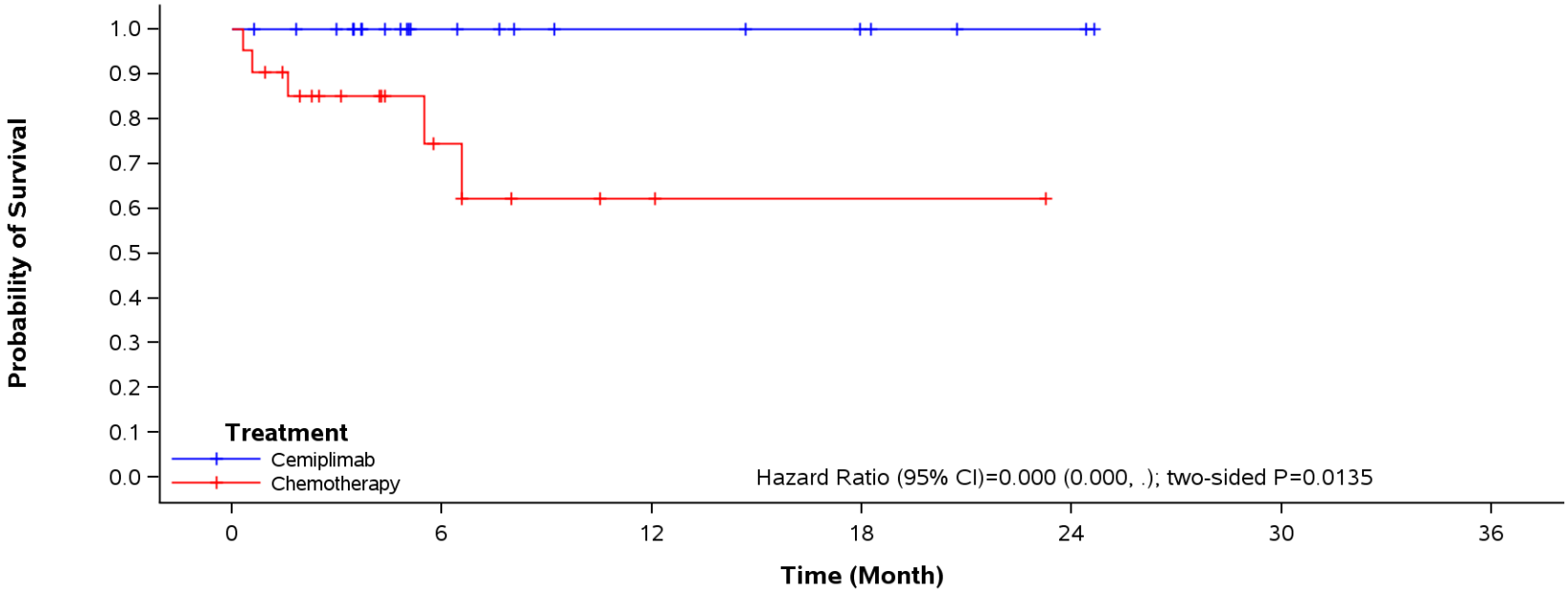
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 3 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 6 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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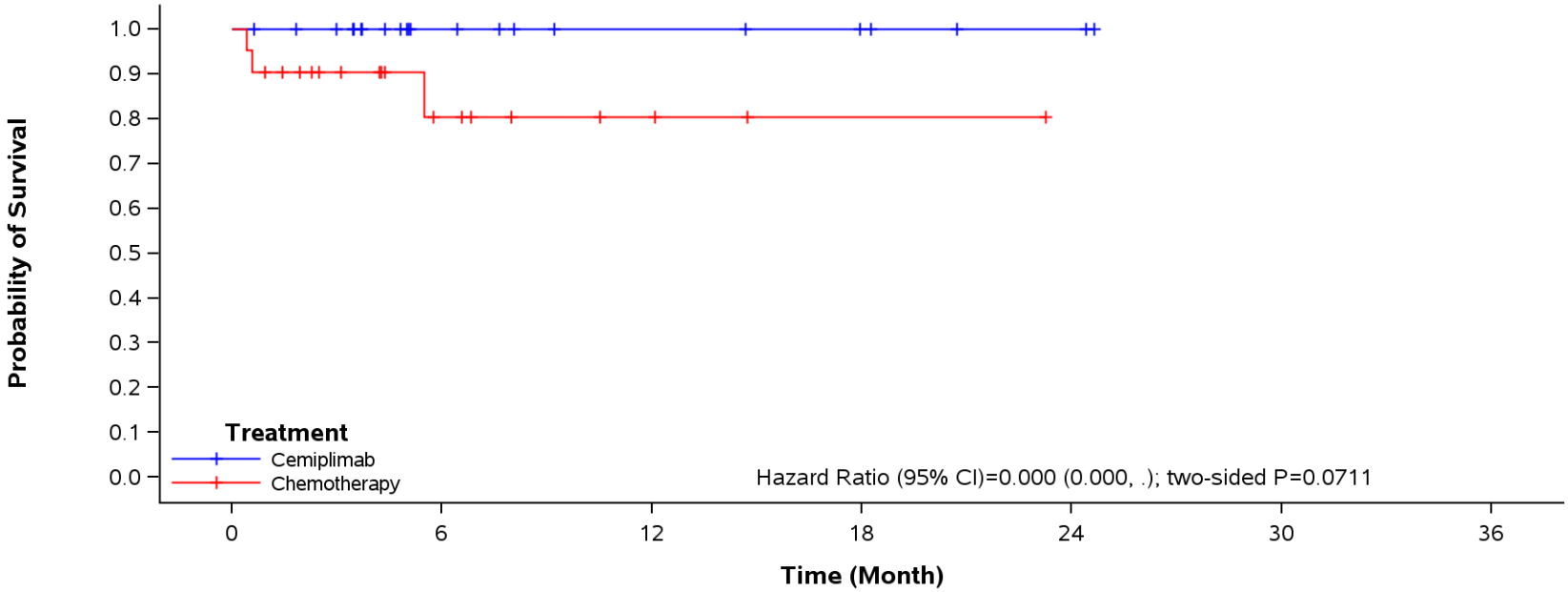
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

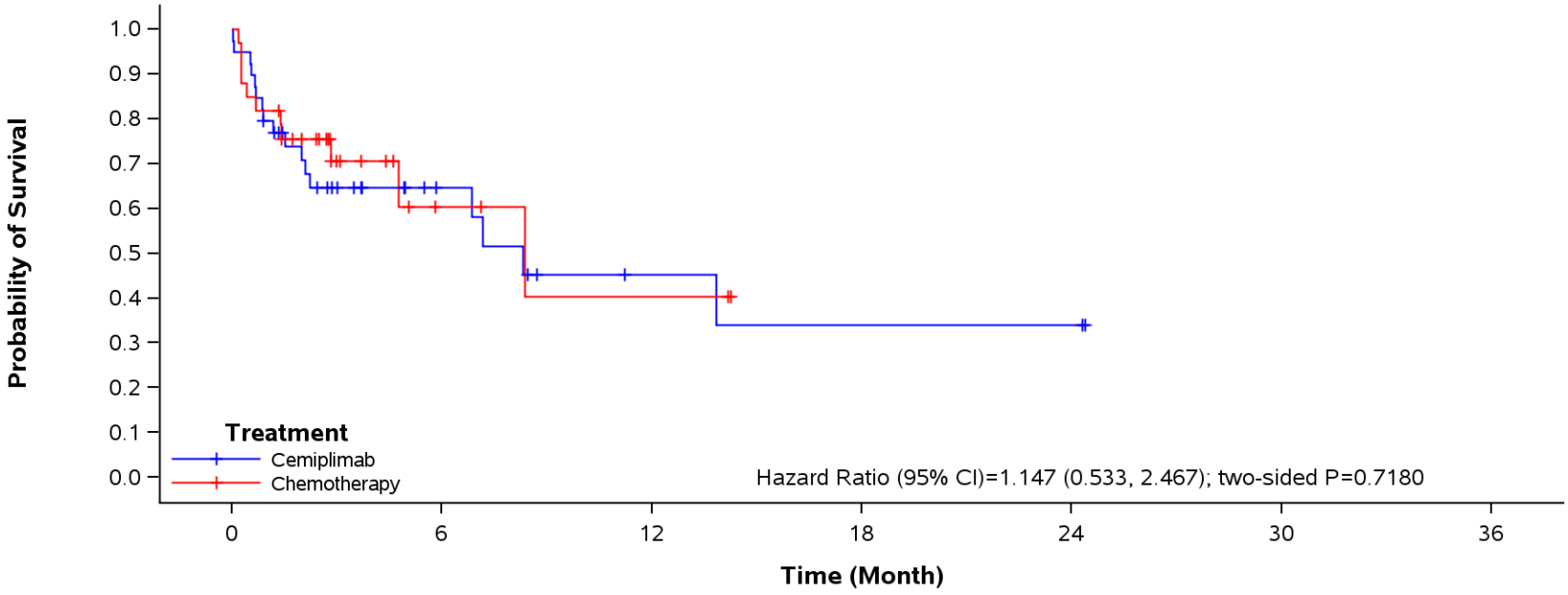
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

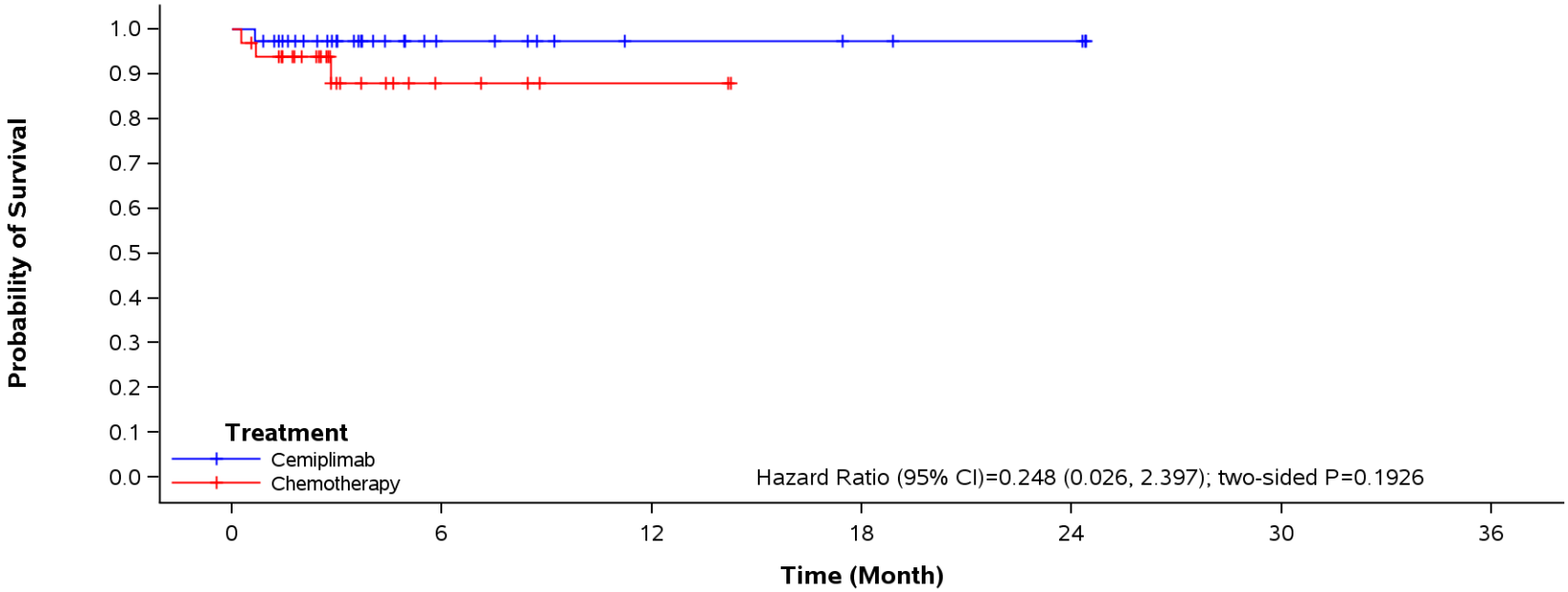
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 4 | 3 | 3 | 0 | 0 |
| Chemotherapy | 33 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders



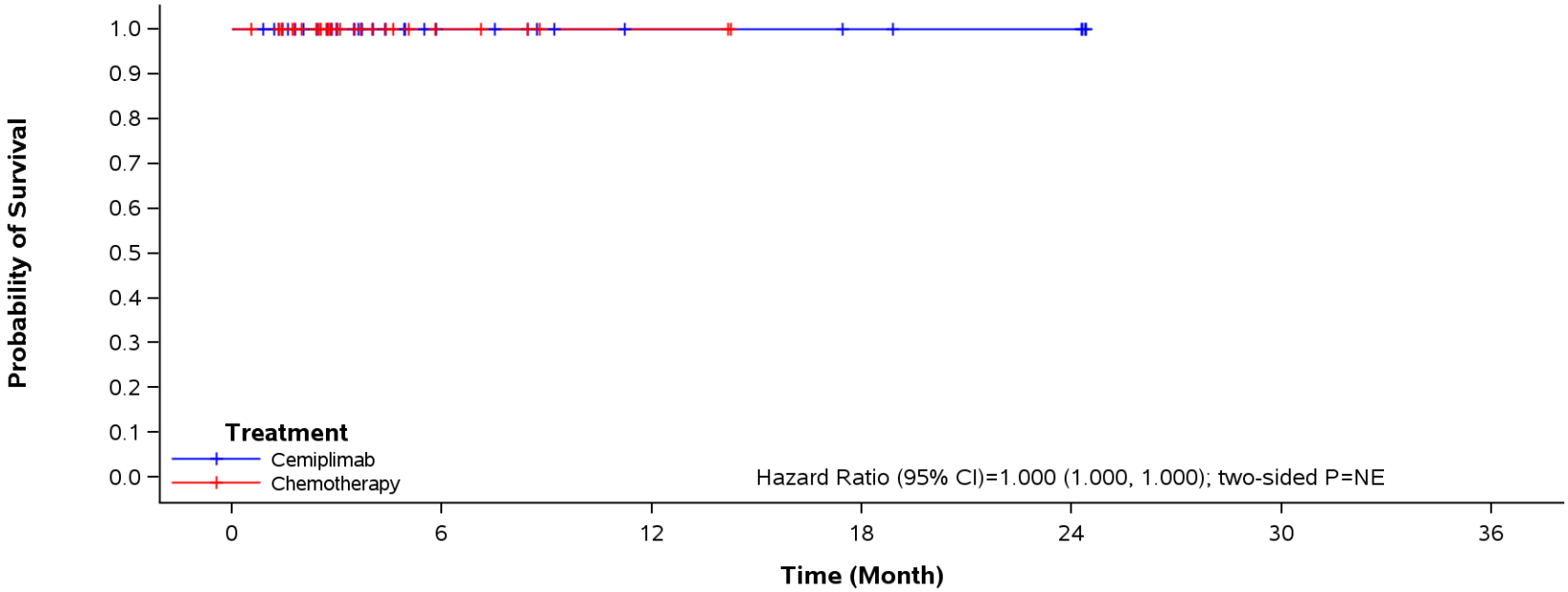

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 6 | 5 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Anaemia



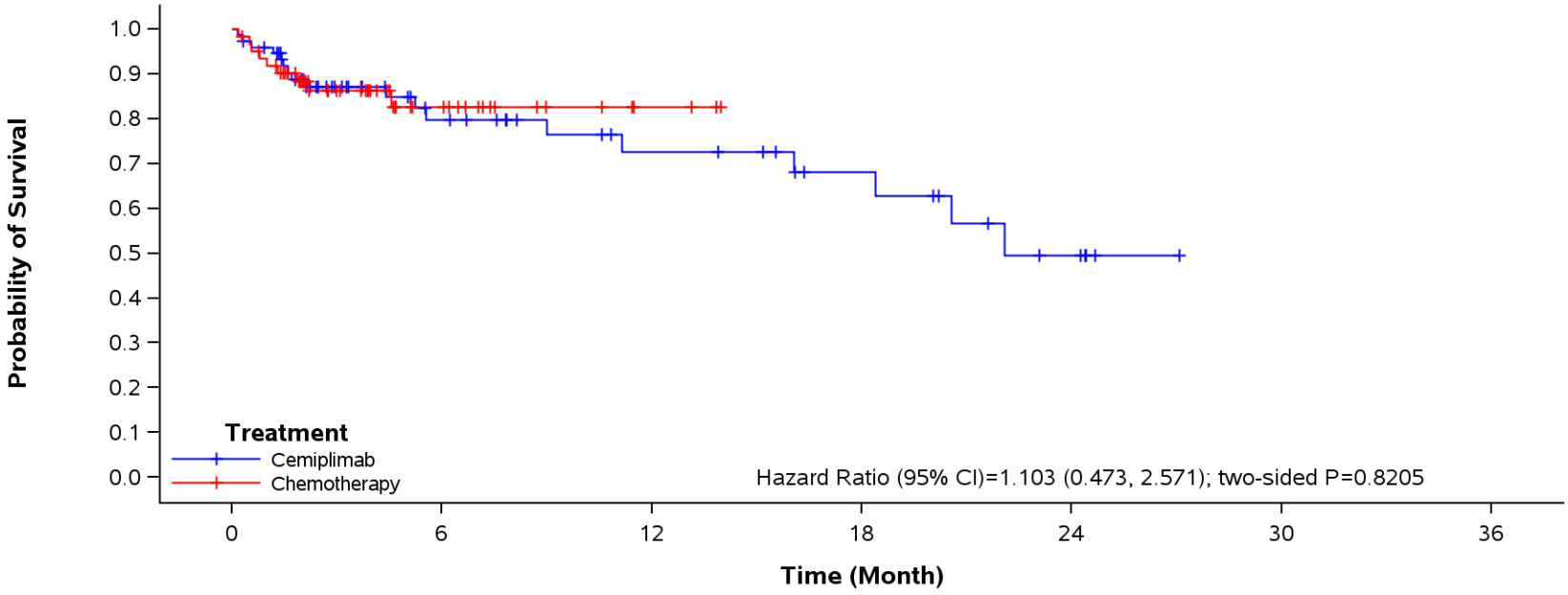

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

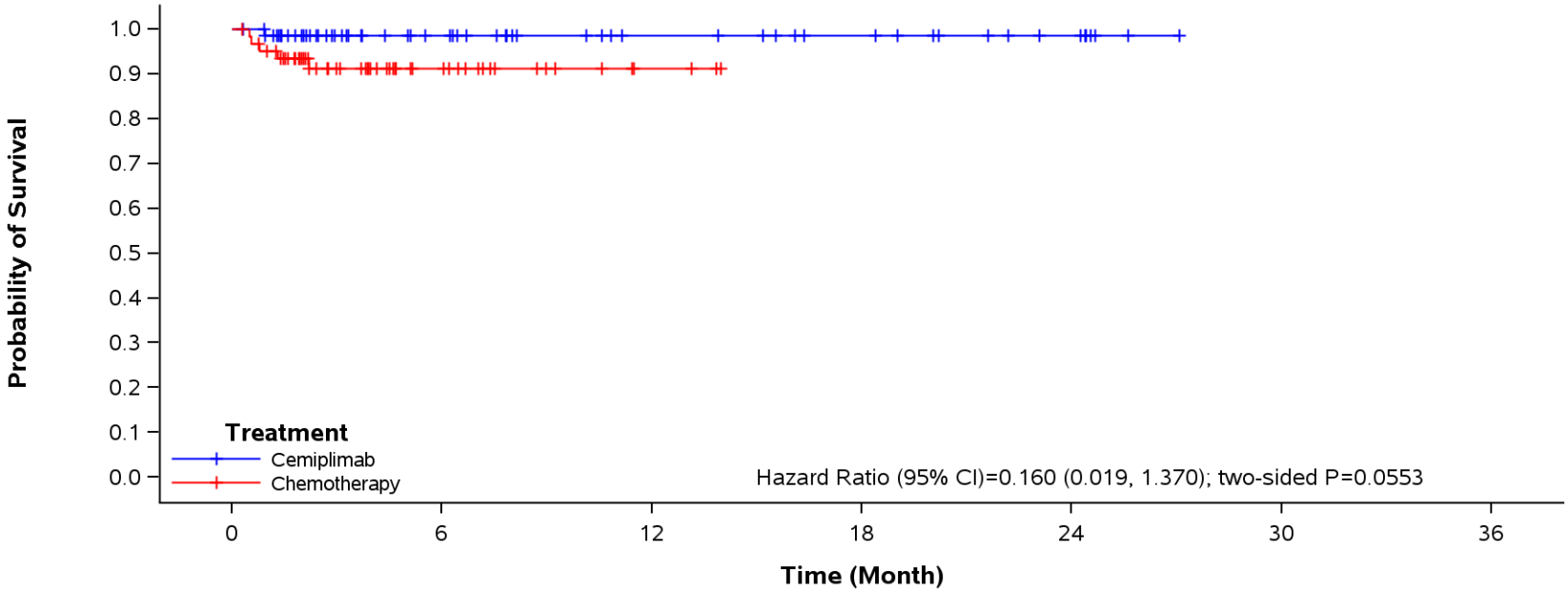
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 31 | 19 | 13 | 6 | 0 | 0 |
| Chemotherapy | 63 | 17 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders



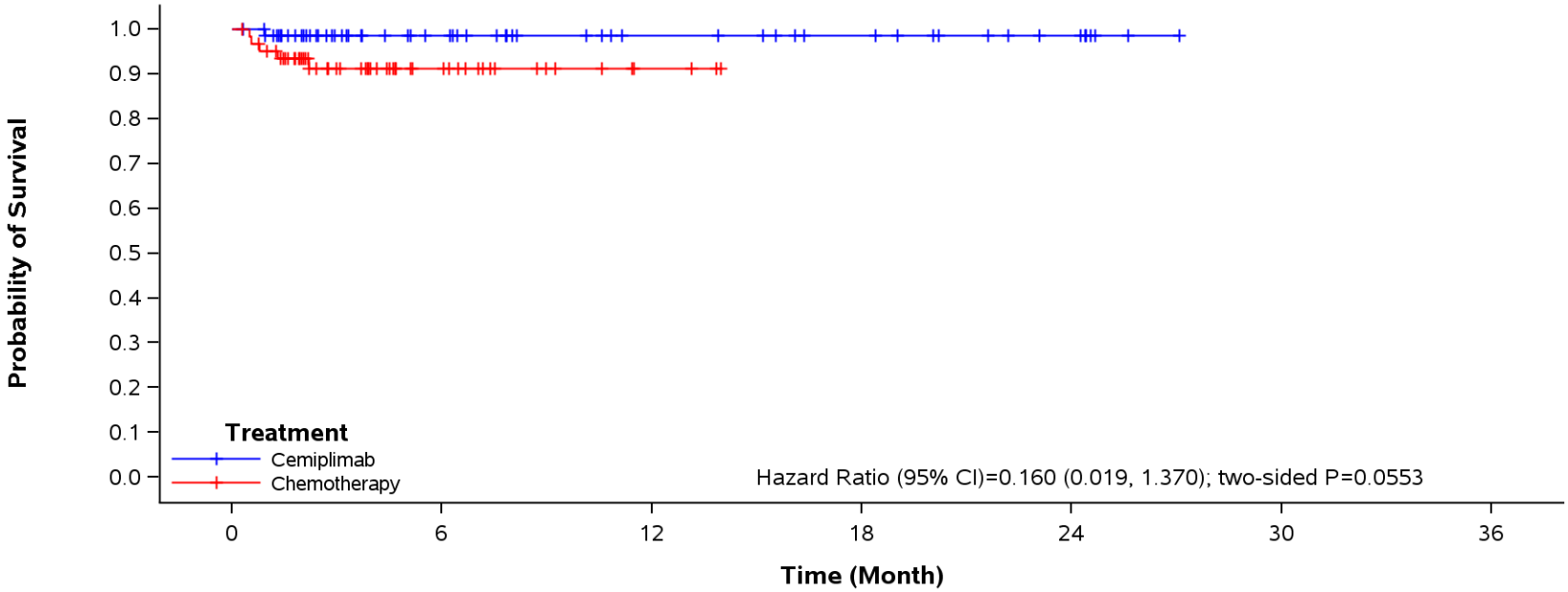

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Anaemia



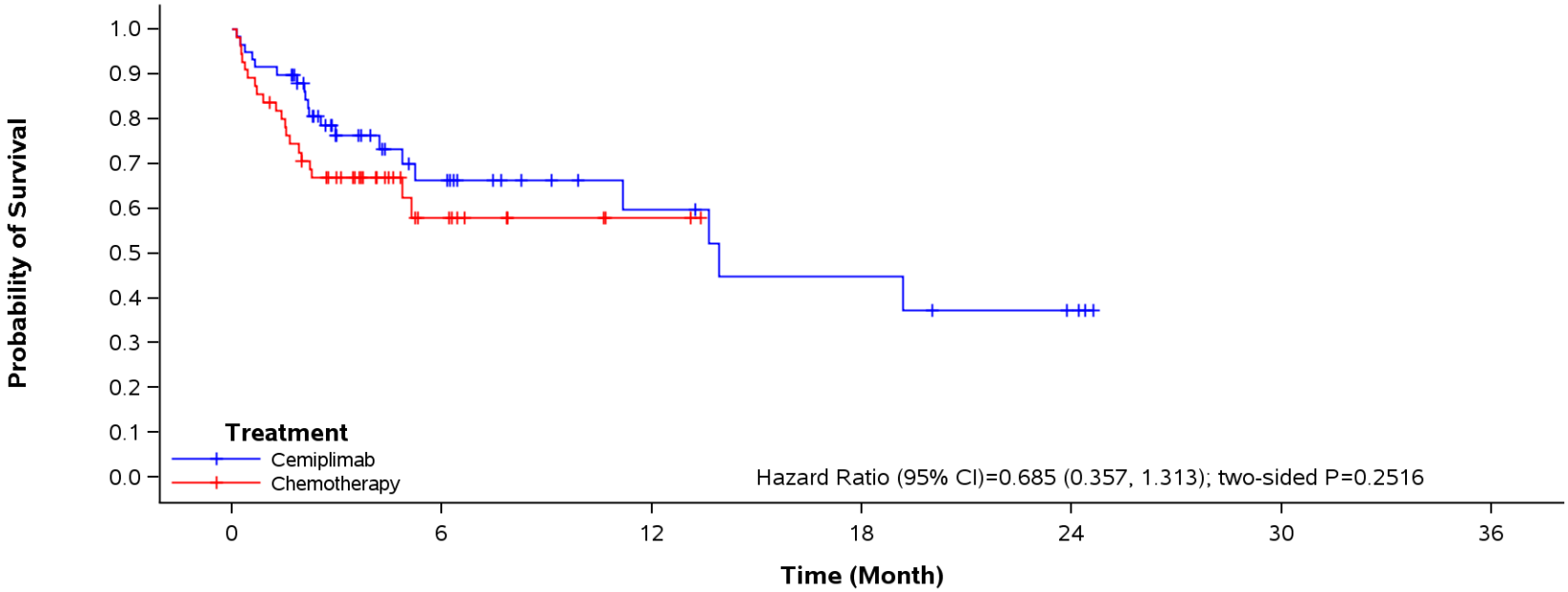

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Number of patients with any treatment-emergent SAE



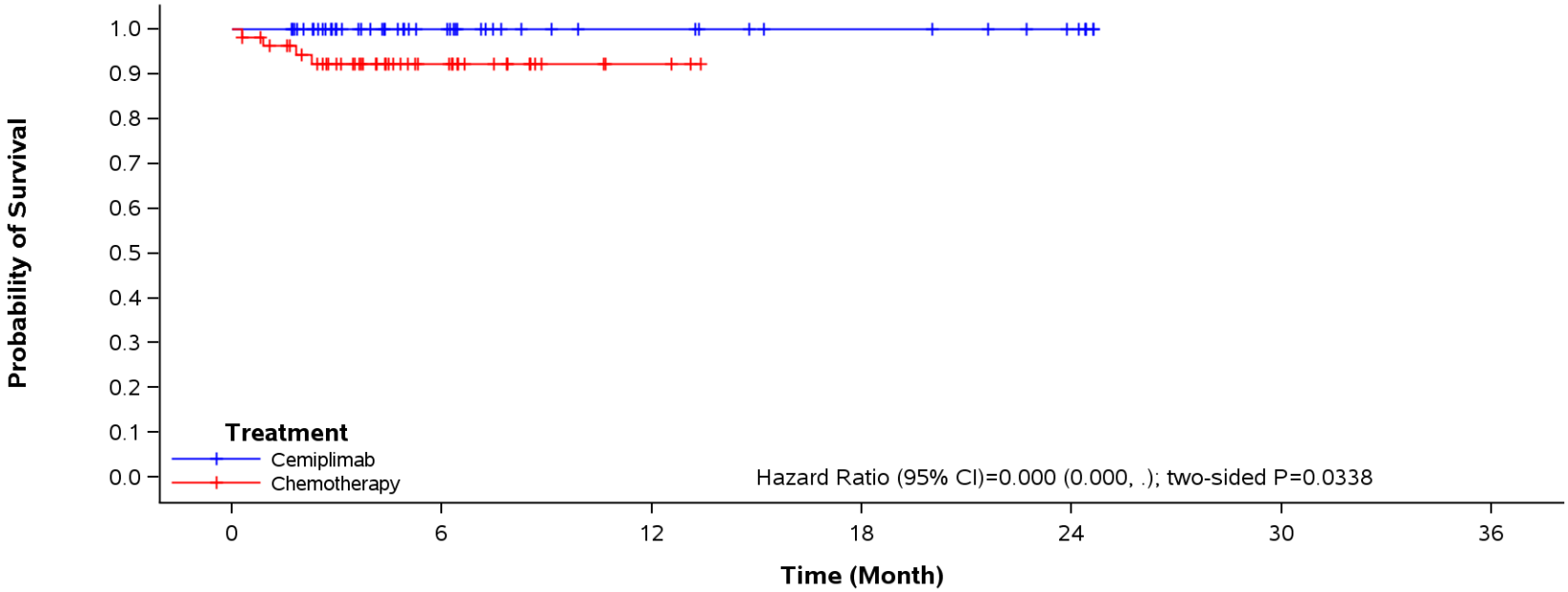

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 19 | 9 | 6 | 3 | 0 | 0 |
| Chemotherapy | 55 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders




**Number of Subjects at risk**

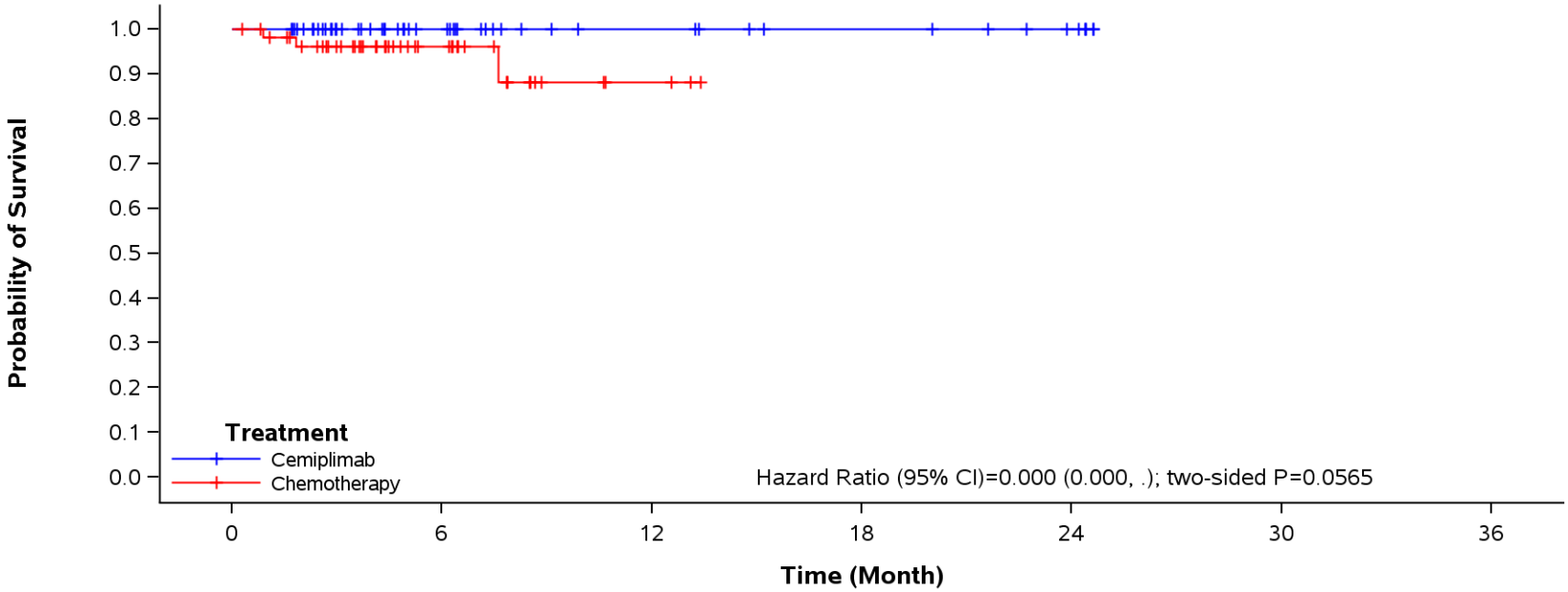
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Anaemia



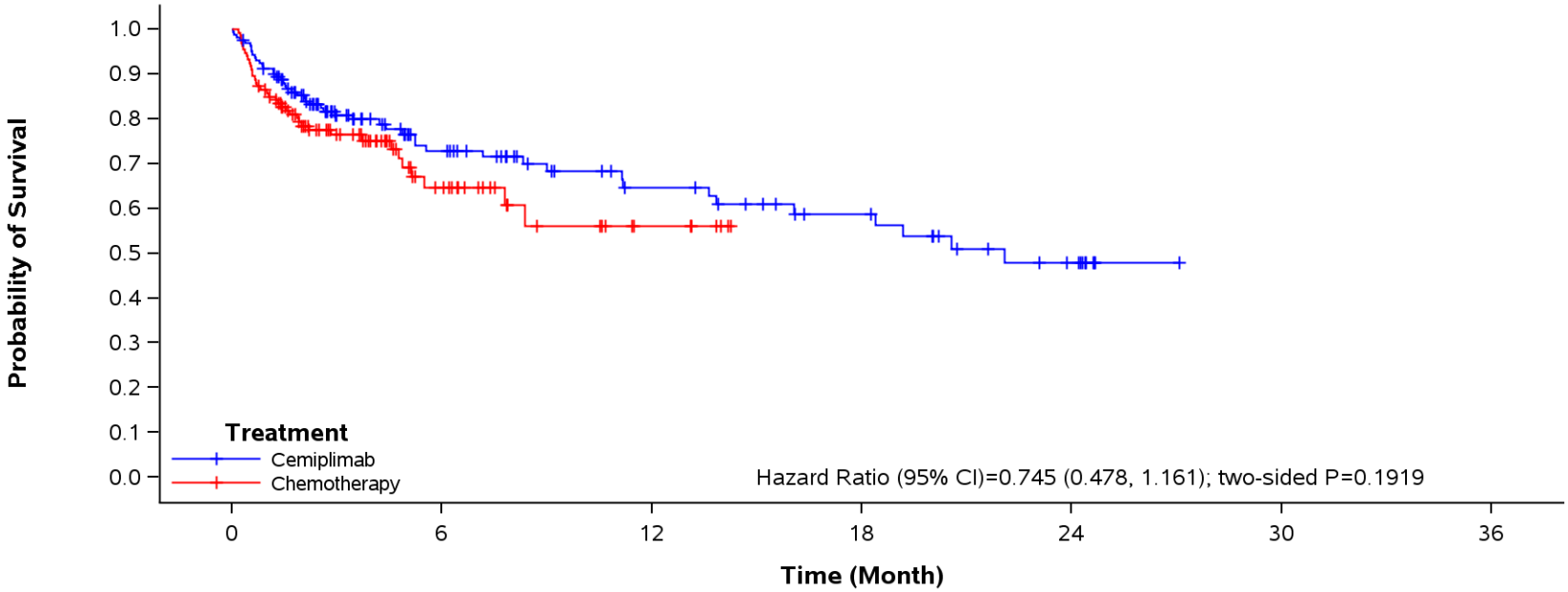

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 59 | 35 | 25 | 13 | 0 | 0 |
| Chemotherapy | 133 | 27 | 6 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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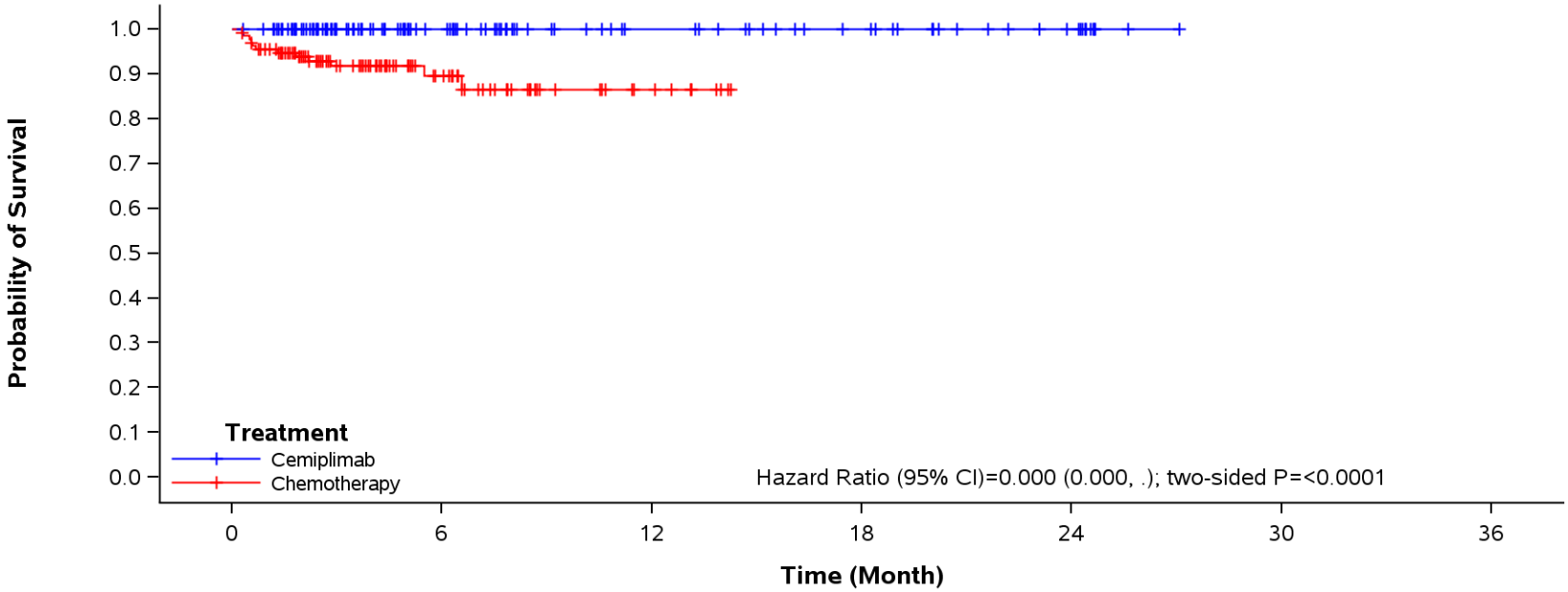
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders



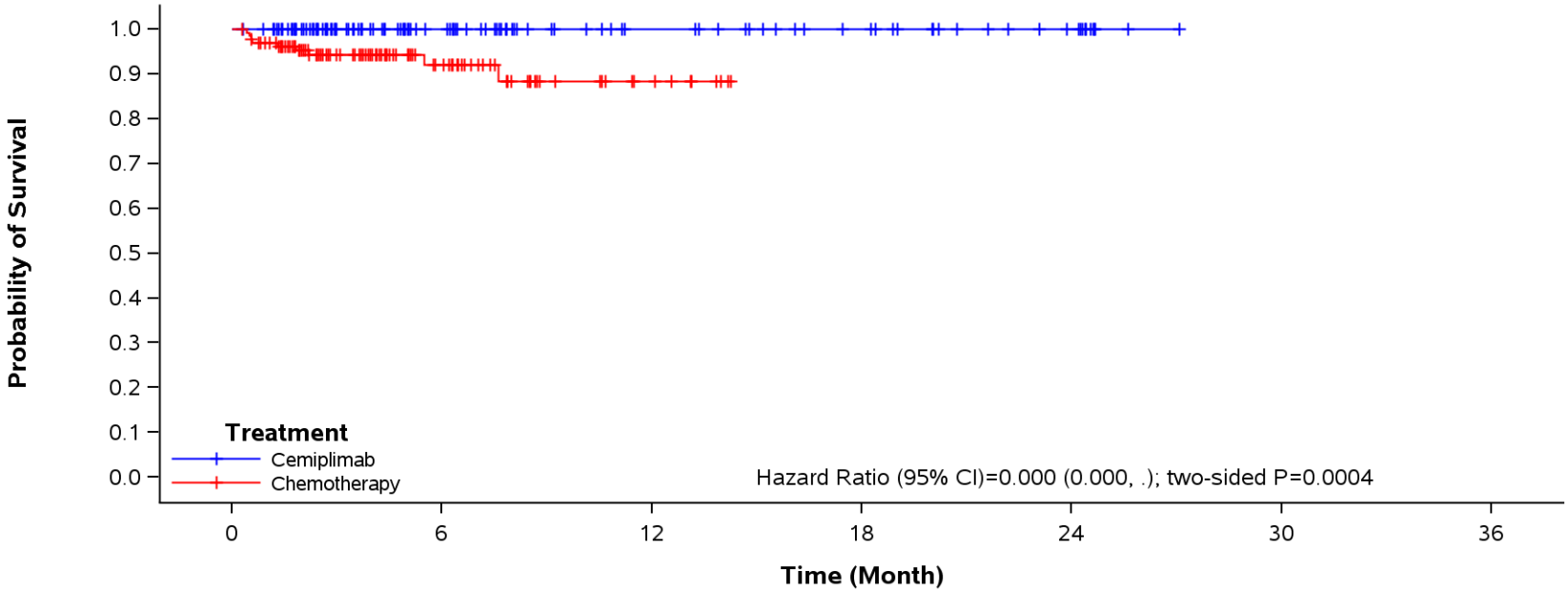

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 38 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



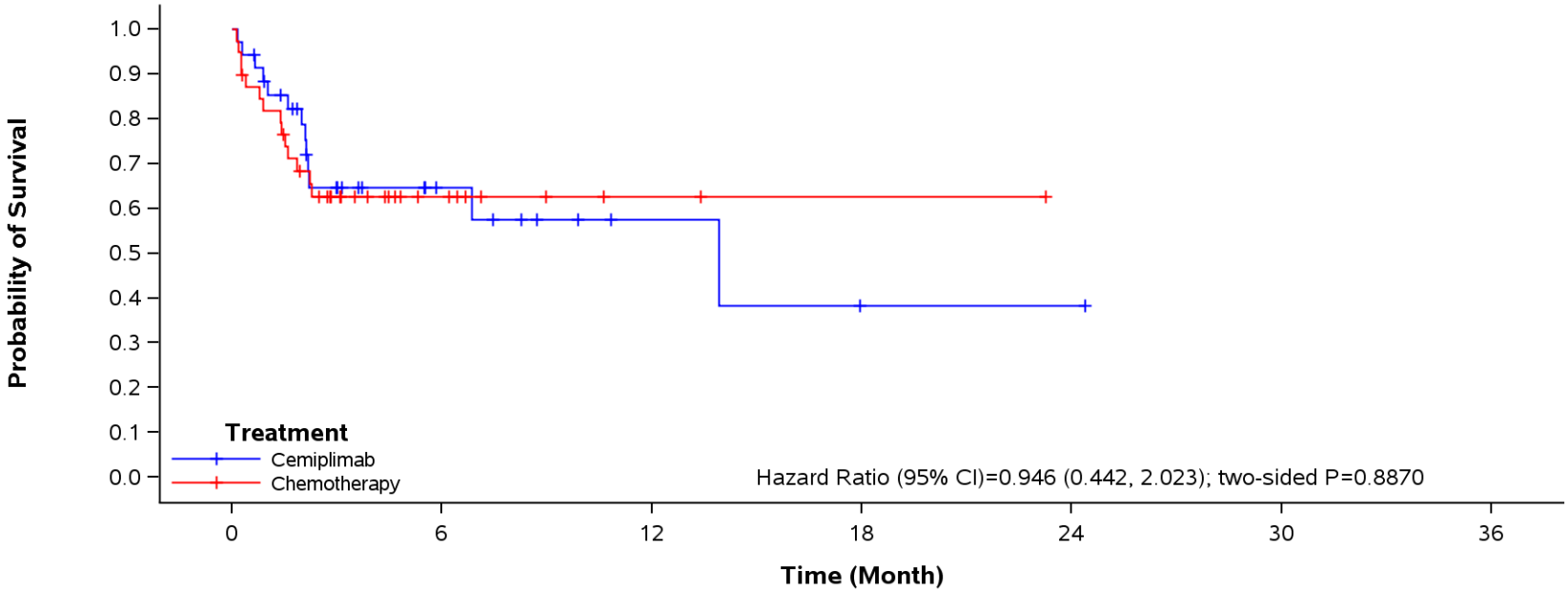

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 39 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

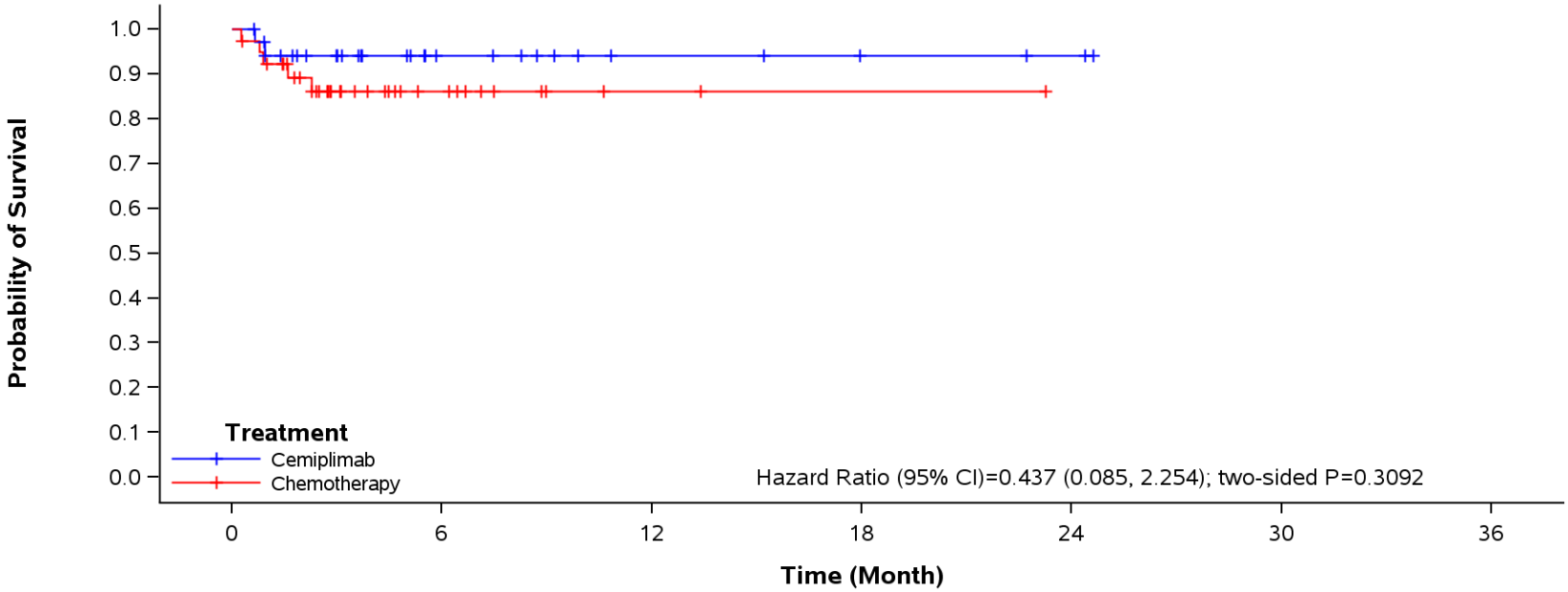
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 3 | 1 | 1 | 0 | 0 |
| Chemotherapy | 39 | 8 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders



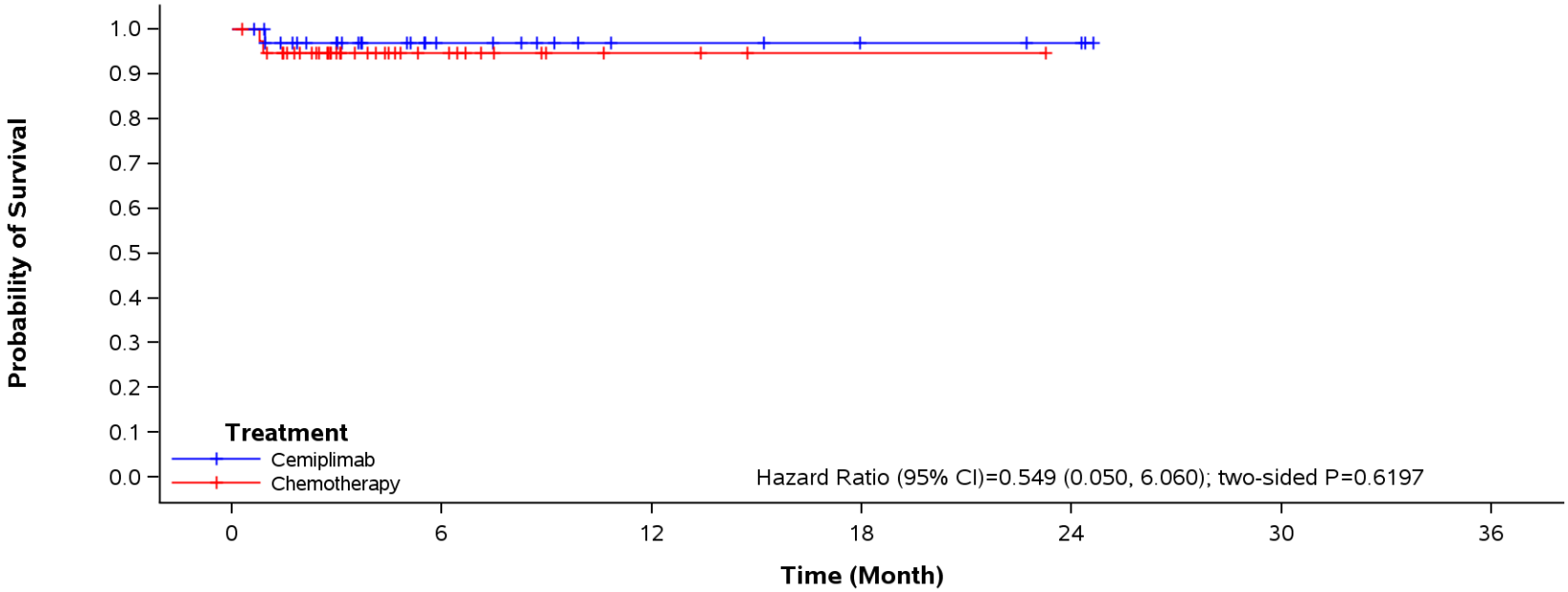

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 11 | 5 | 3 | 2 | 0 | 0 |
| Chemotherapy | 39 | 10 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



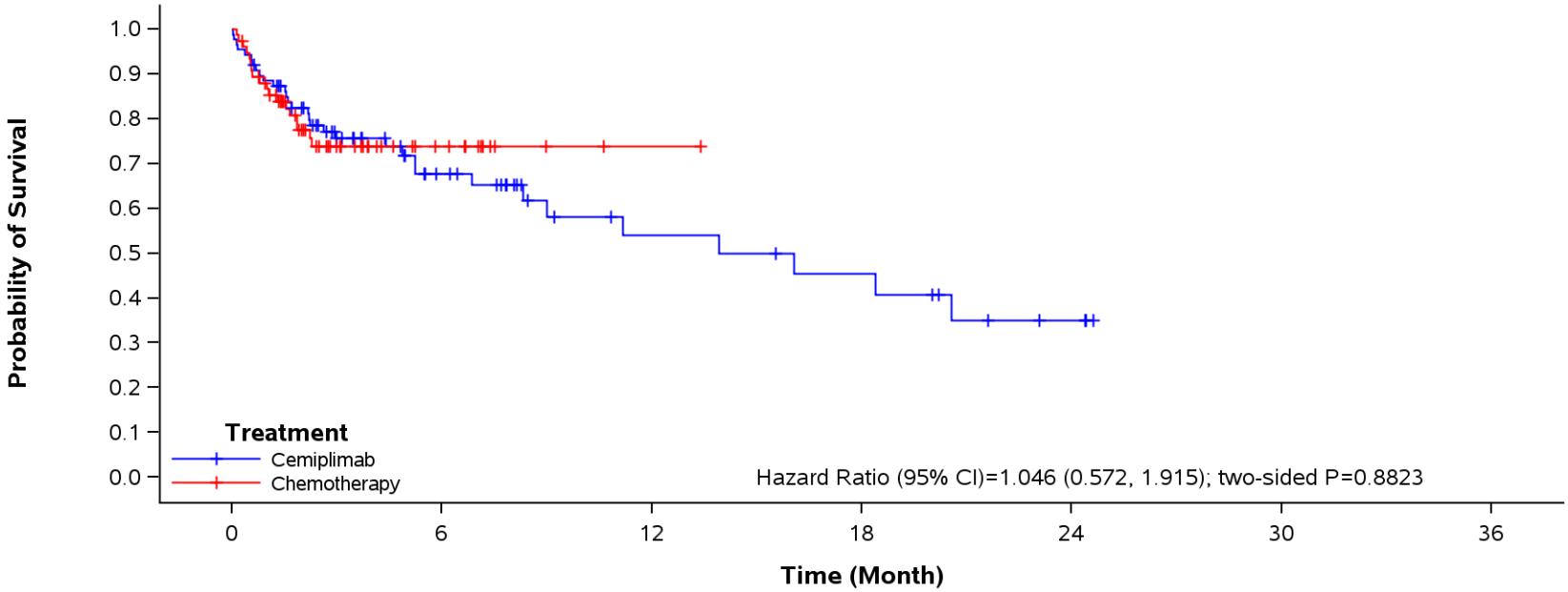

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 30 | 13 | 10 | 4 | 0 | 0 |
| Chemotherapy | 76 | 11 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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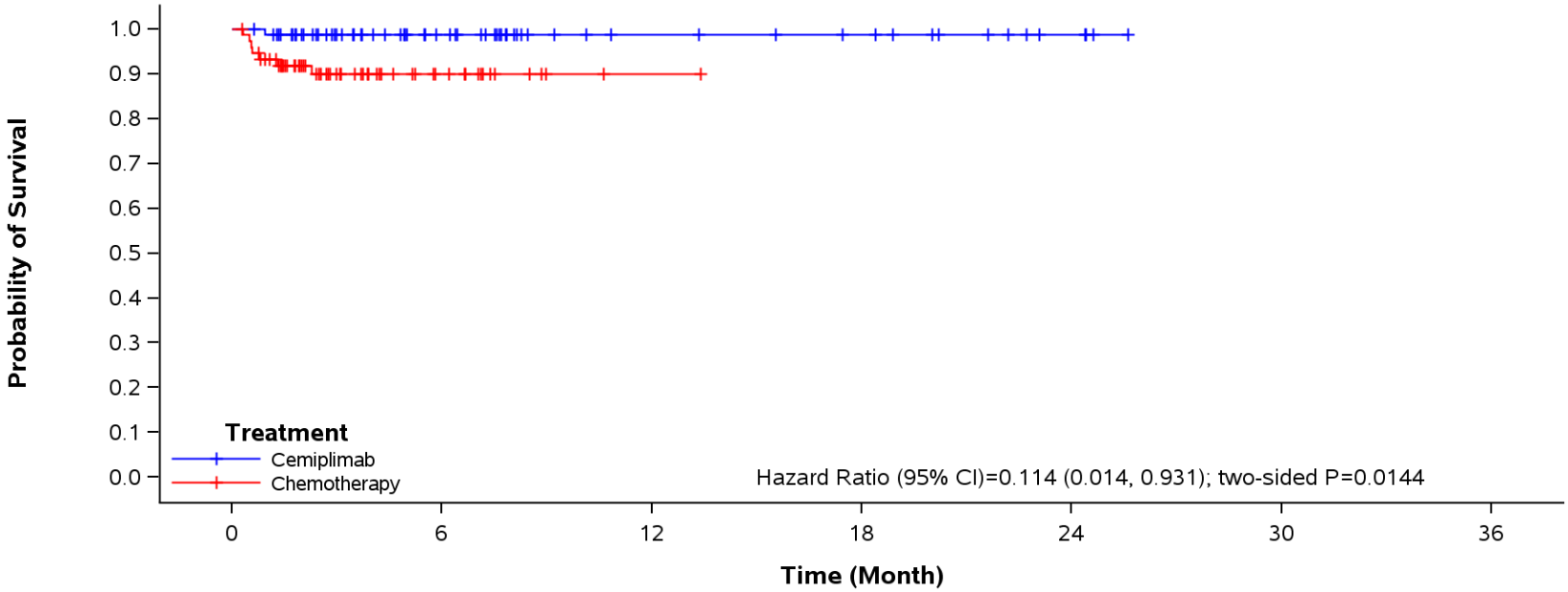
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders



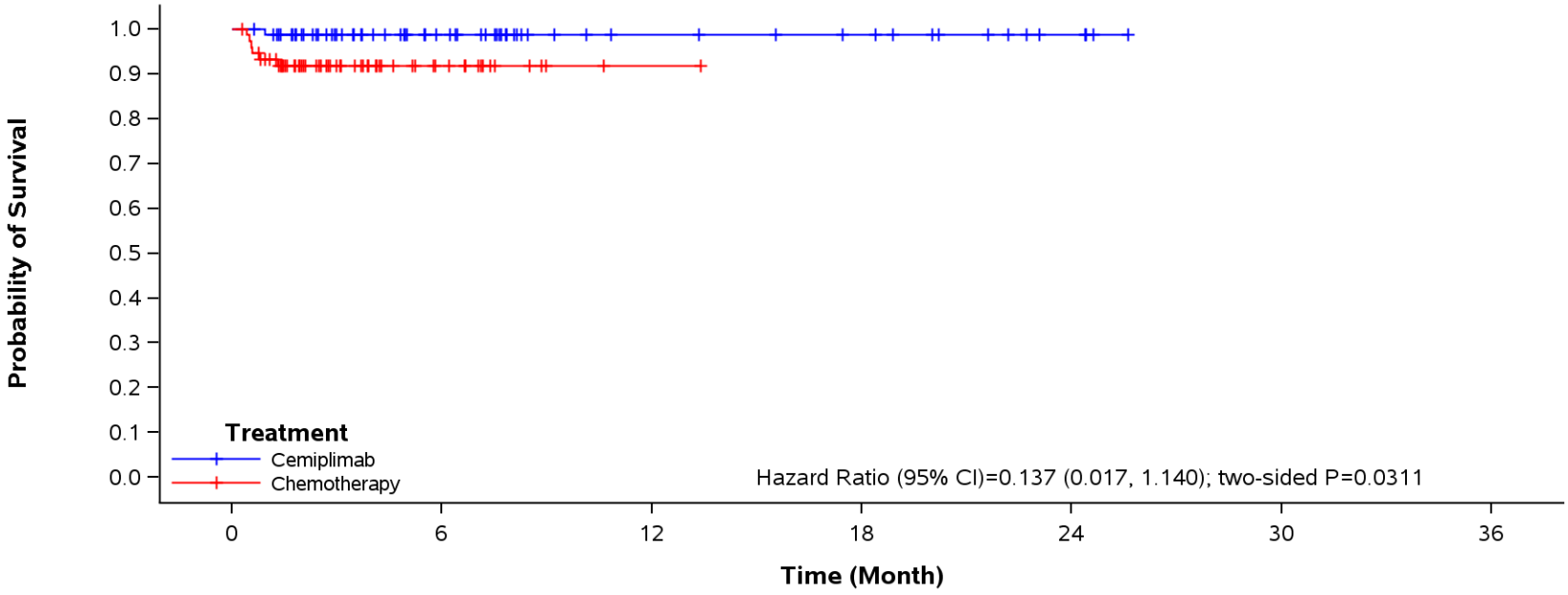

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Anaemia



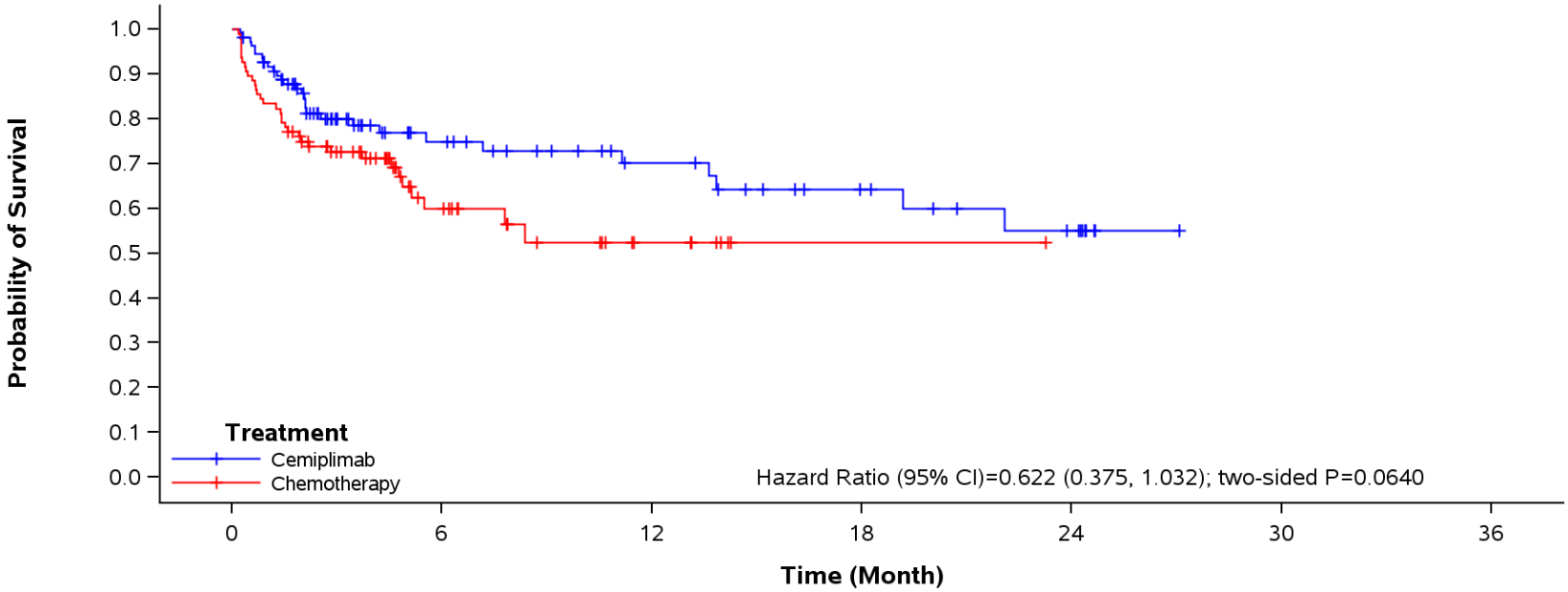

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Number of patients with any treatment-emergent SAE



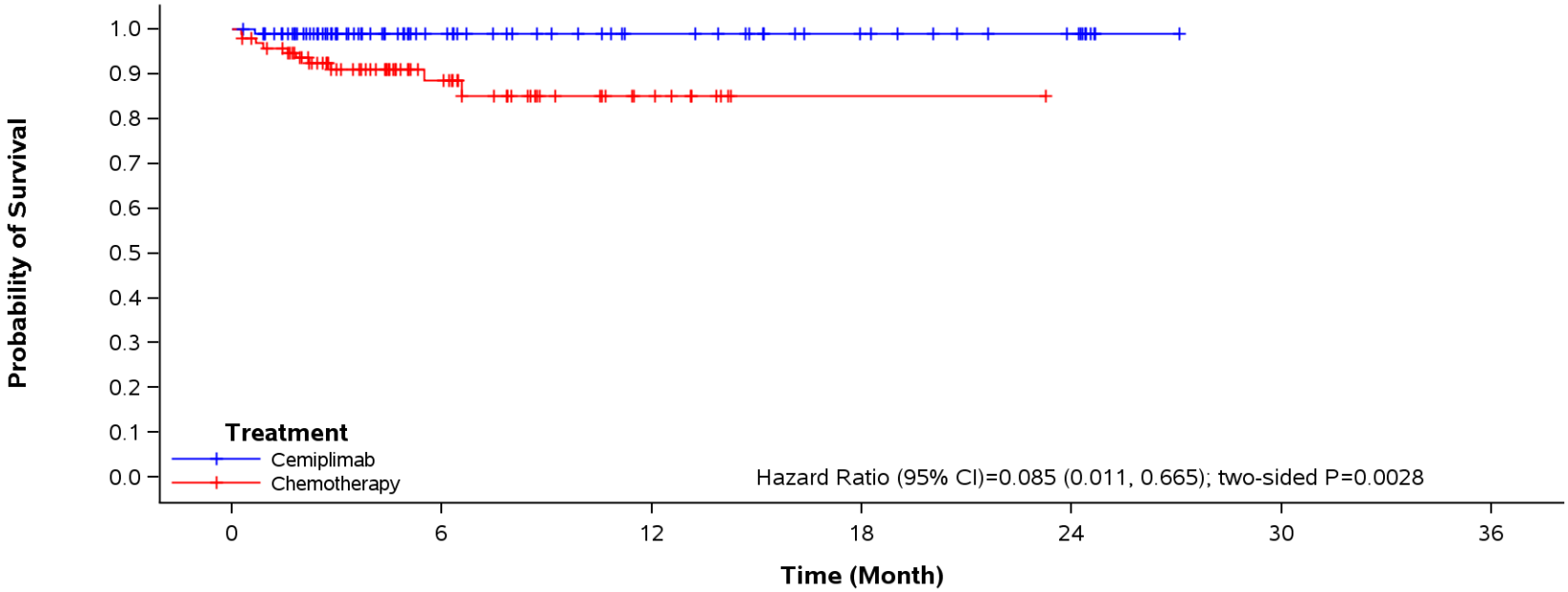

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 38 | 25 | 16 | 10 | 0 | 0 |
| Chemotherapy | 96 | 24 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 28 | 19 | 13 | 0 | 0 |
| Chemotherapy | 96 | 35 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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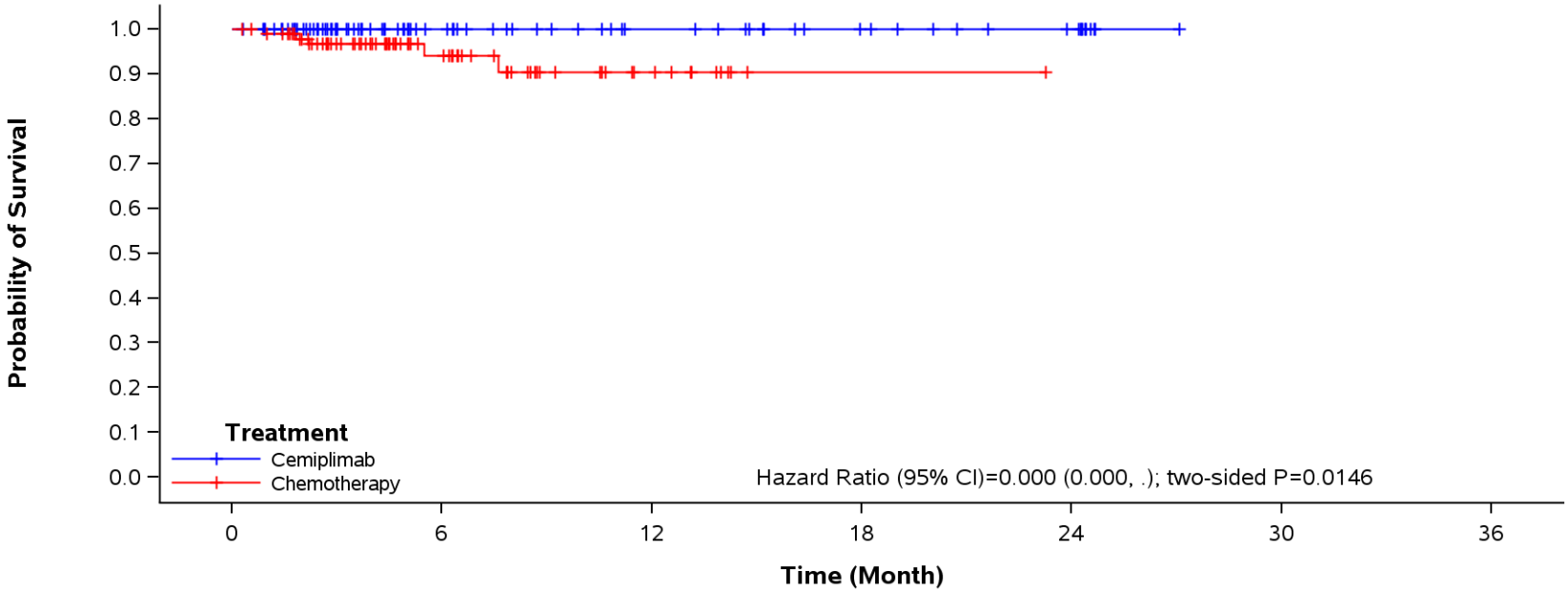
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Anaemia



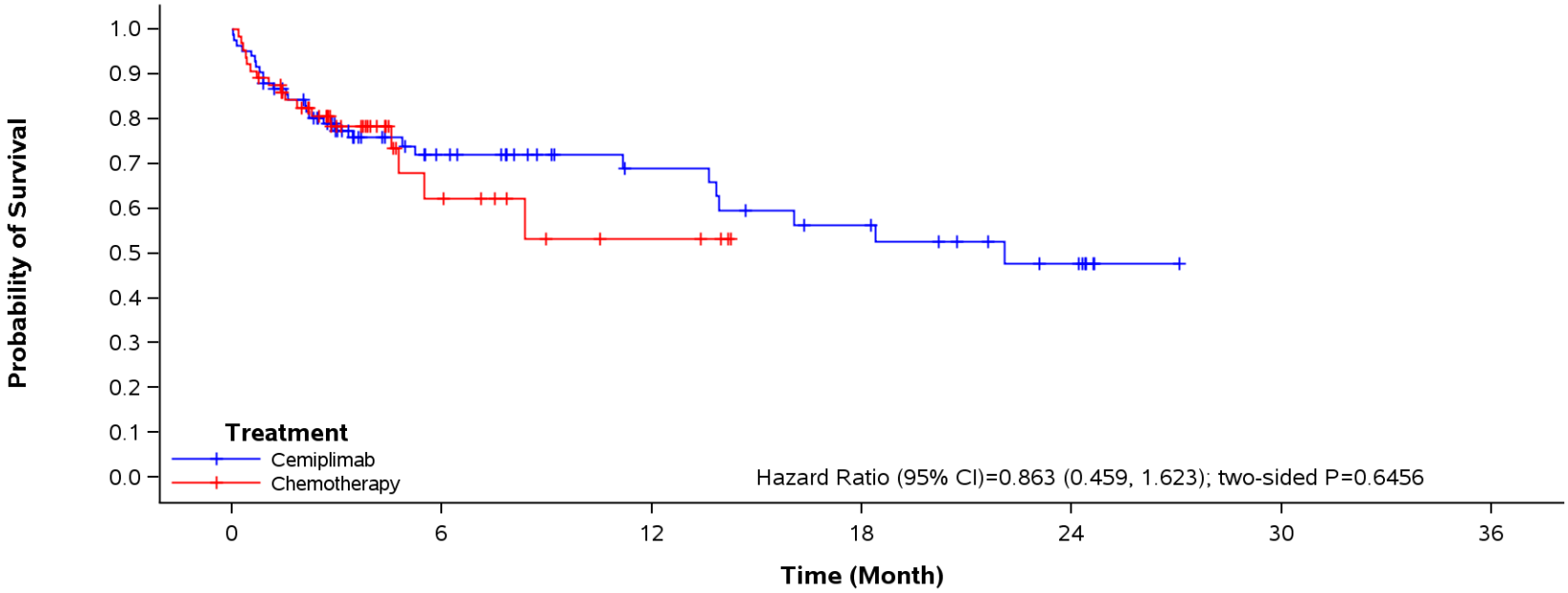

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 37 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

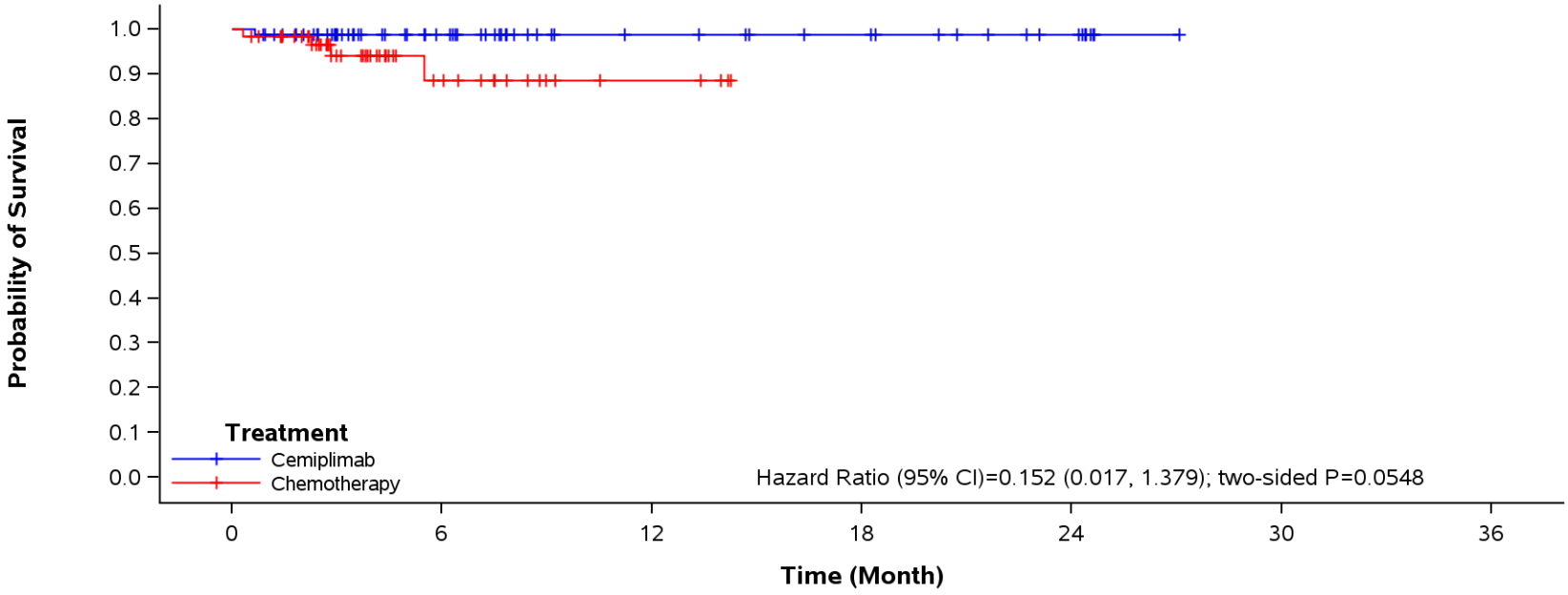
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 34 | 22 | 16 | 9 | 0 | 0 |
| Chemotherapy | 64 | 11 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders



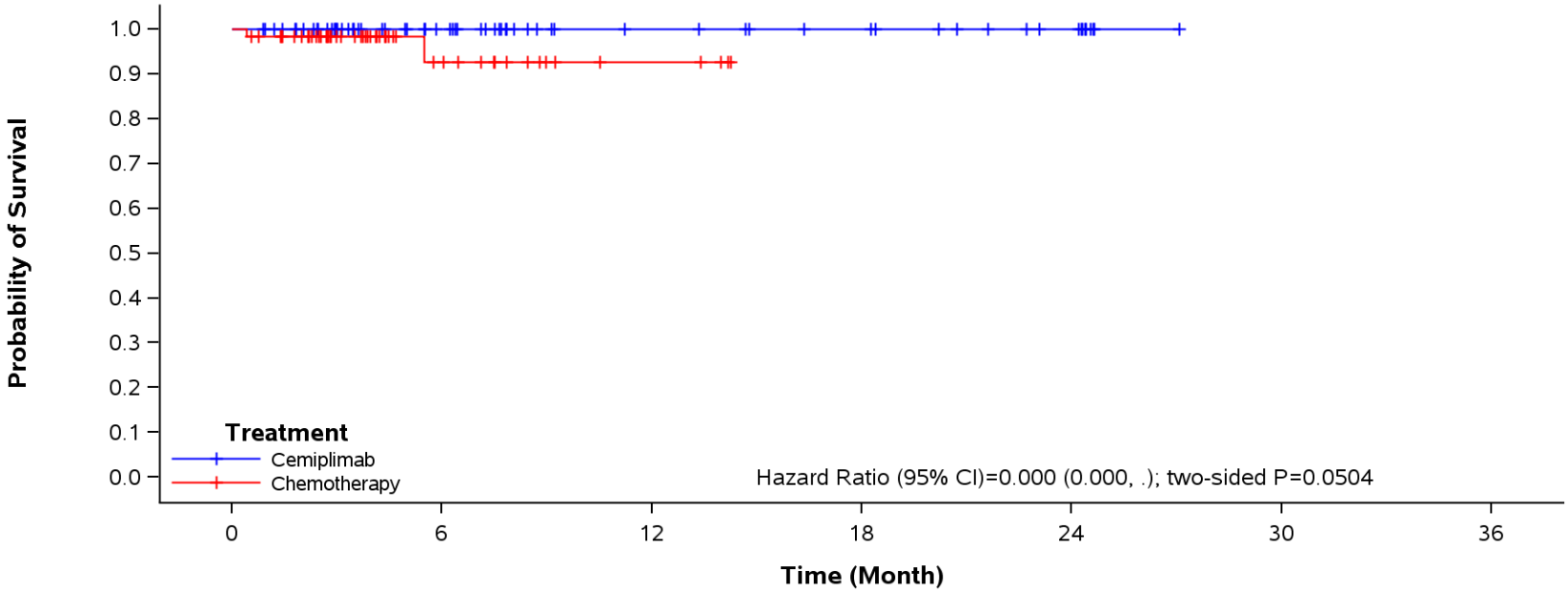

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 43 | 25 | 21 | 14 | 0 | 0 |
| Chemotherapy | 64 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Anaemia



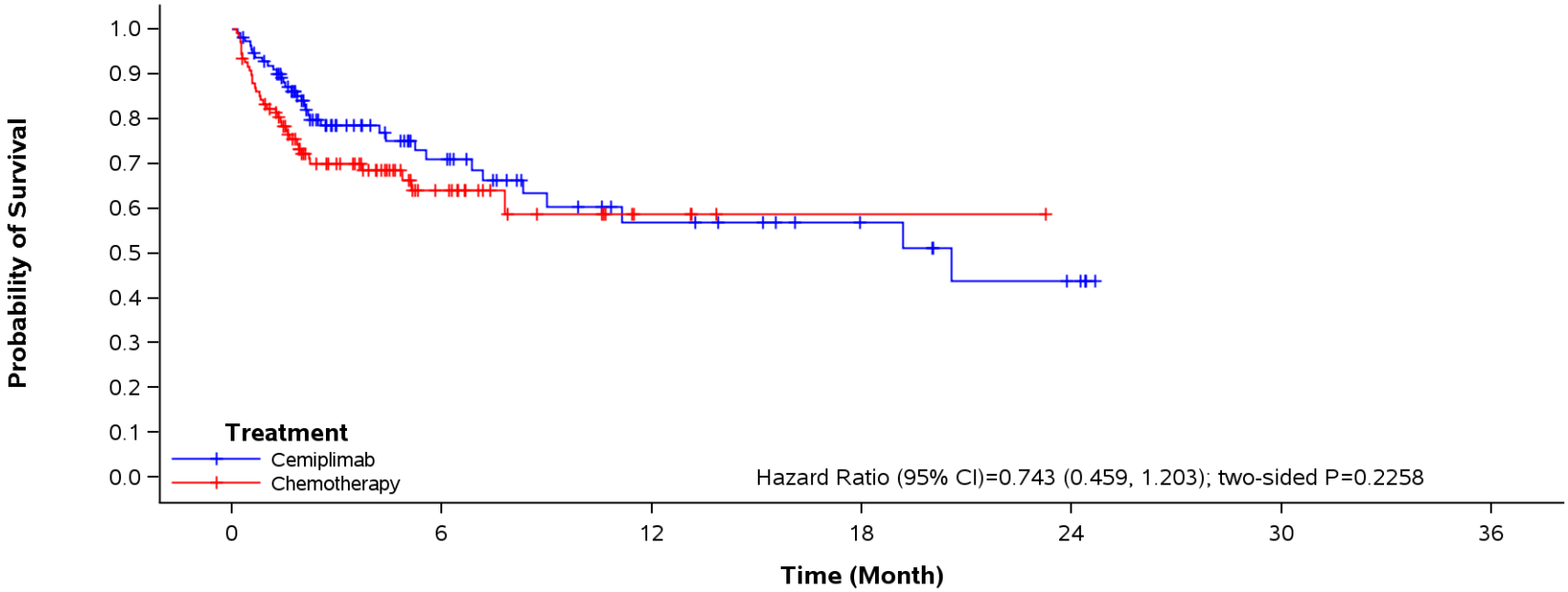

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

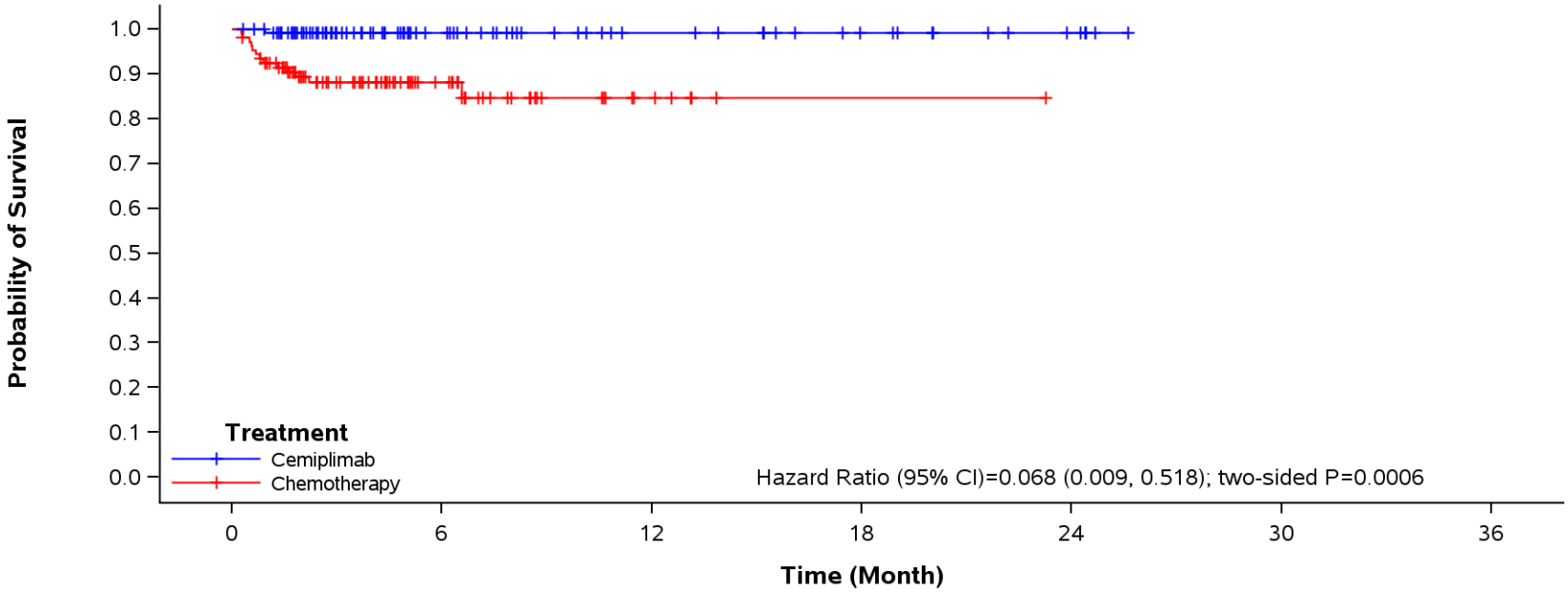
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 34 | 16 | 10 | 5 | 0 | 0 |
| Chemotherapy | 108 | 24 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders



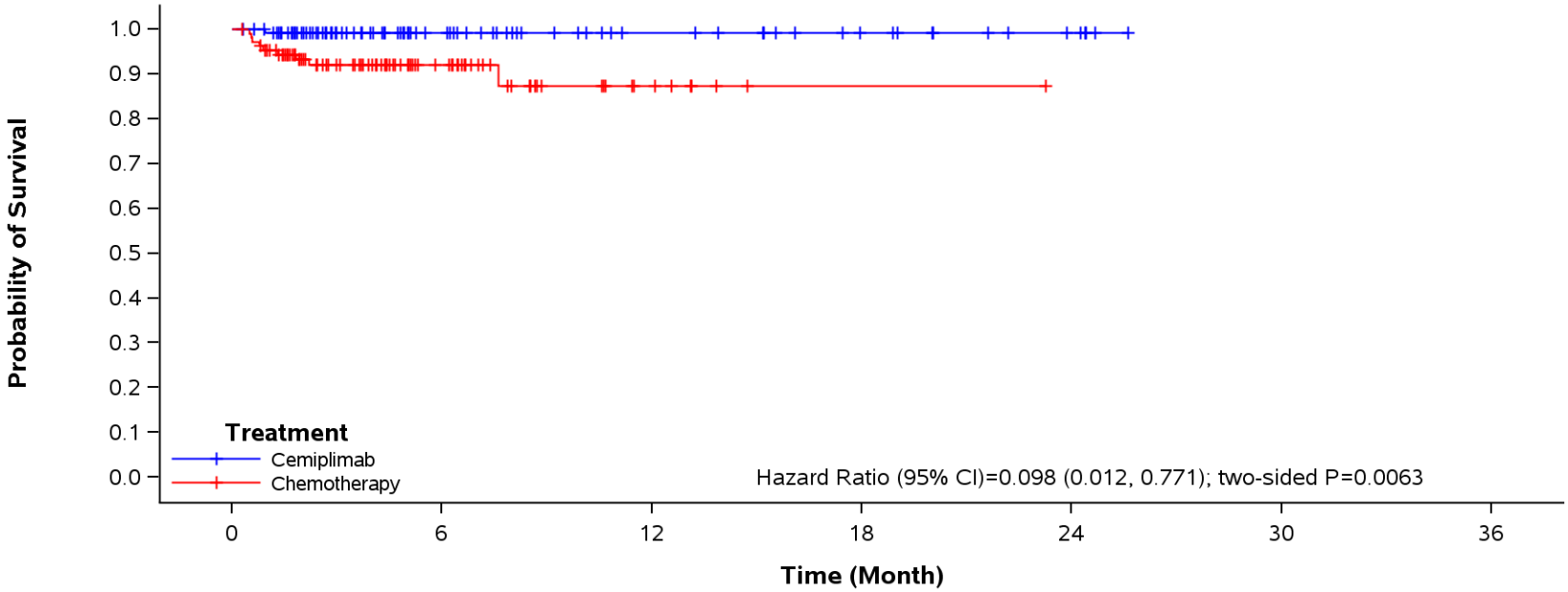

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

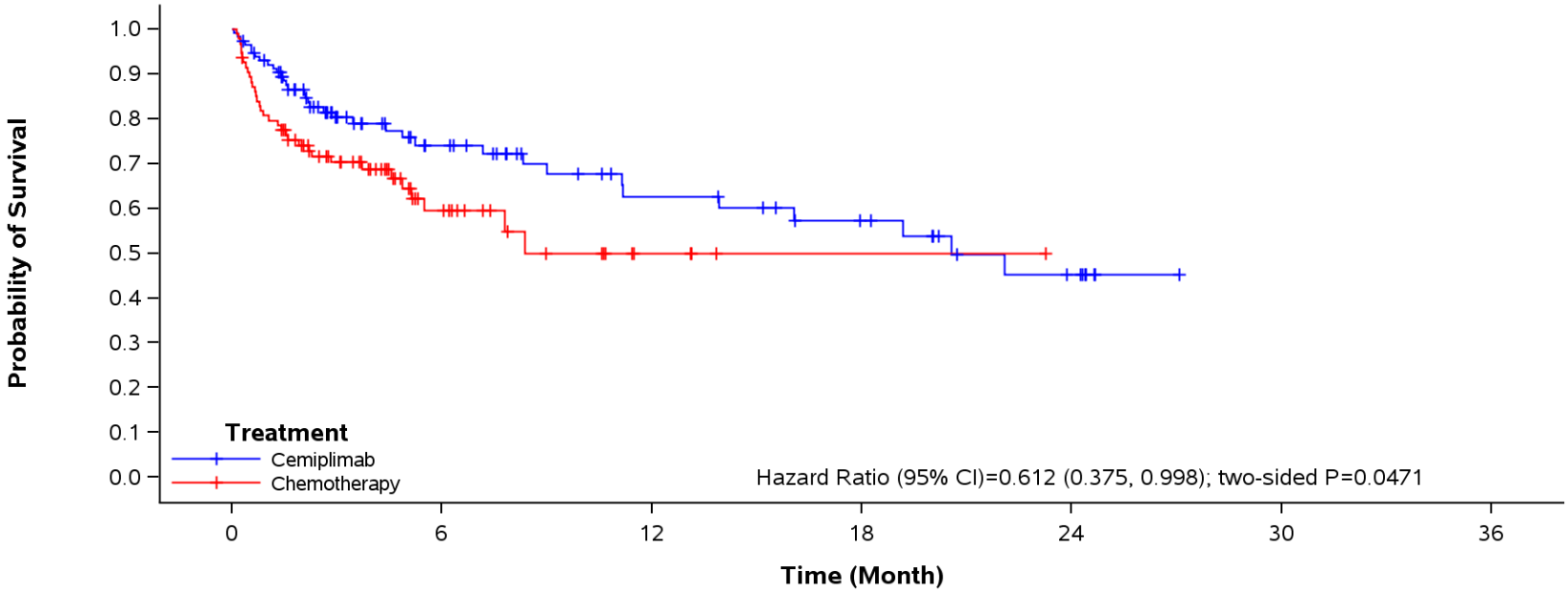
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 42 | 25 | 18 | 9 | 0 | 0 |
| Chemotherapy | 94 | 22 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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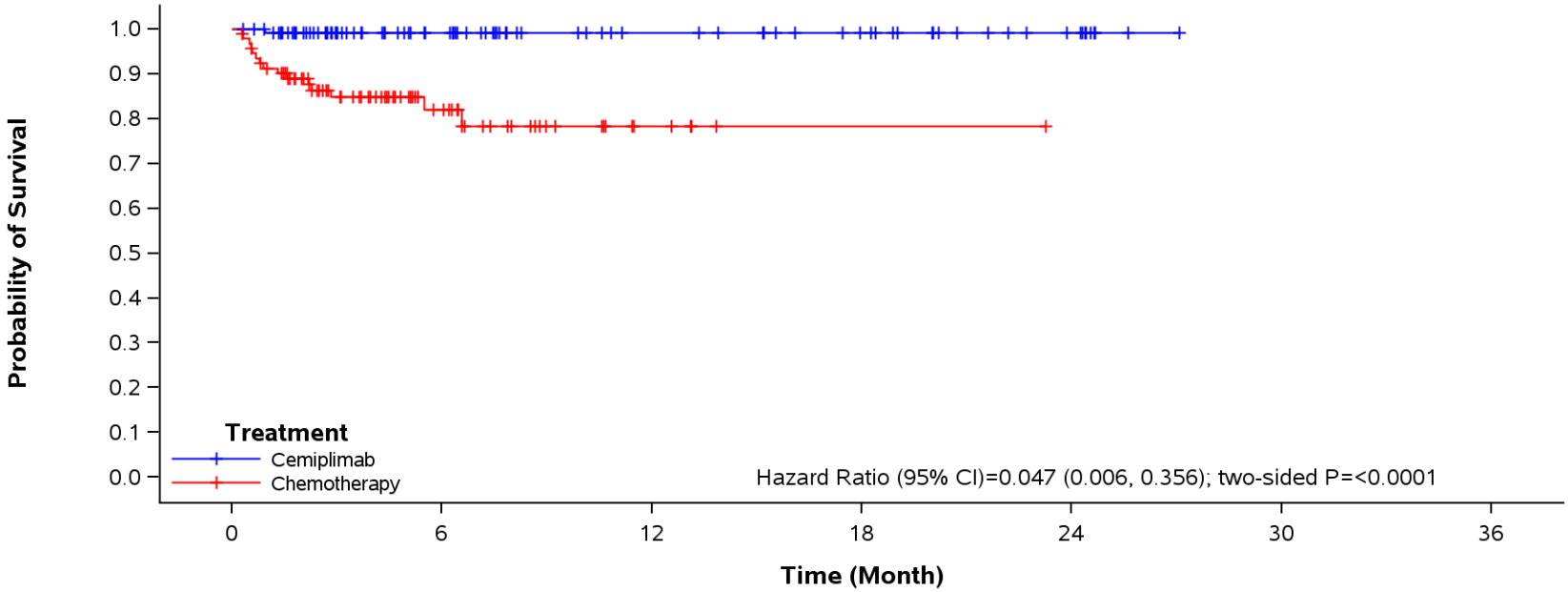
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 29 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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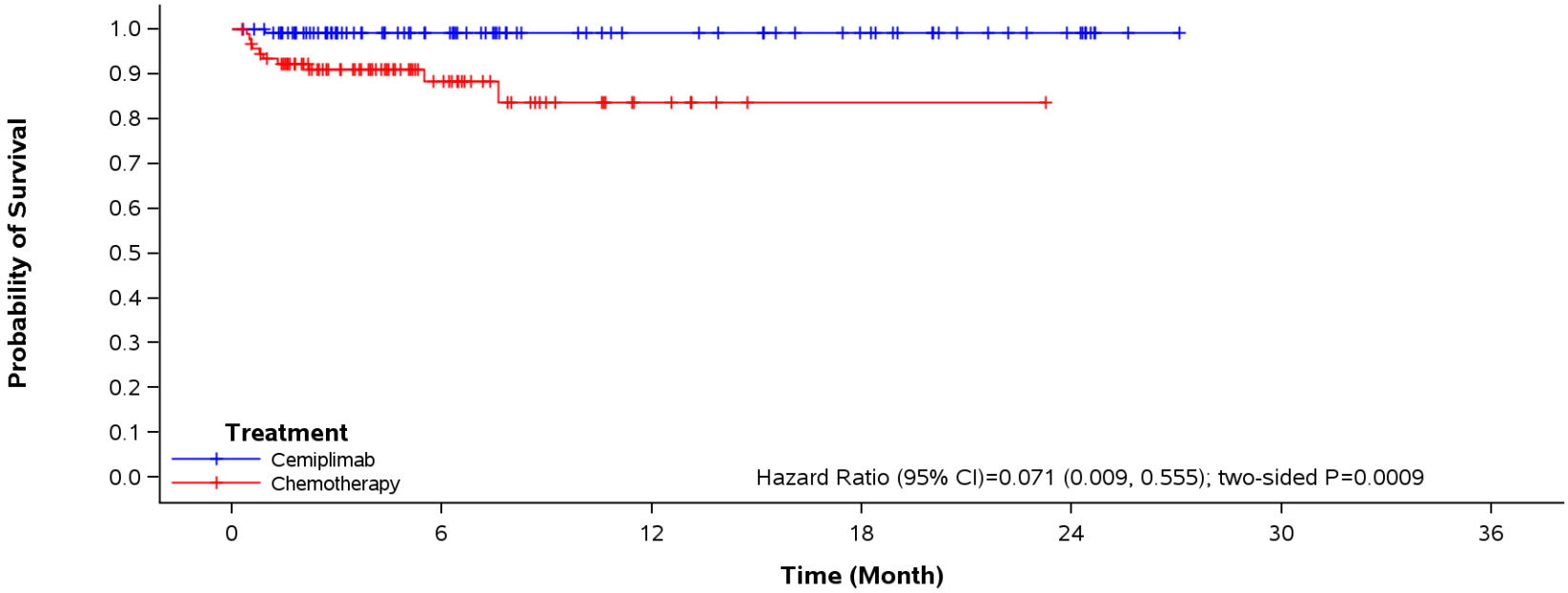
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

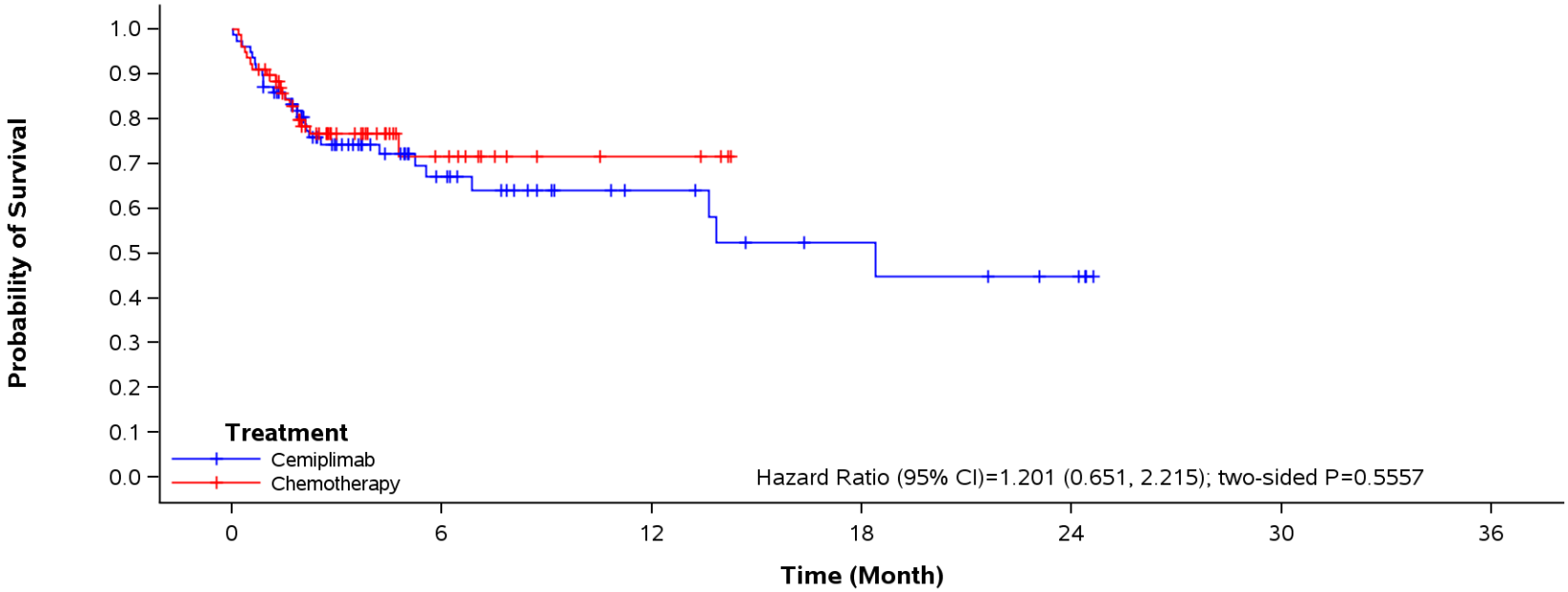
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 31 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 25 | 12 | 7 | 4 | 0 | 0 |
| Chemotherapy | 78 | 13 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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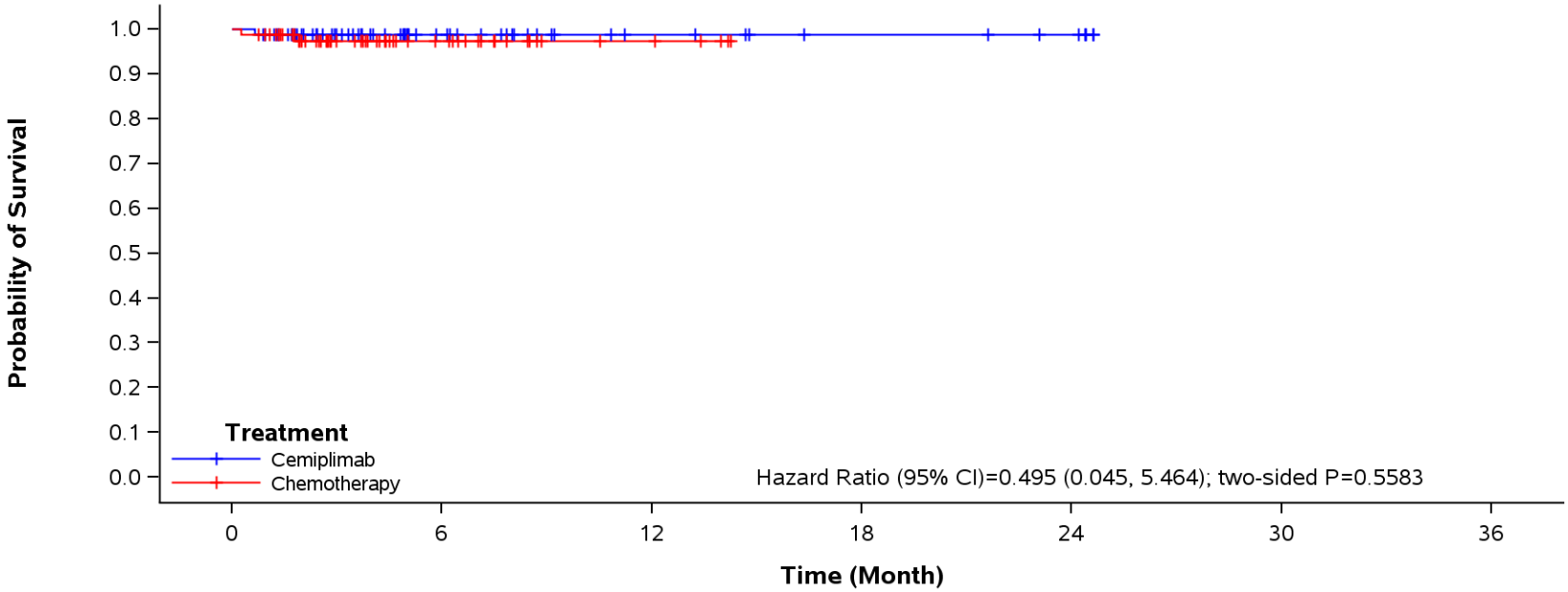
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 30 | 14 | 10 | 8 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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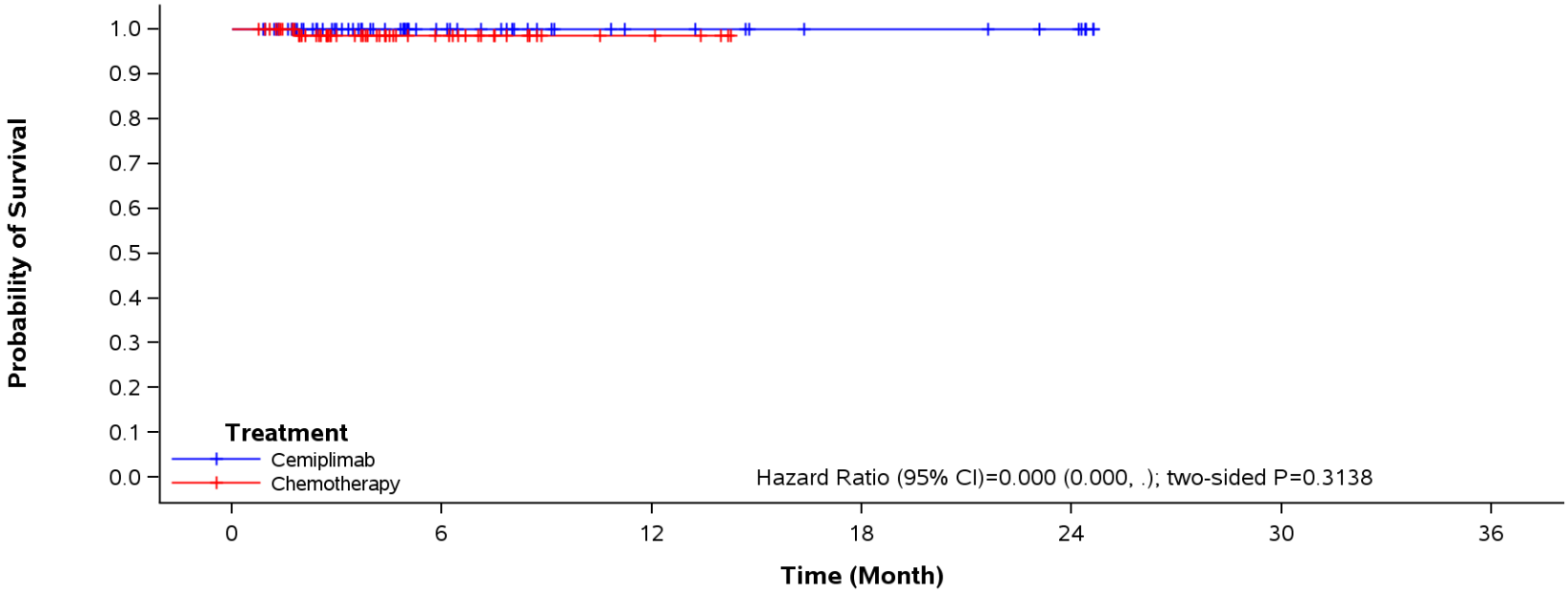
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

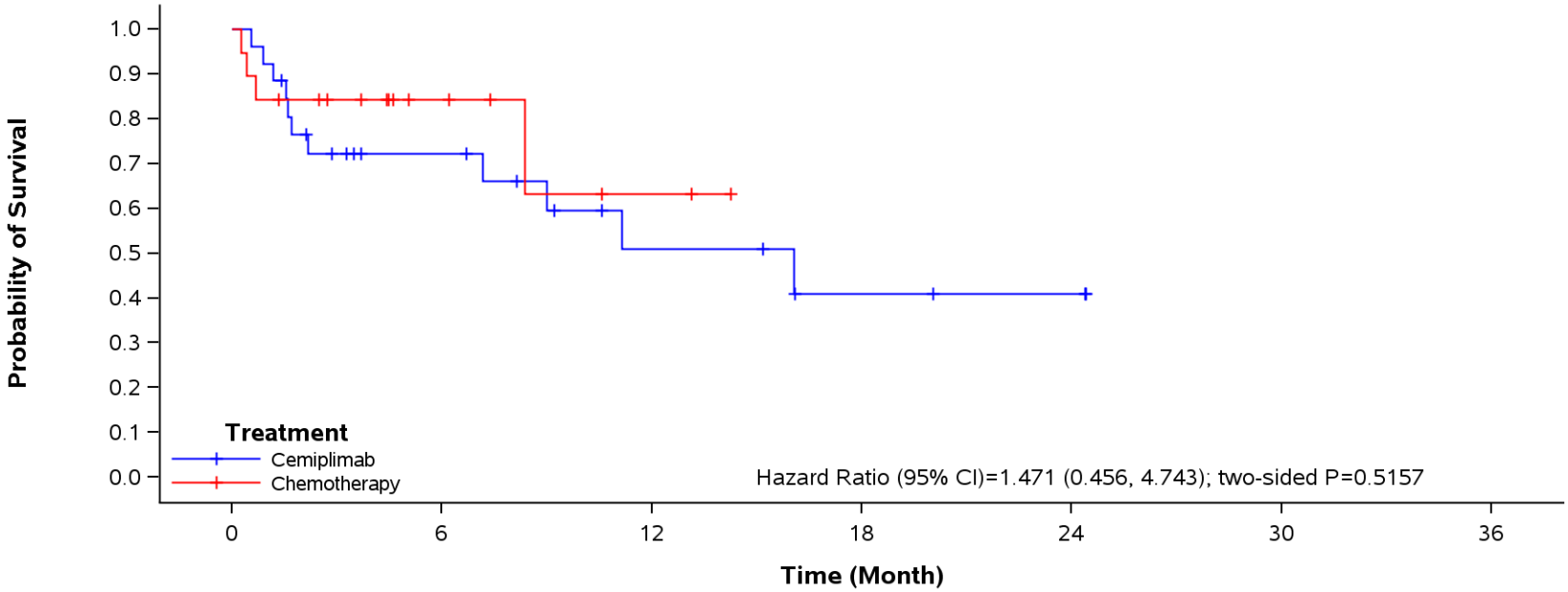
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 13 | 6 | 3 | 2 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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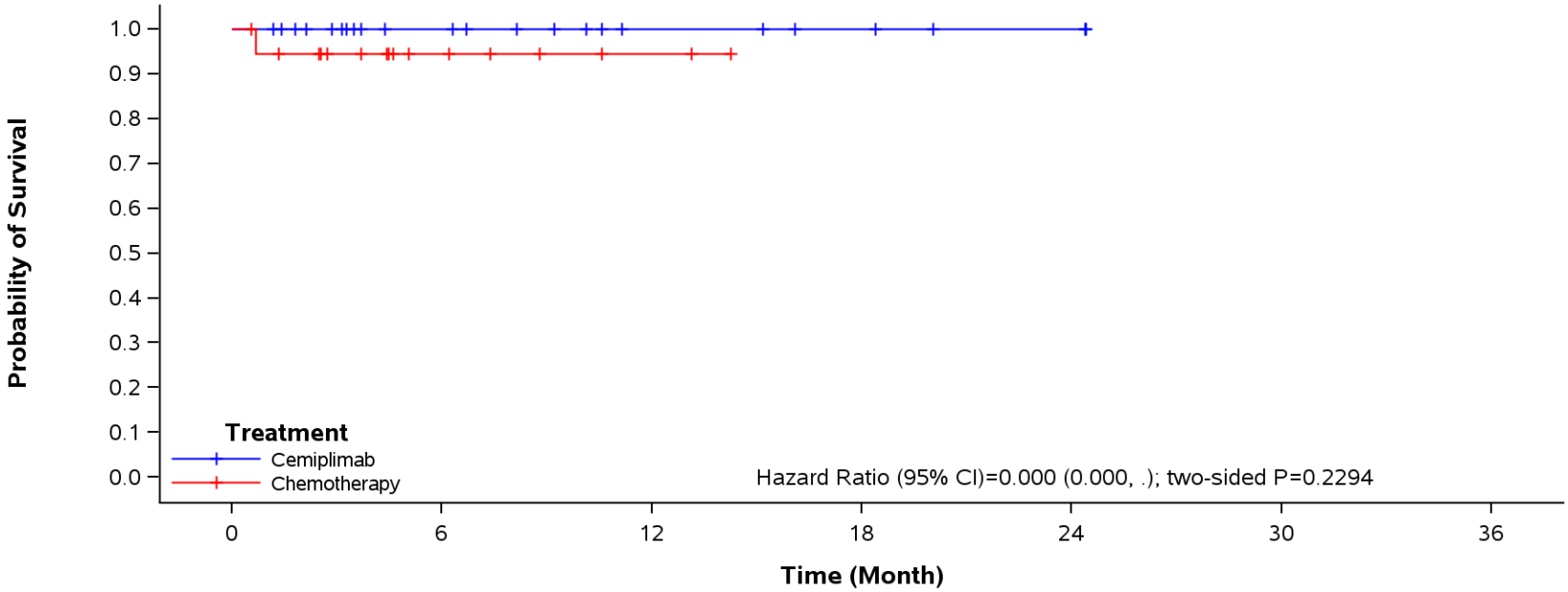
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders



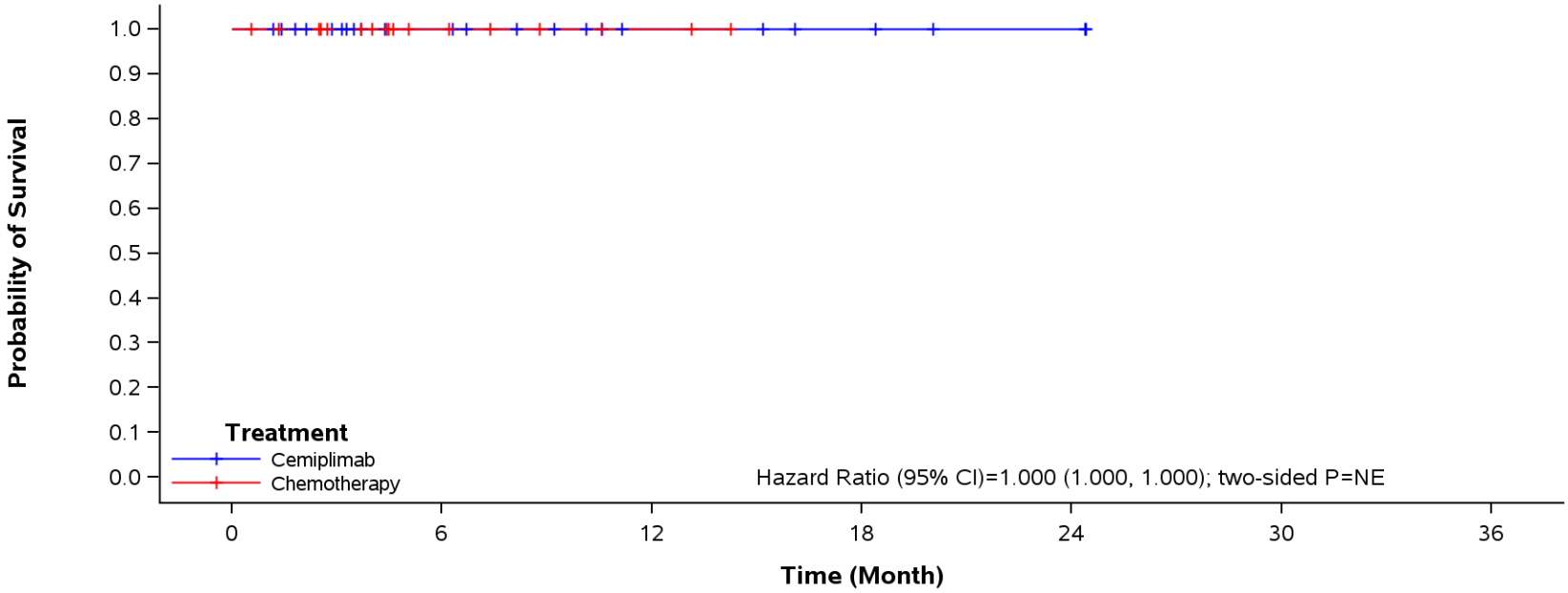

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

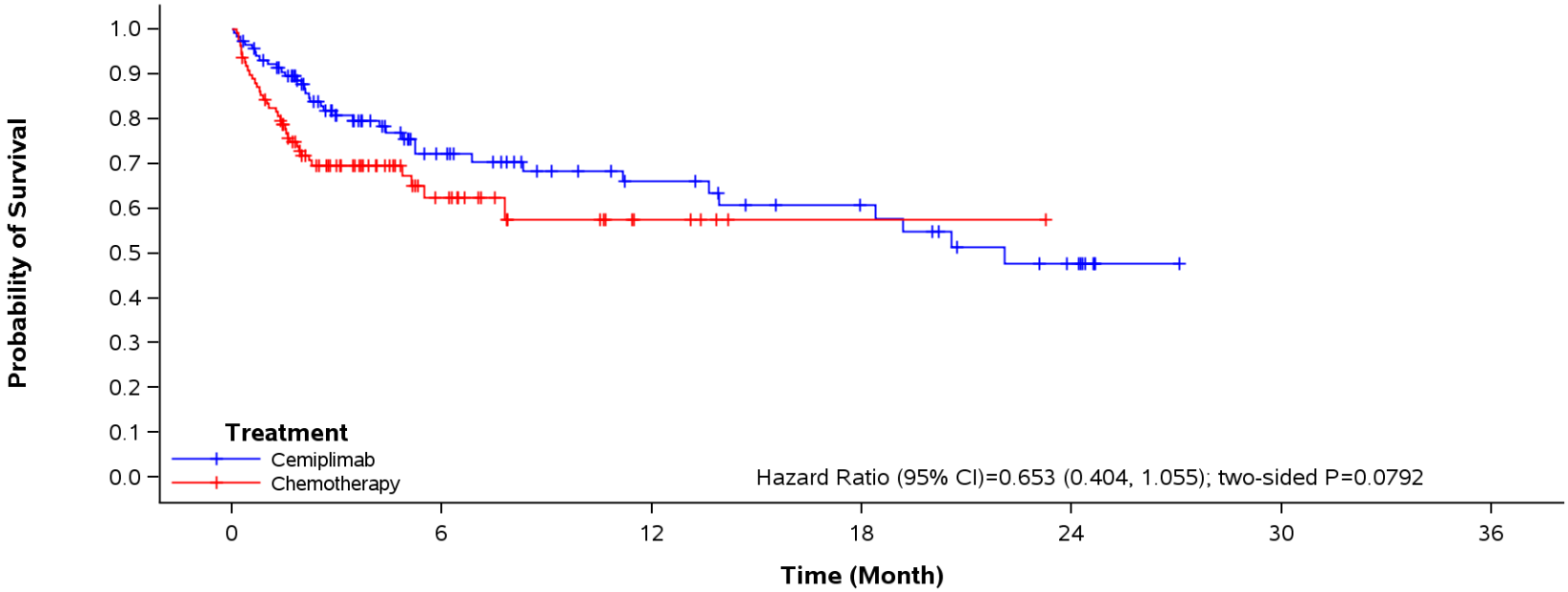
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

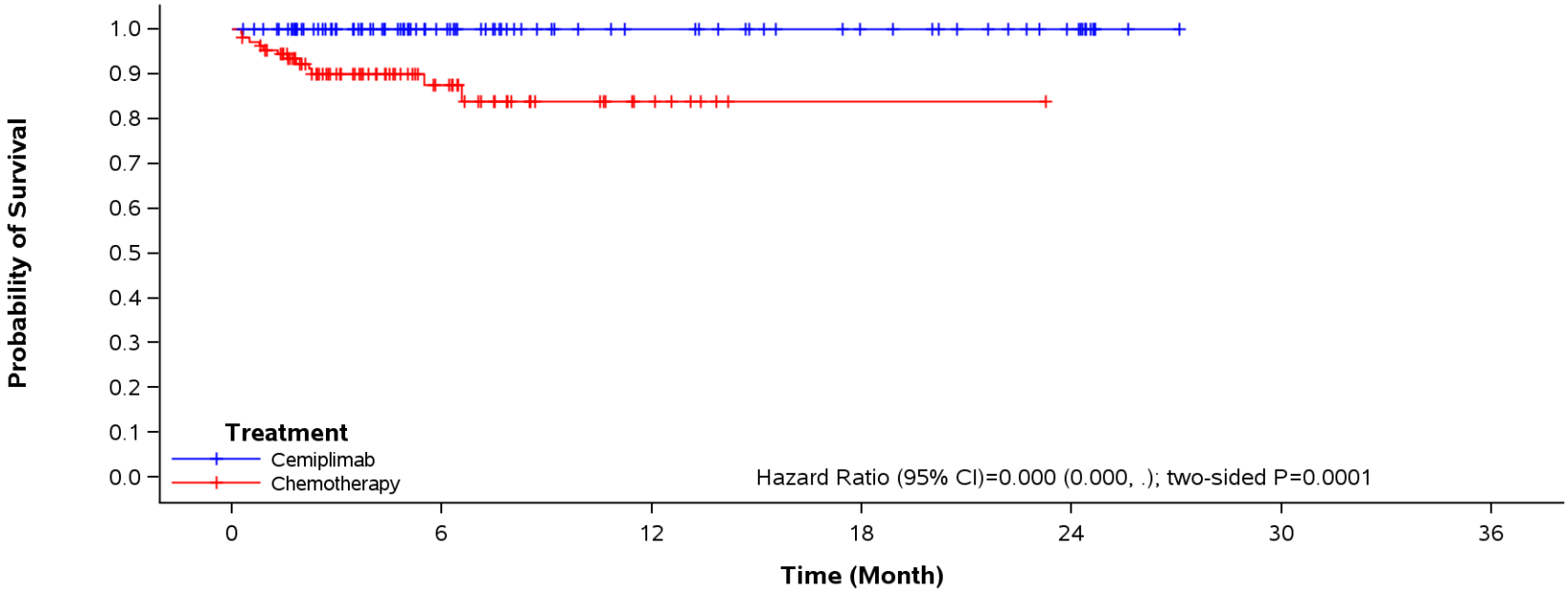
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 44 | 27 | 20 | 11 | 0 | 0 |
| Chemotherapy | 109 | 23 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders



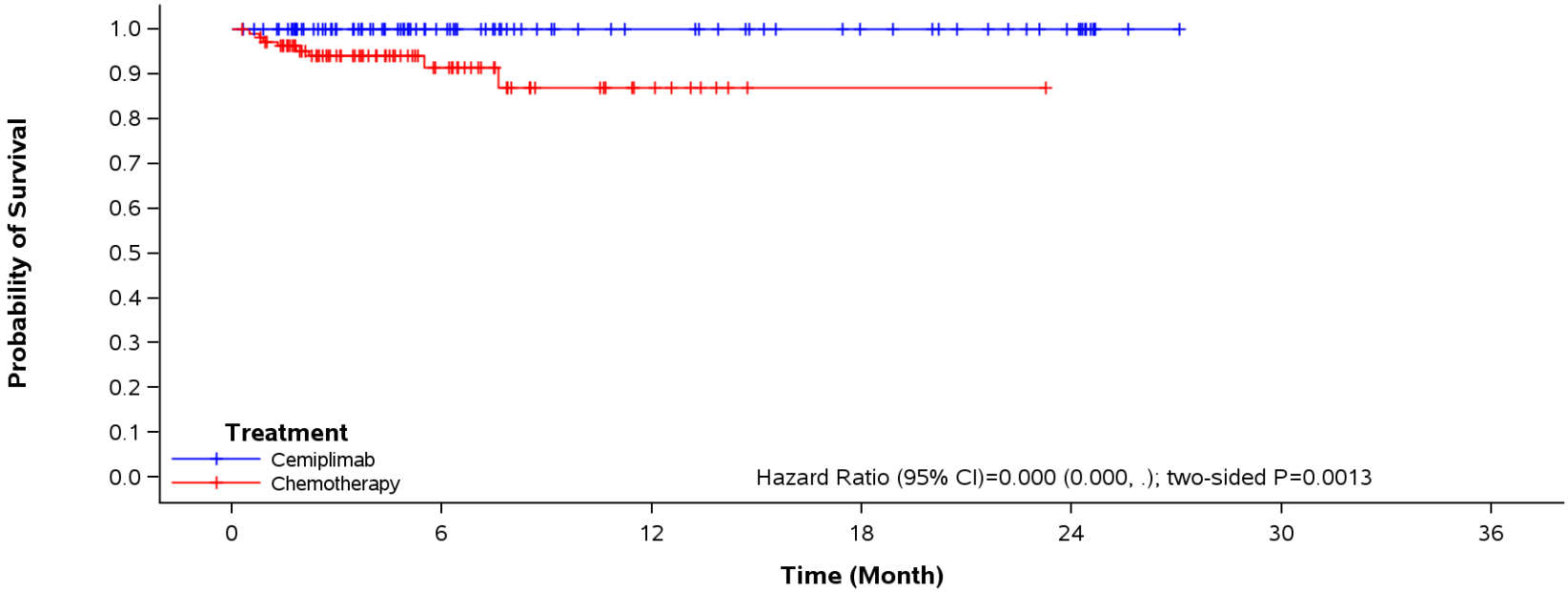

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 32 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Anaemia



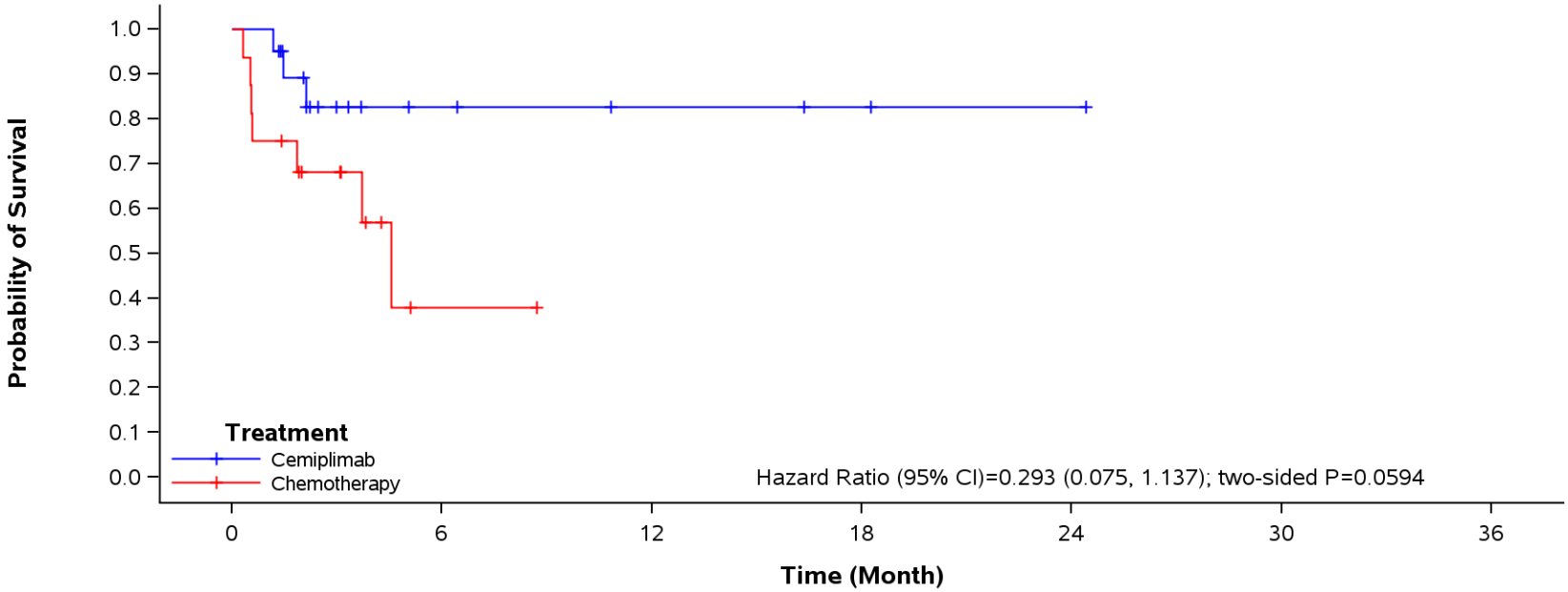

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 34 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Number of patients with any treatment-emergent SAE



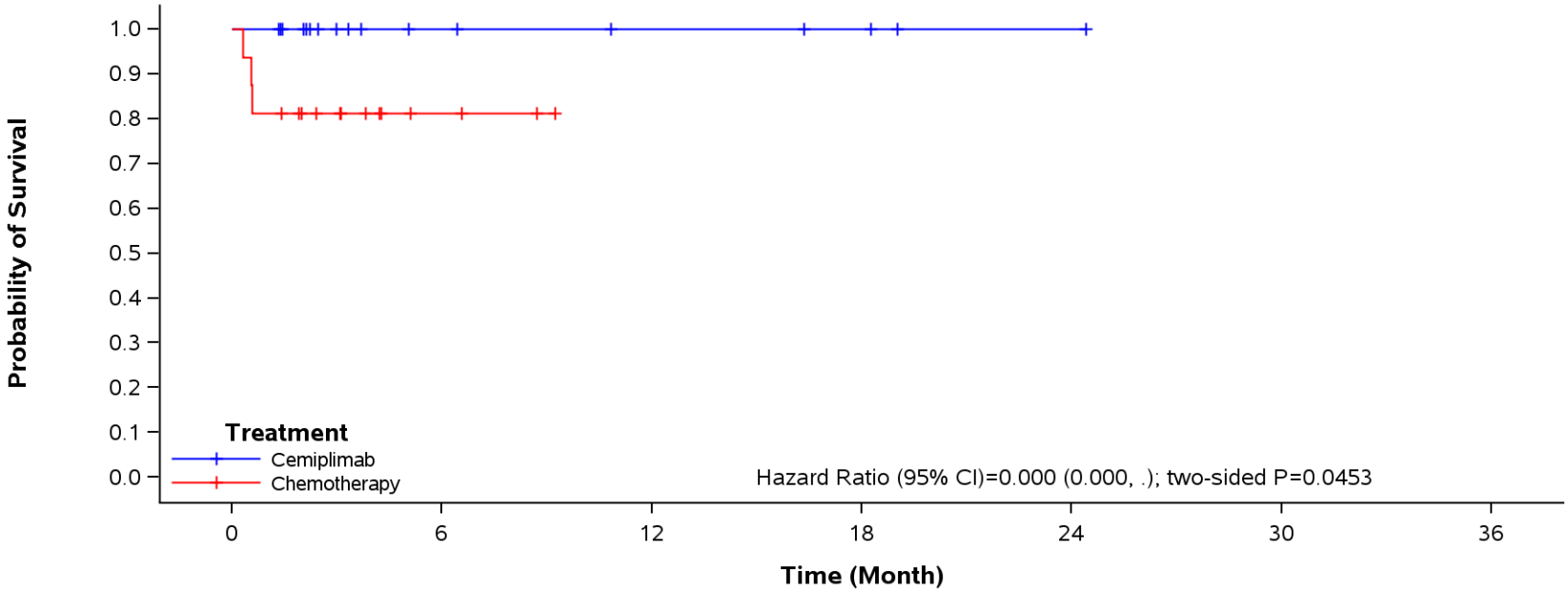

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 2 | 1 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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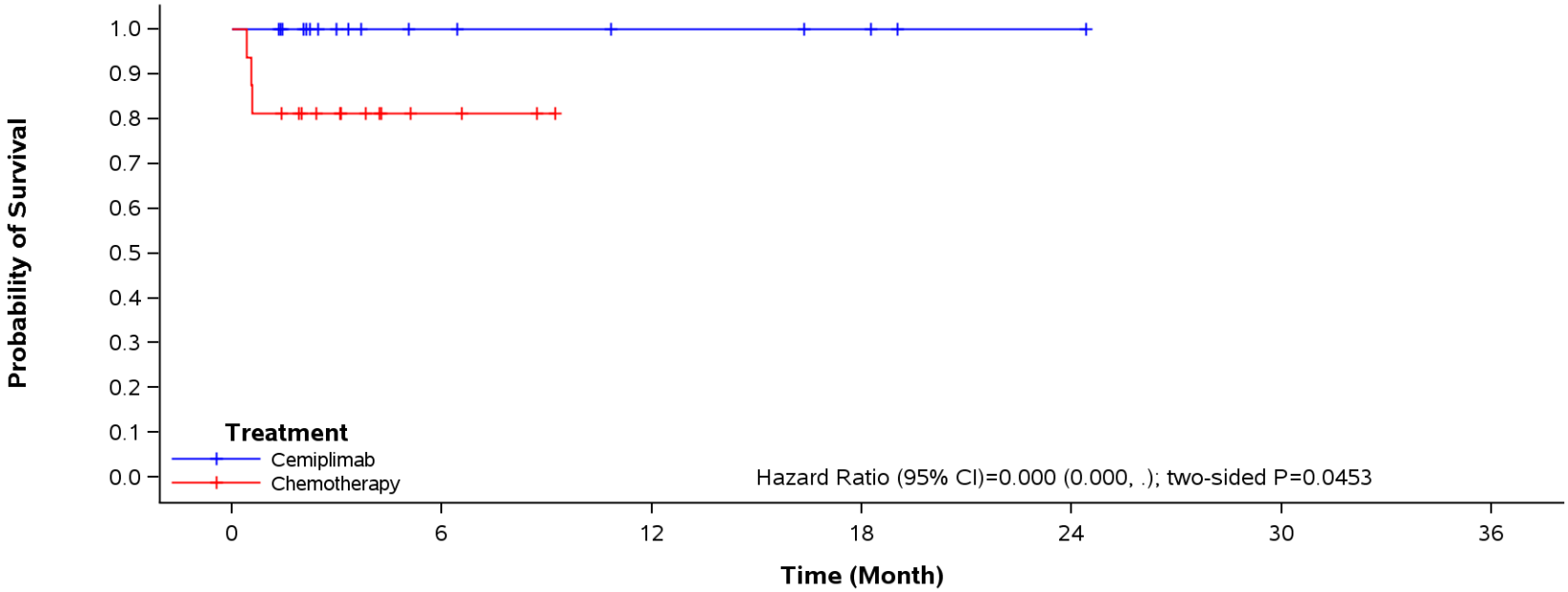
Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

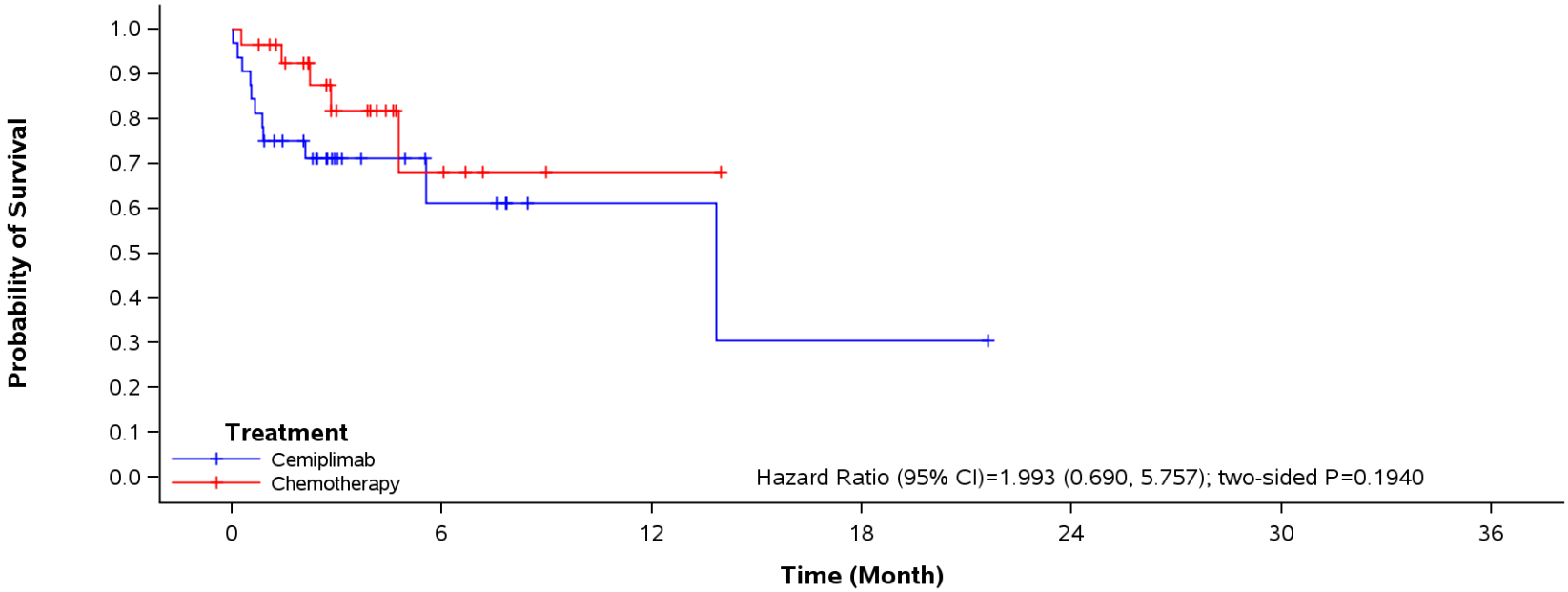
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Number of patients with any treatment-emergent SAE




**Number of Subjects at risk**

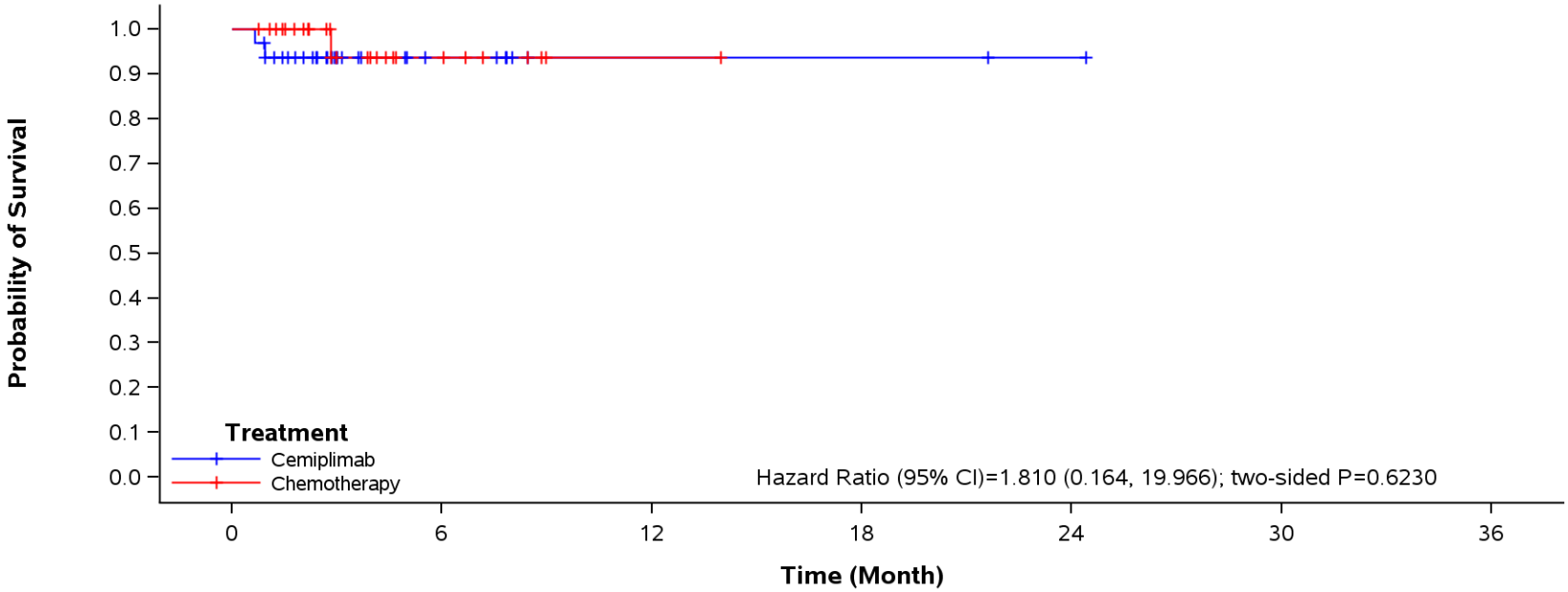
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 6 | 2 | 1 | 0 | 0 | 0 |
| Chemotherapy | 28 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders




Number of Subjects at risk

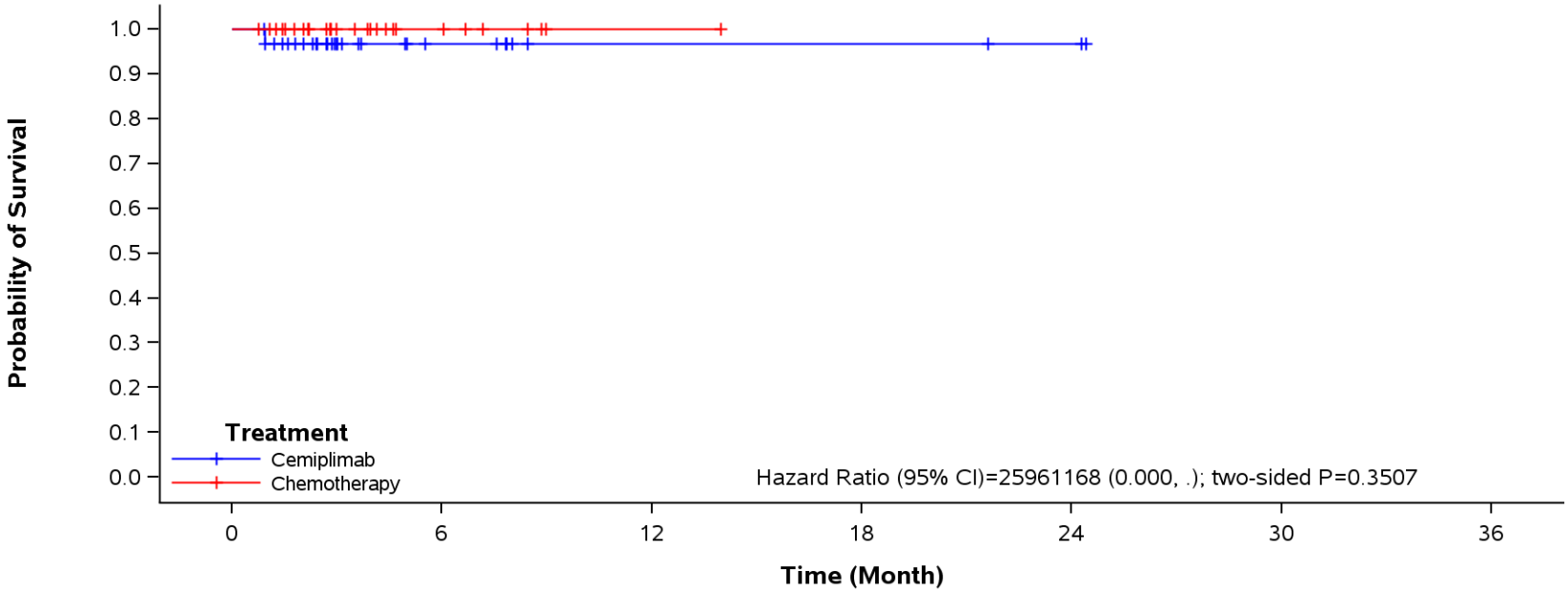
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 7 | 2 | 2 | 1 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:04:49:24, haijin.tang)

Figure 4.2.2. Time to First Any treatment-emergent SAE by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Anaemia



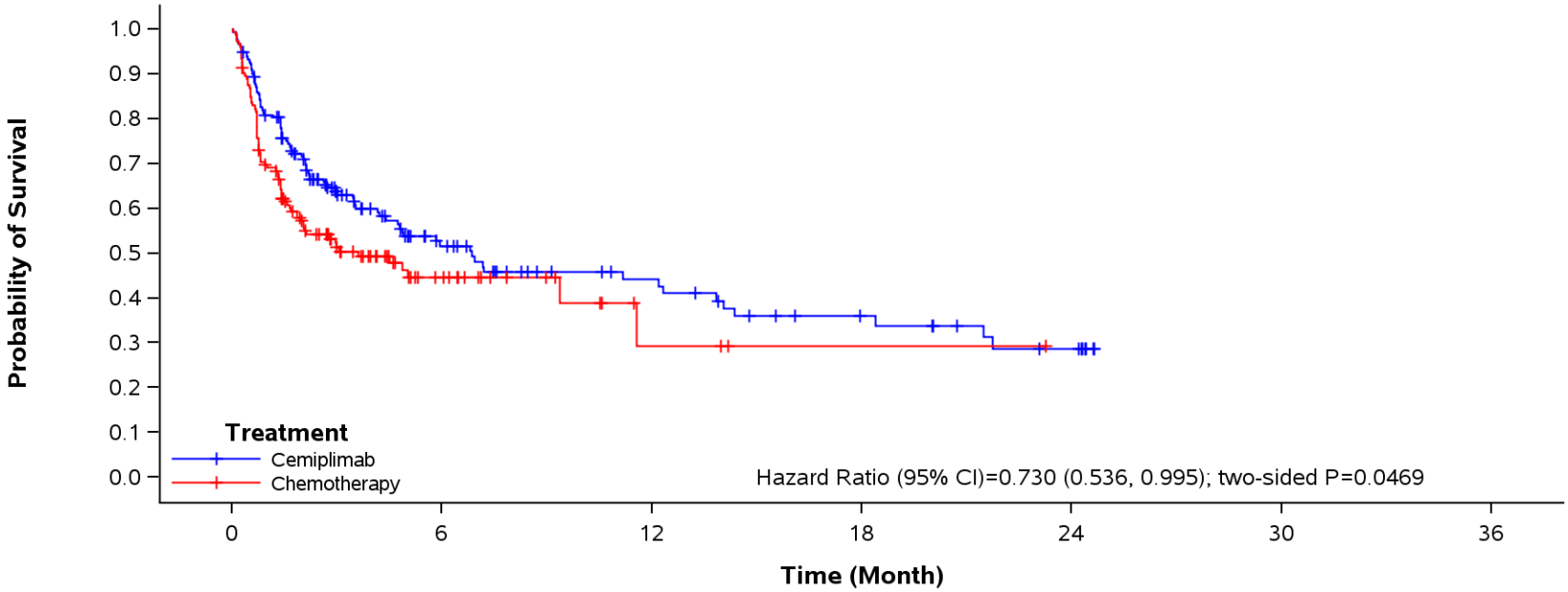

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Number of patients with any TEAE CTCAE Grade >= 3



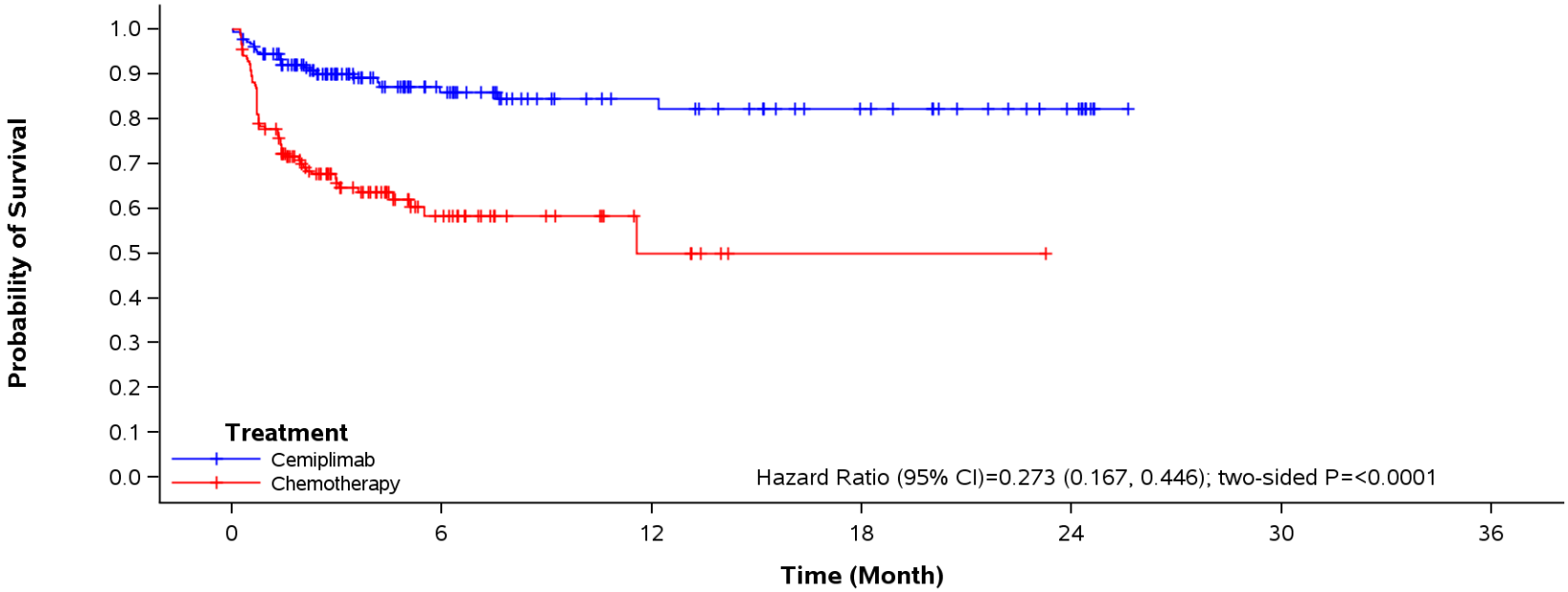

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 49 | 28 | 17 | 10 | 0 | 0 |
| Chemotherapy | 153 | 22 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders



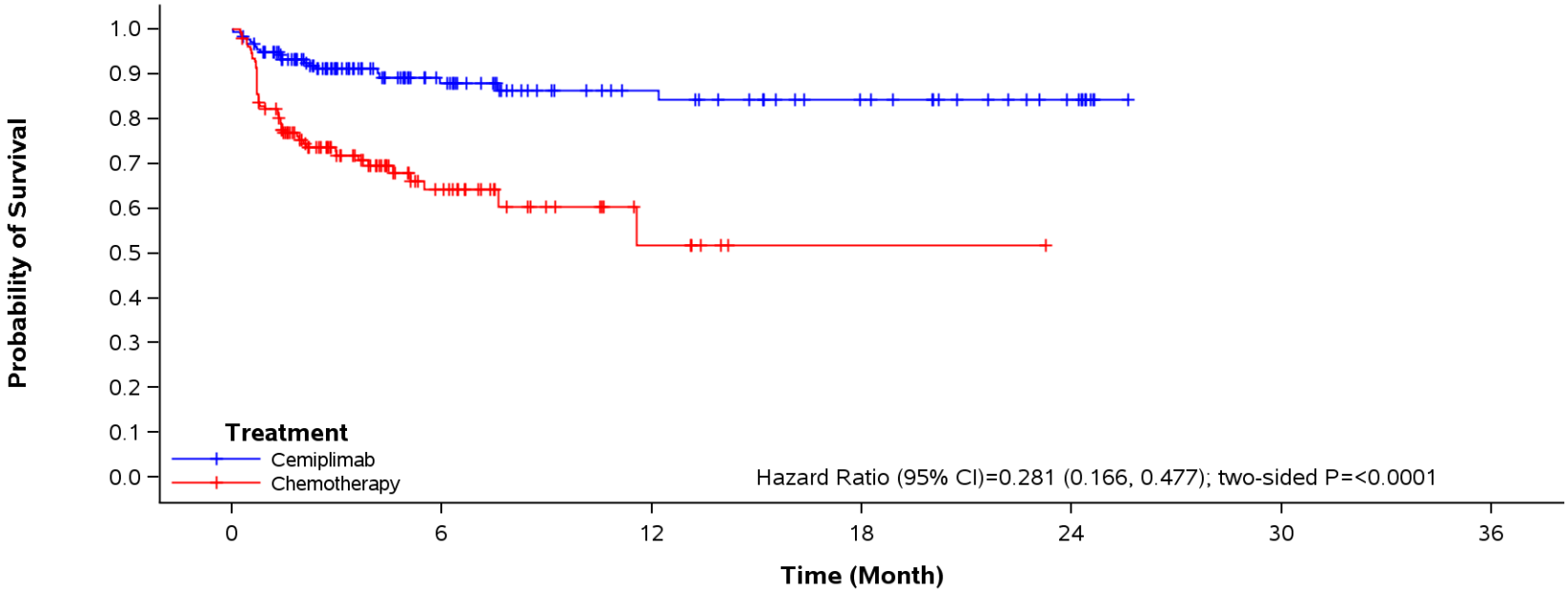

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 70 | 40 | 29 | 17 | 0 | 0 |
| Chemotherapy | 153 | 29 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Anaemia



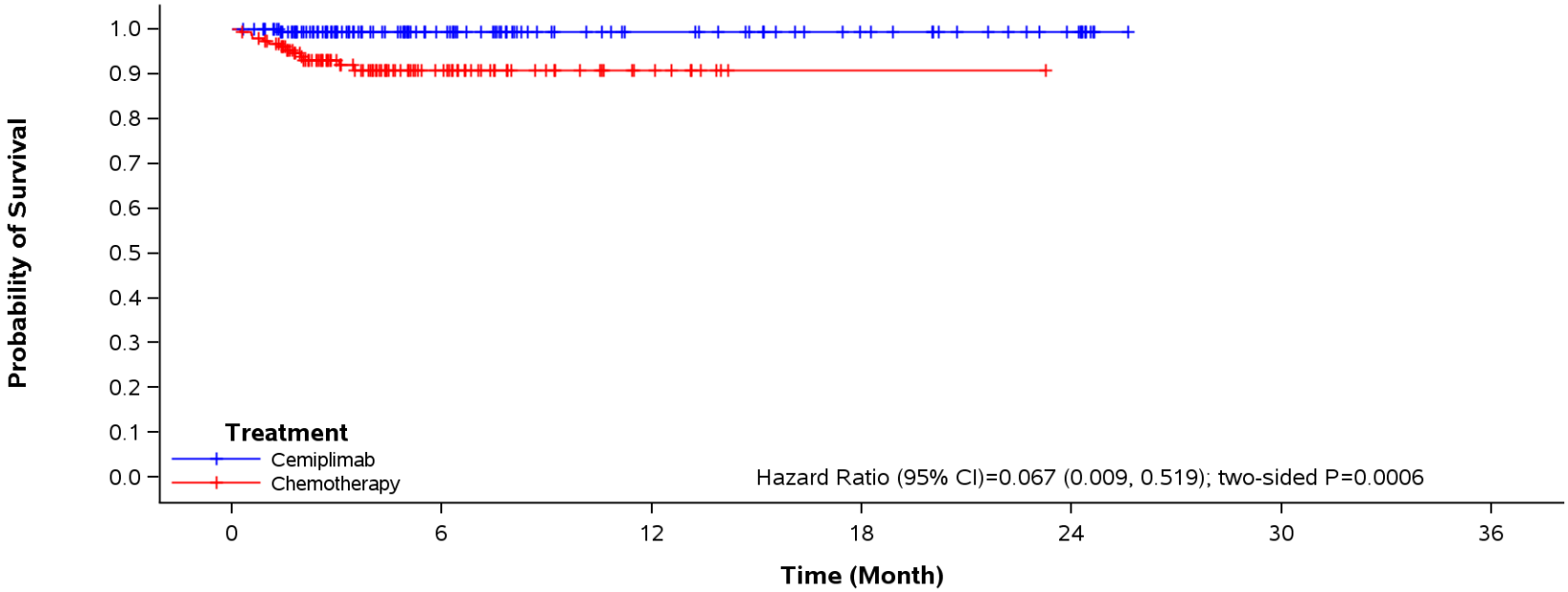

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 71 | 40 | 29 | 17 | 0 | 0 |
| Chemotherapy | 153 | 32 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



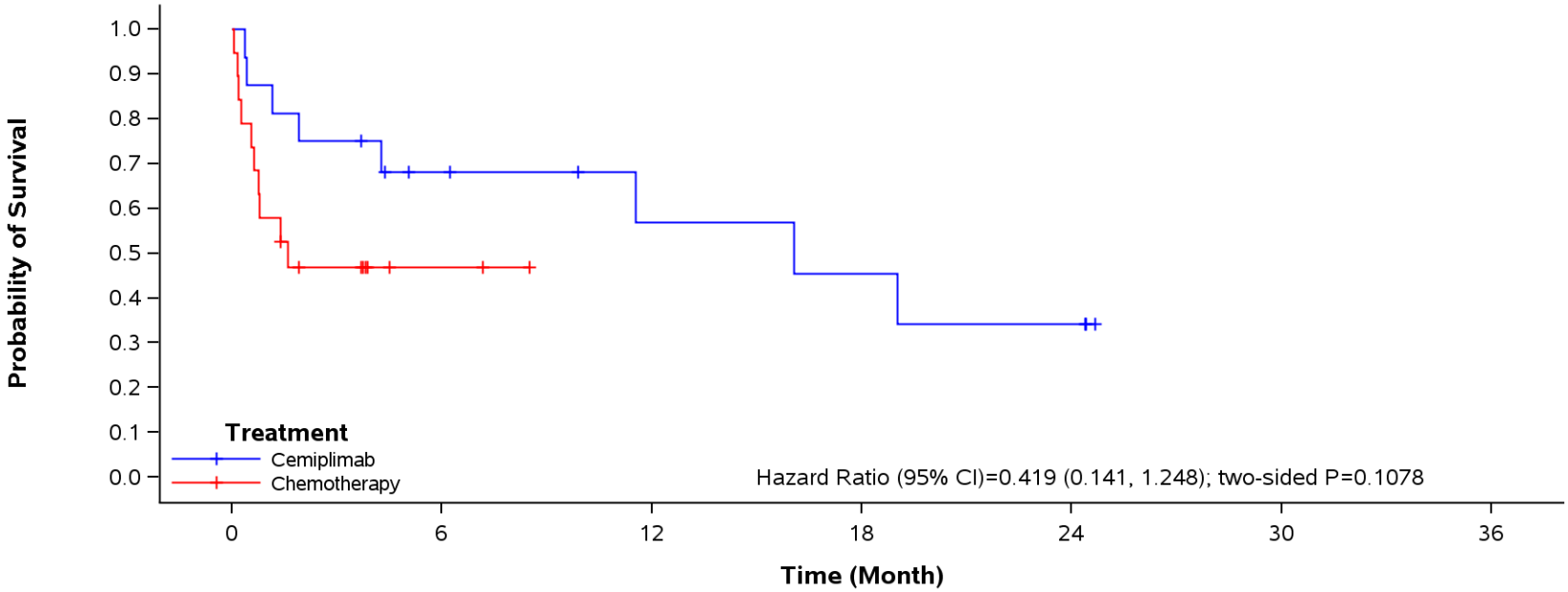

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 41 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
Number of patients with any TEAE CTCAE Grade >= 3



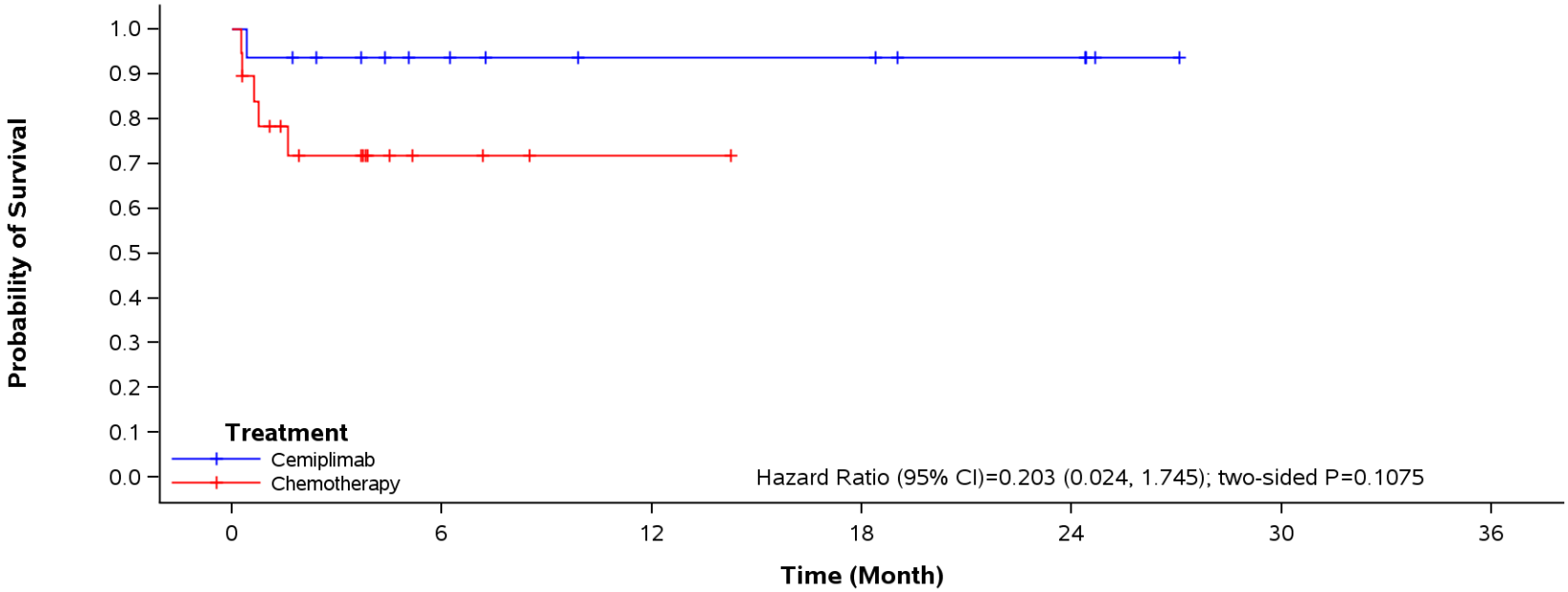

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 8 | 5 | 4 | 3 | 0 | 0 |
| Chemotherapy | 19 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders



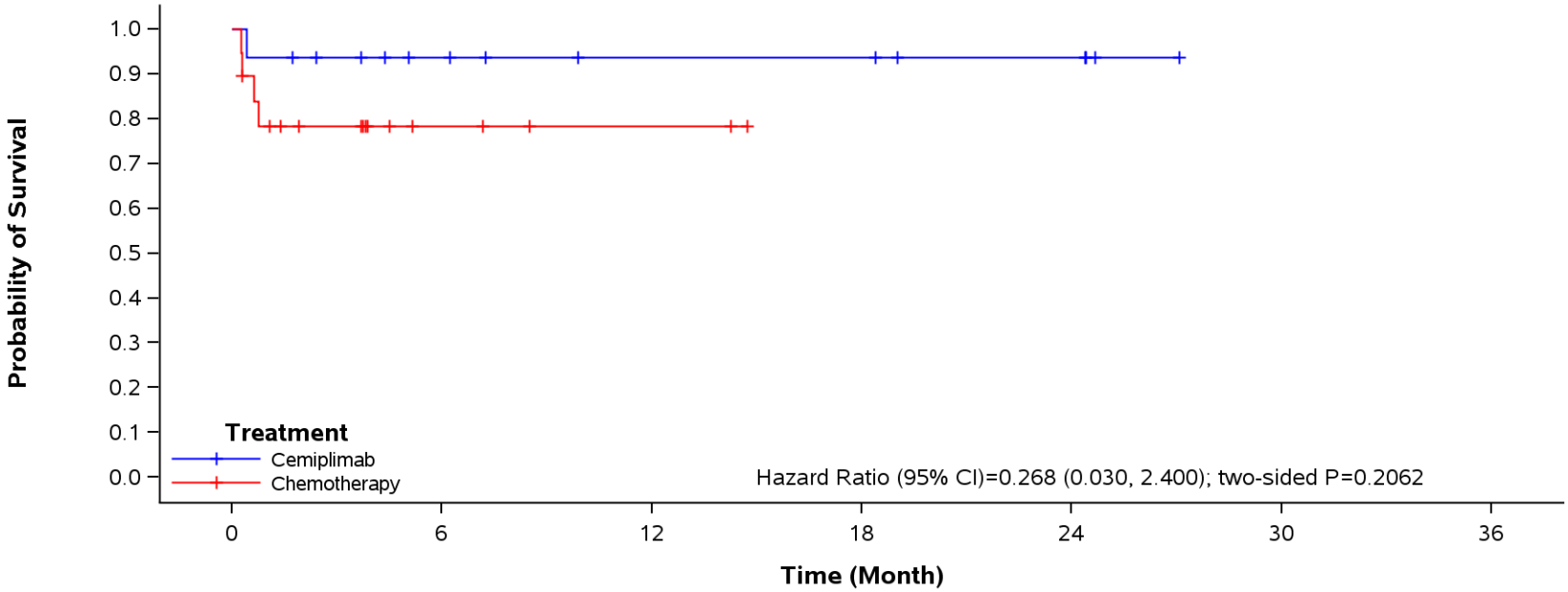

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 3 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Anaemia



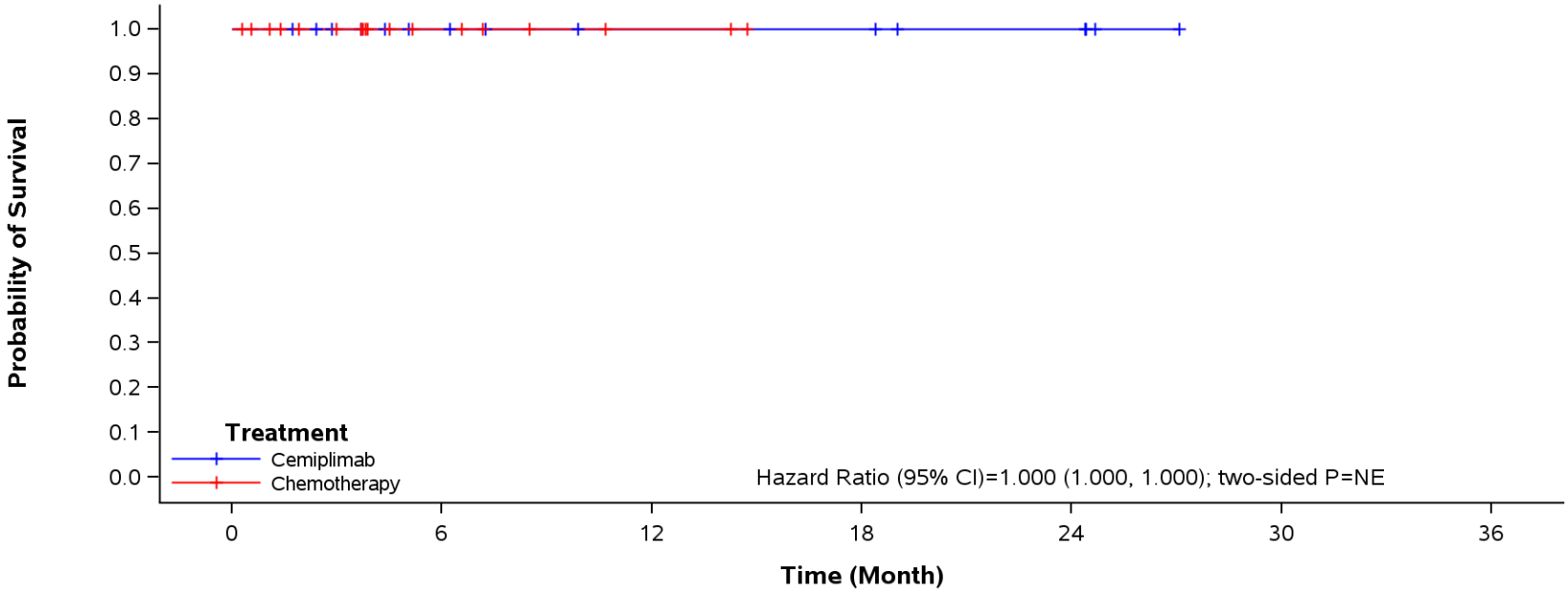

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



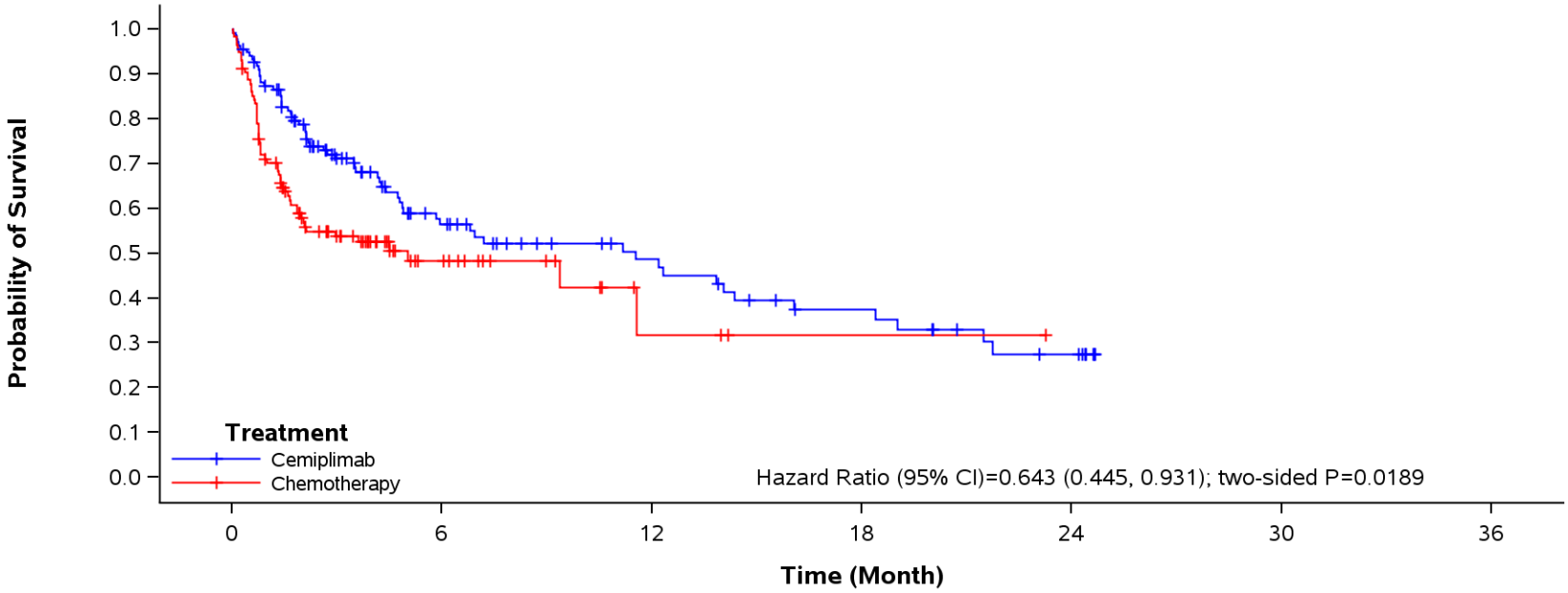

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
Number of patients with any TEAE CTCAE Grade >= 3



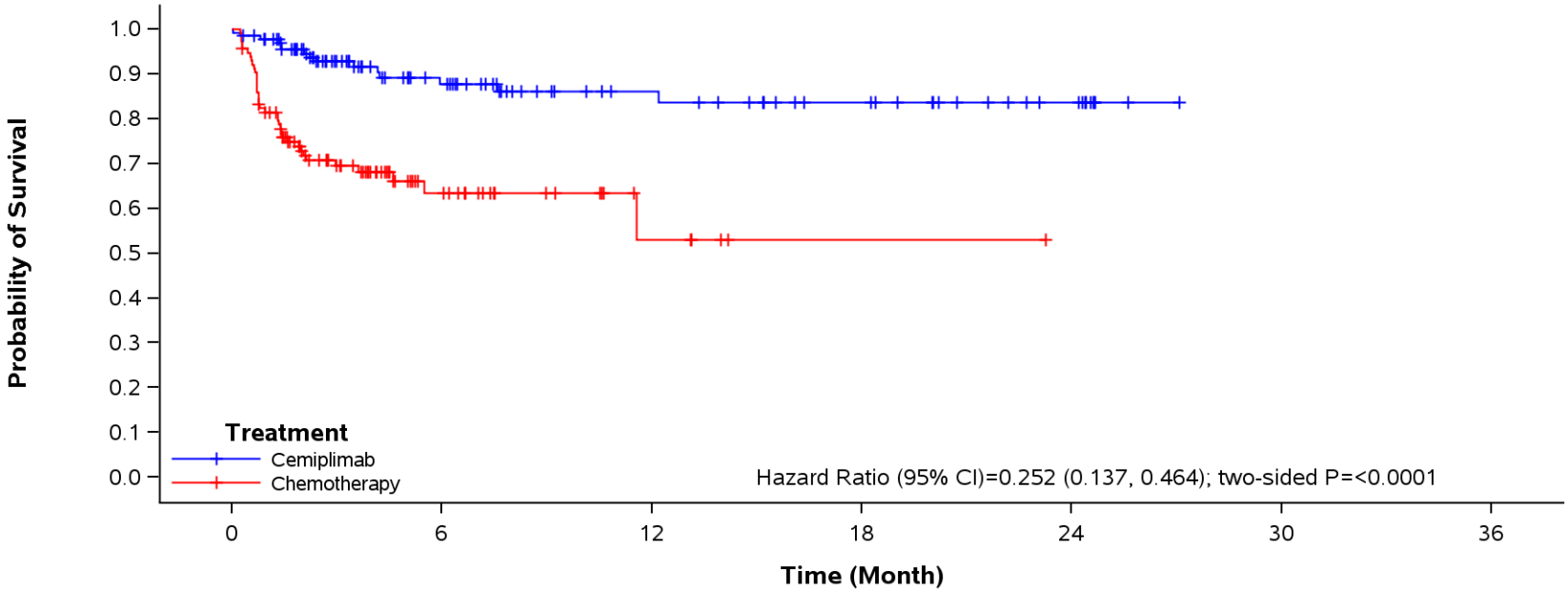

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 44 | 27 | 17 | 9 | 0 | 0 |
| Chemotherapy | 115 | 19 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 61 | 36 | 27 | 15 | 0 | 0 |
| Chemotherapy | 115 | 24 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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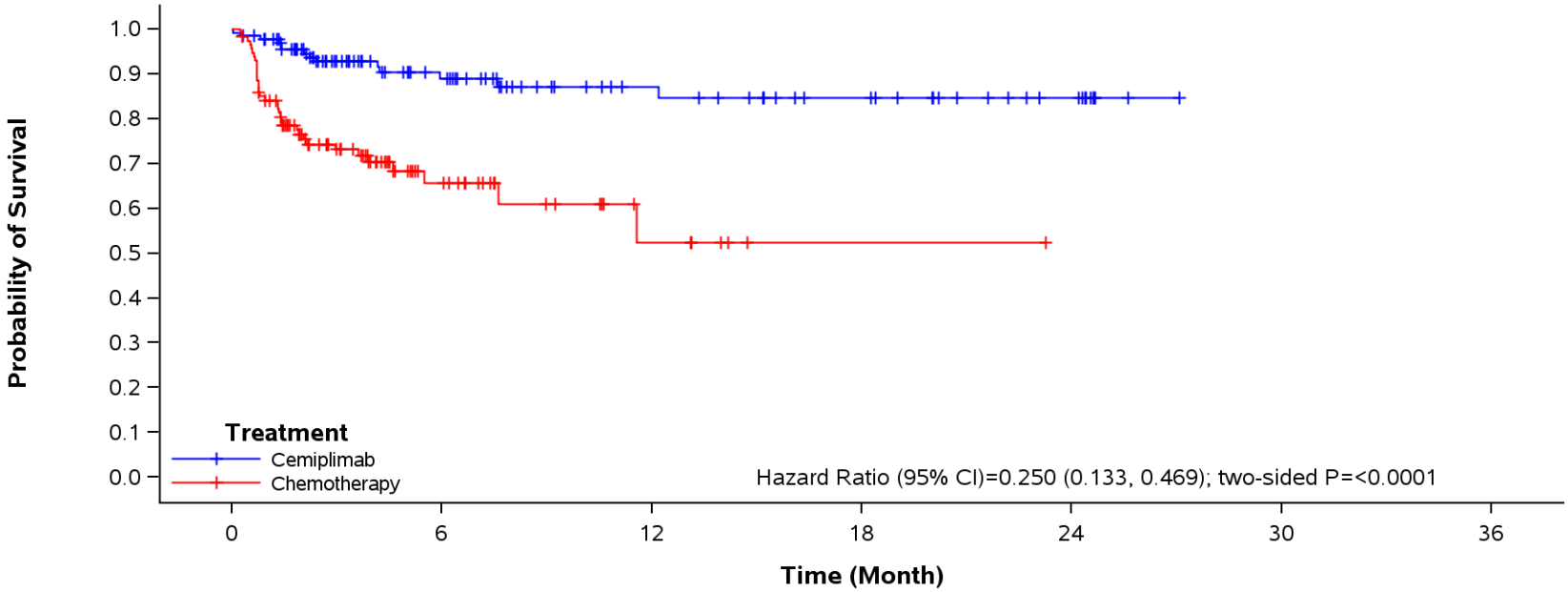
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Anaemia



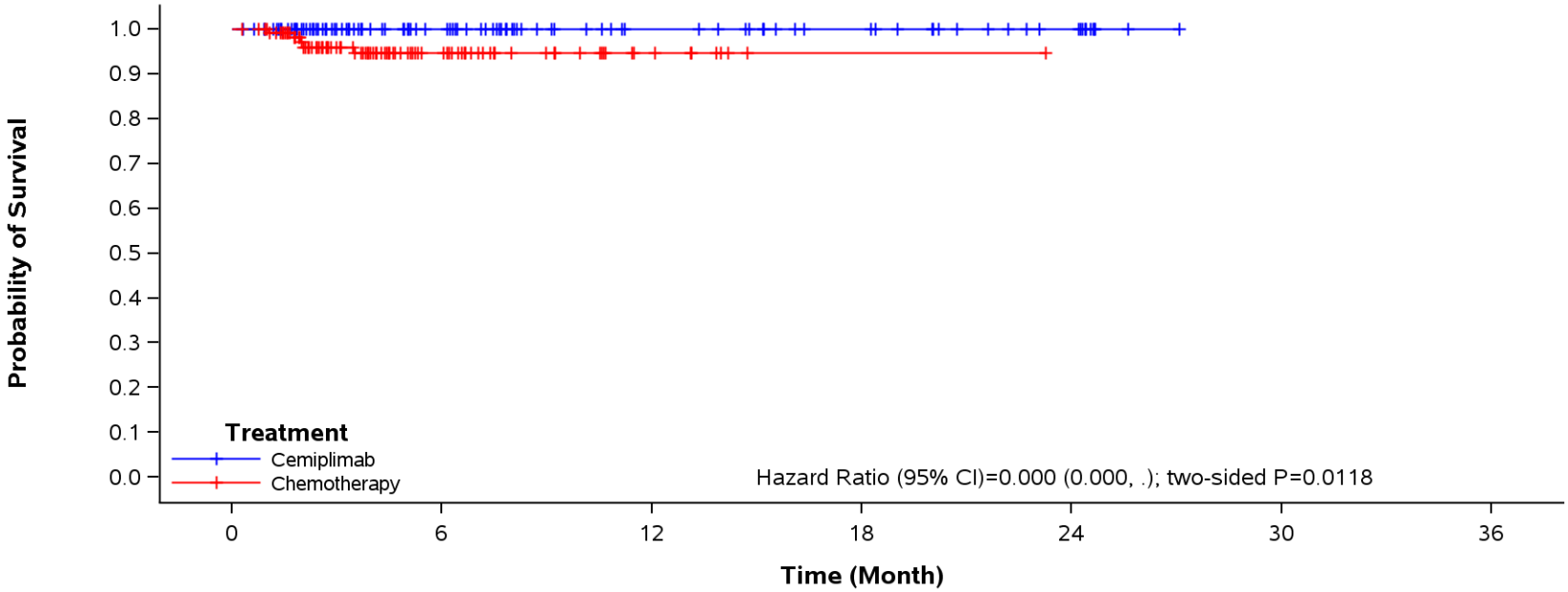

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 62 | 36 | 27 | 15 | 0 | 0 |
| Chemotherapy | 115 | 26 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



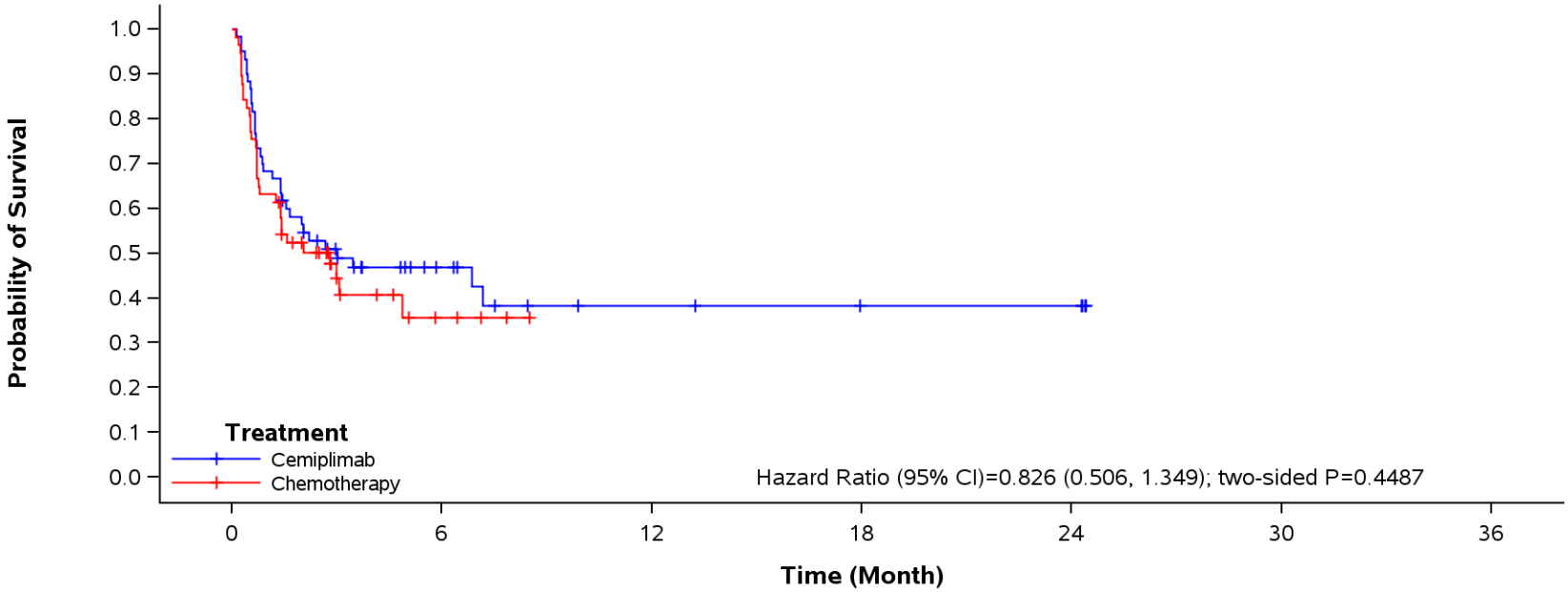

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
Number of patients with any TEAE CTCAE Grade >= 3



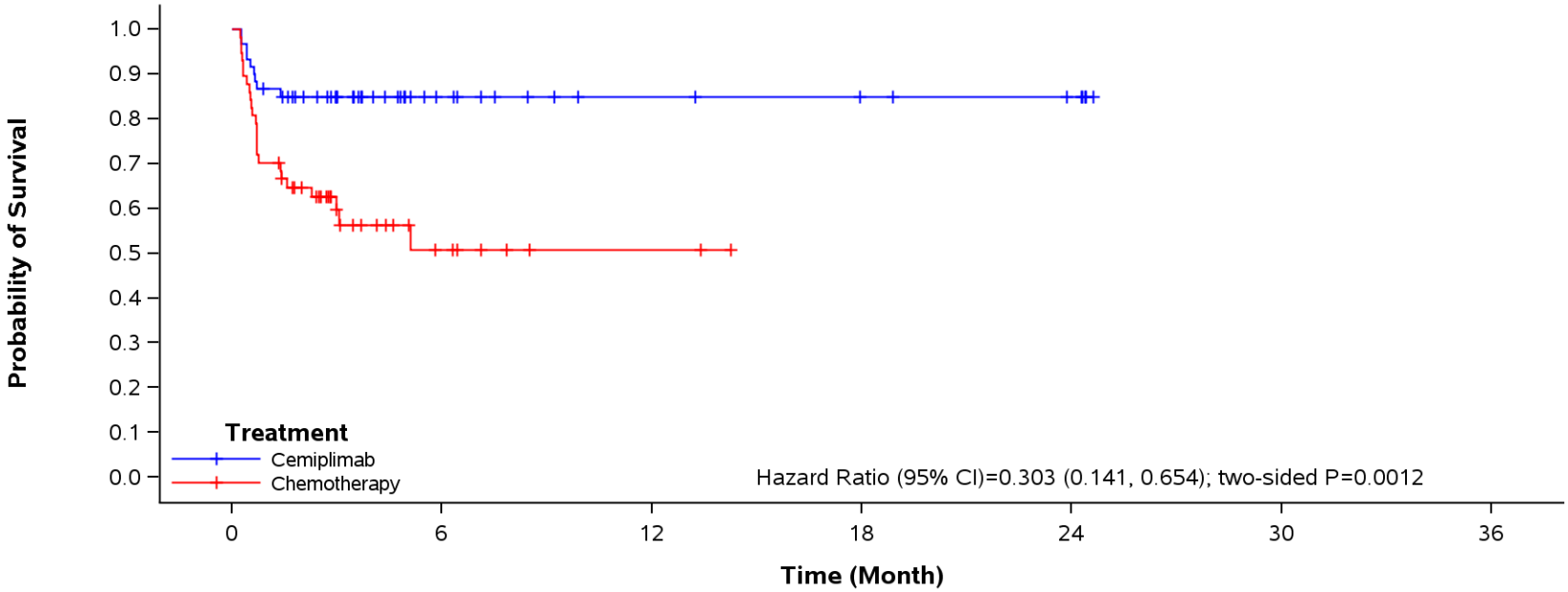

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 13 | 6 | 4 | 4 | 0 | 0 |
| Chemotherapy | 57 | 5 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders



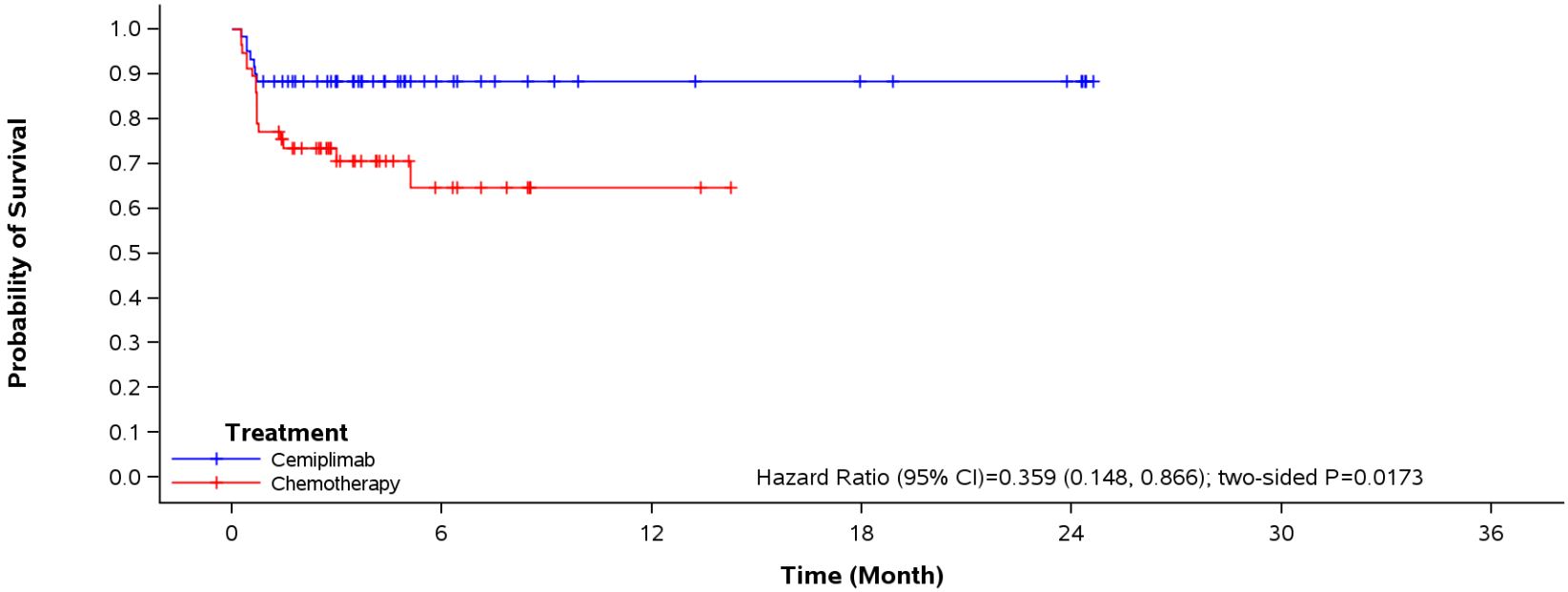

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 10 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Anaemia



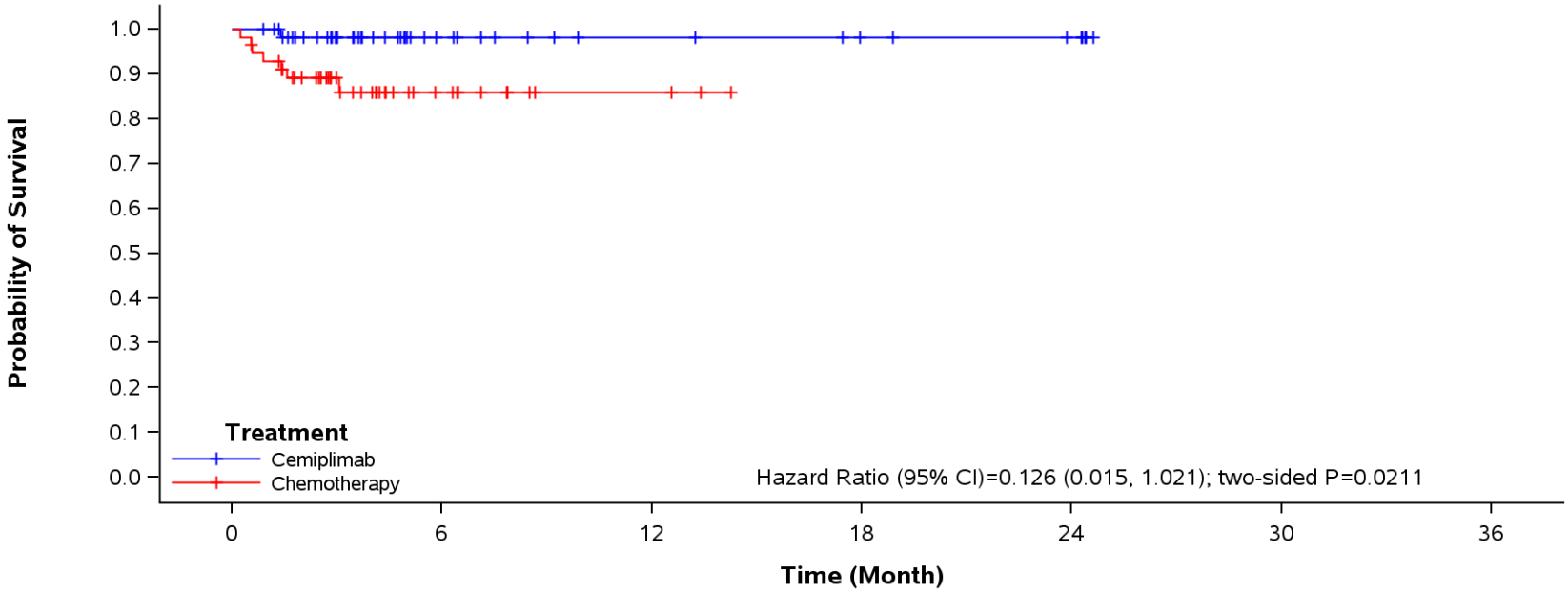

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 10 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 10 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



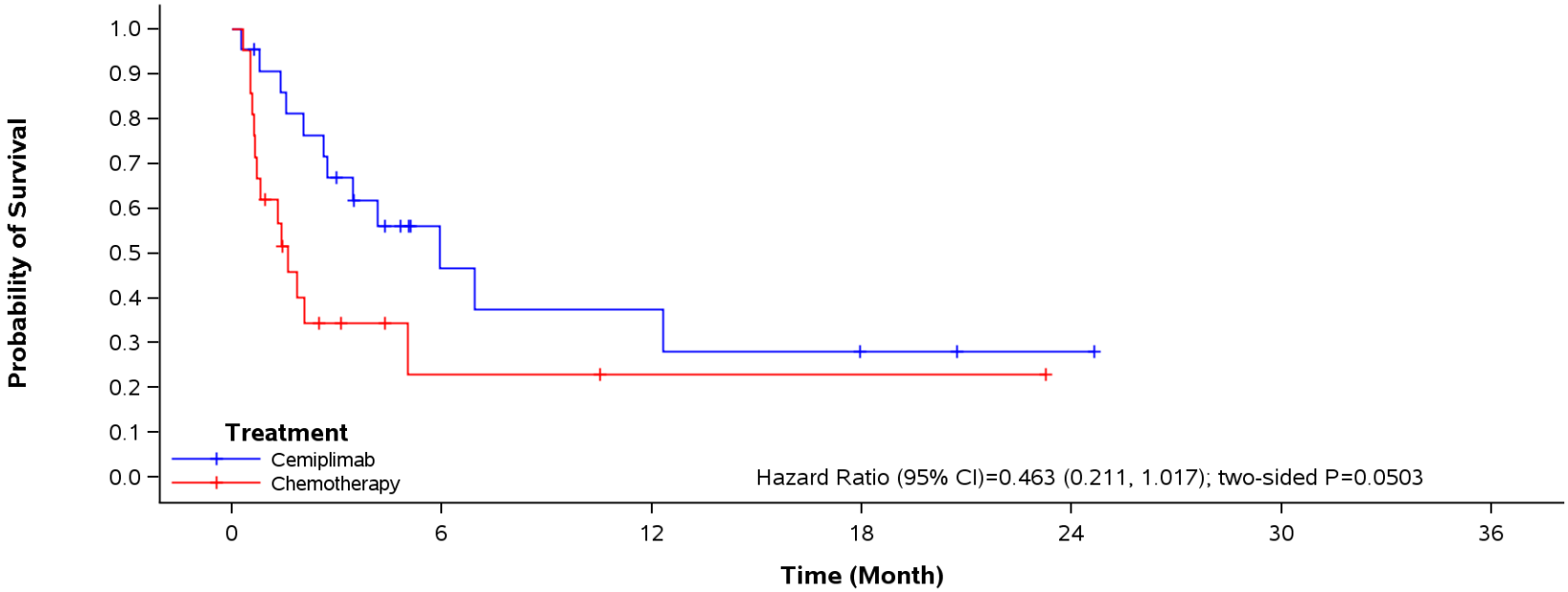

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 12 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Number of patients with any TEAE CTCAE Grade >= 3




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 5 | 4 | 2 | 1 | 0 | 0 |
| Chemotherapy | 21 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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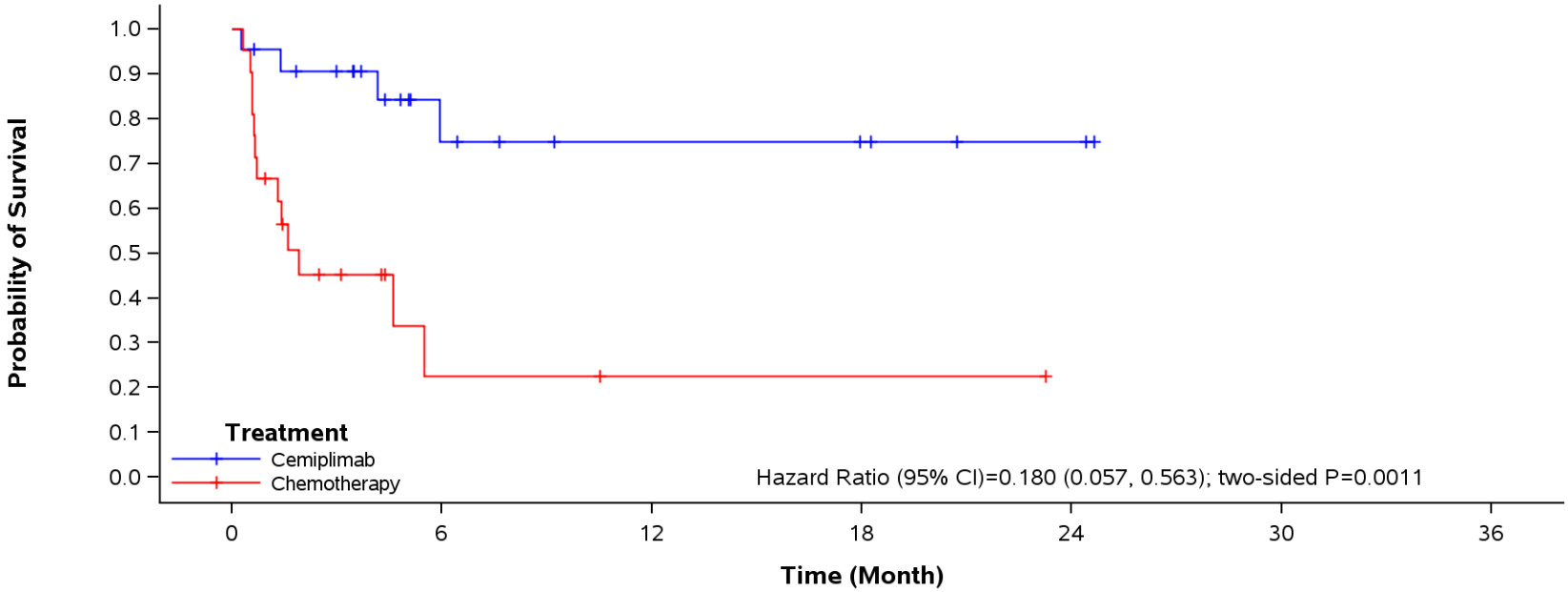
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders



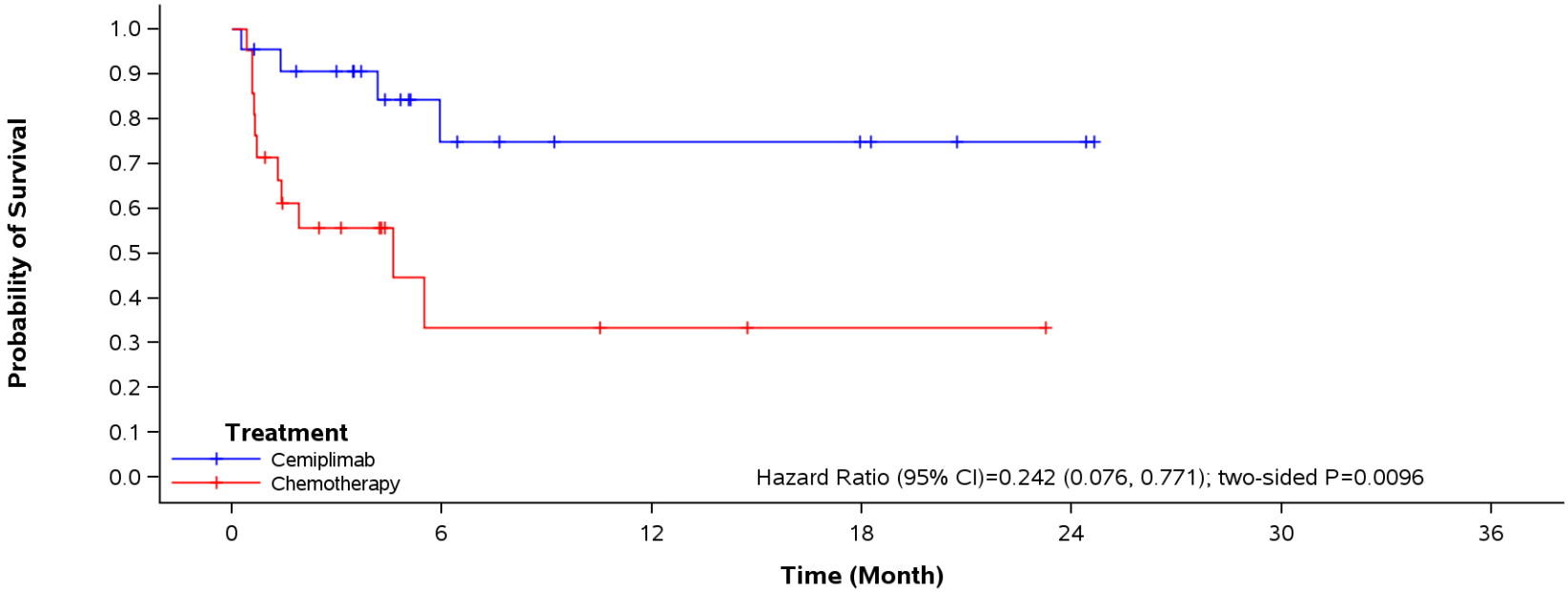

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 5 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 2 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Anaemia



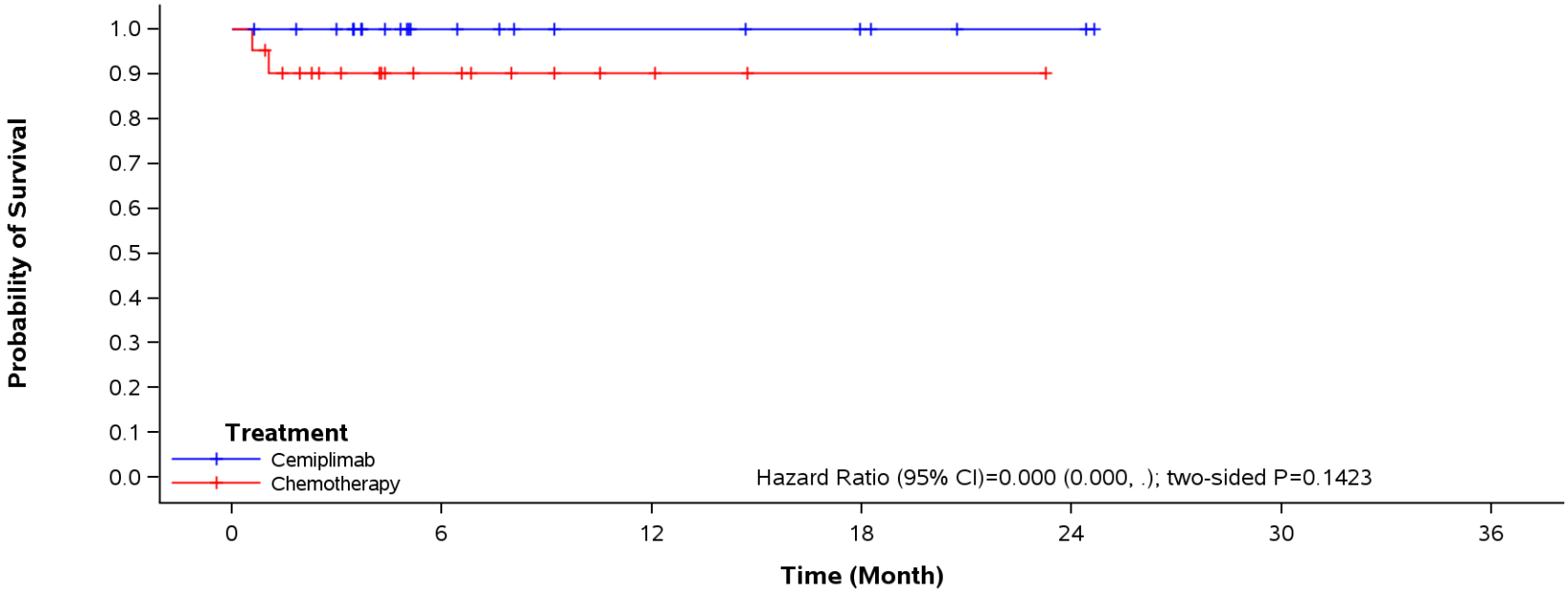

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 5 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 3 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Neutropenia



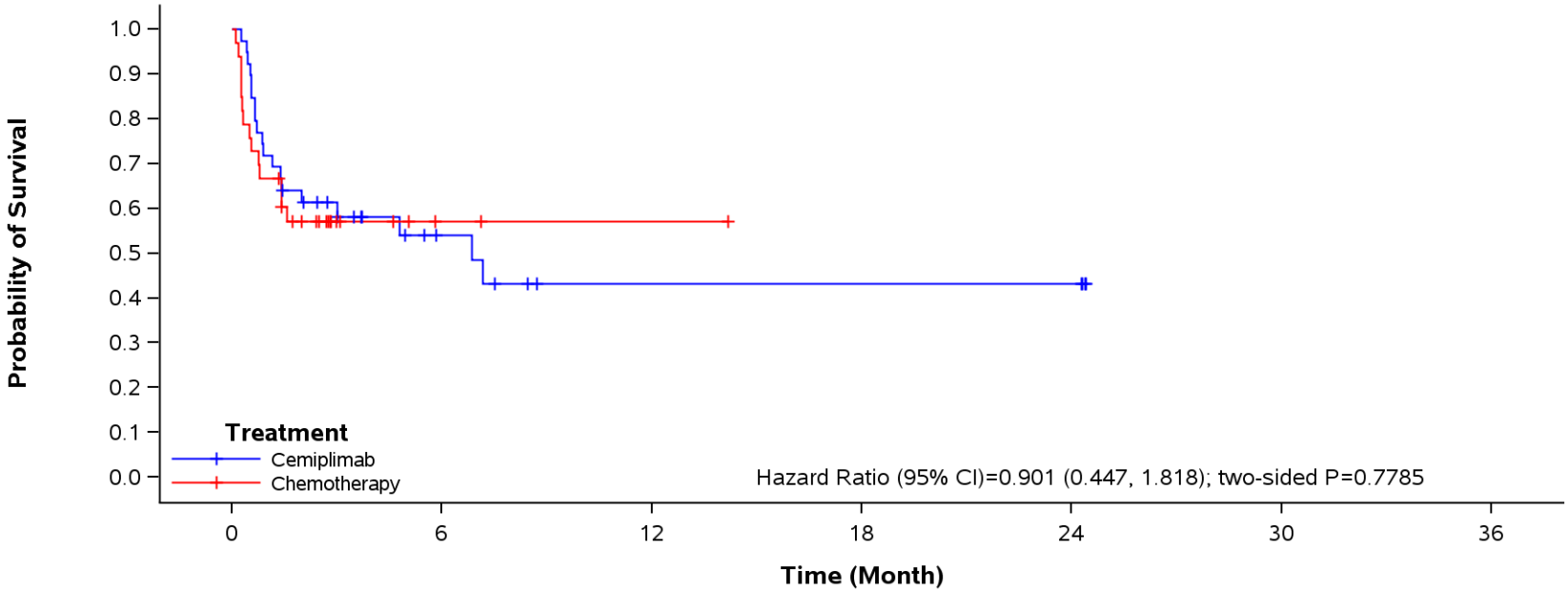

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Number of patients with any TEAE CTCAE Grade >= 3



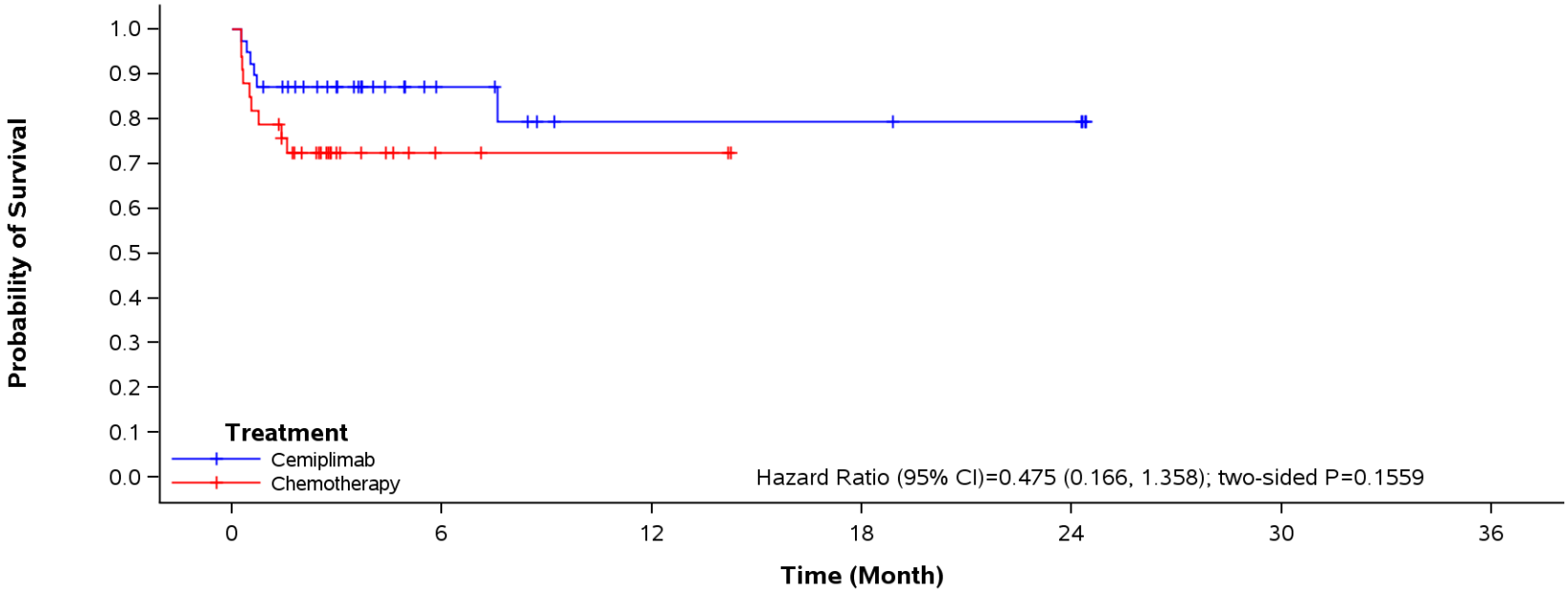

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 10 | 5 | 5 | 5 | 0 | 0 |
| Chemotherapy | 33 | 2 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders



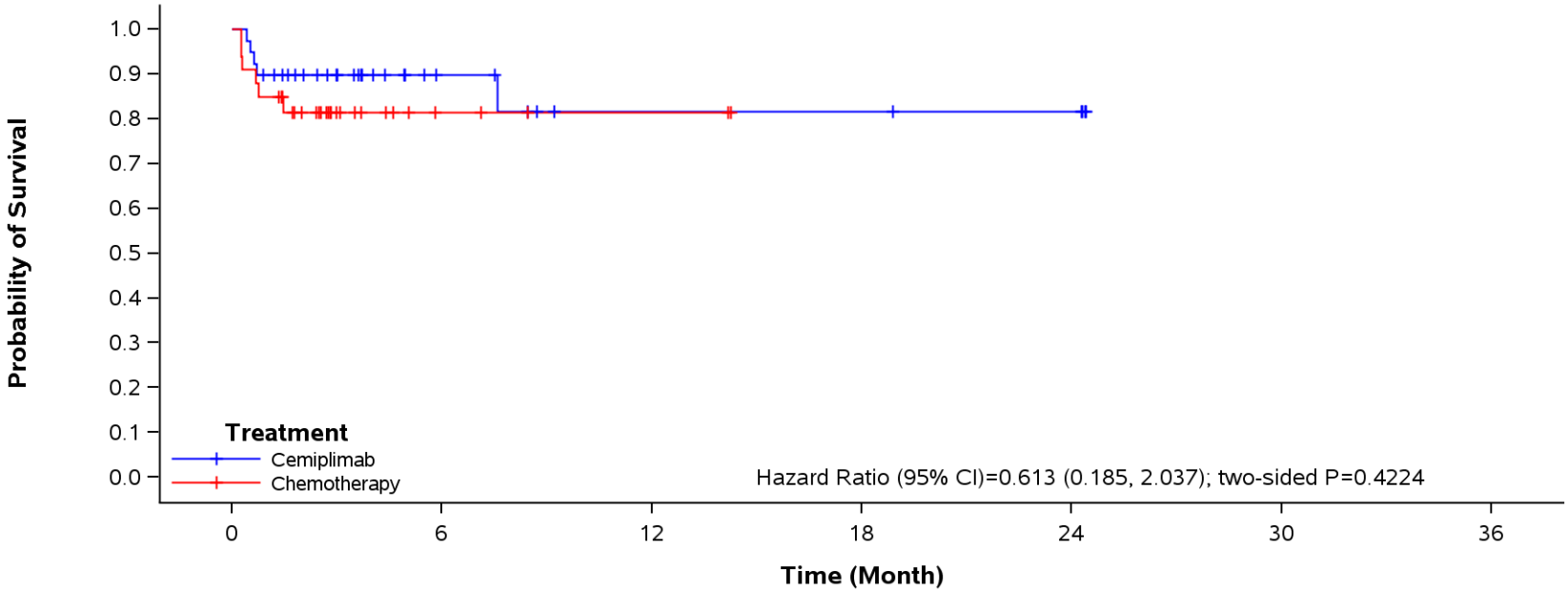

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 3 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Anaemia



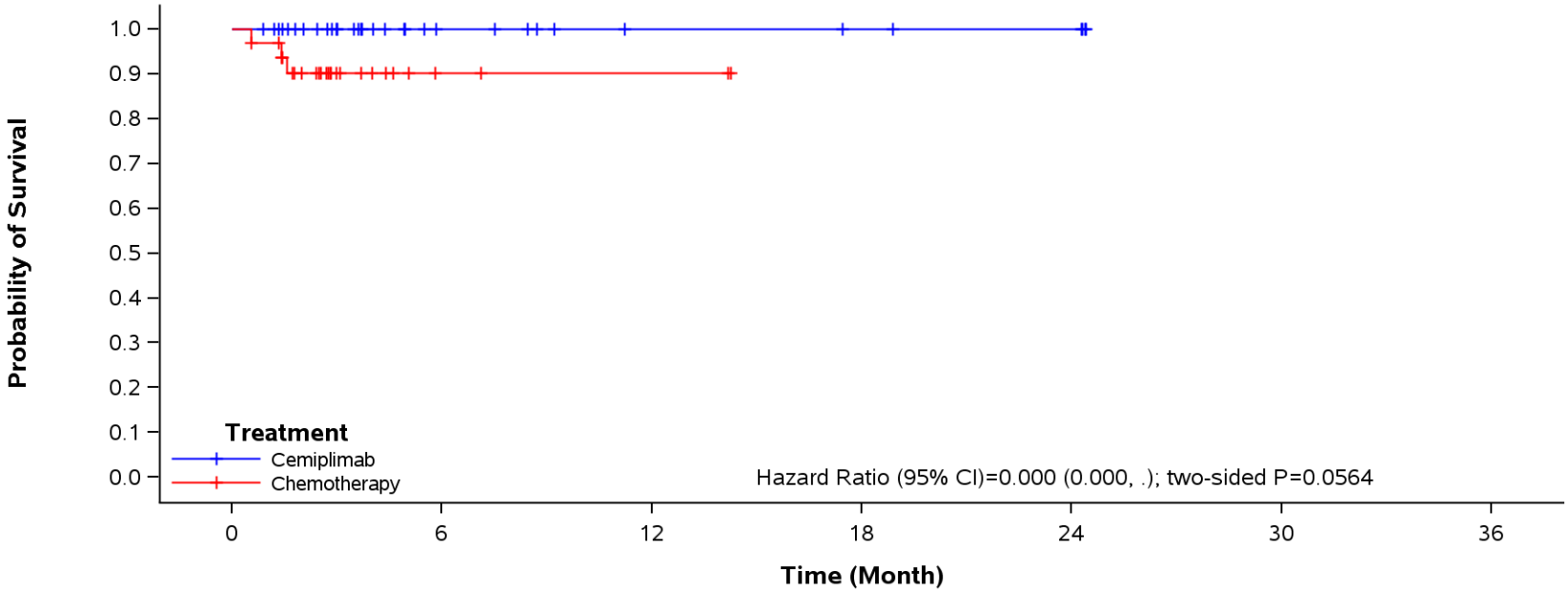

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 12 | 7 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 4 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Neutropenia



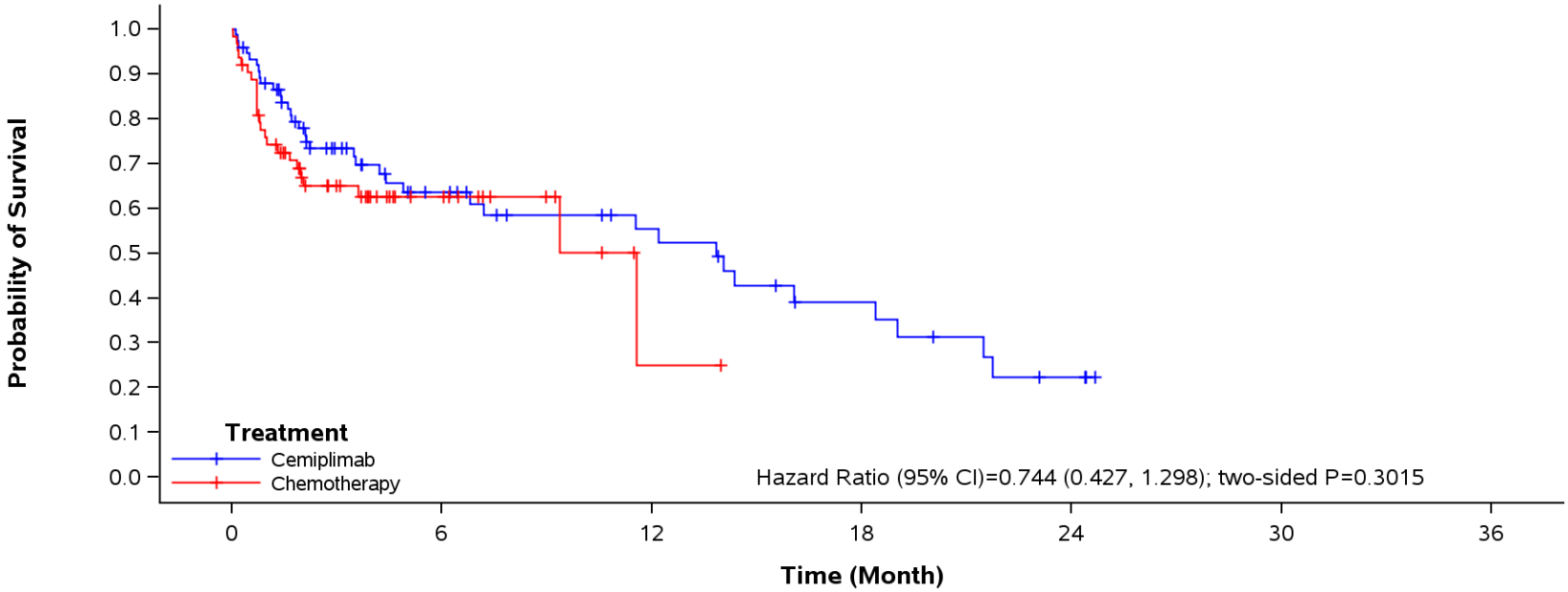

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 3 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Number of patients with any TEAE CTCAE Grade >= 3



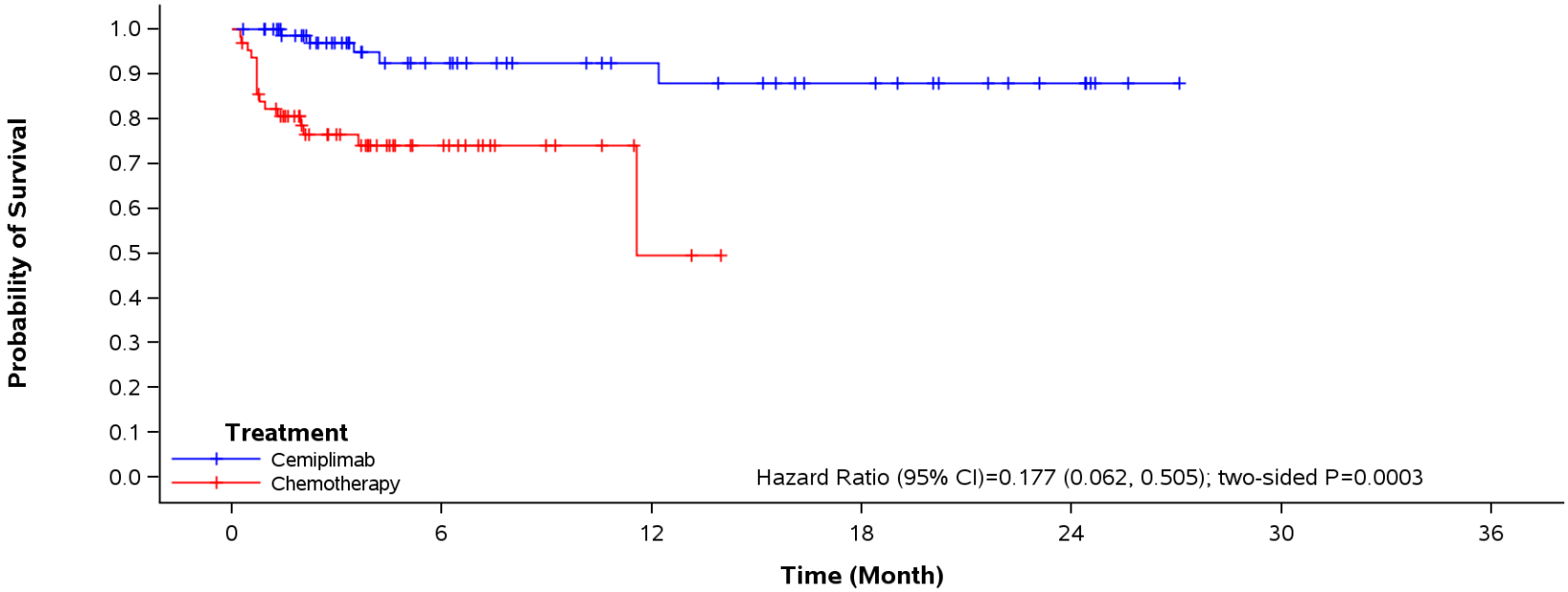

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 28 | 18 | 10 | 4 | 0 | 0 |
| Chemotherapy | 63 | 14 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders



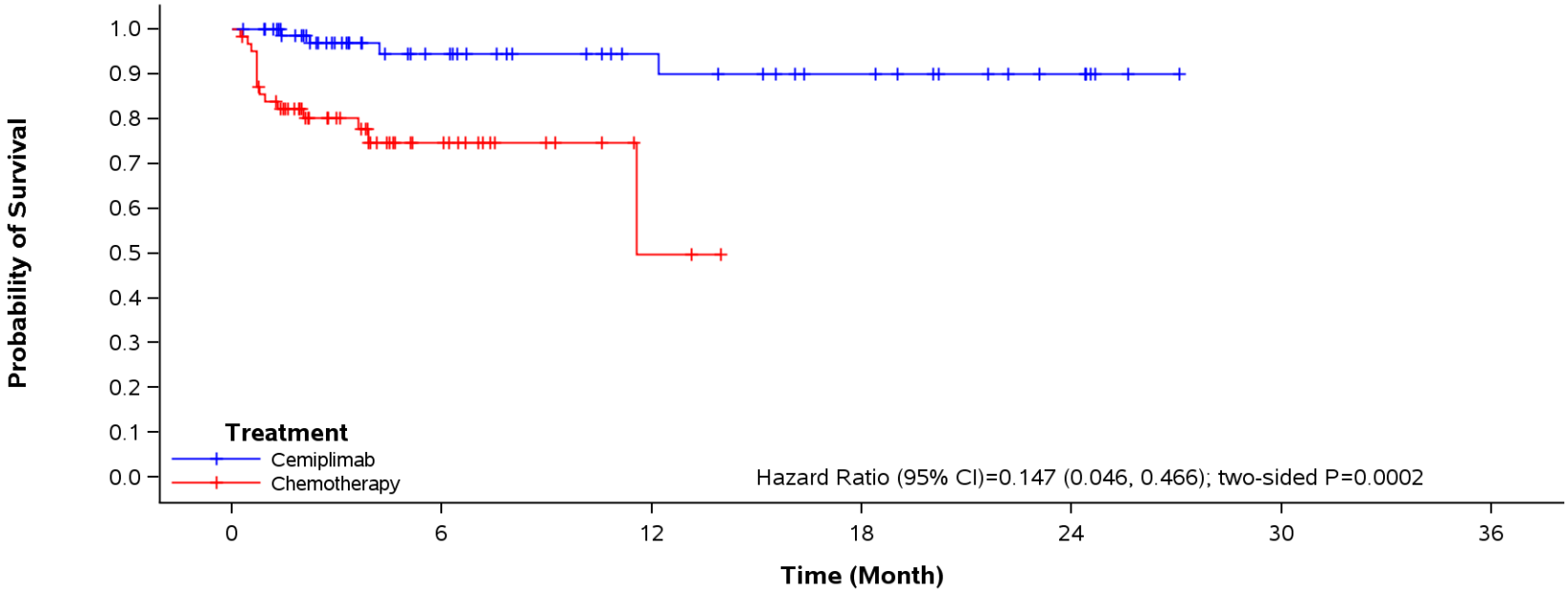

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 33 | 21 | 15 | 8 | 0 | 0 |
| Chemotherapy | 63 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 34 | 21 | 15 | 8 | 0 | 0 |
| Chemotherapy | 63 | 16 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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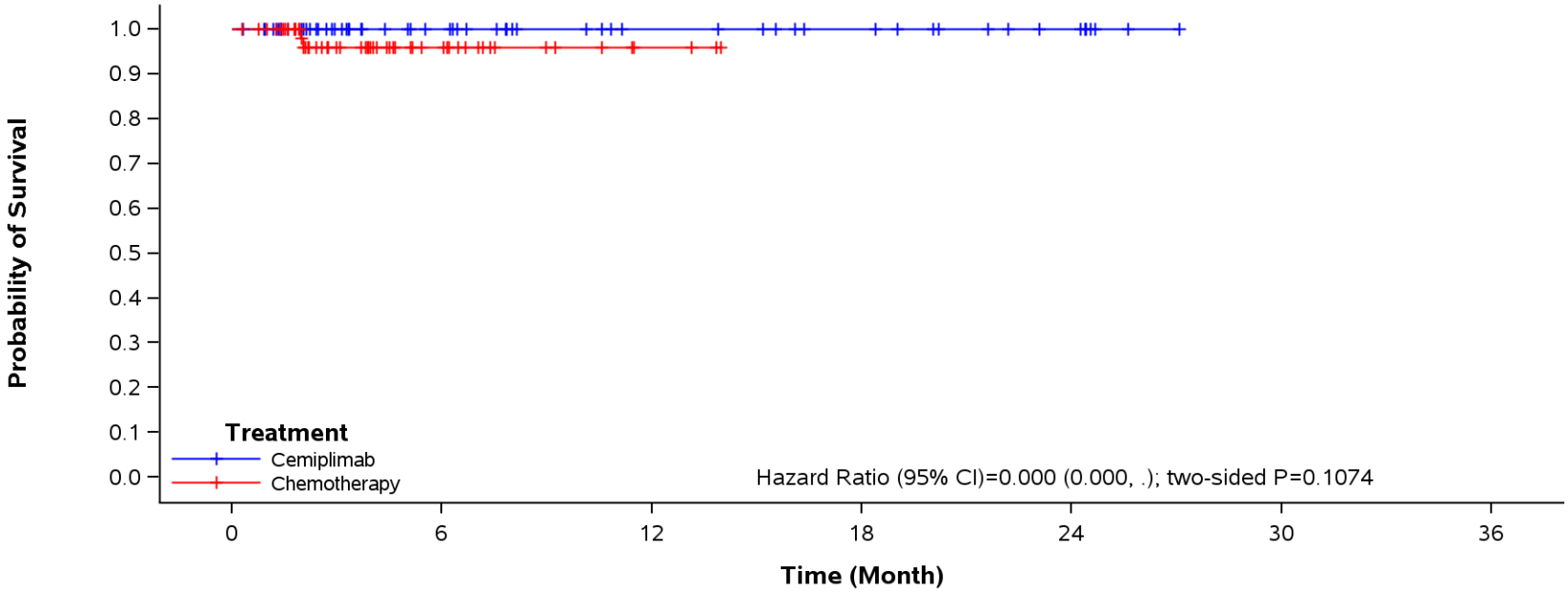
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Neutropenia



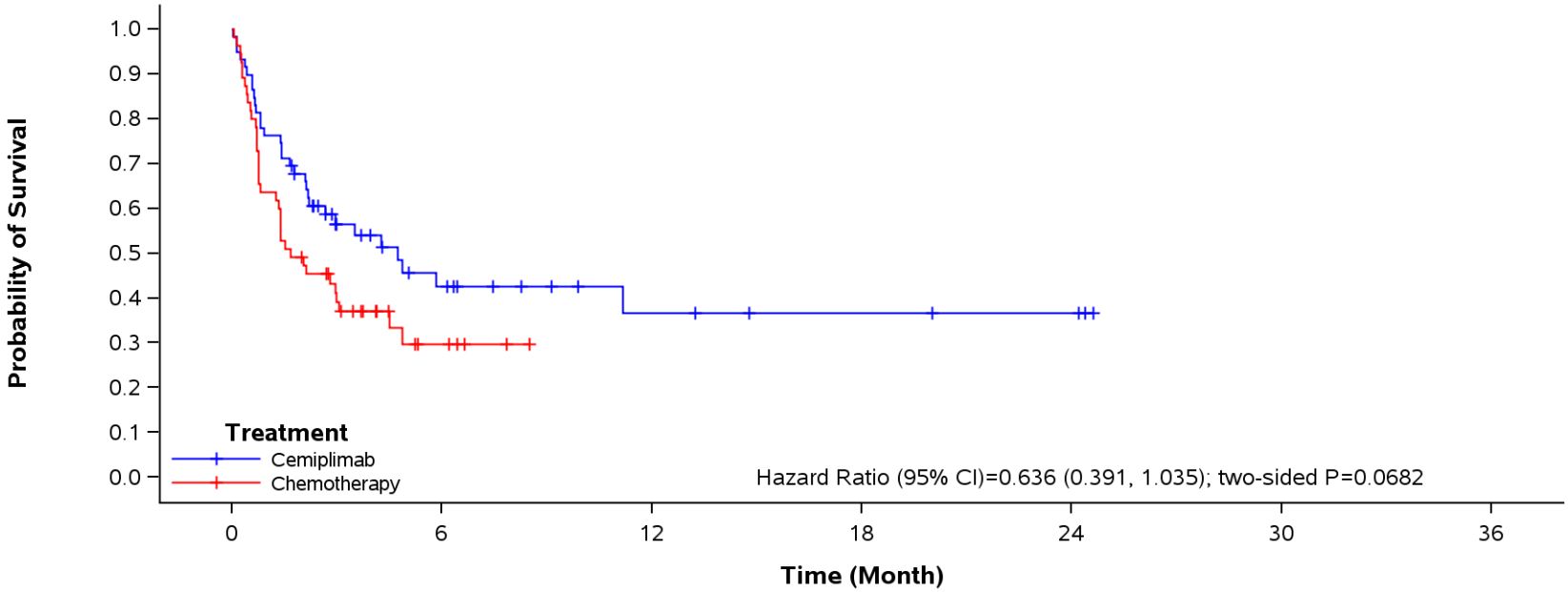

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Number of patients with any TEAE CTCAE Grade >= 3



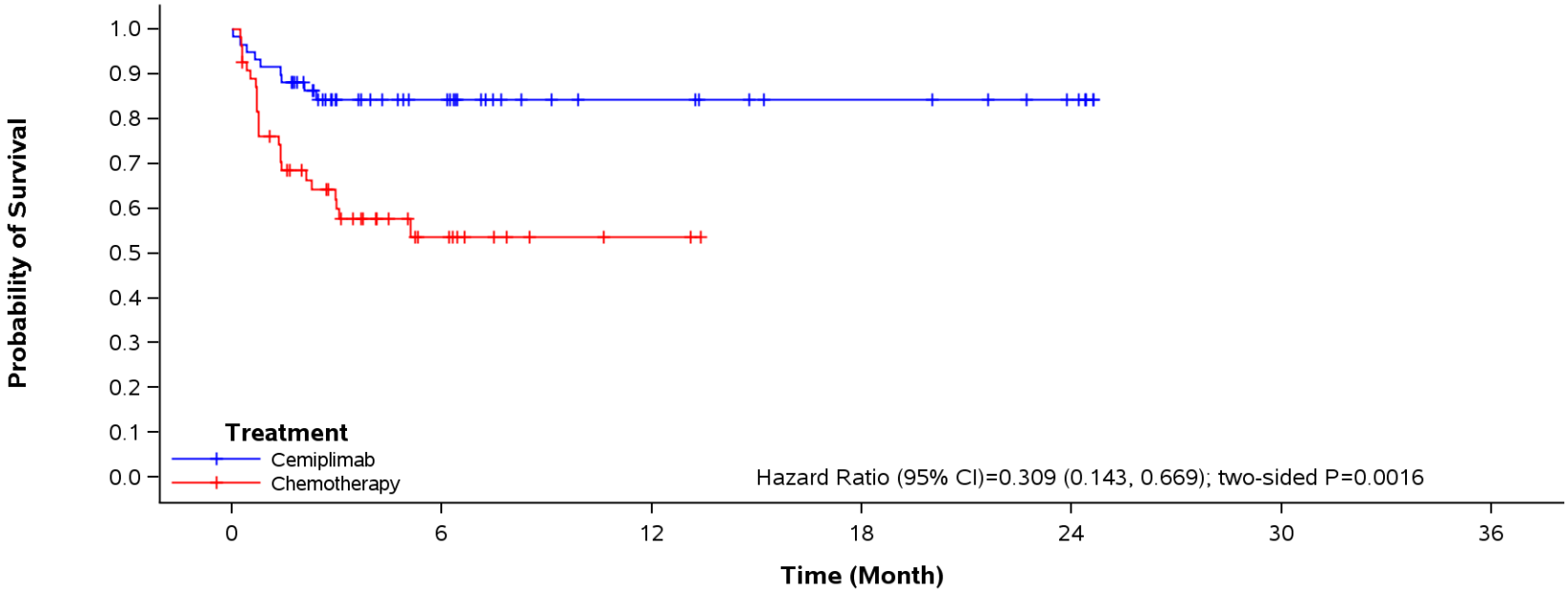

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 14 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 55 | 6 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders



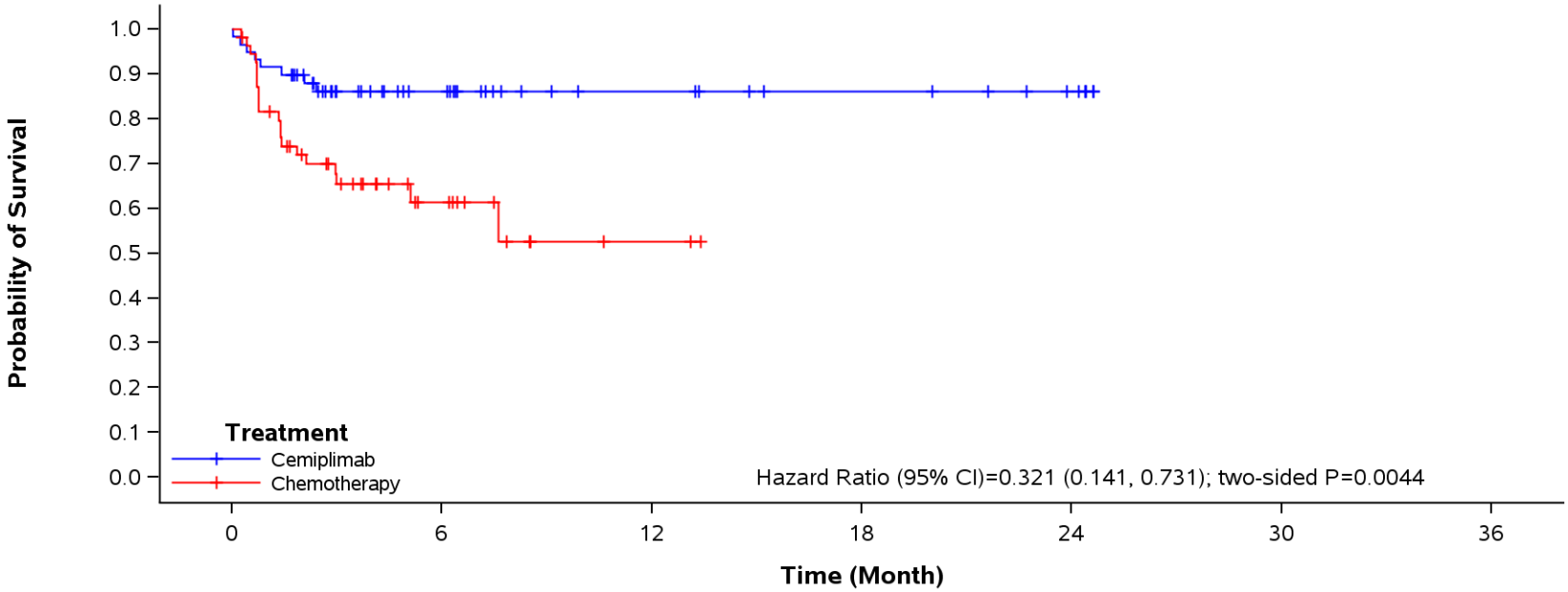

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 11 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 13 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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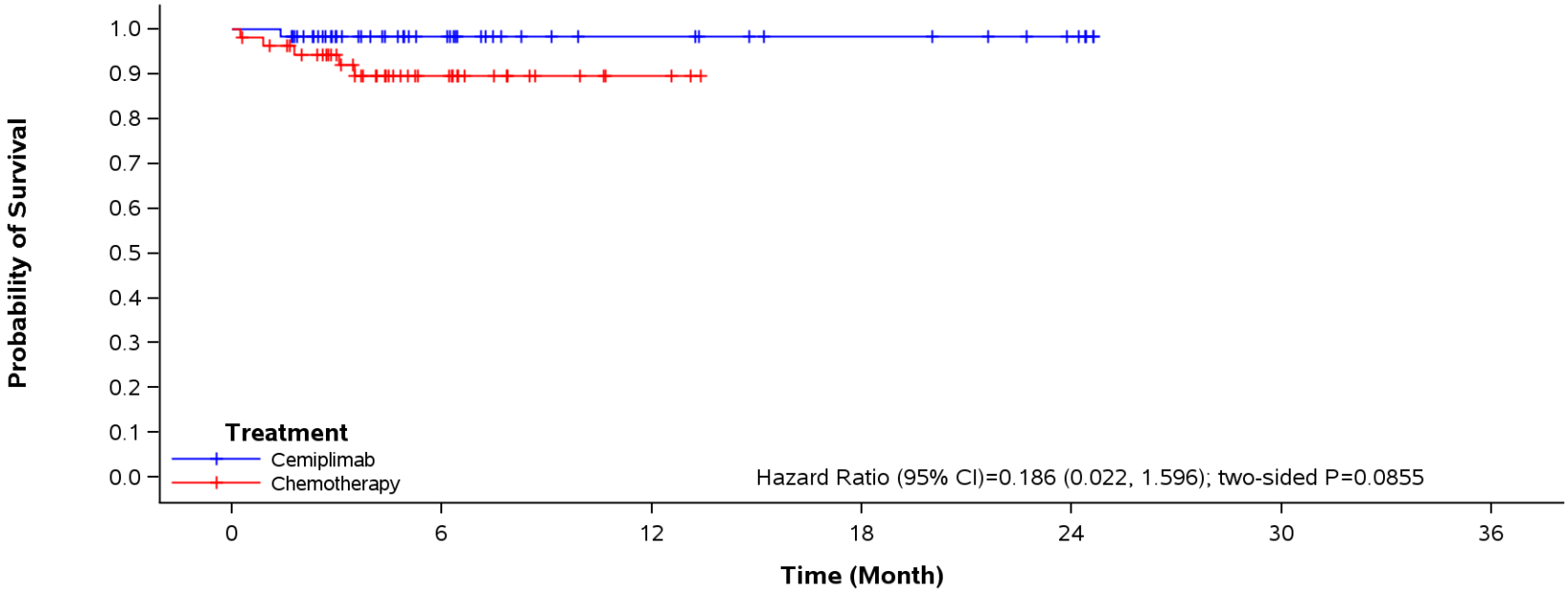
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Neutropenia



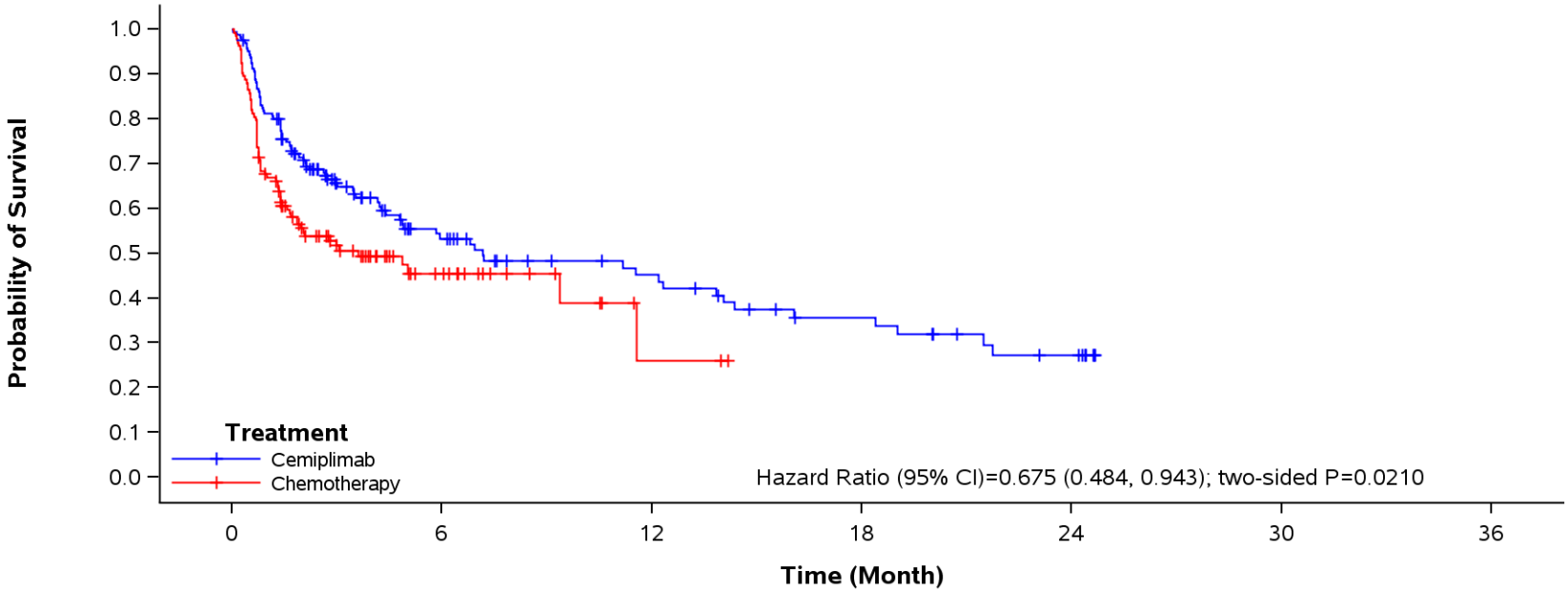

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 18 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Number of patients with any TEAE CTCAE Grade >= 3



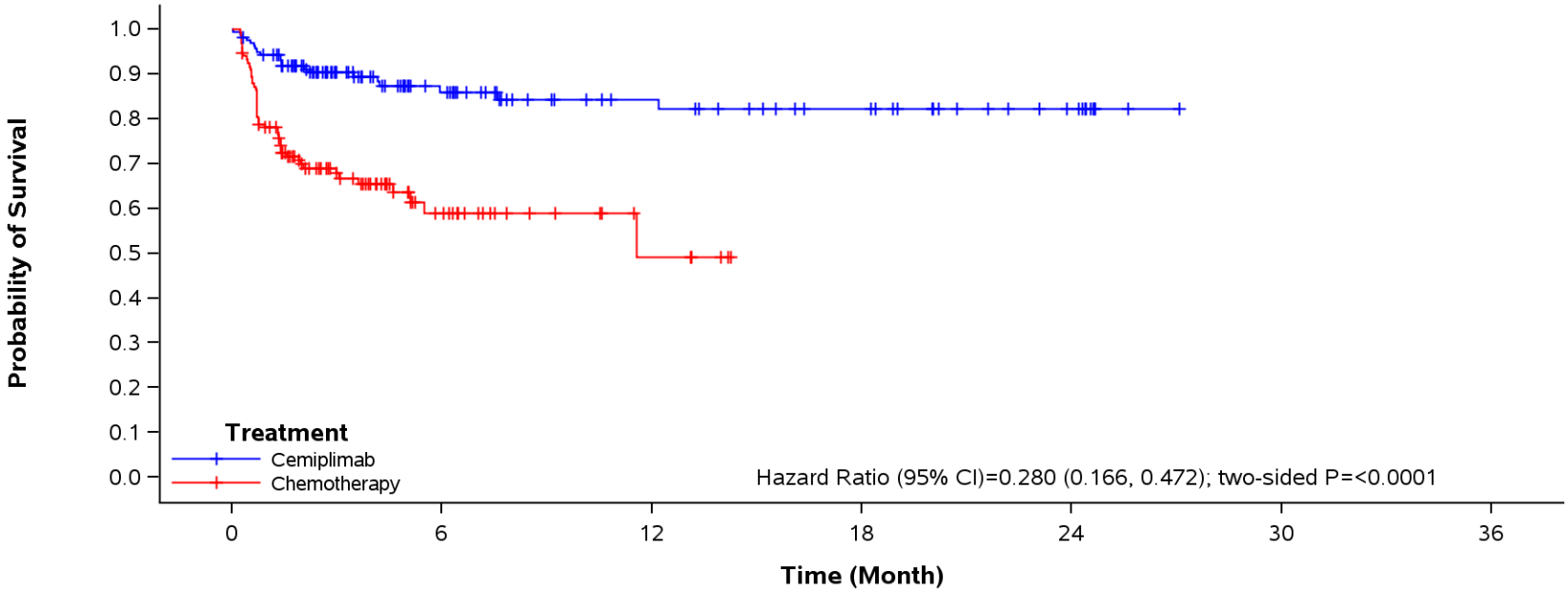

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 48 | 30 | 19 | 11 | 0 | 0 |
| Chemotherapy | 133 | 19 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 67 | 40 | 31 | 18 | 0 | 0 |
| Chemotherapy | 133 | 23 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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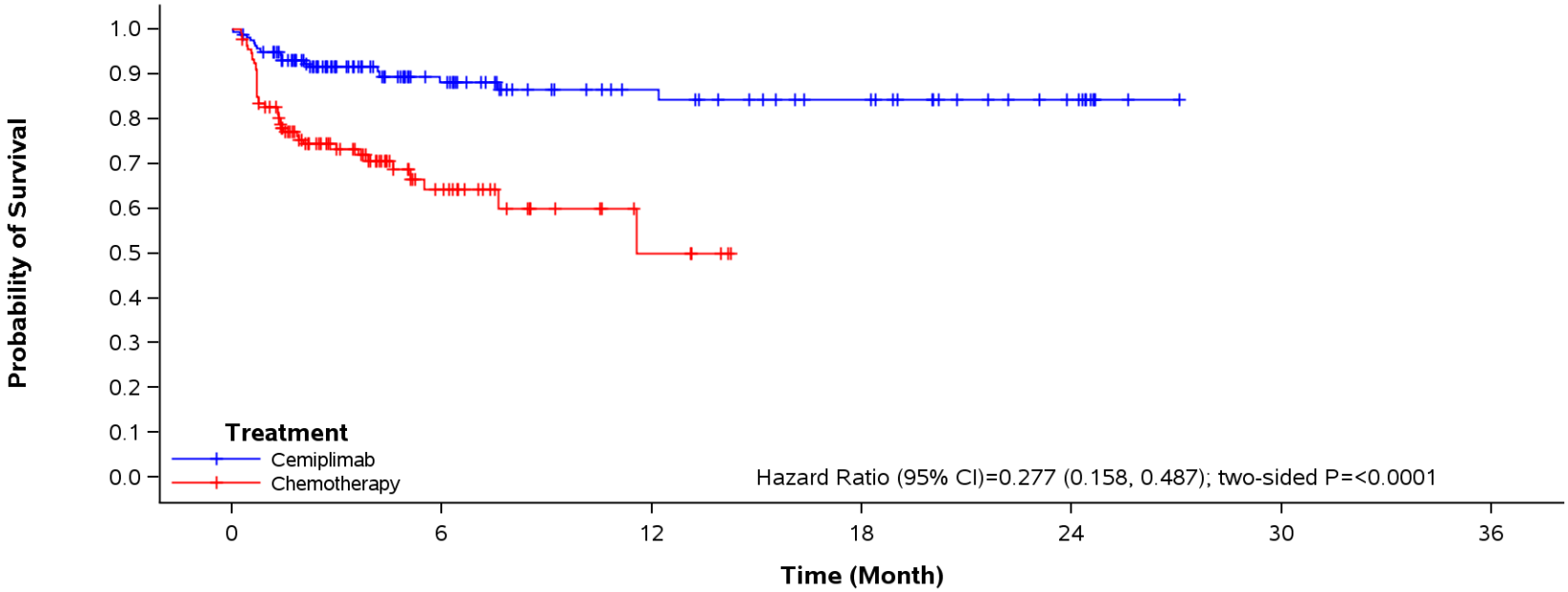
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



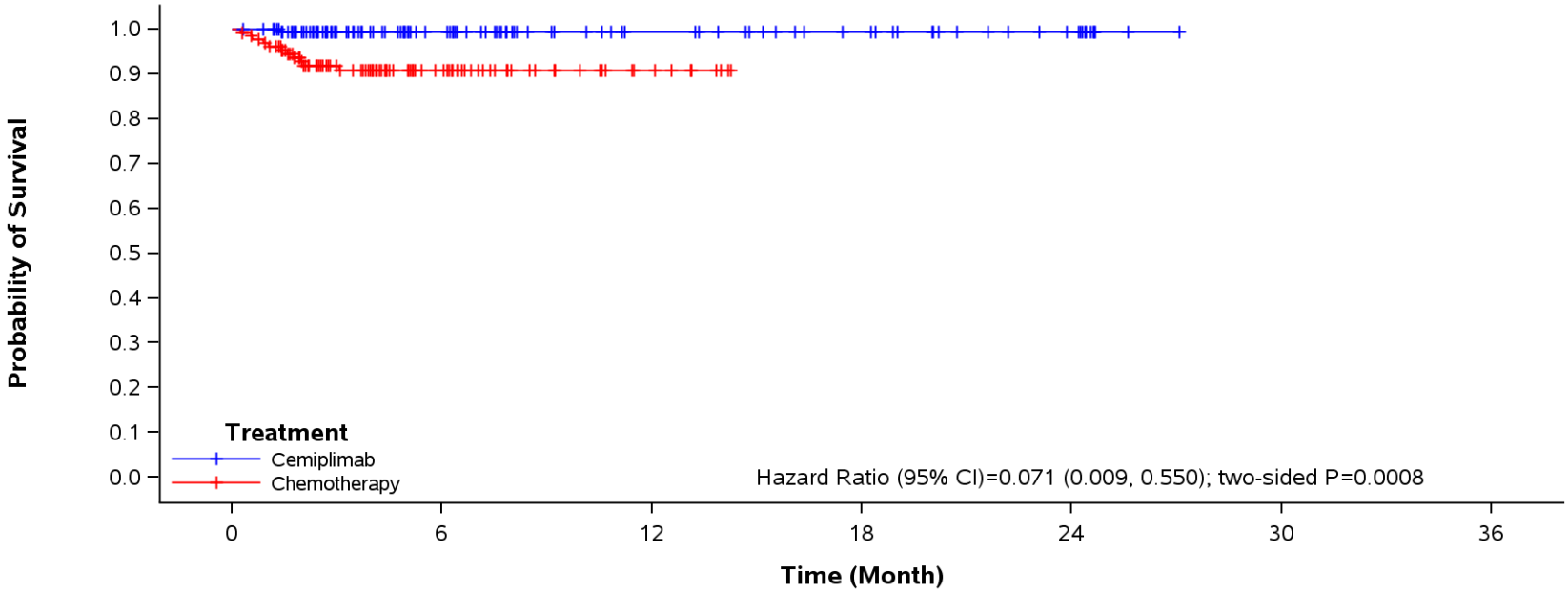

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 68 | 40 | 31 | 18 | 0 | 0 |
| Chemotherapy | 133 | 26 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



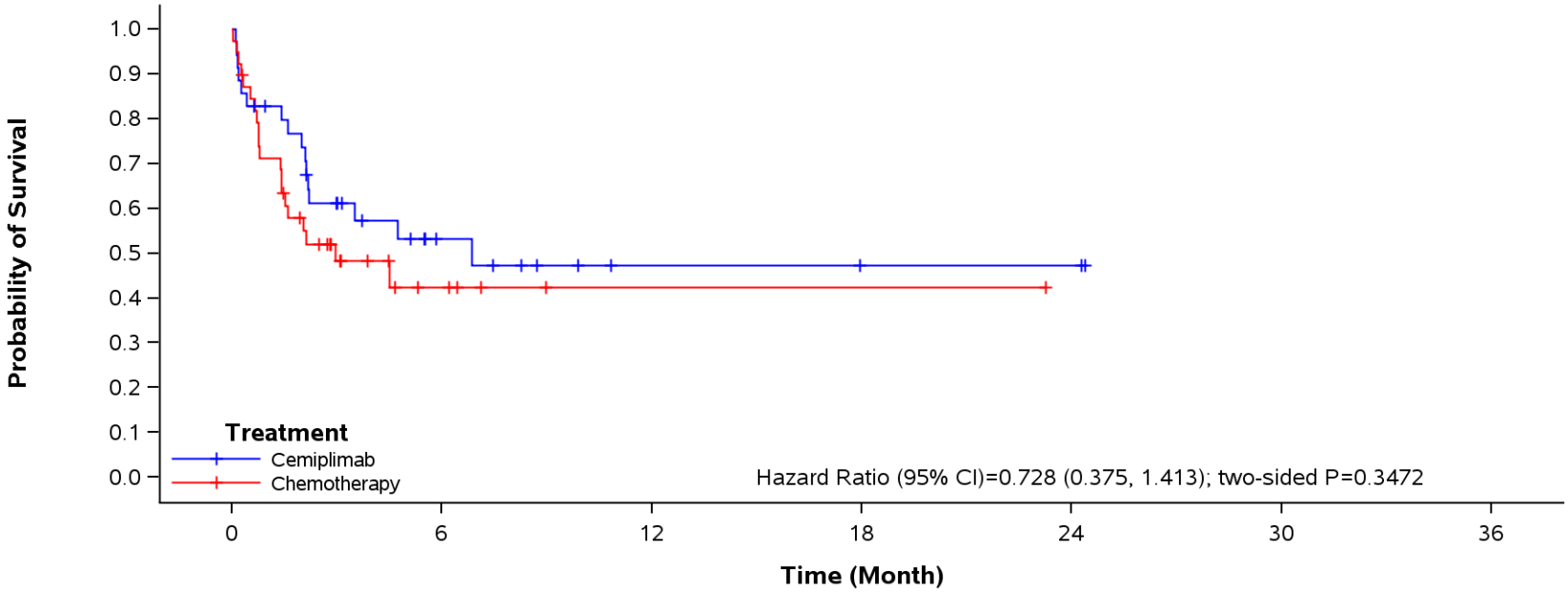

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 37 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Number of patients with any TEAE CTCAE Grade >= 3



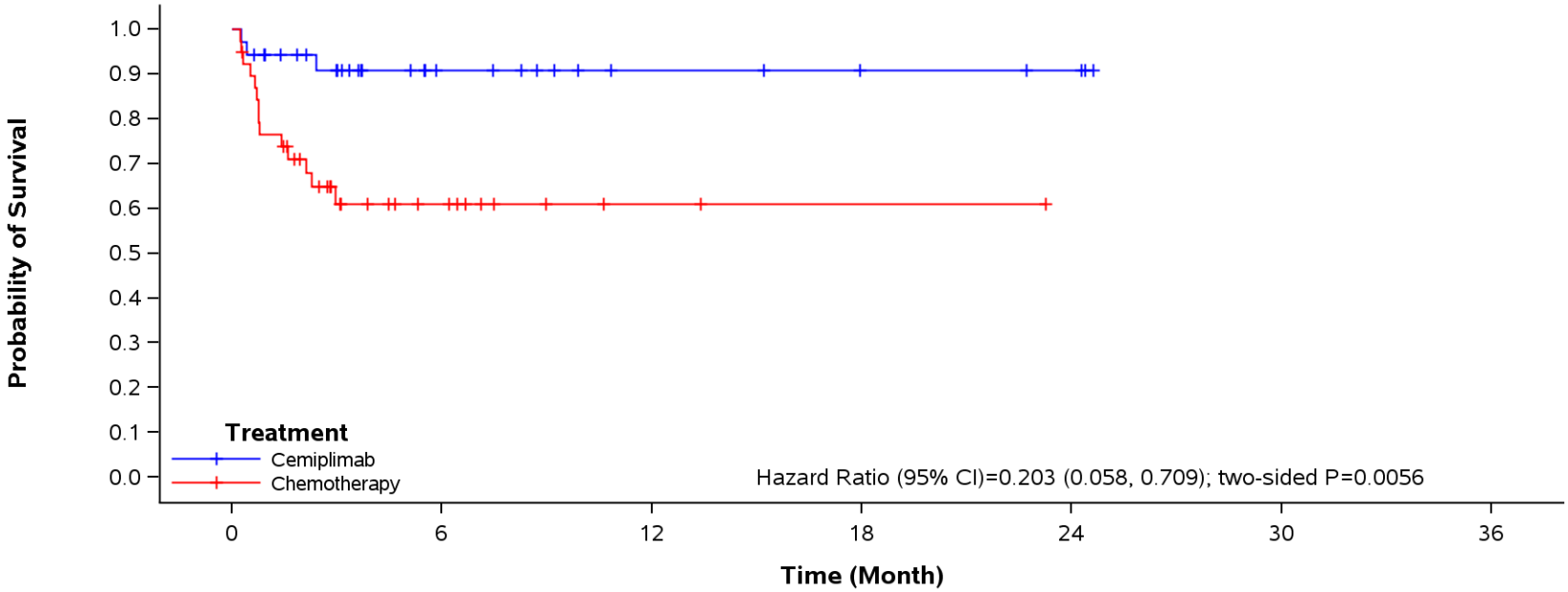

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 9 | 3 | 2 | 2 | 0 | 0 |
| Chemotherapy | 39 | 5 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders



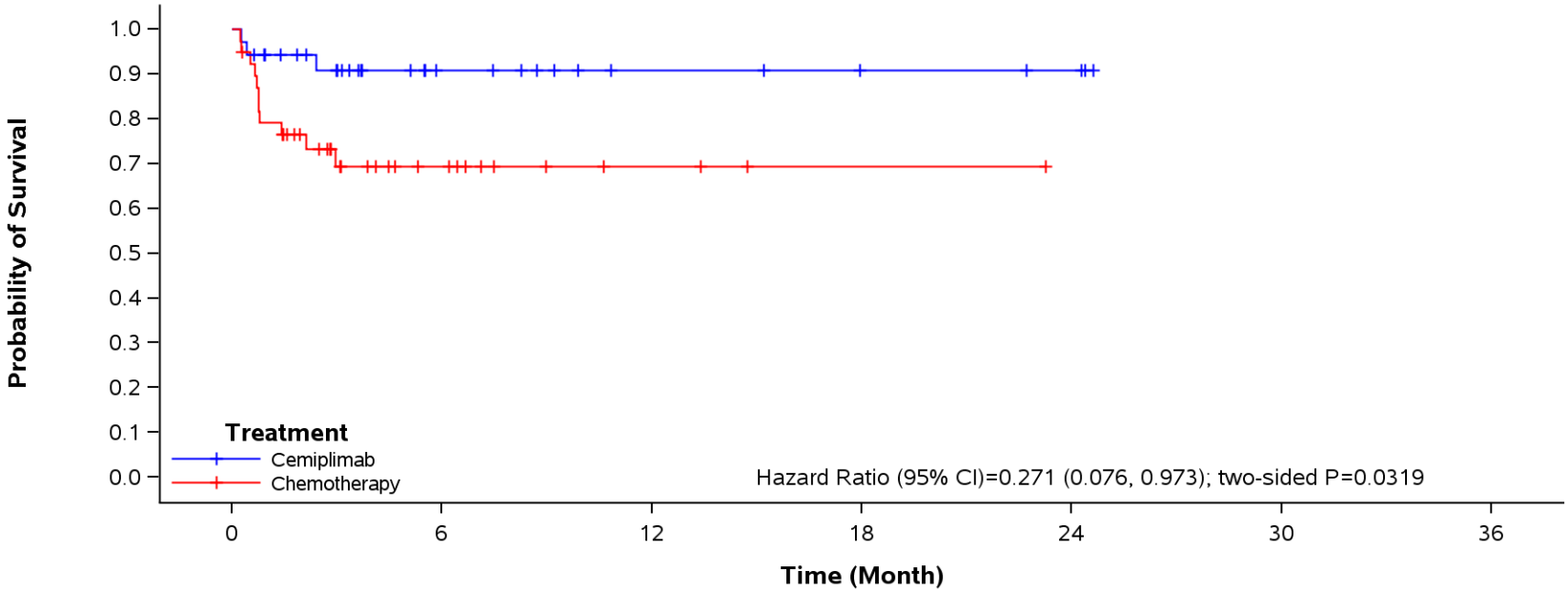

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 9 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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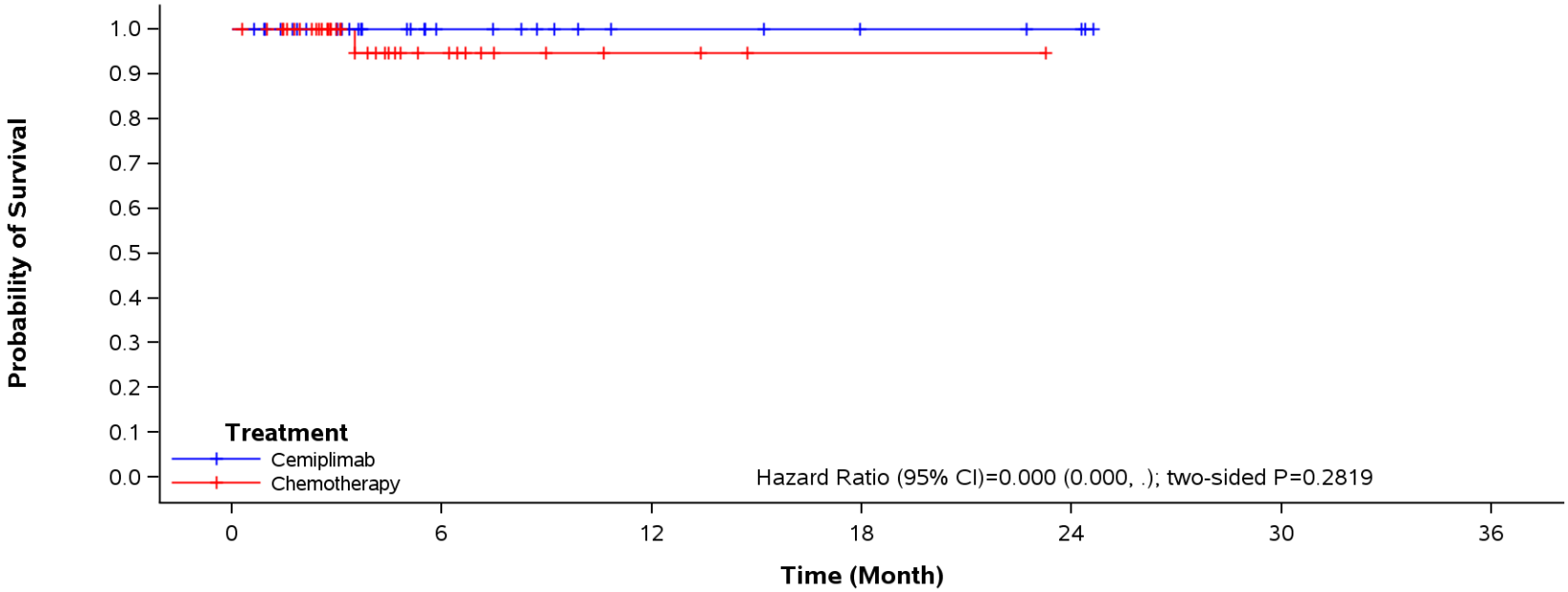
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



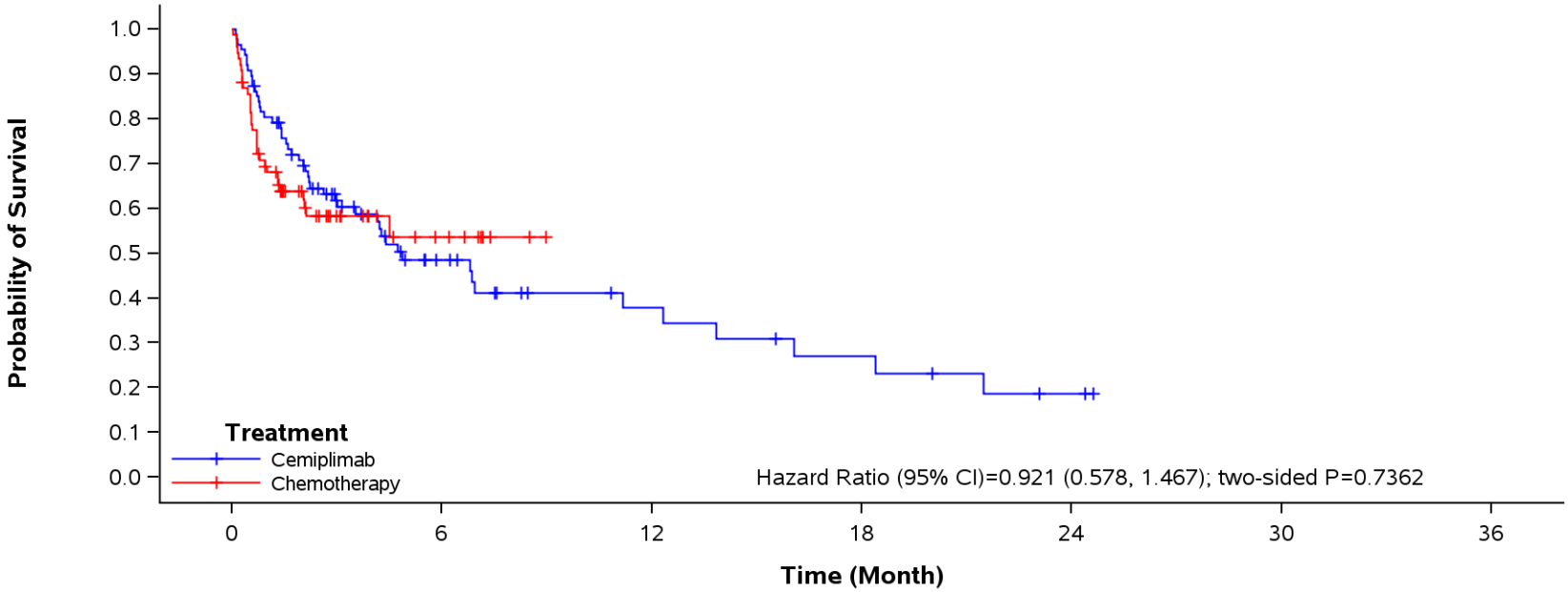

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Number of patients with any TEAE CTCAE Grade >= 3




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 23 | 11 | 7 | 3 | 0 | 0 |
| Chemotherapy | 76 | 8 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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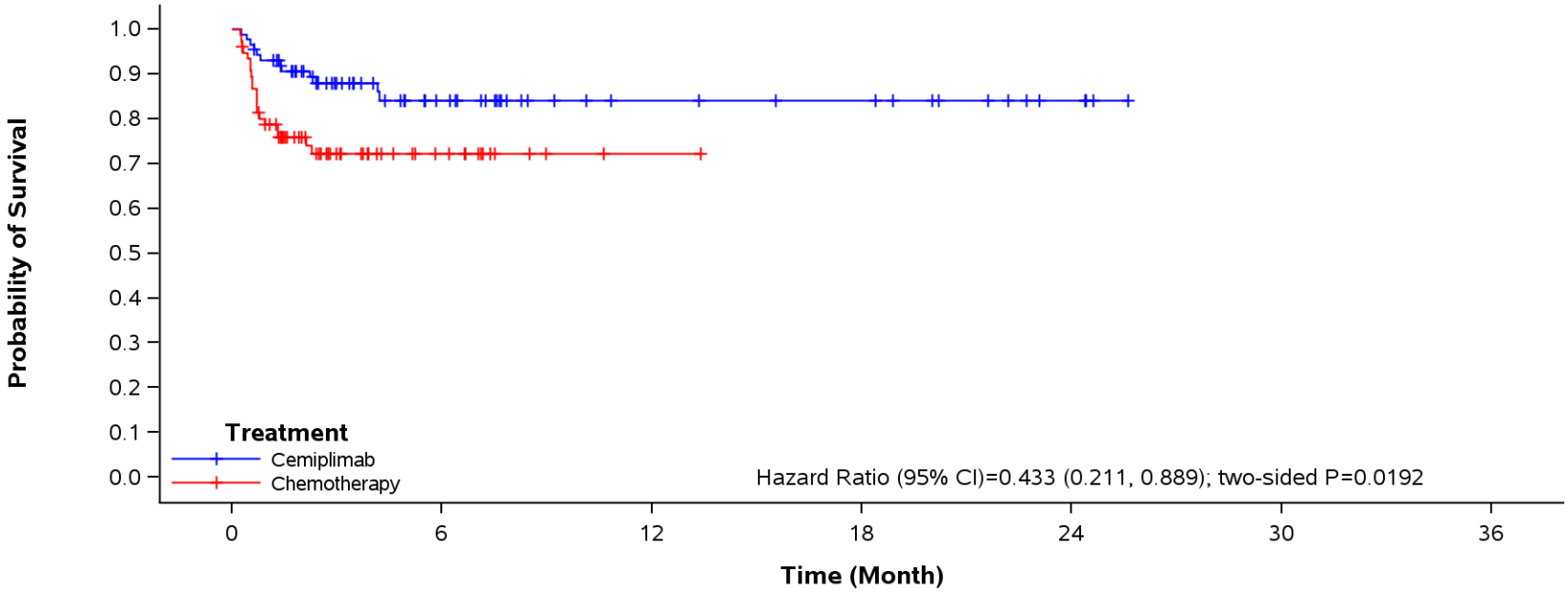
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders



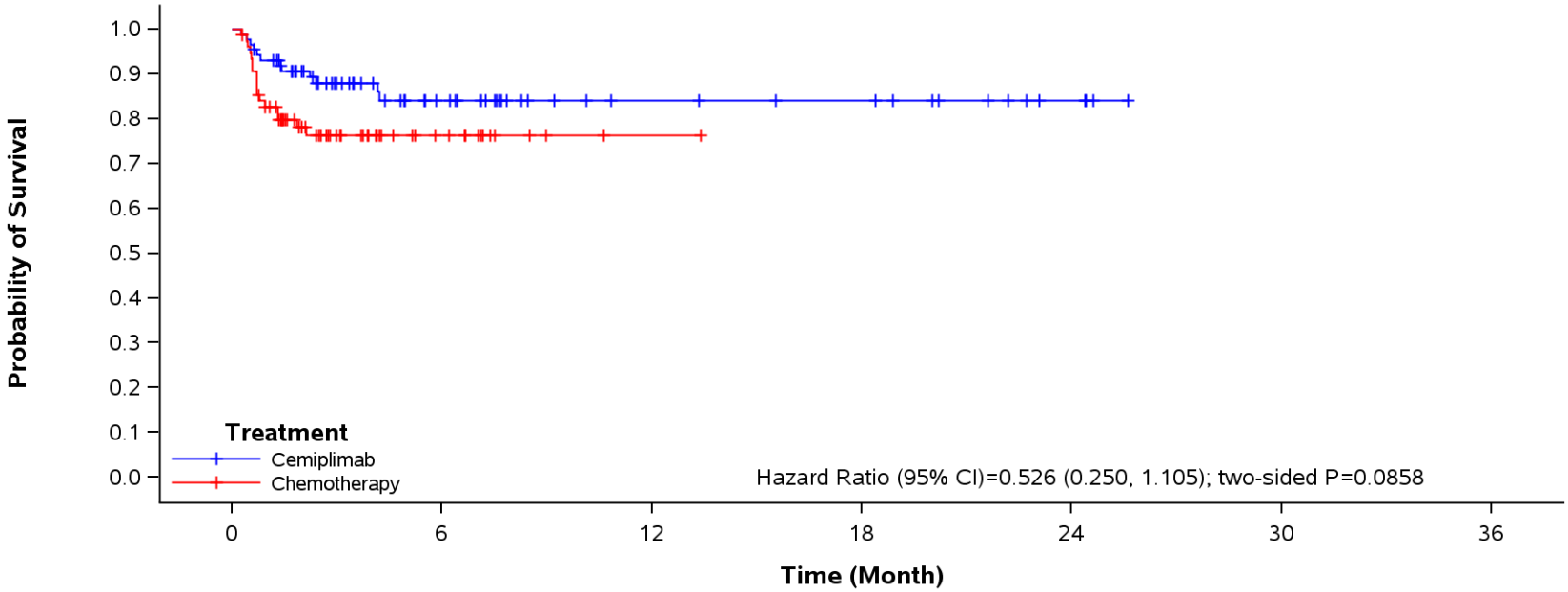

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 37 | 18 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Anaemia



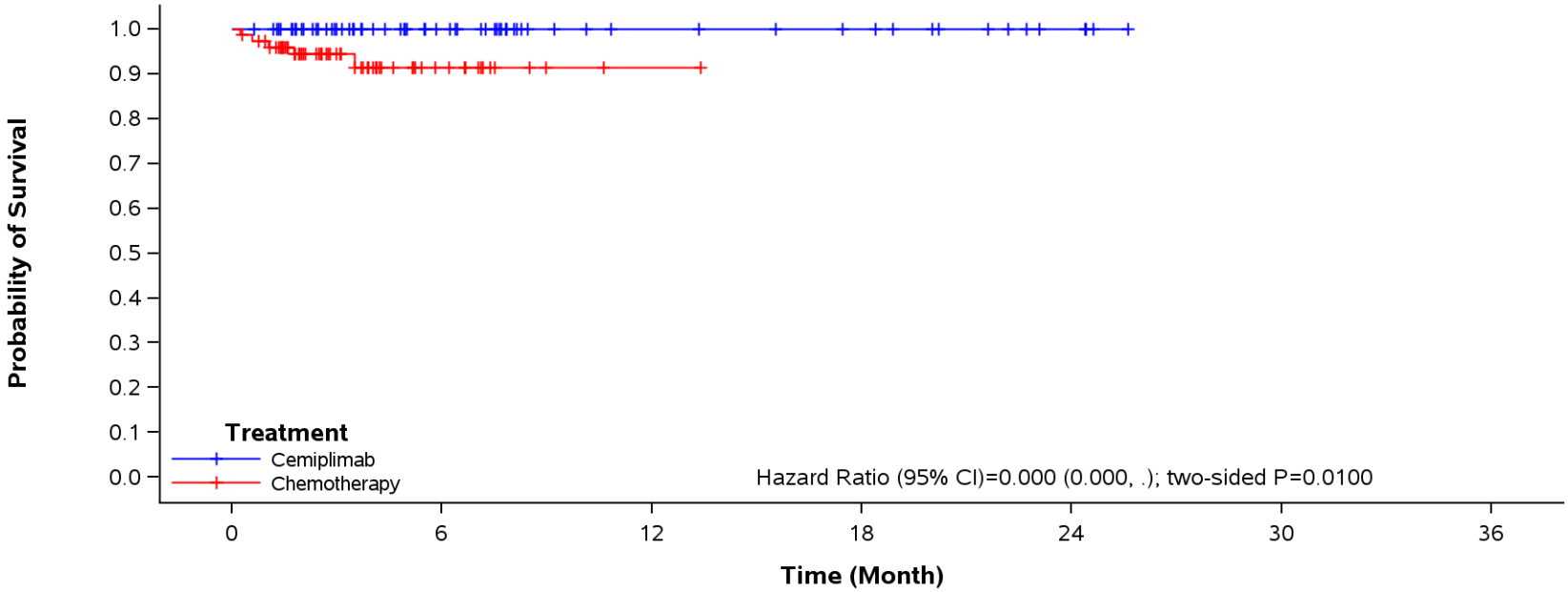

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 37 | 18 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Neutropenia



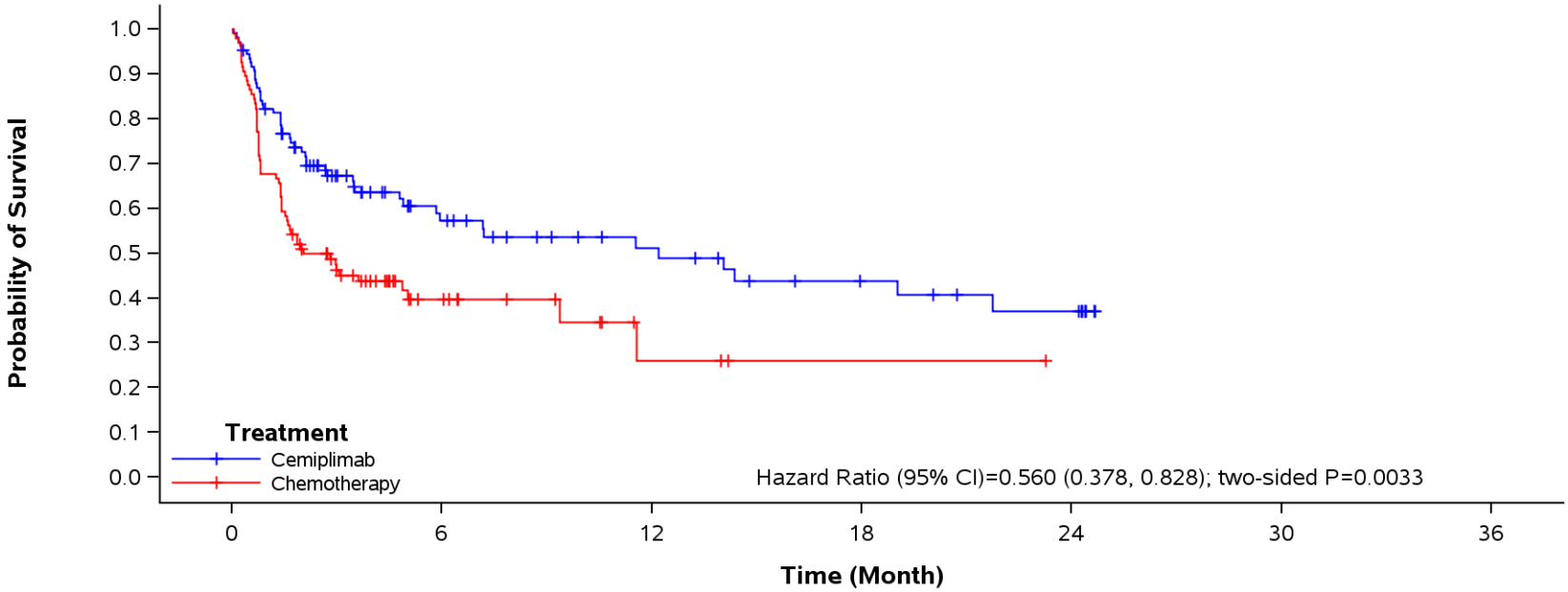

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 12 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Number of patients with any TEAE CTCAE Grade >= 3



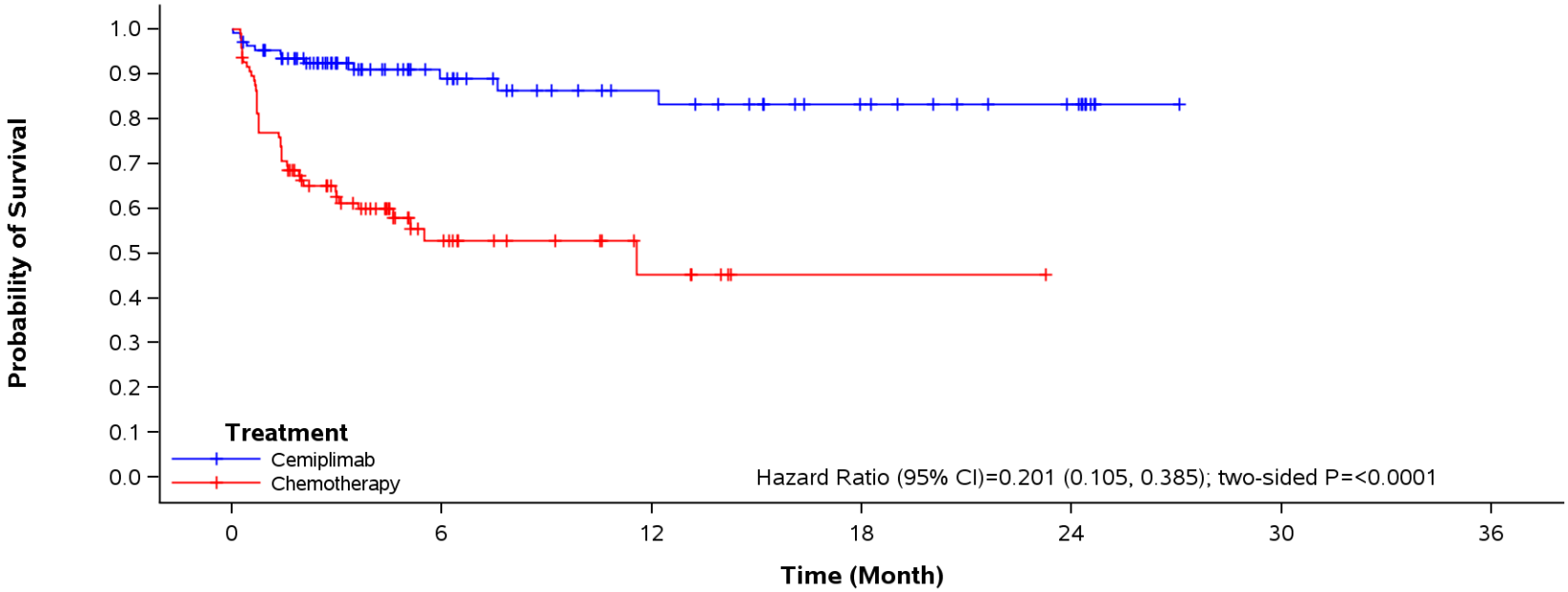

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 34 | 22 | 14 | 10 | 0 | 0 |
| Chemotherapy | 96 | 16 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 42 | 28 | 19 | 13 | 0 | 0 |
| Chemotherapy | 96 | 20 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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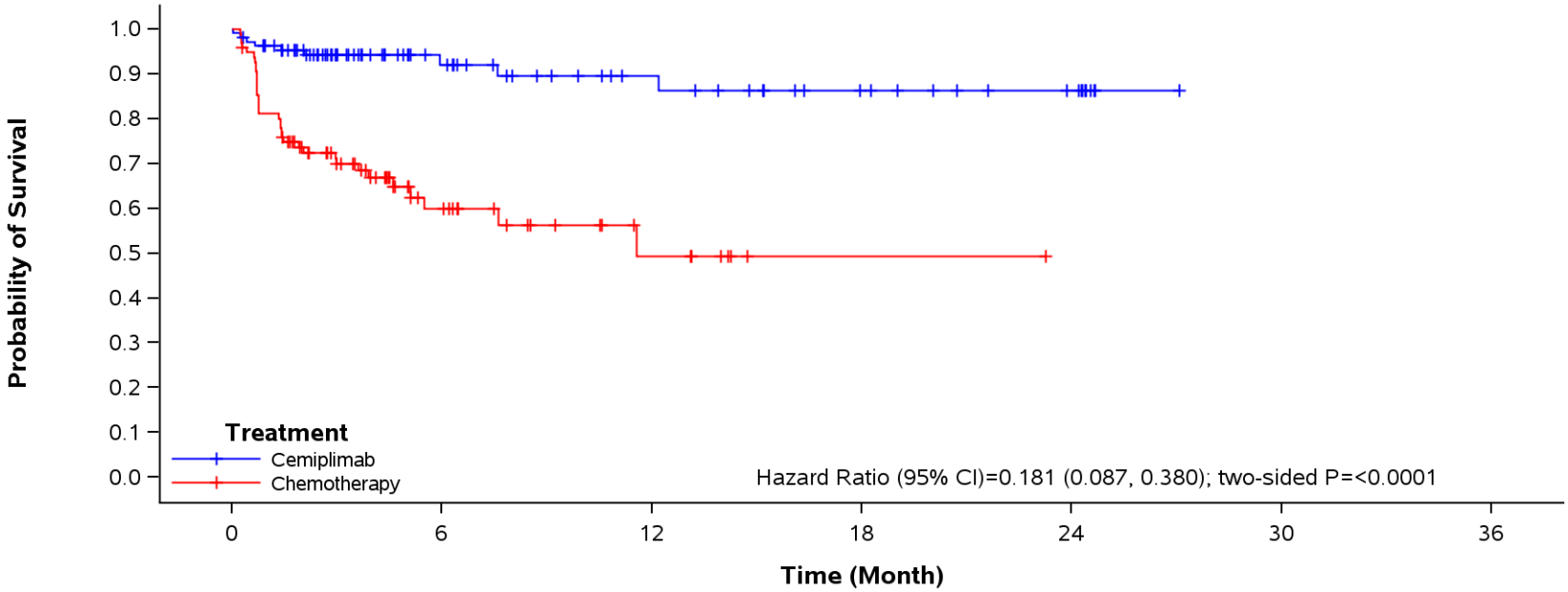
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 28 | 19 | 13 | 0 | 0 |
| Chemotherapy | 96 | 24 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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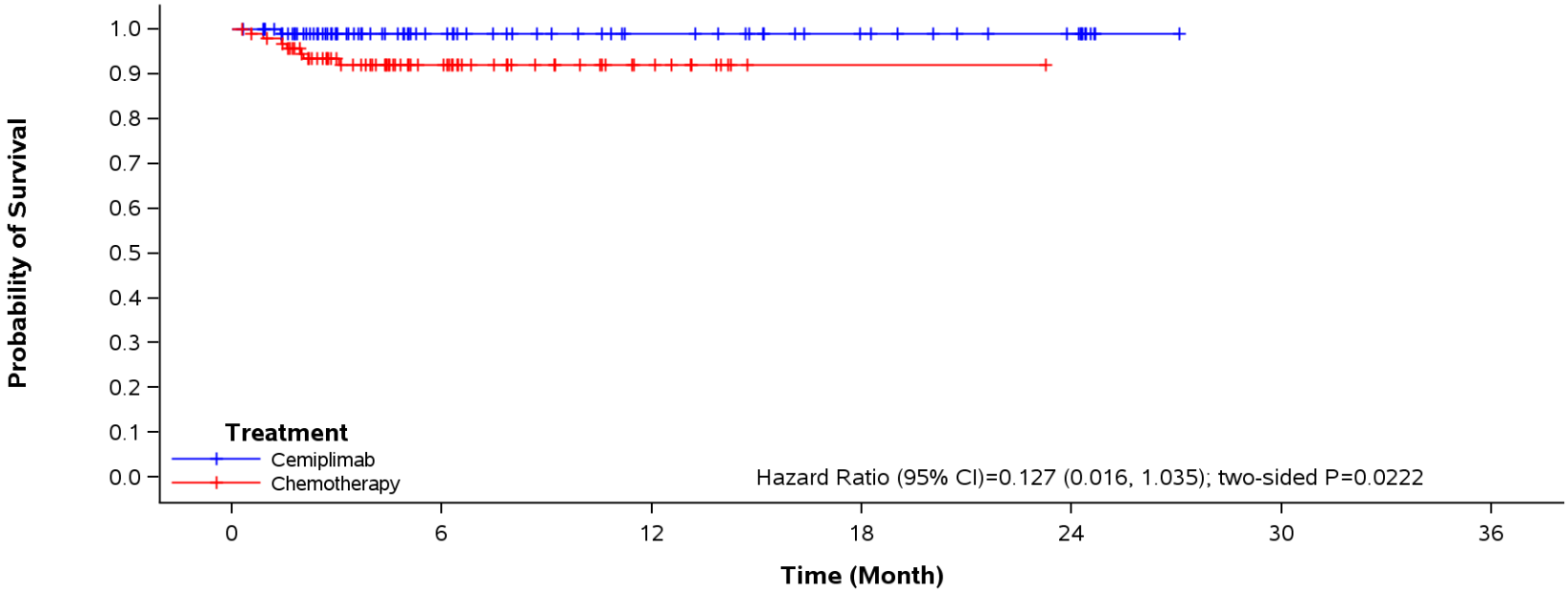
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Neutropenia



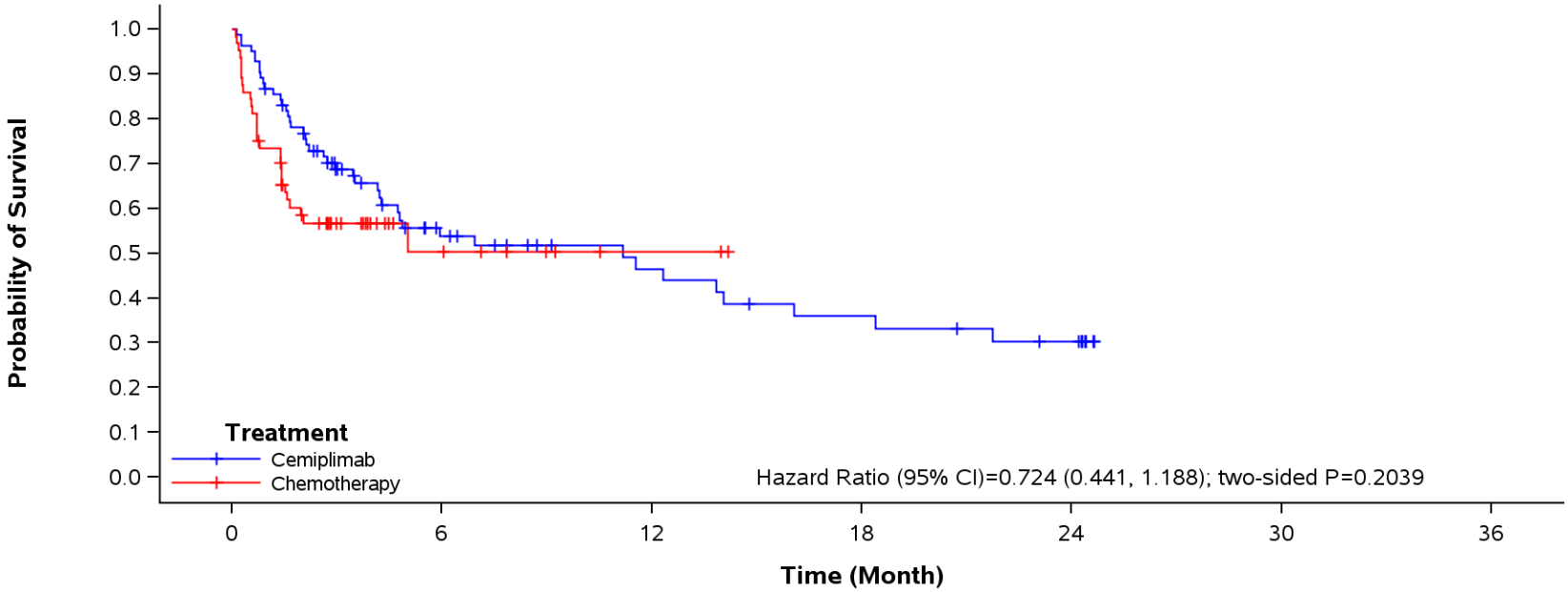

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 35 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
Number of patients with any TEAE CTCAE Grade >= 3



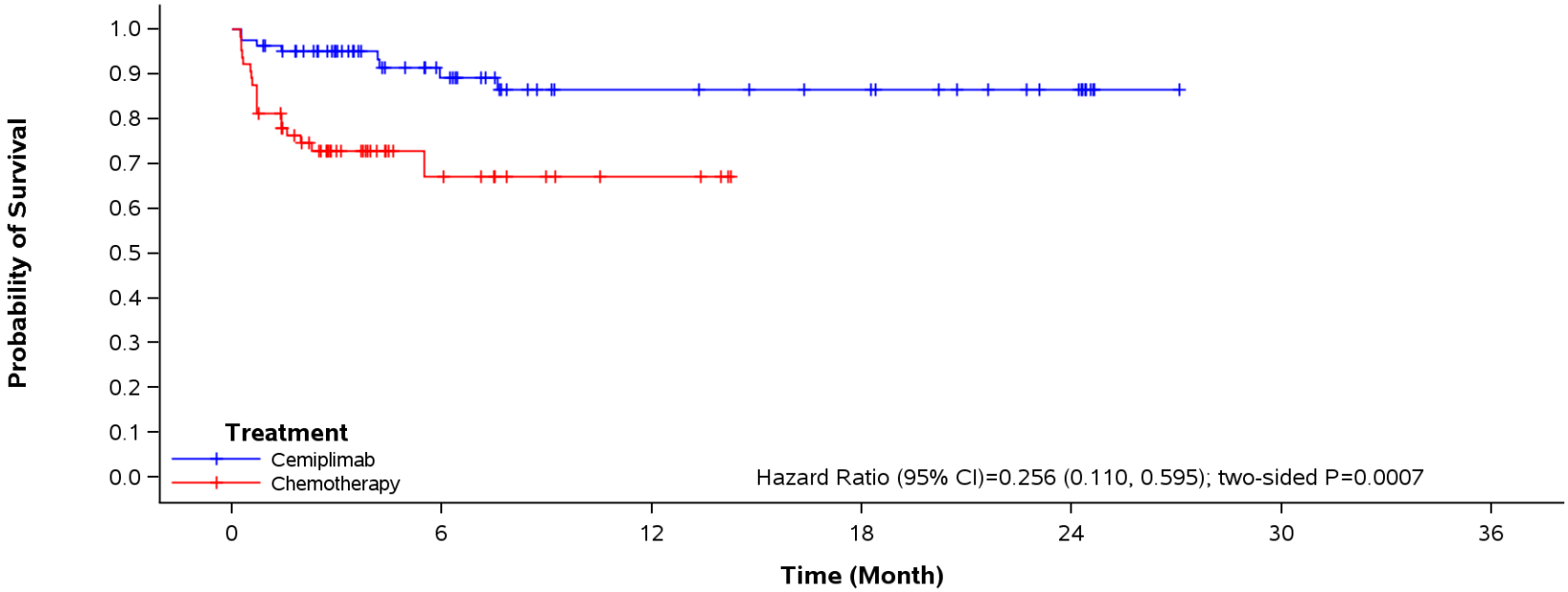

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 28 | 18 | 13 | 9 | 0 | 0 |
| Chemotherapy | 64 | 8 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders



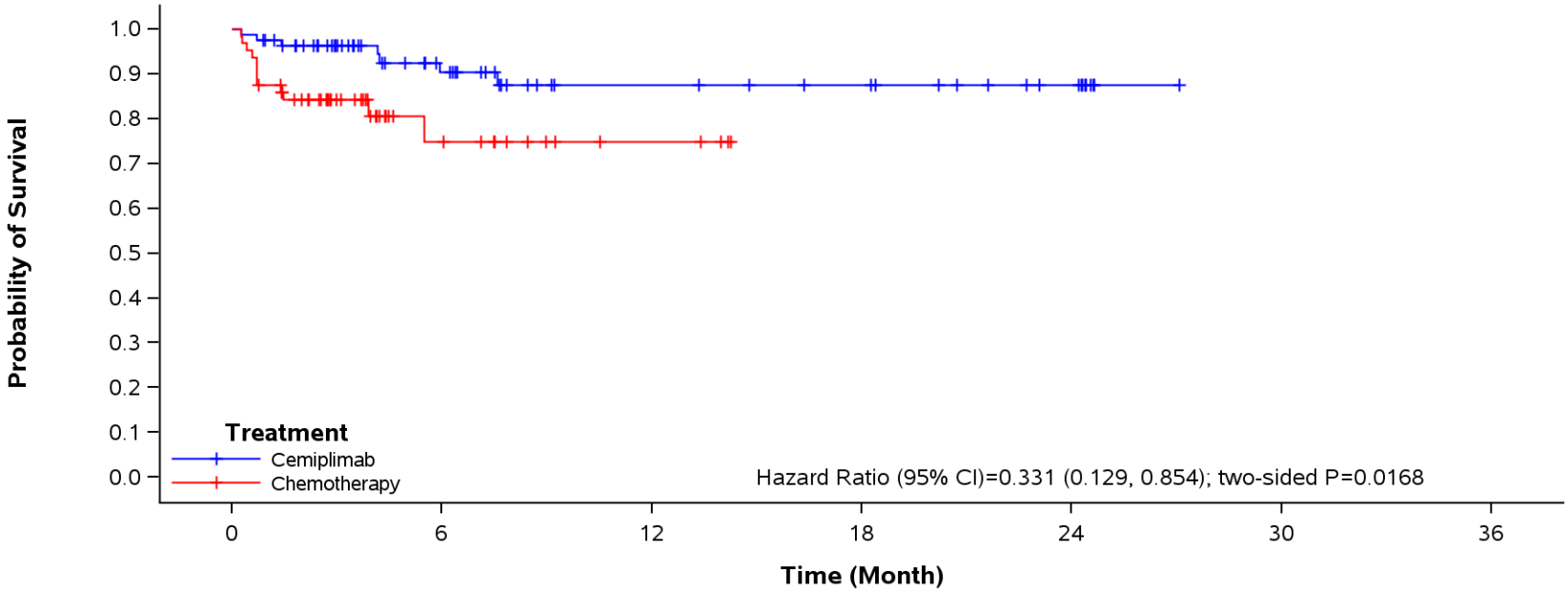

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 41 | 25 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 12 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Anaemia



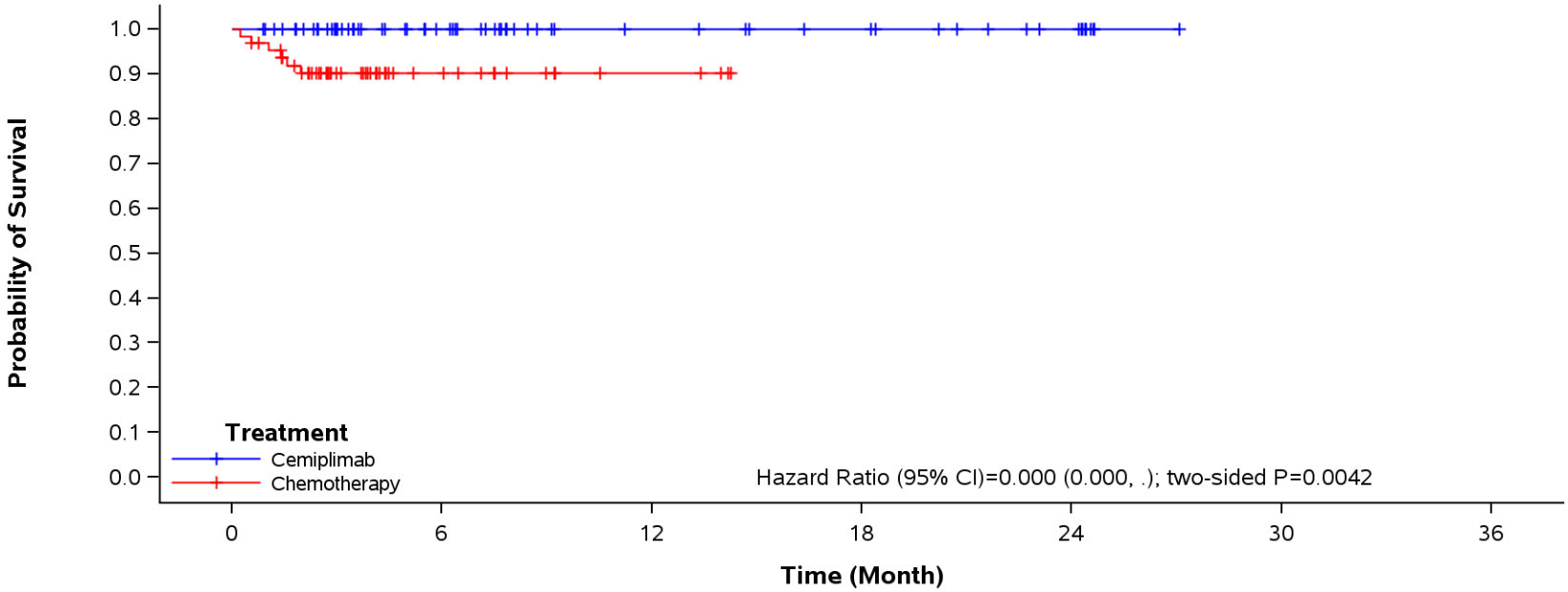

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 41 | 25 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 13 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Neutropenia



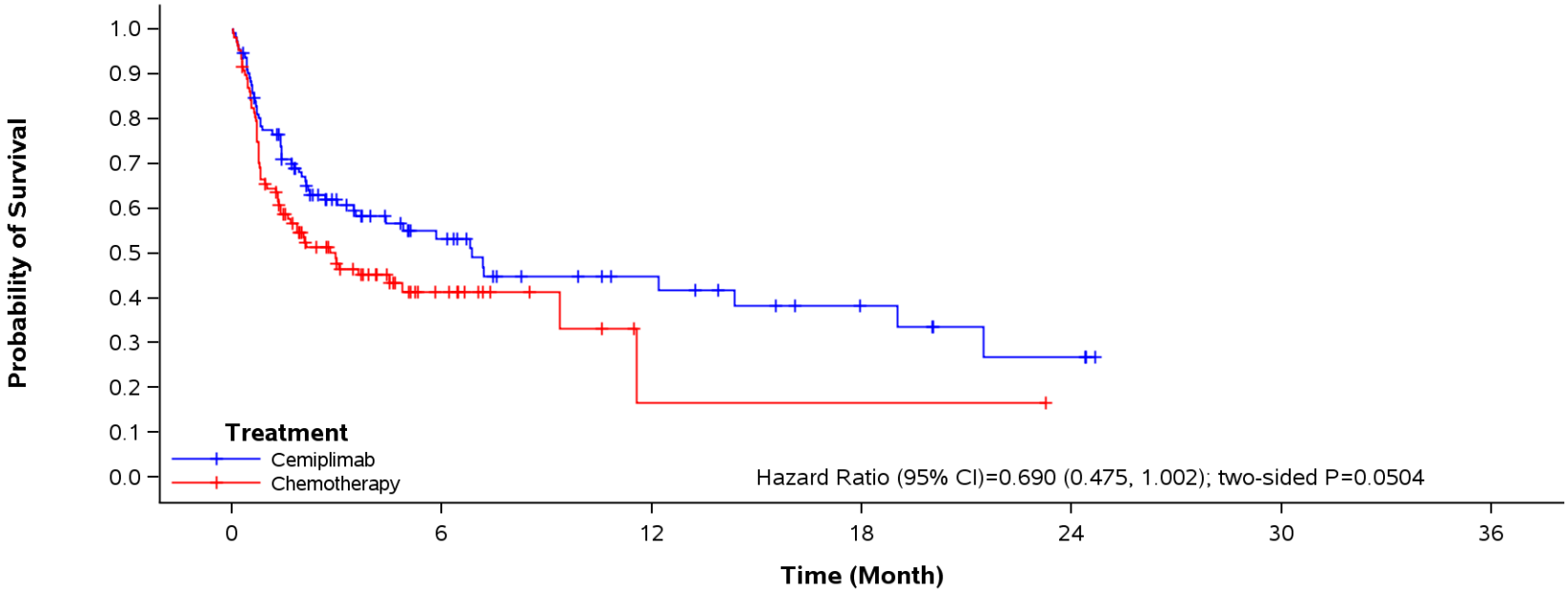

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 14 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
Number of patients with any TEAE CTCAE Grade >= 3



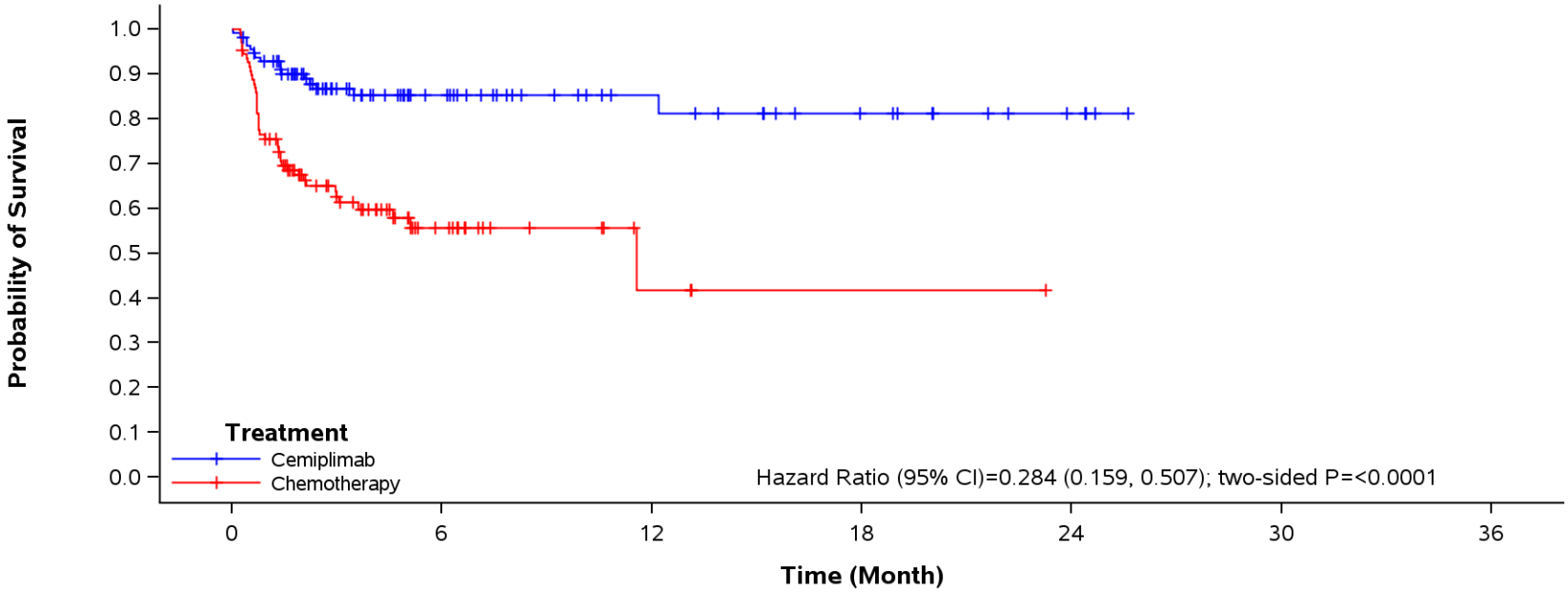

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 29 | 15 | 8 | 4 | 0 | 0 |
| Chemotherapy | 108 | 16 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders




Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 38 | 21 | 13 | 6 | 0 | 0 |
| Chemotherapy | 108 | 20 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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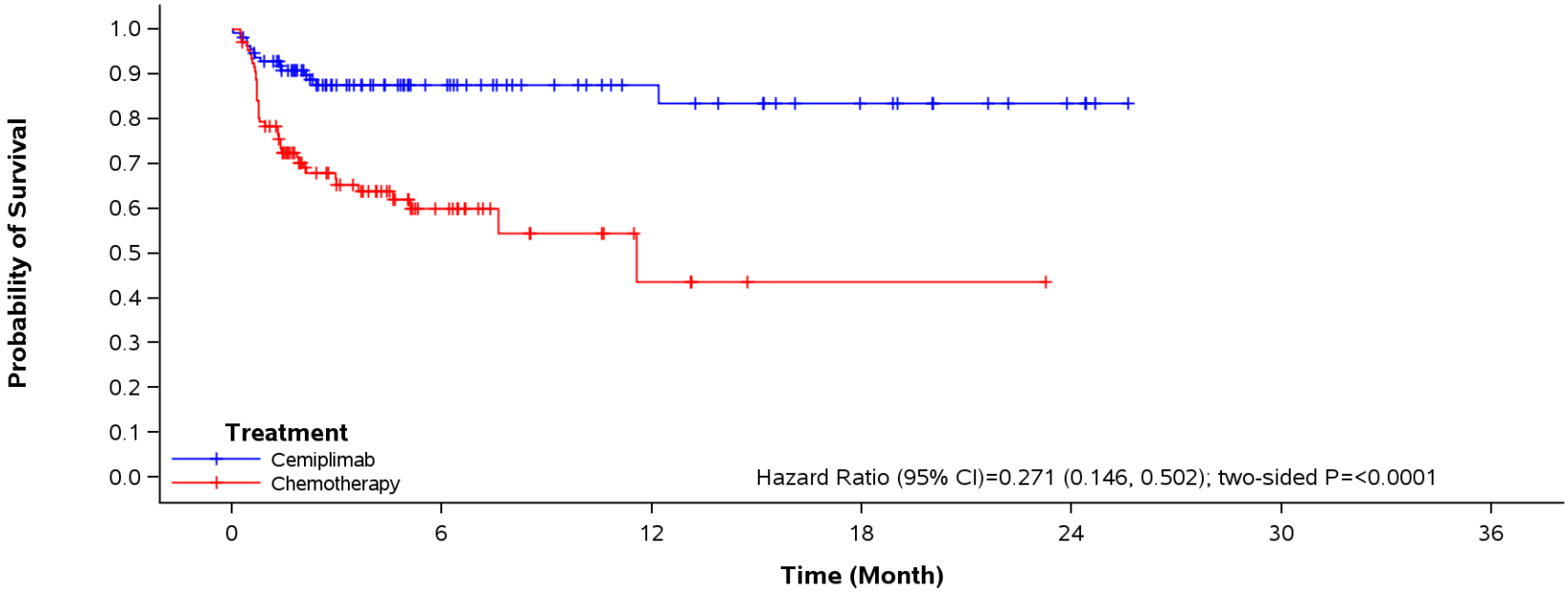
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Anaemia



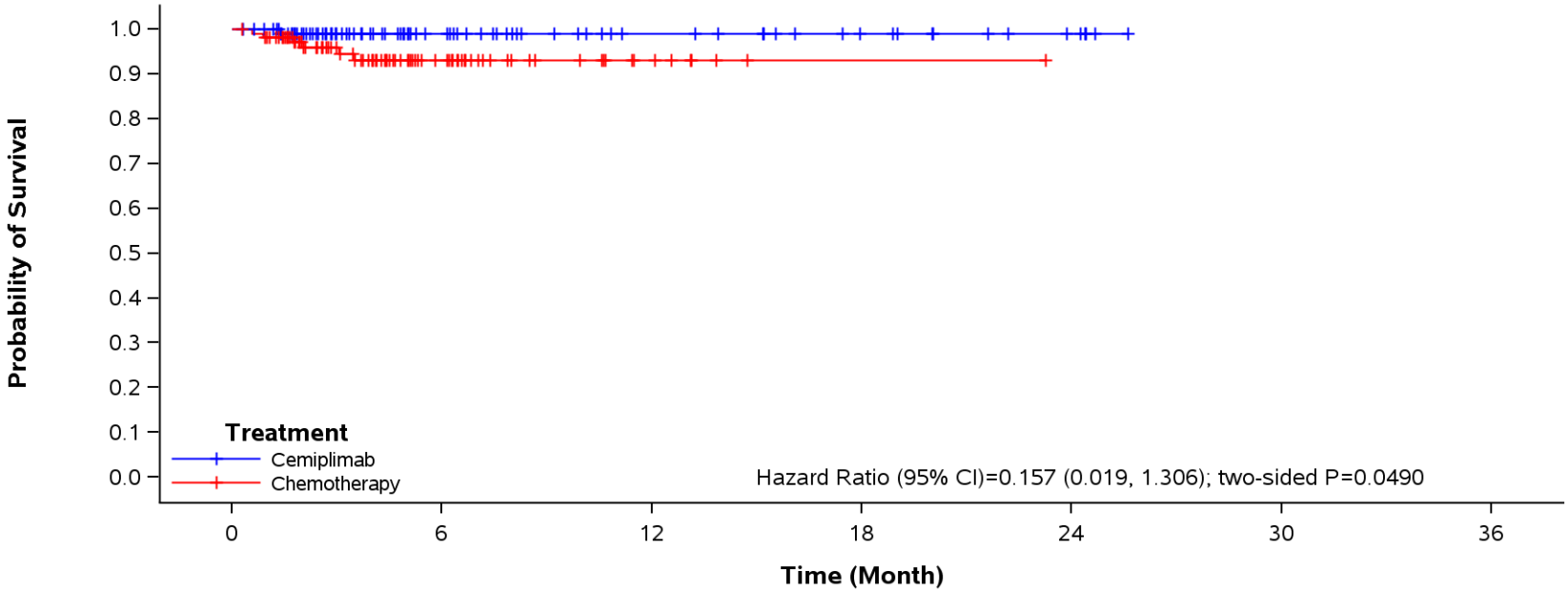

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 39 | 21 | 13 | 6 | 0 | 0 |
| Chemotherapy | 108 | 23 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Neutropenia



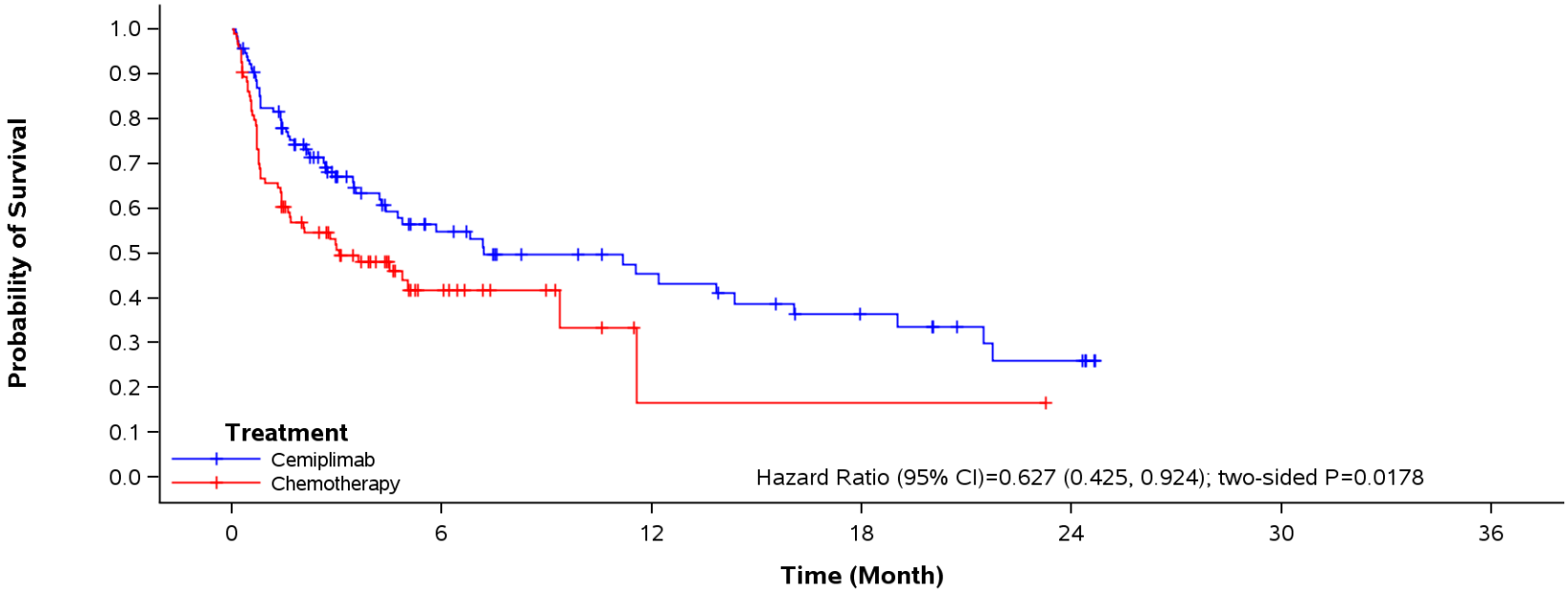

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 33 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Number of patients with any TEAE CTCAE Grade >= 3



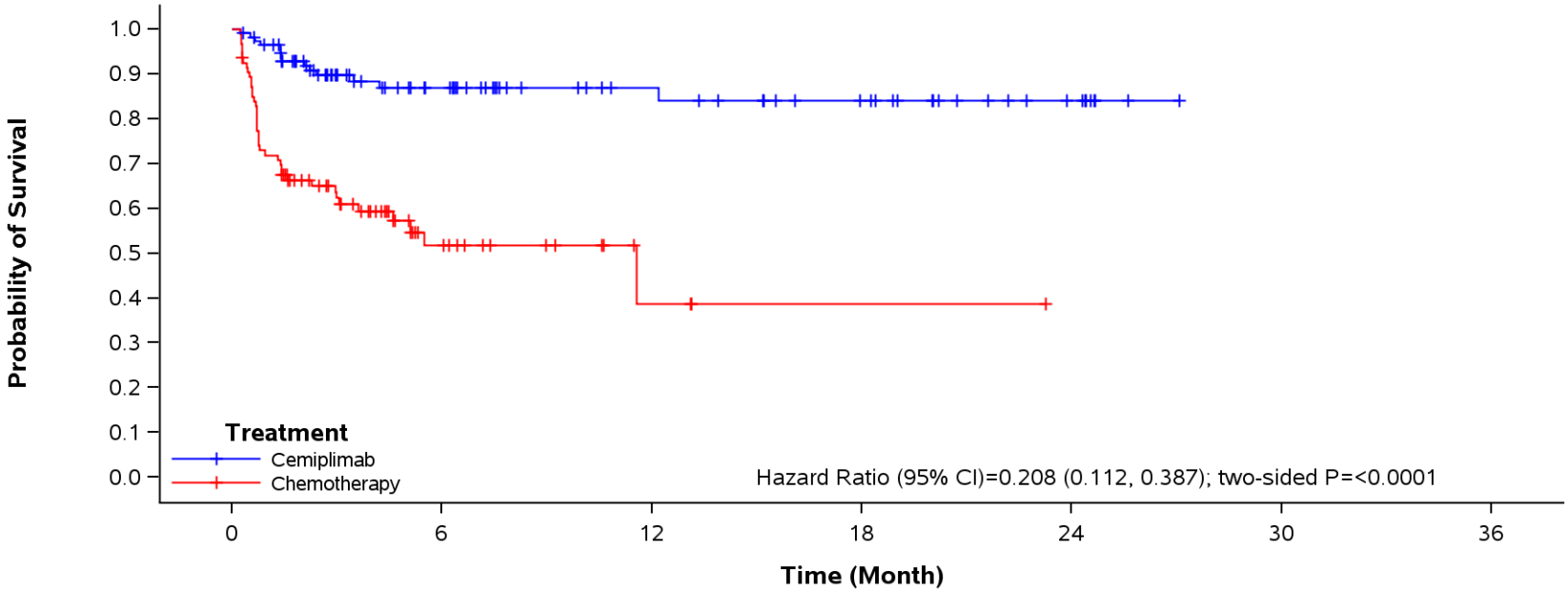

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 34 | 21 | 13 | 7 | 0 | 0 |
| Chemotherapy | 94 | 15 | 1 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 49 | 31 | 23 | 11 | 0 | 0 |
| Chemotherapy | 94 | 17 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

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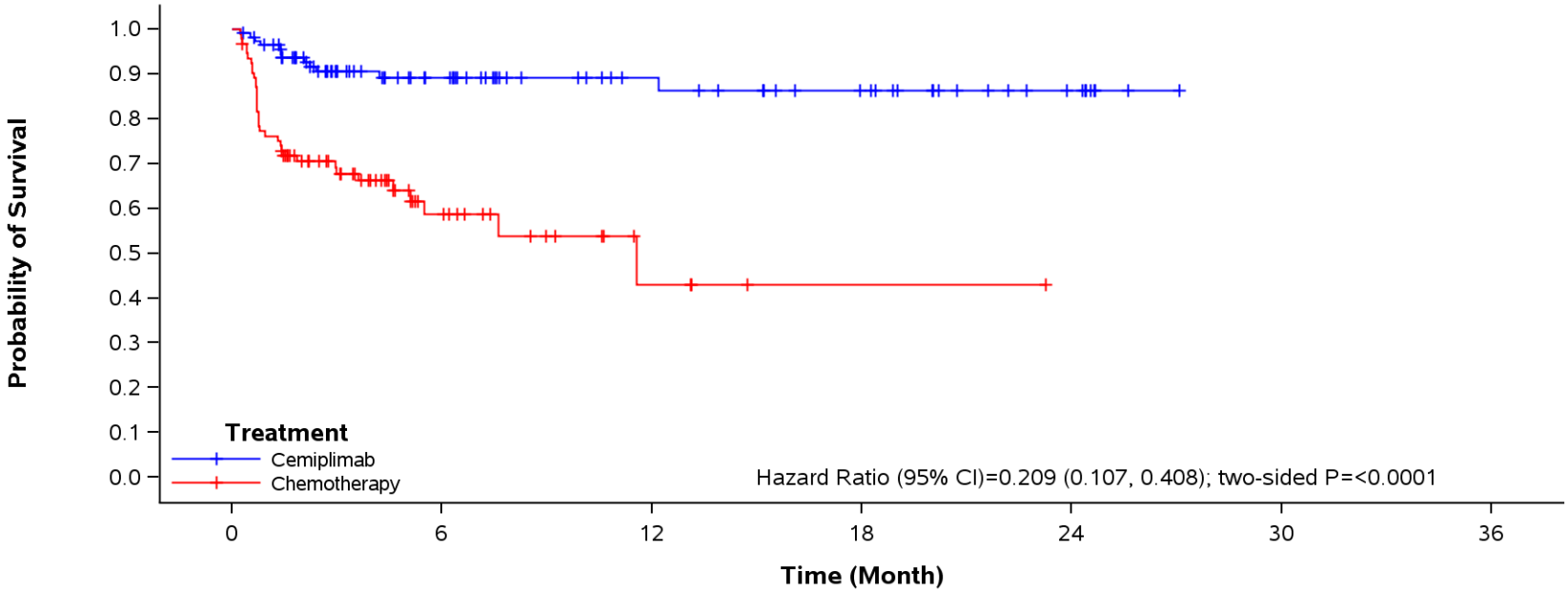
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 50 | 31 | 23 | 11 | 0 | 0 |
| Chemotherapy | 94 | 20 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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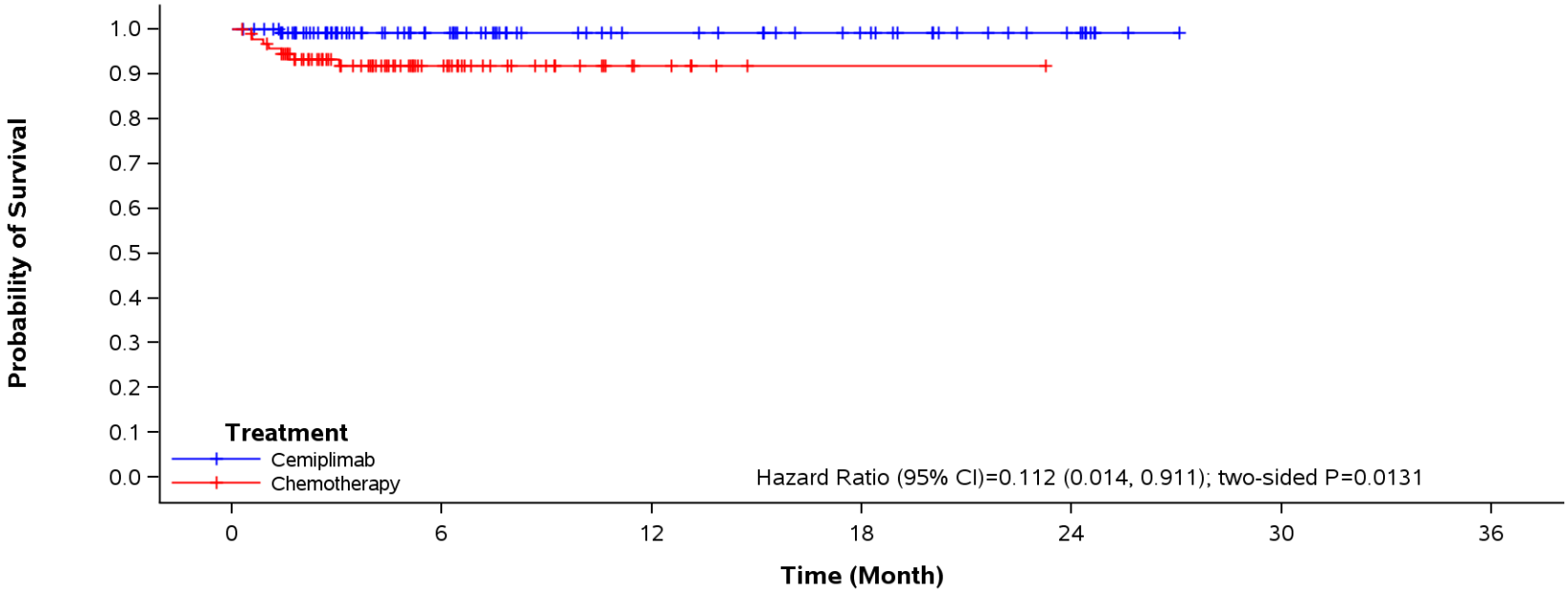
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 31 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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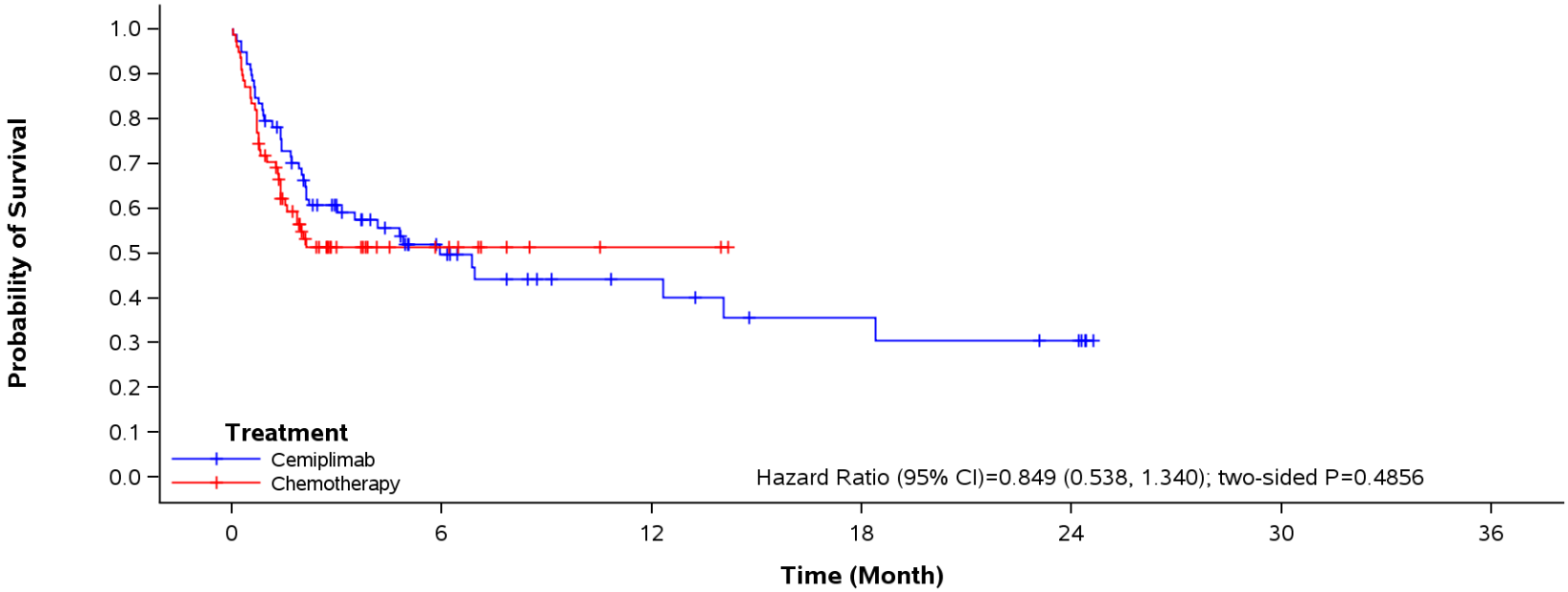
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Number of patients with any TEAE CTCAE Grade >= 3




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 22 | 11 | 7 | 5 | 0 | 0 |
| Chemotherapy | 78 | 9 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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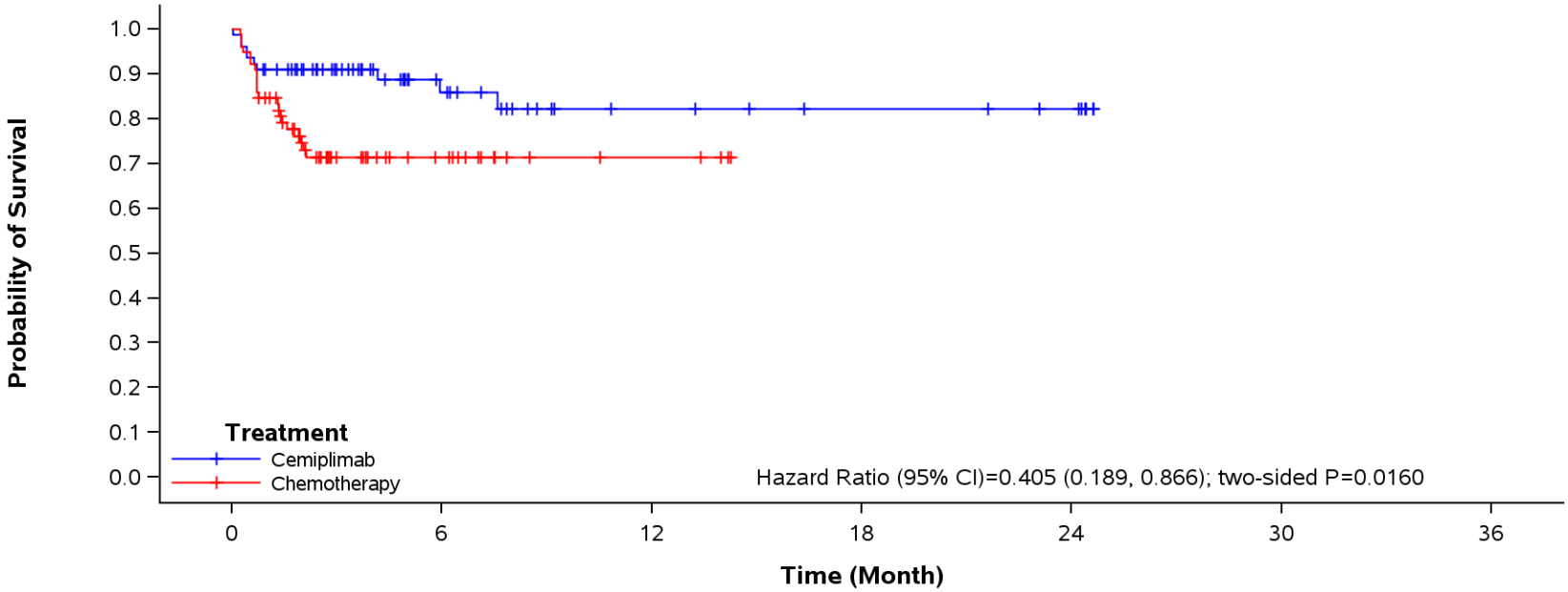
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders



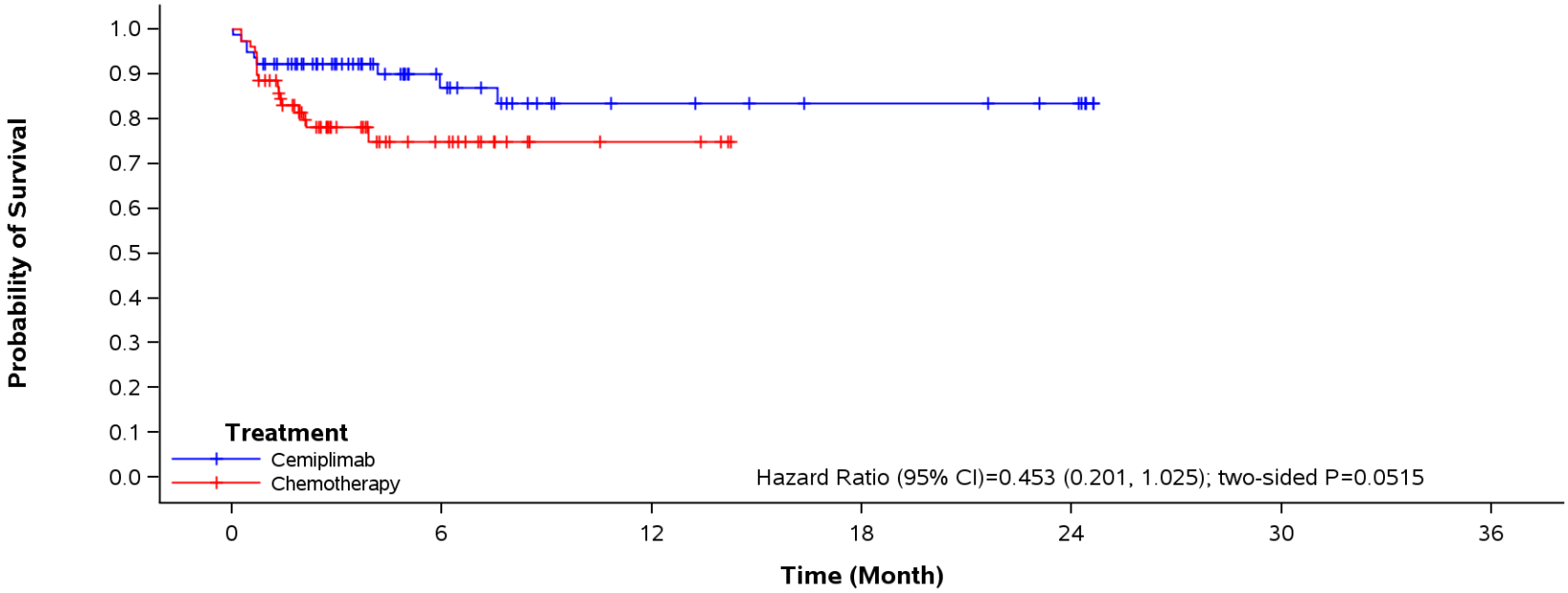

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 29 | 14 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 15 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



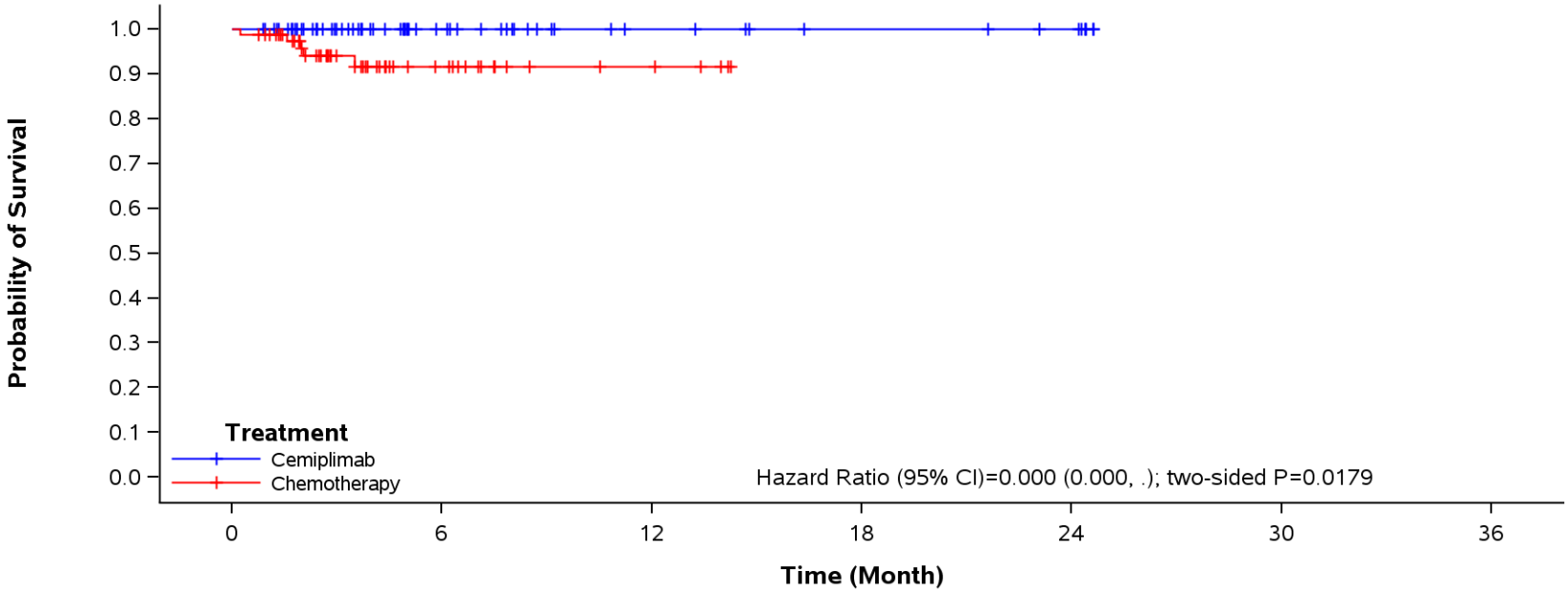

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 29 | 14 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 16 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
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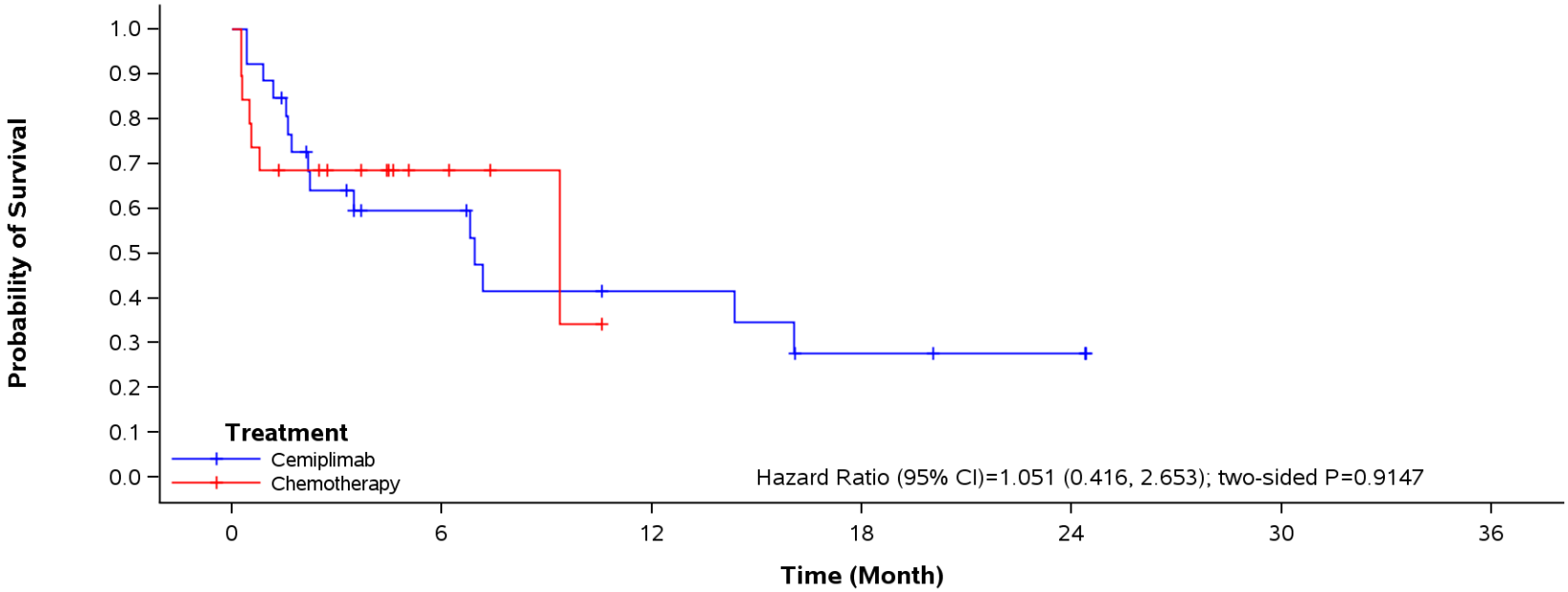
Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Number of patients with any TEAE CTCAE Grade >= 3



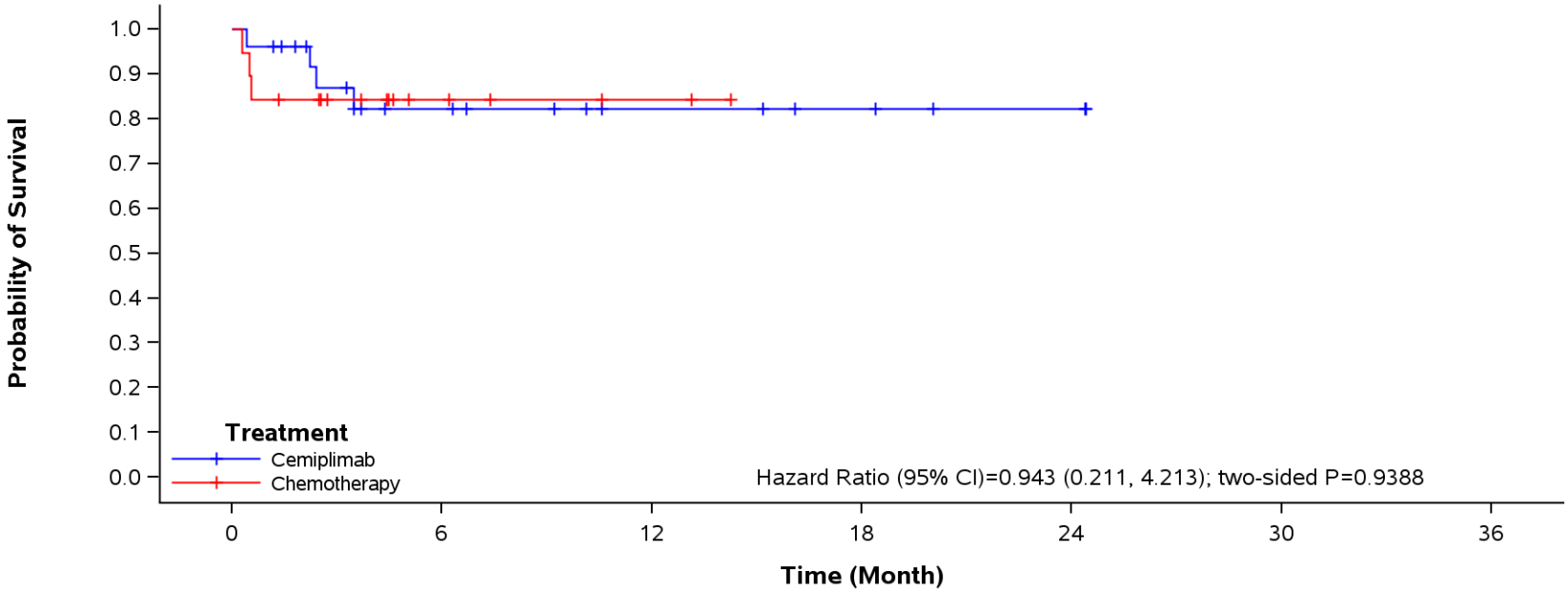

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 11 | 6 | 3 | 2 | 0 | 0 |
| Chemotherapy | 19 | 4 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders



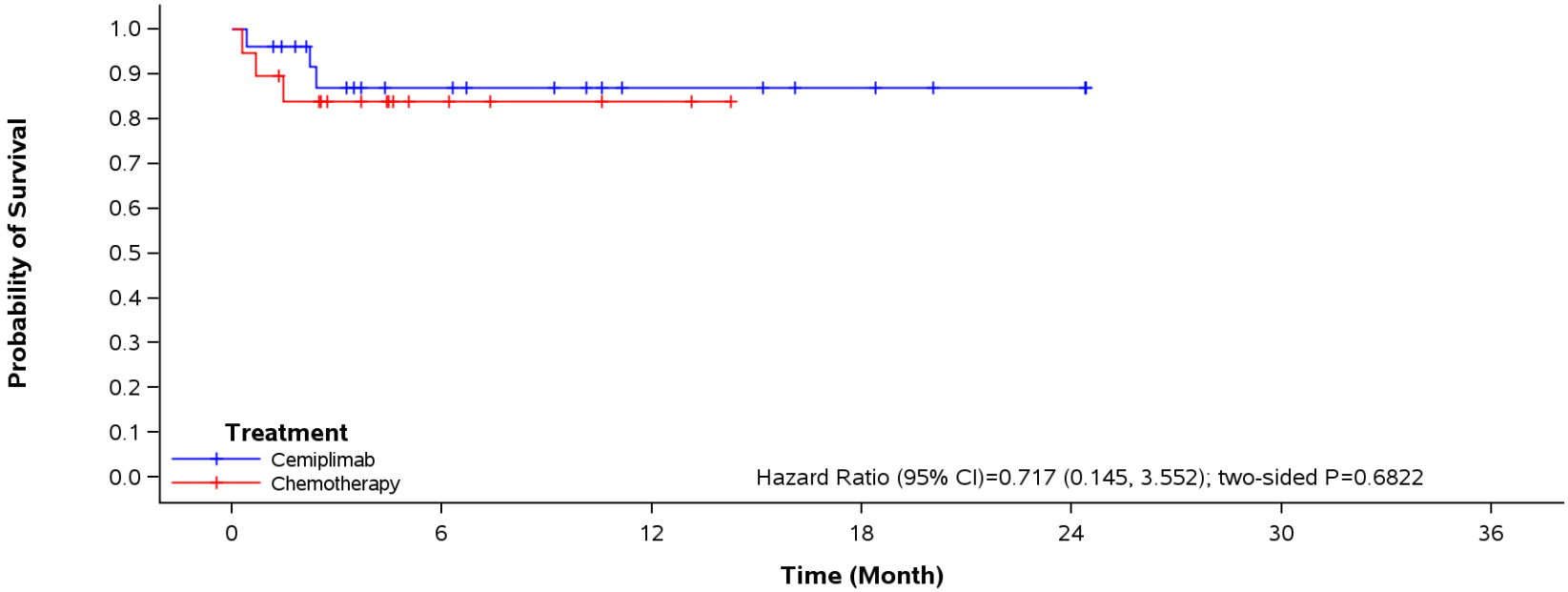

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 12 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



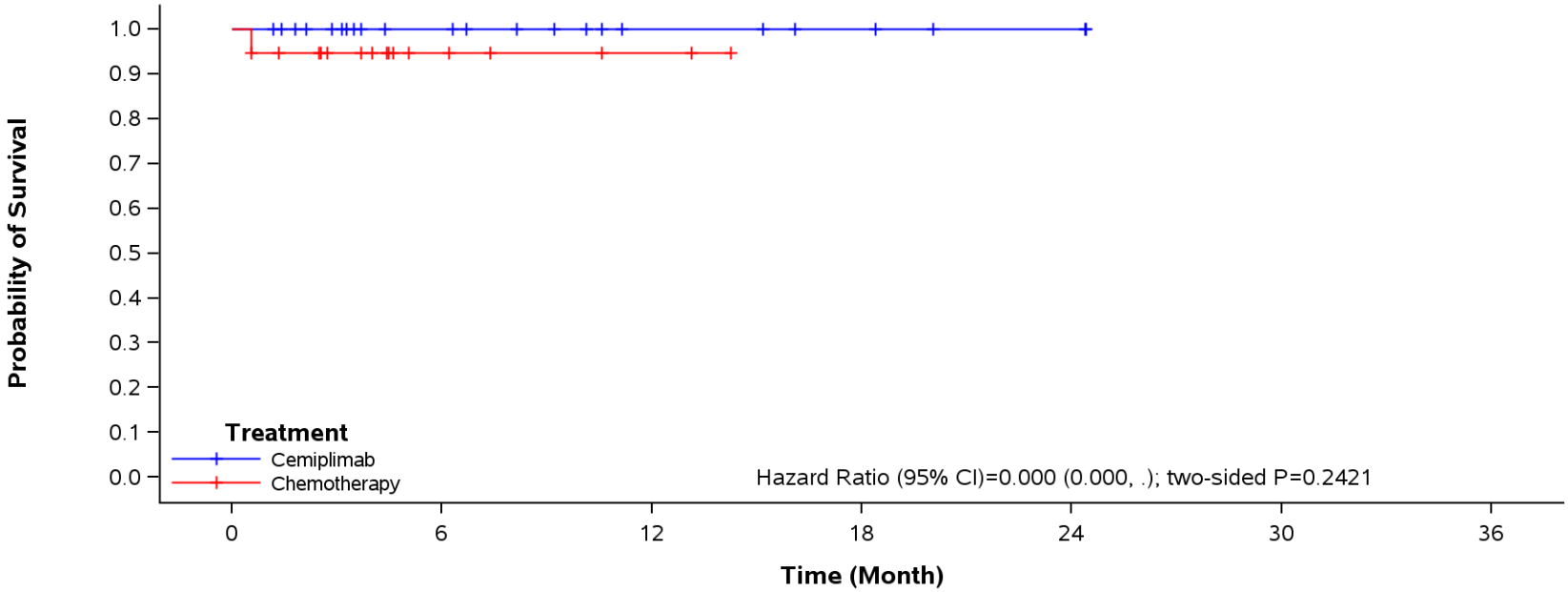

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 13 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



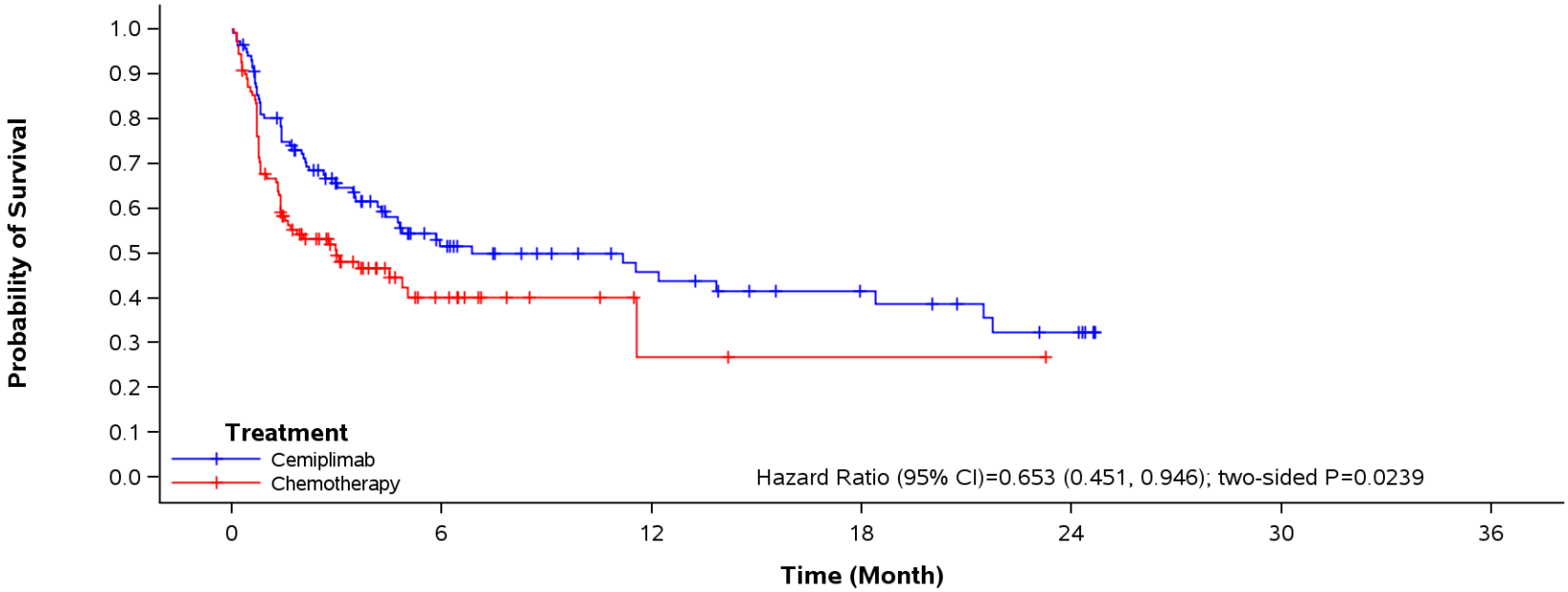

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Number of patients with any TEAE CTCAE Grade >= 3



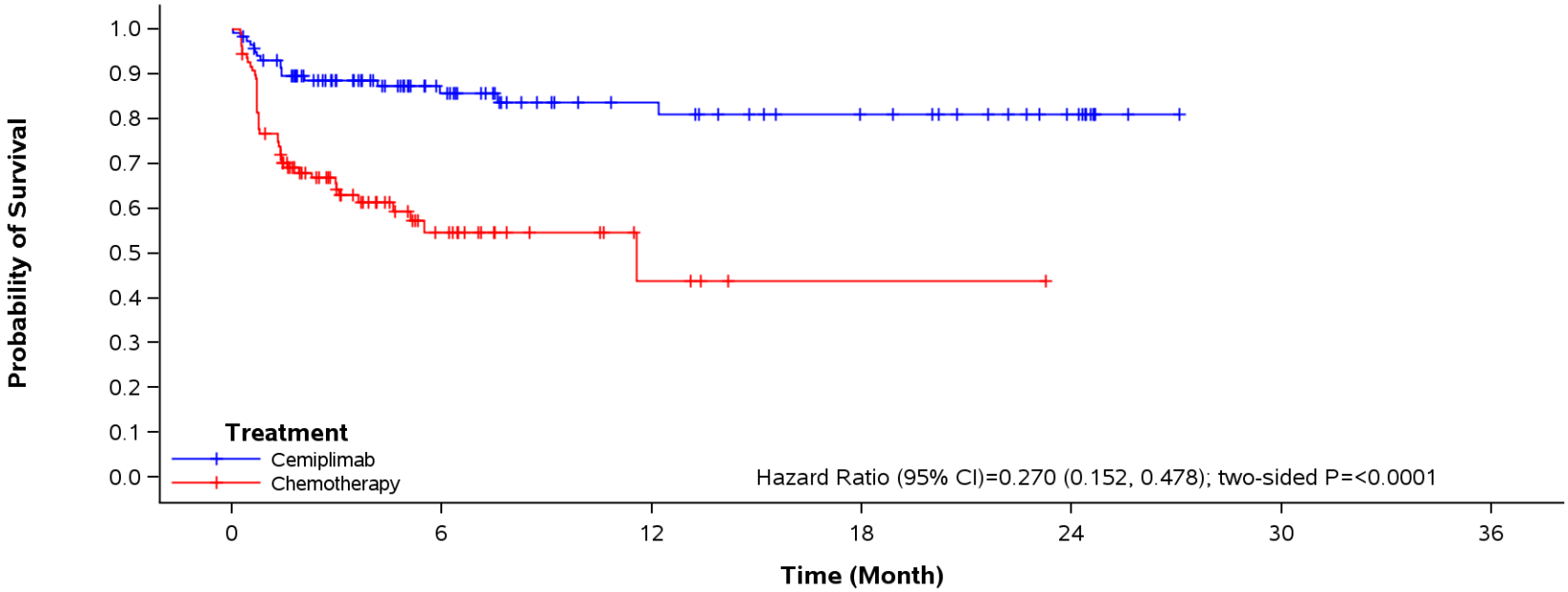

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 36 | 22 | 15 | 9 | 0 | 0 |
| Chemotherapy | 109 | 15 | 2 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders




**Number of Subjects at risk**

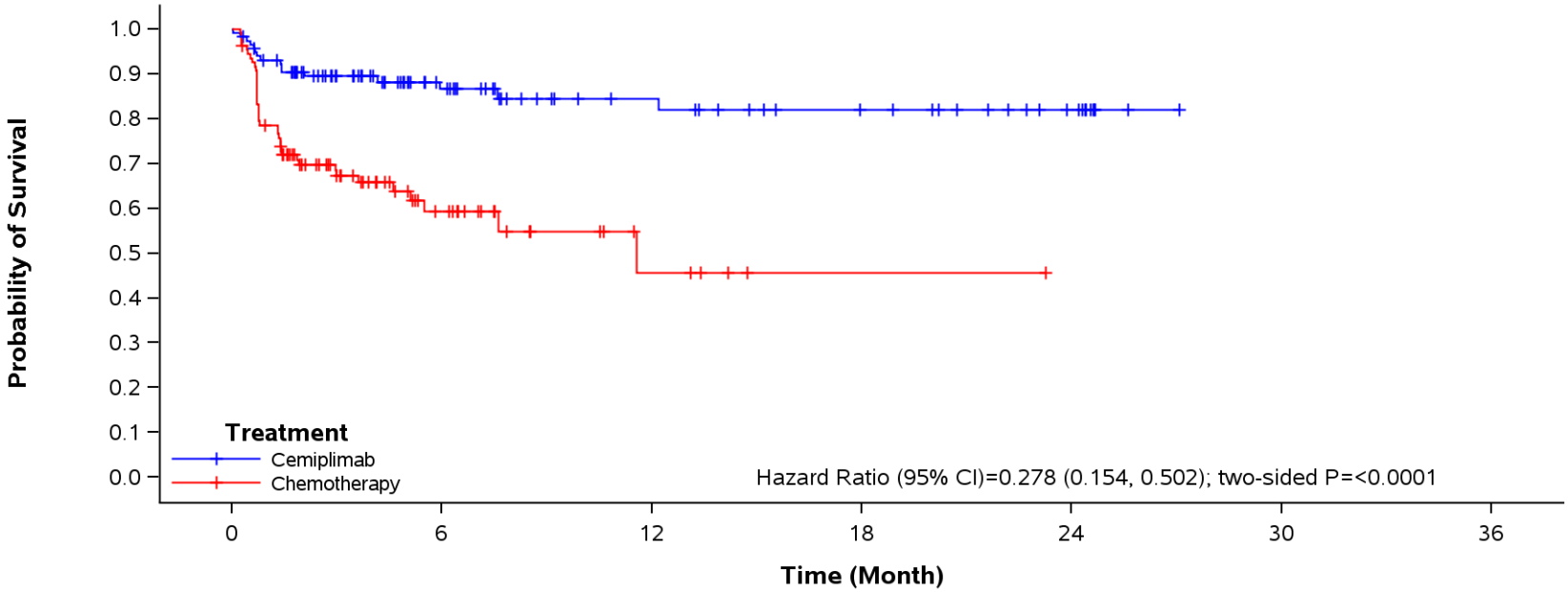
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 54 | 32 | 24 | 15 | 0 | 0 |
| Chemotherapy | 109 | 21 | 4 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:04:50:12, haijin.tang)

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Anaemia



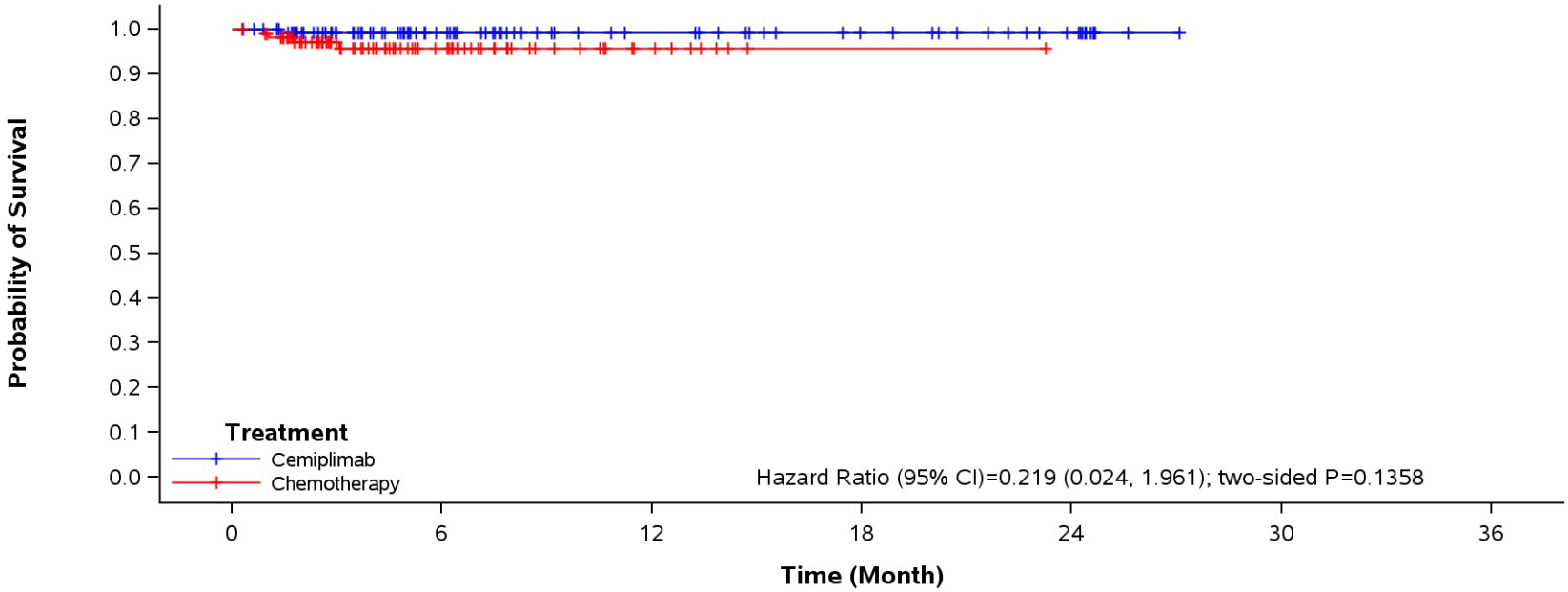

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 54 | 32 | 24 | 15 | 0 | 0 |
| Chemotherapy | 109 | 24 | 5 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Neutropenia



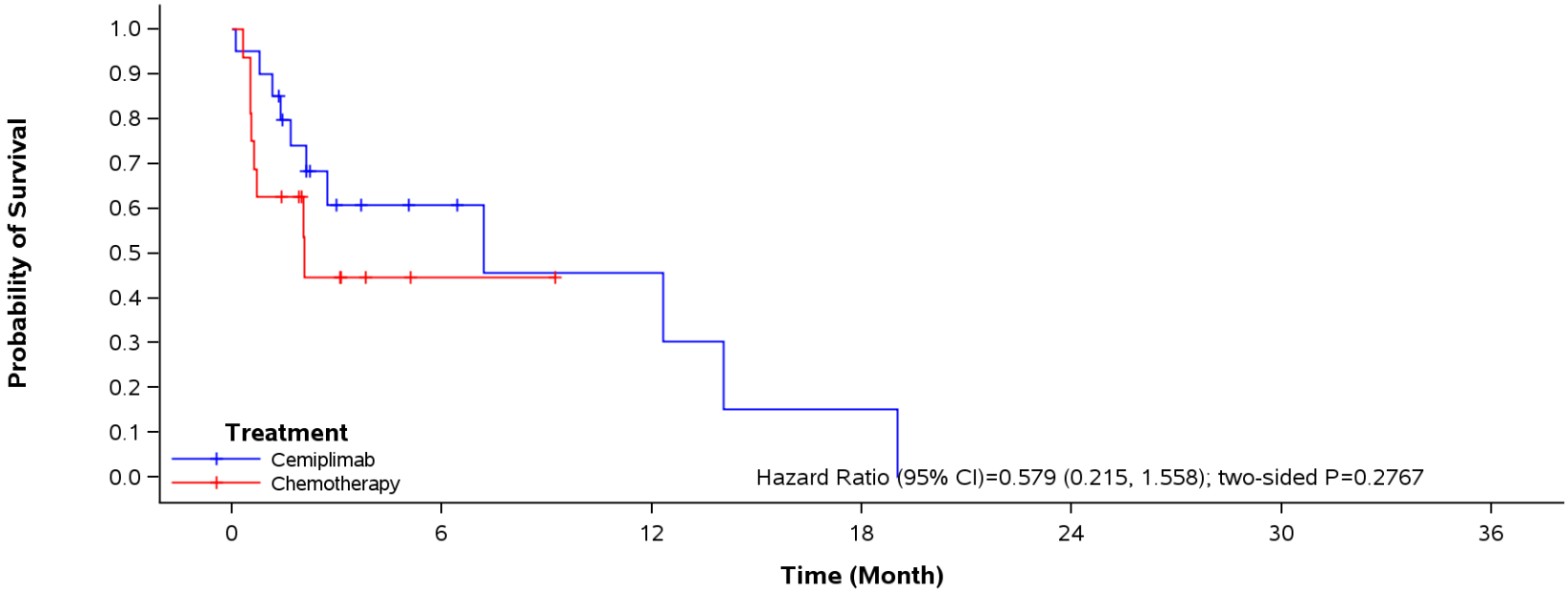

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Number of patients with any TEAE CTCAE Grade >= 3



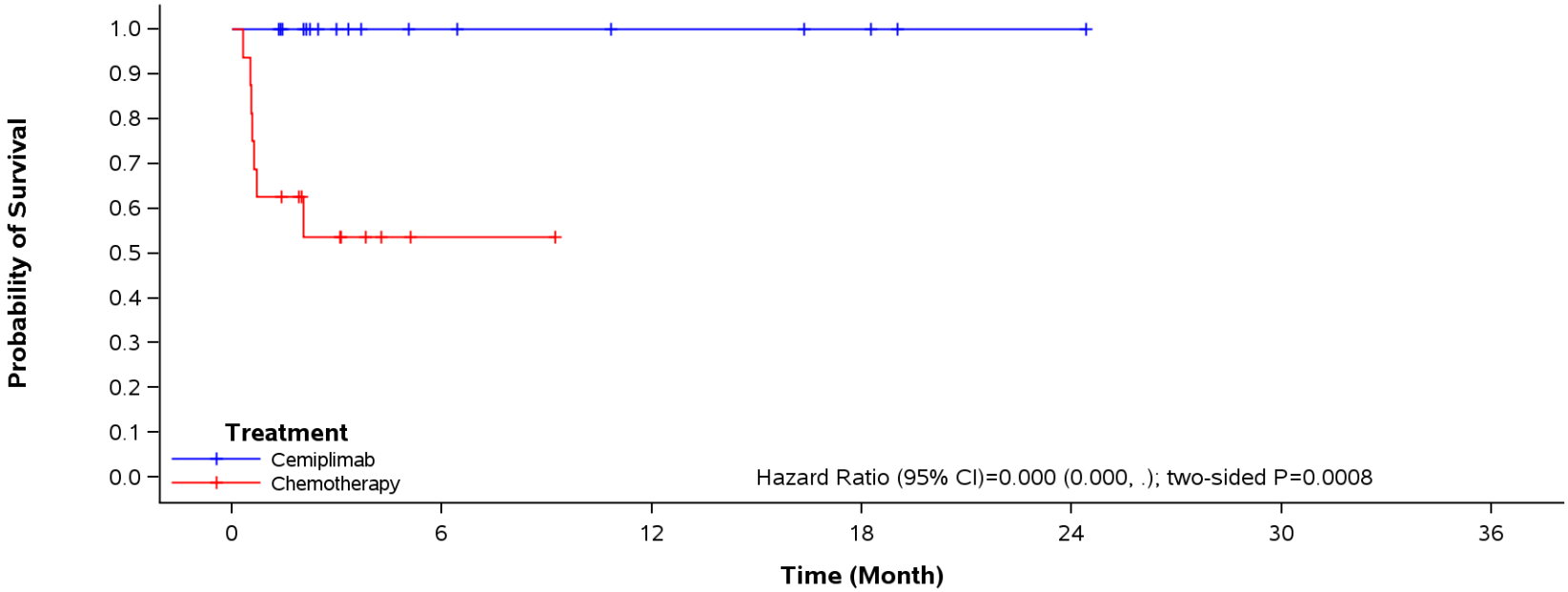

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 5 | 3 | 1 | 0 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders



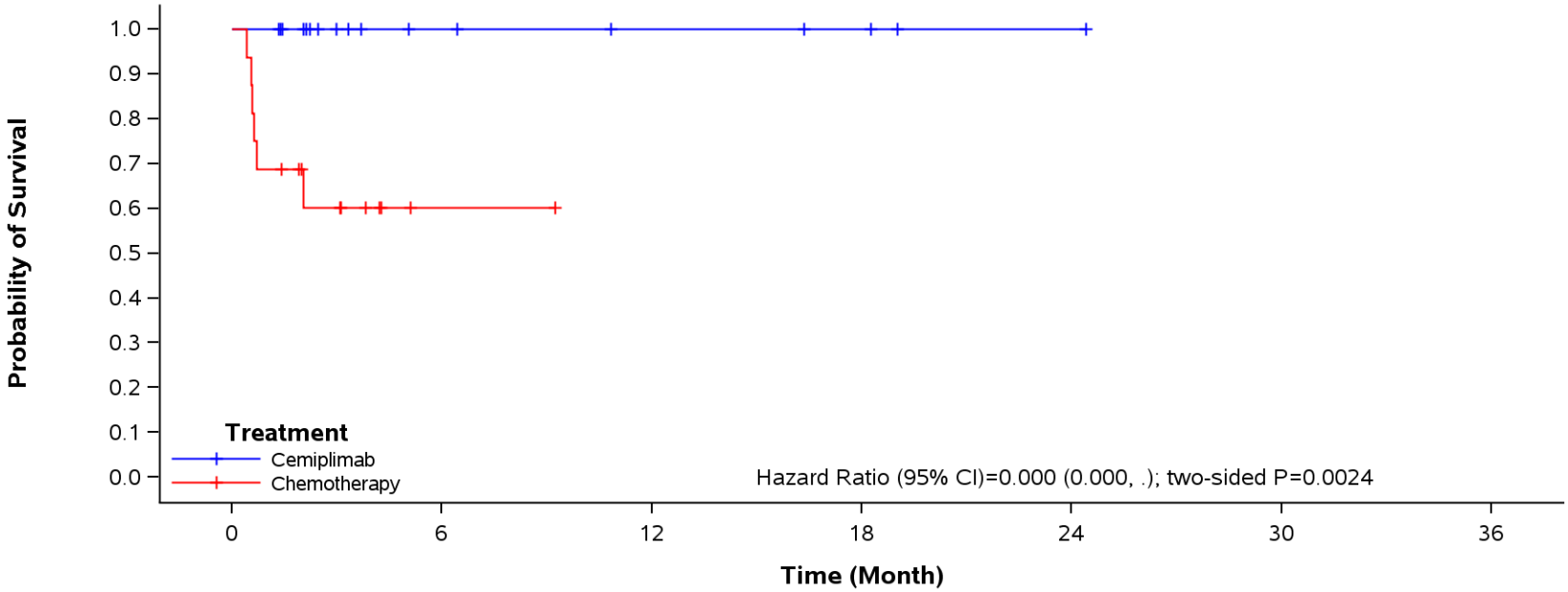

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



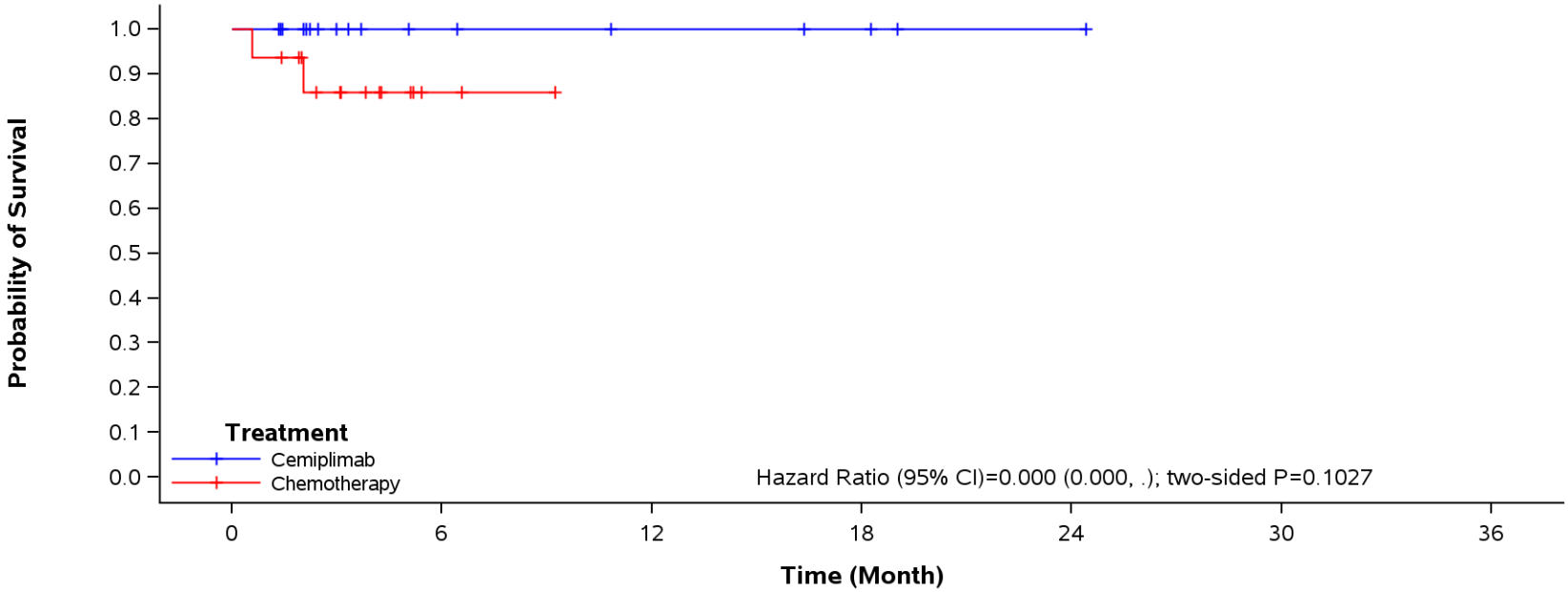

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 1 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



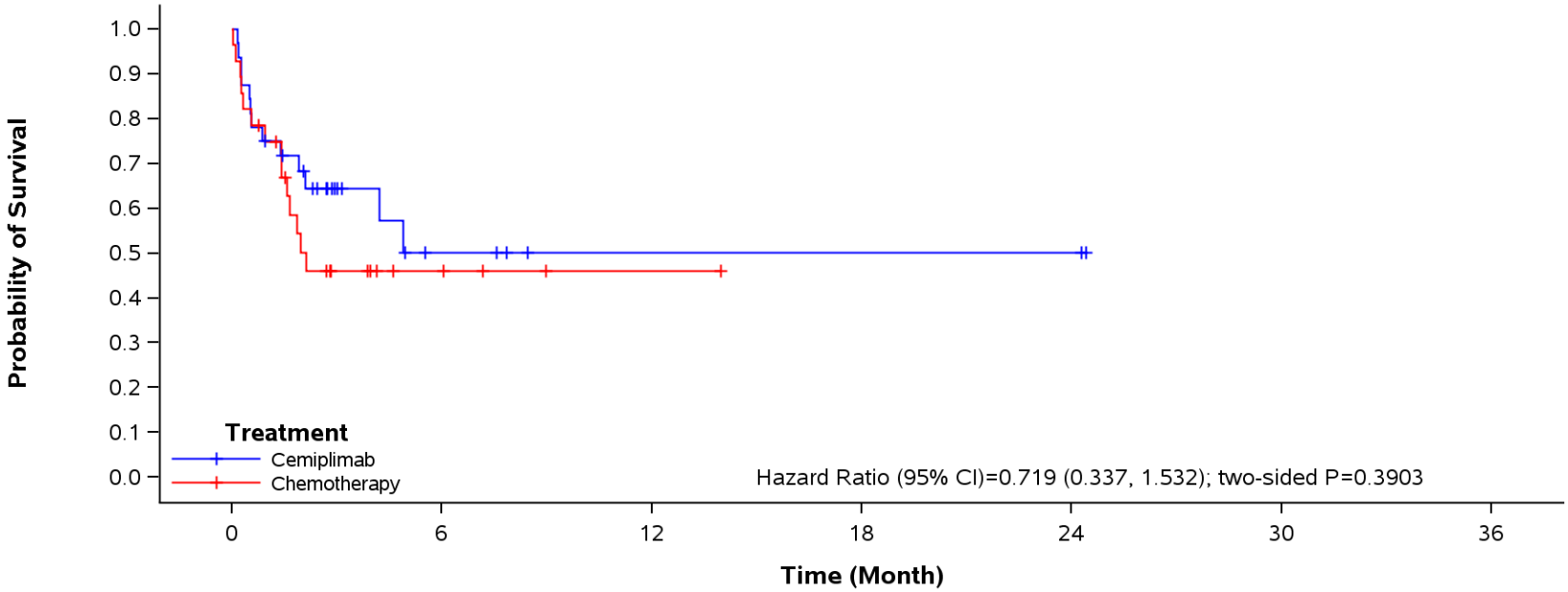

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Number of patients with any TEAE CTCAE Grade >= 3



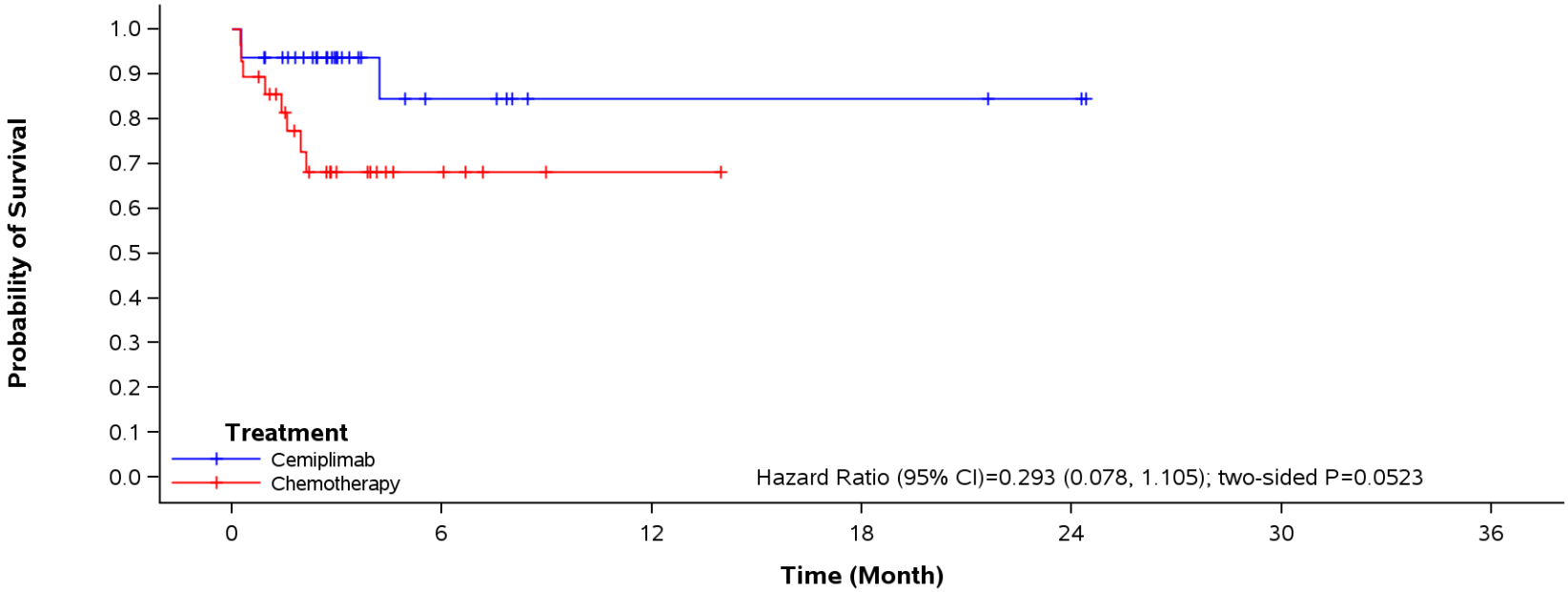

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 5 | 2 | 2 | 2 | 0 | 0 |
| Chemotherapy | 28 | 4 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders



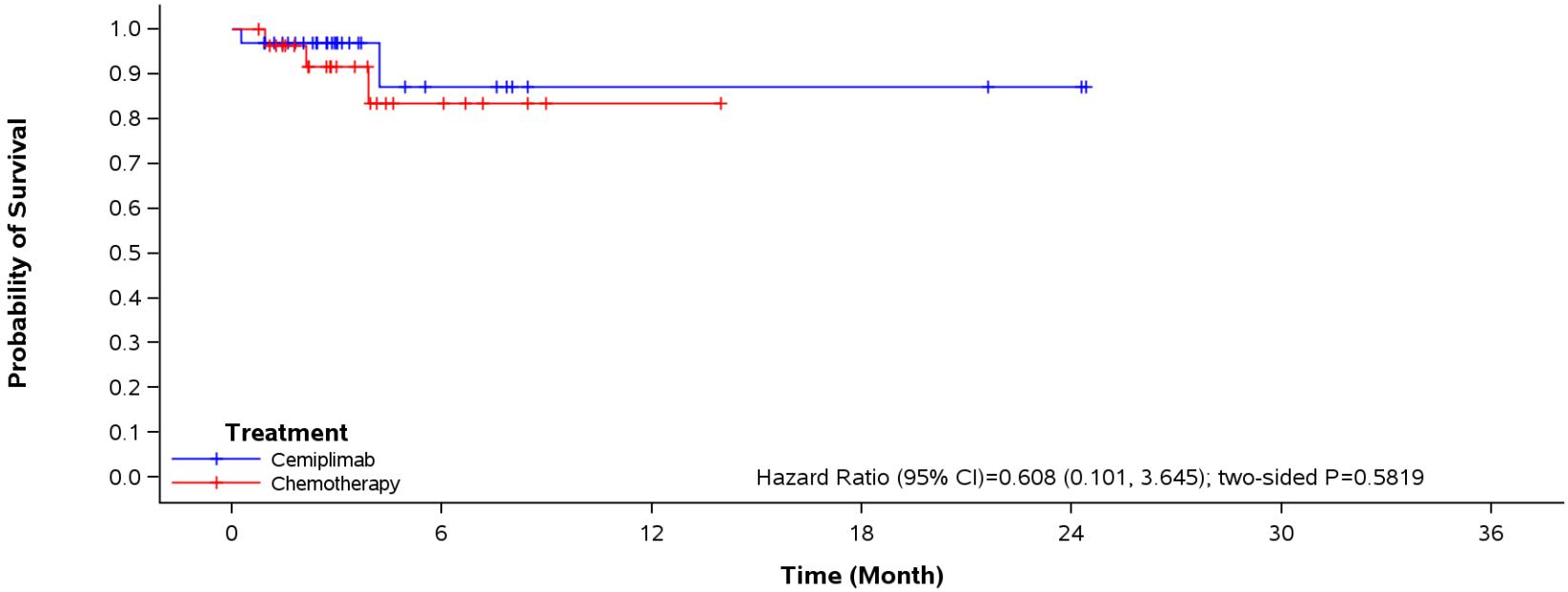

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 7 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Anaemia



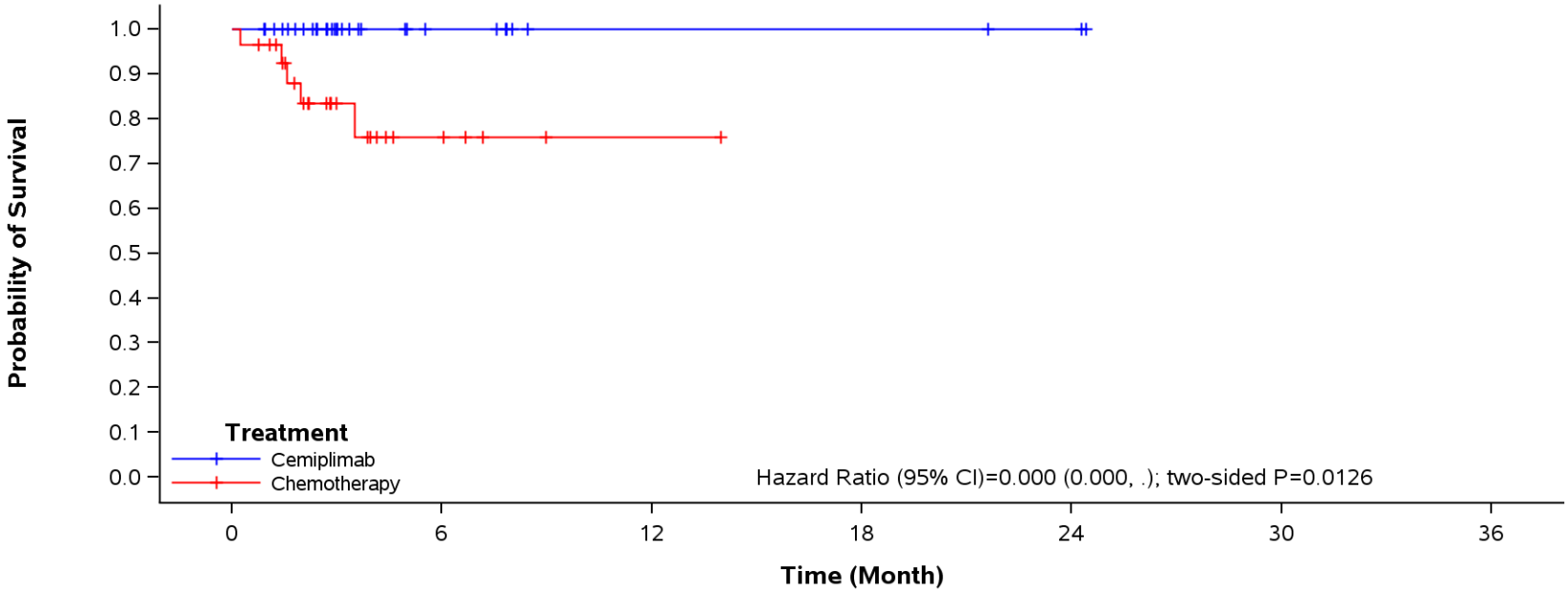

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 7 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 6 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.3. Time to First Any TEAE CTCAE Grade >= 3 by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Neutropenia



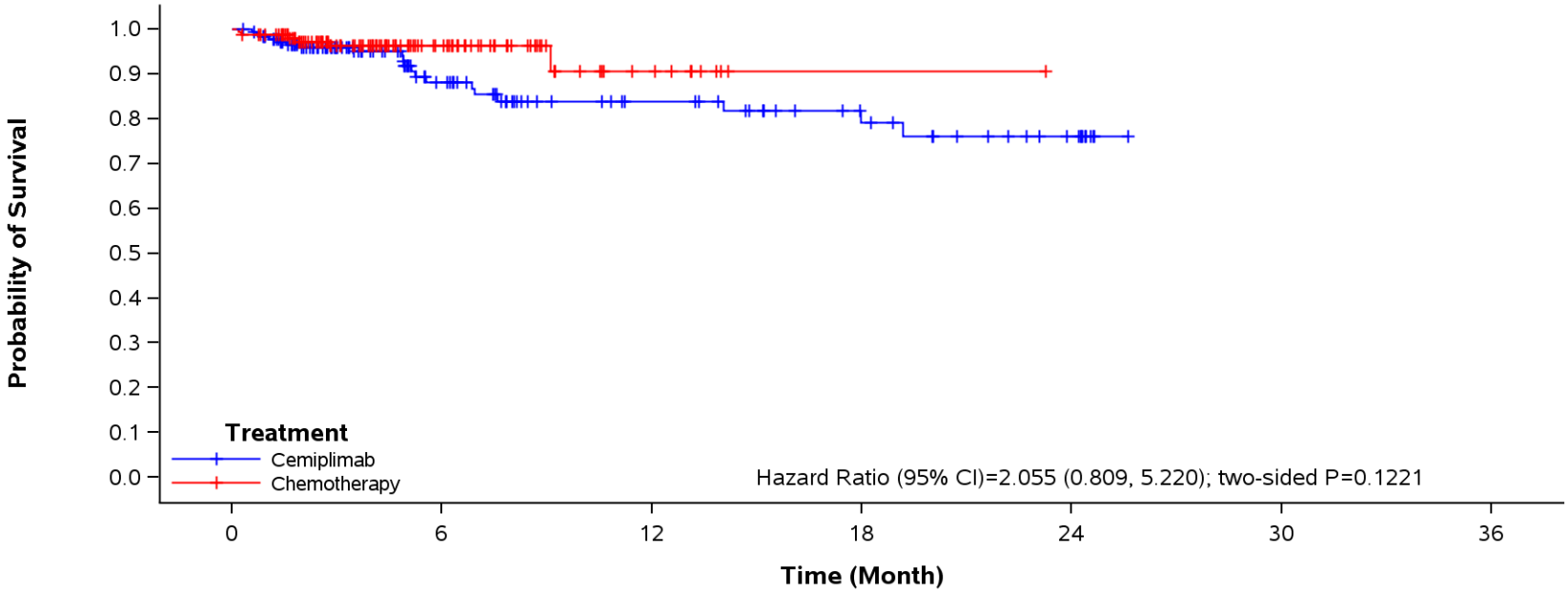

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 5 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.
Only SOC/PT with at least 10 patients in Cemiplimab arm or at least 9 patients in Chemotherapy arm and P-value for Hazard Ratio <0.05 in overall population are analyzed.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
Number of patients with any TEAE leading to discontinuation



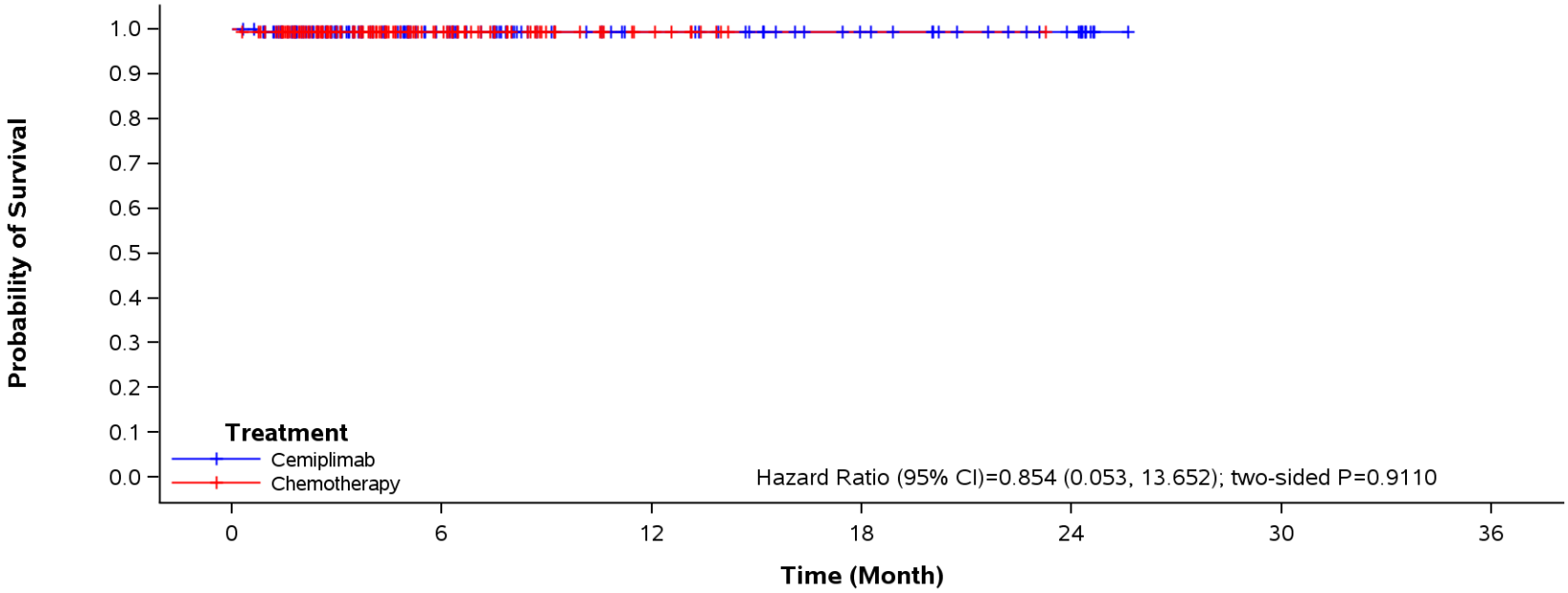

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 69 | 42 | 29 | 18 | 0 | 0 |
| Chemotherapy | 153 | 45 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders



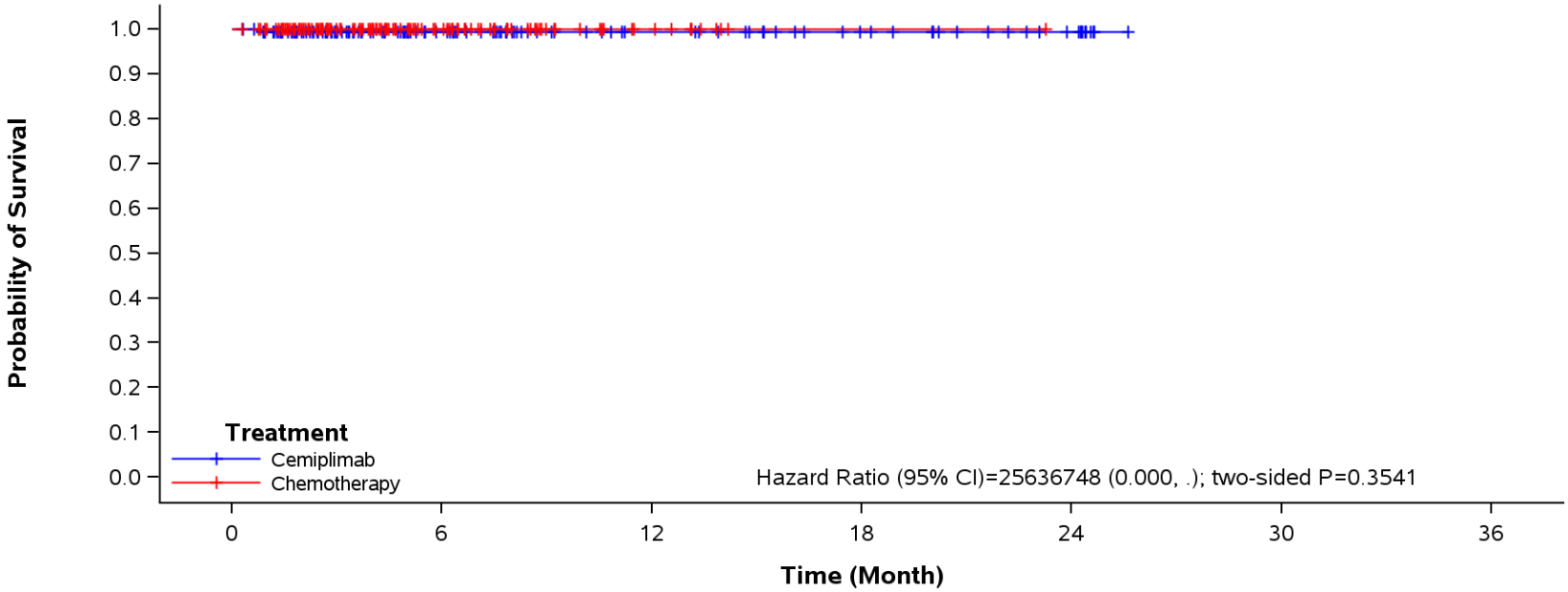

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Anaemia



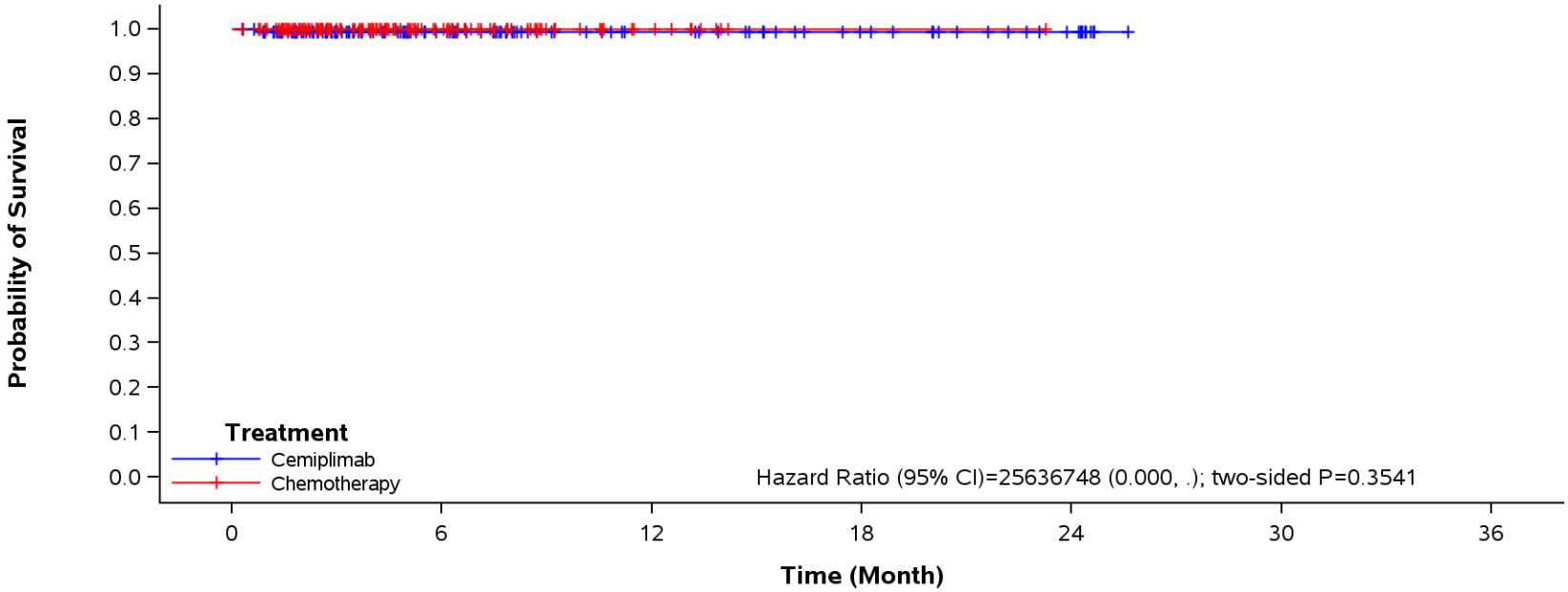

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



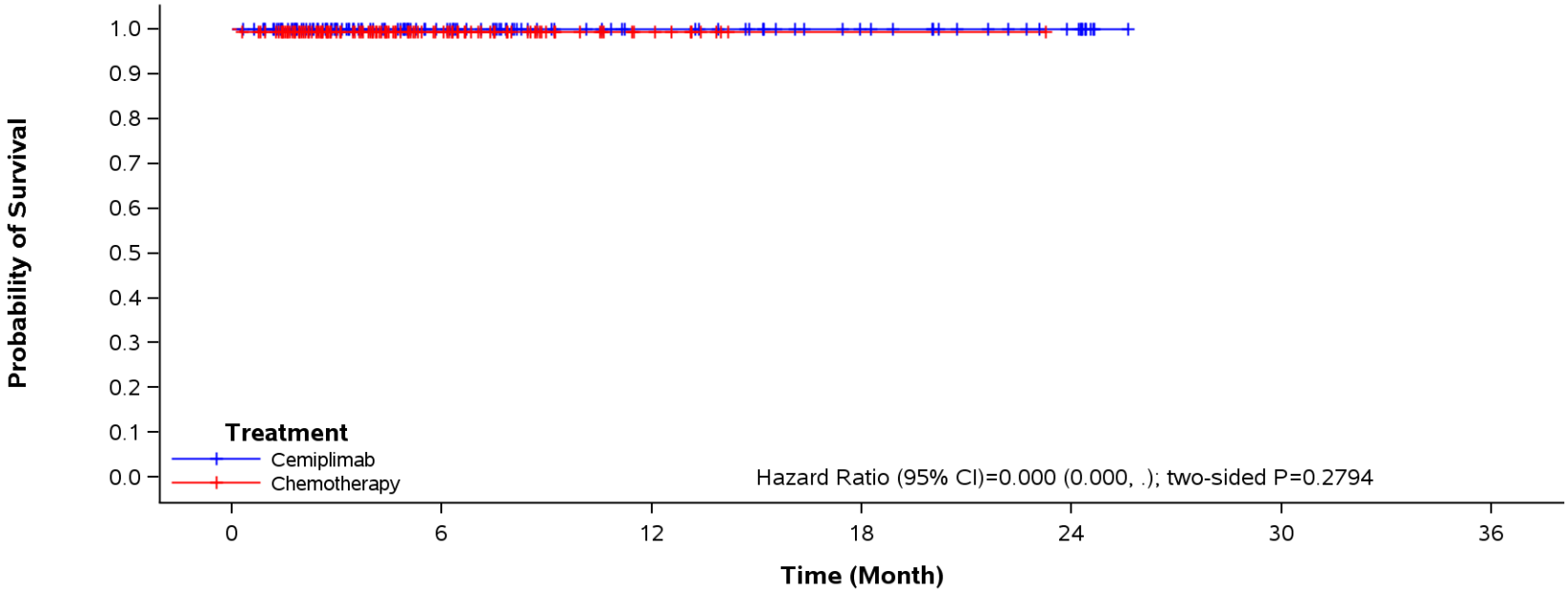

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



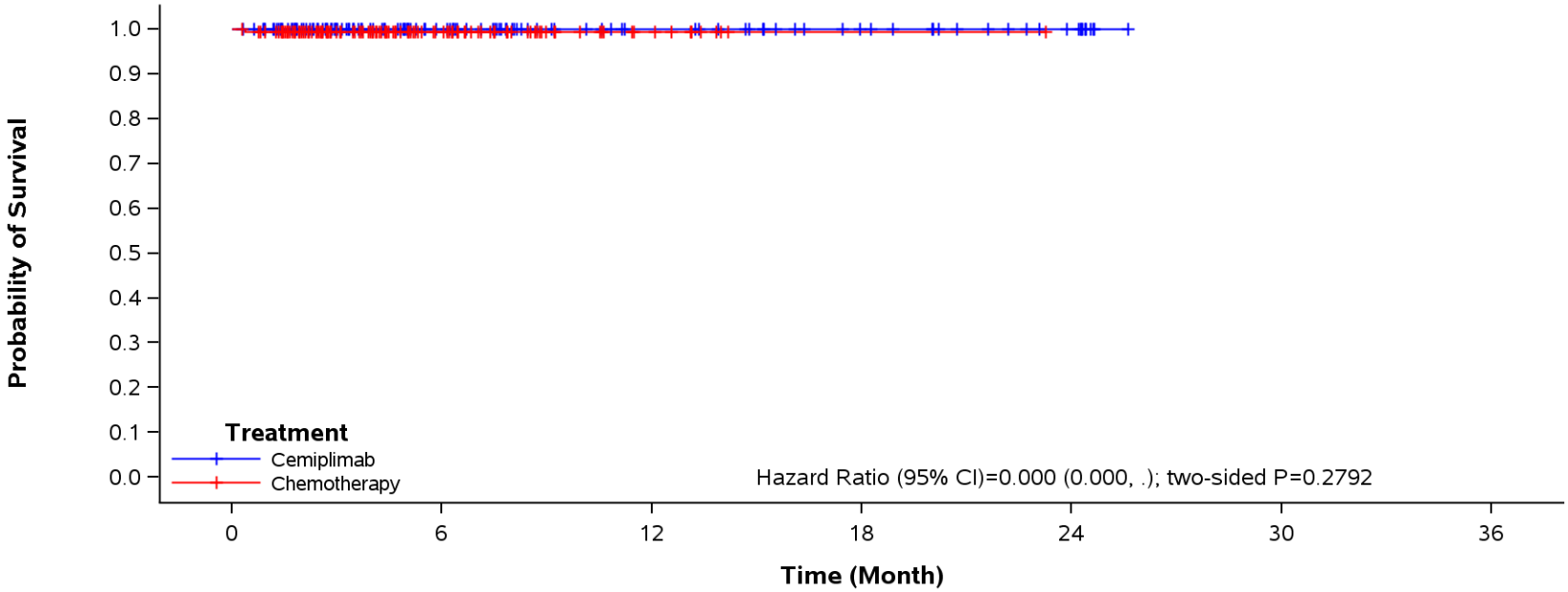

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



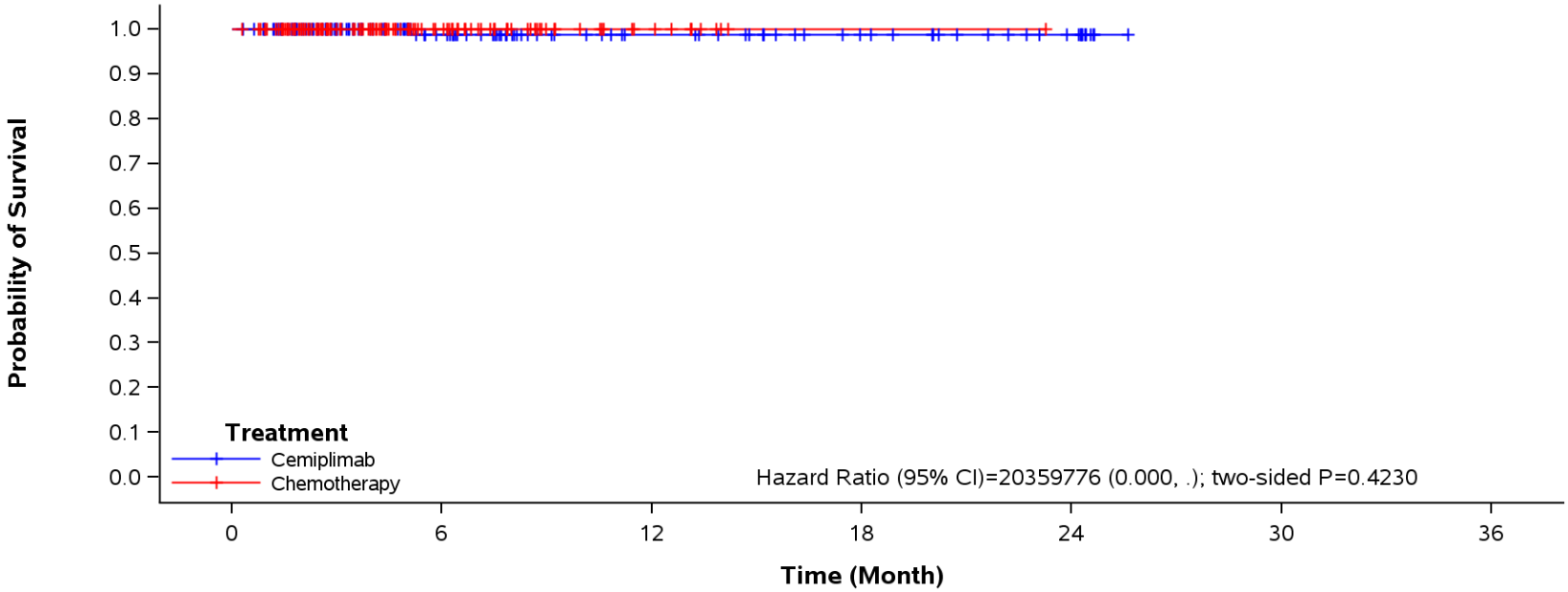

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Cardiac disorders



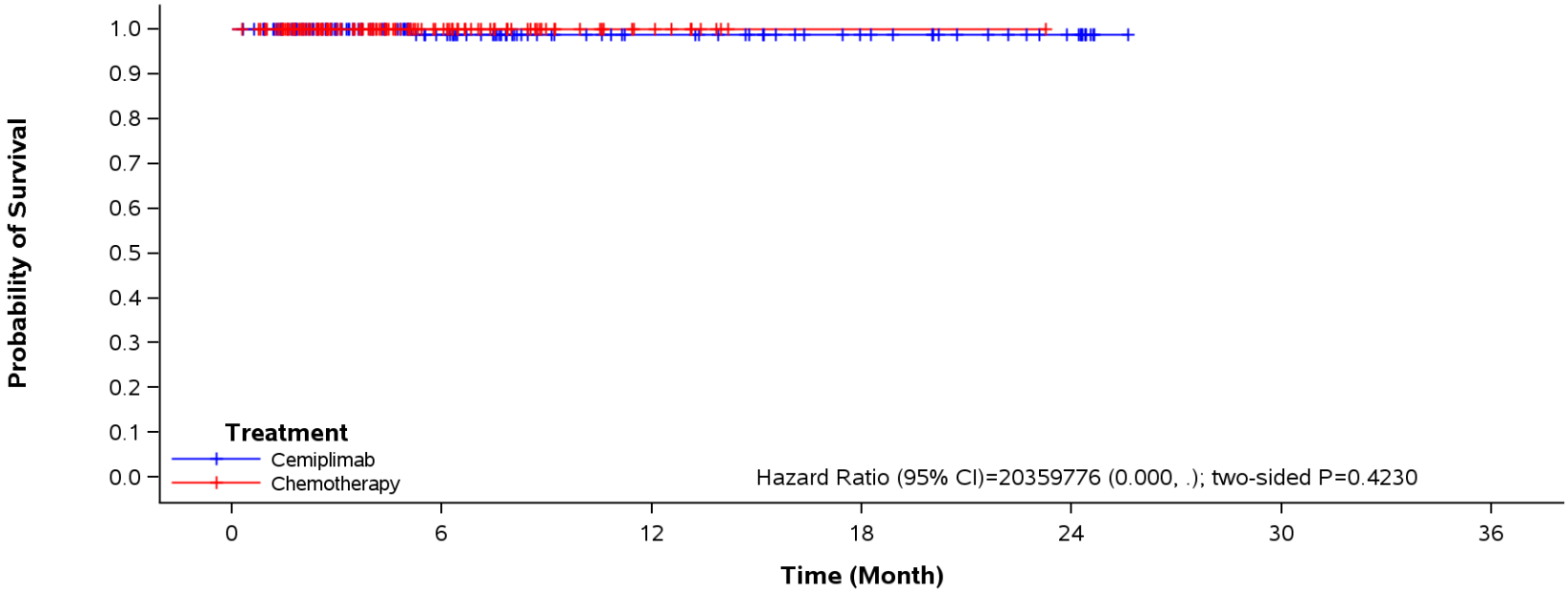

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Cardiac disorders
PT: Autoimmune pericarditis



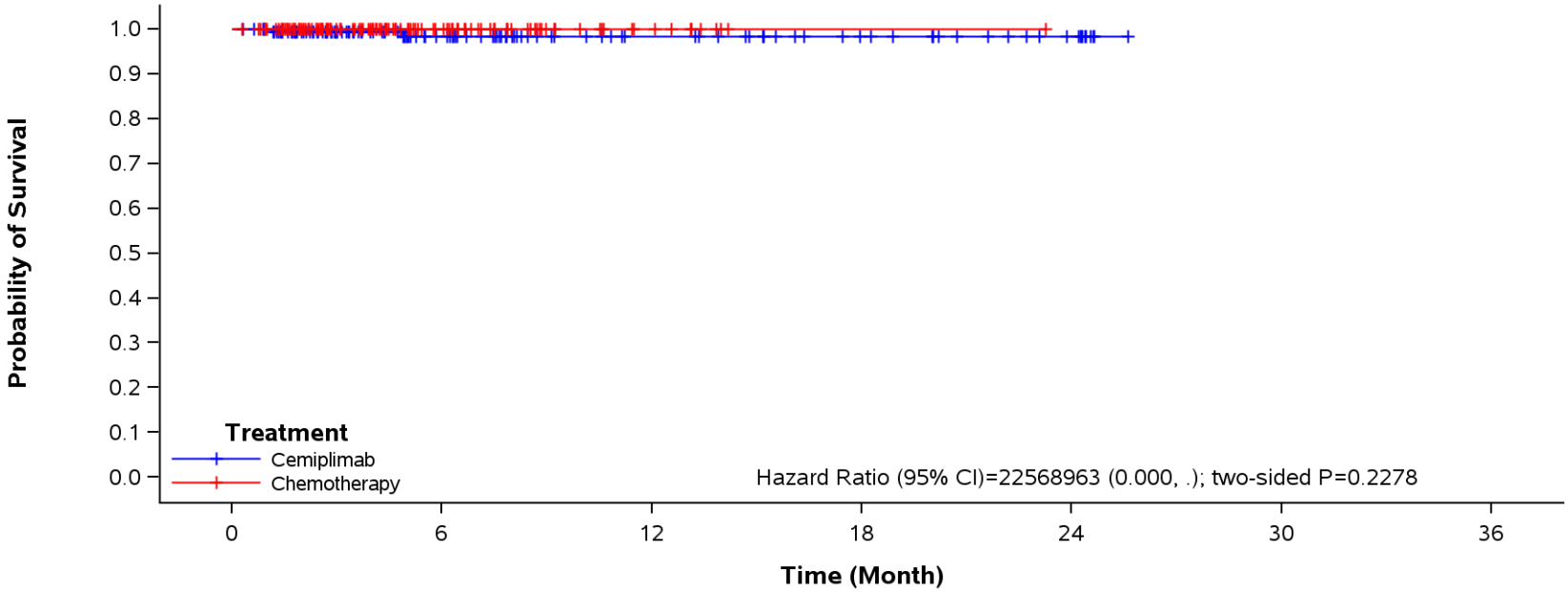

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Endocrine disorders



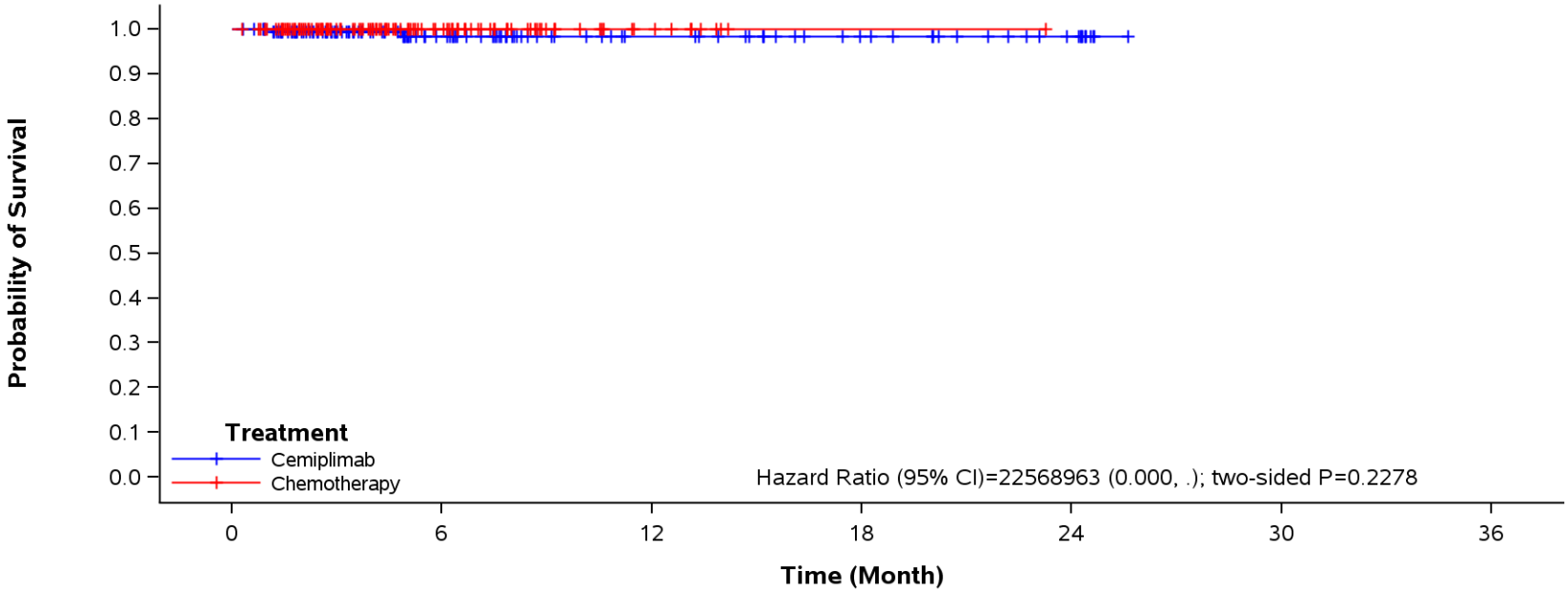

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Endocrine disorders
PT: Hypothyroidism



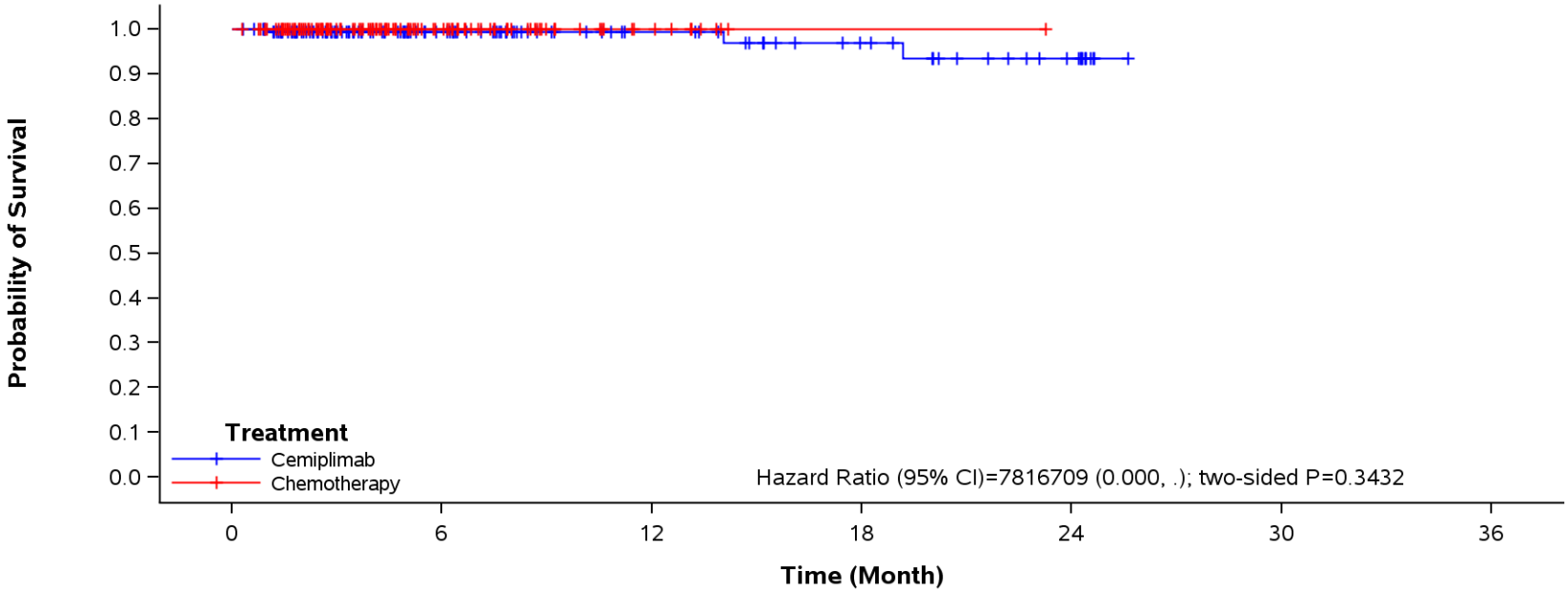

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders



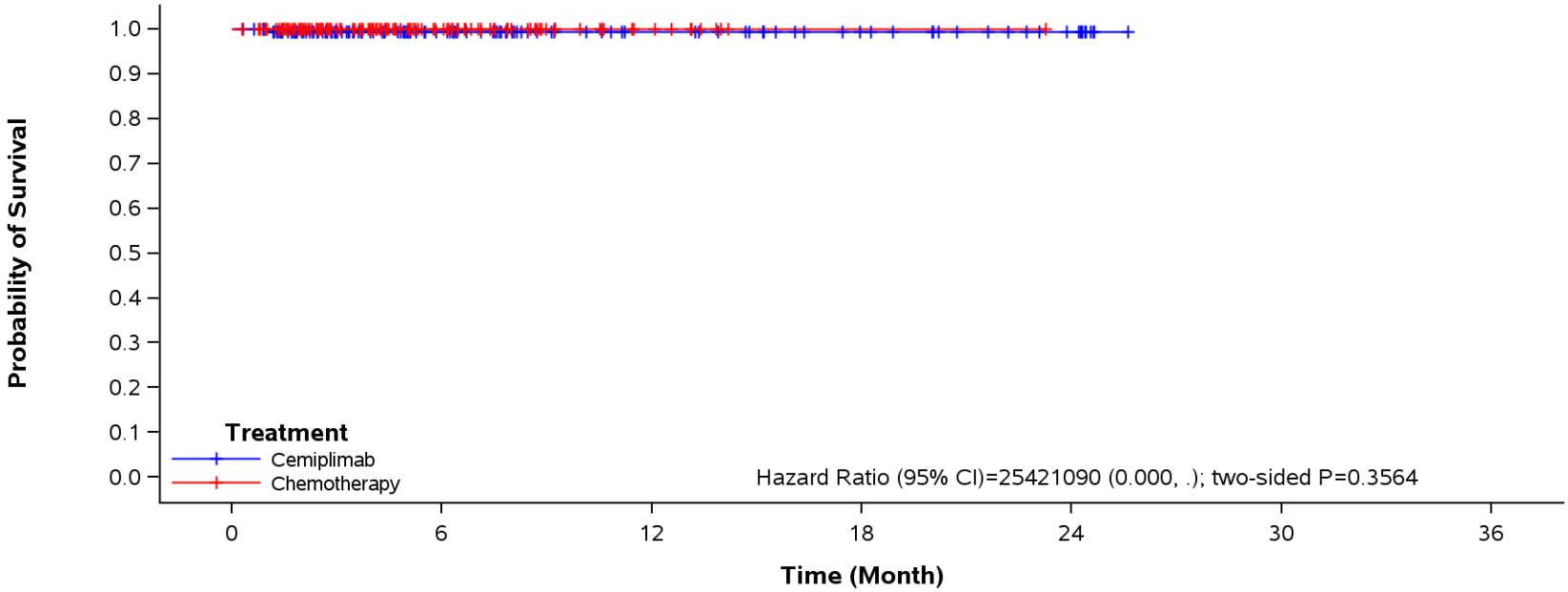

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders
PT: Colitis



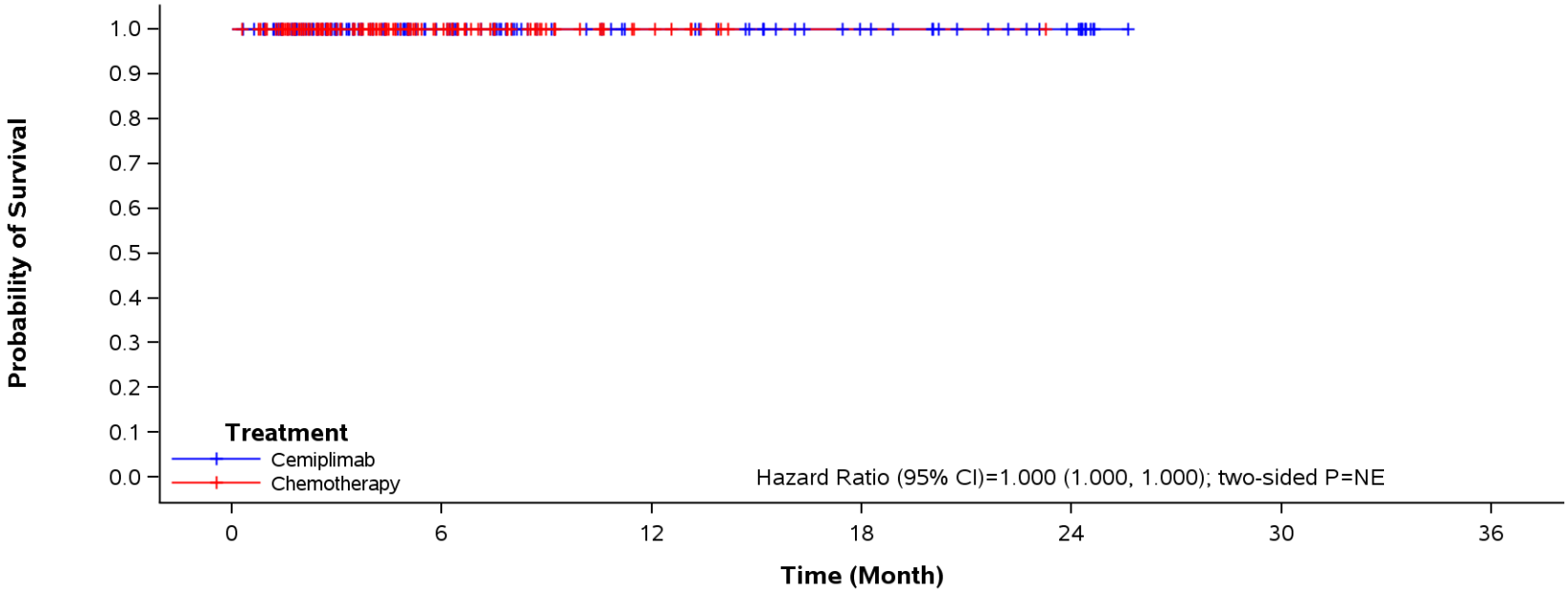

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders
PT: Diverticular perforation



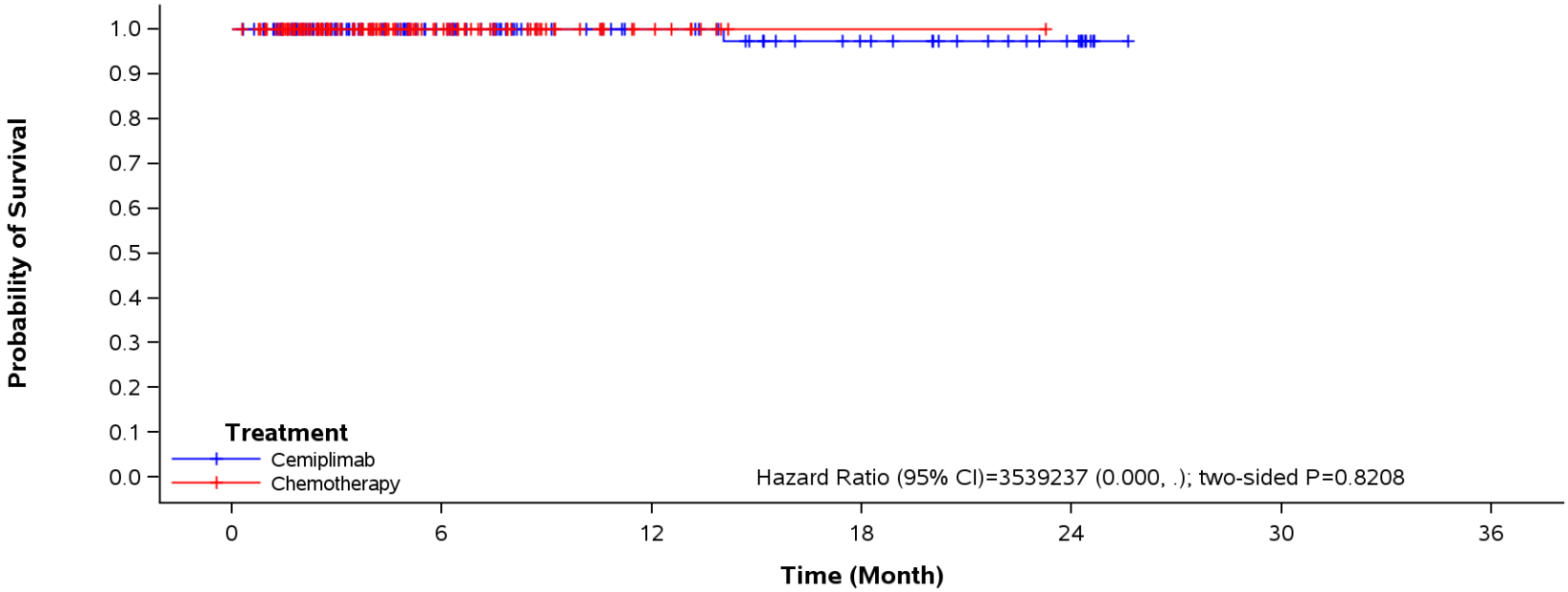

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders
PT: Pancreatic mass



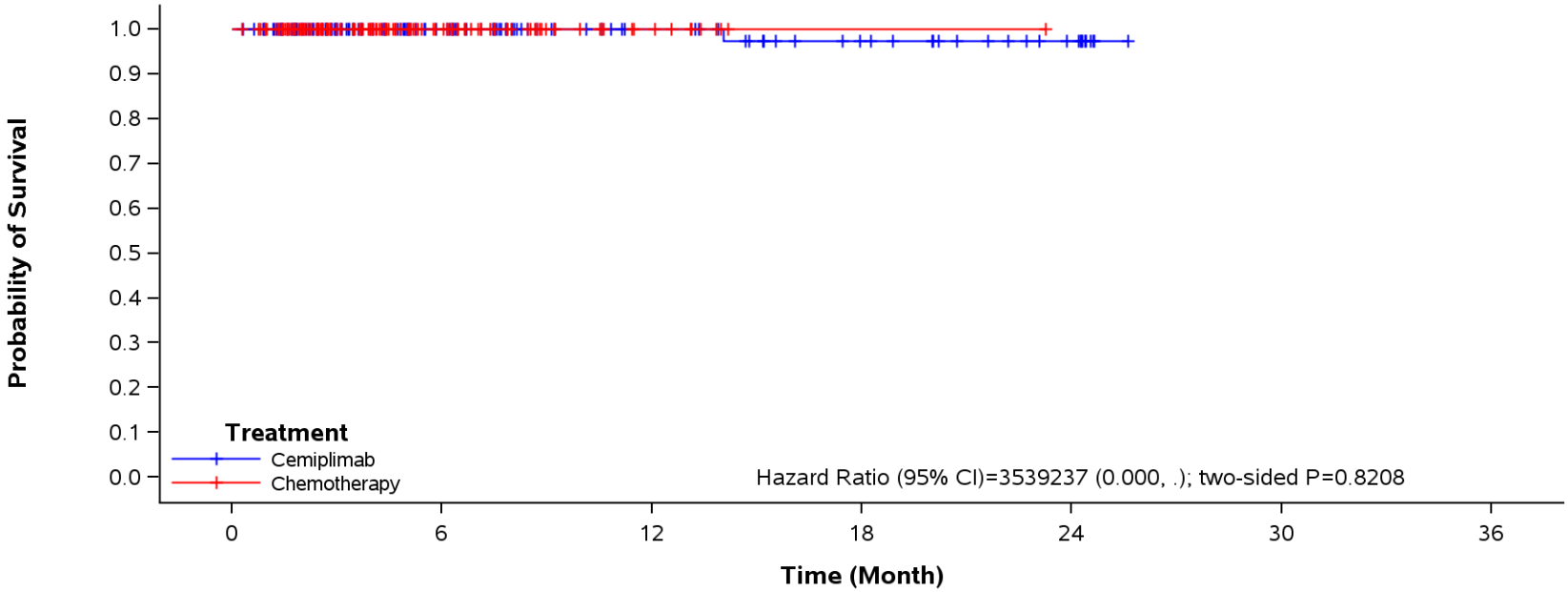

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



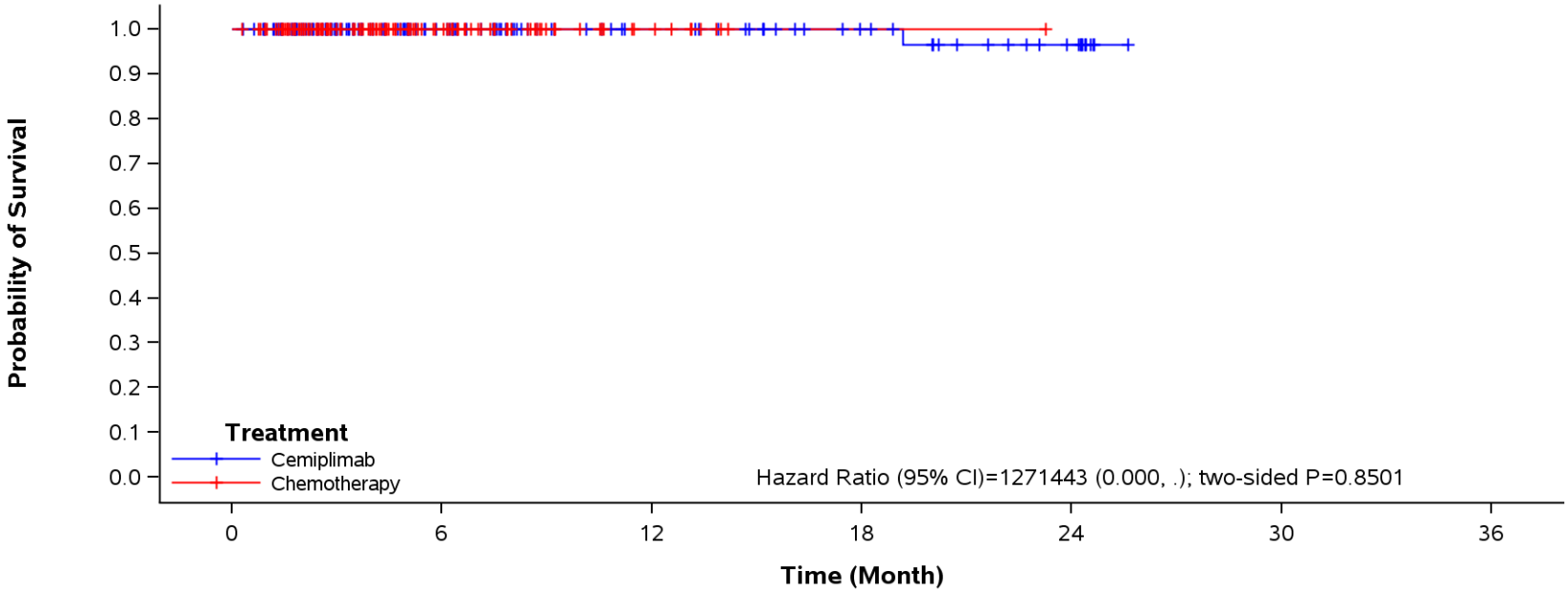

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Gastrointestinal disorders
PT: Proctalgia



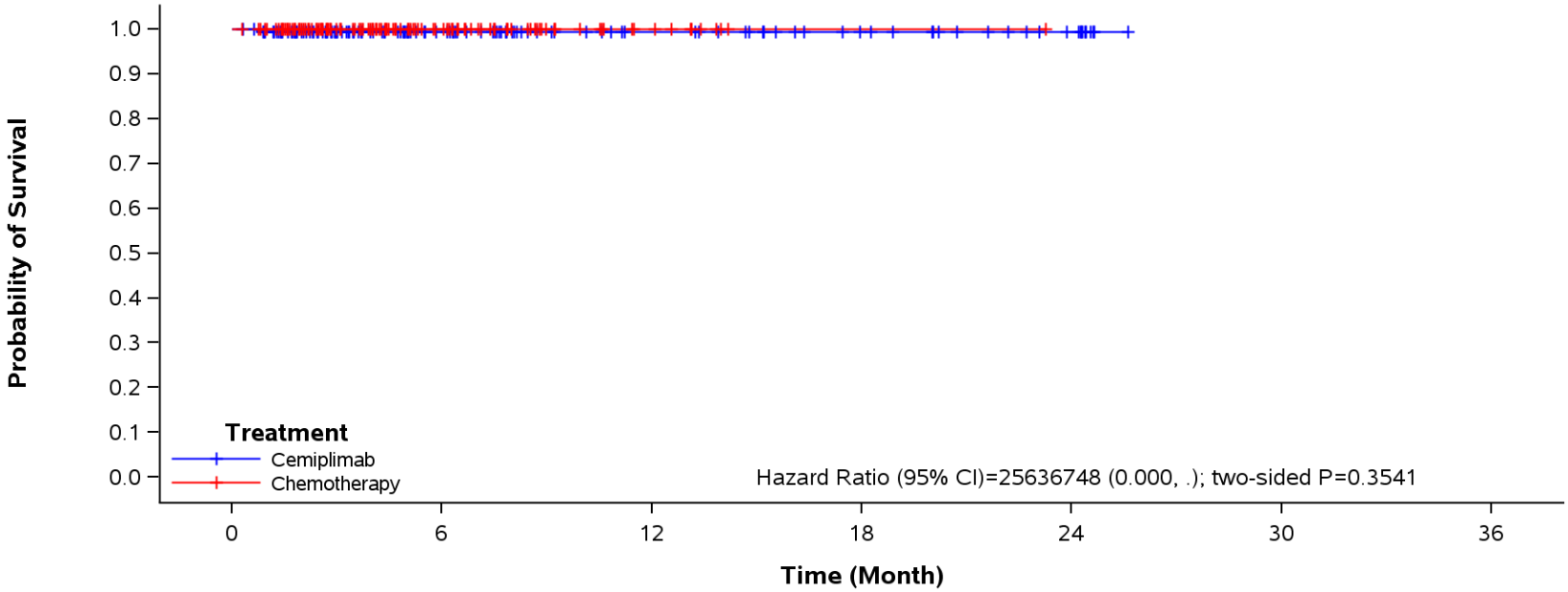

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: General disorders and administration site conditions



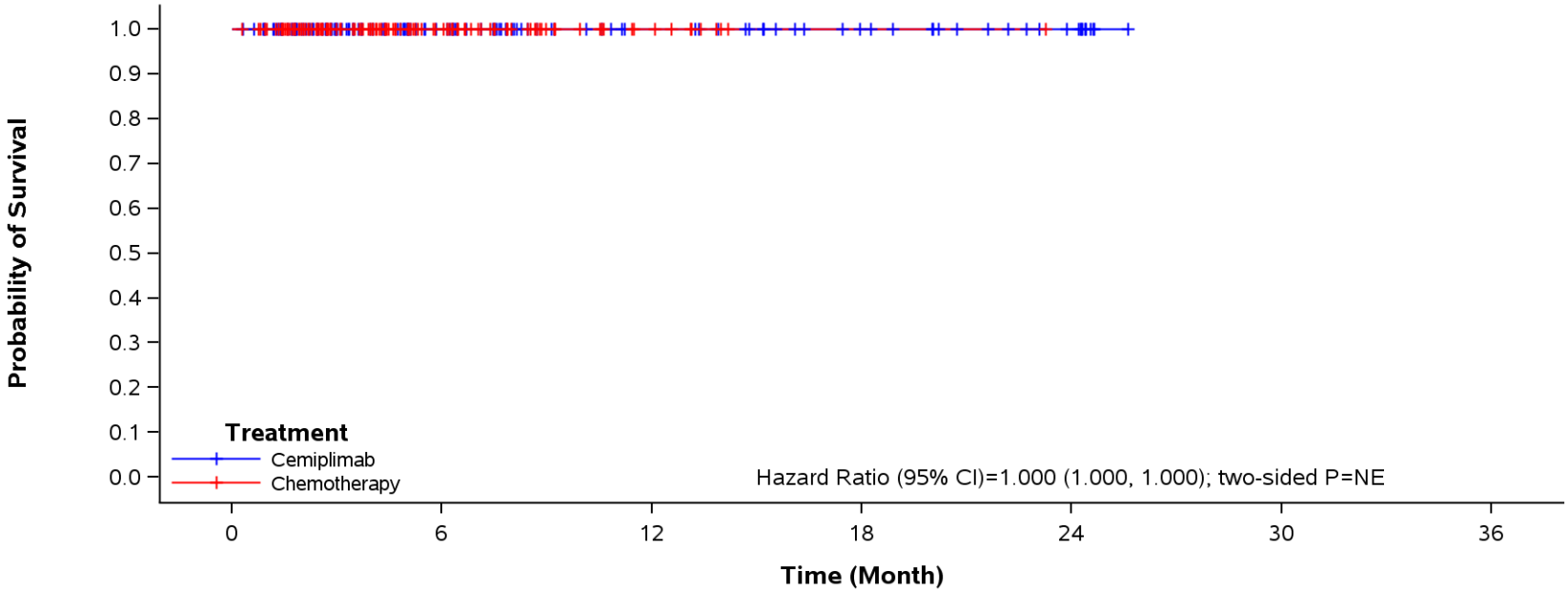

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: General disorders and administration site conditions
PT: Malaise



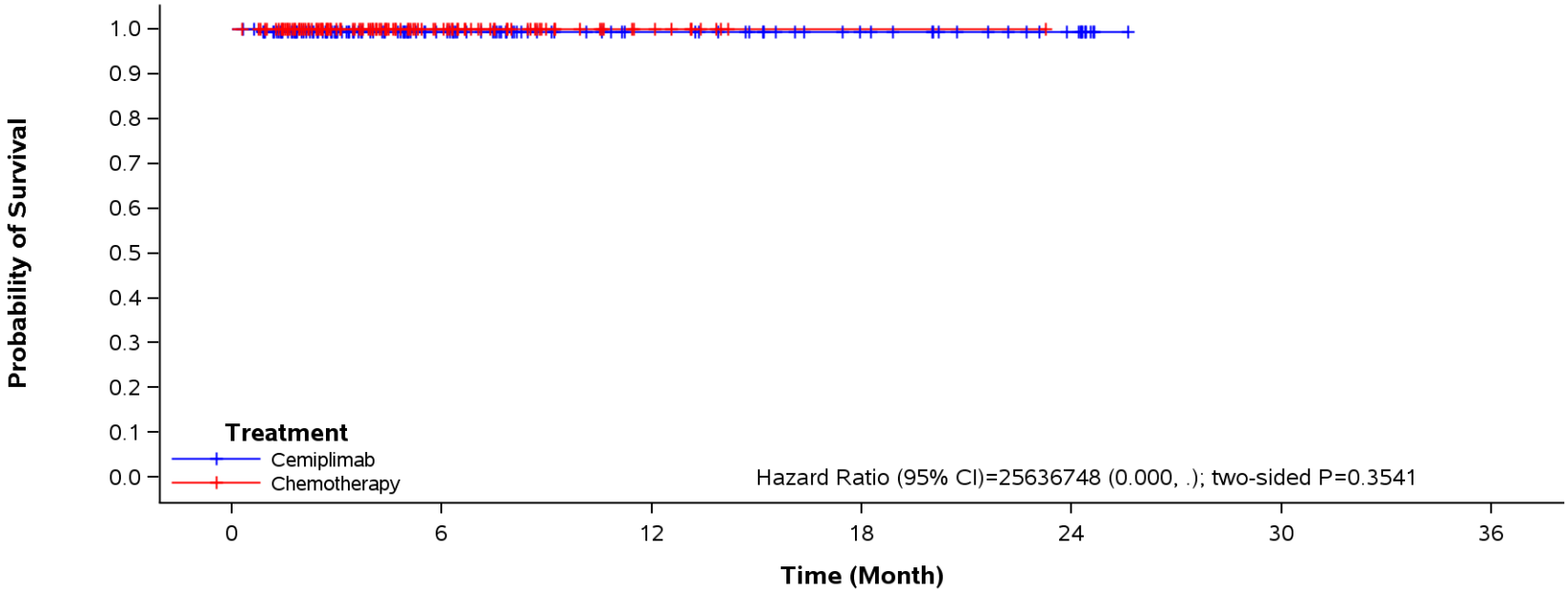

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



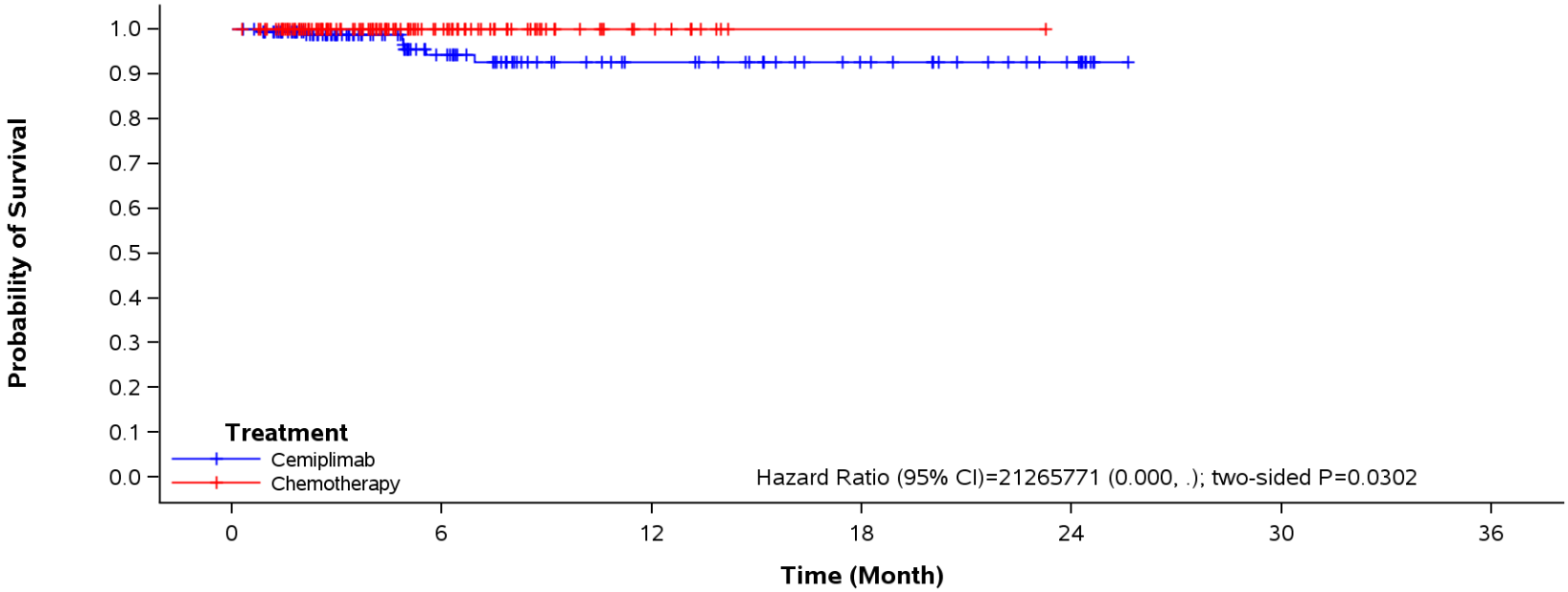

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Hepatobiliary disorders



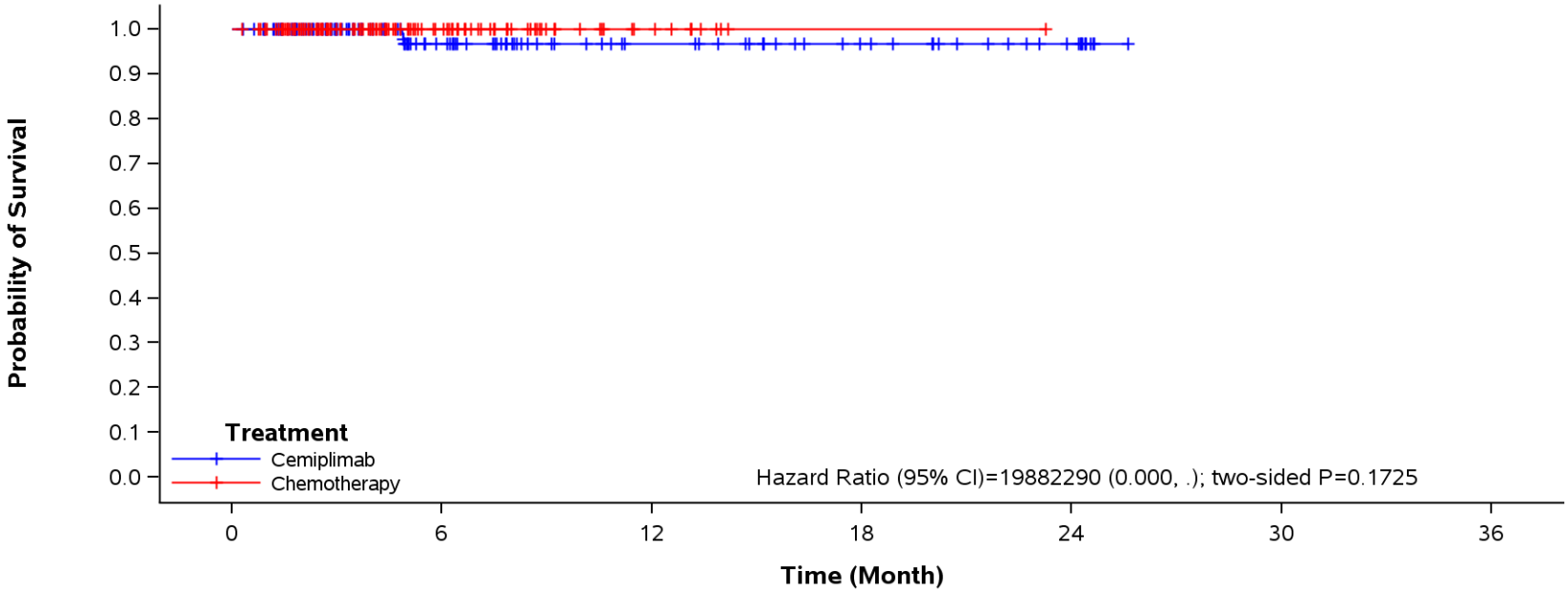

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 72 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



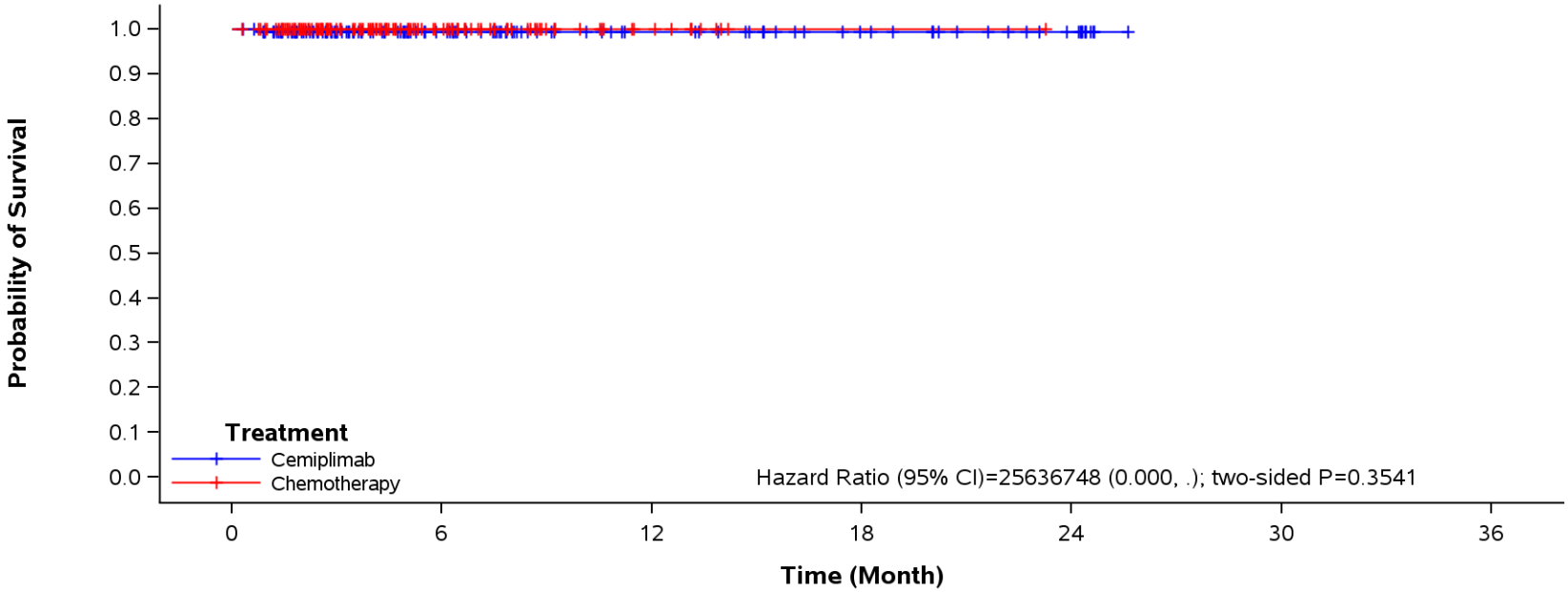

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 73 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



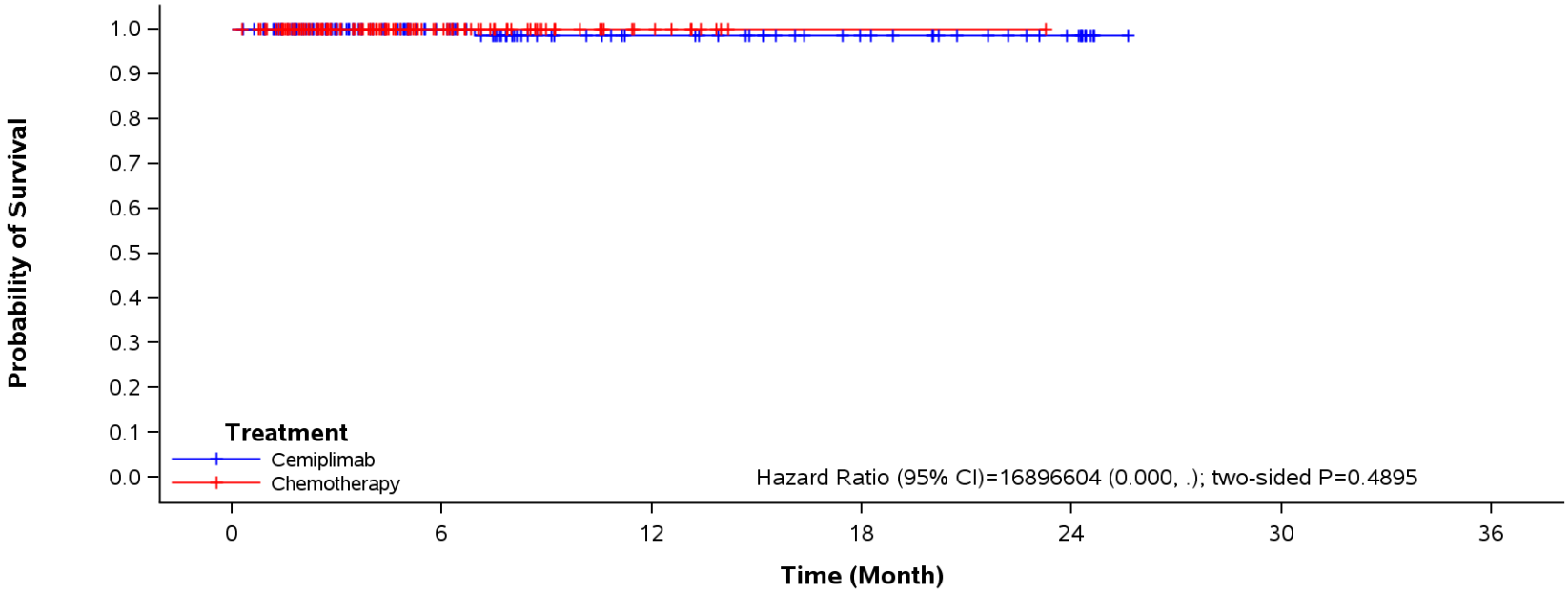

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Hepatobiliary disorders
PT: Hepatitis



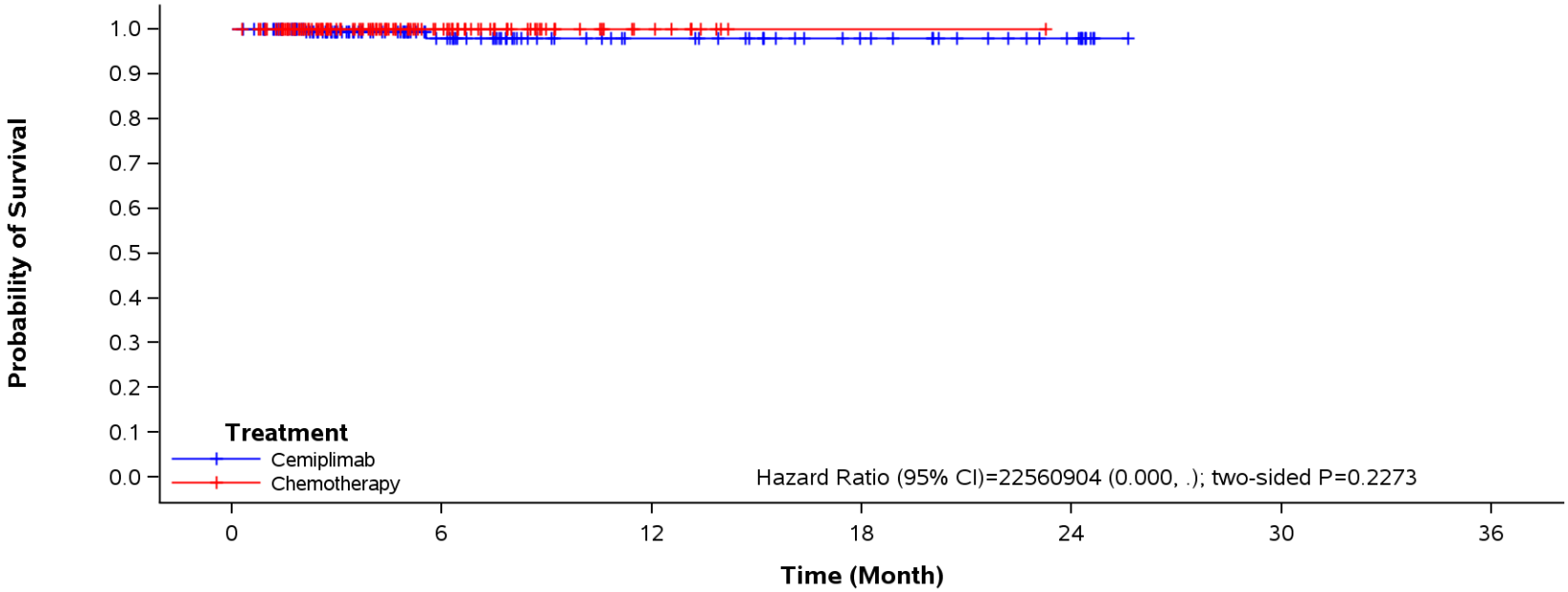

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



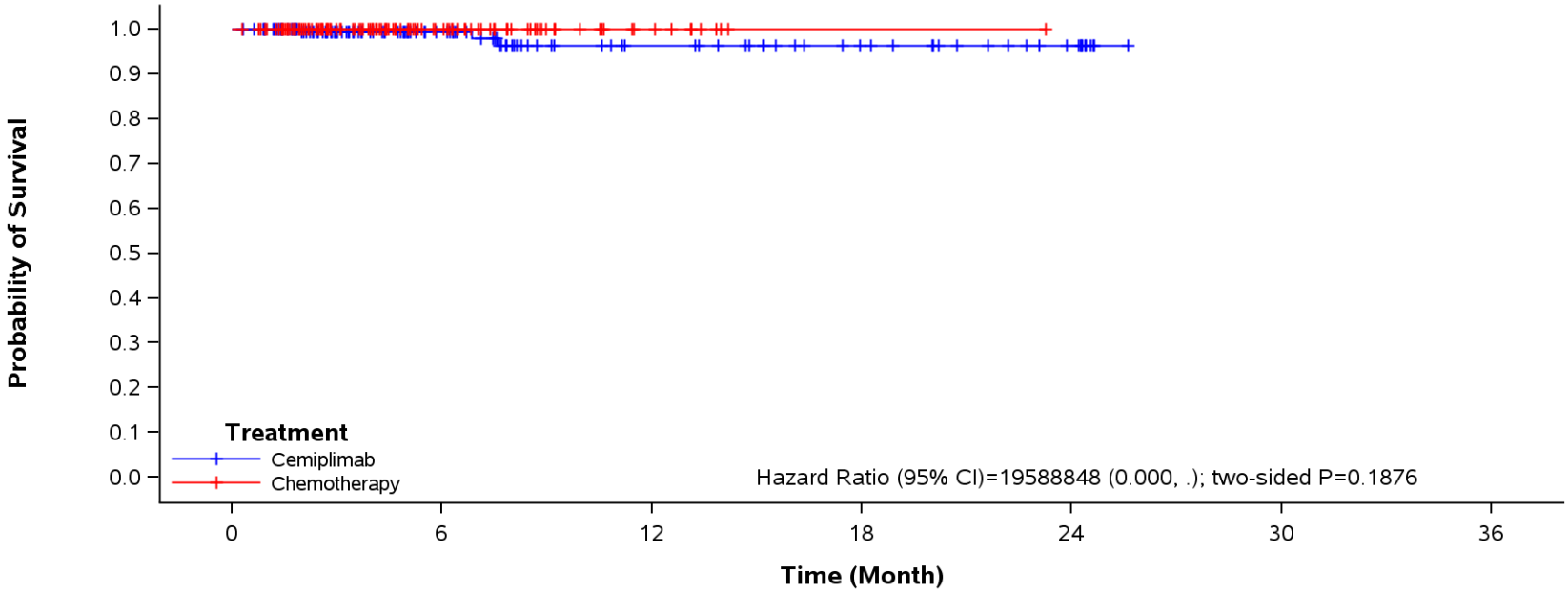

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Infections and infestations



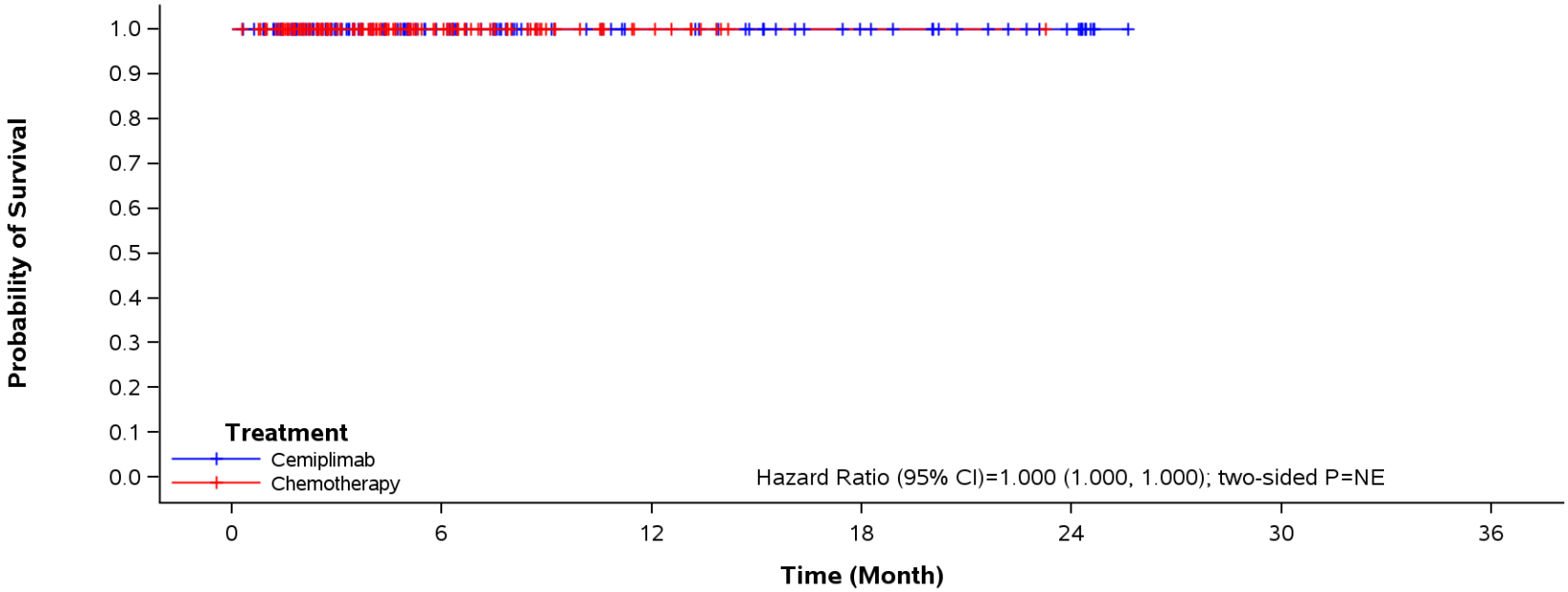

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Infections and infestations
PT: COVID-19 pneumonia



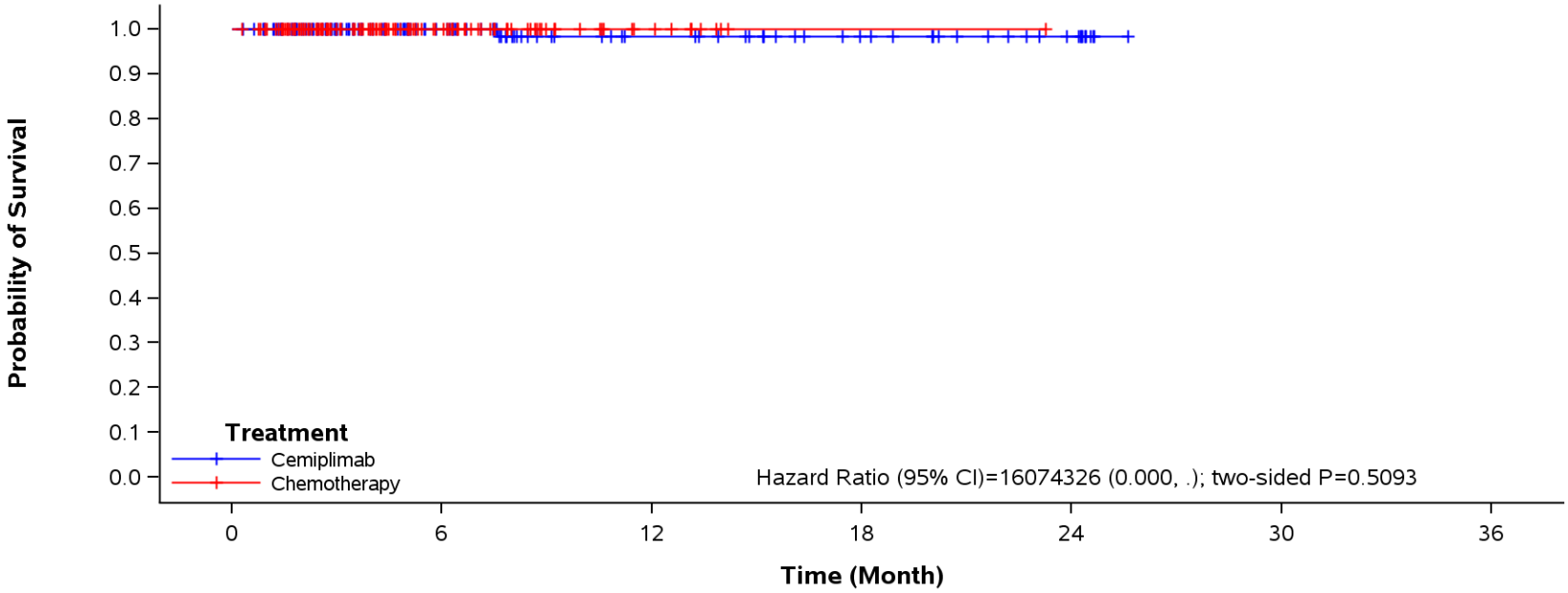

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Infections and infestations
PT: Gastroenteritis



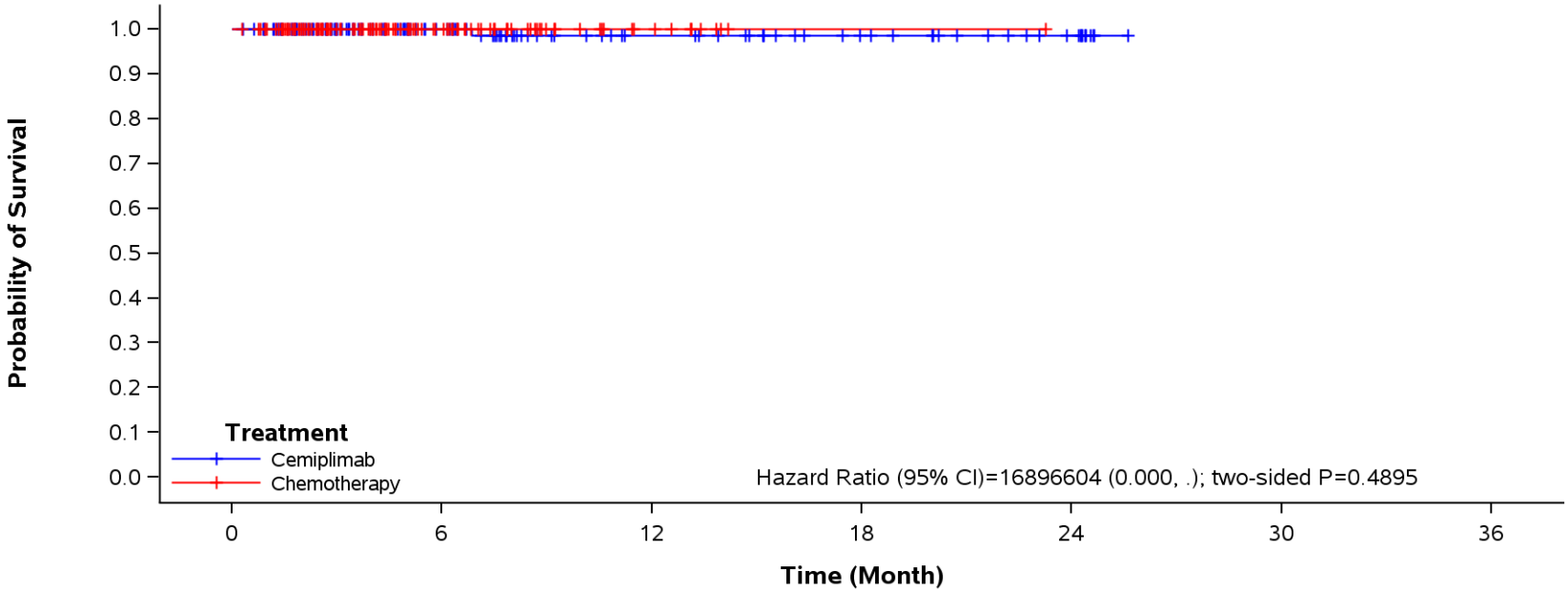

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Infections and infestations
PT: Pelvic abscess



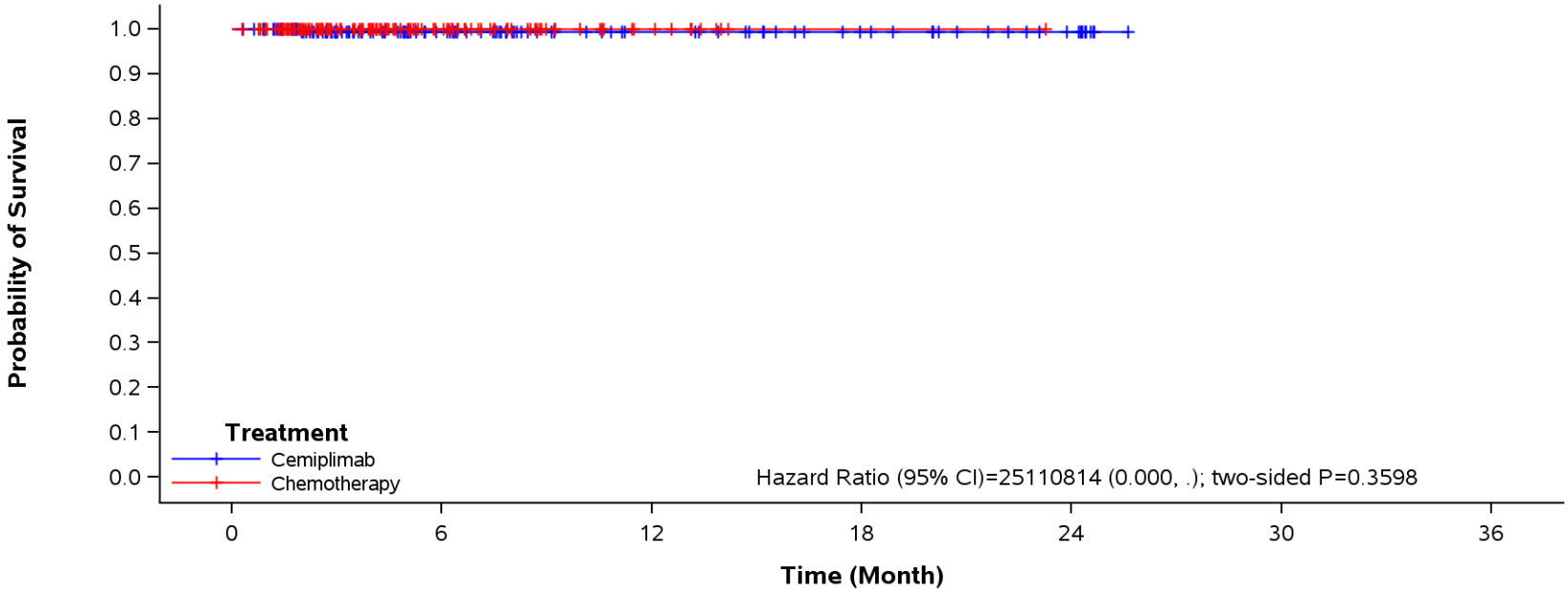

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Infections and infestations
PT: Peritonitis



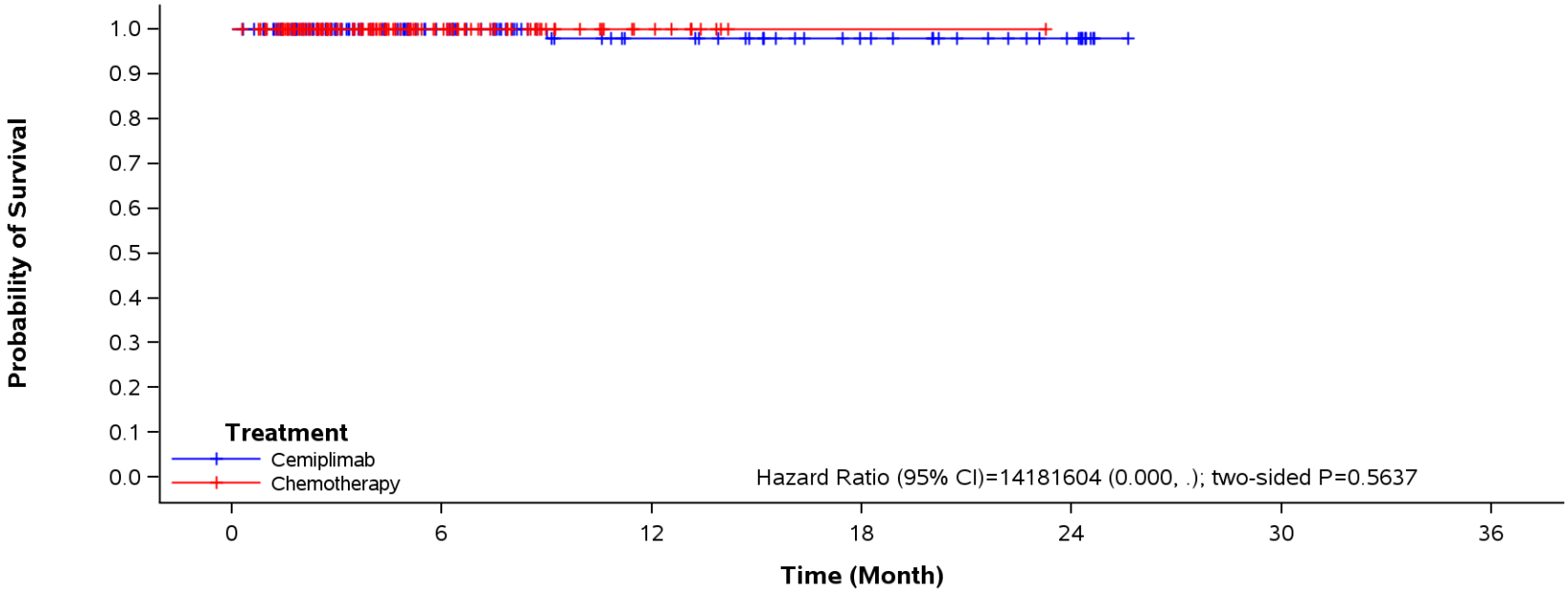

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Infections and infestations
PT: Pneumonia



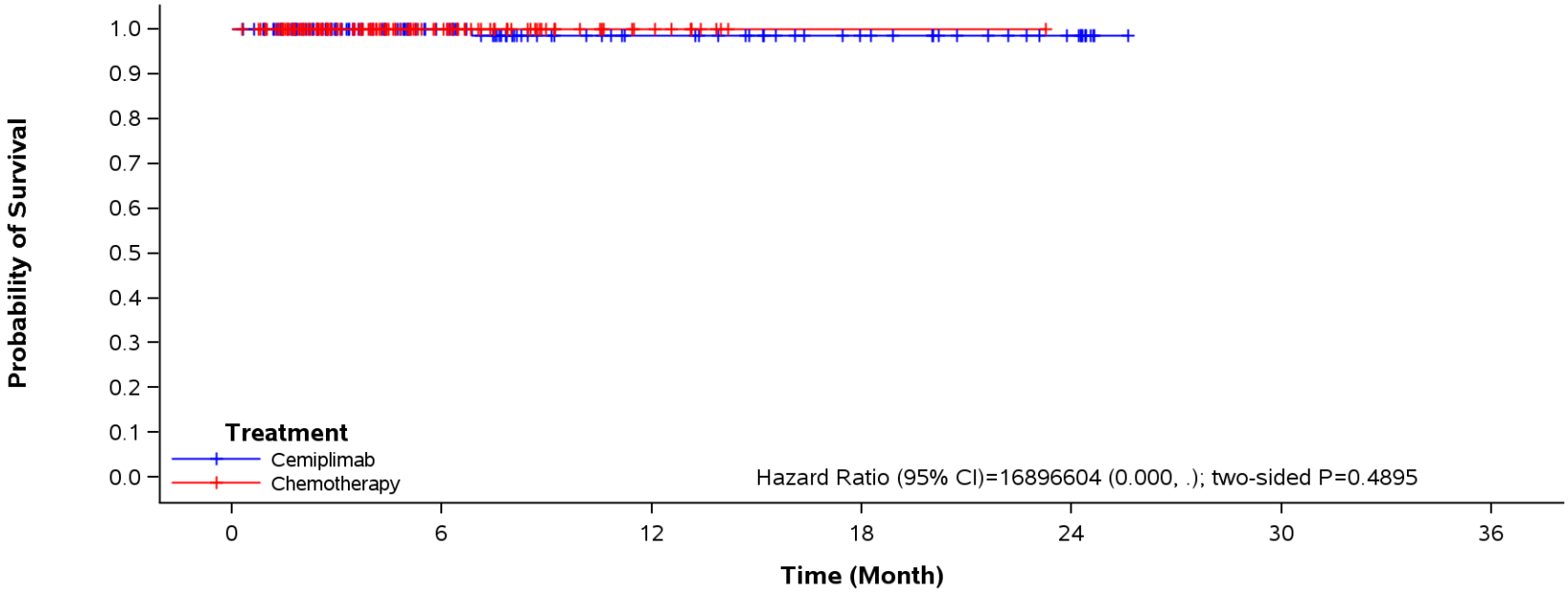

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Infections and infestations
PT: Pyomyositis



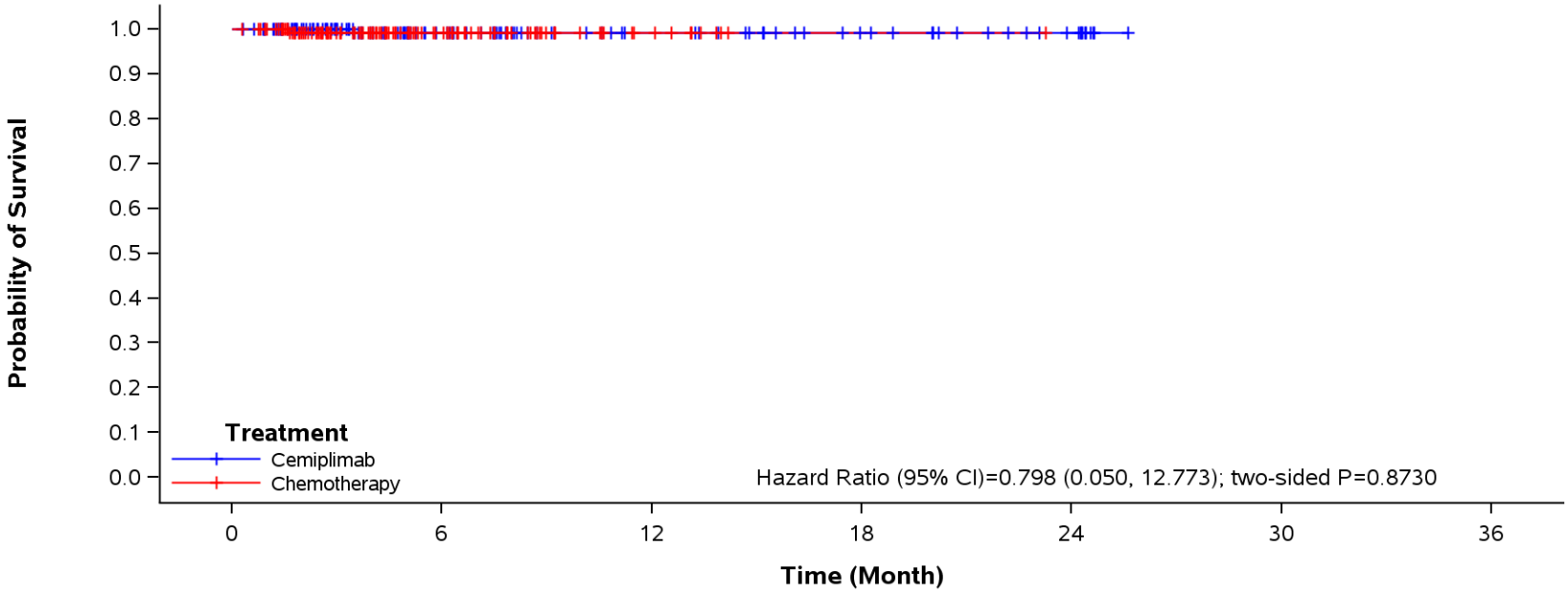

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Injury, poisoning and procedural complications



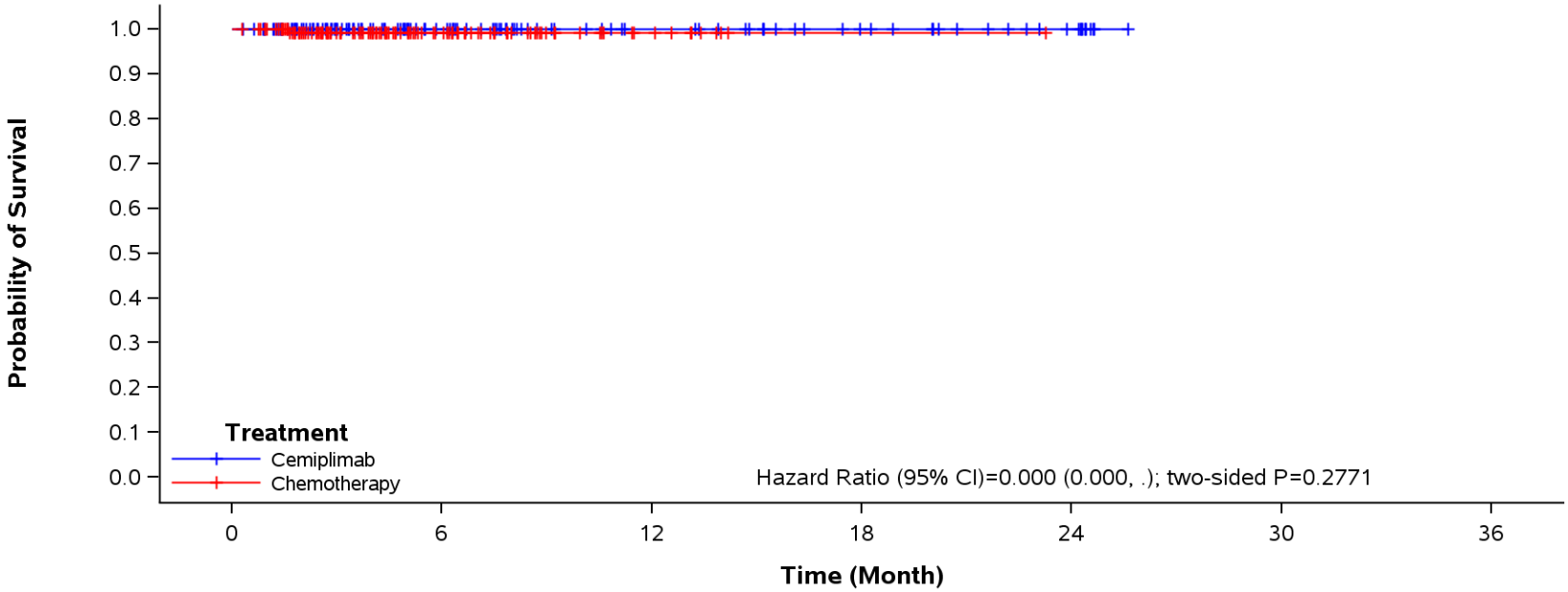

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



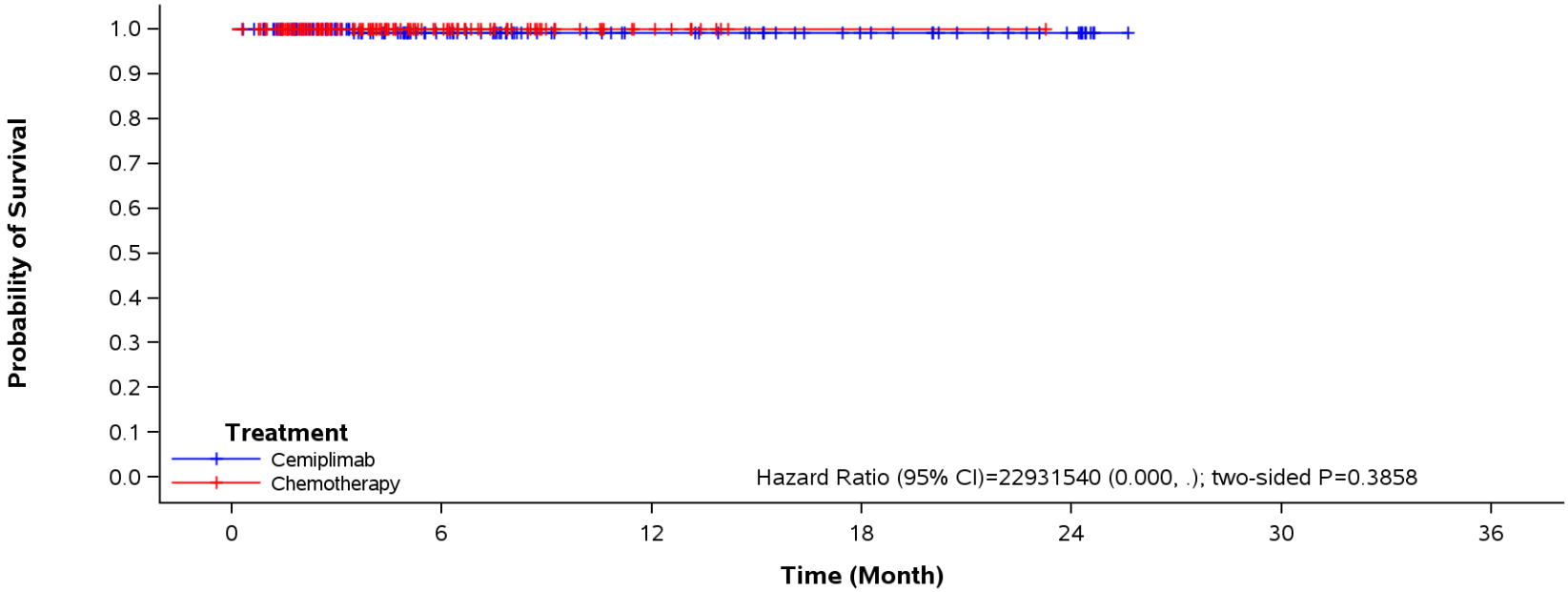

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



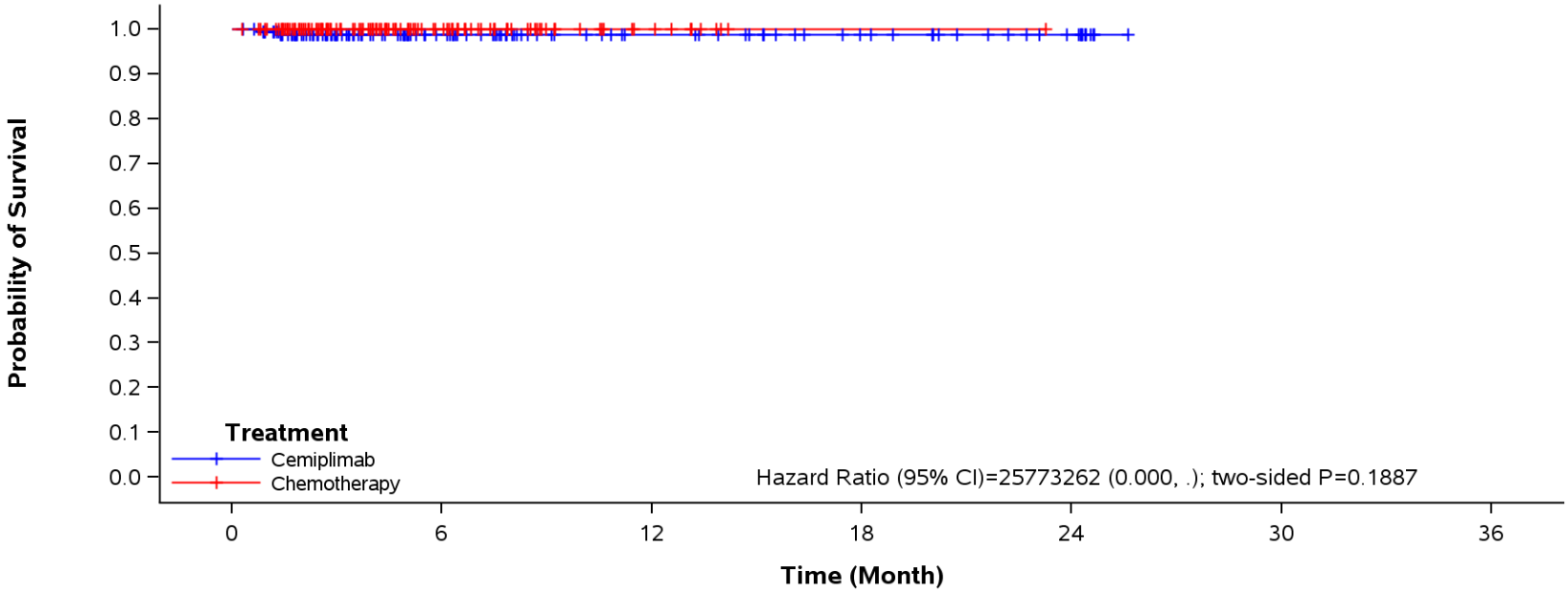

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Investigations



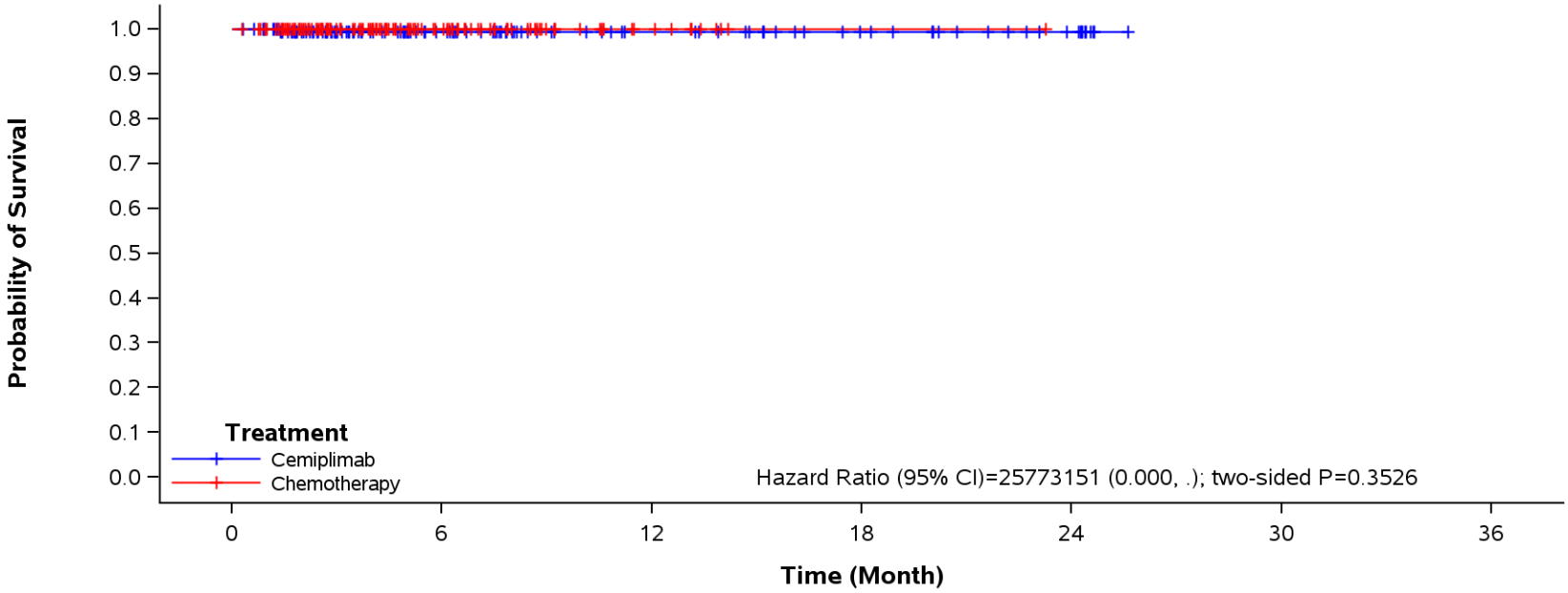

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Investigations
PT: Alanine aminotransferase increased



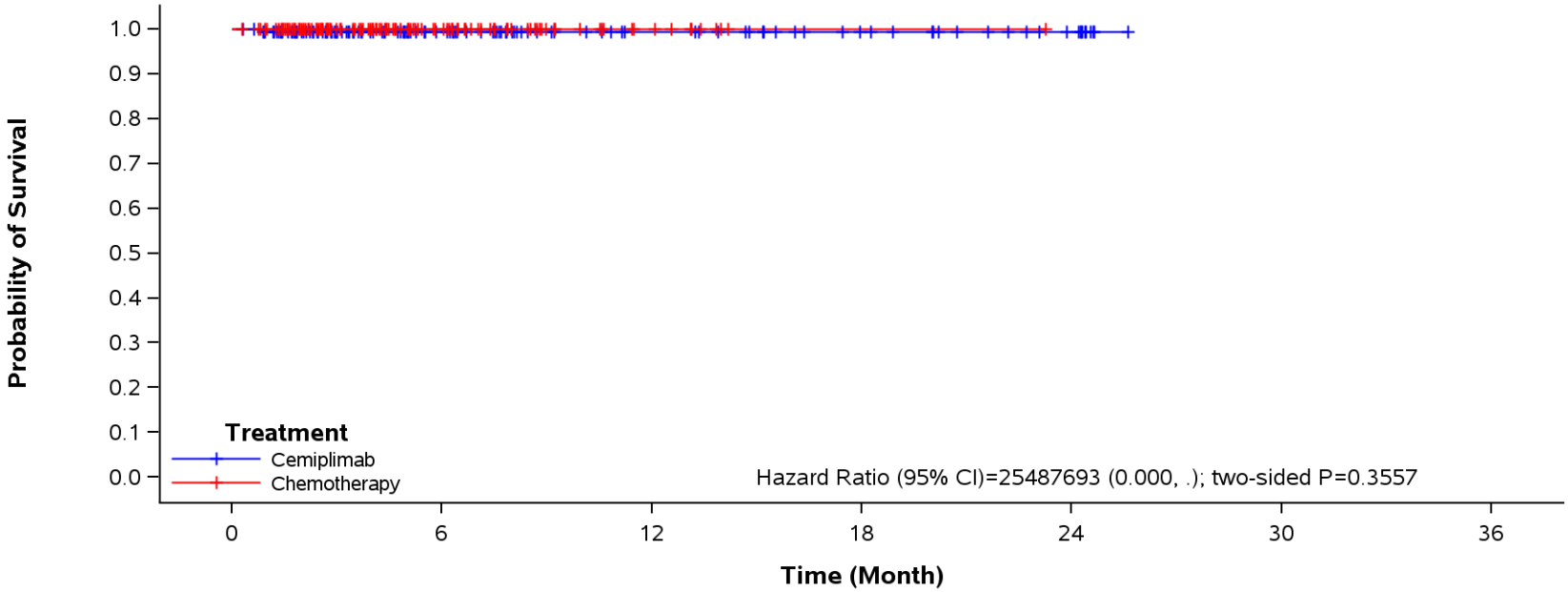

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Investigations
PT: Amylase increased



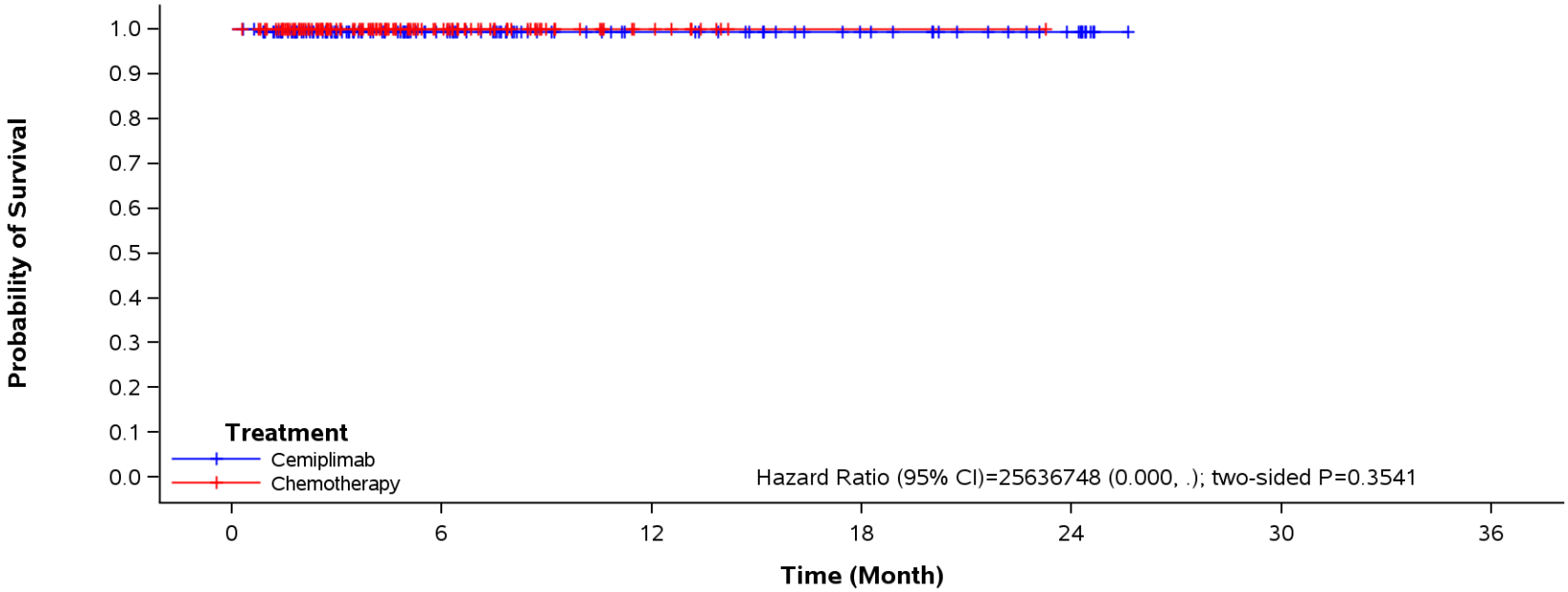

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Investigations
PT: Platelet count decreased



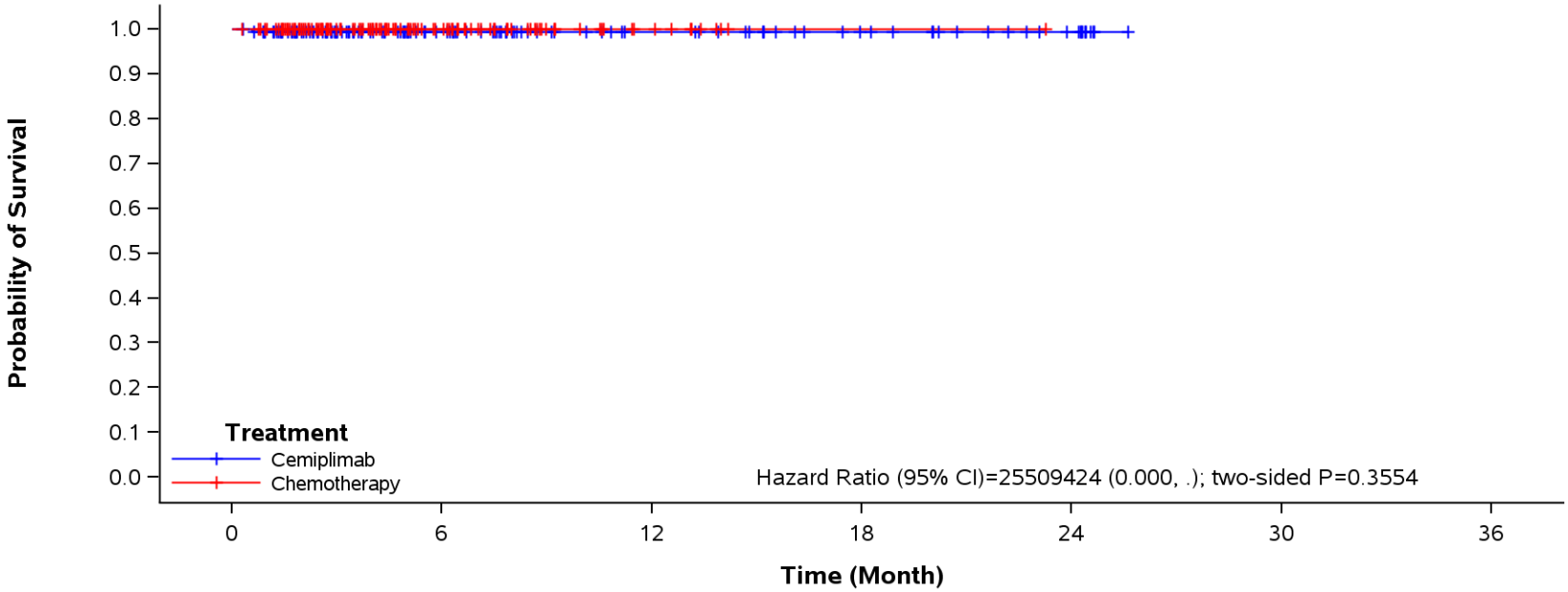

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Metabolism and nutrition disorders



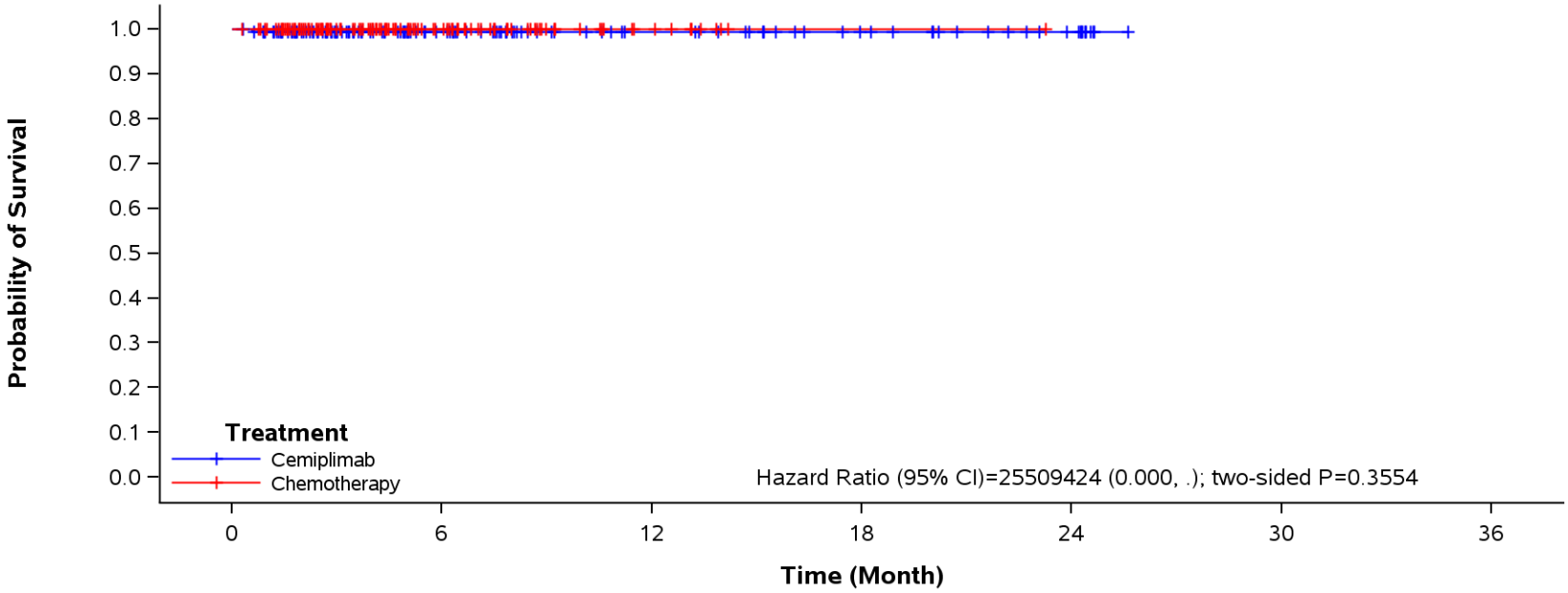

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



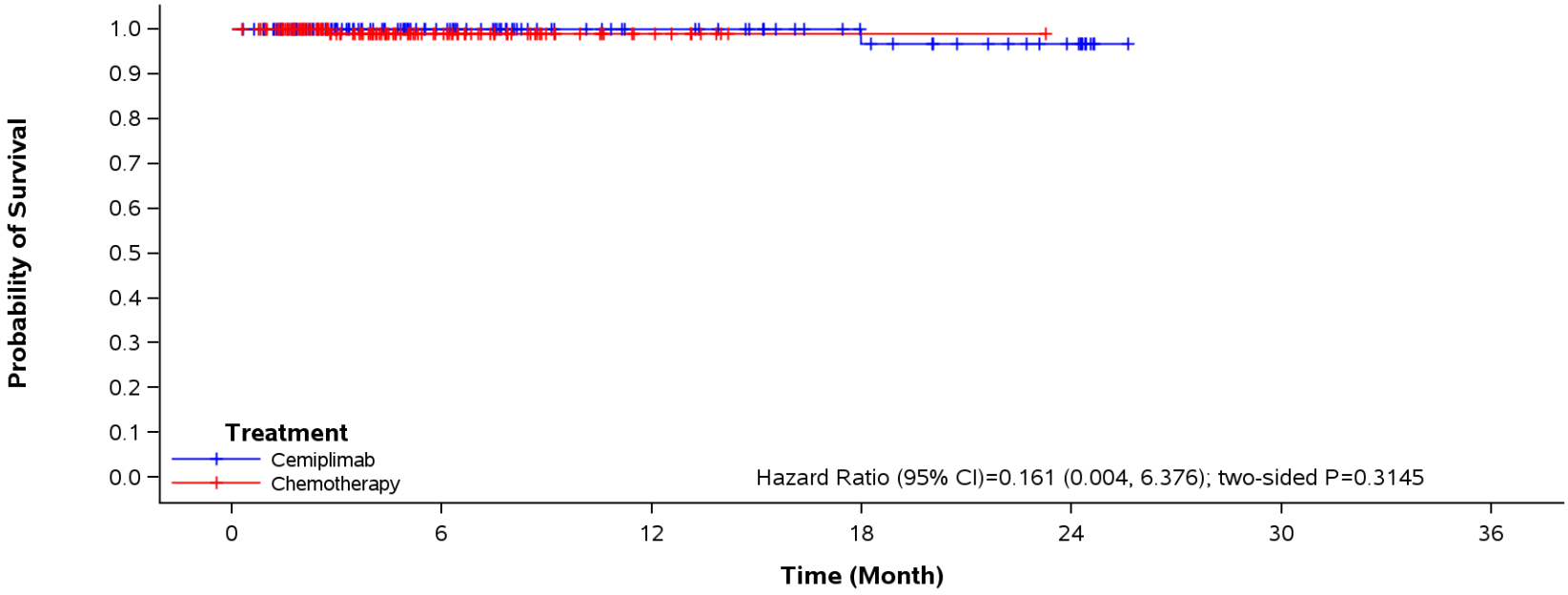

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Musculoskeletal and connective tissue disorders



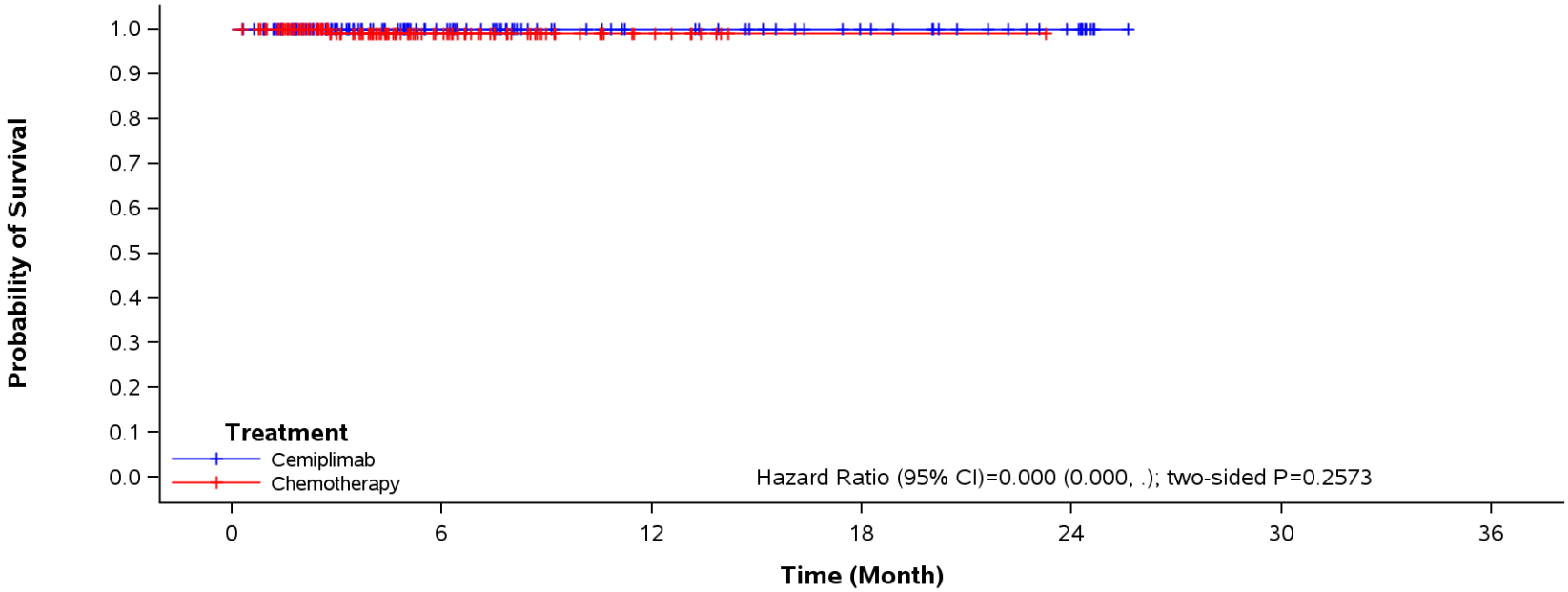

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 29 | 18 | 0 | 0 |
| Chemotherapy | 153 | 45 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



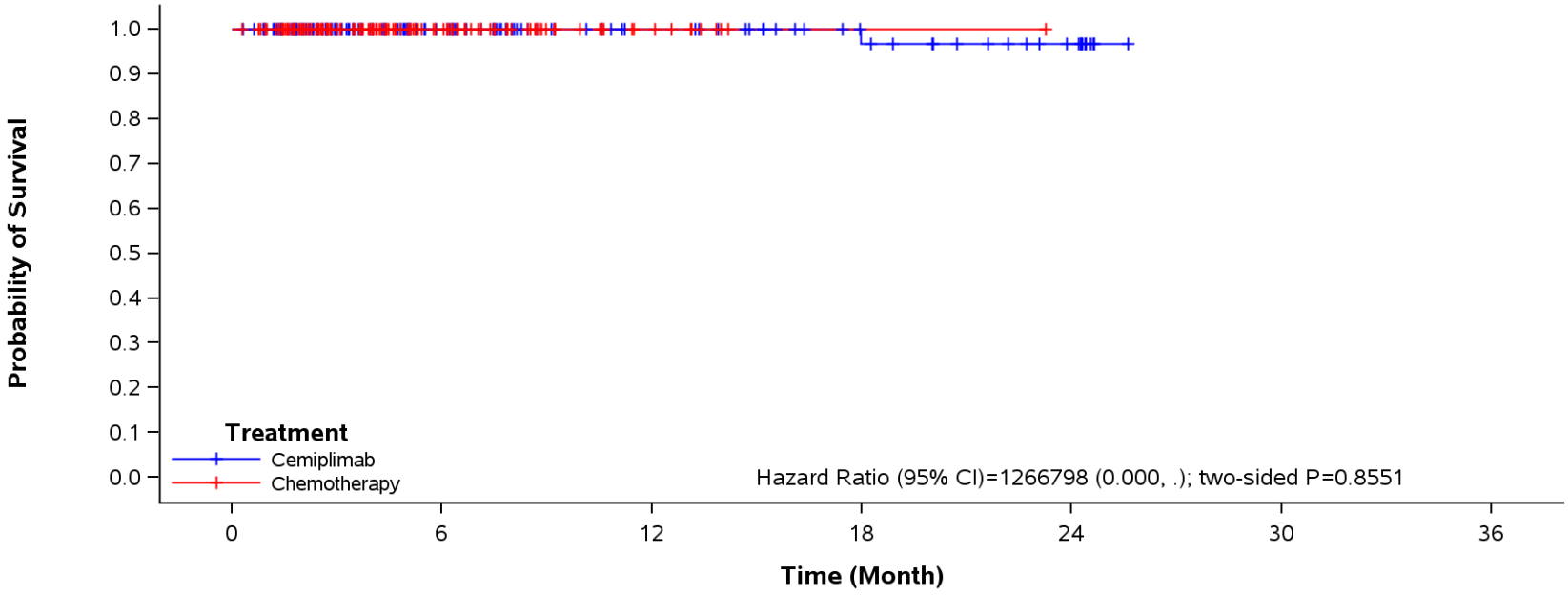

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 45 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



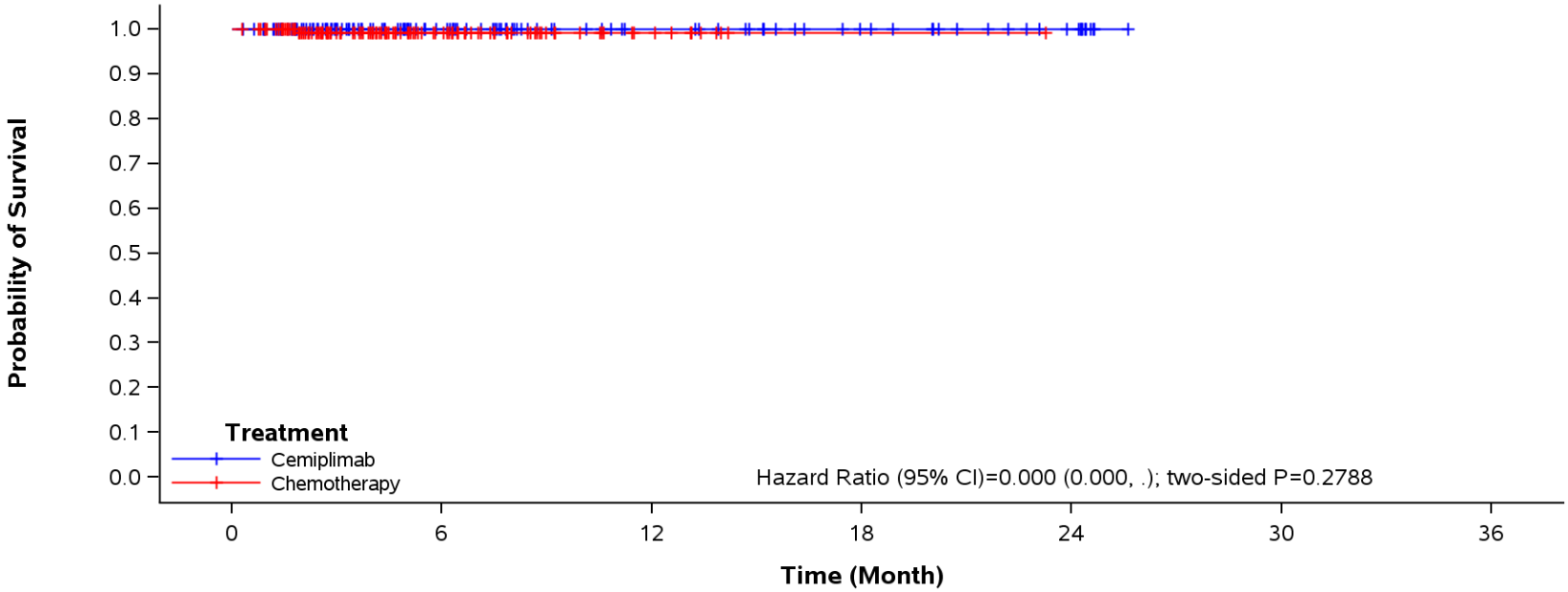

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 29 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Nervous system disorders



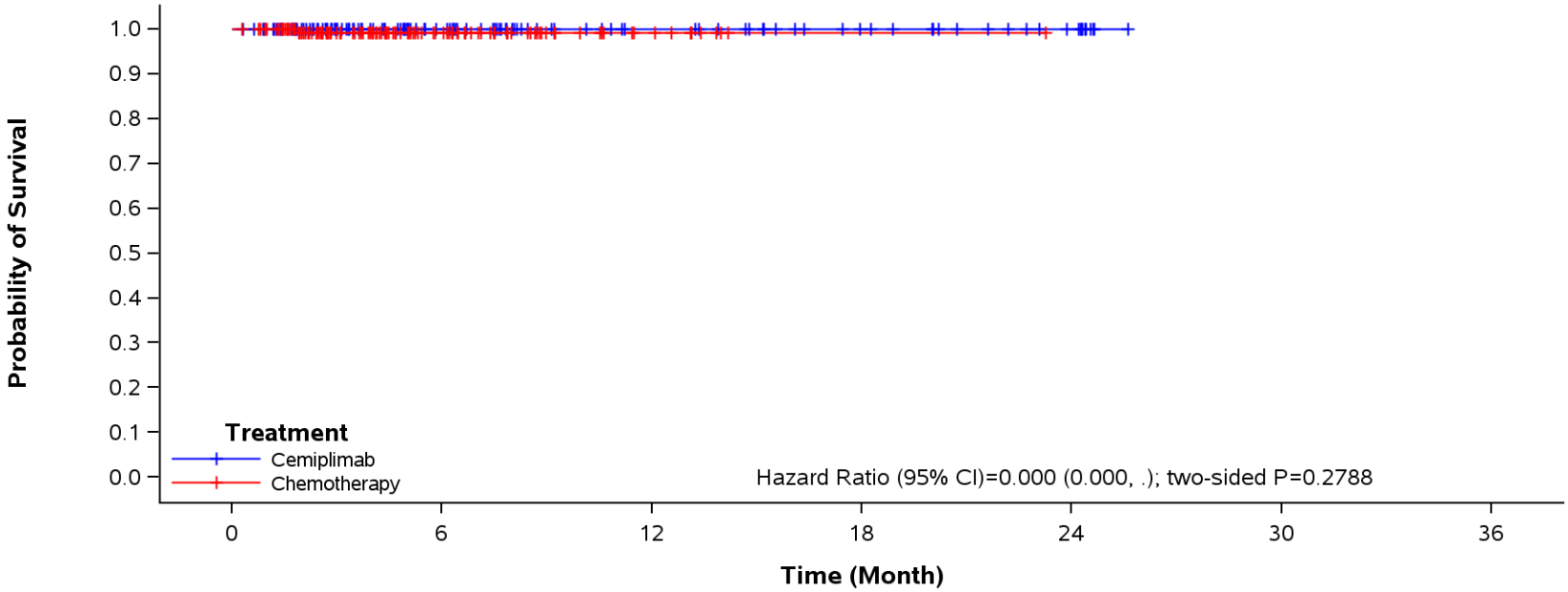

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Nervous system disorders
PT: Neurotoxicity



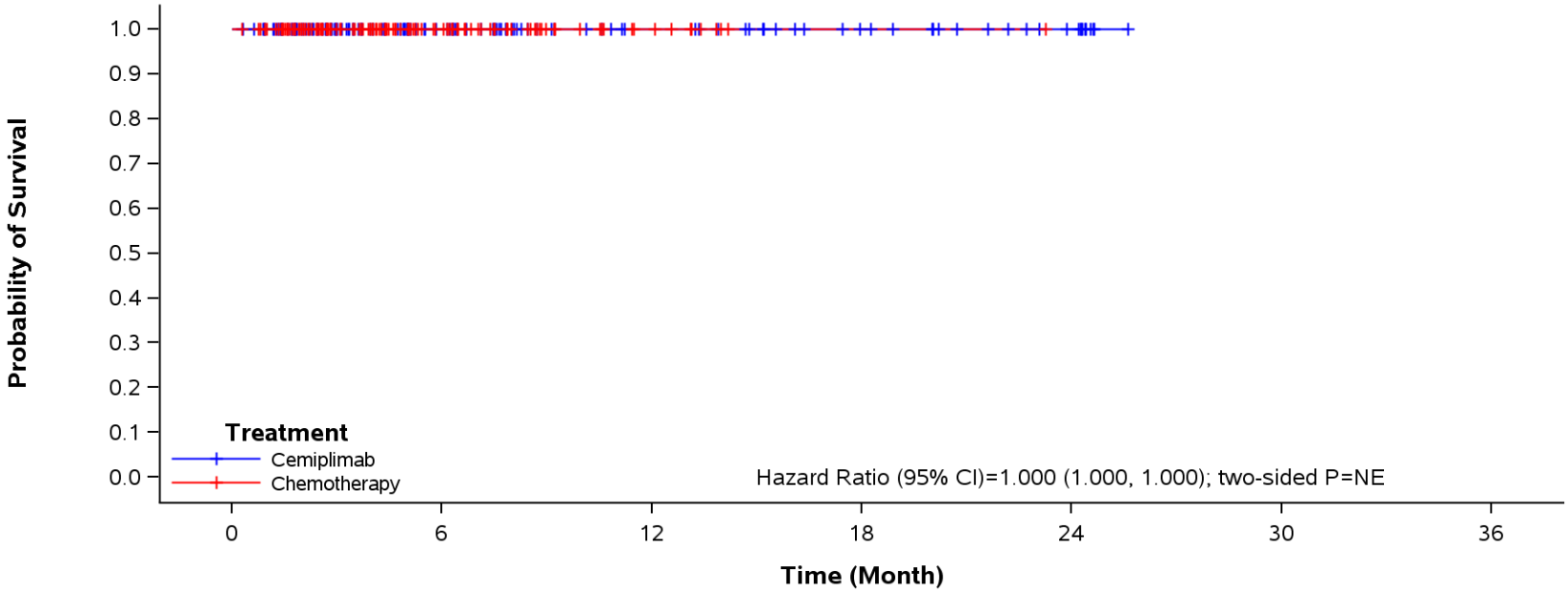

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Nervous system disorders
PT: Transient ischaemic attack



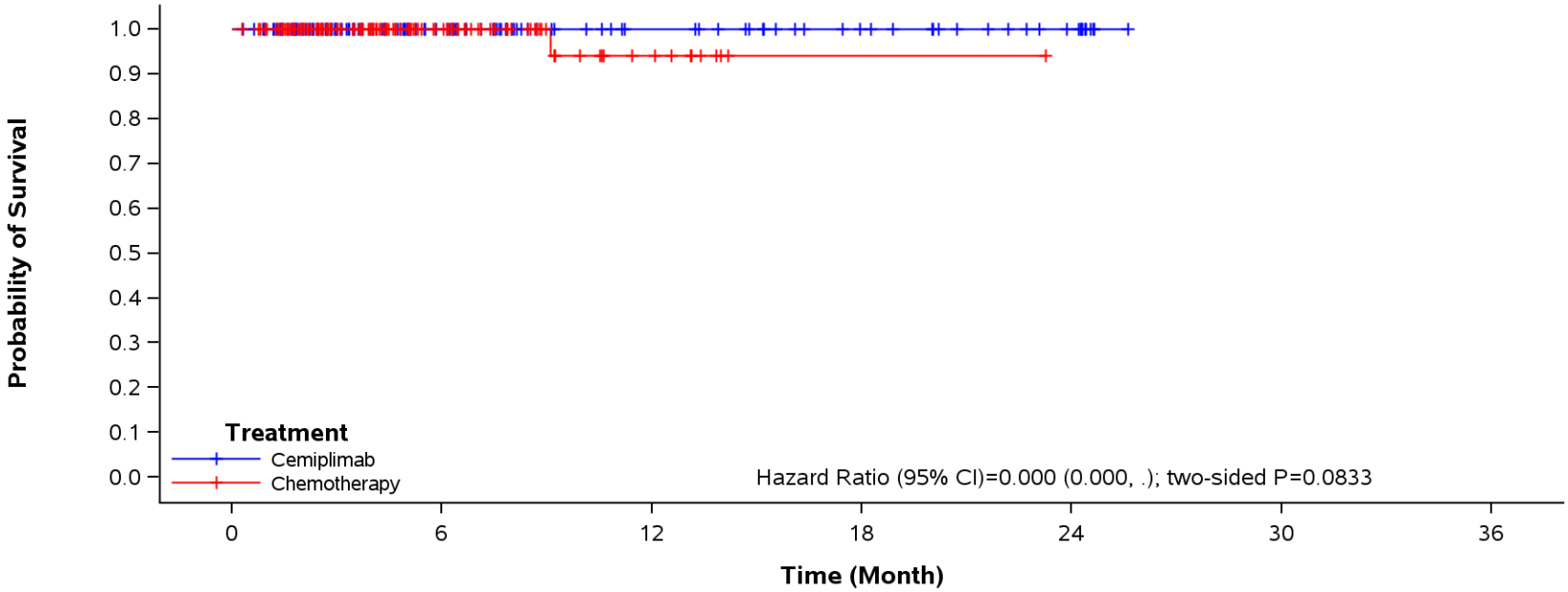

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Psychiatric disorders



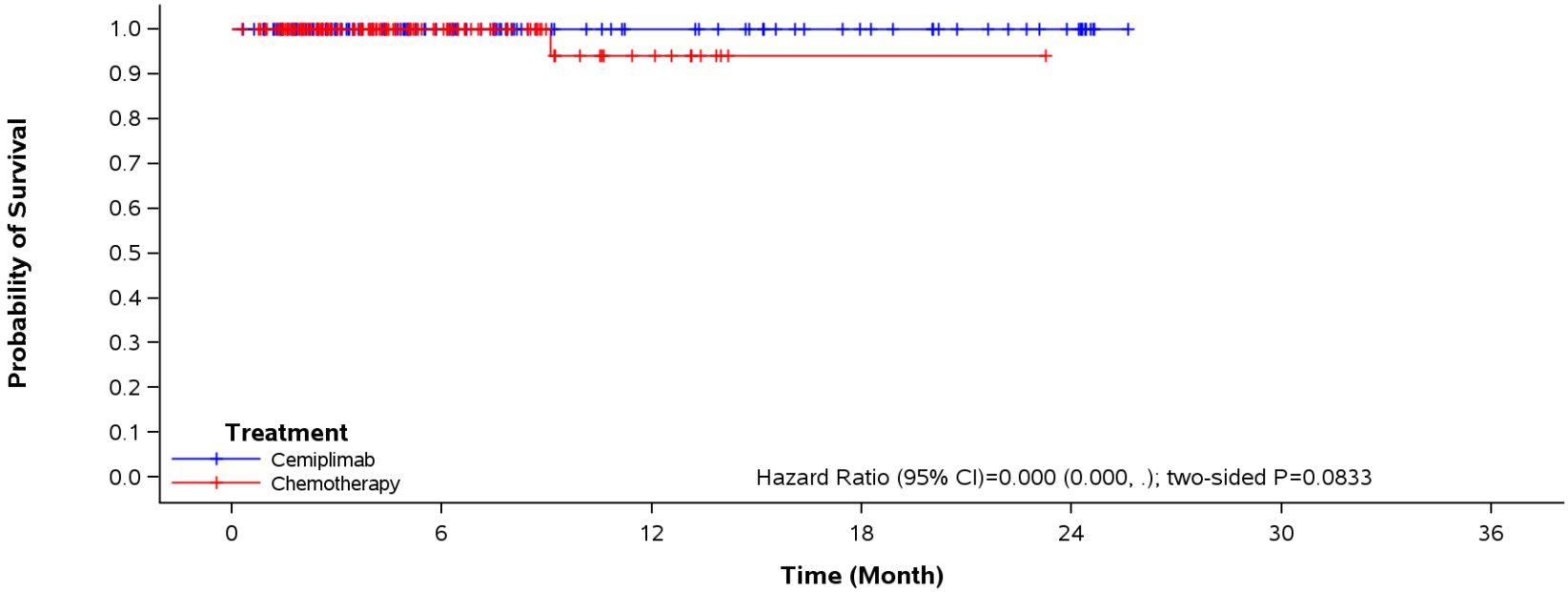

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Psychiatric disorders
PT: Agoraphobia



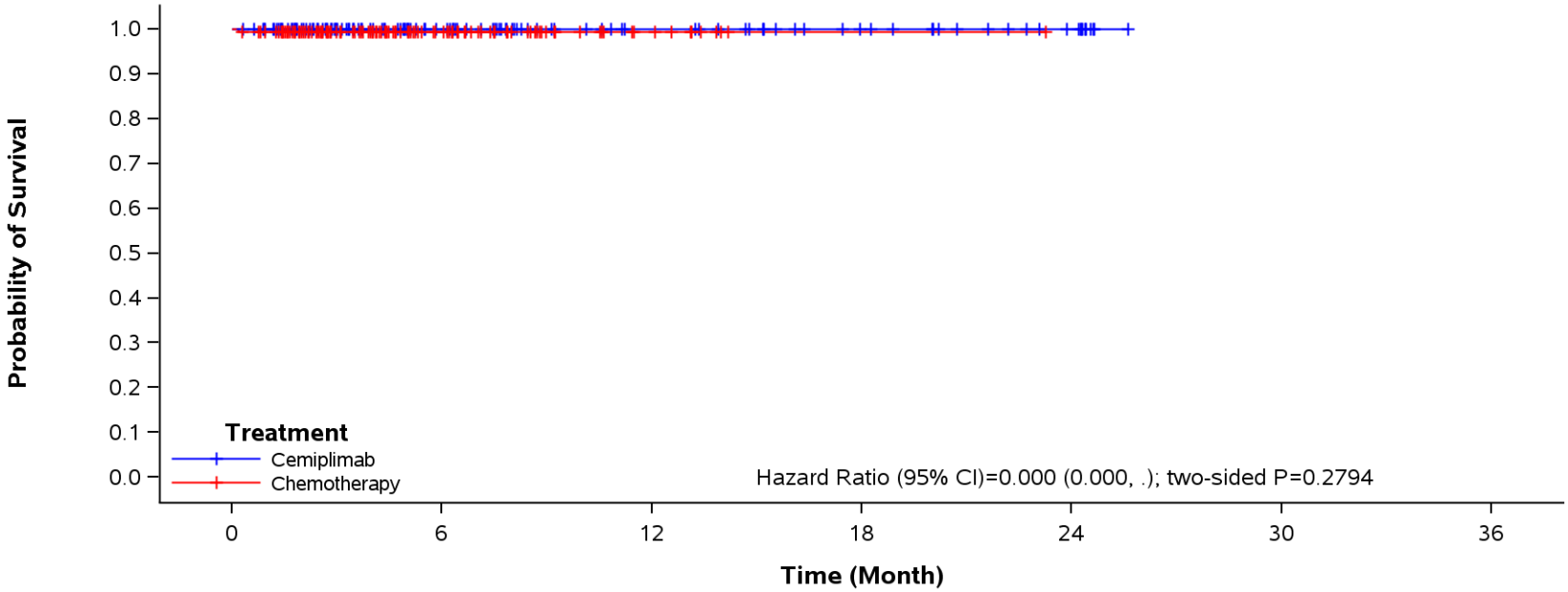

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Renal and urinary disorders



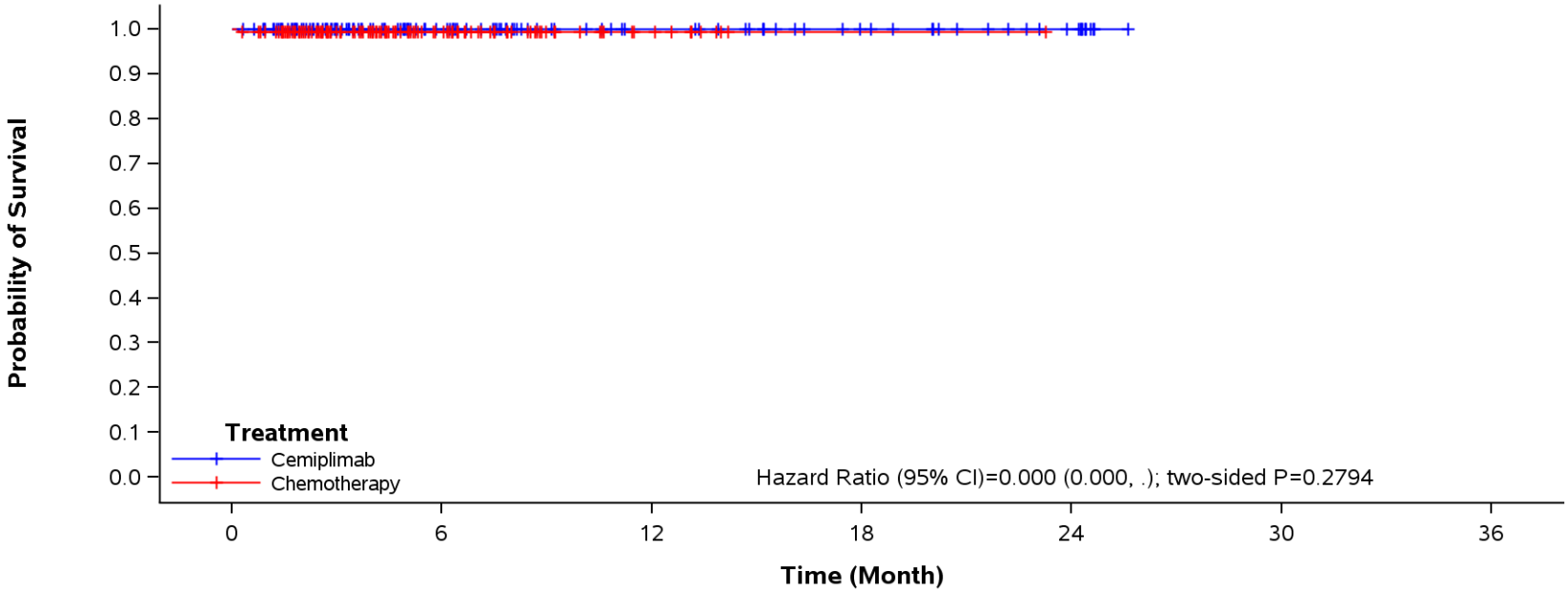

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Renal and urinary disorders
PT: Renal failure



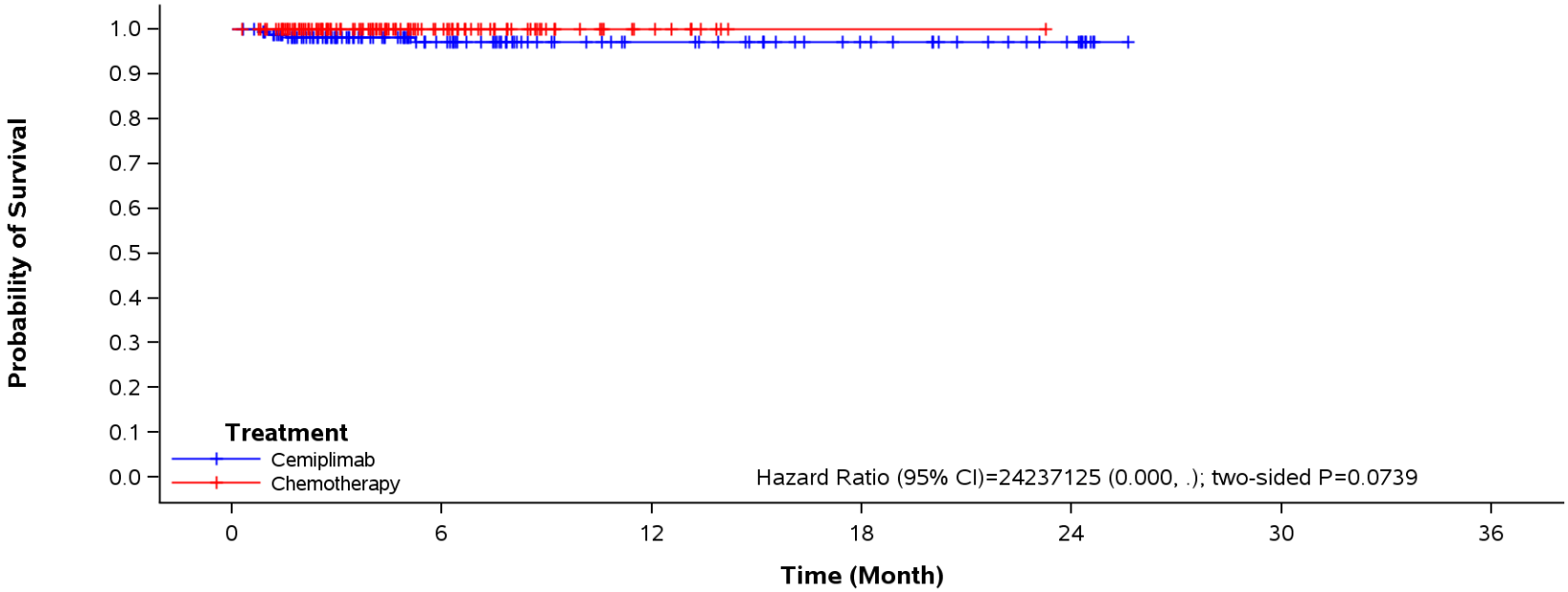

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Respiratory, thoracic and mediastinal disorders



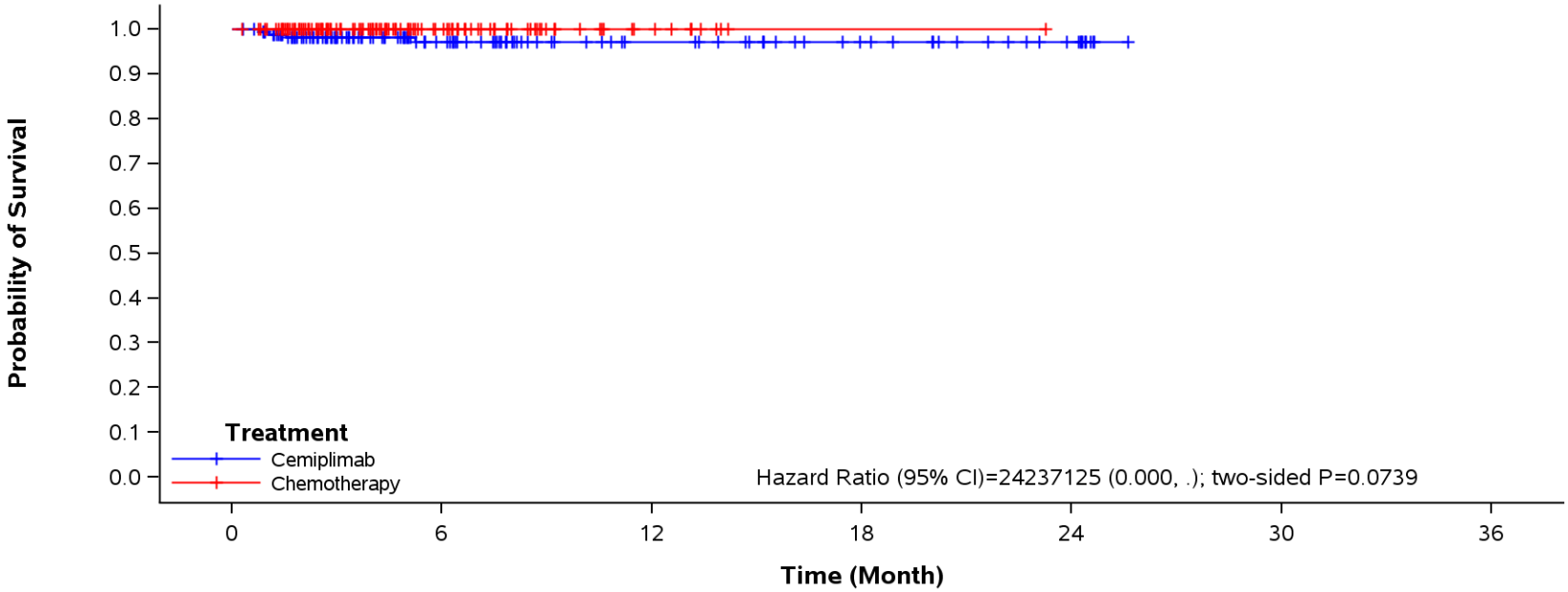

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



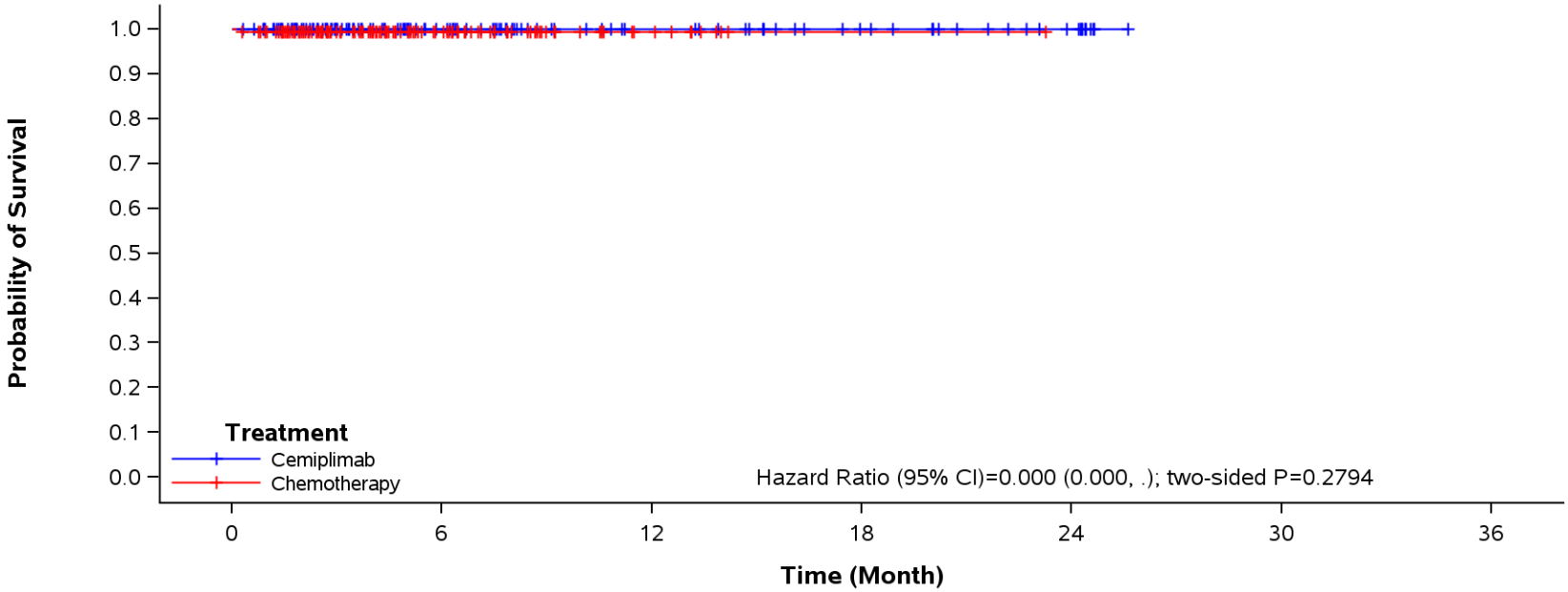

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 75 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Vascular disorders



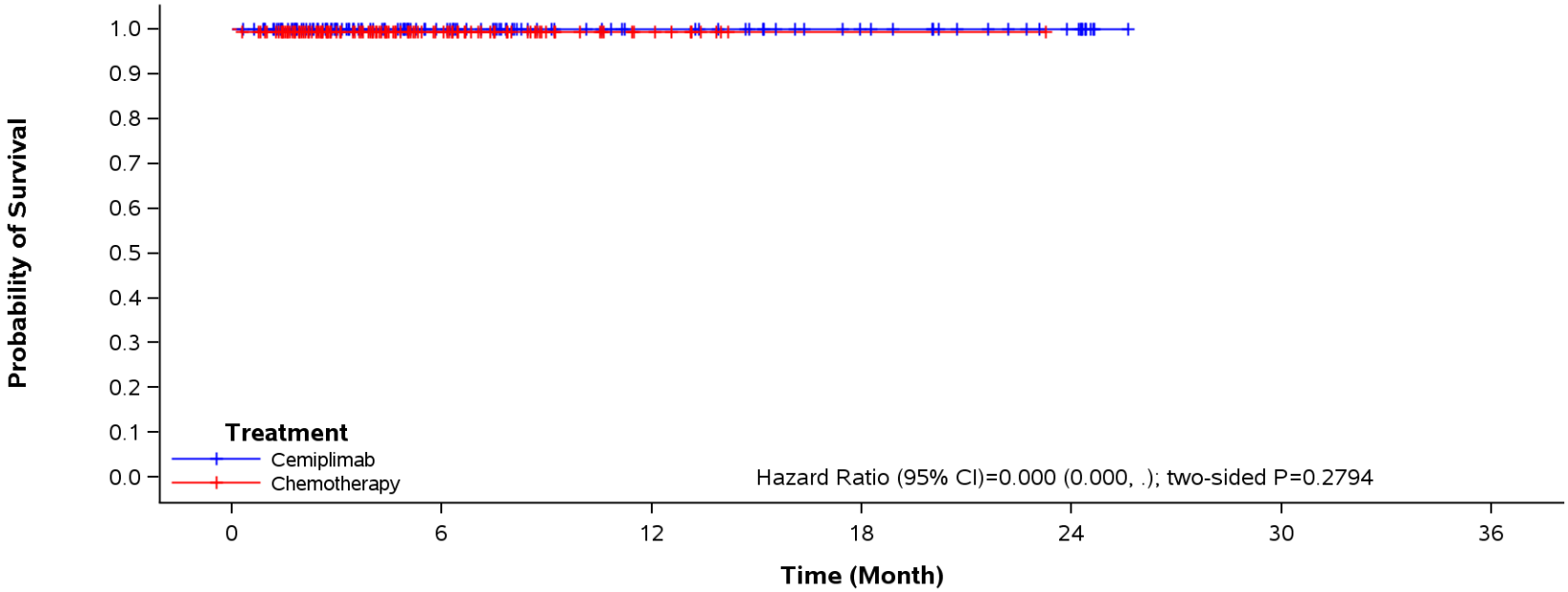

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: <65
SOC: Vascular disorders
PT: Deep vein thrombosis




**Number of Subjects at risk**

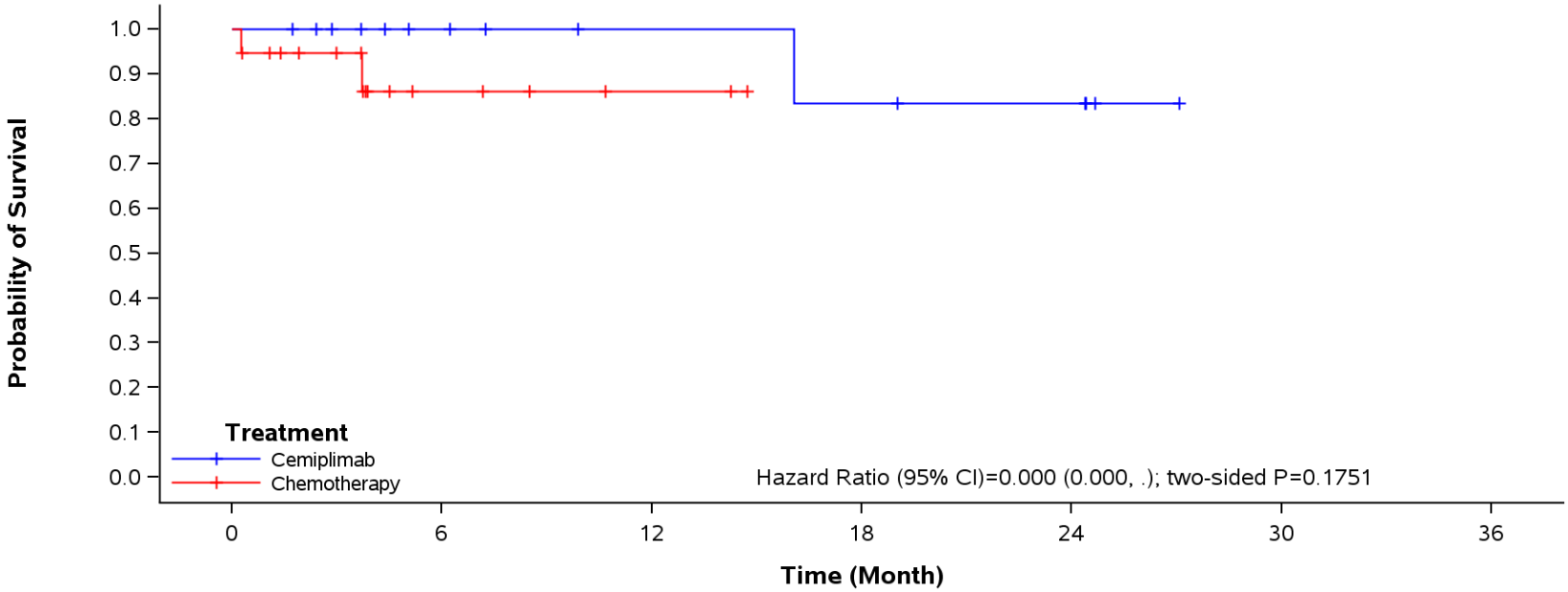
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 179 | 76 | 42 | 30 | 18 | 0 | 0 |
| Chemotherapy | 153 | 46 | 9 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

Number of patients with any TEAE leading to discontinuation




**Number of Subjects at risk**

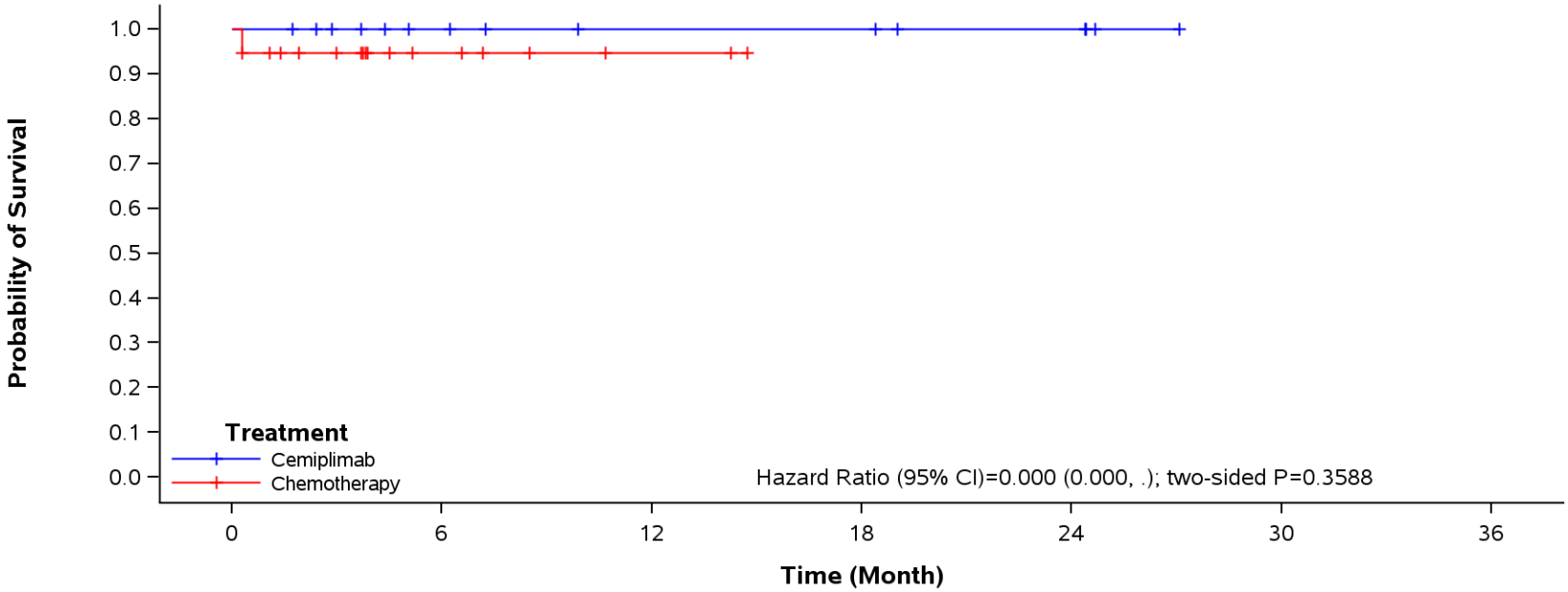
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 4 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders



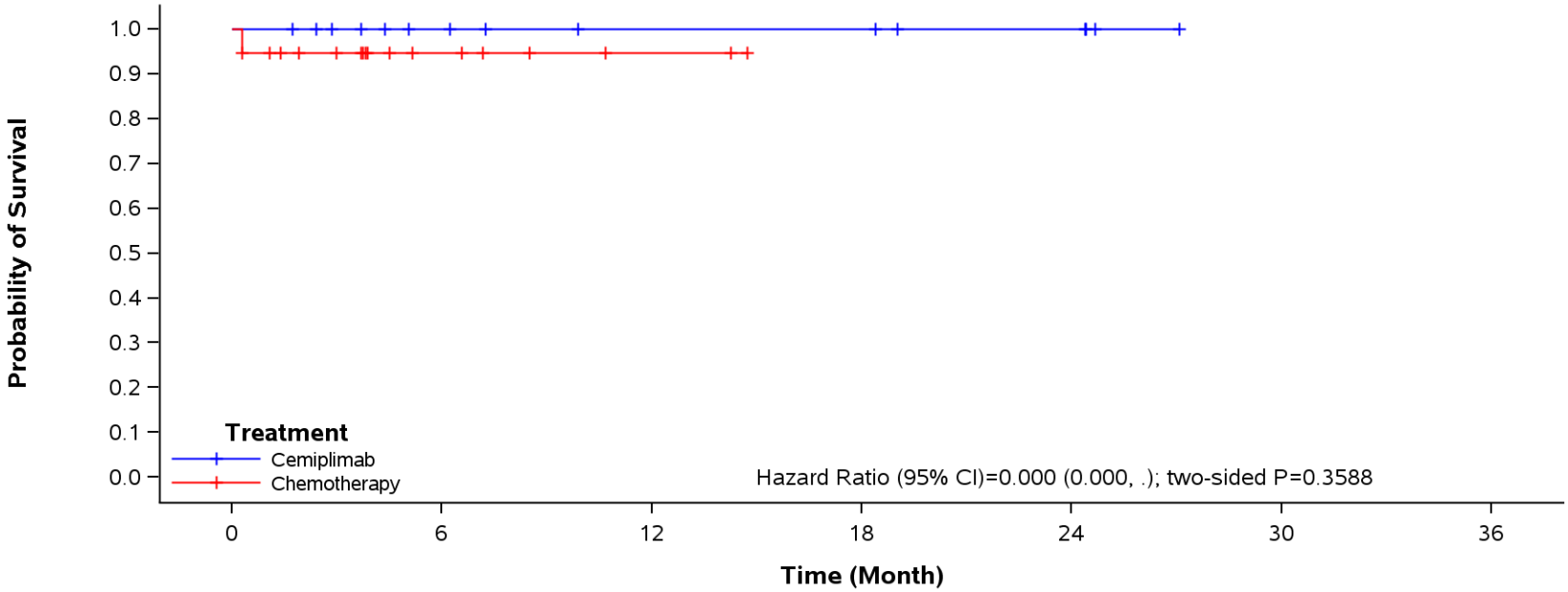

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Anaemia



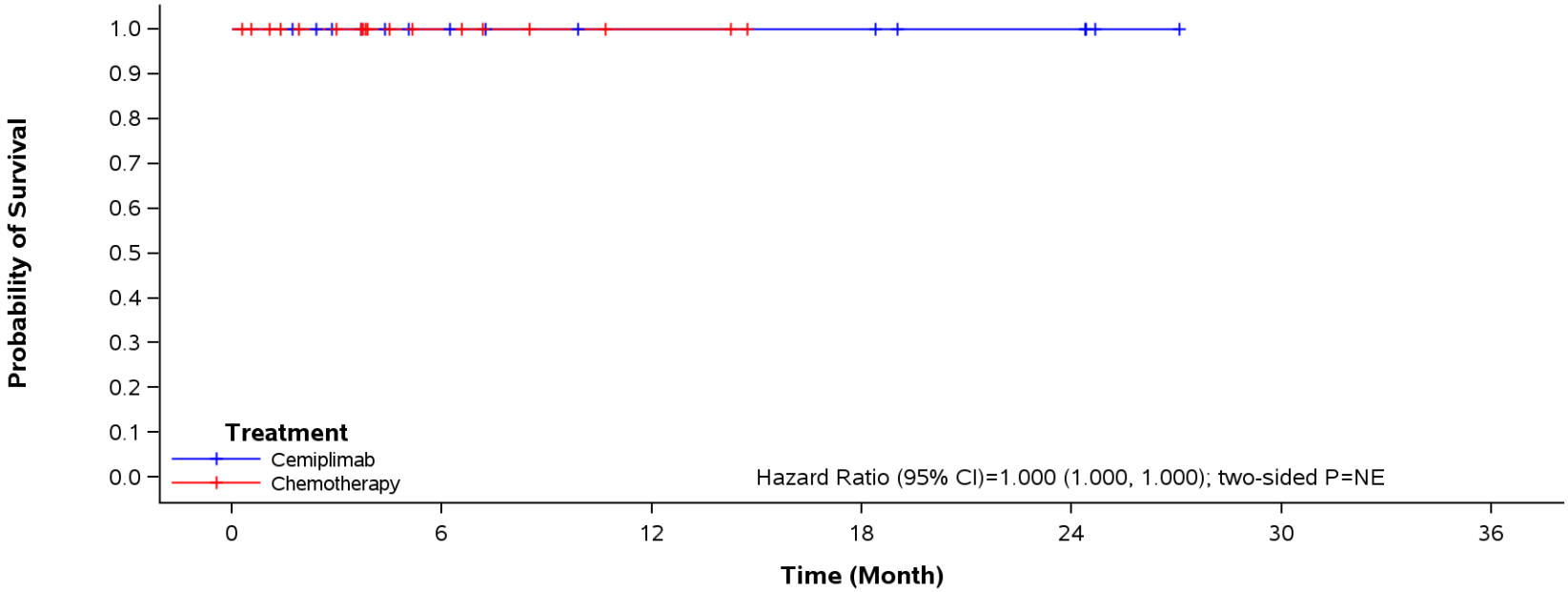

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



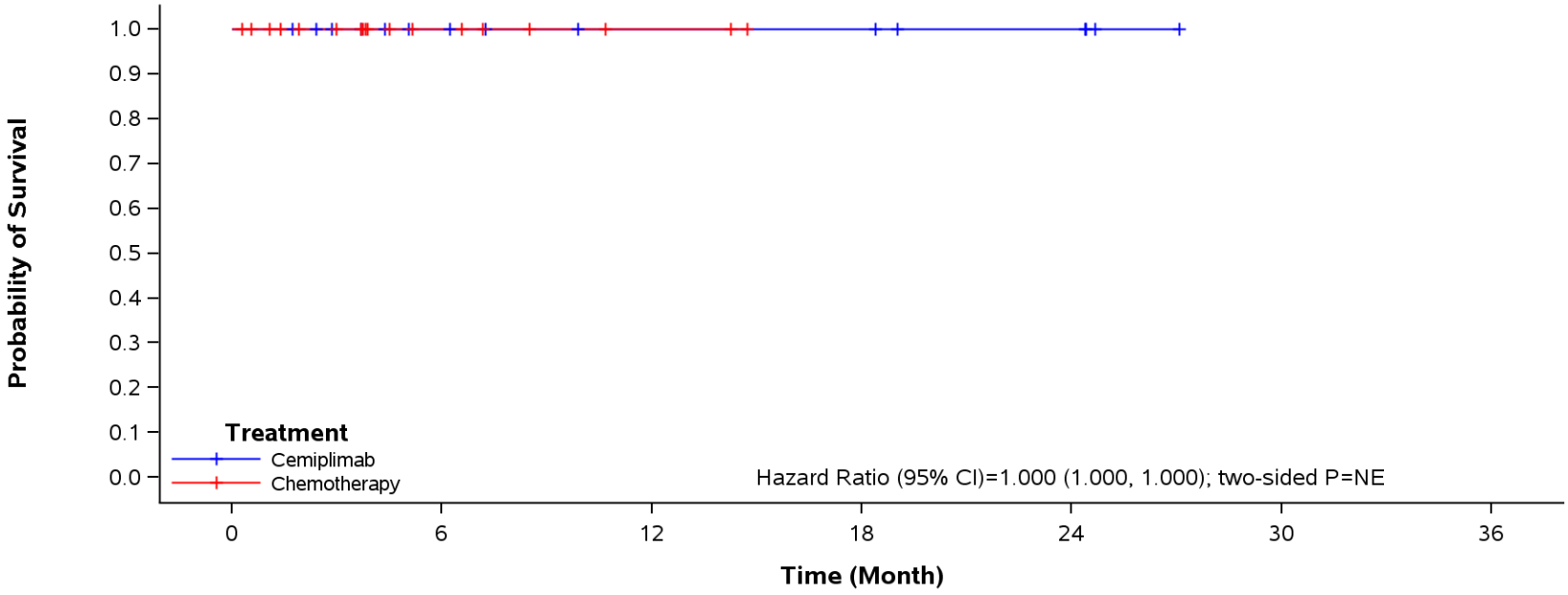

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Neutropenia



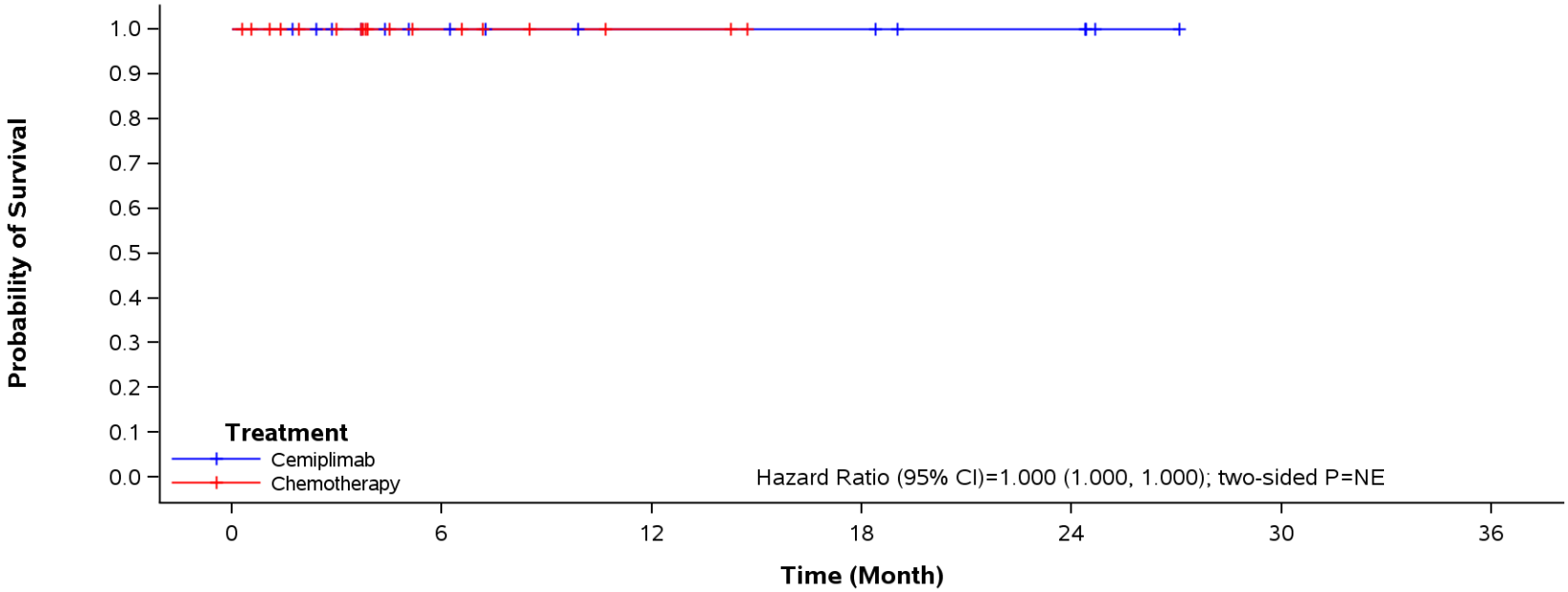

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



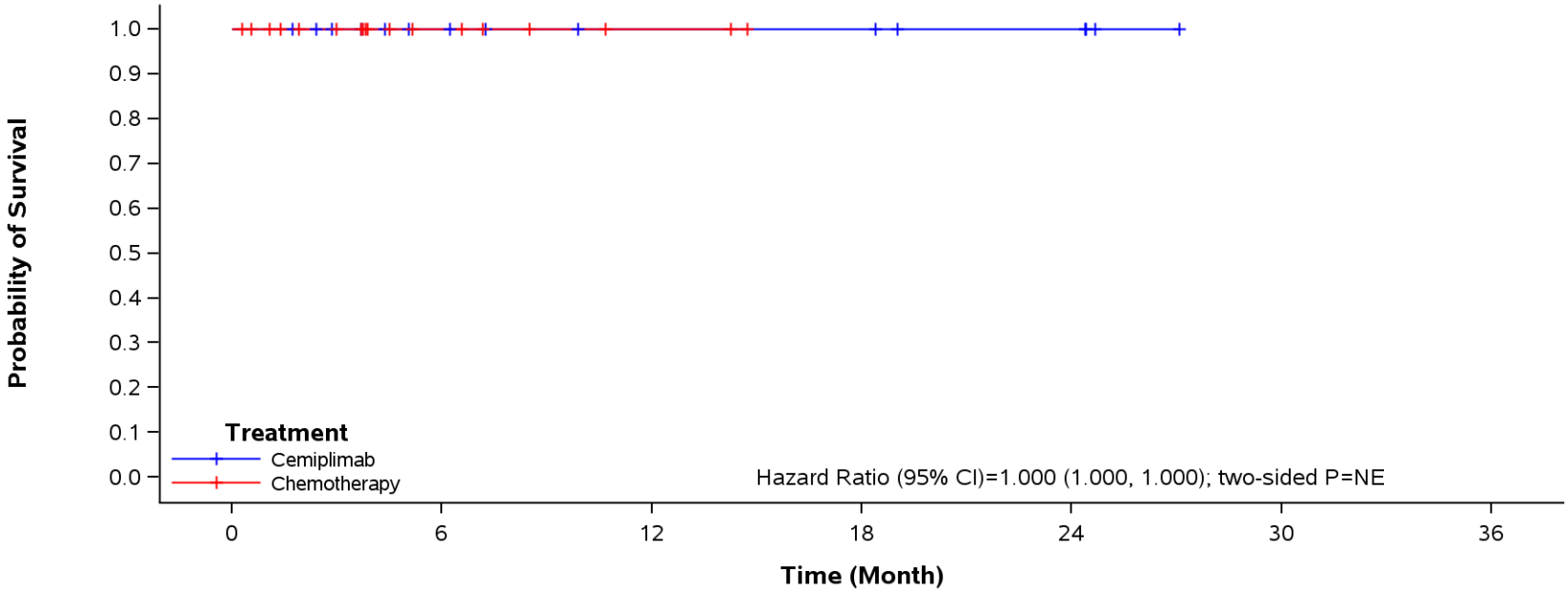

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Cardiac disorders



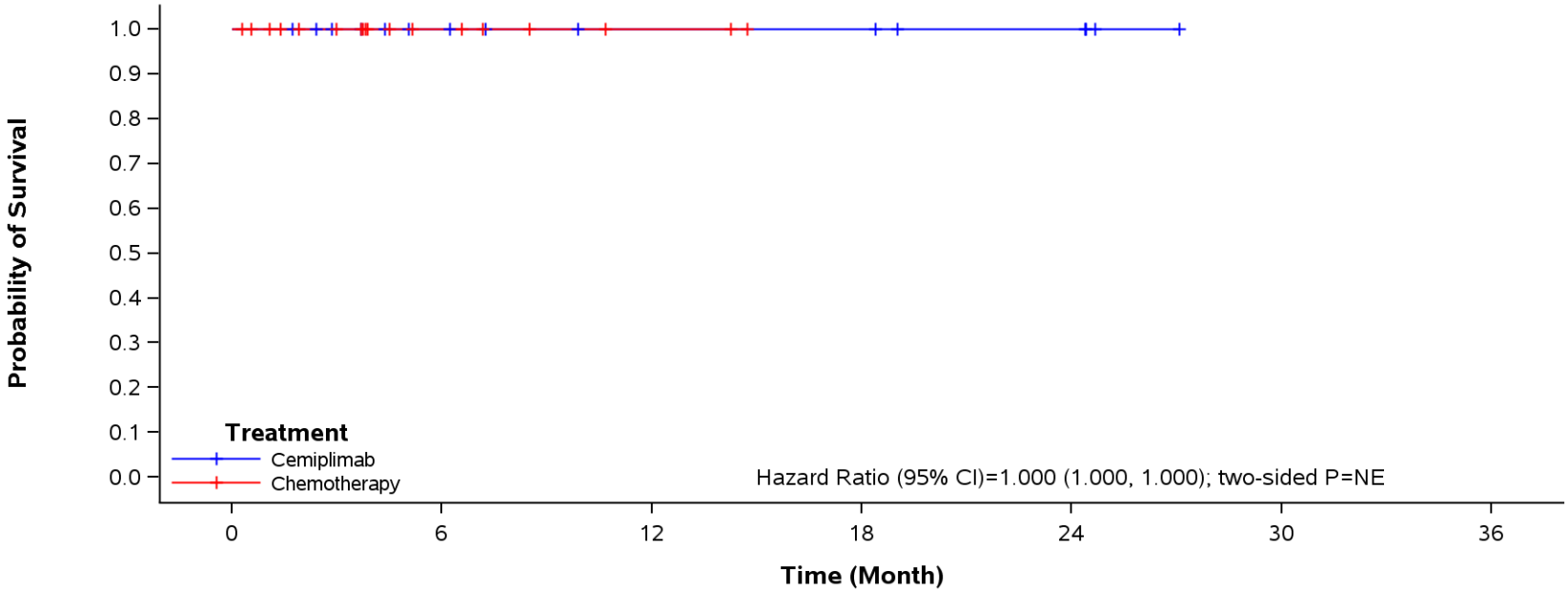

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Cardiac disorders
PT: Autoimmune pericarditis



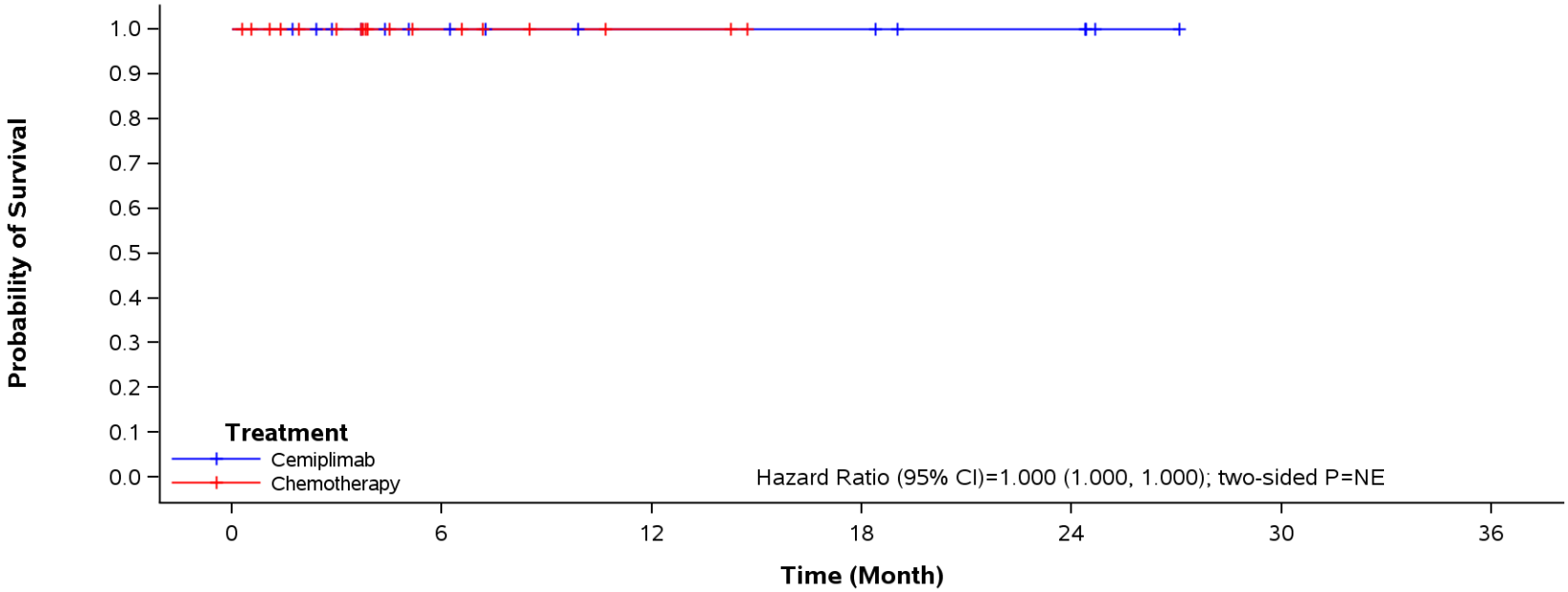

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Endocrine disorders



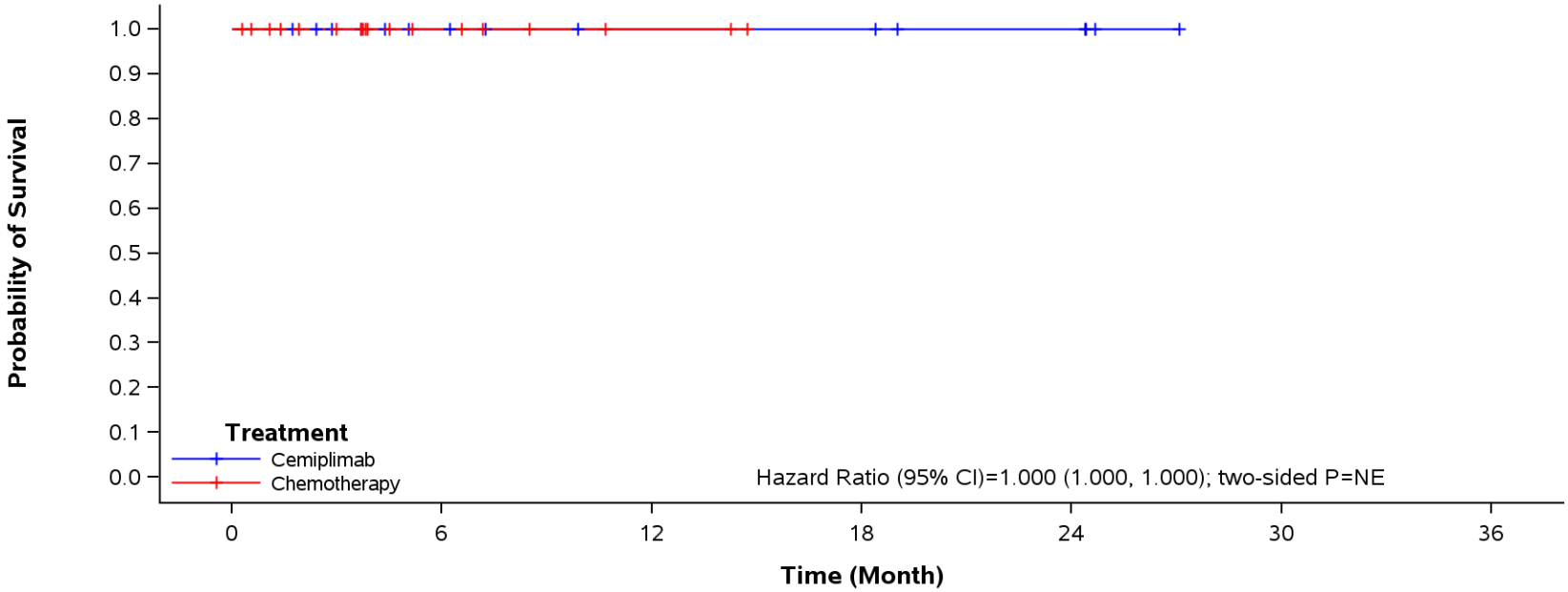

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Endocrine disorders
PT: Hypothyroidism



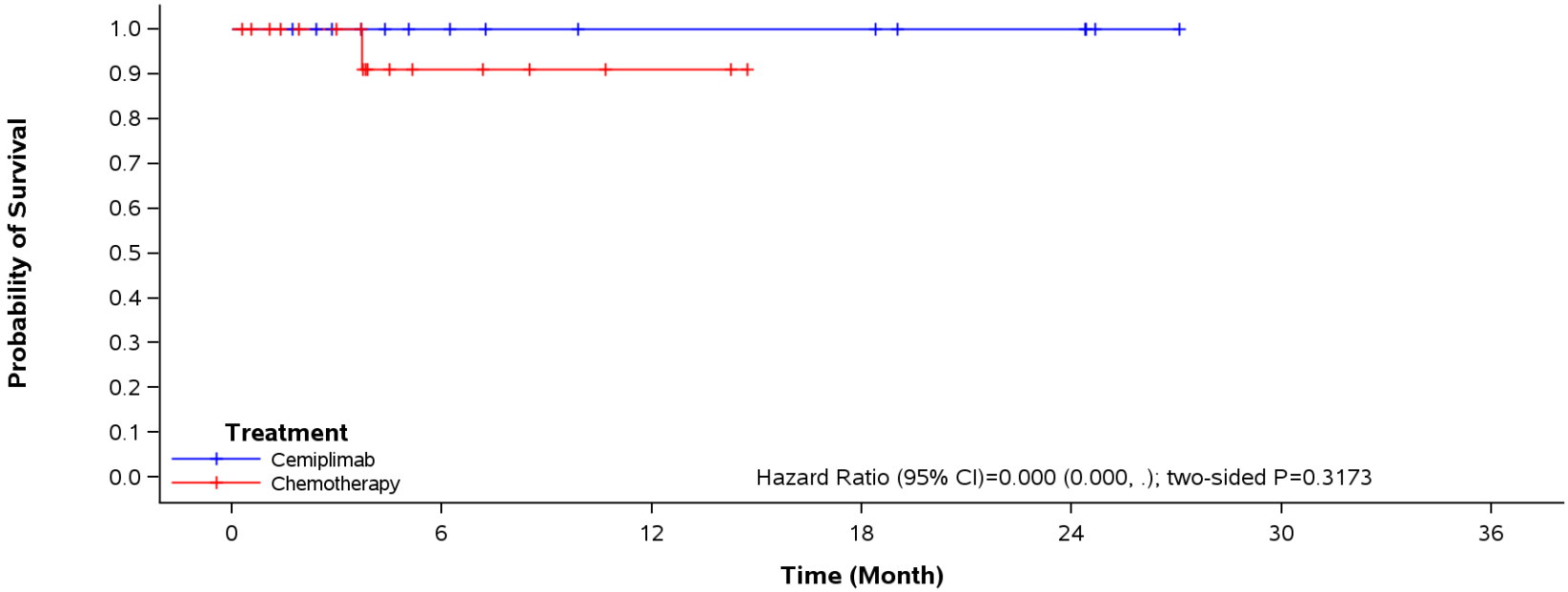

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders



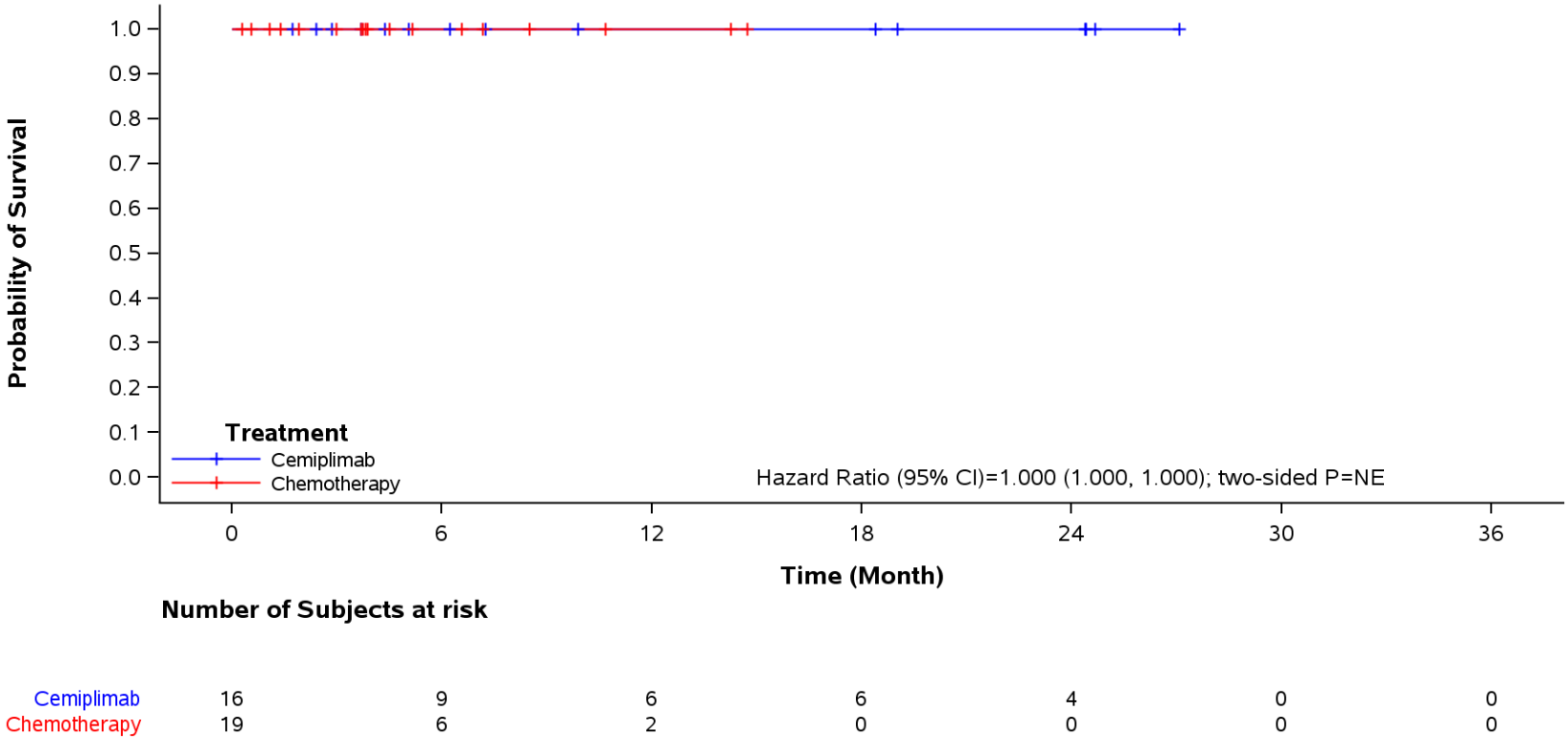

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

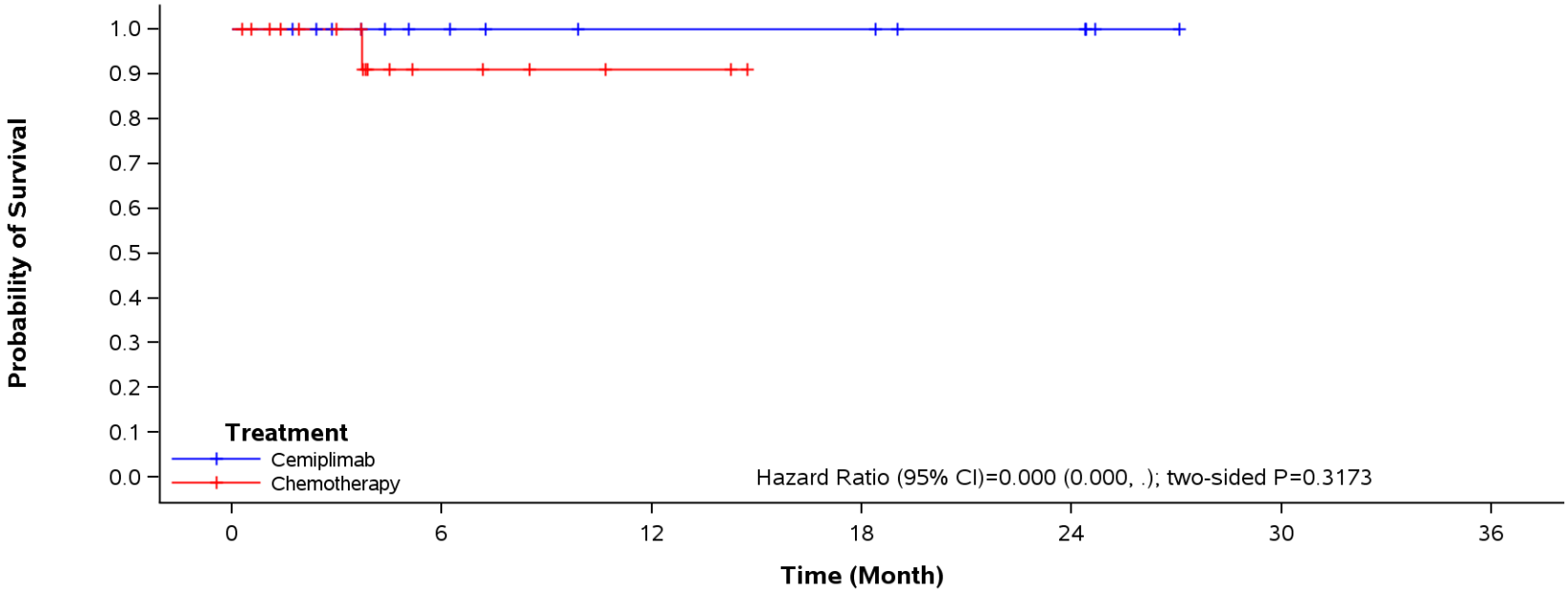
Age Group: >=65
SOC: Gastrointestinal disorders
PT: Colitis




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders
PT: Diverticular perforation



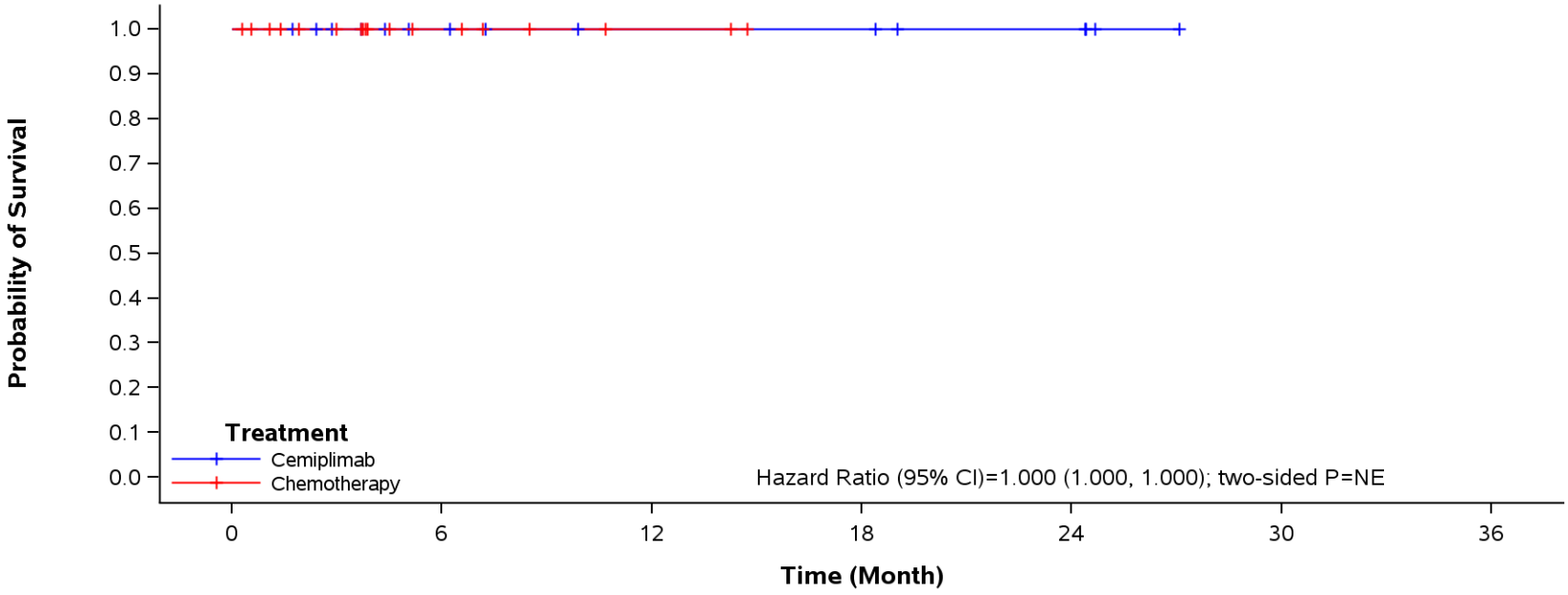

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders
PT: Pancreatic mass



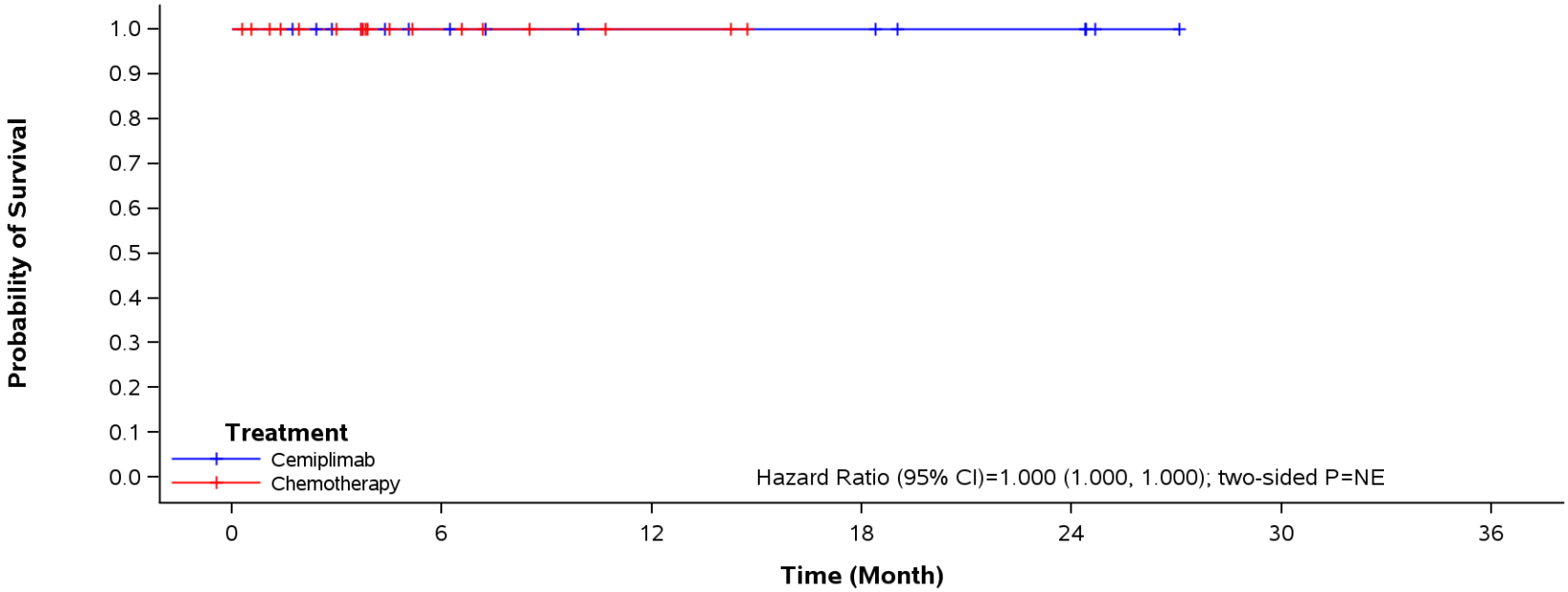

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



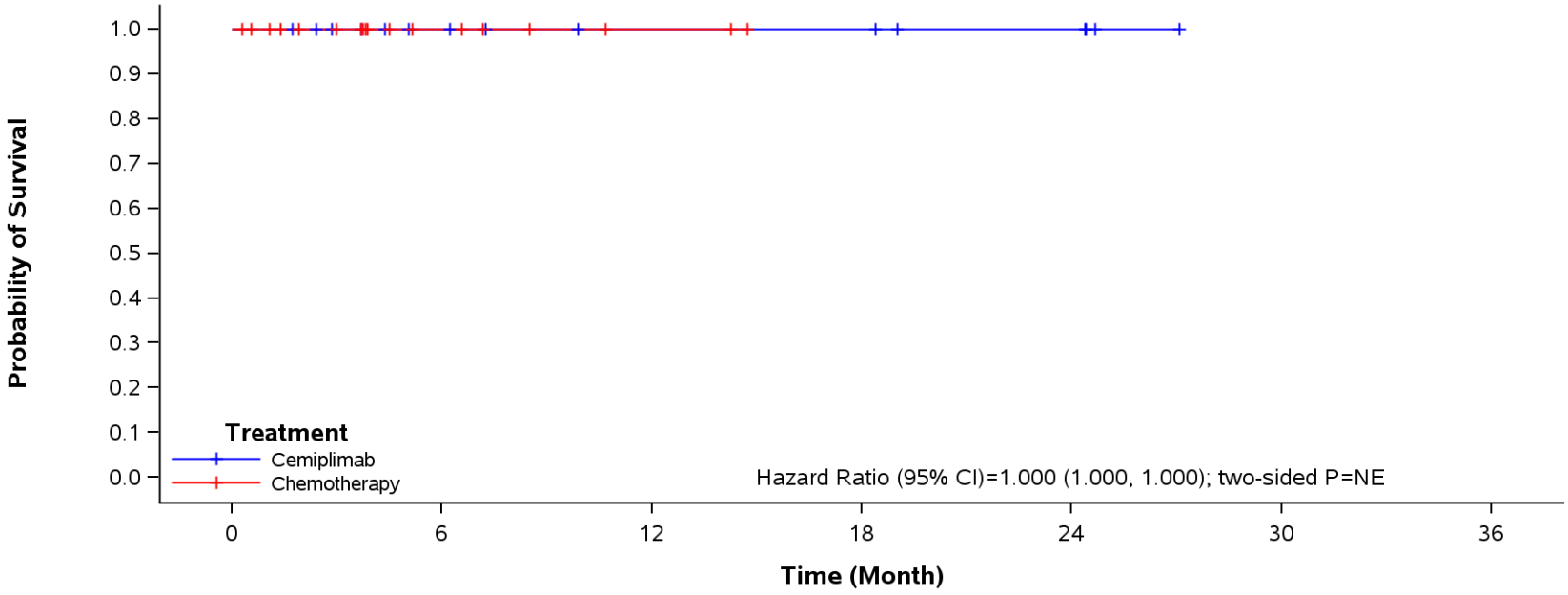

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Gastrointestinal disorders
PT: Proctalgia



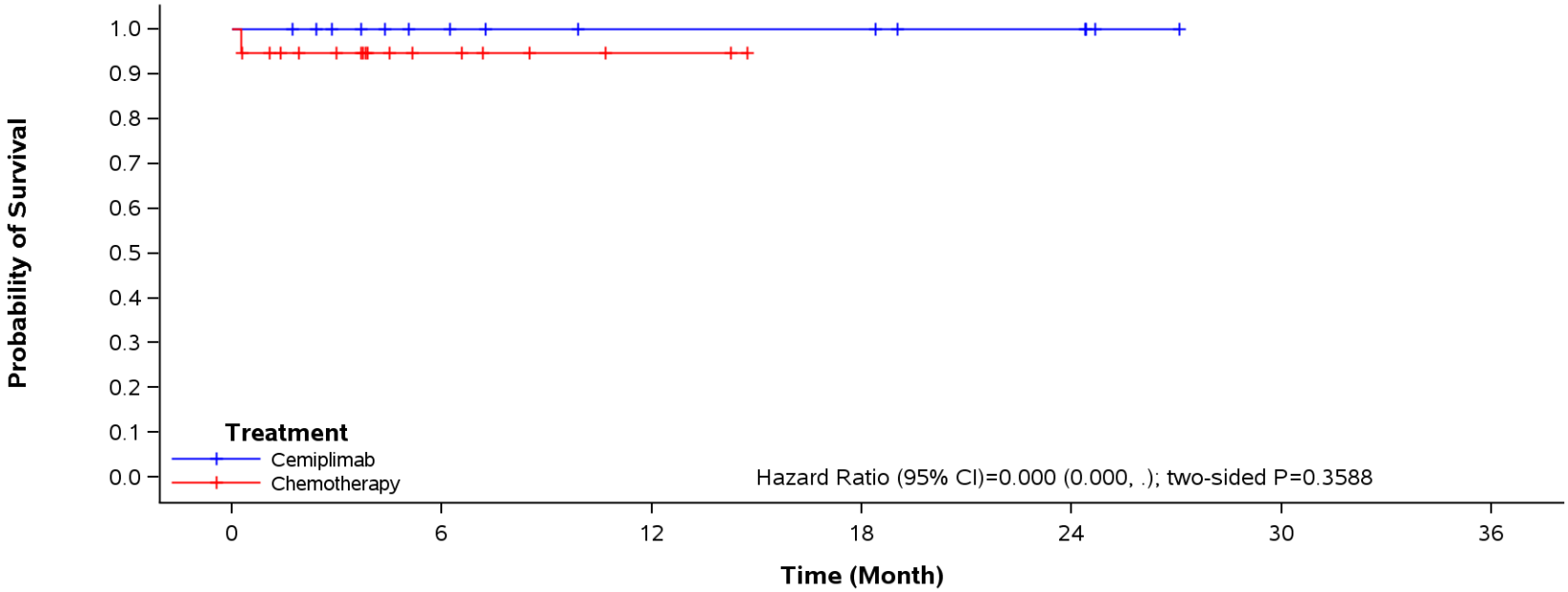

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: General disorders and administration site conditions



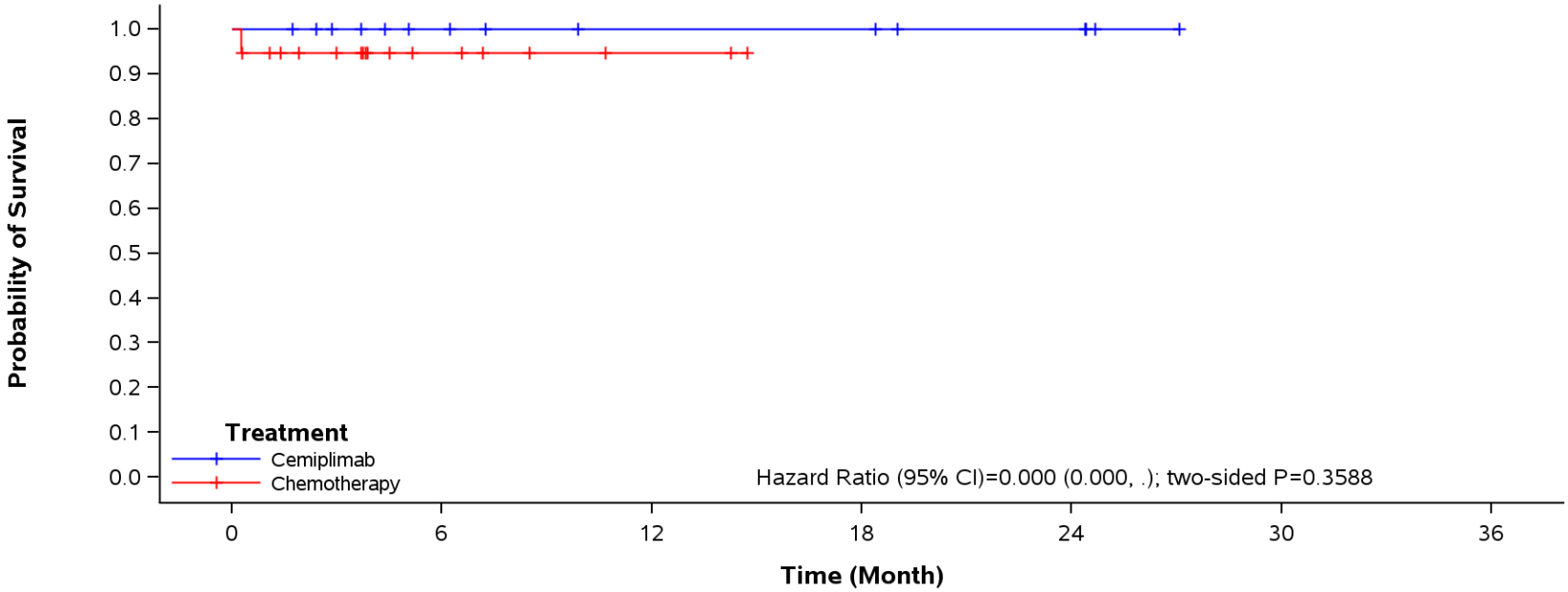

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: General disorders and administration site conditions
PT: Malaise



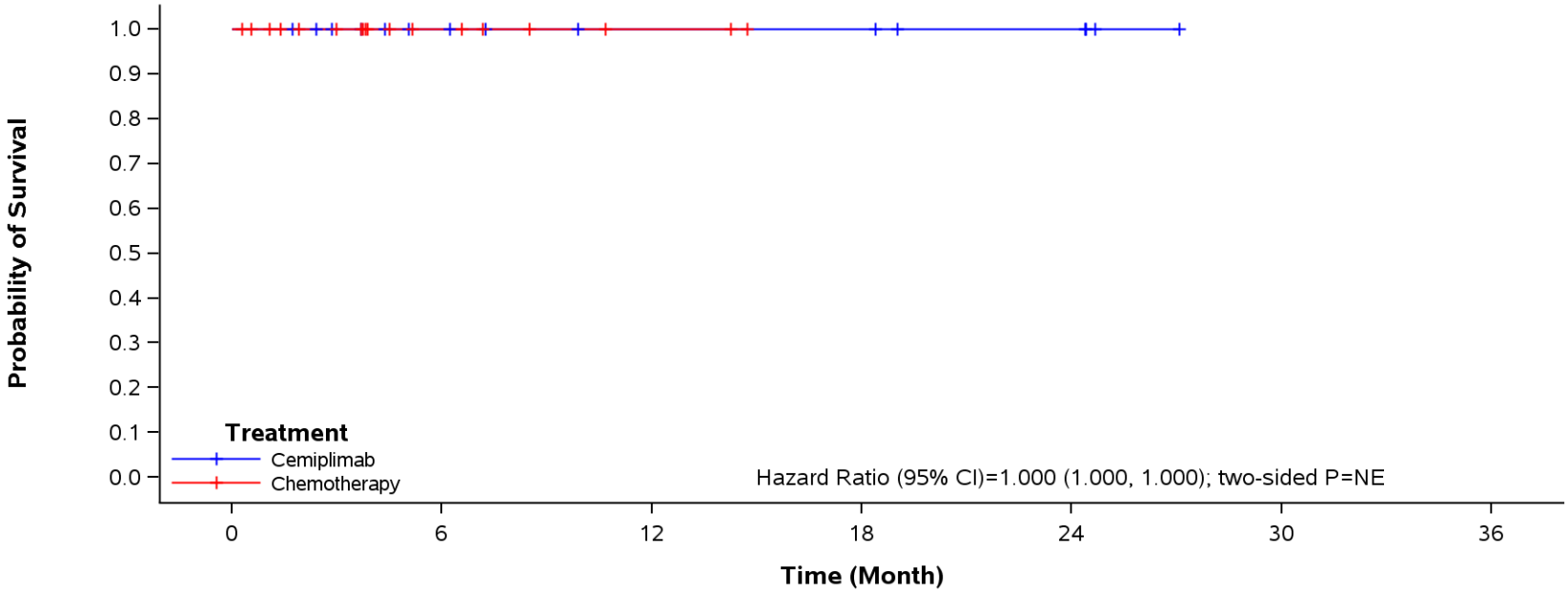

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



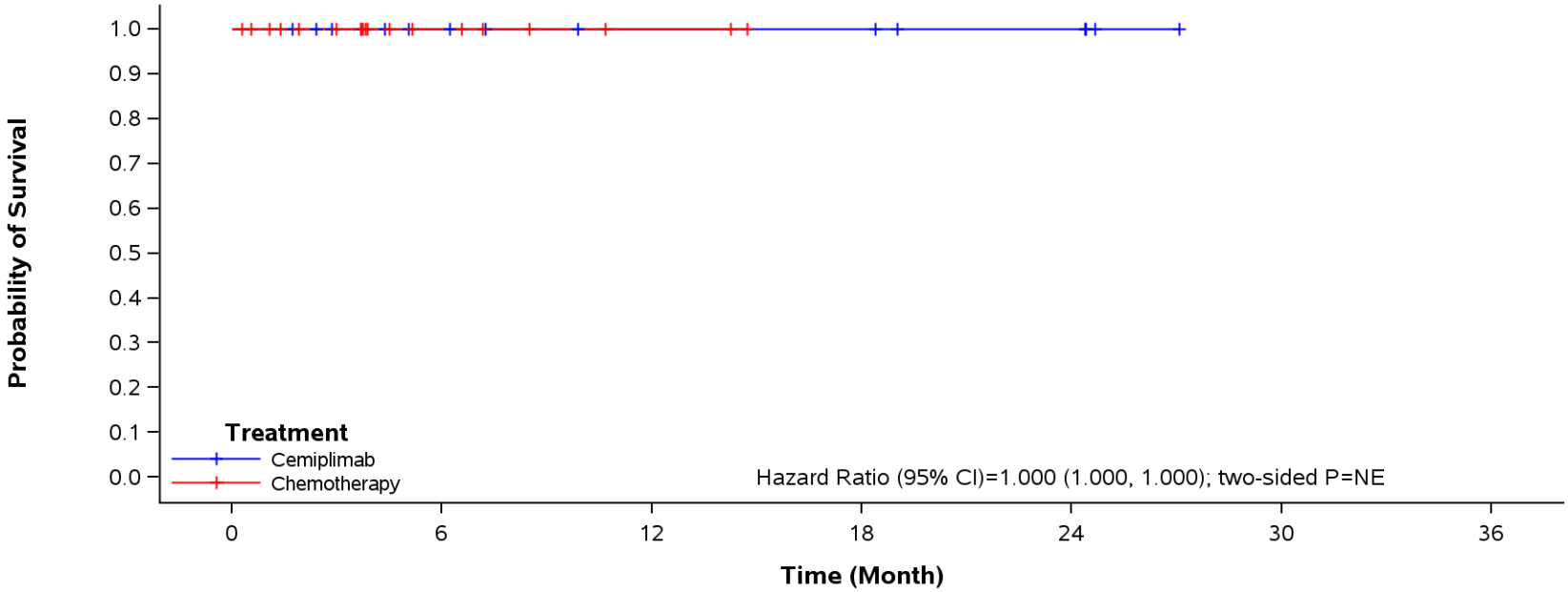

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Hepatobiliary disorders



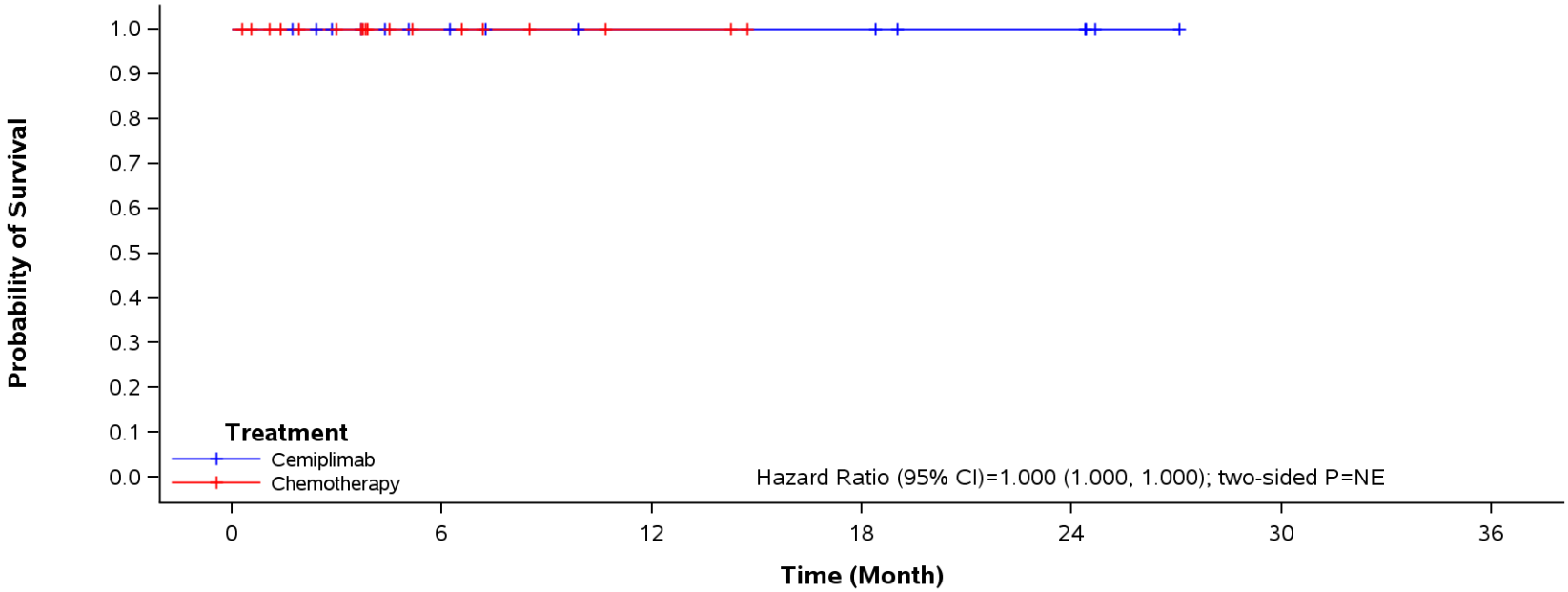

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



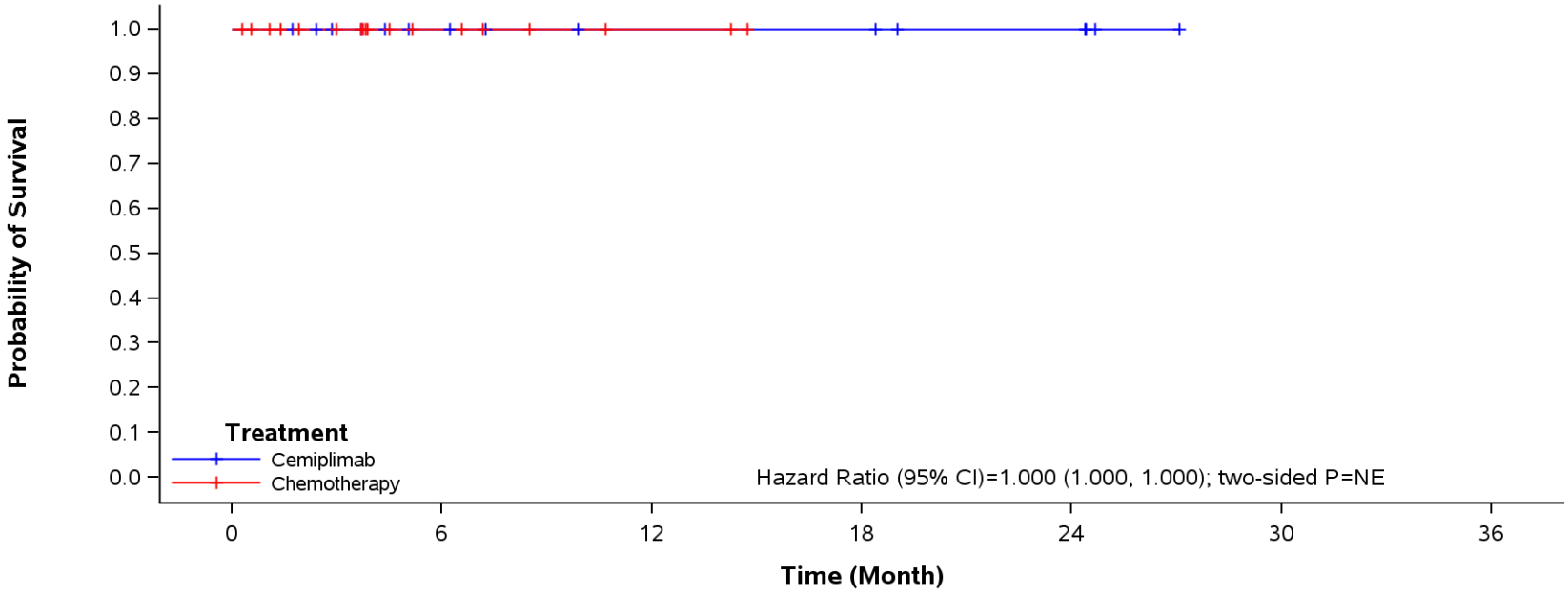

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



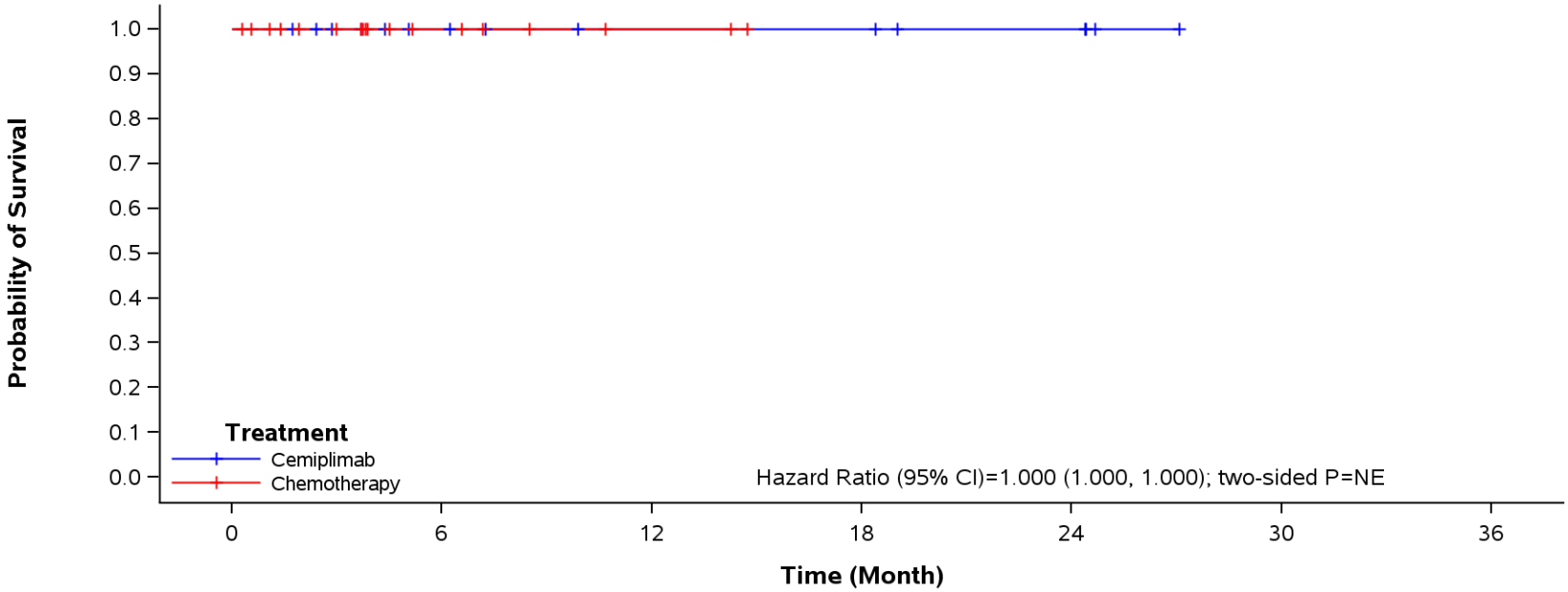

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Hepatobiliary disorders
PT: Hepatitis



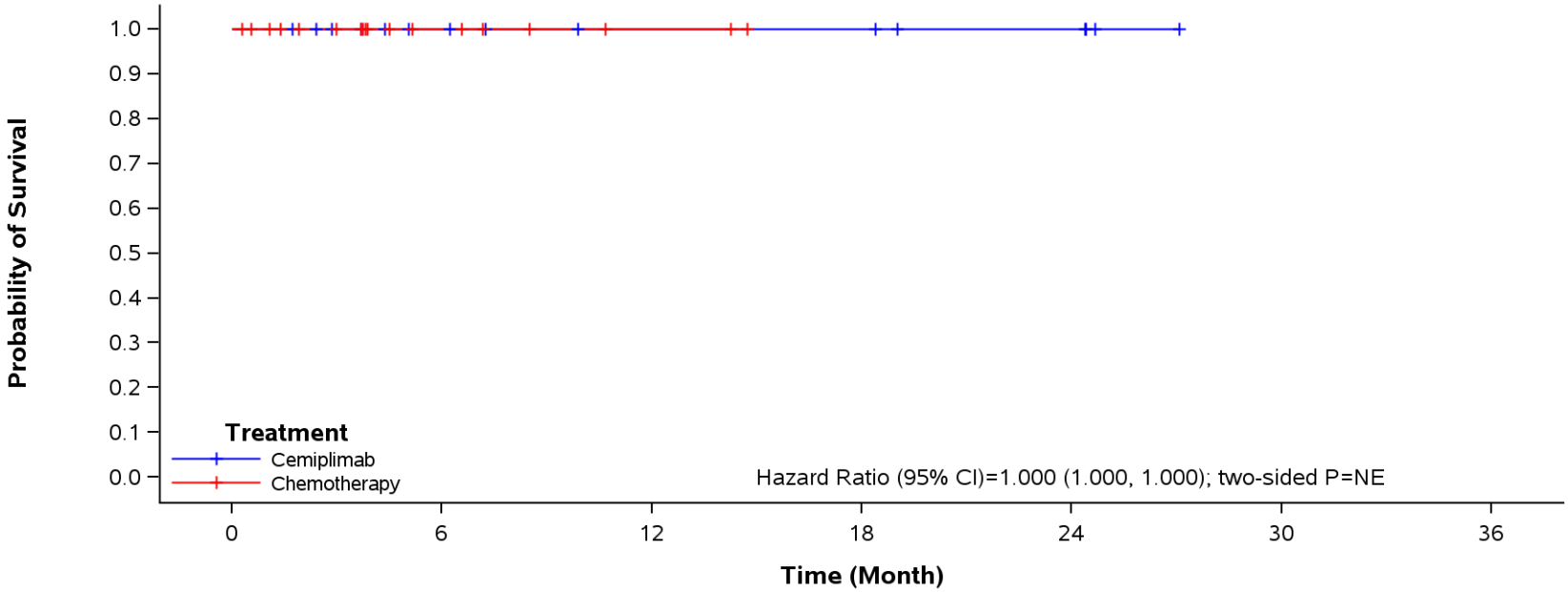

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



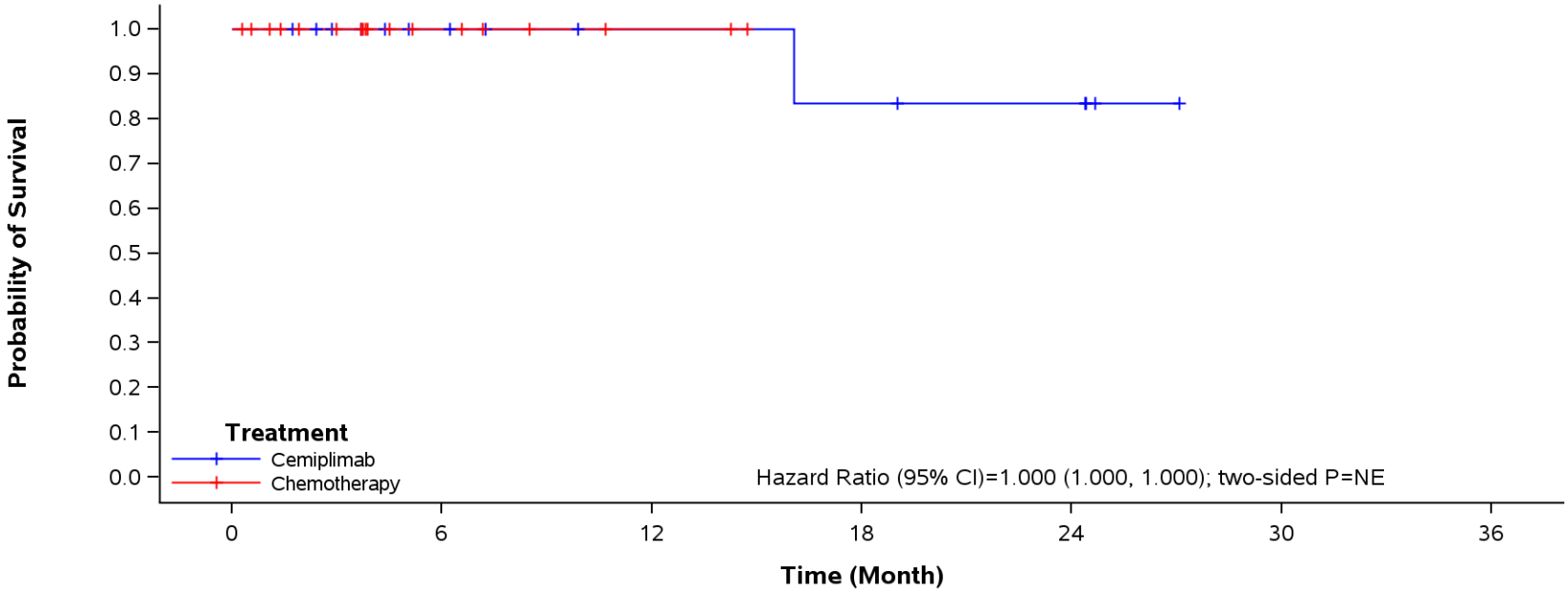

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Infections and infestations



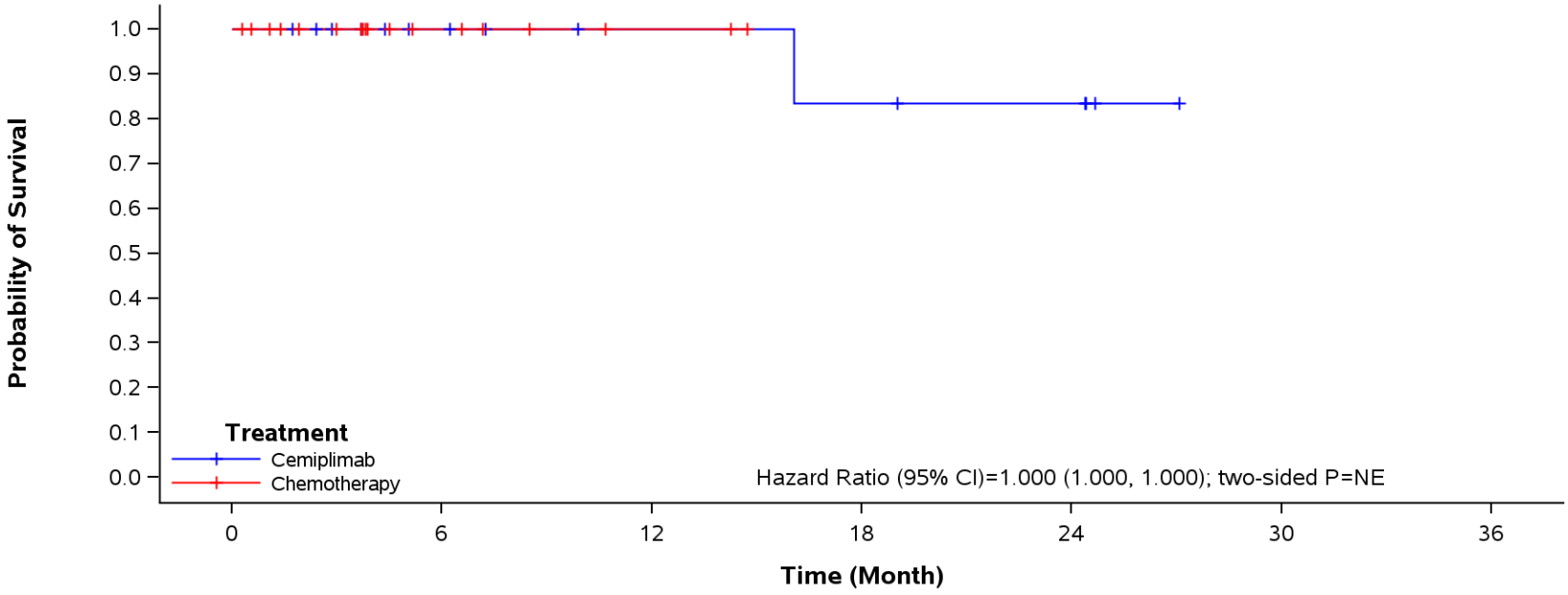

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Infections and infestations
PT: COVID-19 pneumonia



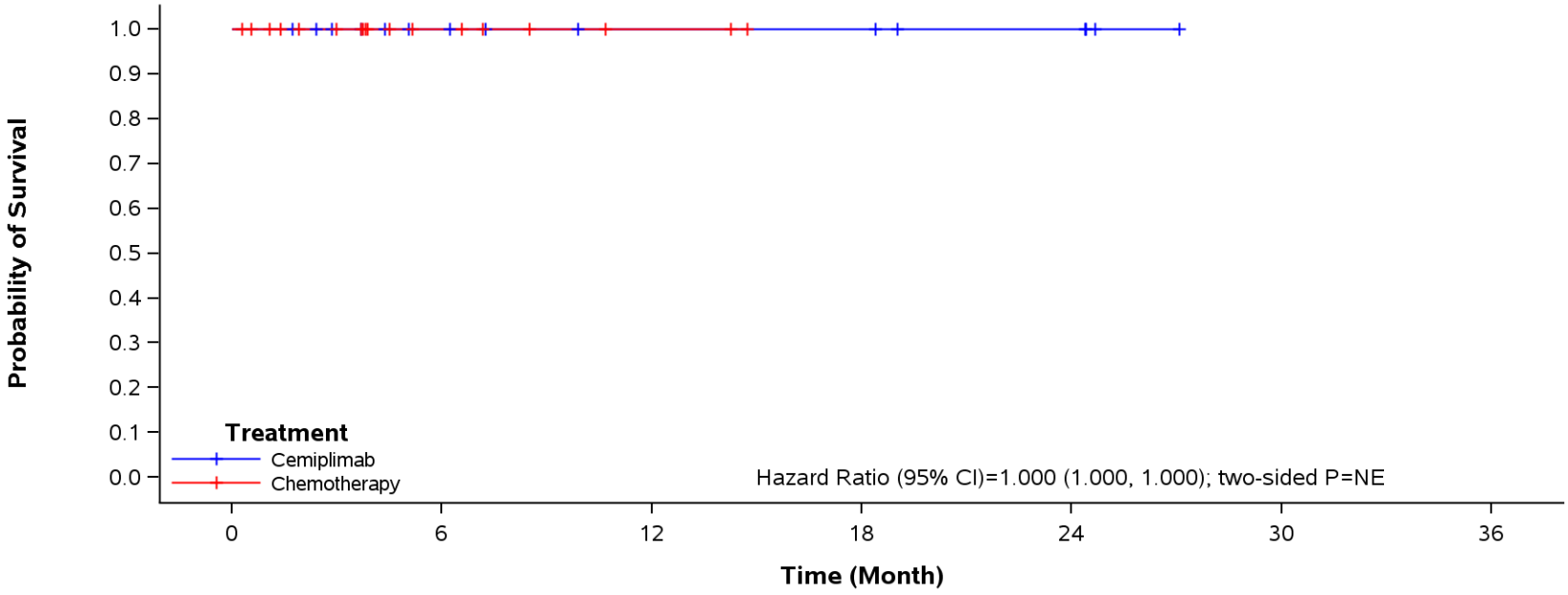

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 5 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Infections and infestations
PT: Gastroenteritis



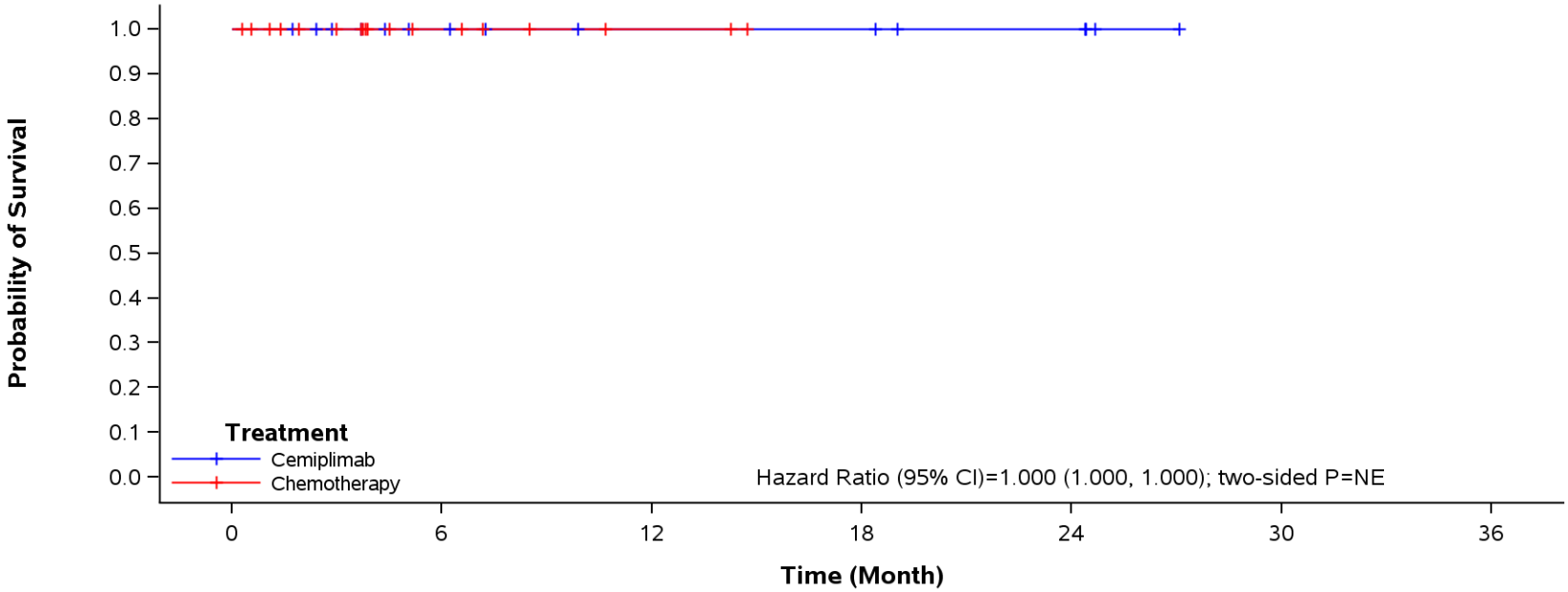

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Infections and infestations
PT: Pelvic abscess



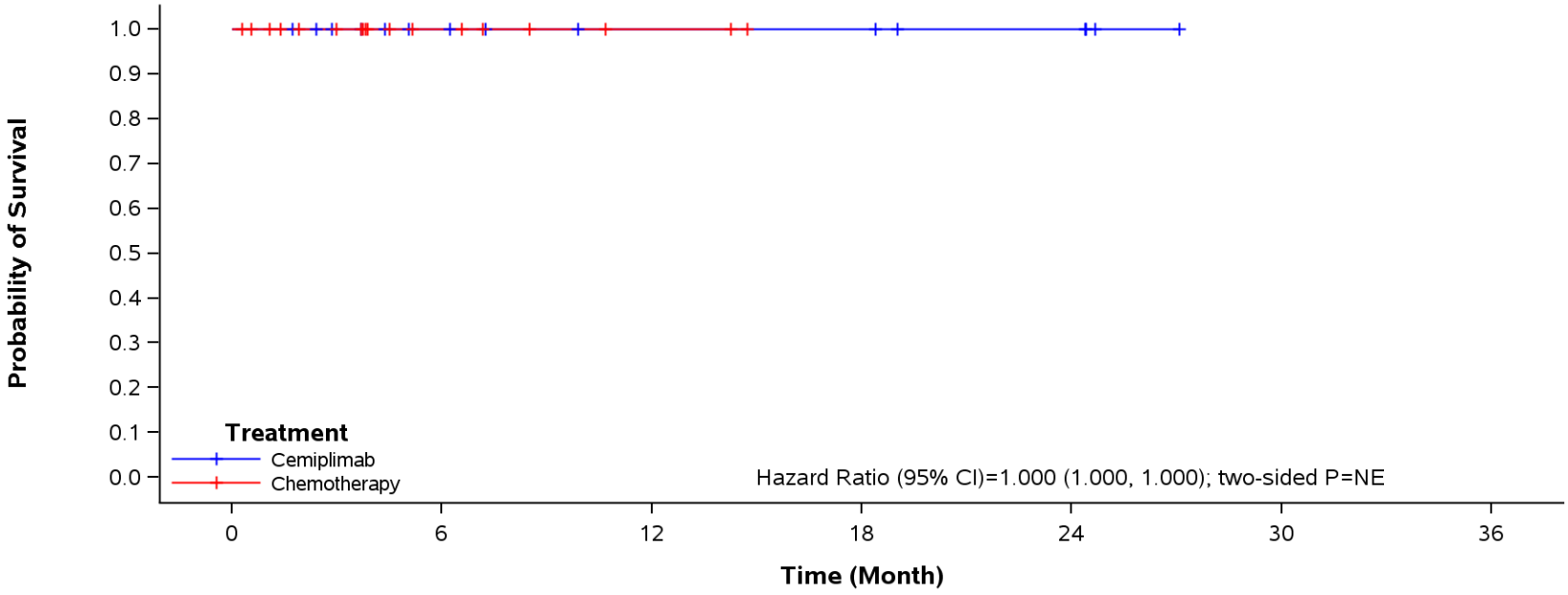

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Infections and infestations
PT: Peritonitis



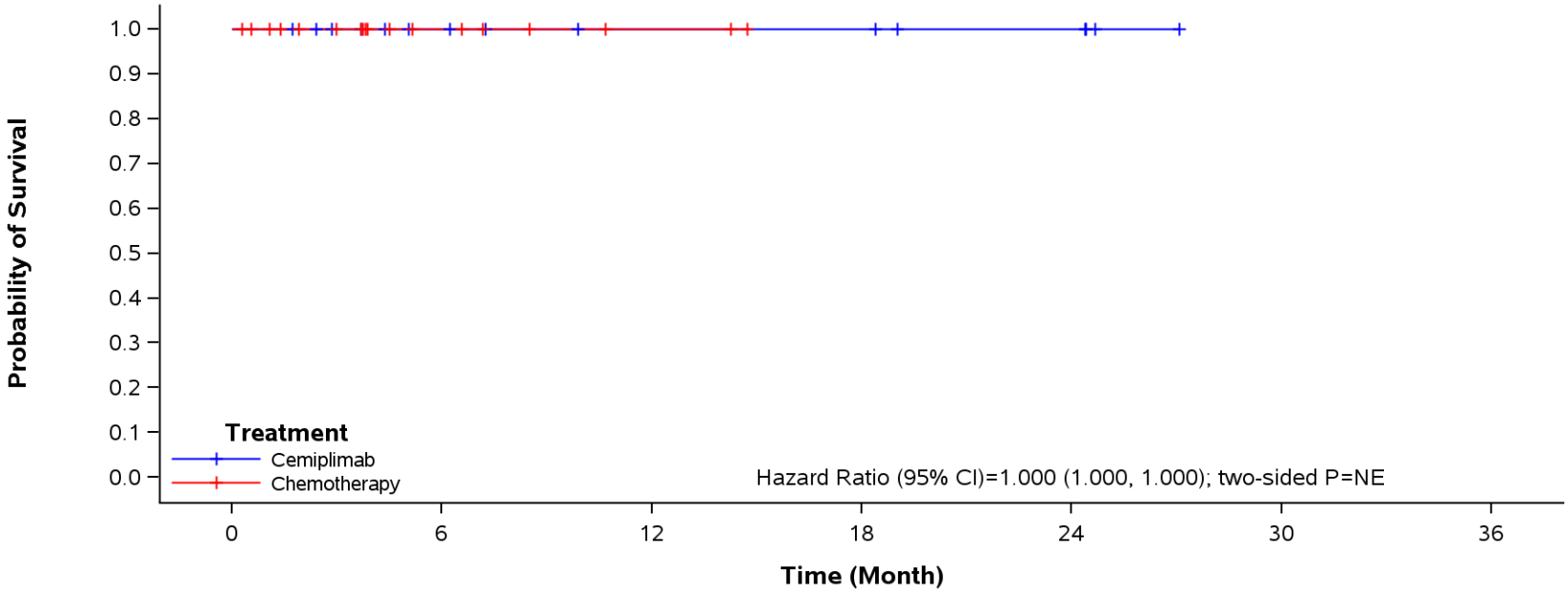

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Infections and infestations
PT: Pneumonia



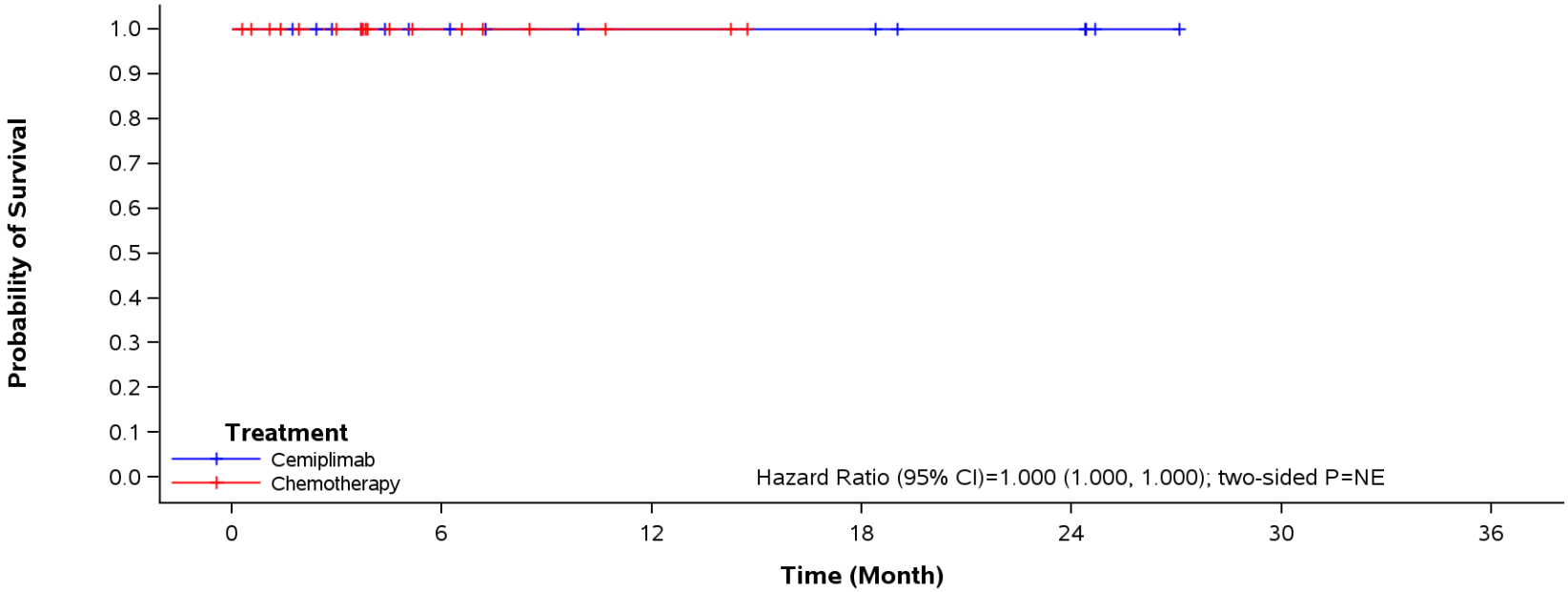

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Infections and infestations
PT: Pyomyositis




**Number of Subjects at risk**

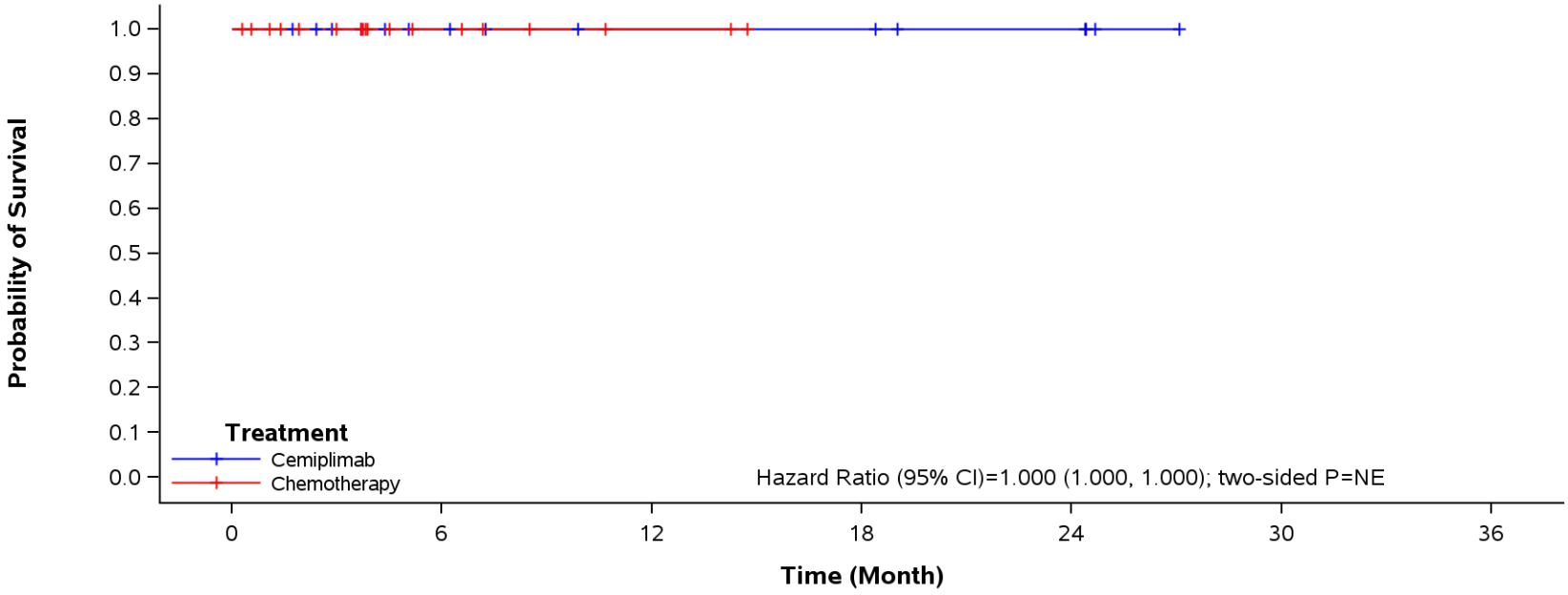
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

SOC: Injury, poisoning and procedural complications




**Number of Subjects at risk**

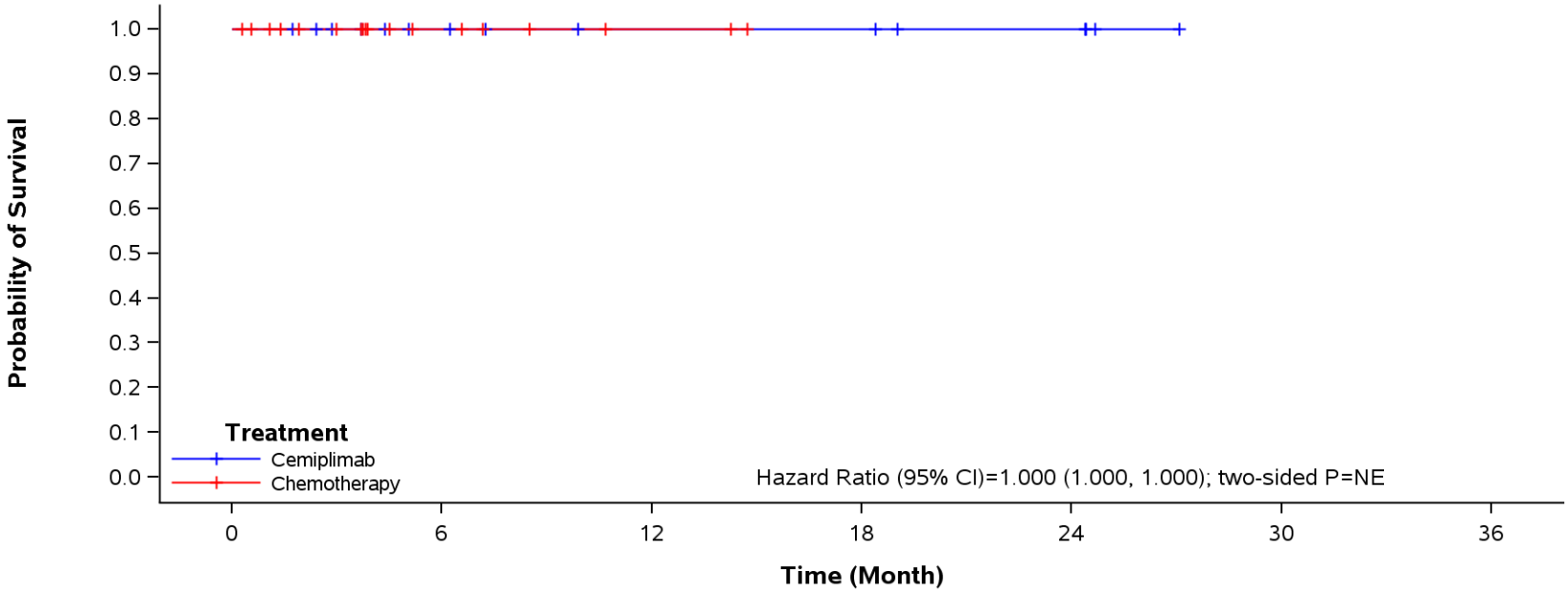
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



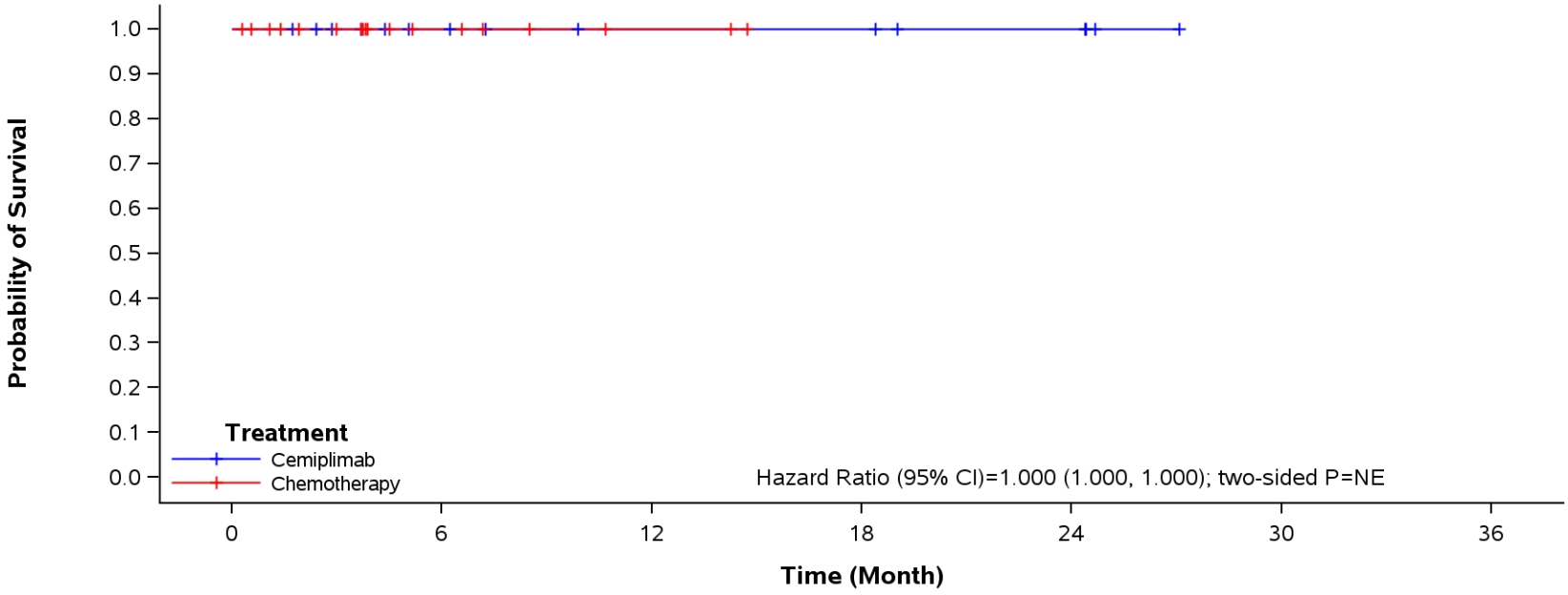

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



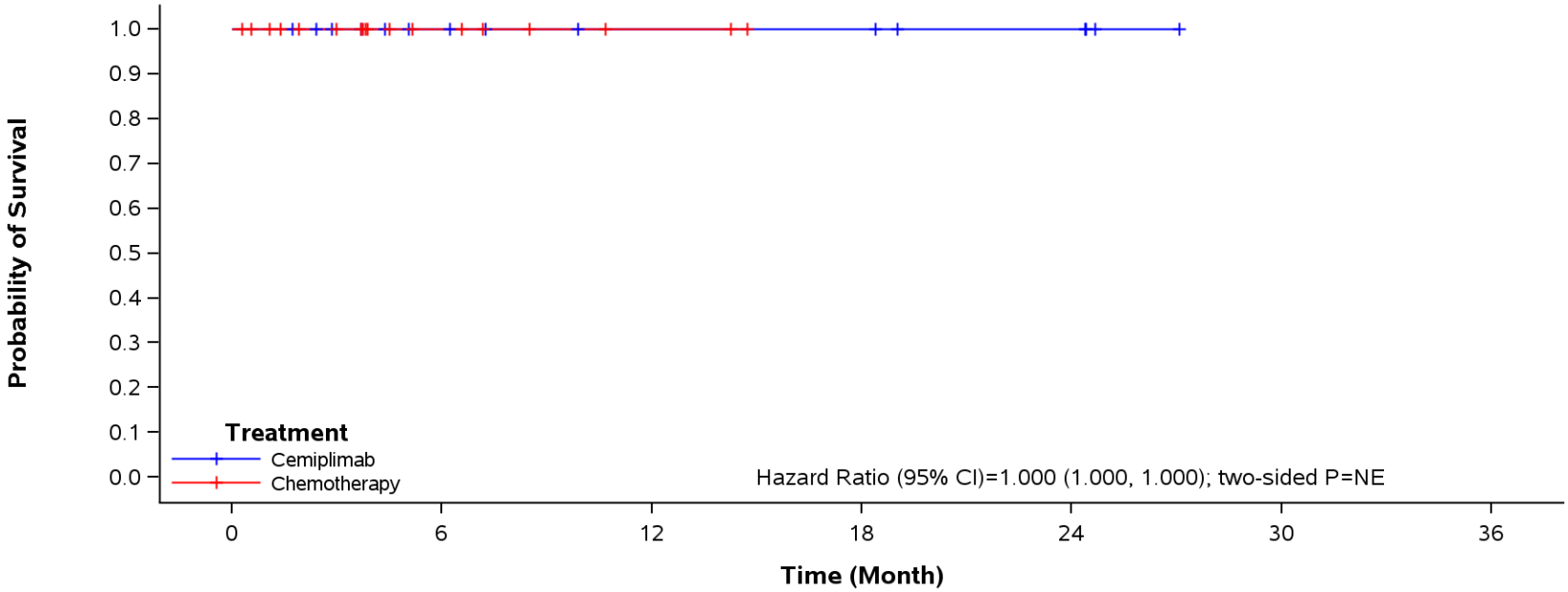

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Investigations



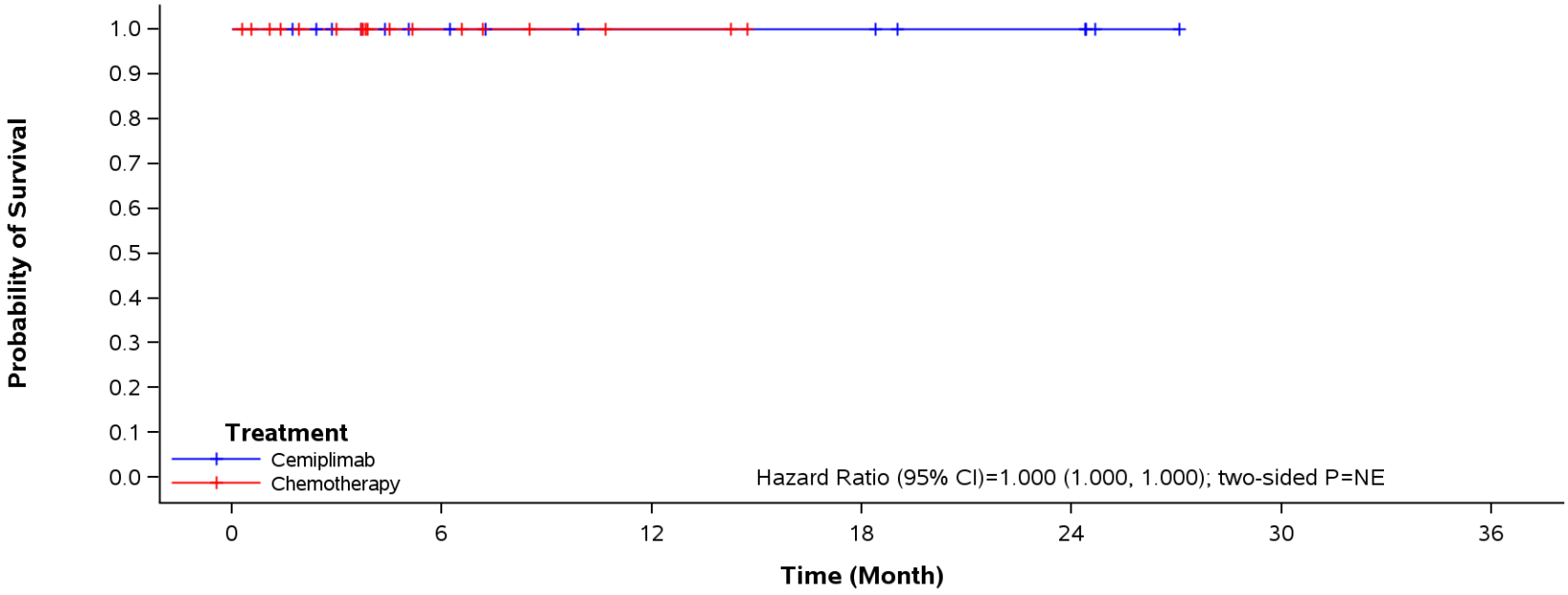

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Investigations
PT: Alanine aminotransferase increased



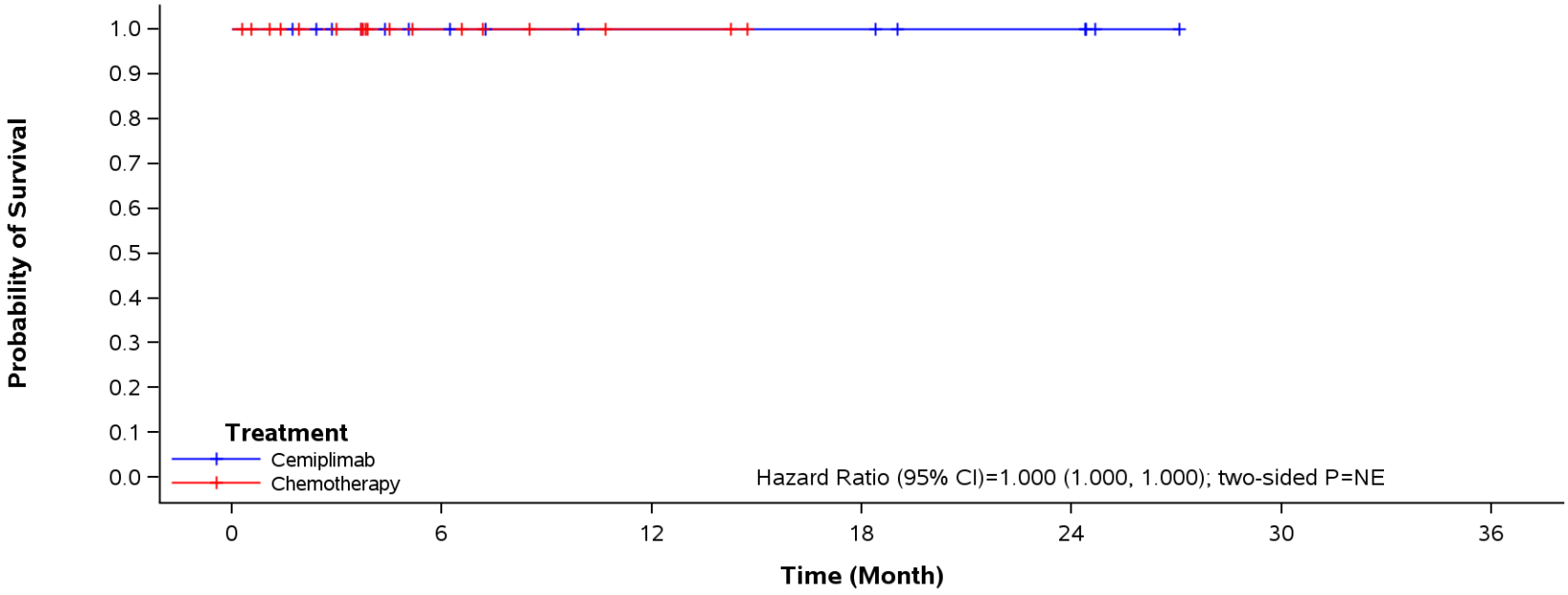

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Investigations
PT: Amylase increased



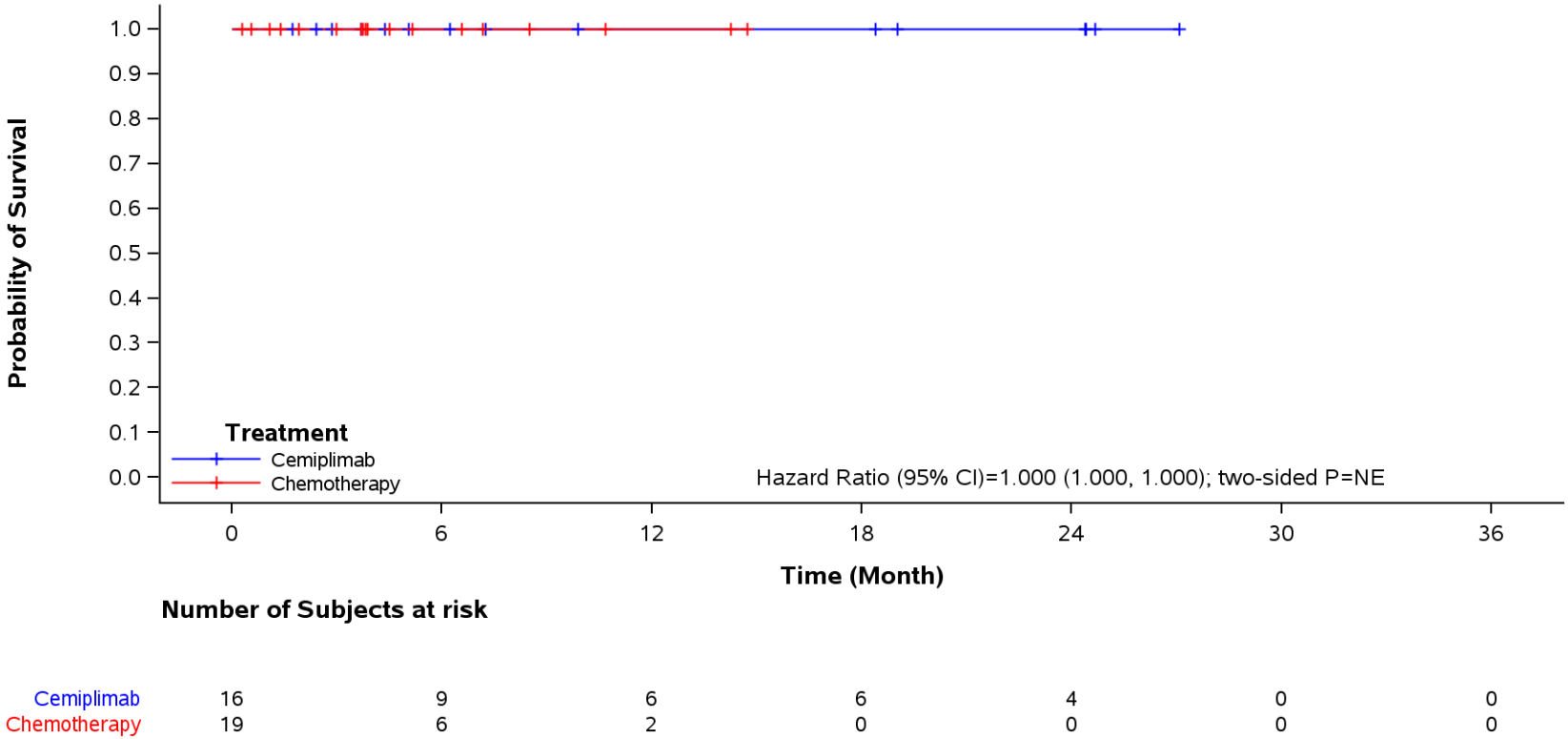

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

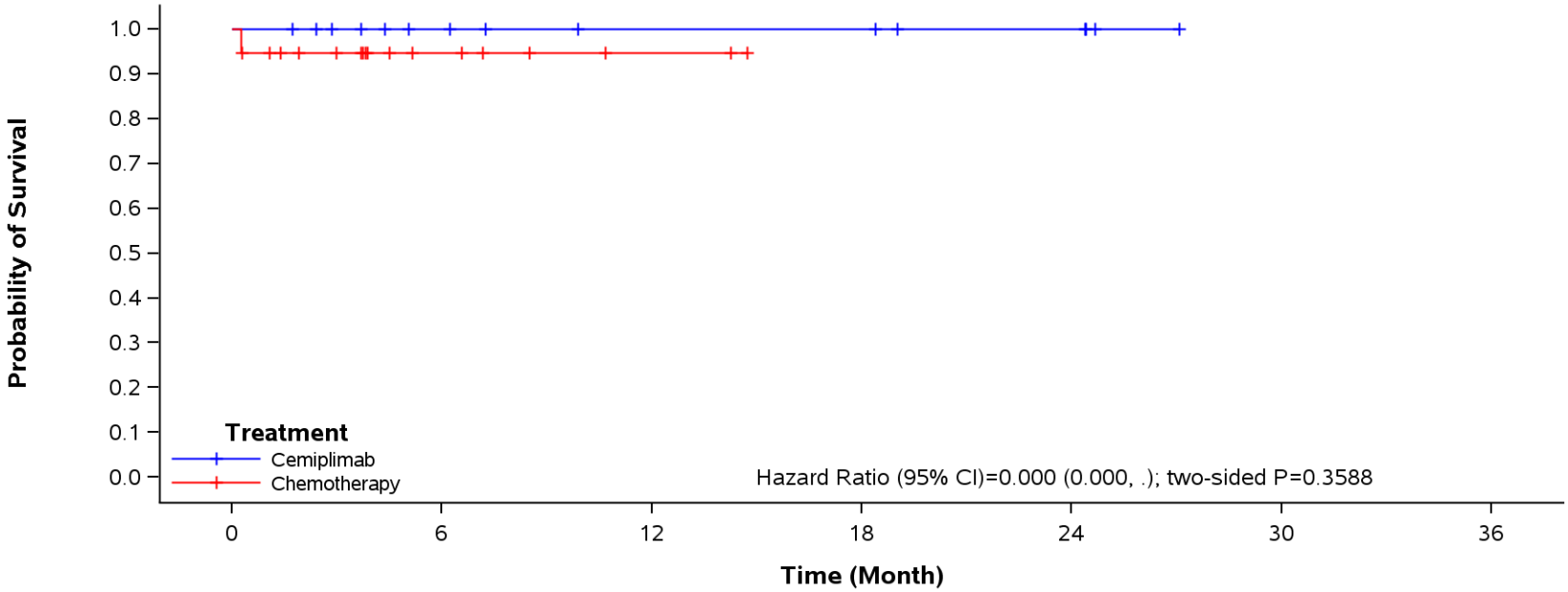
Age Group: >=65
SOC: Investigations
PT: Platelet count decreased




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Metabolism and nutrition disorders



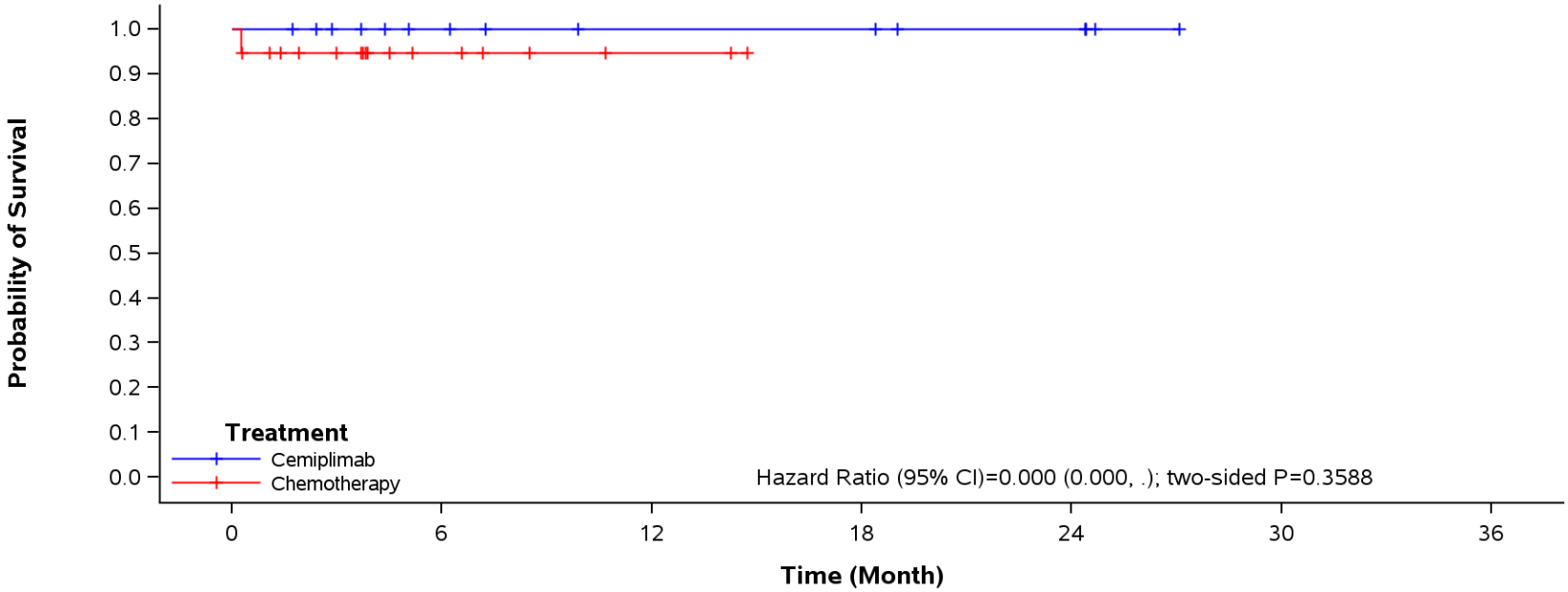

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



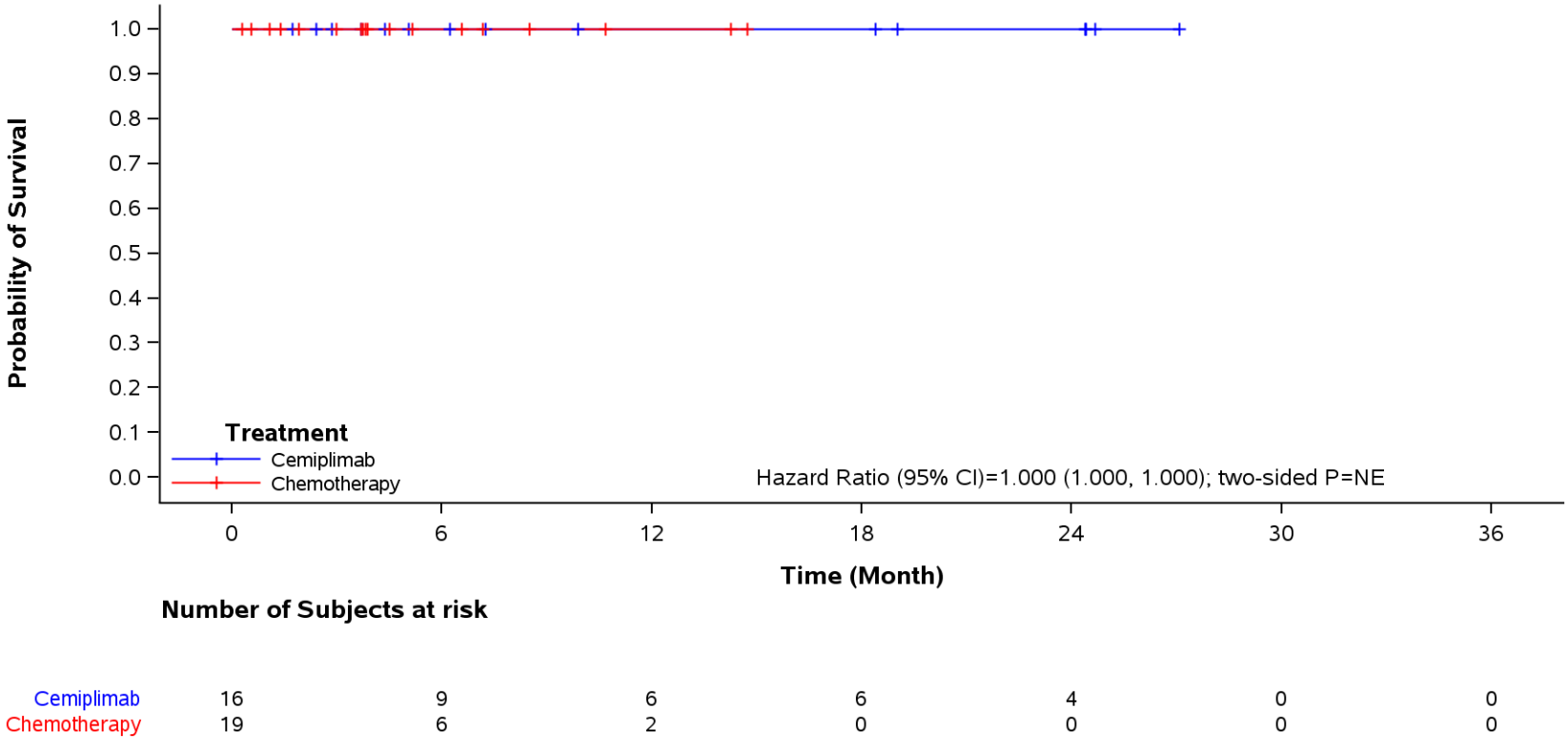

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

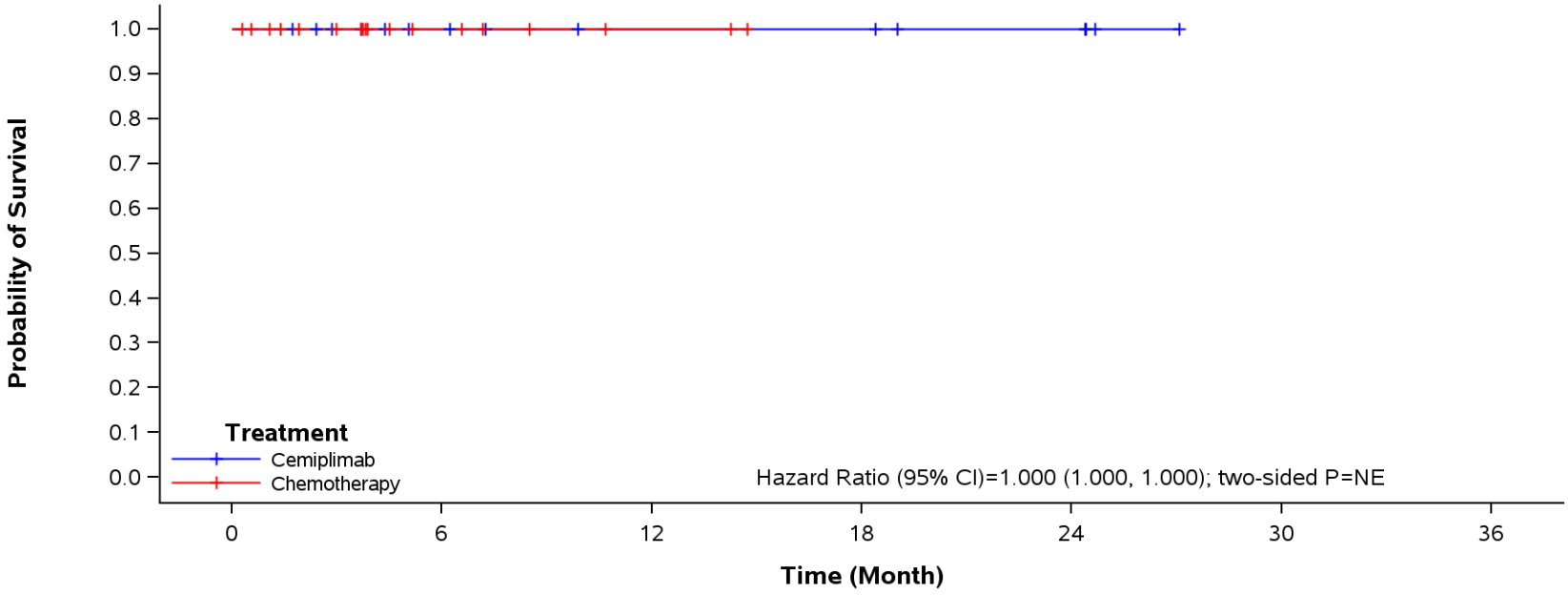
Age Group: >=65
SOC: Musculoskeletal and connective tissue disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



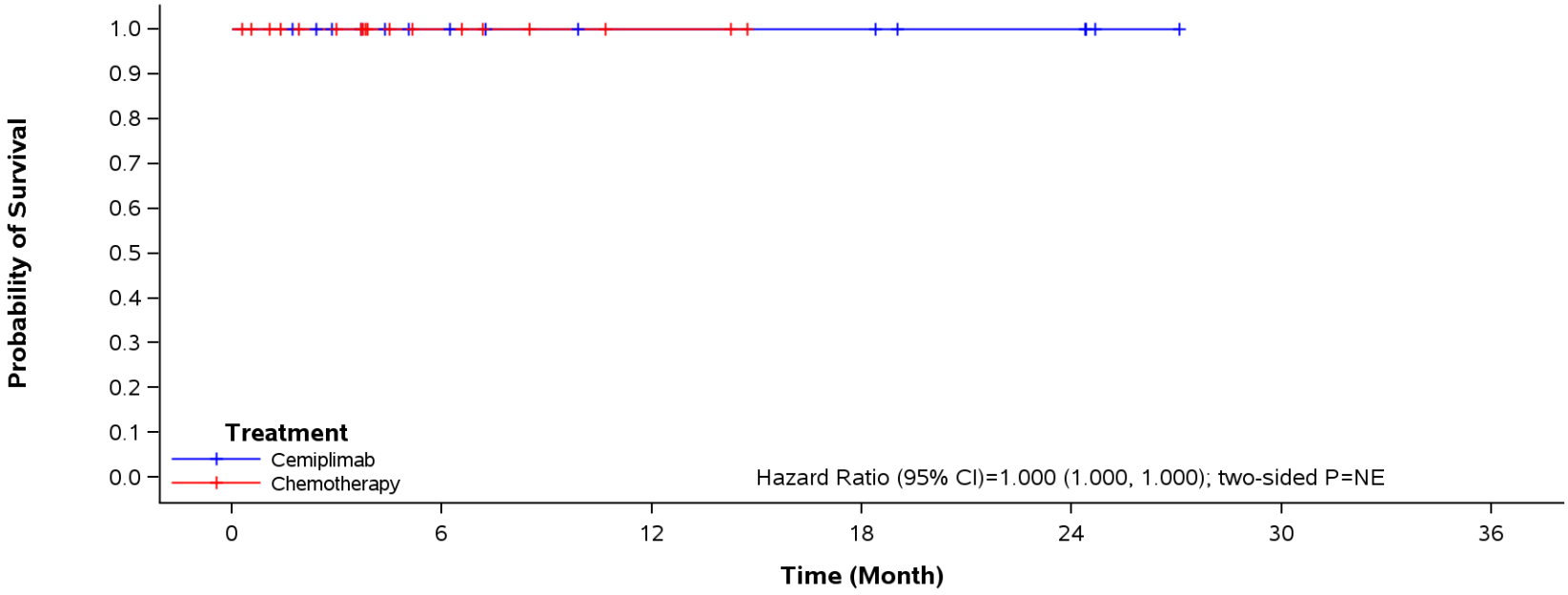

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



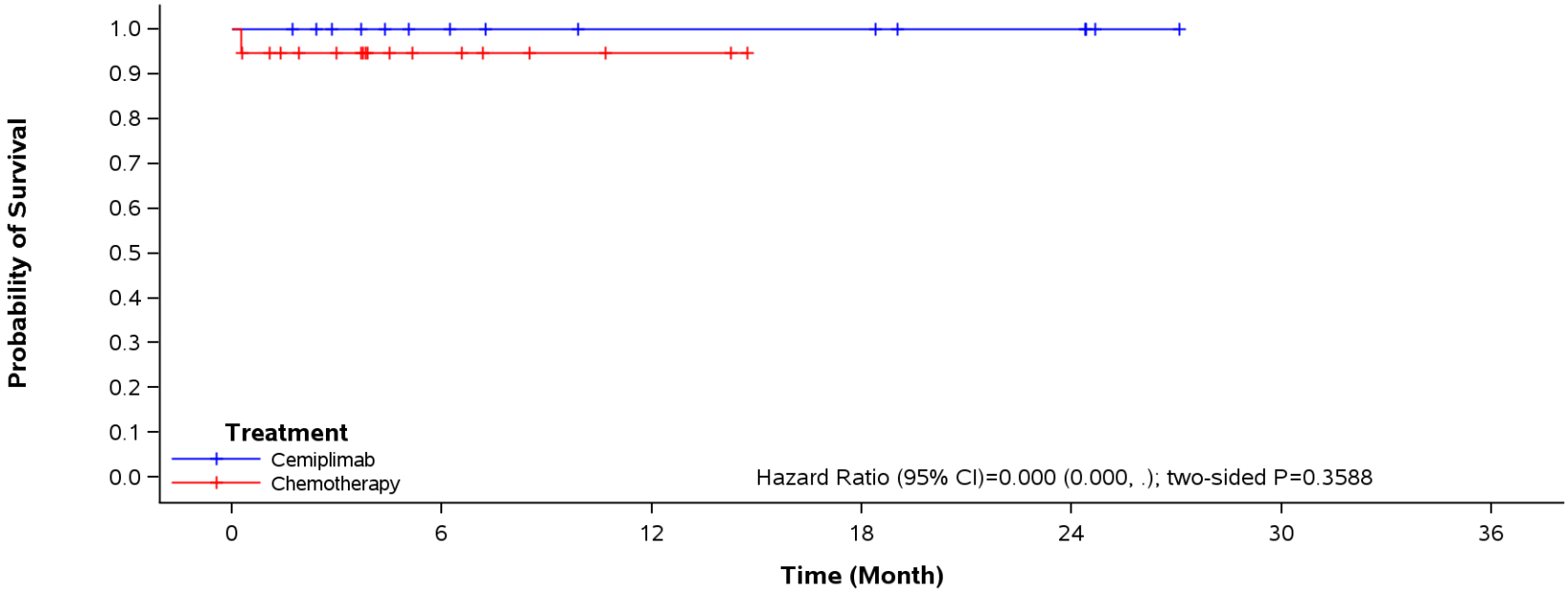

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Nervous system disorders



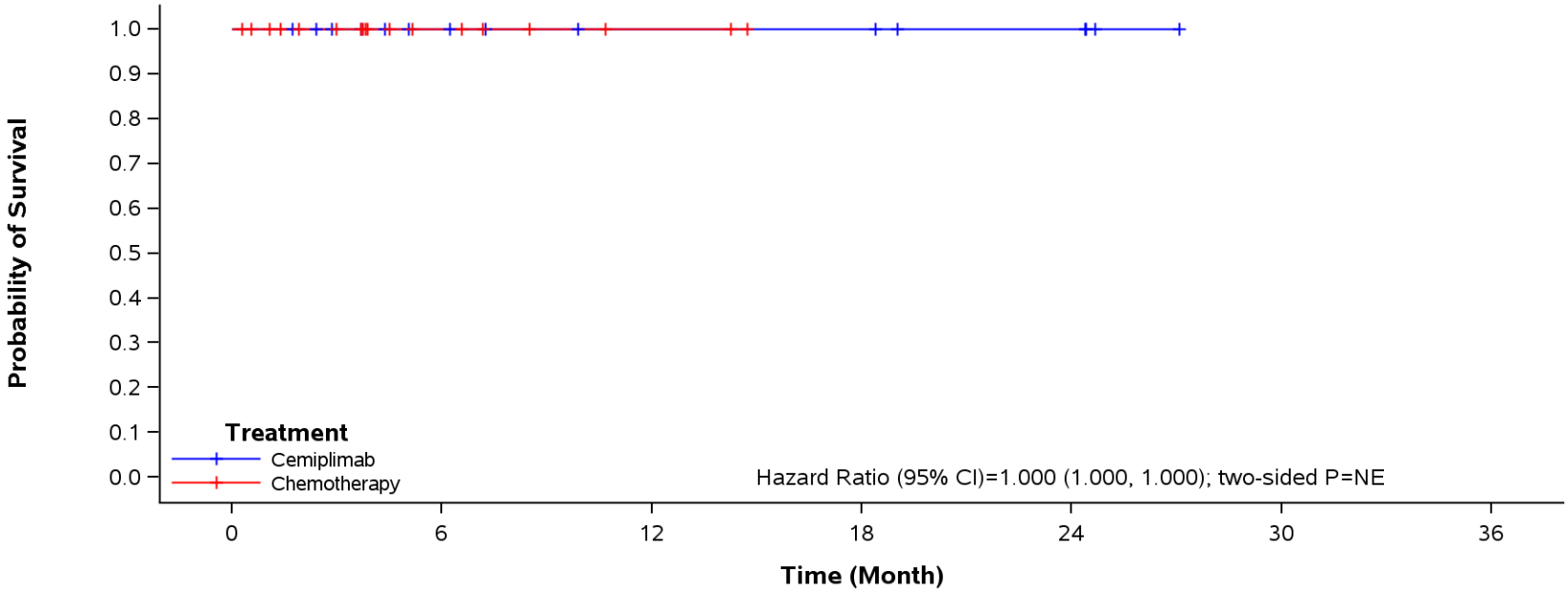

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Nervous system disorders
PT: Neurotoxicity



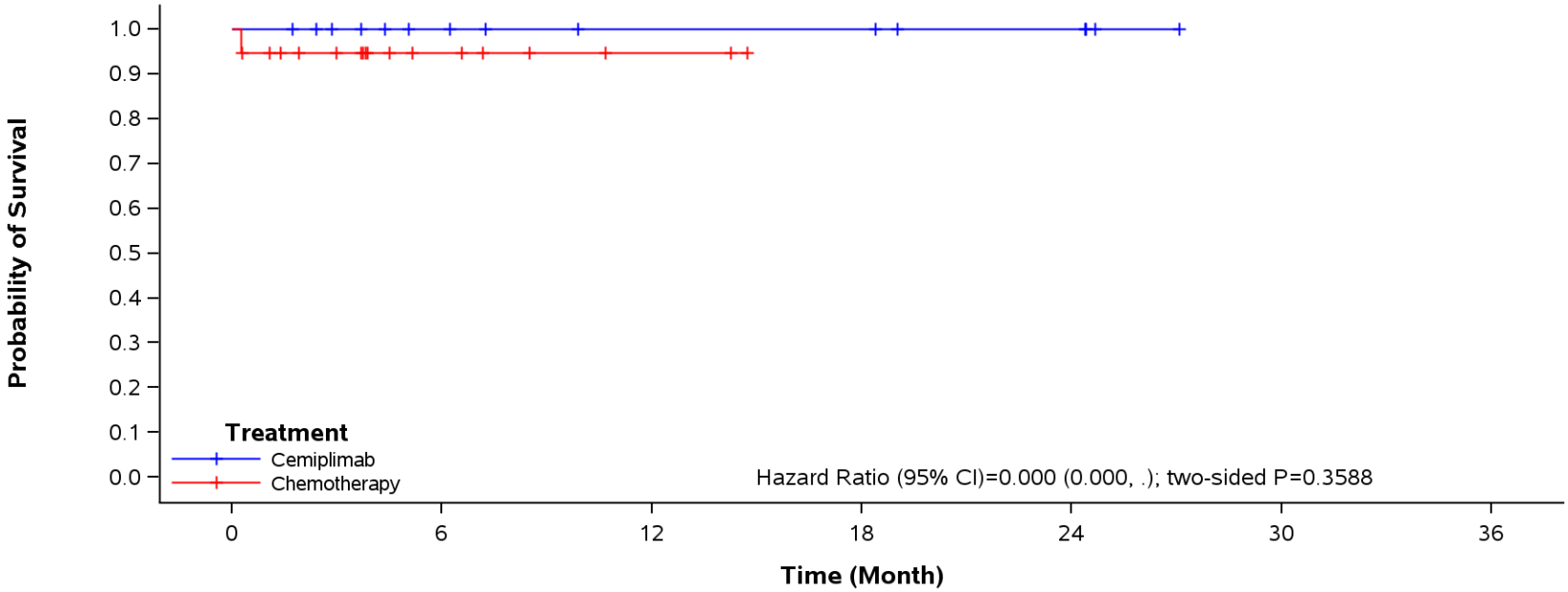

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Nervous system disorders
PT: Transient ischaemic attack



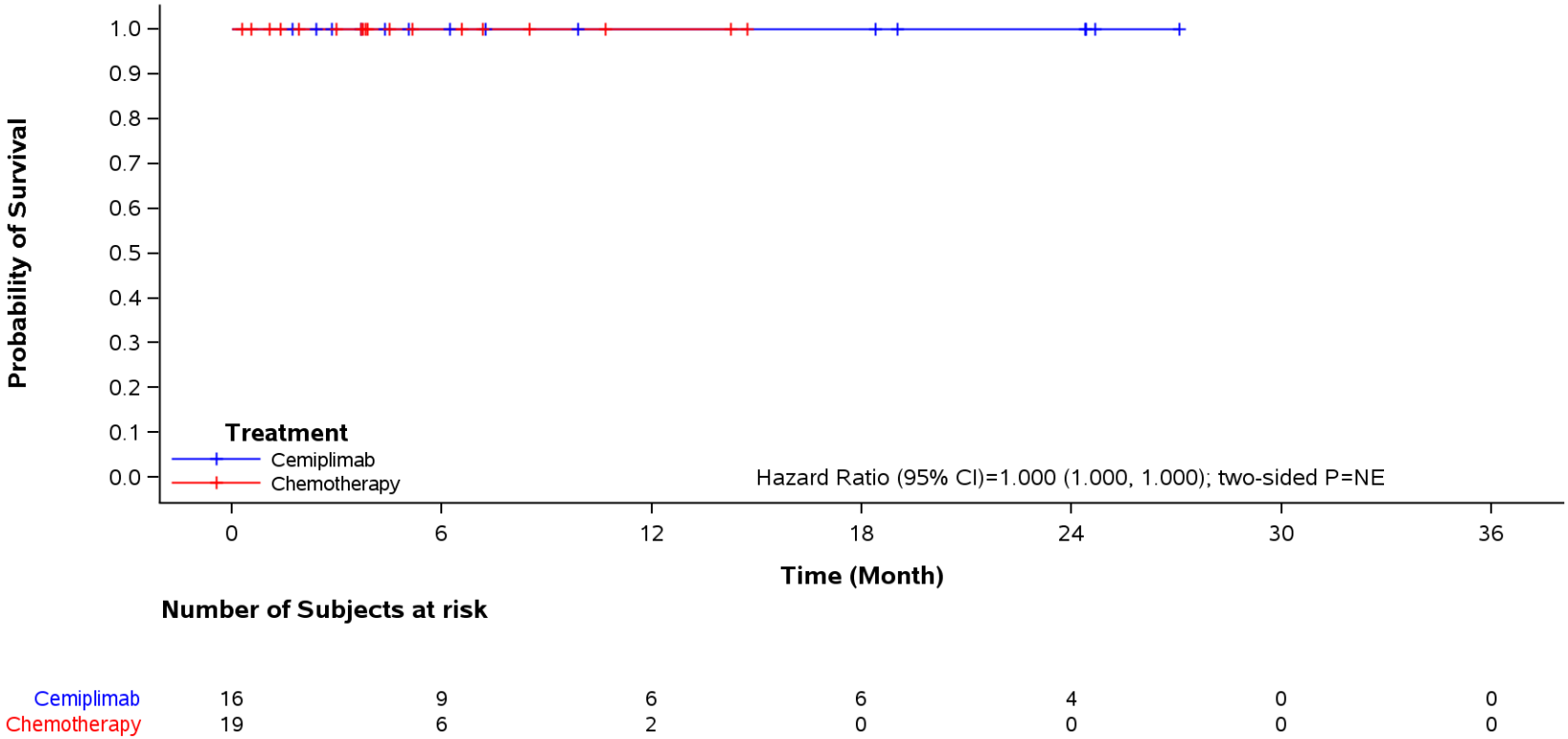

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

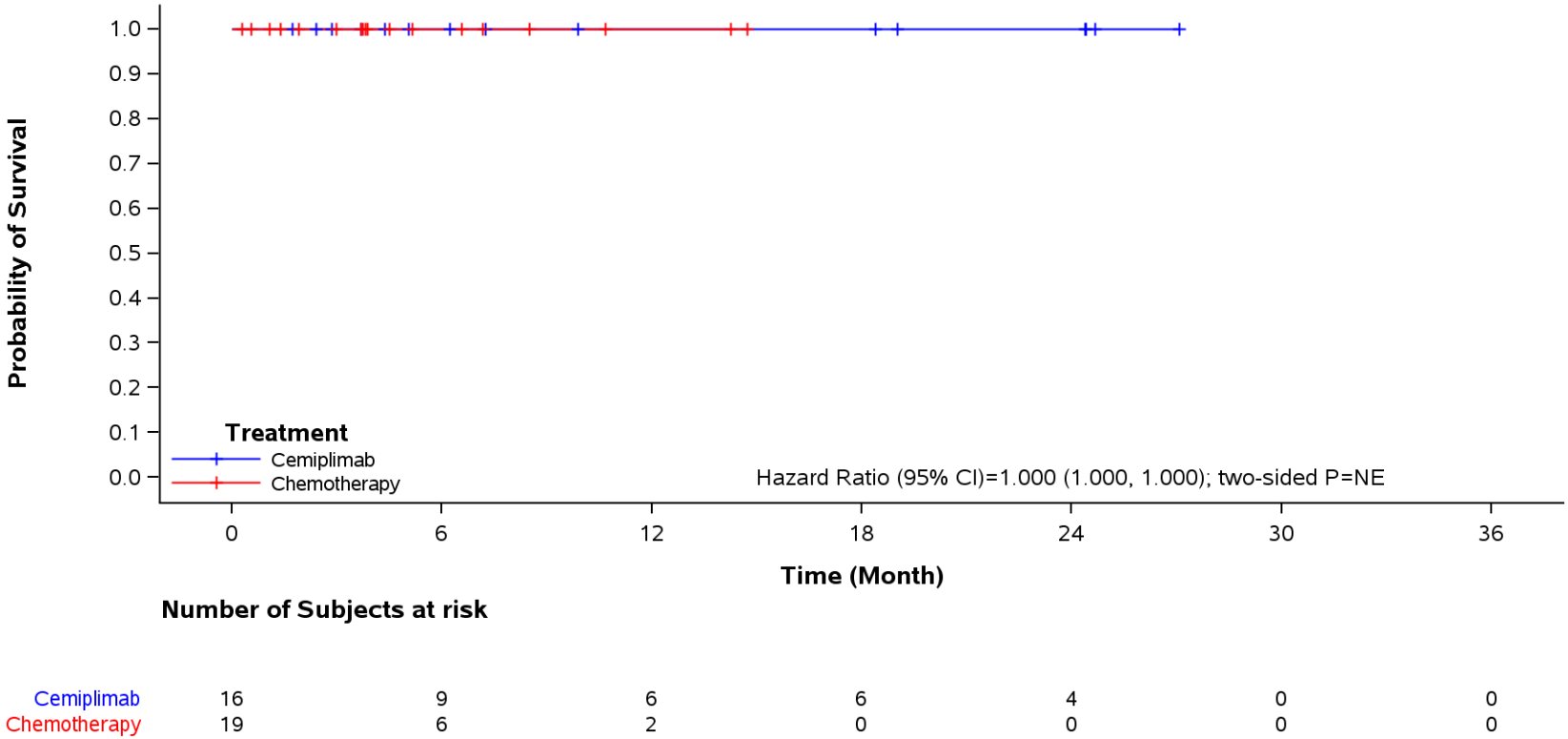
Age Group: >=65
SOC: Psychiatric disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

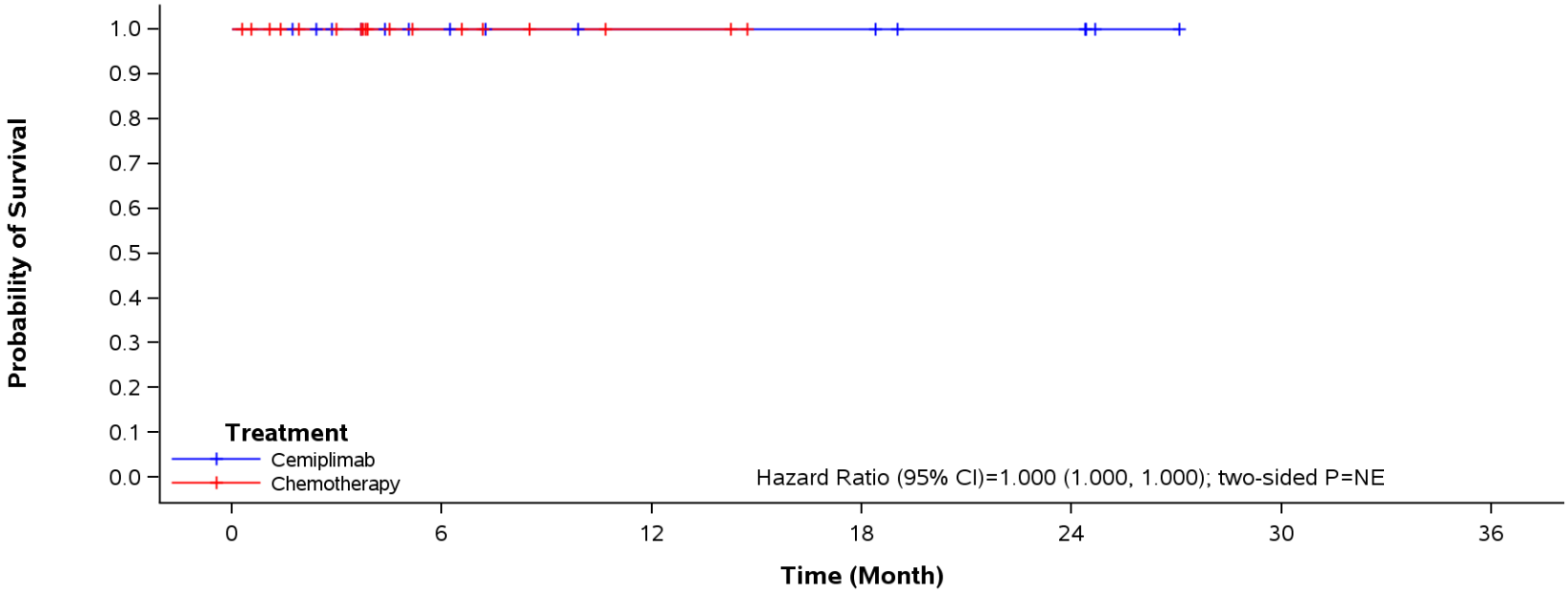
Age Group: >=65
SOC: Psychiatric disorders
PT: Agoraphobia




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Renal and urinary disorders



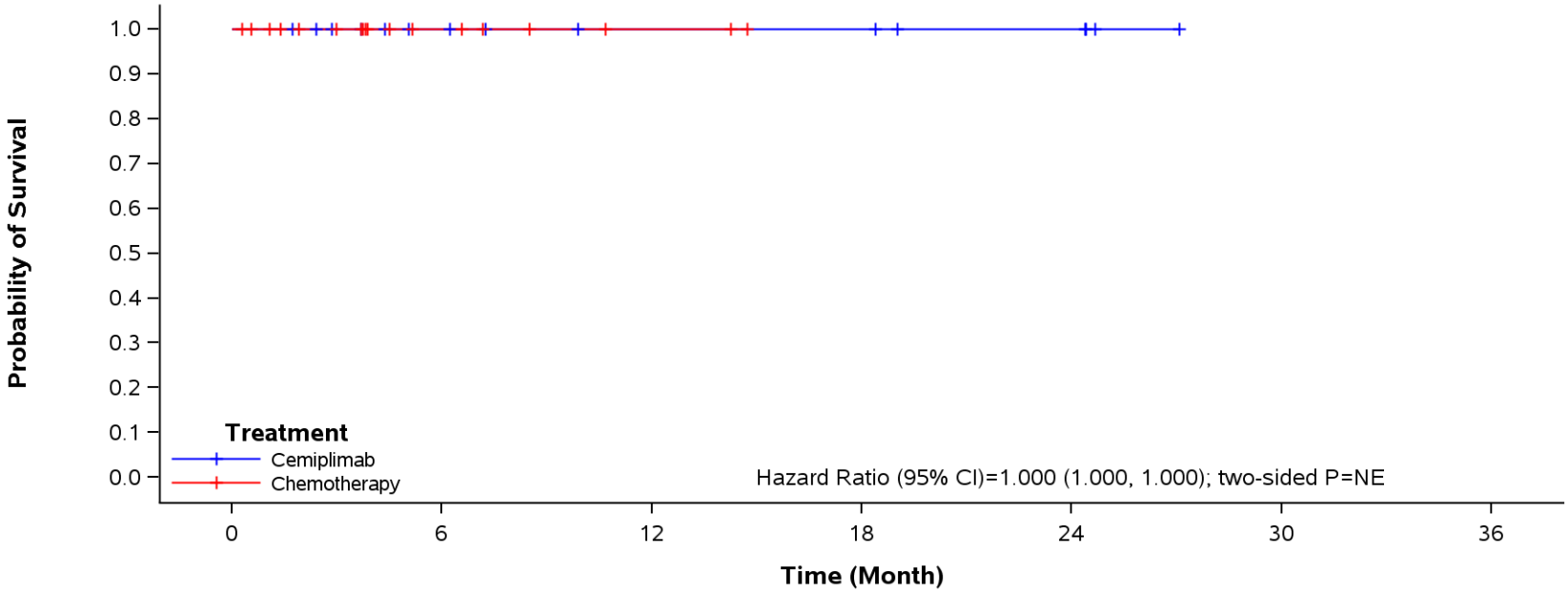

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Renal and urinary disorders
PT: Renal failure




**Number of Subjects at risk**

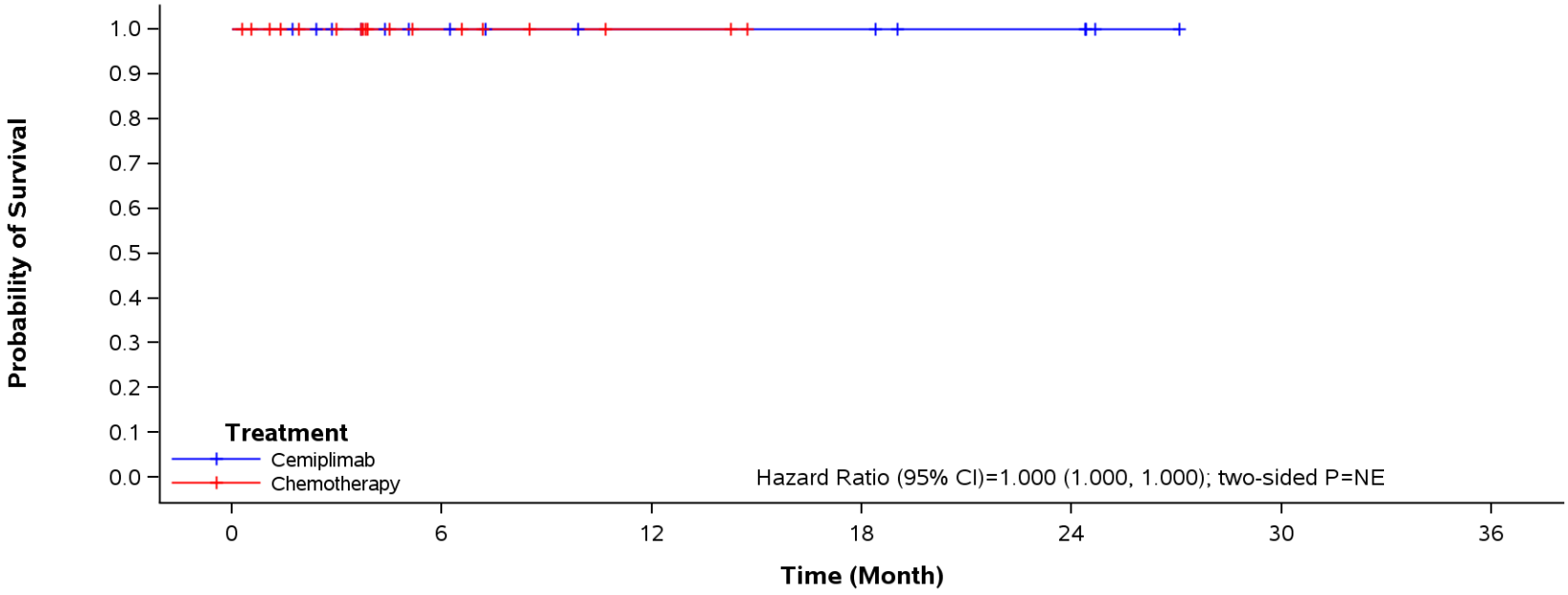
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65

SOC: Respiratory, thoracic and mediastinal disorders




**Number of Subjects at risk**

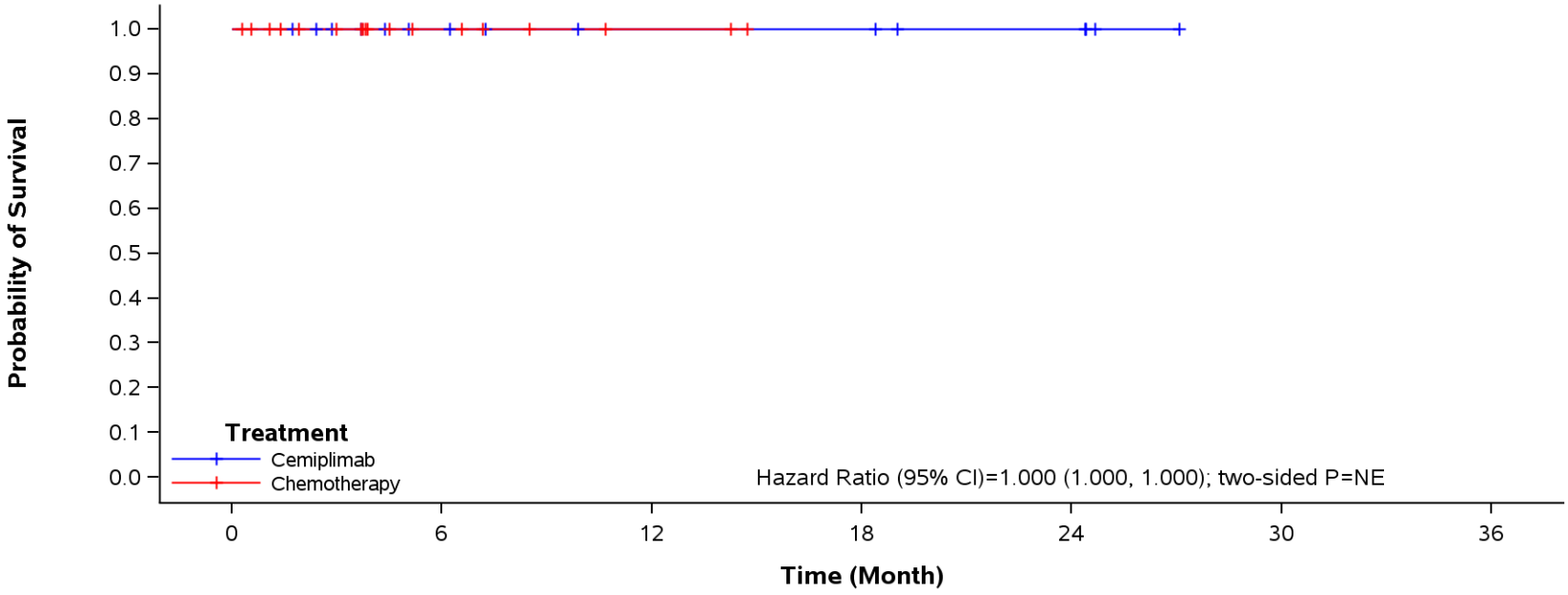
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



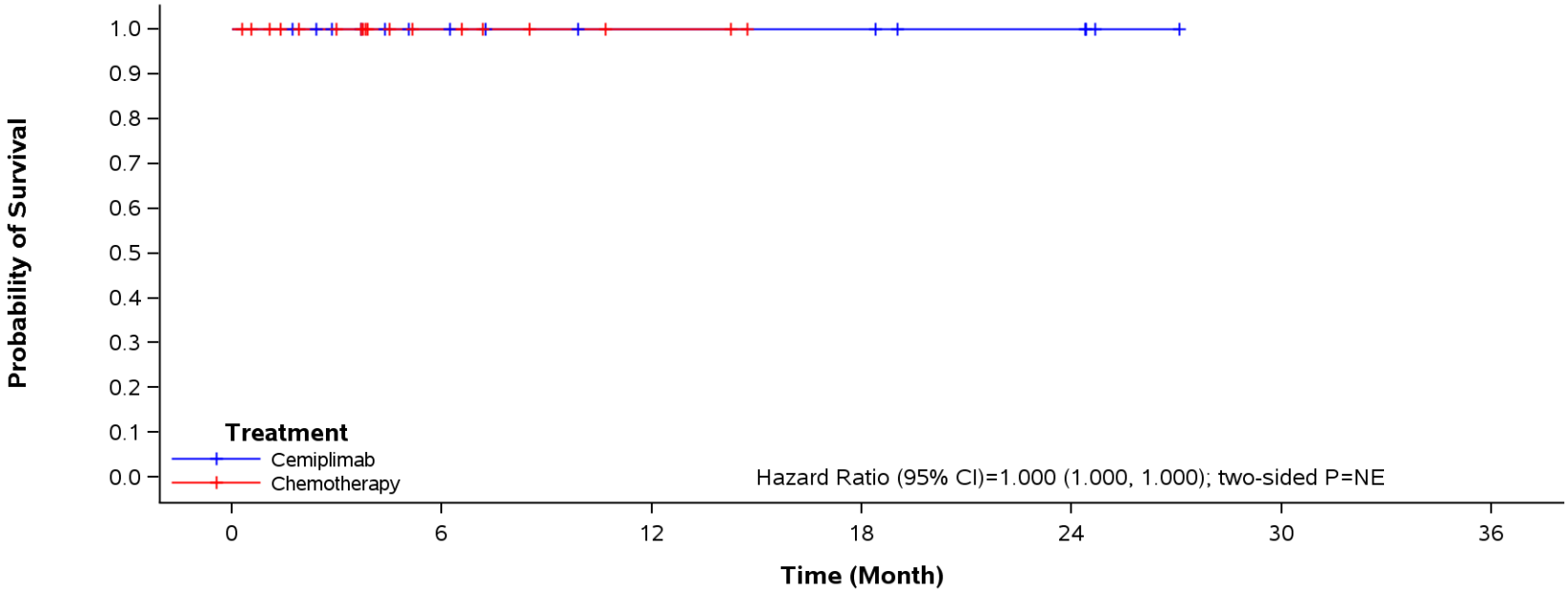

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Vascular disorders



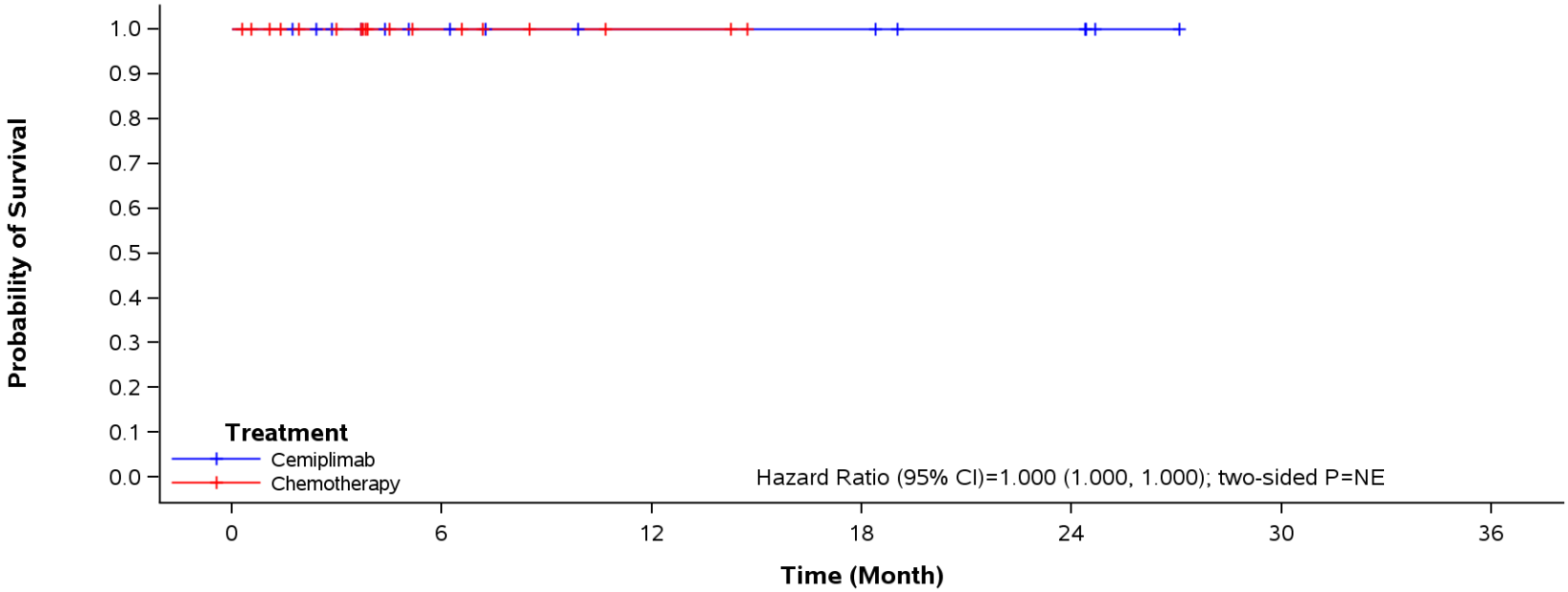

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Age Group: >=65
SOC: Vascular disorders
PT: Deep vein thrombosis




**Number of Subjects at risk**

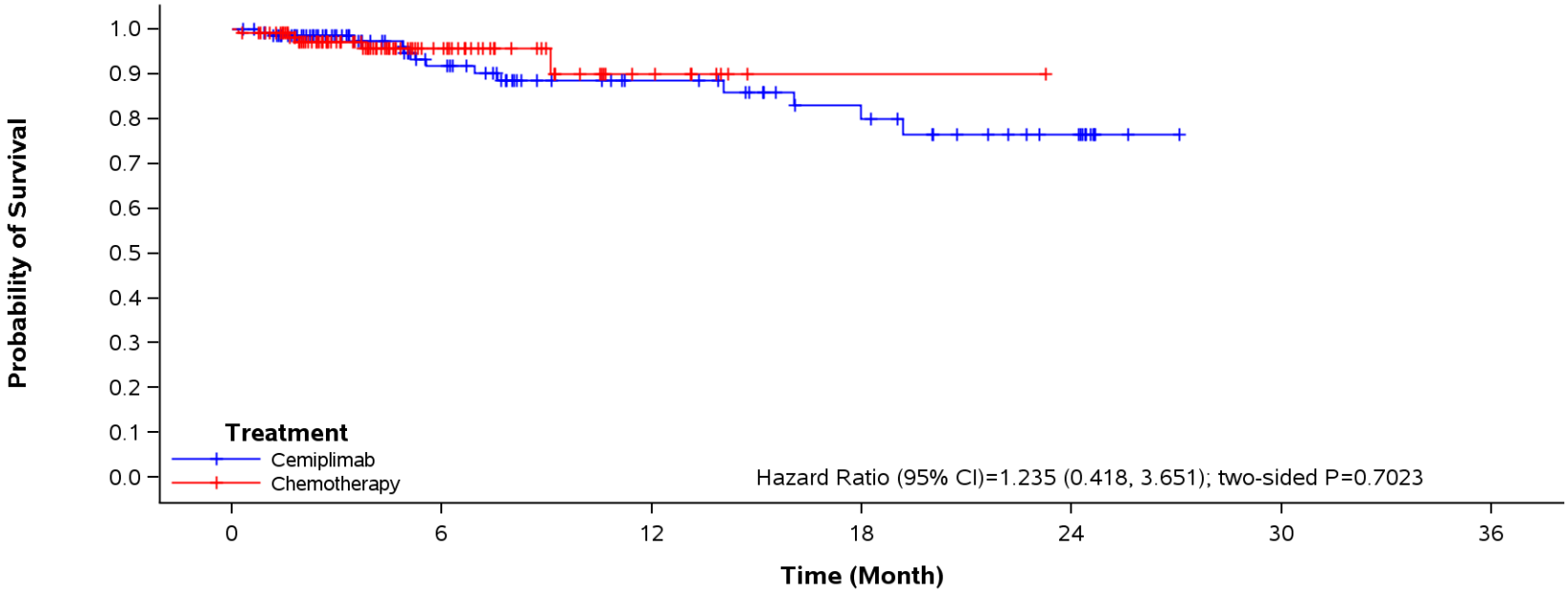
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 16 | 9 | 6 | 6 | 4 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

Number of patients with any TEAE leading to discontinuation




**Number of Subjects at risk**

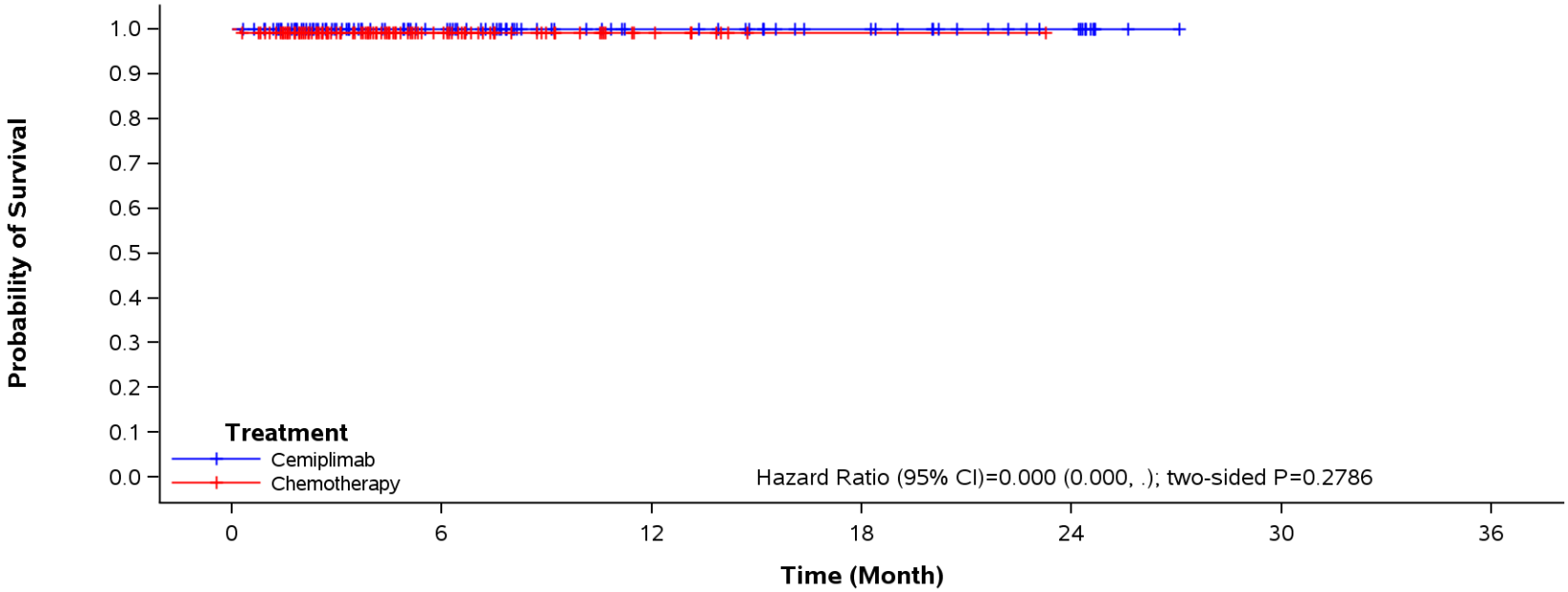
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 61 | 37 | 26 | 16 | 0 | 0 |
| Chemotherapy | 115 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders



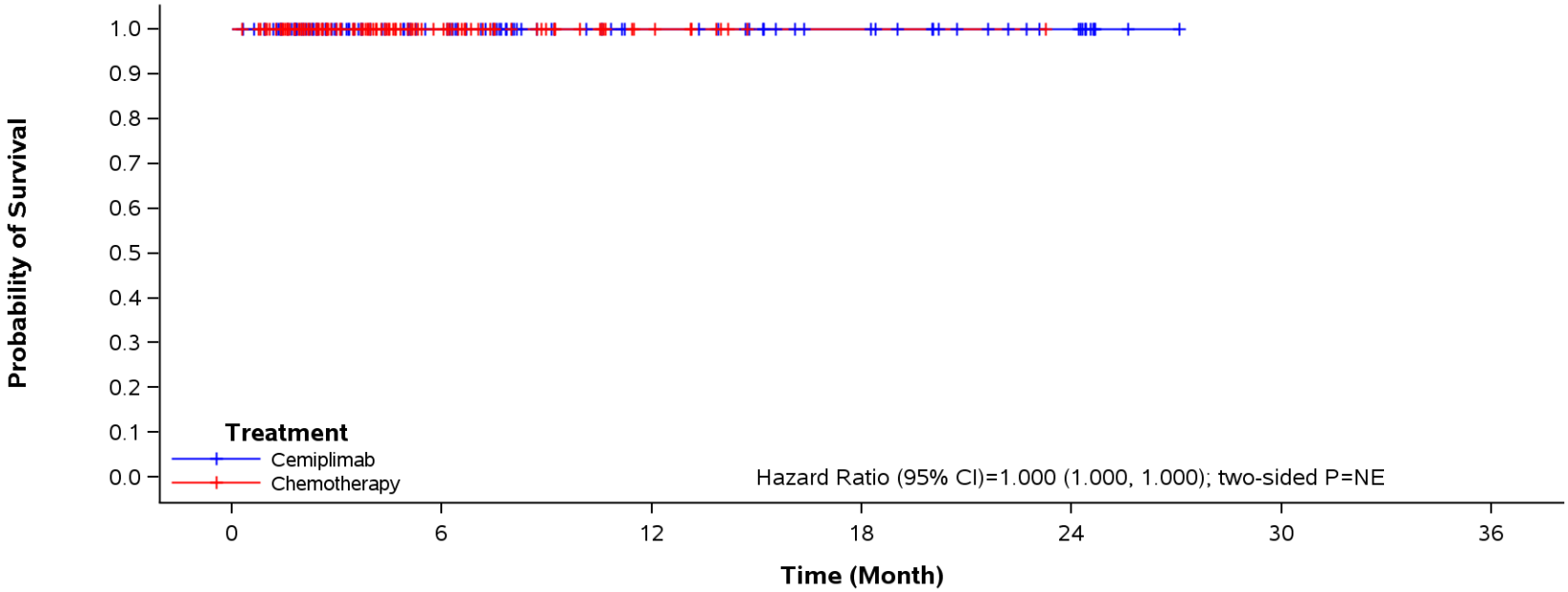

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Anaemia



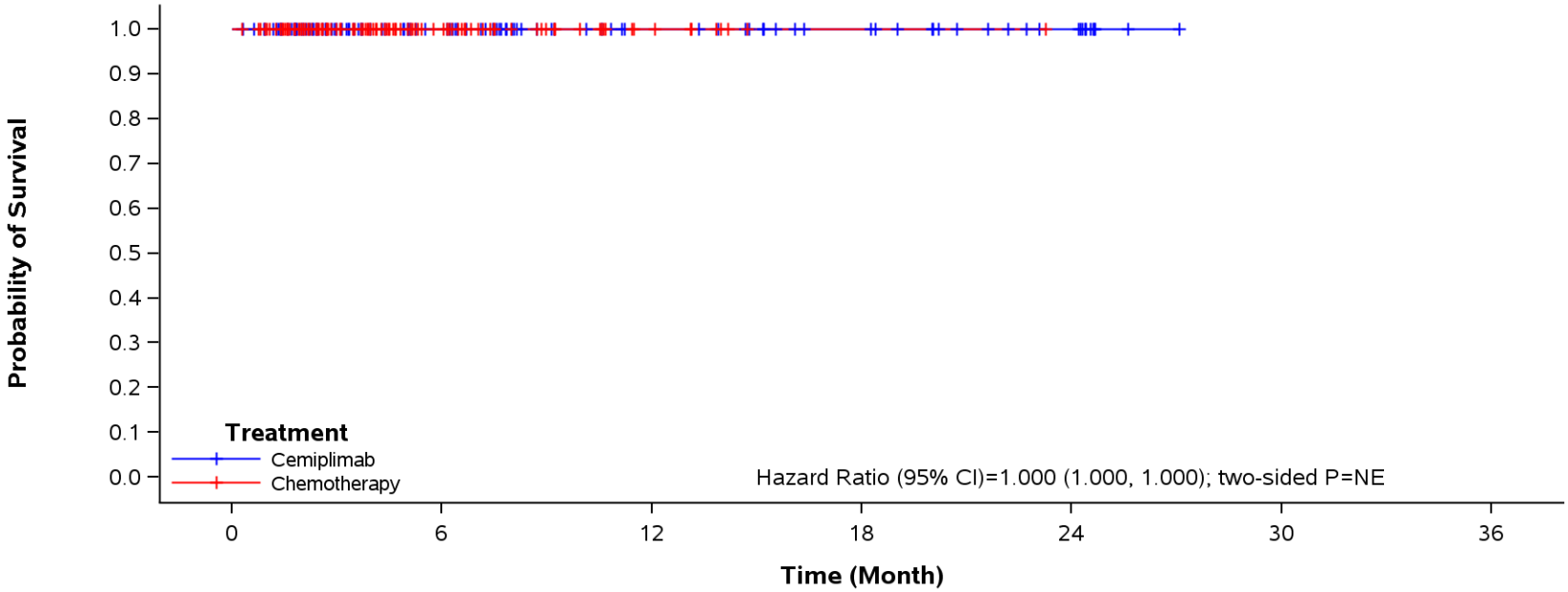

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



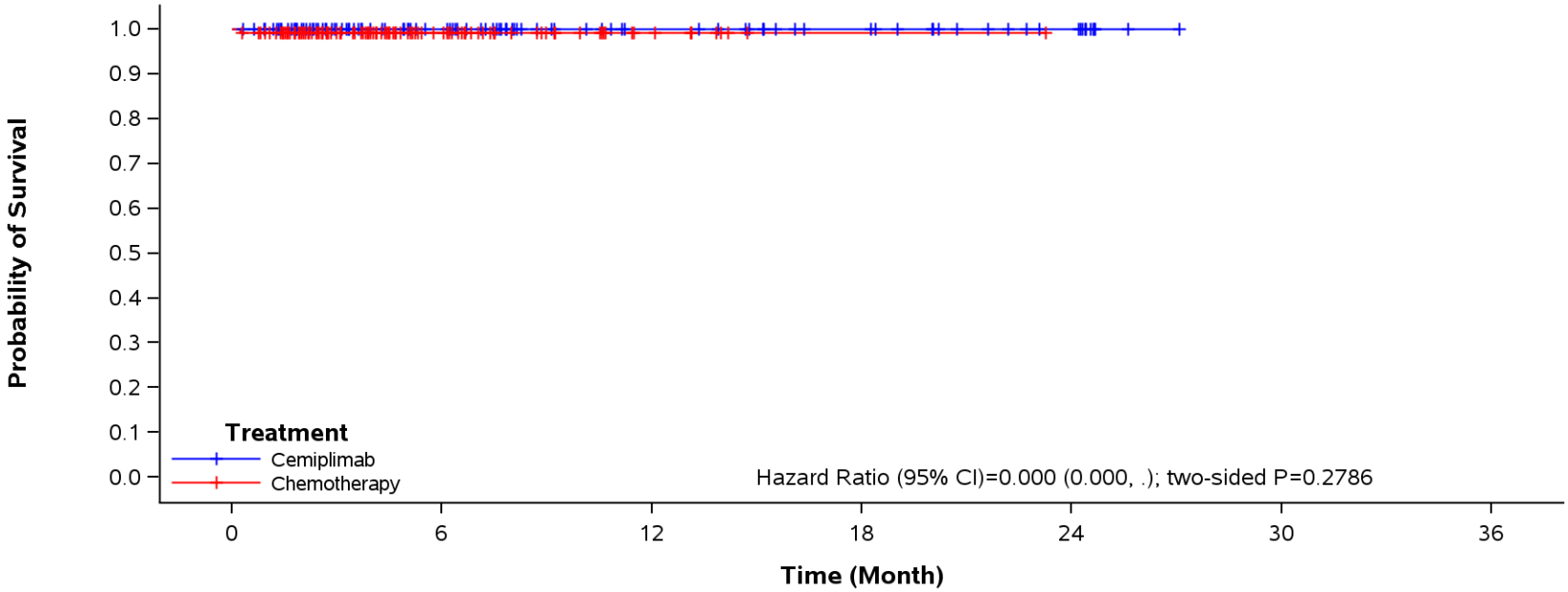

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



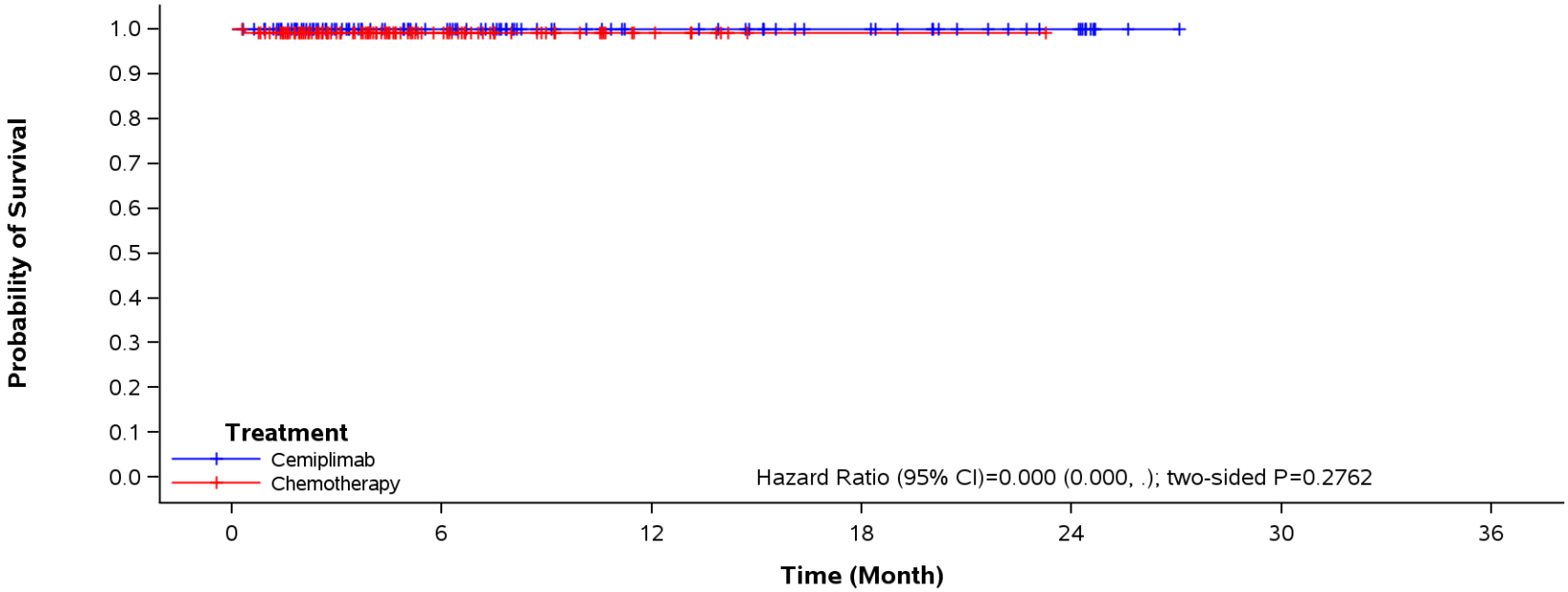

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



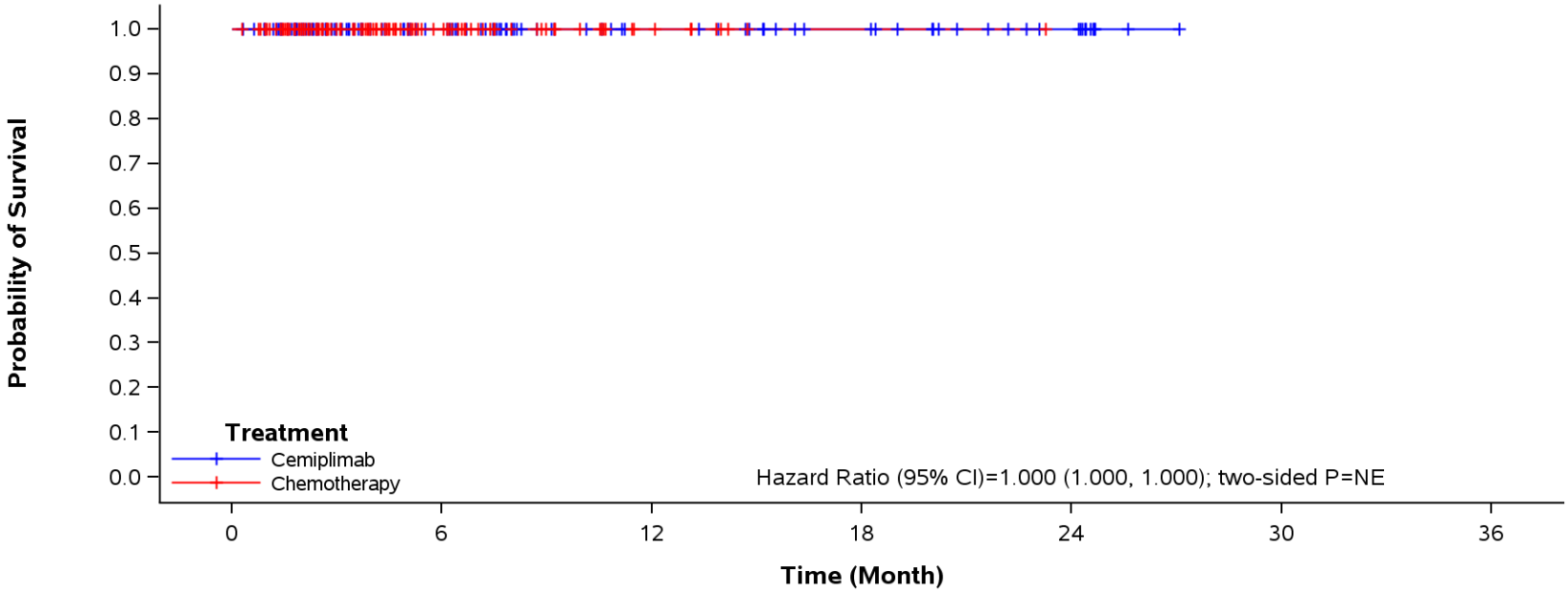

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Cardiac disorders



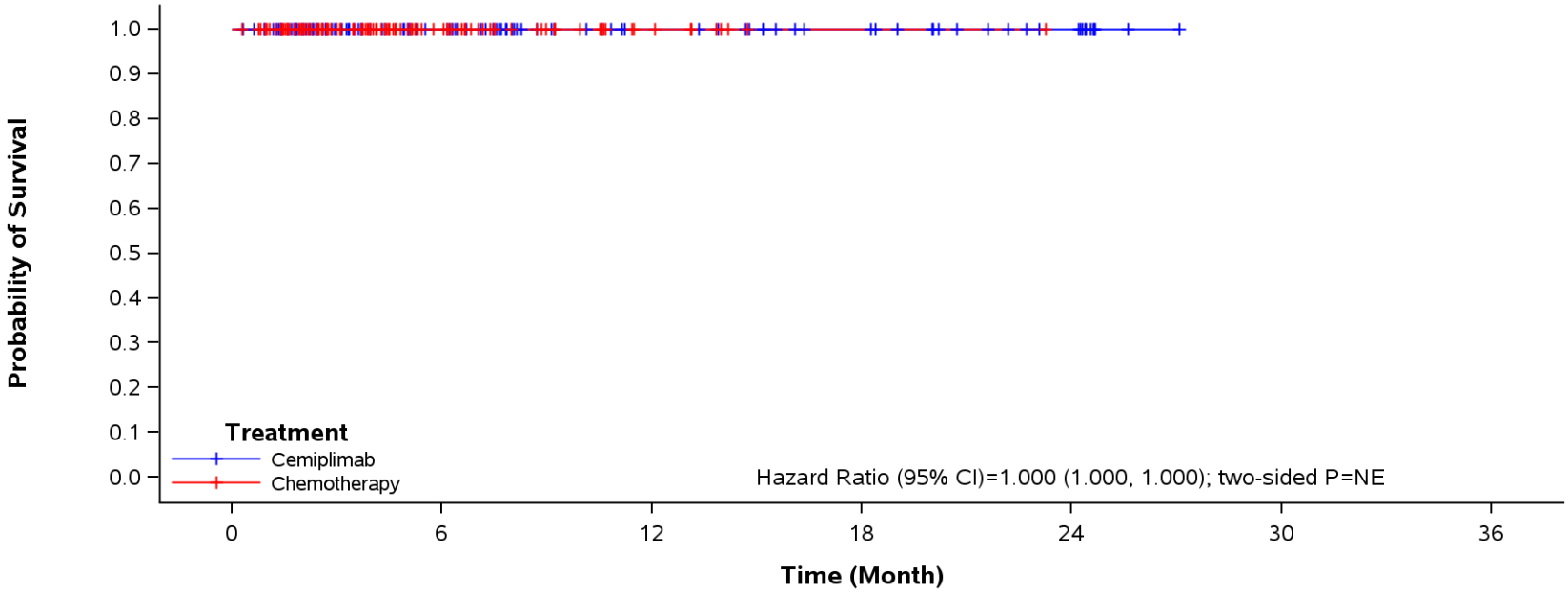

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Cardiac disorders
PT: Autoimmune pericarditis



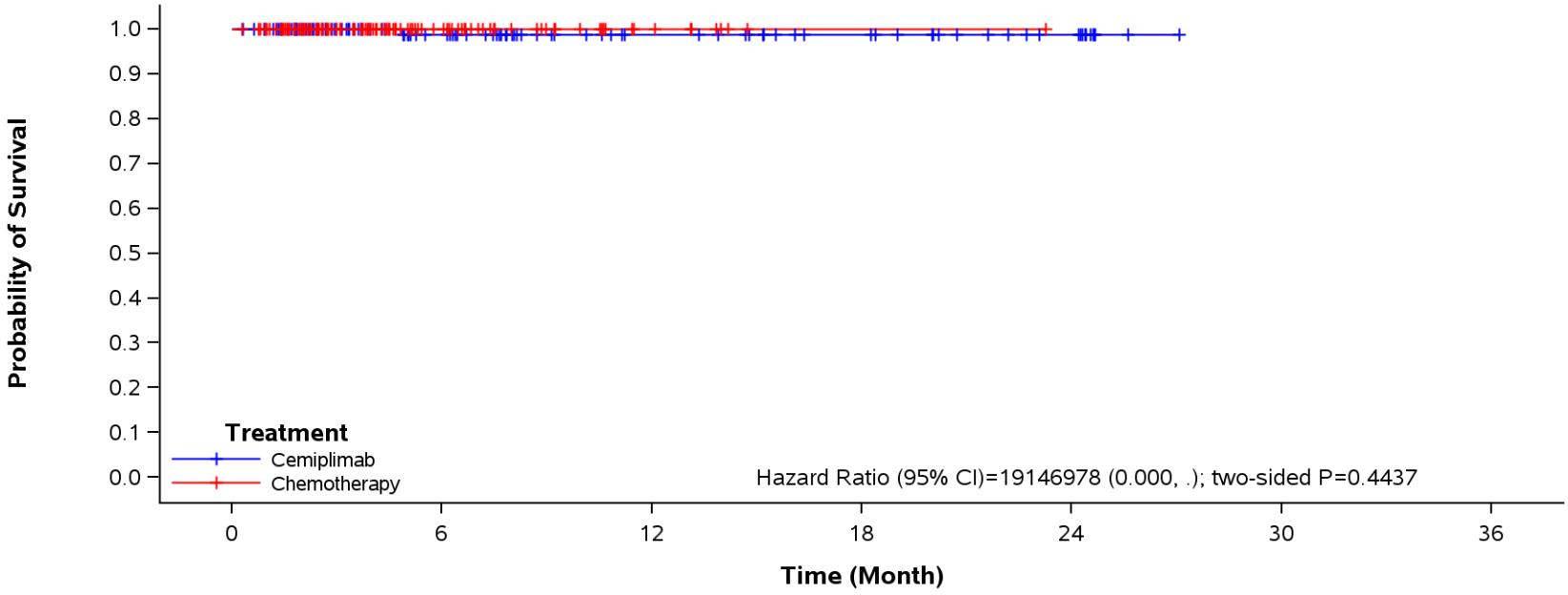

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Endocrine disorders



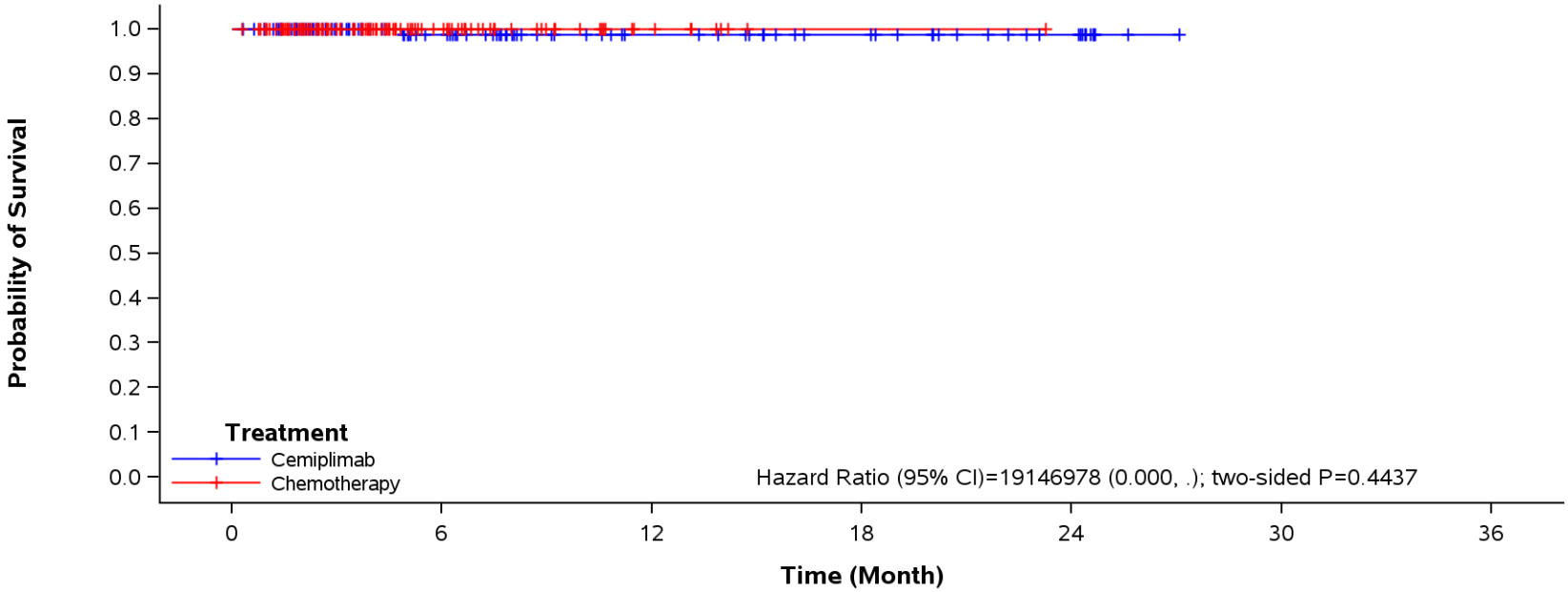

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 65 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Endocrine disorders
PT: Hypothyroidism



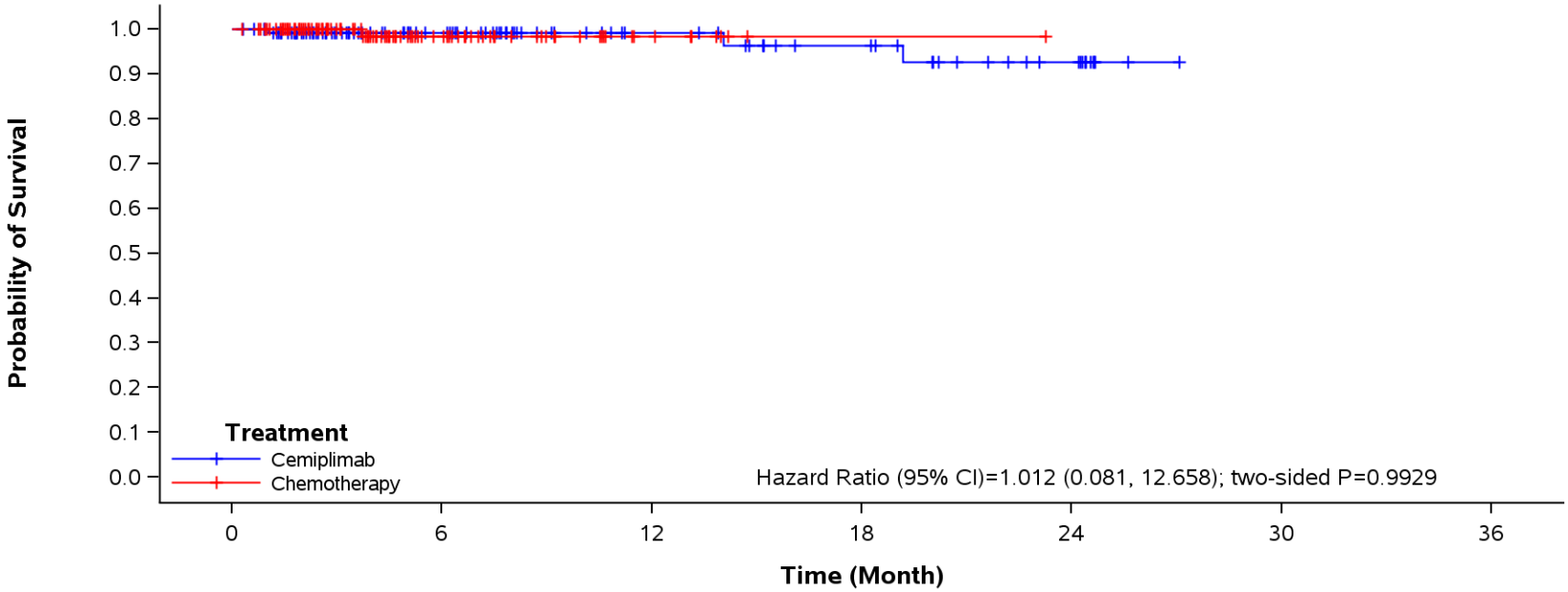

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 65 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders



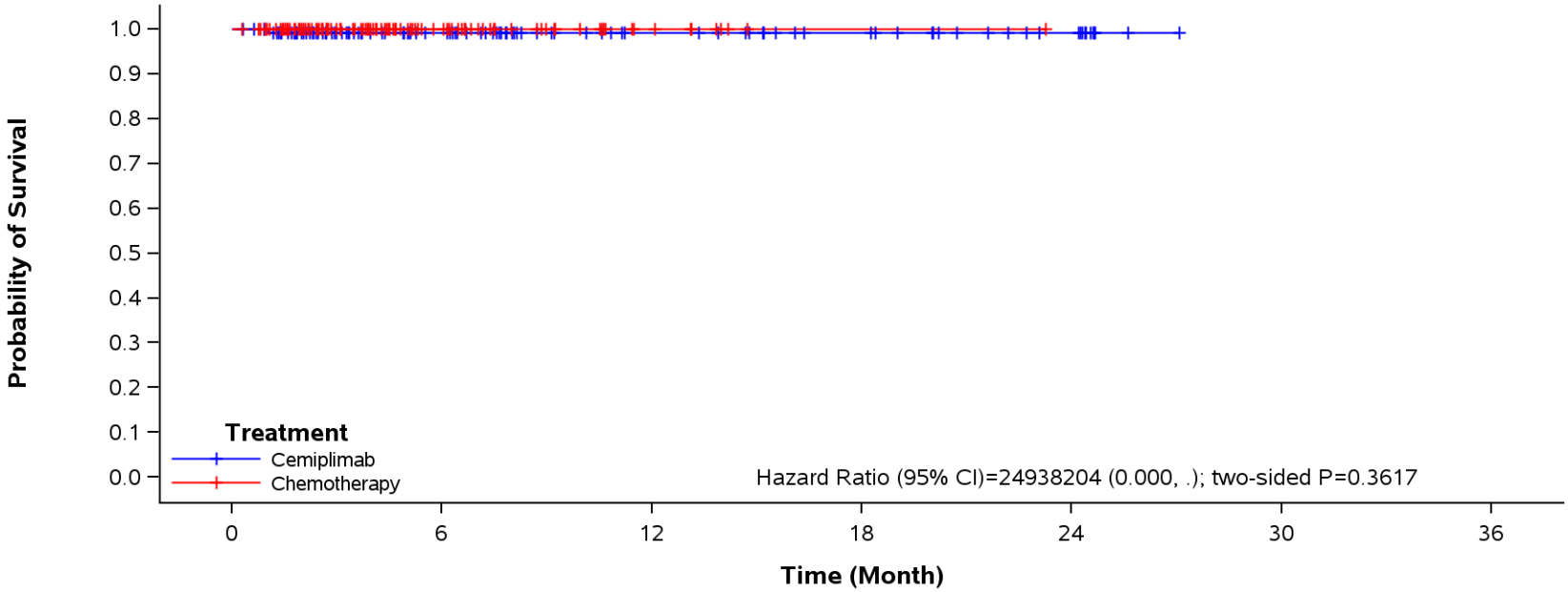

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders
PT: Colitis



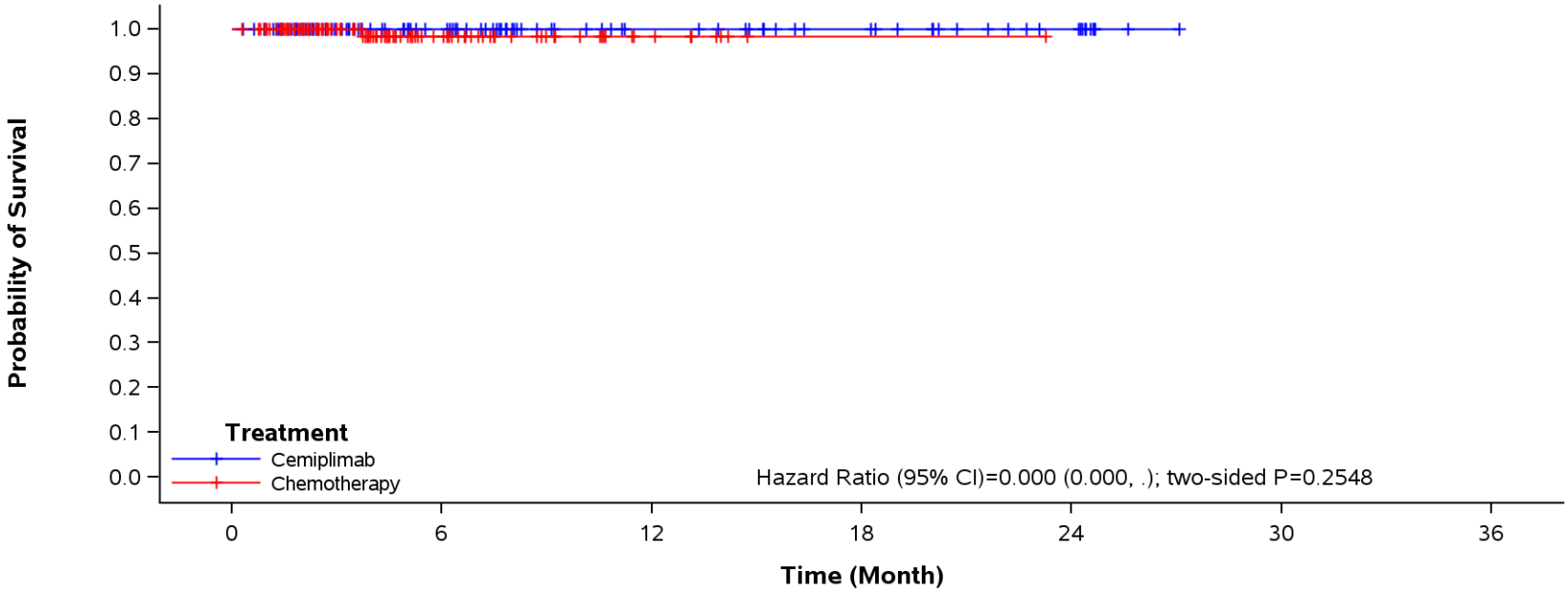

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders
PT: Diverticular perforation



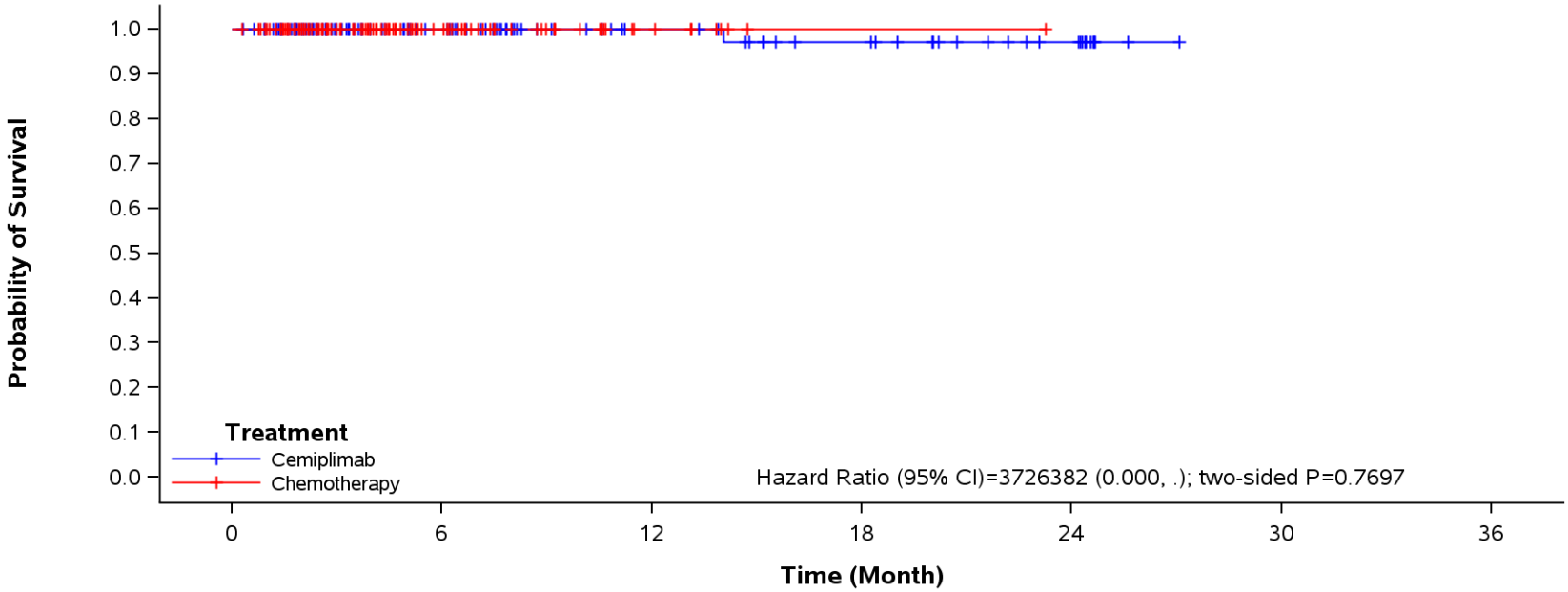

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders
PT: Pancreatic mass



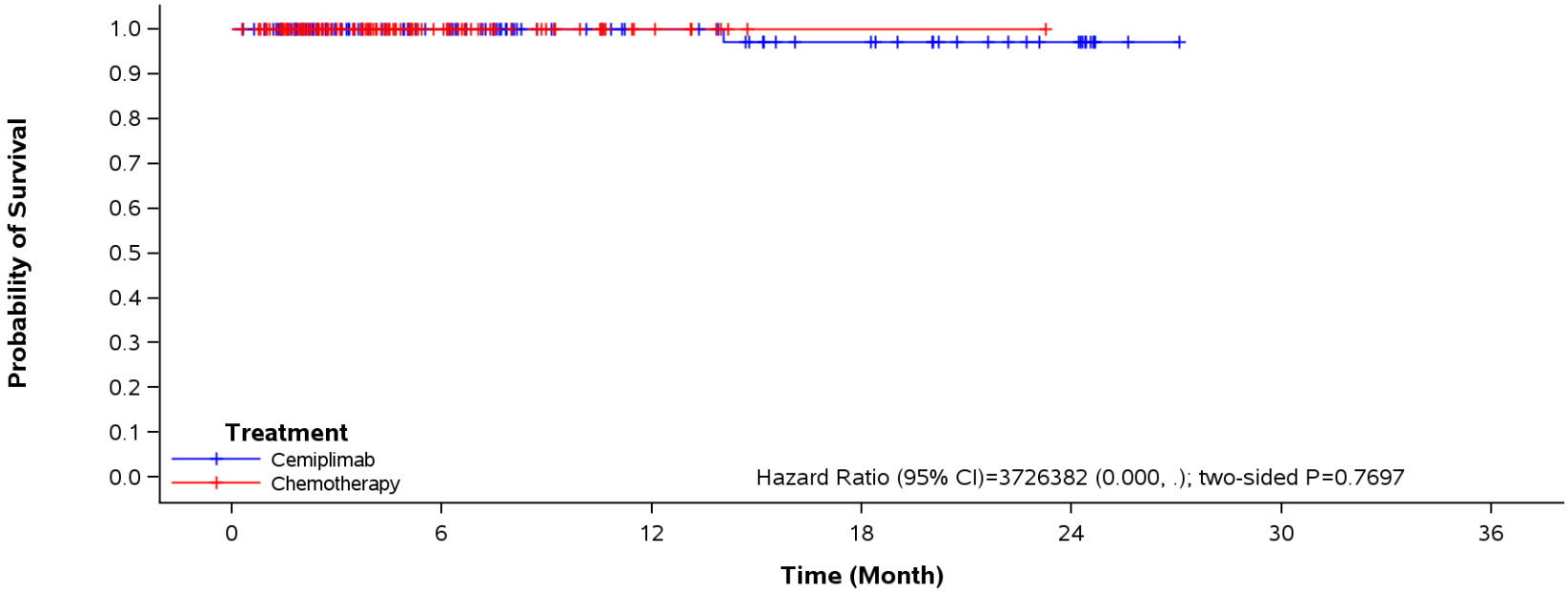

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



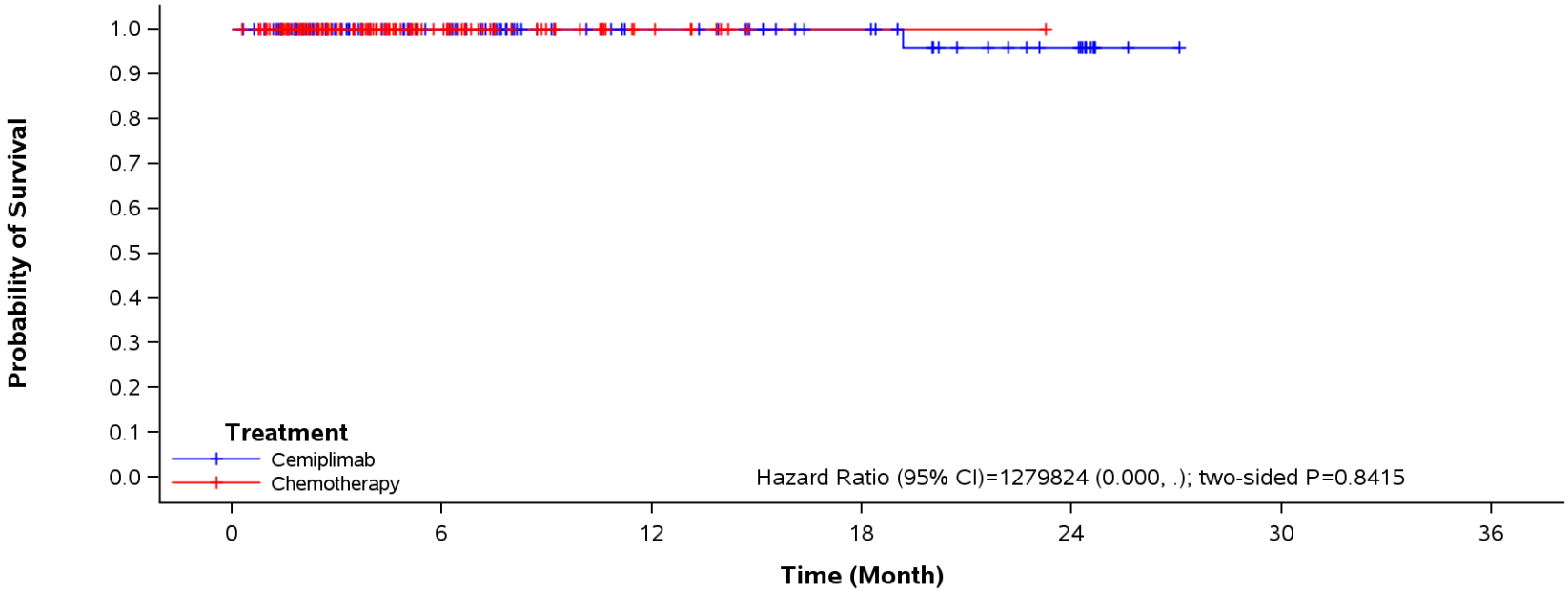

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Gastrointestinal disorders
PT: Proctalgia




**Number of Subjects at risk**

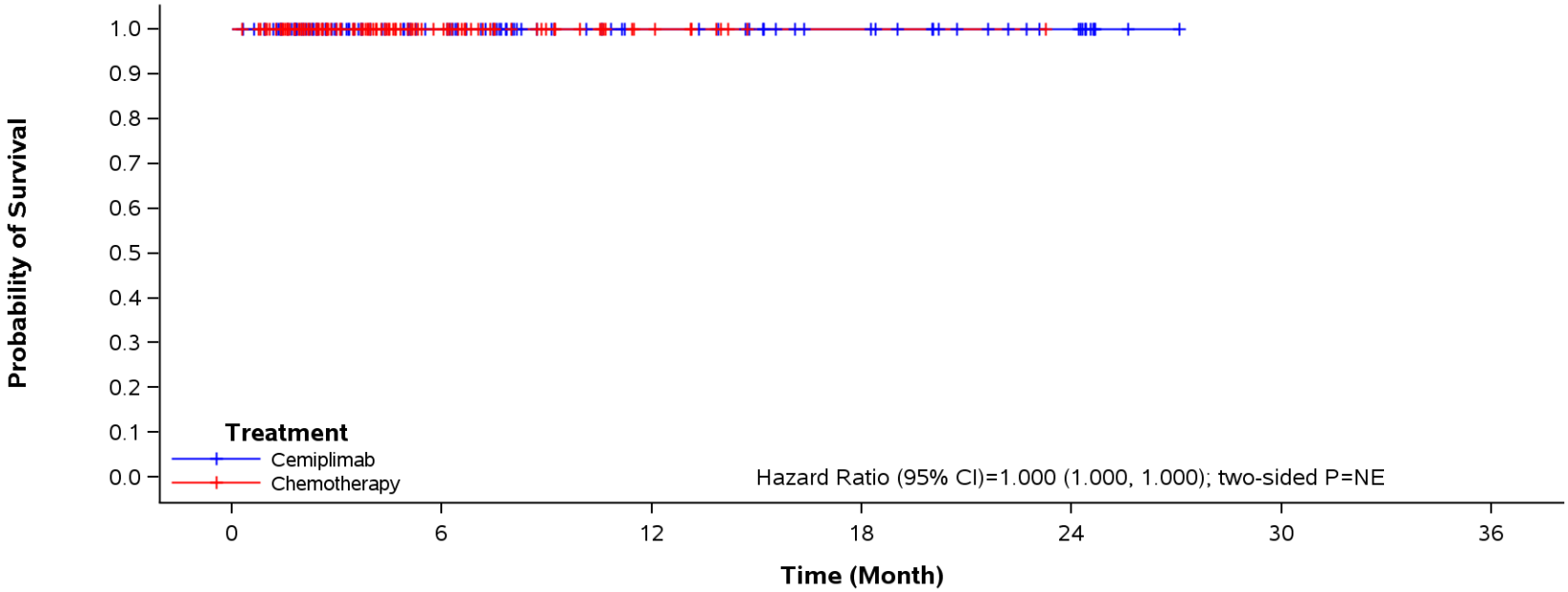
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

SOC: General disorders and administration site conditions




**Number of Subjects at risk**

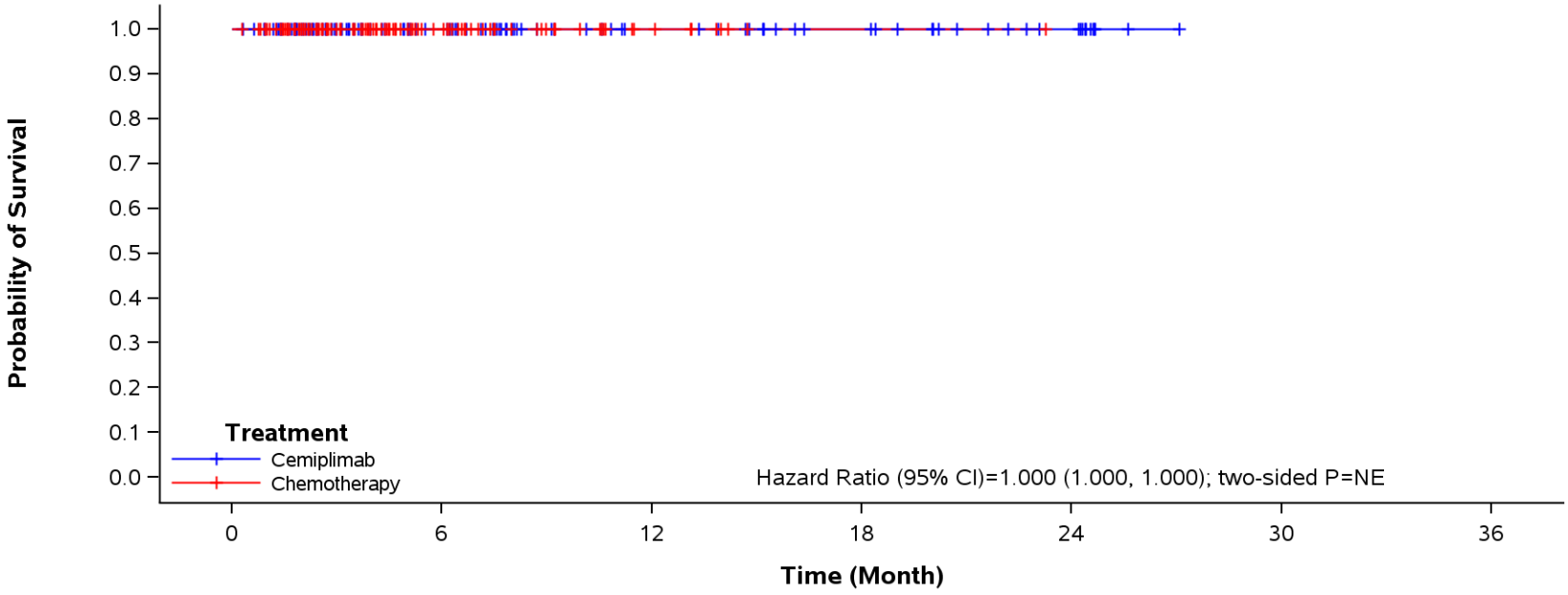
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: General disorders and administration site conditions
PT: Malaise



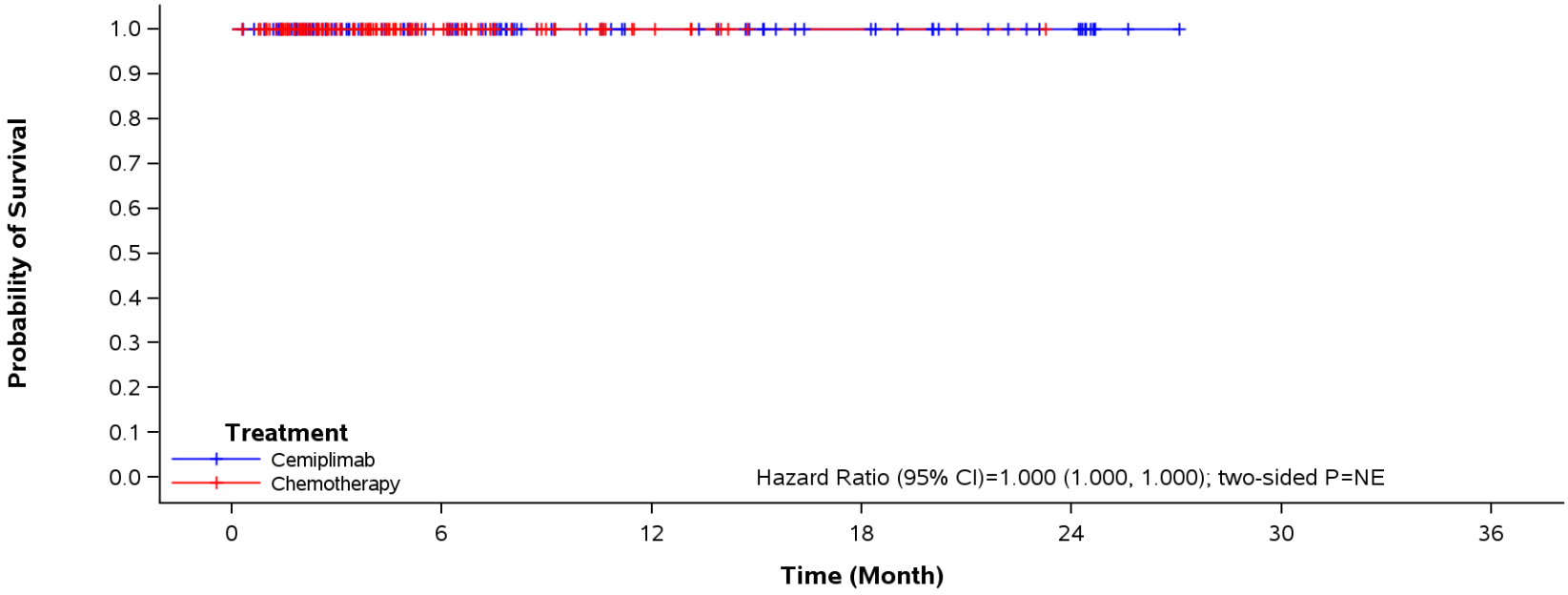

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



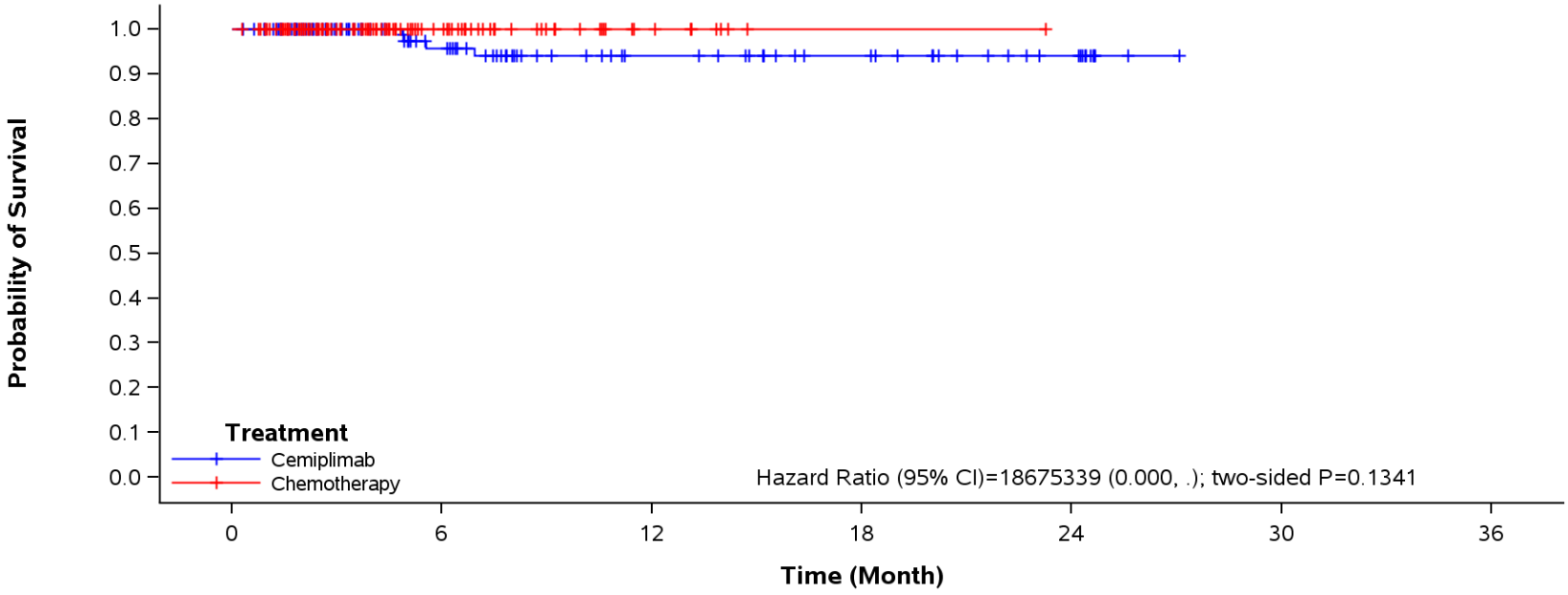

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Hepatobiliary disorders



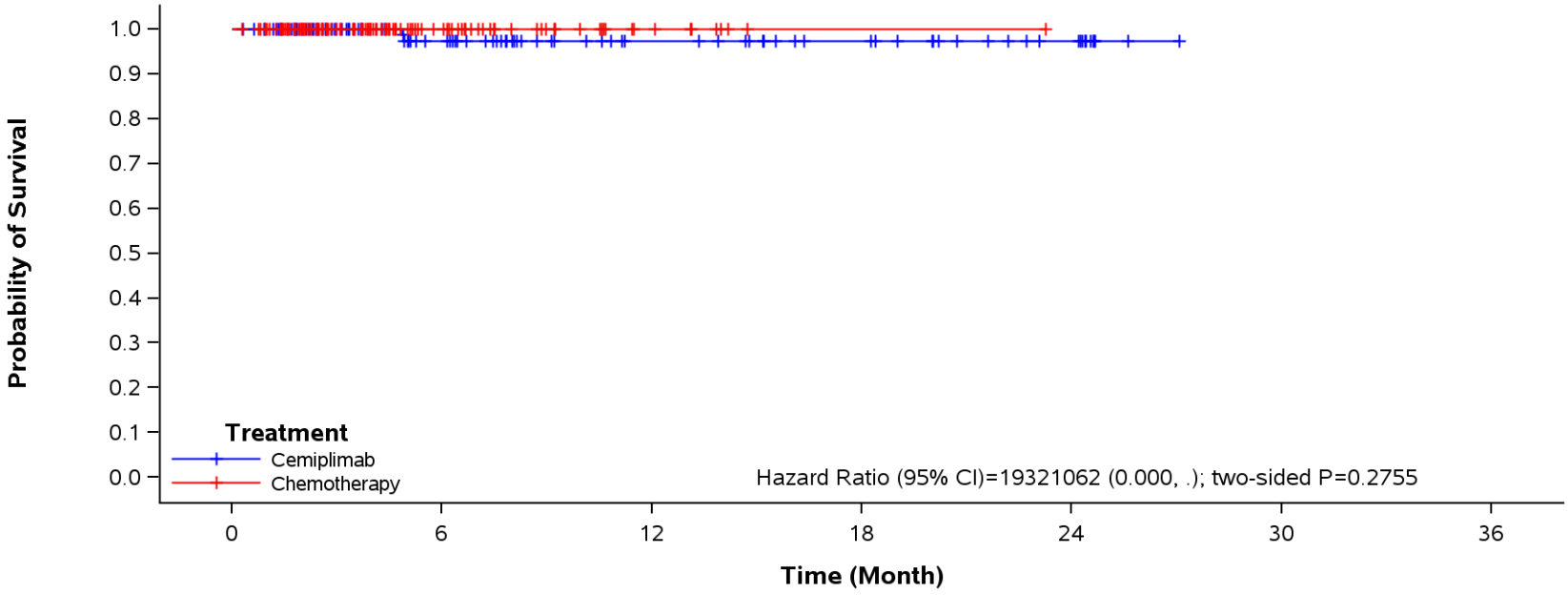

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 63 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



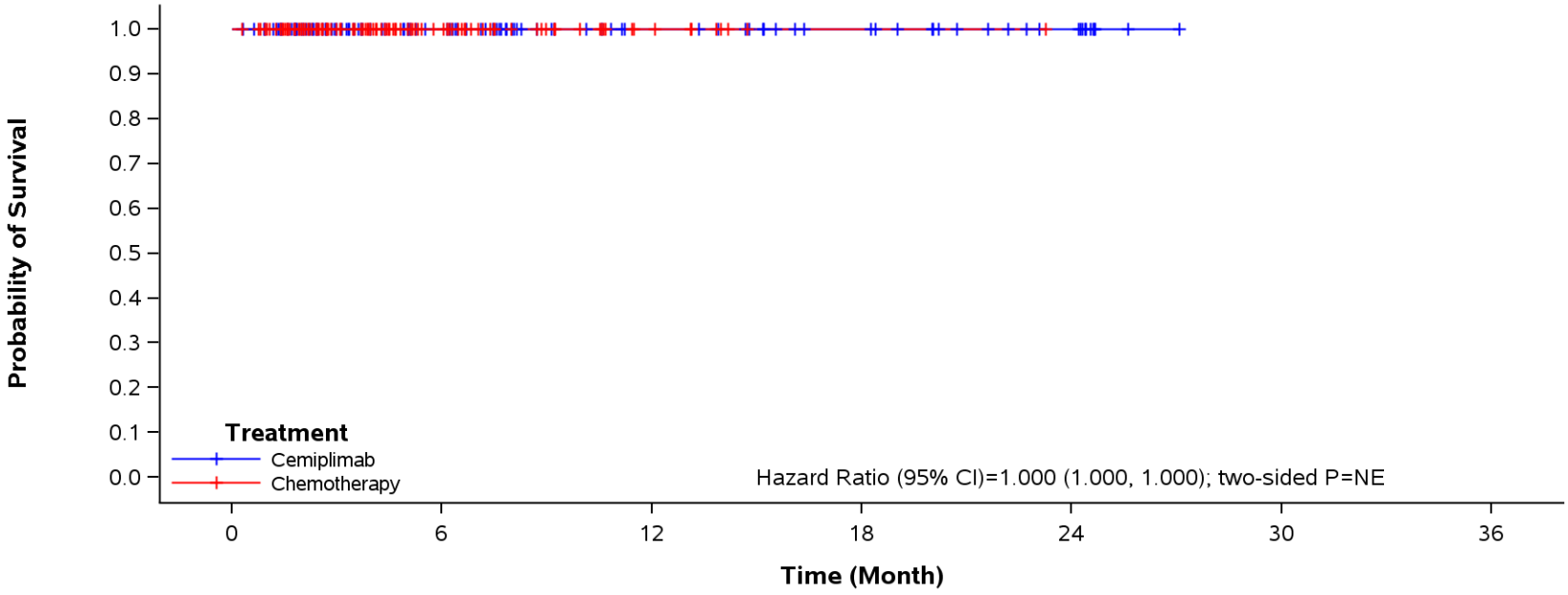

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 64 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



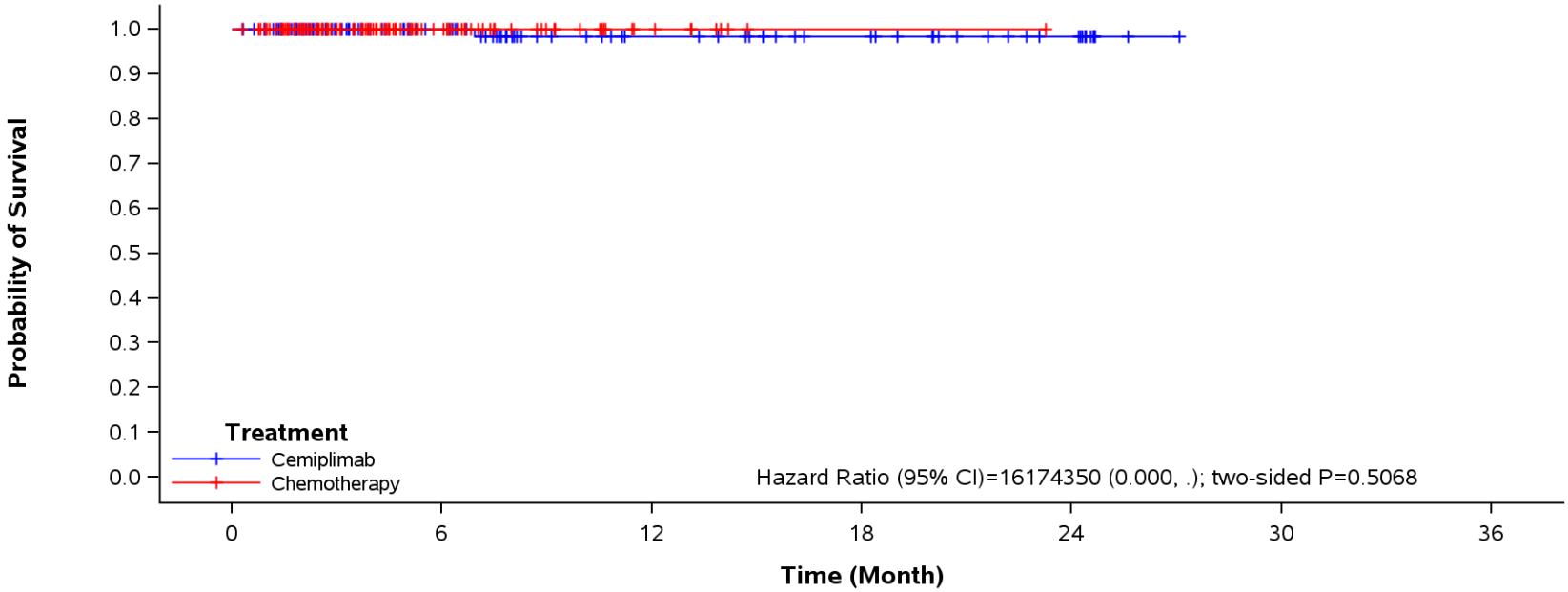

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Hepatobiliary disorders
PT: Hepatitis



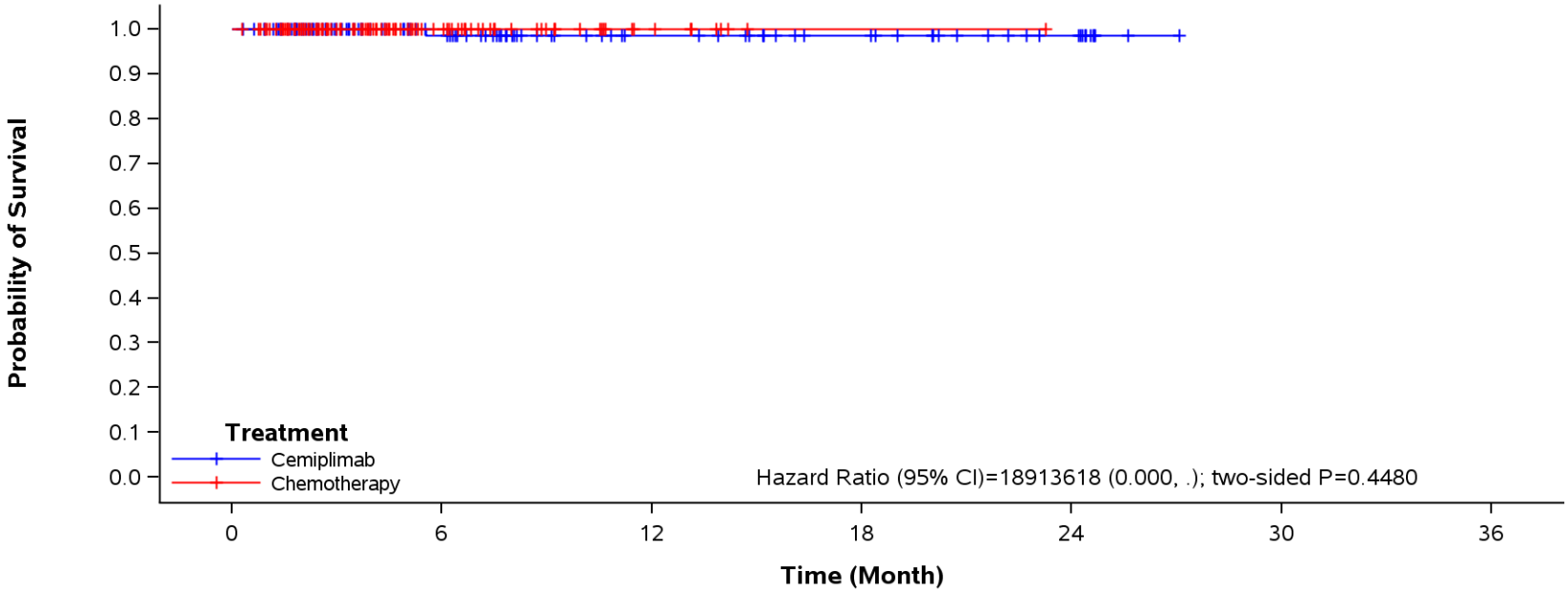

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



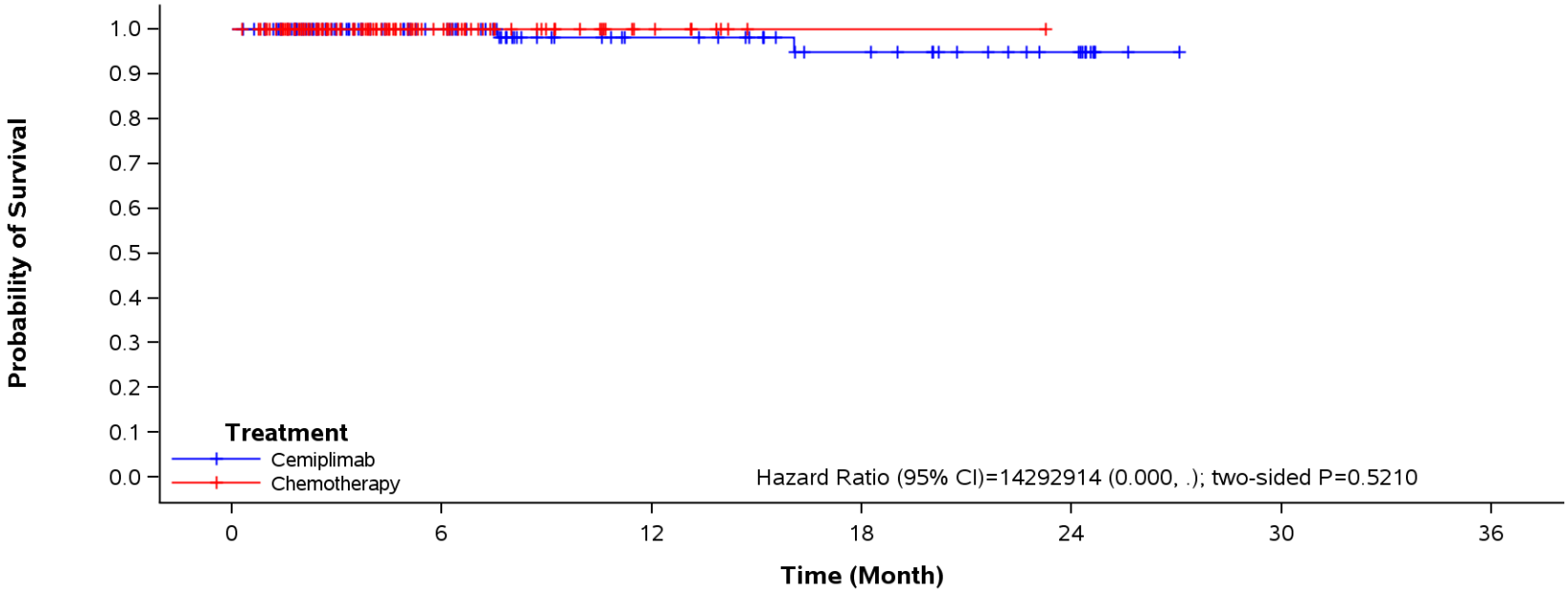

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 65 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Infections and infestations



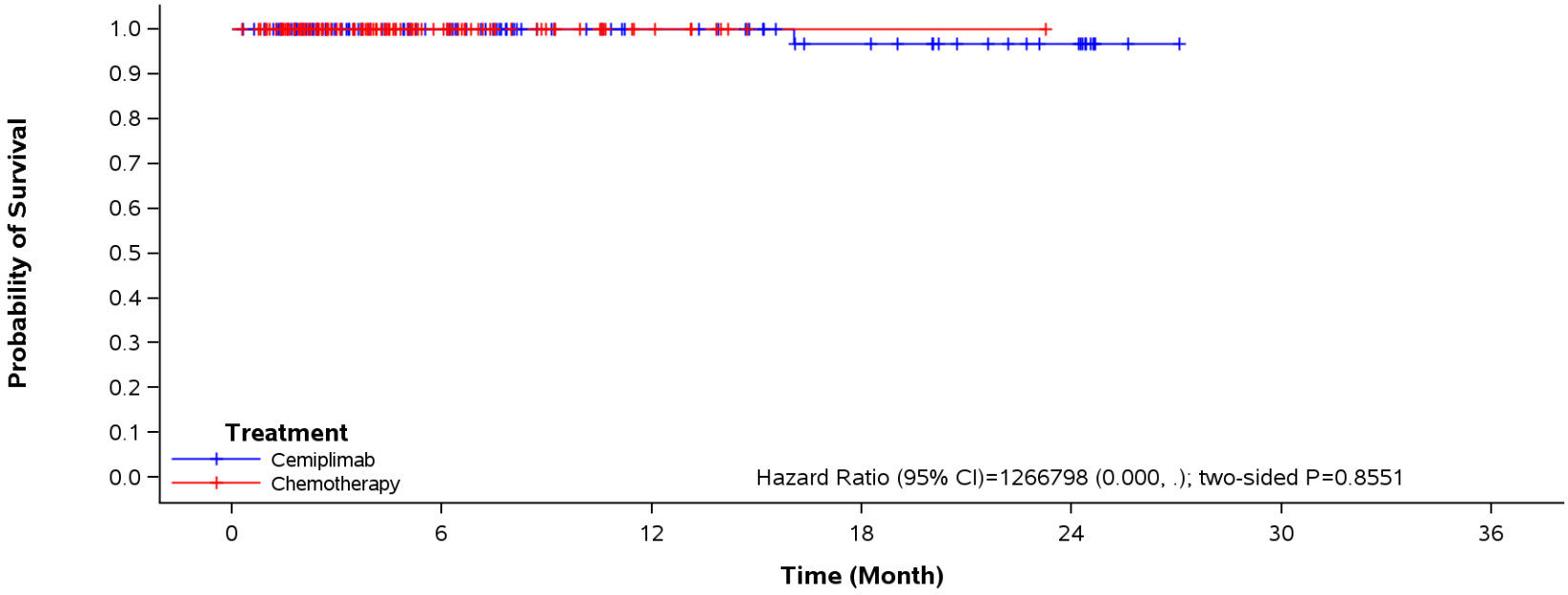

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 27 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Infections and infestations
PT: COVID-19 pneumonia



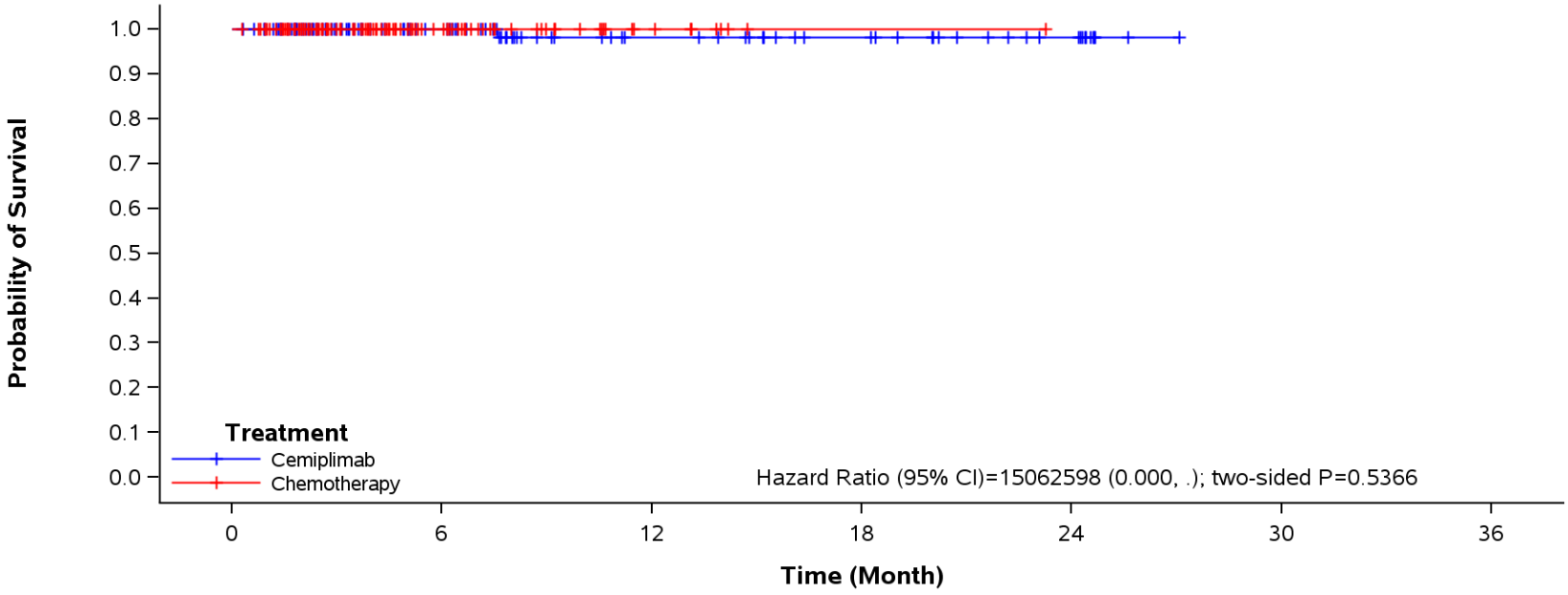

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 27 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Infections and infestations
PT: Gastroenteritis



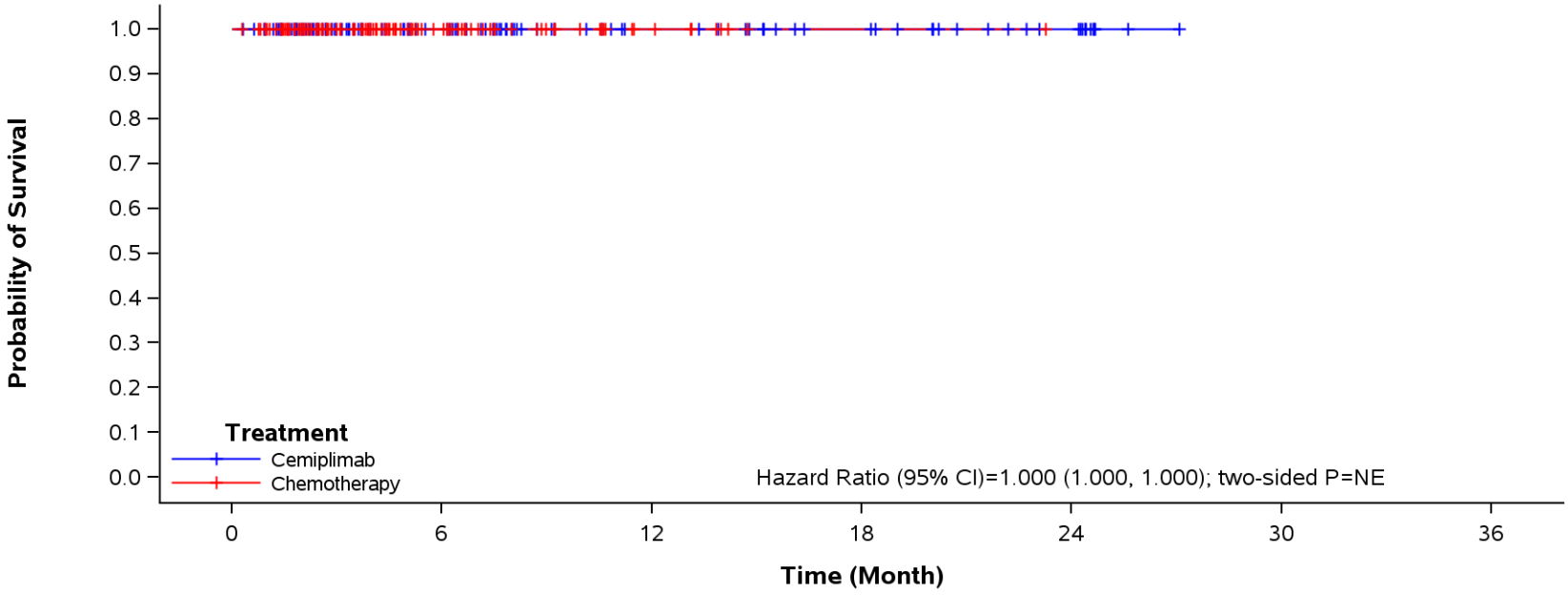

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Infections and infestations
PT: Pelvic abscess



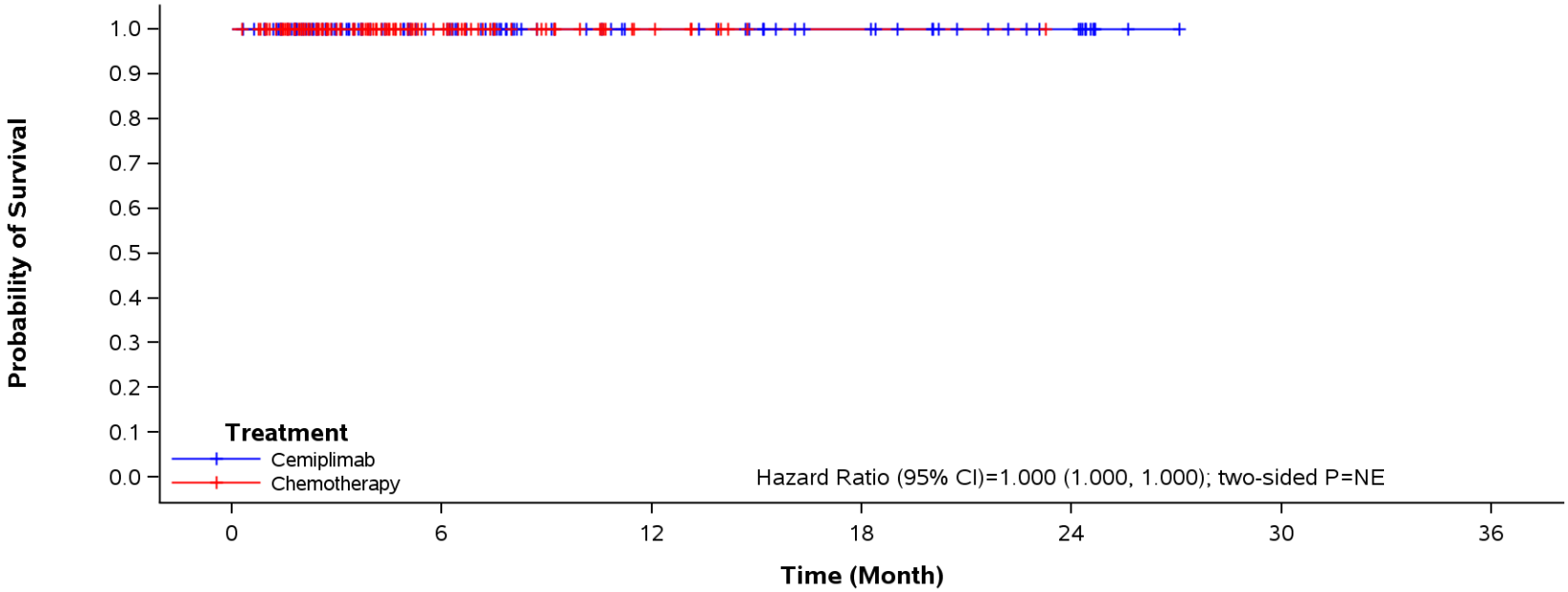

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Infections and infestations
PT: Peritonitis



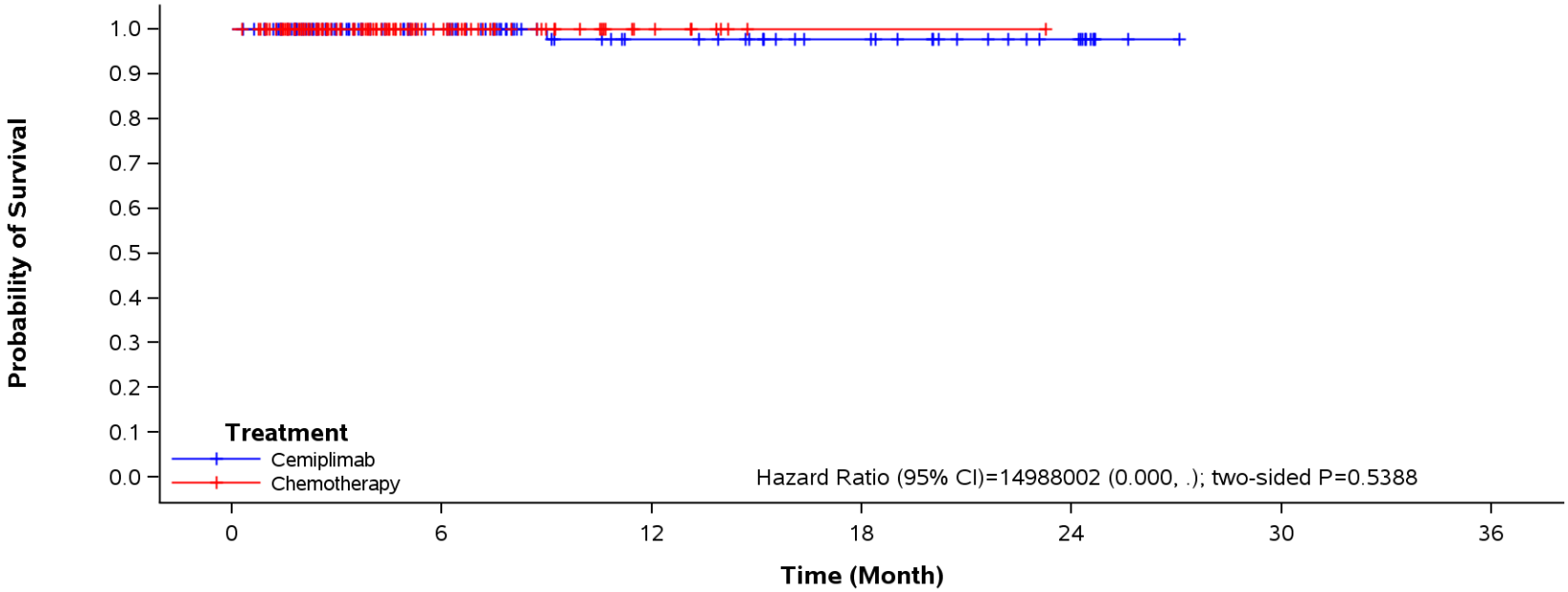

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Infections and infestations
PT: Pneumonia



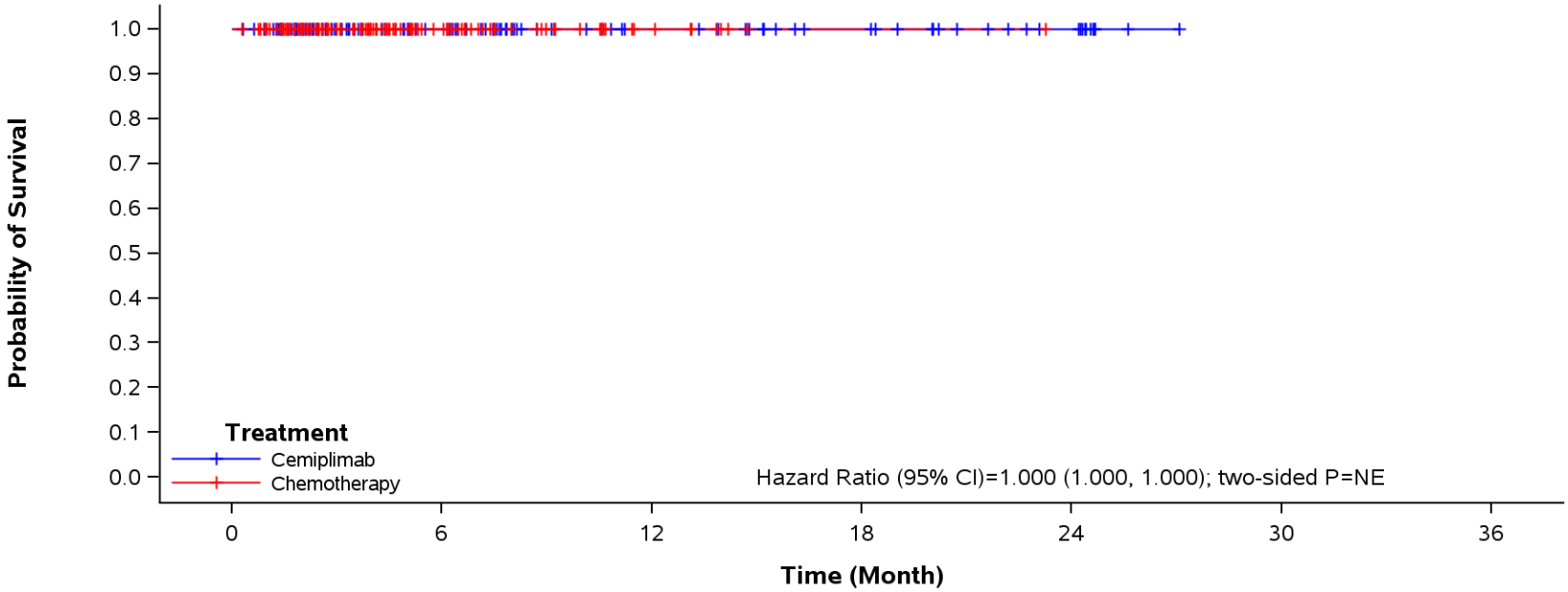

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Infections and infestations
PT: Pyomyositis




**Number of Subjects at risk**

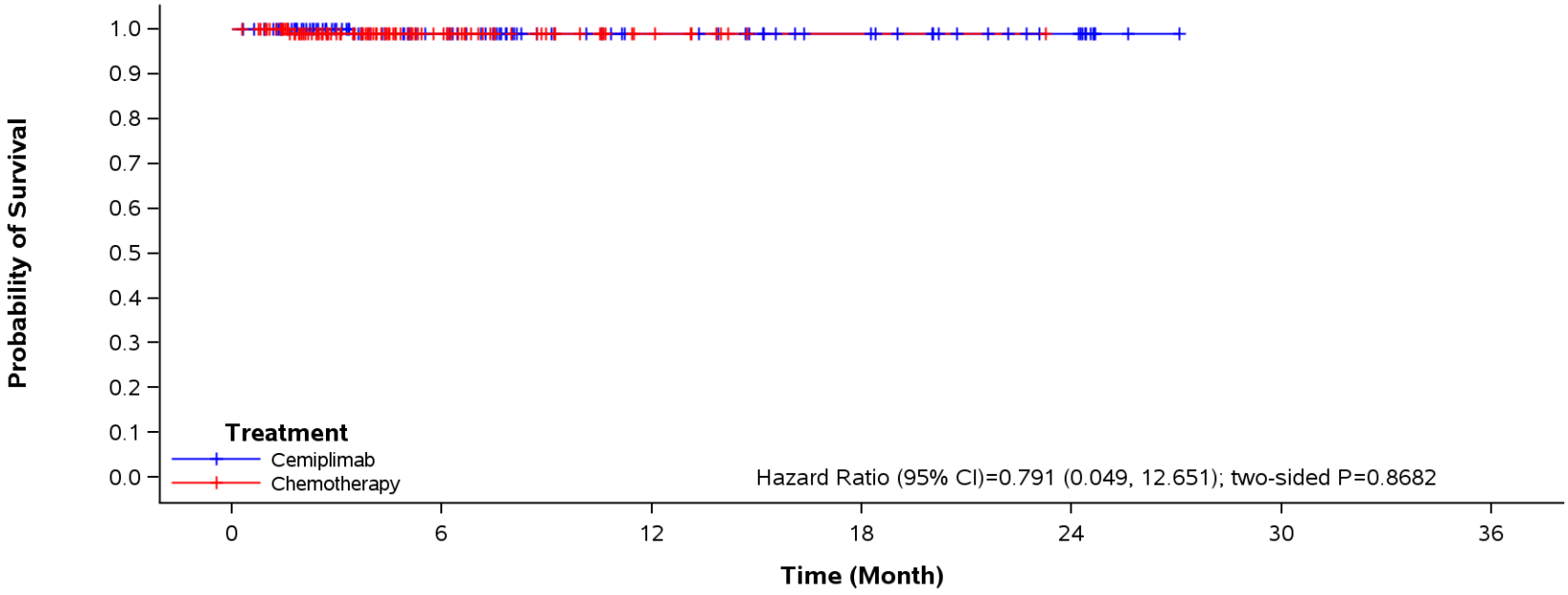
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

SOC: Injury, poisoning and procedural complications




Number of Subjects at risk

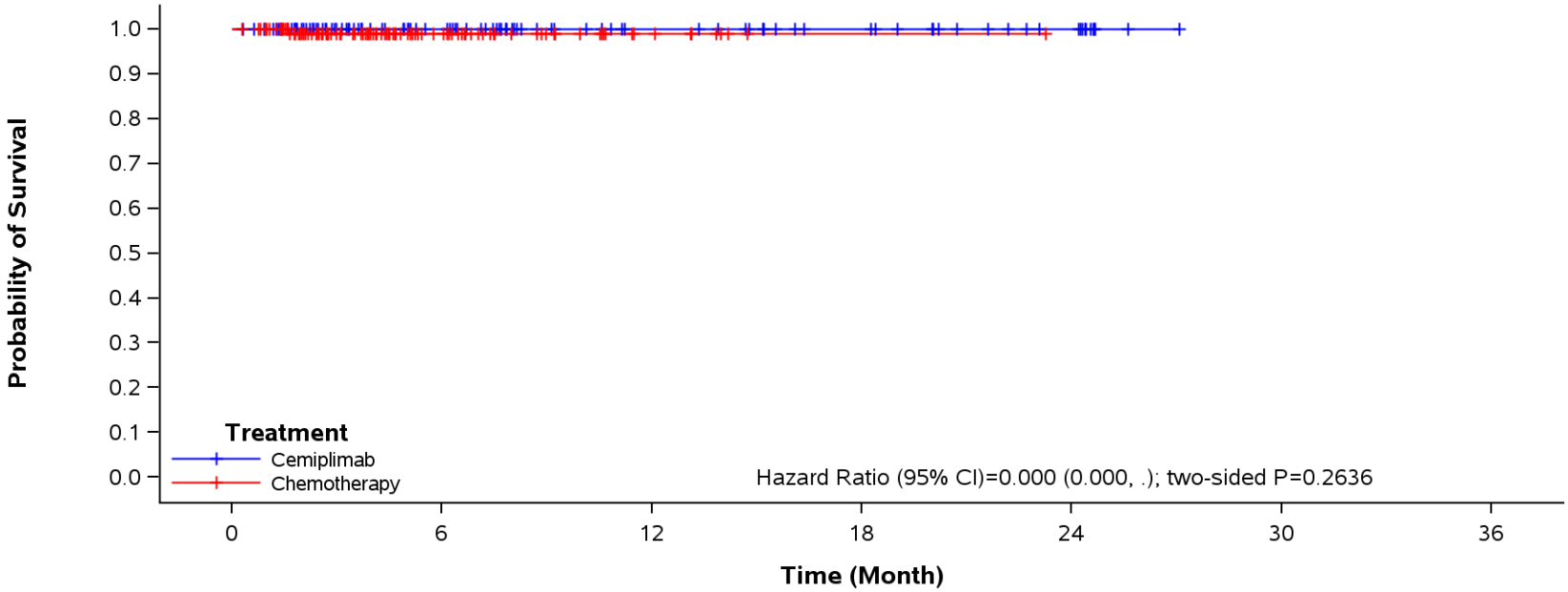
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 65 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



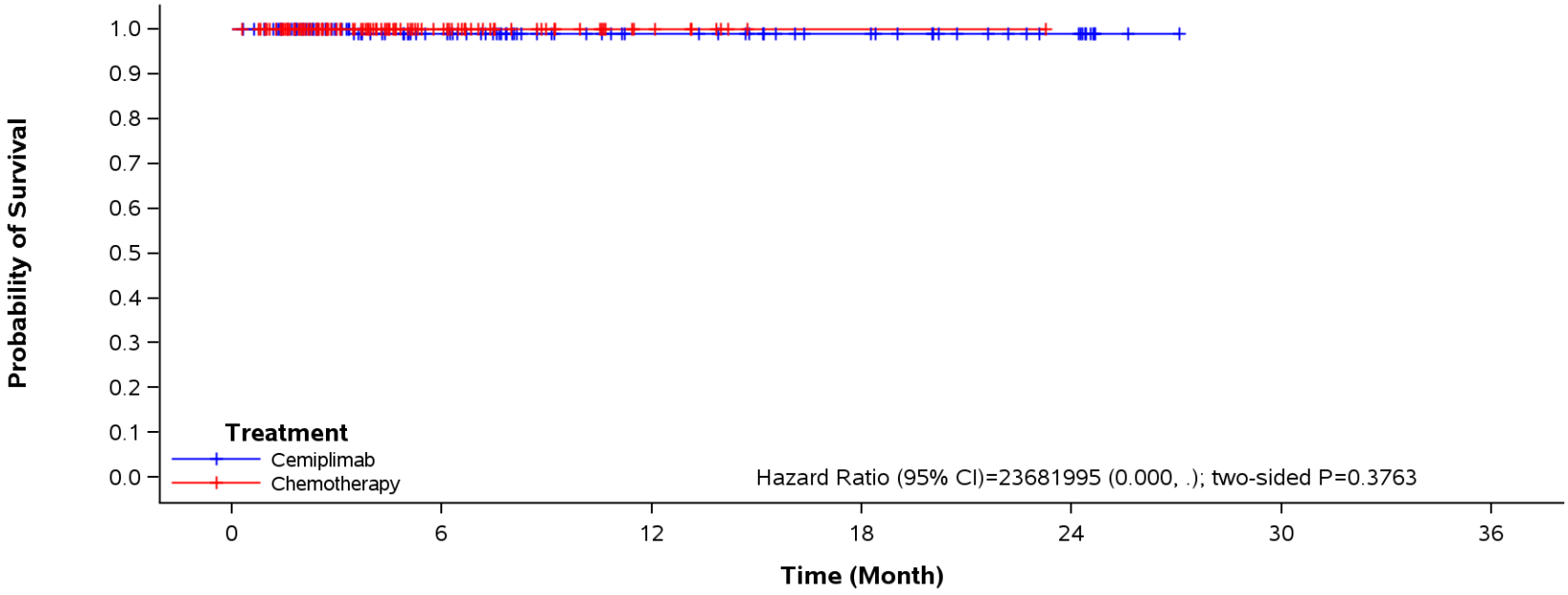

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



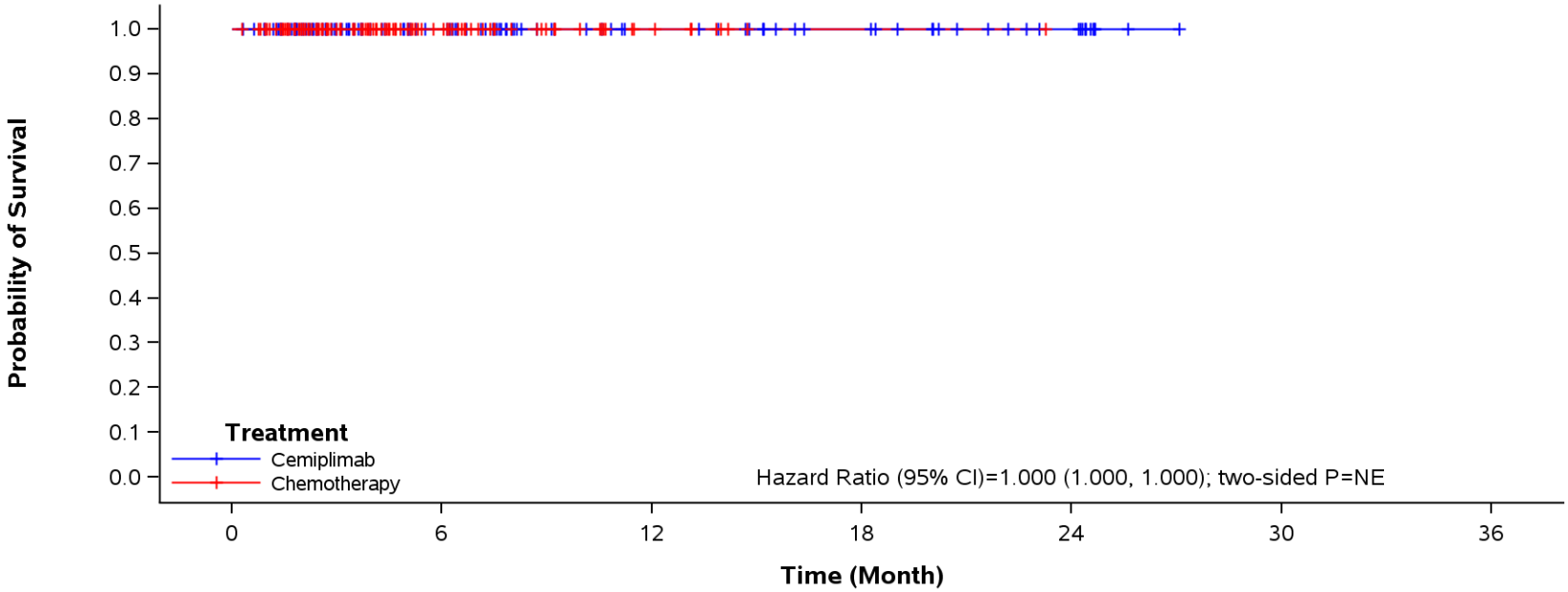

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 65 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Investigations



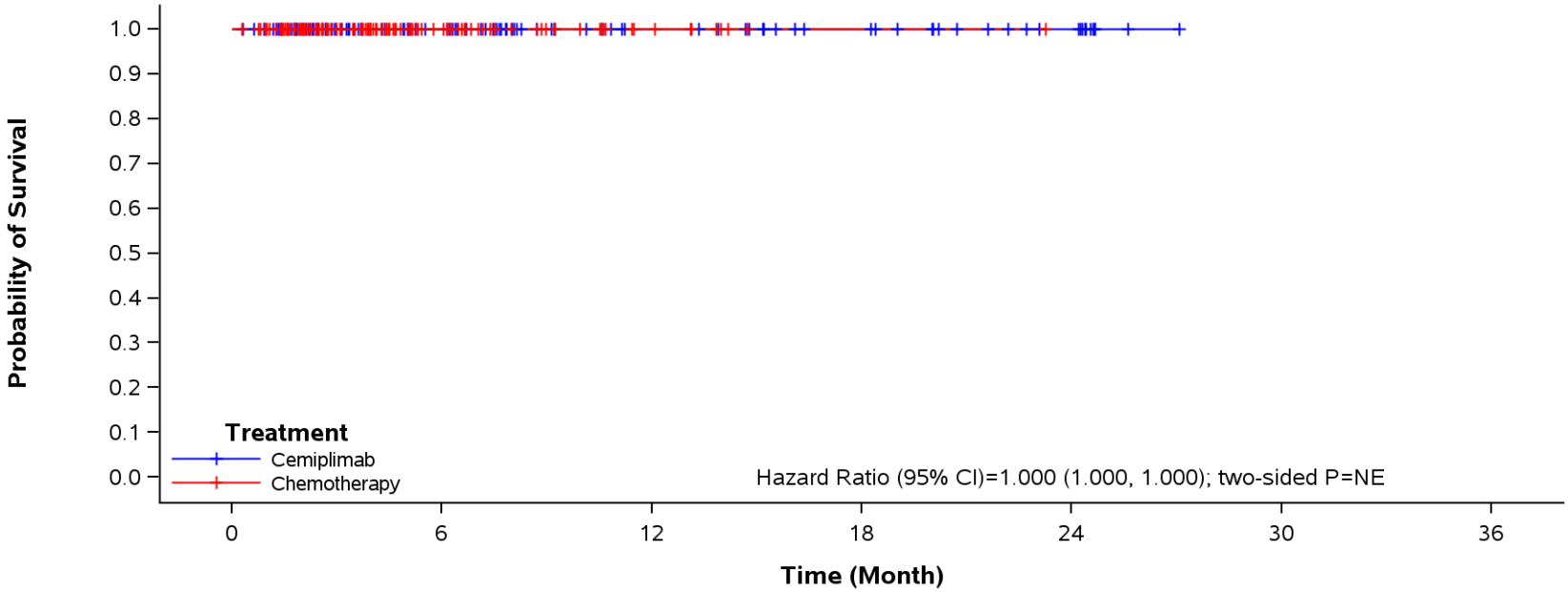

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Investigations
PT: Alanine aminotransferase increased



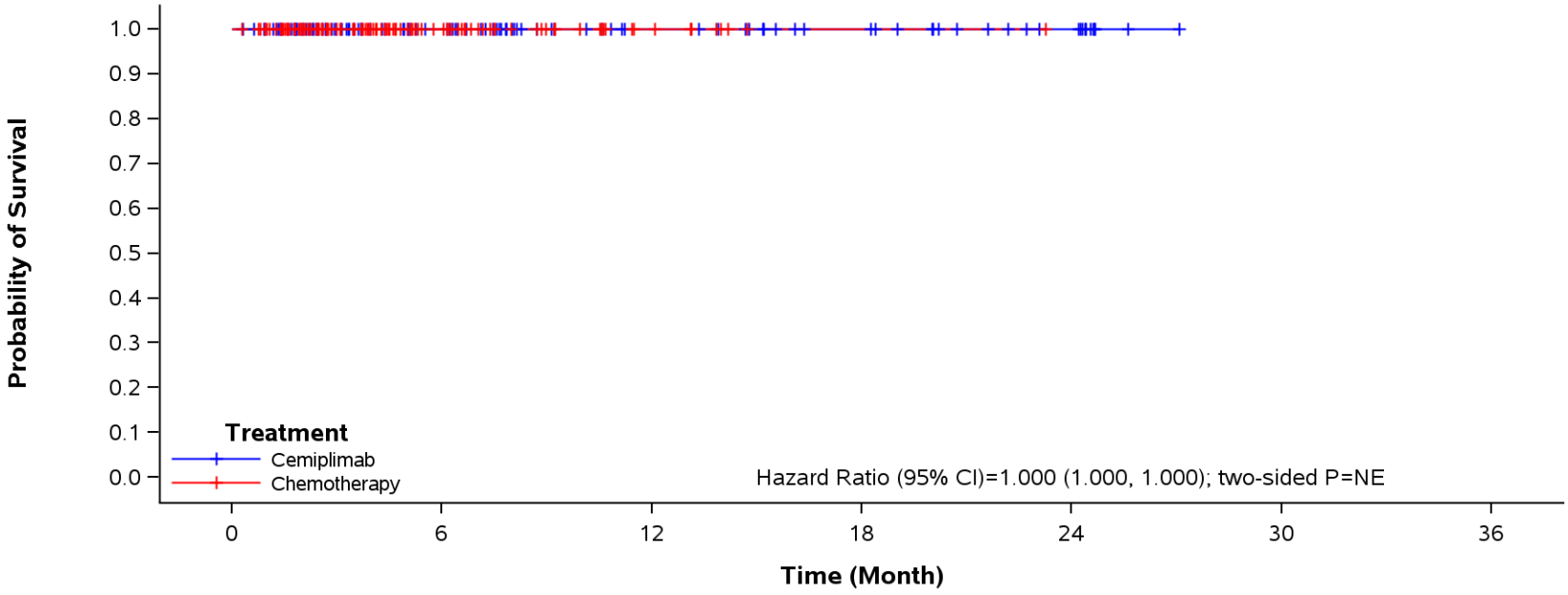

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Investigations
PT: Amylase increased



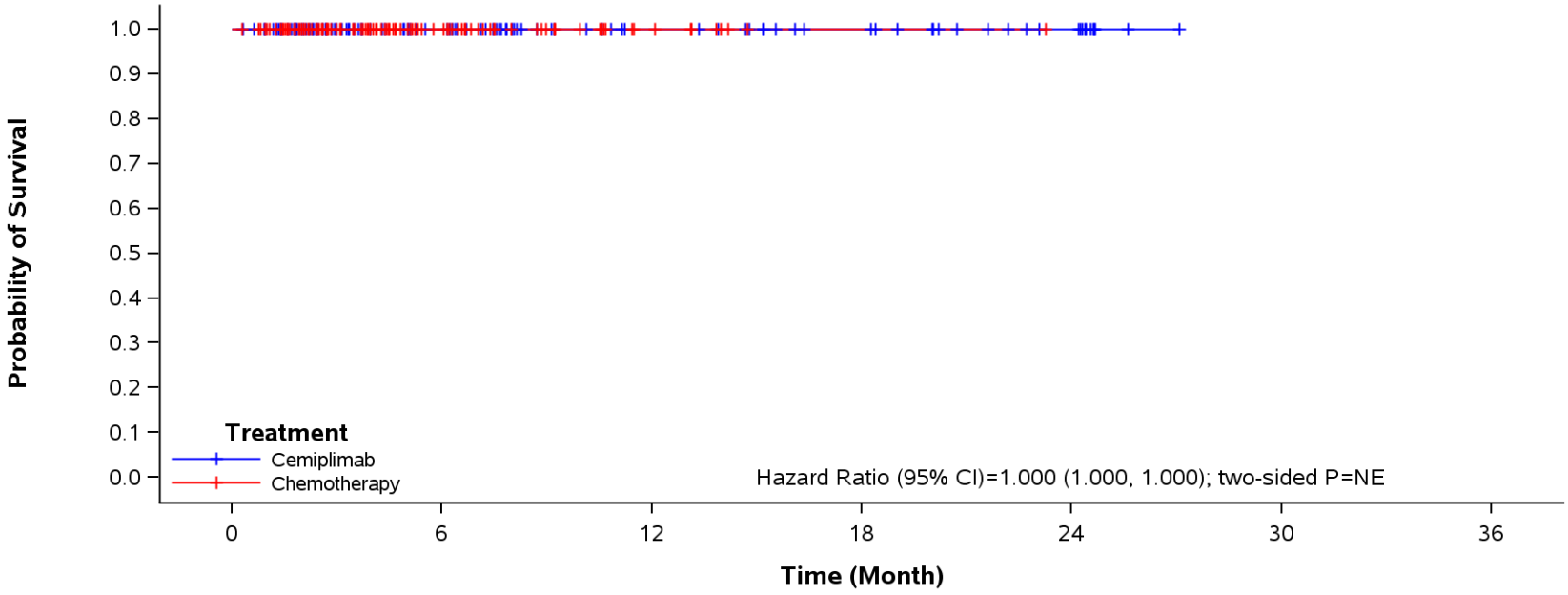

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Investigations
PT: Platelet count decreased



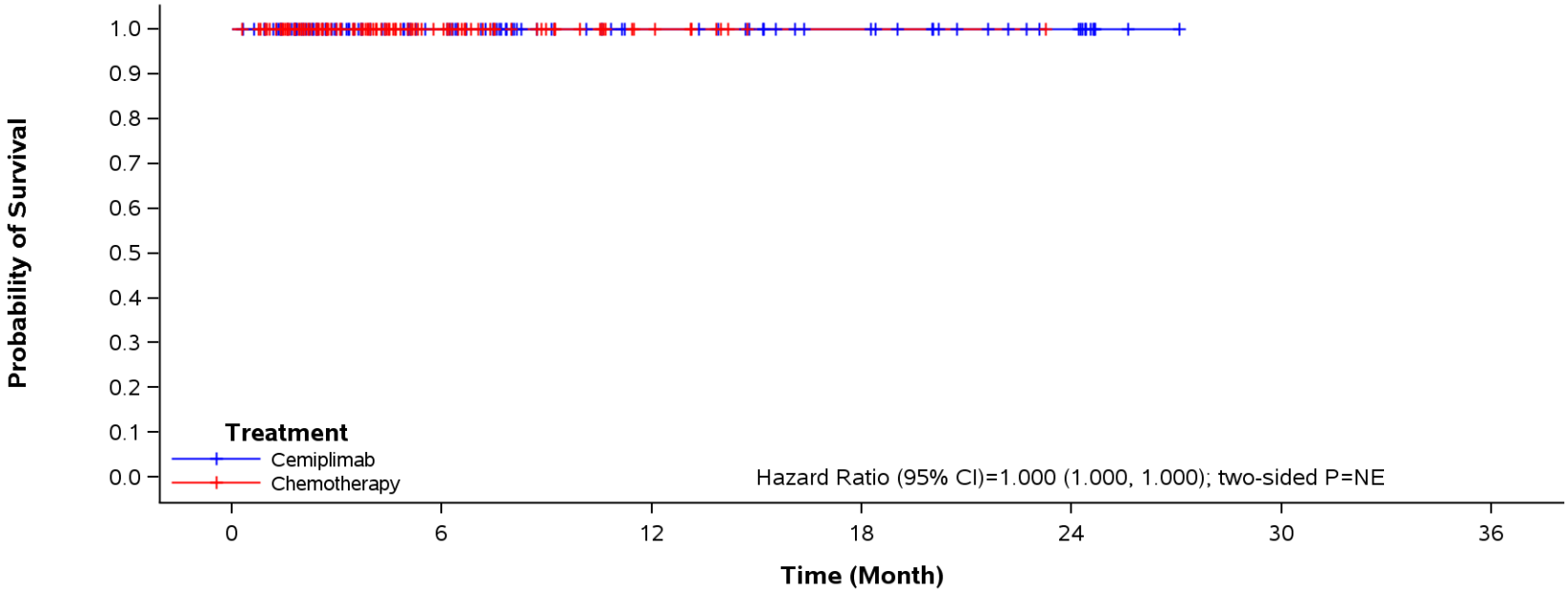

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Metabolism and nutrition disorders



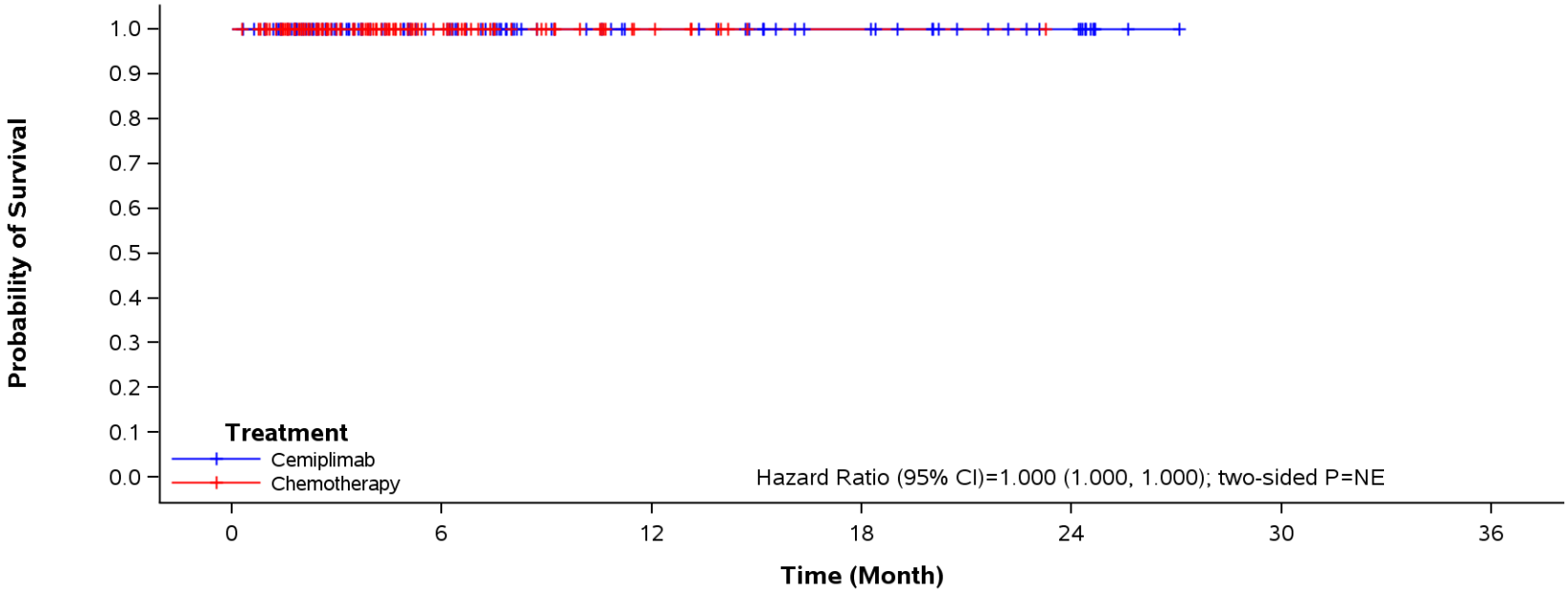

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



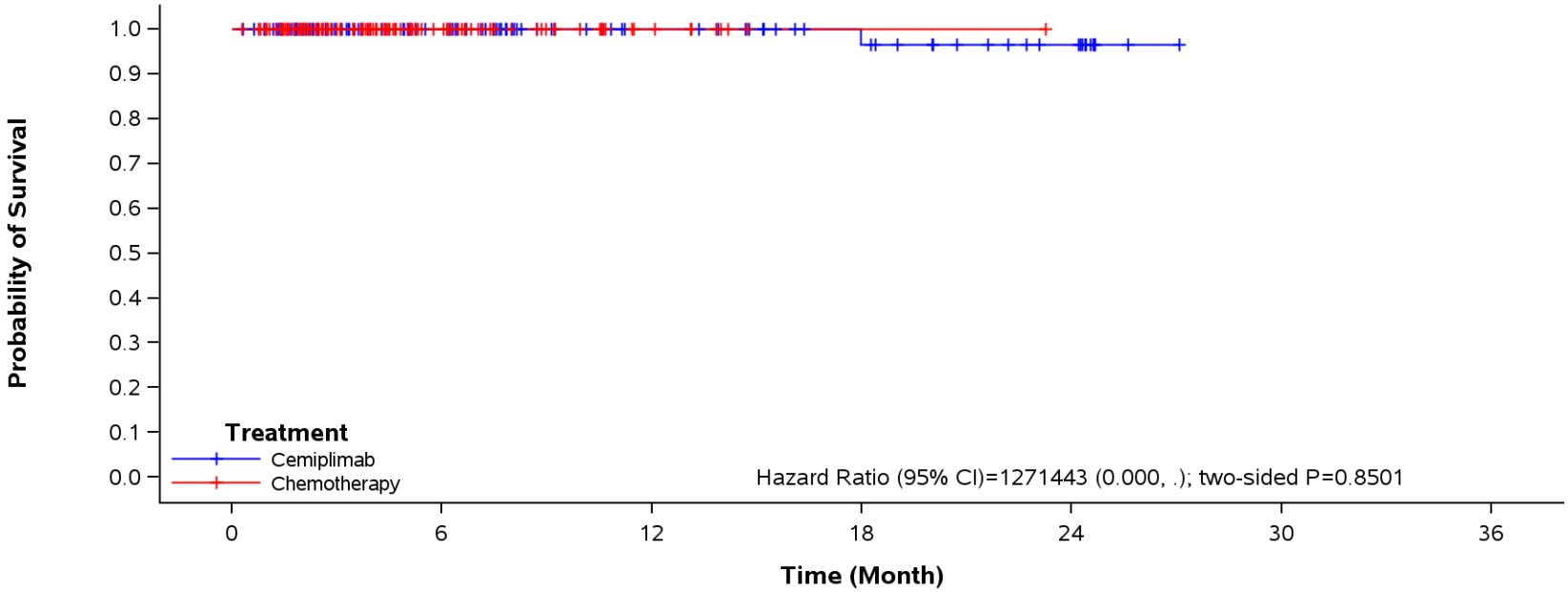

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Musculoskeletal and connective tissue disorders



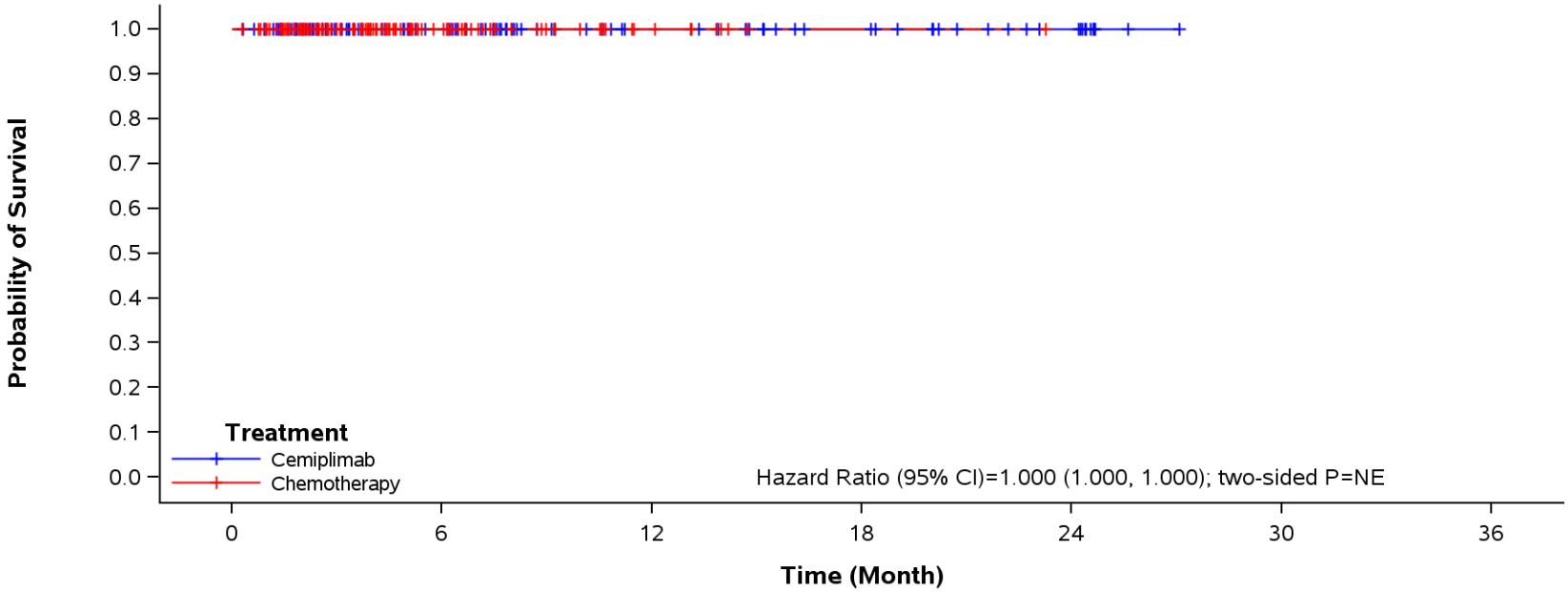

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 27 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



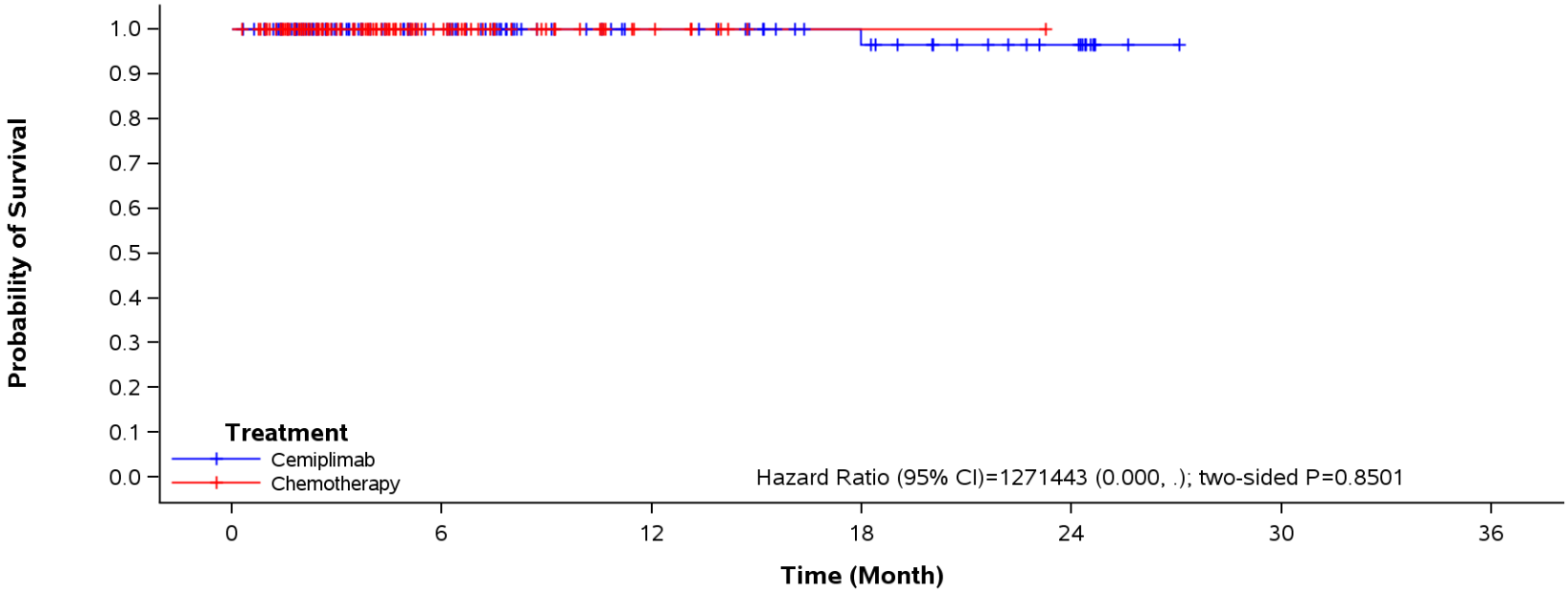

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



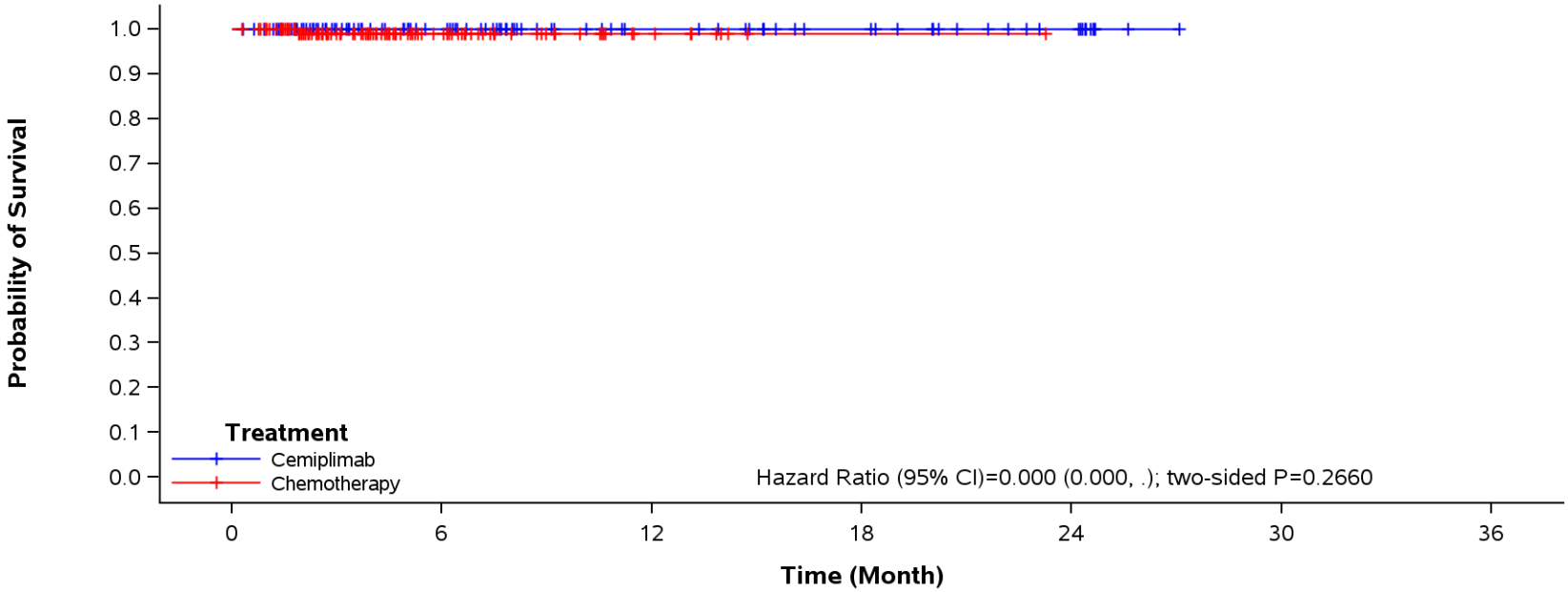

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 27 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Nervous system disorders



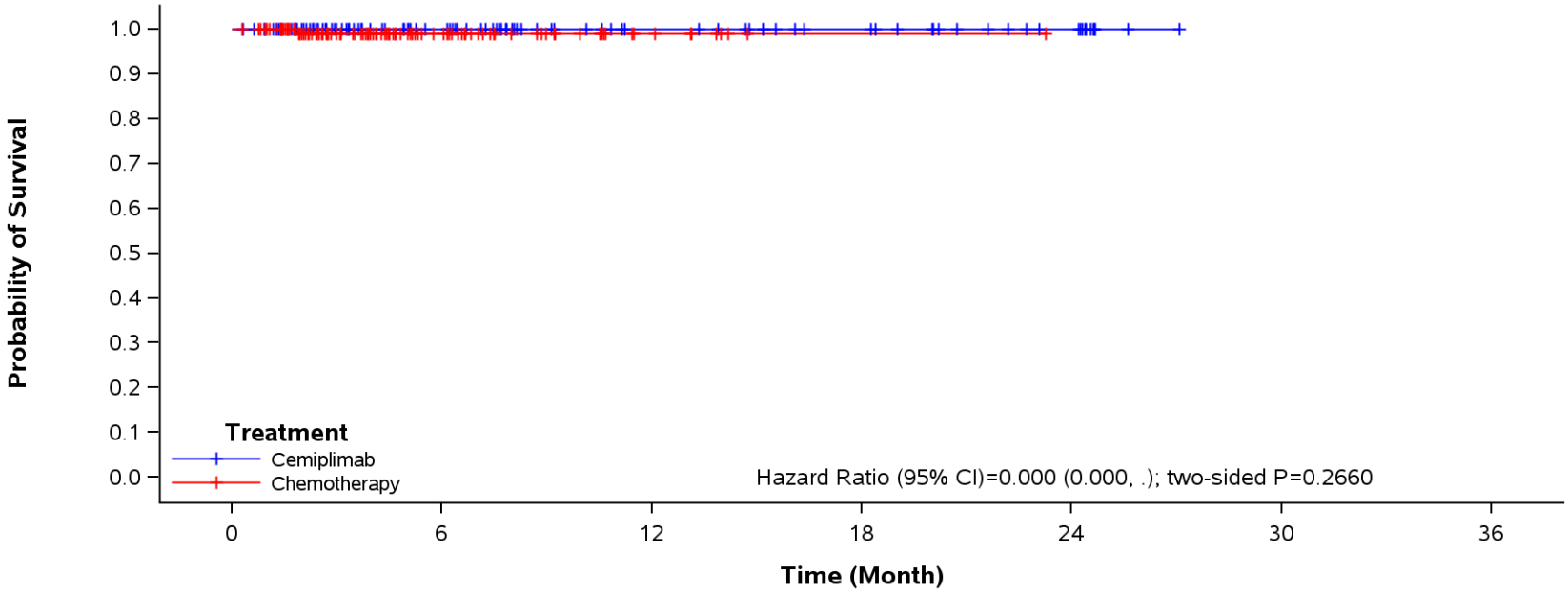

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Nervous system disorders
PT: Neurotoxicity



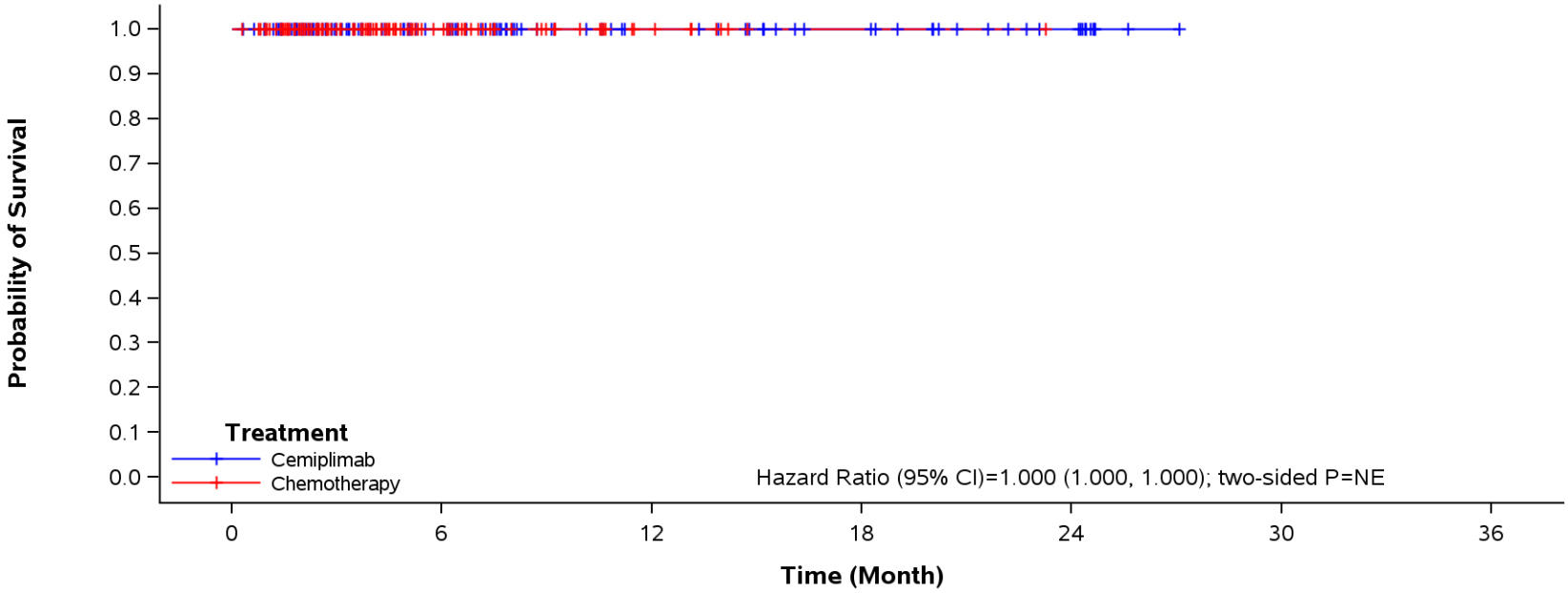

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Nervous system disorders
PT: Transient ischaemic attack



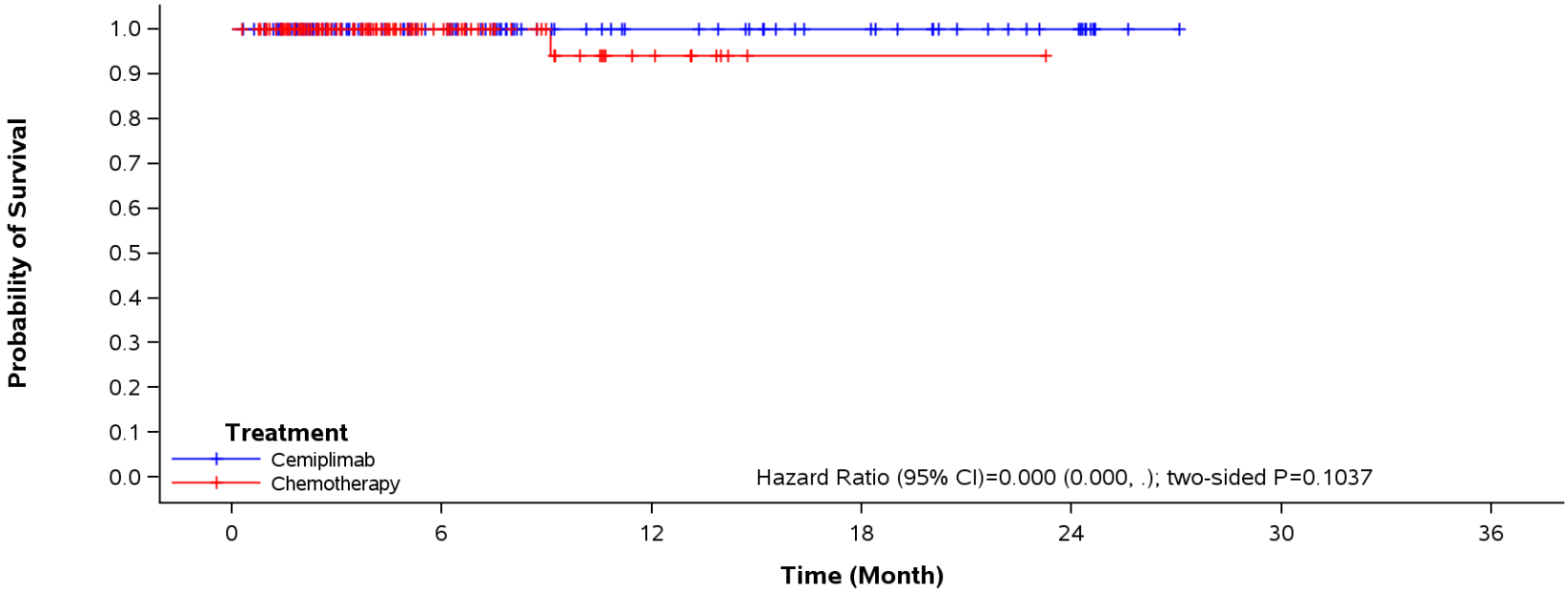

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Psychiatric disorders



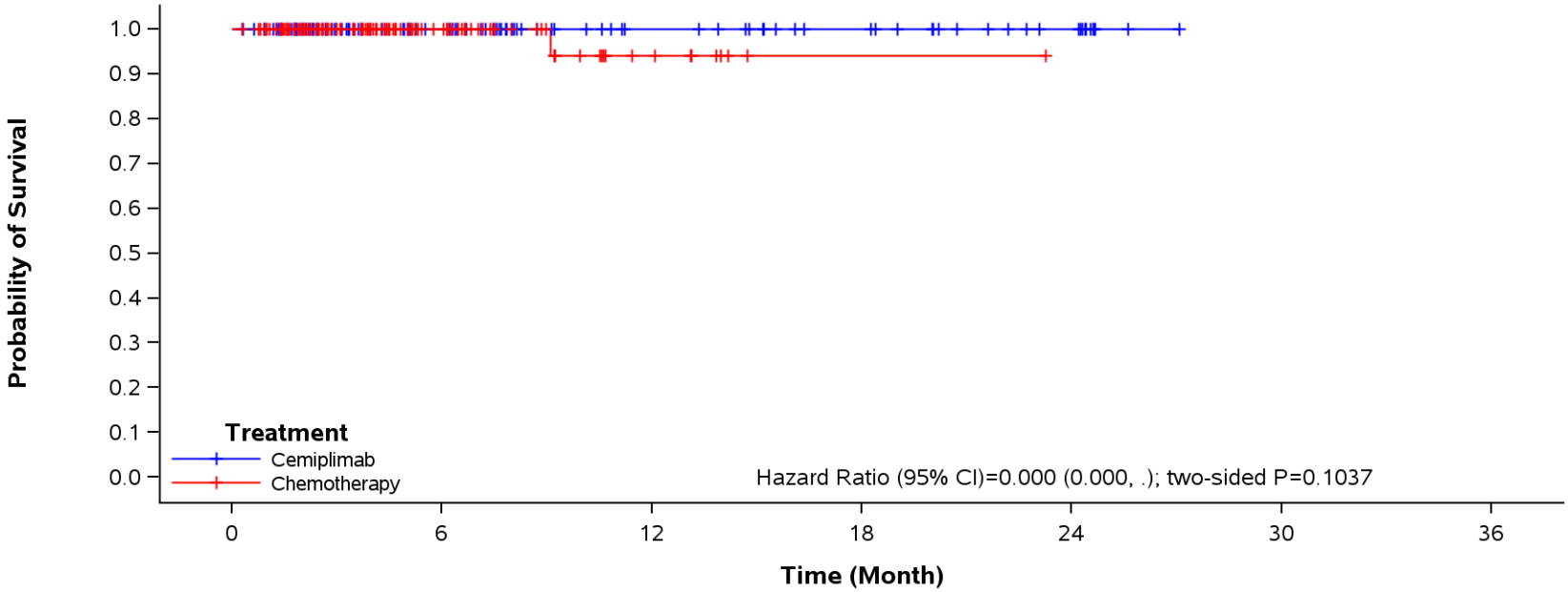

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Psychiatric disorders
PT: Agoraphobia



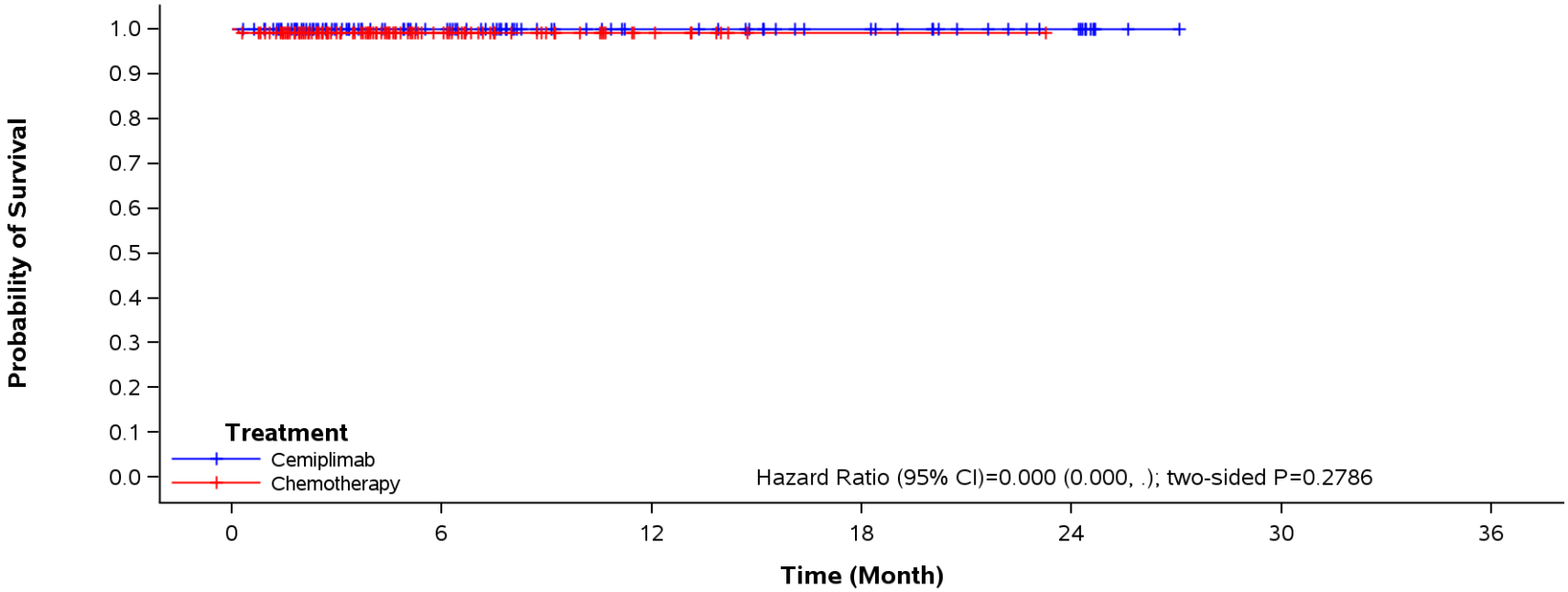

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Renal and urinary disorders



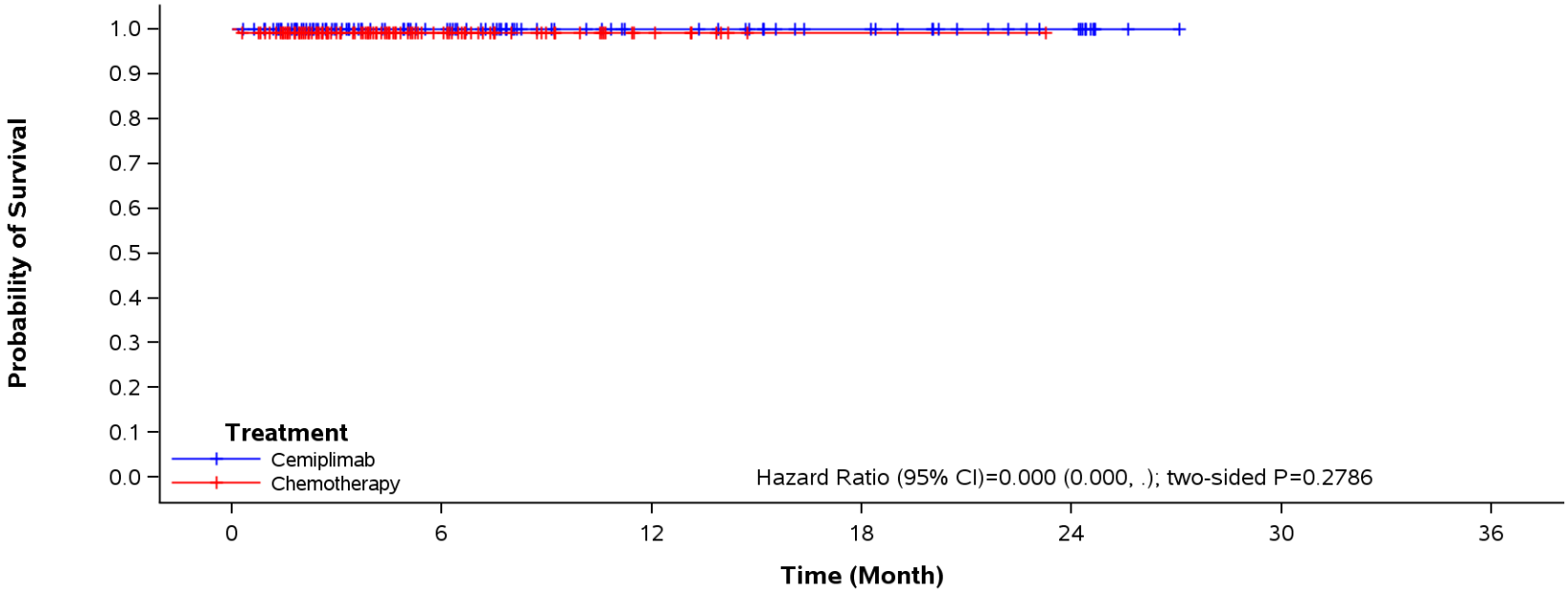

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Renal and urinary disorders
PT: Renal failure




**Number of Subjects at risk**

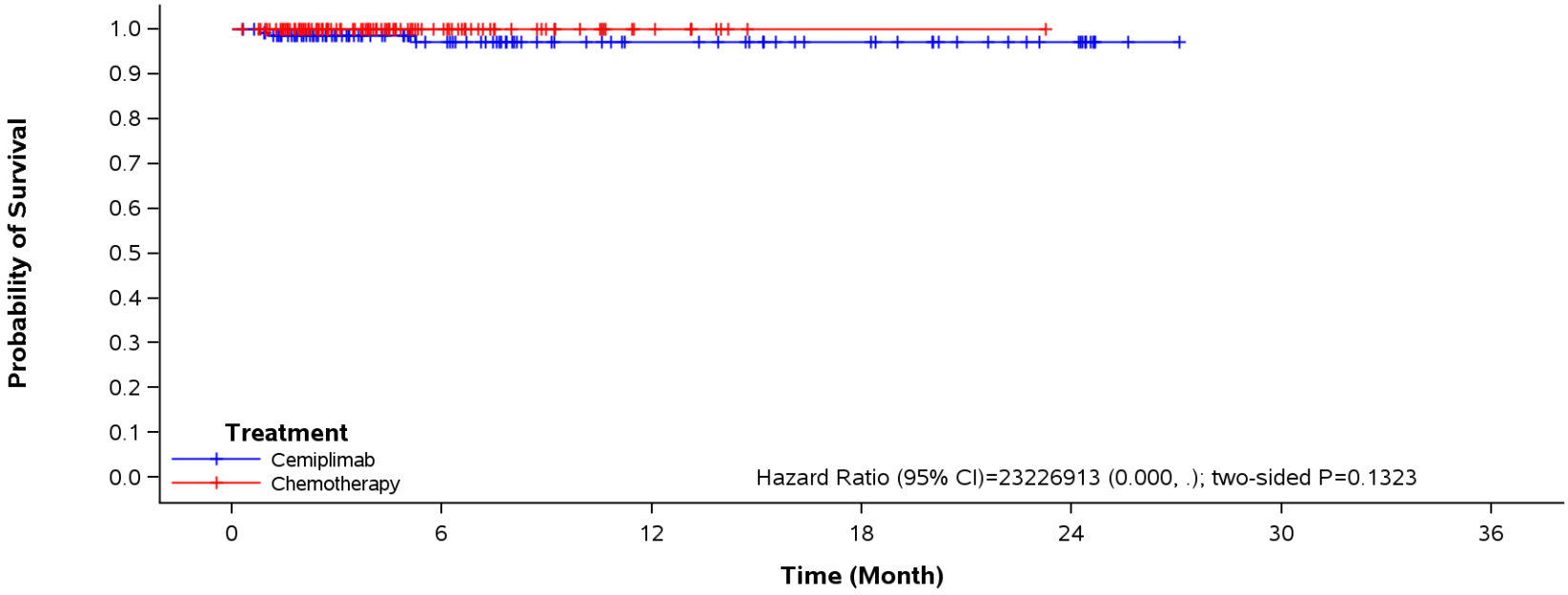
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White

SOC: Respiratory, thoracic and mediastinal disorders




Number of Subjects at risk

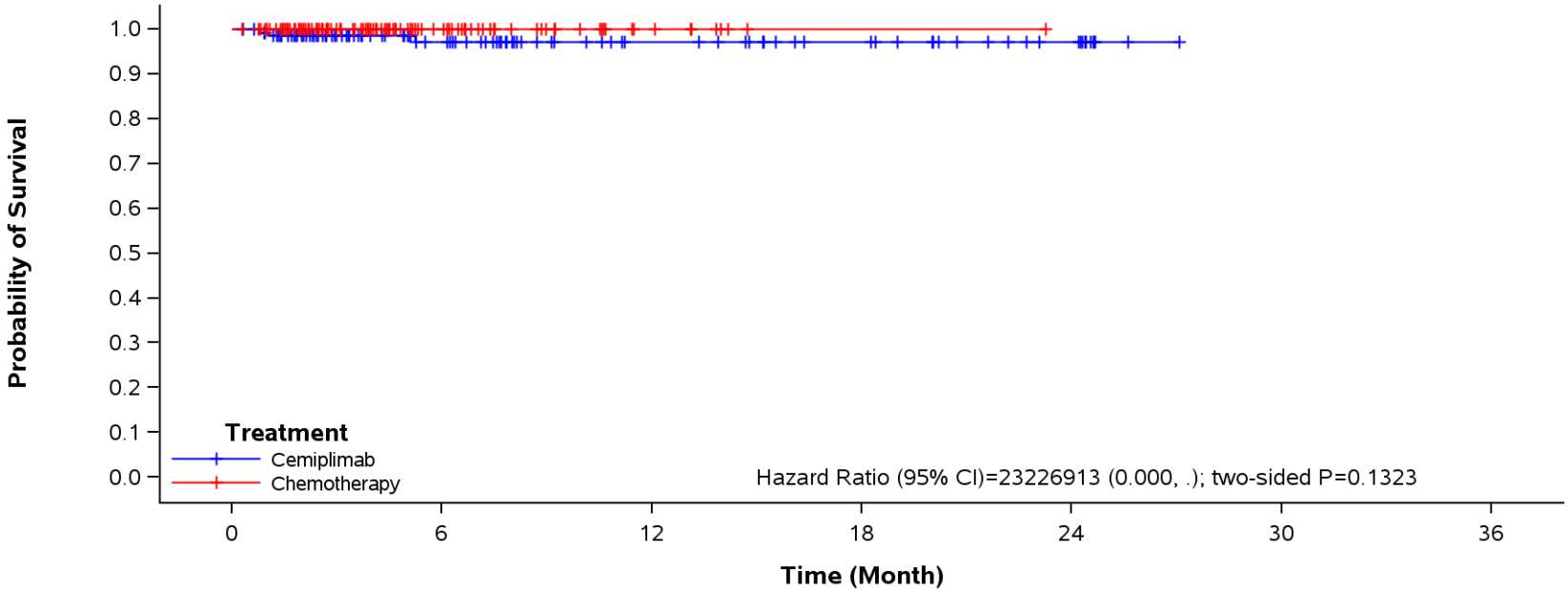
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 65 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



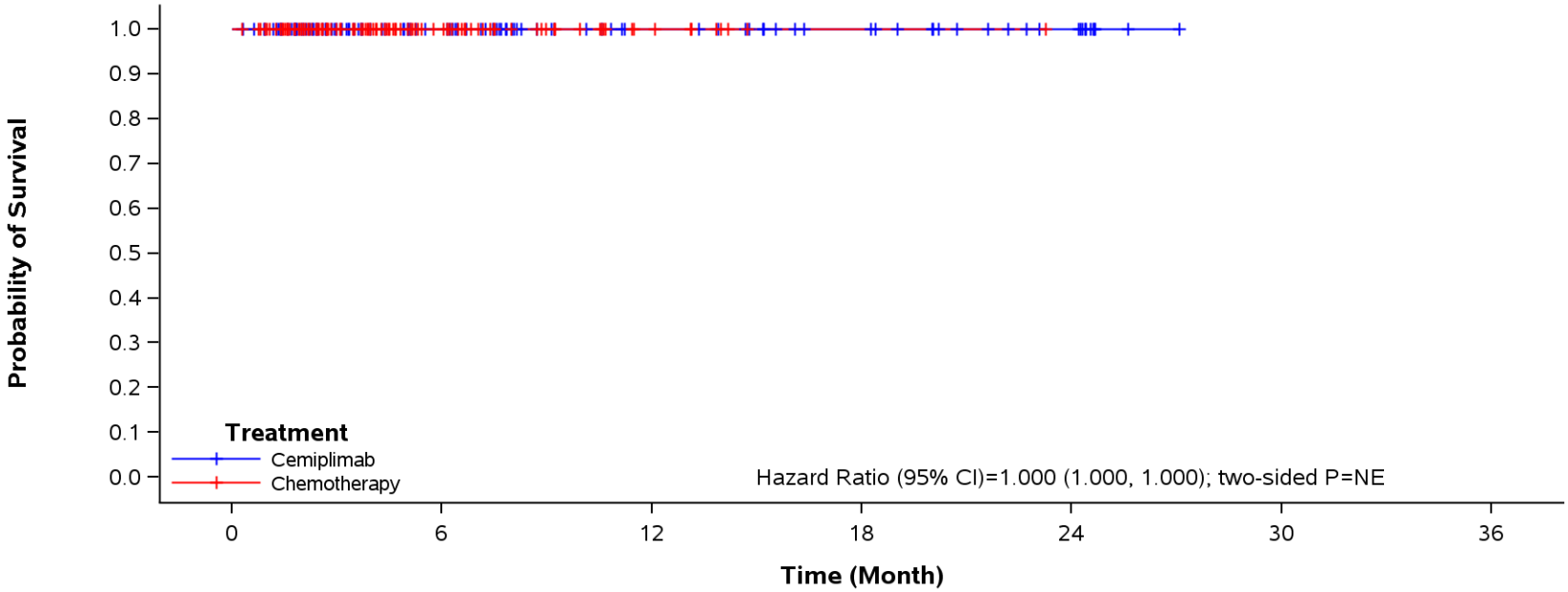

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 65 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Vascular disorders



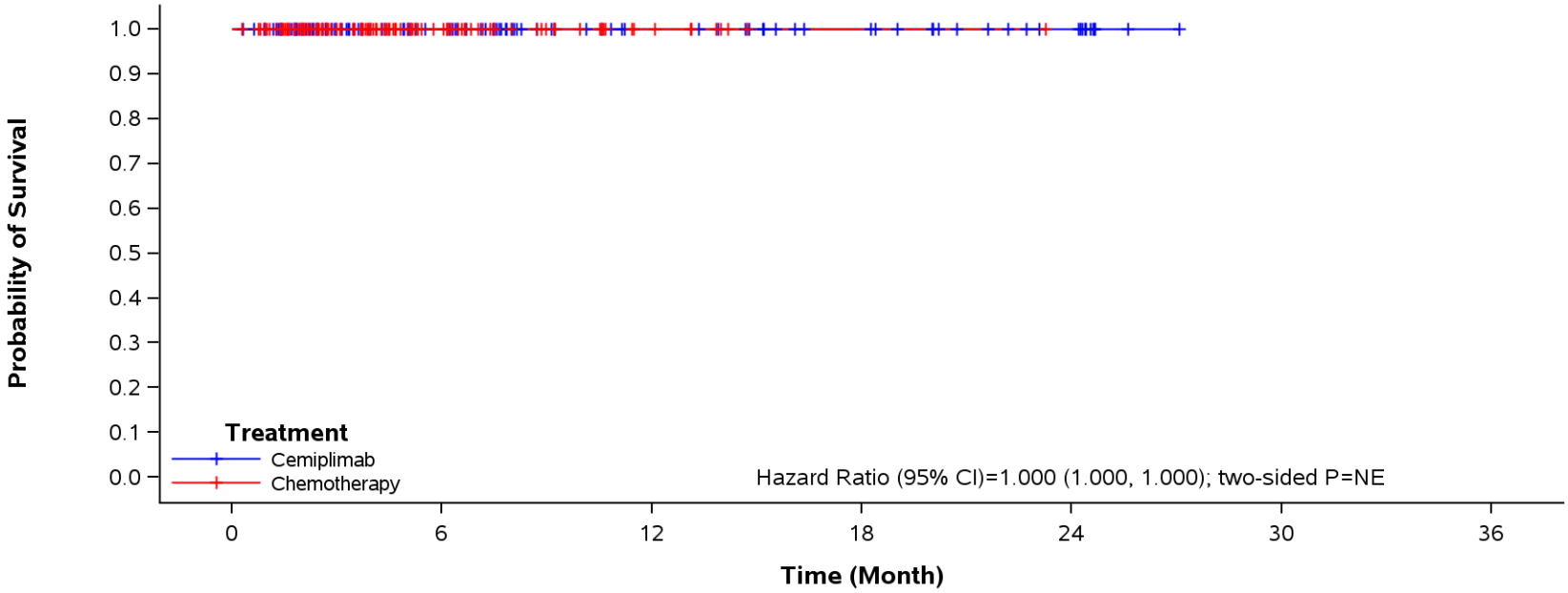

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: White
SOC: Vascular disorders
PT: Deep vein thrombosis




**Number of Subjects at risk**

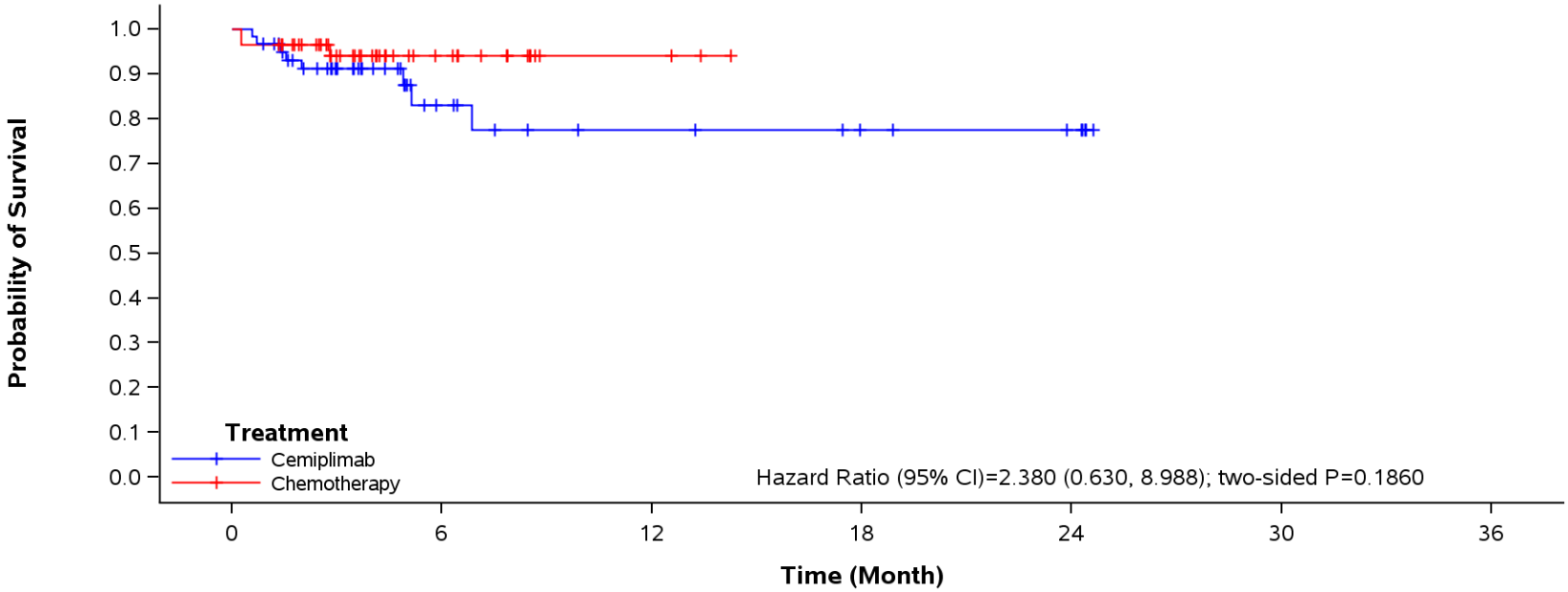
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 135 | 66 | 37 | 28 | 16 | 0 | 0 |
| Chemotherapy | 115 | 37 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

Number of patients with any TEAE leading to discontinuation




**Number of Subjects at risk**

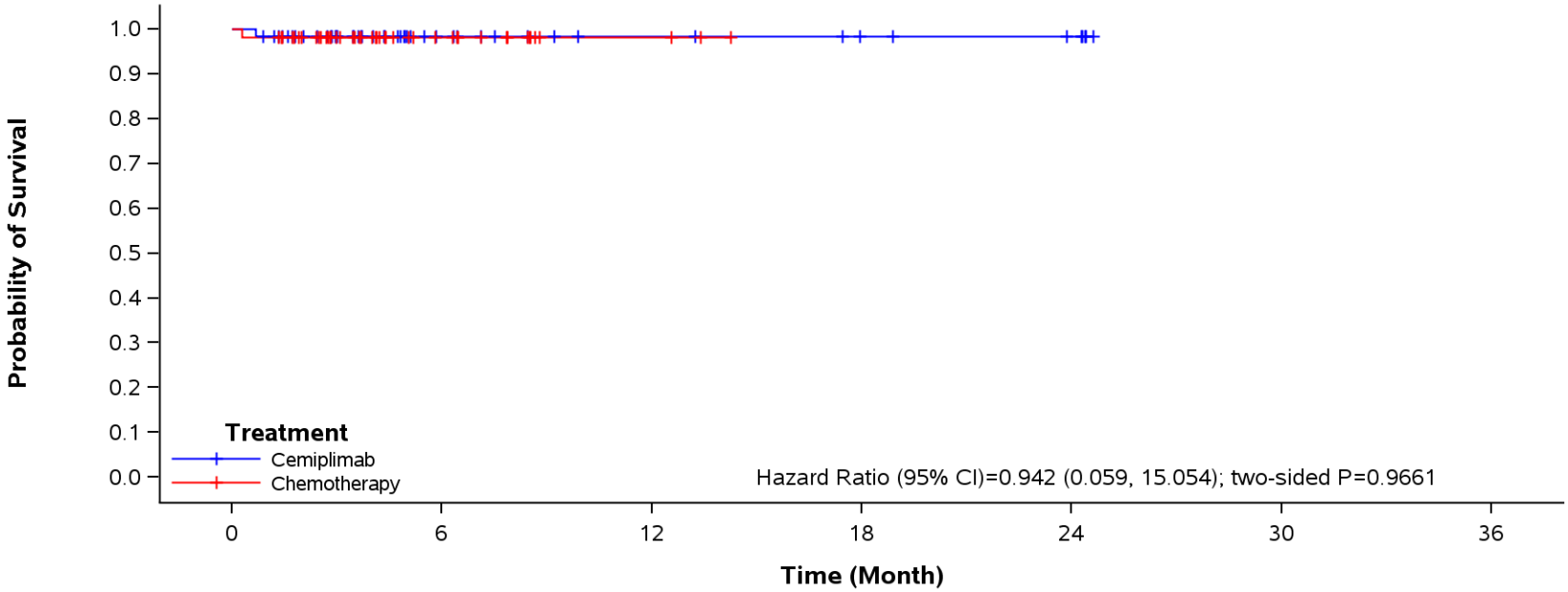
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 17 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders



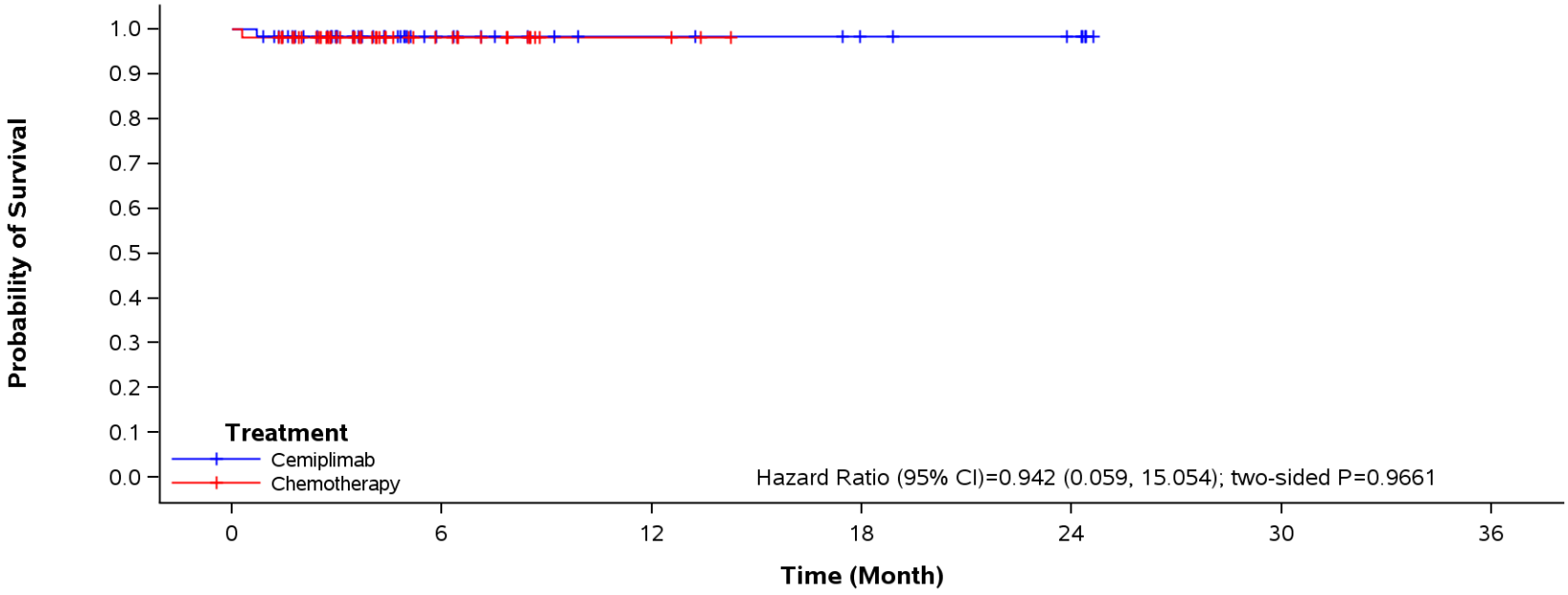

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Anaemia



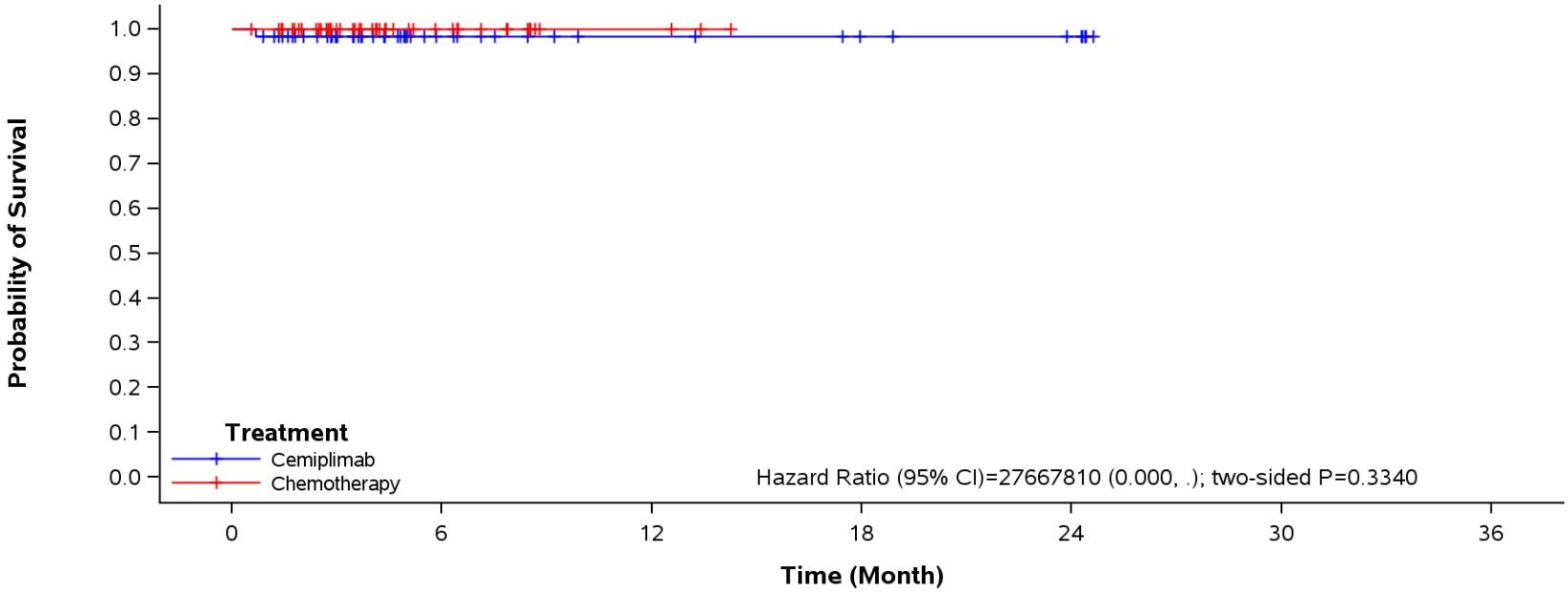

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



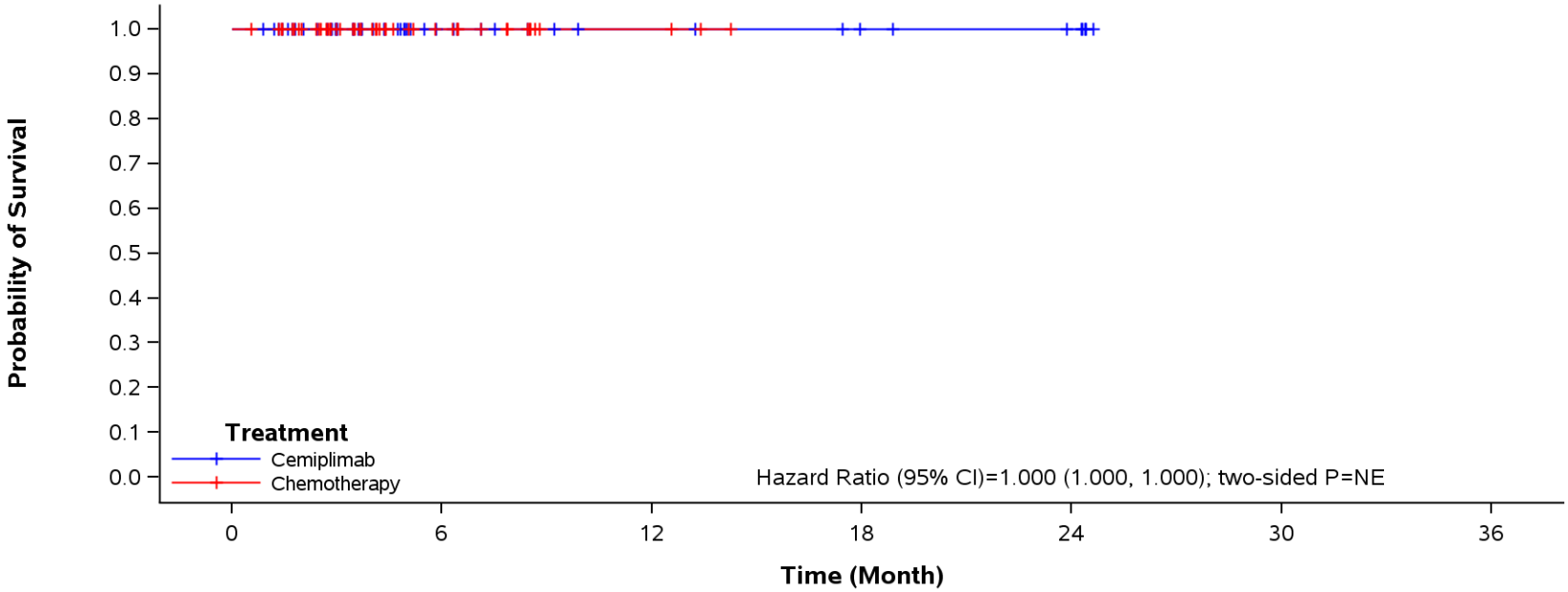

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Neutropenia



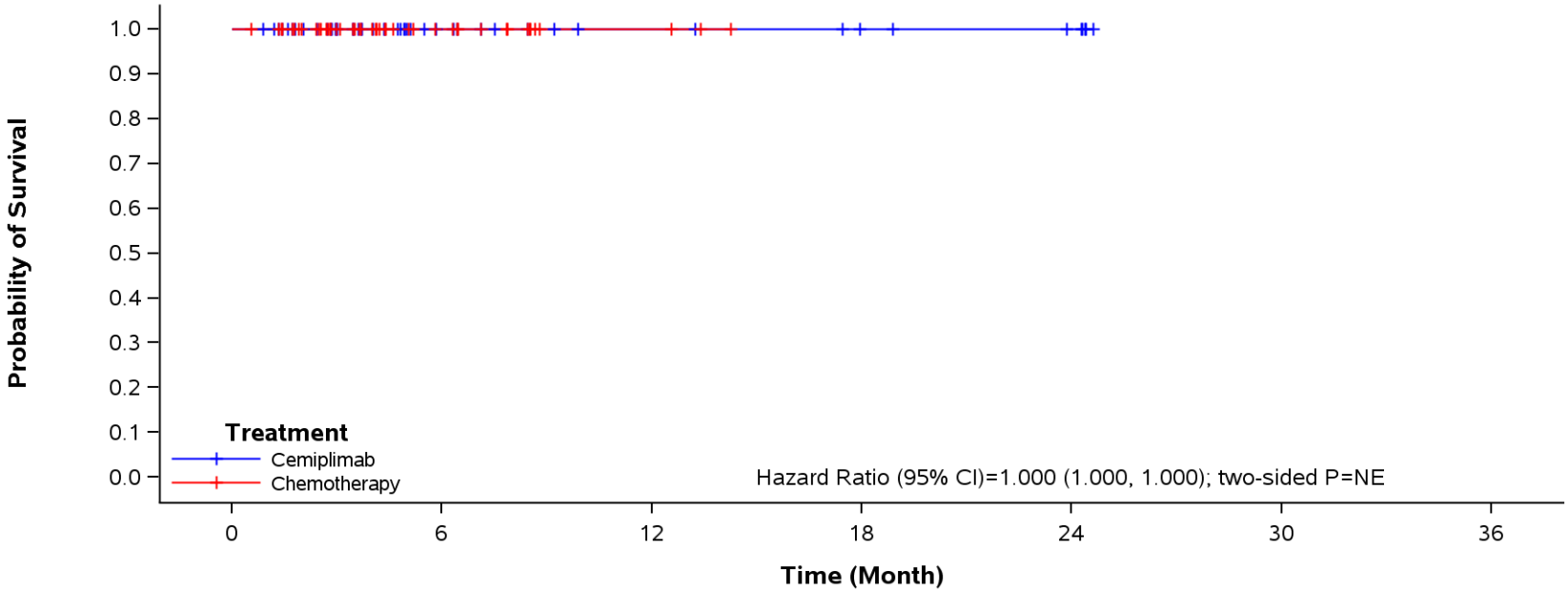

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



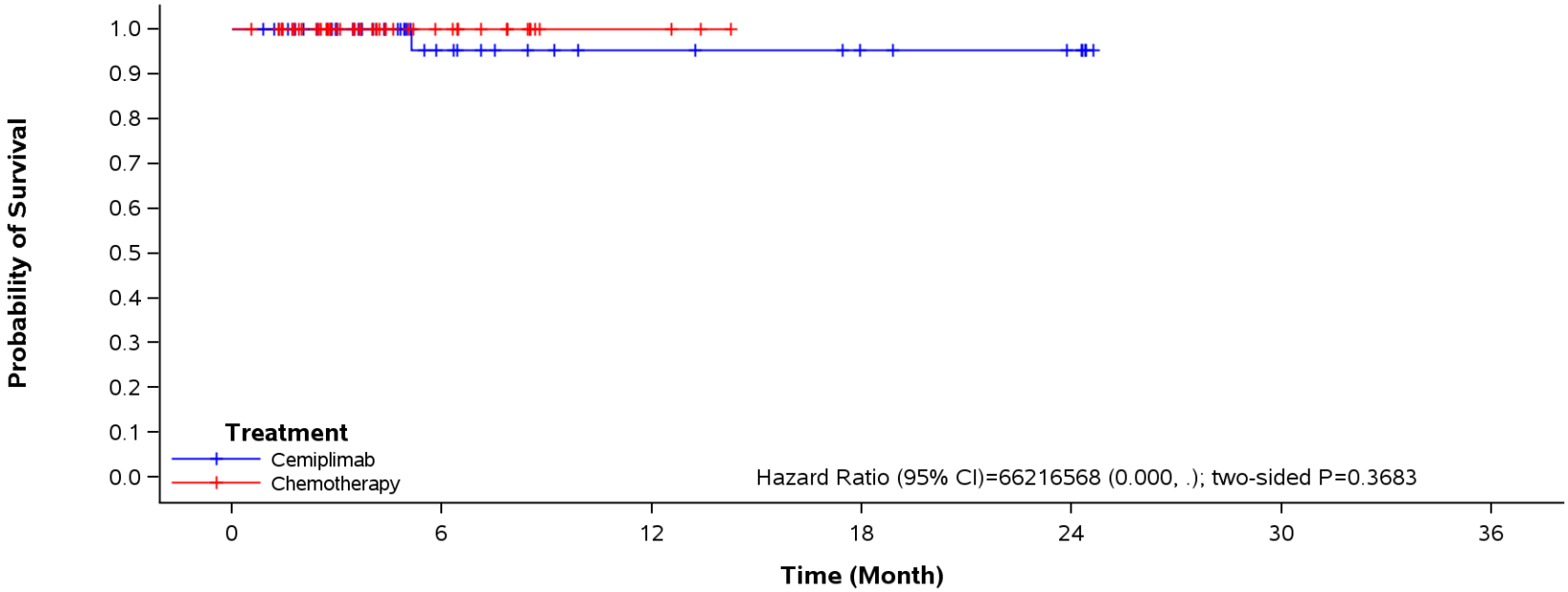

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Cardiac disorders



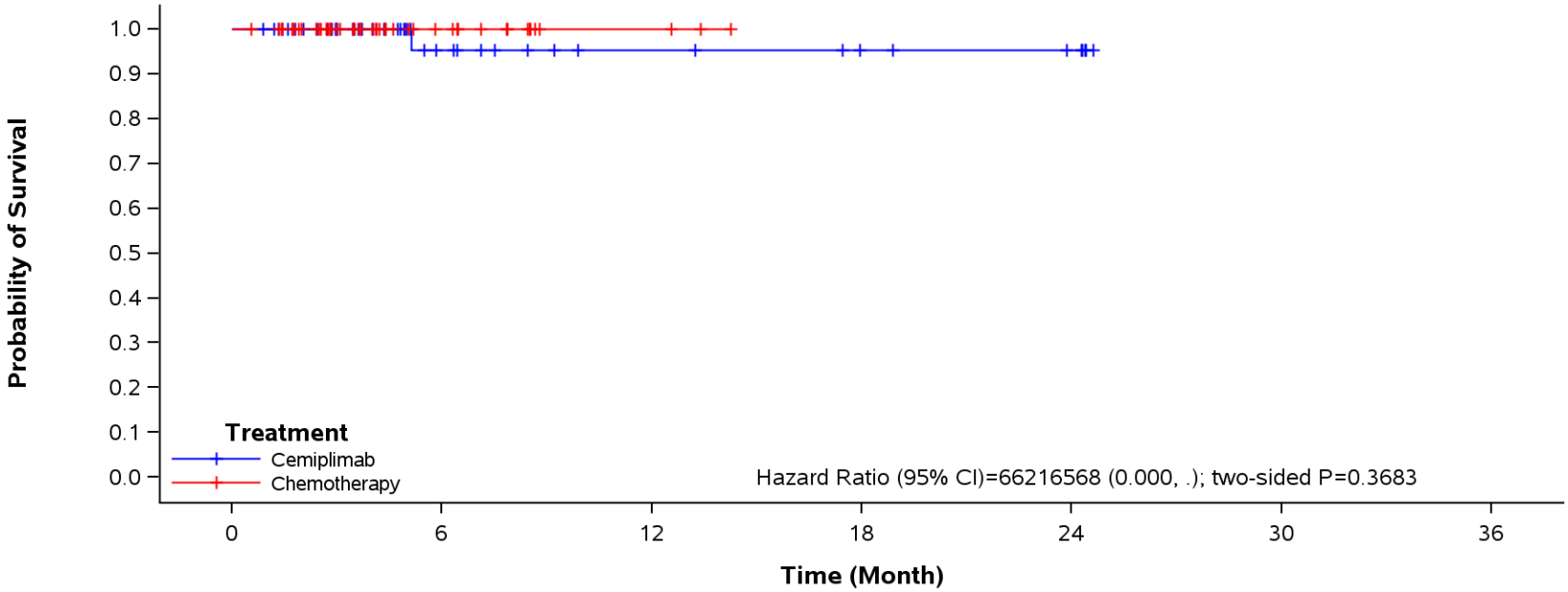

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Cardiac disorders
PT: Autoimmune pericarditis



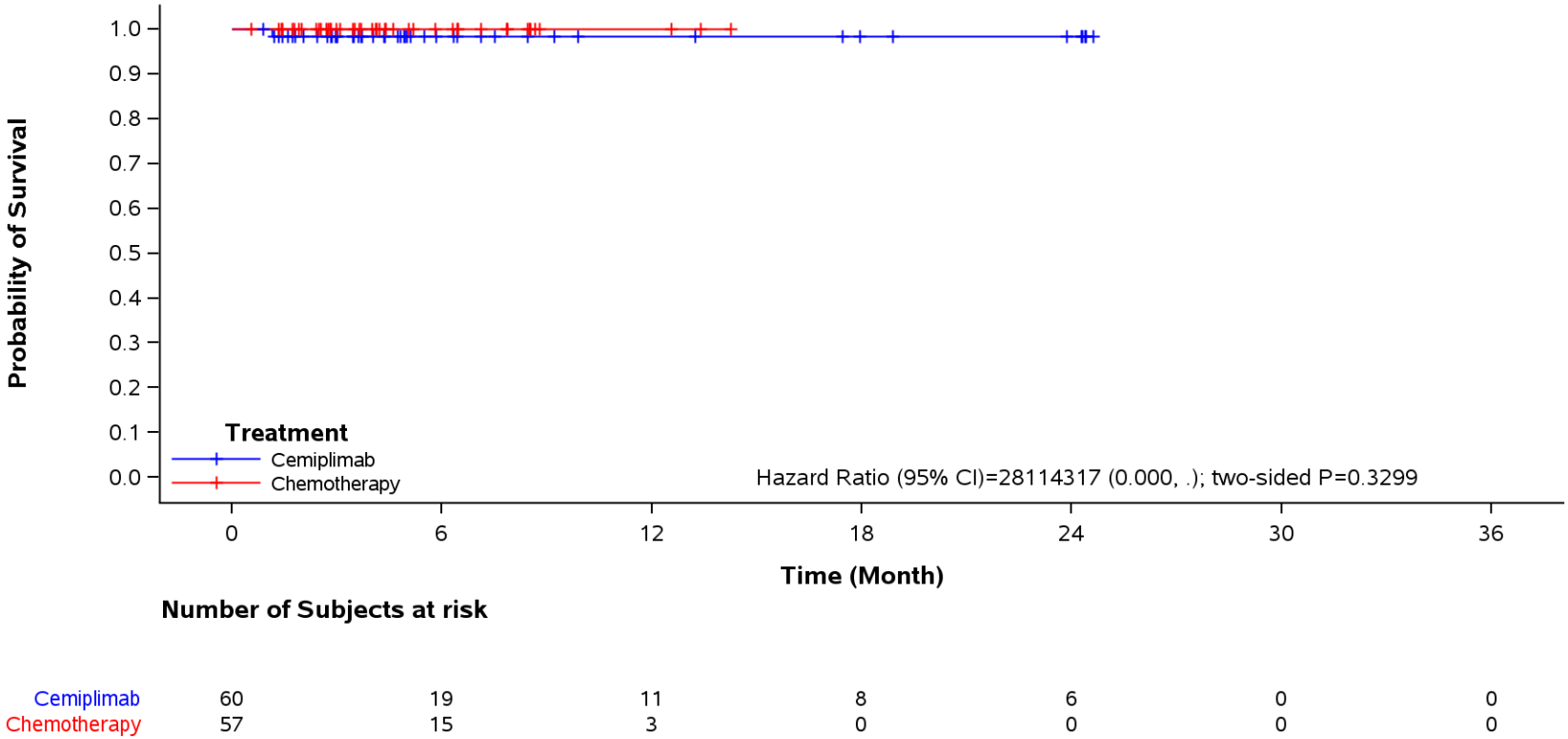

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

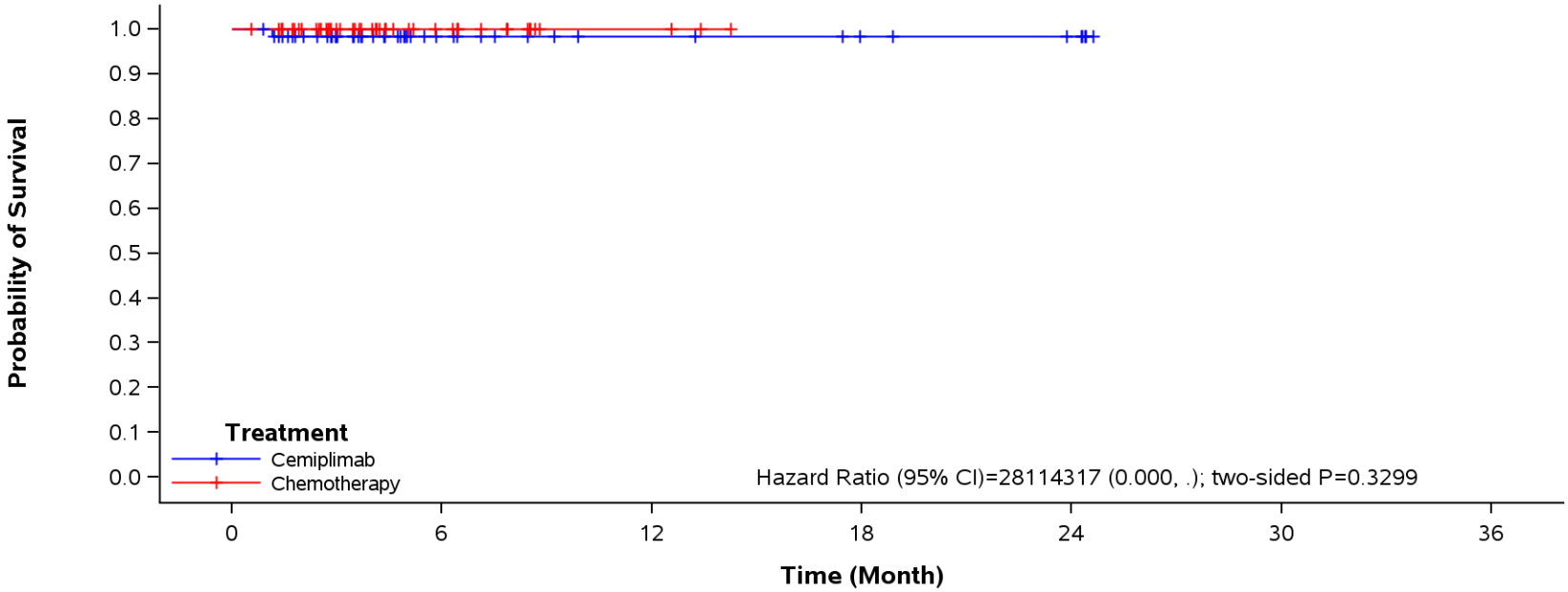
Race: Non-White
SOC: Endocrine disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Endocrine disorders
PT: Hypothyroidism



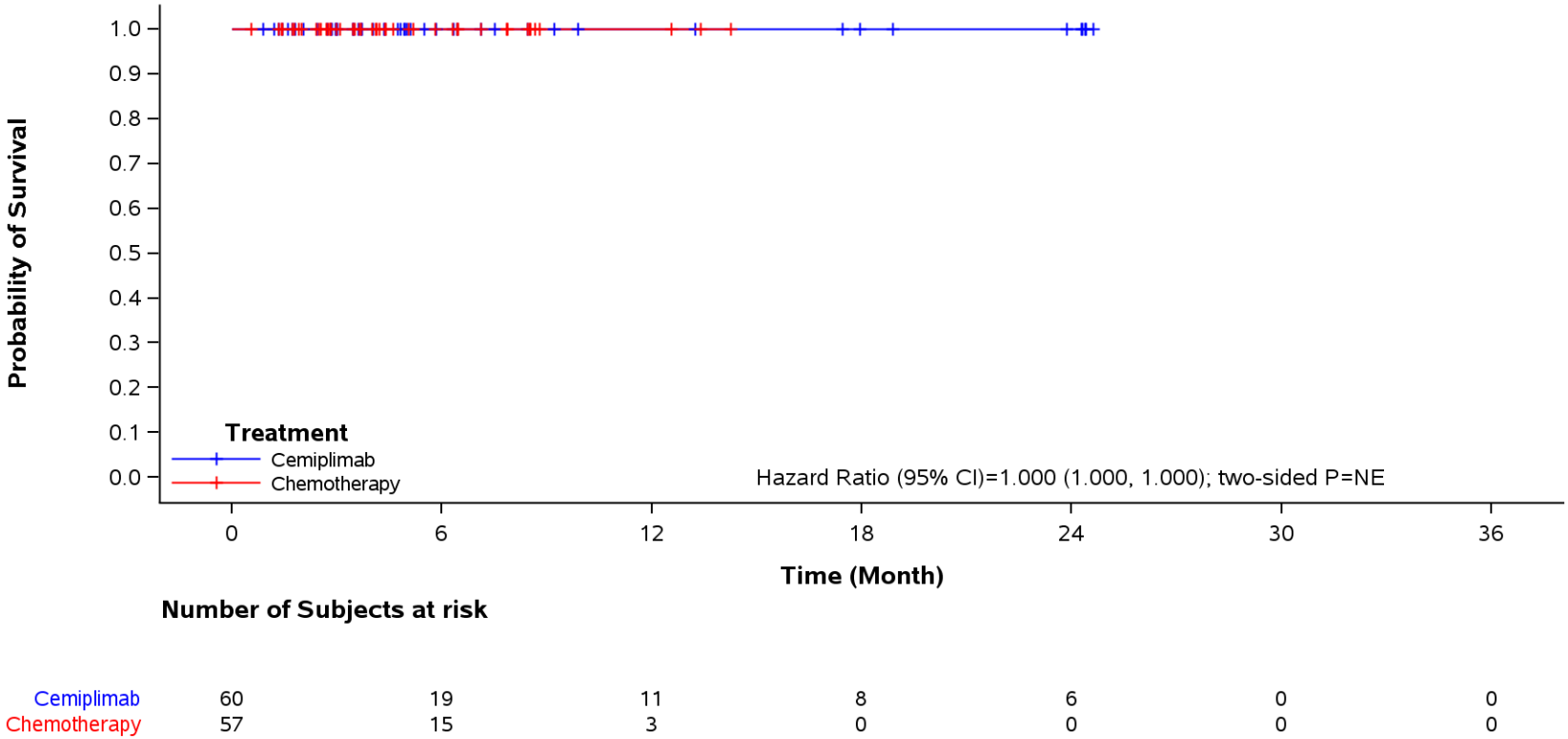

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

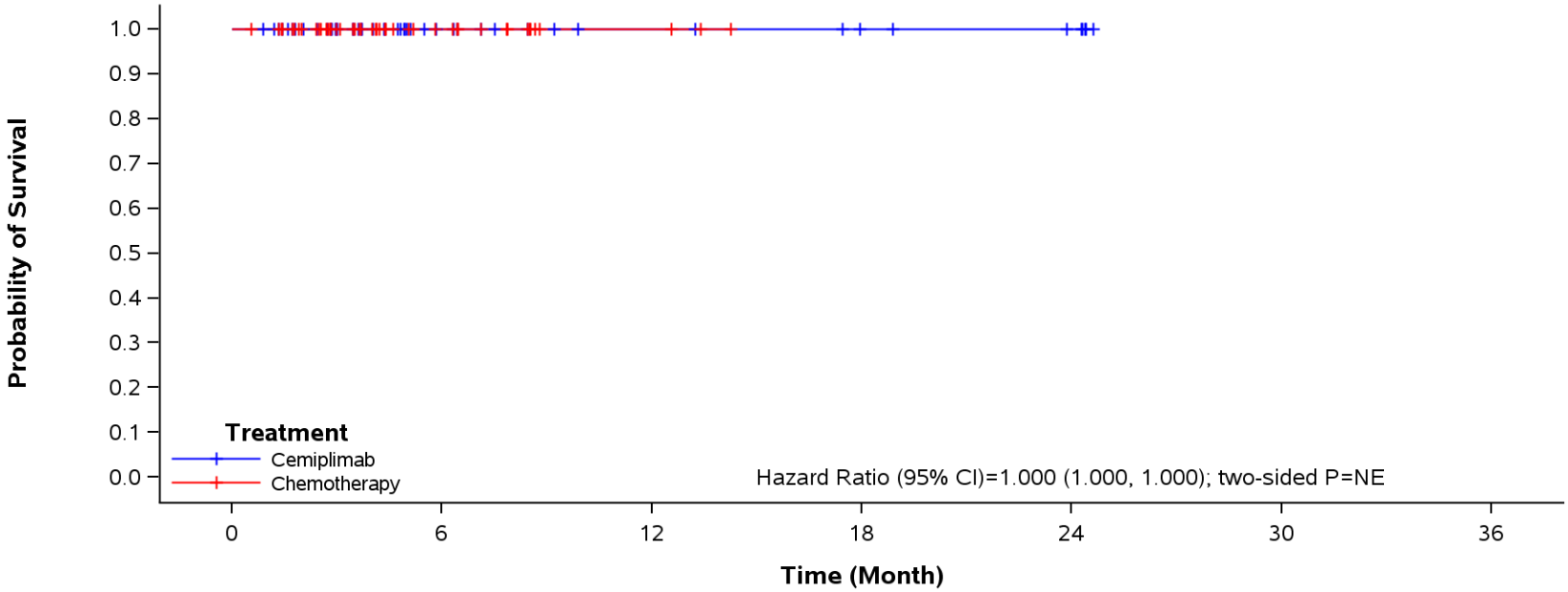
Race: Non-White
SOC: Gastrointestinal disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders
PT: Colitis



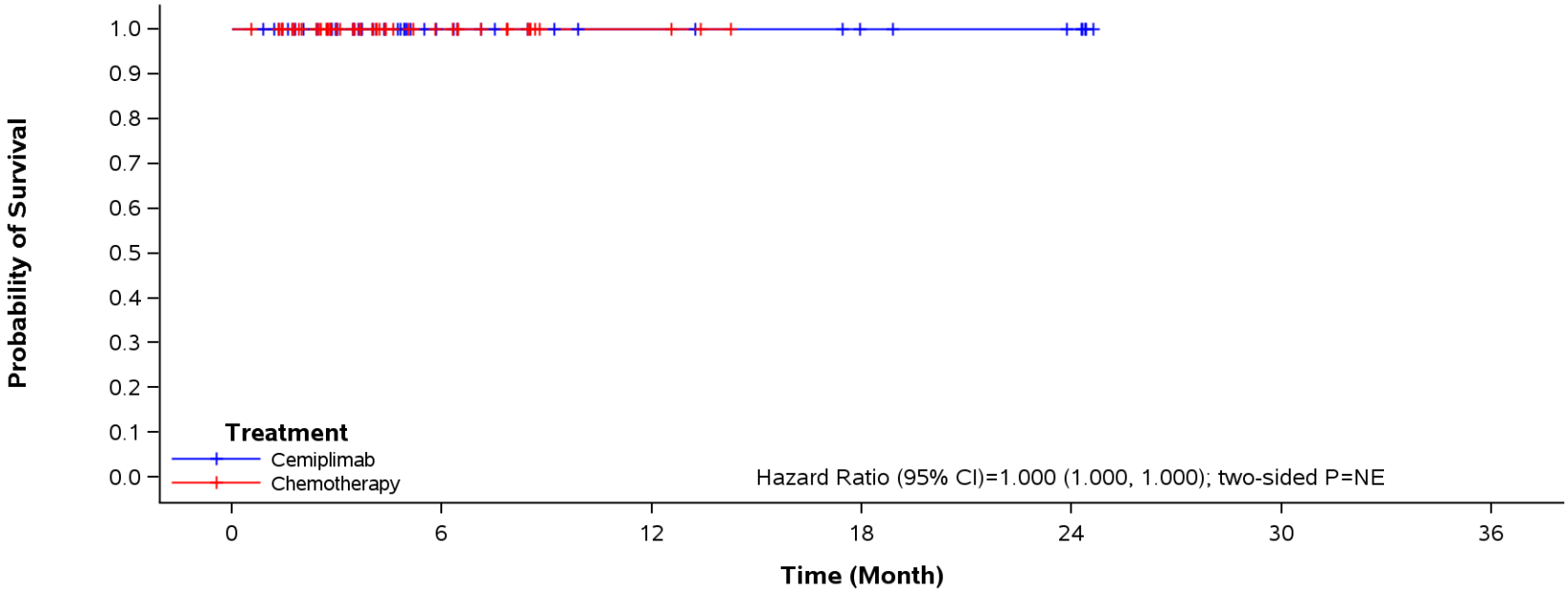

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders
PT: Diverticular perforation



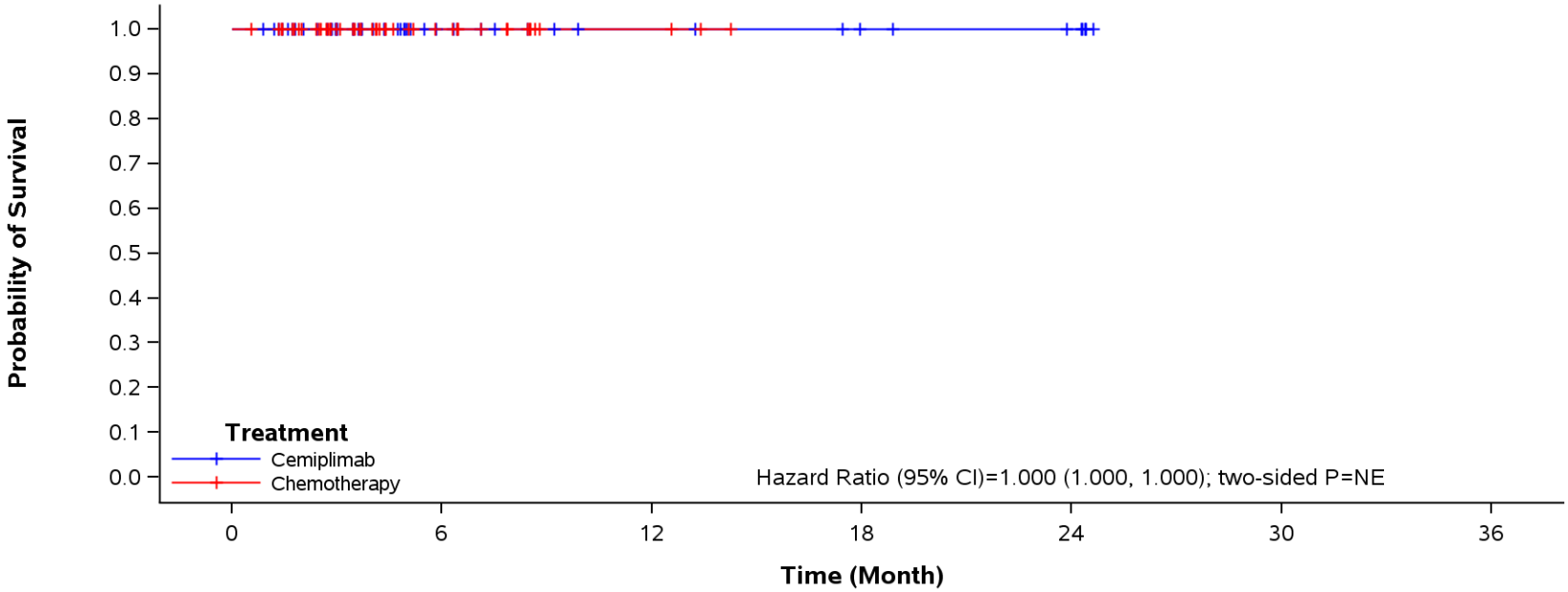

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders
PT: Pancreatic mass



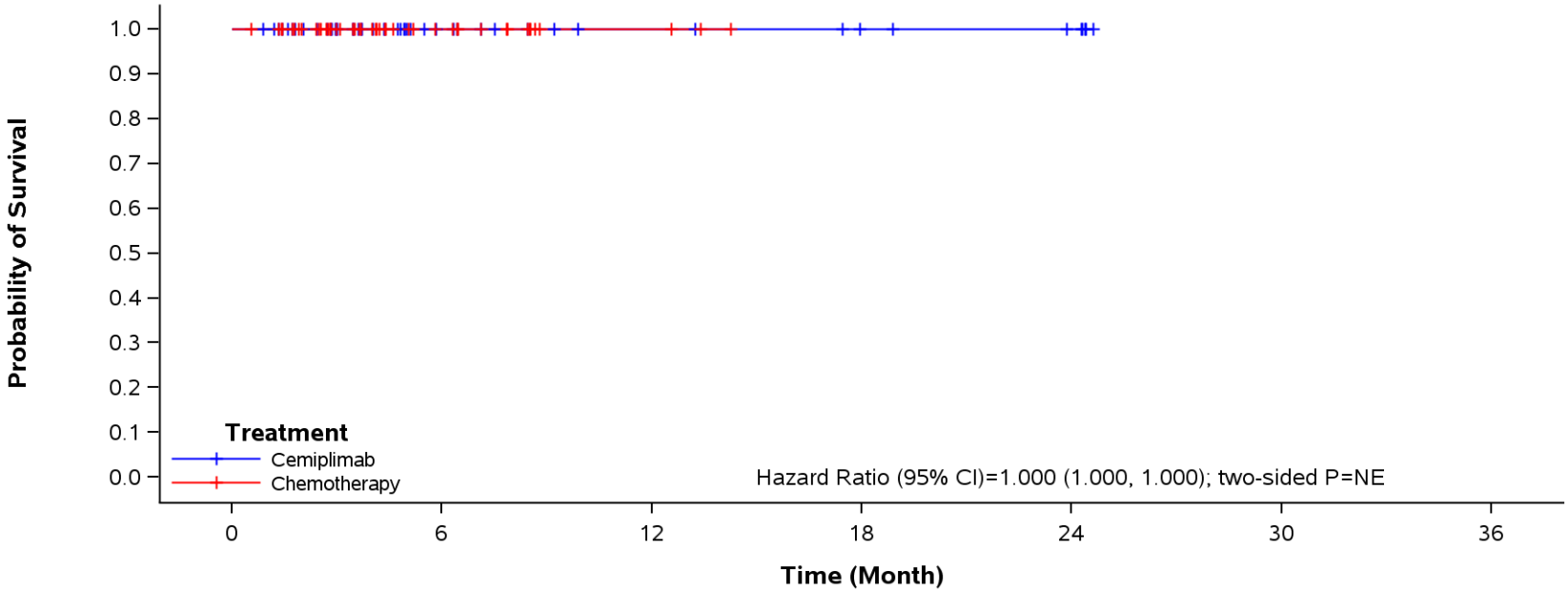

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



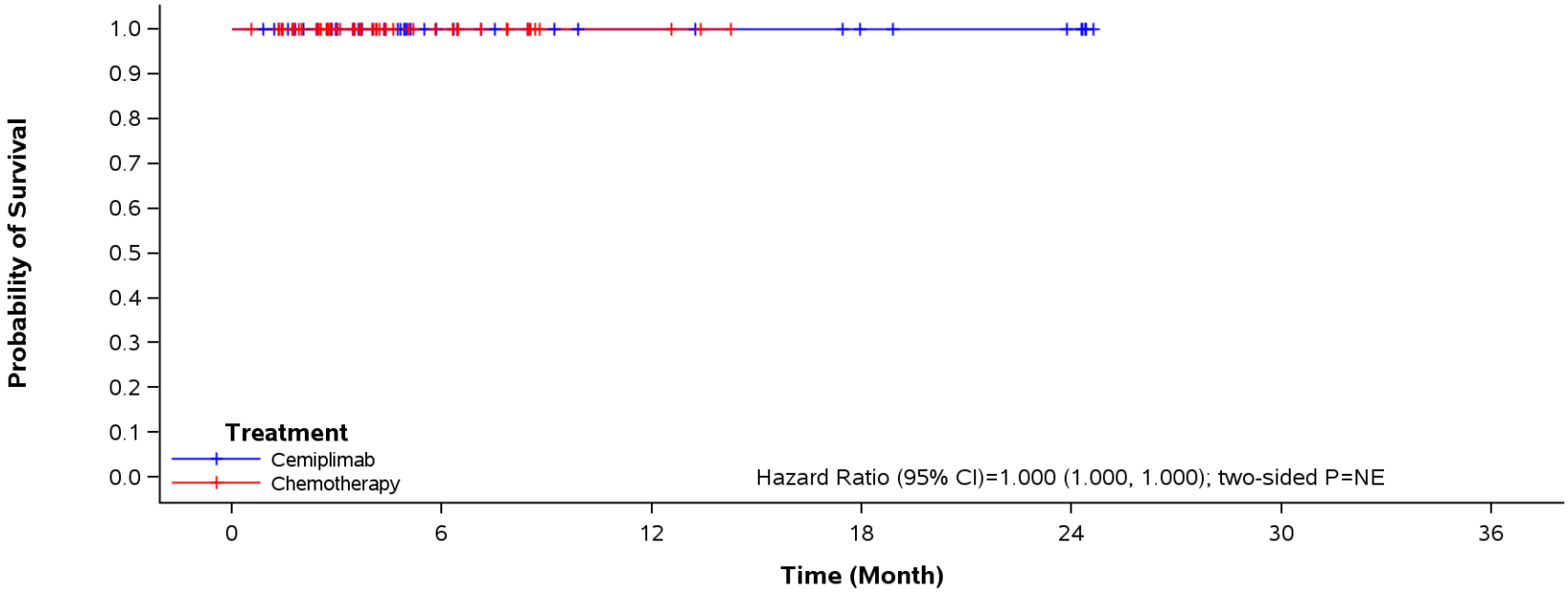

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Gastrointestinal disorders
PT: Proctalgia



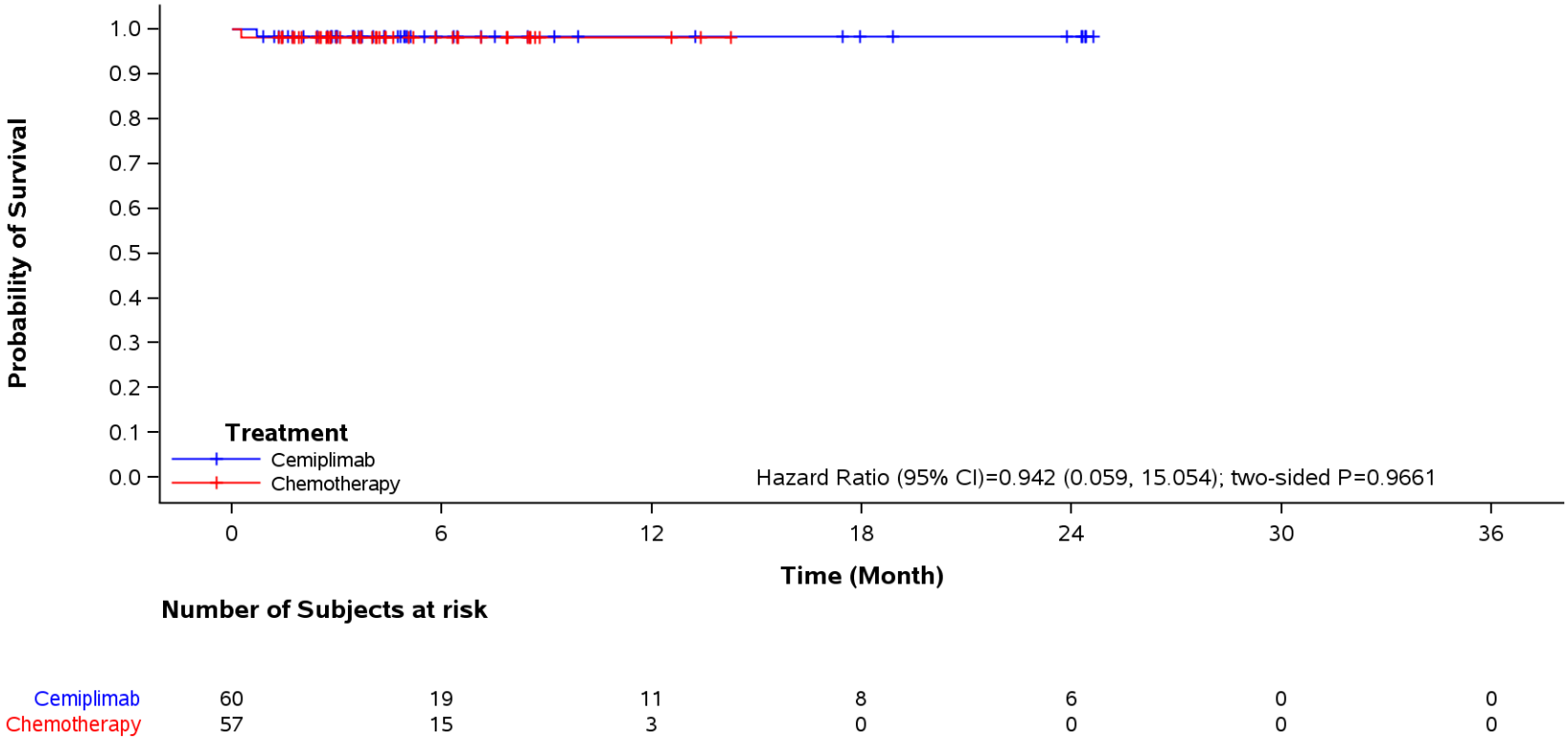

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

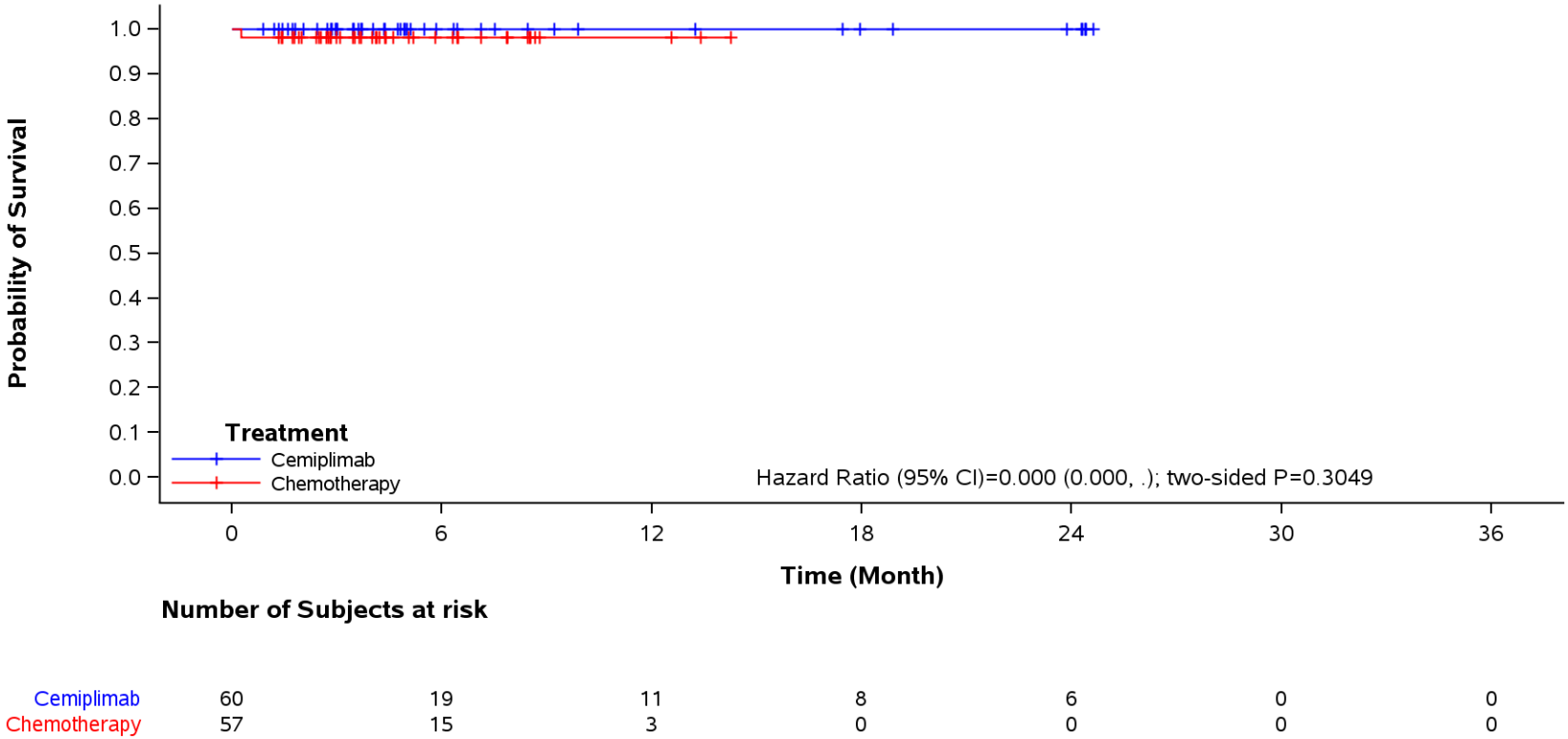
Race: Non-White
SOC: General disorders and administration site conditions




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

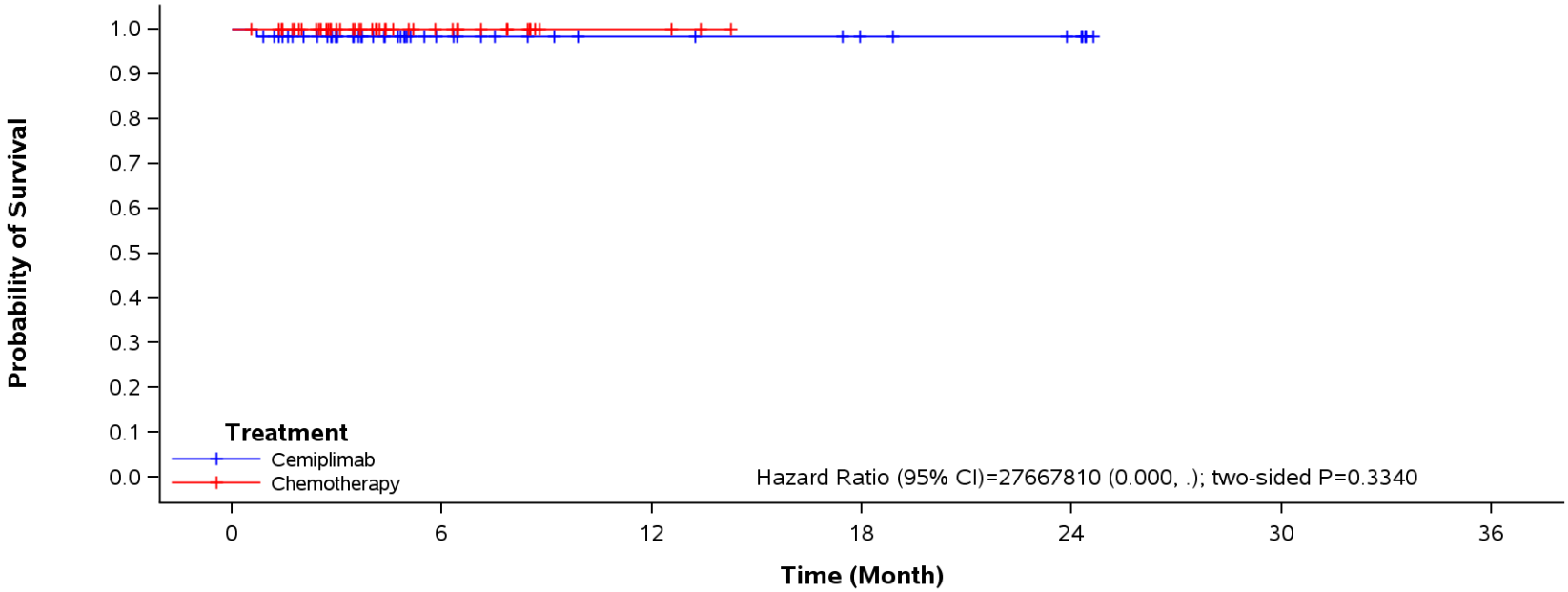
Race: Non-White
SOC: General disorders and administration site conditions
PT: Malaise




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



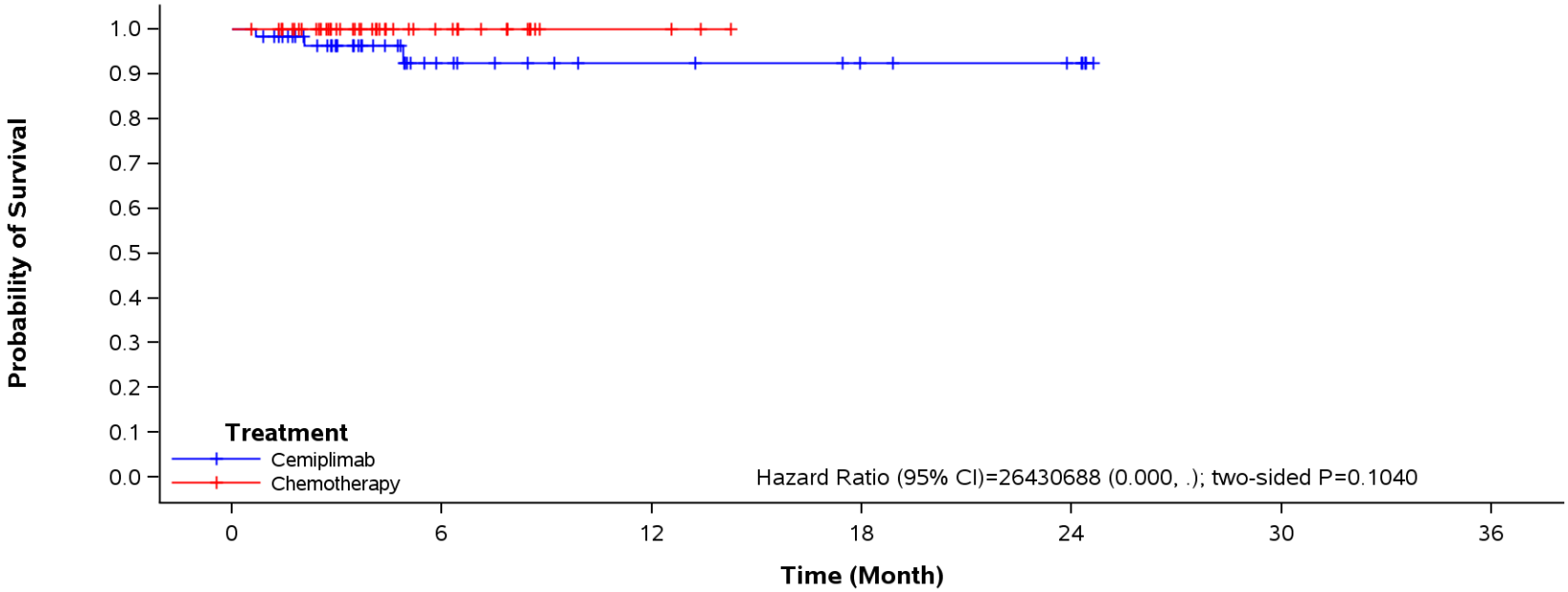

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Hepatobiliary disorders



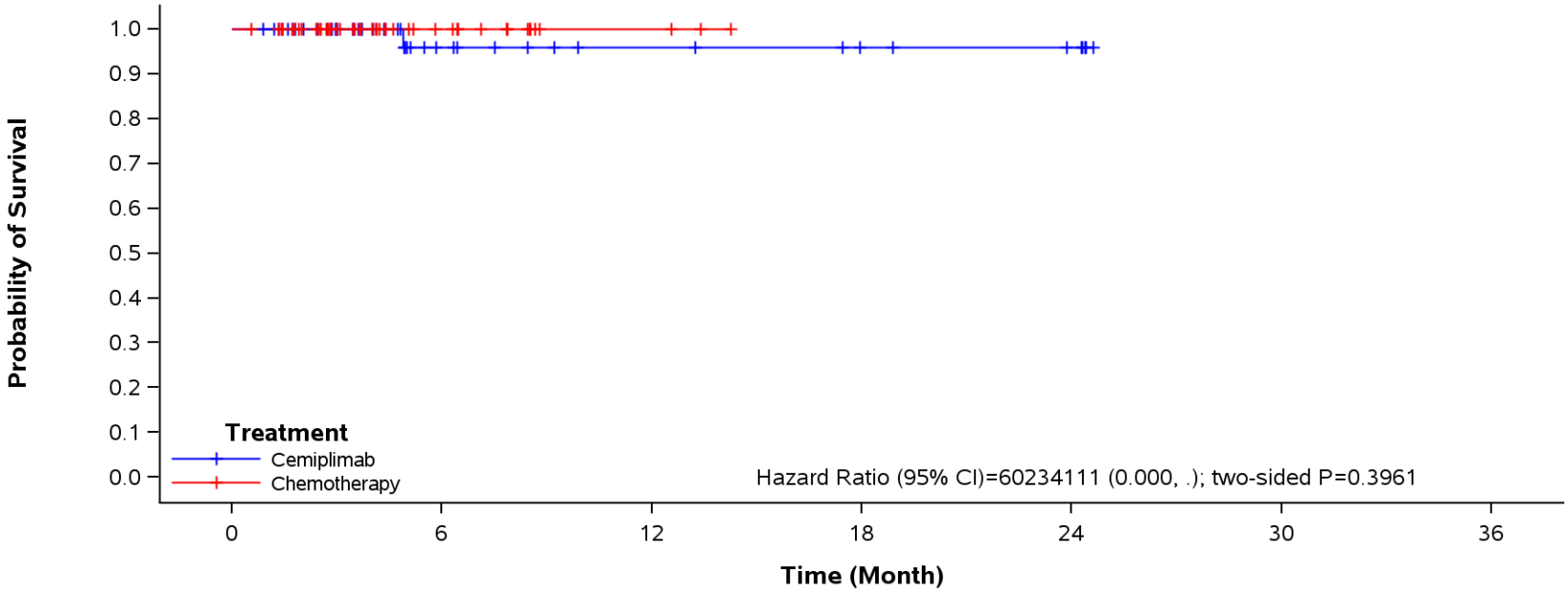

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



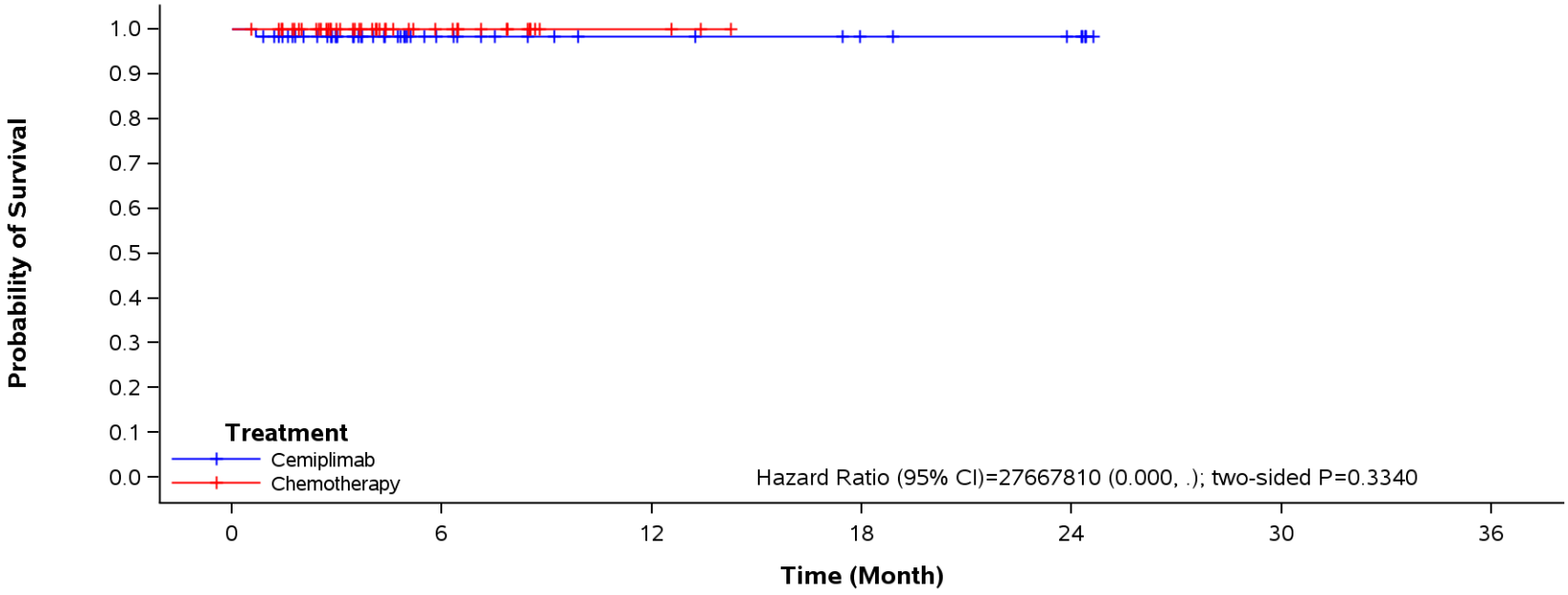

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 18 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



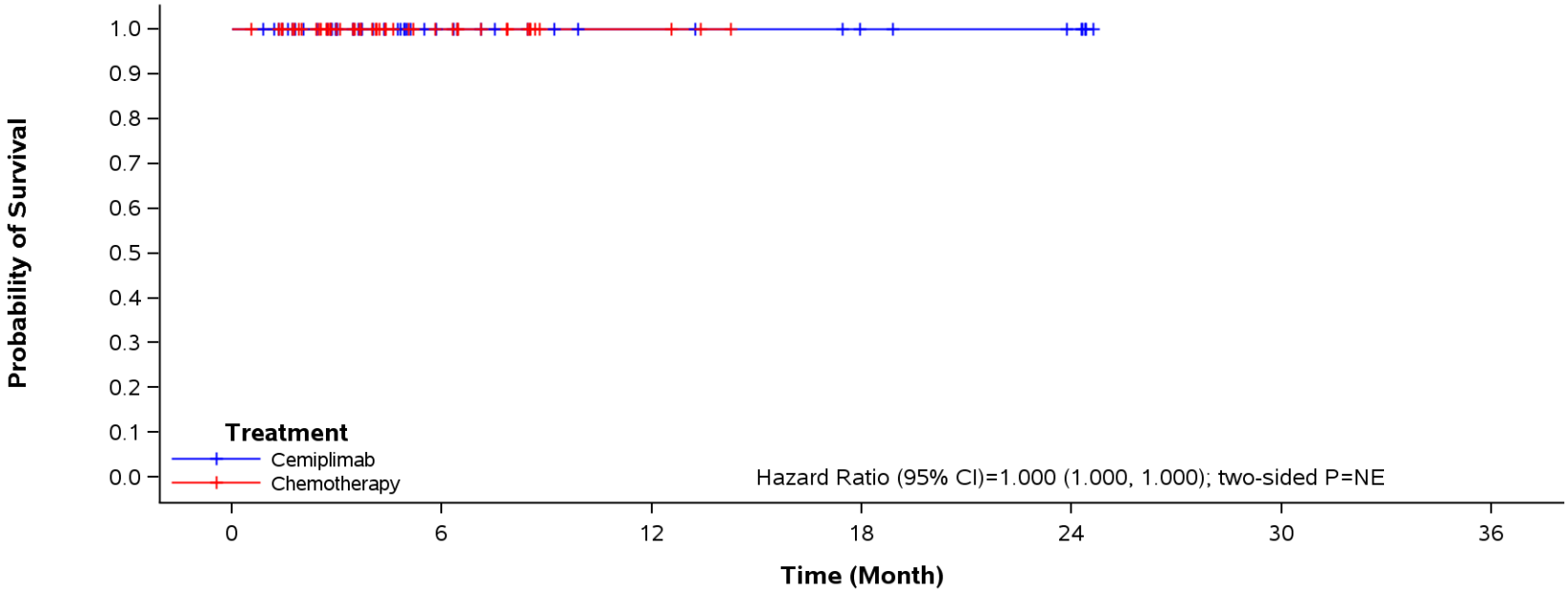

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Hepatobiliary disorders
PT: Hepatitis



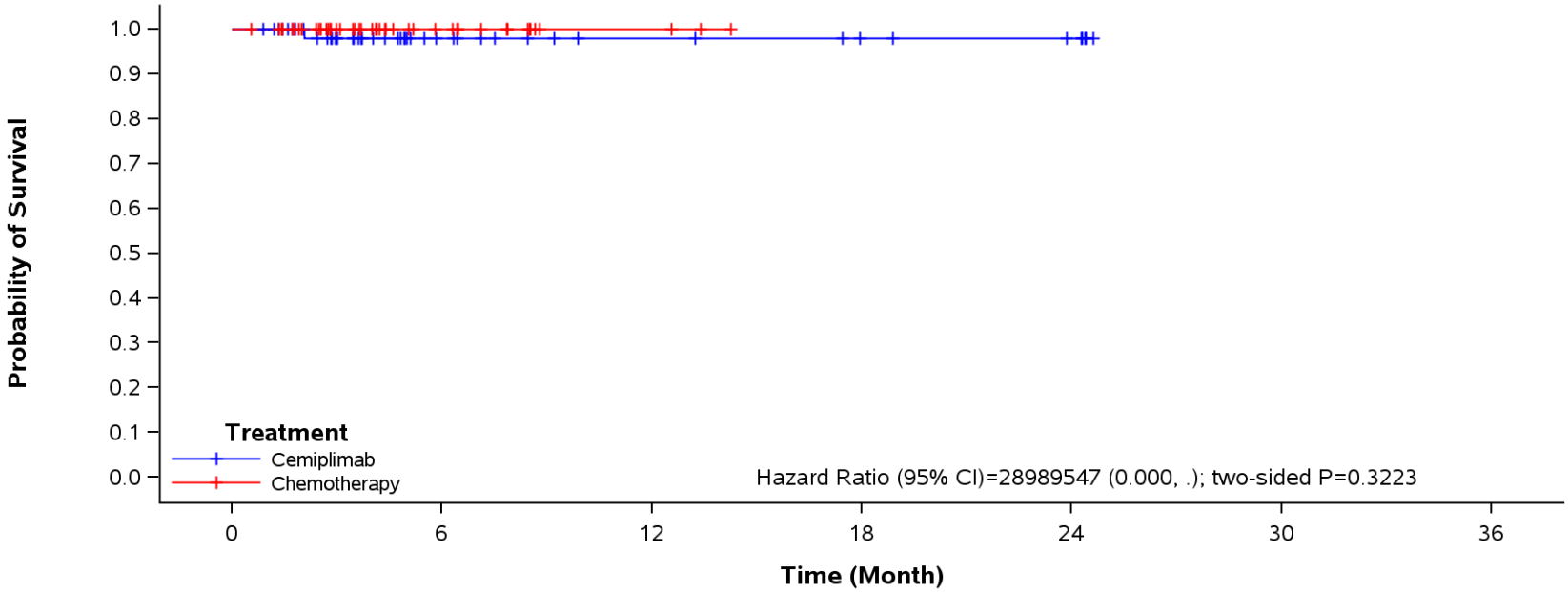

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



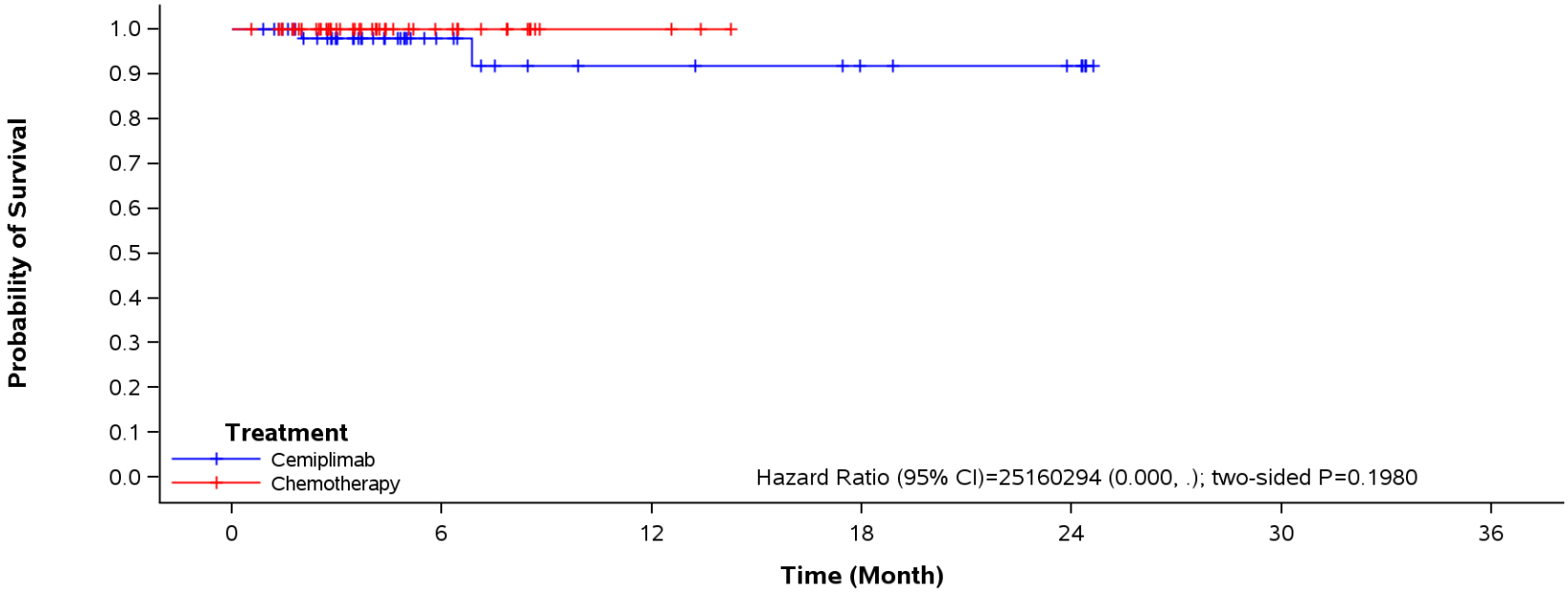

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Infections and infestations



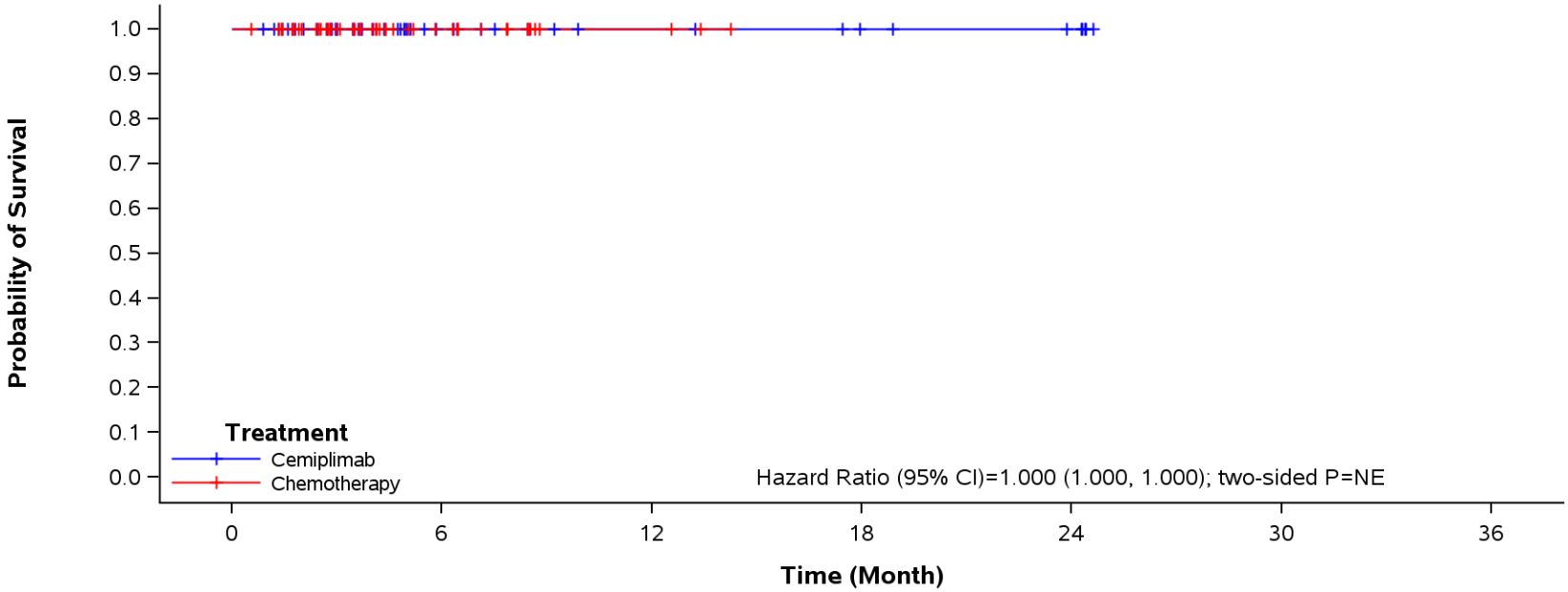

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Infections and infestations
PT: COVID-19 pneumonia



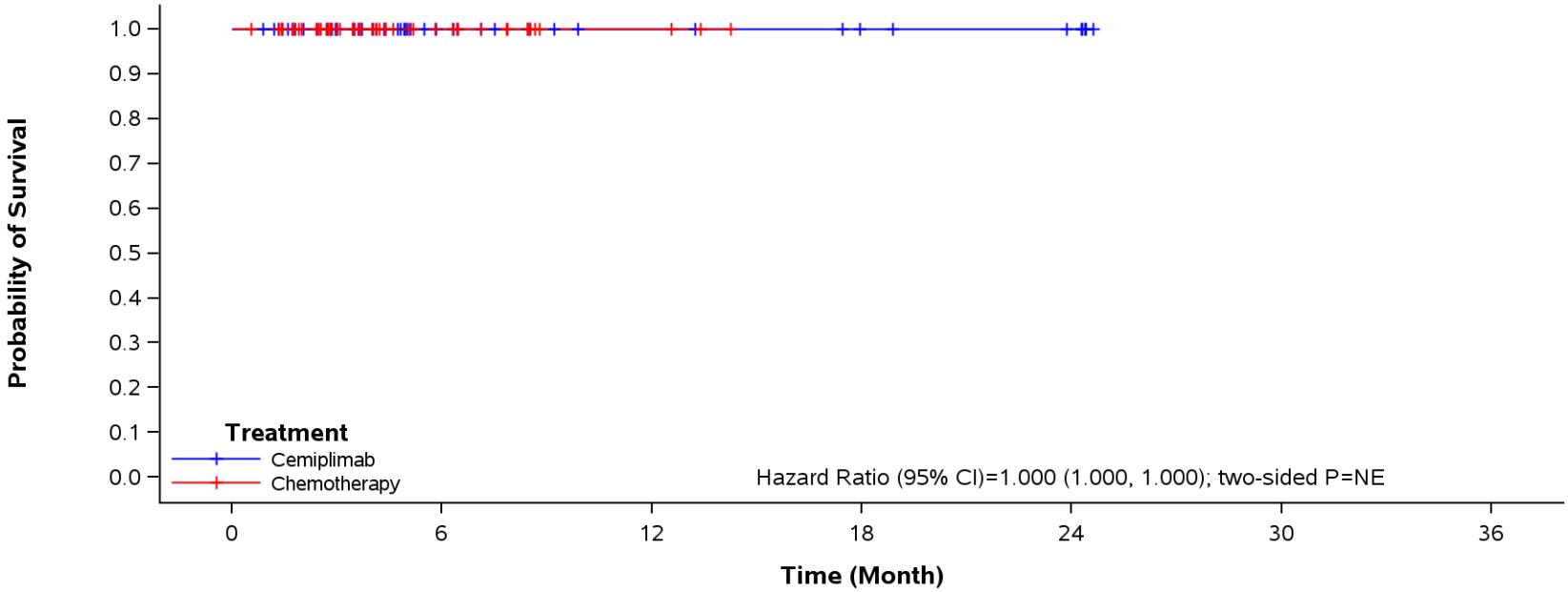

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Infections and infestations
PT: Gastroenteritis



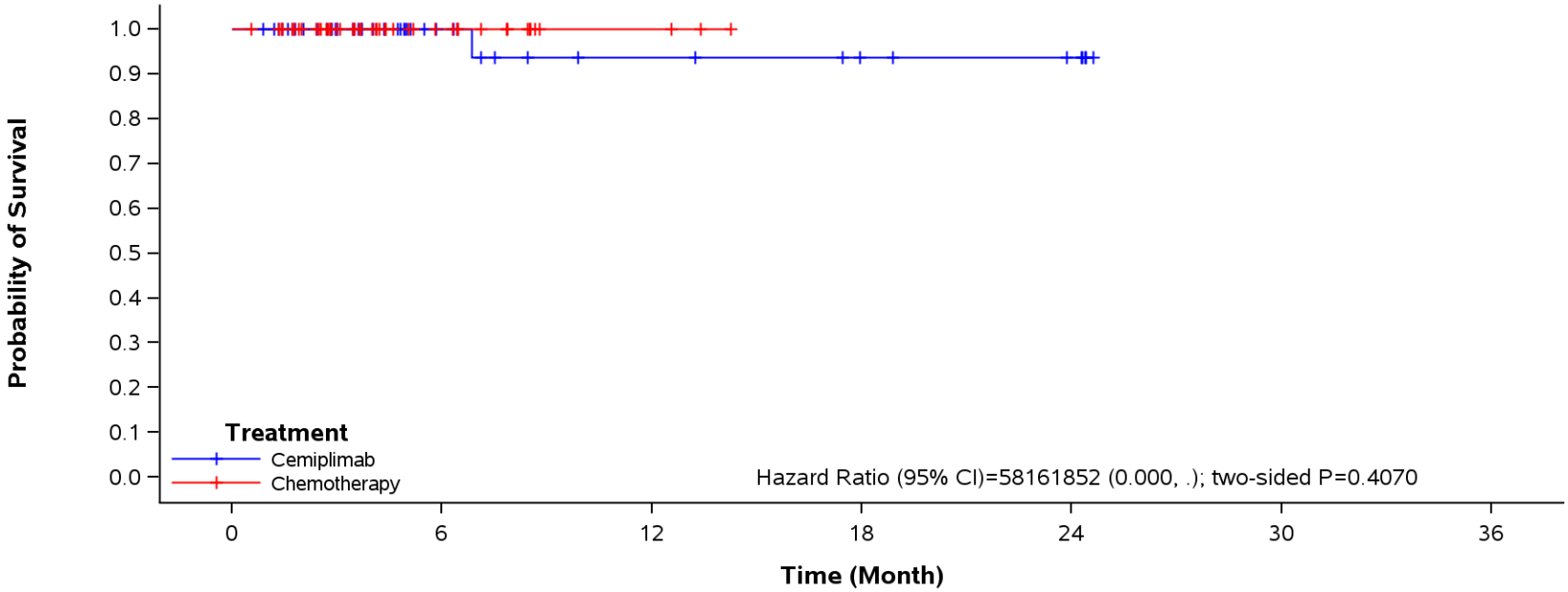

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Infections and infestations
PT: Pelvic abscess



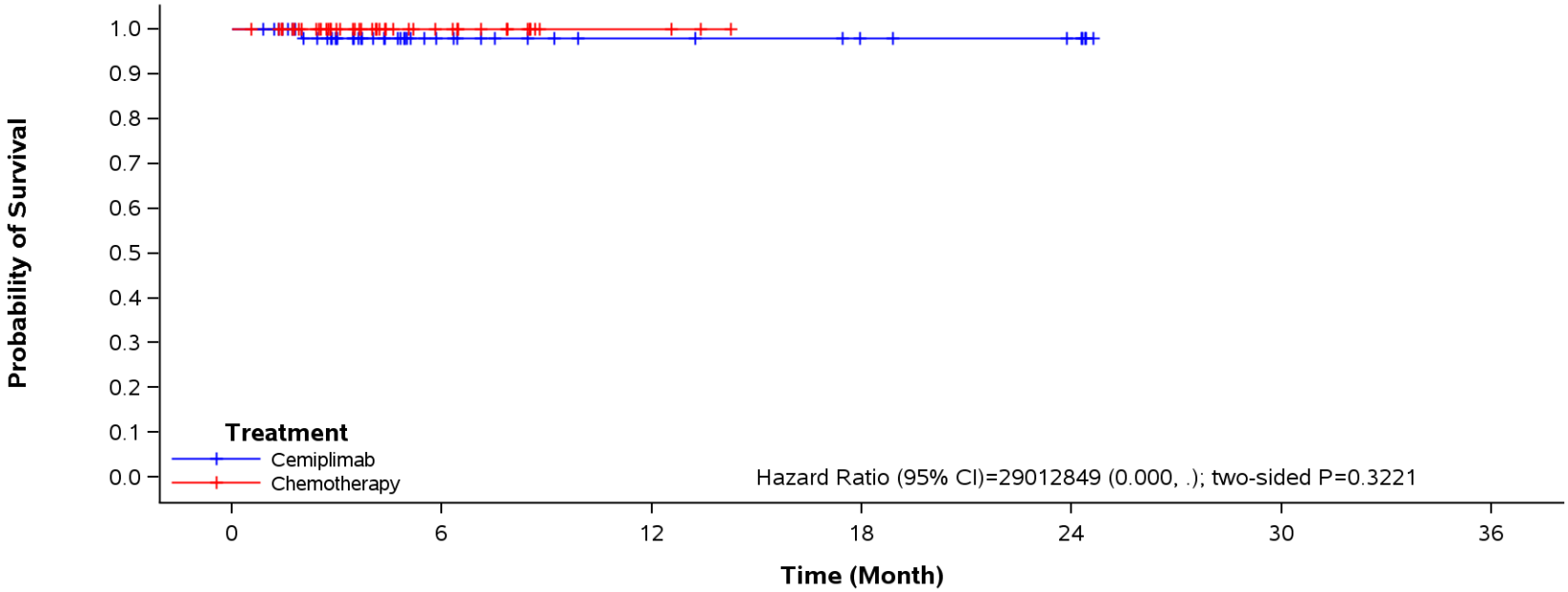

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Infections and infestations
PT: Peritonitis



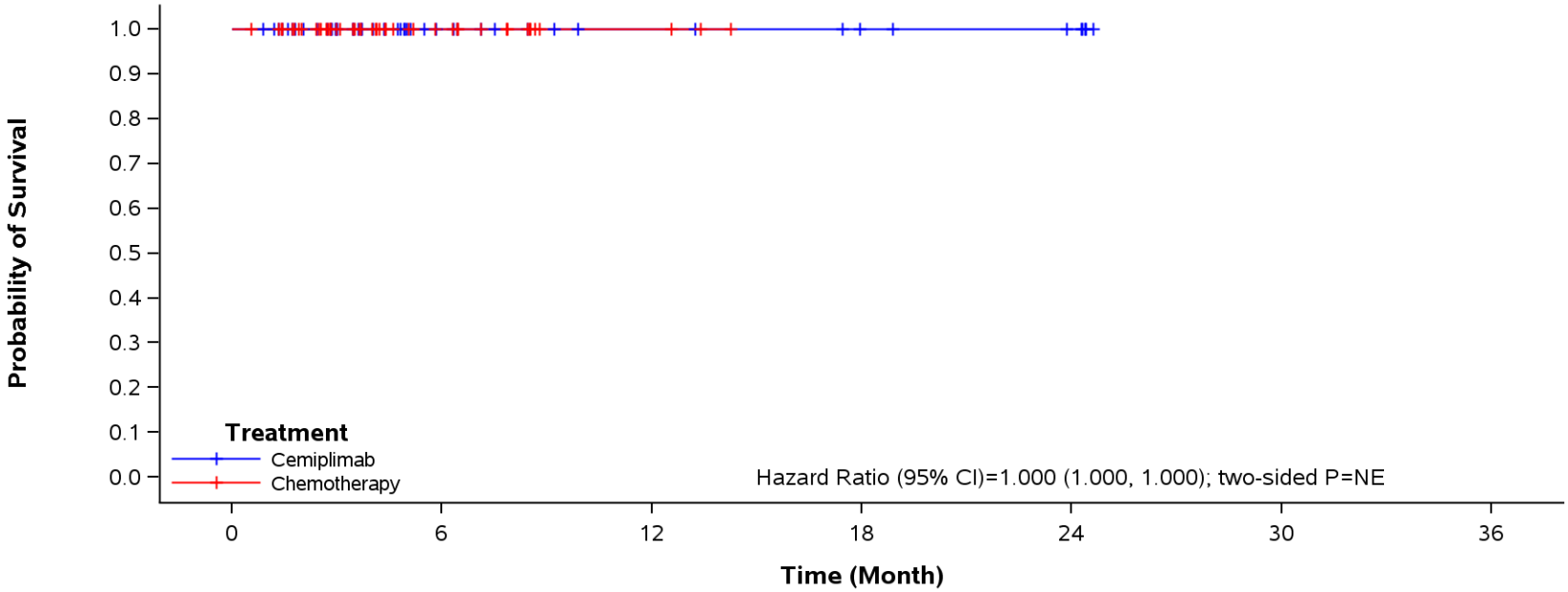

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Infections and infestations
PT: Pneumonia



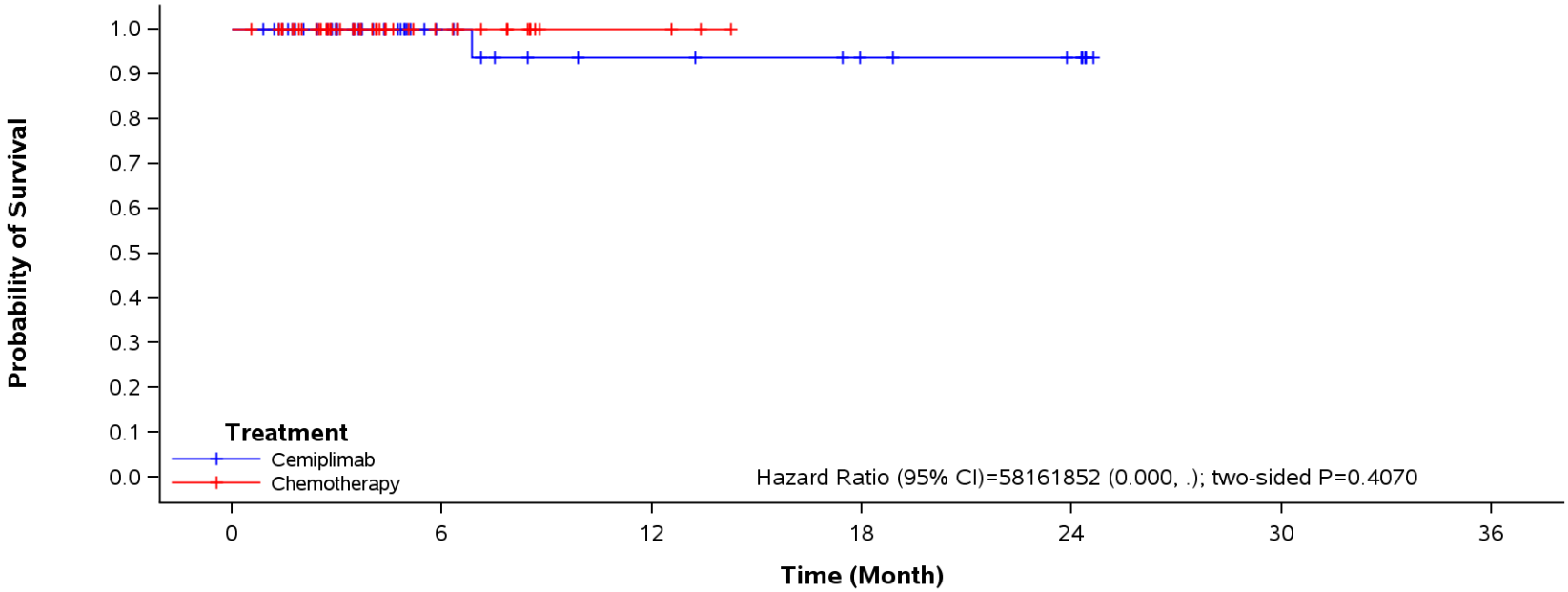

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Infections and infestations
PT: Pyomyositis




**Number of Subjects at risk**

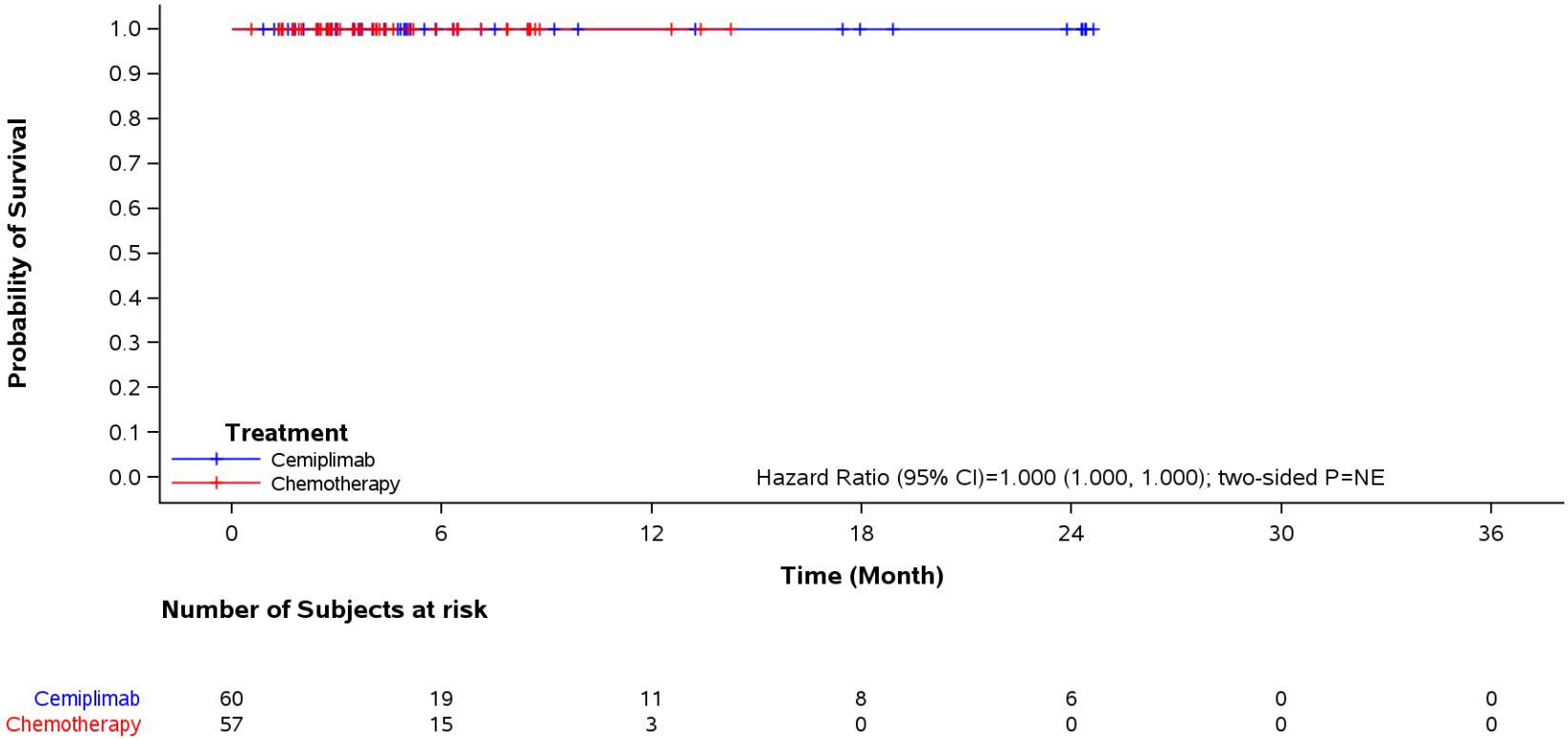
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White

SOC: Injury, poisoning and procedural complications

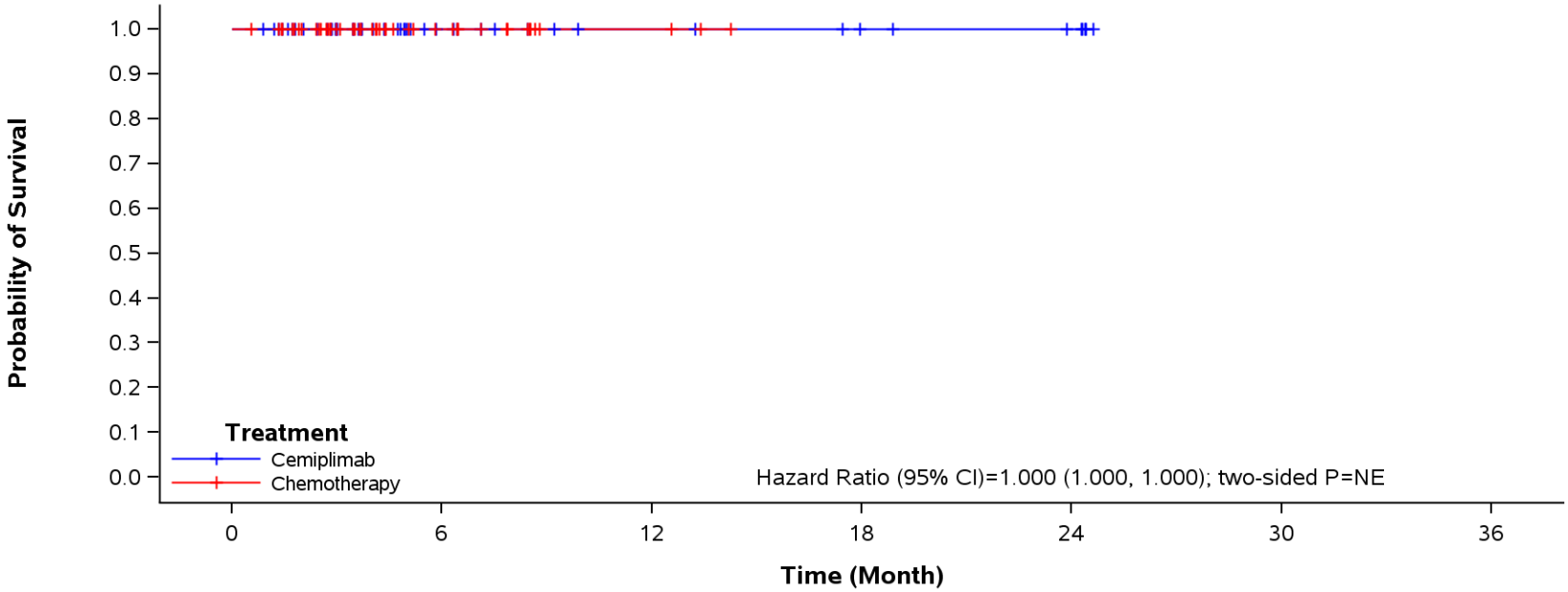



Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



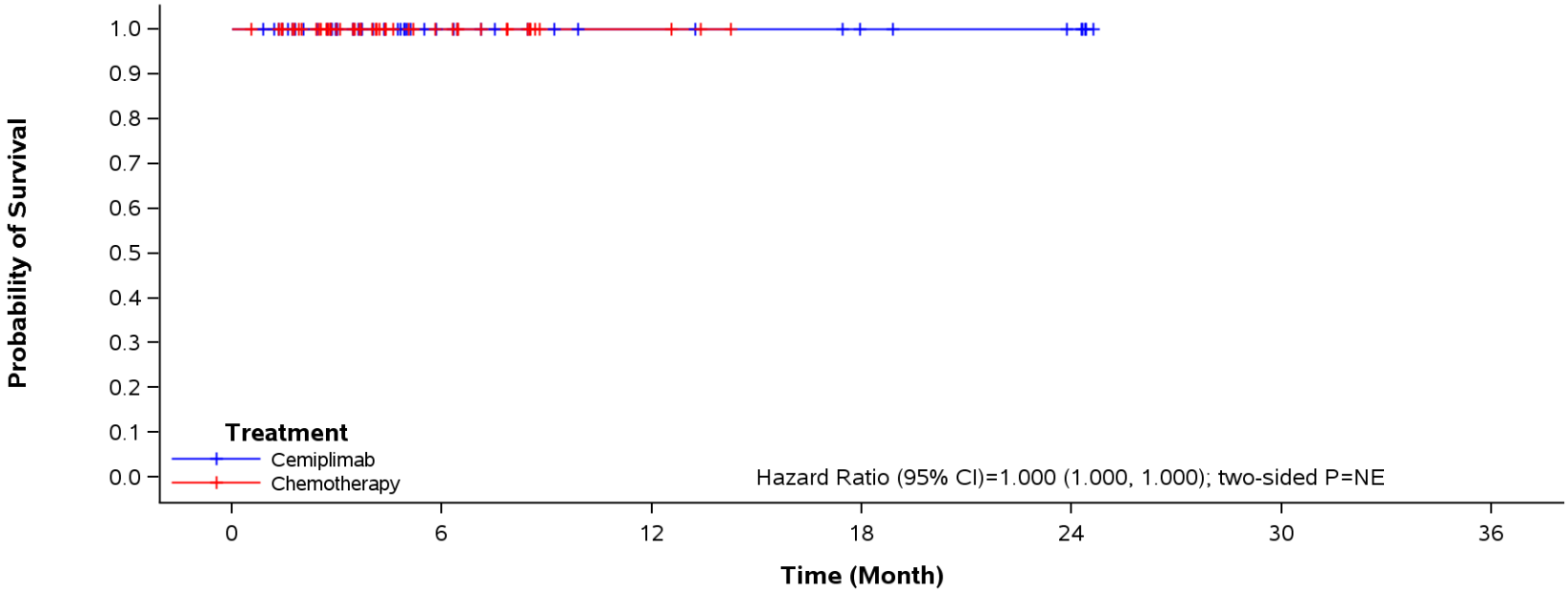

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



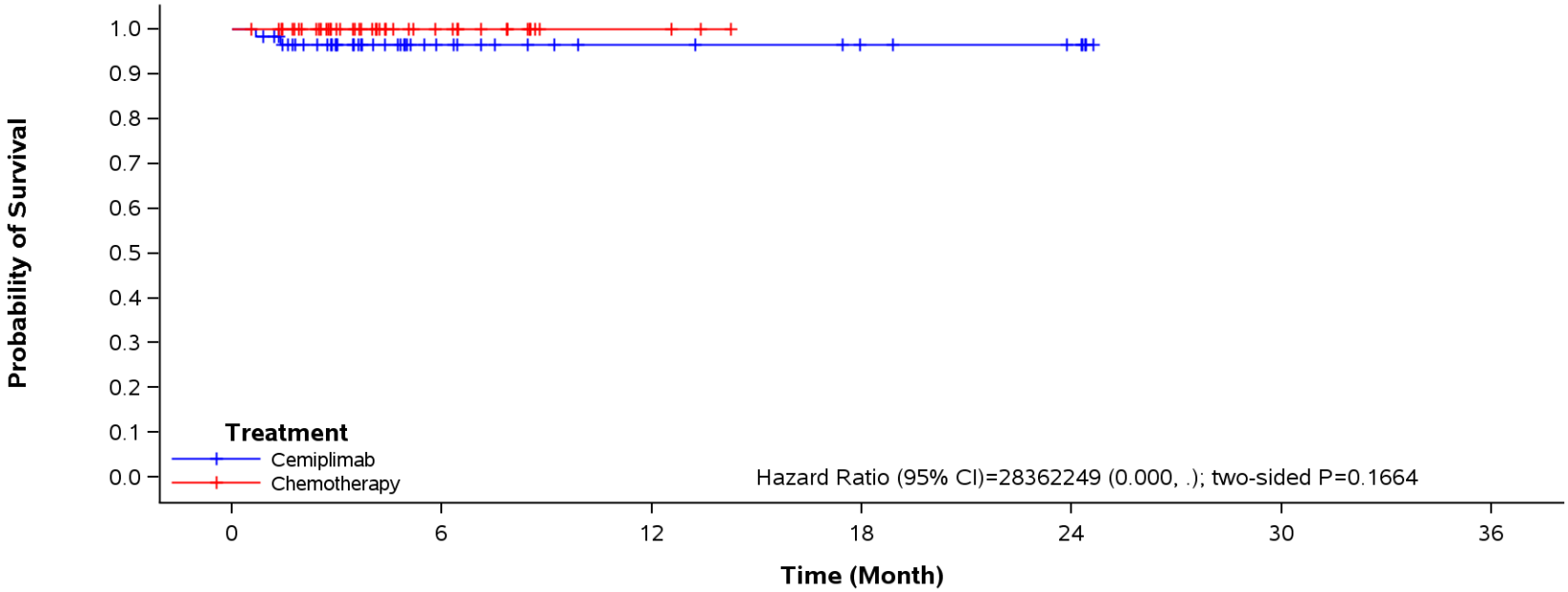

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Investigations



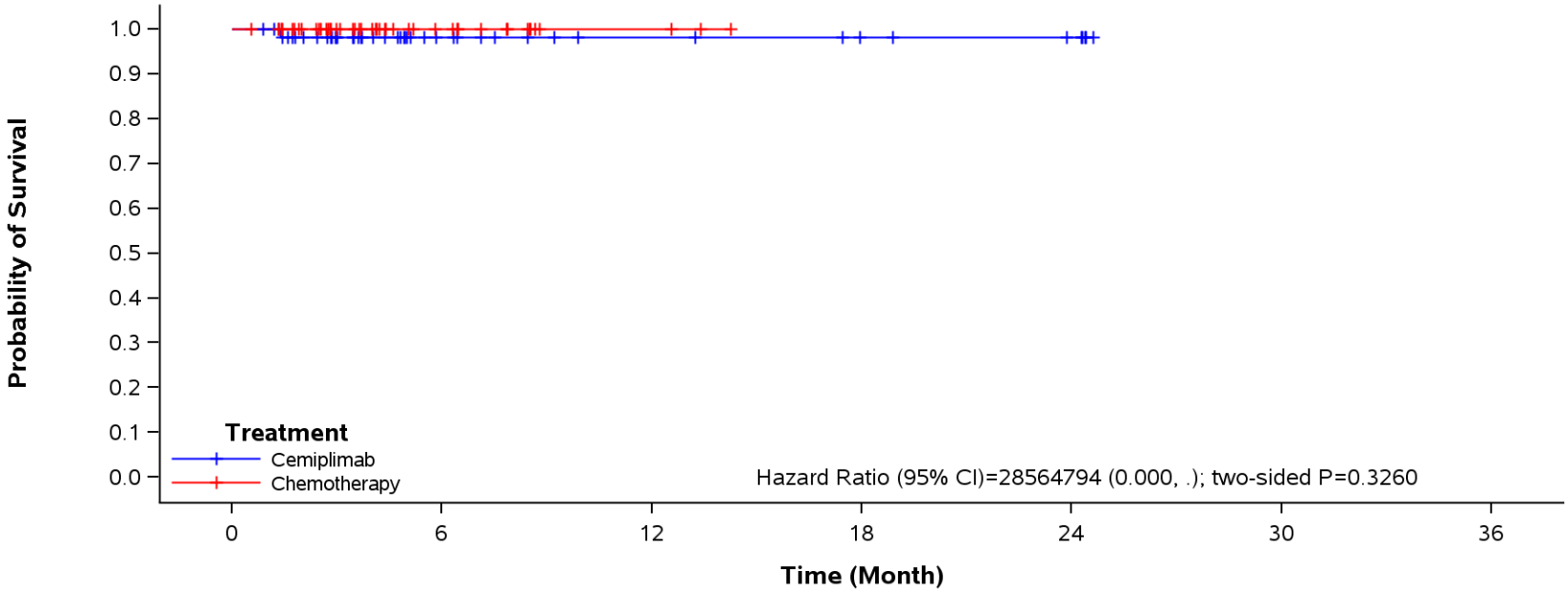

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Investigations
PT: Alanine aminotransferase increased



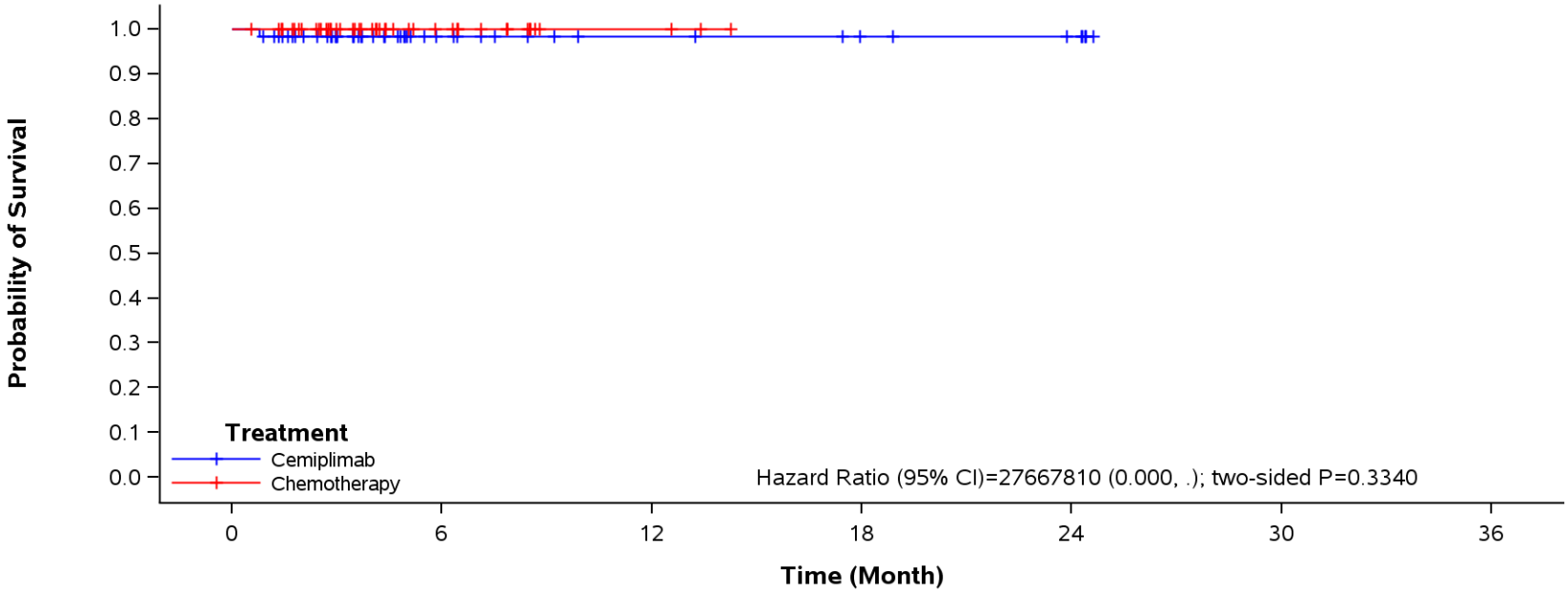

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Investigations
PT: Amylase increased



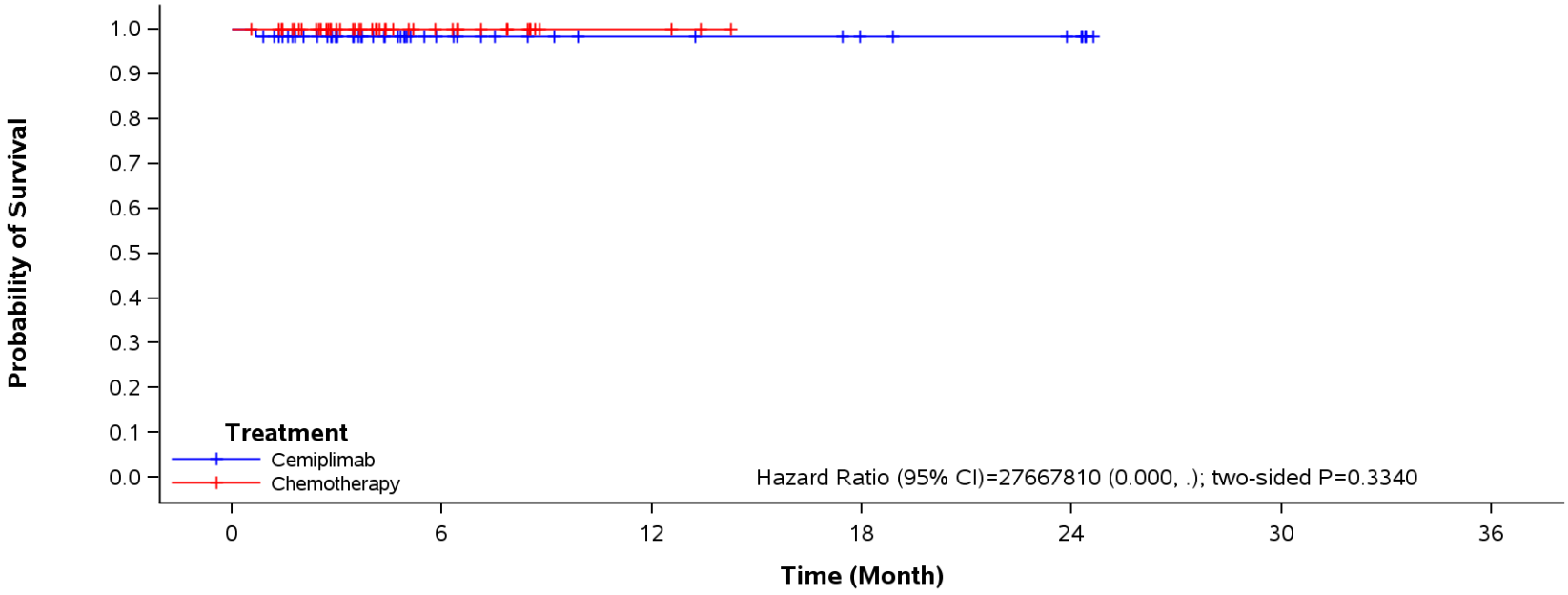

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Investigations
PT: Platelet count decreased



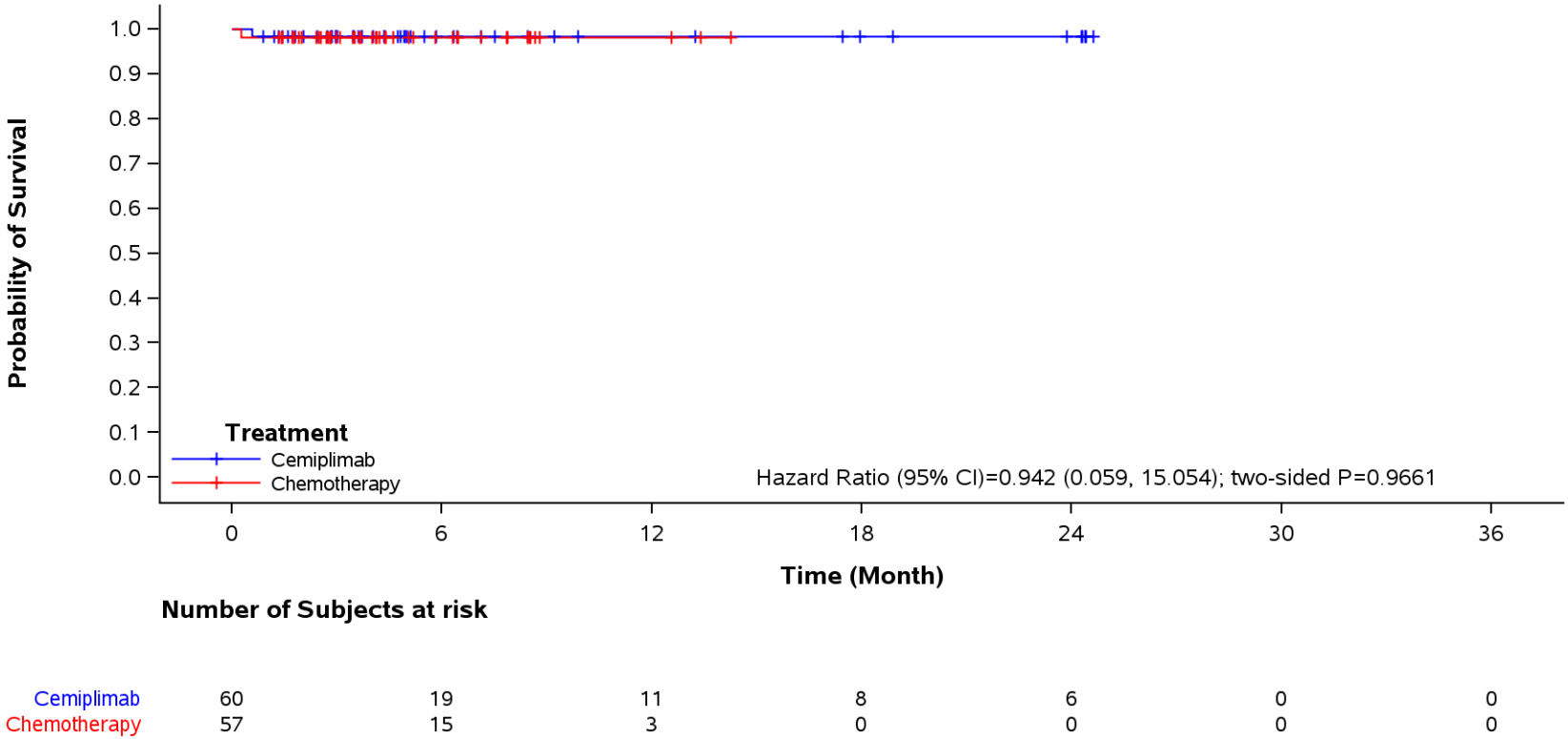

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

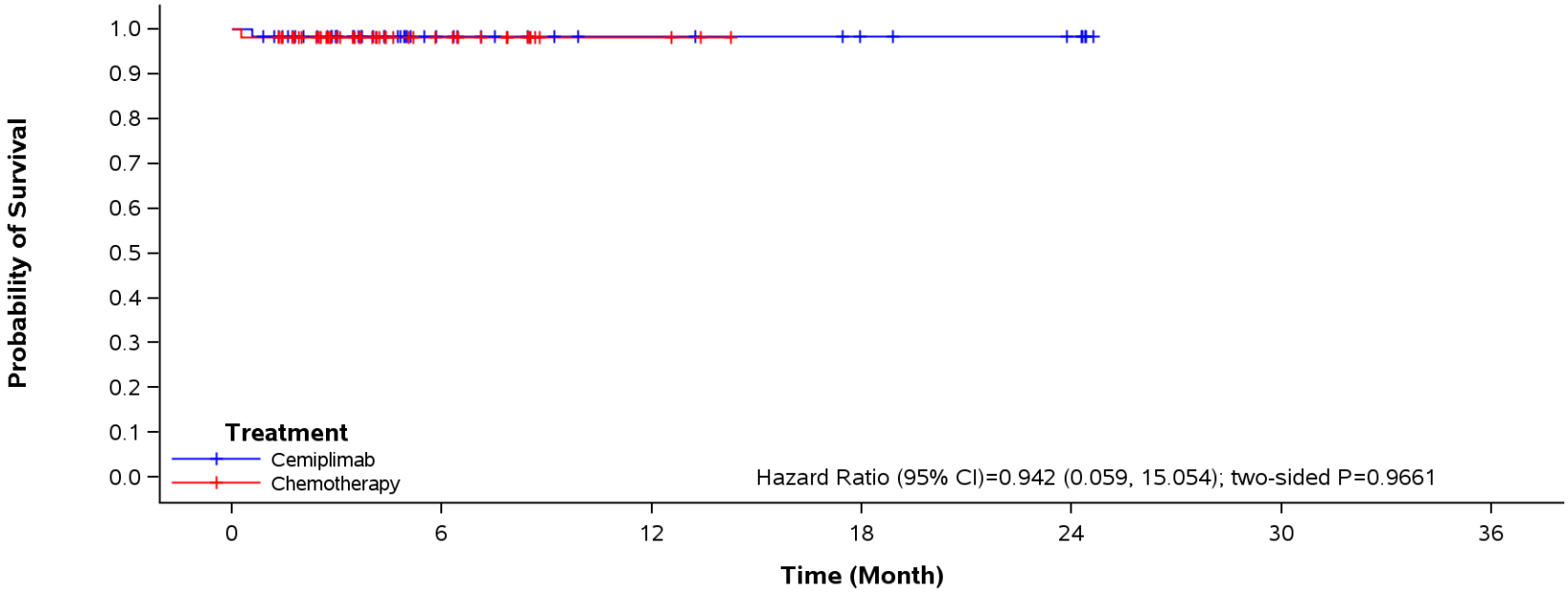
Race: Non-White
SOC: Metabolism and nutrition disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



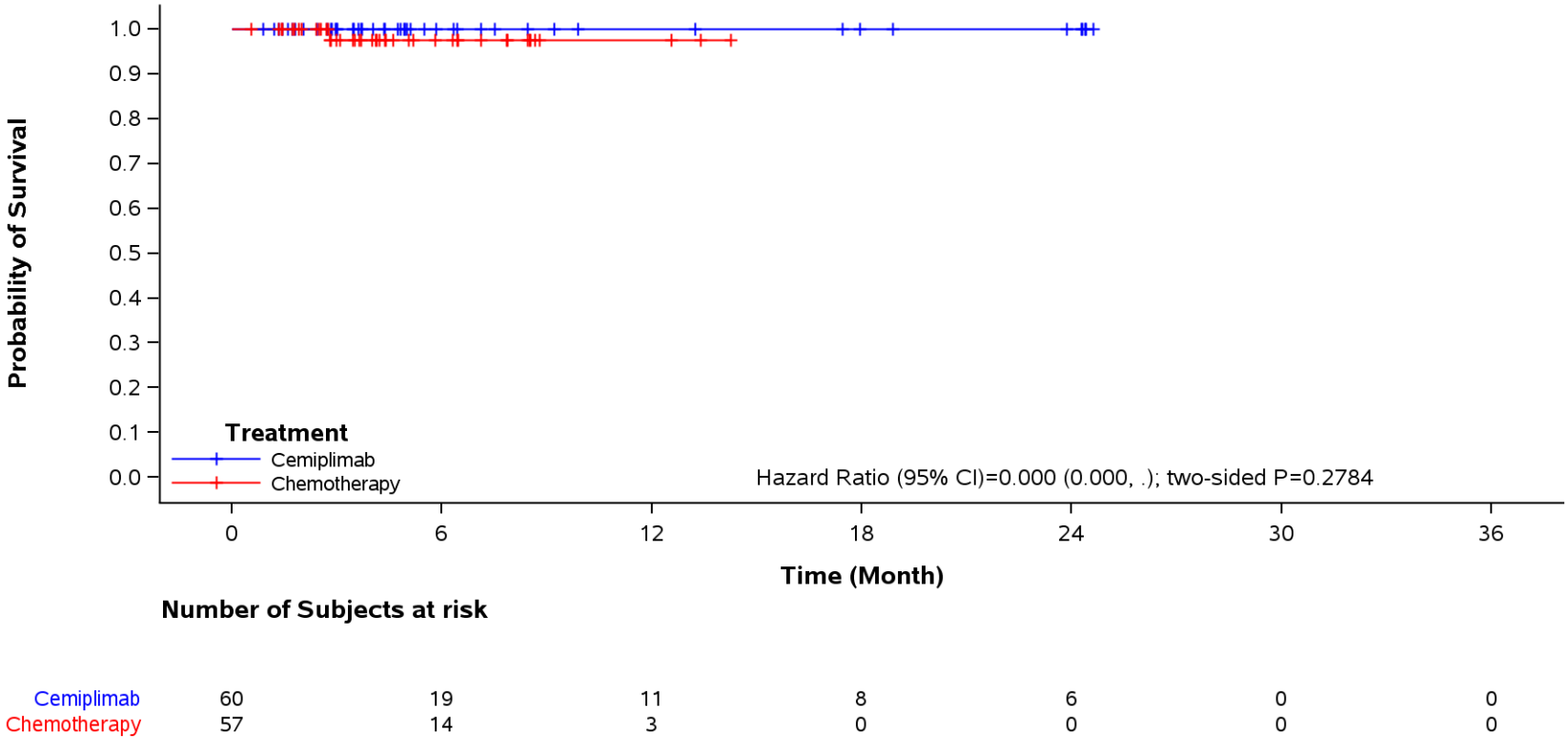

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

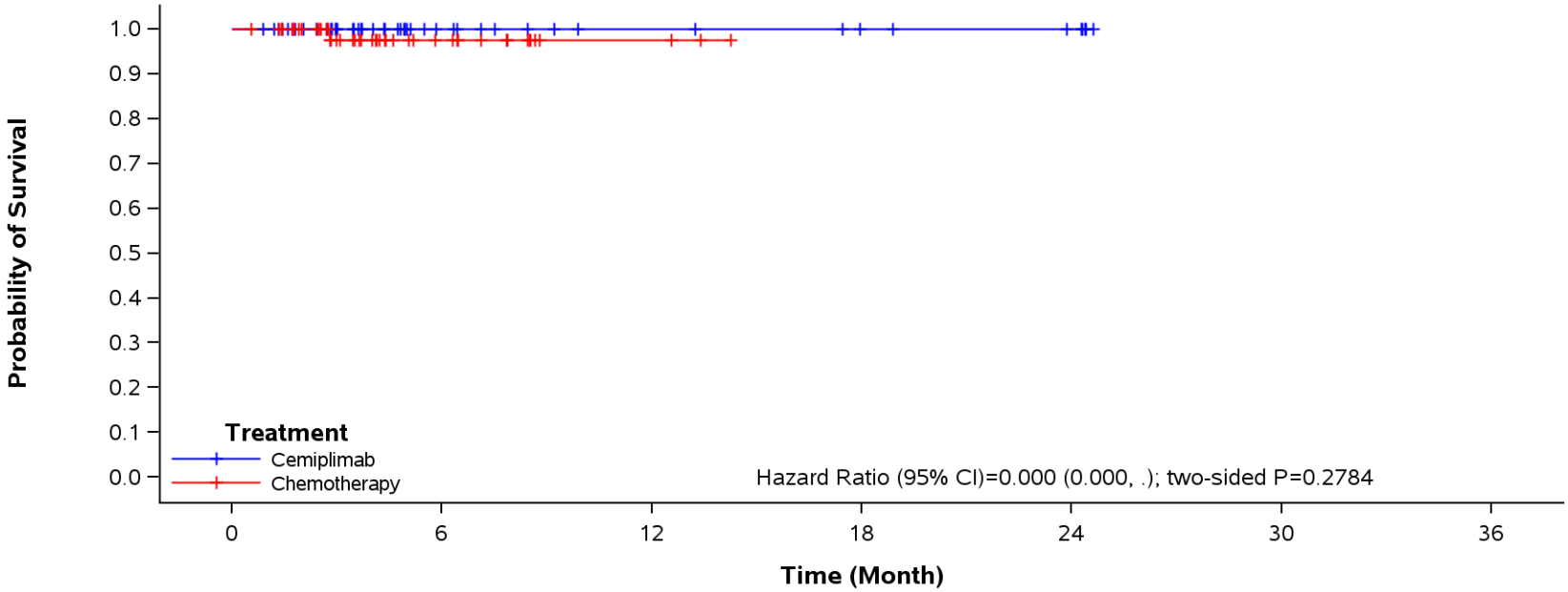
Race: Non-White
SOC: Musculoskeletal and connective tissue disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



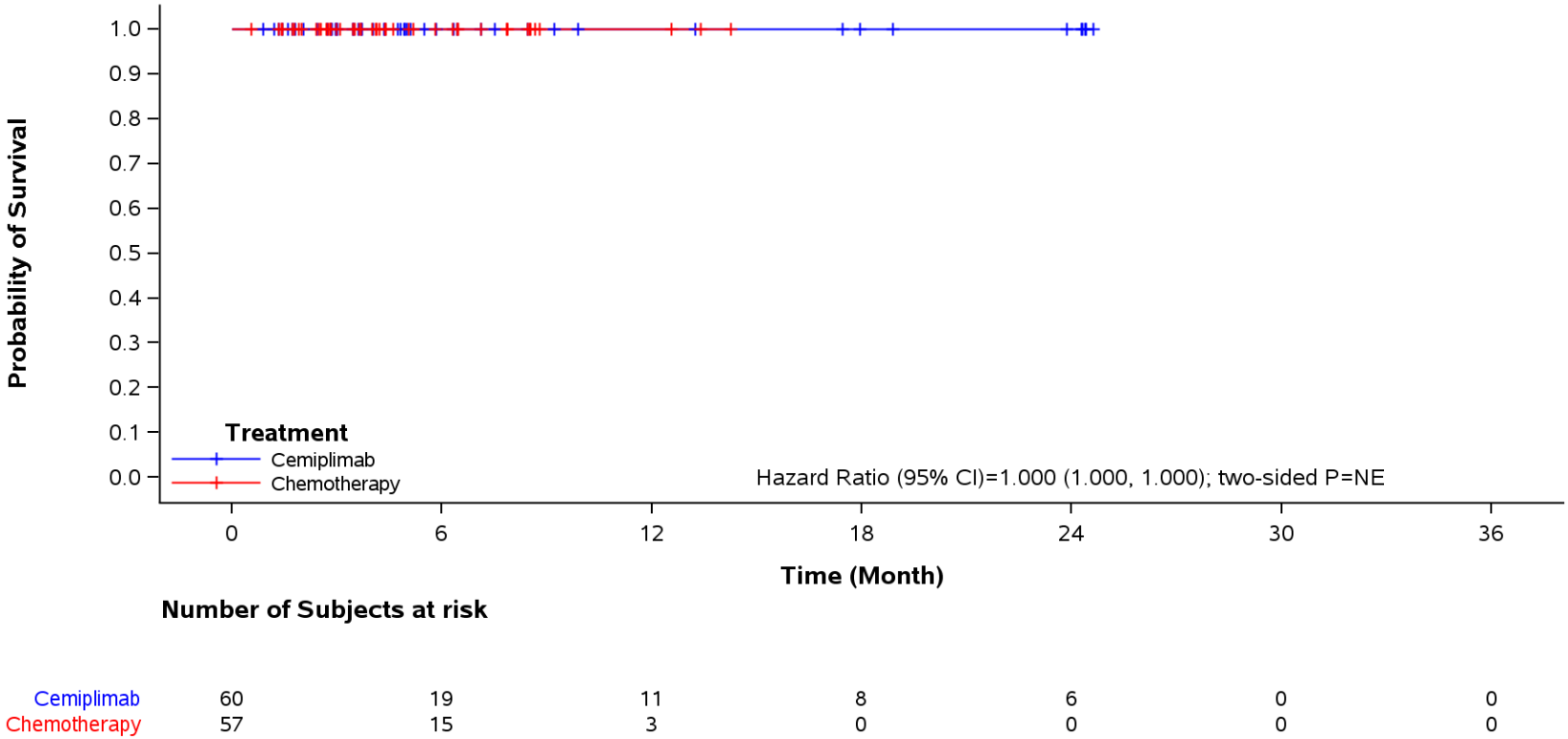

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 14 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

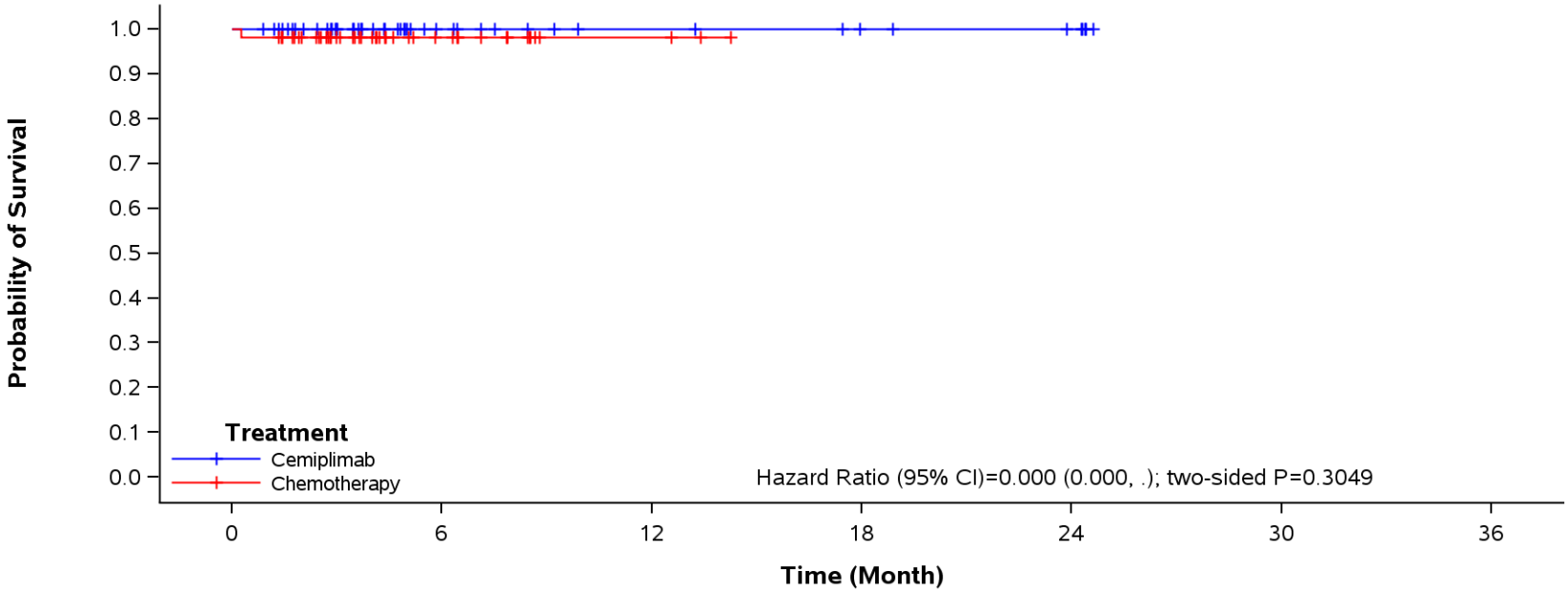
Race: Non-White
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Nervous system disorders



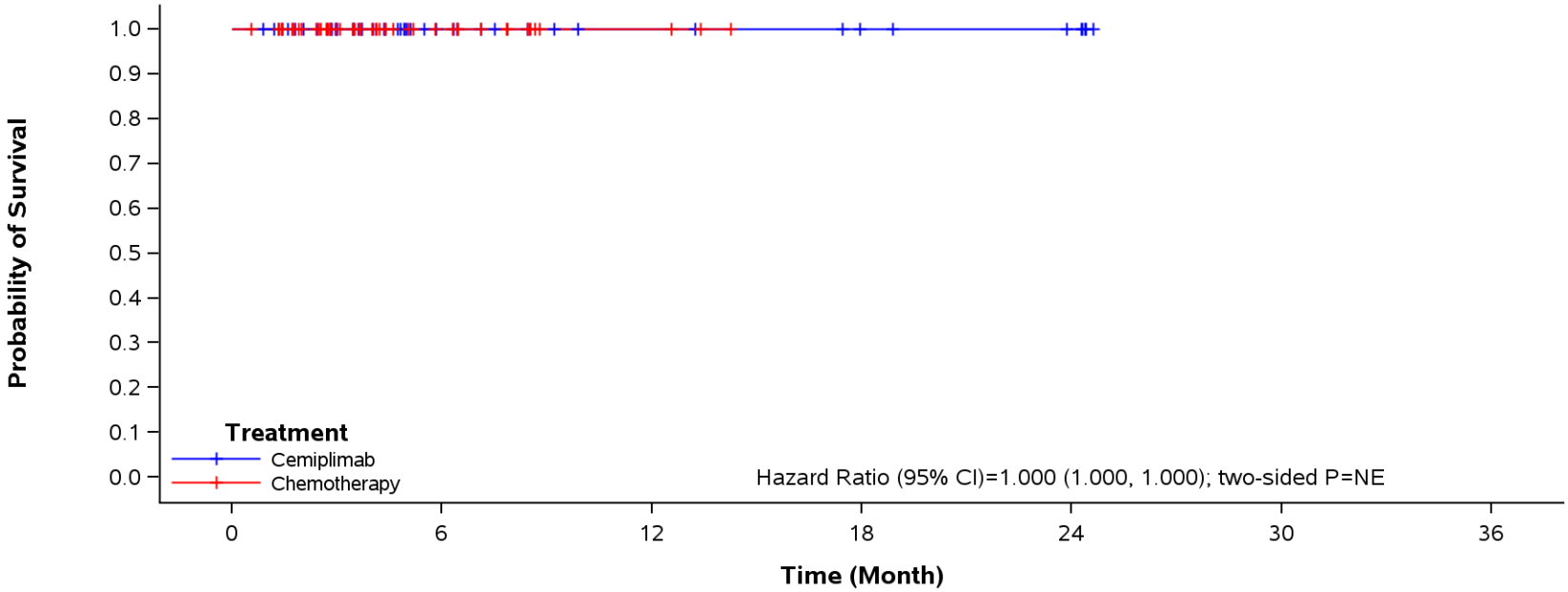

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Nervous system disorders
PT: Neurotoxicity



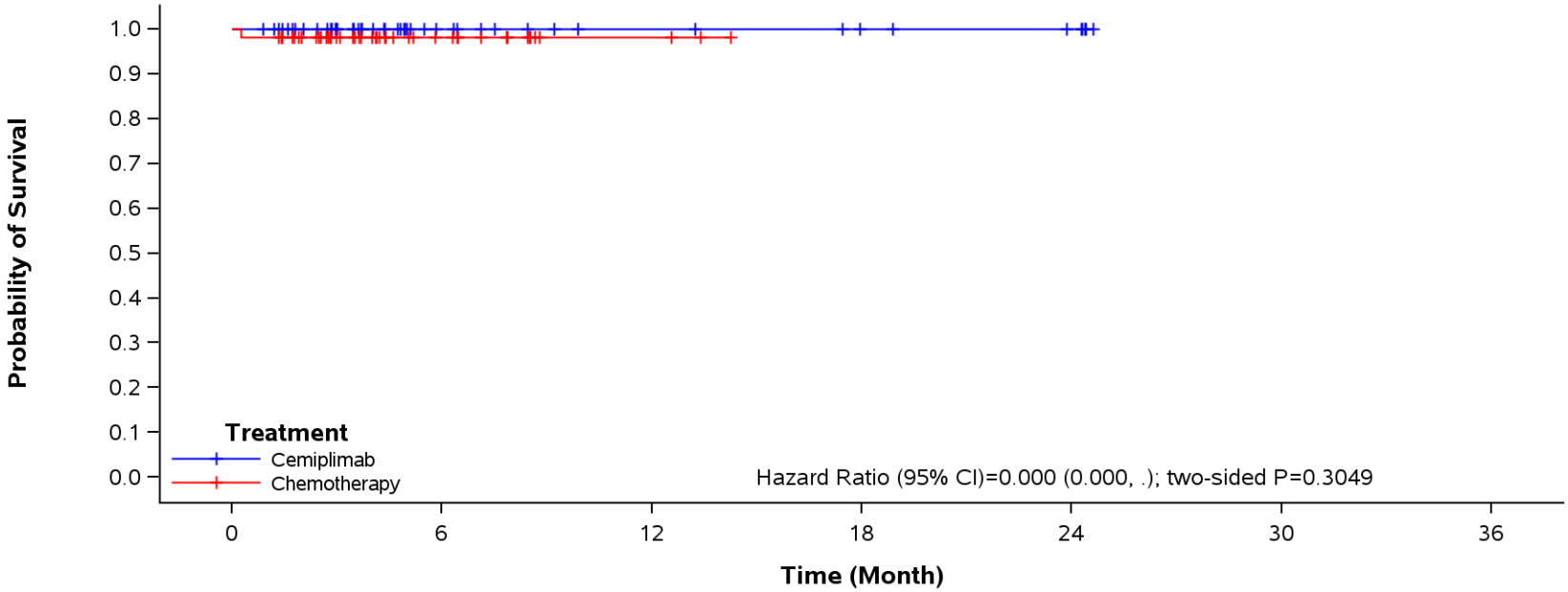

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Nervous system disorders
PT: Transient ischaemic attack



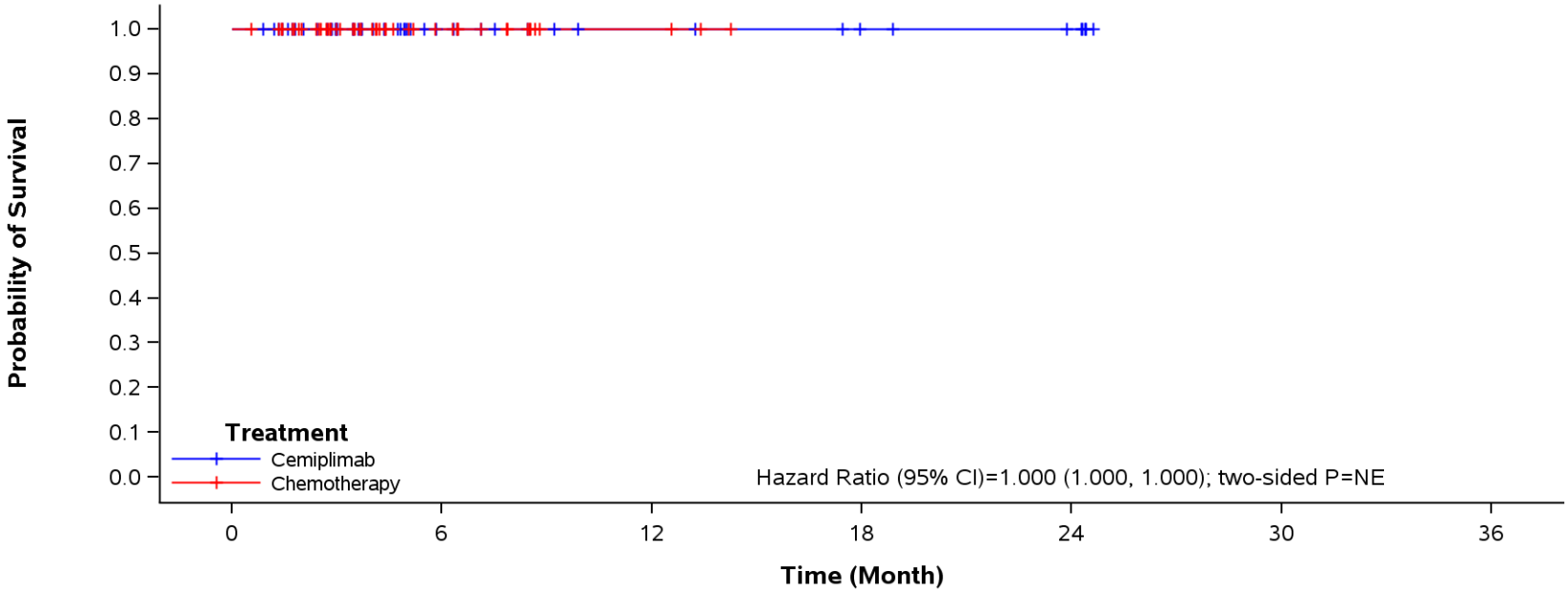

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Psychiatric disorders



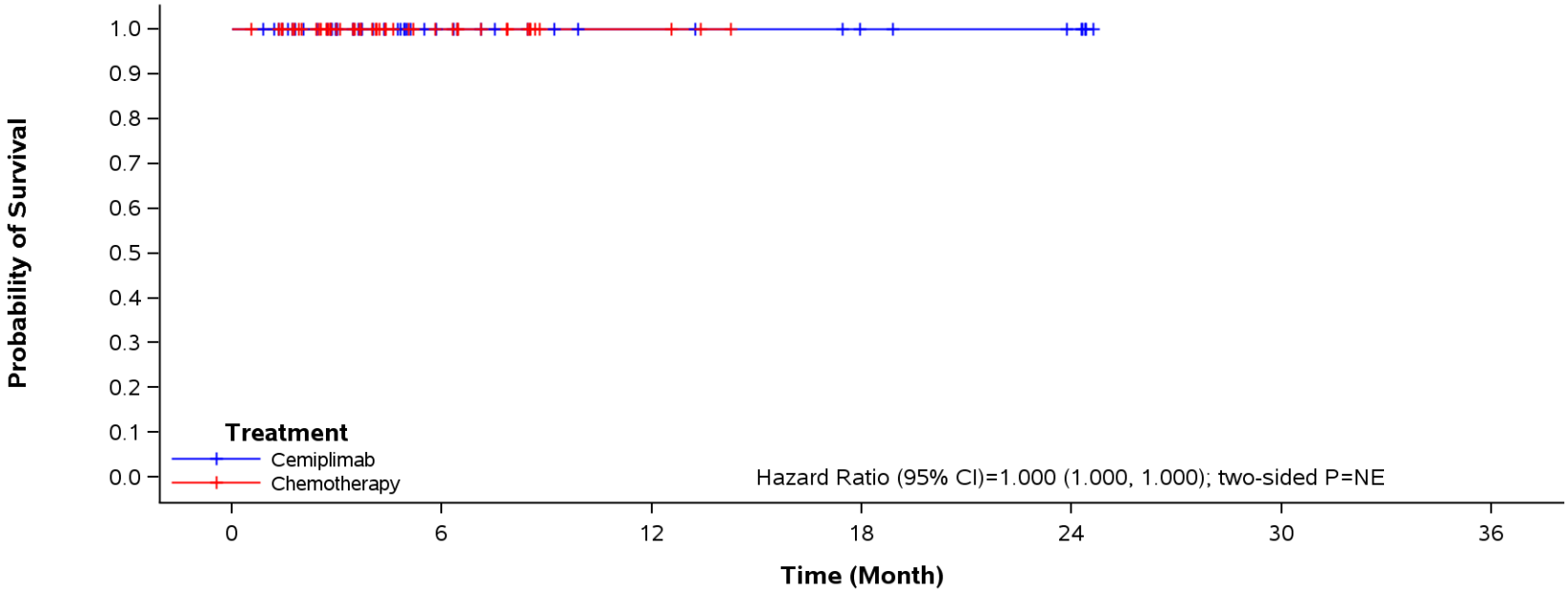

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Psychiatric disorders
PT: Agoraphobia



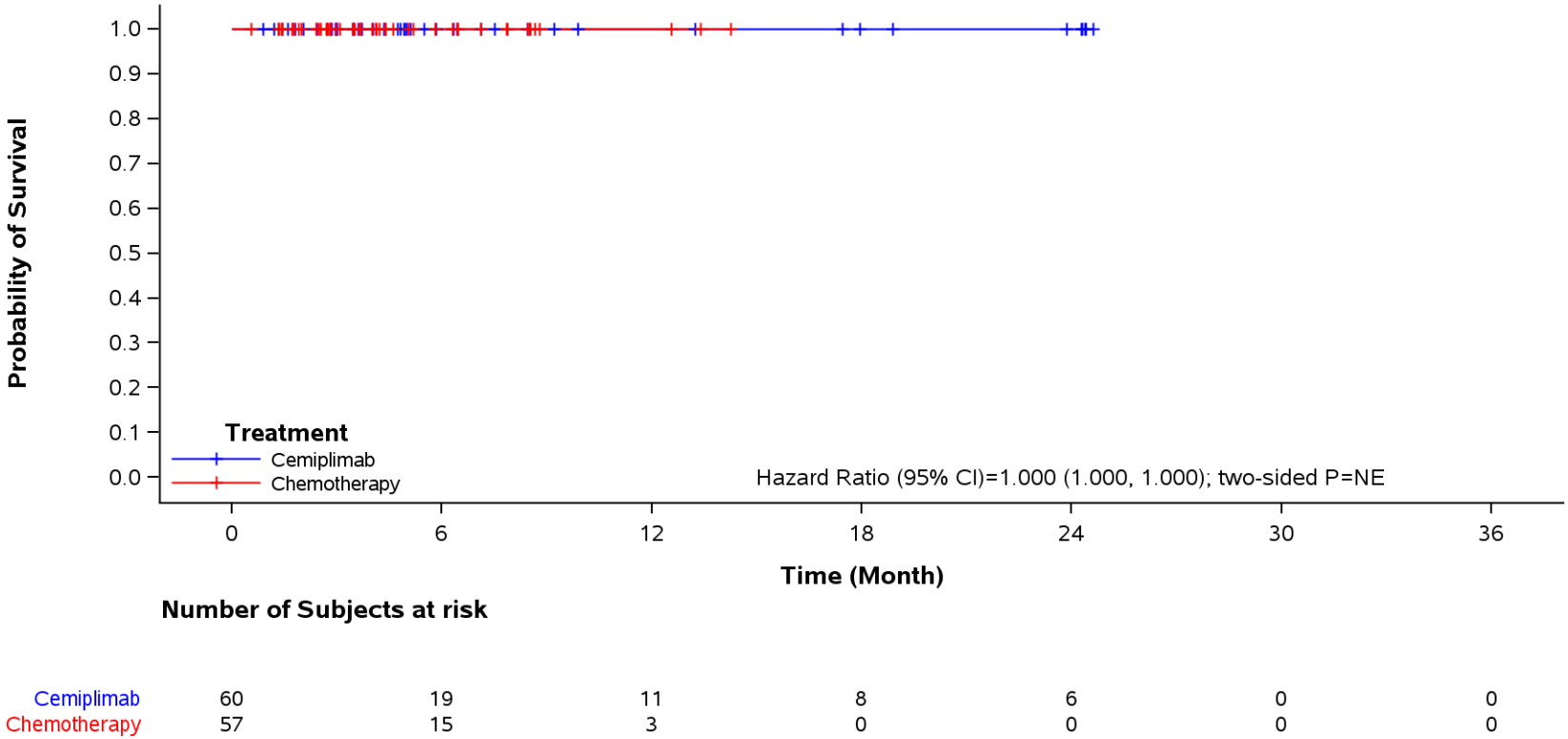

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

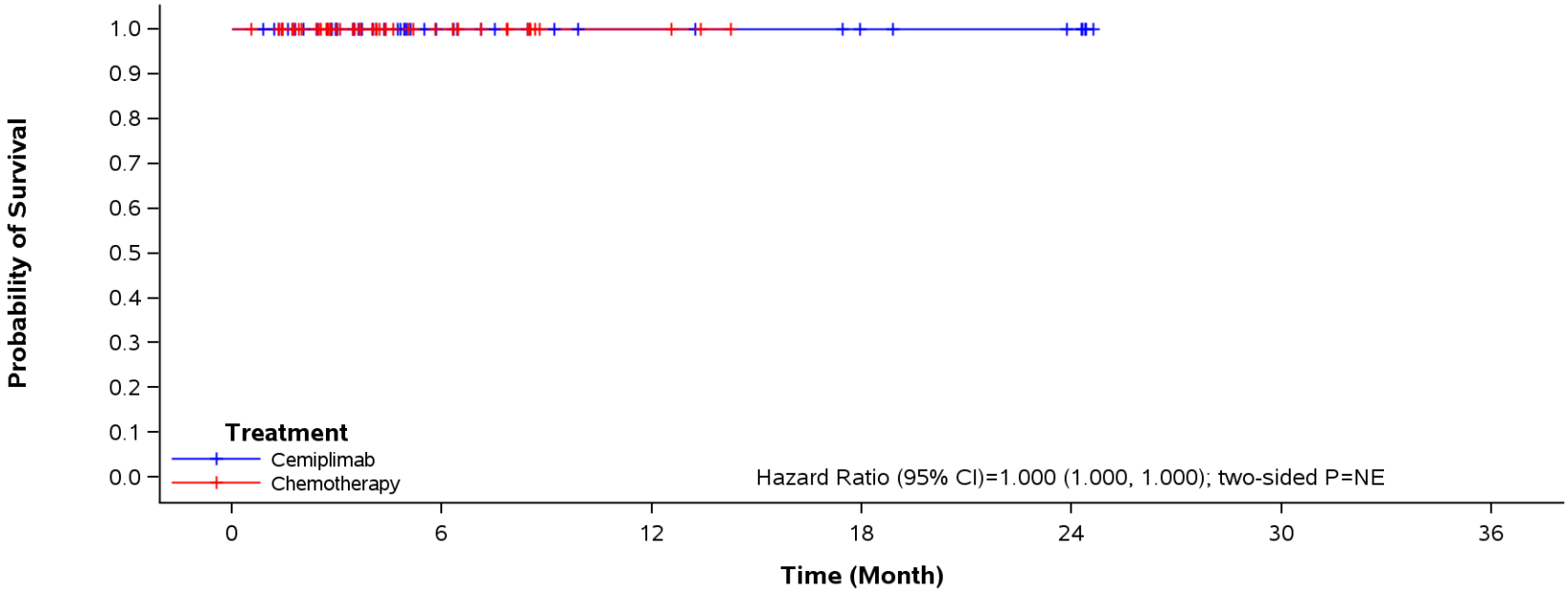
Race: Non-White
SOC: Renal and urinary disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Renal and urinary disorders
PT: Renal failure



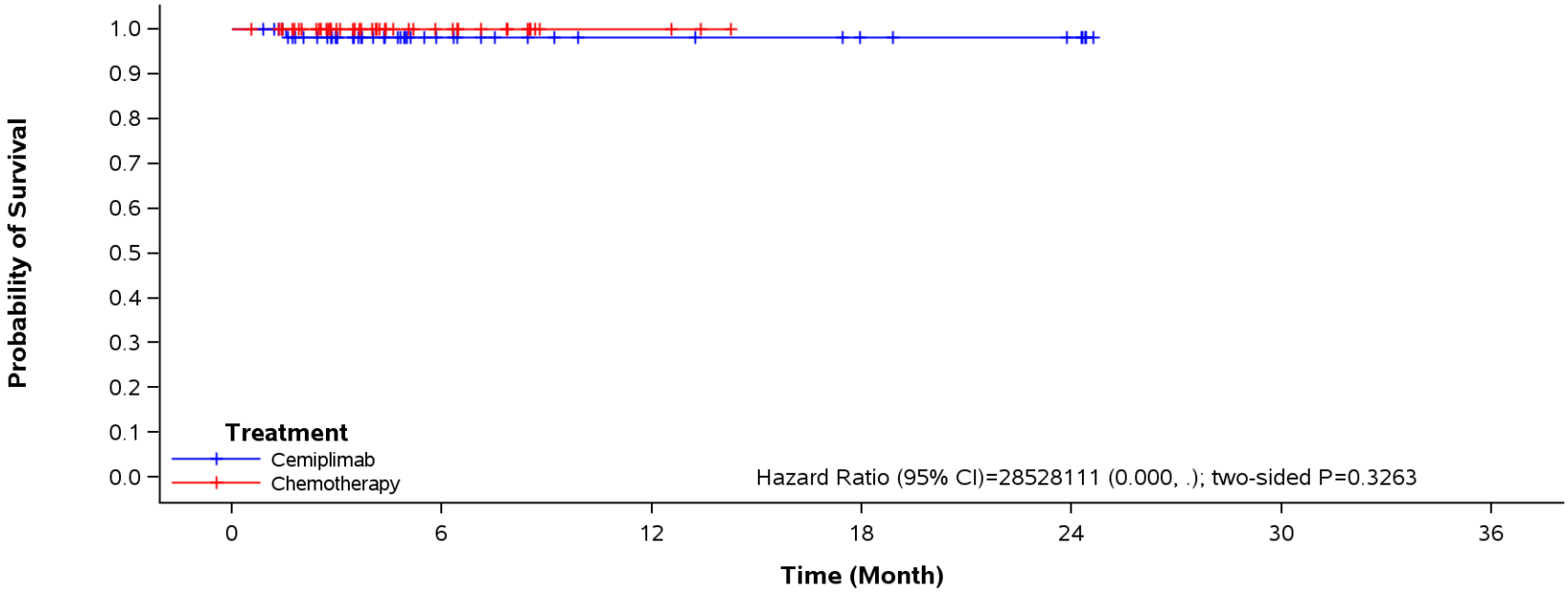

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Respiratory, thoracic and mediastinal disorders



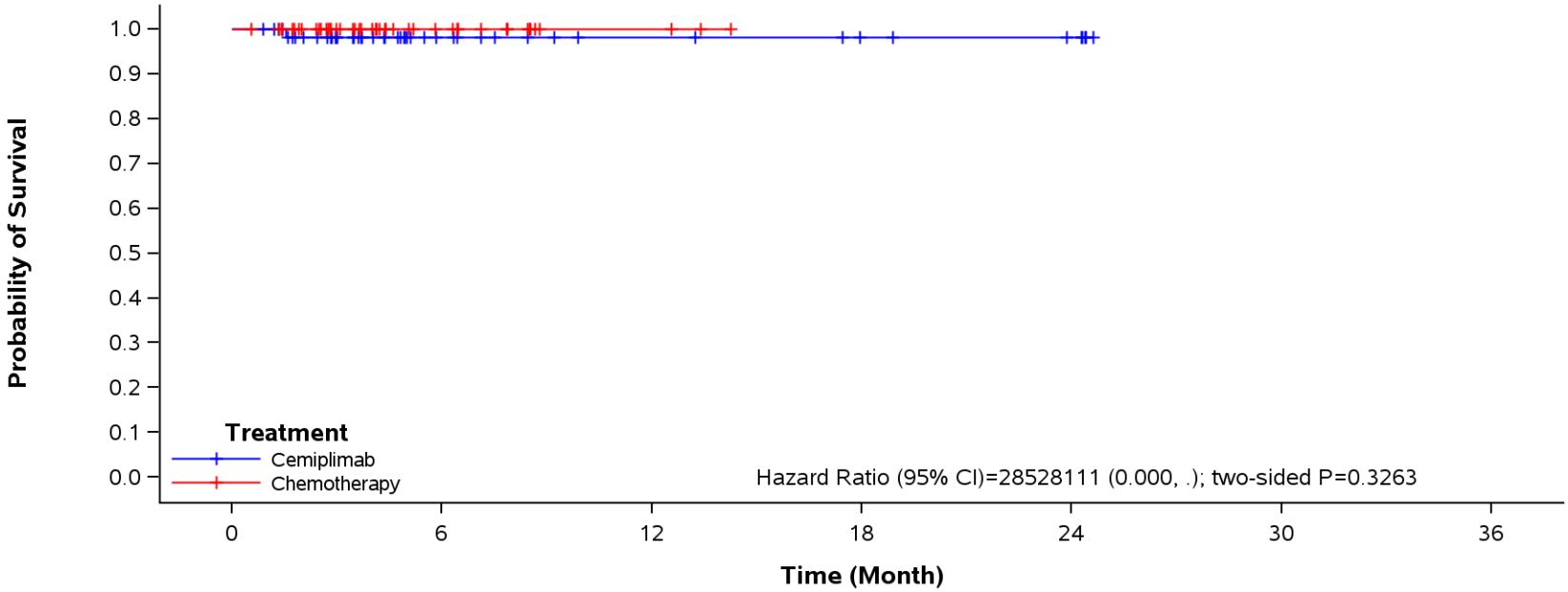

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



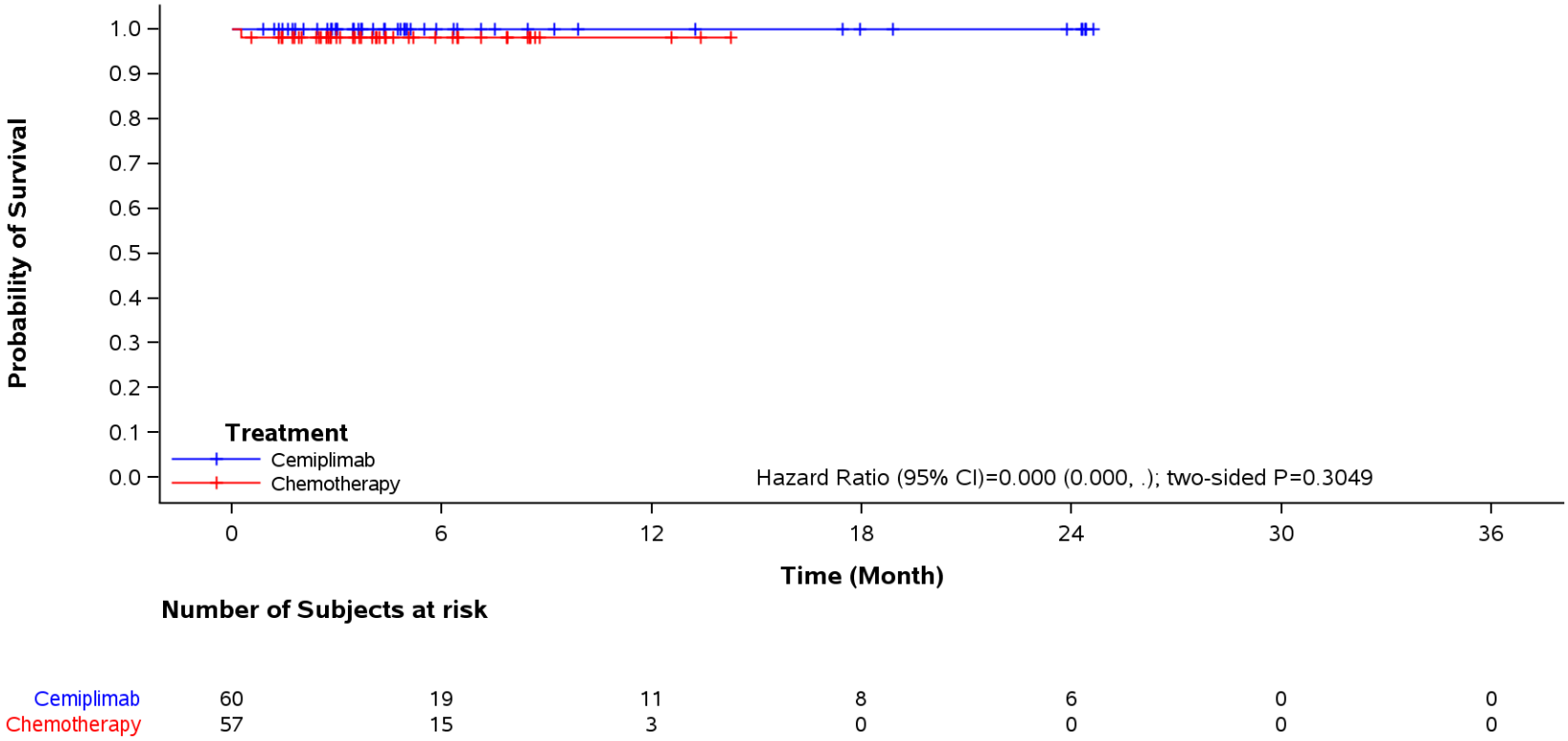

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

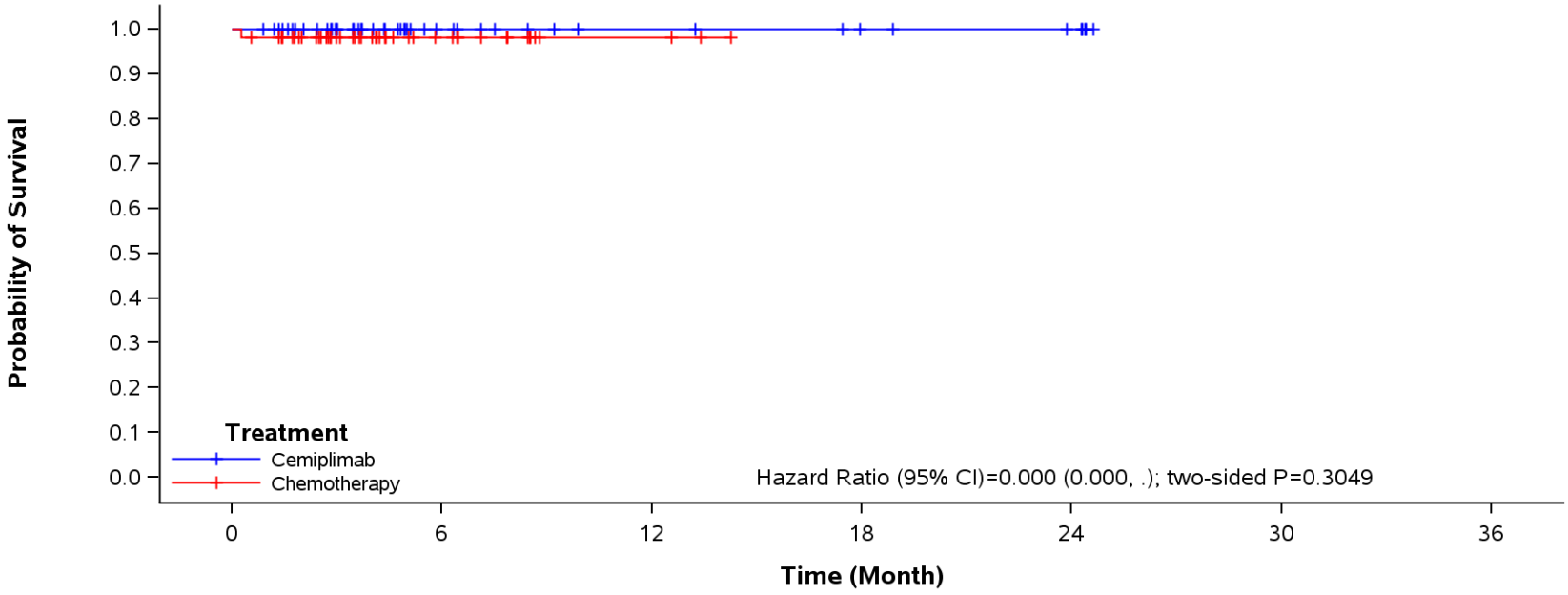
Race: Non-White
SOC: Vascular disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Race: Non-White
SOC: Vascular disorders
PT: Deep vein thrombosis



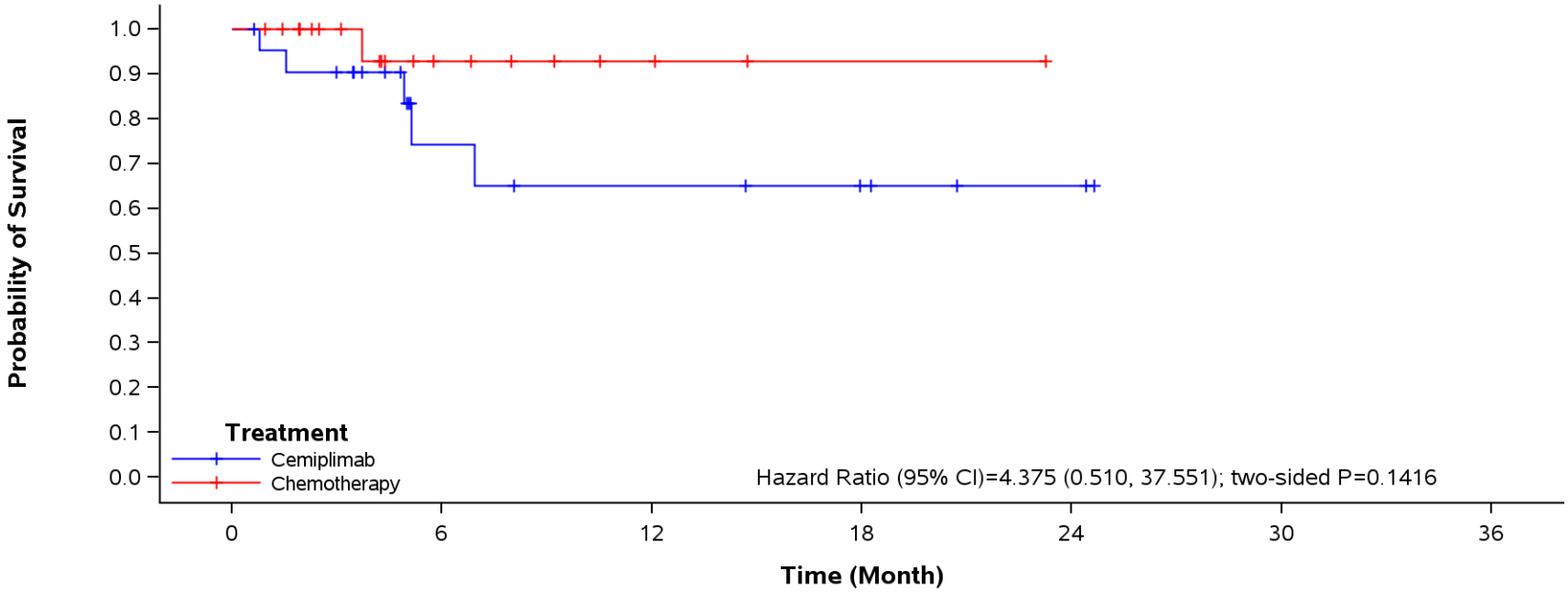

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 60 | 19 | 11 | 8 | 6 | 0 | 0 |
| Chemotherapy | 57 | 15 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
Number of patients with any TEAE leading to discontinuation



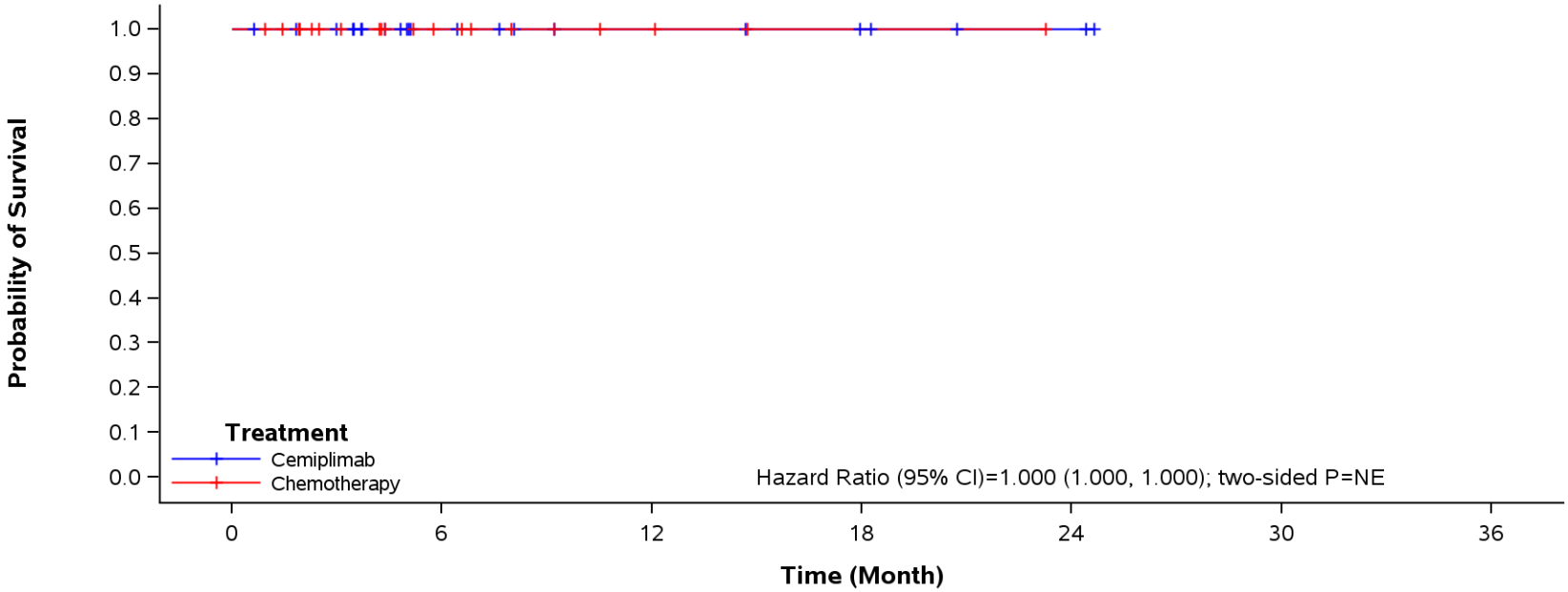

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 8 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders



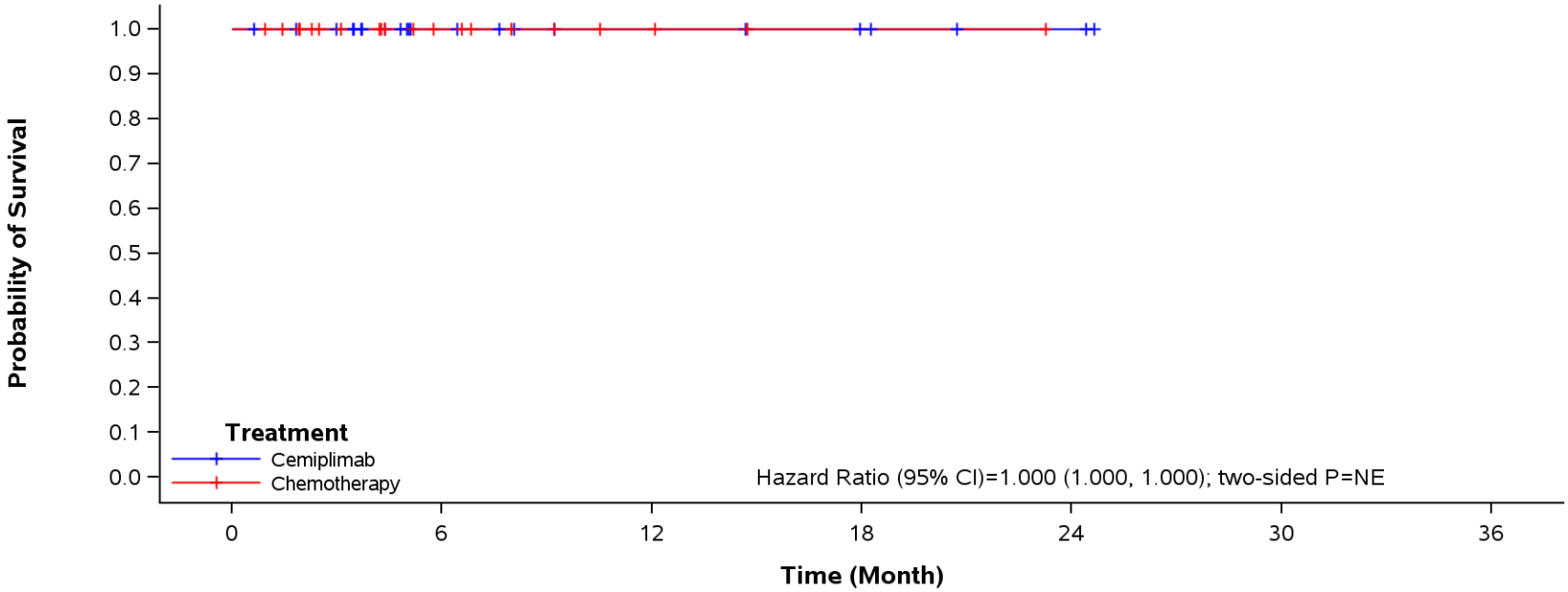

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Anaemia



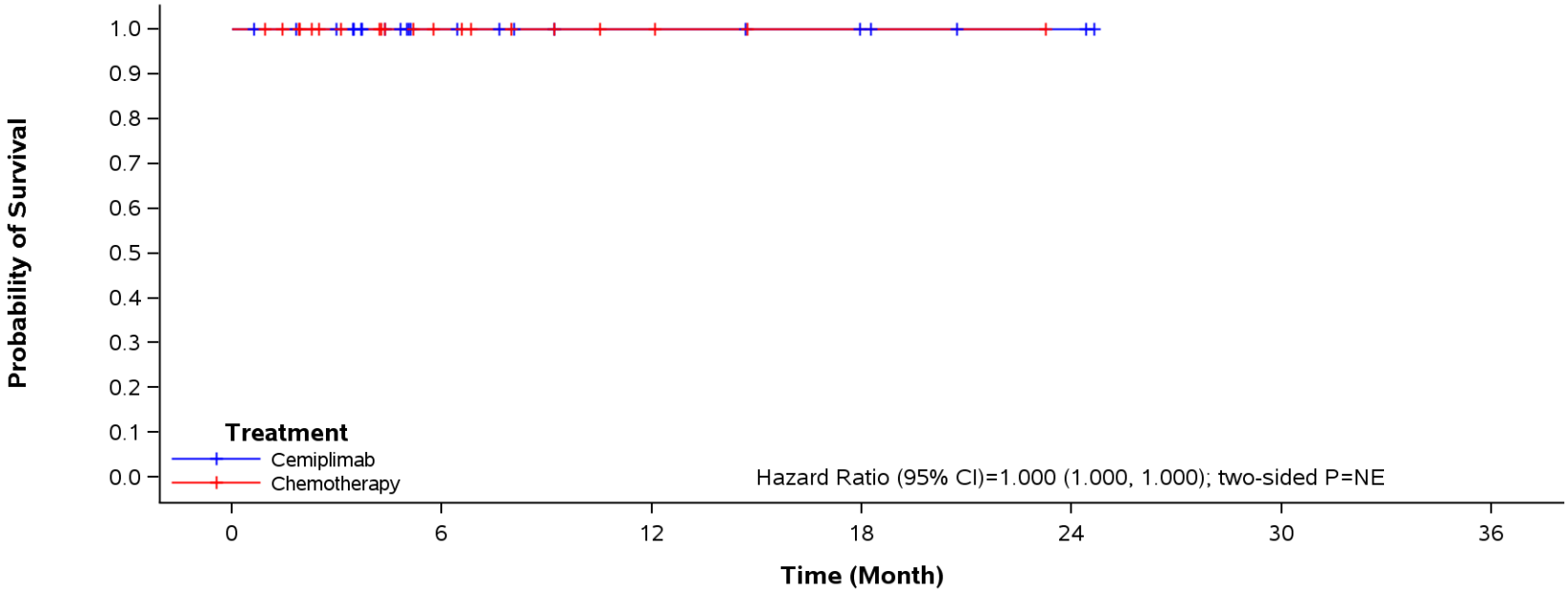

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



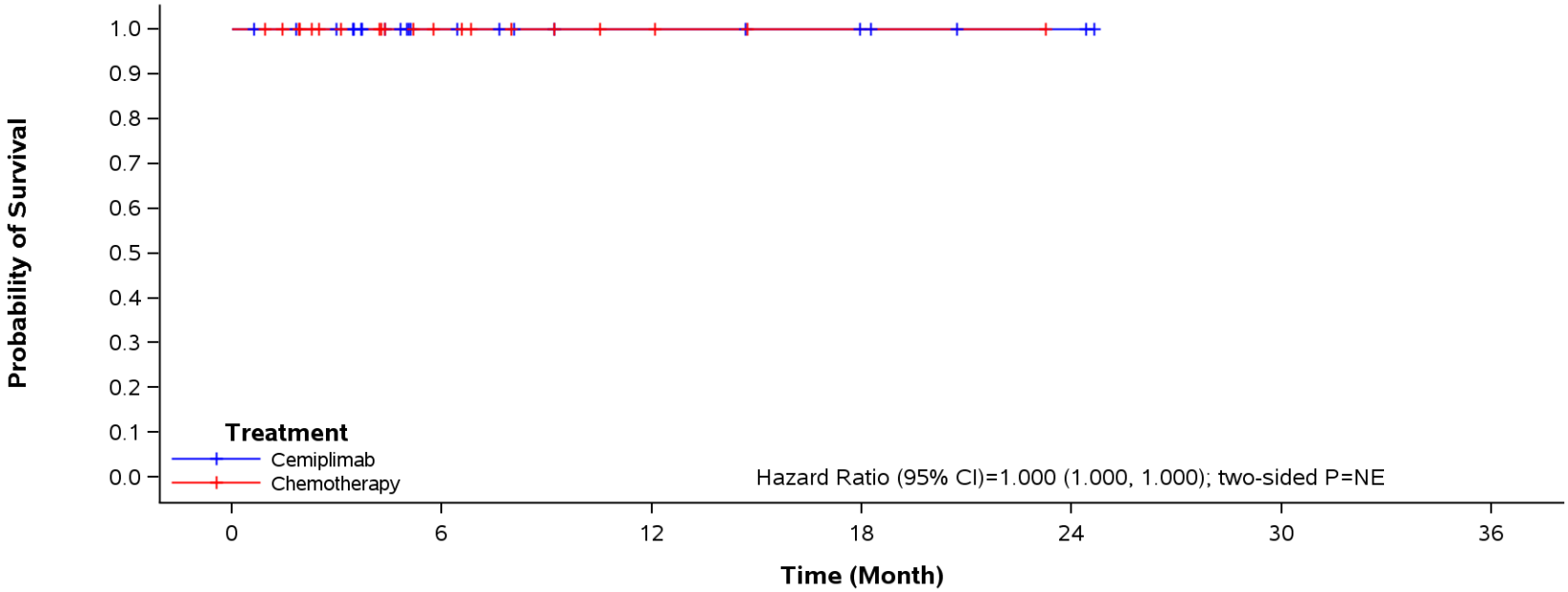

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Neutropenia



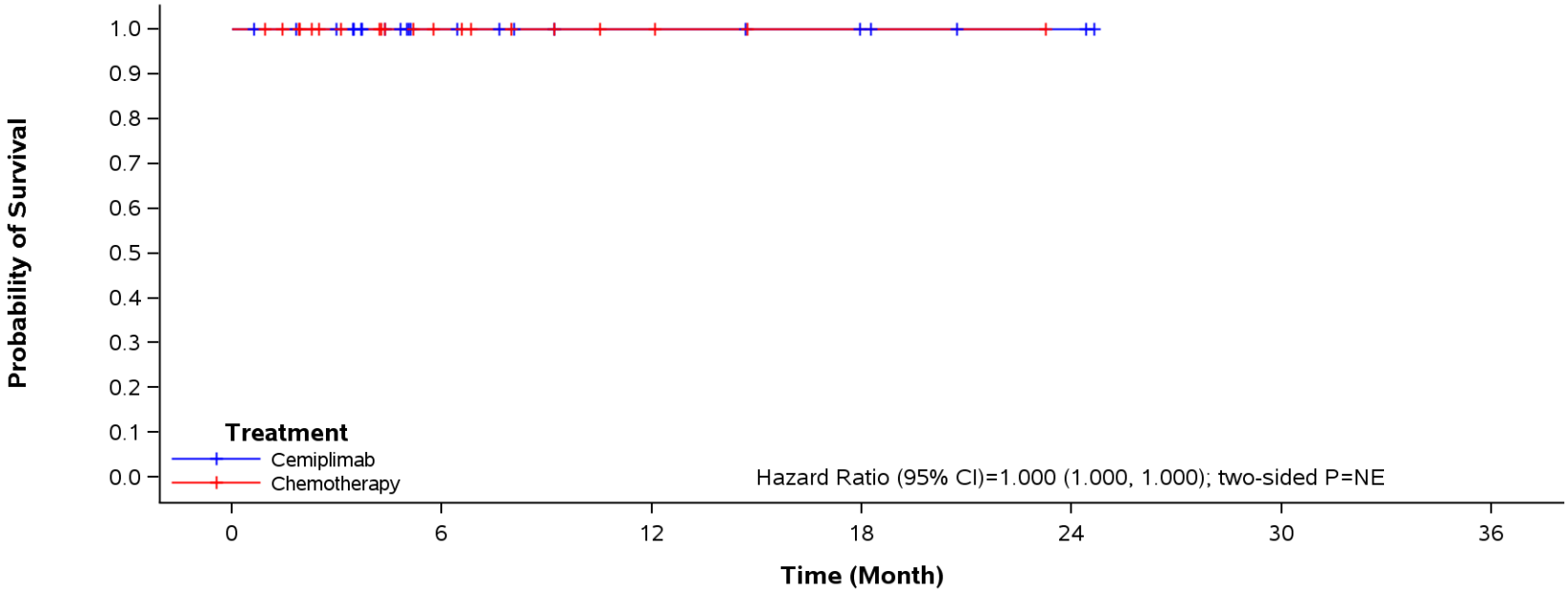

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



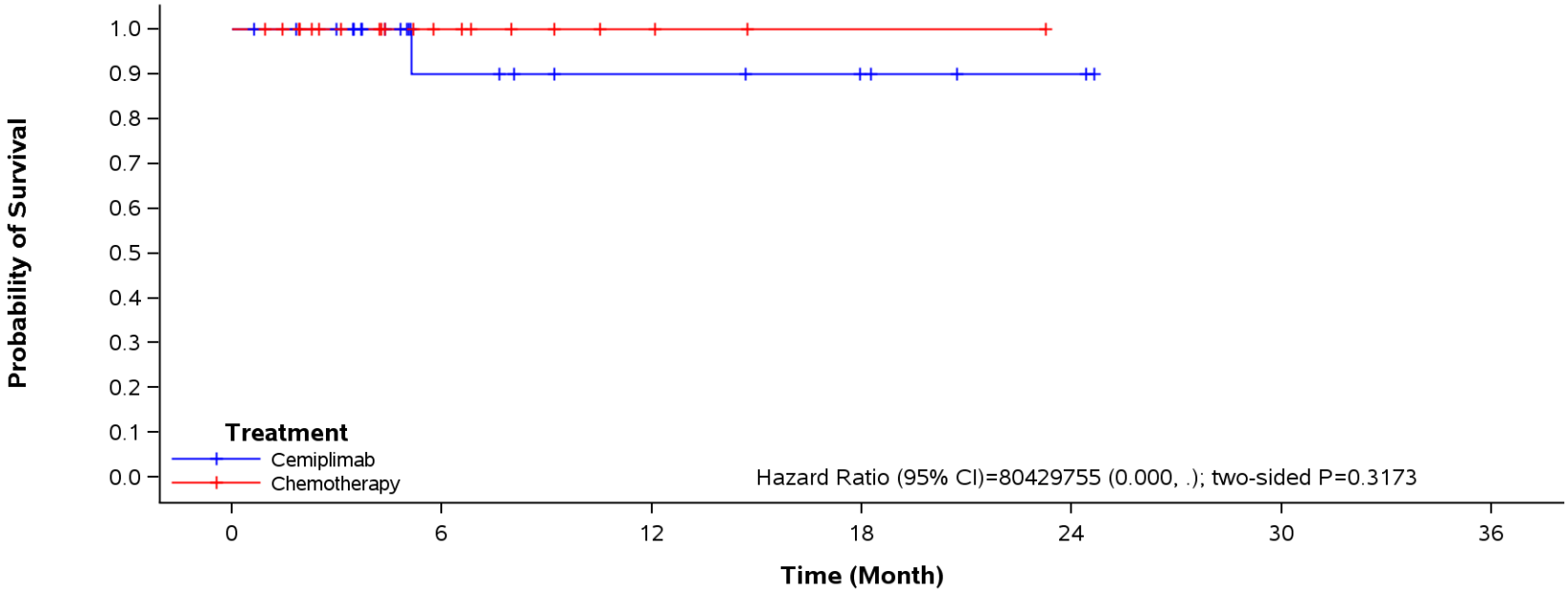

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Cardiac disorders



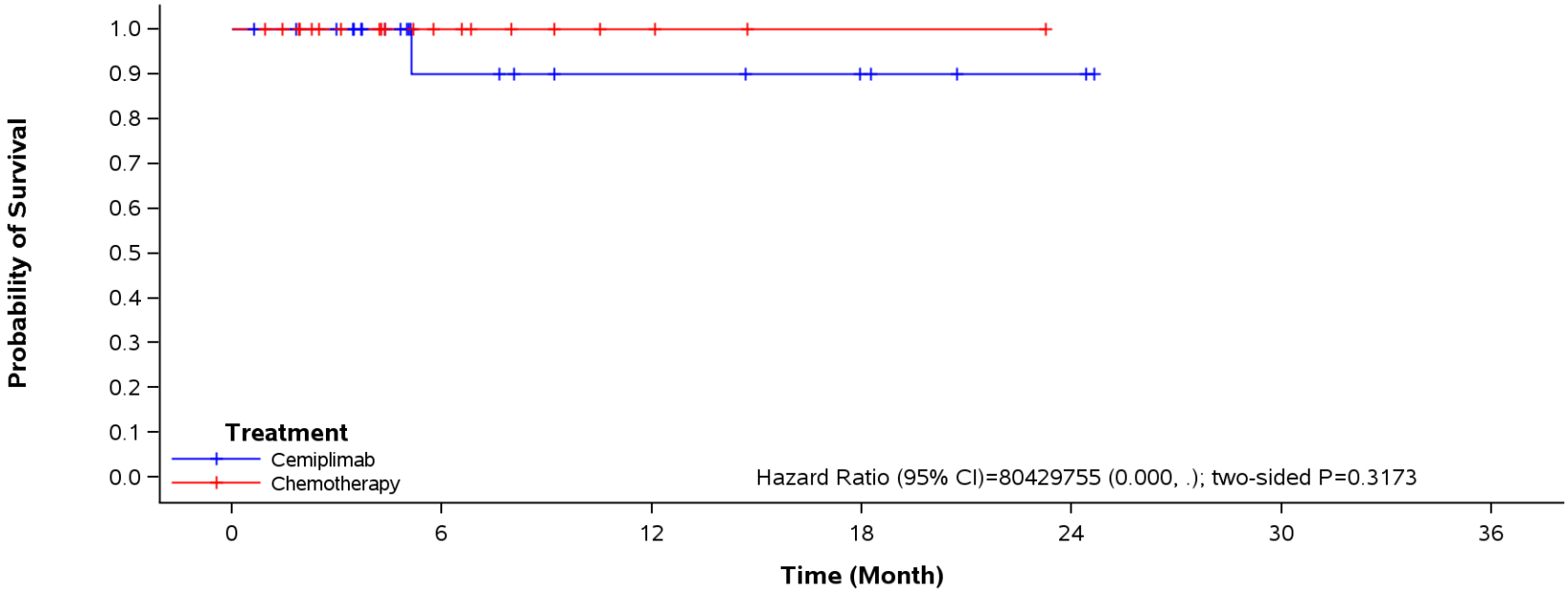

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 9 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Cardiac disorders
PT: Autoimmune pericarditis



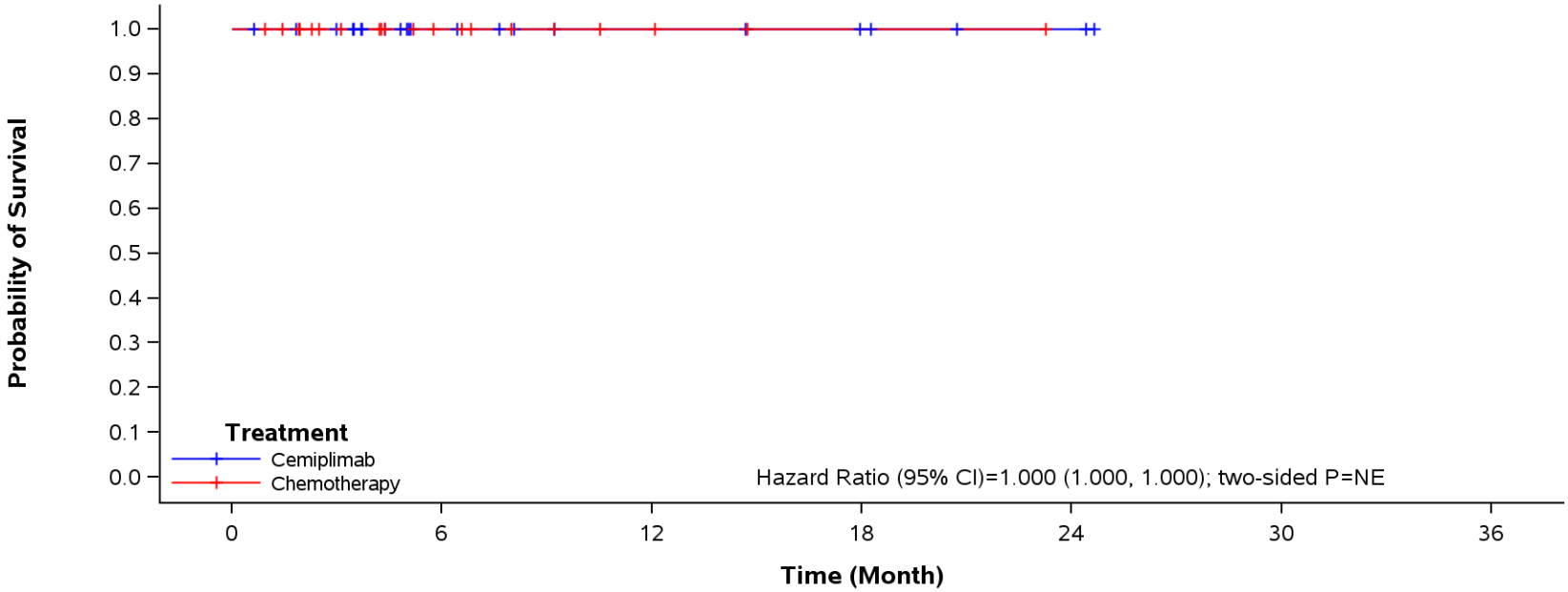

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 9 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Endocrine disorders



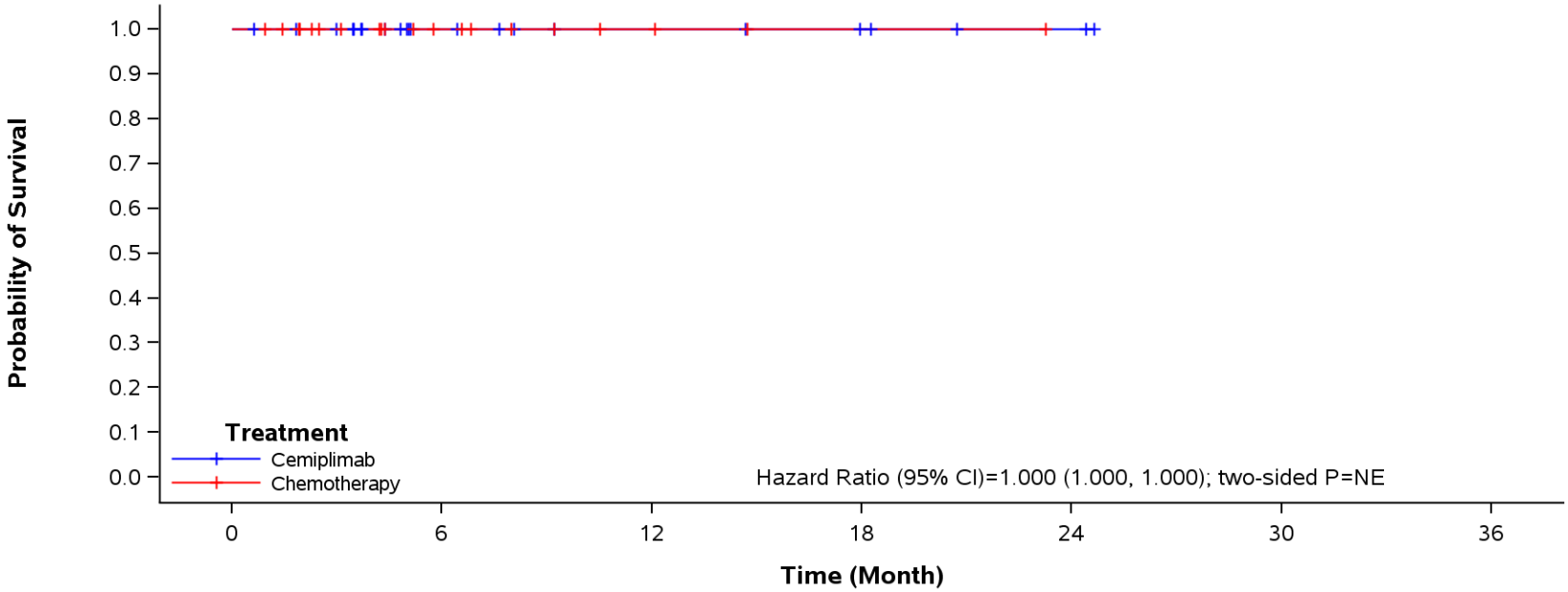

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Endocrine disorders
PT: Hypothyroidism



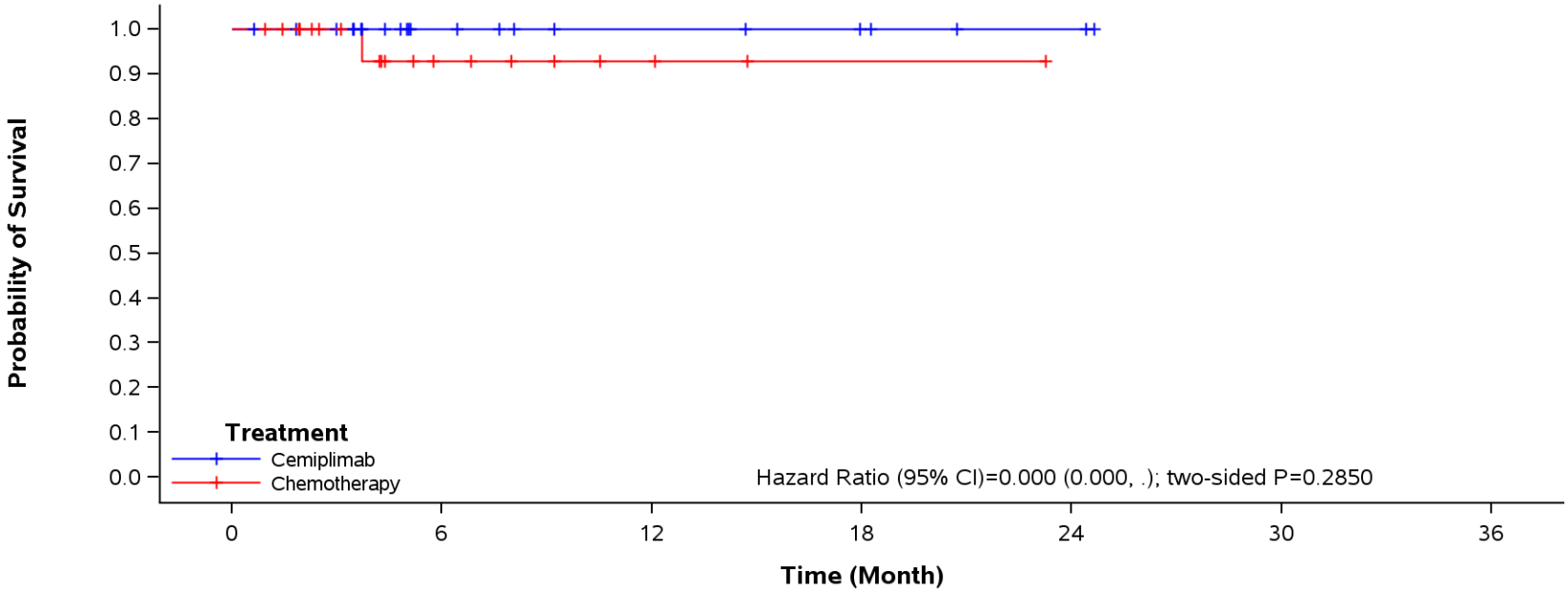

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders



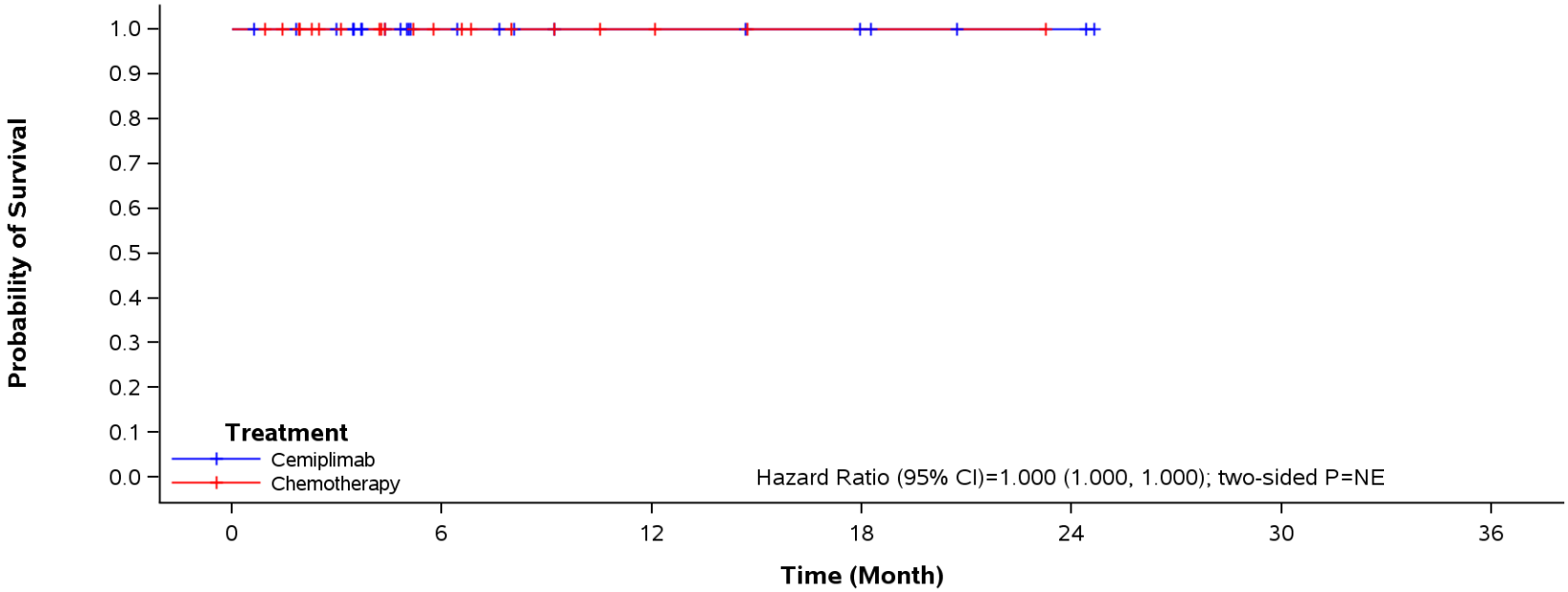

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders
PT: Colitis



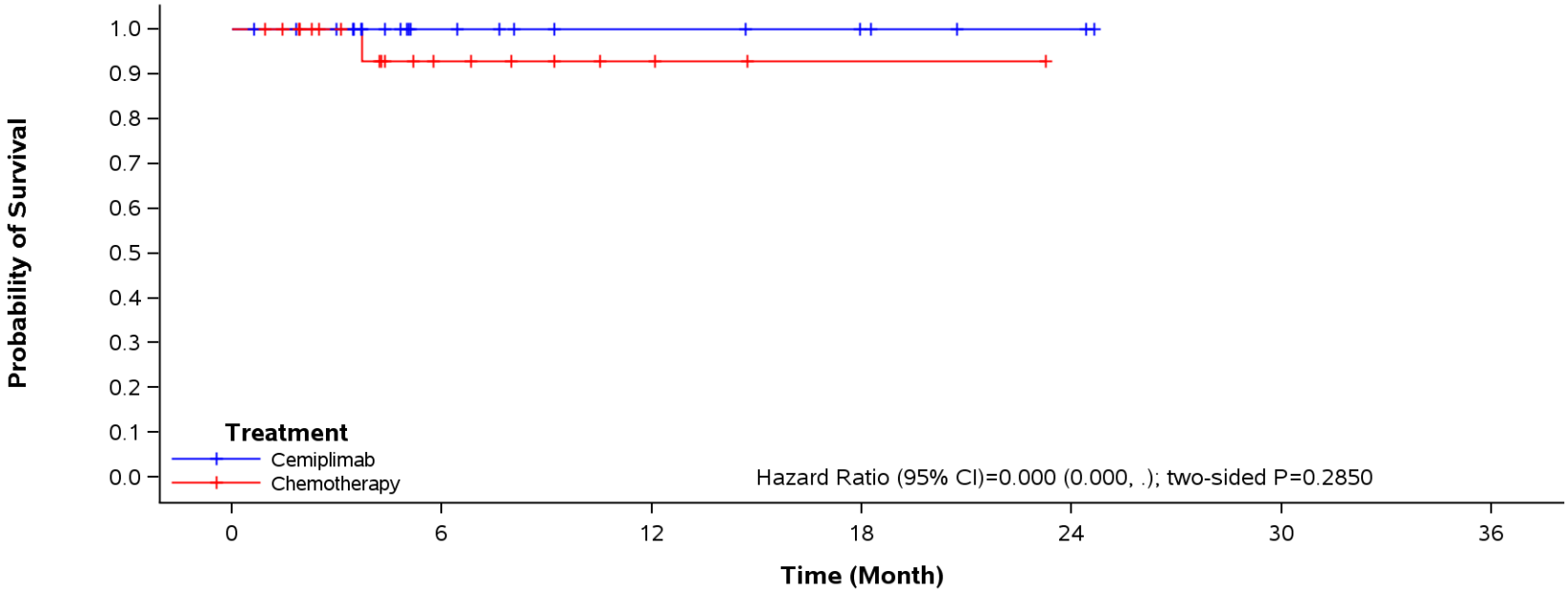

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders
PT: Diverticular perforation



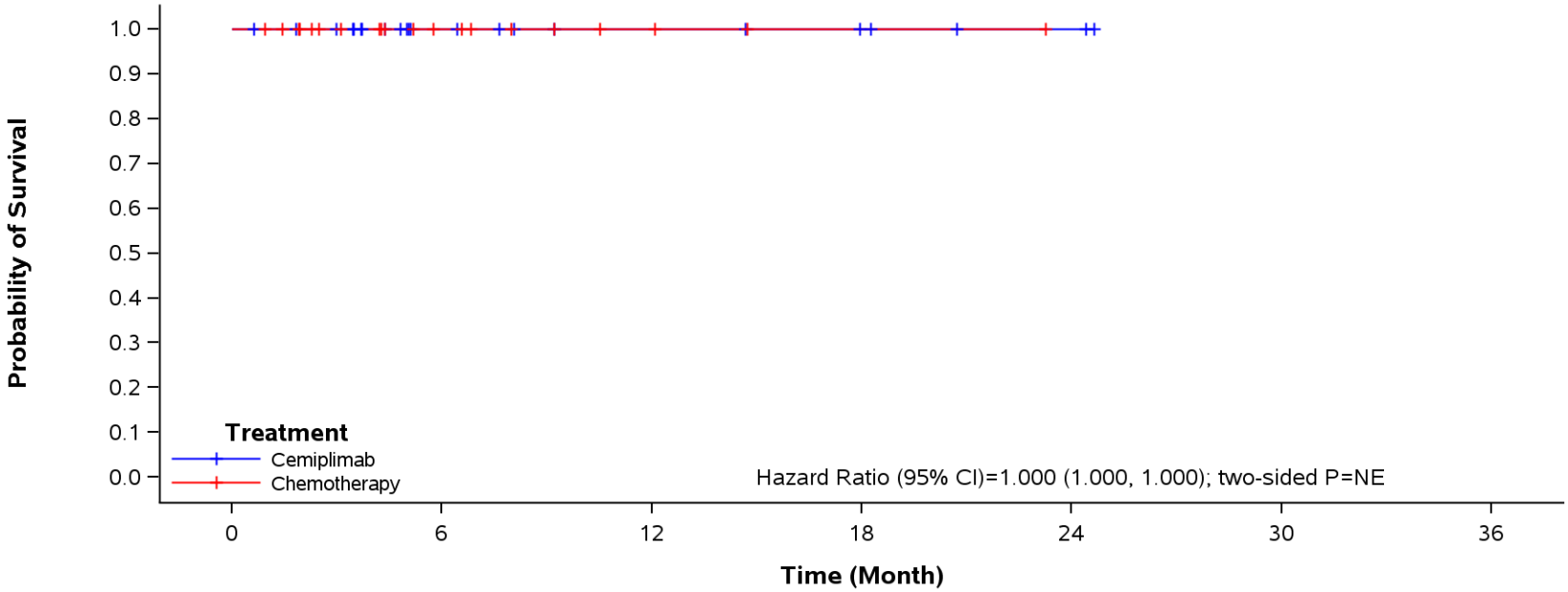

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 7 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders
PT: Pancreatic mass



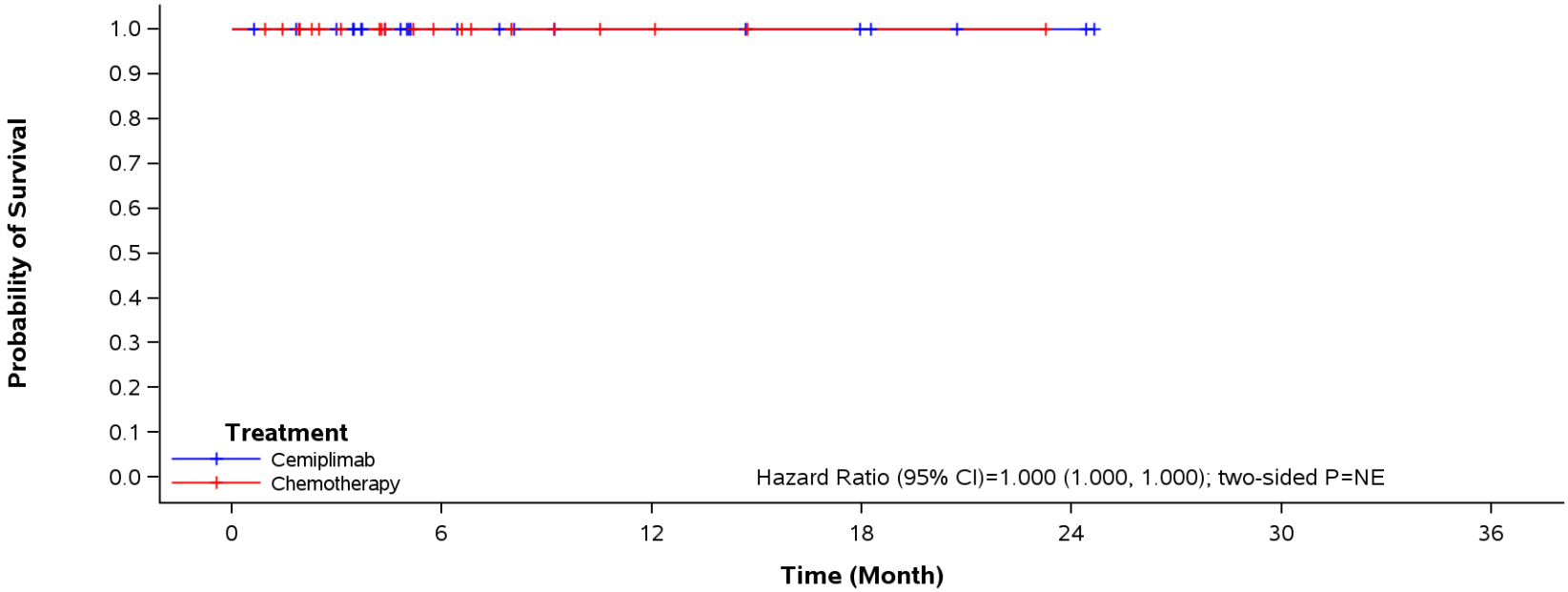

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



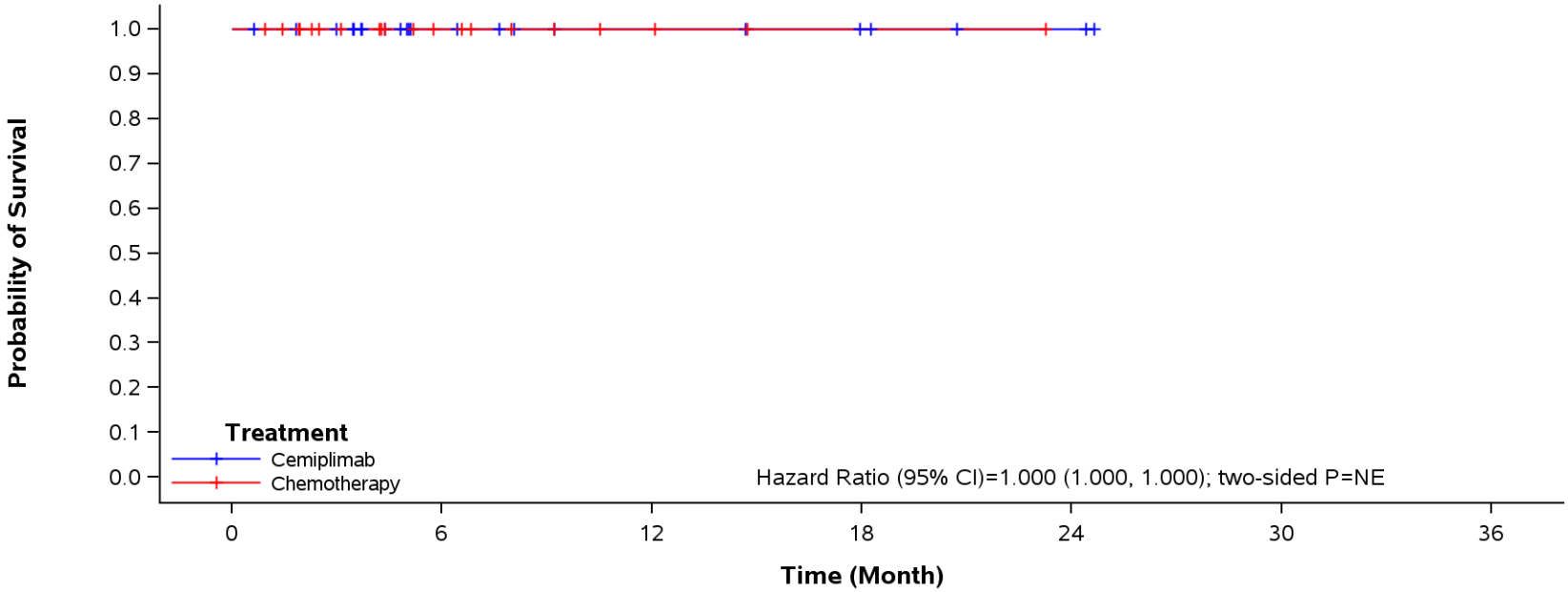

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Gastrointestinal disorders
PT: Proctalgia



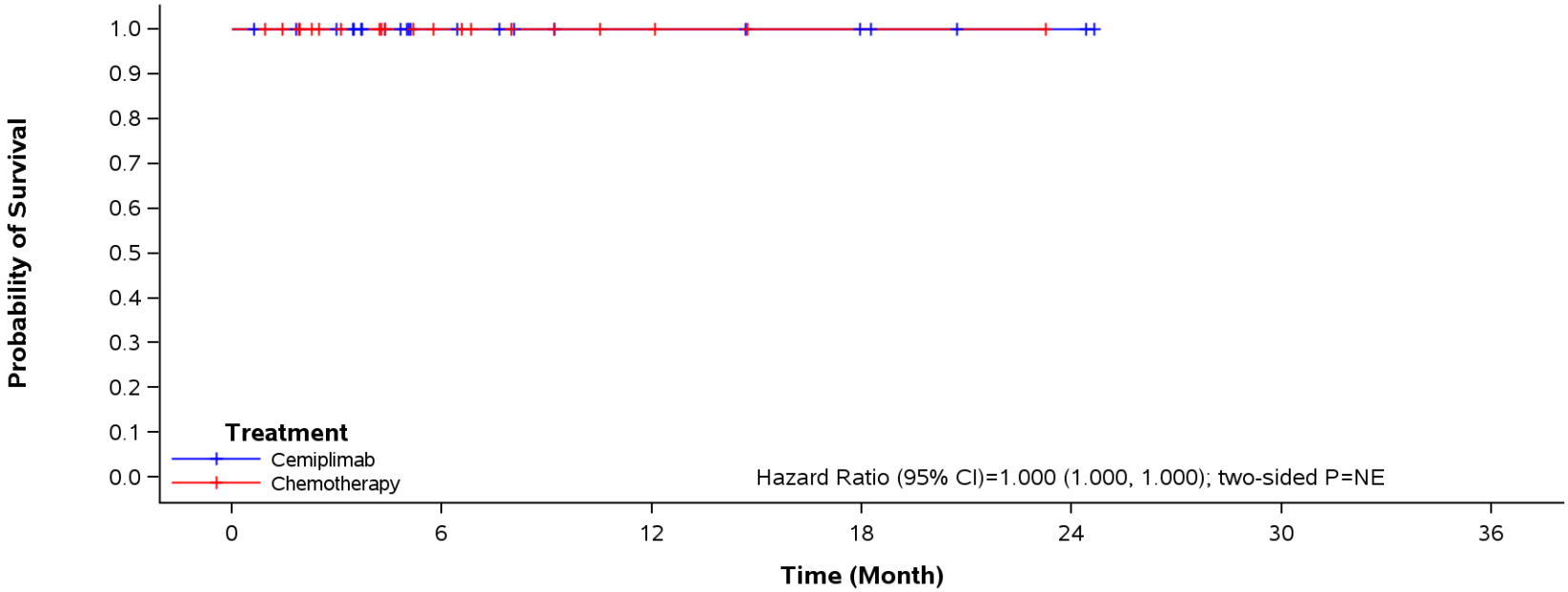

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: General disorders and administration site conditions



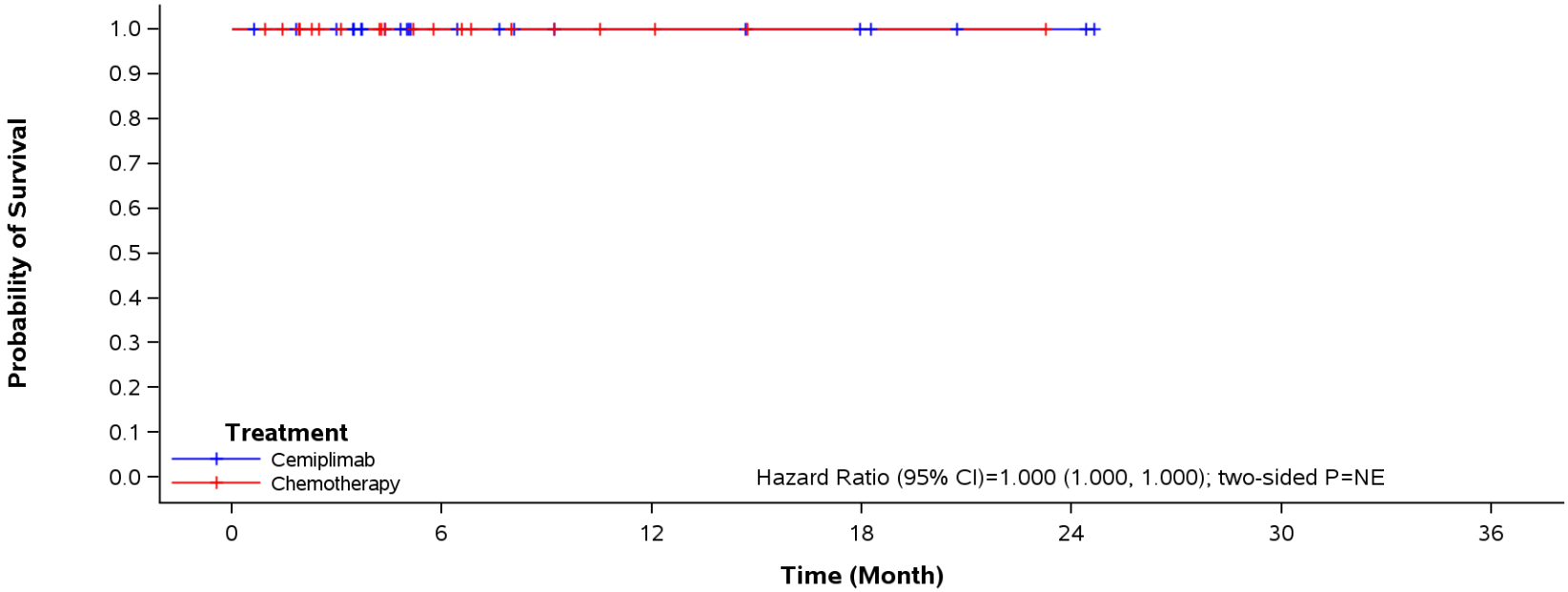

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: General disorders and administration site conditions
PT: Malaise



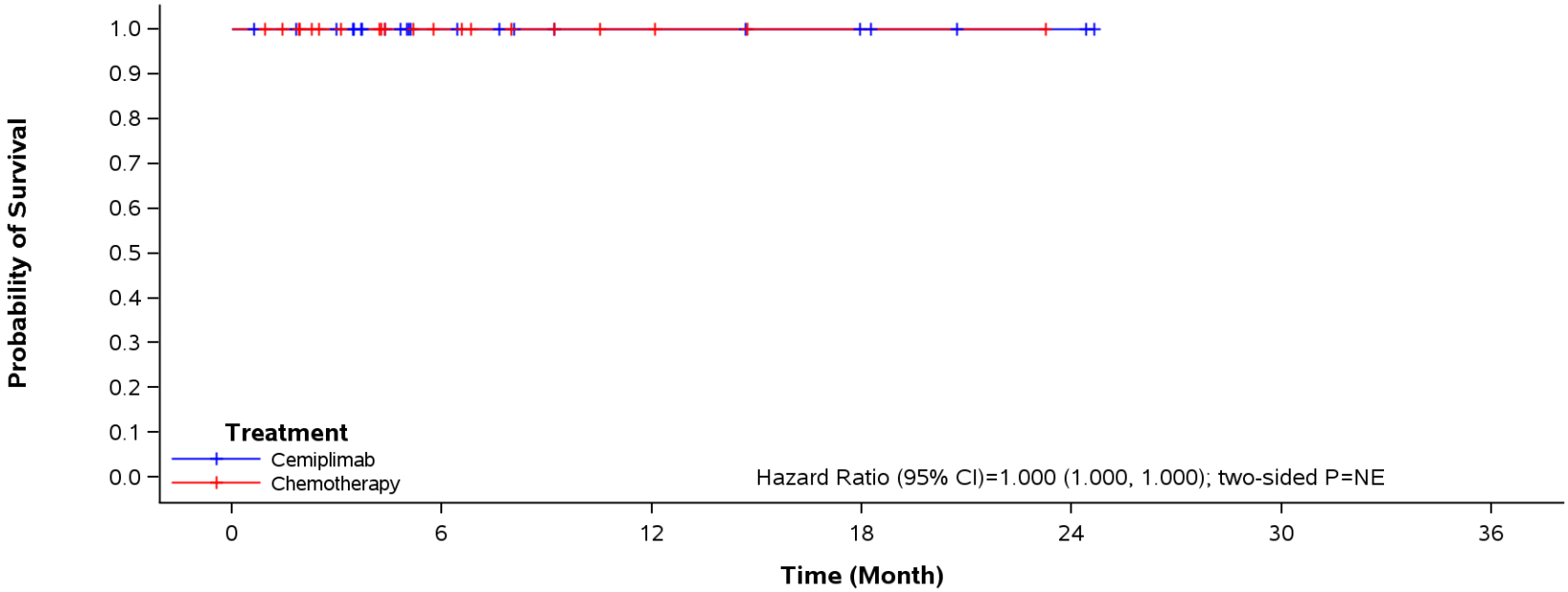

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



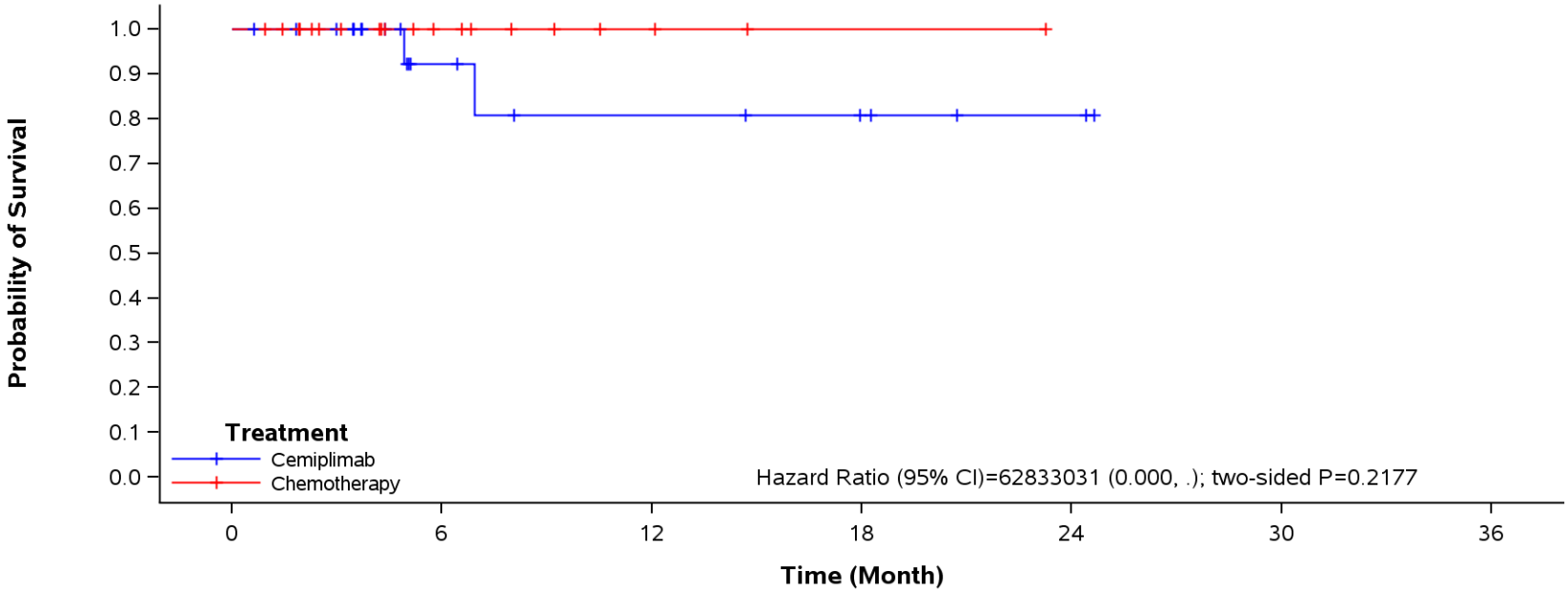

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Hepatobiliary disorders



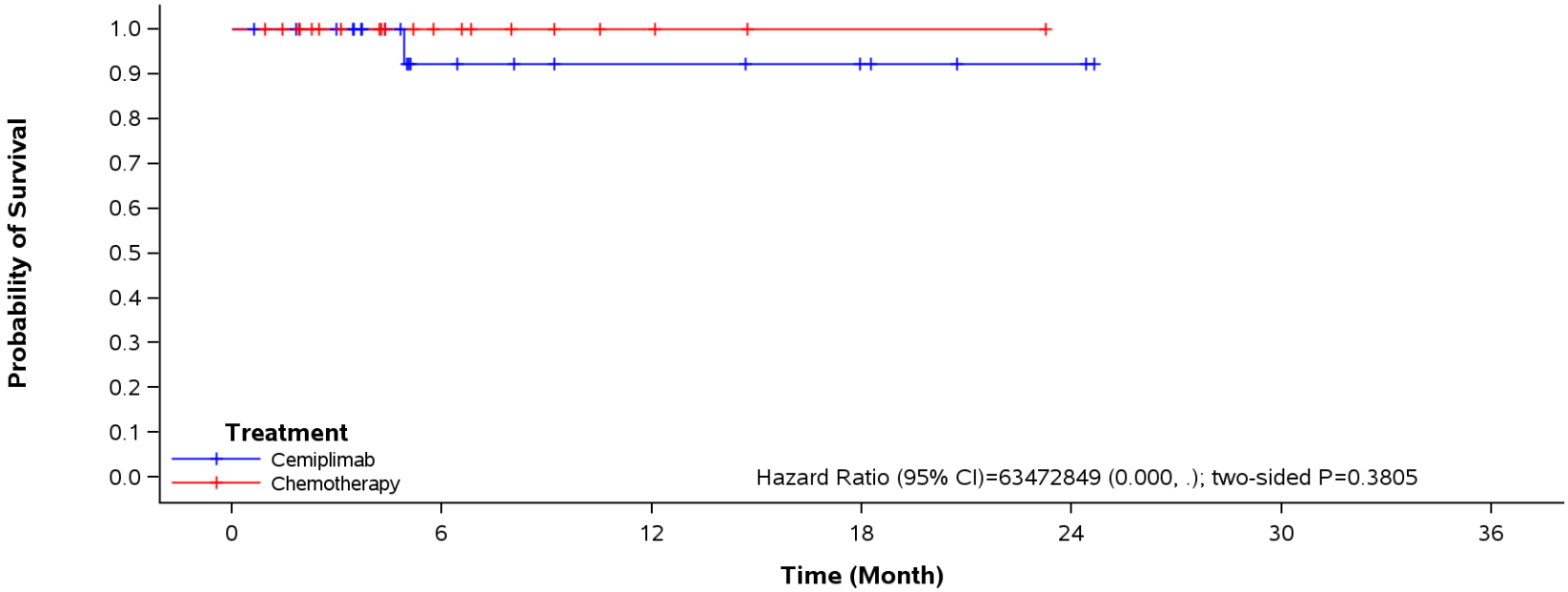

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 9 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



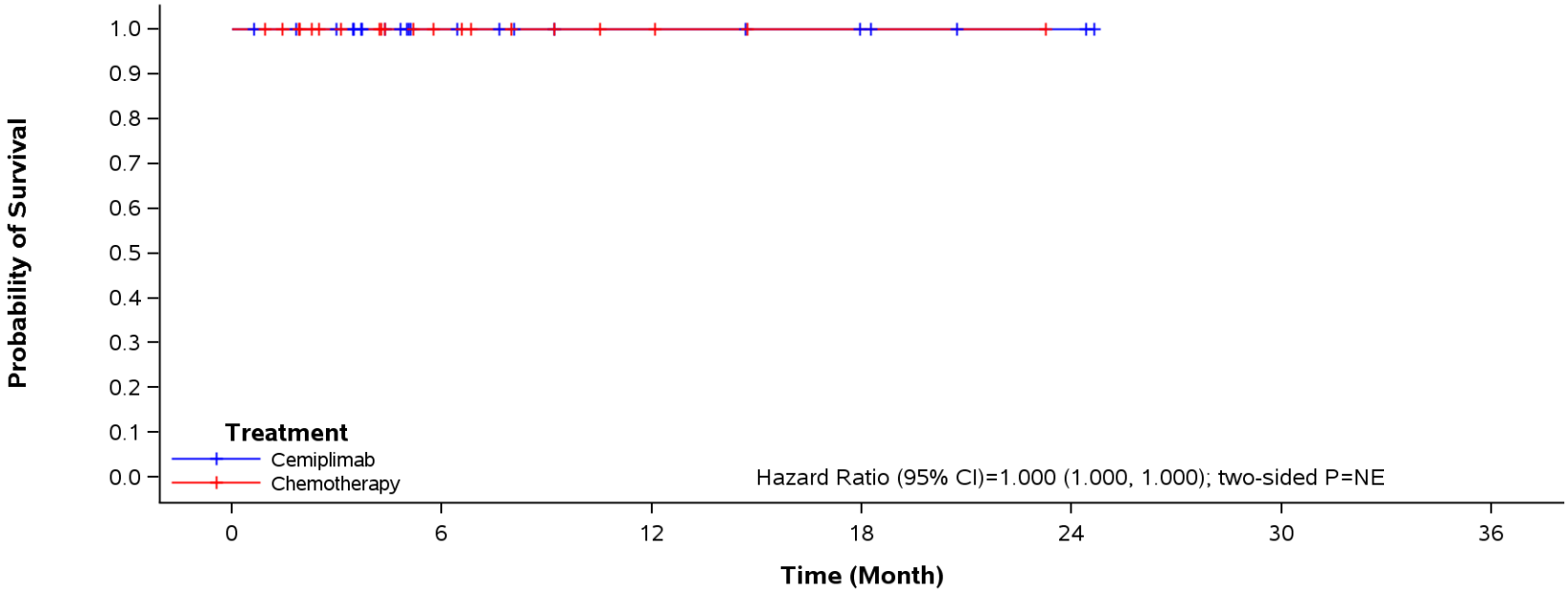

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 9 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



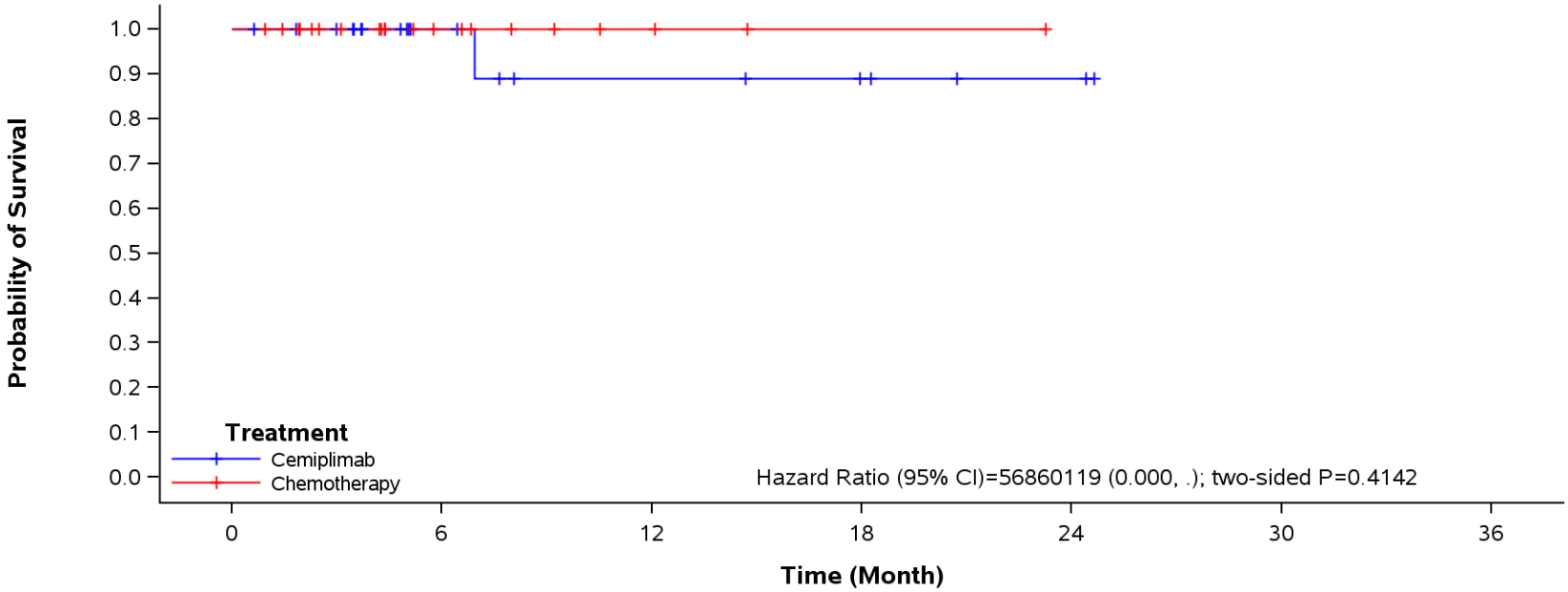

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Hepatobiliary disorders
PT: Hepatitis



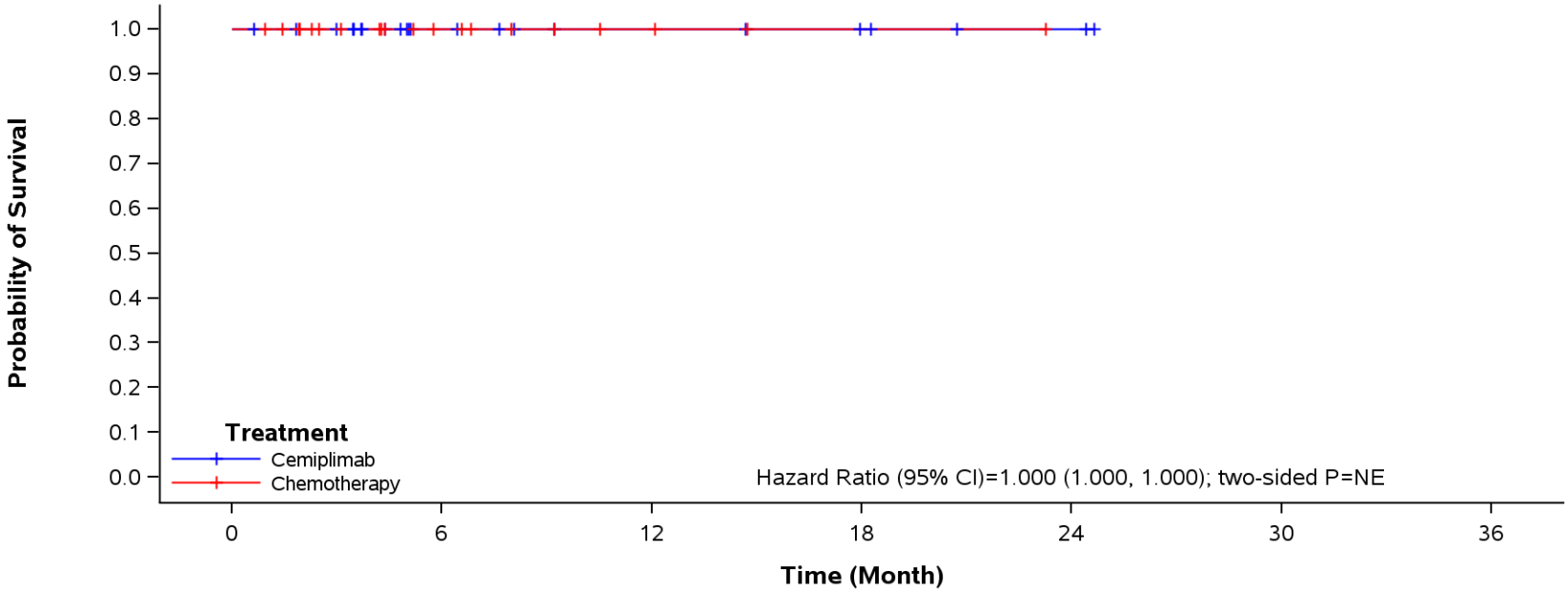

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



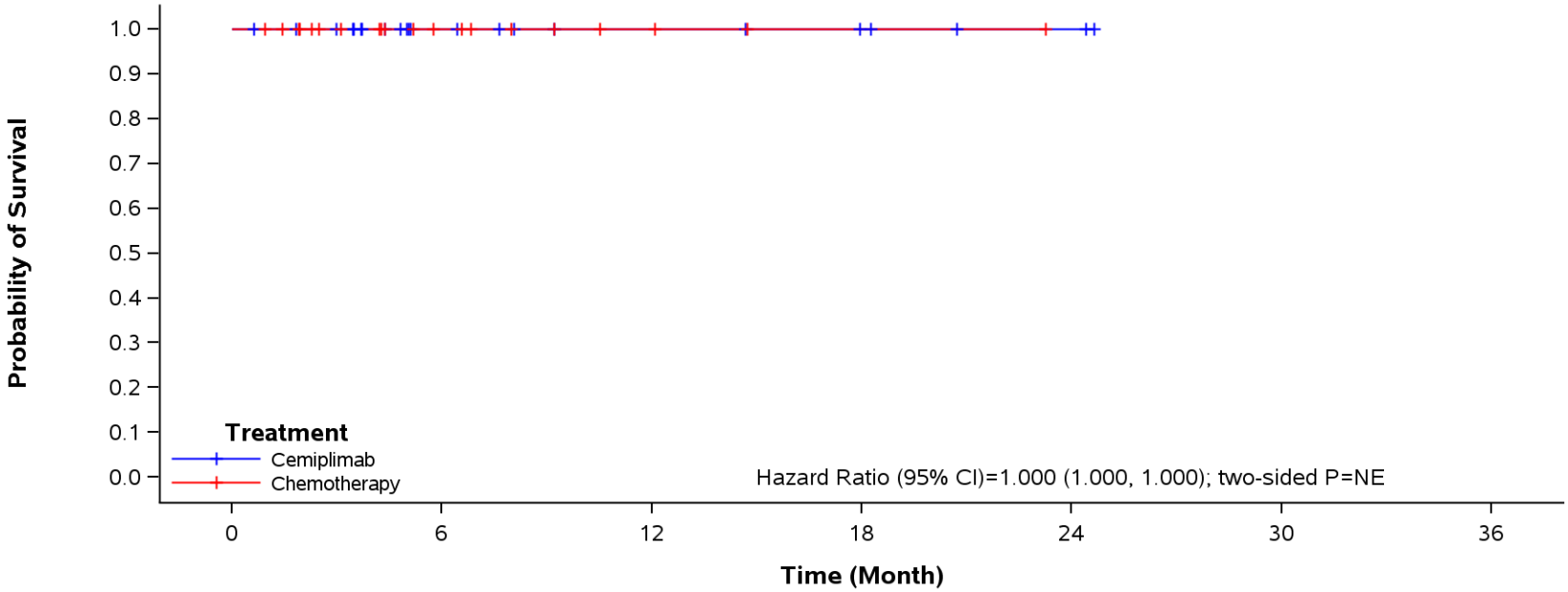

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Infections and infestations



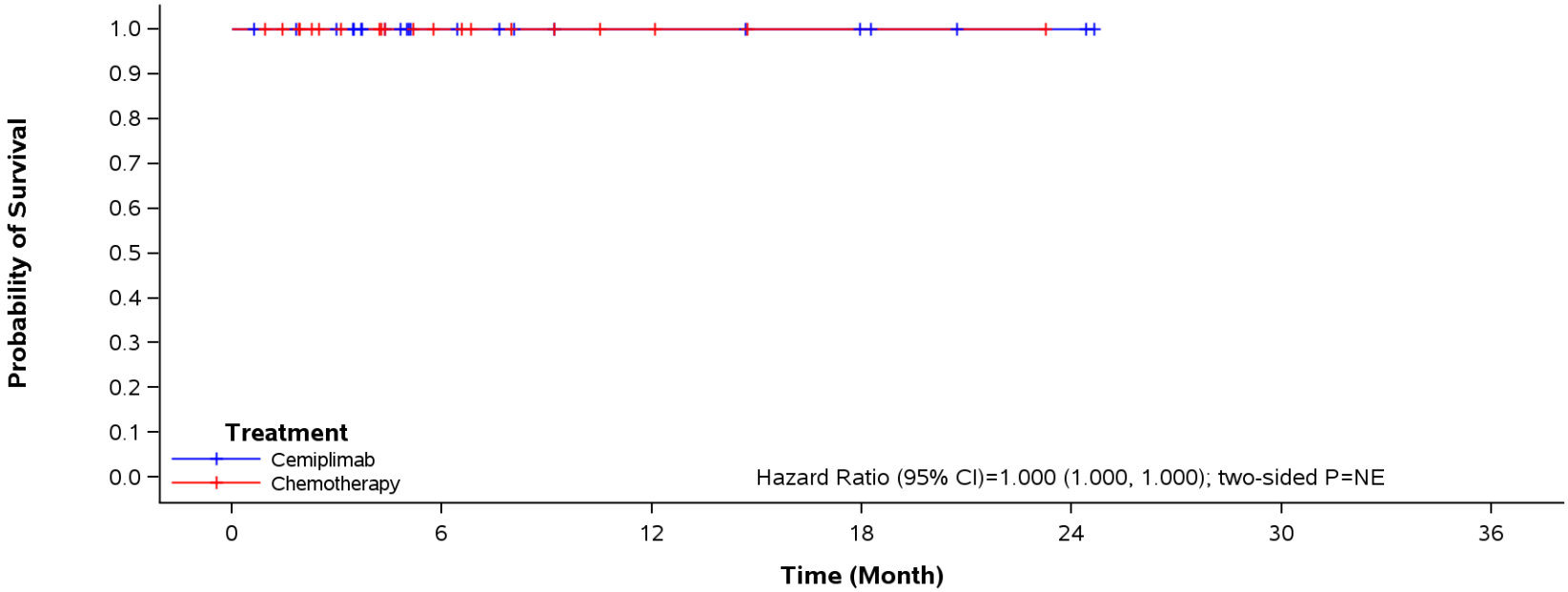

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Infections and infestations
PT: COVID-19 pneumonia



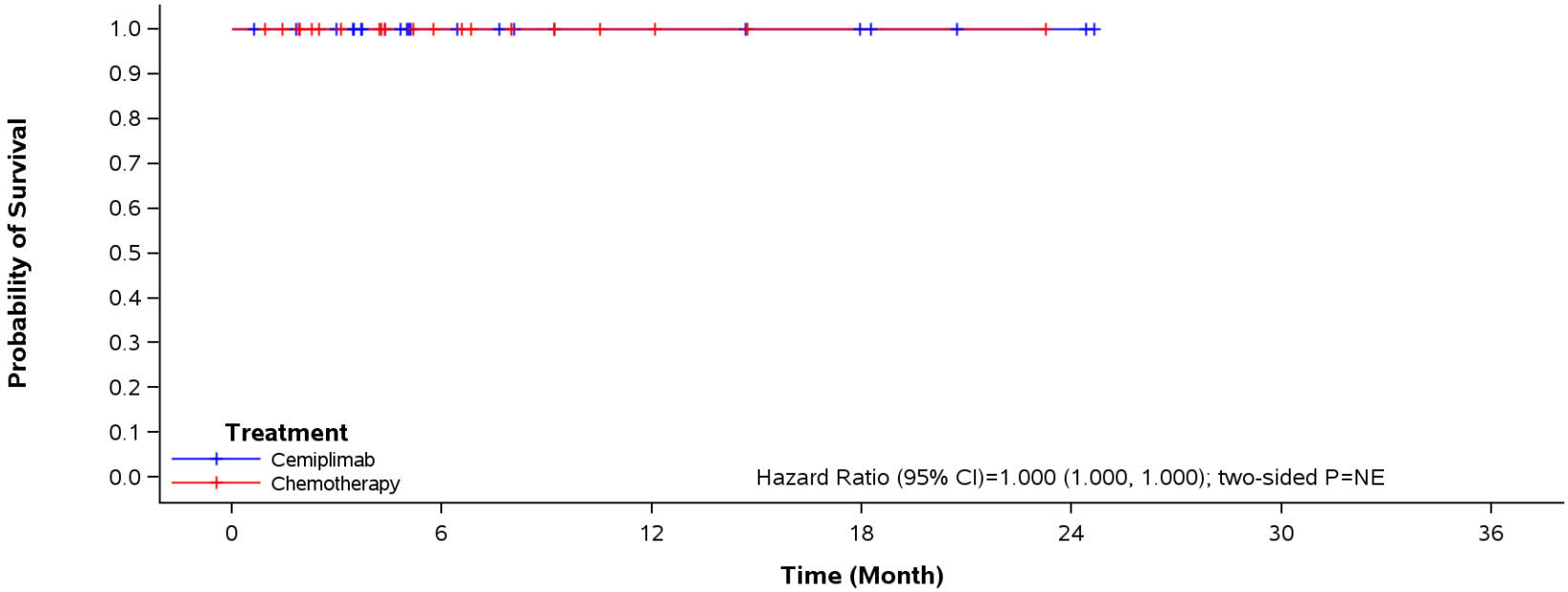

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Infections and infestations
PT: Gastroenteritis



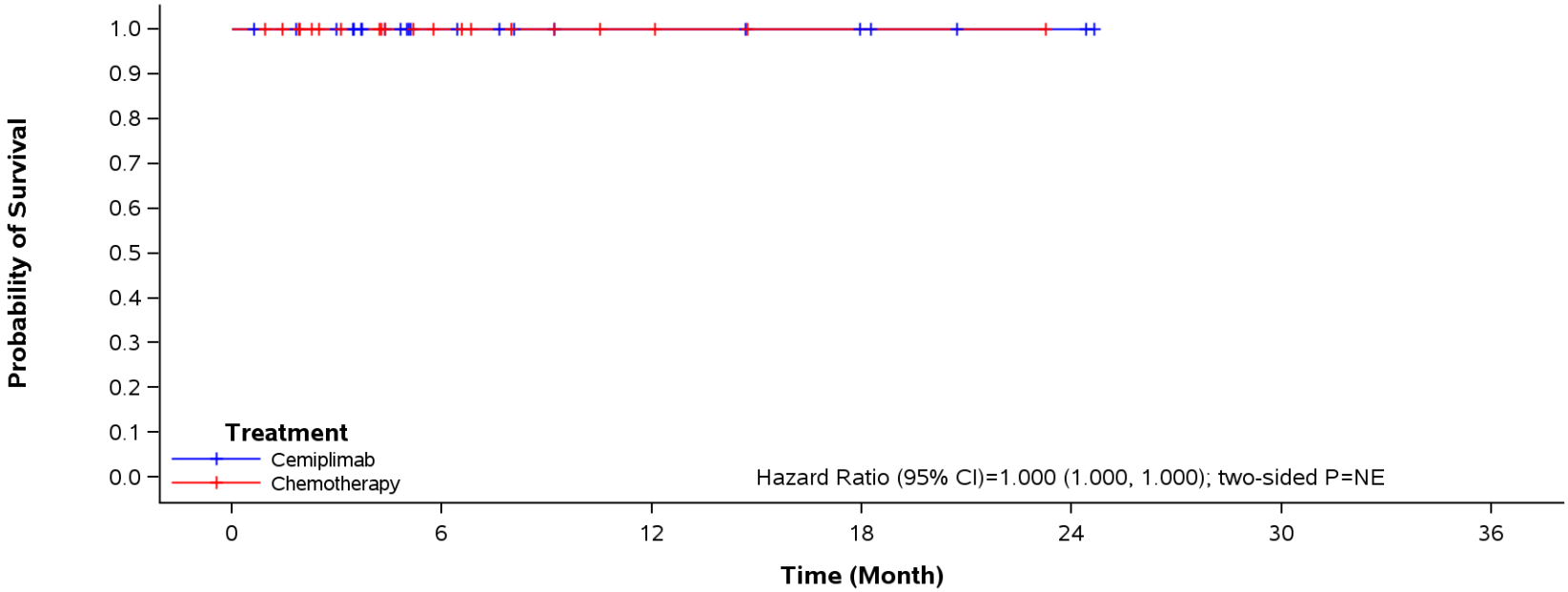

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Infections and infestations
PT: Pelvic abscess



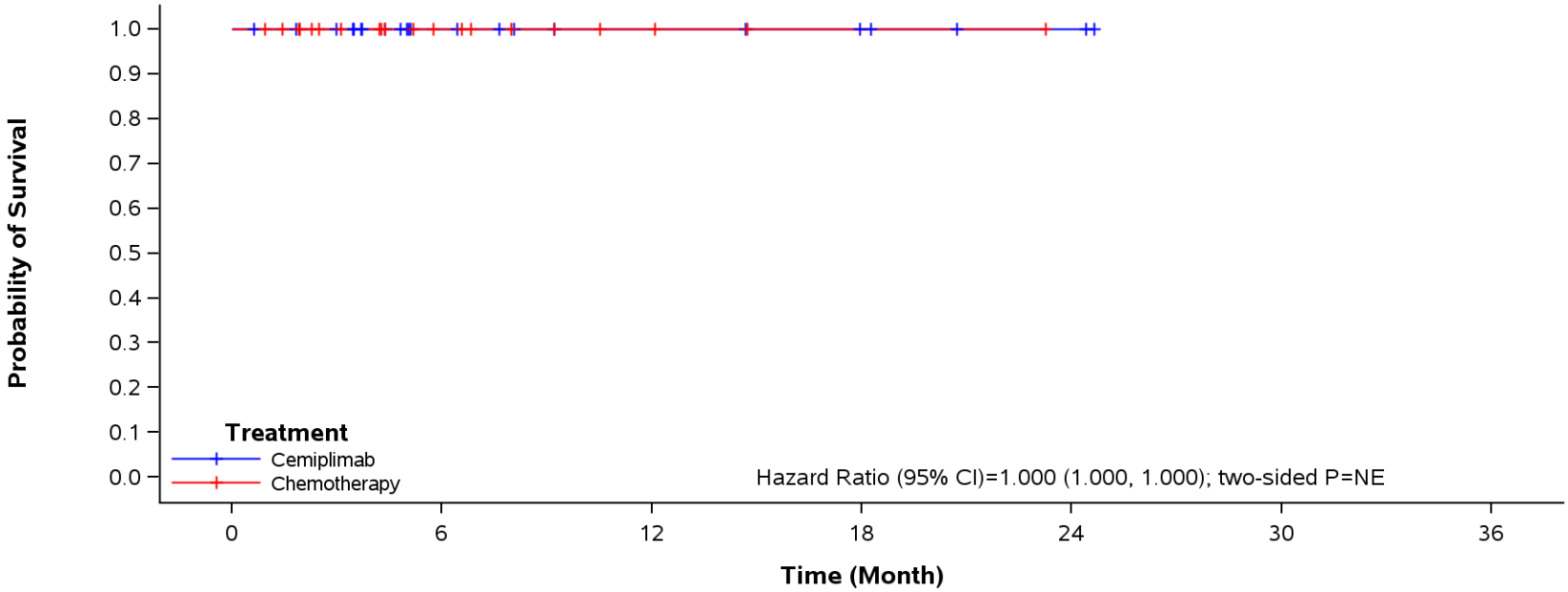

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Infections and infestations
PT: Peritonitis



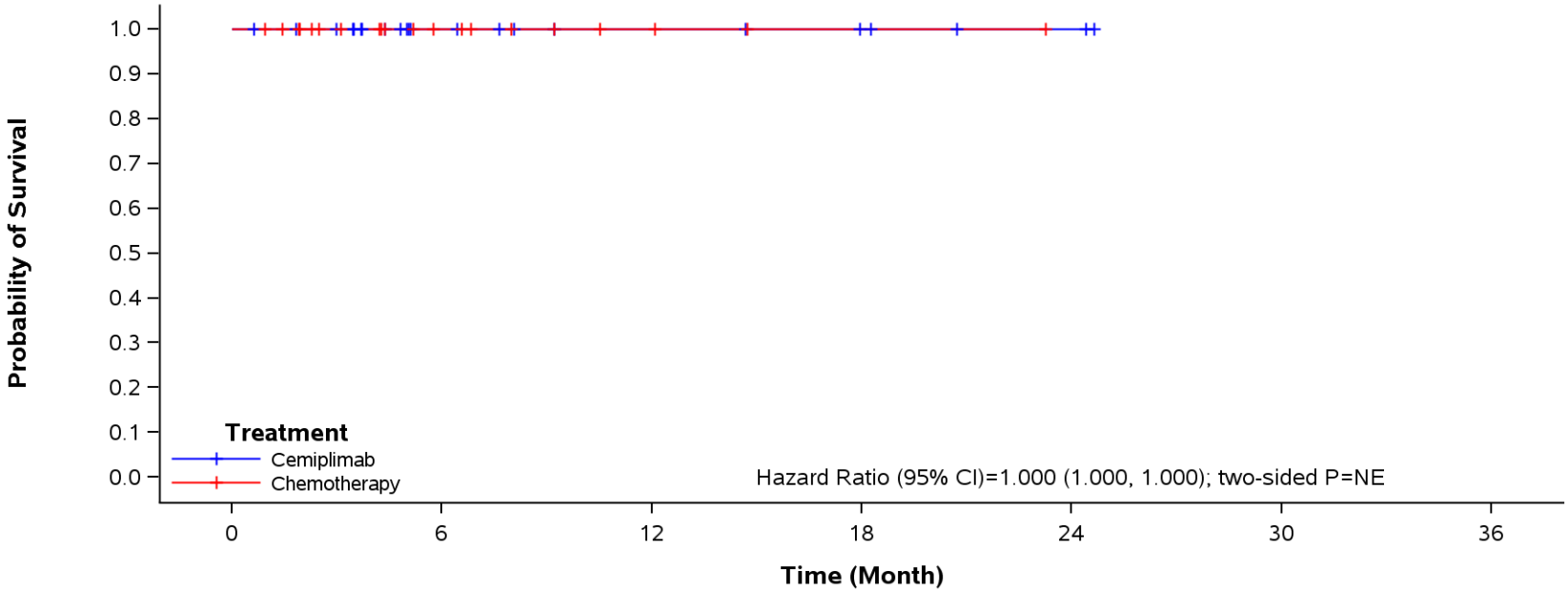

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Infections and infestations
PT: Pneumonia



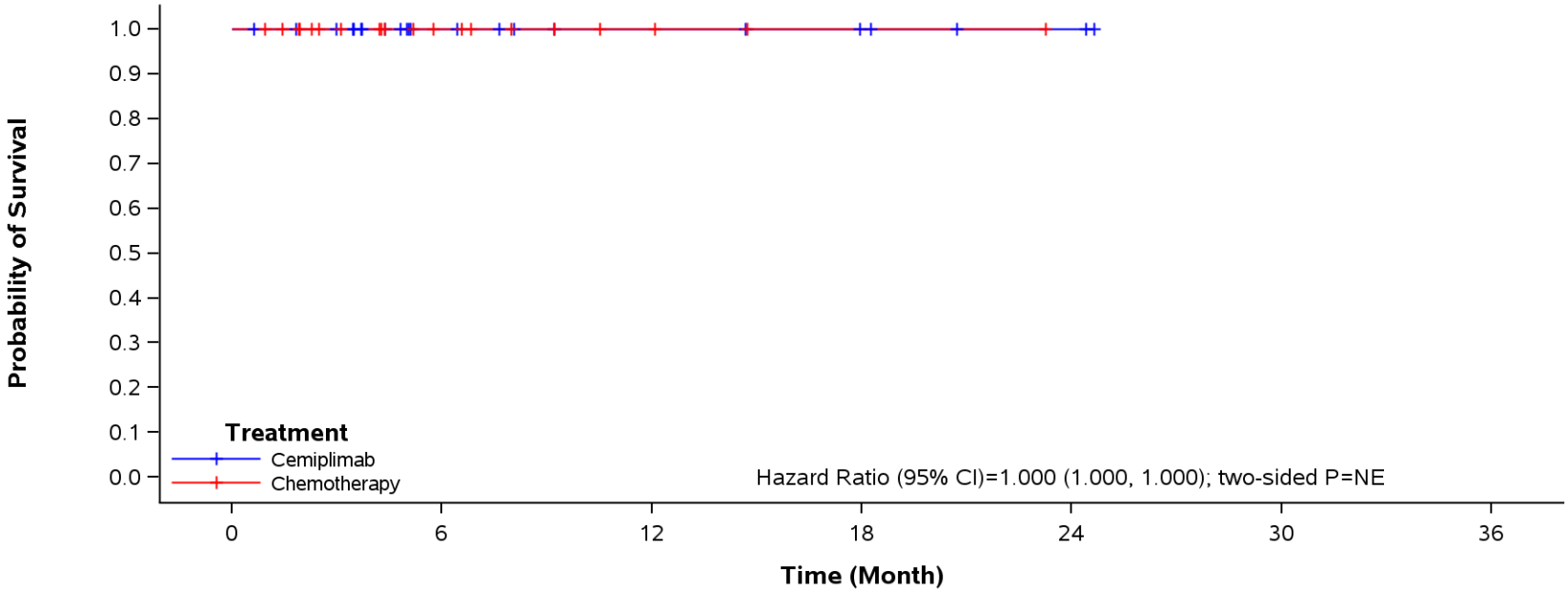

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Infections and infestations
PT: Pyomyositis



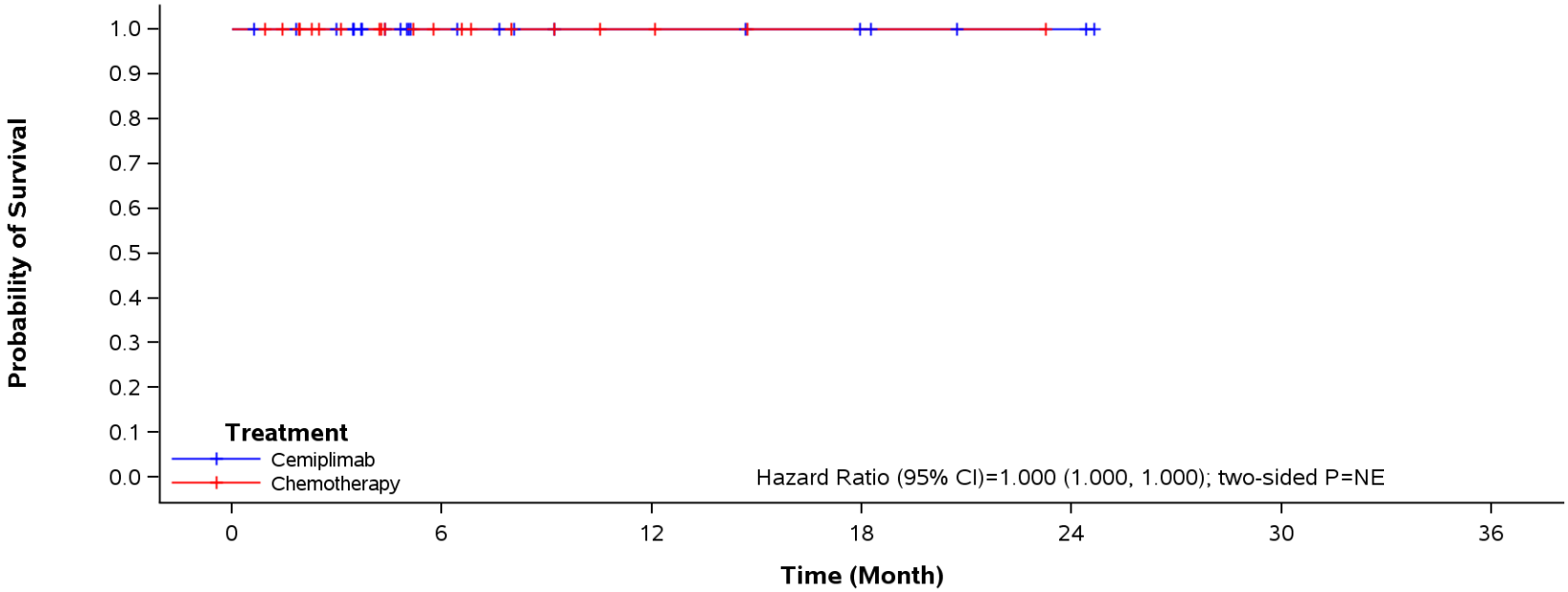

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Injury, poisoning and procedural complications



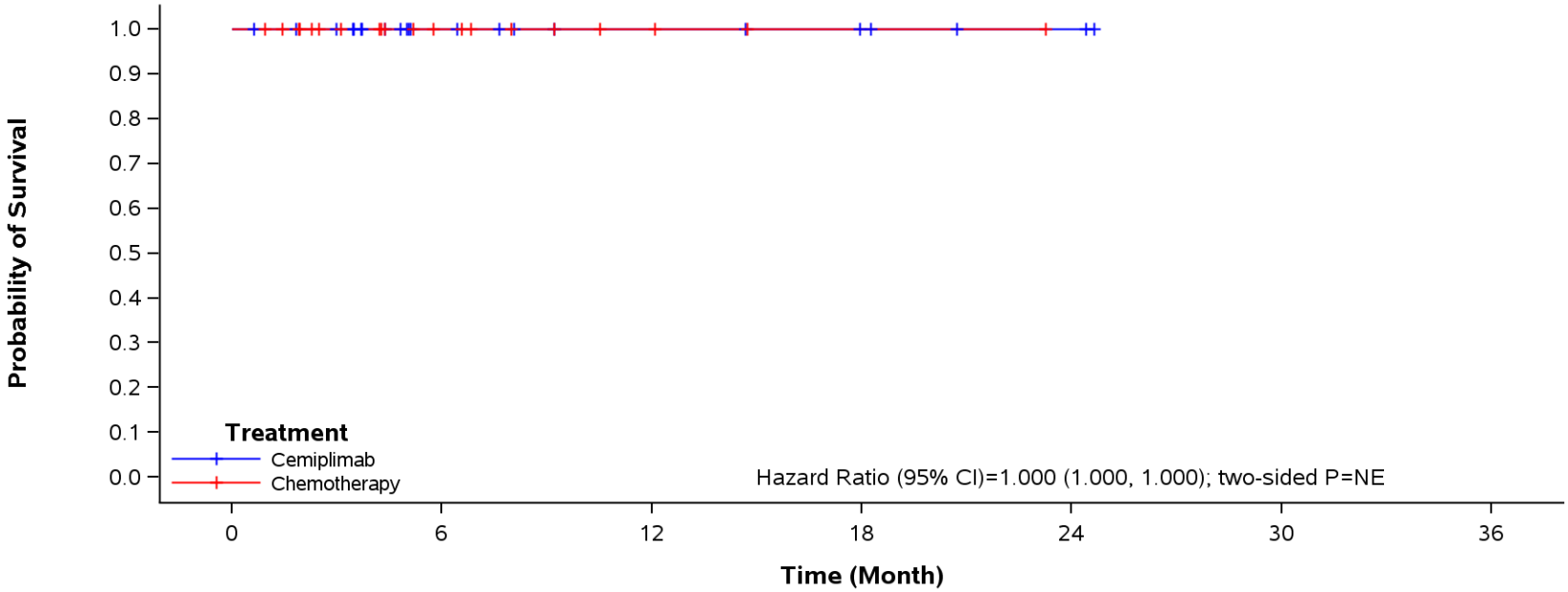

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



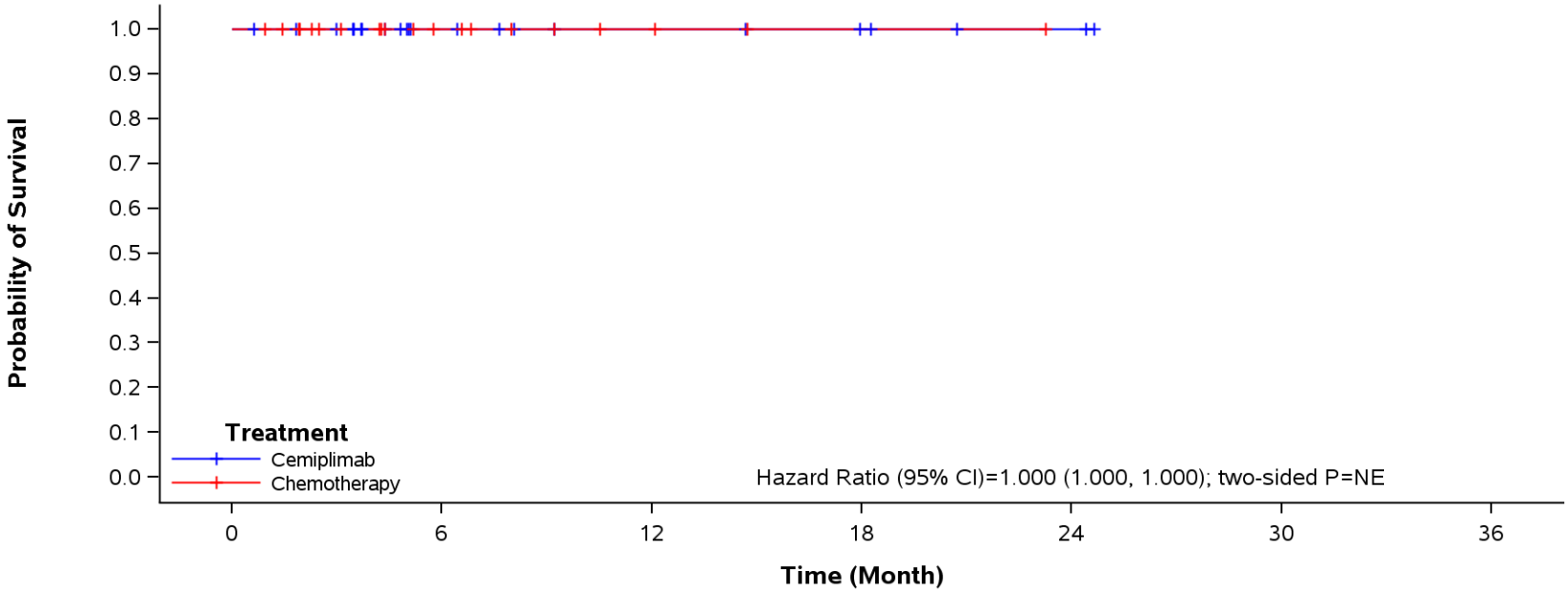

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



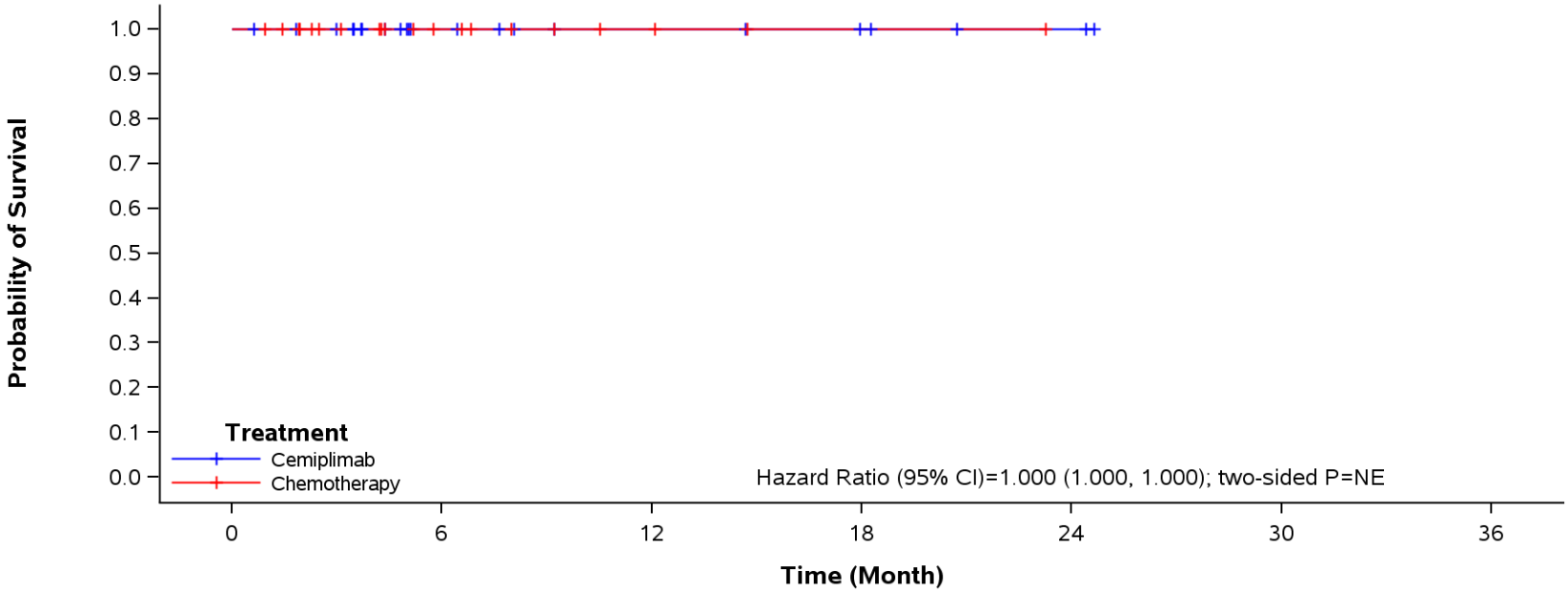

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Investigations



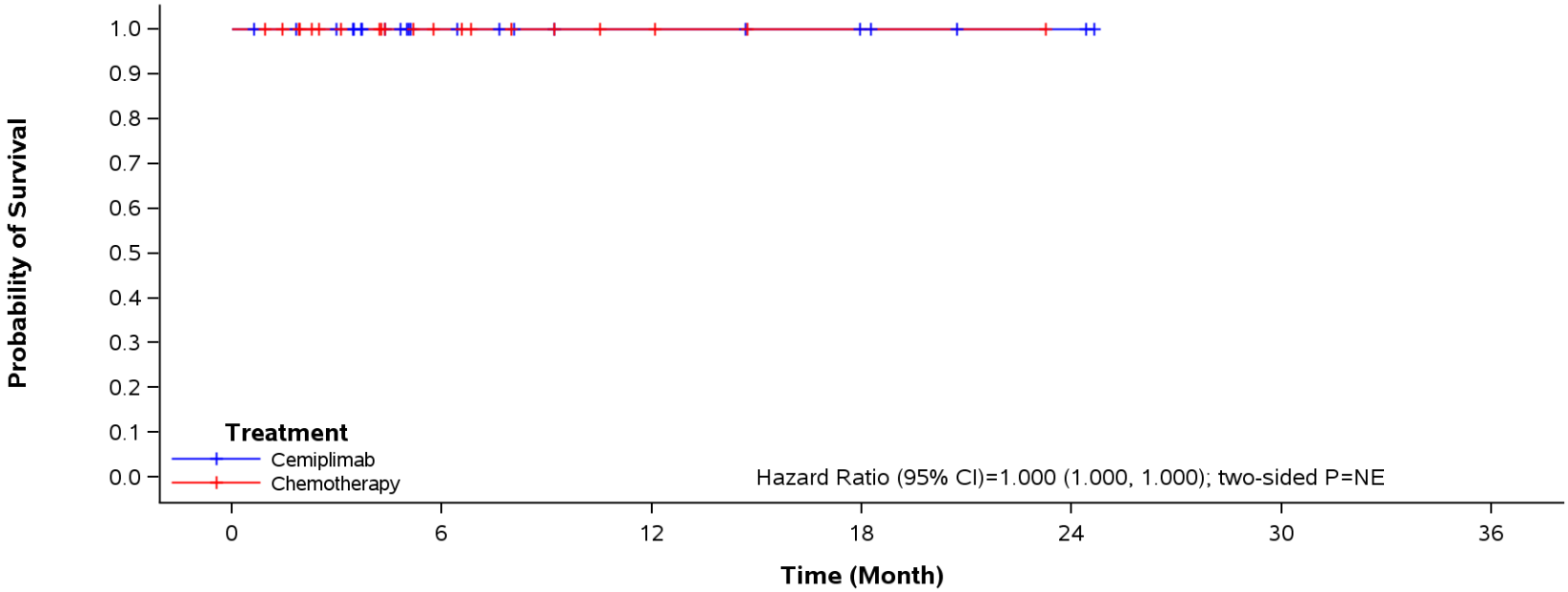

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Investigations
PT: Alanine aminotransferase increased



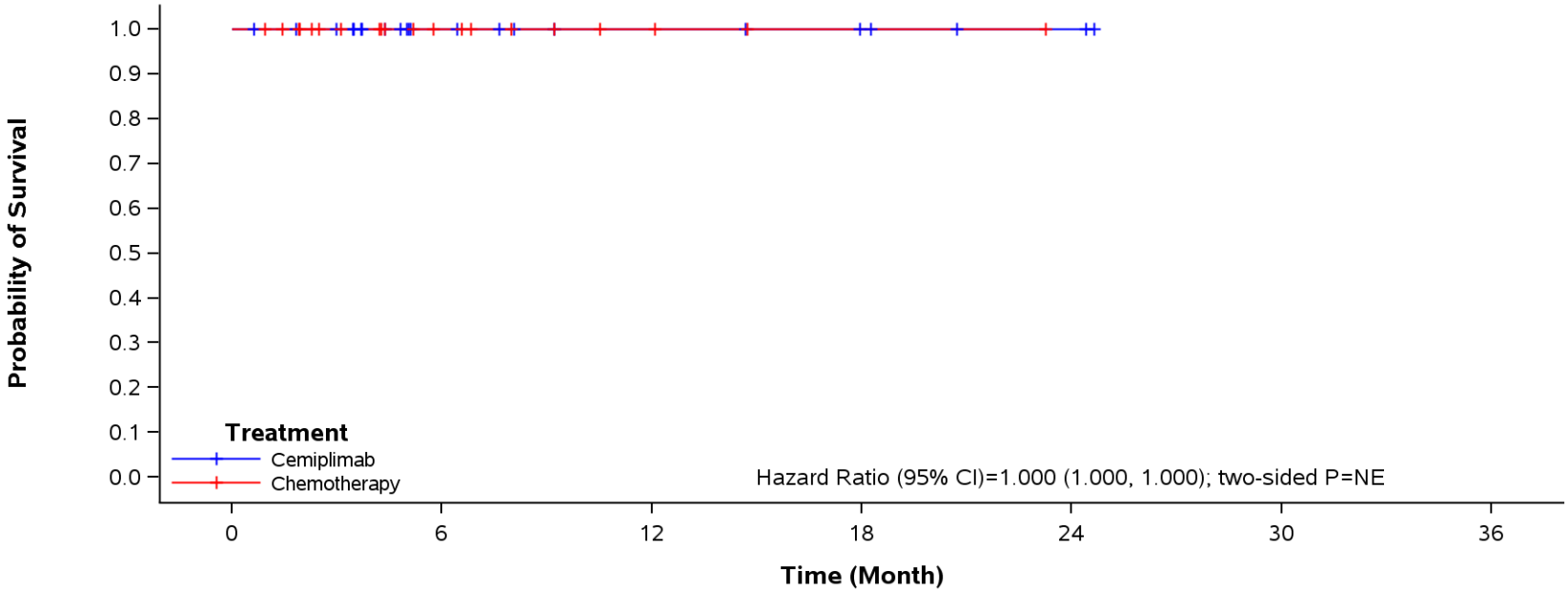

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Investigations
PT: Amylase increased



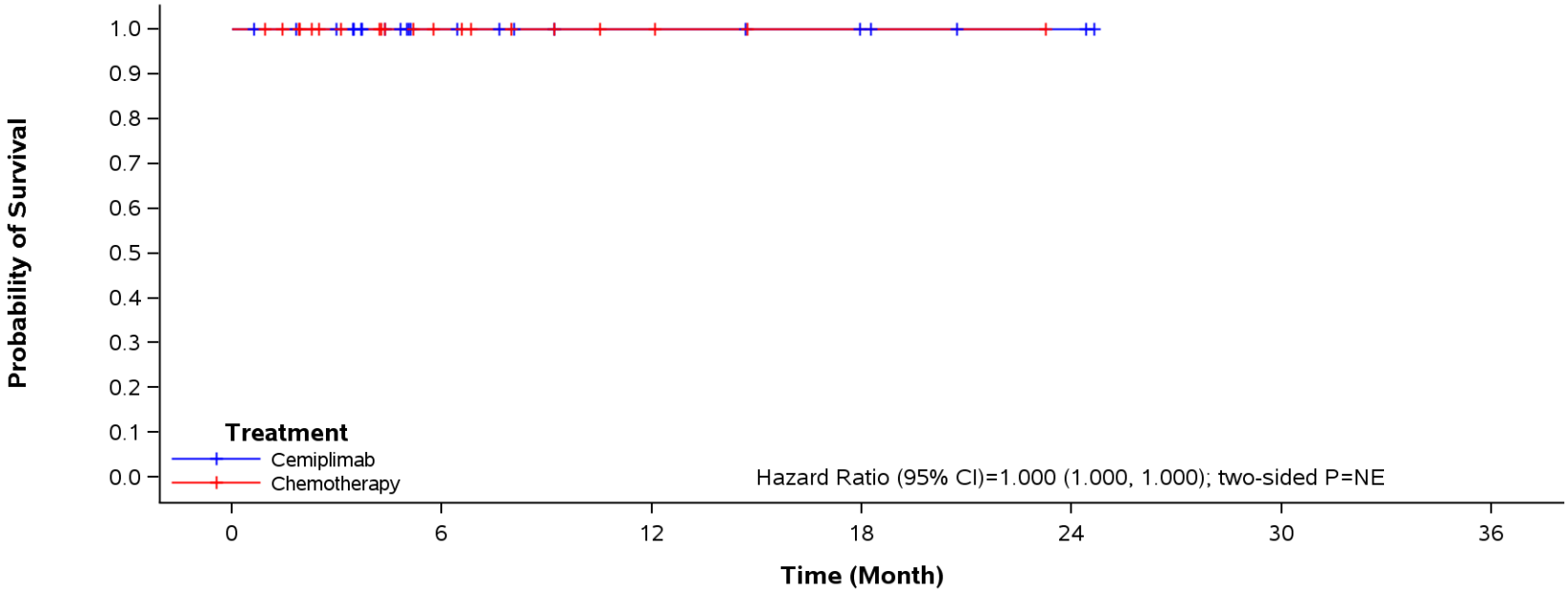

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Investigations
PT: Platelet count decreased



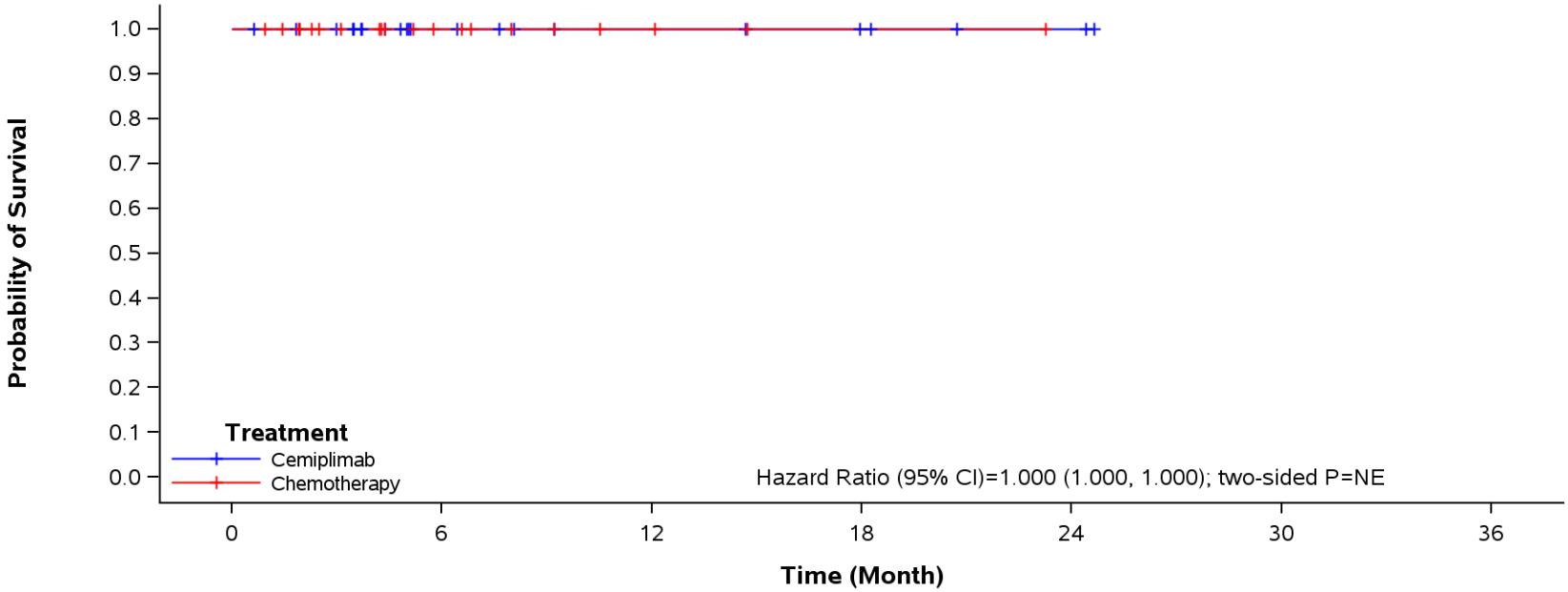

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Metabolism and nutrition disorders



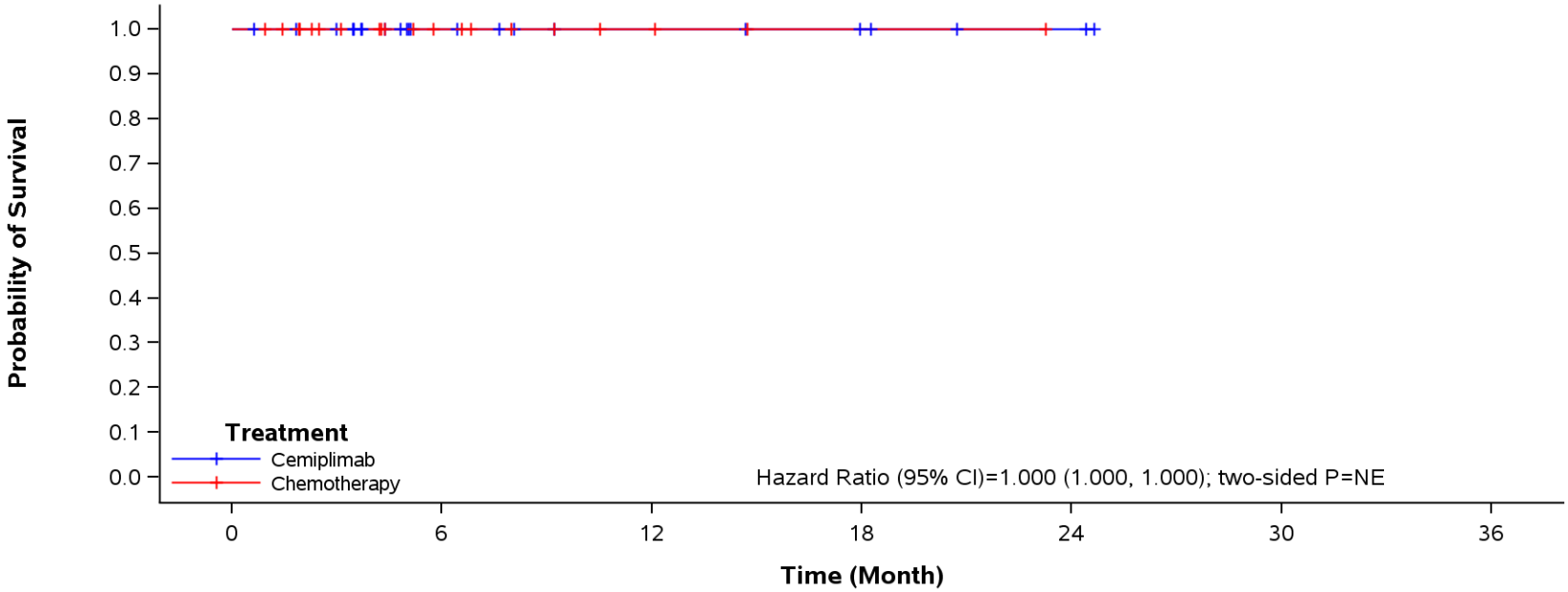

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



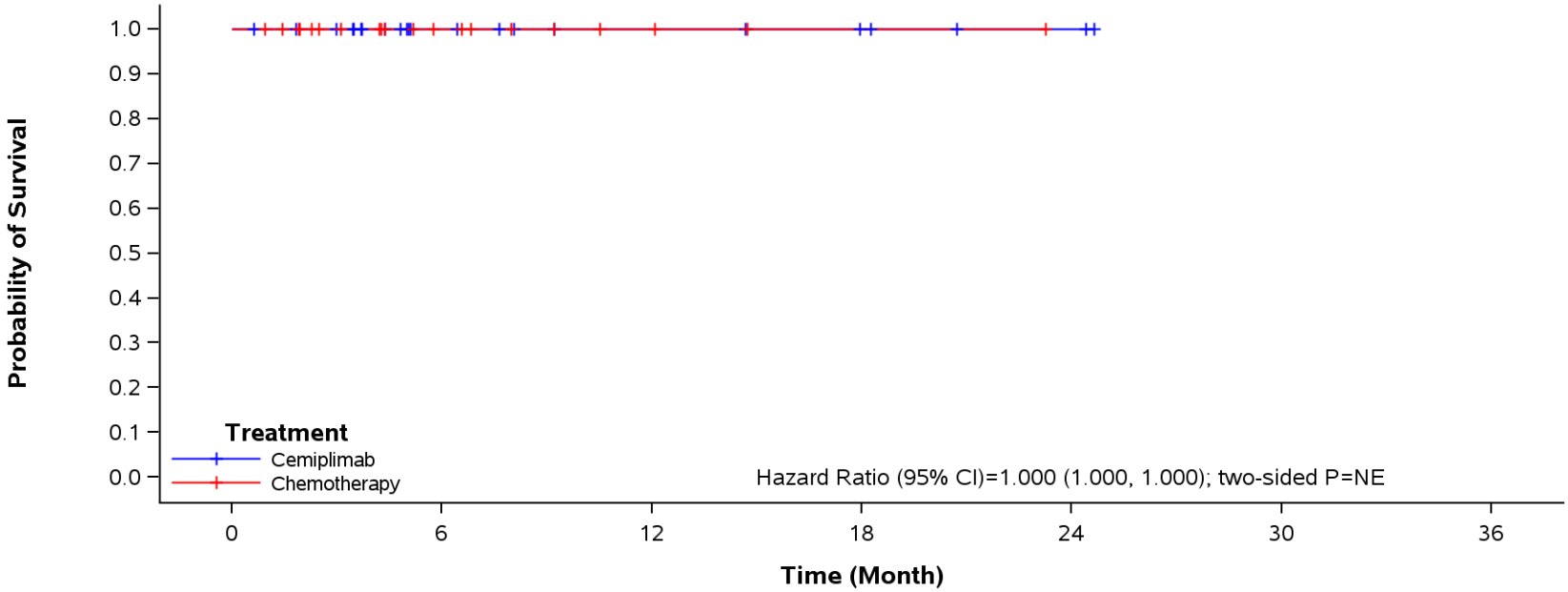

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Musculoskeletal and connective tissue disorders



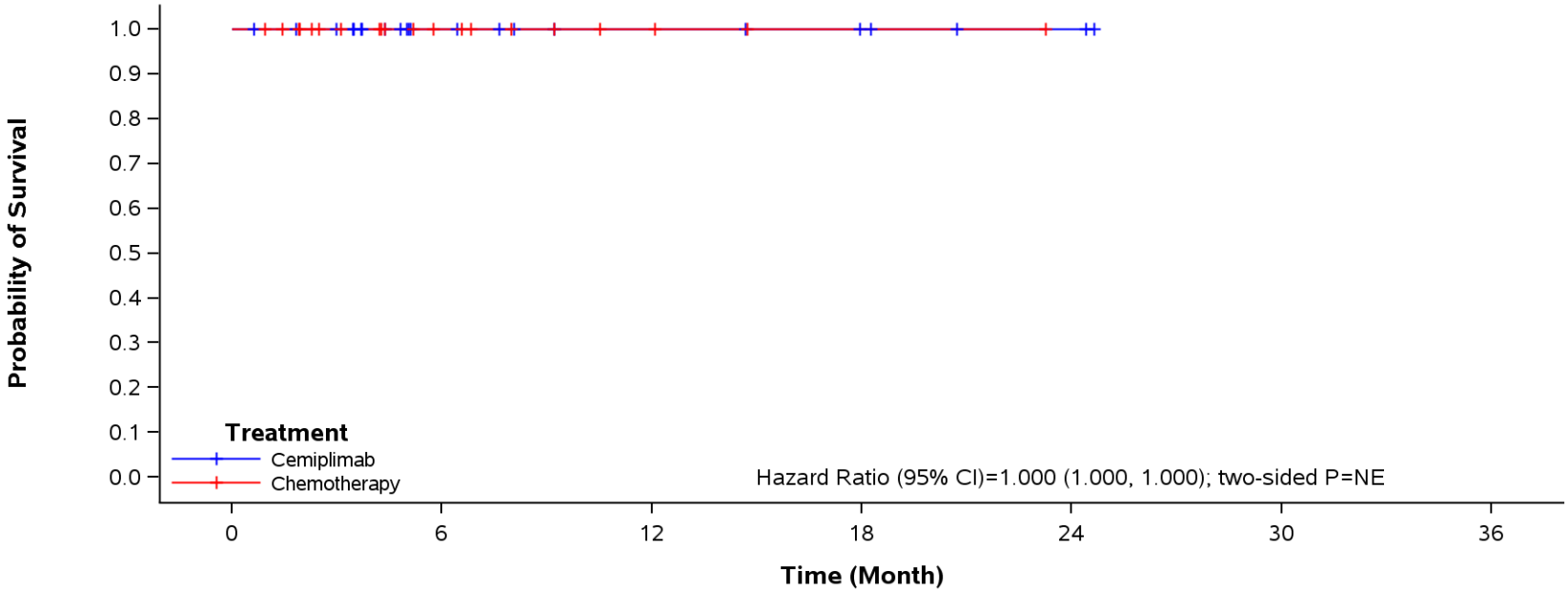

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



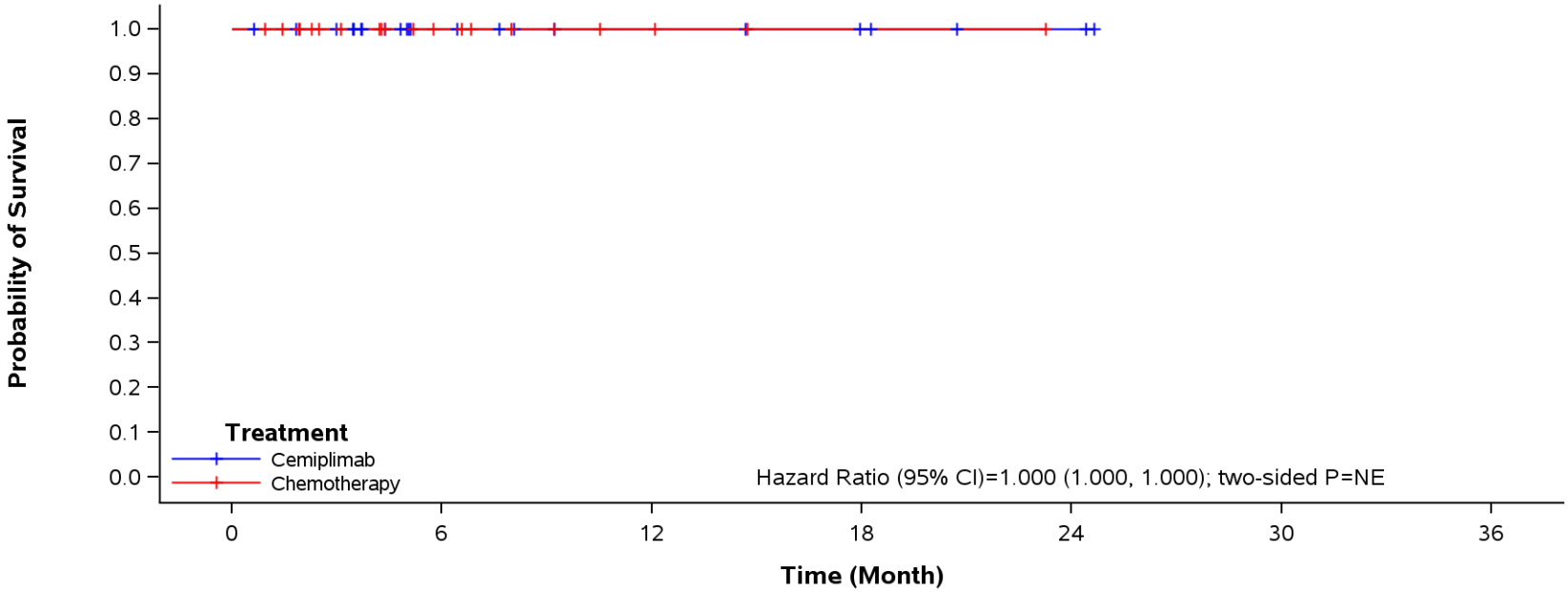

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



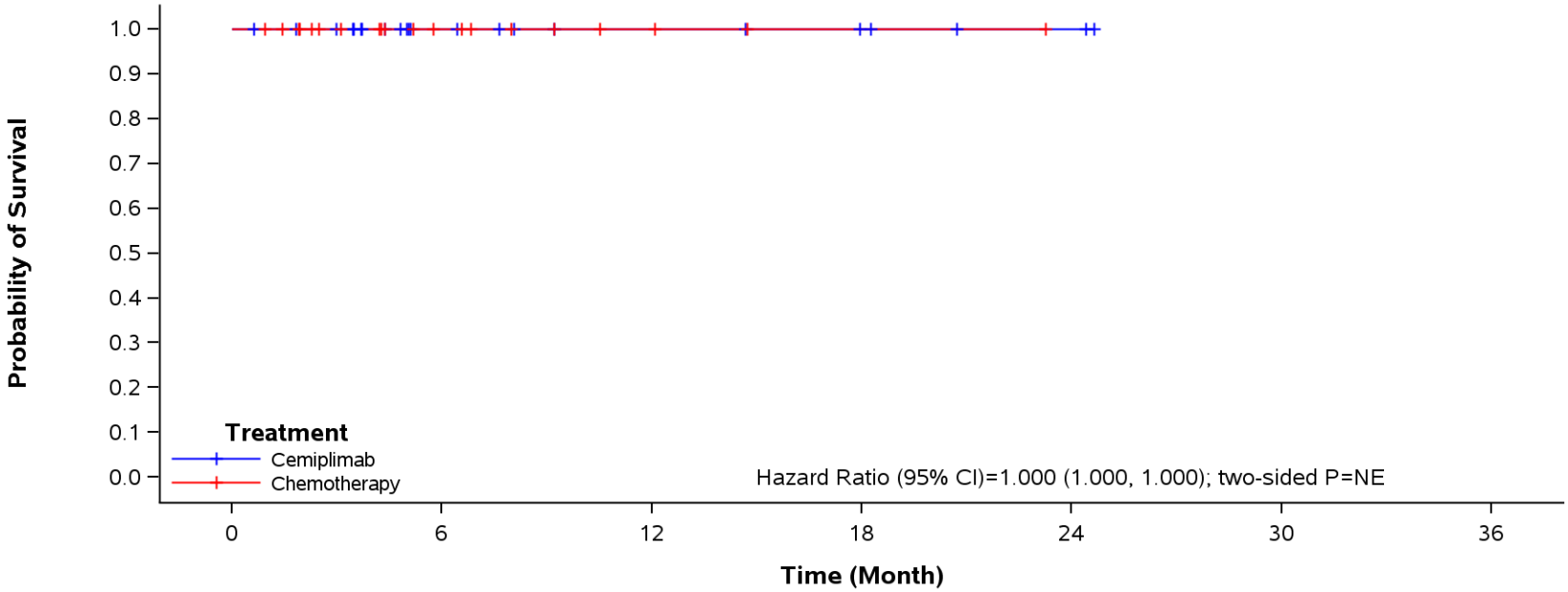

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Nervous system disorders



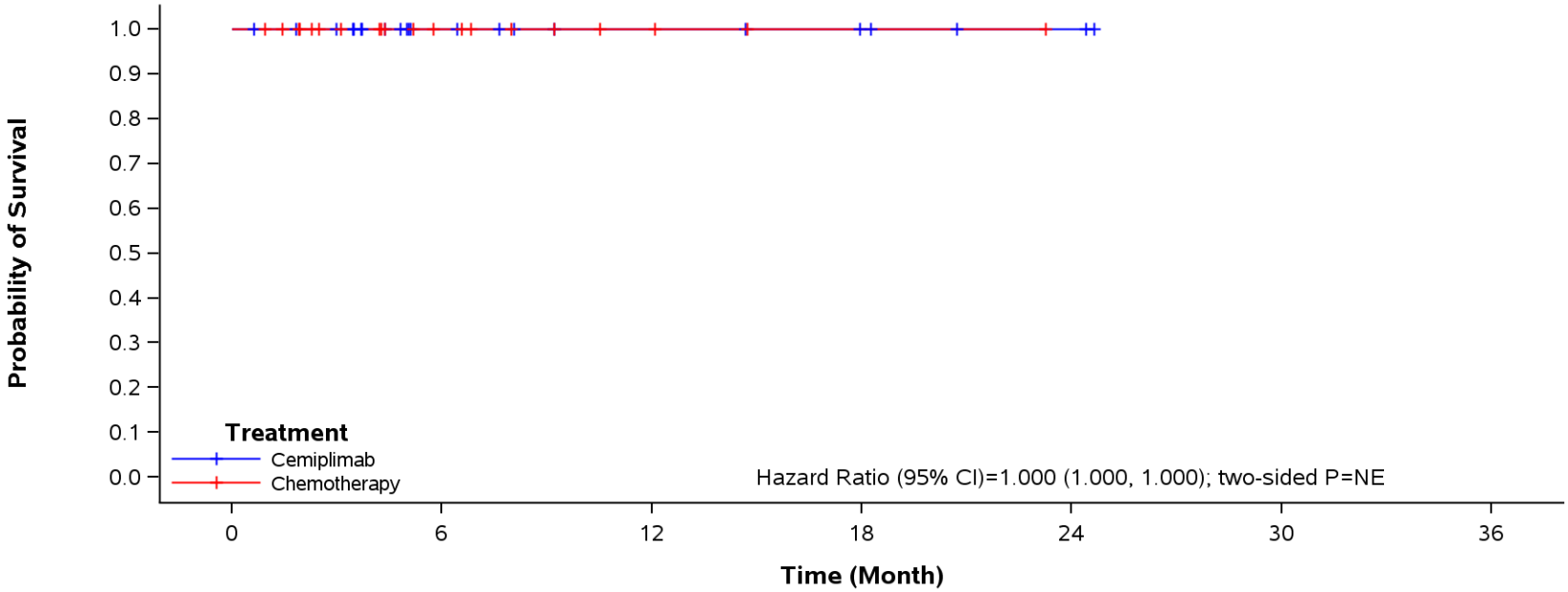

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Nervous system disorders
PT: Neurotoxicity



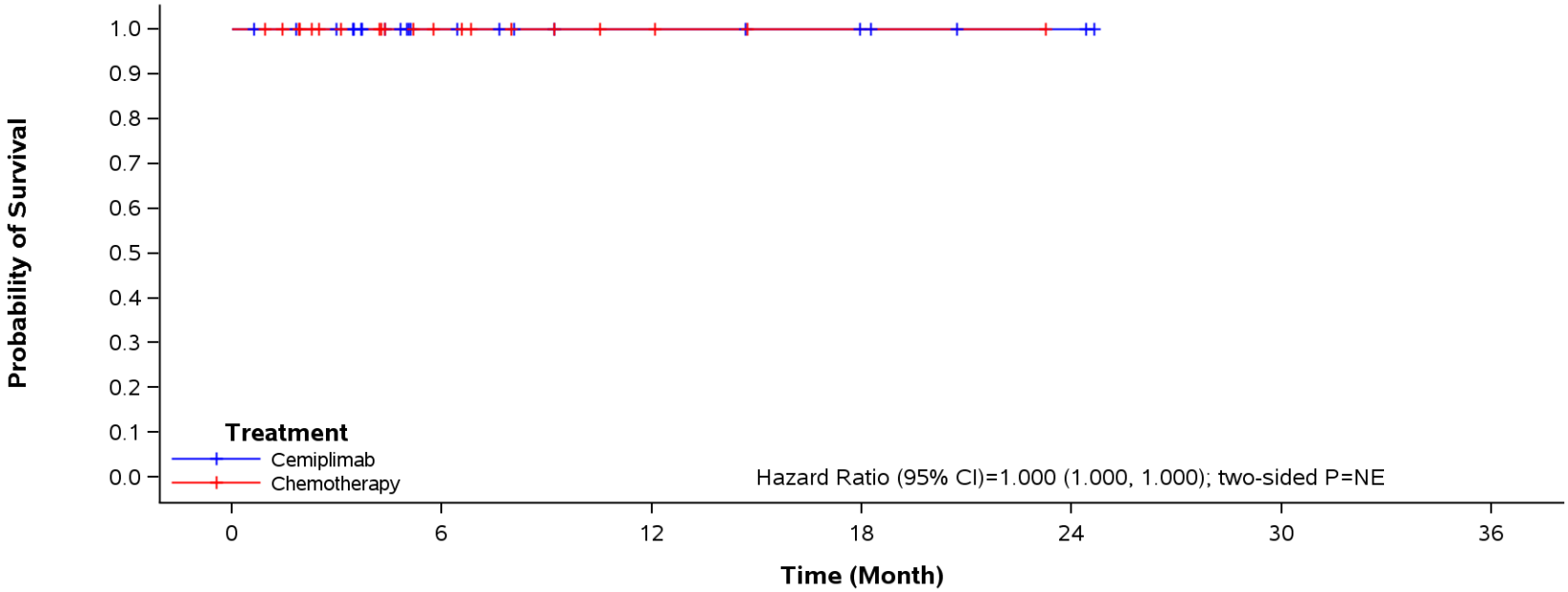

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Nervous system disorders
PT: Transient ischaemic attack



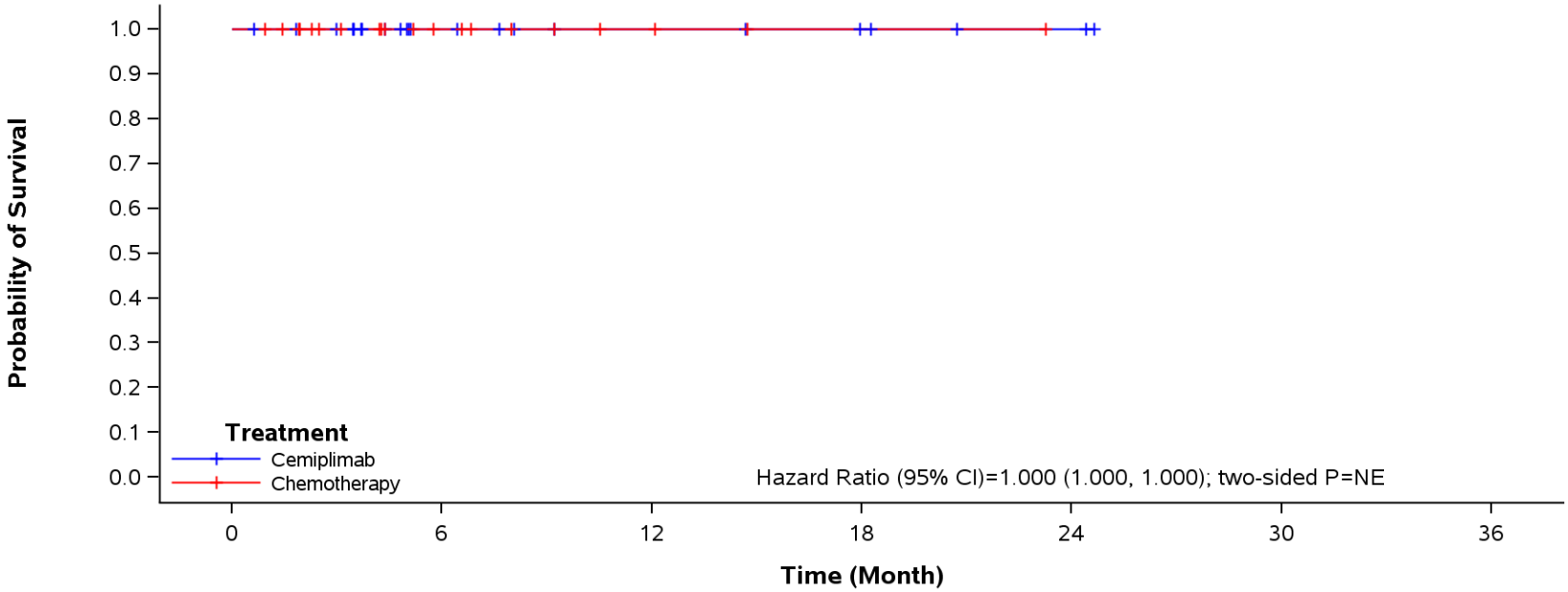

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Psychiatric disorders



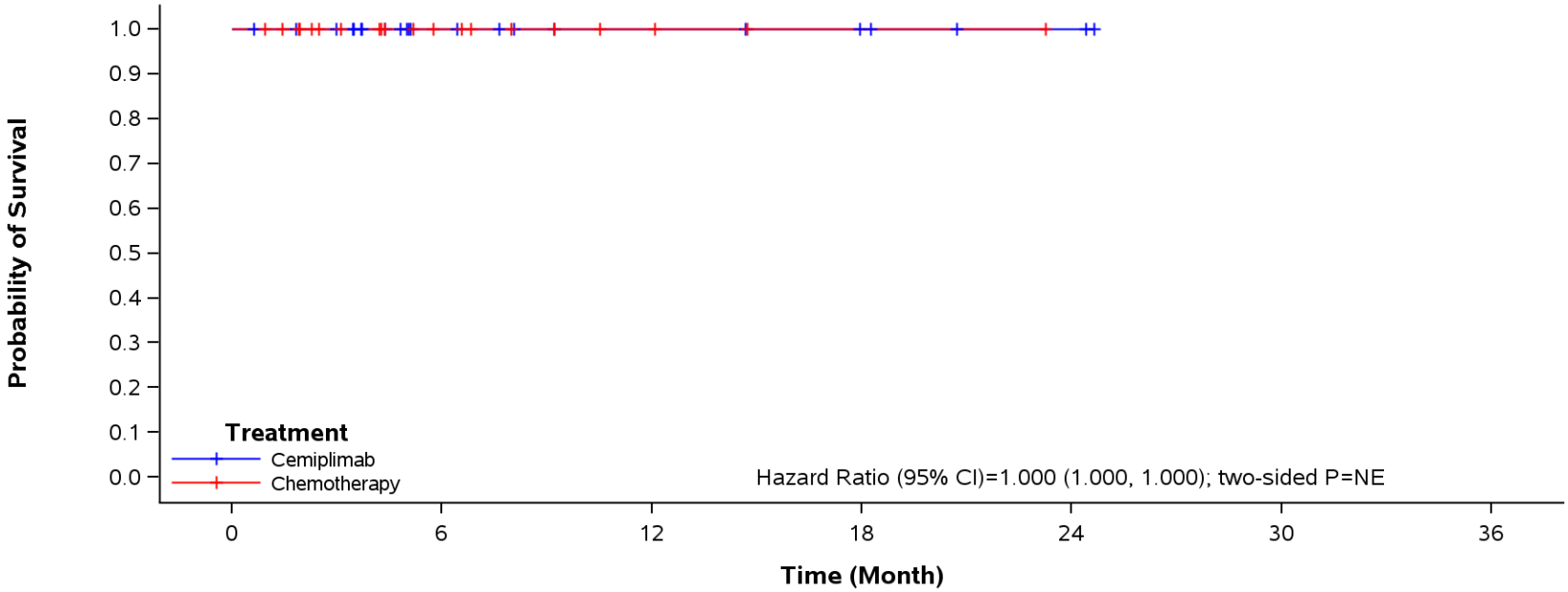

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Psychiatric disorders
PT: Agoraphobia



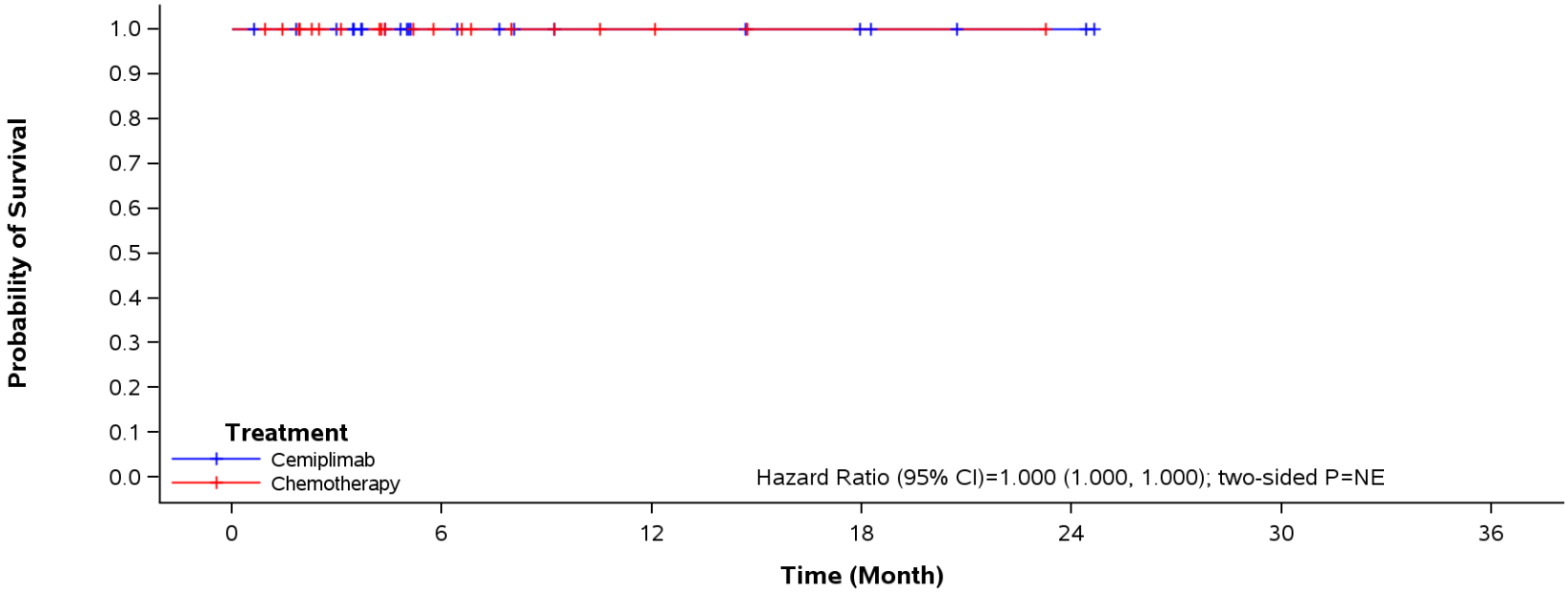

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Renal and urinary disorders



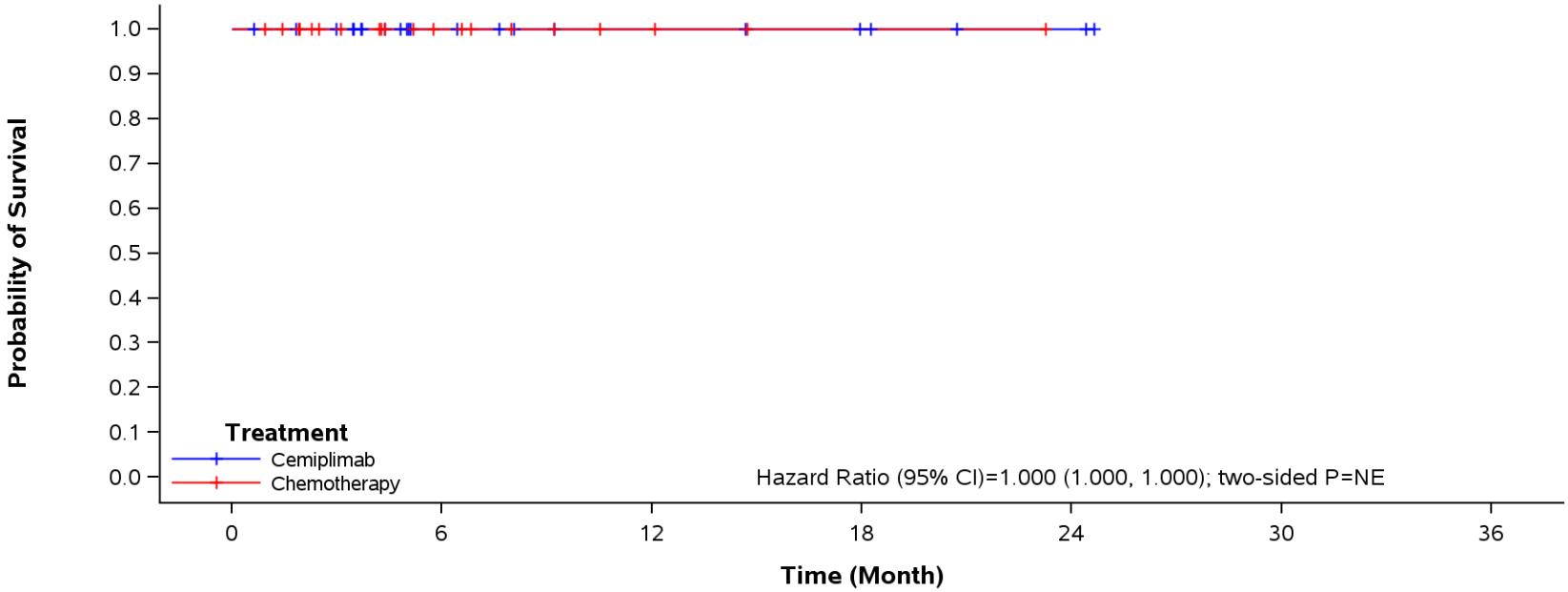

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Renal and urinary disorders
PT: Renal failure



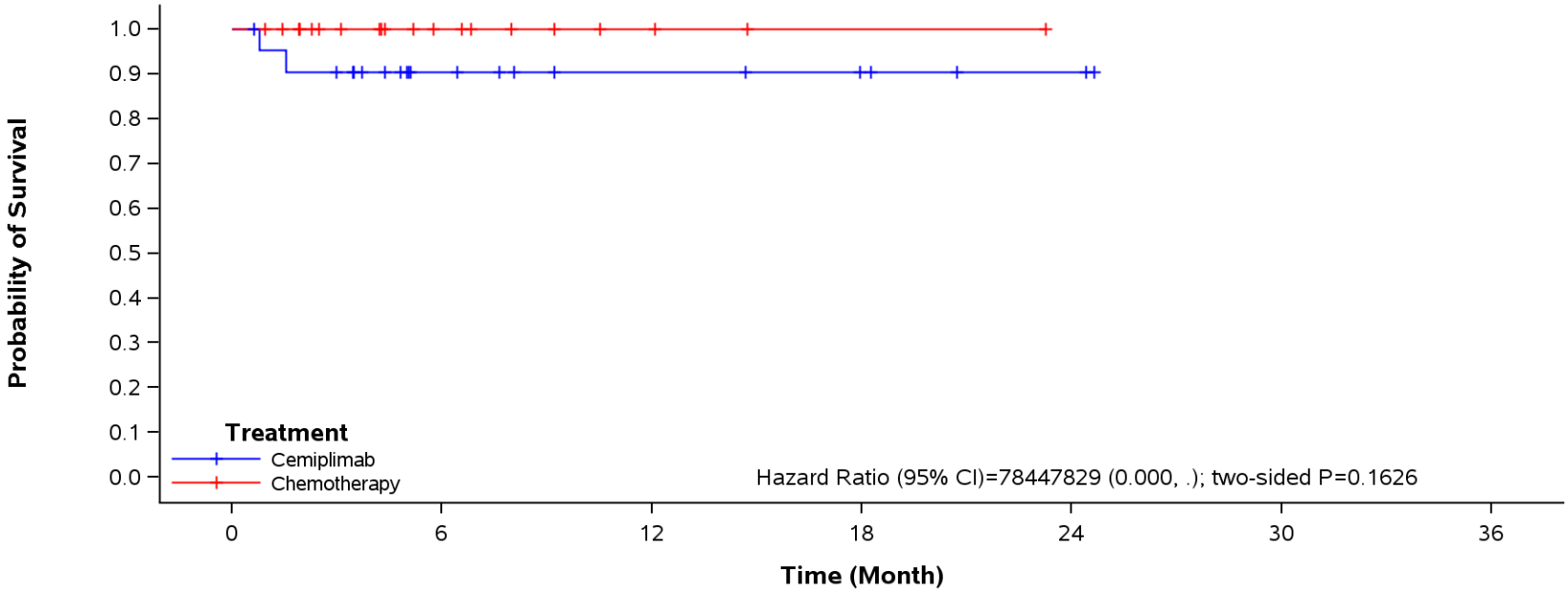

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Respiratory, thoracic and mediastinal disorders



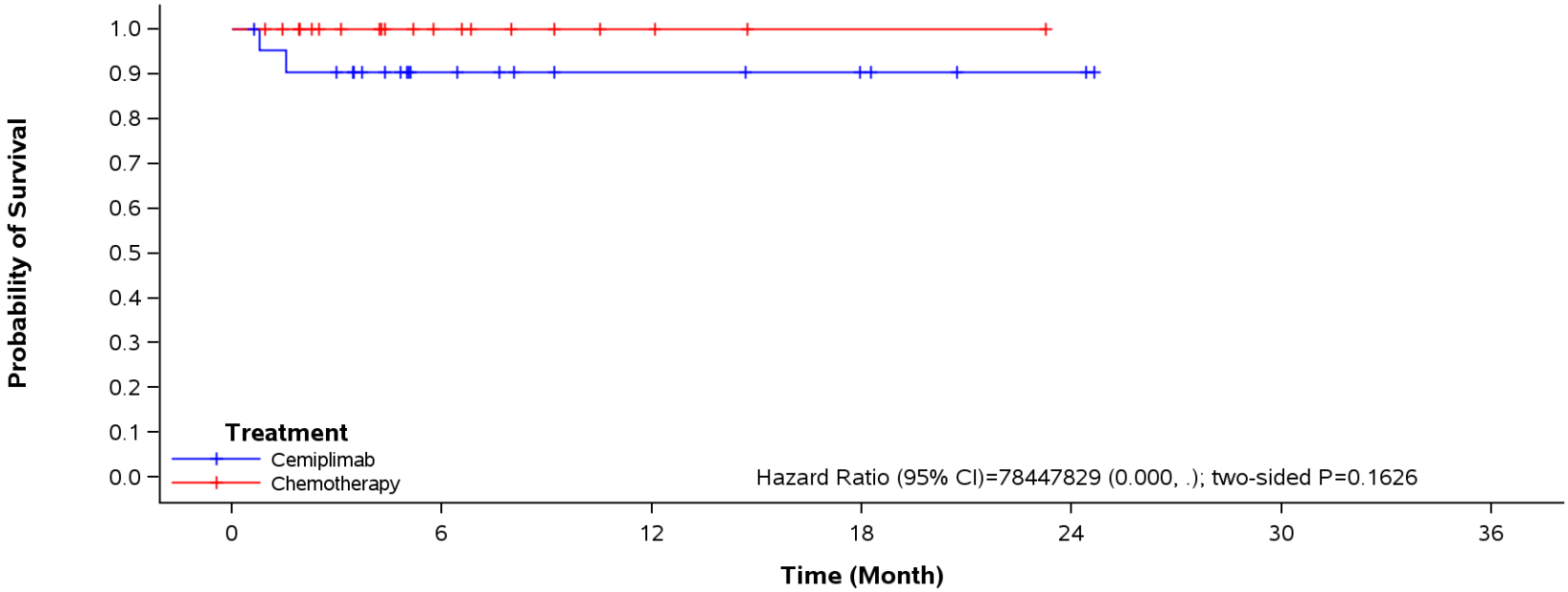

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



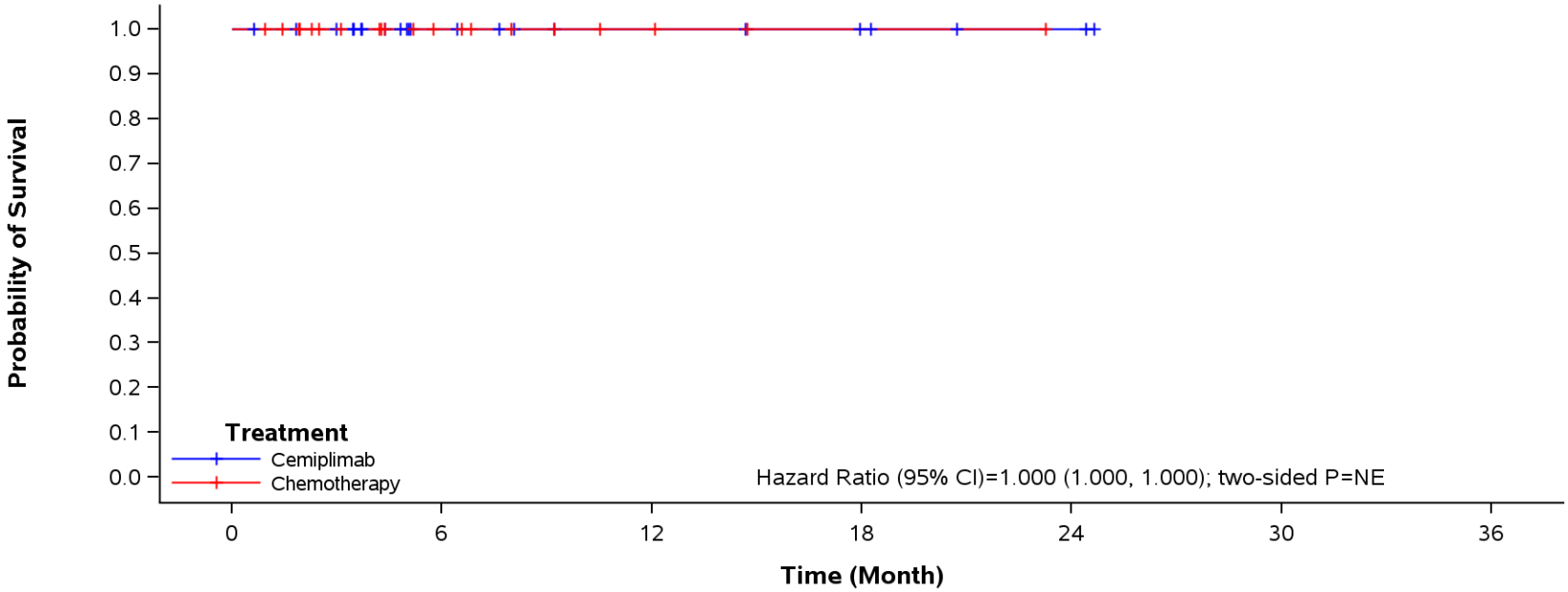

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Vascular disorders



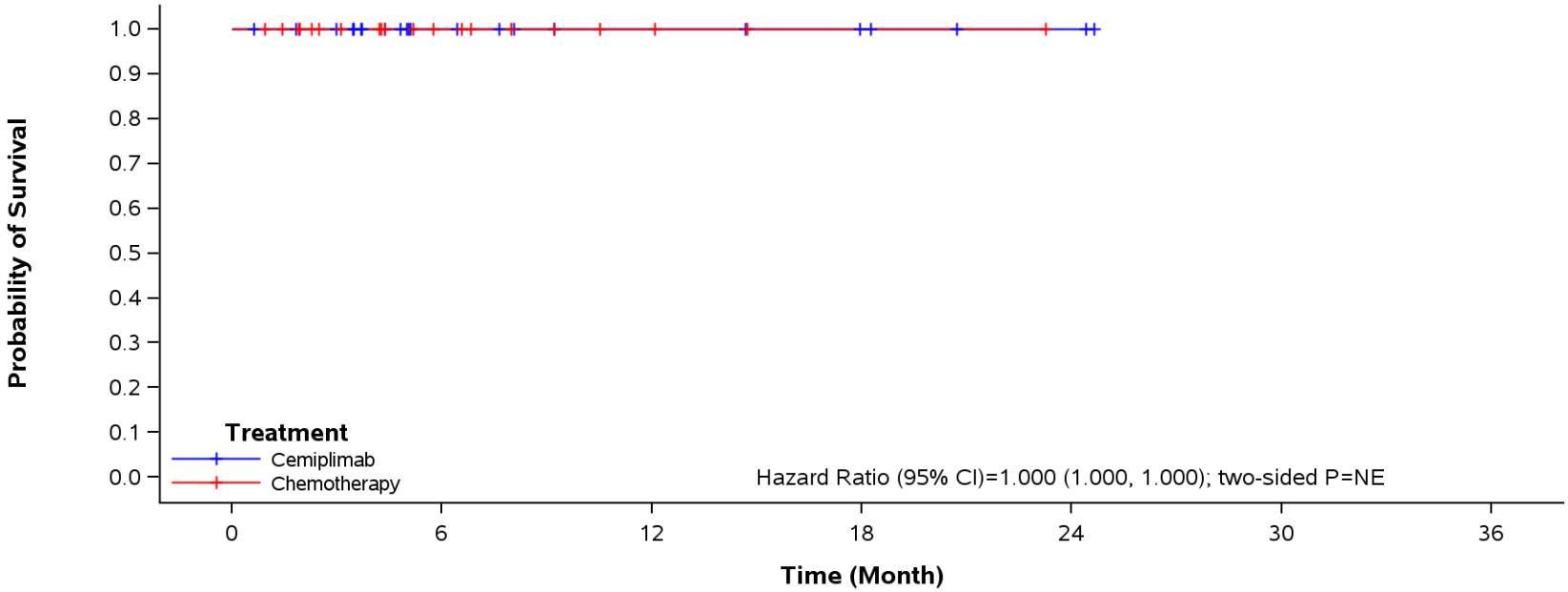

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: North America
SOC: Vascular disorders
PT: Deep vein thrombosis



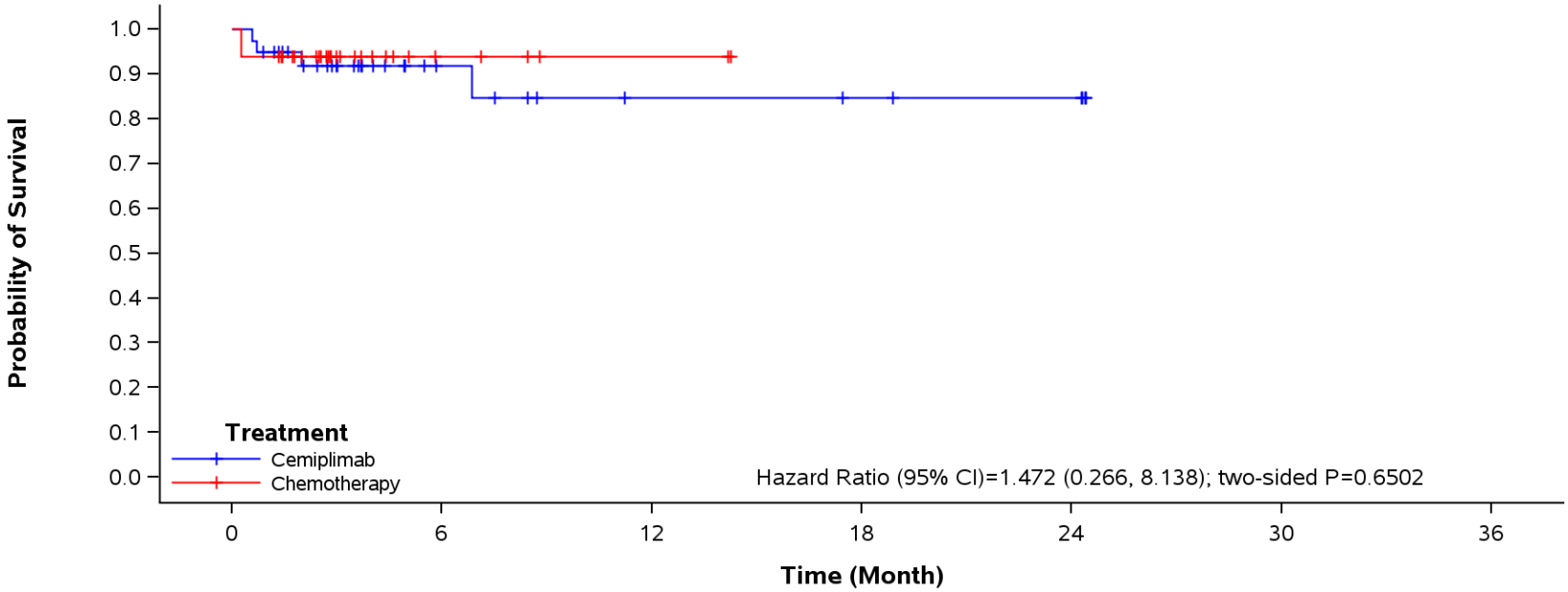

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 22 | 10 | 6 | 4 | 2 | 0 | 0 |
| Chemotherapy | 21 | 8 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
Number of patients with any TEAE leading to discontinuation



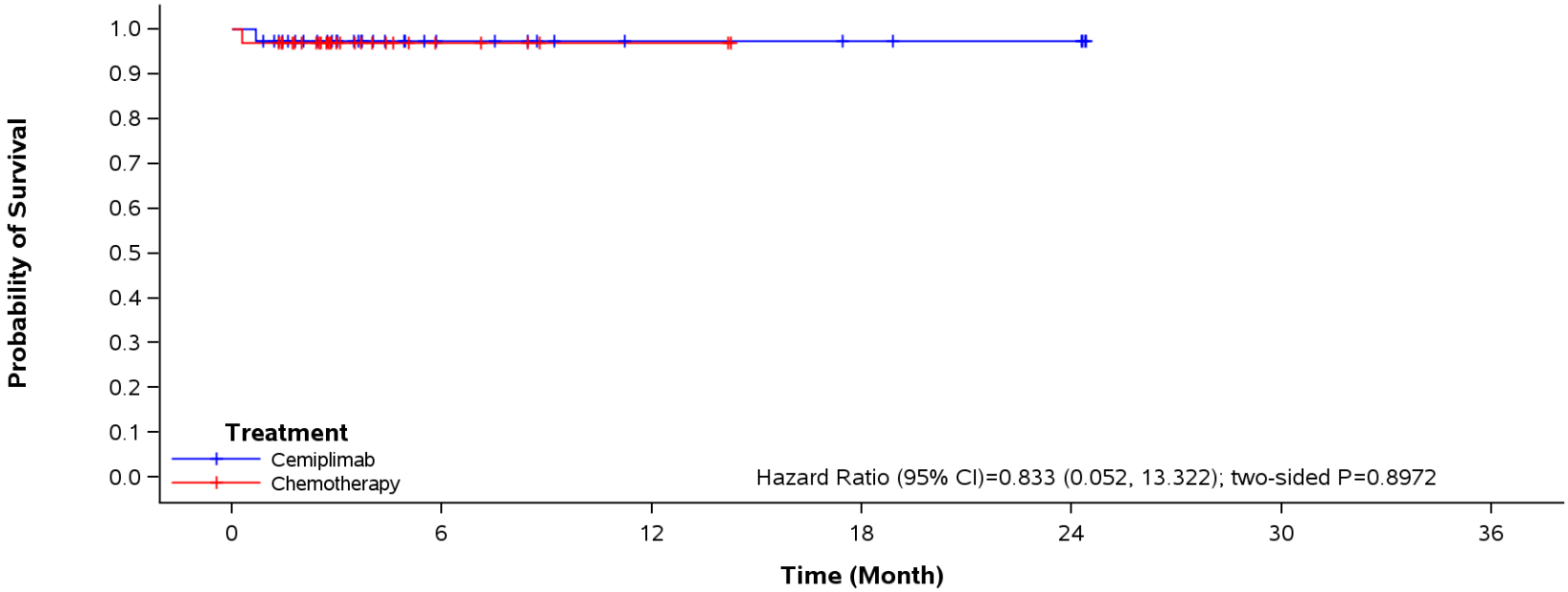

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders



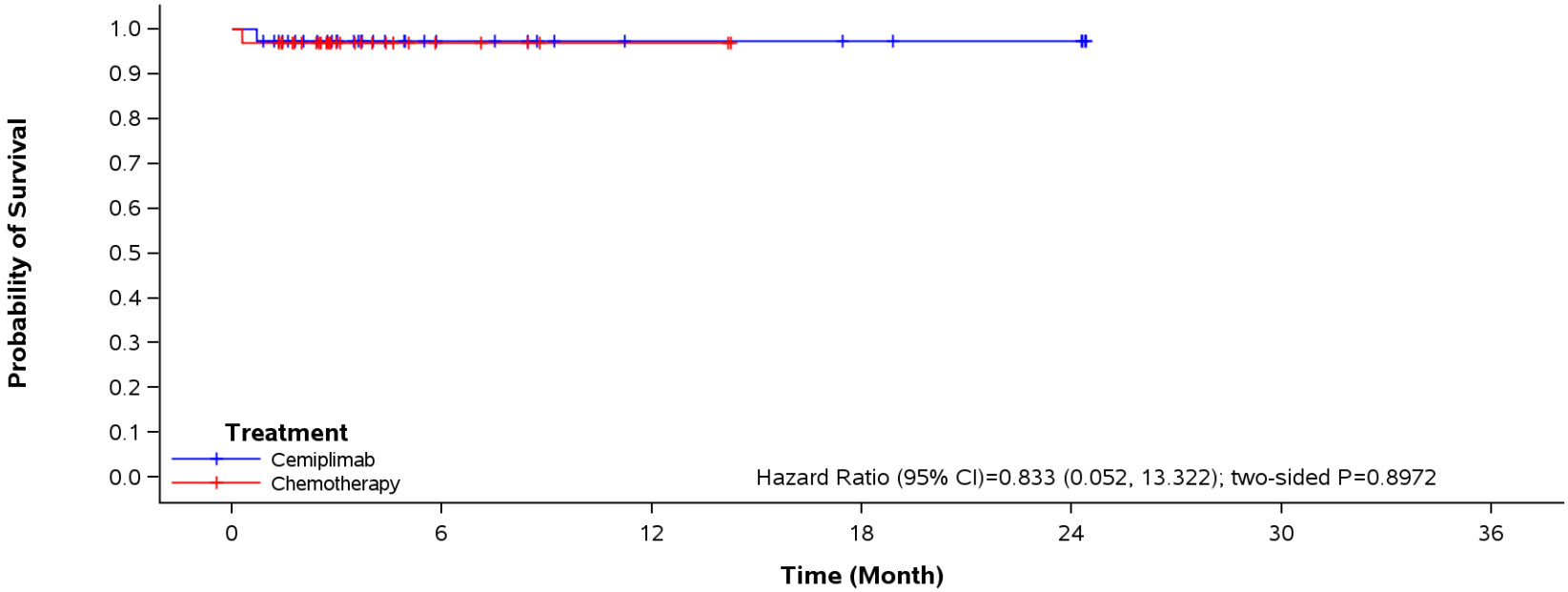

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Anaemia



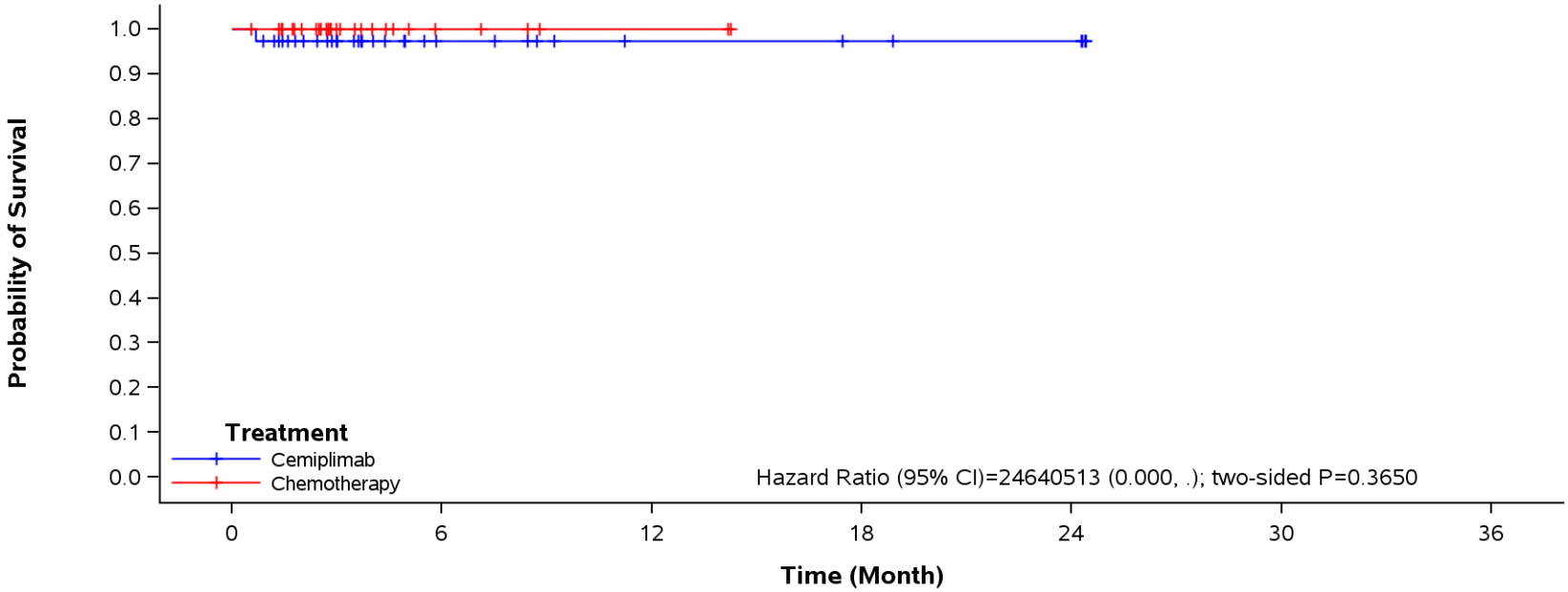

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



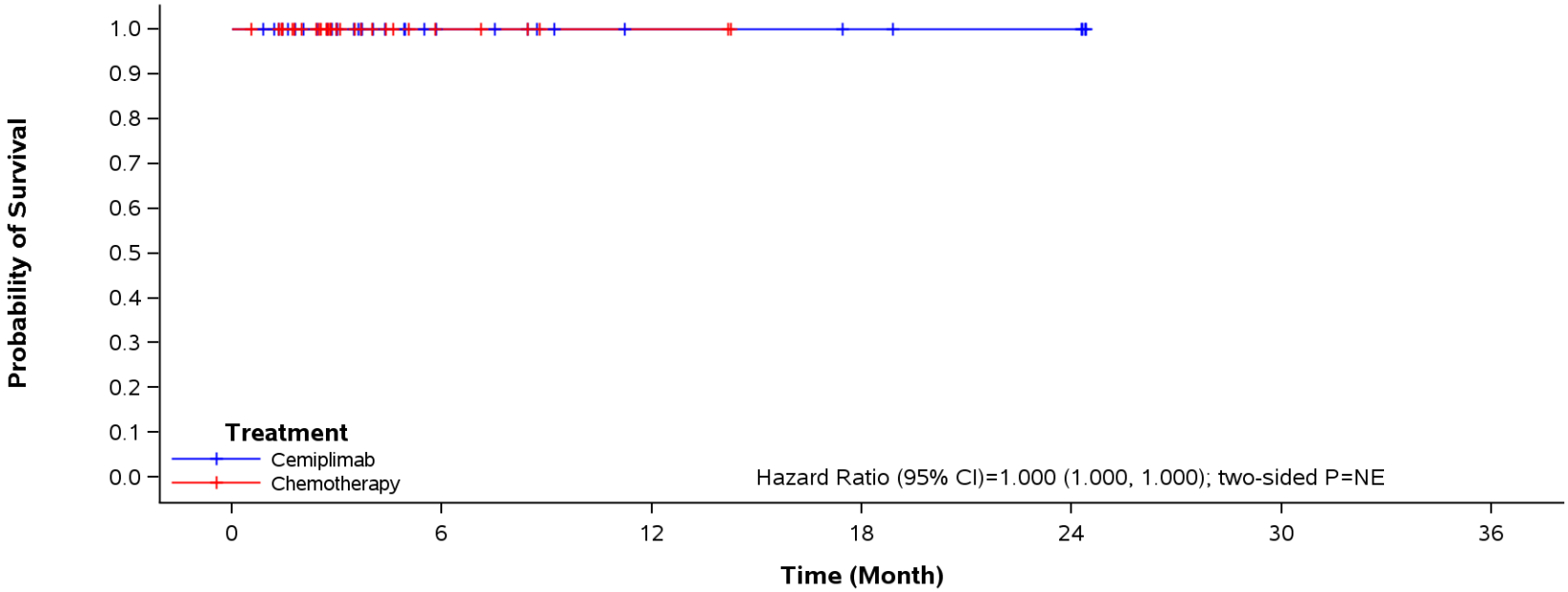

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Neutropenia



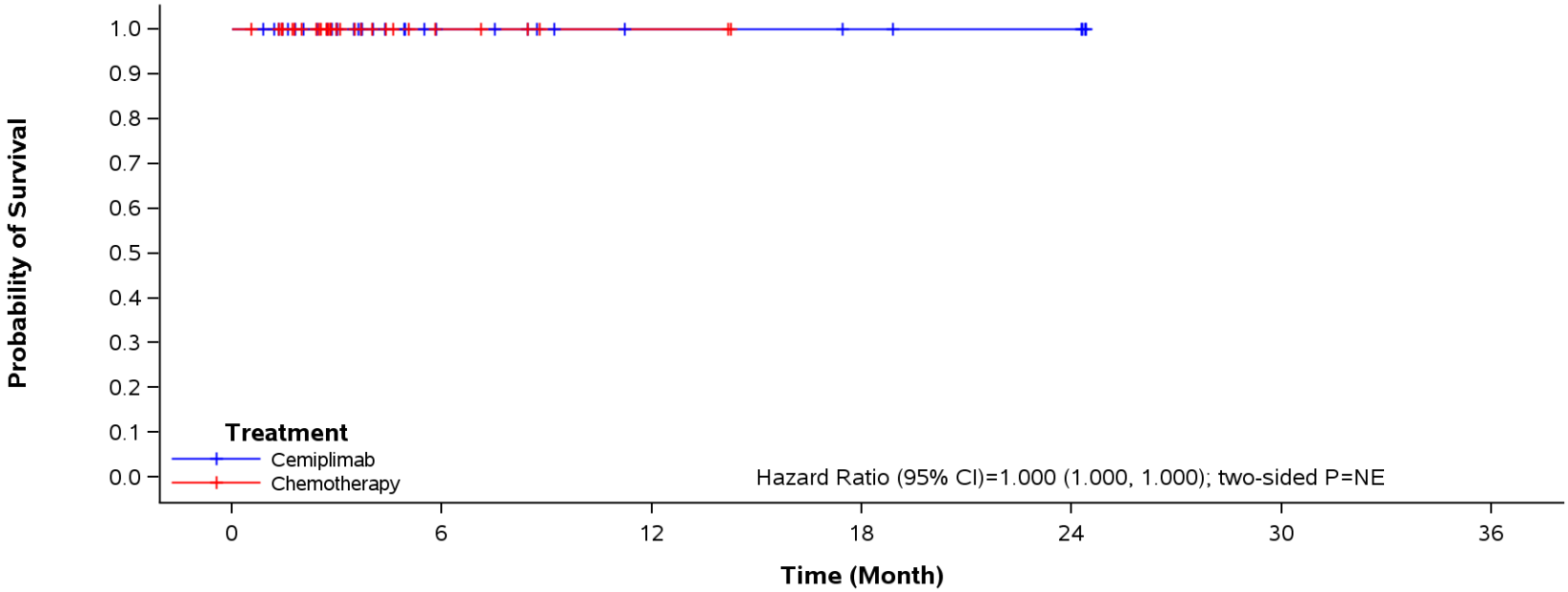

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



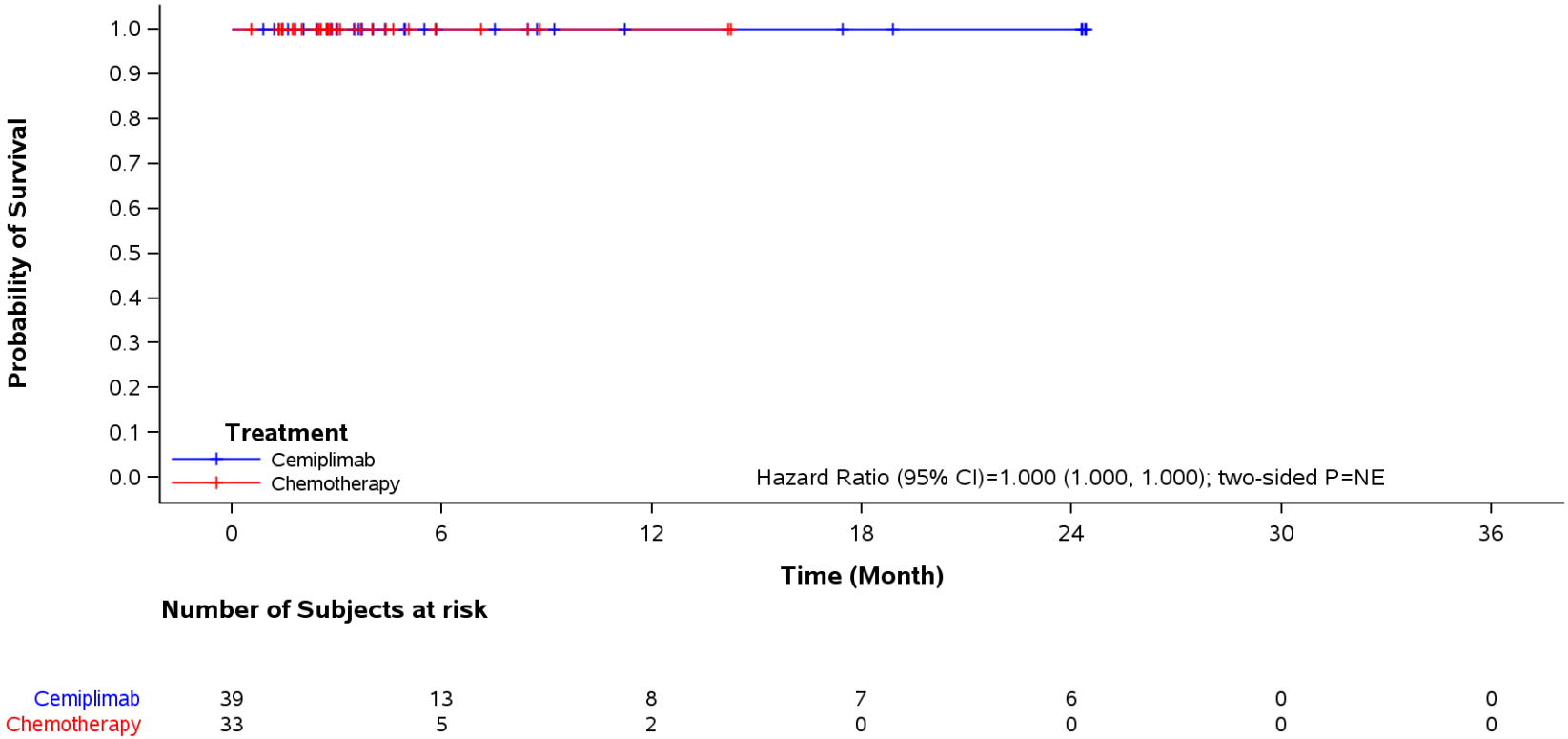

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

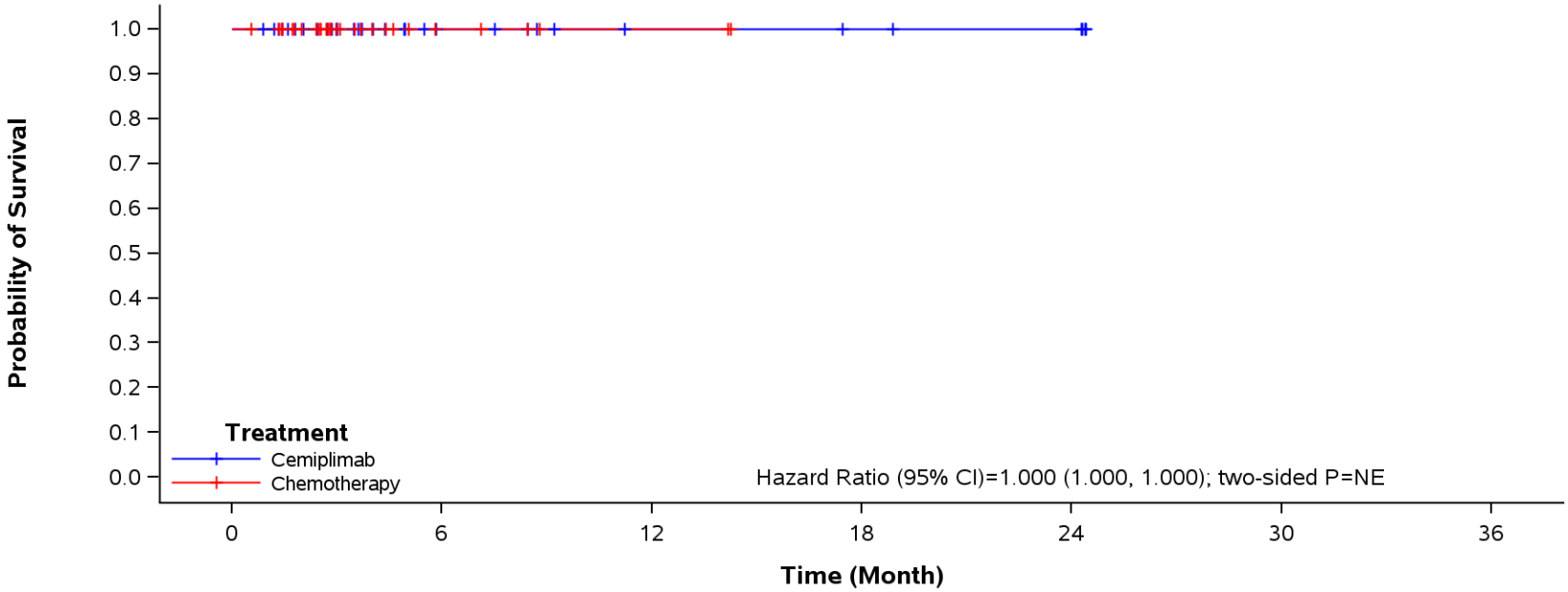
Geographic region: Asia
SOC: Cardiac disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Cardiac disorders
PT: Autoimmune pericarditis



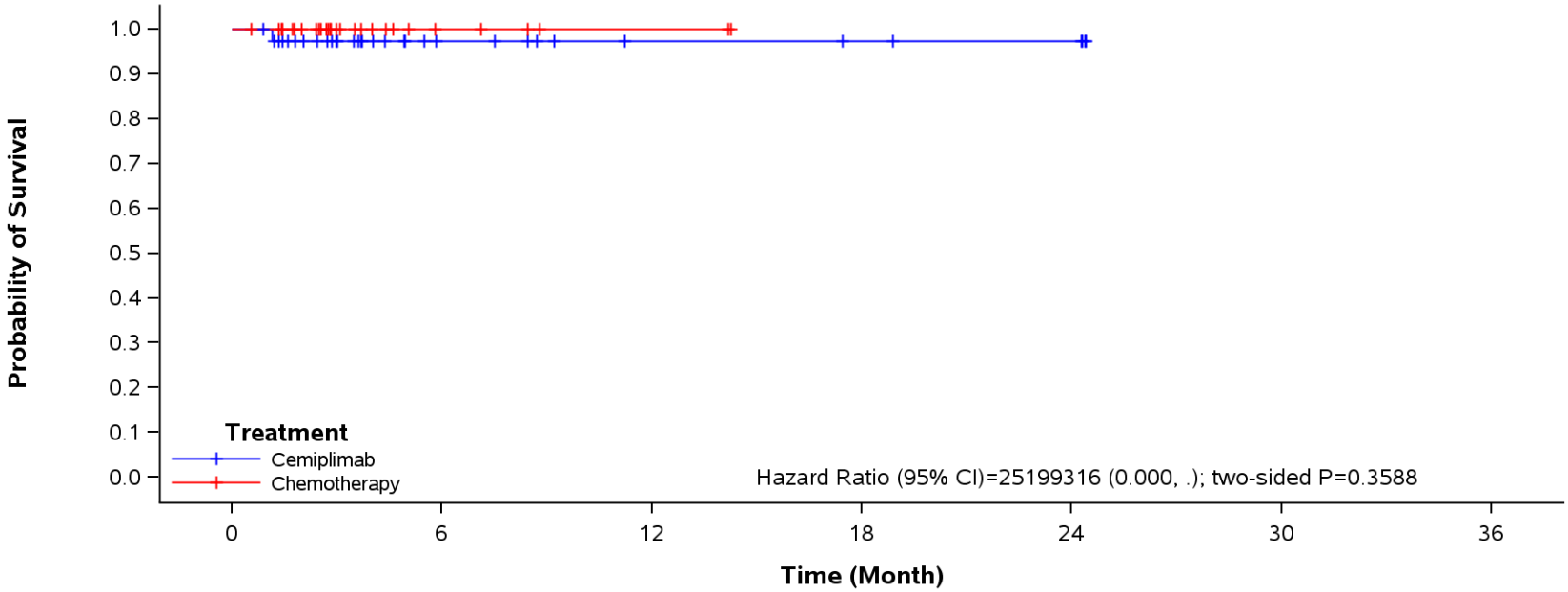

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Endocrine disorders



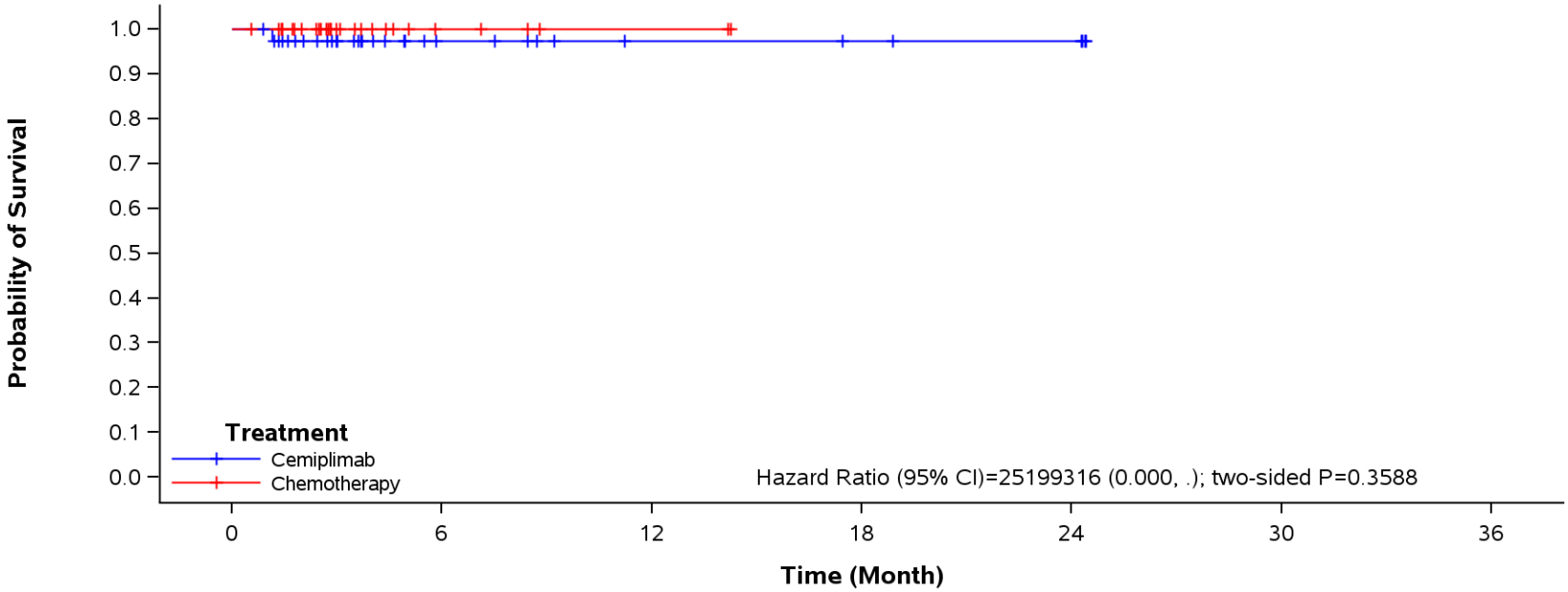

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Endocrine disorders
PT: Hypothyroidism



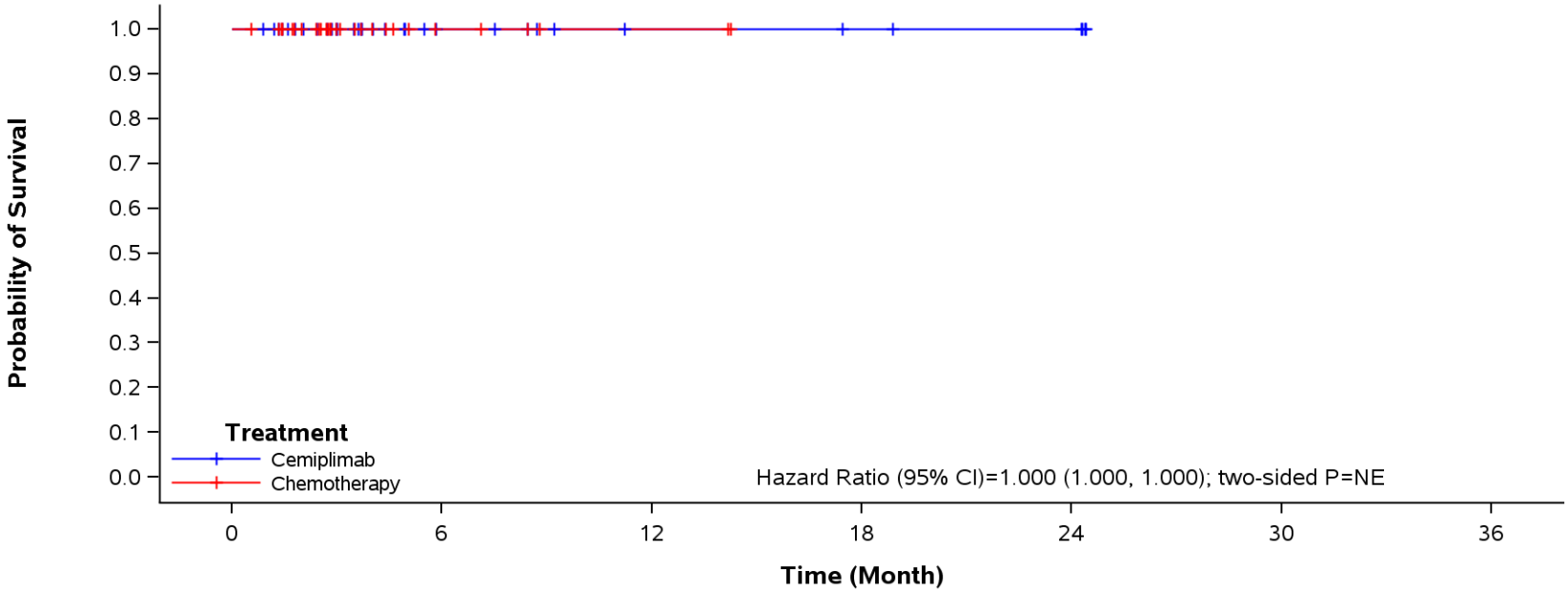

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders



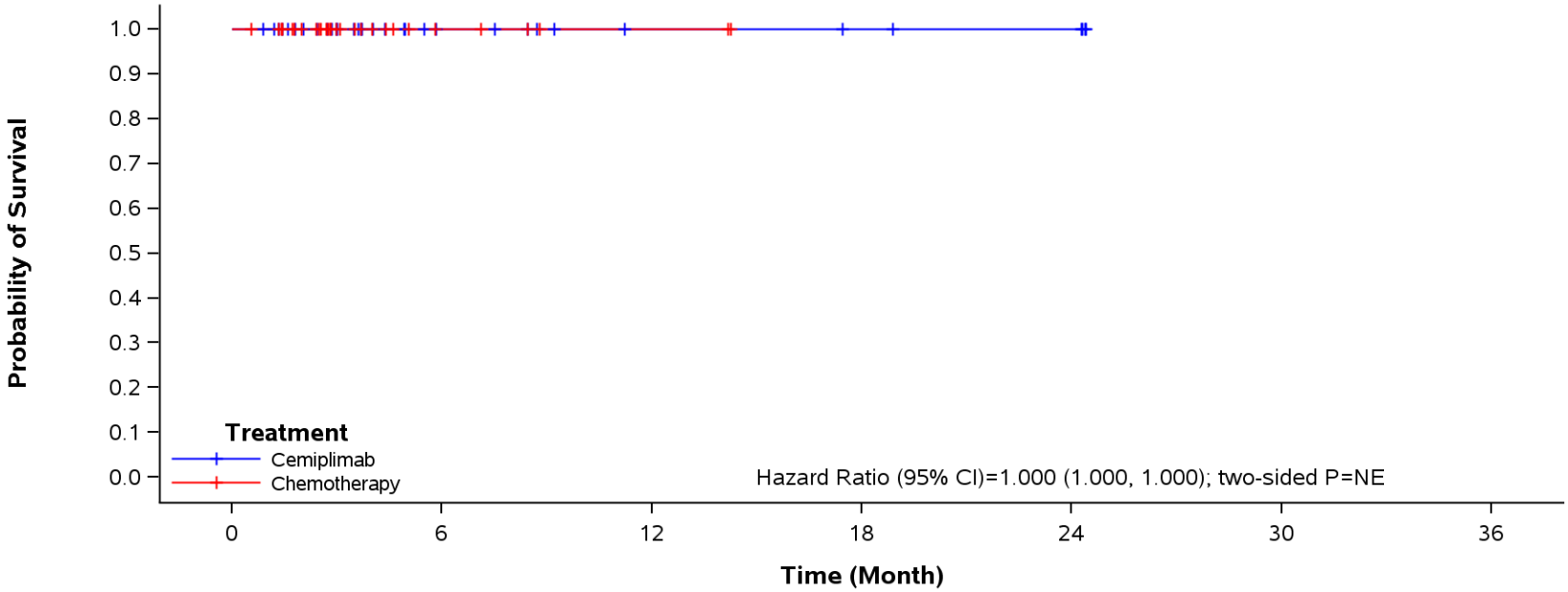

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders
PT: Colitis



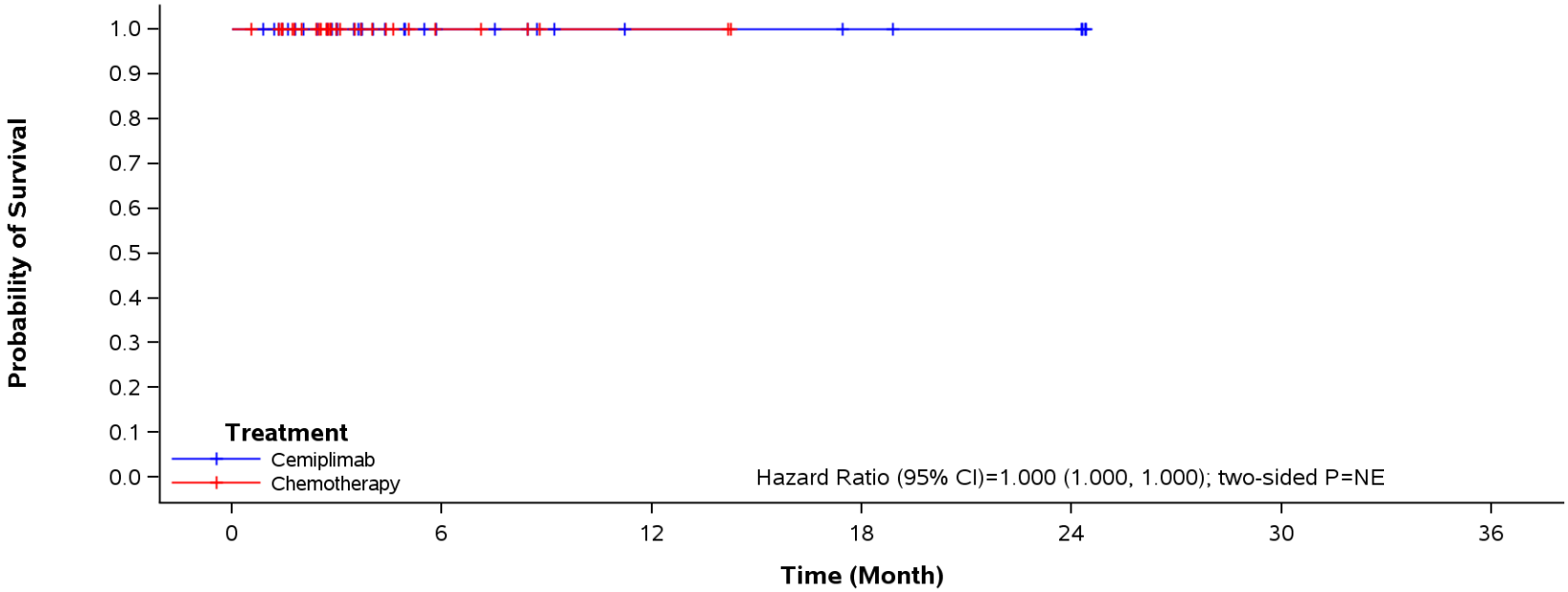

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders
PT: Diverticular perforation



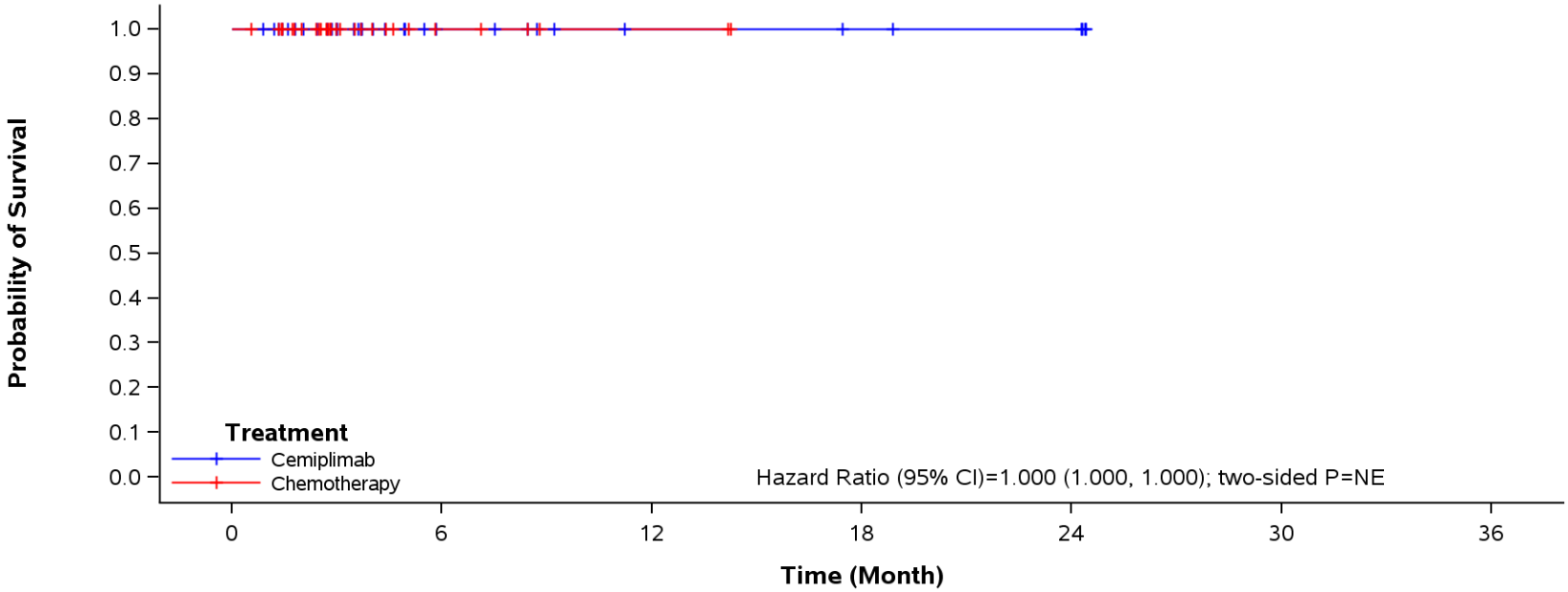

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders
PT: Pancreatic mass



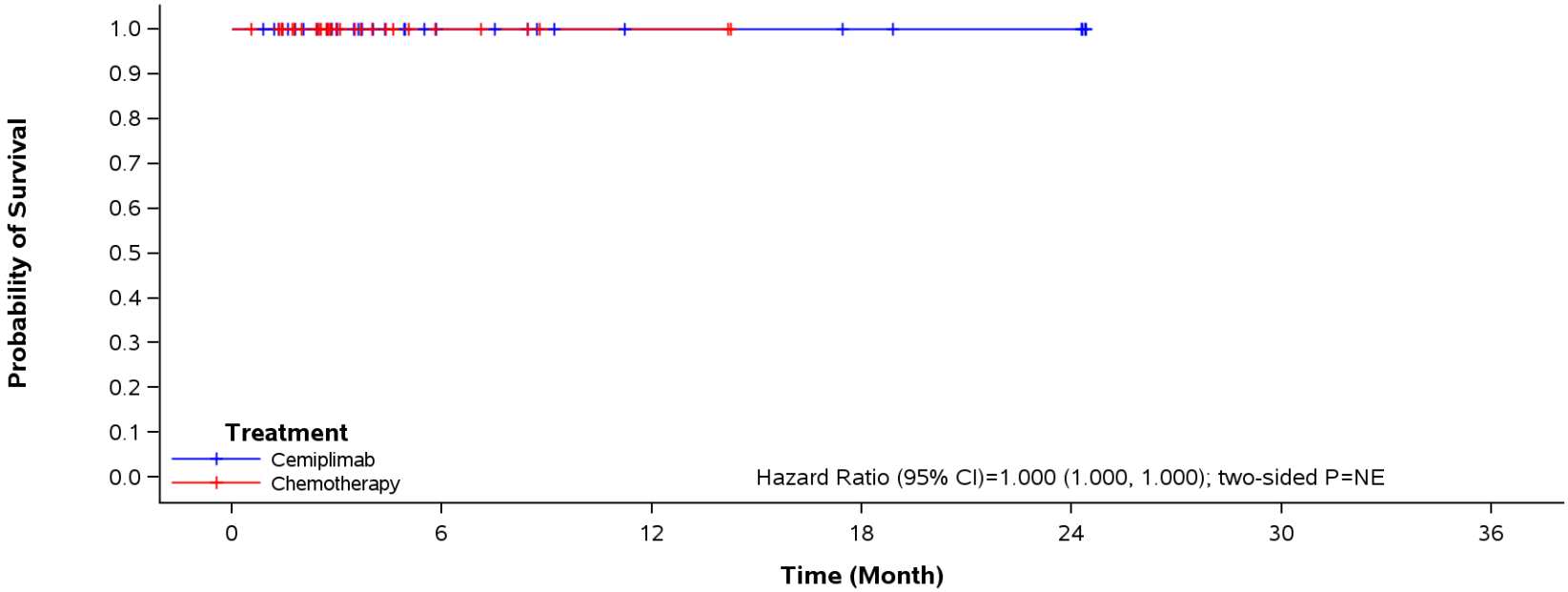

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



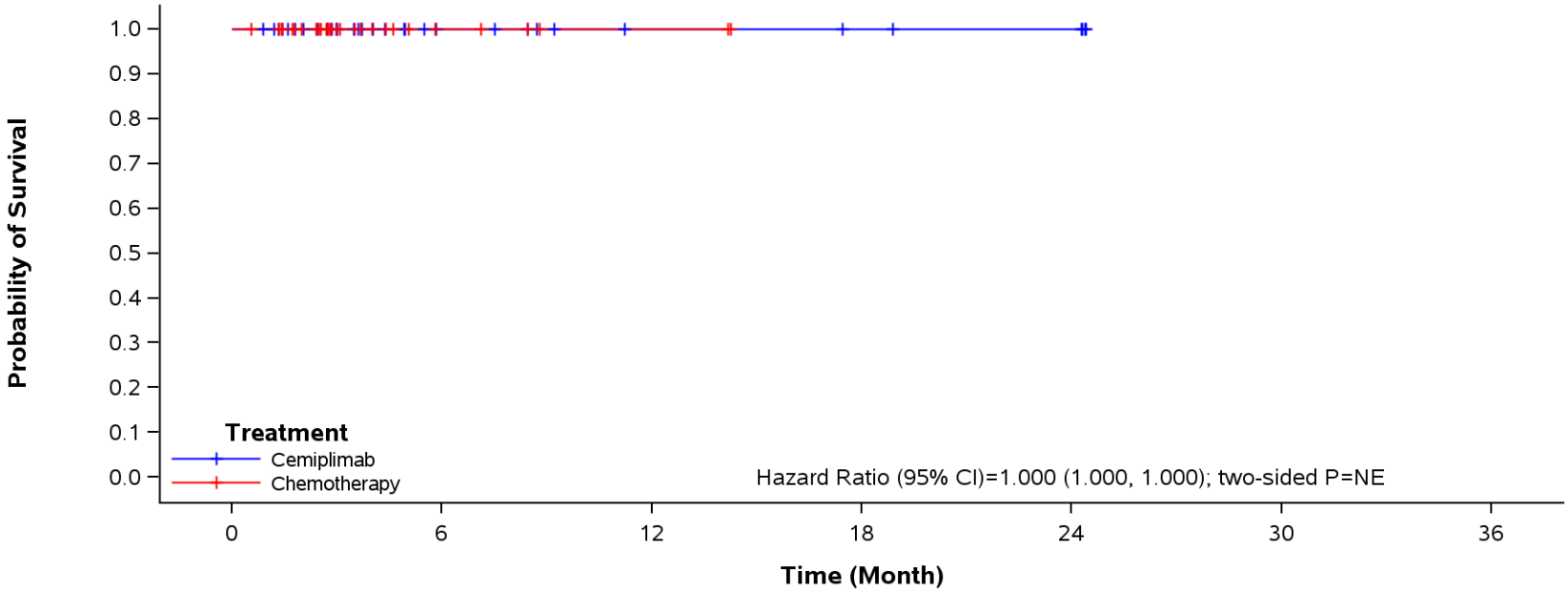

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Gastrointestinal disorders
PT: Proctalgia



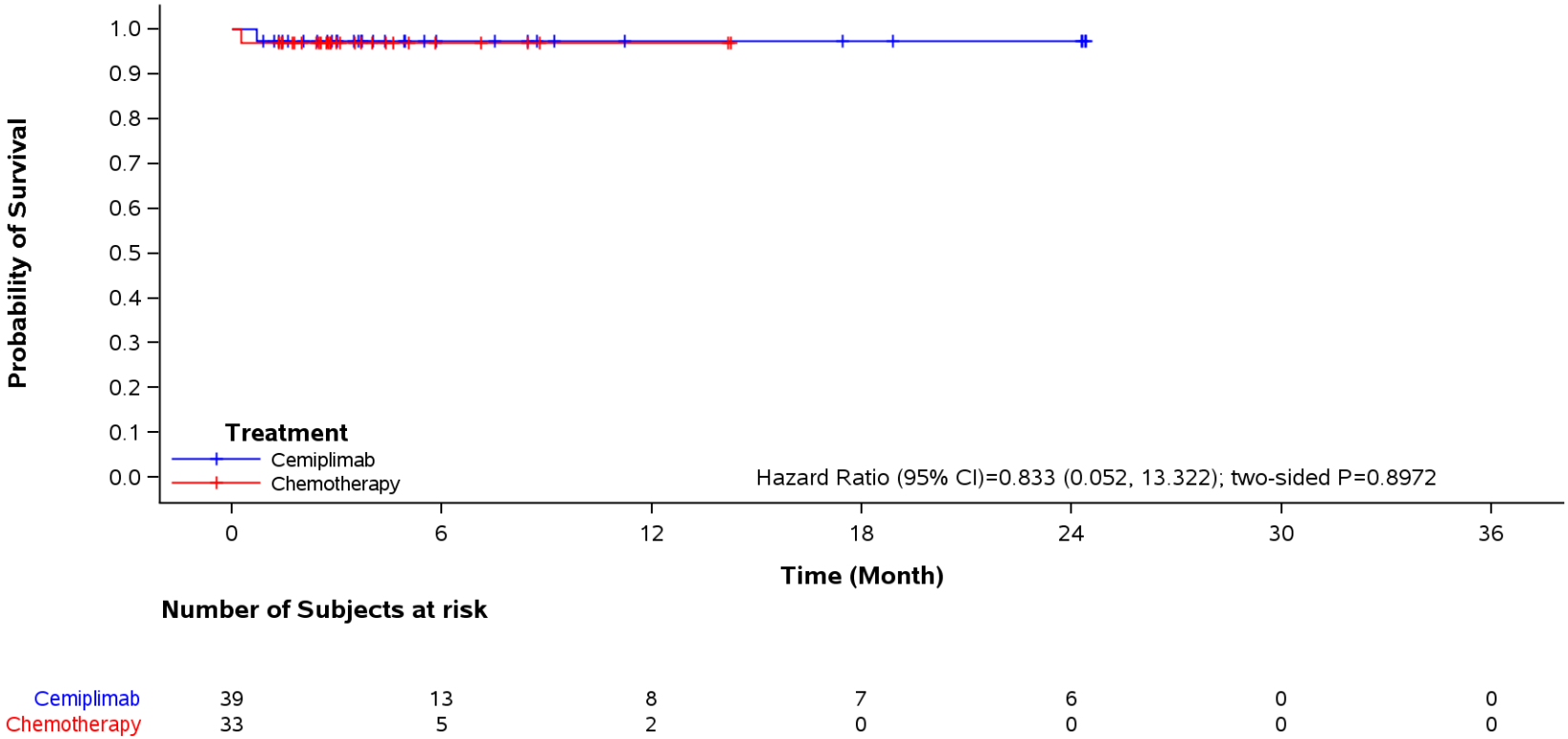

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

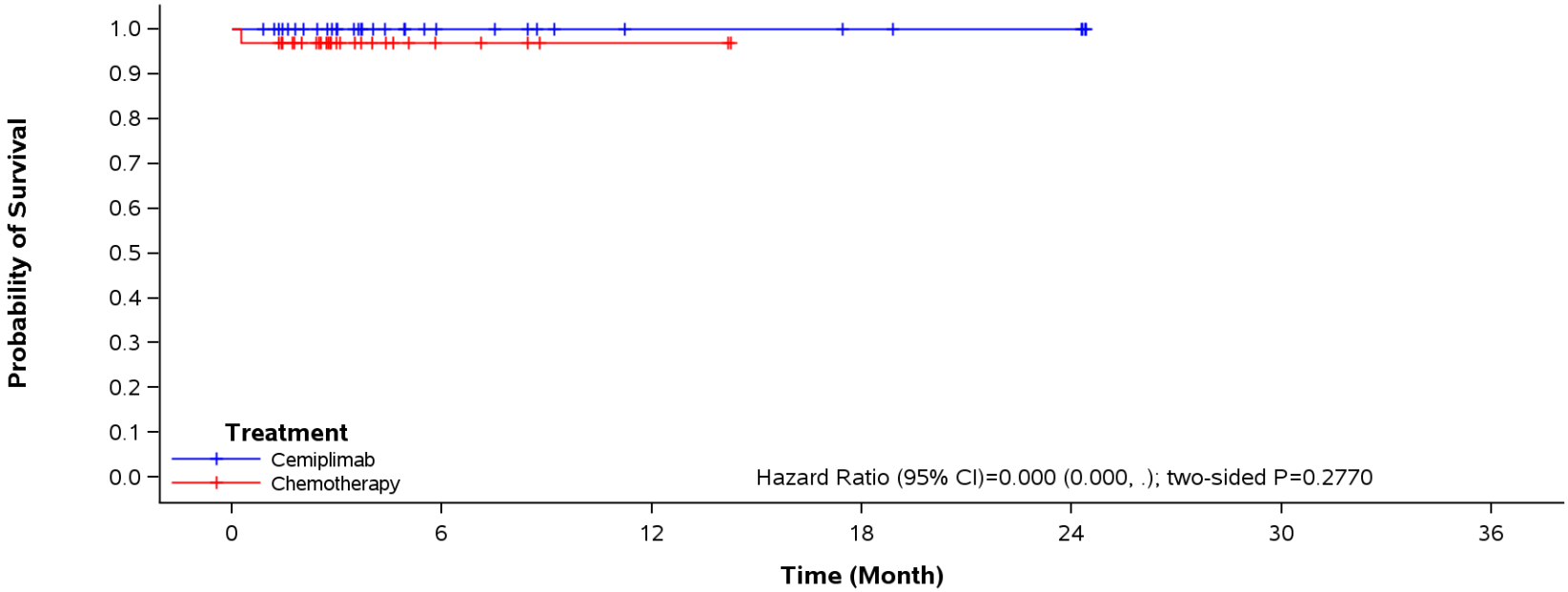
Geographic region: Asia
SOC: General disorders and administration site conditions




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: General disorders and administration site conditions
PT: Malaise



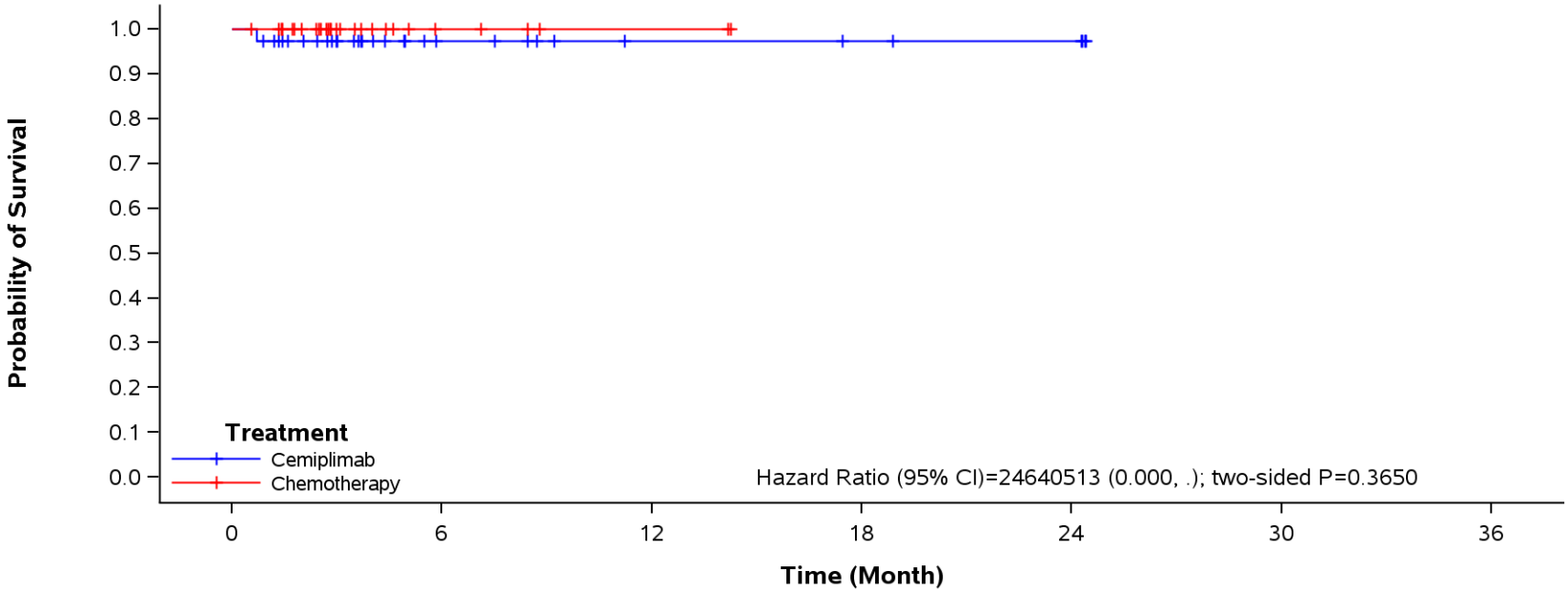

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



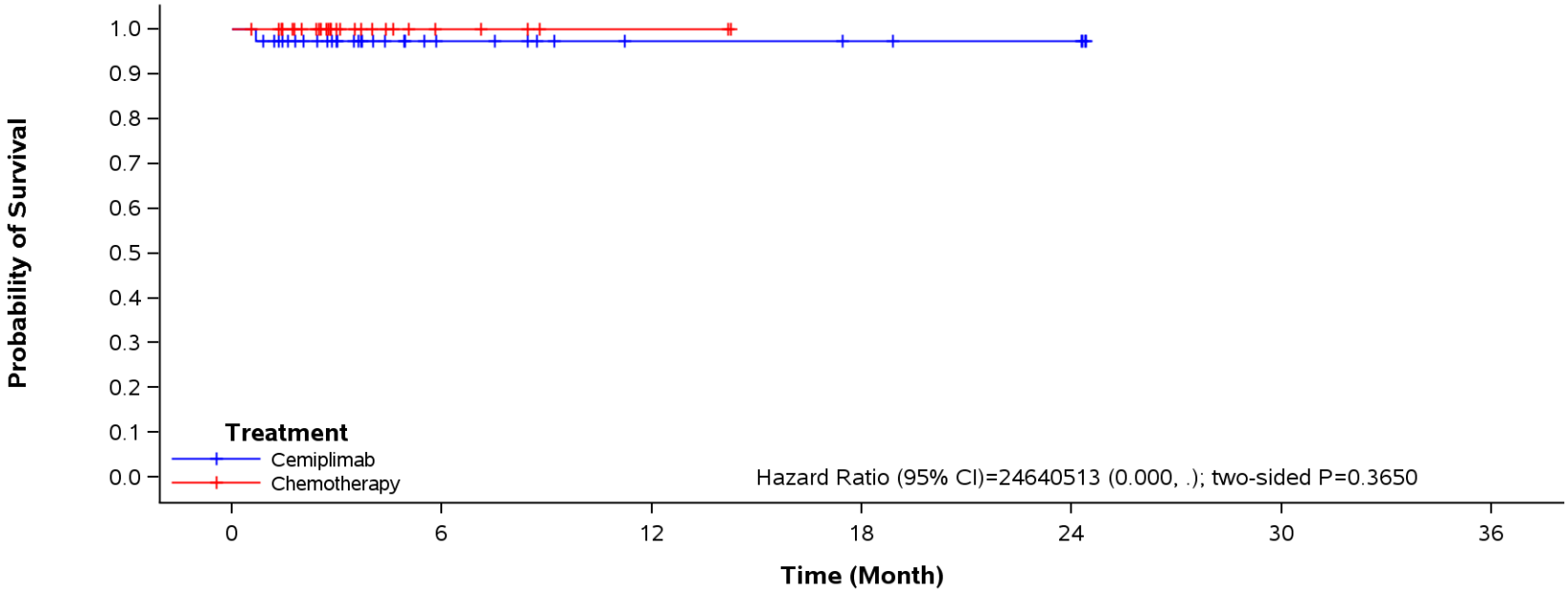

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Hepatobiliary disorders



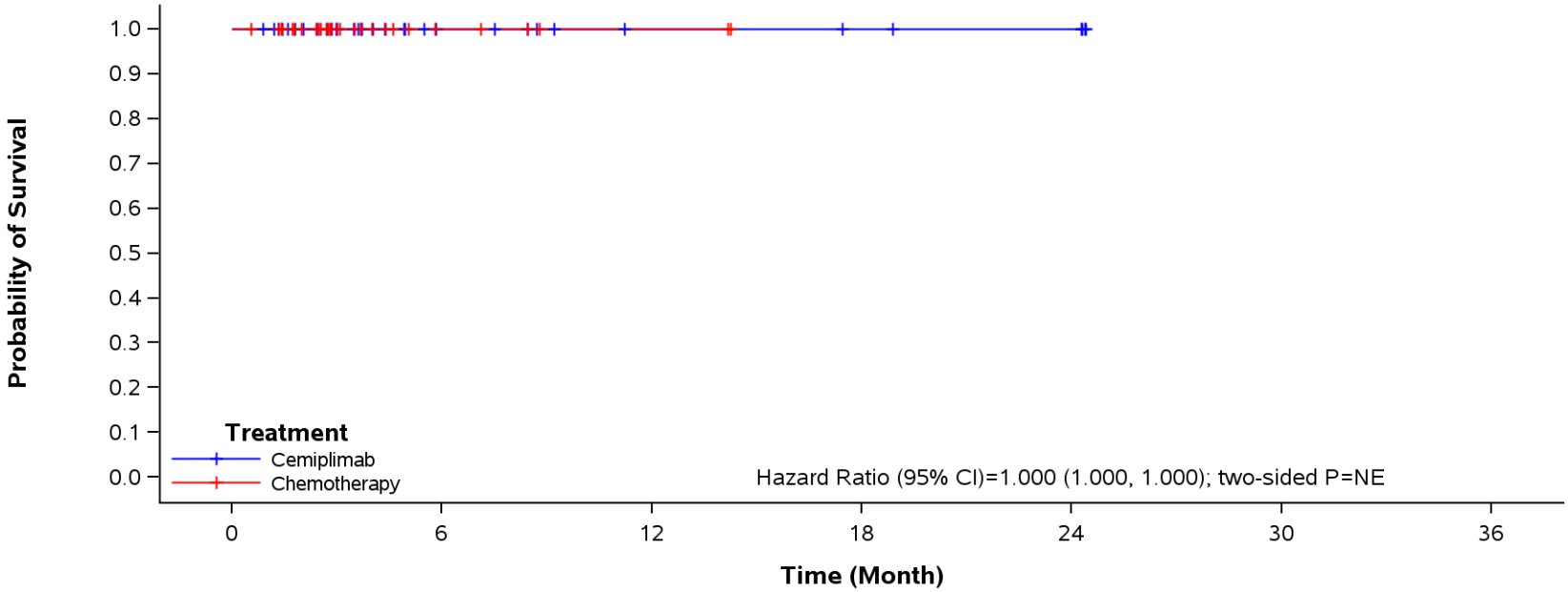

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



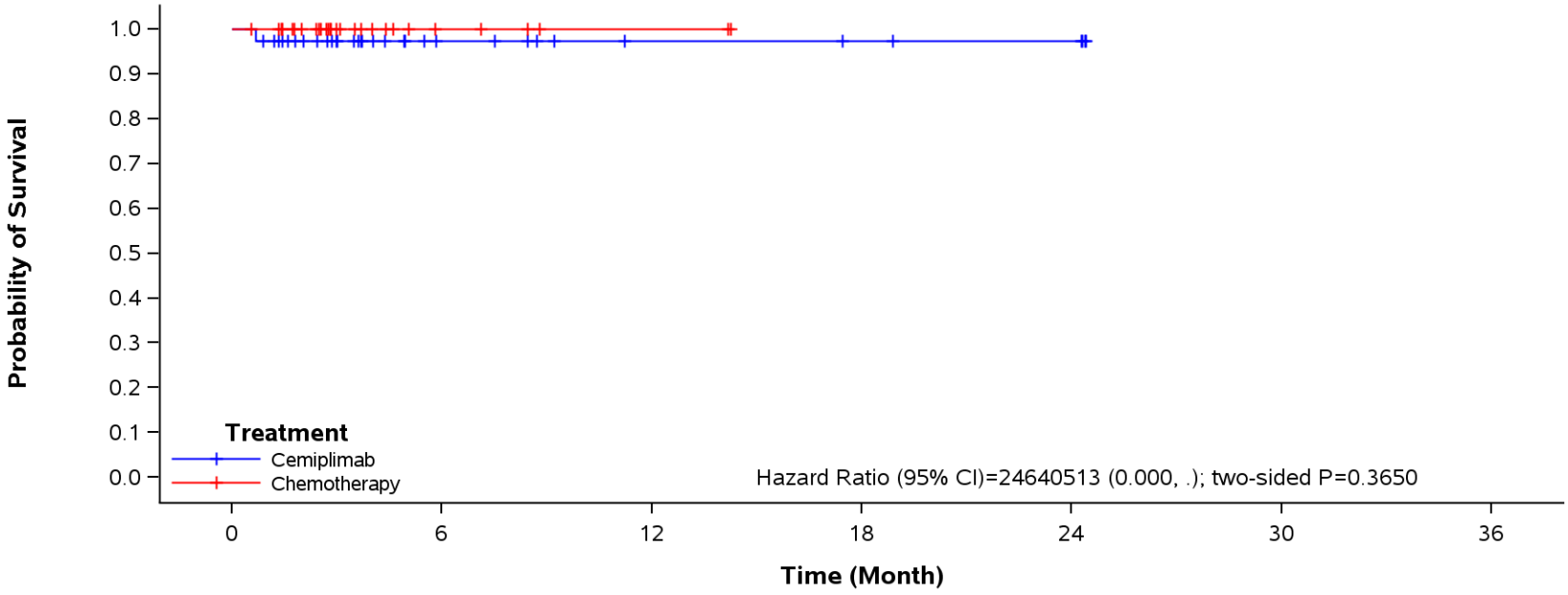

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



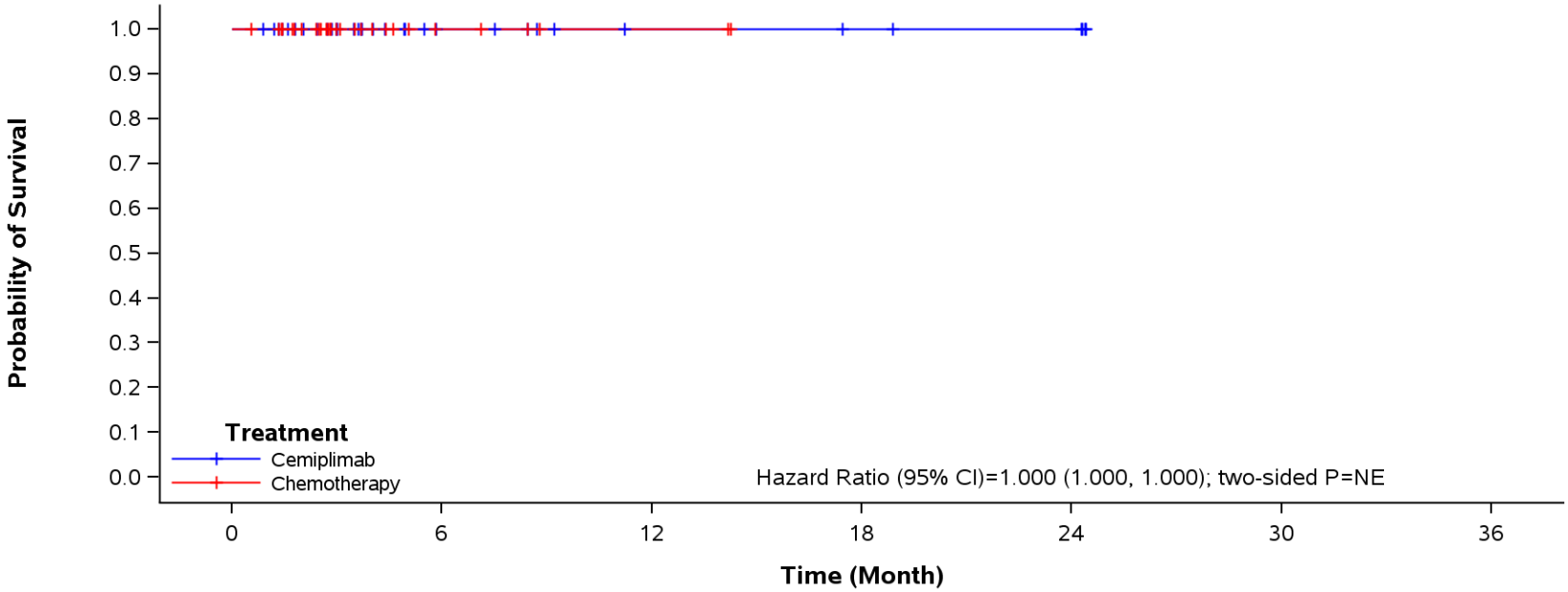

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Hepatobiliary disorders
PT: Hepatitis



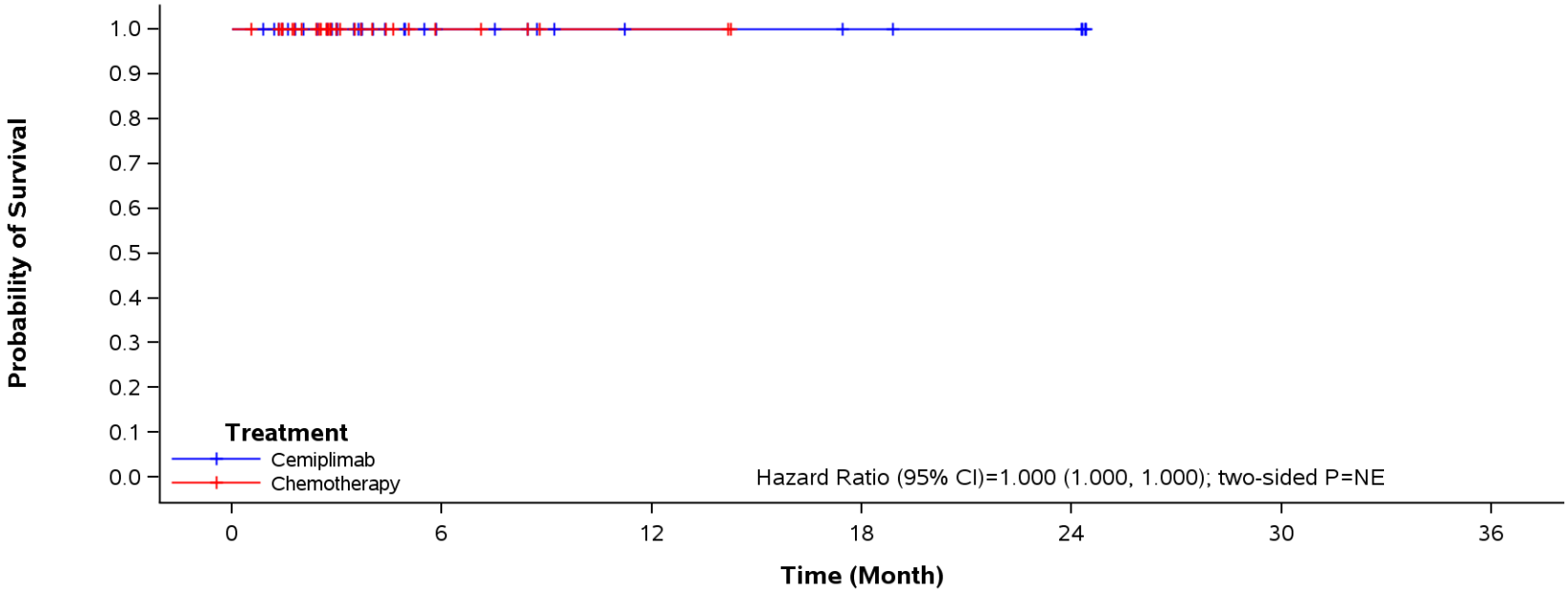

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



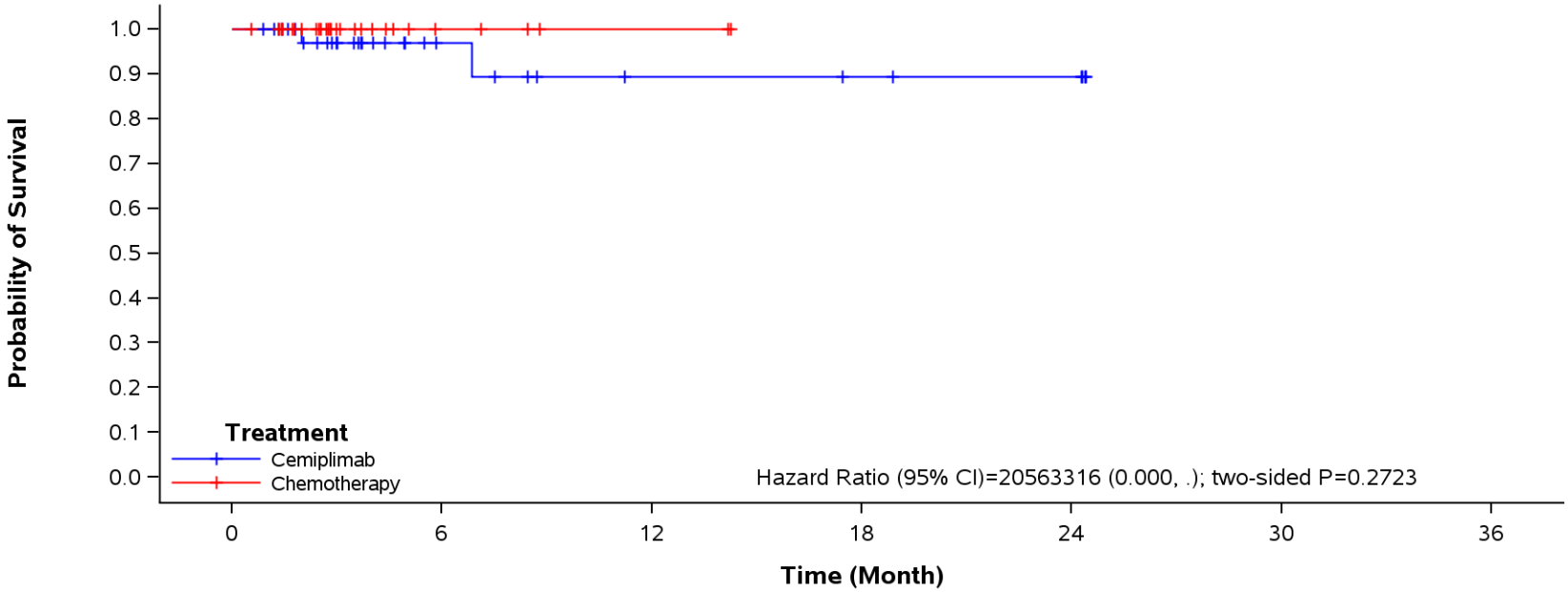

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Infections and infestations



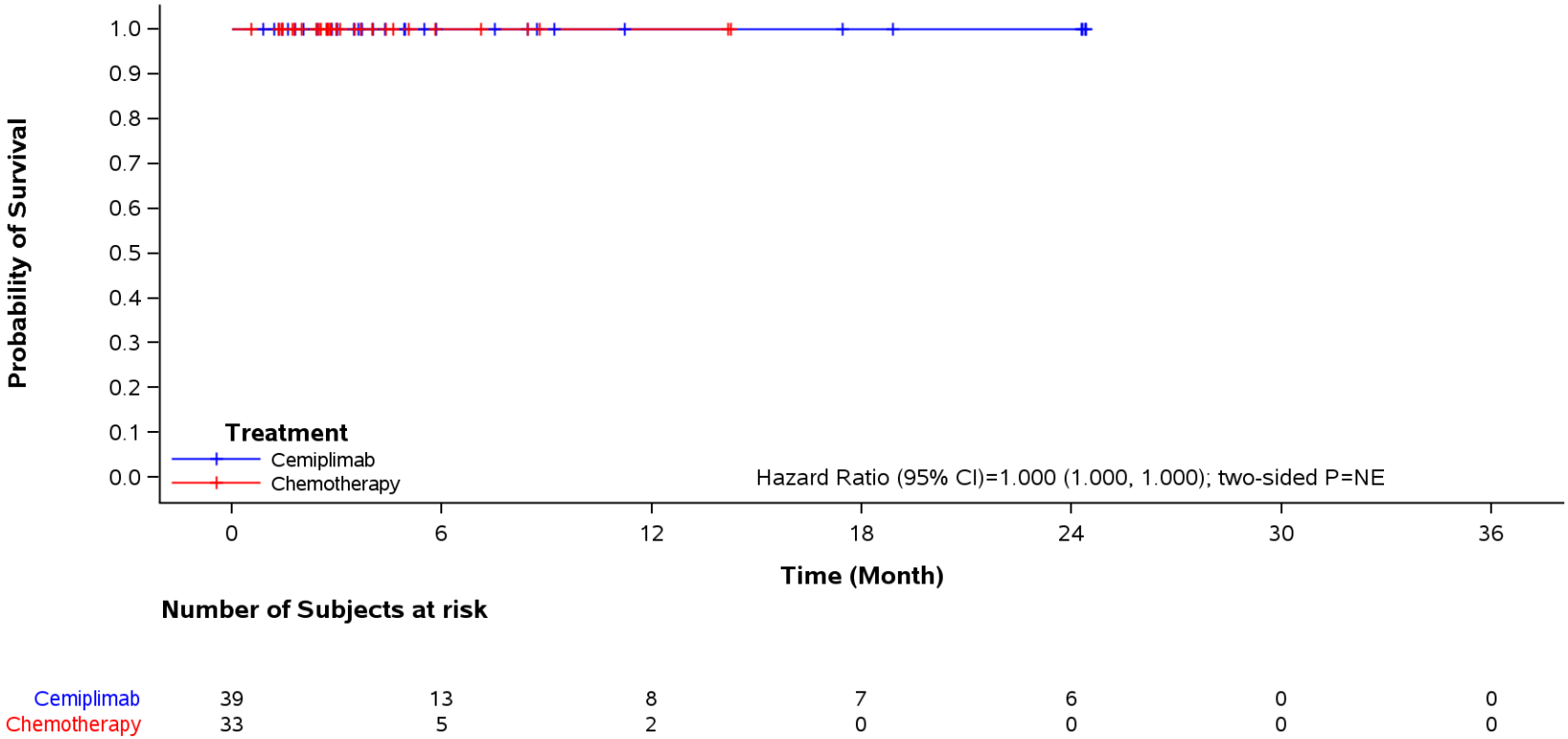

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

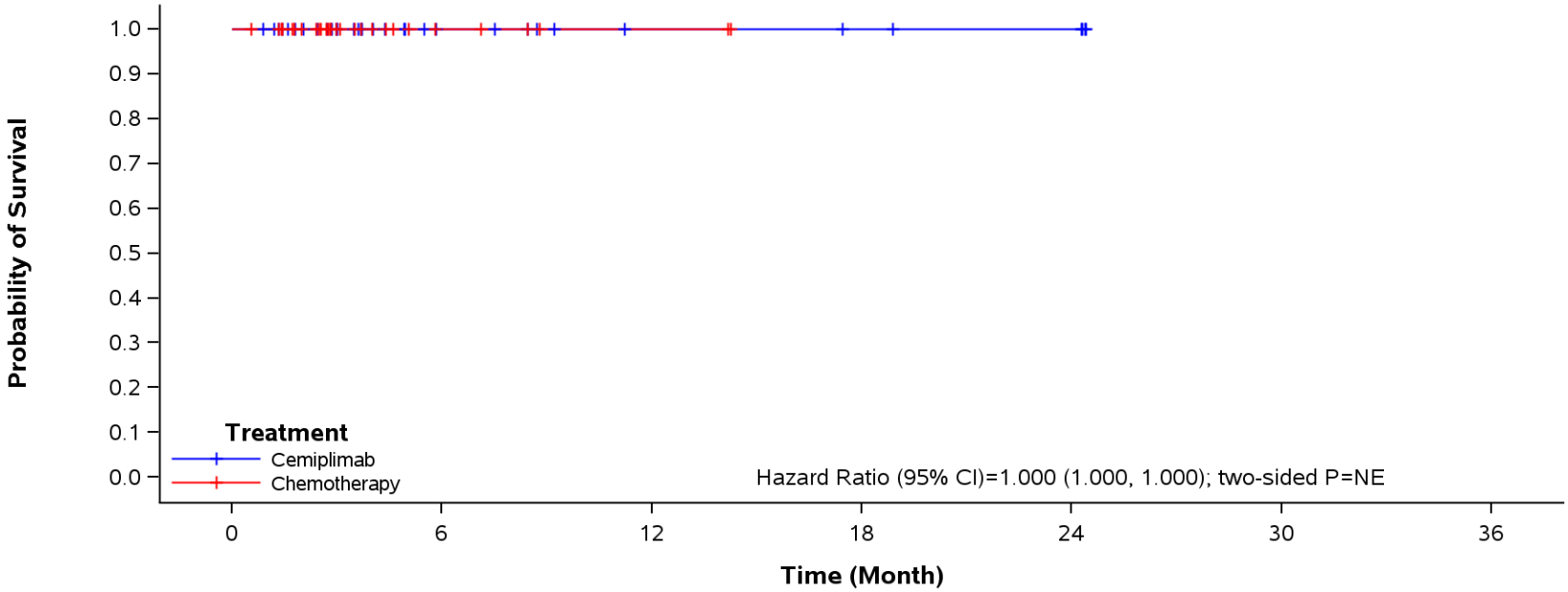
Geographic region: Asia
SOC: Infections and infestations
PT: COVID-19 pneumonia




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Infections and infestations
PT: Gastroenteritis



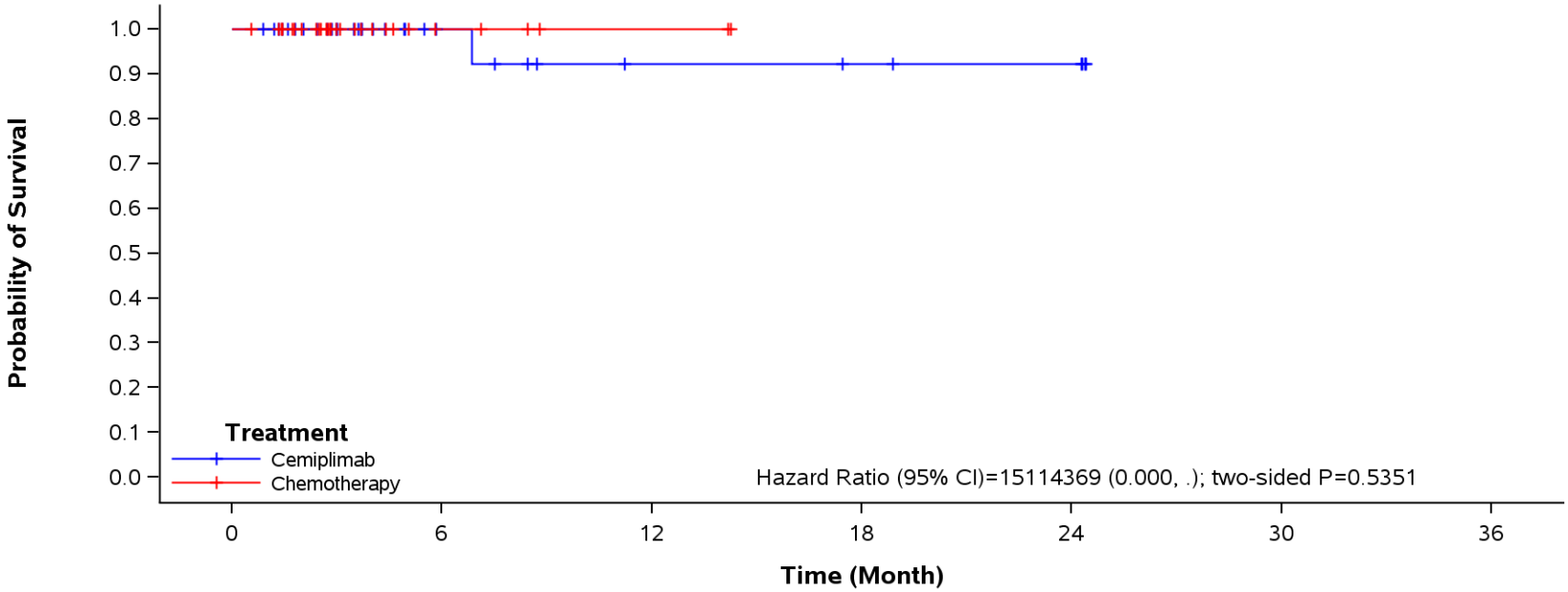

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Infections and infestations
PT: Pelvic abscess



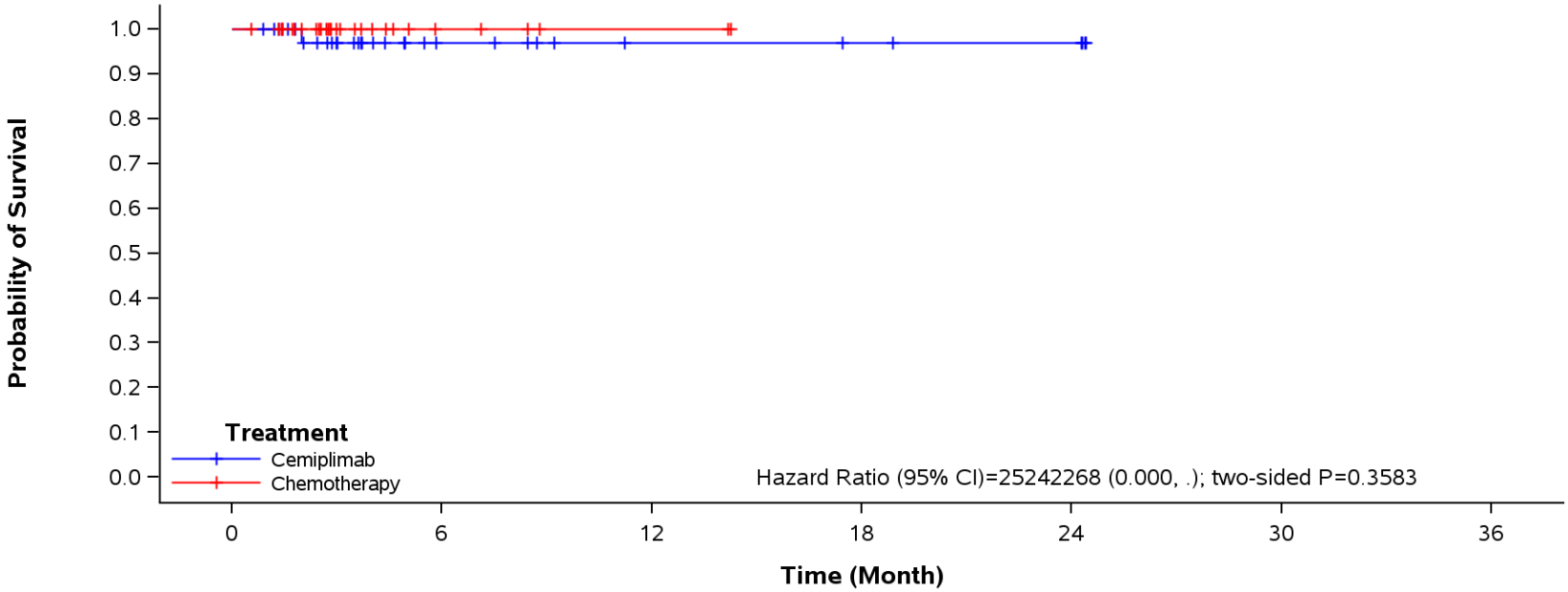

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Infections and infestations
PT: Peritonitis



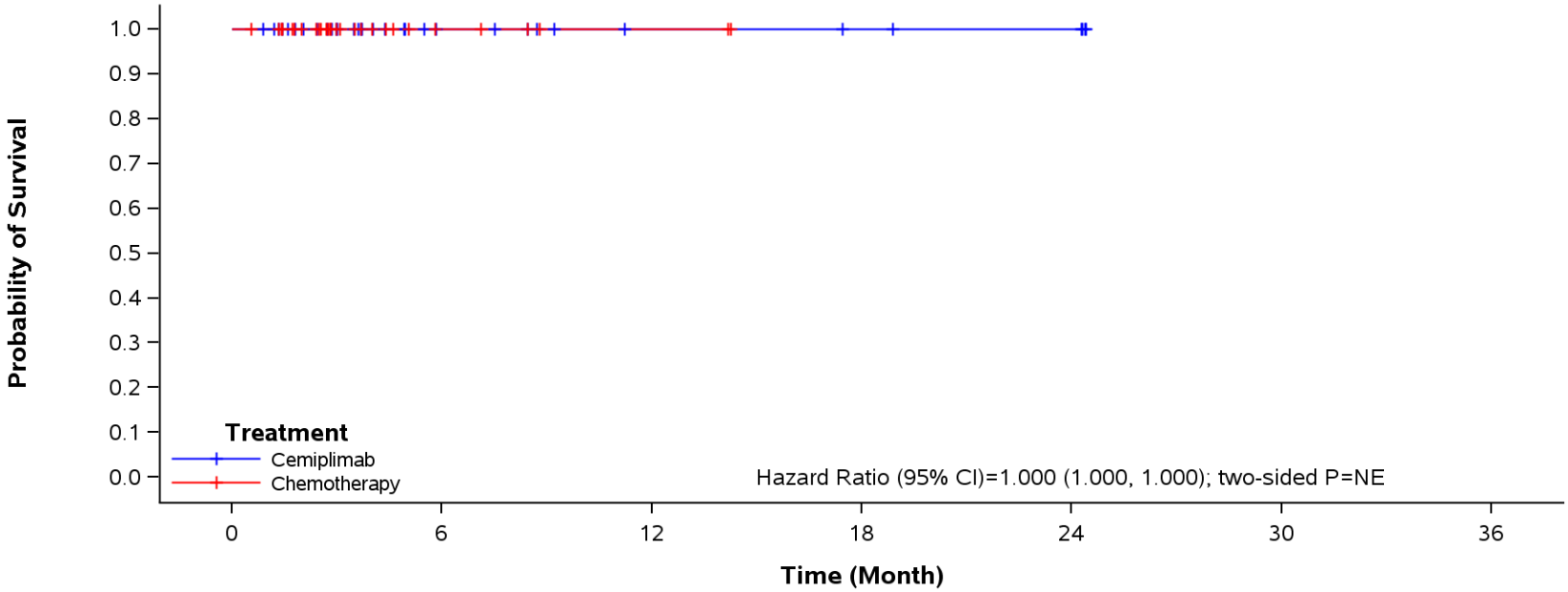

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Infections and infestations
PT: Pneumonia



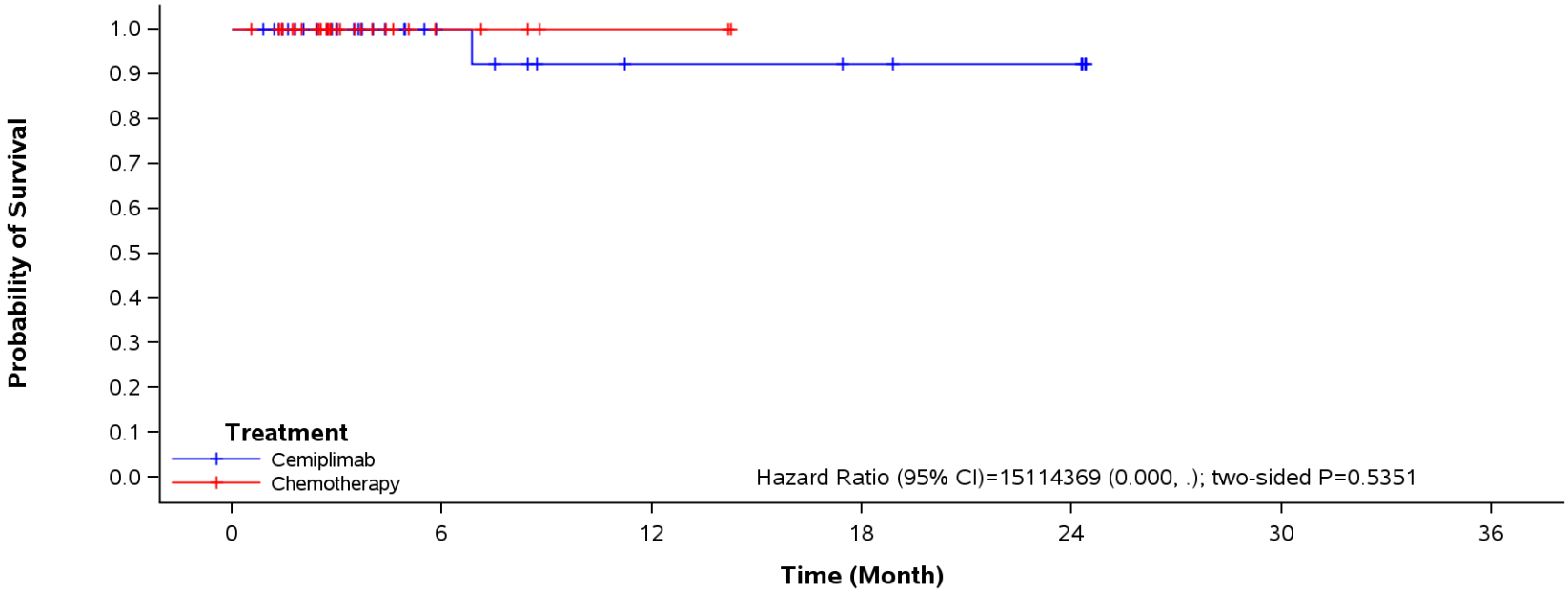

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Infections and infestations
PT: Pyomyositis



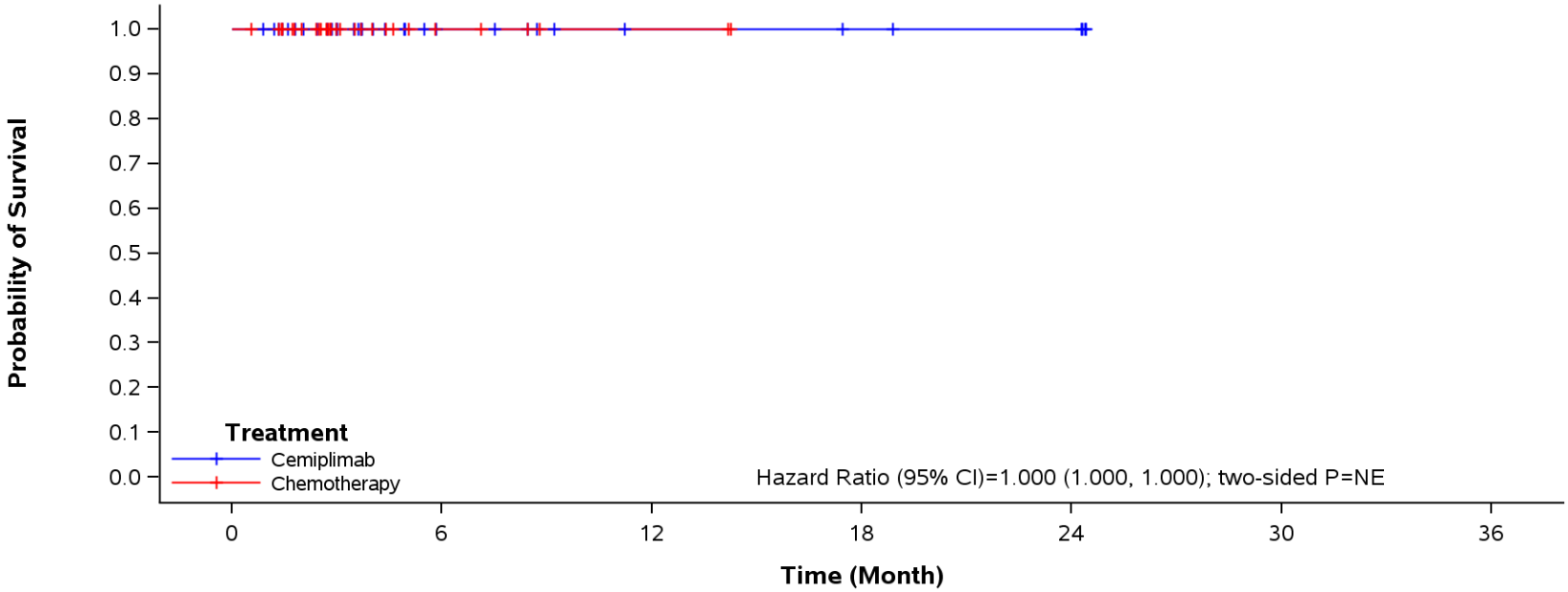

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Injury, poisoning and procedural complications



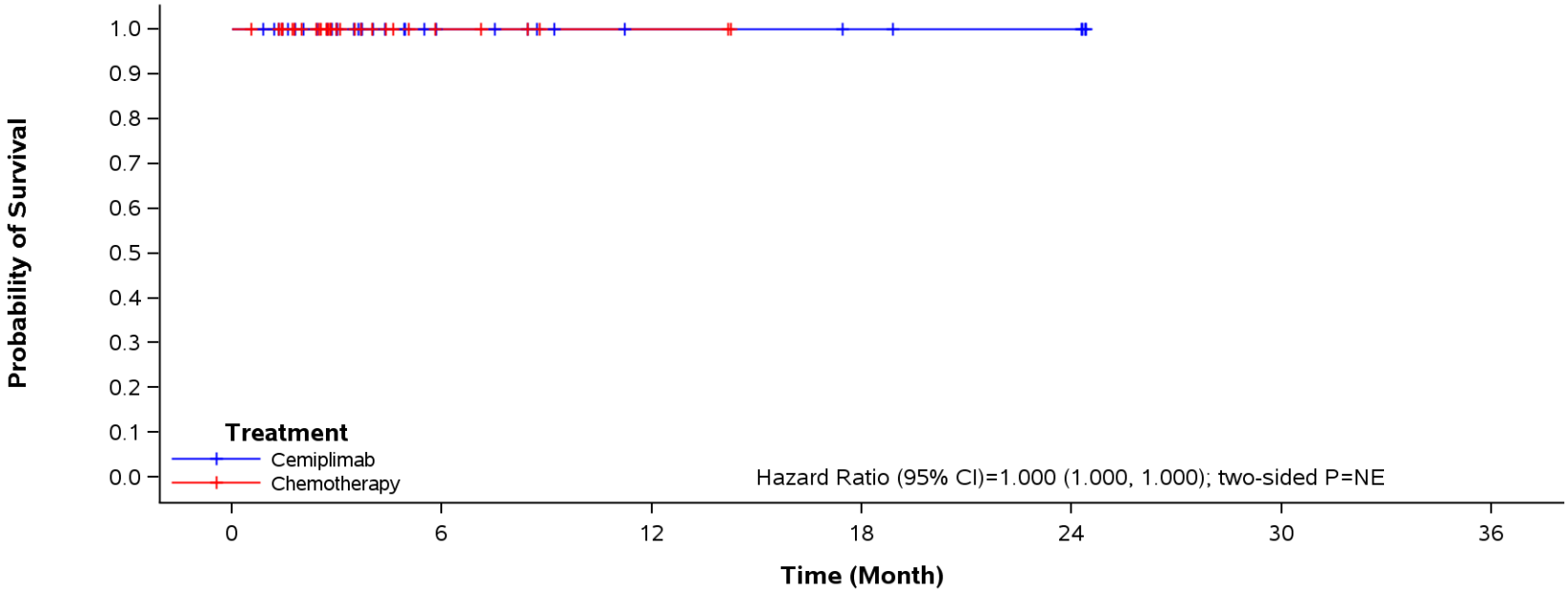

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



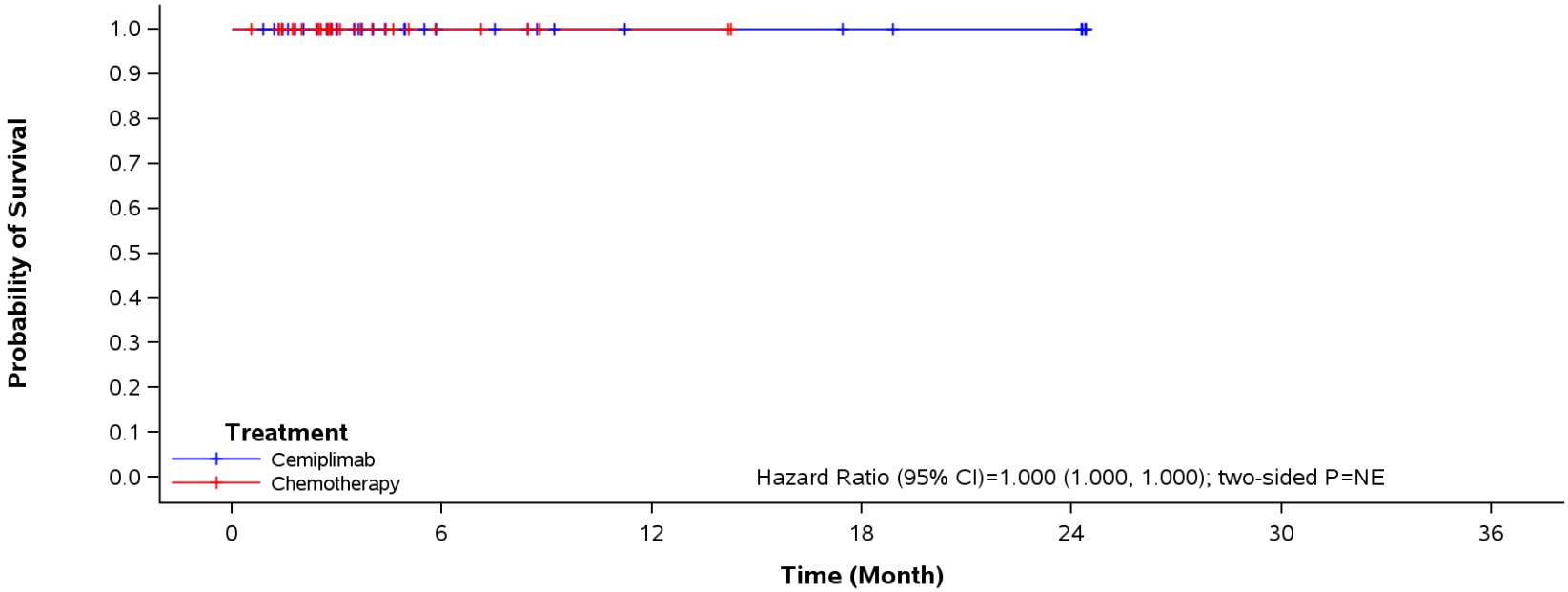

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



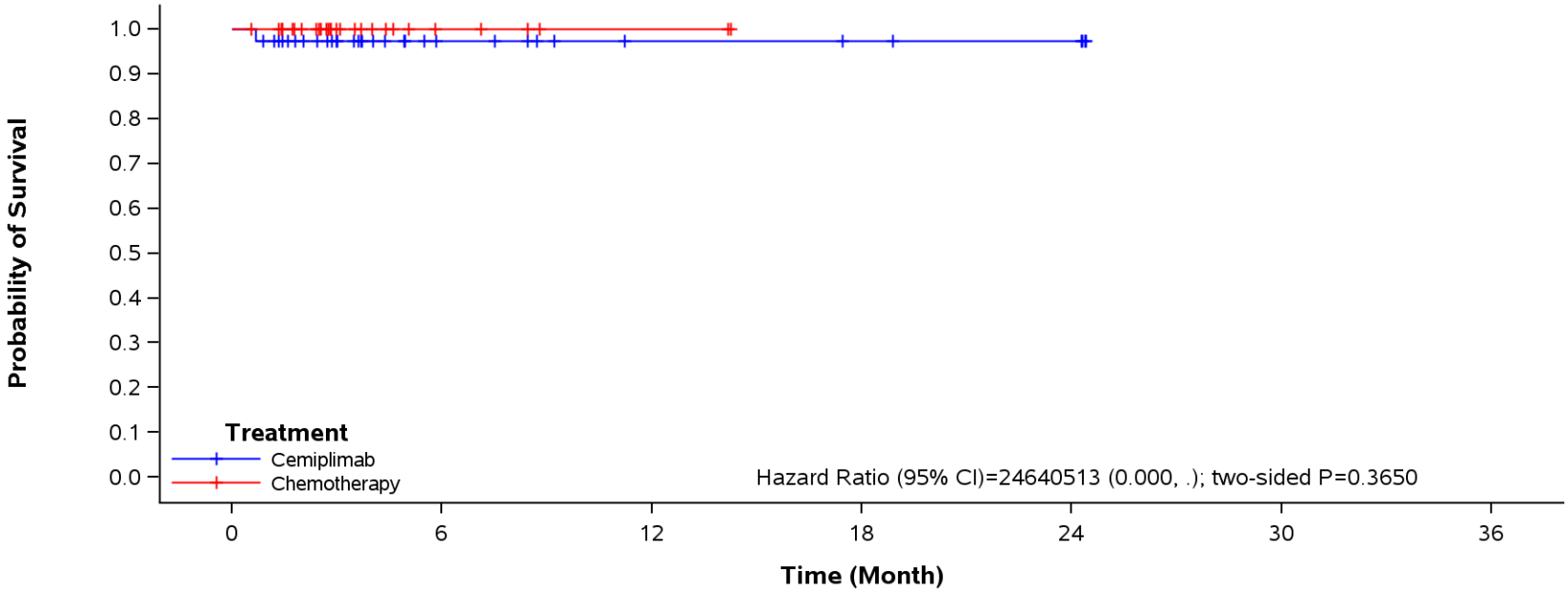

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Investigations



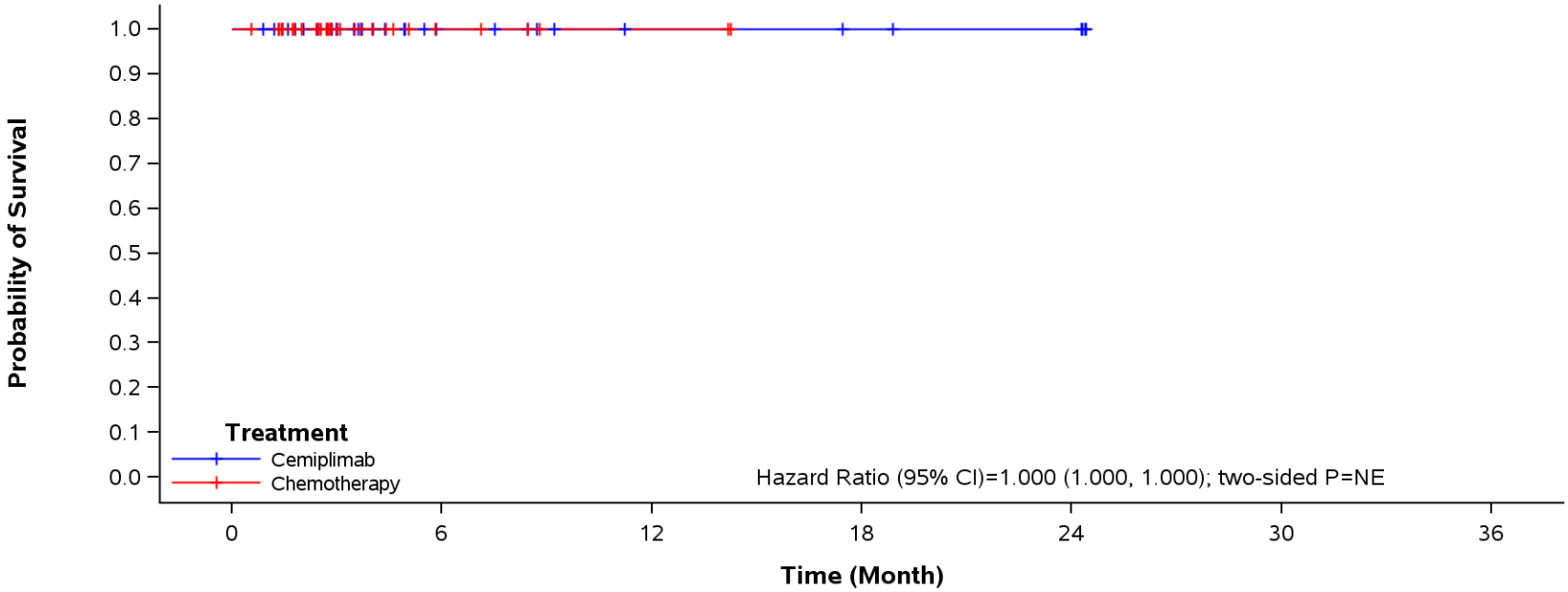

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Investigations
PT: Alanine aminotransferase increased



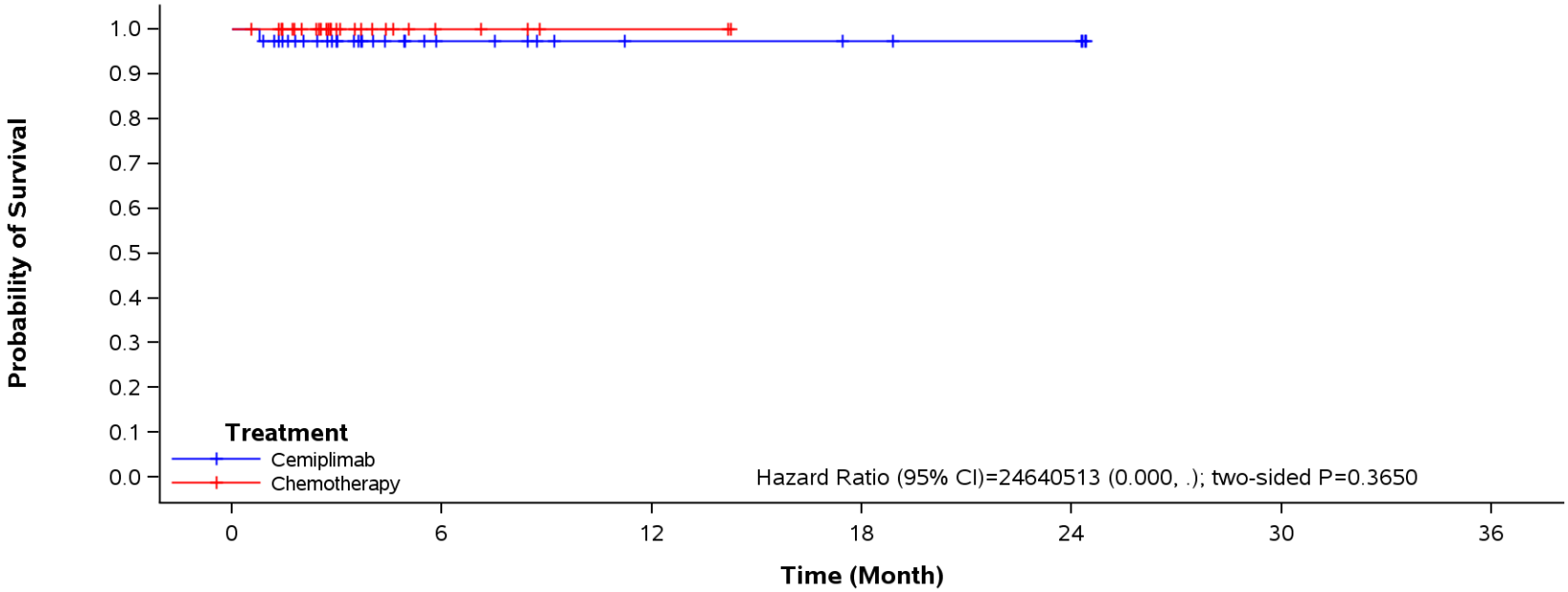

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Investigations
PT: Amylase increased



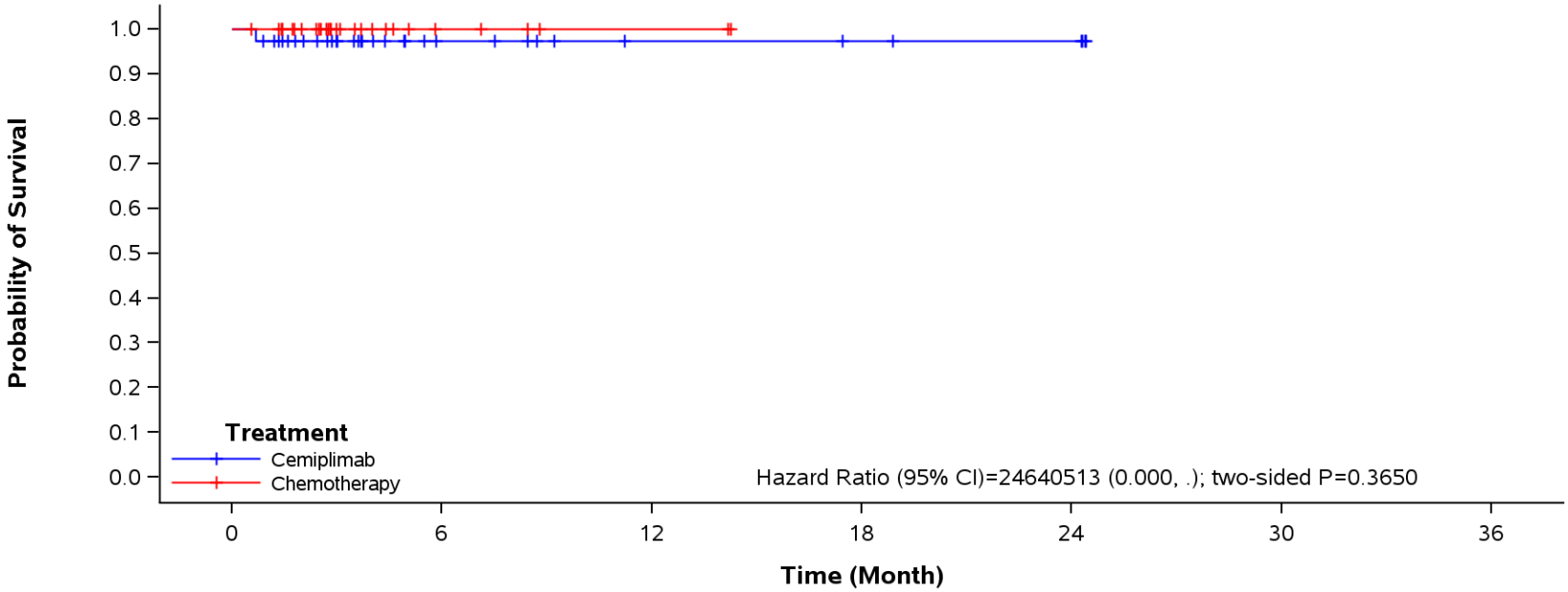

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Investigations
PT: Platelet count decreased



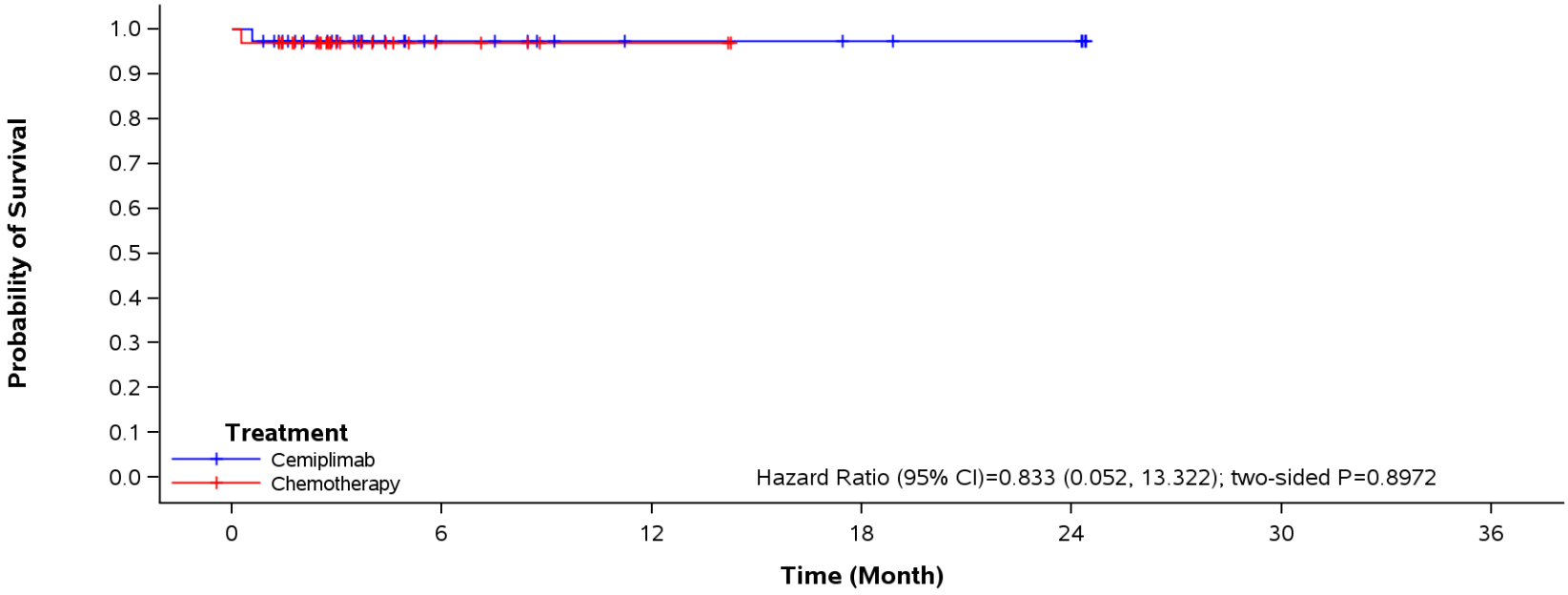

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Metabolism and nutrition disorders



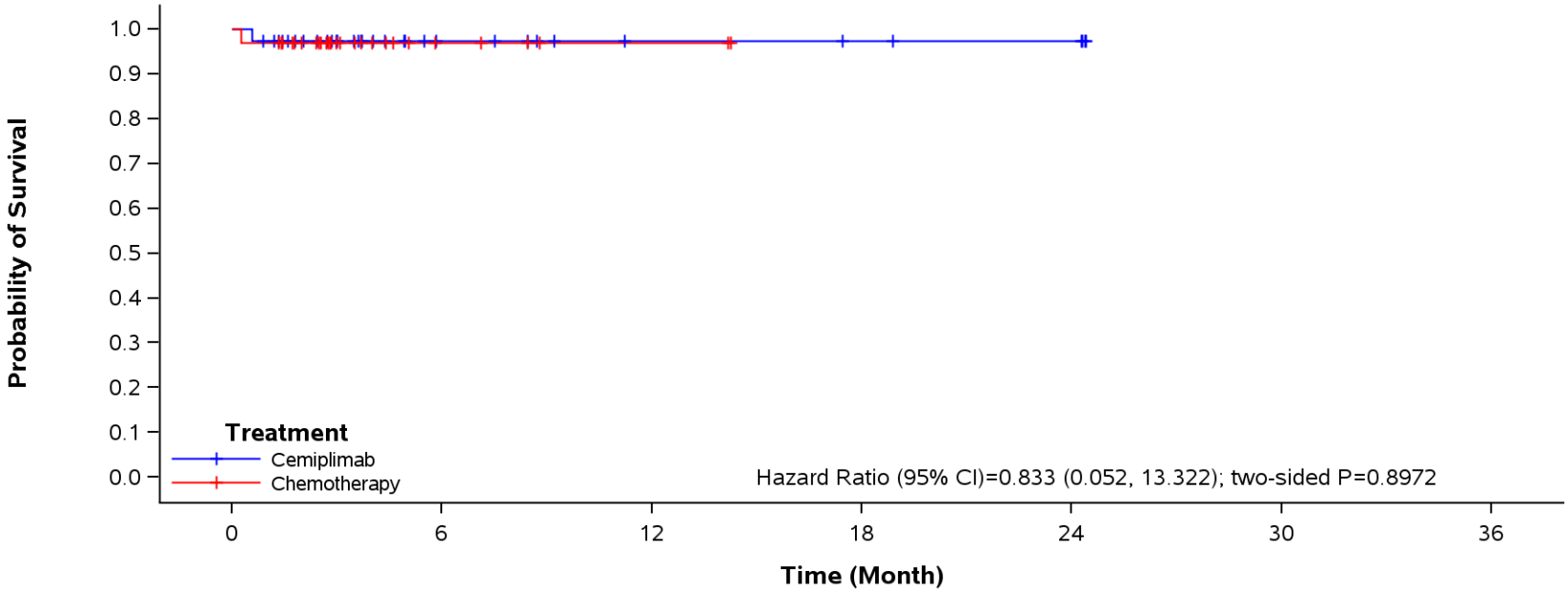

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



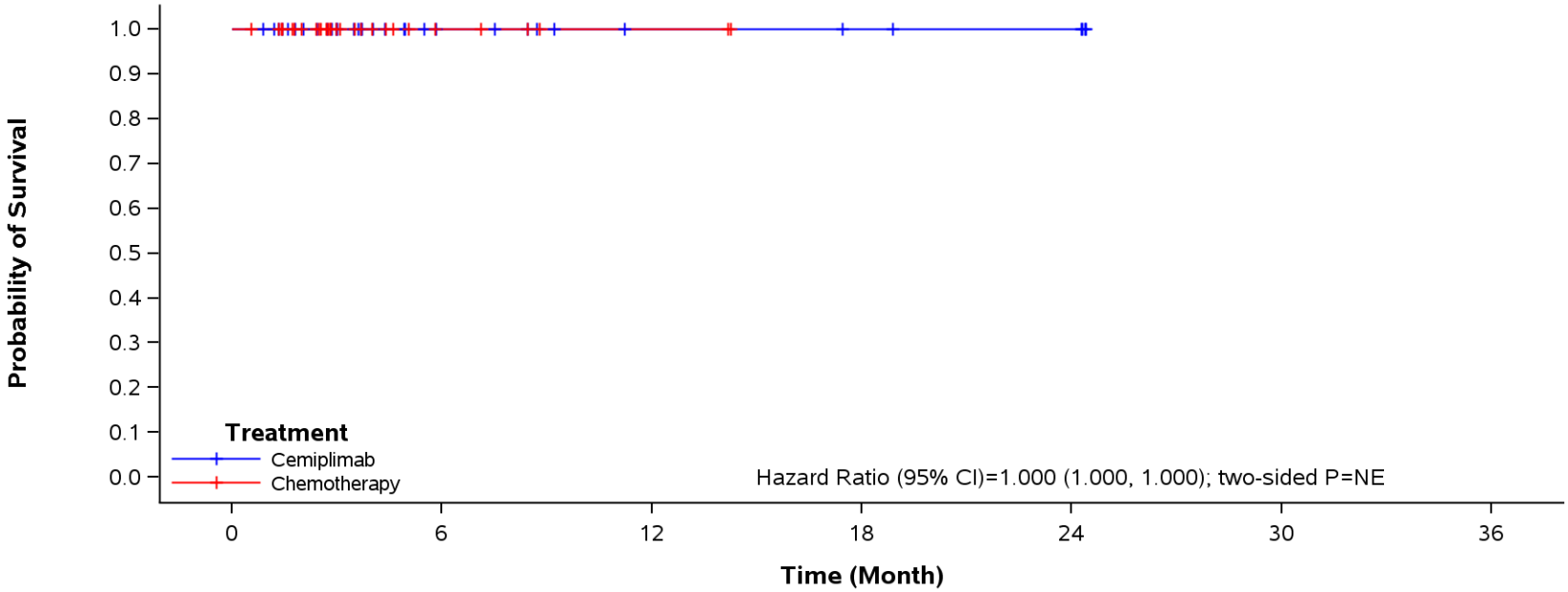

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Musculoskeletal and connective tissue disorders



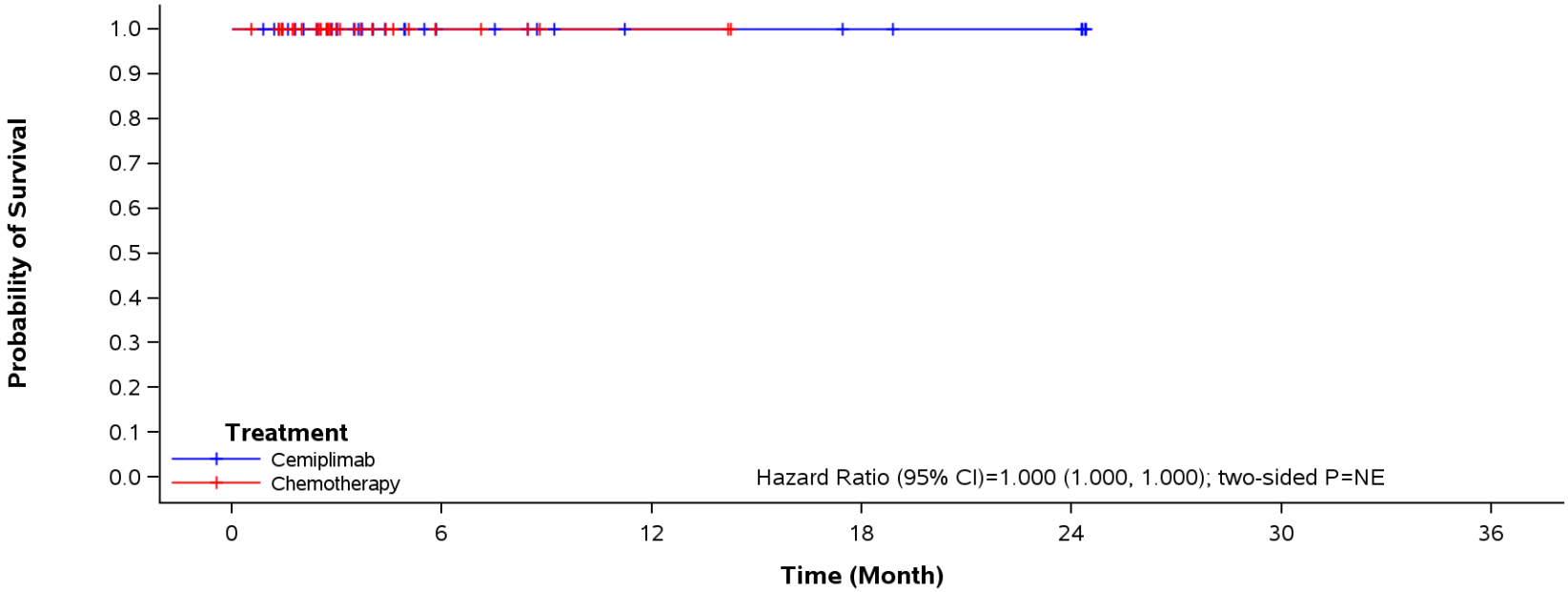

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



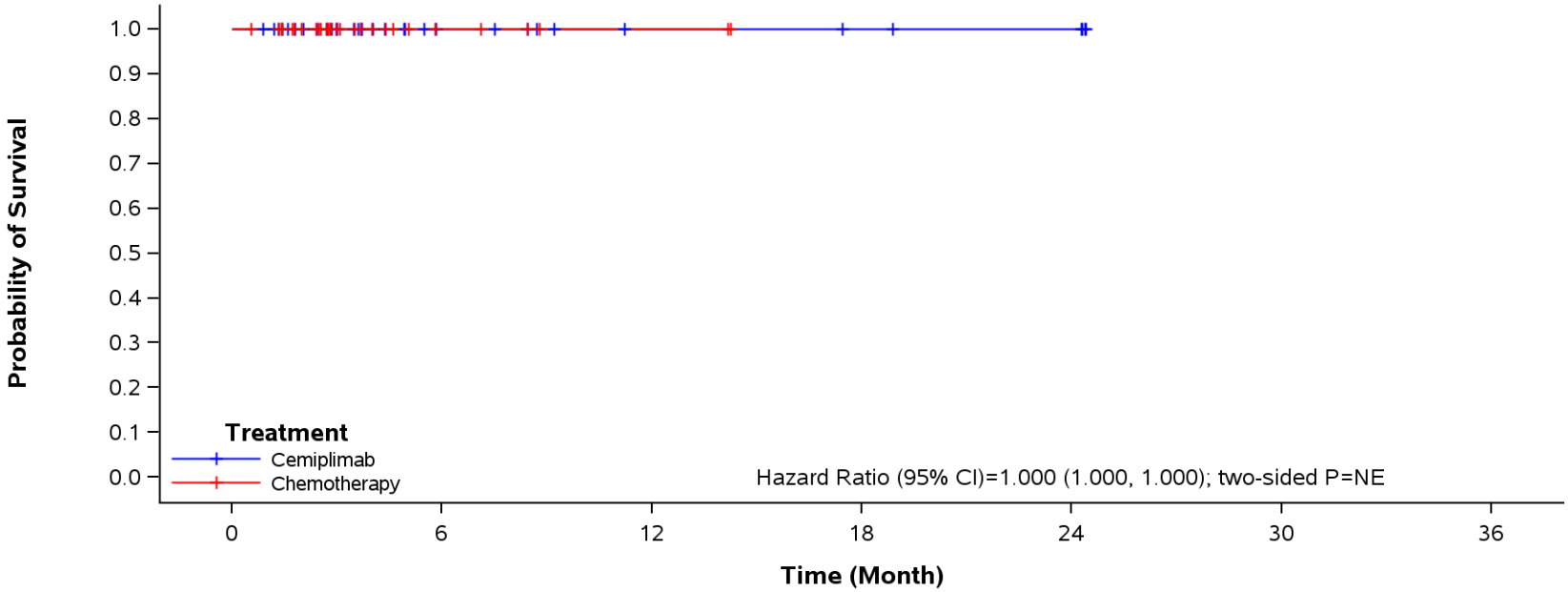

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



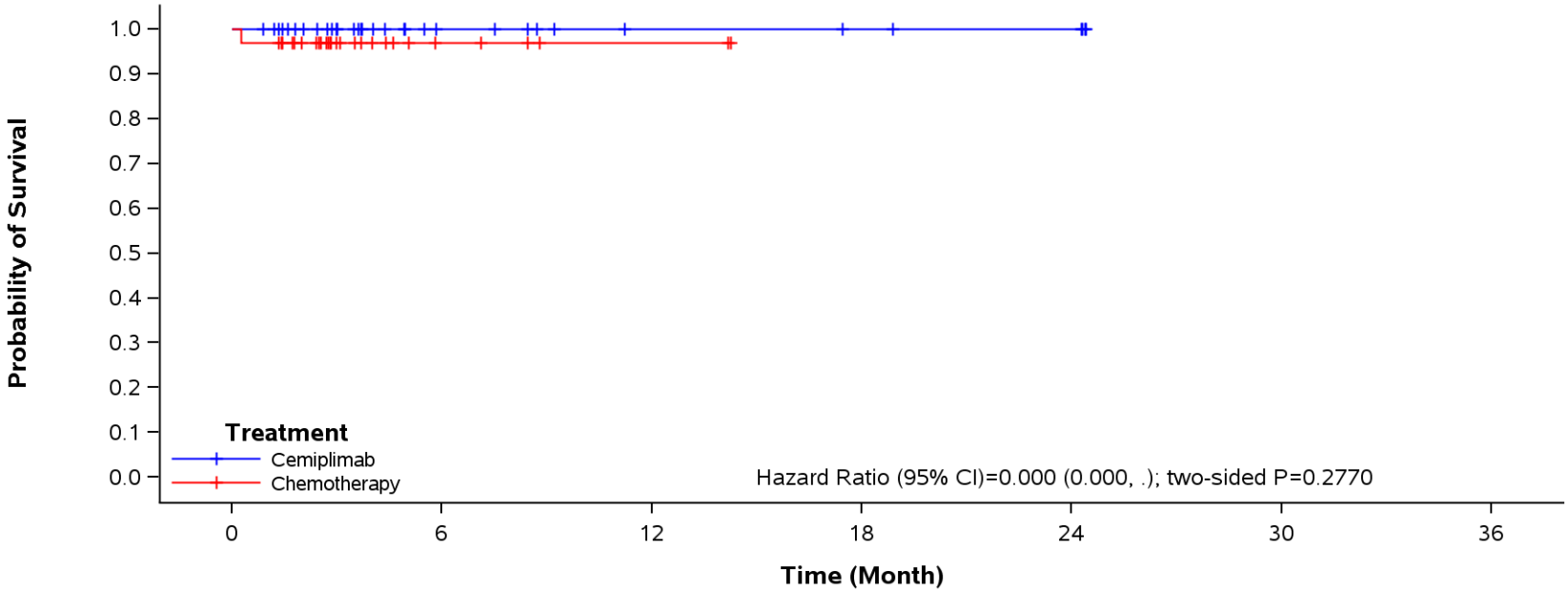

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Nervous system disorders



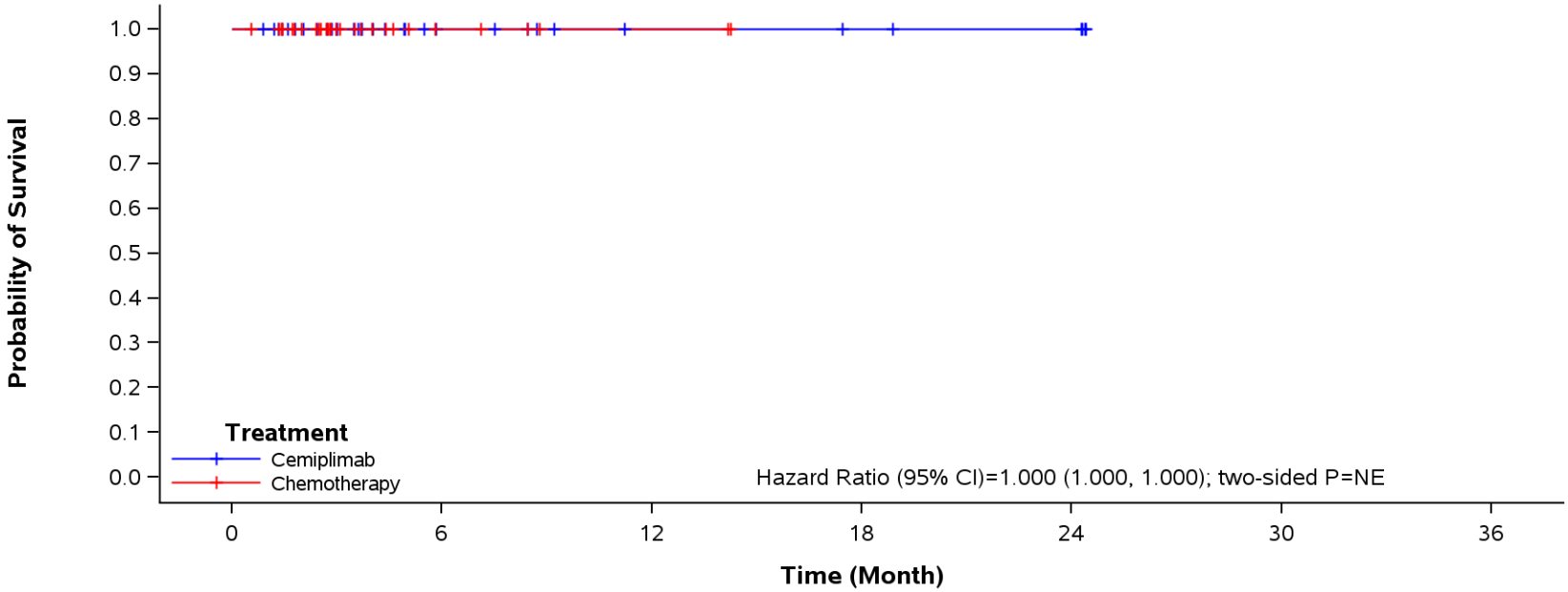

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Nervous system disorders
PT: Neurotoxicity



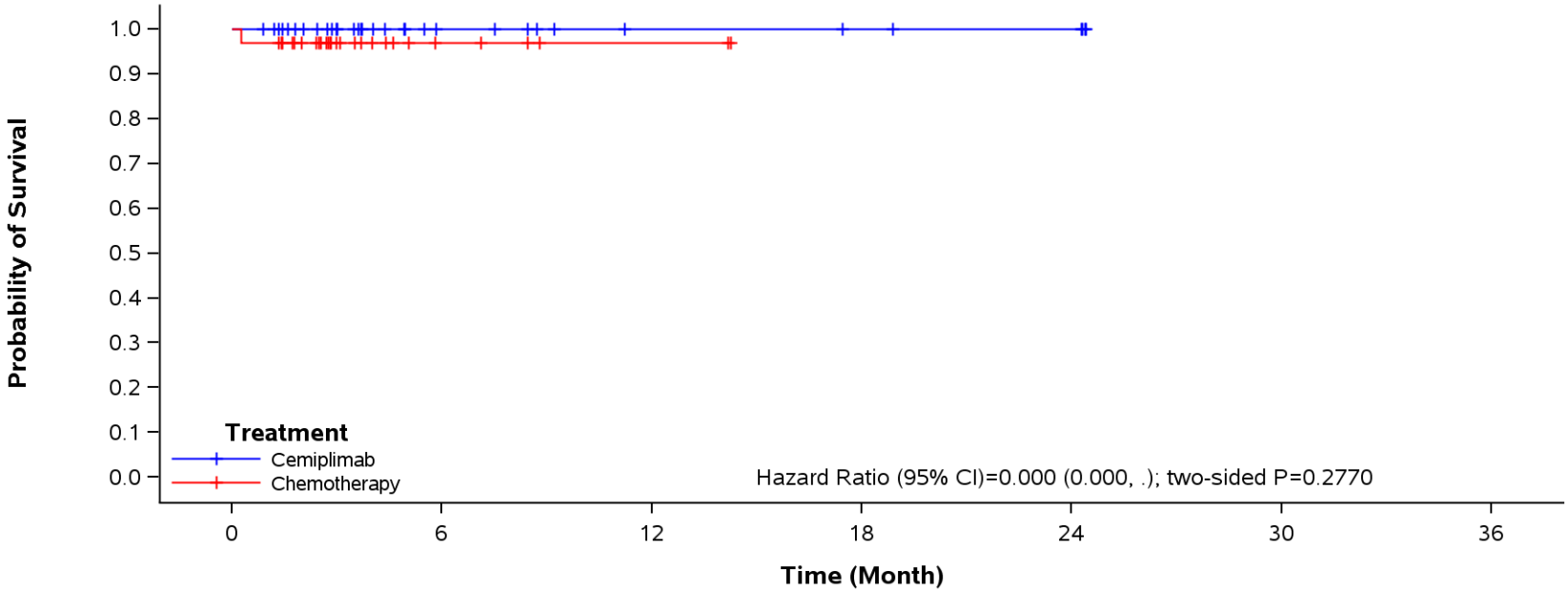

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Nervous system disorders
PT: Transient ischaemic attack



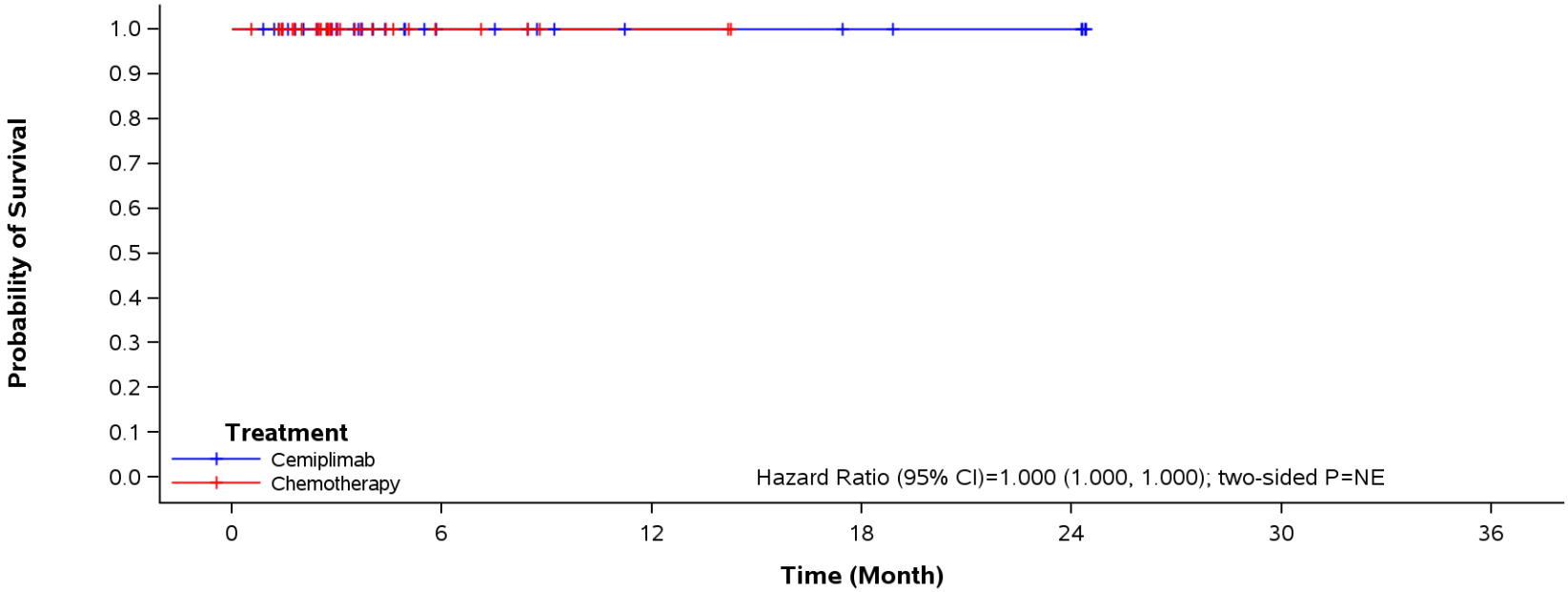

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Psychiatric disorders



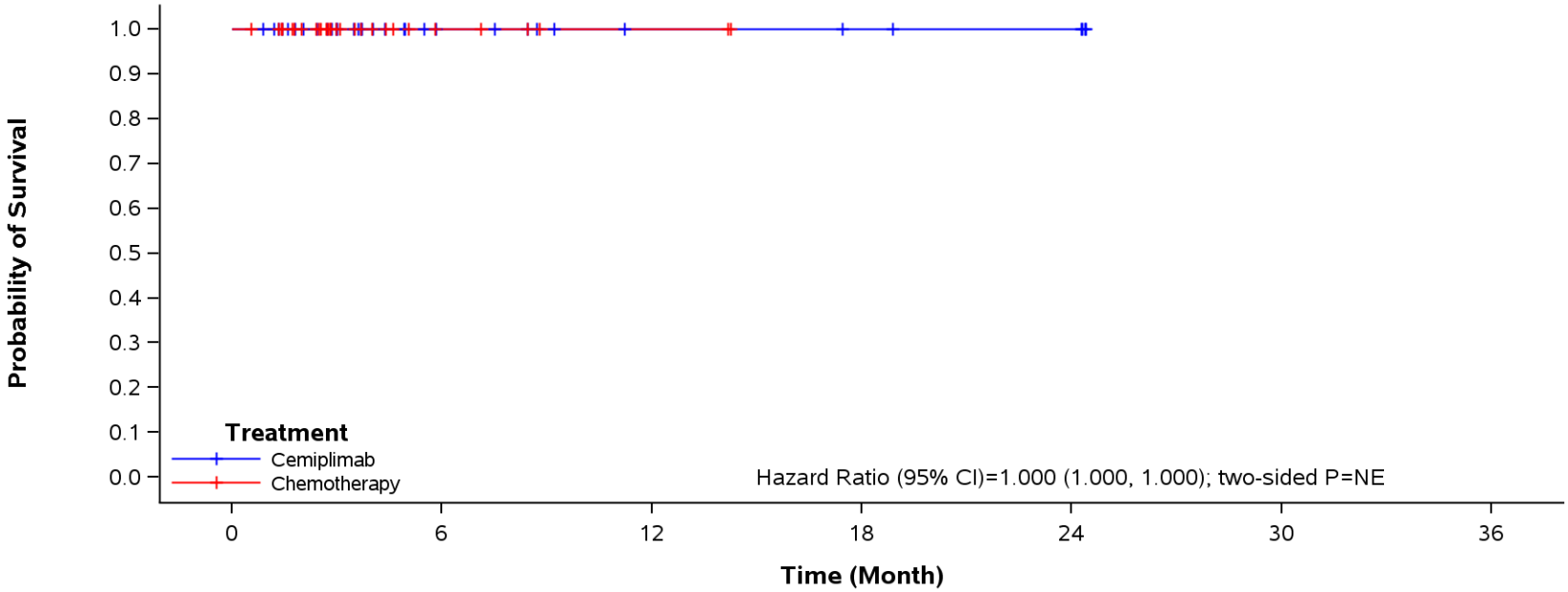

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Psychiatric disorders
PT: Agoraphobia



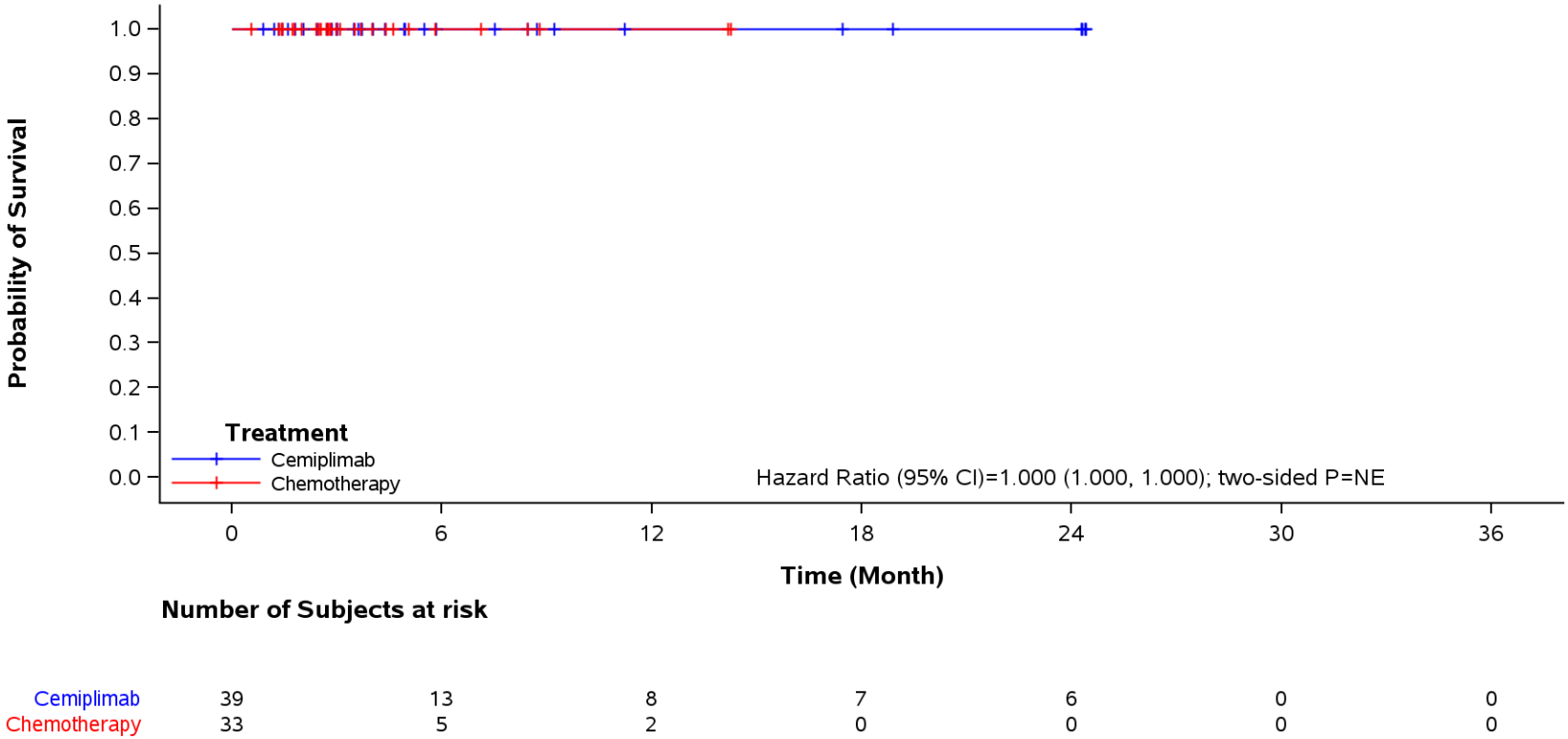

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

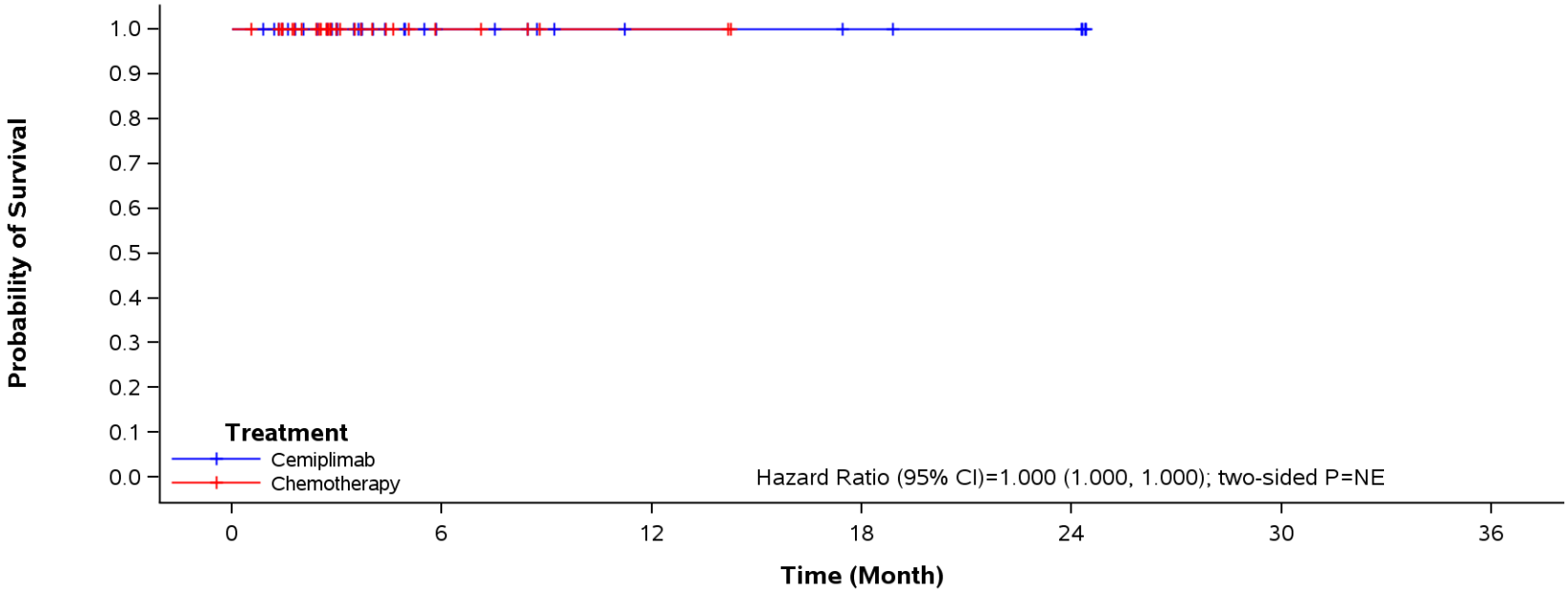
Geographic region: Asia
SOC: Renal and urinary disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Renal and urinary disorders
PT: Renal failure



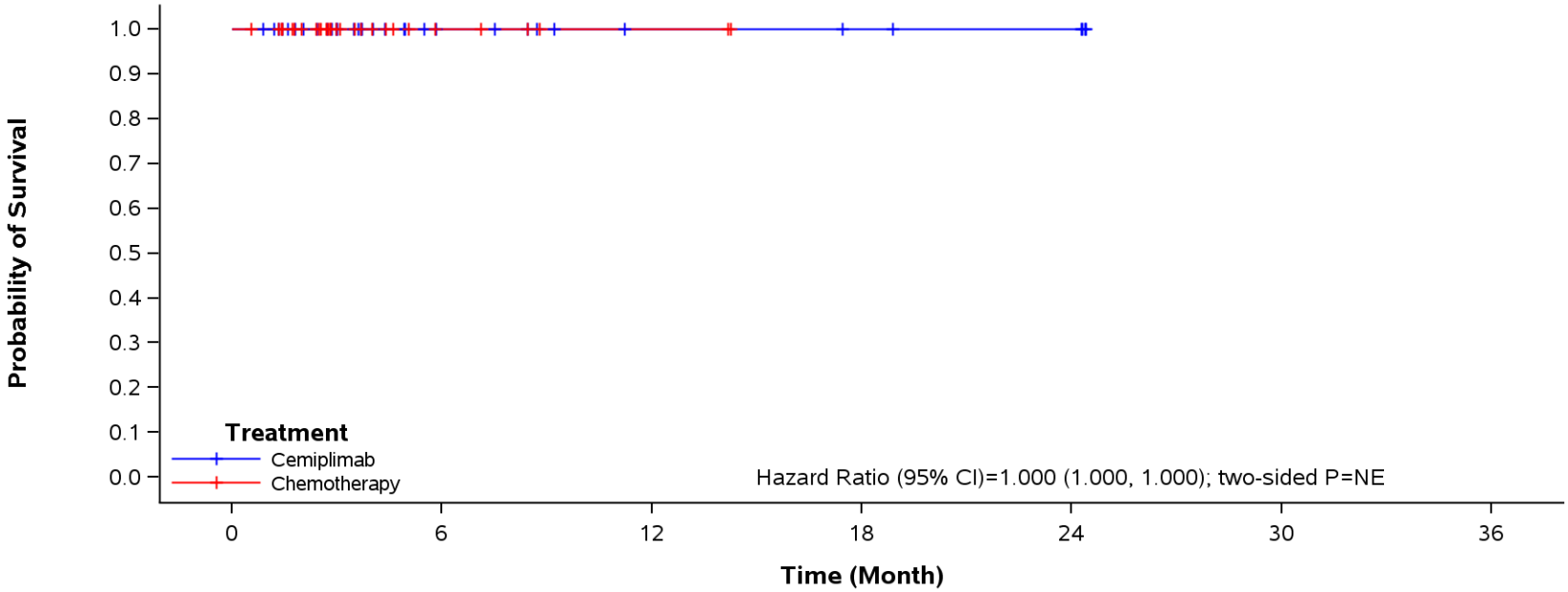

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Respiratory, thoracic and mediastinal disorders



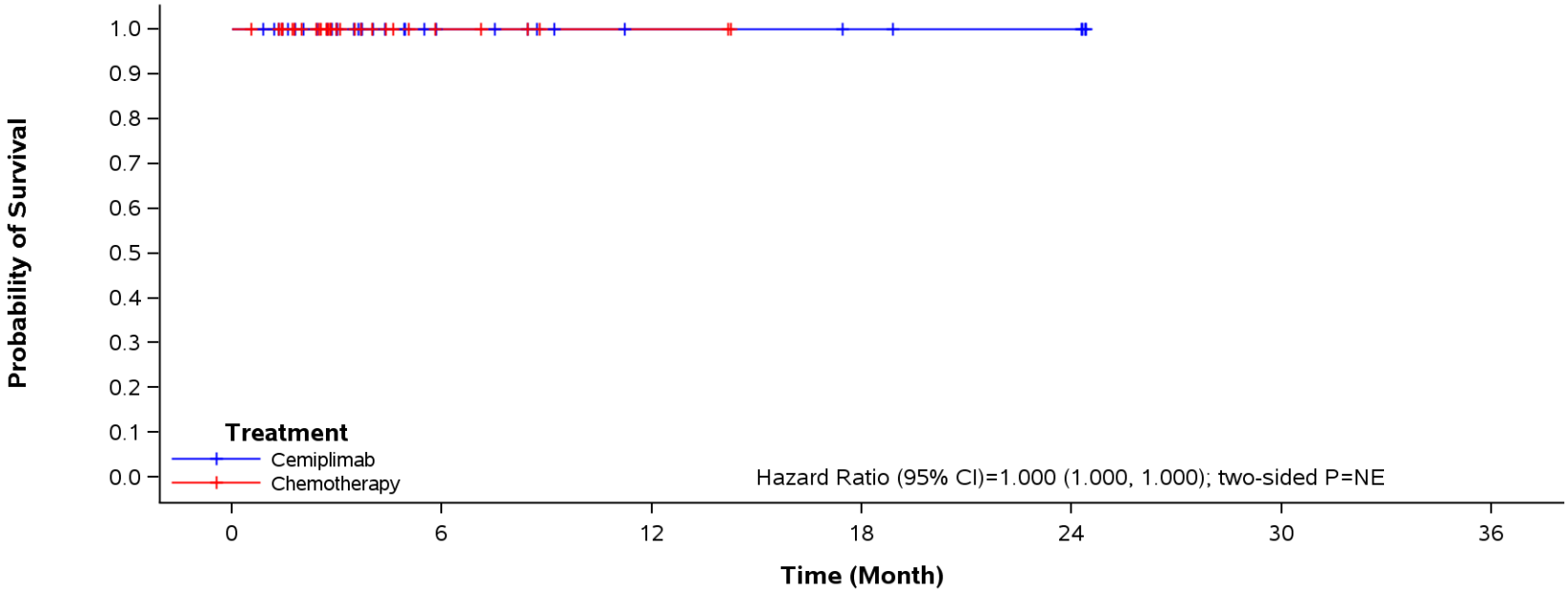

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



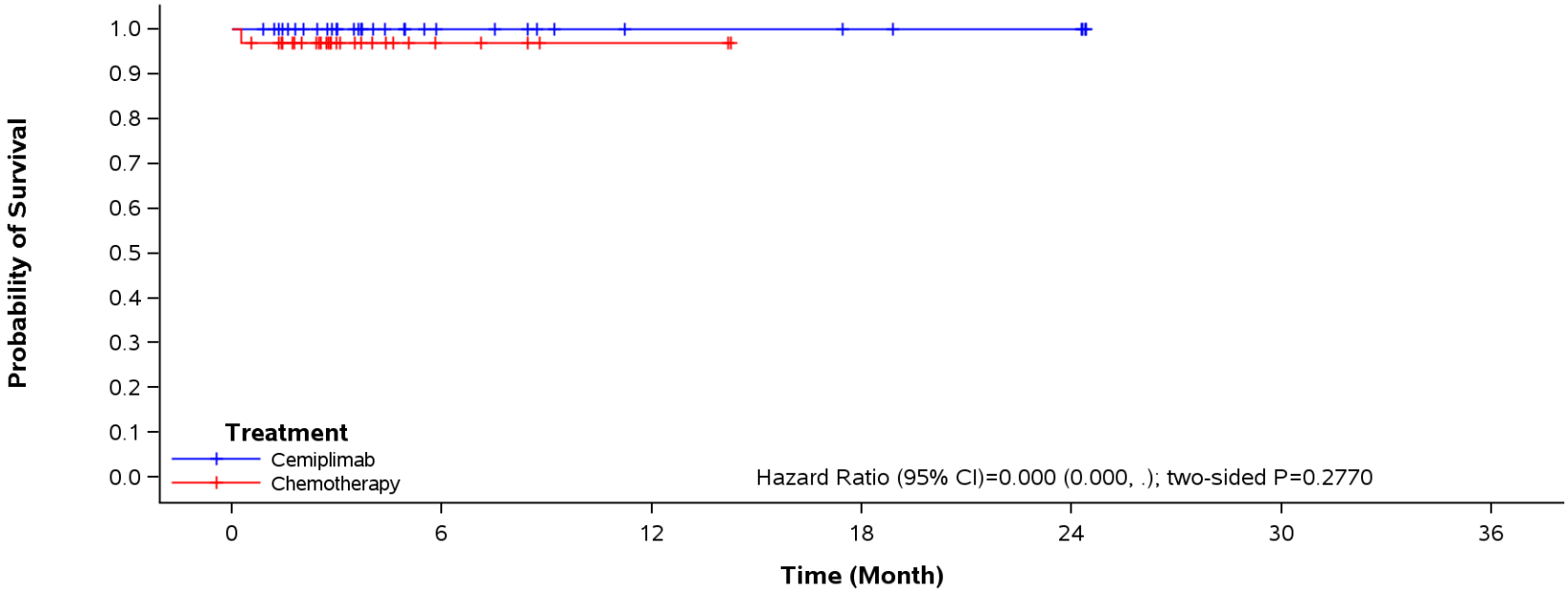

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Vascular disorders



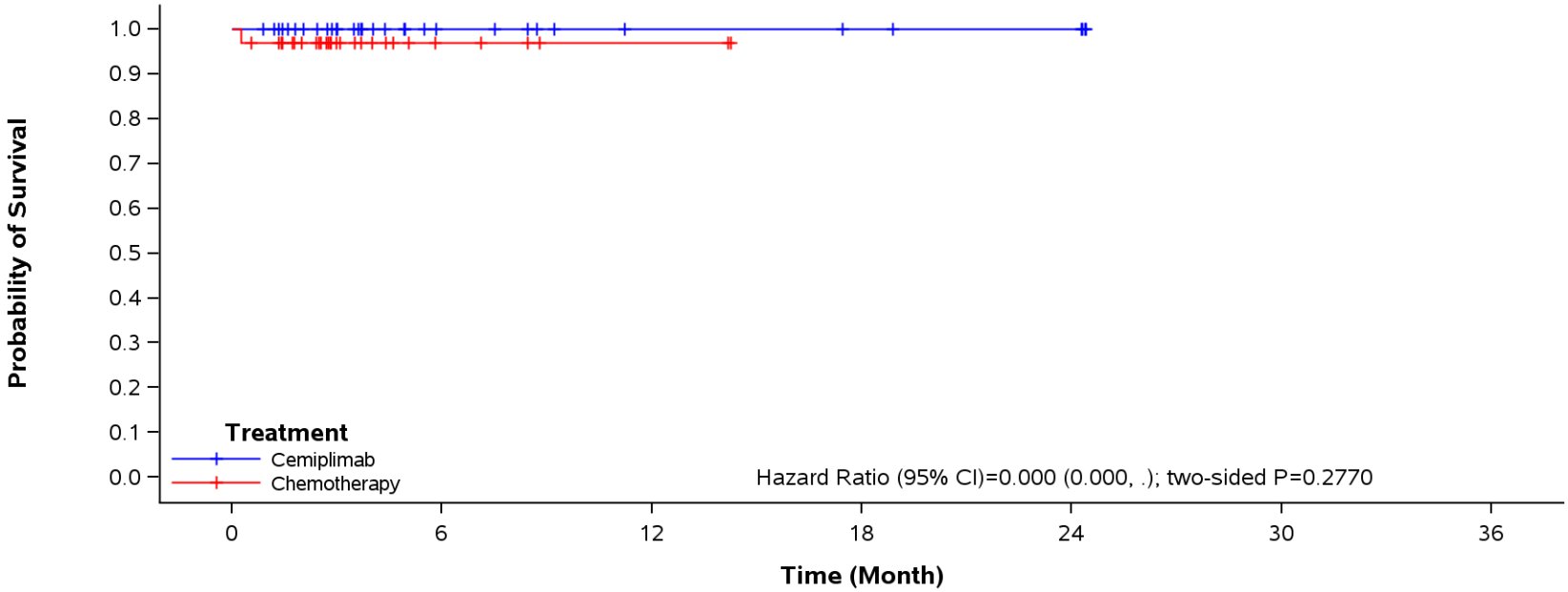

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Asia
SOC: Vascular disorders
PT: Deep vein thrombosis



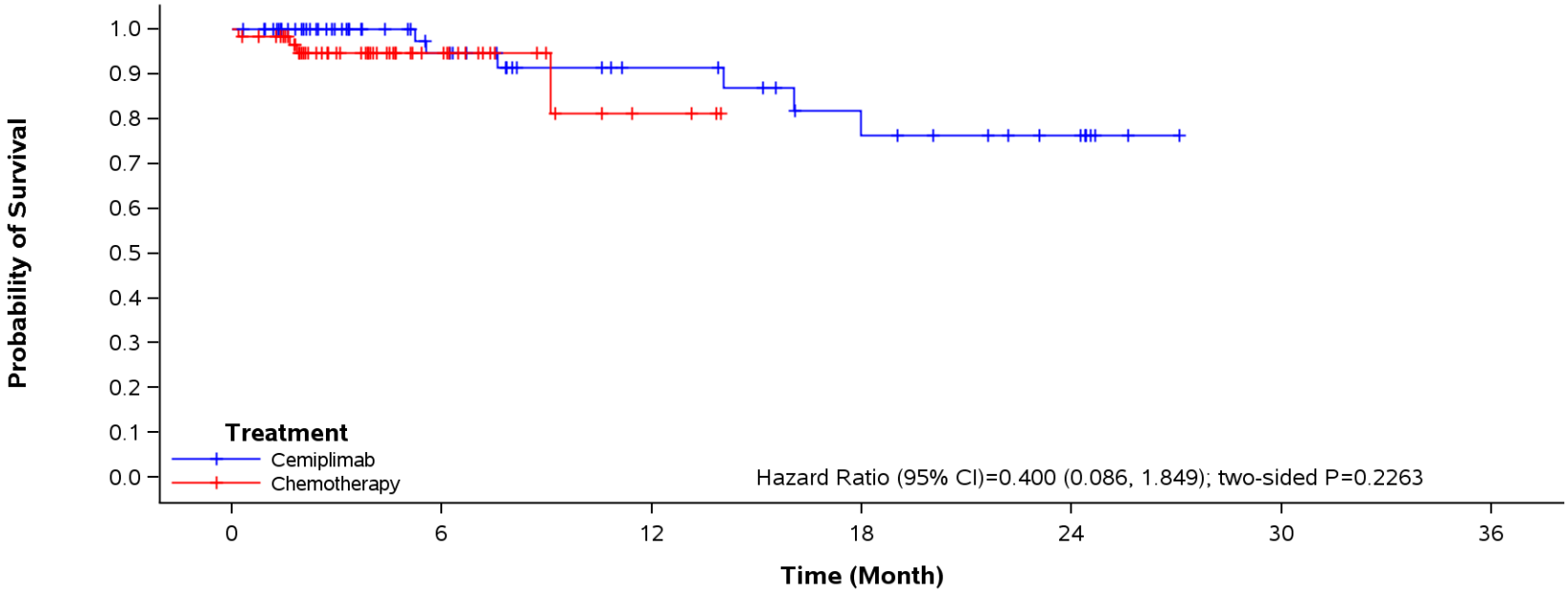

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 39 | 13 | 8 | 7 | 6 | 0 | 0 |
| Chemotherapy | 33 | 5 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
Number of patients with any TEAE leading to discontinuation



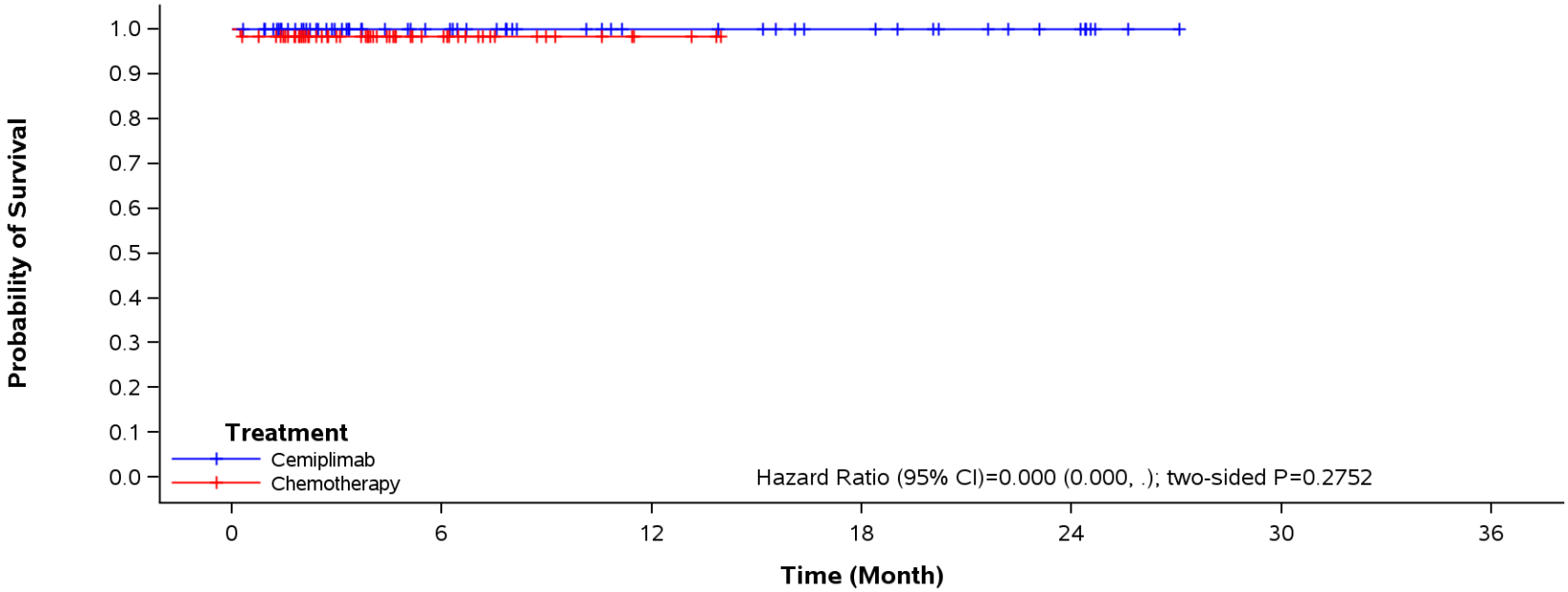

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 34 | 21 | 14 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders



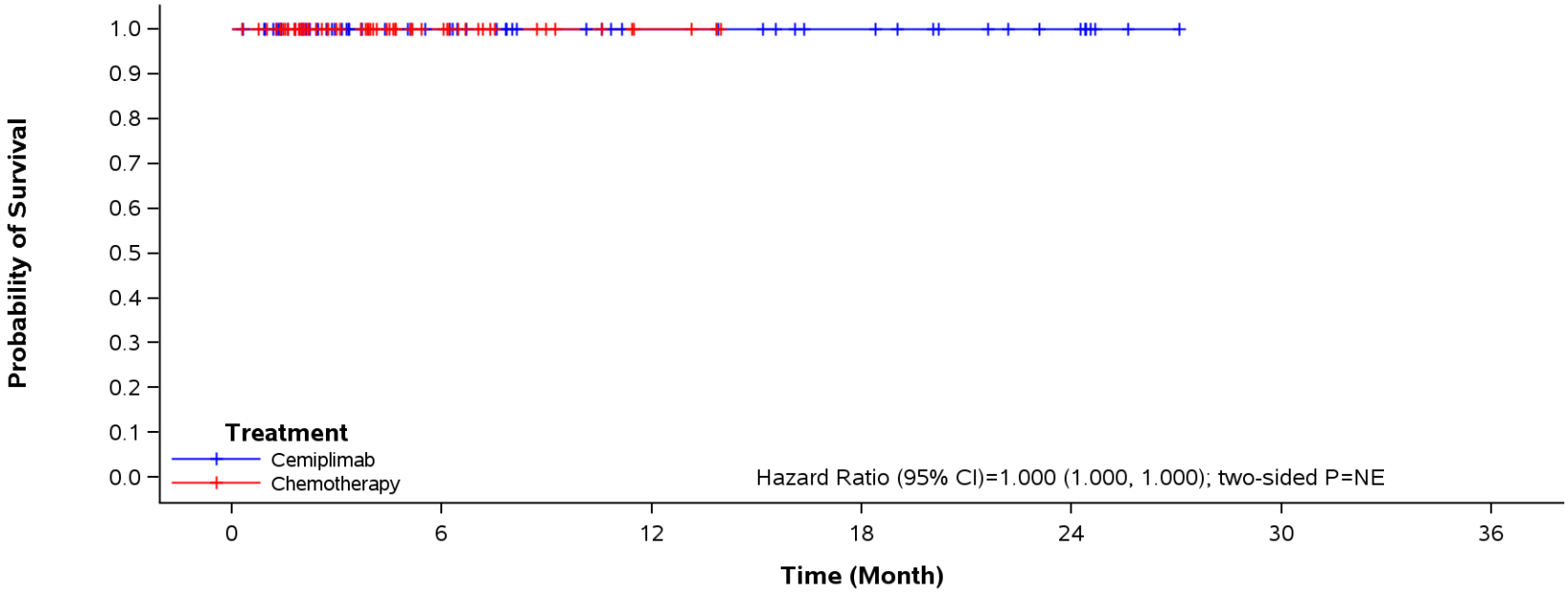

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Anaemia



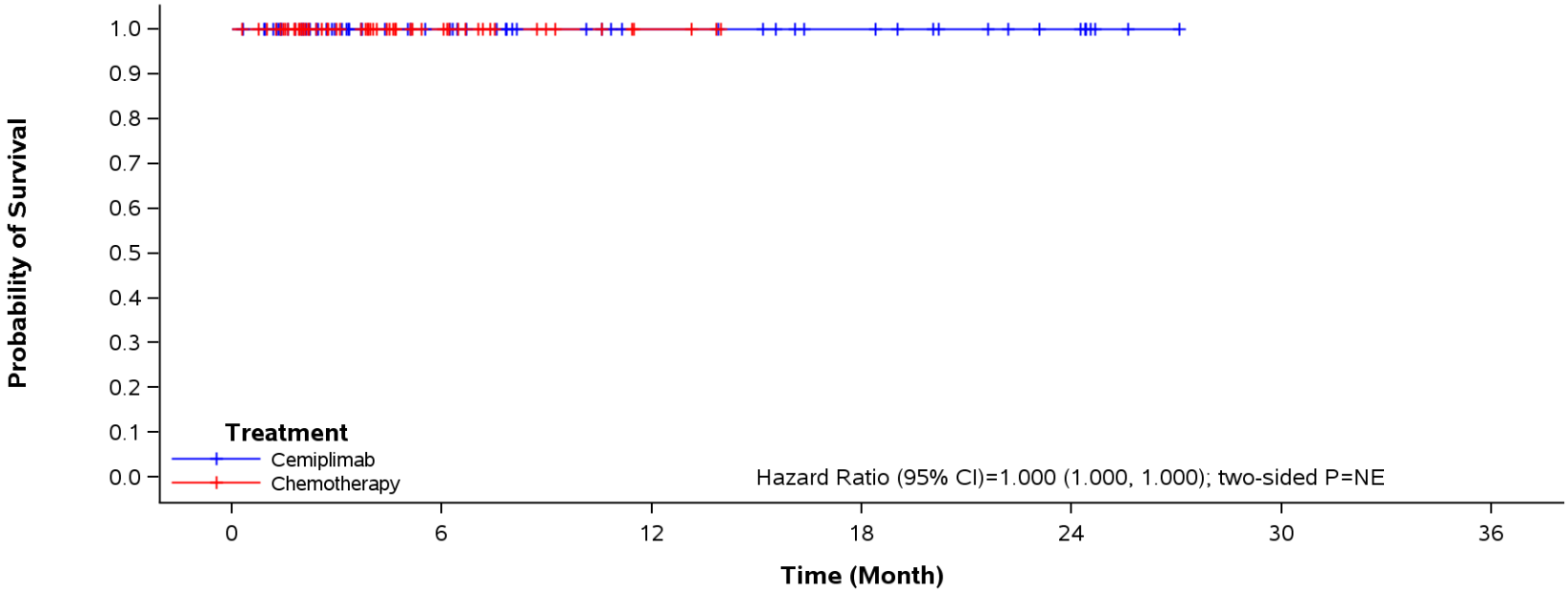

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



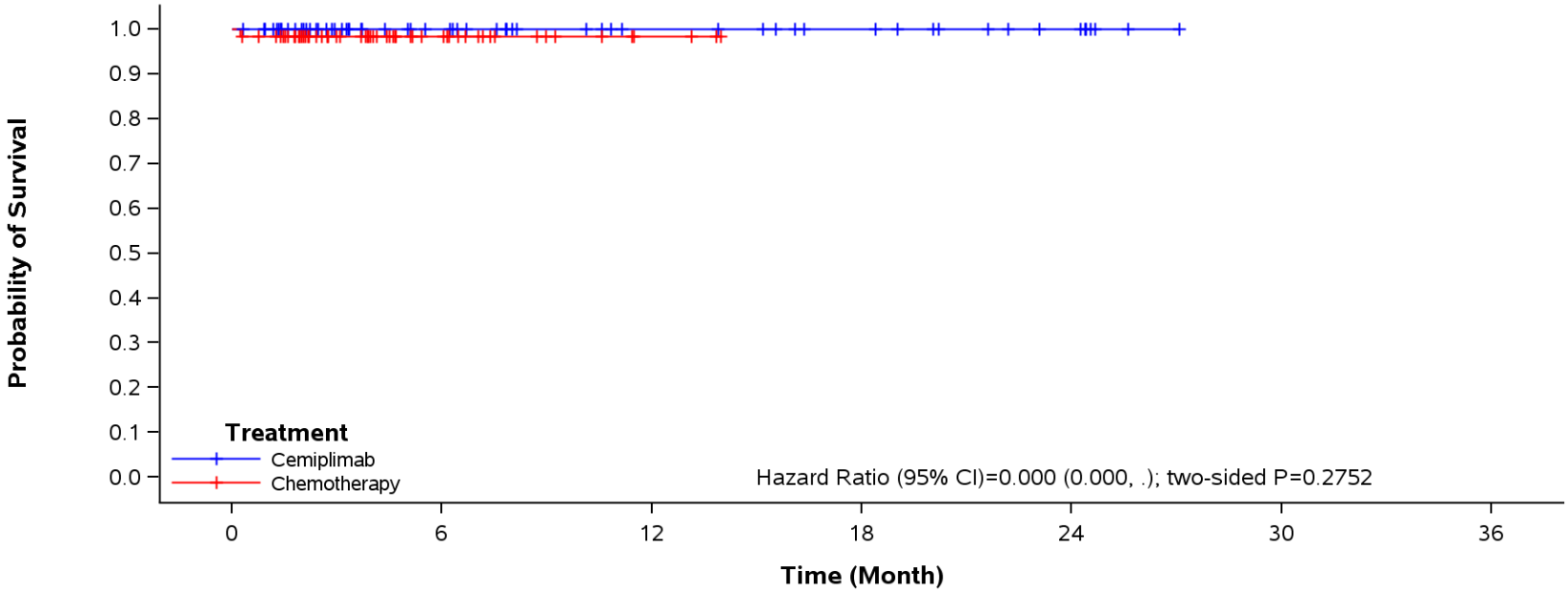

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Neutropenia



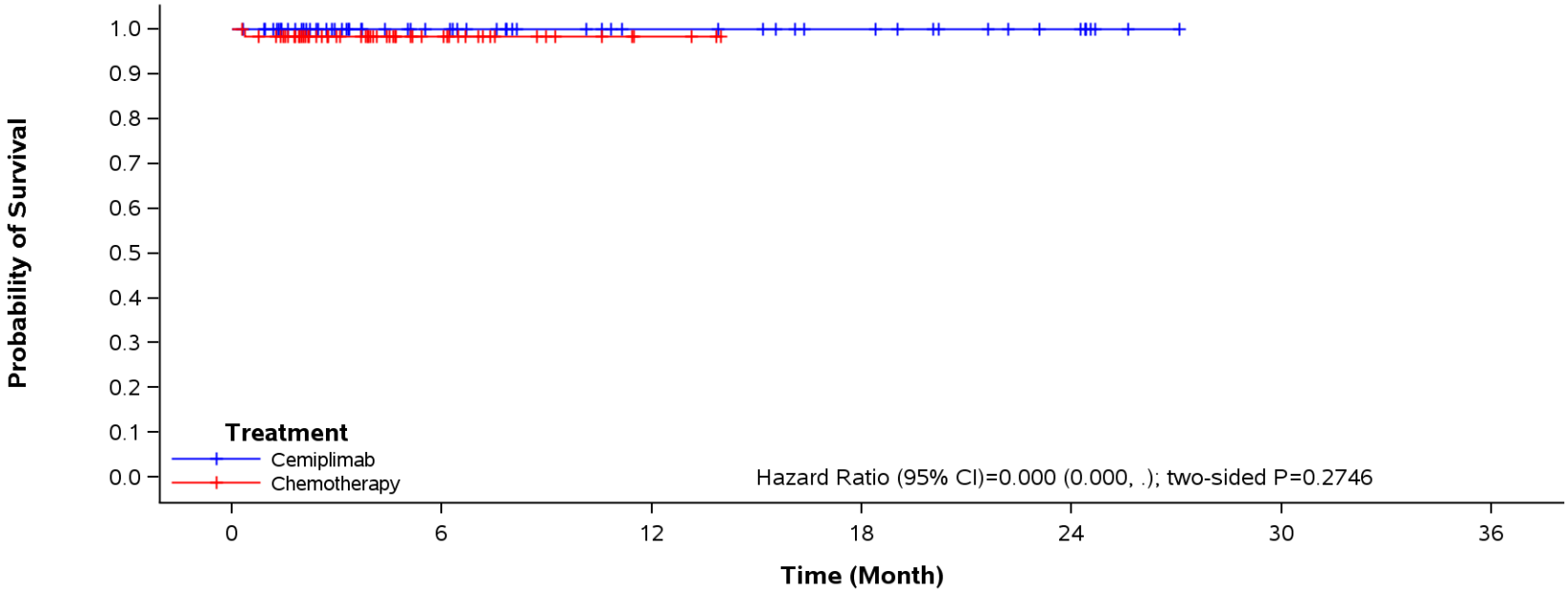

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



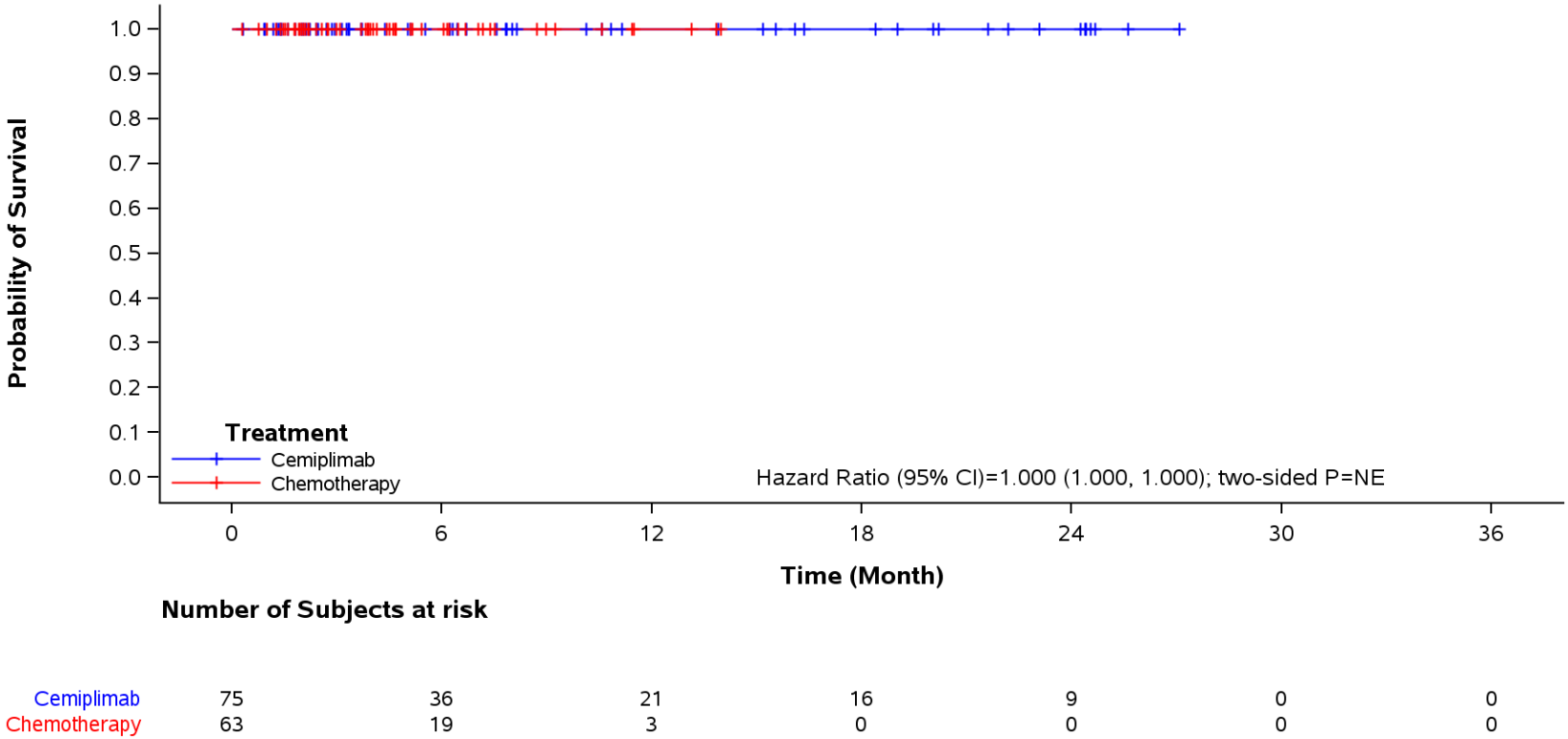

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

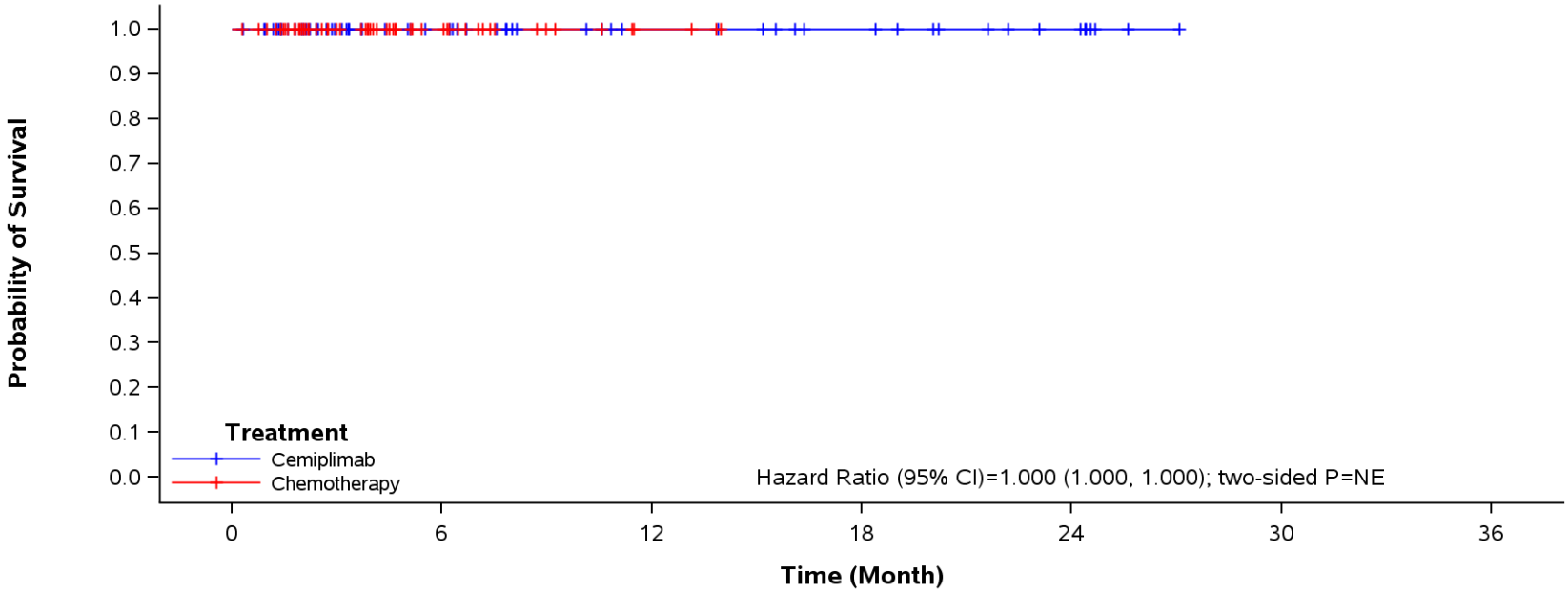
Geographic region: Europe
SOC: Cardiac disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Cardiac disorders
PT: Autoimmune pericarditis



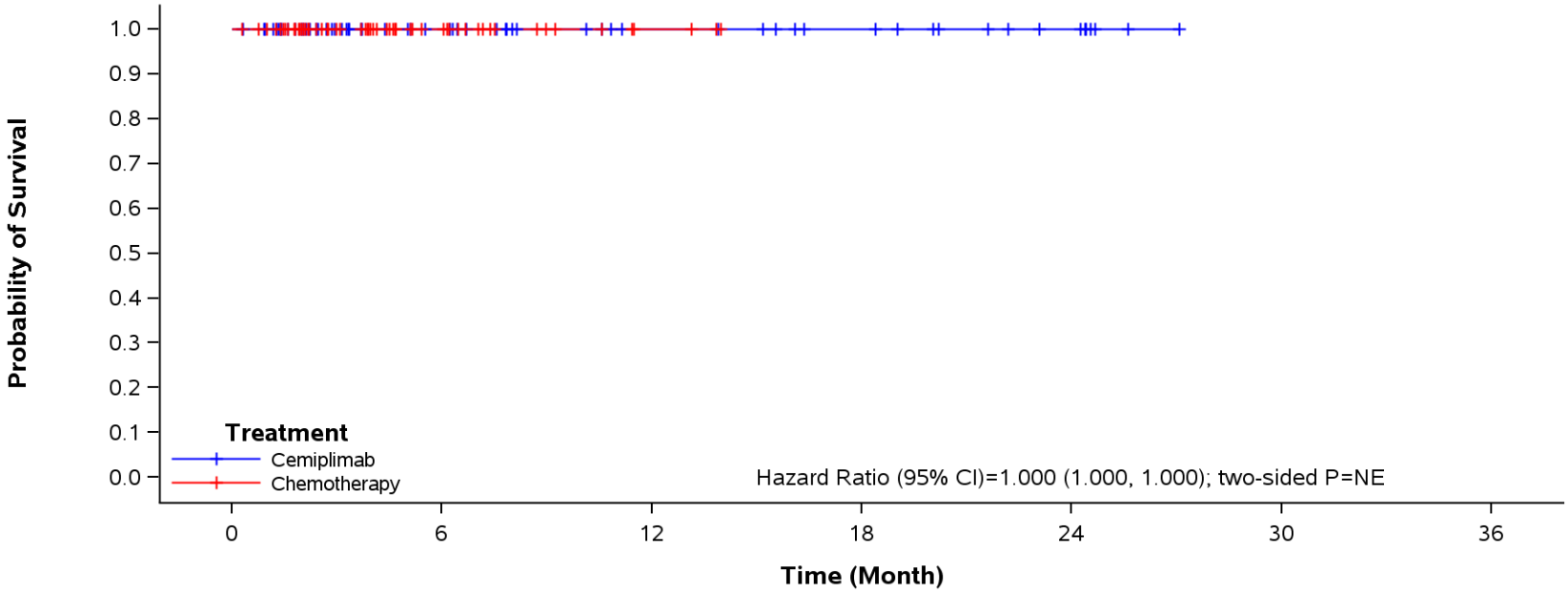

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Endocrine disorders



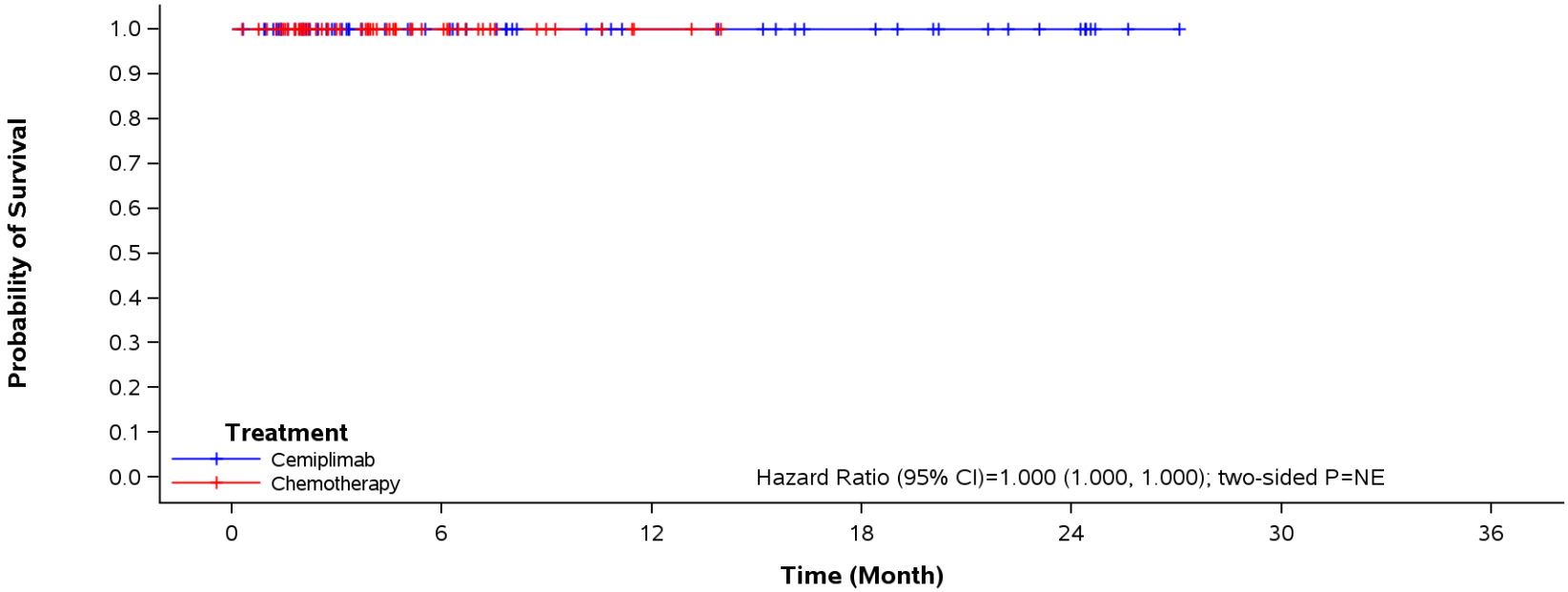

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Endocrine disorders
PT: Hypothyroidism



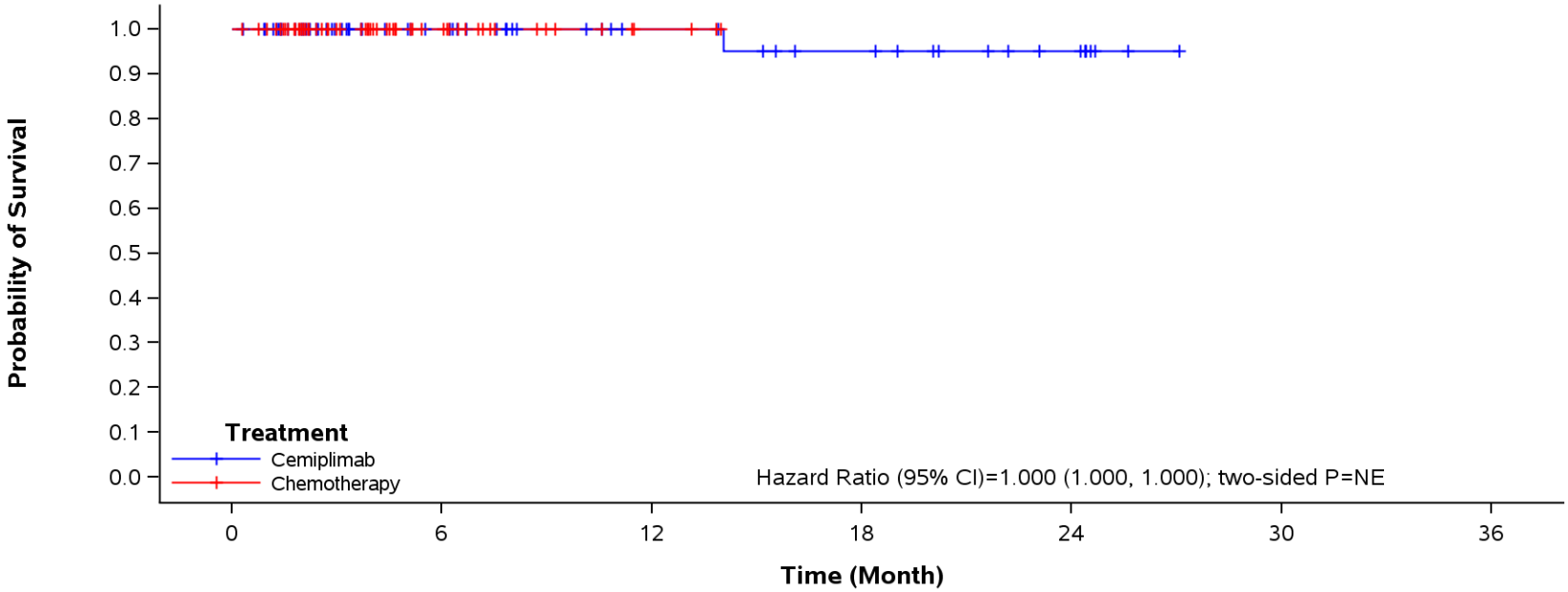

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders



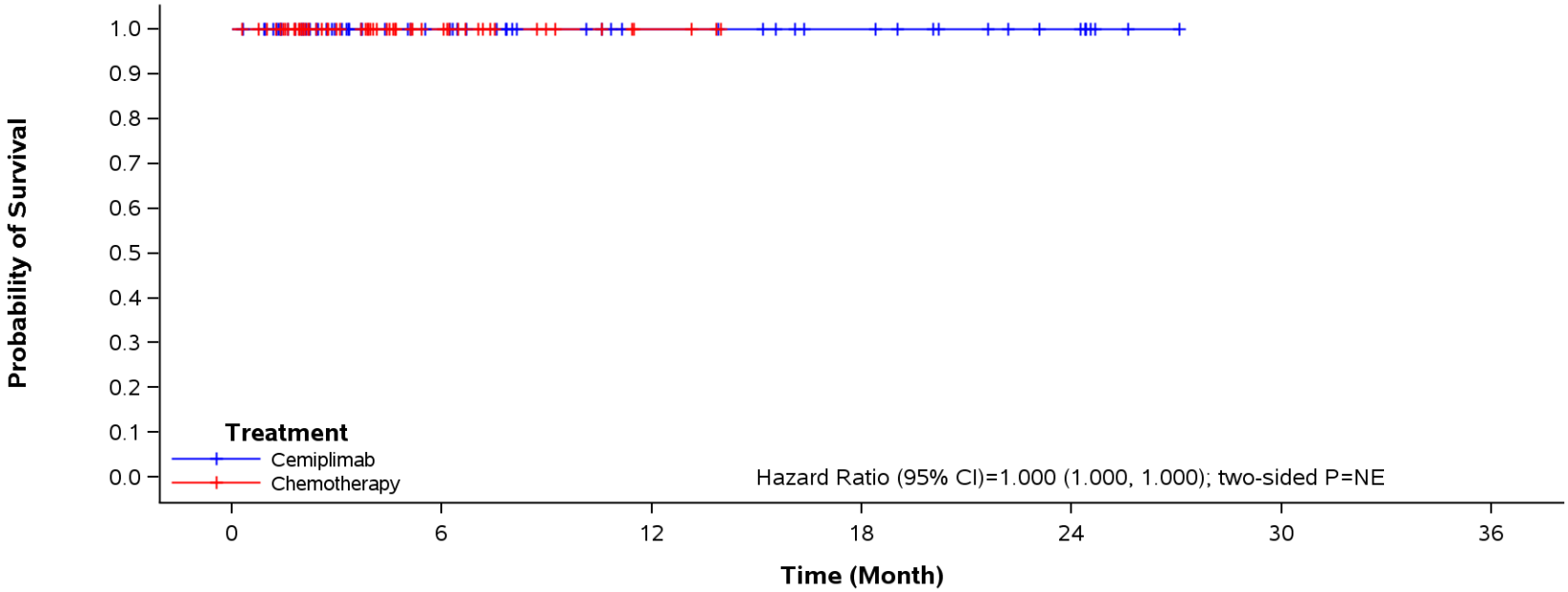

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders
PT: Colitis



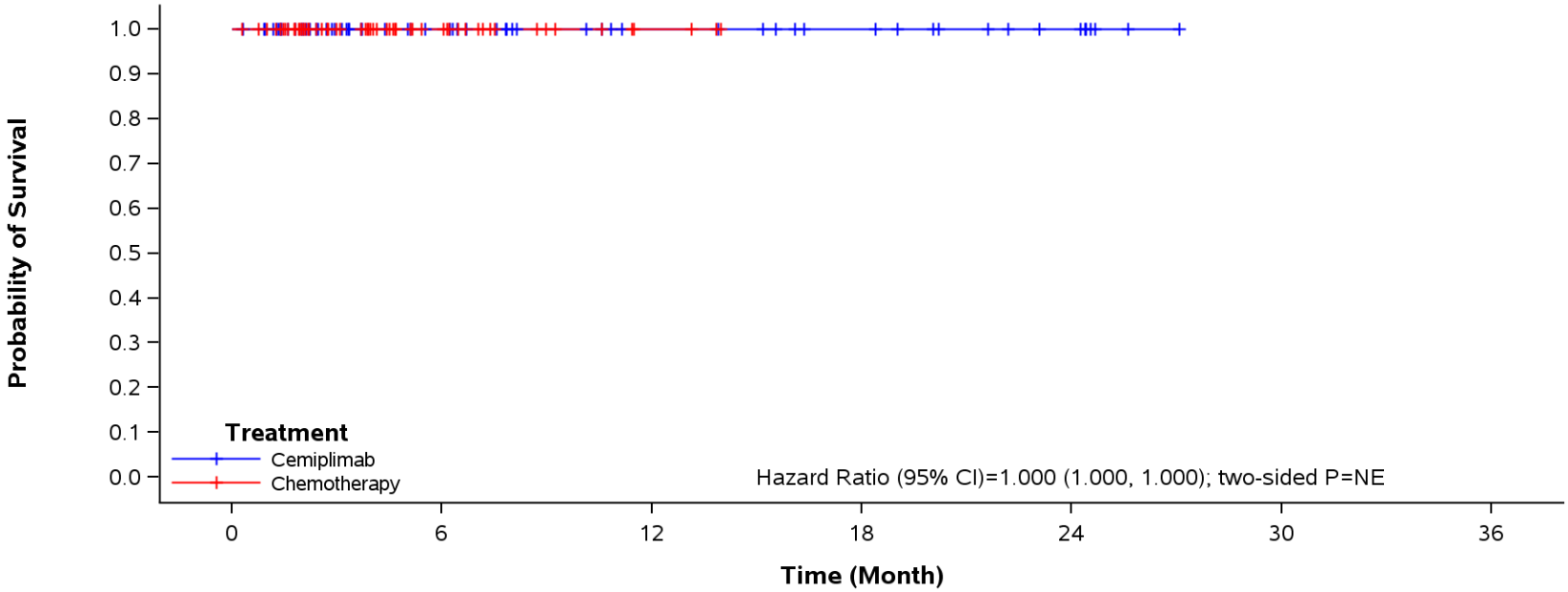

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders
PT: Diverticular perforation



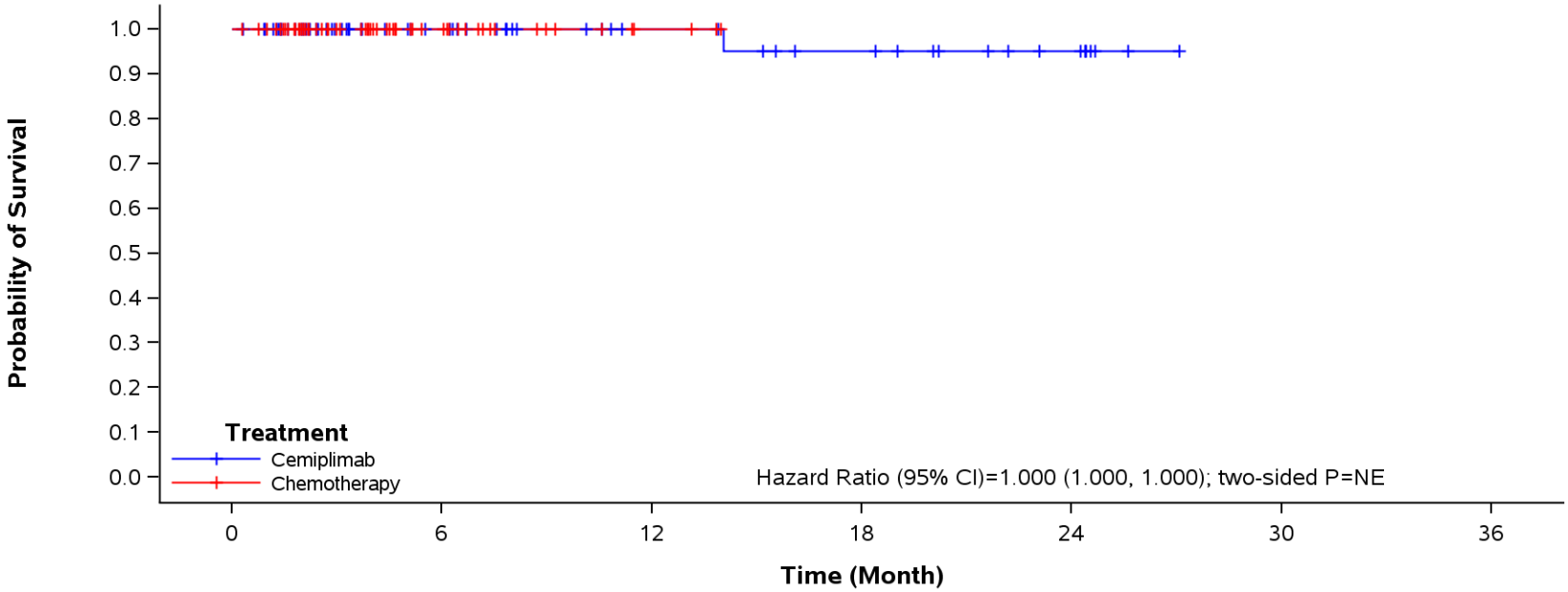

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders
PT: Pancreatic mass



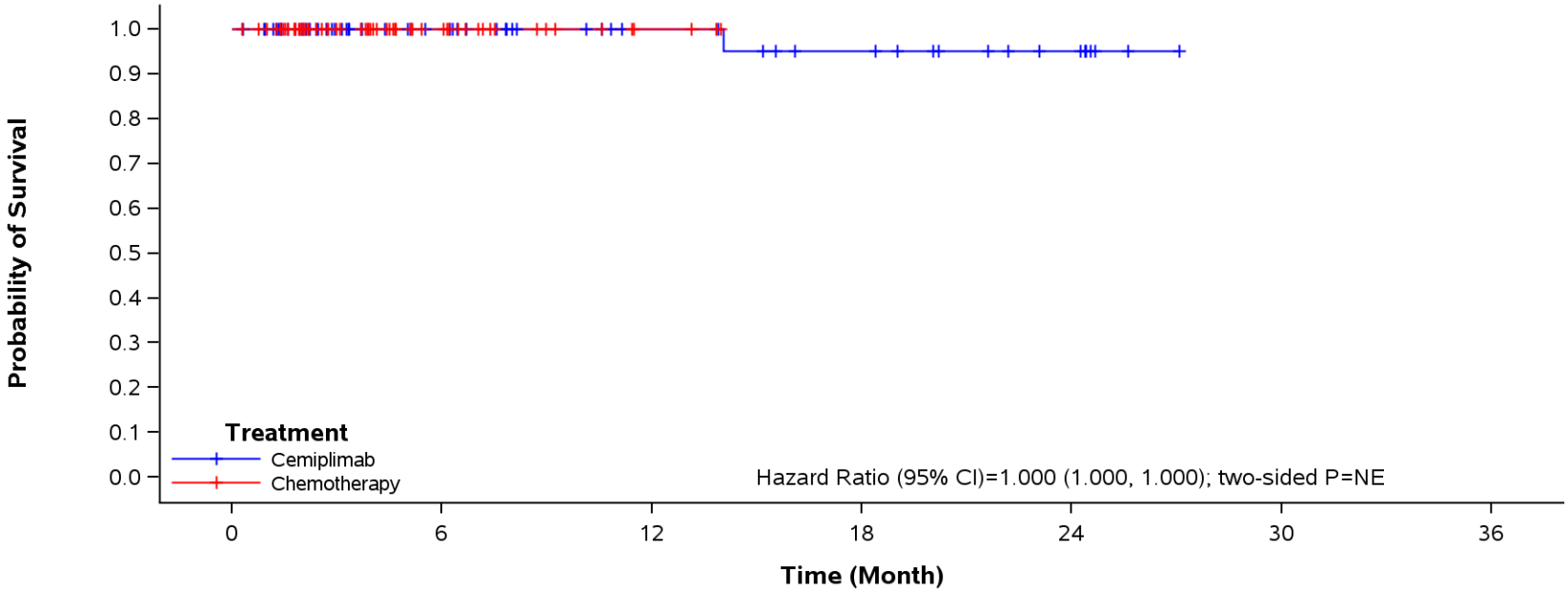

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



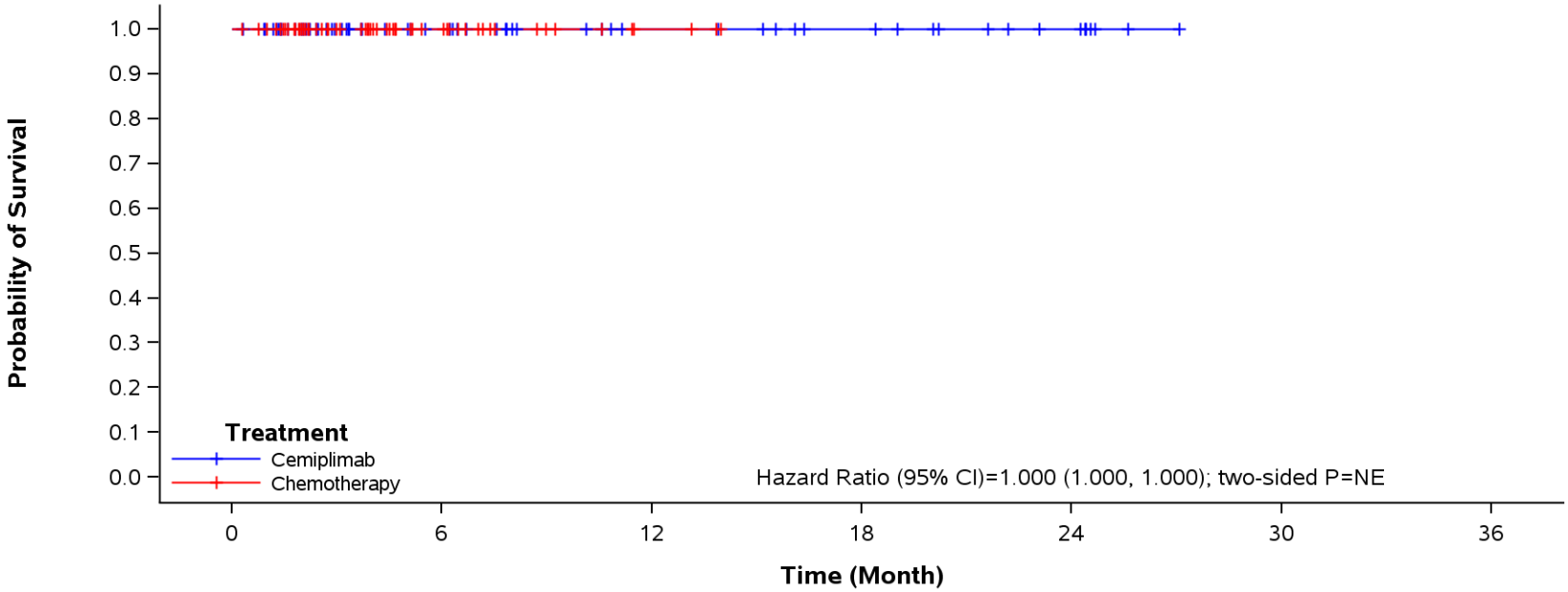

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Gastrointestinal disorders
PT: Proctalgia



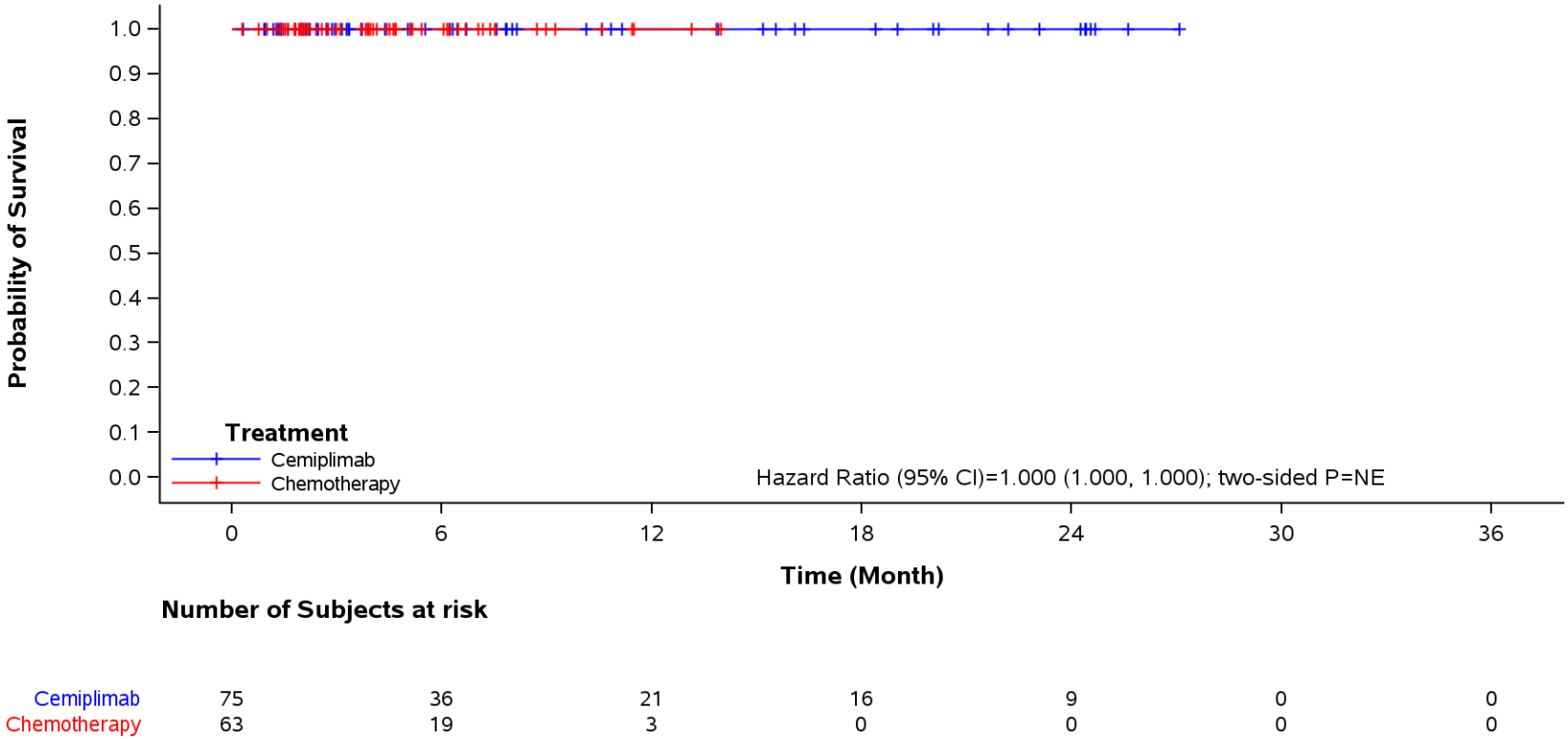

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

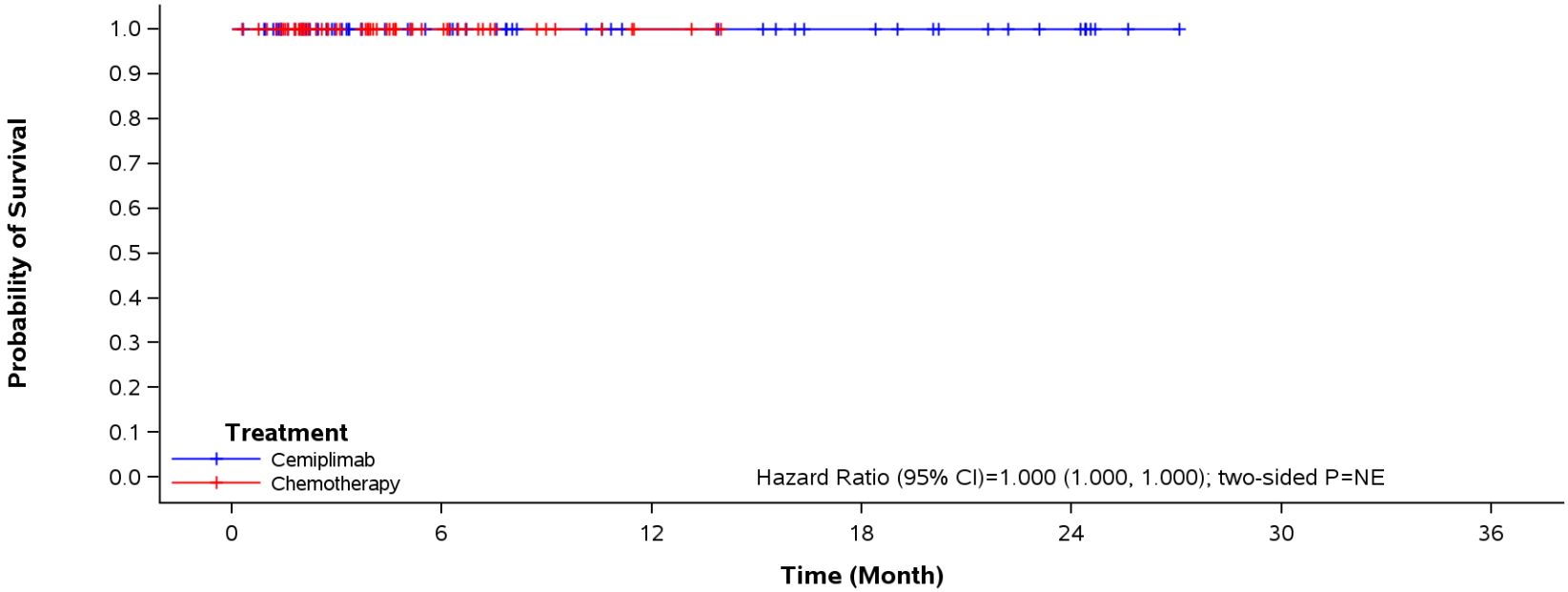
Geographic region: Europe
SOC: General disorders and administration site conditions




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: General disorders and administration site conditions
PT: Malaise



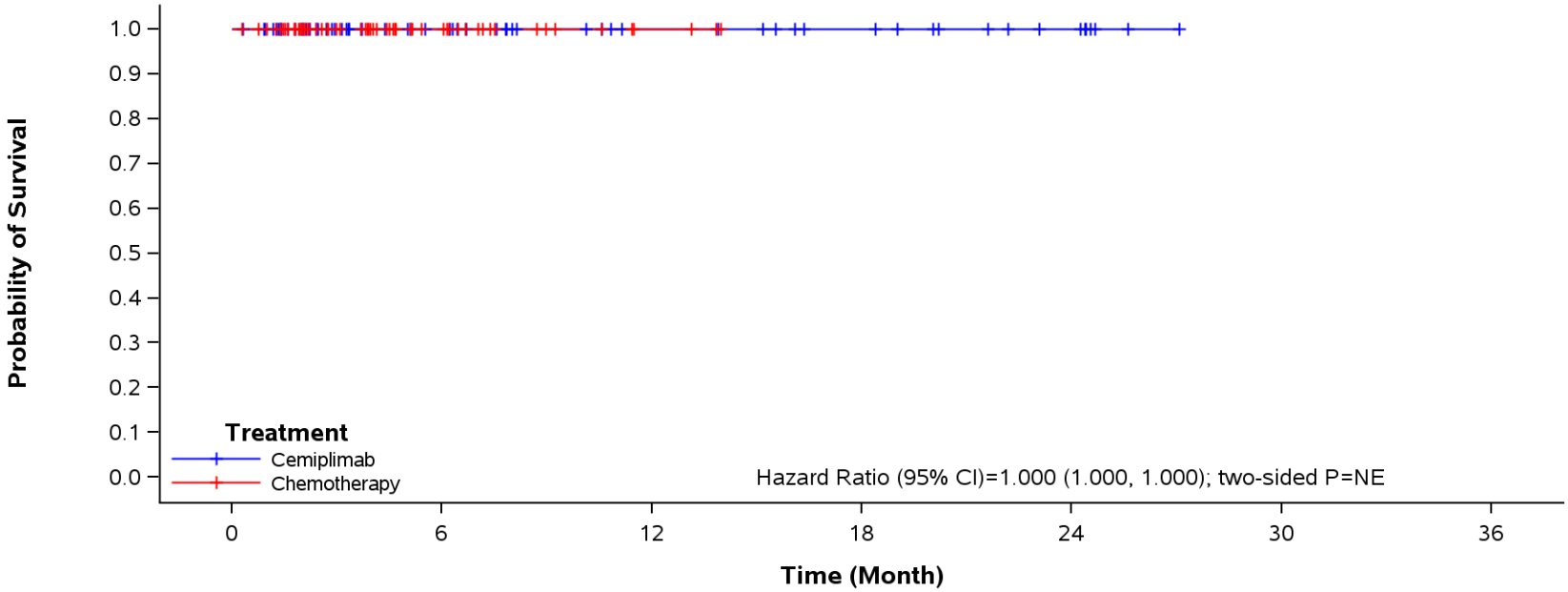

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



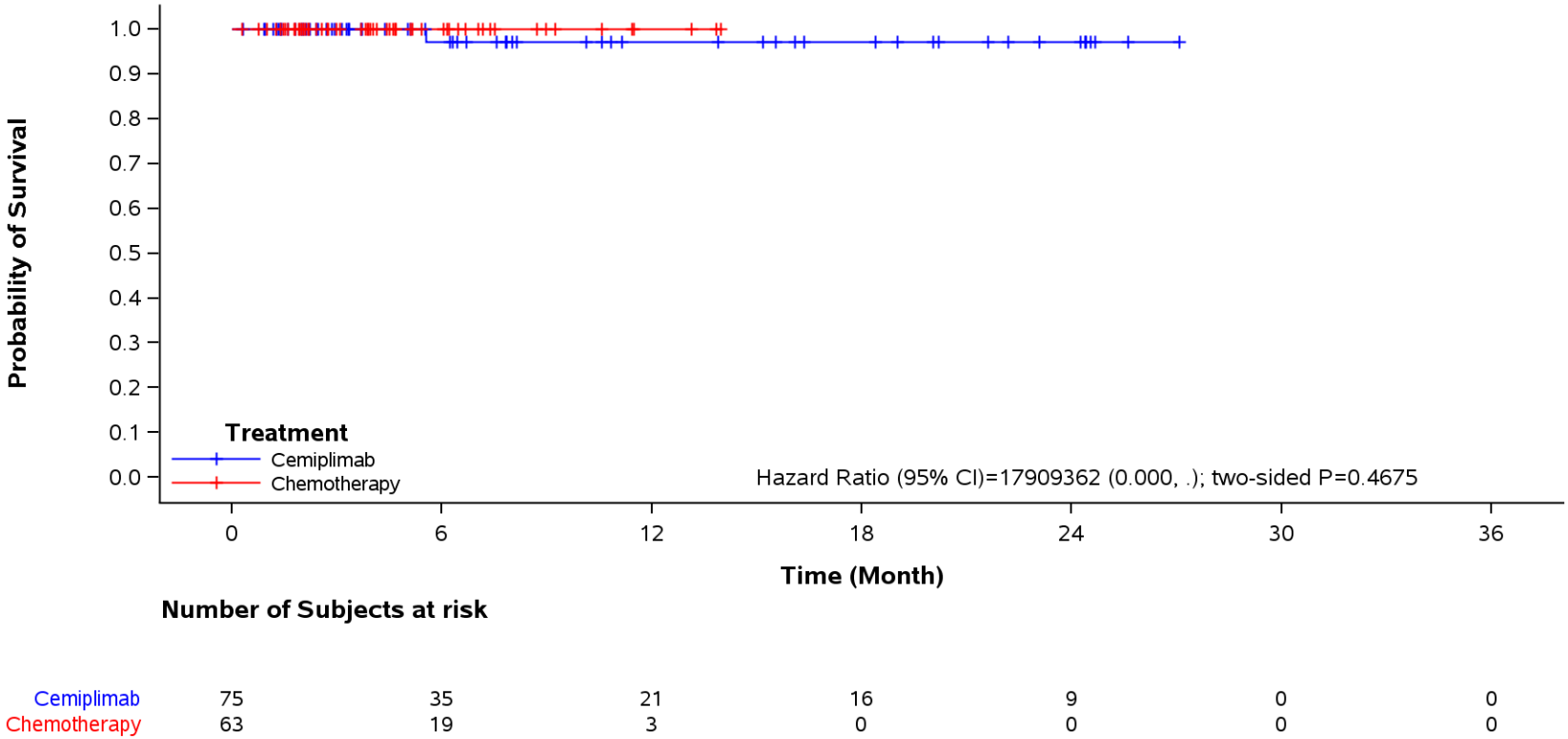

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

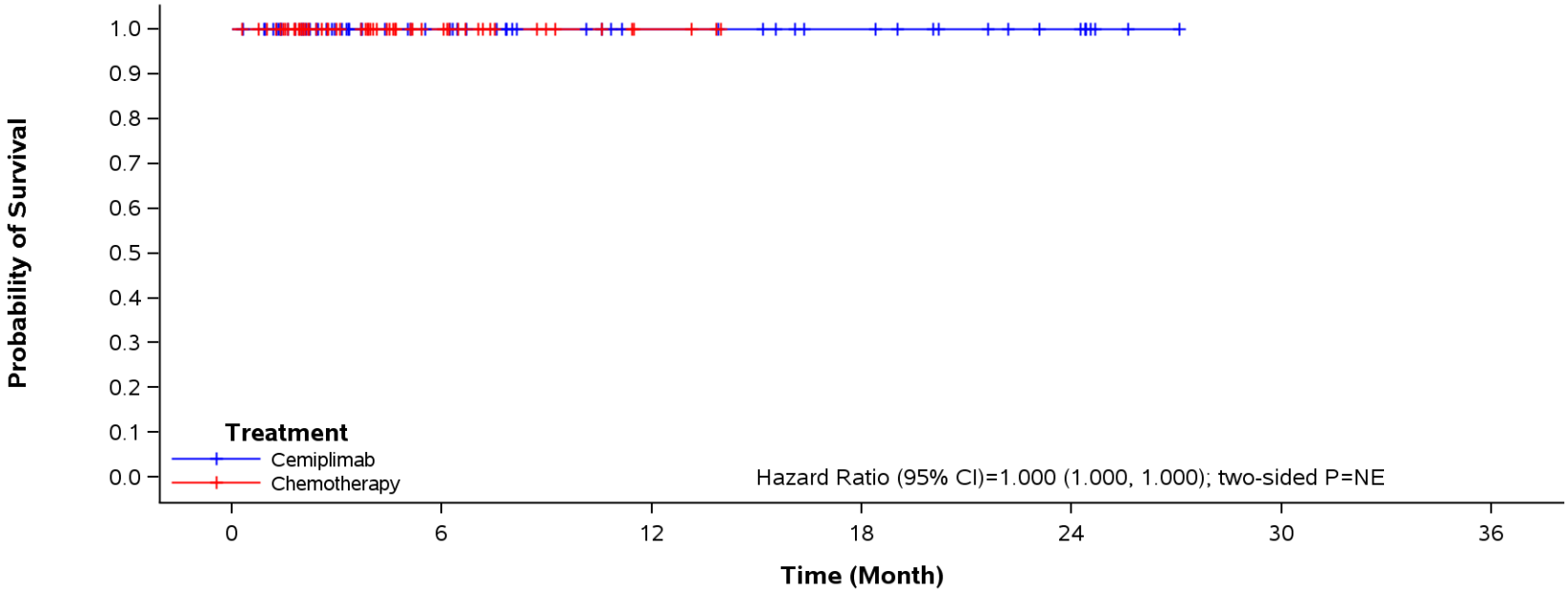
Geographic region: Europe
SOC: Hepatobiliary disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



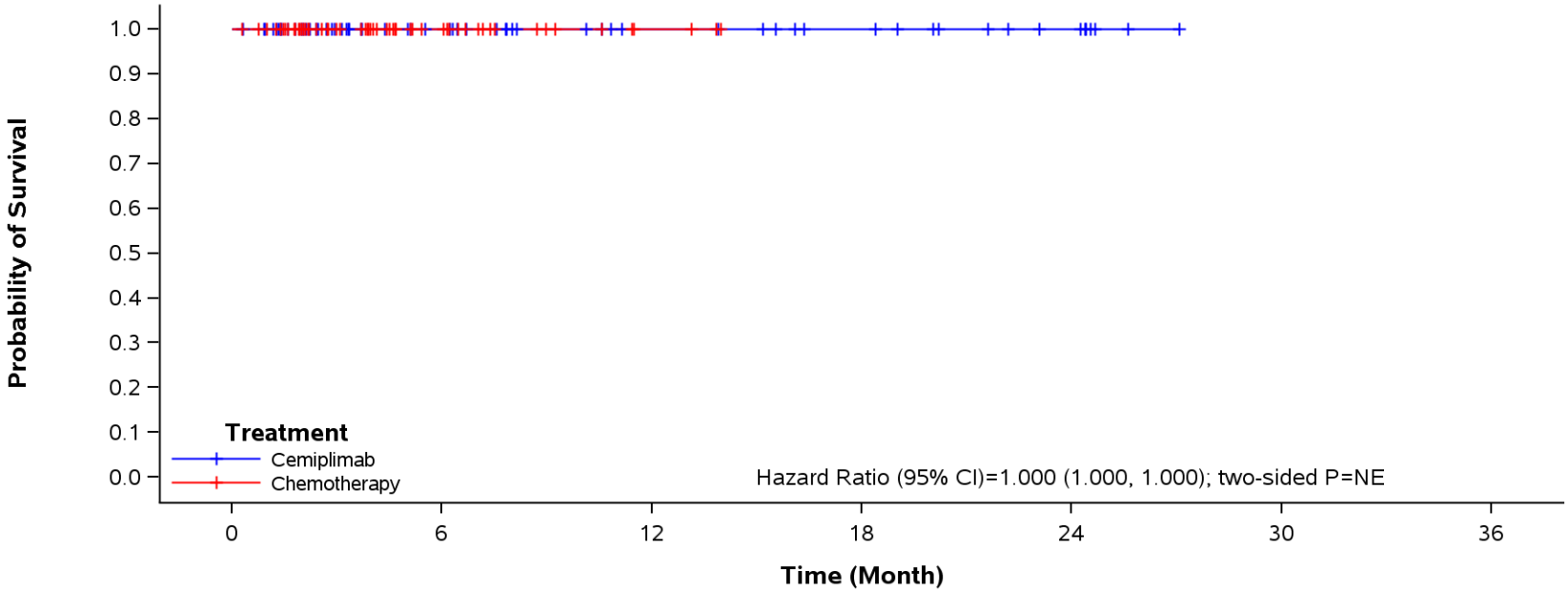

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



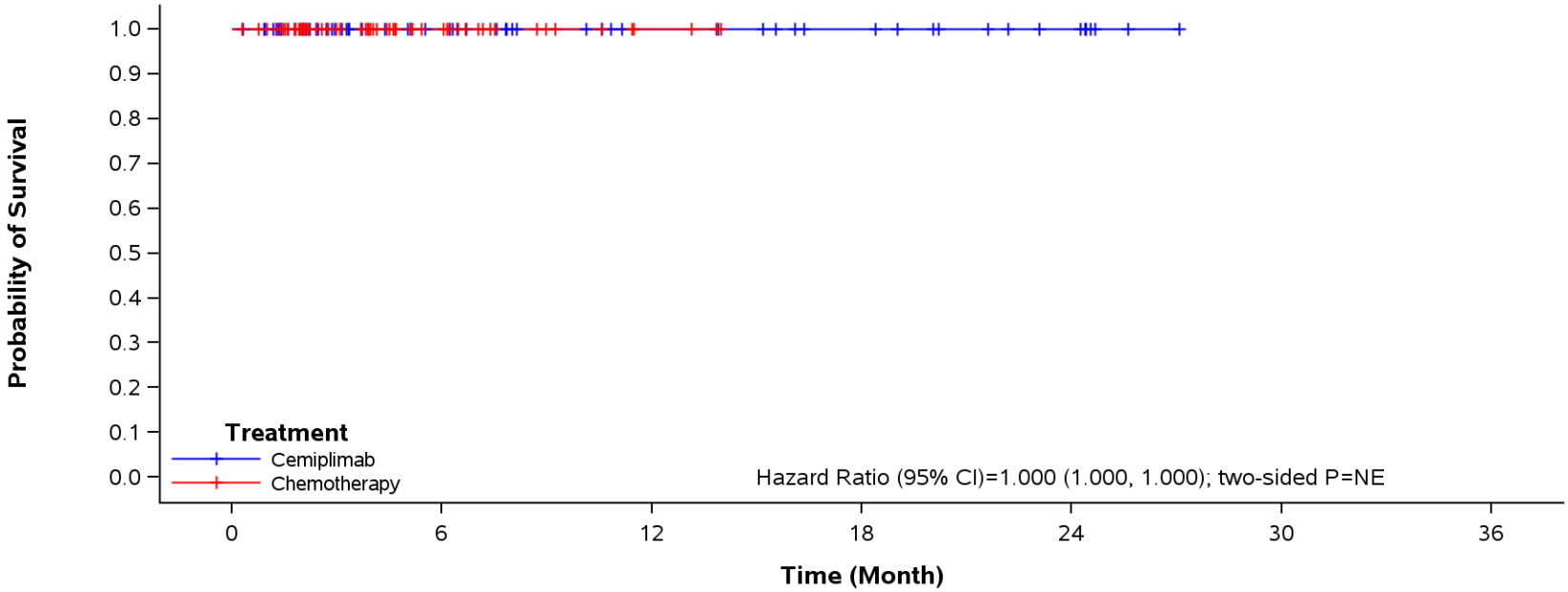

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Hepatobiliary disorders
PT: Hepatitis



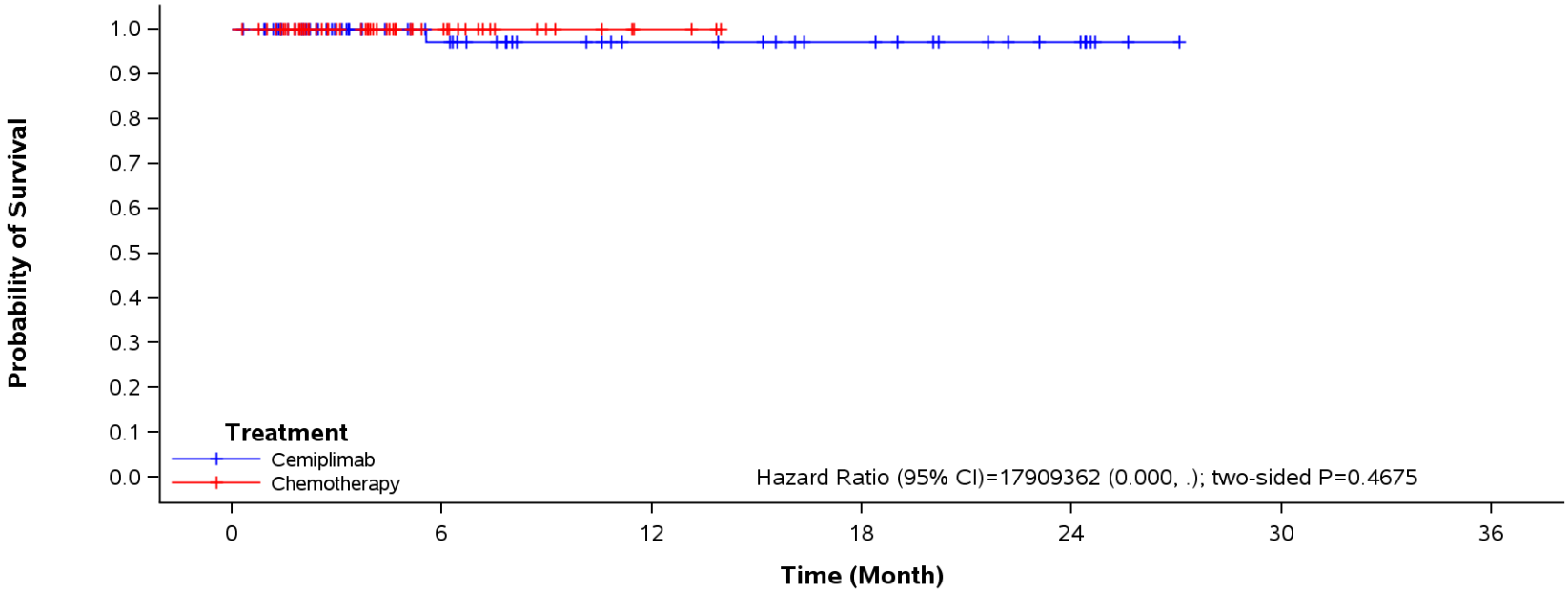

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



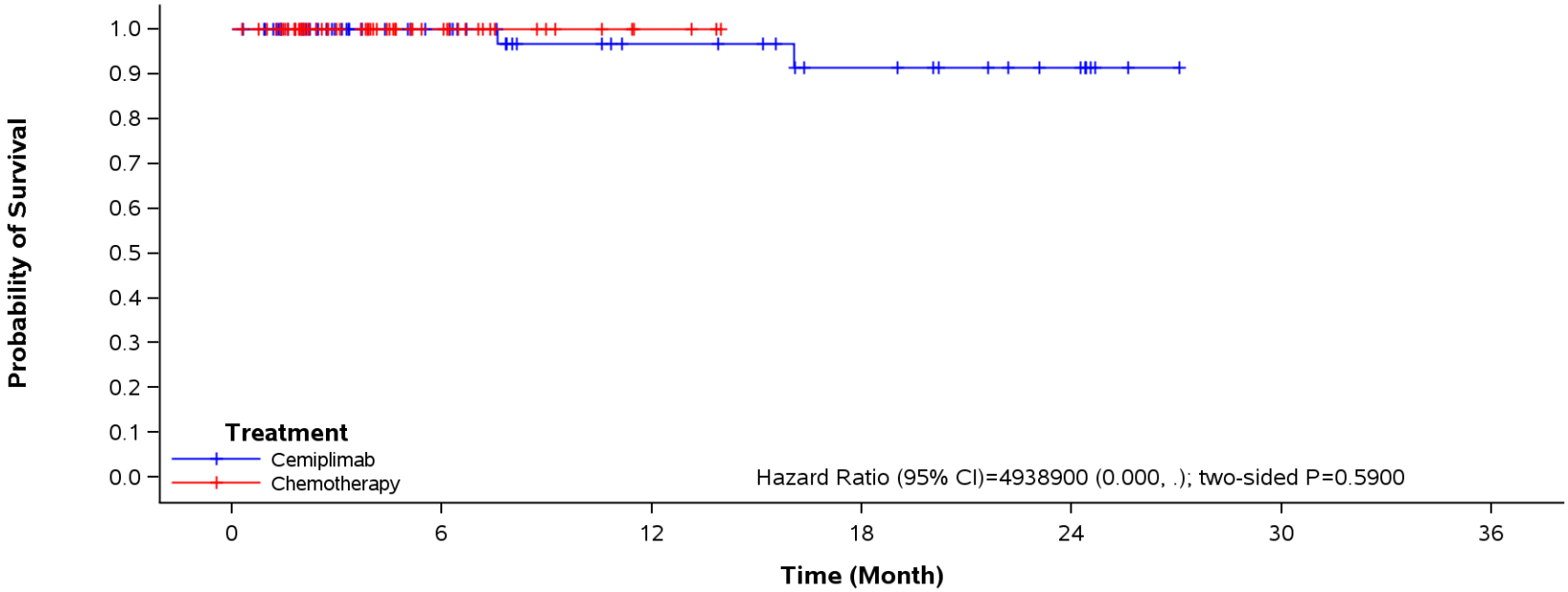

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 35 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Infections and infestations



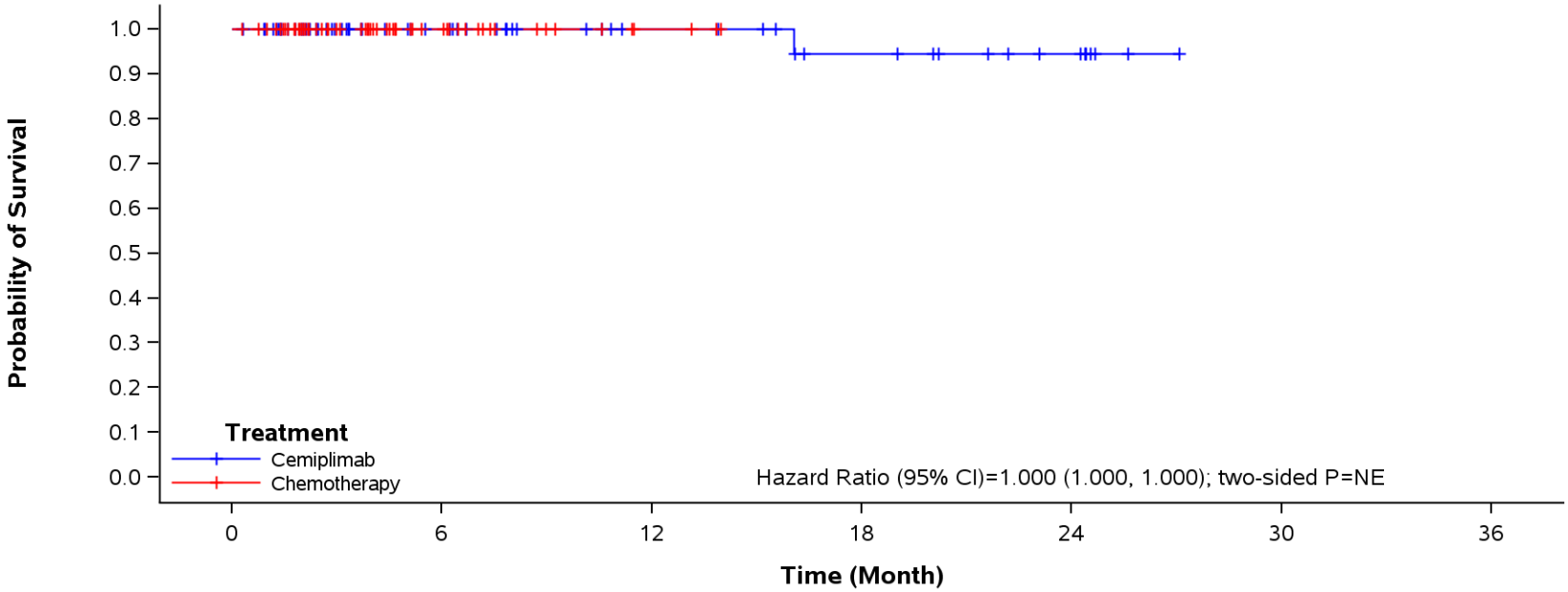

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 15 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Infections and infestations
PT: COVID-19 pneumonia



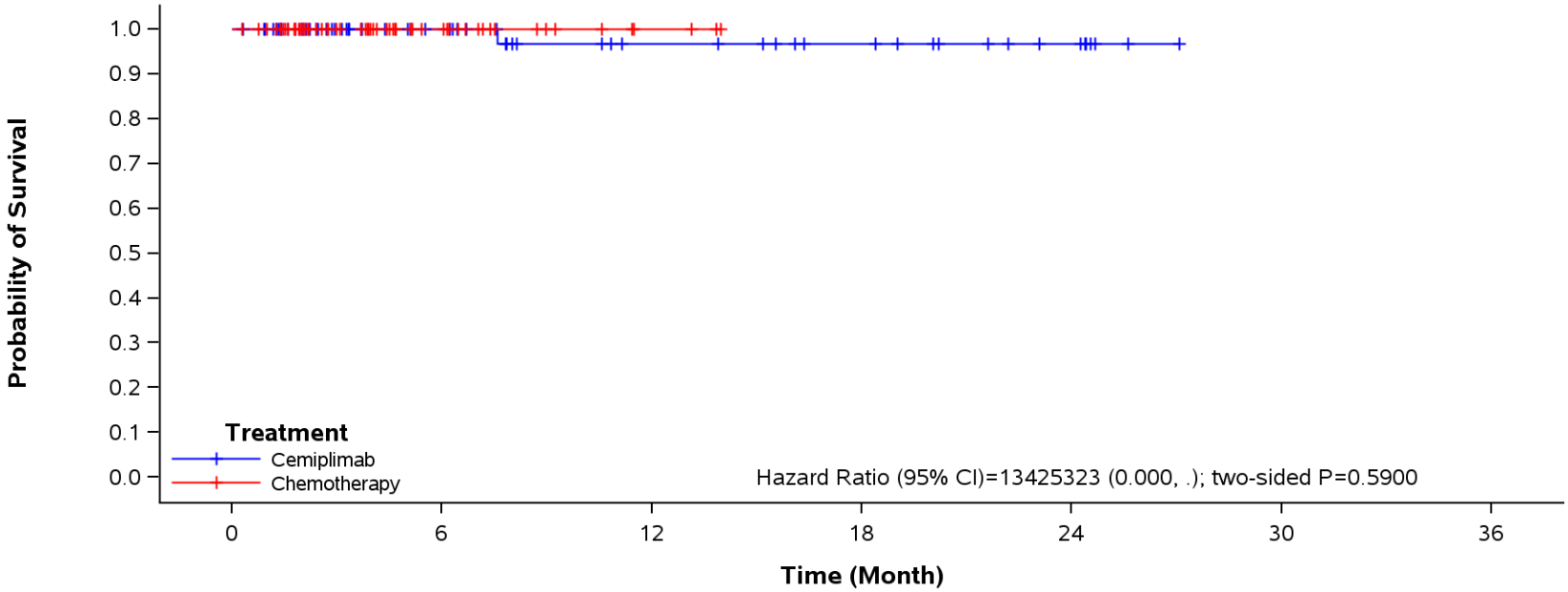

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 15 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Infections and infestations
PT: Gastroenteritis



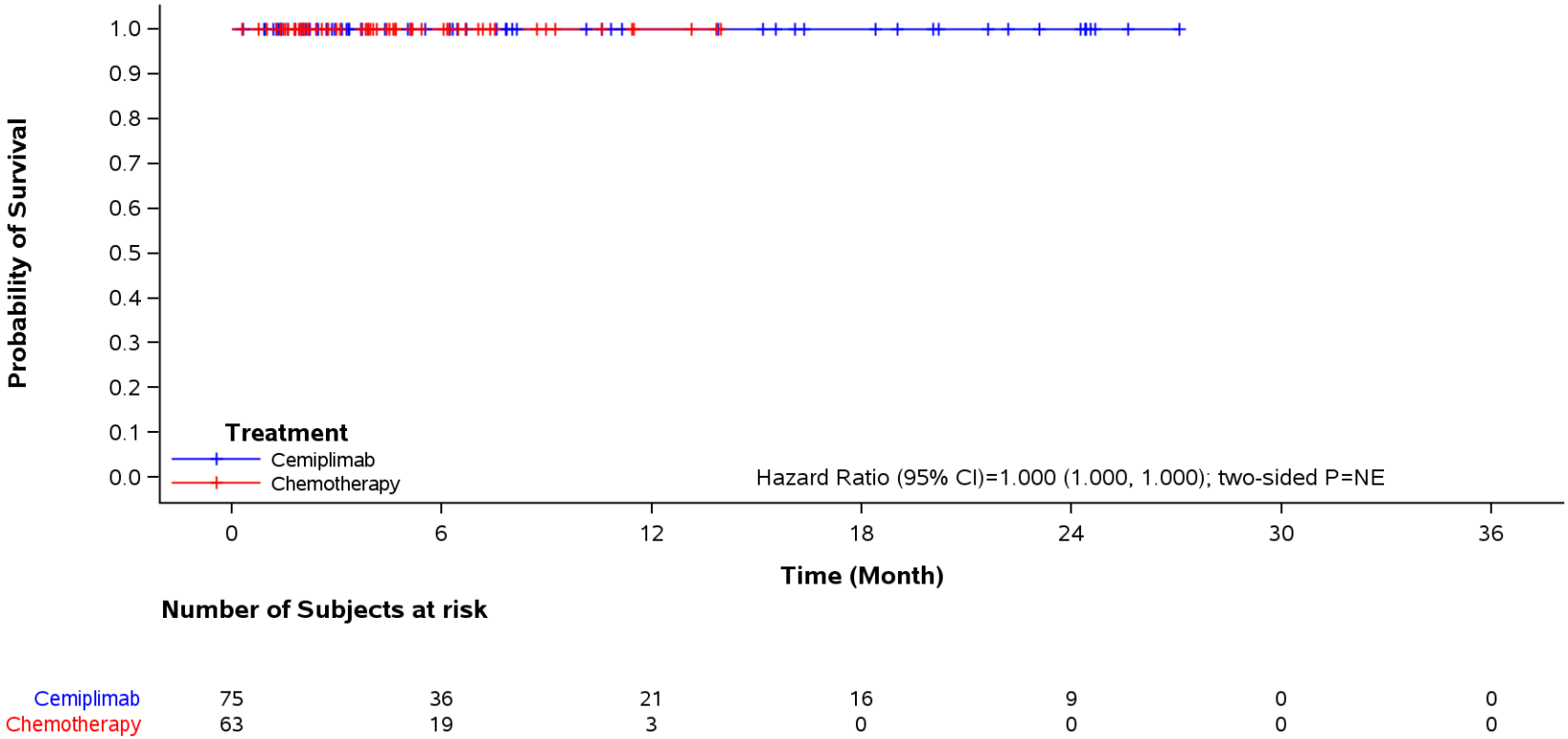

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

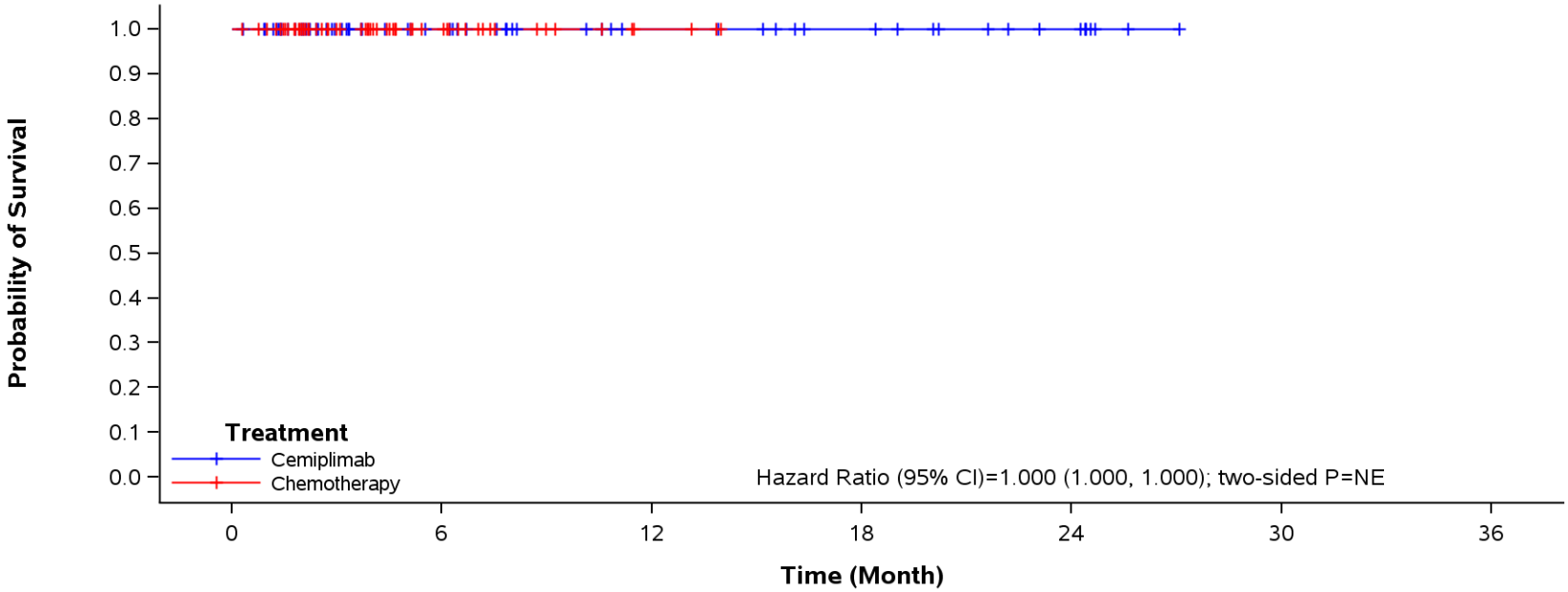
Geographic region: Europe
SOC: Infections and infestations
PT: Pelvic abscess




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Infections and infestations
PT: Peritonitis



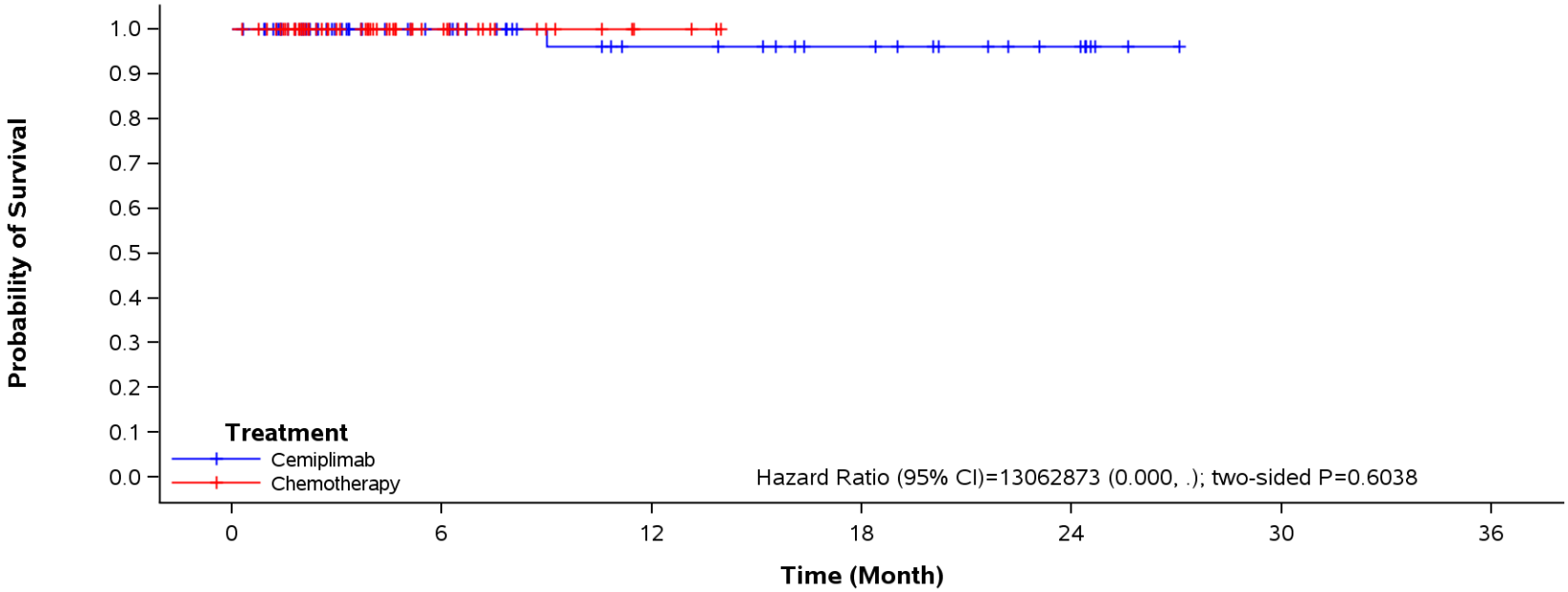

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Infections and infestations
PT: Pneumonia



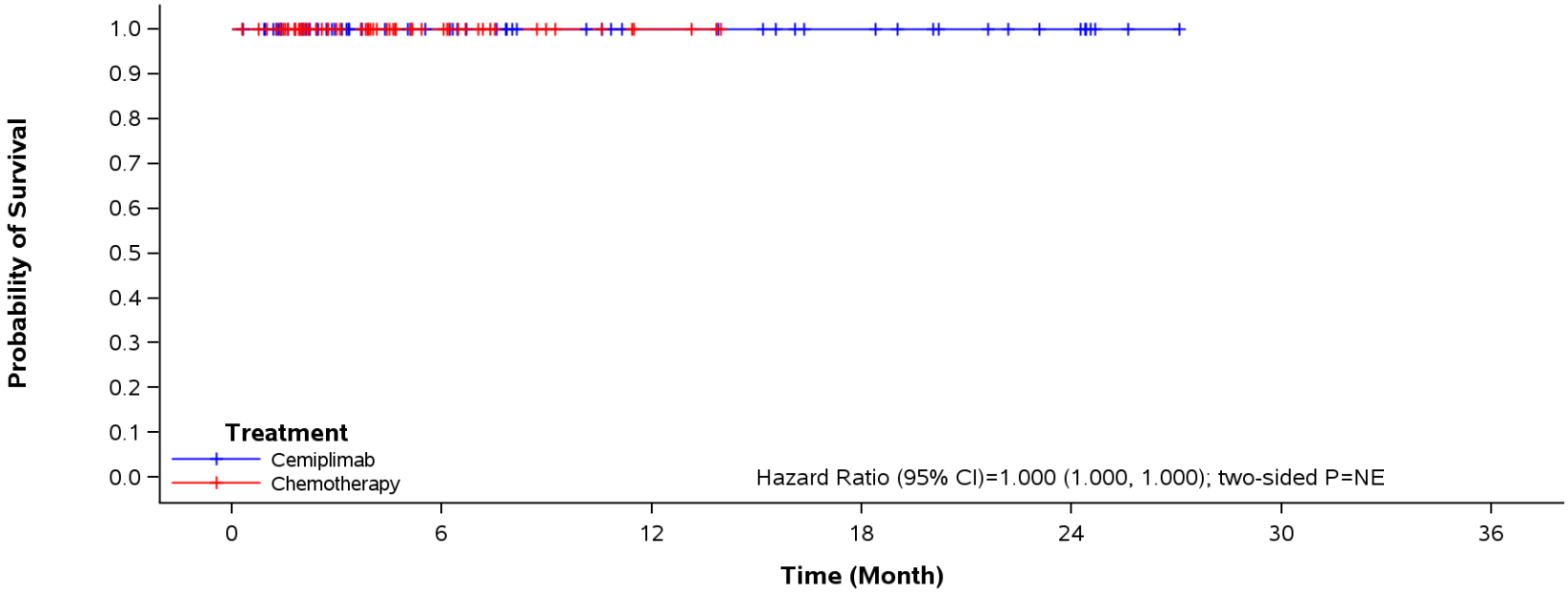

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Infections and infestations
PT: Pyomyositis



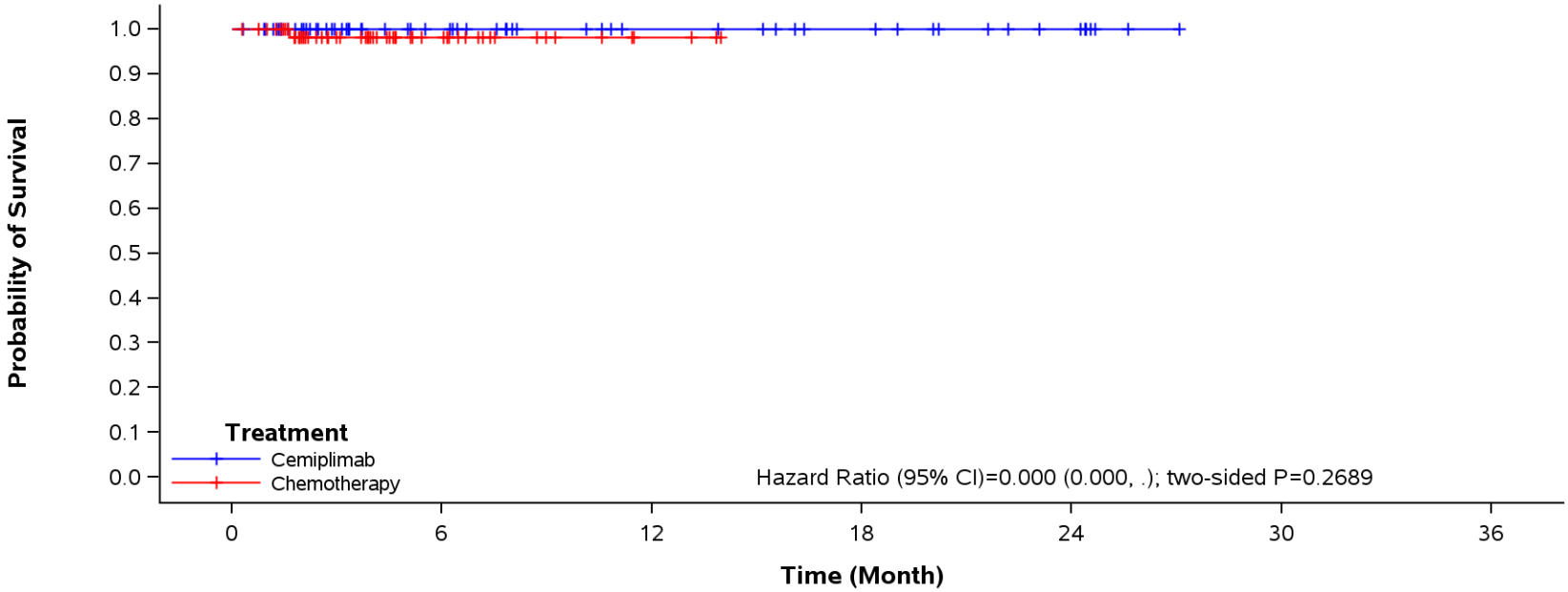

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Injury, poisoning and procedural complications



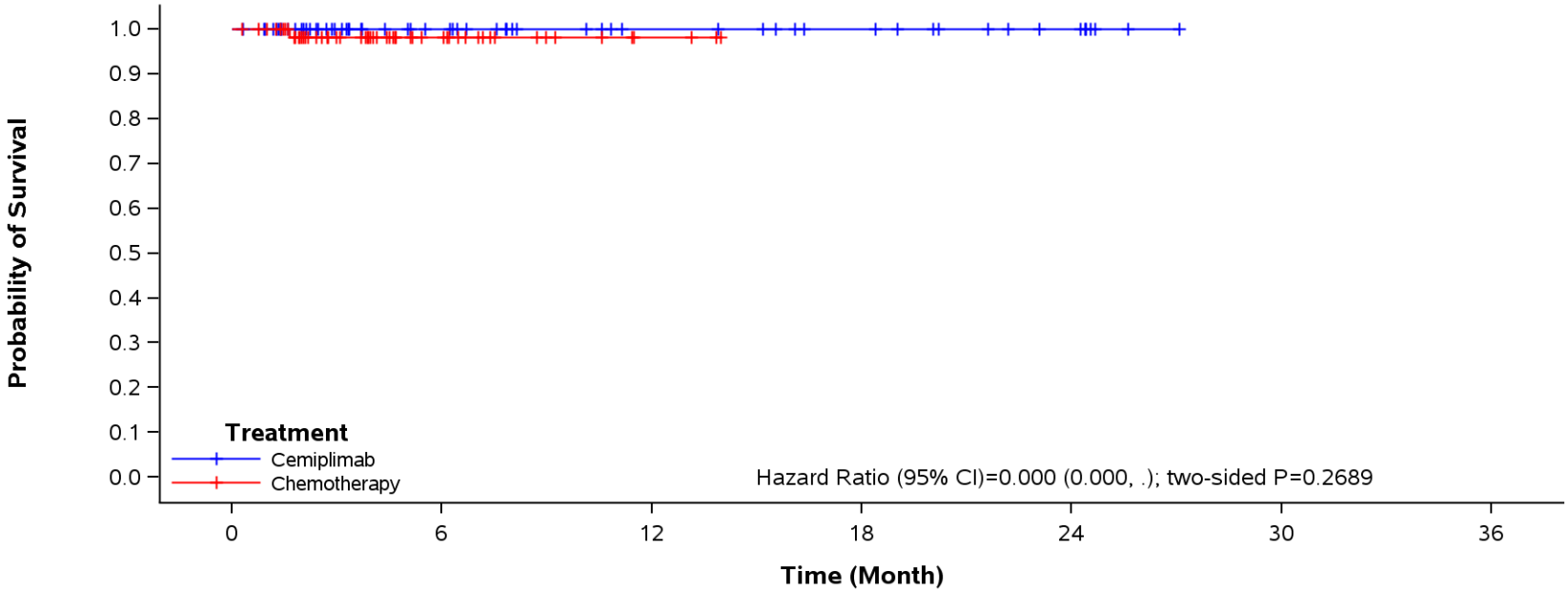

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



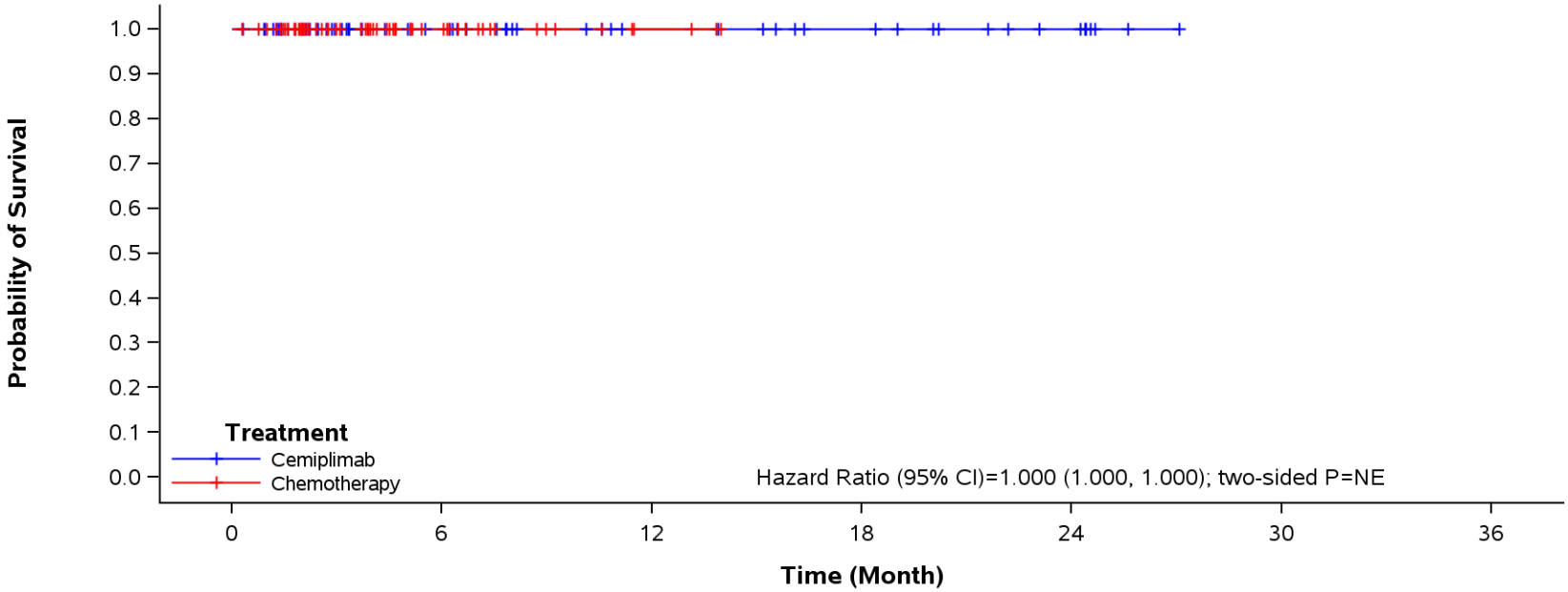

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



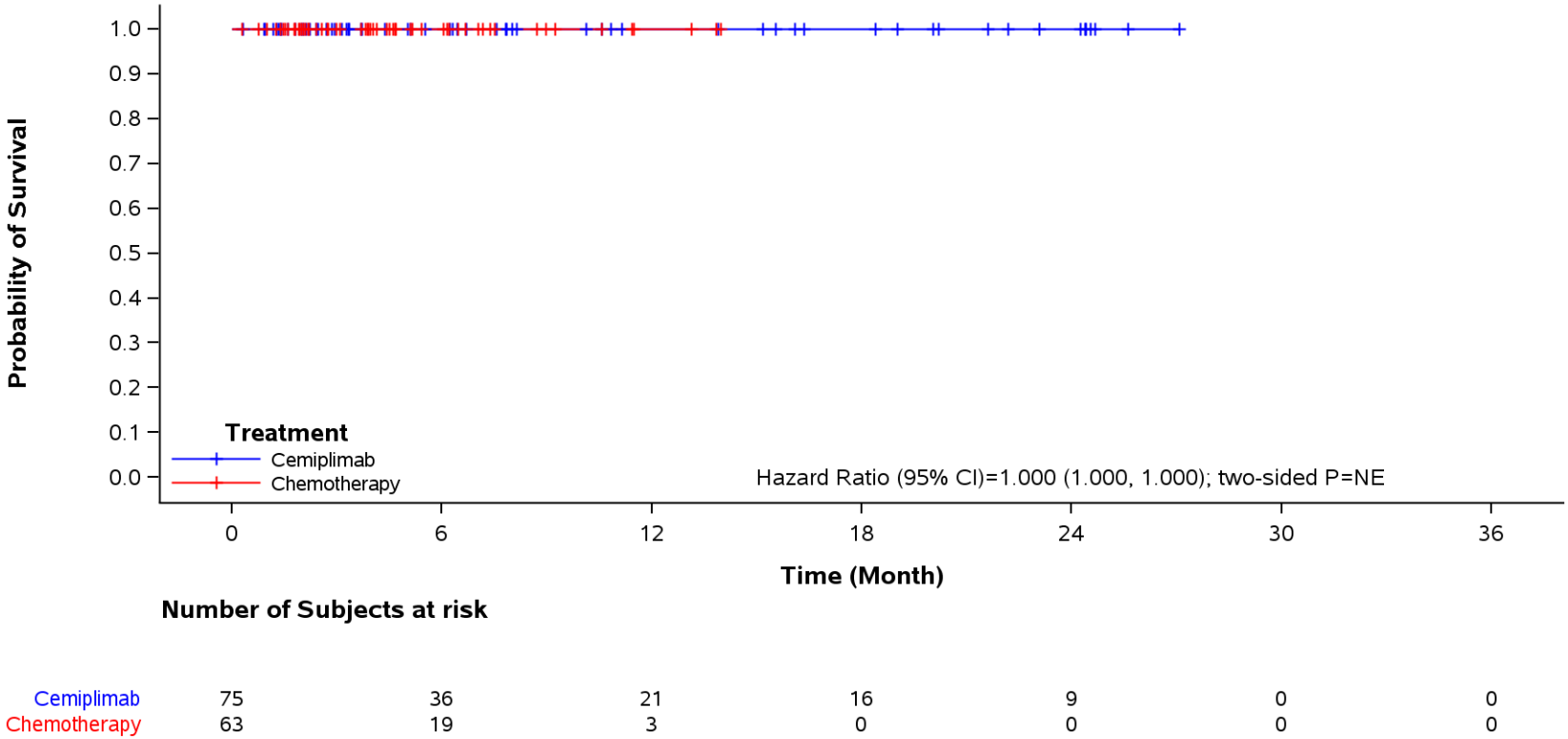

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

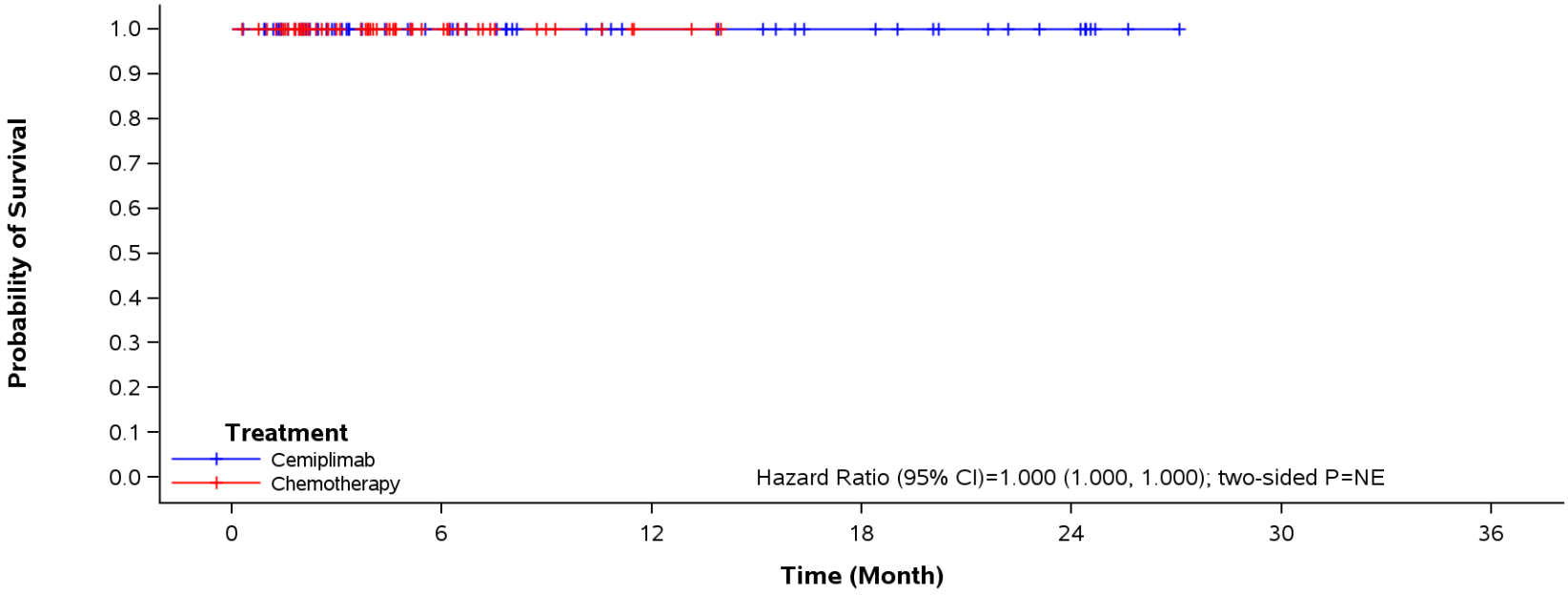
Geographic region: Europe
SOC: Investigations




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Investigations
PT: Alanine aminotransferase increased



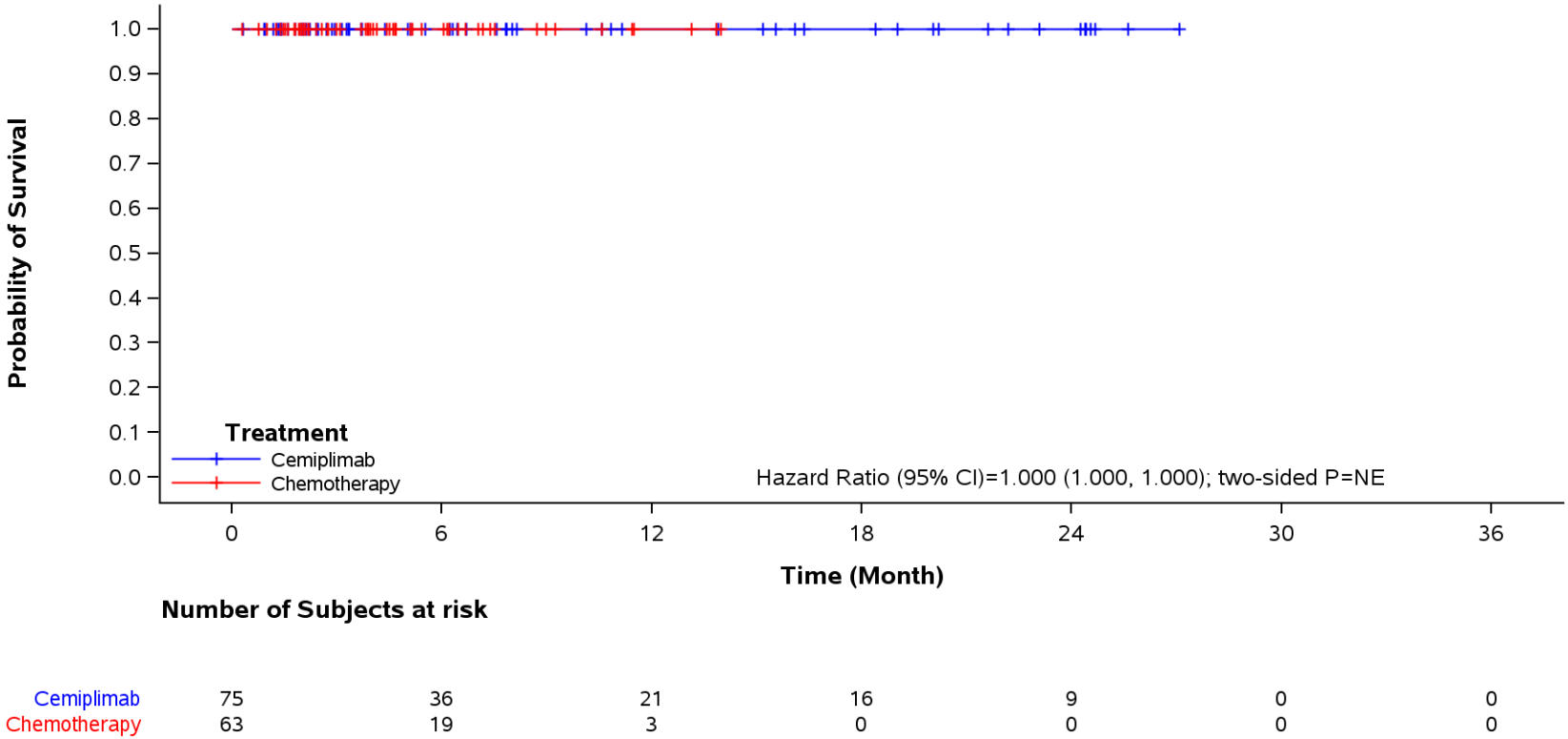

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

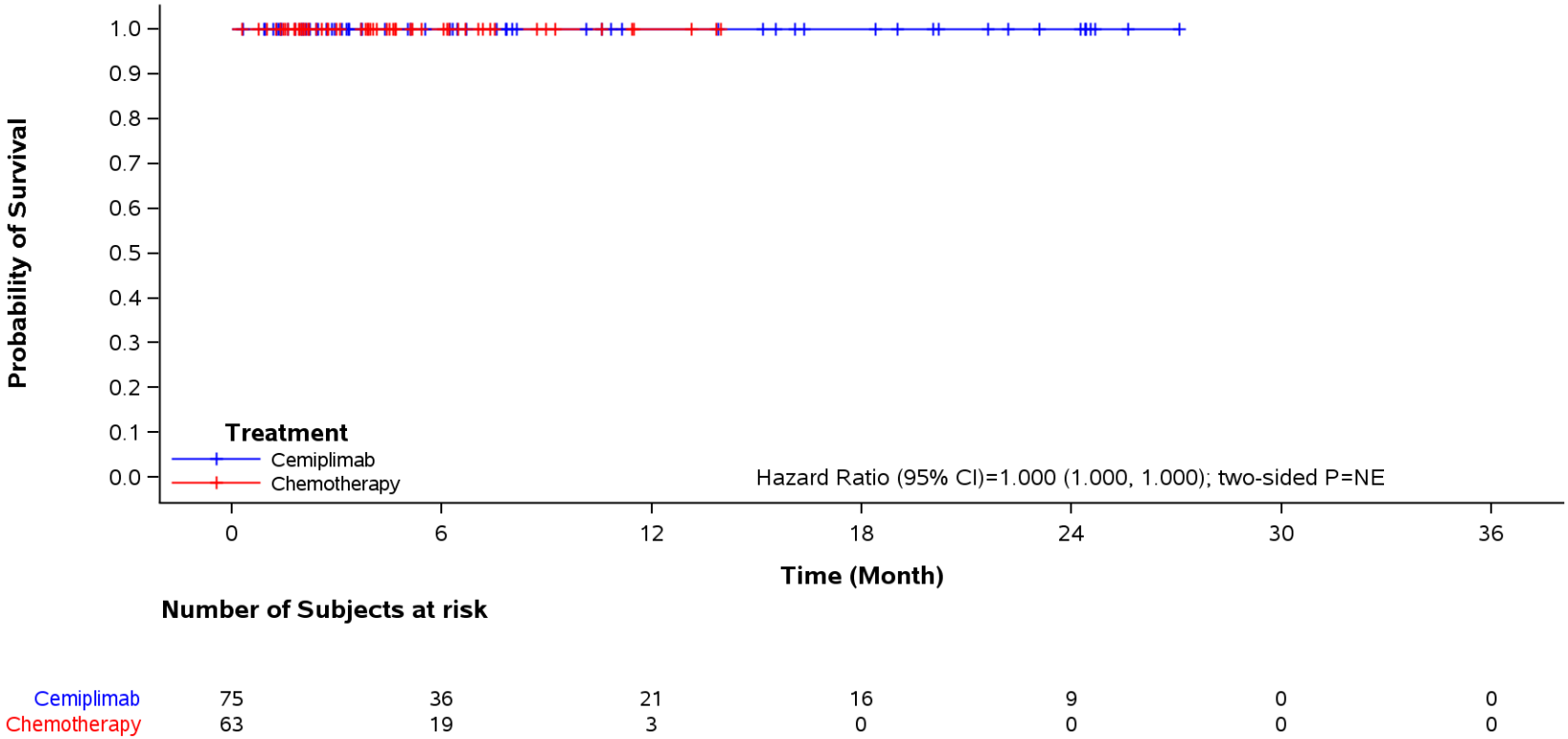
Geographic region: Europe
SOC: Investigations
PT: Amylase increased




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

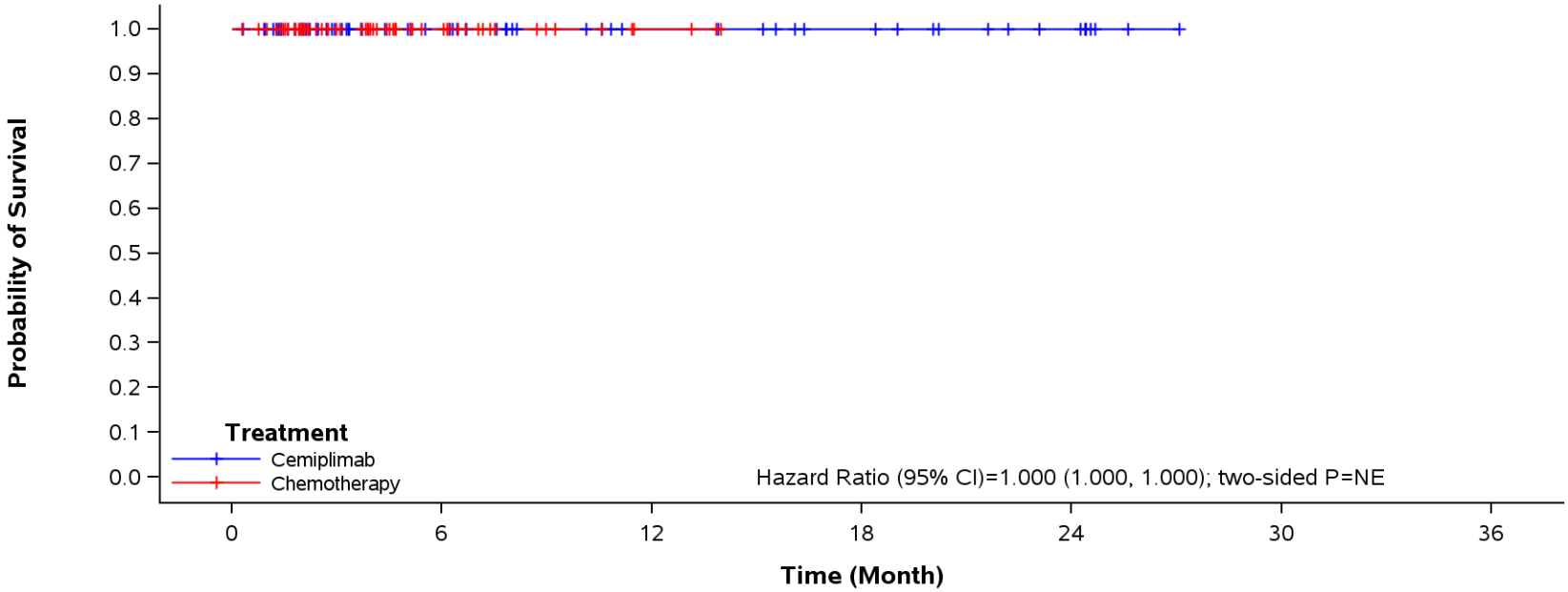
Geographic region: Europe
SOC: Investigations
PT: Platelet count decreased




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Metabolism and nutrition disorders



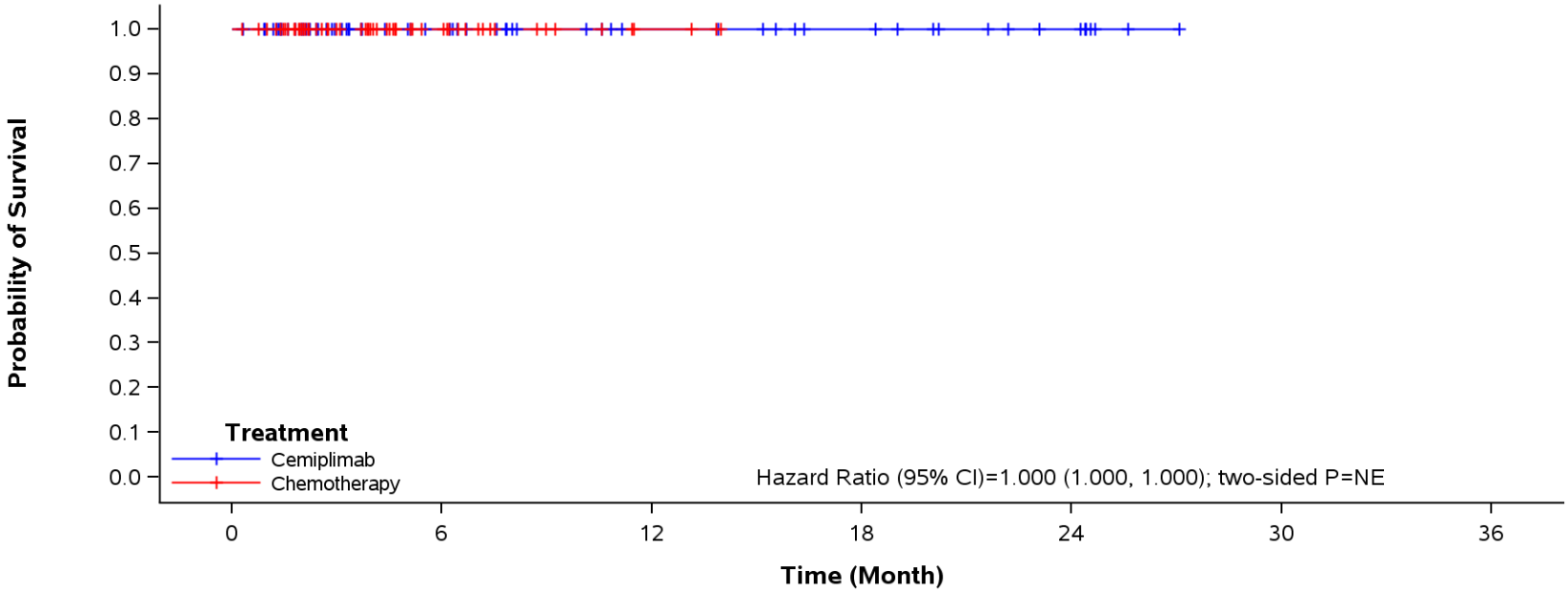

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



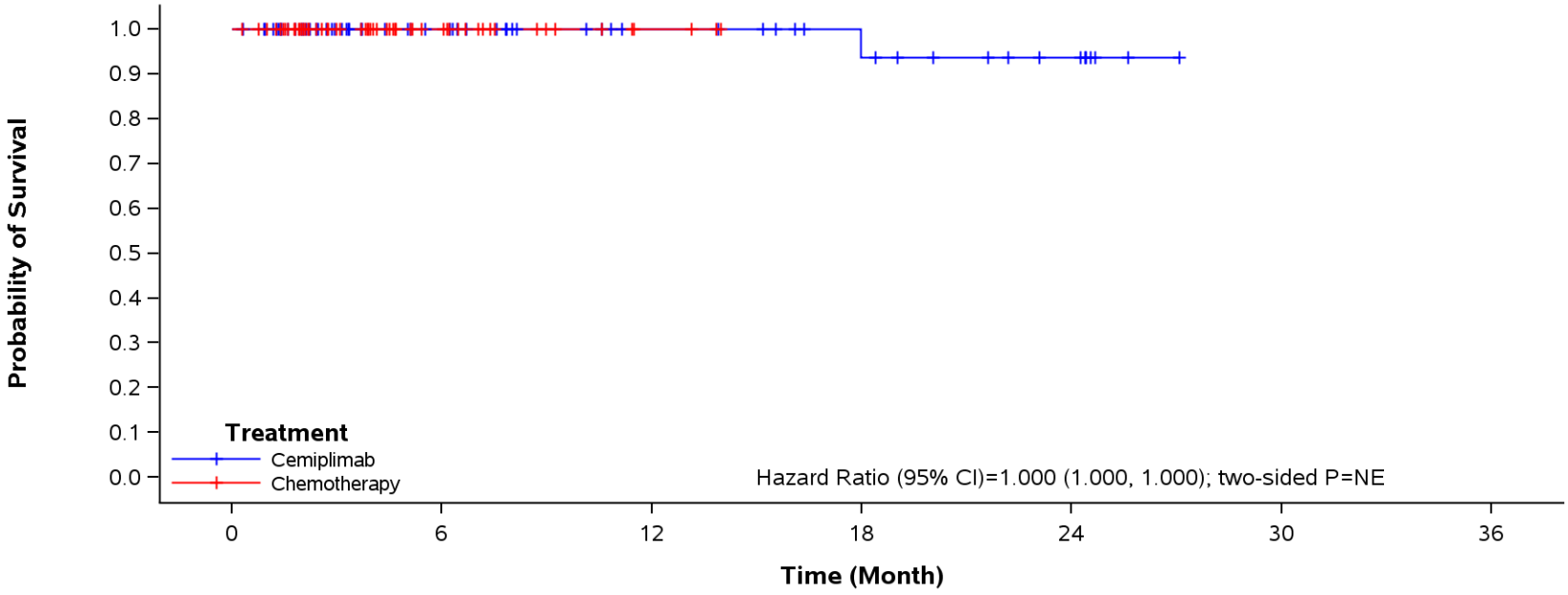

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Musculoskeletal and connective tissue disorders



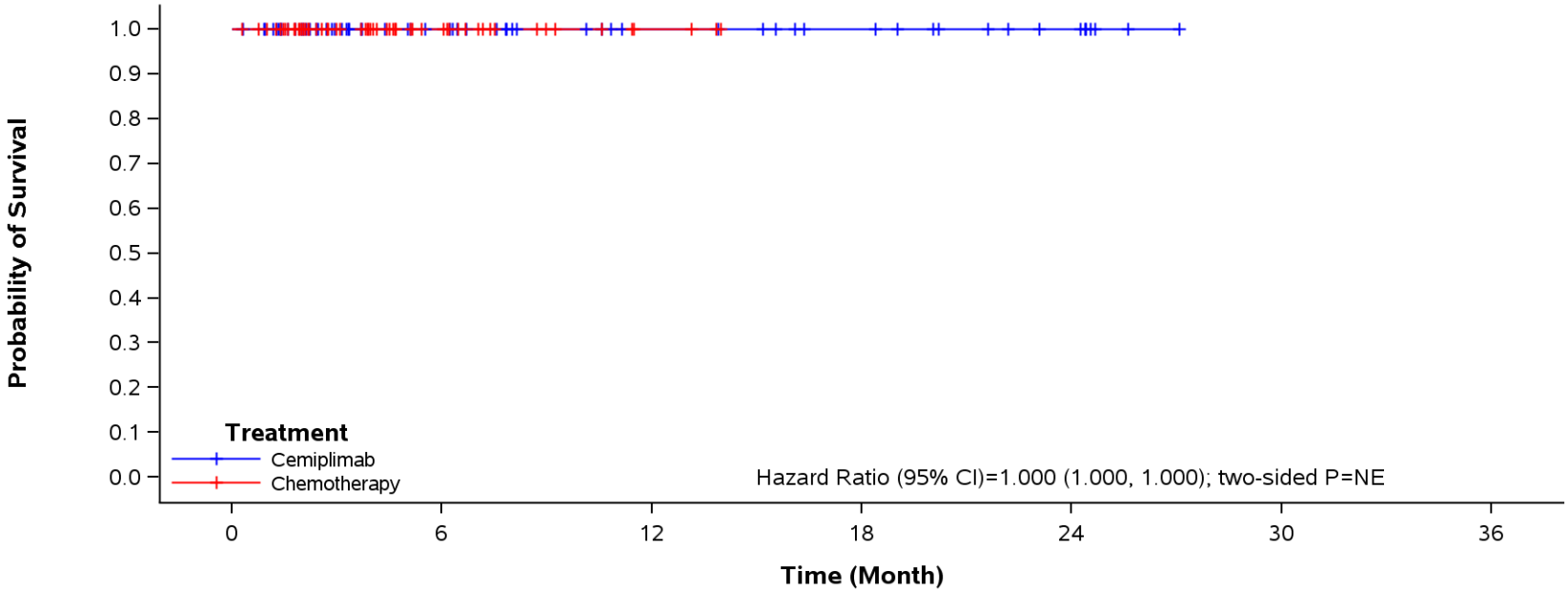

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 15 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



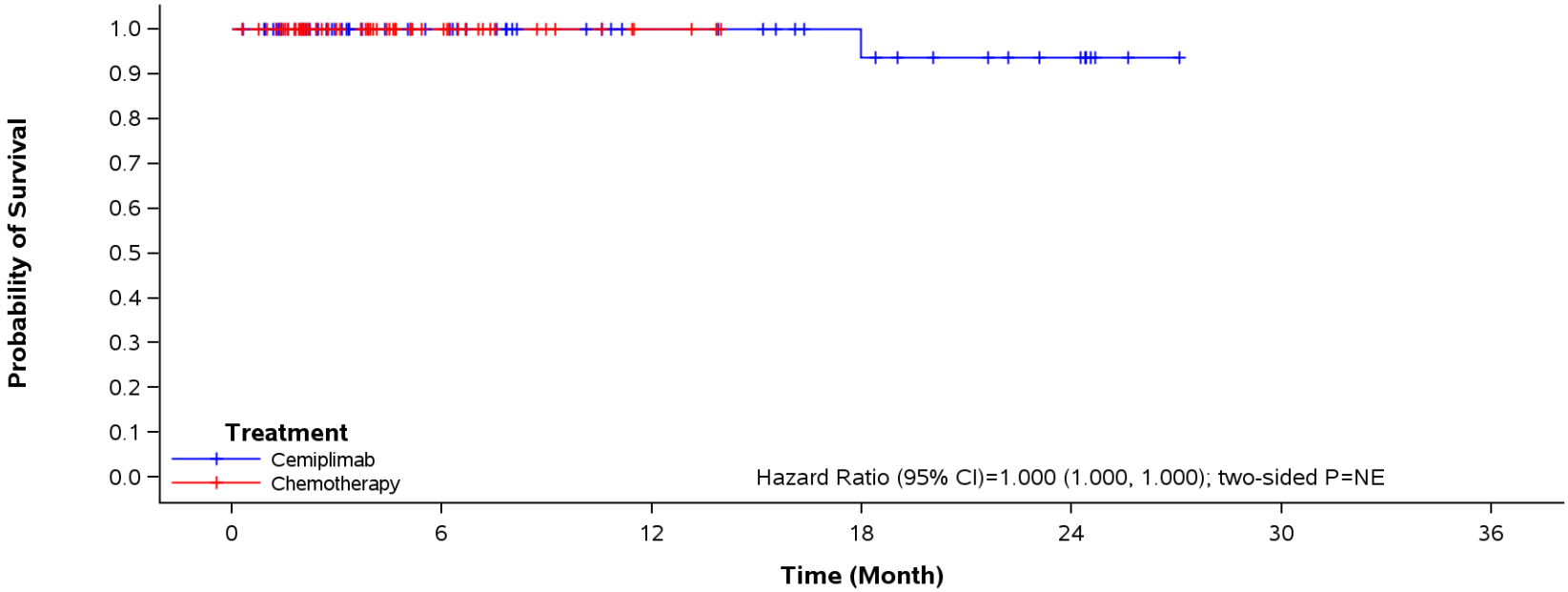

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



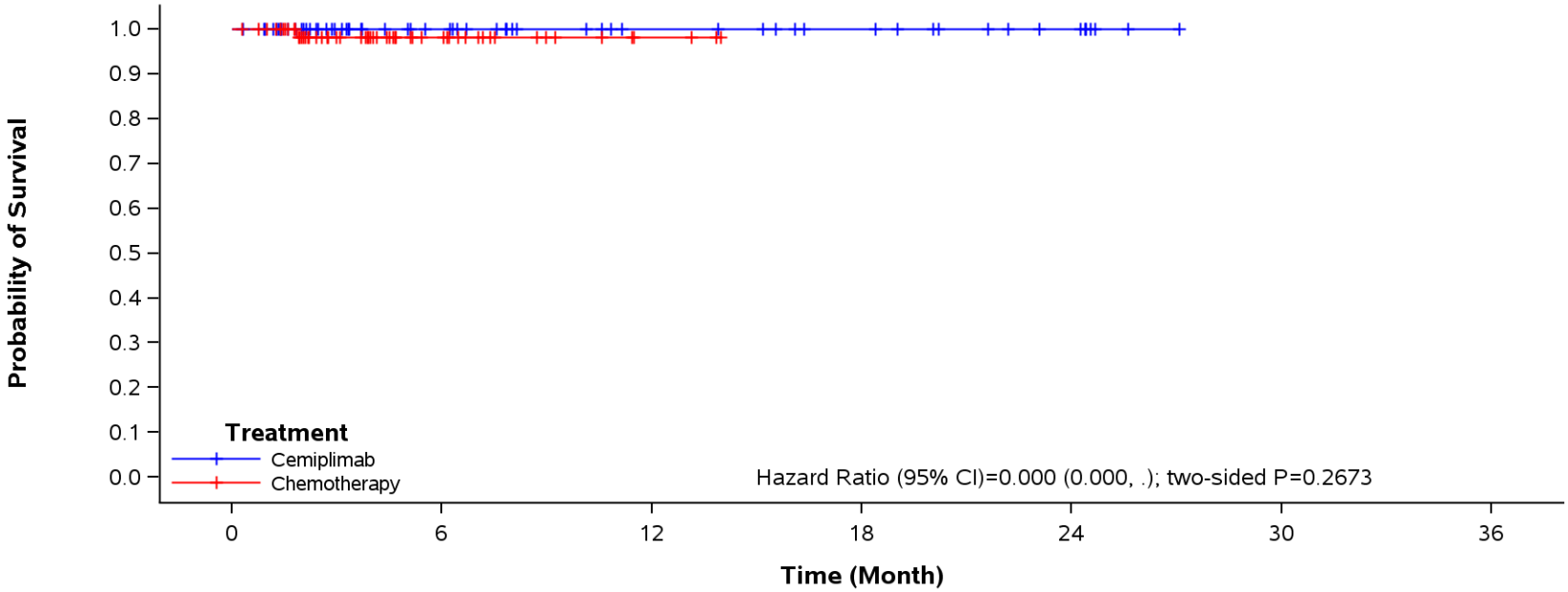

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 15 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Nervous system disorders



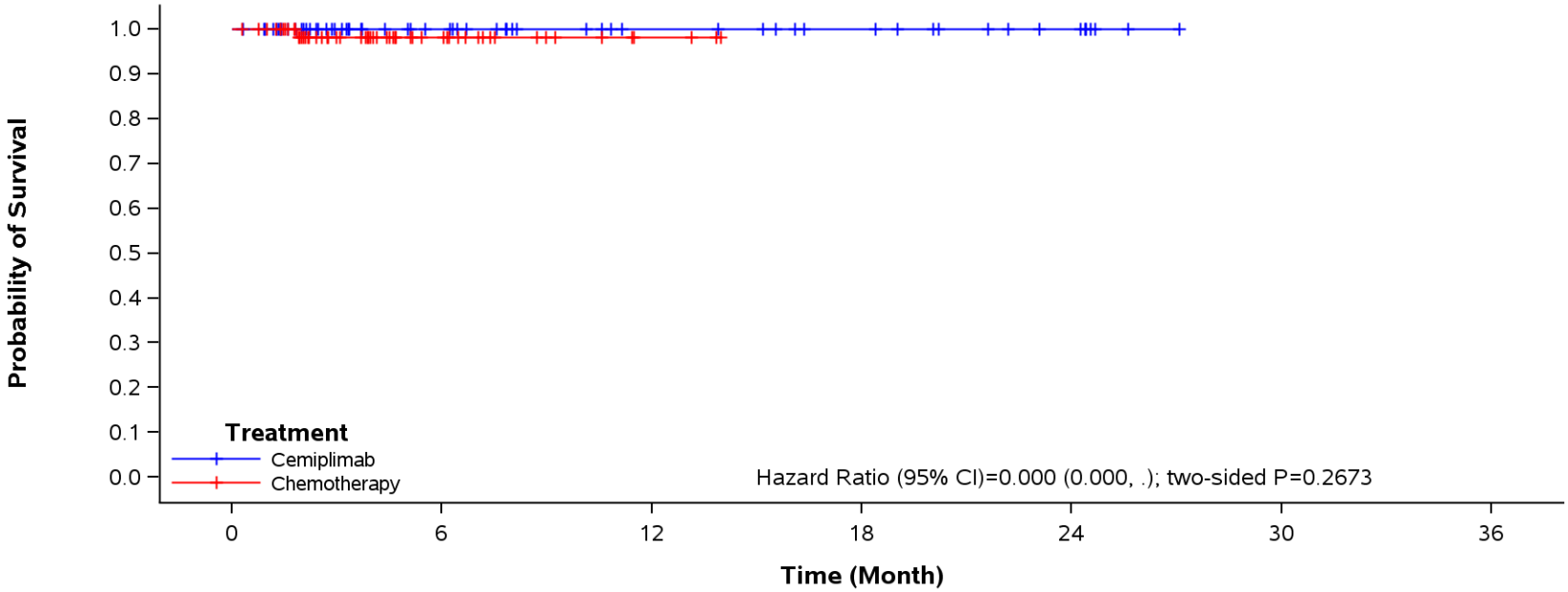

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Nervous system disorders
PT: Neurotoxicity



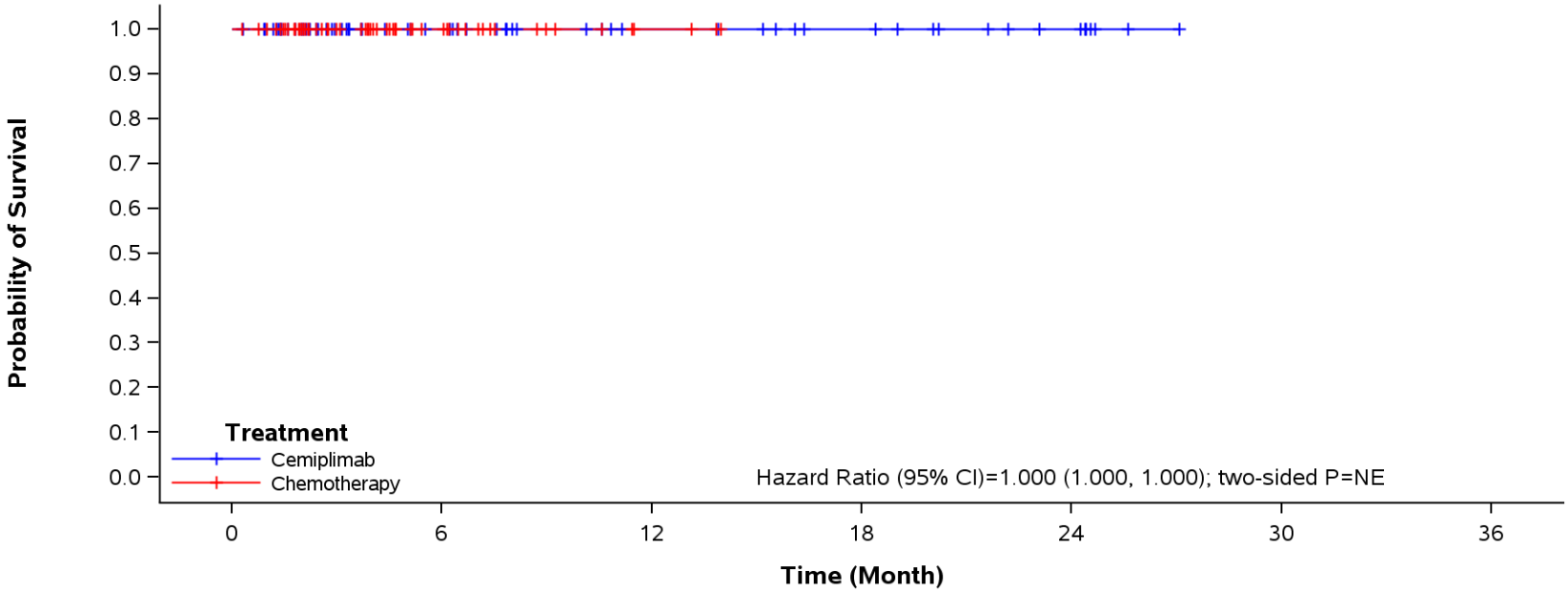

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Nervous system disorders
PT: Transient ischaemic attack



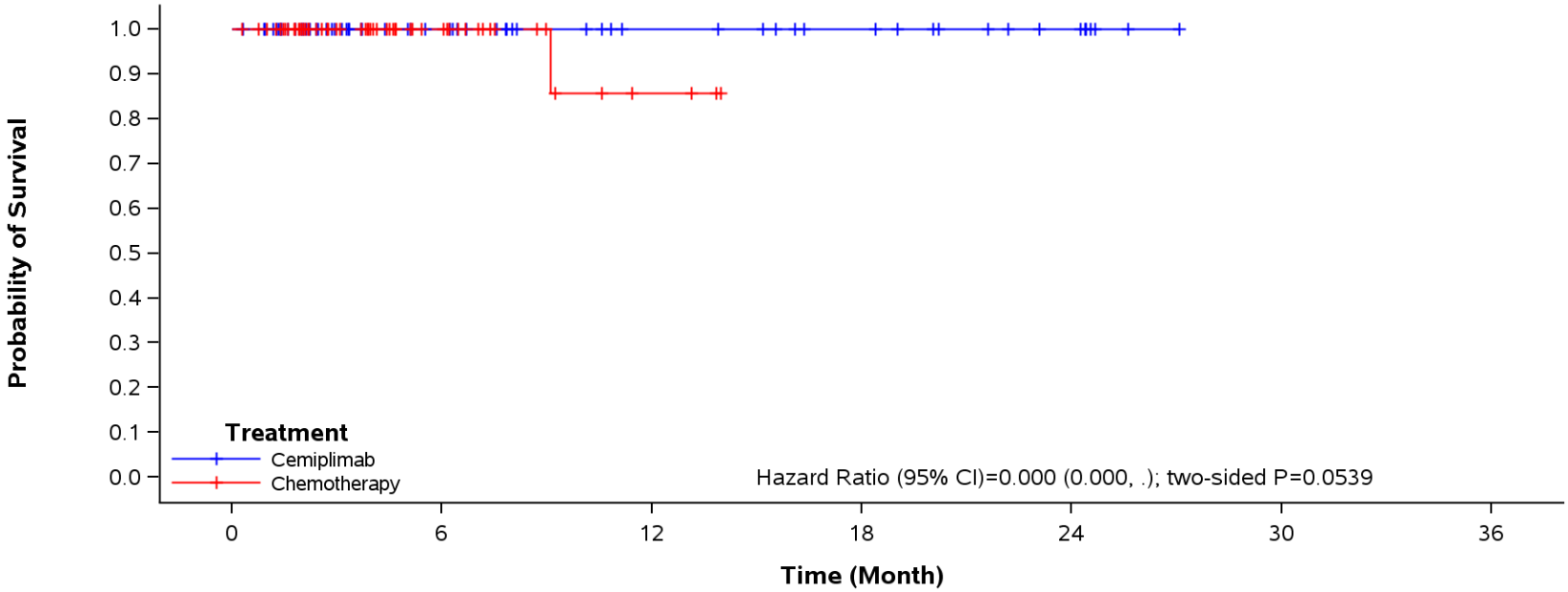

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Psychiatric disorders



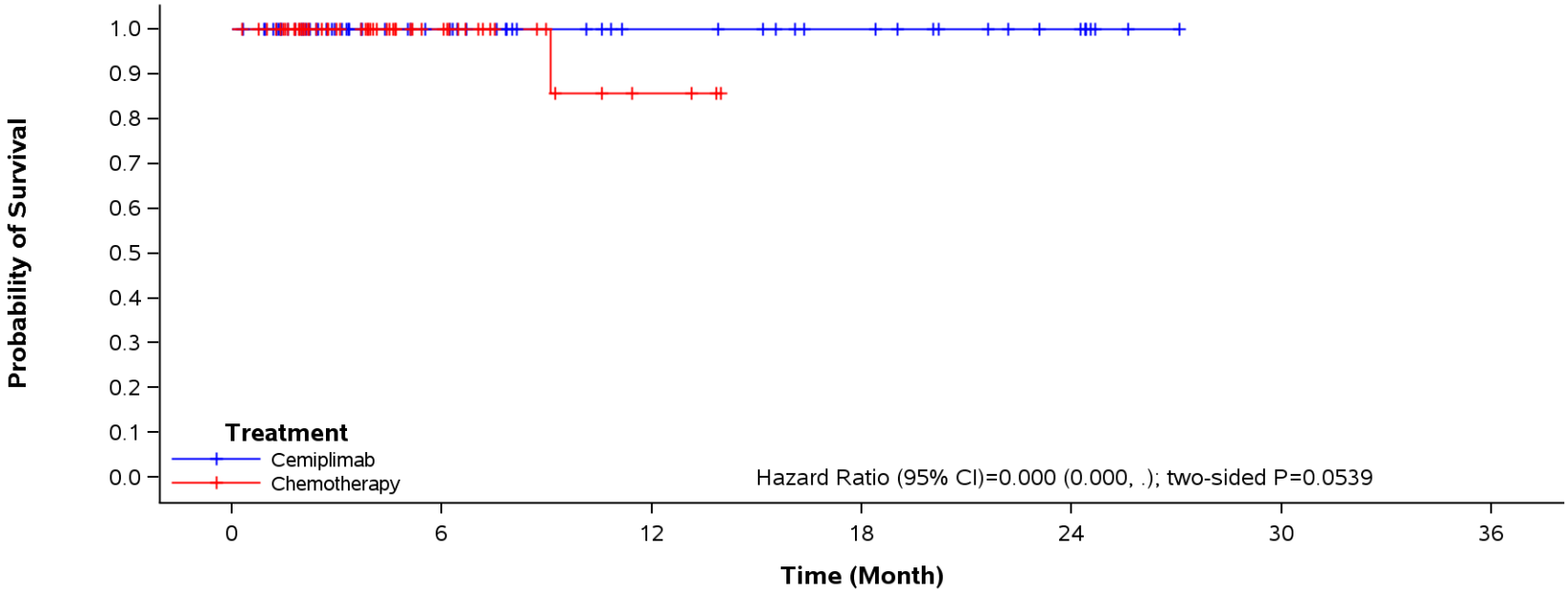

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Psychiatric disorders
PT: Agoraphobia



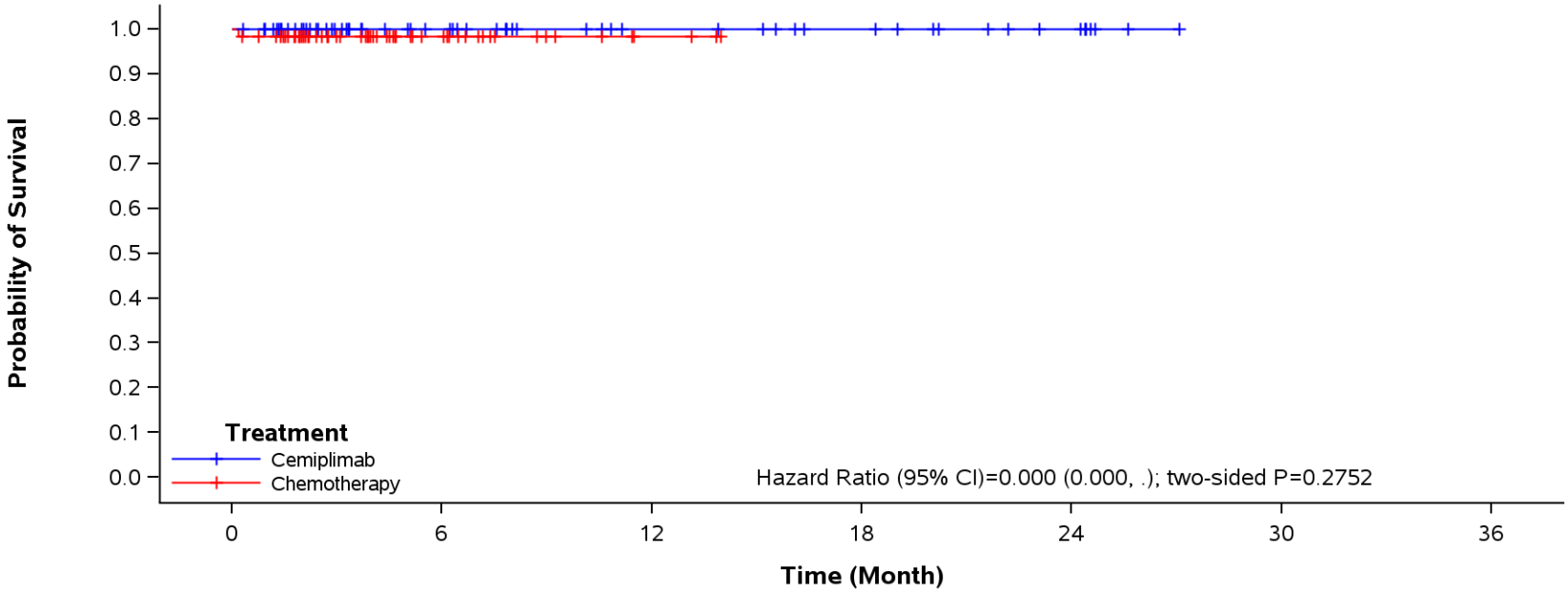

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Renal and urinary disorders



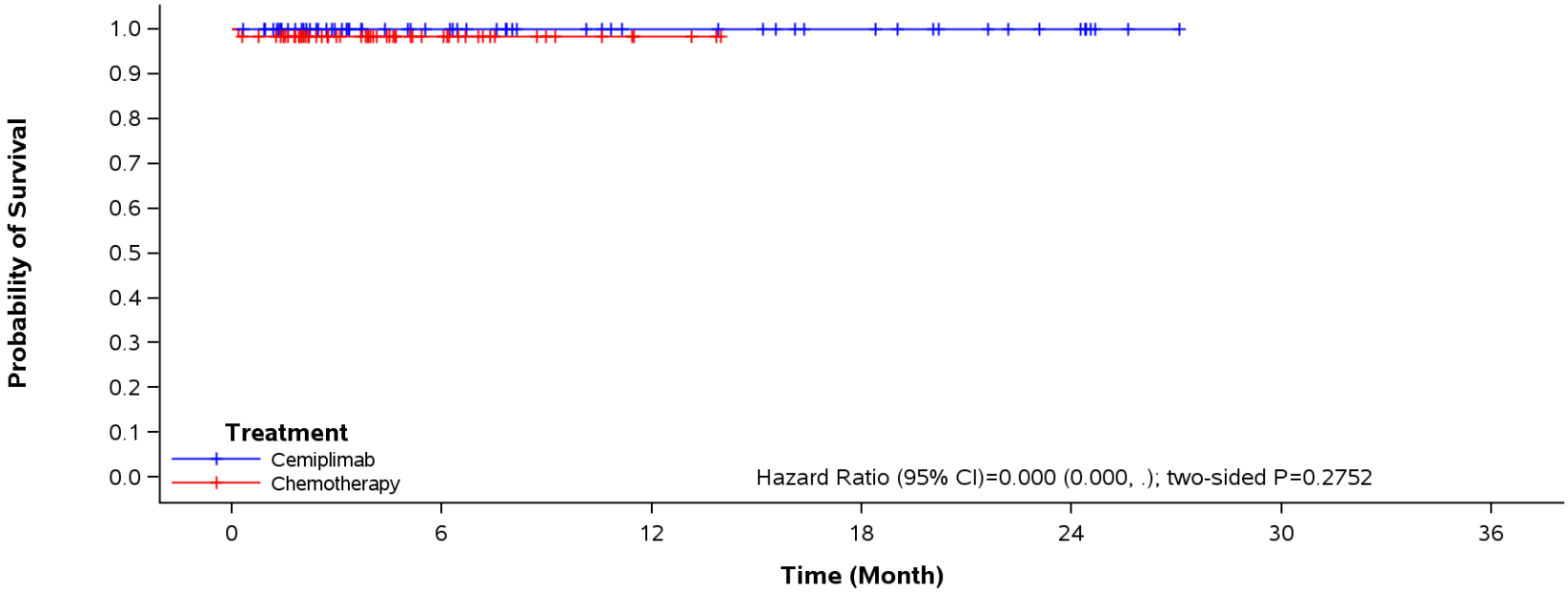

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Renal and urinary disorders
PT: Renal failure



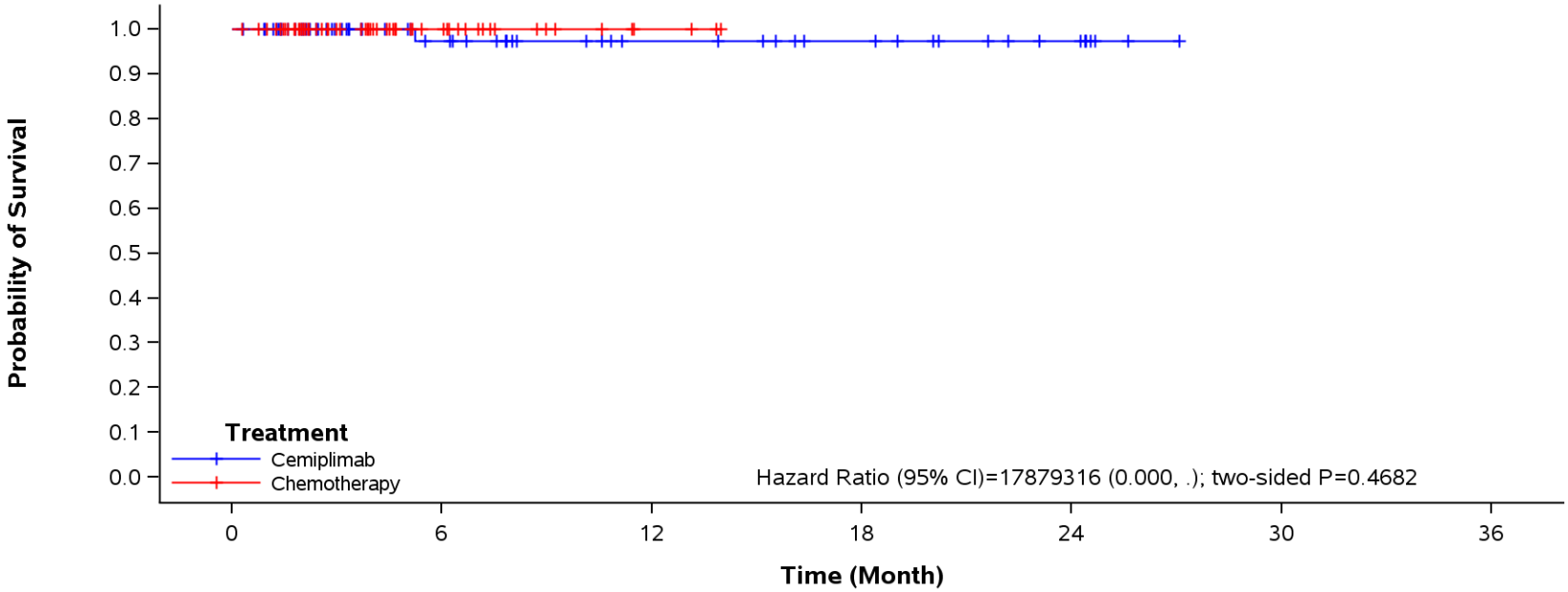

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Respiratory, thoracic and mediastinal disorders



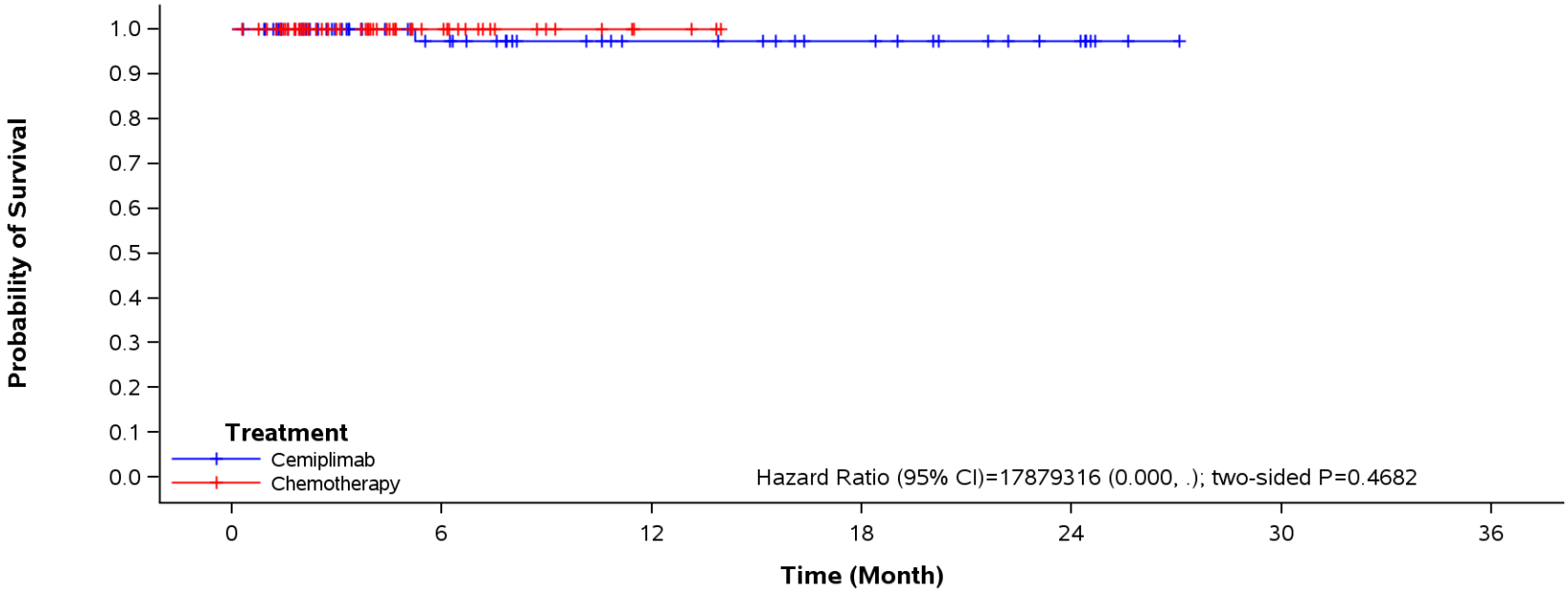

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 35 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



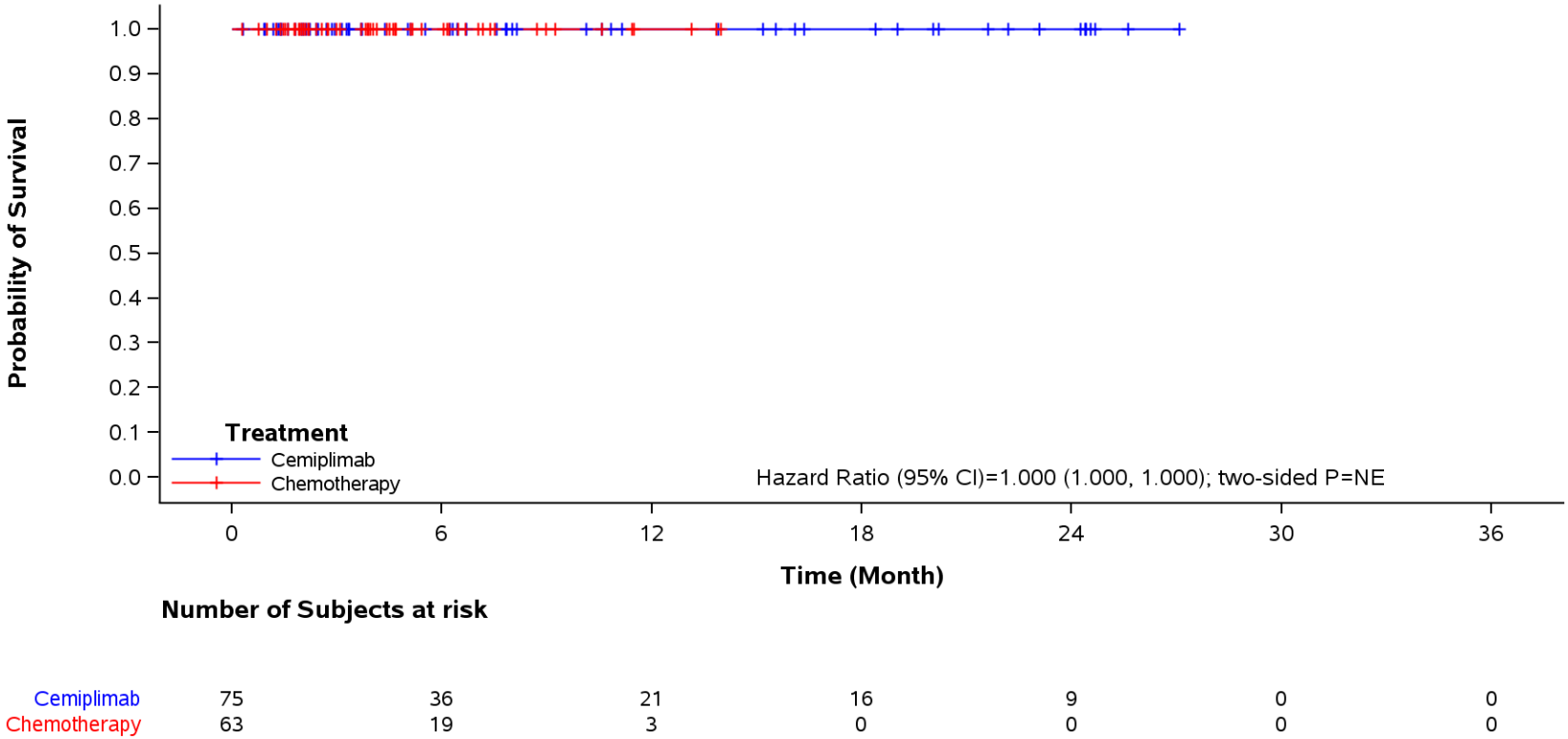

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 35 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

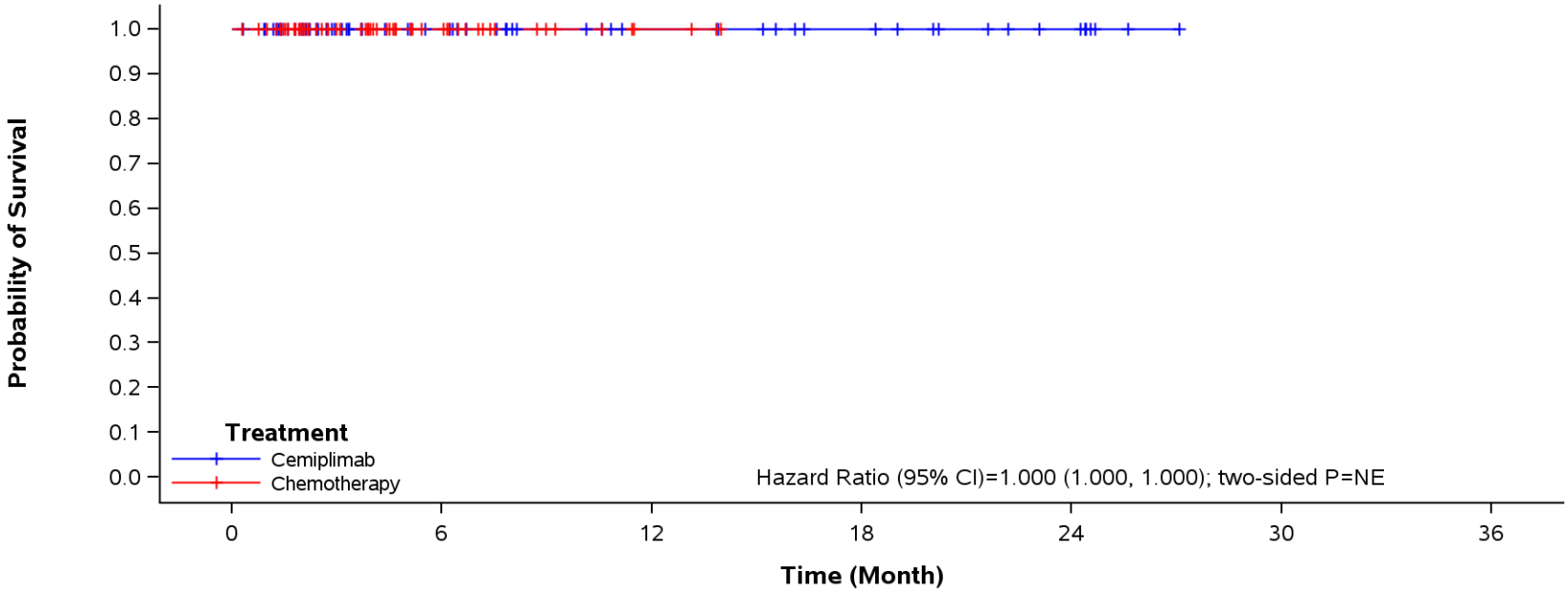
Geographic region: Europe
SOC: Vascular disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: Europe
SOC: Vascular disorders
PT: Deep vein thrombosis



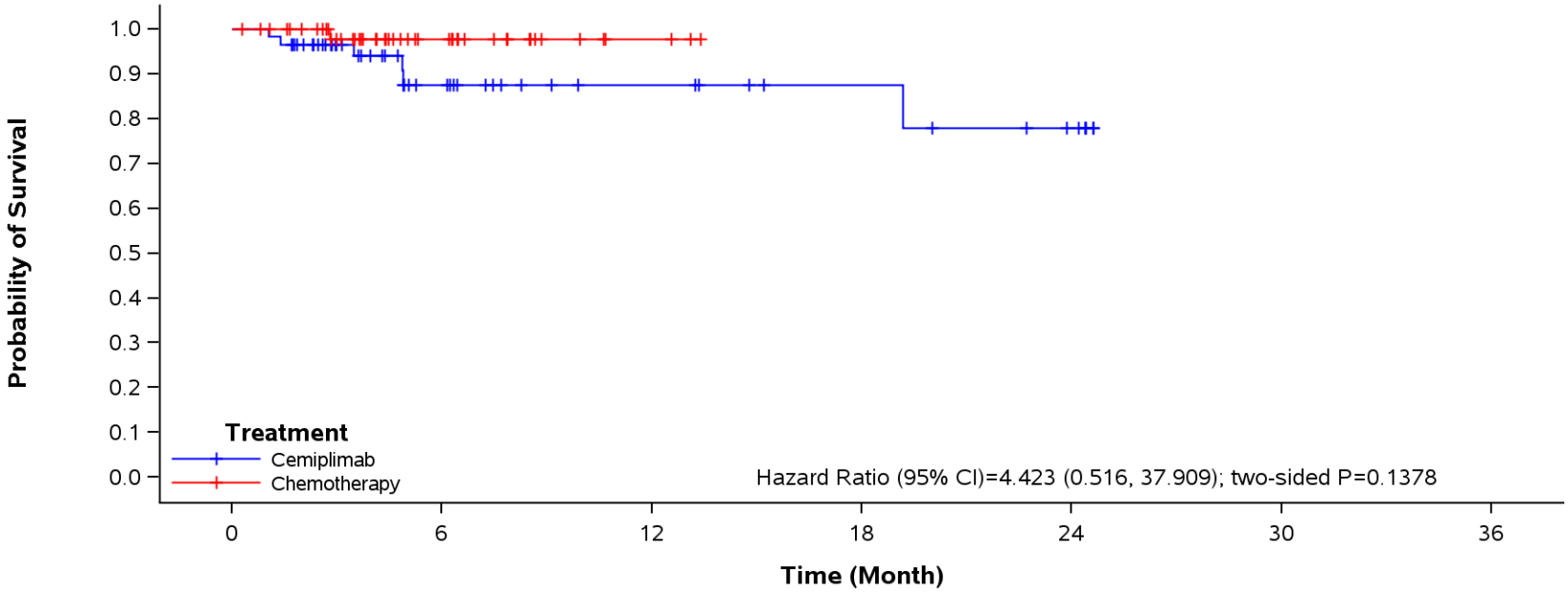

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 75 | 36 | 21 | 16 | 9 | 0 | 0 |
| Chemotherapy | 63 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
Number of patients with any TEAE leading to discontinuation



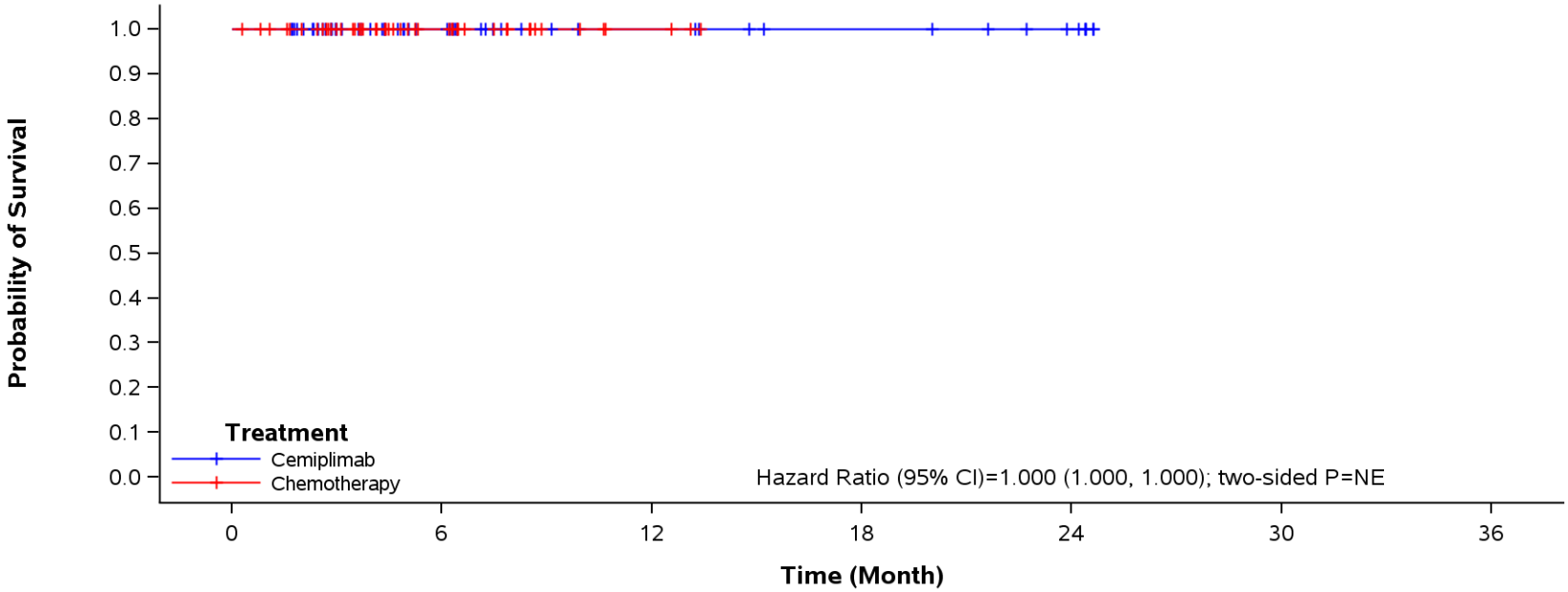

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 23 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders



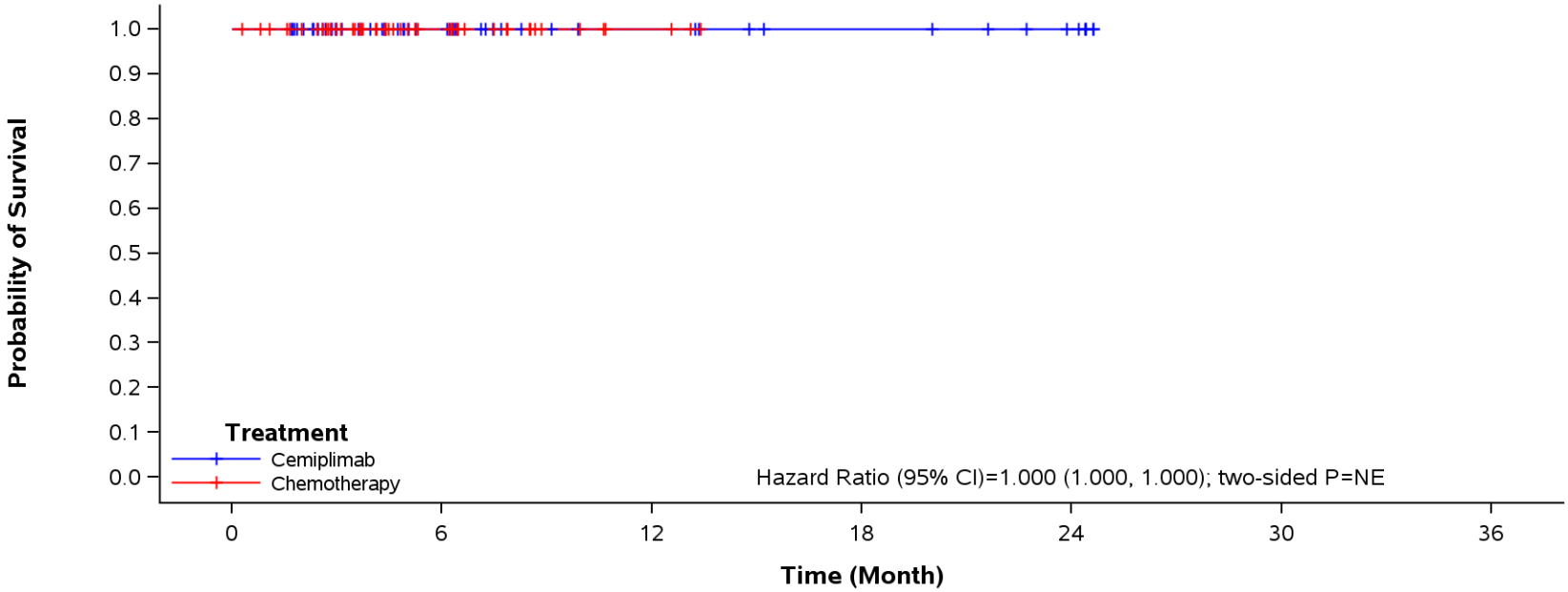

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Anaemia



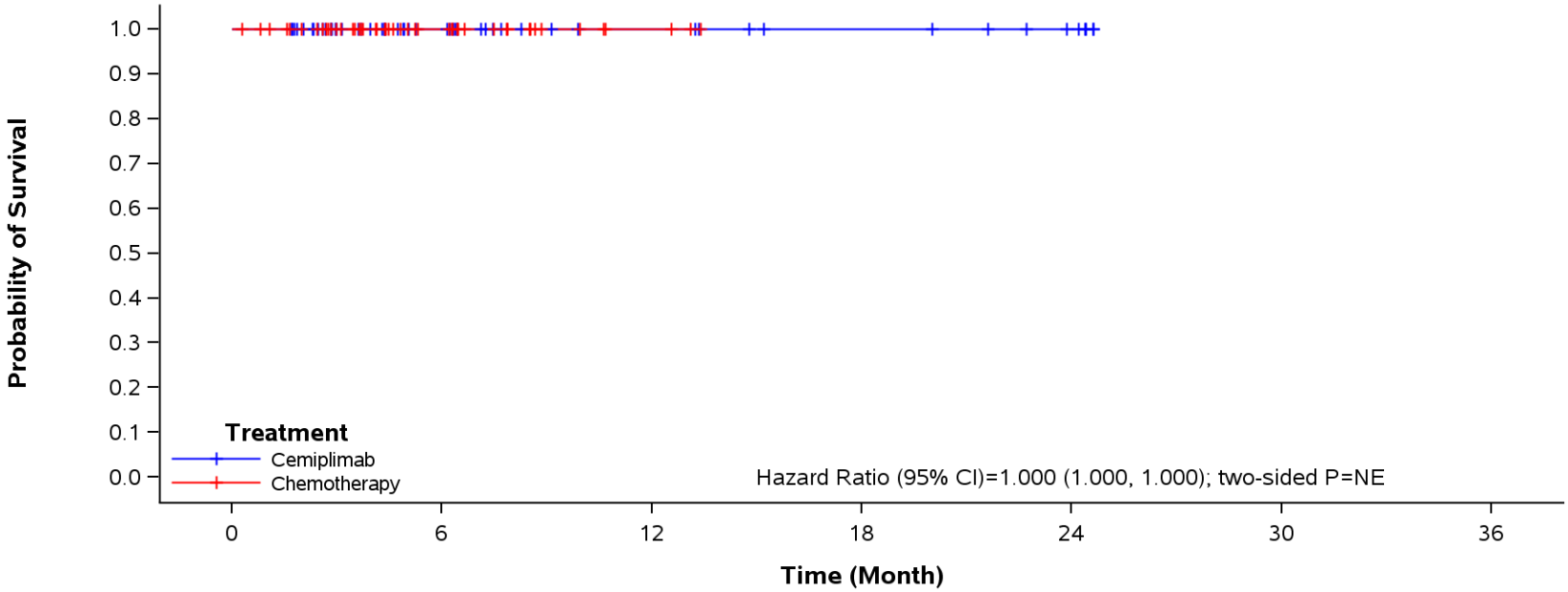

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



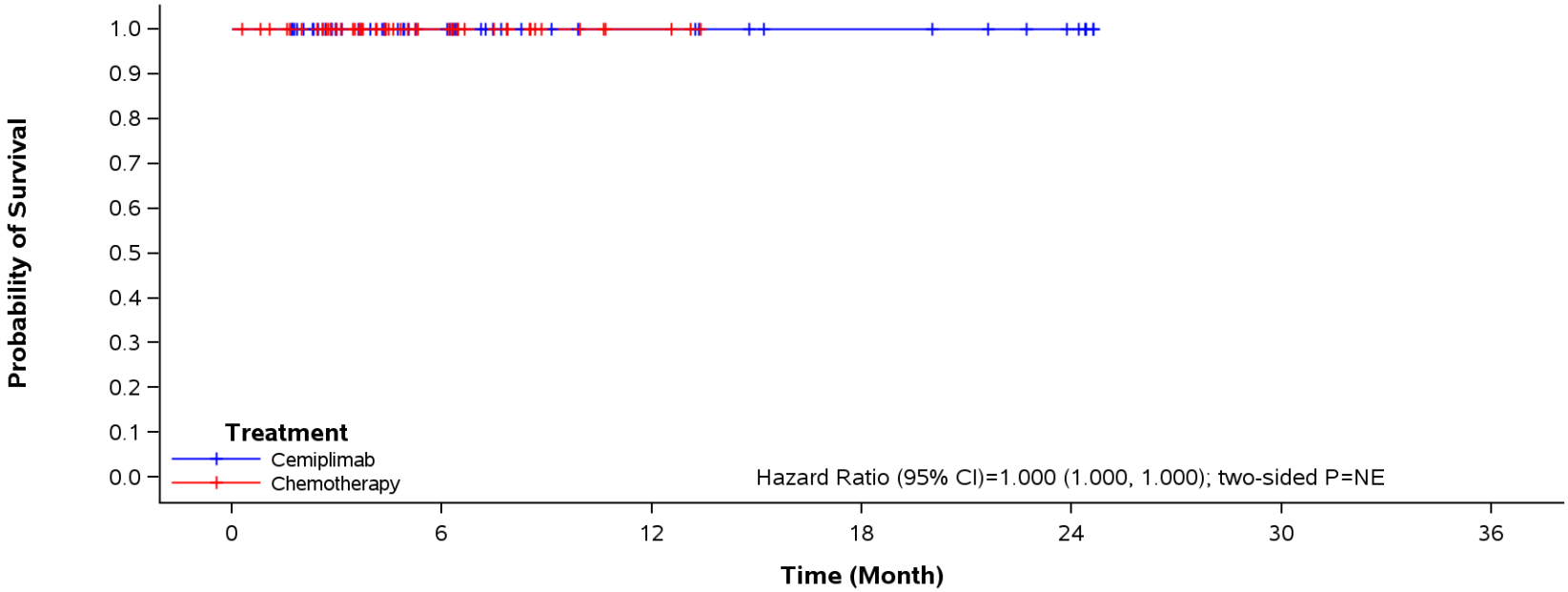

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Neutropenia



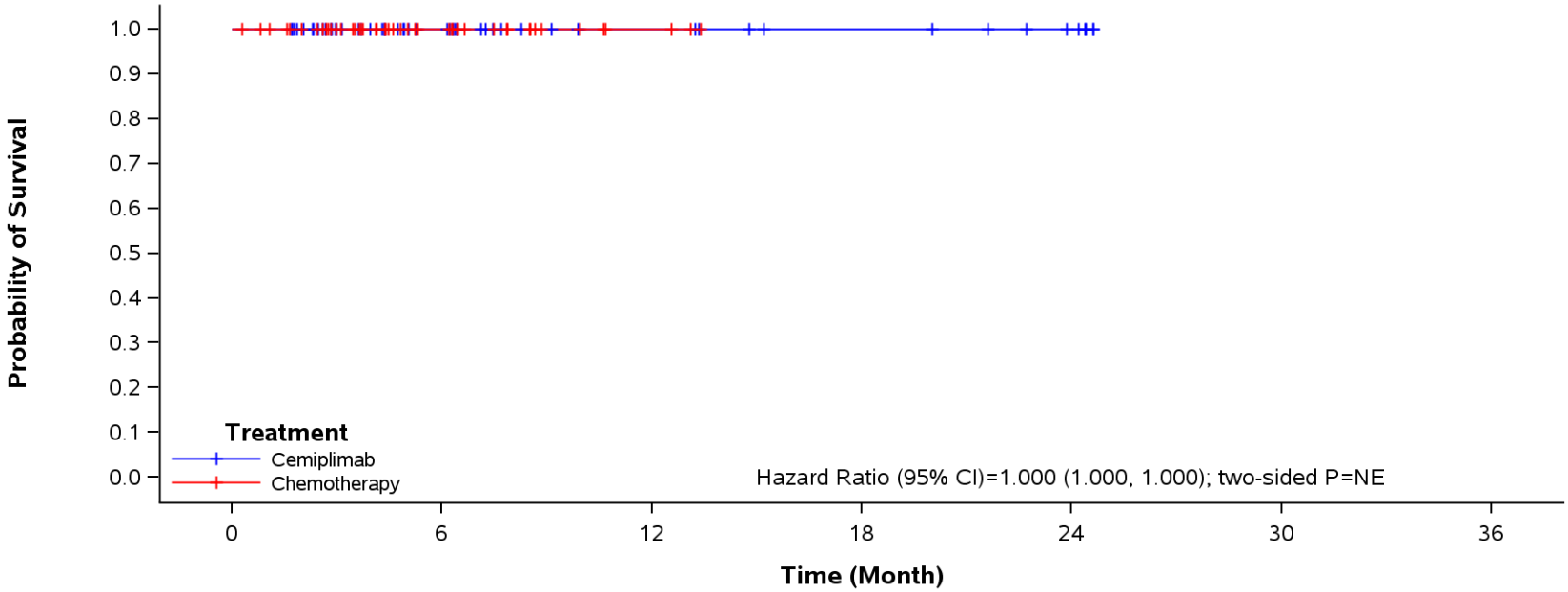

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



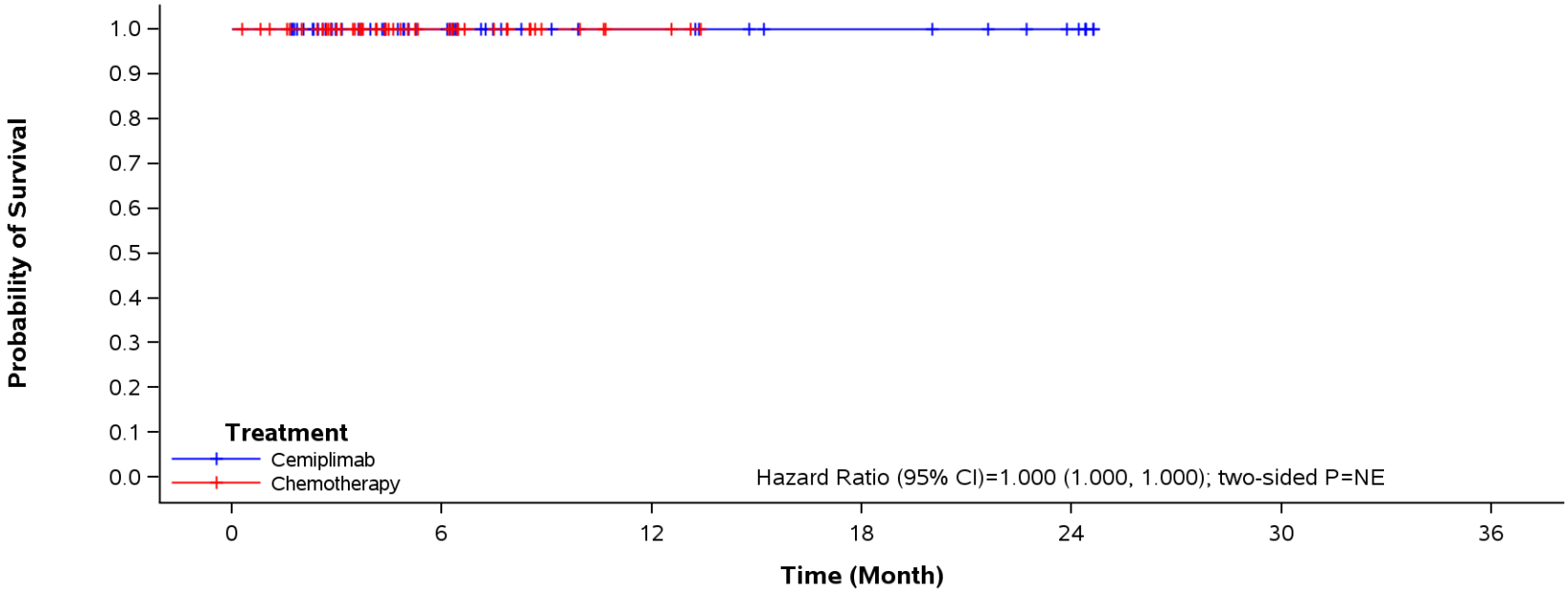

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Cardiac disorders



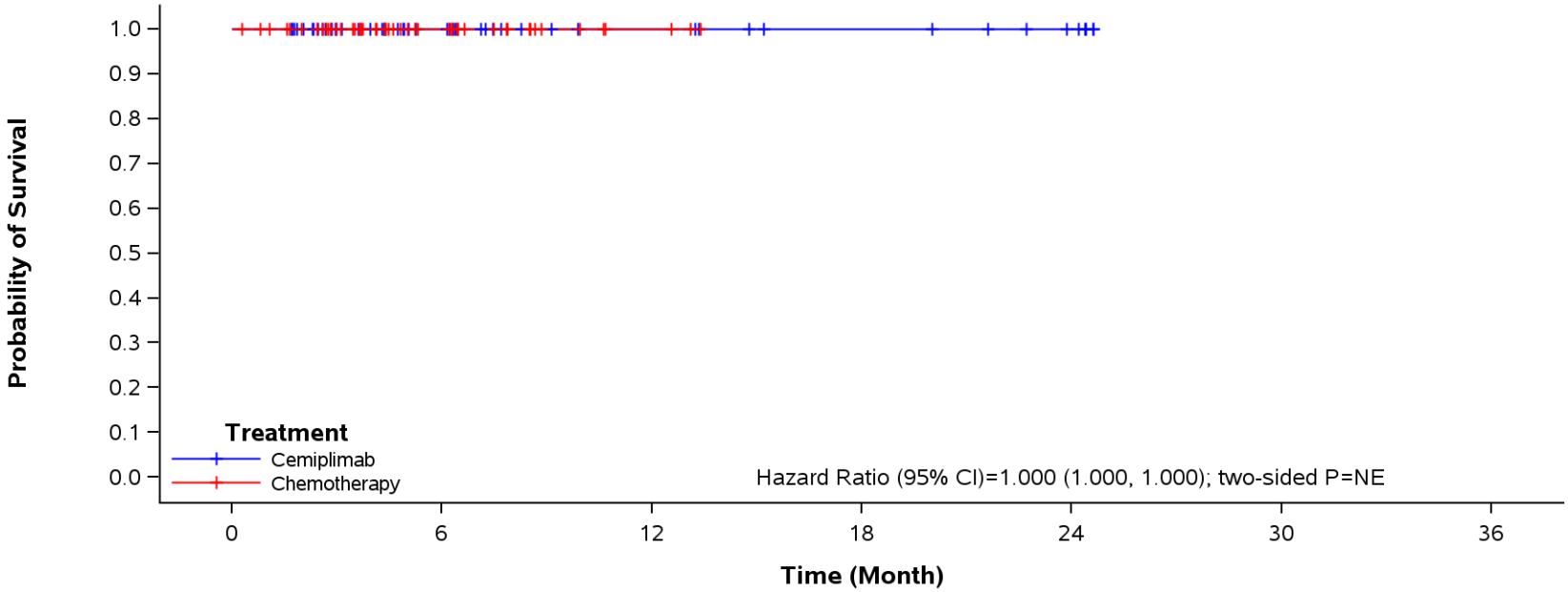

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Cardiac disorders
PT: Autoimmune pericarditis



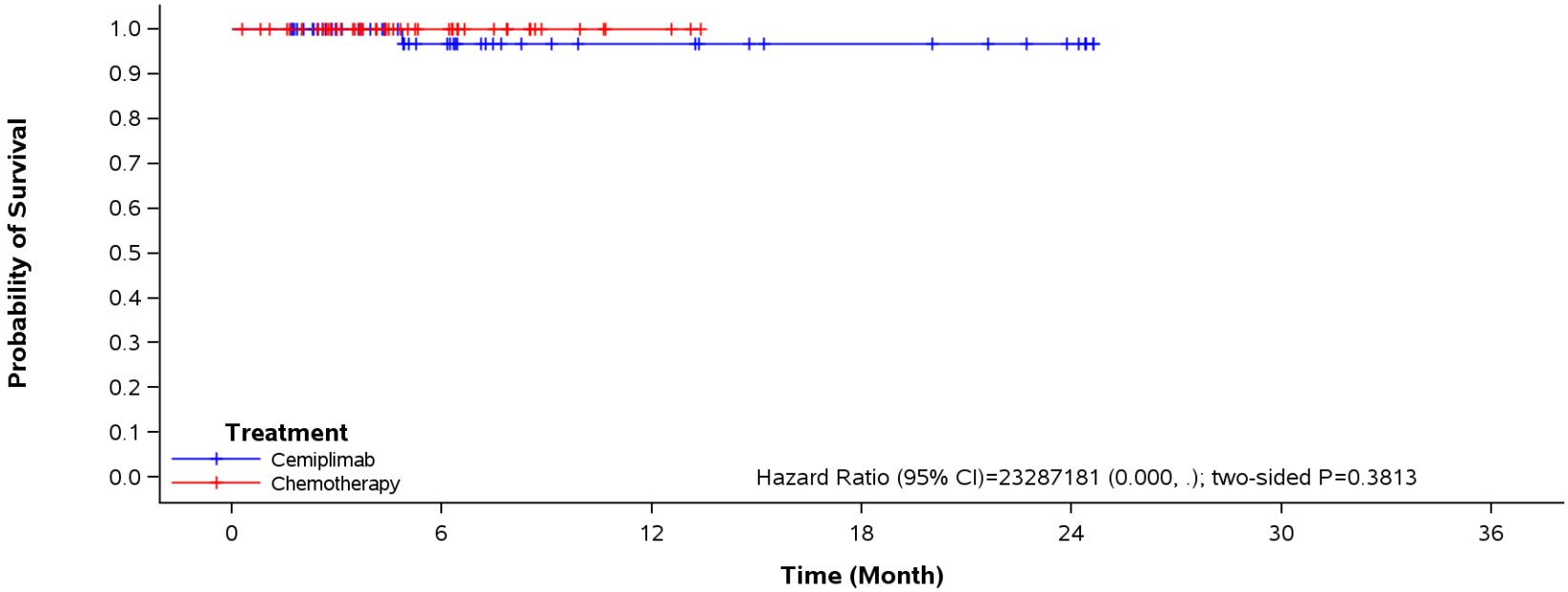

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Endocrine disorders



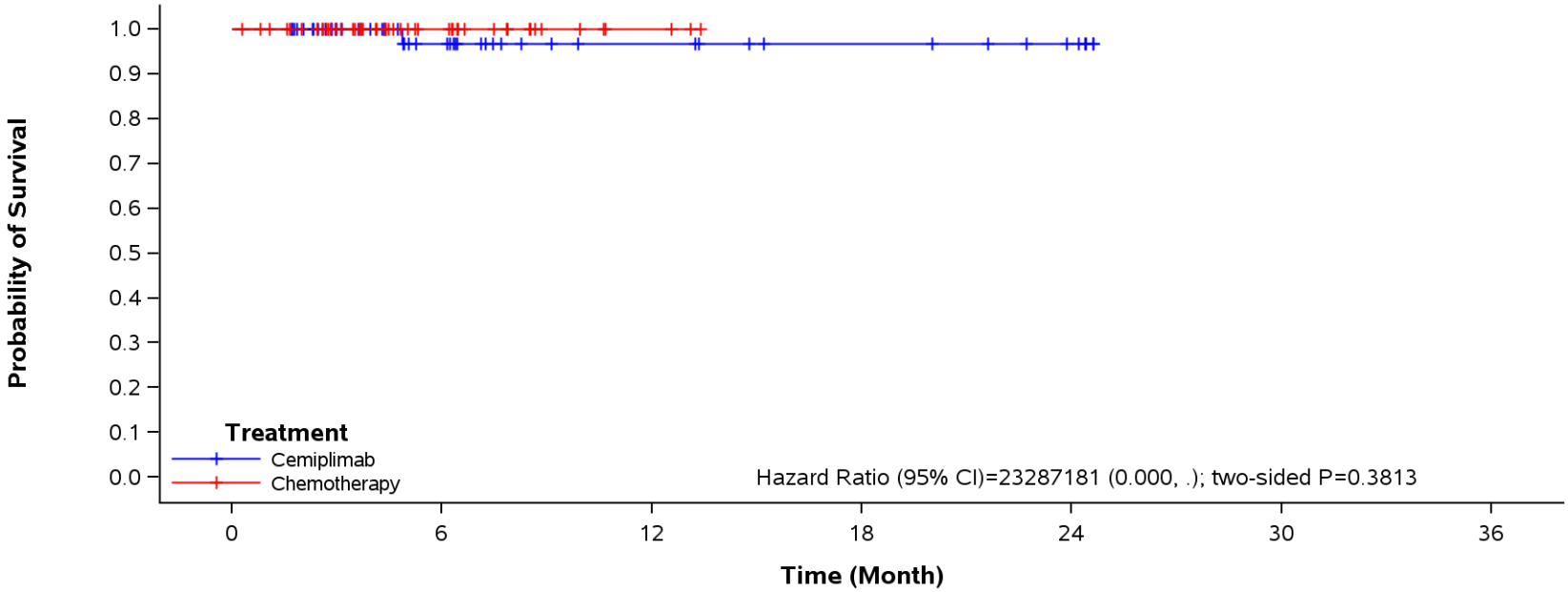

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Endocrine disorders
PT: Hypothyroidism



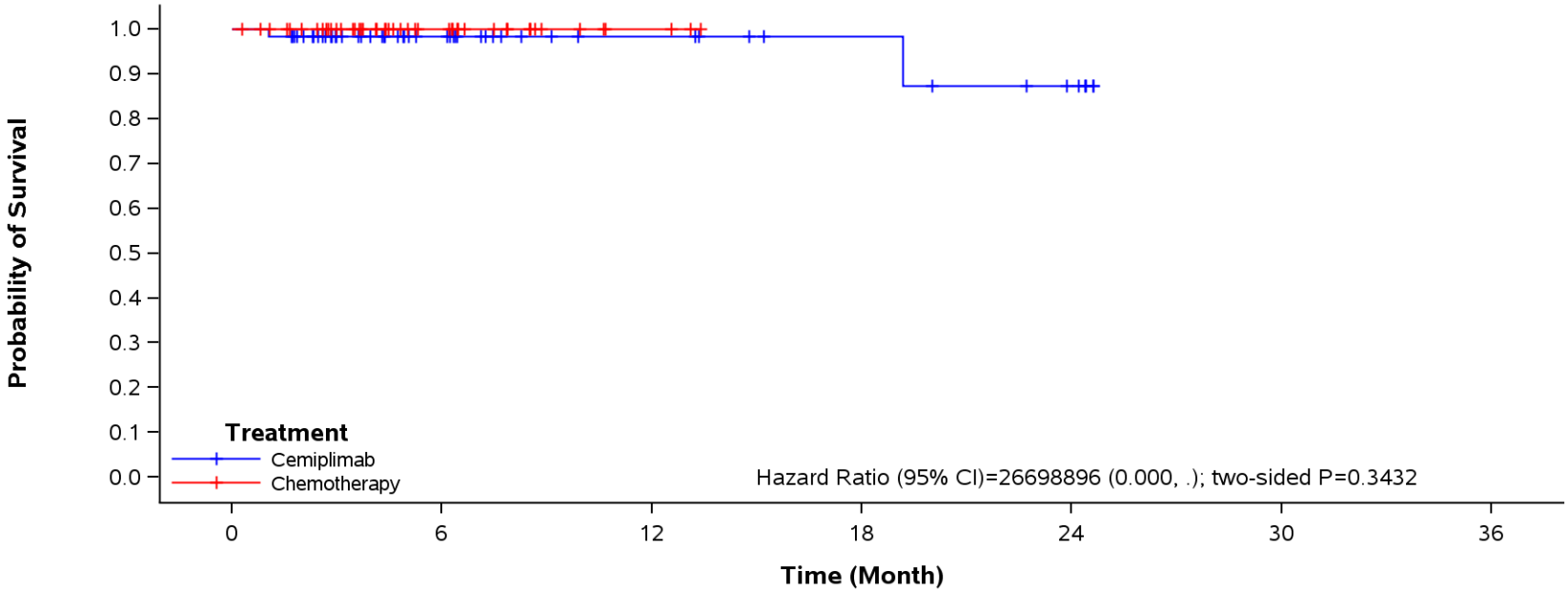

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders



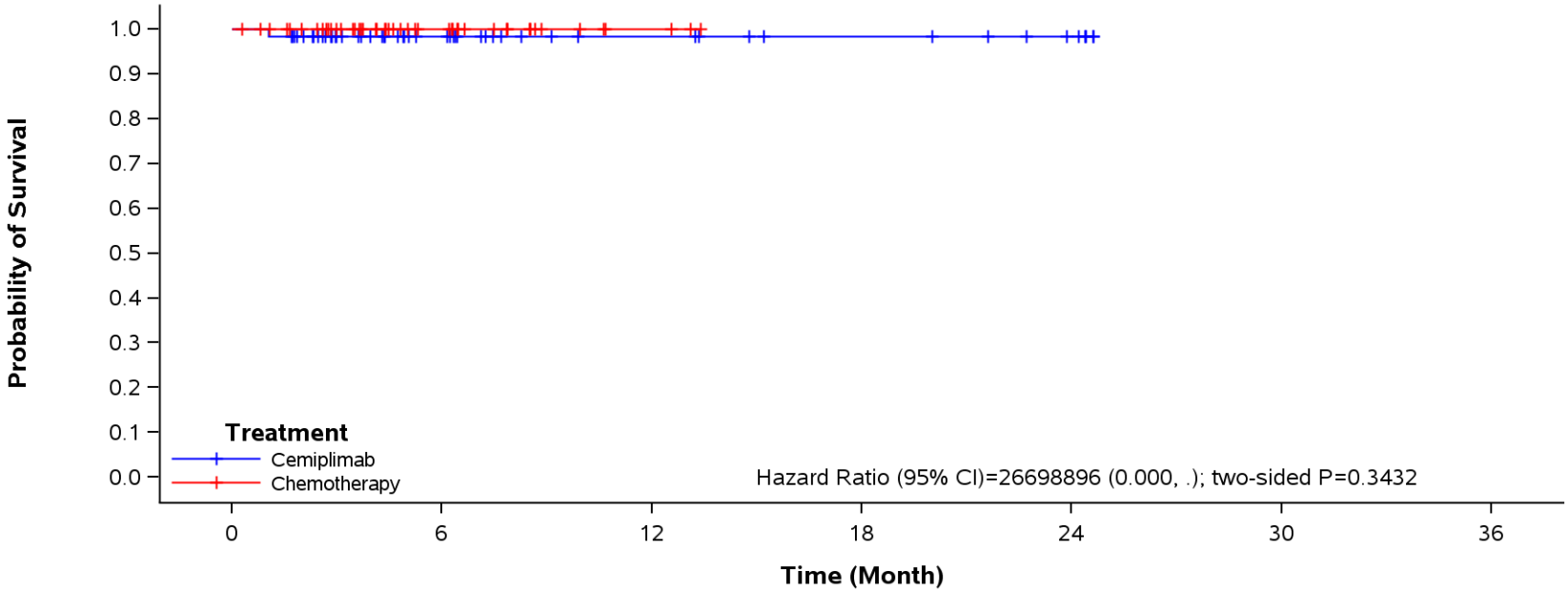

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders
PT: Colitis



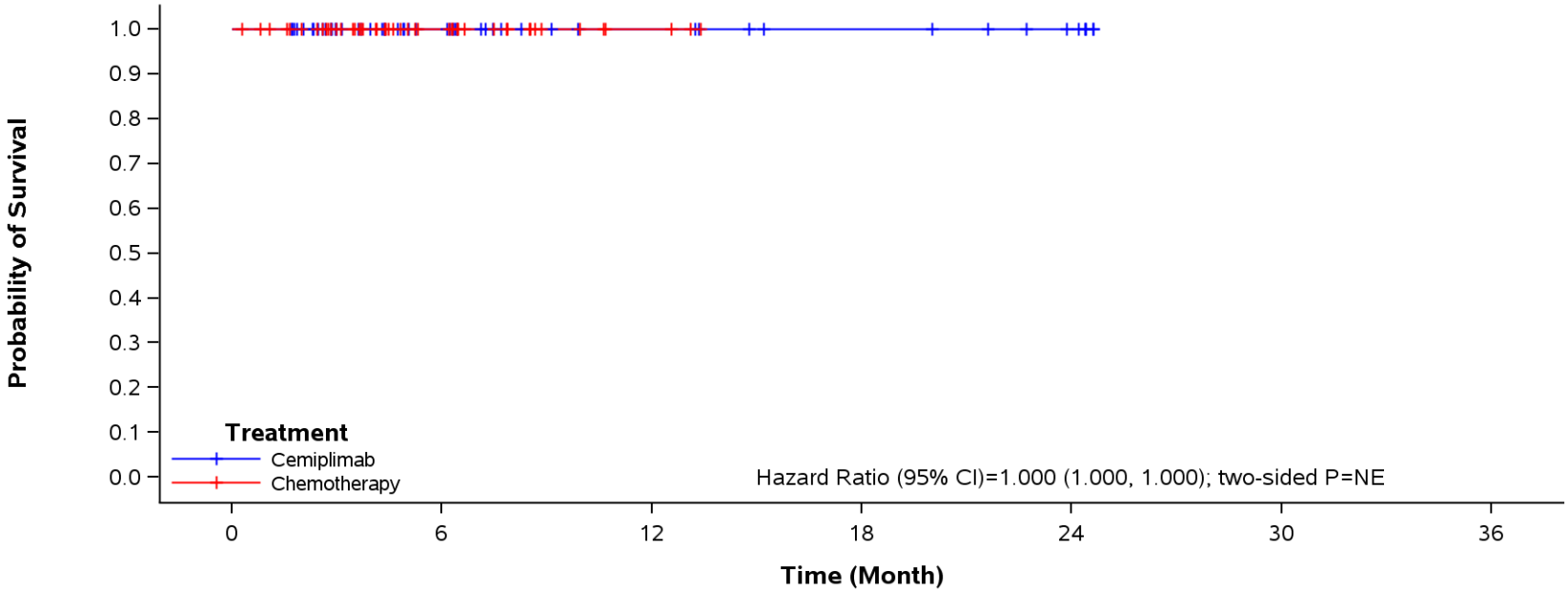

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders
PT: Diverticular perforation



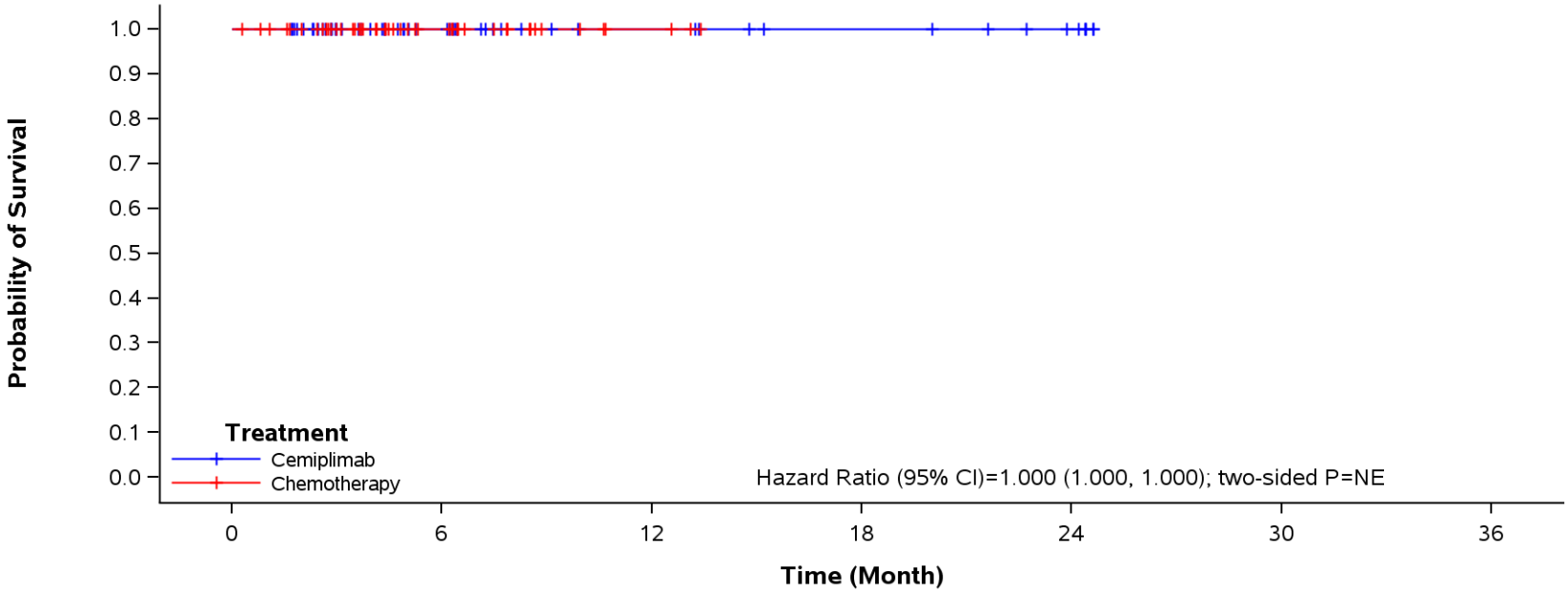

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders
PT: Pancreatic mass



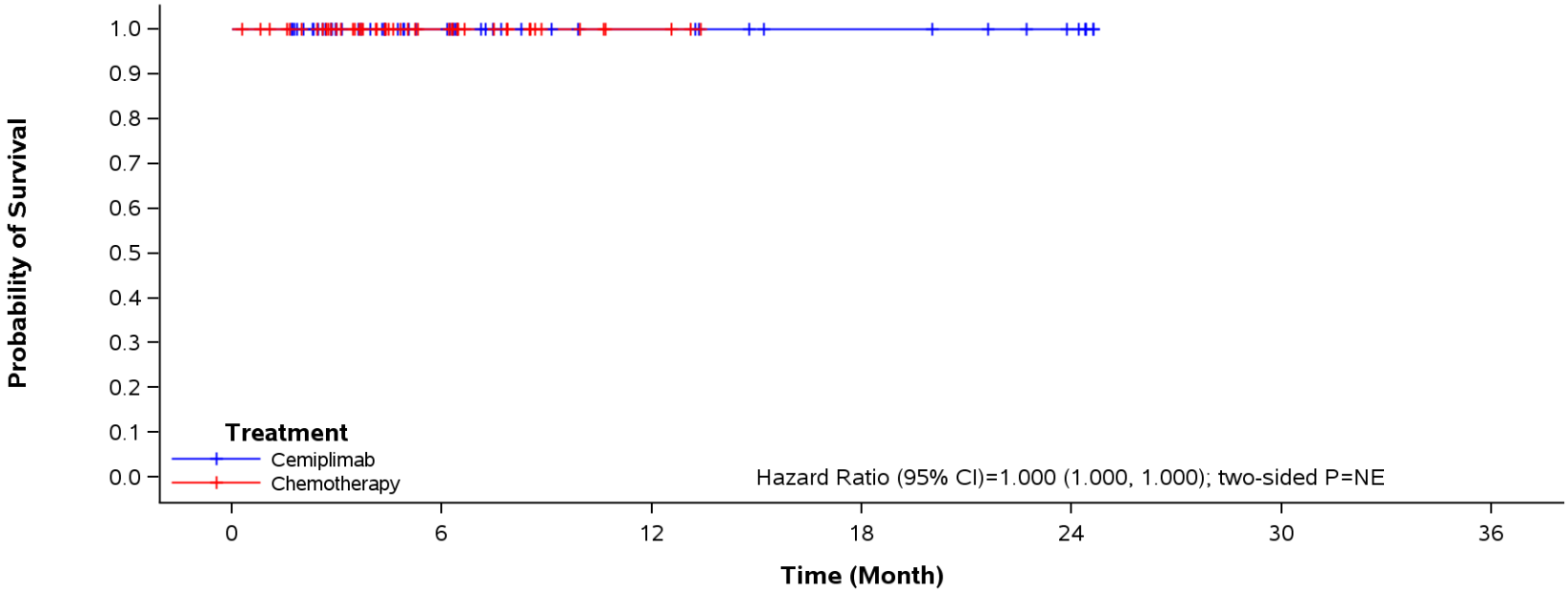

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



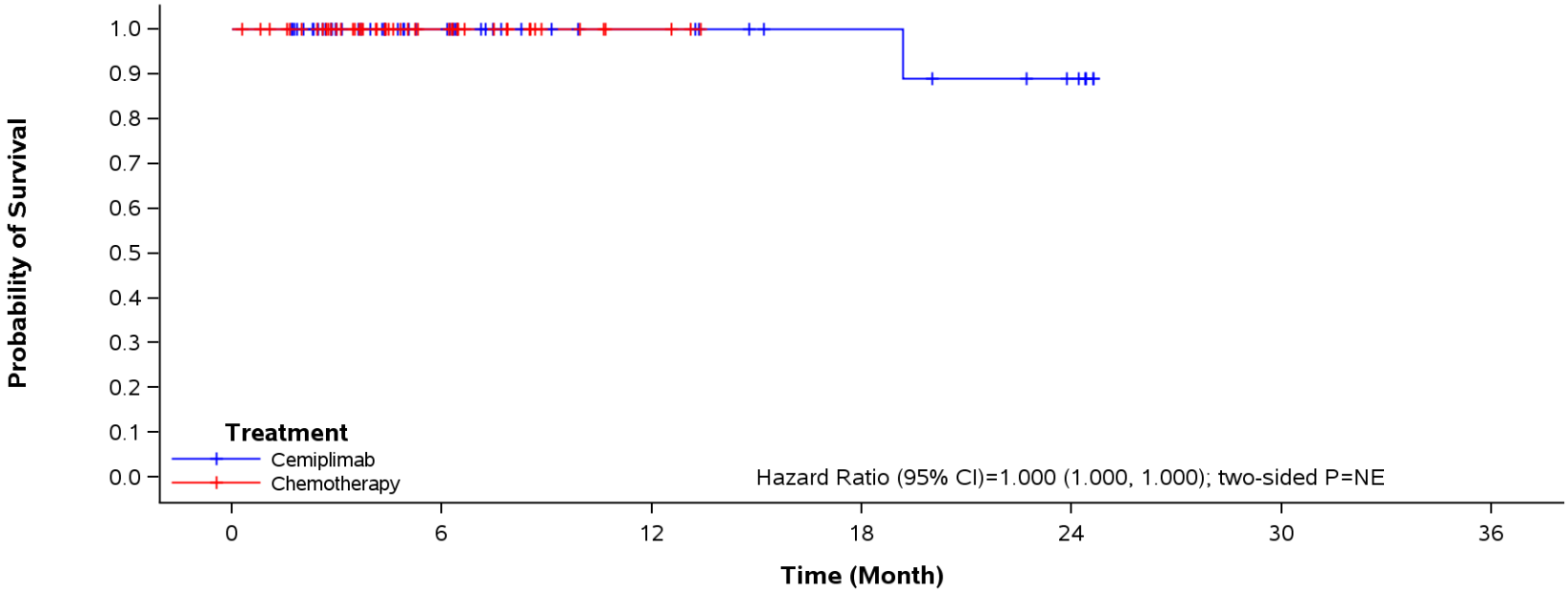

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Gastrointestinal disorders
PT: Proctalgia



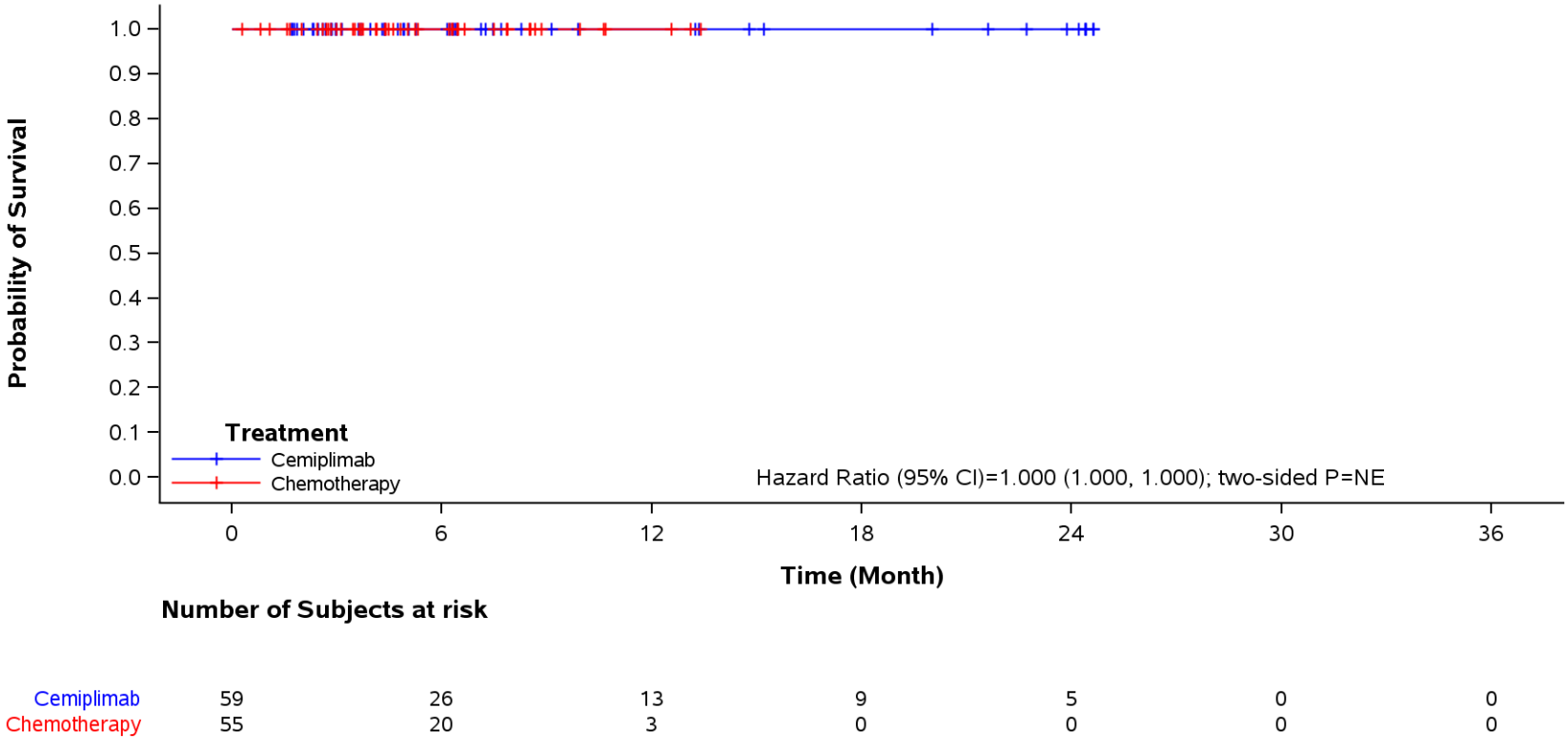

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

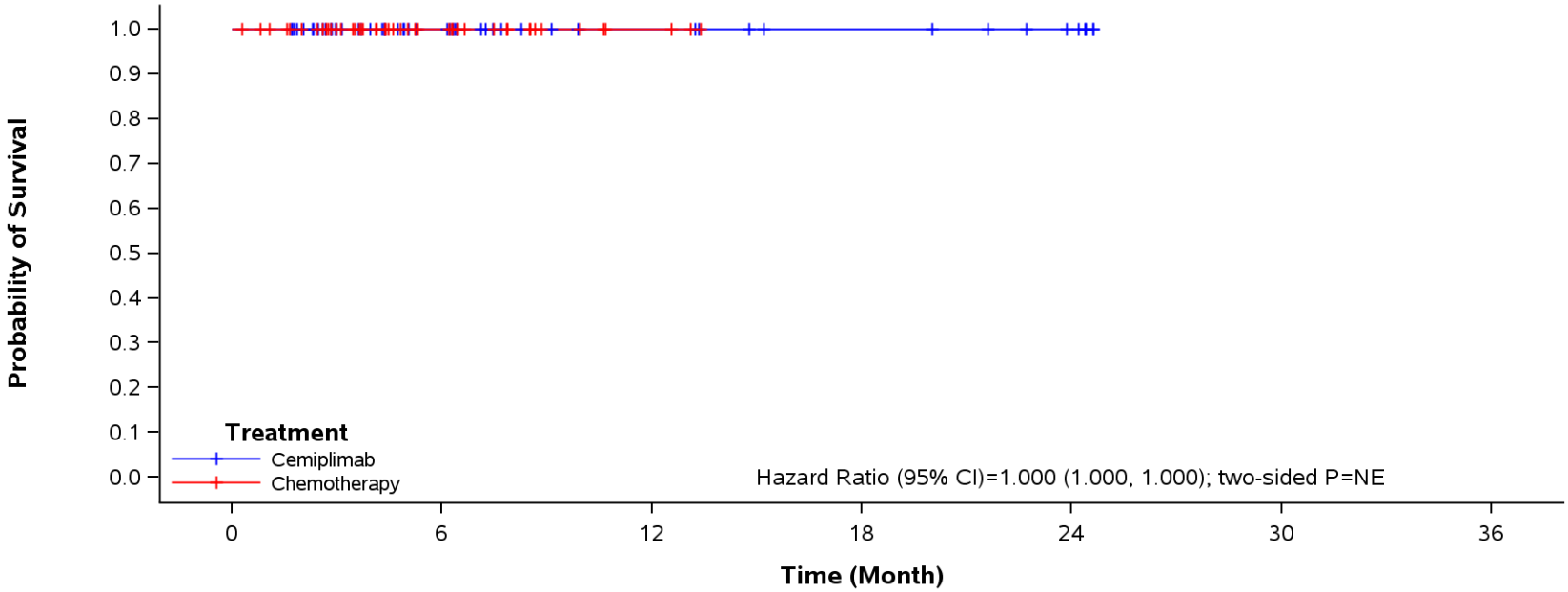
Geographic region: ROW
SOC: General disorders and administration site conditions




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: General disorders and administration site conditions
PT: Malaise



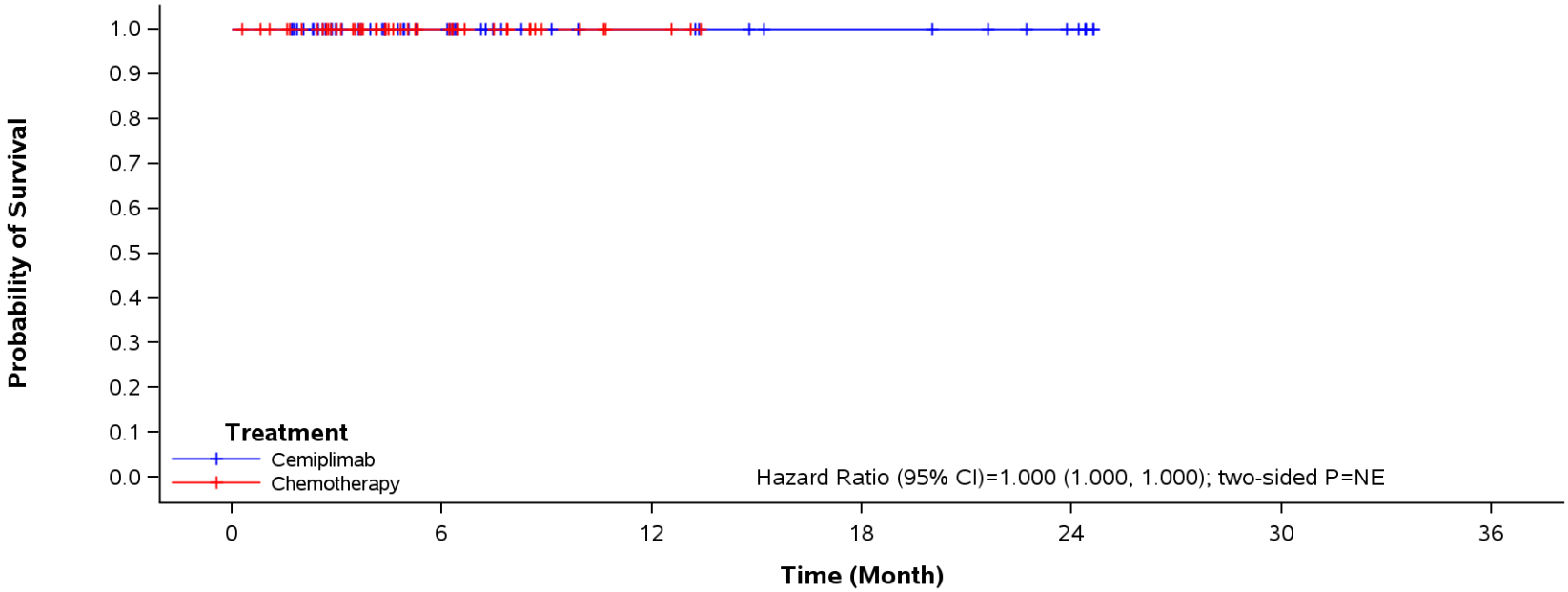

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



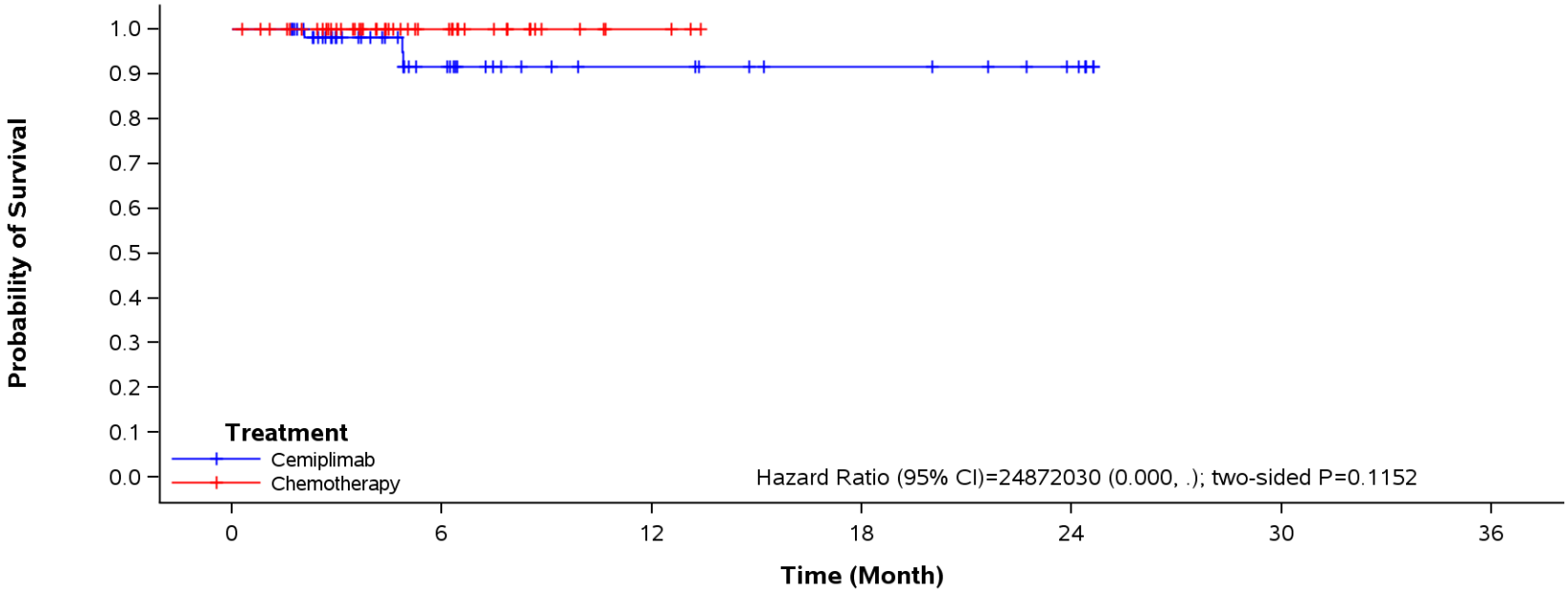

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Hepatobiliary disorders



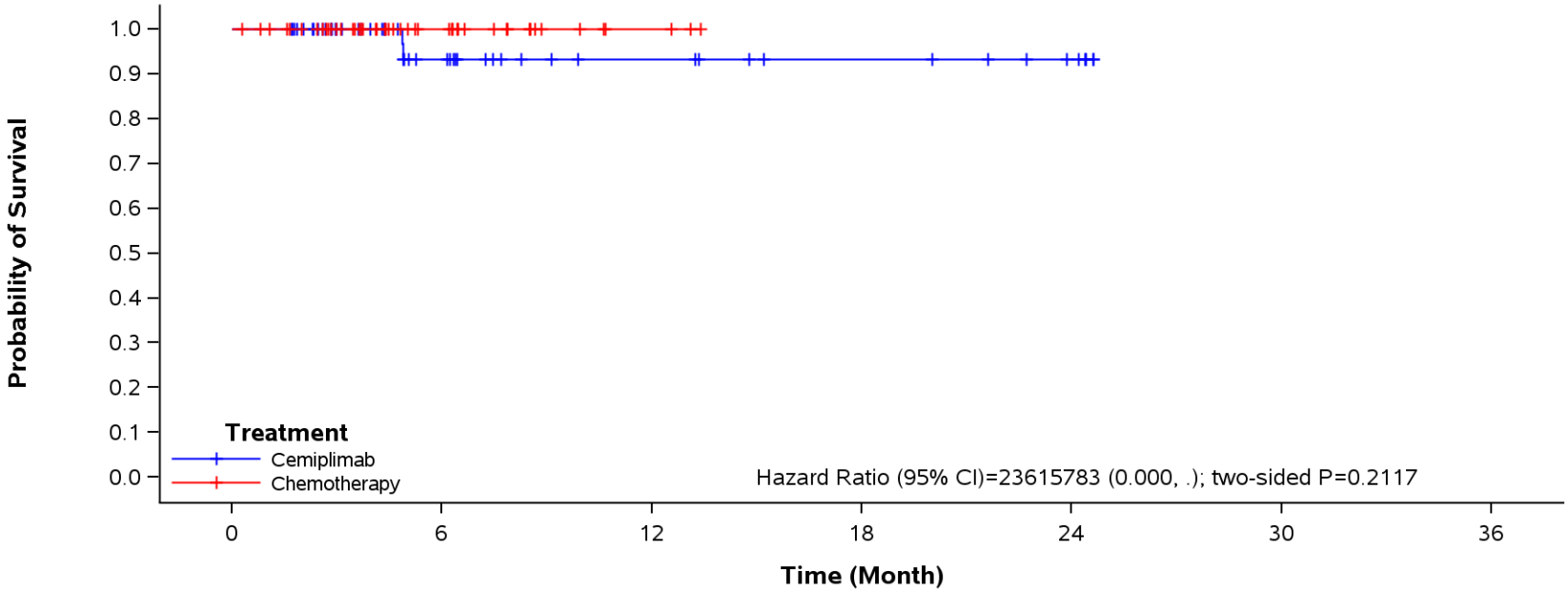

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 24 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



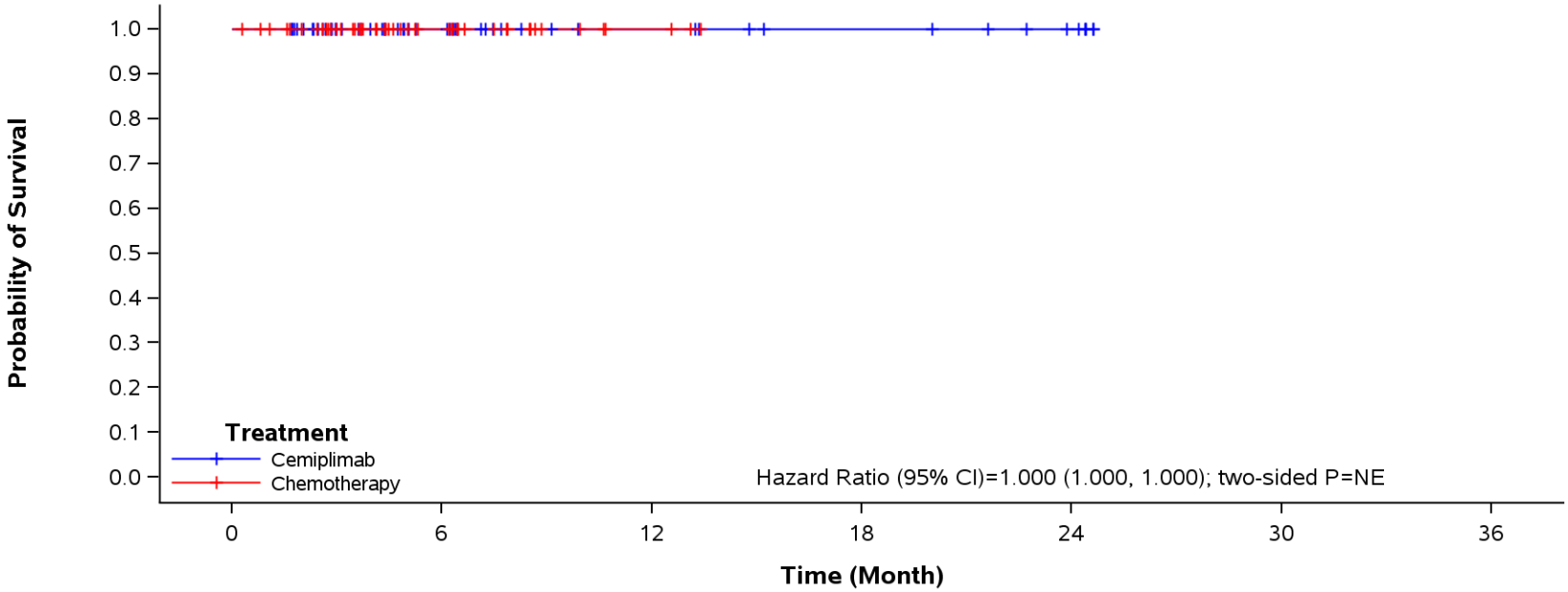

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 24 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



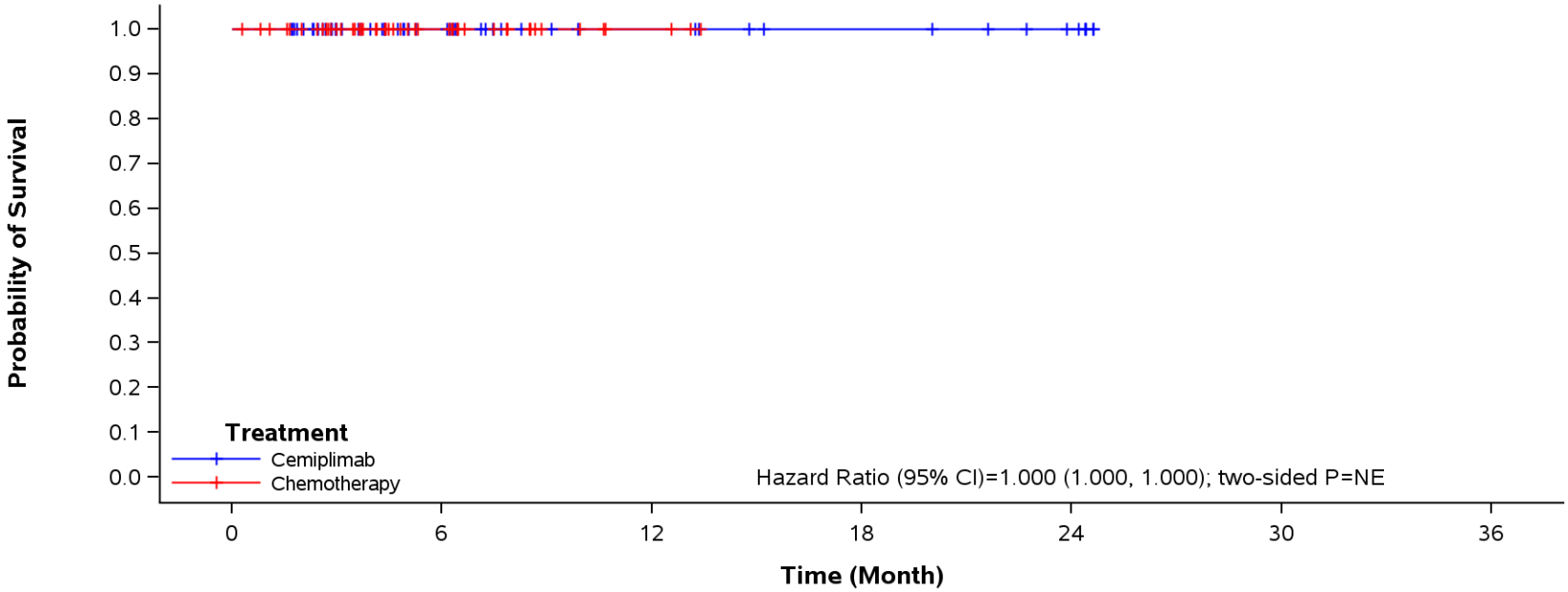

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Hepatobiliary disorders
PT: Hepatitis



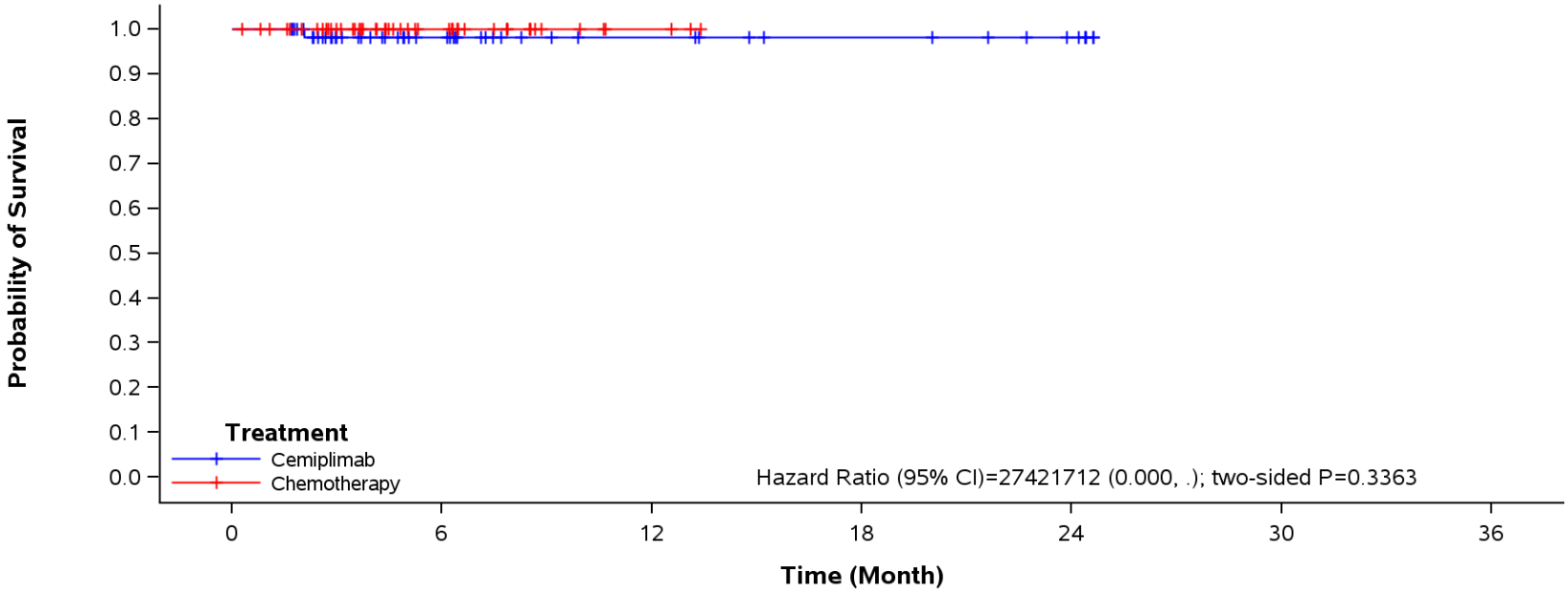

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



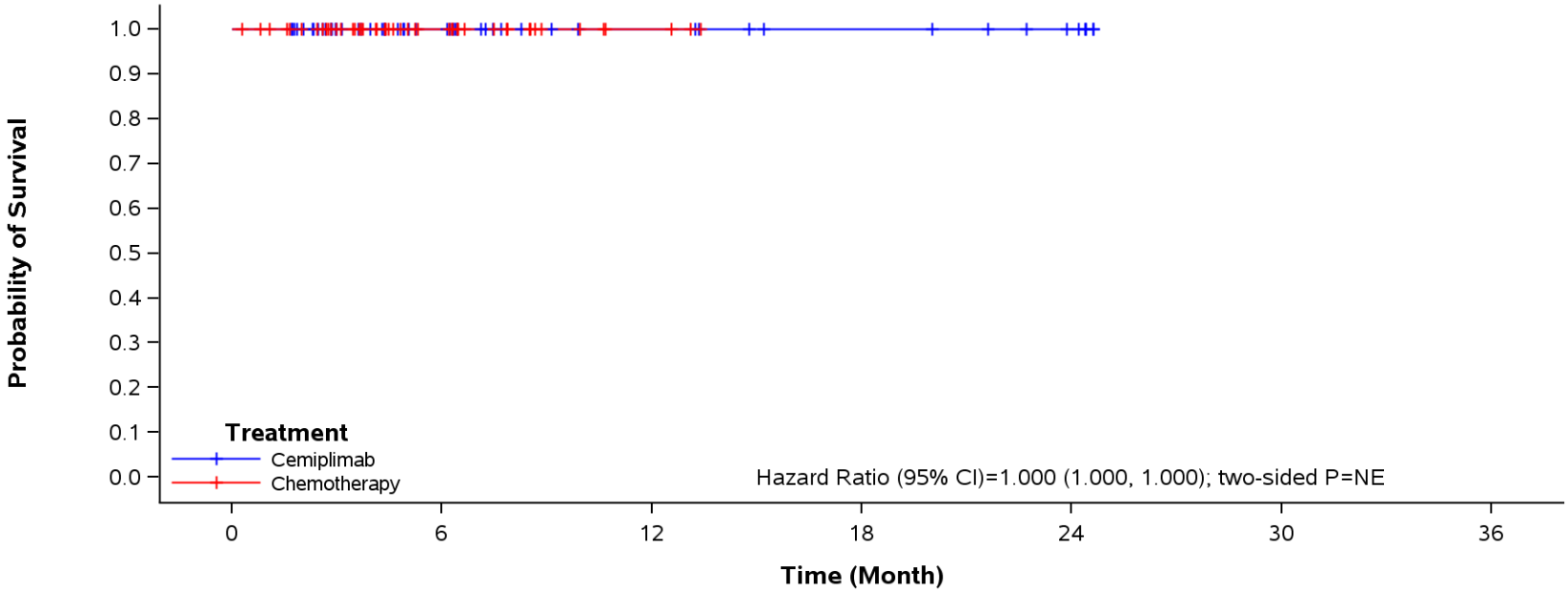

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Infections and infestations



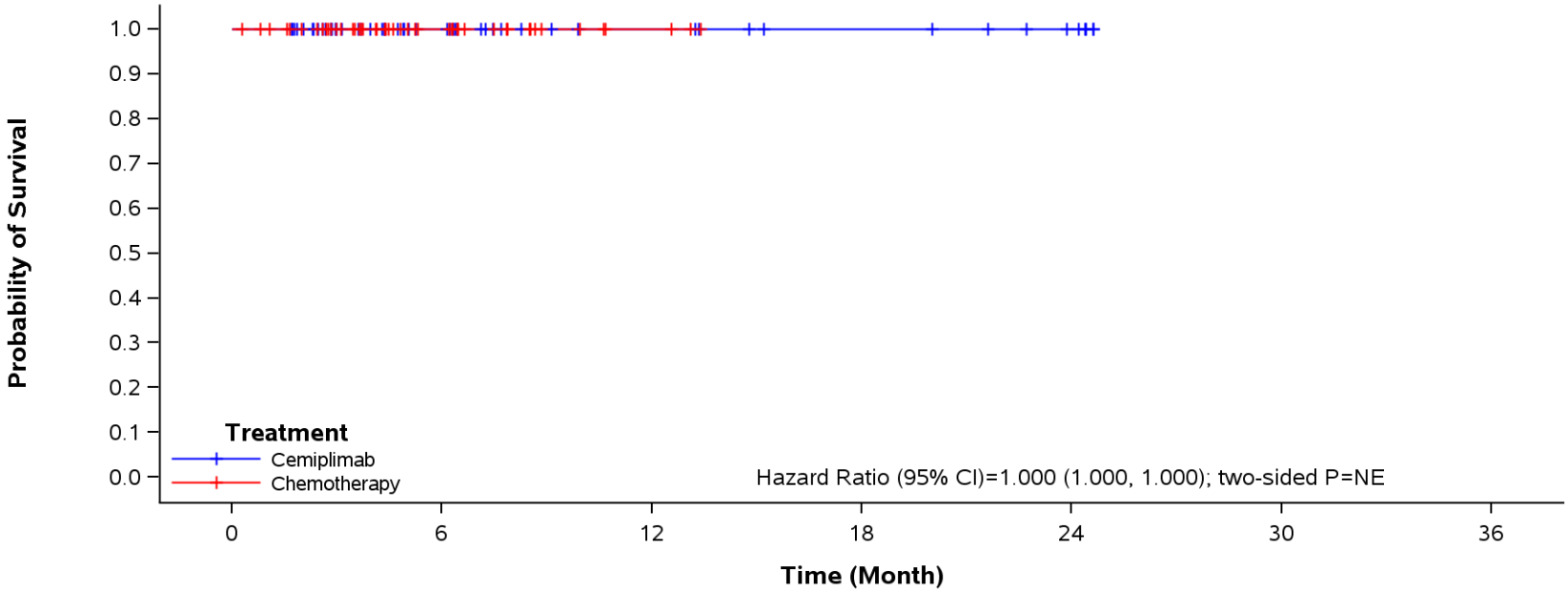

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Infections and infestations
PT: COVID-19 pneumonia



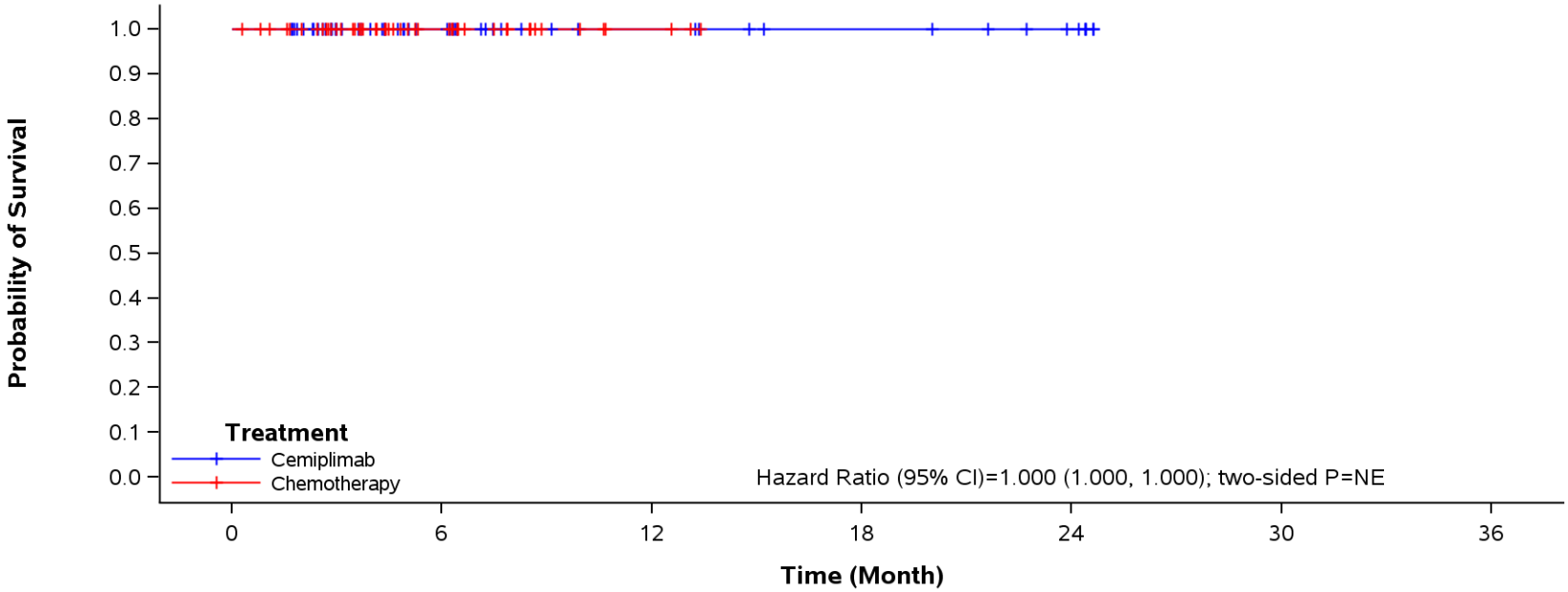

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Infections and infestations
PT: Gastroenteritis



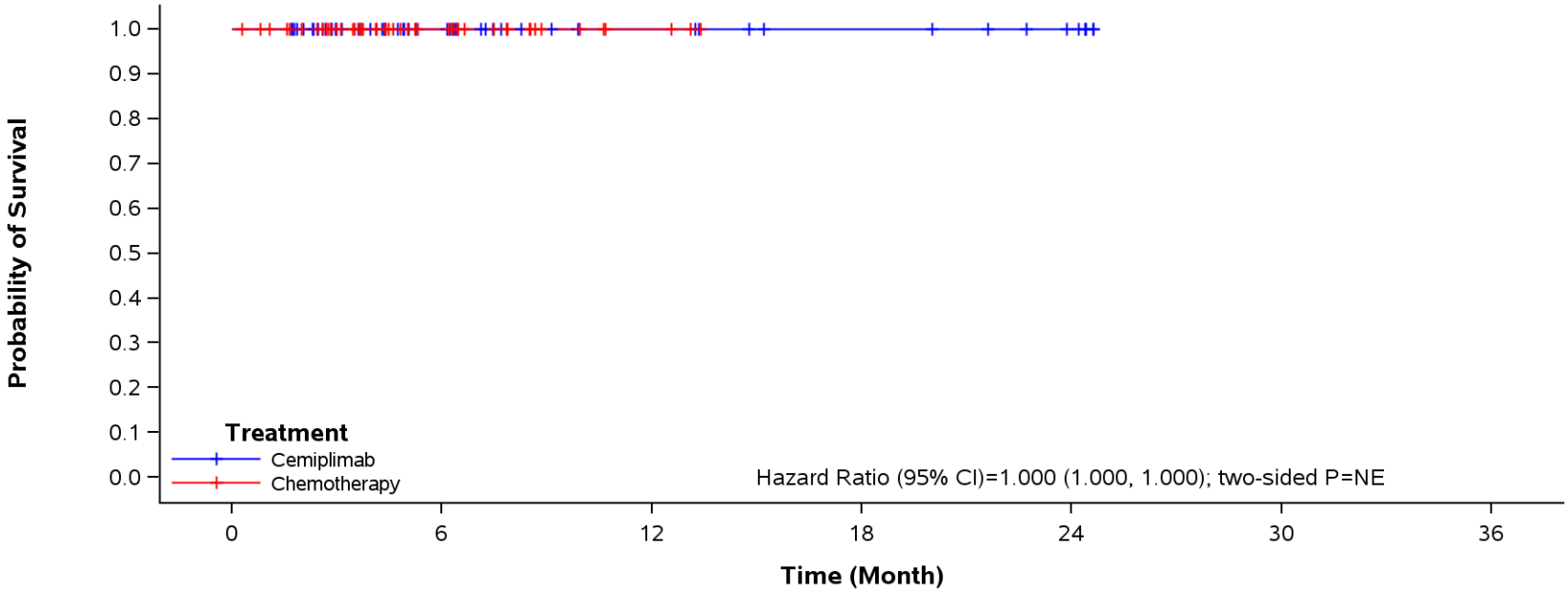

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Infections and infestations
PT: Pelvic abscess



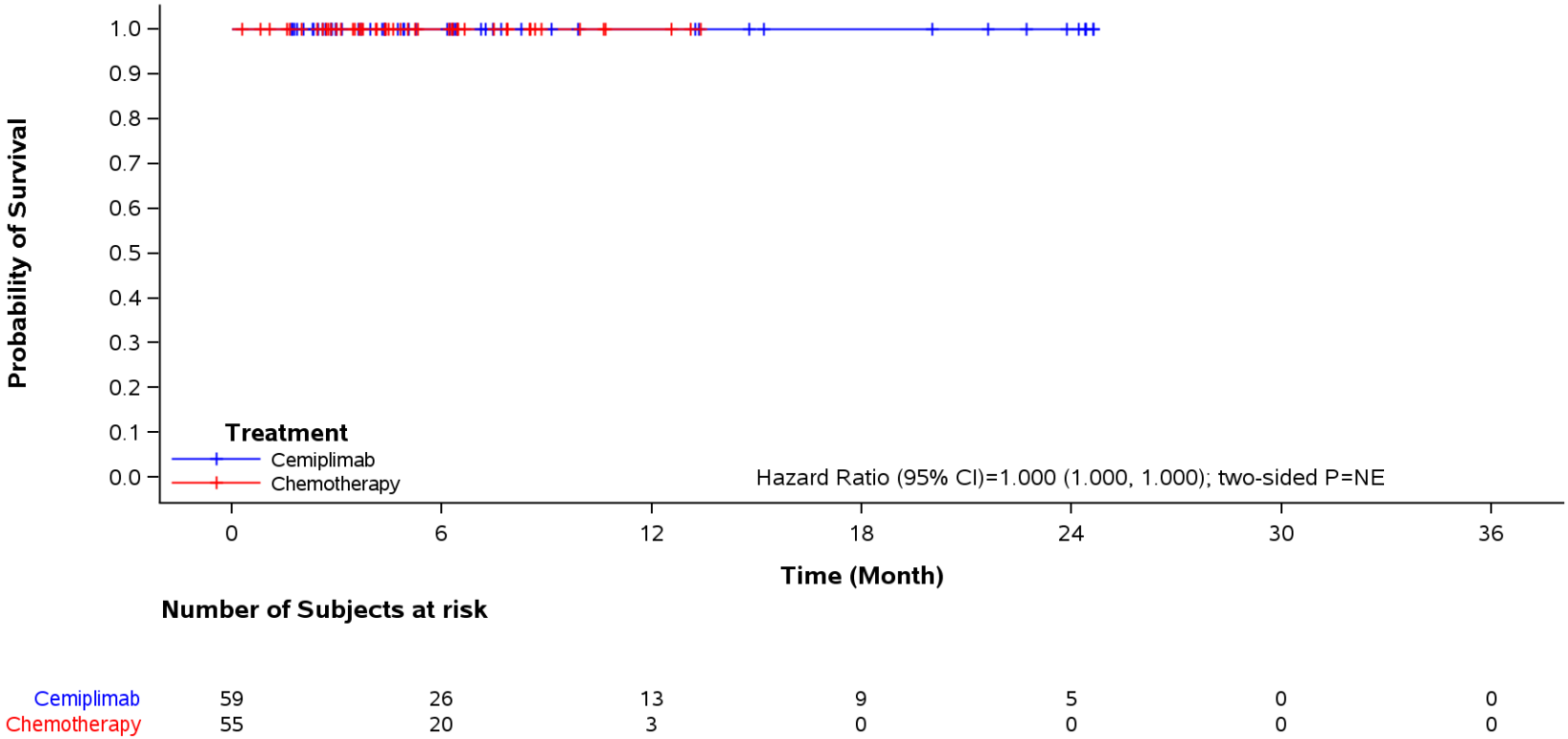

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

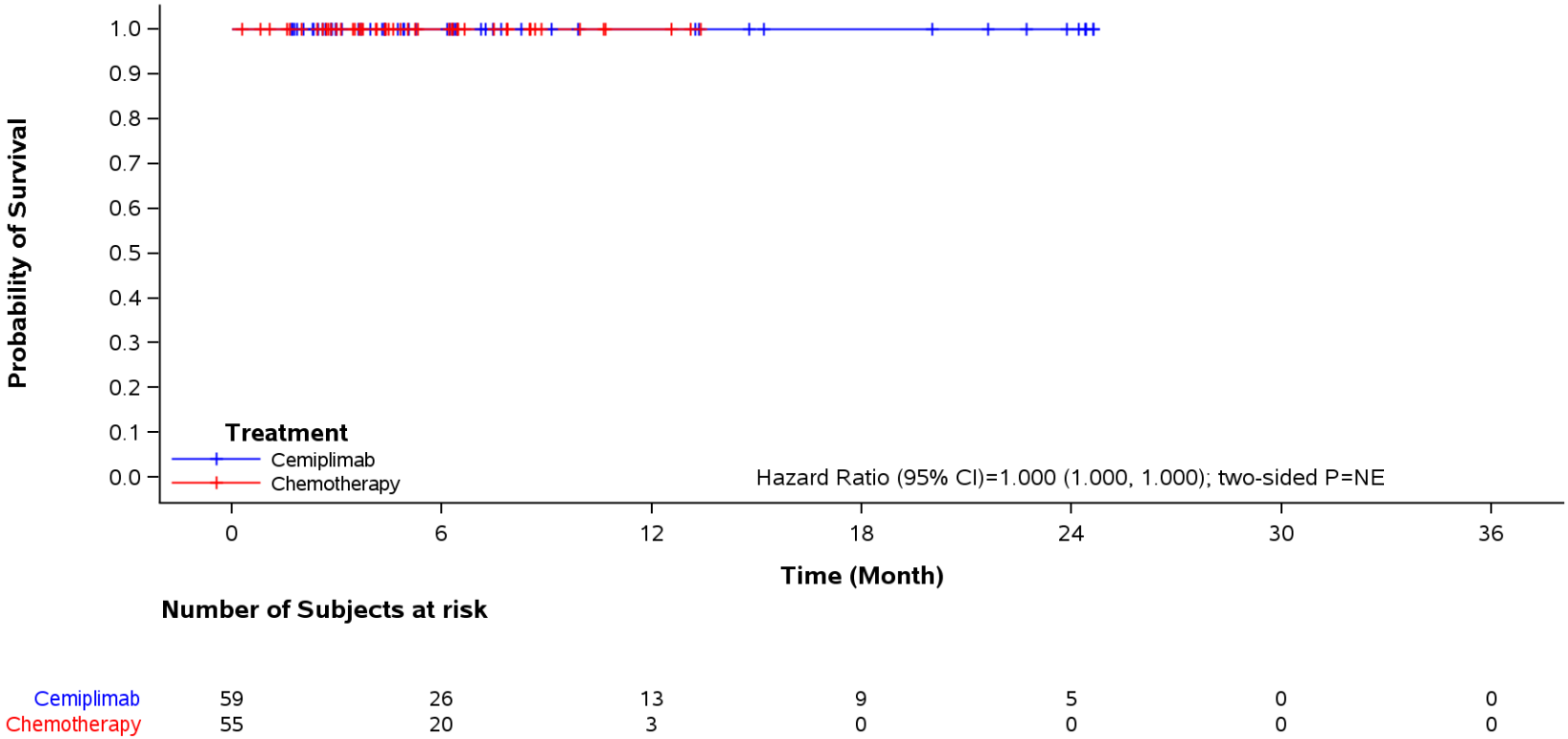
Geographic region: ROW
SOC: Infections and infestations
PT: Peritonitis




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

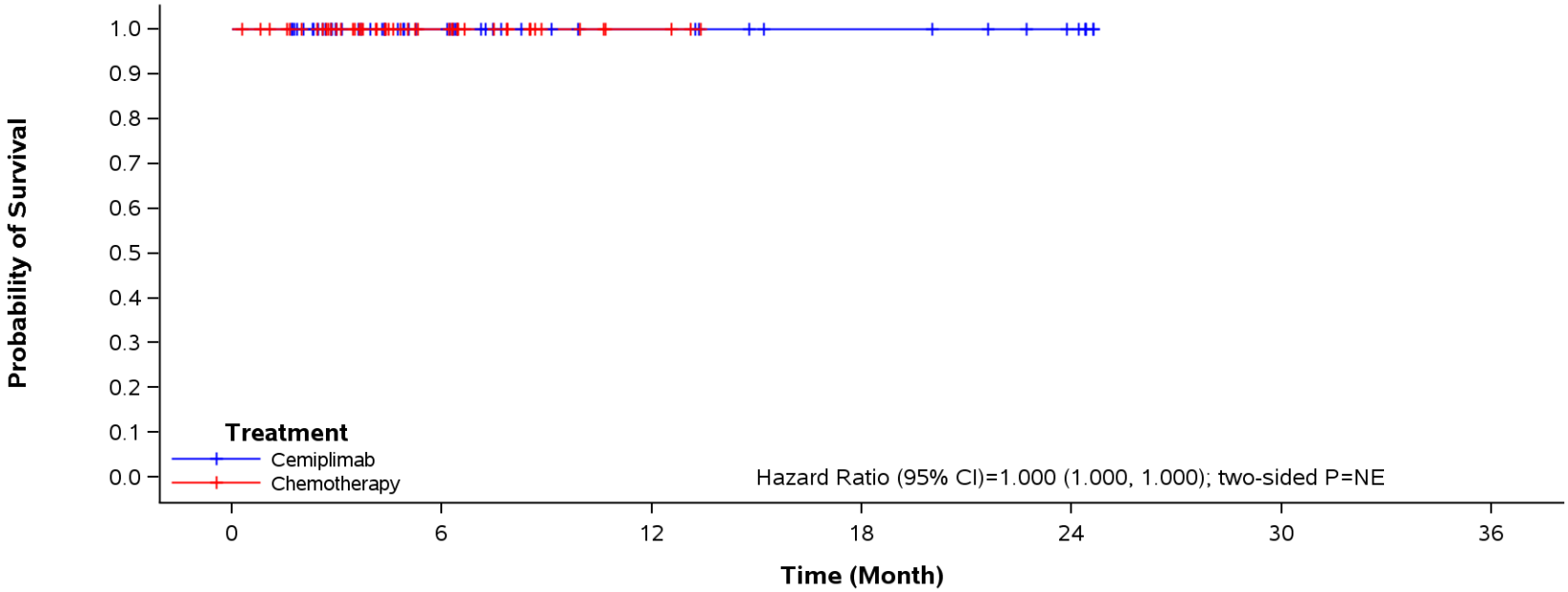
Geographic region: ROW
SOC: Infections and infestations
PT: Pneumonia




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Infections and infestations
PT: Pyomyositis



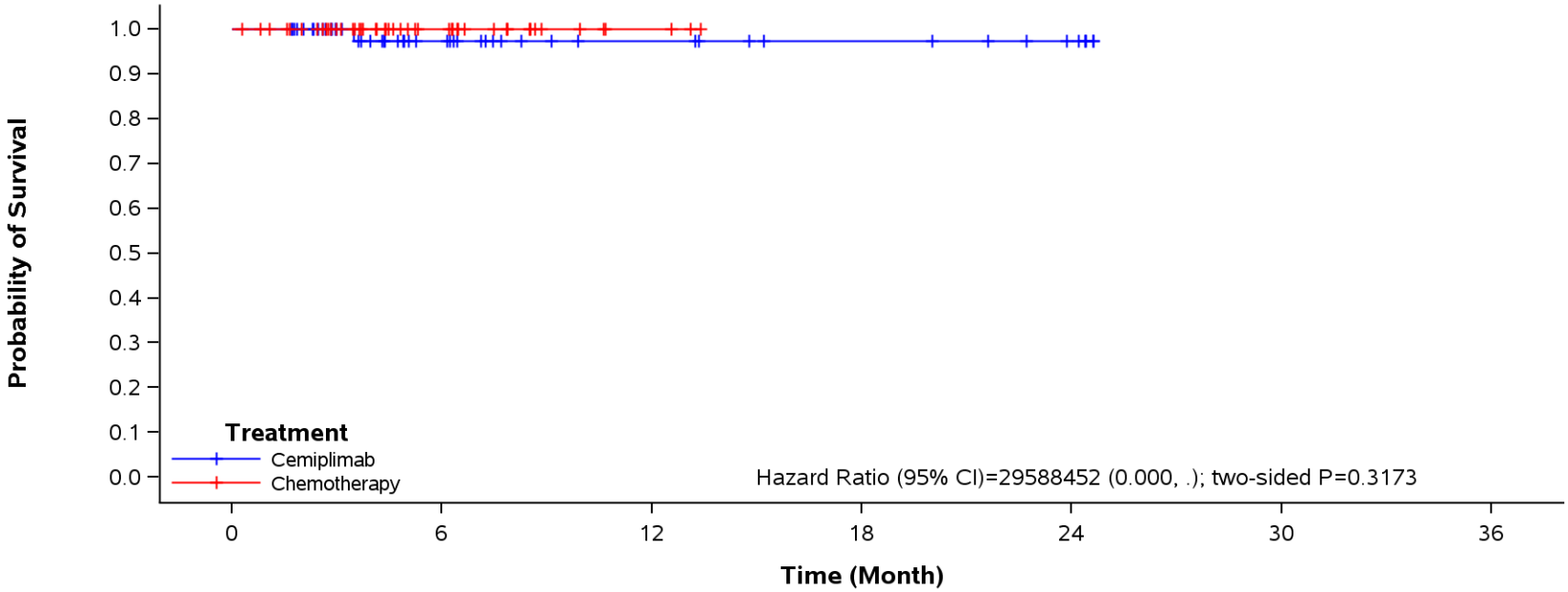

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Injury, poisoning and procedural complications



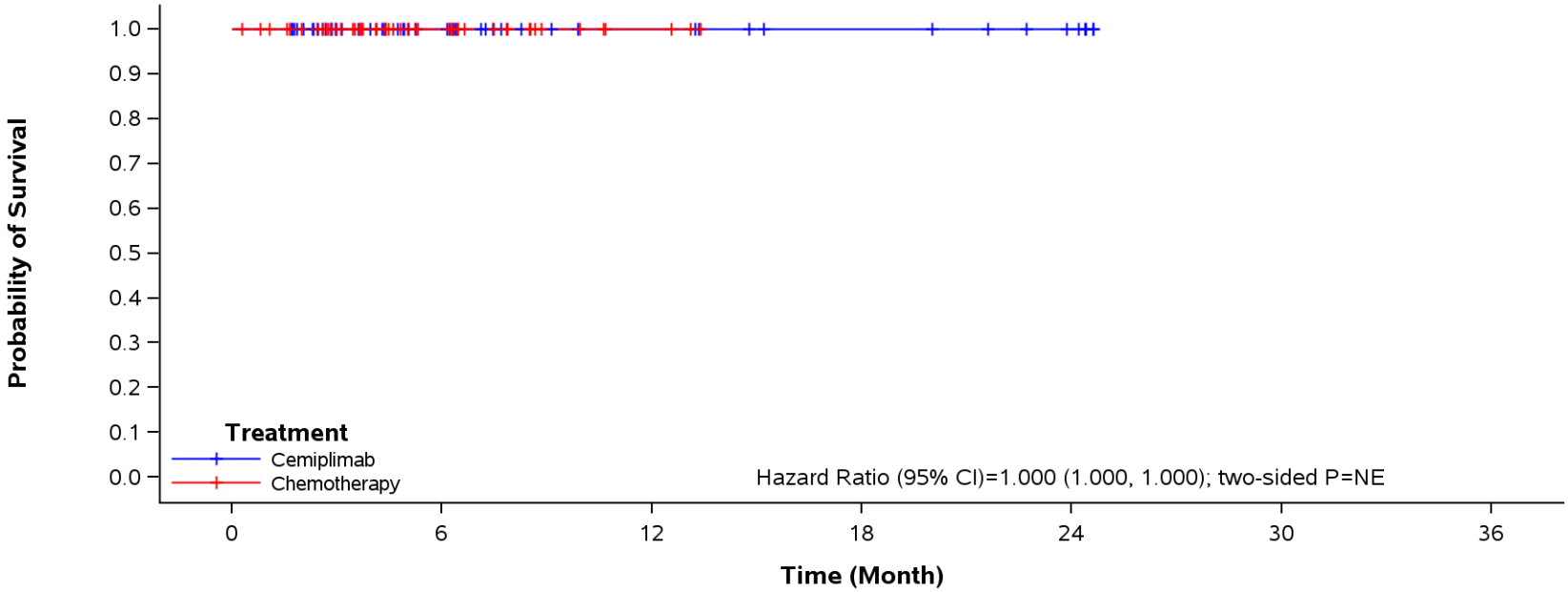

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



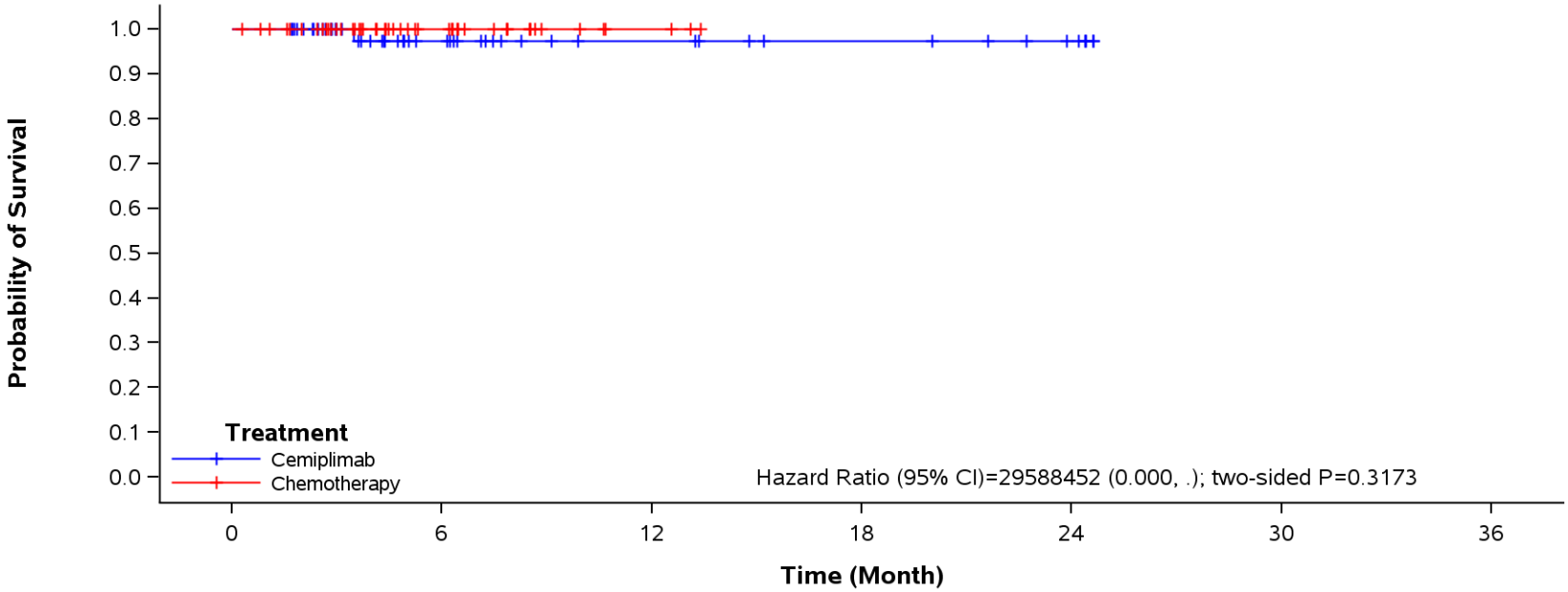

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



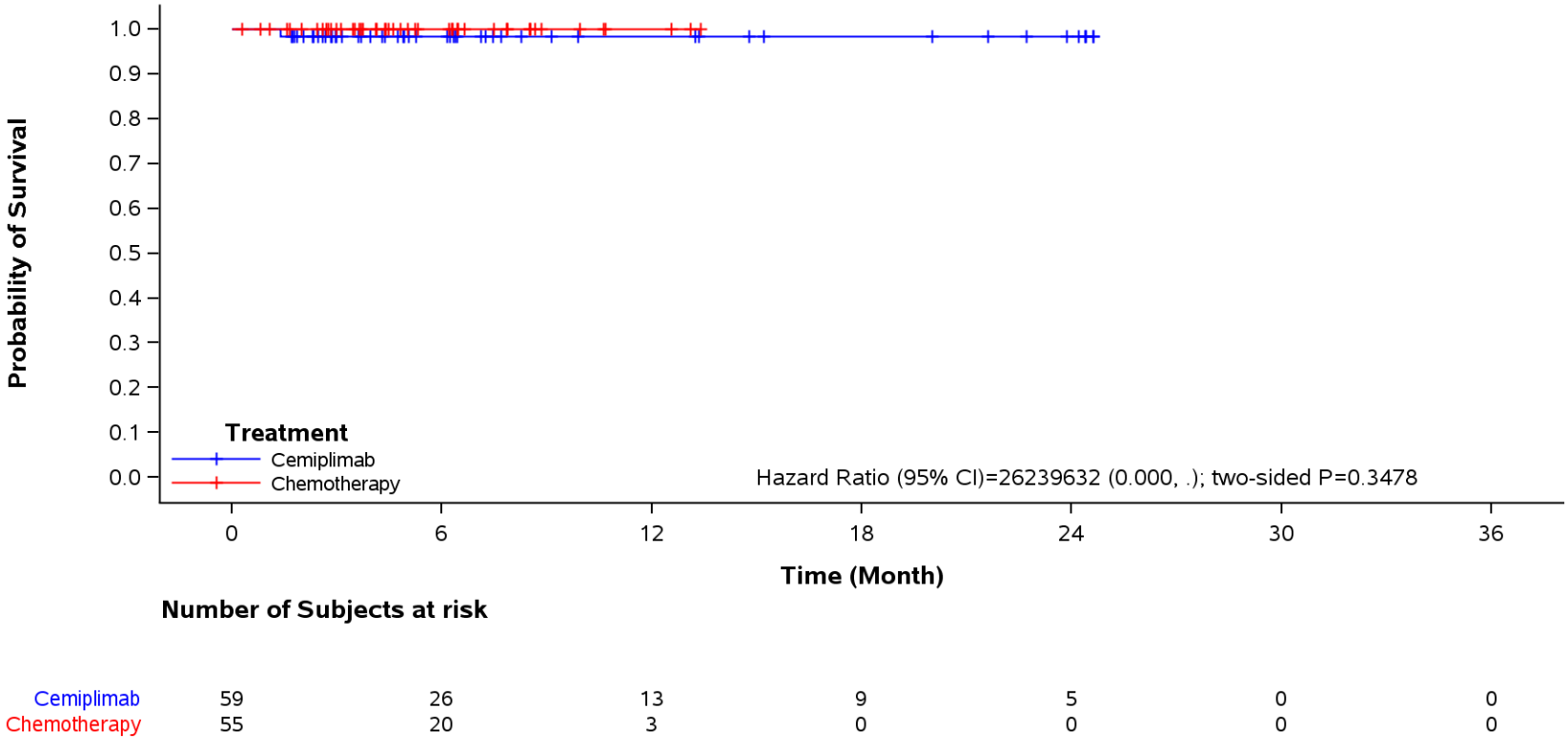

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 25 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

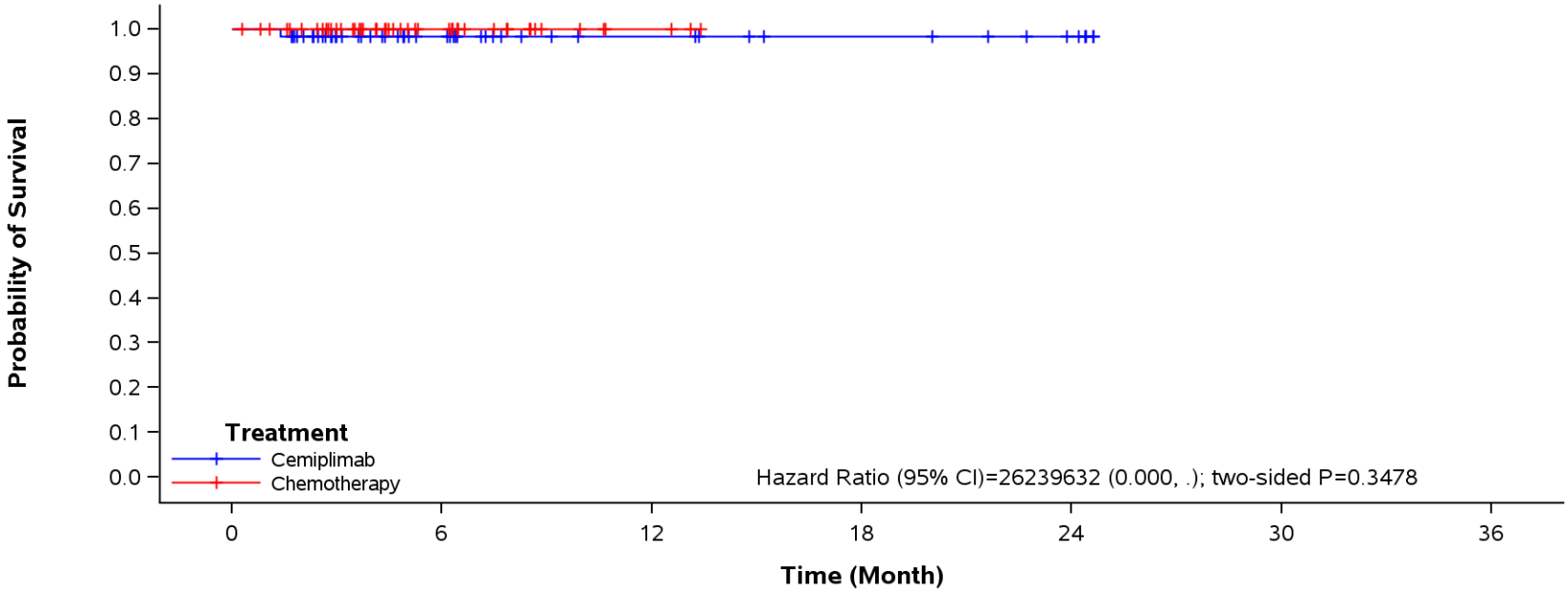
Geographic region: ROW
SOC: Investigations




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Investigations
PT: Alanine aminotransferase increased



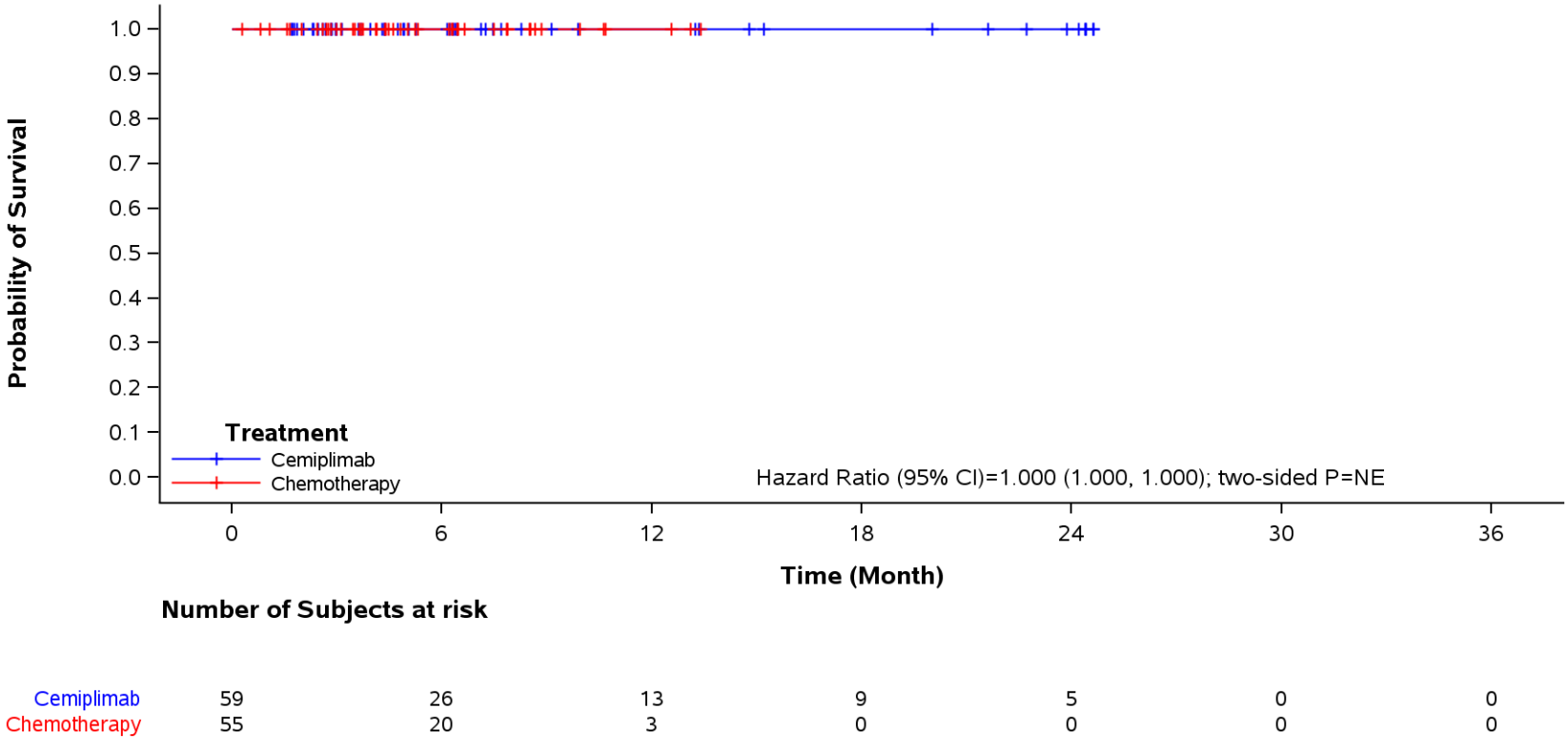

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

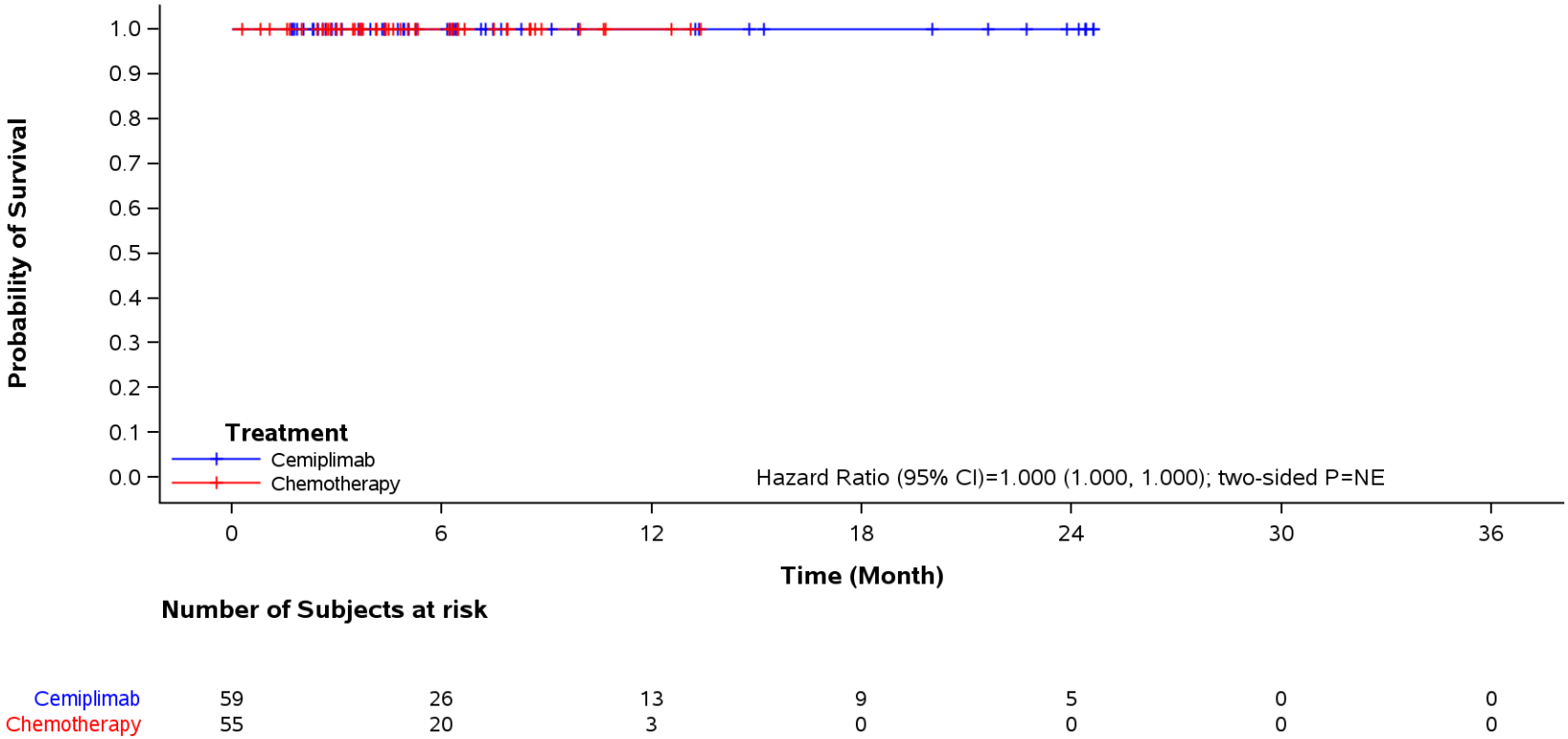
Geographic region: ROW
SOC: Investigations
PT: Amylase increased




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

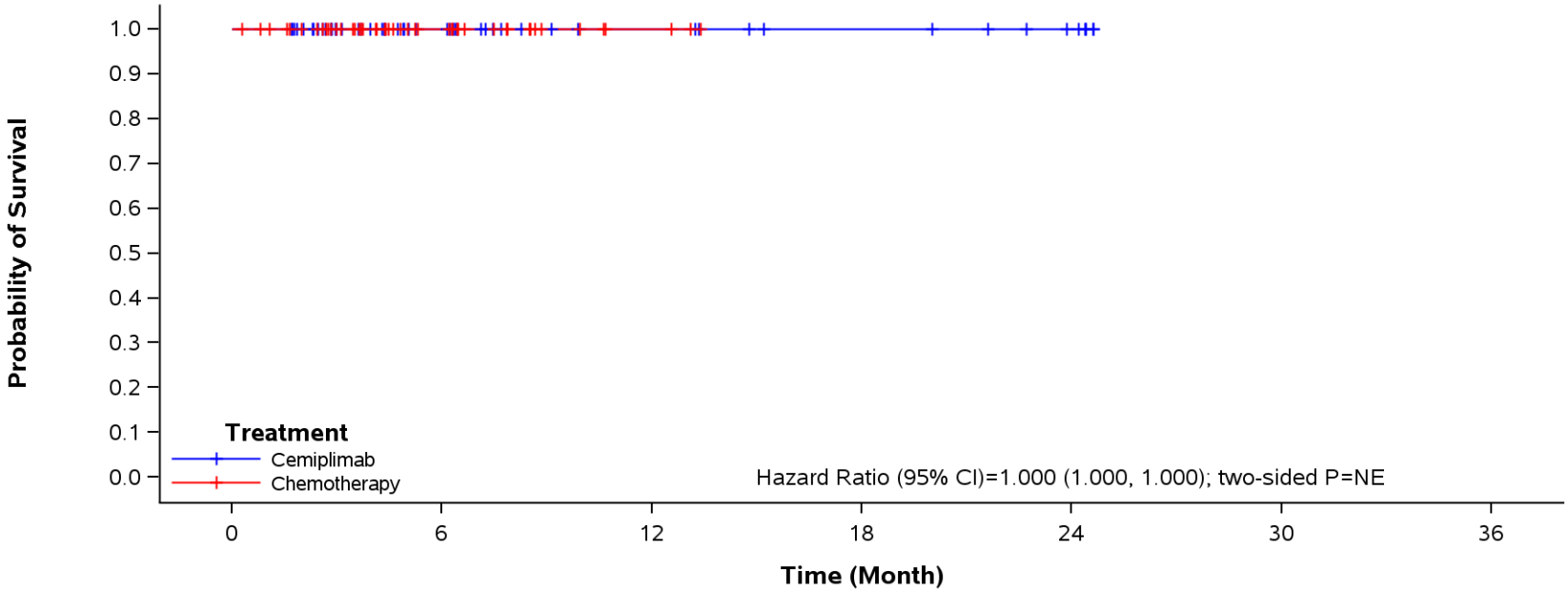
Geographic region: ROW
SOC: Investigations
PT: Platelet count decreased




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Metabolism and nutrition disorders



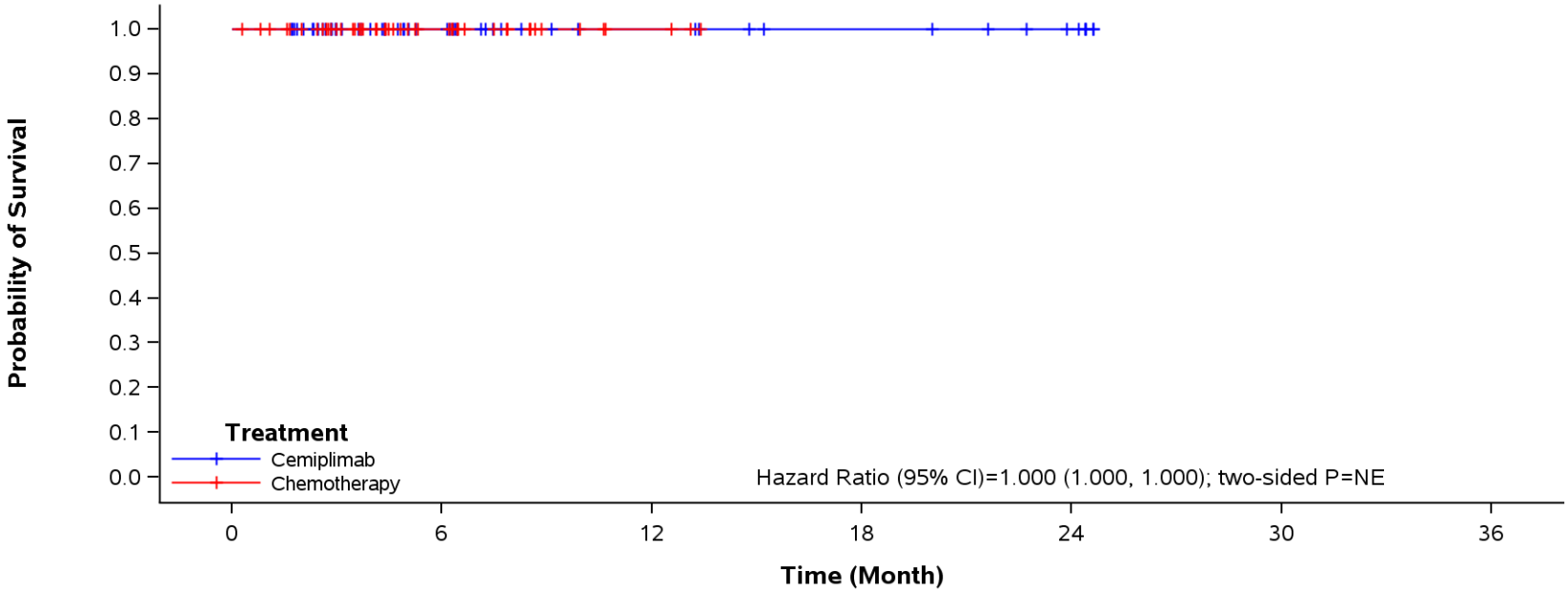

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



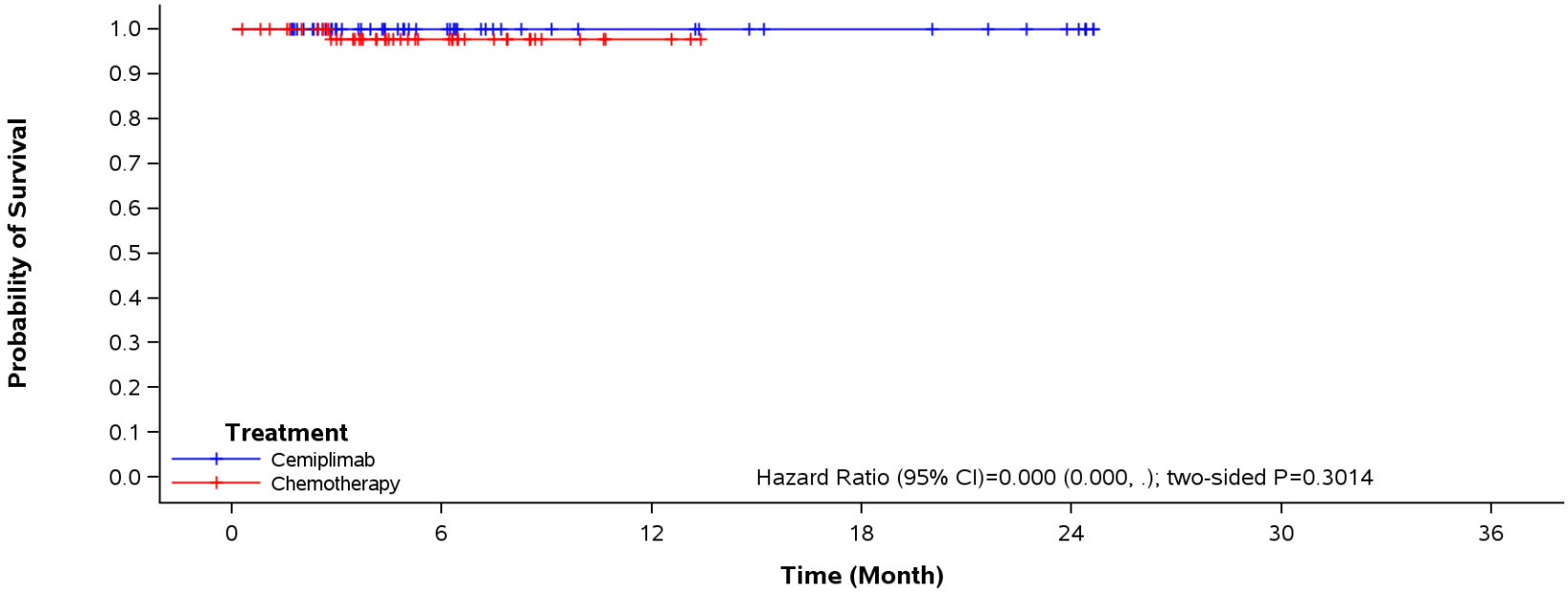

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Musculoskeletal and connective tissue disorders



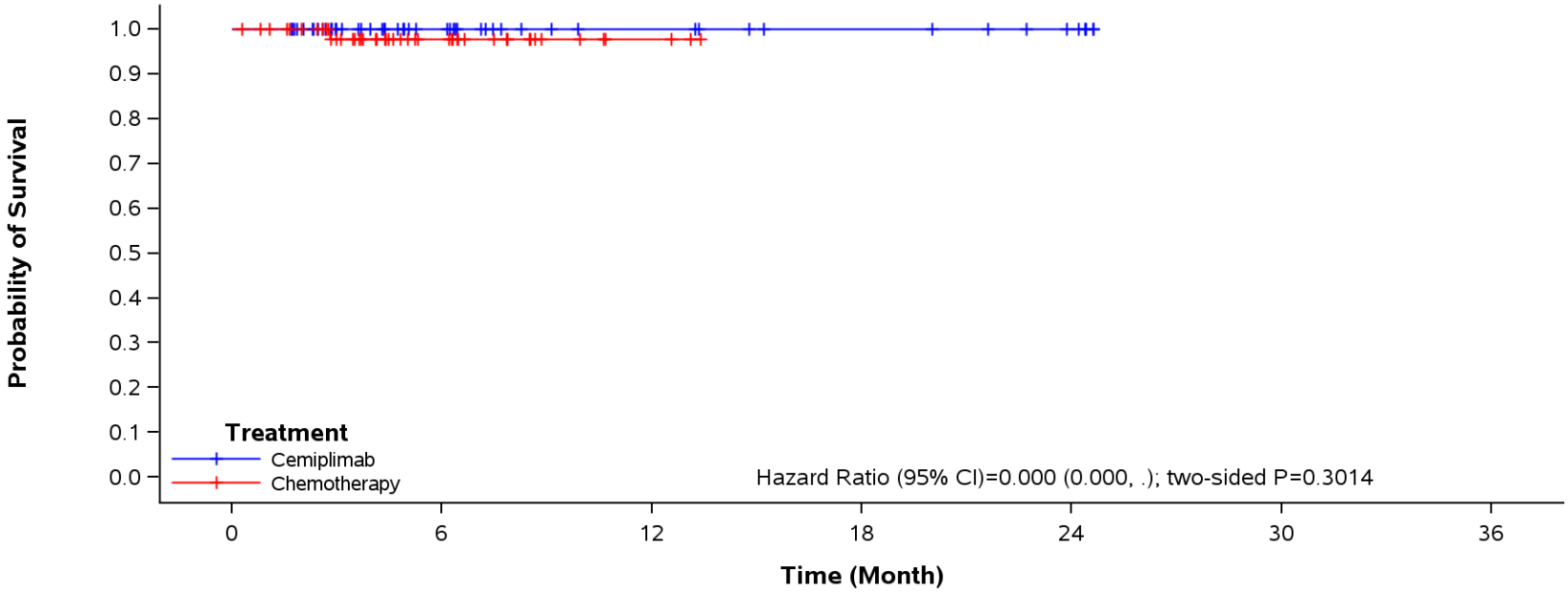

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



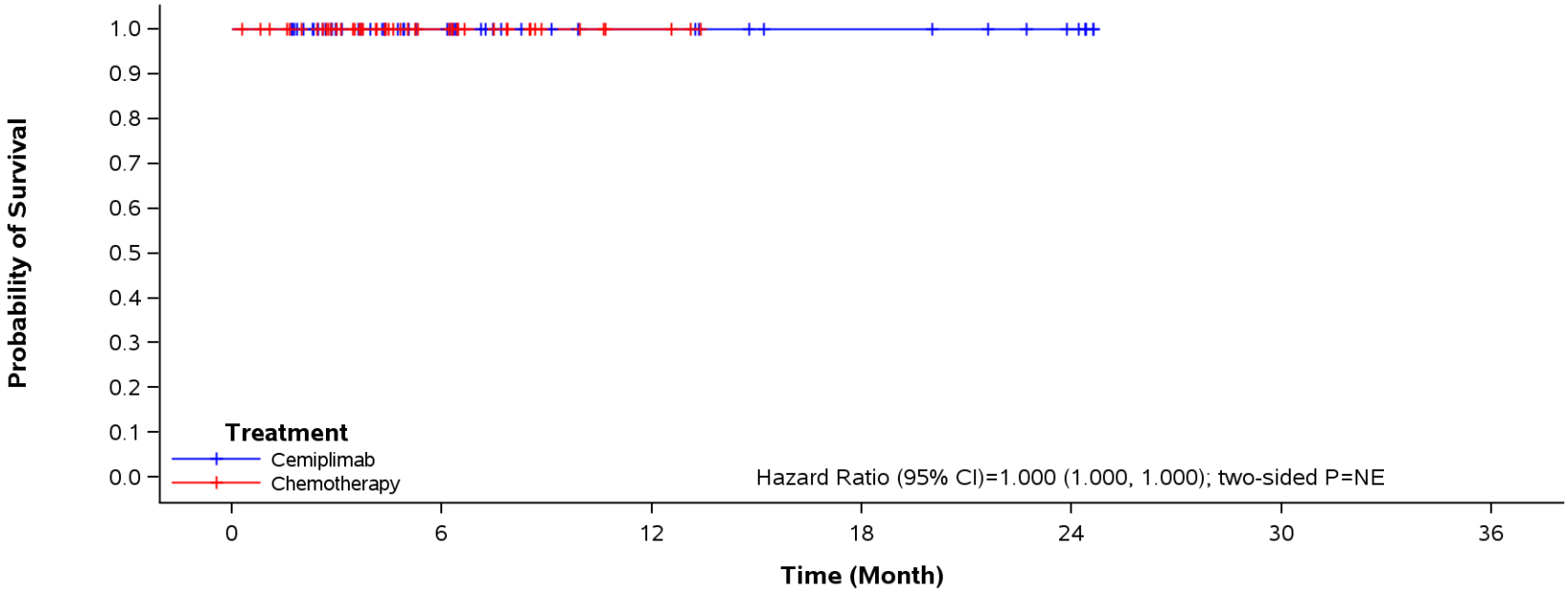

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 19 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



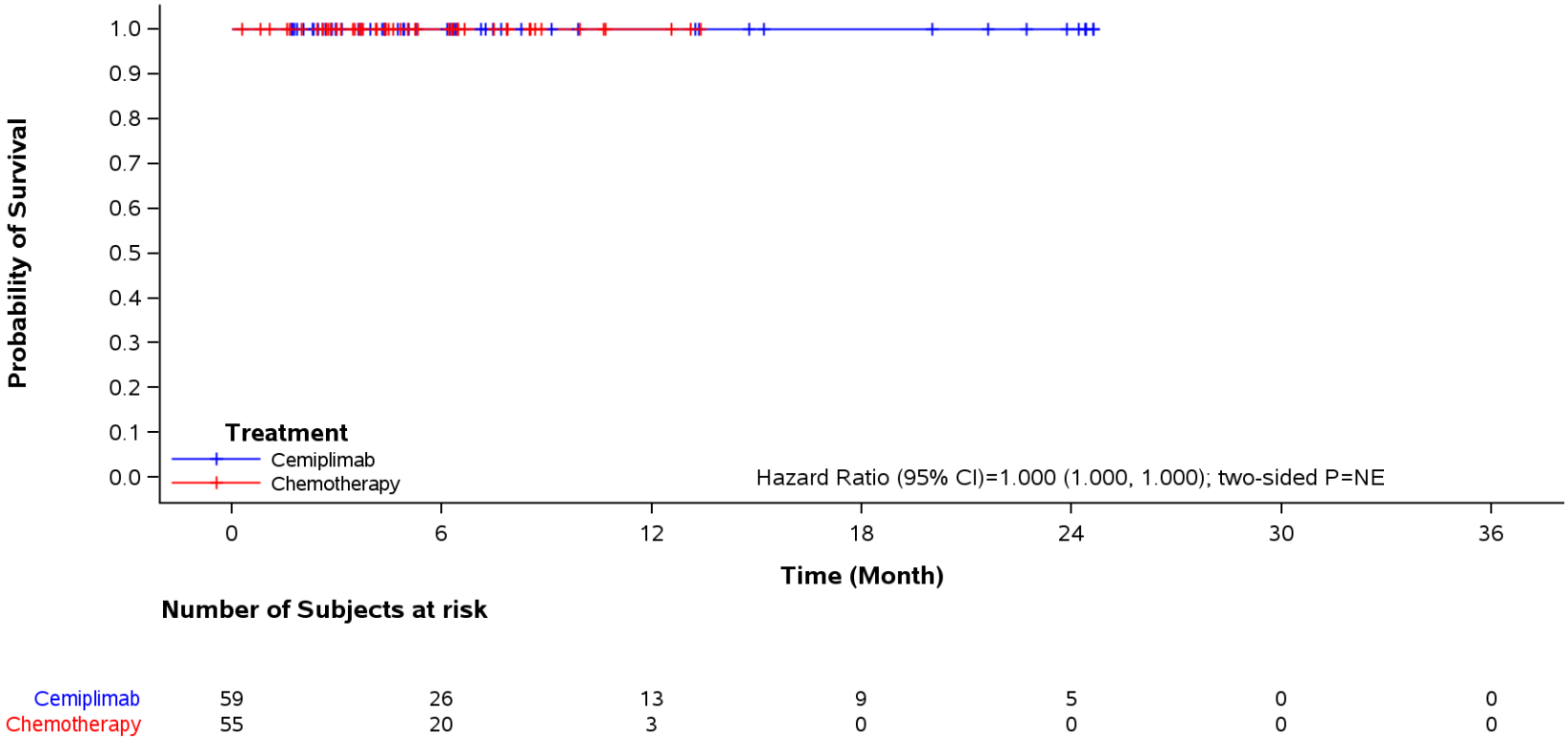

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

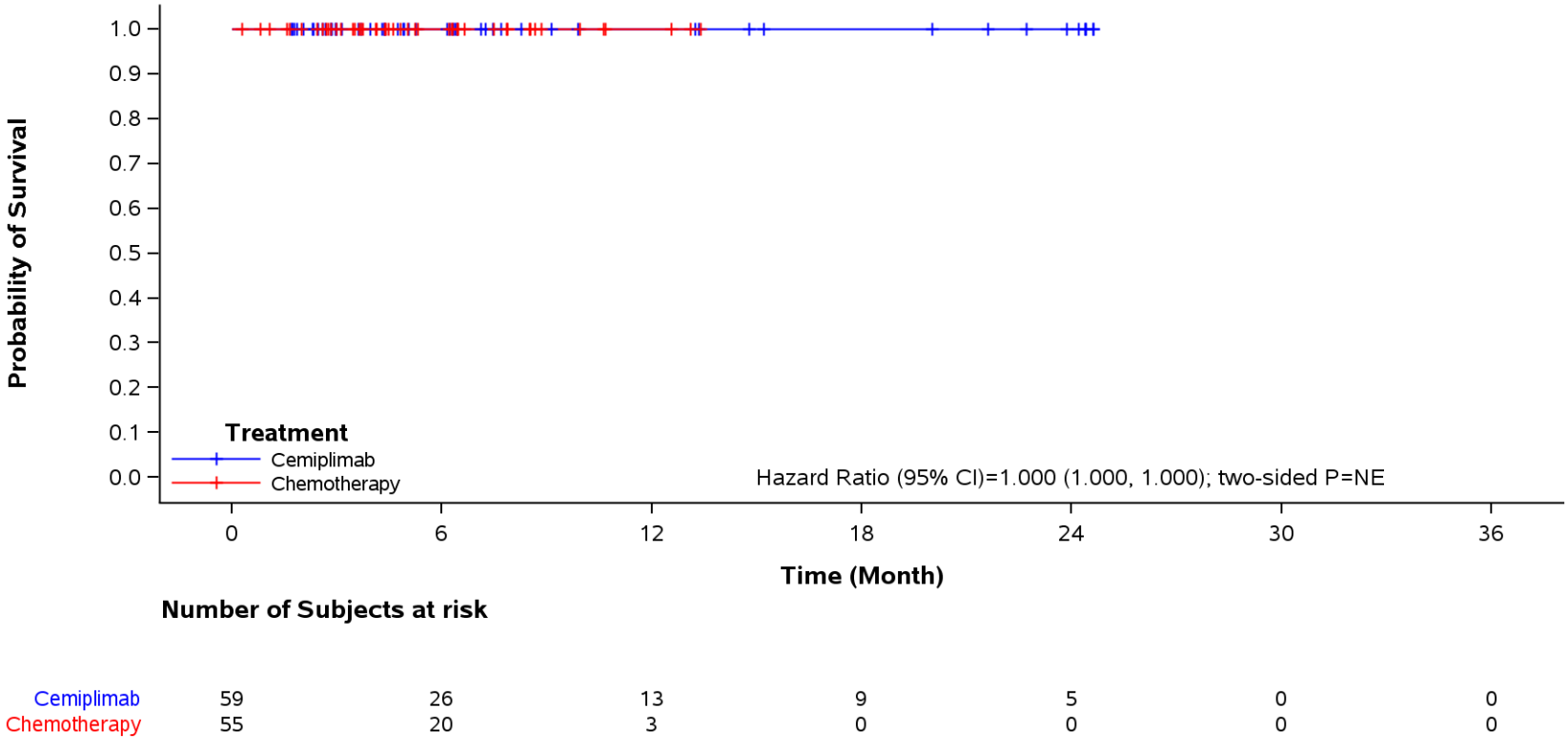
Geographic region: ROW
SOC: Nervous system disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

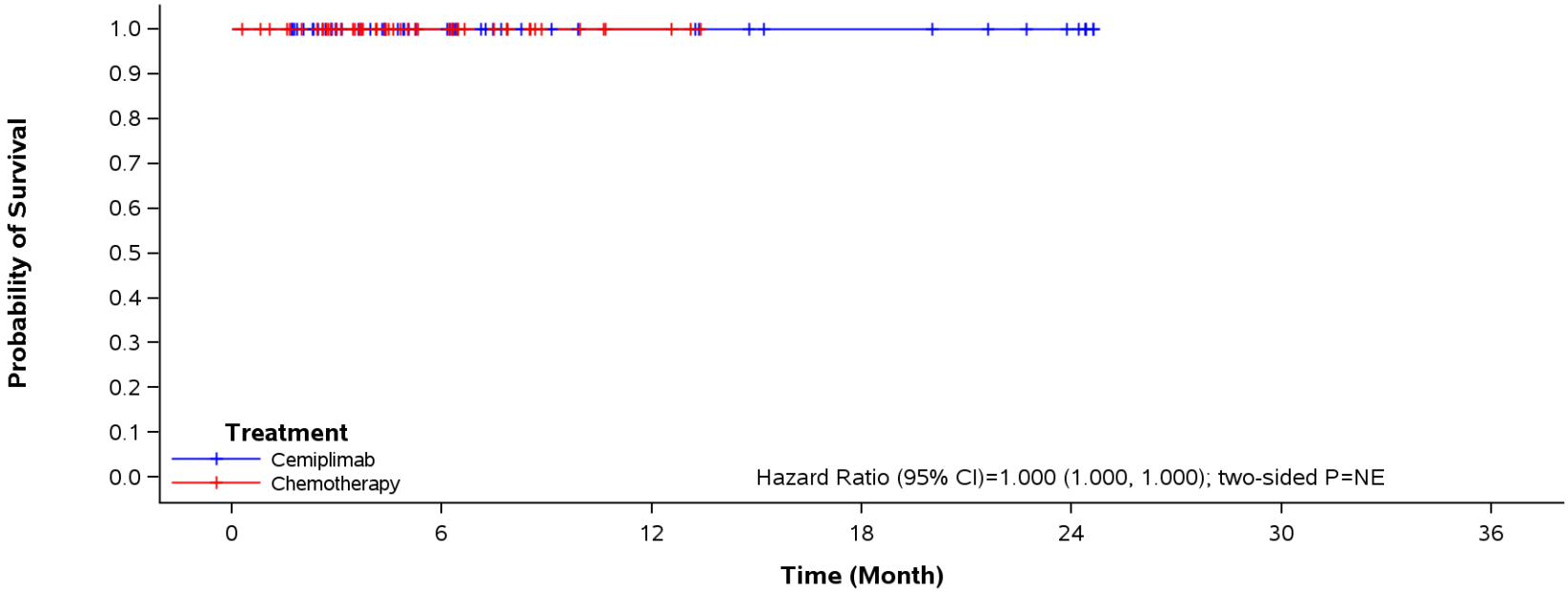
Geographic region: ROW
SOC: Nervous system disorders
PT: Neurotoxicity




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Nervous system disorders
PT: Transient ischaemic attack



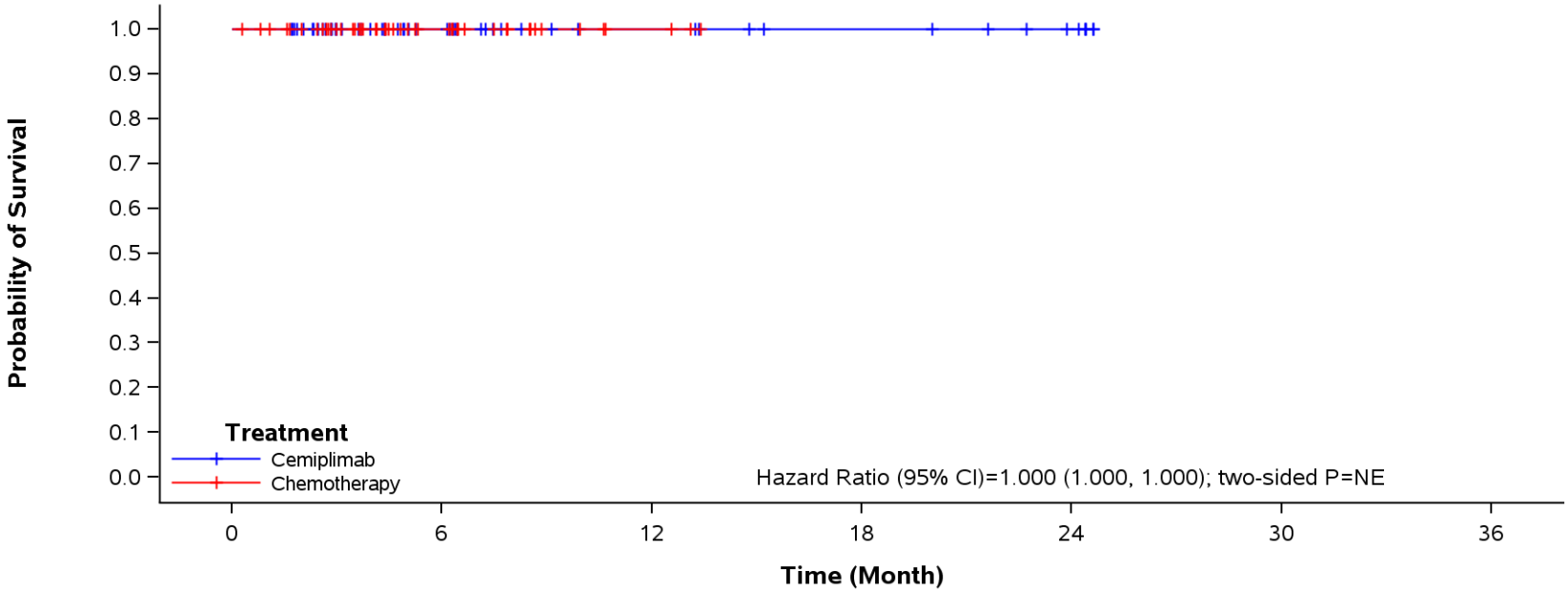

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Psychiatric disorders



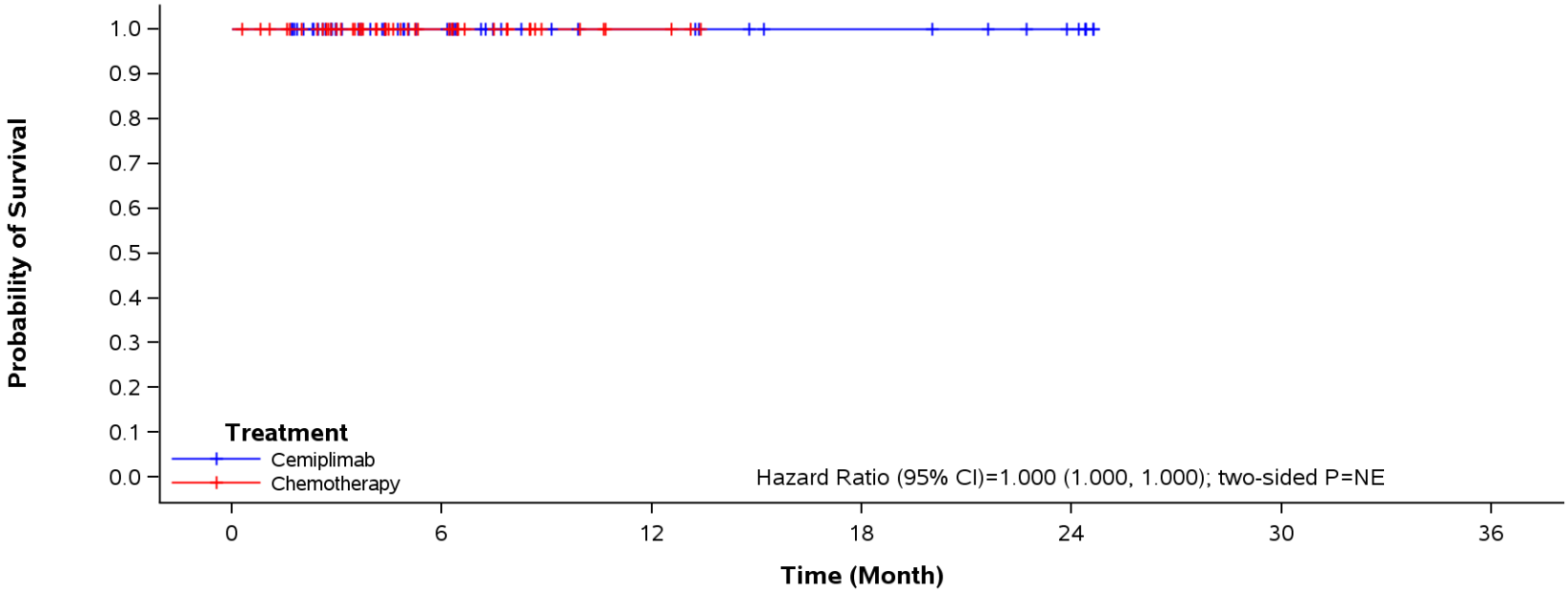

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Psychiatric disorders
PT: Agoraphobia



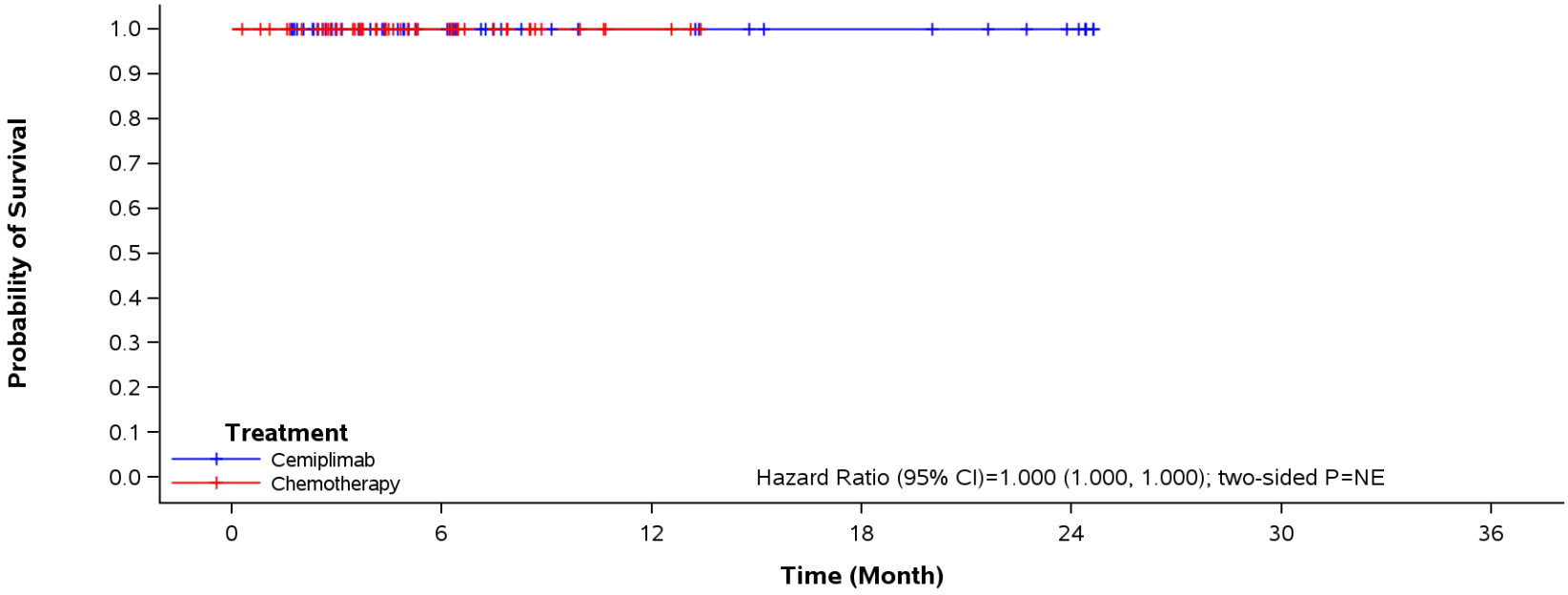

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Renal and urinary disorders



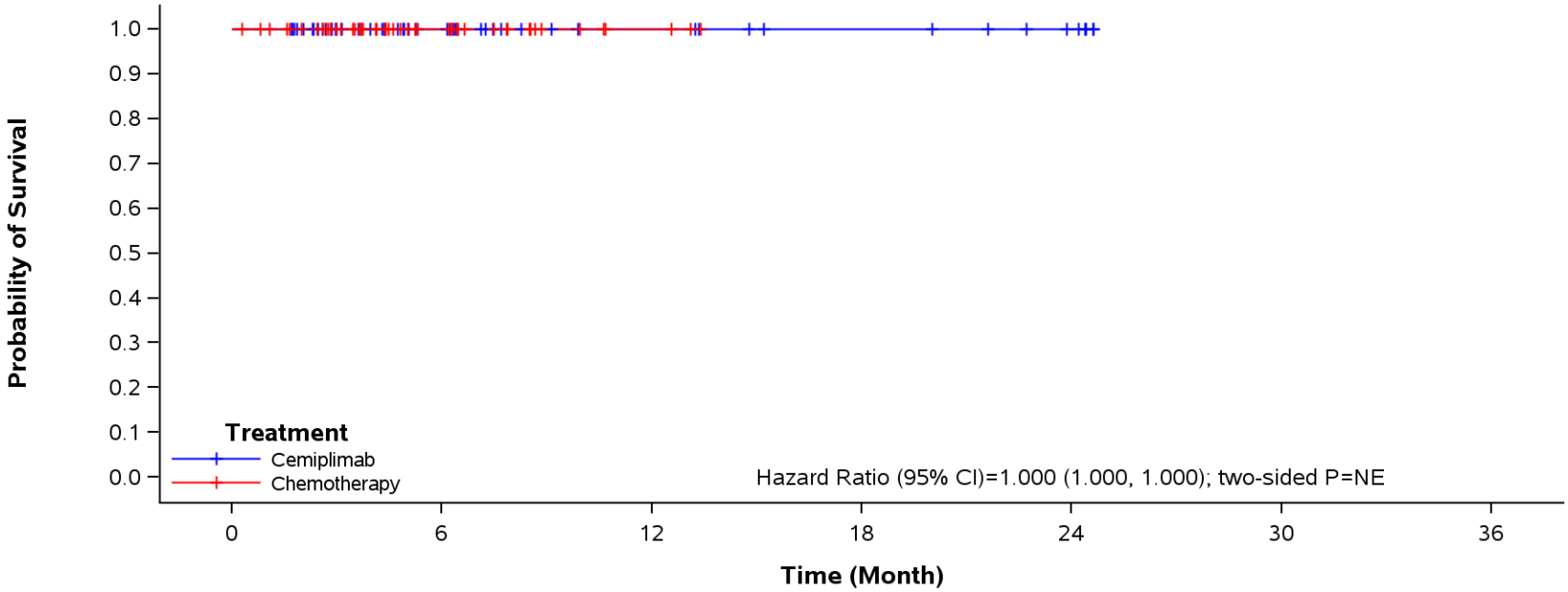

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Renal and urinary disorders
PT: Renal failure



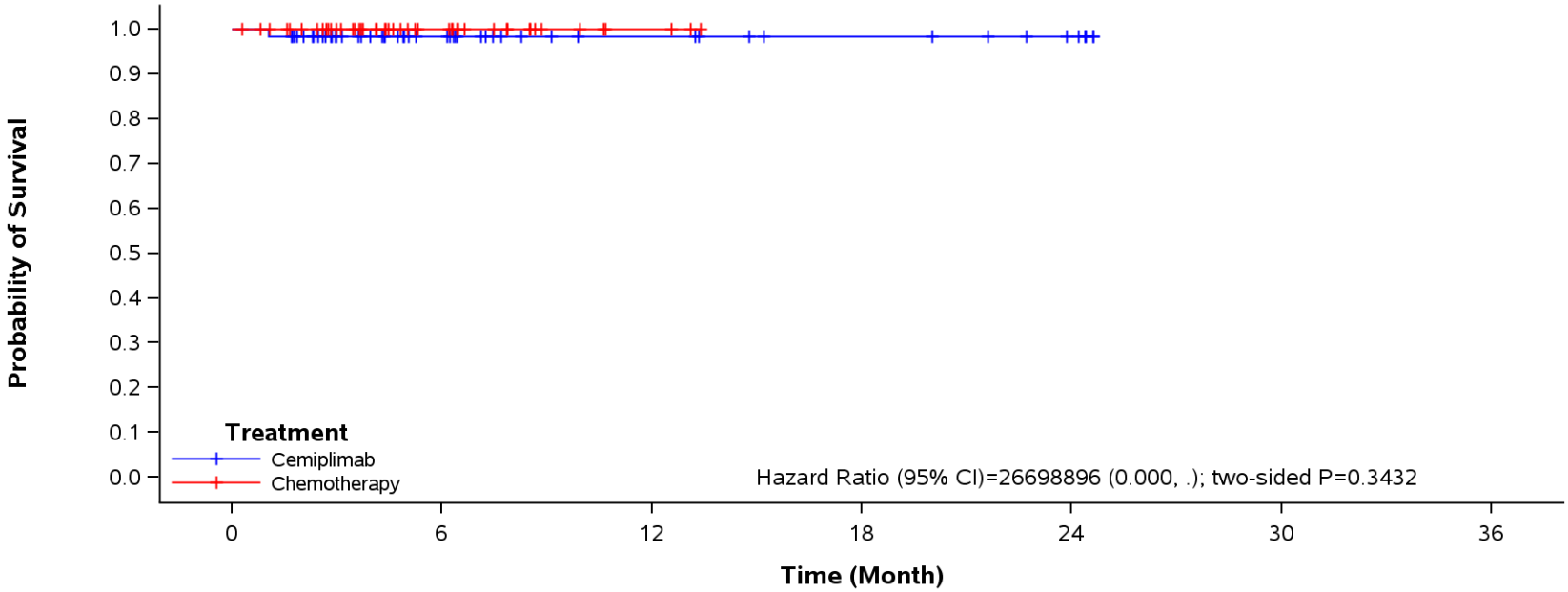

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Respiratory, thoracic and mediastinal disorders



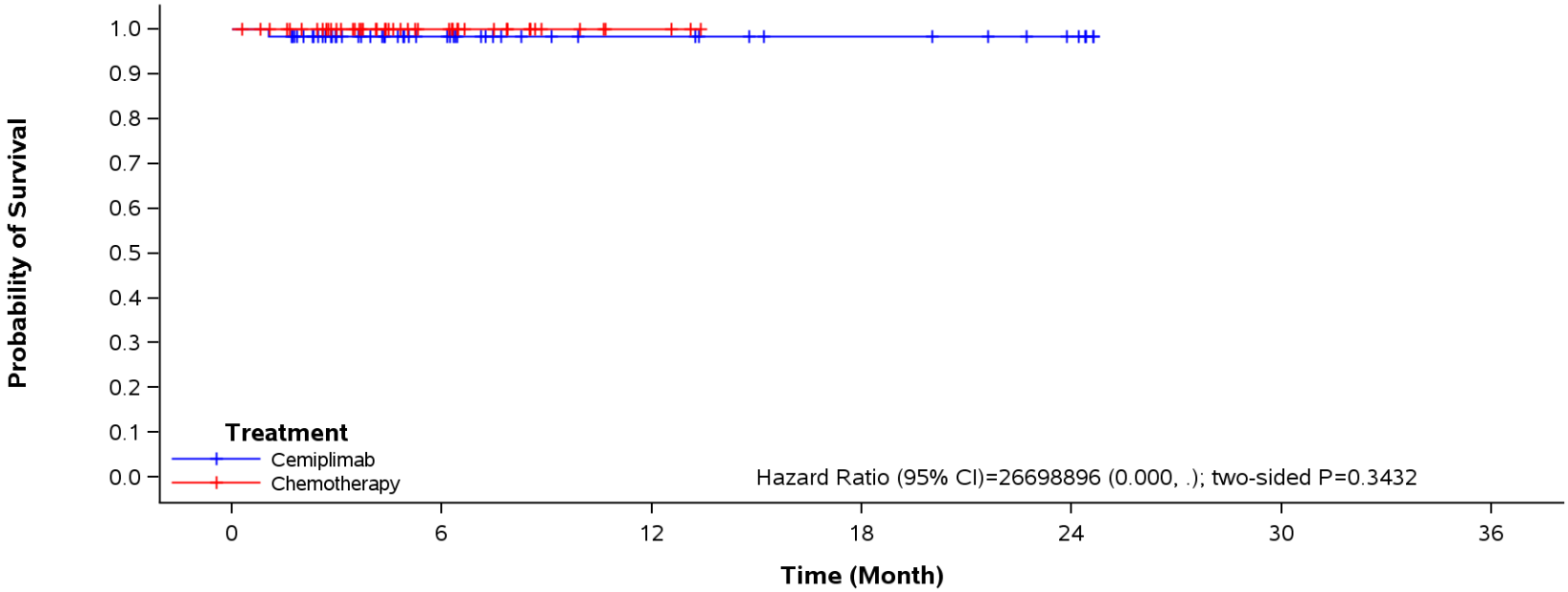

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



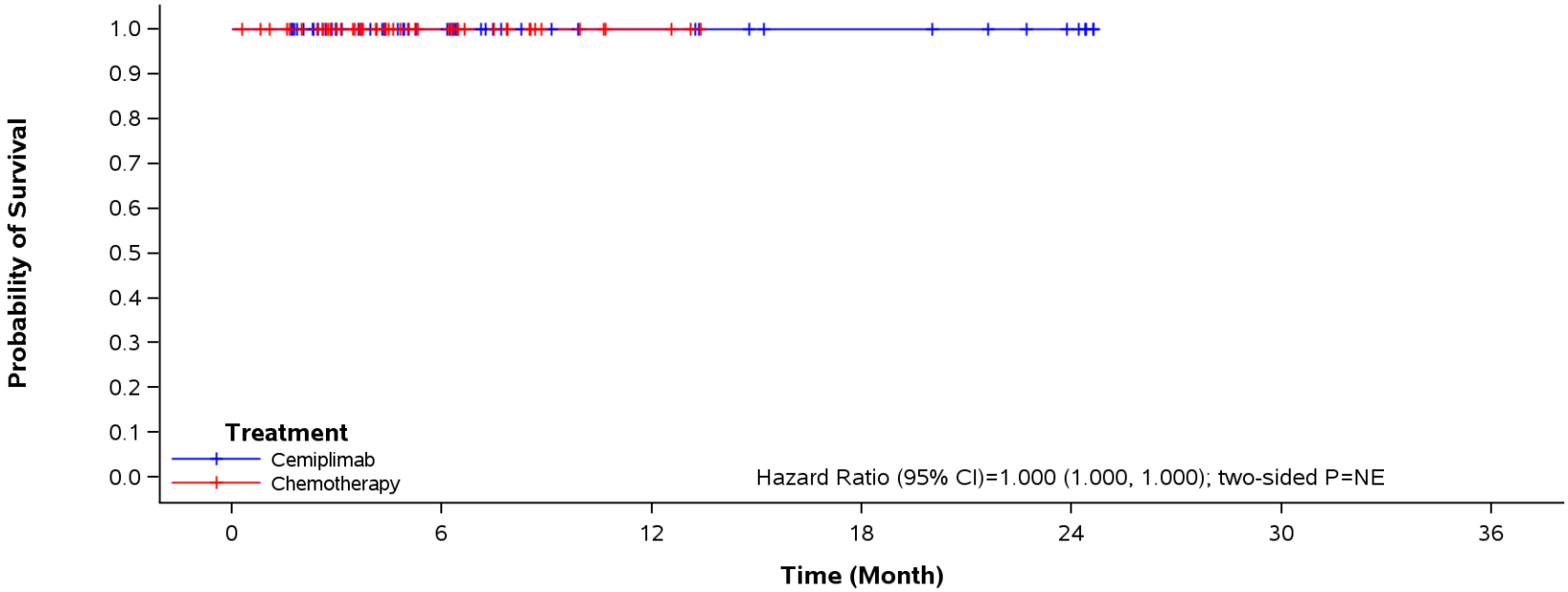

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Vascular disorders



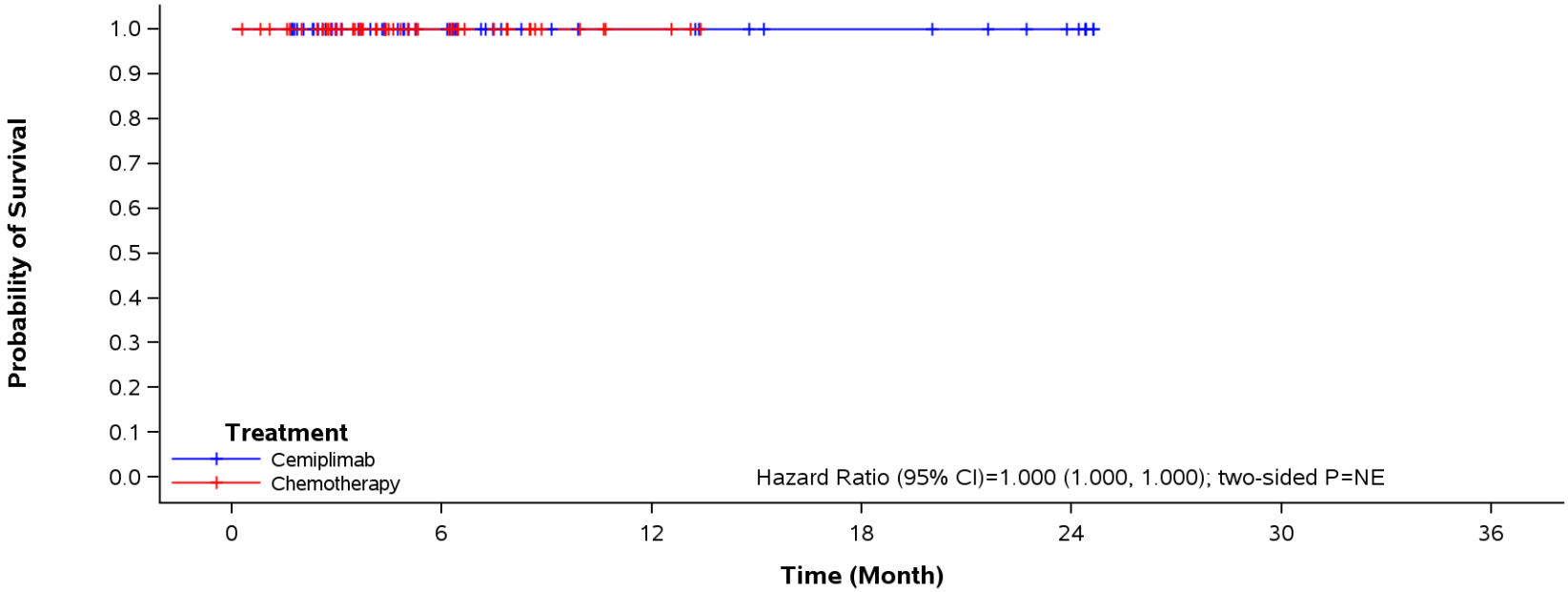

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Geographic region: ROW
SOC: Vascular disorders
PT: Deep vein thrombosis



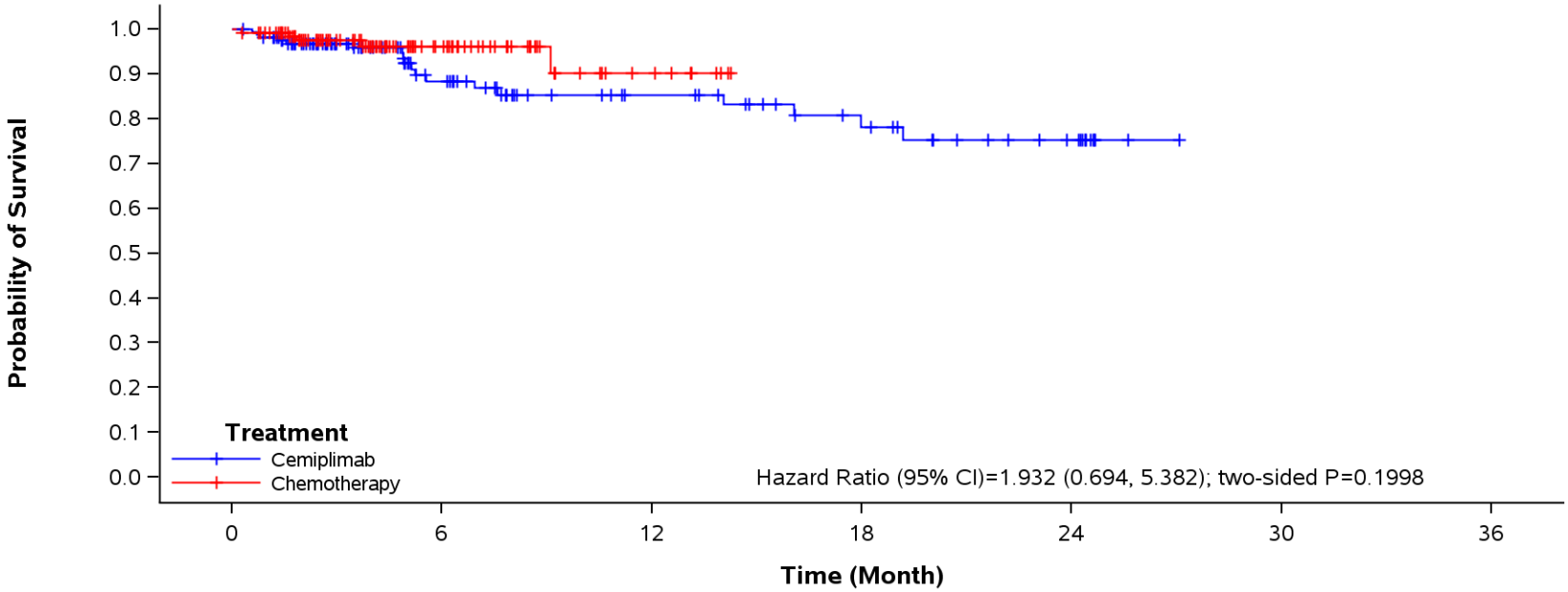

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 59 | 26 | 13 | 9 | 5 | 0 | 0 |
| Chemotherapy | 55 | 20 | 3 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
Number of patients with any TEAE leading to discontinuation



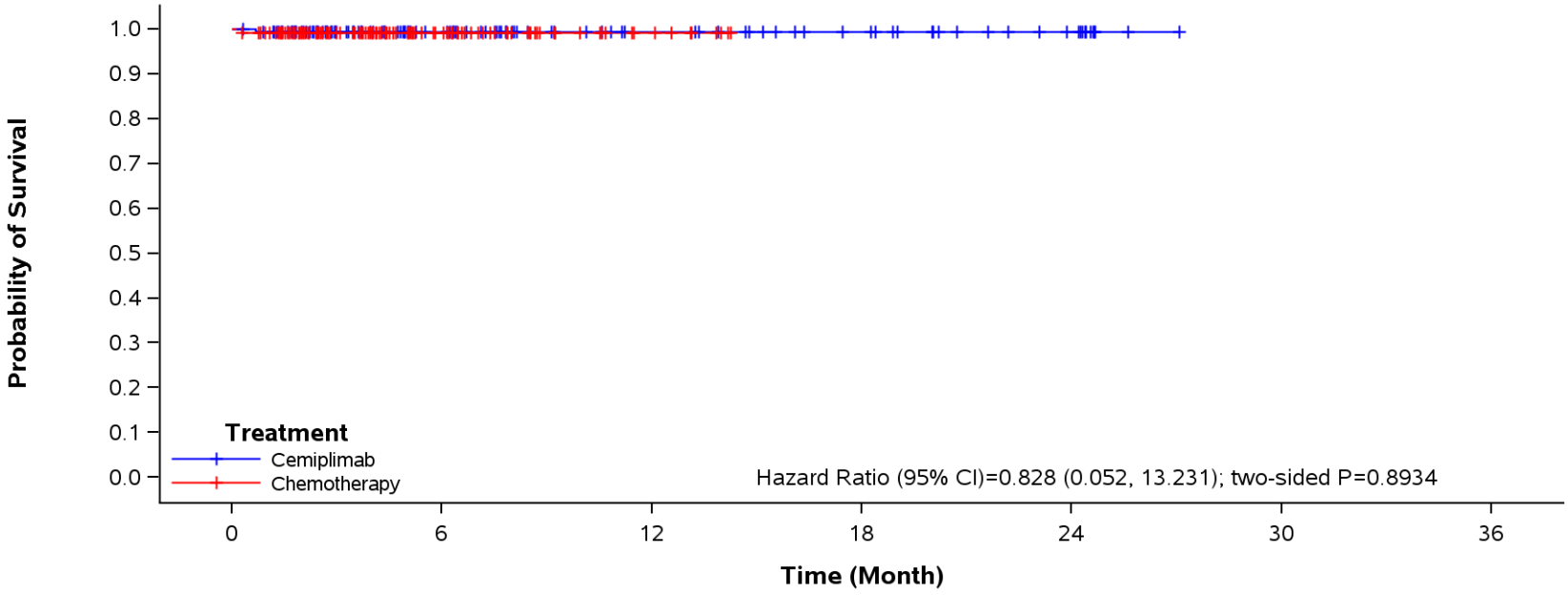

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 66 | 42 | 30 | 19 | 0 | 0 |
| Chemotherapy | 133 | 40 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders



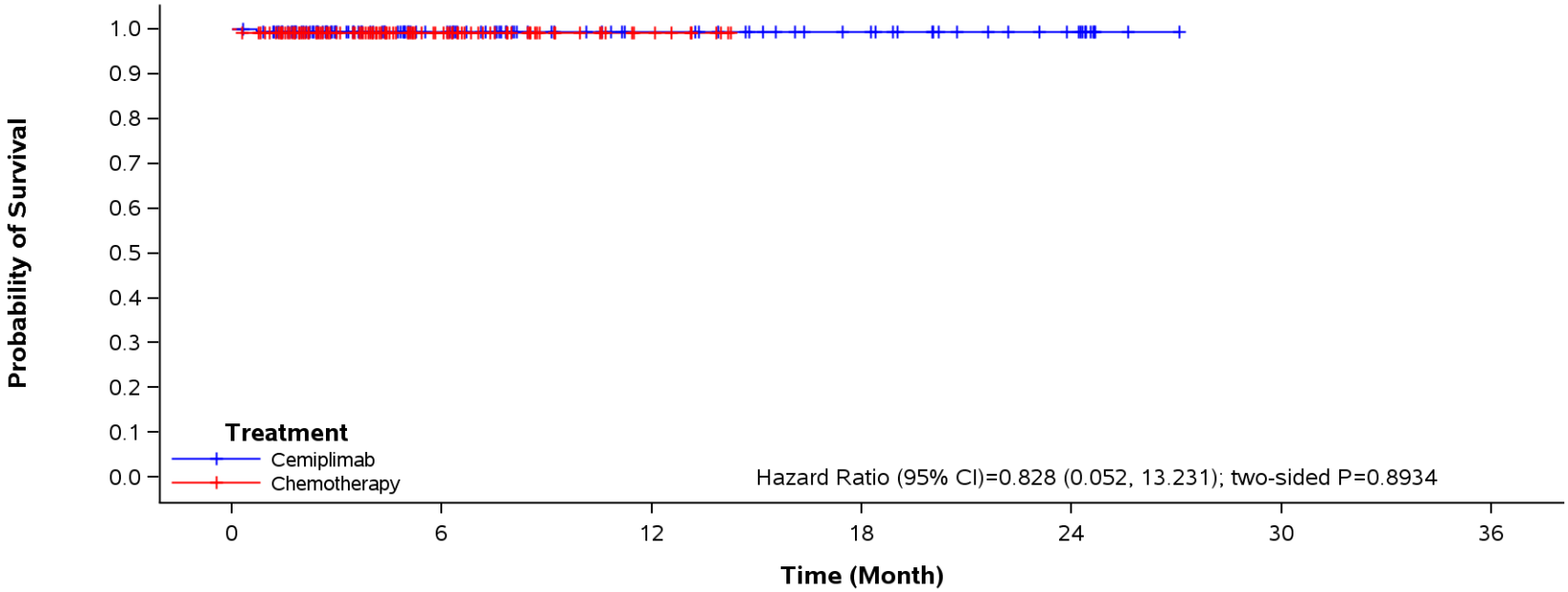

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



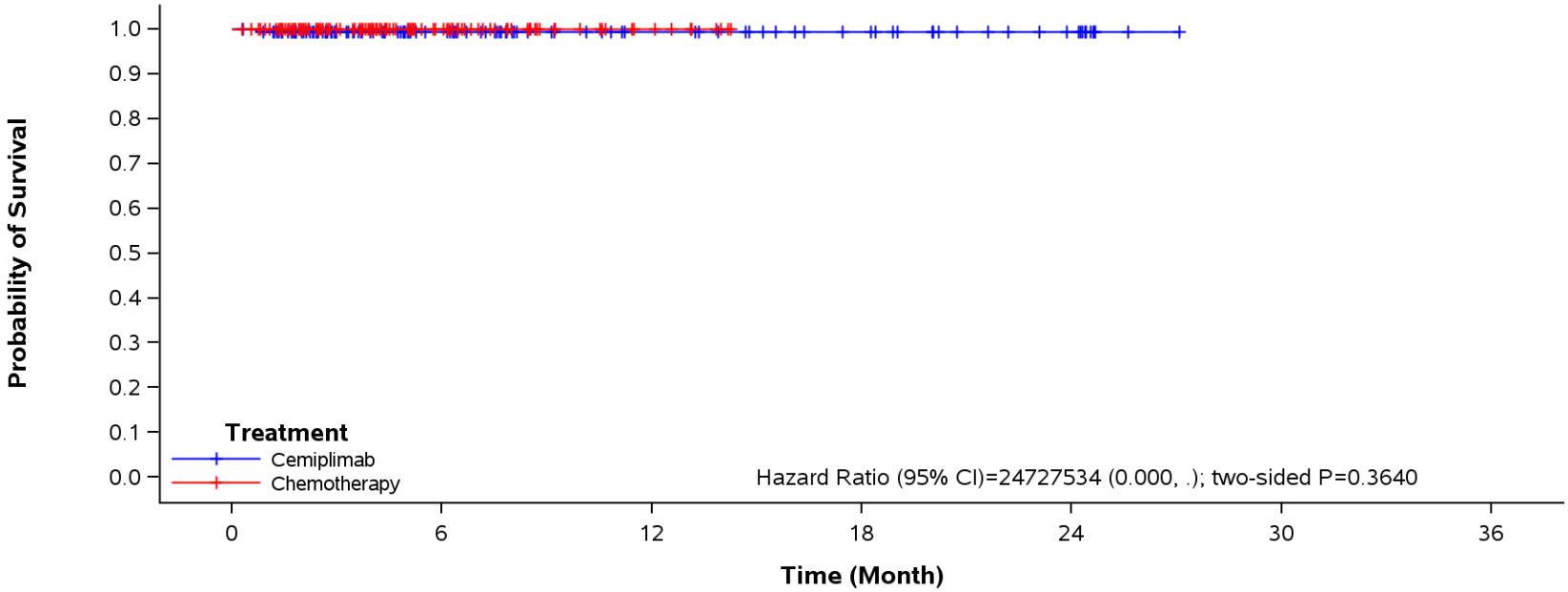

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



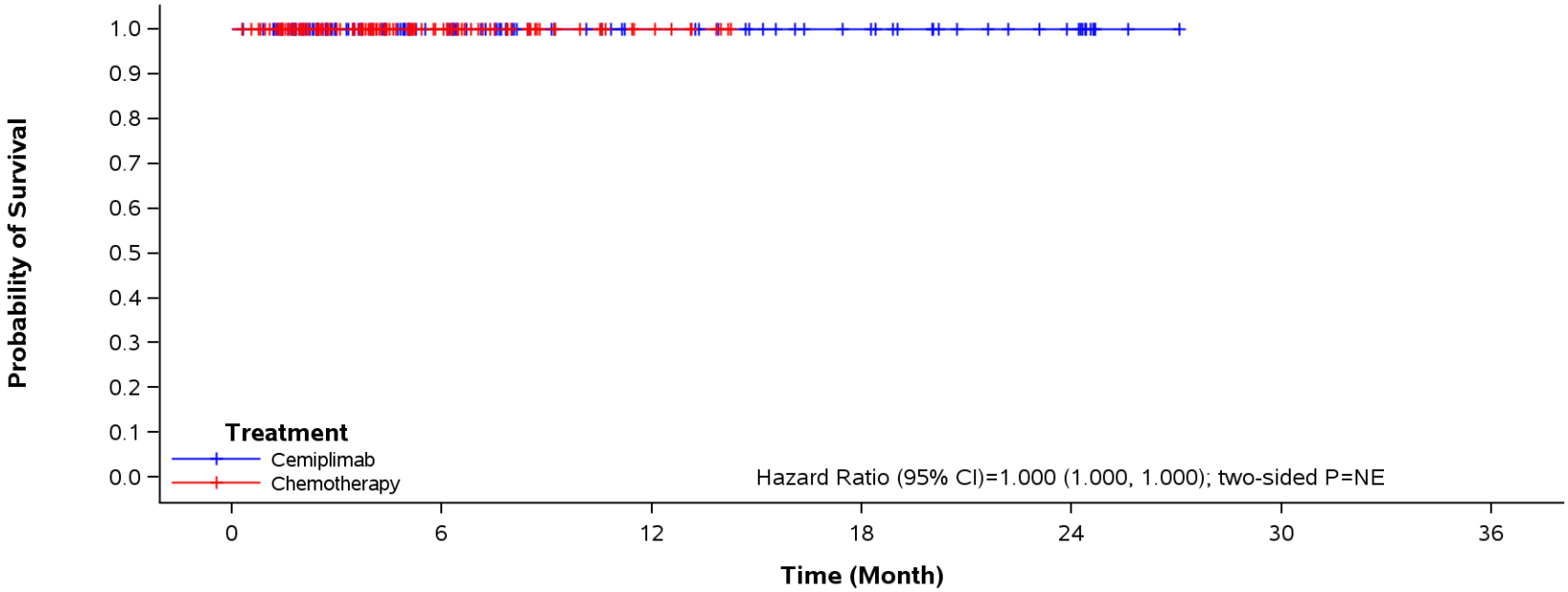

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



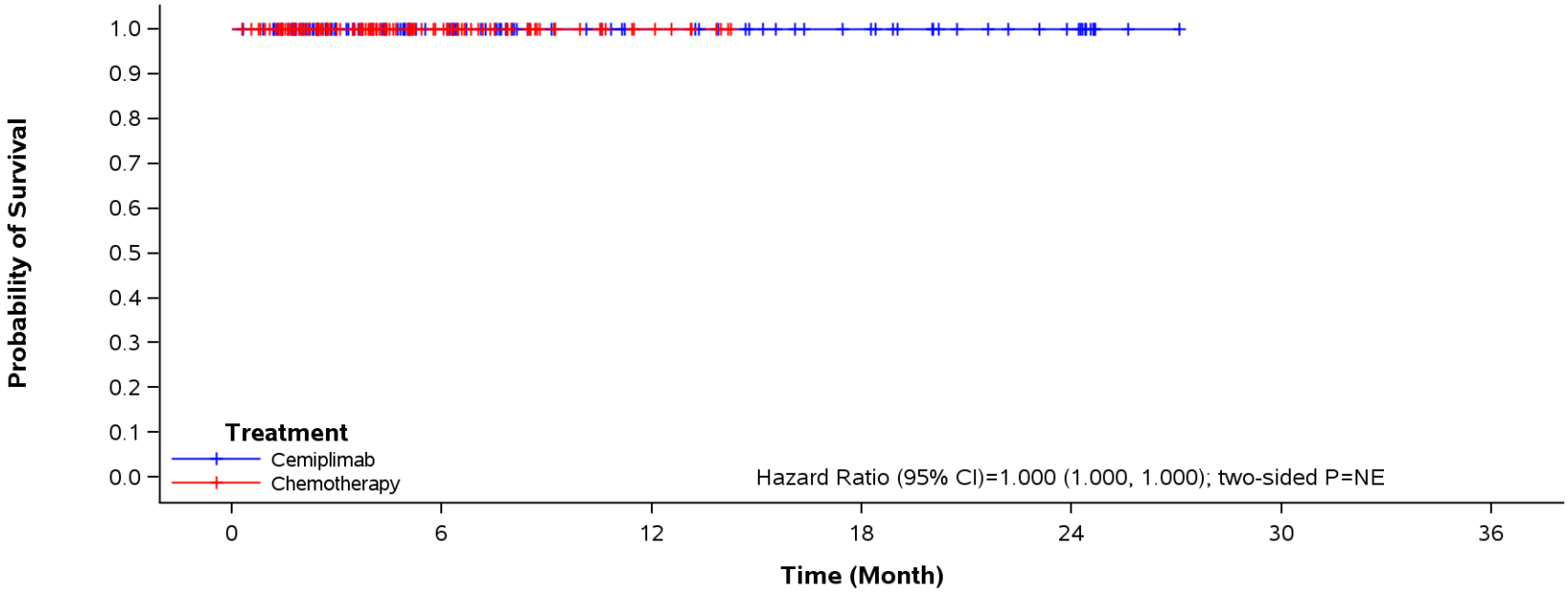

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



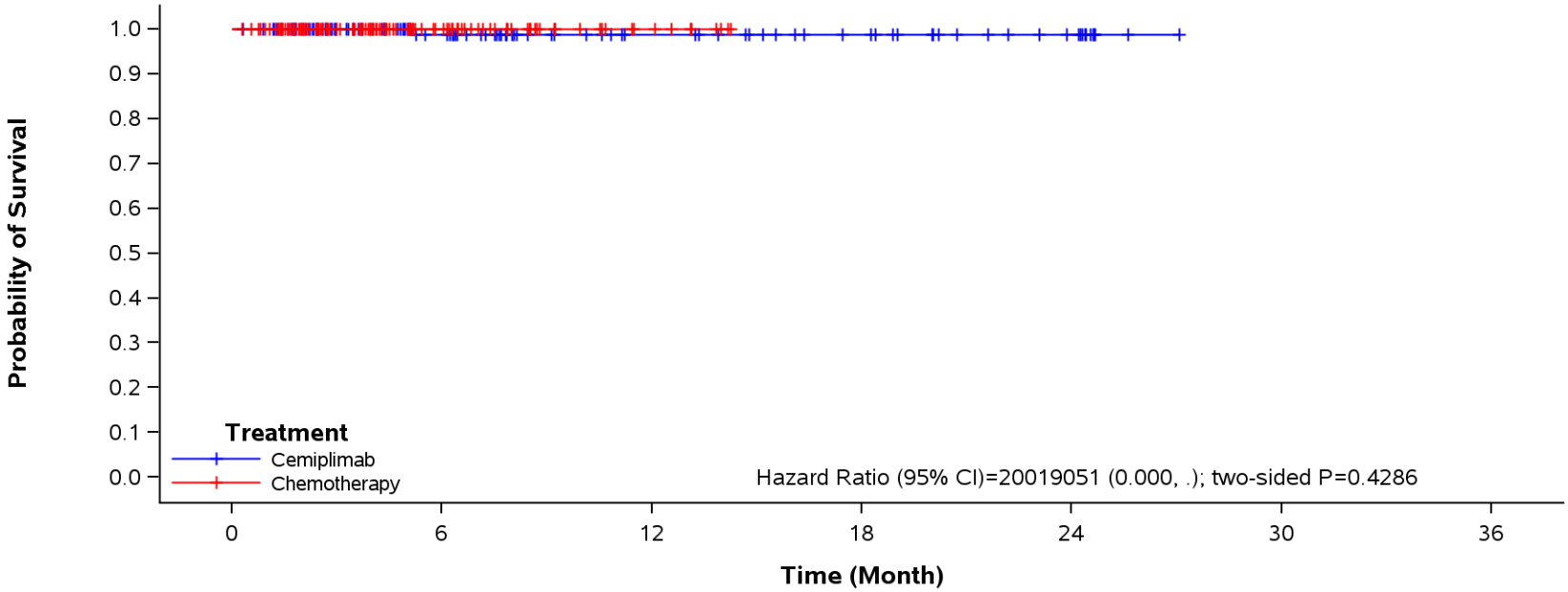

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Cardiac disorders



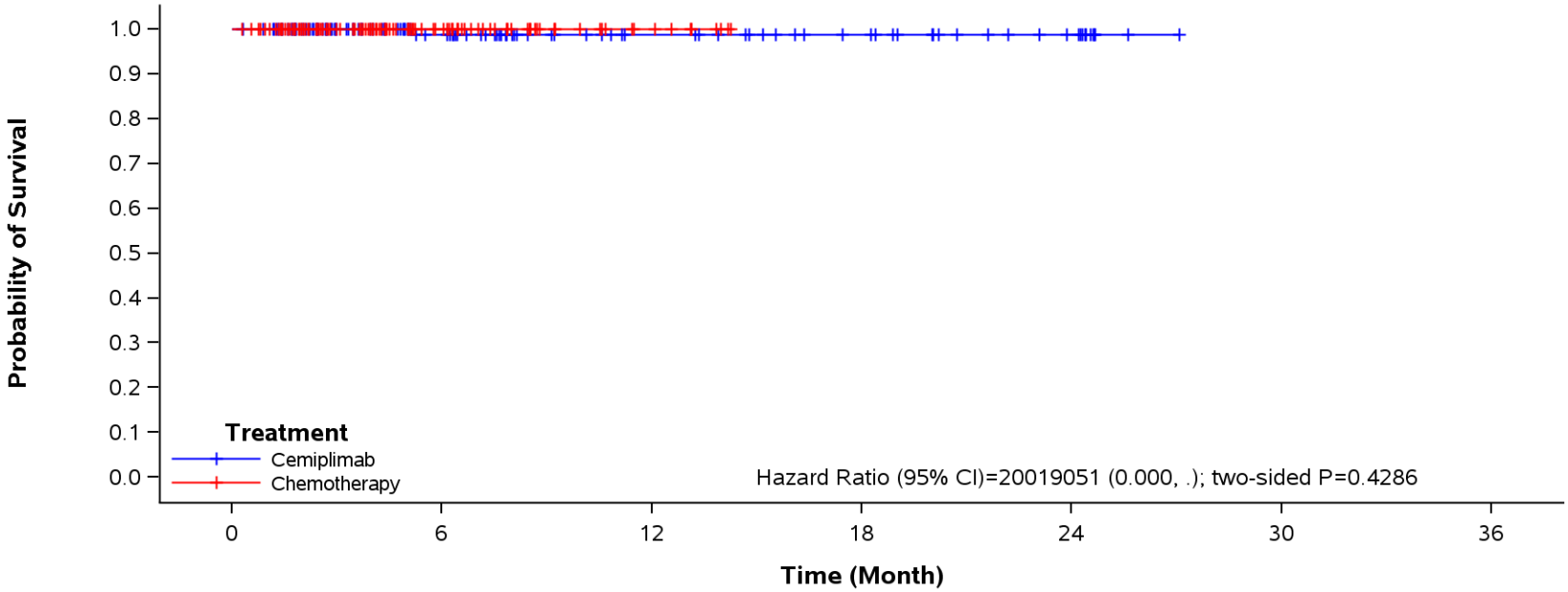

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 72 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Cardiac disorders
PT: Autoimmune pericarditis



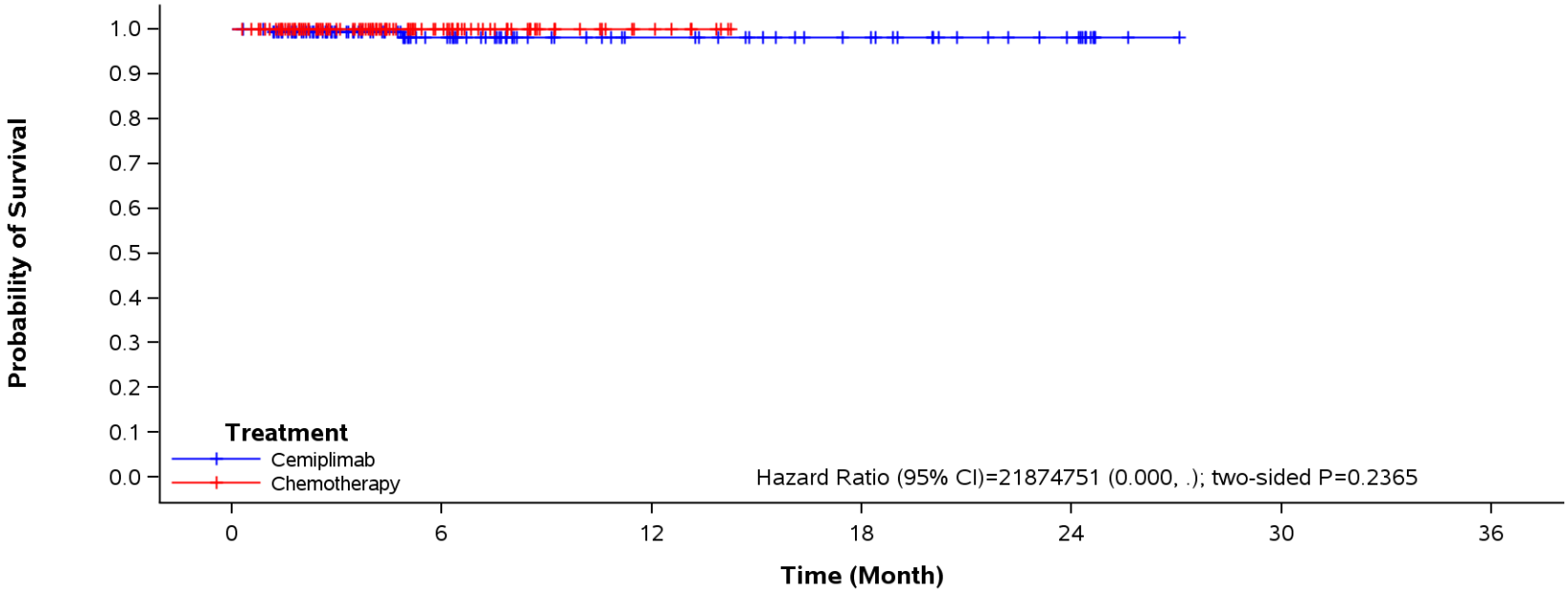

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 72 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Endocrine disorders



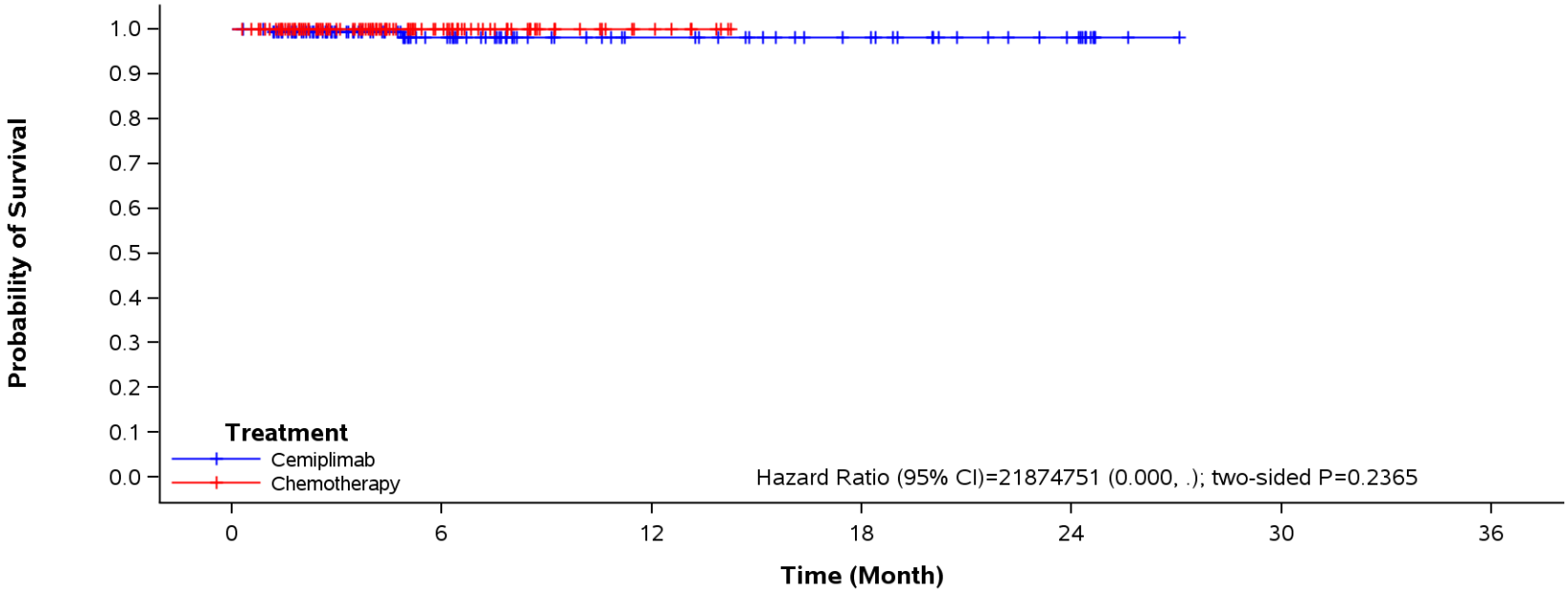

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 72 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Endocrine disorders
PT: Hypothyroidism



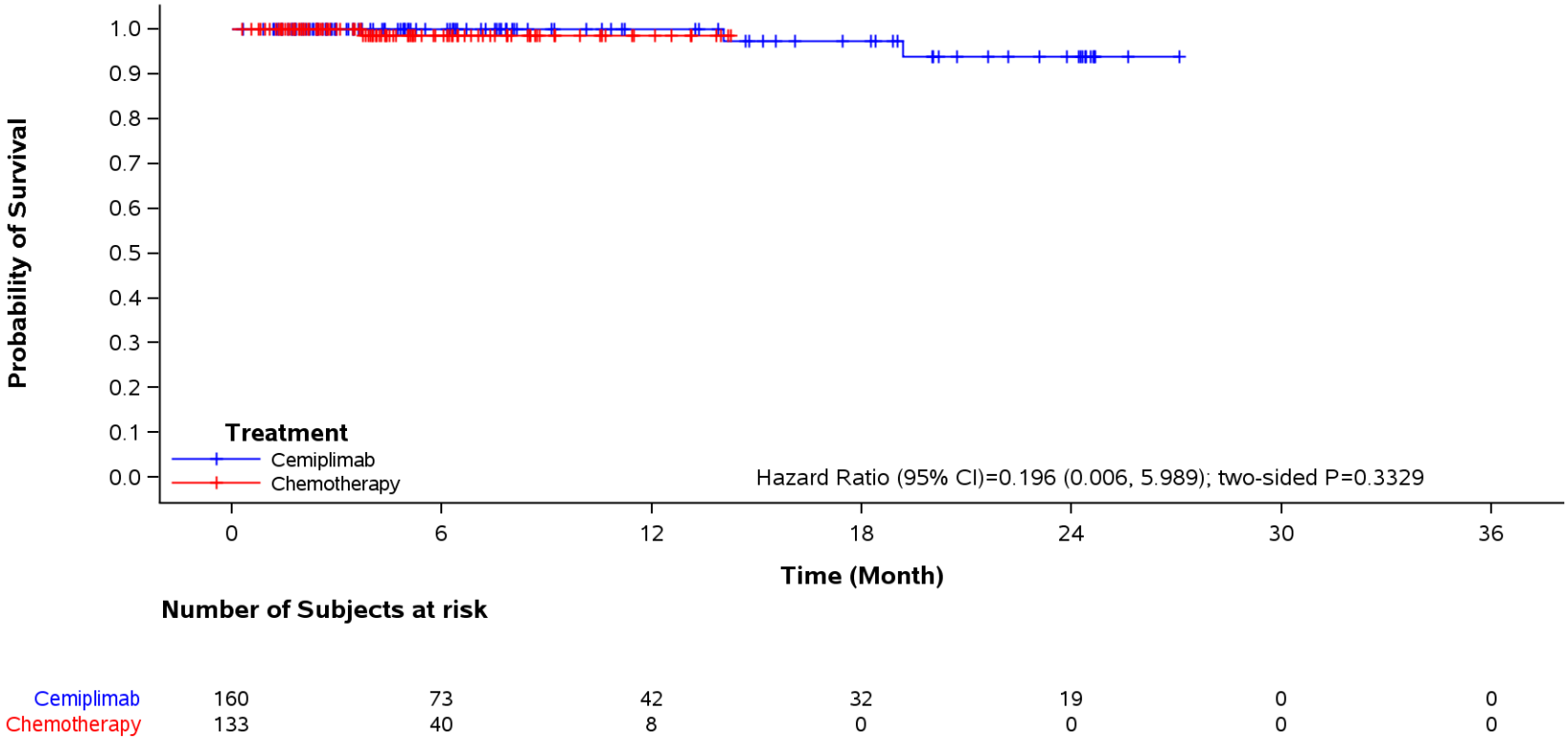

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 72 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

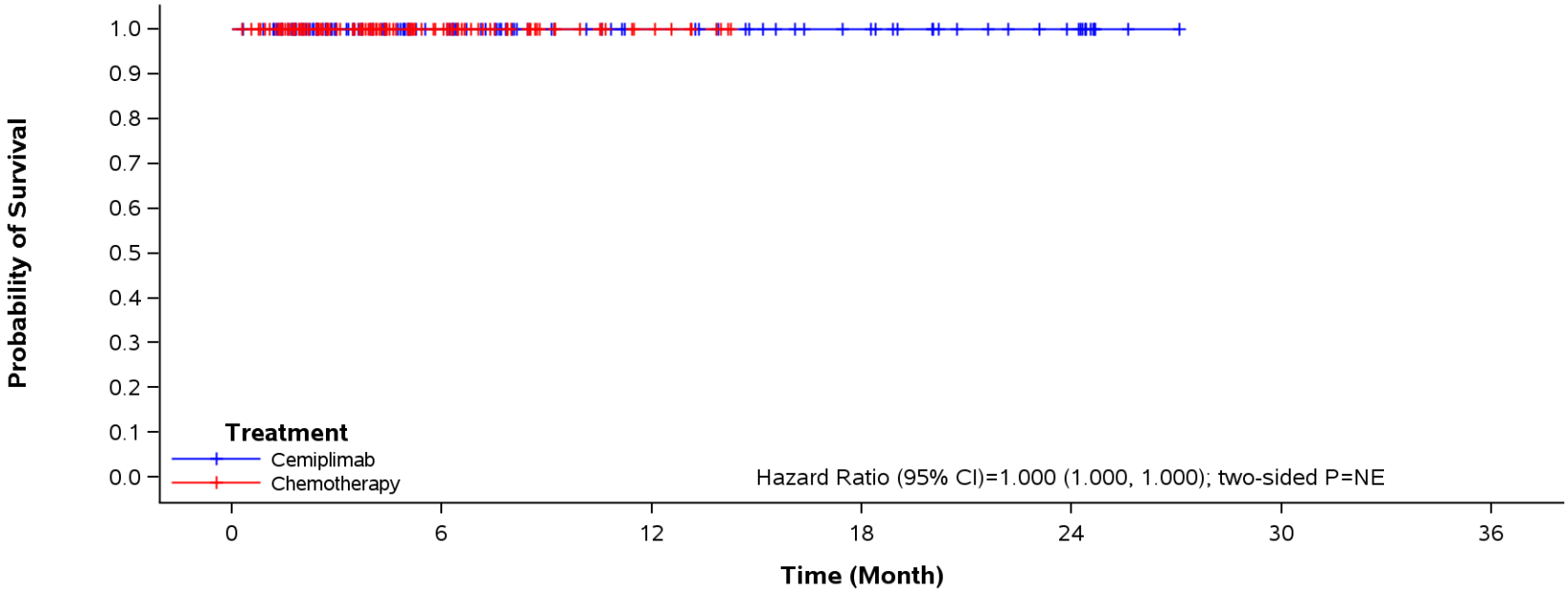
Histology: Squamous
SOC: Gastrointestinal disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders
PT: Colitis



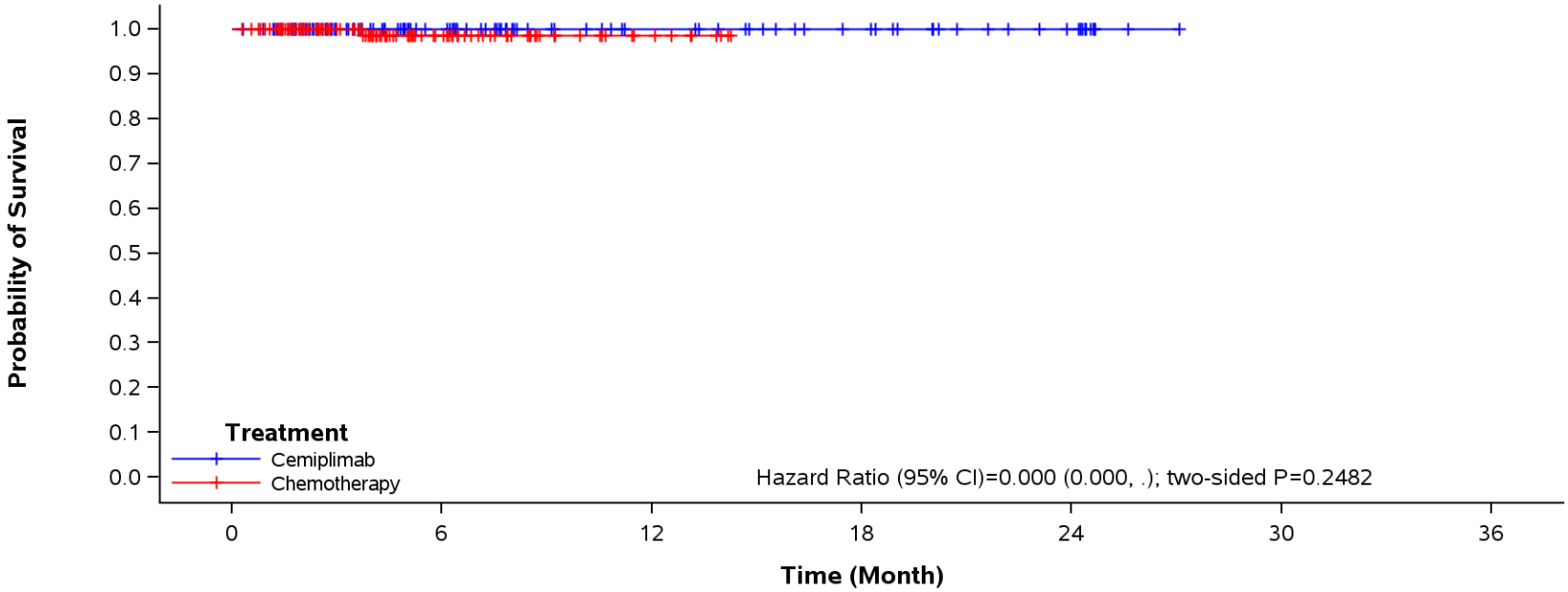

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders
PT: Diverticular perforation



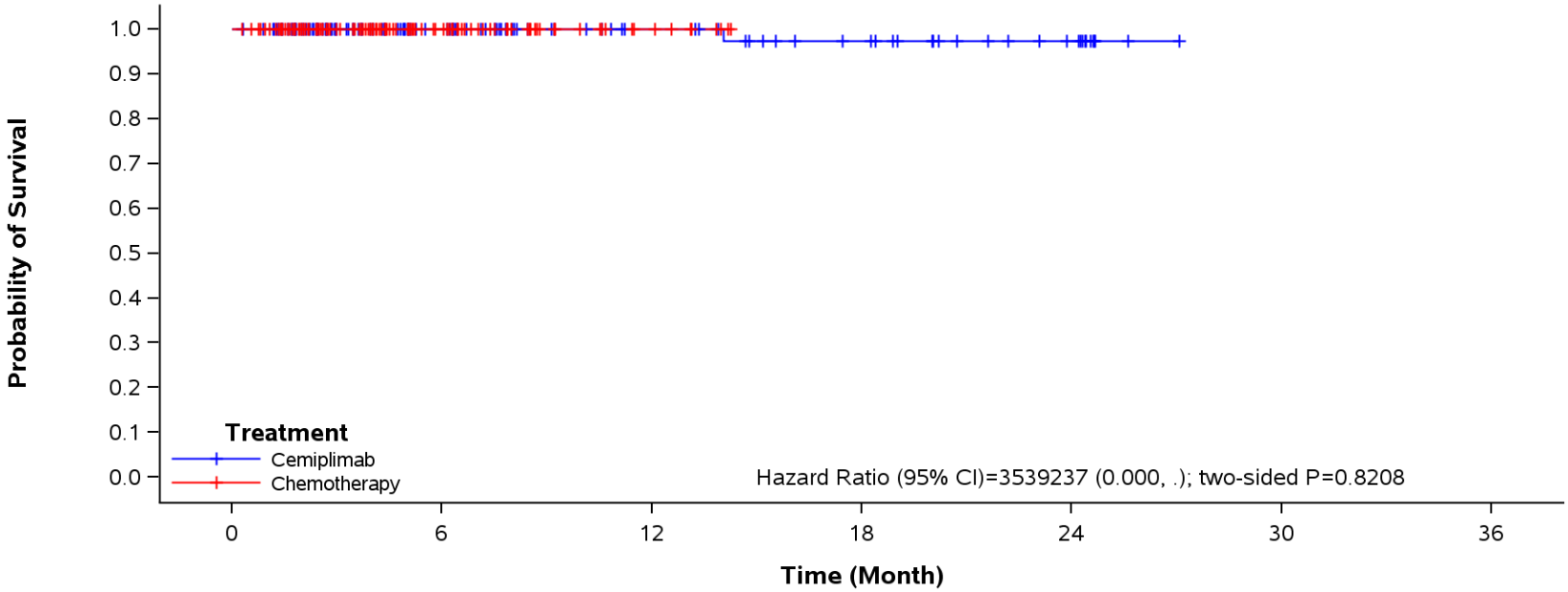

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 40 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders
PT: Pancreatic mass



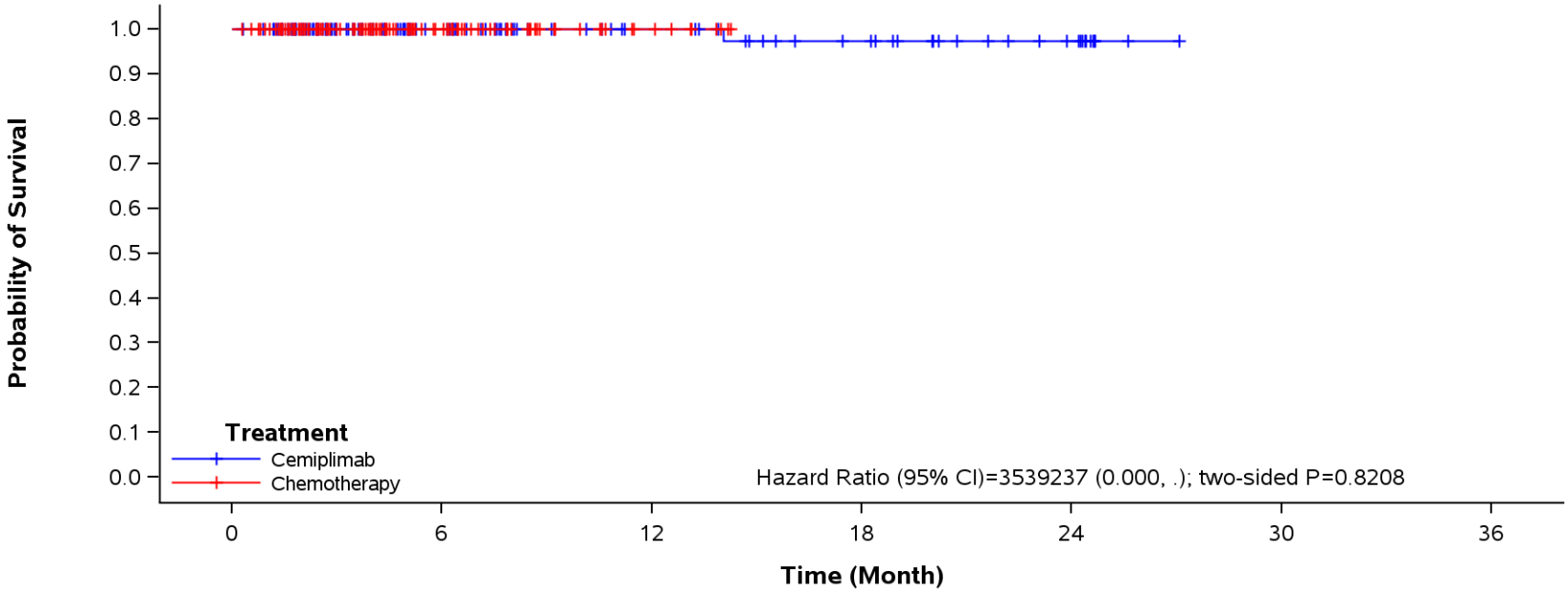

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



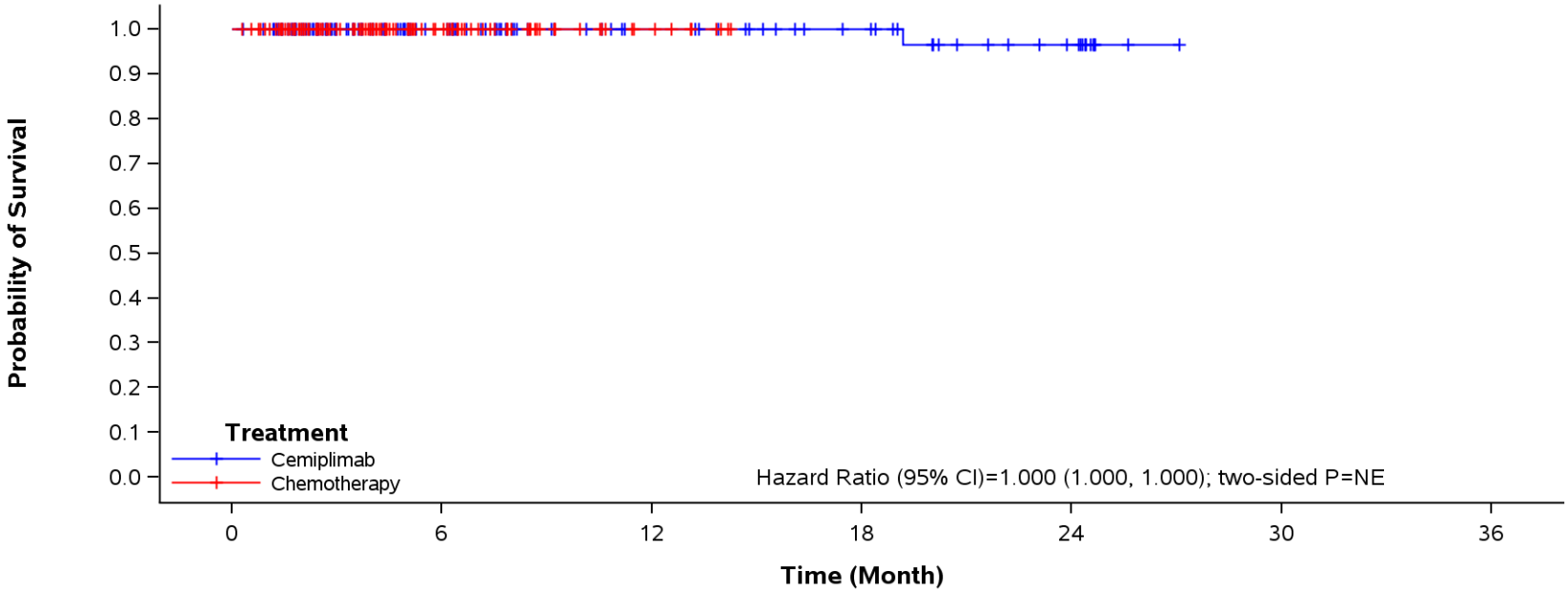

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Gastrointestinal disorders
PT: Proctalgia



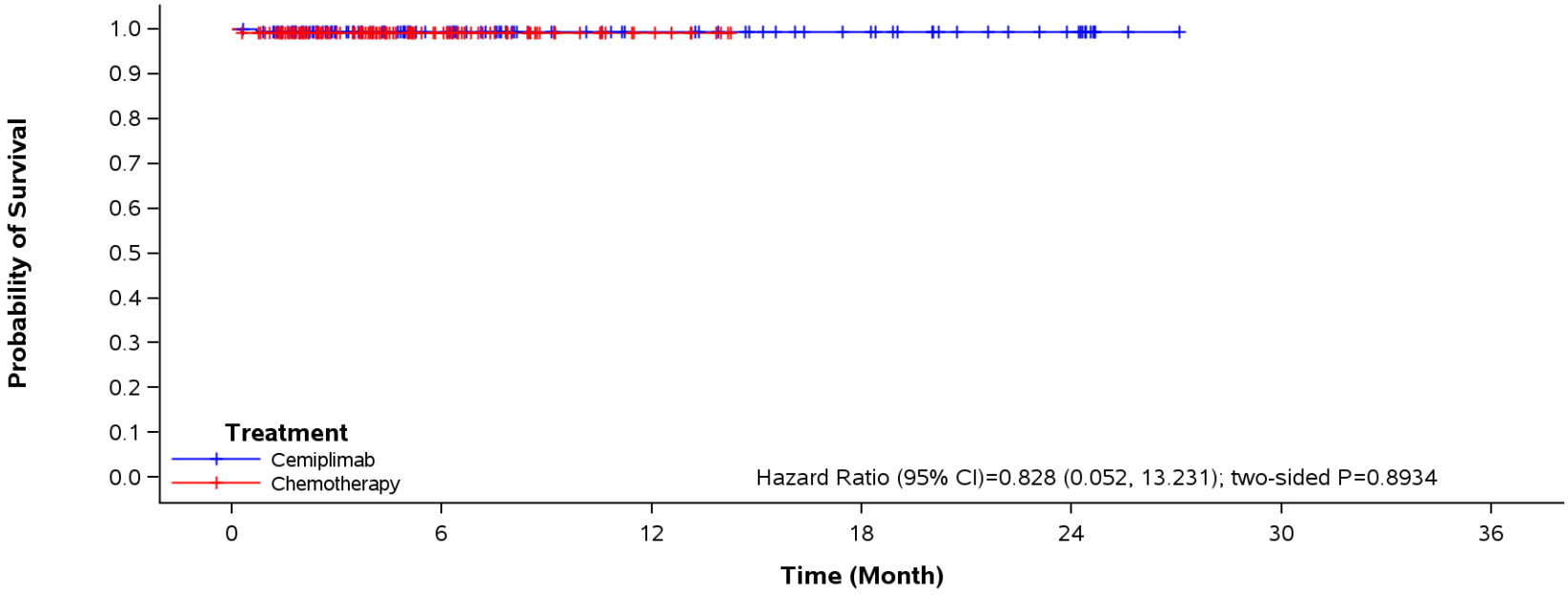

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: General disorders and administration site conditions



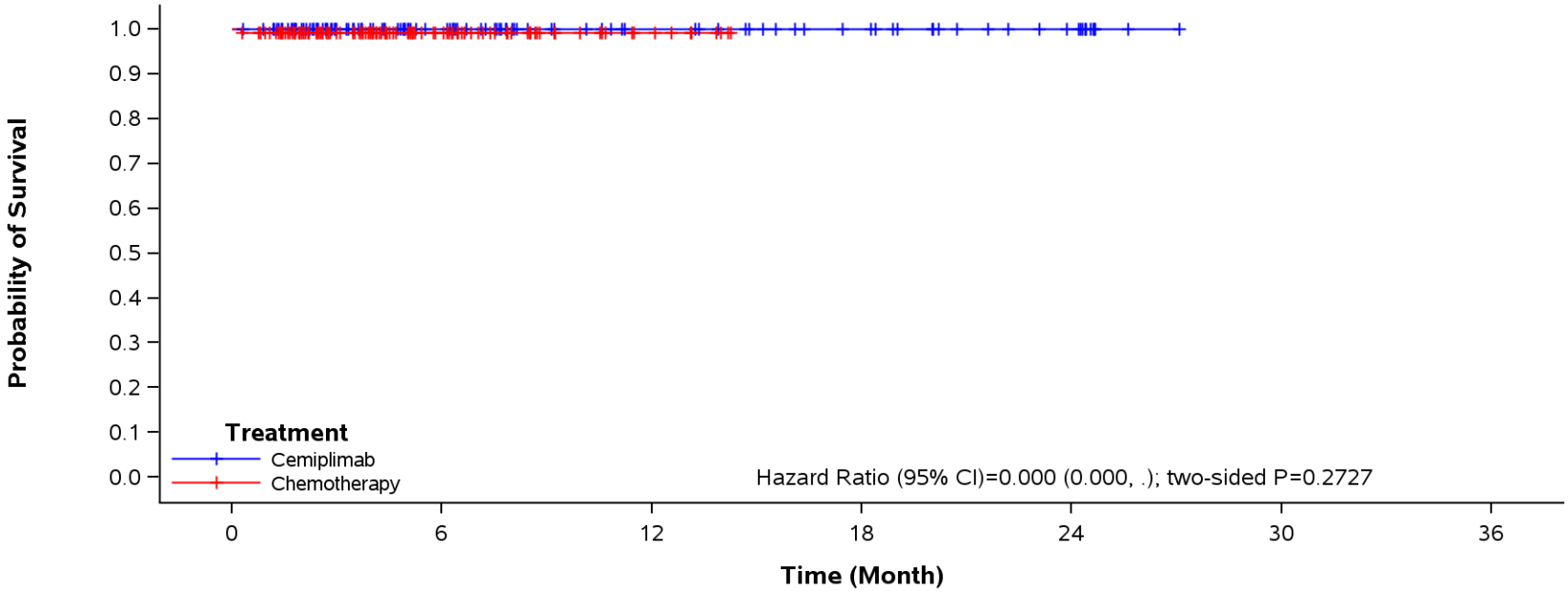

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: General disorders and administration site conditions
PT: Malaise



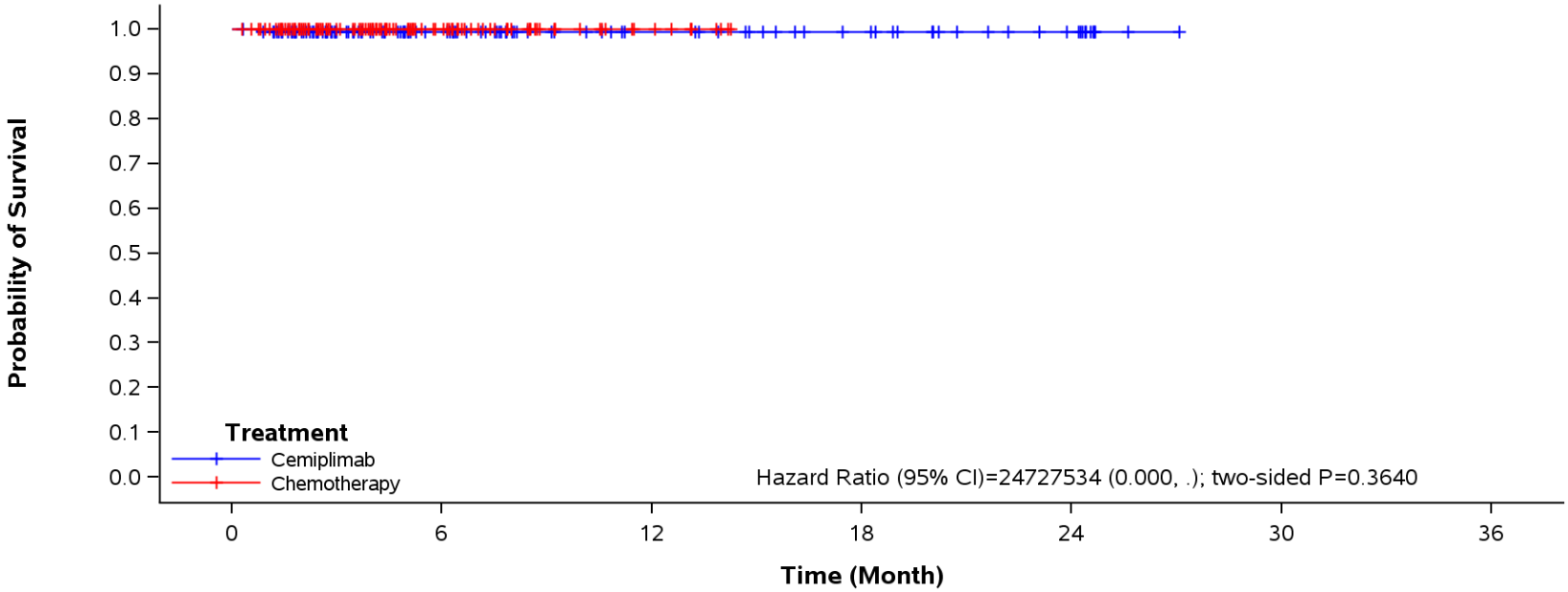

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



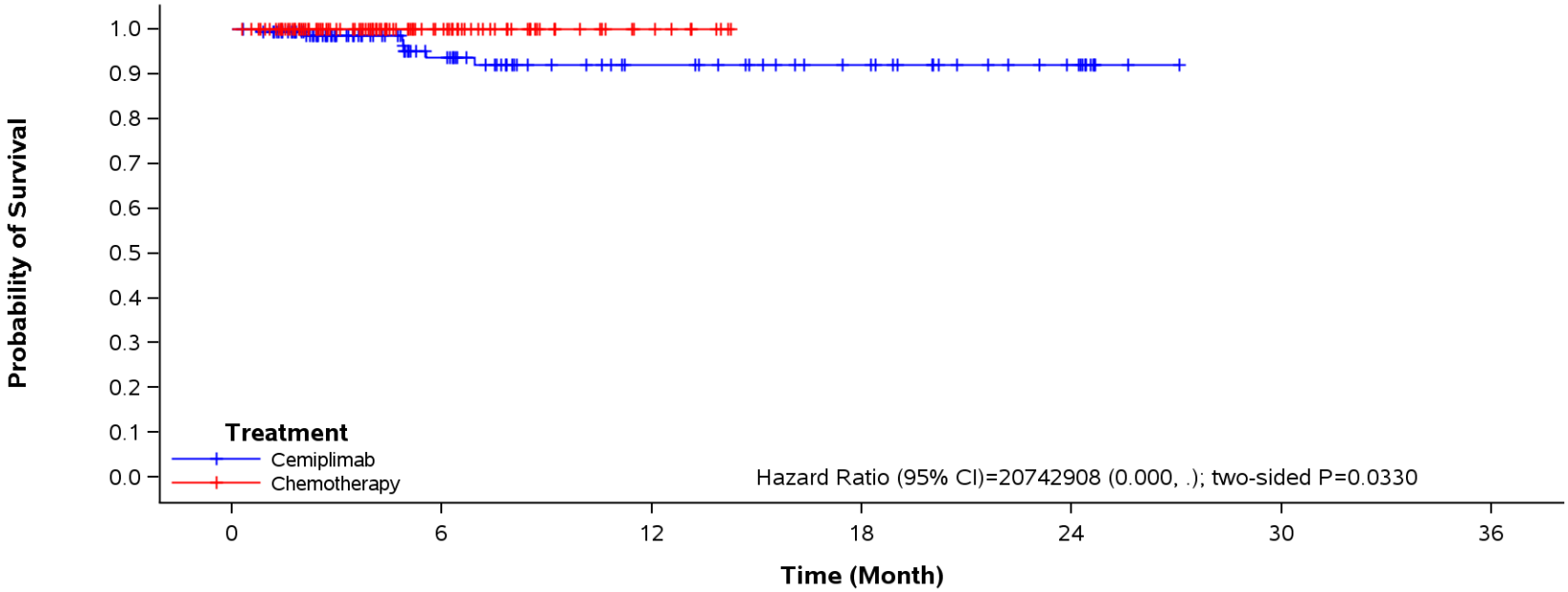

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Hepatobiliary disorders



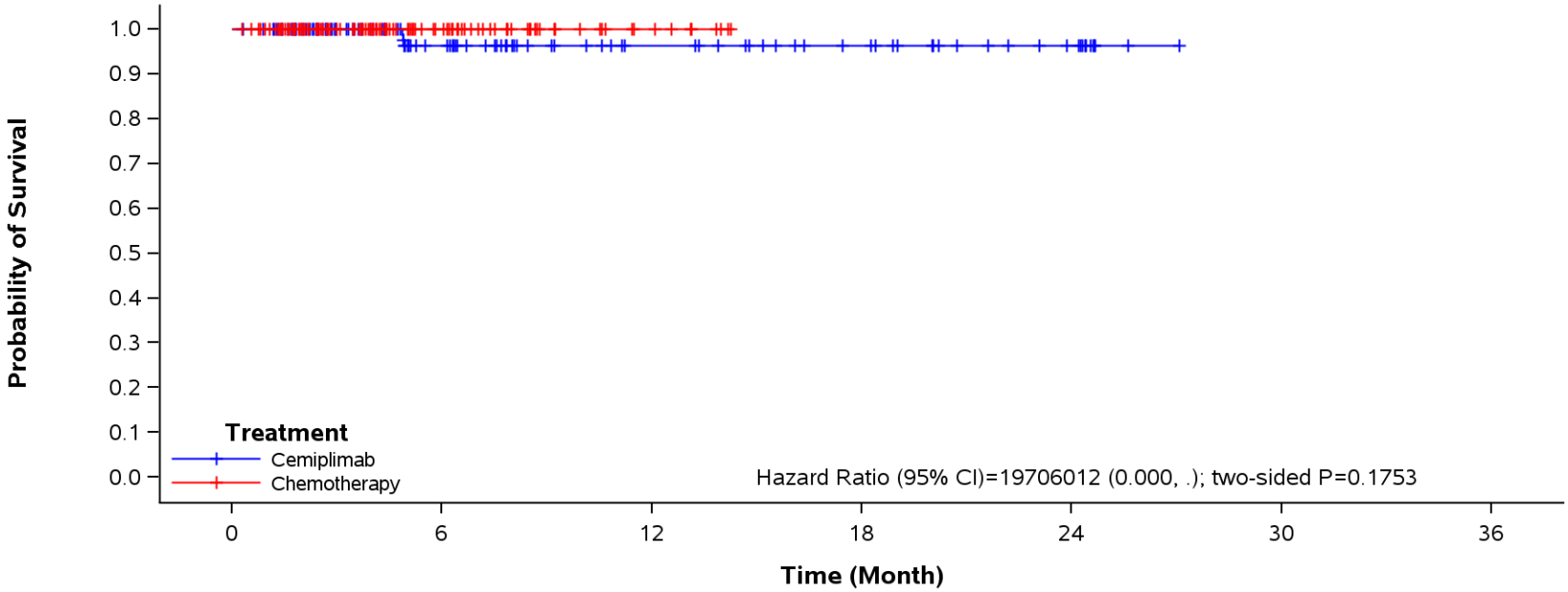

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 69 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



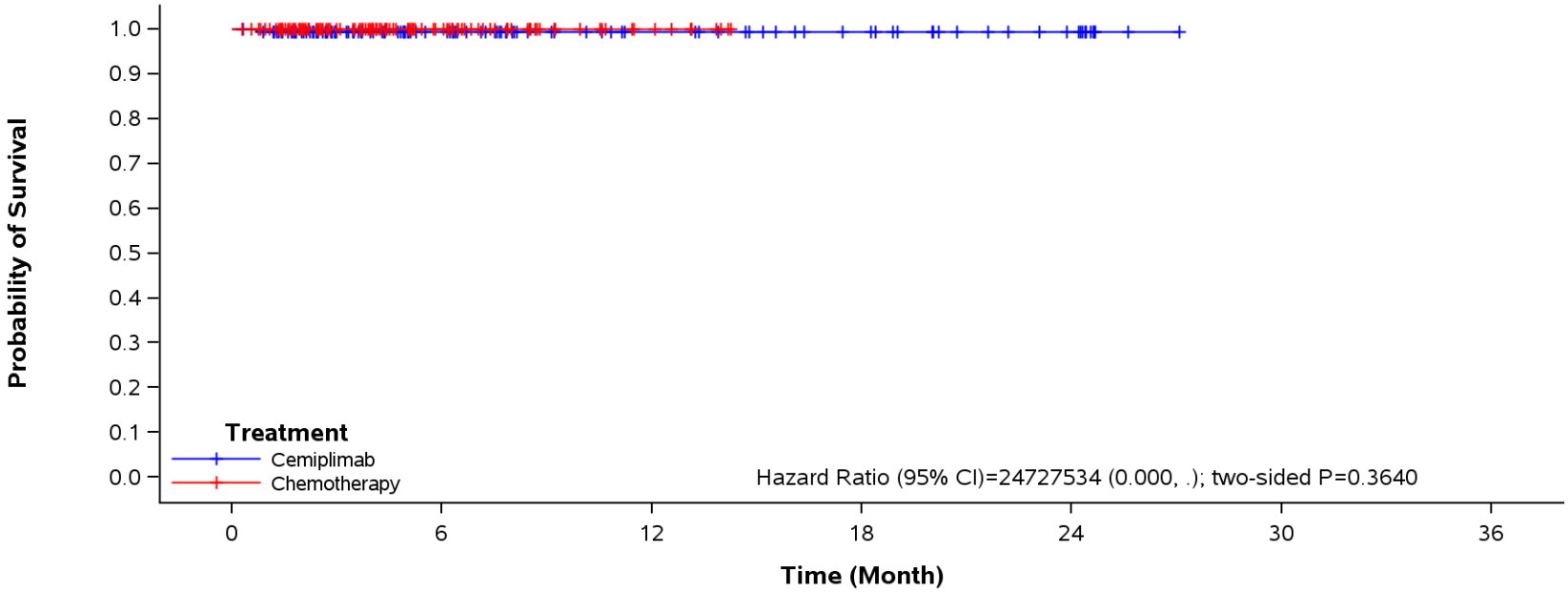

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 70 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



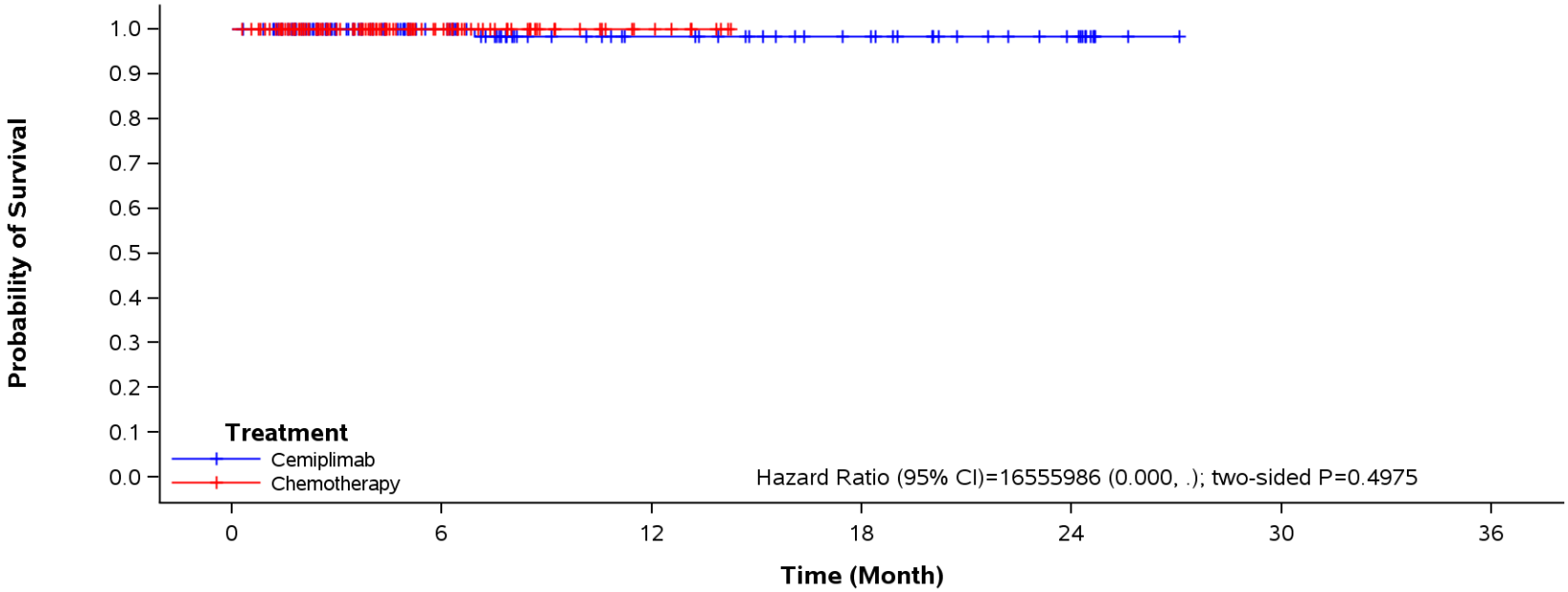

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Hepatobiliary disorders
PT: Hepatitis



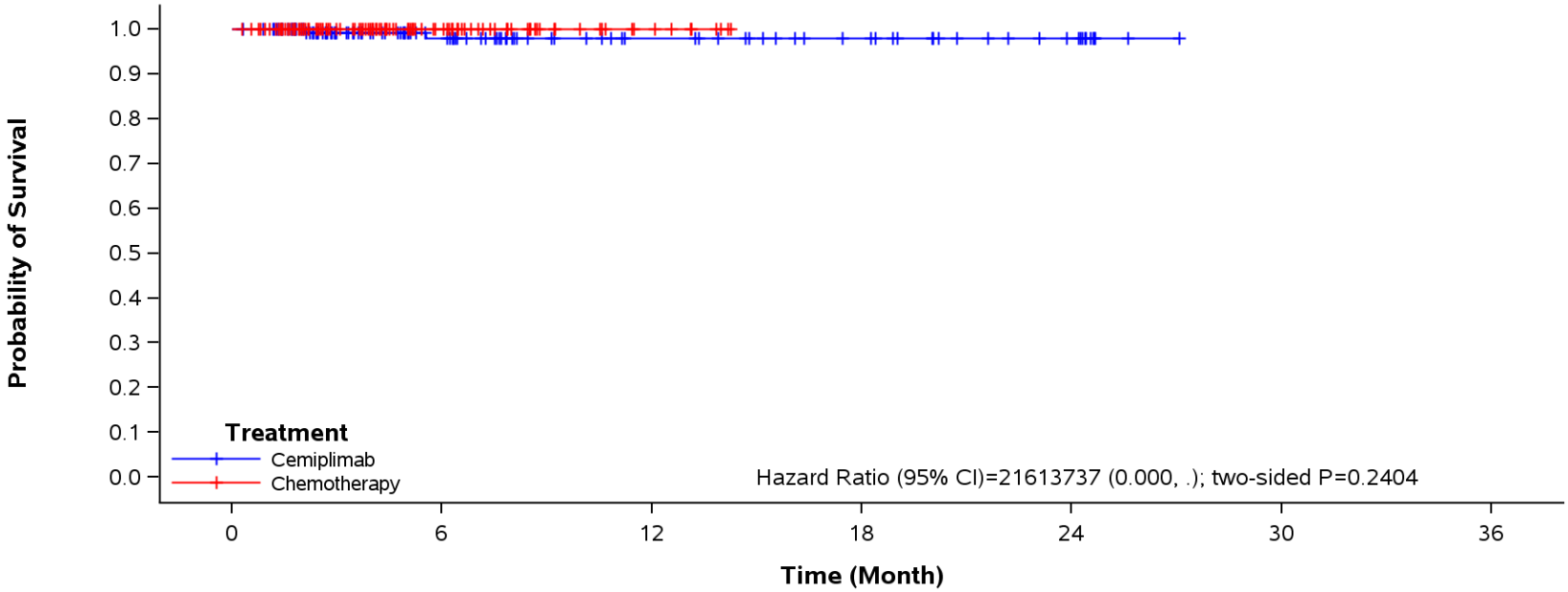

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



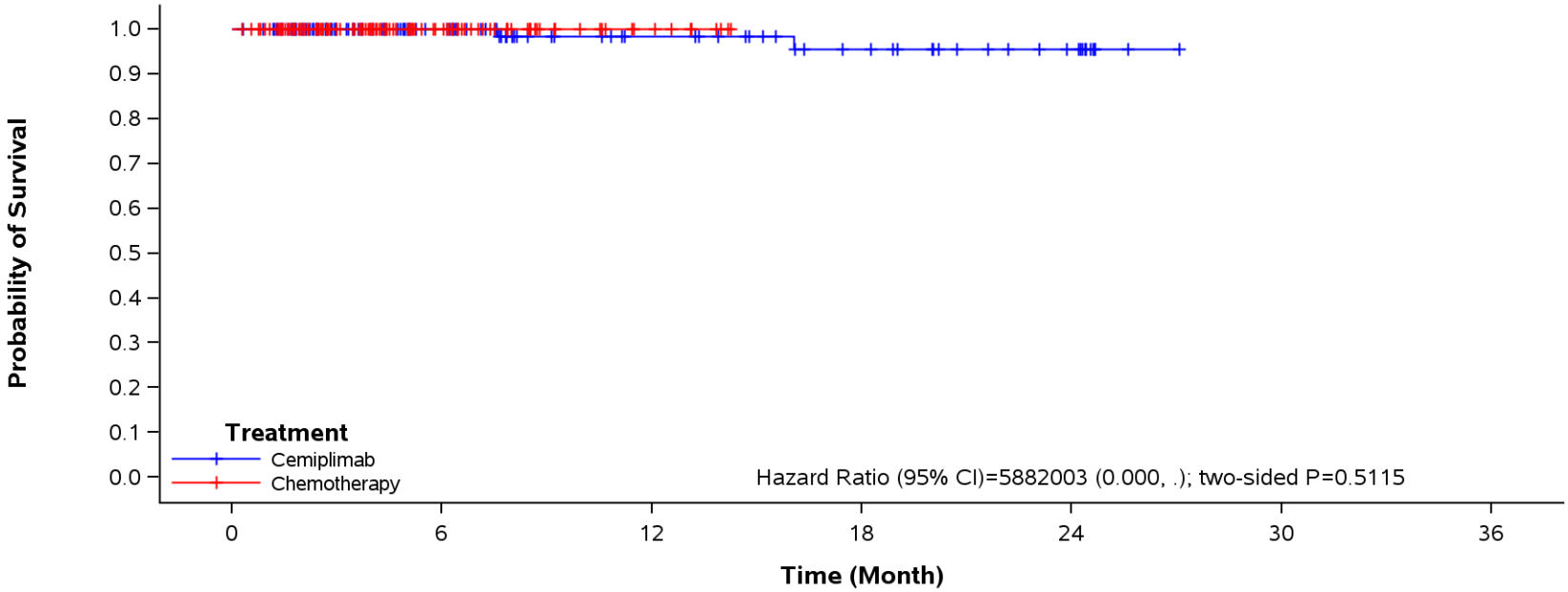

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 72 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Infections and infestations



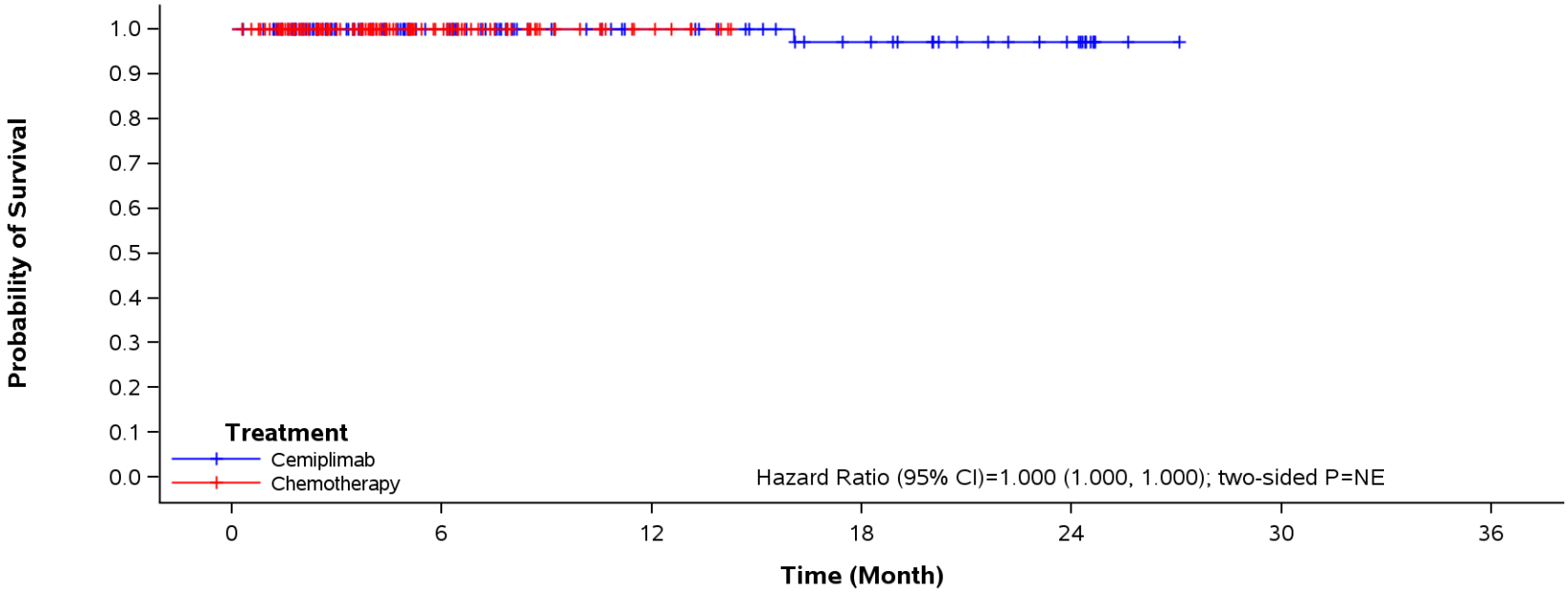

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 31 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Infections and infestations
PT: COVID-19 pneumonia



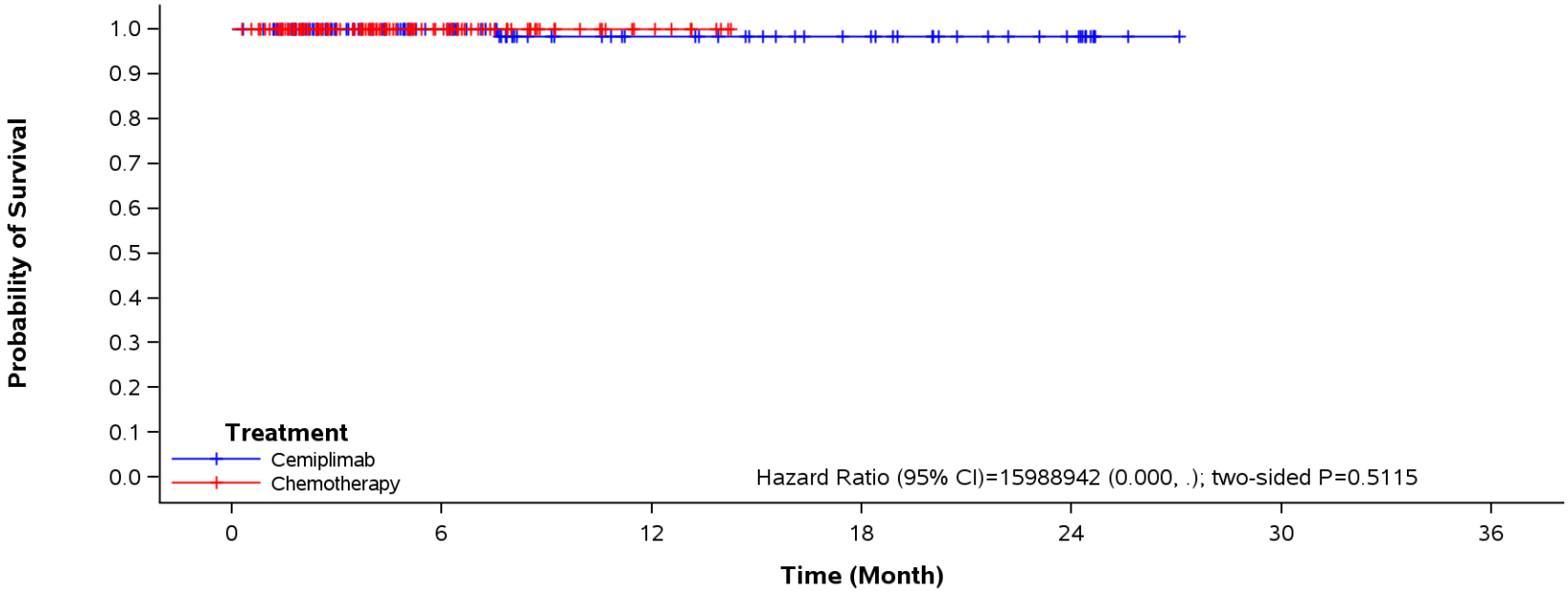

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 31 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Infections and infestations
PT: Gastroenteritis



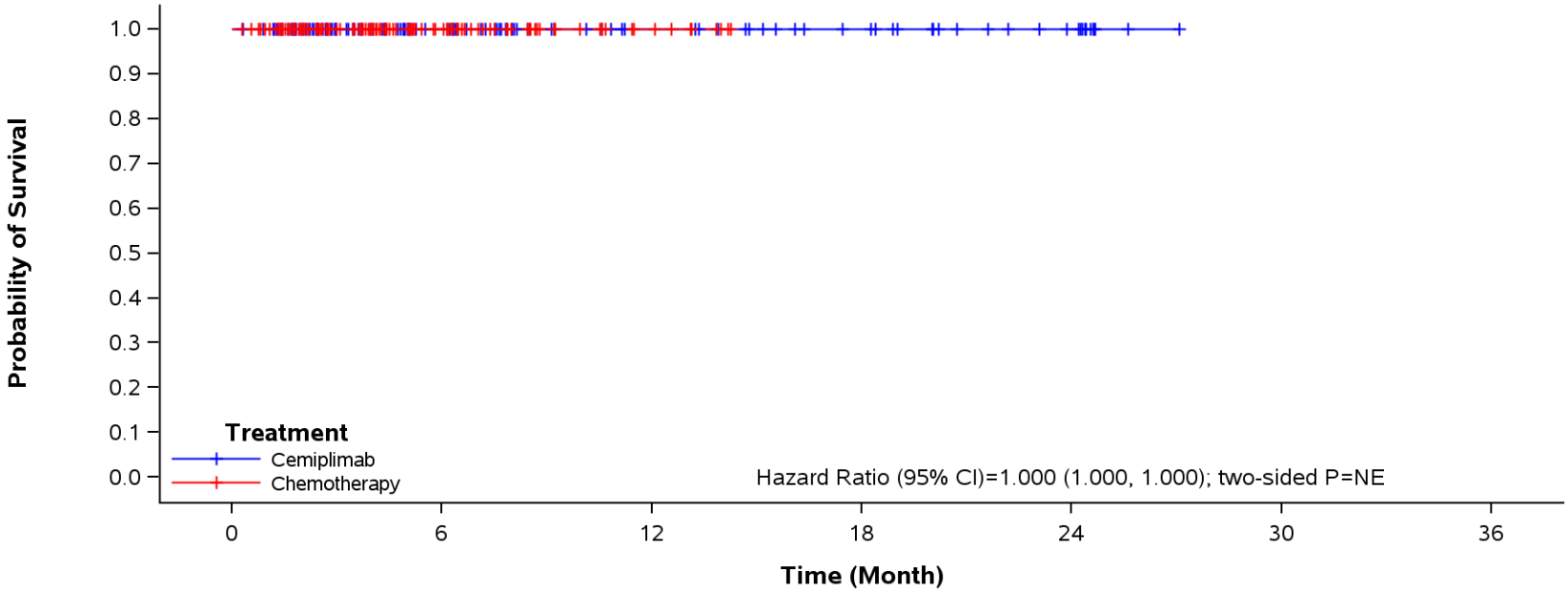

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Infections and infestations
PT: Pelvic abscess



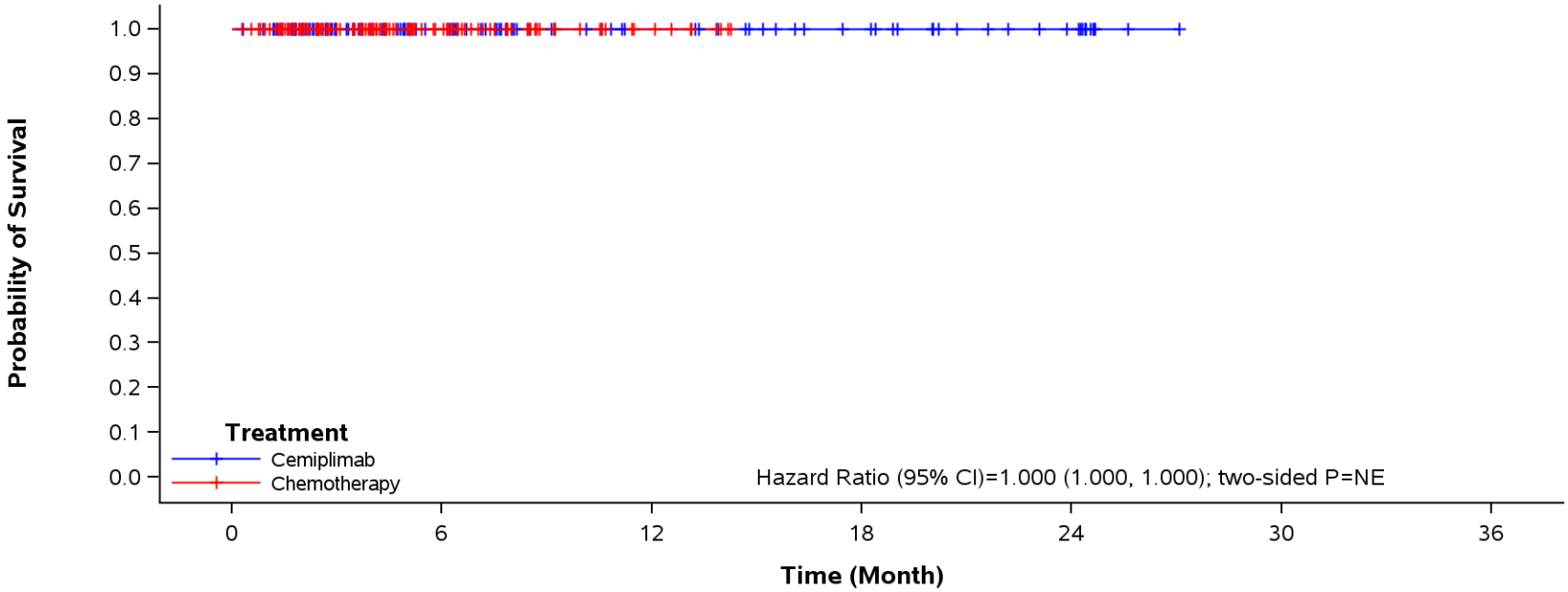

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Infections and infestations
PT: Peritonitis



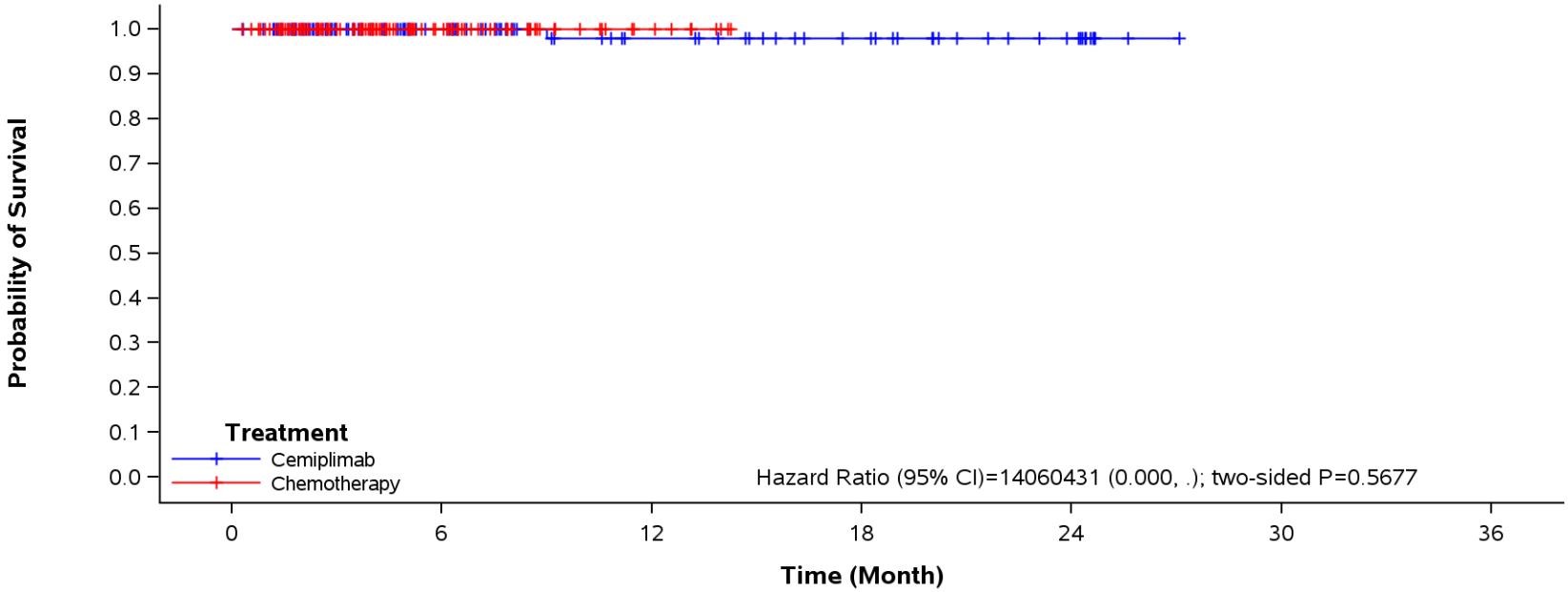

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Infections and infestations
PT: Pneumonia



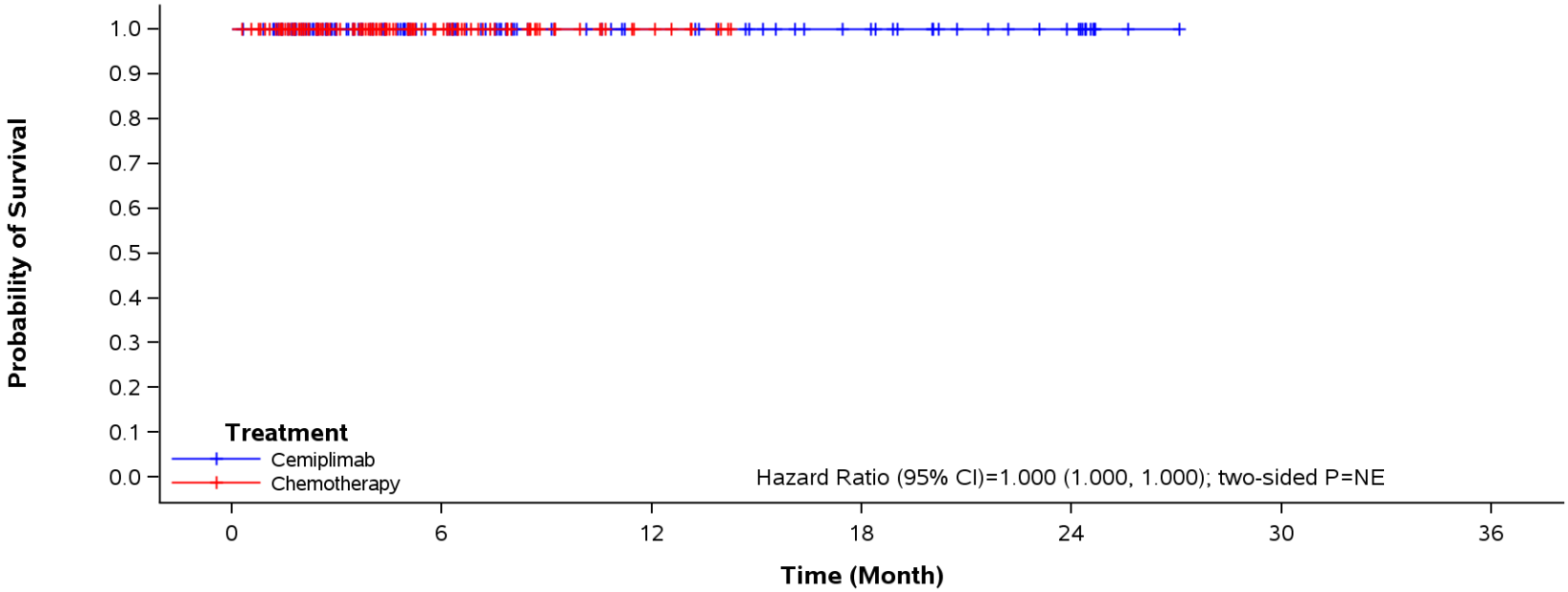

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Infections and infestations
PT: Pyomyositis



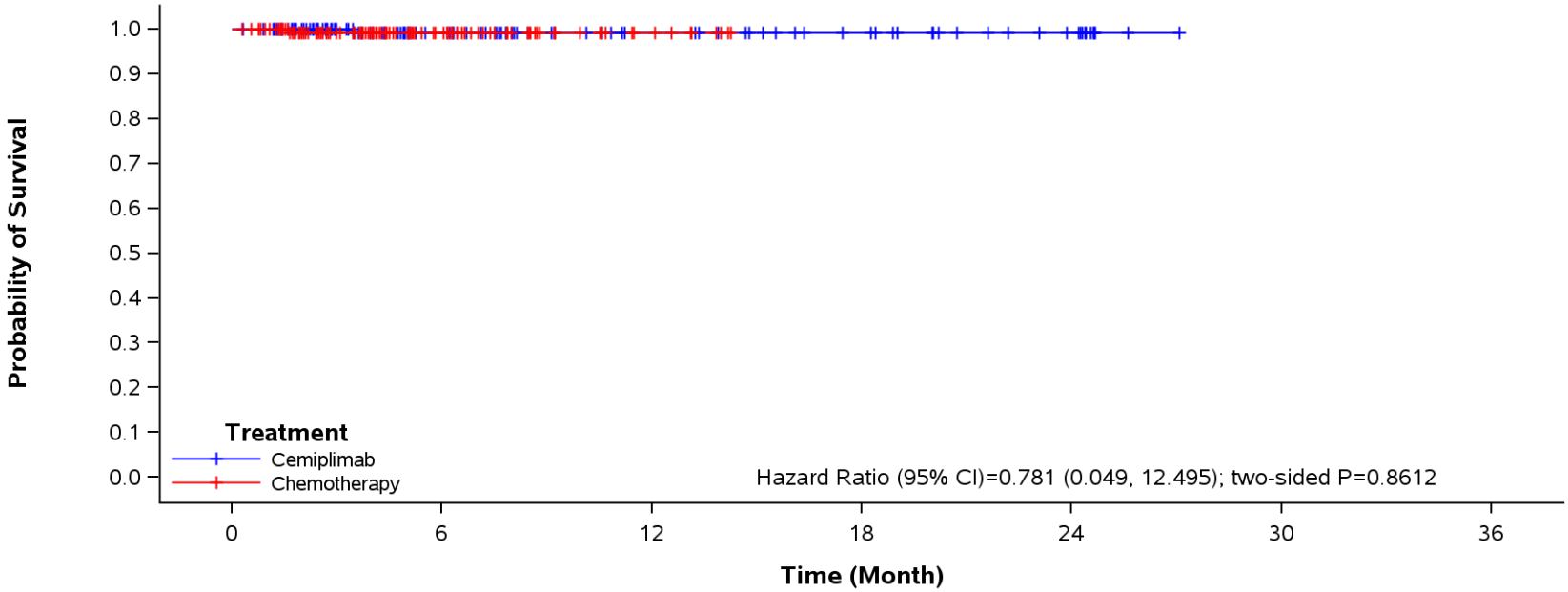

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Injury, poisoning and procedural complications



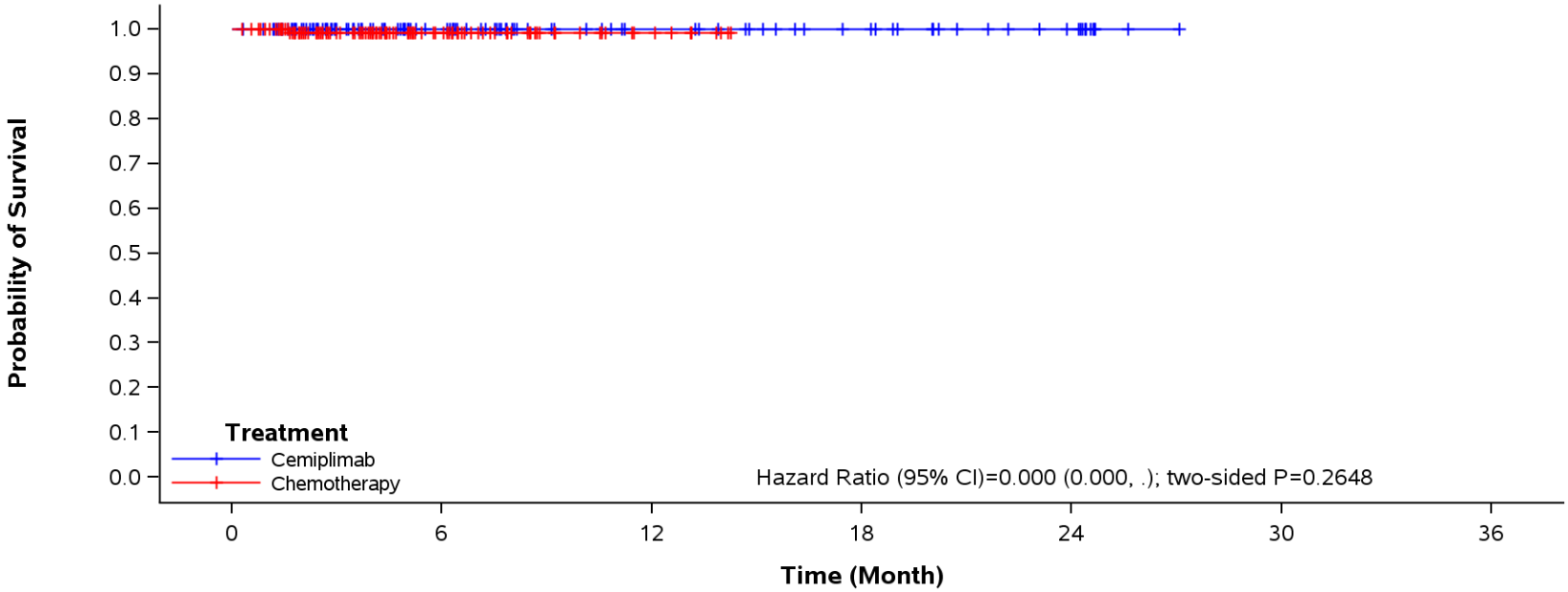

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 72 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



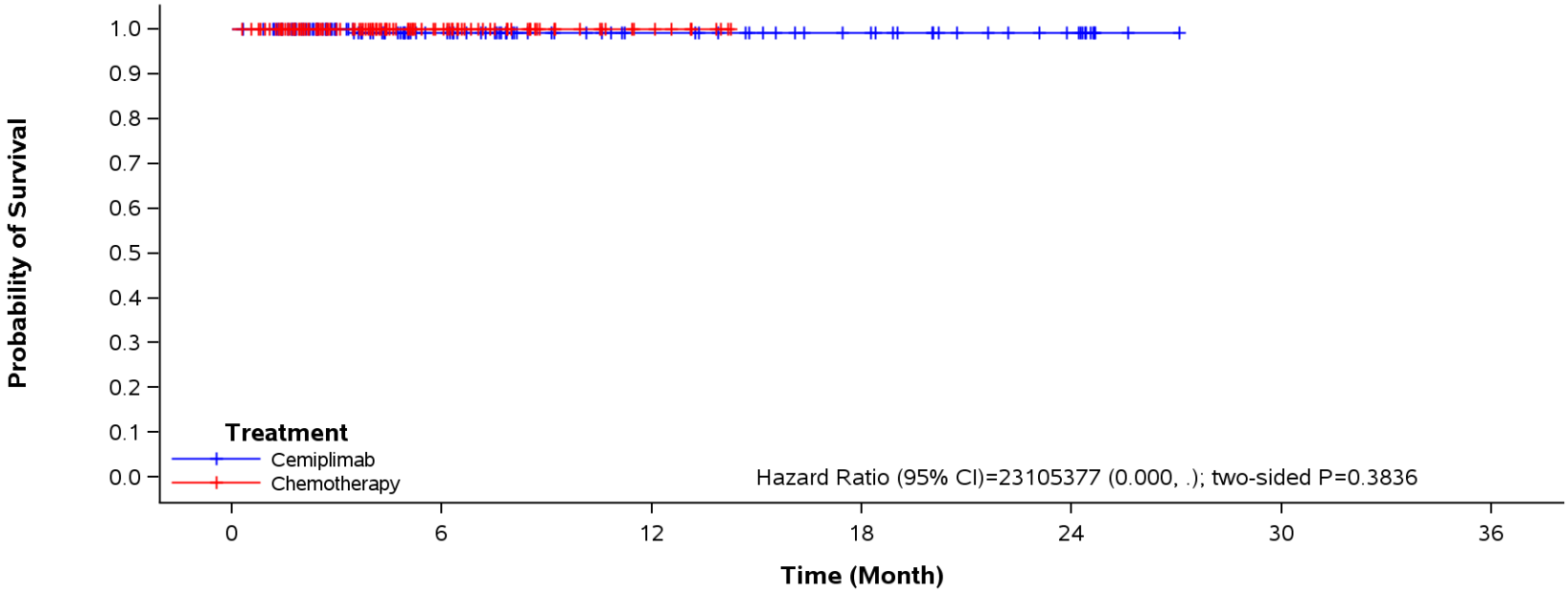

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



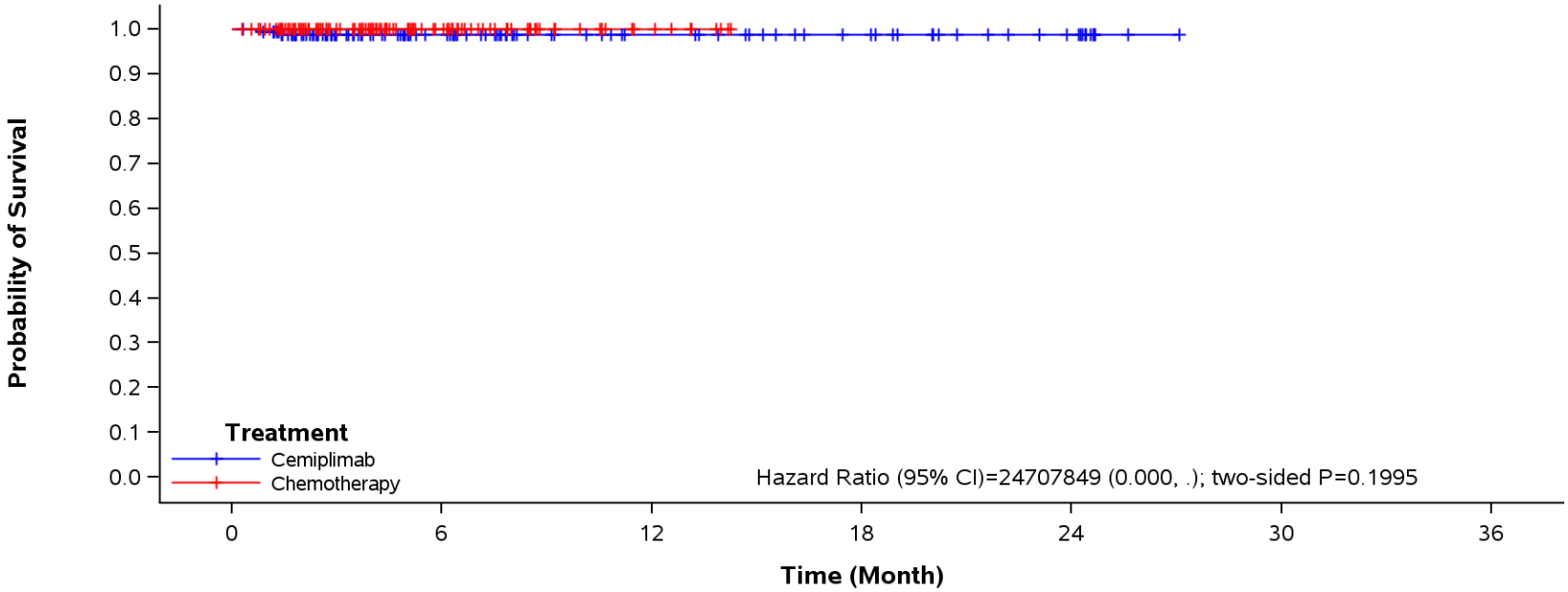

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 72 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Investigations



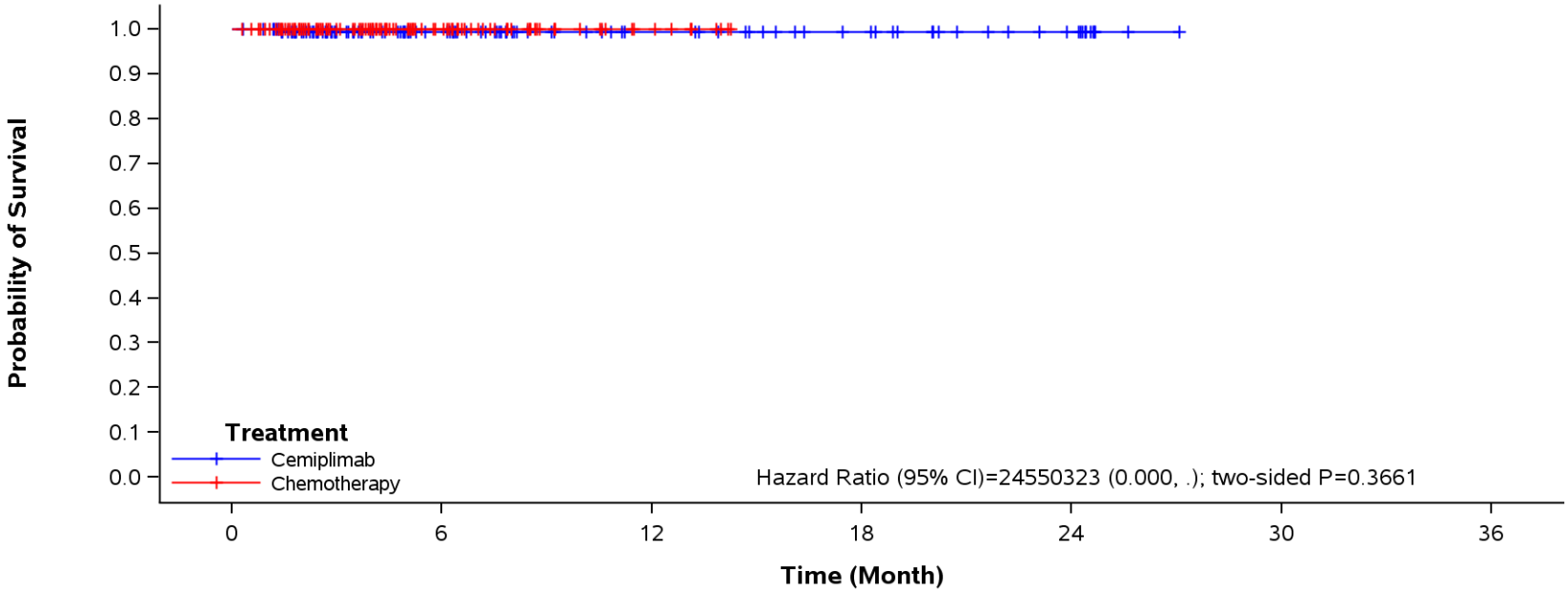

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Investigations
PT: Alanine aminotransferase increased



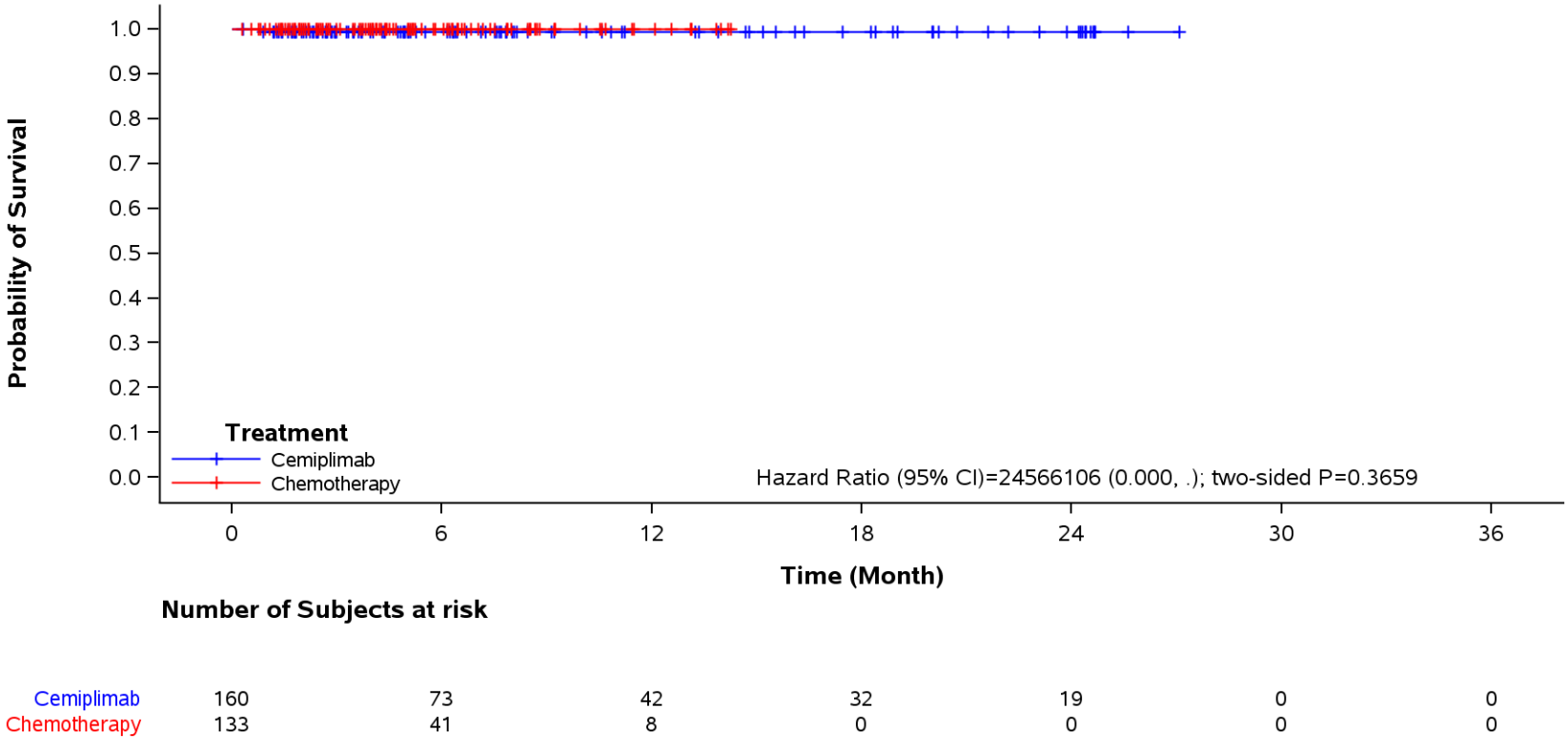

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

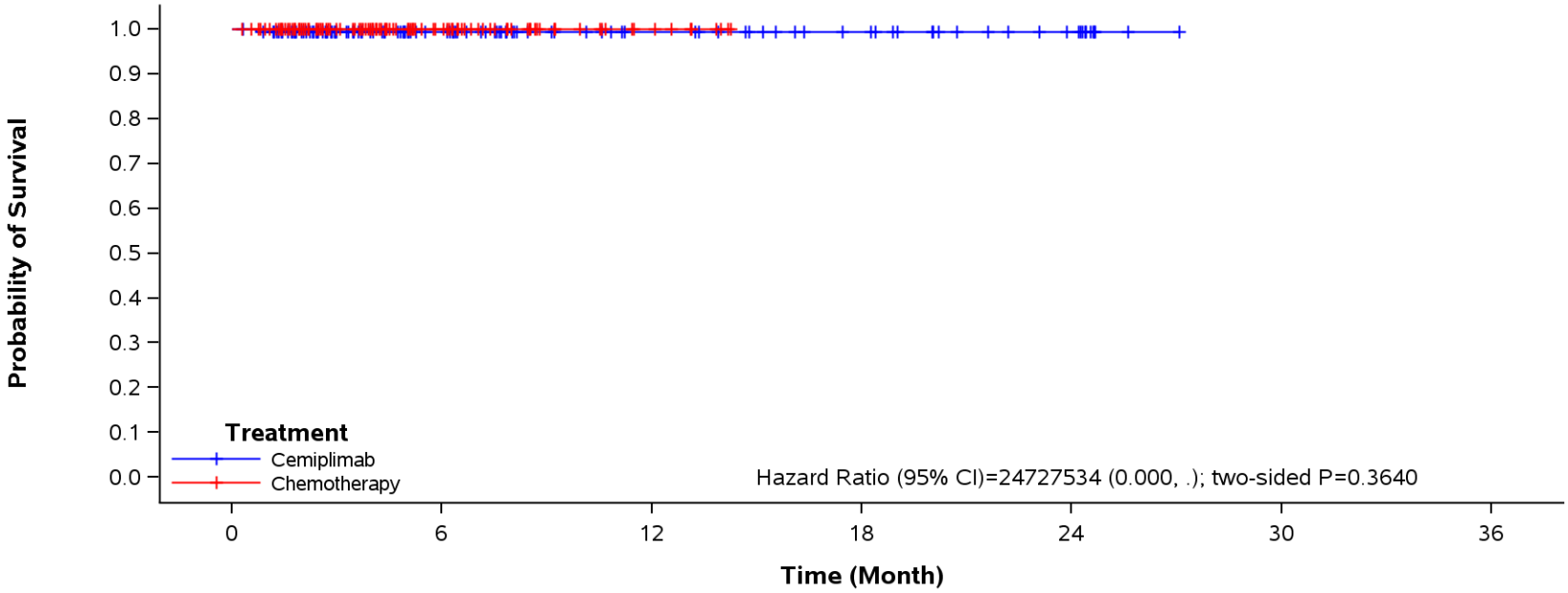
Histology: Squamous
SOC: Investigations
PT: Amylase increased




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Investigations
PT: Platelet count decreased



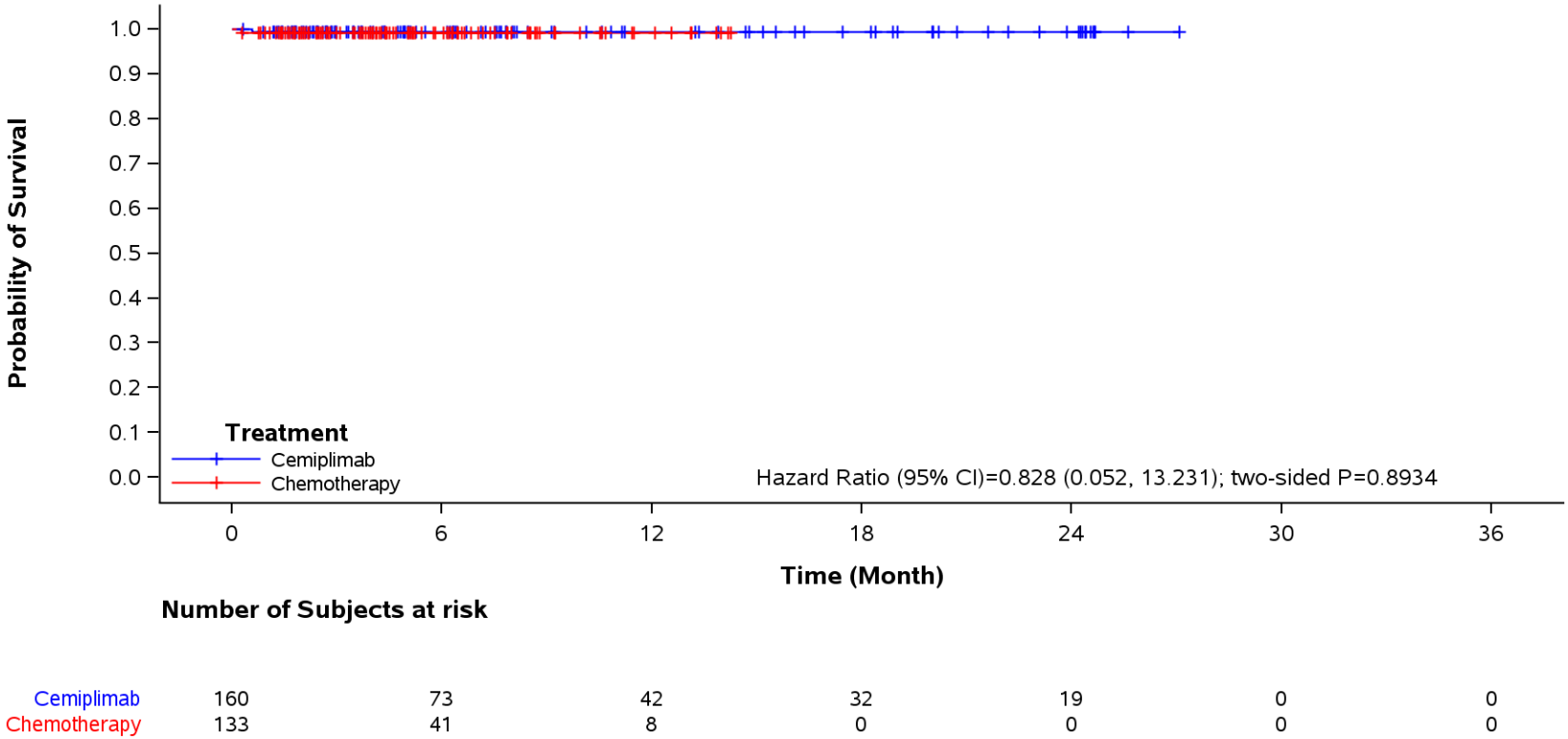

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

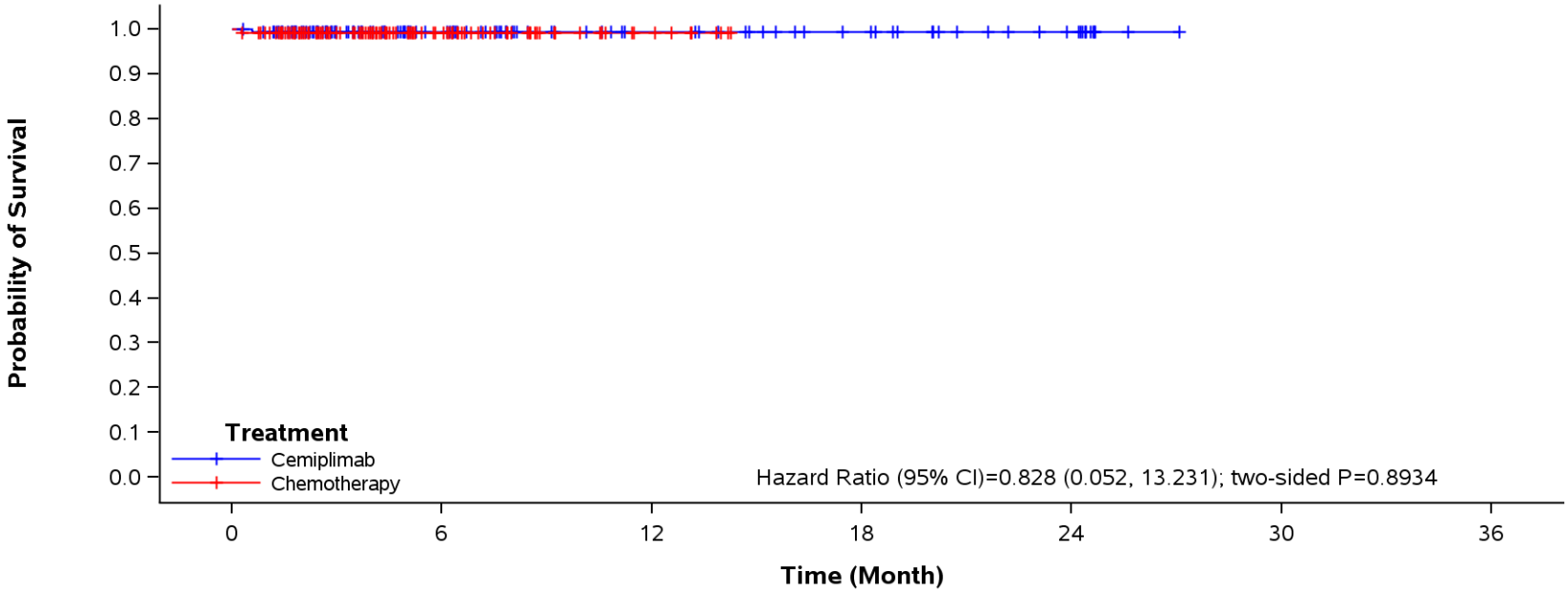
Histology: Squamous
SOC: Metabolism and nutrition disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



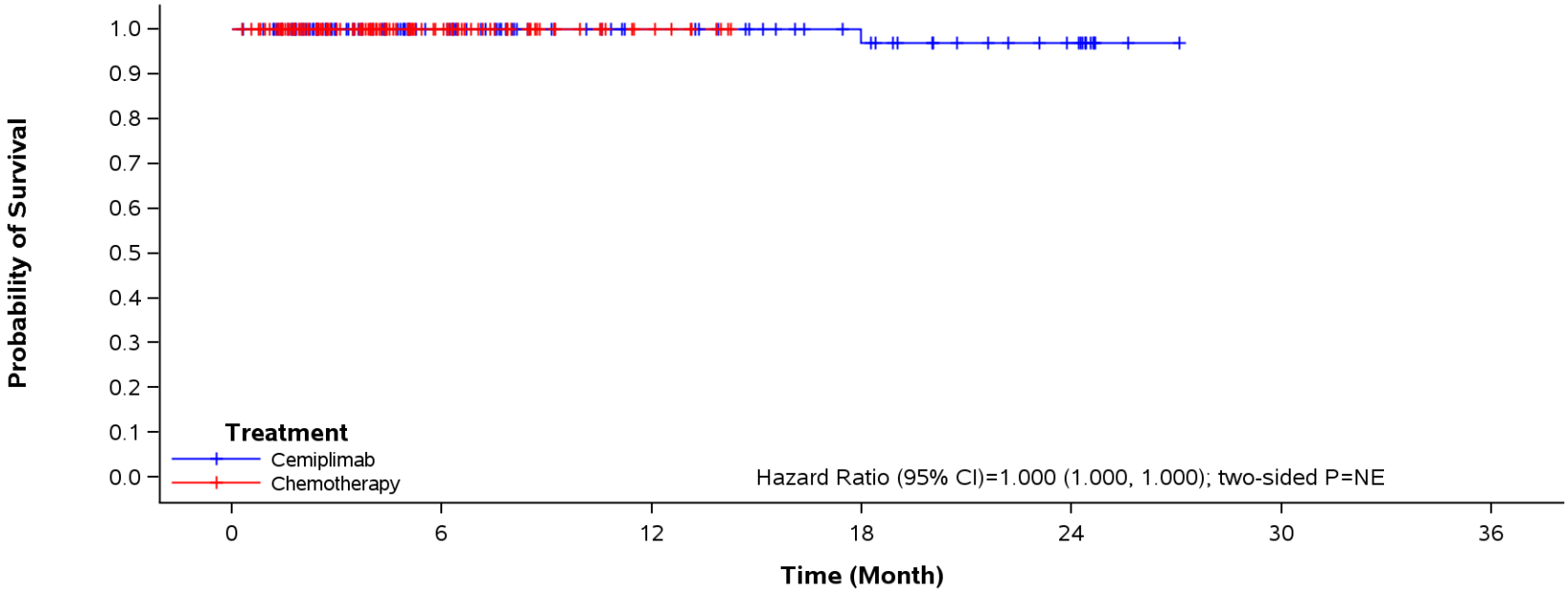

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Musculoskeletal and connective tissue disorders



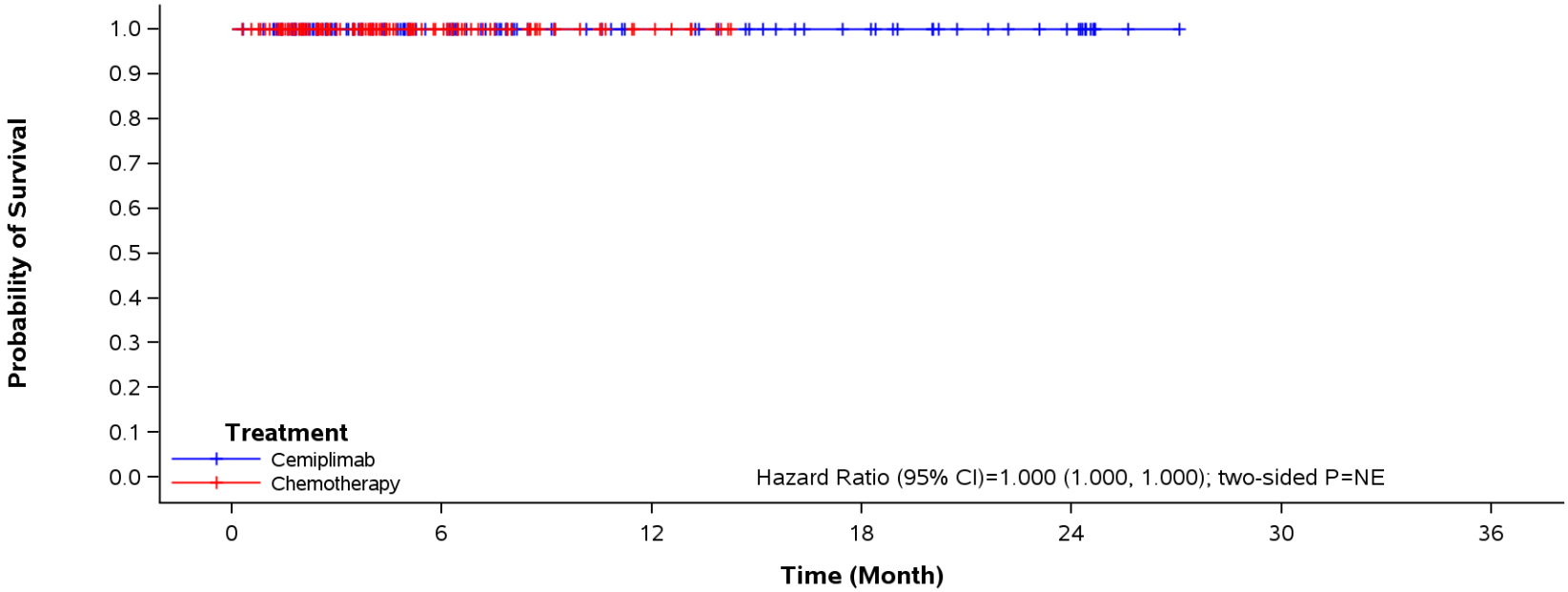

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 31 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



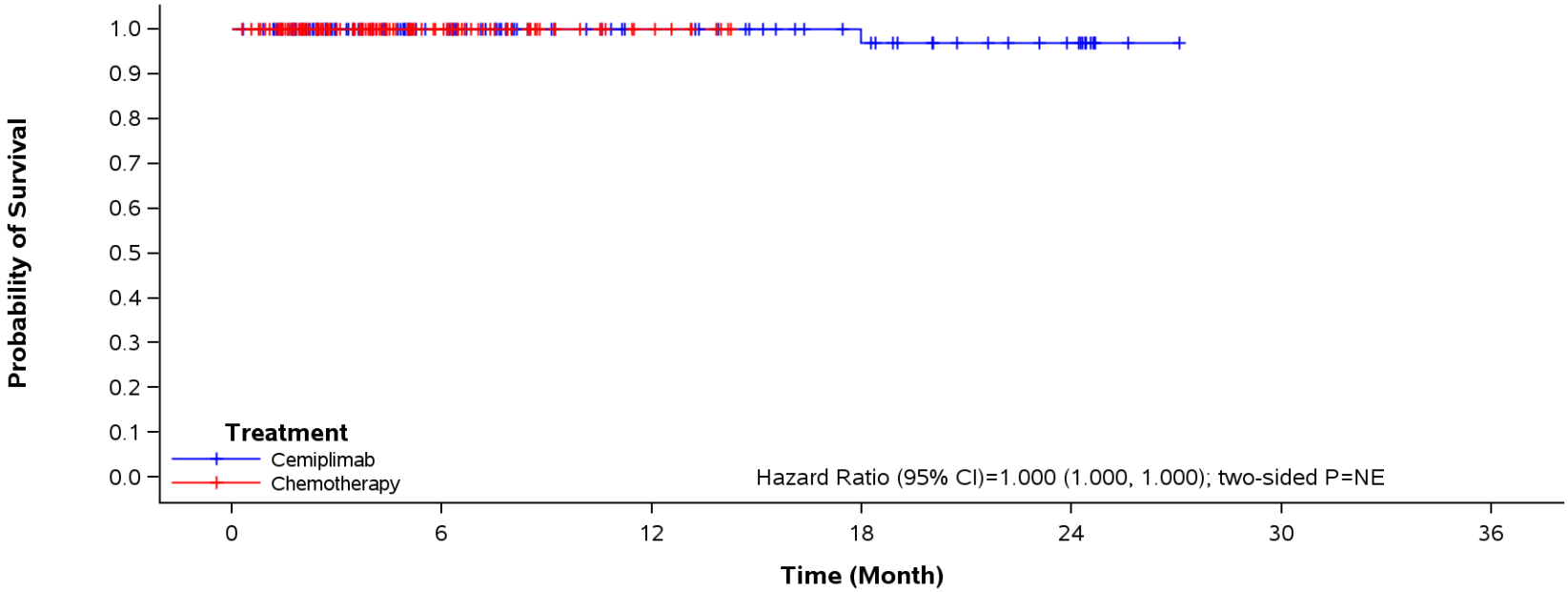

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



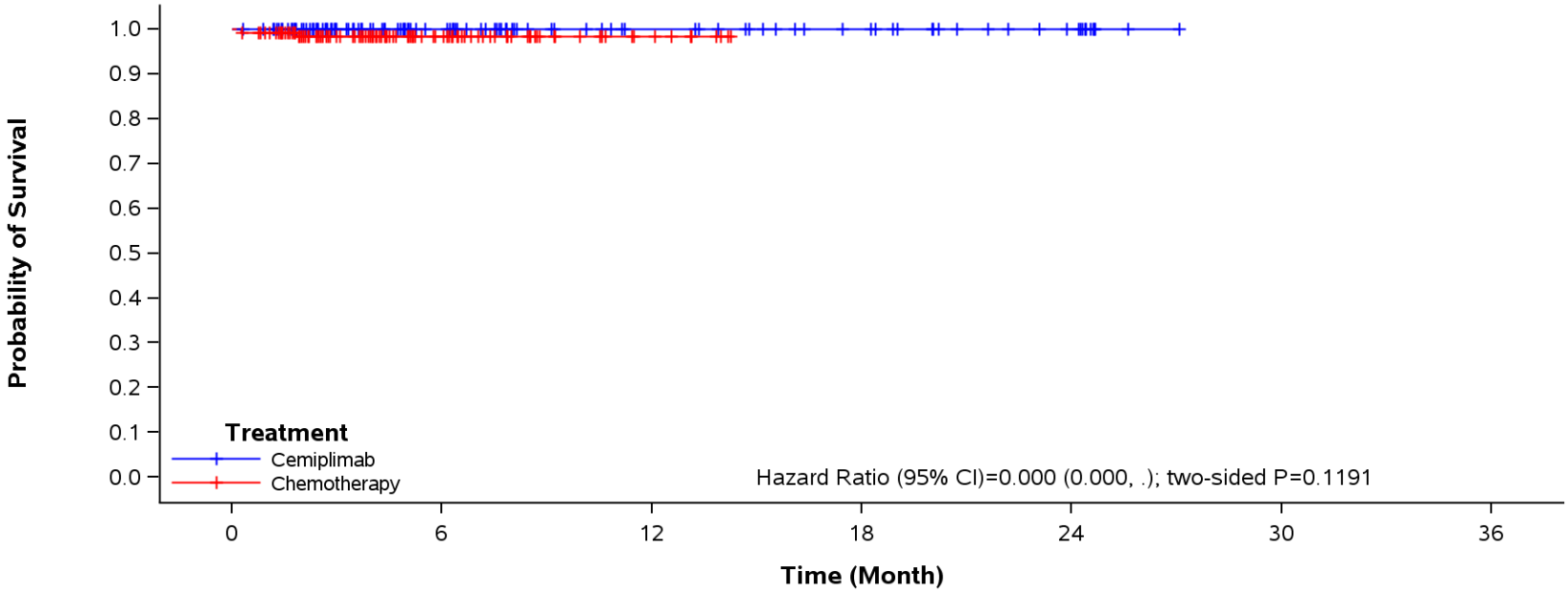

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 31 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Nervous system disorders



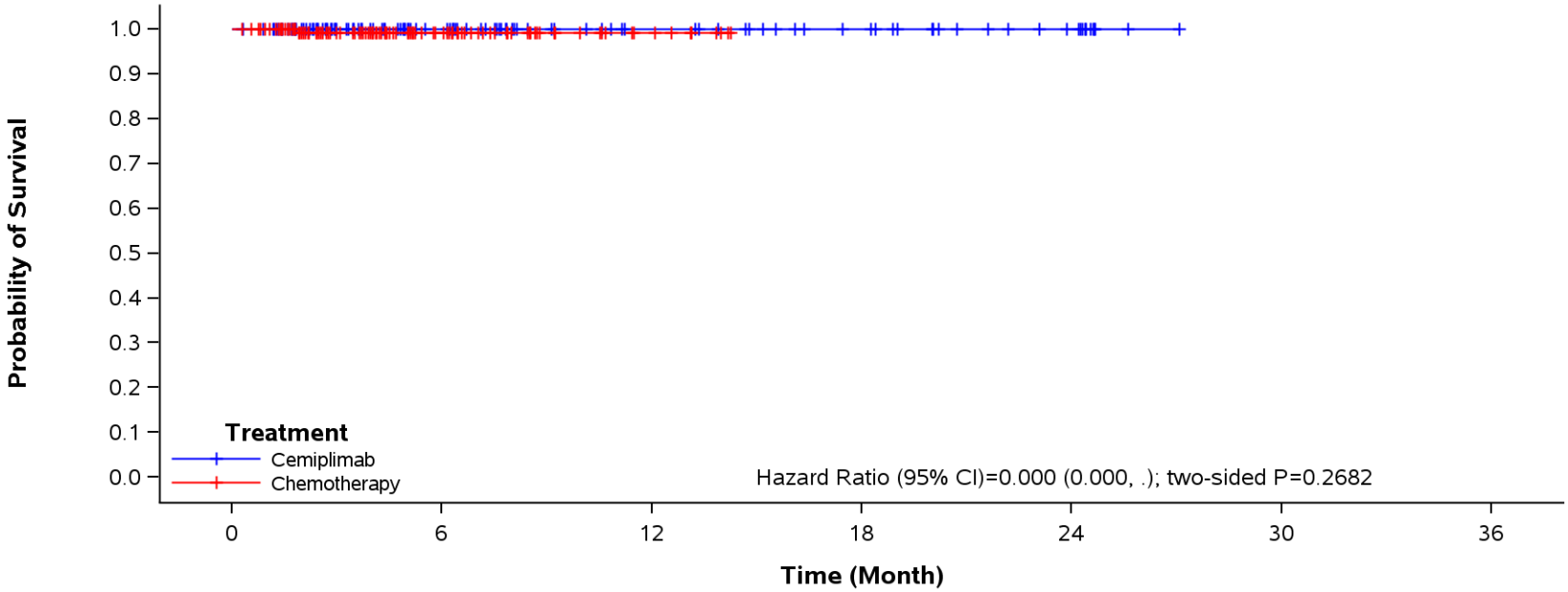

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Nervous system disorders
PT: Neurotoxicity



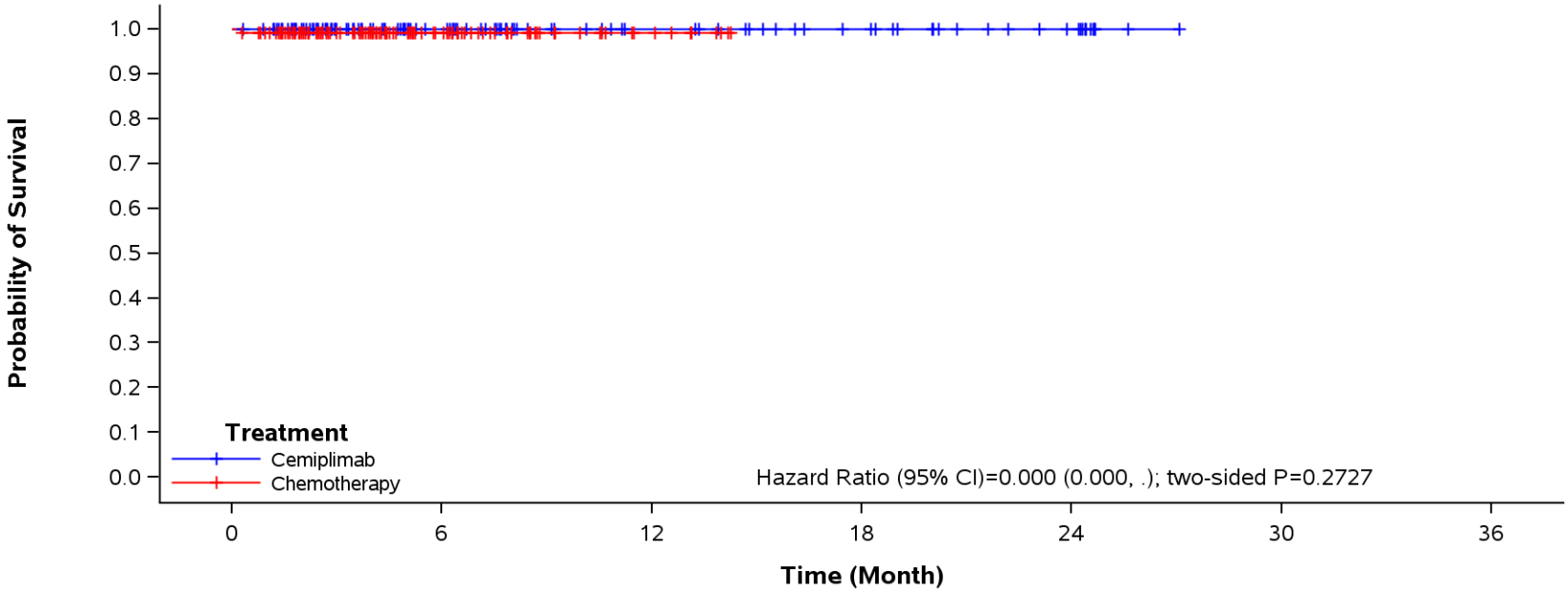

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Nervous system disorders
PT: Transient ischaemic attack



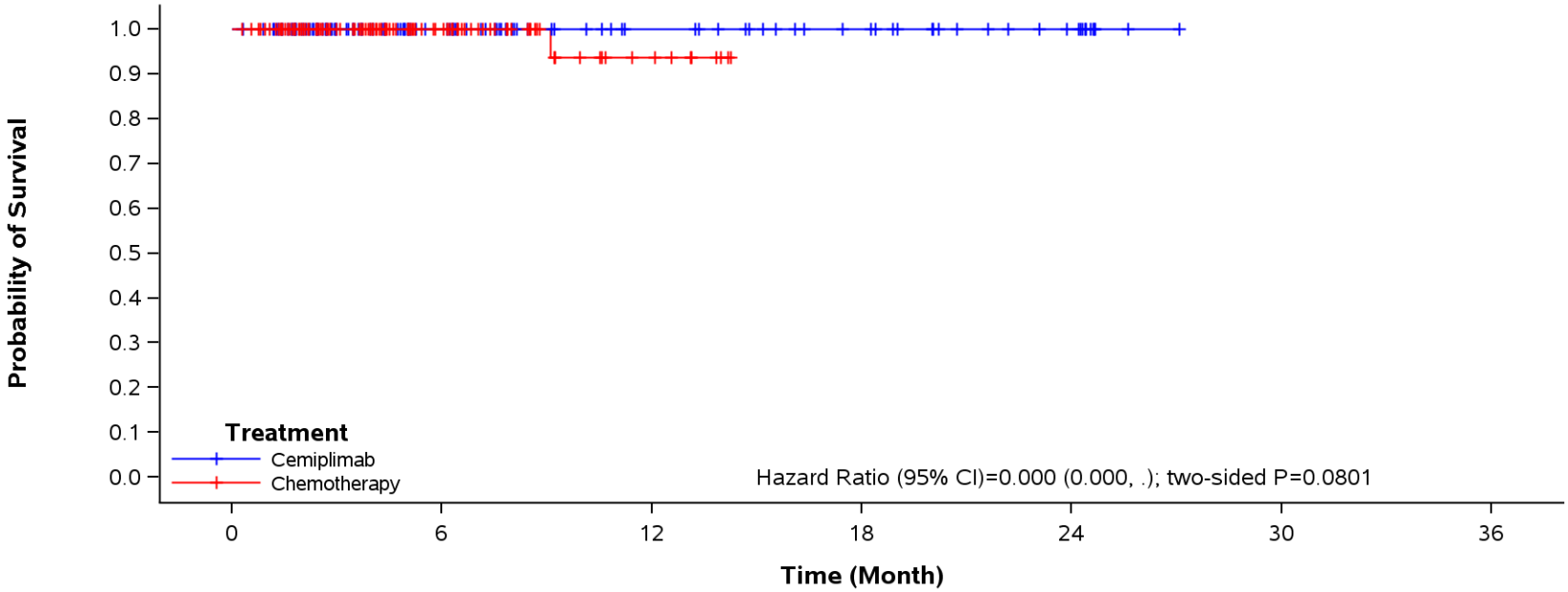

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Psychiatric disorders



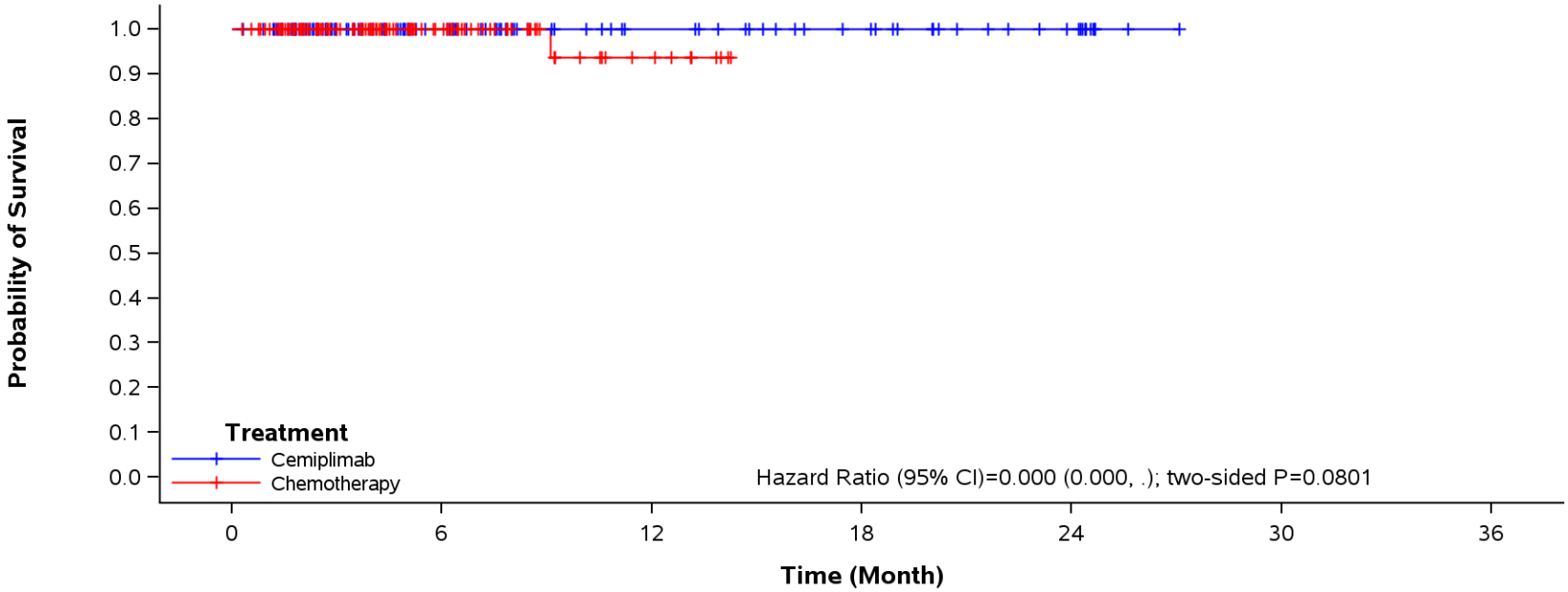

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Psychiatric disorders
PT: Agoraphobia



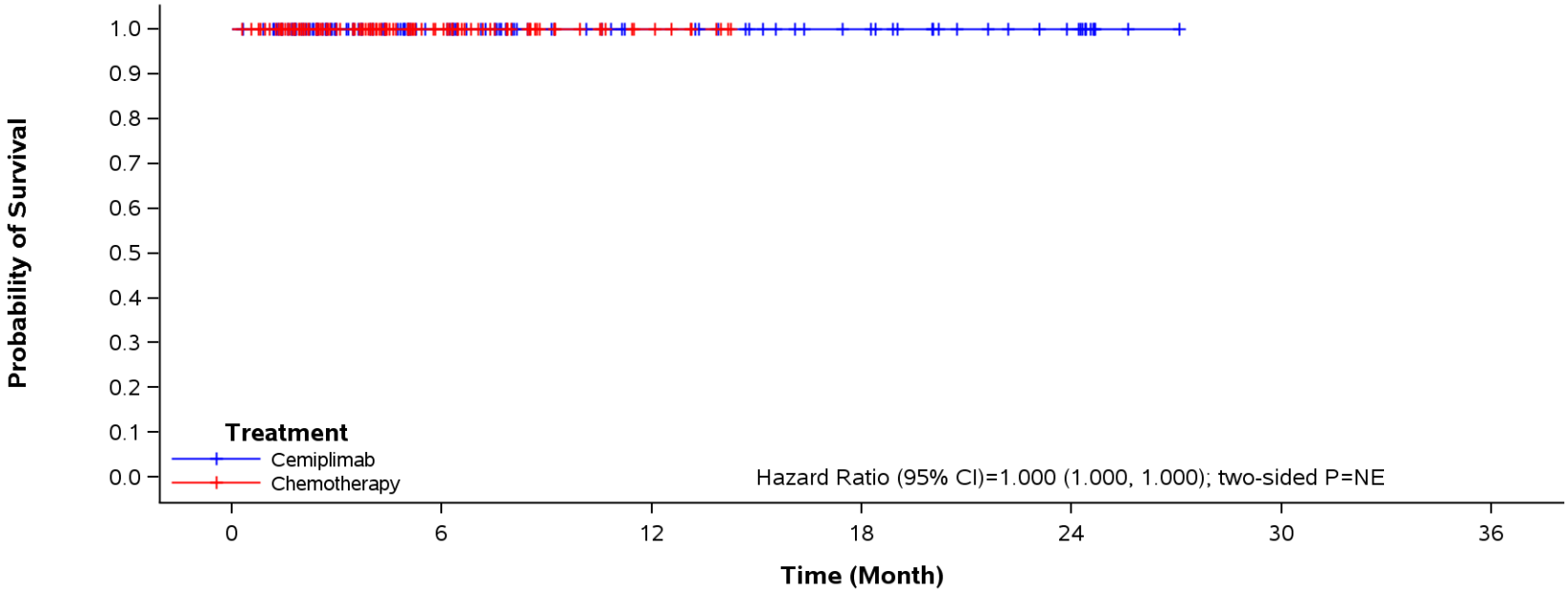

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Renal and urinary disorders



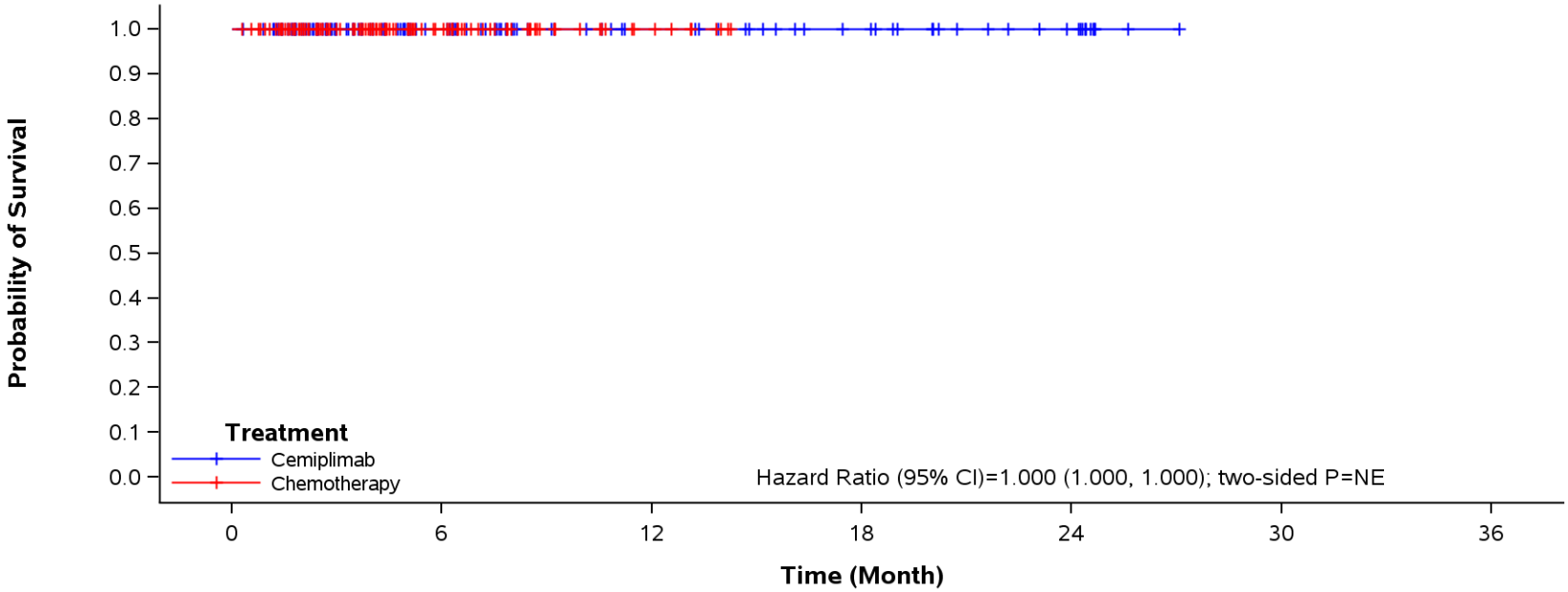

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Renal and urinary disorders
PT: Renal failure



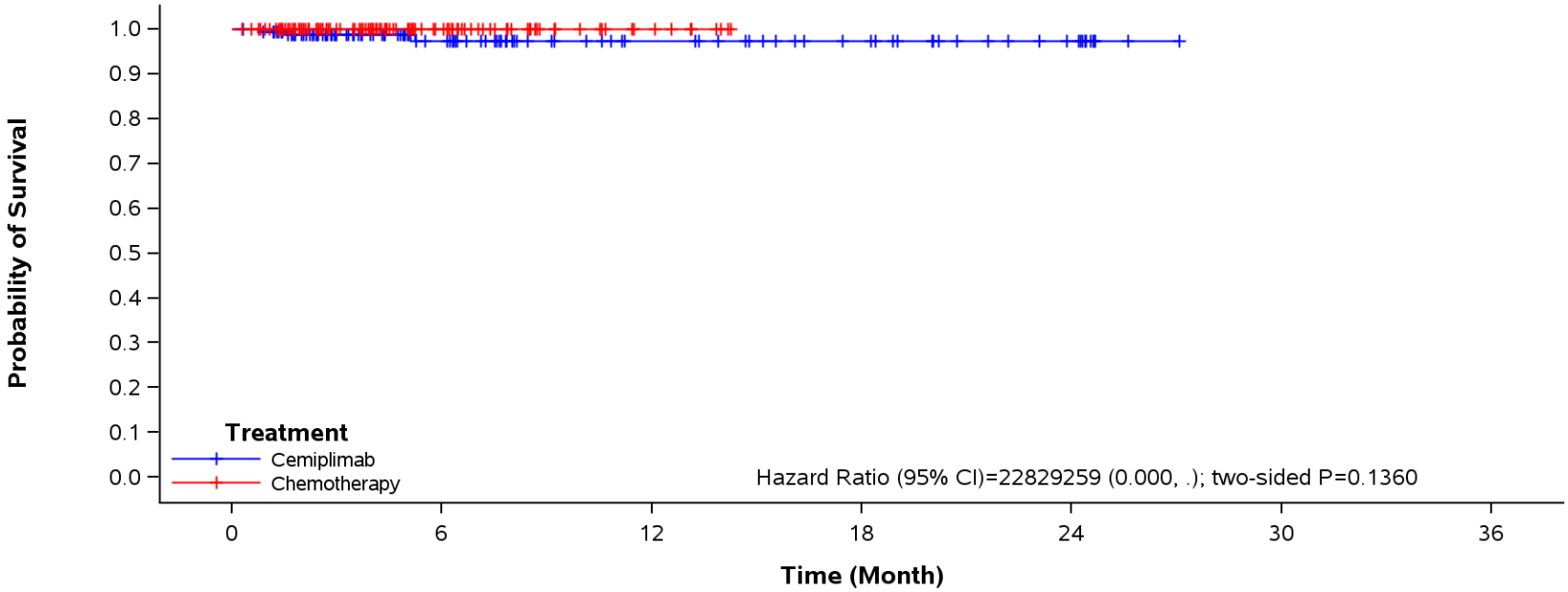

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Respiratory, thoracic and mediastinal disorders



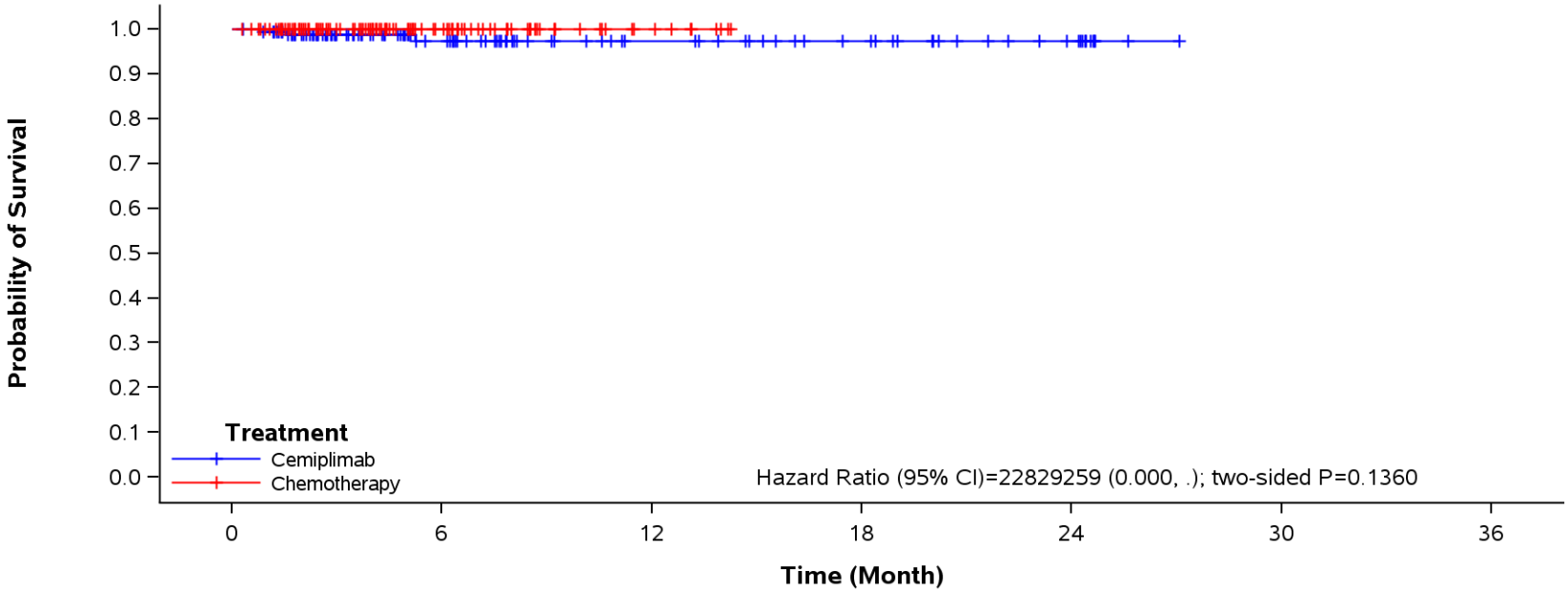

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 72 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



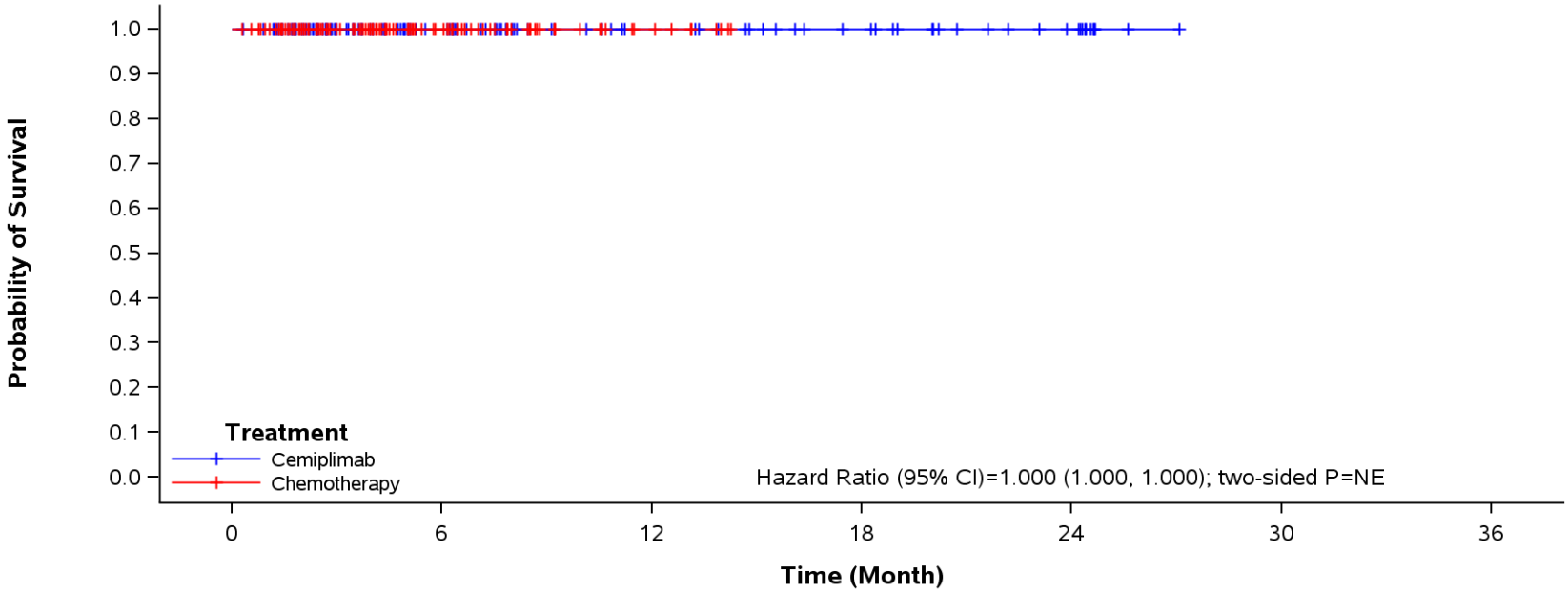

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 72 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Vascular disorders



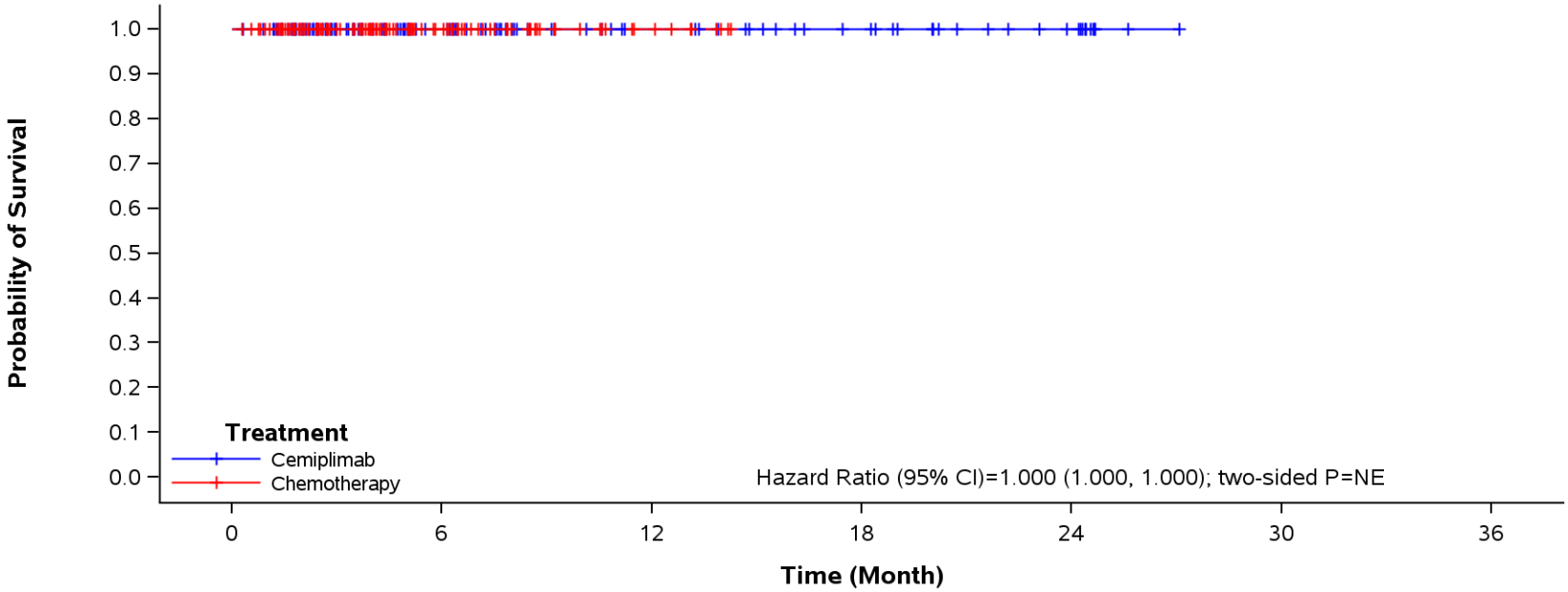

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Squamous
SOC: Vascular disorders
PT: Deep vein thrombosis



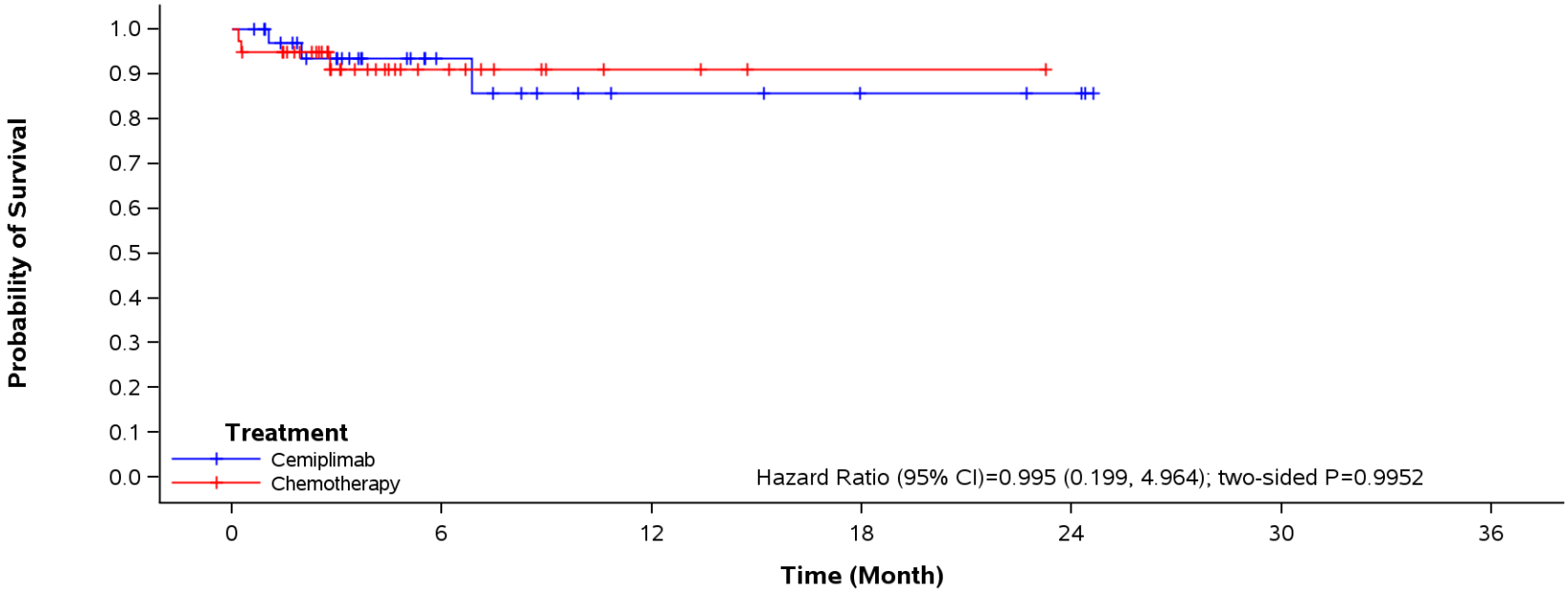

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 160 | 73 | 42 | 32 | 19 | 0 | 0 |
| Chemotherapy | 133 | 41 | 8 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
Number of patients with any TEAE leading to discontinuation



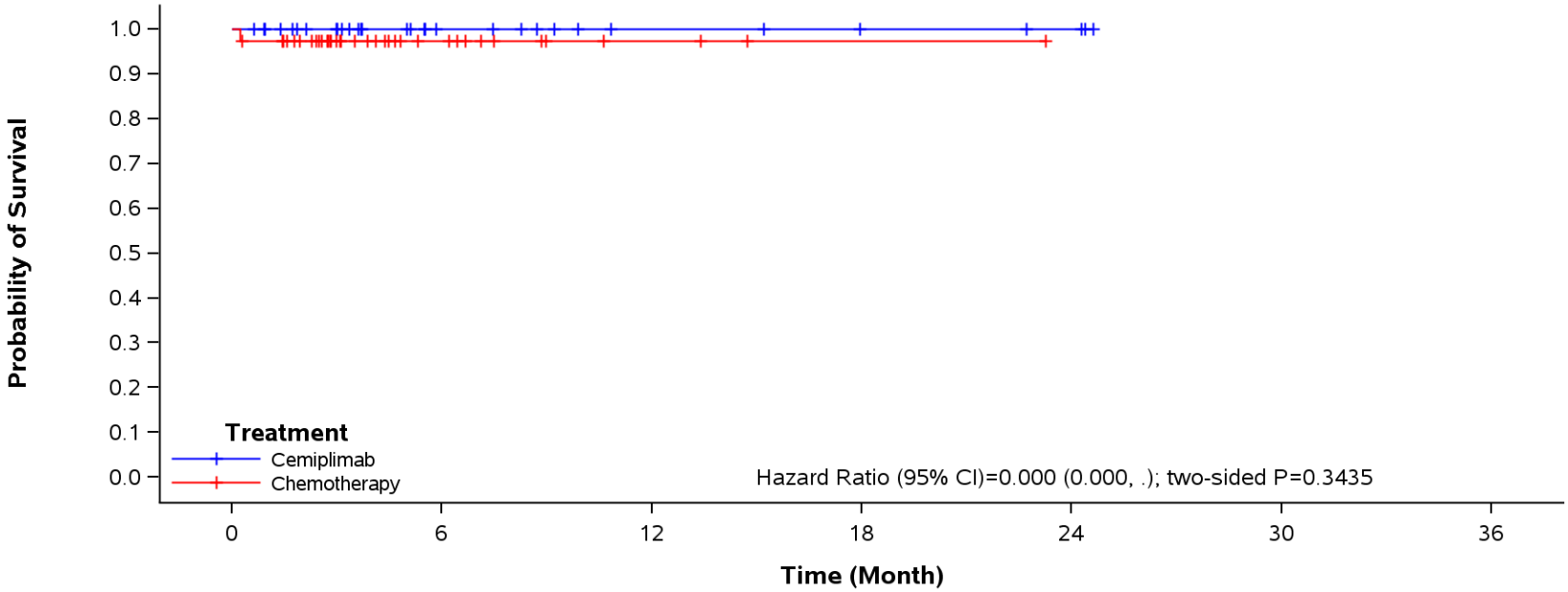

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders



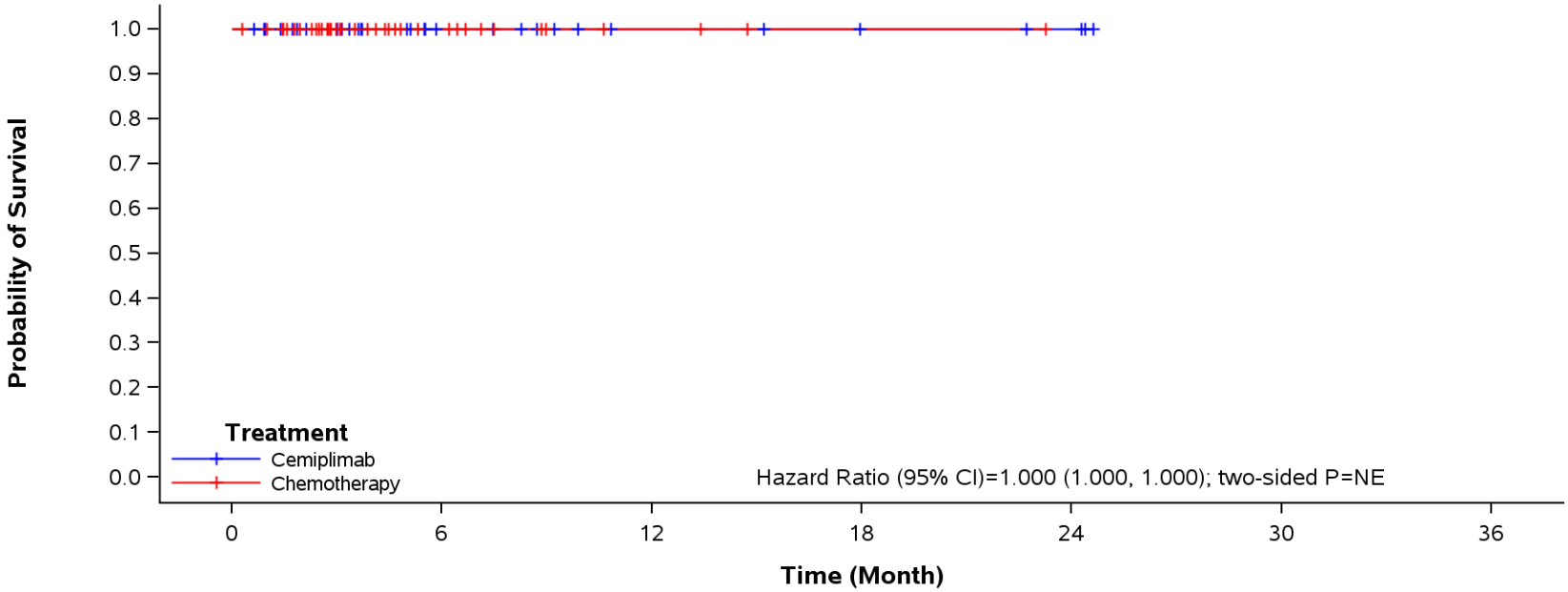

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Anaemia



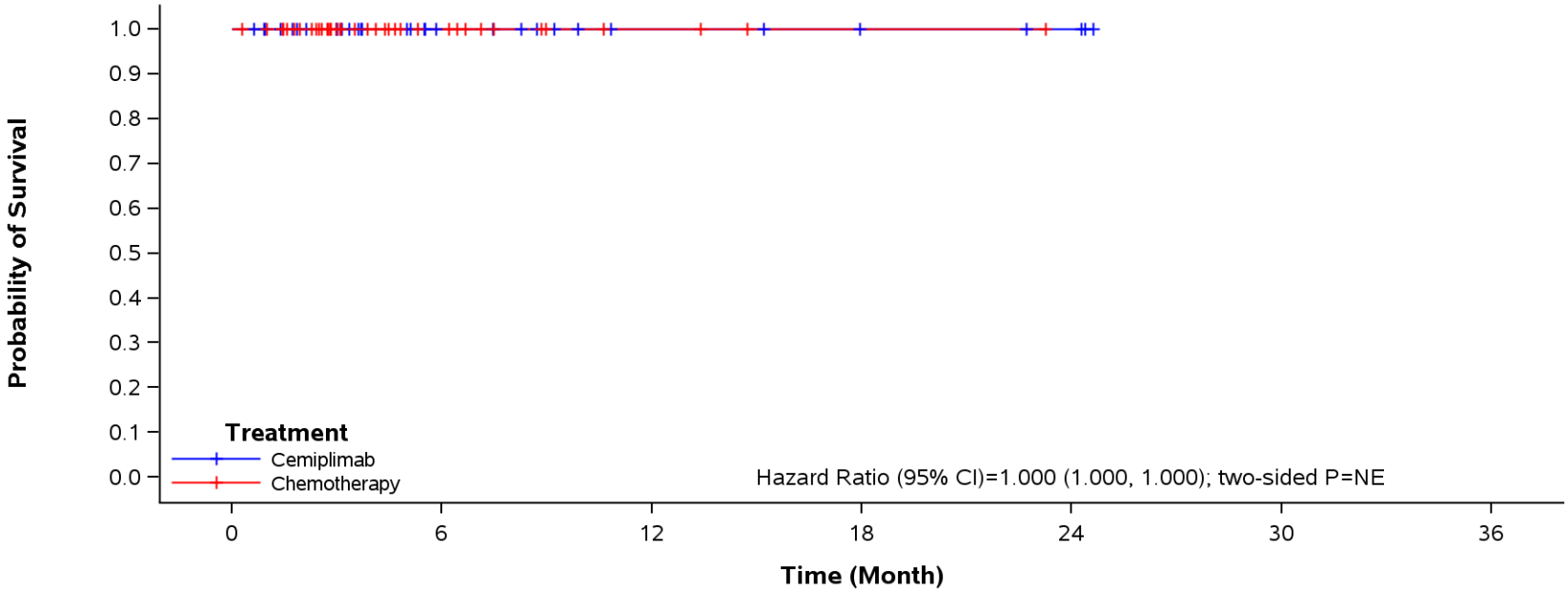

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



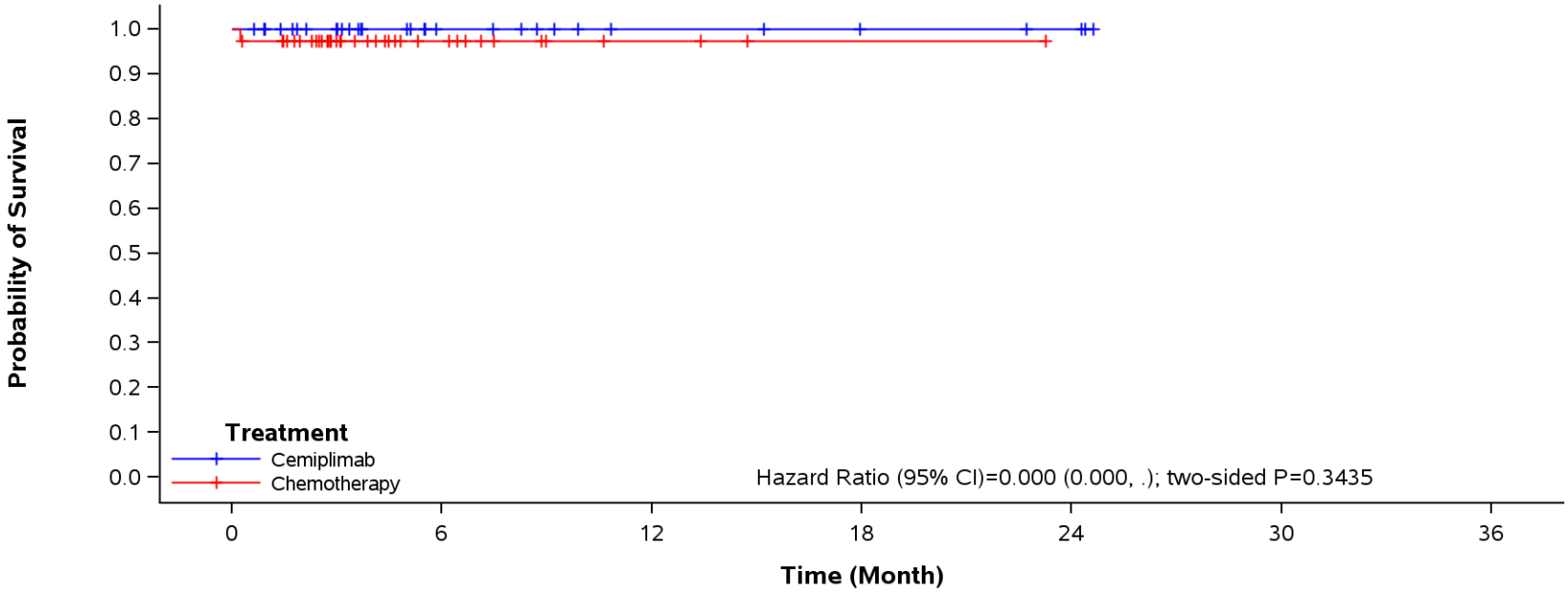

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Neutropenia



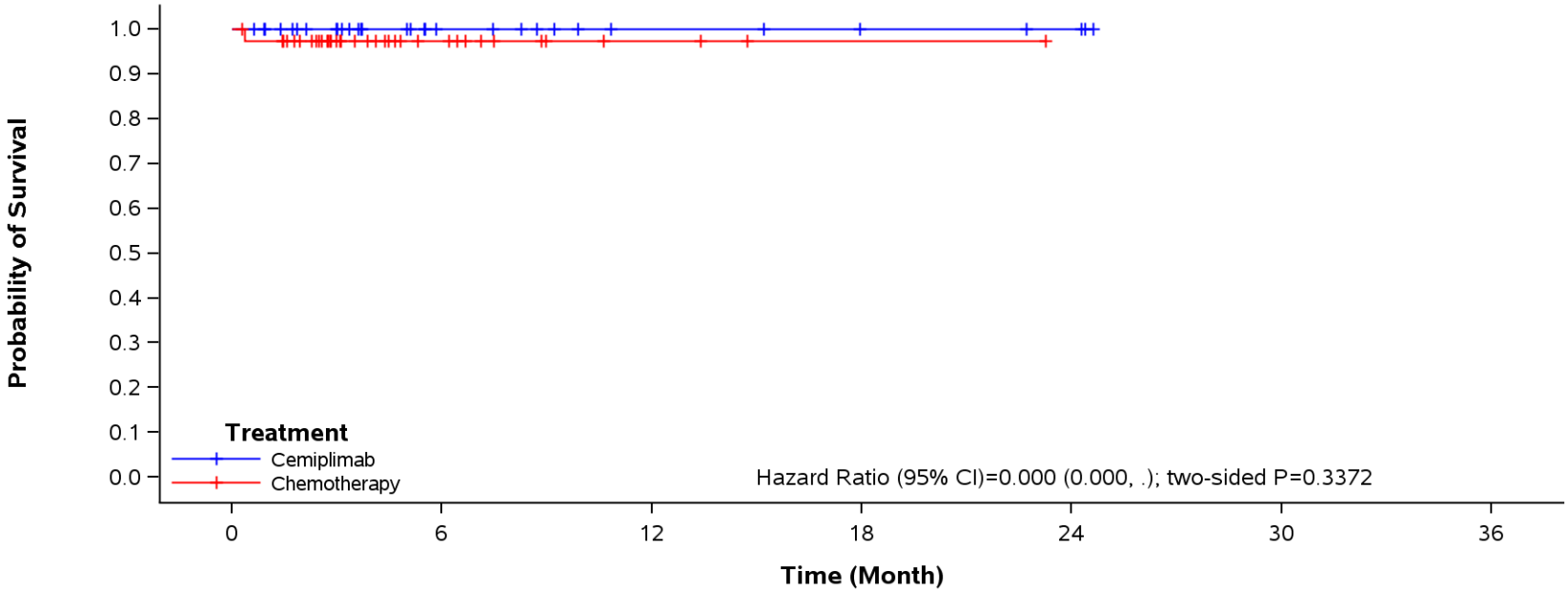

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



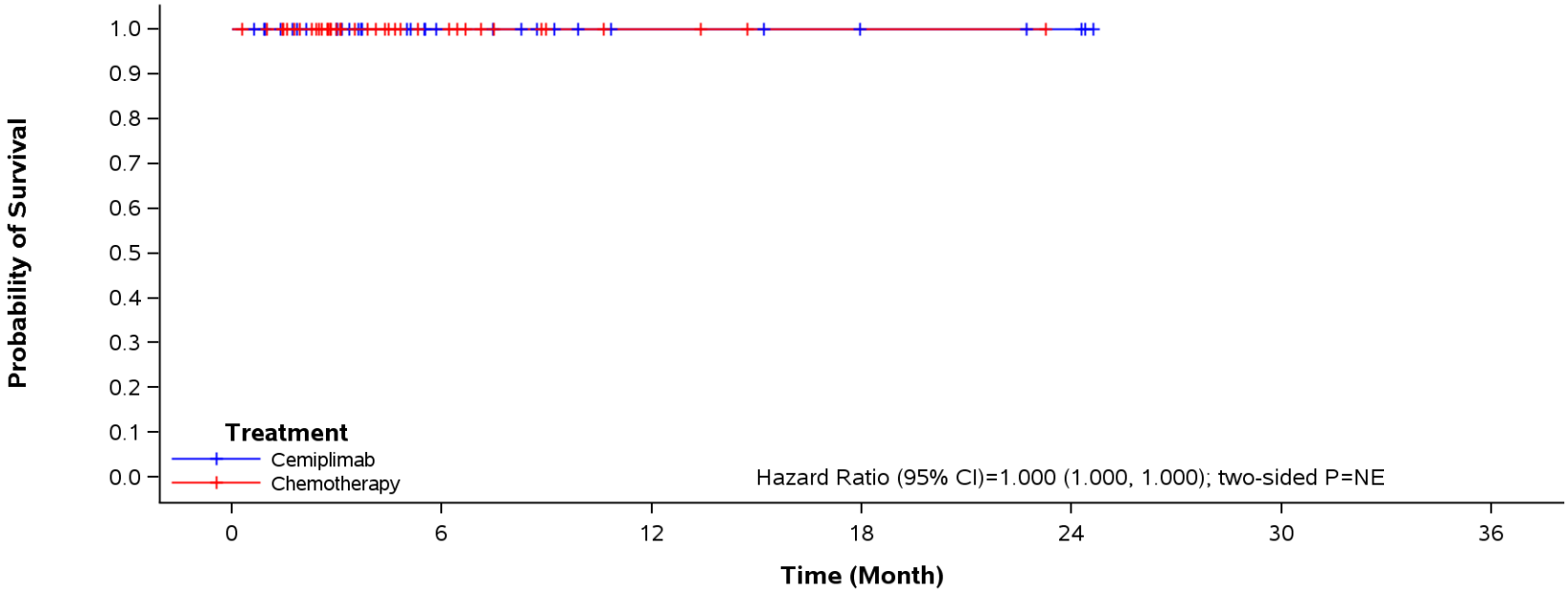

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Cardiac disorders



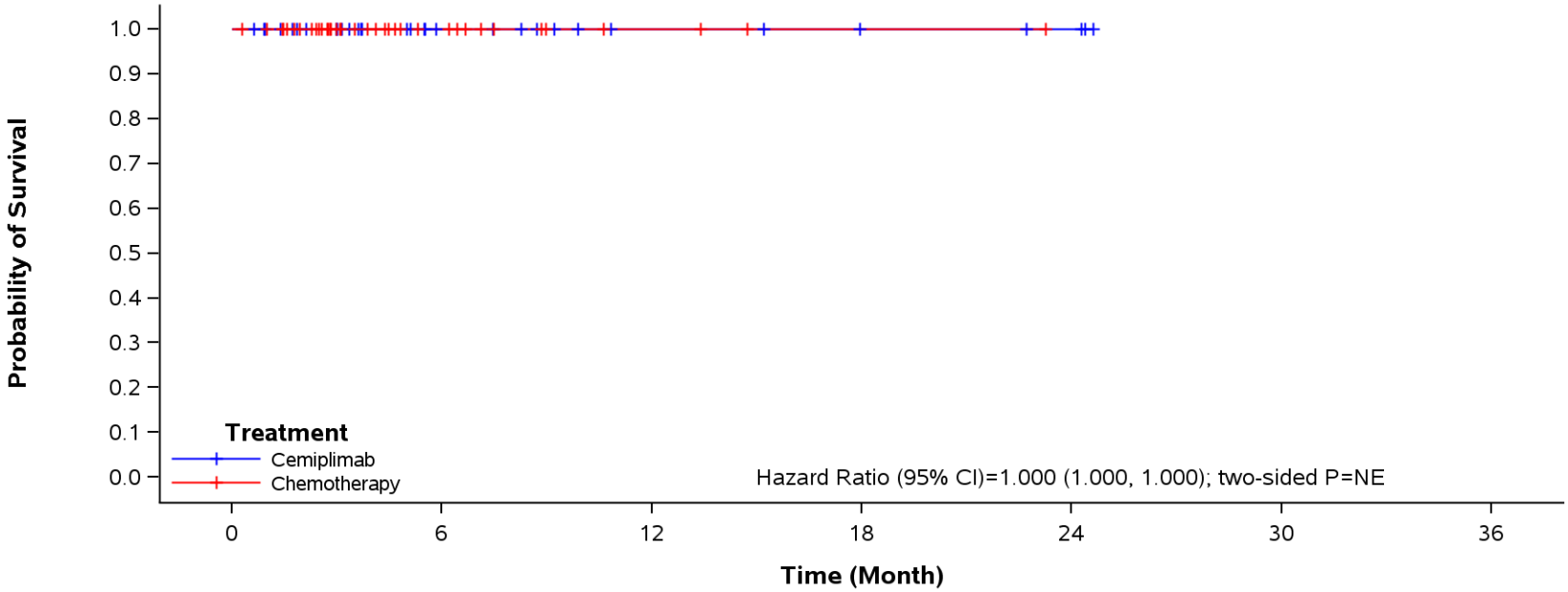

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Cardiac disorders
PT: Autoimmune pericarditis



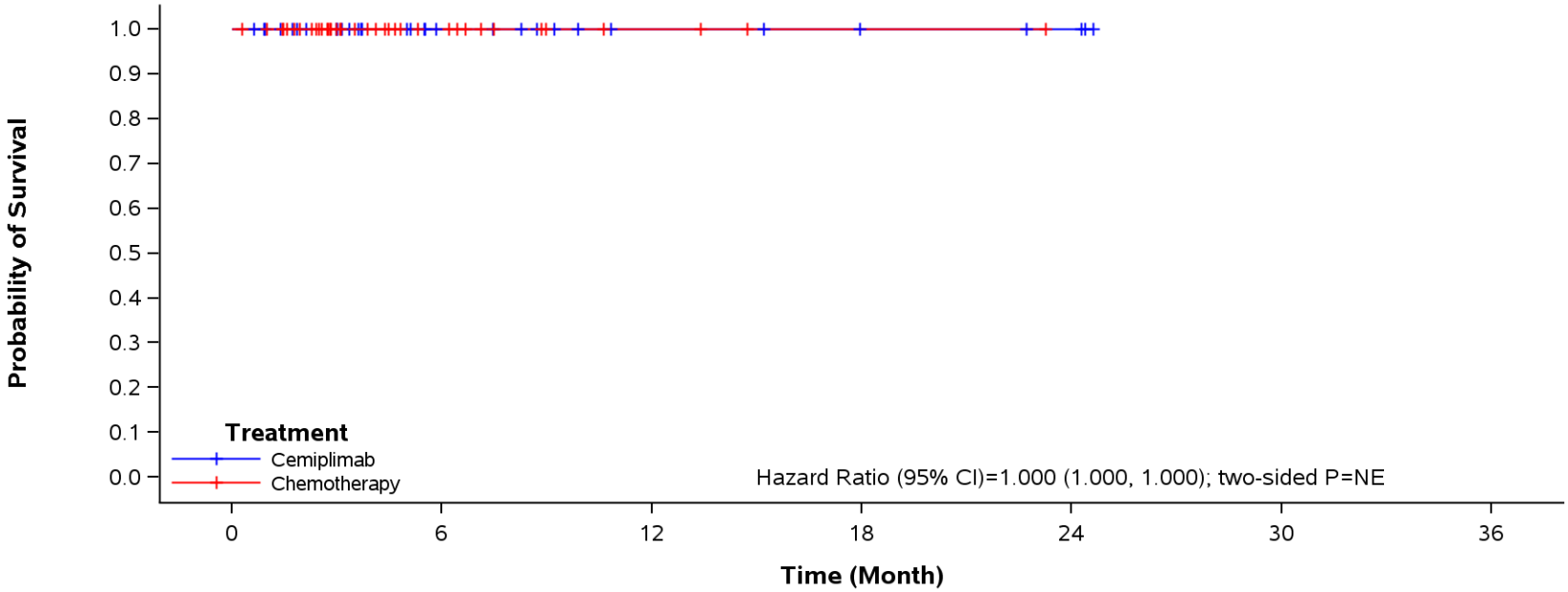

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Endocrine disorders



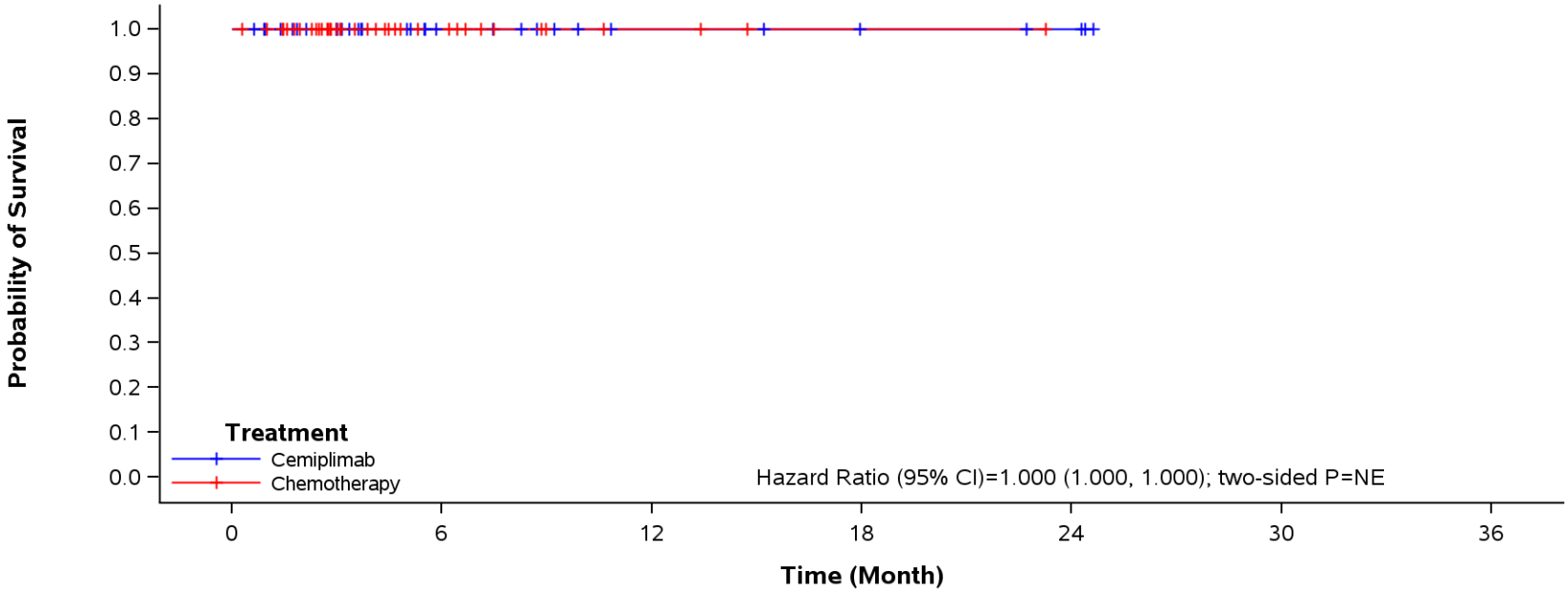

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Endocrine disorders
PT: Hypothyroidism



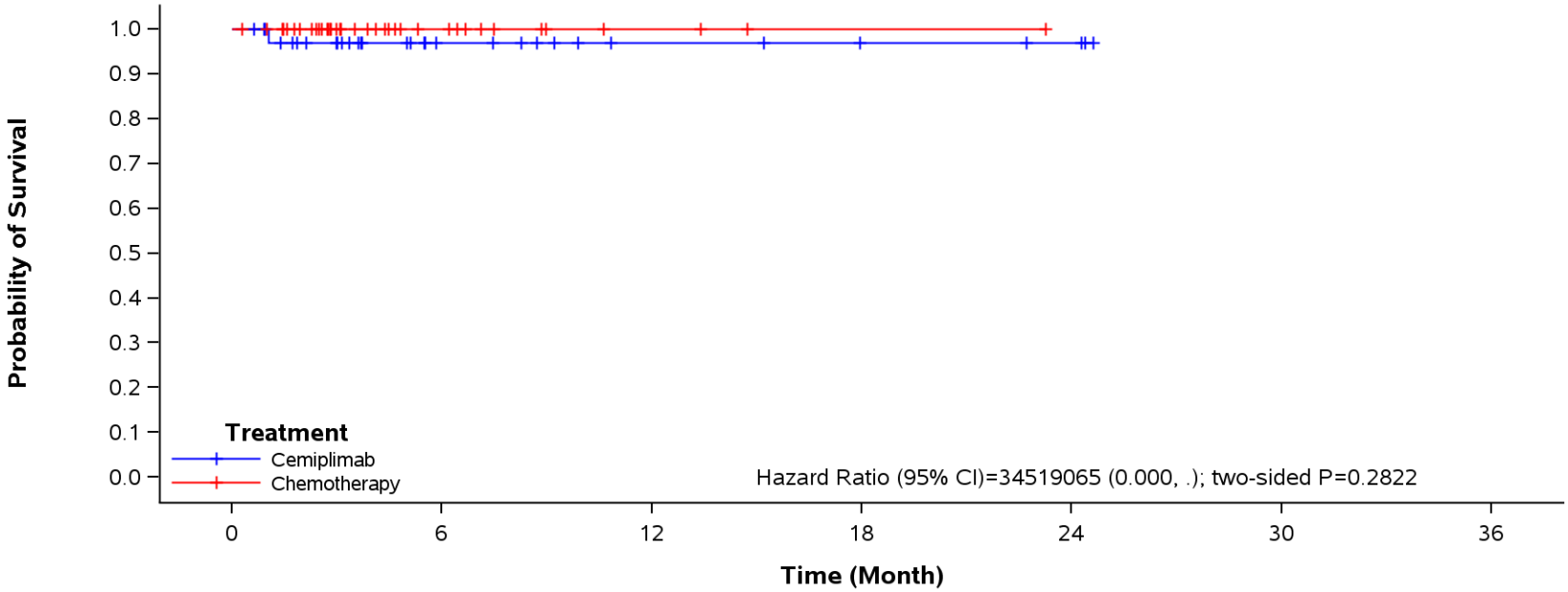

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders



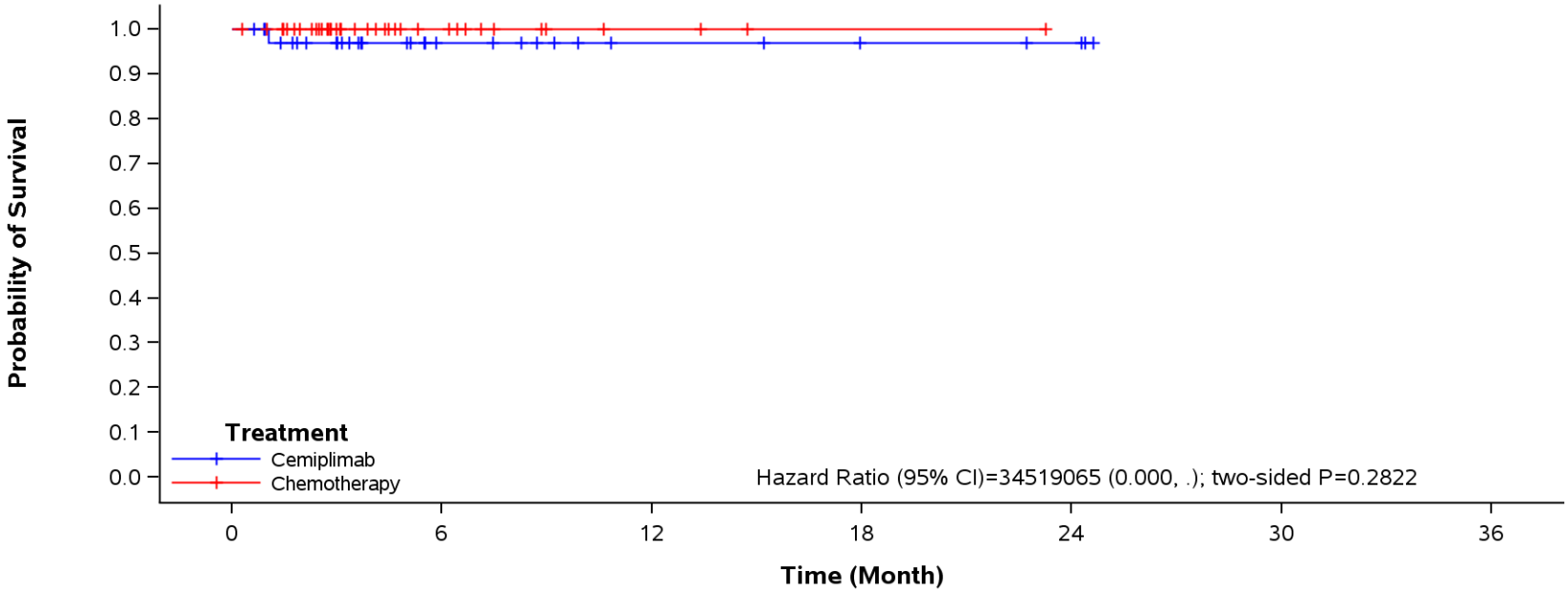

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders
PT: Colitis



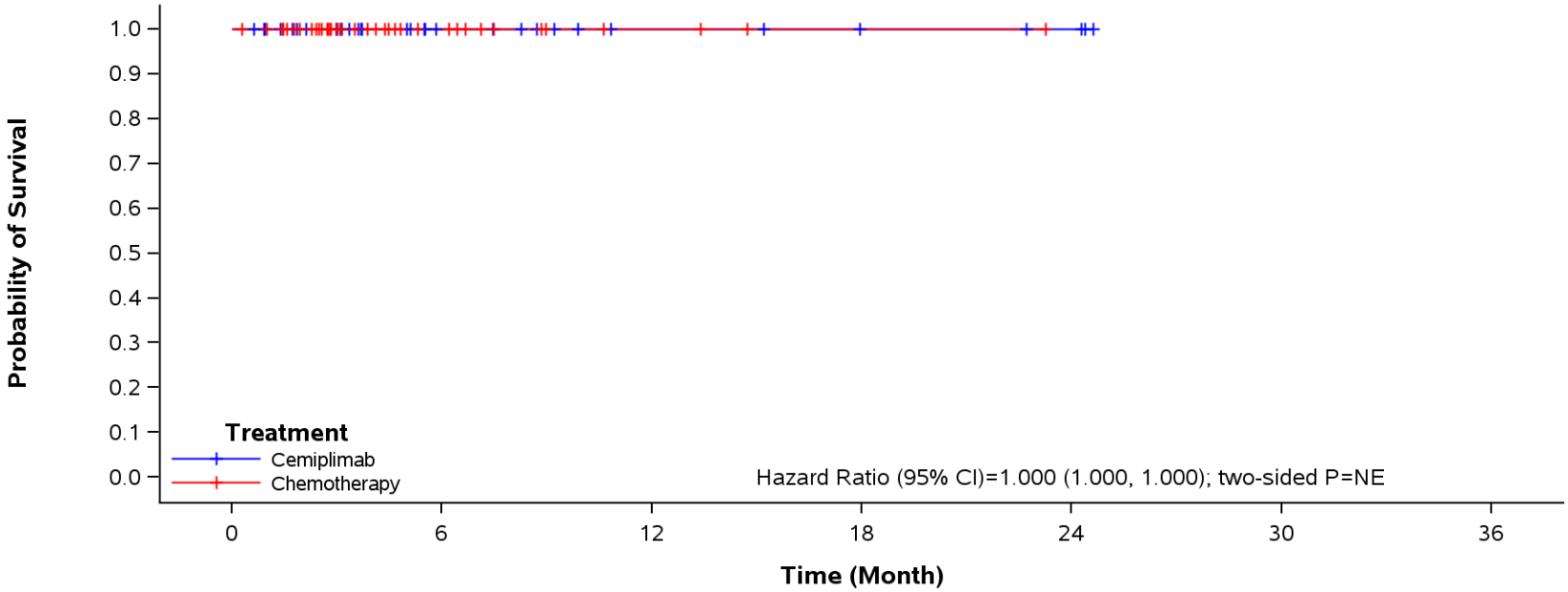

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders
PT: Diverticular perforation



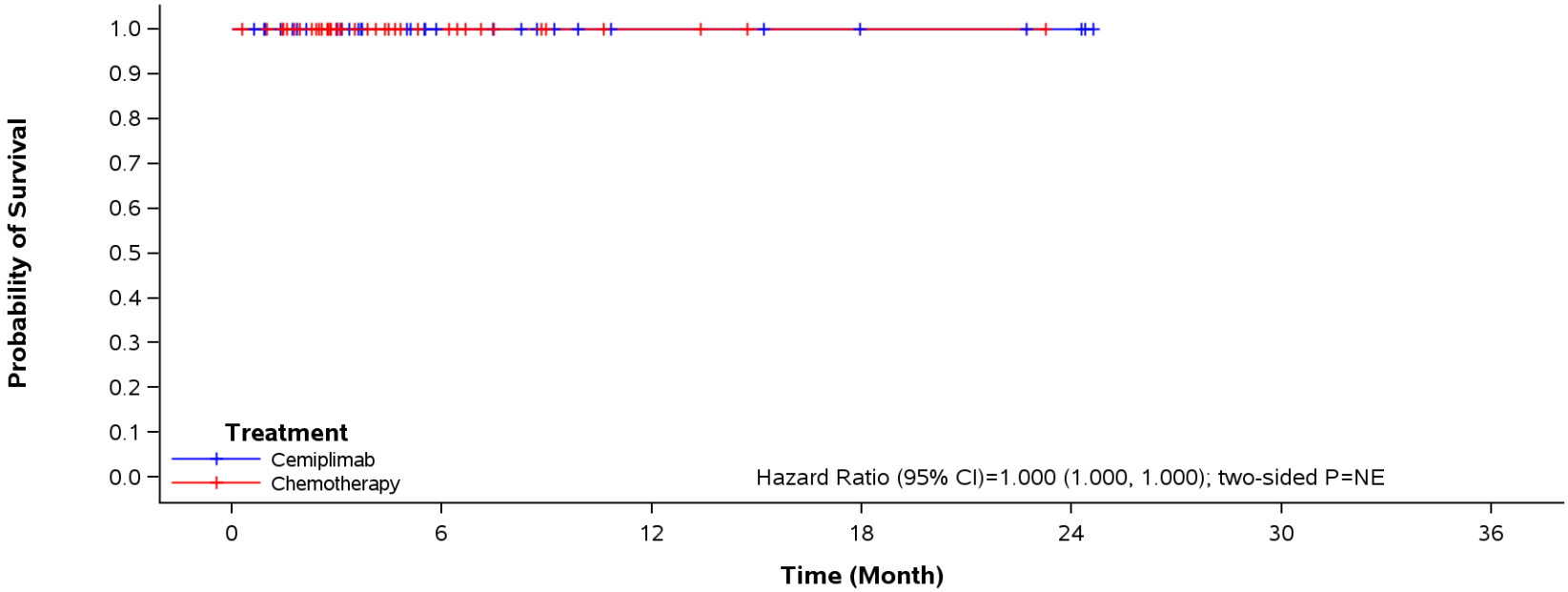

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders
PT: Pancreatic mass



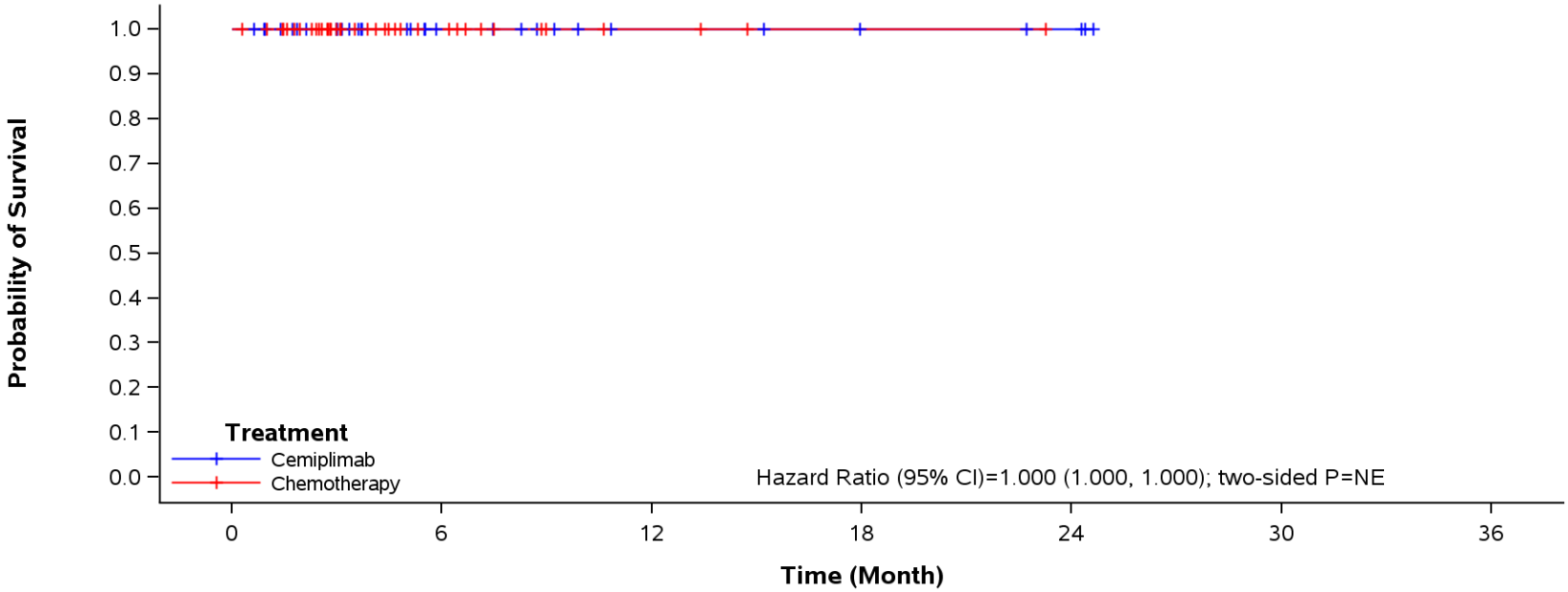

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



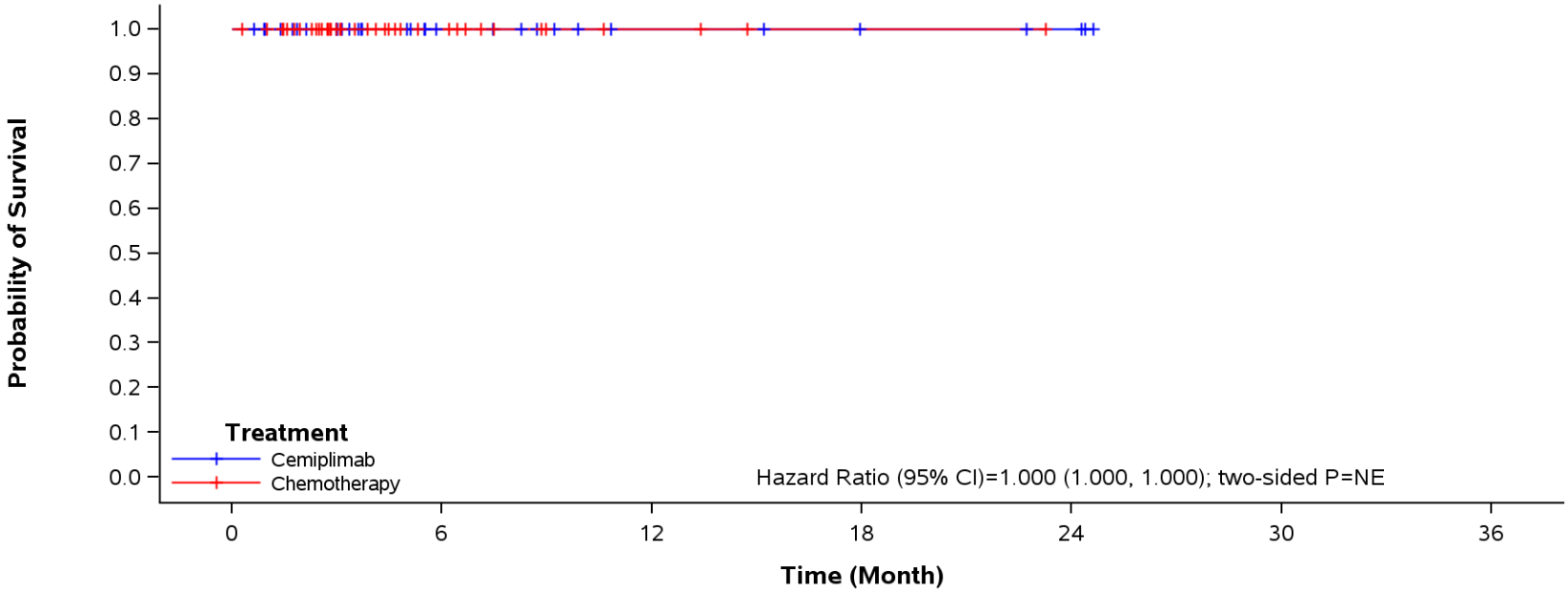

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Gastrointestinal disorders
PT: Proctalgia



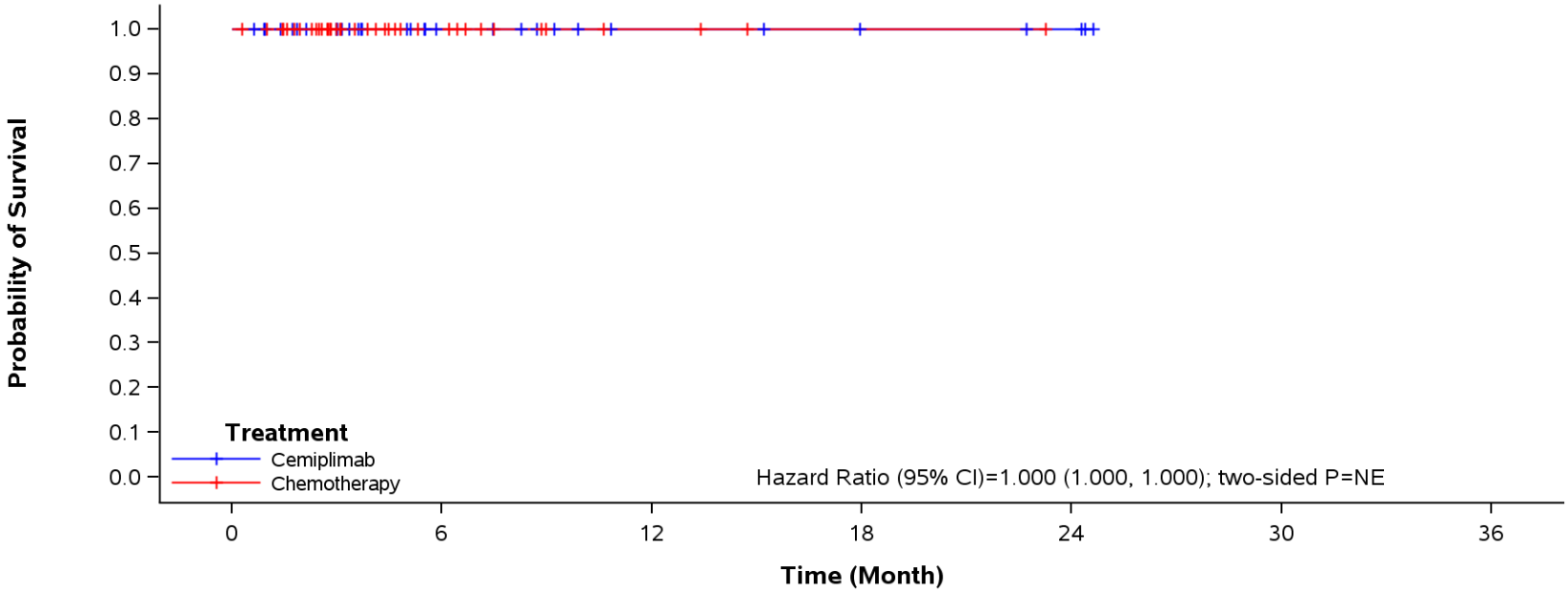

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: General disorders and administration site conditions



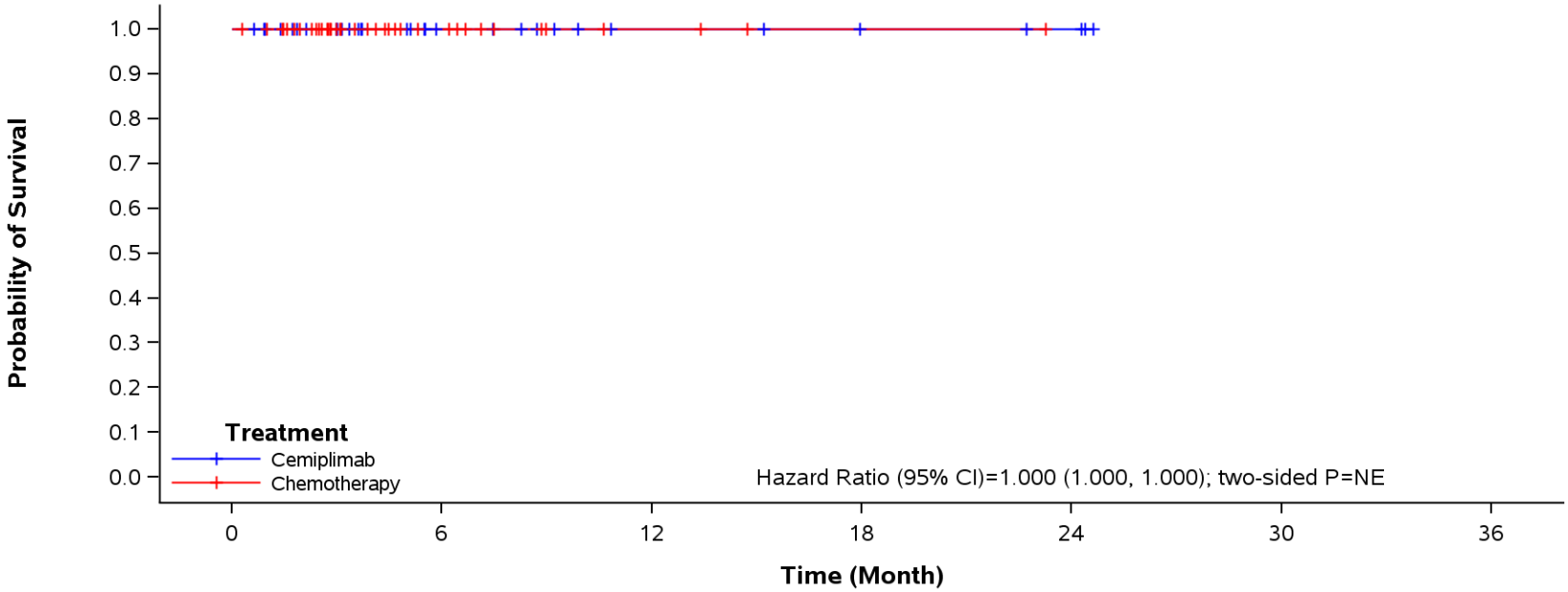

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: General disorders and administration site conditions
PT: Malaise



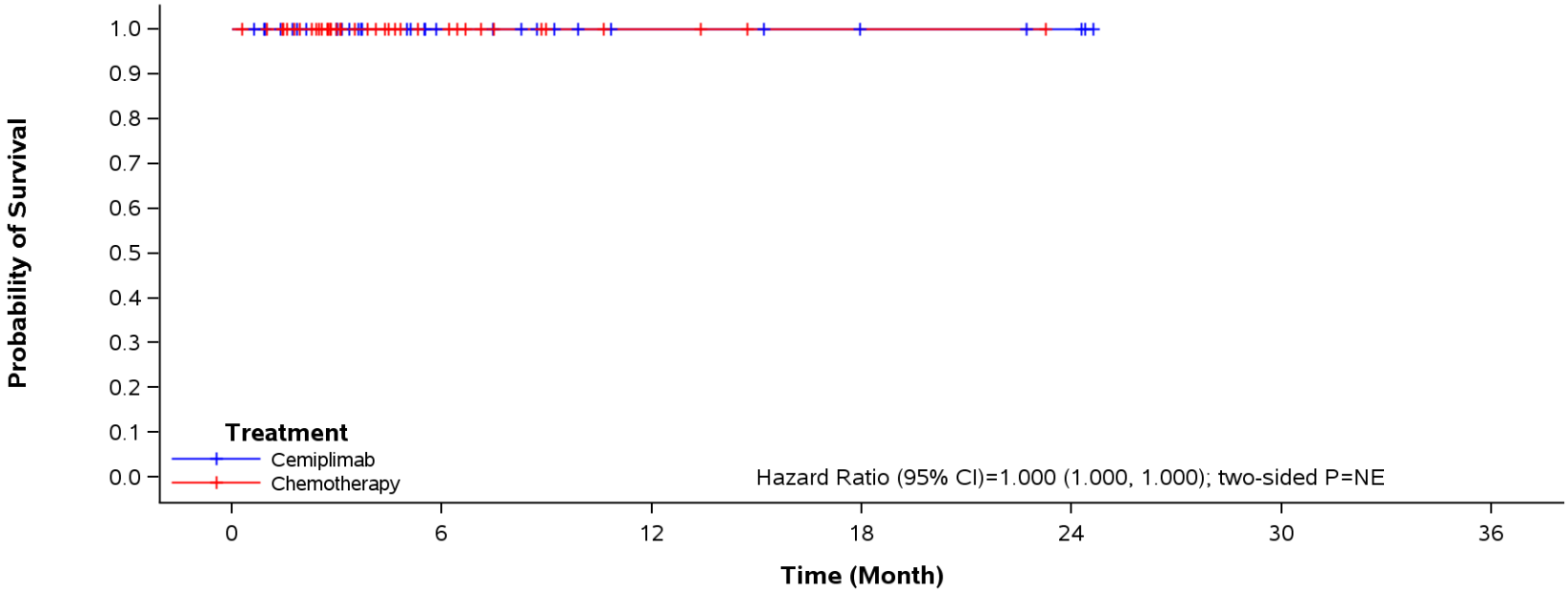

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



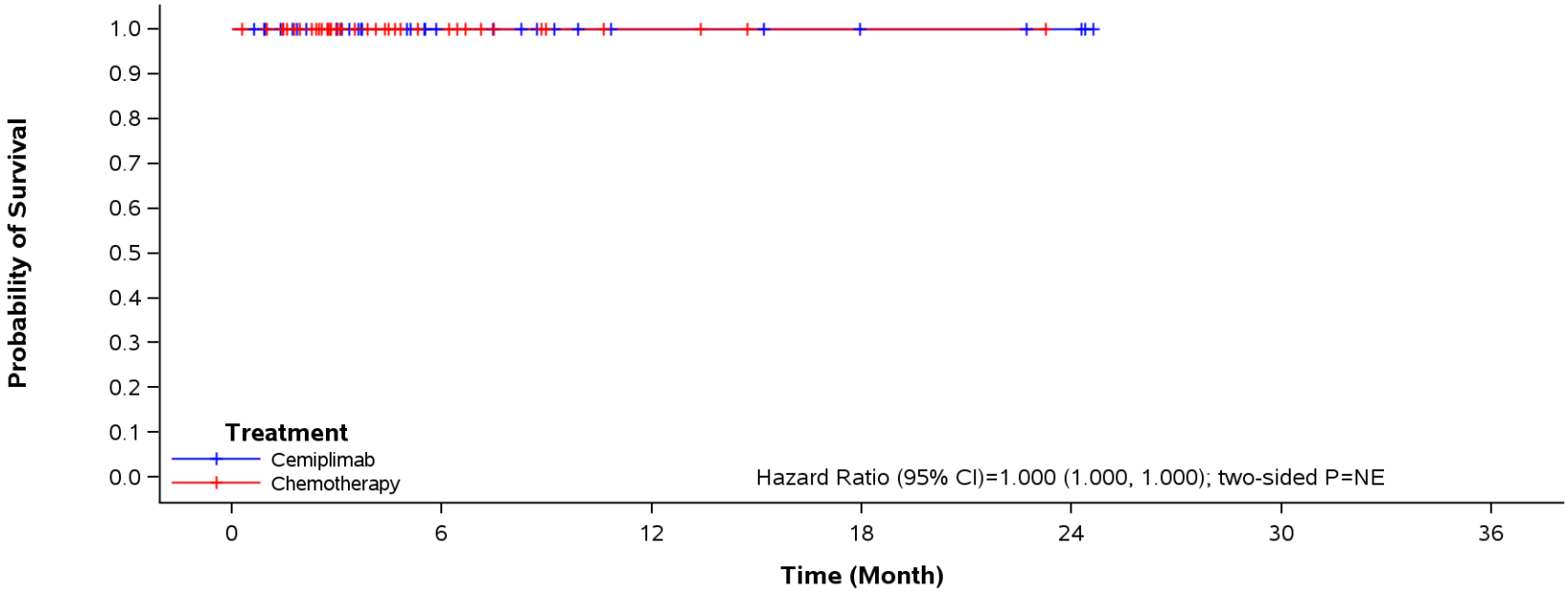

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Hepatobiliary disorders



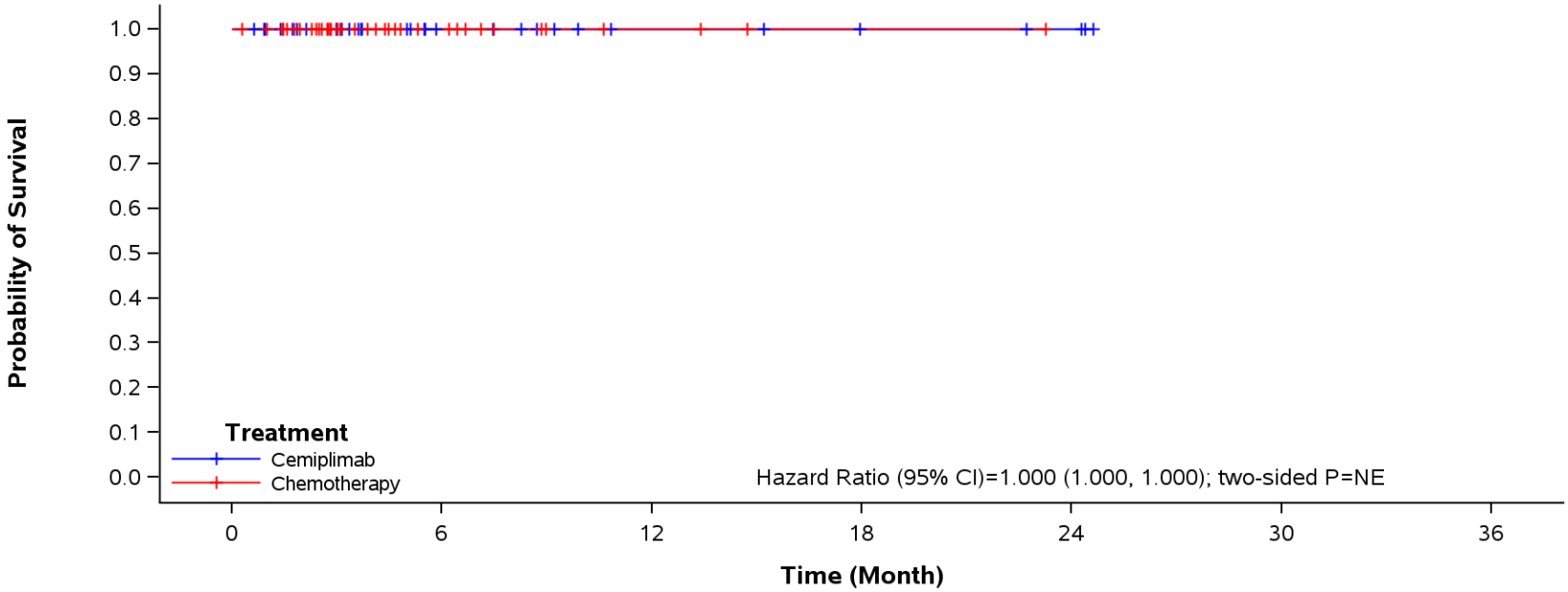

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



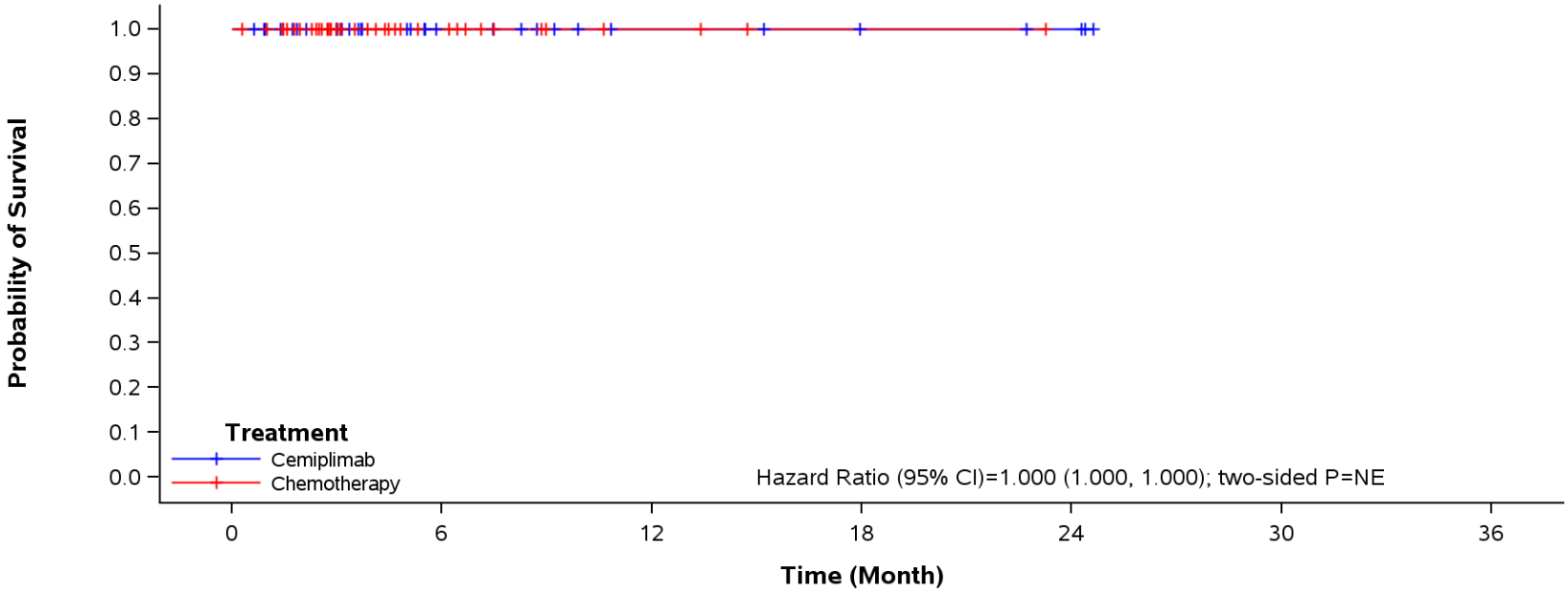

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



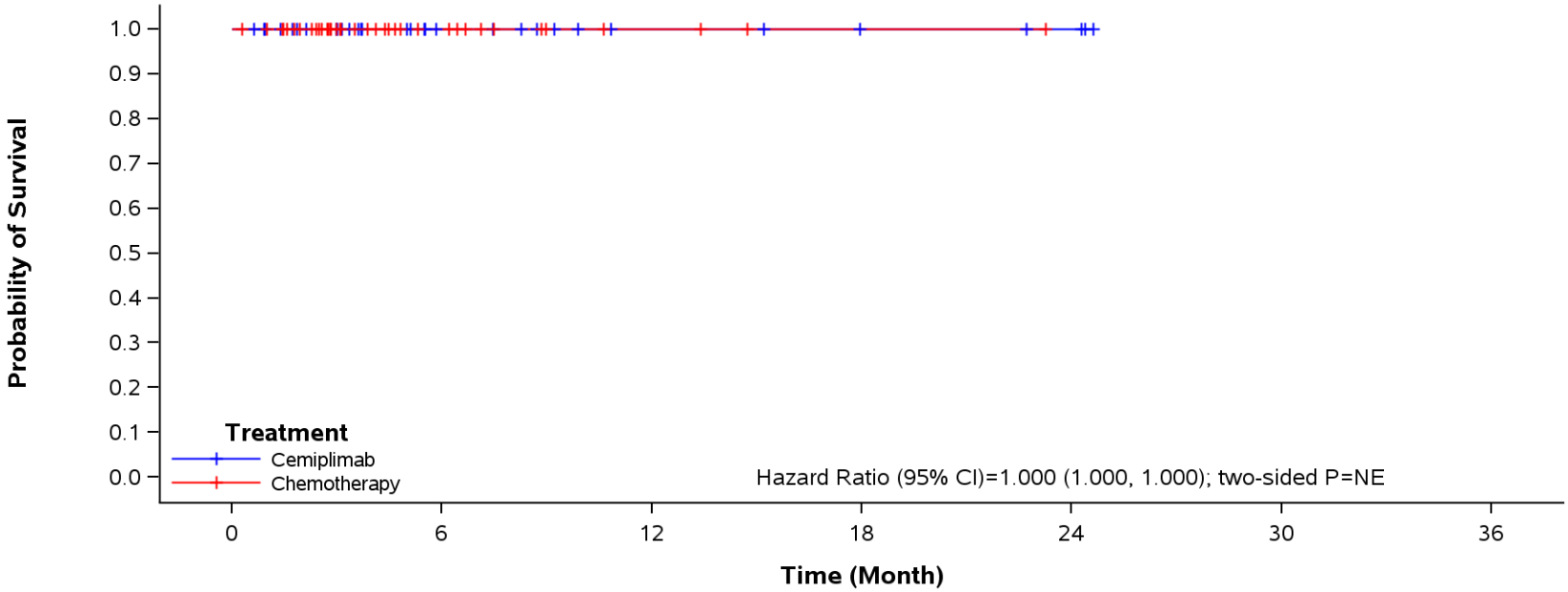

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Hepatobiliary disorders
PT: Hepatitis



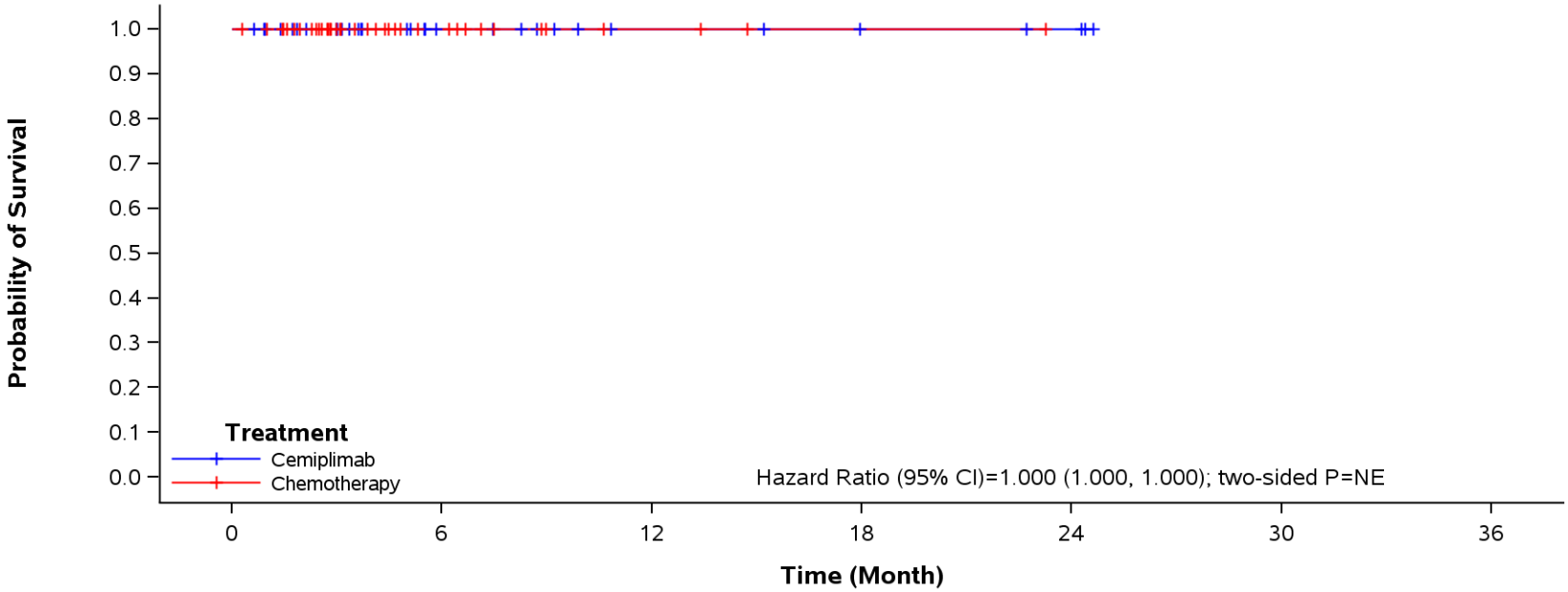

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



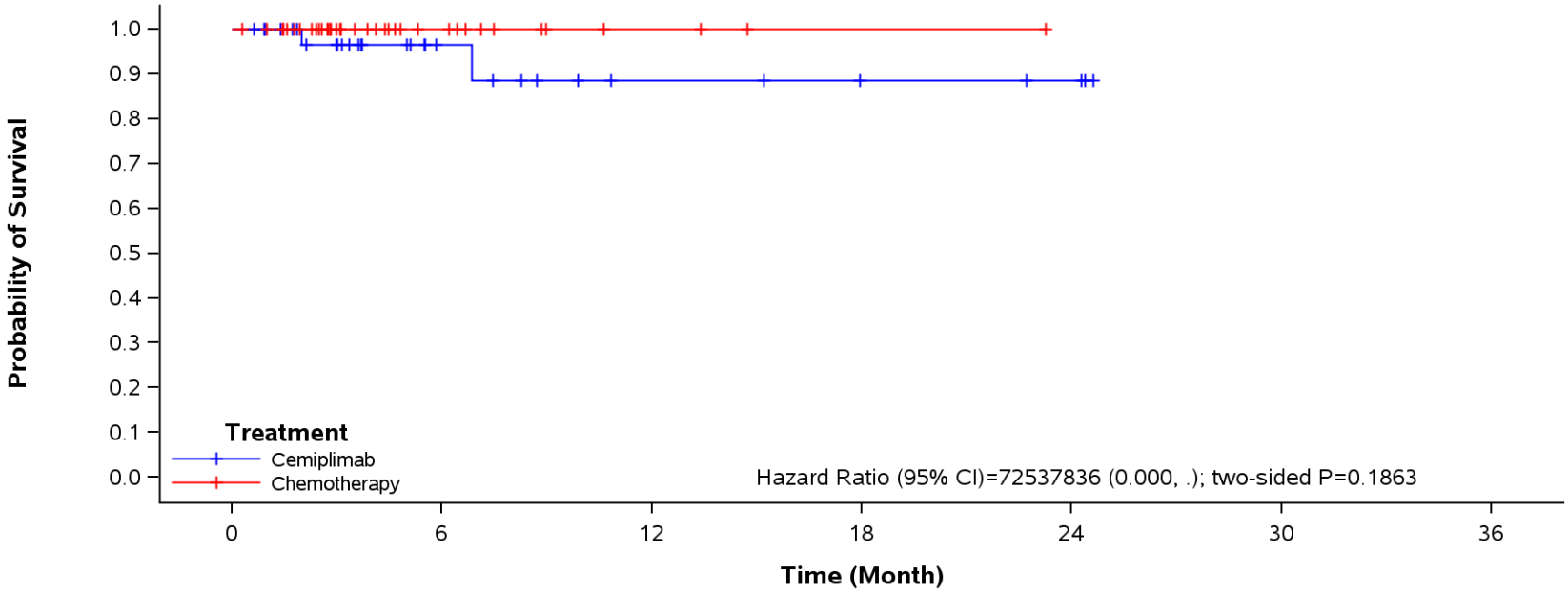

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Infections and infestations



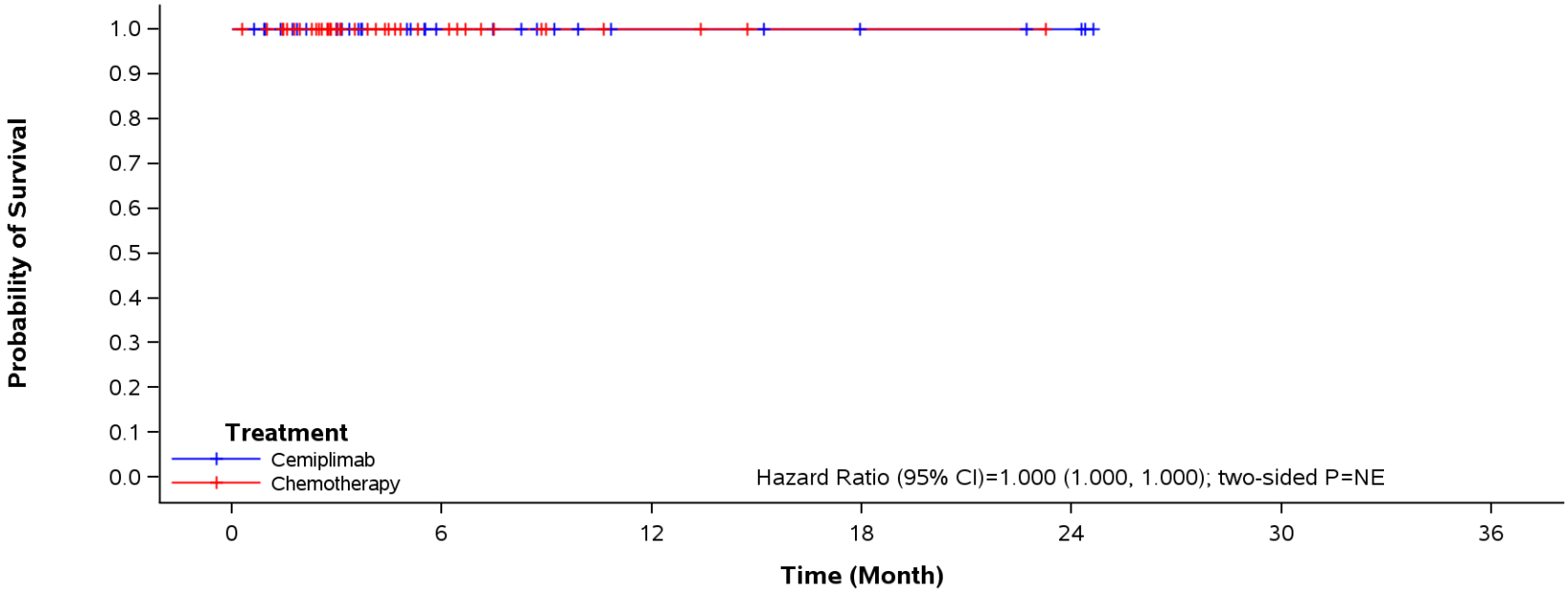

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Infections and infestations
PT: COVID-19 pneumonia



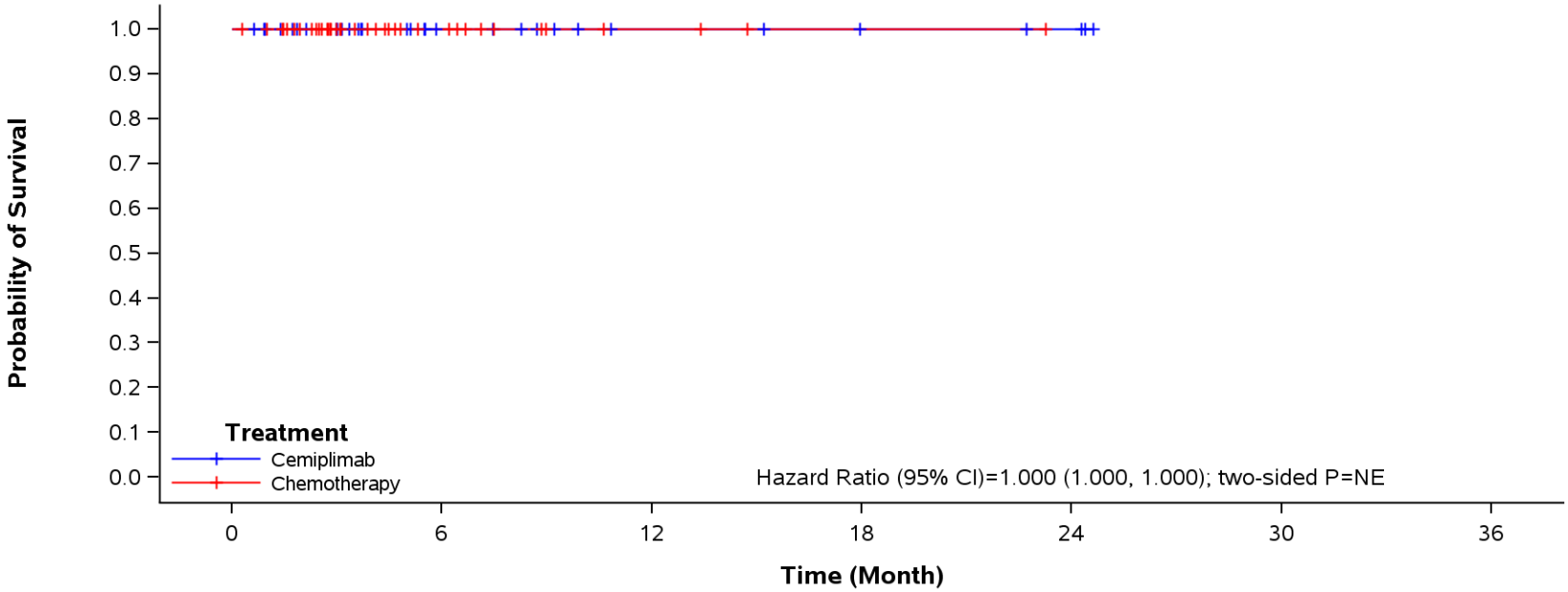

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Infections and infestations
PT: Gastroenteritis



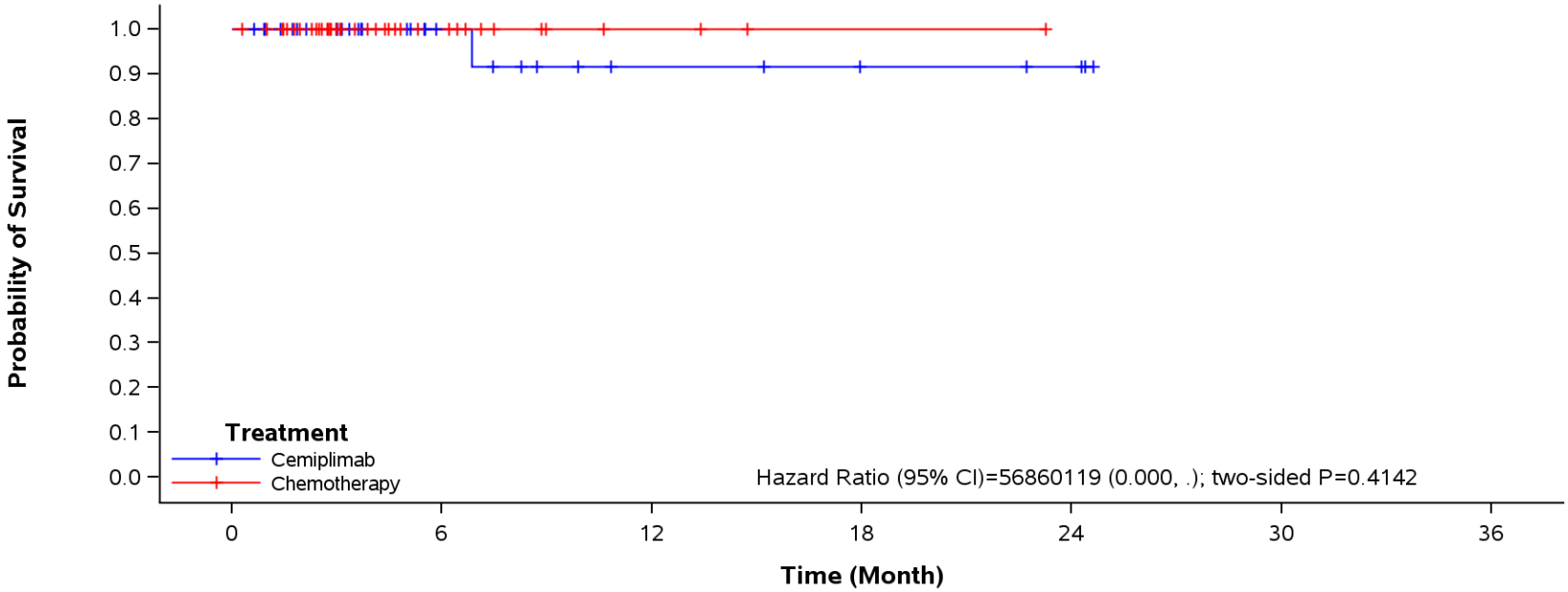

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Infections and infestations
PT: Pelvic abscess



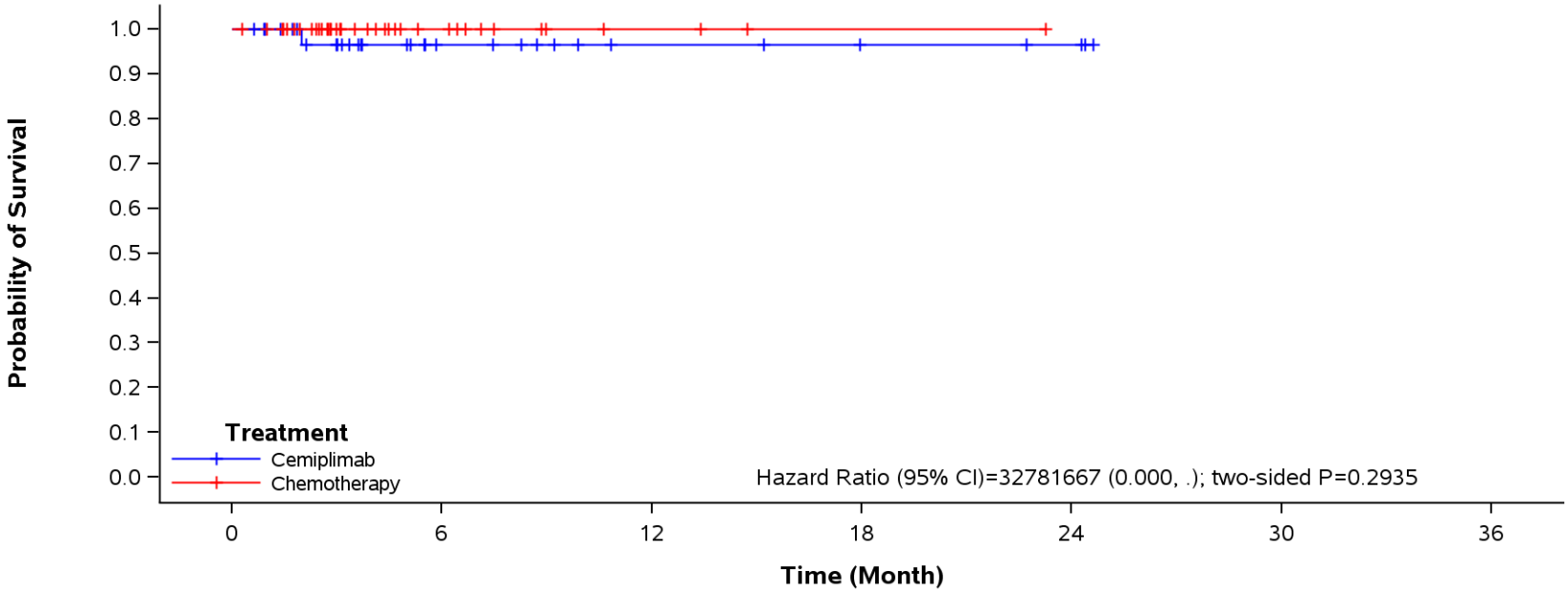

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Infections and infestations
PT: Peritonitis



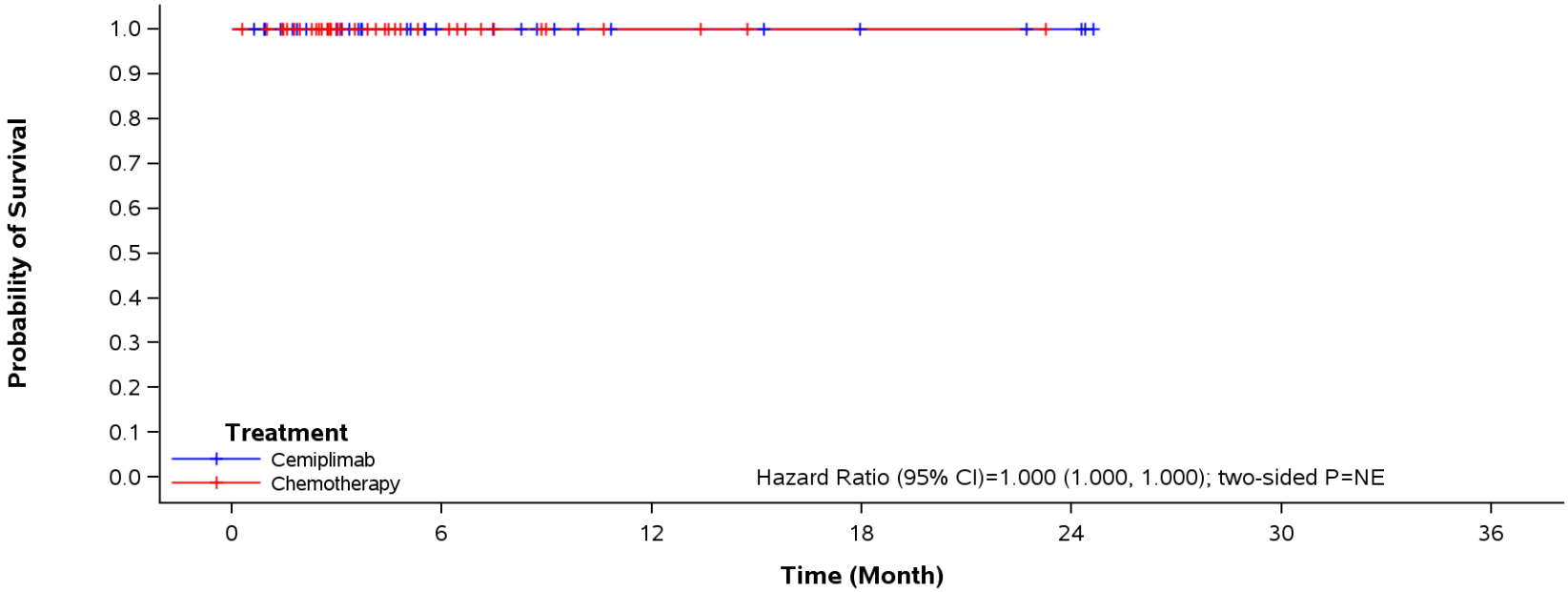

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Infections and infestations
PT: Pneumonia



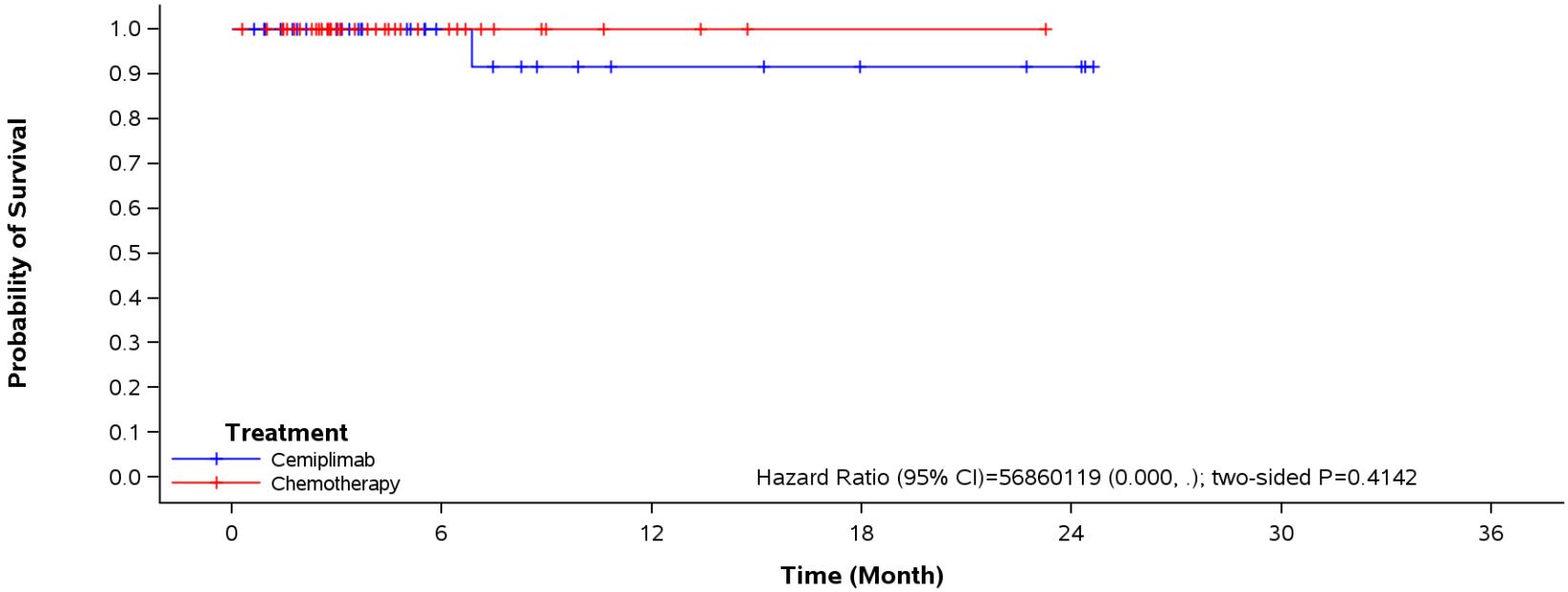

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Infections and infestations
PT: Pyomyositis



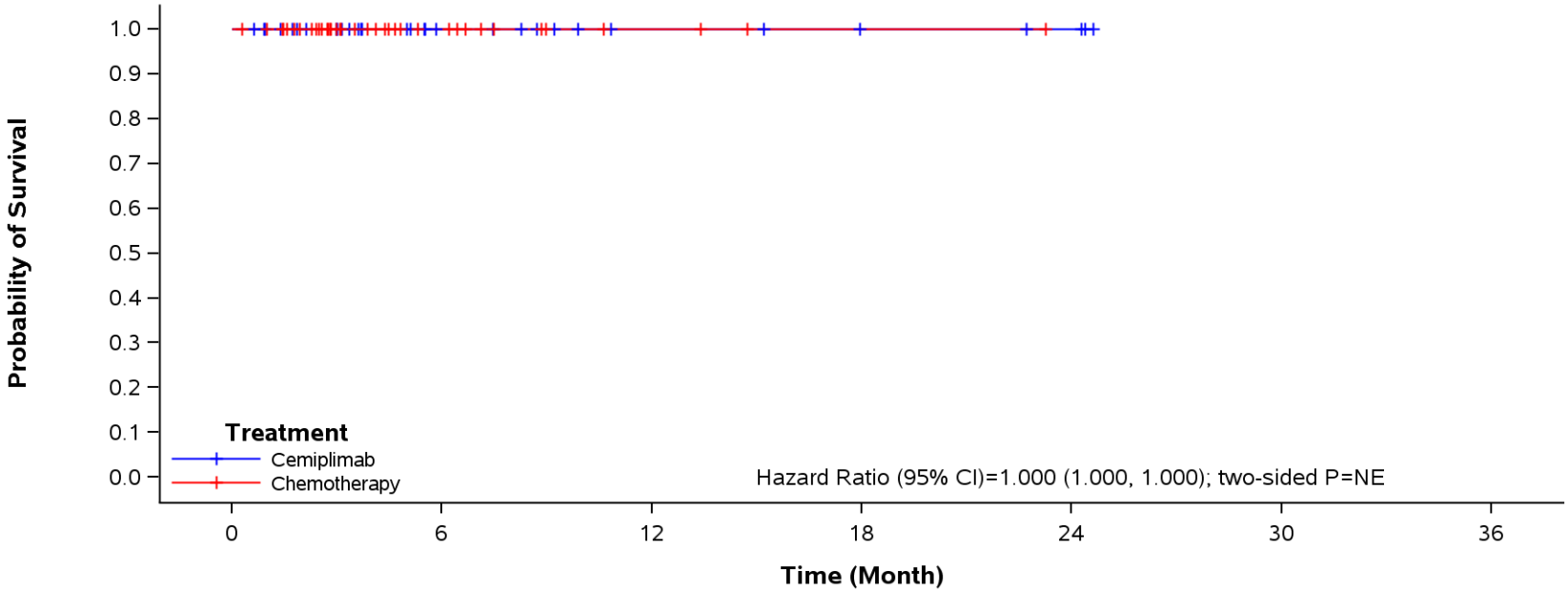

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Injury, poisoning and procedural complications



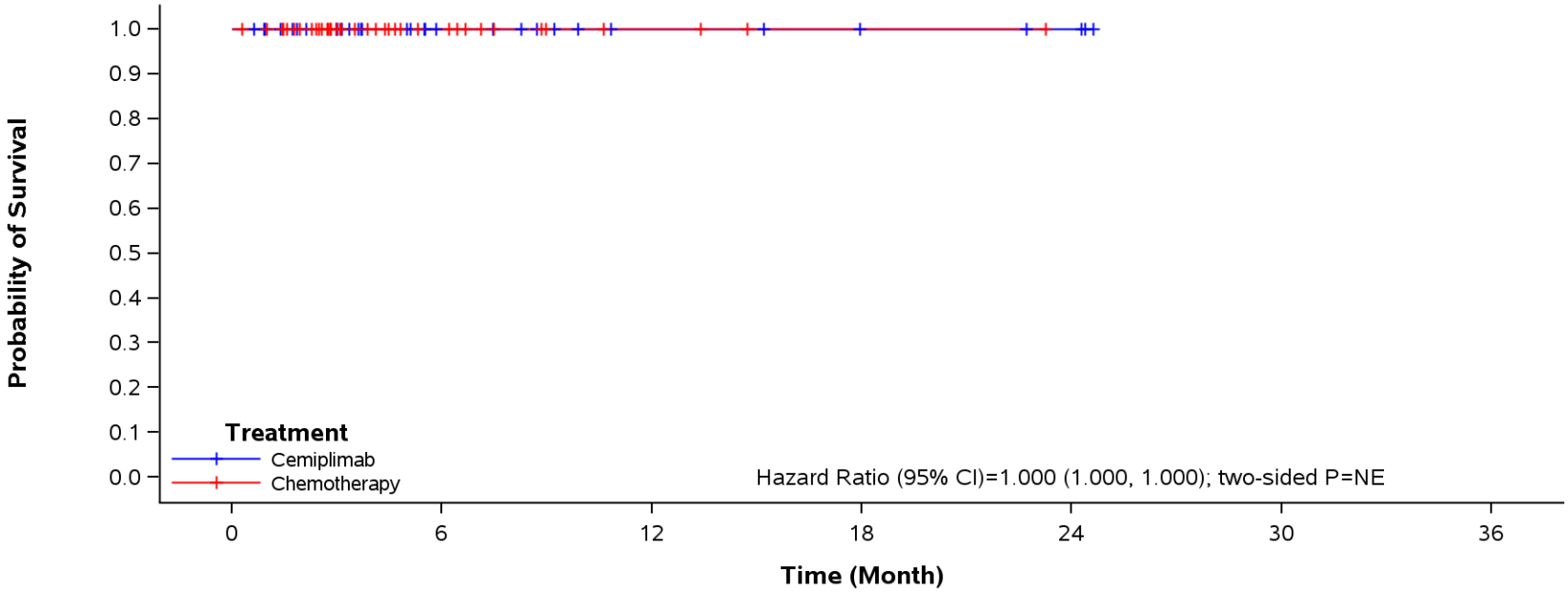

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



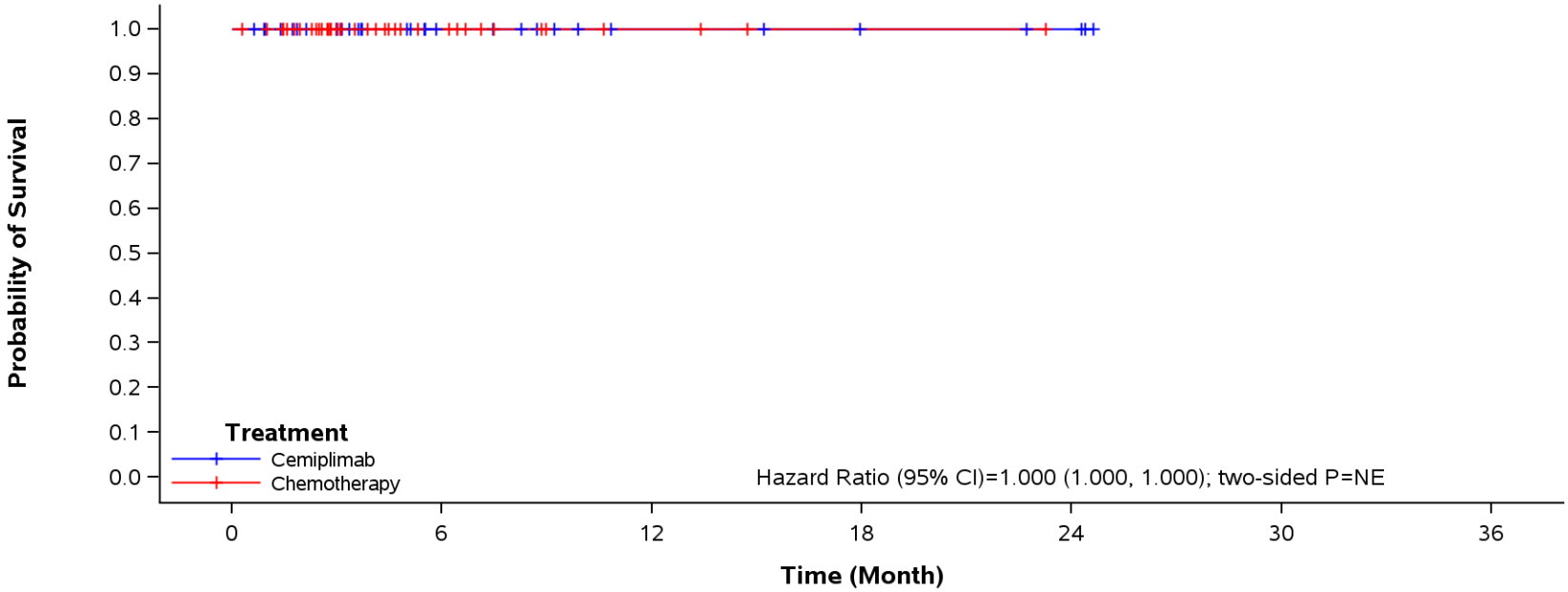

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



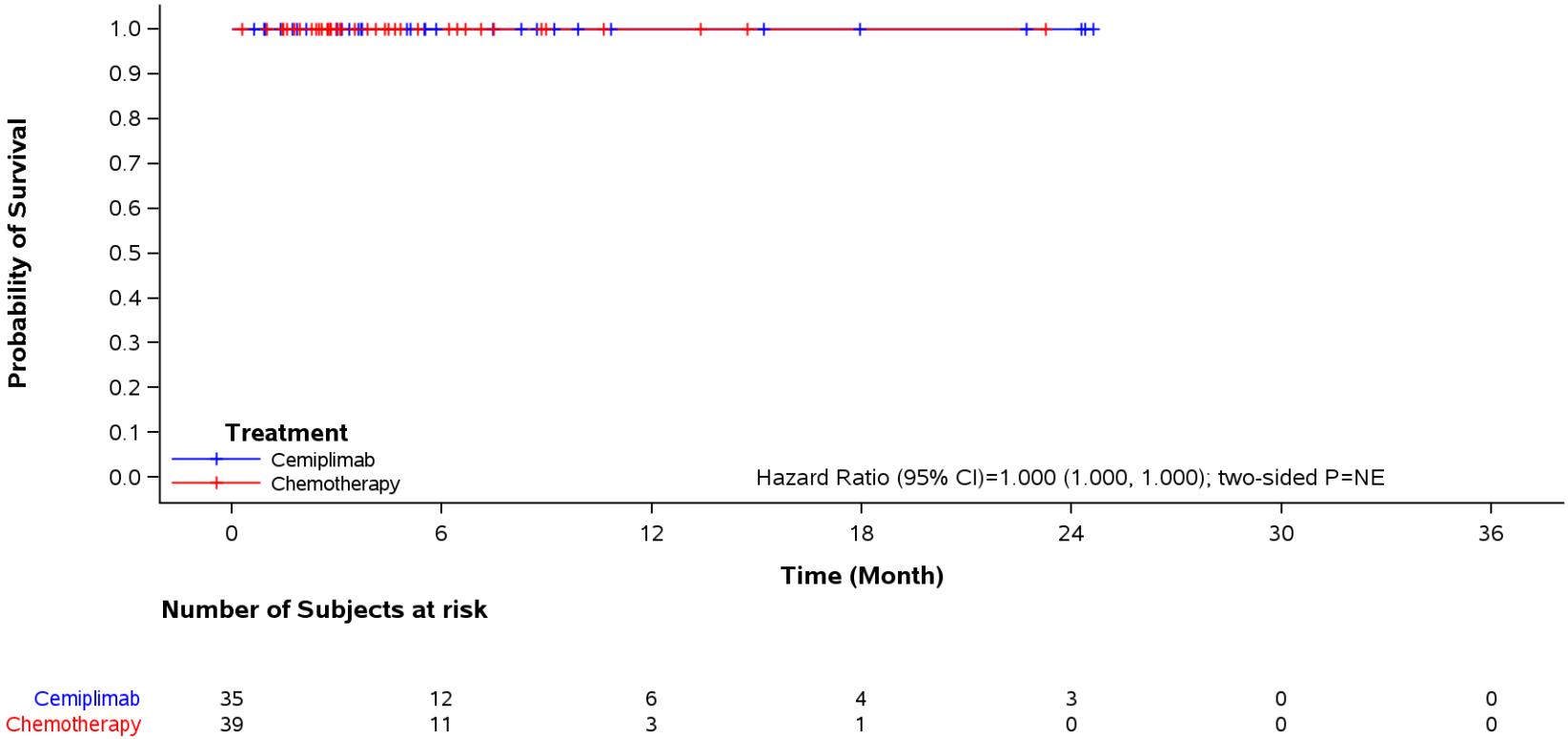

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

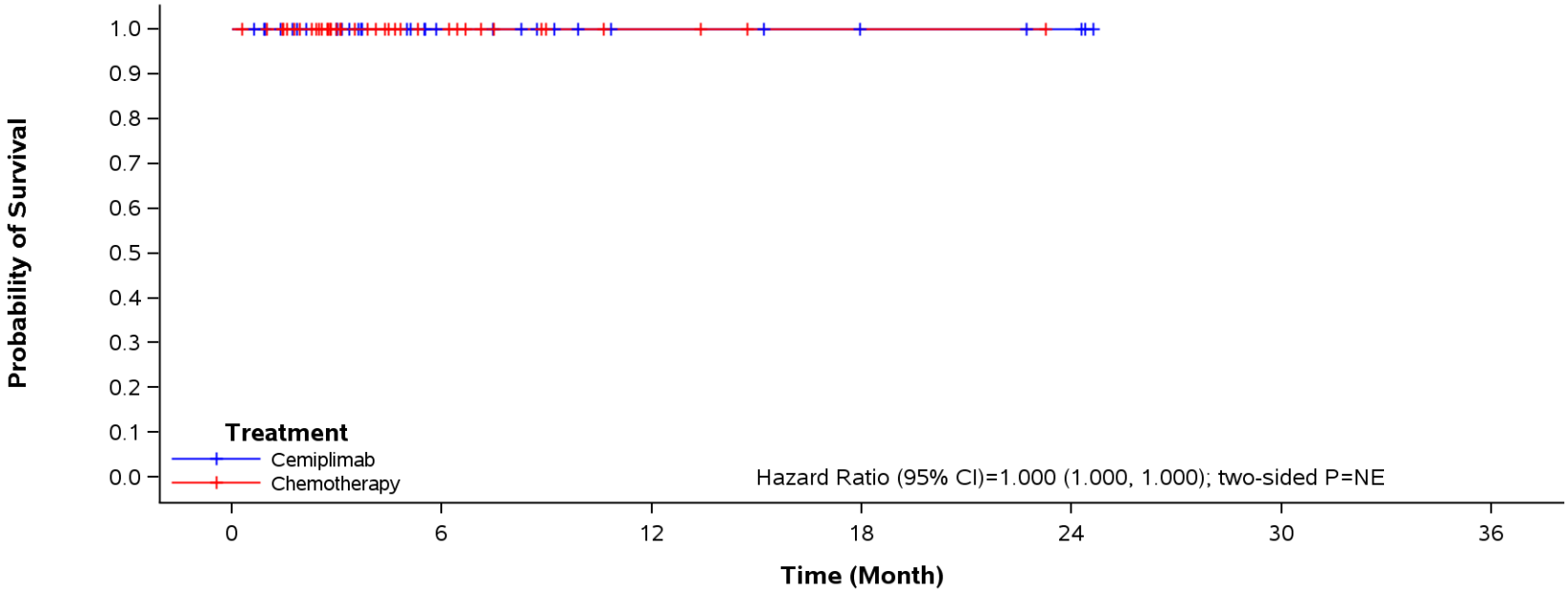
Histology: Adenocarcinoma/adenosquamous
SOC: Investigations




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Investigations
PT: Alanine aminotransferase increased



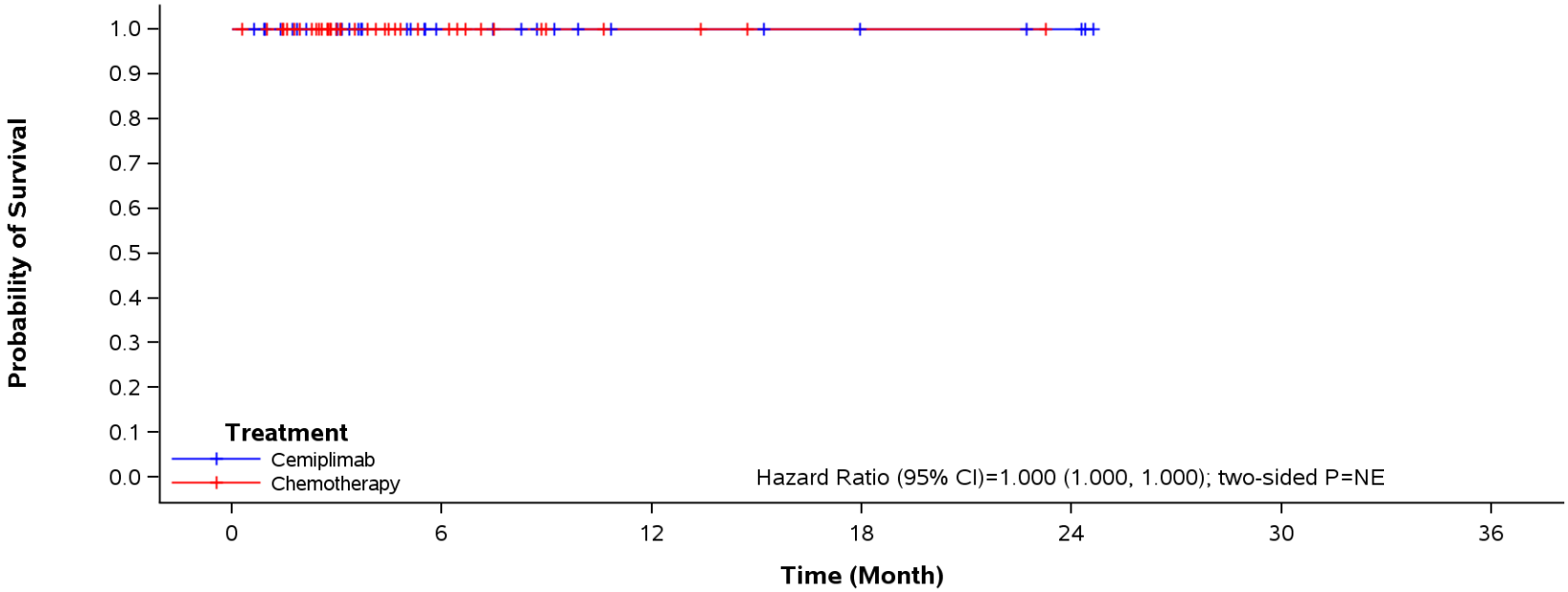

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Investigations
PT: Amylase increased



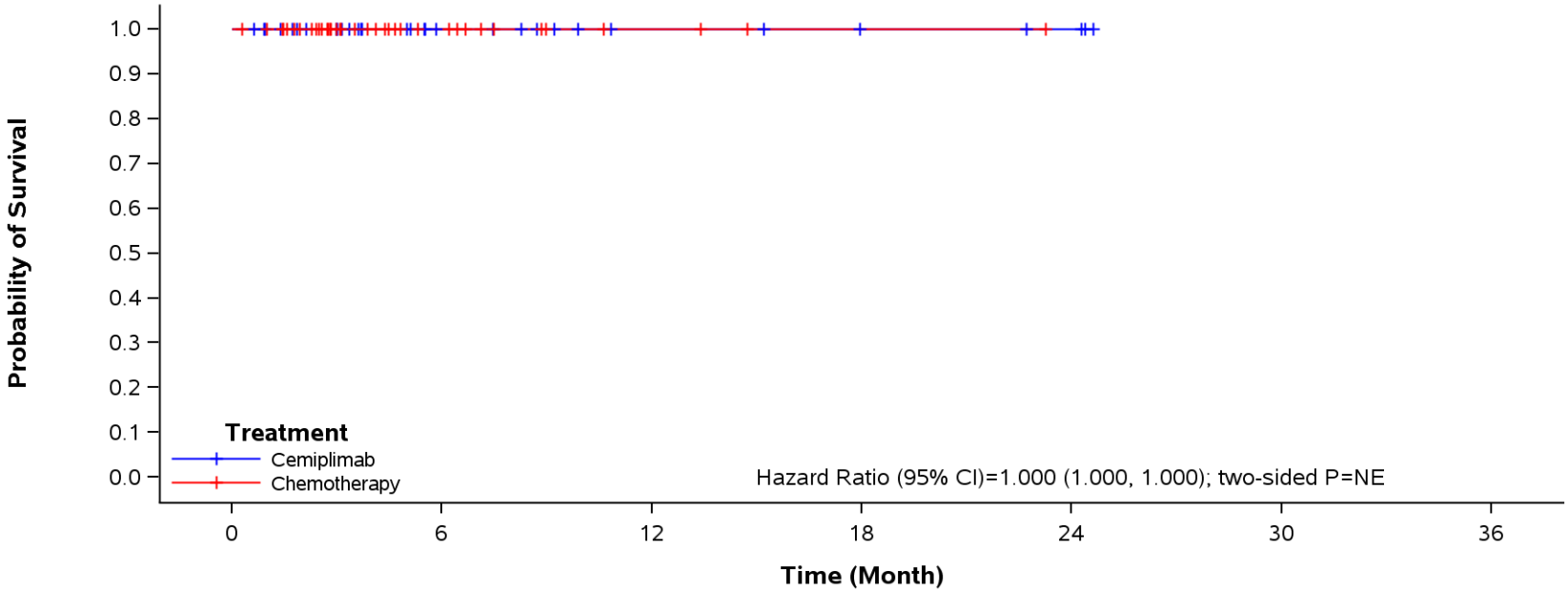

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Investigations
PT: Platelet count decreased



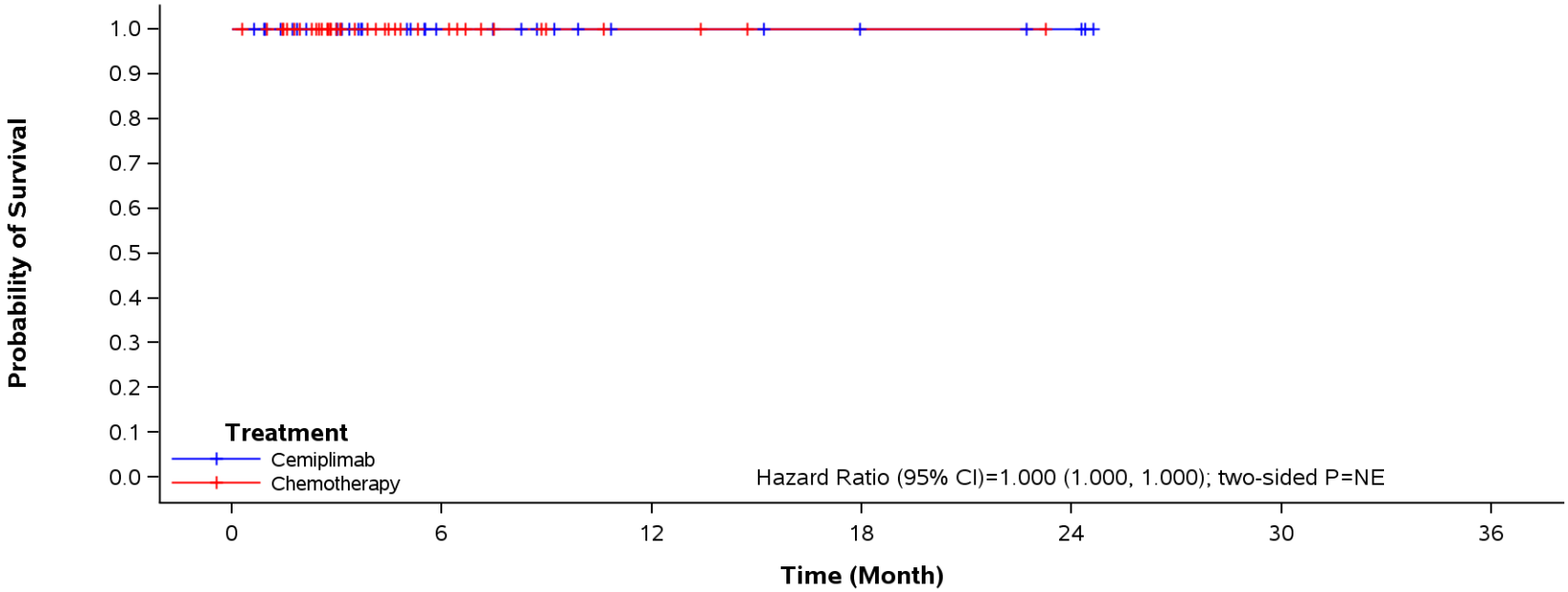

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Metabolism and nutrition disorders



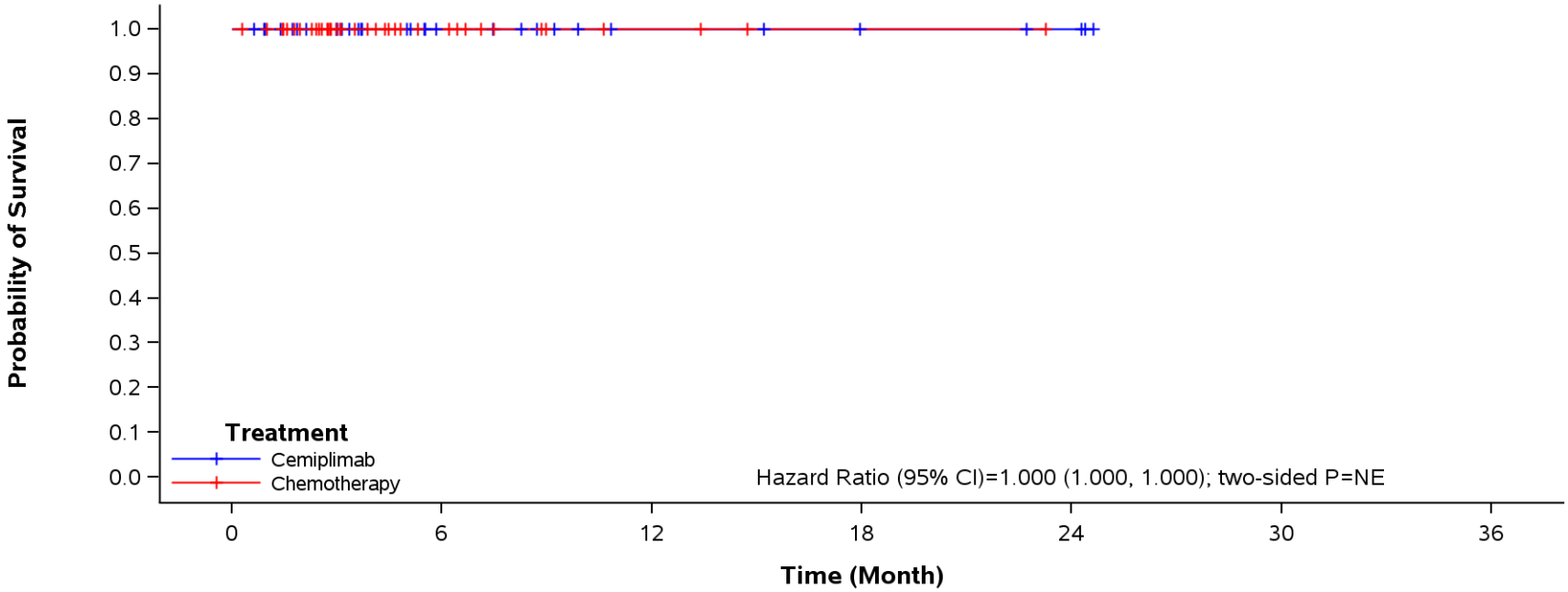

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



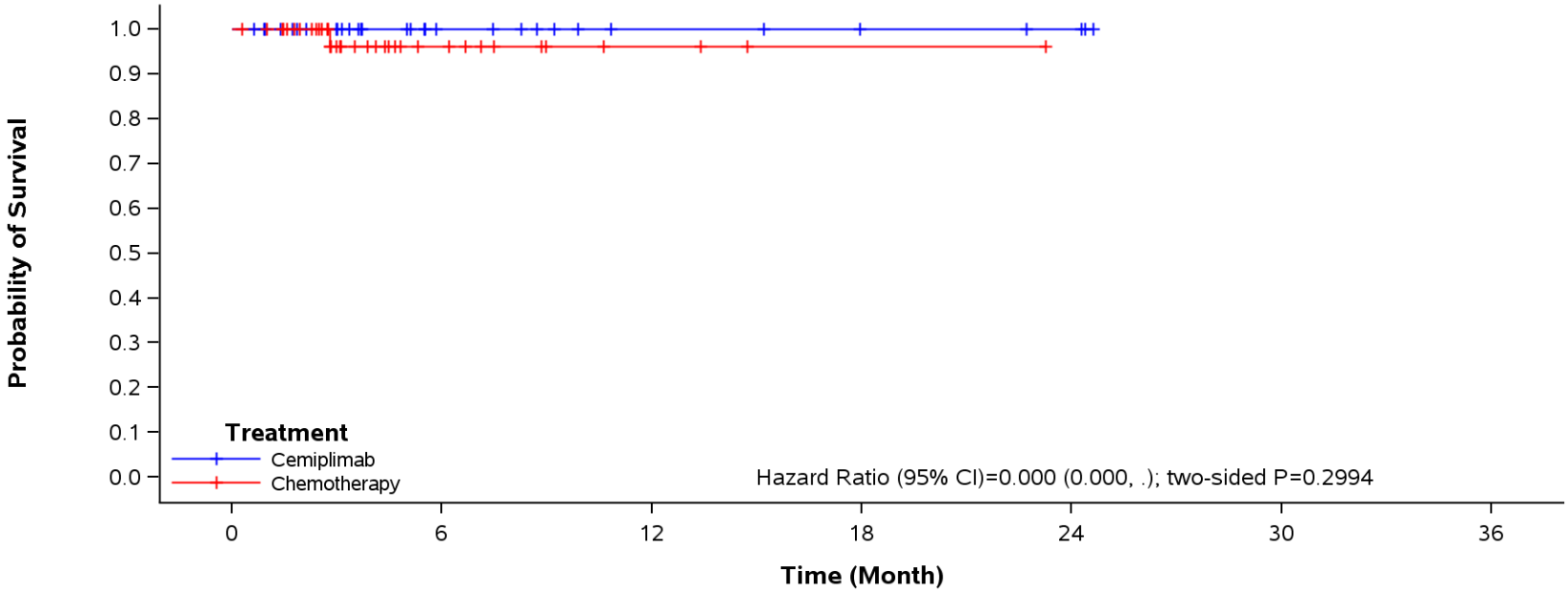

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Musculoskeletal and connective tissue disorders



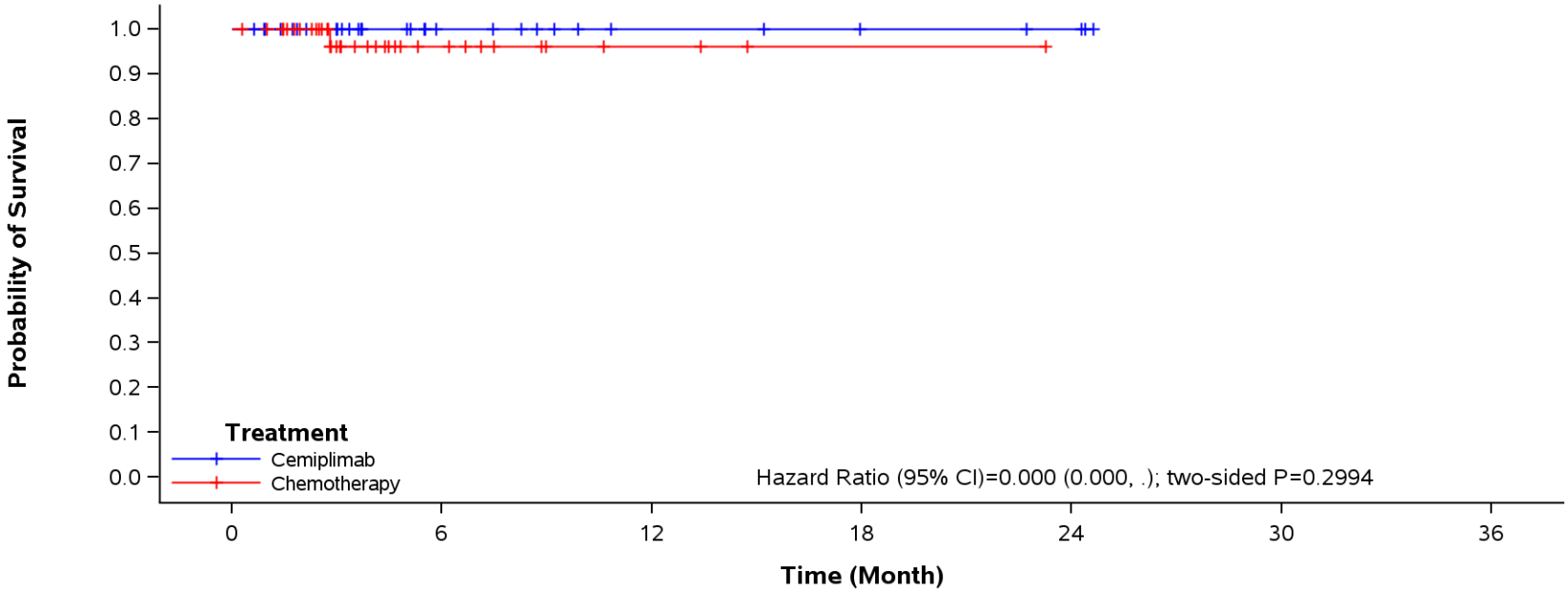

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



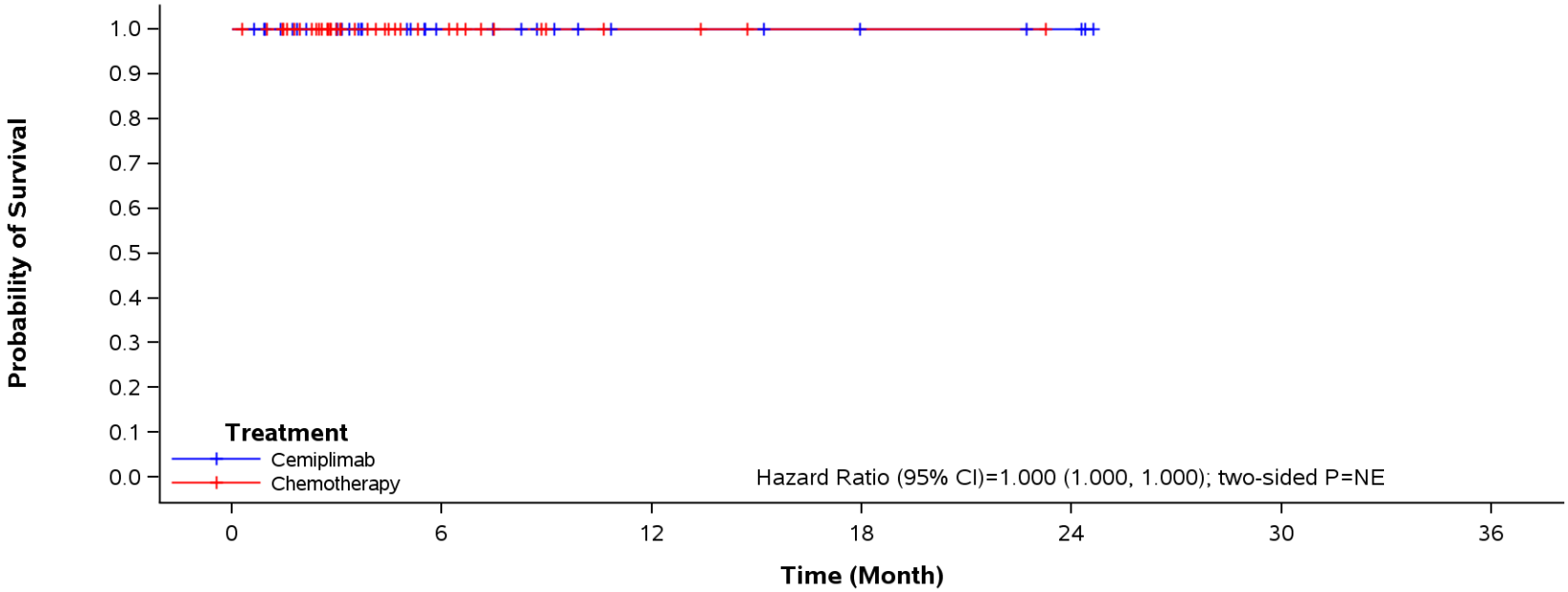

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 10 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



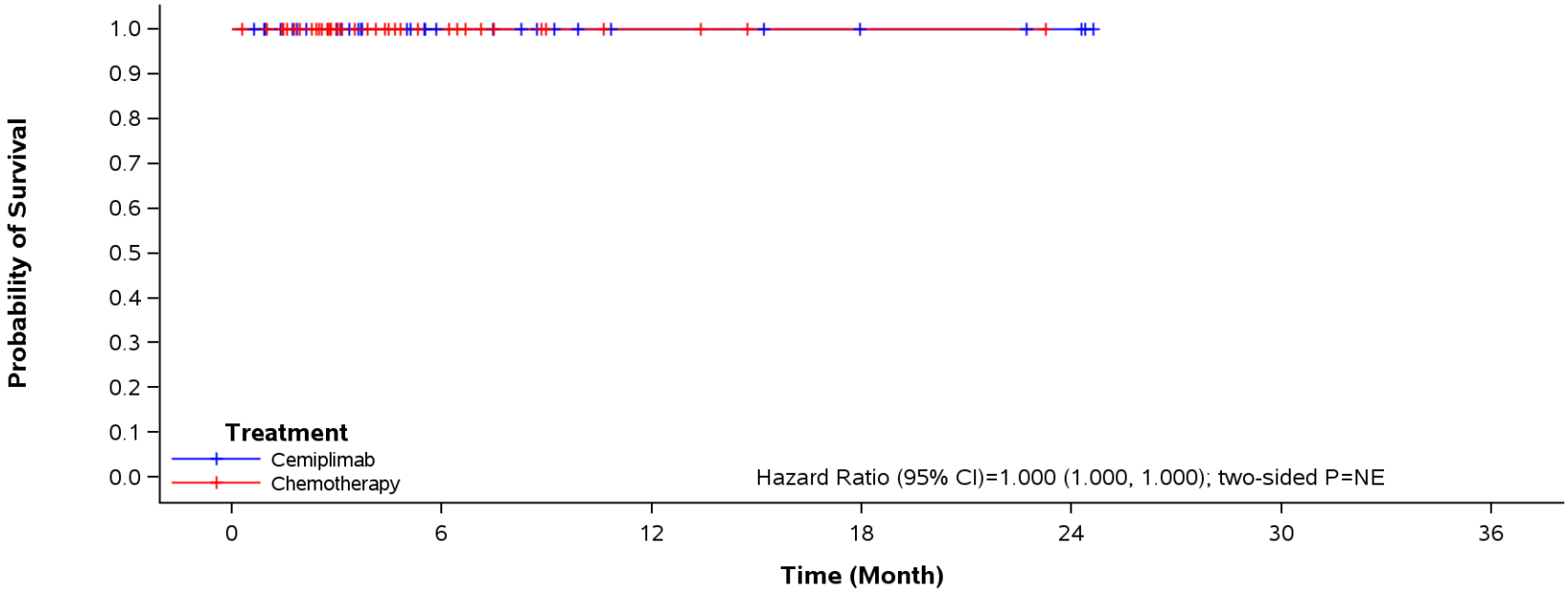

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Nervous system disorders



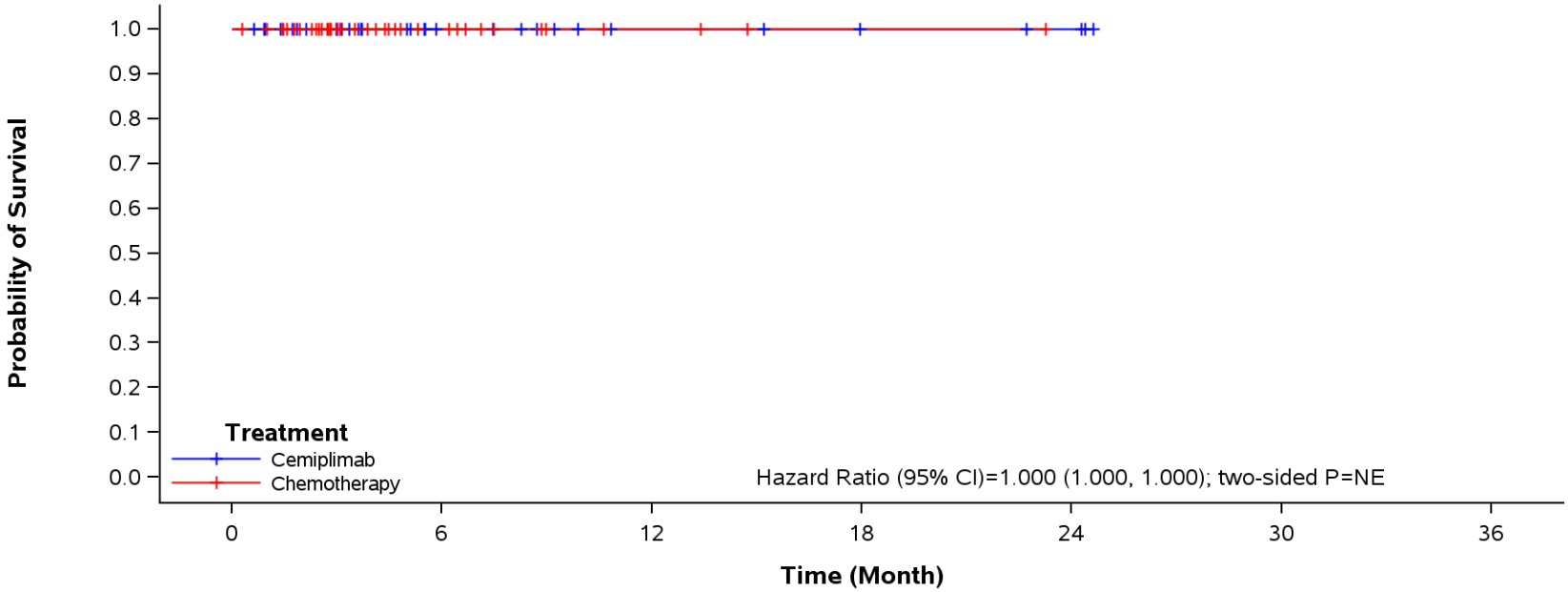

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Nervous system disorders
PT: Neurotoxicity



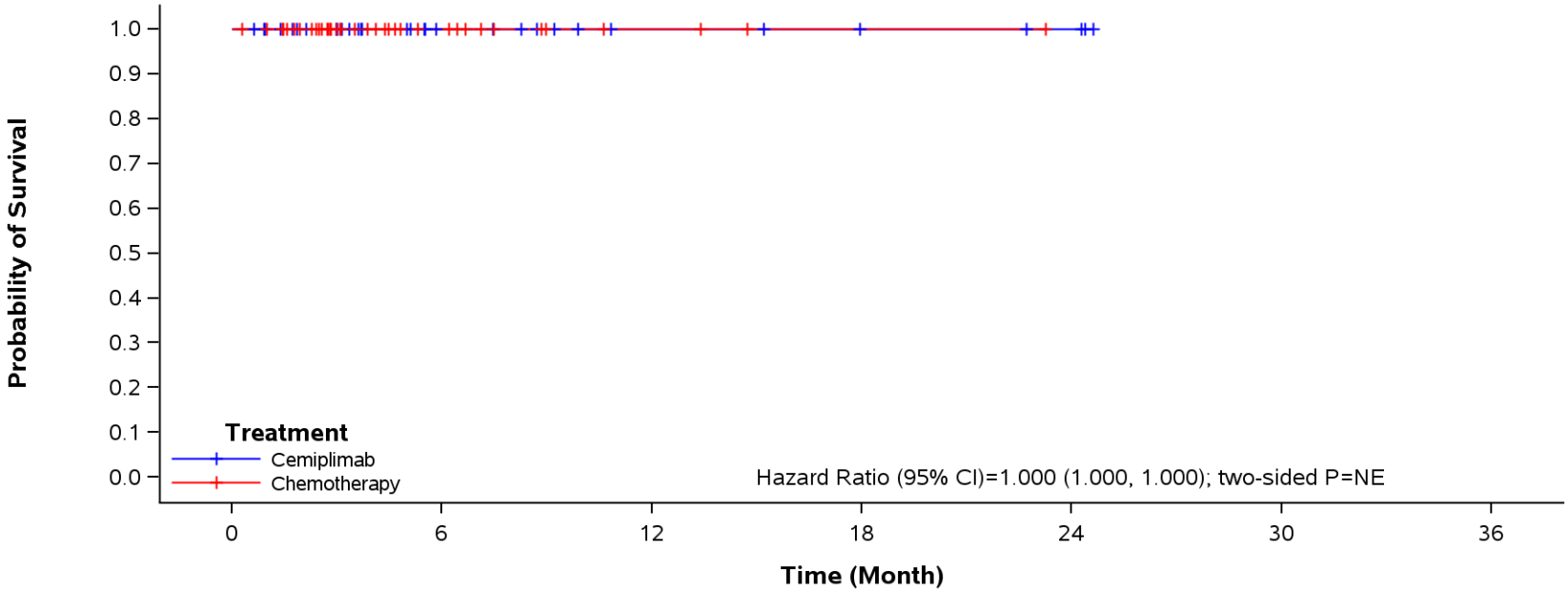

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Nervous system disorders
PT: Transient ischaemic attack



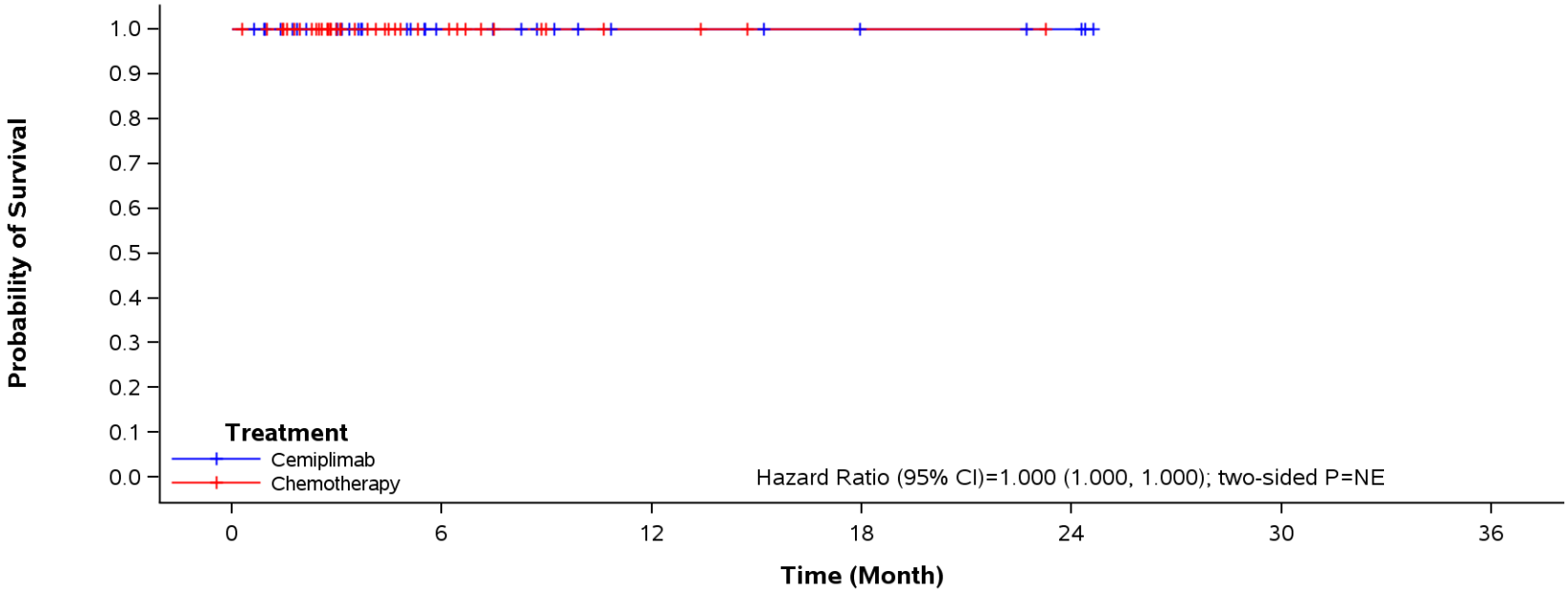

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Psychiatric disorders



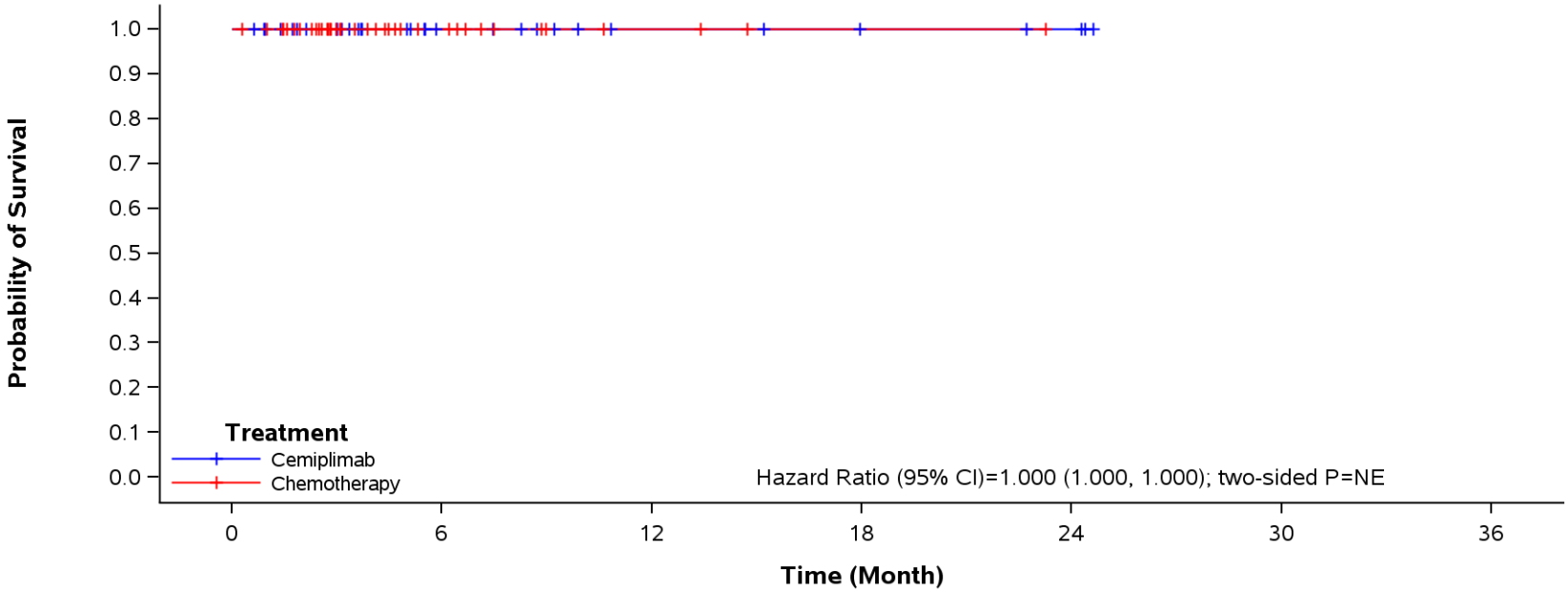

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Psychiatric disorders
PT: Agoraphobia



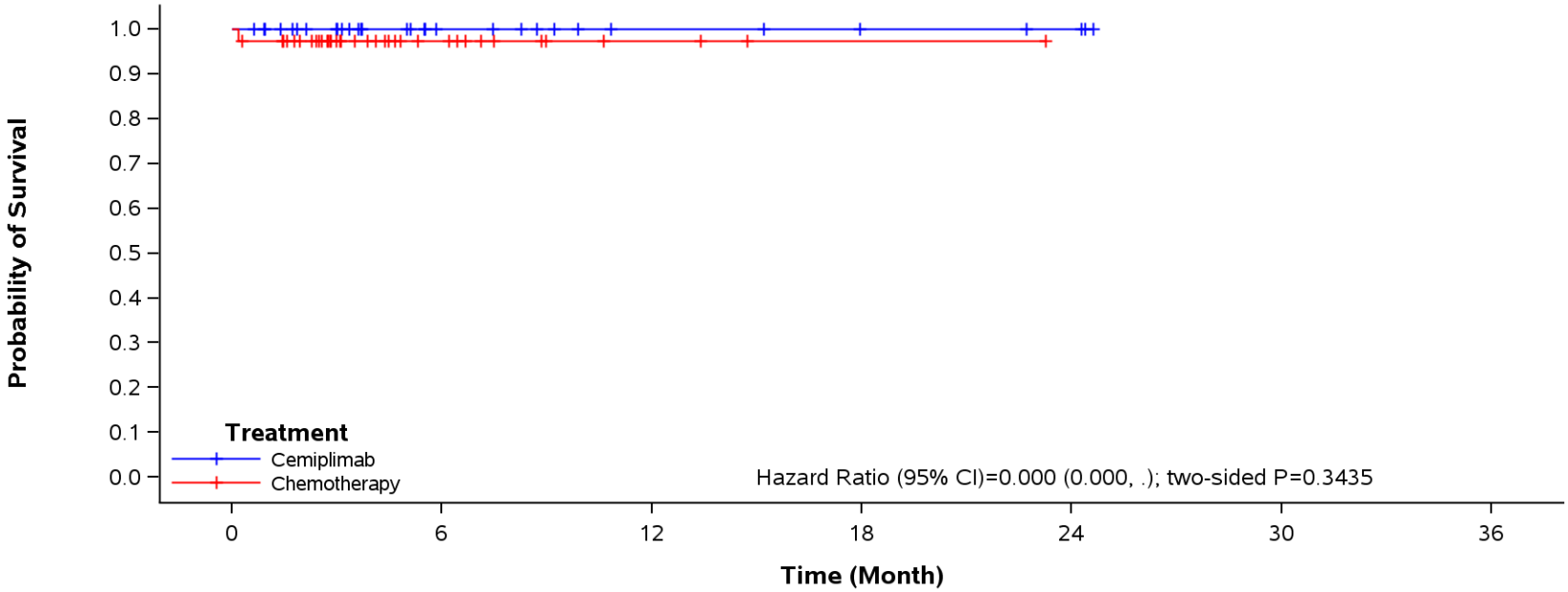

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Renal and urinary disorders



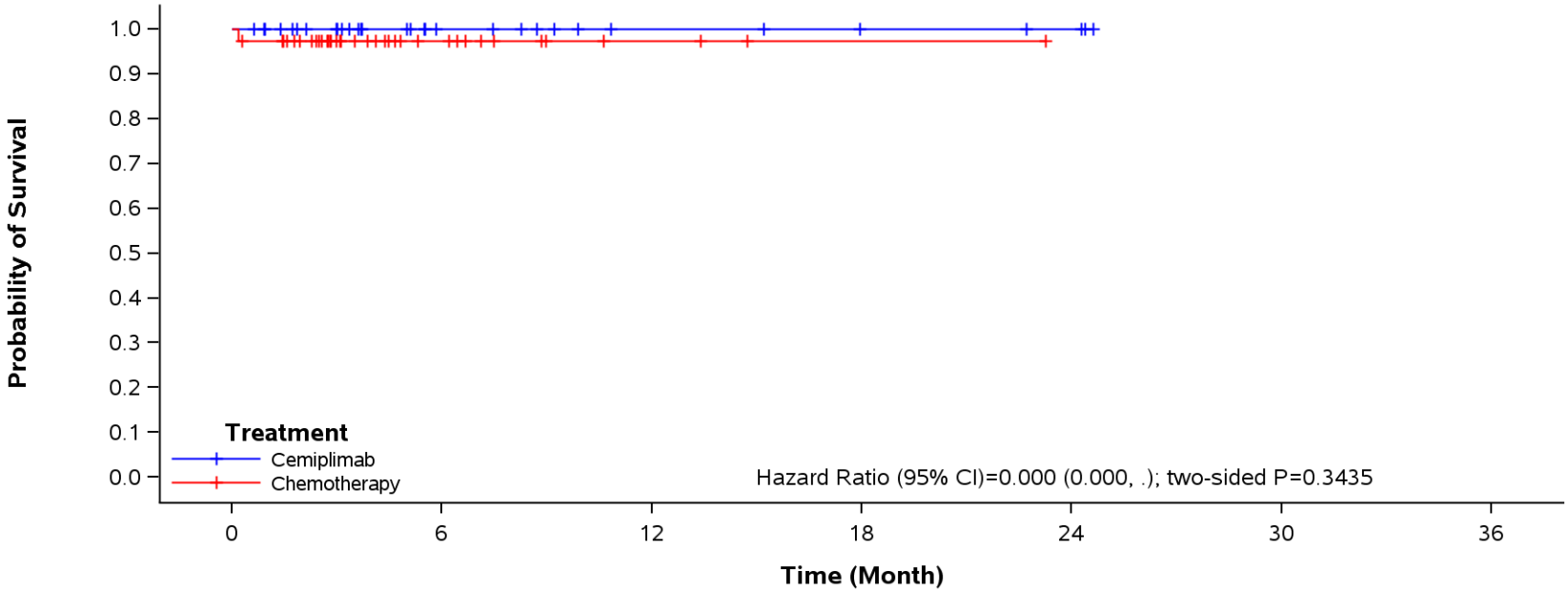

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Renal and urinary disorders
PT: Renal failure



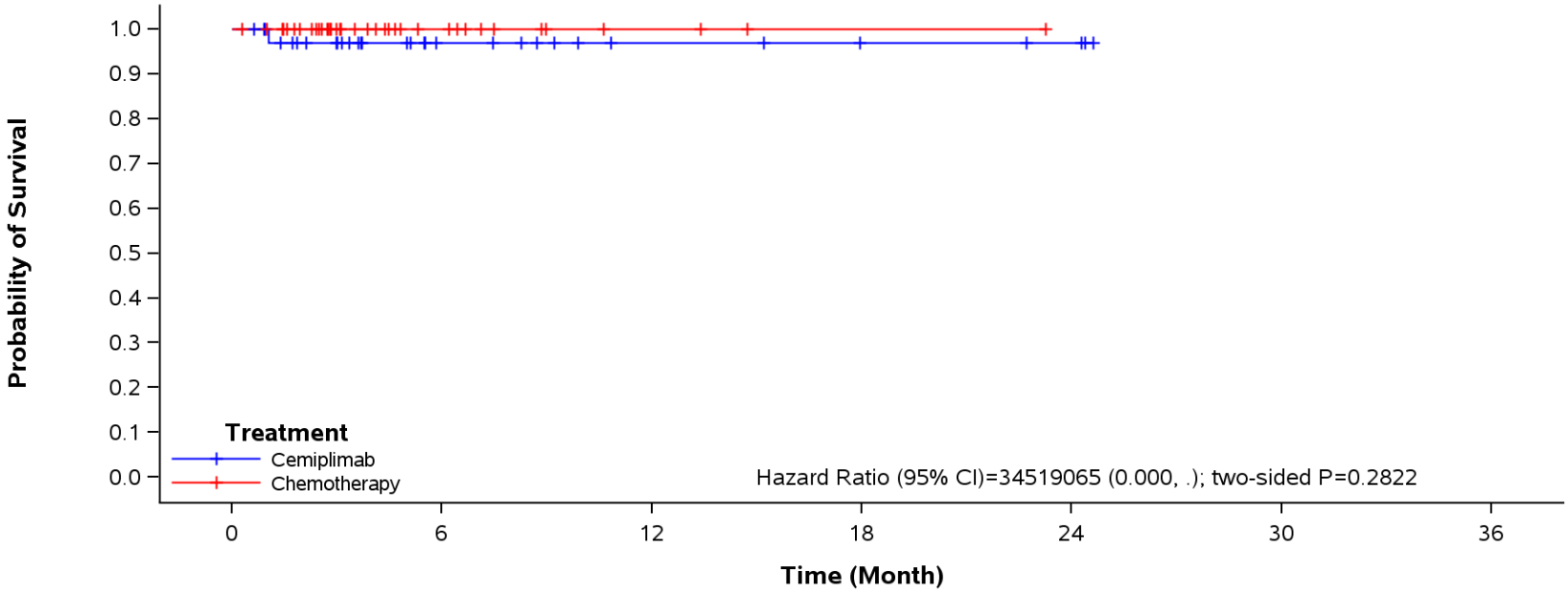

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Respiratory, thoracic and mediastinal disorders



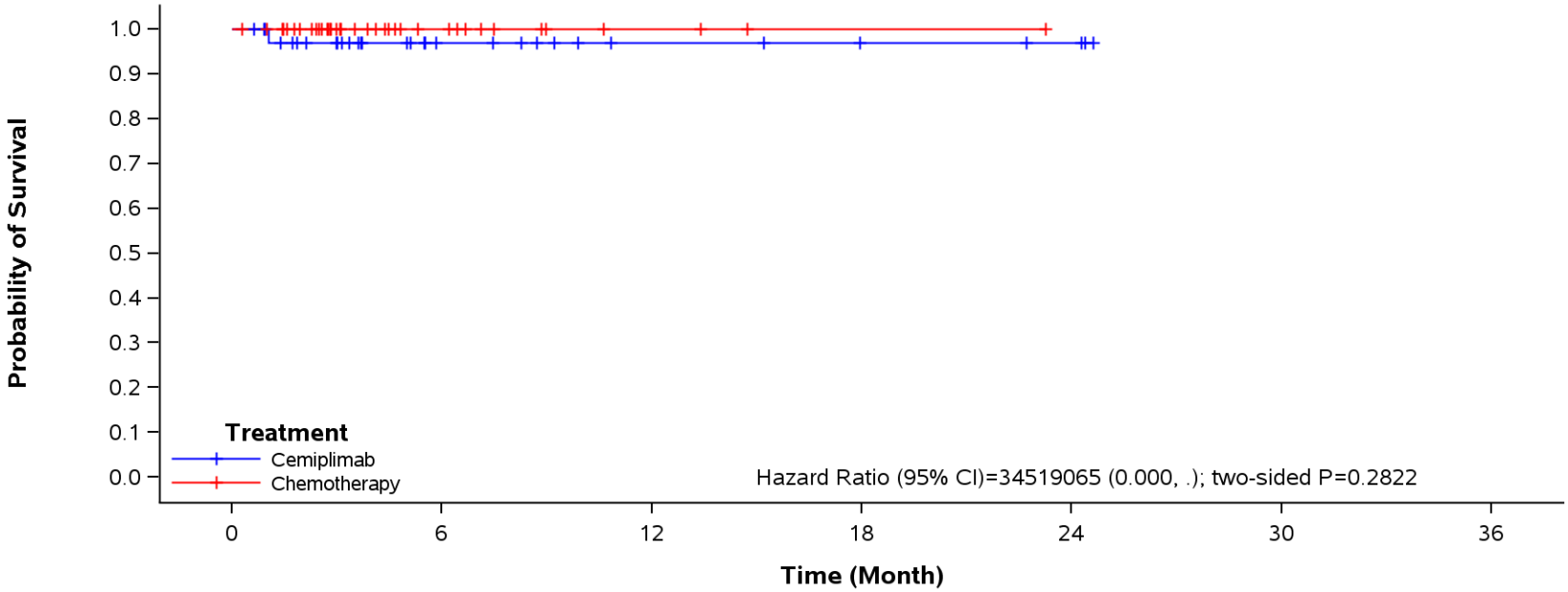

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



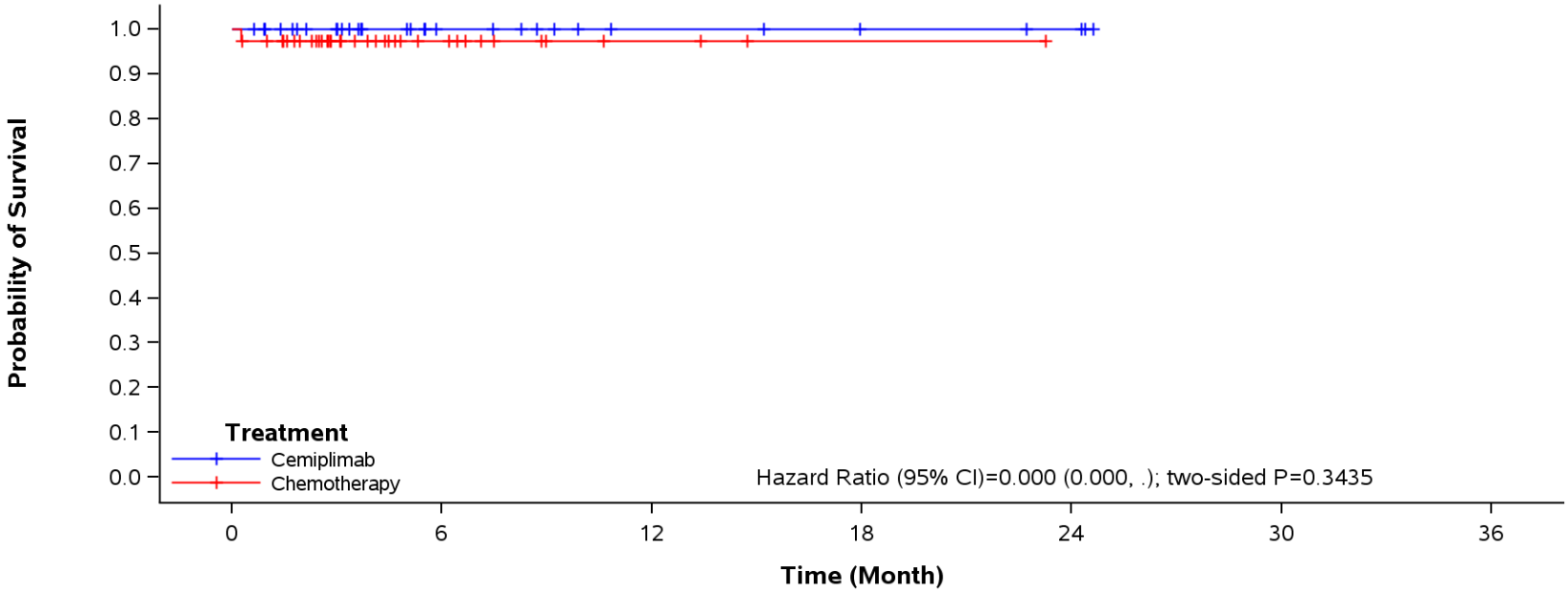

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Vascular disorders



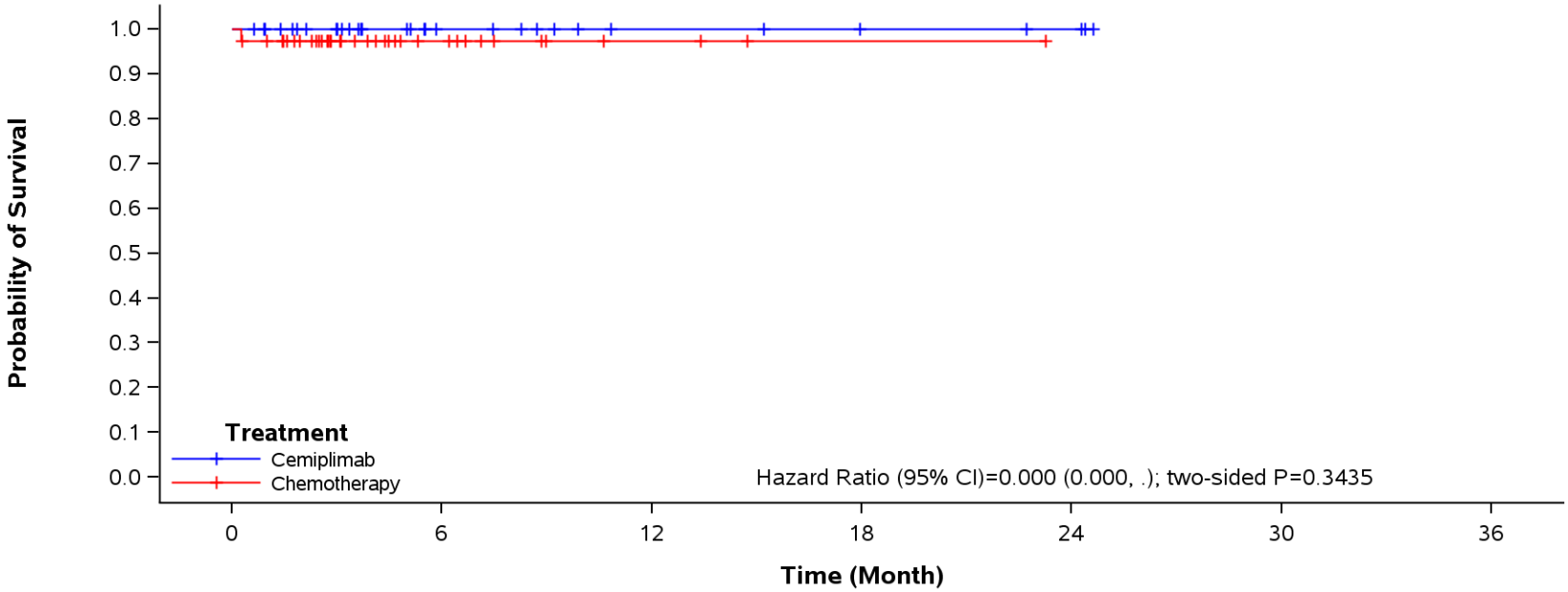

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Histology: Adenocarcinoma/adenosquamous
SOC: Vascular disorders
PT: Deep vein thrombosis



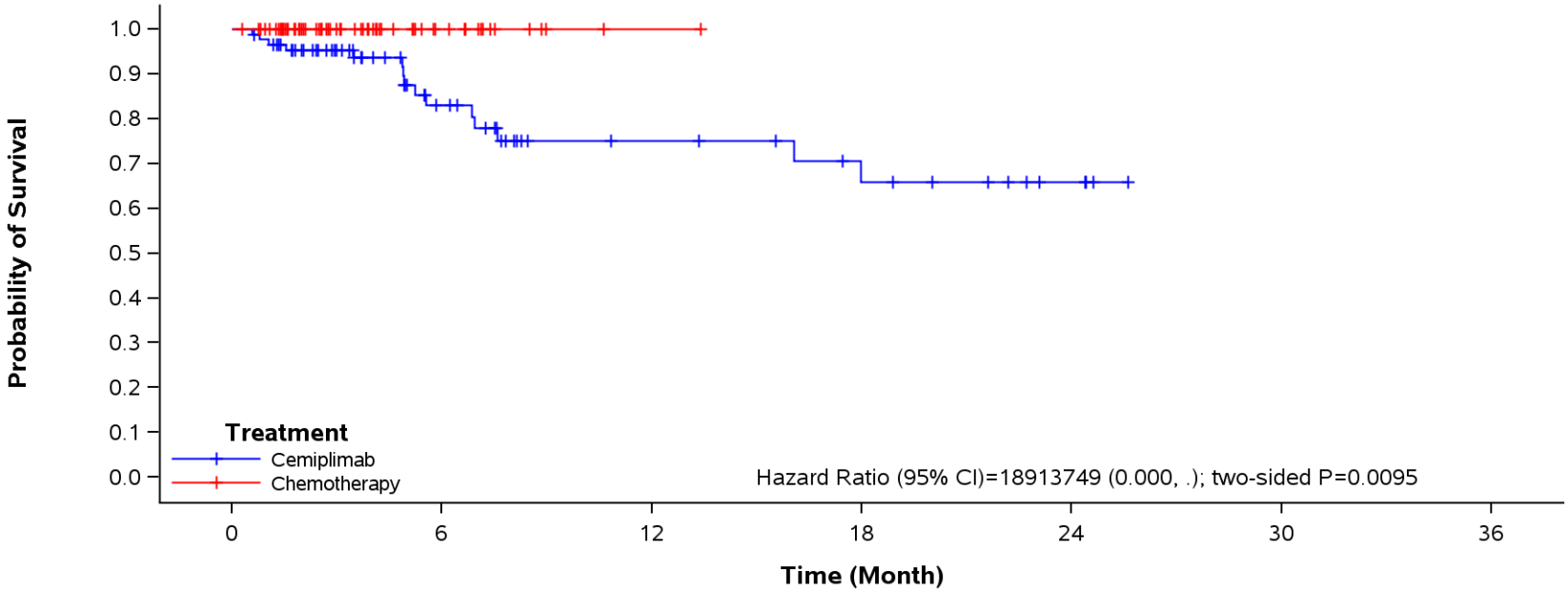

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 35 | 12 | 6 | 4 | 3 | 0 | 0 |
| Chemotherapy | 39 | 11 | 3 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
Number of patients with any TEAE leading to discontinuation



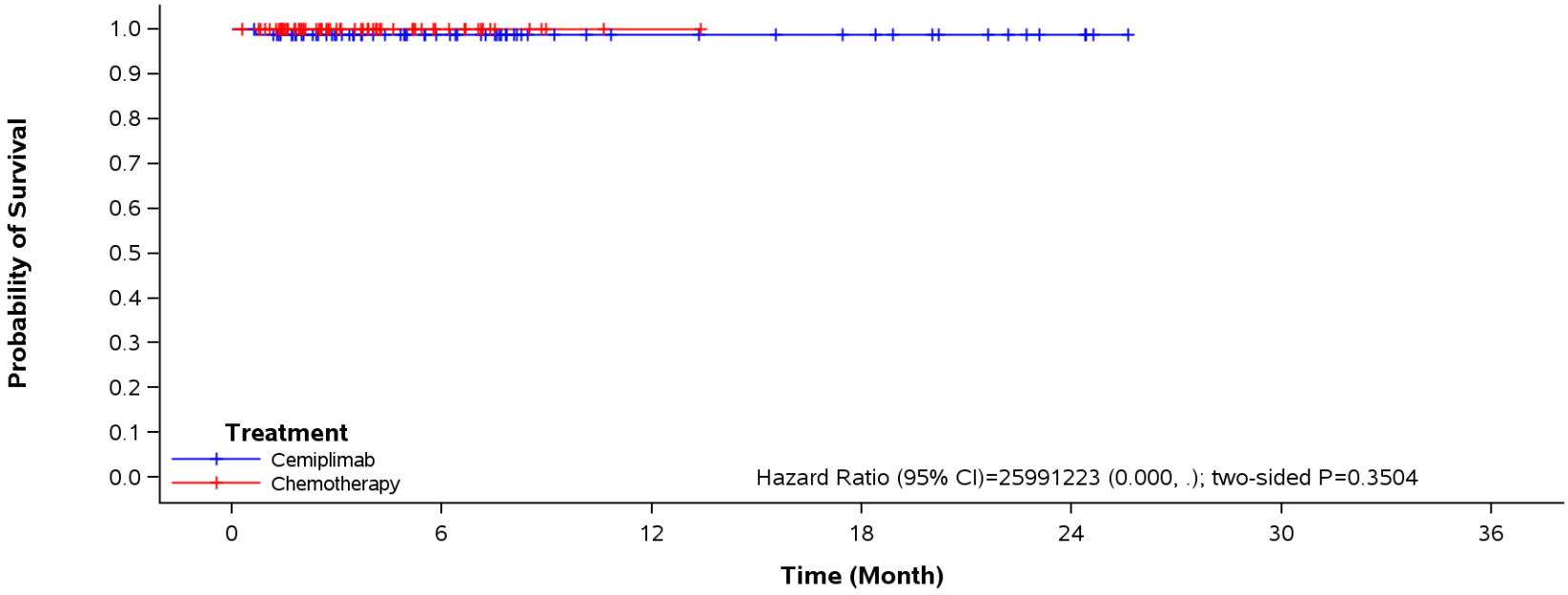

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 35 | 19 | 14 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders



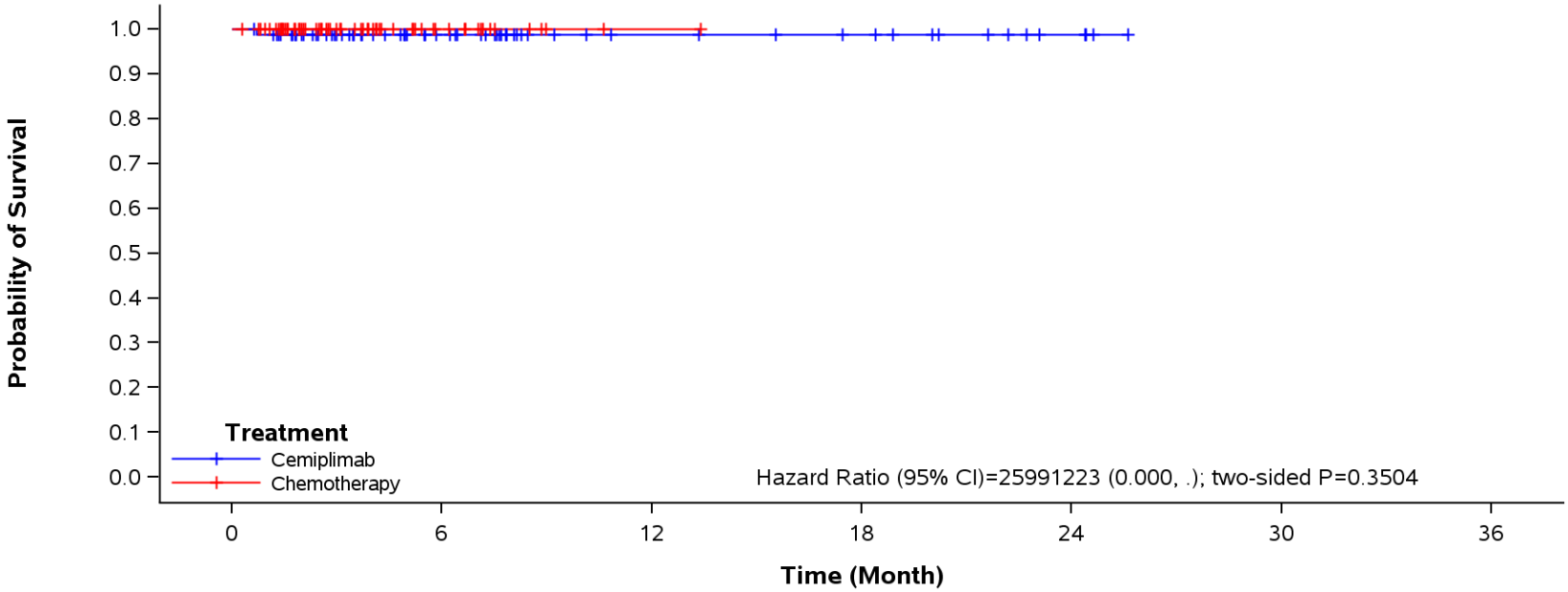

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Anaemia



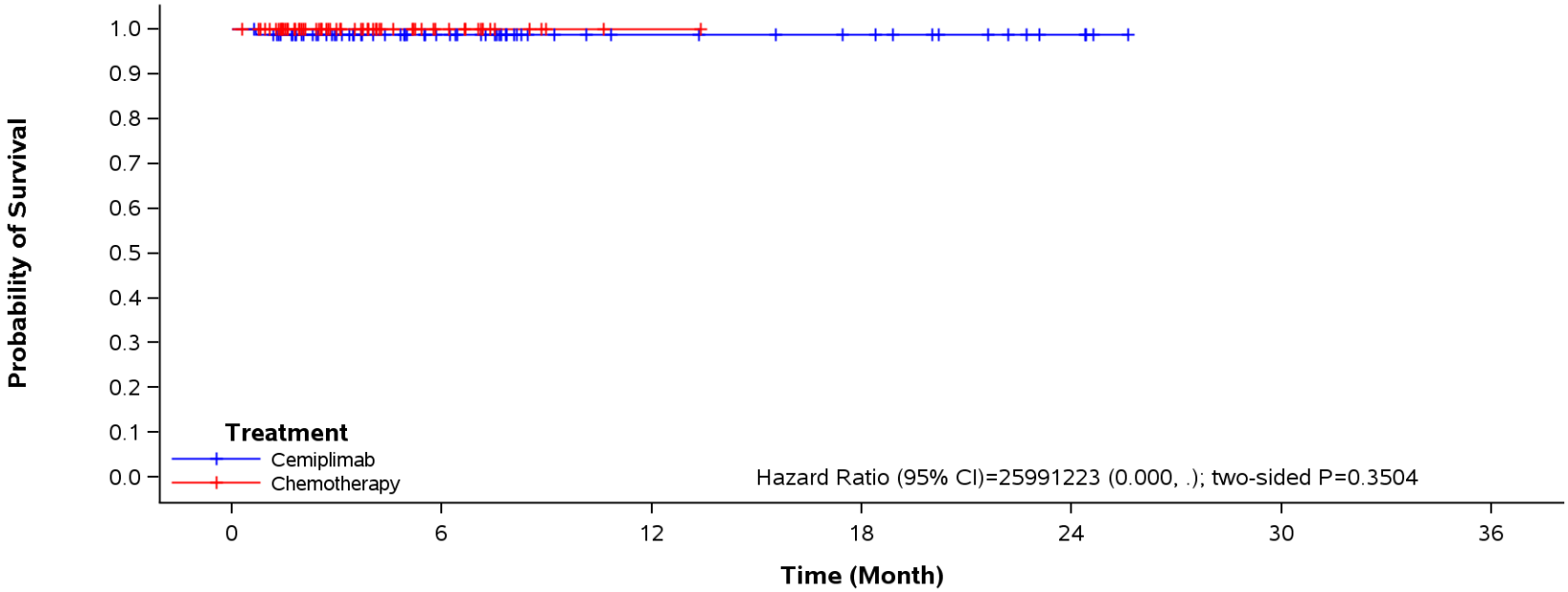

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



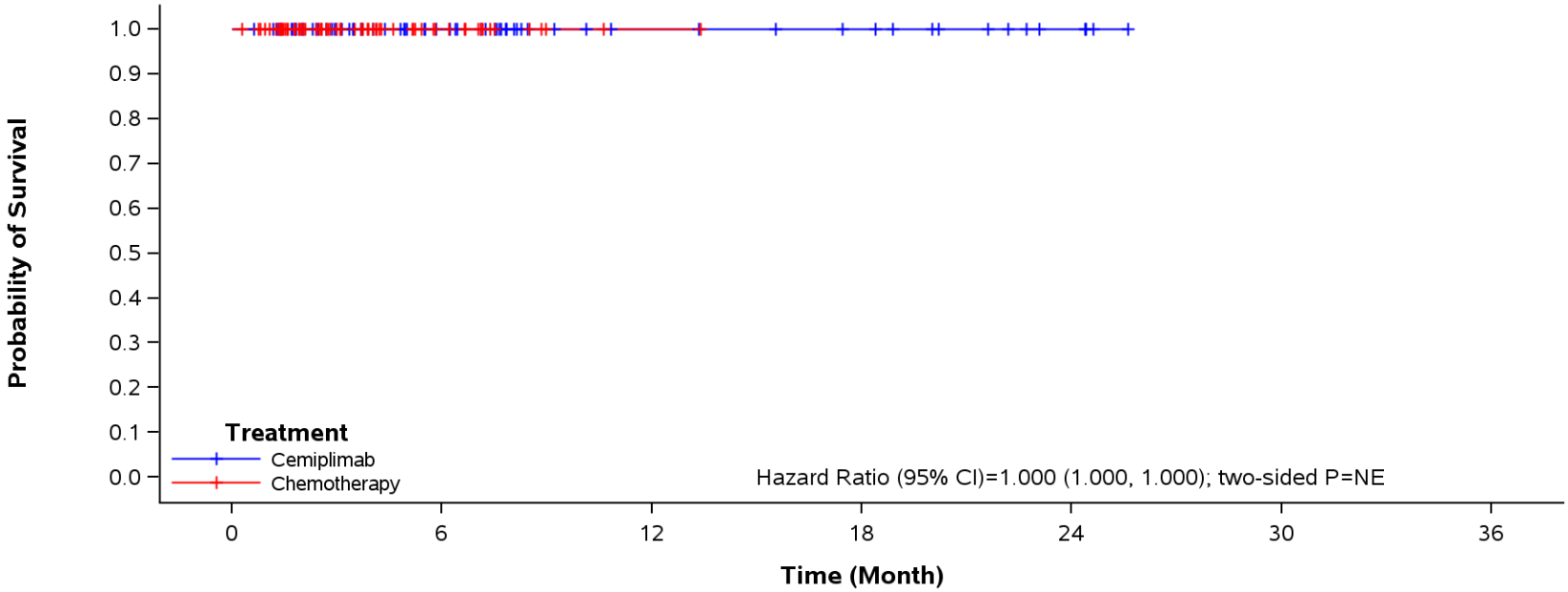

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Neutropenia



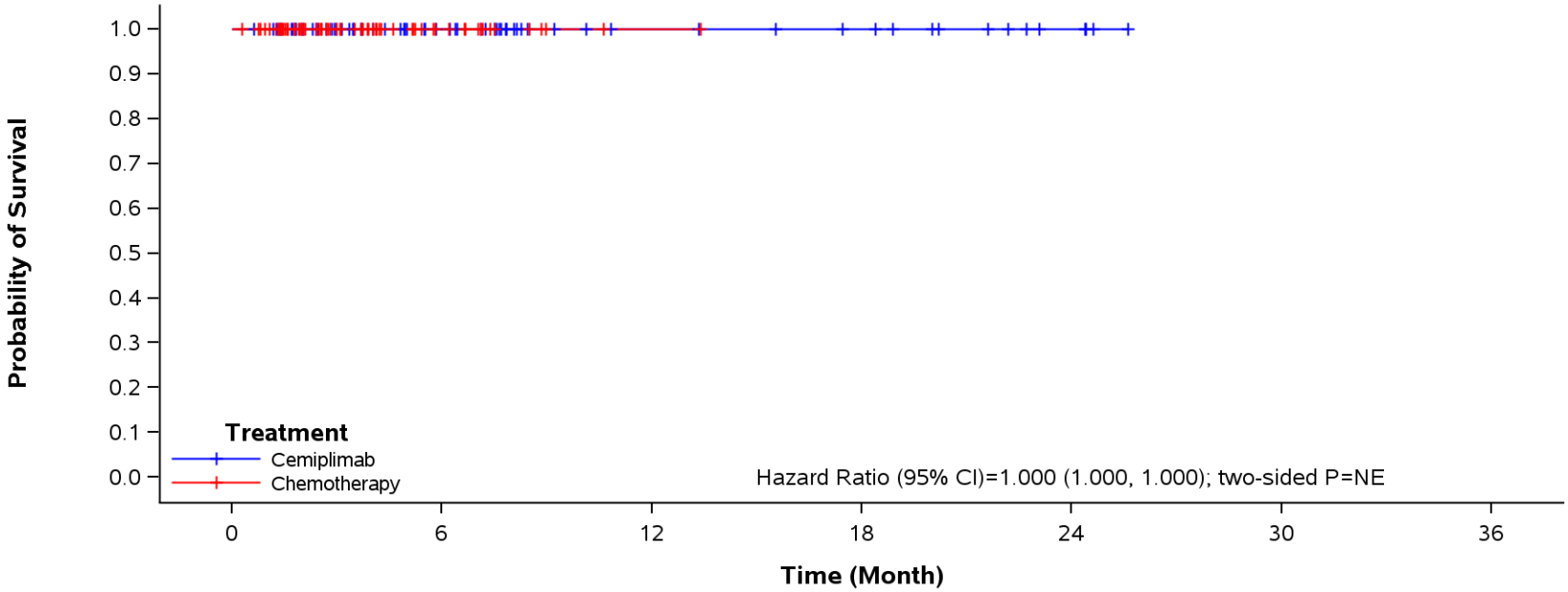

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



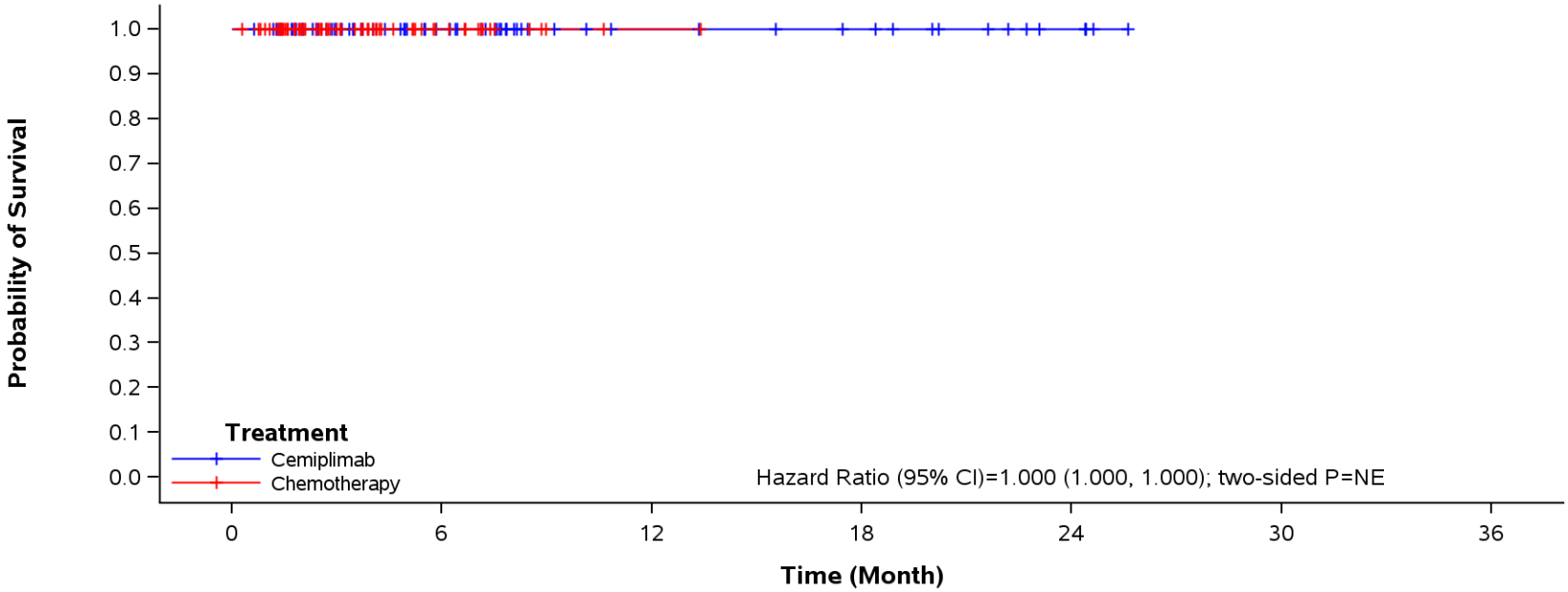

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Cardiac disorders



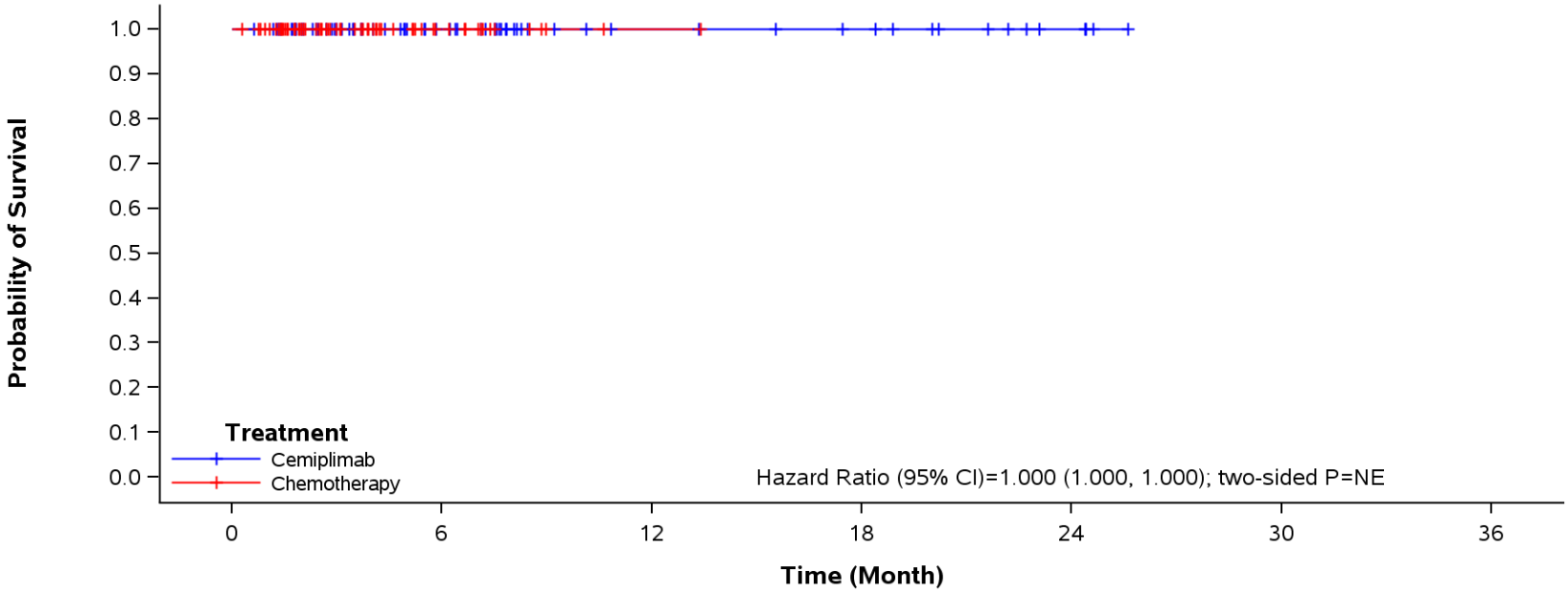

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Cardiac disorders
PT: Autoimmune pericarditis



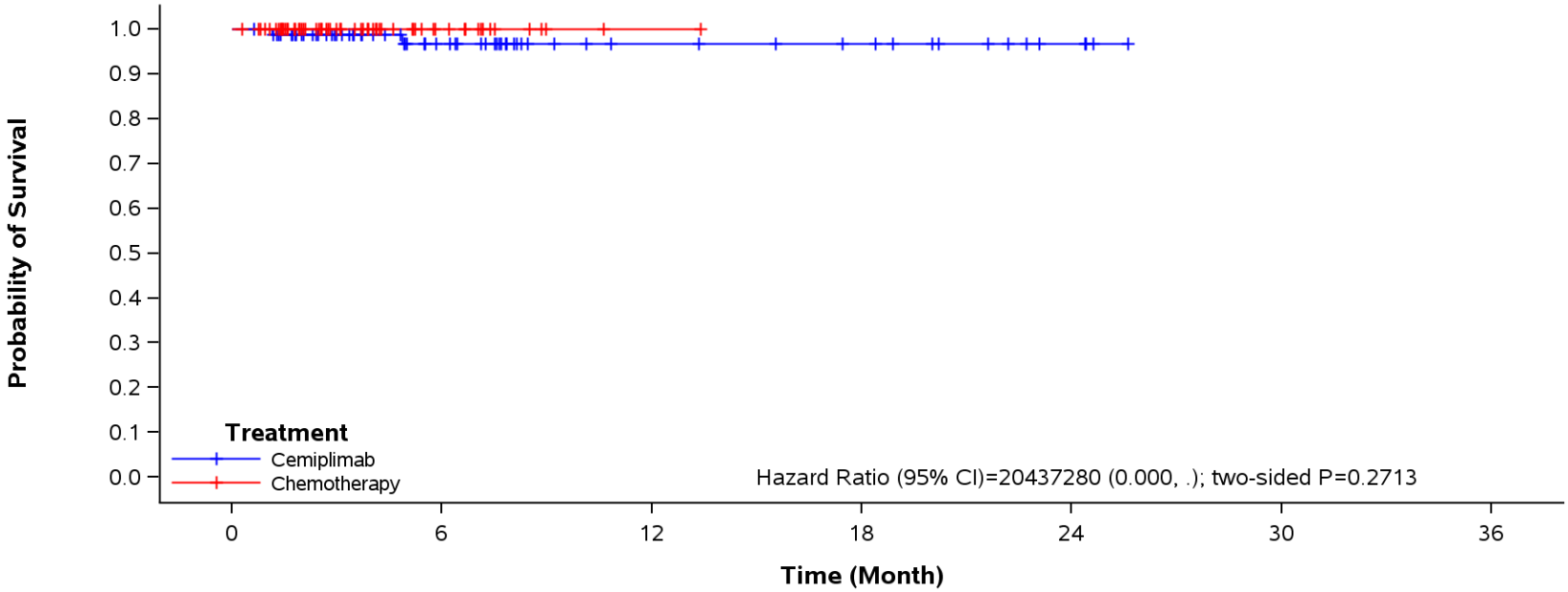

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Endocrine disorders



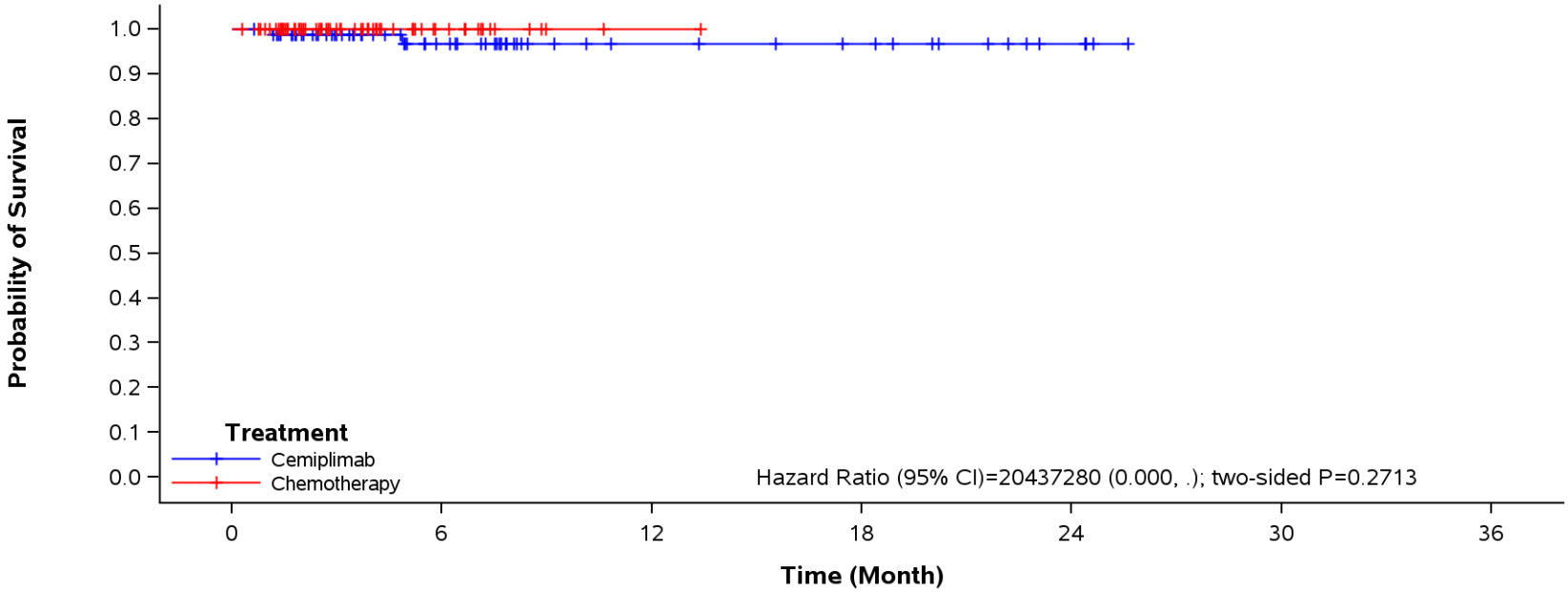

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Endocrine disorders
PT: Hypothyroidism



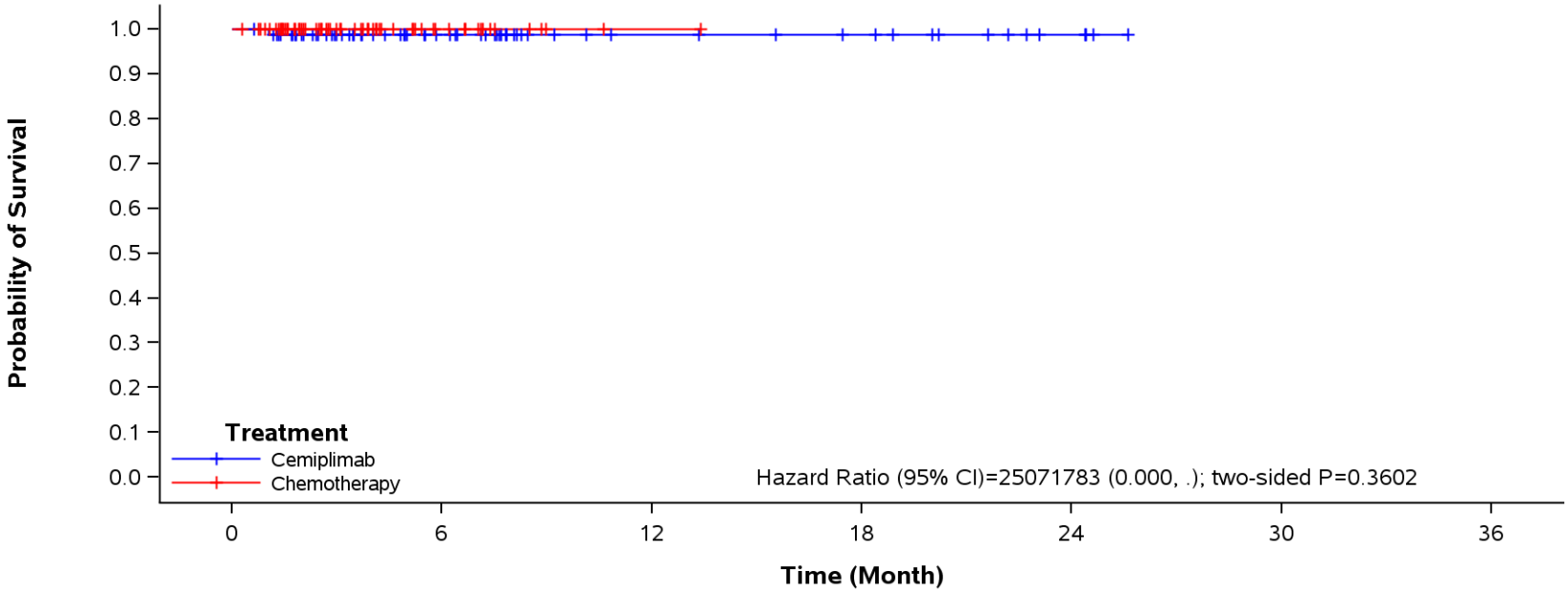

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders



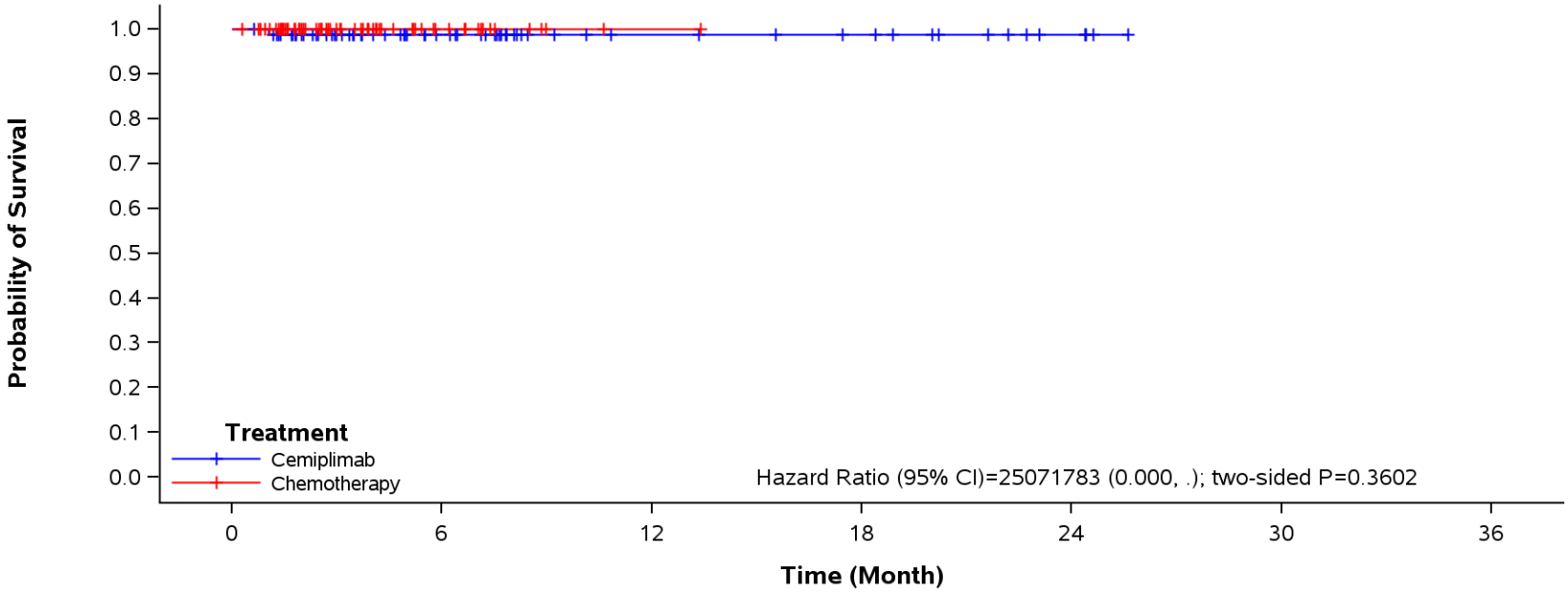

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders
PT: Colitis



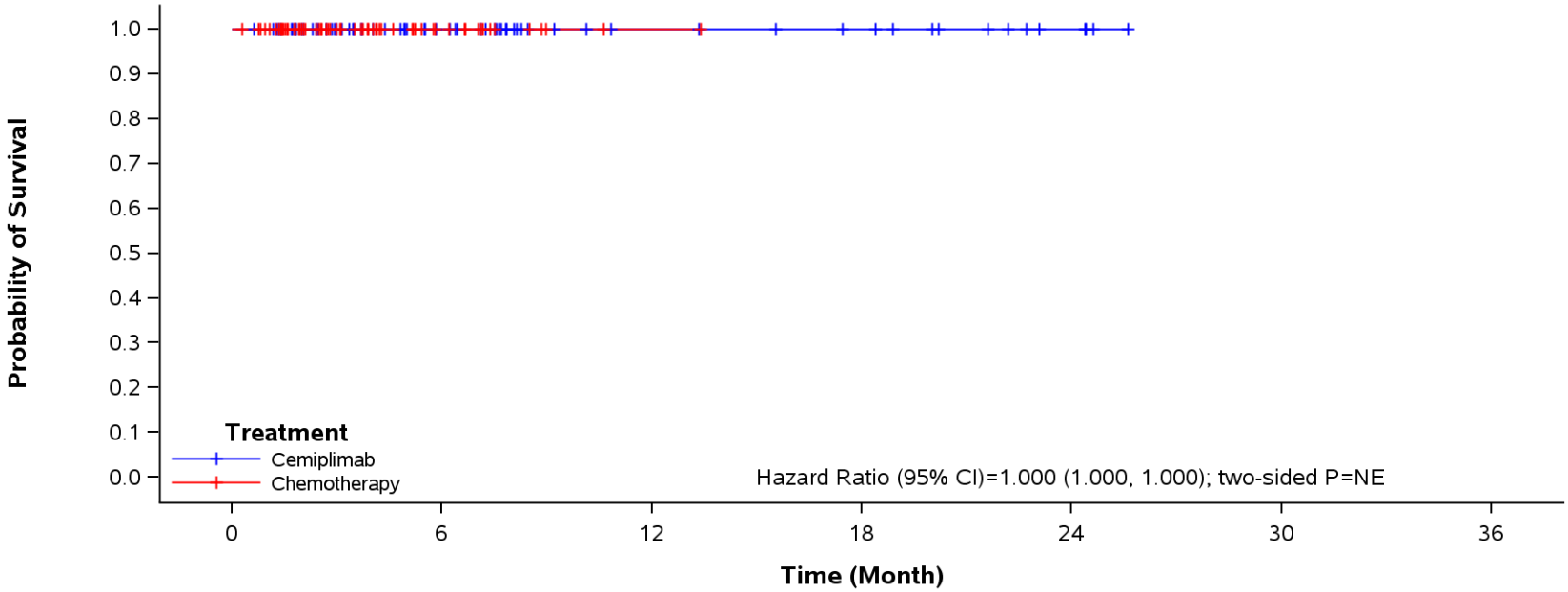

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders
PT: Diverticular perforation



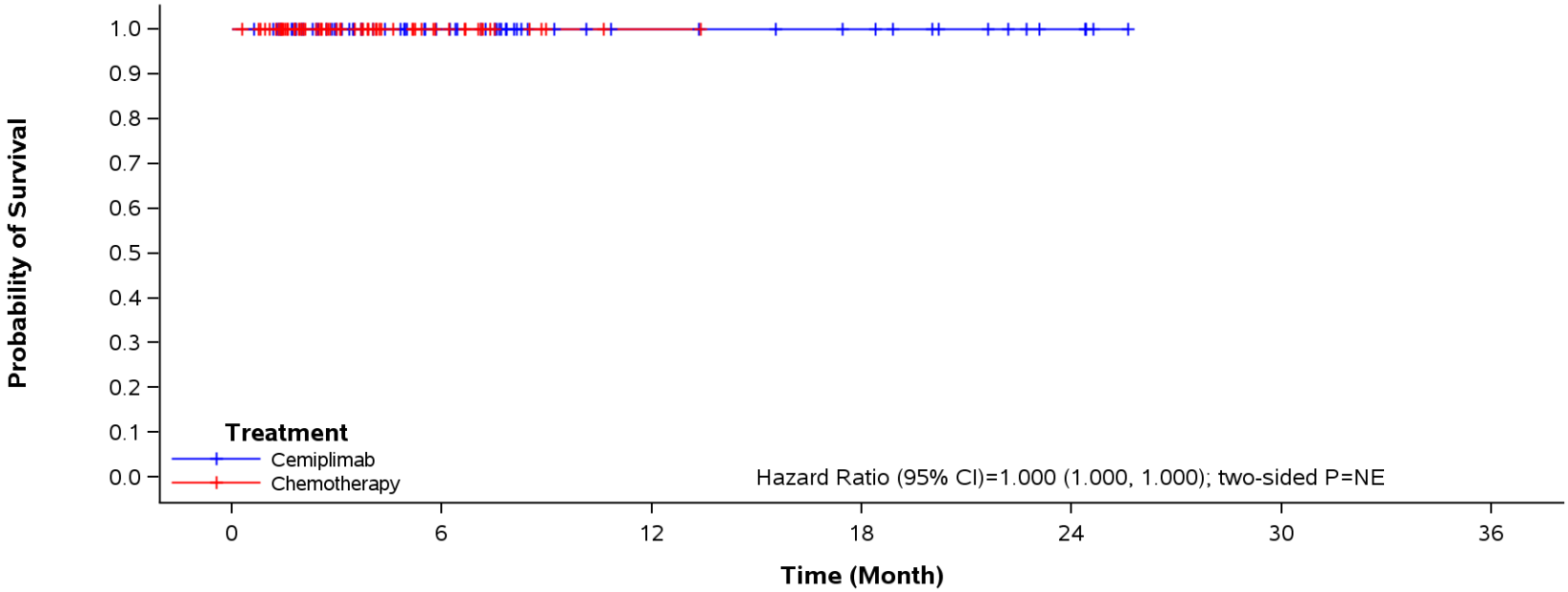

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders
PT: Pancreatic mass



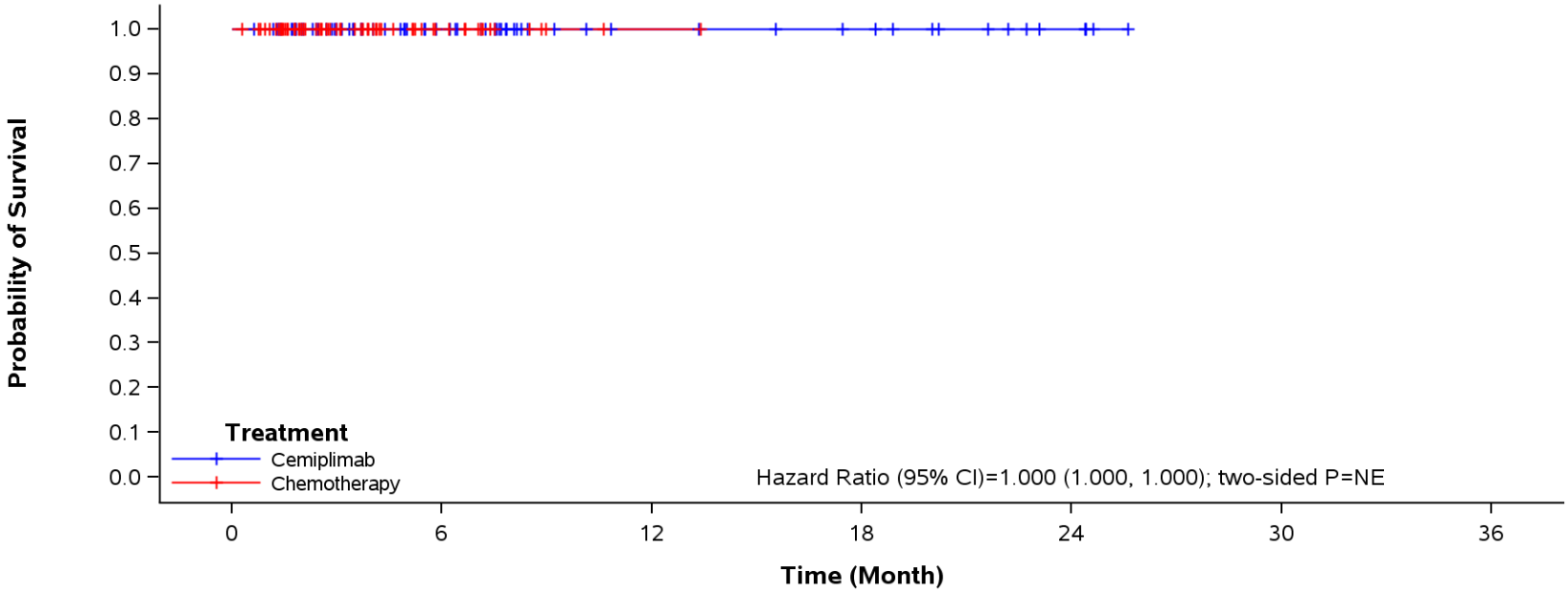

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



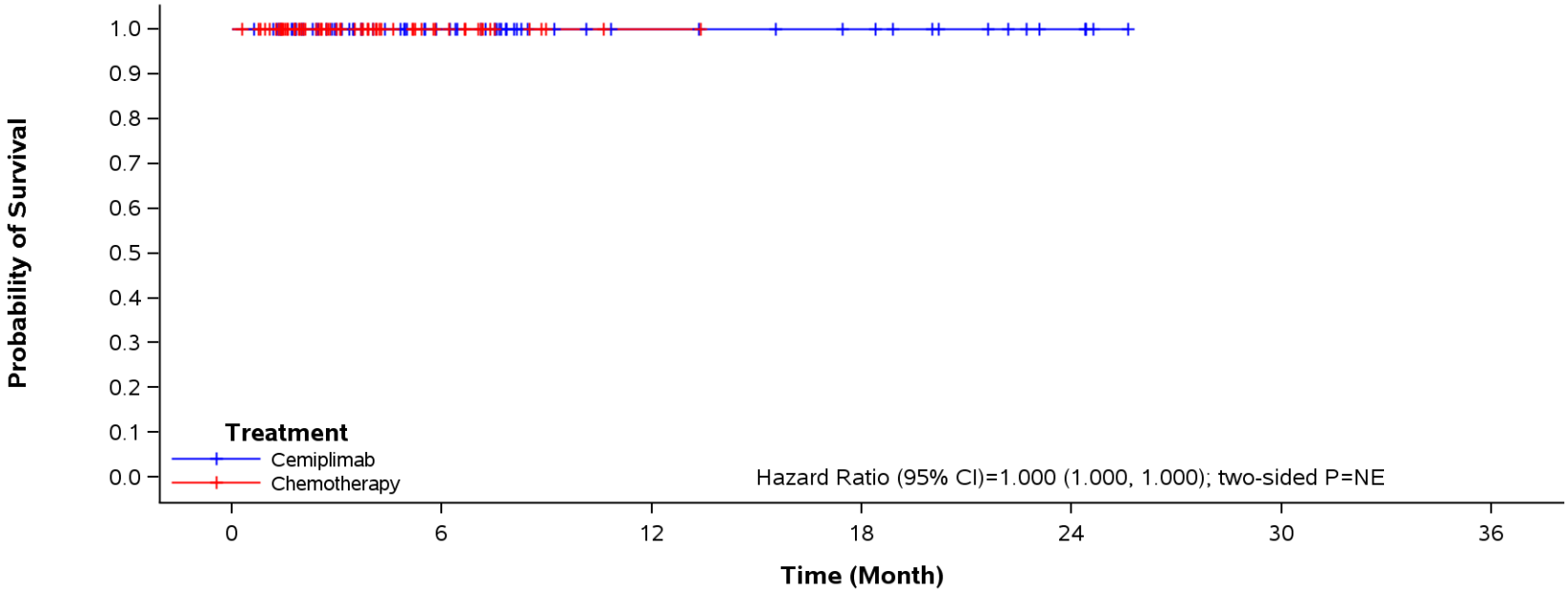

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Gastrointestinal disorders
PT: Proctalgia




**Number of Subjects at risk**

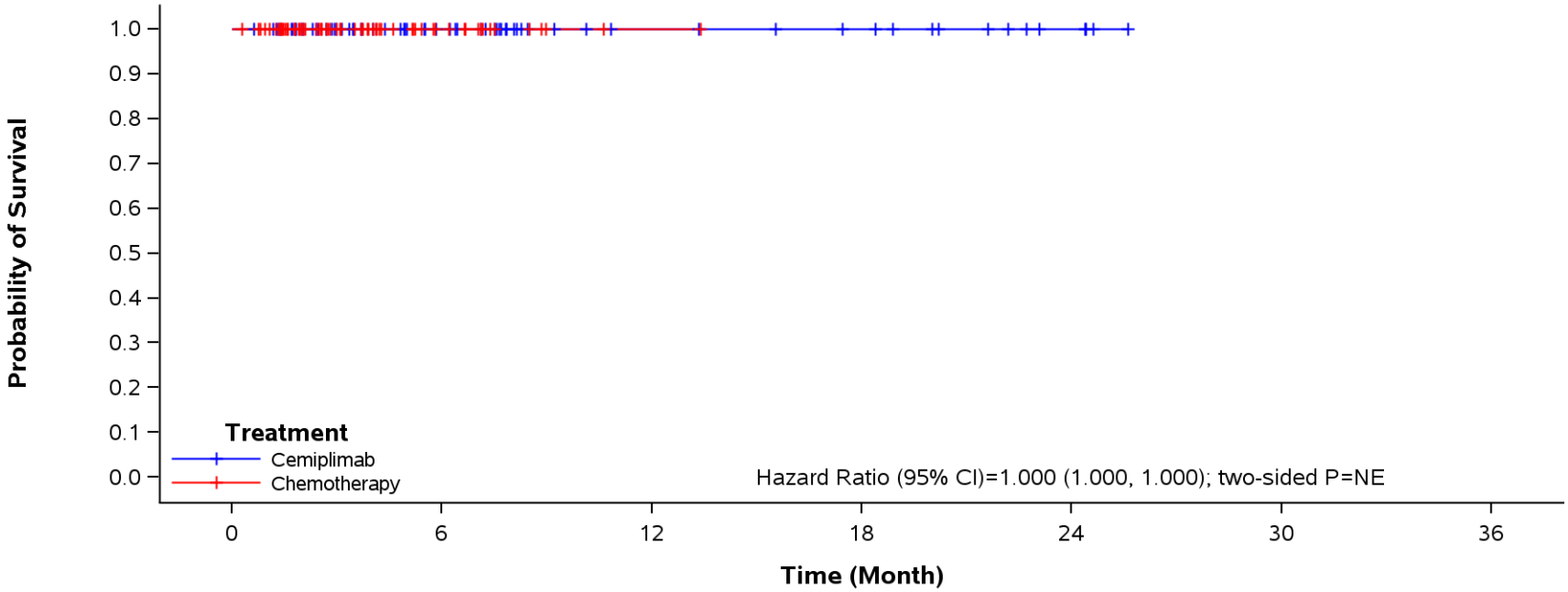
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

SOC: General disorders and administration site conditions




**Number of Subjects at risk**

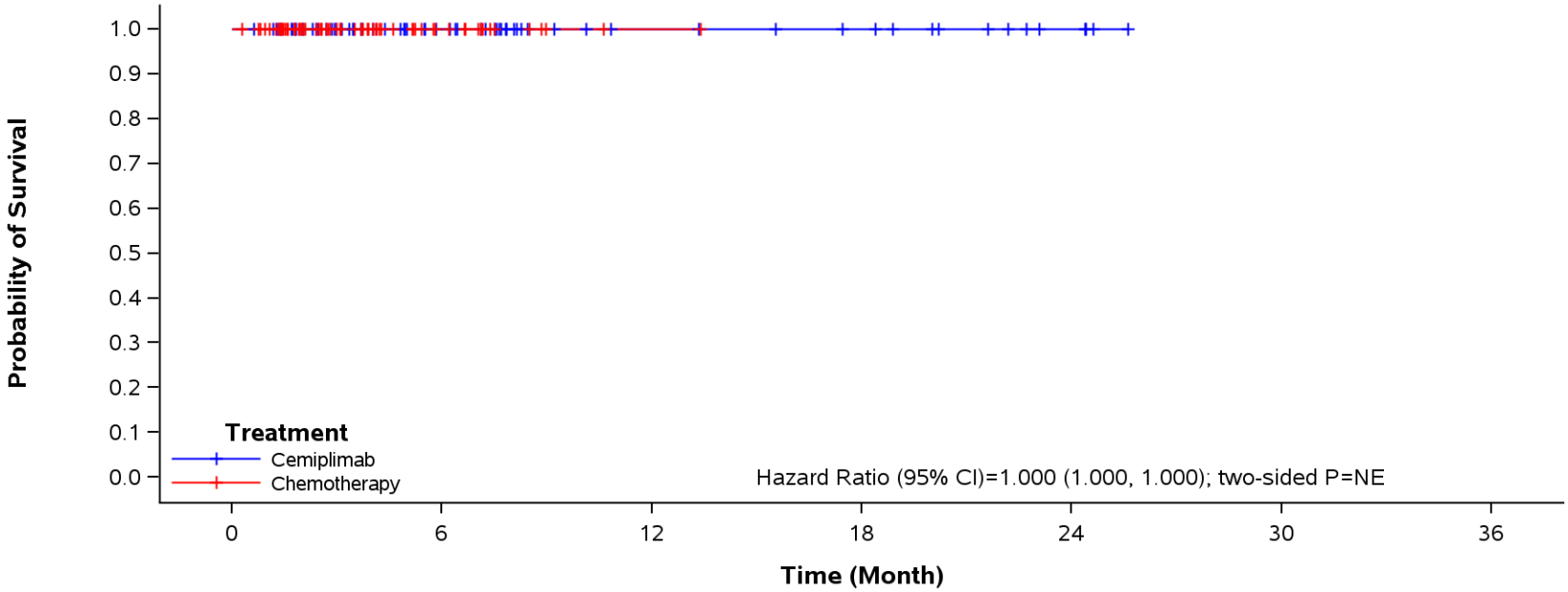
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: General disorders and administration site conditions
PT: Malaise



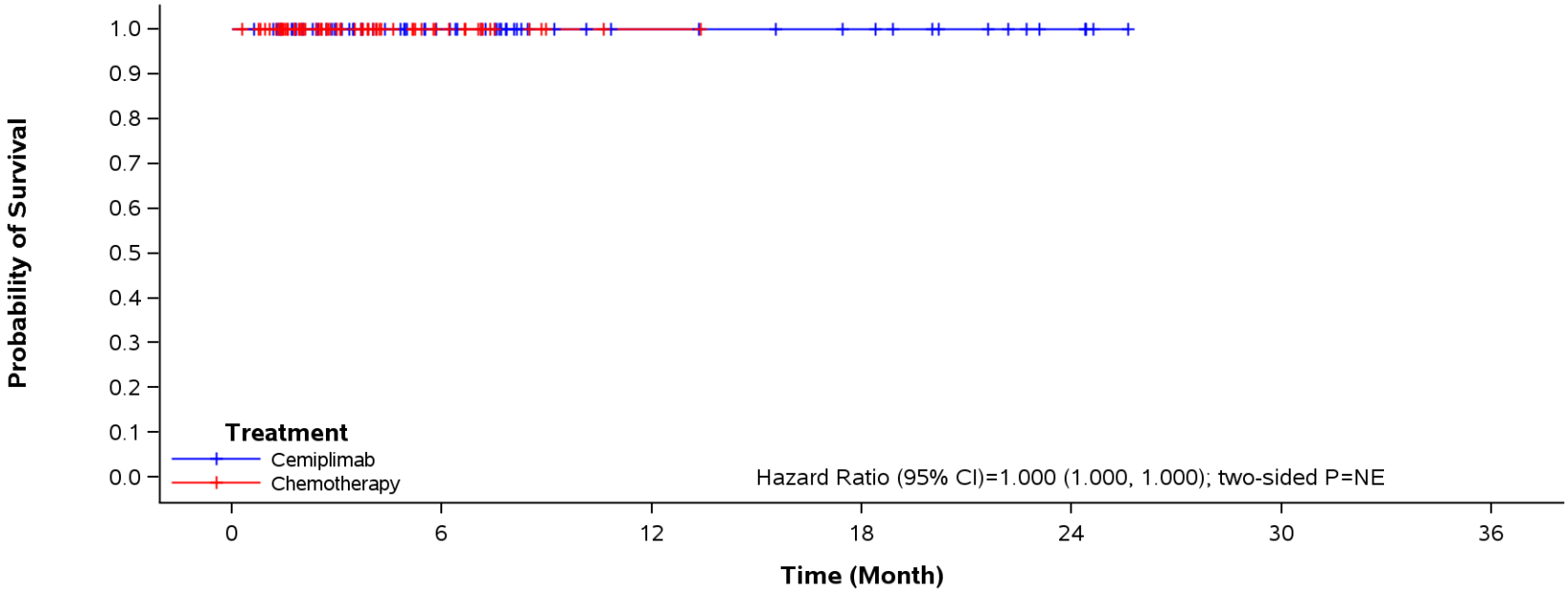

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



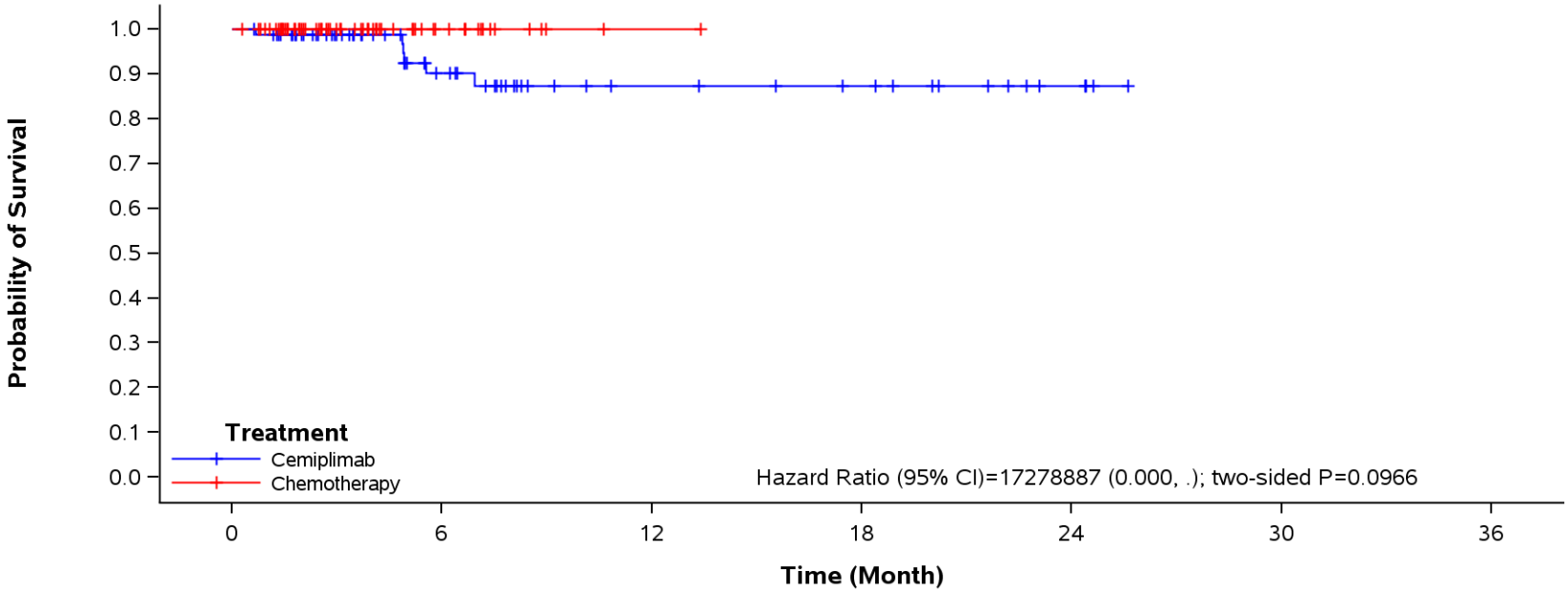

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Hepatobiliary disorders



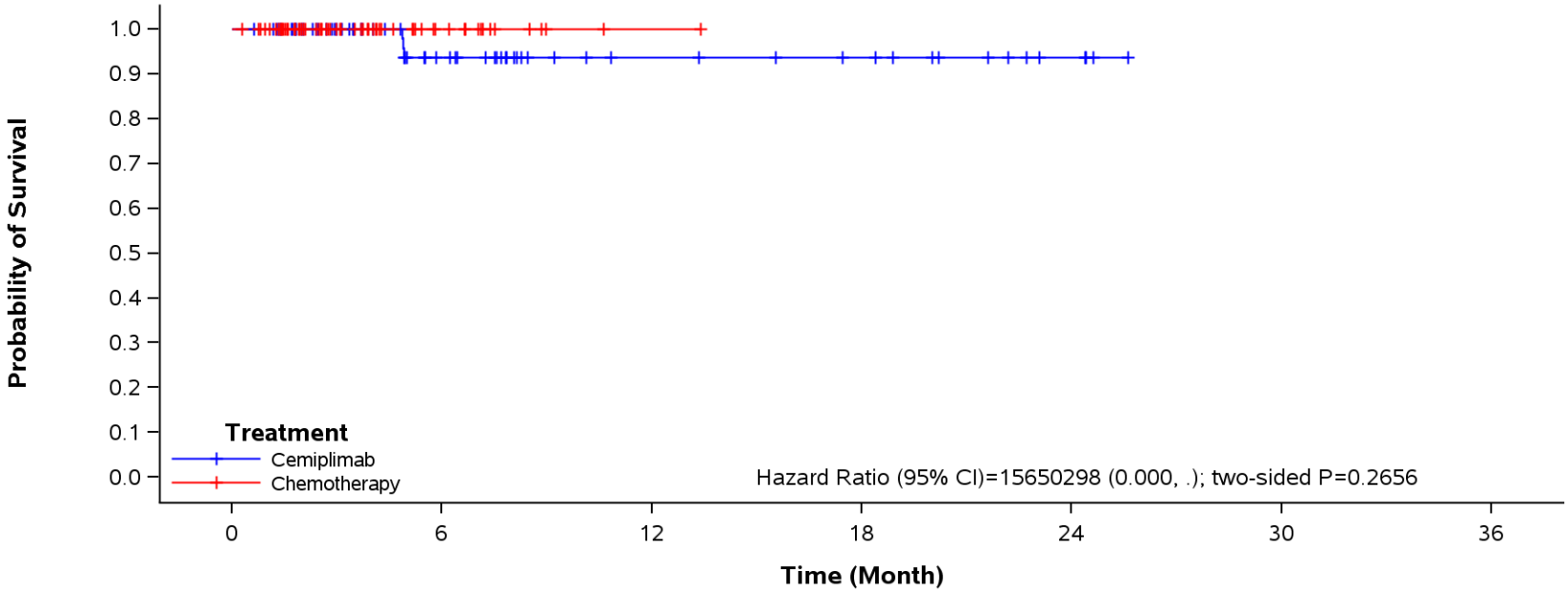

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 37 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



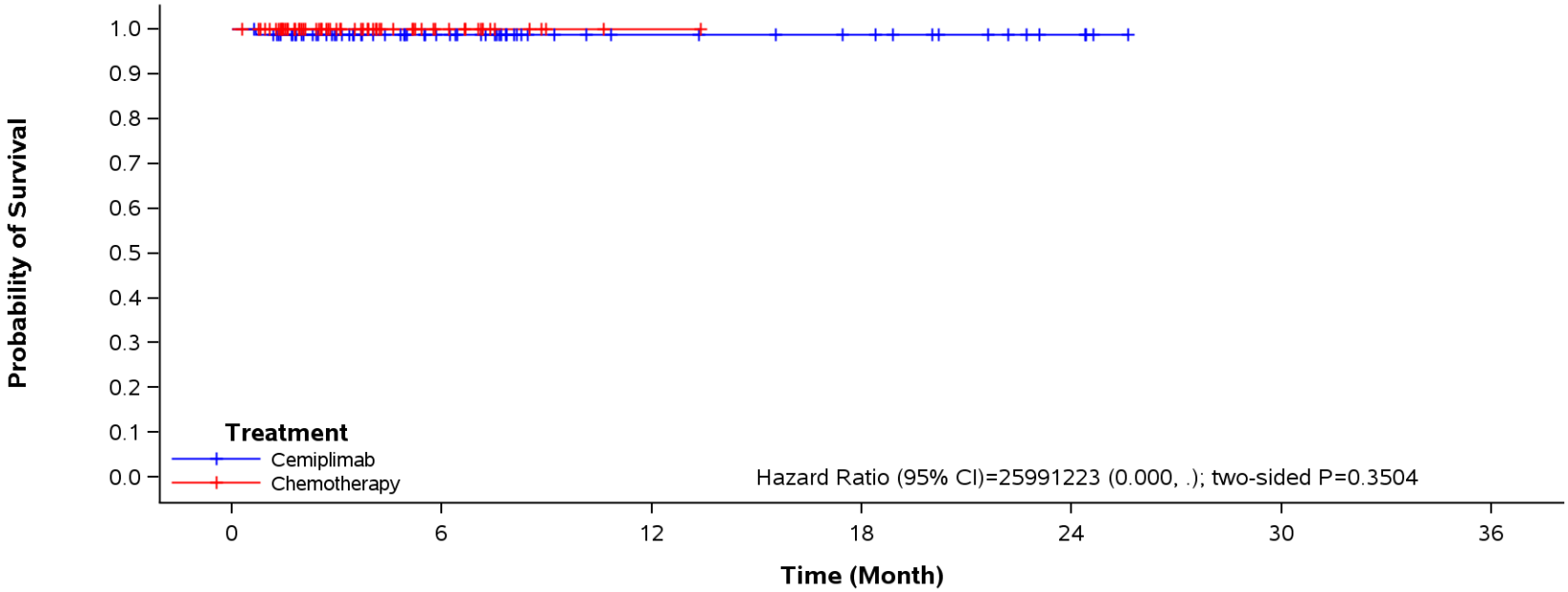

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 38 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



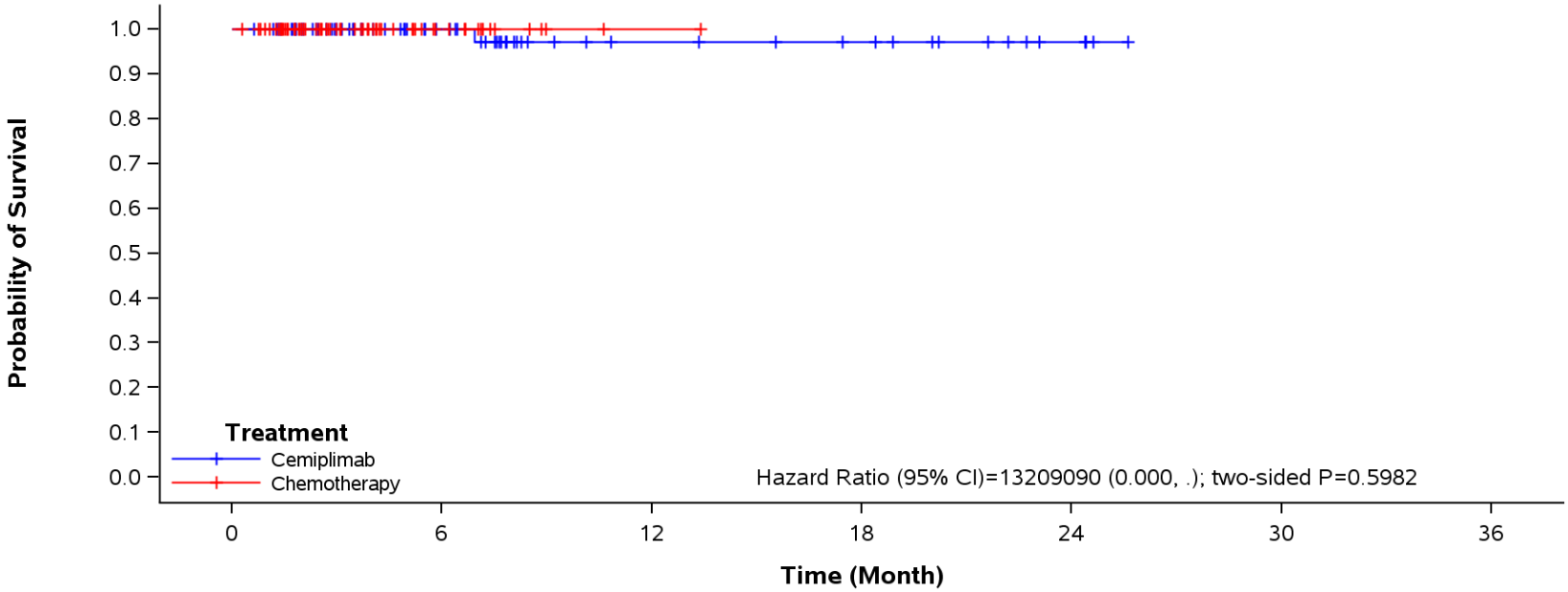

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Hepatobiliary disorders
PT: Hepatitis



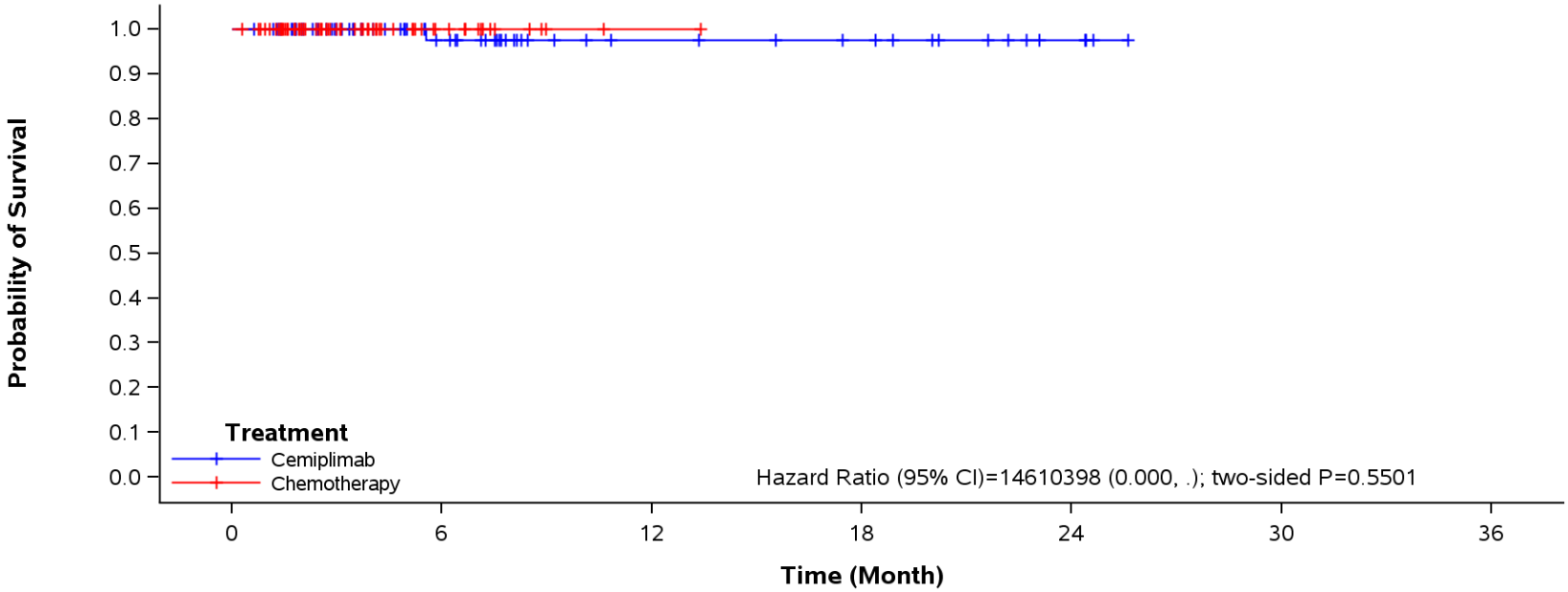

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



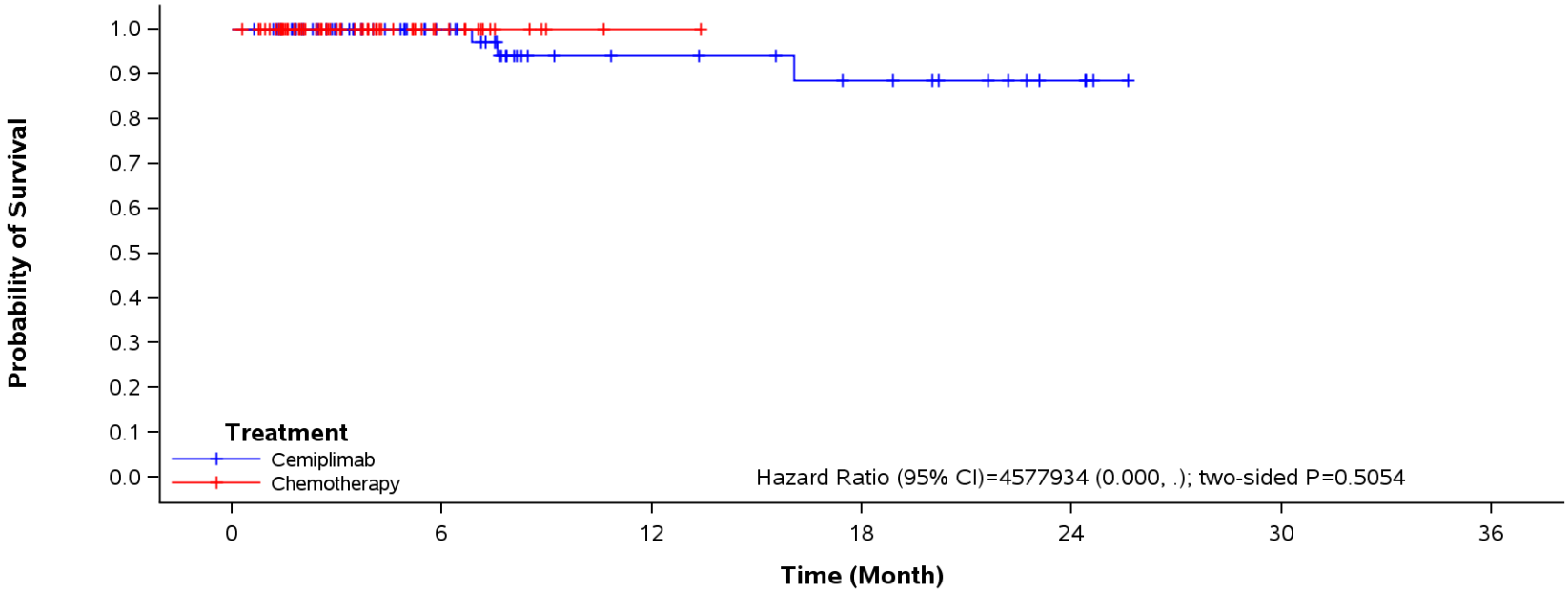

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Infections and infestations



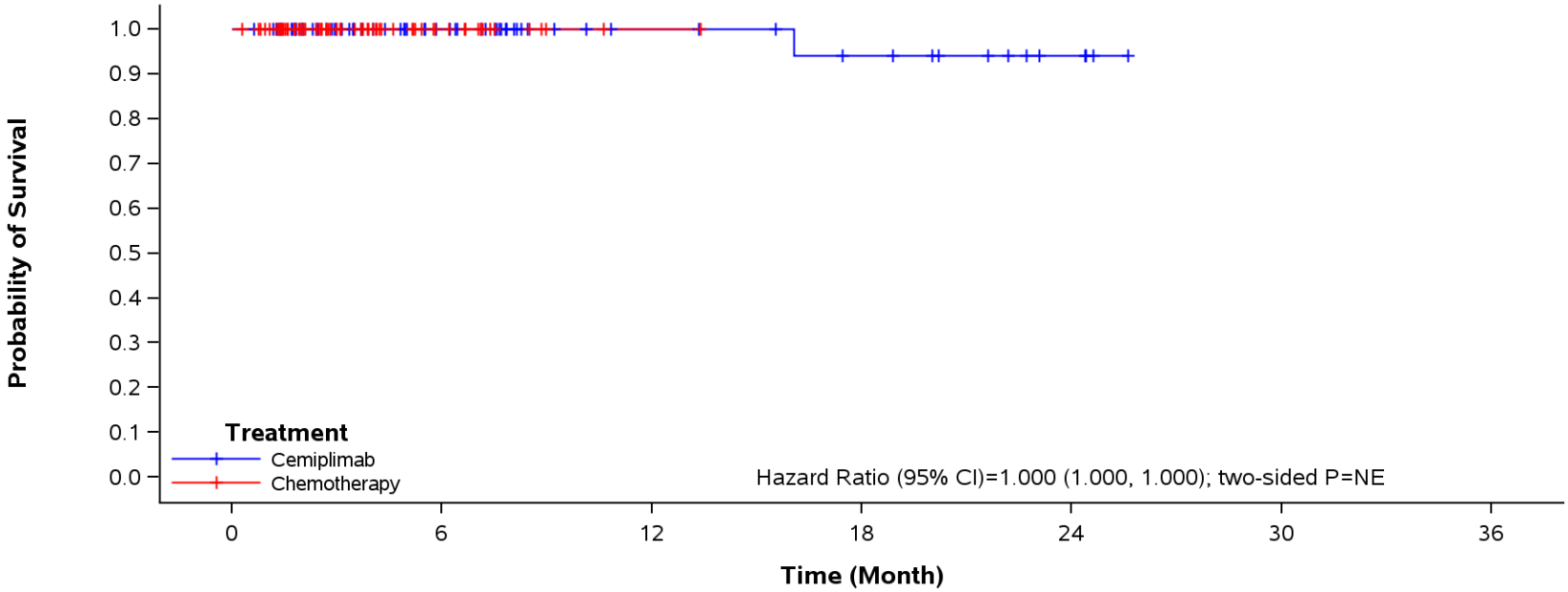

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 15 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Infections and infestations
PT: COVID-19 pneumonia



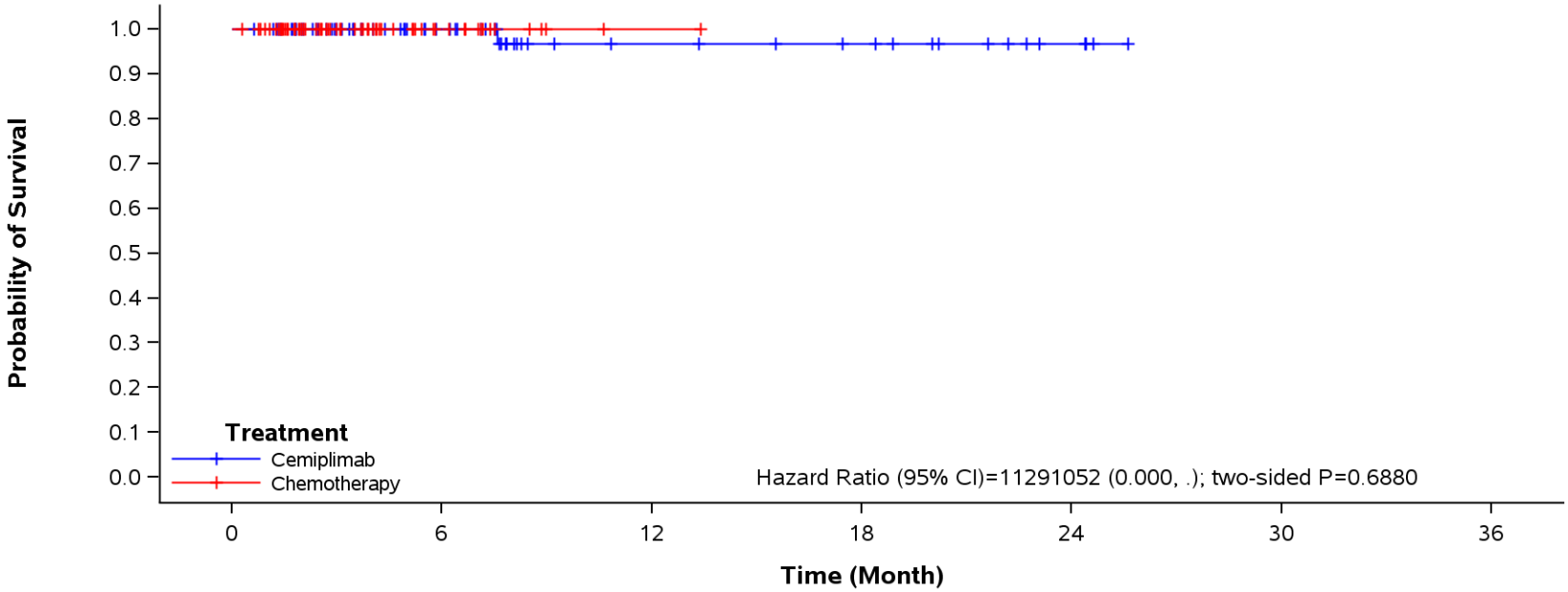

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 15 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Infections and infestations
PT: Gastroenteritis



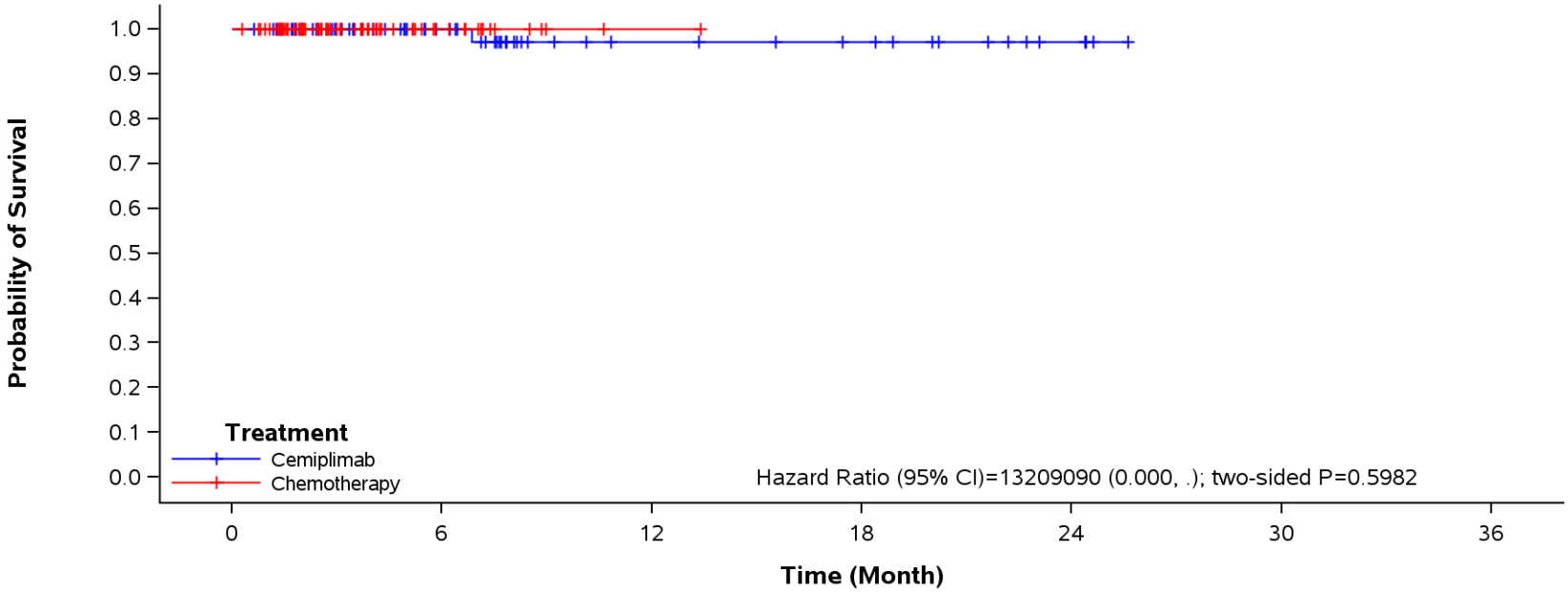

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Infections and infestations
PT: Pelvic abscess



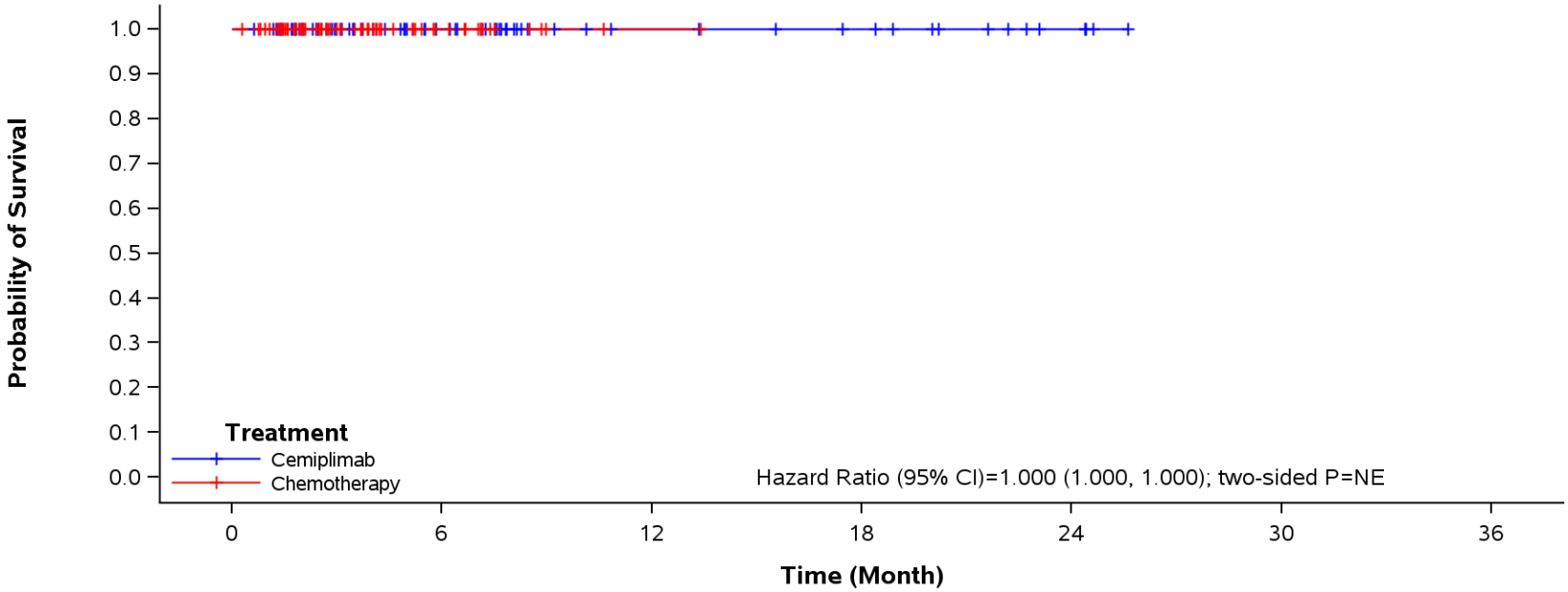

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Infections and infestations
PT: Peritonitis



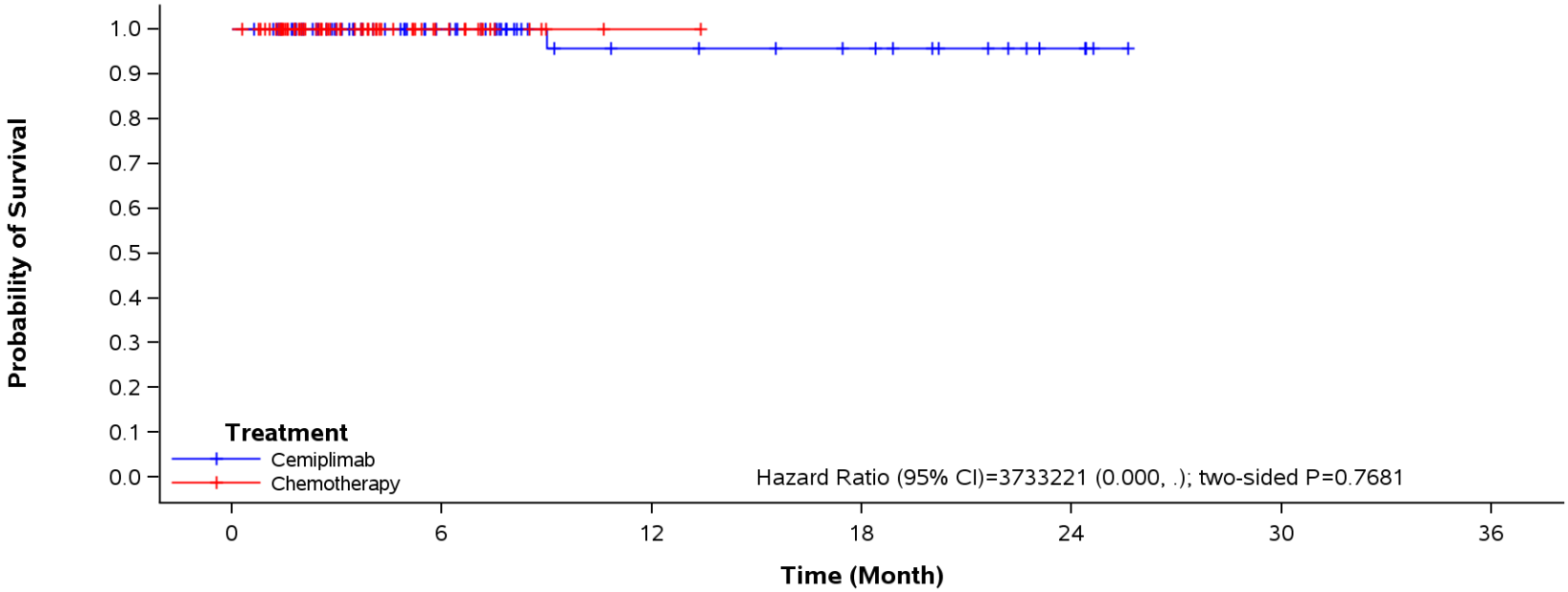

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Infections and infestations
PT: Pneumonia



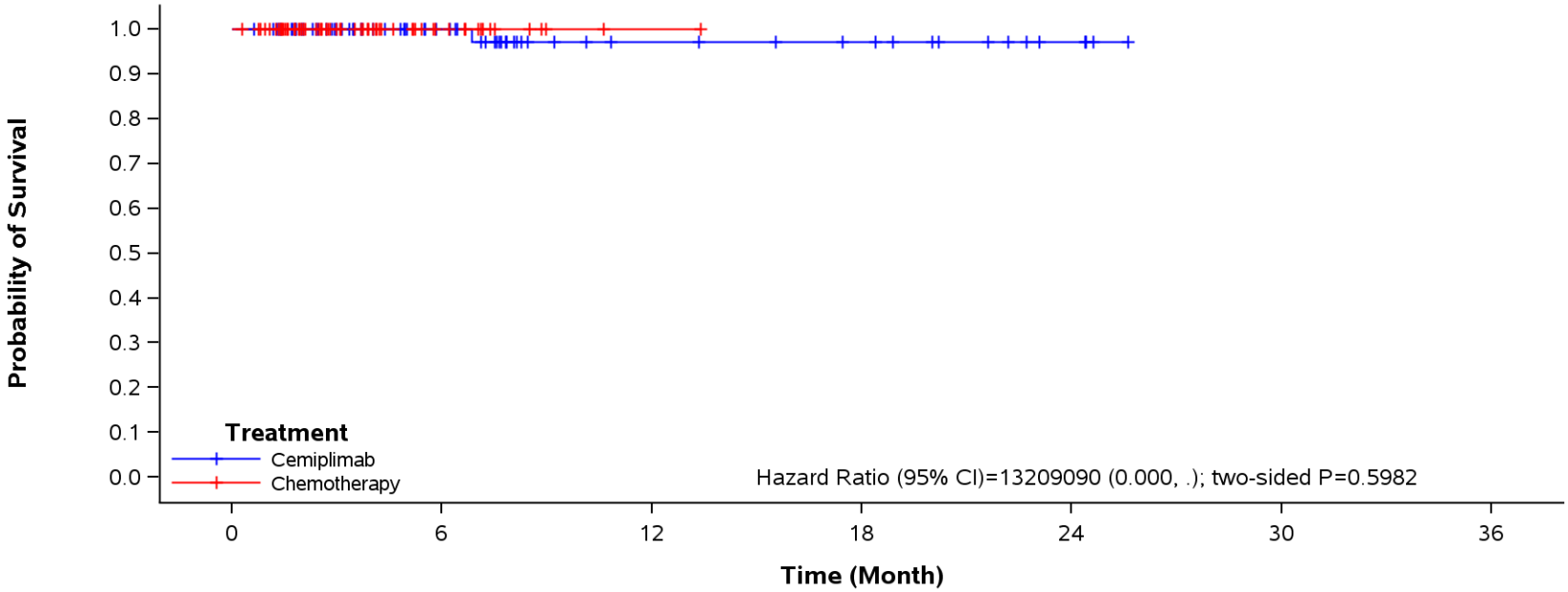

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Infections and infestations
PT: Pyomyositis




**Number of Subjects at risk**

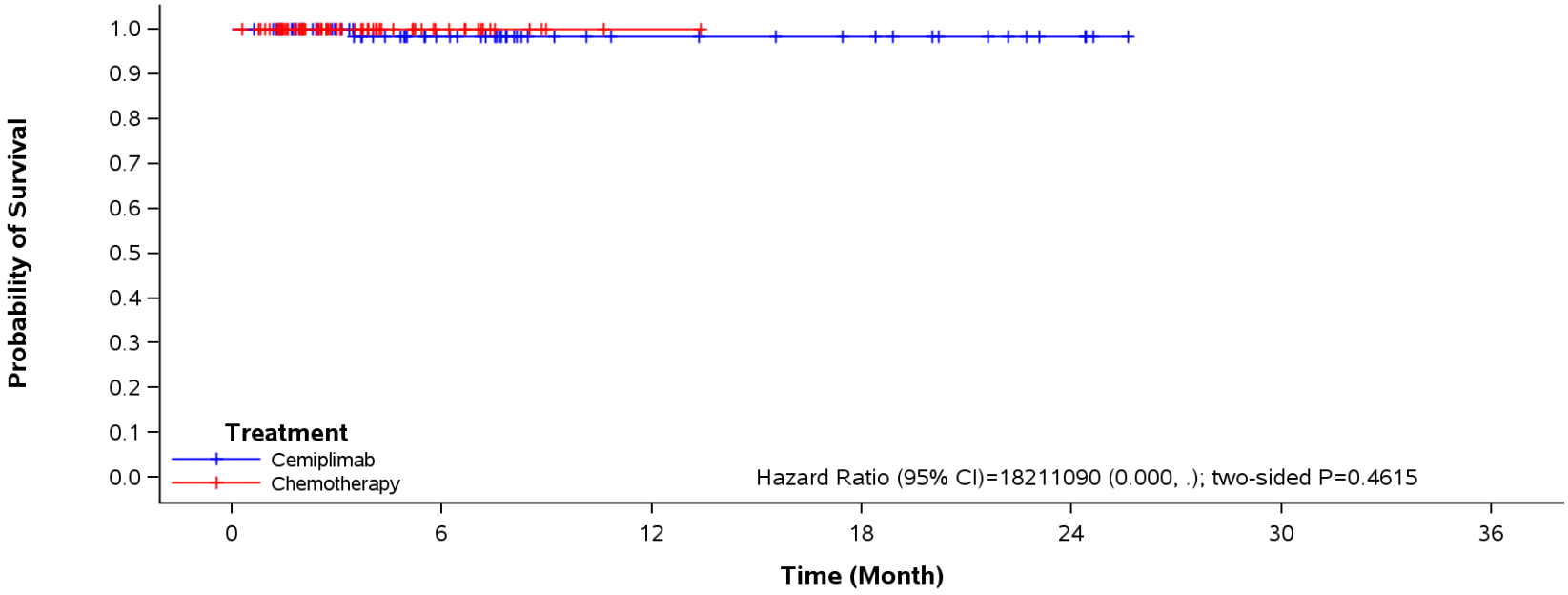
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

SOC: Injury, poisoning and procedural complications




**Number of Subjects at risk**

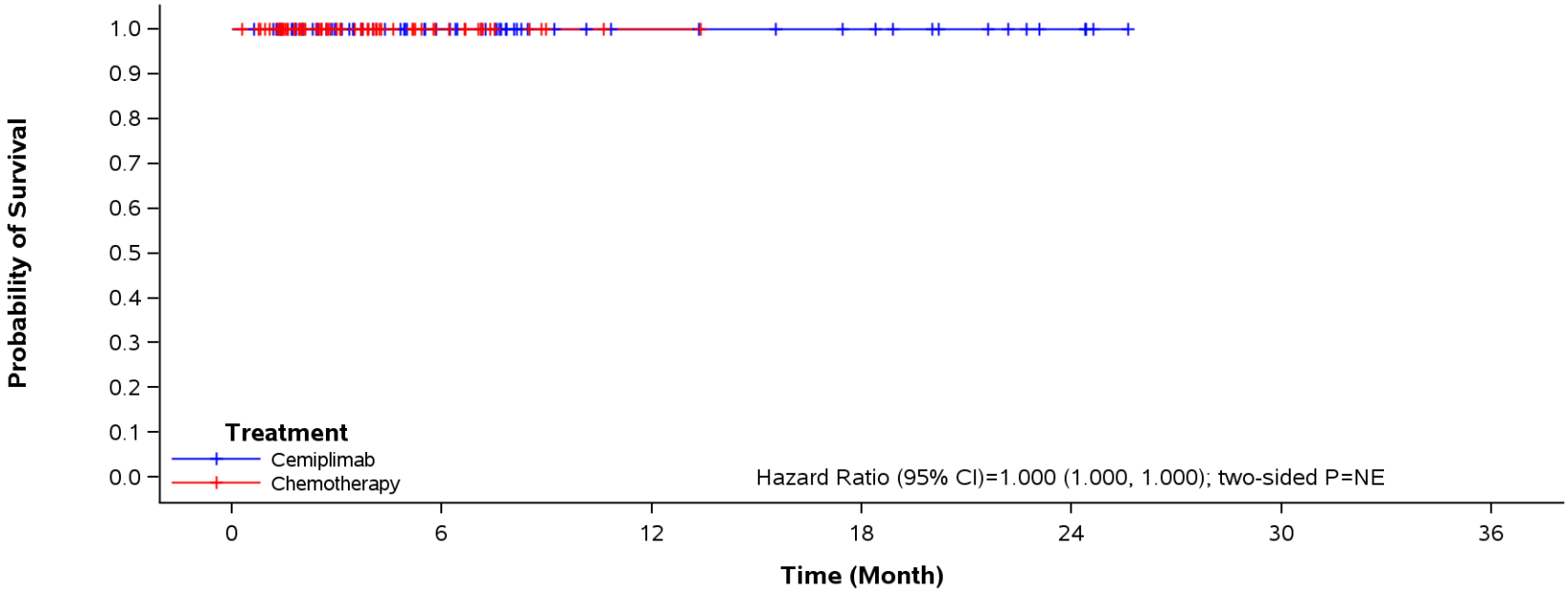
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



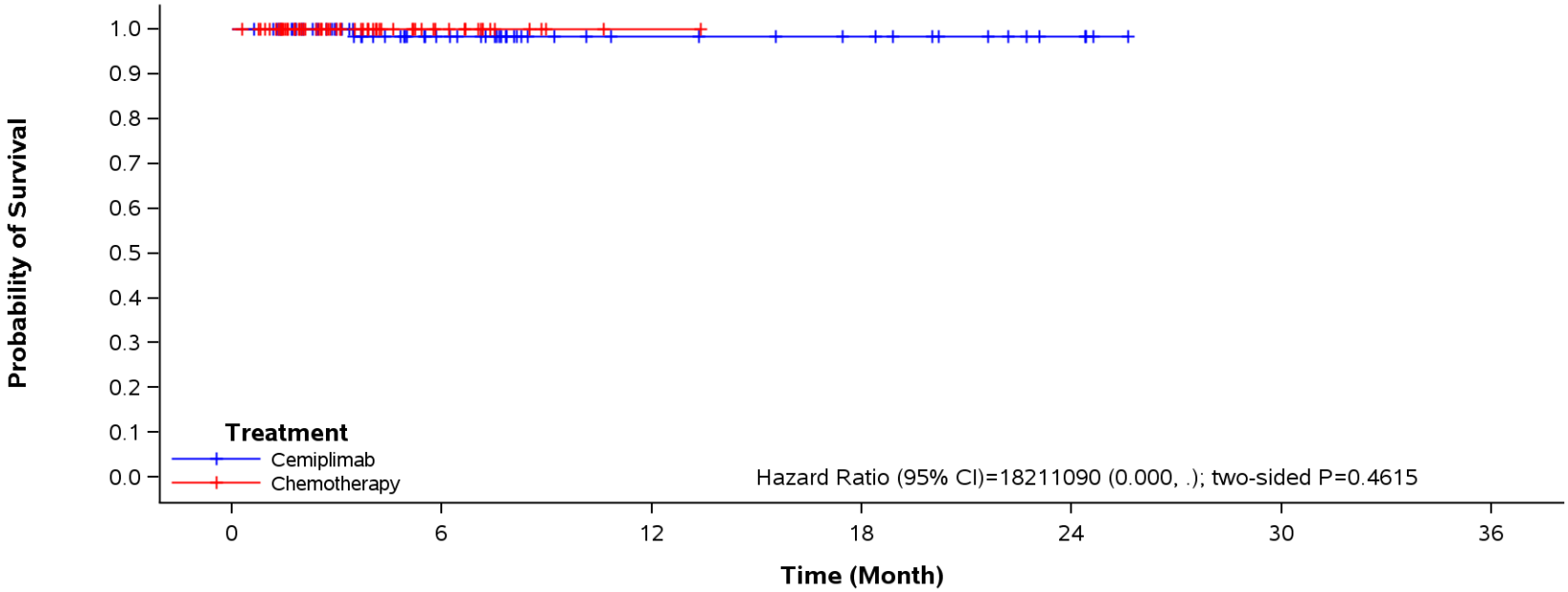

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



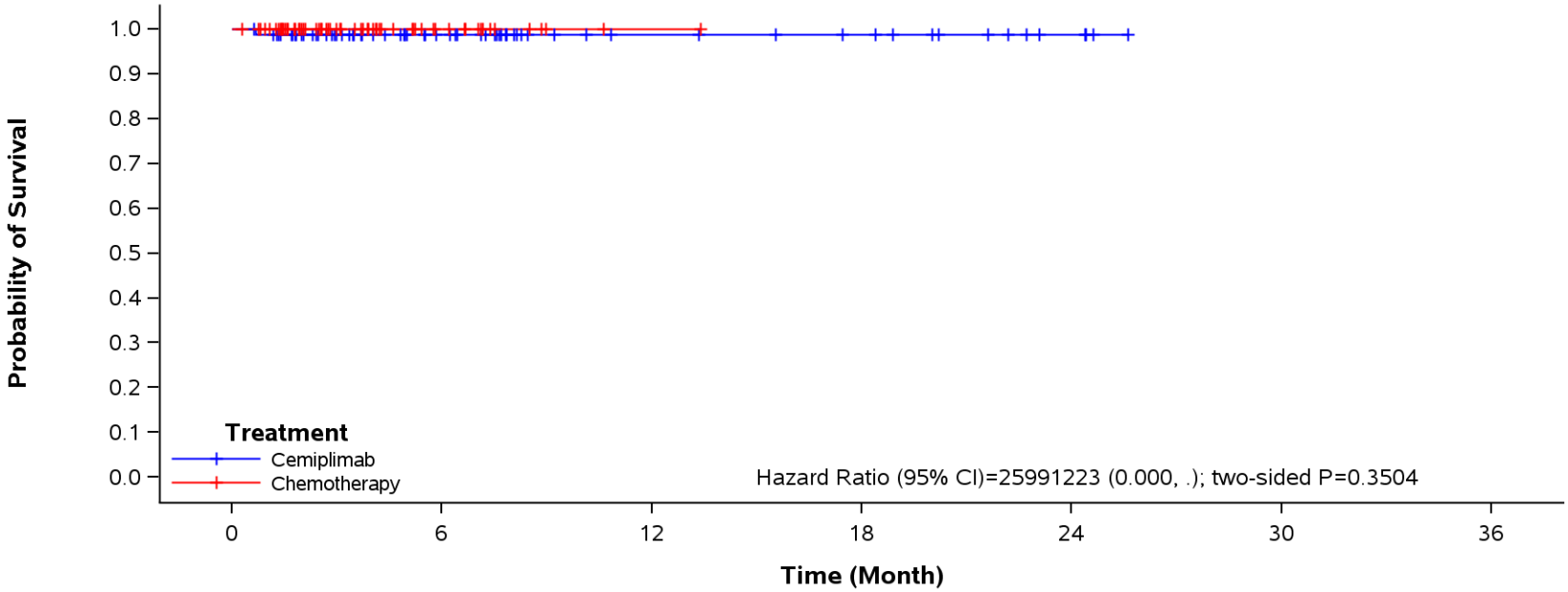

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Investigations



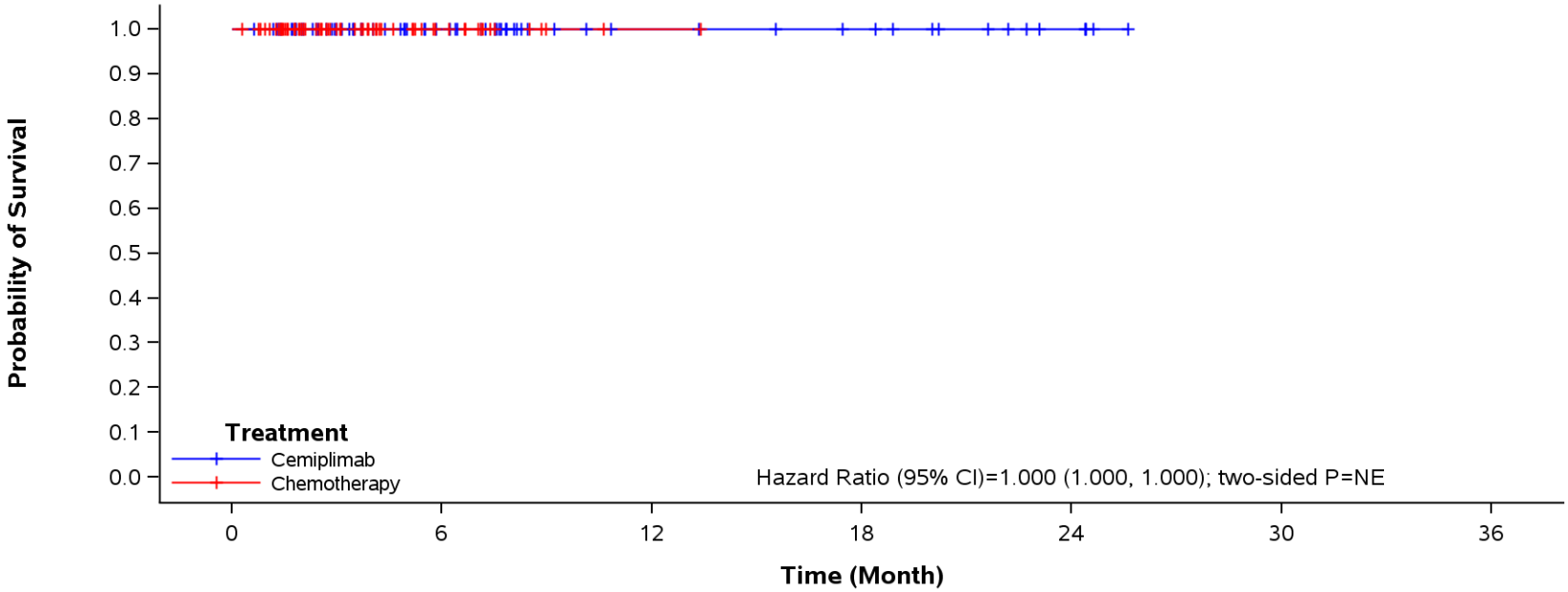

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Investigations
PT: Alanine aminotransferase increased



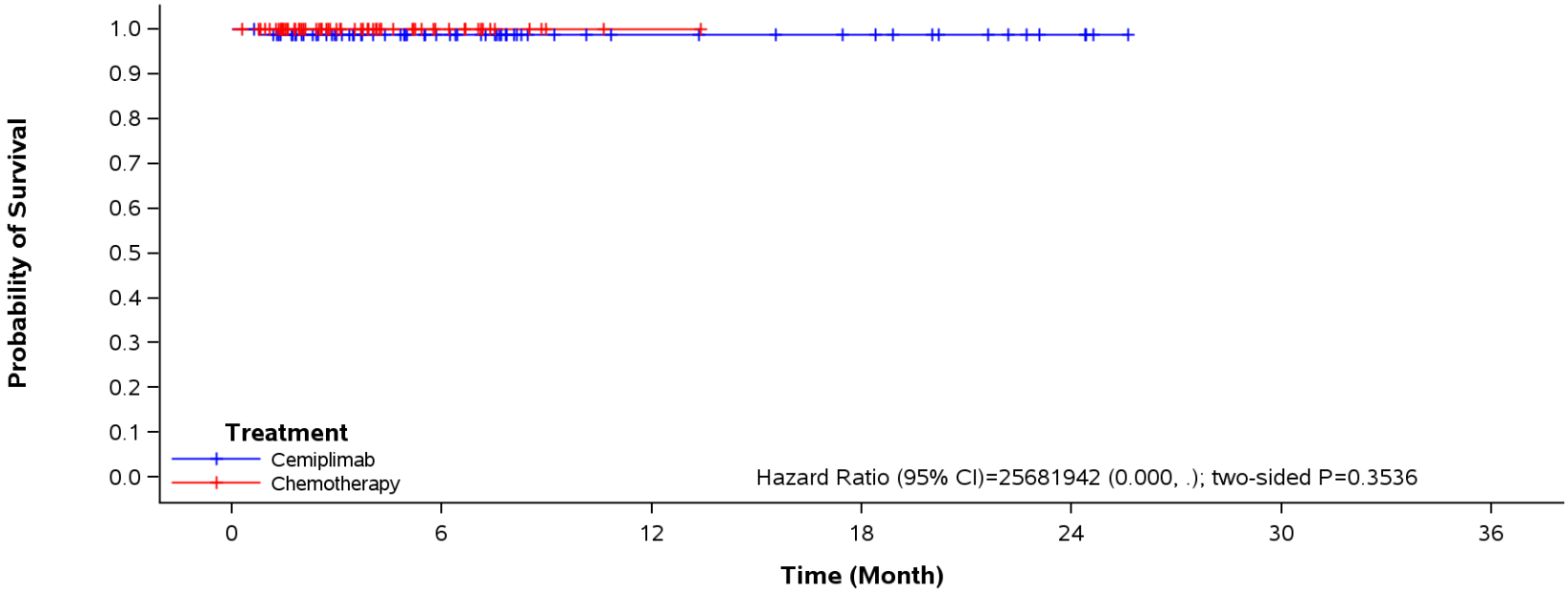

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Investigations
PT: Amylase increased



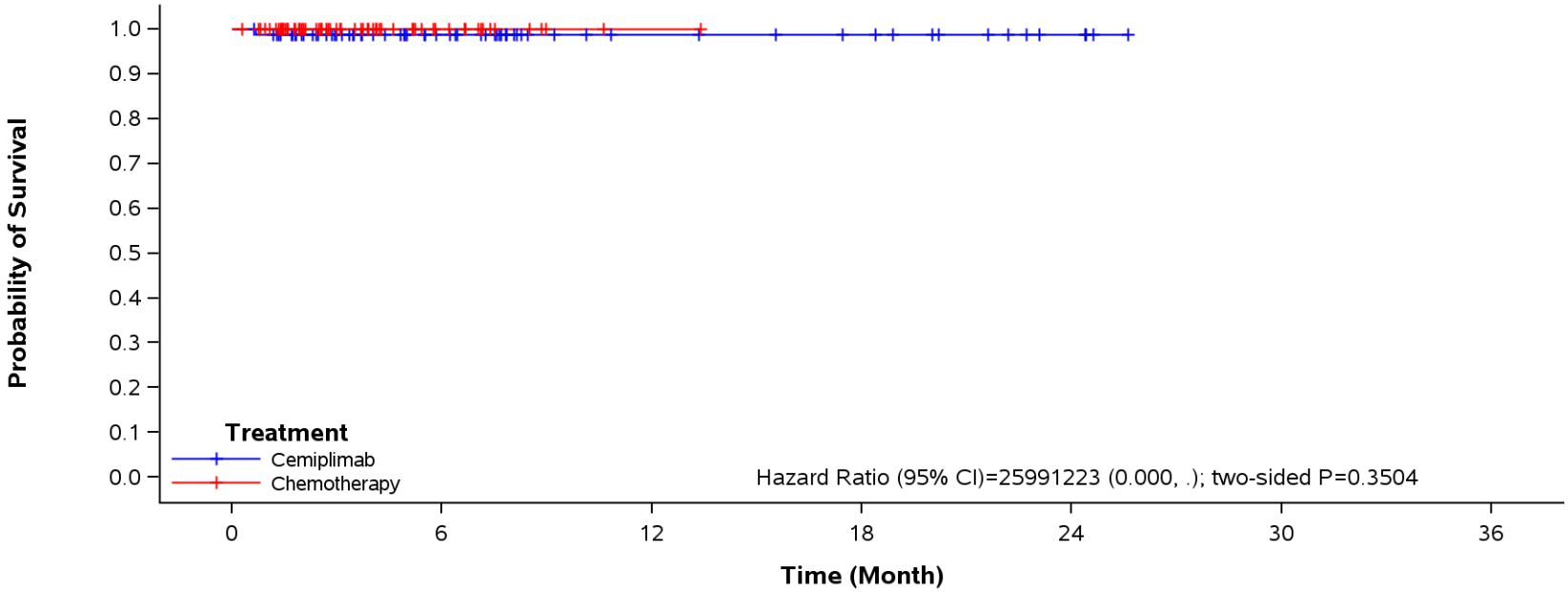

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Investigations
PT: Platelet count decreased



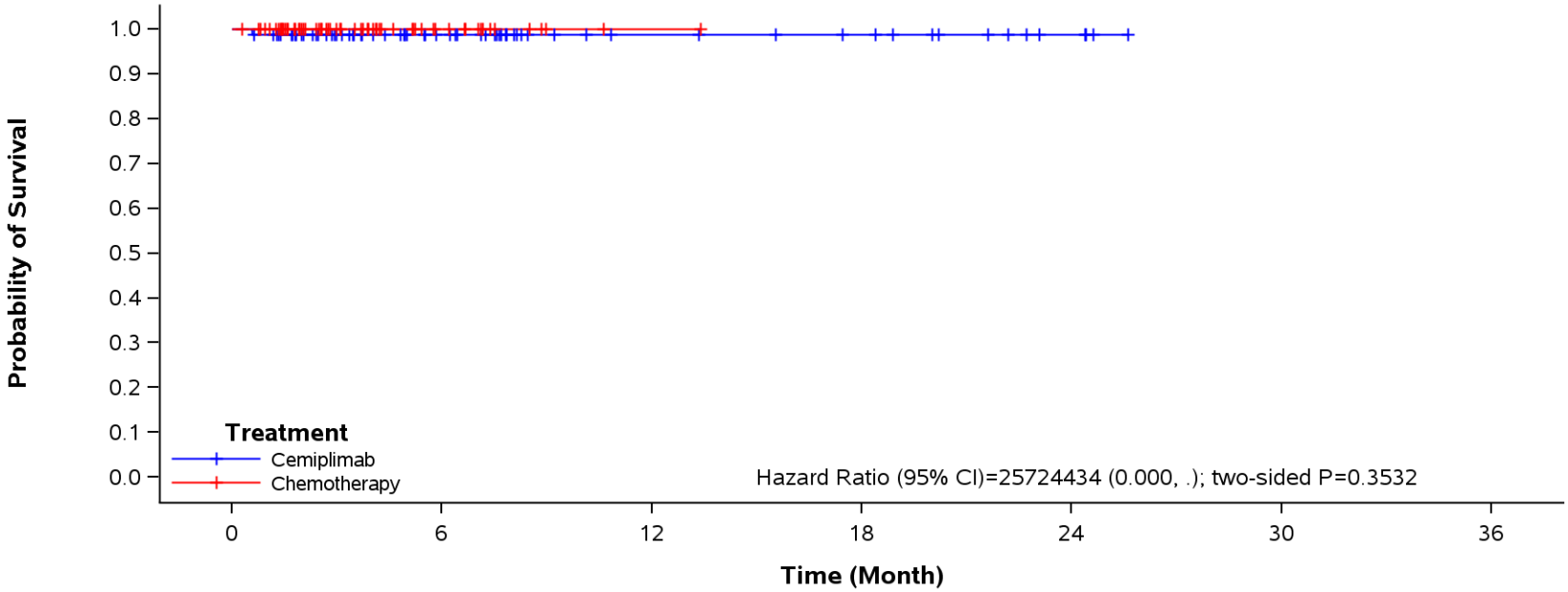

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Metabolism and nutrition disorders



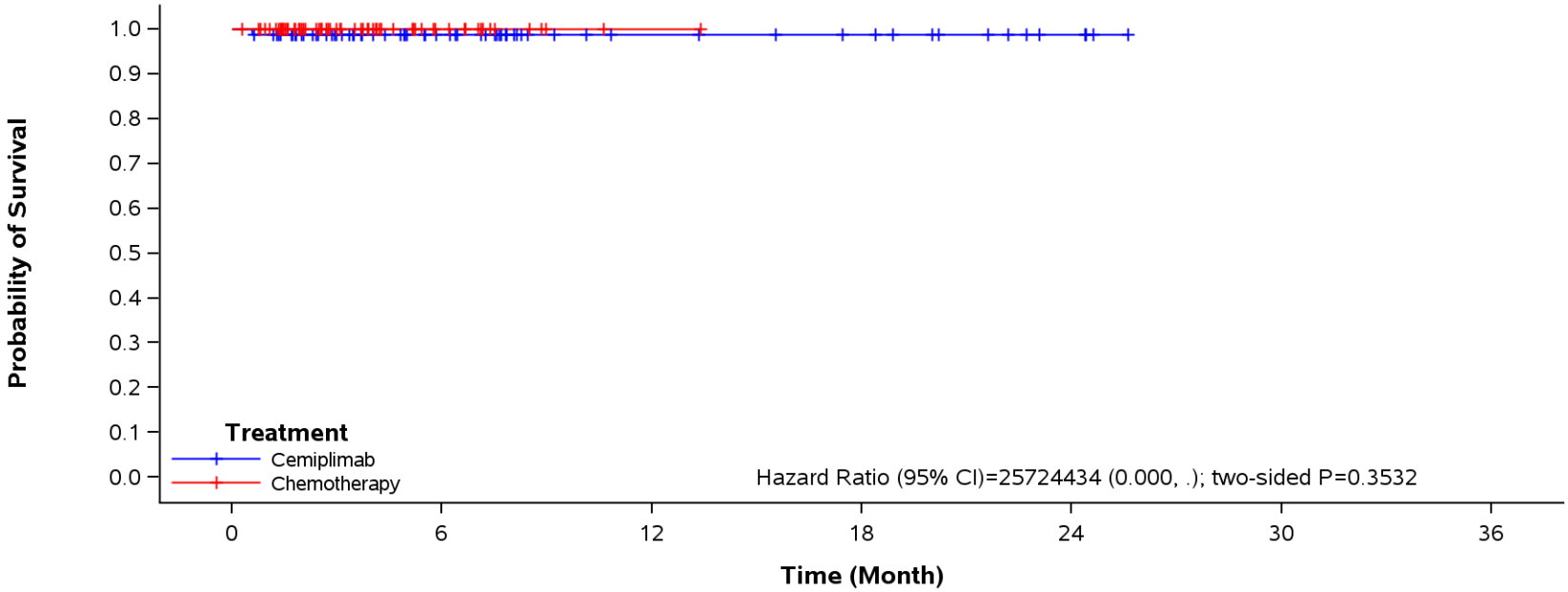

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



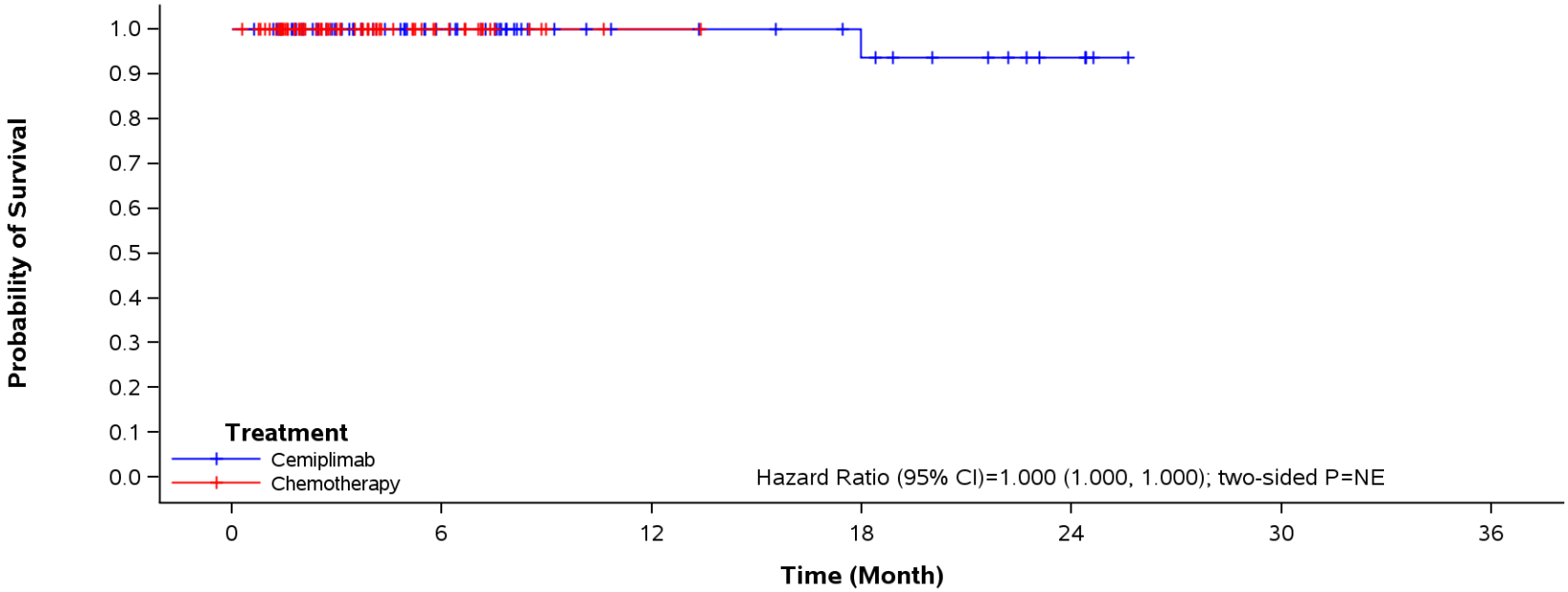

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Musculoskeletal and connective tissue disorders



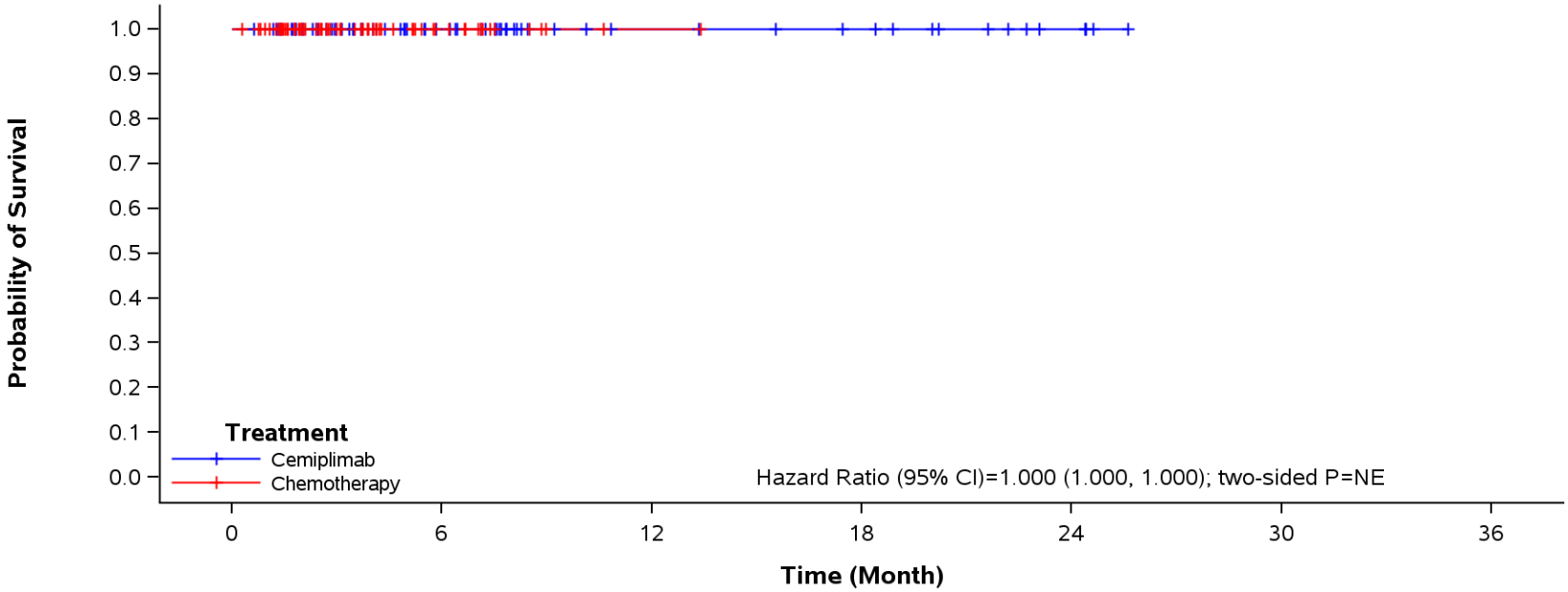

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 15 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



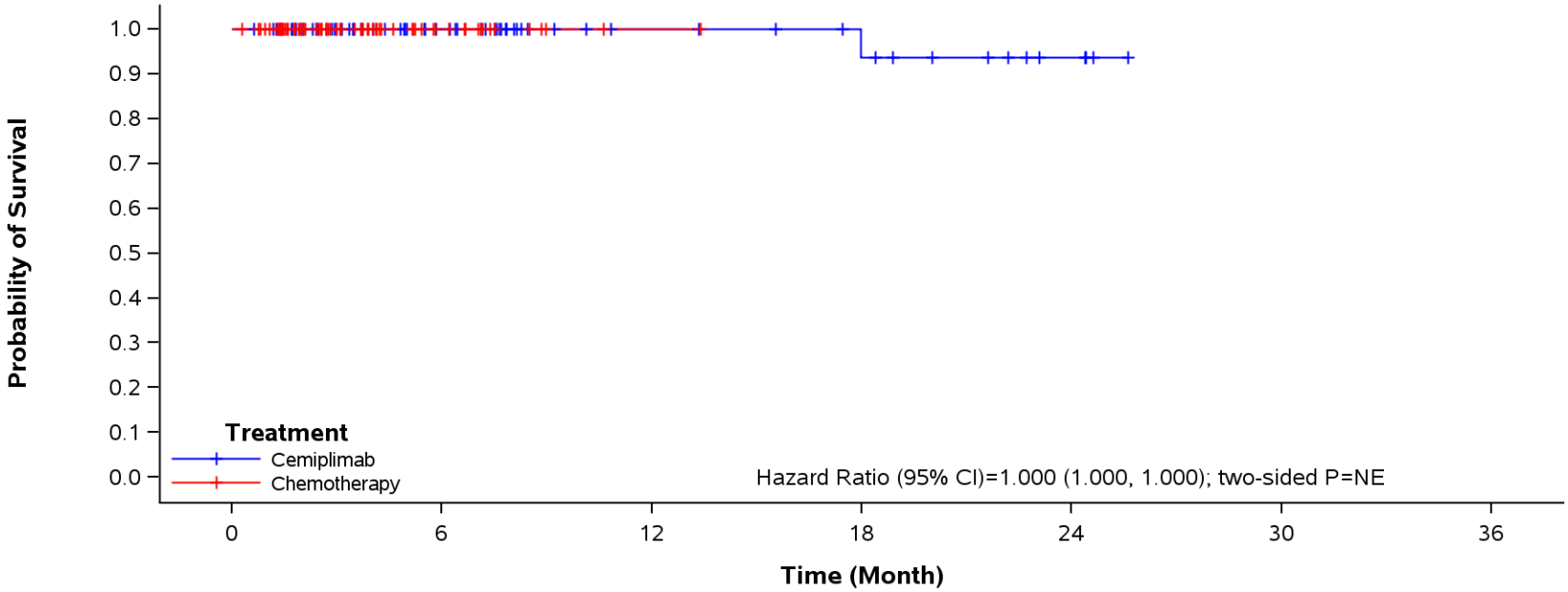

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



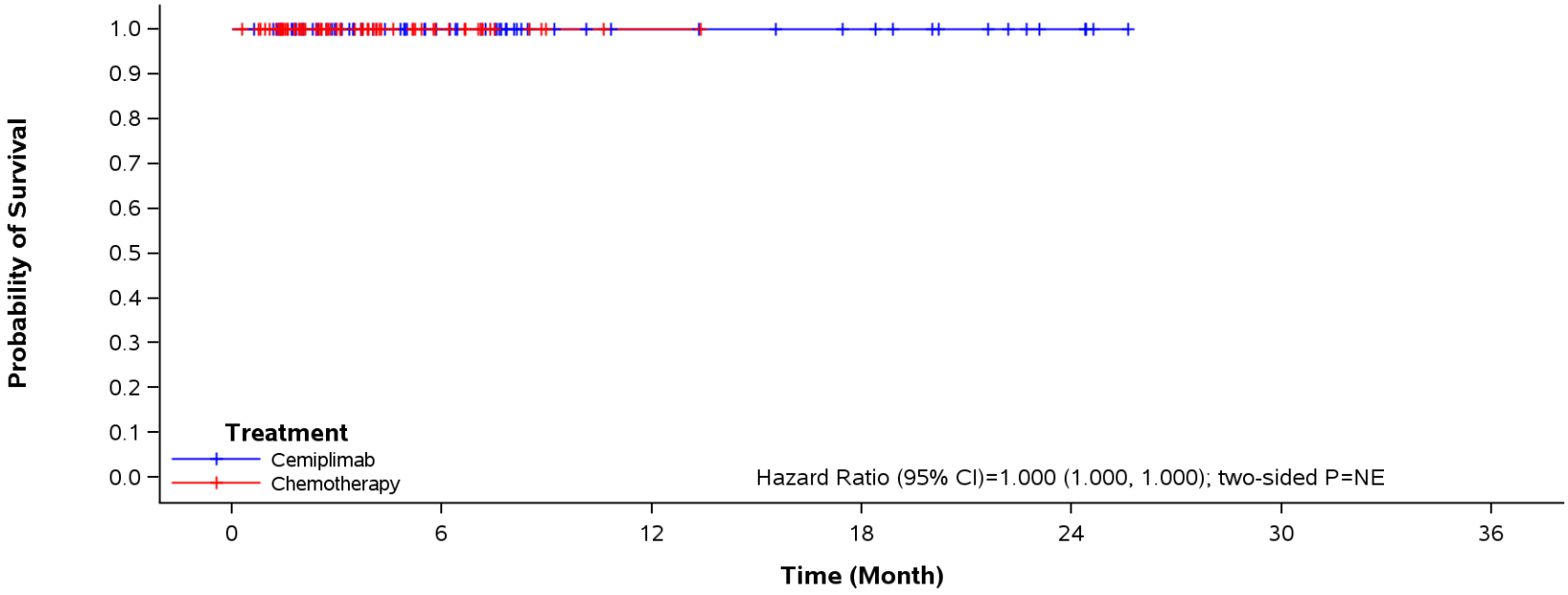

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 15 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Nervous system disorders



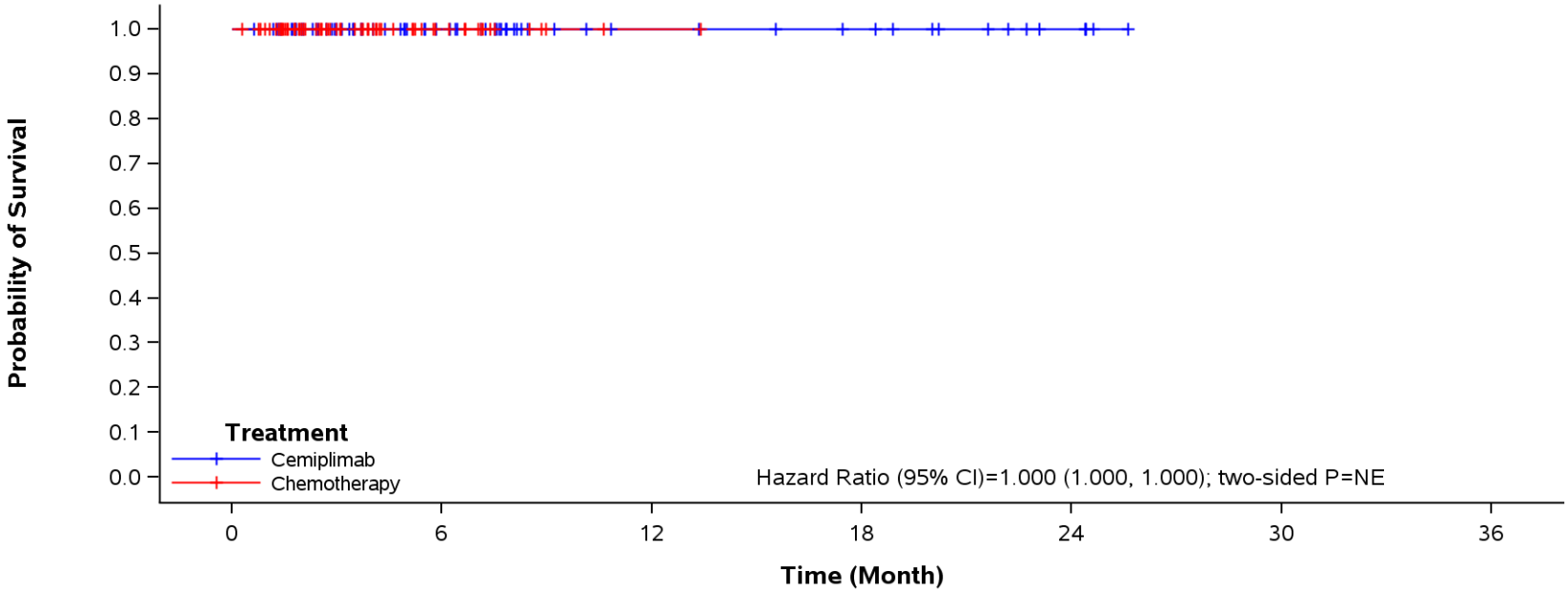

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Nervous system disorders
PT: Neurotoxicity



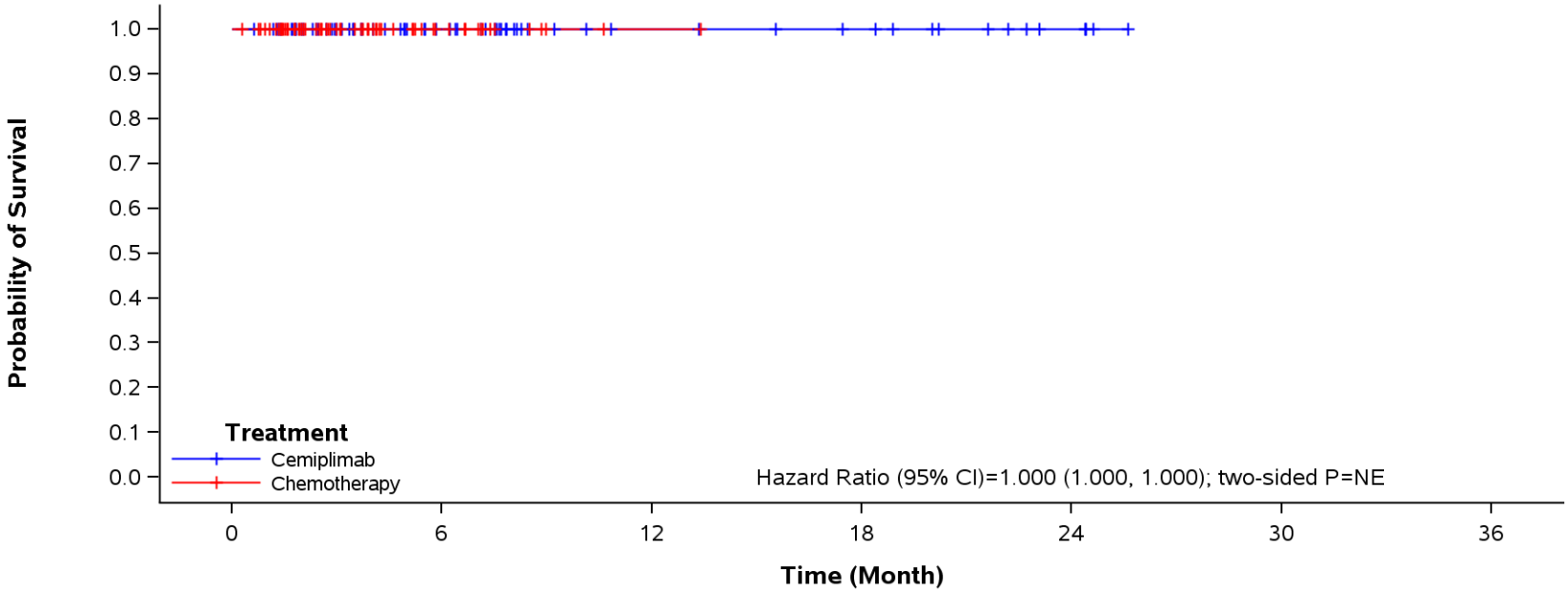

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Nervous system disorders
PT: Transient ischaemic attack



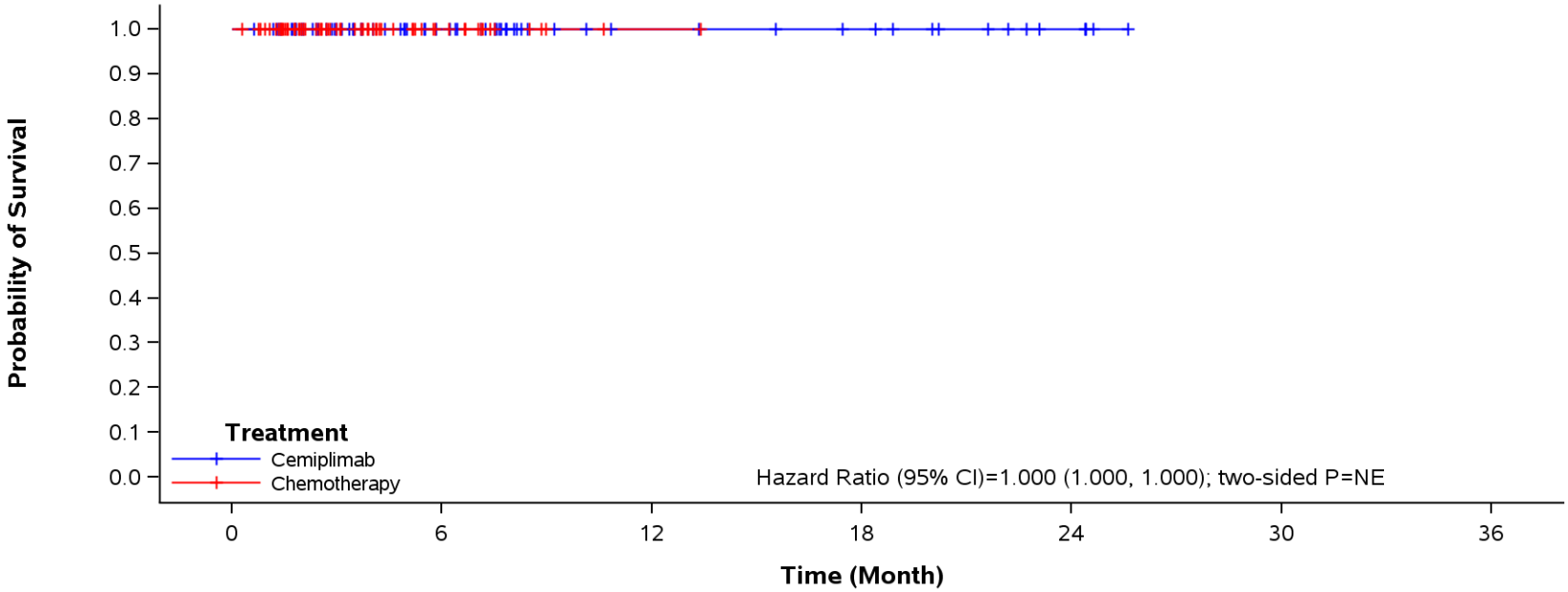

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Psychiatric disorders



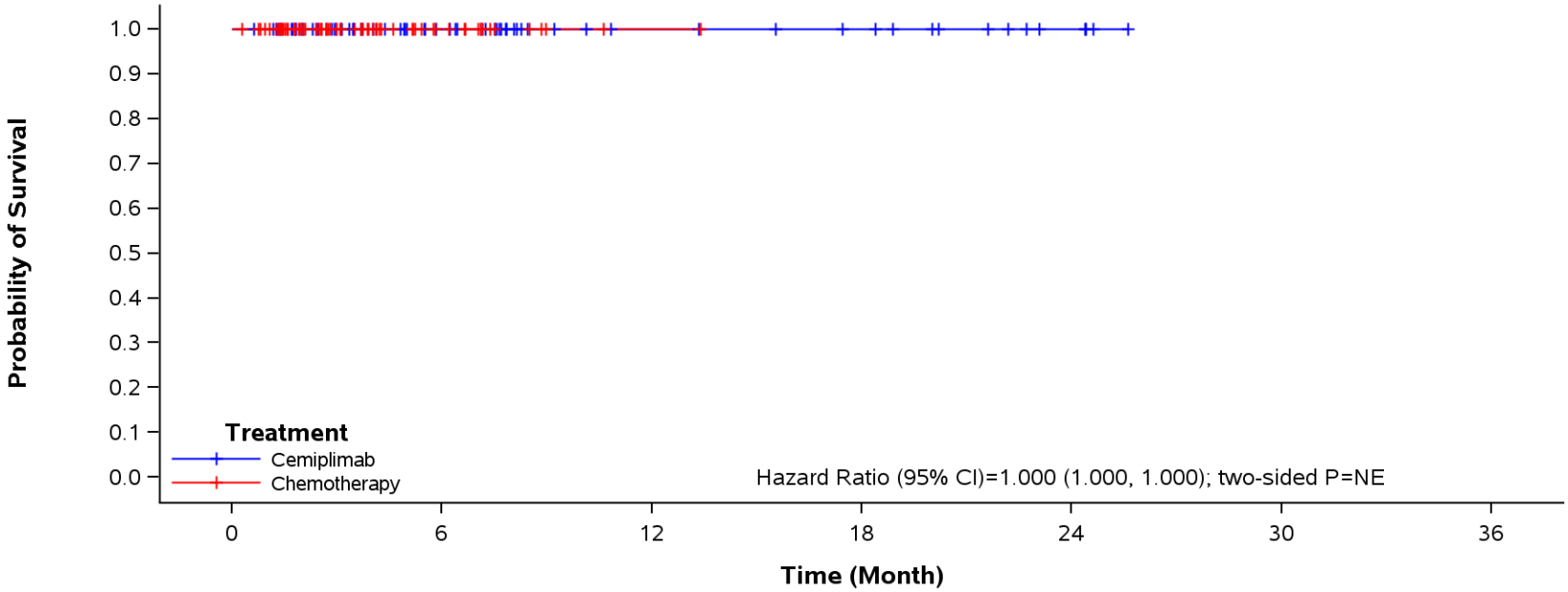

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Psychiatric disorders
PT: Agoraphobia



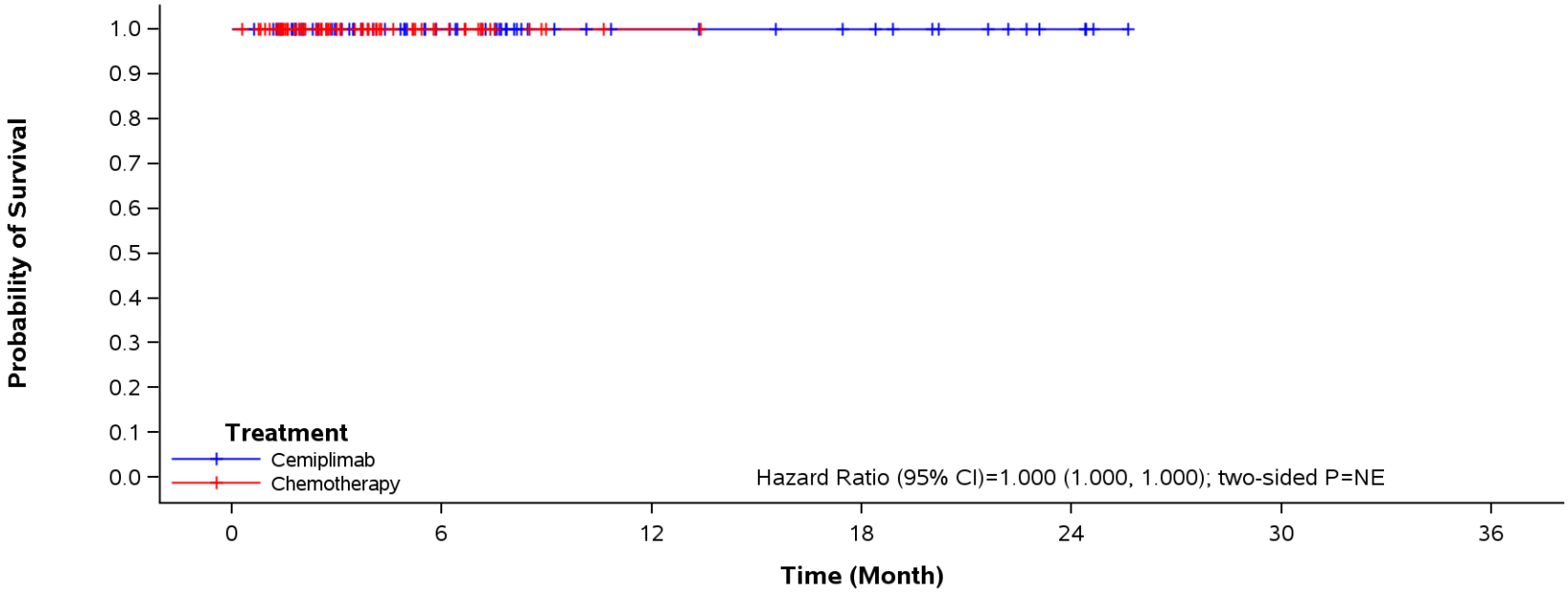

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Renal and urinary disorders



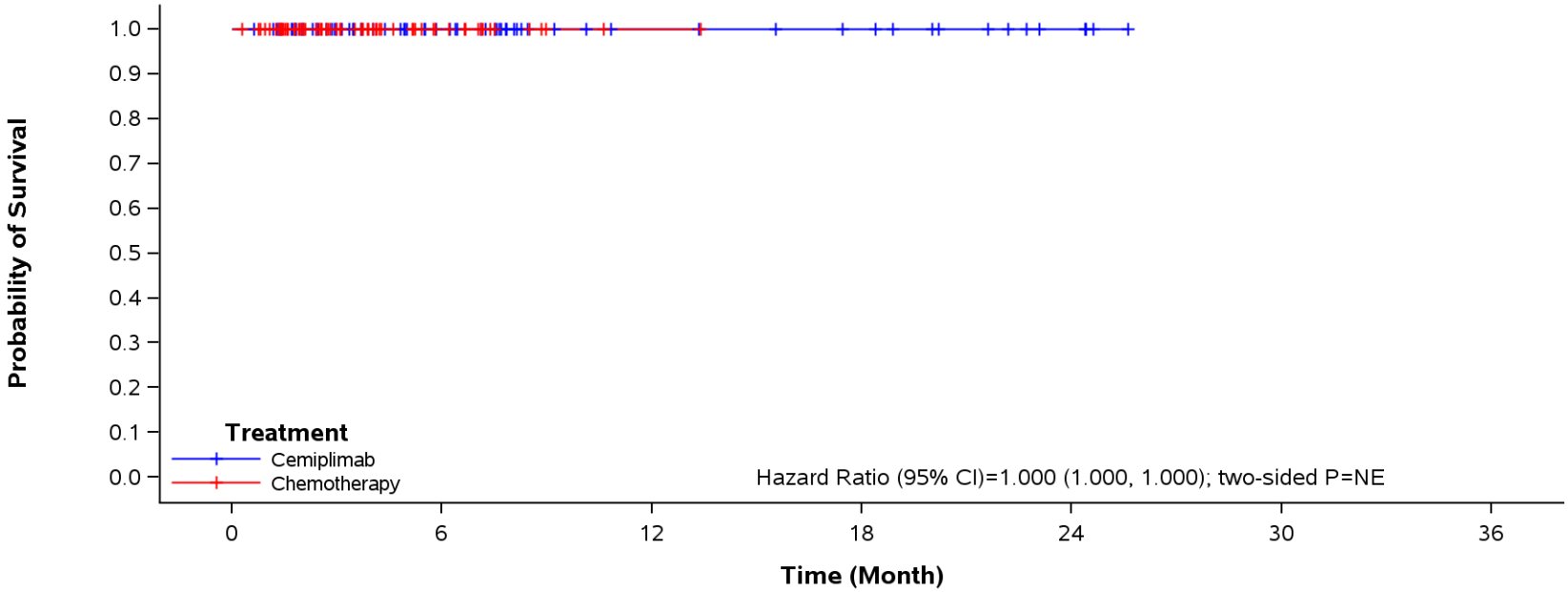

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Renal and urinary disorders
PT: Renal failure




**Number of Subjects at risk**

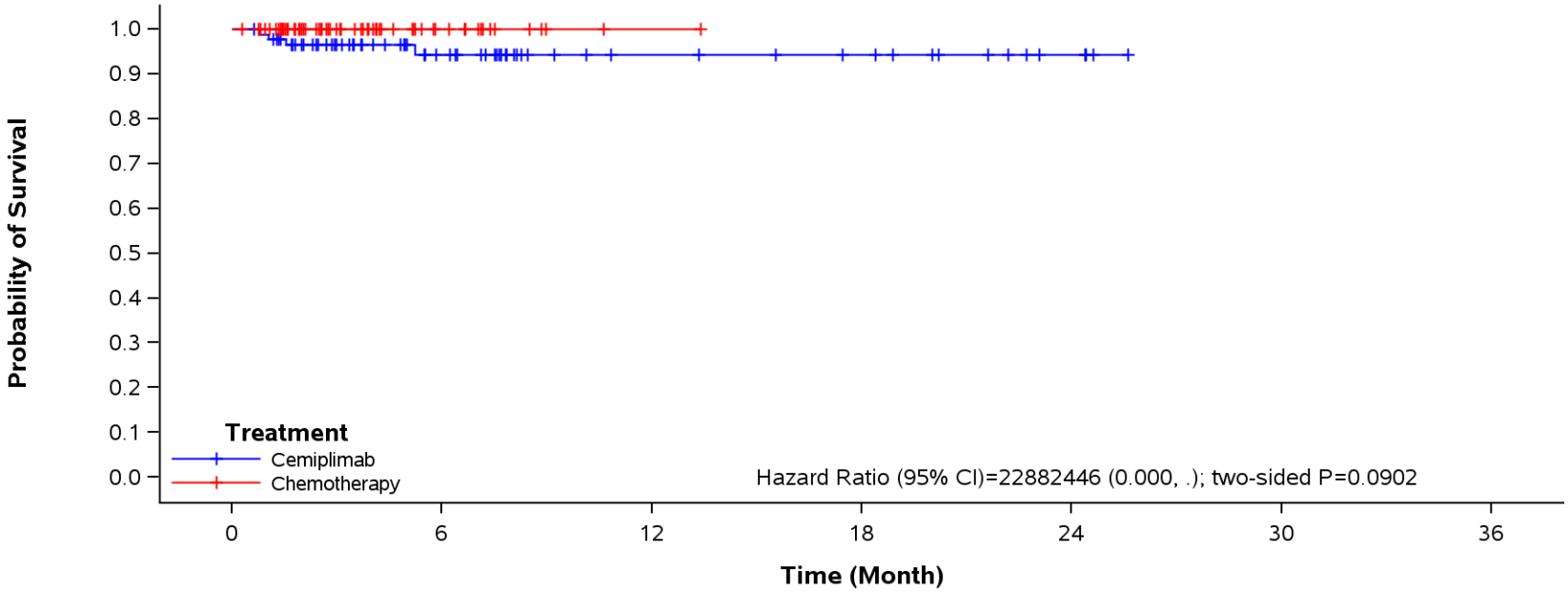
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes

SOC: Respiratory, thoracic and mediastinal disorders




**Number of Subjects at risk**

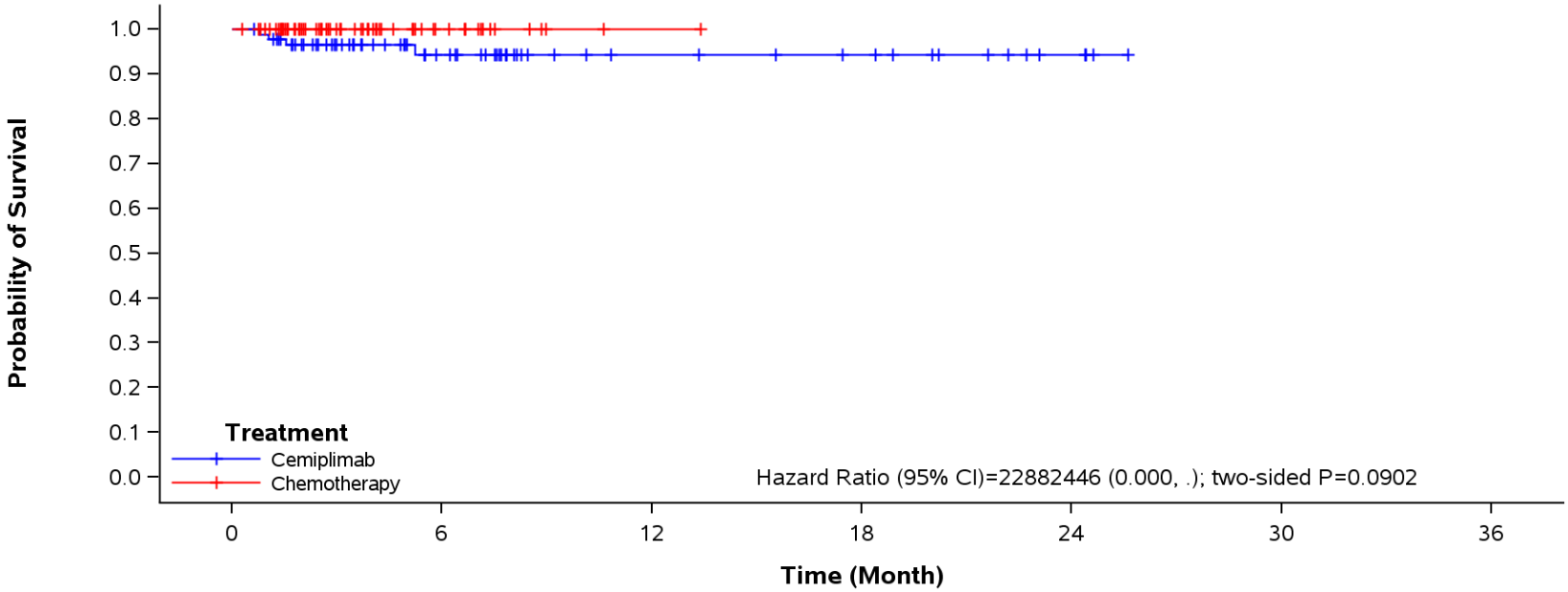
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



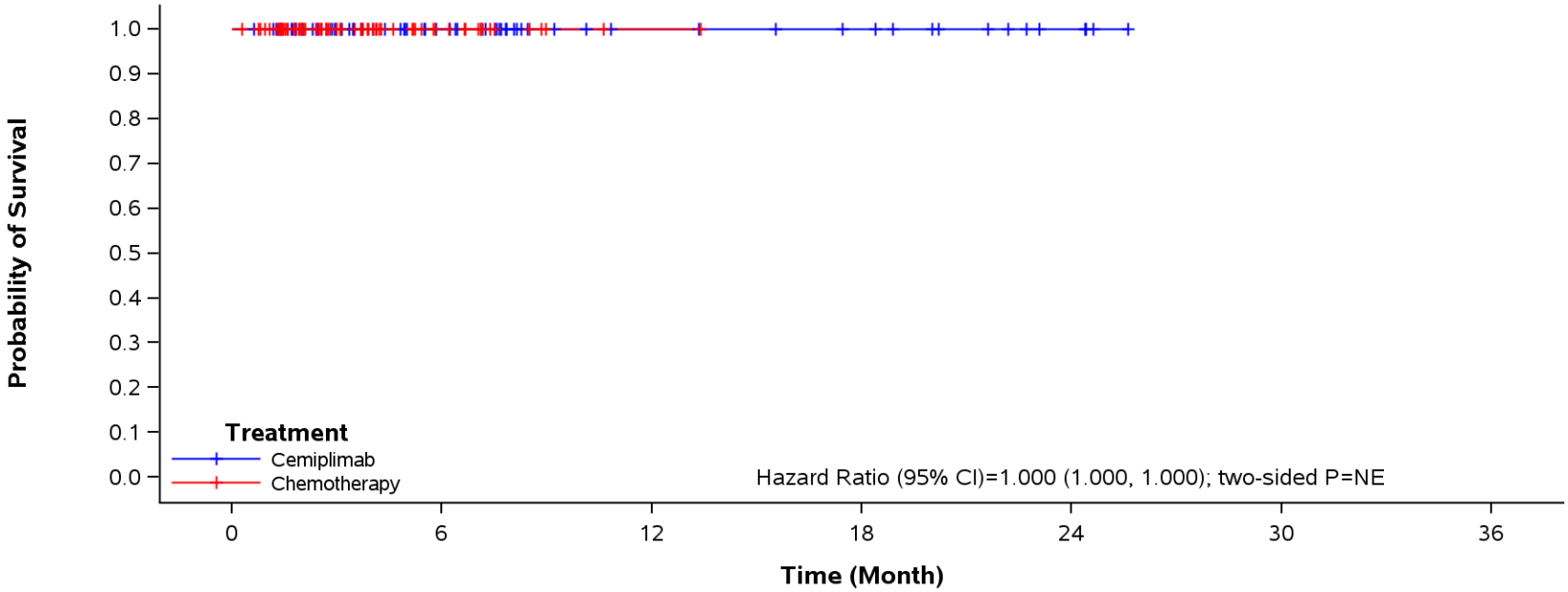

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 40 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Vascular disorders



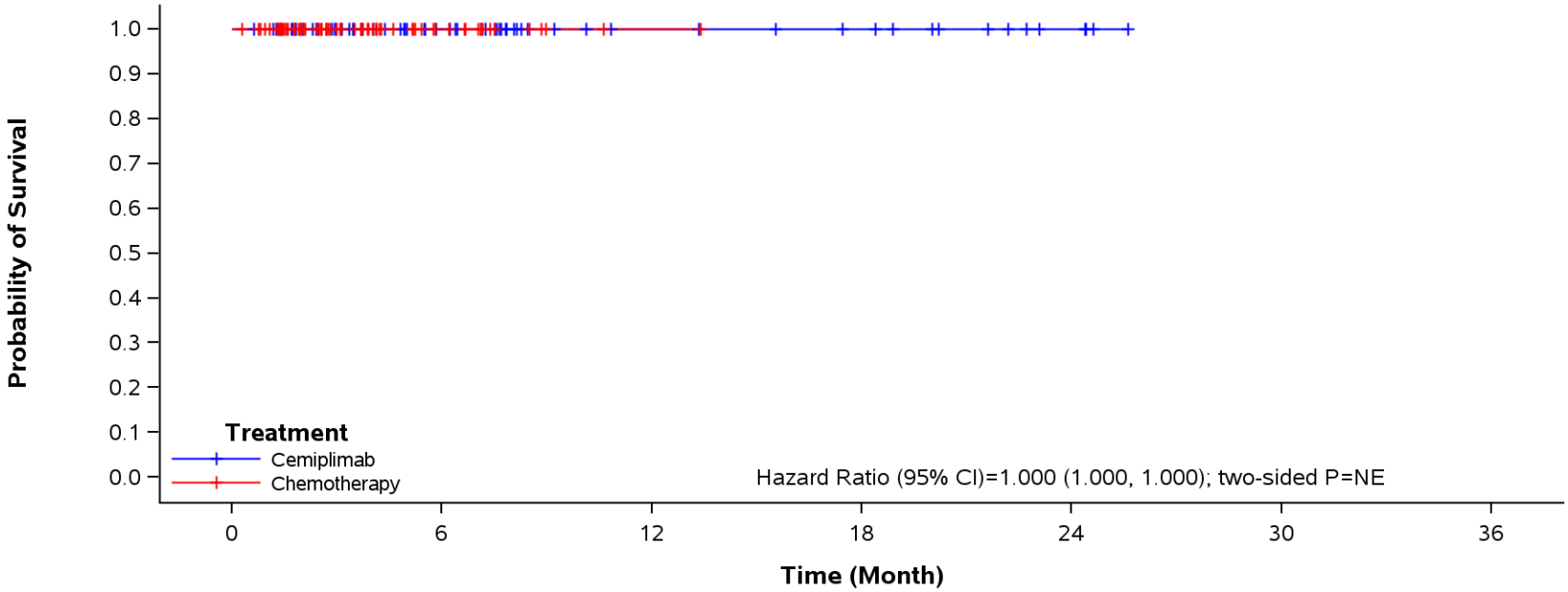

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: Yes
SOC: Vascular disorders
PT: Deep vein thrombosis



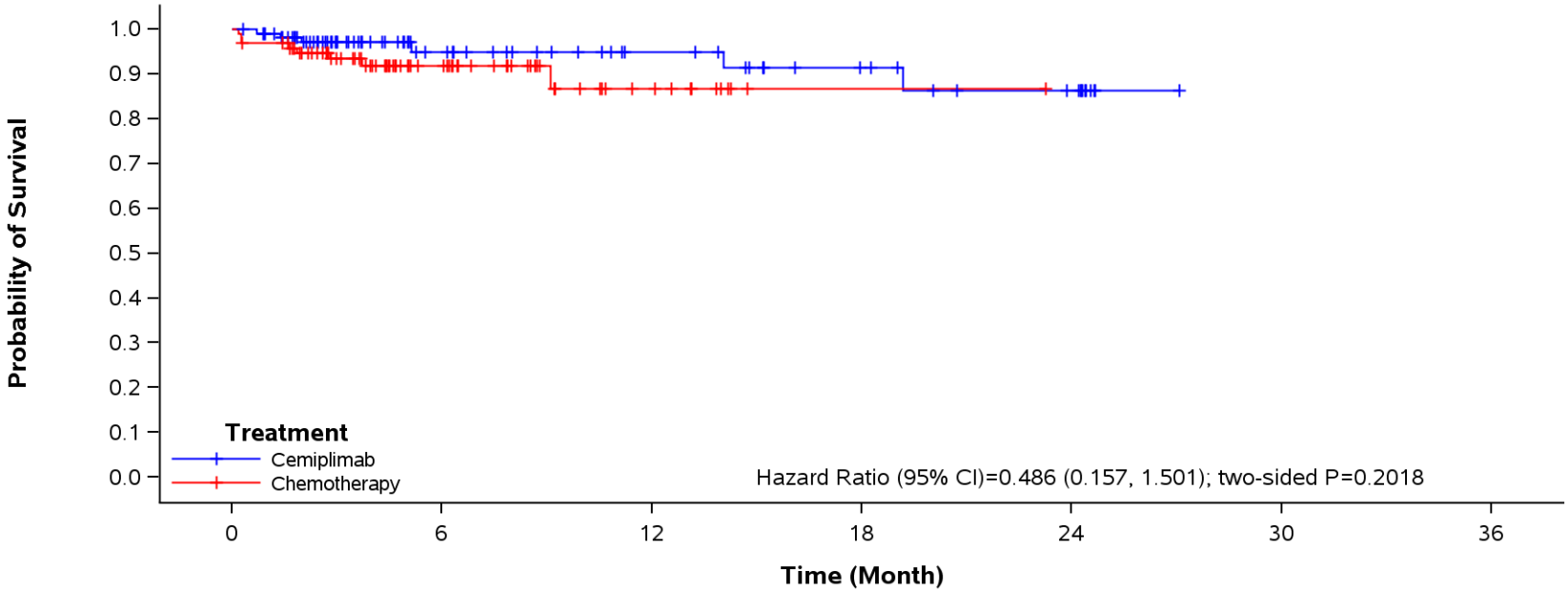

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 87 | 41 | 19 | 16 | 8 | 0 | 0 |
| Chemotherapy | 76 | 13 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
Number of patients with any TEAE leading to discontinuation



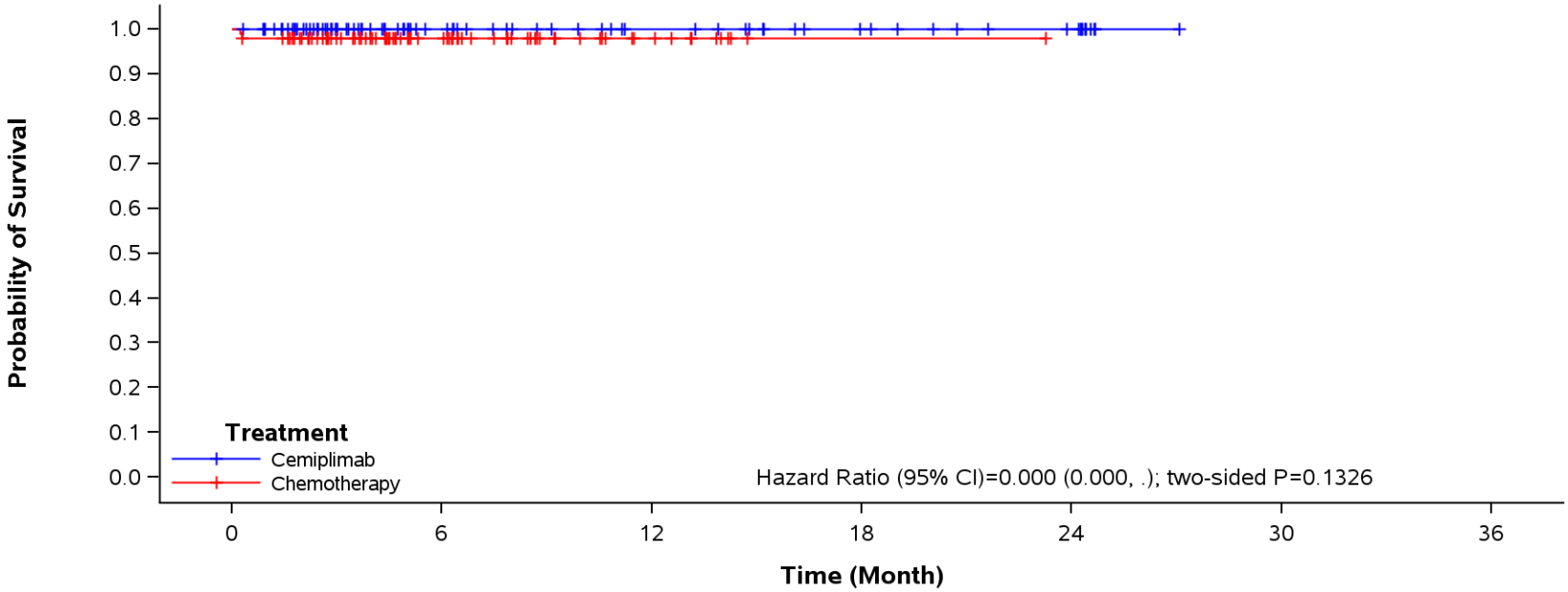

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 37 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders



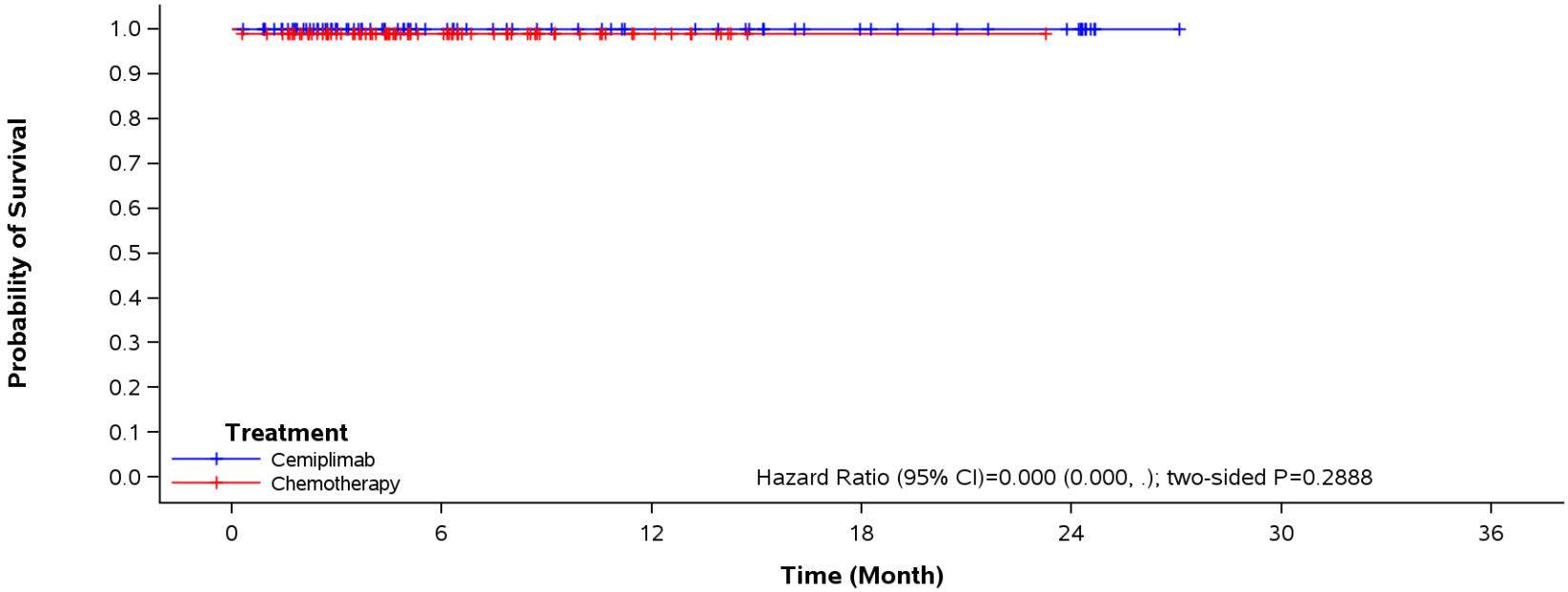

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Anaemia



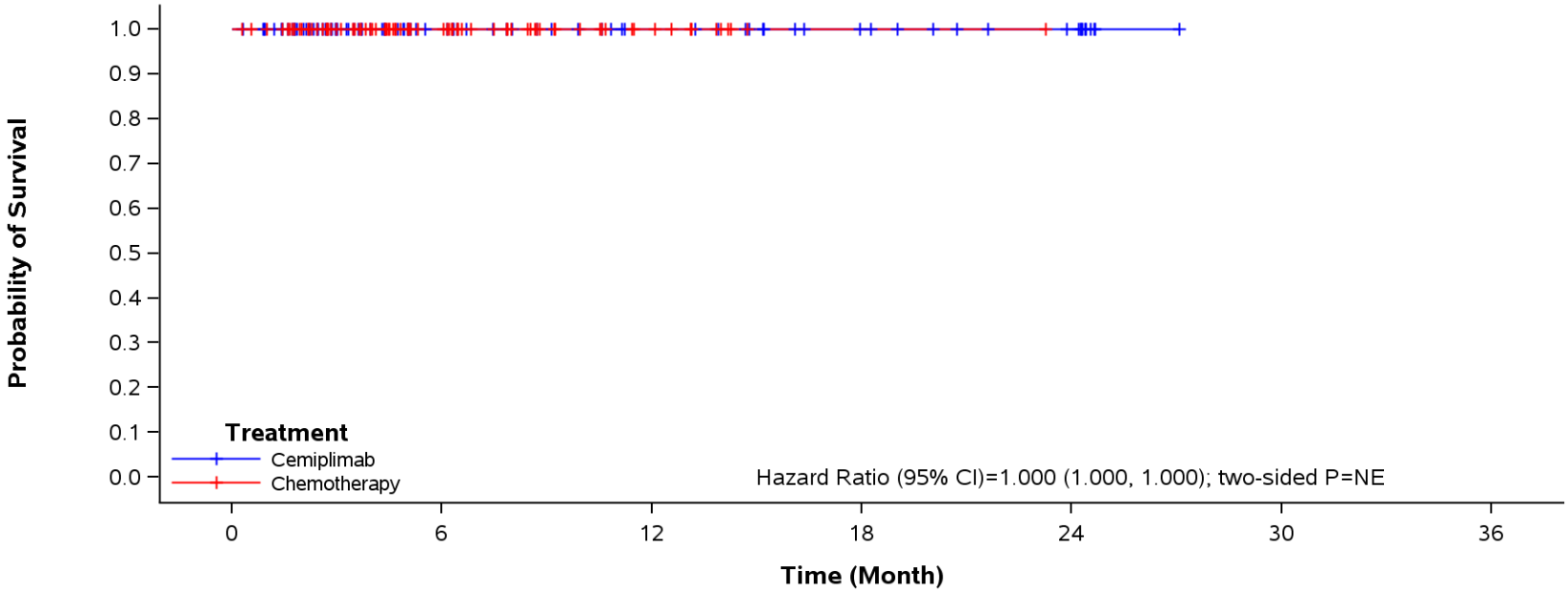

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



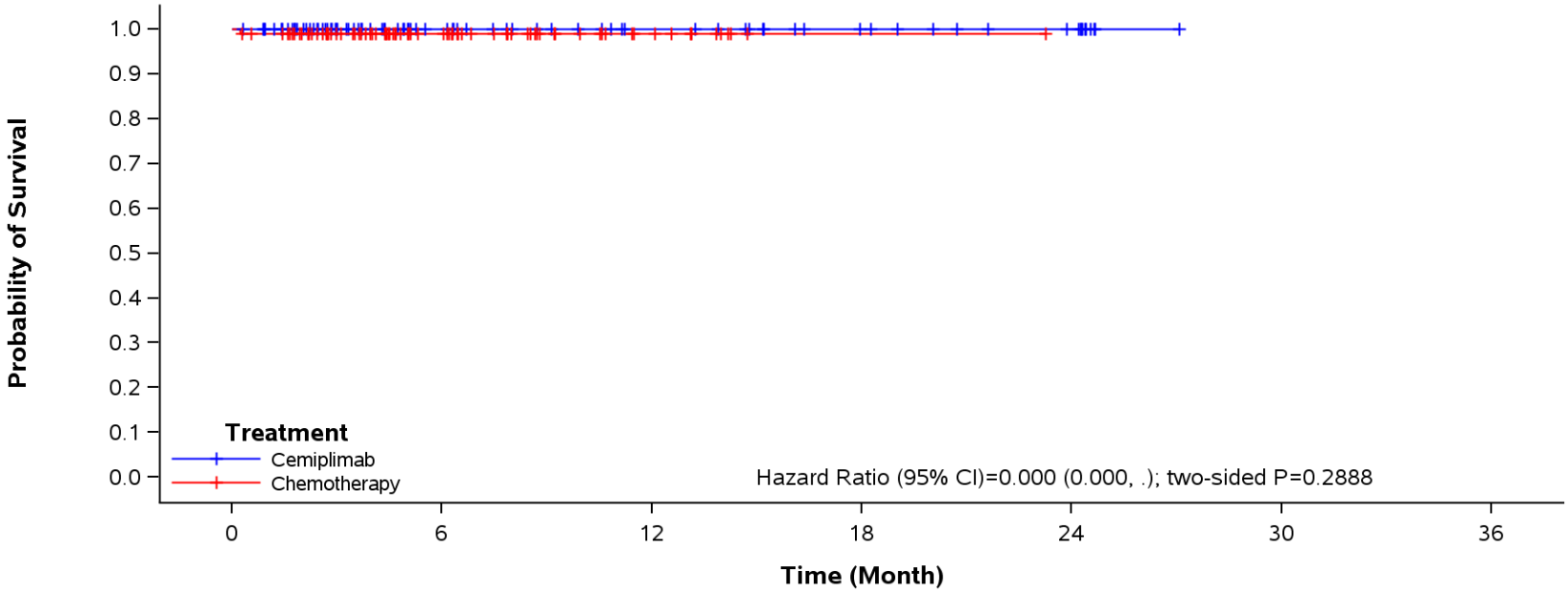

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Neutropenia



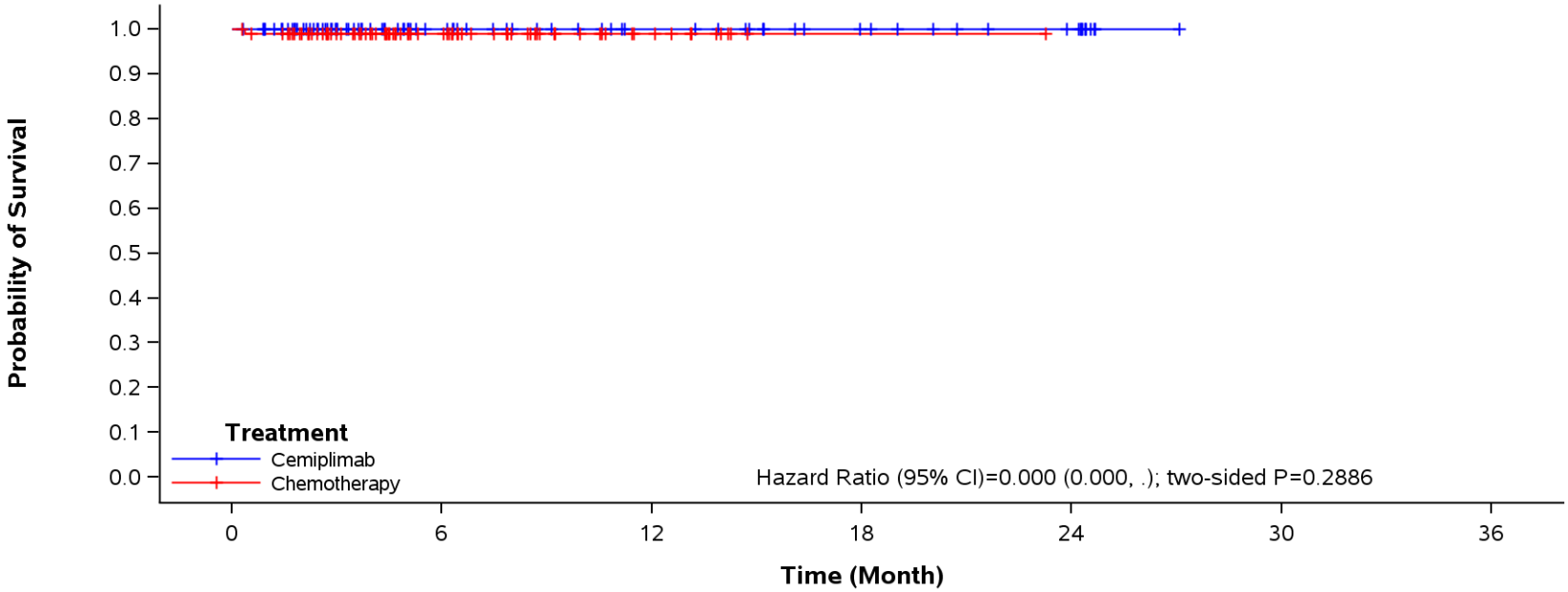

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



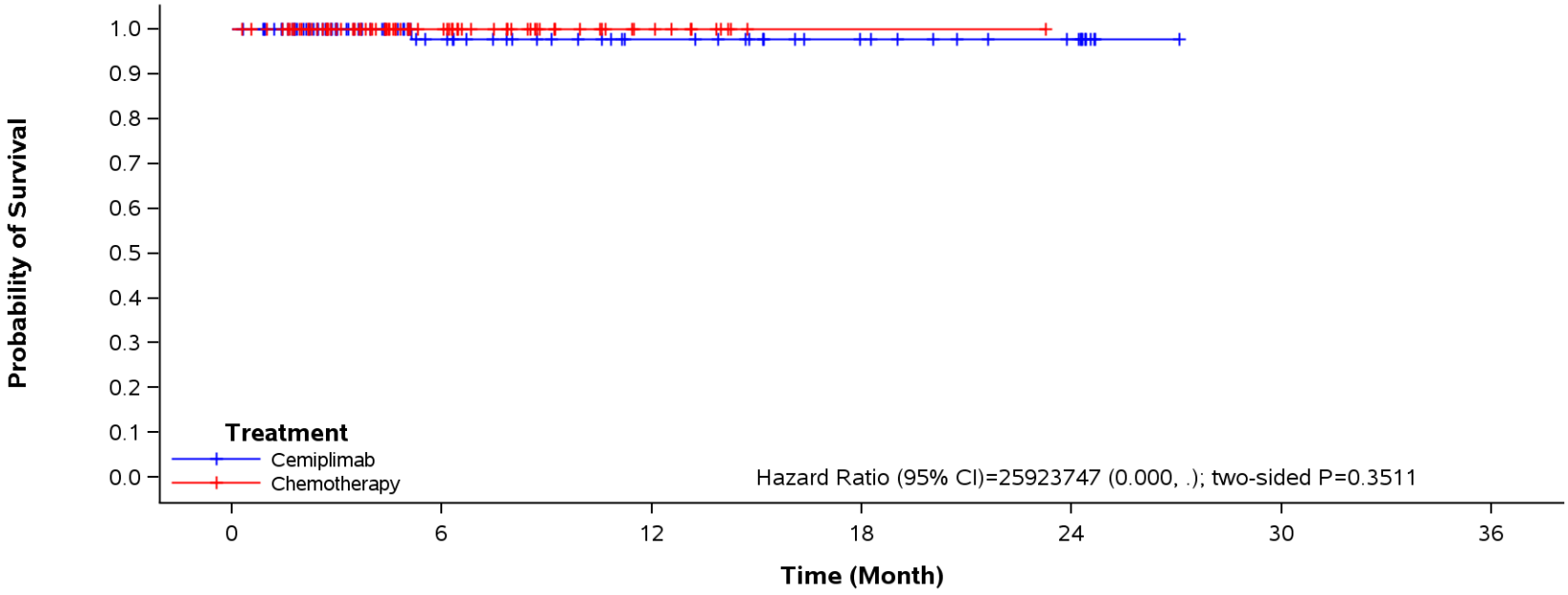

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Cardiac disorders



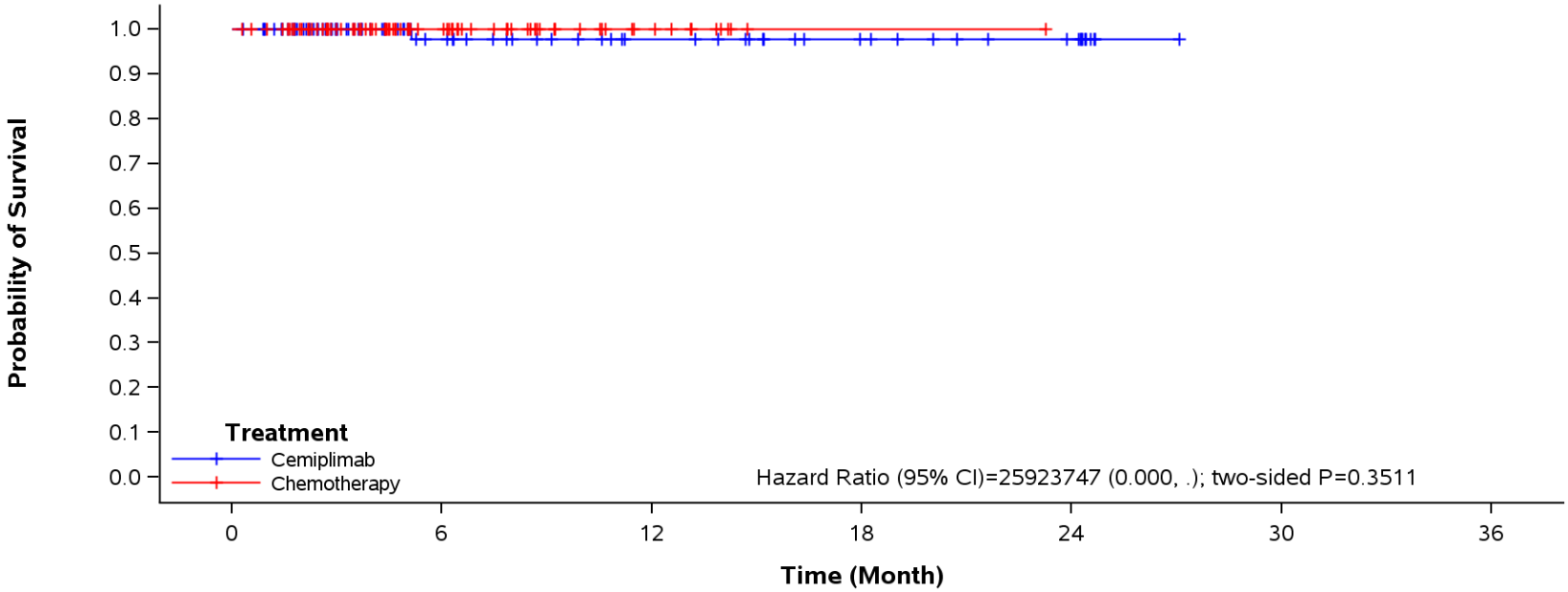

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Cardiac disorders
PT: Autoimmune pericarditis



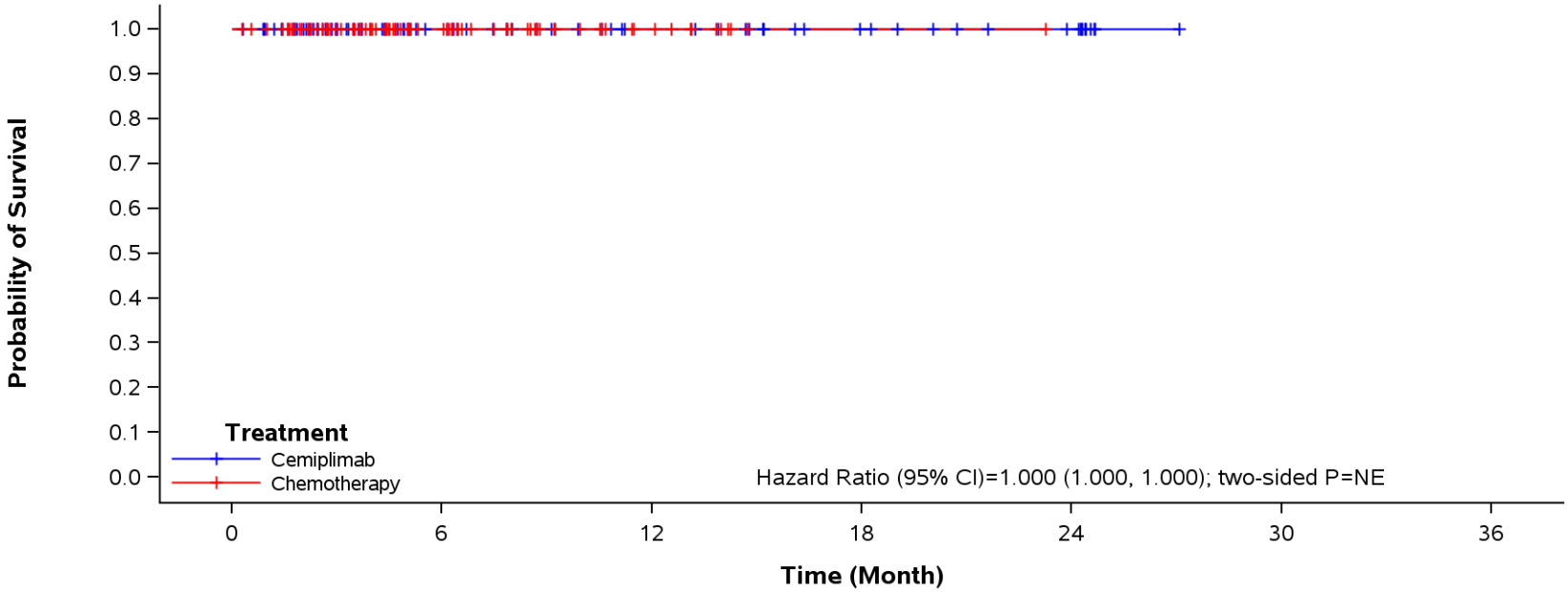

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 43 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Endocrine disorders



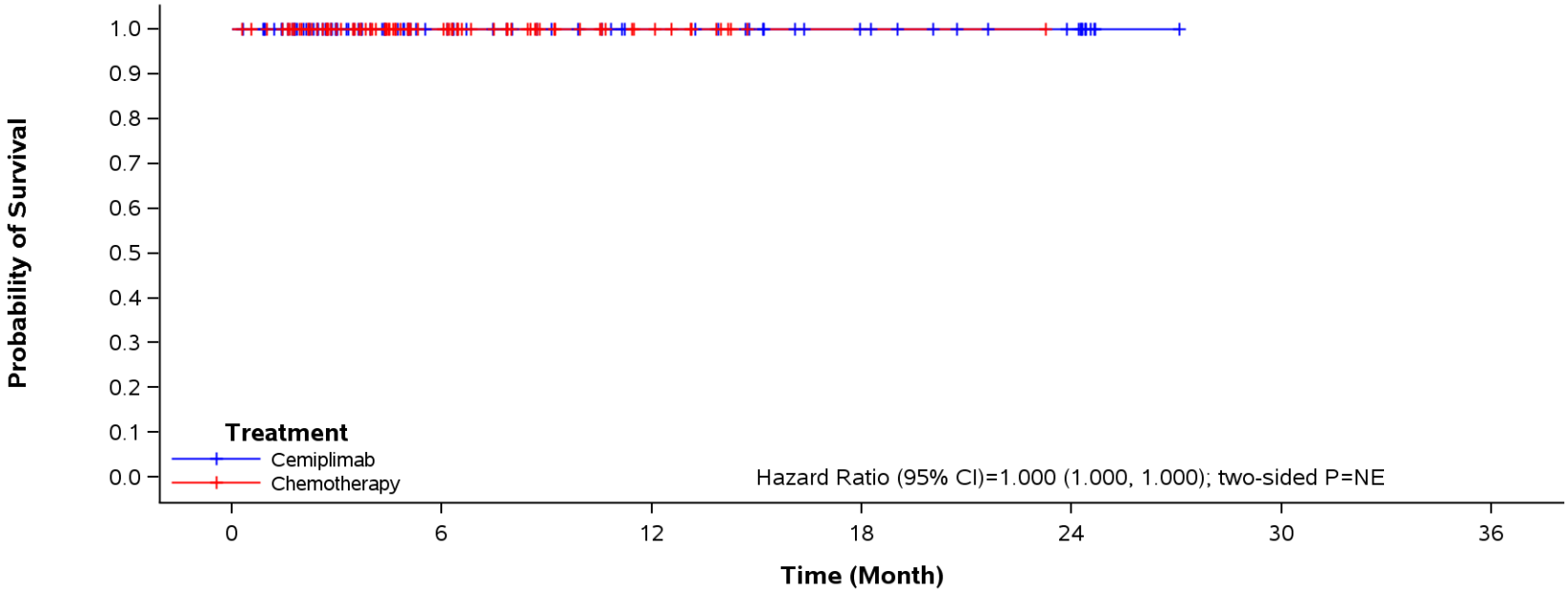

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Endocrine disorders
PT: Hypothyroidism



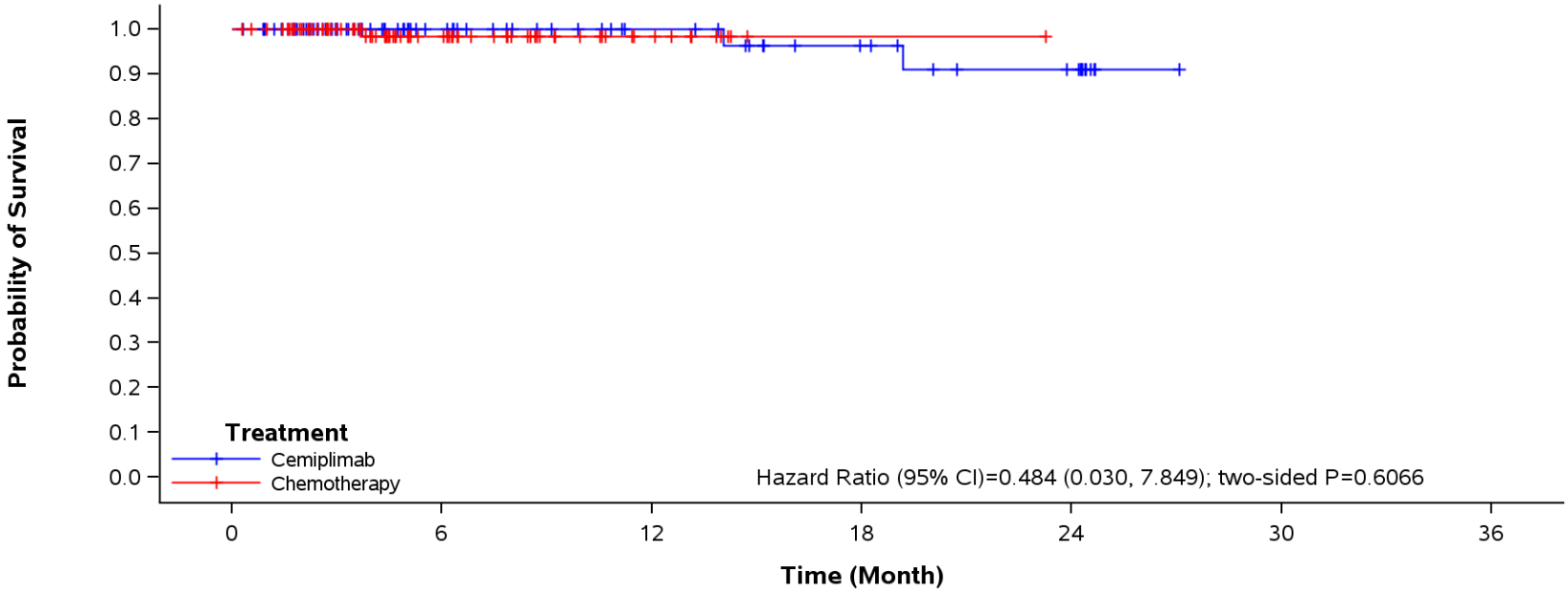

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders



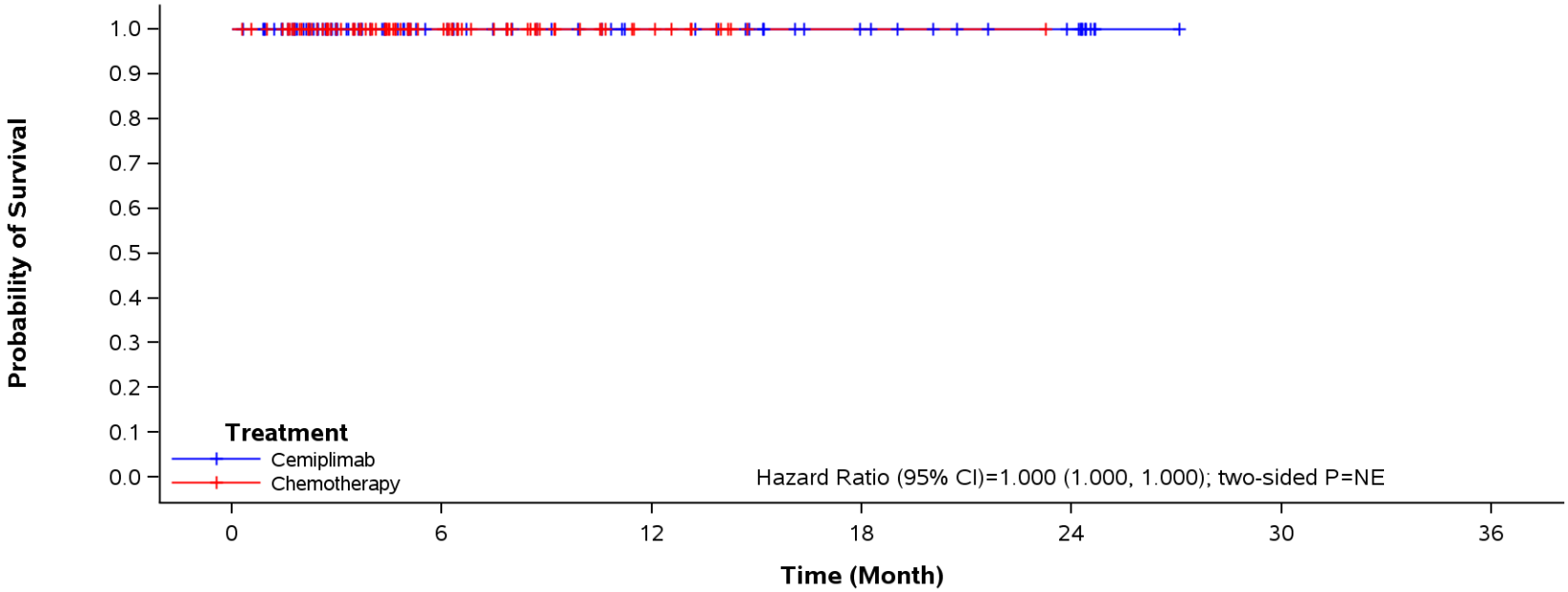

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 38 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders
PT: Colitis



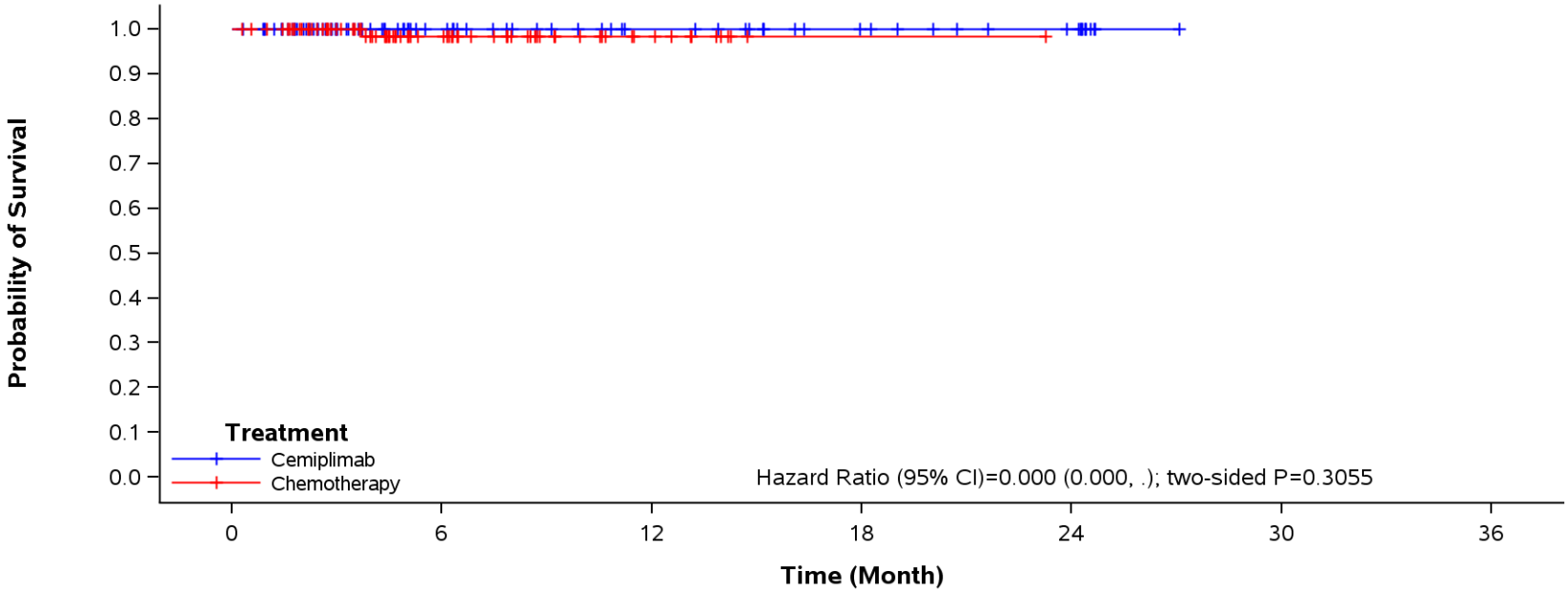

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders
PT: Diverticular perforation



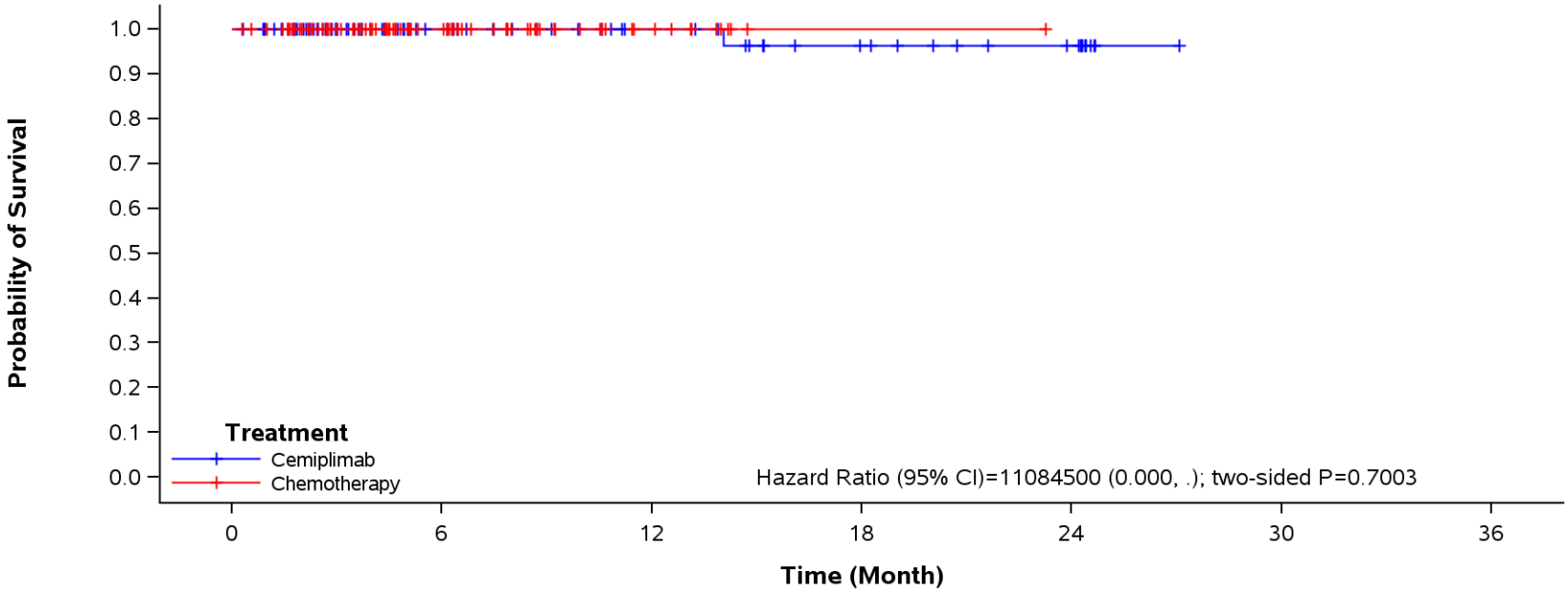

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 38 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders
PT: Pancreatic mass



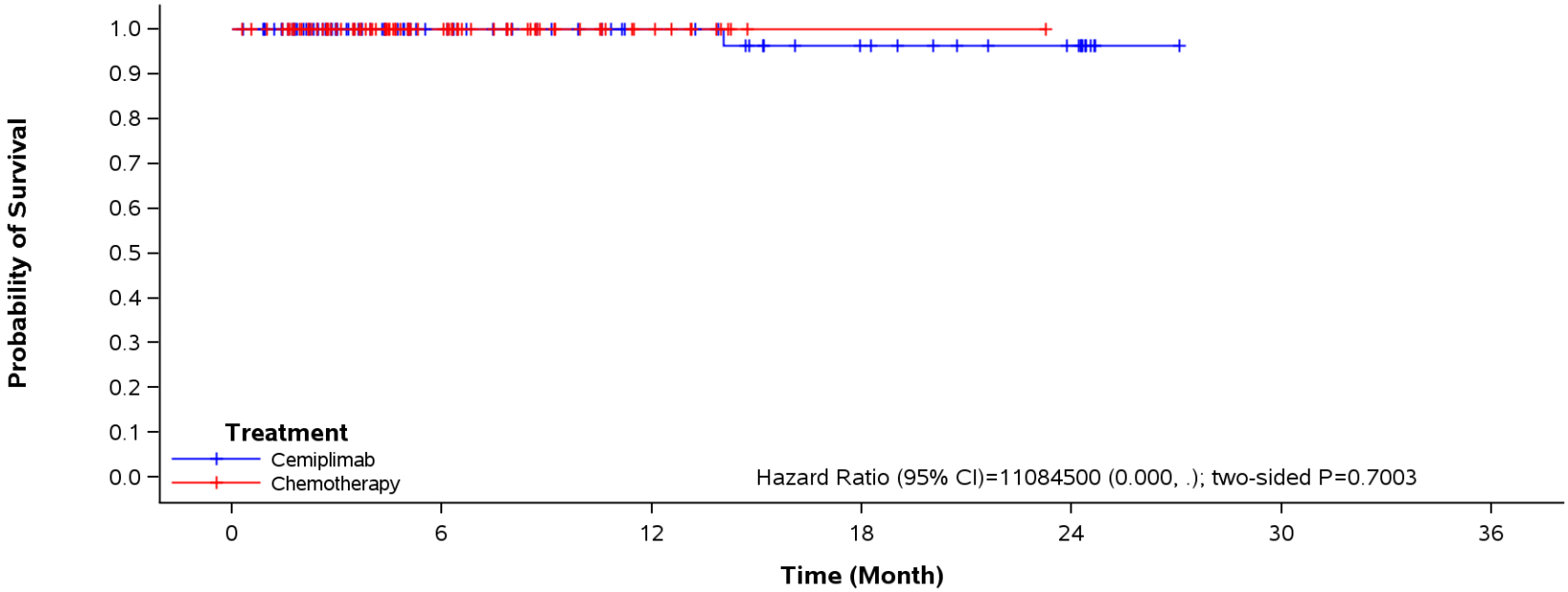

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



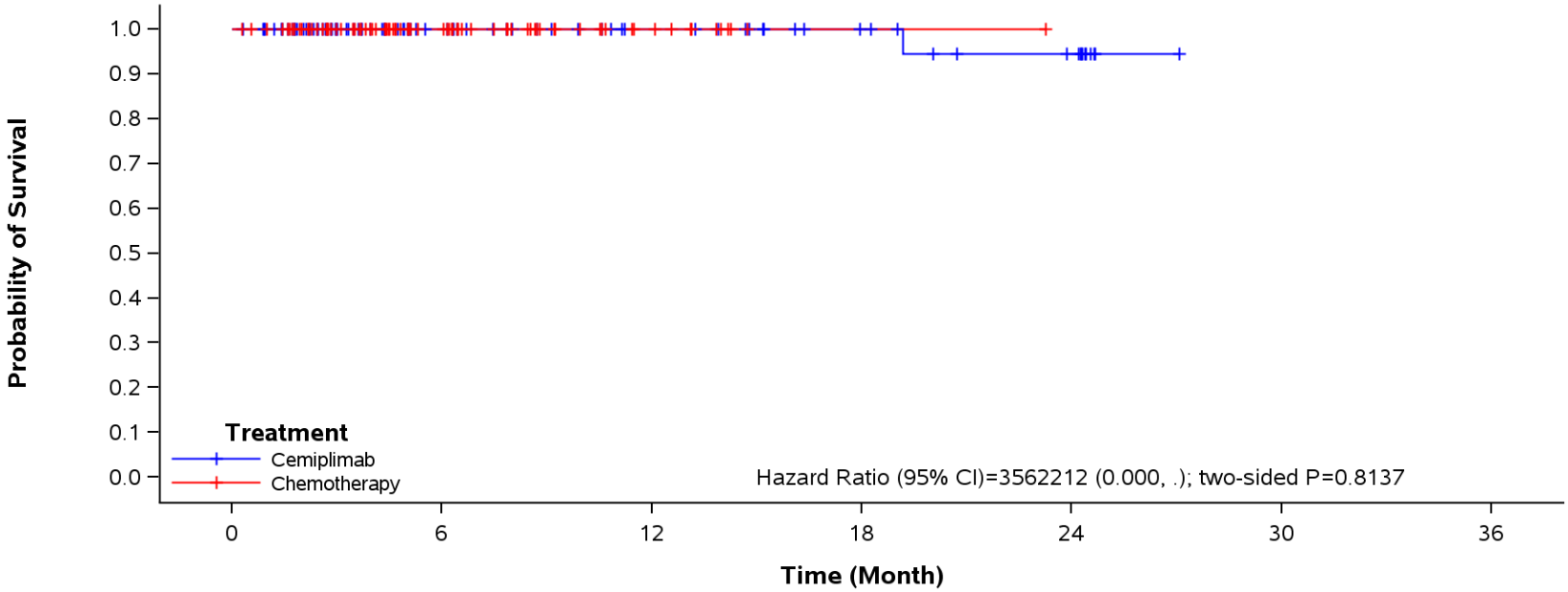

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Gastrointestinal disorders
PT: Proctalgia




**Number of Subjects at risk**

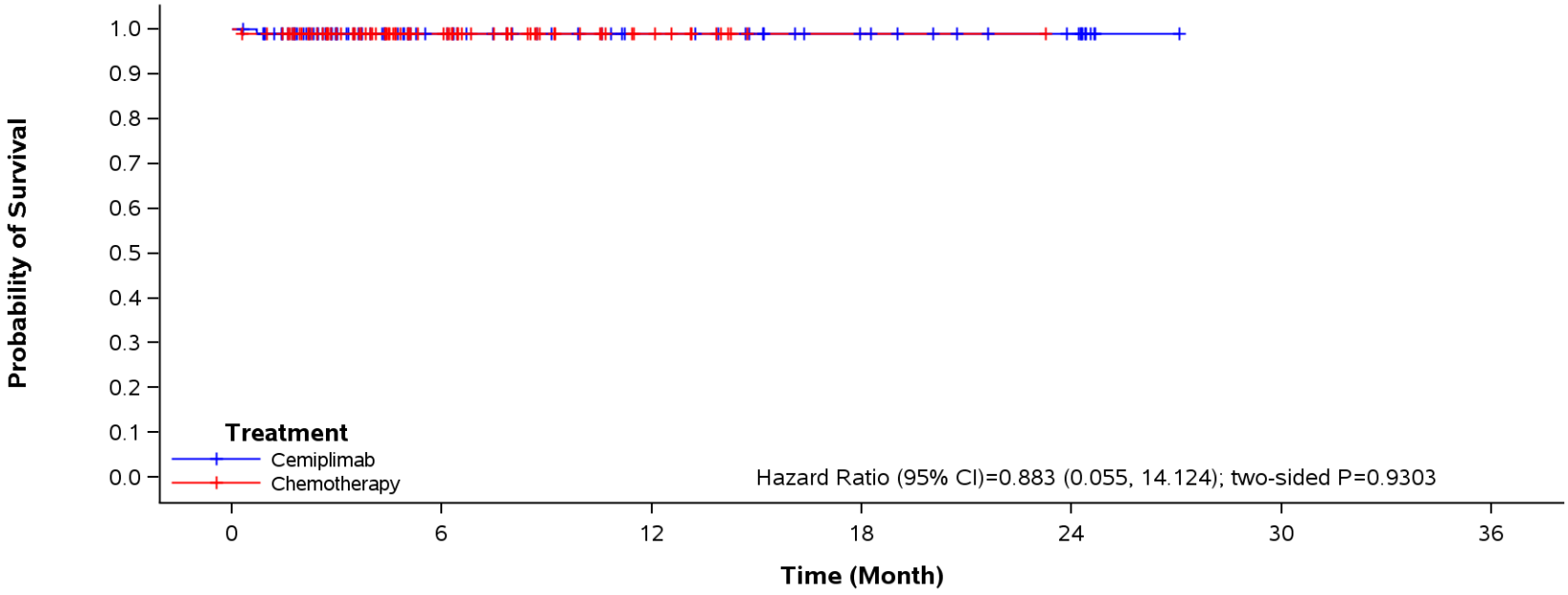
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

SOC: General disorders and administration site conditions




**Number of Subjects at risk**

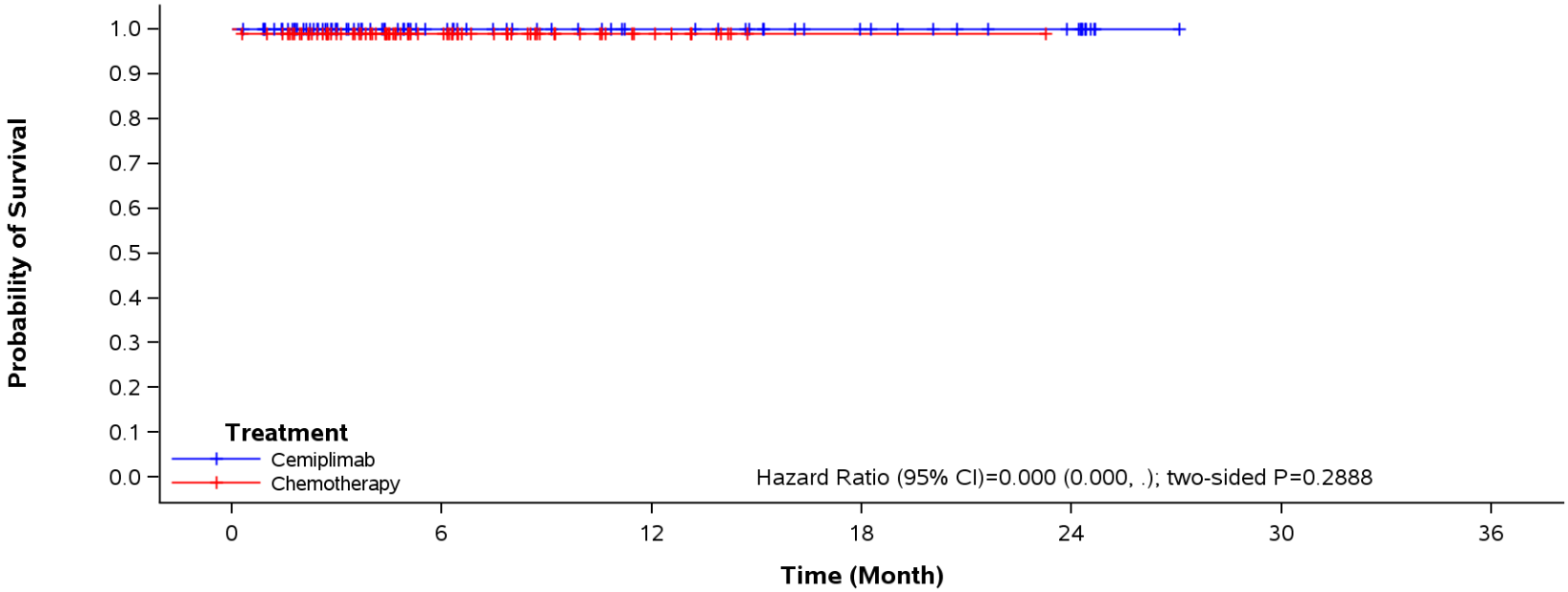
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: General disorders and administration site conditions
PT: Malaise



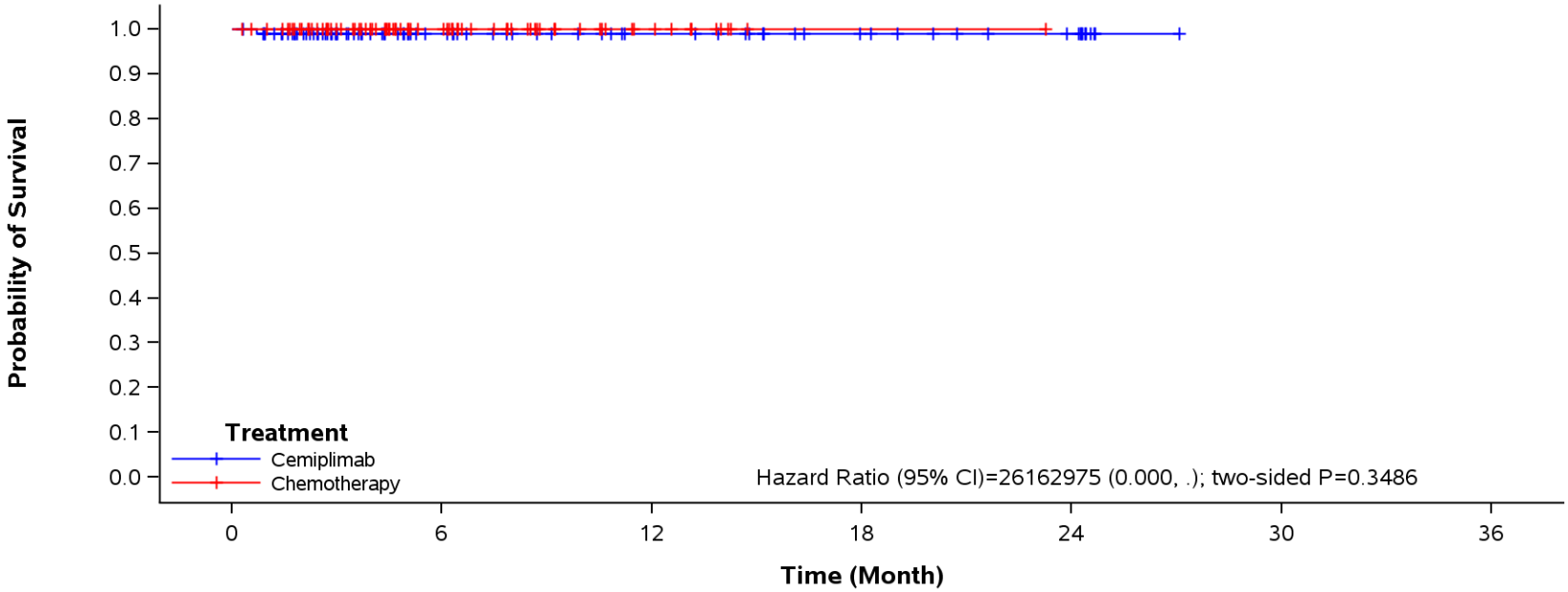

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



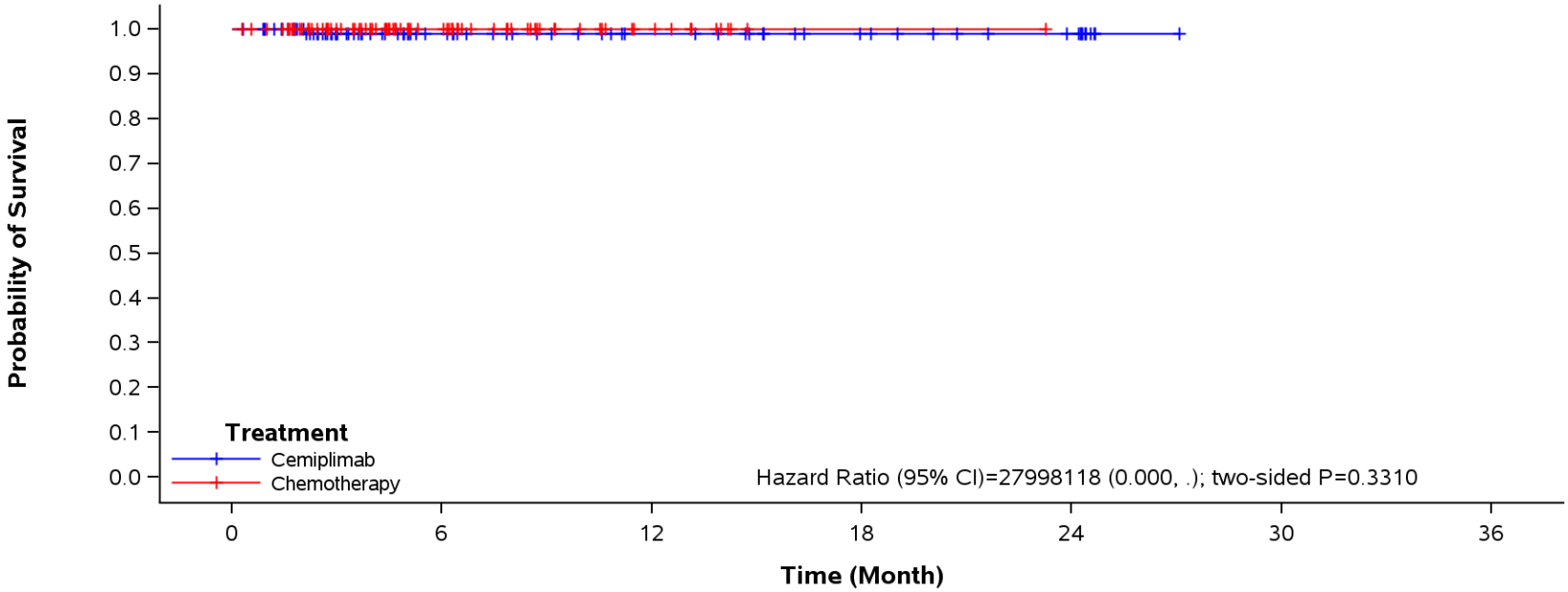

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Hepatobiliary disorders



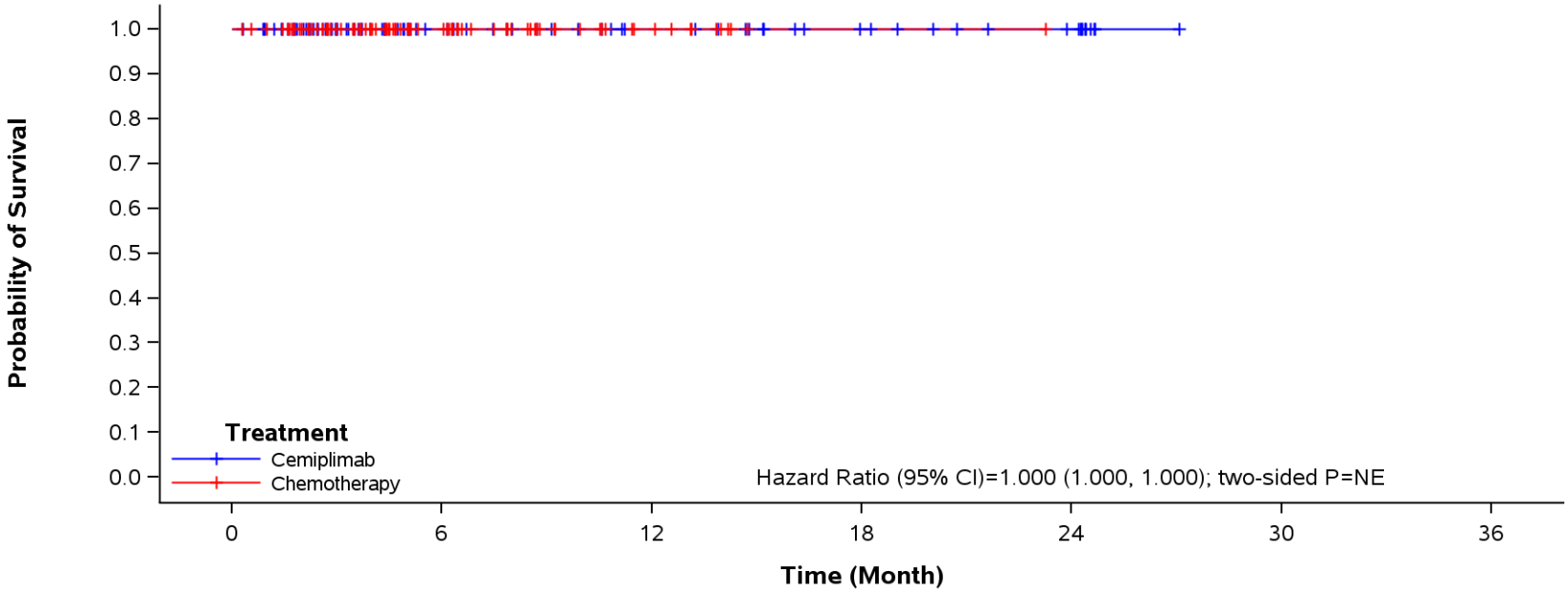

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



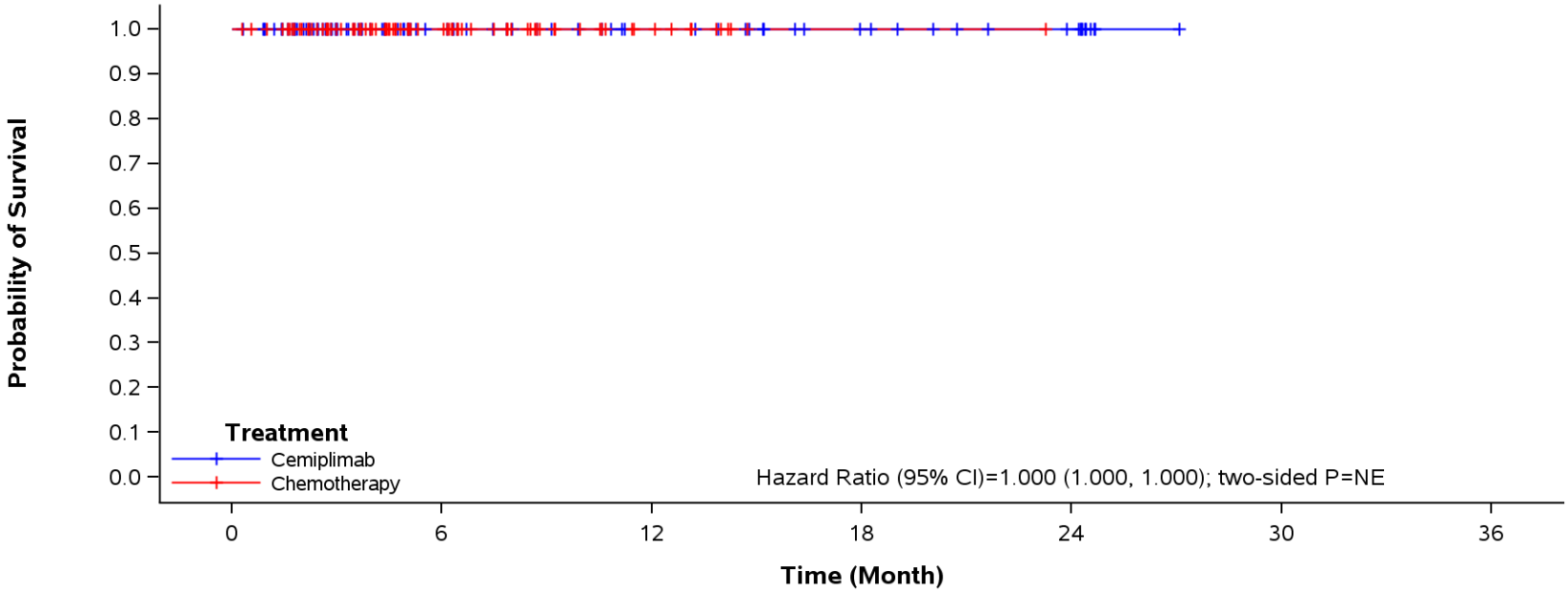

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



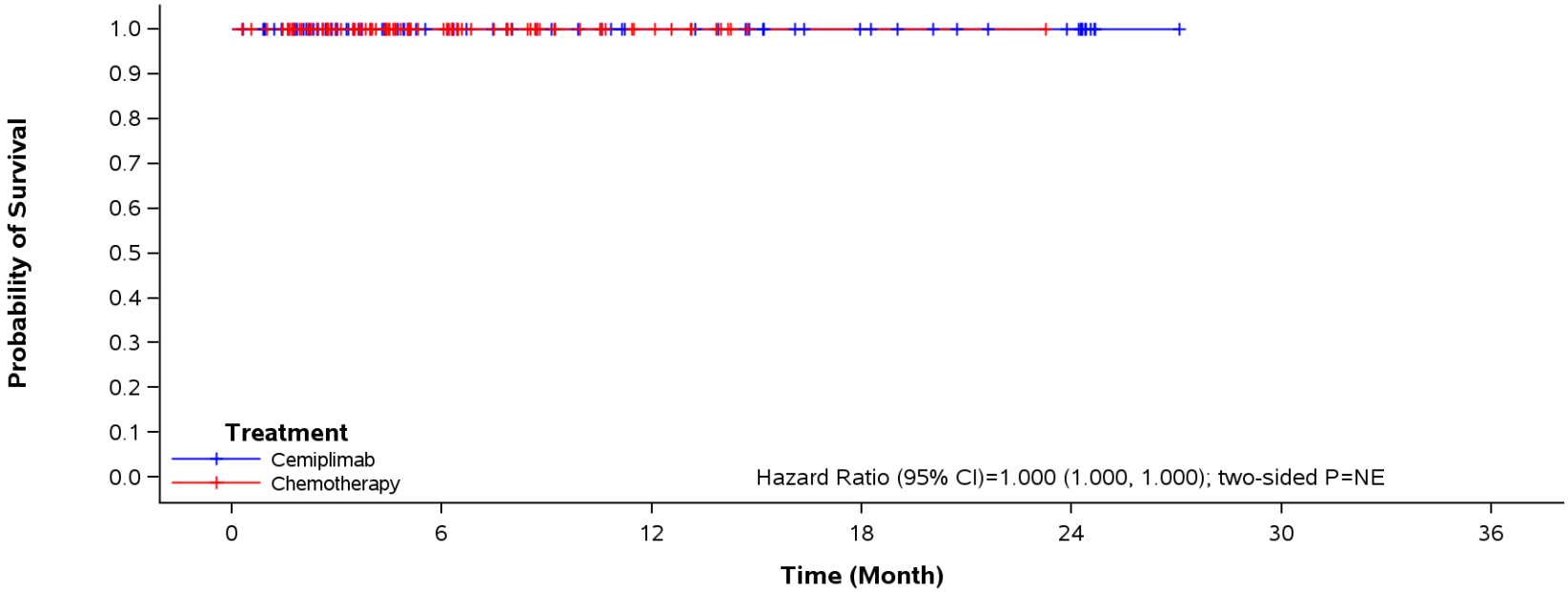

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Hepatobiliary disorders
PT: Hepatitis



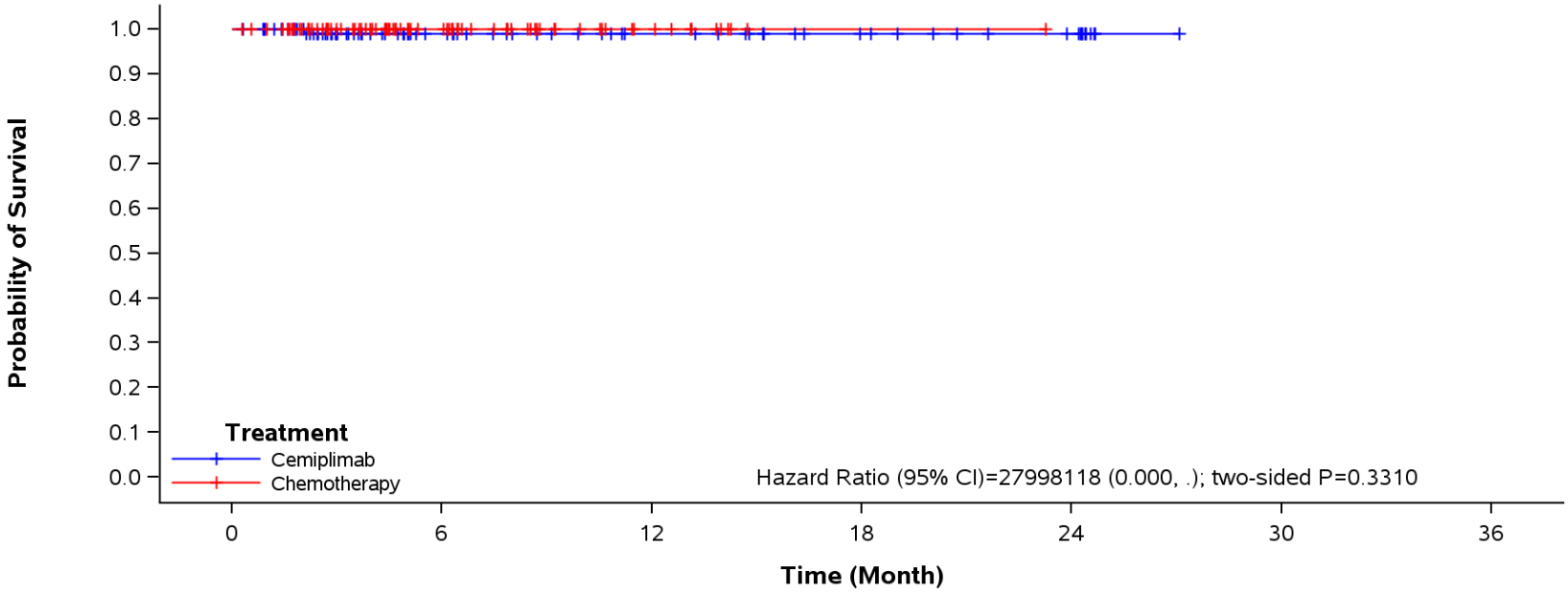

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



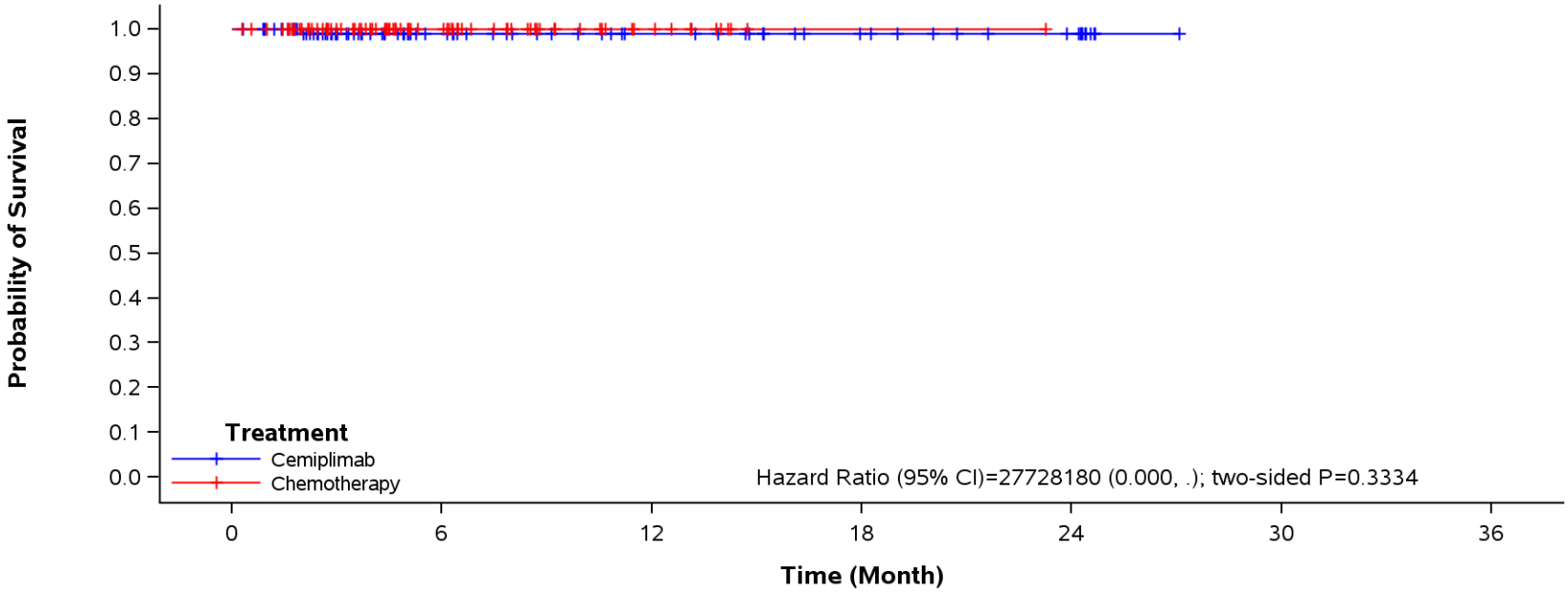

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Infections and infestations



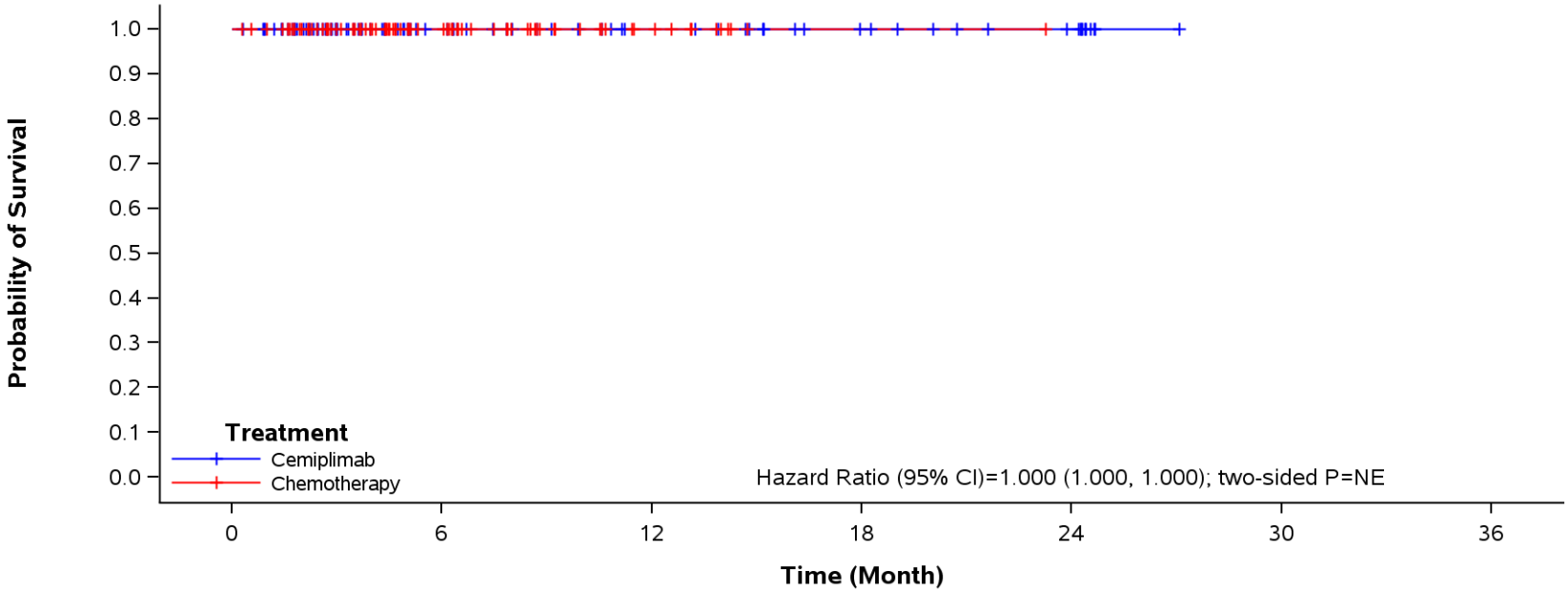

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Infections and infestations
PT: COVID-19 pneumonia



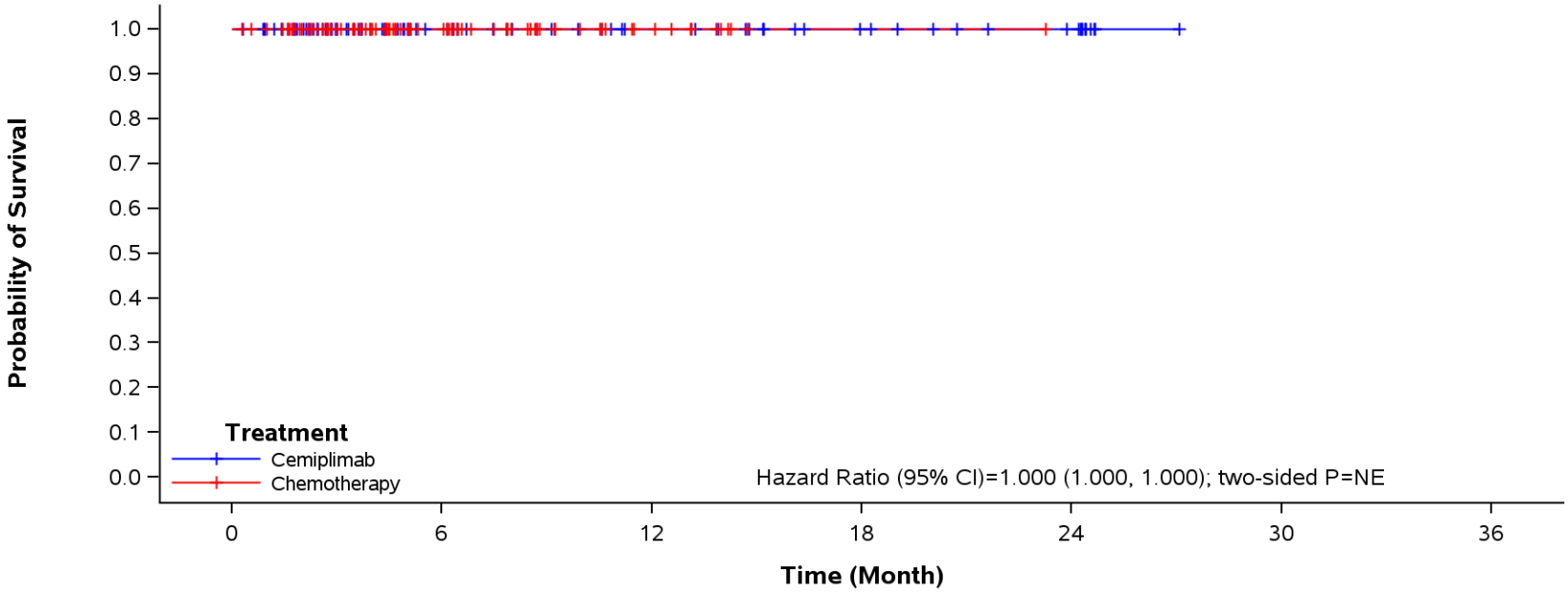

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Infections and infestations
PT: Gastroenteritis



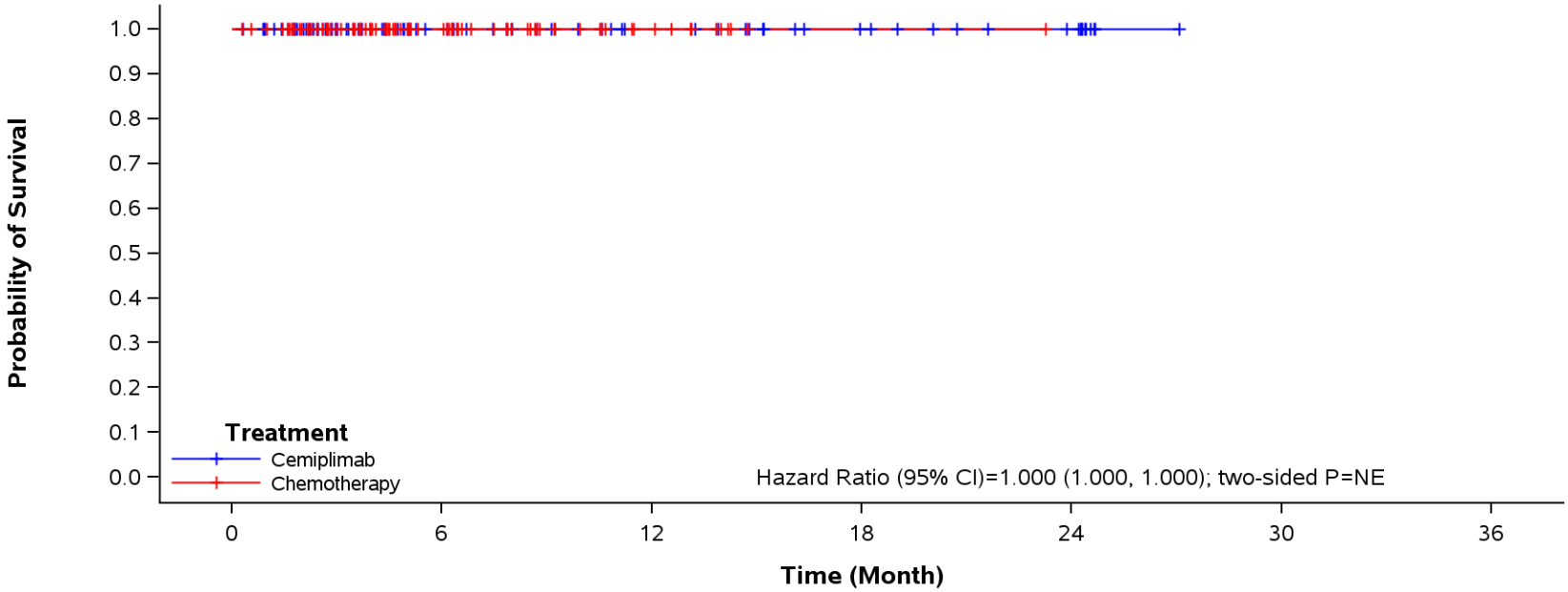

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Infections and infestations
PT: Pelvic abscess



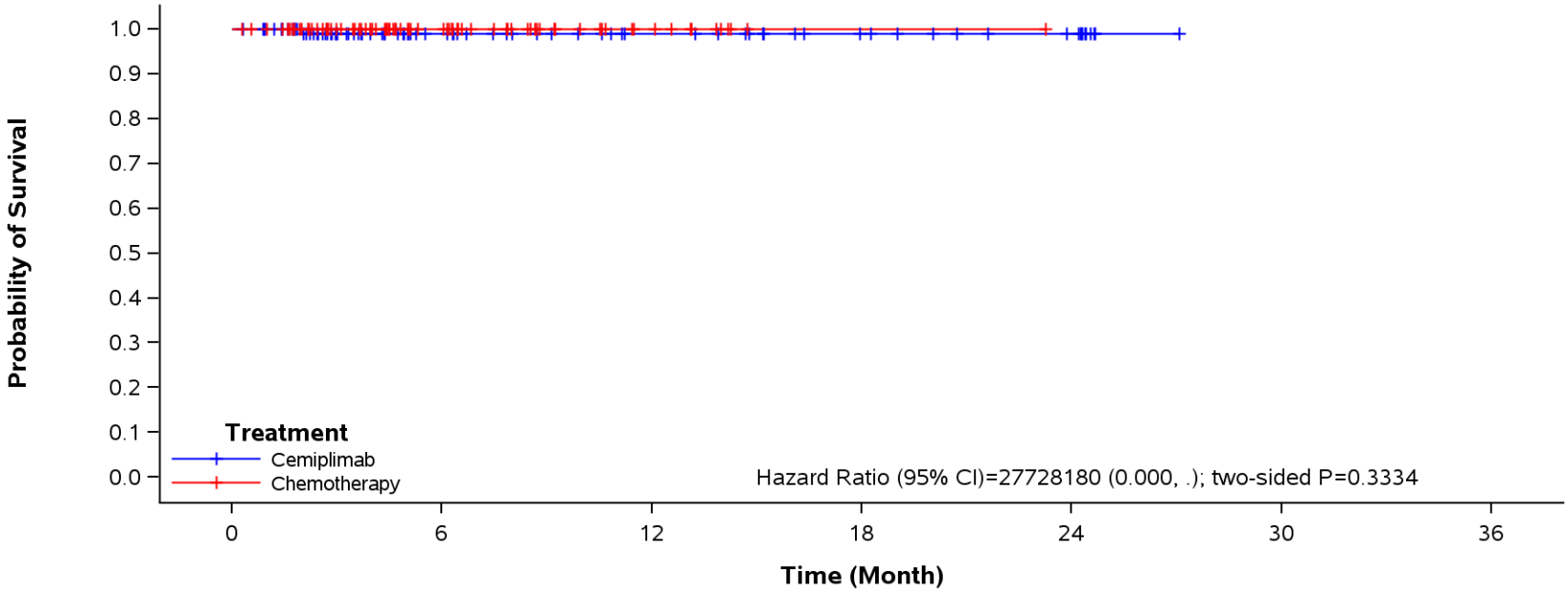

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

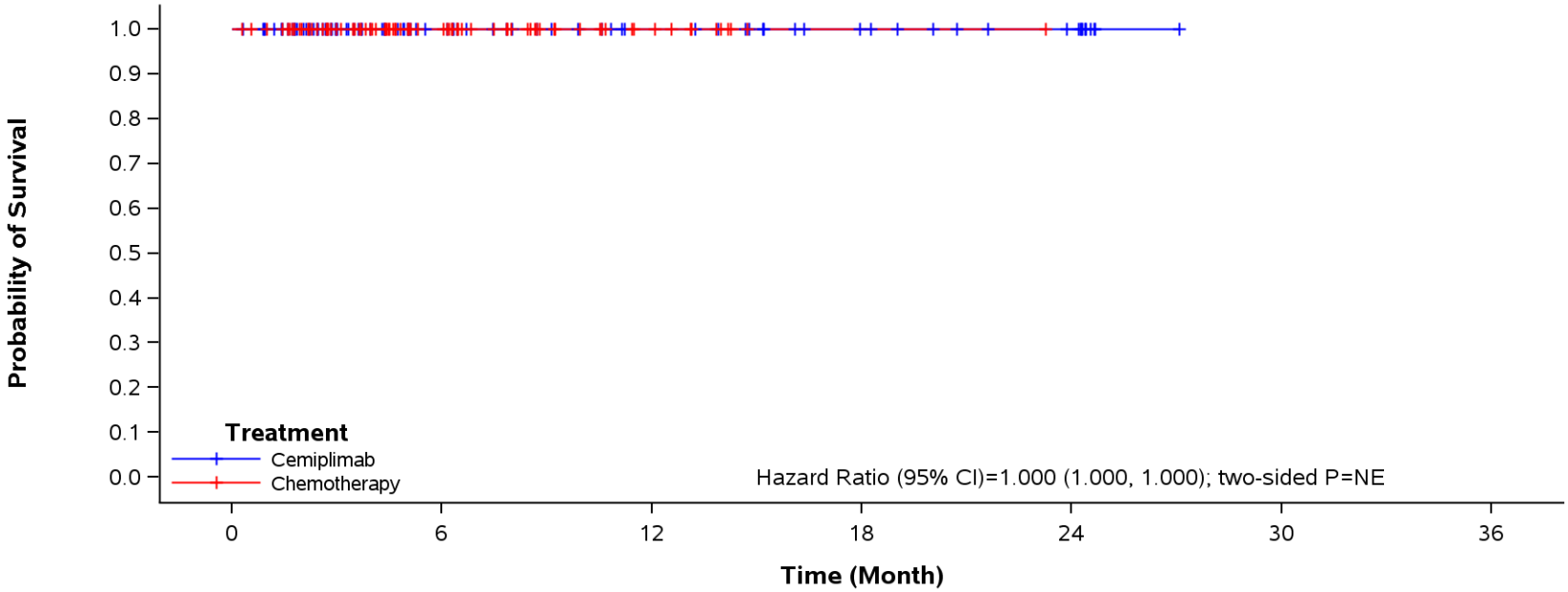
Prior Bevacizumab use: No
SOC: Infections and infestations
PT: Peritonitis




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Infections and infestations
PT: Pneumonia



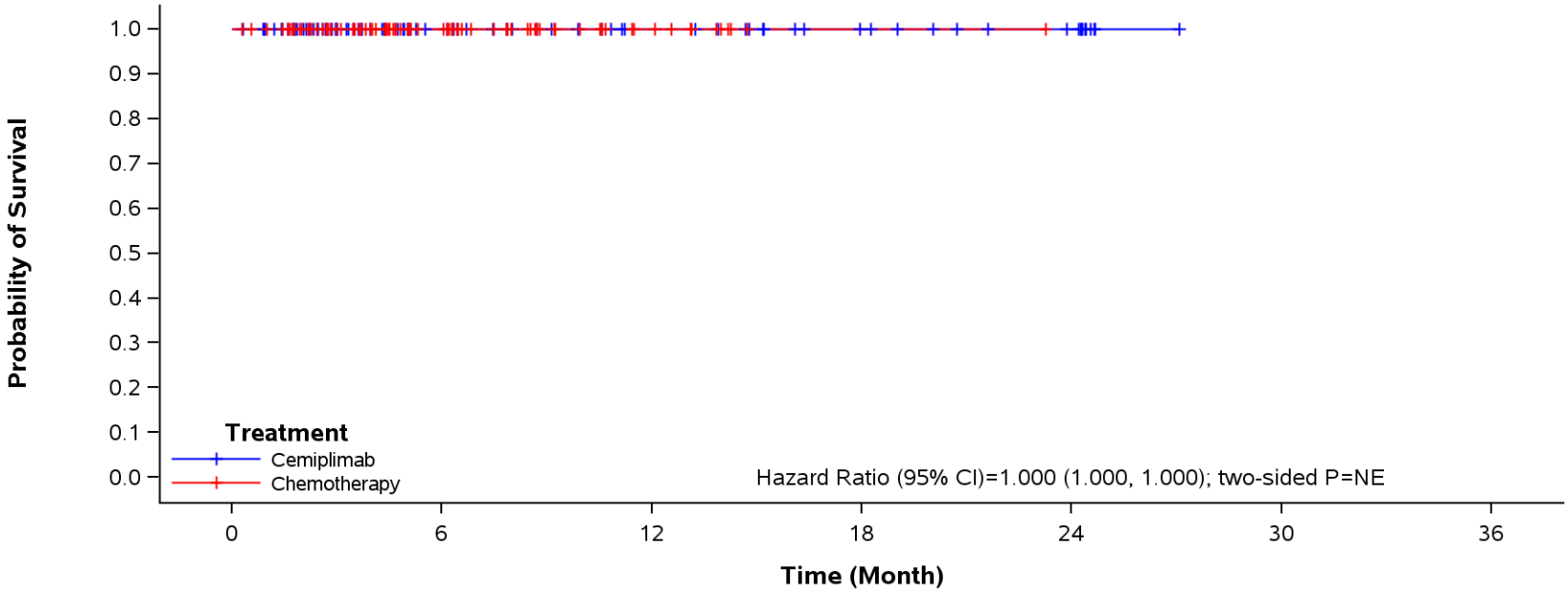

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Infections and infestations
PT: Pyomyositis

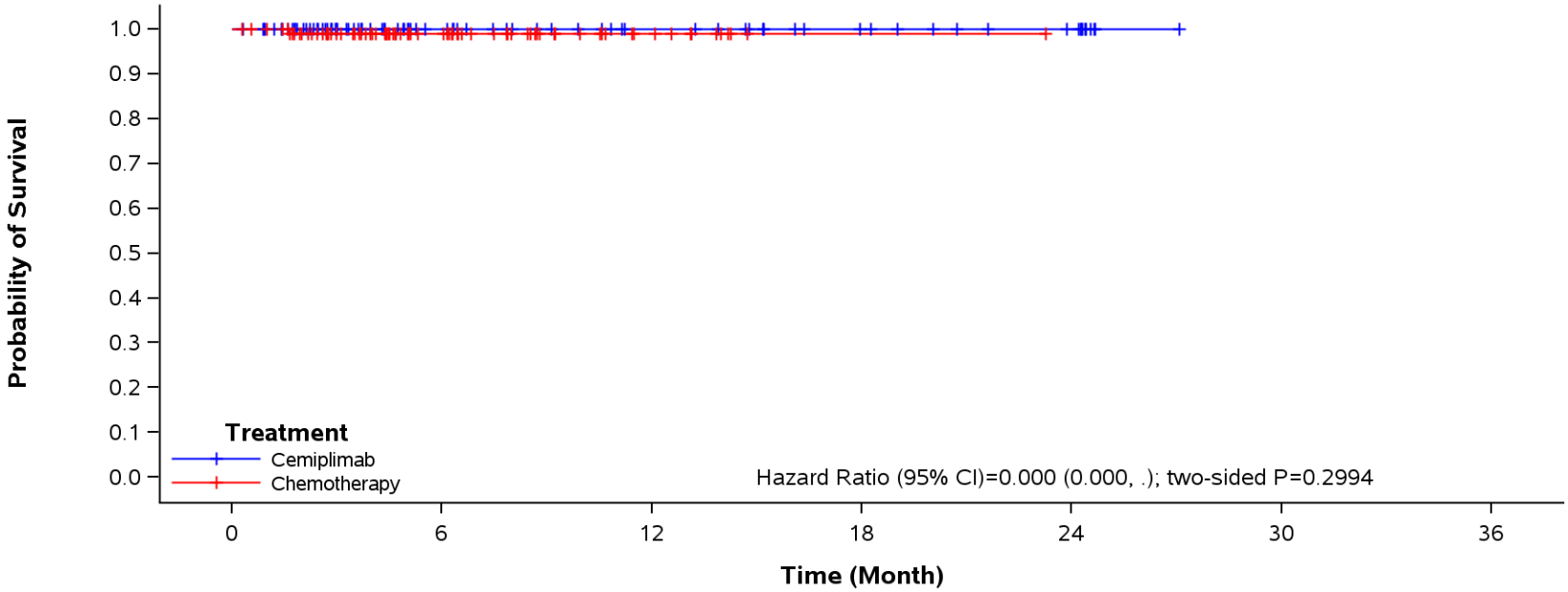



Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

SOC: Injury, poisoning and procedural complications




**Number of Subjects at risk**

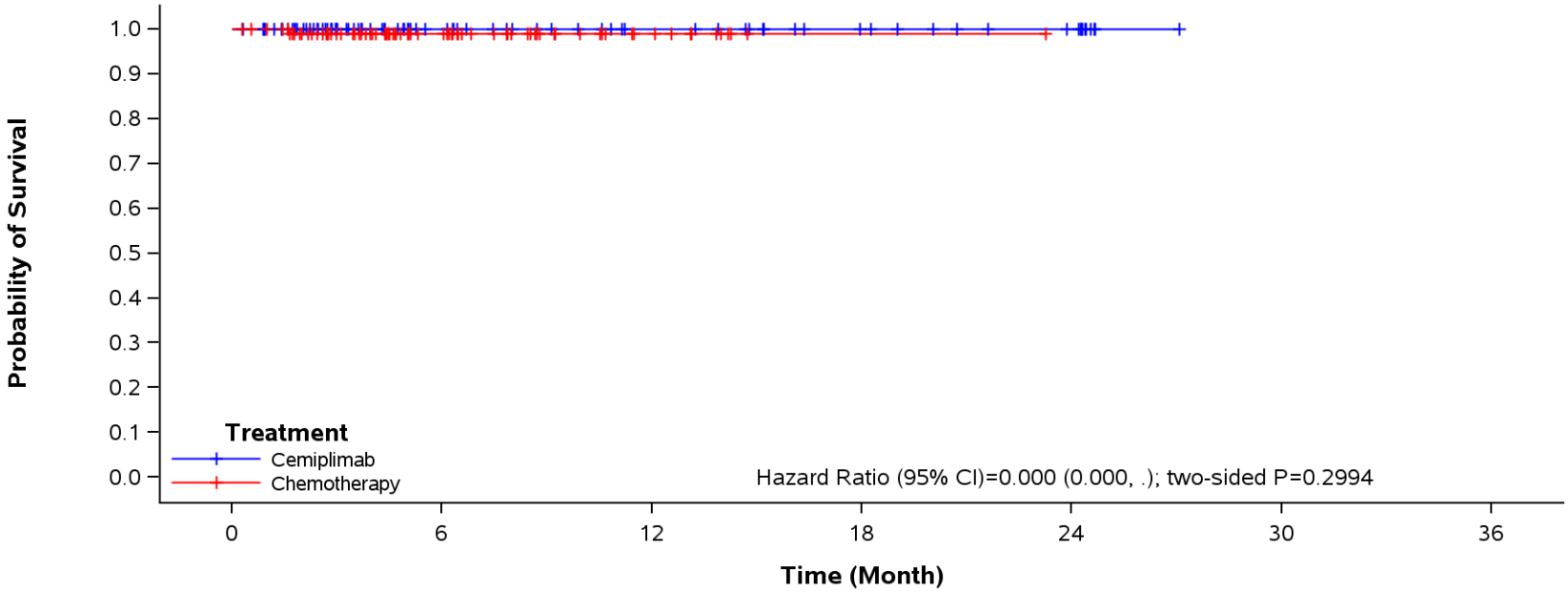
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



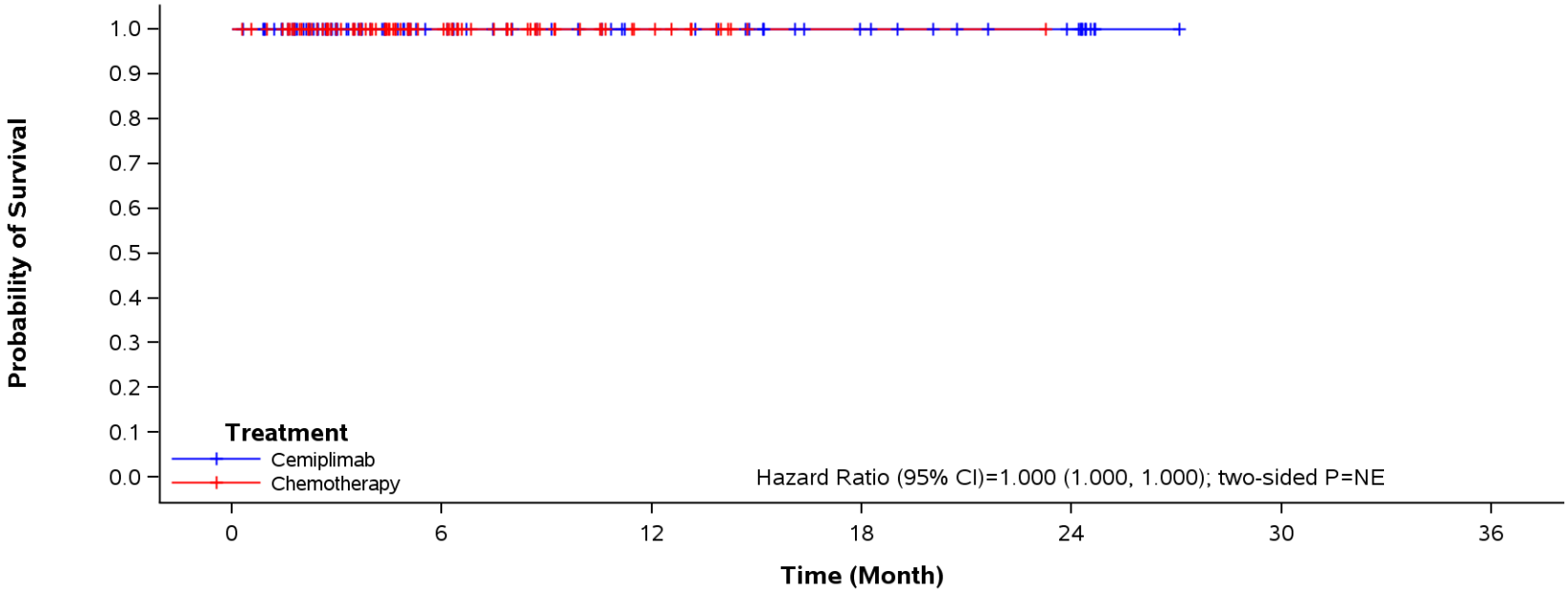

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



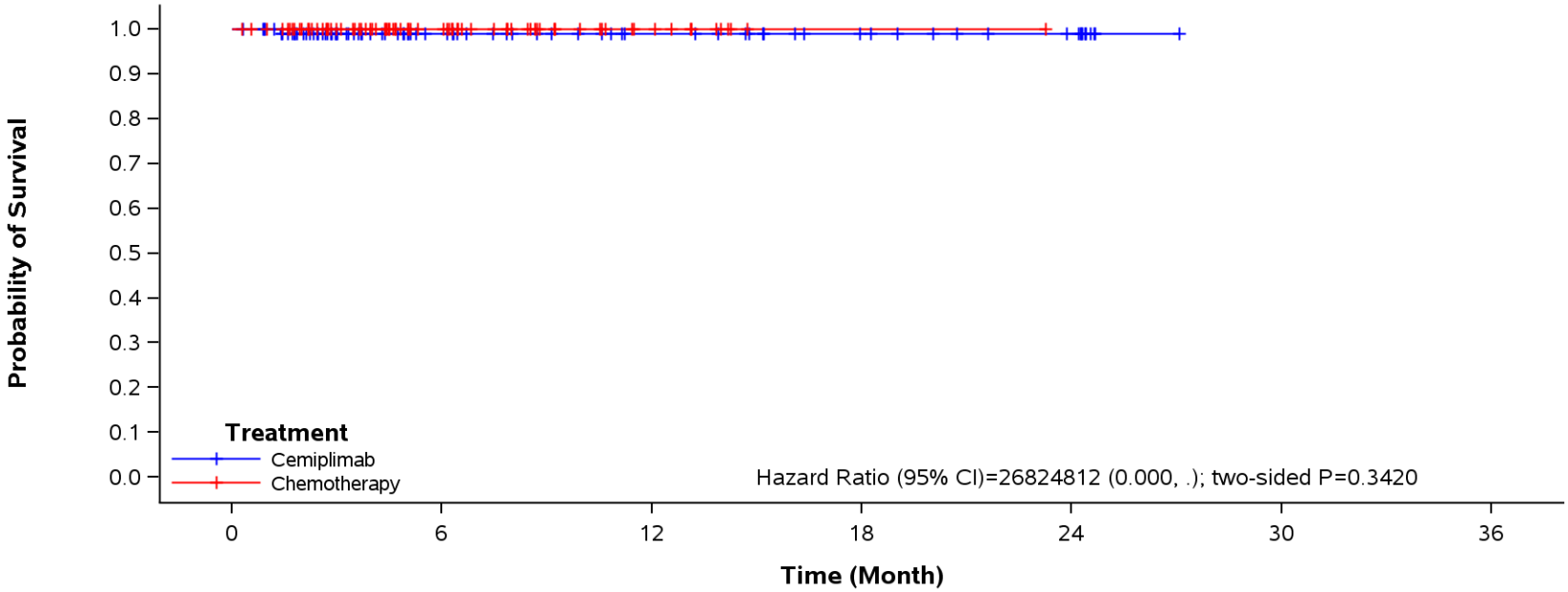

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Investigations



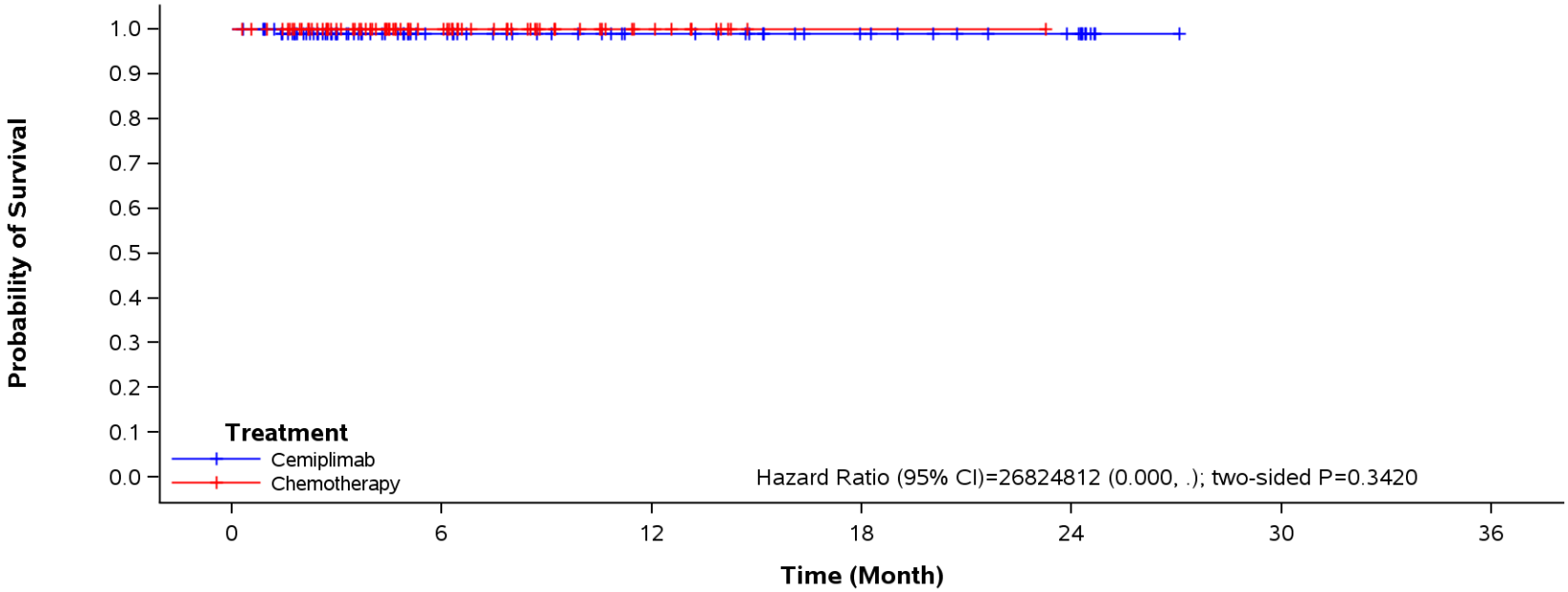

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Investigations
PT: Alanine aminotransferase increased



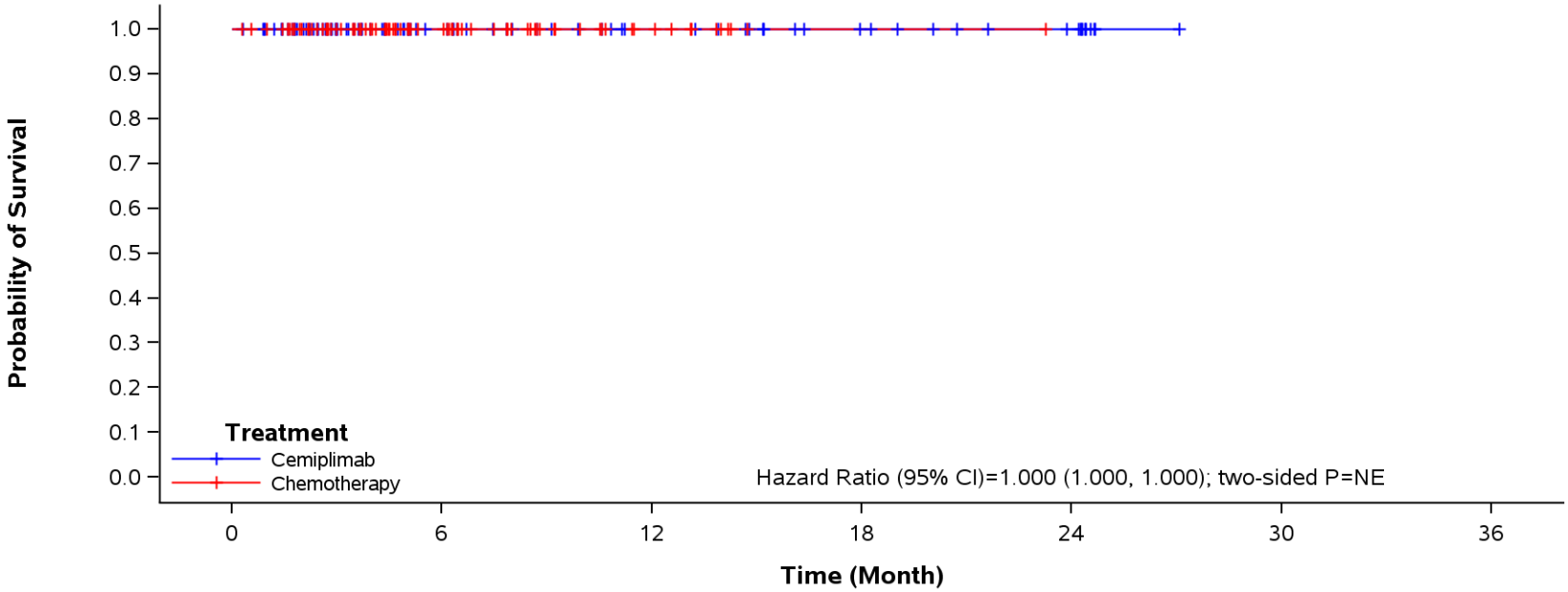

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Investigations
PT: Amylase increased



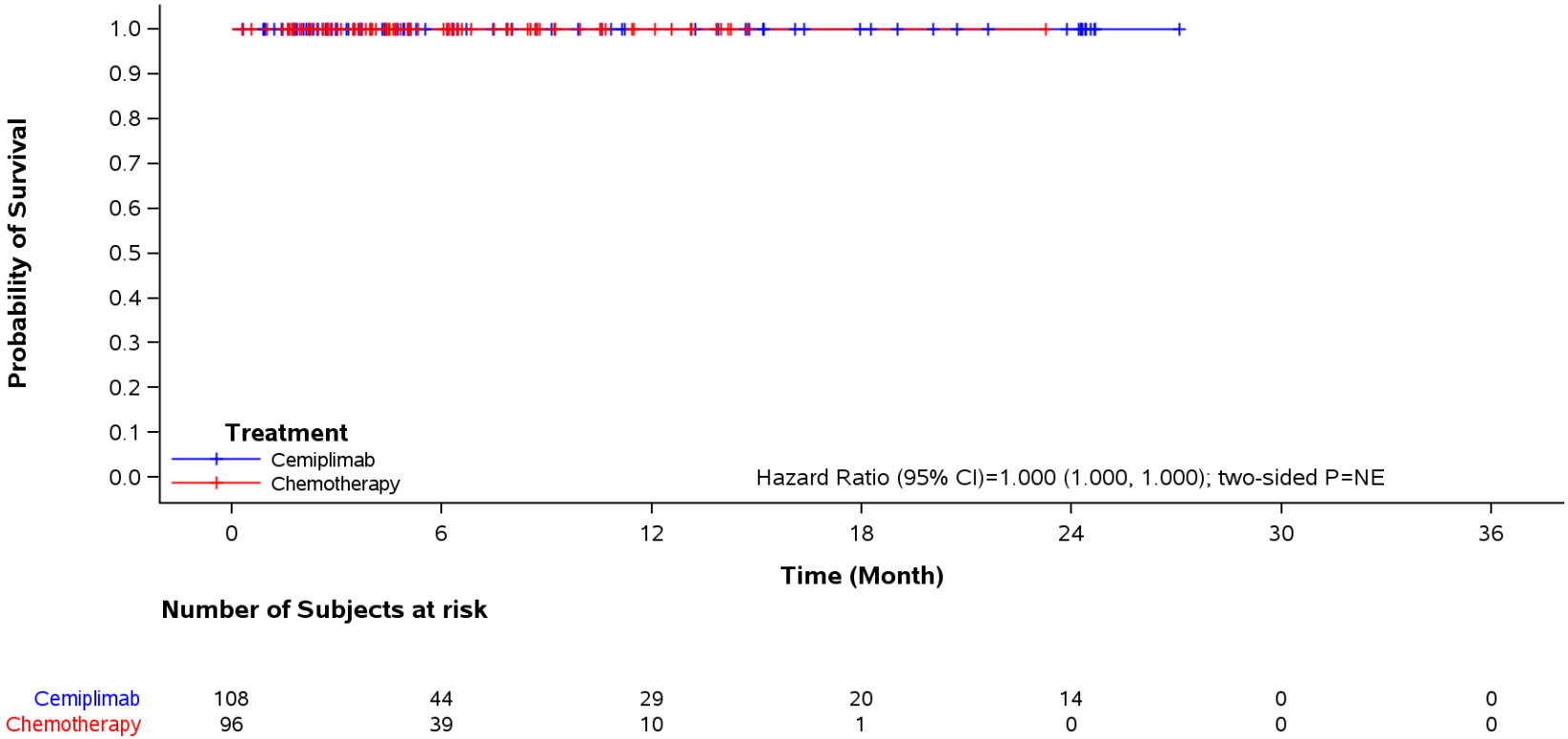

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

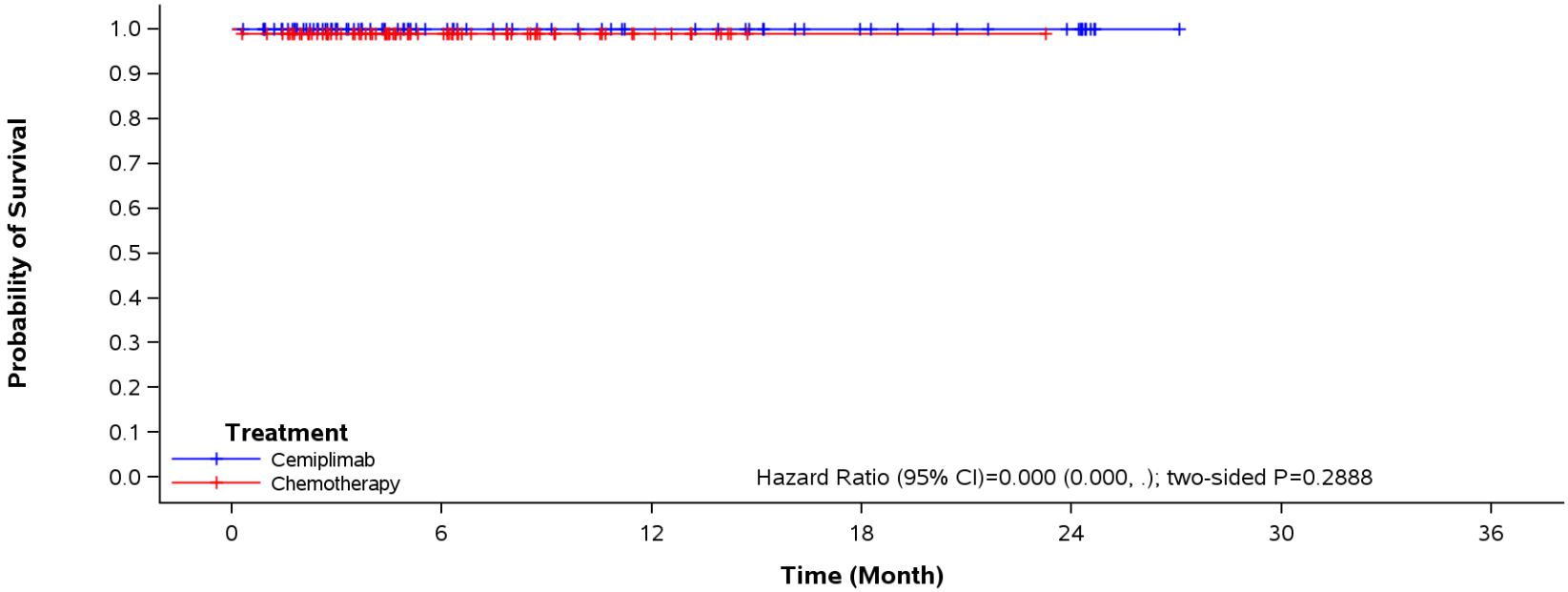
Prior Bevacizumab use: No
SOC: Investigations
PT: Platelet count decreased




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Metabolism and nutrition disorders



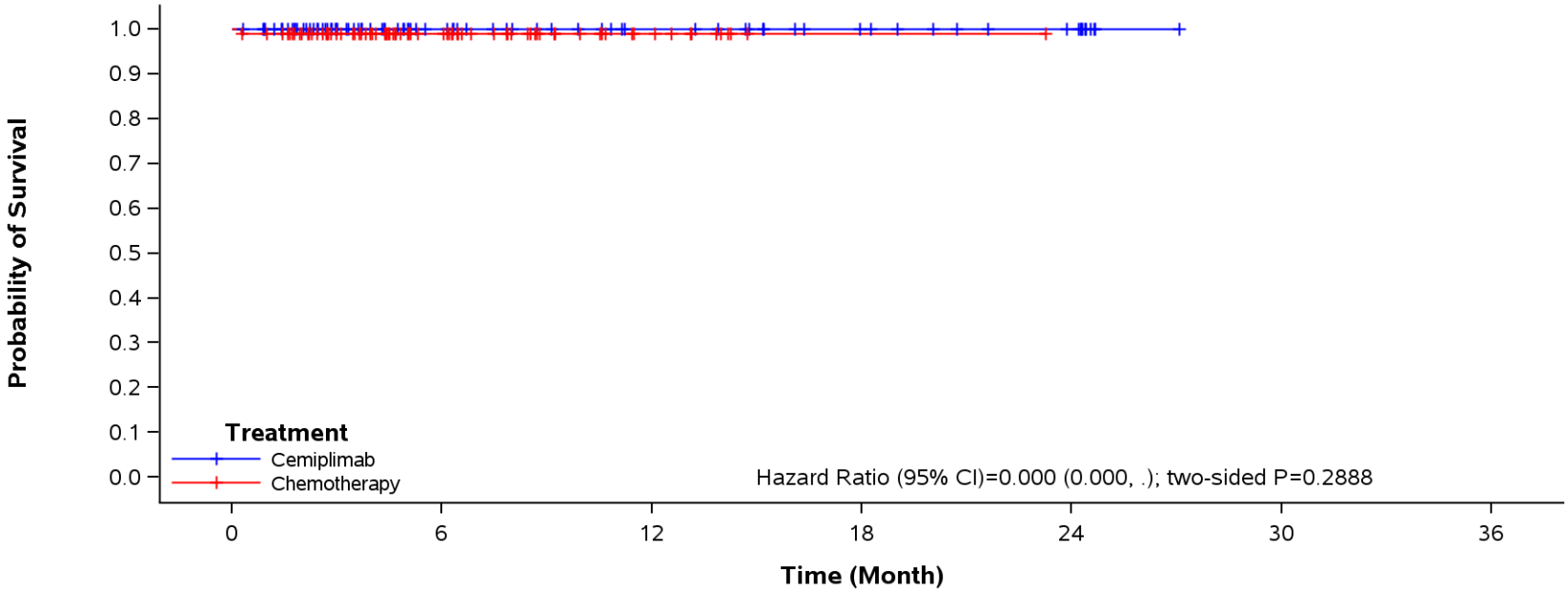

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Metabolism and nutrition disorders
PT: Decreased appetite




**Number of Subjects at risk**

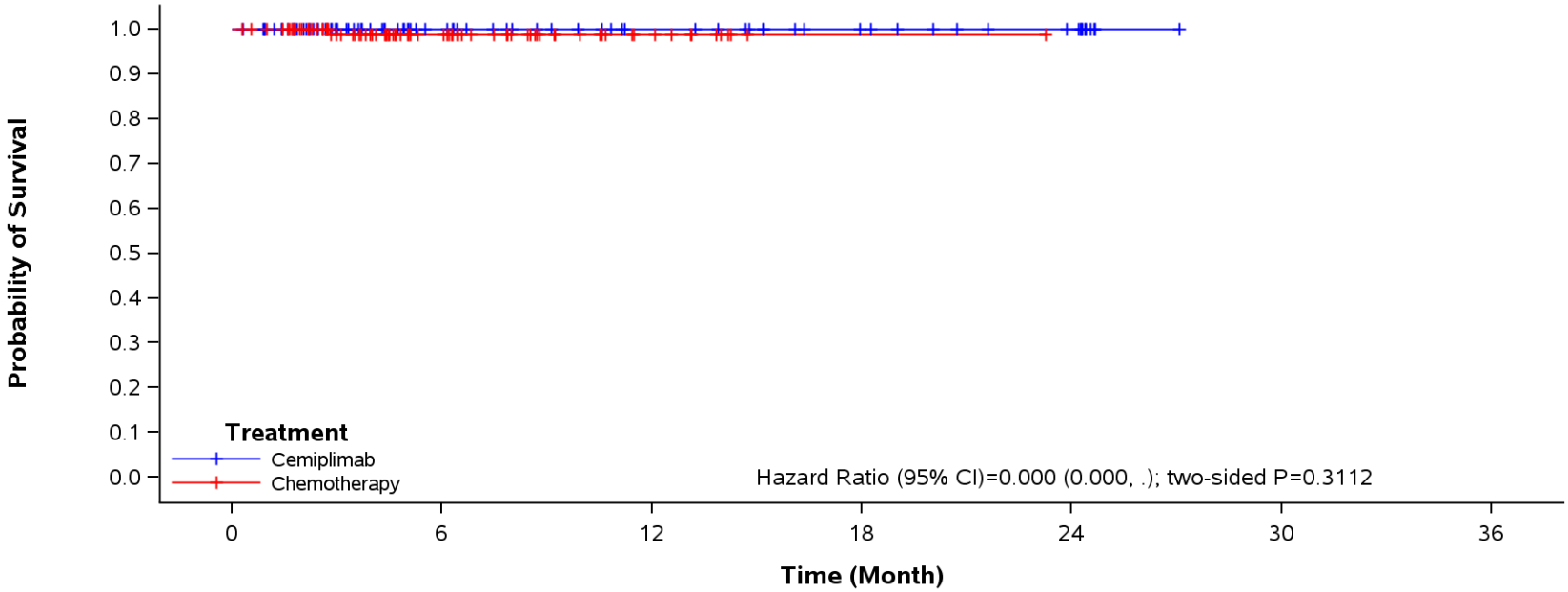
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

SOC: Musculoskeletal and connective tissue disorders




**Number of Subjects at risk**

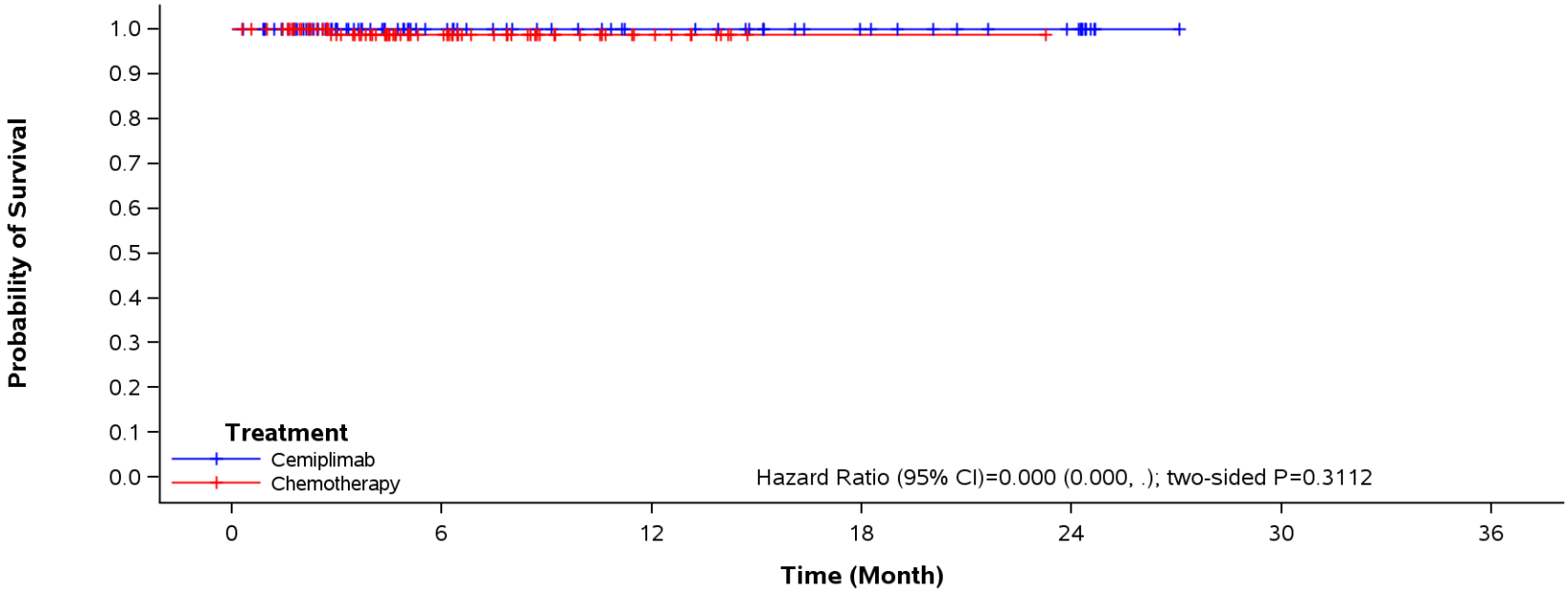
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 38 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



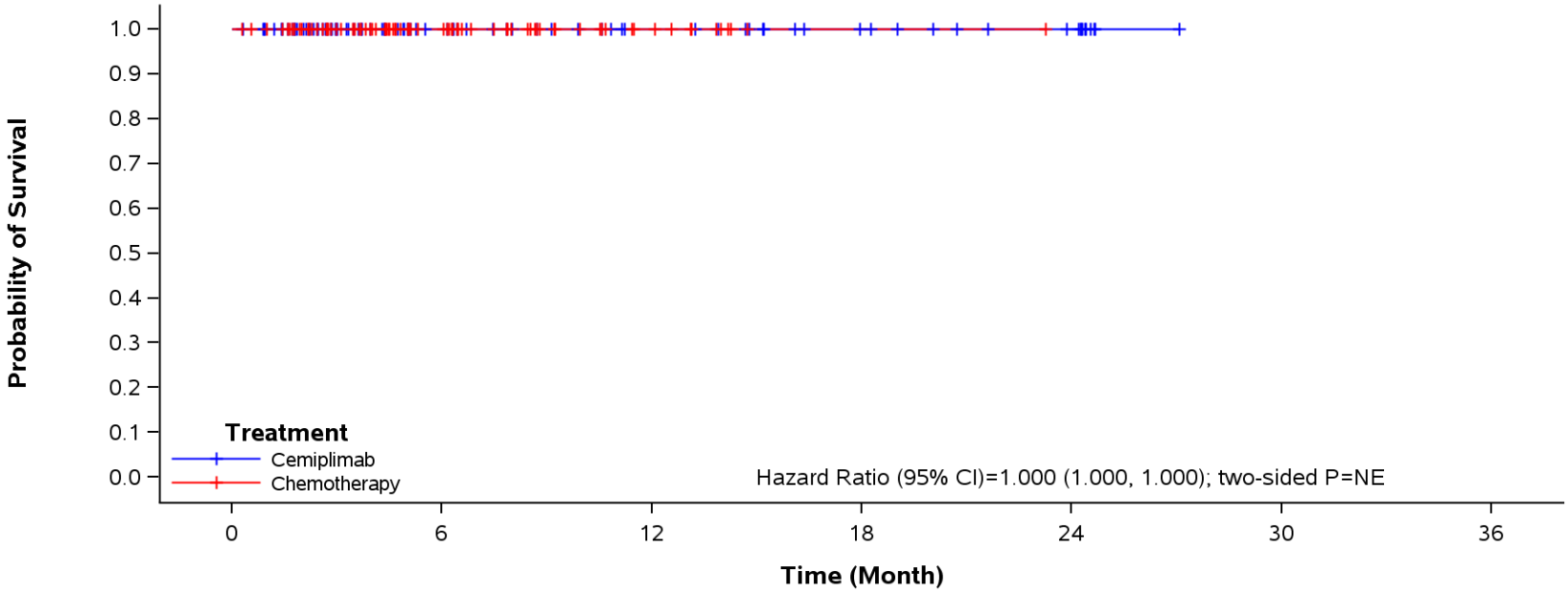

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 38 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



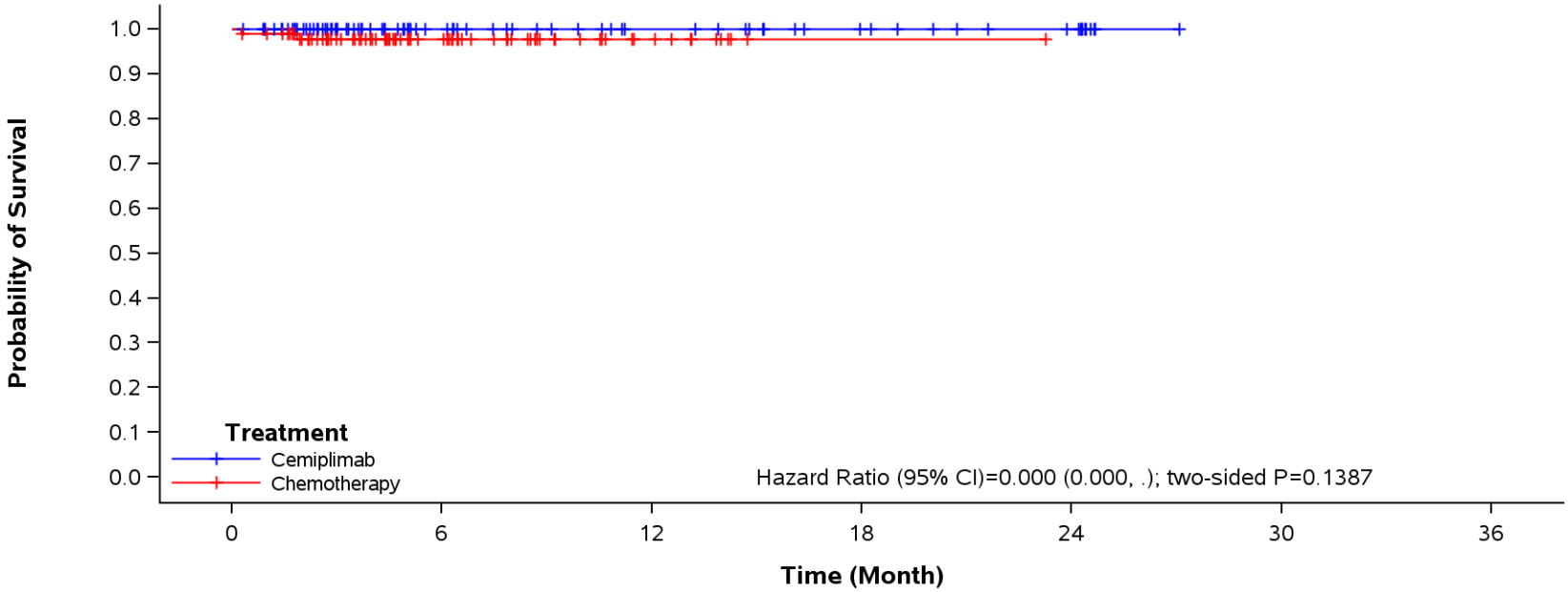

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Nervous system disorders



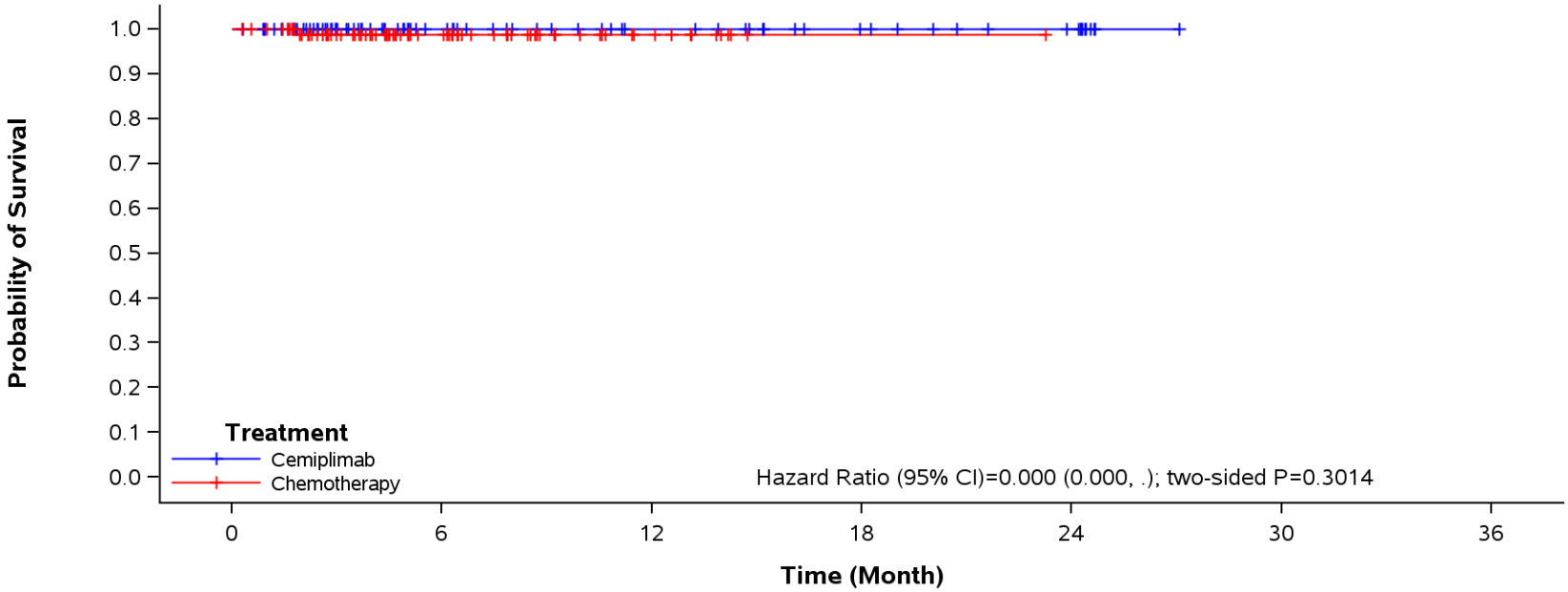

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Nervous system disorders
PT: Neurotoxicity



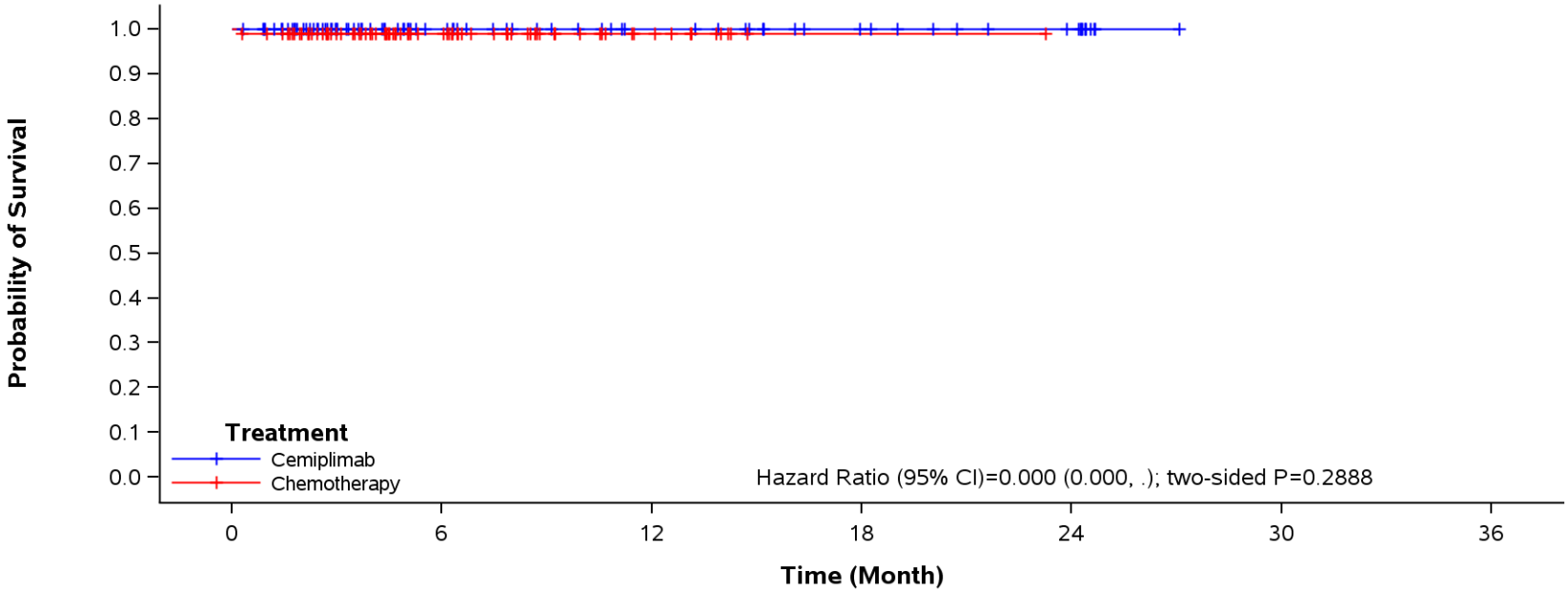

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Nervous system disorders
PT: Transient ischaemic attack



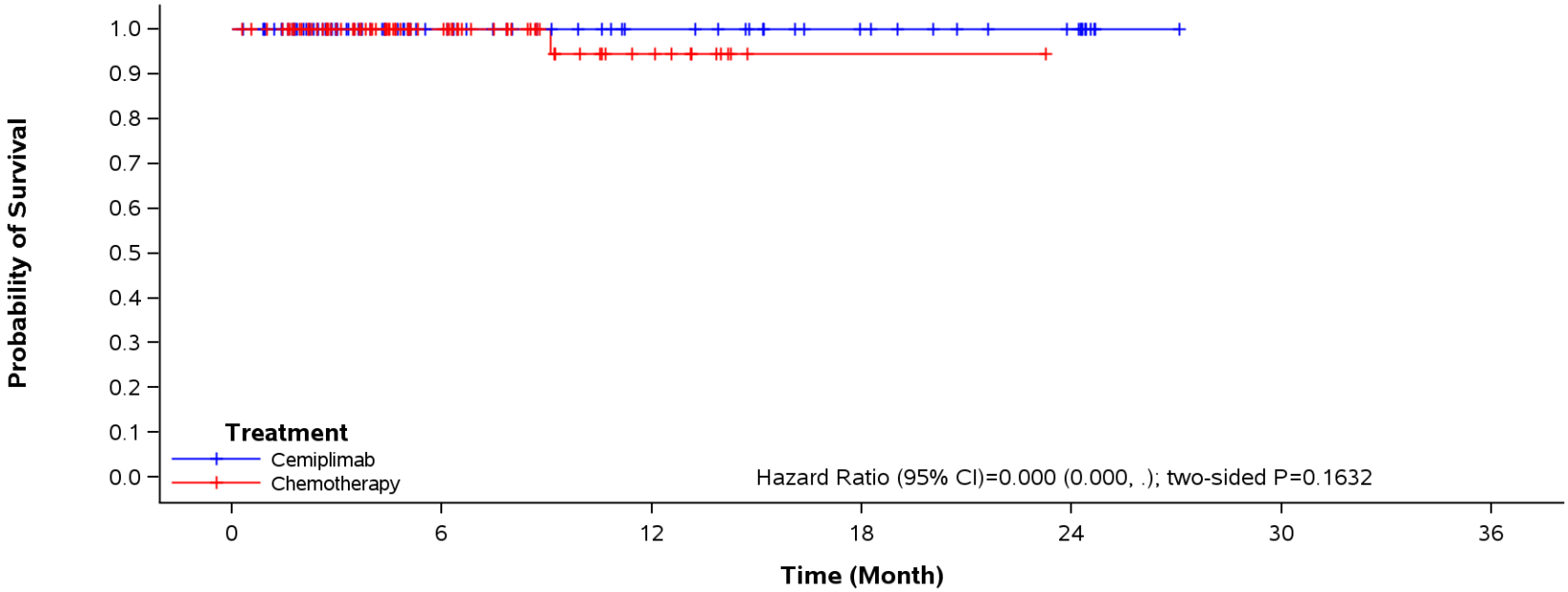

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Psychiatric disorders



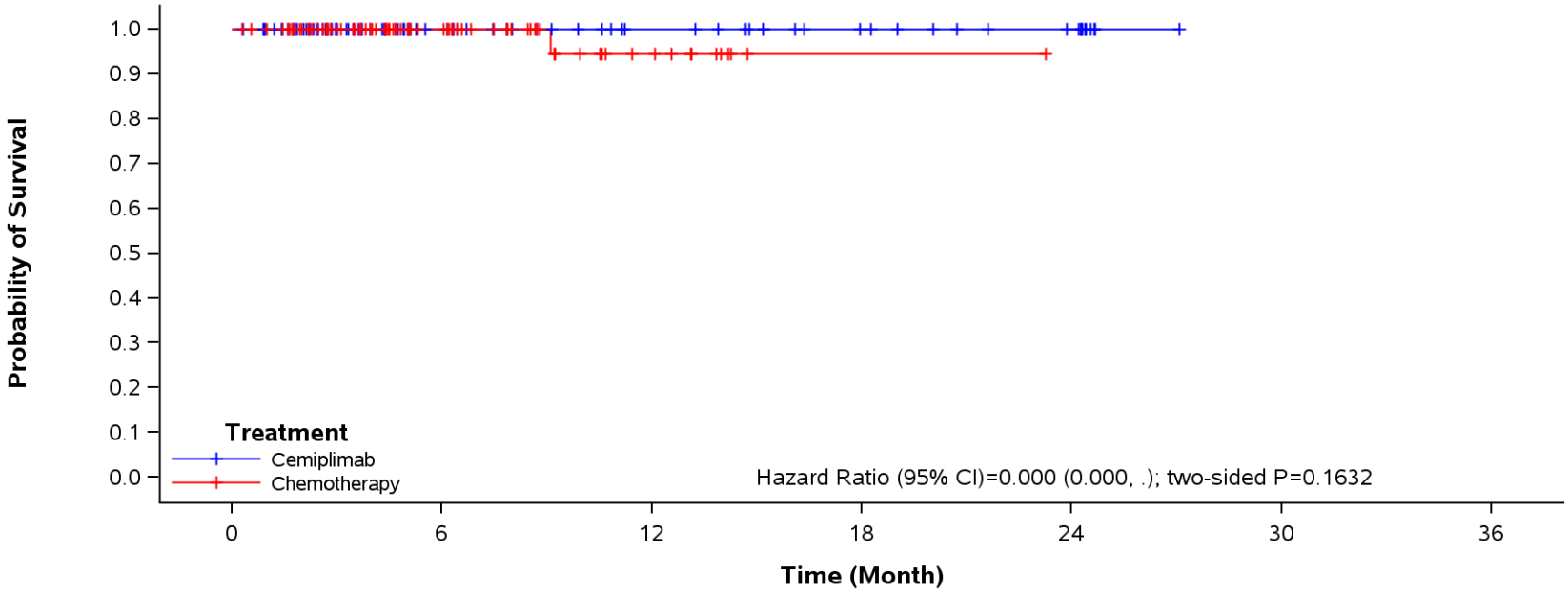

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Psychiatric disorders
PT: Agoraphobia



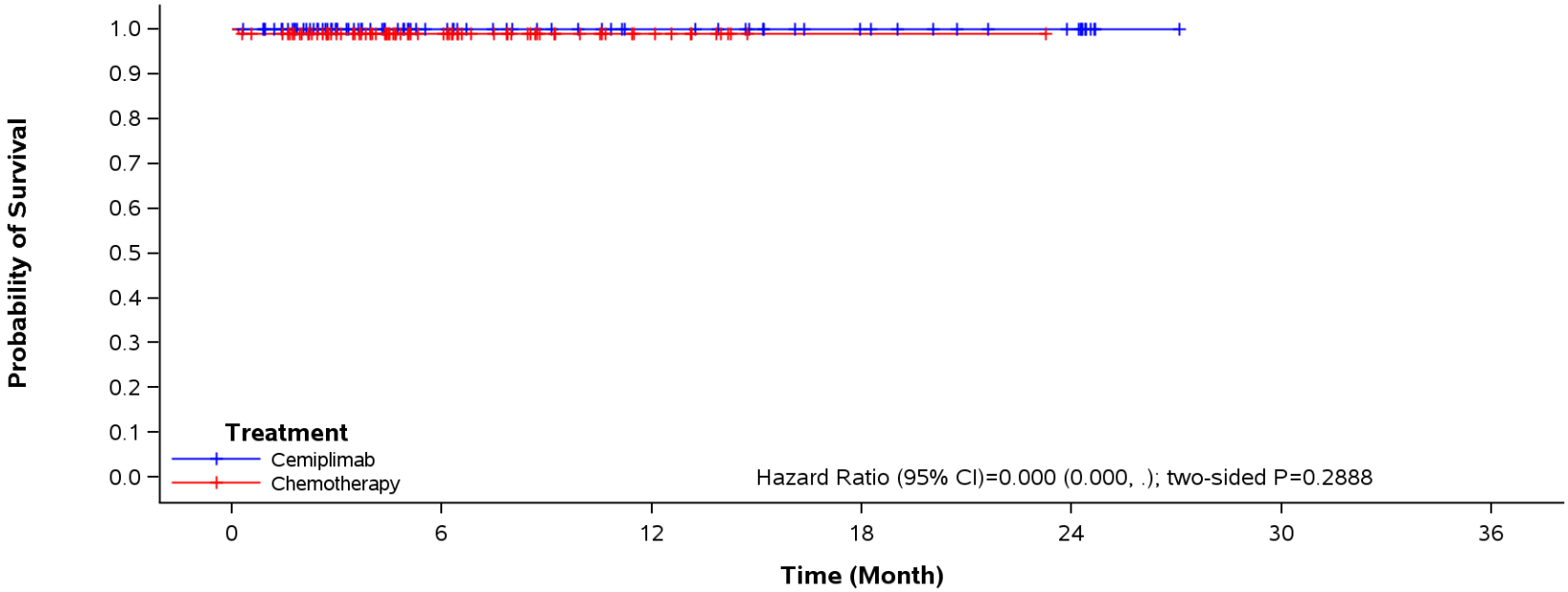

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Renal and urinary disorders



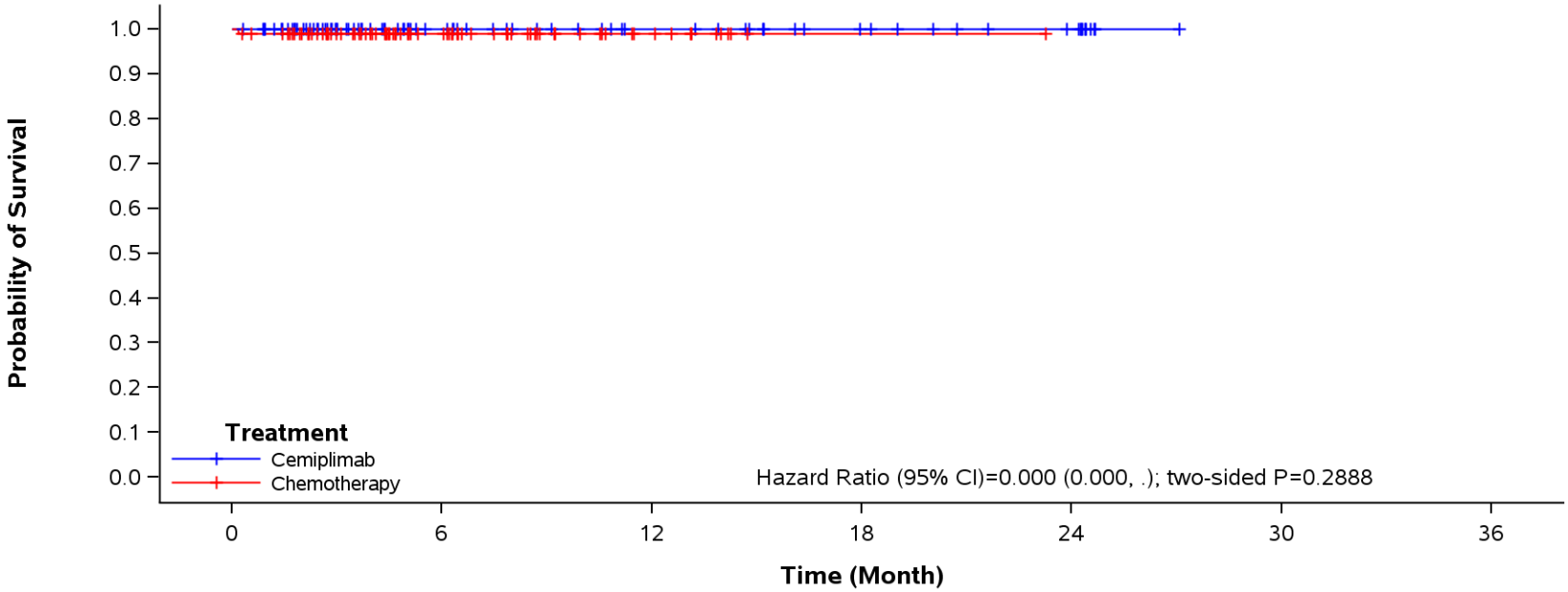

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Renal and urinary disorders
PT: Renal failure




**Number of Subjects at risk**

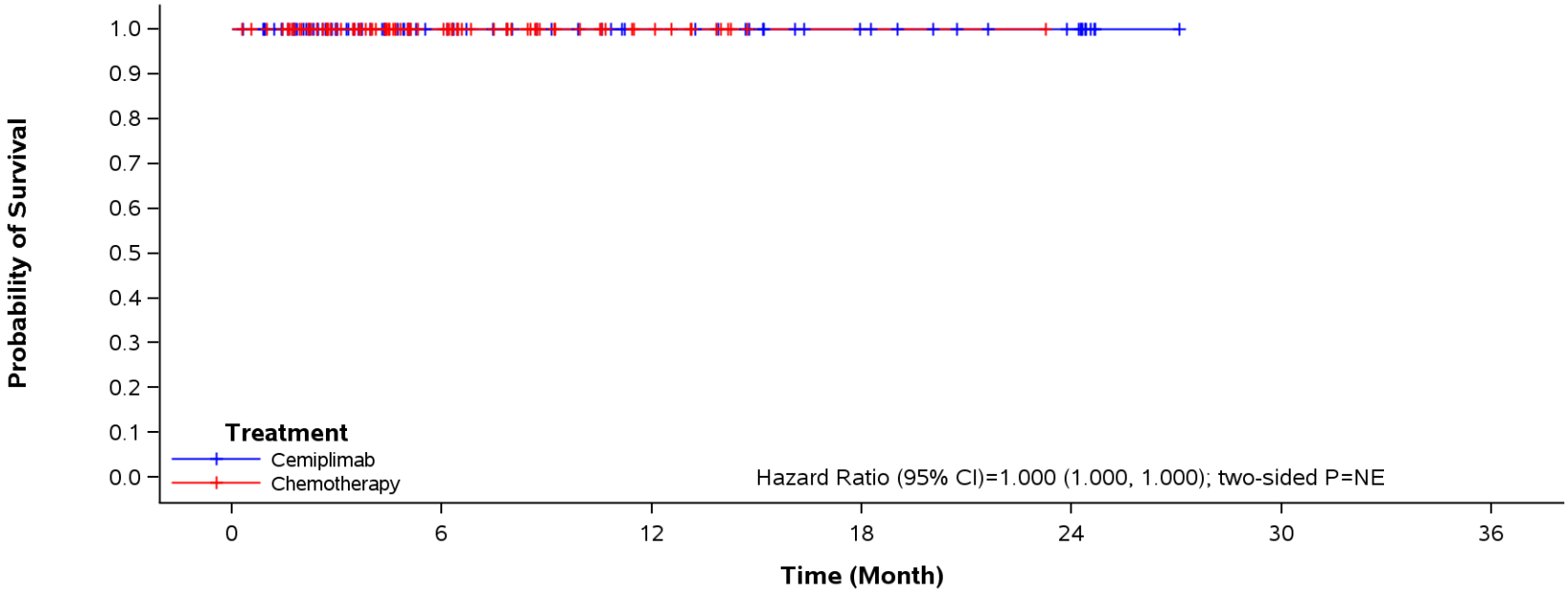
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No

SOC: Respiratory, thoracic and mediastinal disorders




**Number of Subjects at risk**

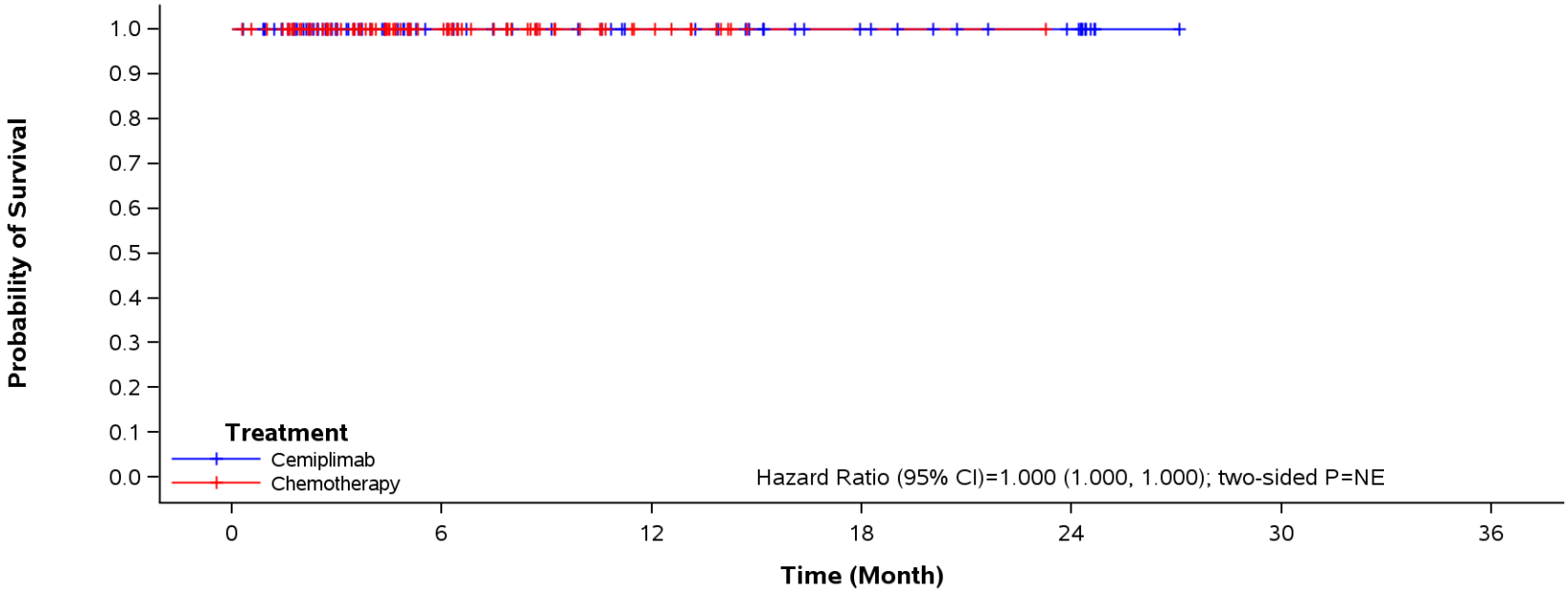
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



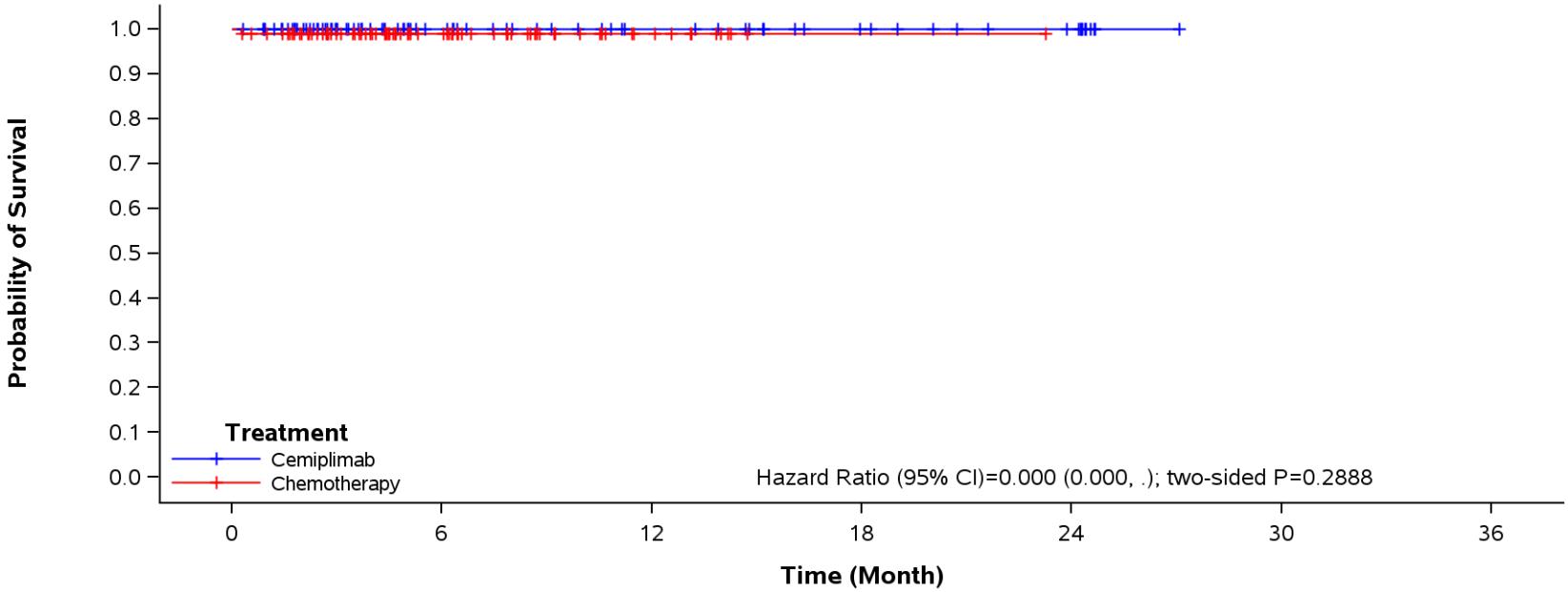

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Vascular disorders



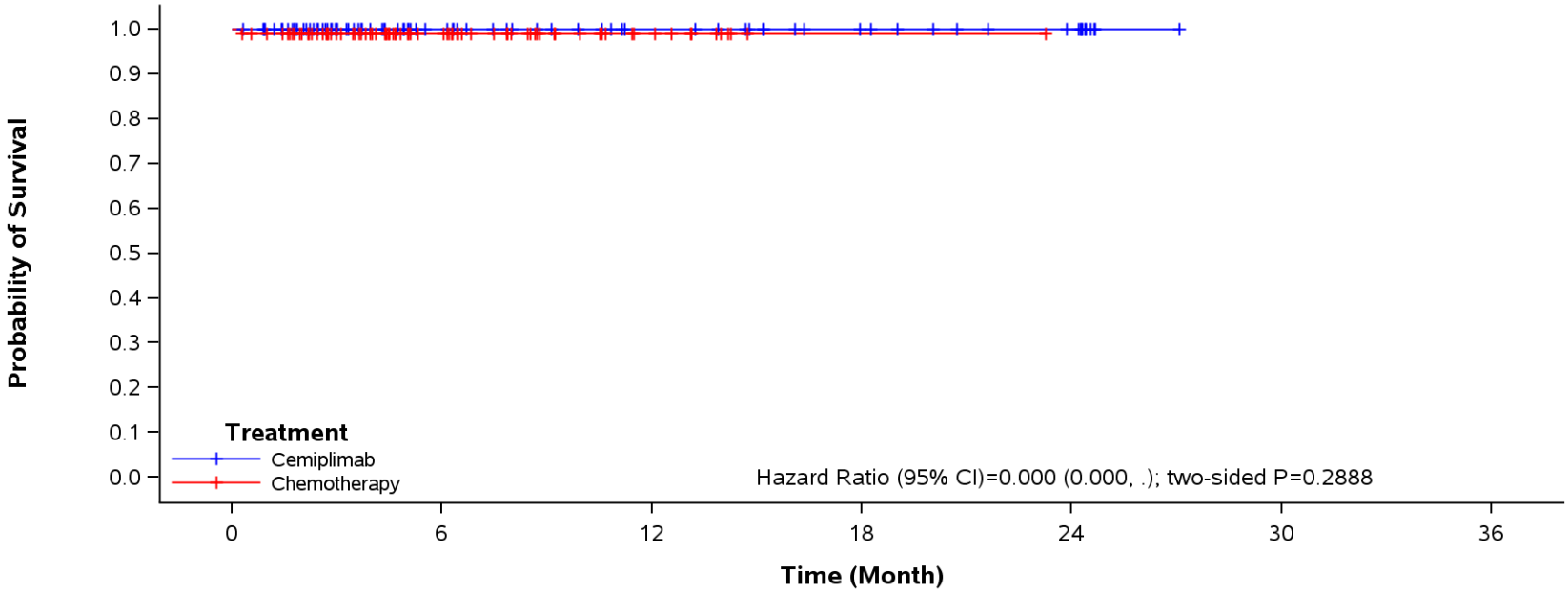

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Prior Bevacizumab use: No
SOC: Vascular disorders
PT: Deep vein thrombosis




**Number of Subjects at risk**

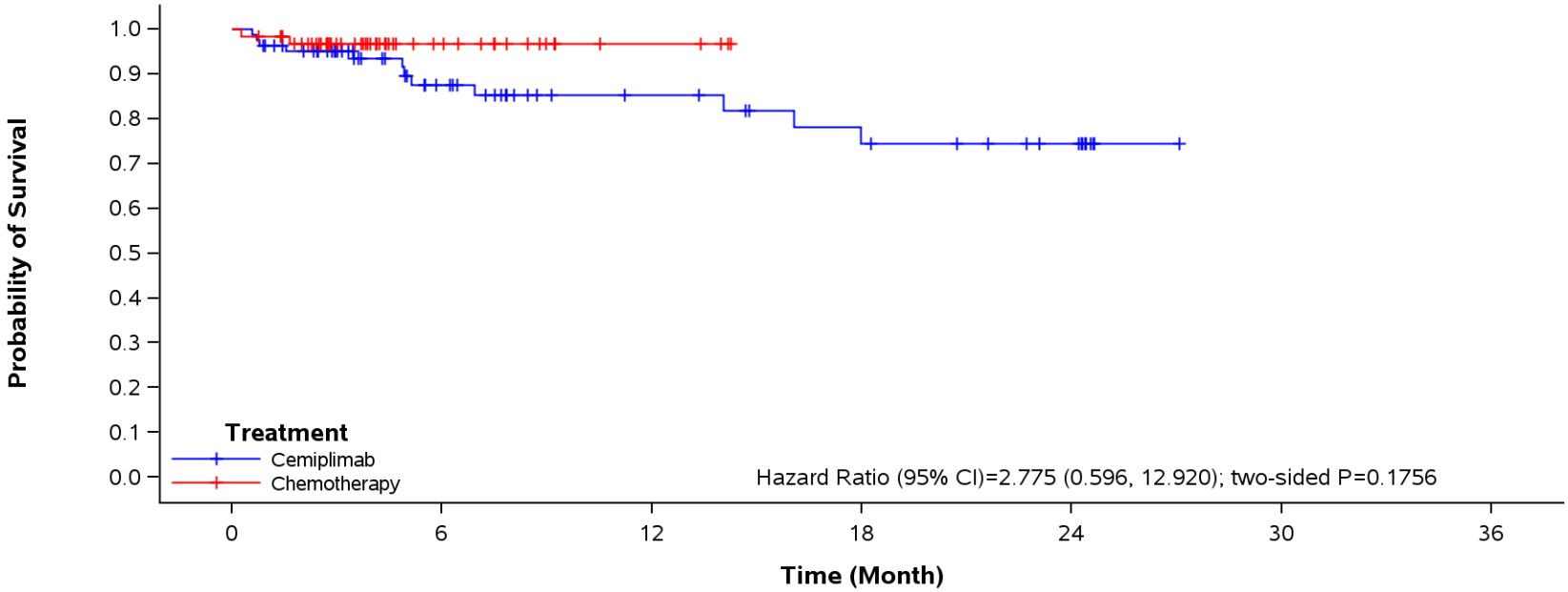
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 108 | 44 | 29 | 20 | 14 | 0 | 0 |
| Chemotherapy | 96 | 39 | 10 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

Number of patients with any TEAE leading to discontinuation




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 40 | 26 | 20 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

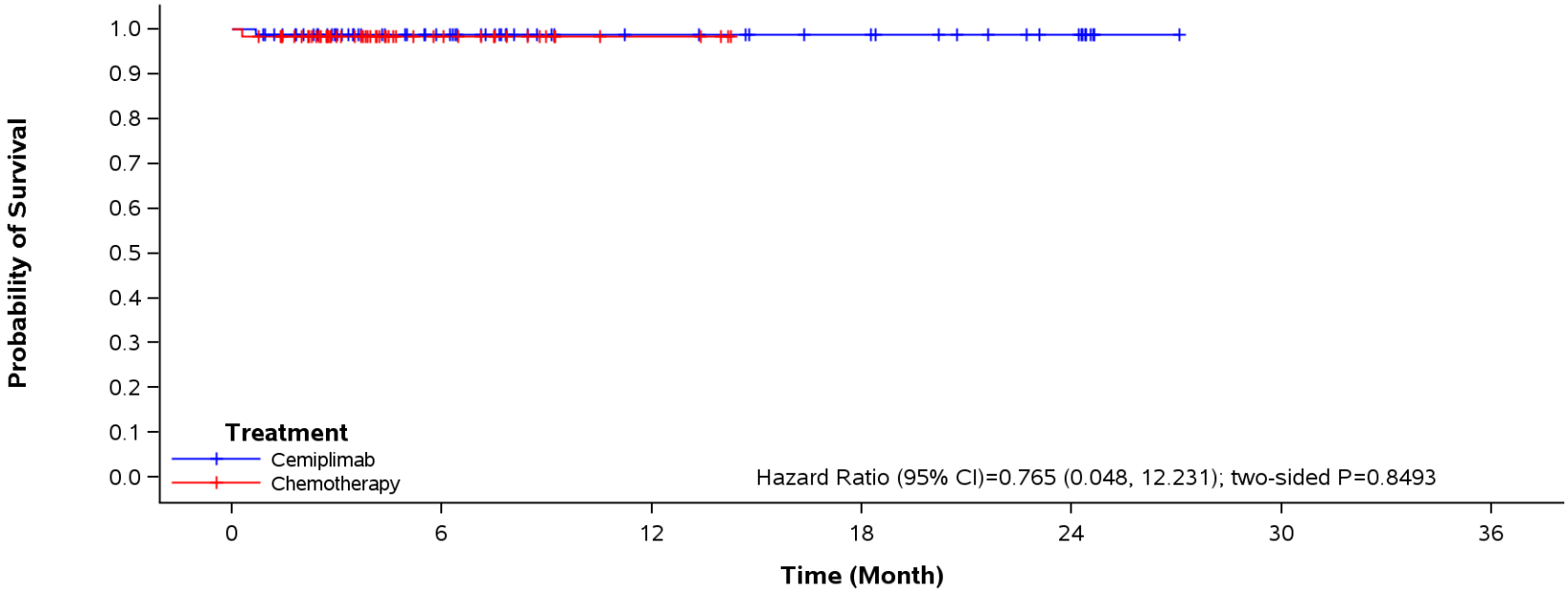
Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

SOC: Blood and lymphatic system disorders




Number of Subjects at risk

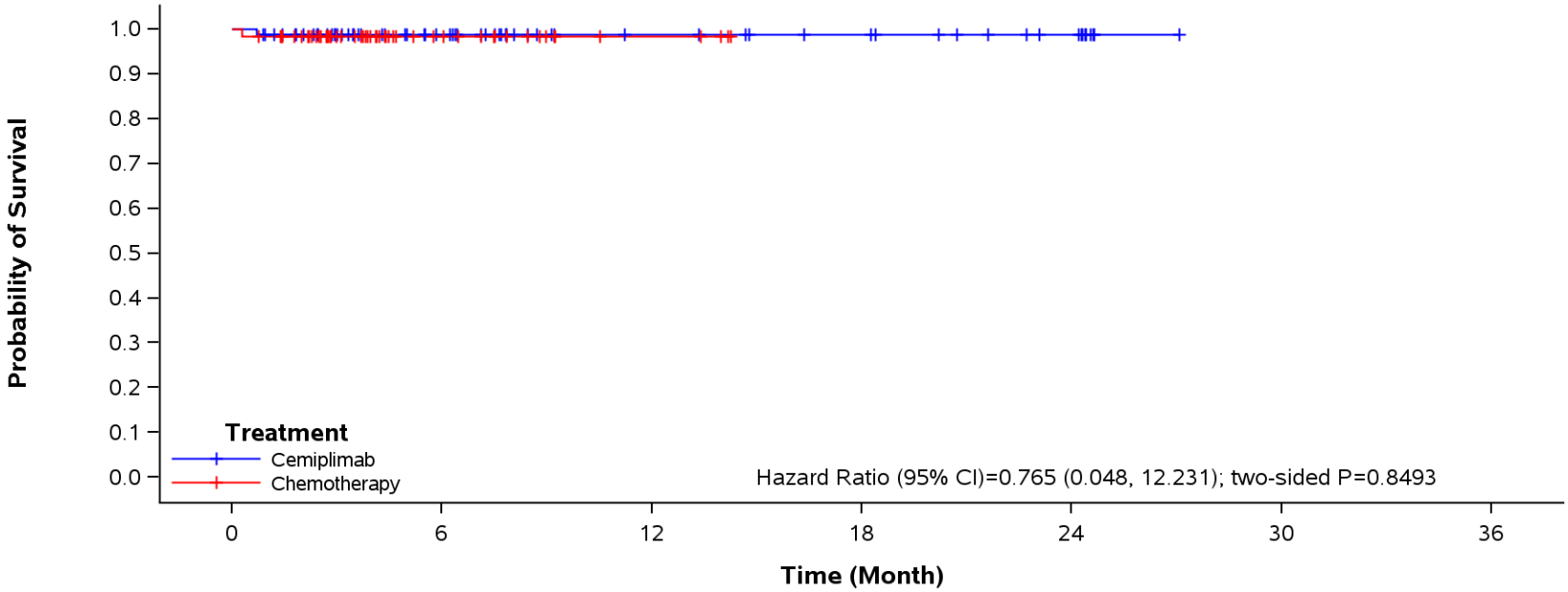
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Anaemia



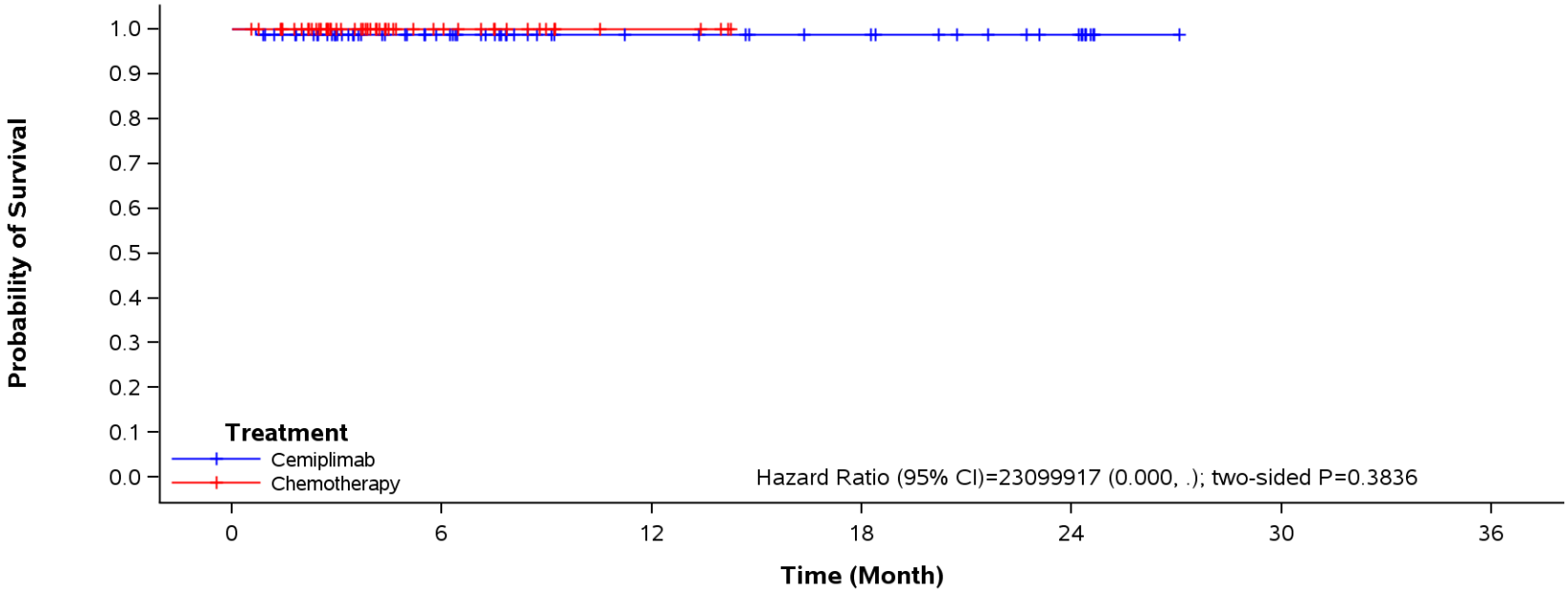

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



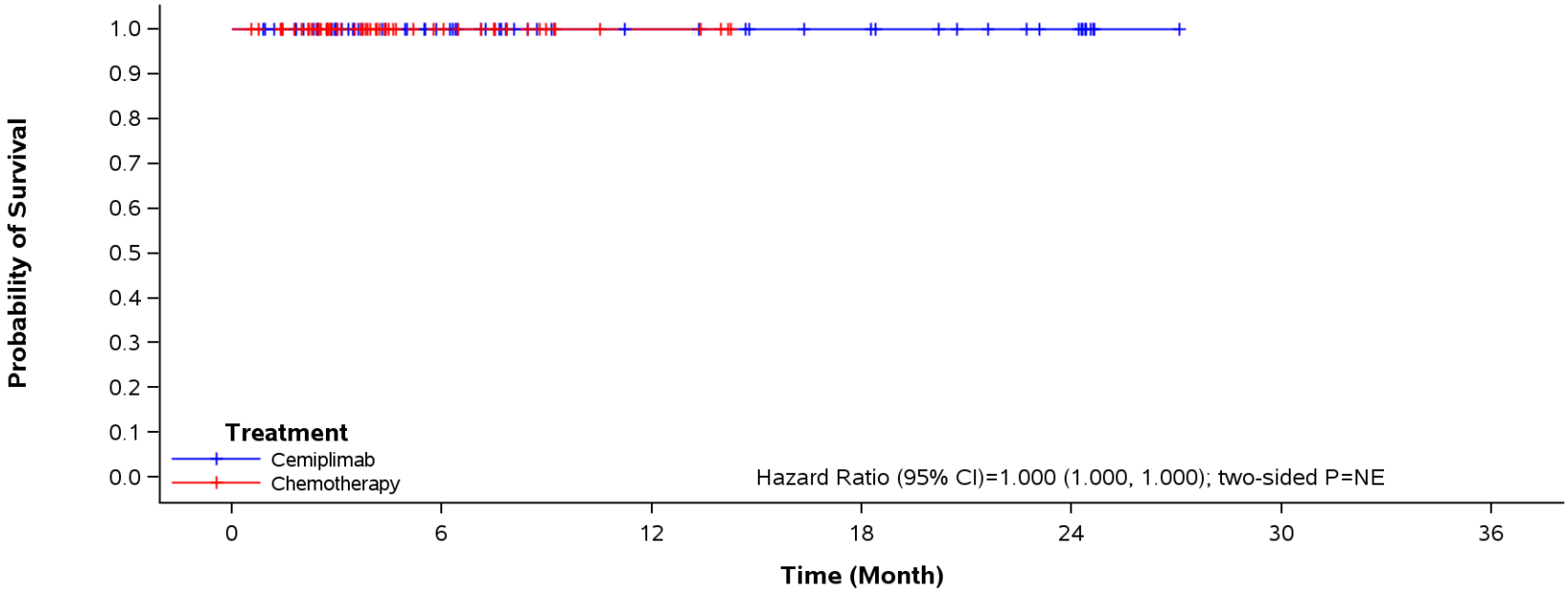

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Neutropenia



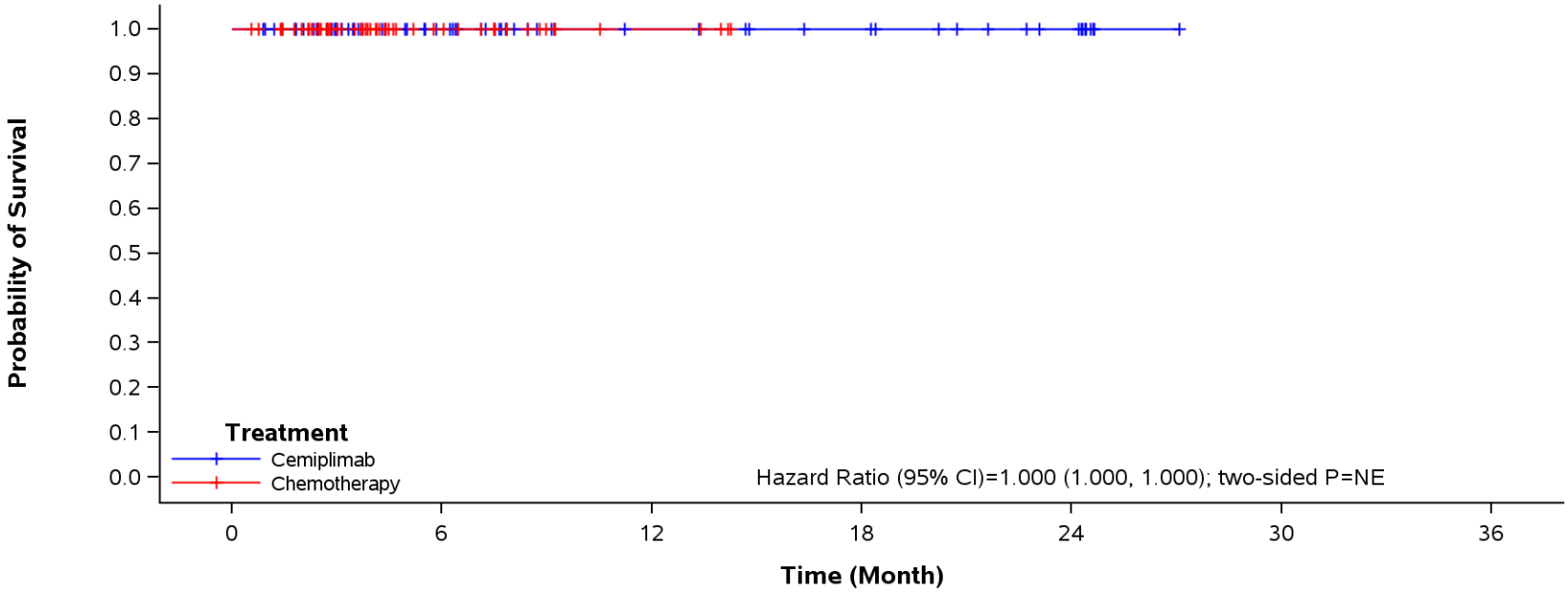

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



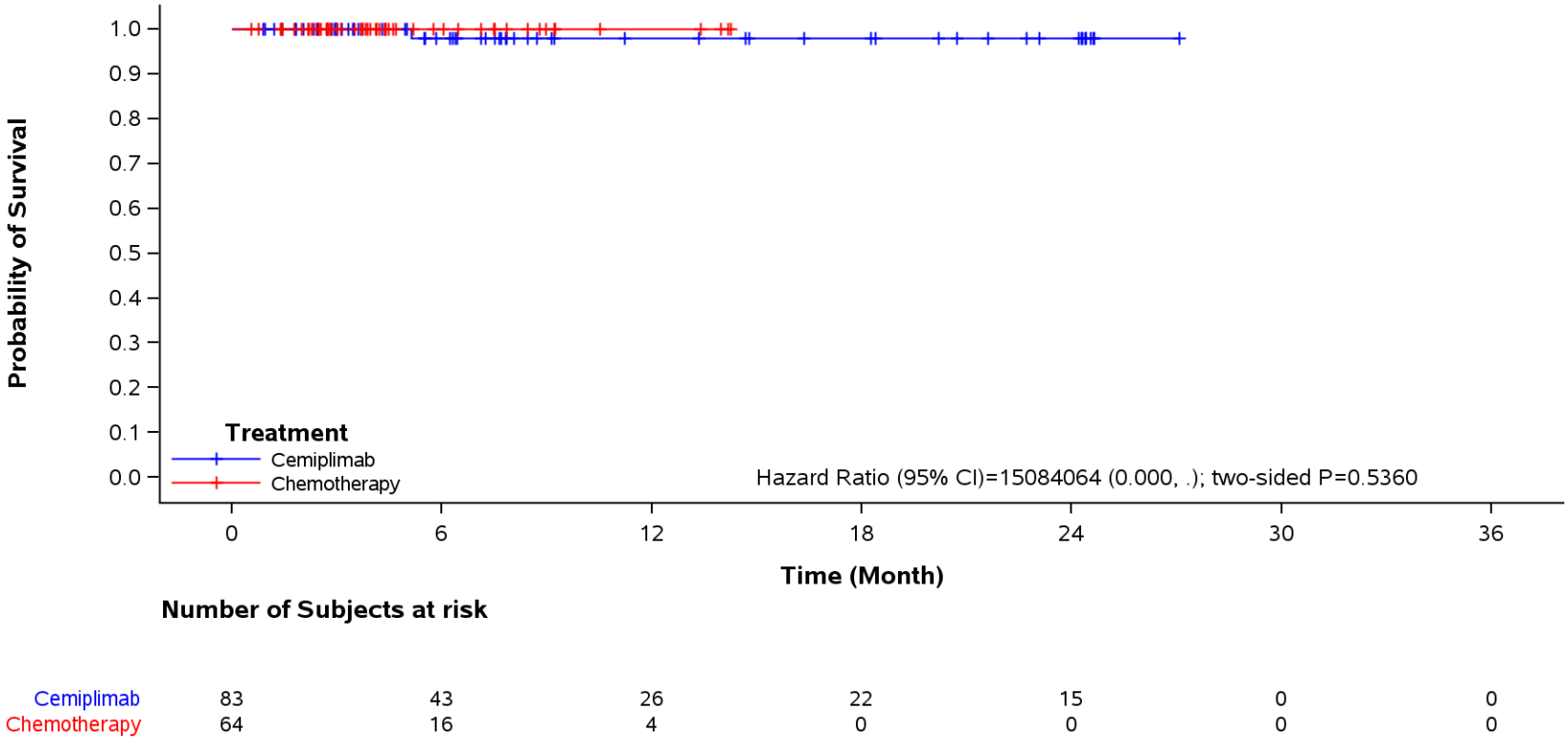

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

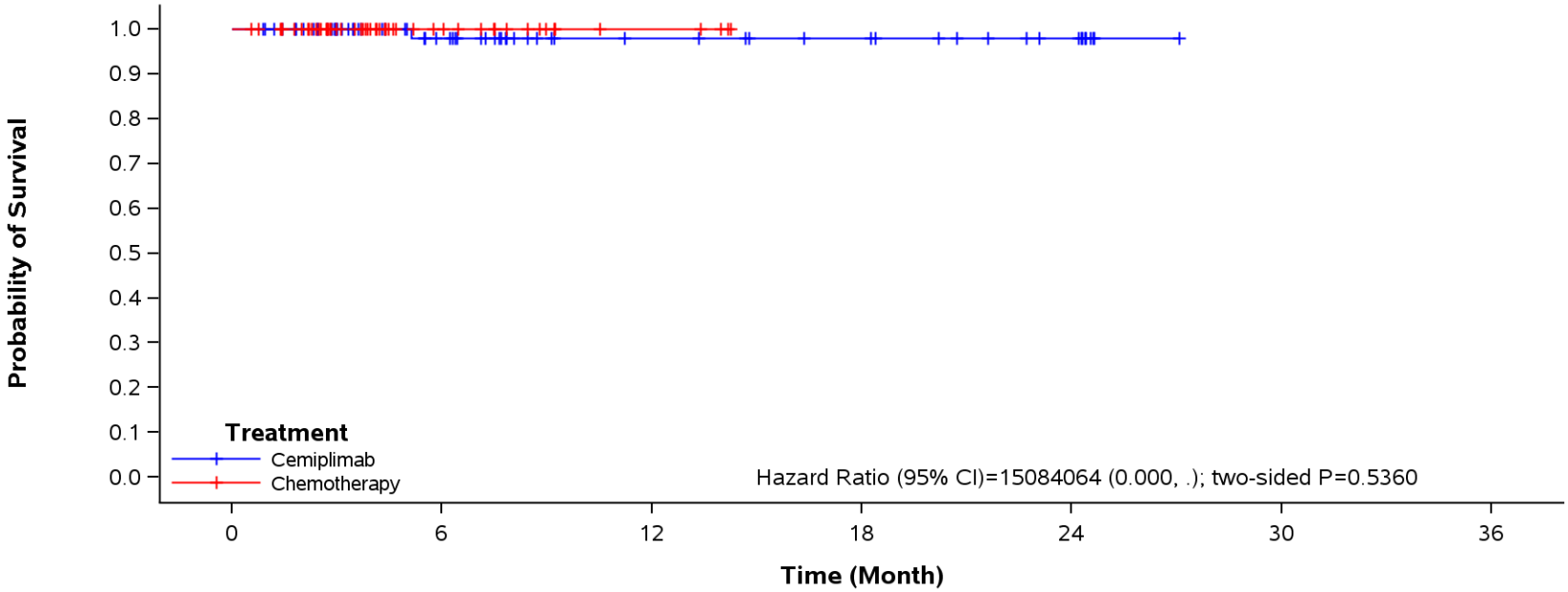
Baseline ECOG Status: 0
SOC: Cardiac disorders




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Cardiac disorders
PT: Autoimmune pericarditis



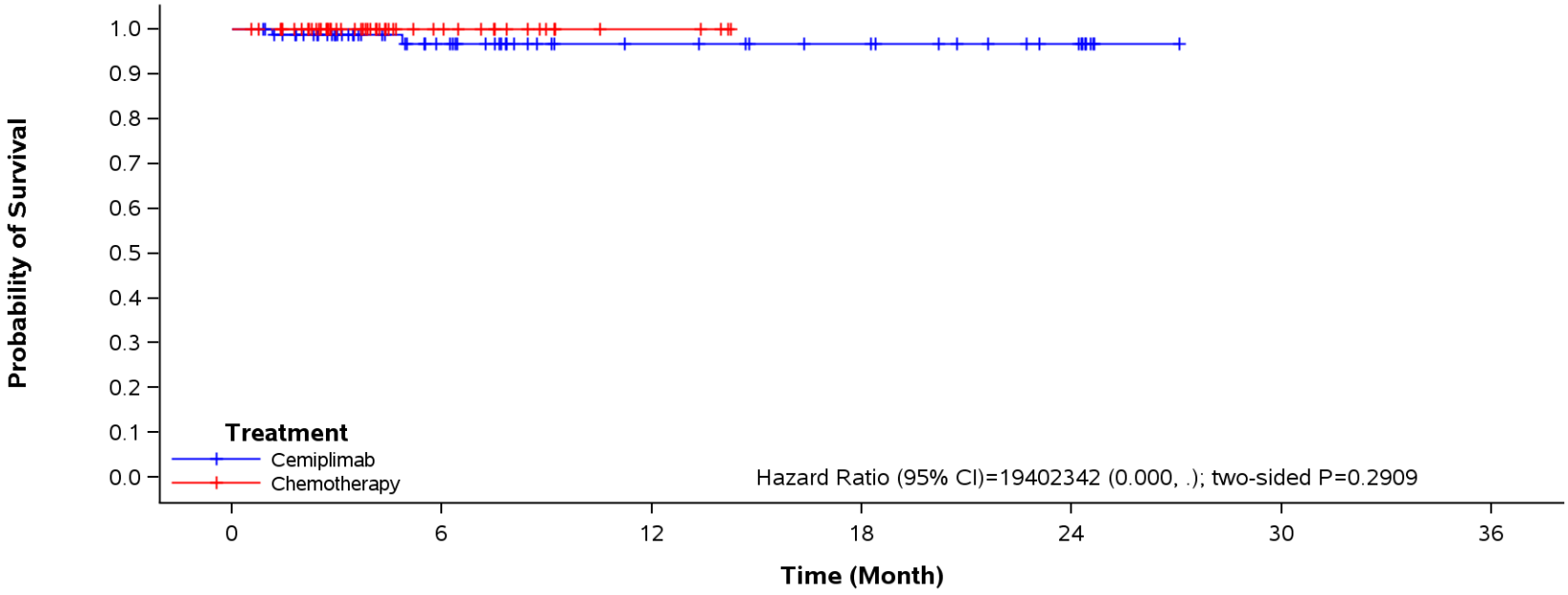

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 43 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Endocrine disorders



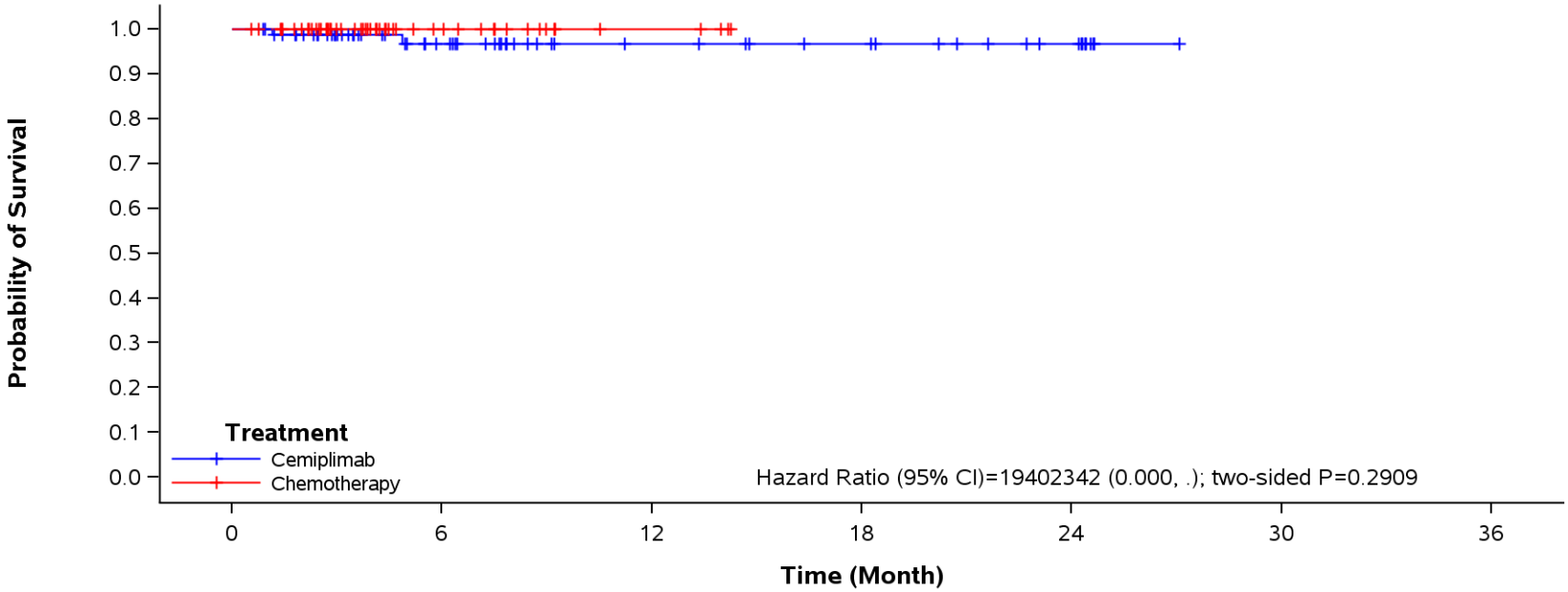

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 43 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Endocrine disorders
PT: Hypothyroidism



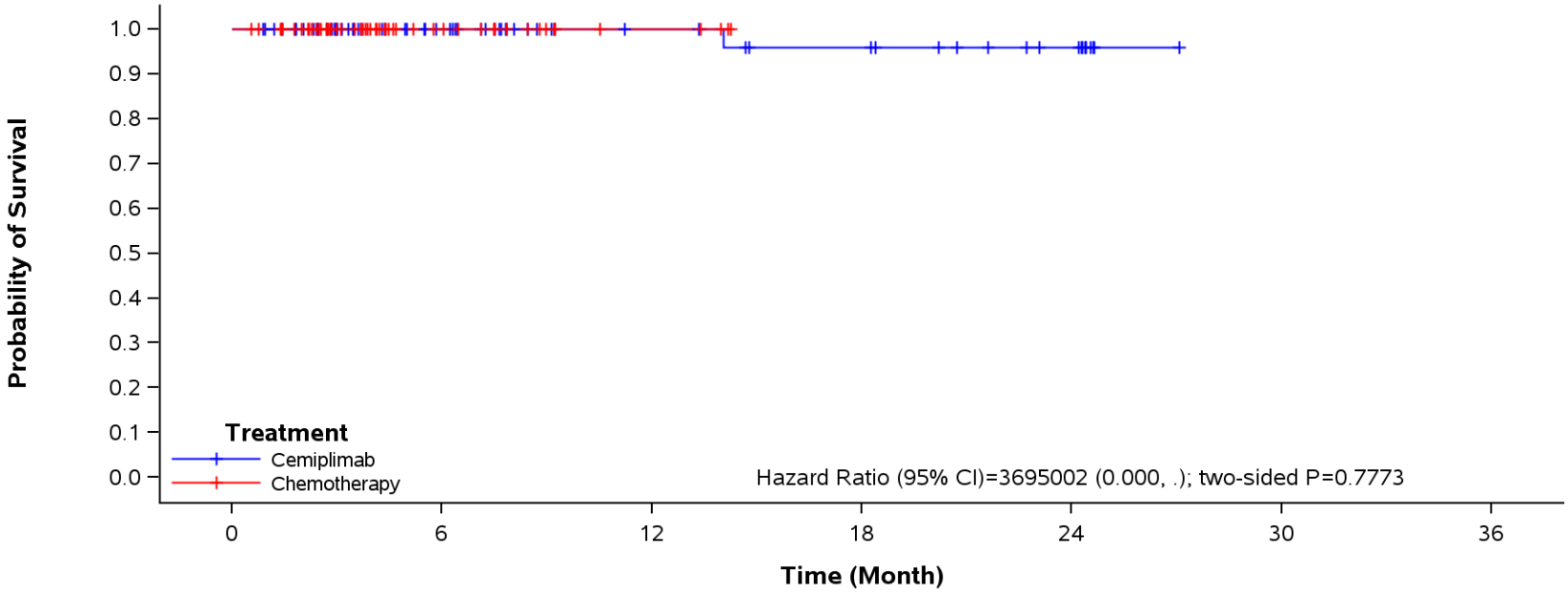

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 43 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders



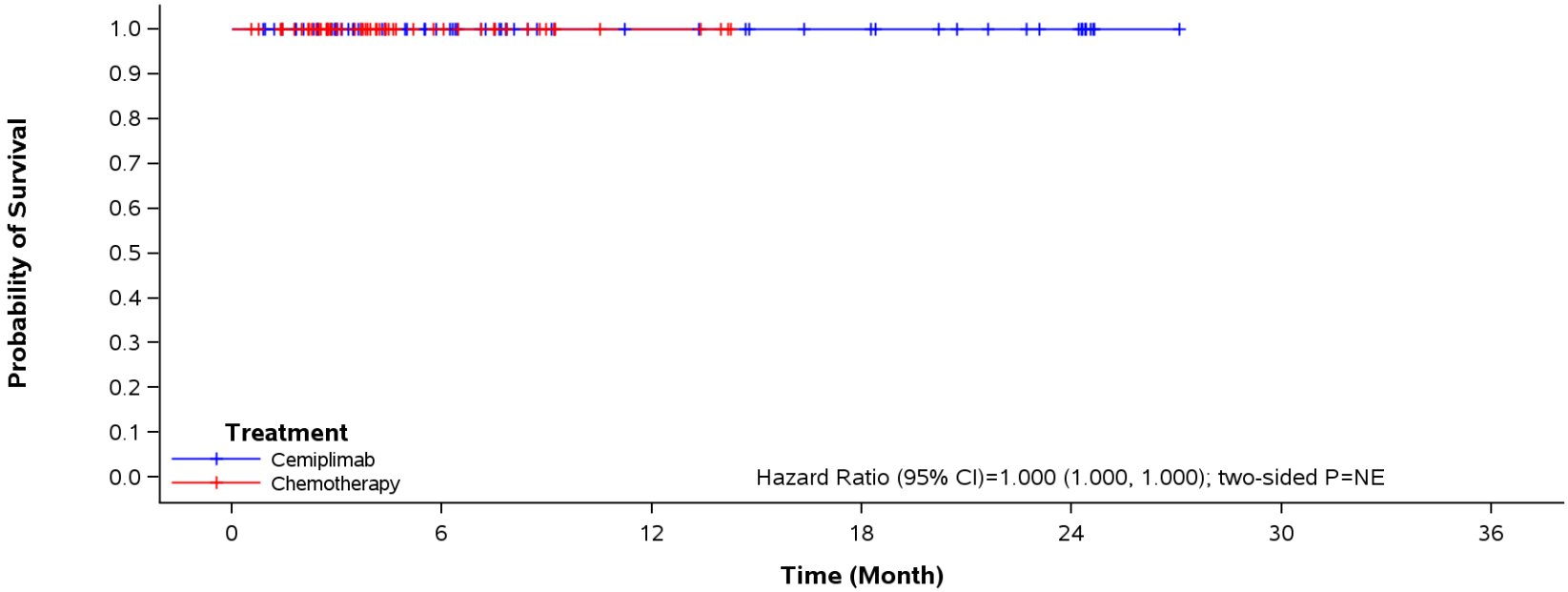

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders
PT: Colitis



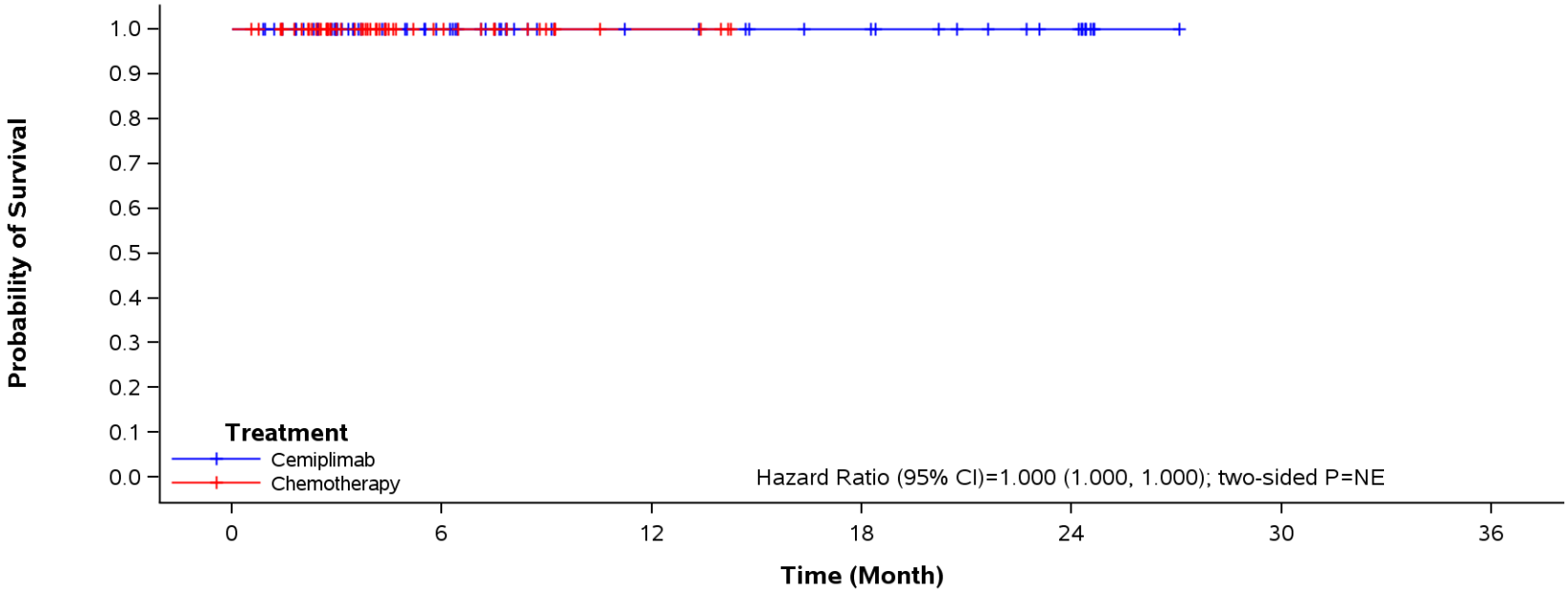

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders
PT: Diverticular perforation



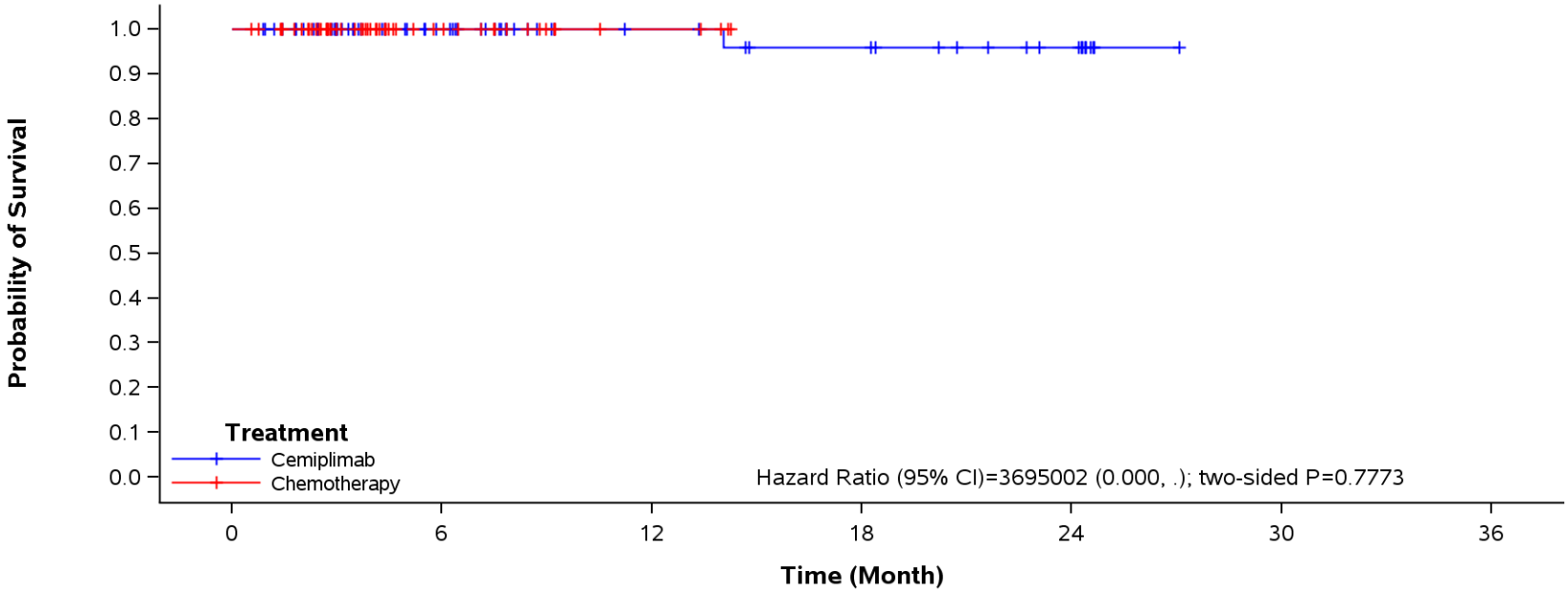

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders
PT: Pancreatic mass



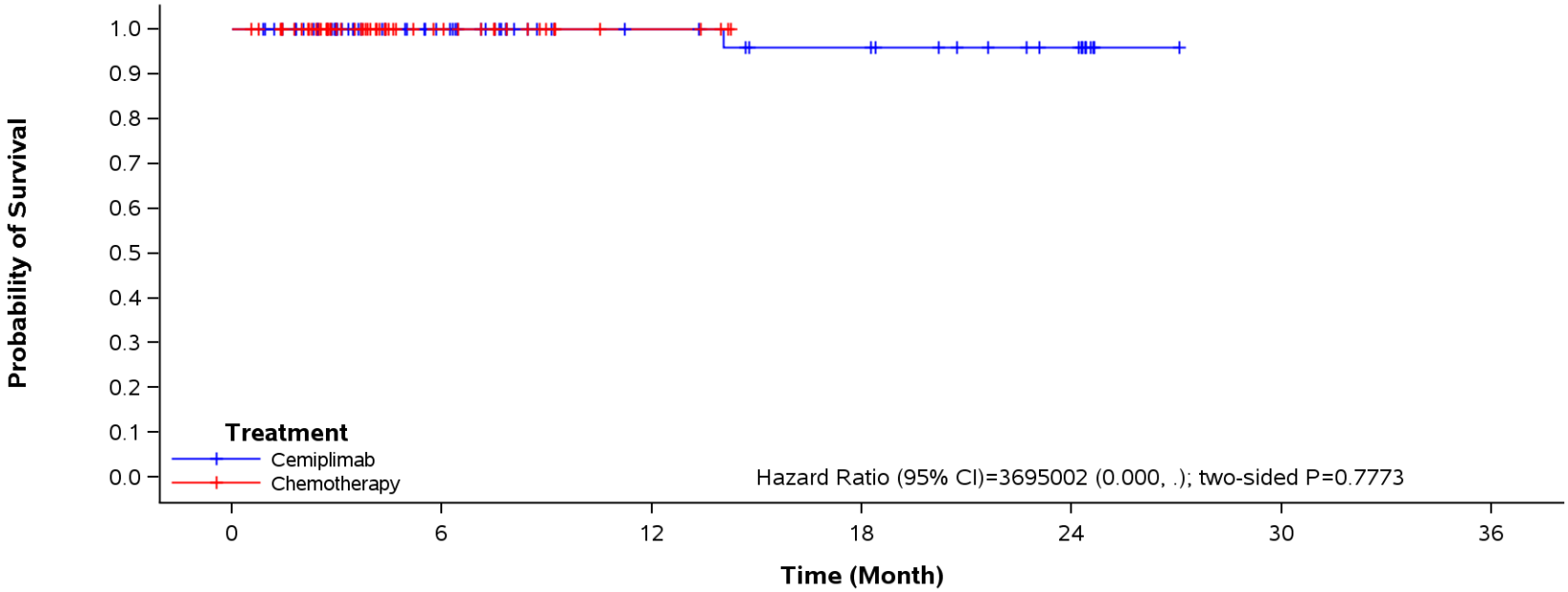

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



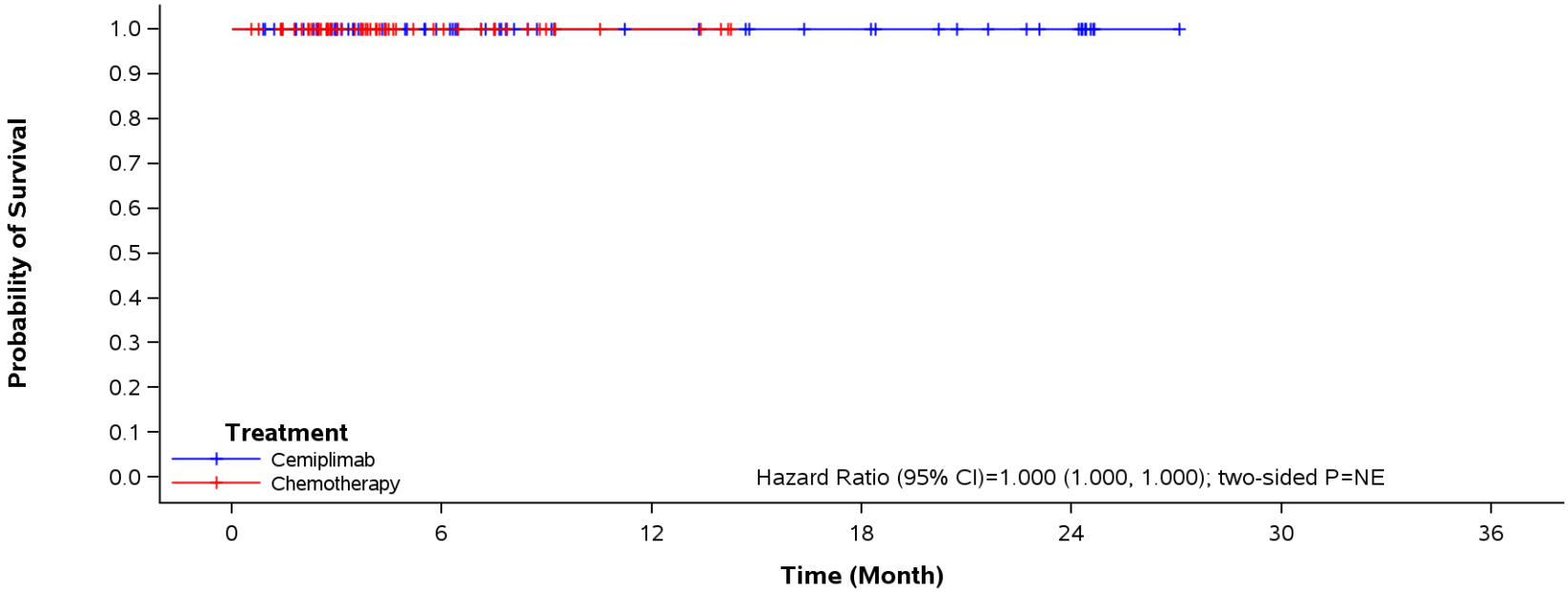

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Gastrointestinal disorders
PT: Proctalgia




**Number of Subjects at risk**

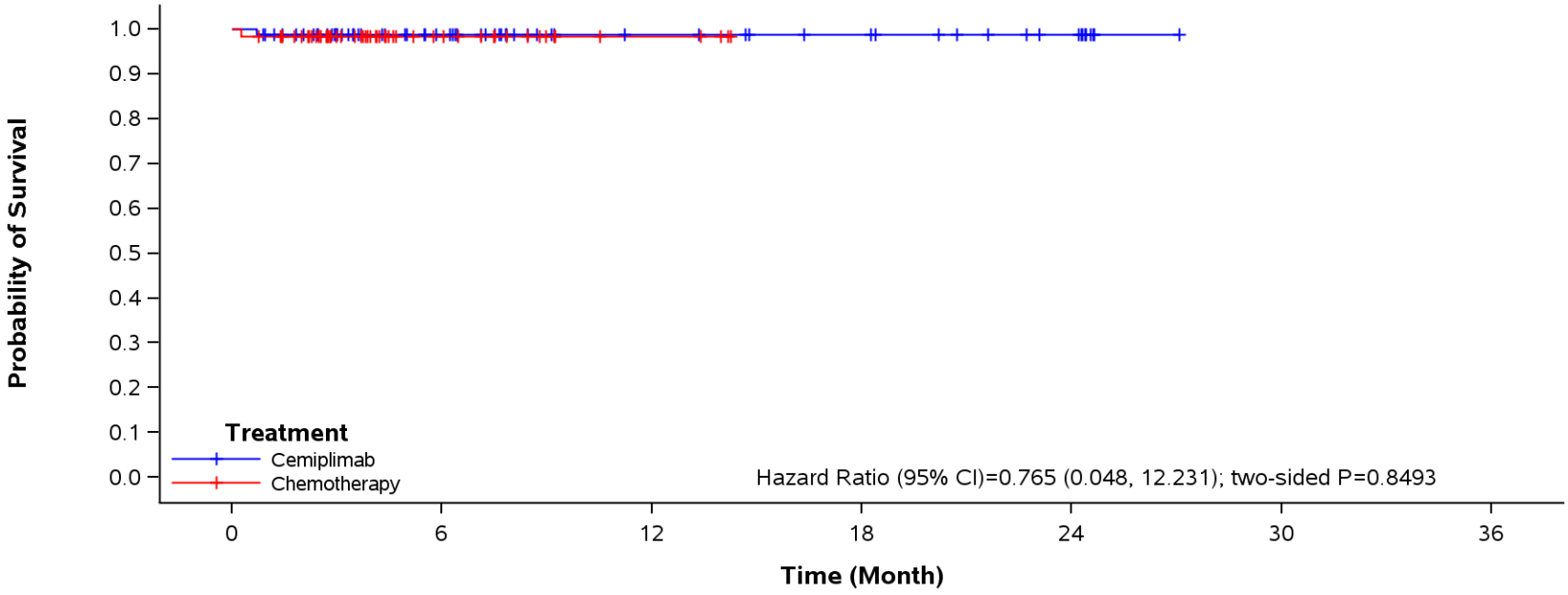
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

SOC: General disorders and administration site conditions




Number of Subjects at risk

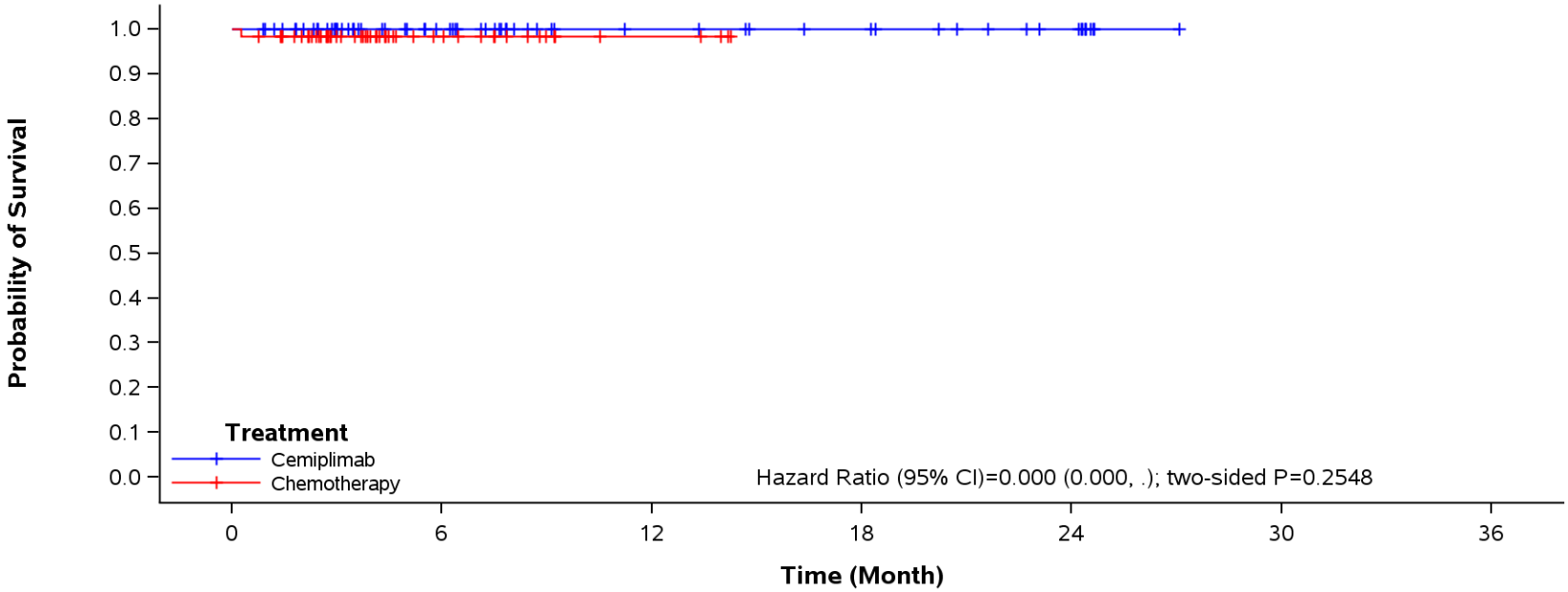
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: General disorders and administration site conditions
PT: Malaise



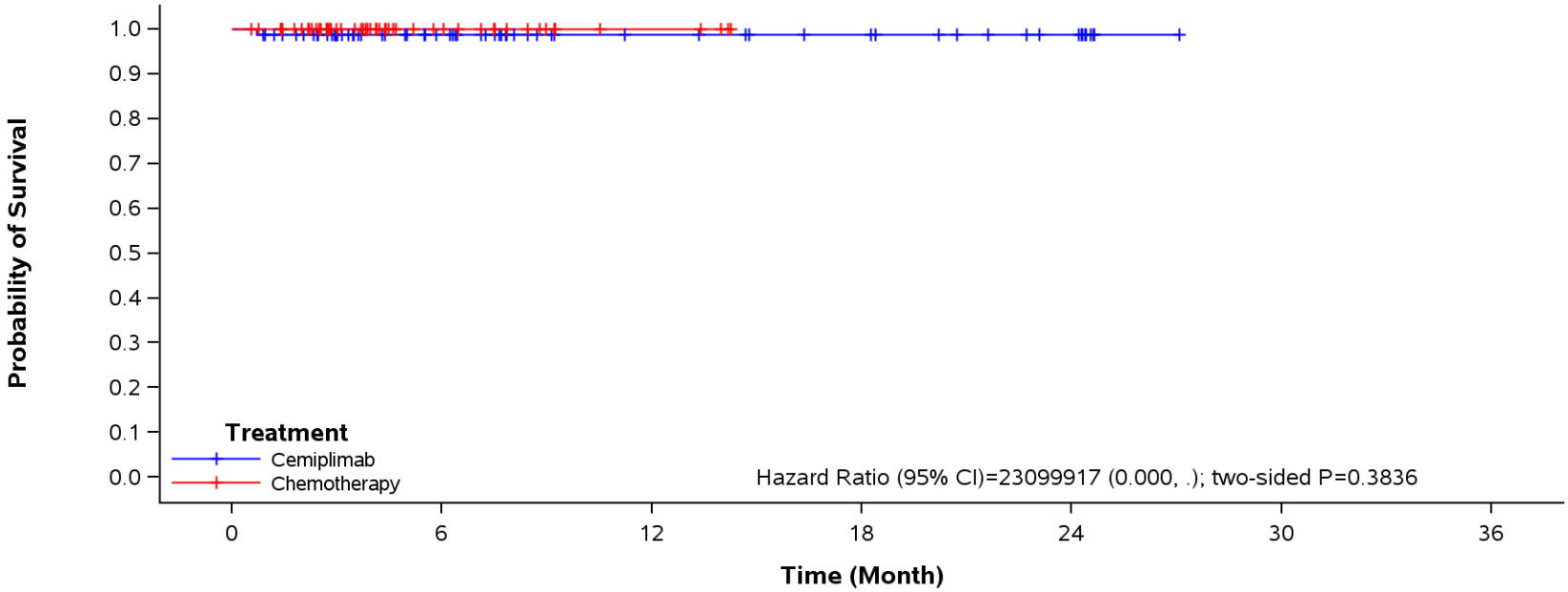

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



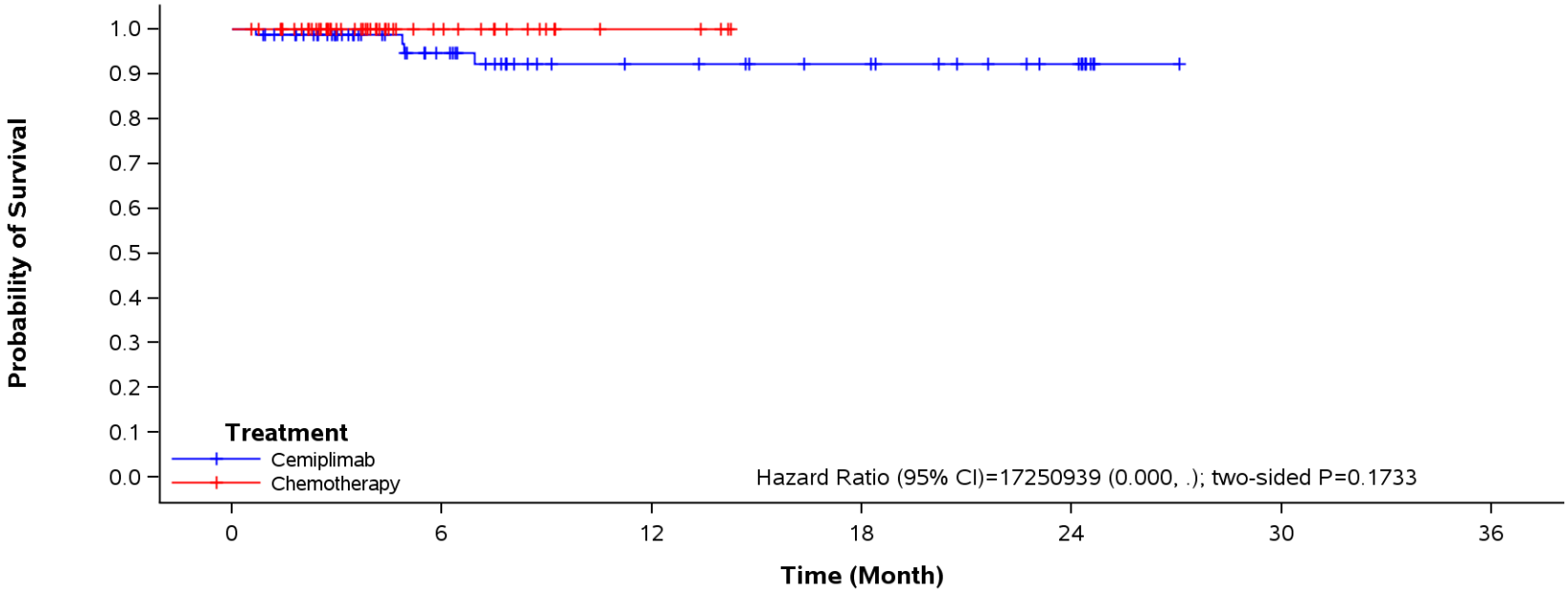

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Hepatobiliary disorders



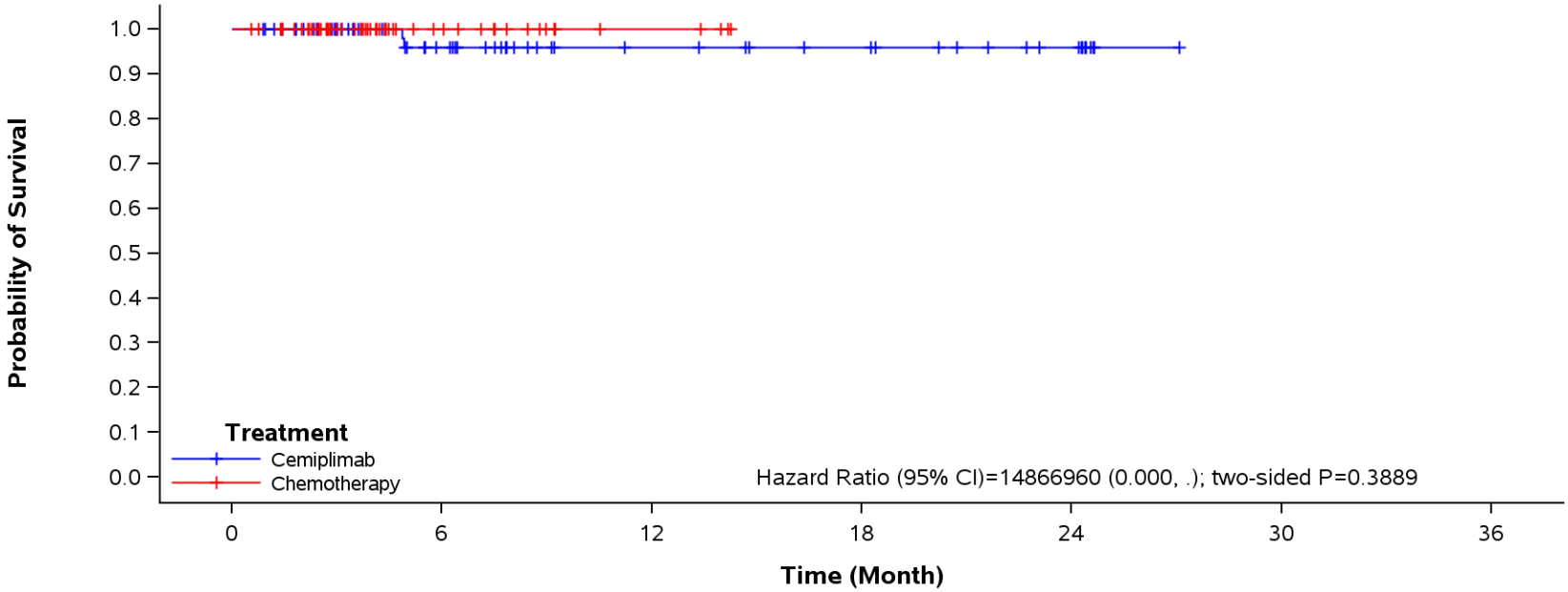

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 42 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



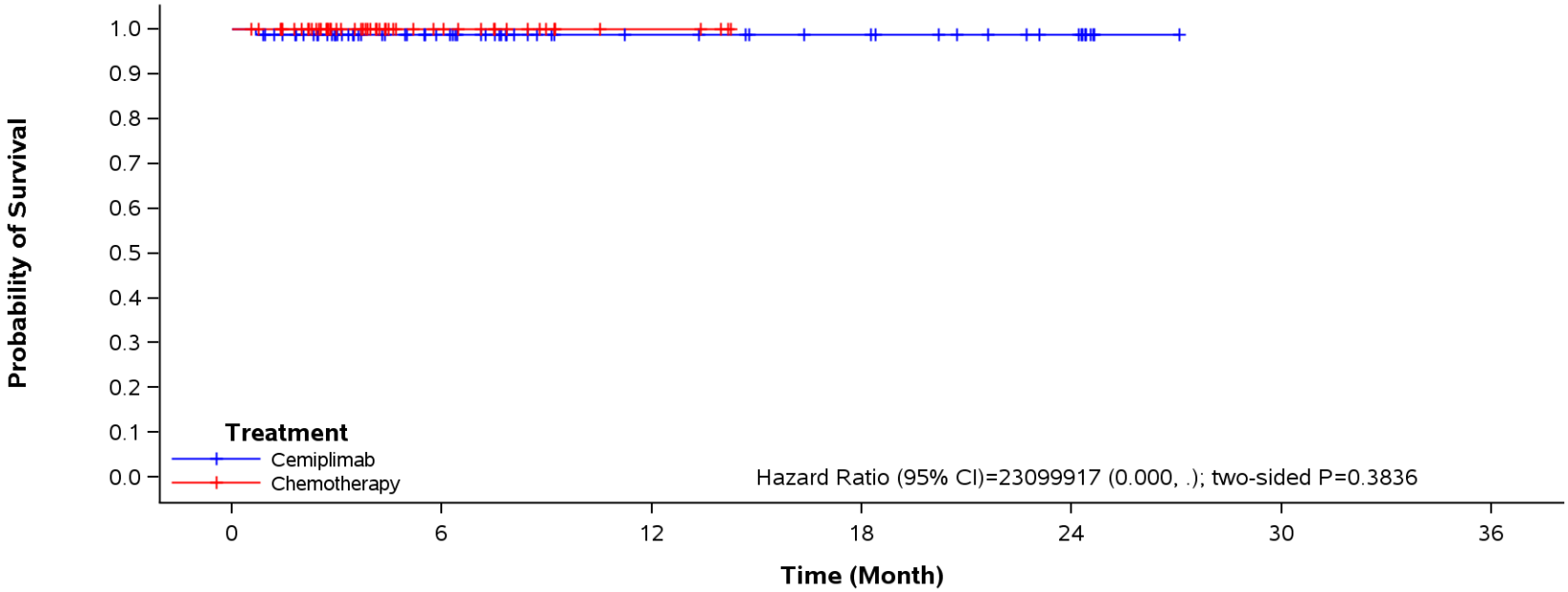

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 42 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



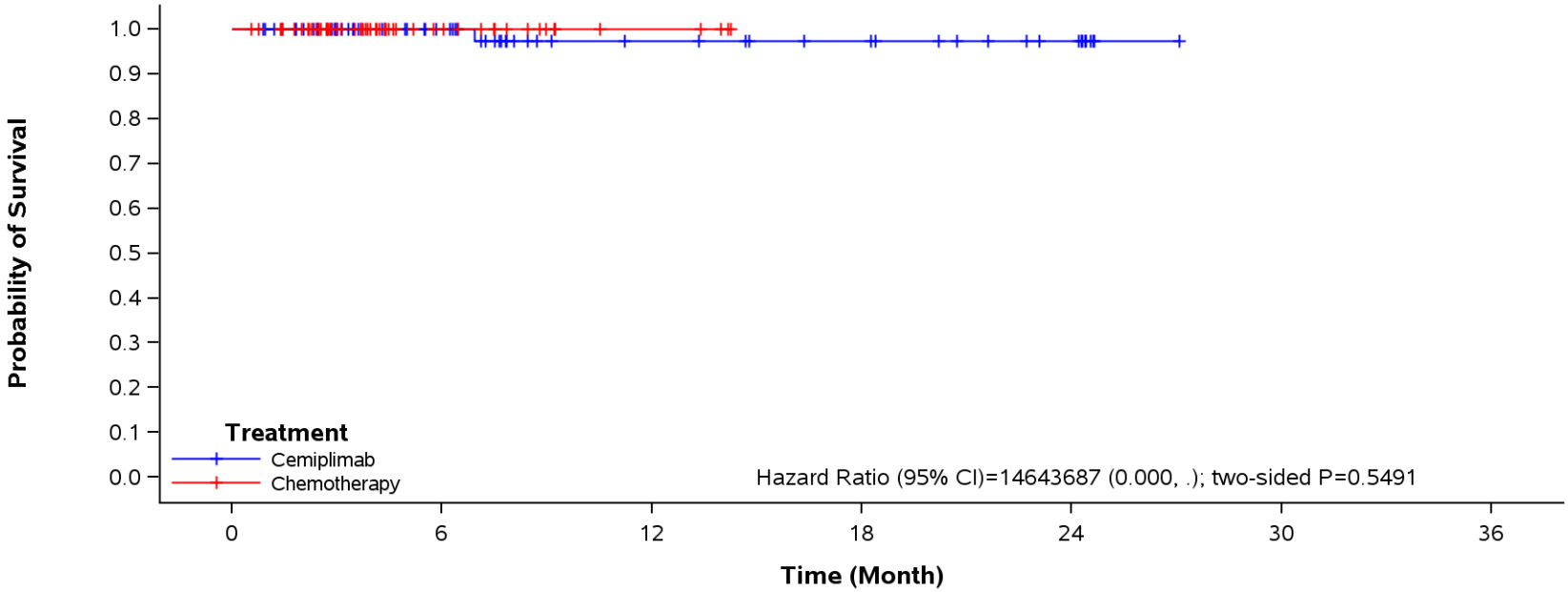

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Hepatobiliary disorders
PT: Hepatitis



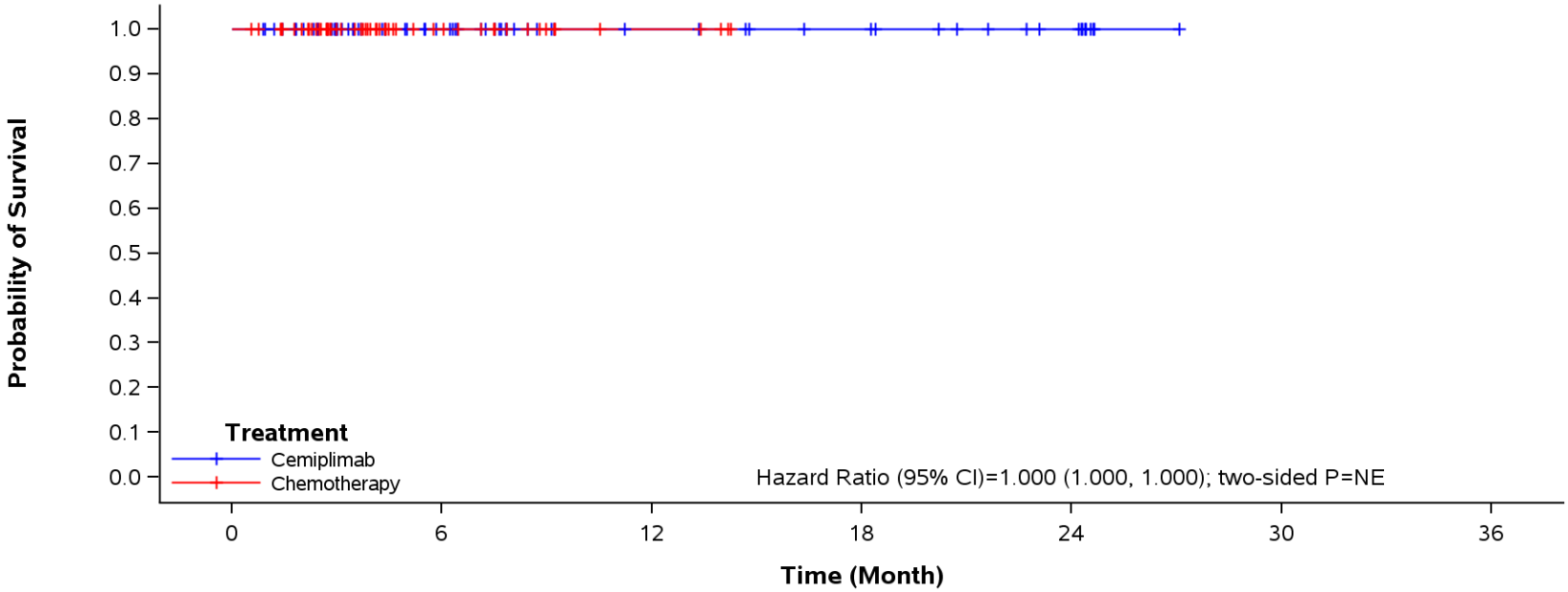

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



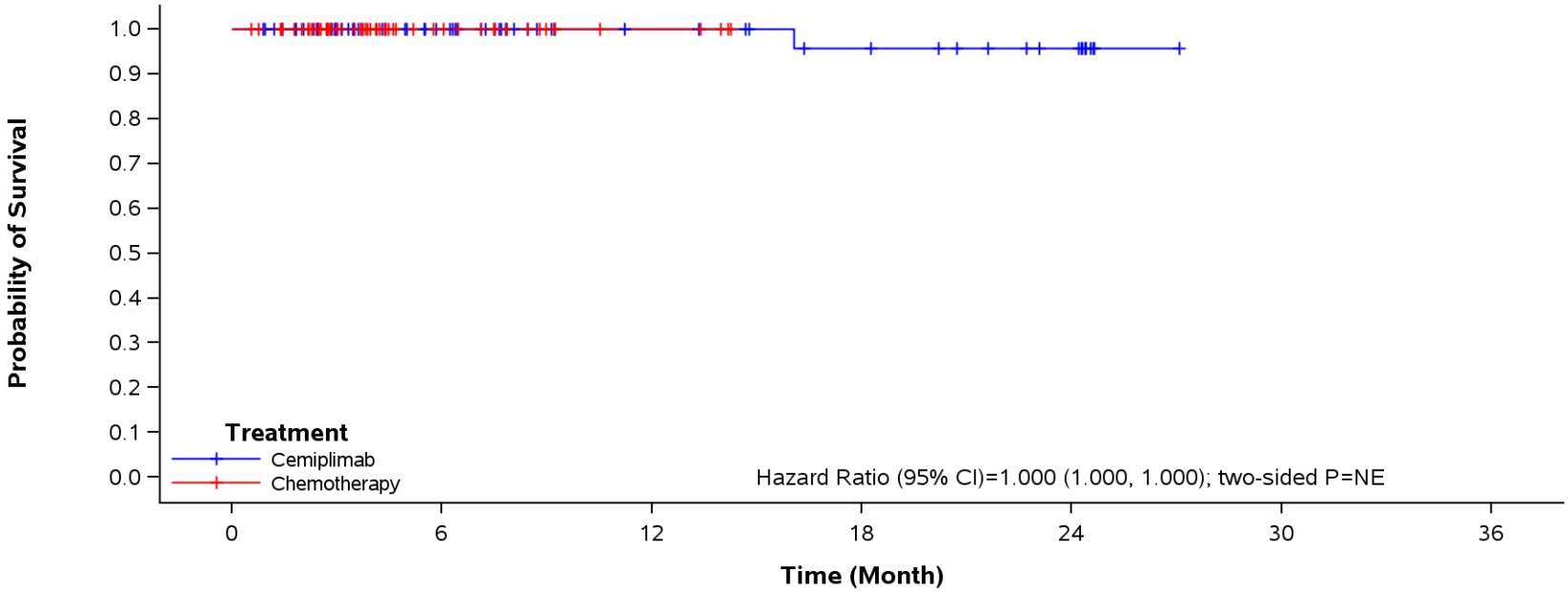

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Infections and infestations




Number of Subjects at risk

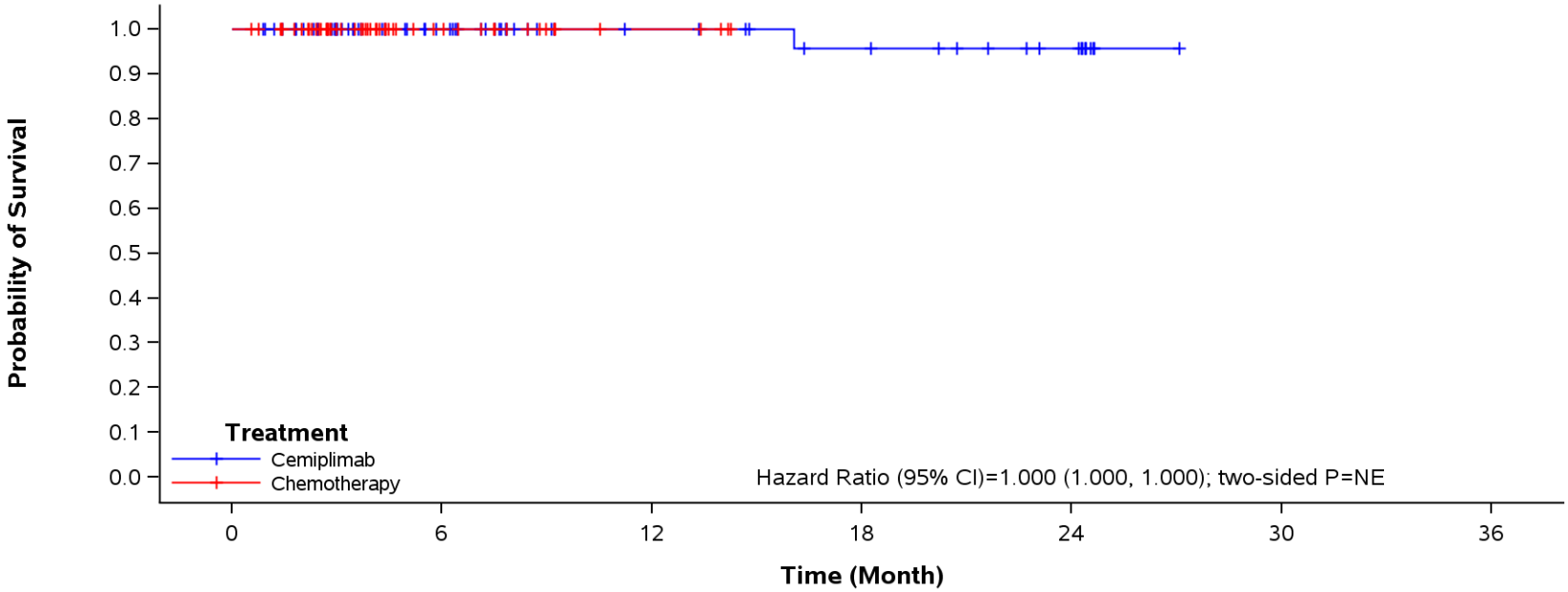
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 21 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:05:00:36, haijin.tang)

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Infections and infestations
PT: COVID-19 pneumonia



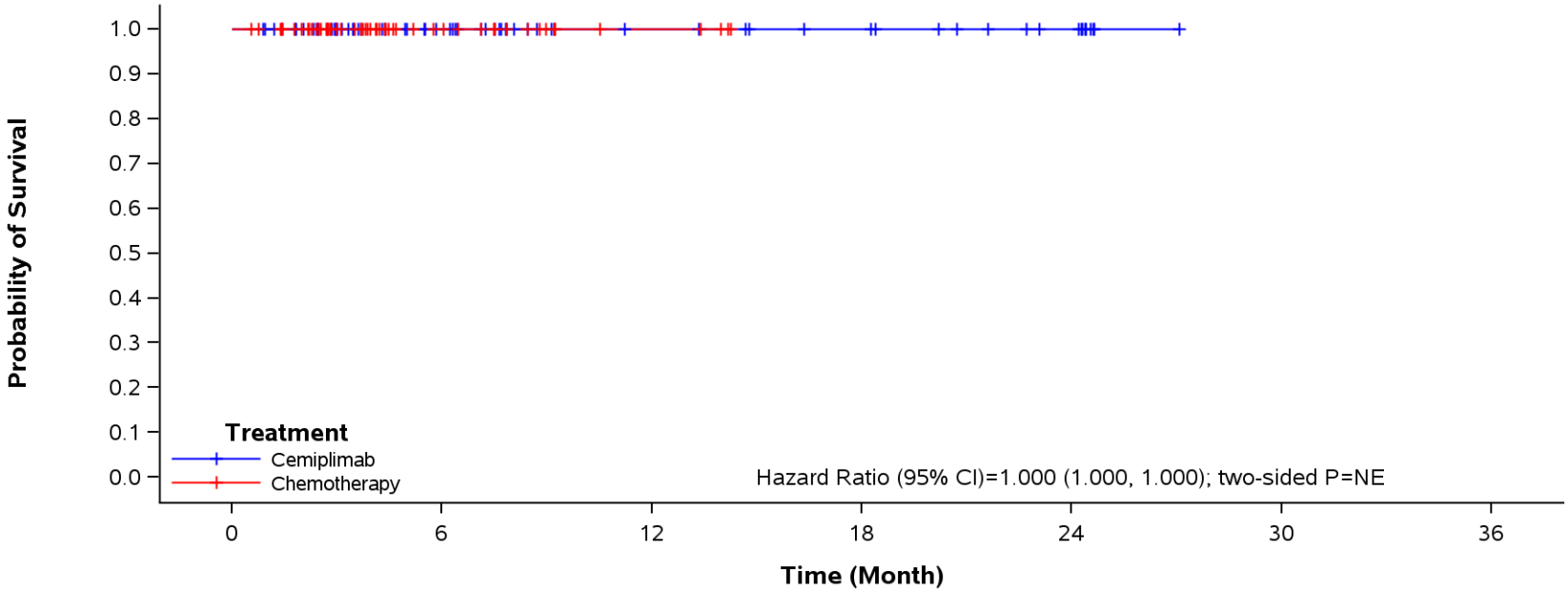

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 21 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Infections and infestations
PT: Gastroenteritis



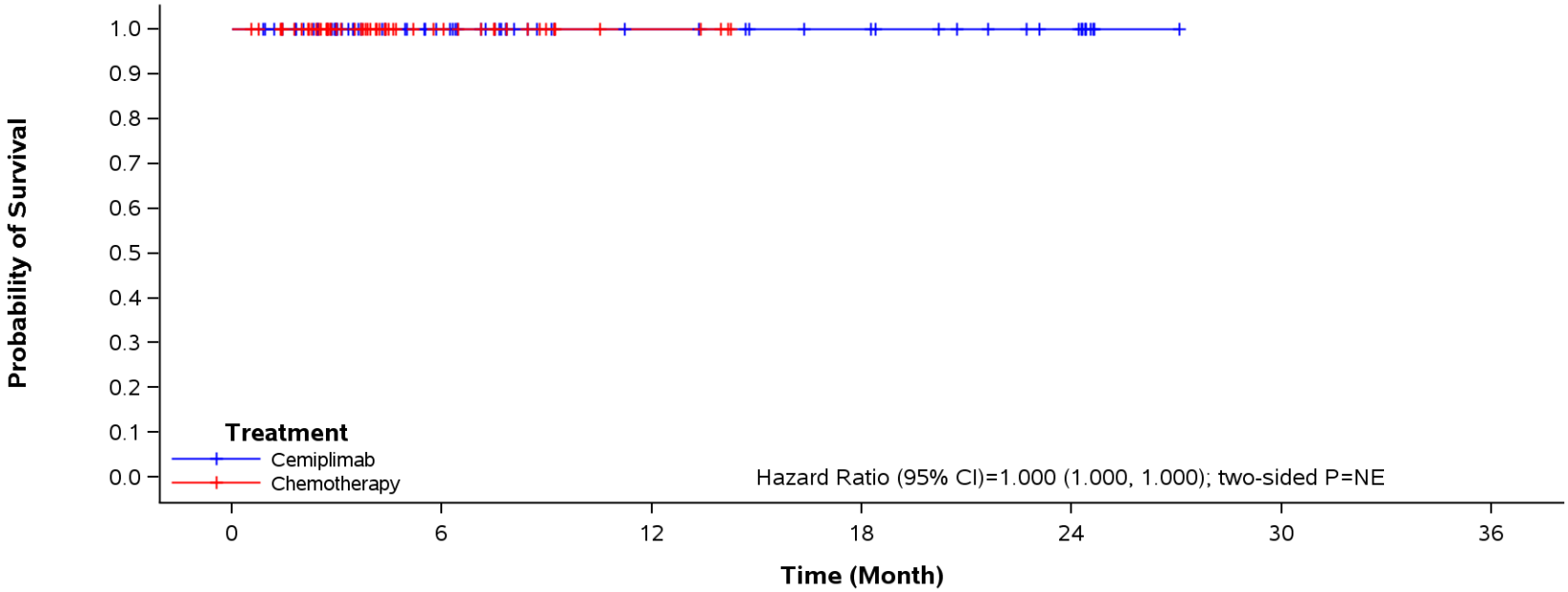

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Infections and infestations
PT: Pelvic abscess



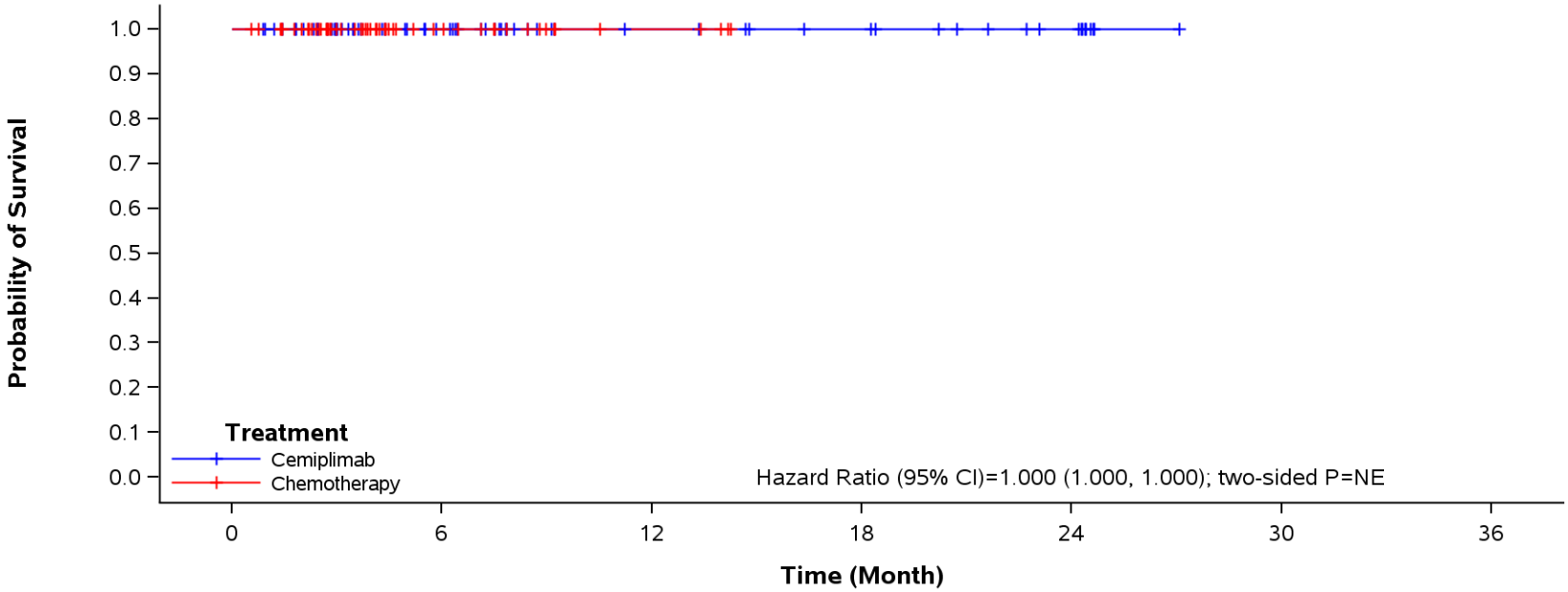

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Infections and infestations
PT: Peritonitis



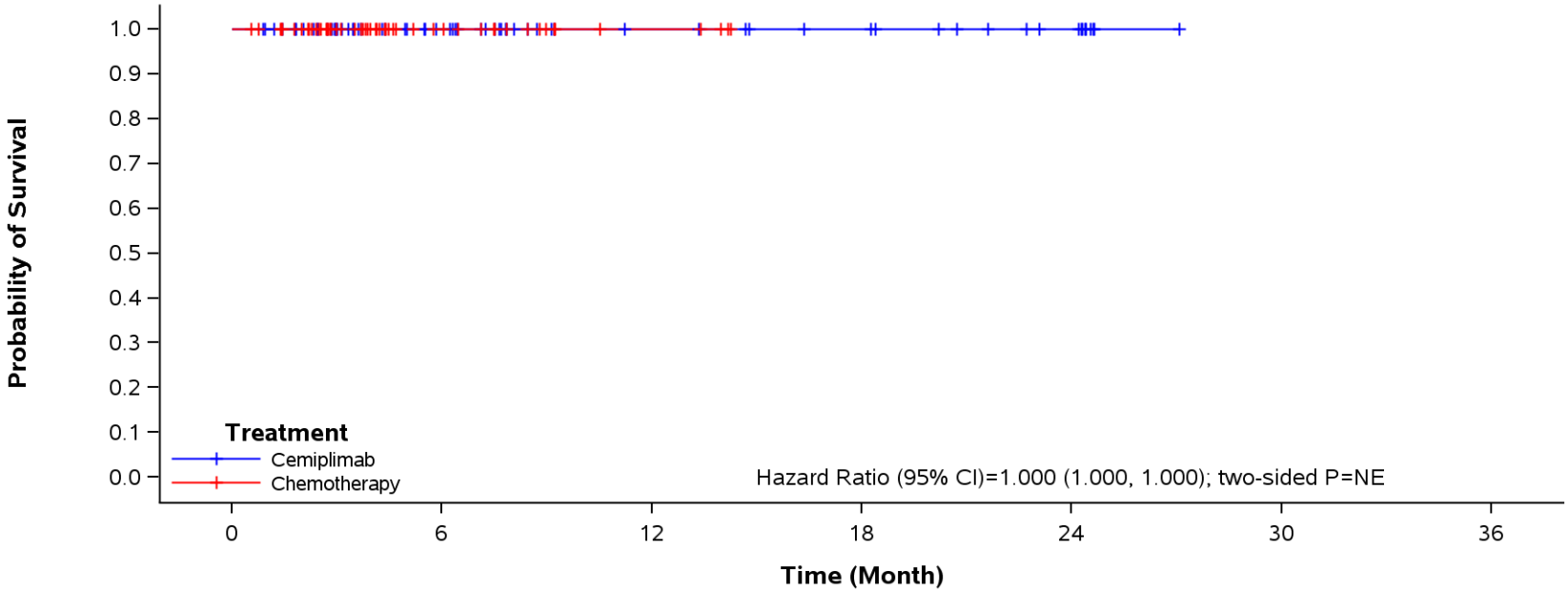

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Infections and infestations
PT: Pneumonia



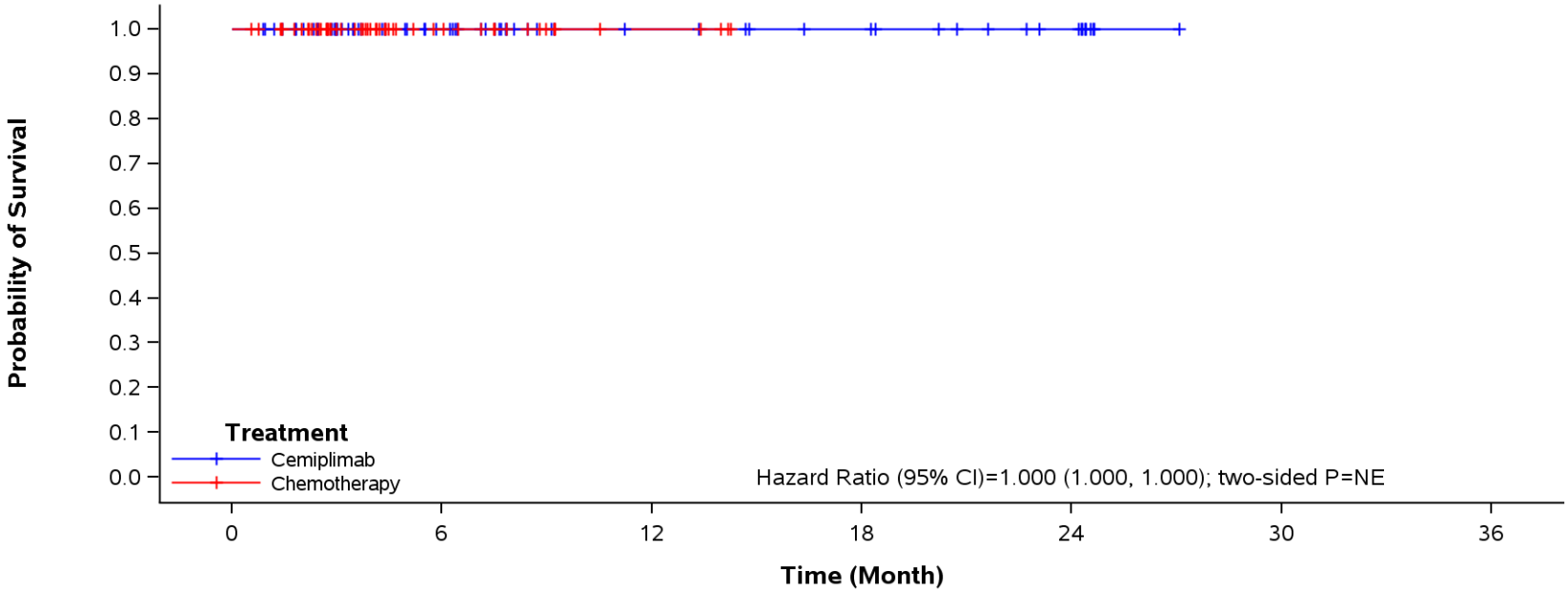

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Infections and infestations
PT: Pyomyositis




**Number of Subjects at risk**

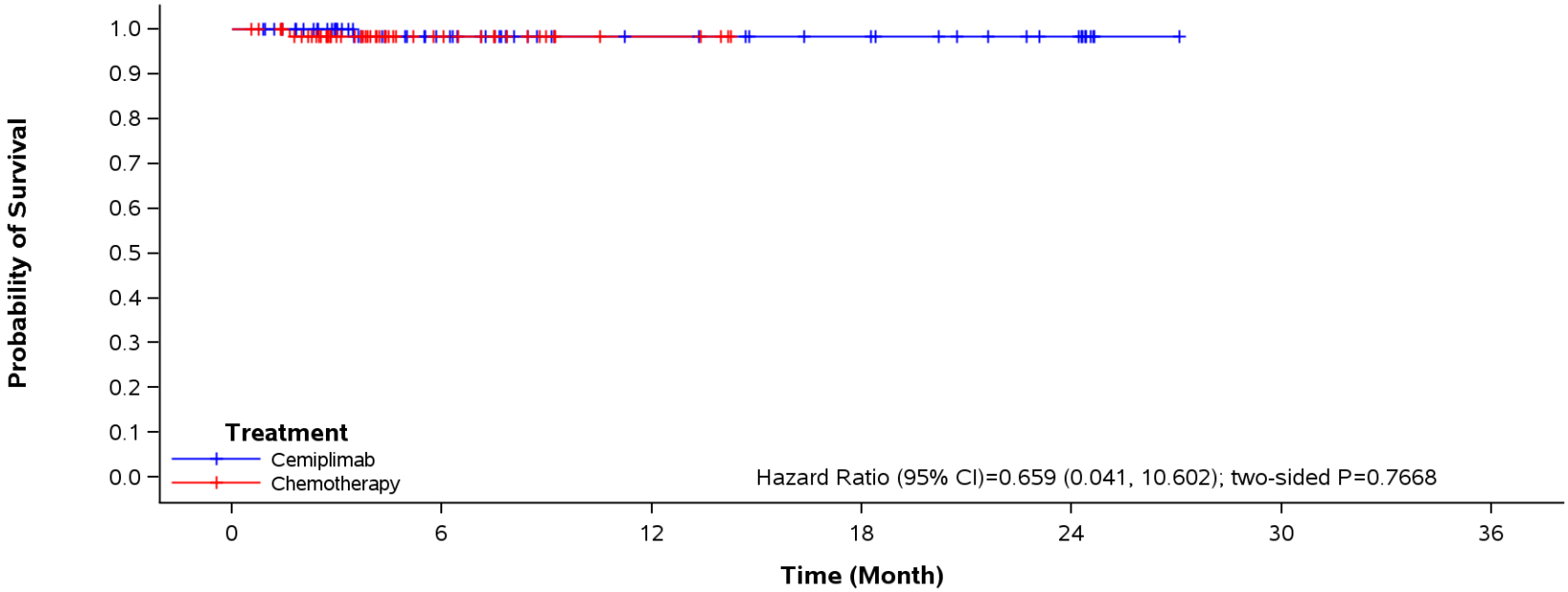
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

SOC: Injury, poisoning and procedural complications




**Number of Subjects at risk**

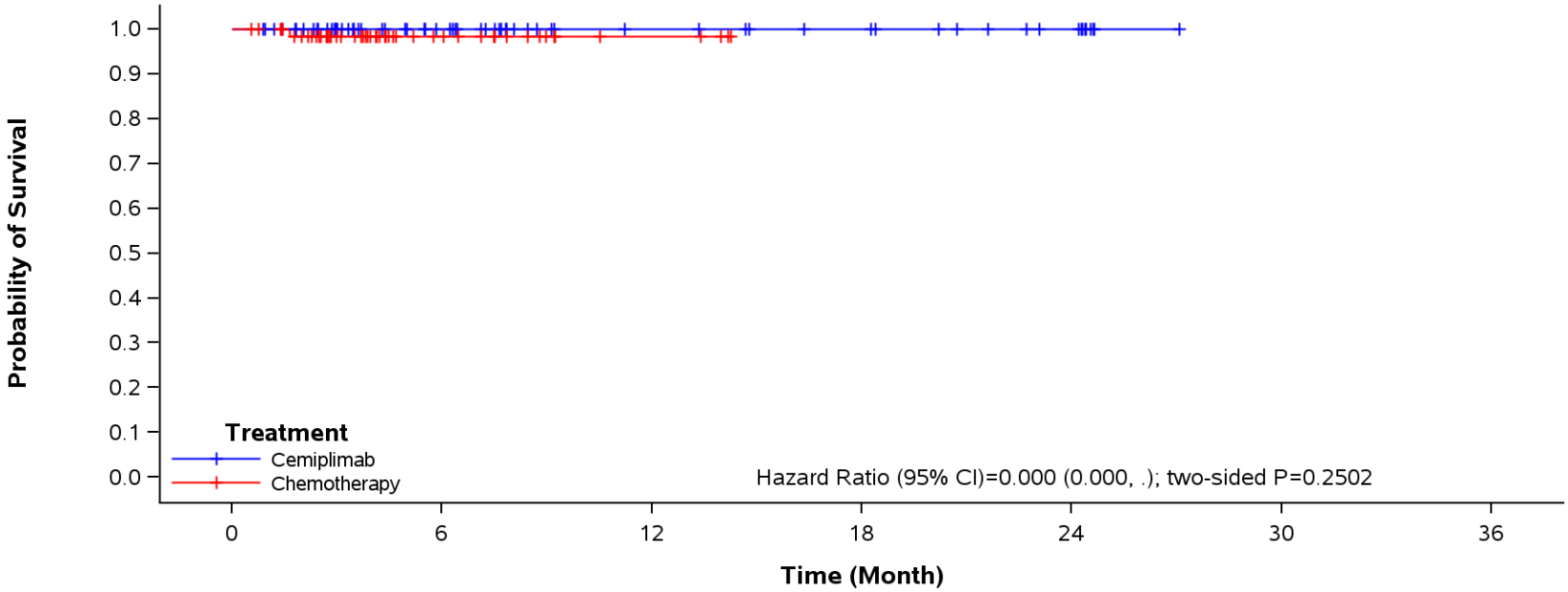
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 43 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



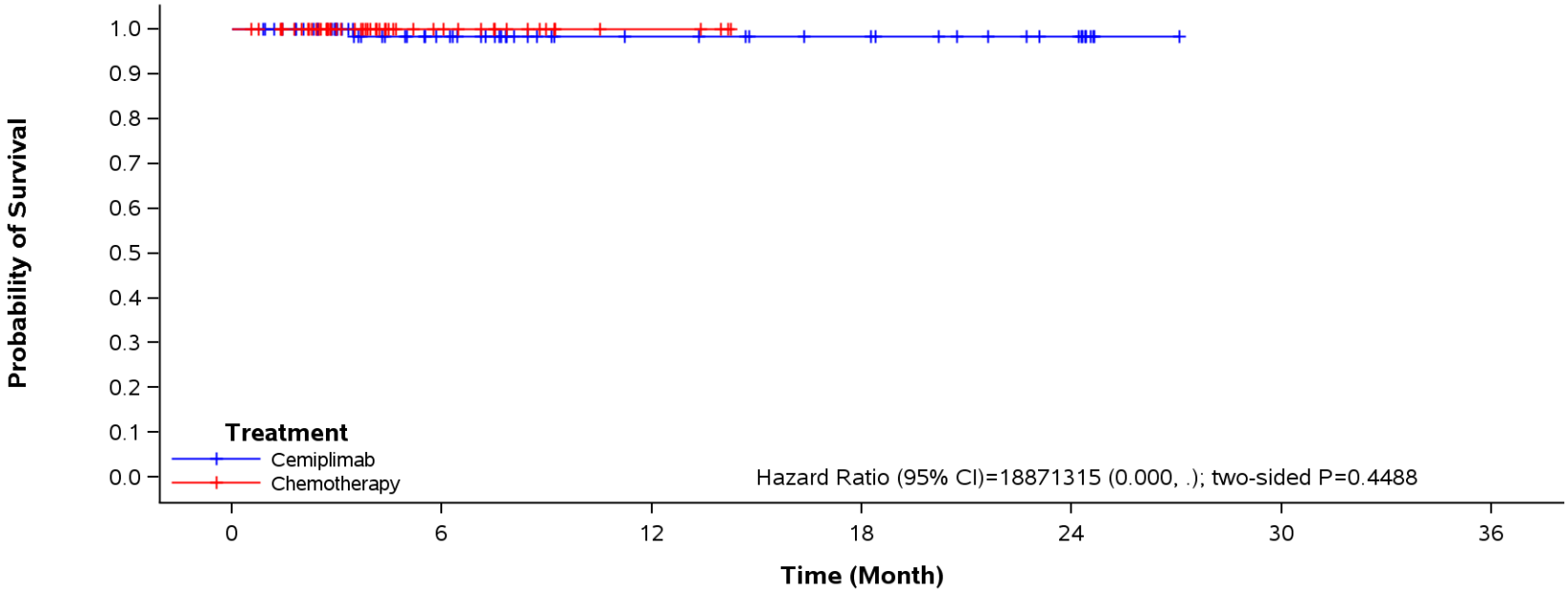

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



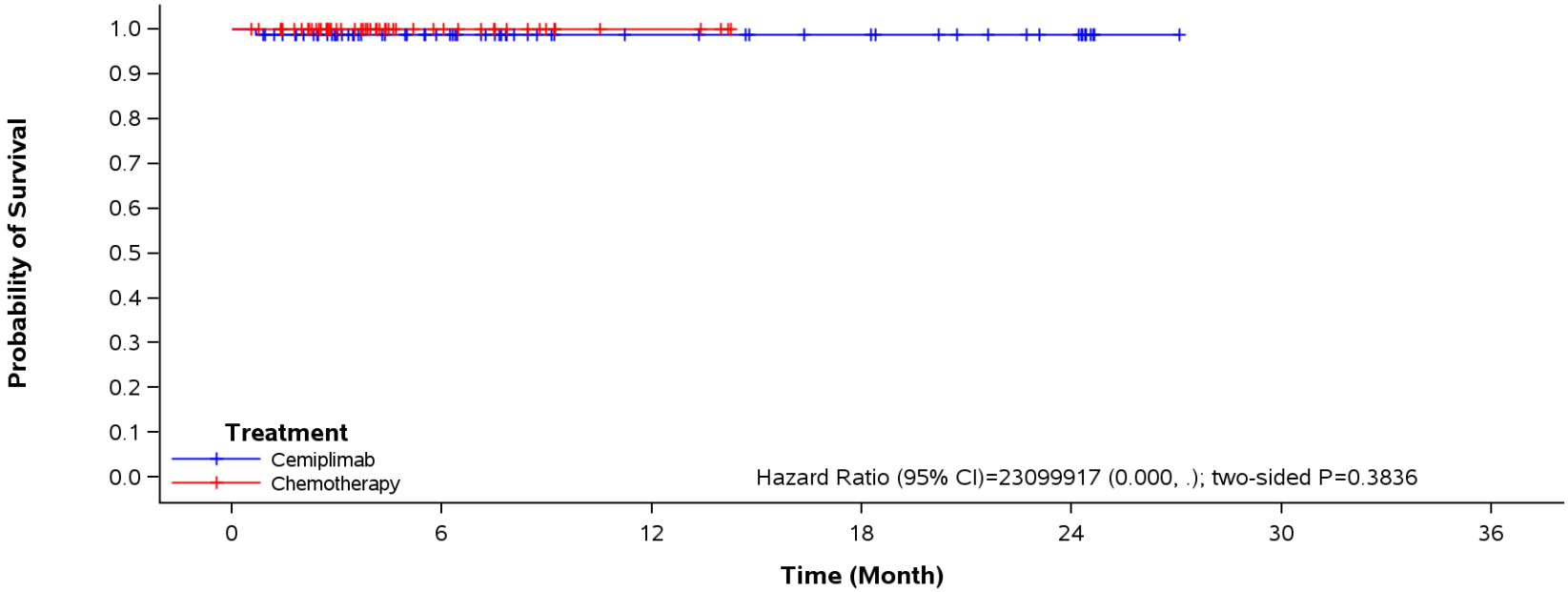

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 43 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Investigations



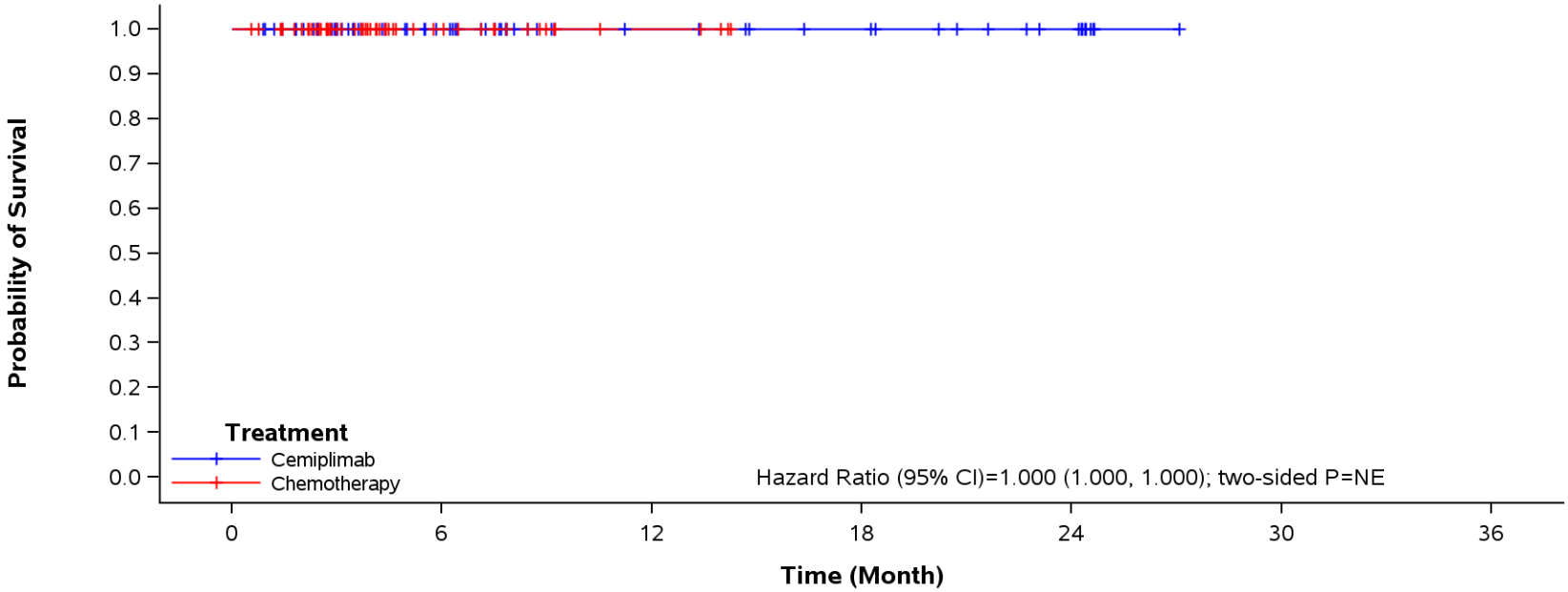

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Investigations
PT: Alanine aminotransferase increased



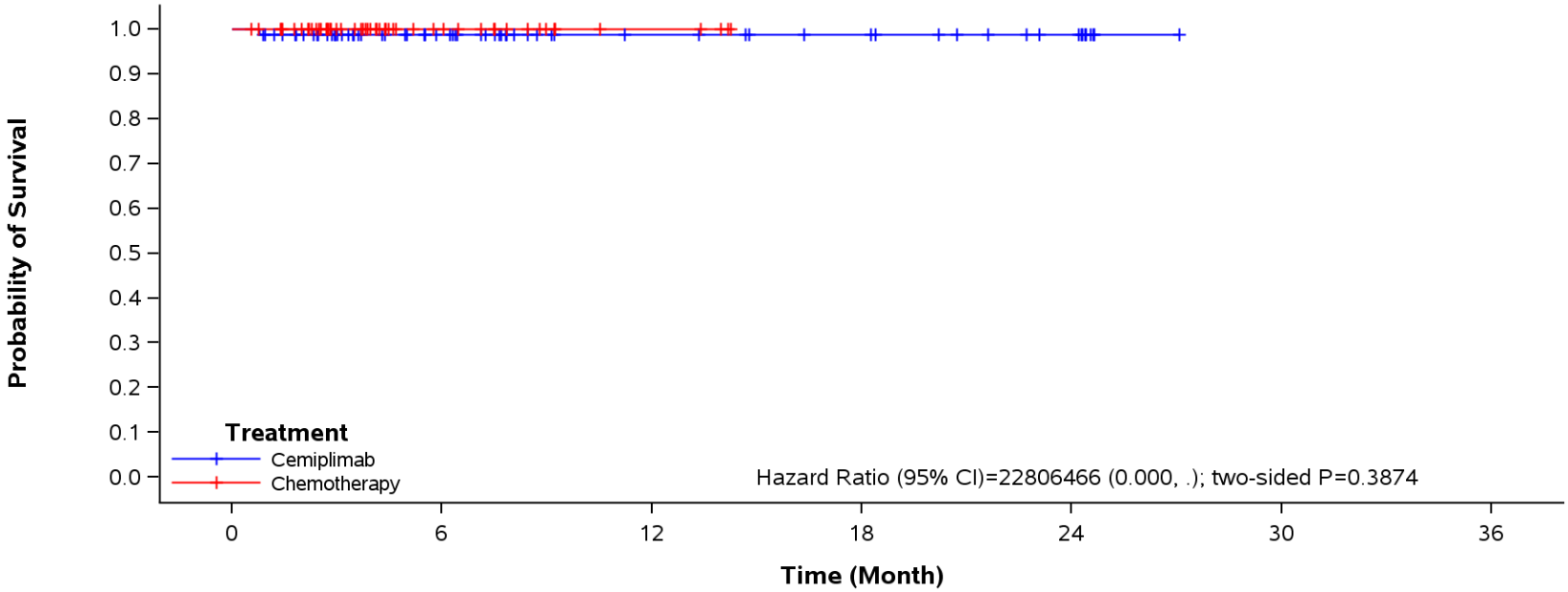

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Investigations
PT: Amylase increased



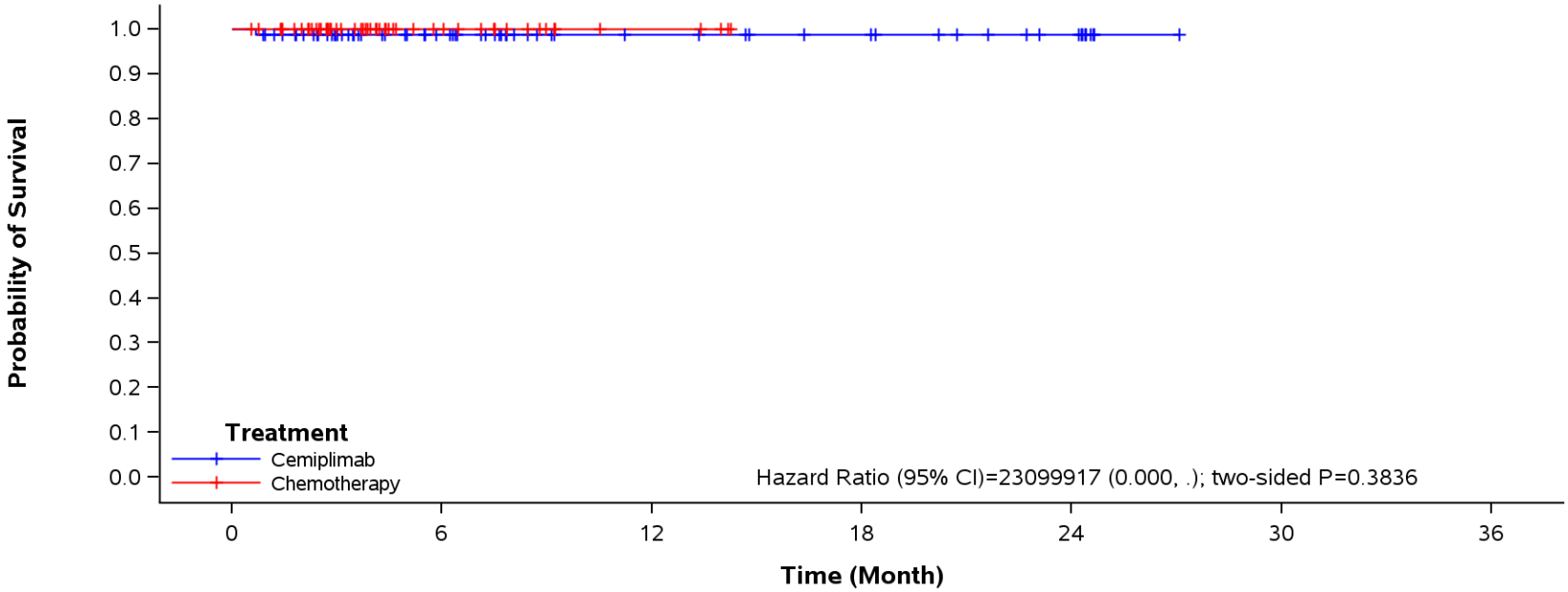

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Investigations
PT: Platelet count decreased



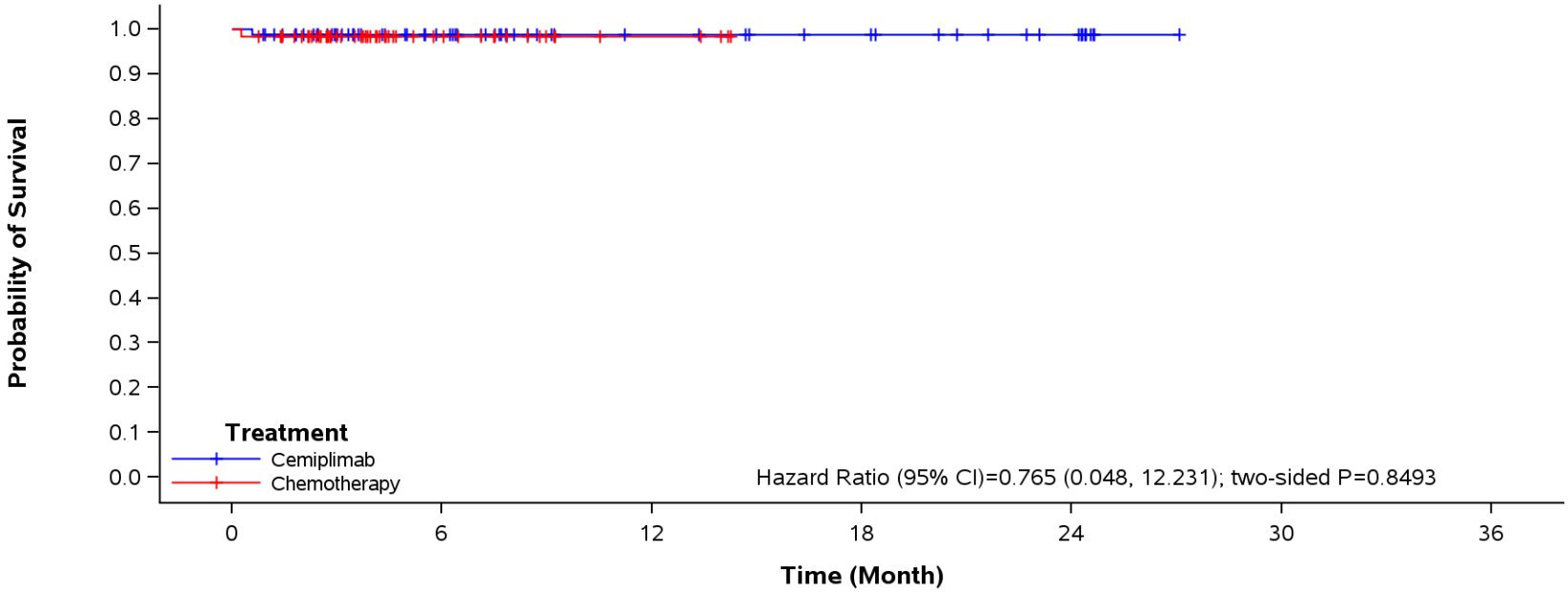

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Metabolism and nutrition disorders



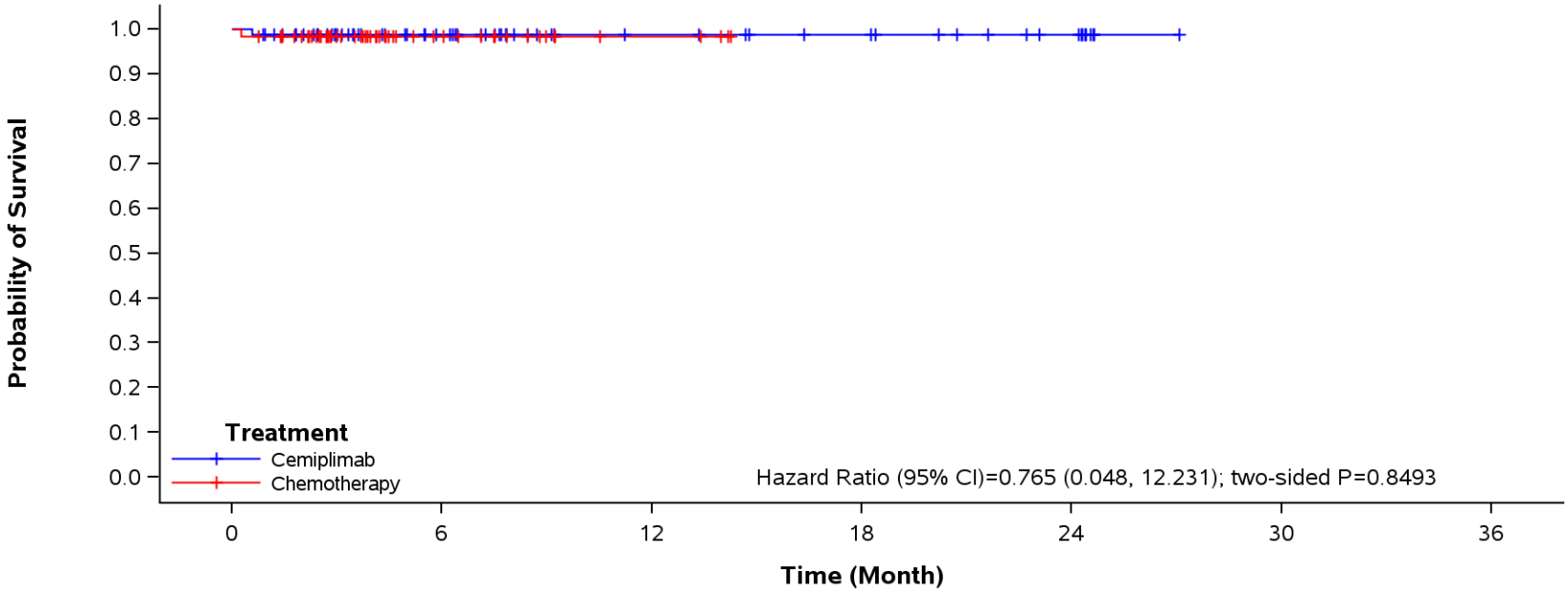

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Metabolism and nutrition disorders
PT: Decreased appetite




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

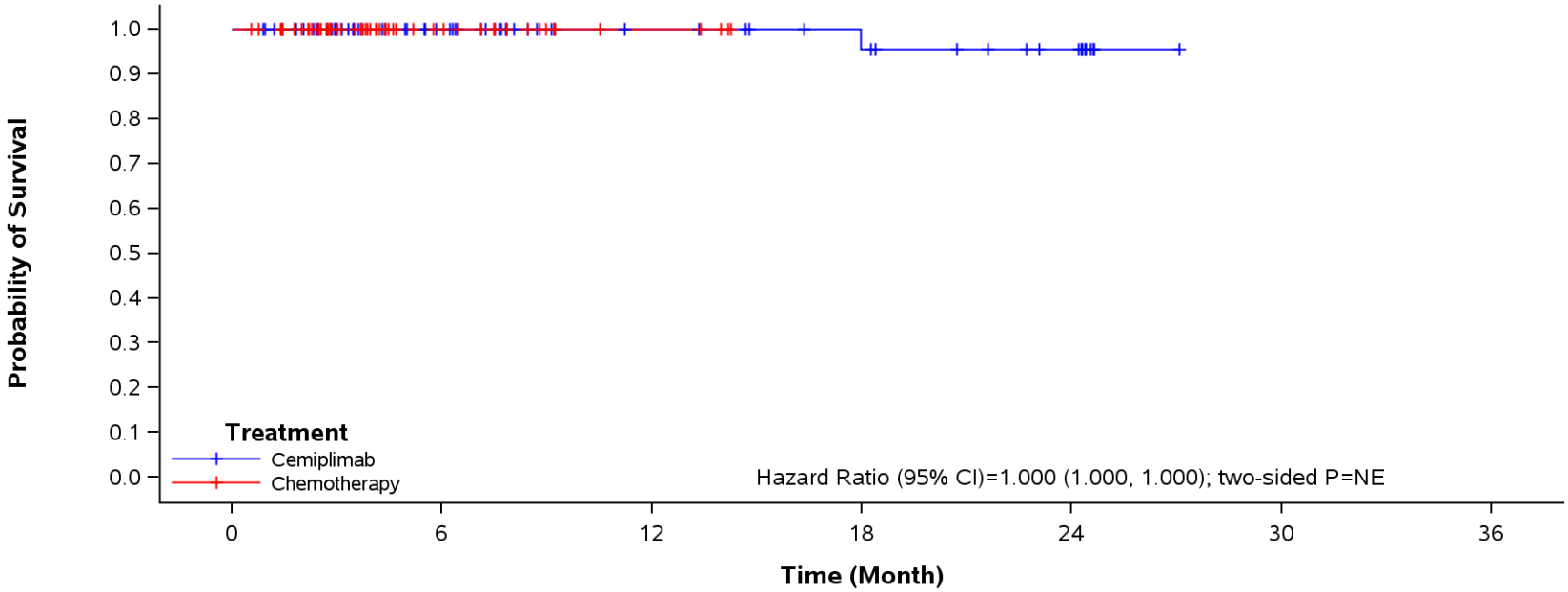
Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:05:00:36, haijin.tang)

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

SOC: Musculoskeletal and connective tissue disorders




**Number of Subjects at risk**

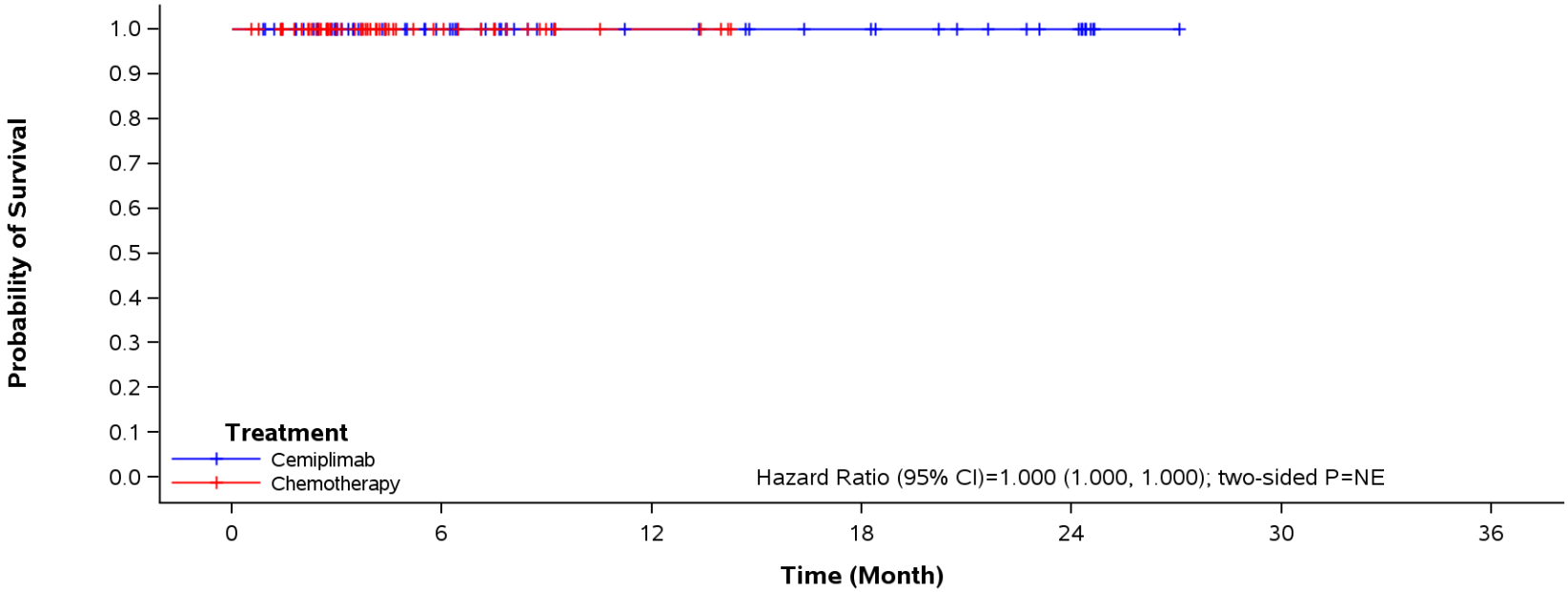
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 21 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



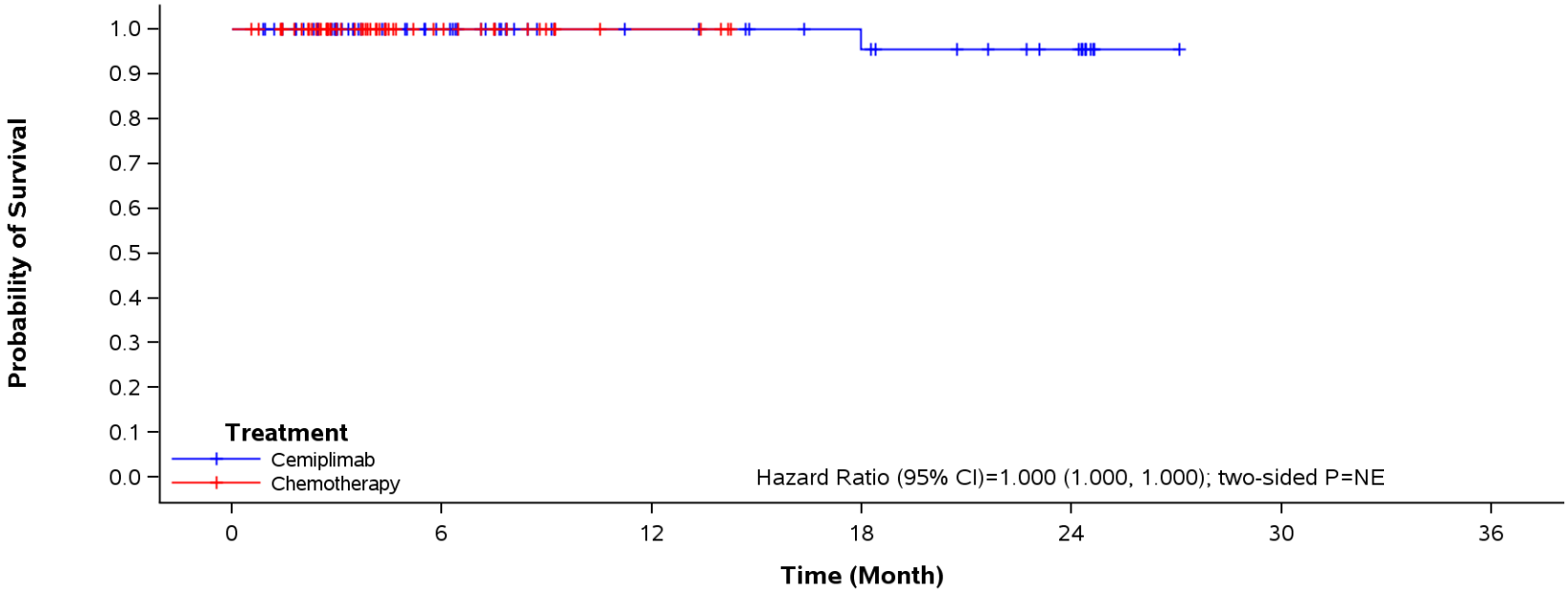

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



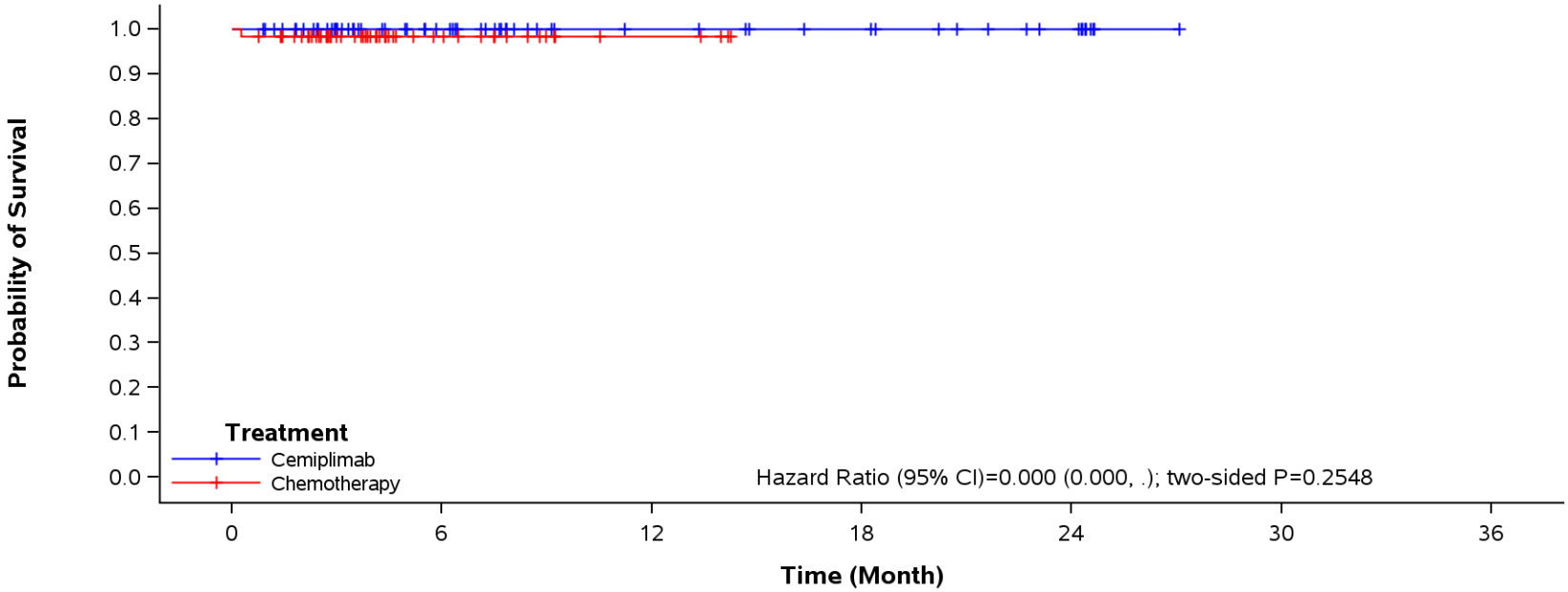

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 21 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Nervous system disorders



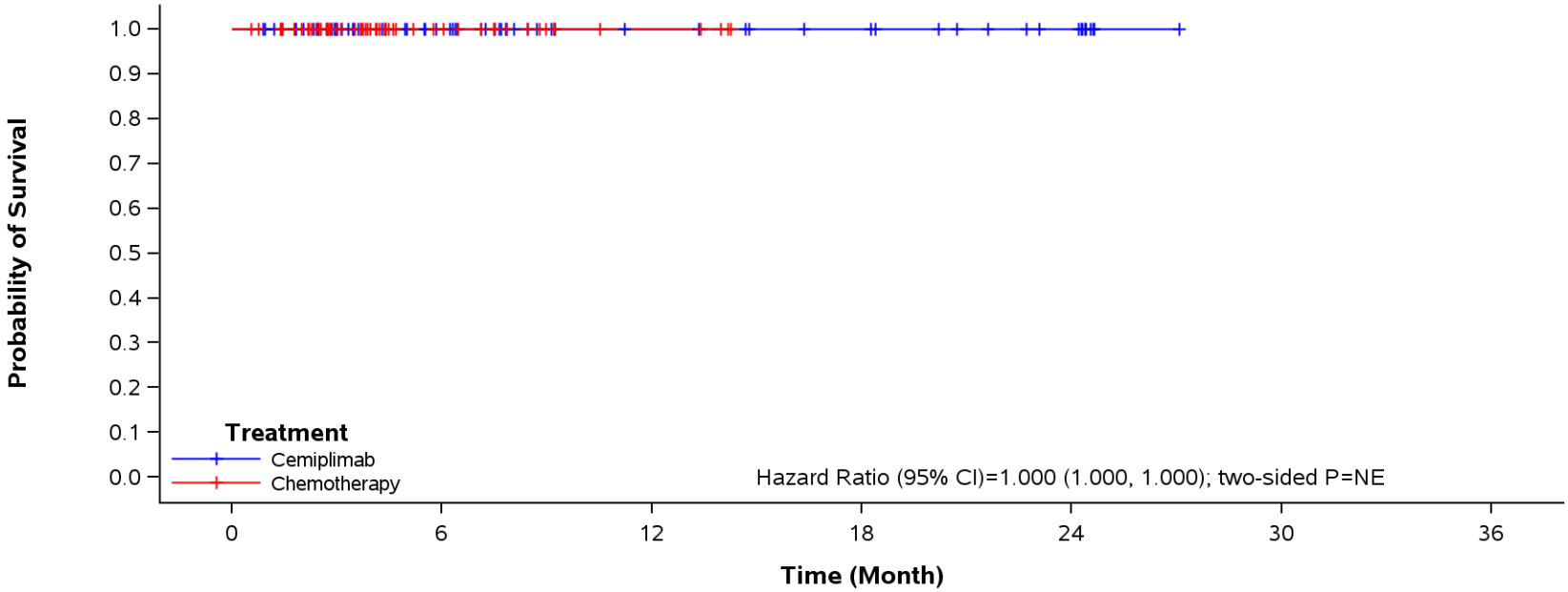

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Nervous system disorders
PT: Neurotoxicity



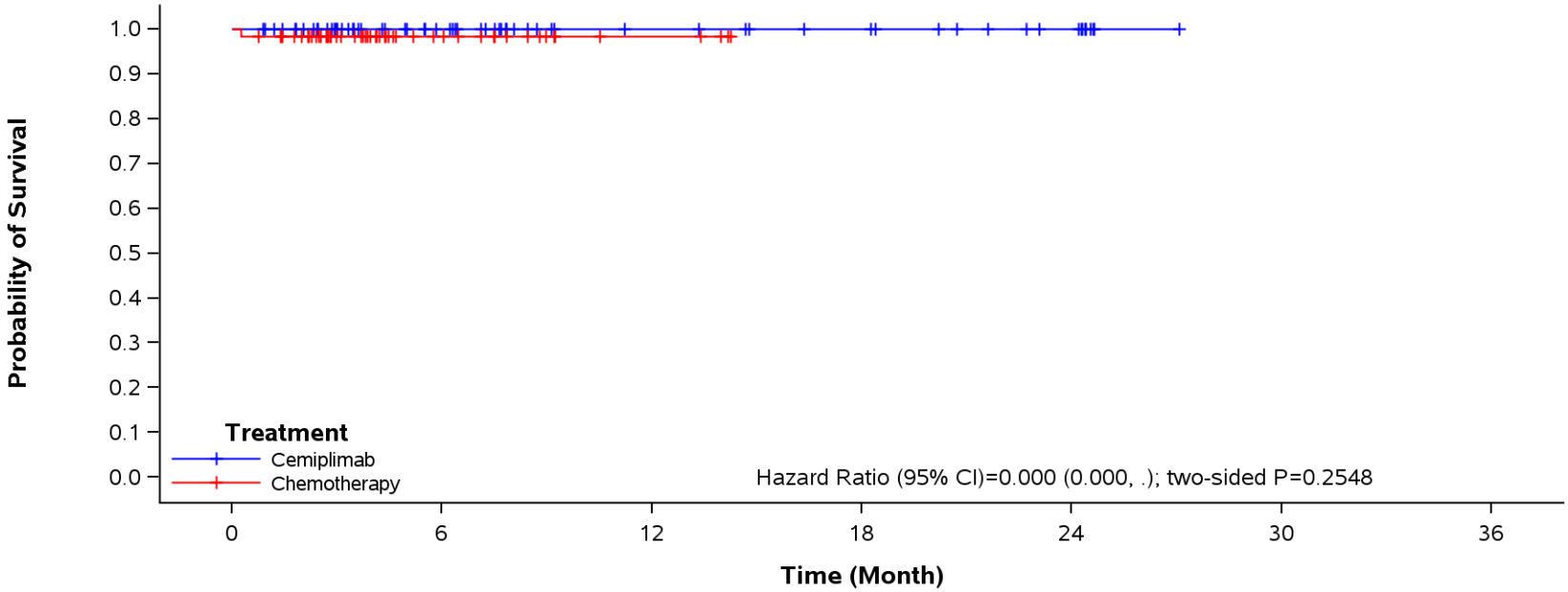

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Nervous system disorders
PT: Transient ischaemic attack



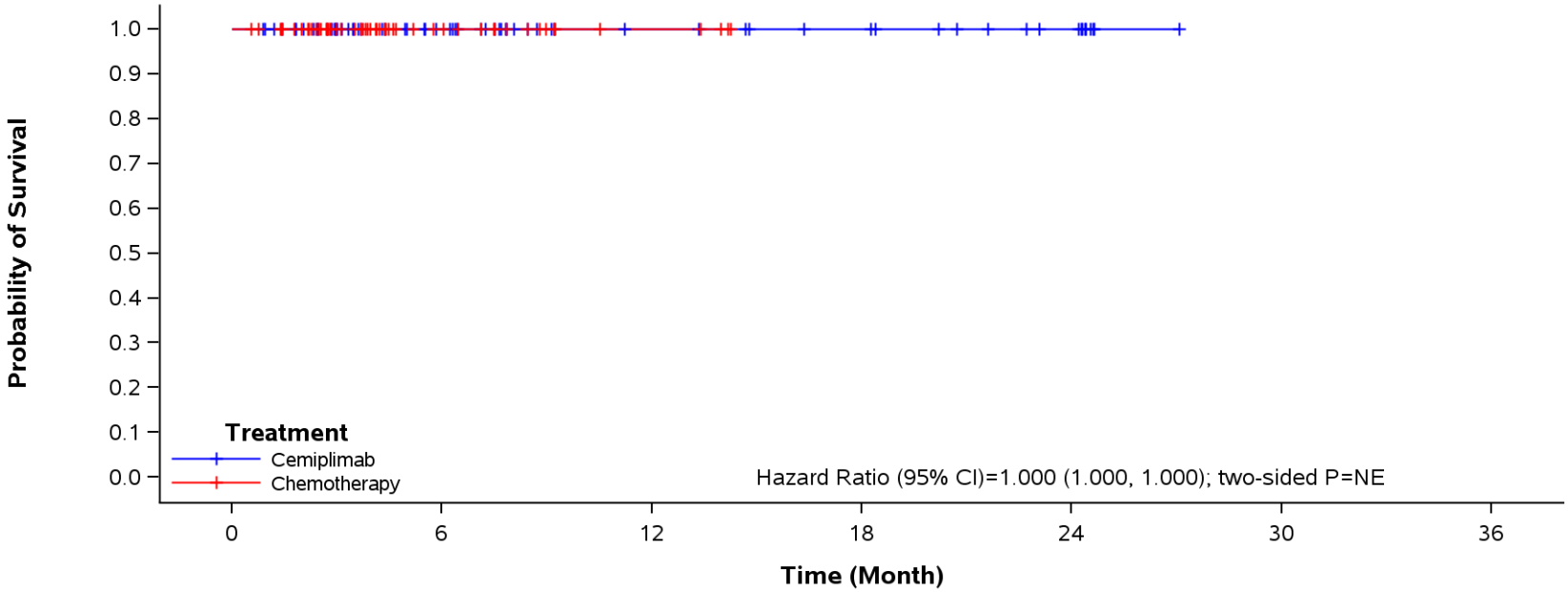

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Psychiatric disorders



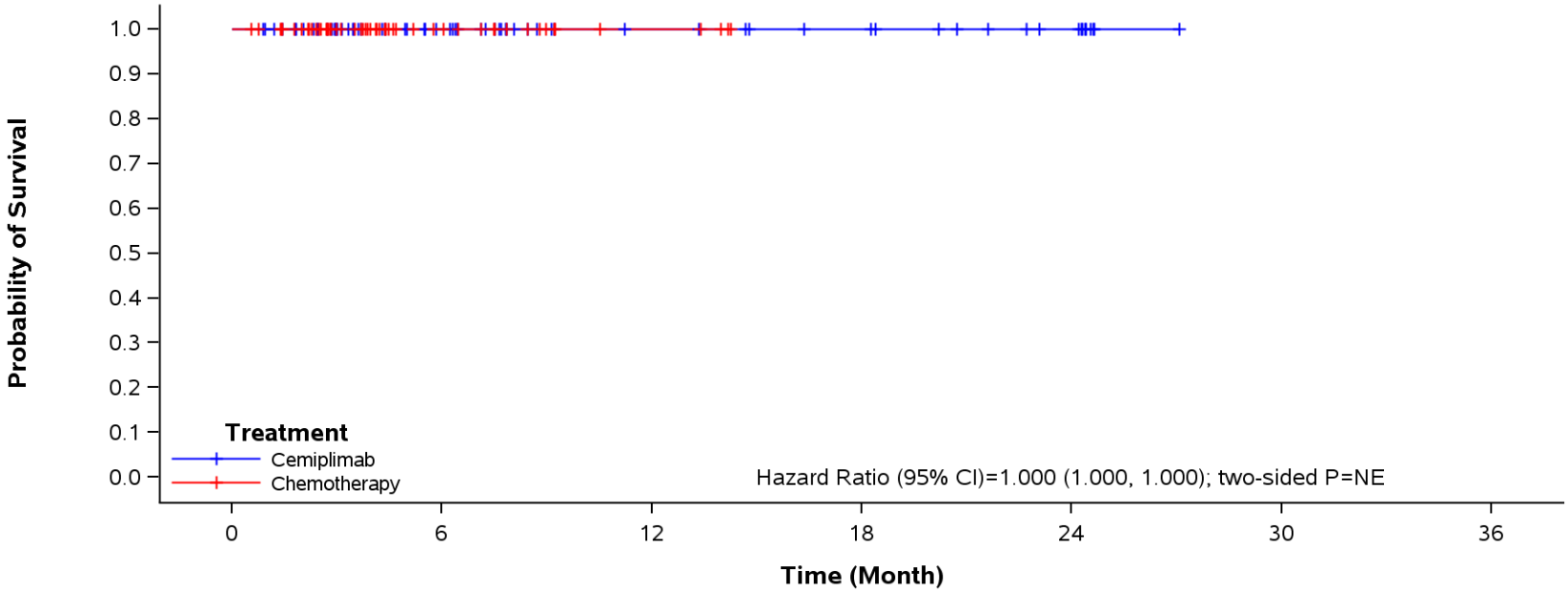

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Psychiatric disorders
PT: Agoraphobia



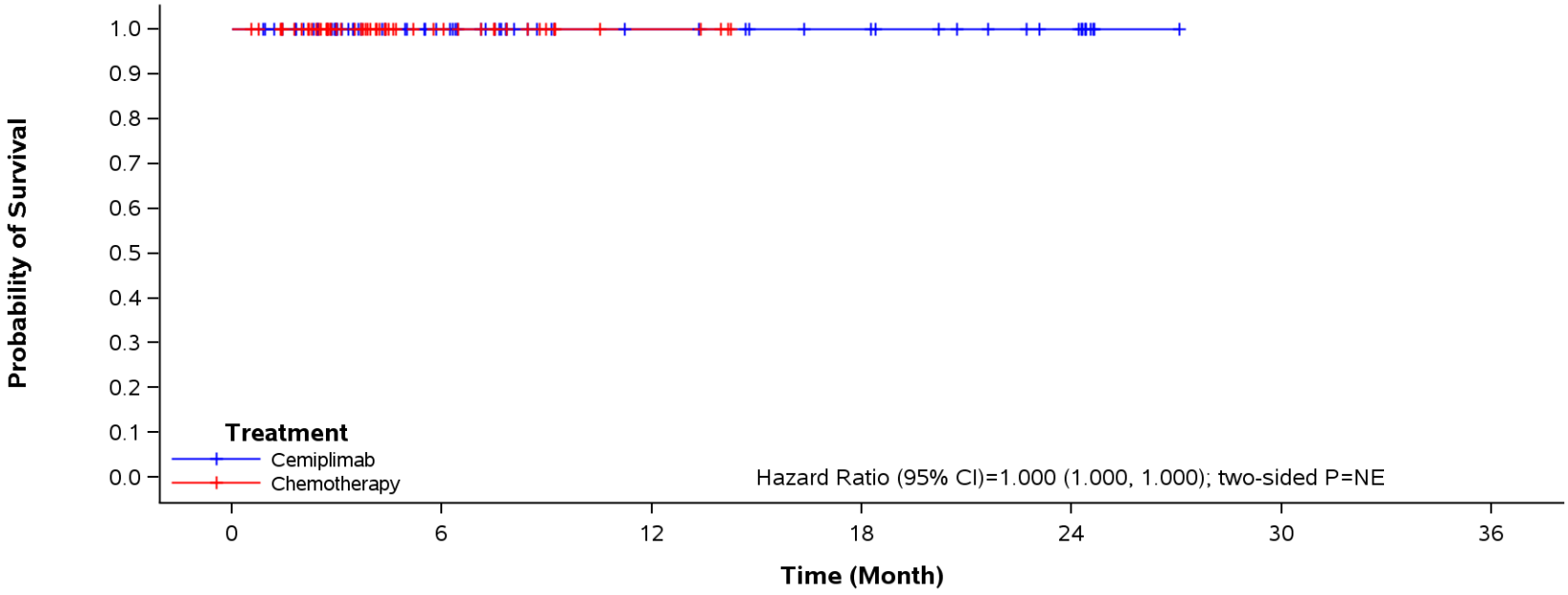

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Renal and urinary disorders



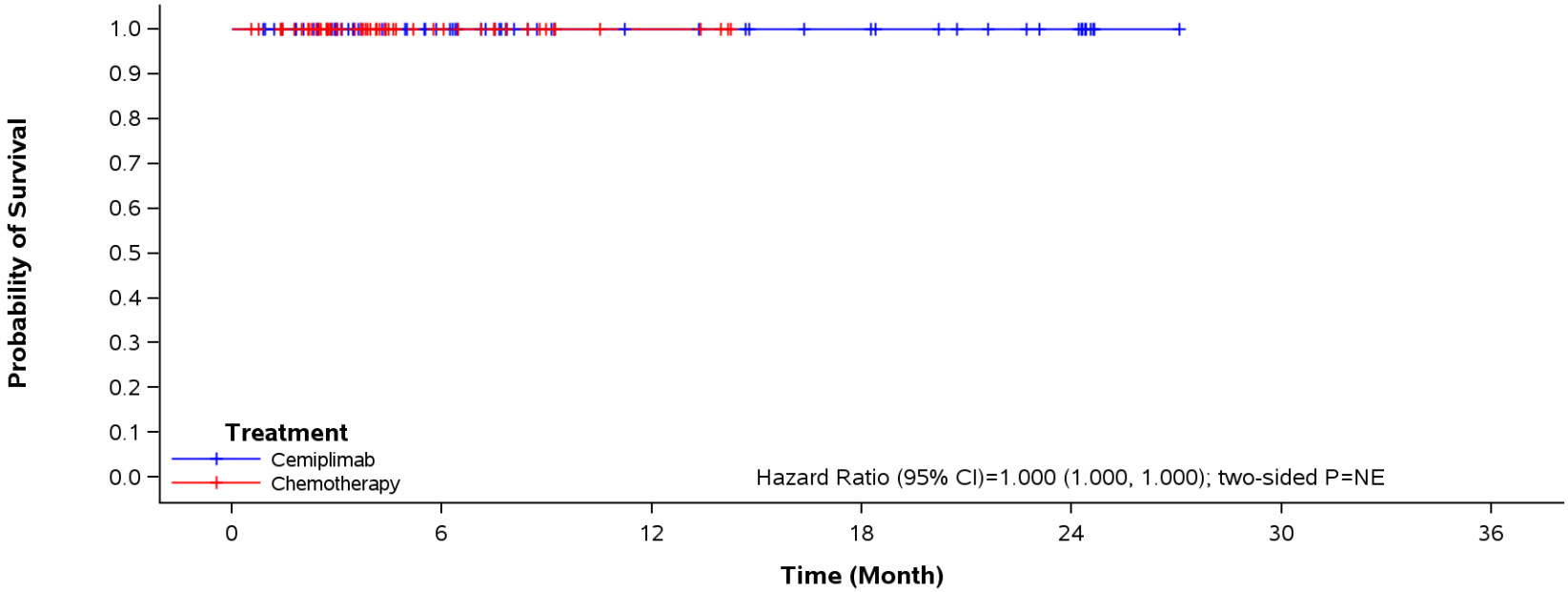

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Renal and urinary disorders
PT: Renal failure




**Number of Subjects at risk**

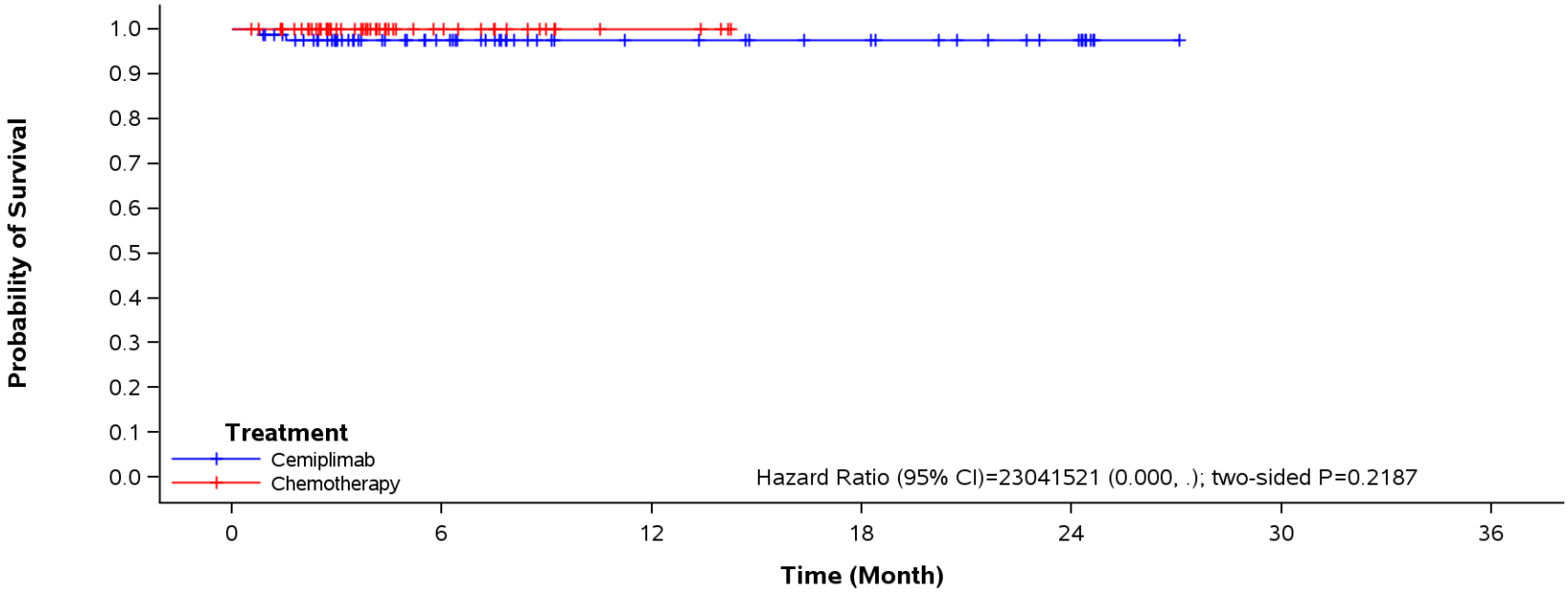
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0

SOC: Respiratory, thoracic and mediastinal disorders




**Number of Subjects at risk**

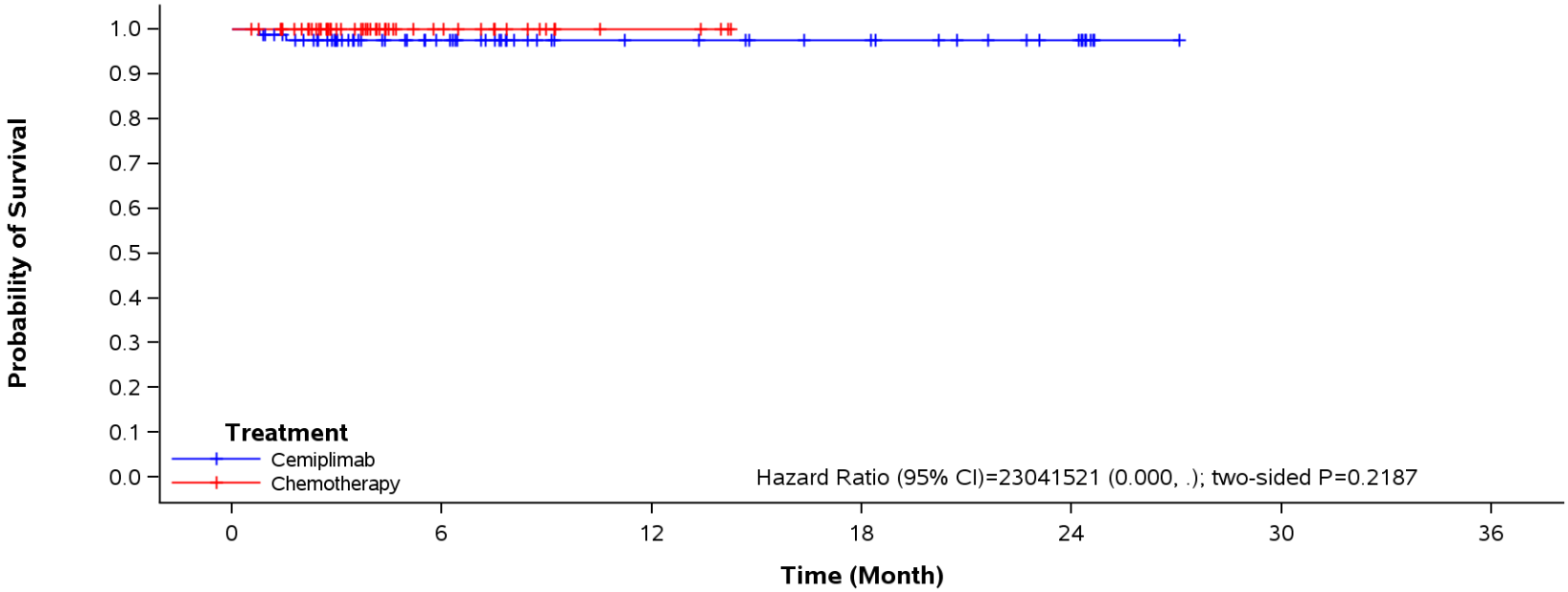
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



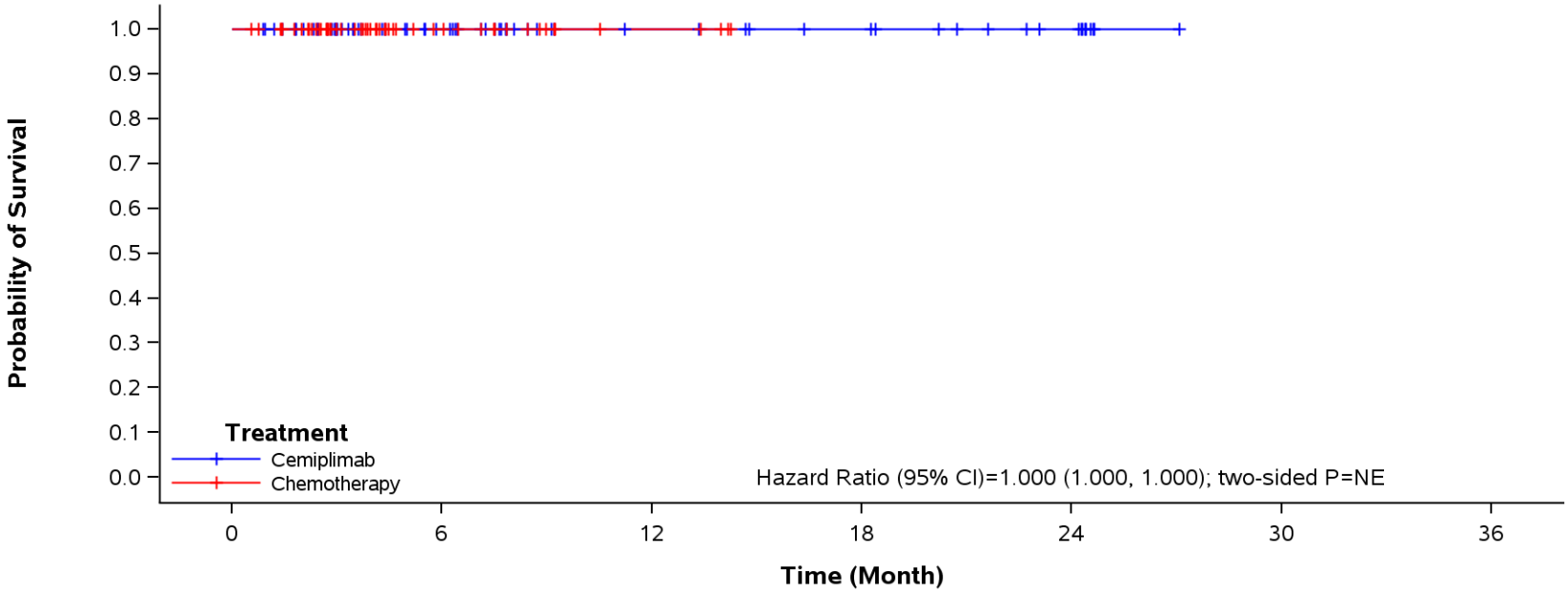

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Vascular disorders



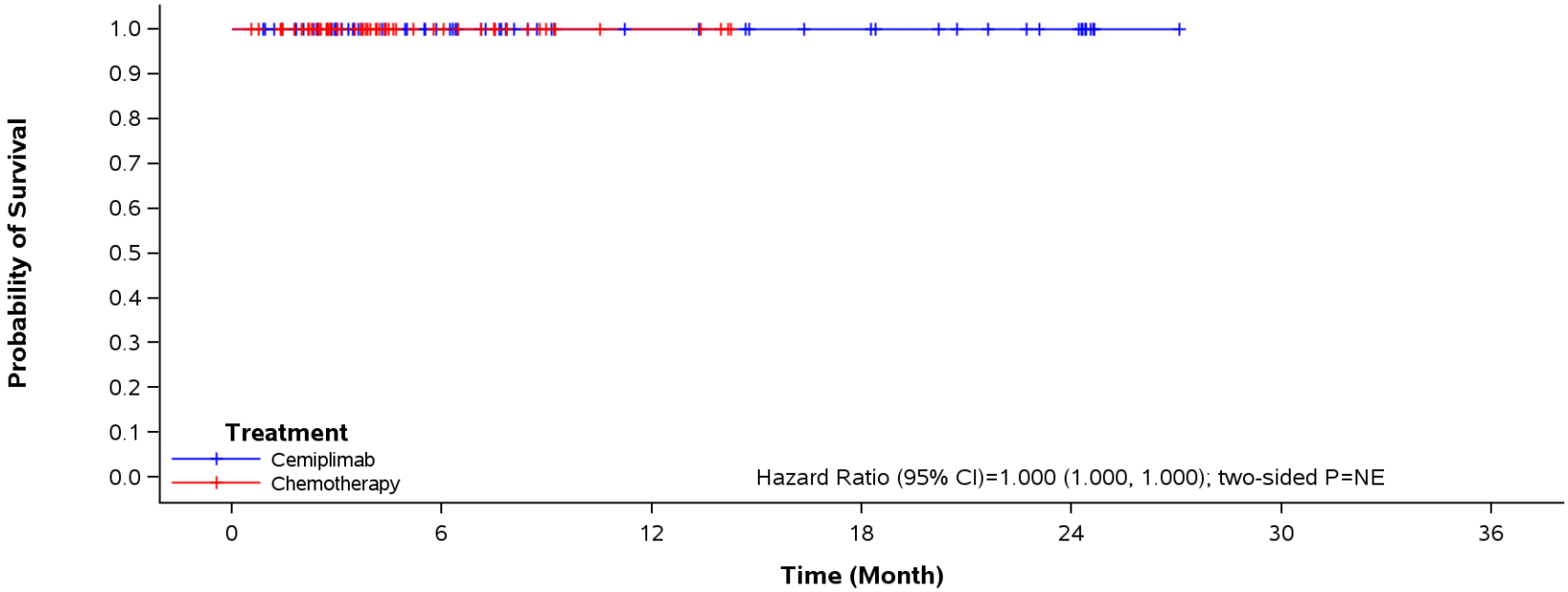

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 0
SOC: Vascular disorders
PT: Deep vein thrombosis




**Number of Subjects at risk**

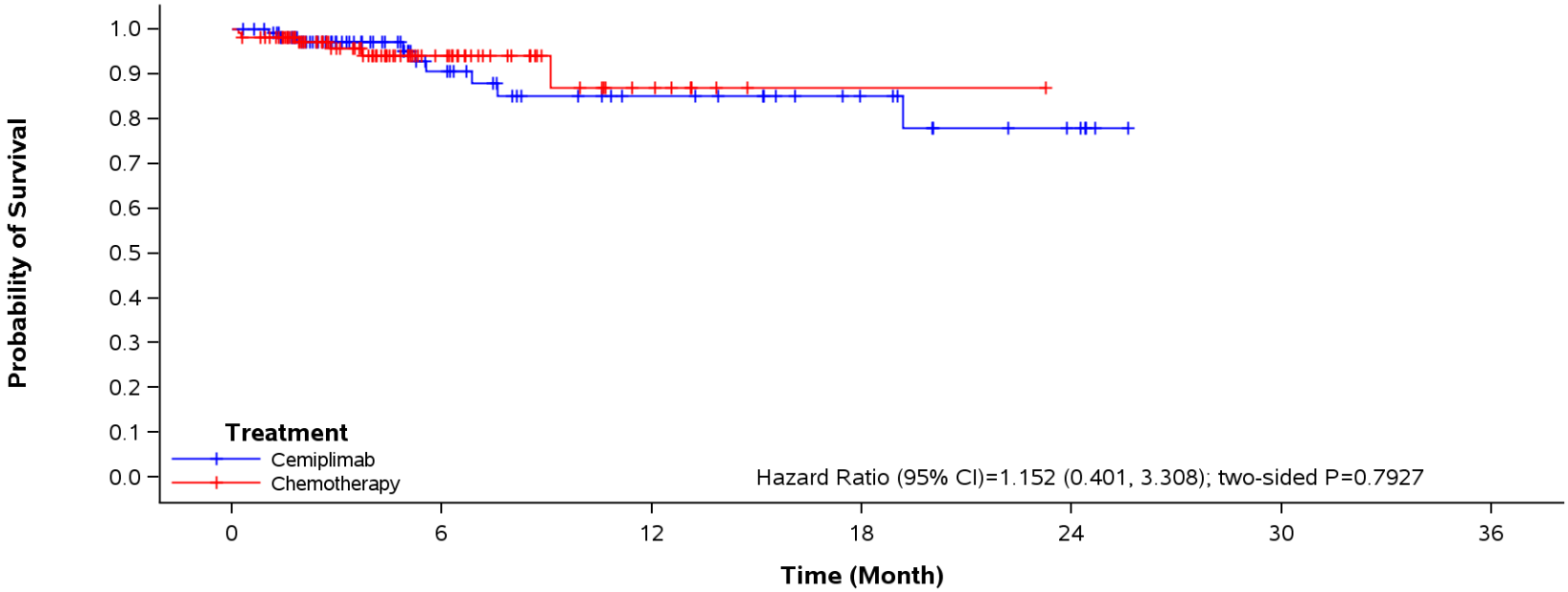
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 83 | 44 | 26 | 22 | 15 | 0 | 0 |
| Chemotherapy | 64 | 16 | 4 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

Number of patients with any TEAE leading to discontinuation




**Number of Subjects at risk**

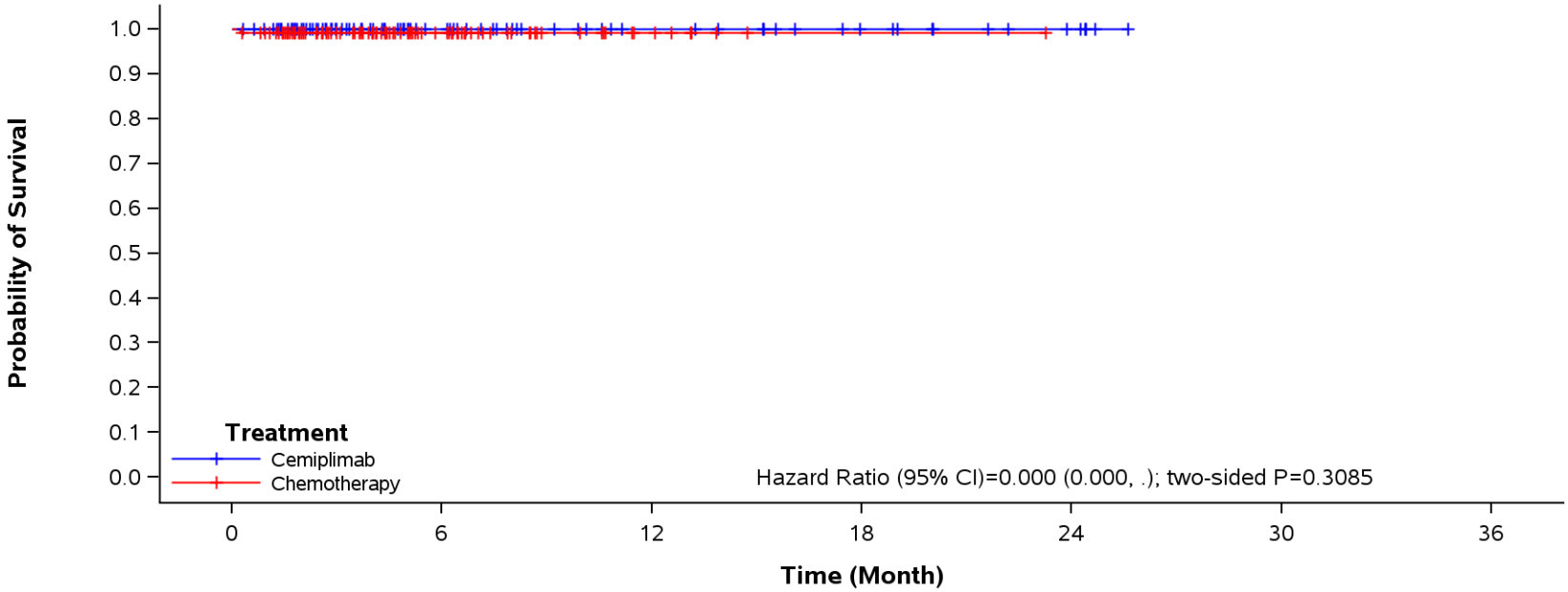
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 38 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 34 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders



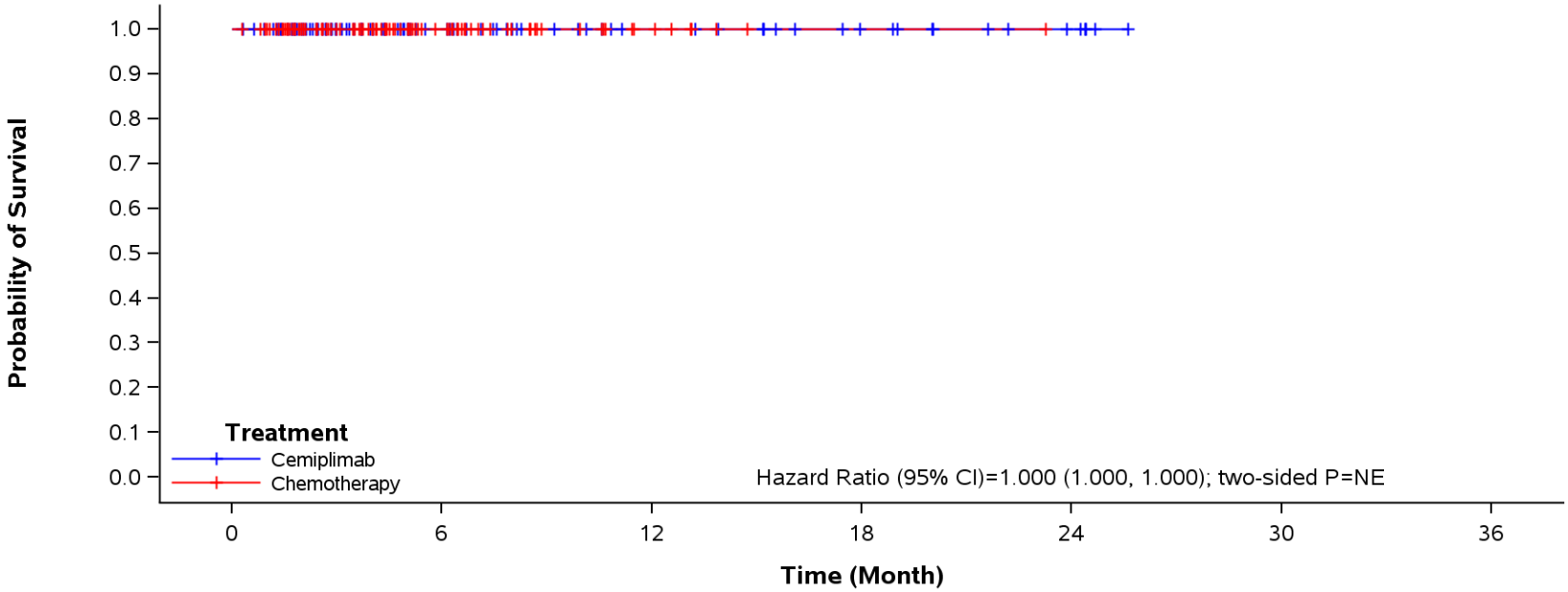

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Anaemia



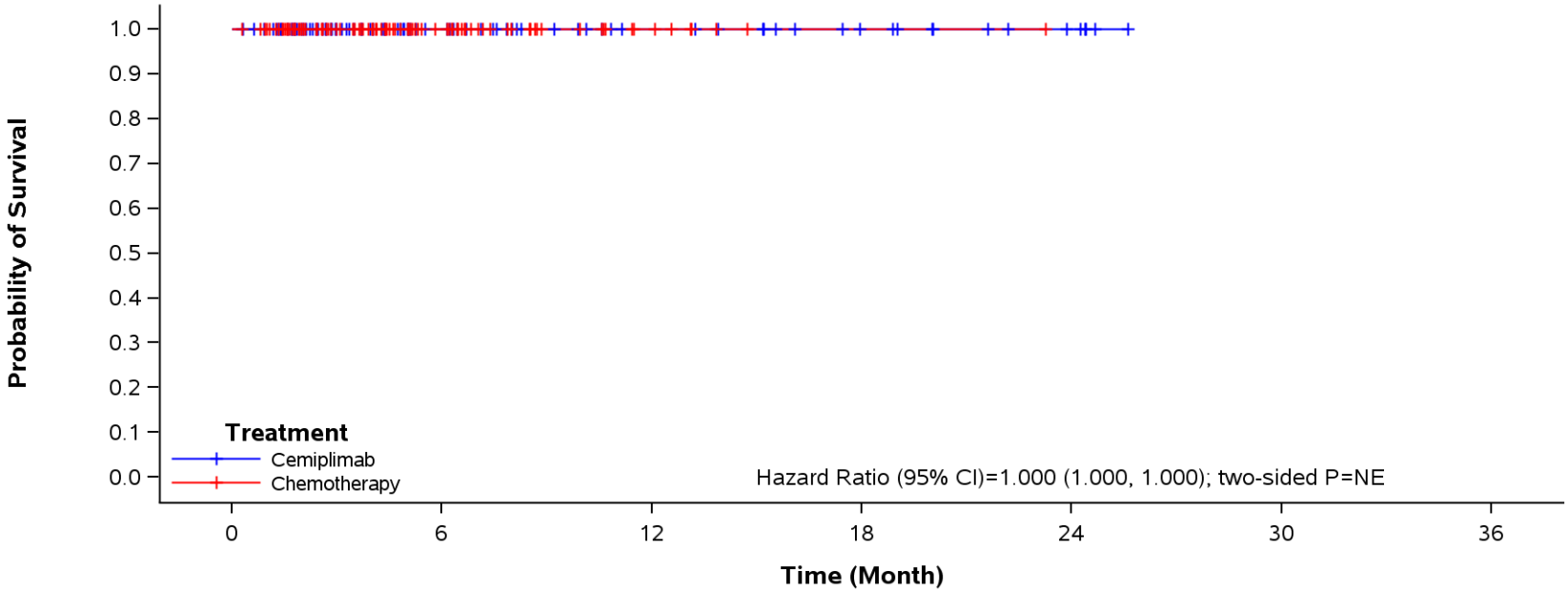

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



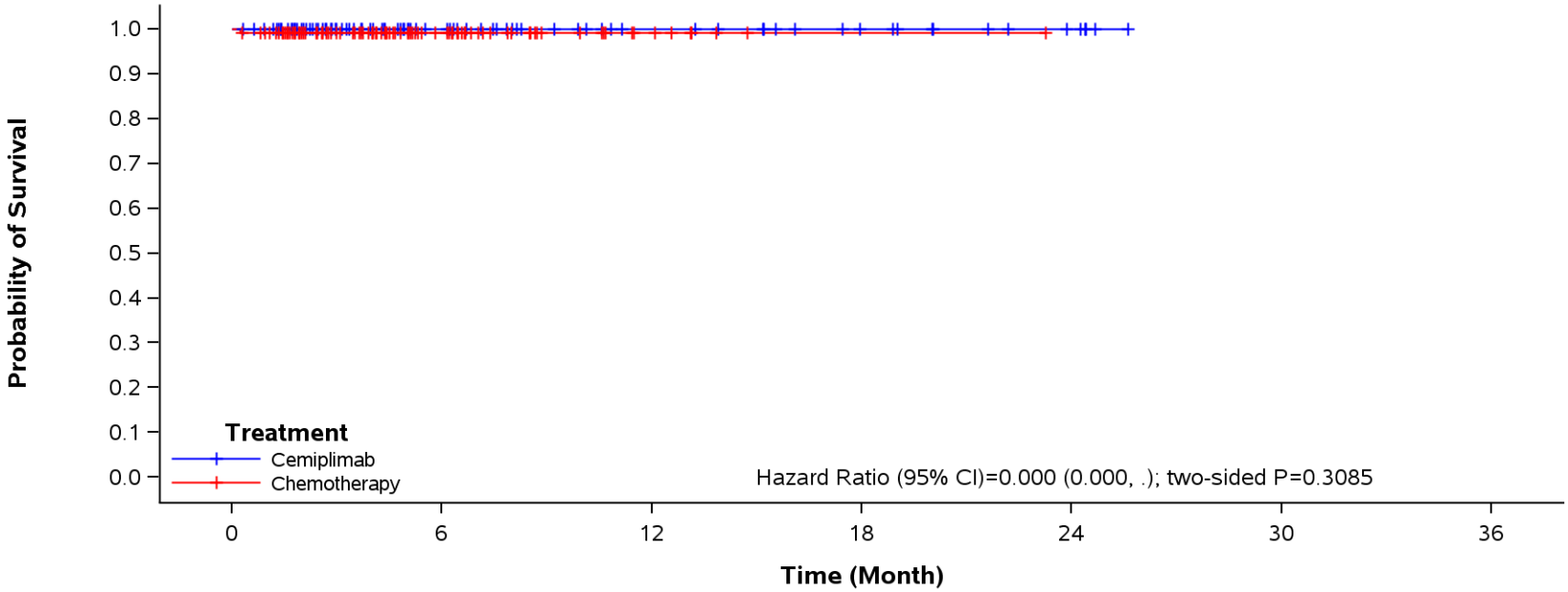

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Neutropenia



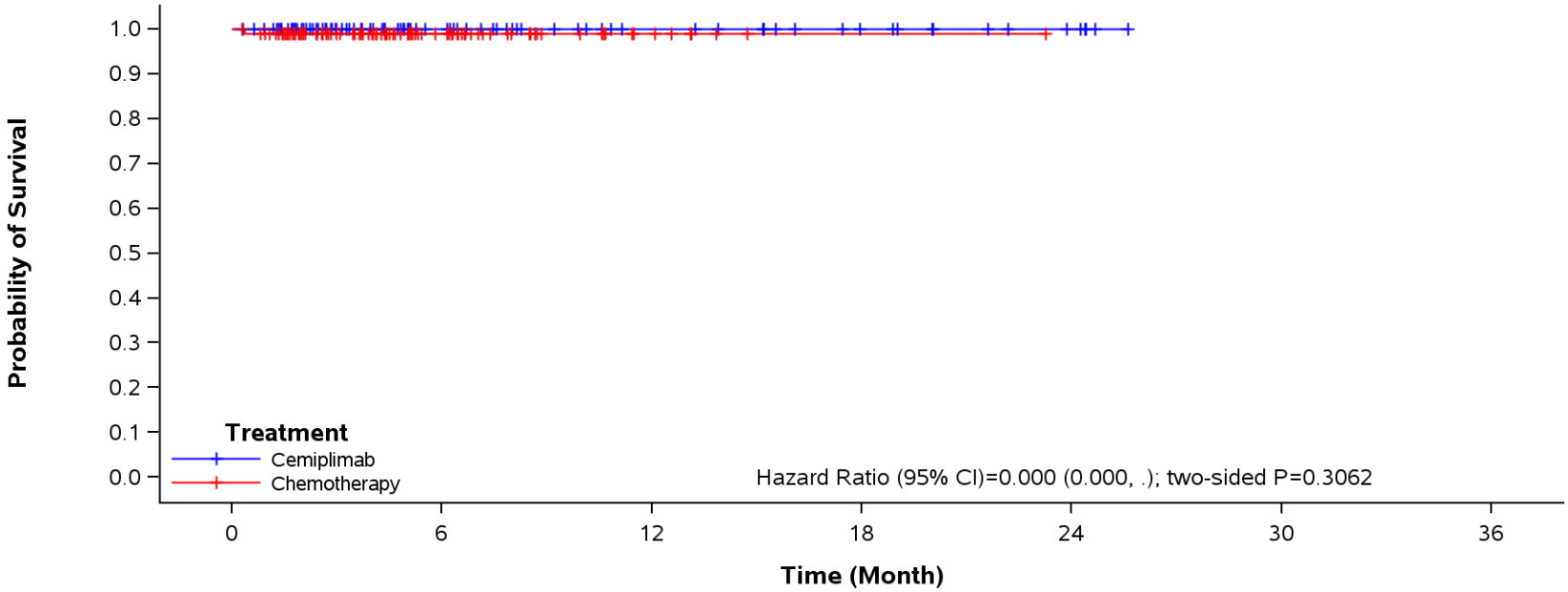

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



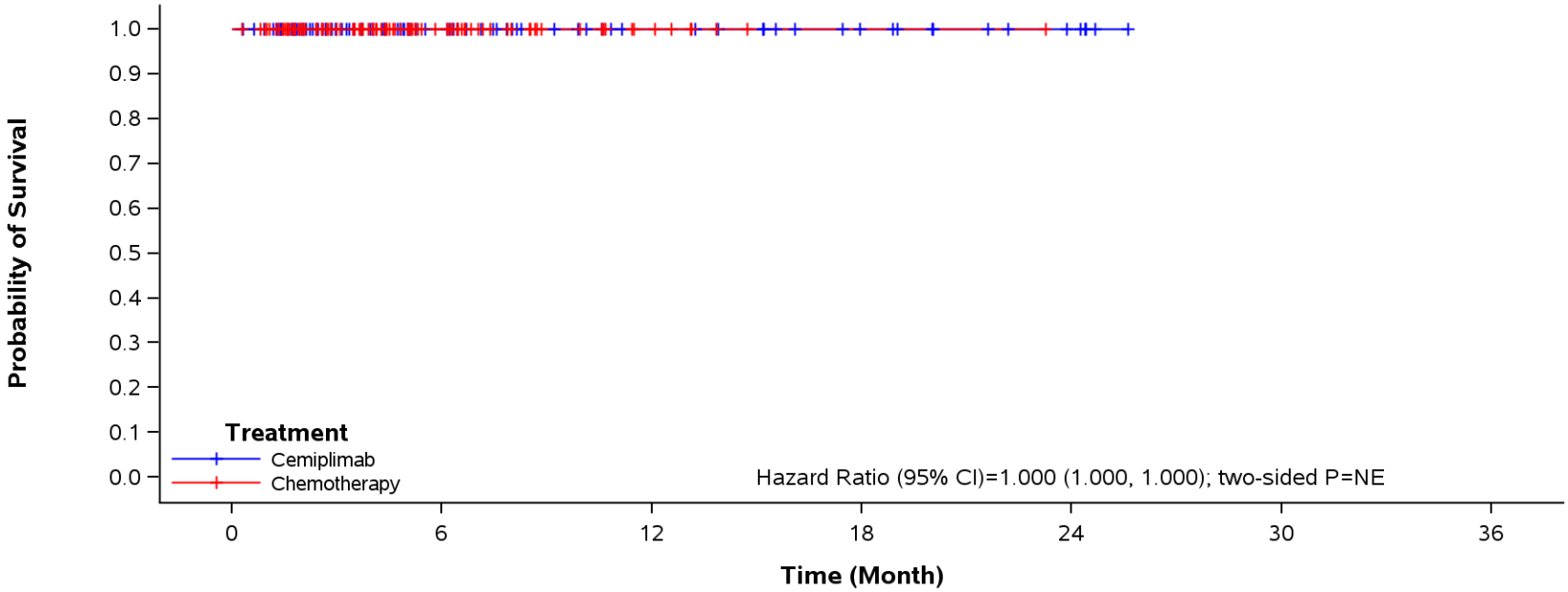

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Cardiac disorders



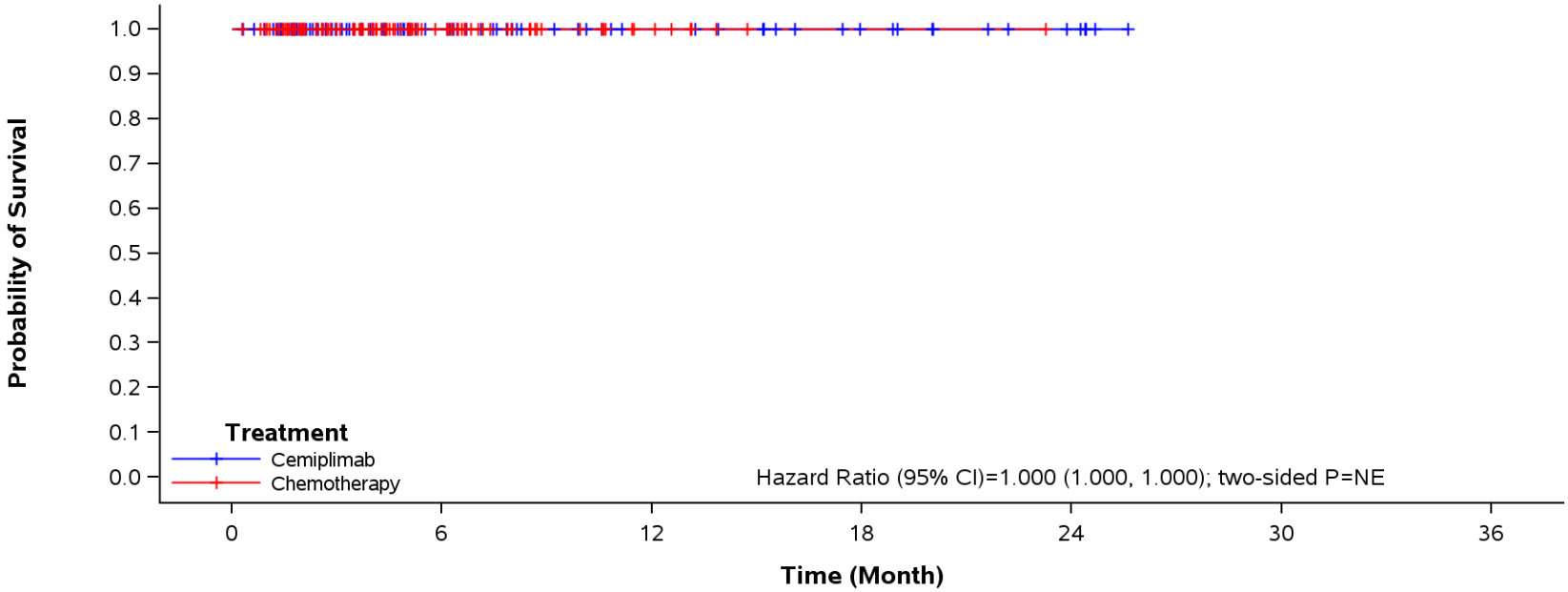

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Cardiac disorders
PT: Autoimmune pericarditis



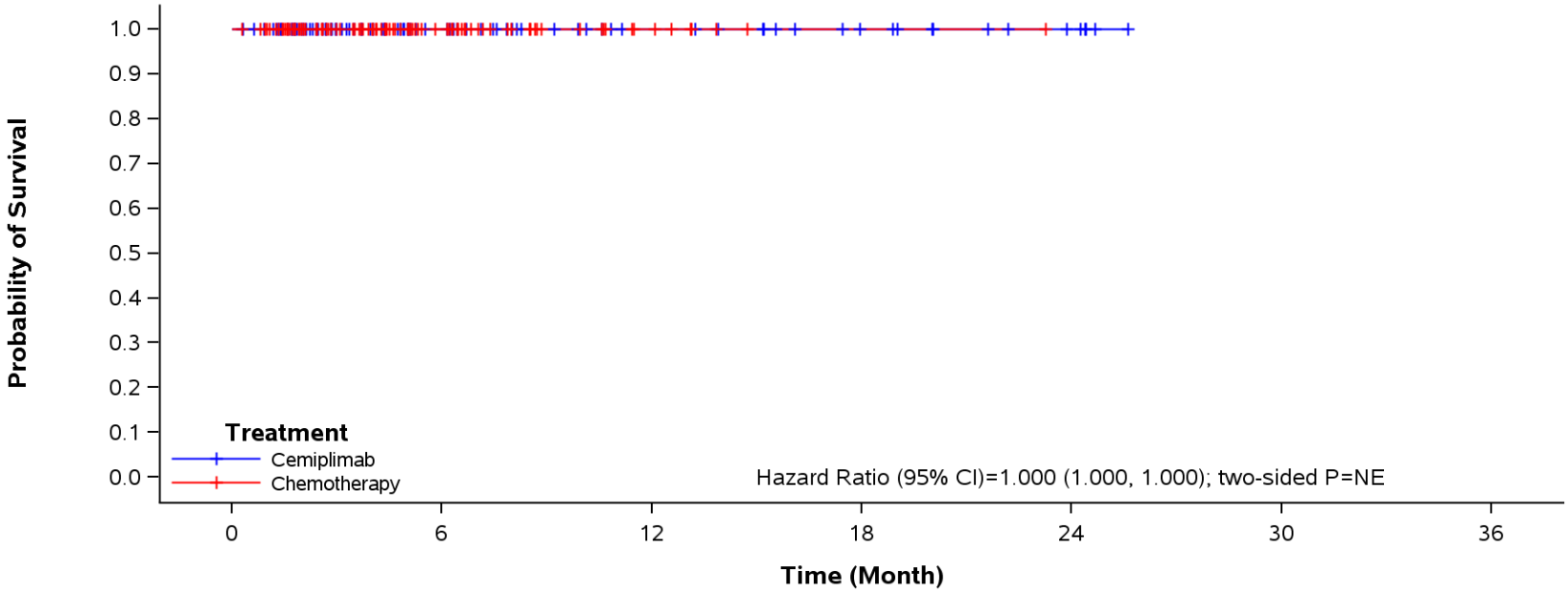

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Endocrine disorders



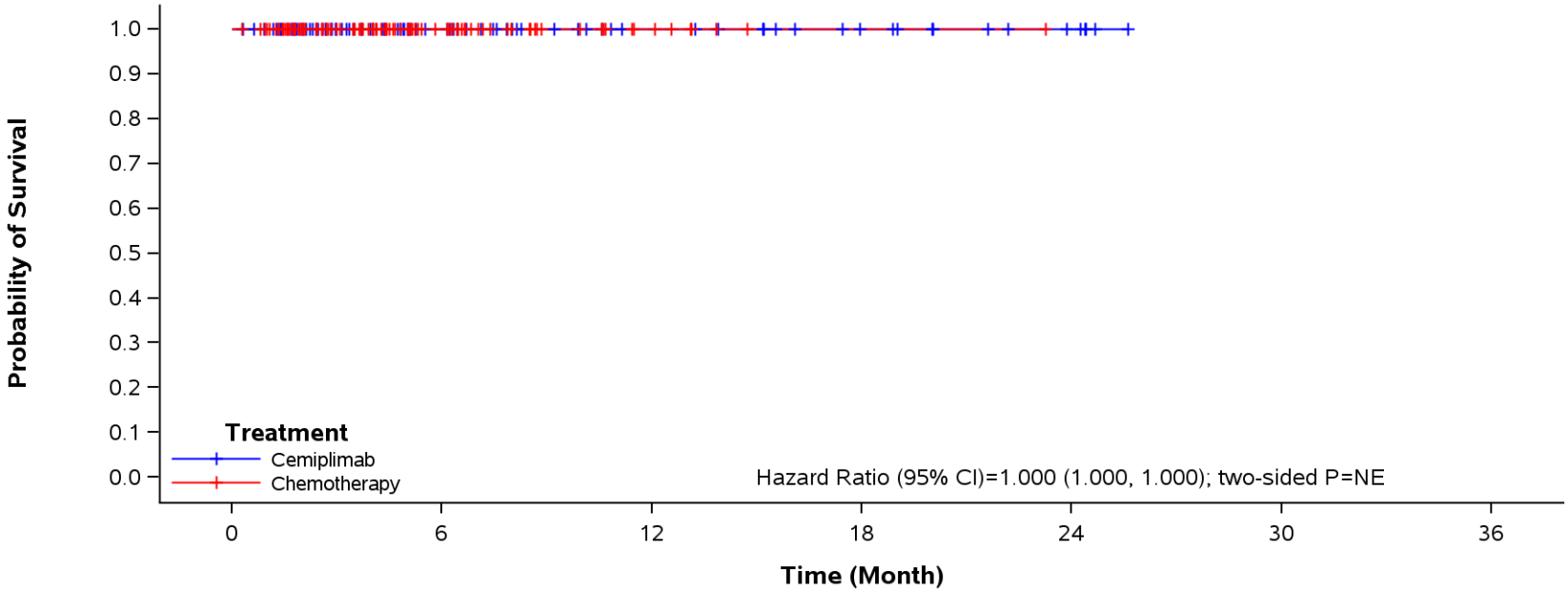

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Endocrine disorders
PT: Hypothyroidism



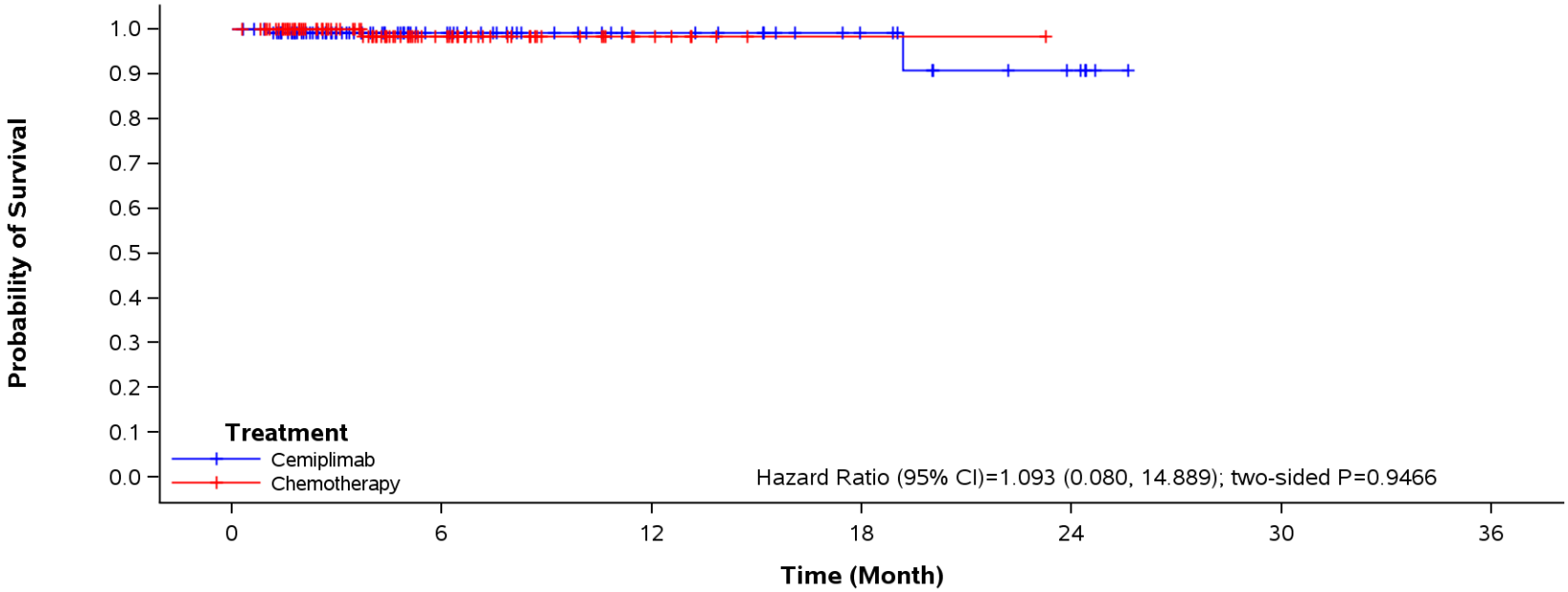

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders



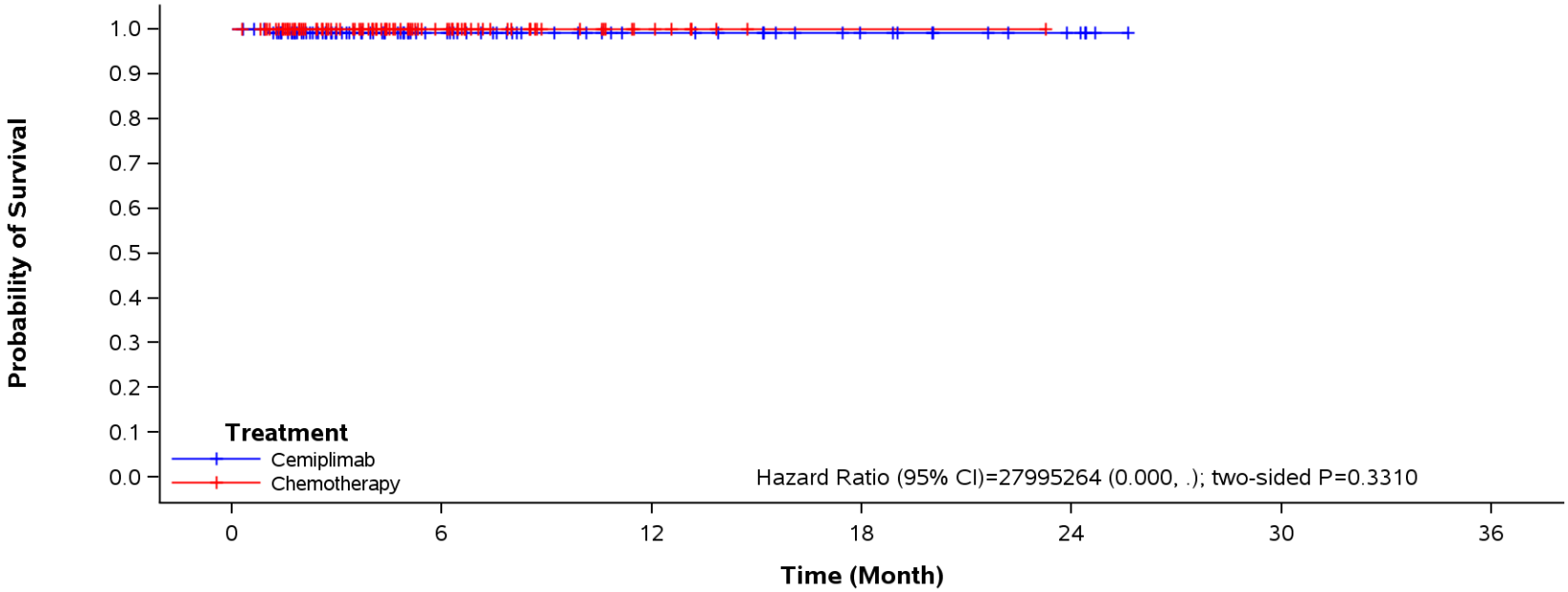

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders
PT: Colitis



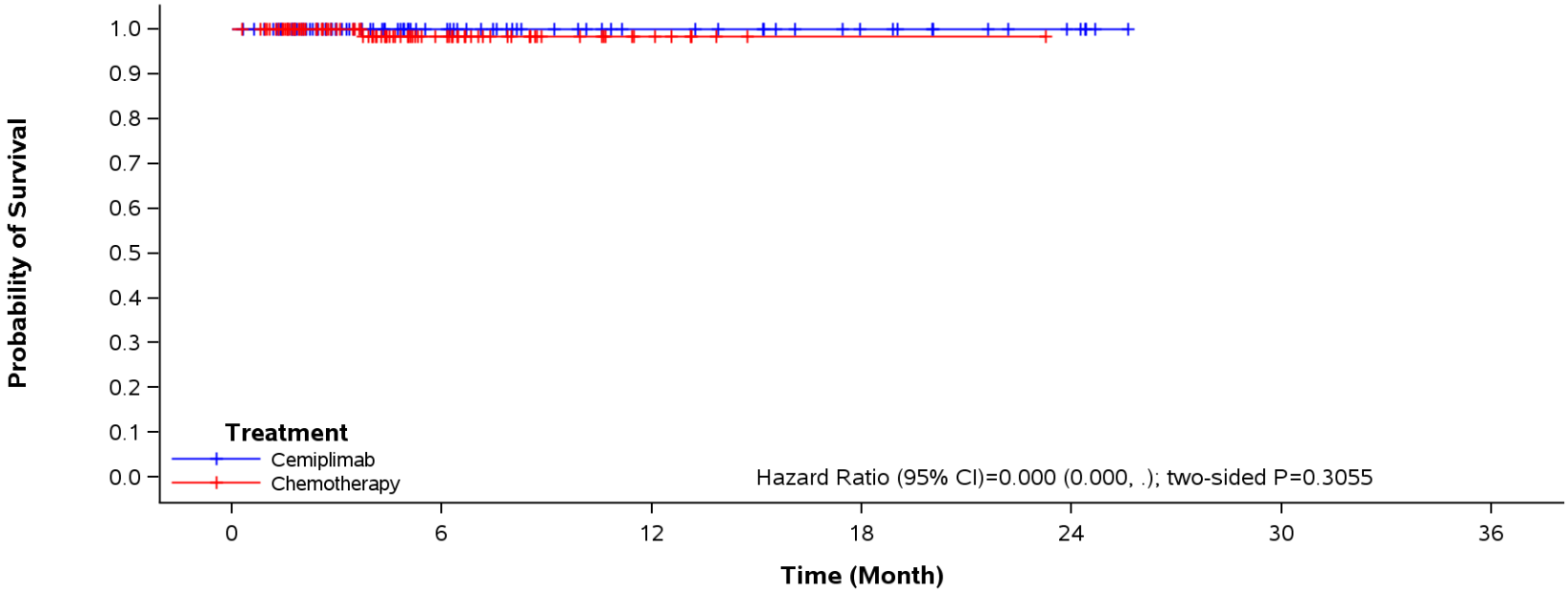

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders
PT: Diverticular perforation



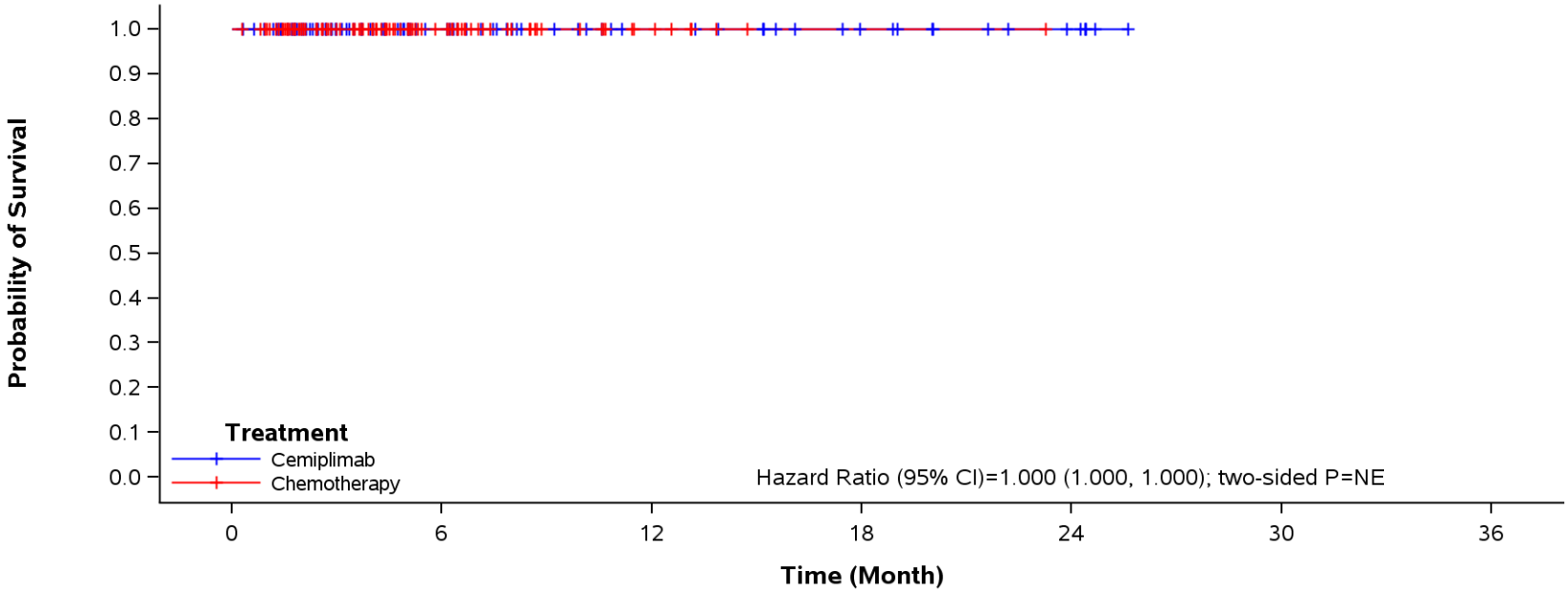

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders
PT: Pancreatic mass



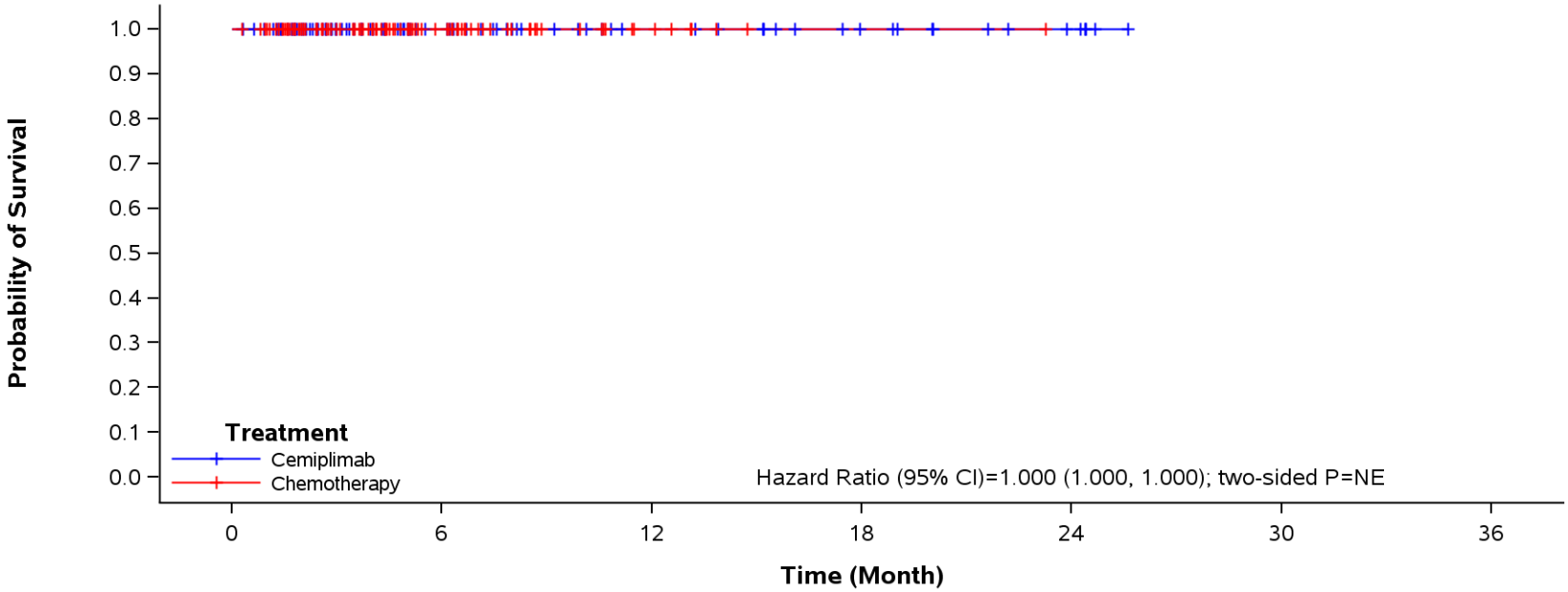

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



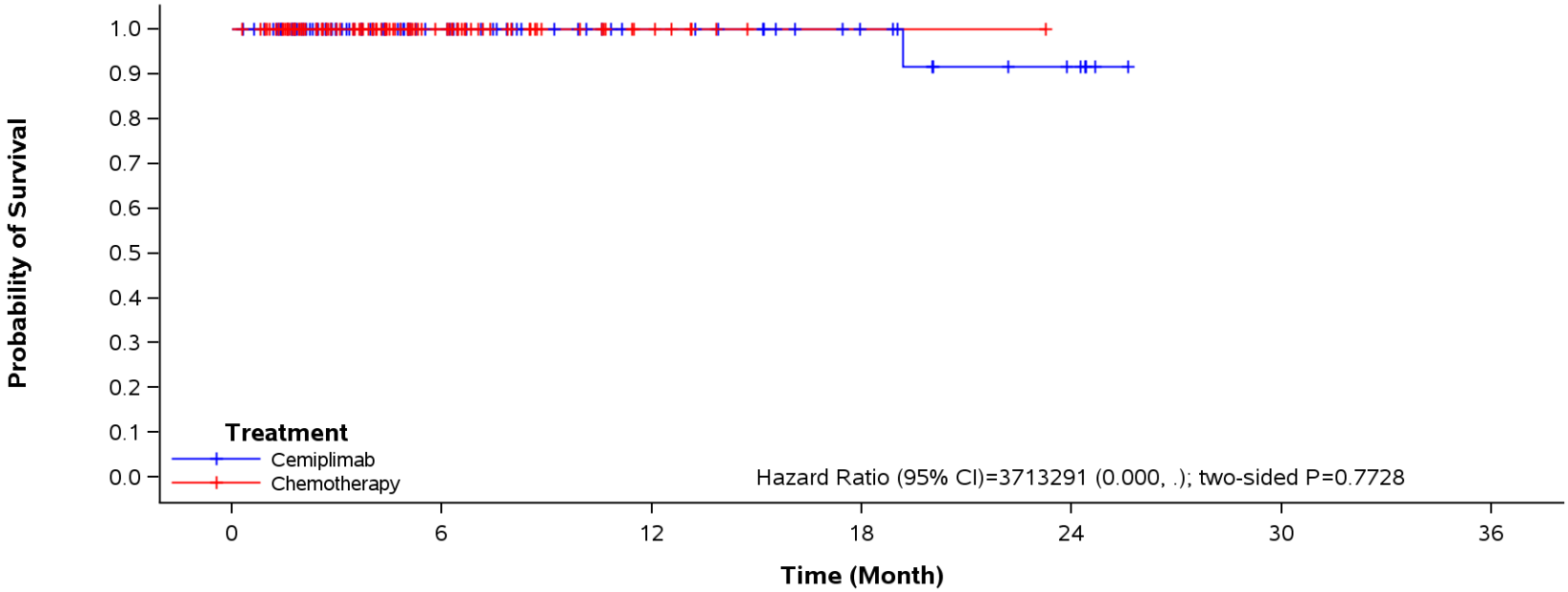

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Gastrointestinal disorders
PT: Proctalgia




**Number of Subjects at risk**

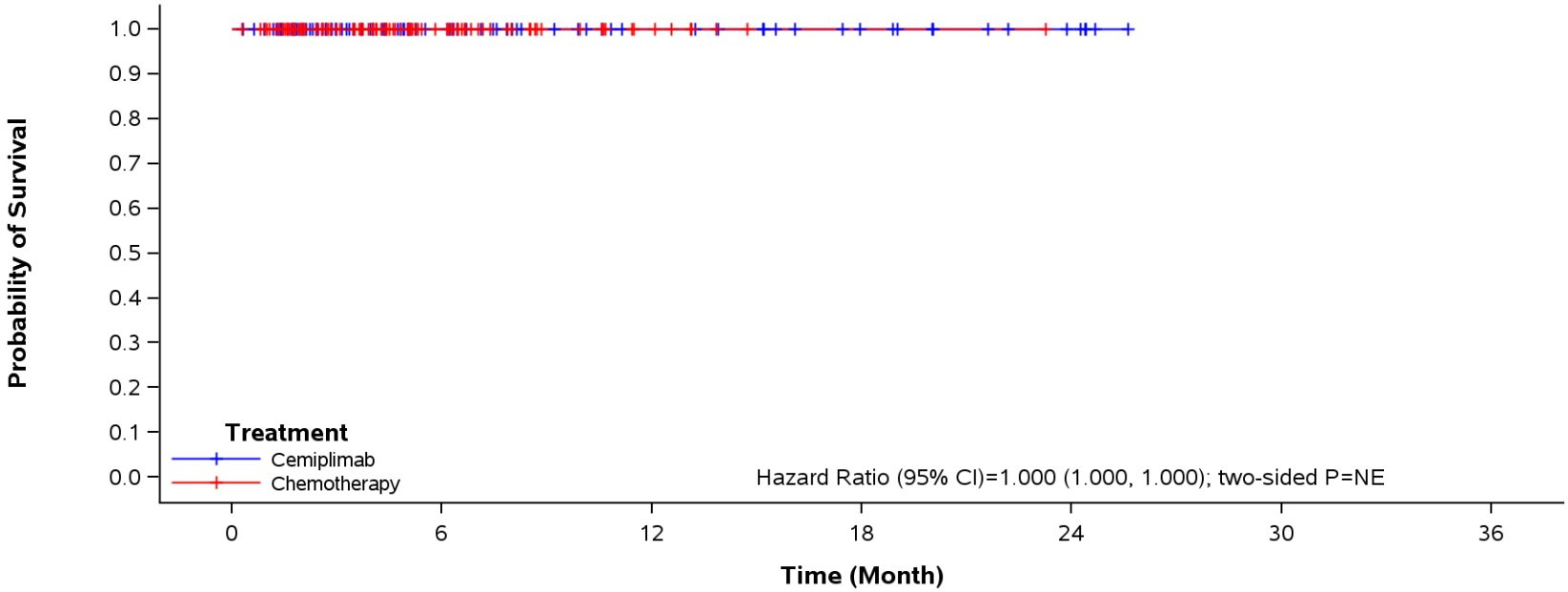
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

SOC: General disorders and administration site conditions




**Number of Subjects at risk**

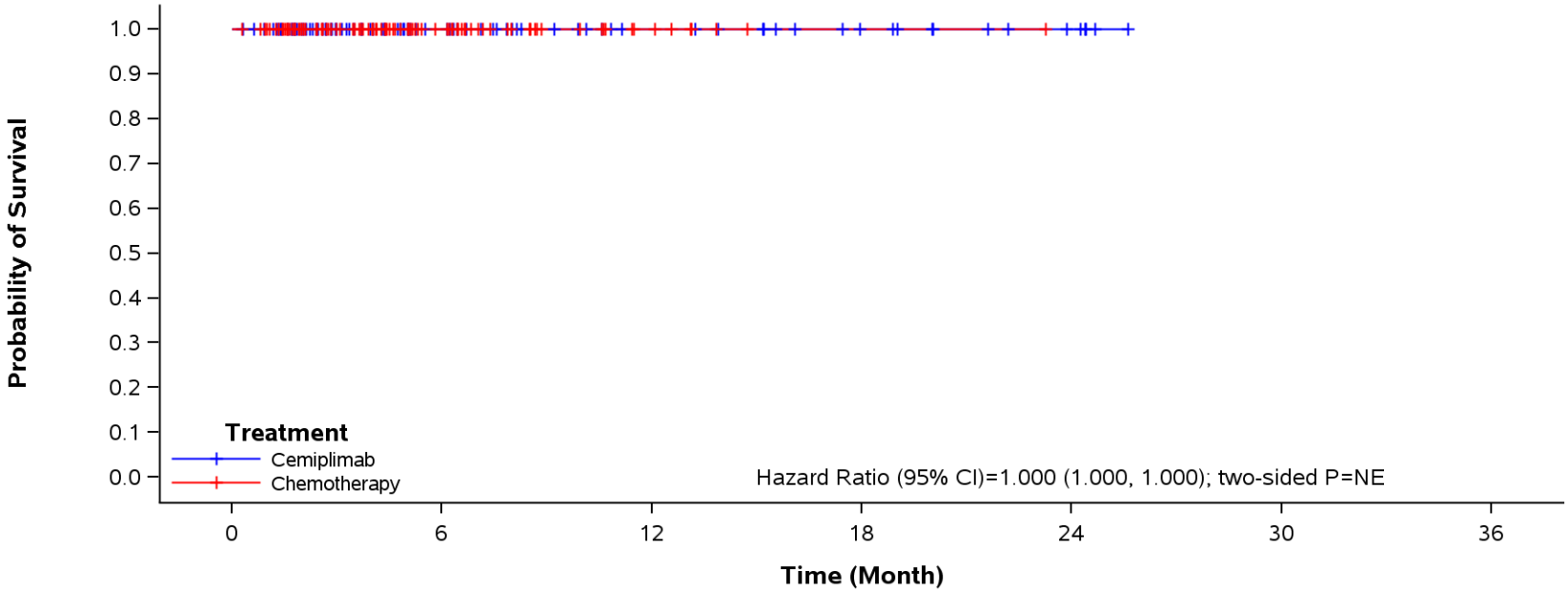
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: General disorders and administration site conditions
PT: Malaise



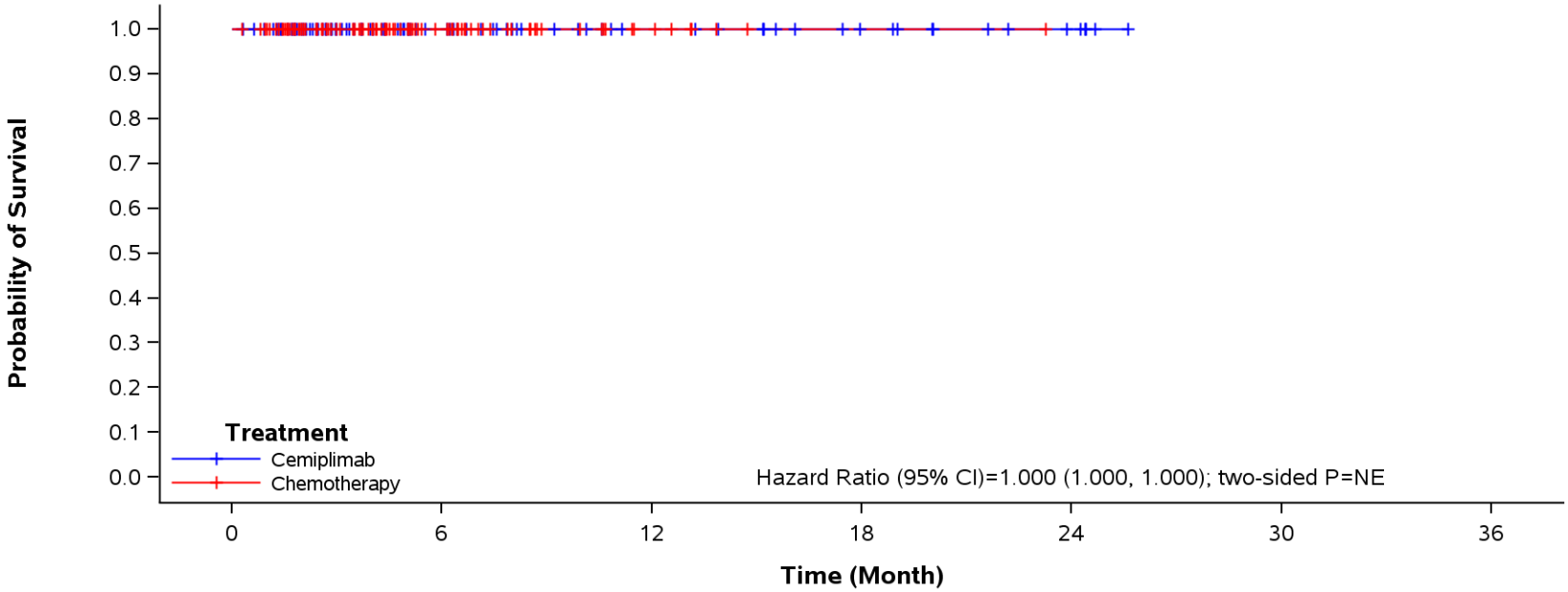

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



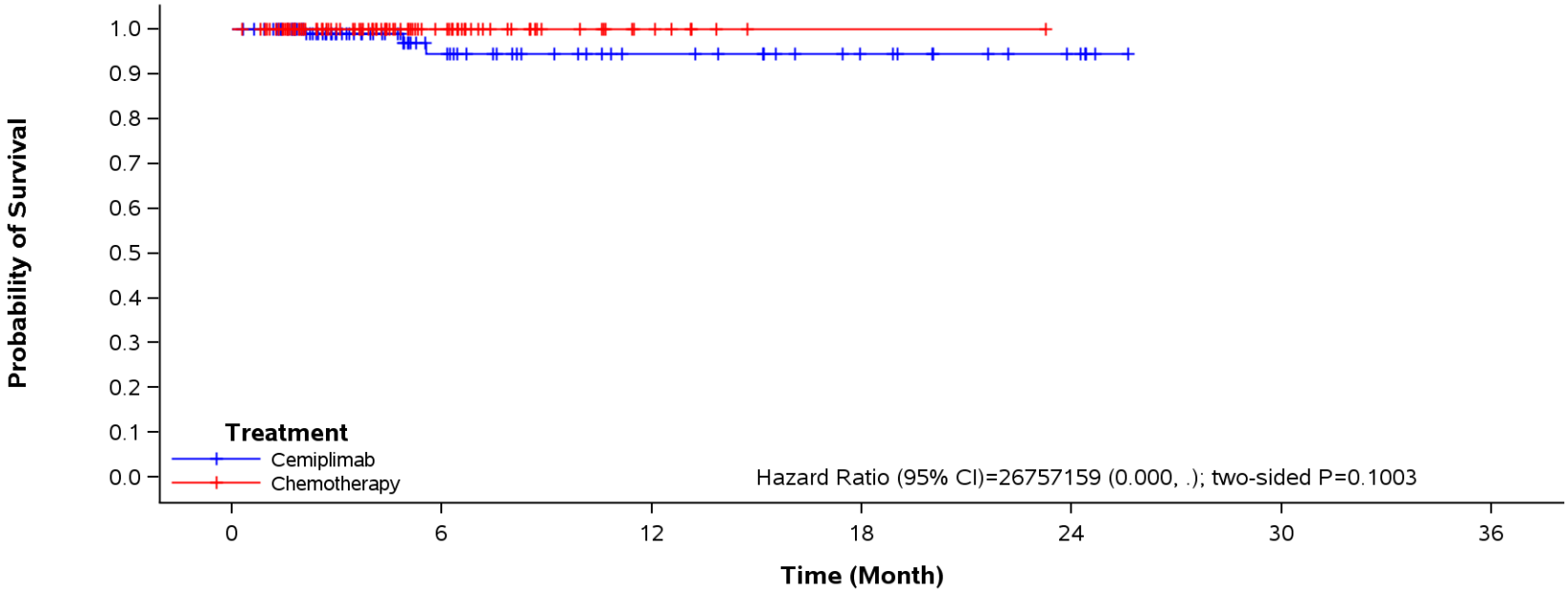

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Hepatobiliary disorders



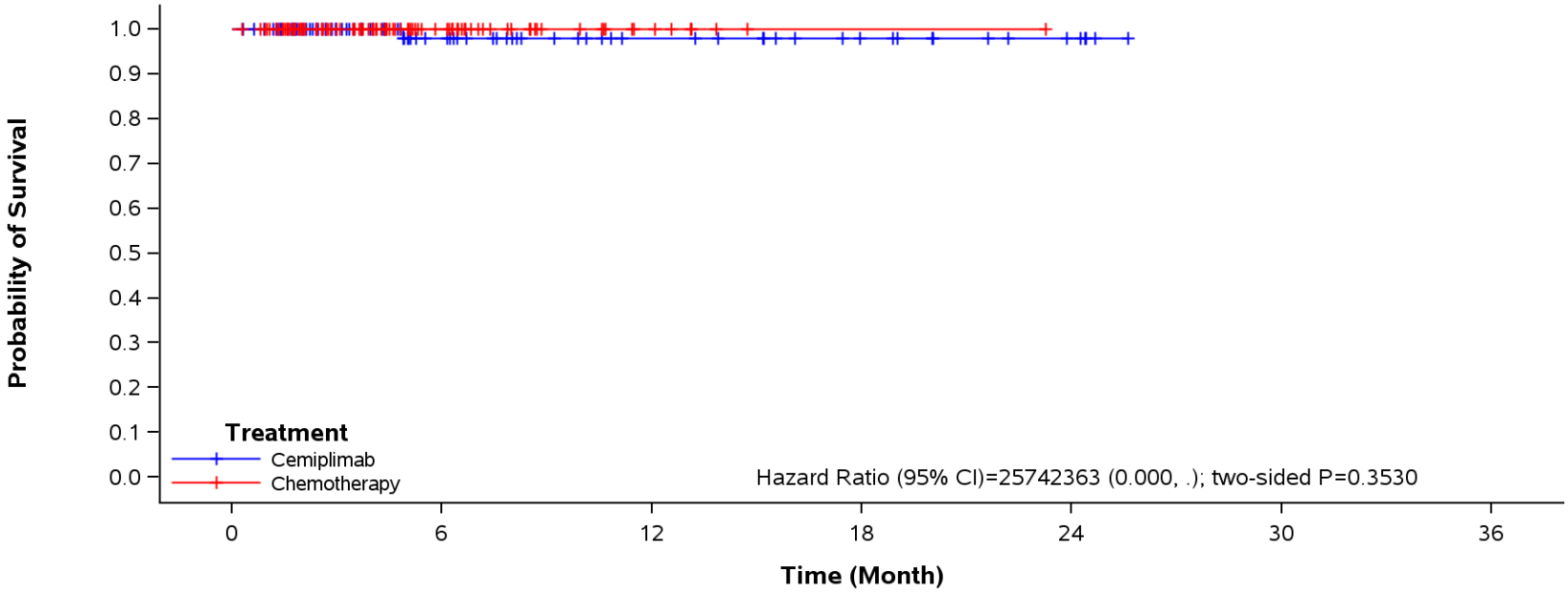

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 39 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



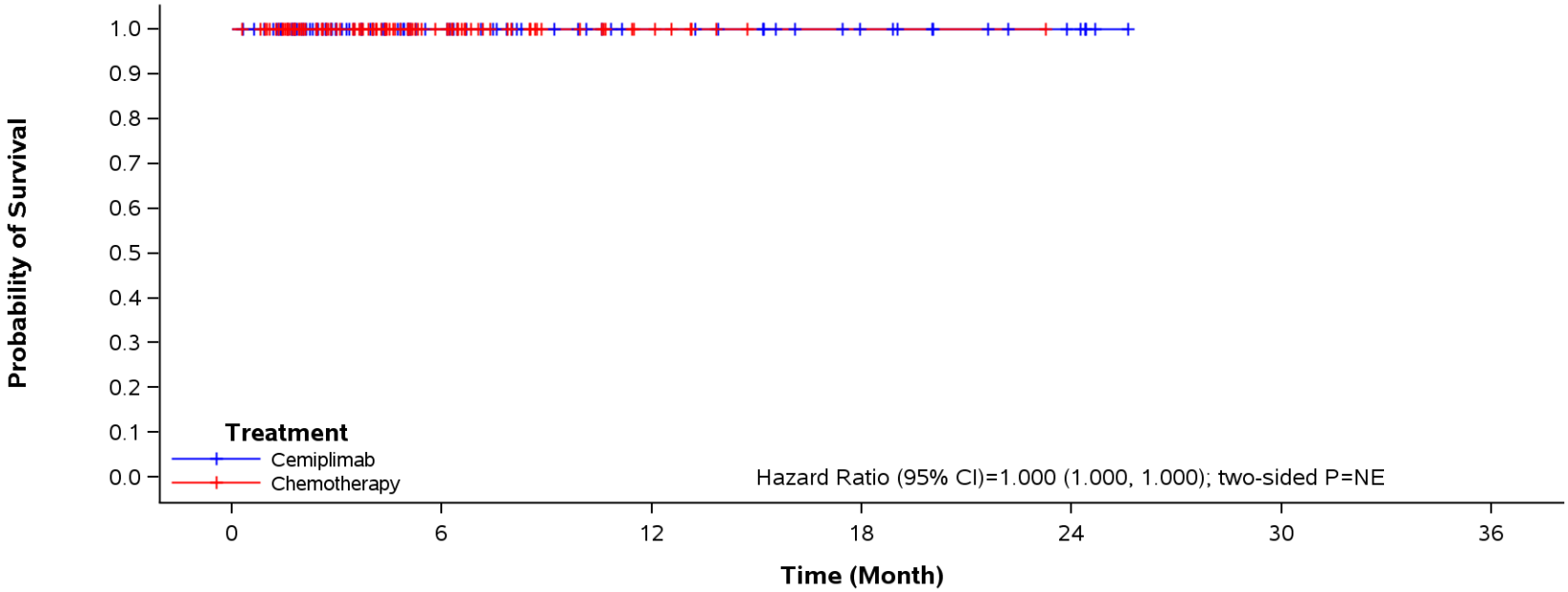

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



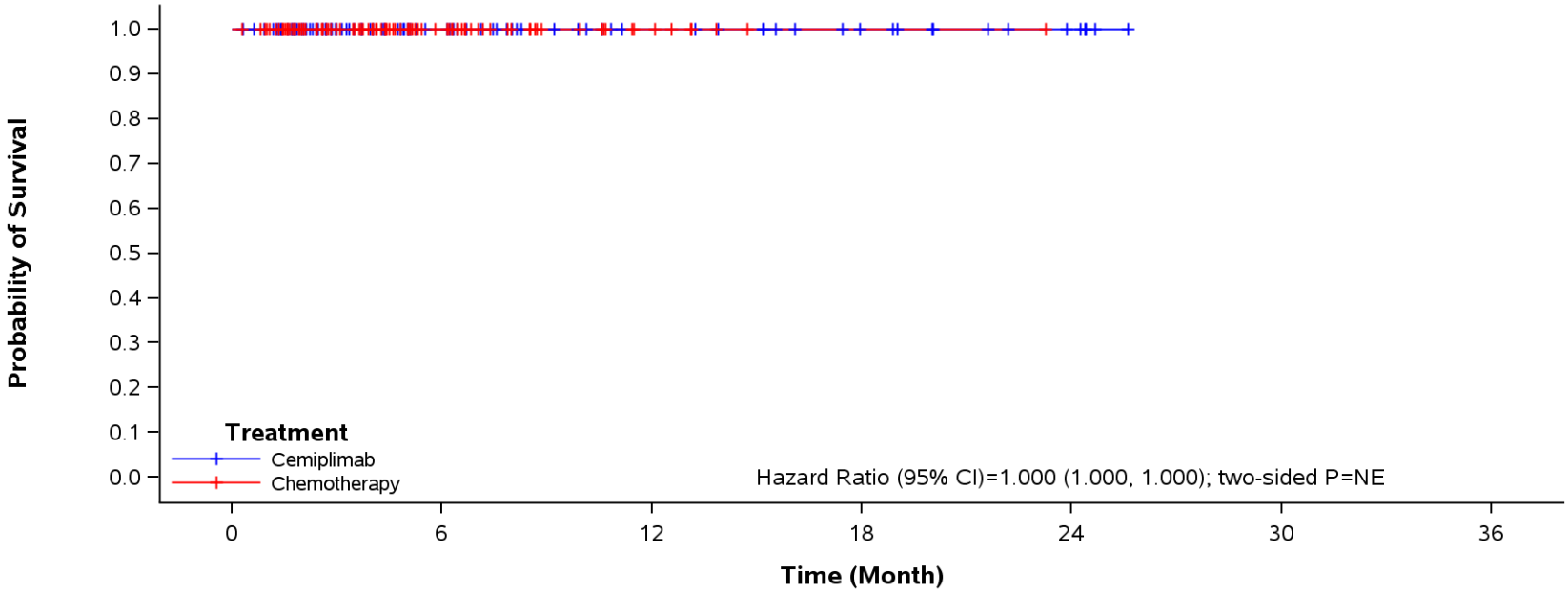

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Hepatobiliary disorders
PT: Hepatitis



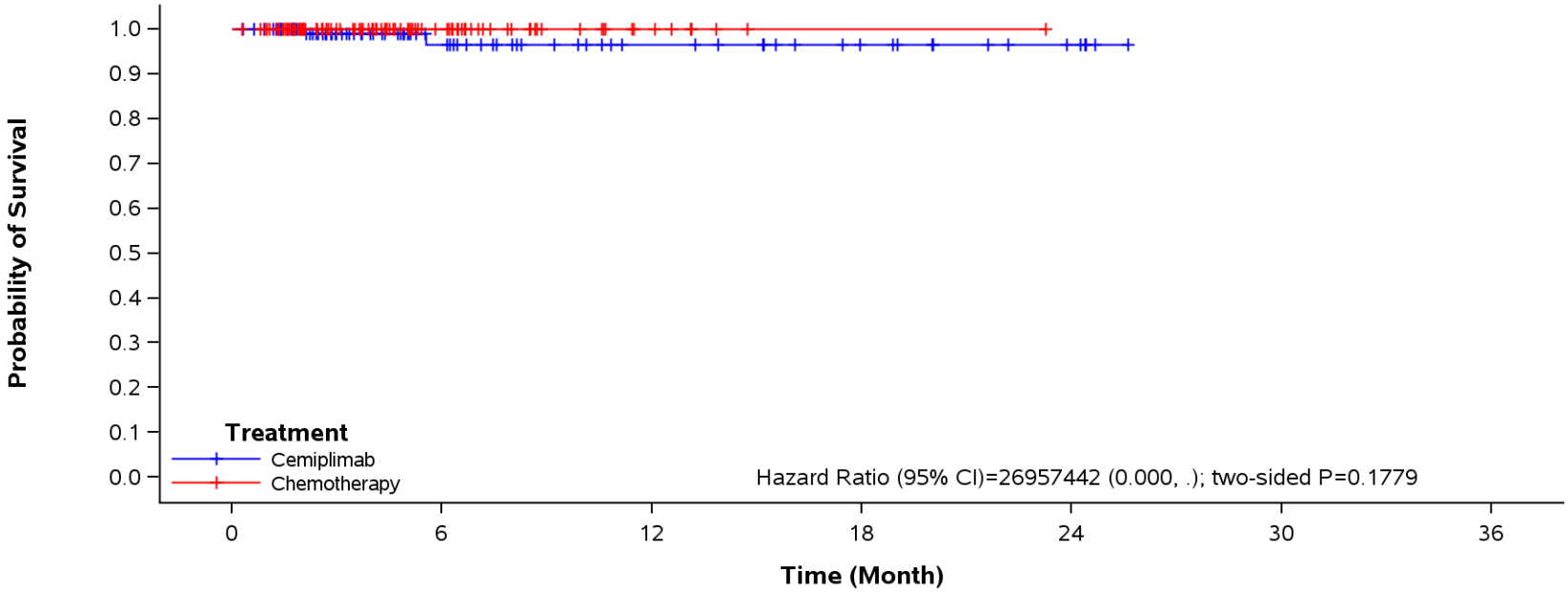

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



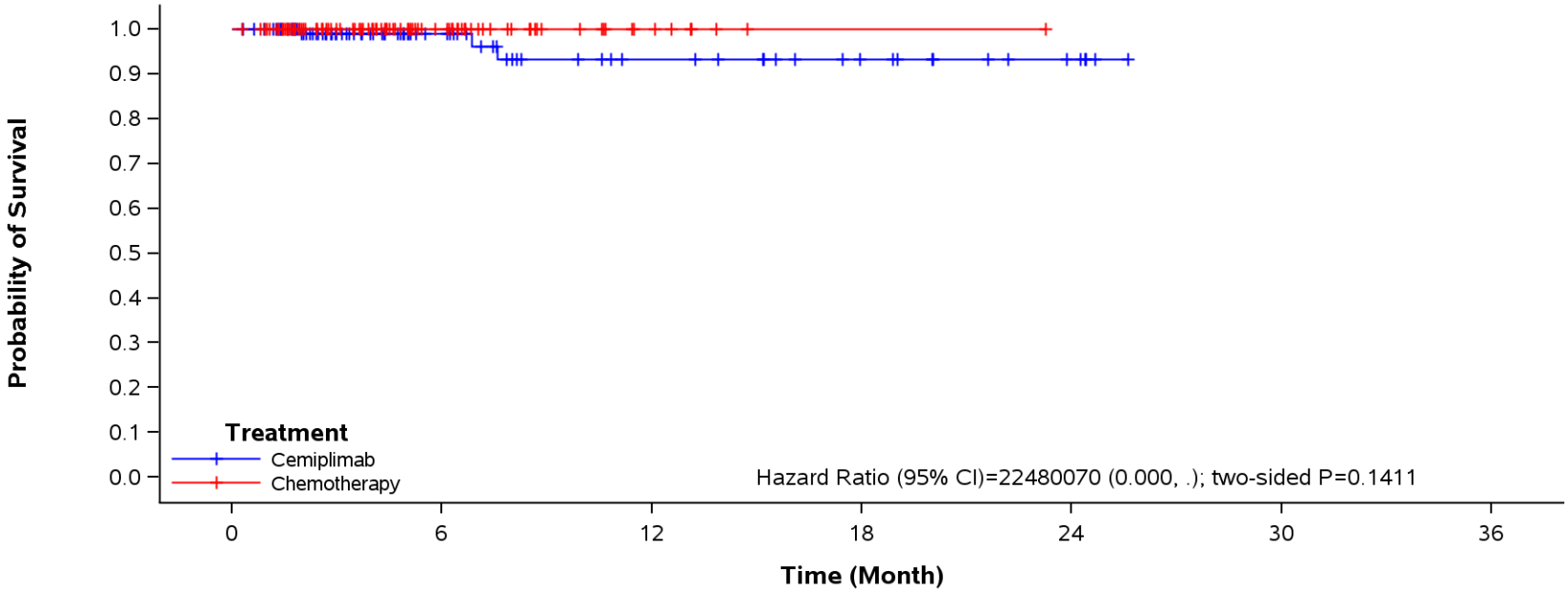

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Infections and infestations



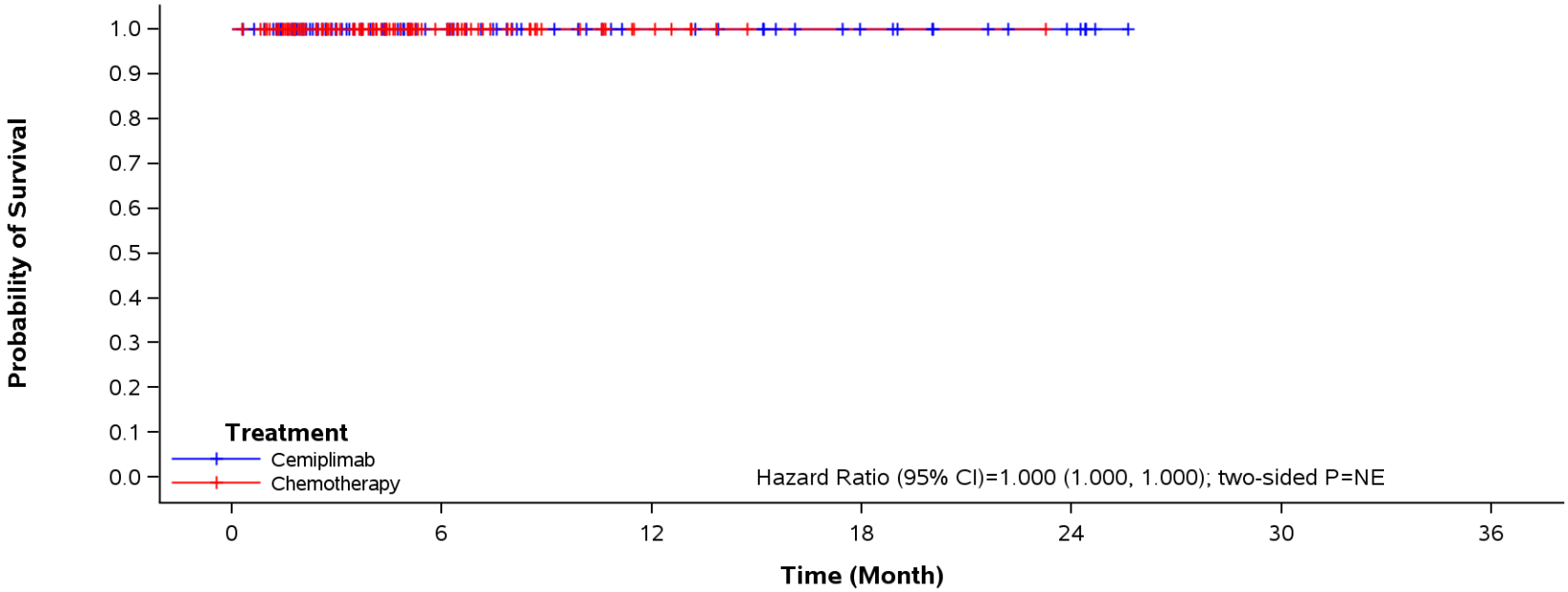

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Infections and infestations
PT: COVID-19 pneumonia



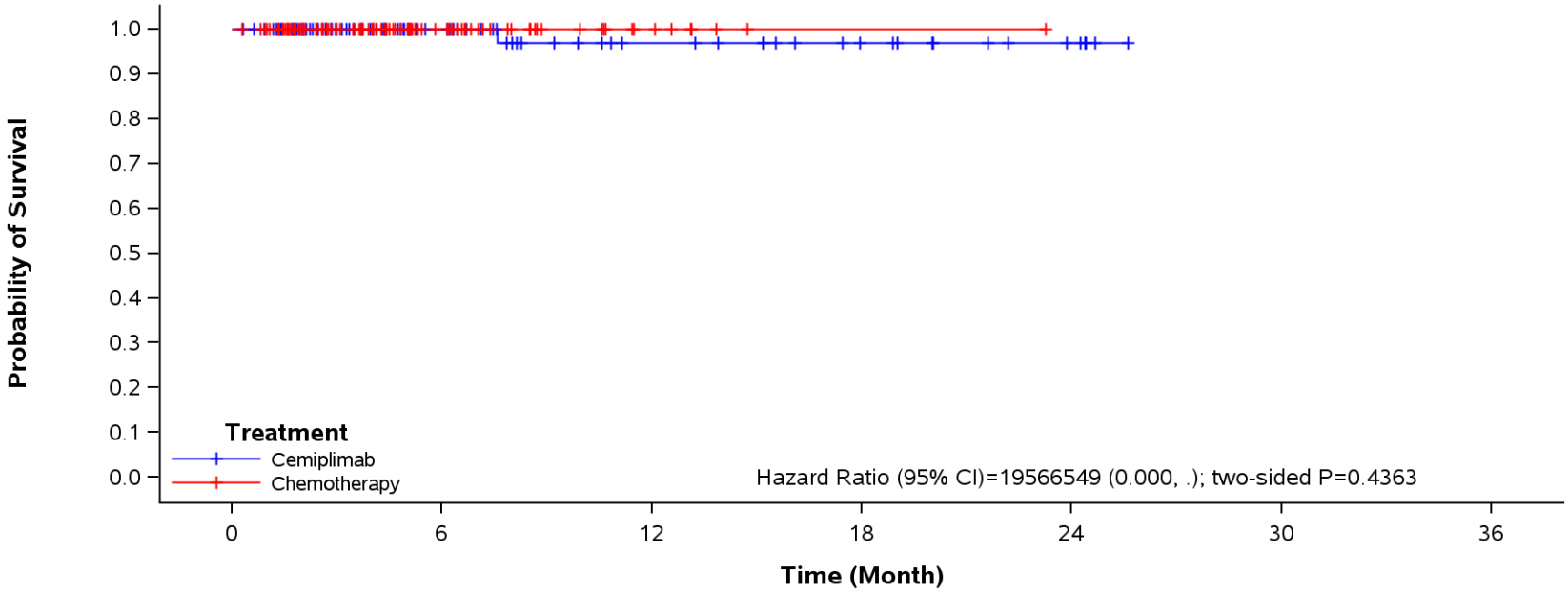

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Infections and infestations
PT: Gastroenteritis



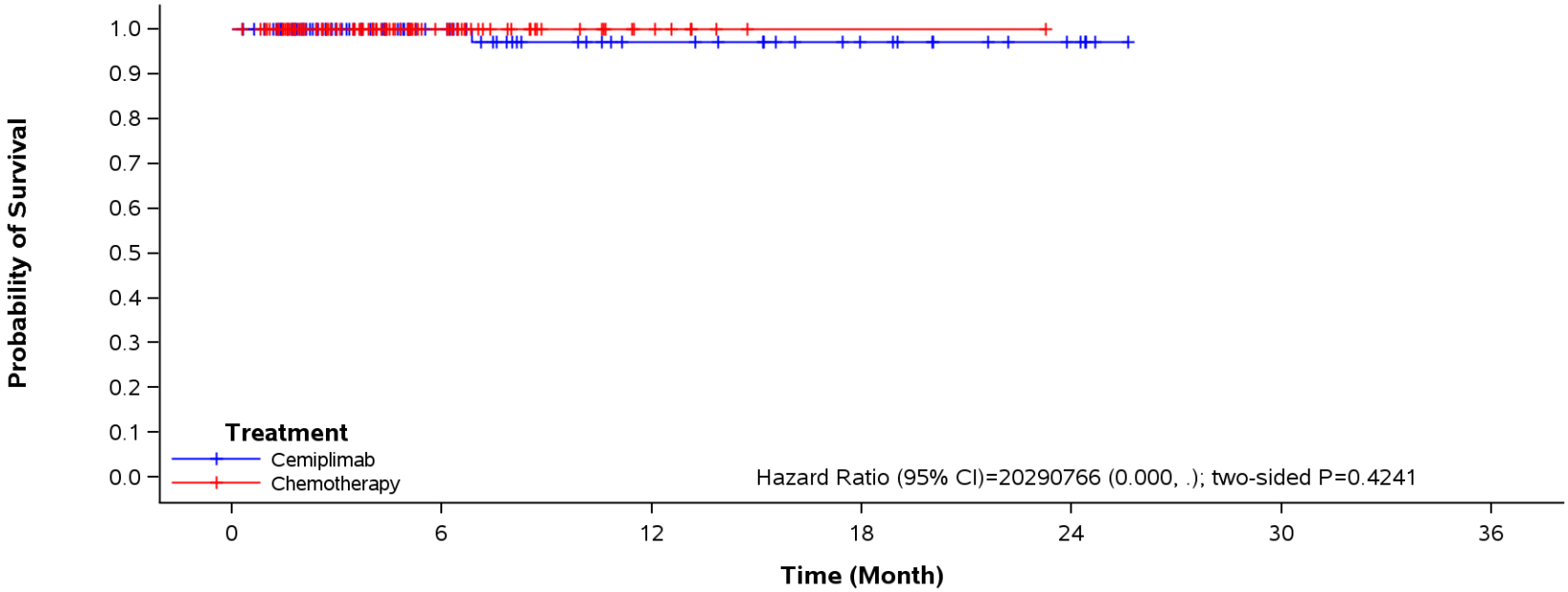

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Infections and infestations
PT: Pelvic abscess



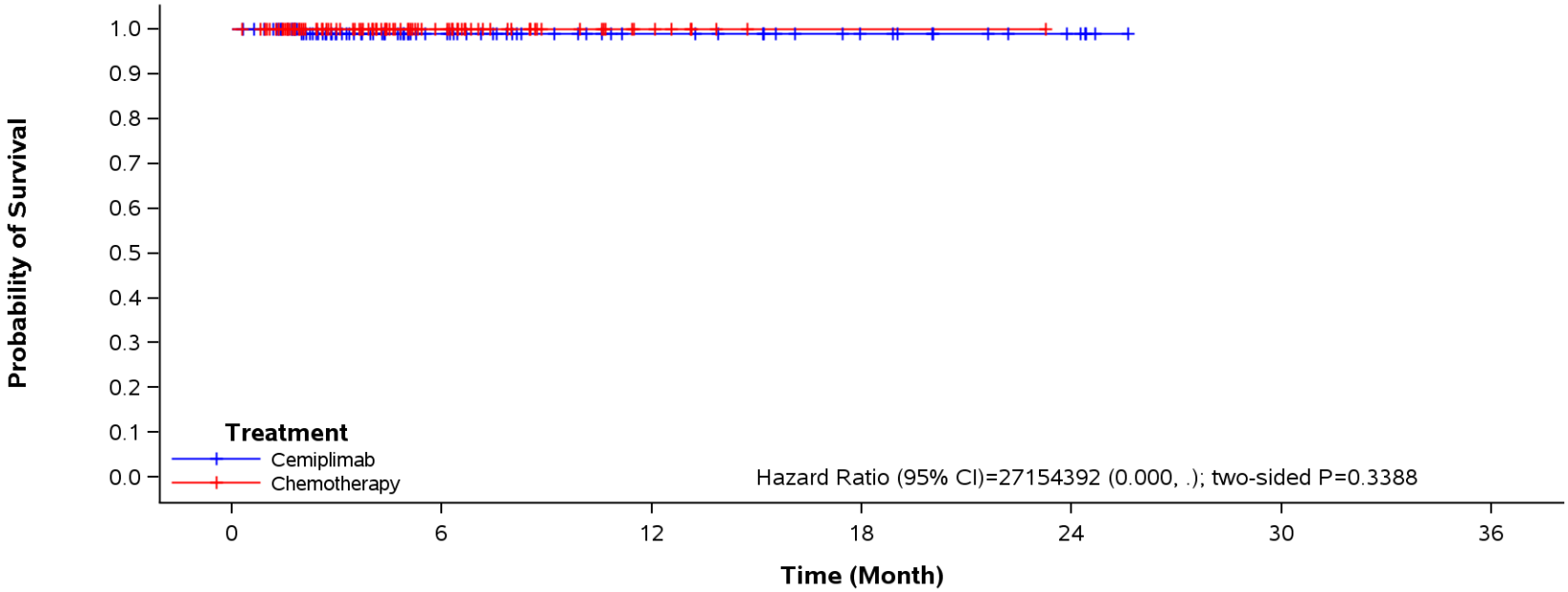

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Infections and infestations
PT: Peritonitis



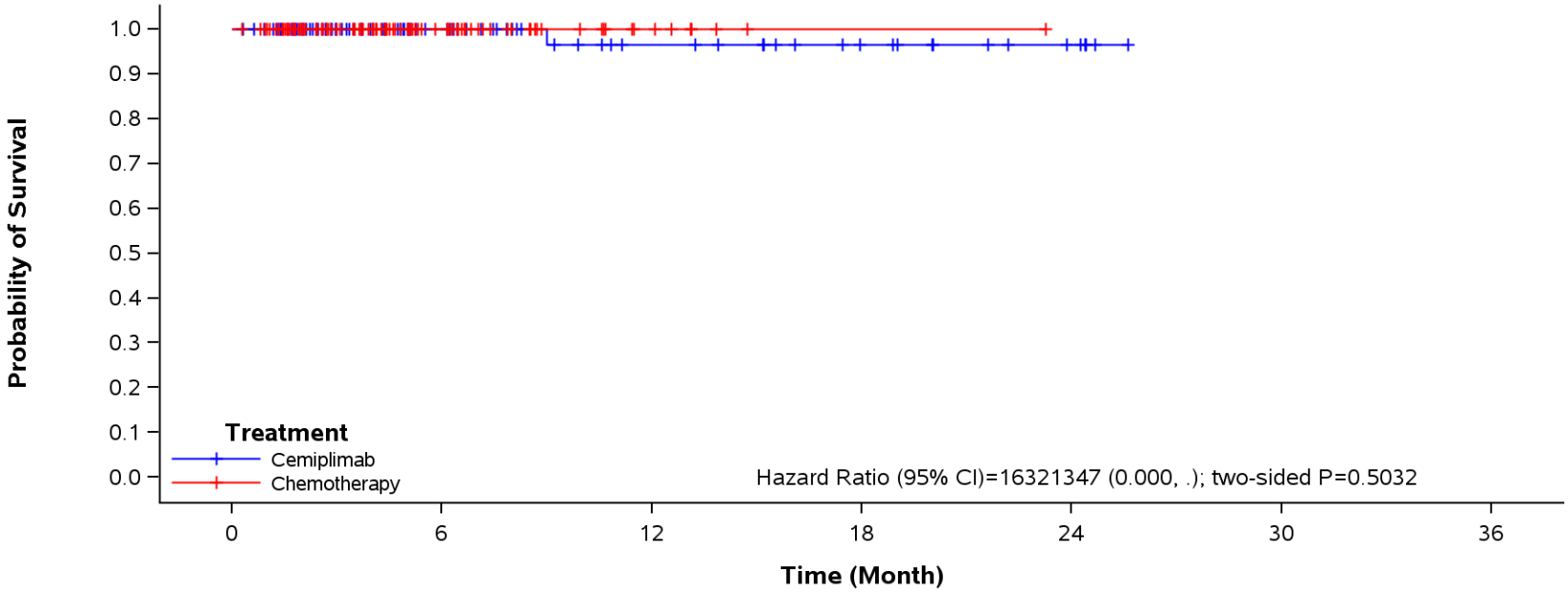

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Infections and infestations
PT: Pneumonia



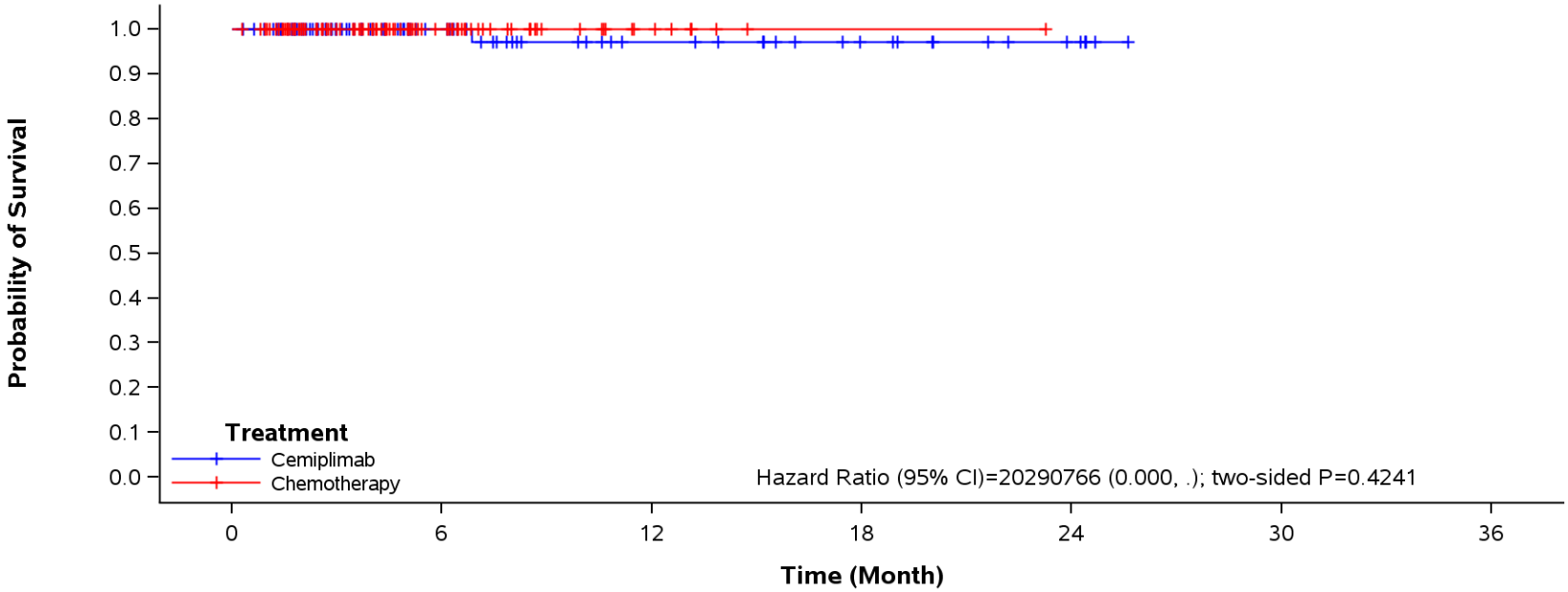

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Infections and infestations
PT: Pyomyositis




**Number of Subjects at risk**

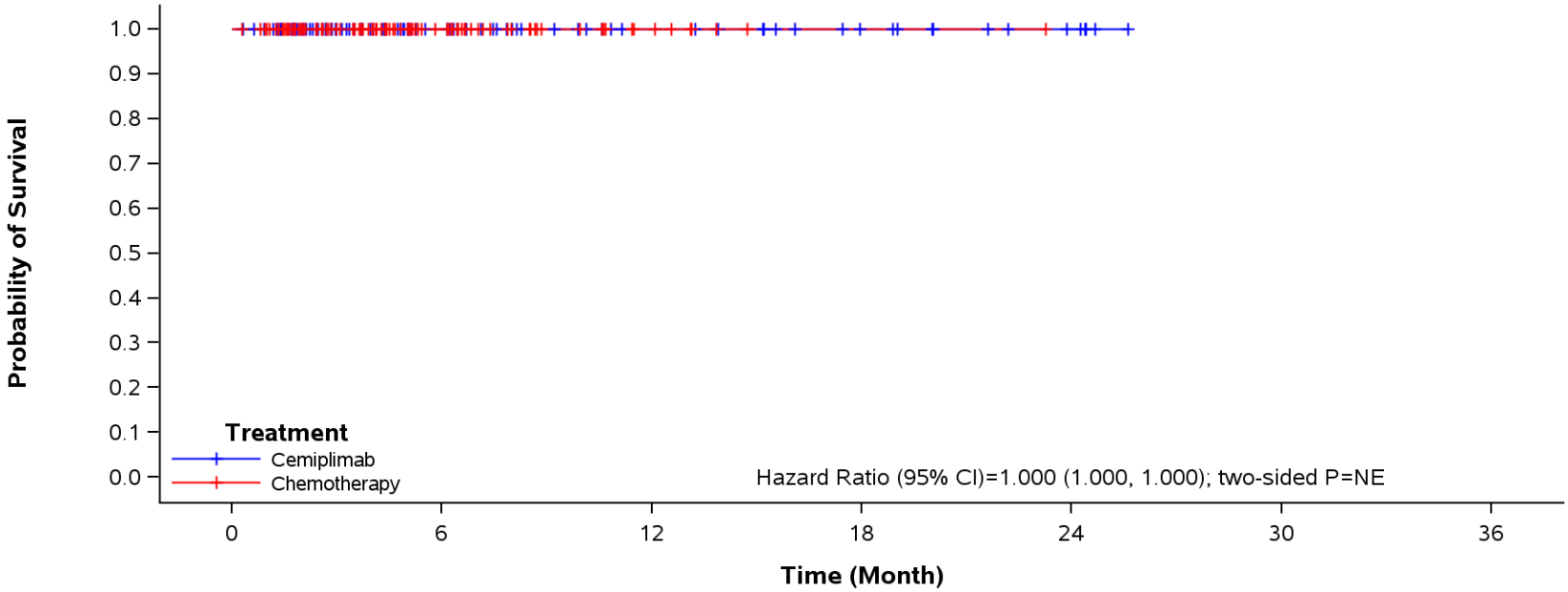
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

SOC: Injury, poisoning and procedural complications




**Number of Subjects at risk**

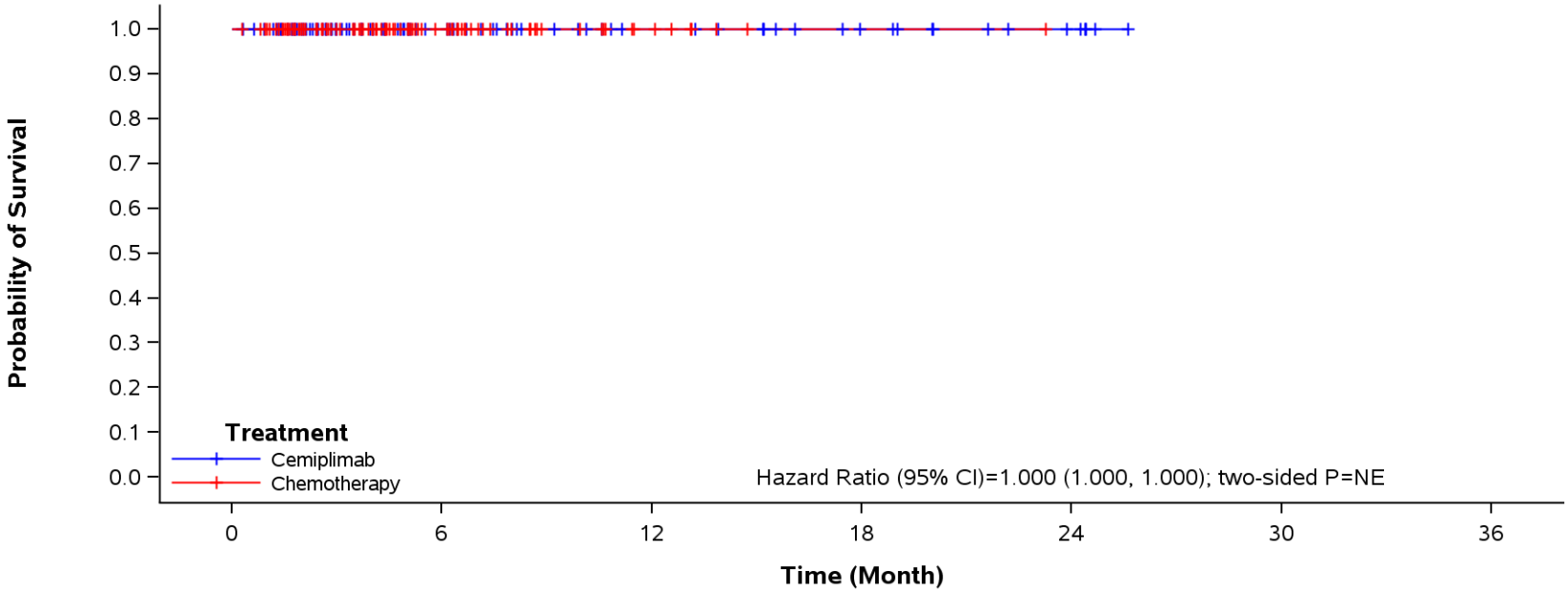
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



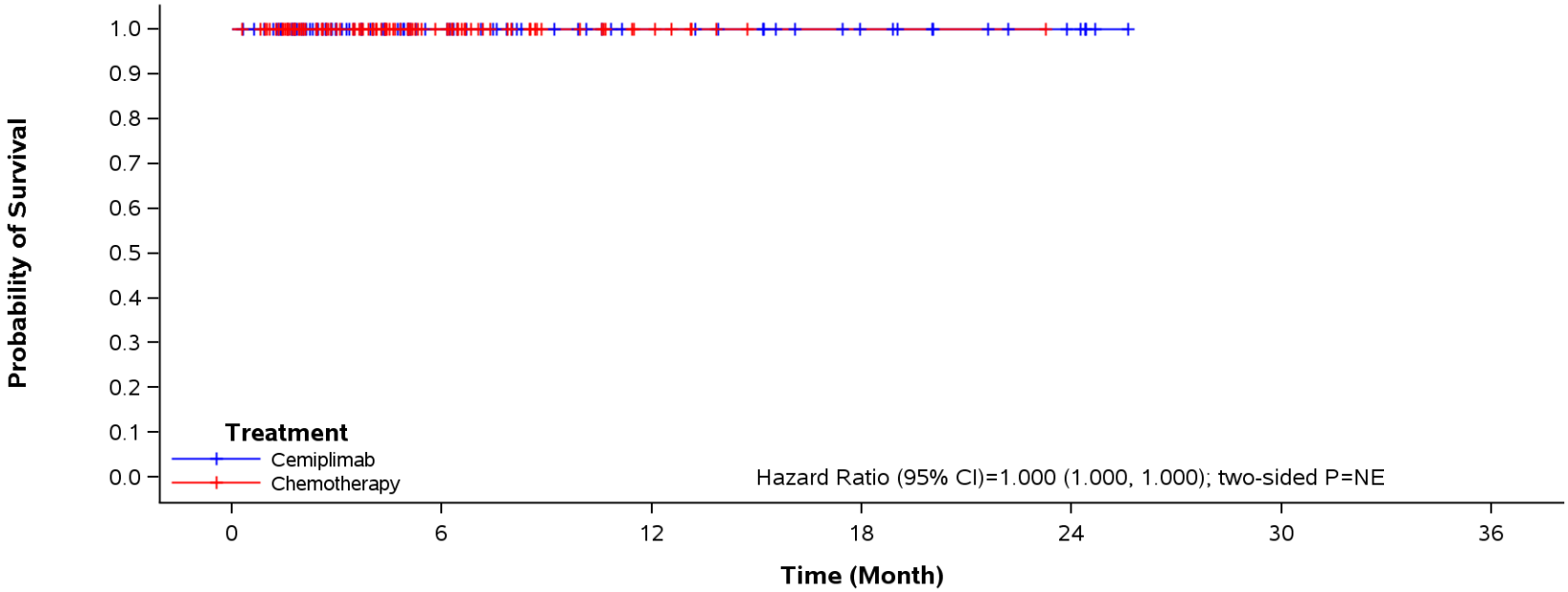

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



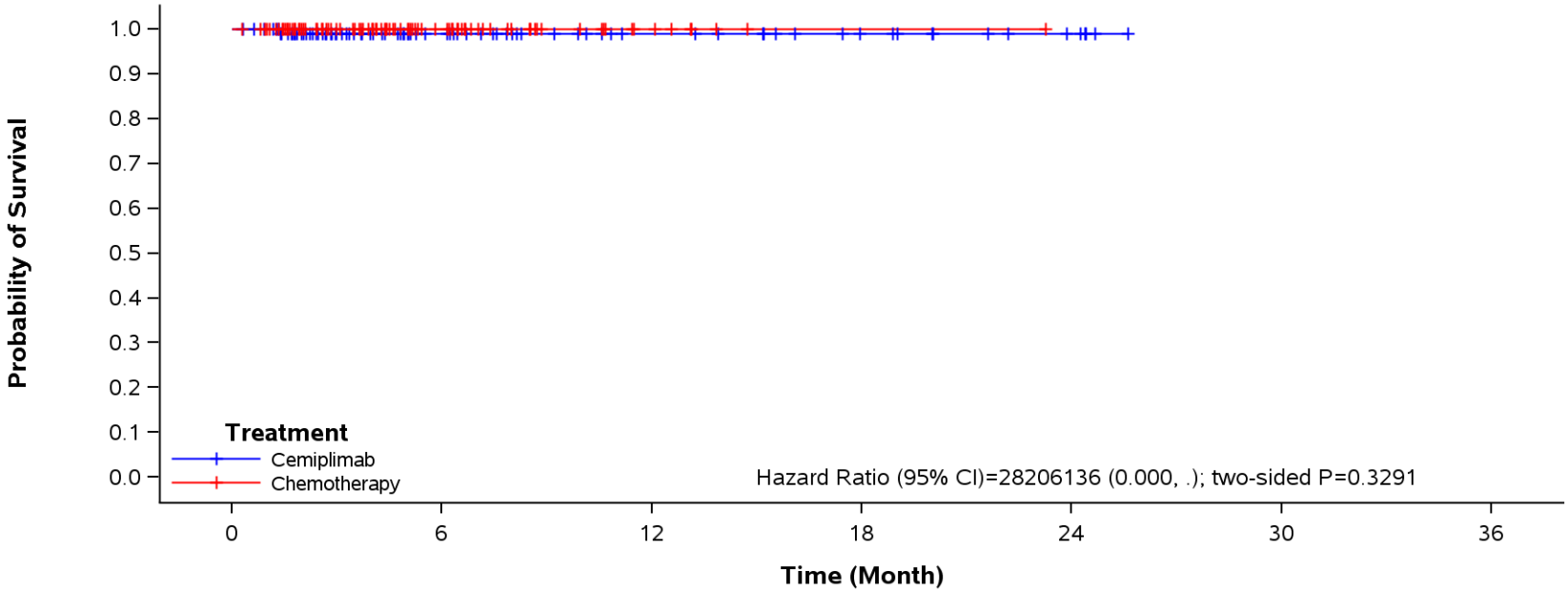

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Investigations



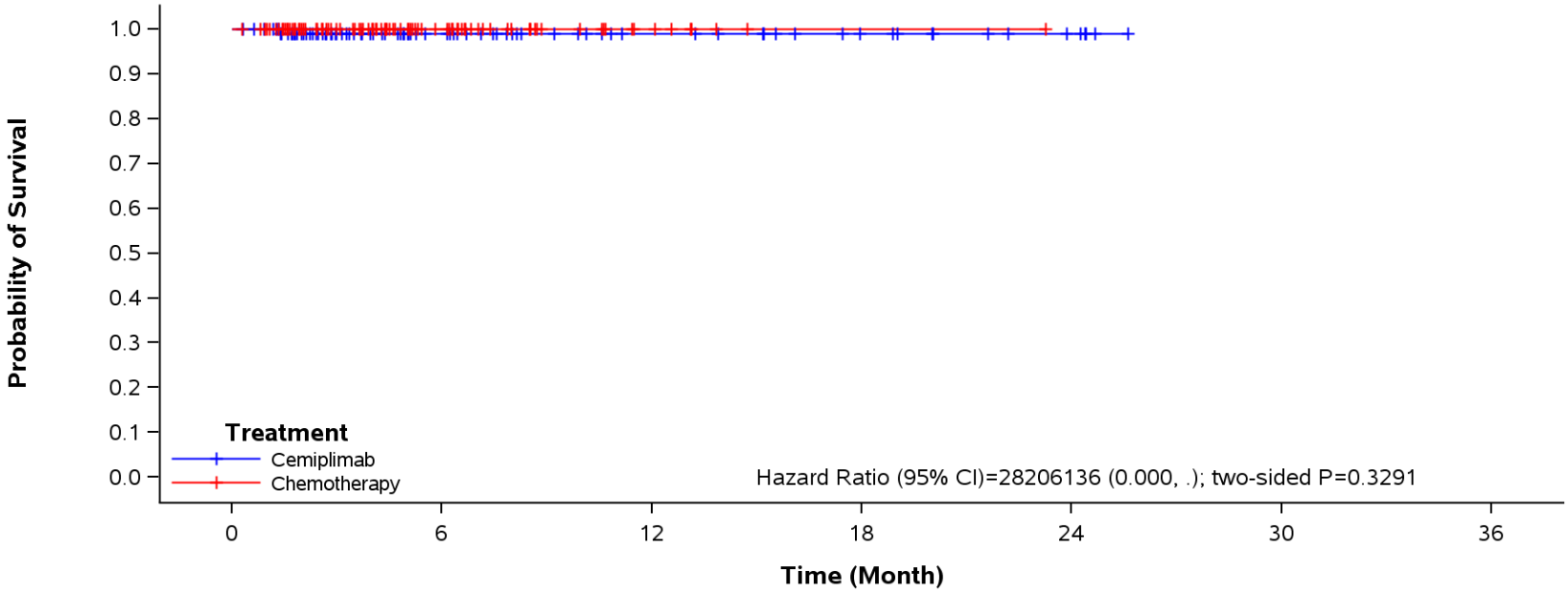

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Investigations
PT: Alanine aminotransferase increased



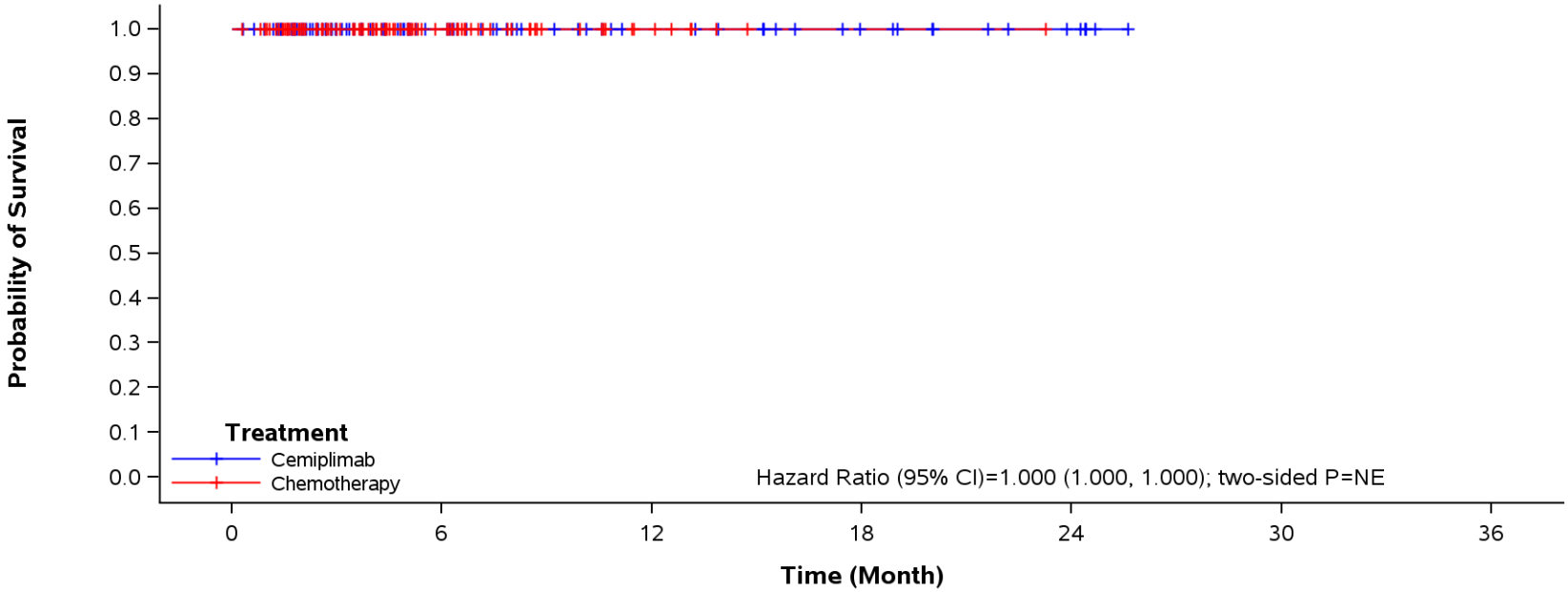

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Investigations
PT: Amylase increased



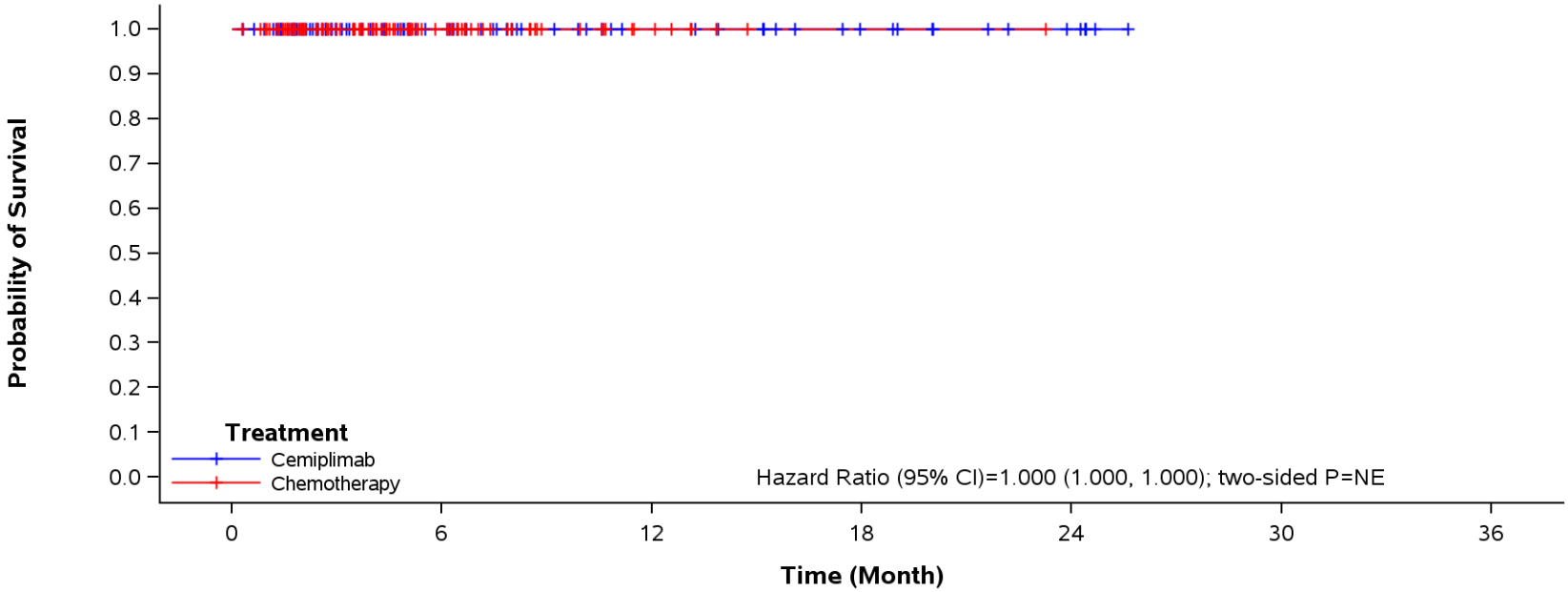

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Investigations
PT: Platelet count decreased



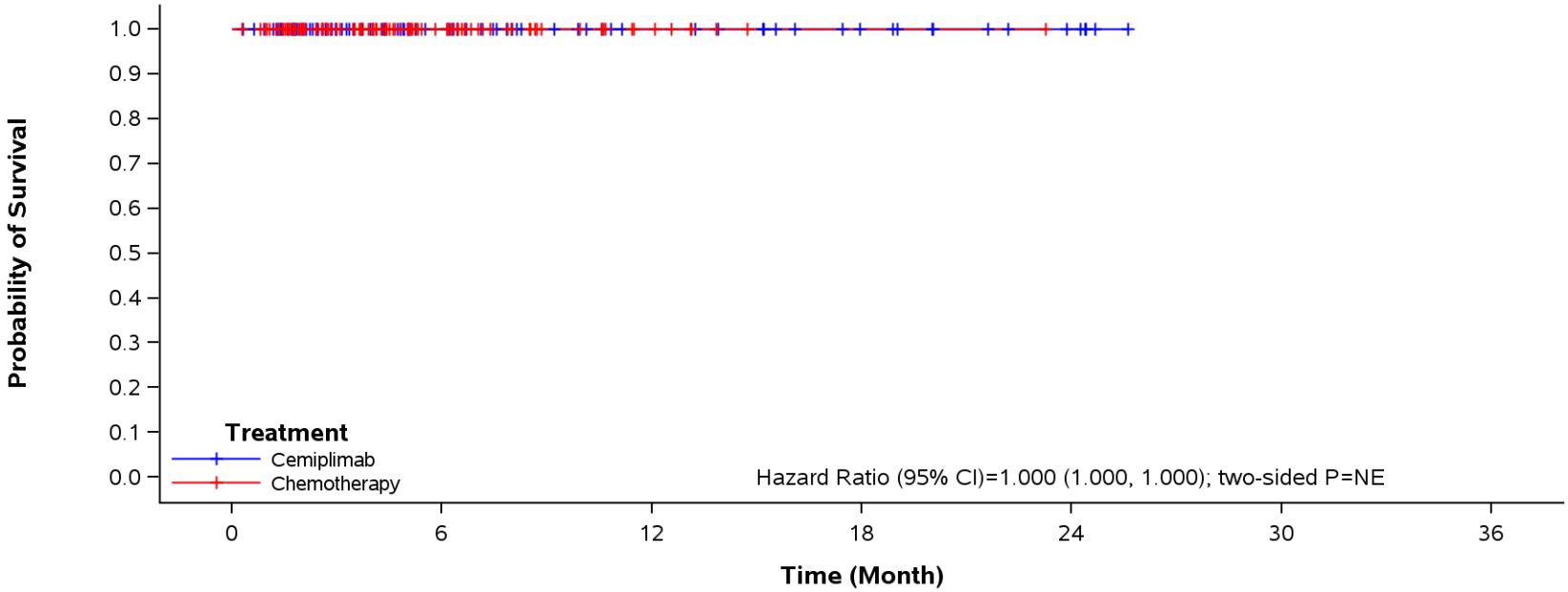

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Metabolism and nutrition disorders



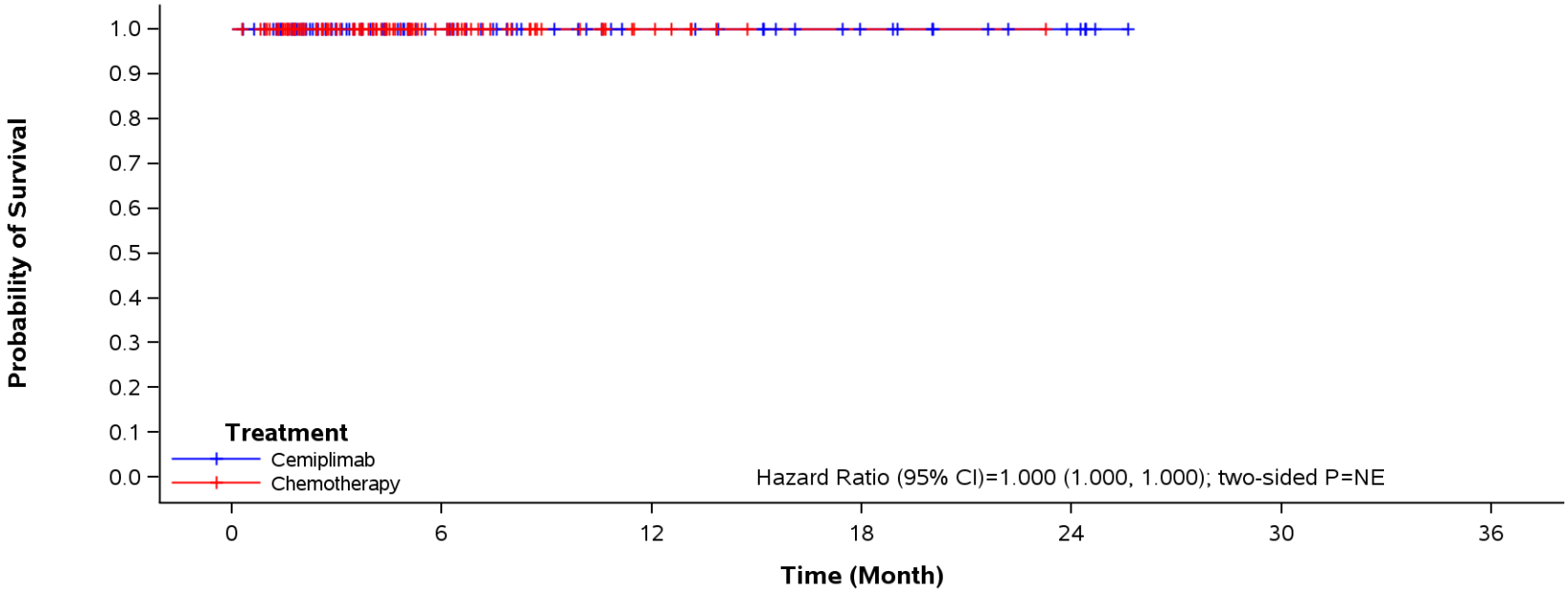

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Metabolism and nutrition disorders
PT: Decreased appetite




**Number of Subjects at risk**

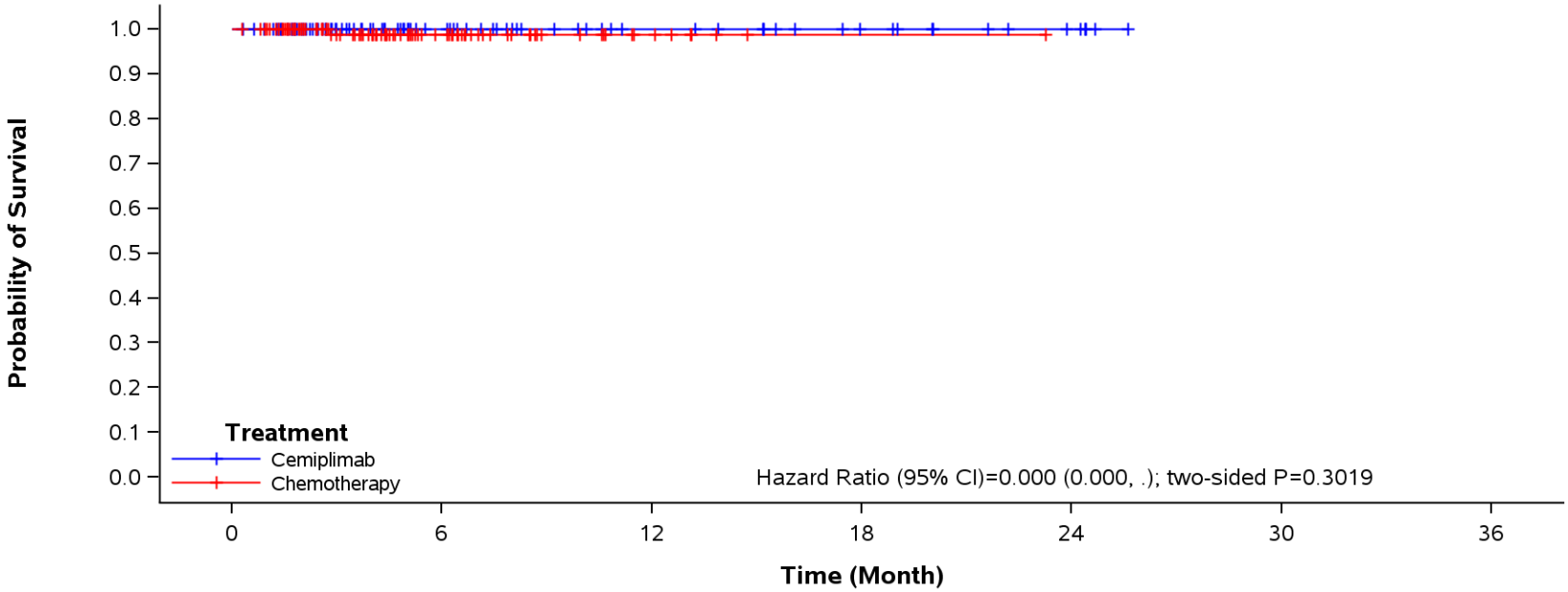
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

SOC: Musculoskeletal and connective tissue disorders




**Number of Subjects at risk**

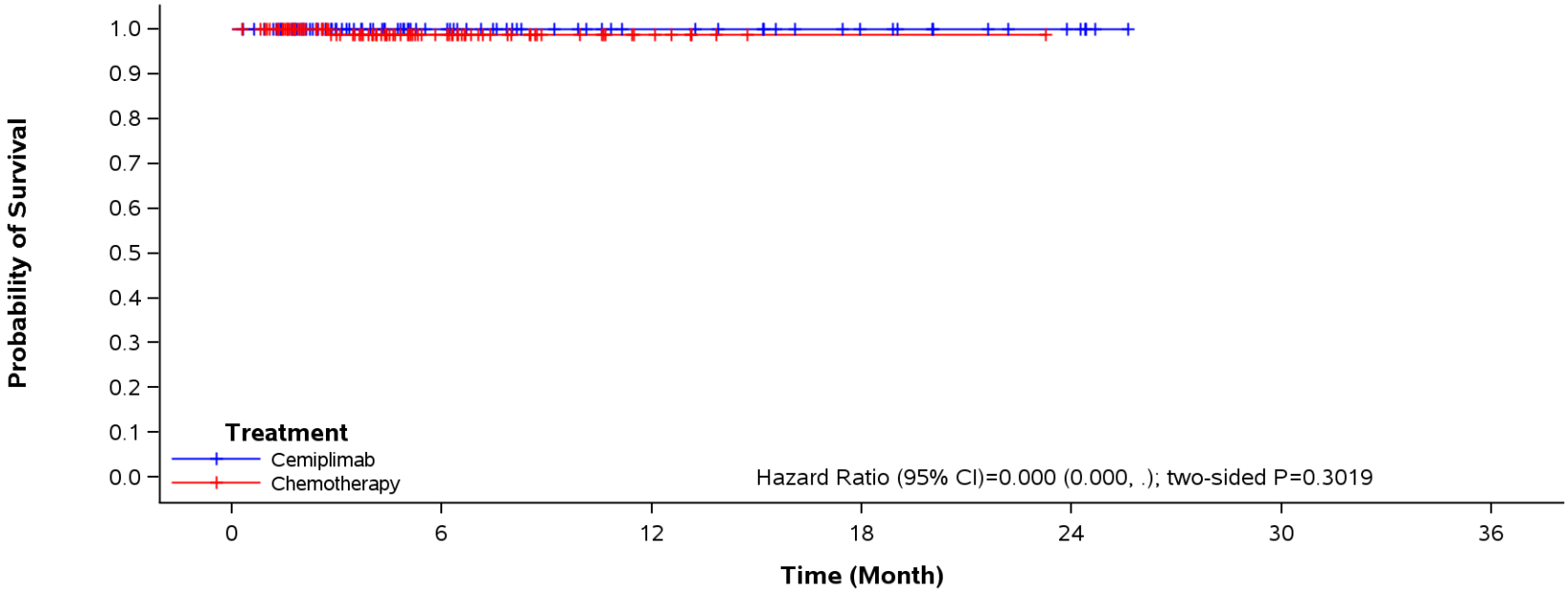
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



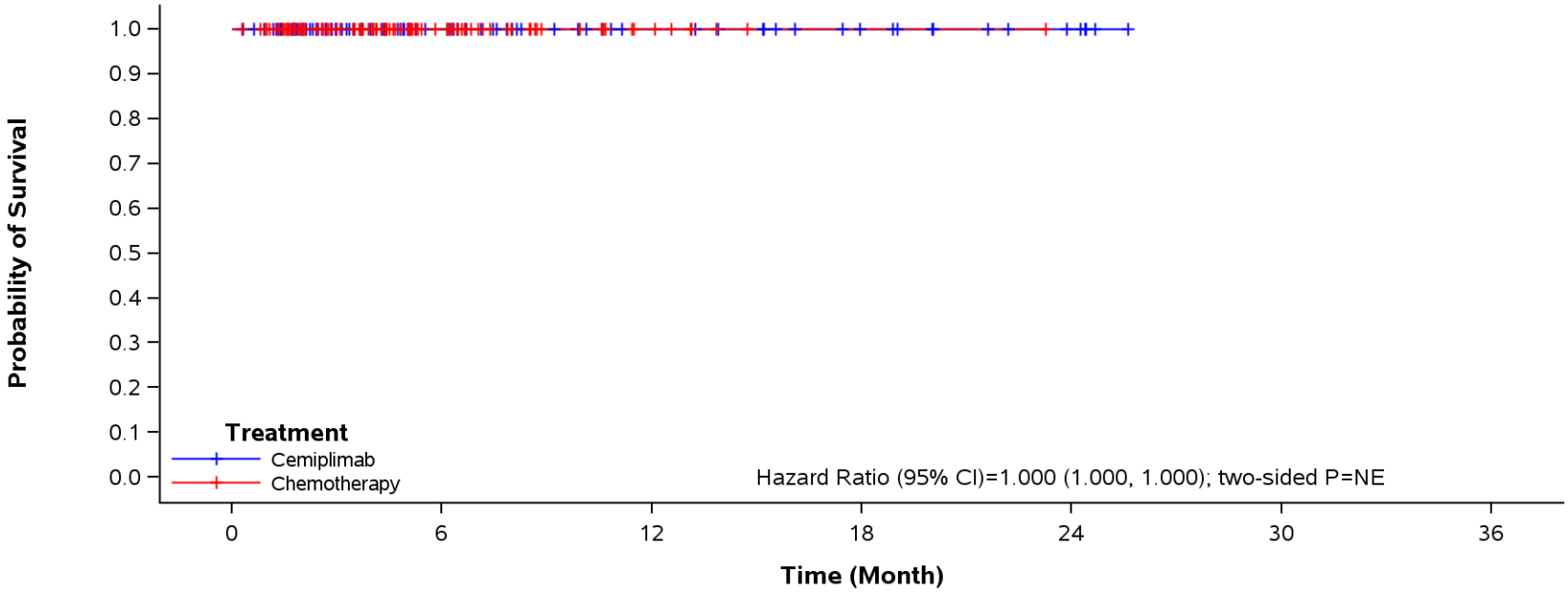

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 35 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



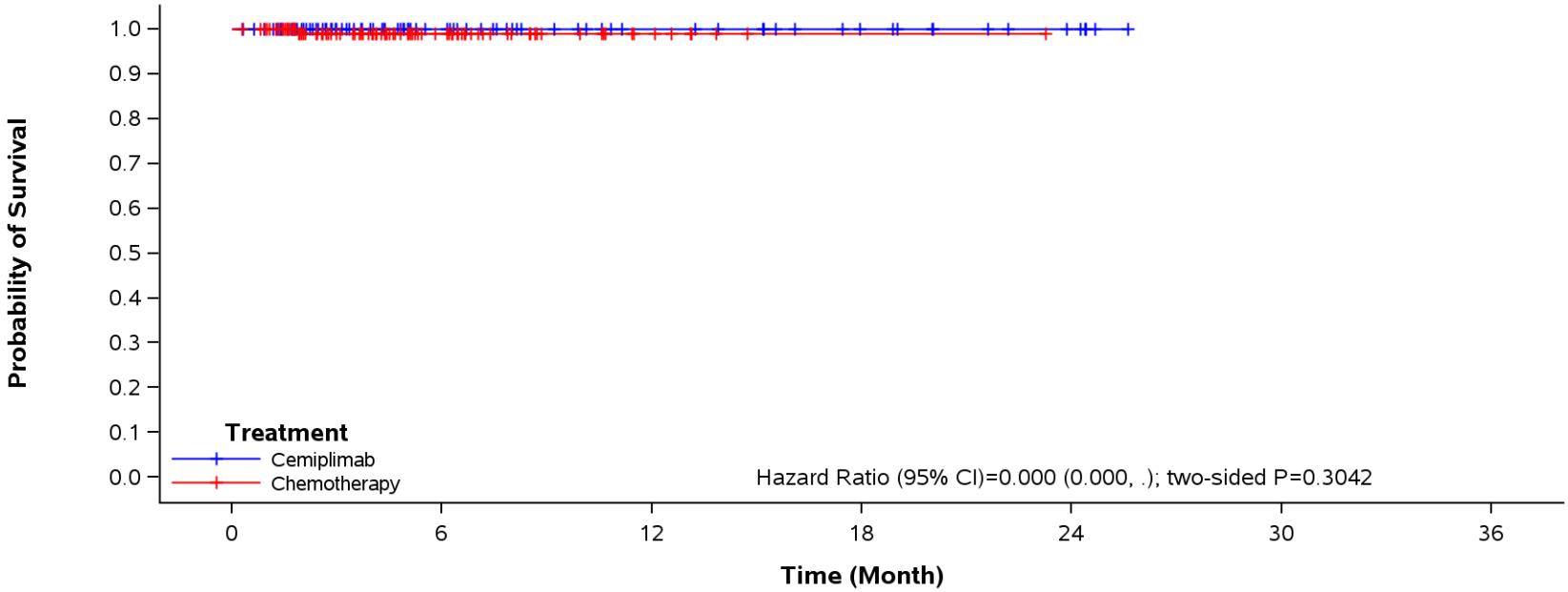

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Nervous system disorders



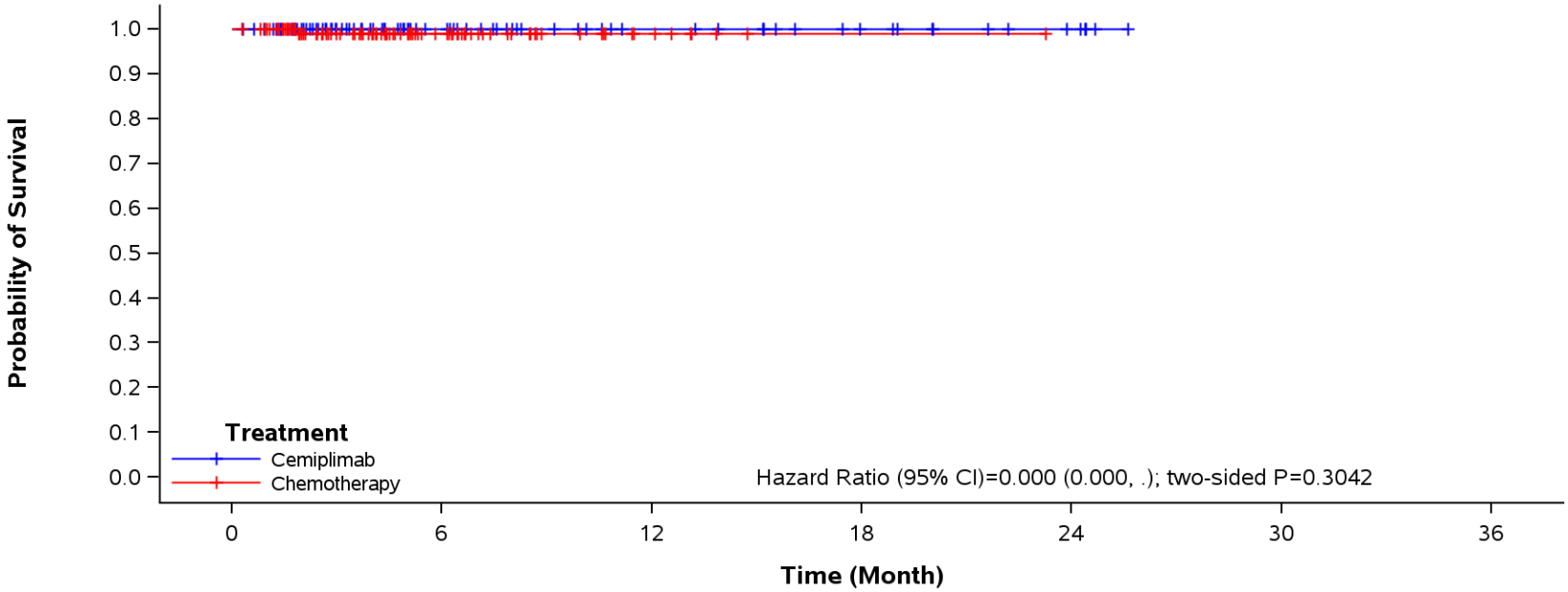

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Nervous system disorders
PT: Neurotoxicity



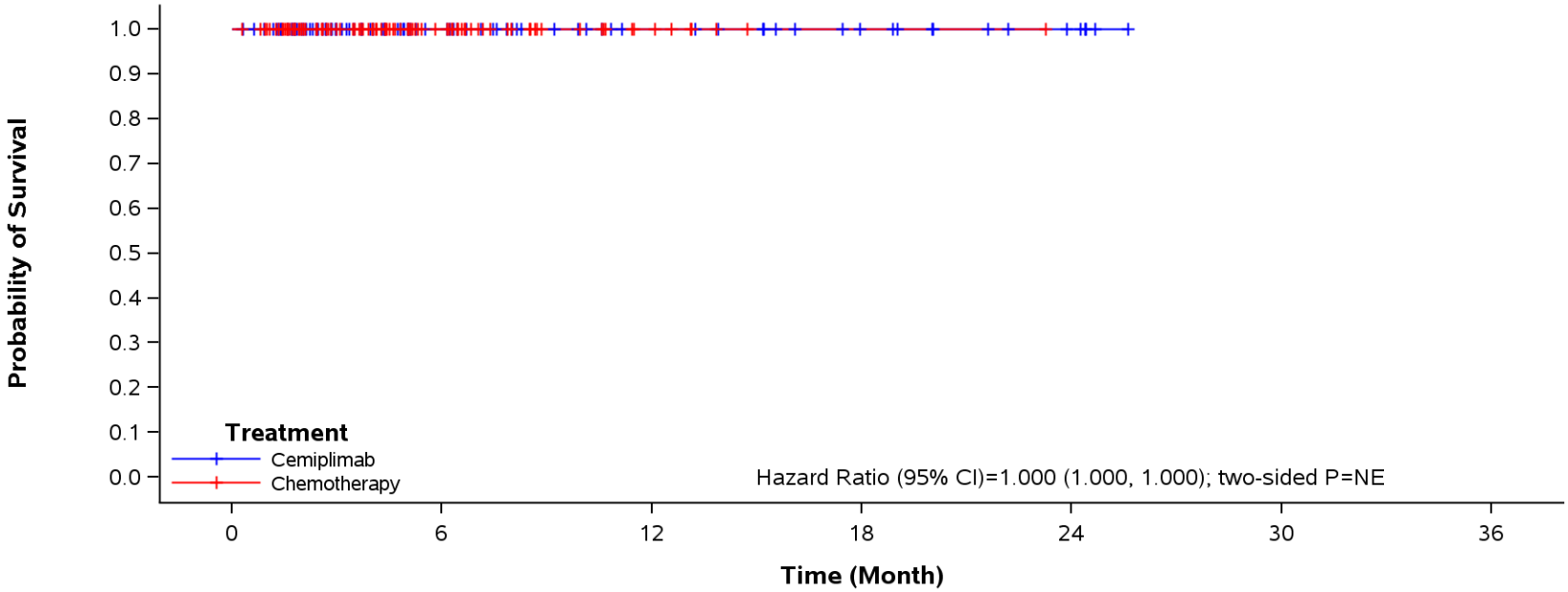

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Nervous system disorders
PT: Transient ischaemic attack



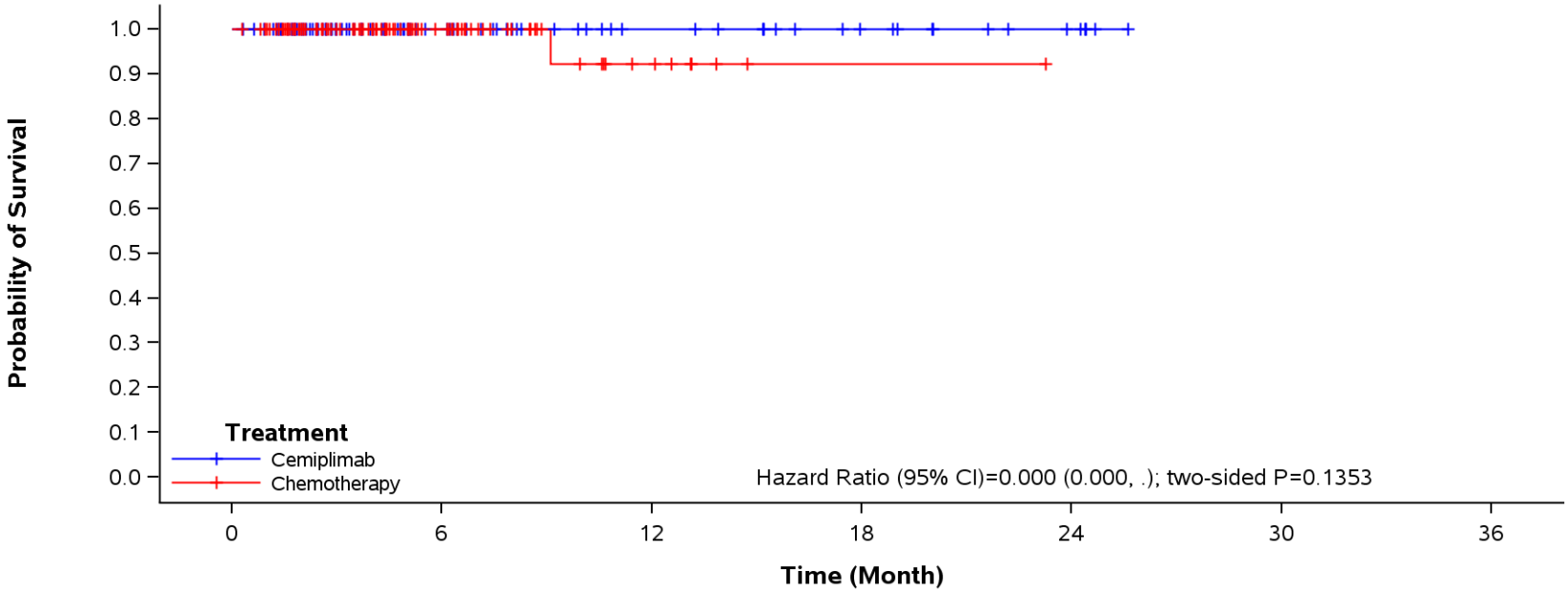

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Psychiatric disorders



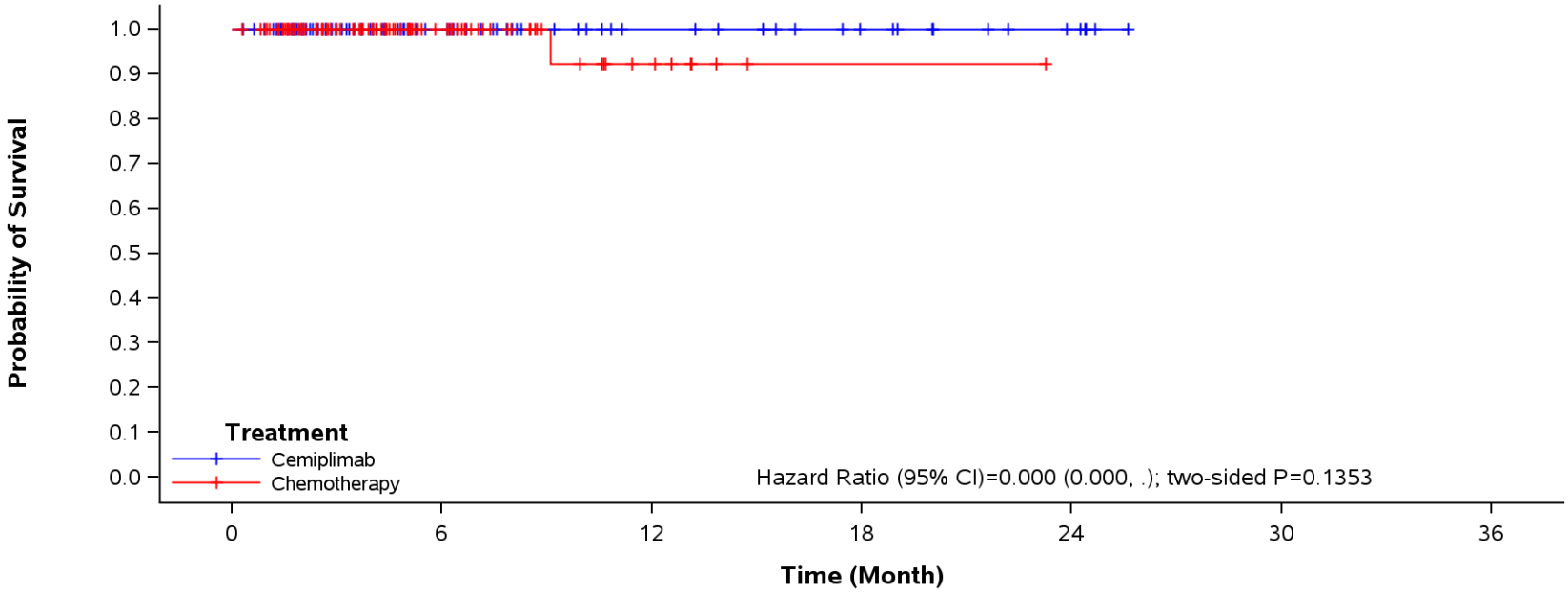

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Psychiatric disorders
PT: Agoraphobia



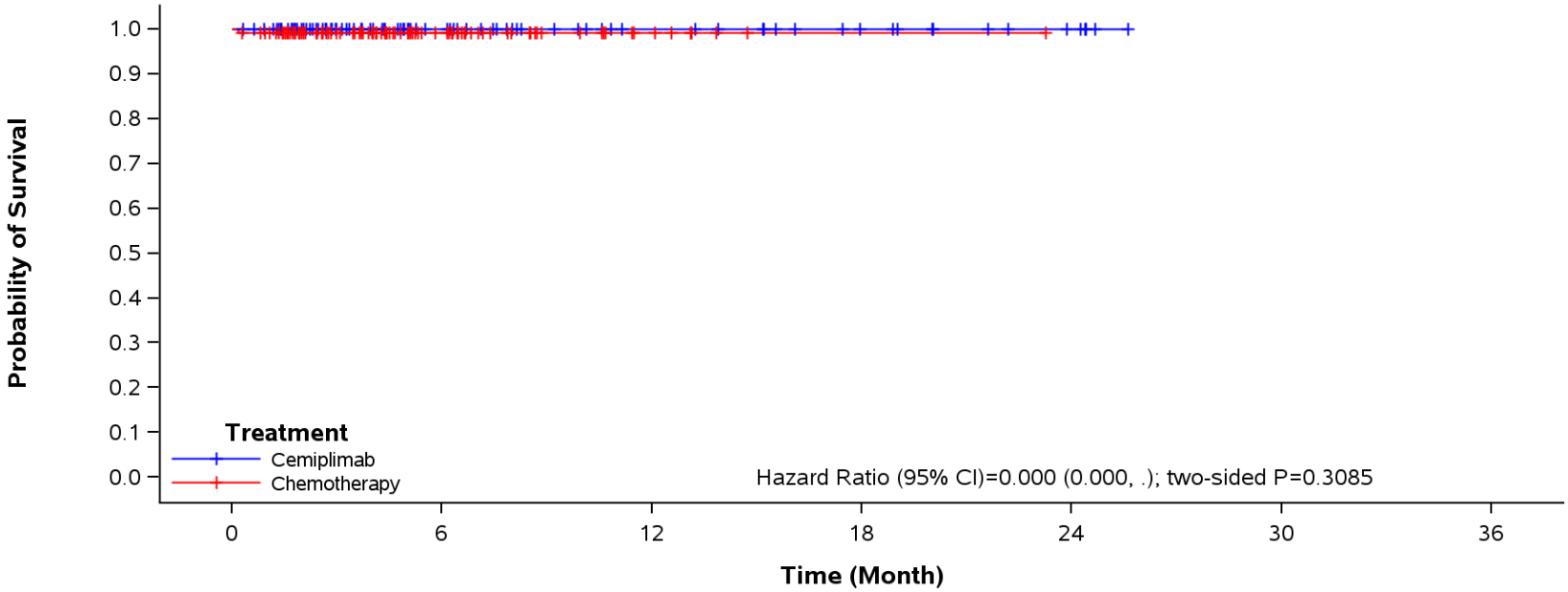

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Renal and urinary disorders



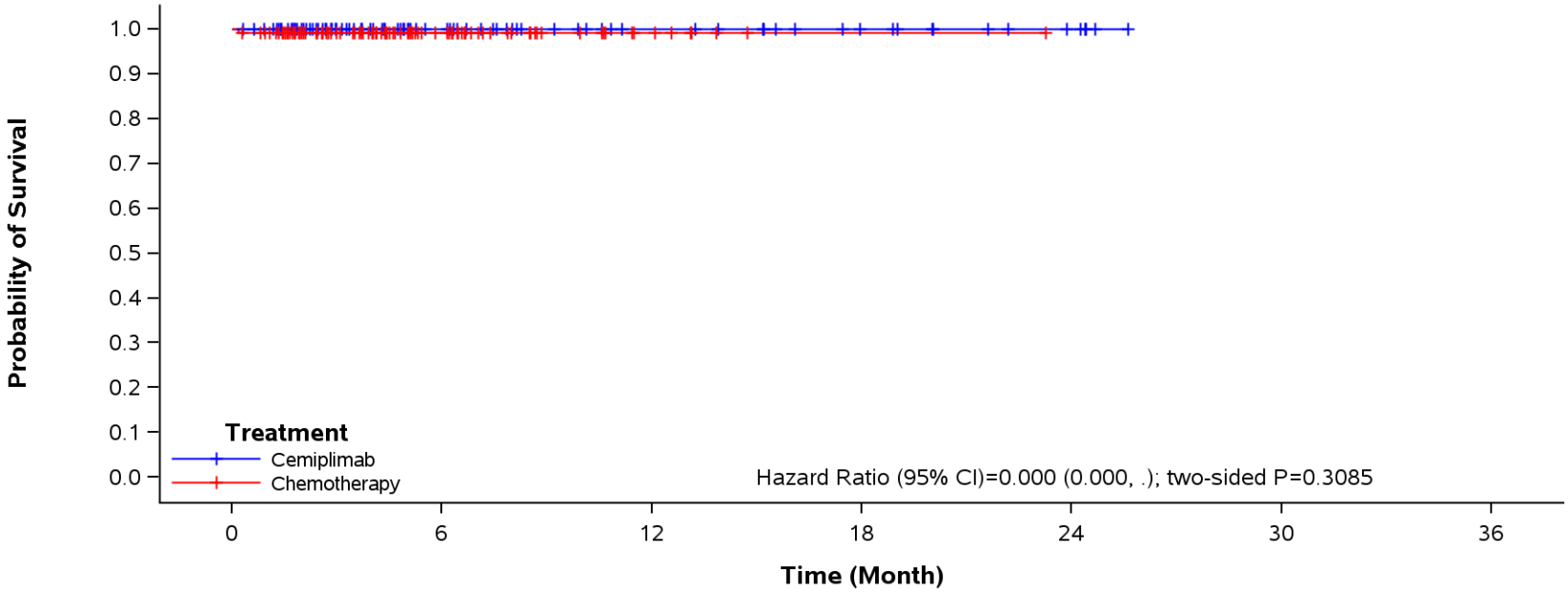

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Renal and urinary disorders
PT: Renal failure




**Number of Subjects at risk**

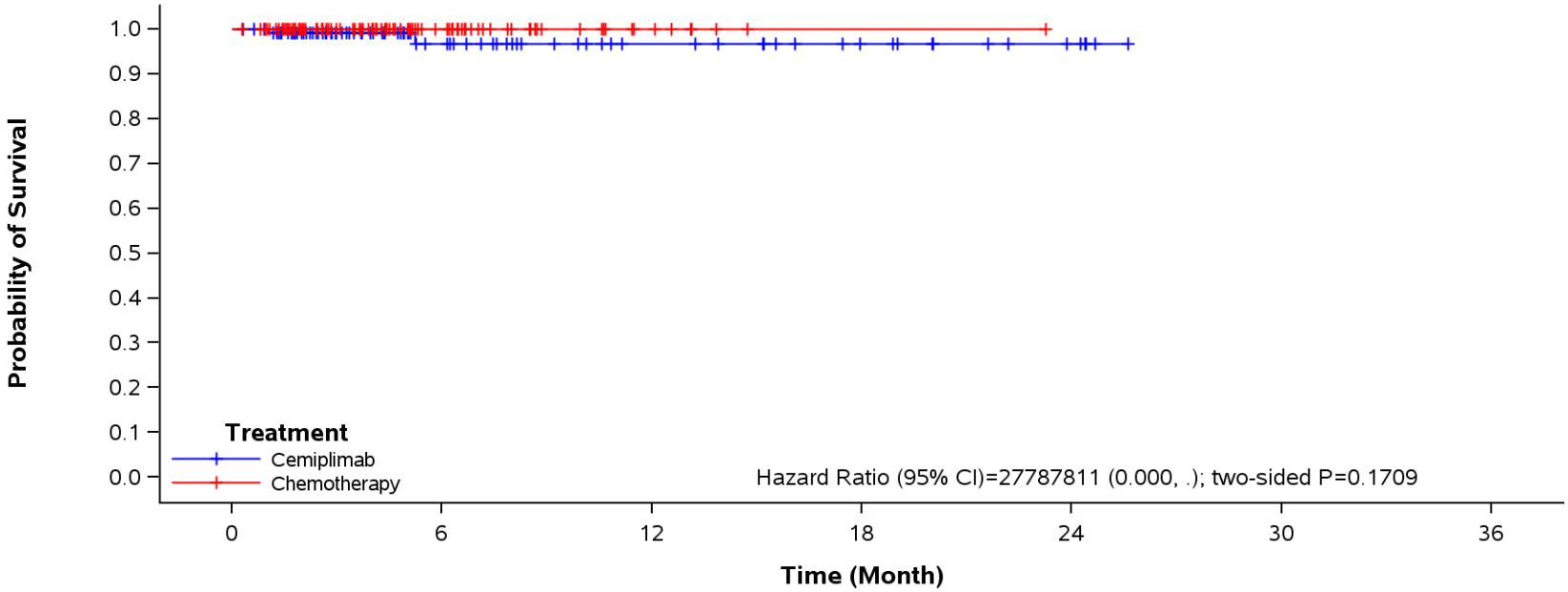
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1

SOC: Respiratory, thoracic and mediastinal disorders




**Number of Subjects at risk**

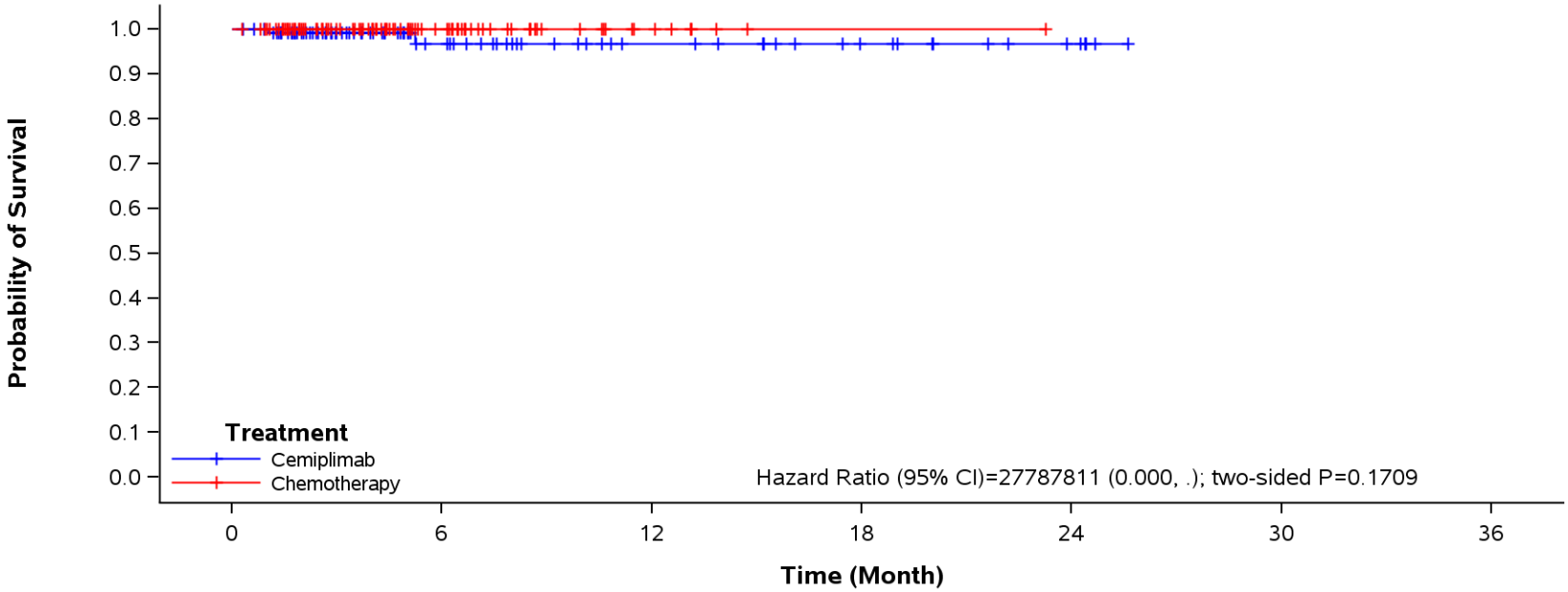
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.

Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



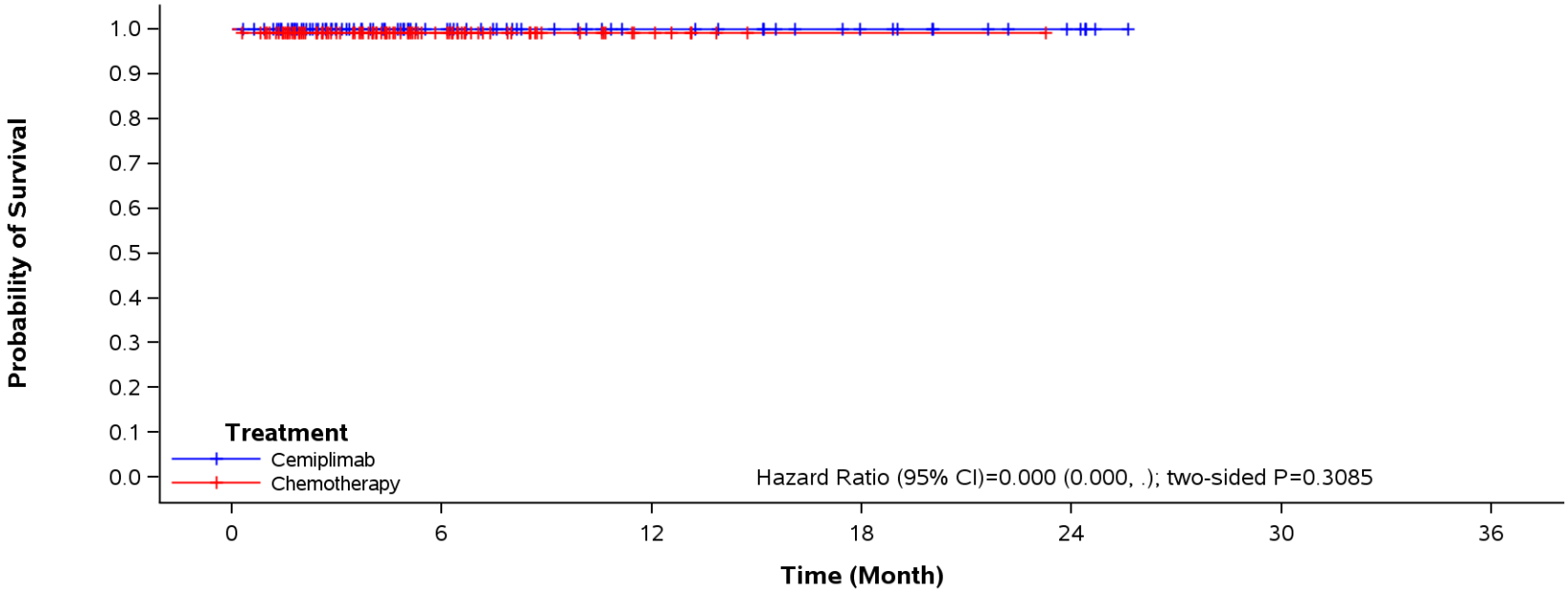

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 40 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Vascular disorders



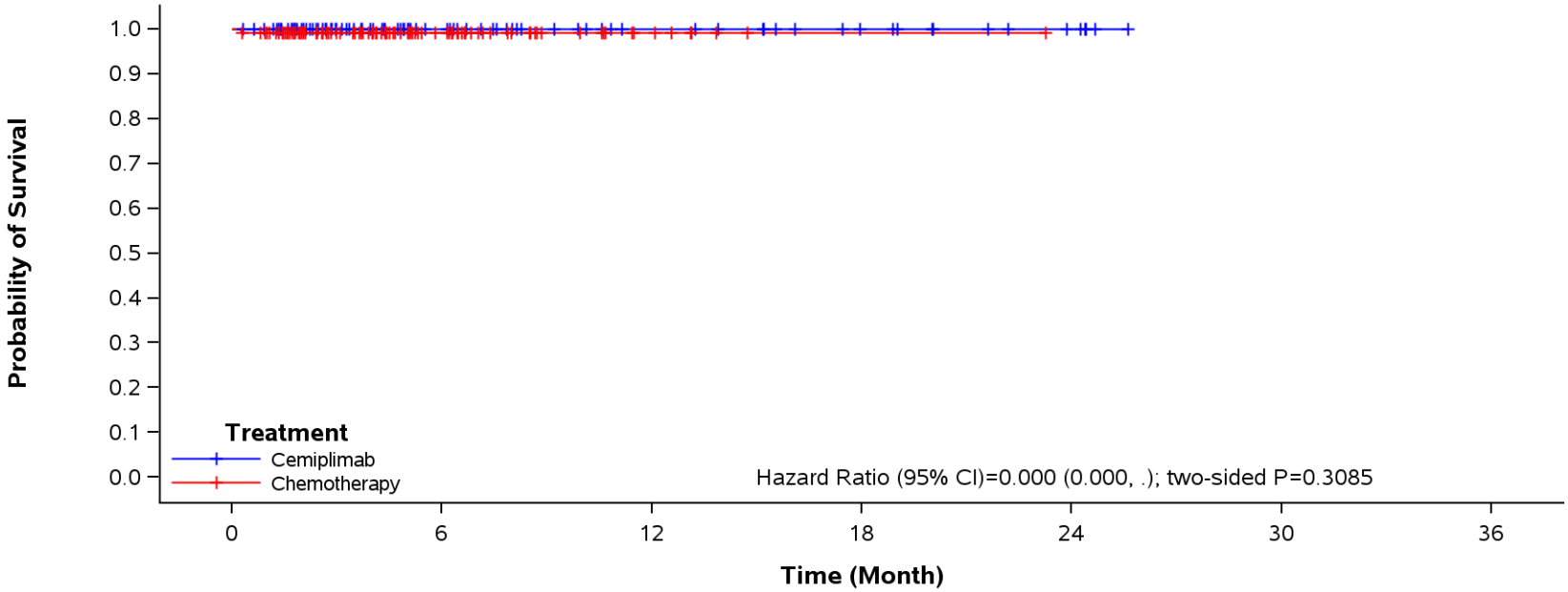

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Baseline ECOG Status: 1
SOC: Vascular disorders
PT: Deep vein thrombosis



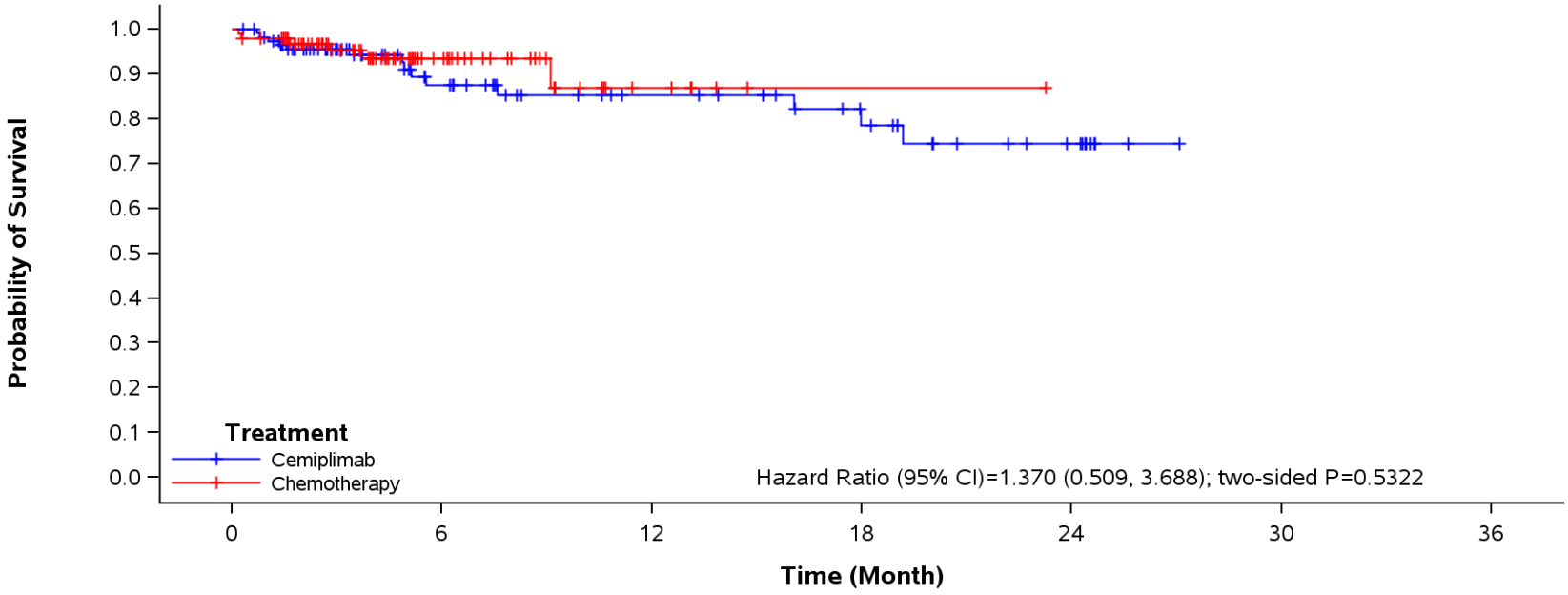

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 112 | 41 | 22 | 14 | 7 | 0 | 0 |
| Chemotherapy | 108 | 36 | 7 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
Number of patients with any TEAE leading to discontinuation



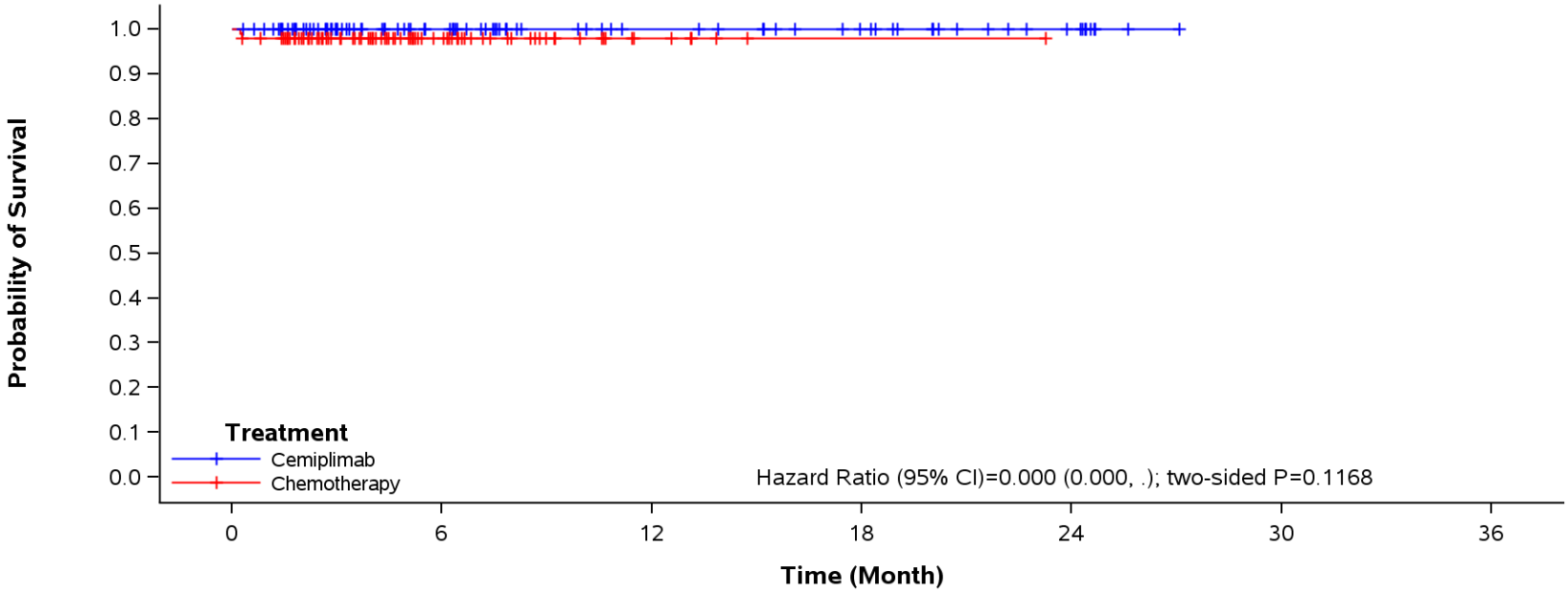

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 48 | 32 | 22 | 12 | 0 | 0 |
| Chemotherapy | 94 | 31 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders



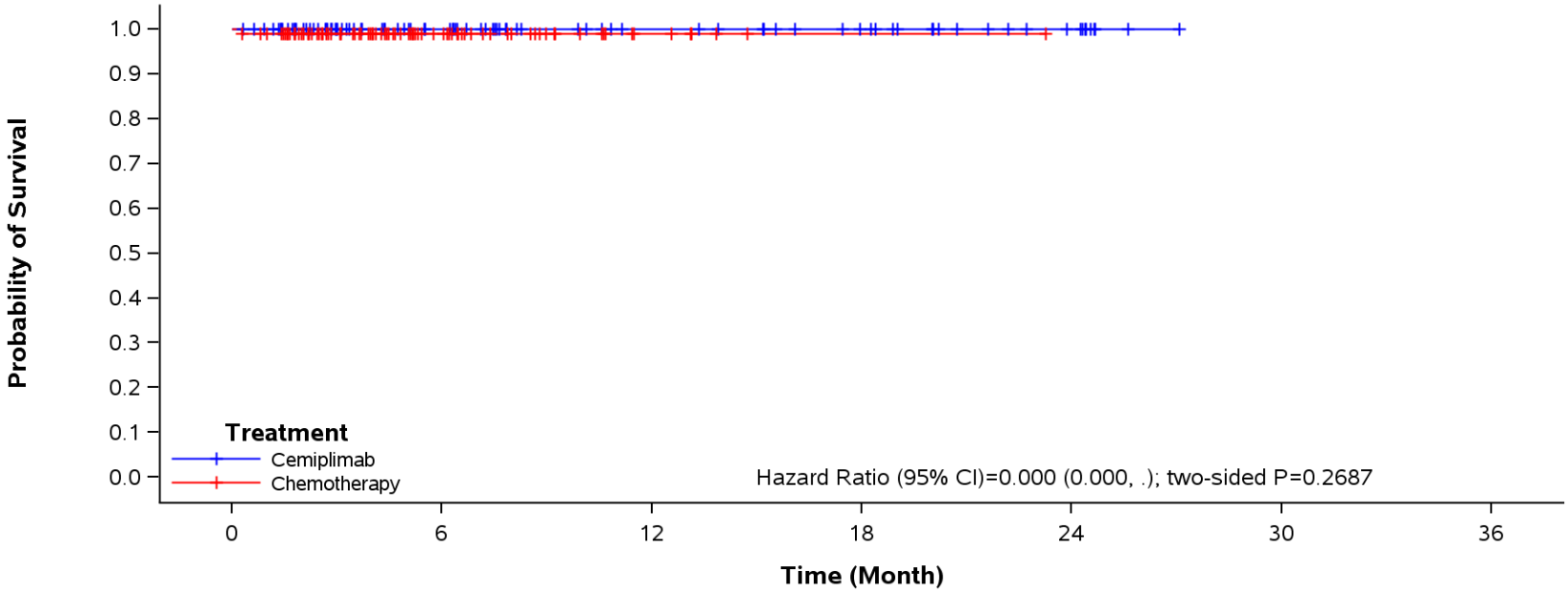

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



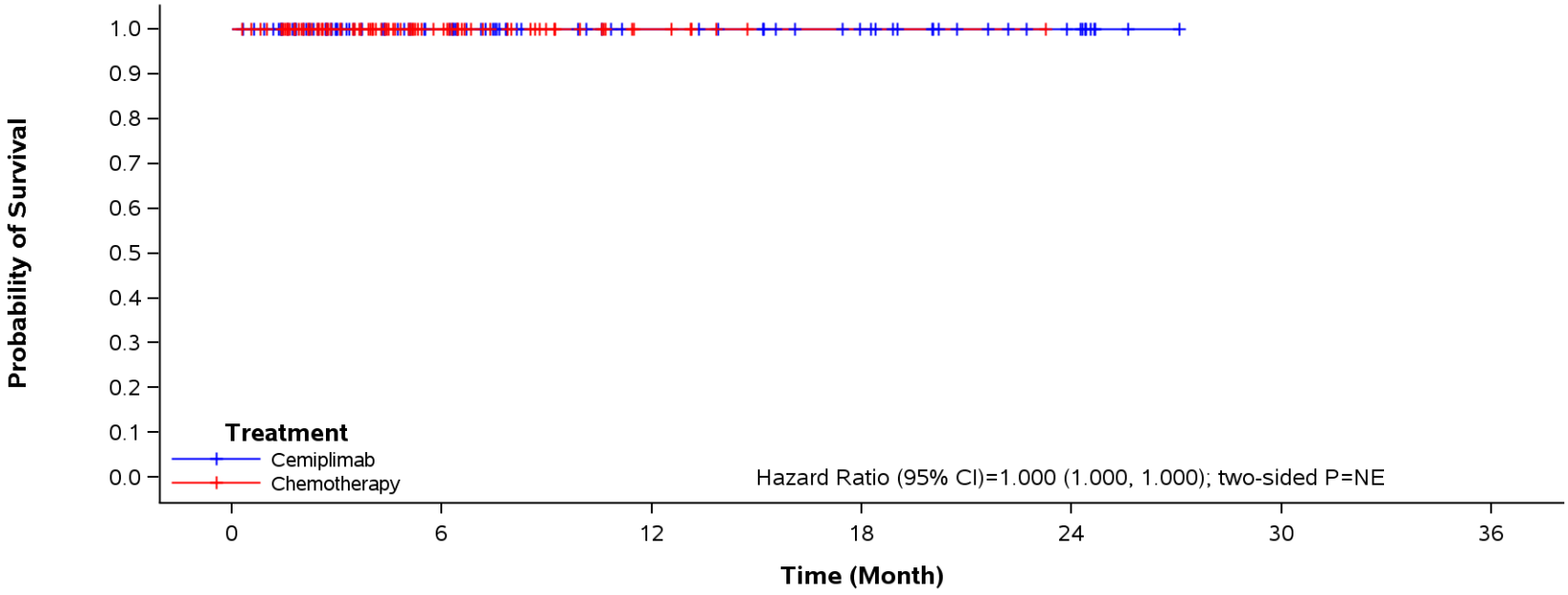

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



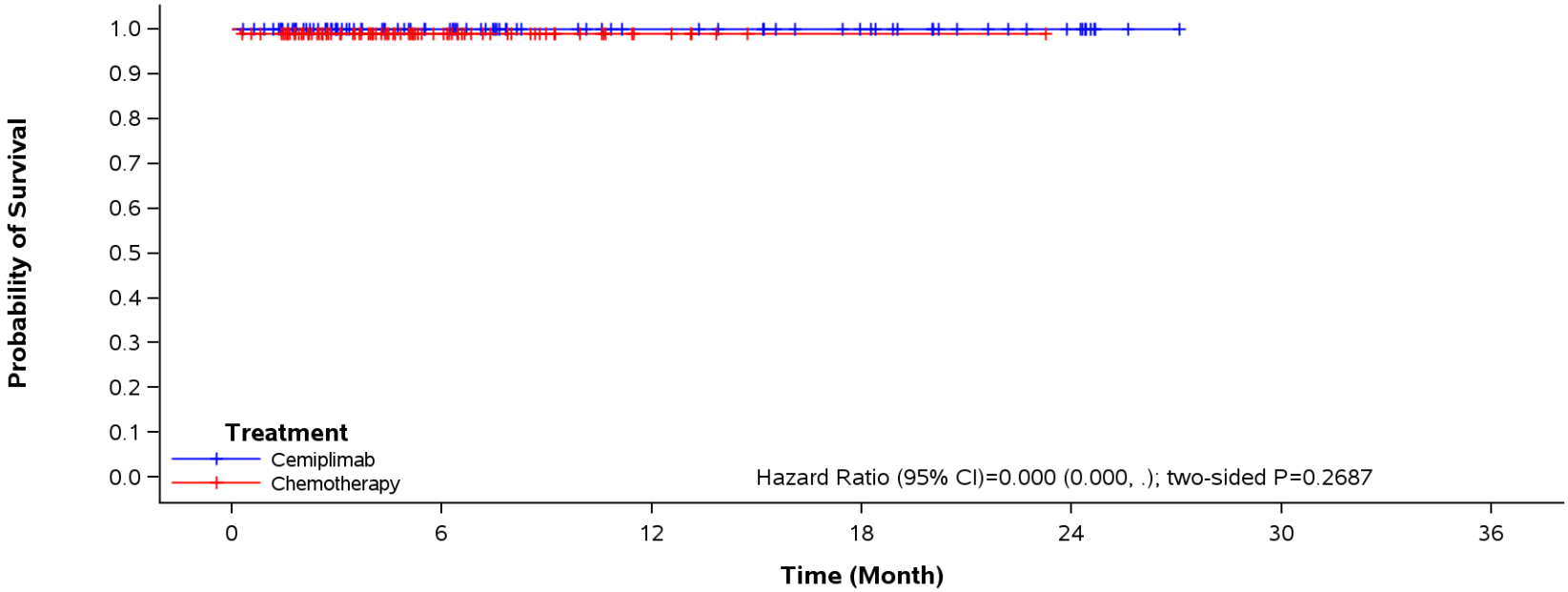

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia



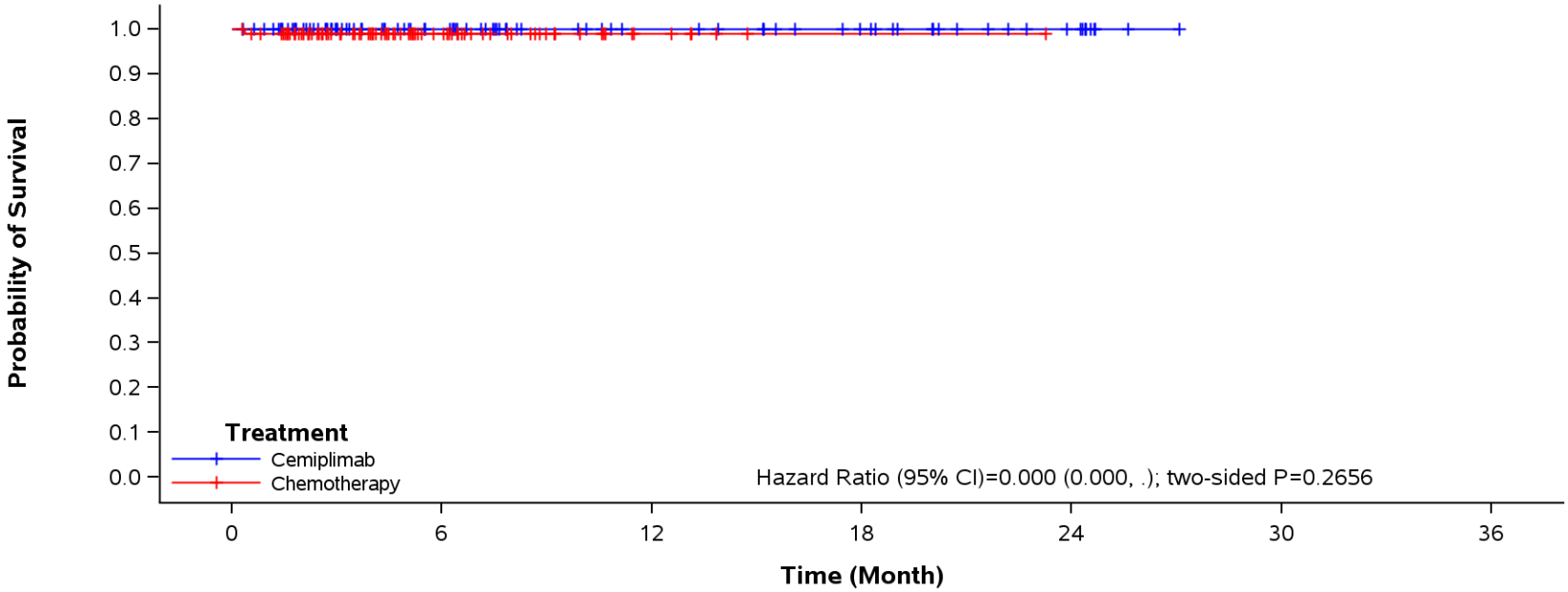

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



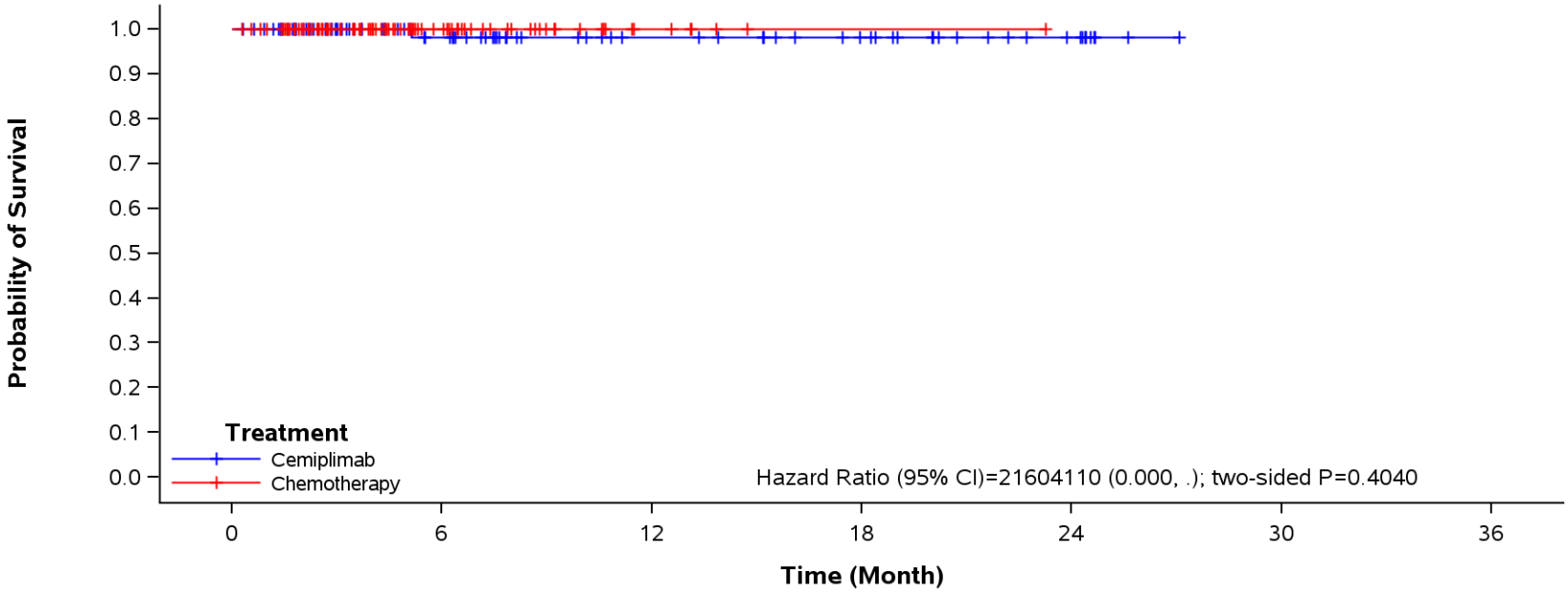

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Cardiac disorders



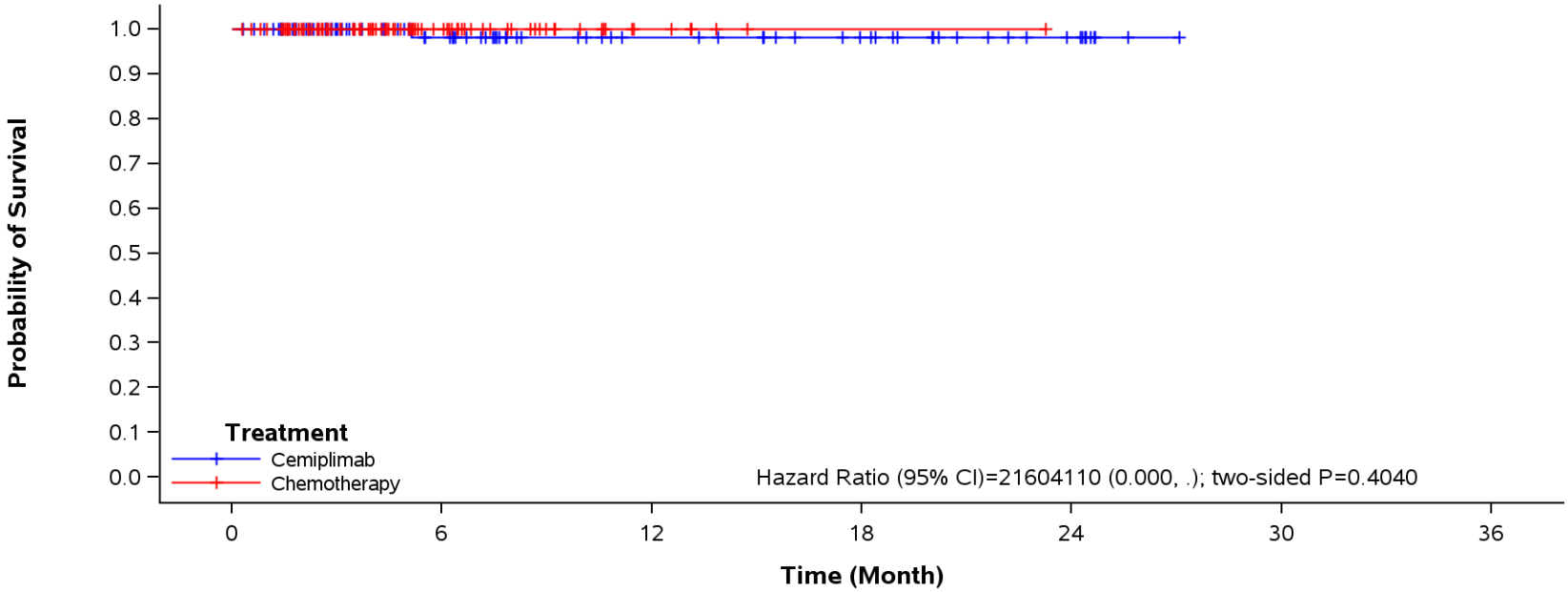

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 52 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Cardiac disorders
PT: Autoimmune pericarditis



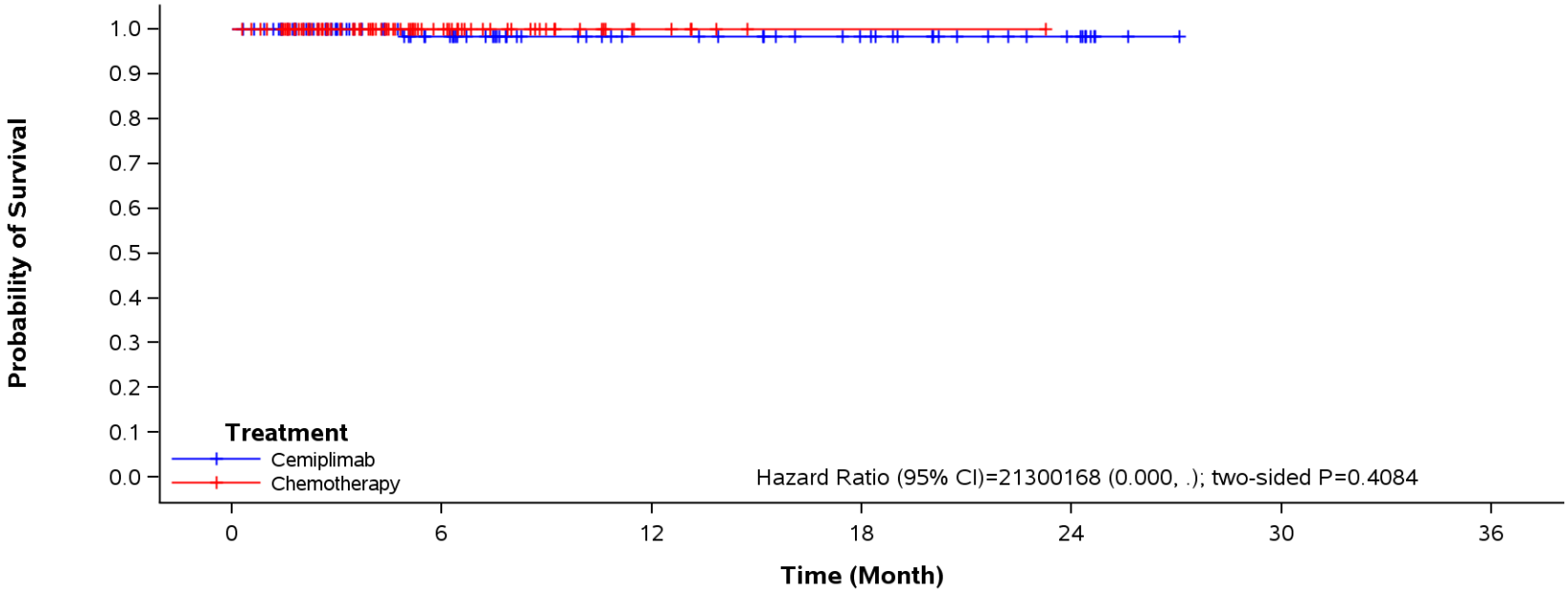

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 52 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Endocrine disorders



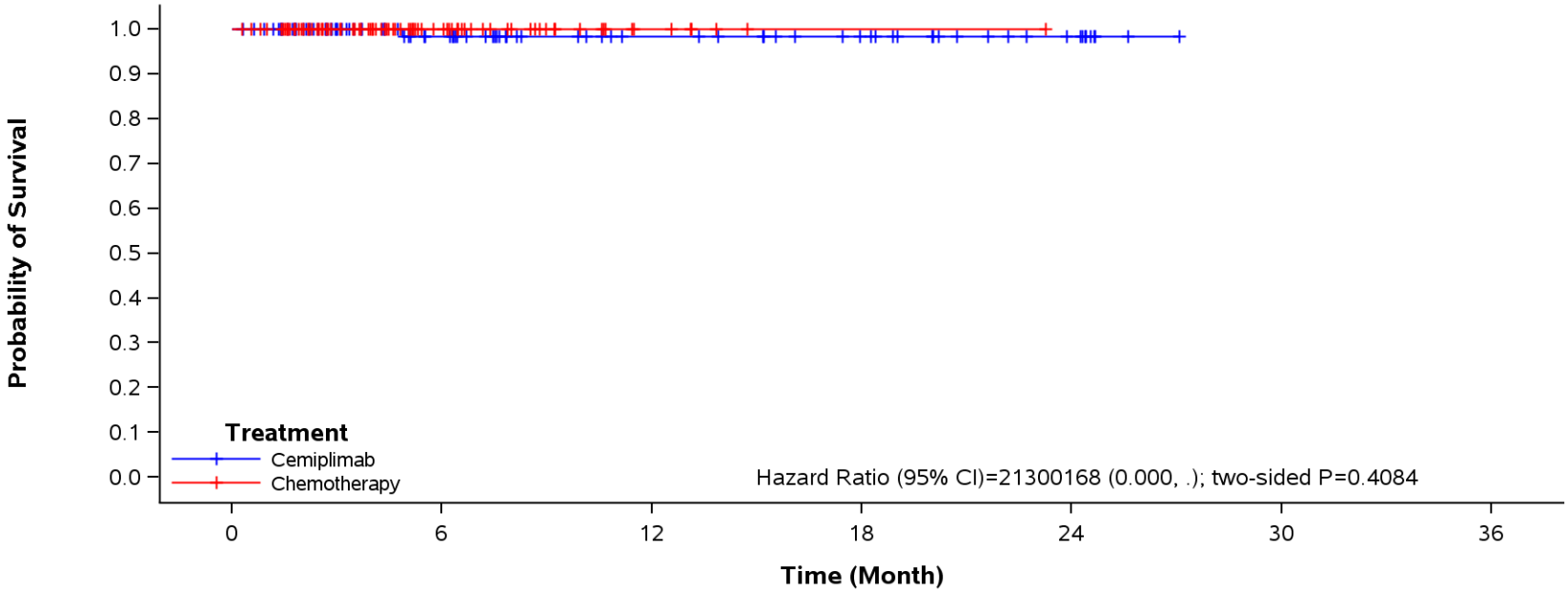

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 52 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Endocrine disorders
PT: Hypothyroidism



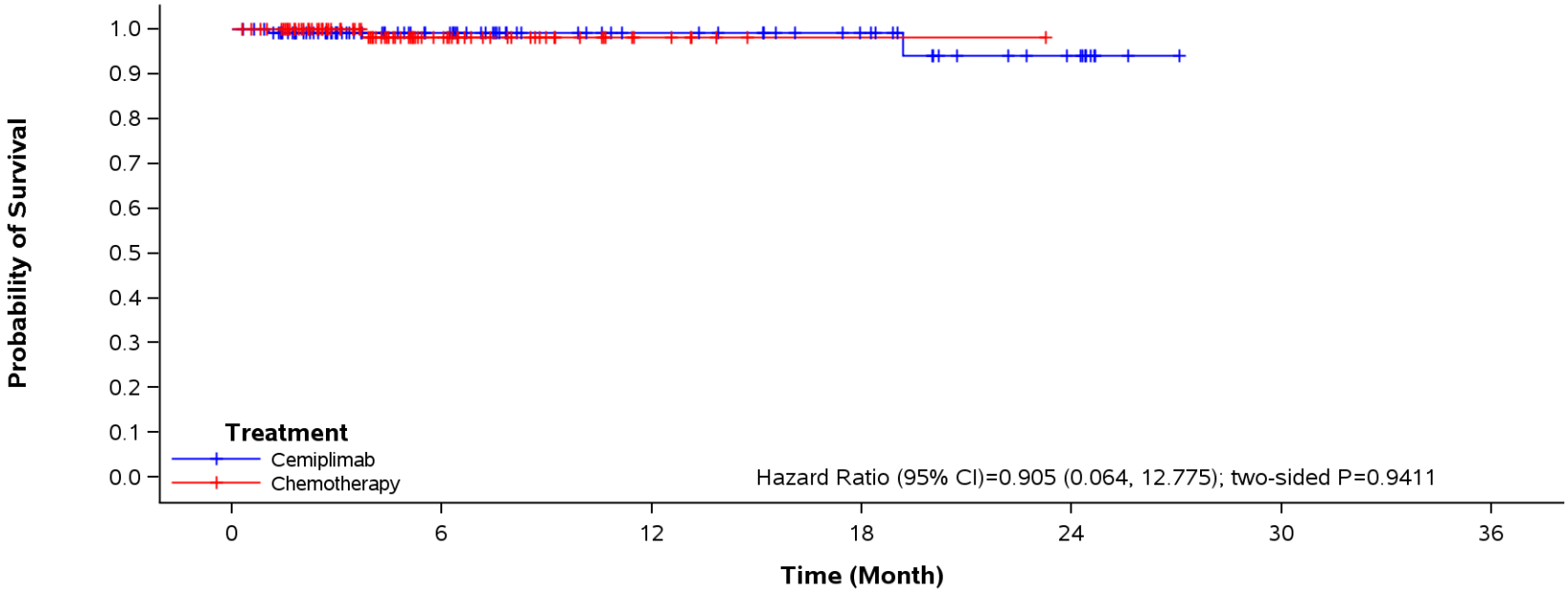

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 52 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders



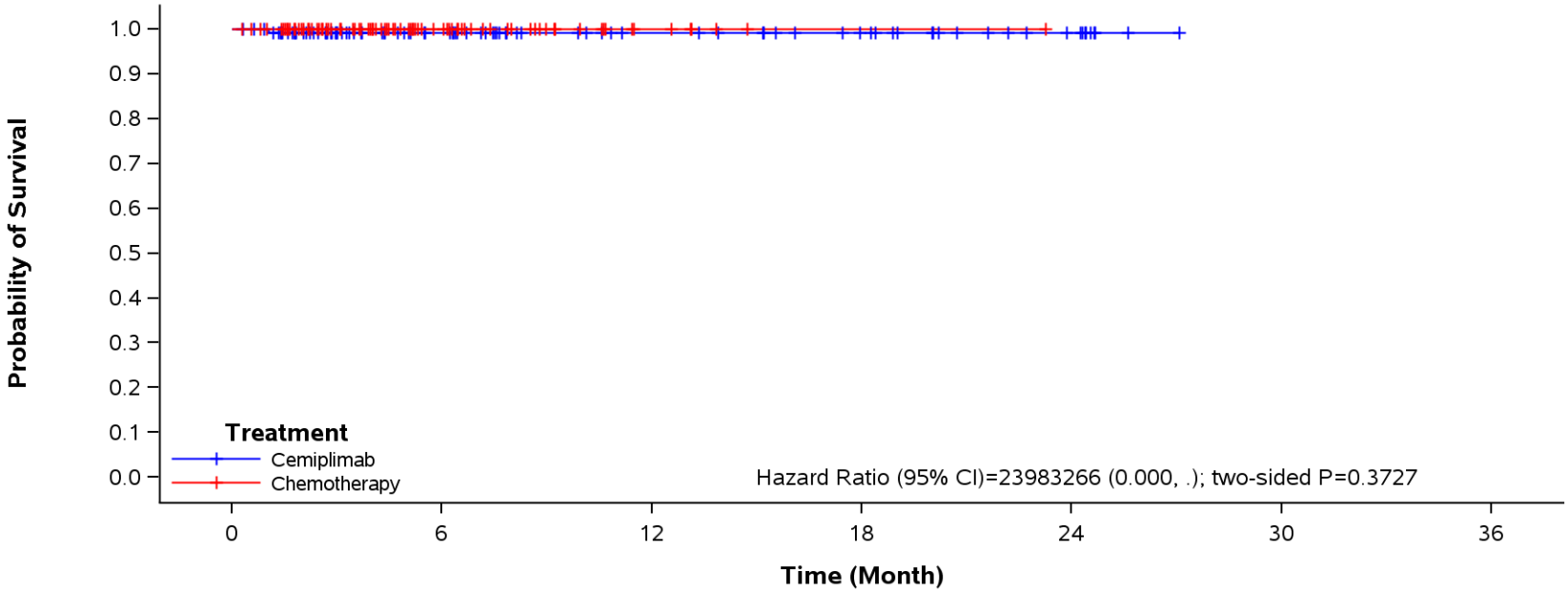

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 32 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders
PT: Colitis



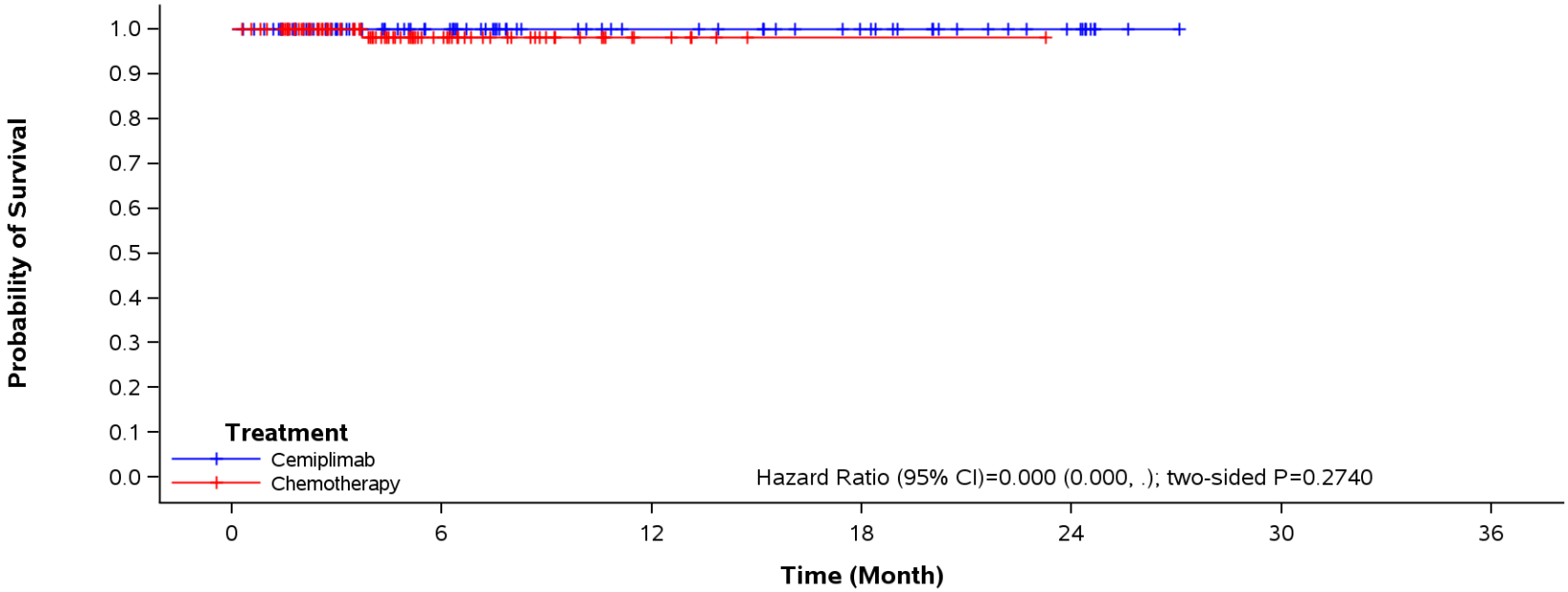

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders
PT: Diverticular perforation



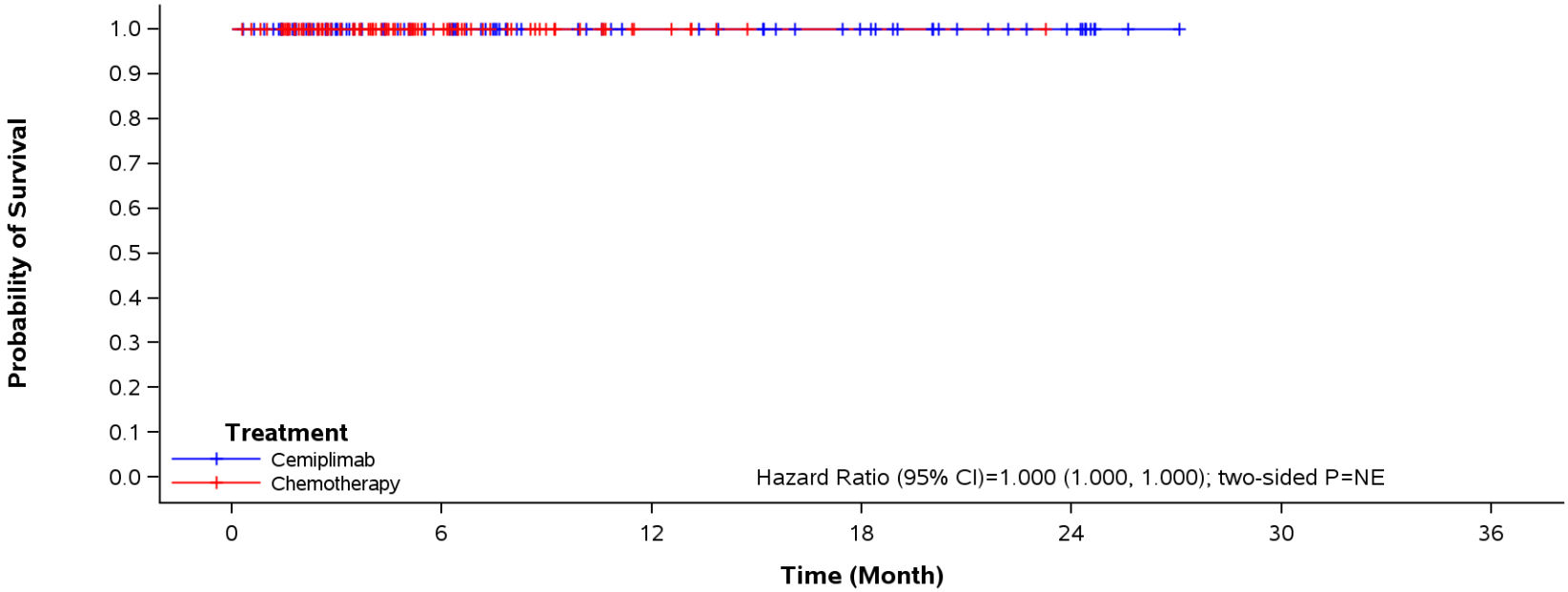

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 32 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders
PT: Pancreatic mass



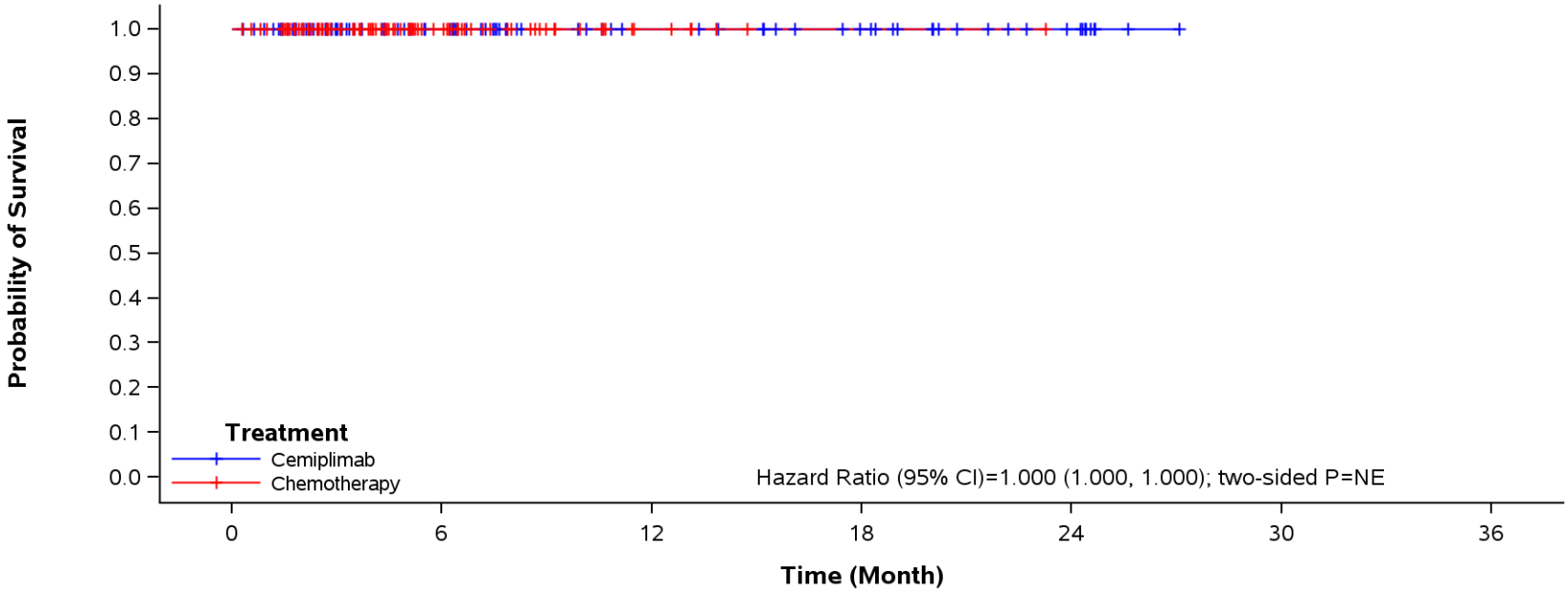

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



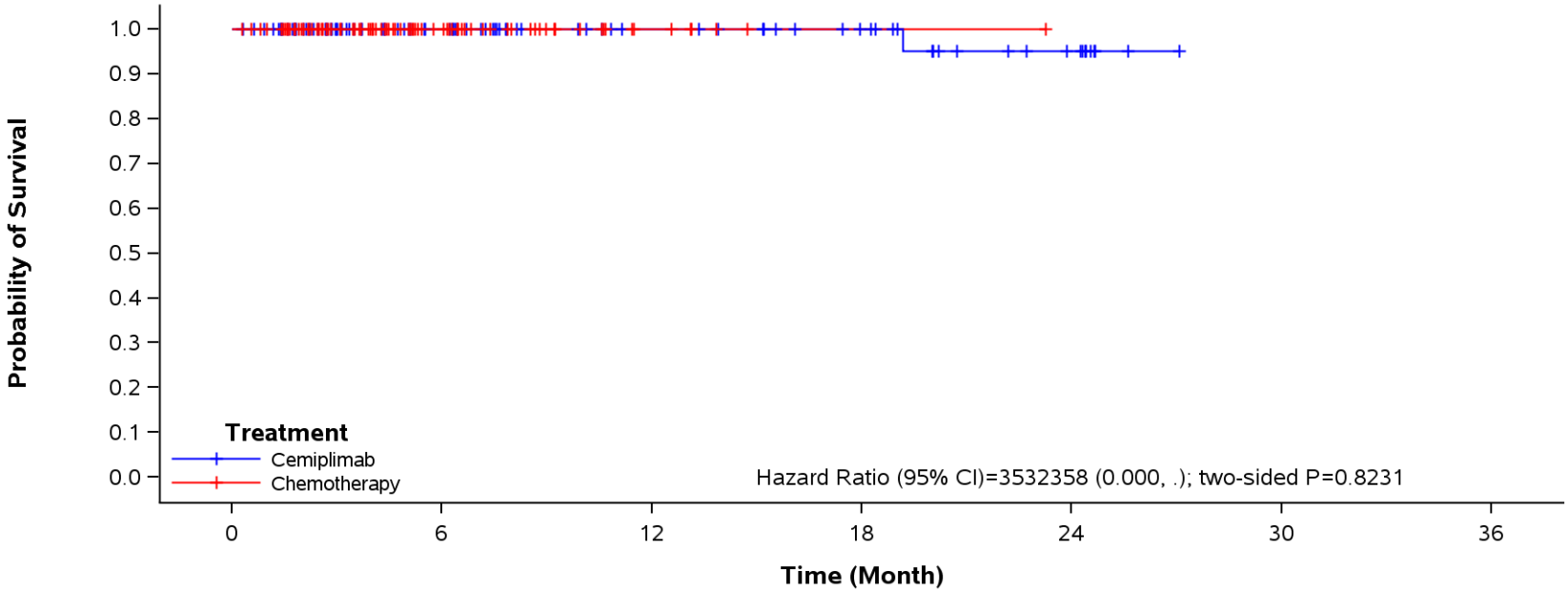

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Gastrointestinal disorders
PT: Proctalgia



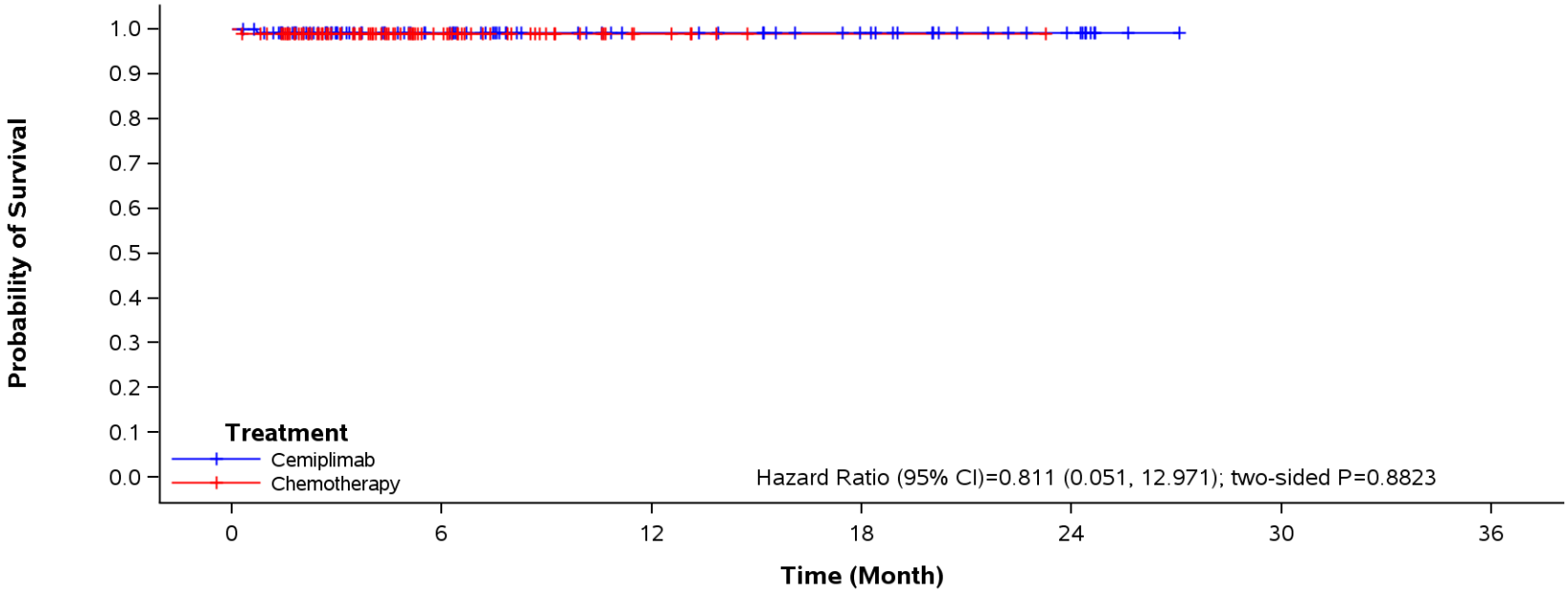

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: General disorders and administration site conditions



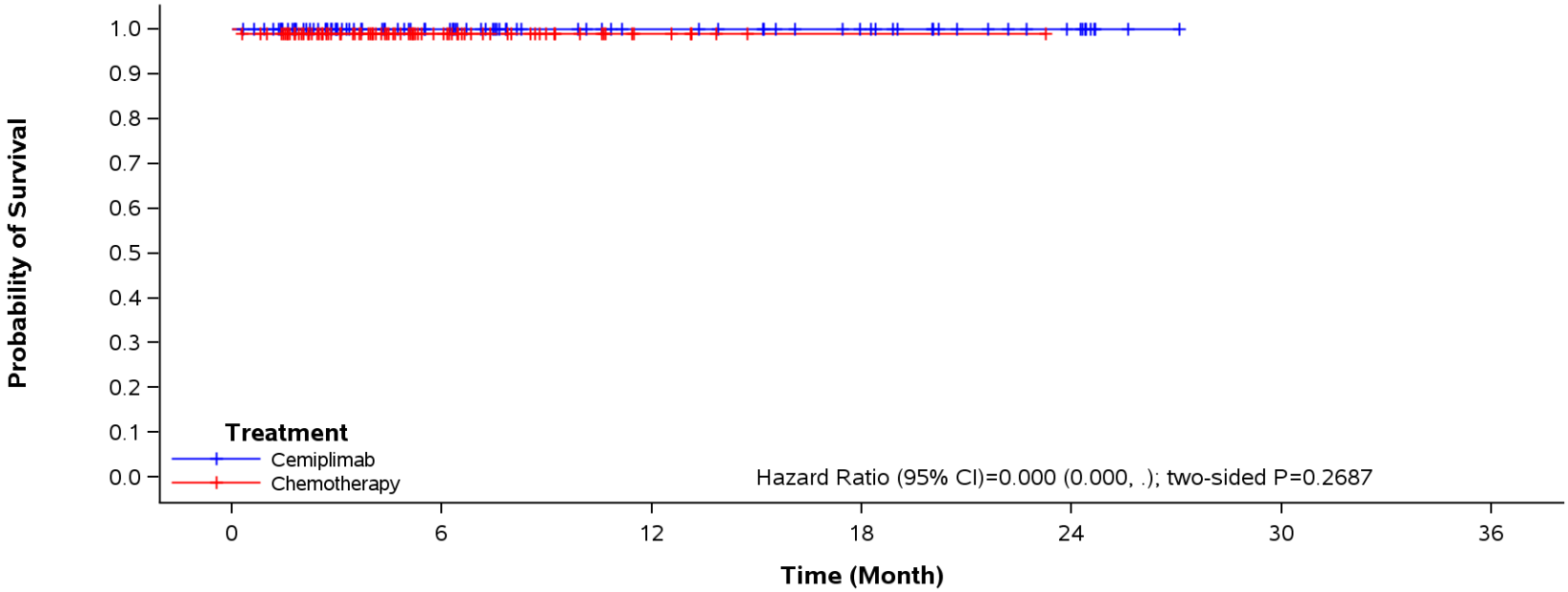

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: General disorders and administration site conditions
PT: Malaise



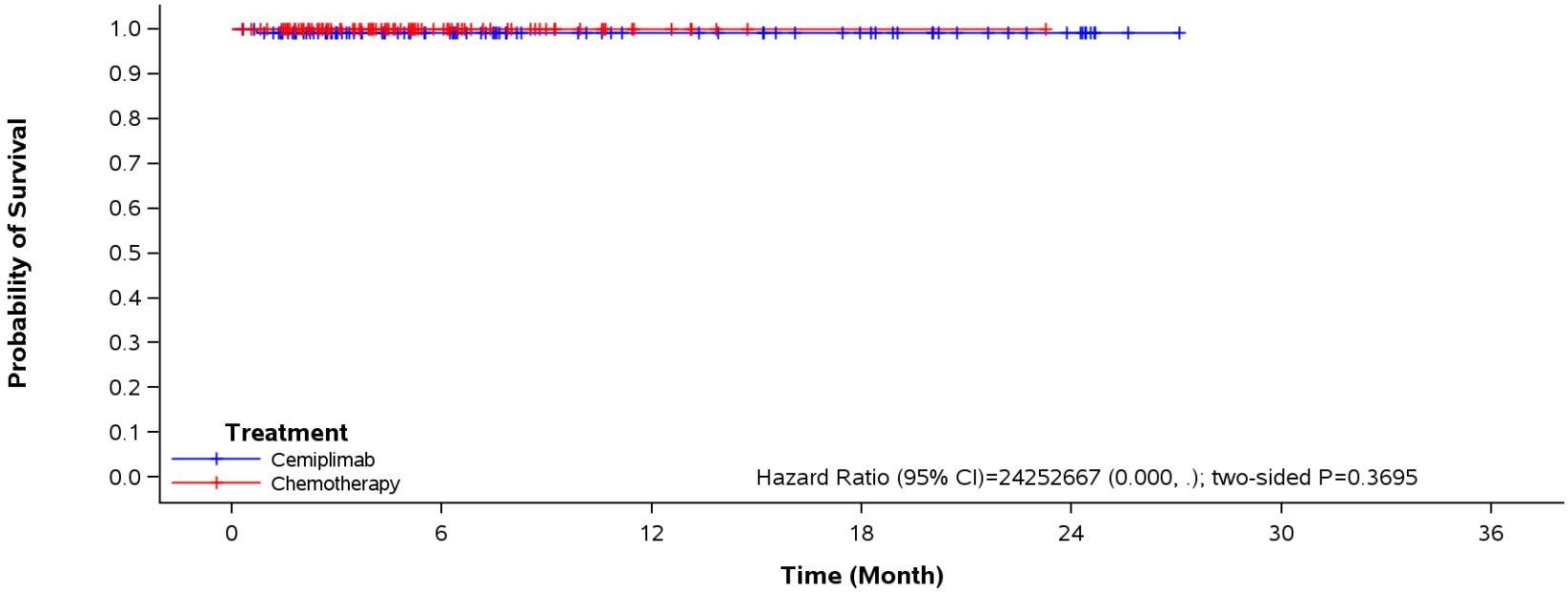

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



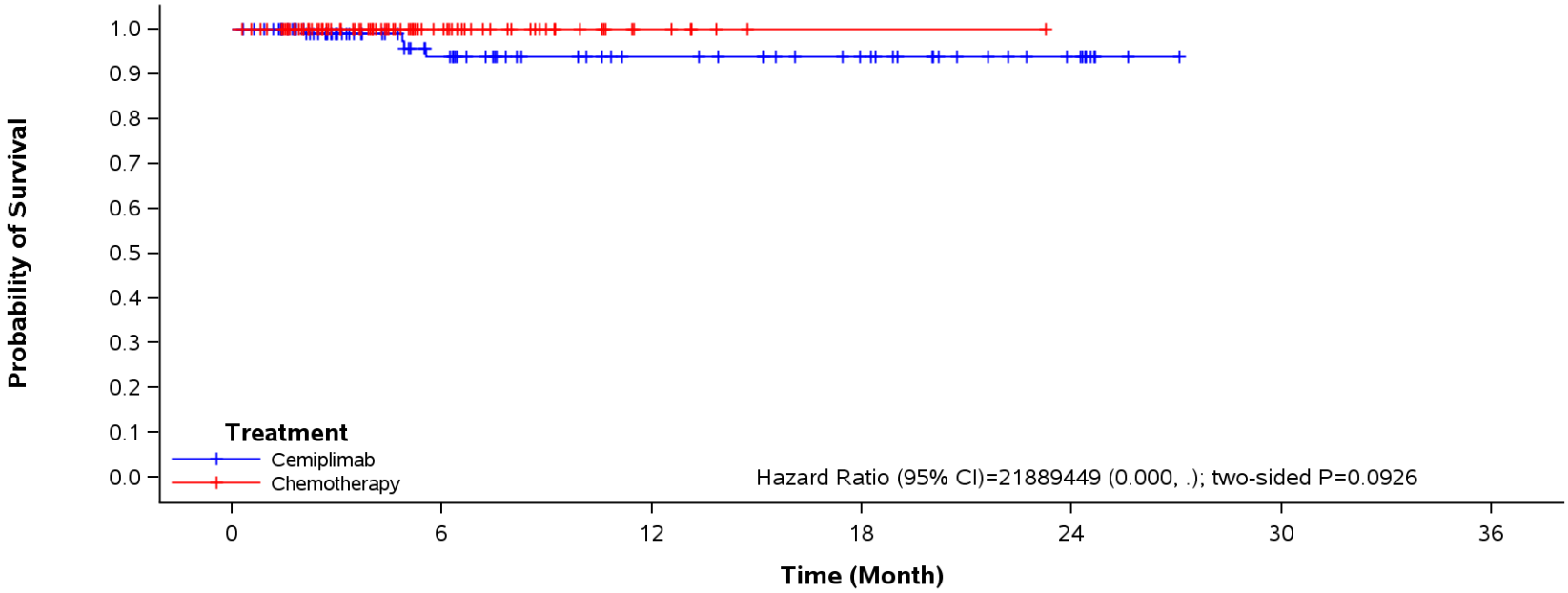

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Hepatobiliary disorders



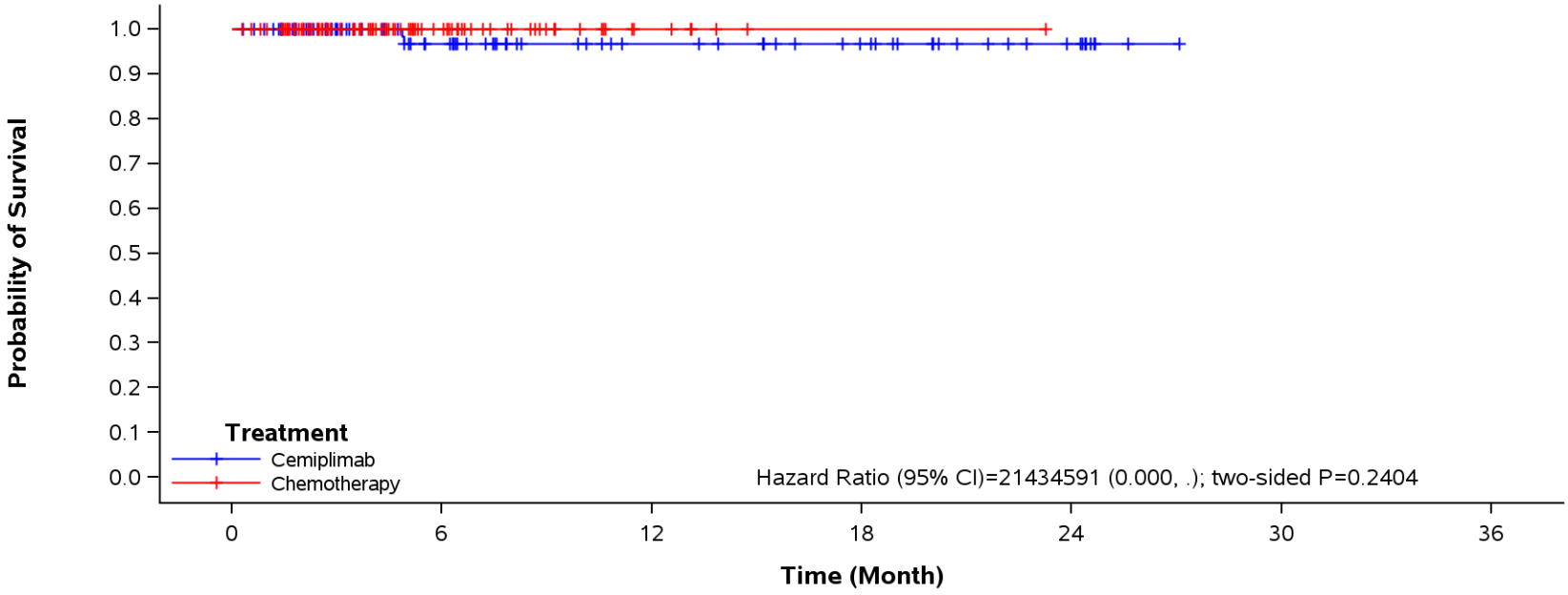

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 50 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



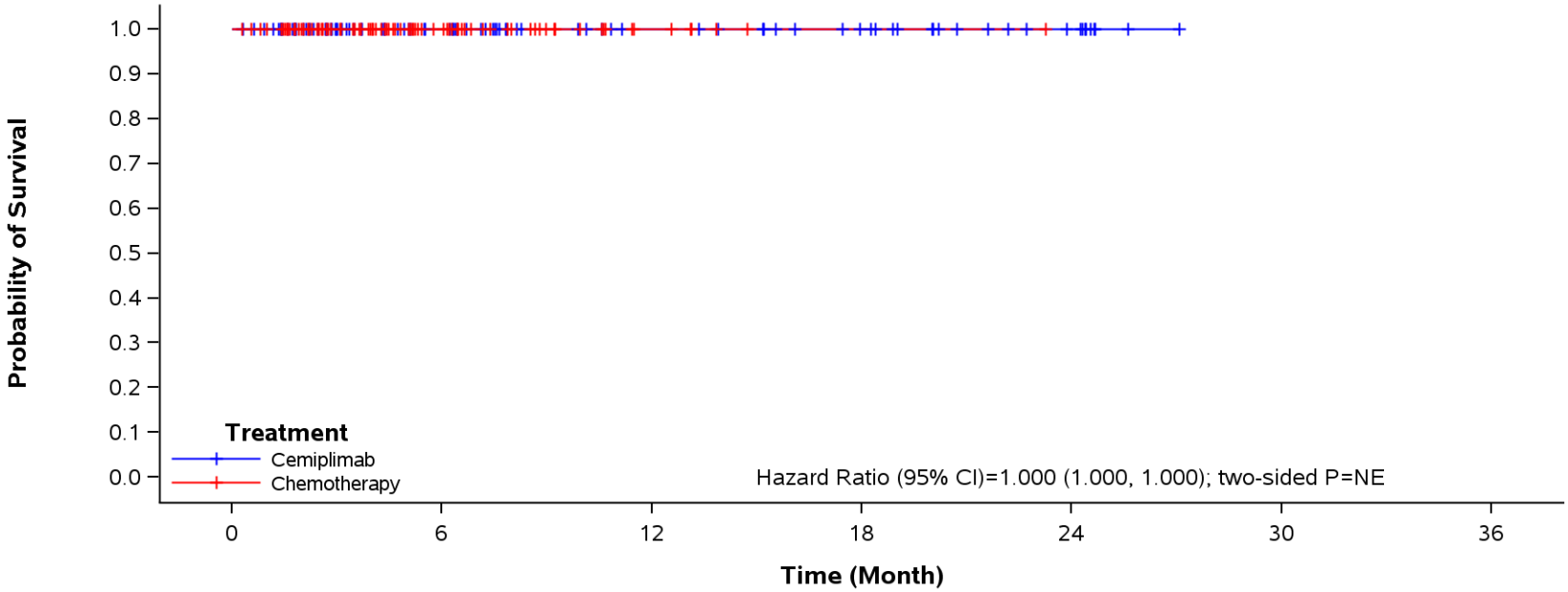

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 51 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



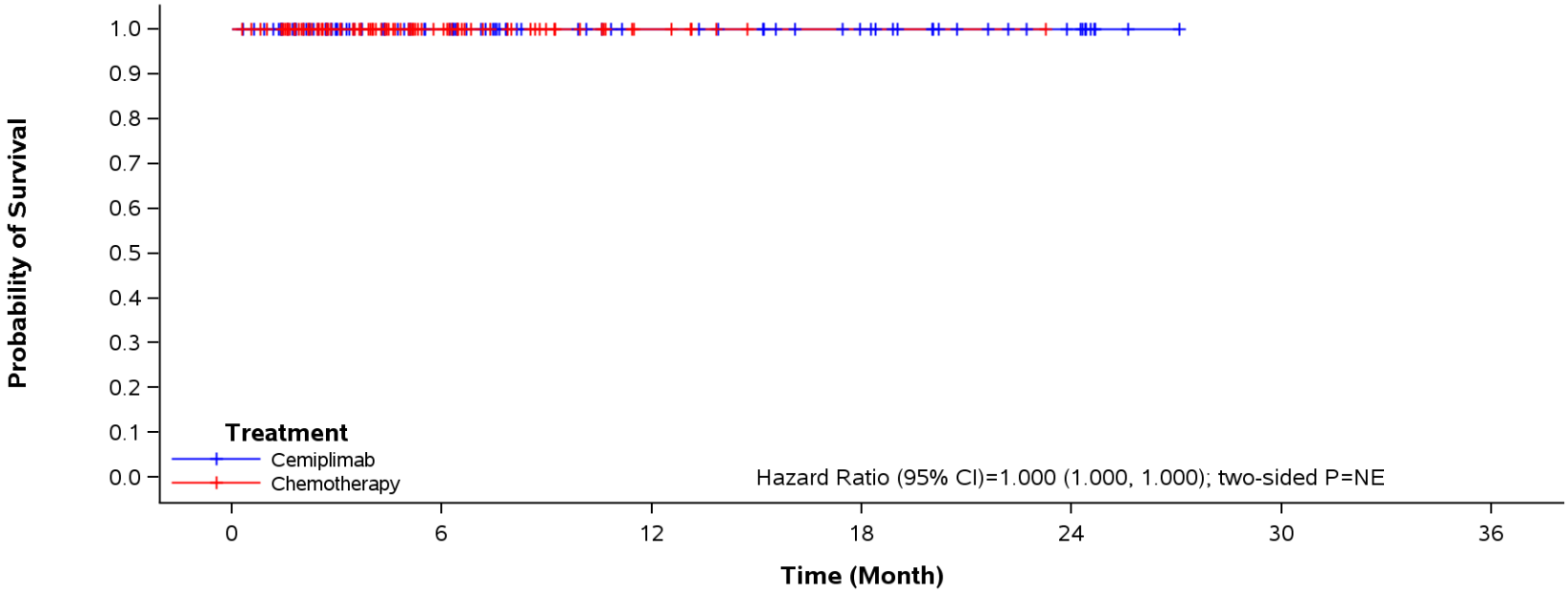

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Hepatobiliary disorders
PT: Hepatitis



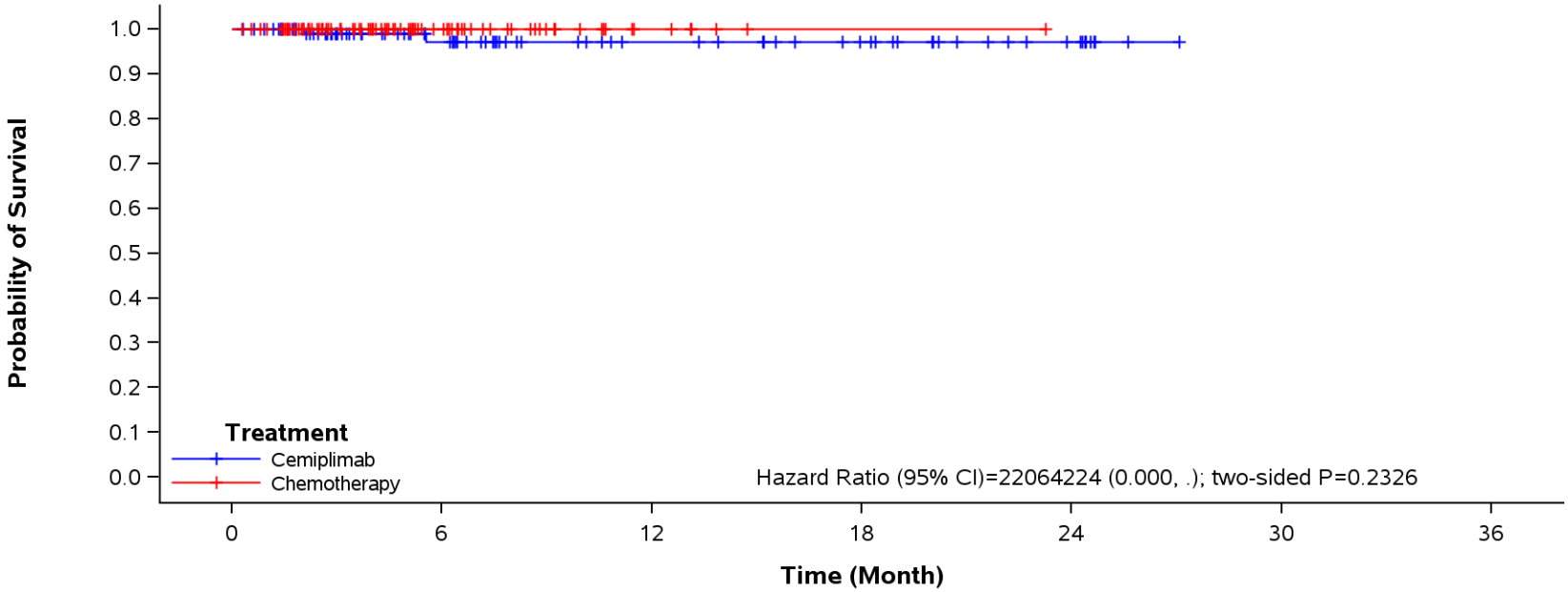

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



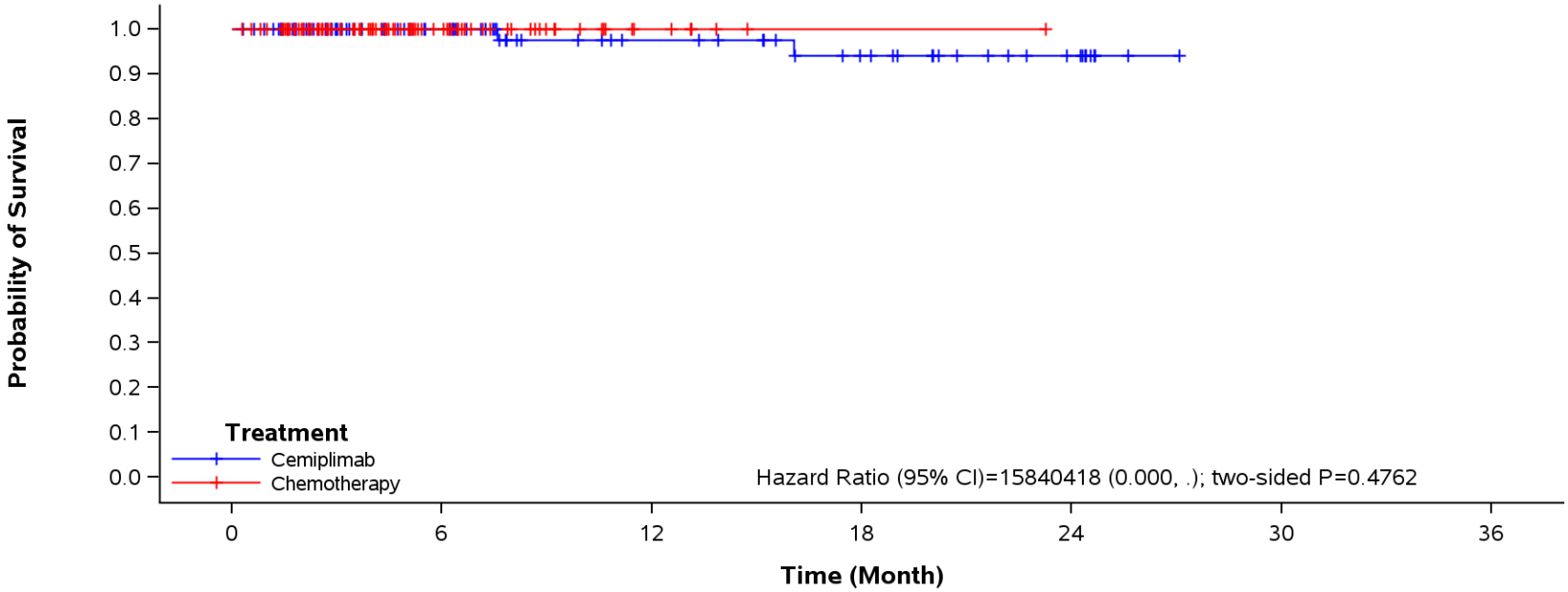

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 52 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Infections and infestations



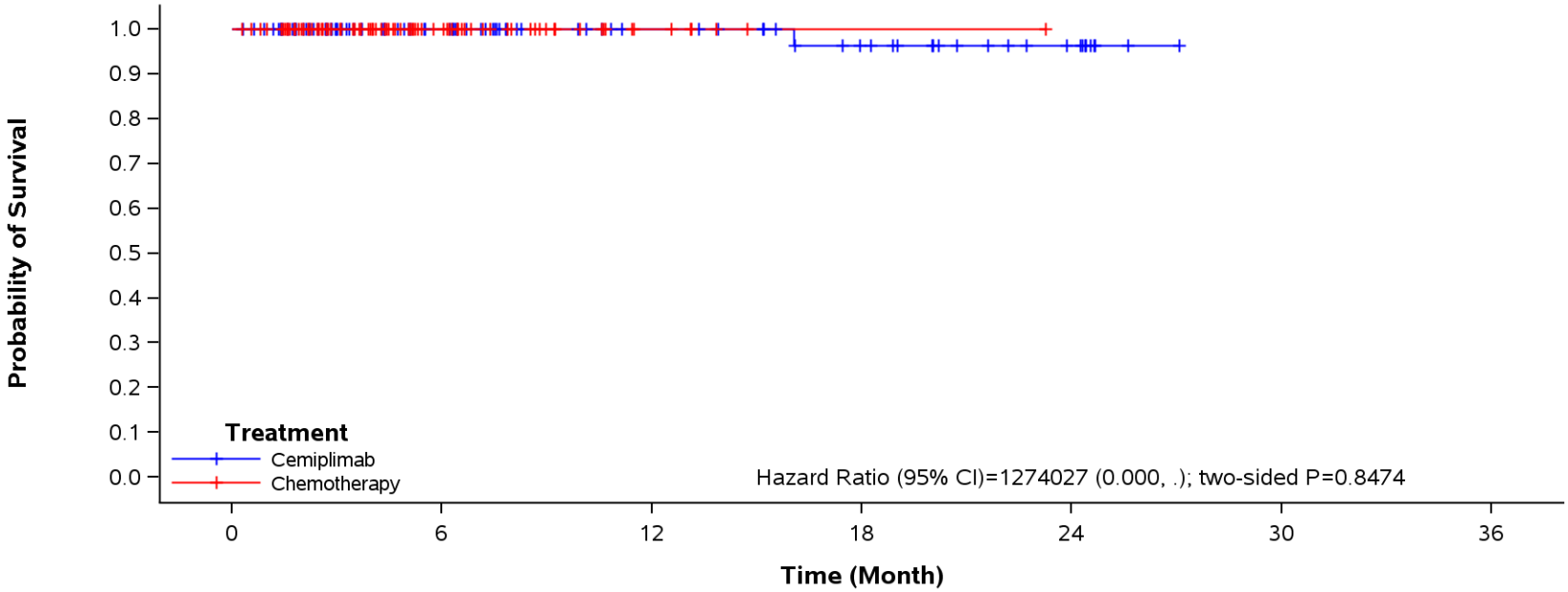

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 23 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Infections and infestations
PT: COVID-19 pneumonia



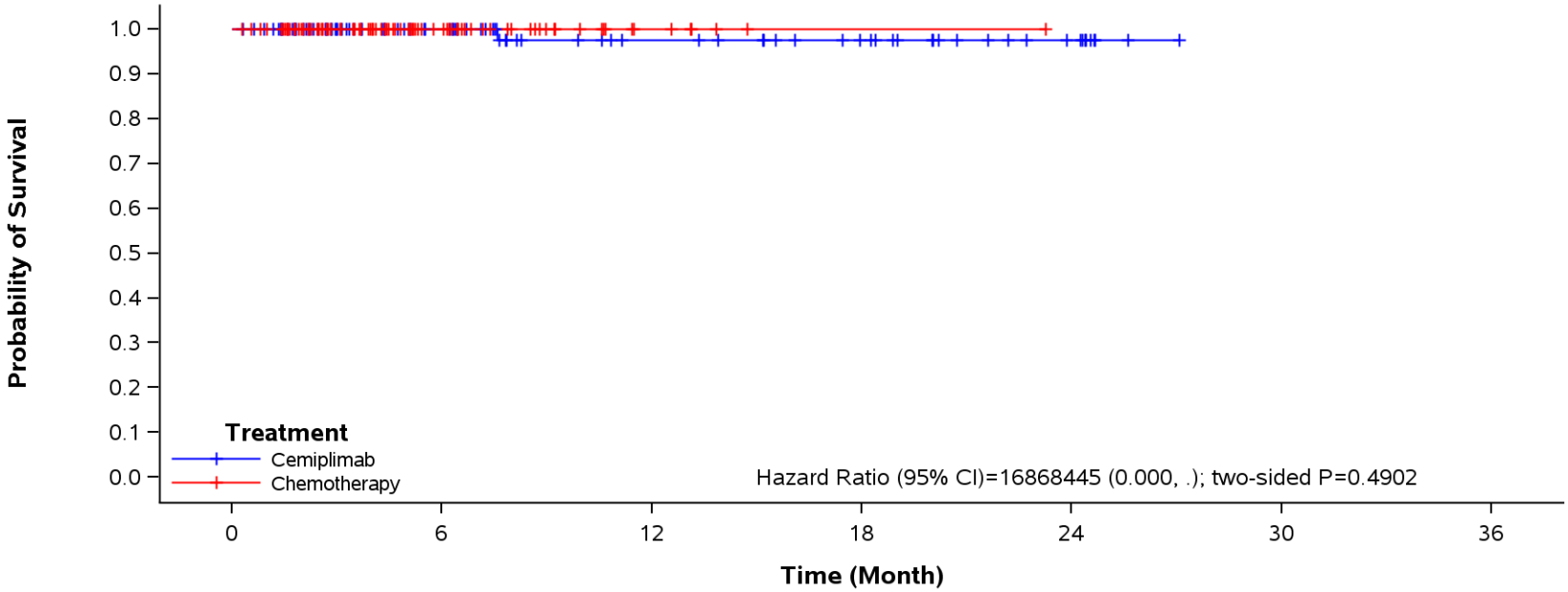

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 23 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Infections and infestations
PT: Gastroenteritis



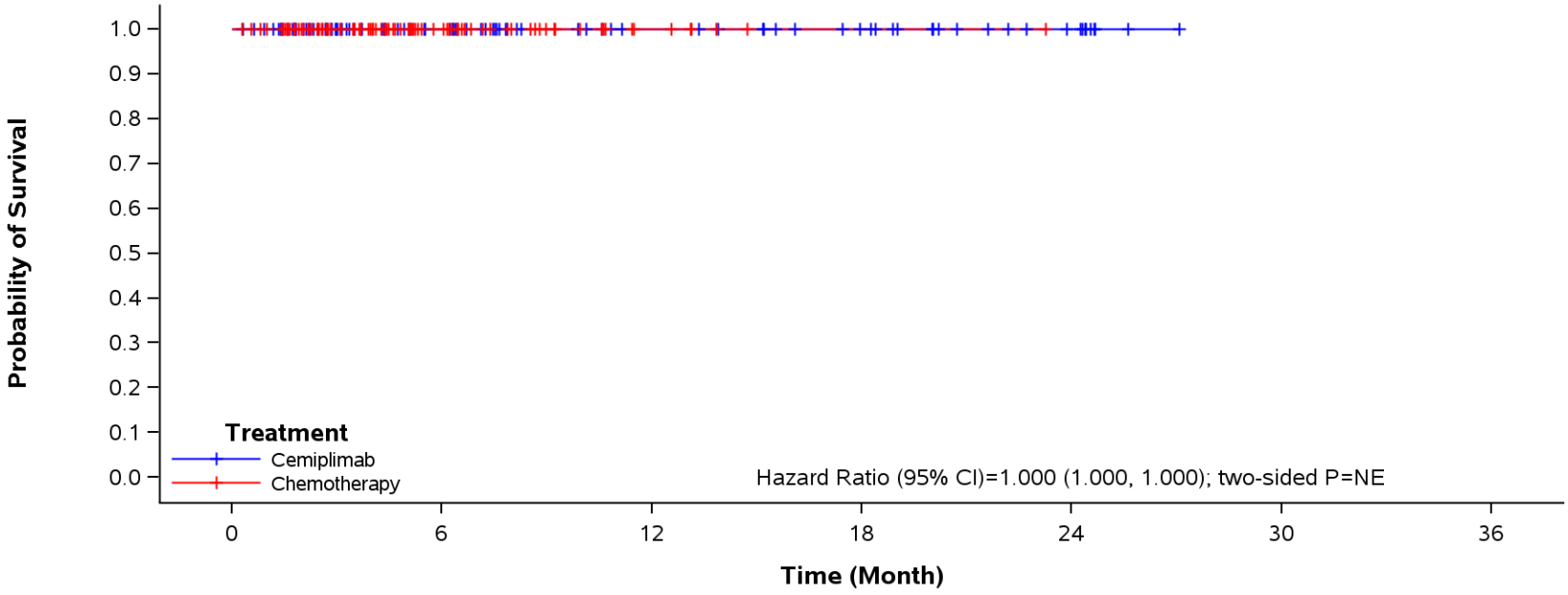

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Infections and infestations
PT: Pelvic abscess



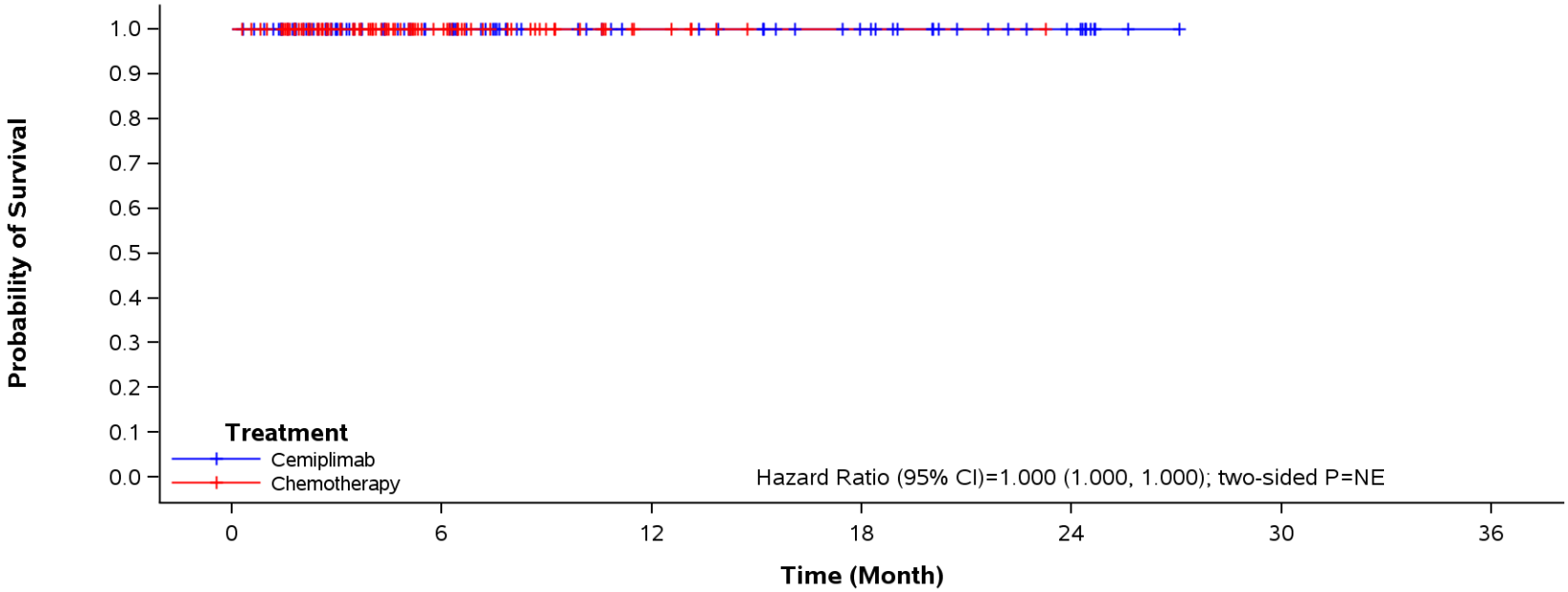

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Infections and infestations
PT: Peritonitis



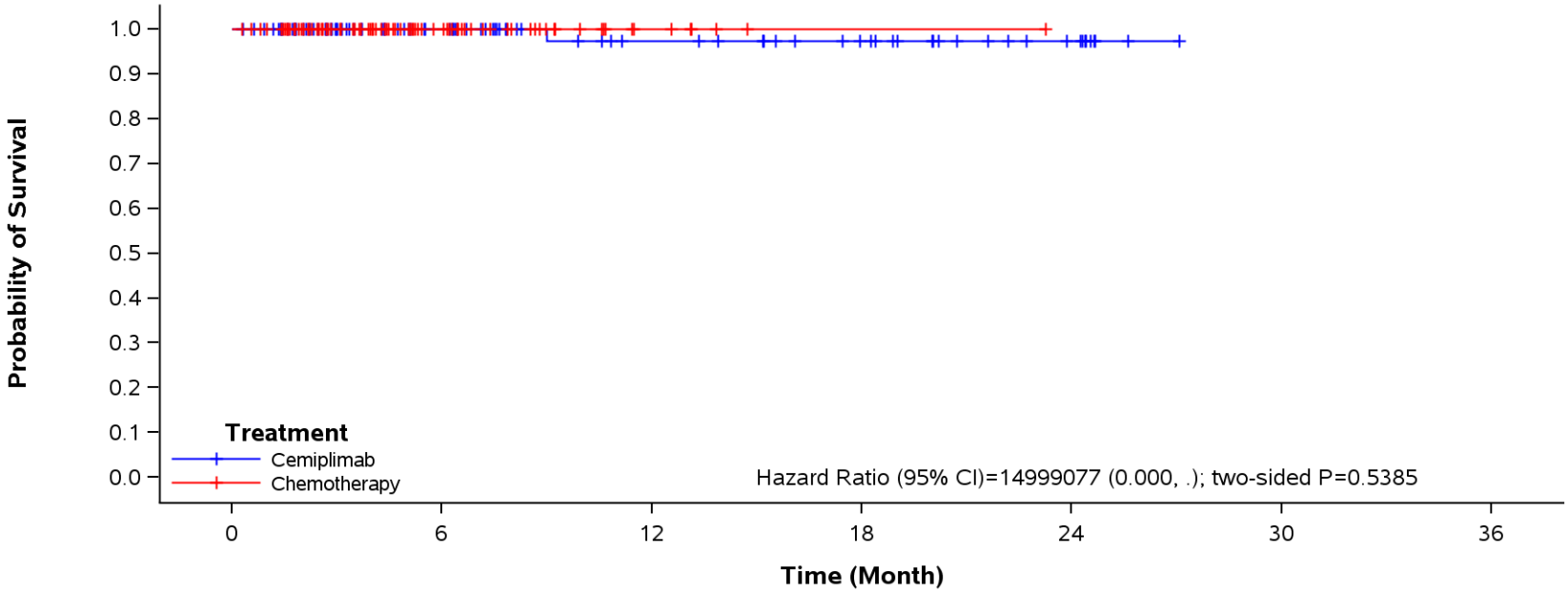

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Infections and infestations
PT: Pneumonia



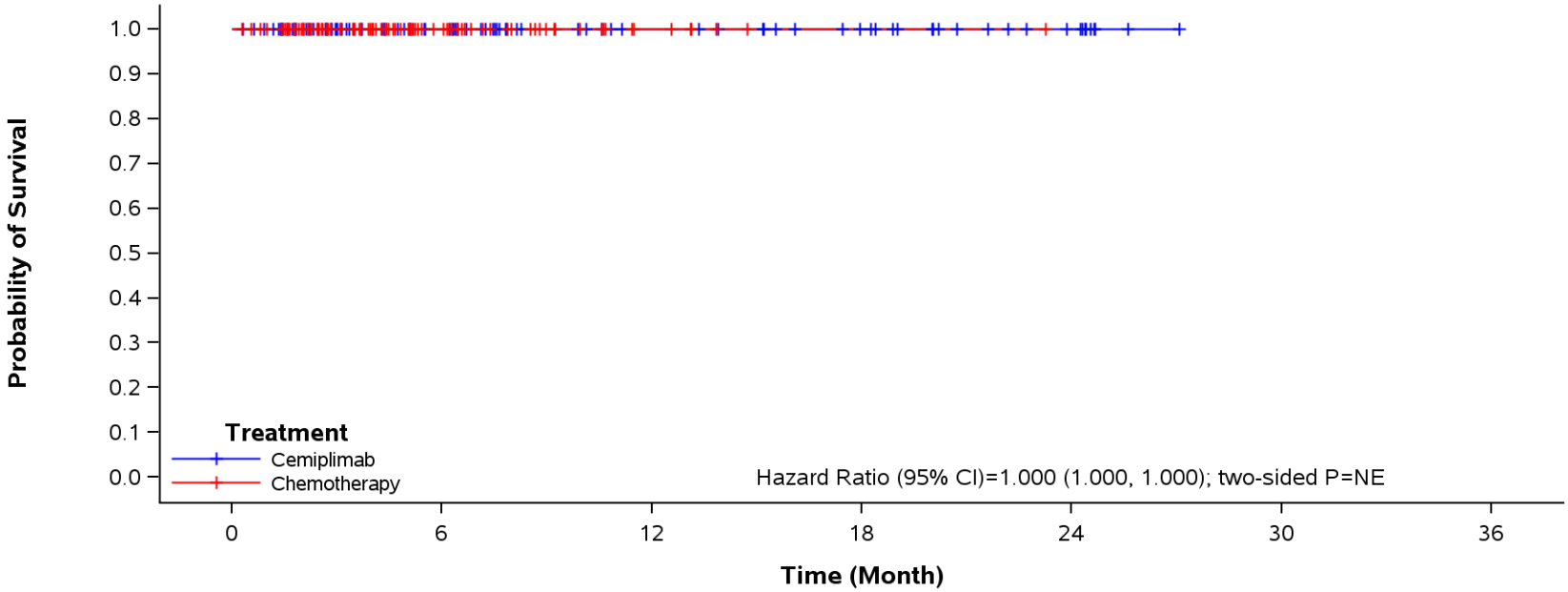

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Infections and infestations
PT: Pyomyositis



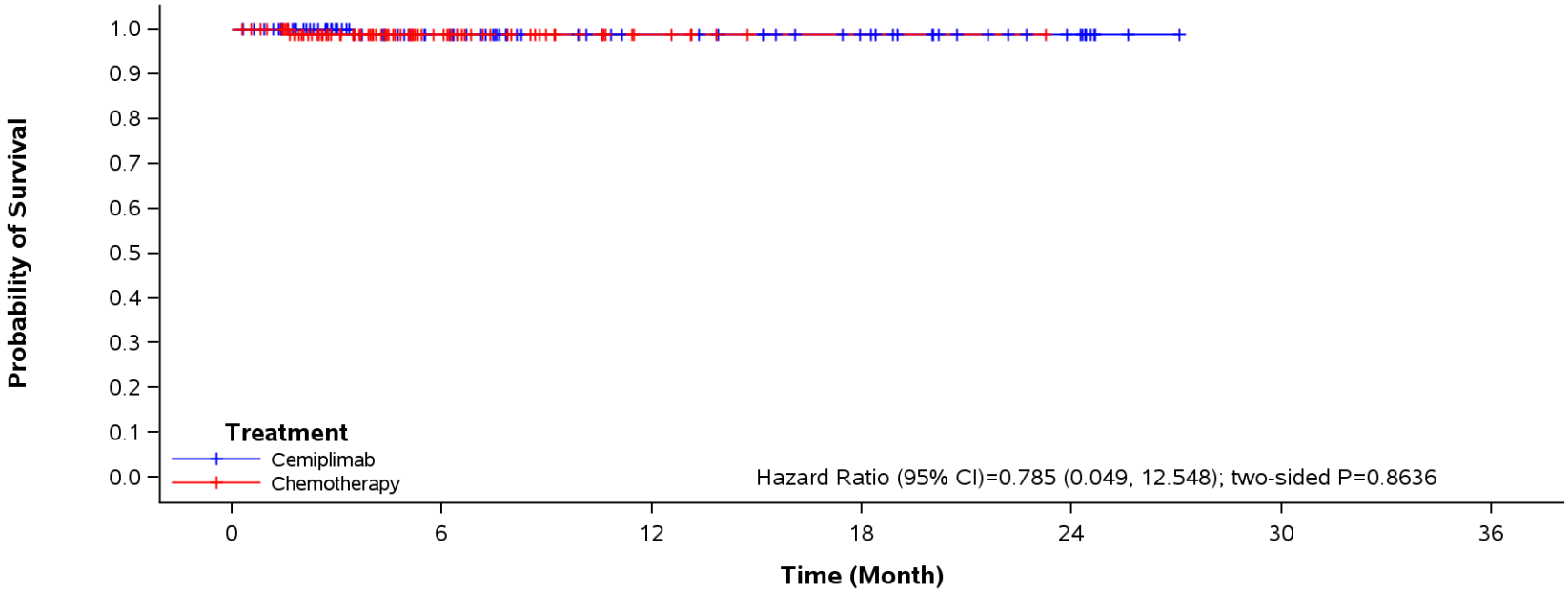

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Injury, poisoning and procedural complications



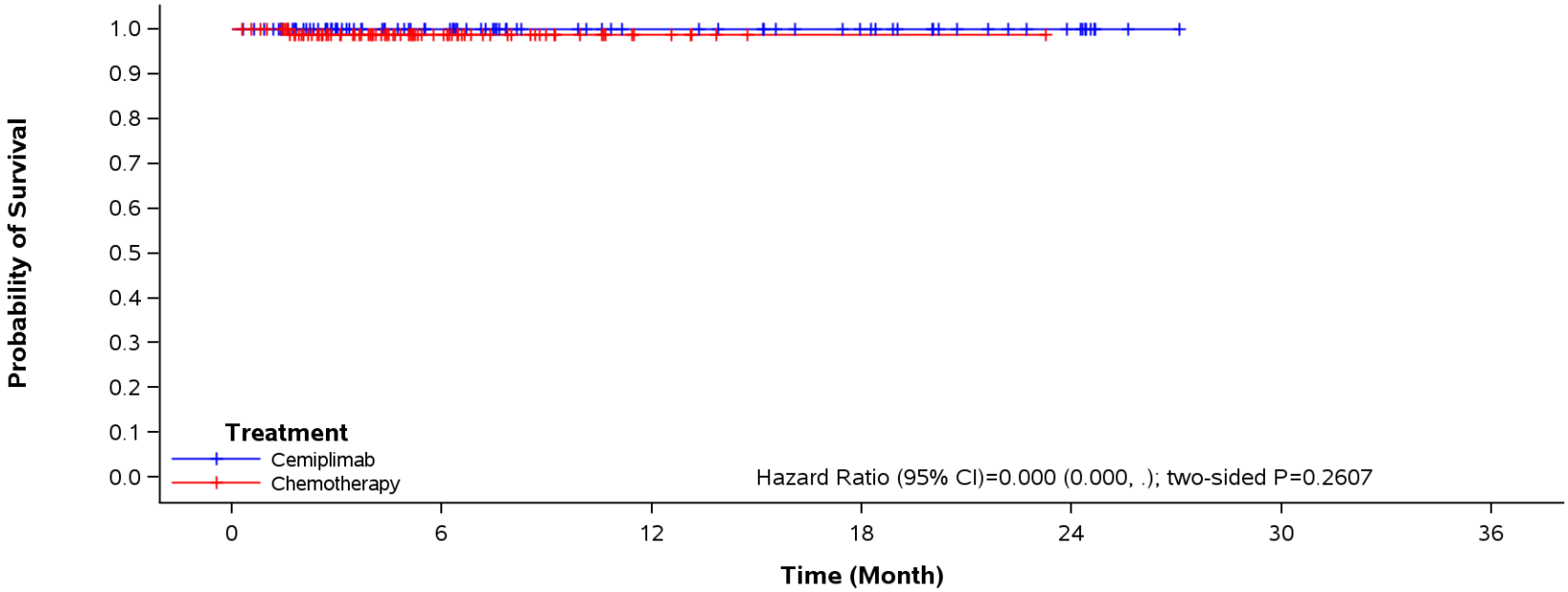

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 52 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



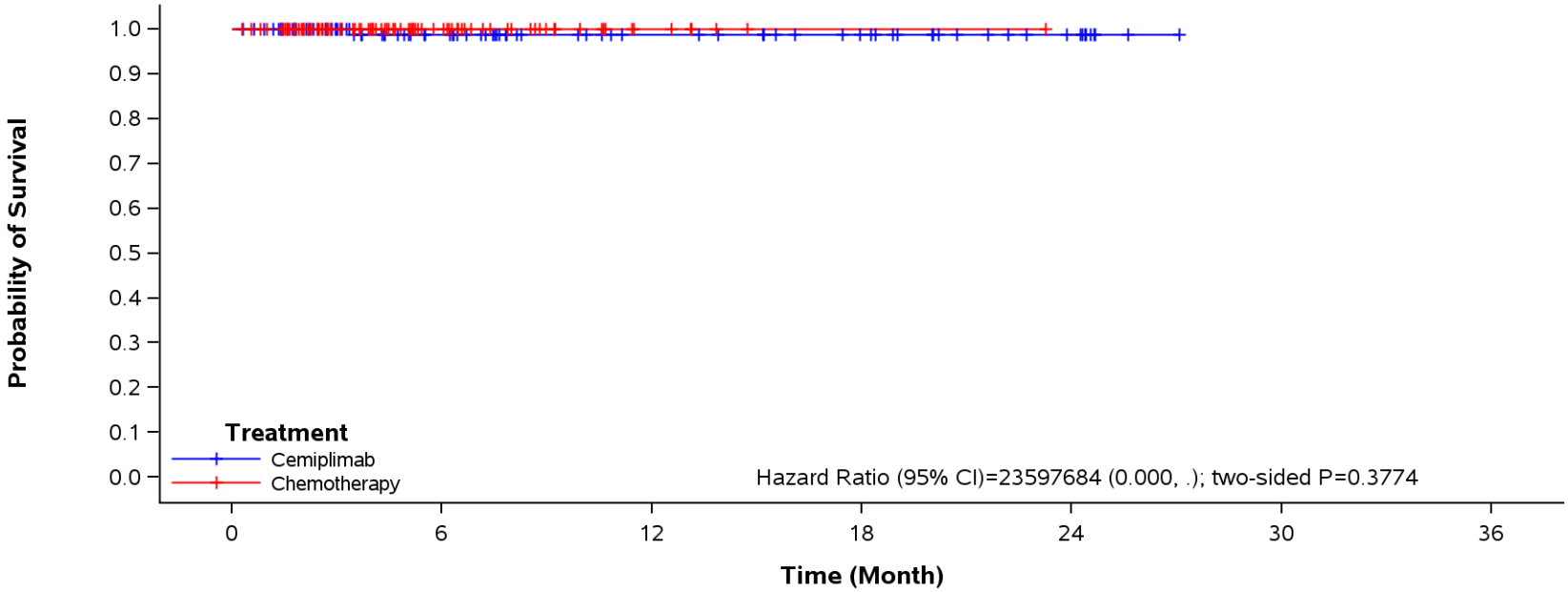

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



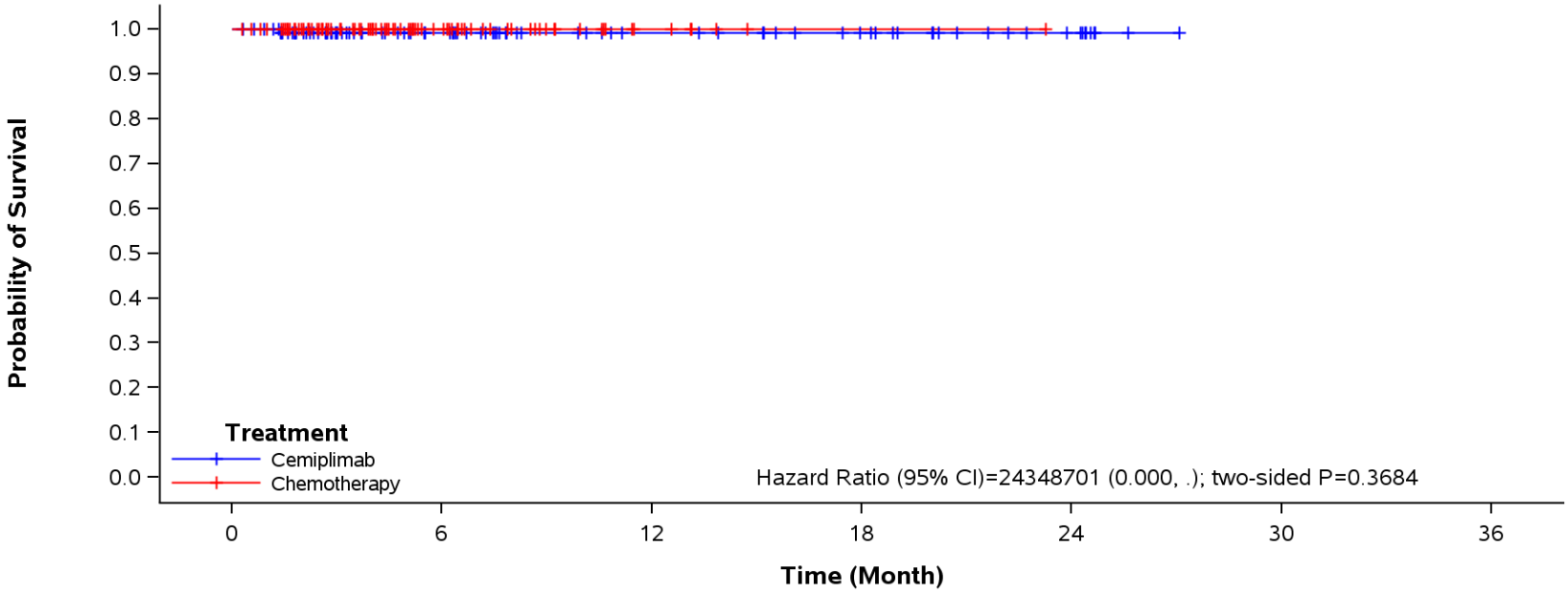

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 52 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Investigations



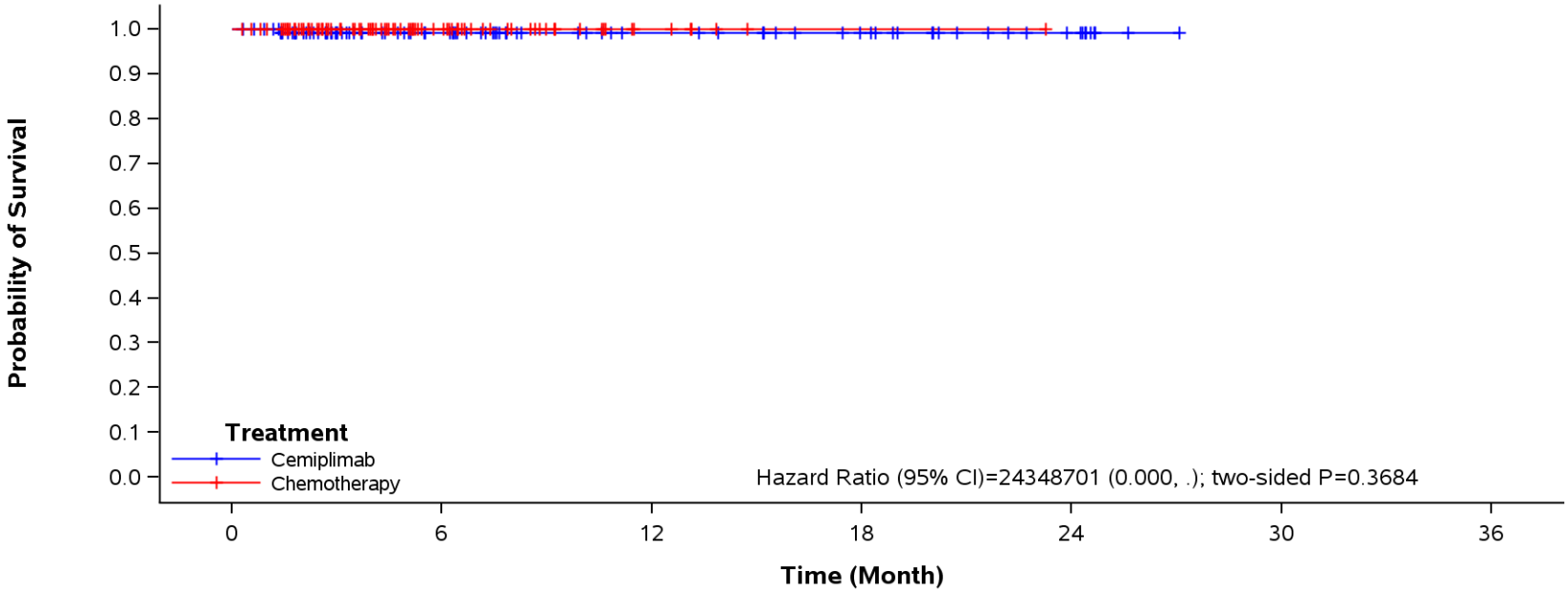

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Investigations
PT: Alanine aminotransferase increased



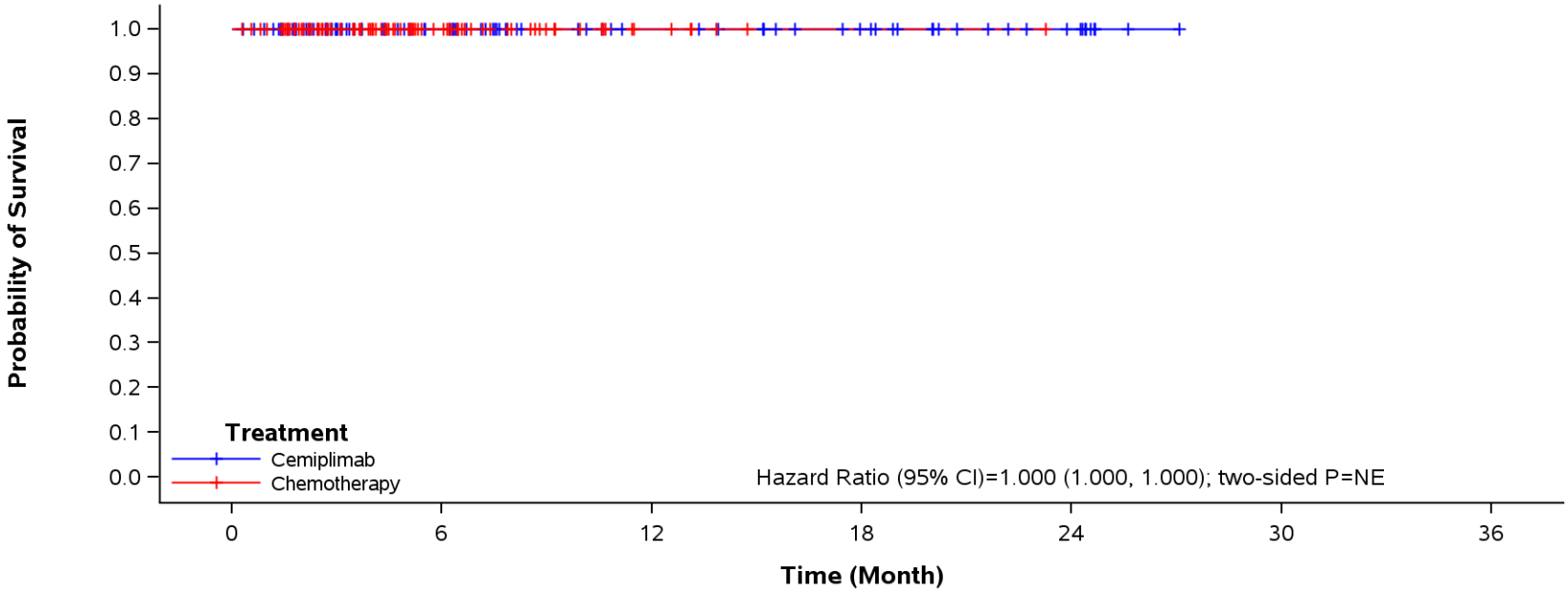

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Investigations
PT: Amylase increased



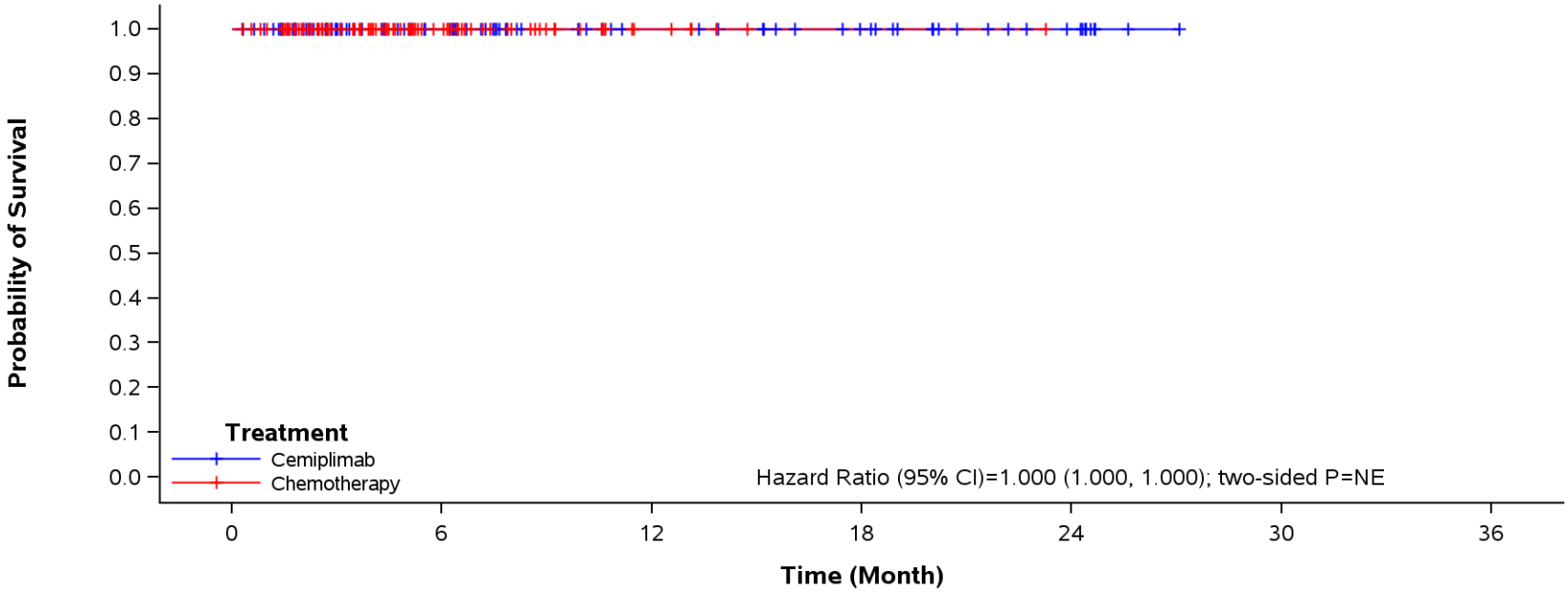

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Investigations
PT: Platelet count decreased



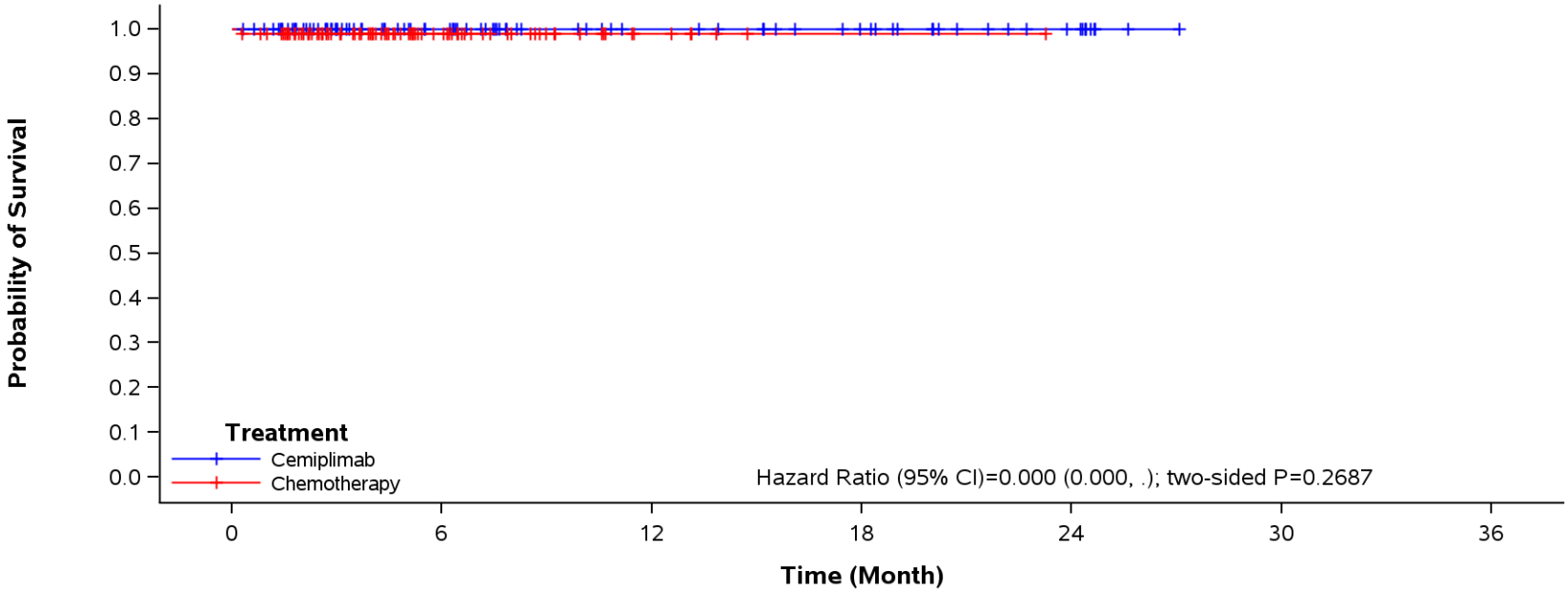

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Metabolism and nutrition disorders



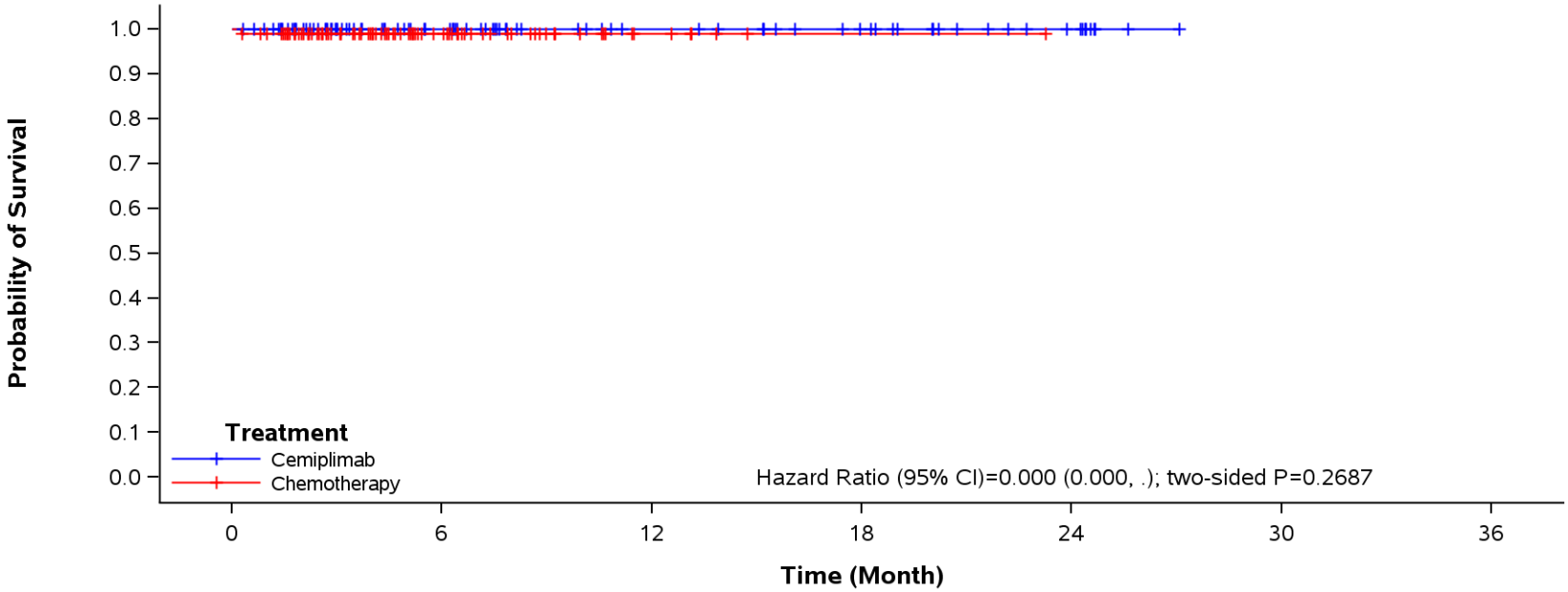

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



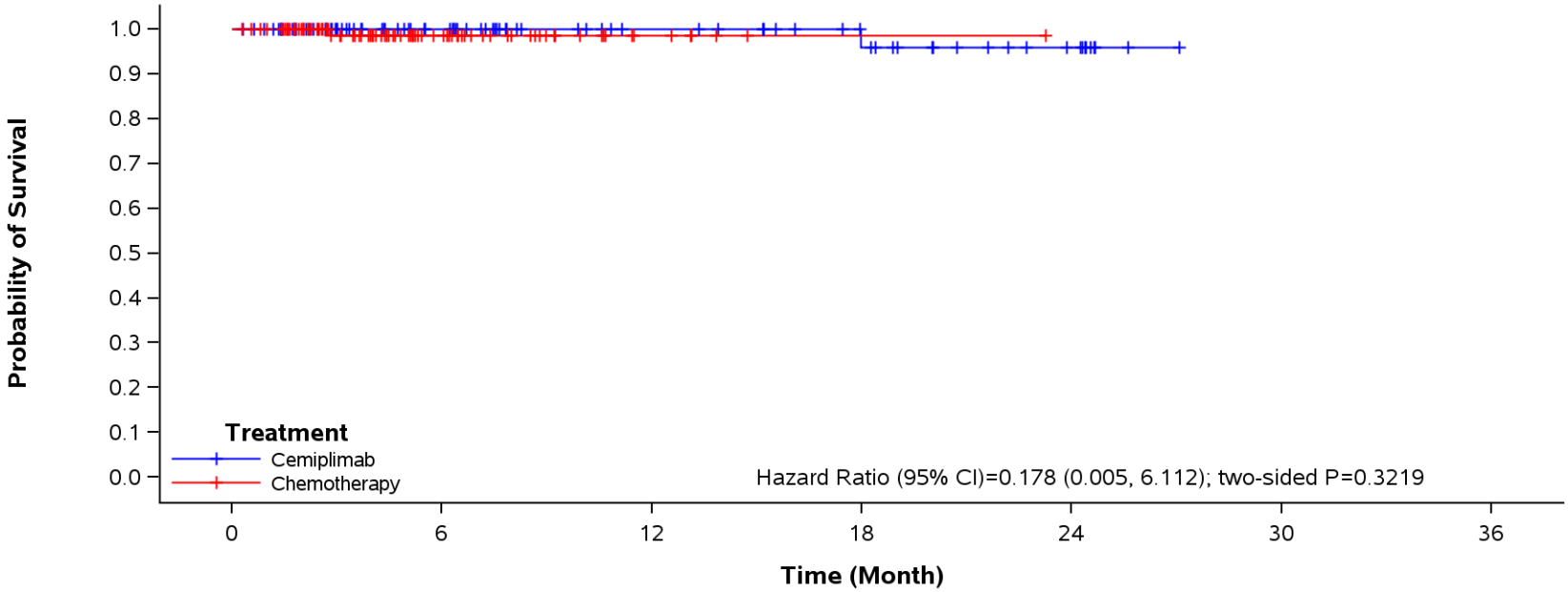

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Musculoskeletal and connective tissue disorders




**Number of Subjects at risk**

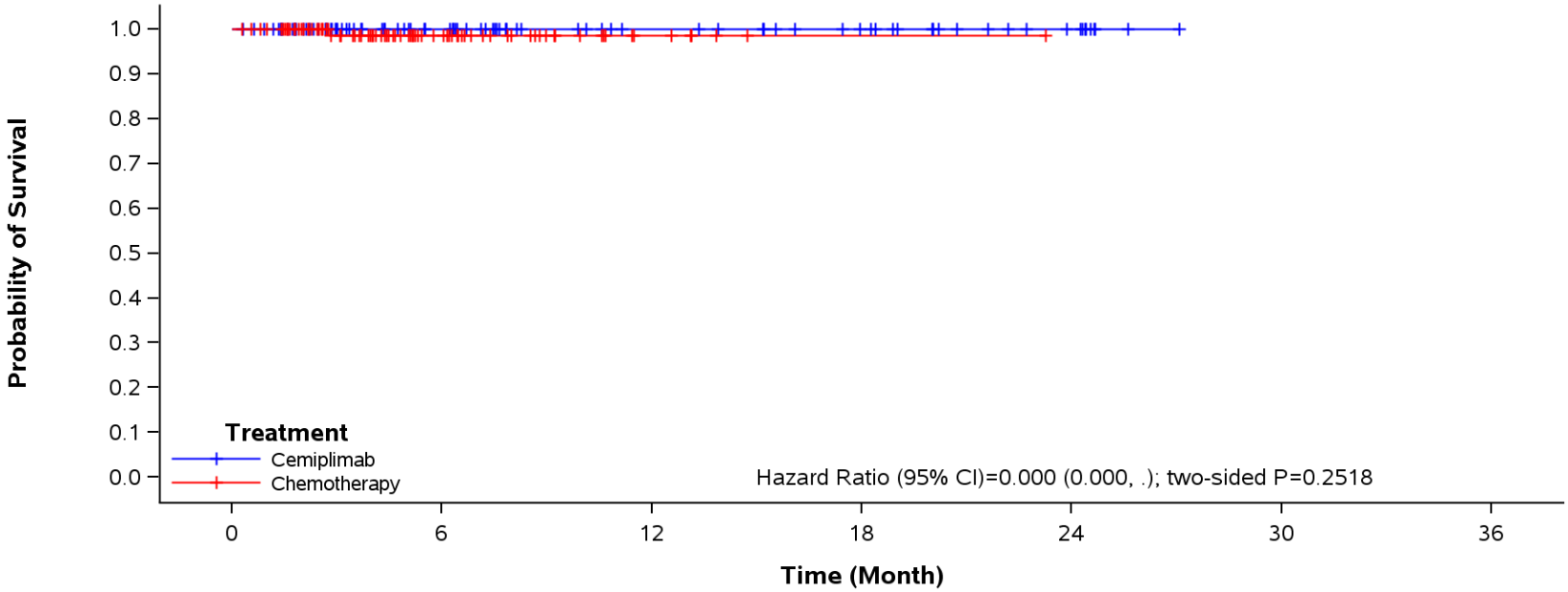
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 23 | 12 | 0 | 0 |
| Chemotherapy | 94 | 32 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas
(14NOV22:05:00:36, haijin.tang)

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



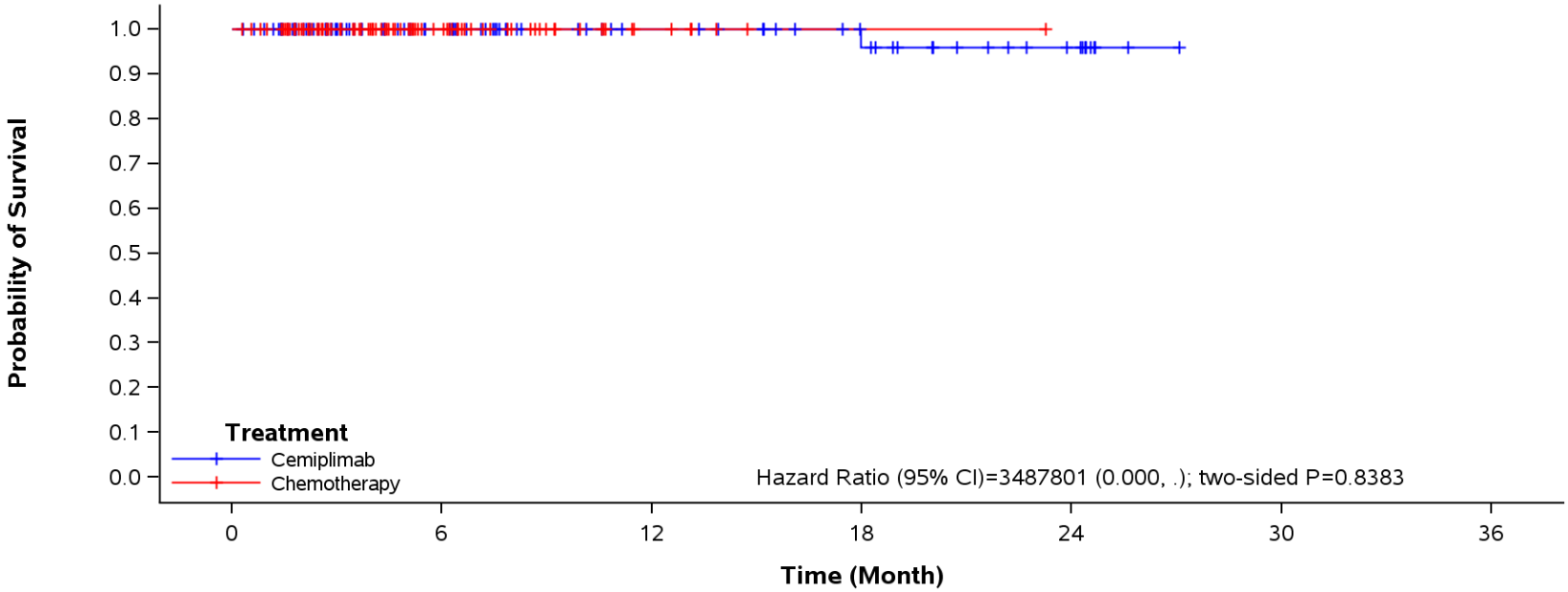

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 32 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



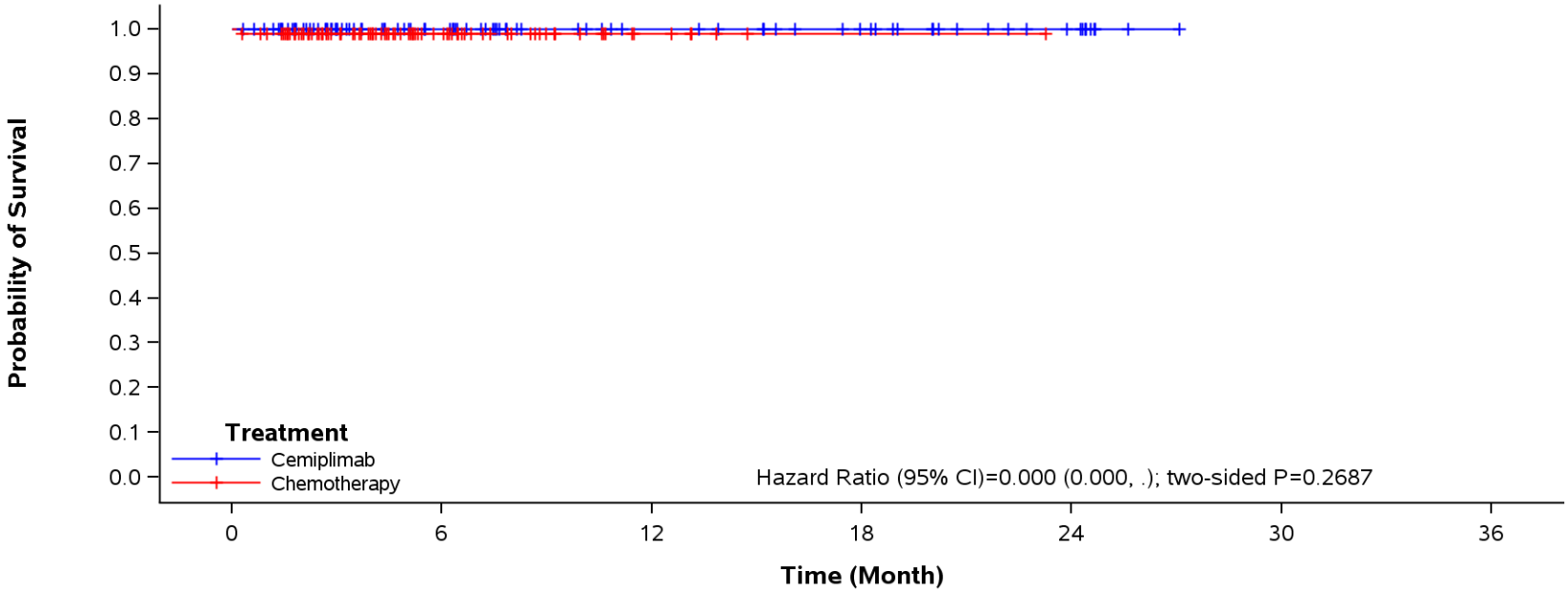

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 23 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Nervous system disorders



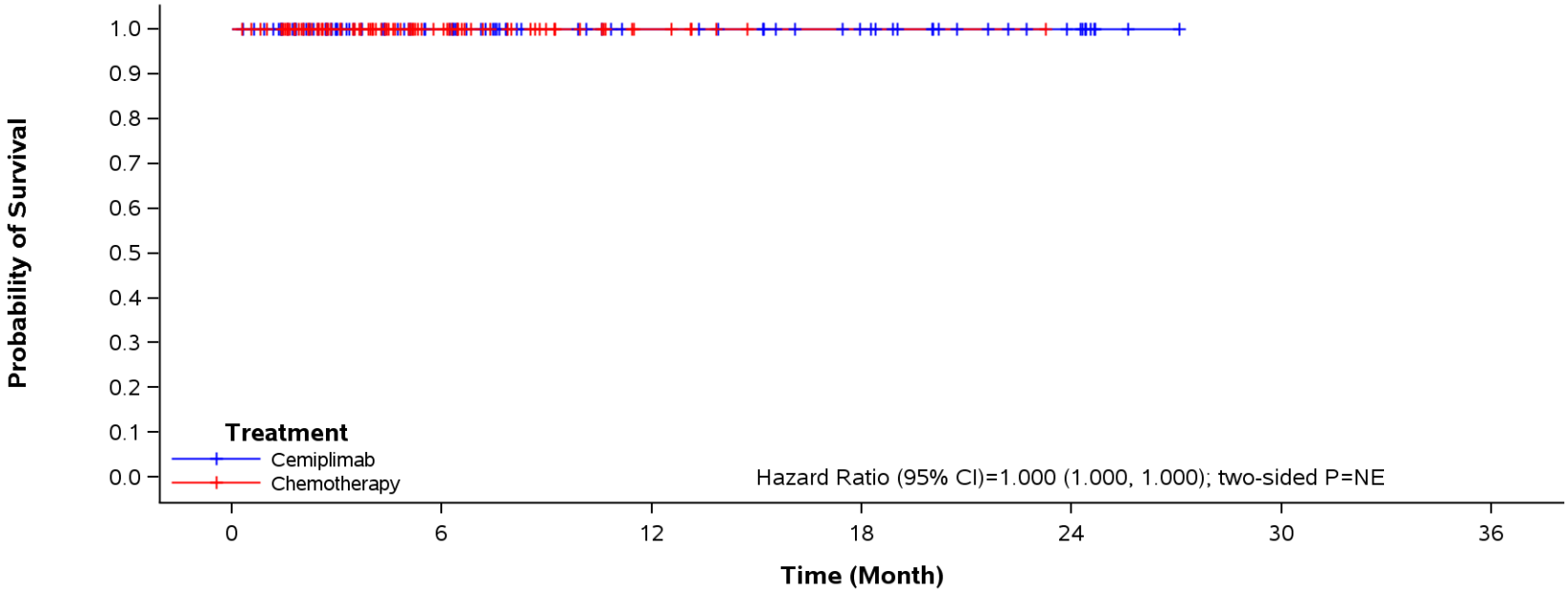

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Nervous system disorders
PT: Neurotoxicity



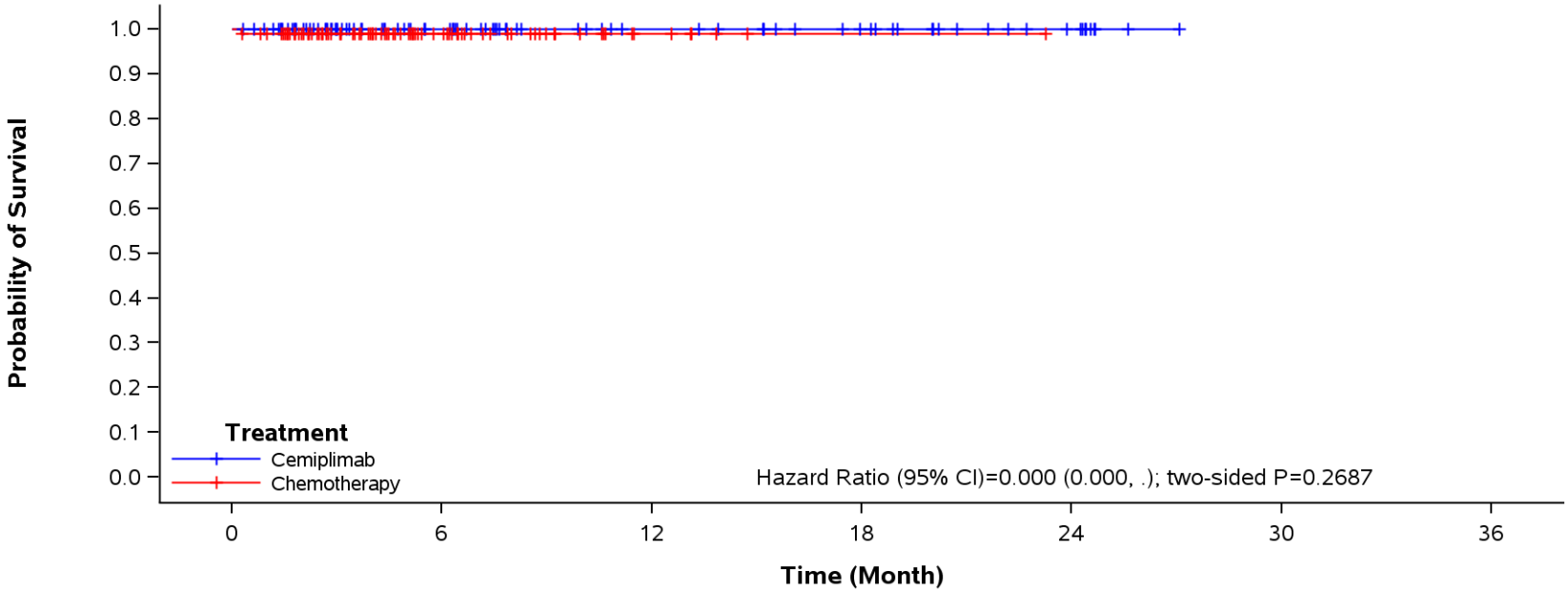

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Nervous system disorders
PT: Transient ischaemic attack



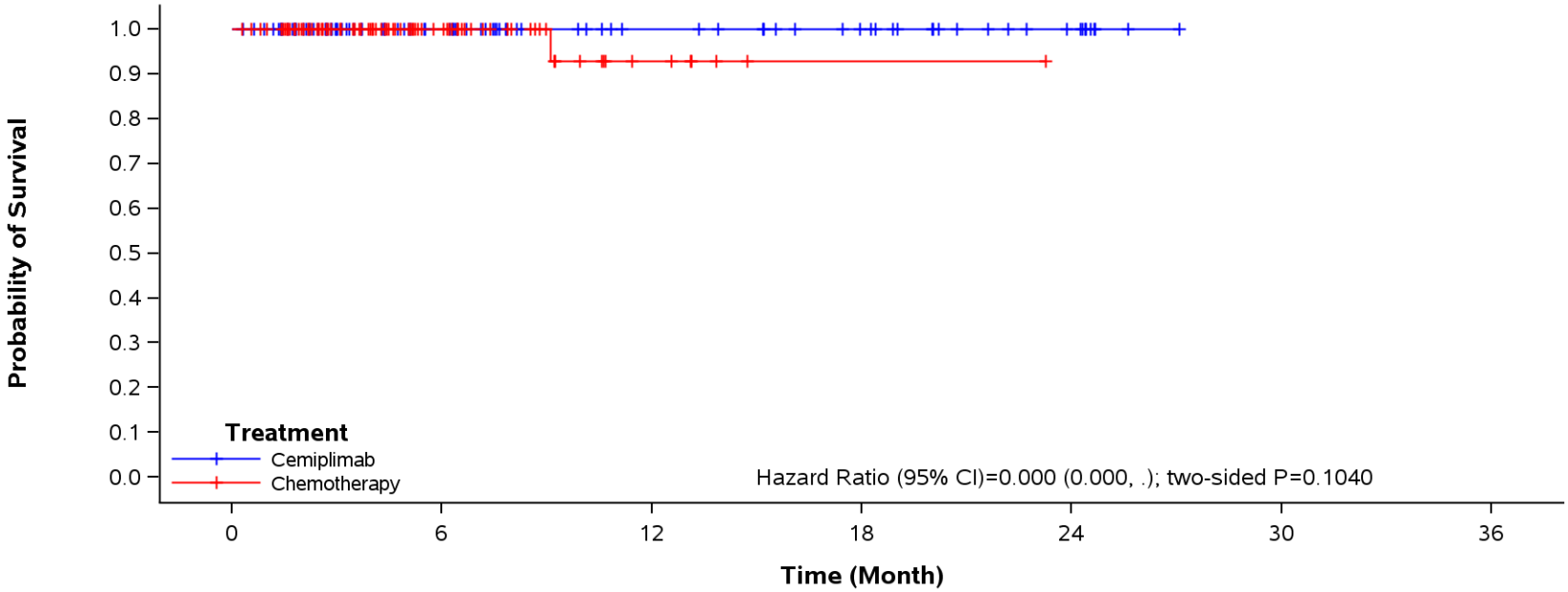

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Psychiatric disorders



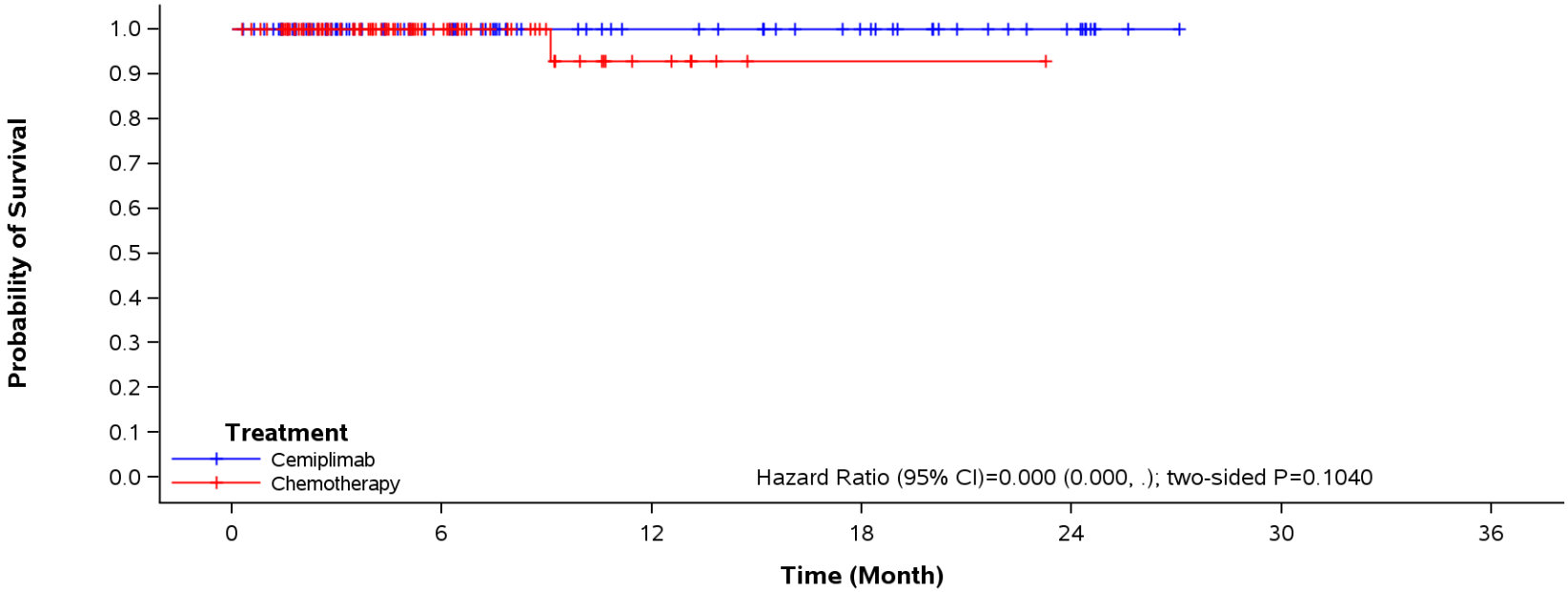

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Psychiatric disorders
PT: Agoraphobia



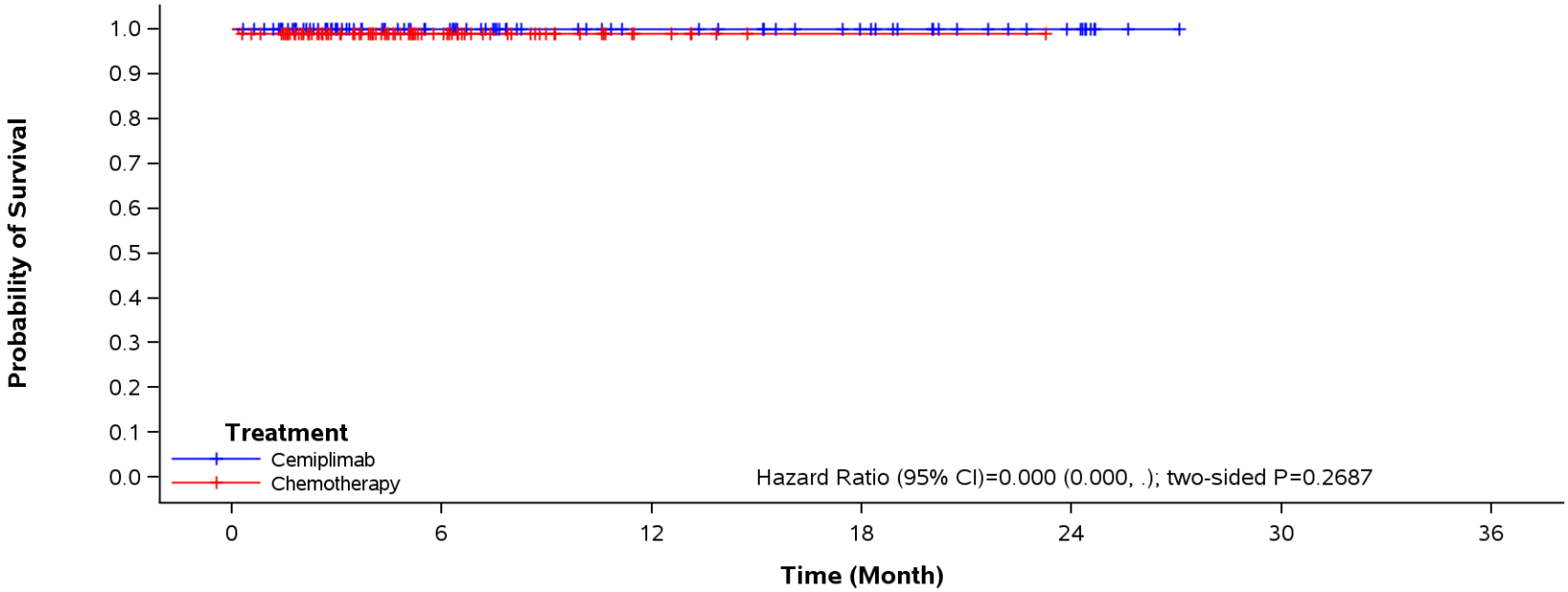

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Renal and urinary disorders



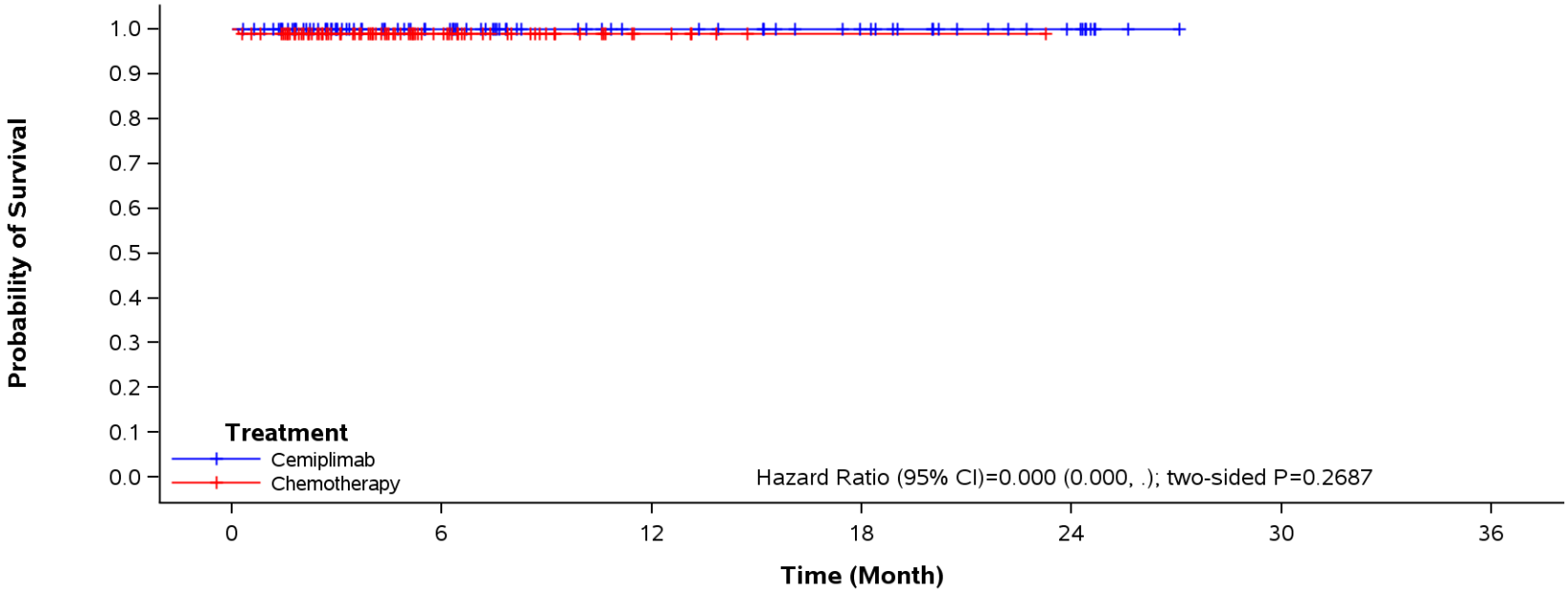

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Renal and urinary disorders
PT: Renal failure



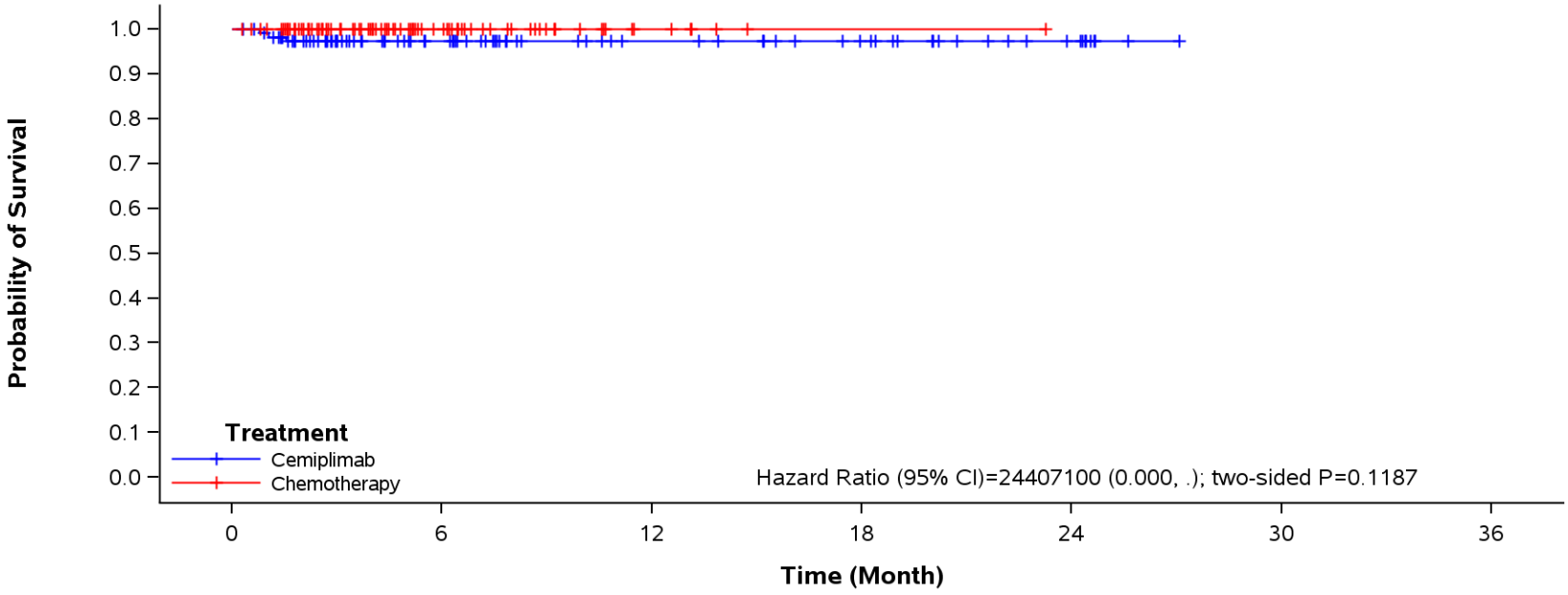

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Respiratory, thoracic and mediastinal disorders



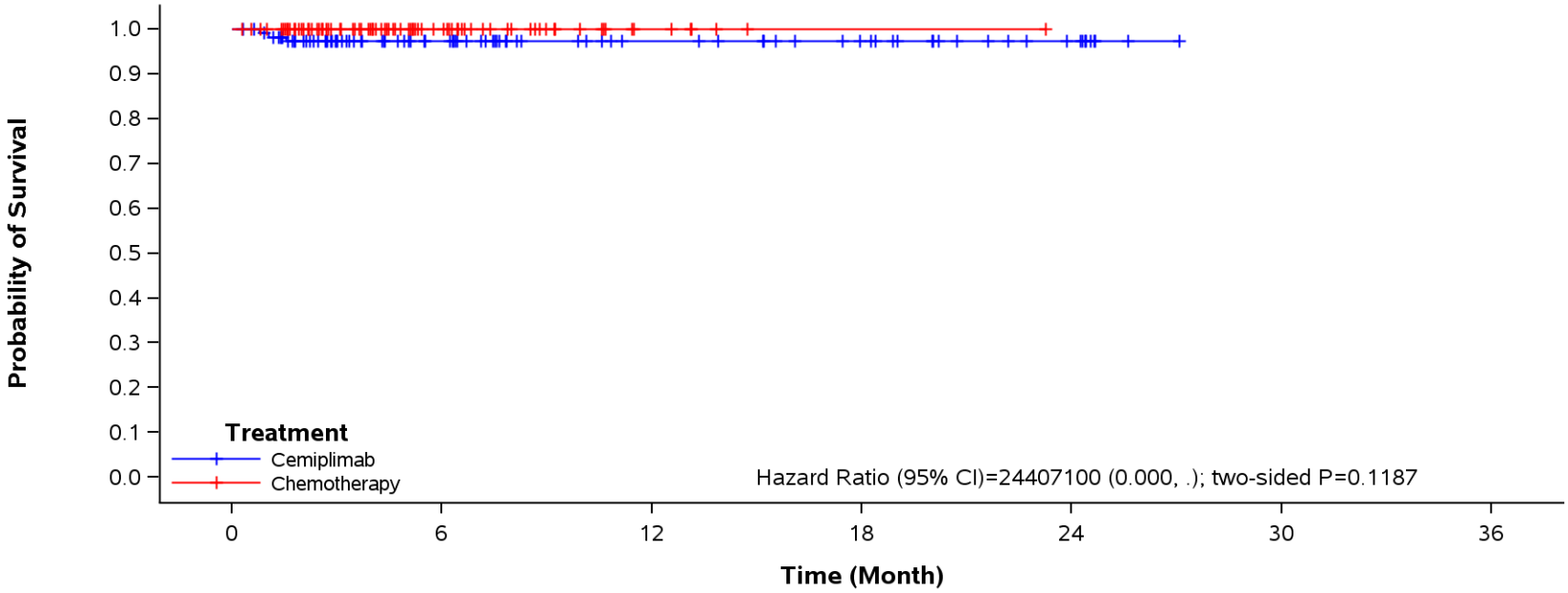

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



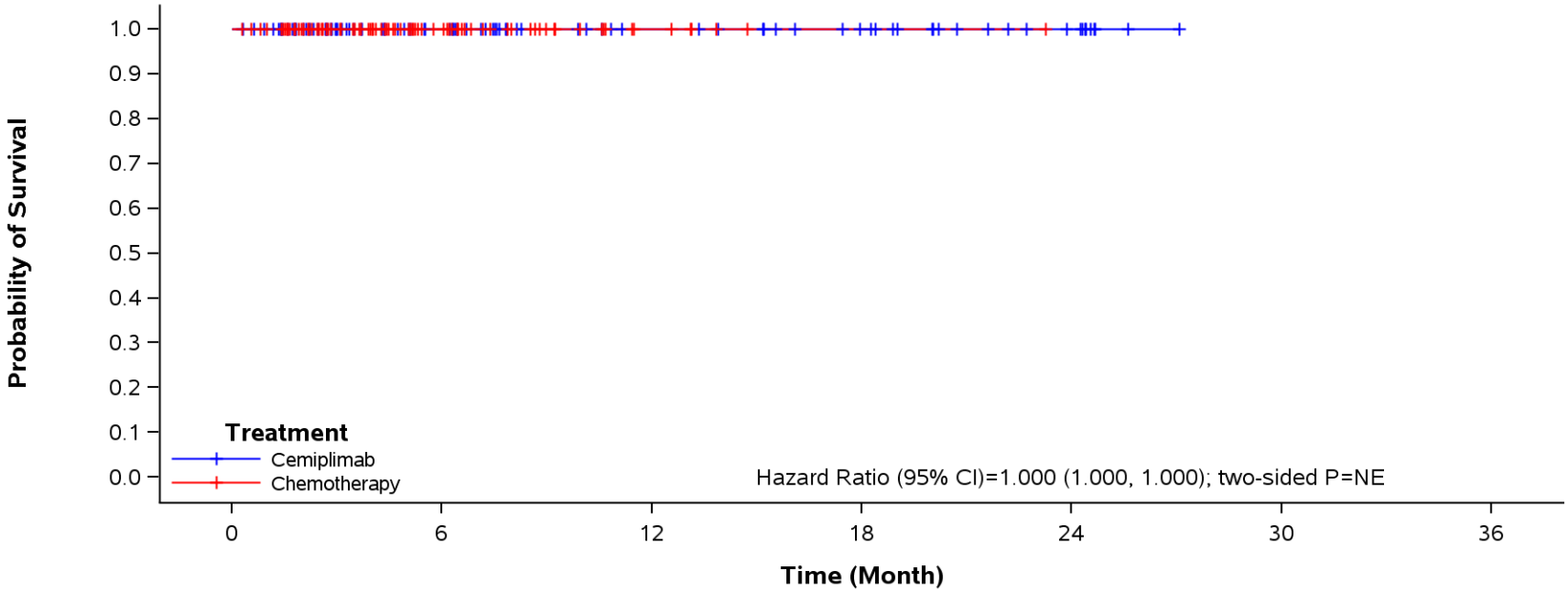

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Vascular disorders



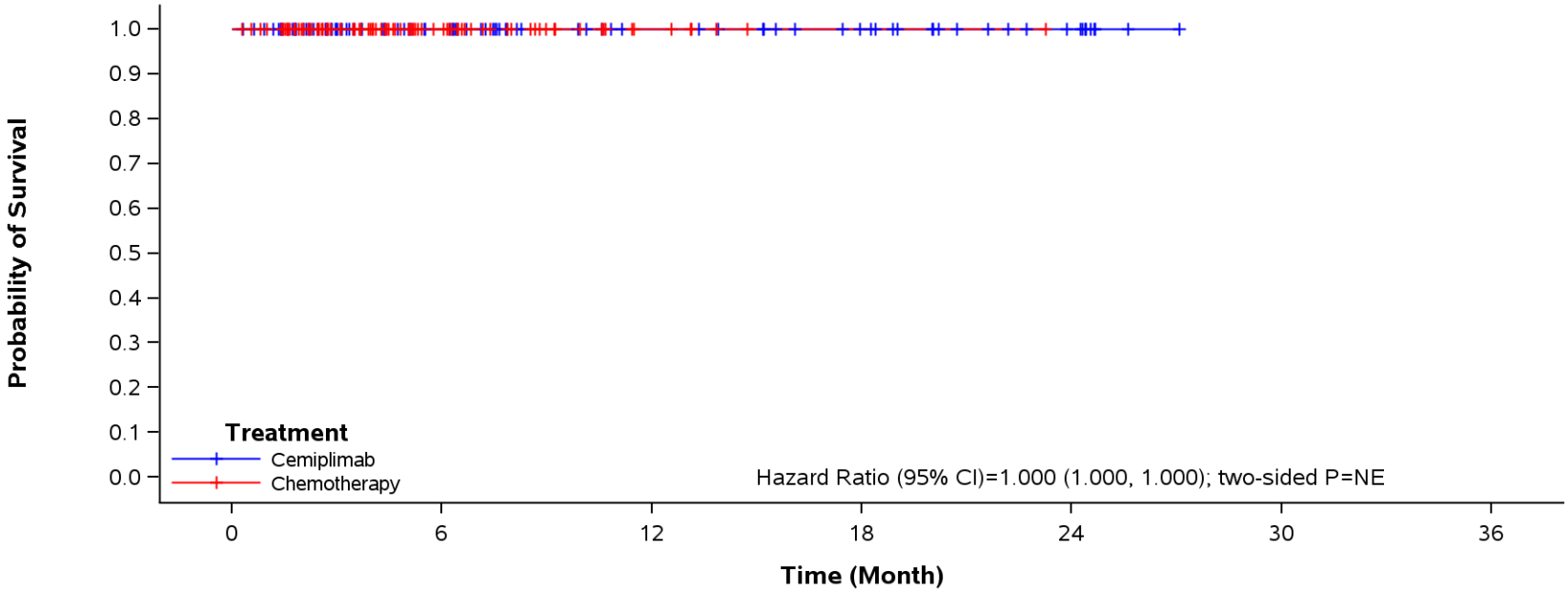

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: 1 line
SOC: Vascular disorders
PT: Deep vein thrombosis



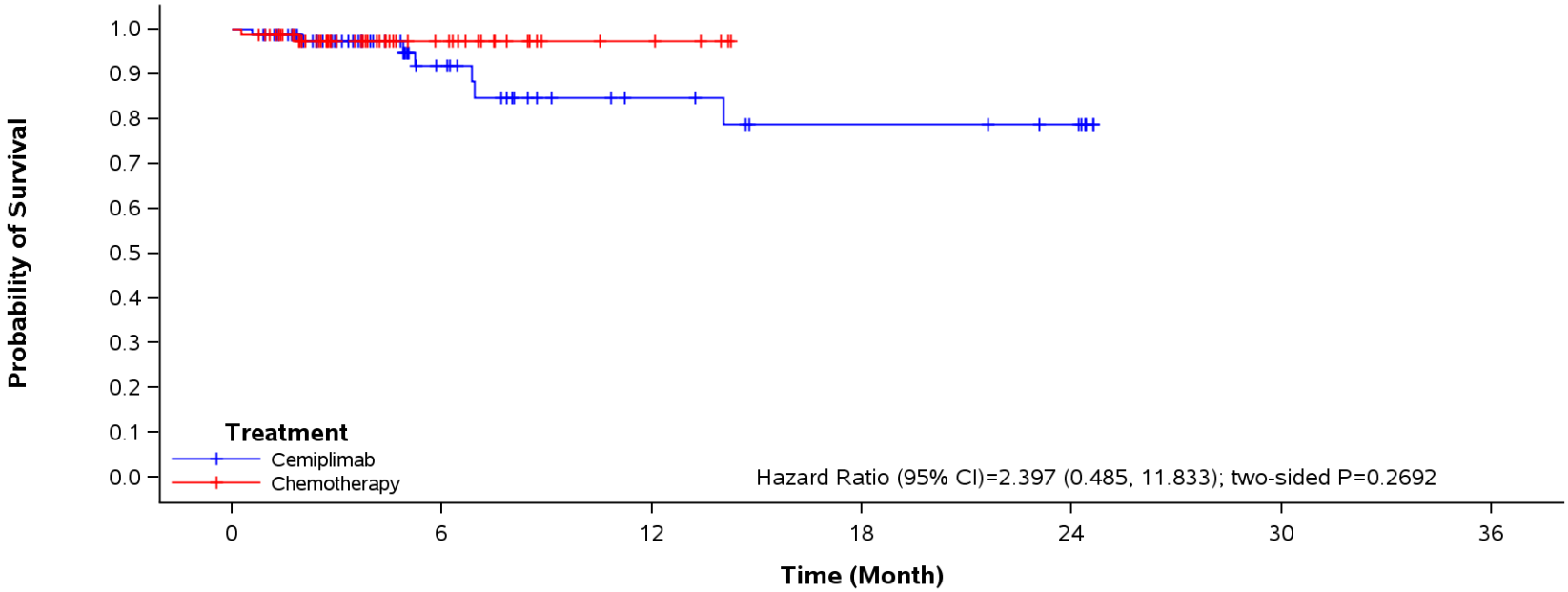

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 115 | 53 | 32 | 24 | 12 | 0 | 0 |
| Chemotherapy | 94 | 33 | 6 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
Number of patients with any TEAE leading to discontinuation



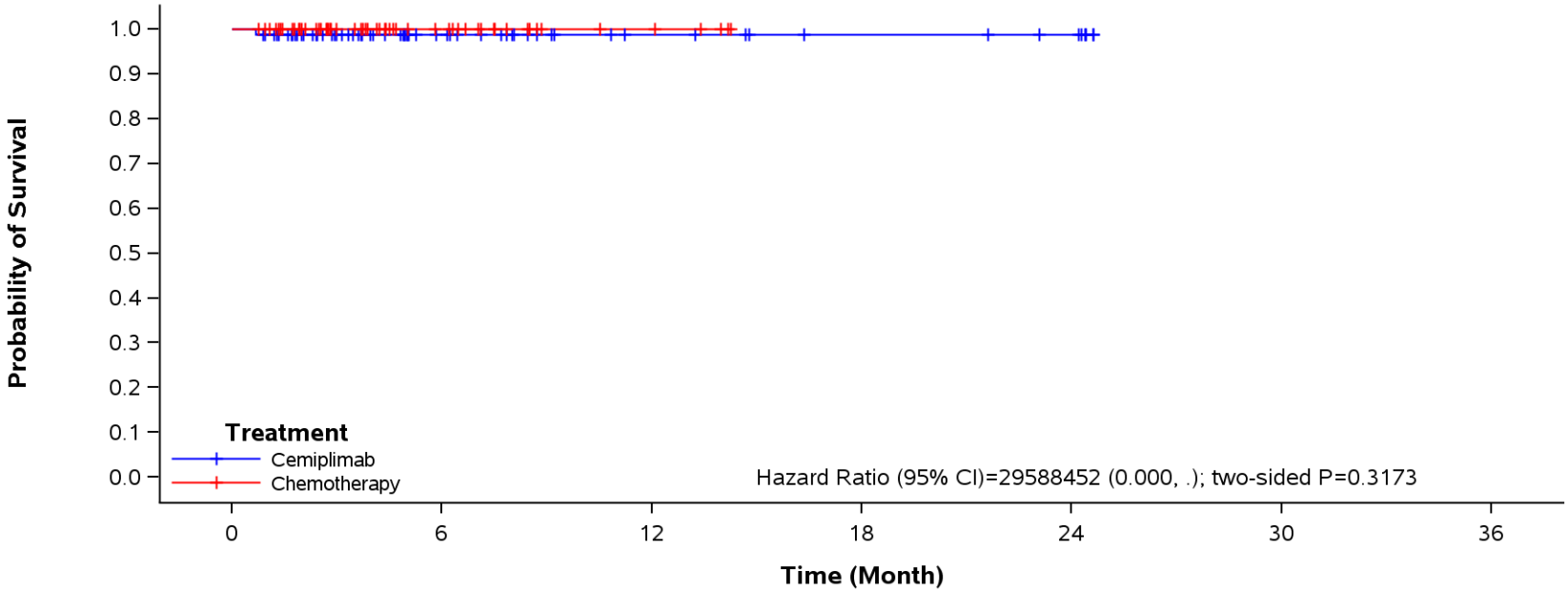

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 29 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders



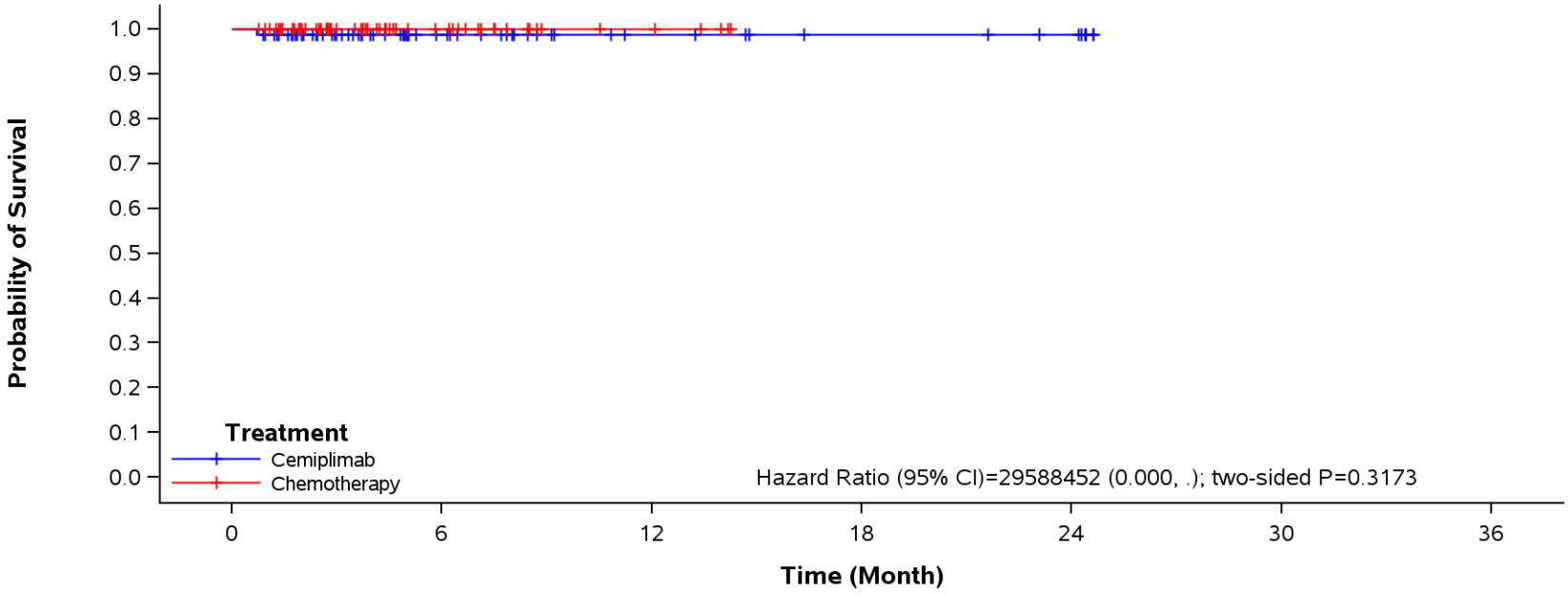

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Anaemia



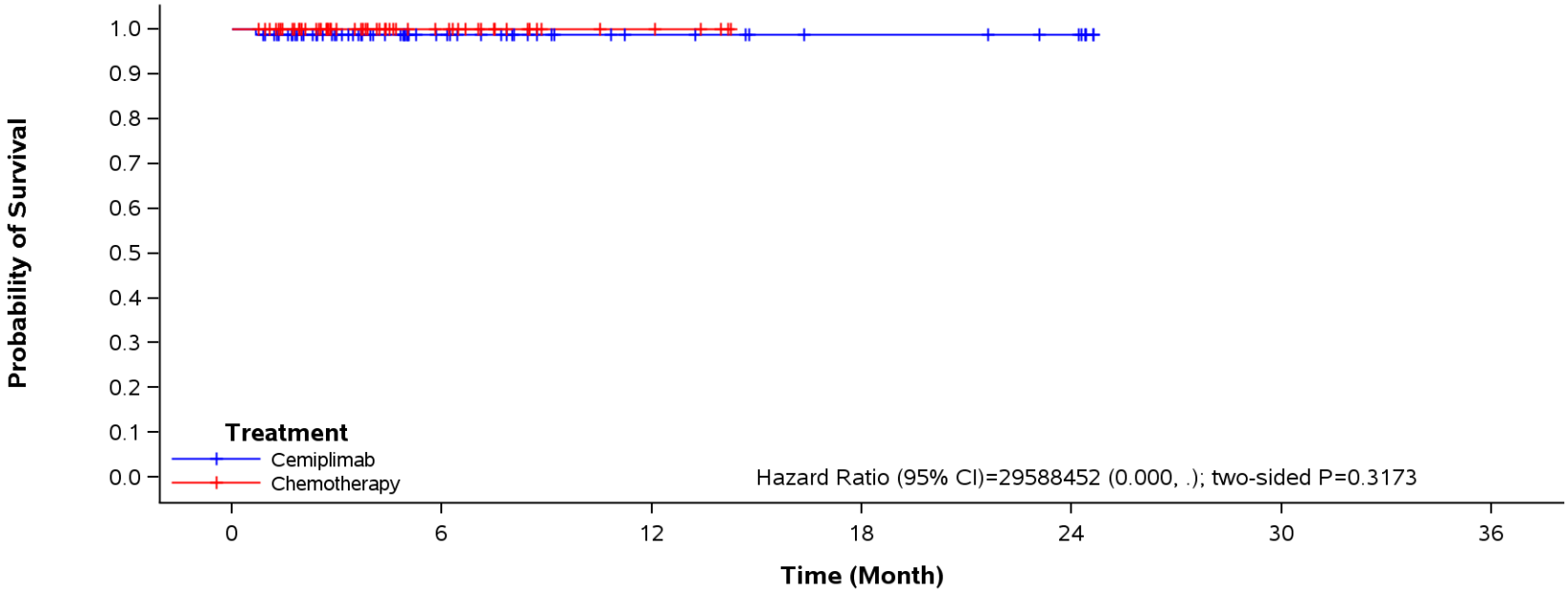

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



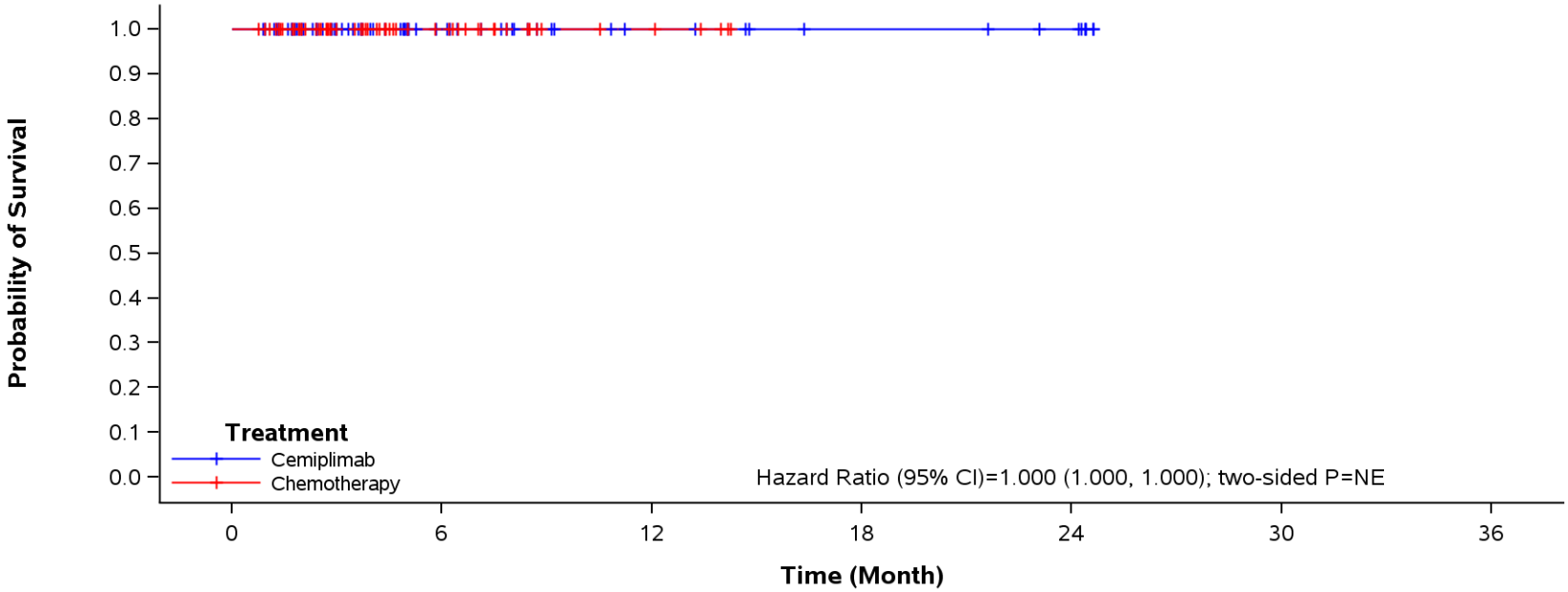

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Neutropenia



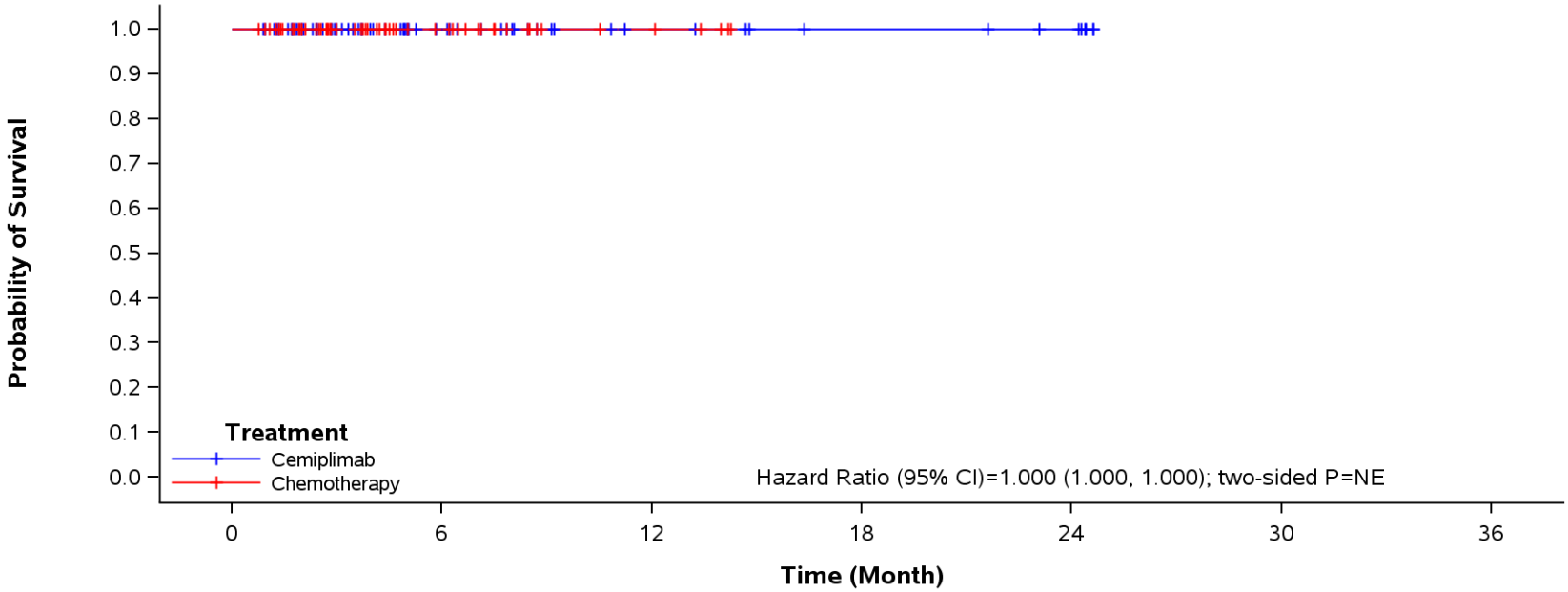

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



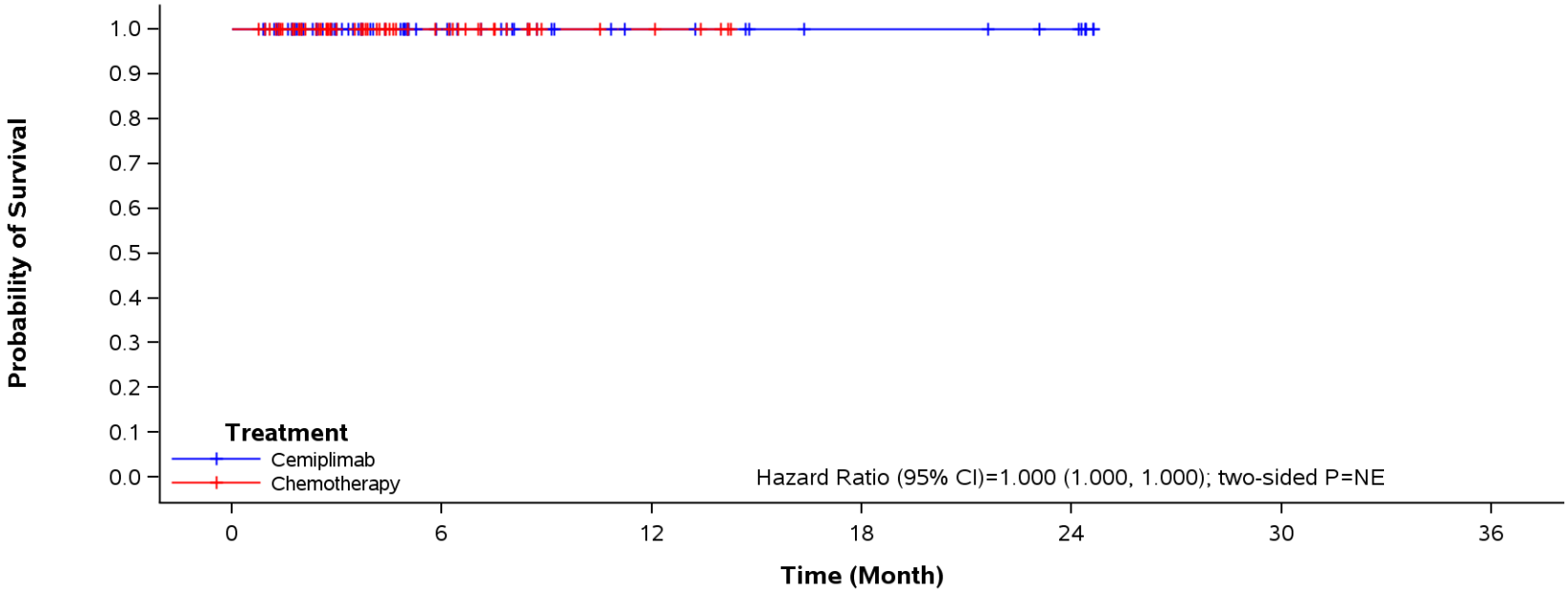

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Cardiac disorders



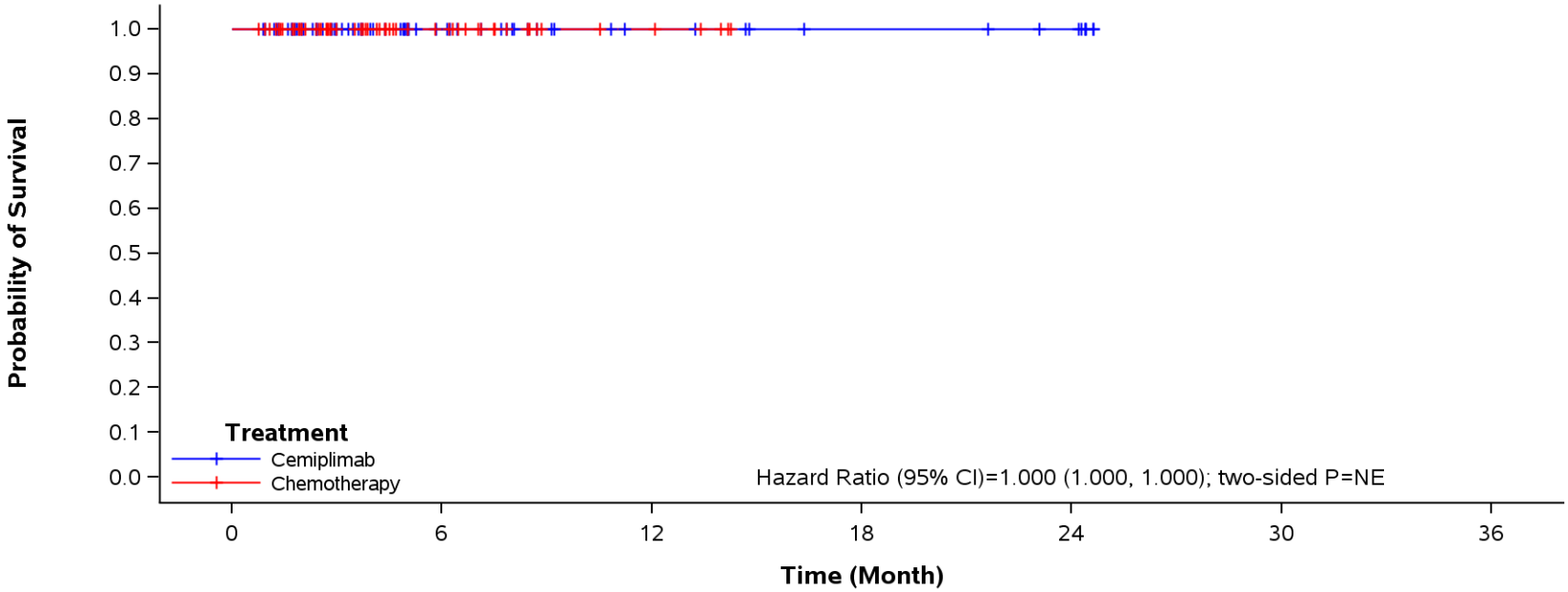

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Cardiac disorders
PT: Autoimmune pericarditis



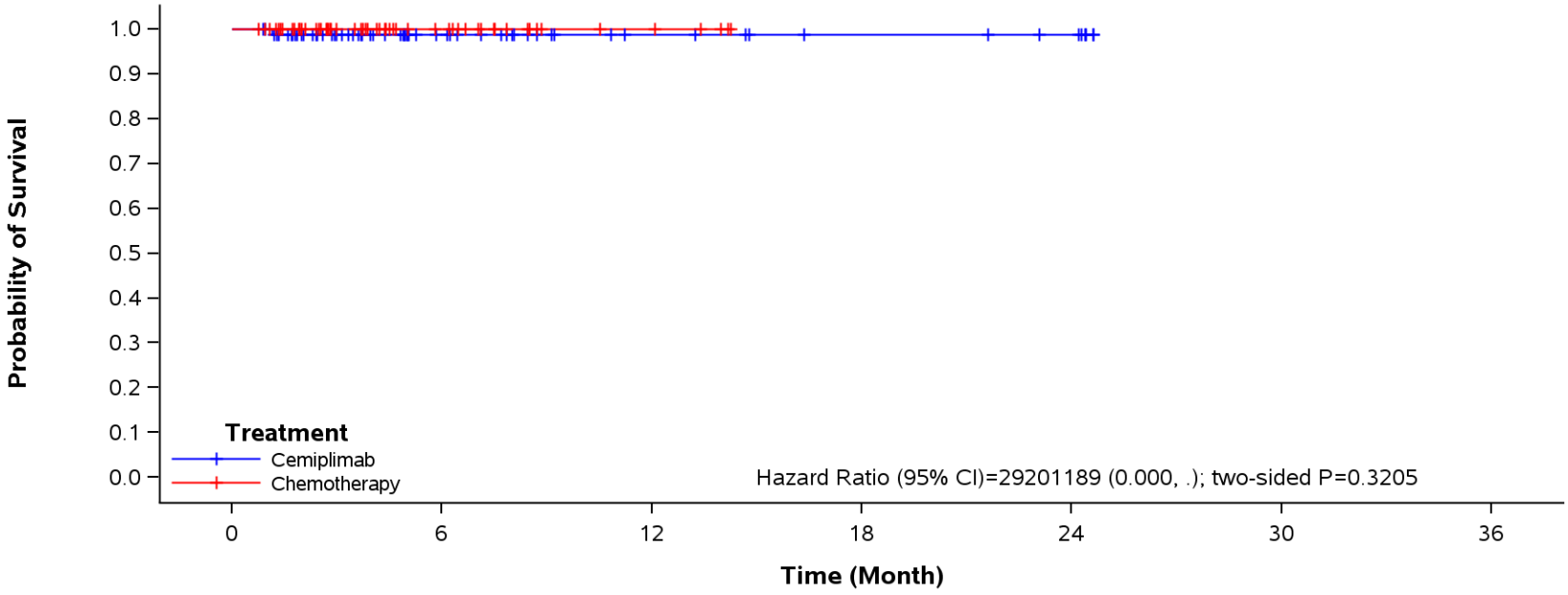

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Endocrine disorders



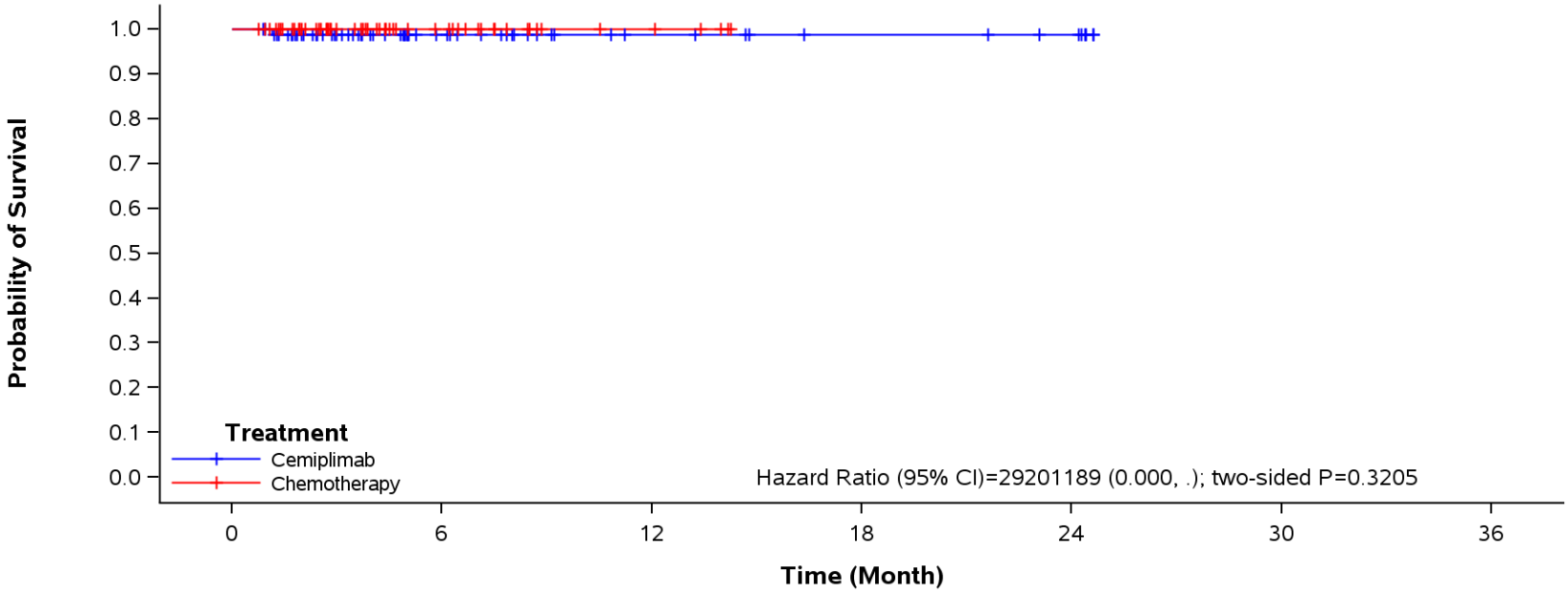

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Endocrine disorders
PT: Hypothyroidism



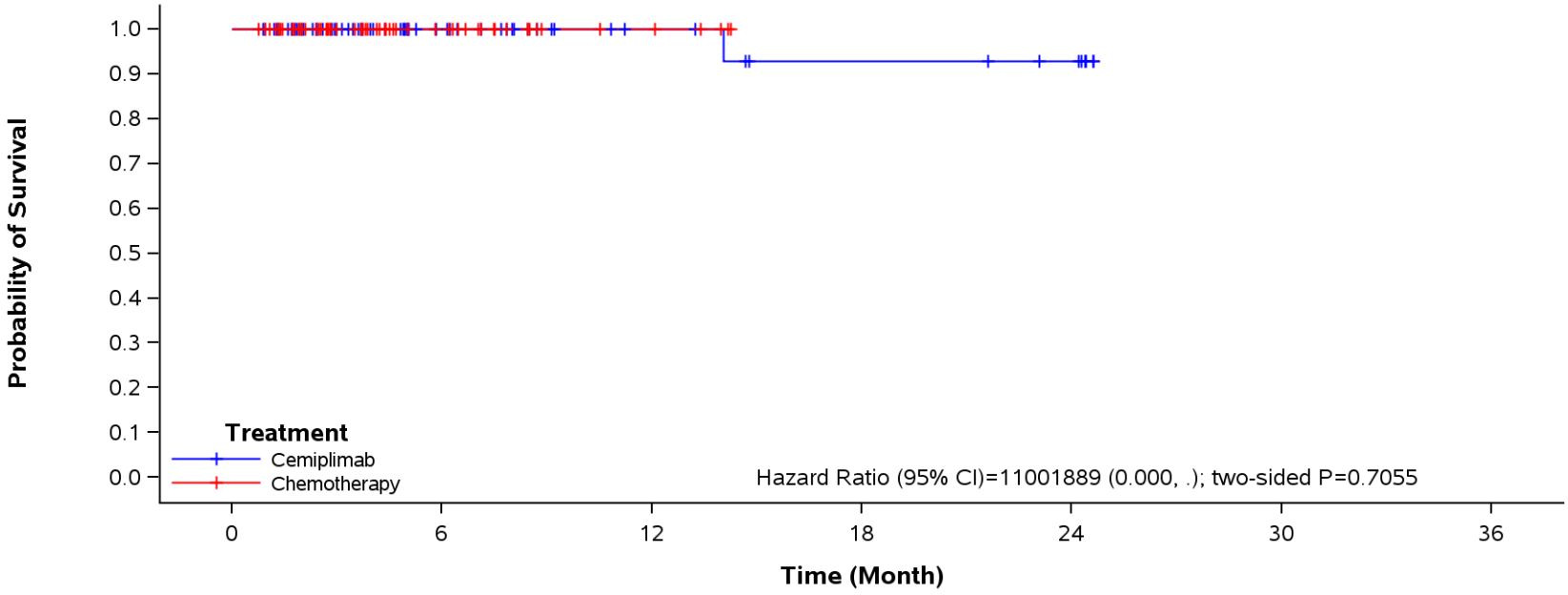

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders



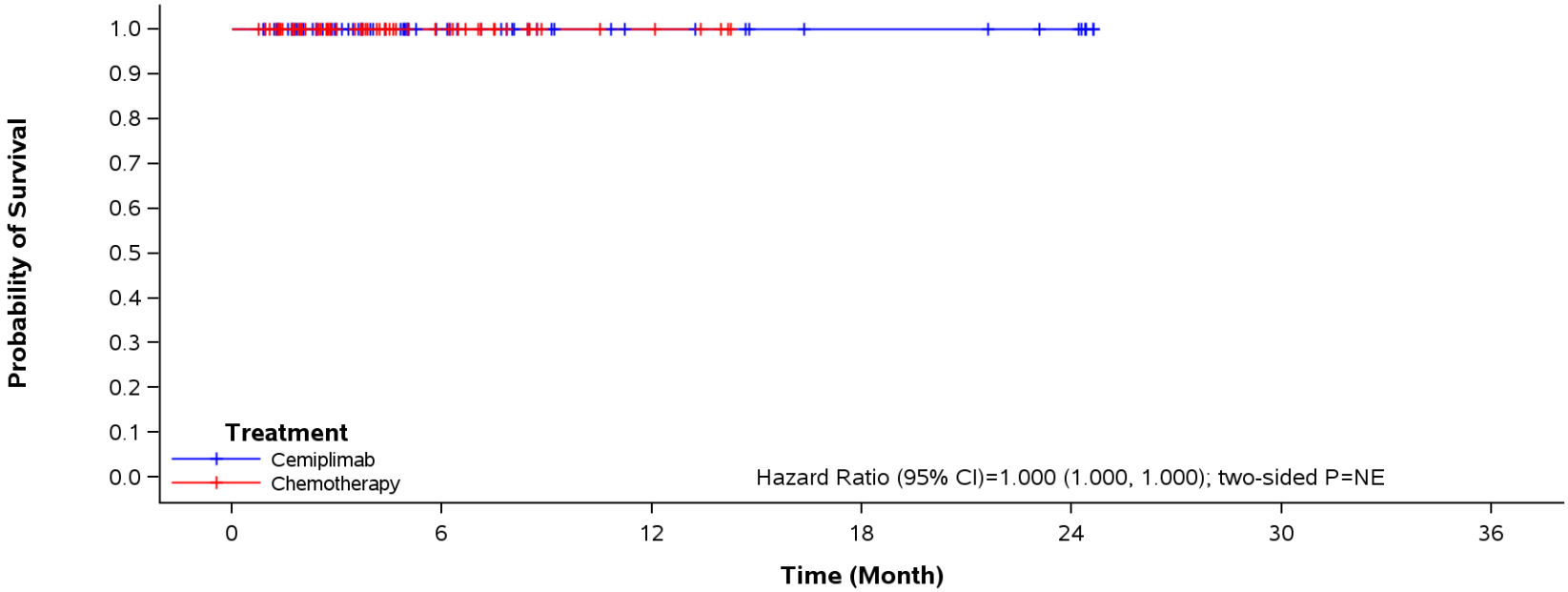

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders
PT: Colitis



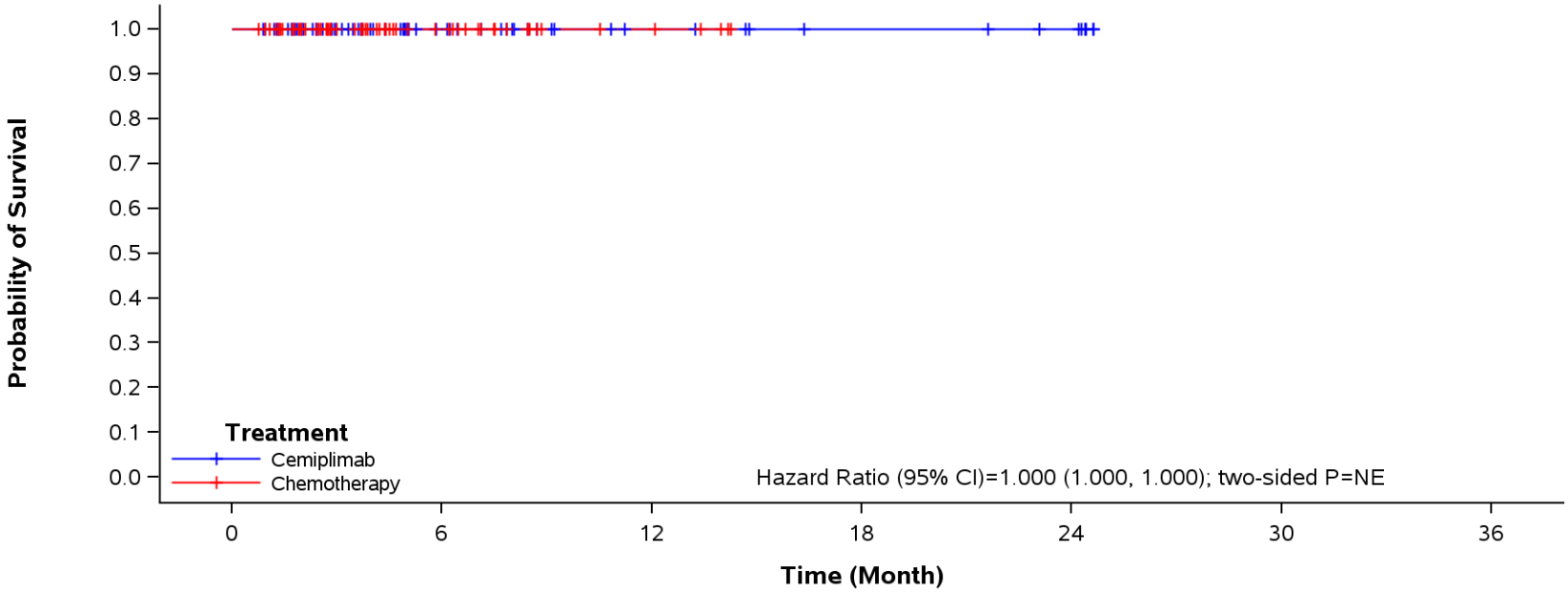

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders
PT: Diverticular perforation



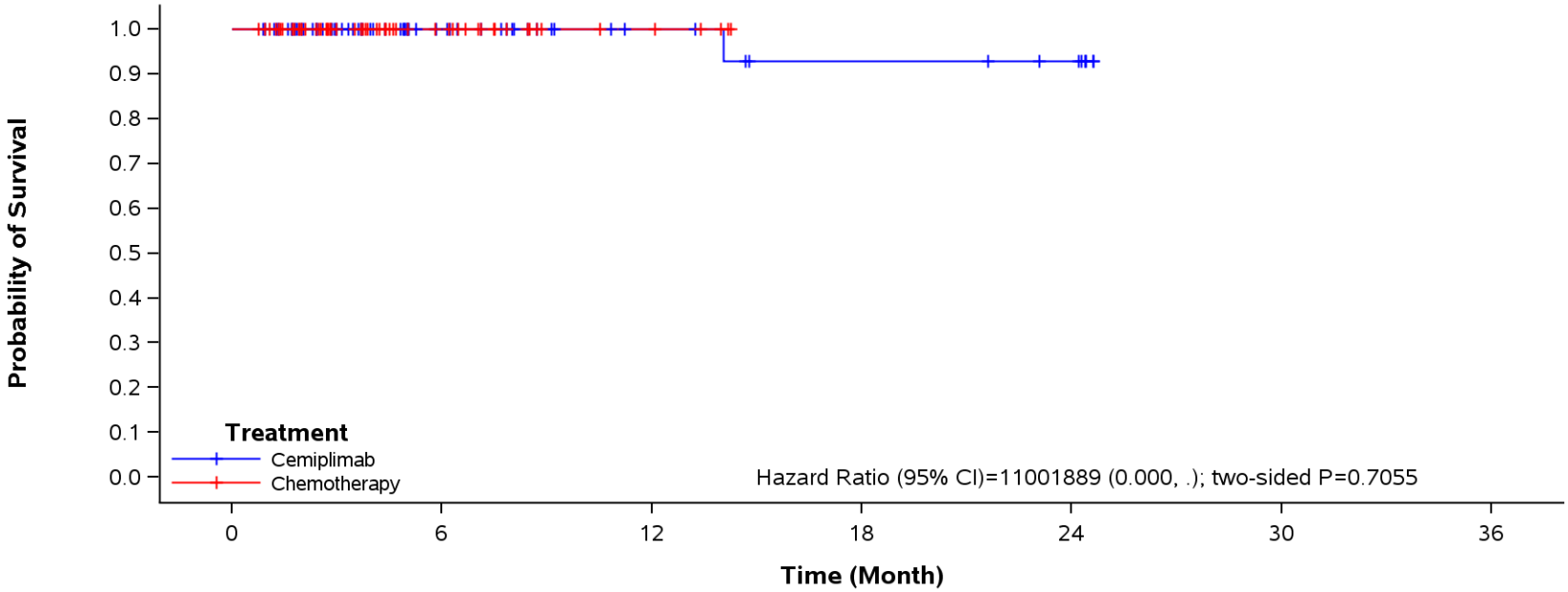

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders
PT: Pancreatic mass



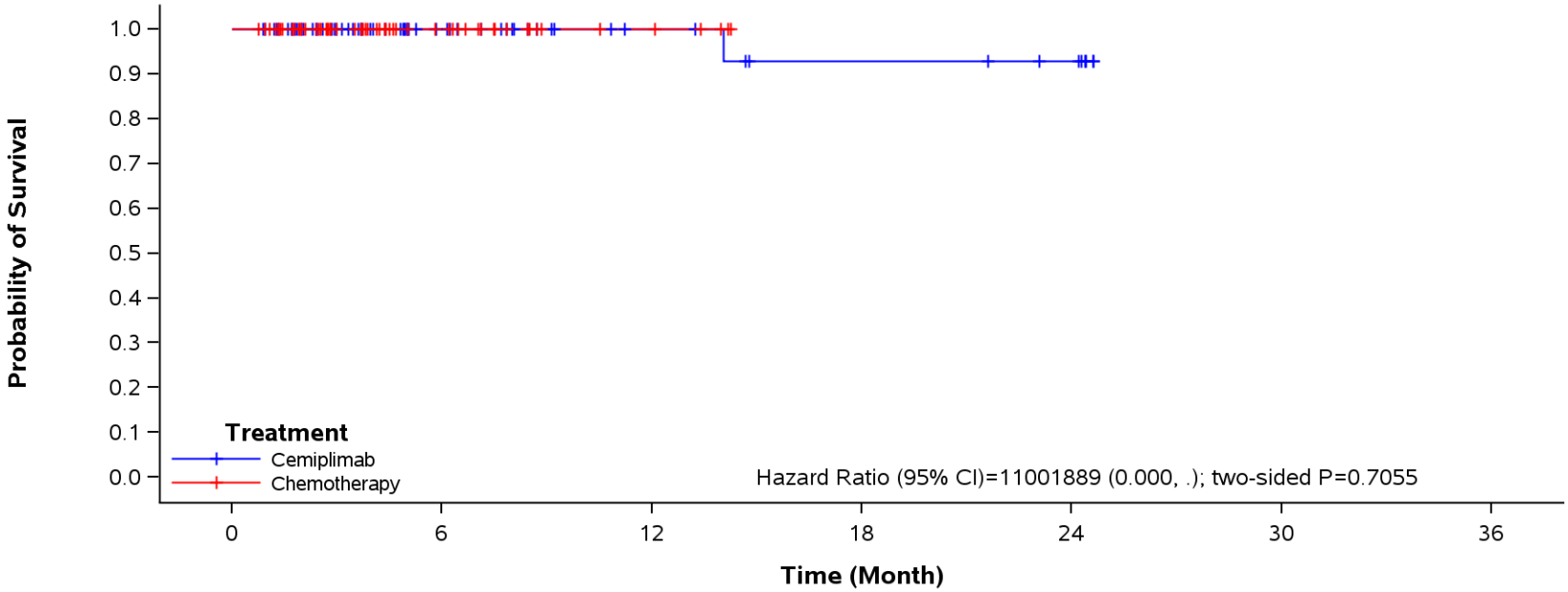

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



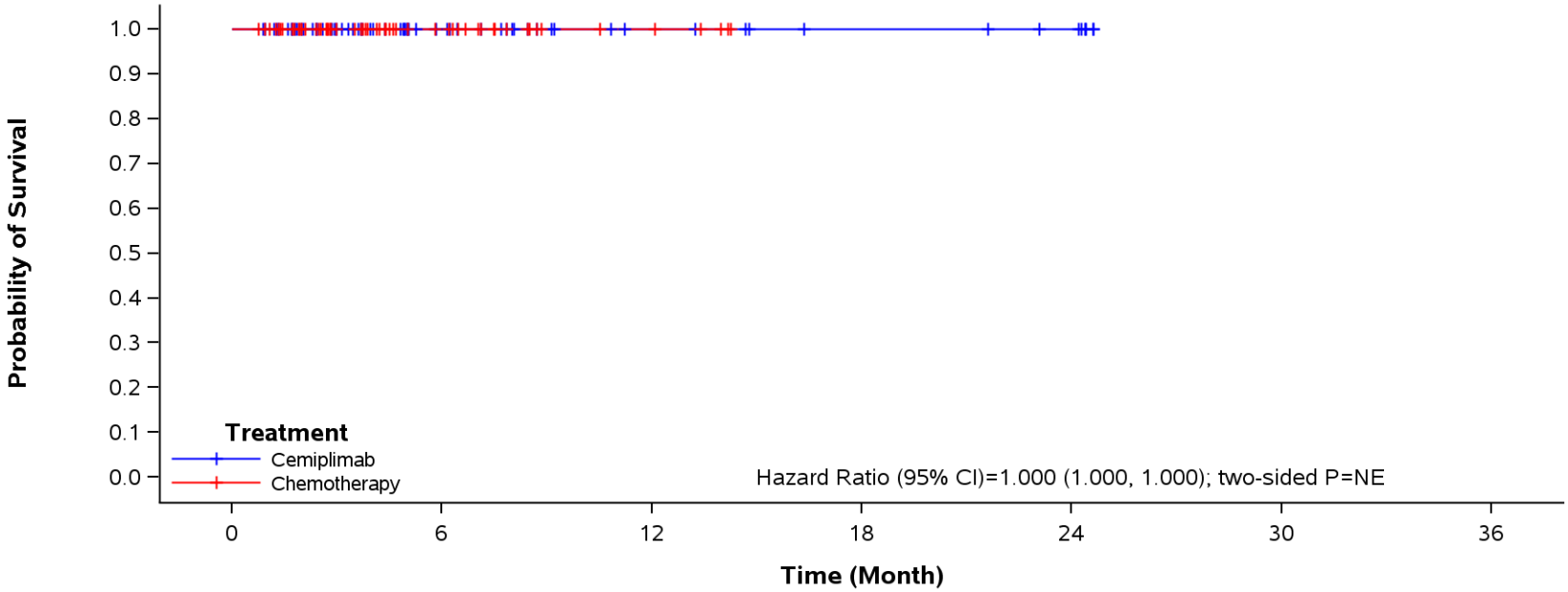

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Gastrointestinal disorders
PT: Proctalgia



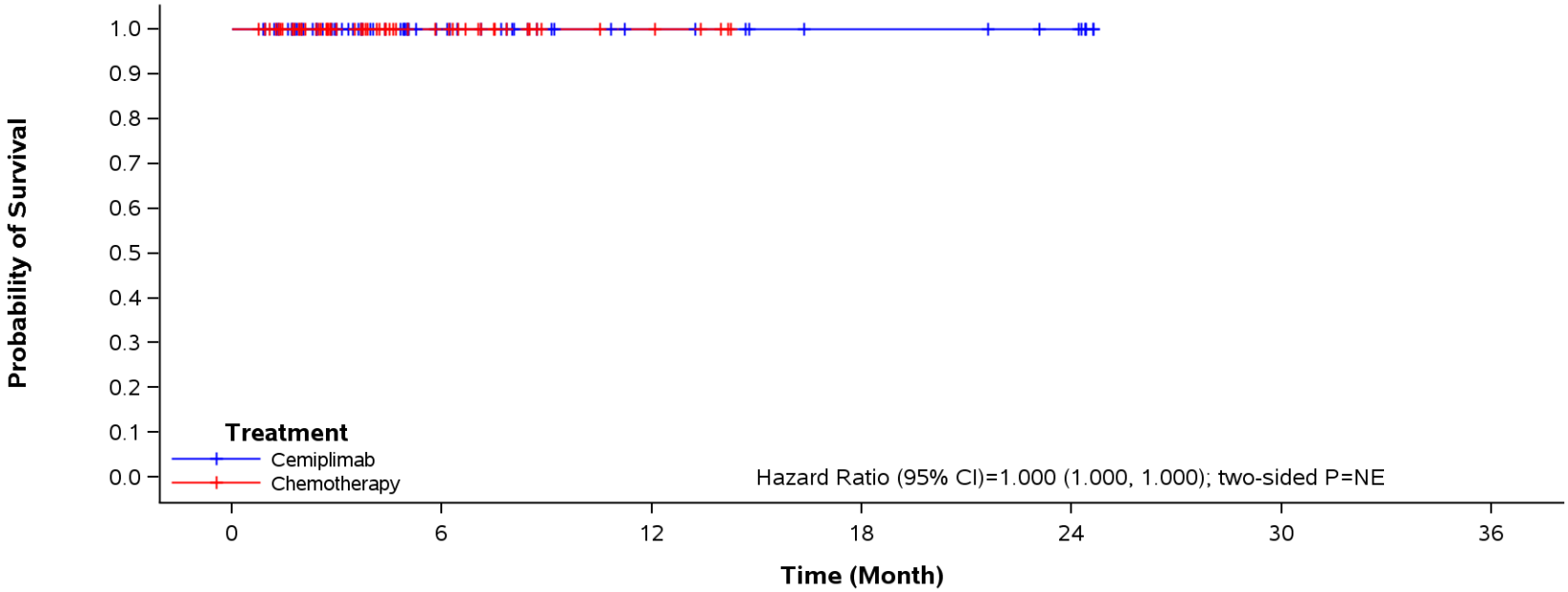

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: General disorders and administration site conditions



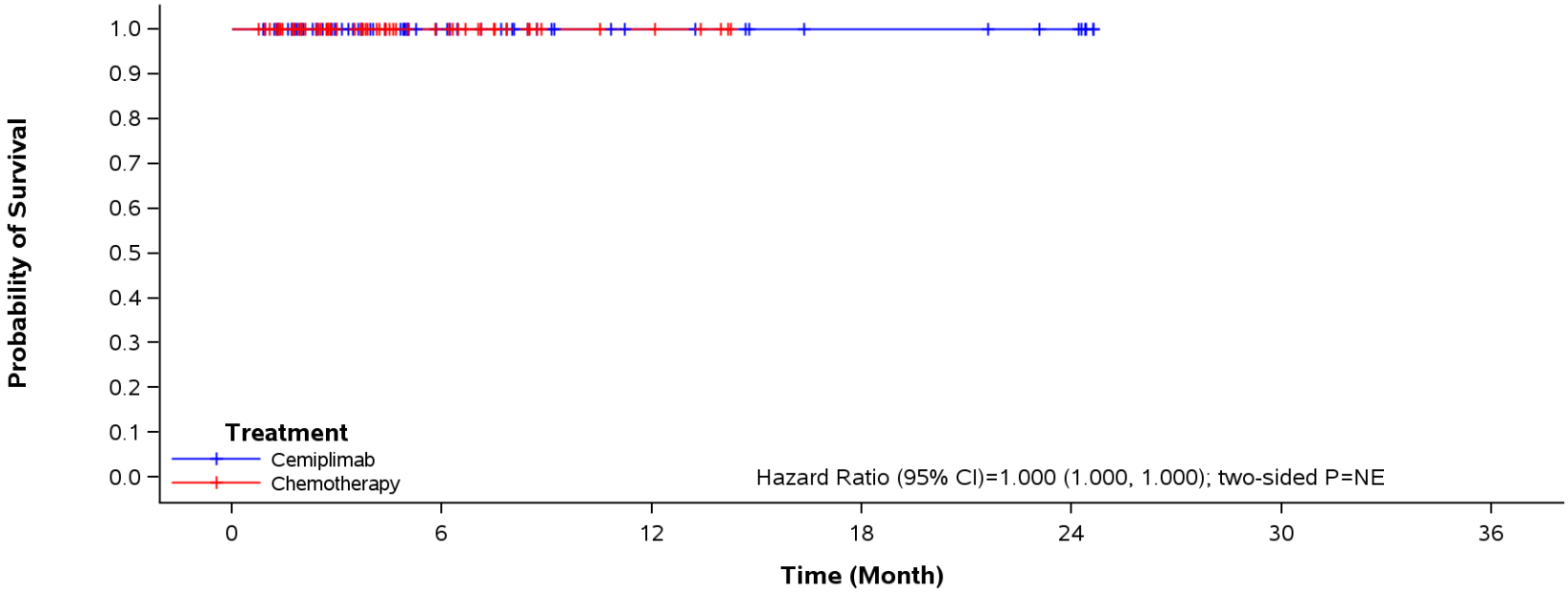

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: General disorders and administration site conditions
PT: Malaise



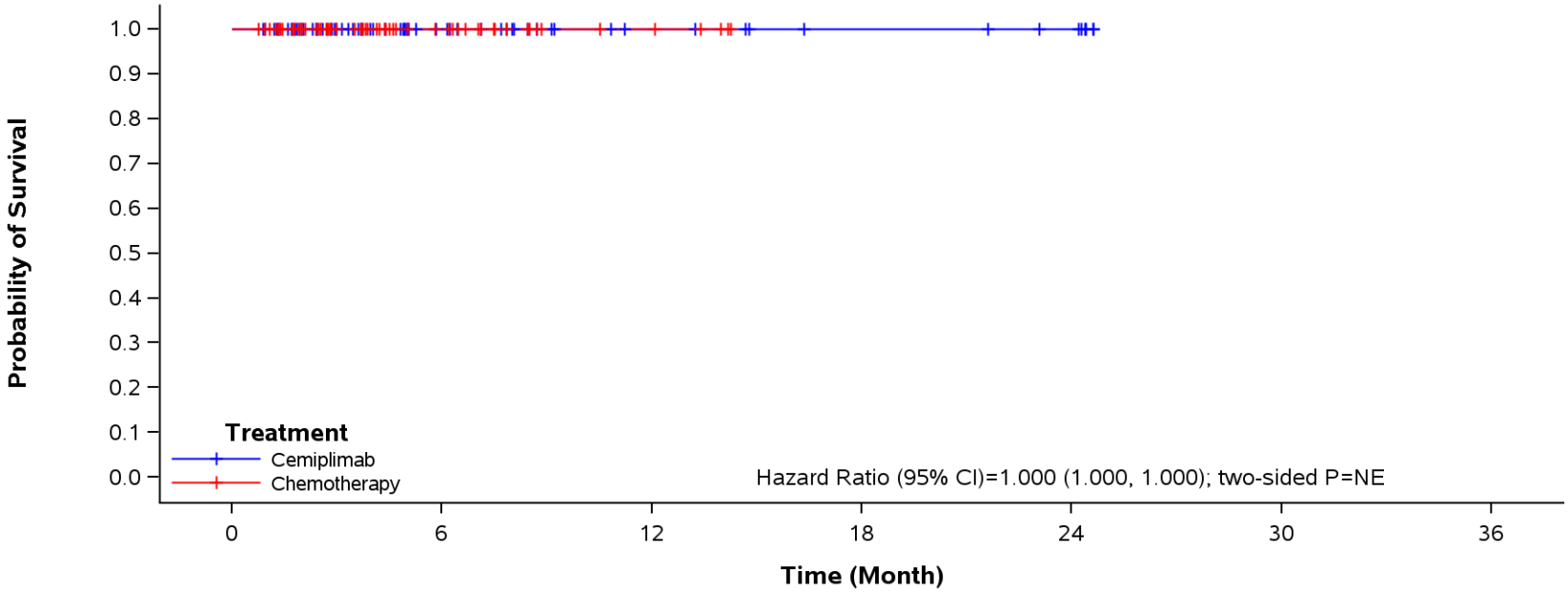

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



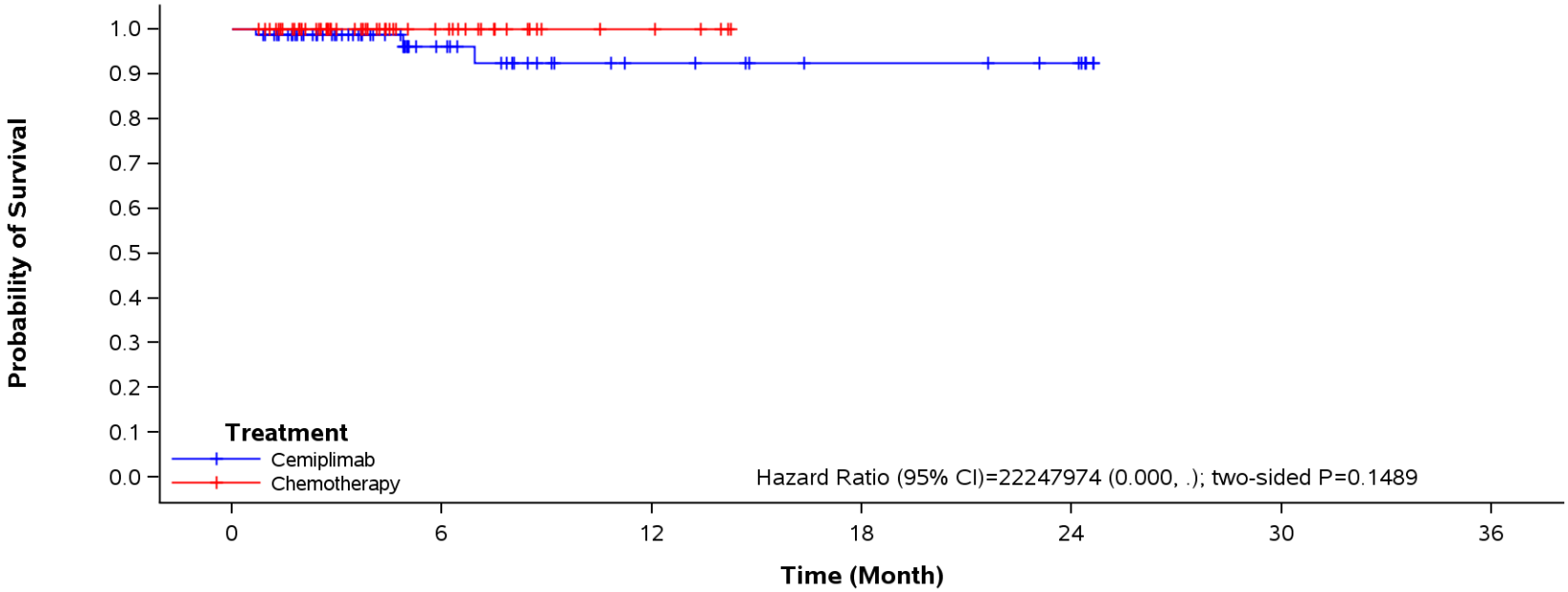

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Hepatobiliary disorders



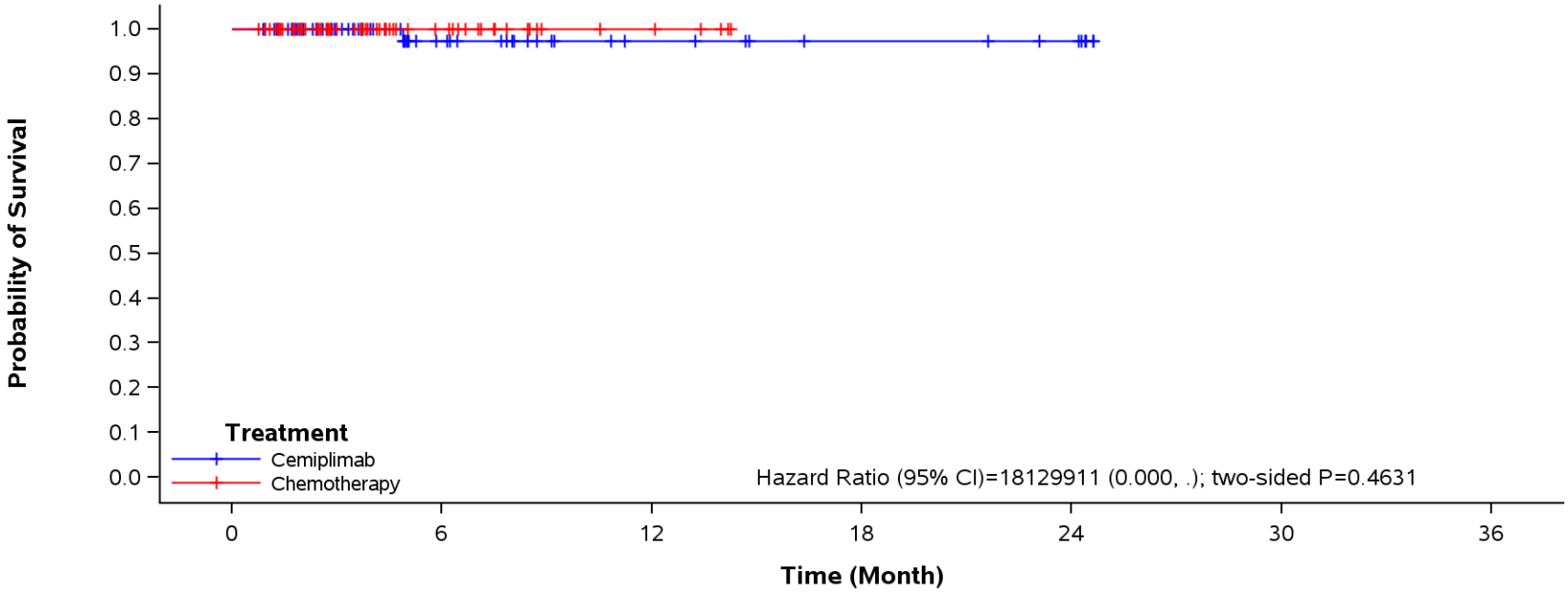

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 30 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



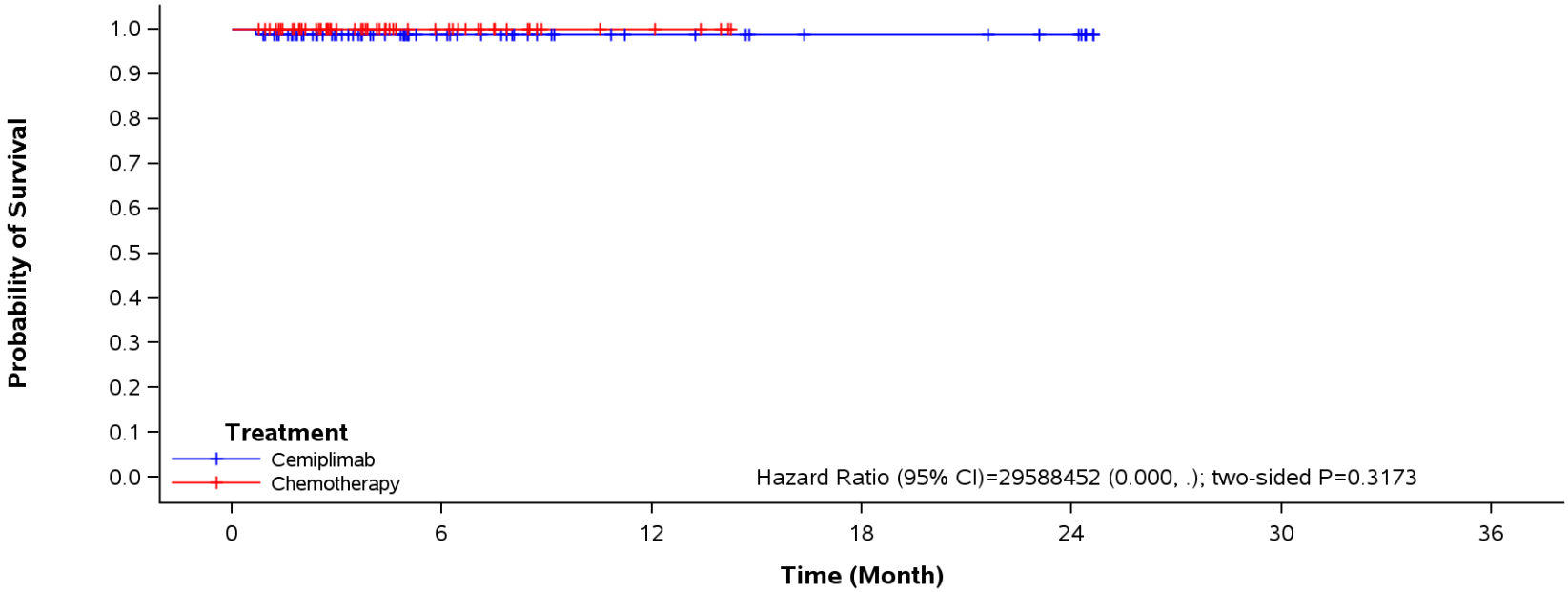

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 30 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



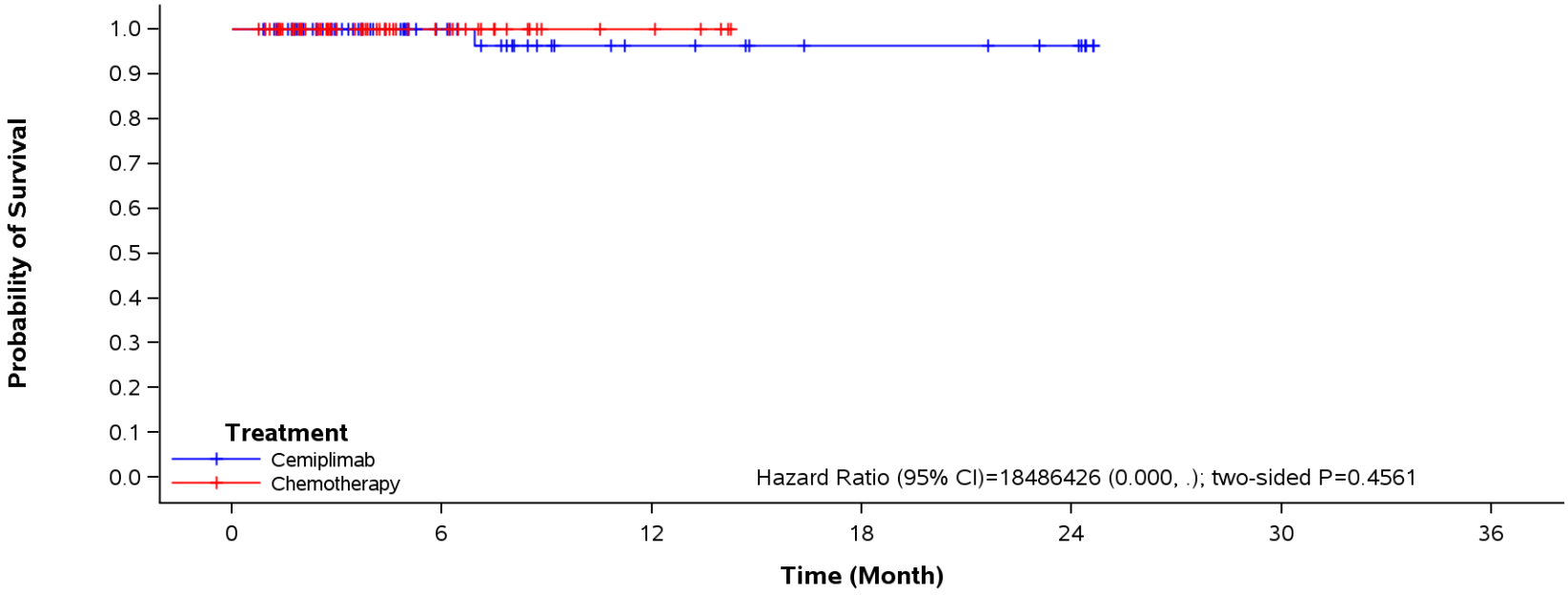

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Hepatobiliary disorders
PT: Hepatitis



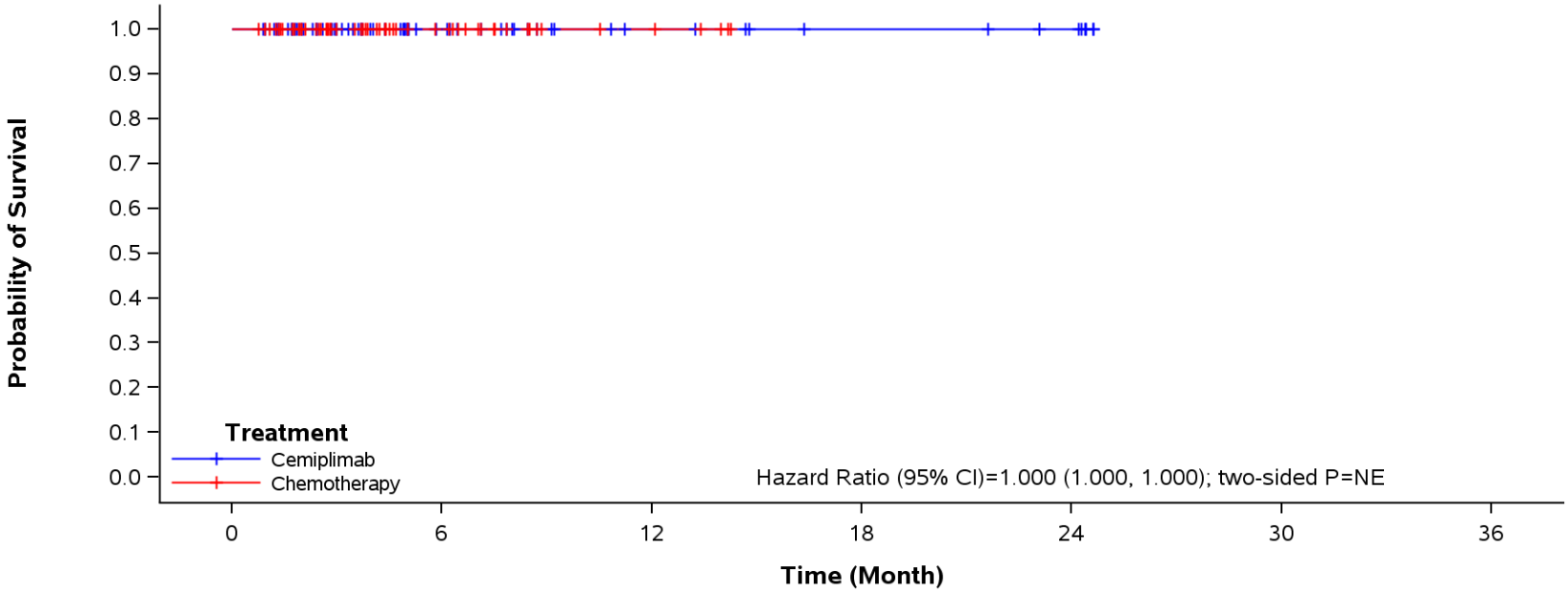

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



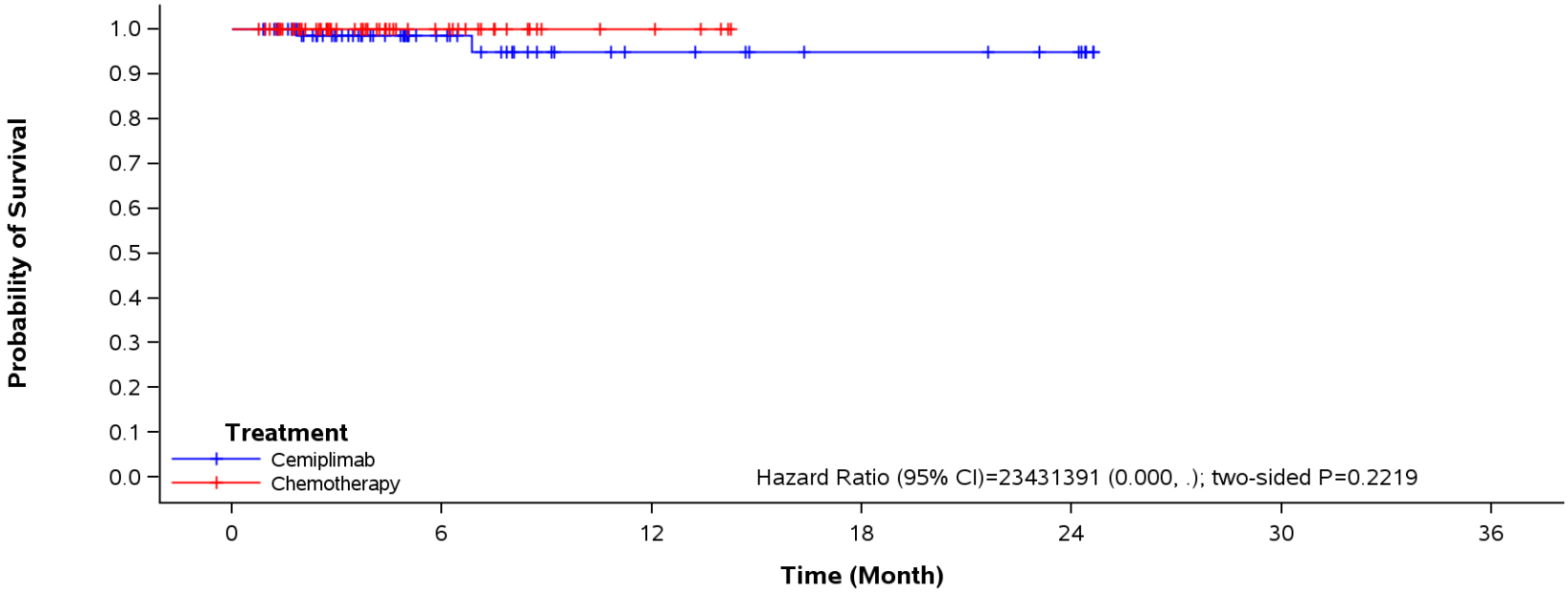

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Infections and infestations



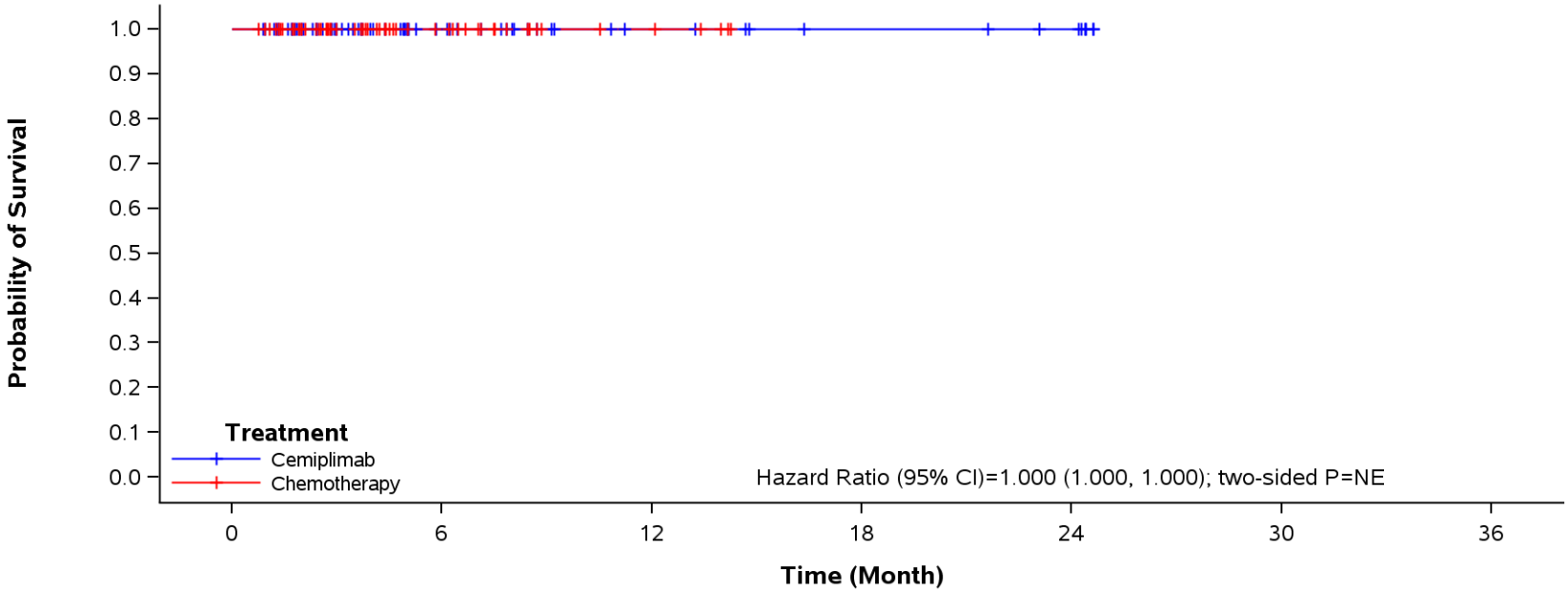

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Infections and infestations
PT: COVID-19 pneumonia



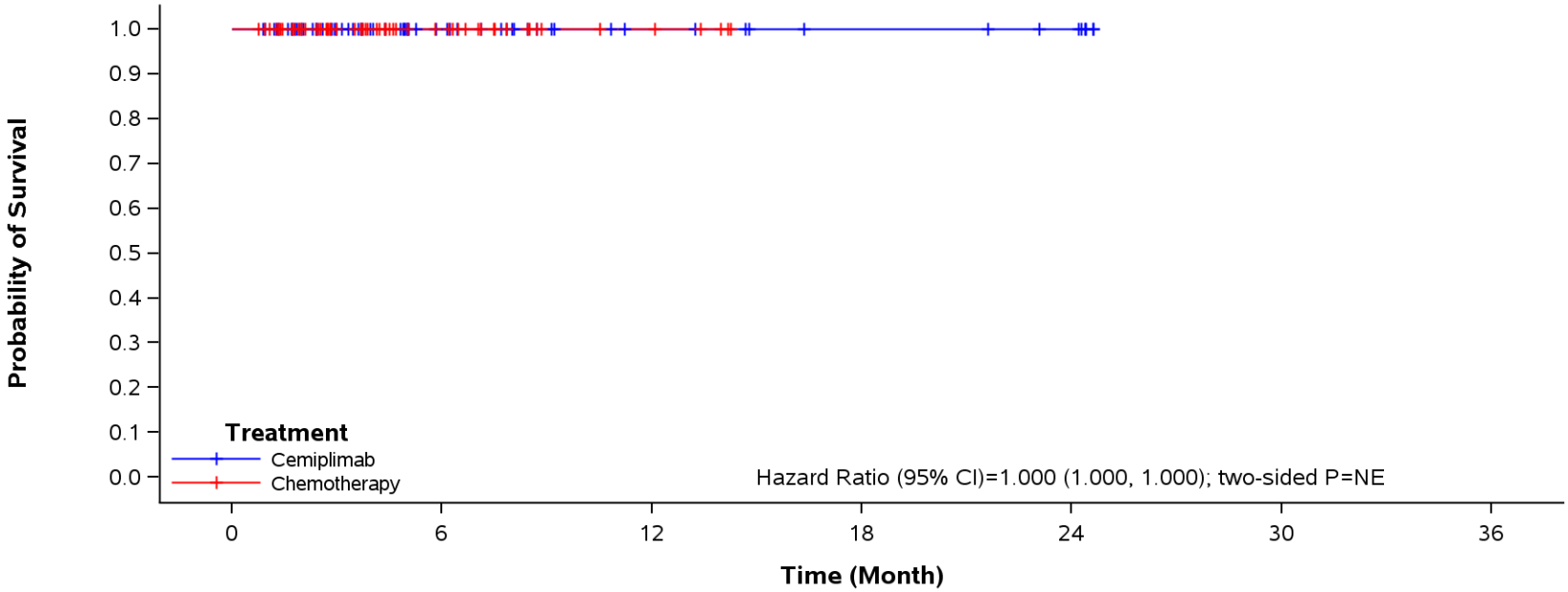

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Infections and infestations
PT: Gastroenteritis



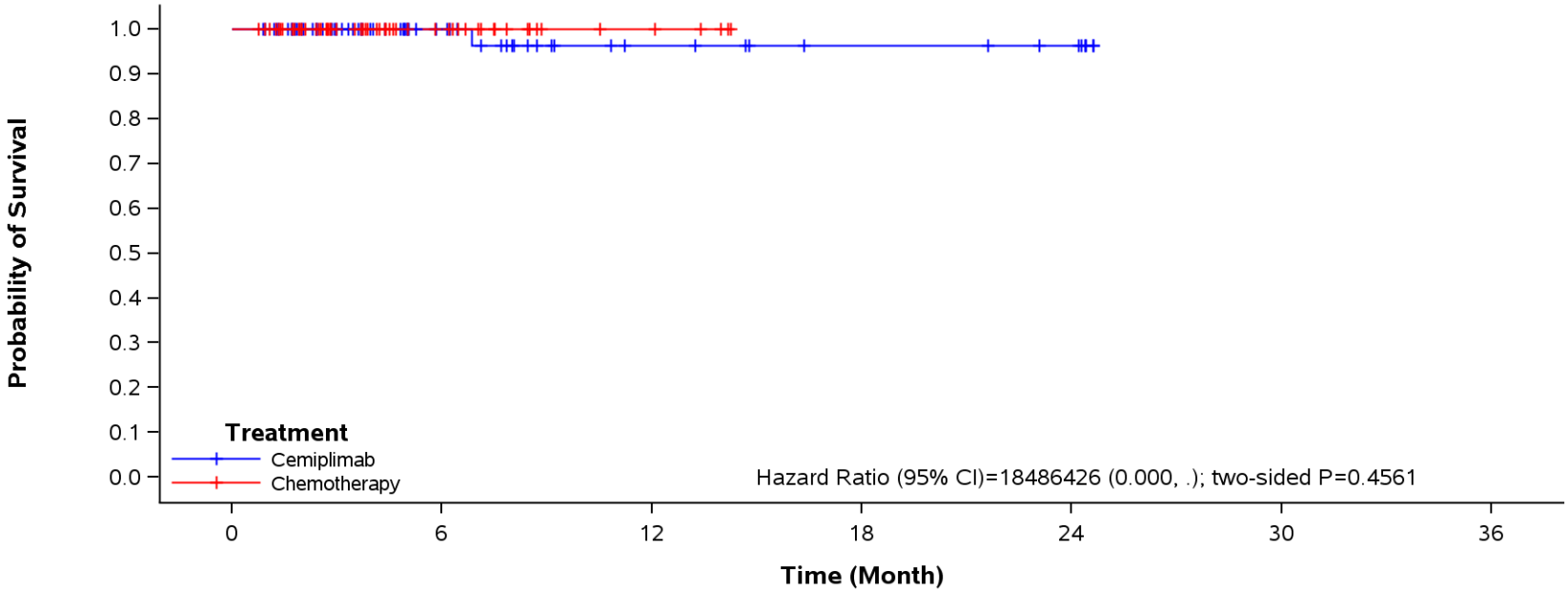

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Infections and infestations
PT: Pelvic abscess



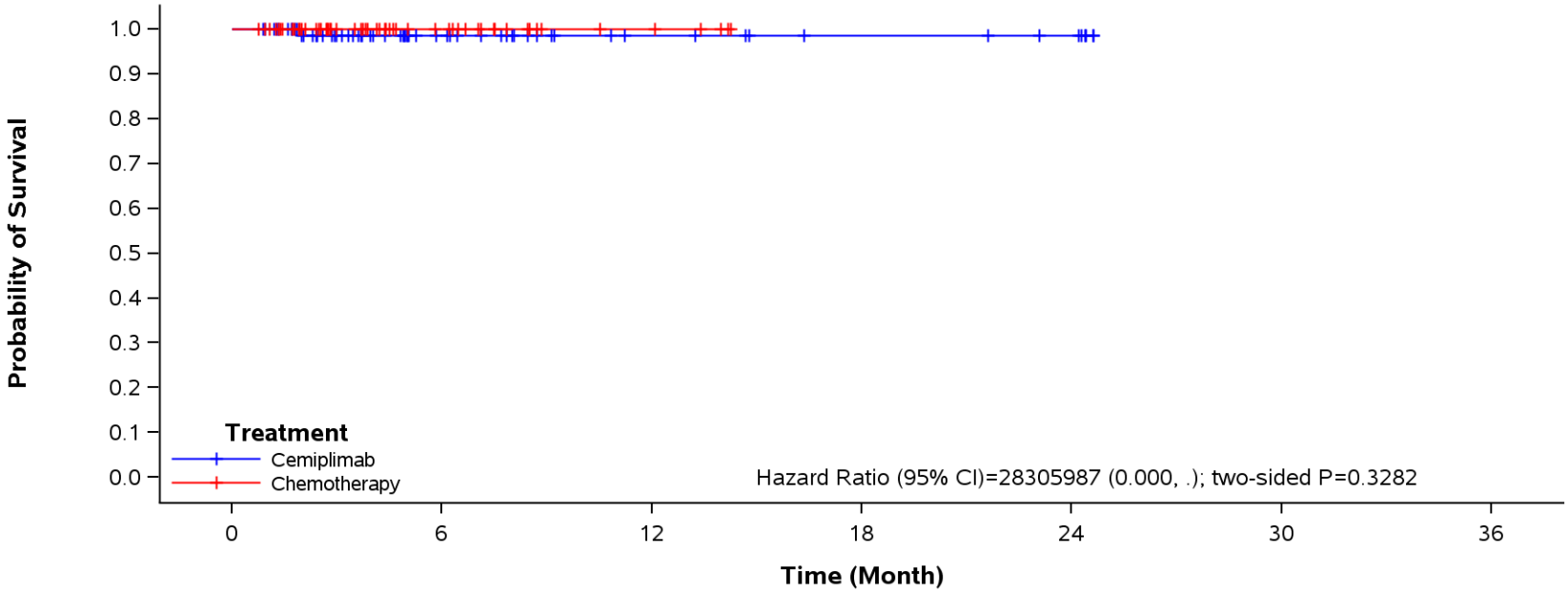

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Infections and infestations
PT: Peritonitis



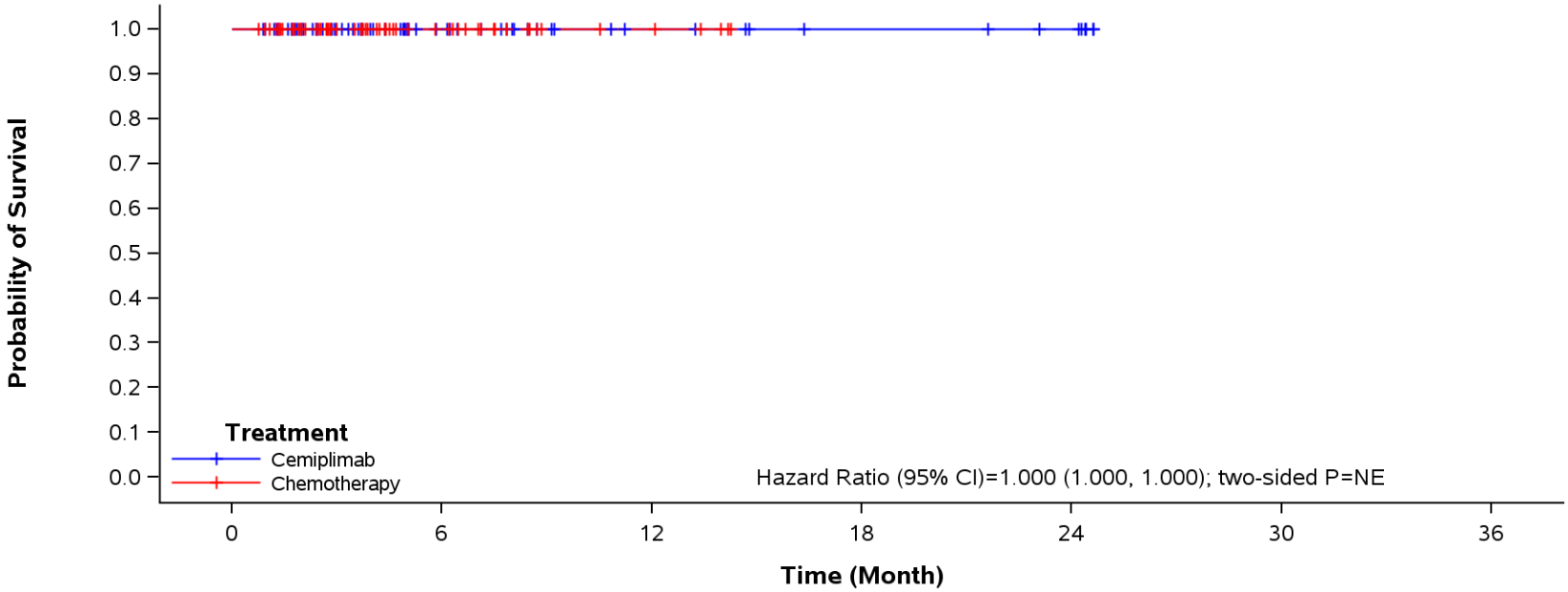

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Infections and infestations
PT: Pneumonia



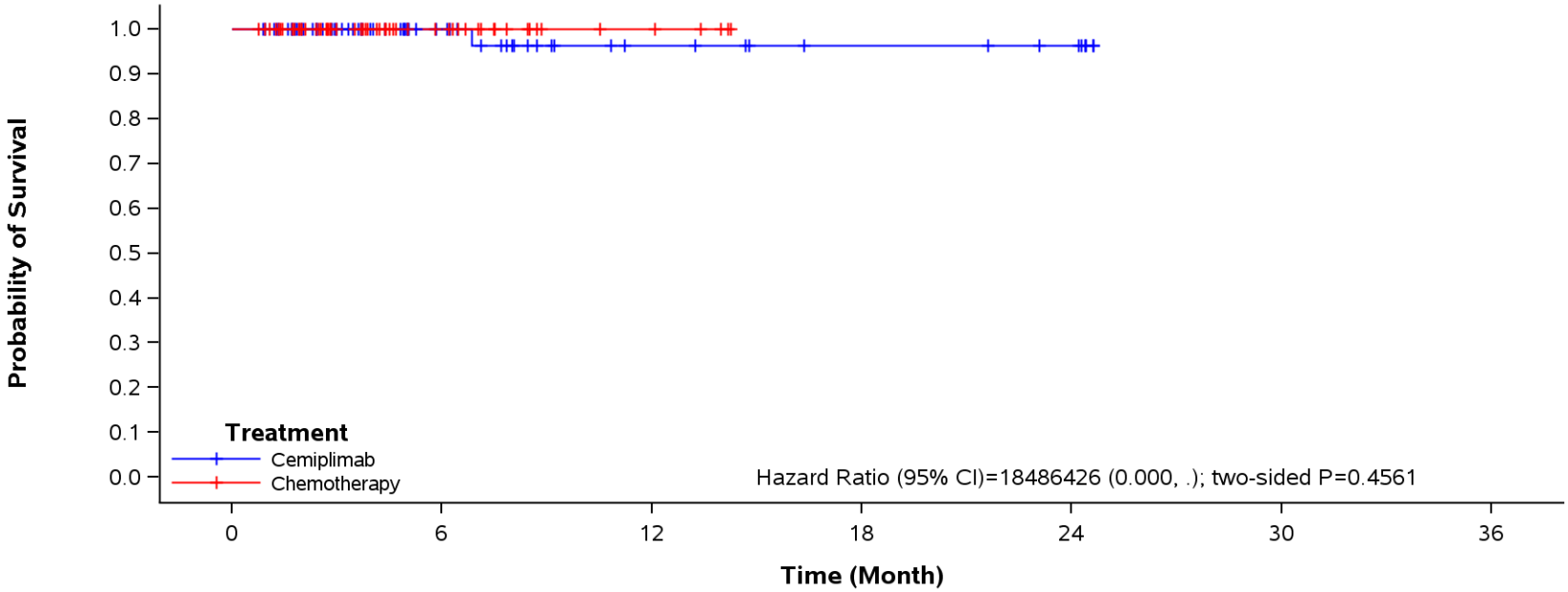

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Infections and infestations
PT: Pyomyositis



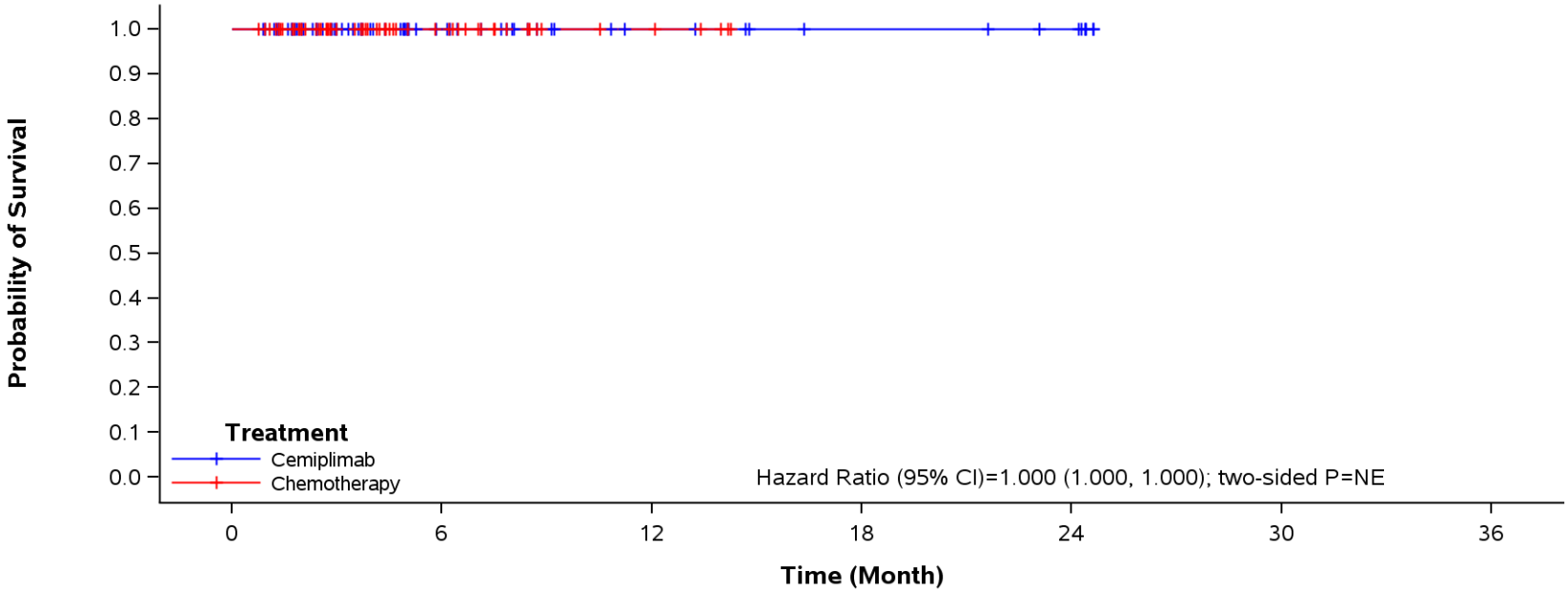

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Injury, poisoning and procedural complications



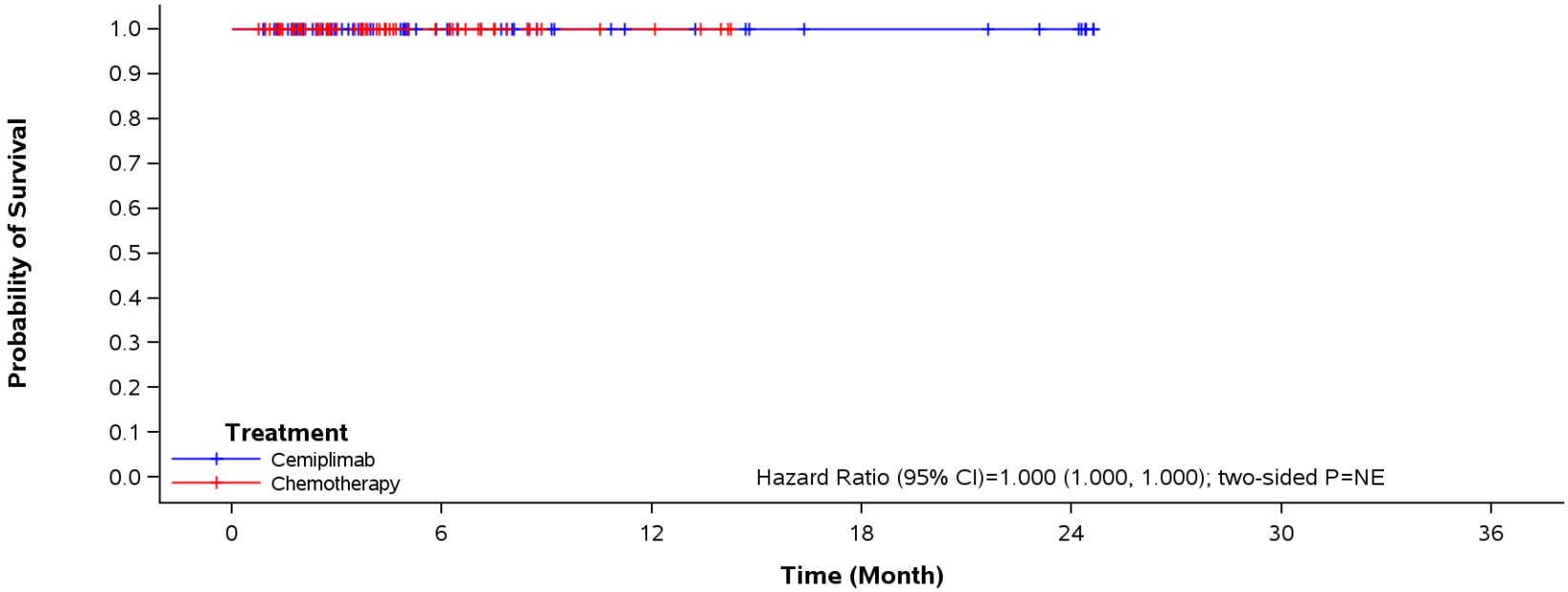

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



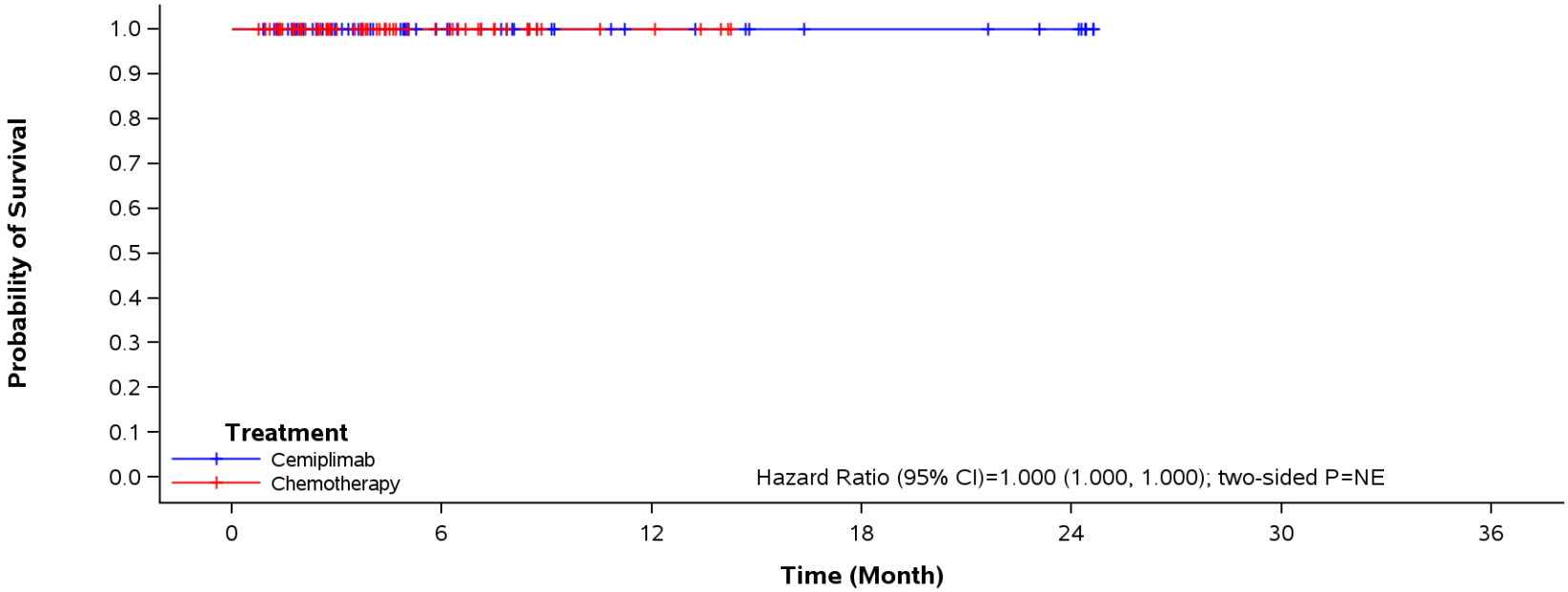

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



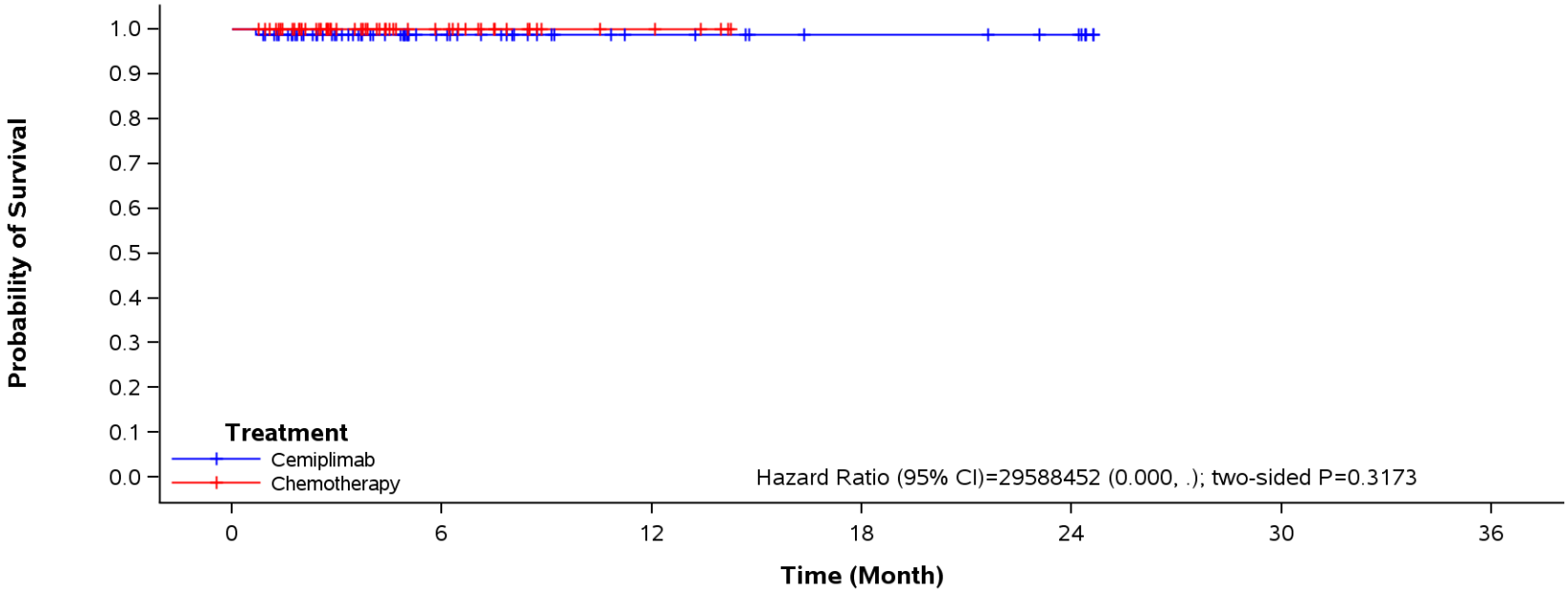

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Investigations



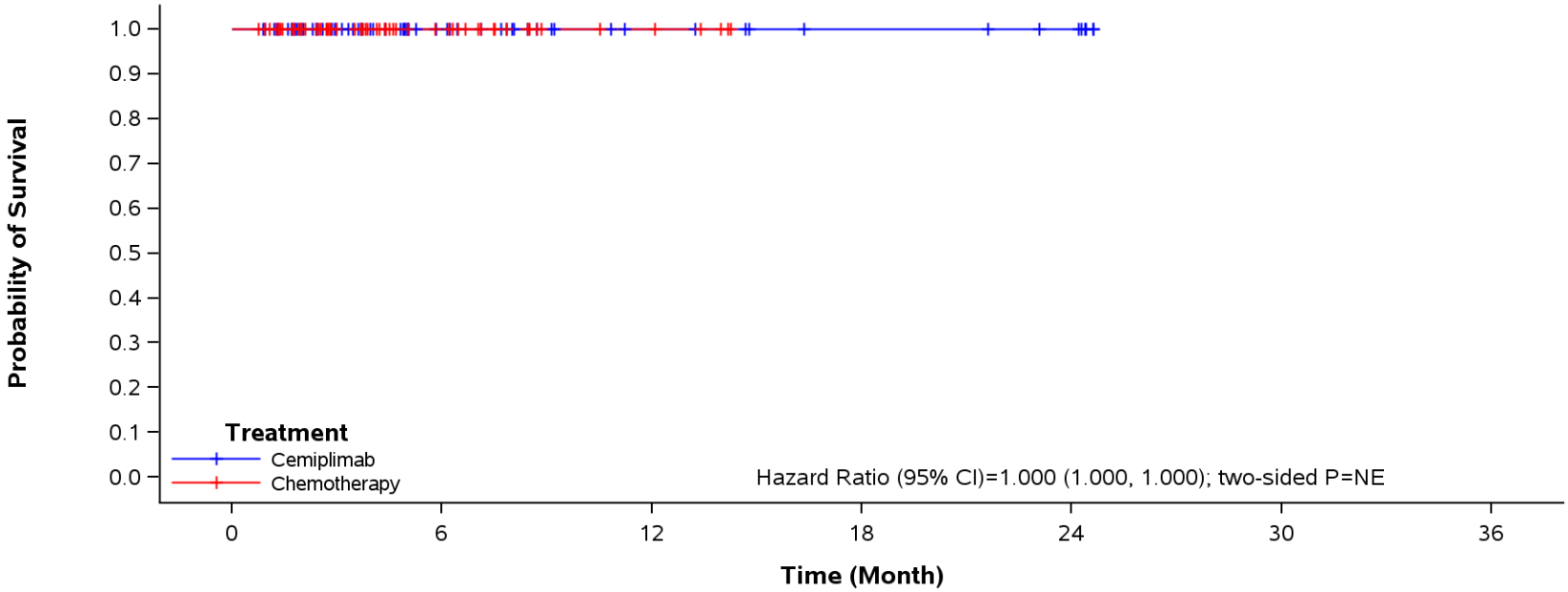

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Investigations
PT: Alanine aminotransferase increased



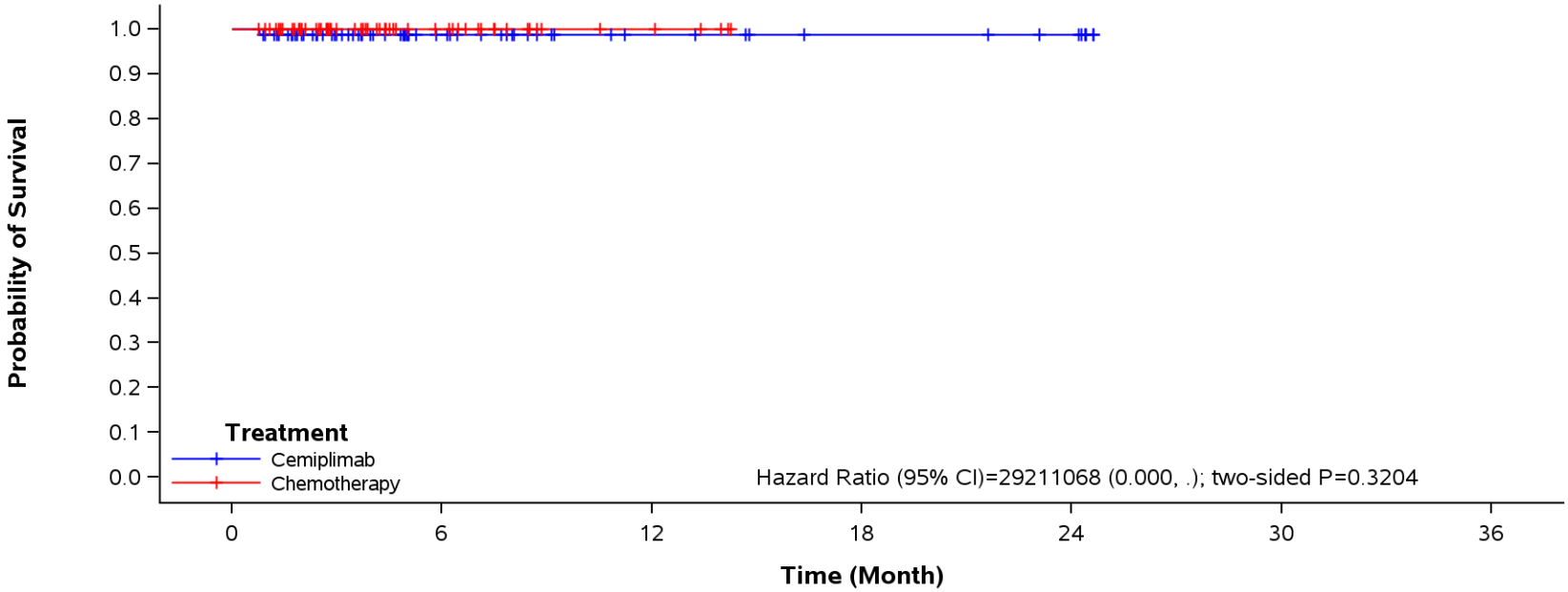

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Investigations
PT: Amylase increased



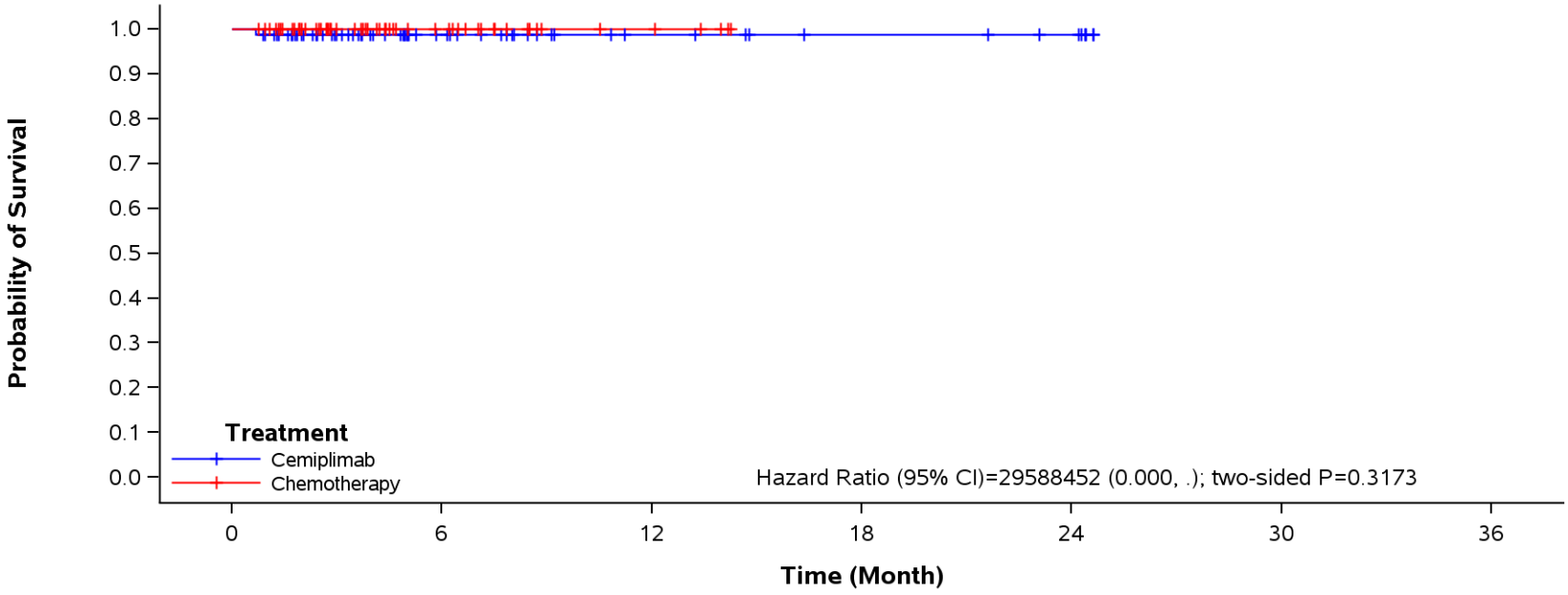

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Investigations
PT: Platelet count decreased



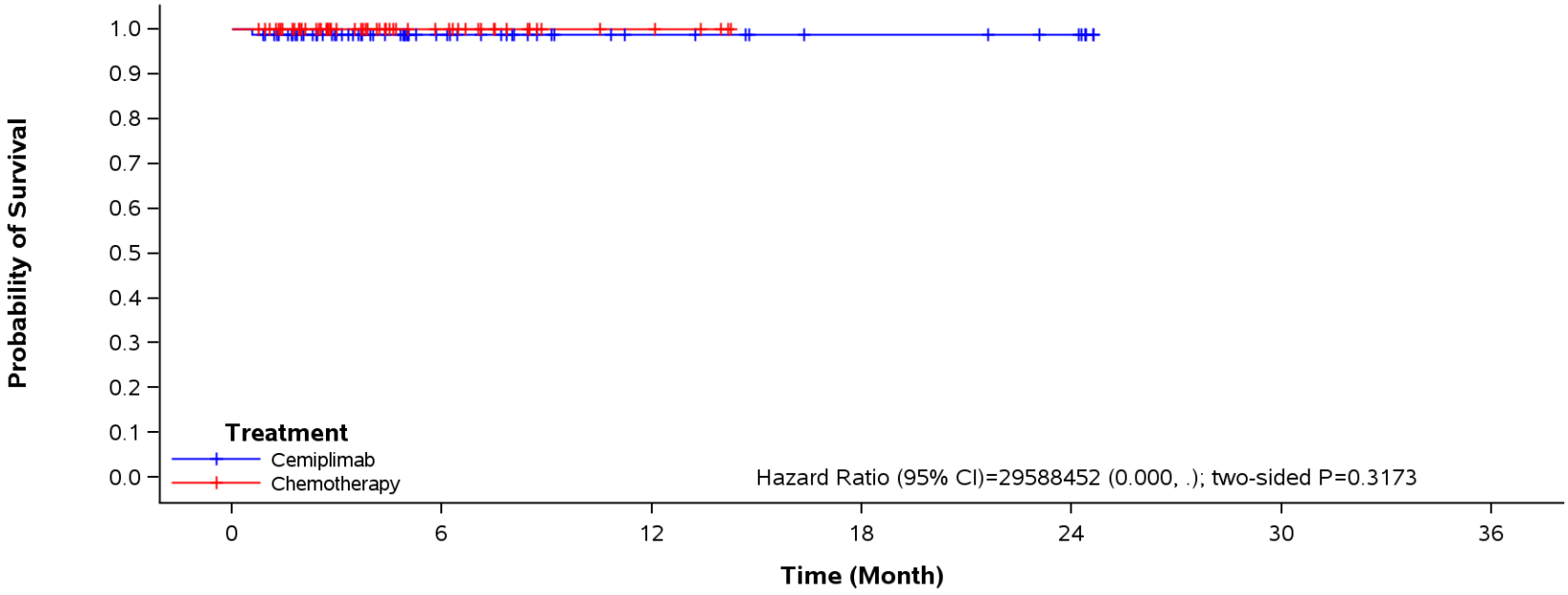

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Metabolism and nutrition disorders



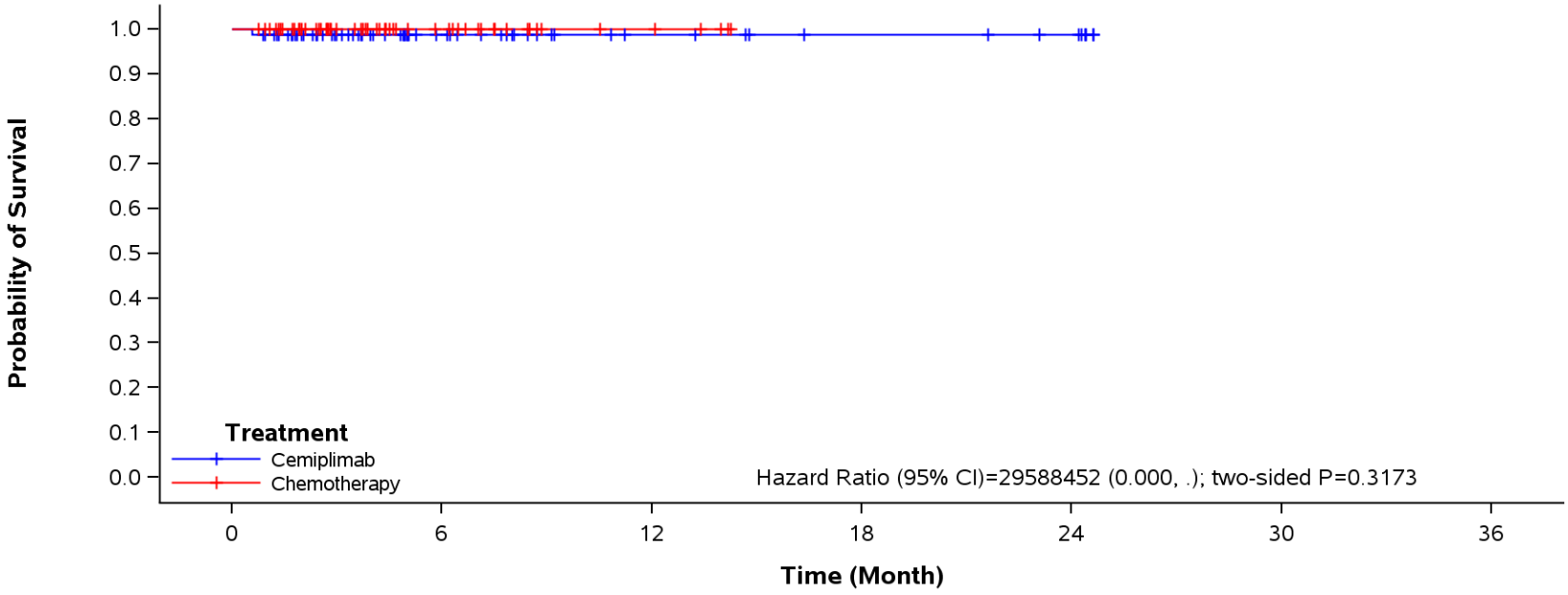

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



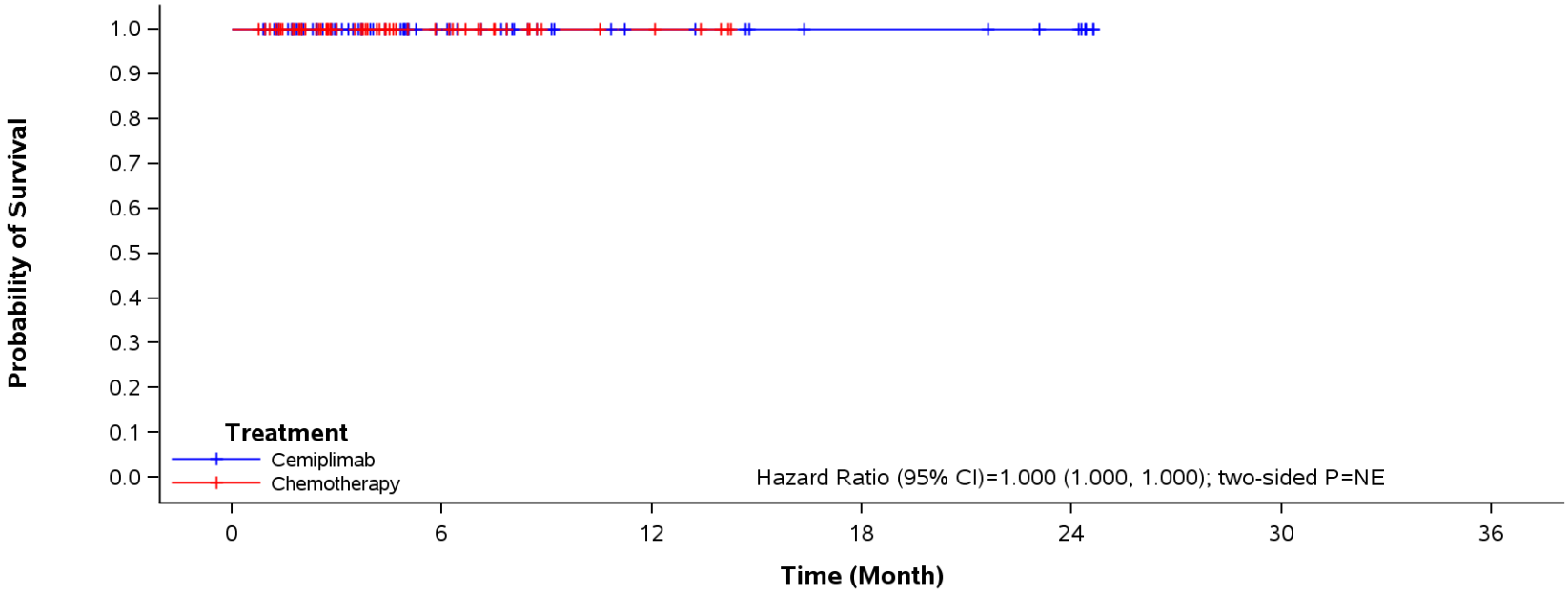

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Musculoskeletal and connective tissue disorders



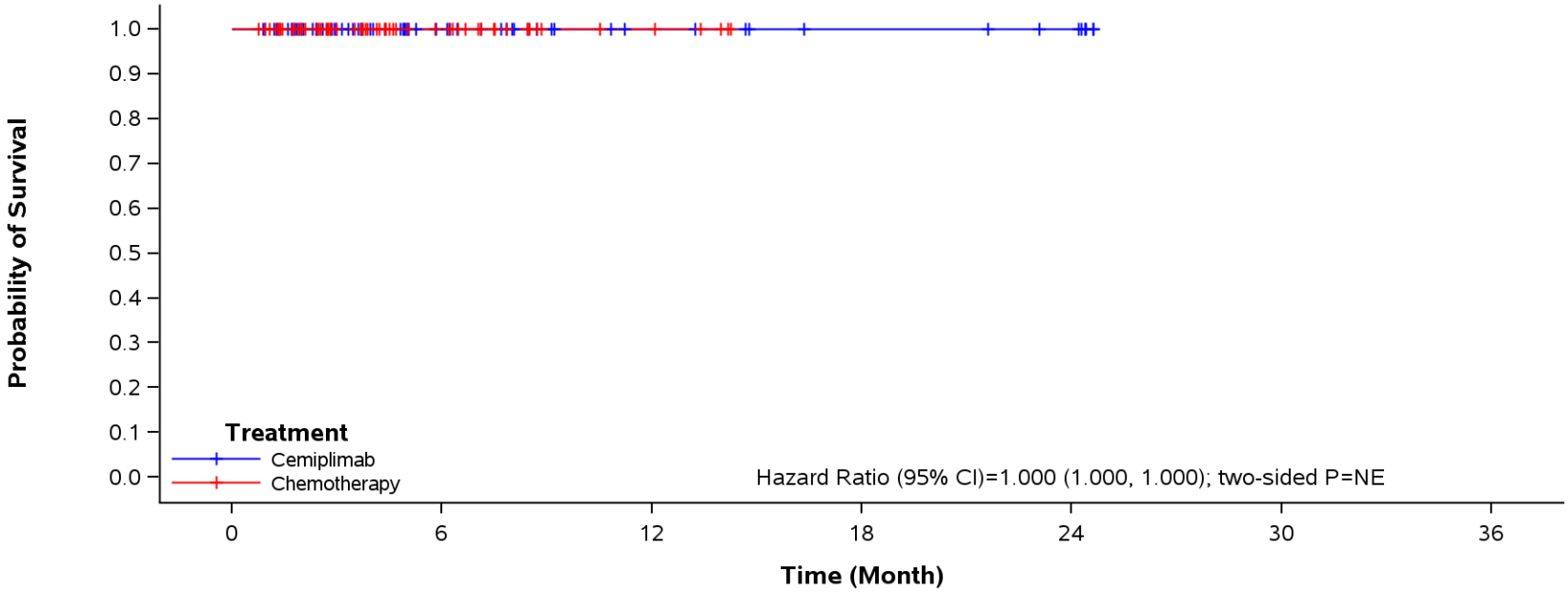

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



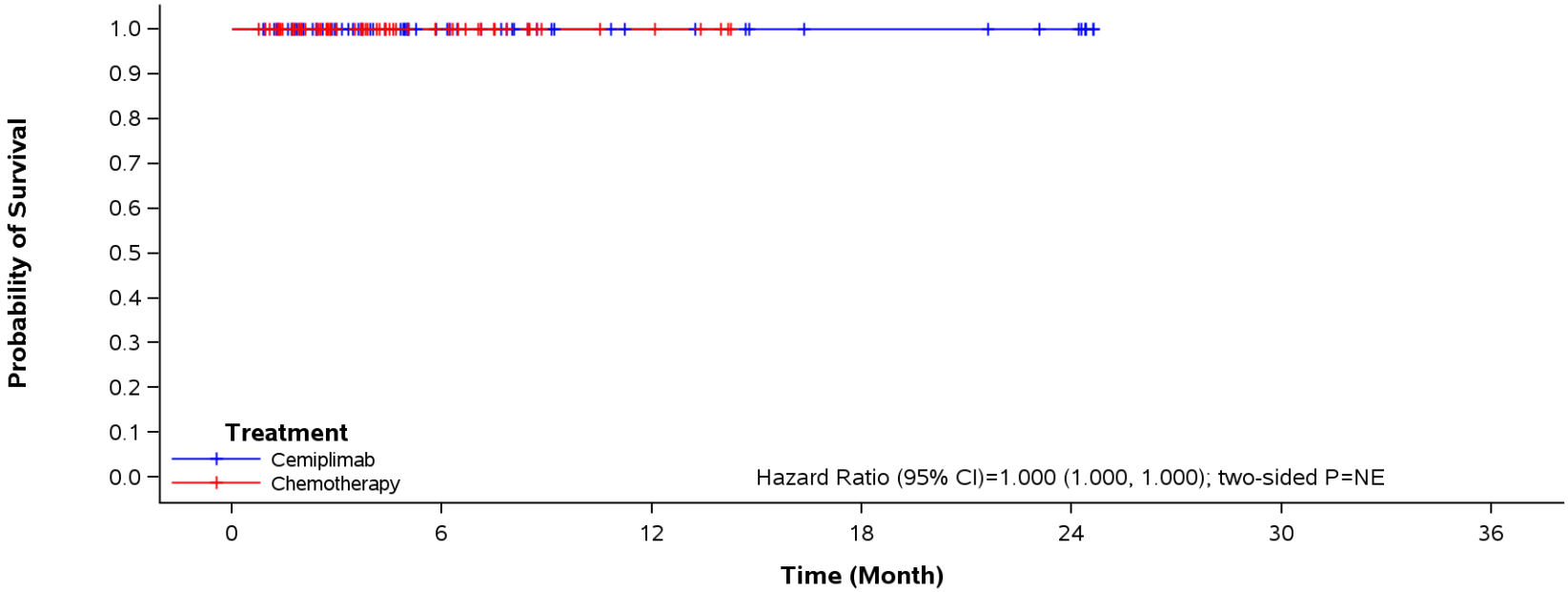

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



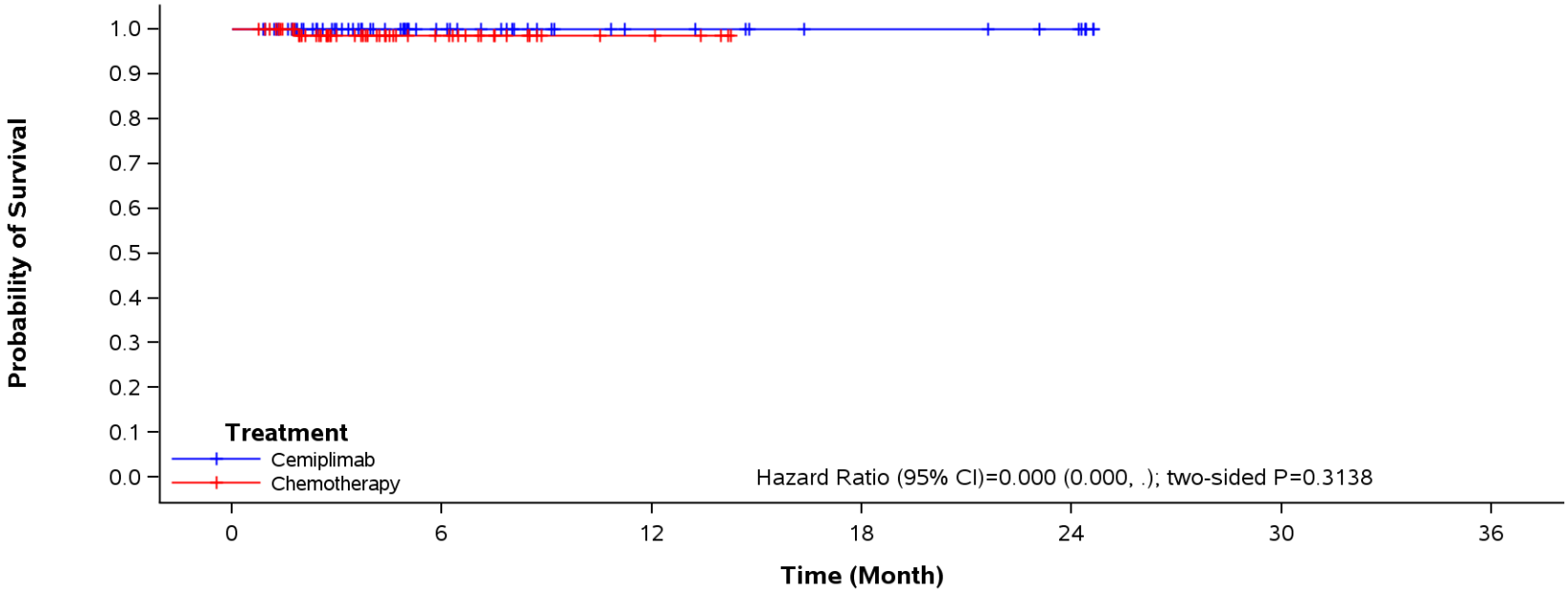

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Nervous system disorders



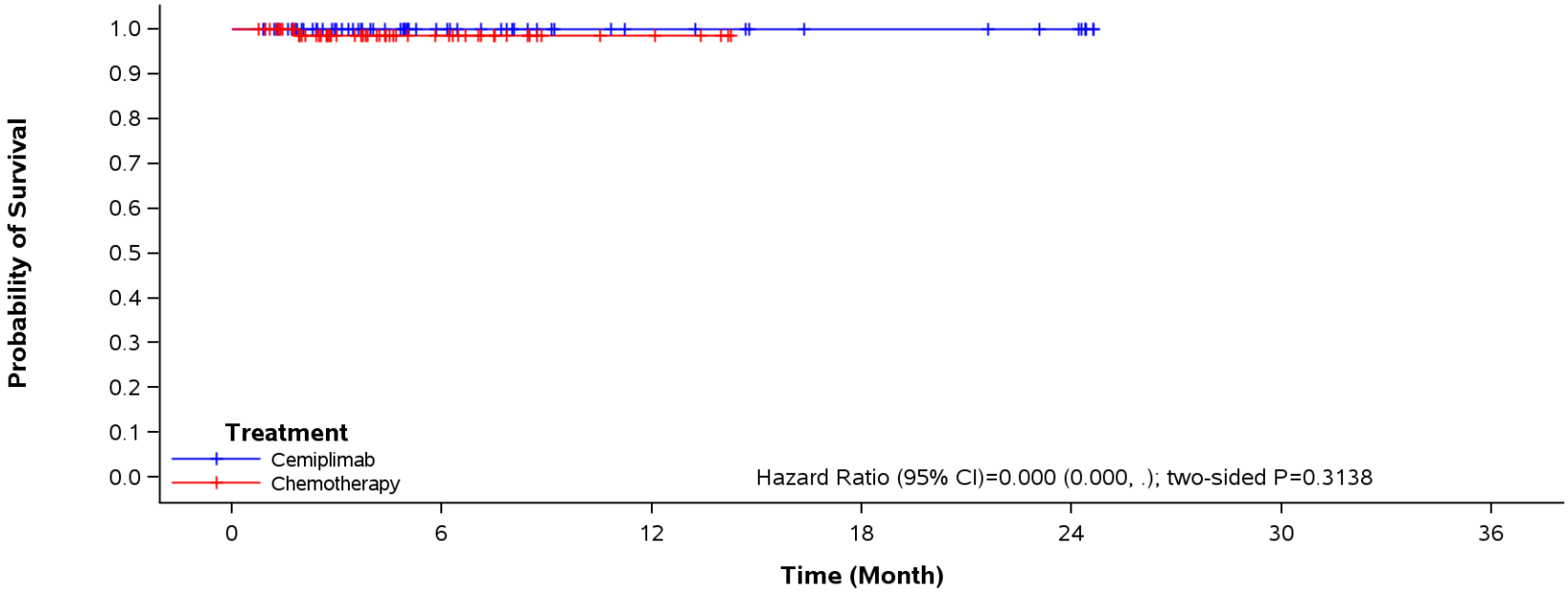

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Nervous system disorders
PT: Neurotoxicity



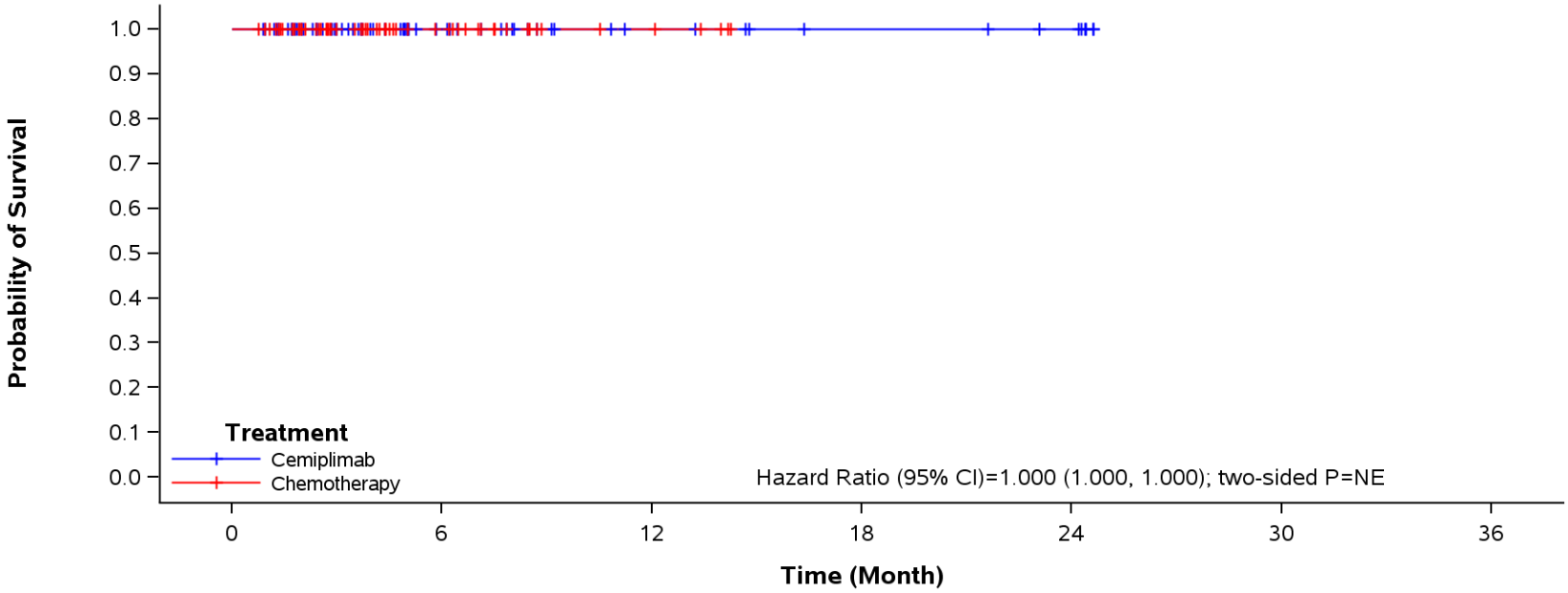

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Nervous system disorders
PT: Transient ischaemic attack



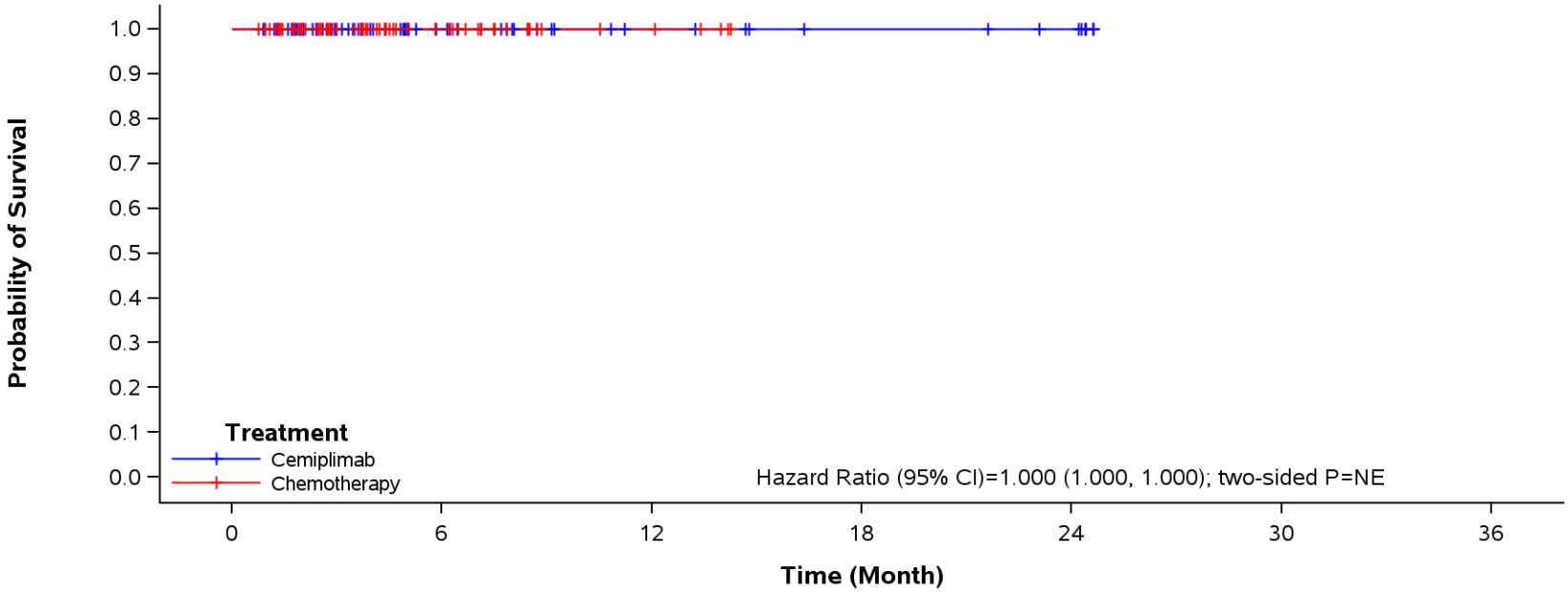

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Psychiatric disorders



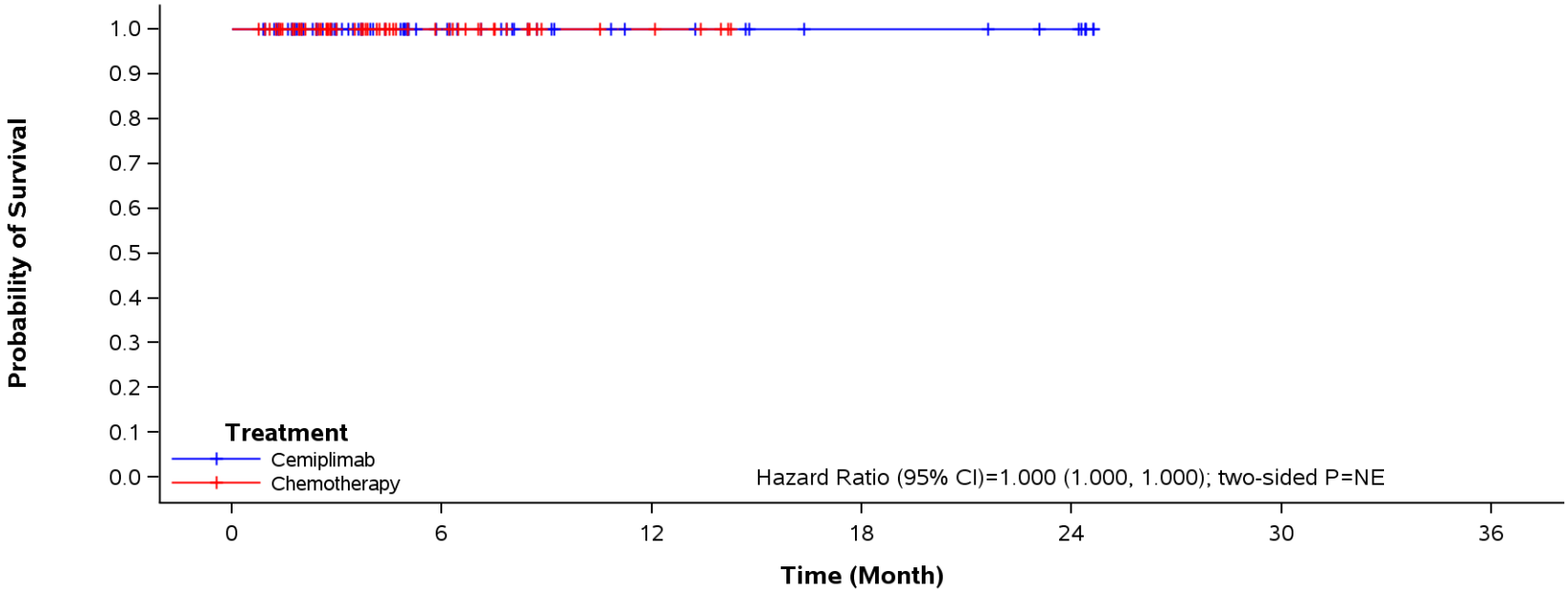

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Psychiatric disorders
PT: Agoraphobia



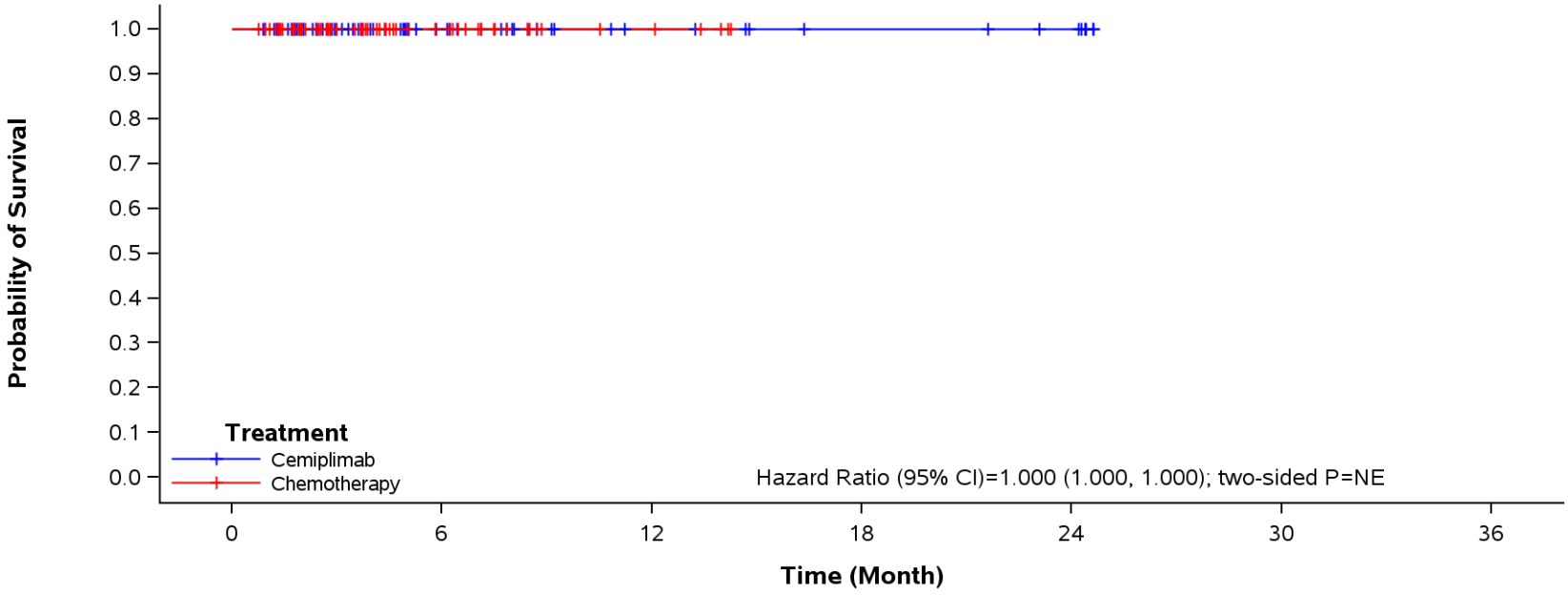

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Renal and urinary disorders



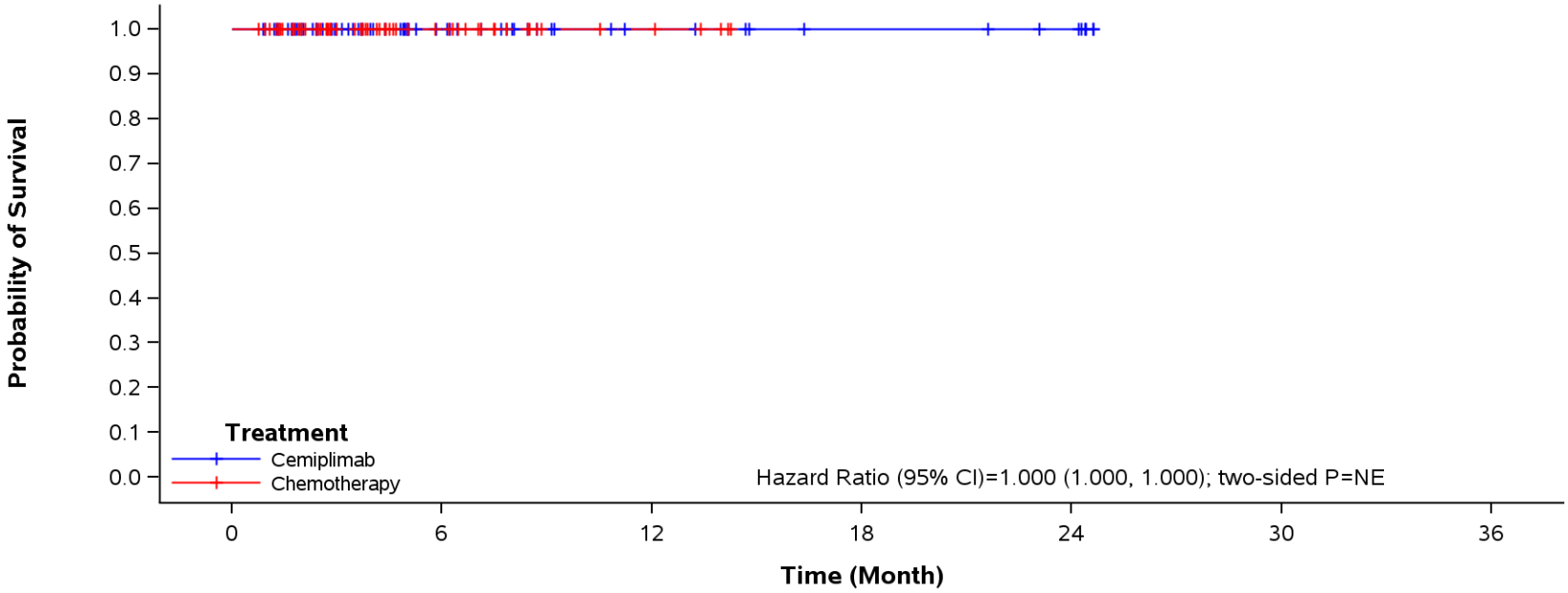

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Renal and urinary disorders
PT: Renal failure



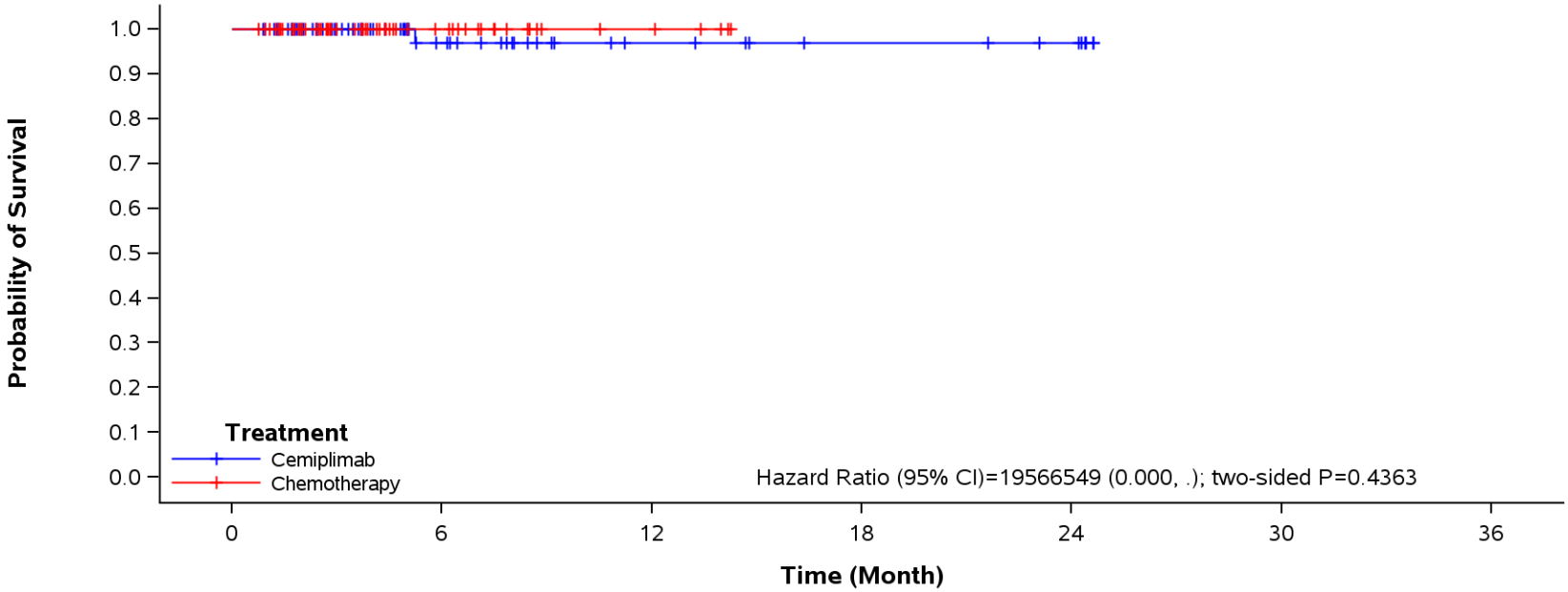

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Respiratory, thoracic and mediastinal disorders



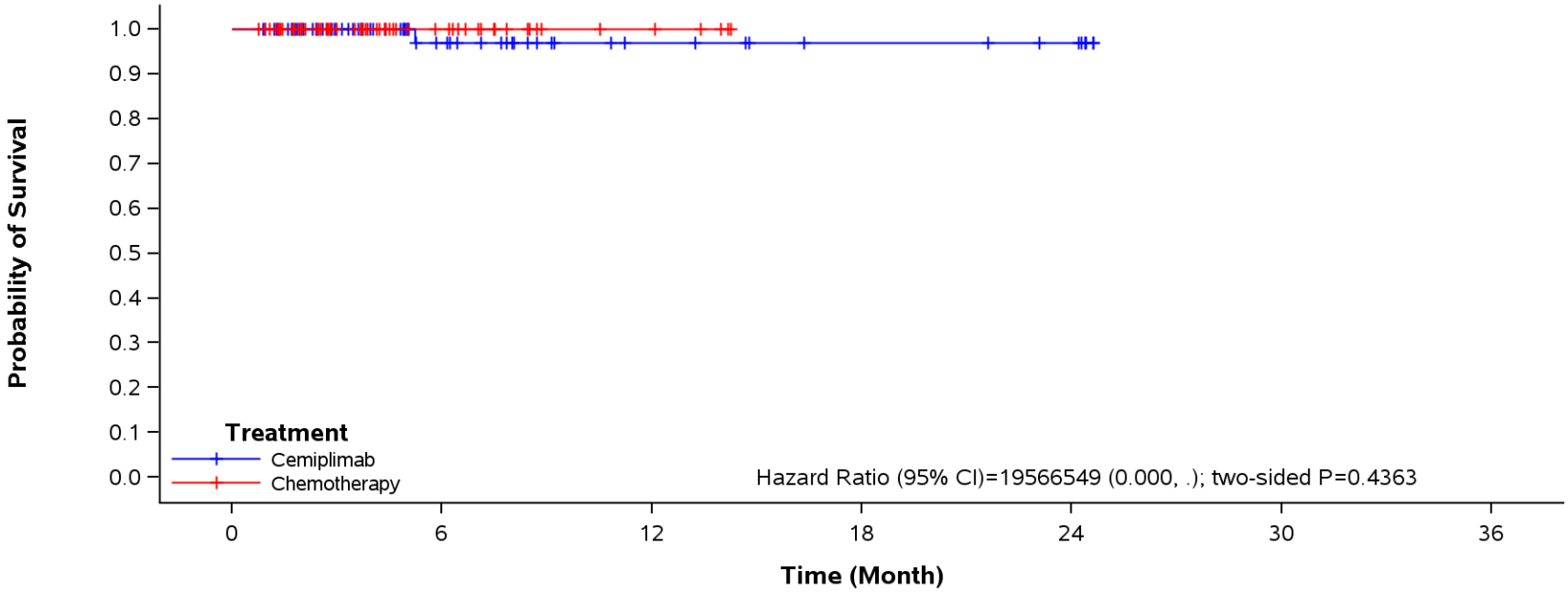

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 30 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis




**Number of Subjects at risk**

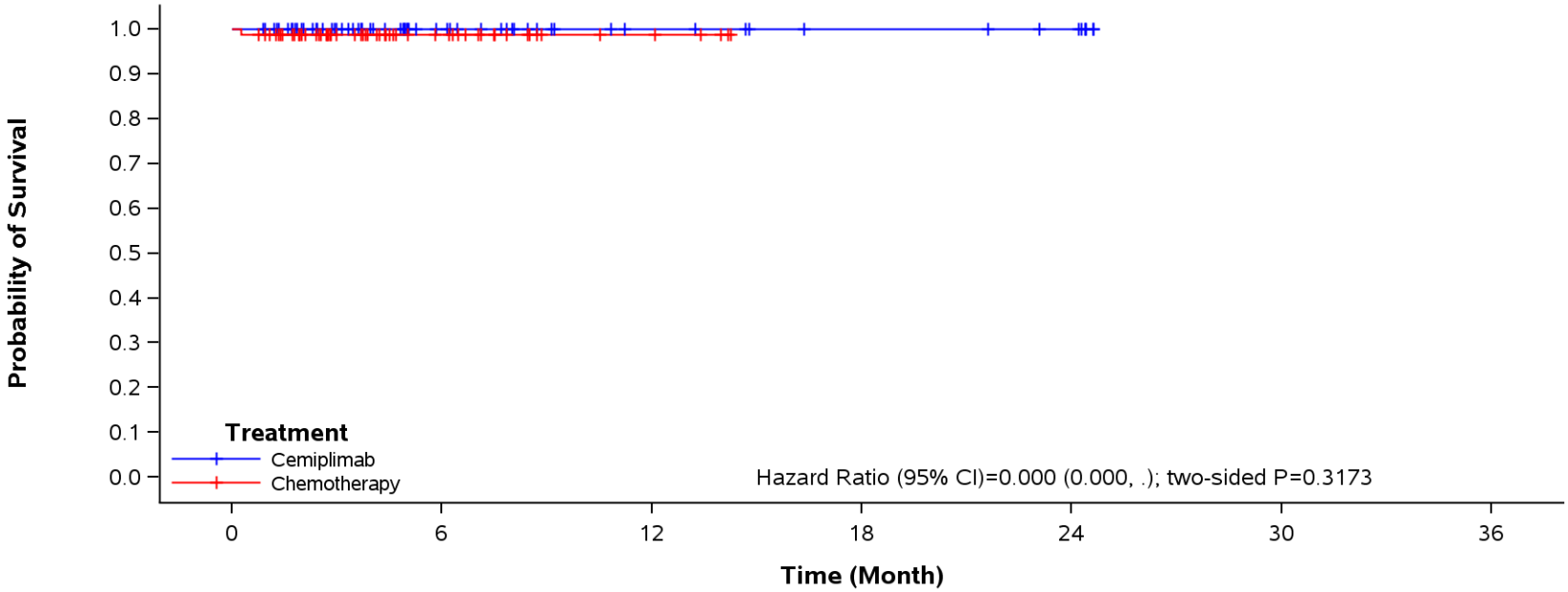
| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 30 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Program: /home/haijin.tang/sasdata/Data/Development/MA/R2810/R2810-ONC/MA/HTA-Germany-1676-JAN2022Cut/Analysis_MA/Programs/f-tte-subgroup-ae-socpt-nopdl1.sas (14NOV22:05:00:36, haijin.tang)

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Vascular disorders



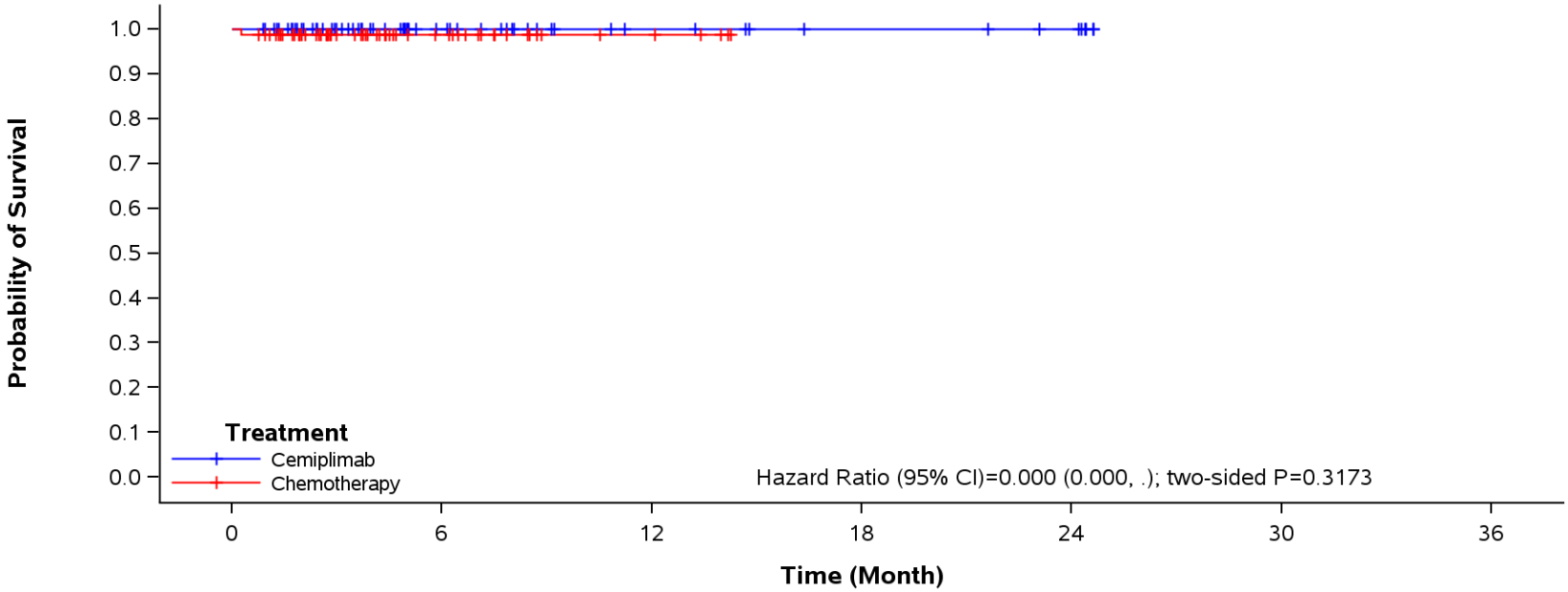

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Number of prior lines of systemic therapy for recurrent or metastatic disease: >1 line
SOC: Vascular disorders
PT: Deep vein thrombosis



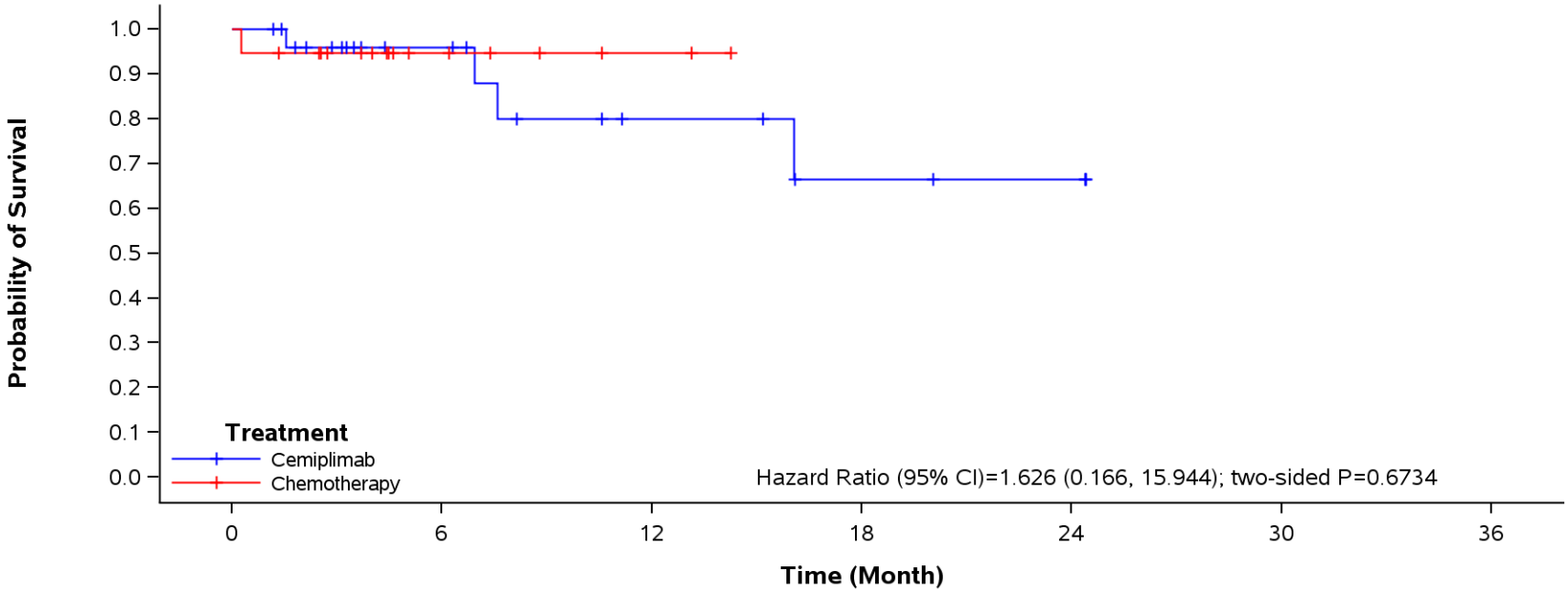

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 78 | 31 | 15 | 11 | 9 | 0 | 0 |
| Chemotherapy | 78 | 19 | 5 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
Number of patients with any TEAE leading to discontinuation



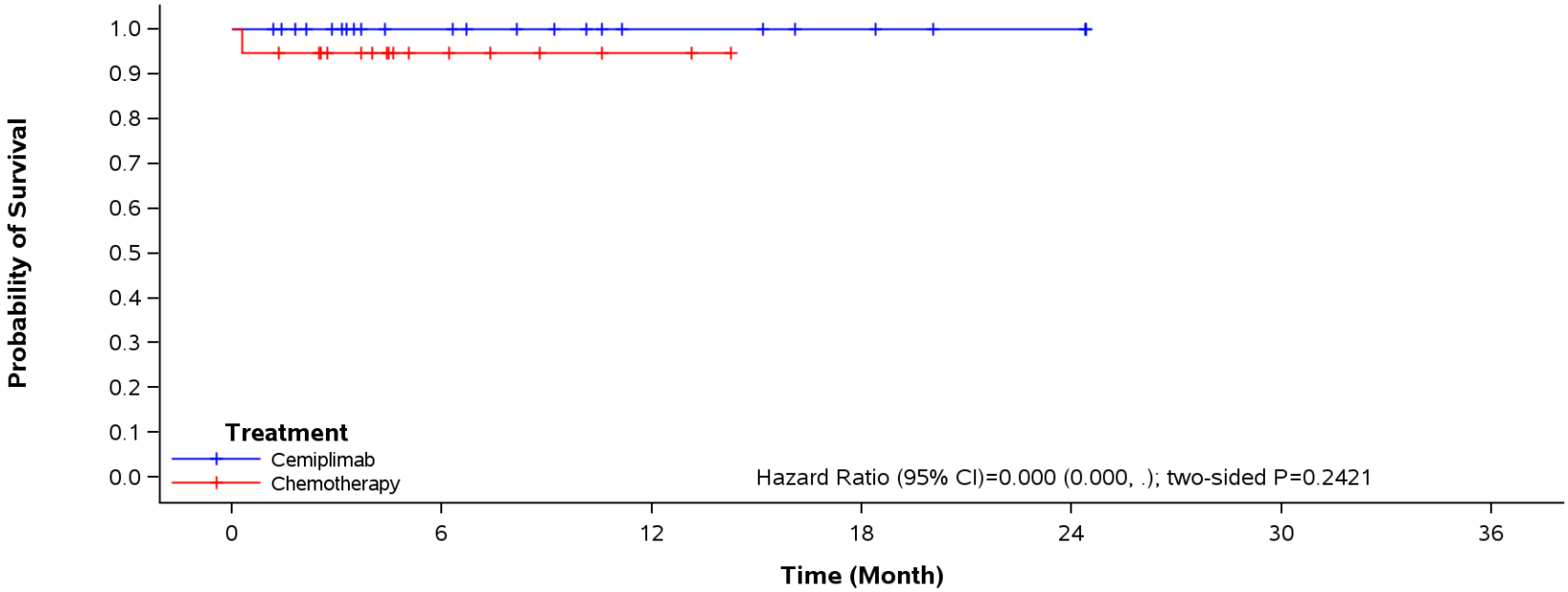

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 4 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders



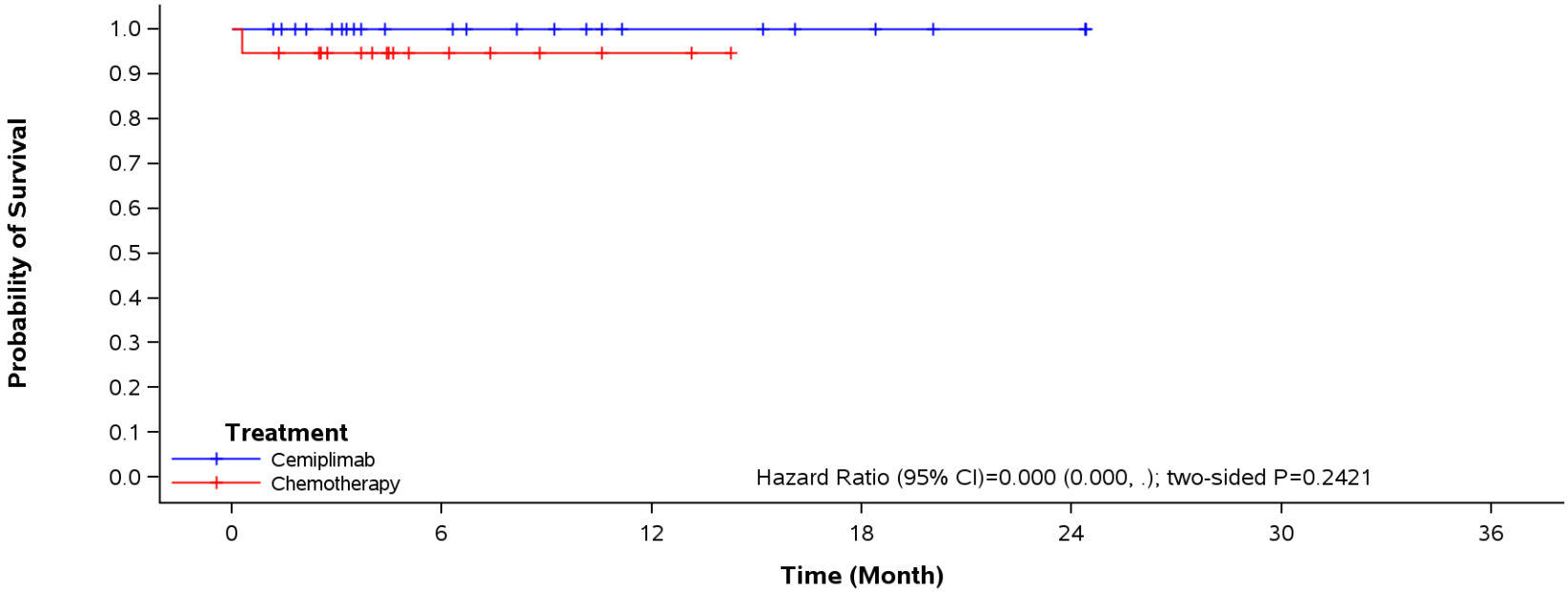

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



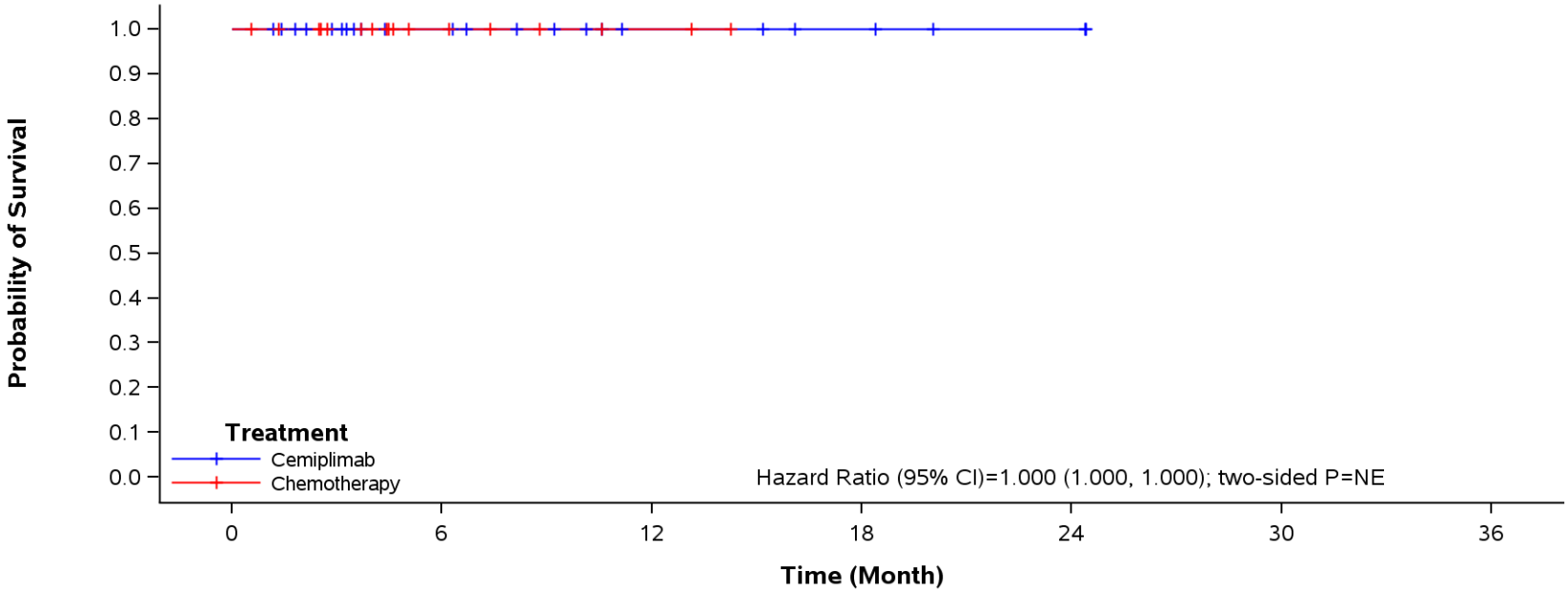

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



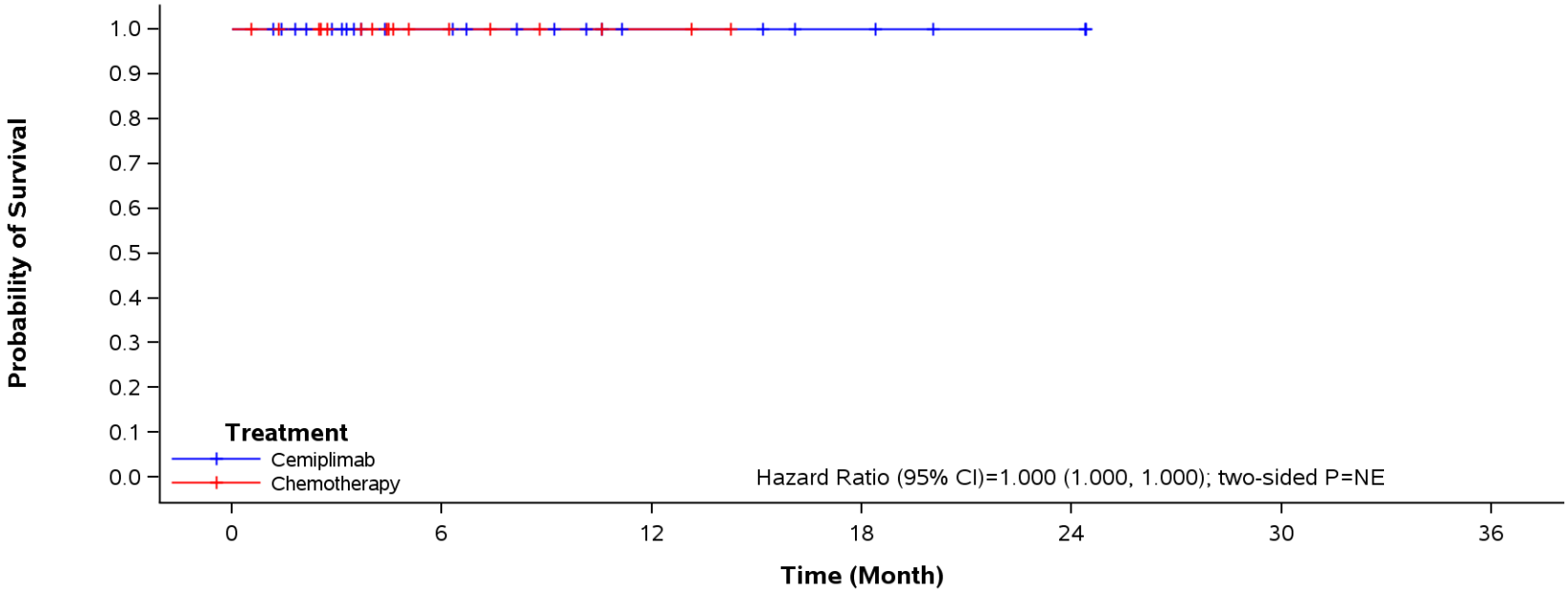

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



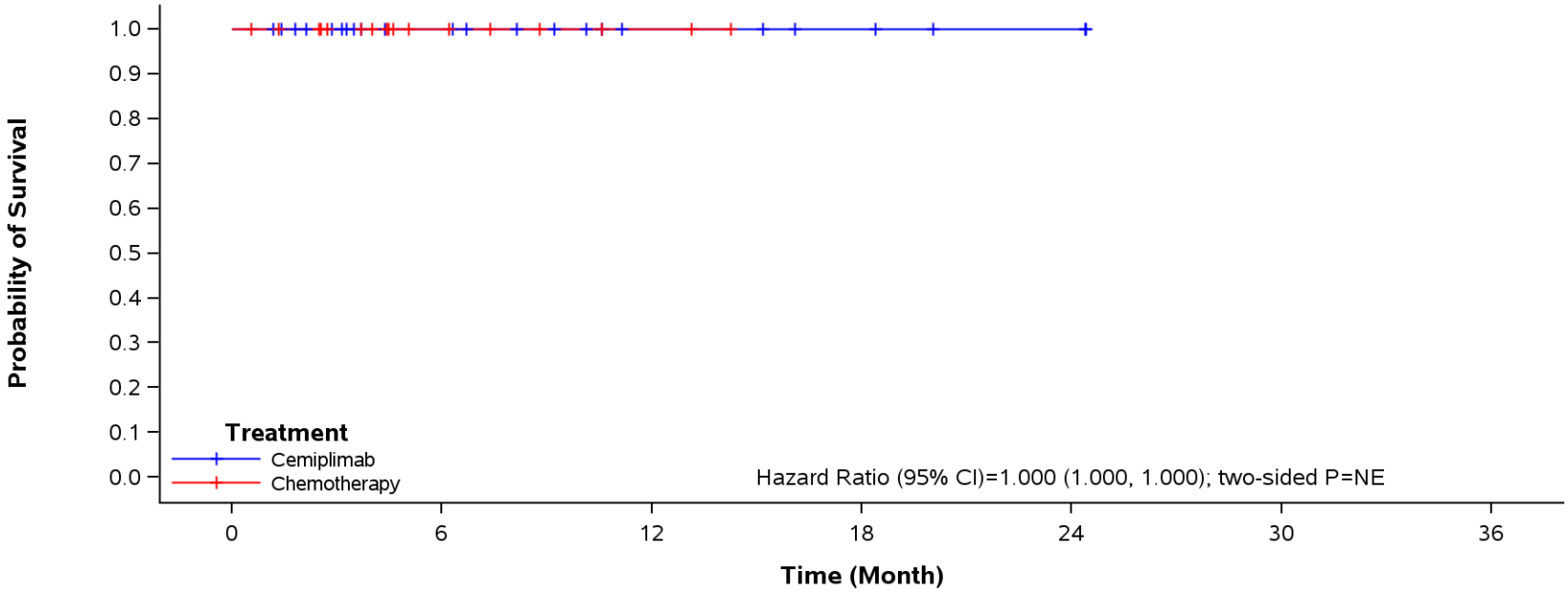

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



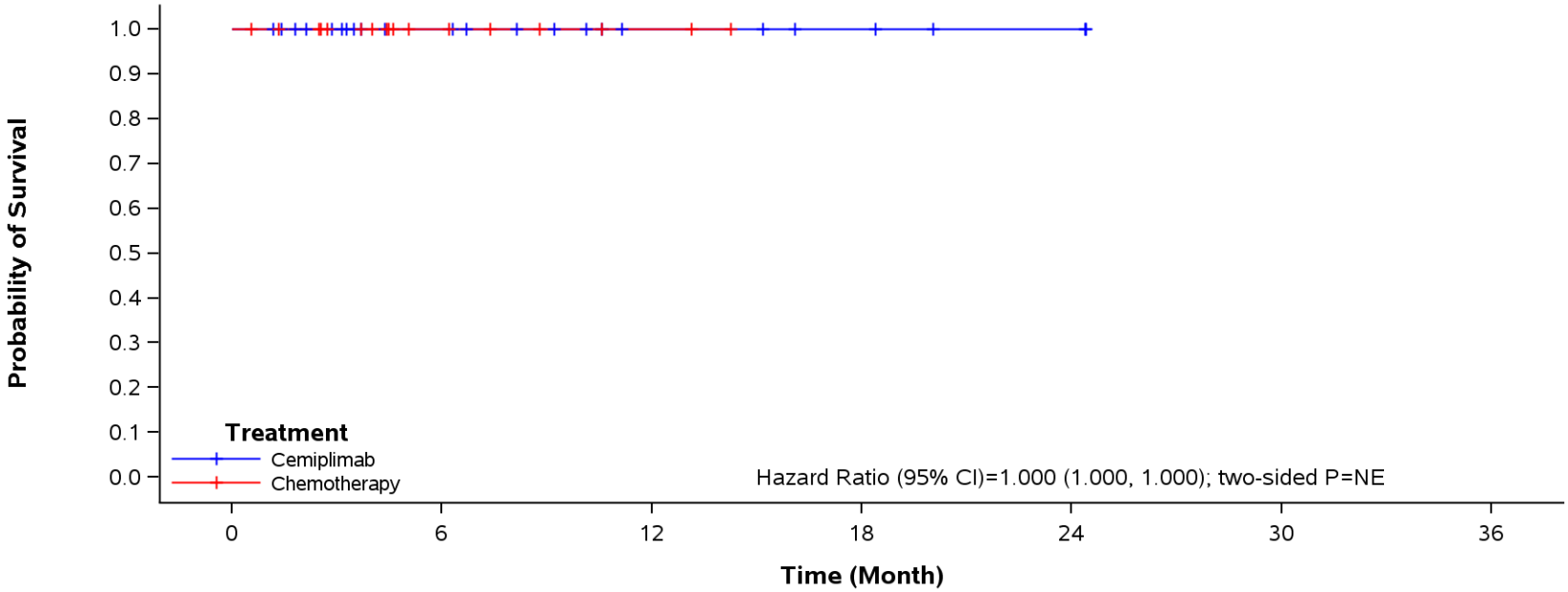

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Cardiac disorders



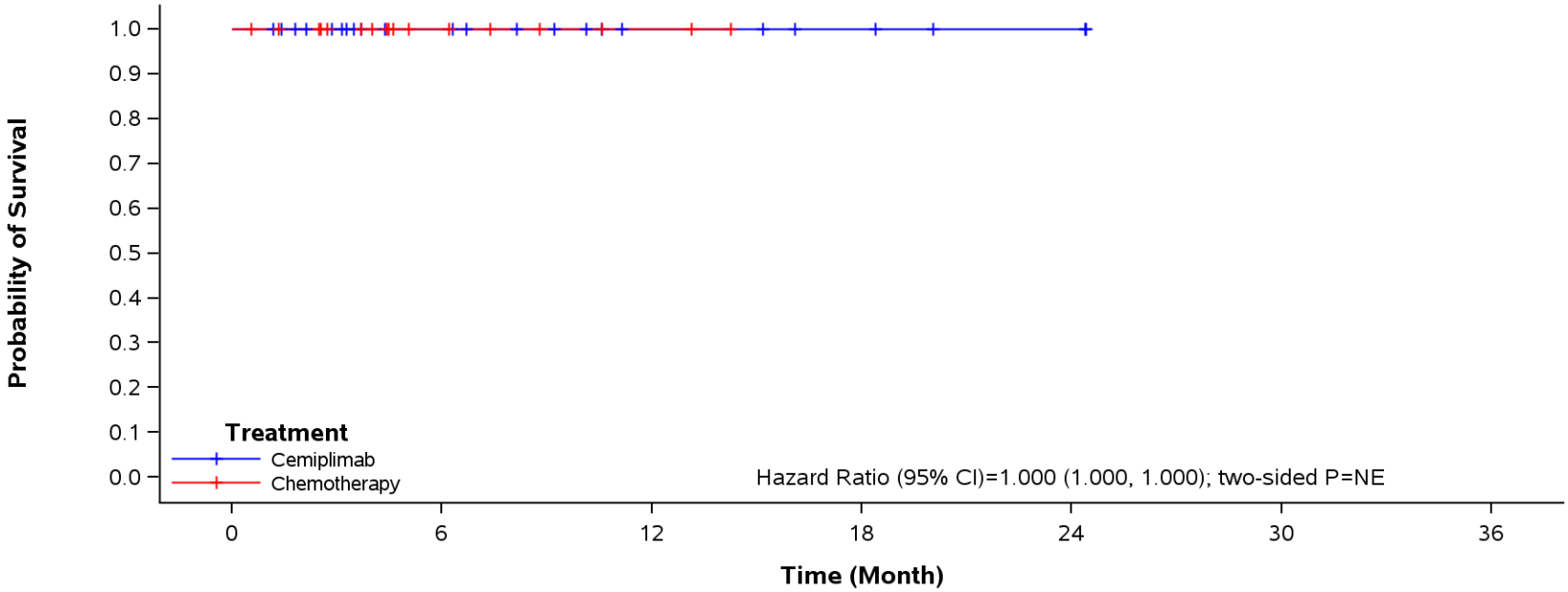

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Cardiac disorders
PT: Autoimmune pericarditis



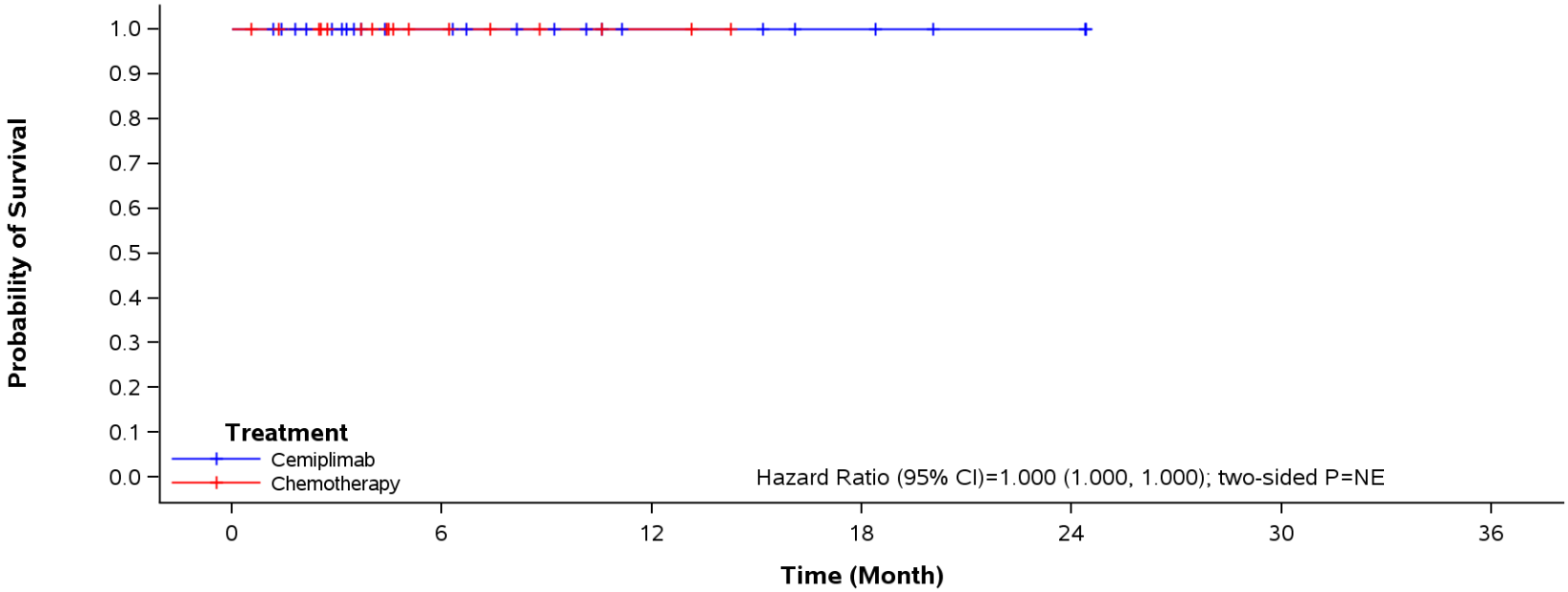

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Endocrine disorders



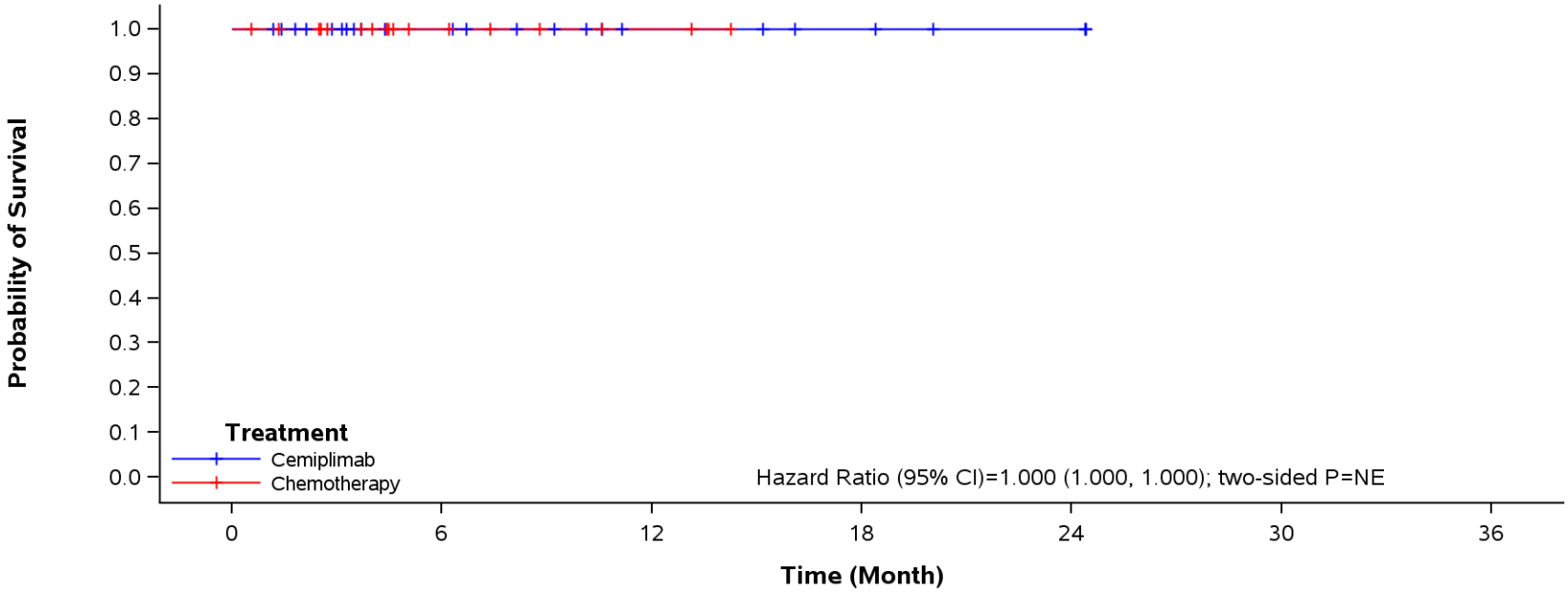

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Endocrine disorders
PT: Hypothyroidism



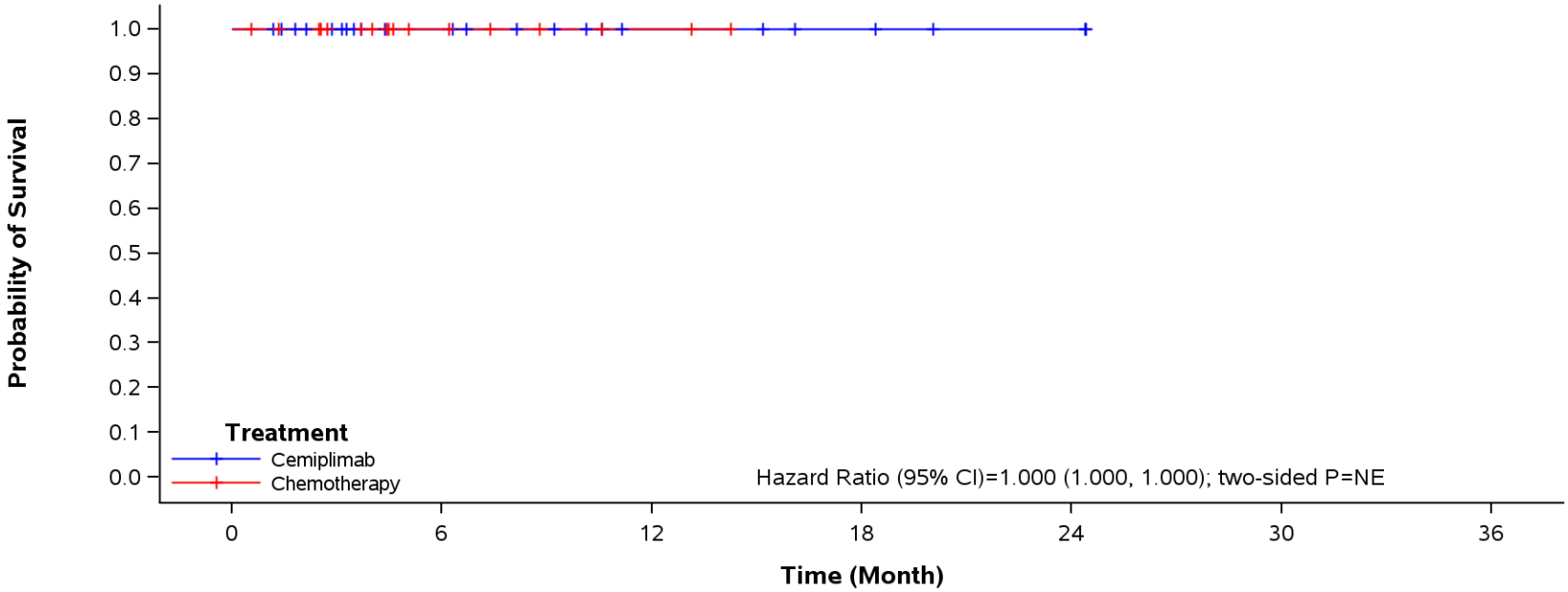

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders



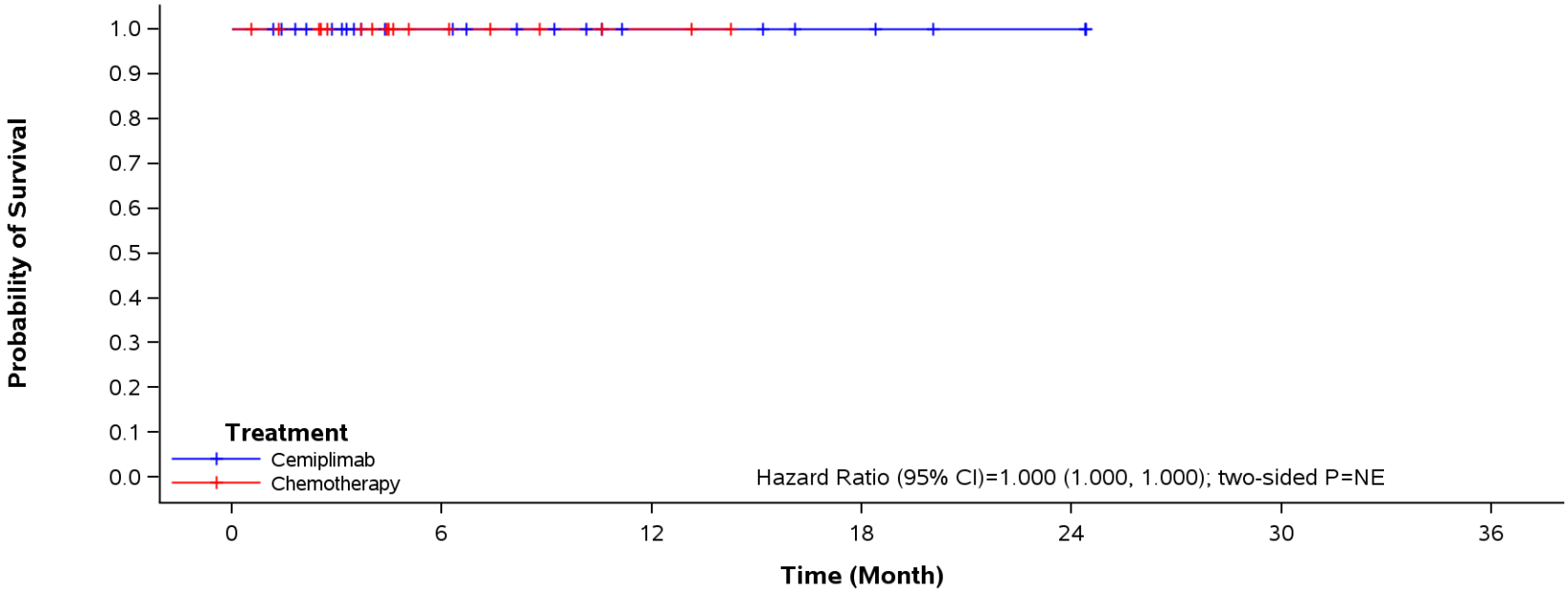

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders
PT: Colitis



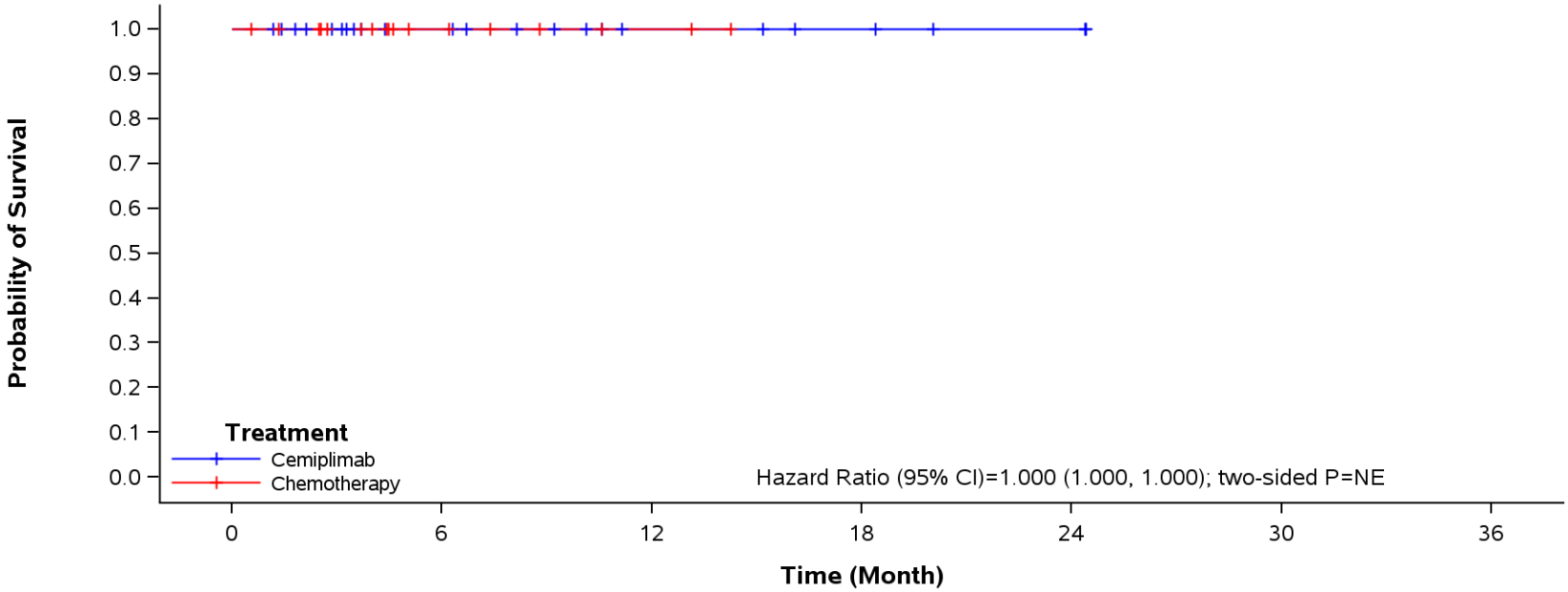

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders
PT: Diverticular perforation



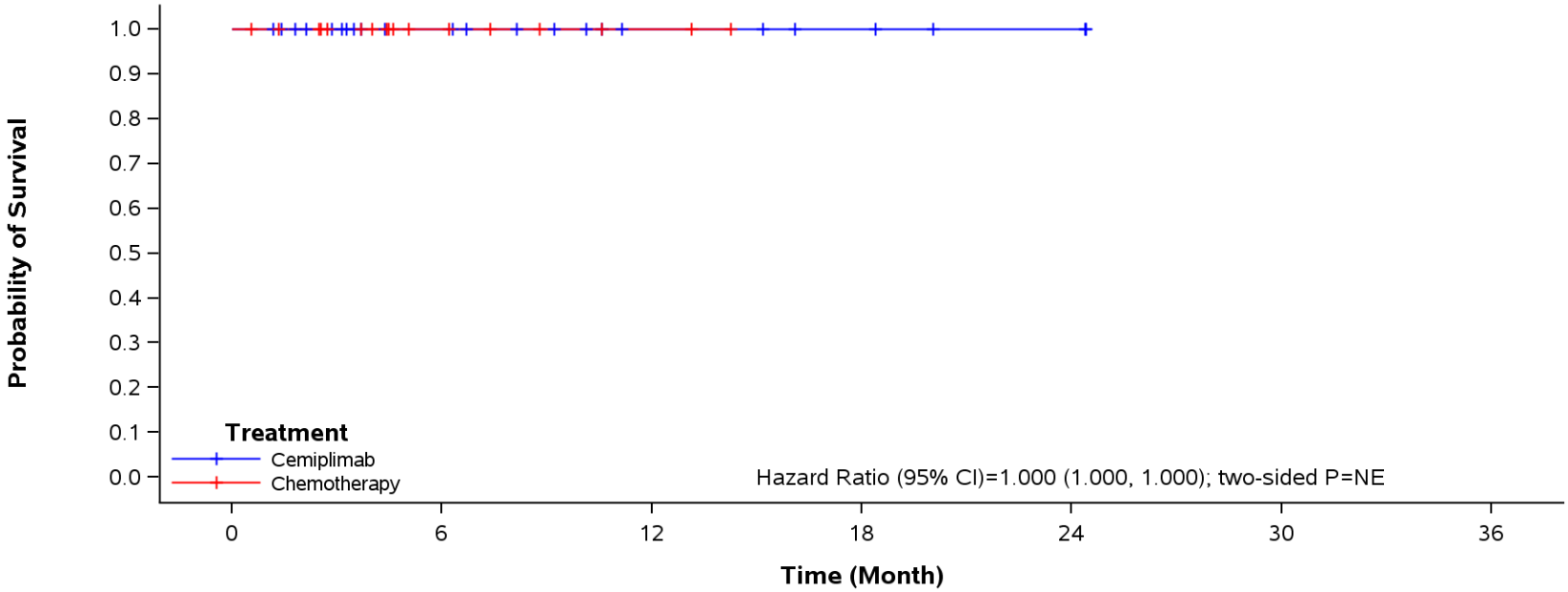

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders
PT: Pancreatic mass



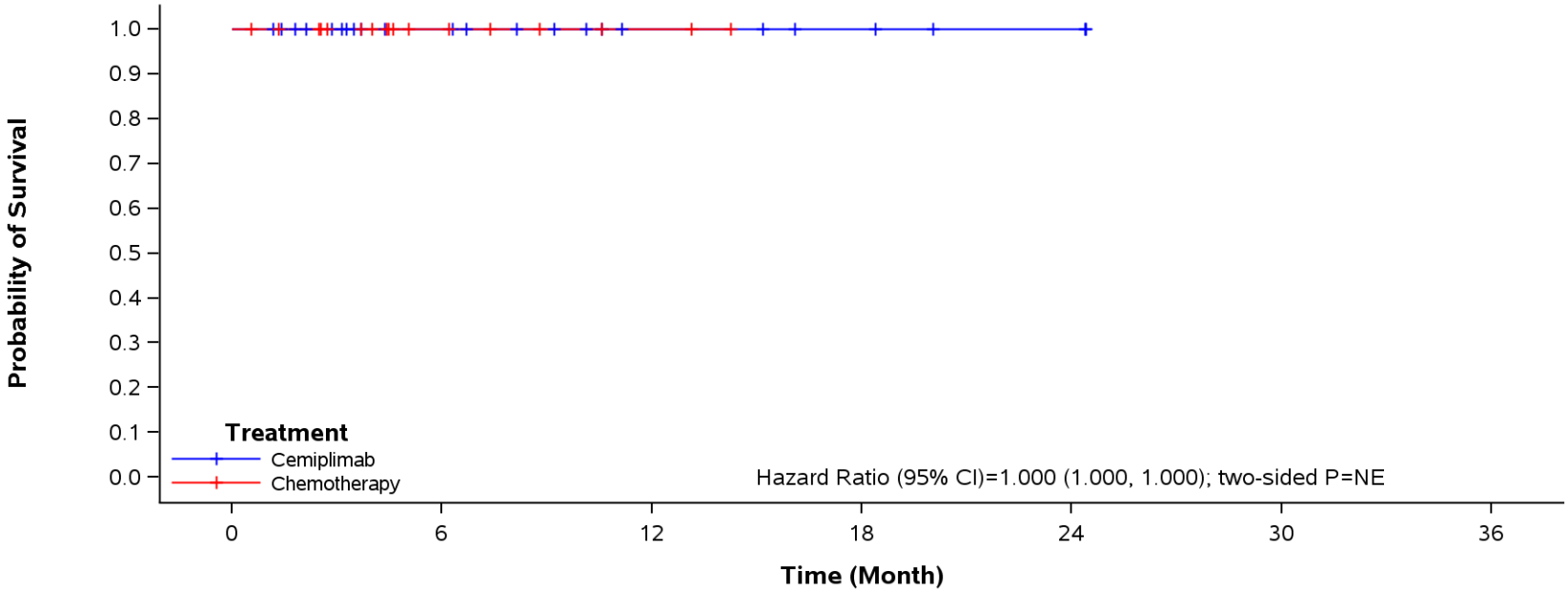

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



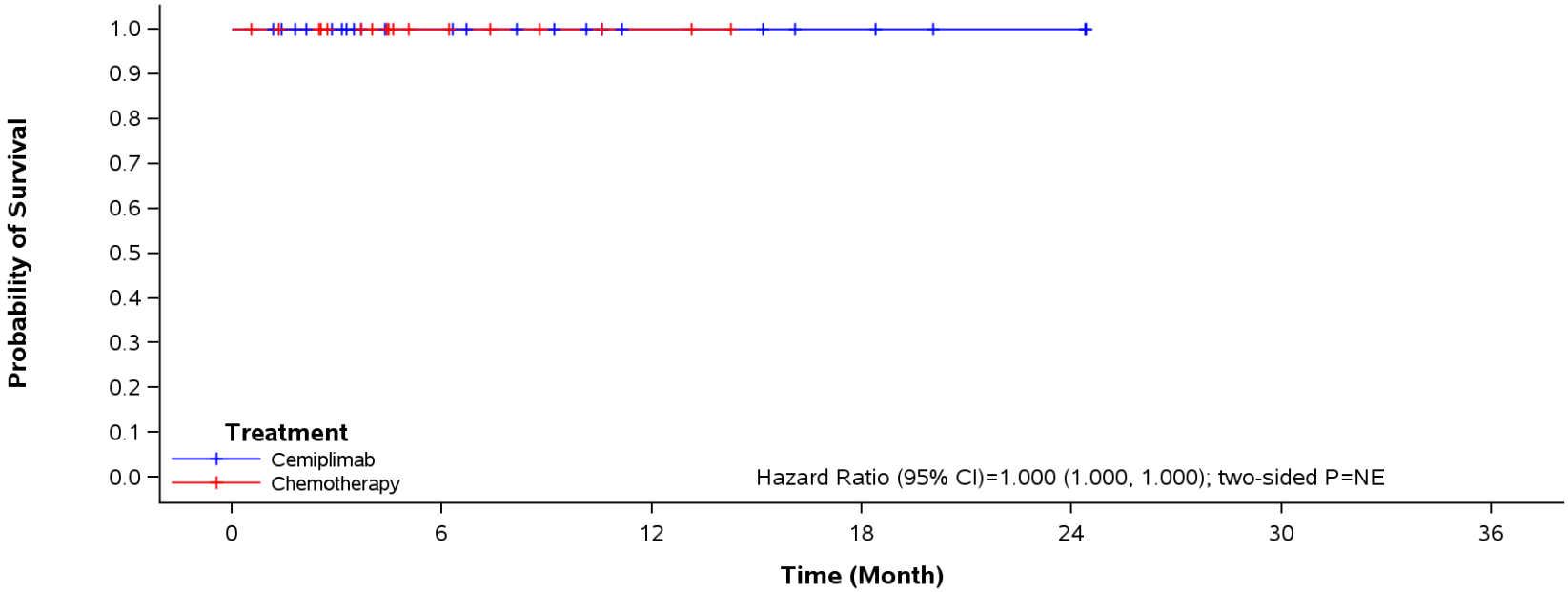

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Gastrointestinal disorders
PT: Proctalgia



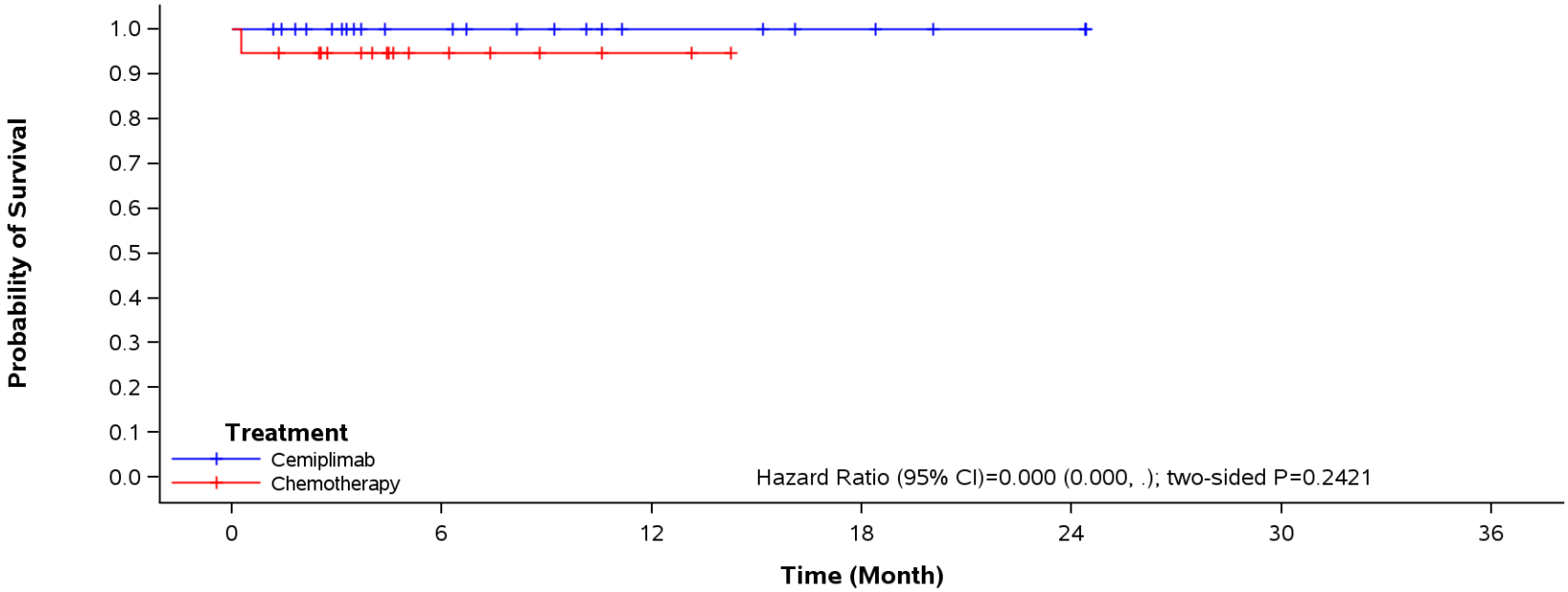

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: General disorders and administration site conditions



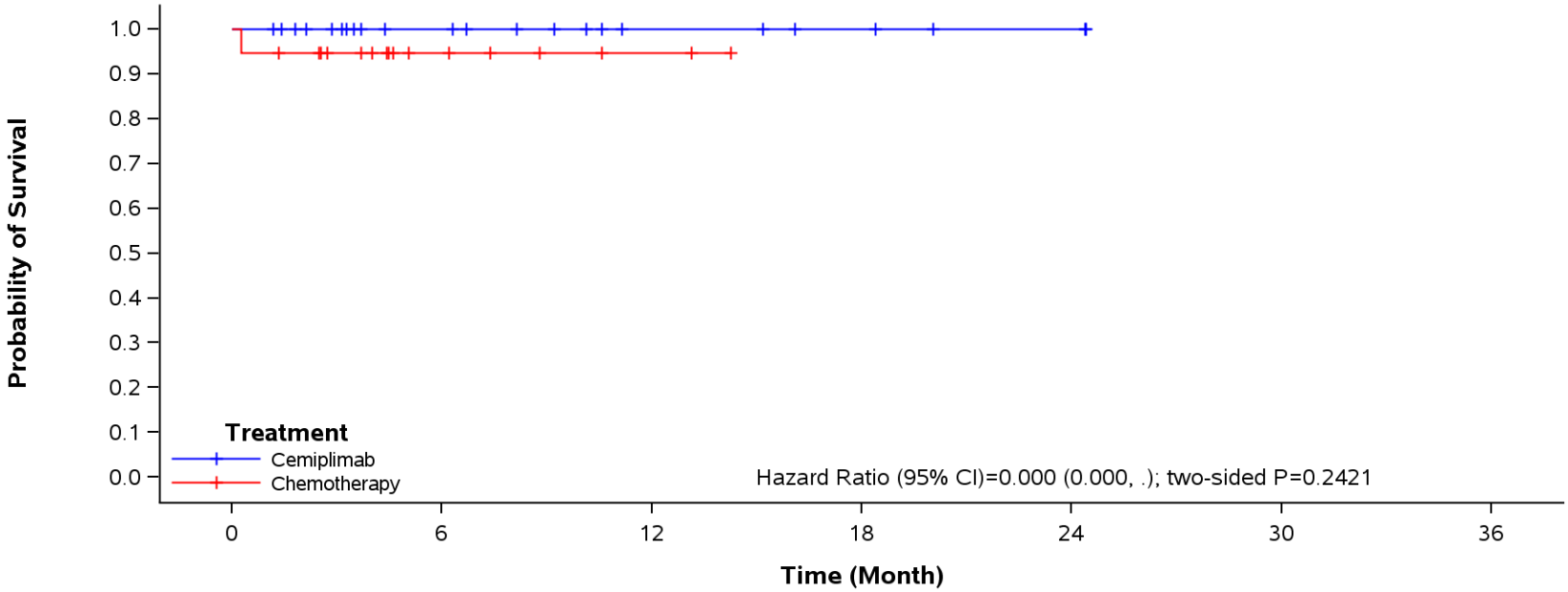

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: General disorders and administration site conditions
PT: Malaise



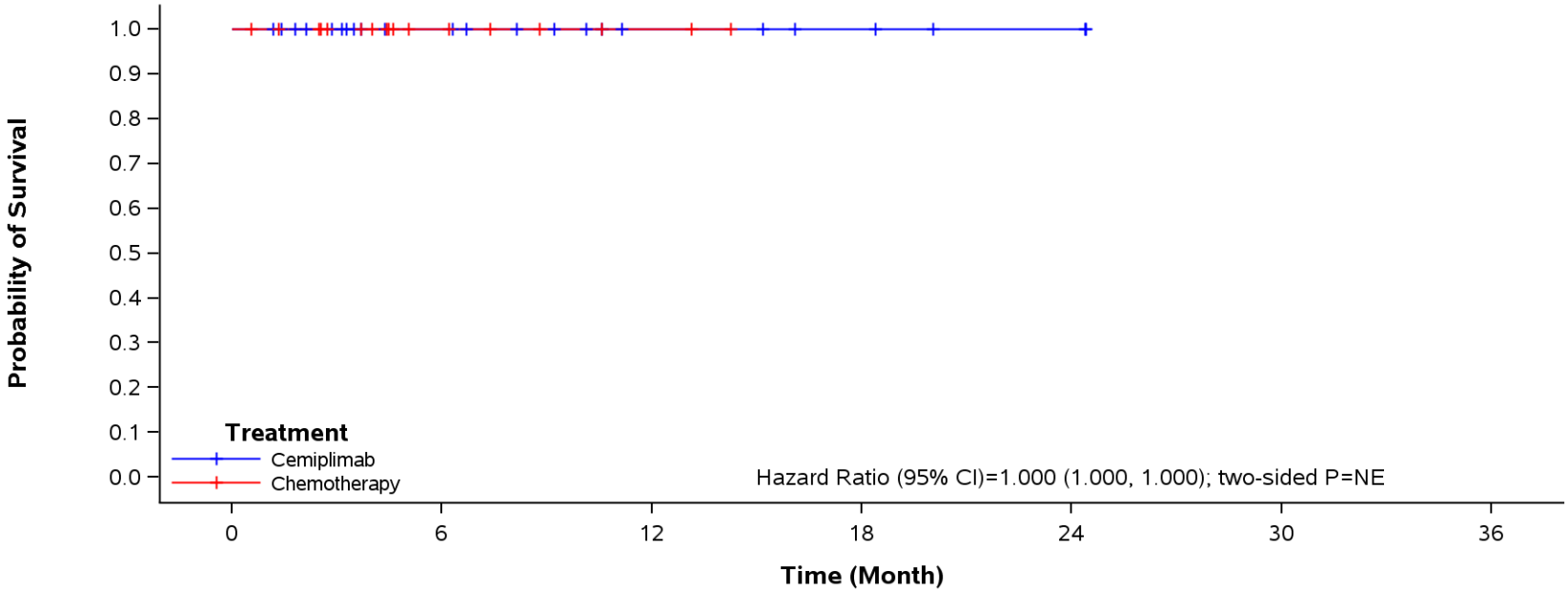

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



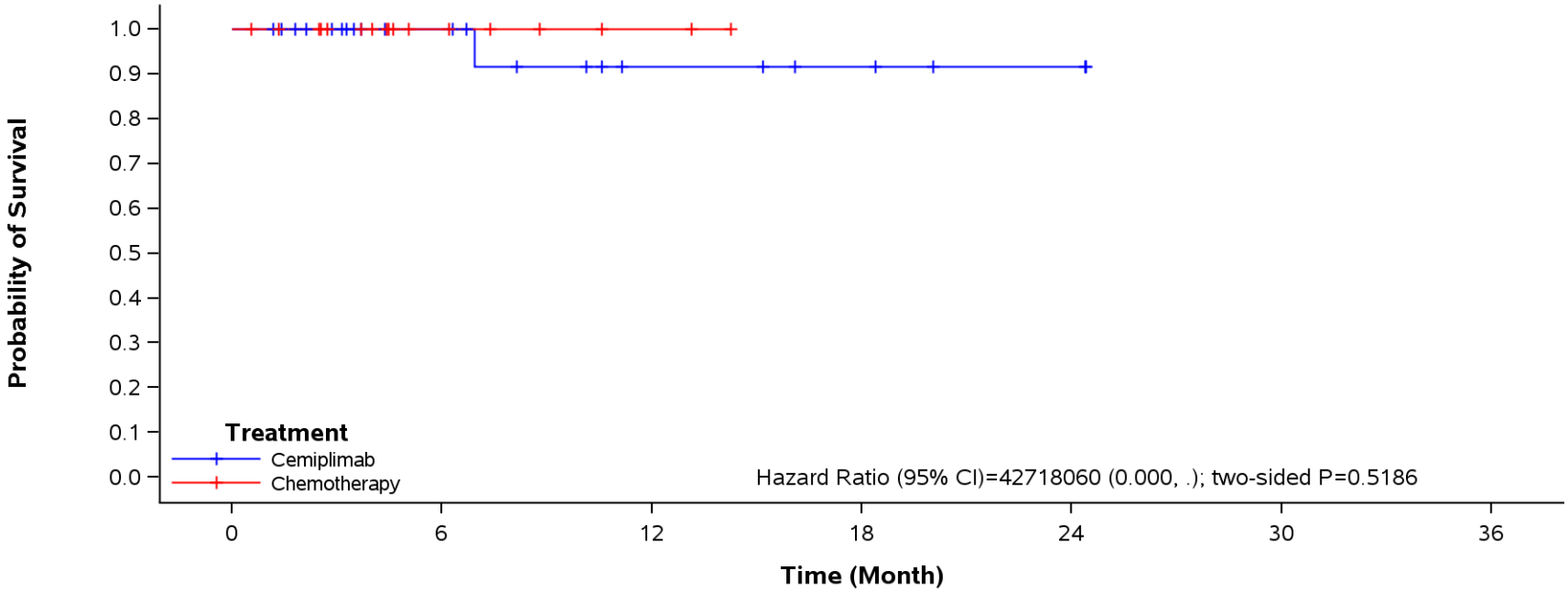

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Hepatobiliary disorders



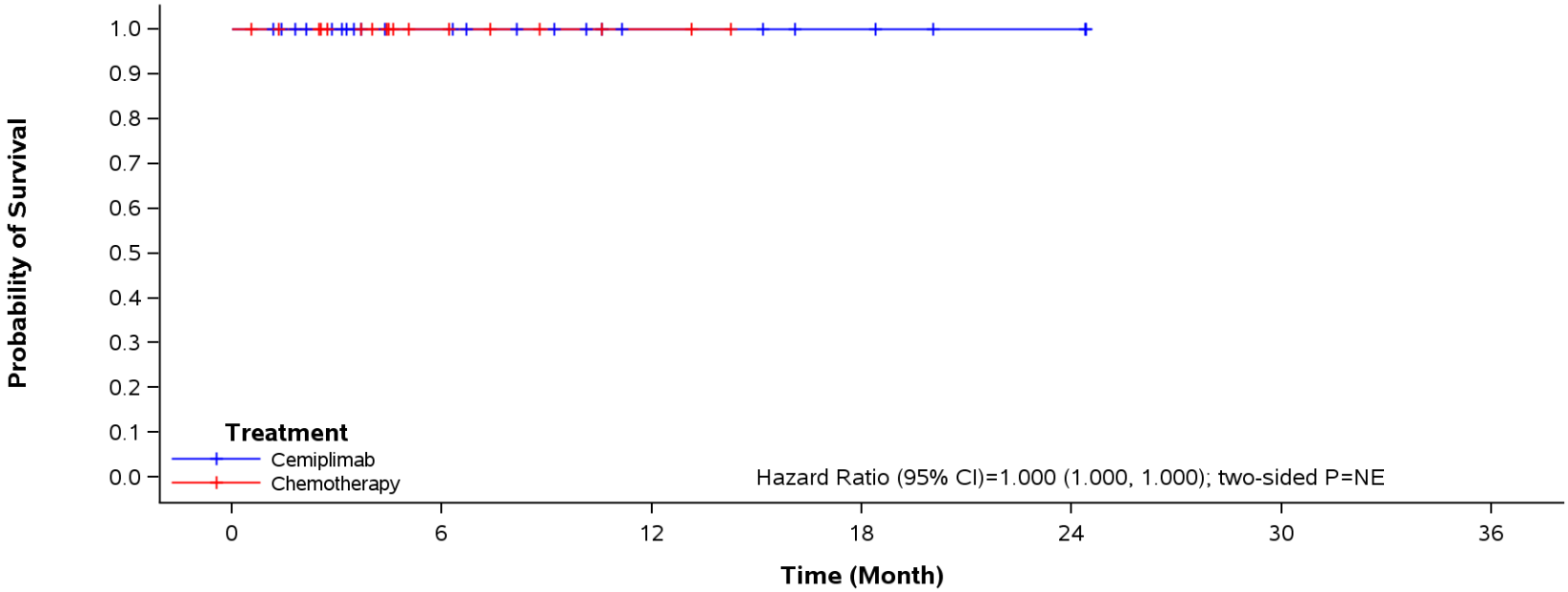

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



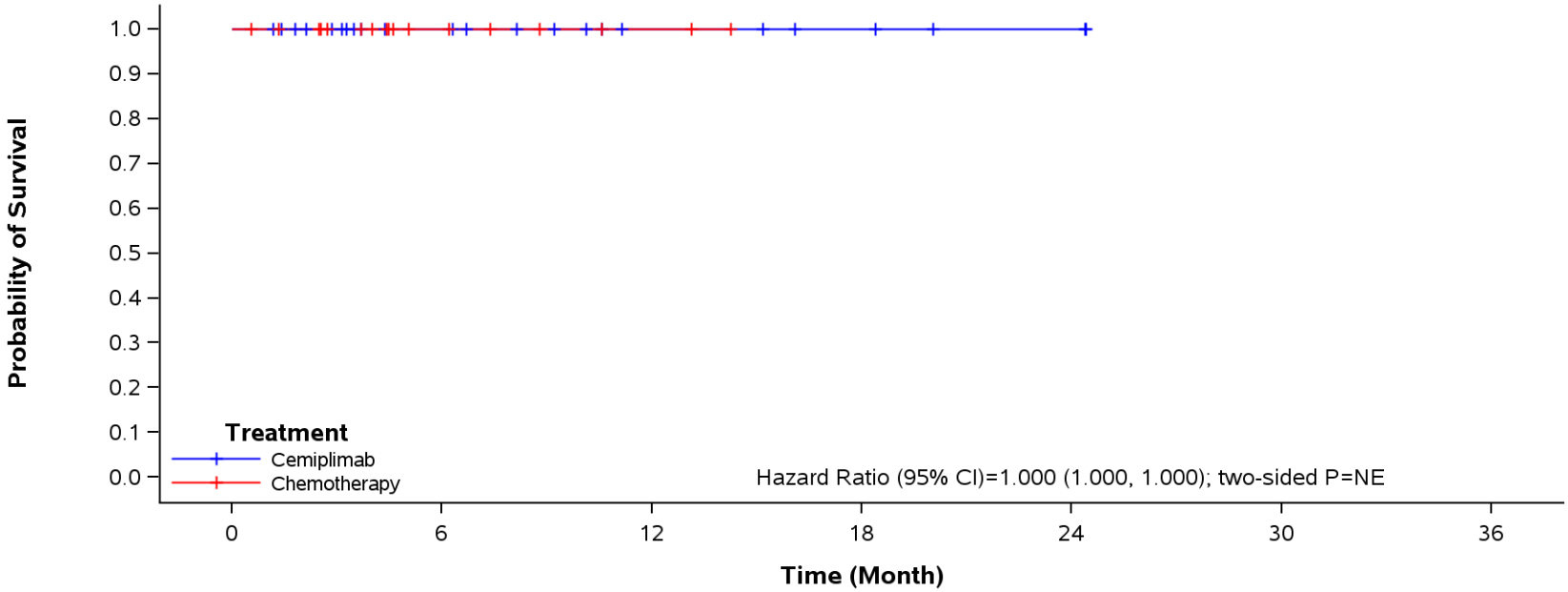

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



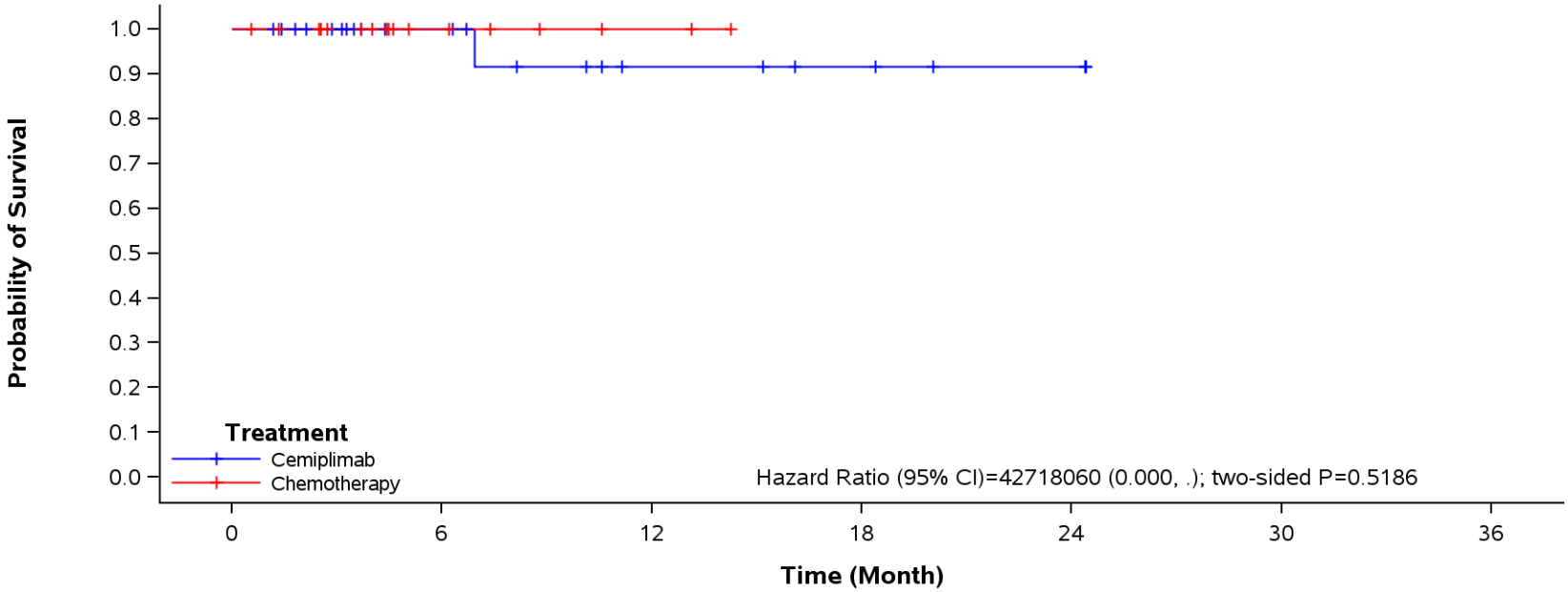

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Hepatobiliary disorders
PT: Hepatitis



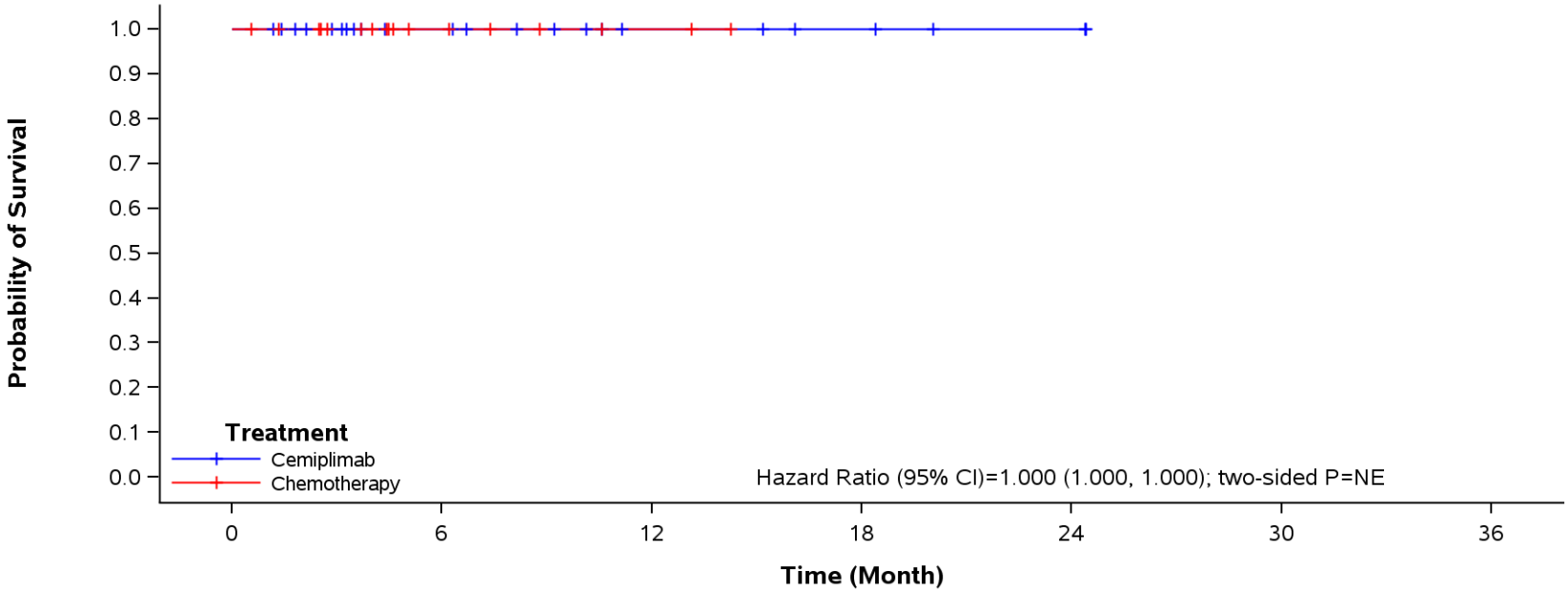

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



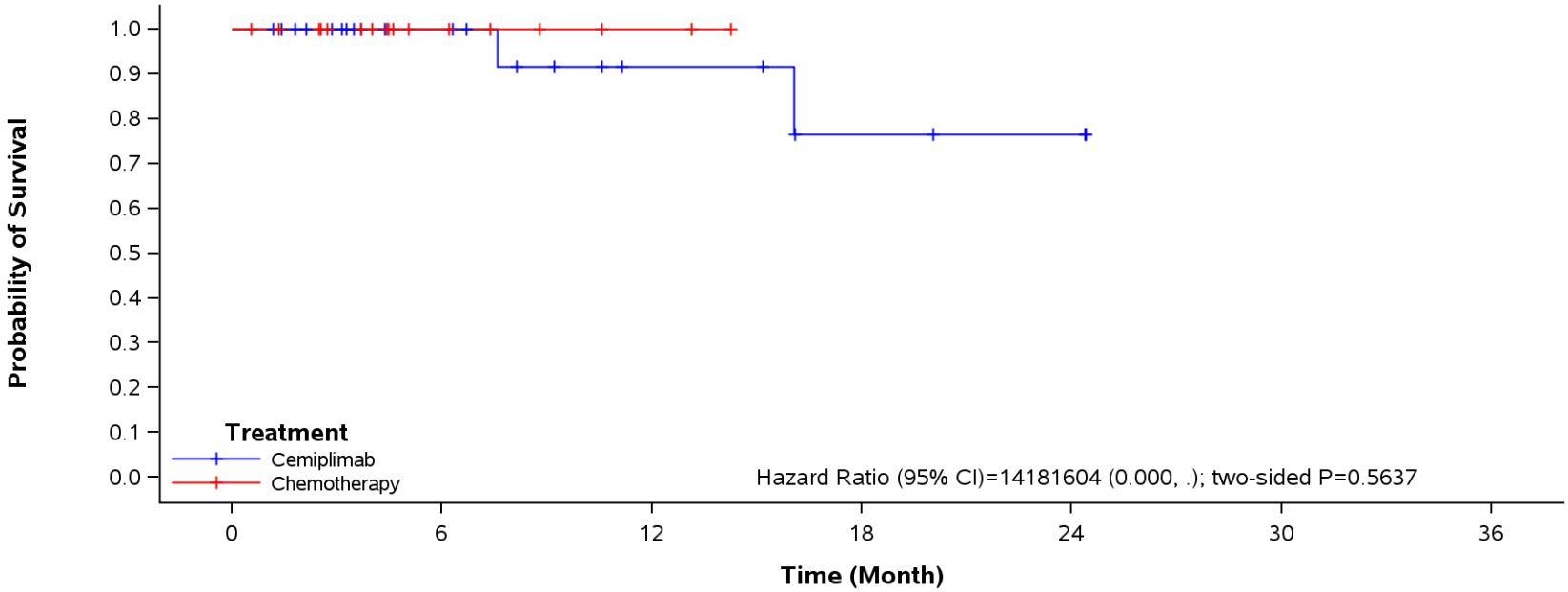

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Infections and infestations



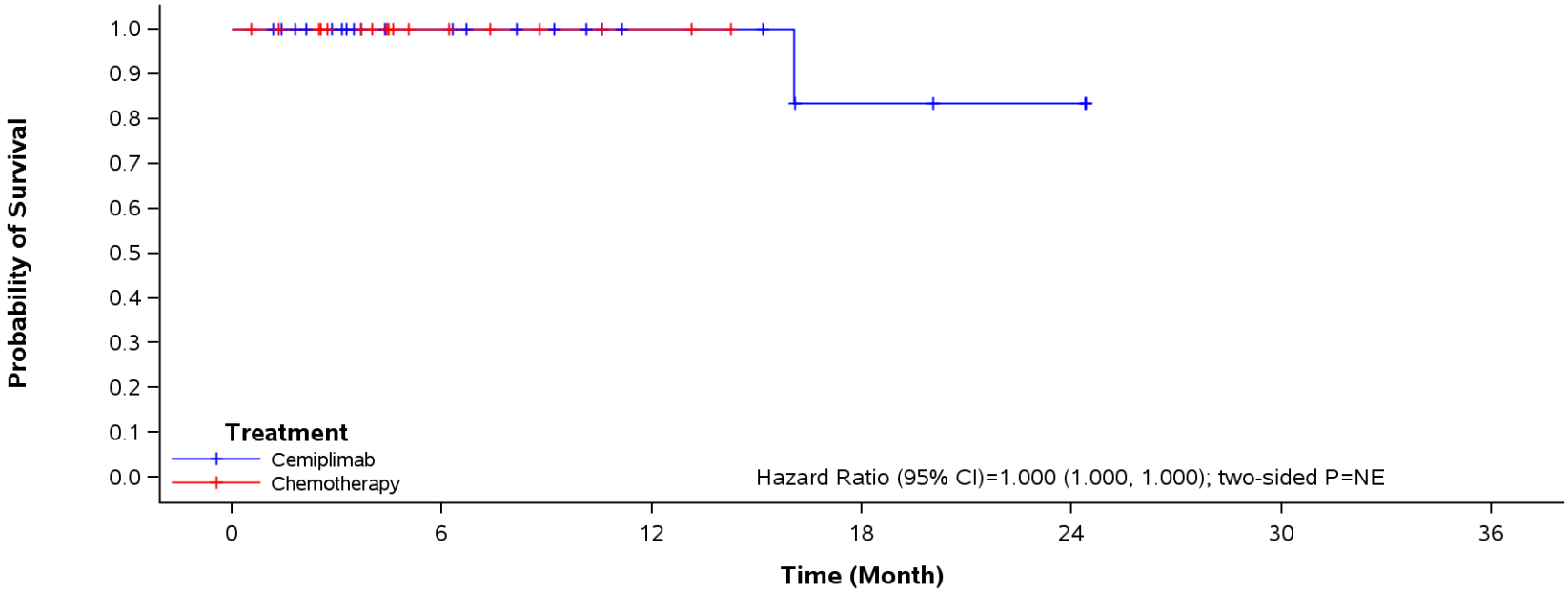

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 4 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Infections and infestations
PT: COVID-19 pneumonia



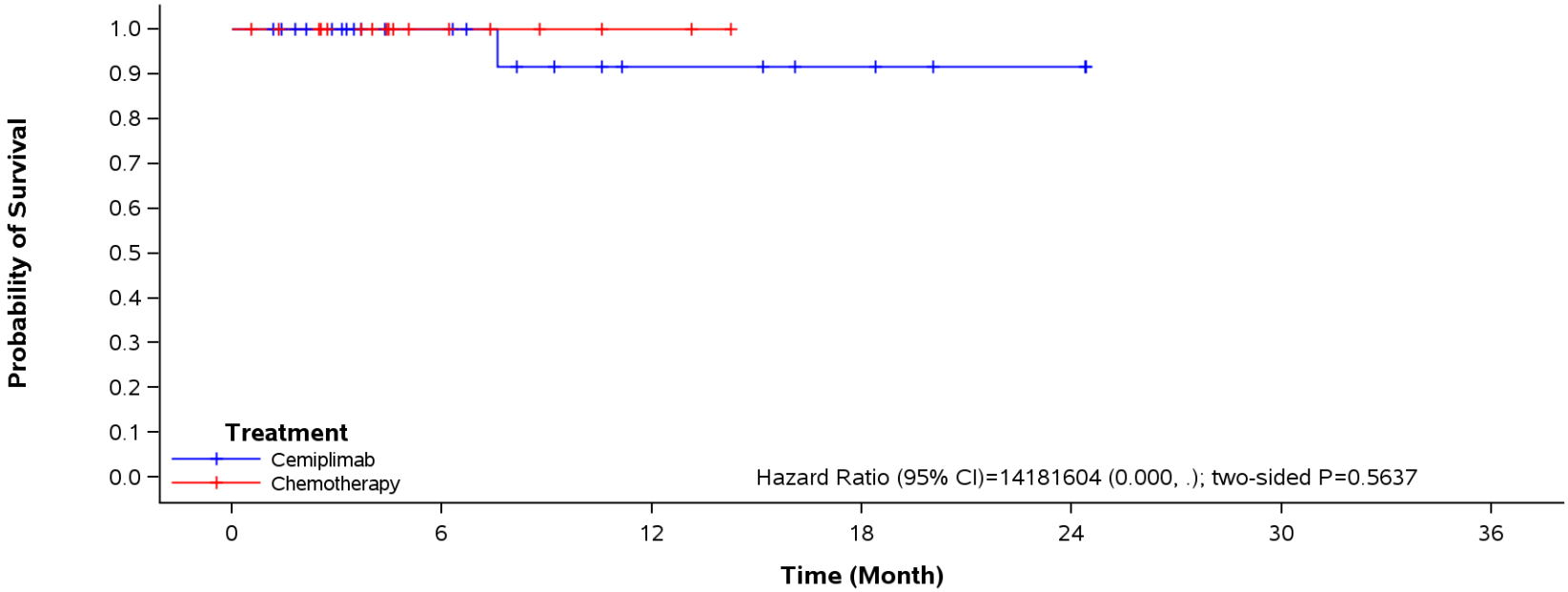

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 4 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Infections and infestations
PT: Gastroenteritis



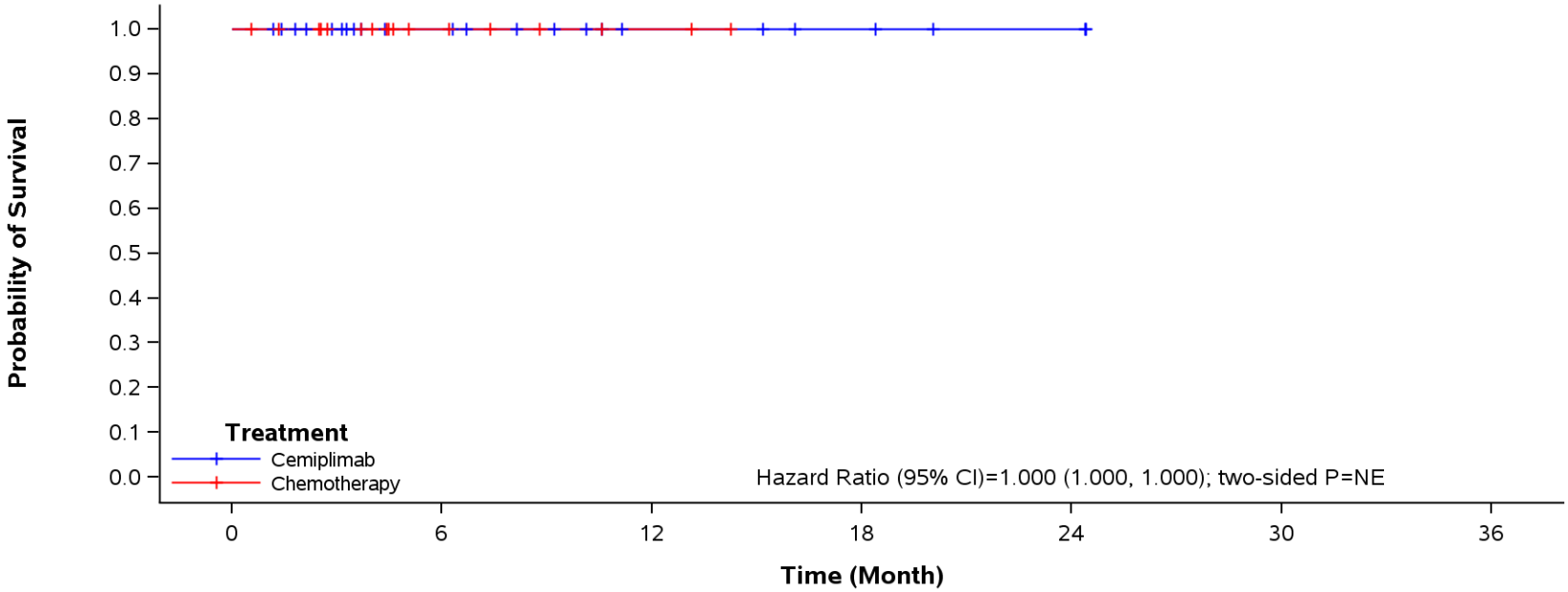

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Infections and infestations
PT: Pelvic abscess



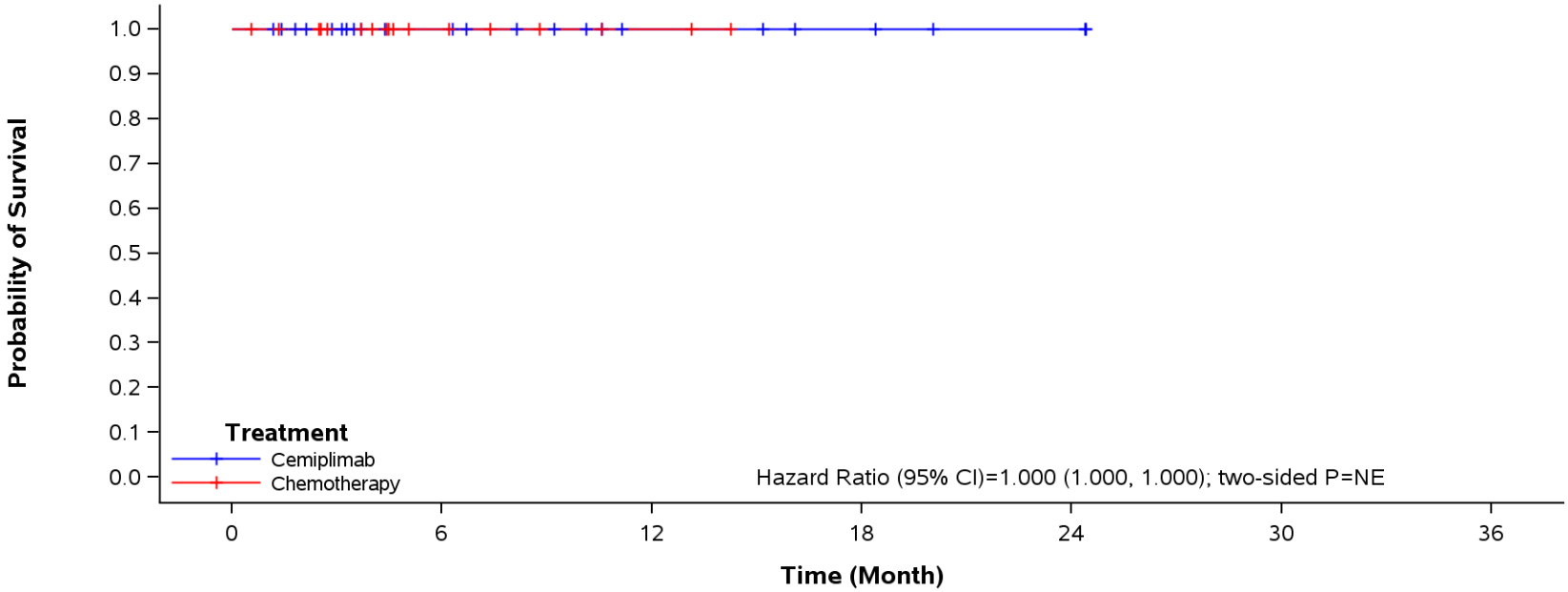

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Infections and infestations
PT: Peritonitis



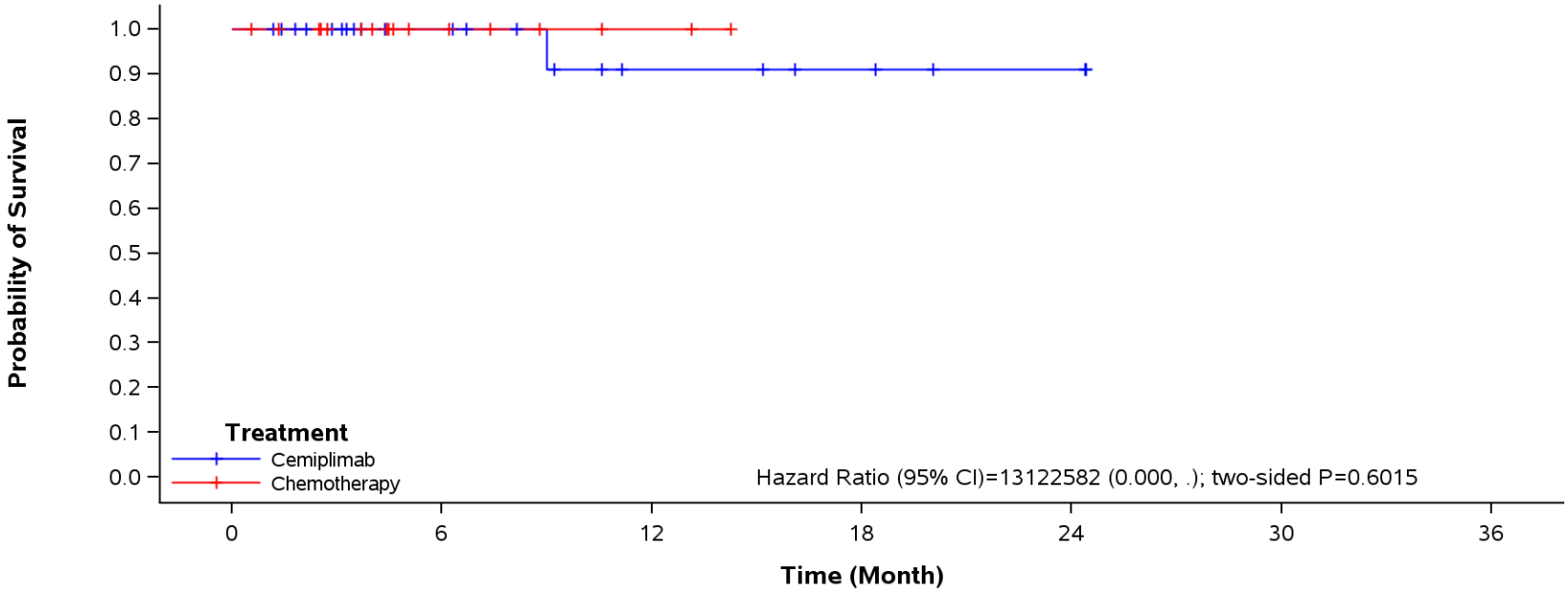

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Infections and infestations
PT: Pneumonia



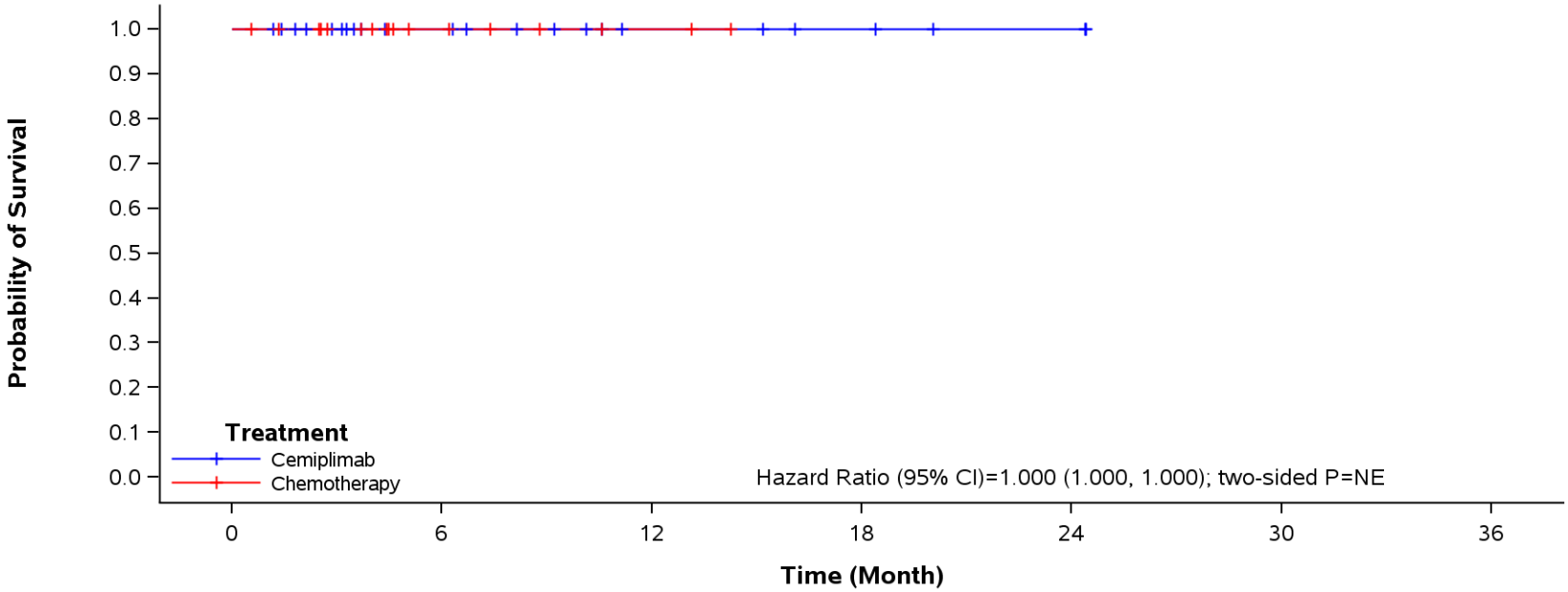

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Infections and infestations
PT: Pyomyositis



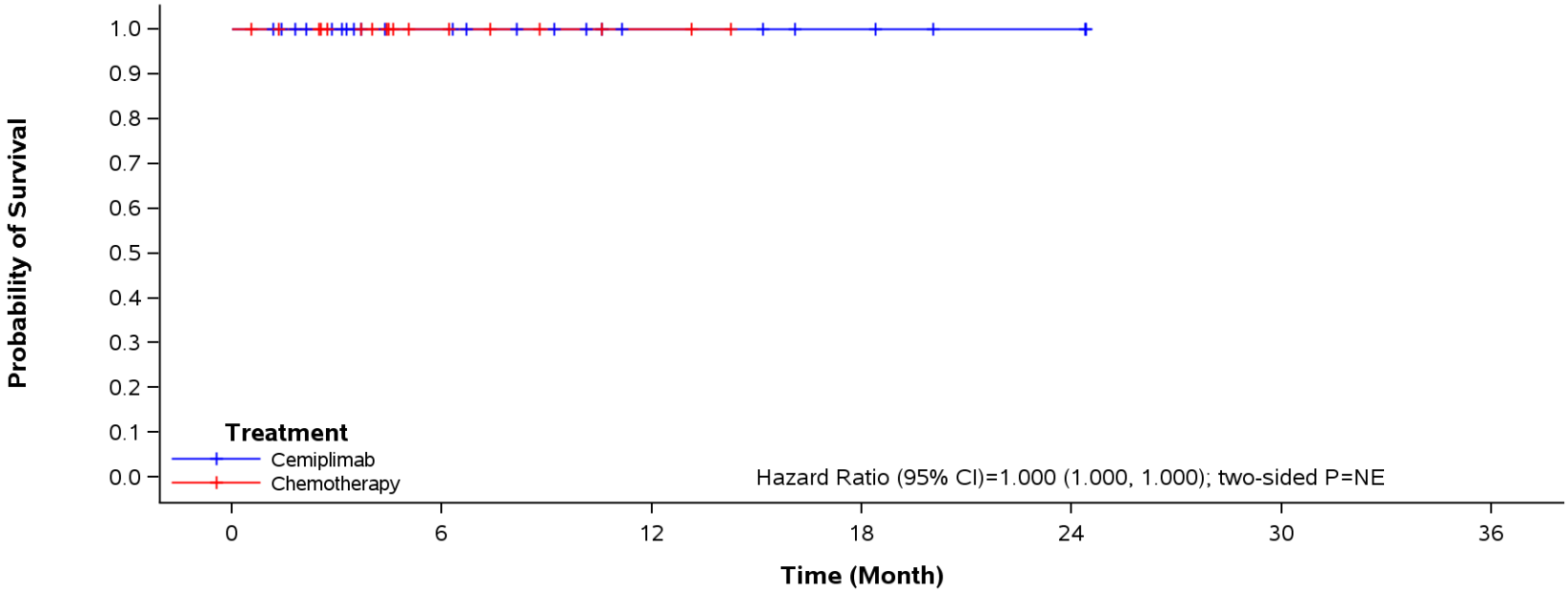

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Injury, poisoning and procedural complications



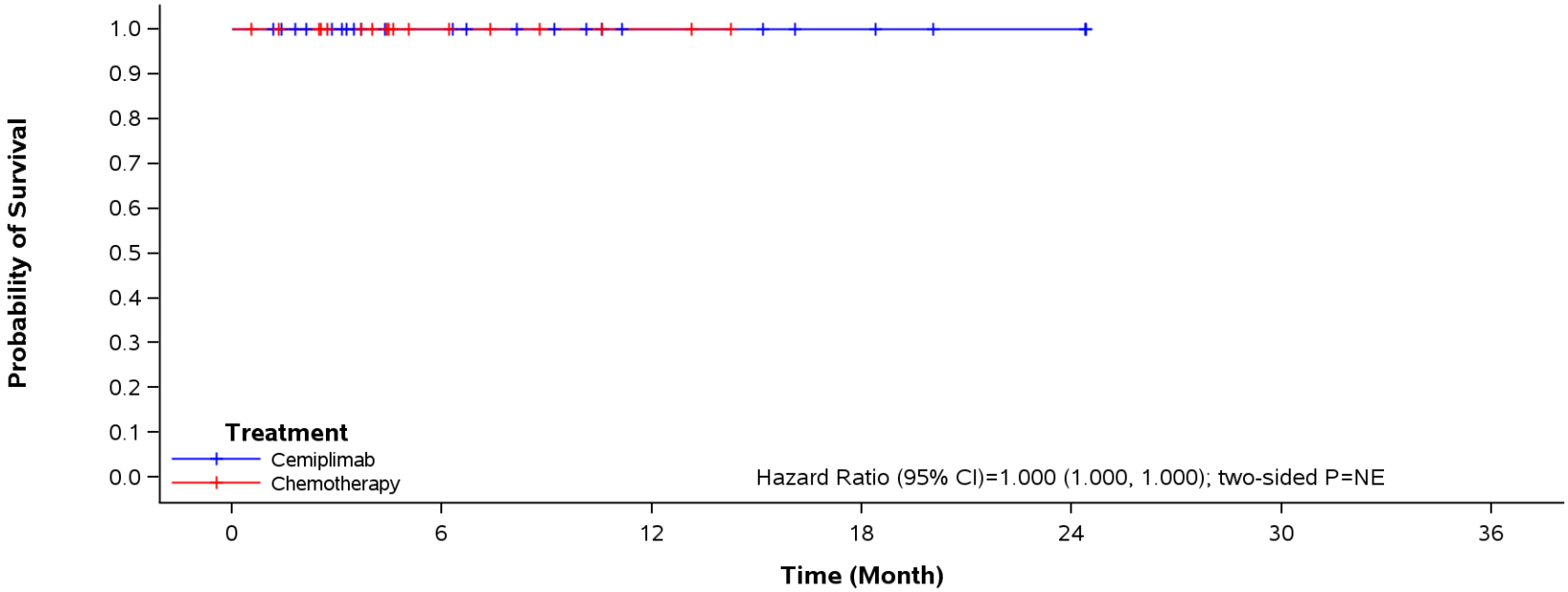

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



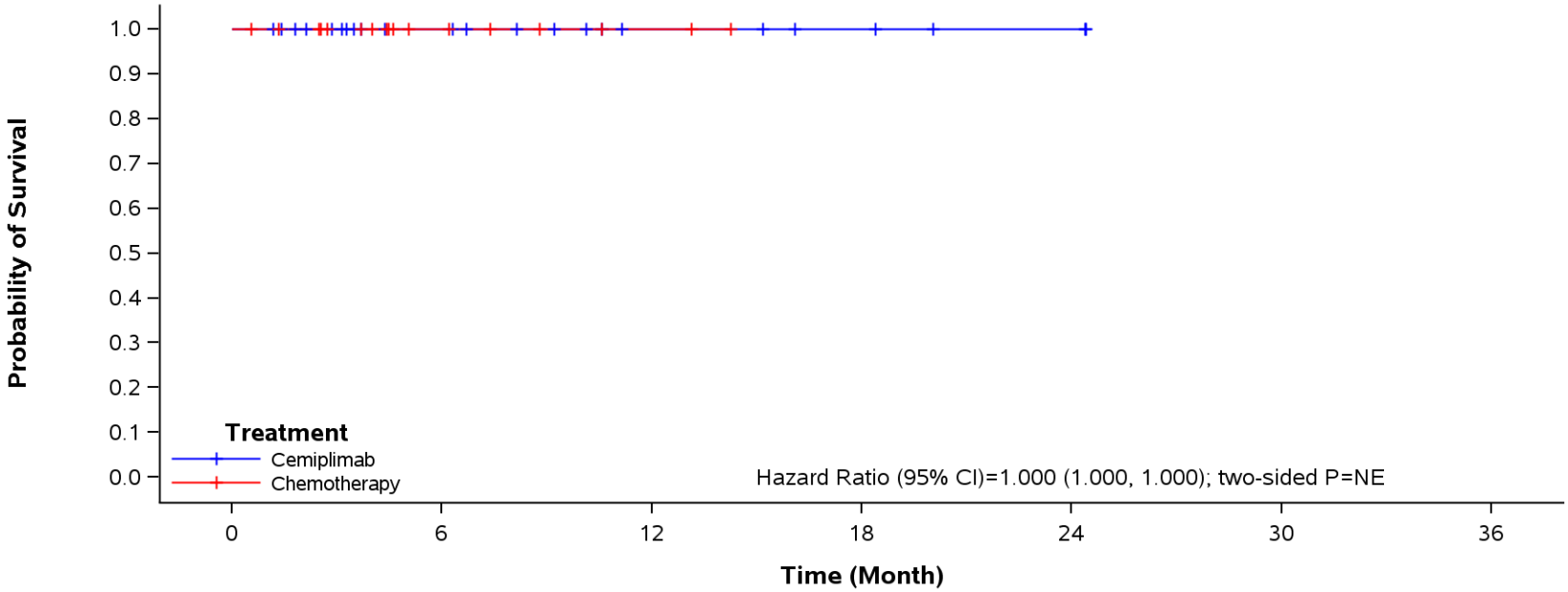

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



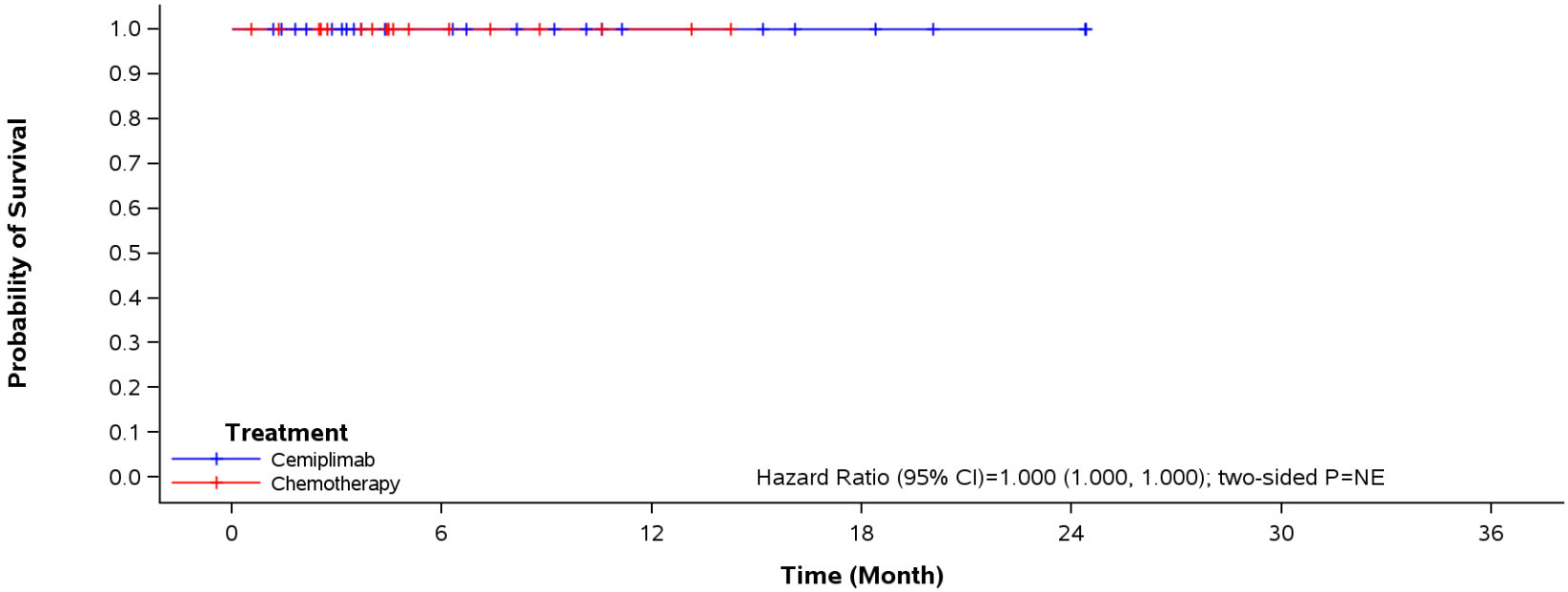

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Investigations



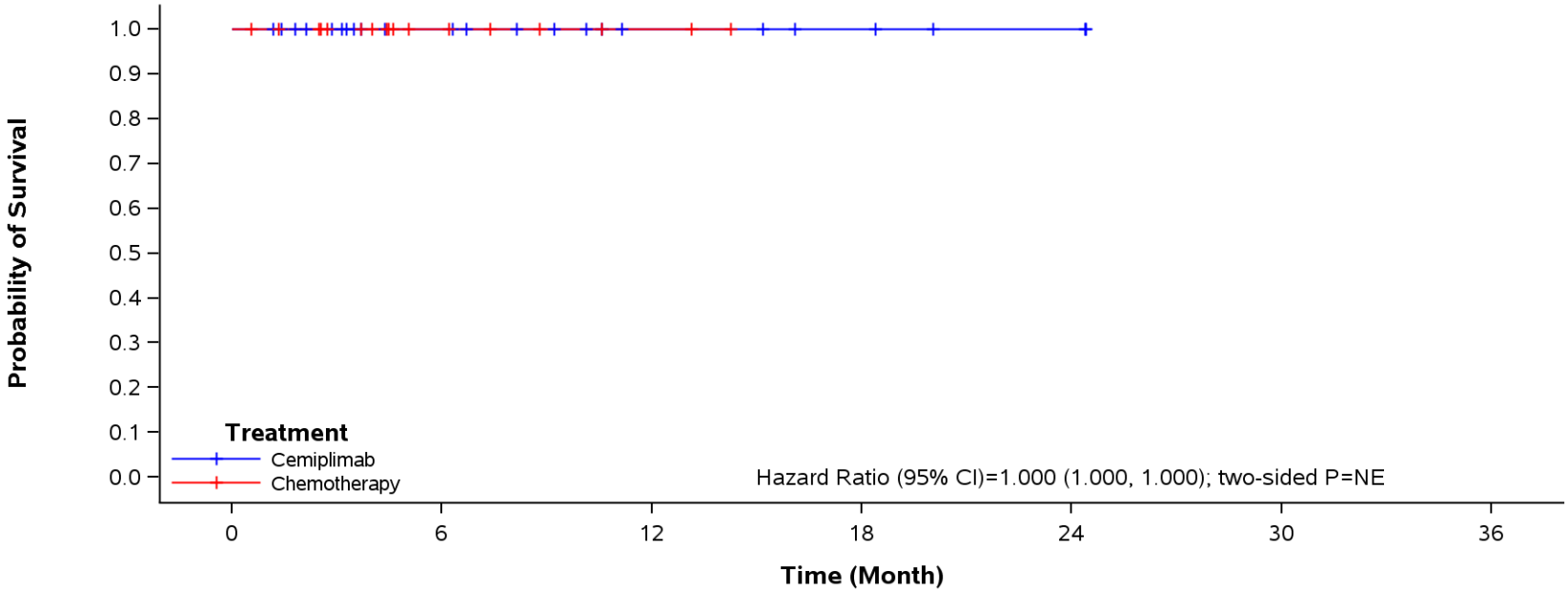

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Investigations
PT: Alanine aminotransferase increased



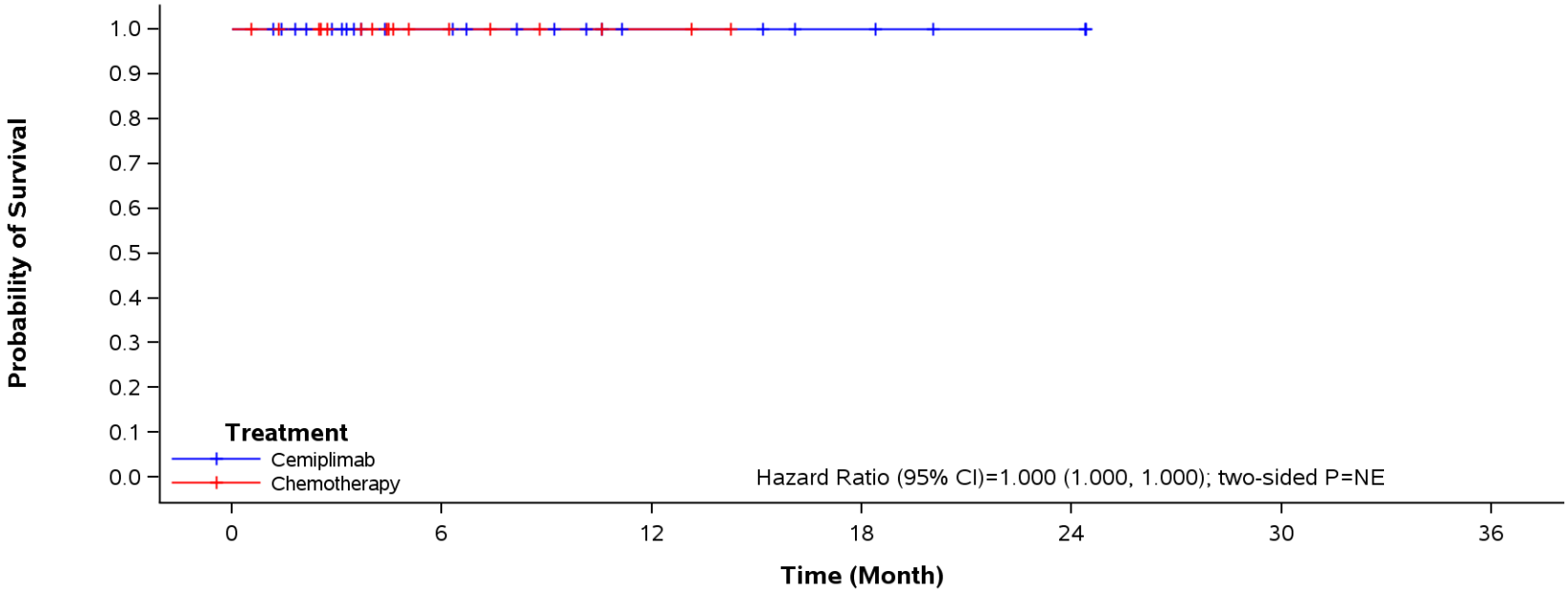

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Investigations
PT: Amylase increased



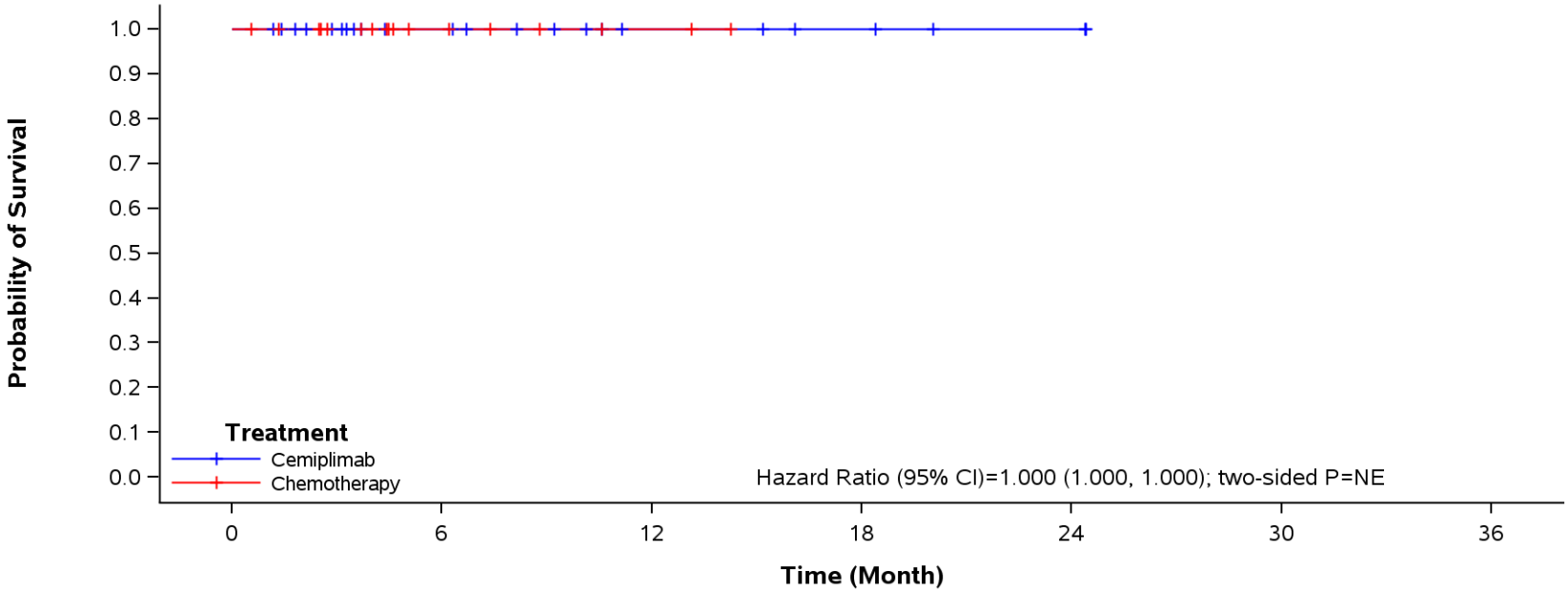

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Investigations
PT: Platelet count decreased



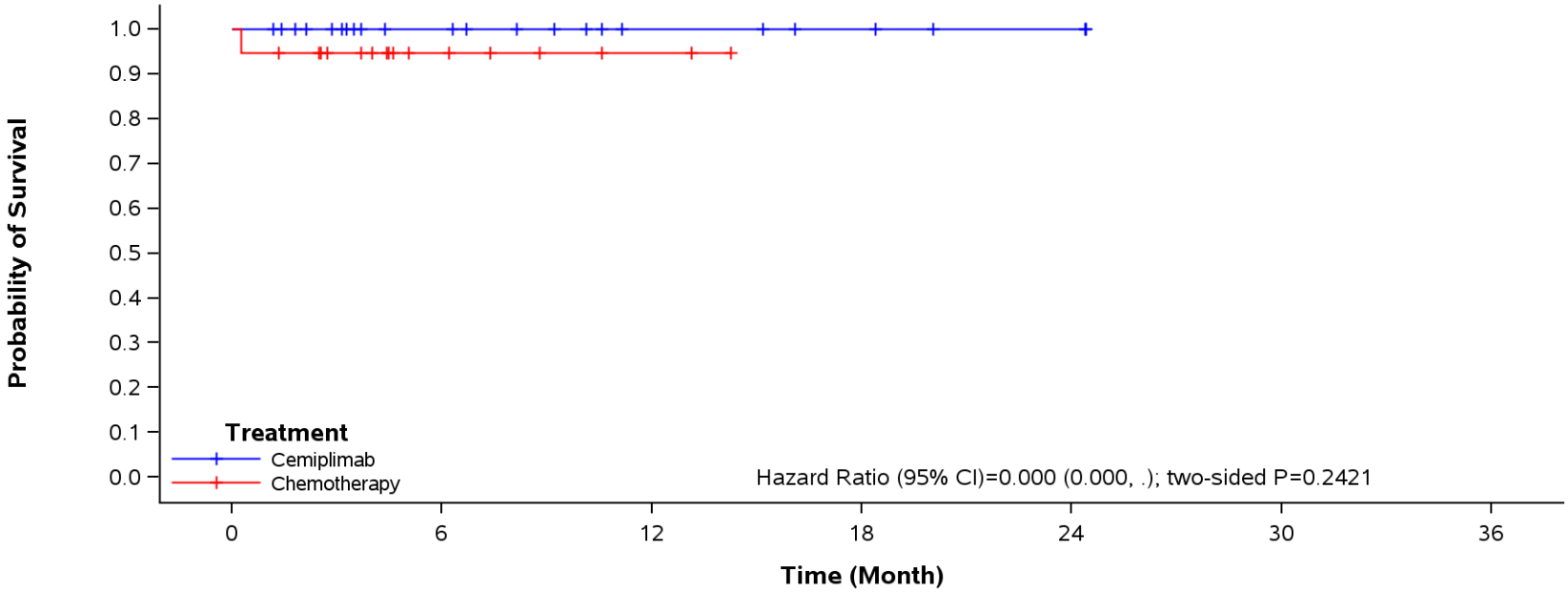

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Metabolism and nutrition disorders



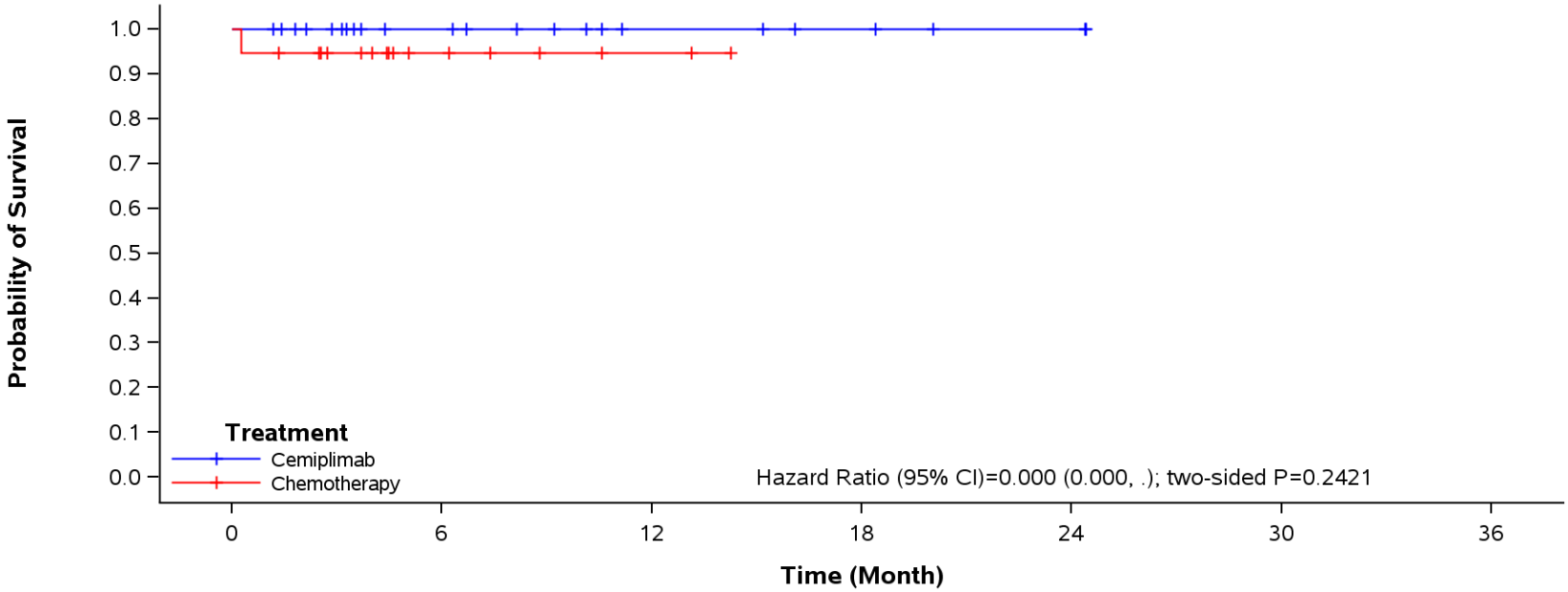

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



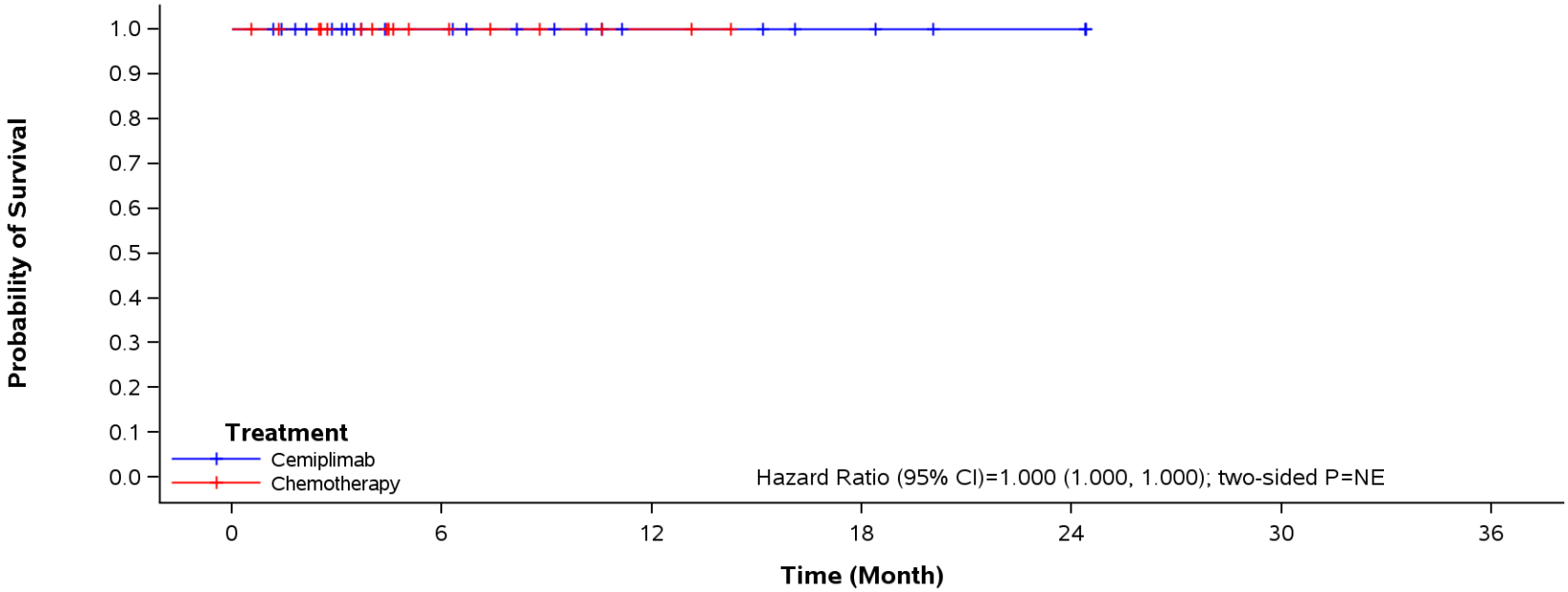

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Musculoskeletal and connective tissue disorders



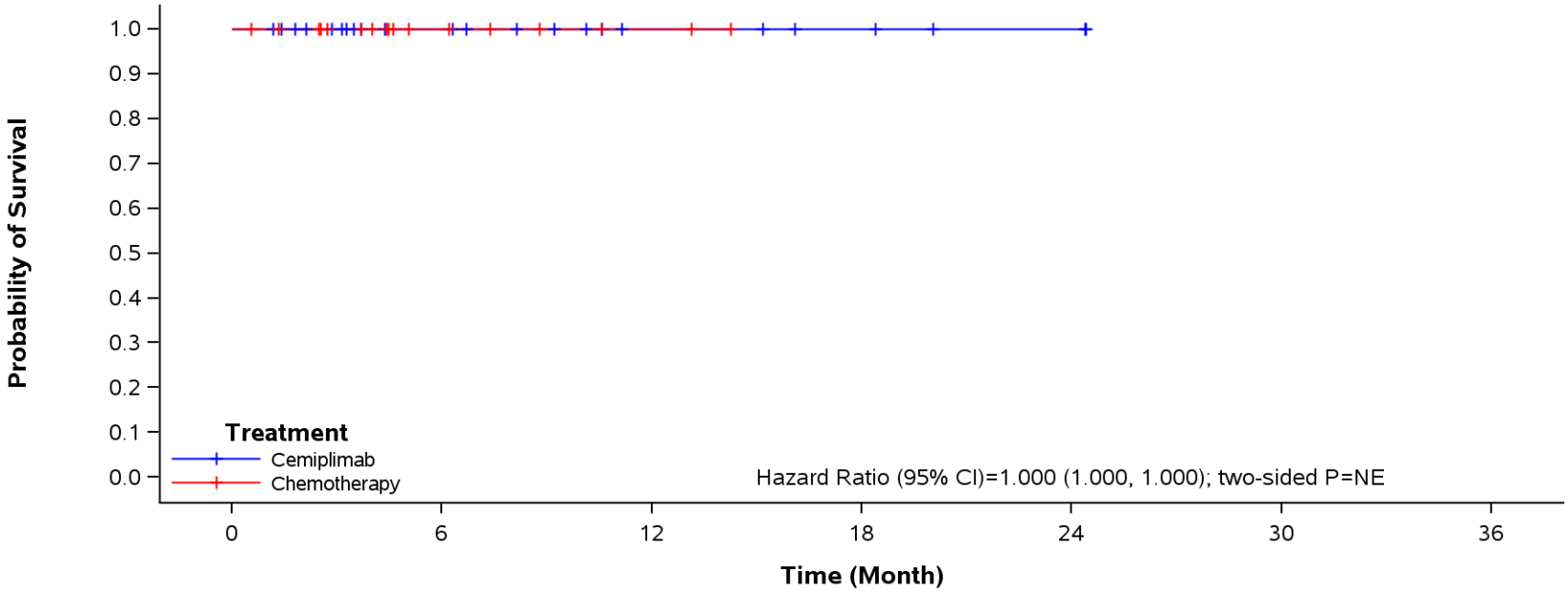

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



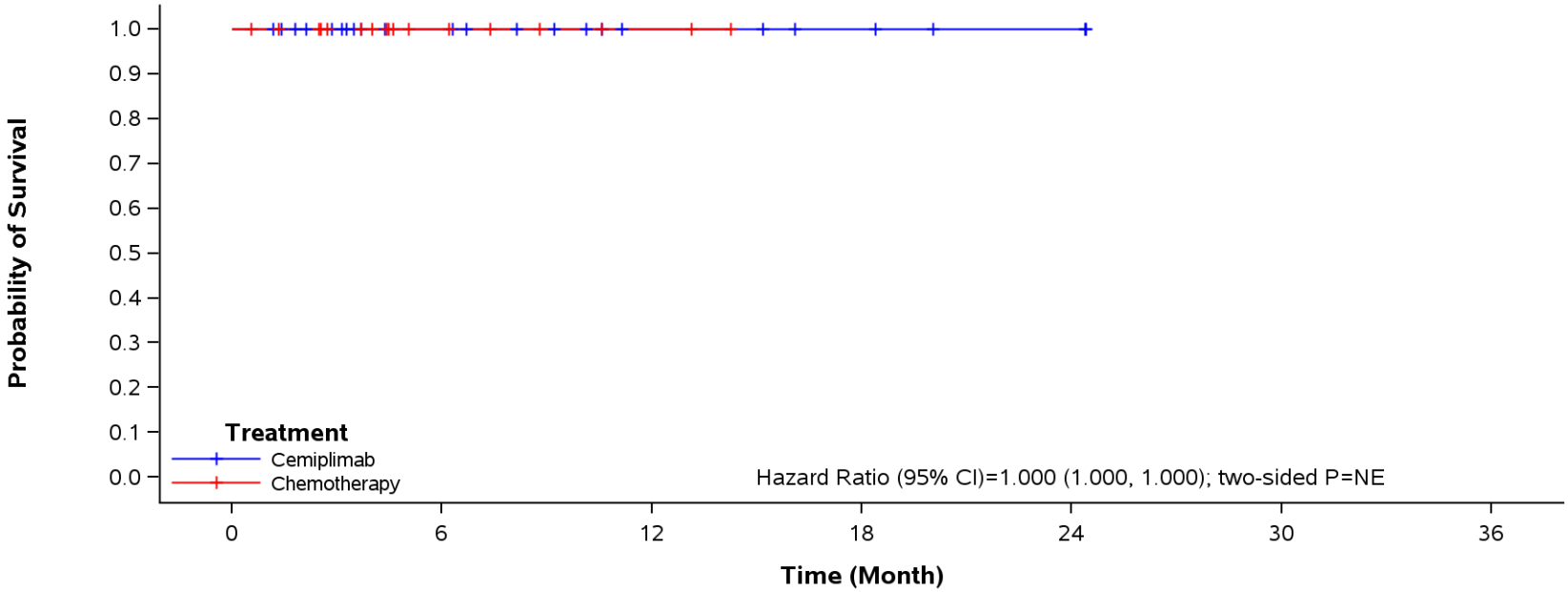

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



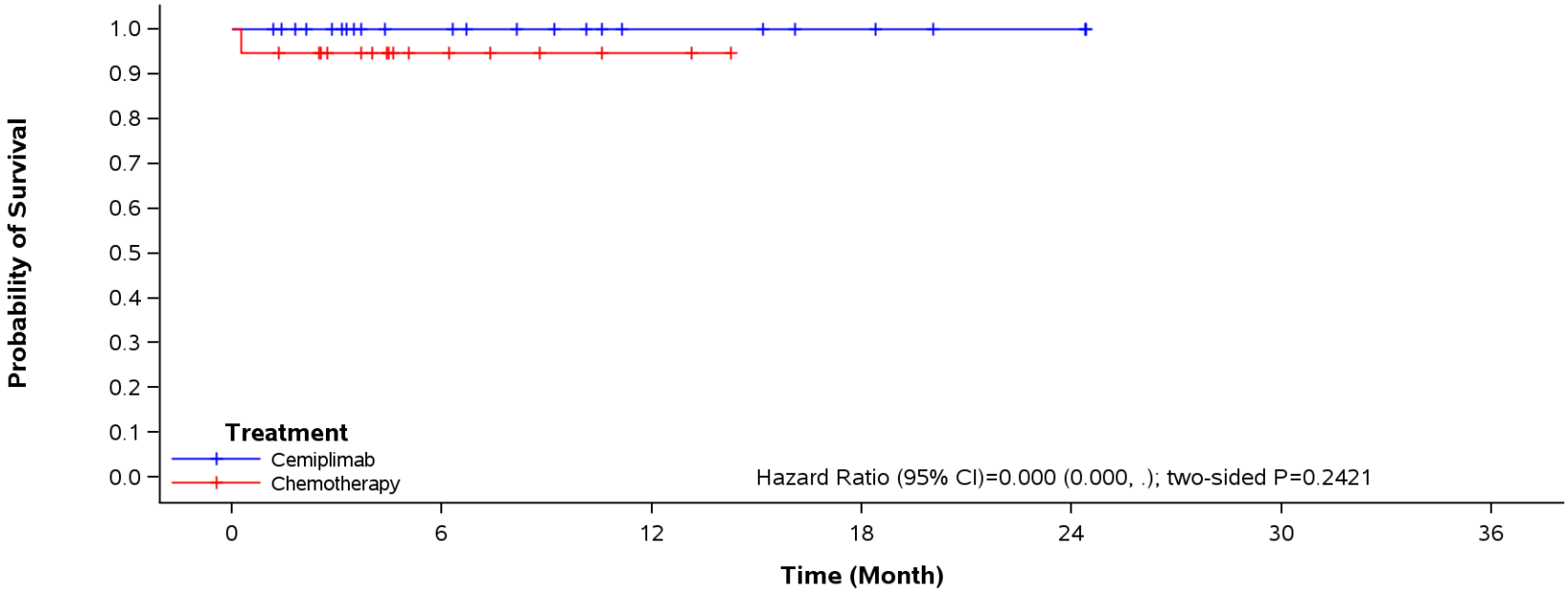

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Nervous system disorders



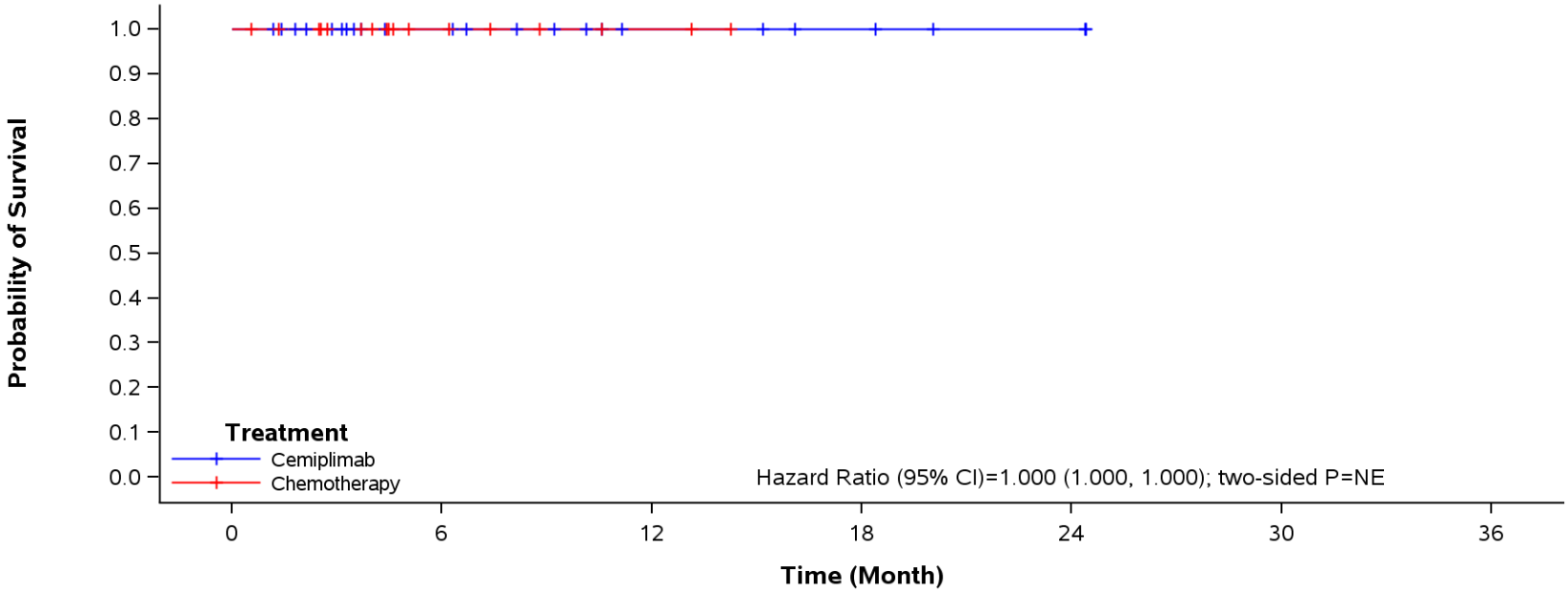

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Nervous system disorders
PT: Neurotoxicity



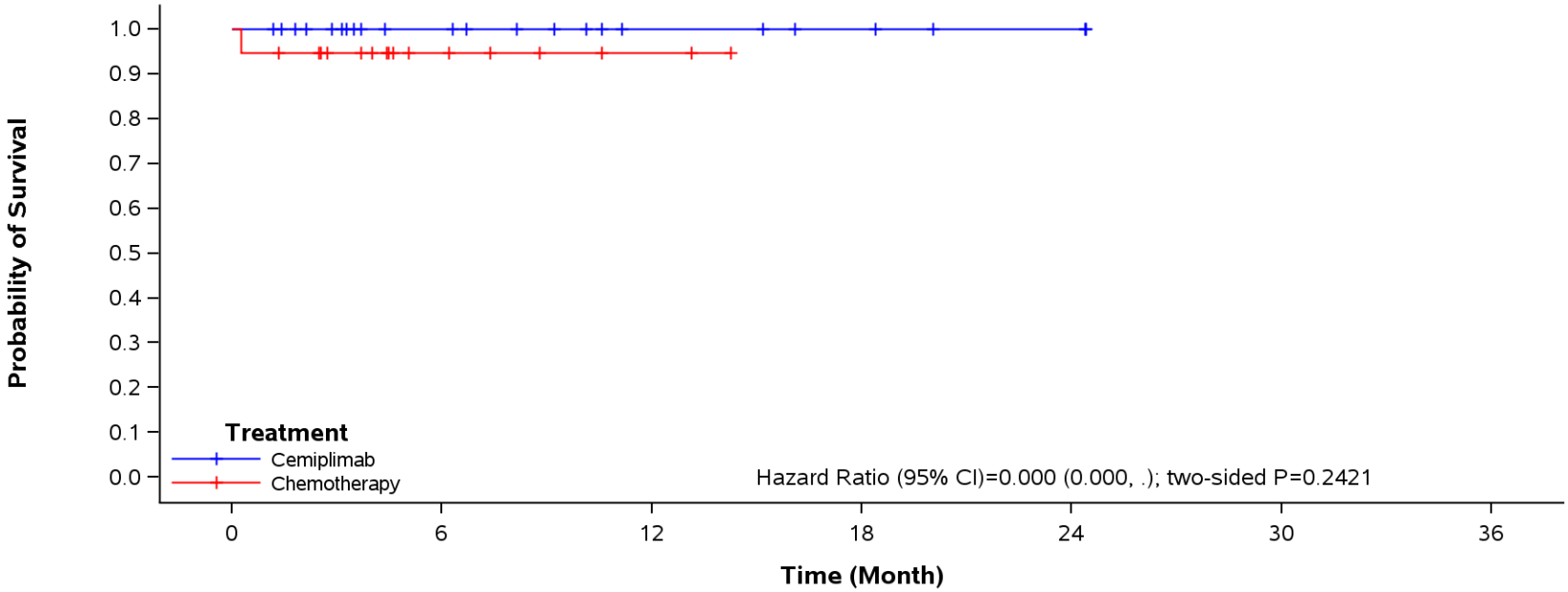

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Nervous system disorders
PT: Transient ischaemic attack



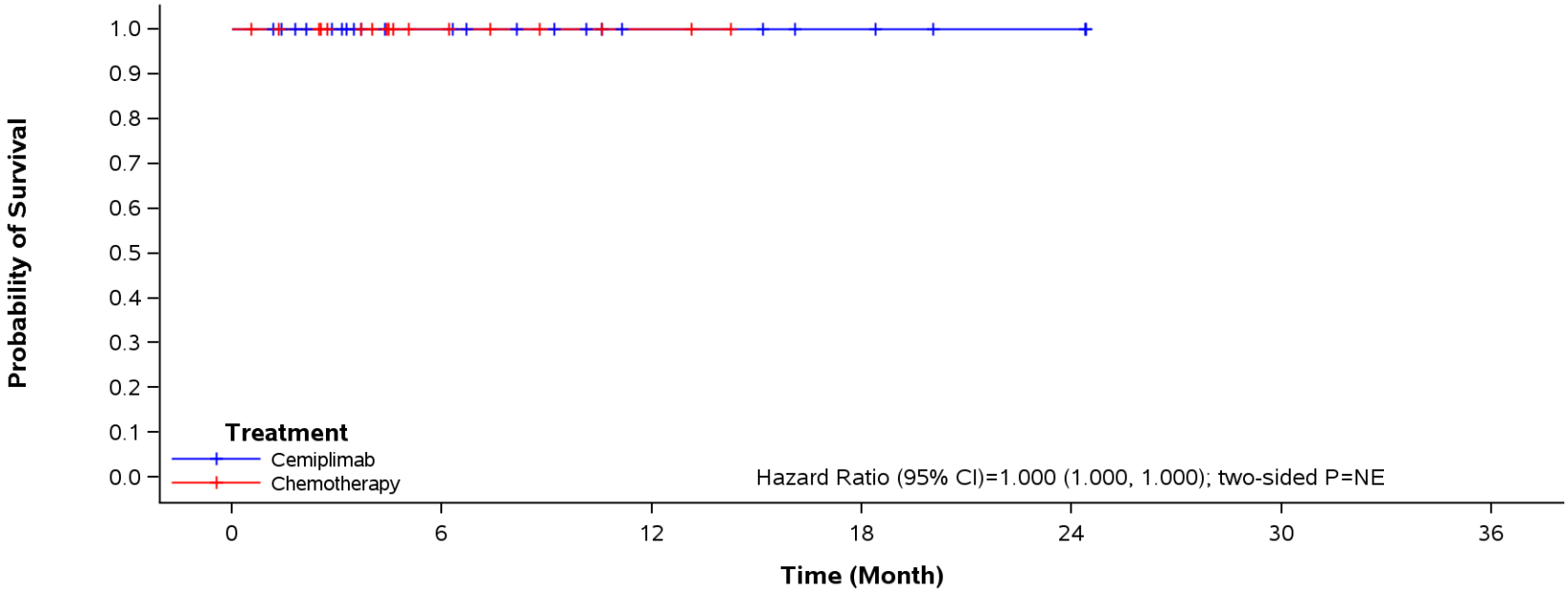

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Psychiatric disorders



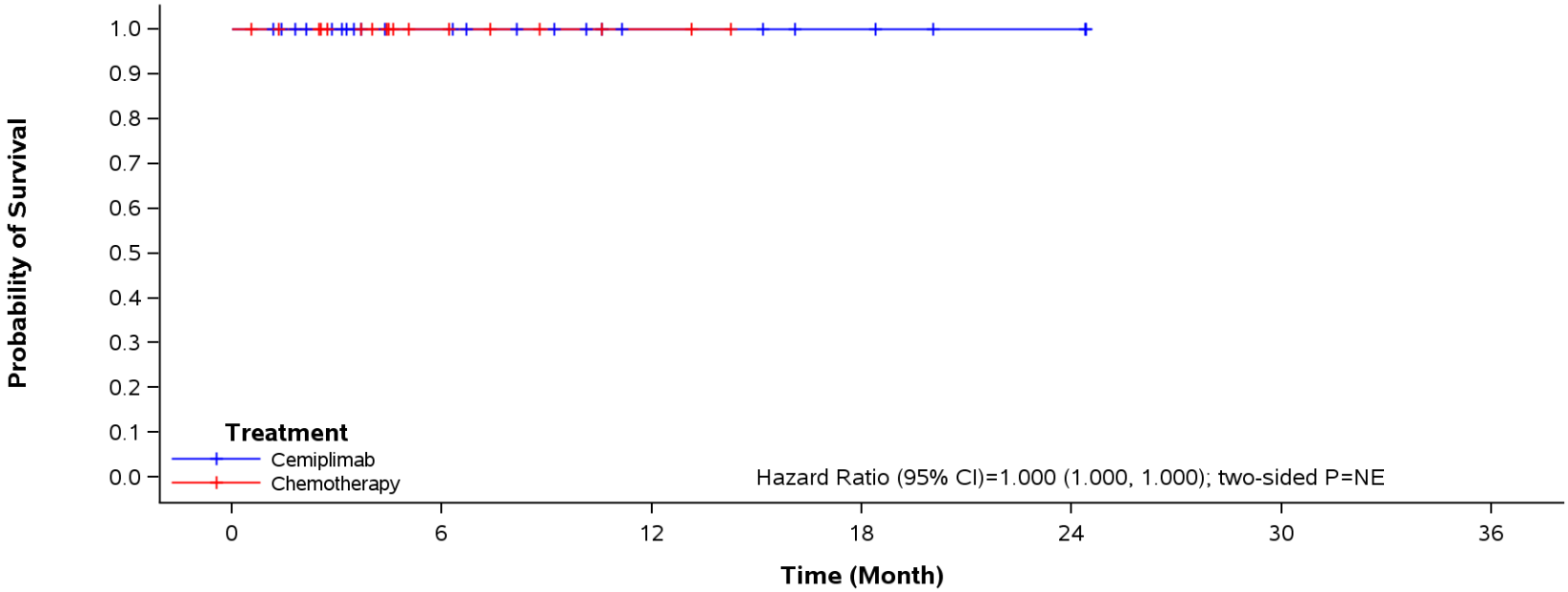

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Psychiatric disorders
PT: Agoraphobia



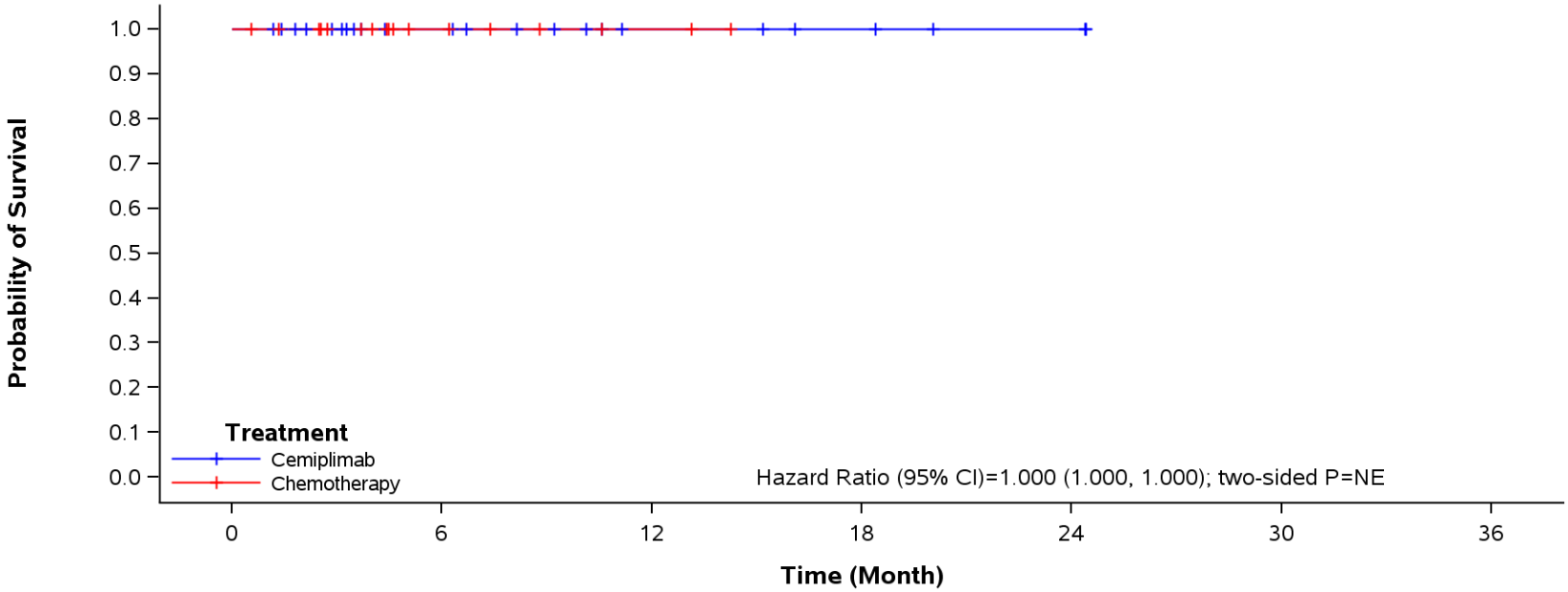

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Renal and urinary disorders



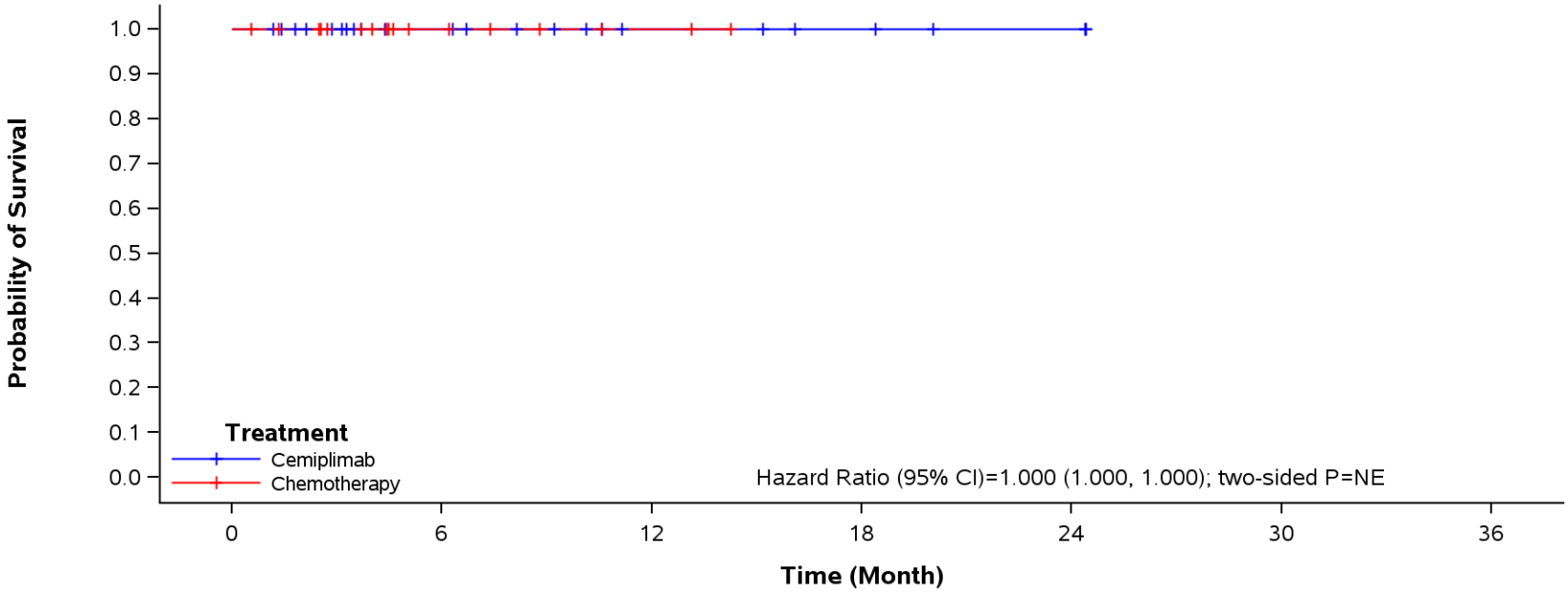

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Renal and urinary disorders
PT: Renal failure



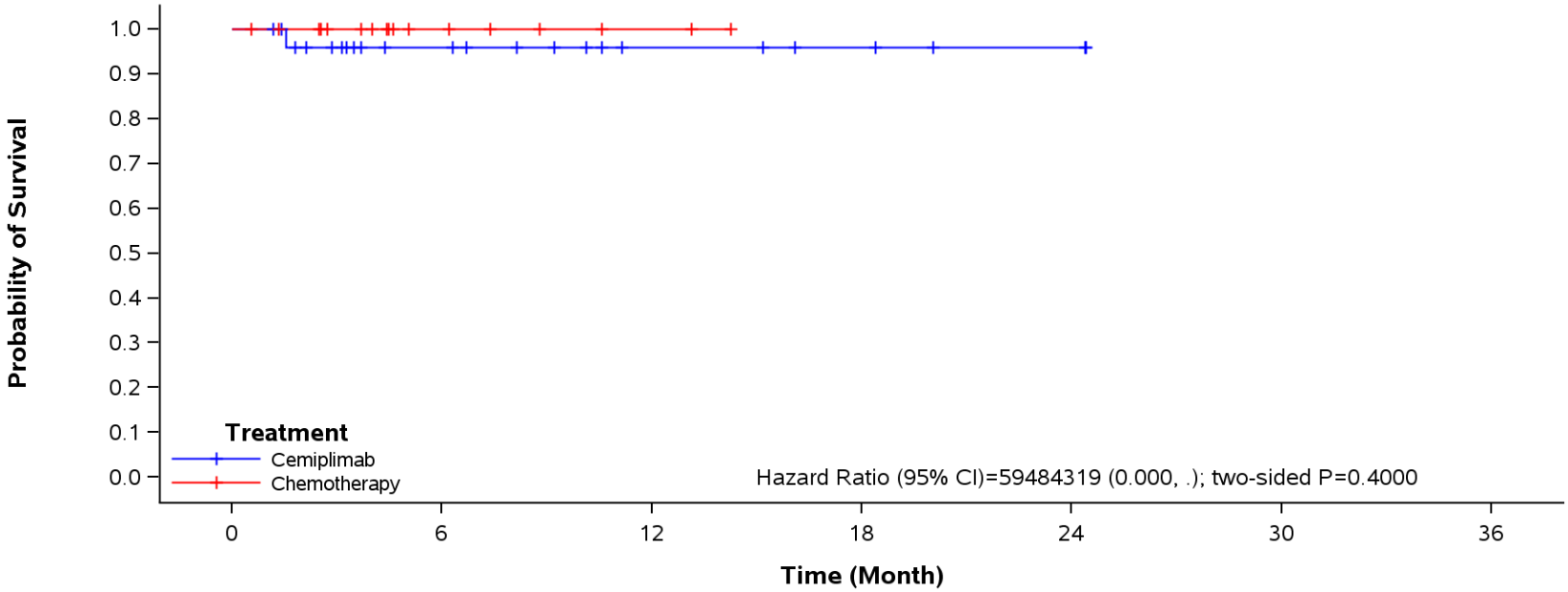

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Respiratory, thoracic and mediastinal disorders



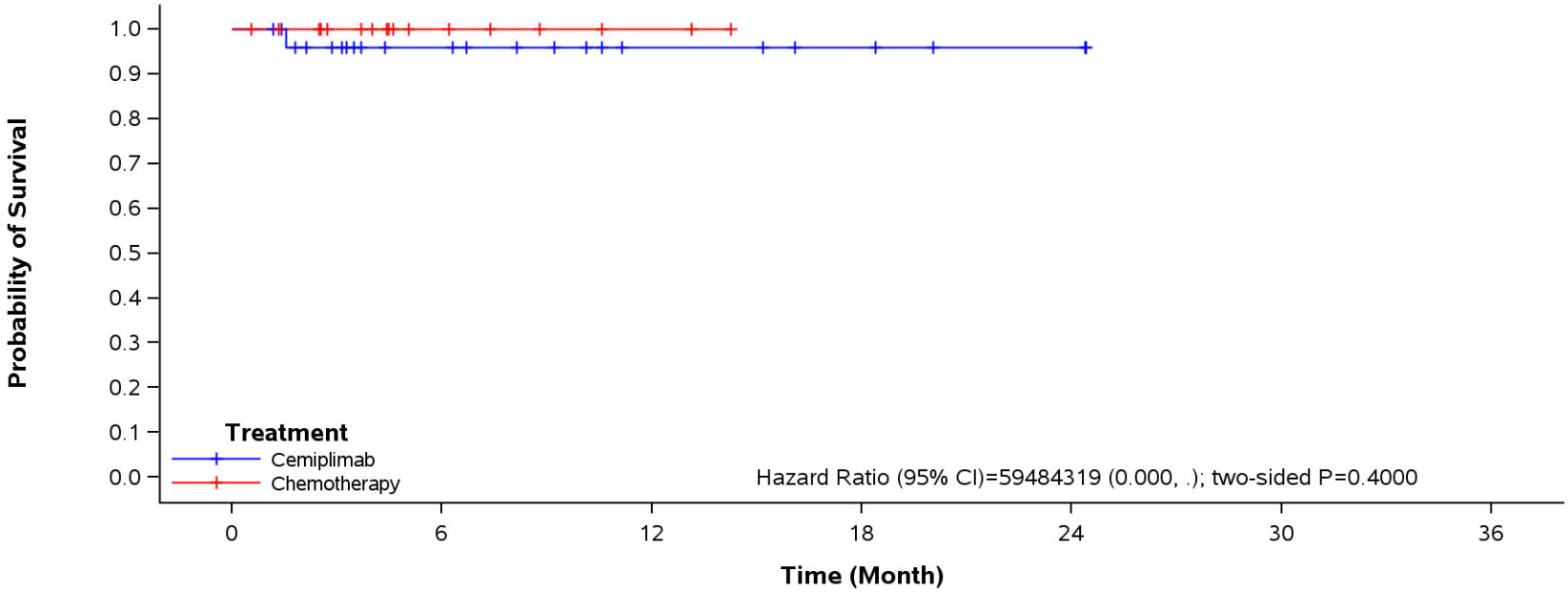

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



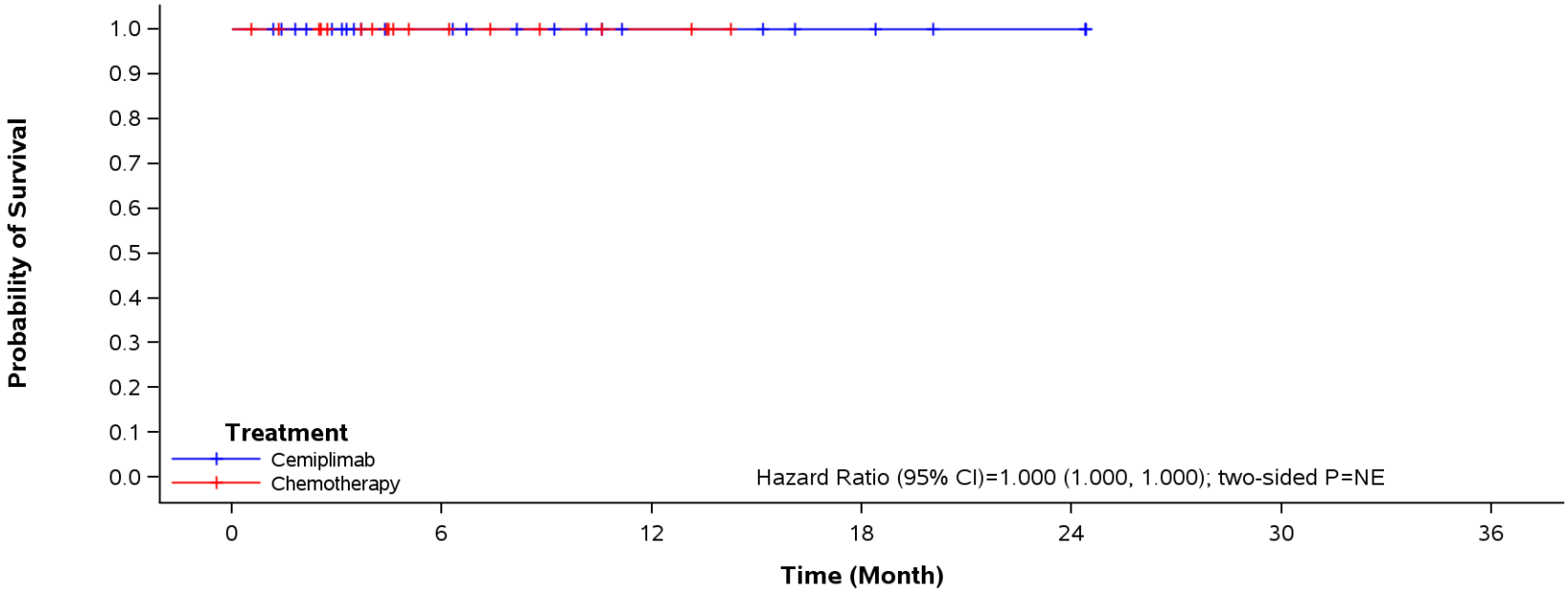

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Vascular disorders



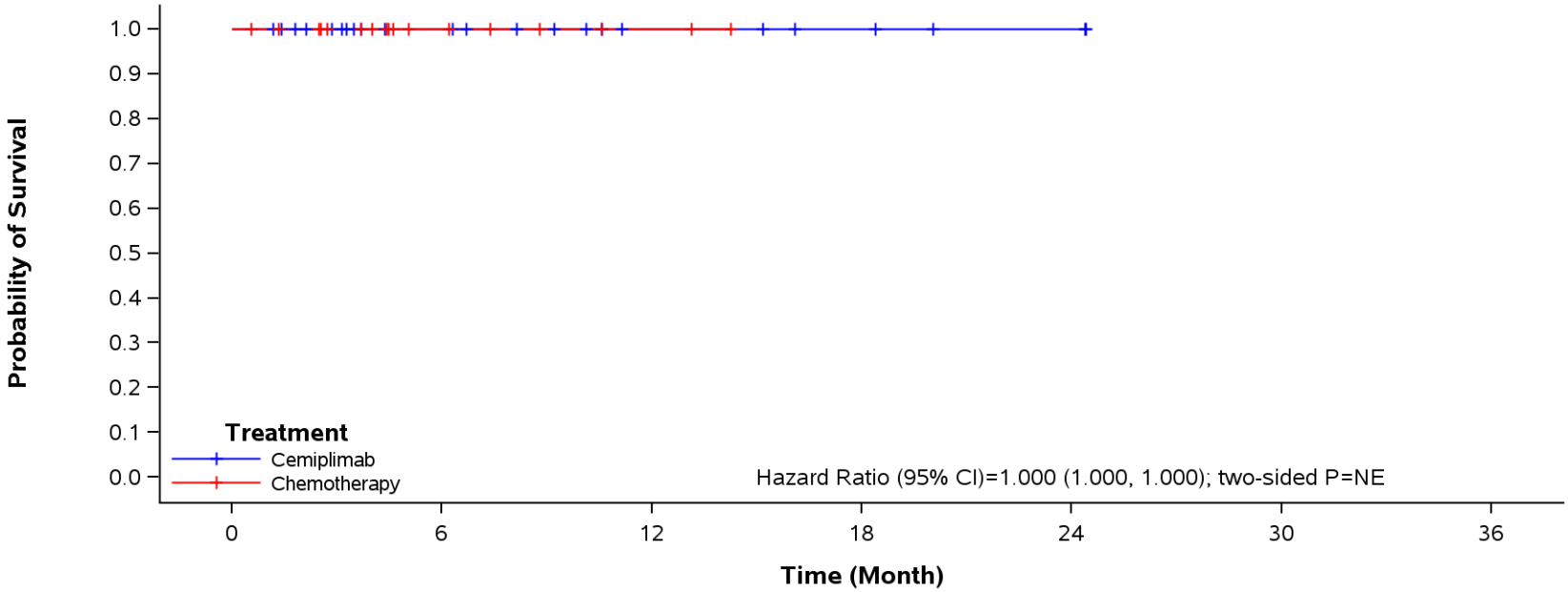

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Irinotecan
SOC: Vascular disorders
PT: Deep vein thrombosis



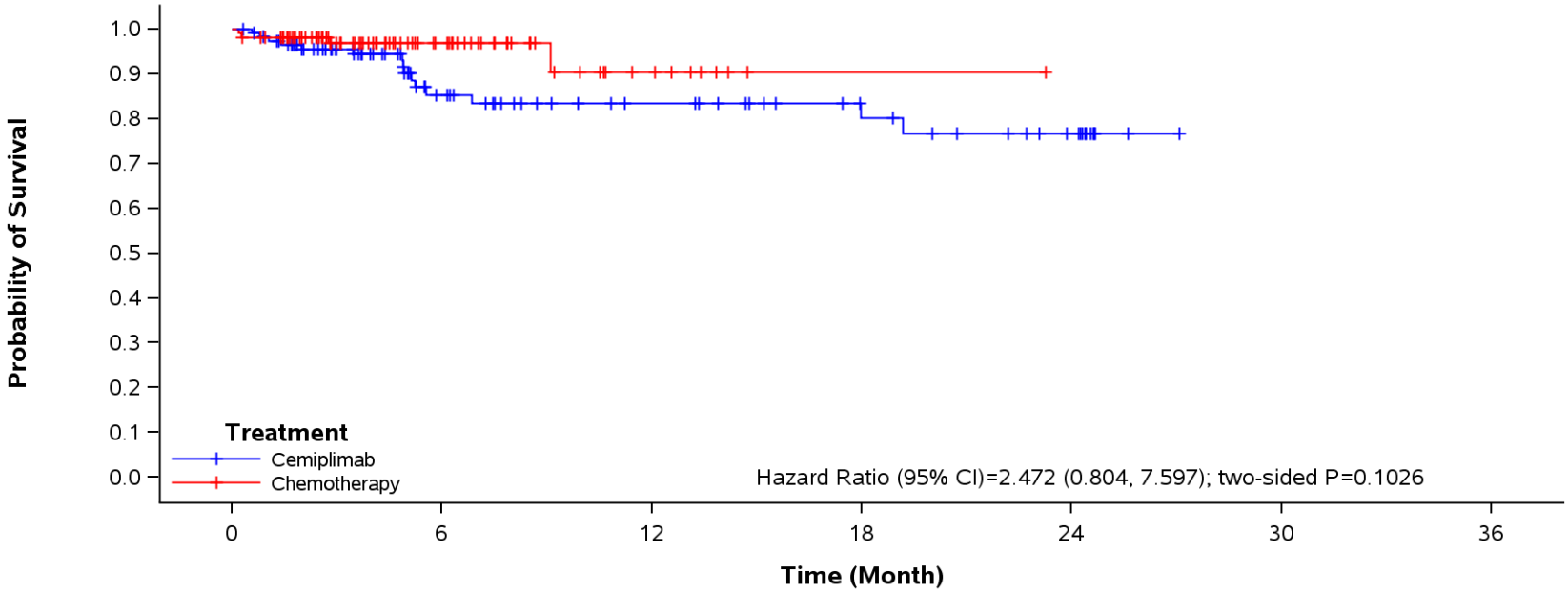

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 26 | 14 | 7 | 5 | 3 | 0 | 0 |
| Chemotherapy | 19 | 6 | 2 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
Number of patients with any TEAE leading to discontinuation



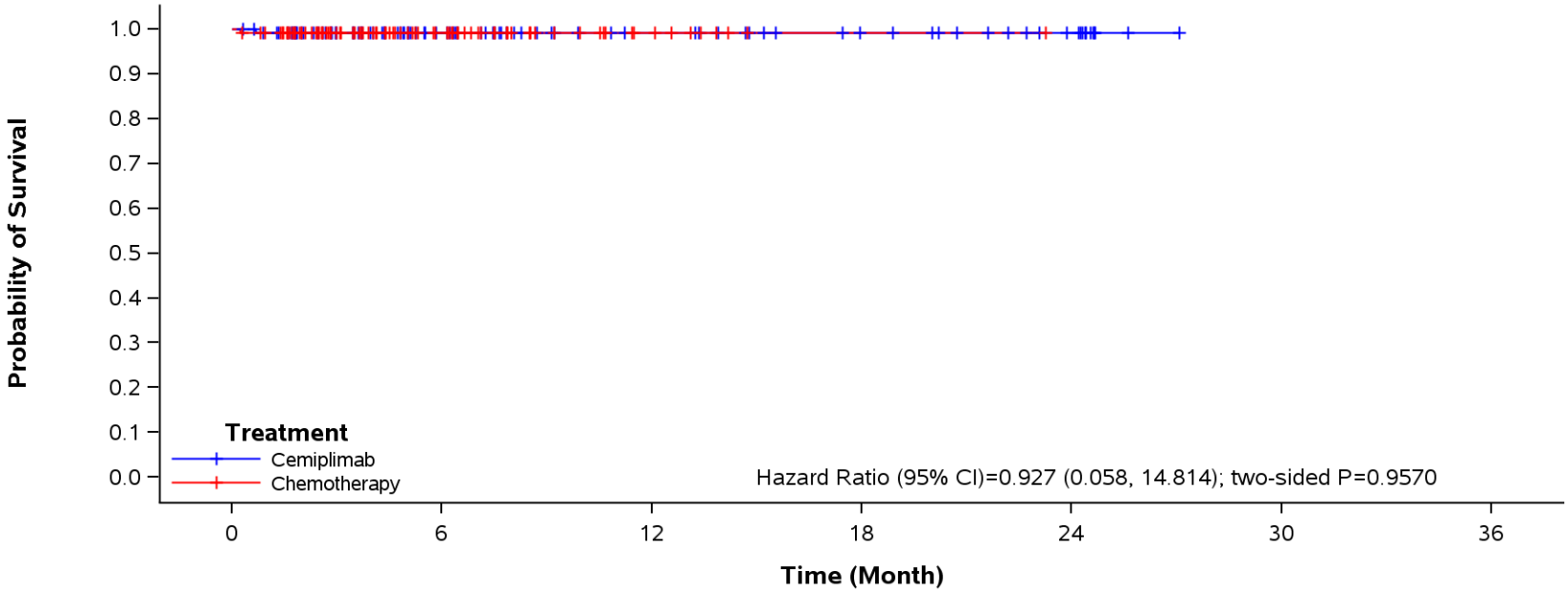

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 50 | 34 | 24 | 16 | 0 | 0 |
| Chemotherapy | 109 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders



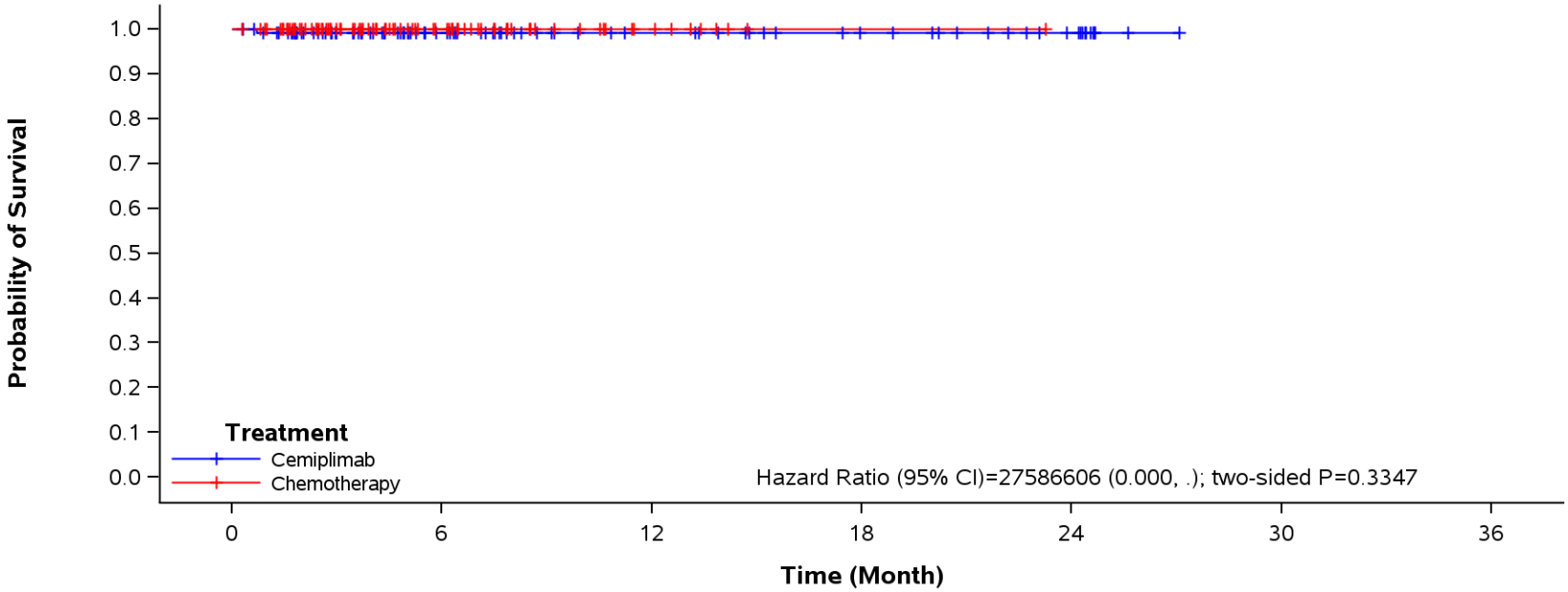

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Anaemia



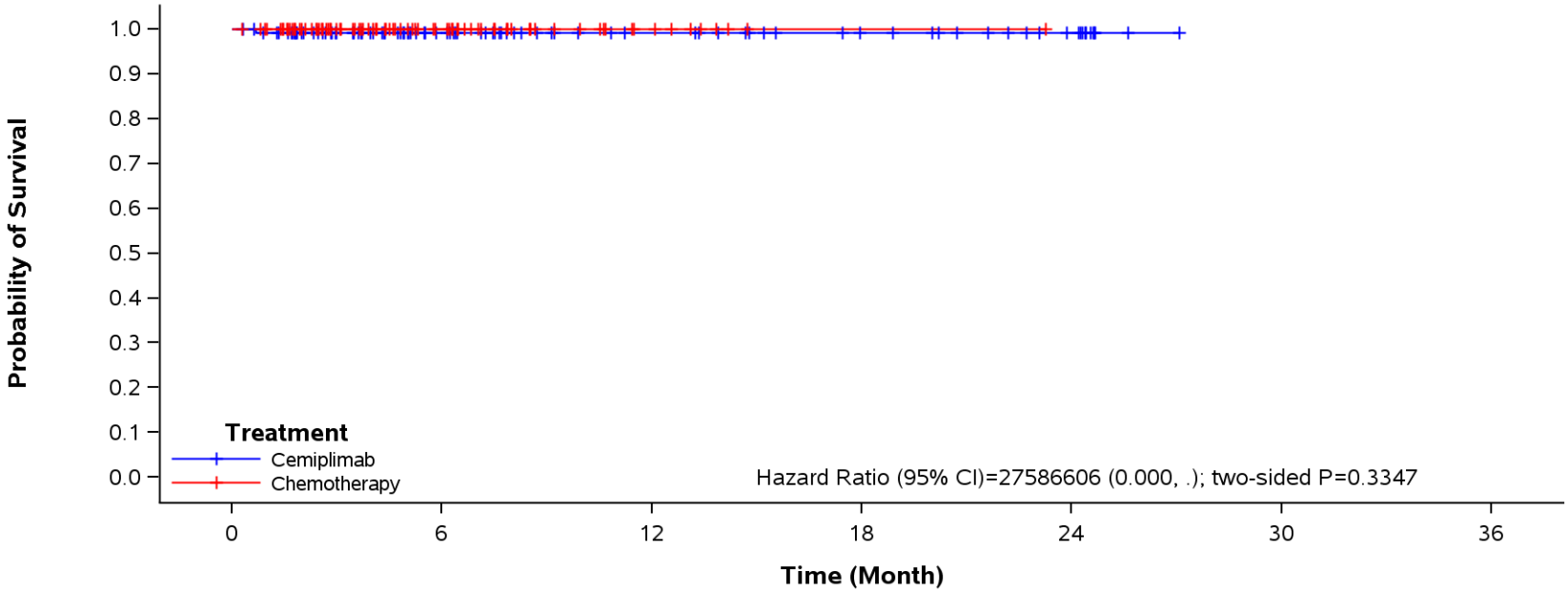

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



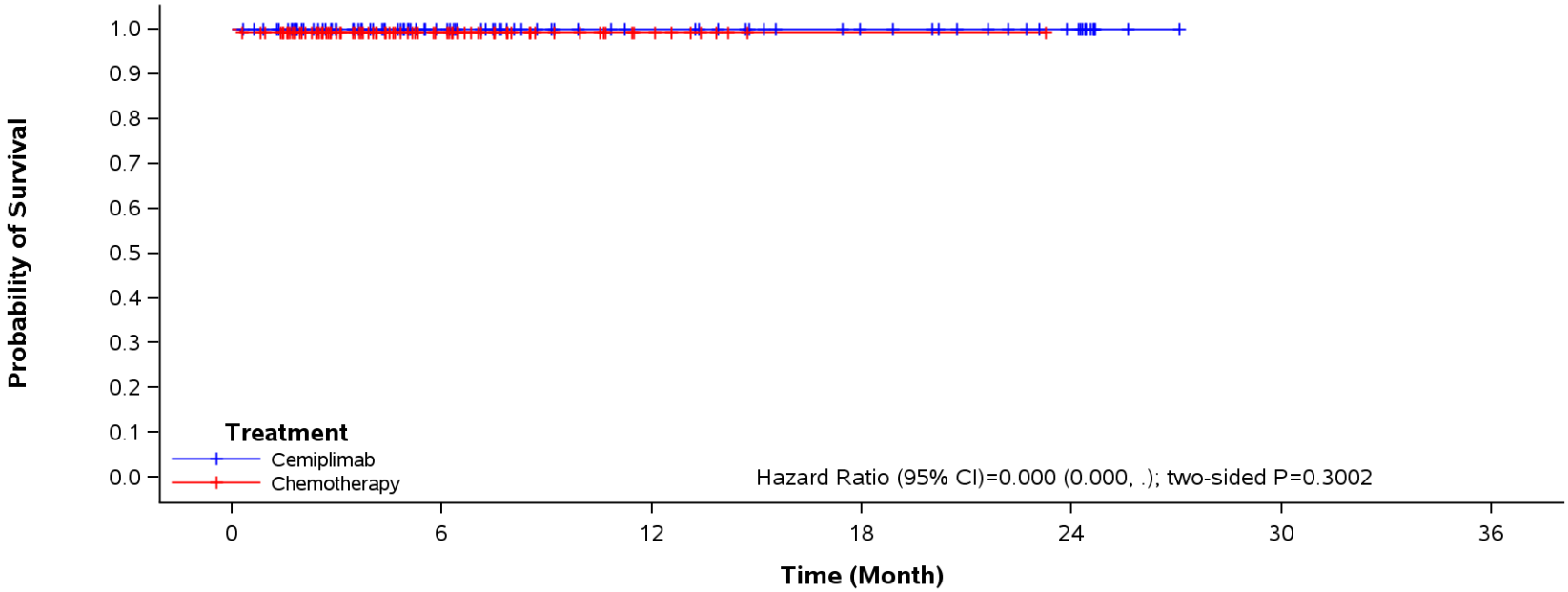

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Neutropenia



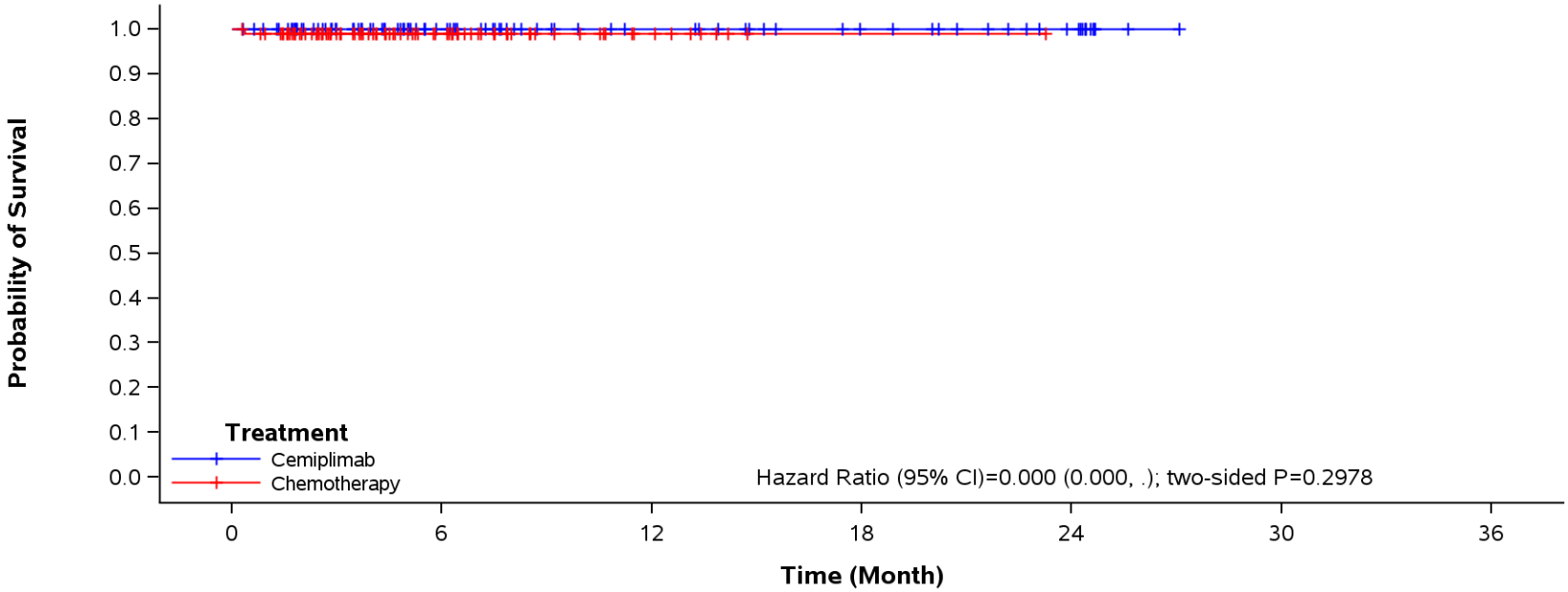

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



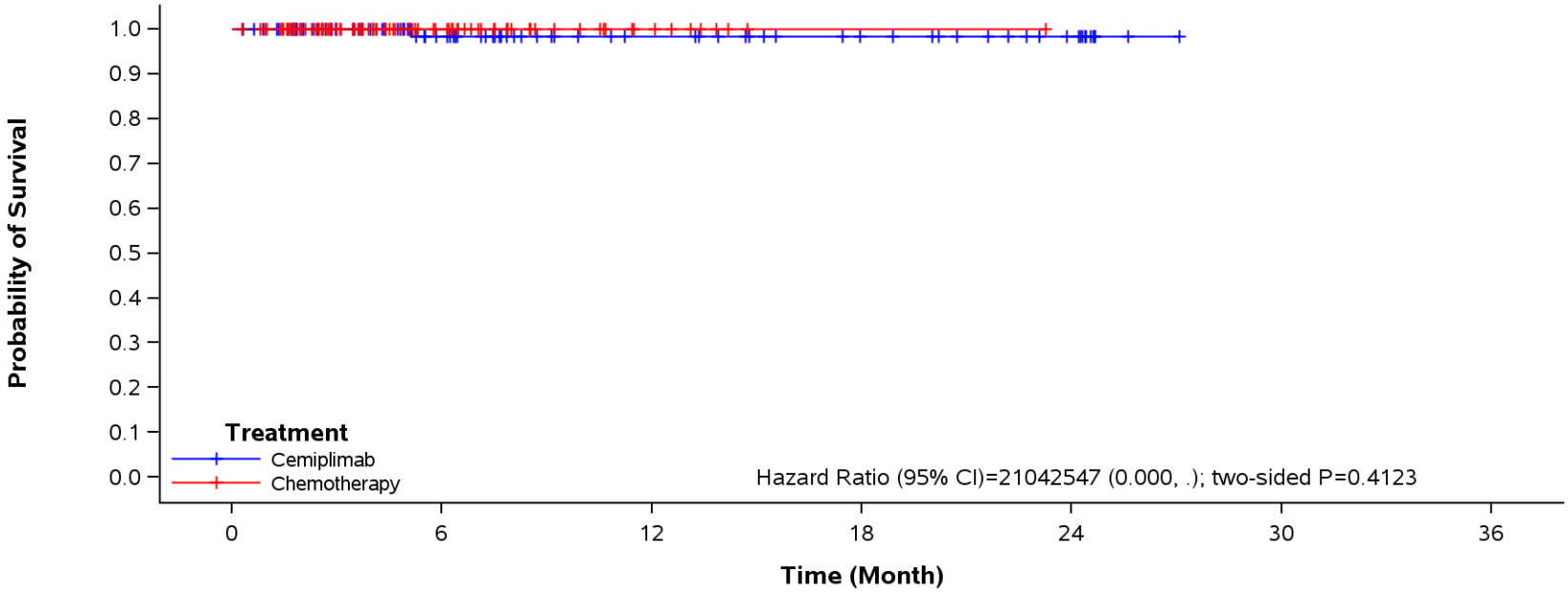

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Cardiac disorders



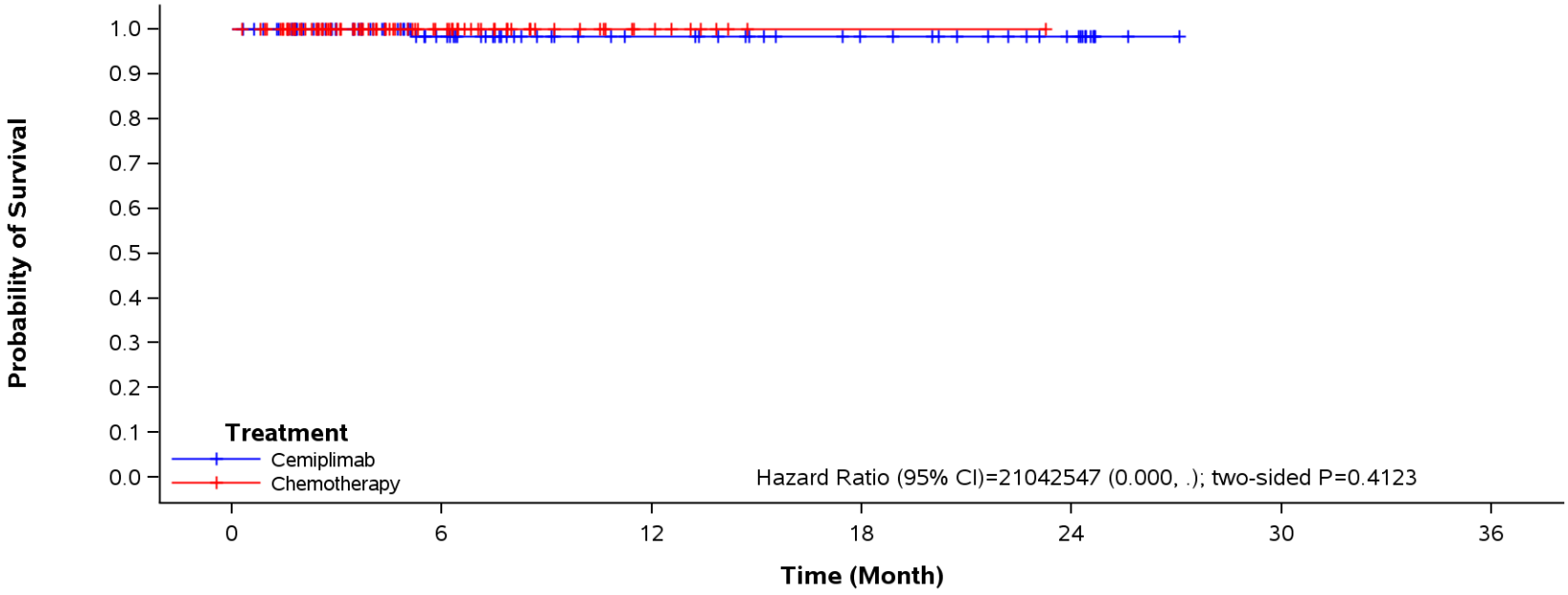

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Cardiac disorders
PT: Autoimmune pericarditis



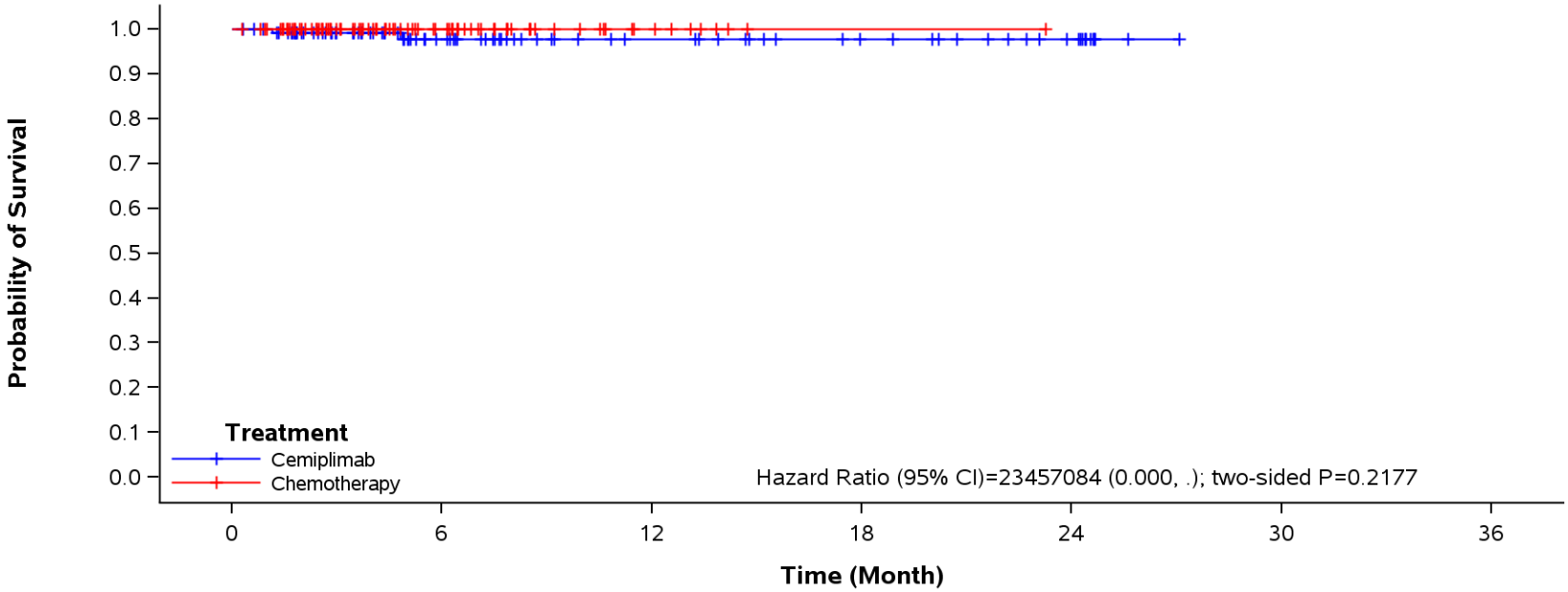

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Endocrine disorders



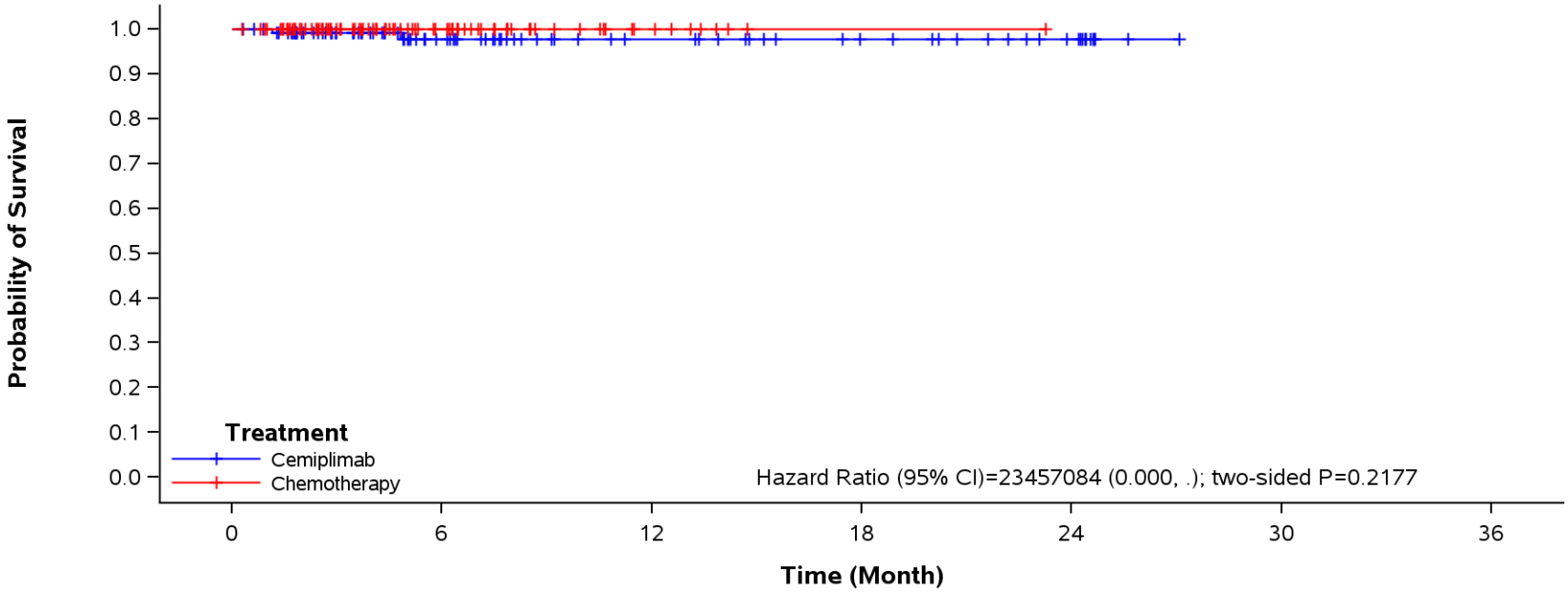

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Endocrine disorders
PT: Hypothyroidism



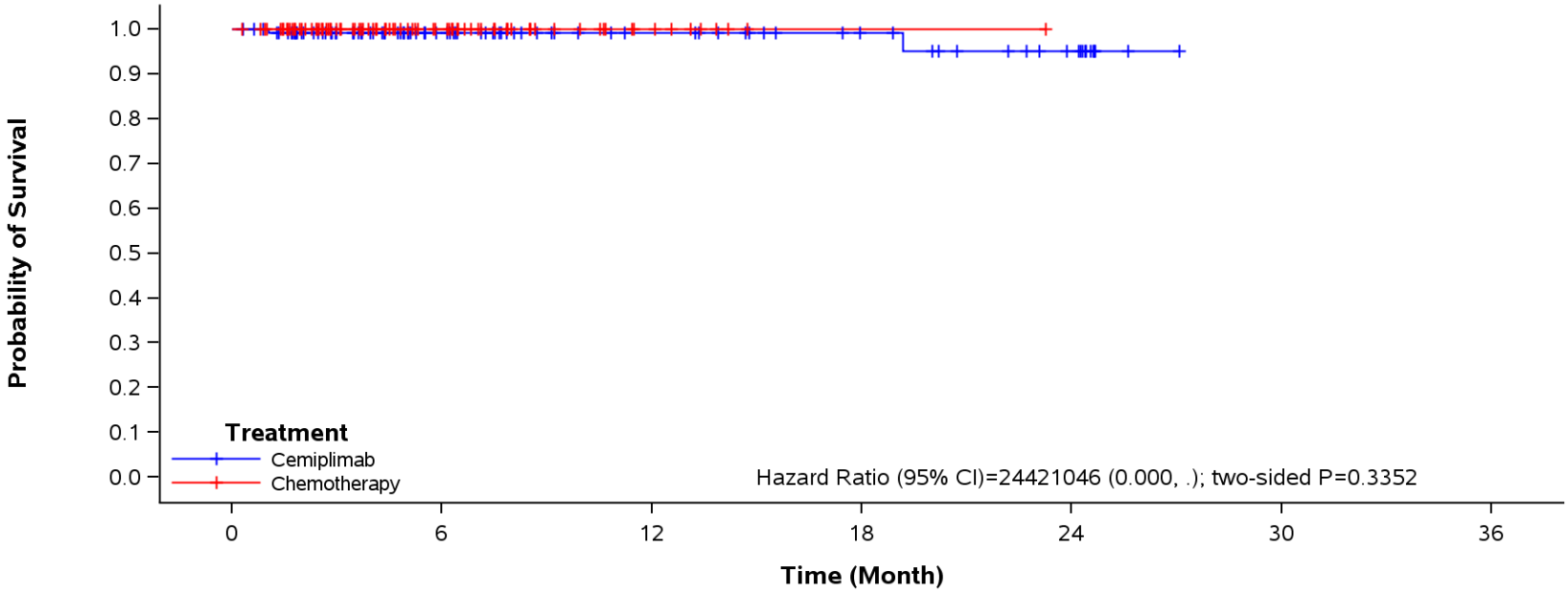

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders



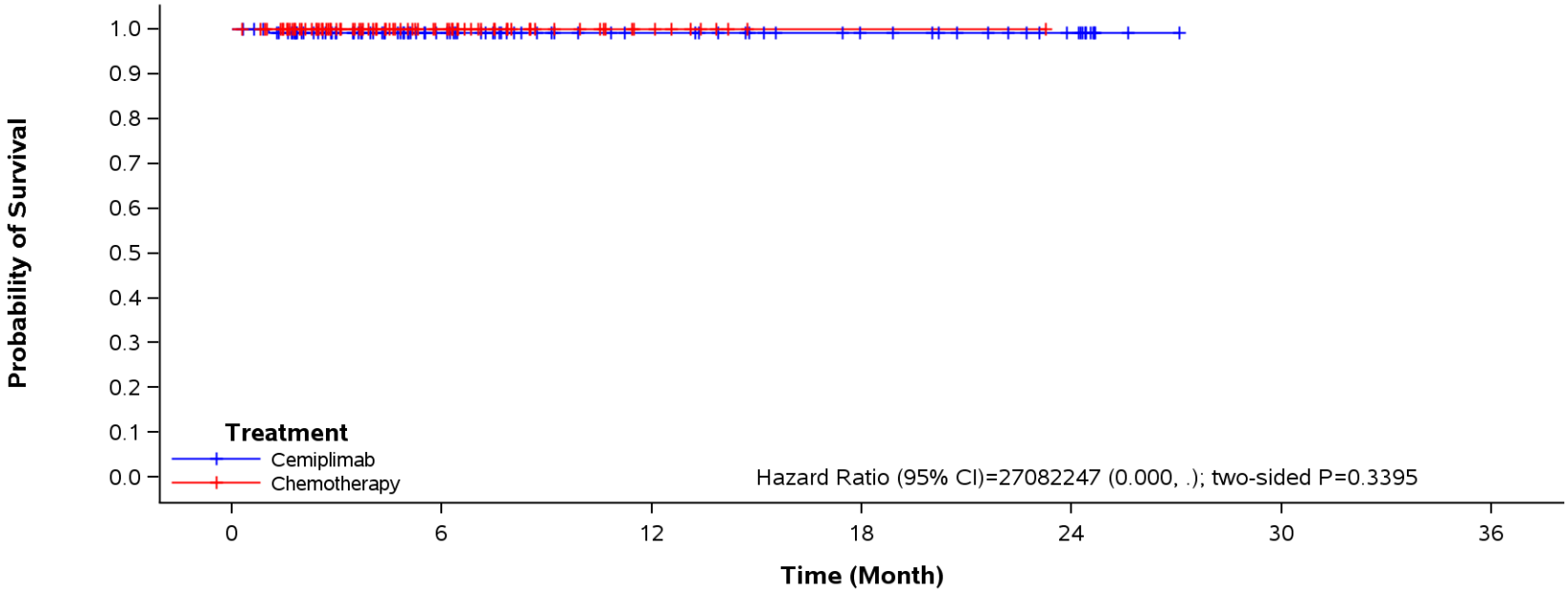

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders
PT: Colitis



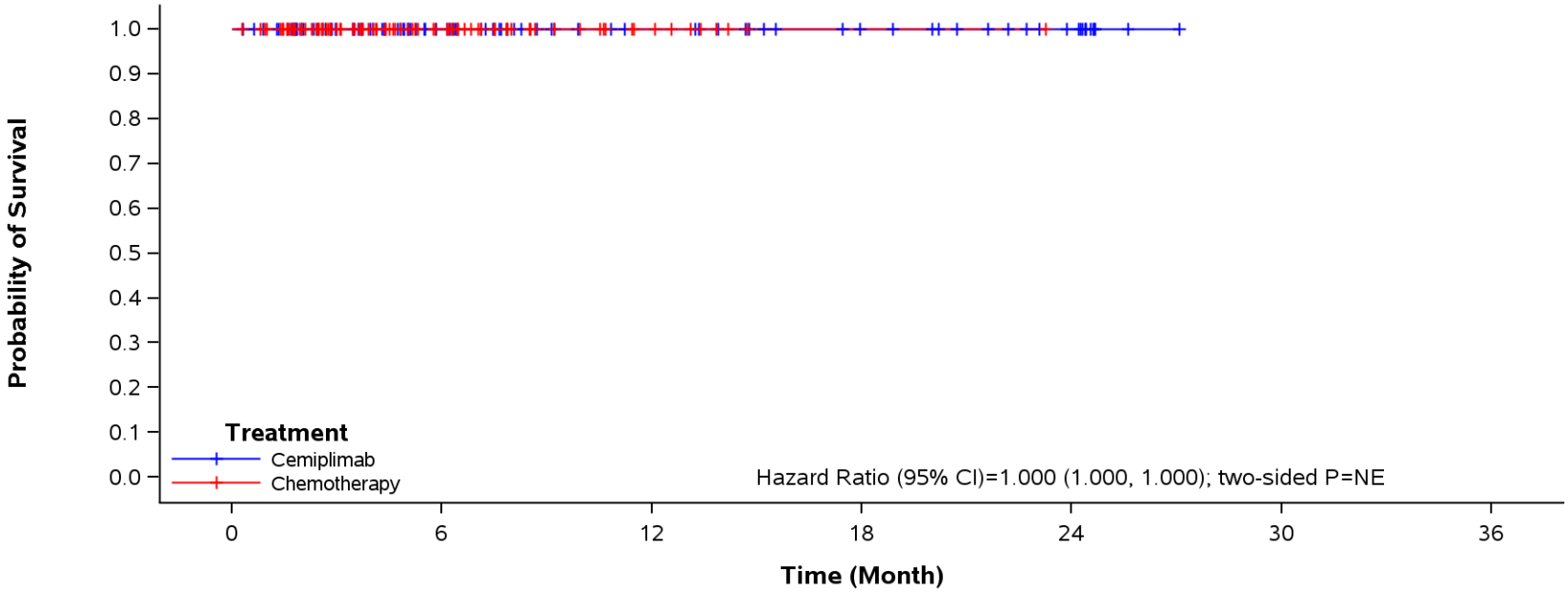

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders
PT: Diverticular perforation



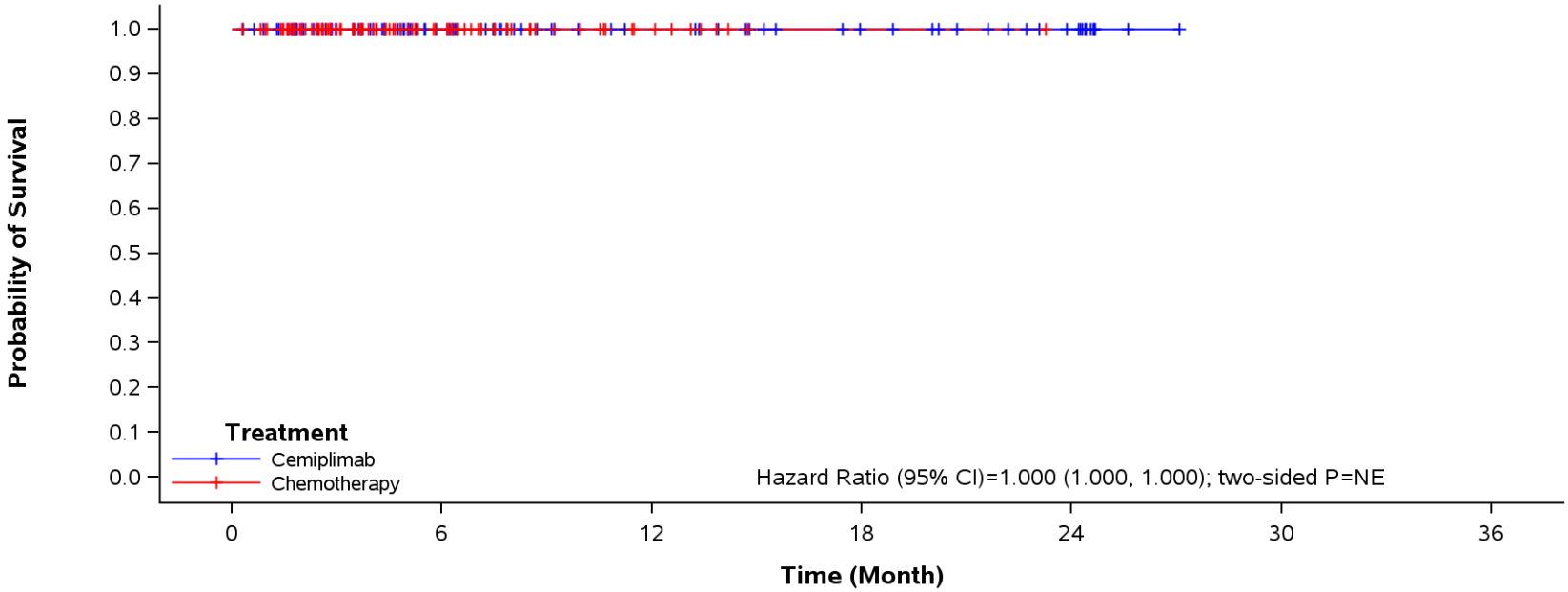

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders
PT: Pancreatic mass



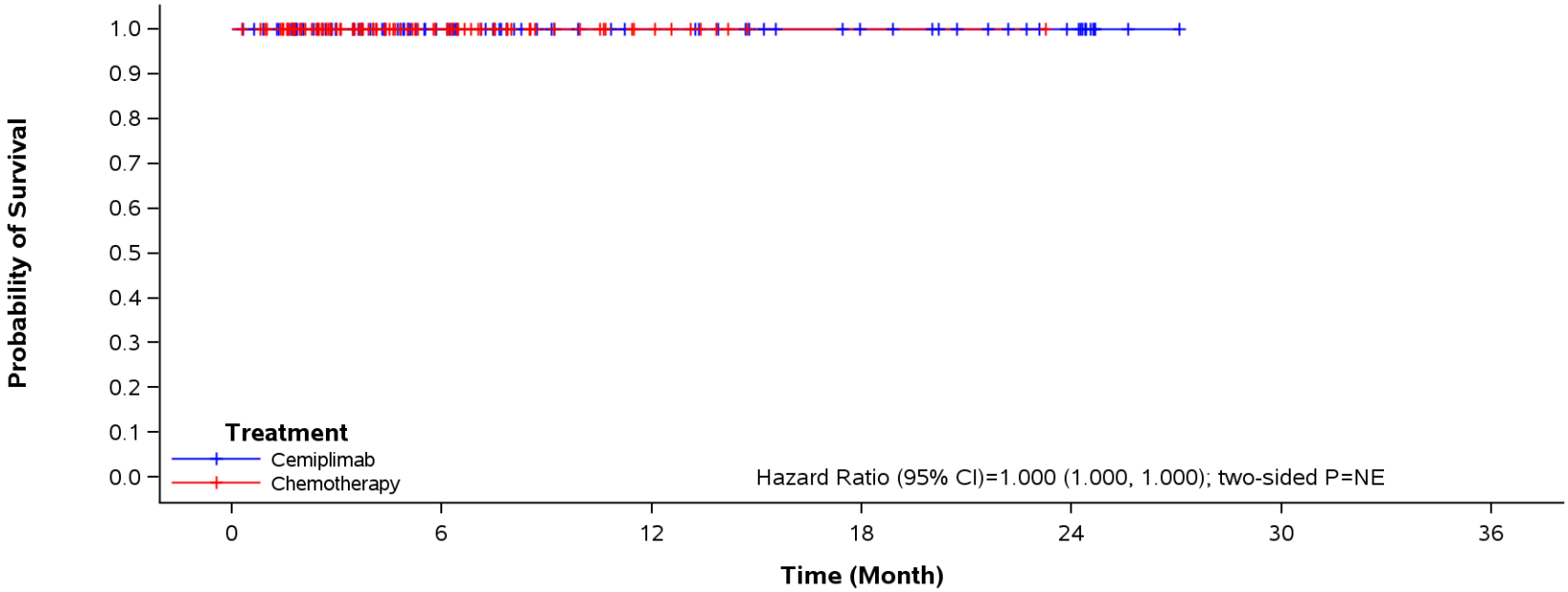

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



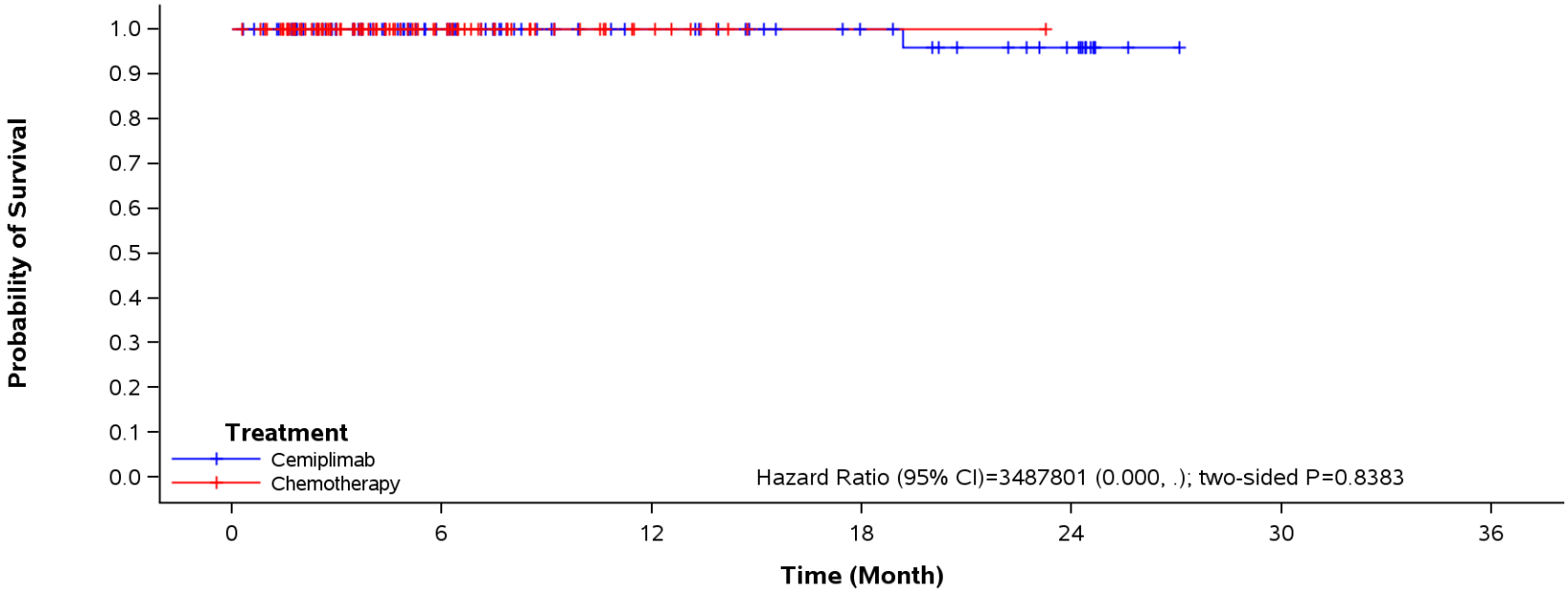

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Gastrointestinal disorders
PT: Proctalgia



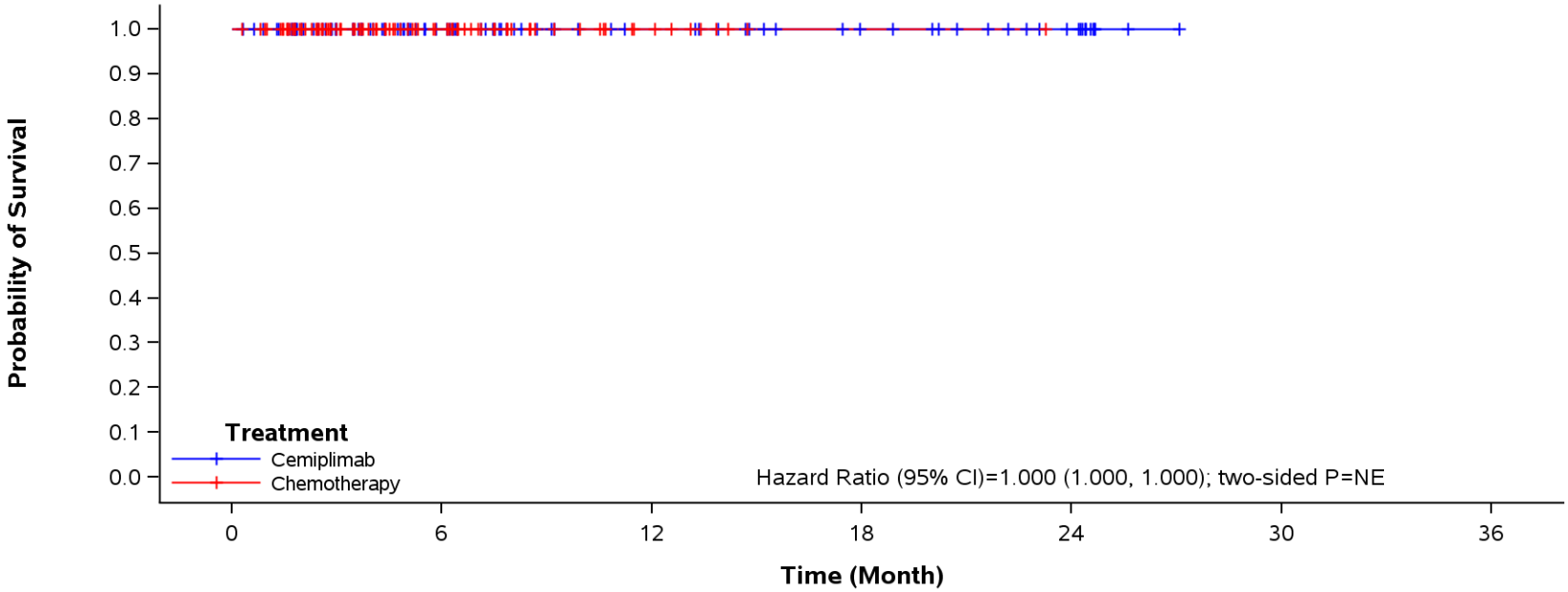

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: General disorders and administration site conditions



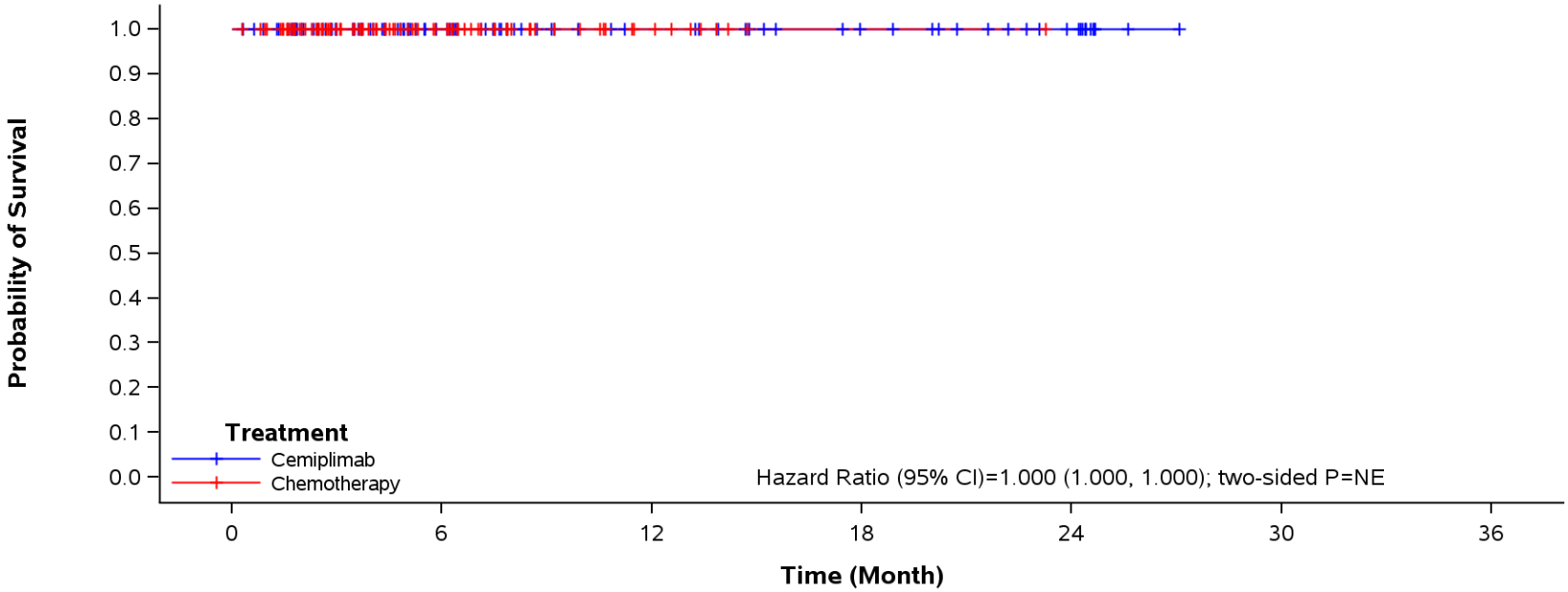

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: General disorders and administration site conditions
PT: Malaise



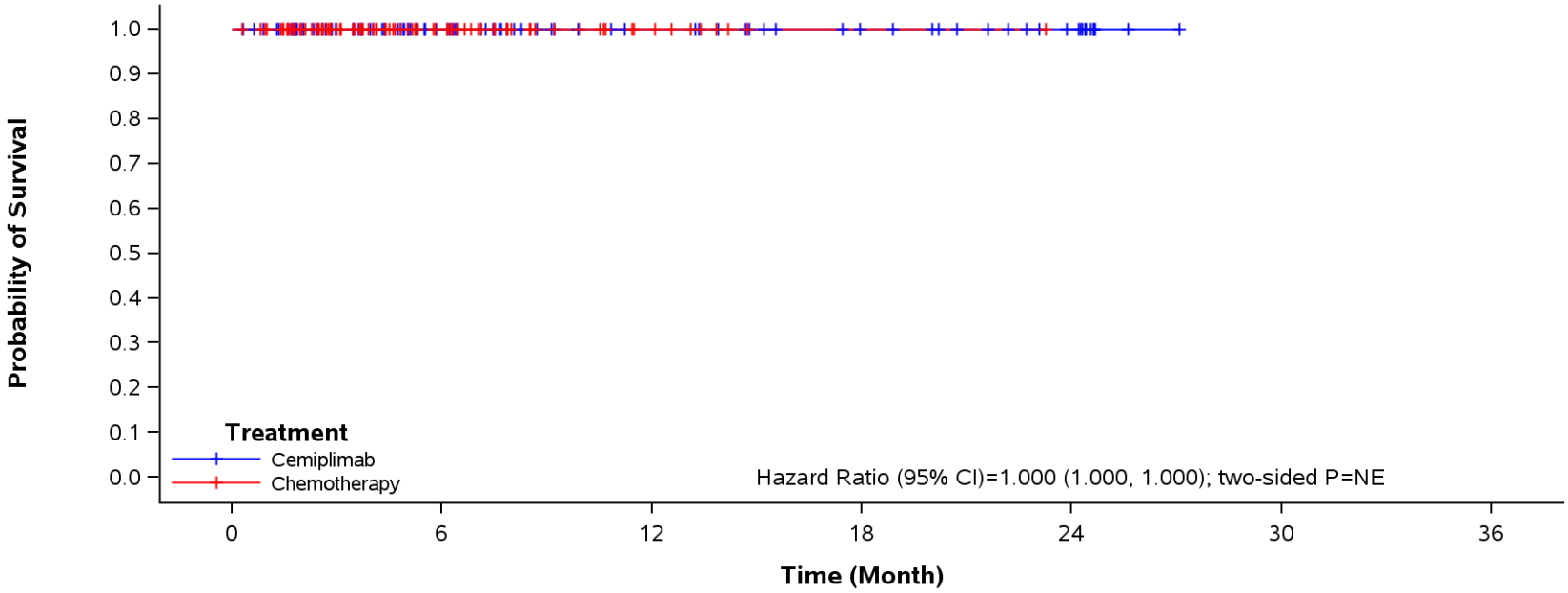

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



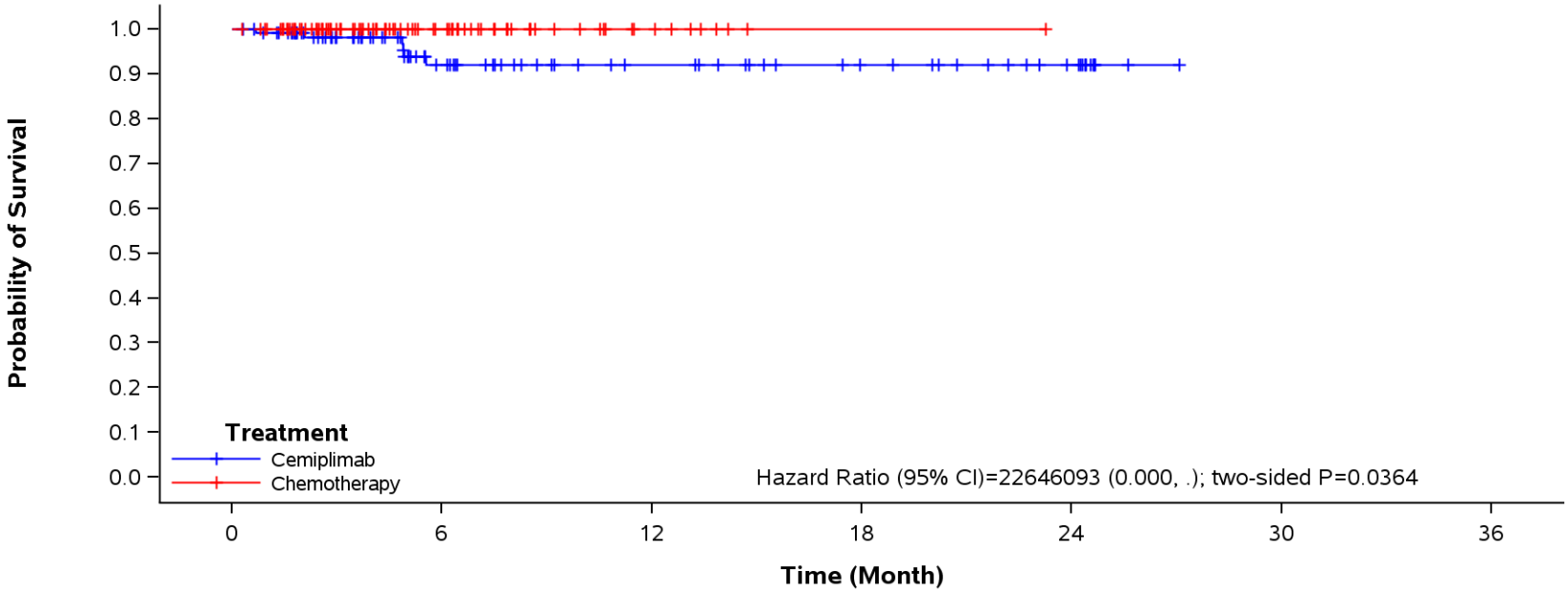

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Hepatobiliary disorders



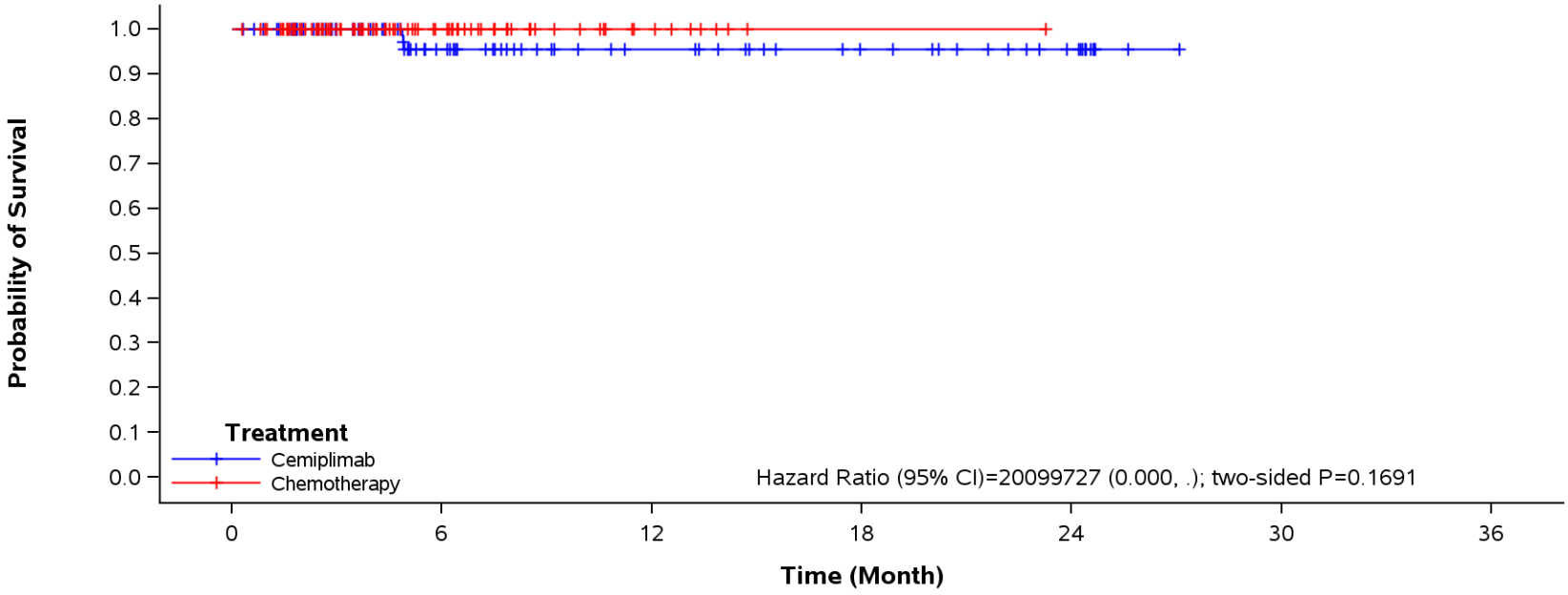

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 53 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



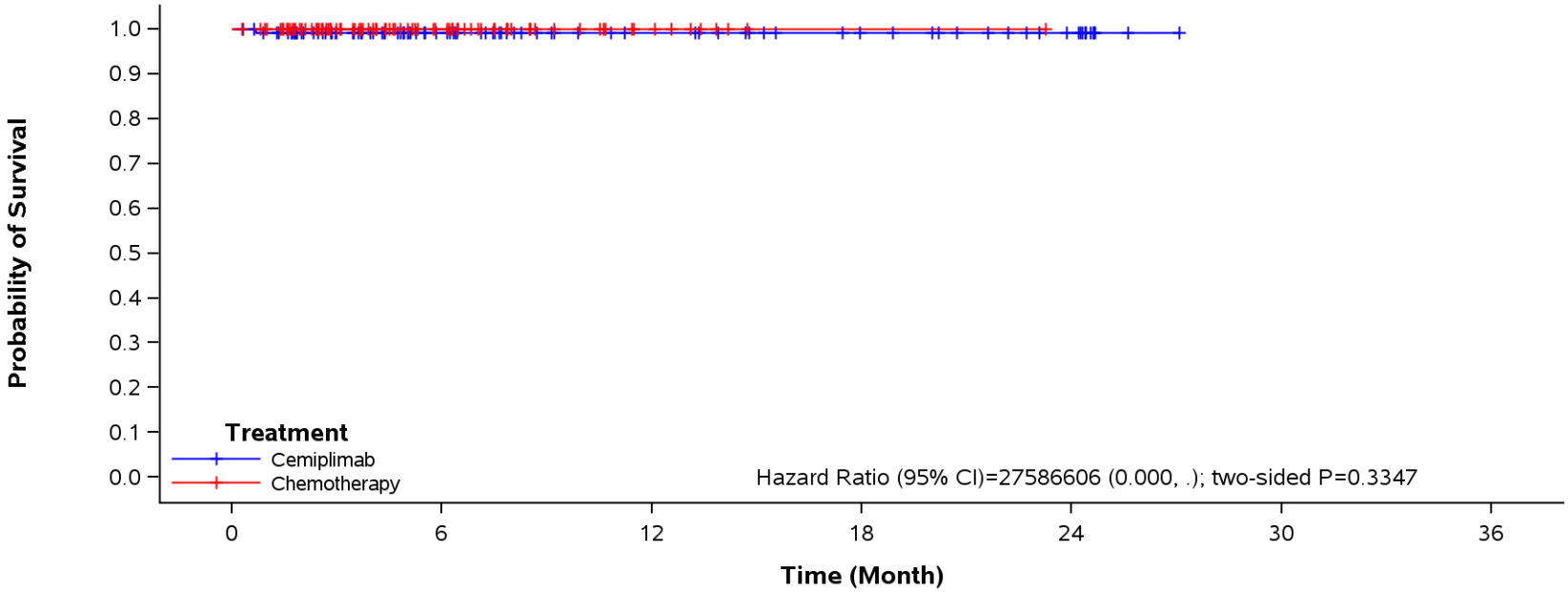

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 54 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



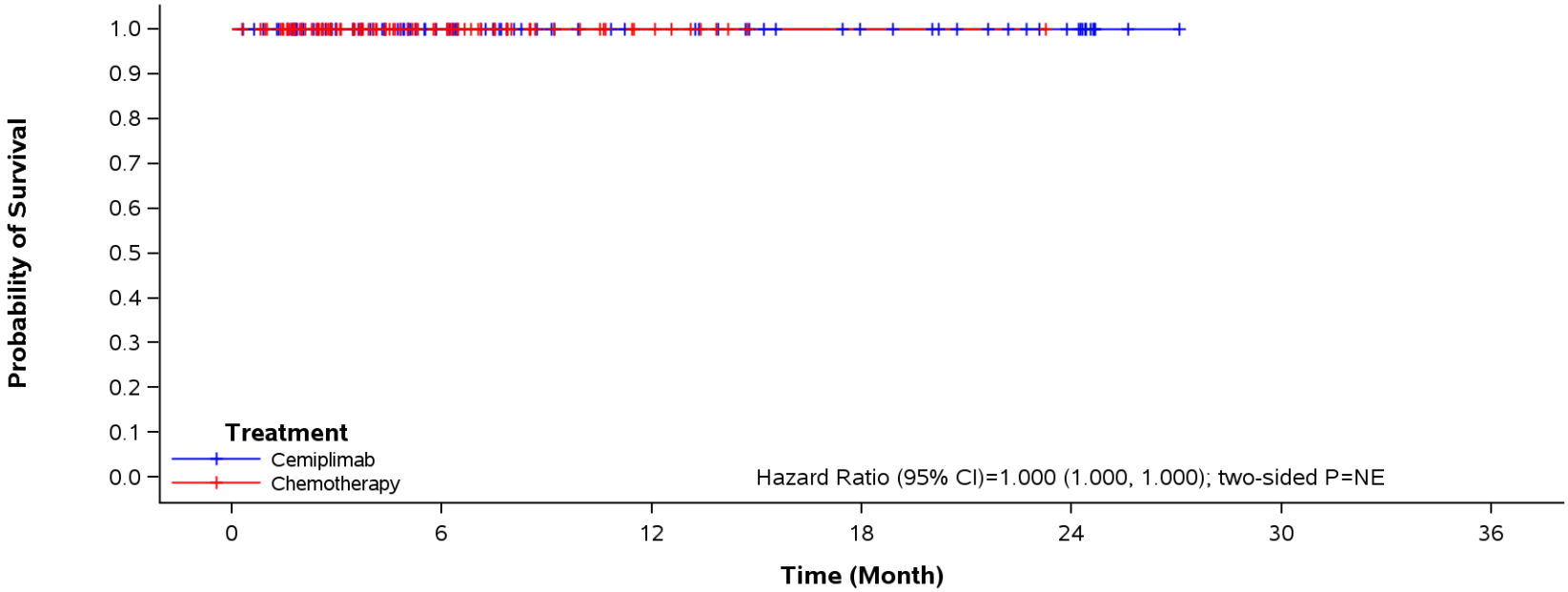

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Hepatobiliary disorders
PT: Hepatitis



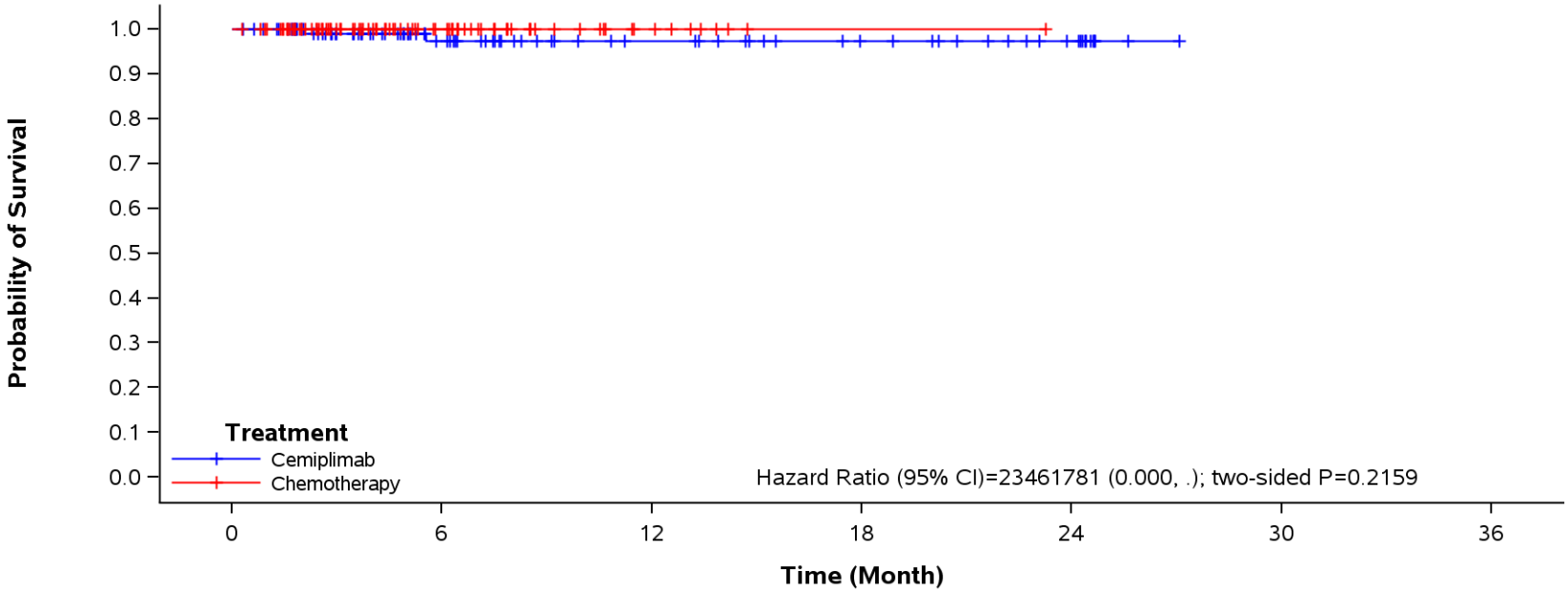

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



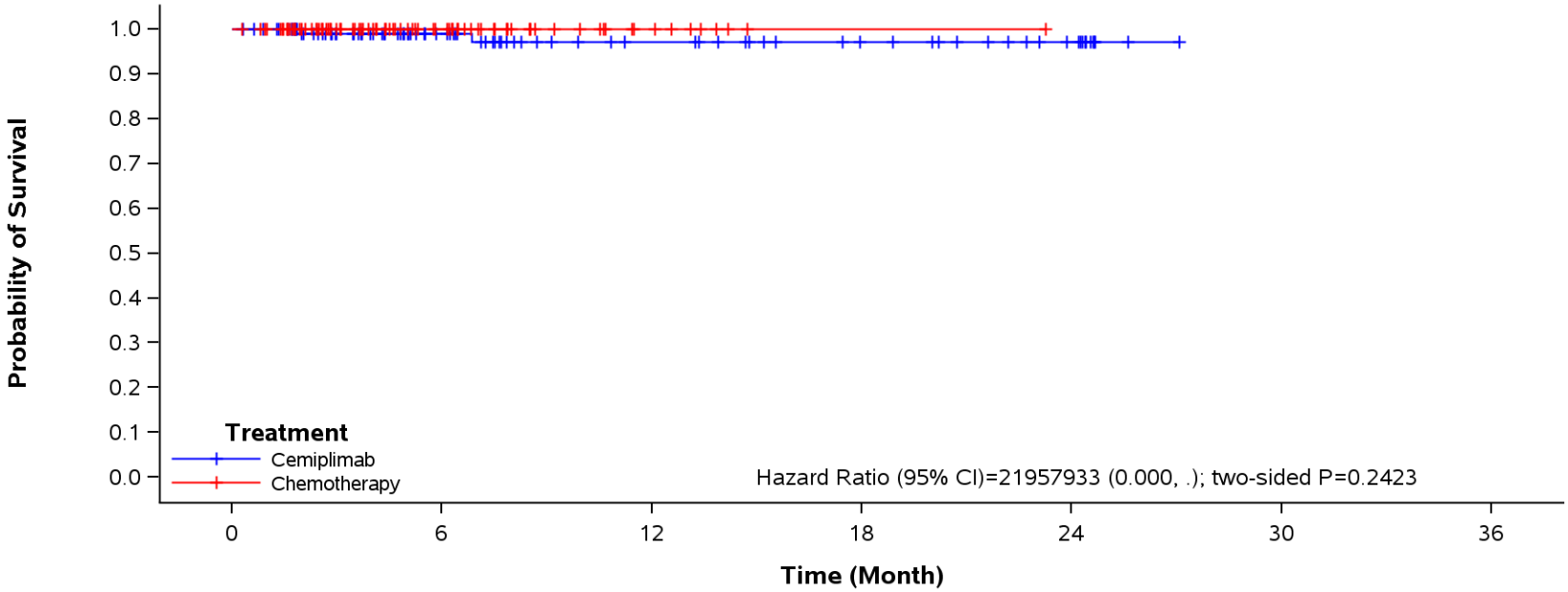

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Infections and infestations



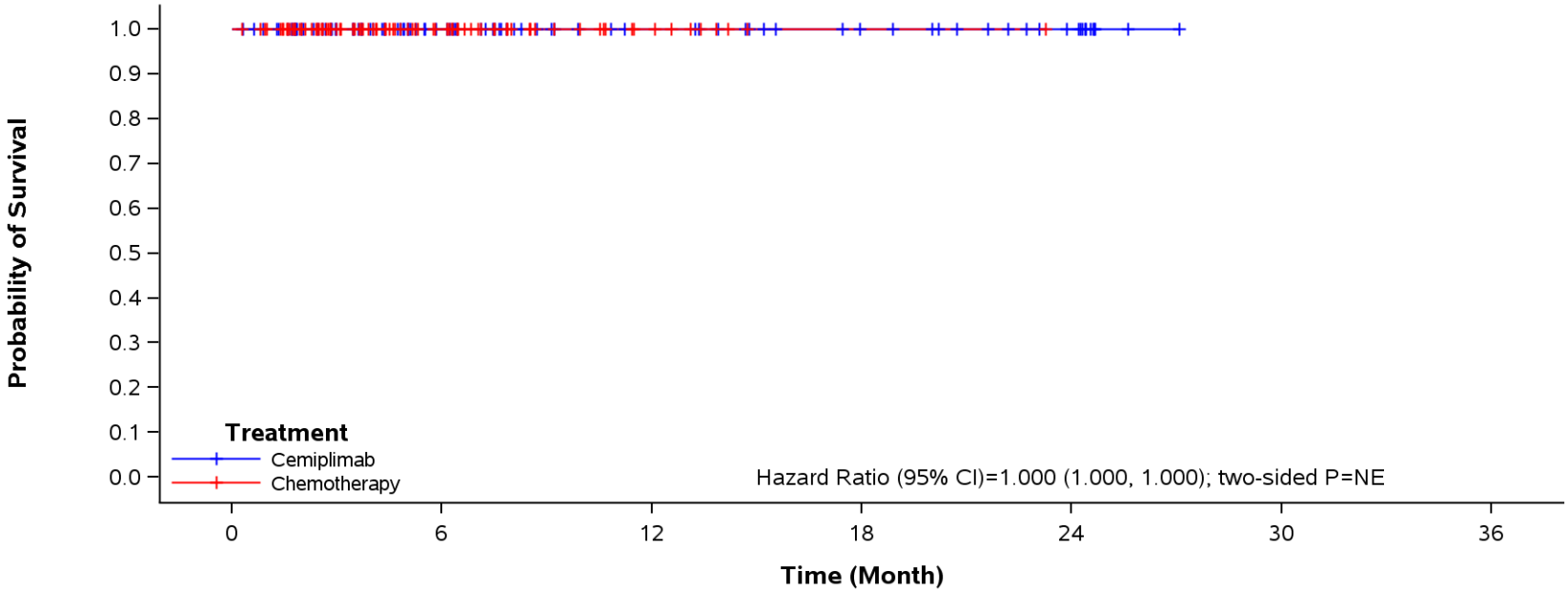

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Infections and infestations
PT: COVID-19 pneumonia



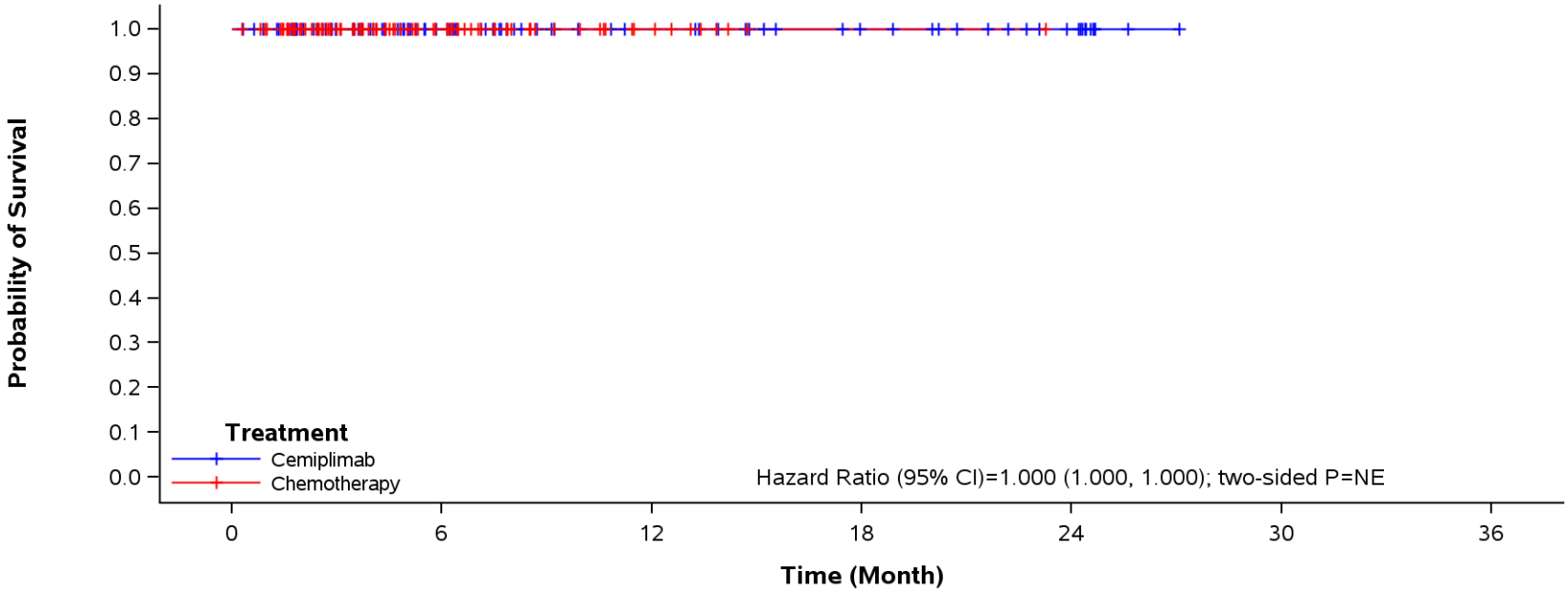

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Infections and infestations
PT: Gastroenteritis



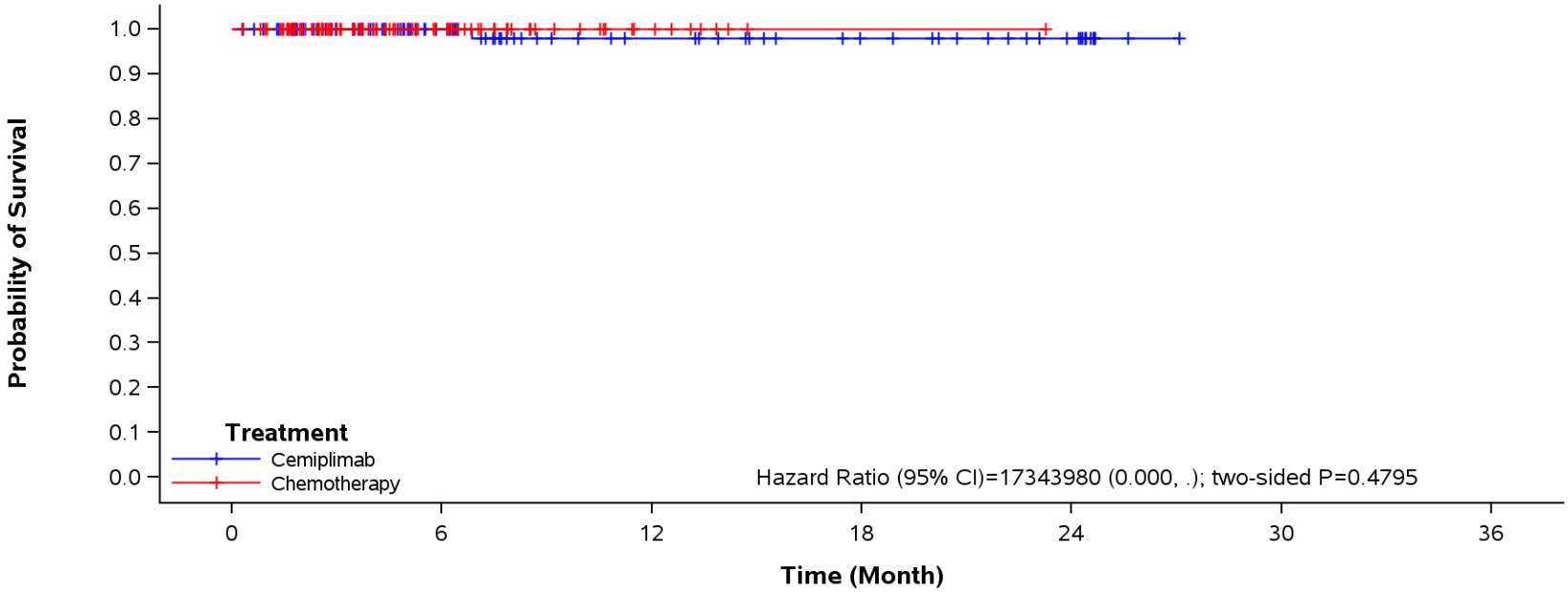

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Infections and infestations
PT: Pelvic abscess



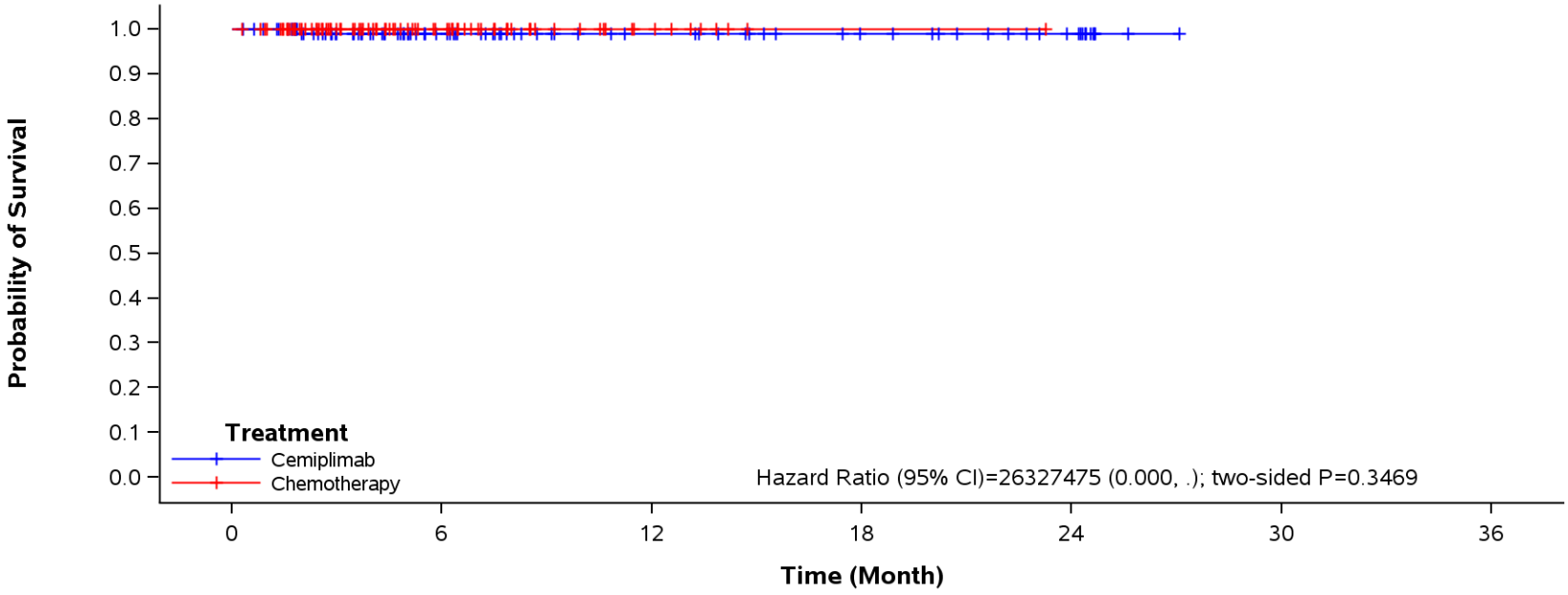

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Infections and infestations
PT: Peritonitis



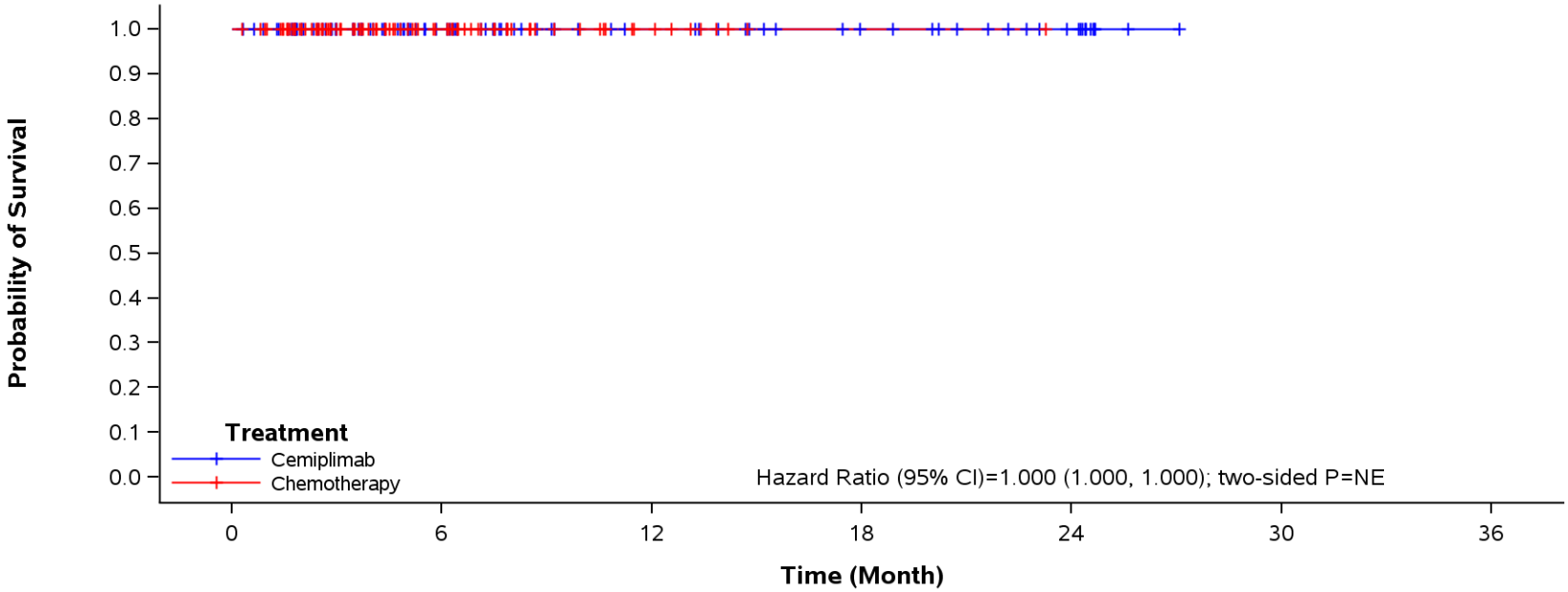

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Infections and infestations
PT: Pneumonia



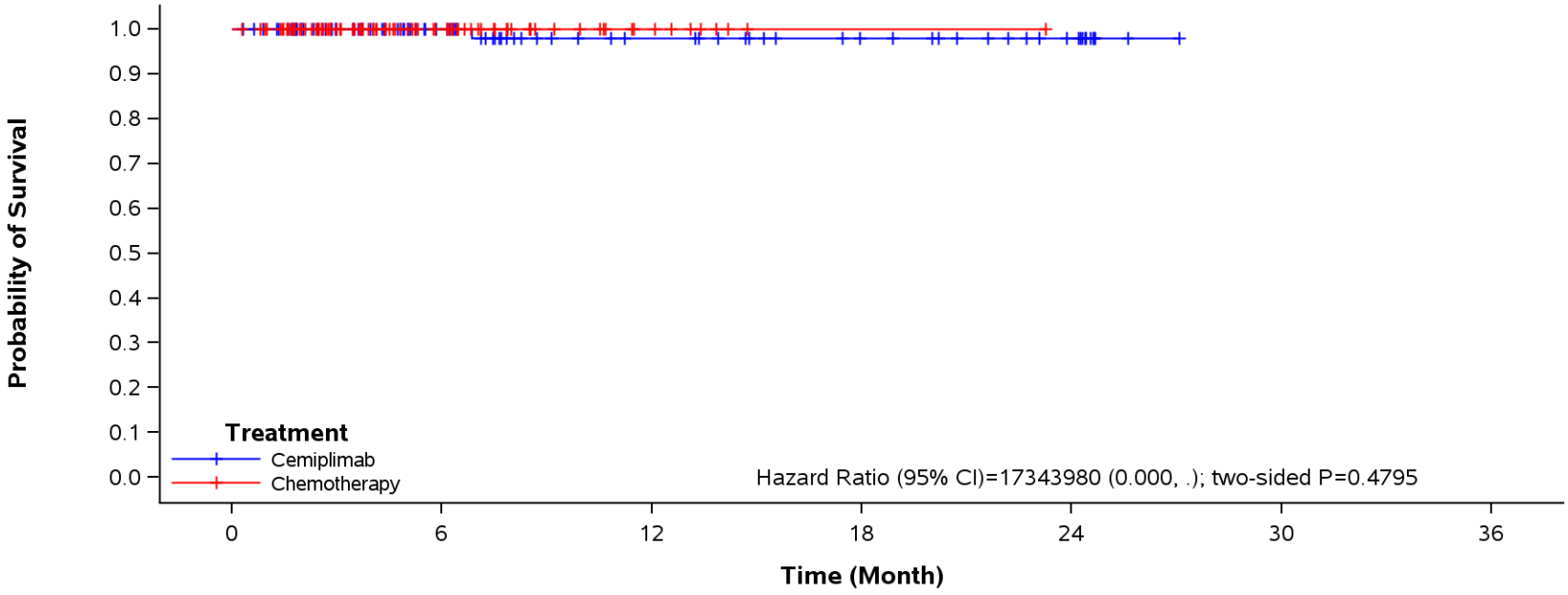

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Infections and infestations
PT: Pyomyositis



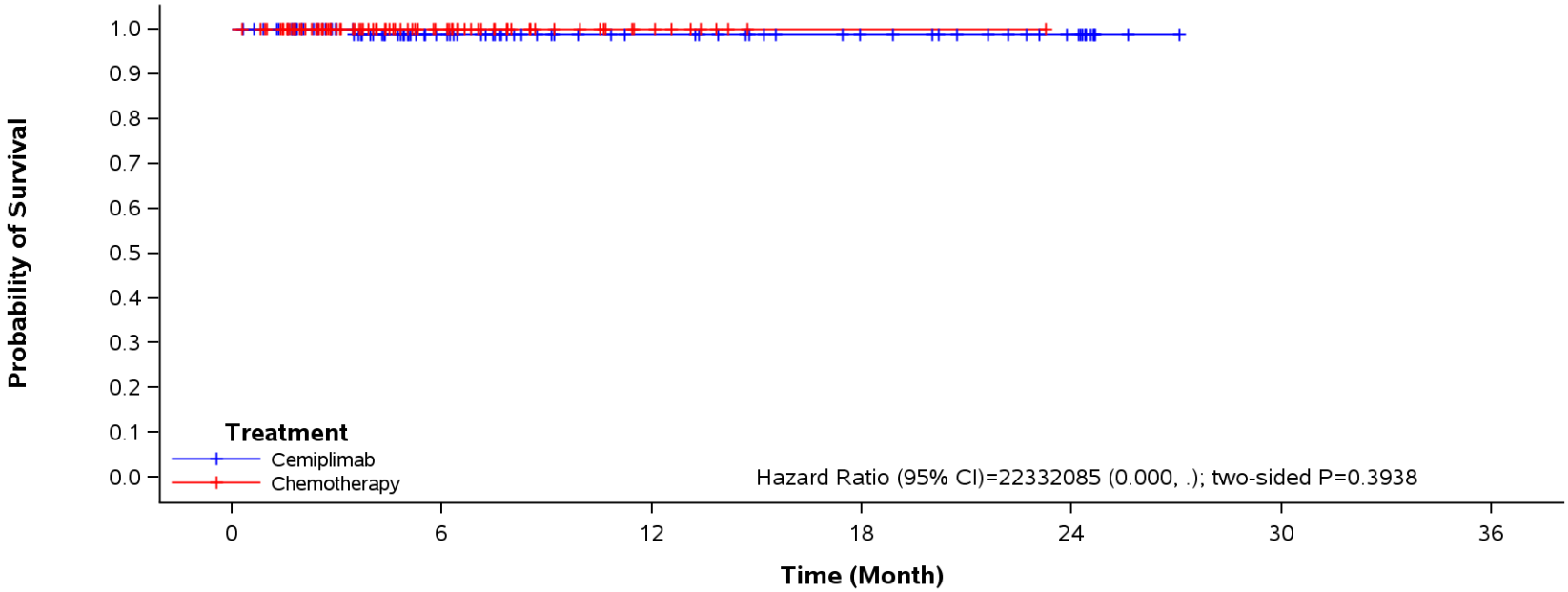

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Injury, poisoning and procedural complications



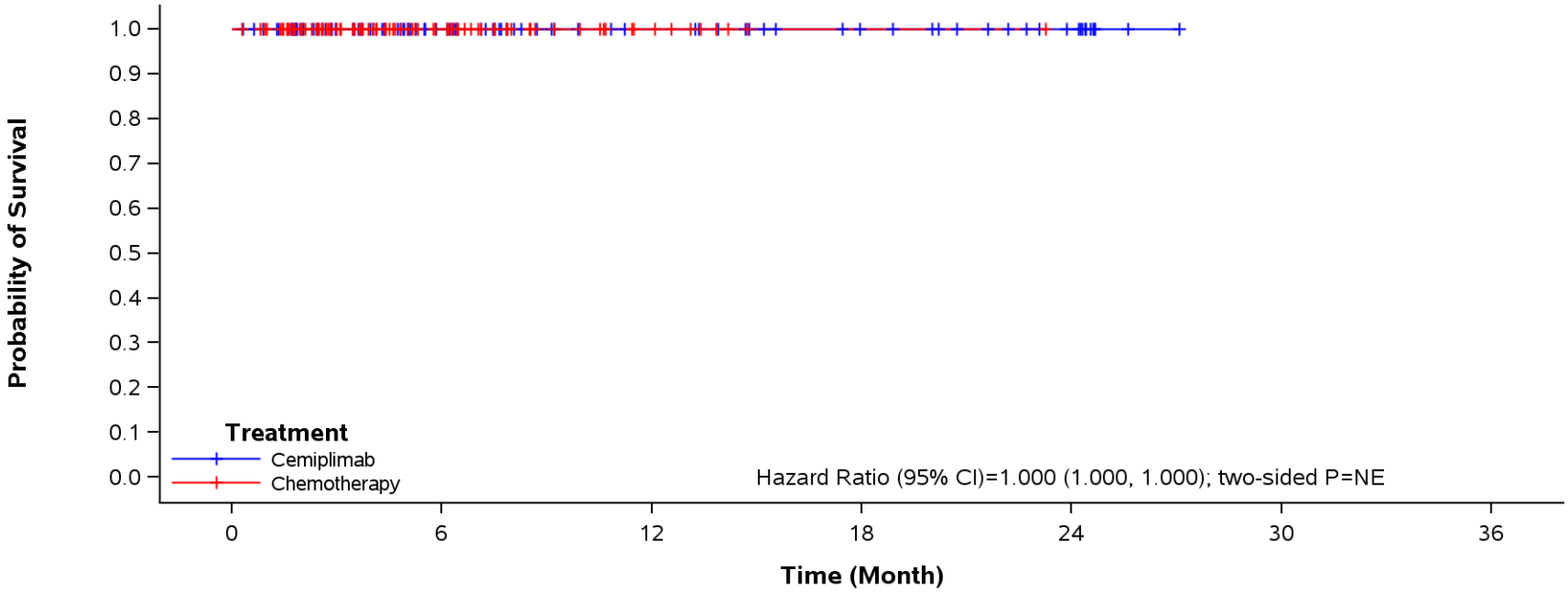

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



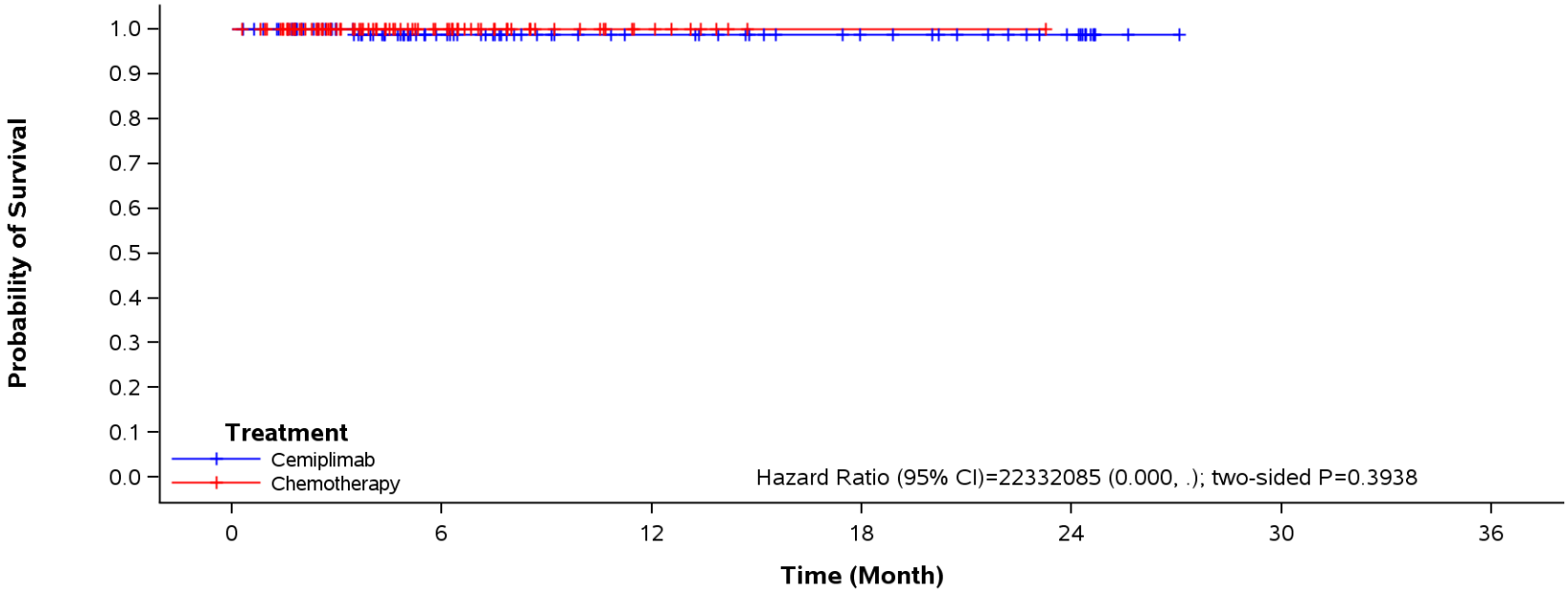

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



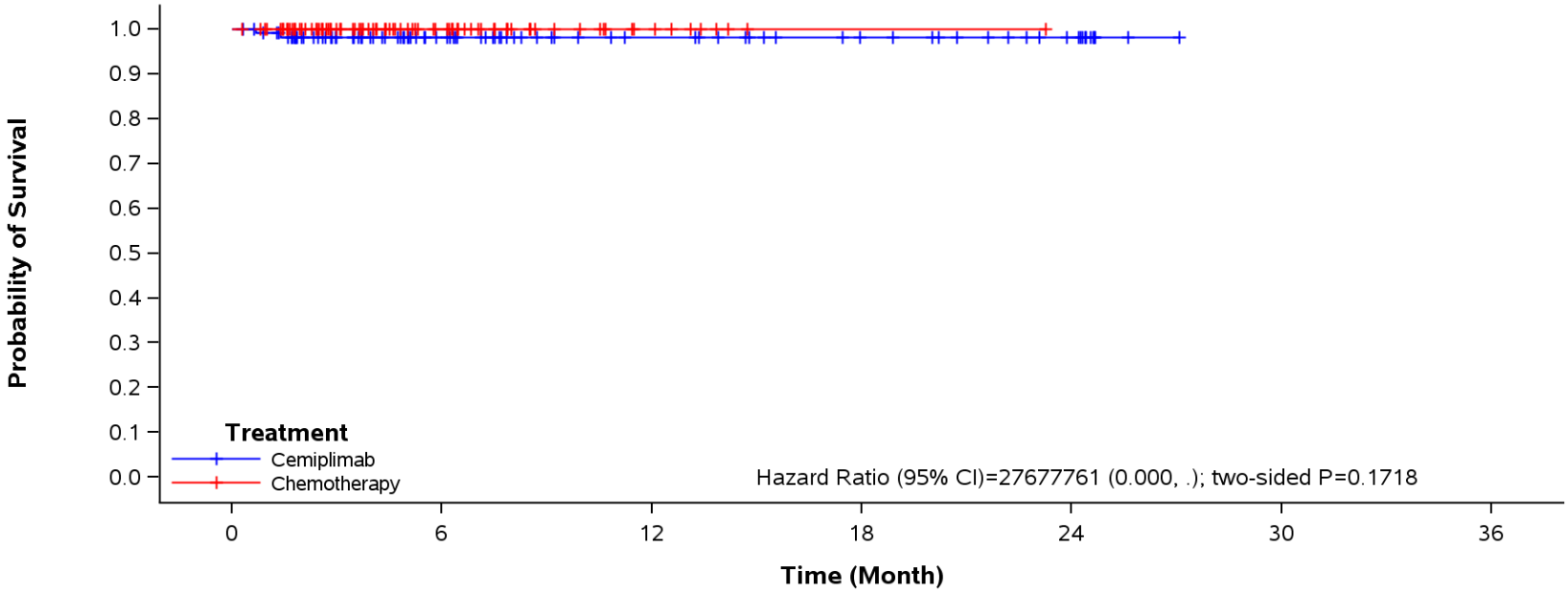

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Investigations



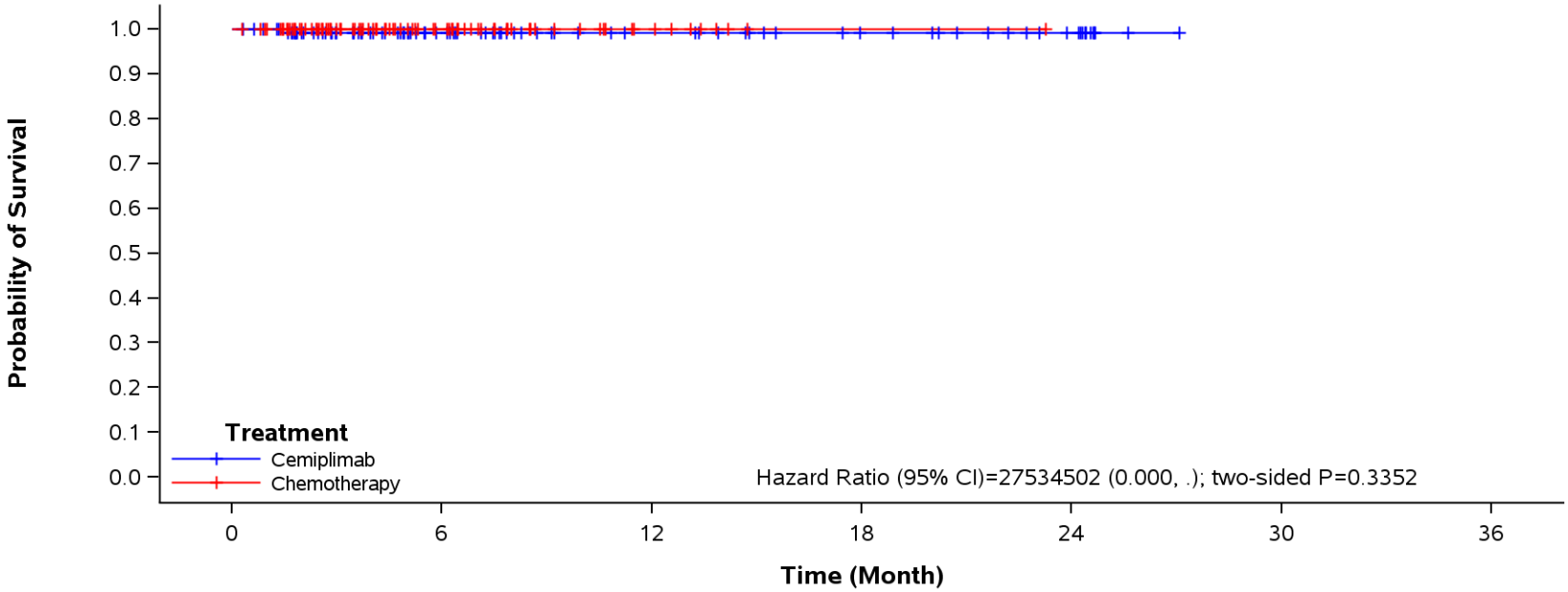

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Investigations
PT: Alanine aminotransferase increased



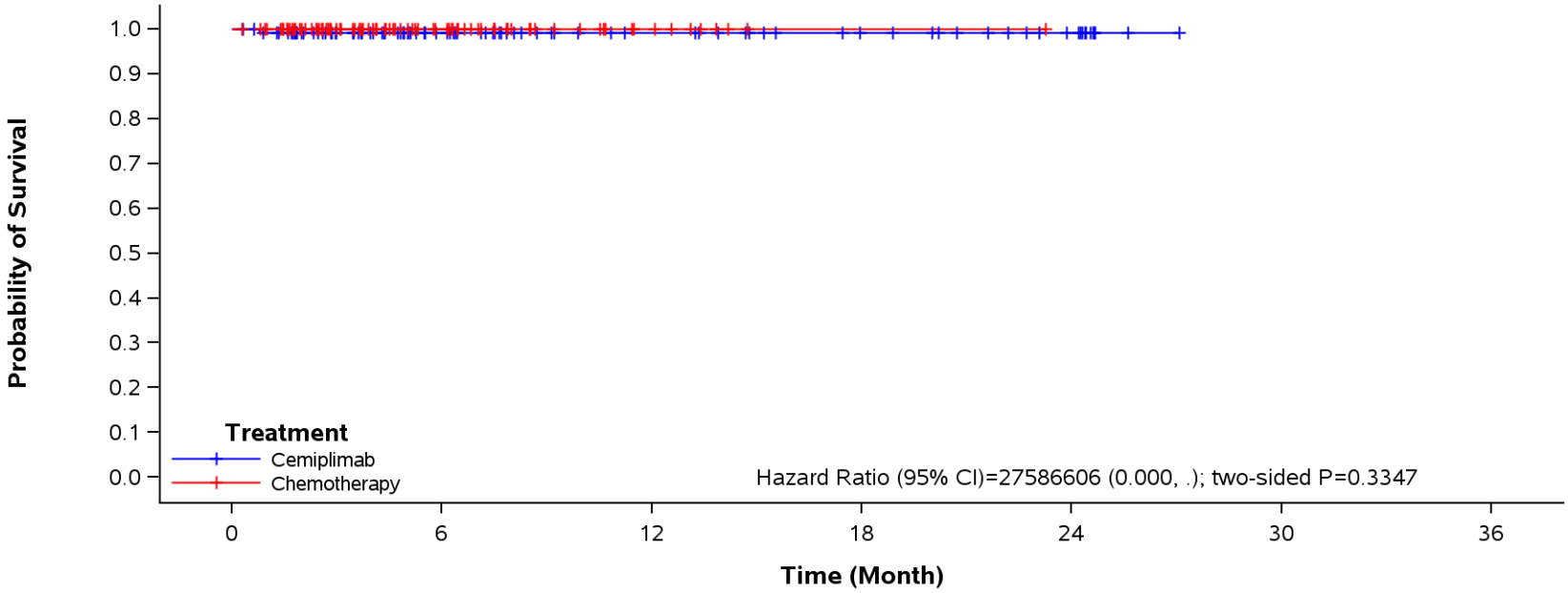

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Investigations
PT: Amylase increased



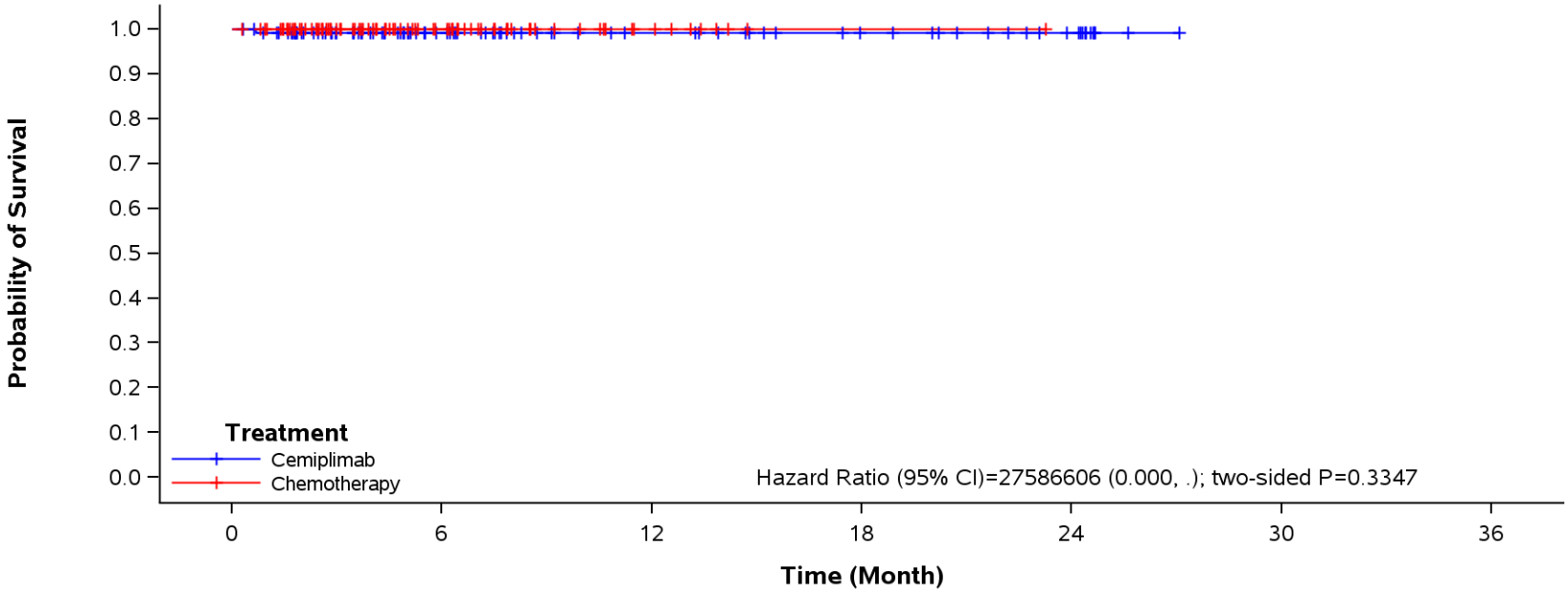

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Investigations
PT: Platelet count decreased



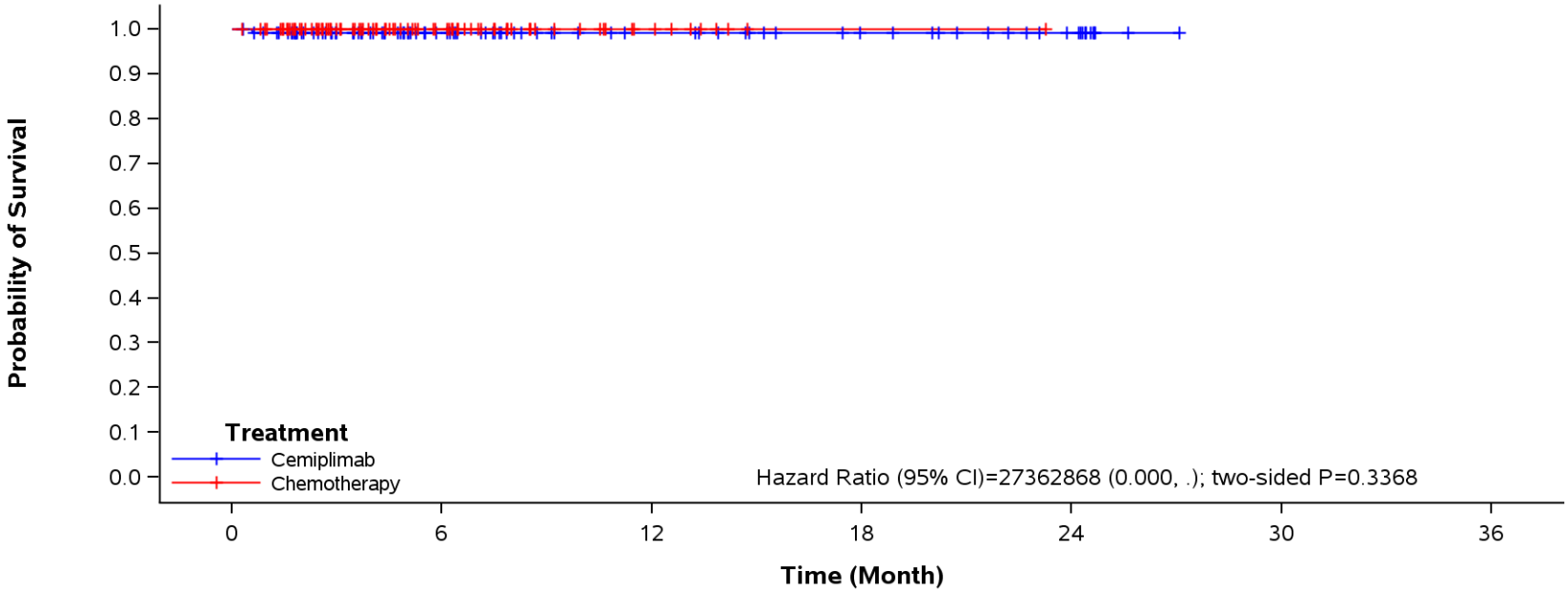

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Metabolism and nutrition disorders



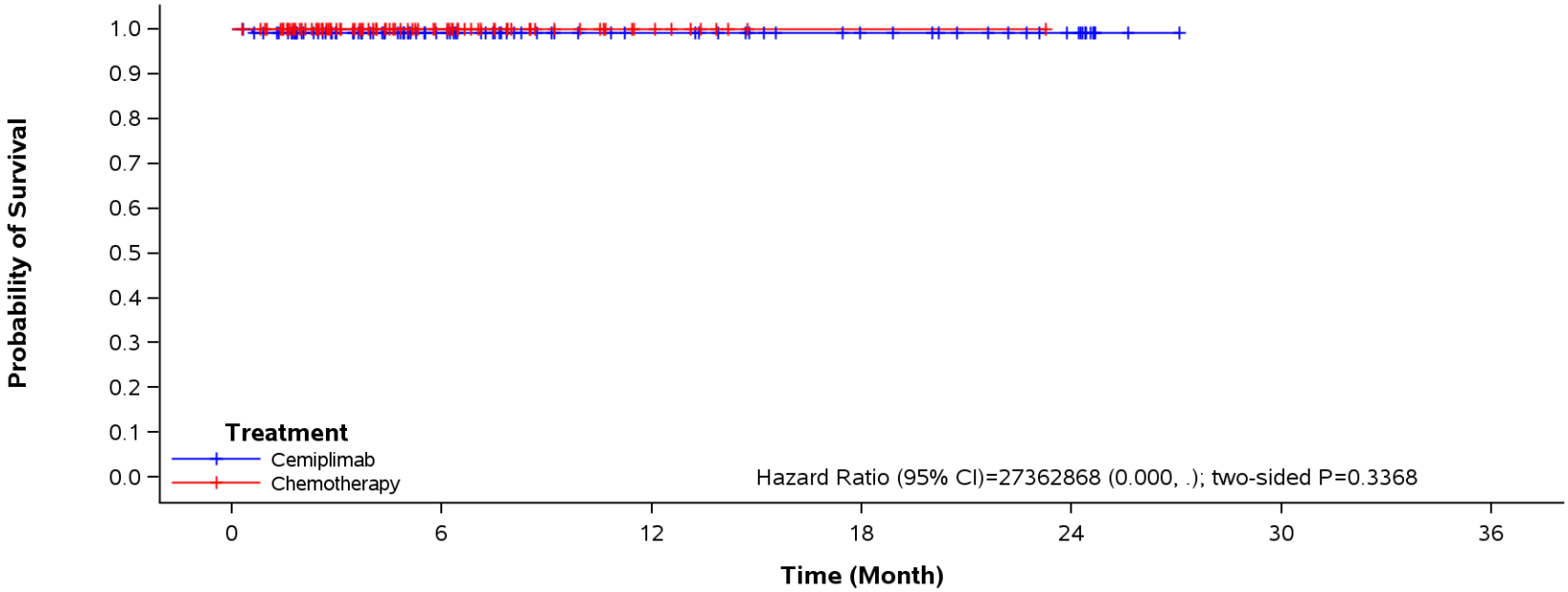

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



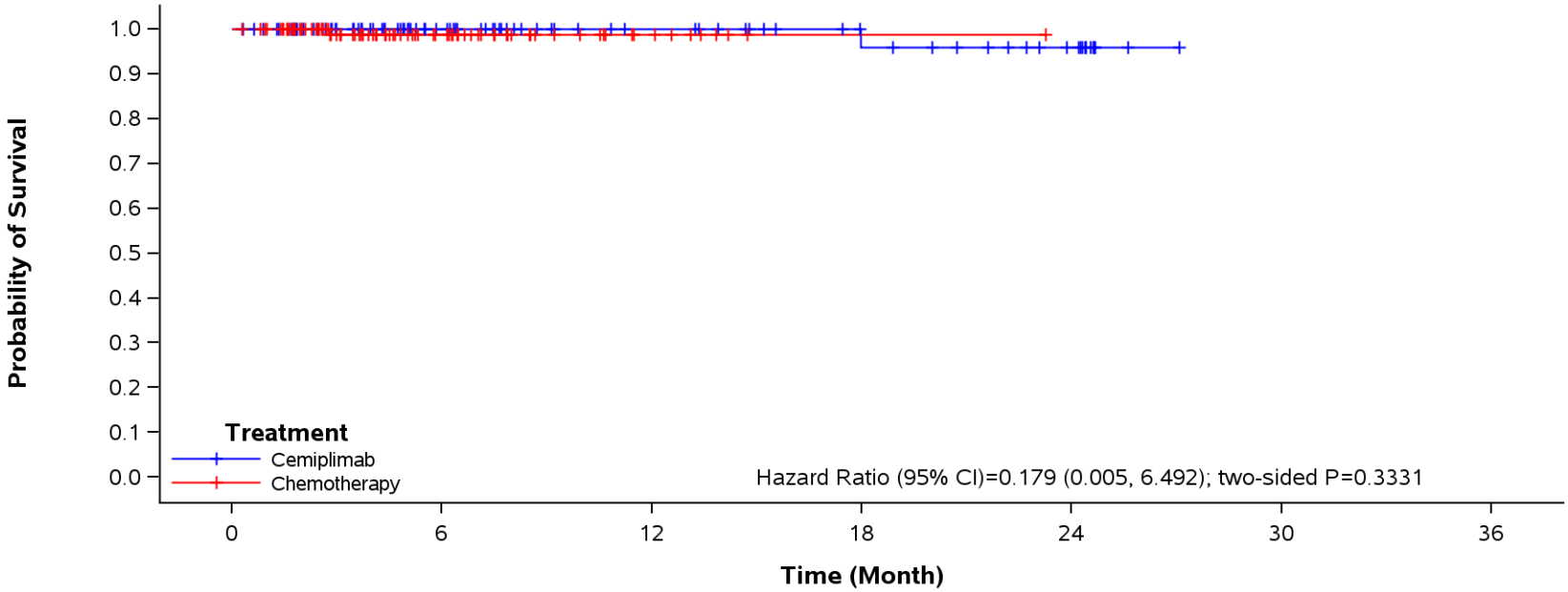

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Musculoskeletal and connective tissue disorders



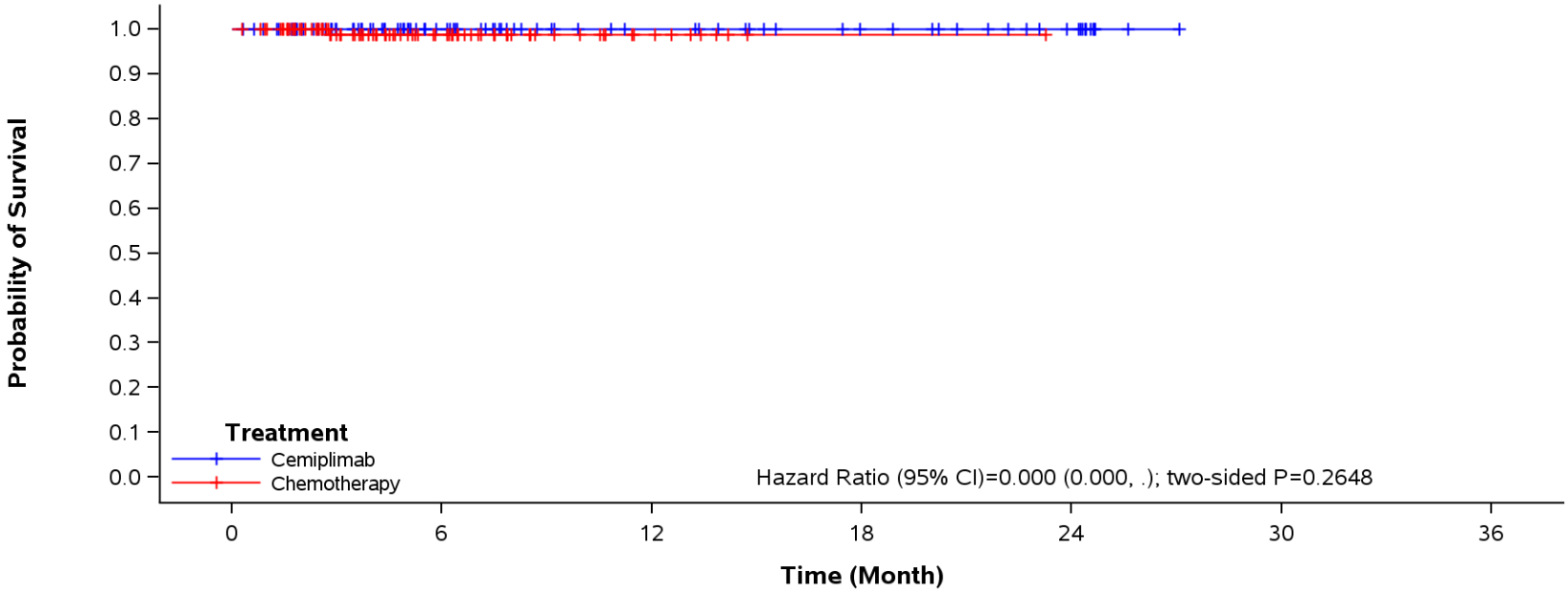

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 24 | 16 | 0 | 0 |
| Chemotherapy | 109 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



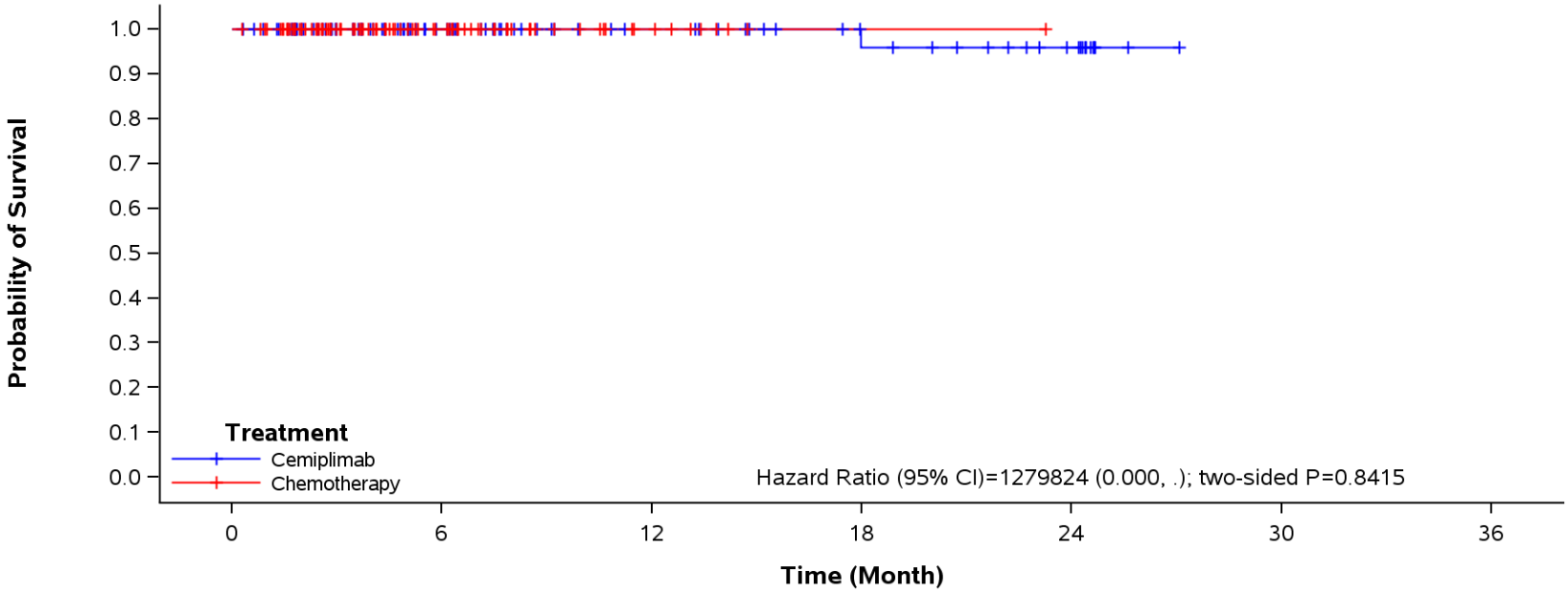

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 35 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



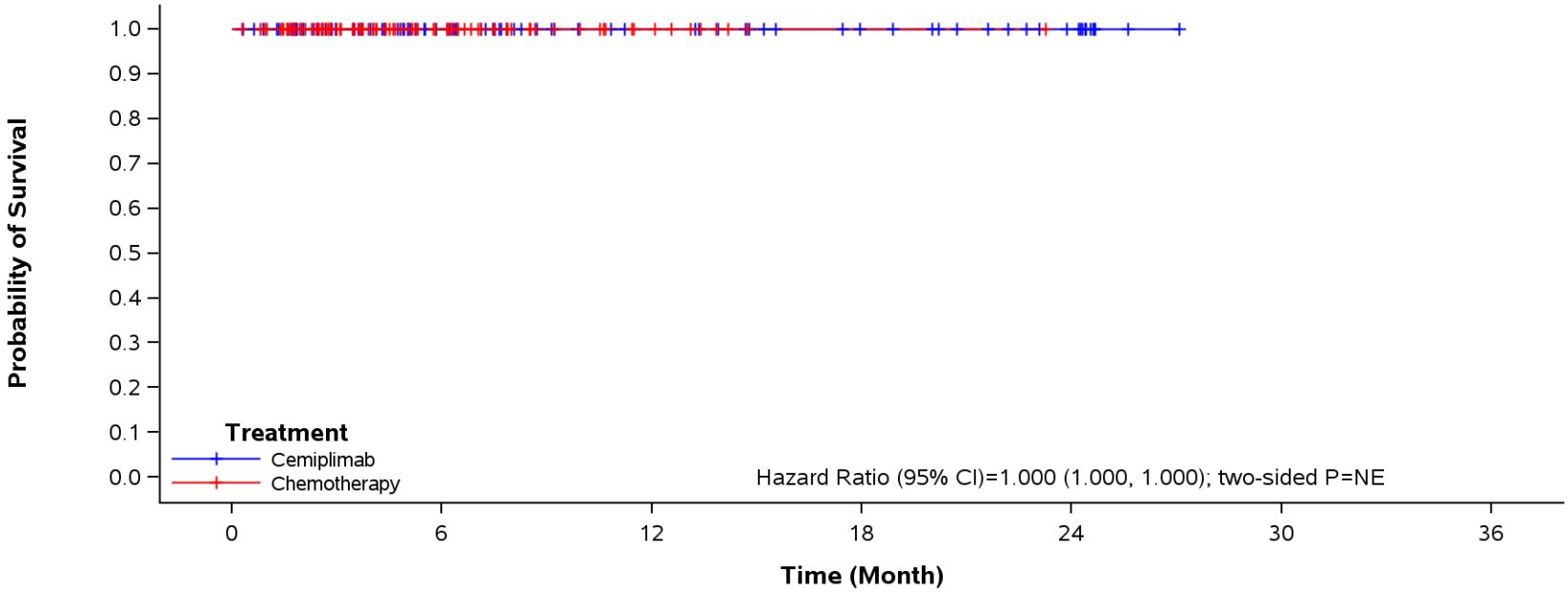

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 24 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Nervous system disorders



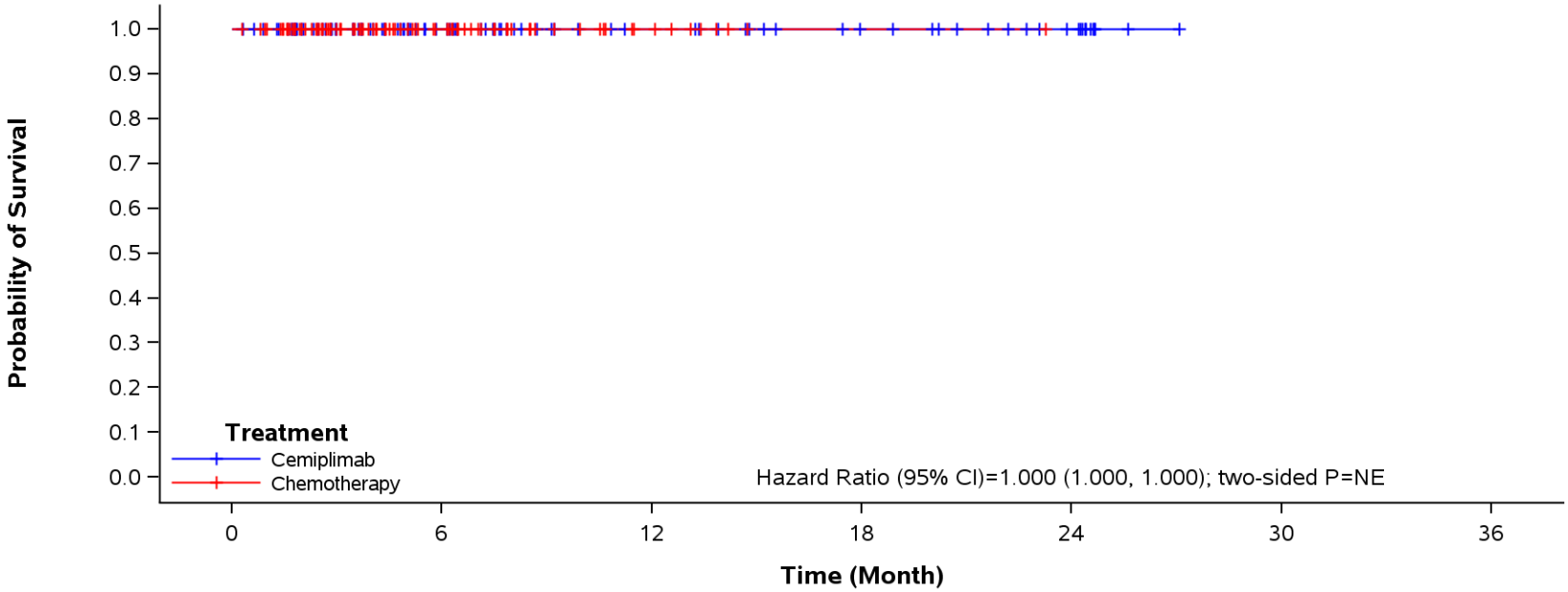

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Nervous system disorders
PT: Neurotoxicity



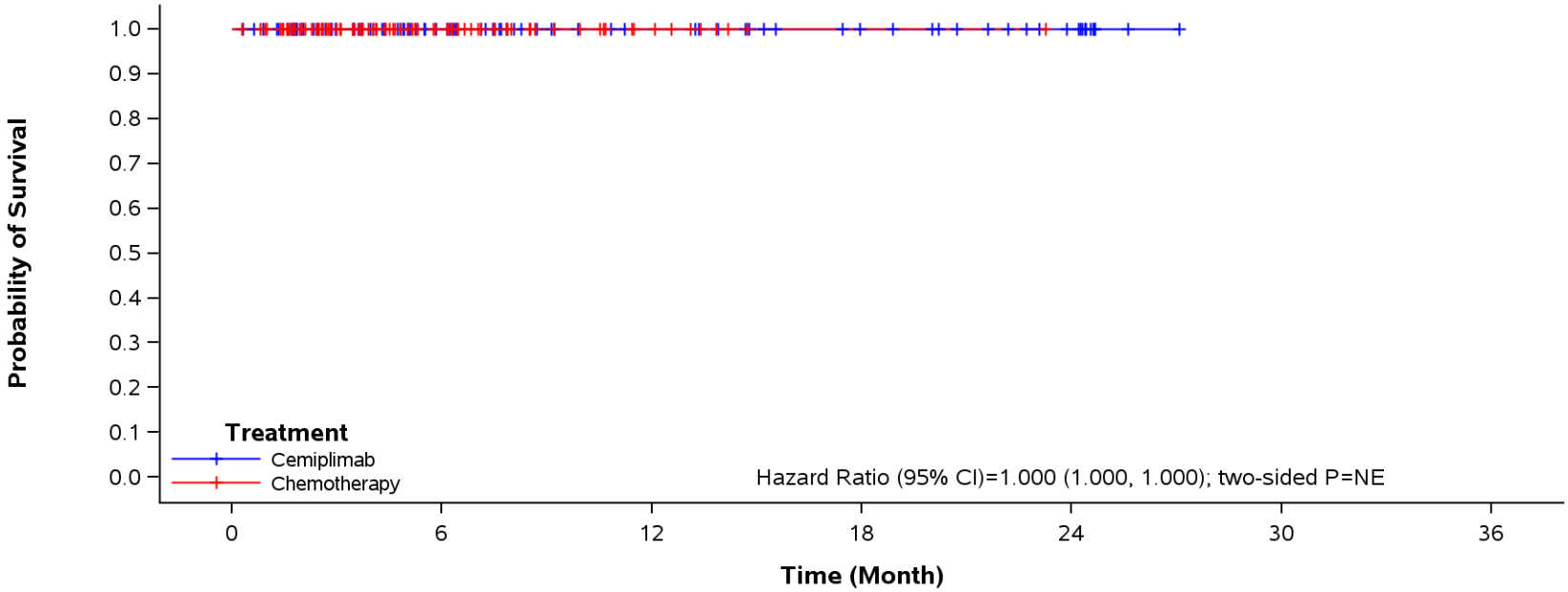

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Nervous system disorders
PT: Transient ischaemic attack



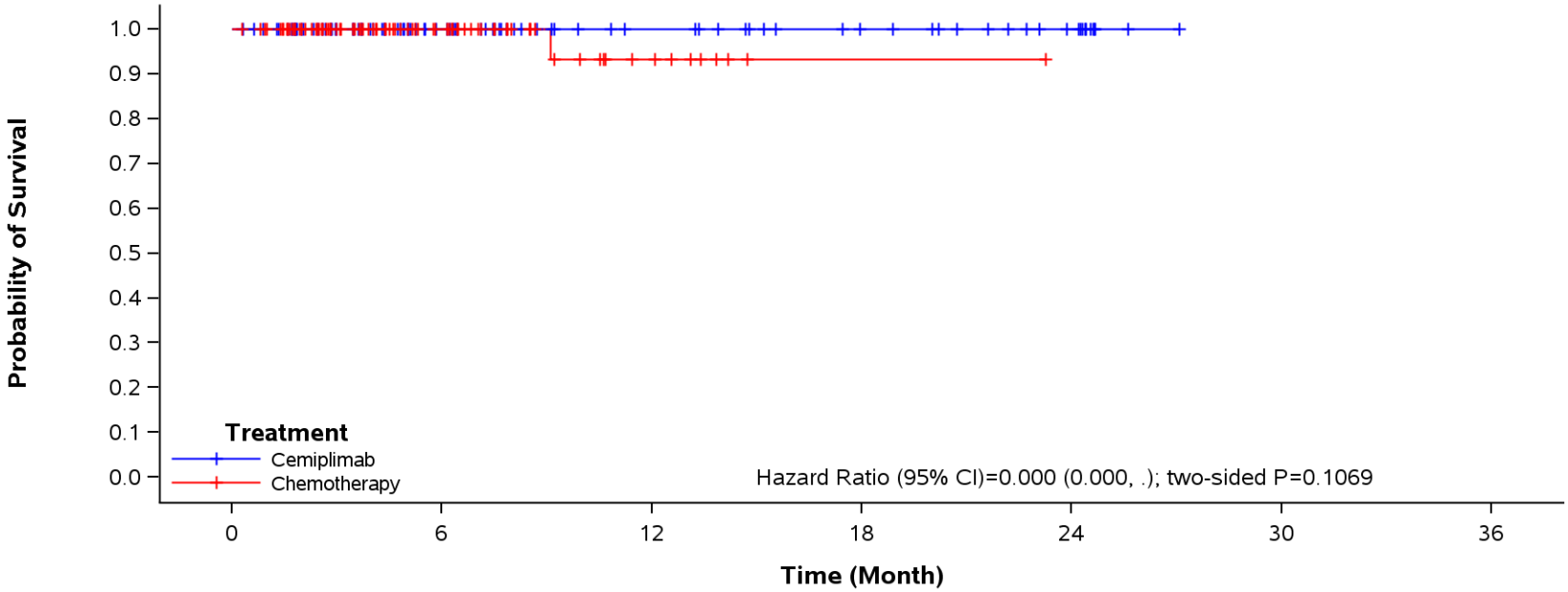

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Psychiatric disorders



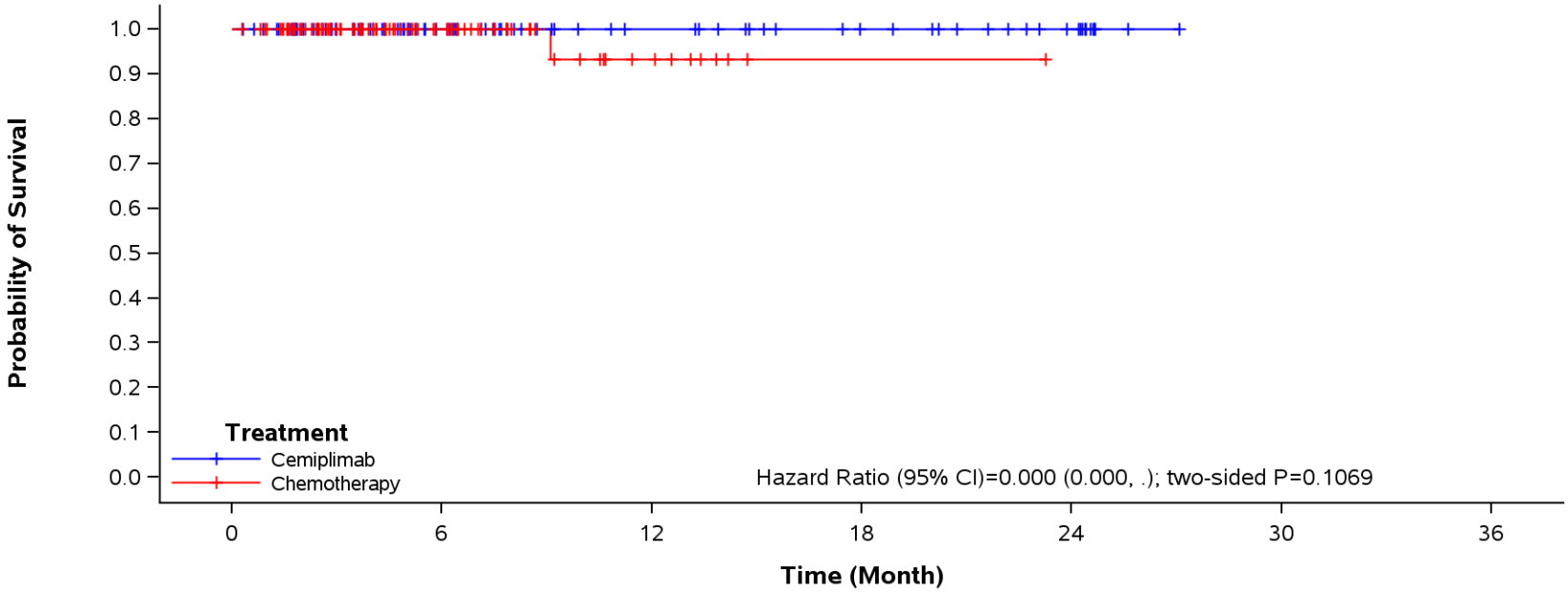

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Psychiatric disorders
PT: Agoraphobia



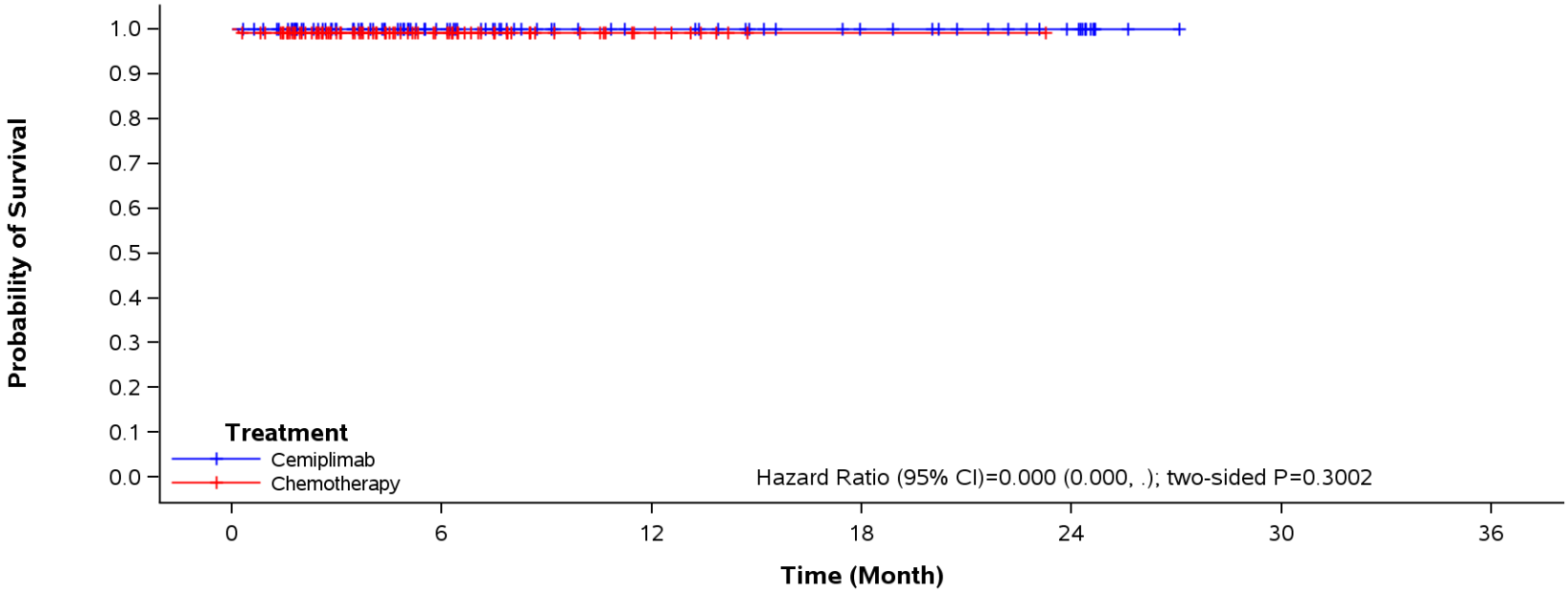

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Renal and urinary disorders



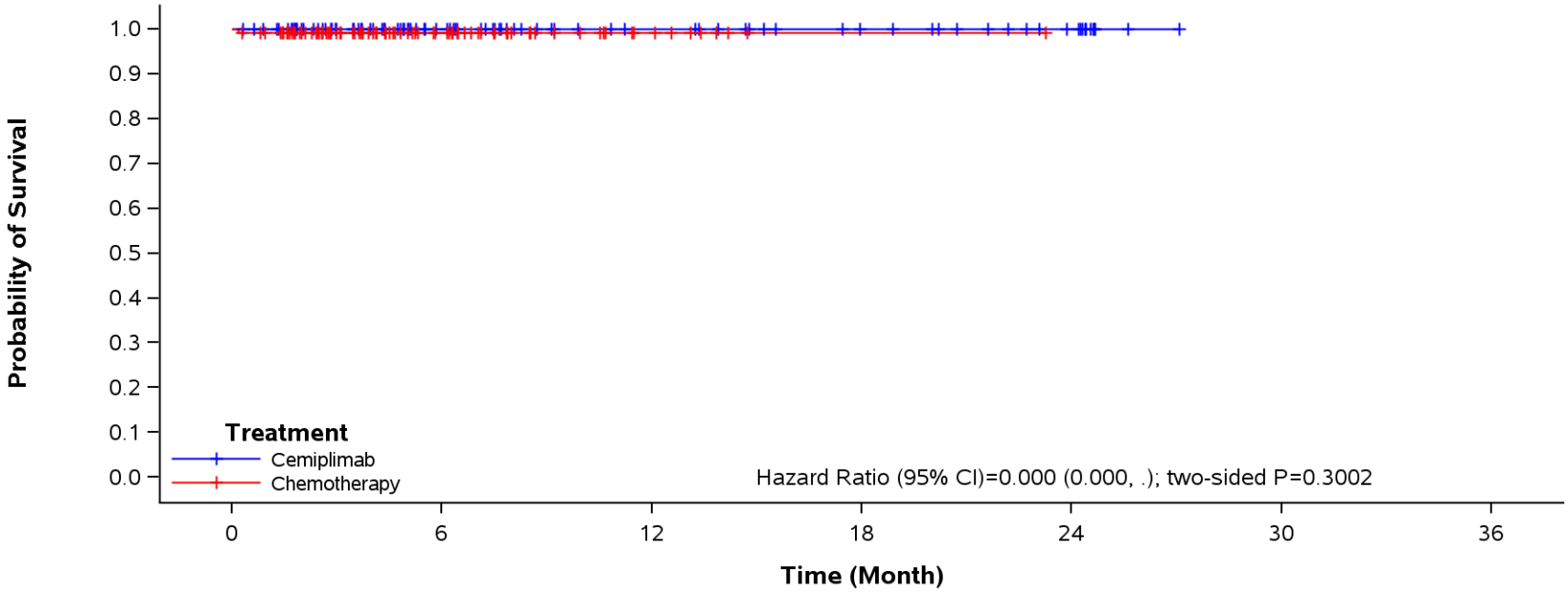

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Renal and urinary disorders
PT: Renal failure



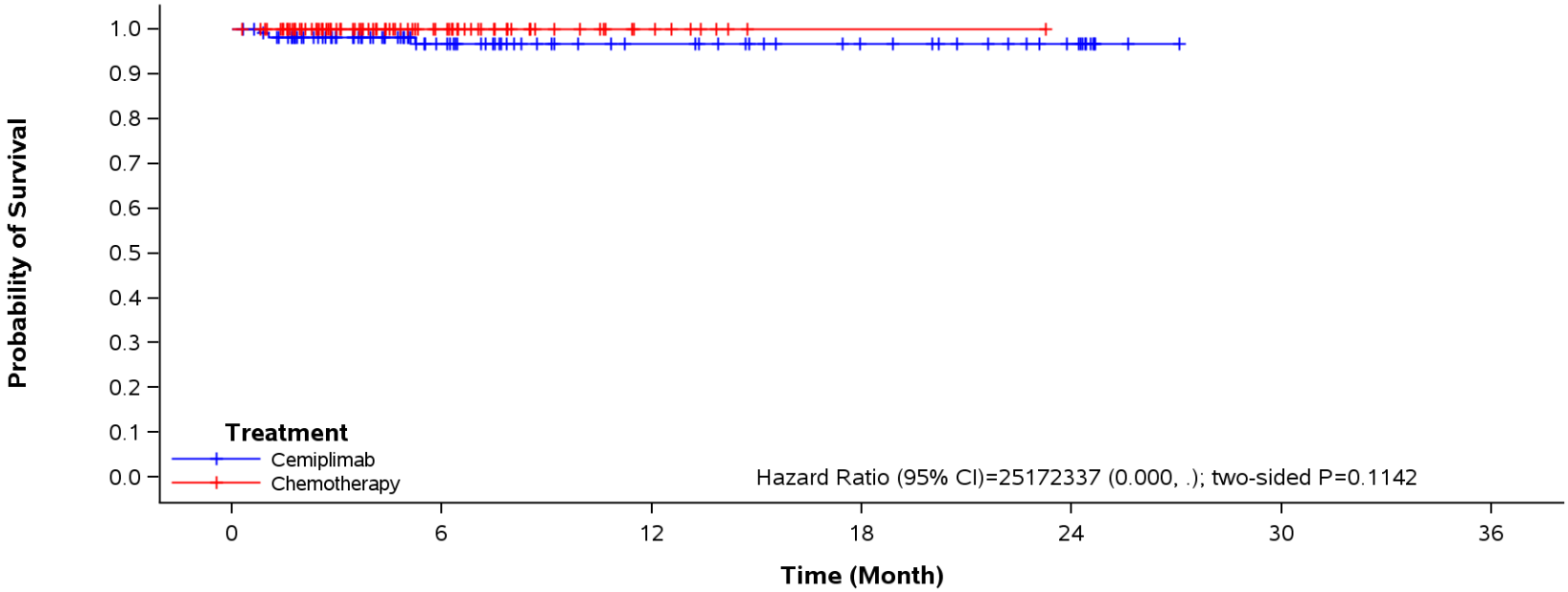

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Respiratory, thoracic and mediastinal disorders



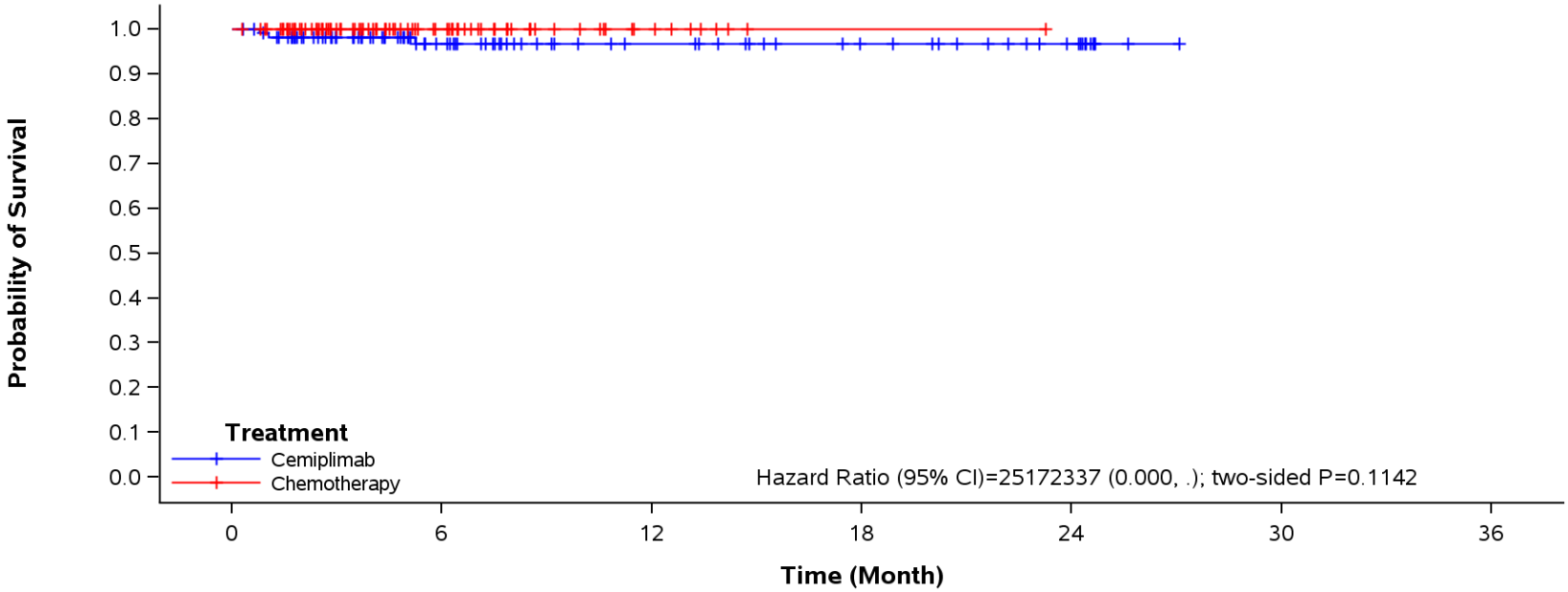

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



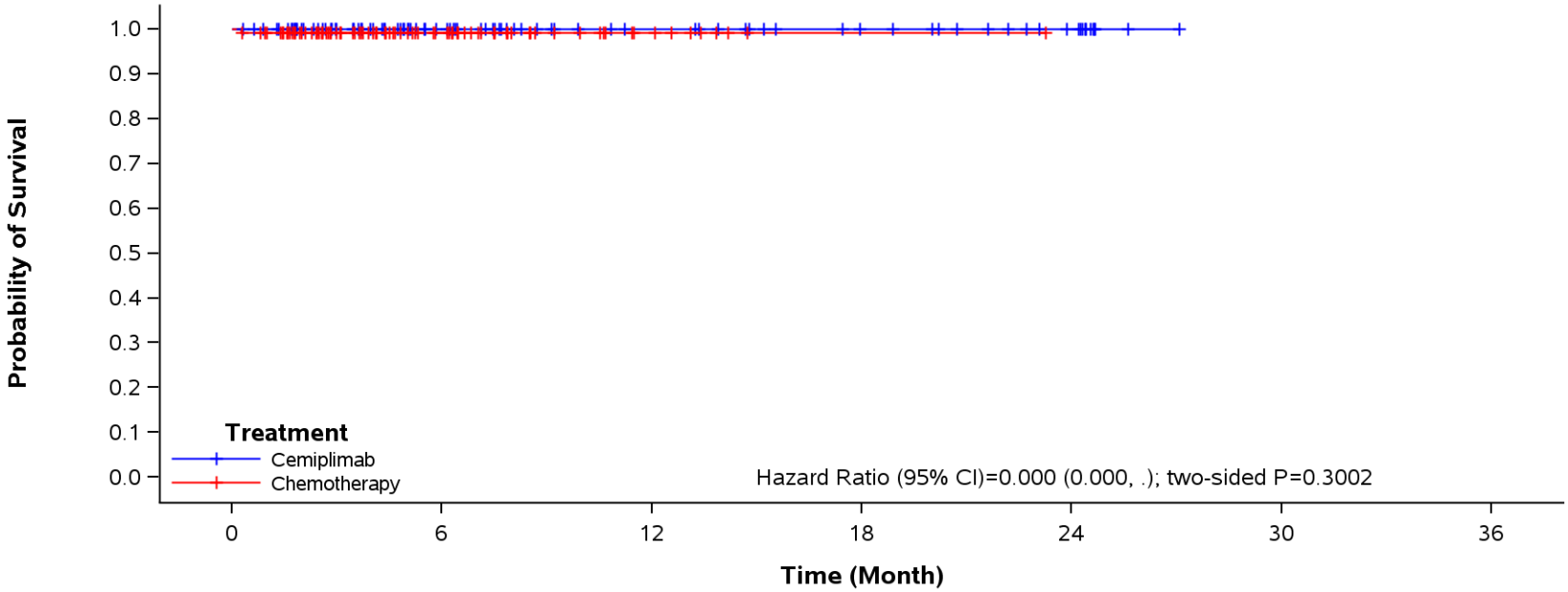

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 56 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Vascular disorders



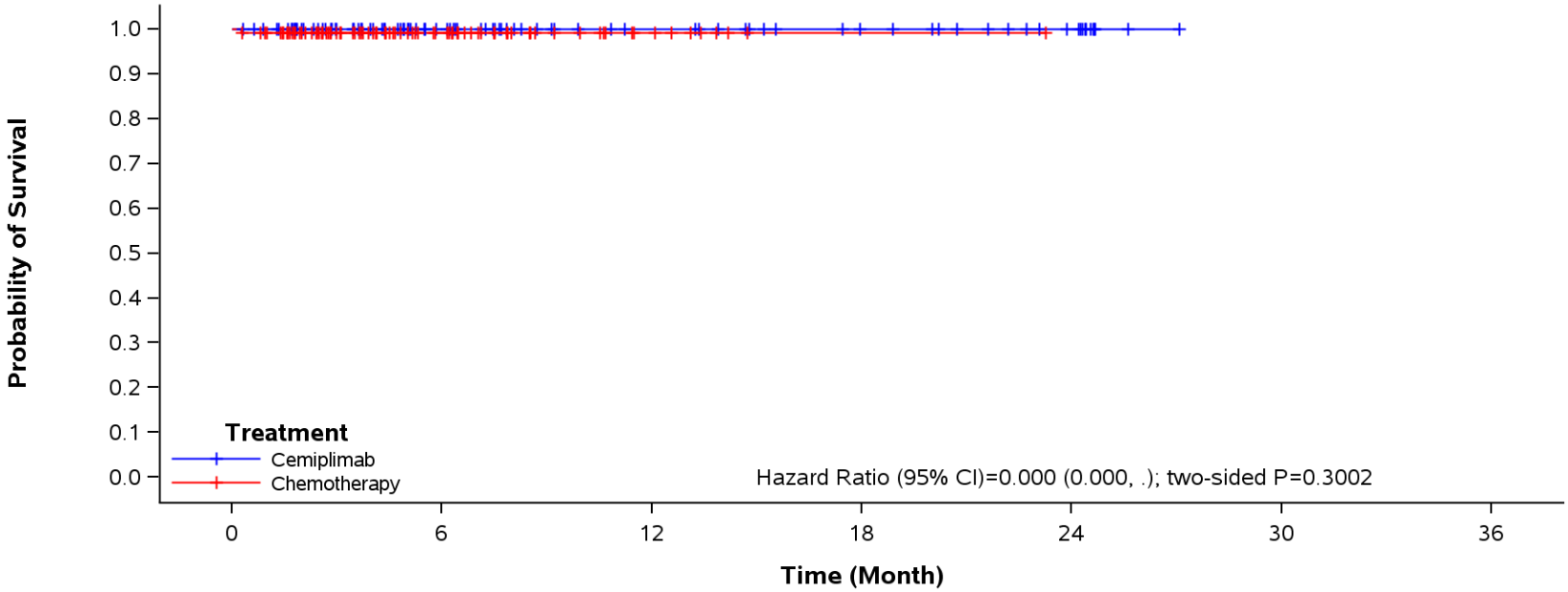

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Pemetrexed
SOC: Vascular disorders
PT: Deep vein thrombosis



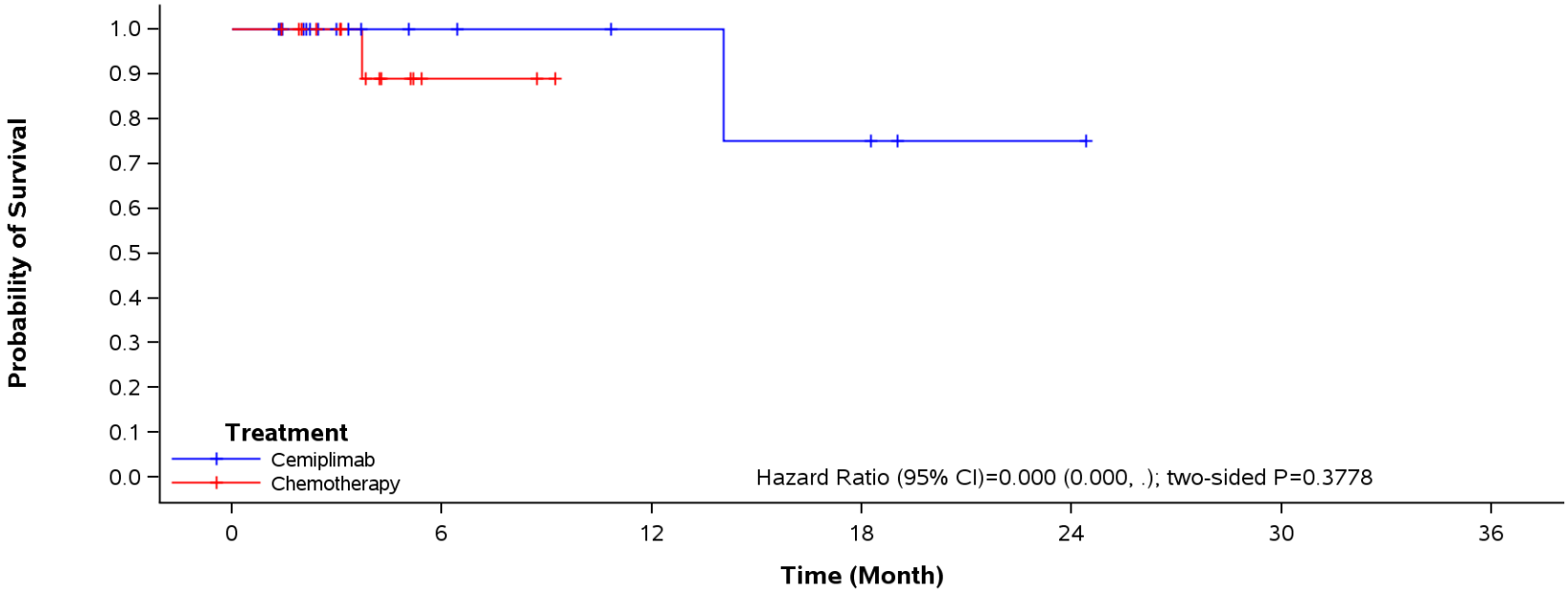

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 117 | 57 | 34 | 25 | 16 | 0 | 0 |
| Chemotherapy | 109 | 36 | 8 | 1 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
Number of patients with any TEAE leading to discontinuation



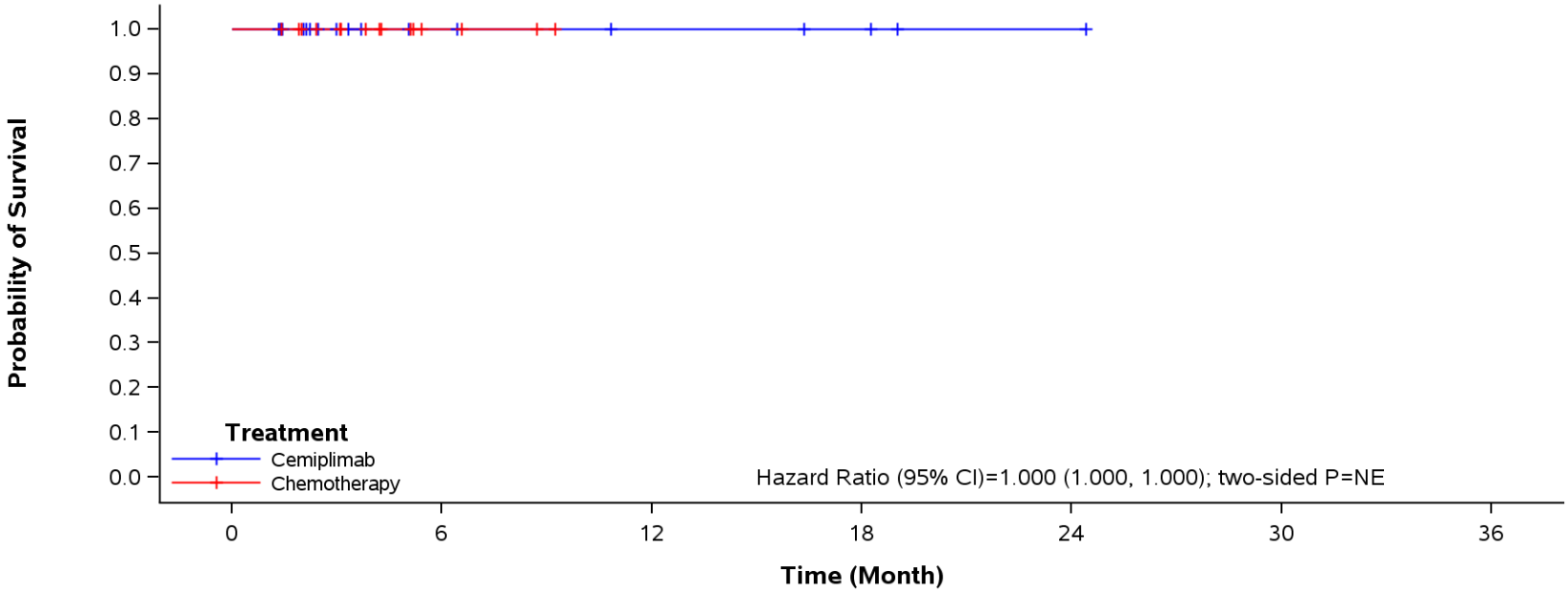

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders



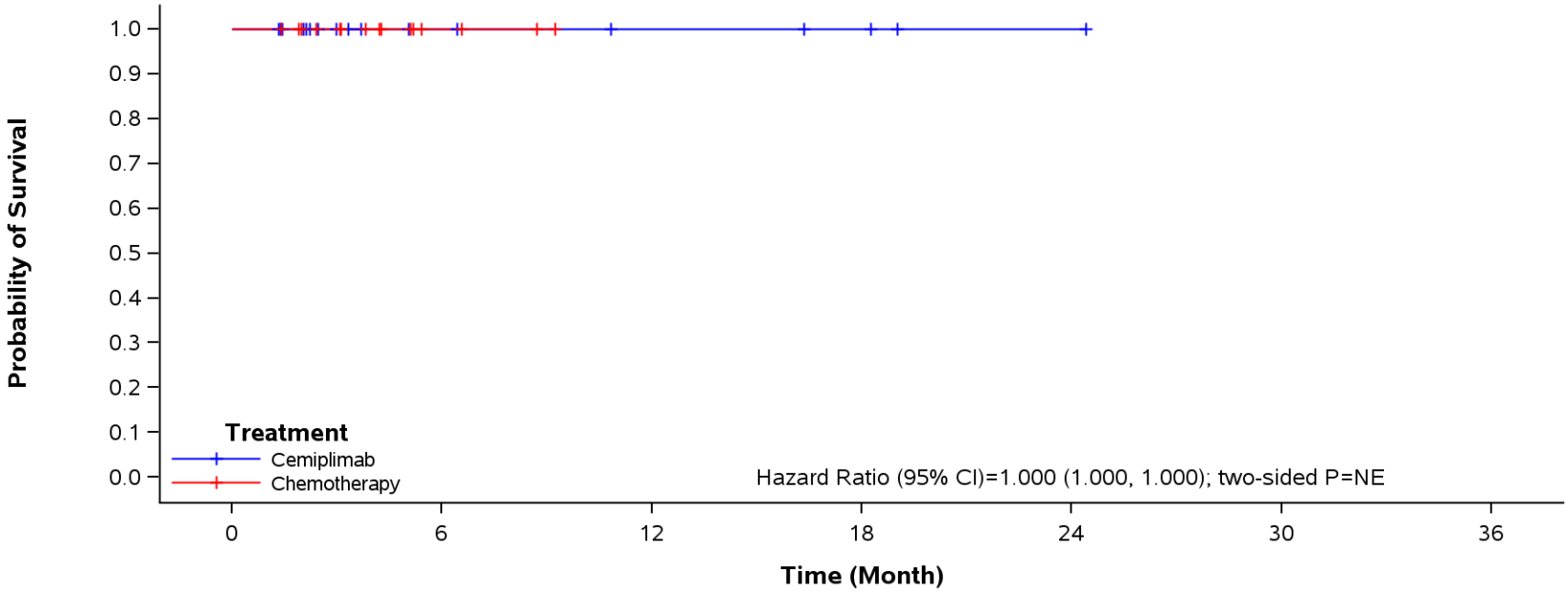

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Anaemia



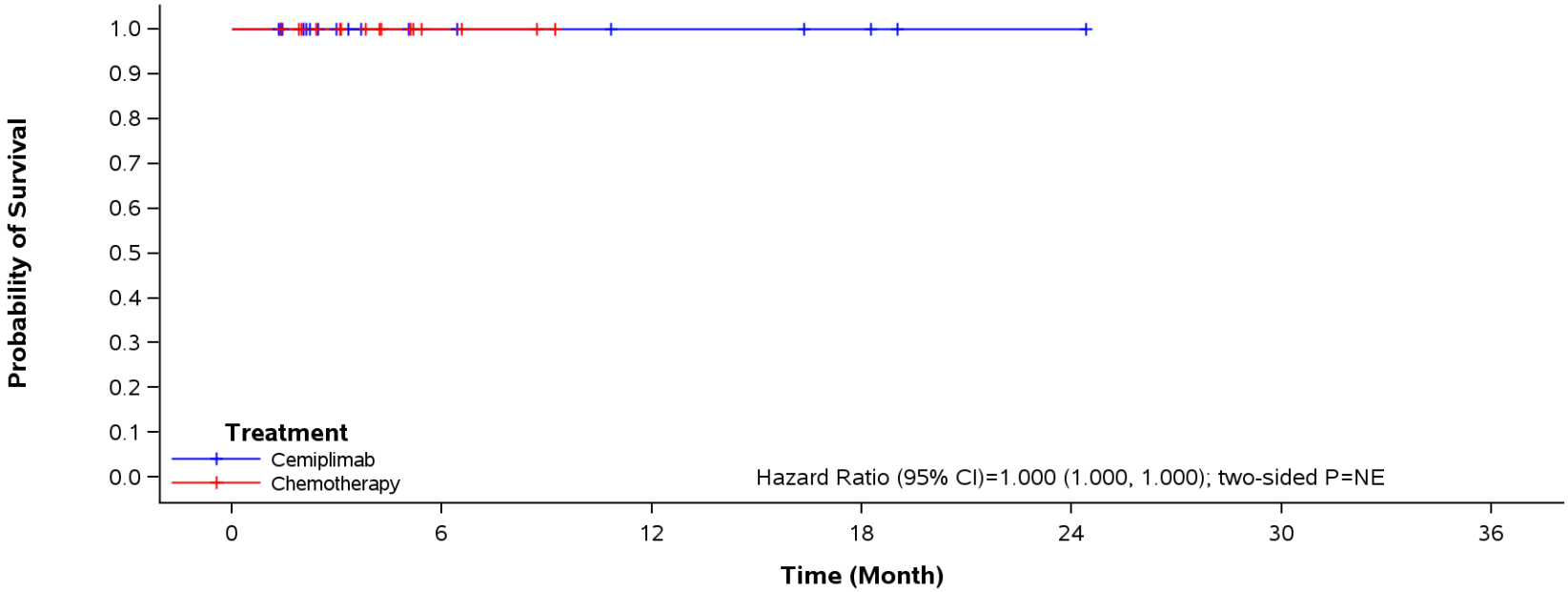

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



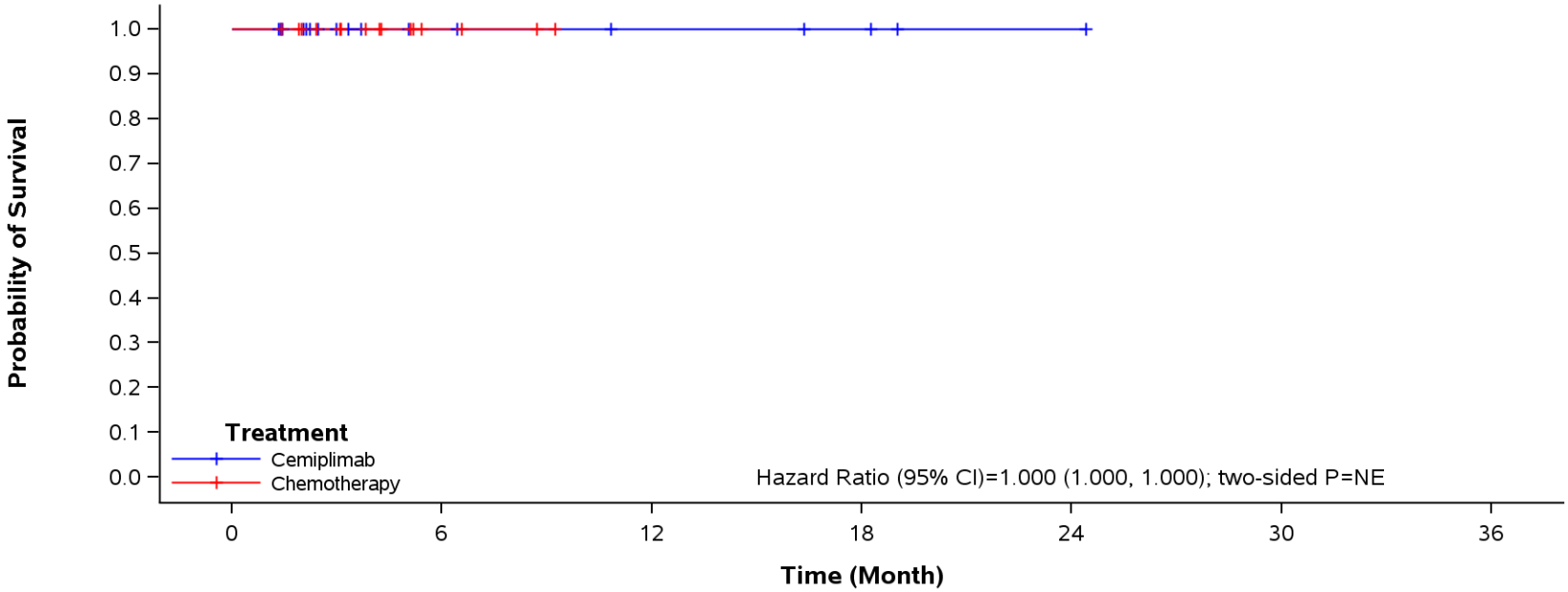

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Neutropenia



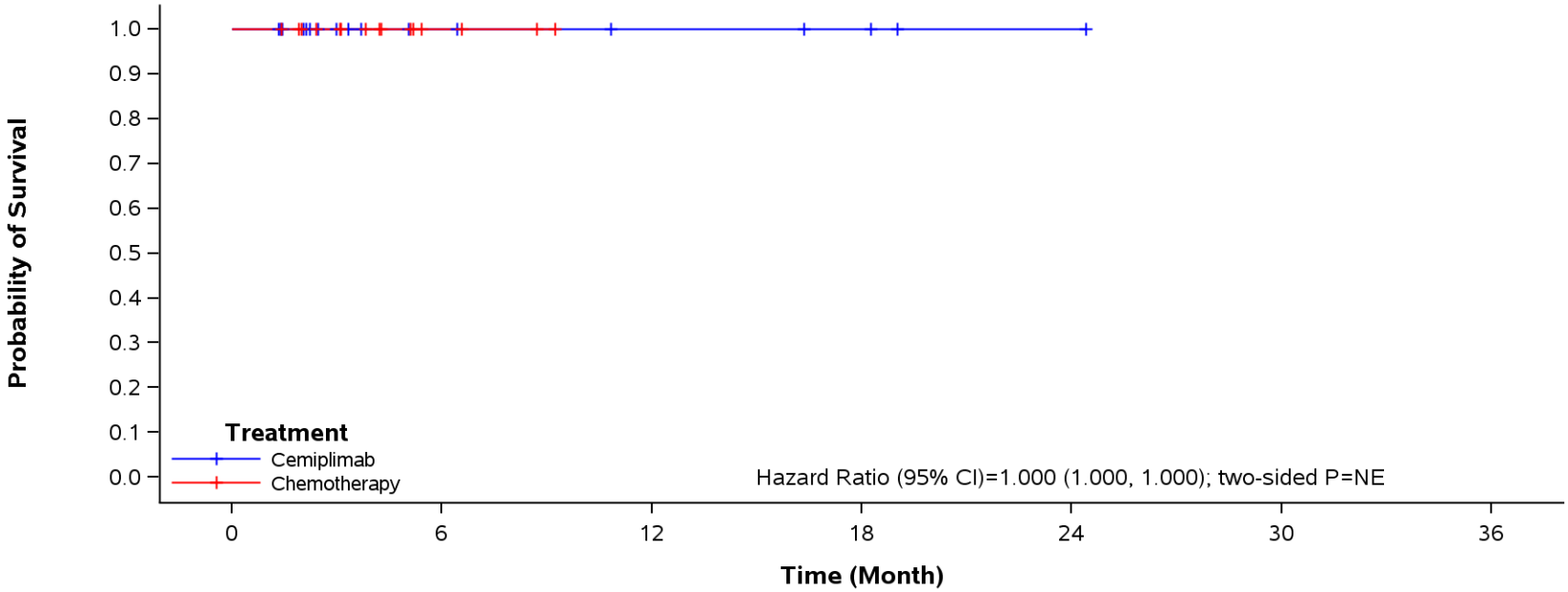

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



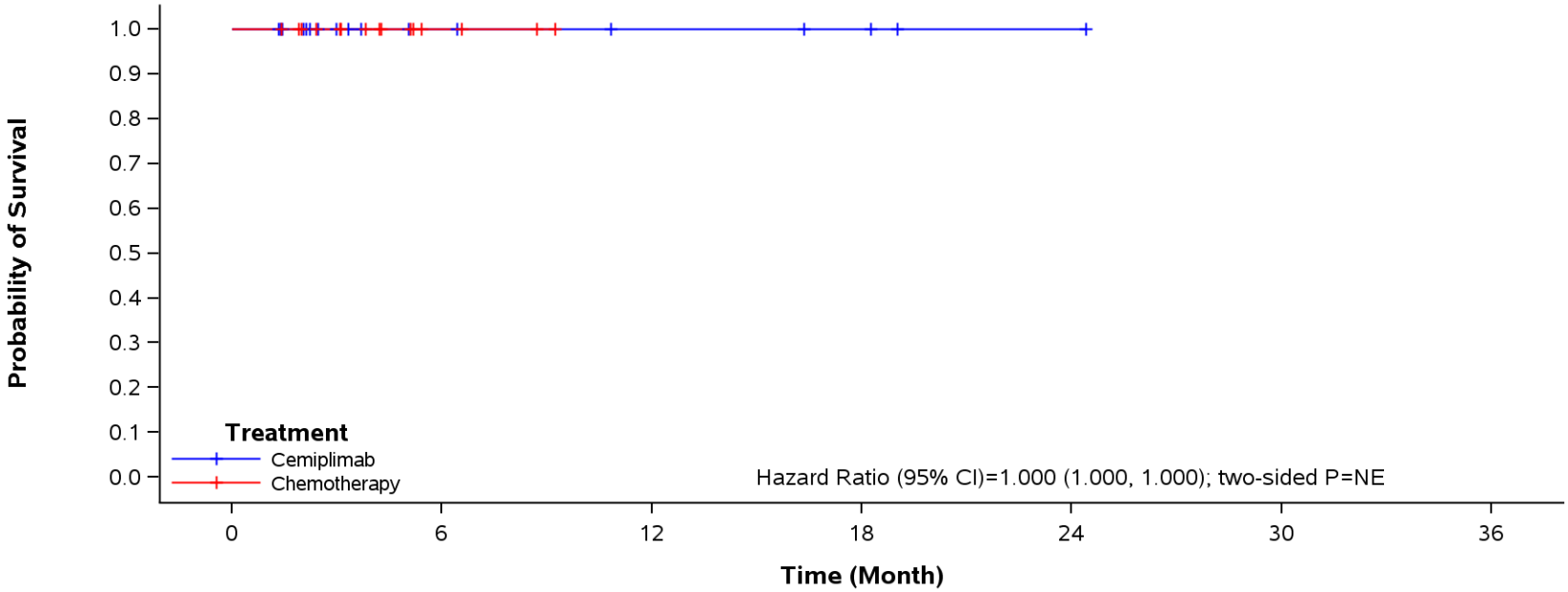

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Cardiac disorders



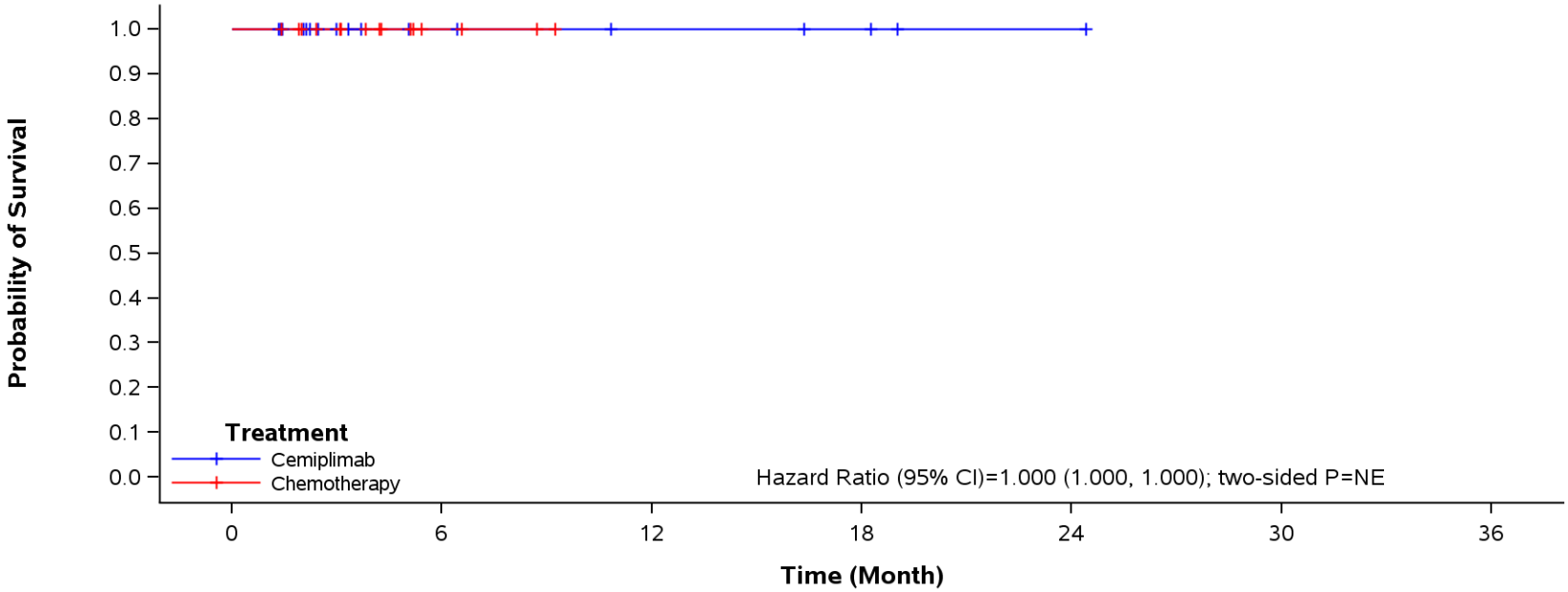

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Cardiac disorders
PT: Autoimmune pericarditis



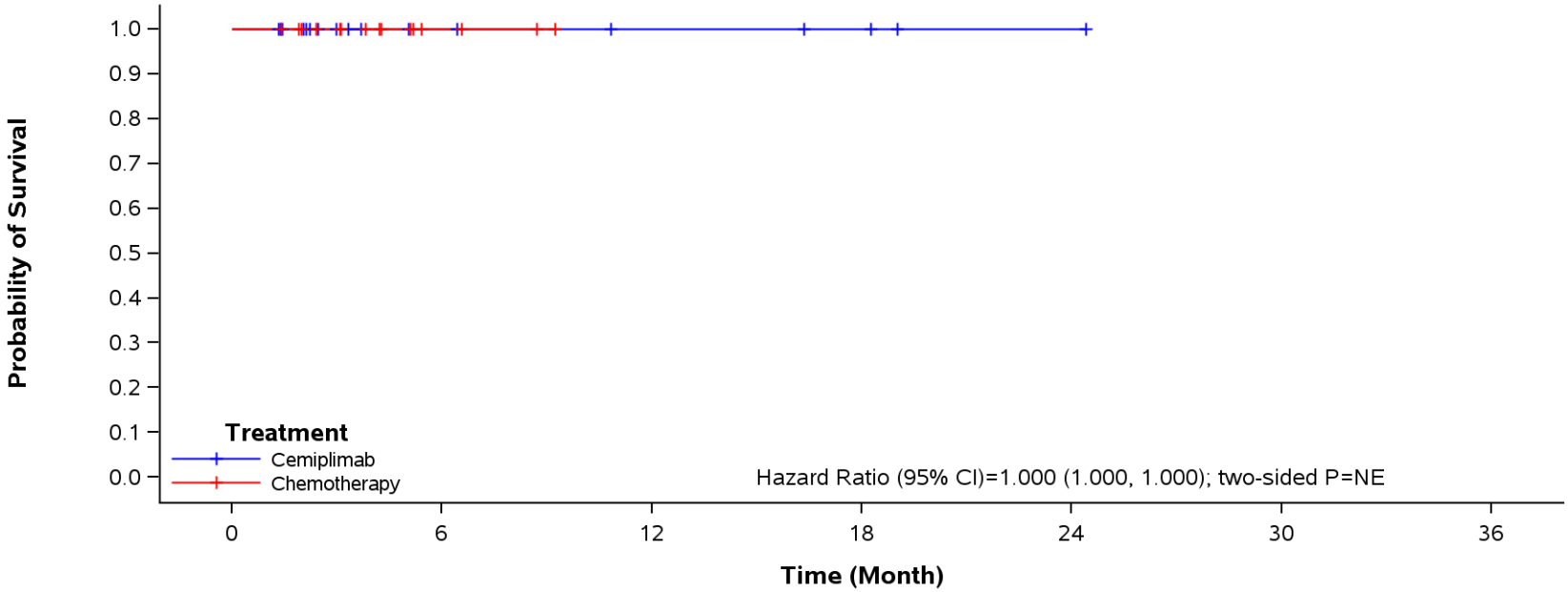

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Endocrine disorders



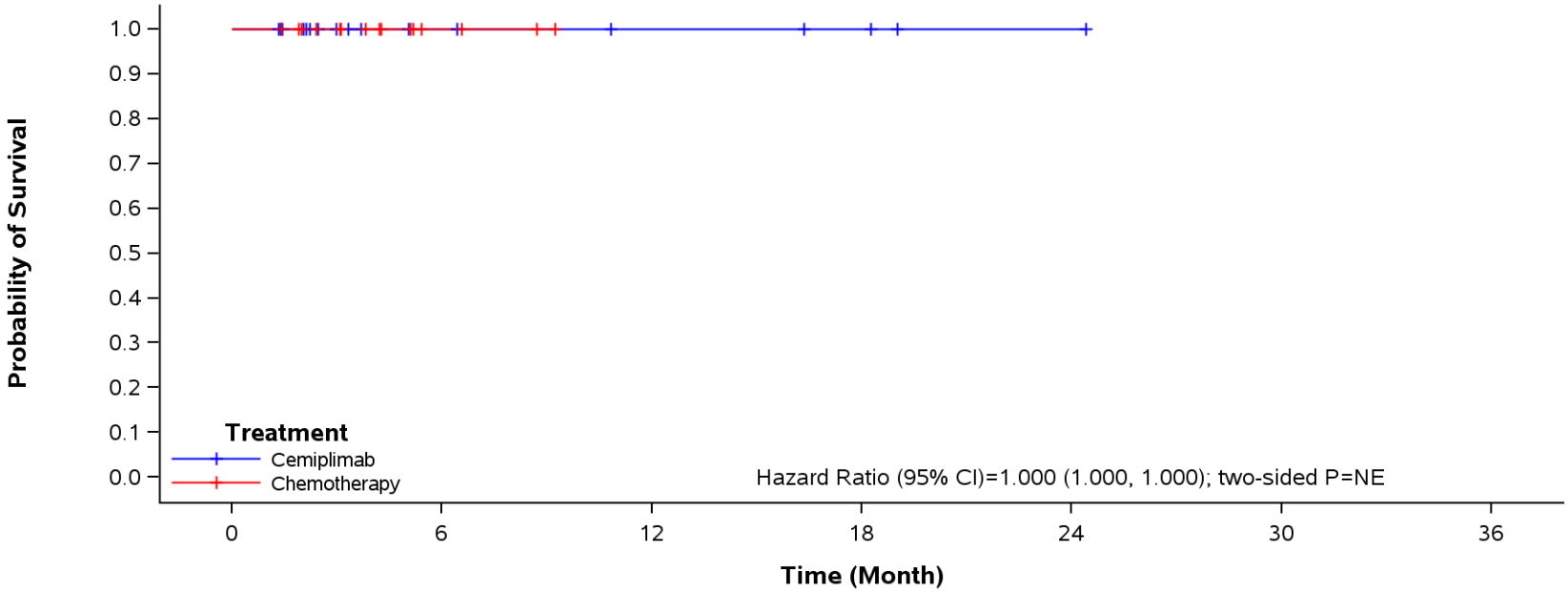

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Endocrine disorders
PT: Hypothyroidism



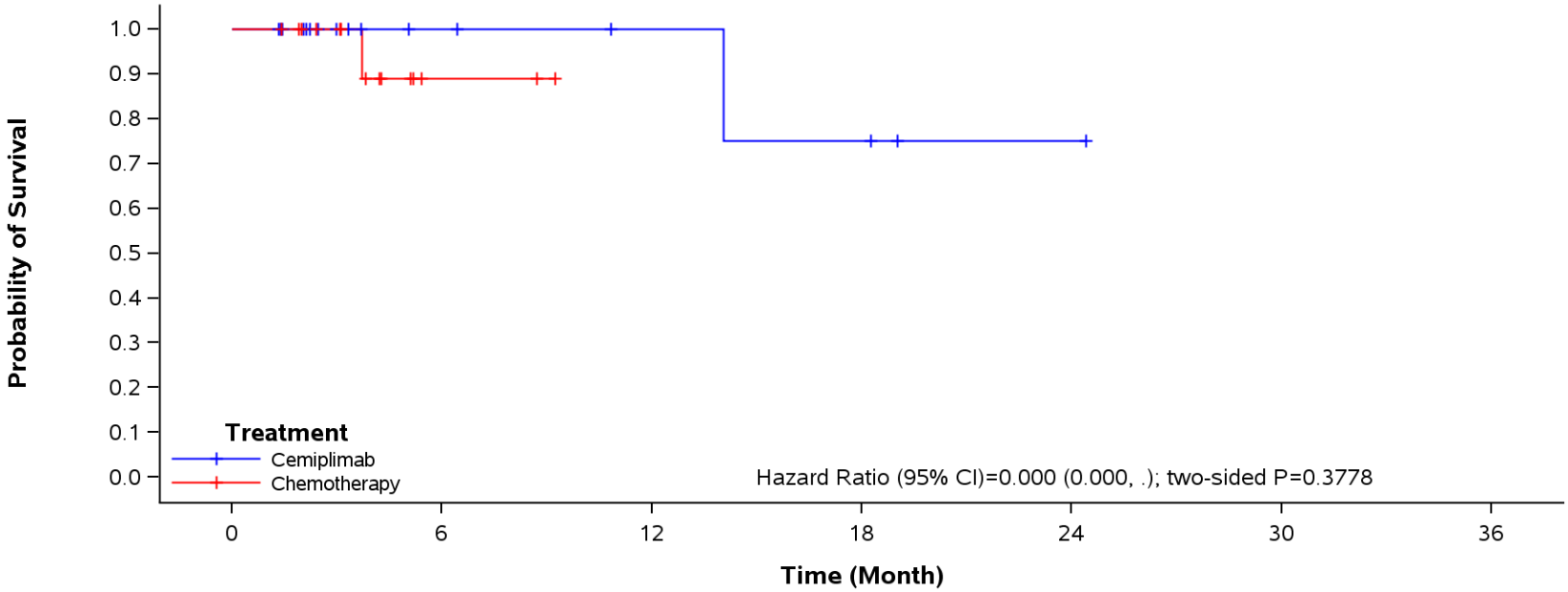

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders



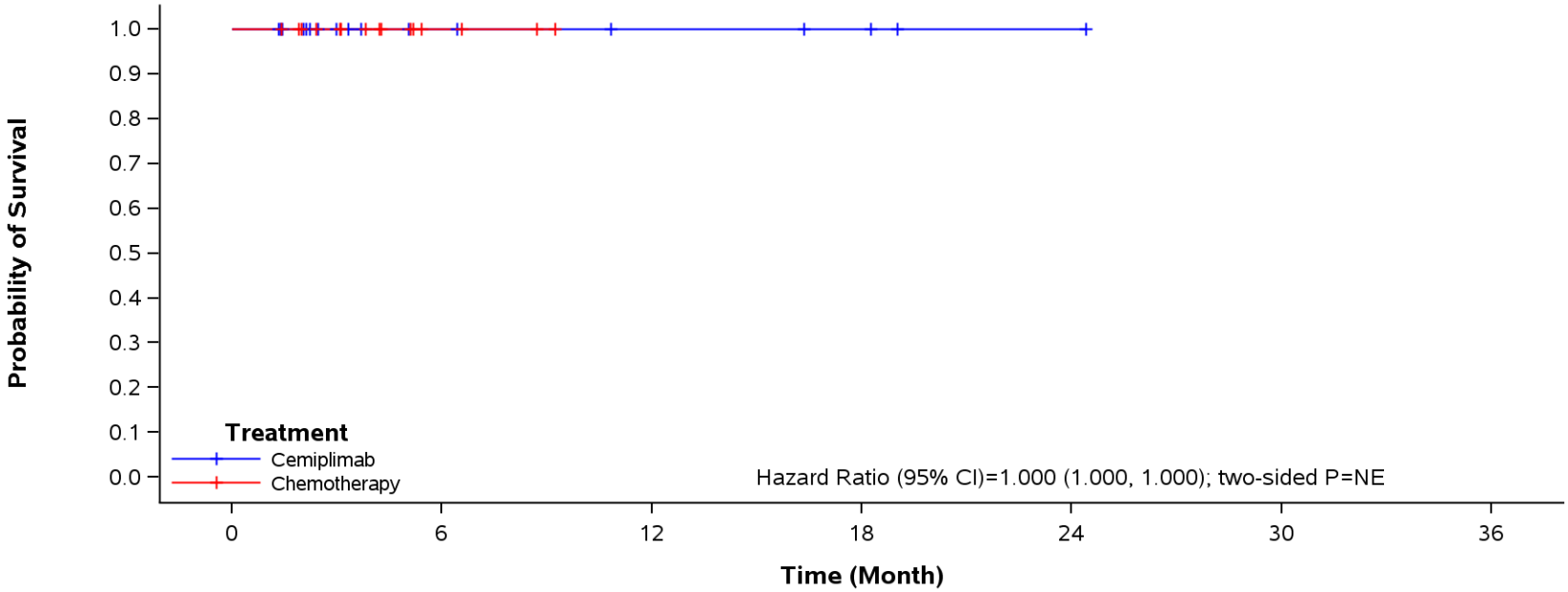

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders
PT: Colitis



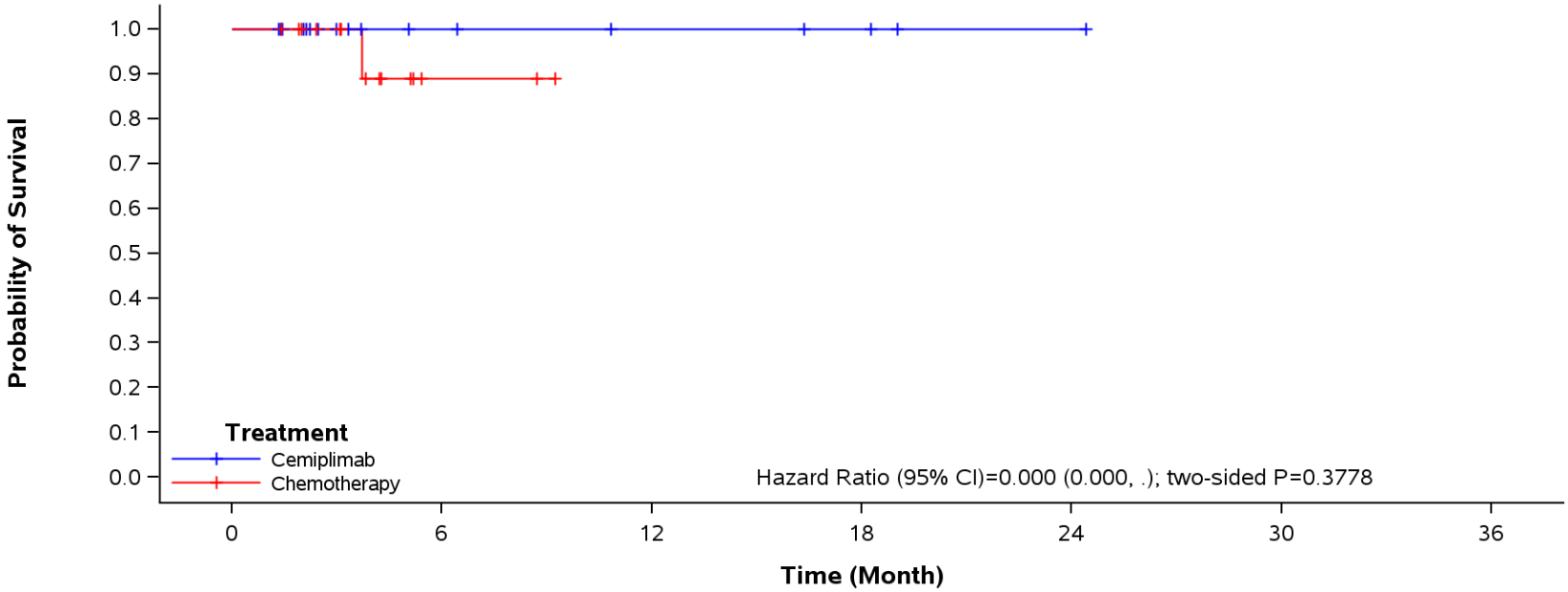

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders
PT: Diverticular perforation



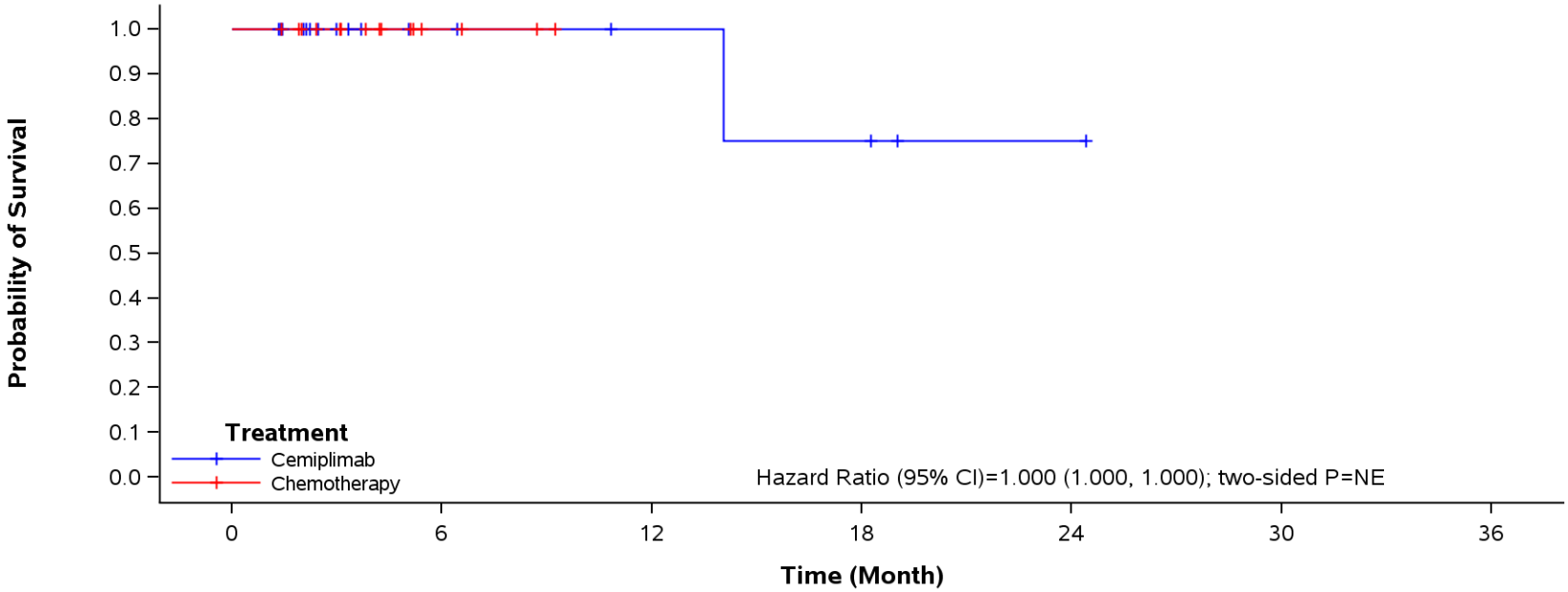

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 2 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders
PT: Pancreatic mass



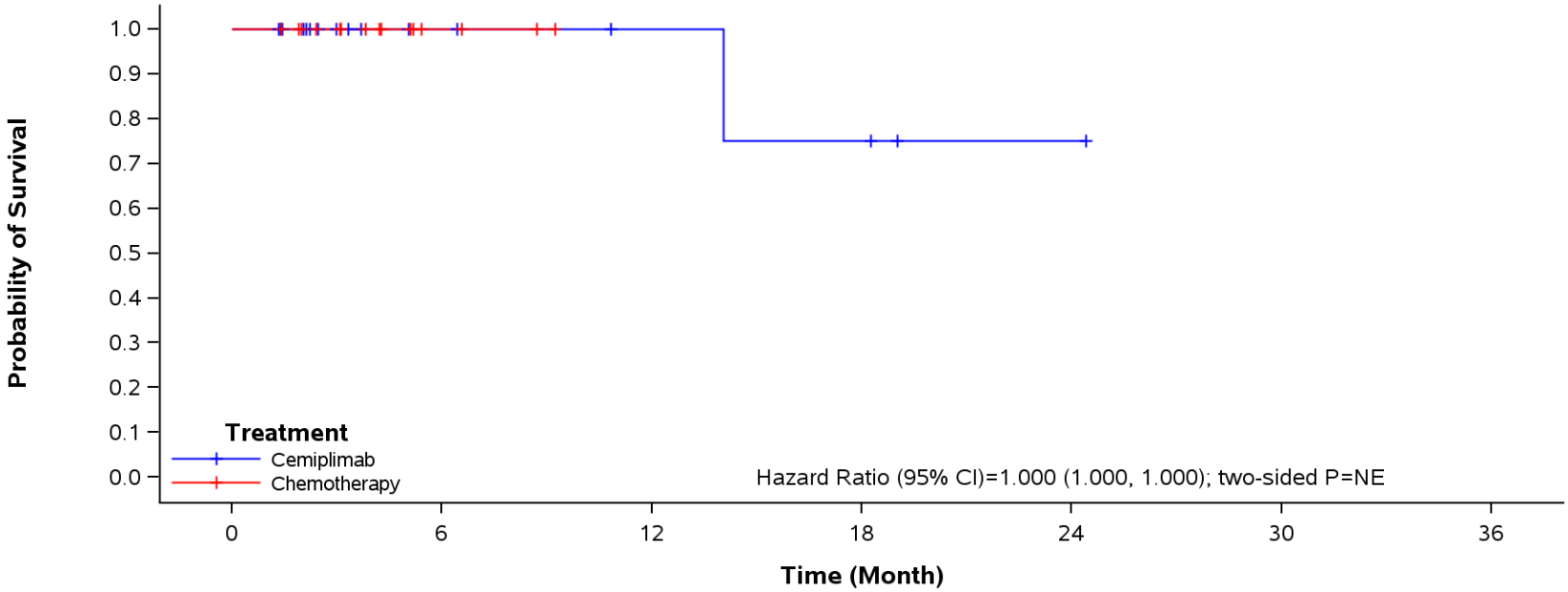

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



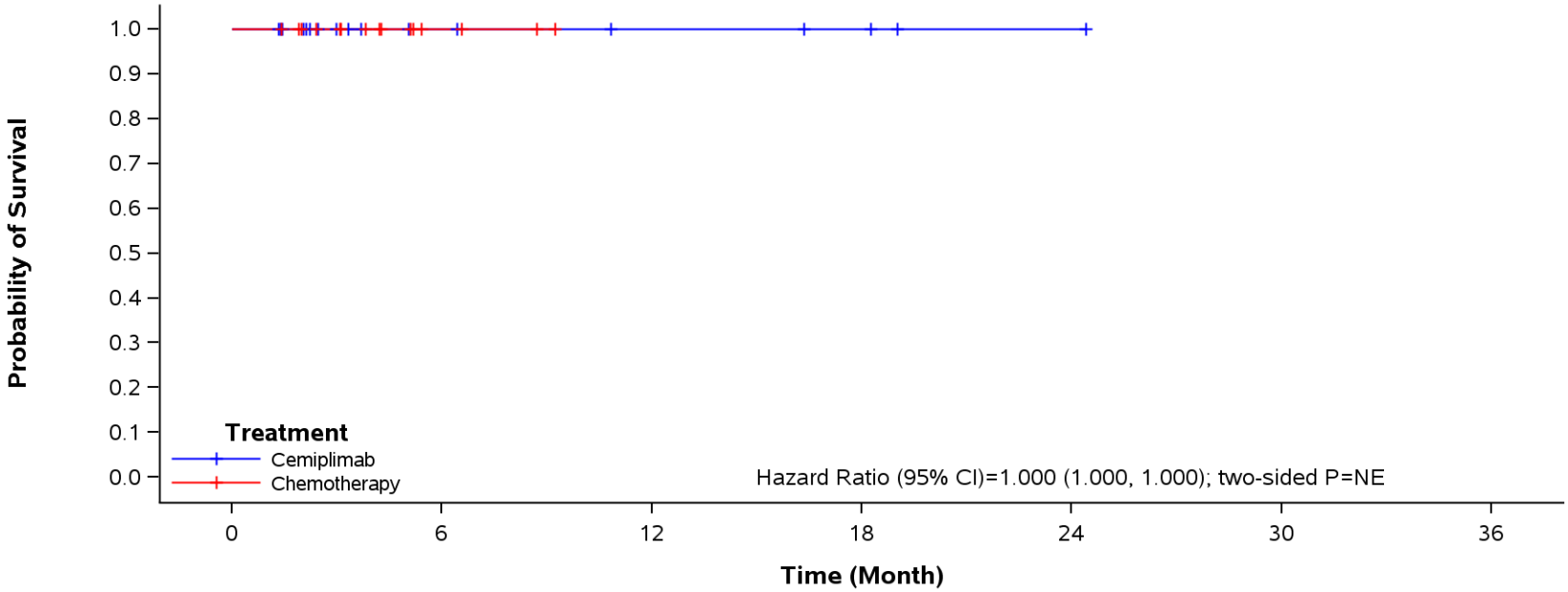

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Gastrointestinal disorders
PT: Proctalgia



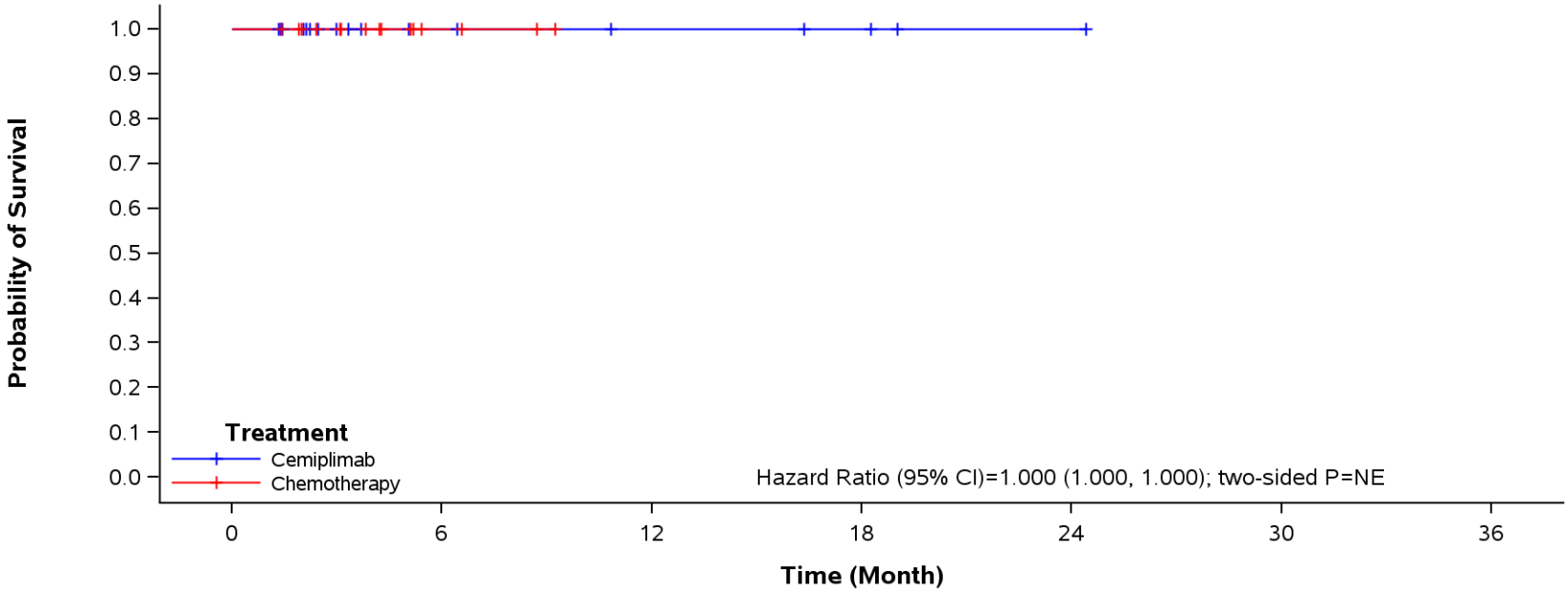

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: General disorders and administration site conditions



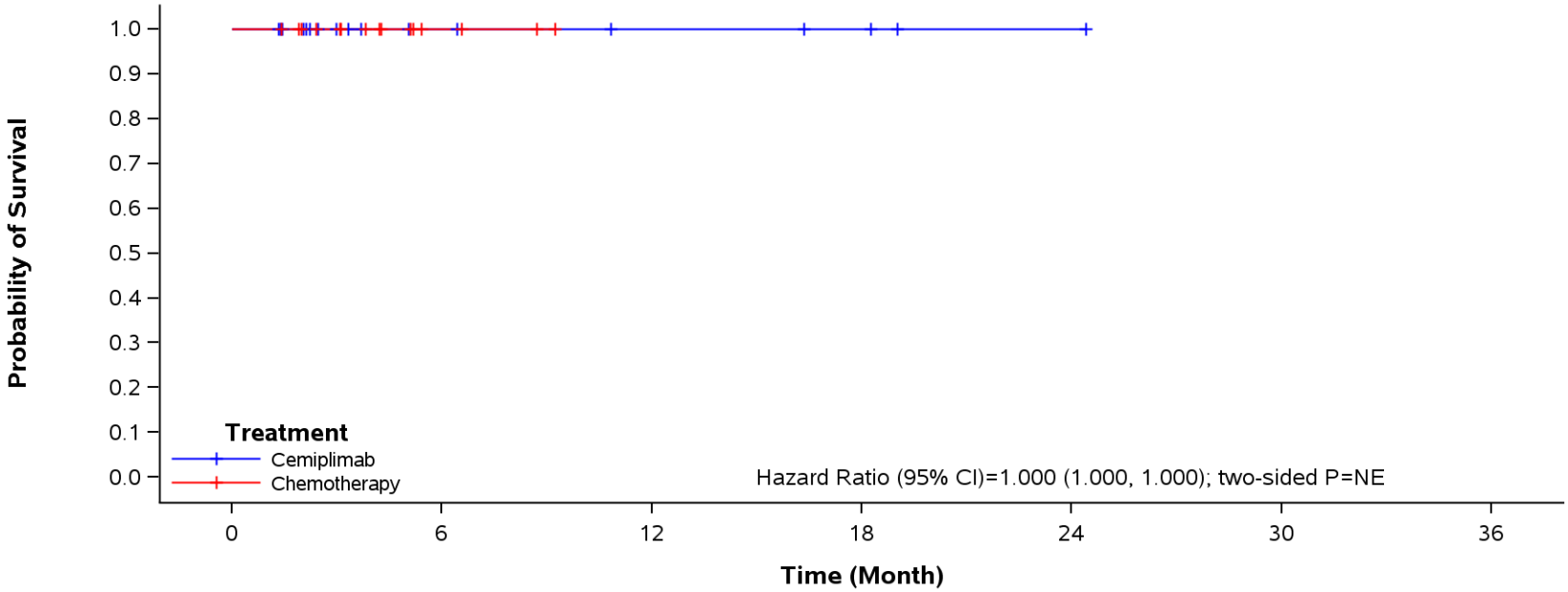

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: General disorders and administration site conditions
PT: Malaise



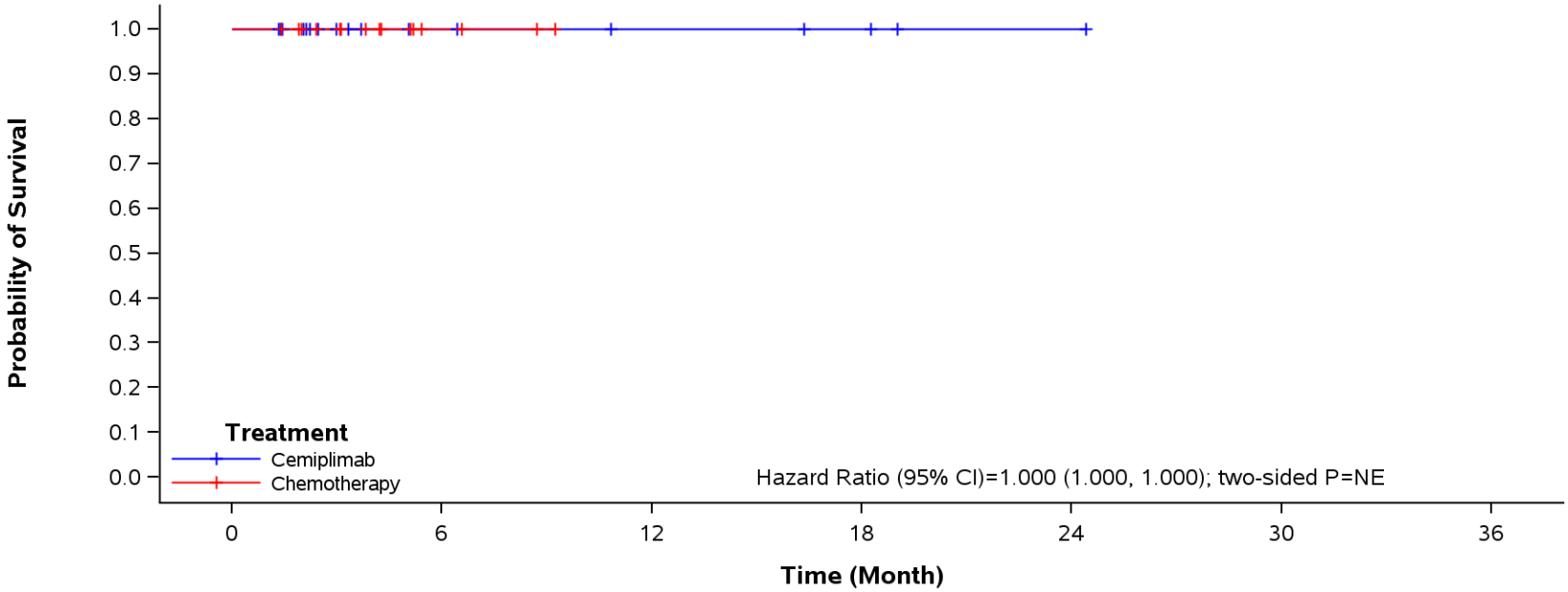

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



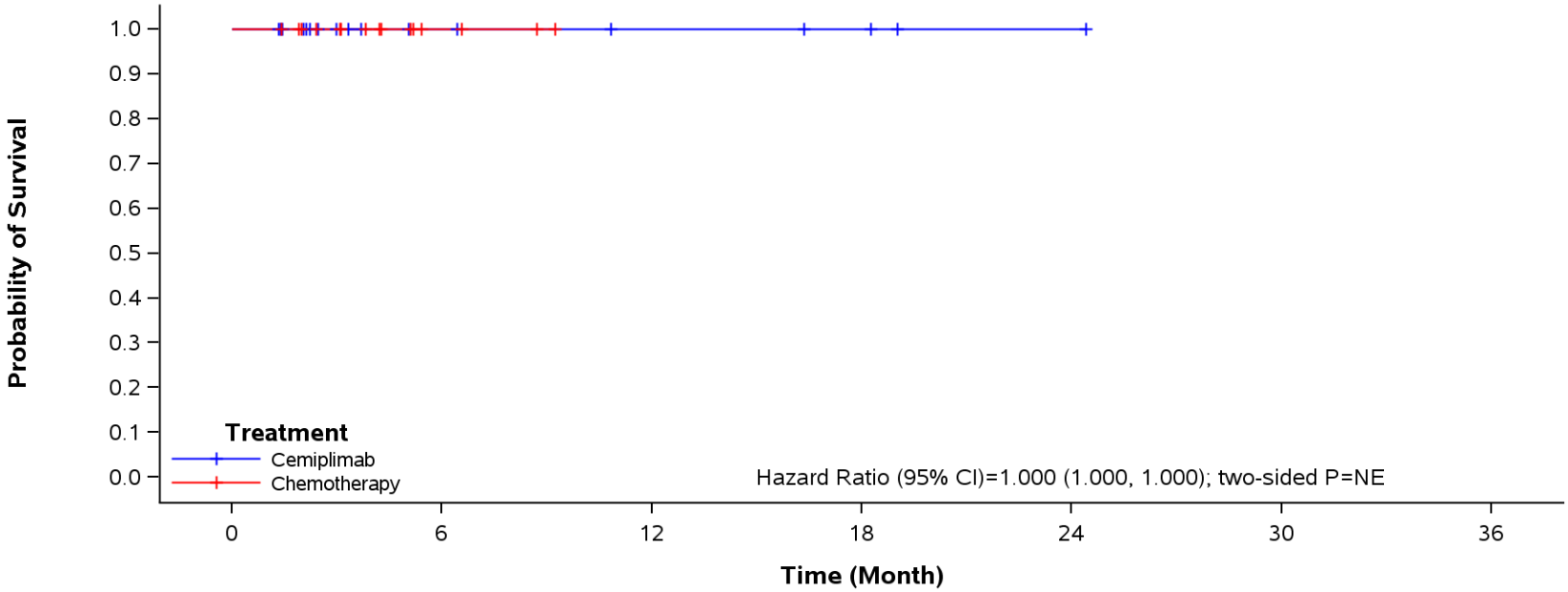

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Hepatobiliary disorders



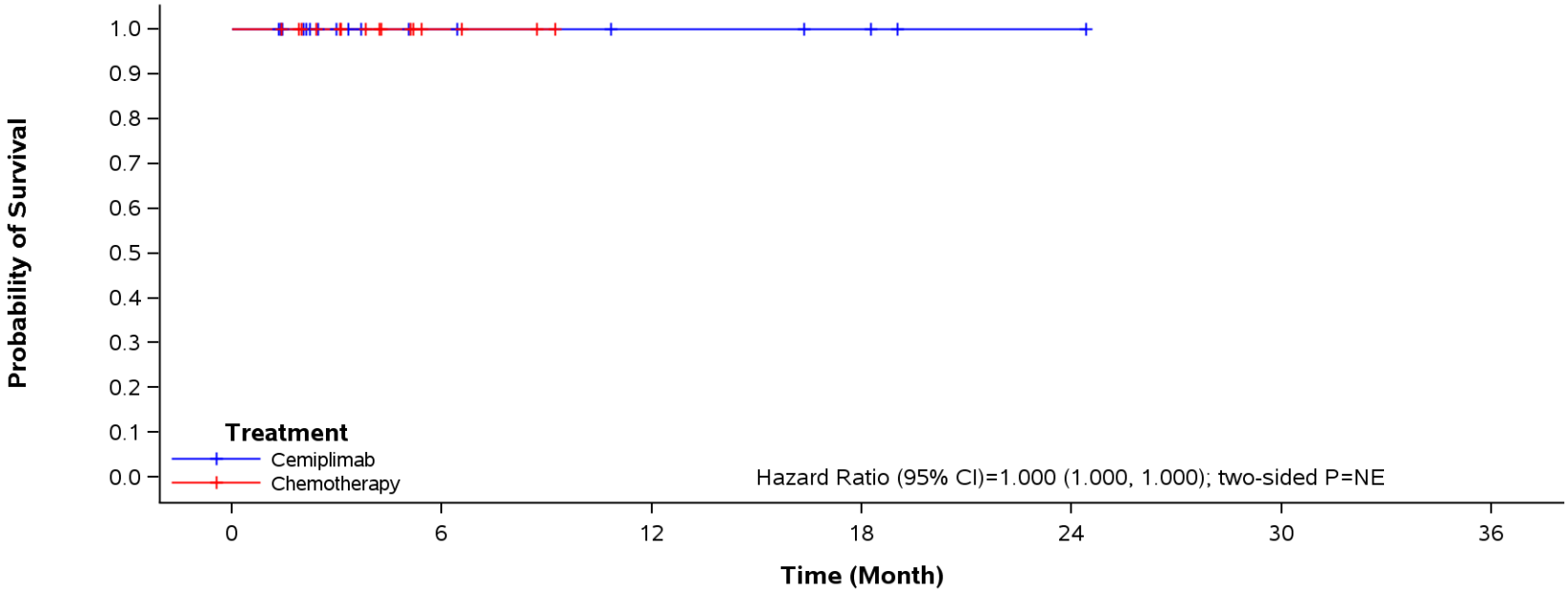

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



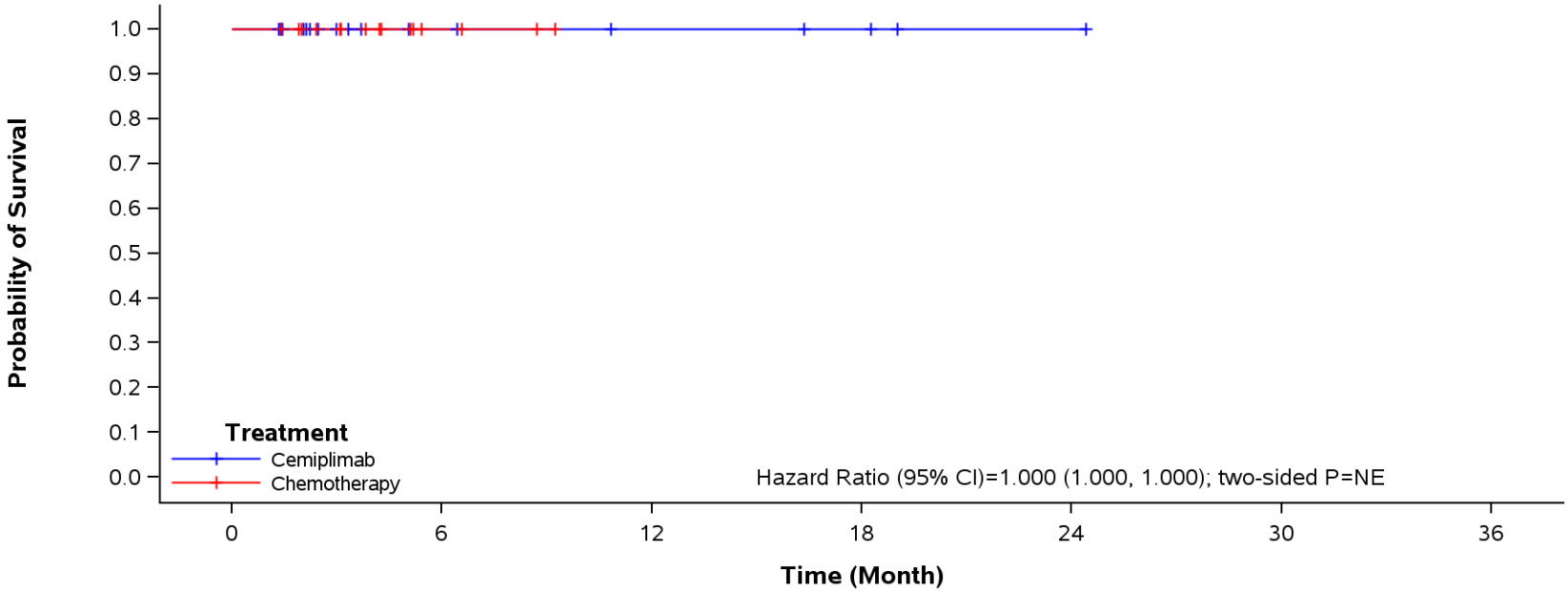

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal



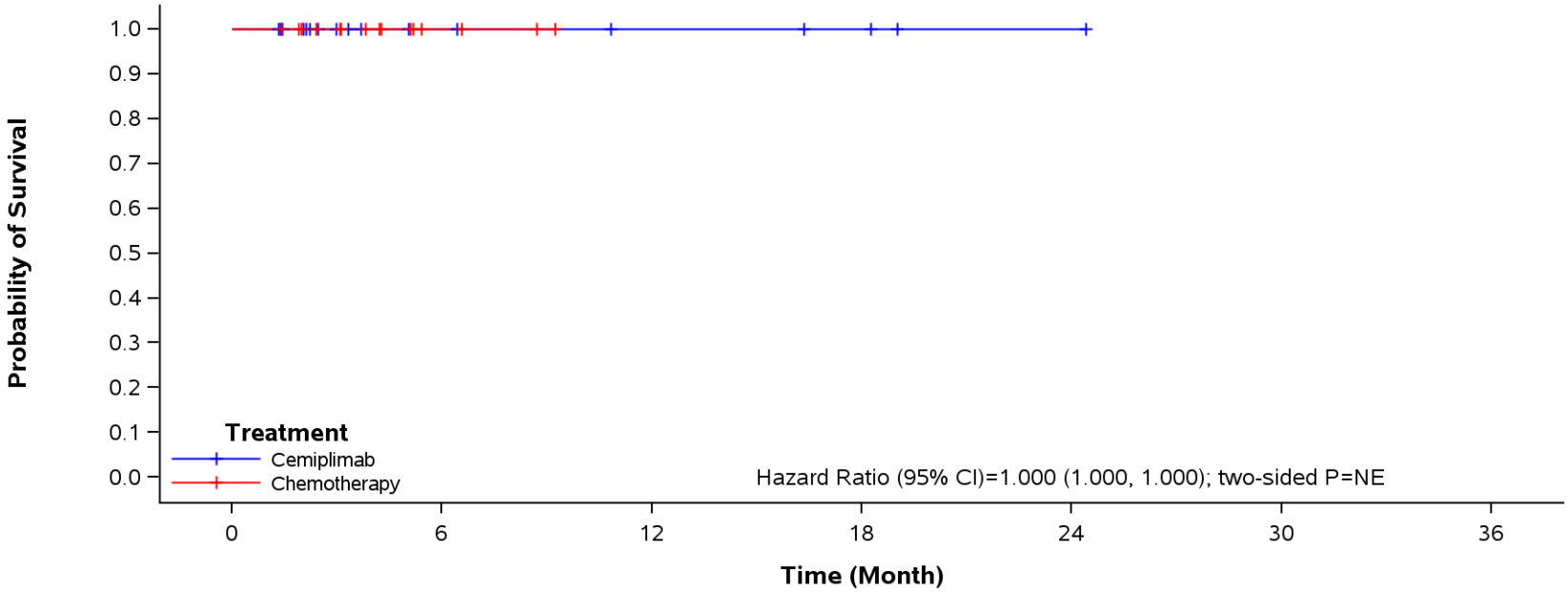

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Hepatobiliary disorders
PT: Hepatitis



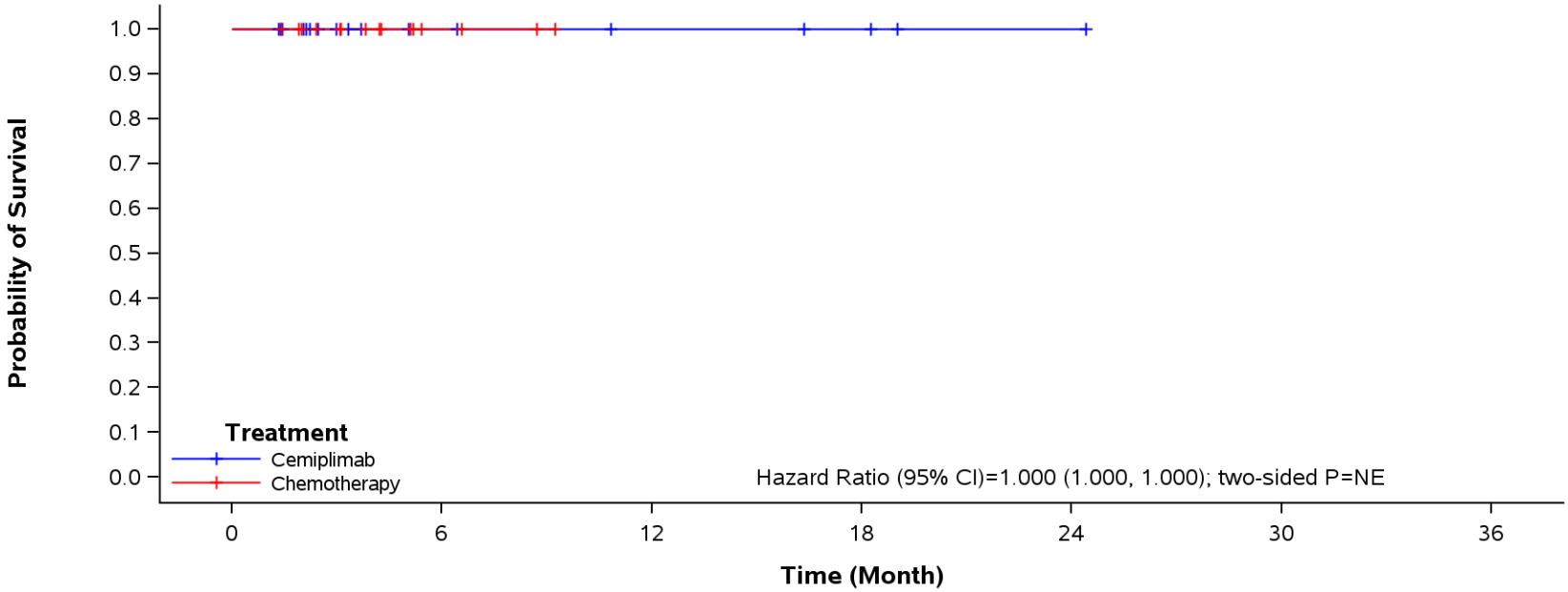

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Hepatobiliary disorders
PT: Immune-mediated hepatitis



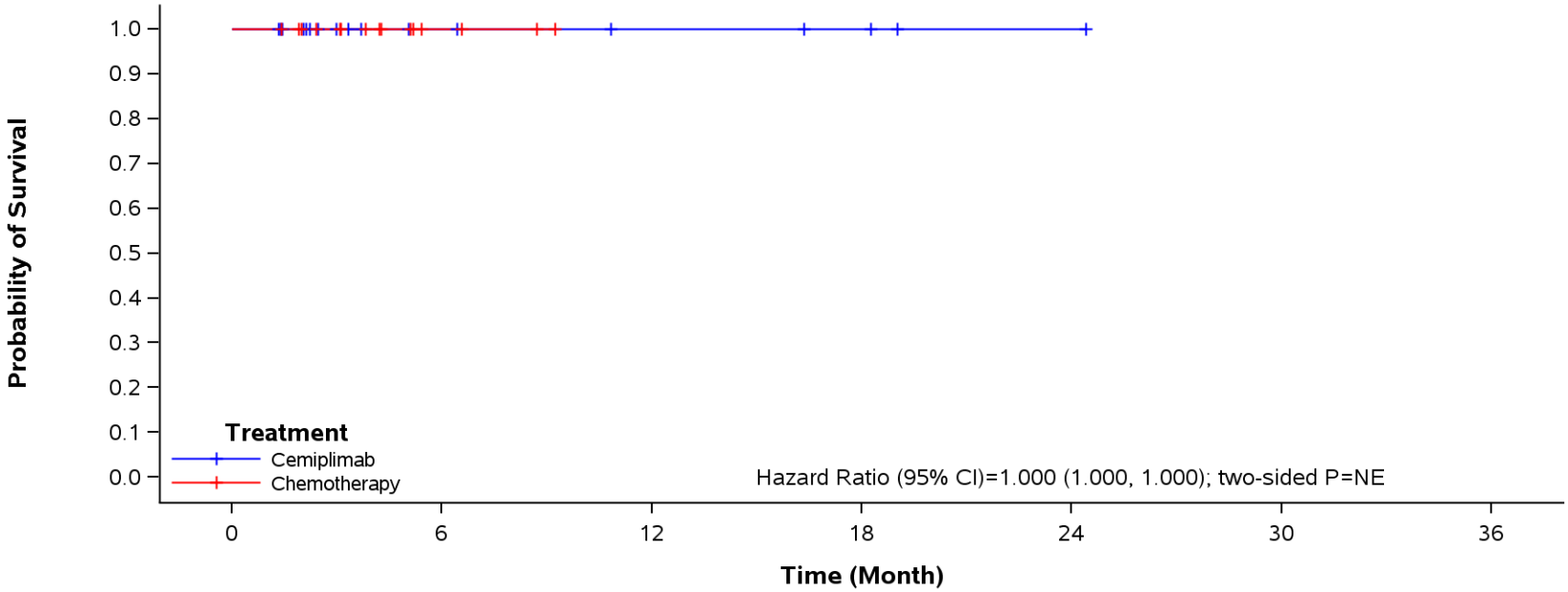

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Infections and infestations



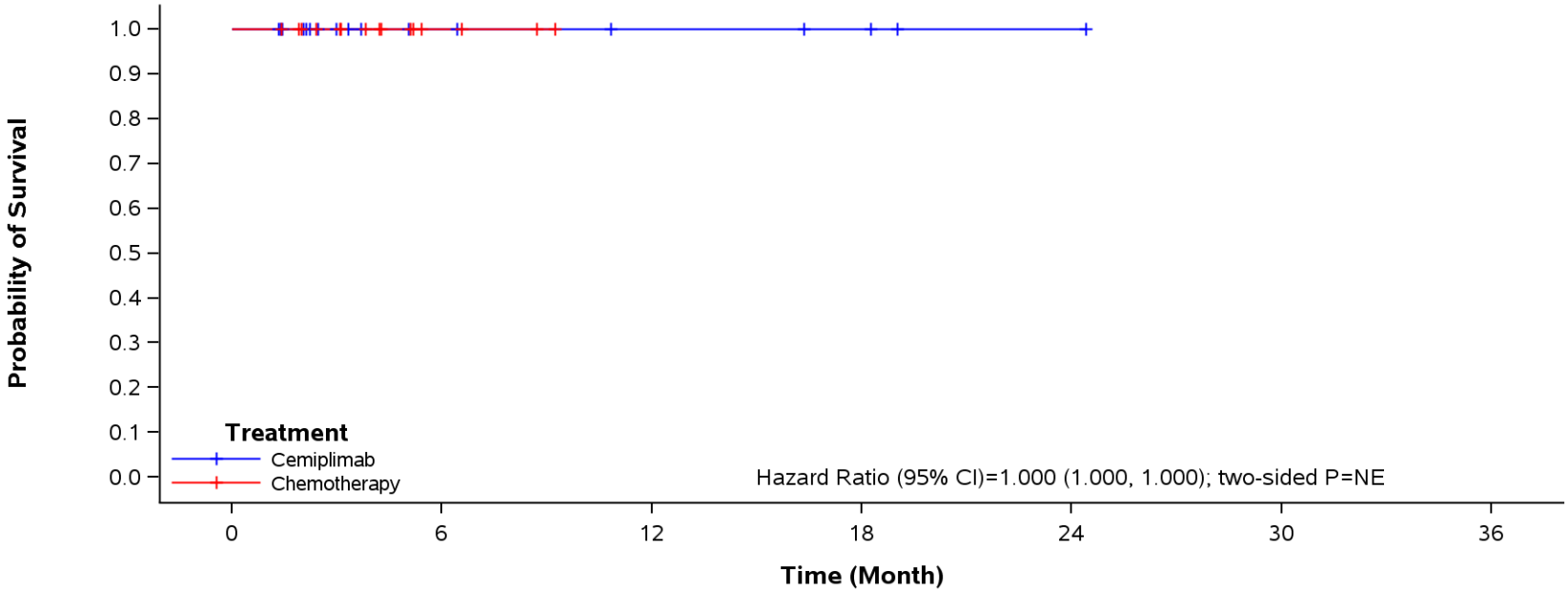

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Infections and infestations
PT: COVID-19 pneumonia



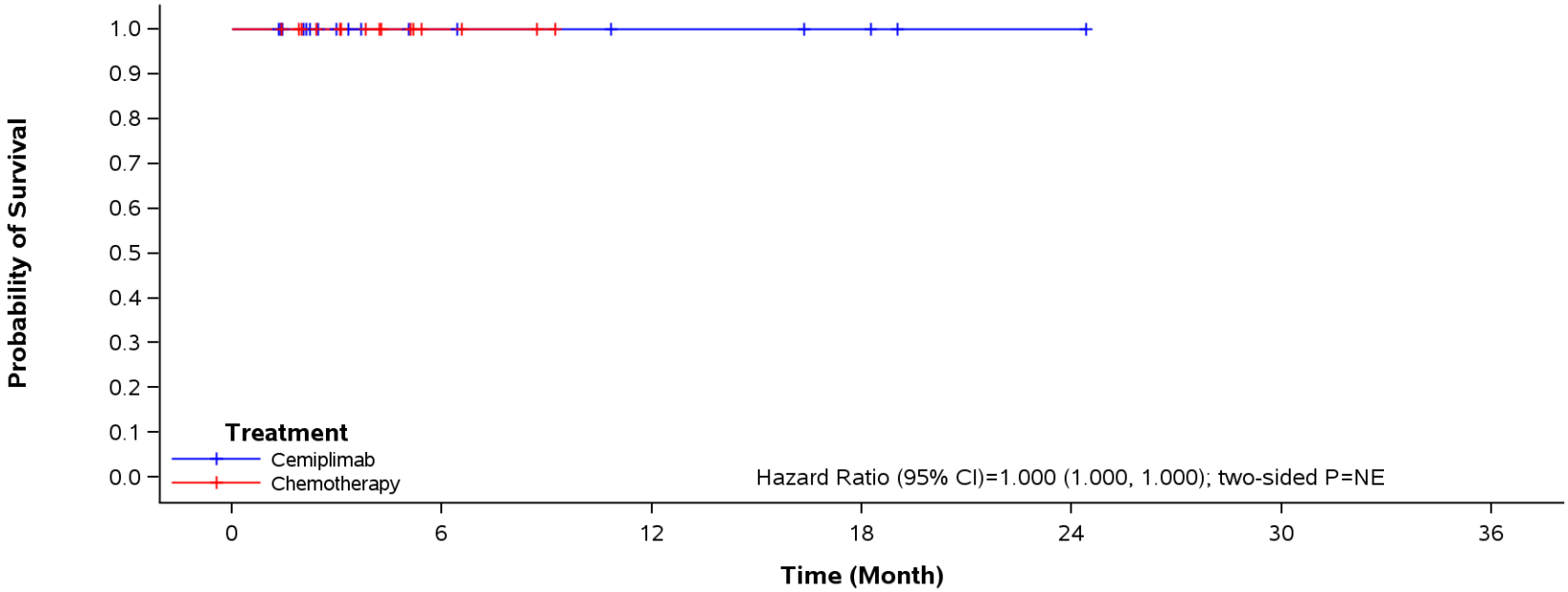

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Infections and infestations
PT: Gastroenteritis



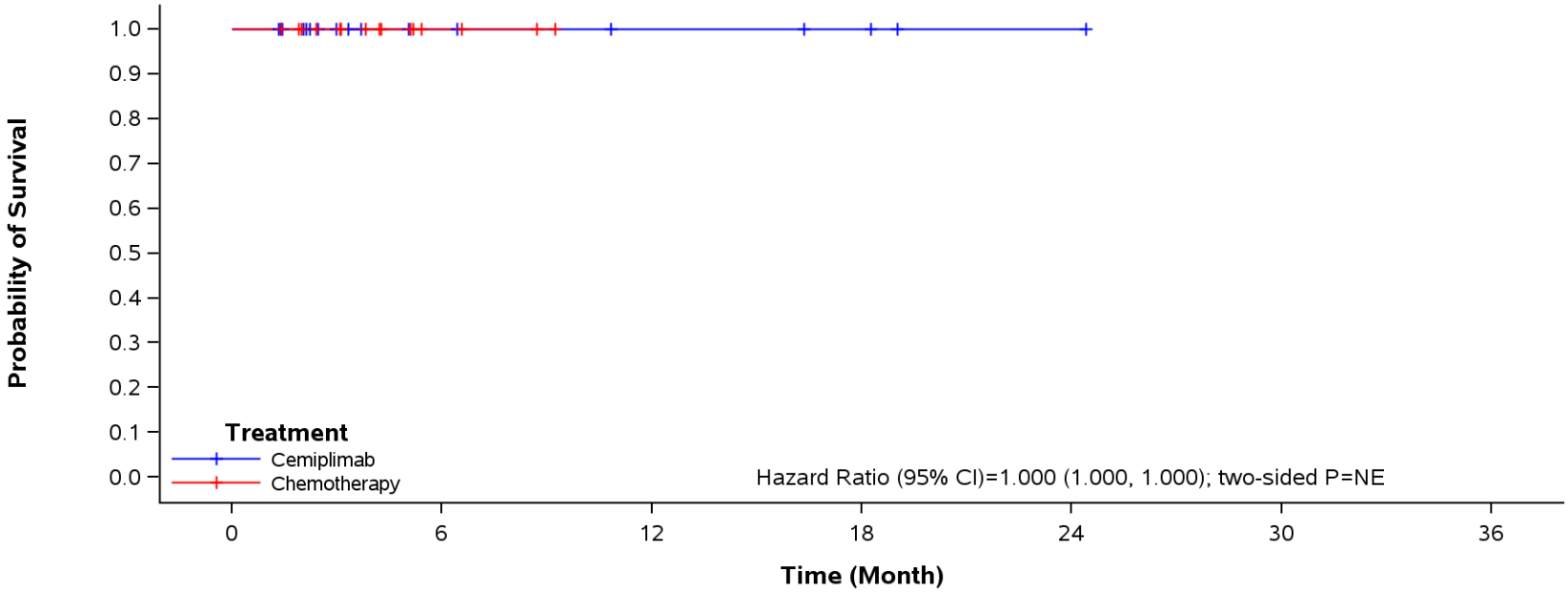

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Infections and infestations
PT: Pelvic abscess



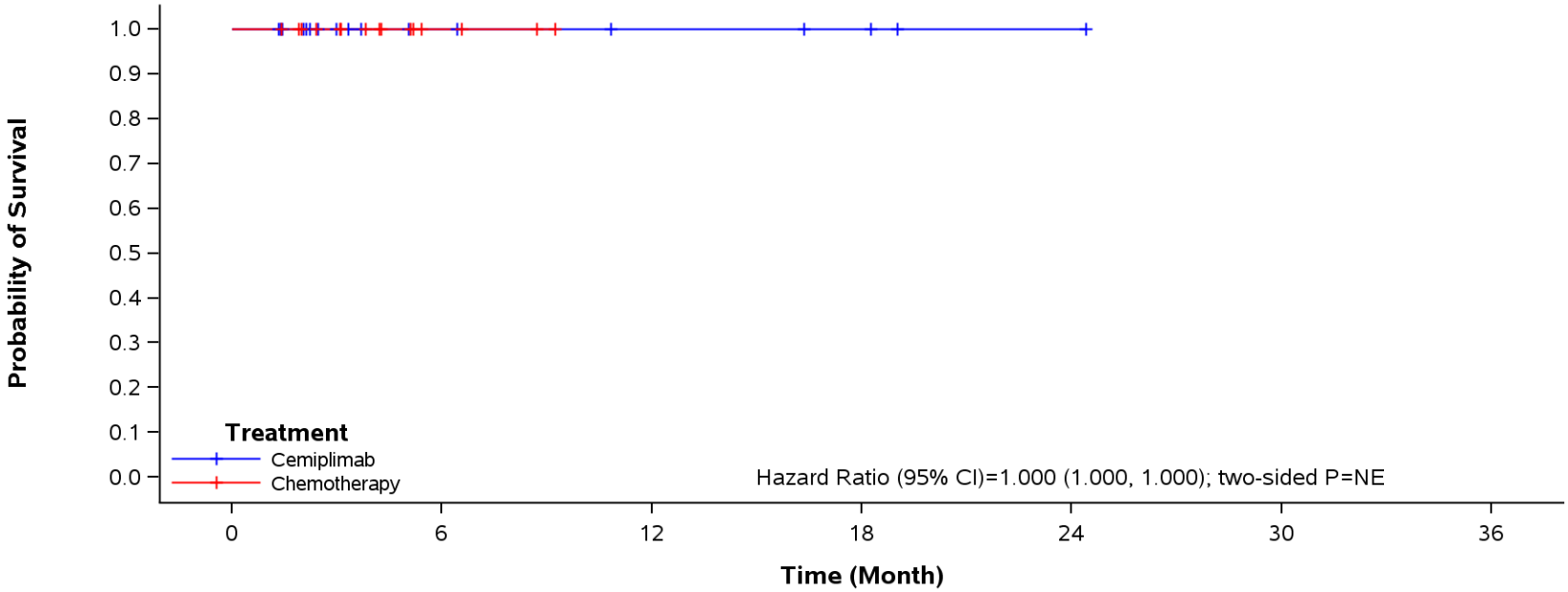

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Infections and infestations
PT: Peritonitis



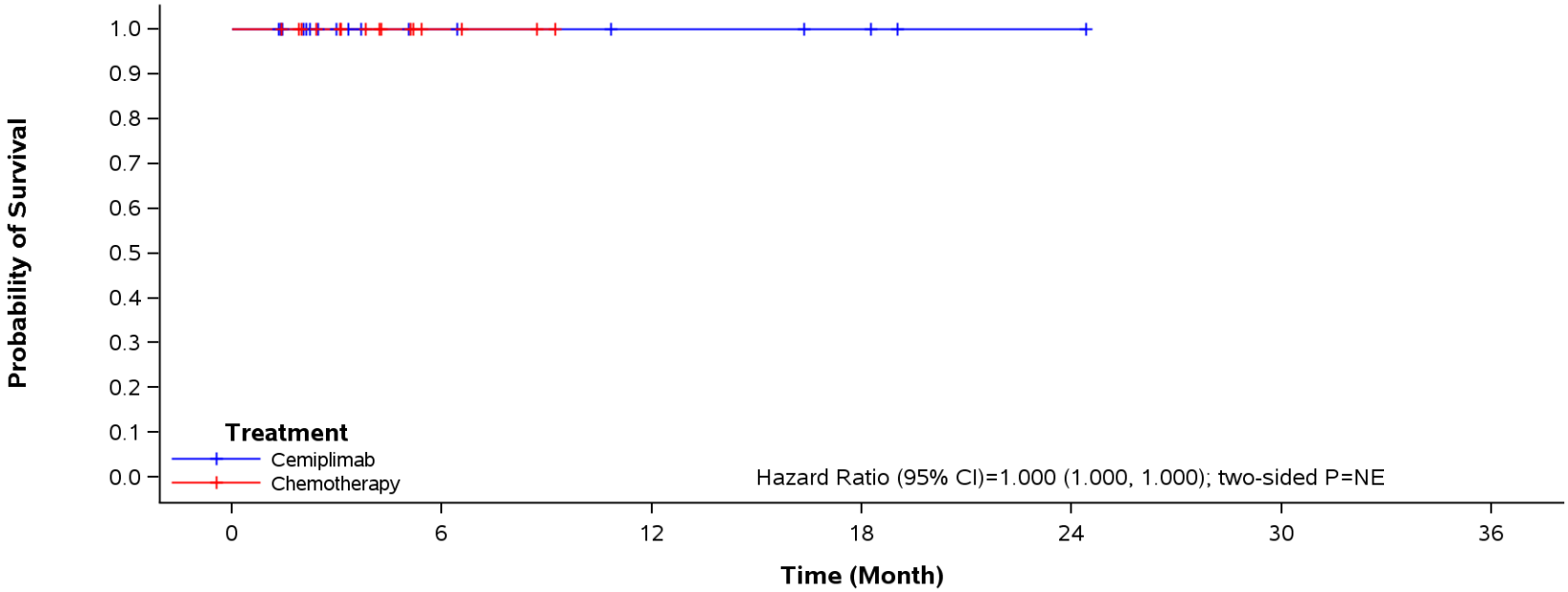

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Infections and infestations
PT: Pneumonia



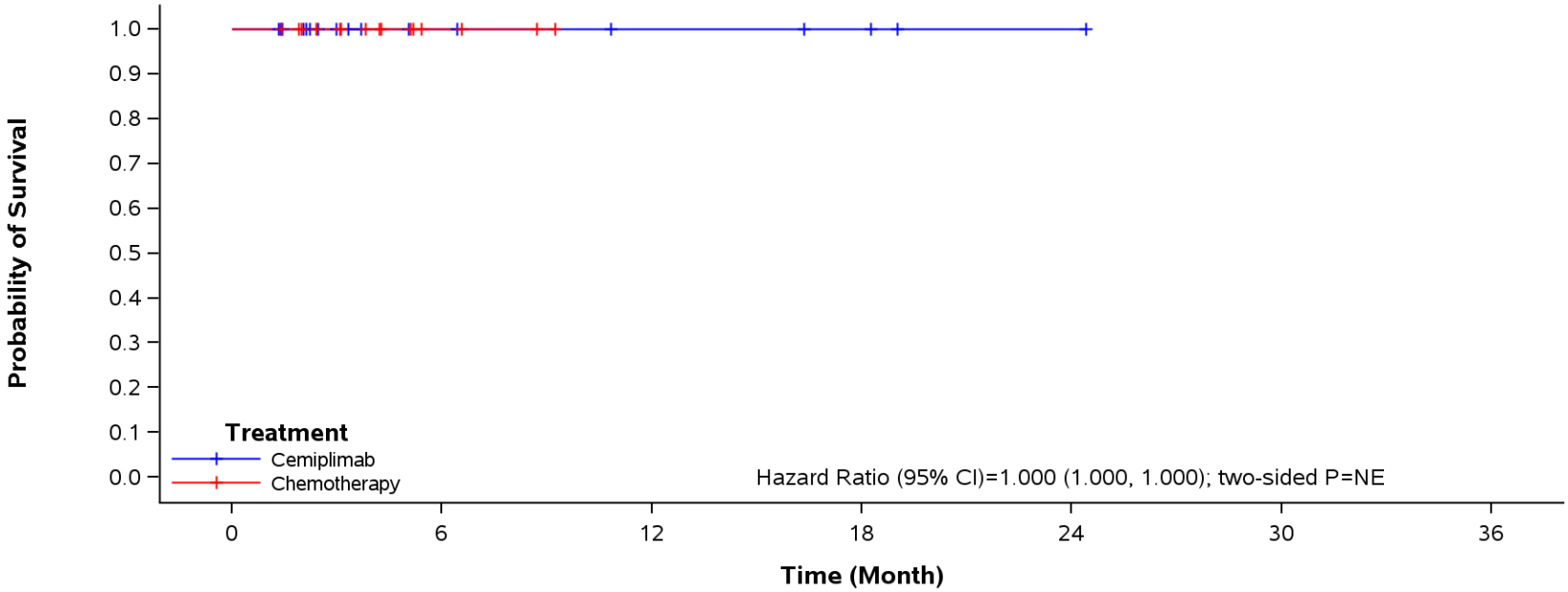

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Infections and infestations
PT: Pyomyositis



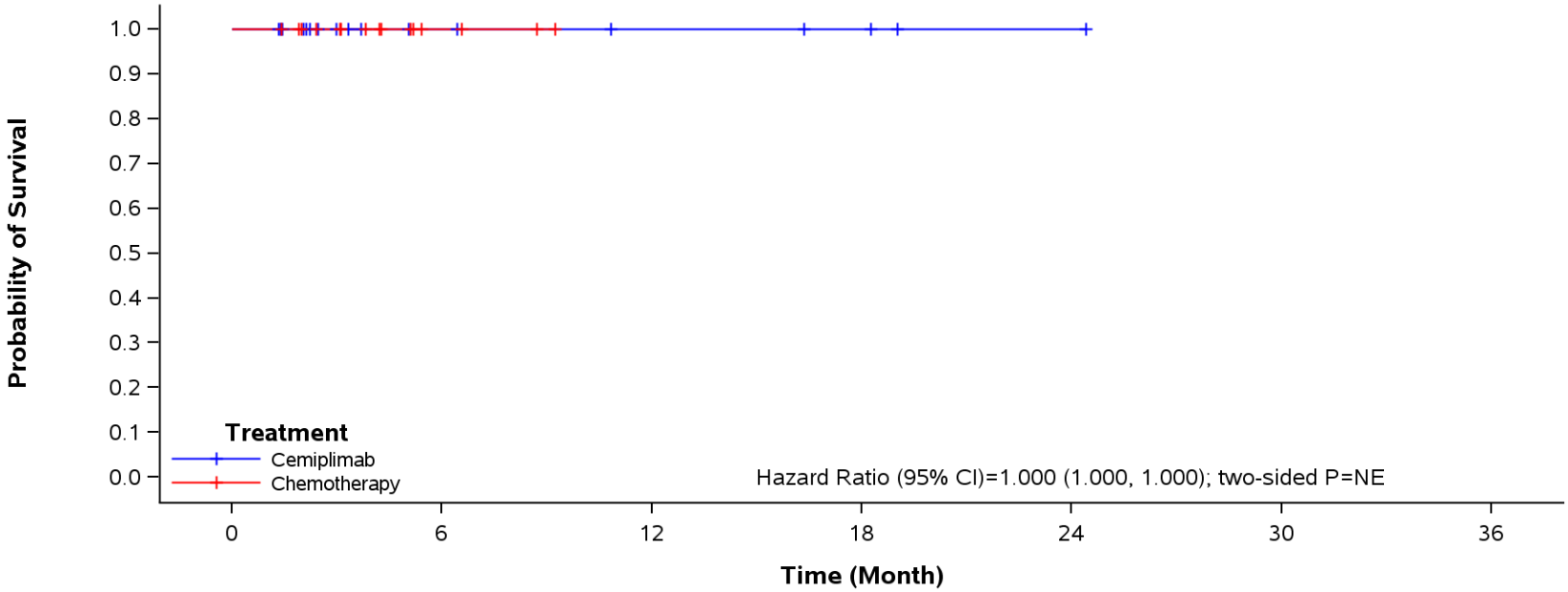

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Injury, poisoning and procedural complications



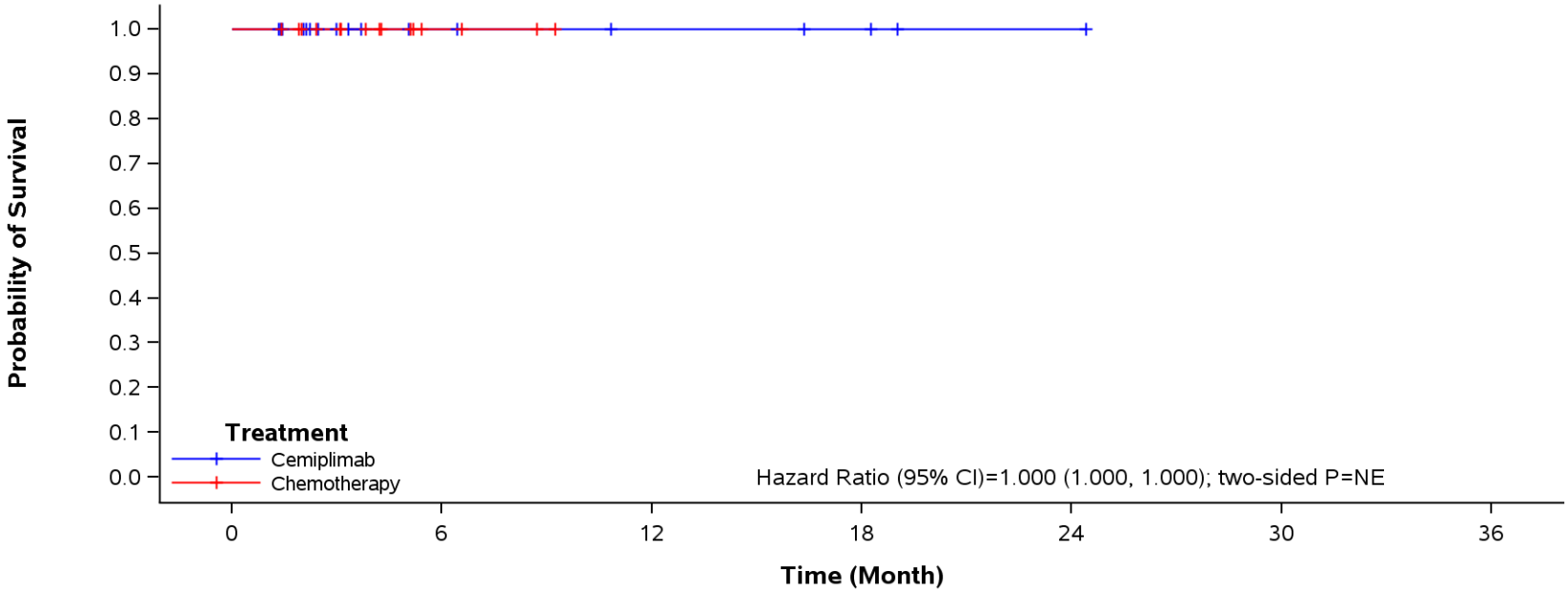

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Injury, poisoning and procedural complications
PT: Infusion related reaction



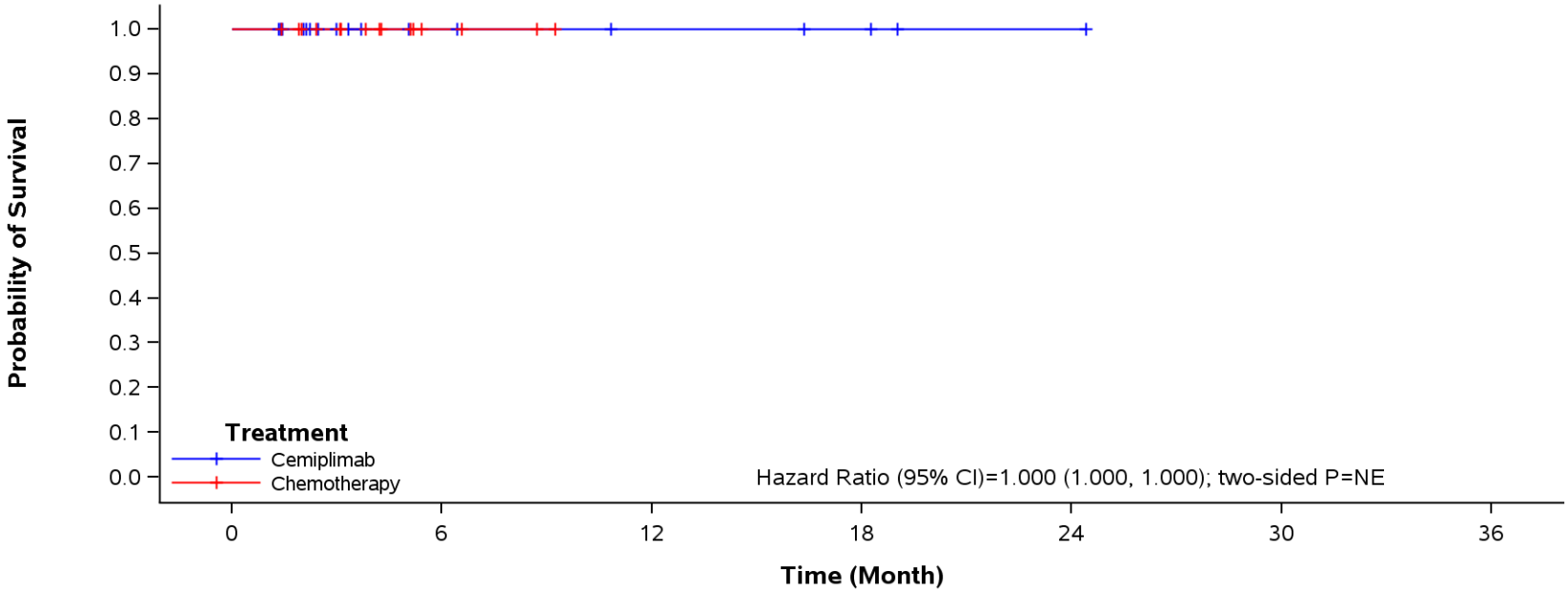

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Injury, poisoning and procedural complications
PT: Spinal compression fracture



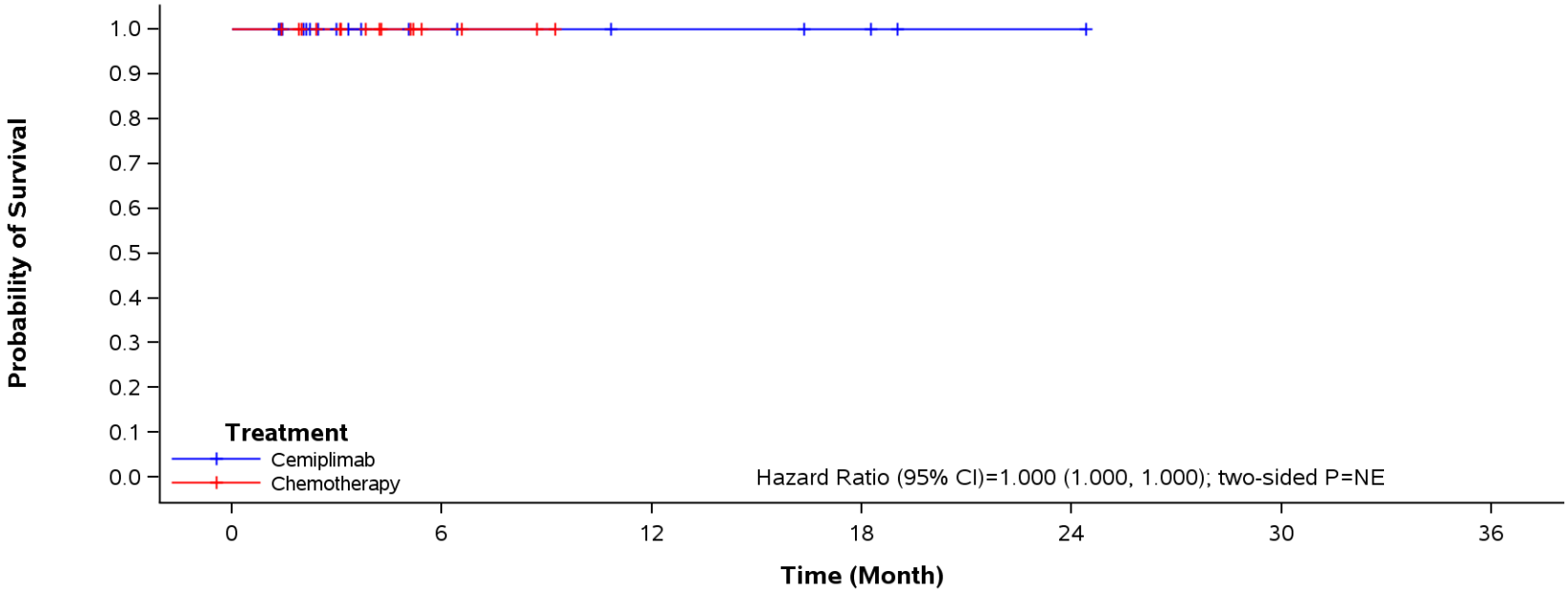

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Investigations



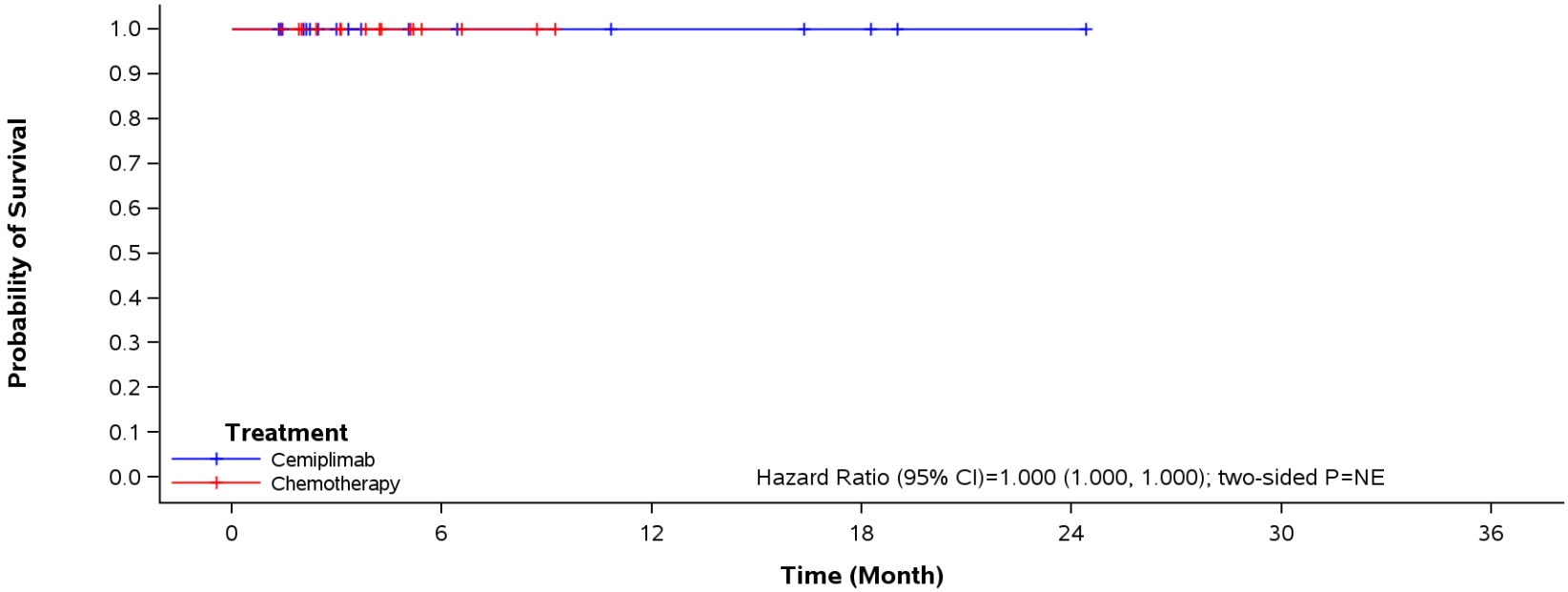

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Investigations
PT: Alanine aminotransferase increased



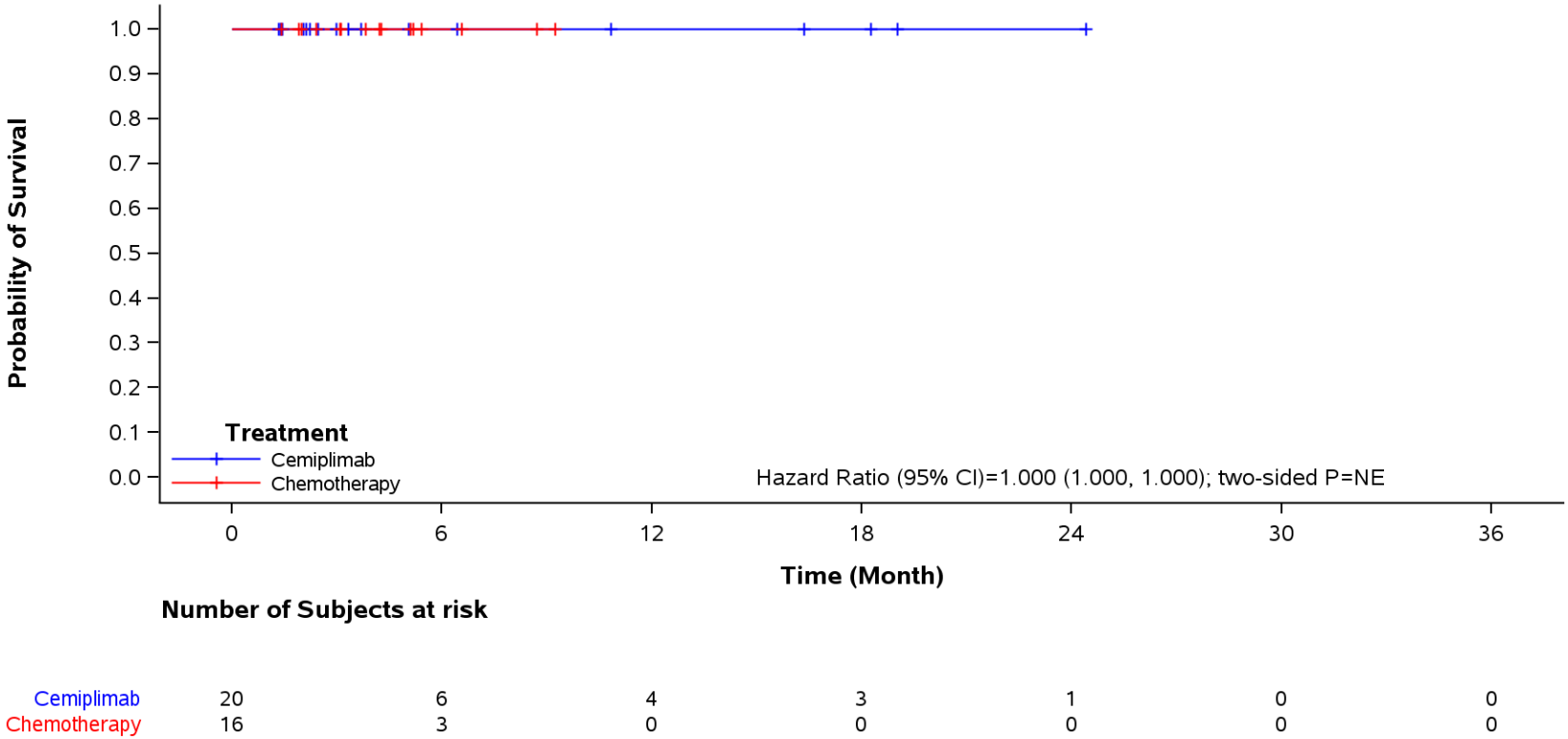

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

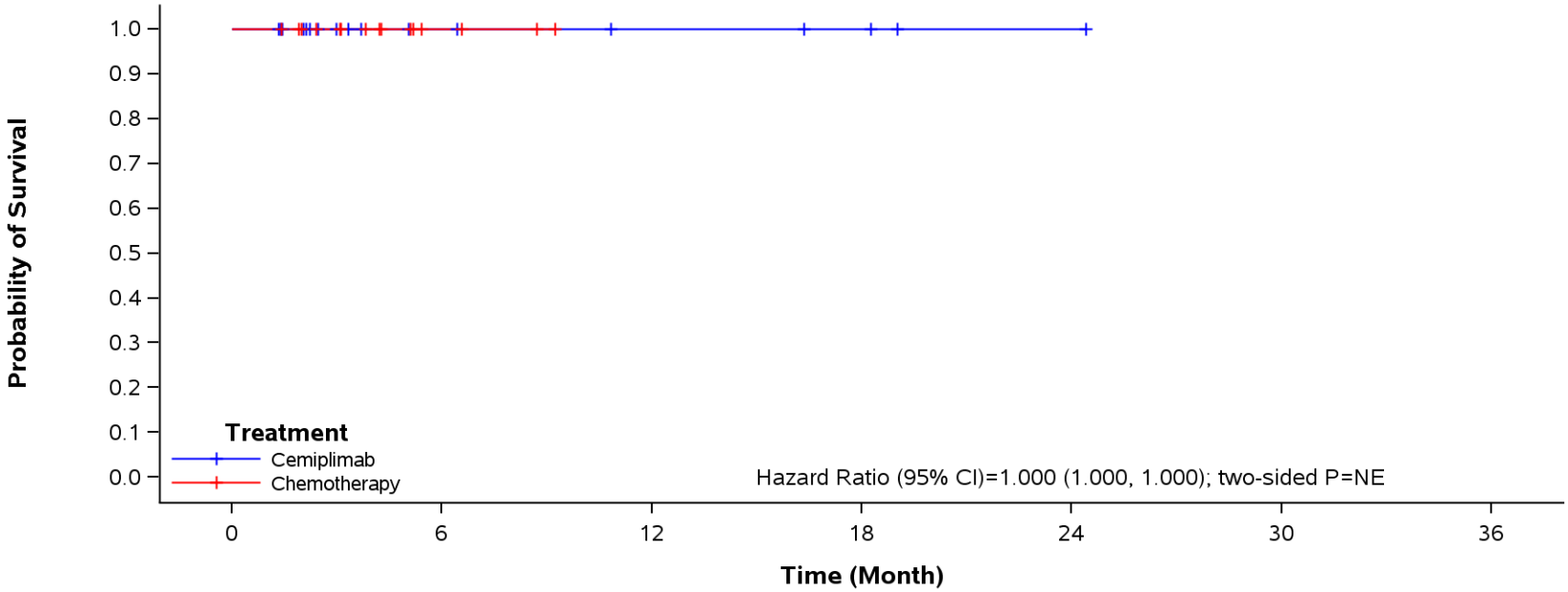
Choice of IC chemotherapy: Topotecan
SOC: Investigations
PT: Amylase increased




Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Investigations
PT: Platelet count decreased



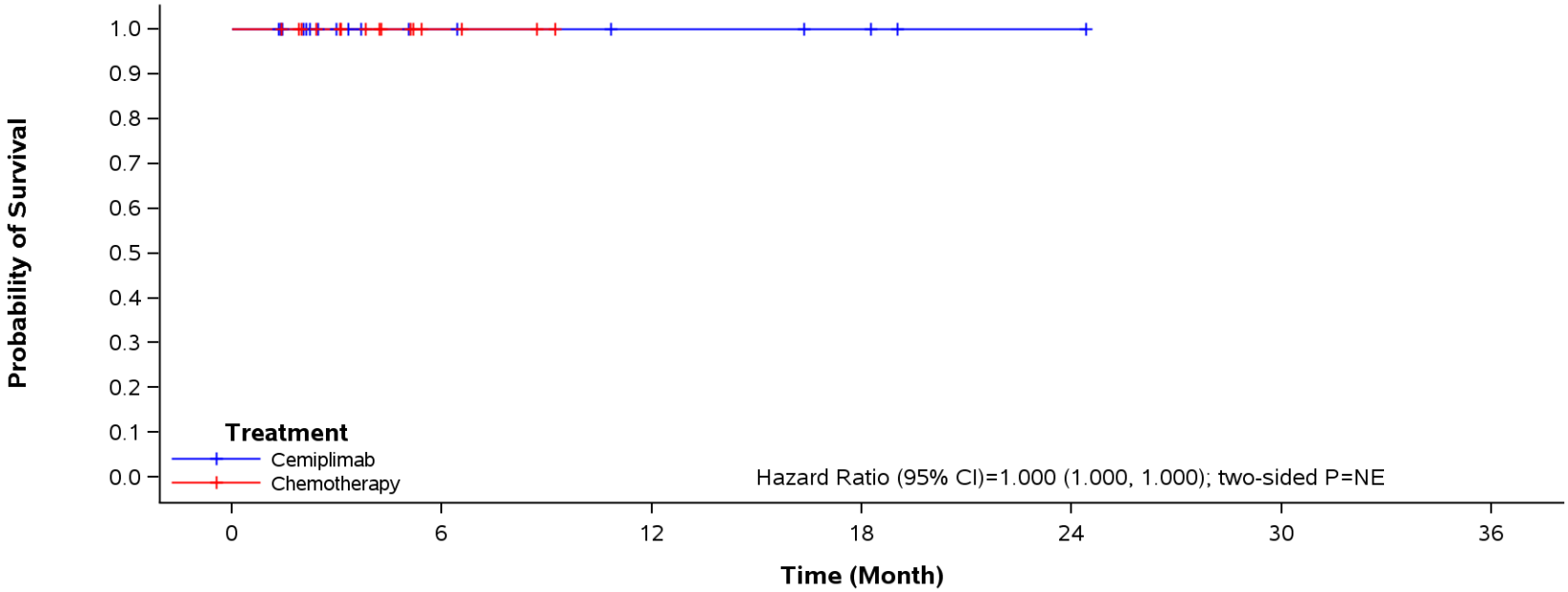

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Metabolism and nutrition disorders



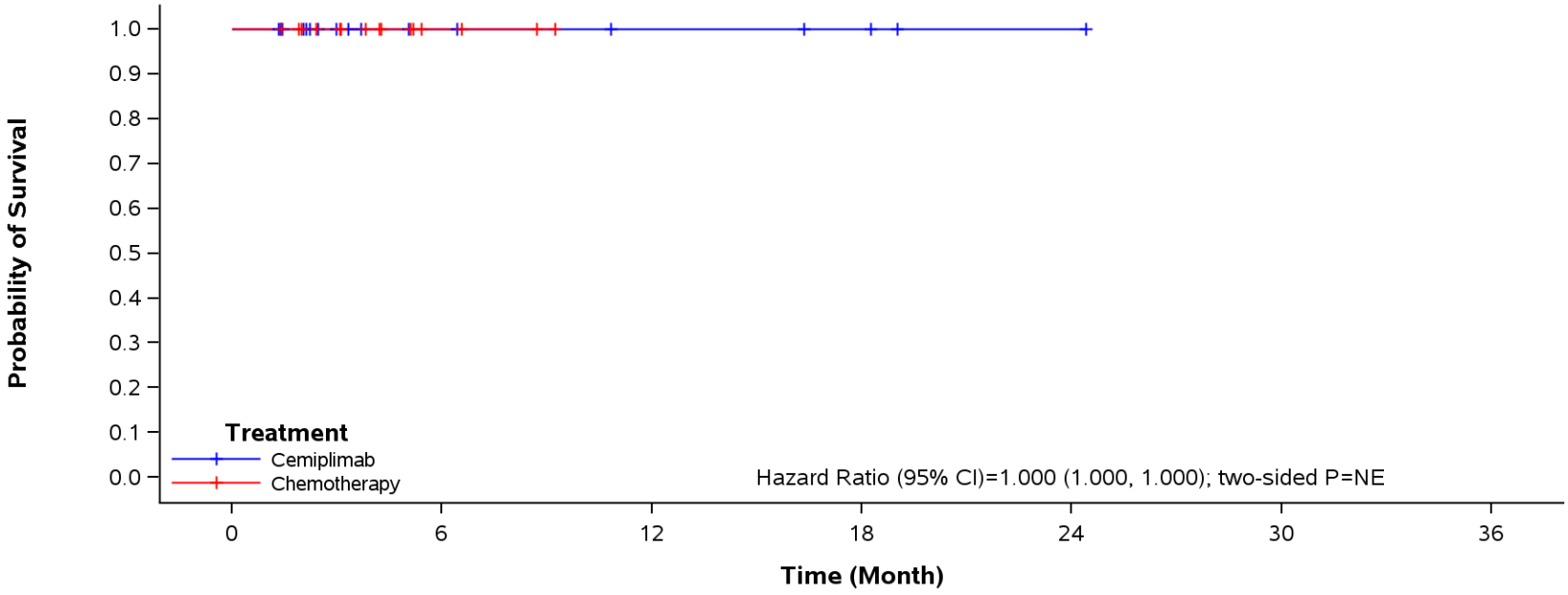

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Metabolism and nutrition disorders
PT: Decreased appetite



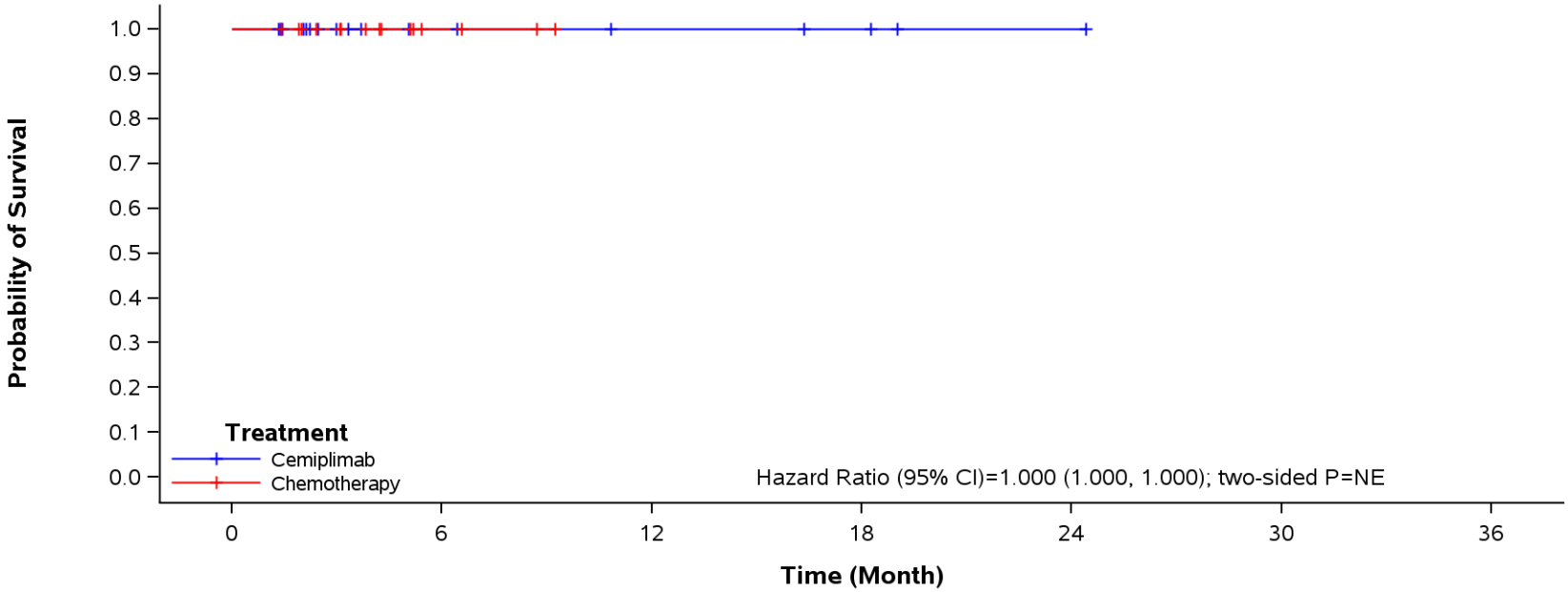

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Musculoskeletal and connective tissue disorders



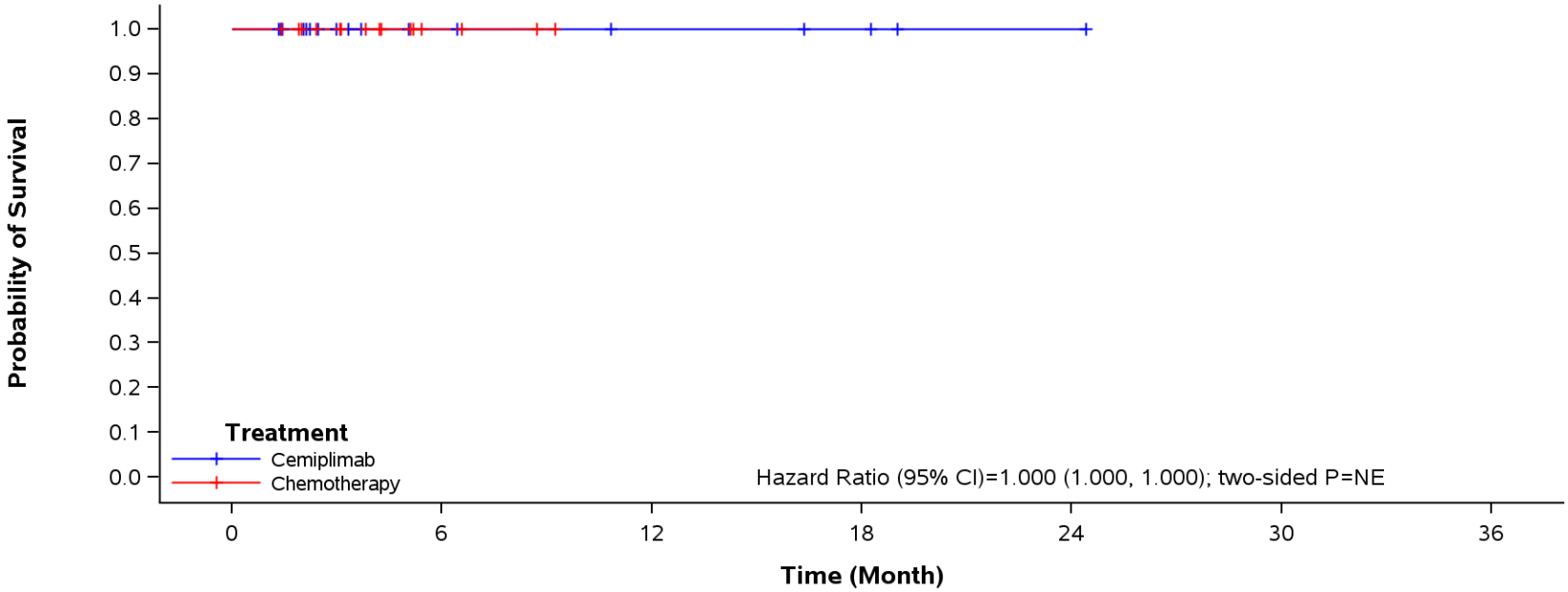

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Musculoskeletal and connective tissue disorders
PT: Muscular weakness



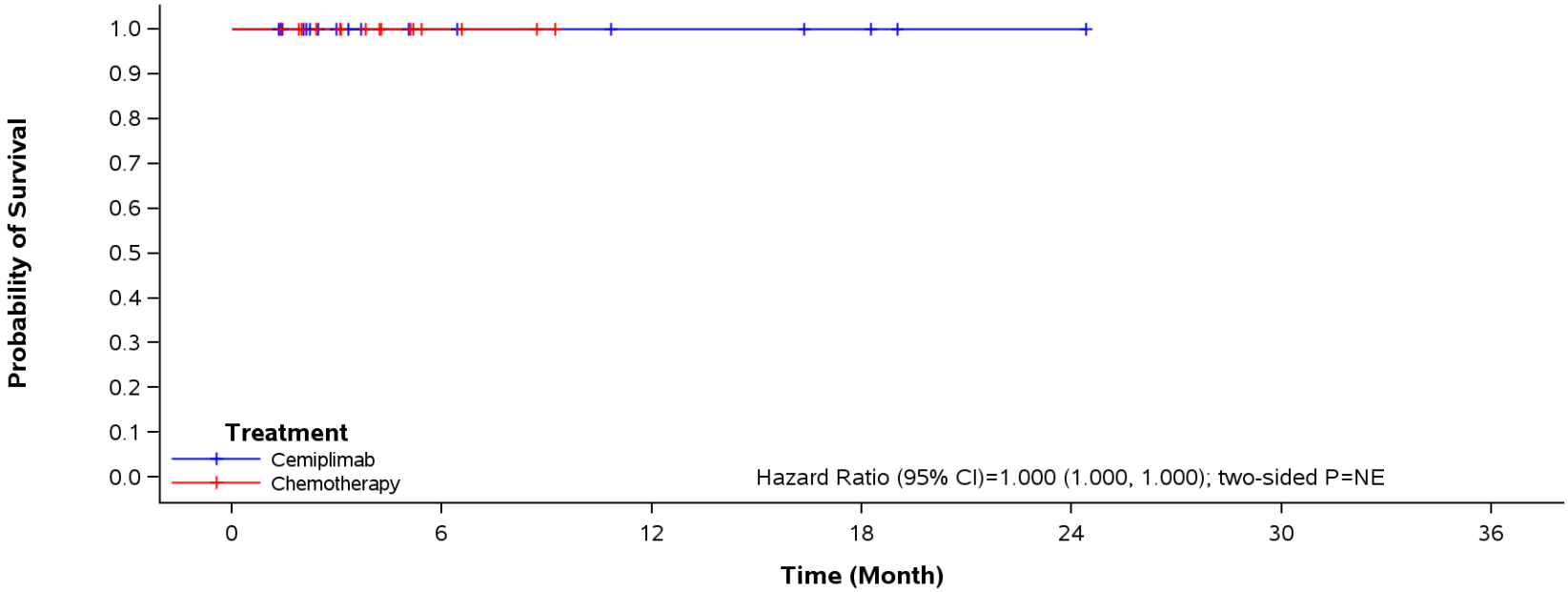

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Musculoskeletal and connective tissue disorders
PT: Polyarthritis



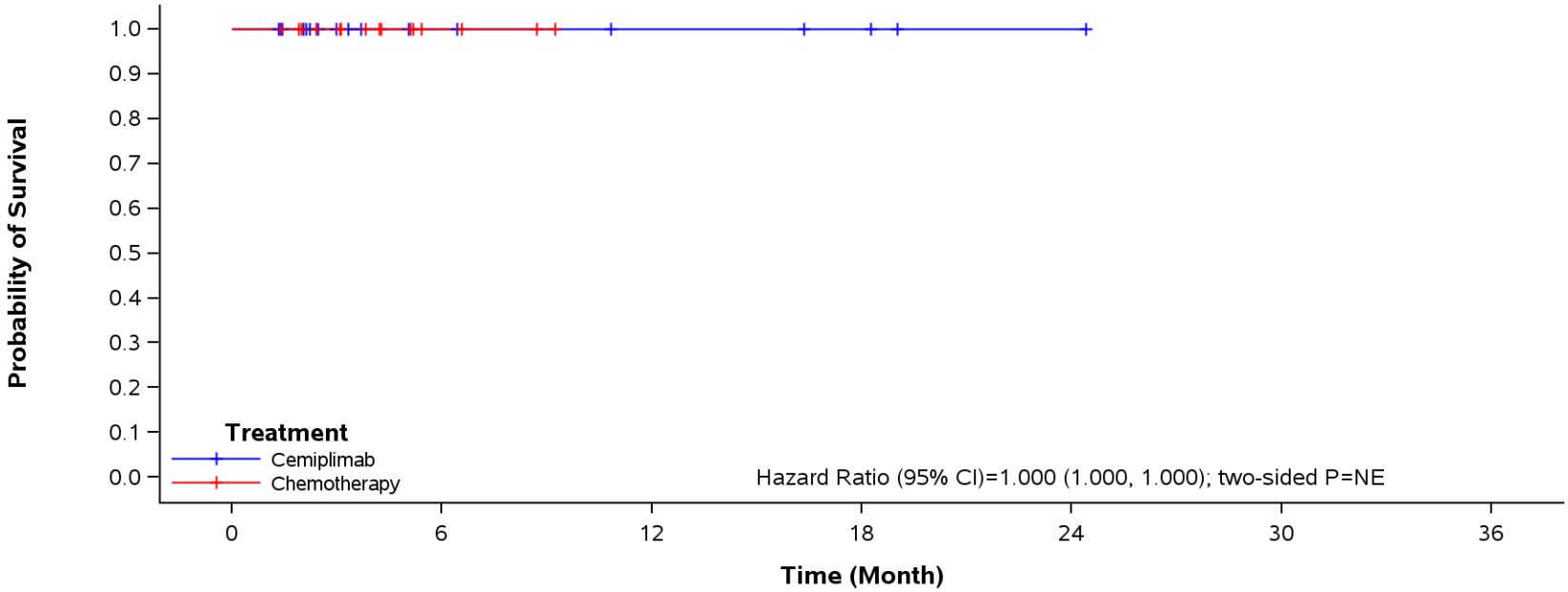

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Nervous system disorders



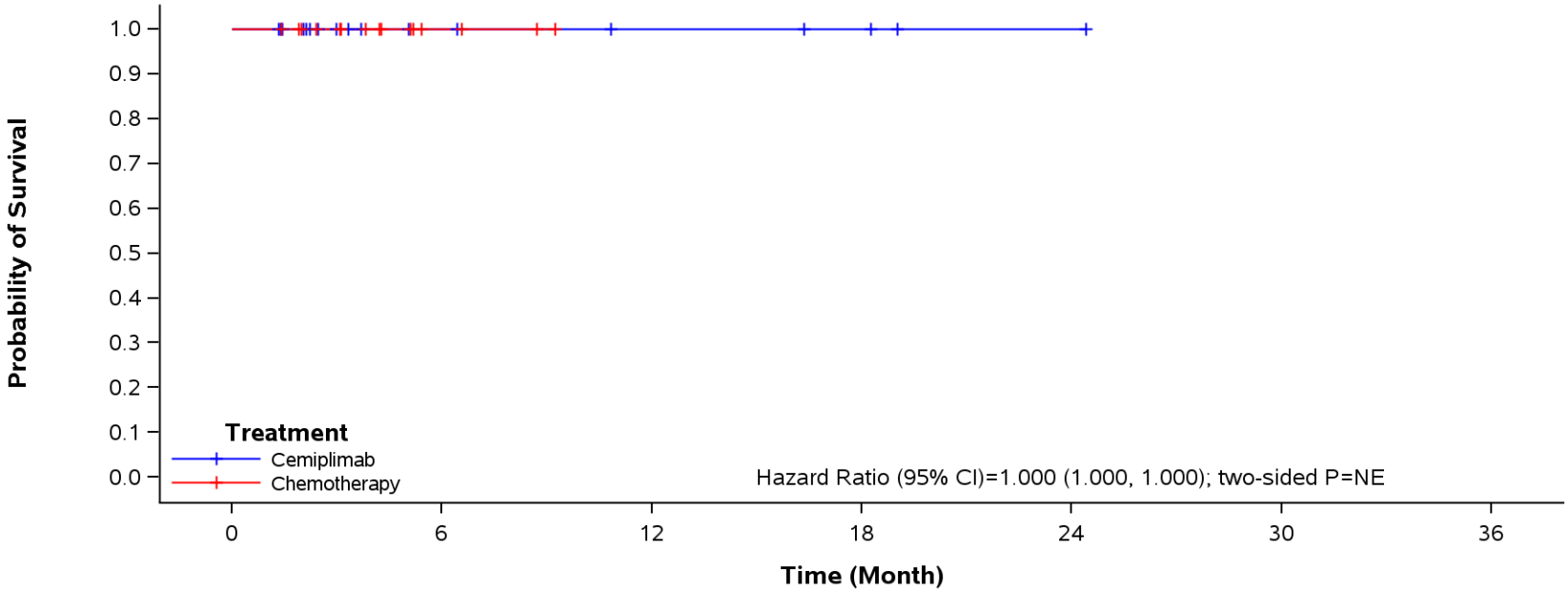

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Nervous system disorders
PT: Neurotoxicity



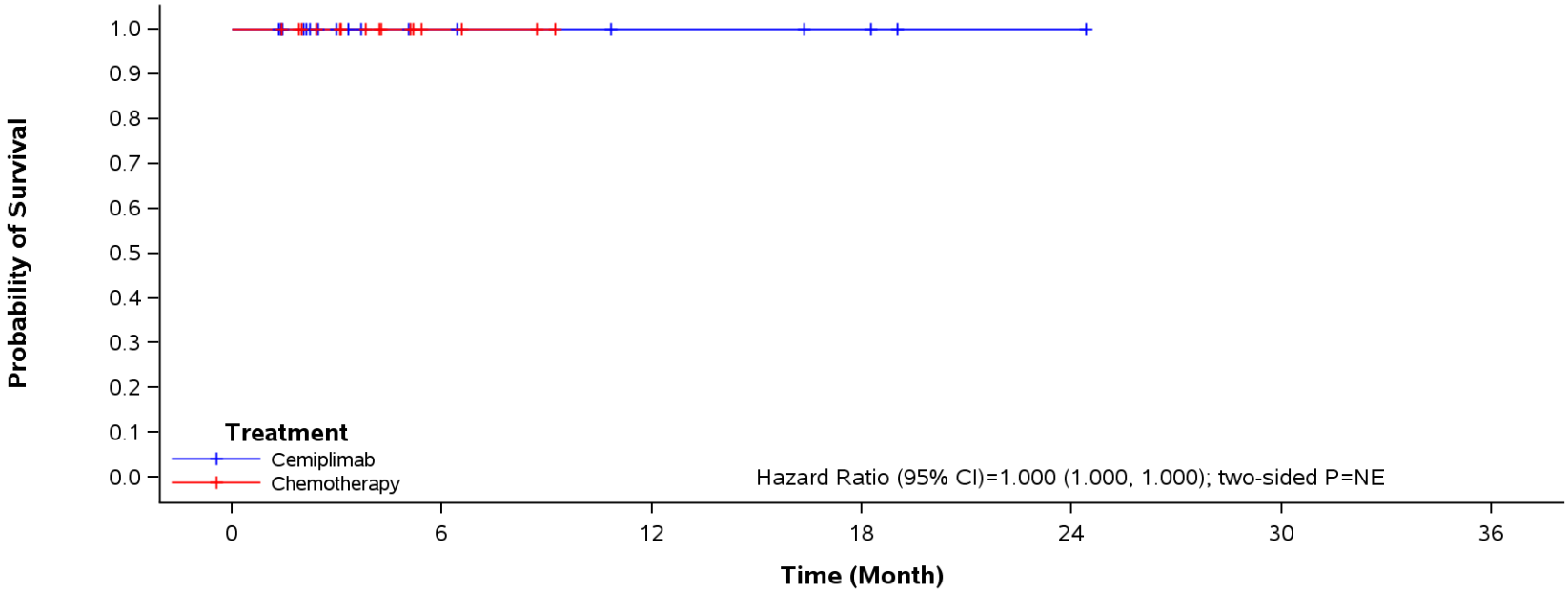

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Nervous system disorders
PT: Transient ischaemic attack



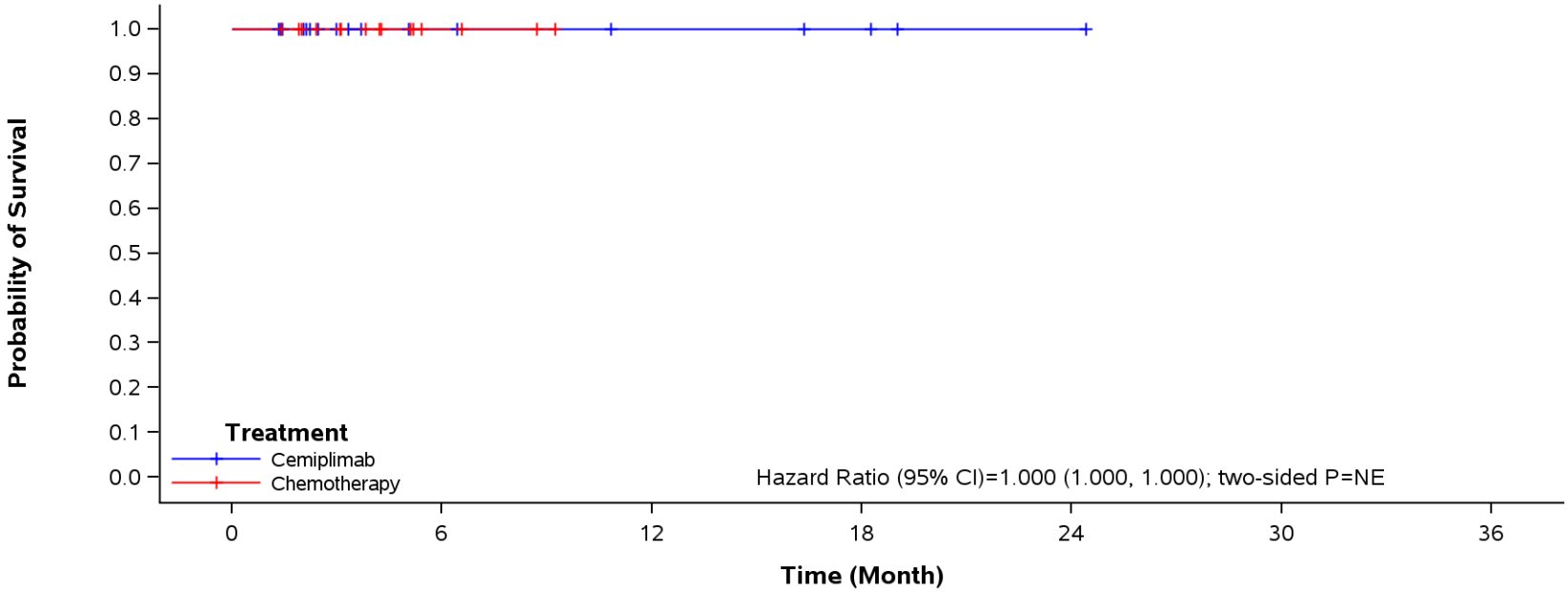

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Psychiatric disorders



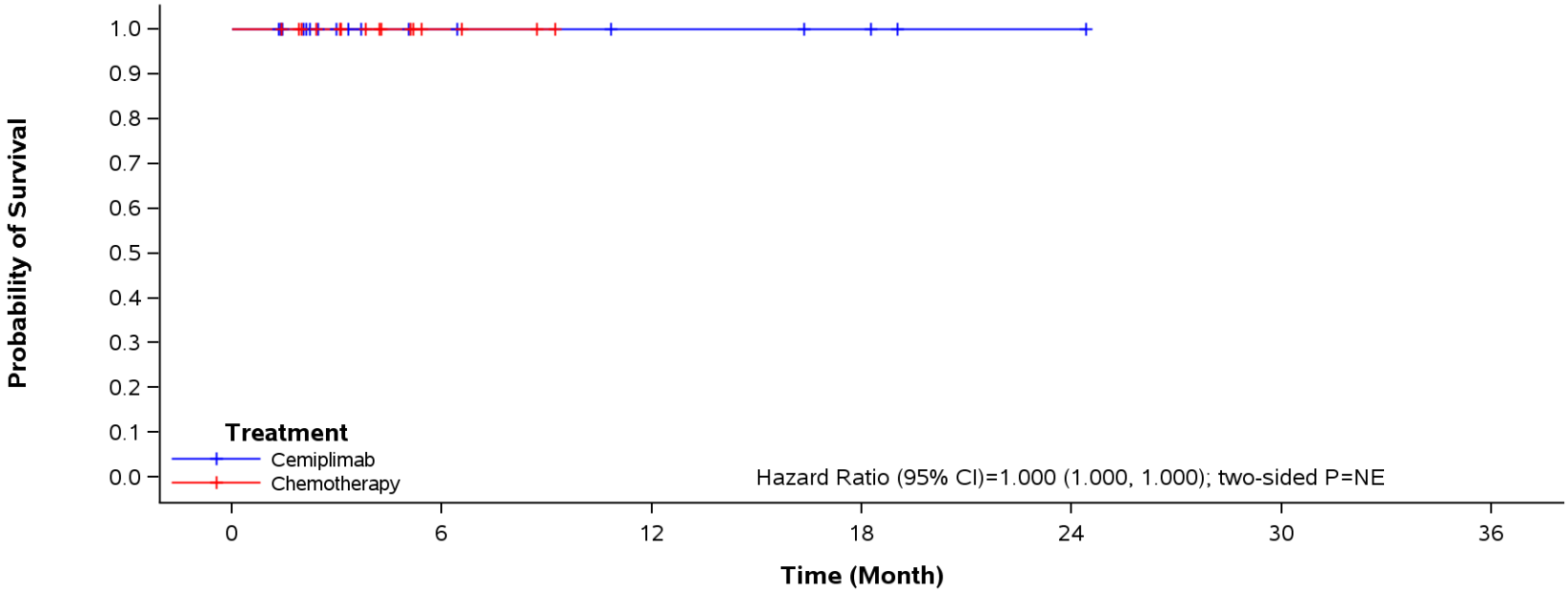

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Psychiatric disorders
PT: Agoraphobia



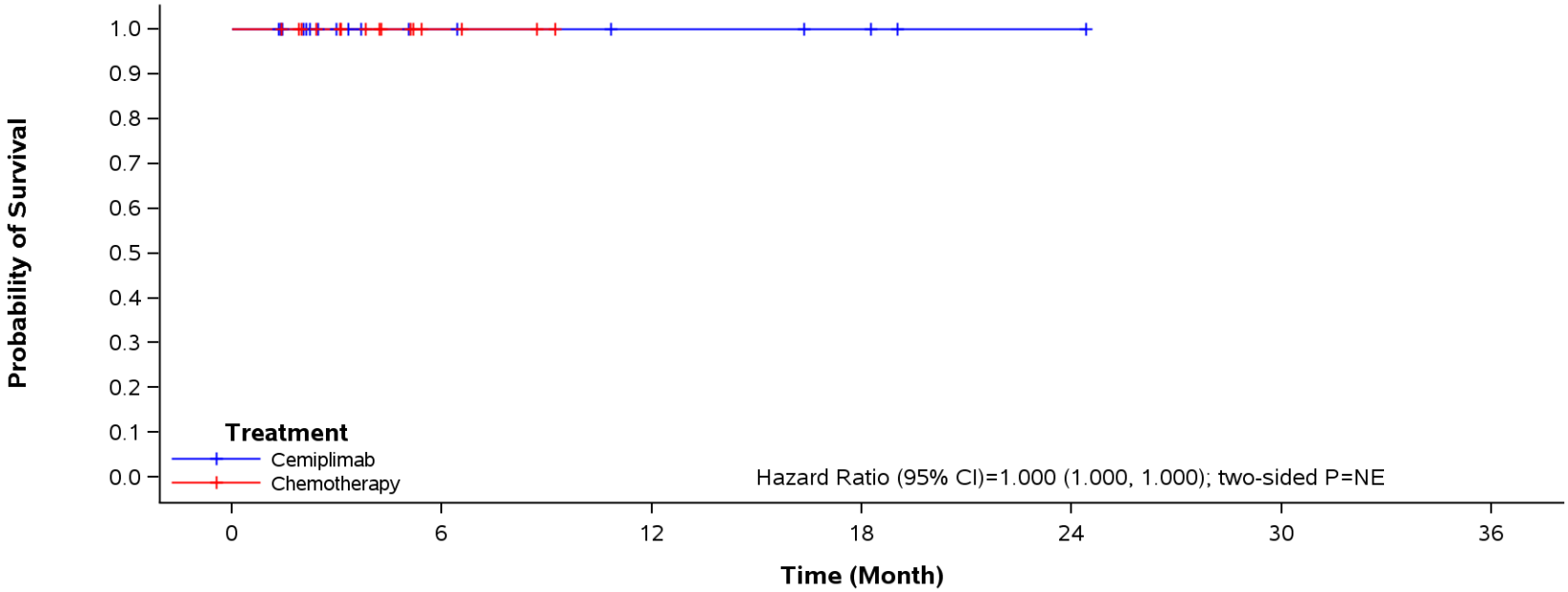

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Renal and urinary disorders



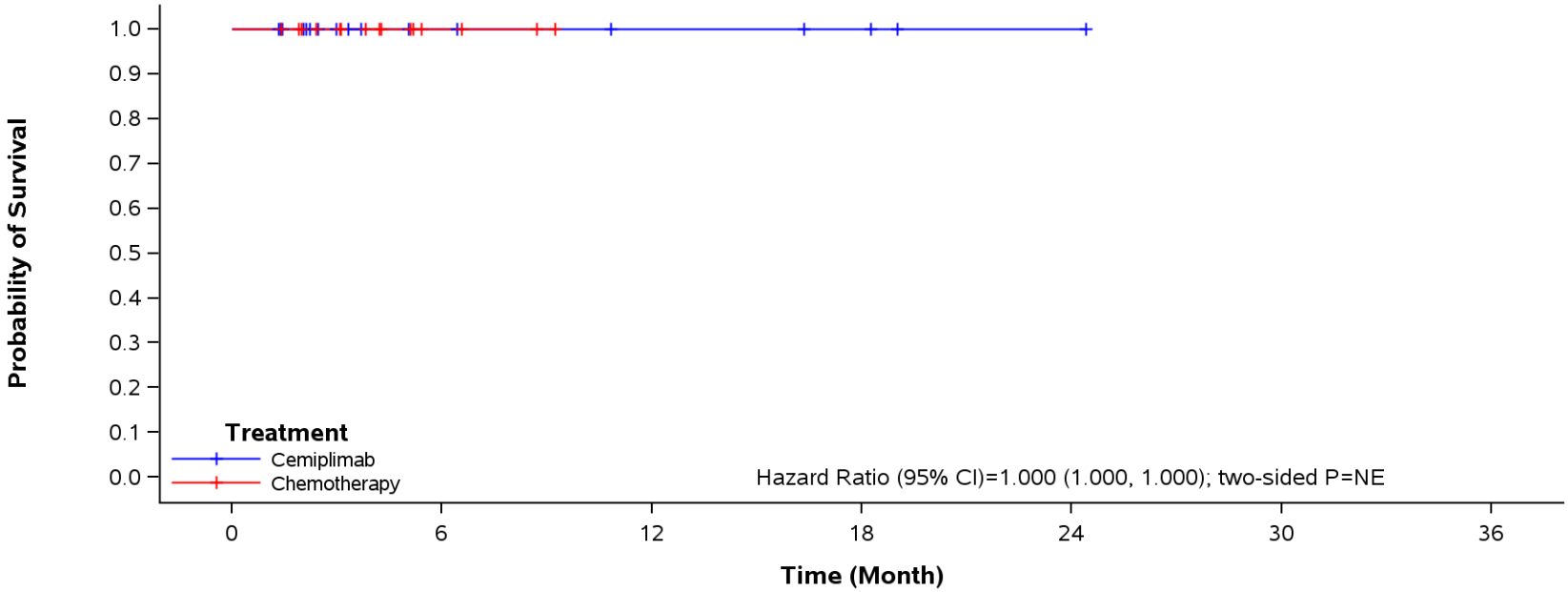

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Renal and urinary disorders
PT: Renal failure



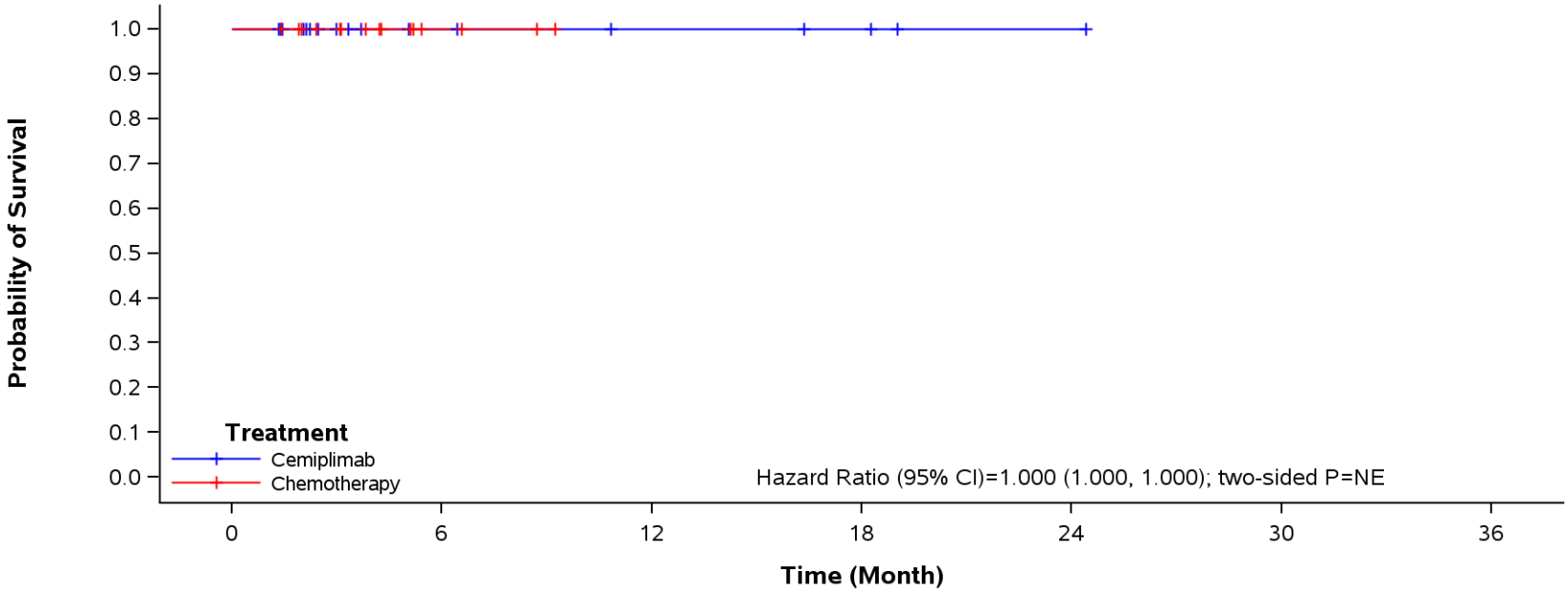

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Respiratory, thoracic and mediastinal disorders



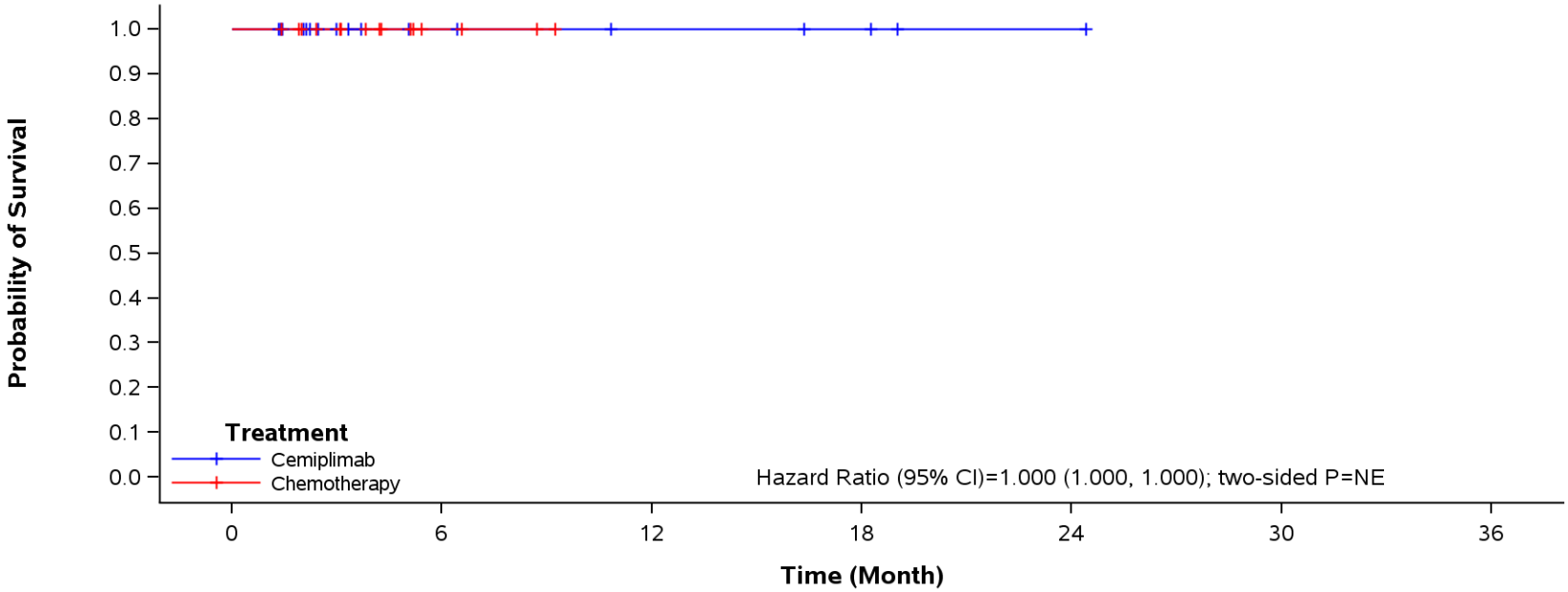

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



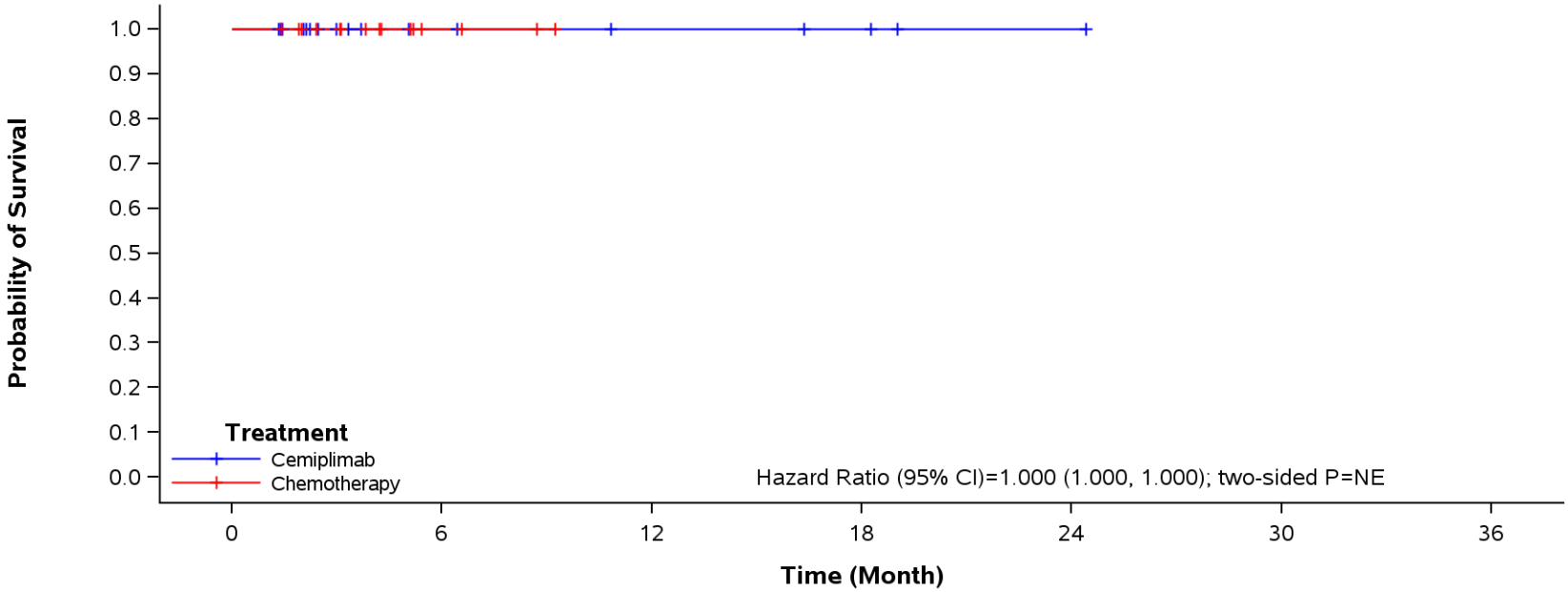

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Vascular disorders



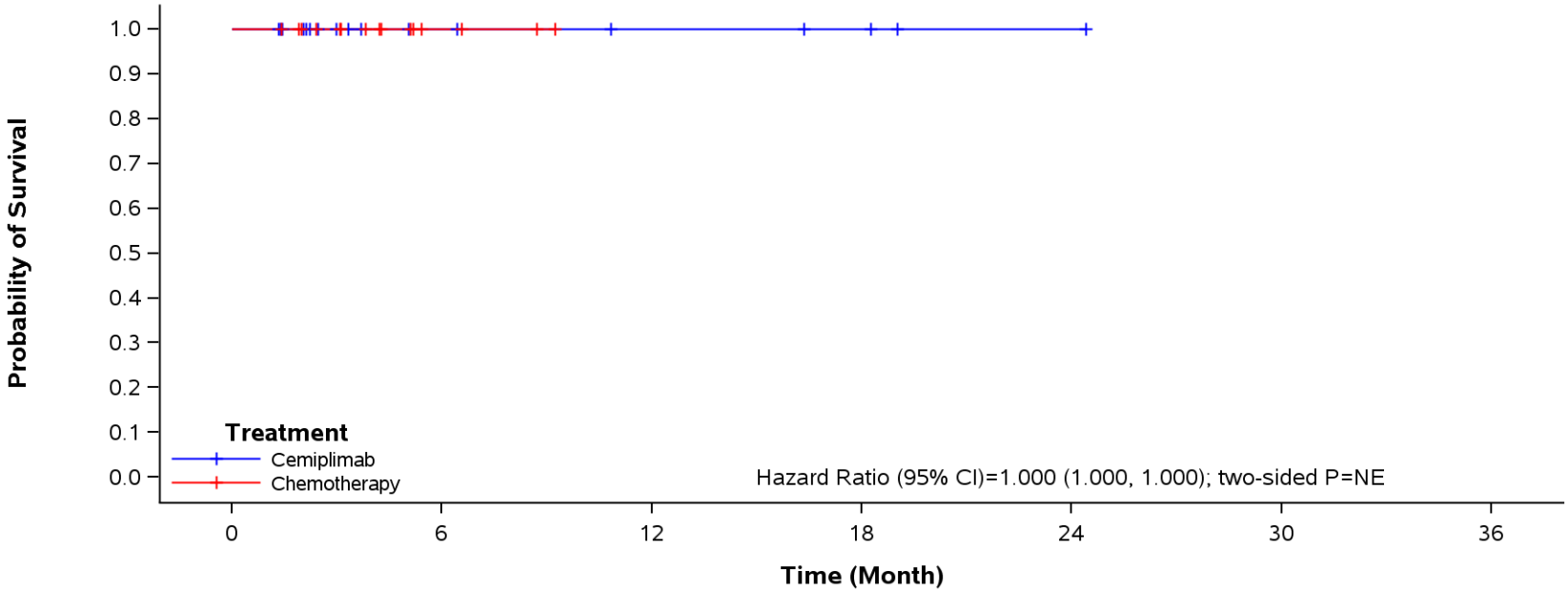

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Topotecan
SOC: Vascular disorders
PT: Deep vein thrombosis



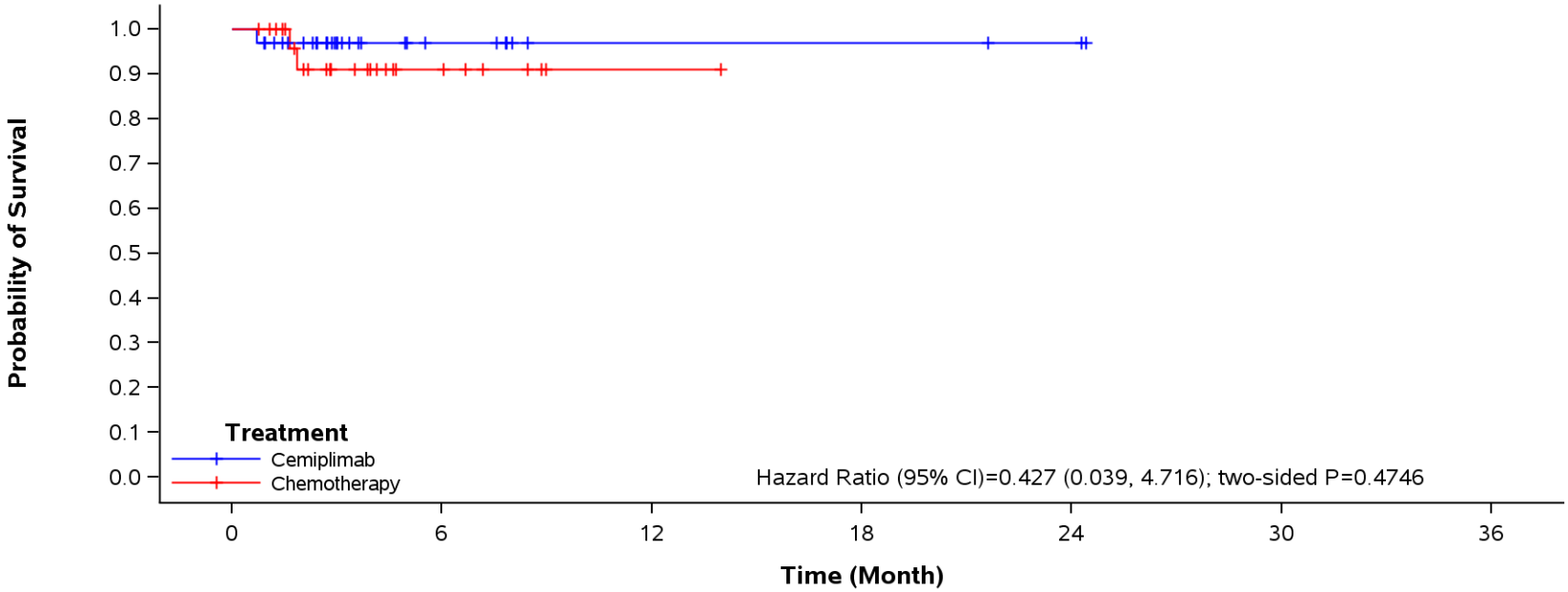

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 20 | 6 | 4 | 3 | 1 | 0 | 0 |
| Chemotherapy | 16 | 3 | 0 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
Number of patients with any TEAE leading to discontinuation



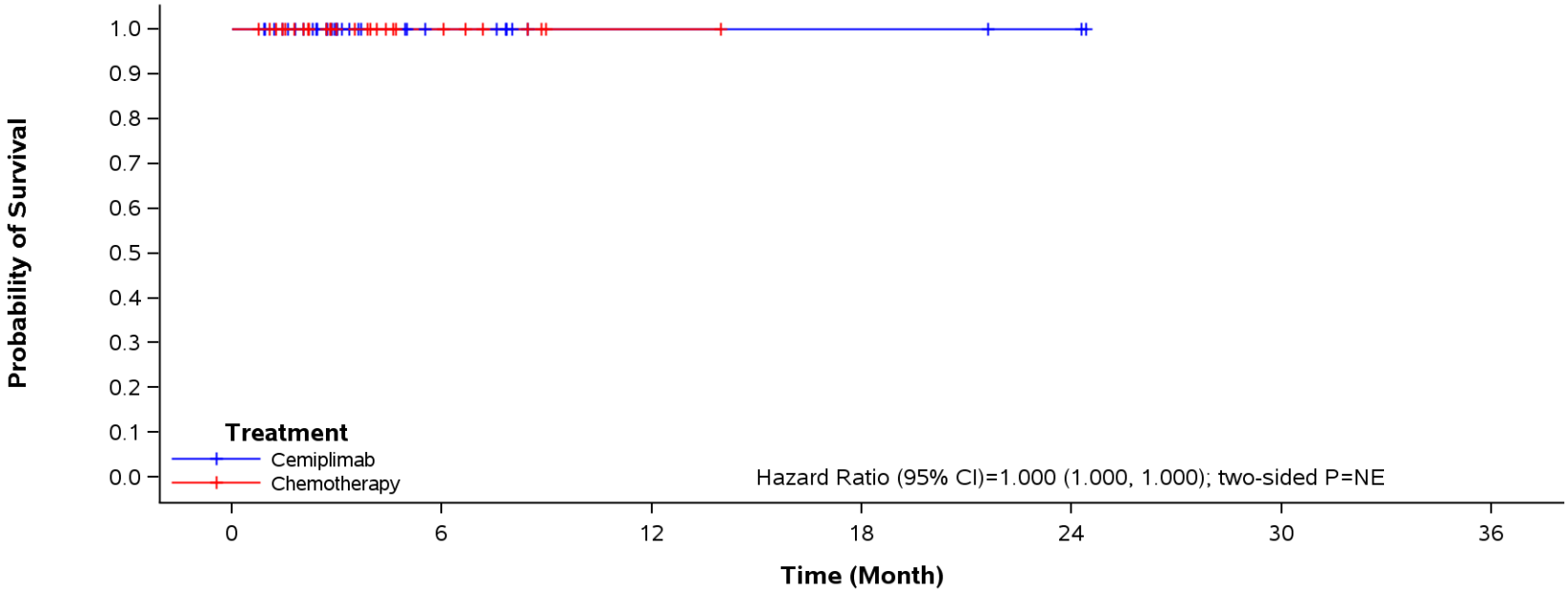

Number of Subjects at risk

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders



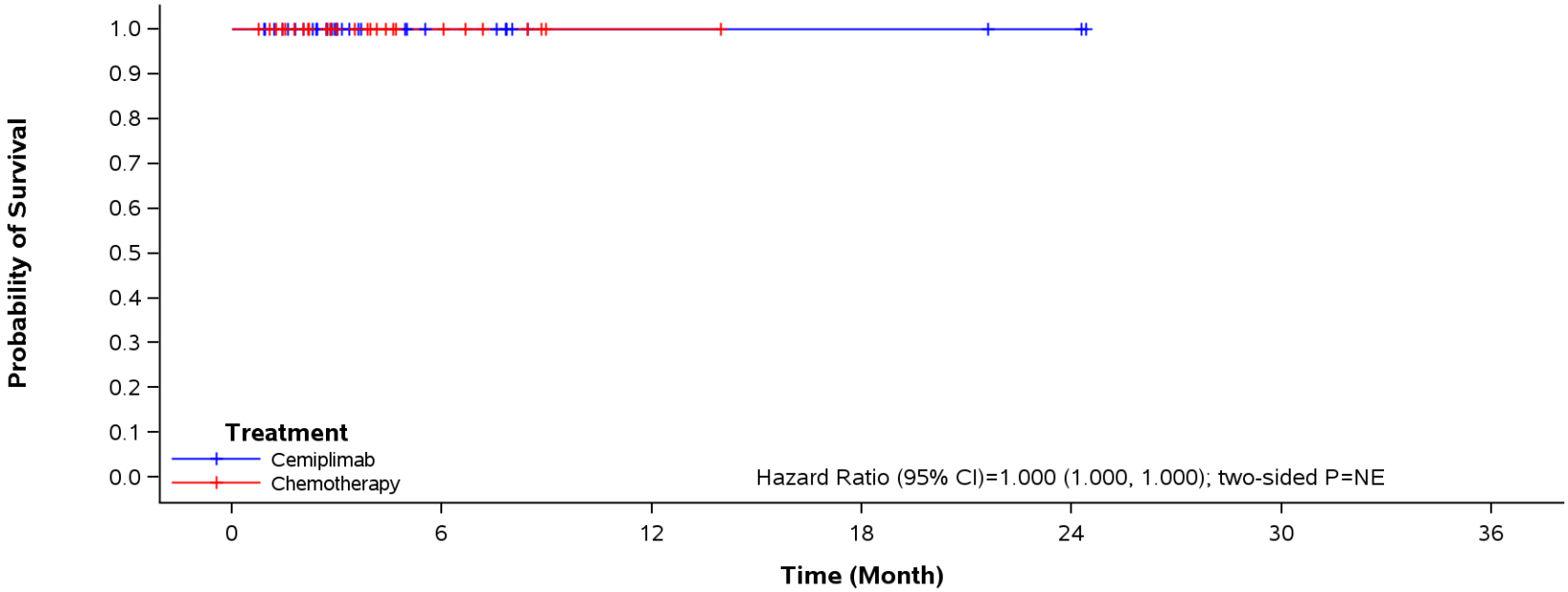

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Anaemia



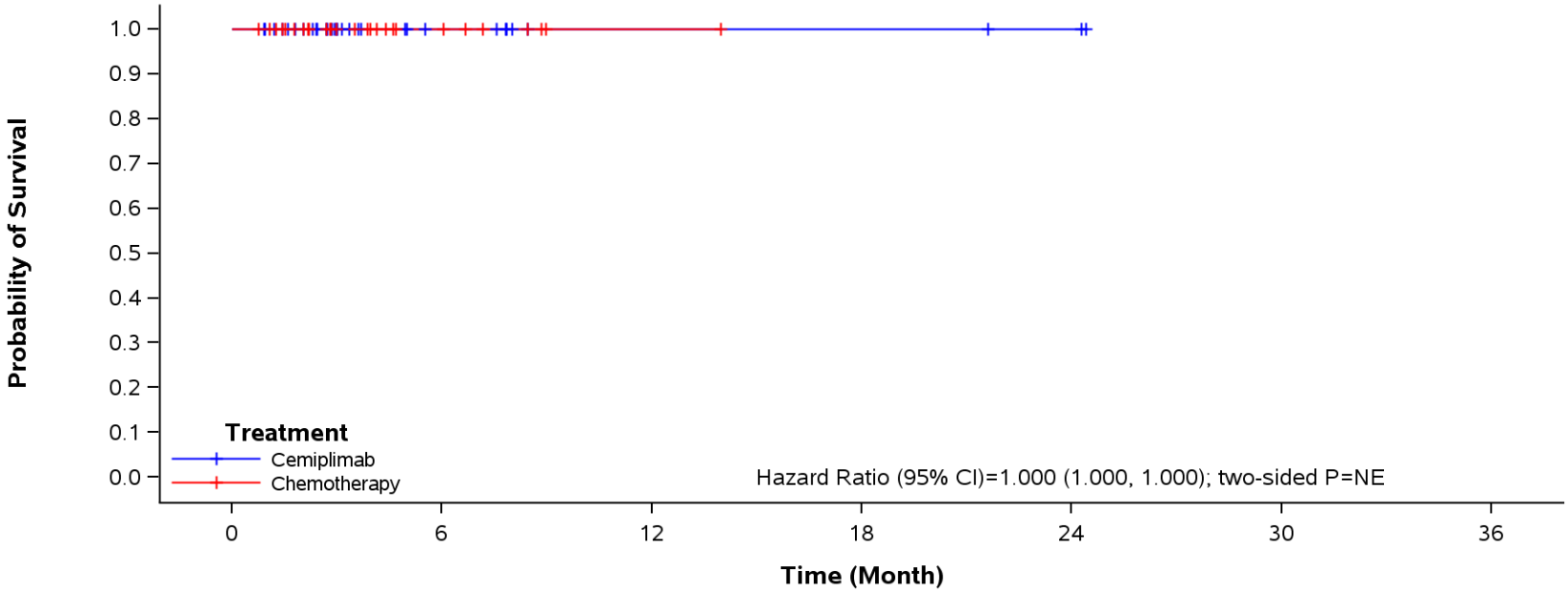

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Disseminated intravascular coagulation



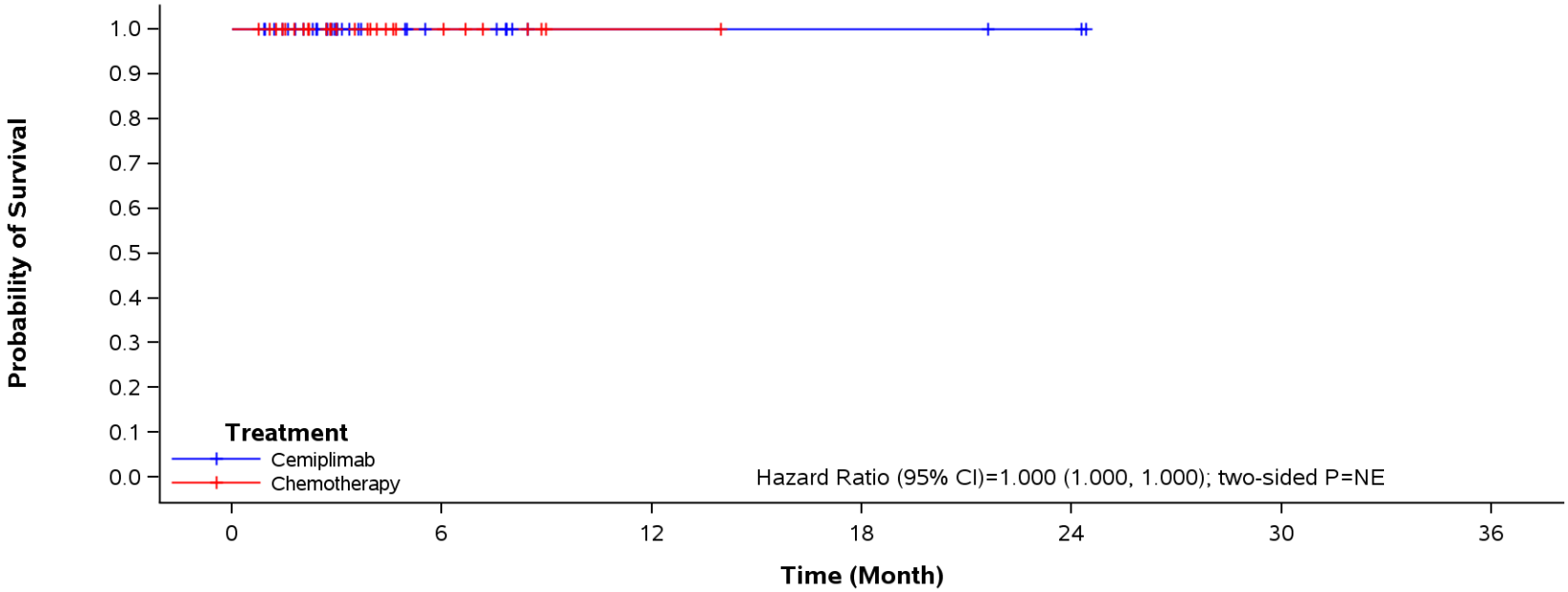

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Neutropenia



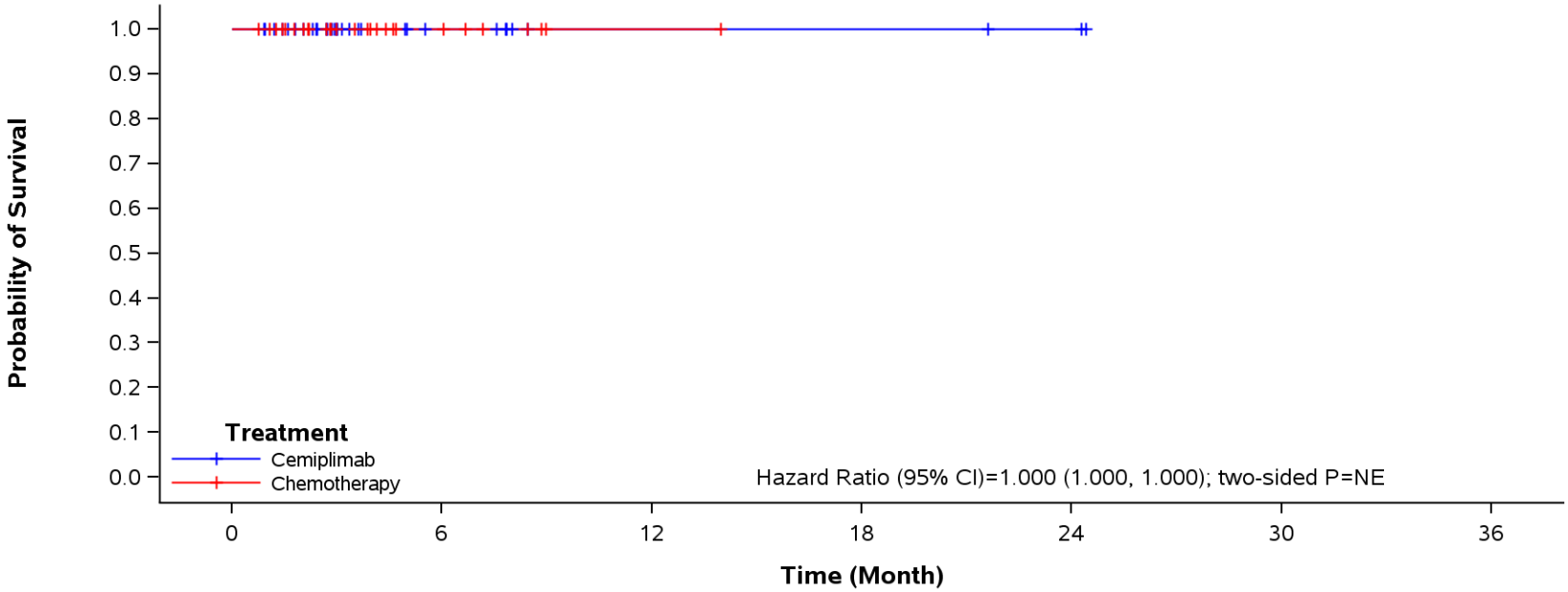

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Blood and lymphatic system disorders
PT: Thrombocytopenia



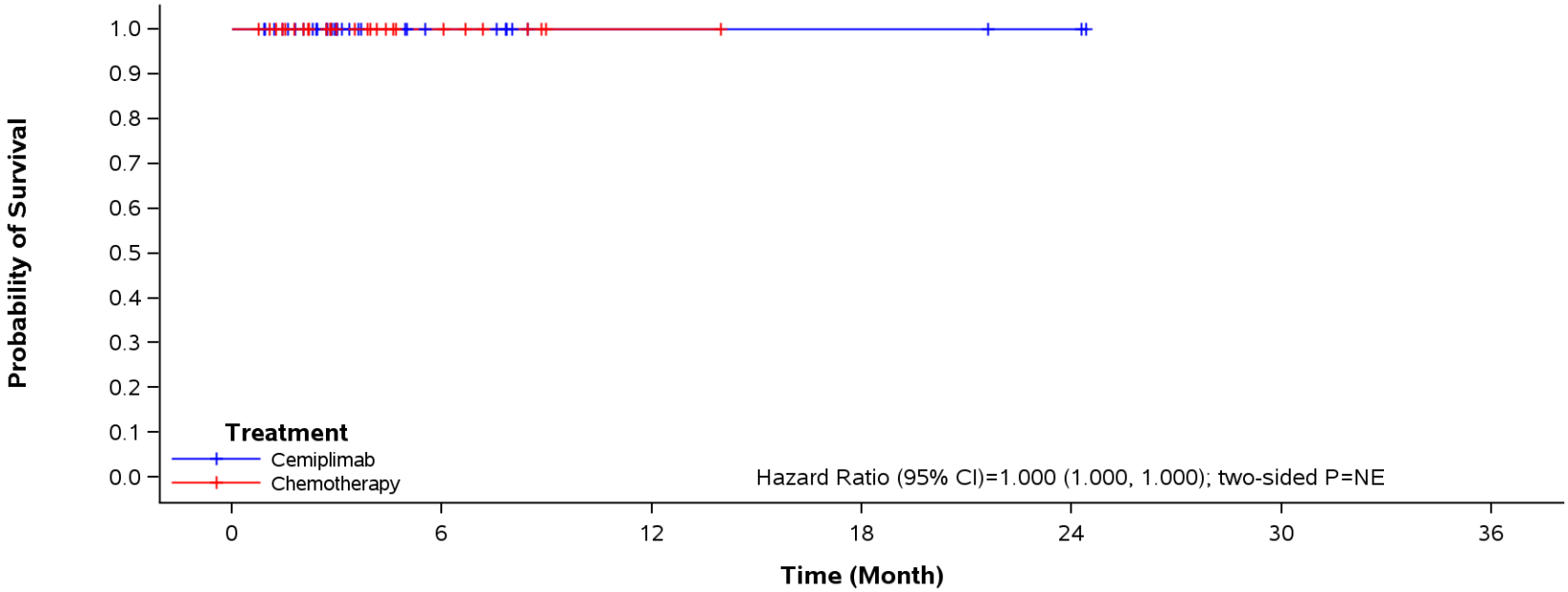

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Cardiac disorders



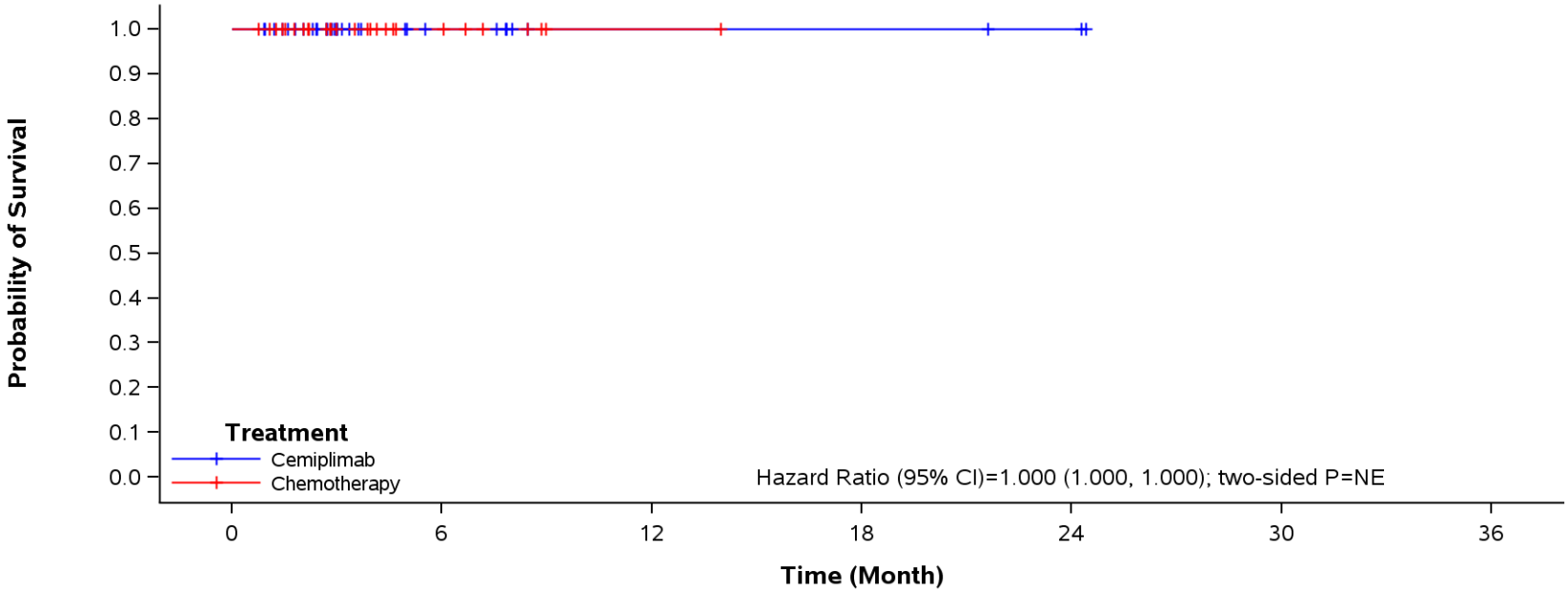

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Cardiac disorders
PT: Autoimmune pericarditis



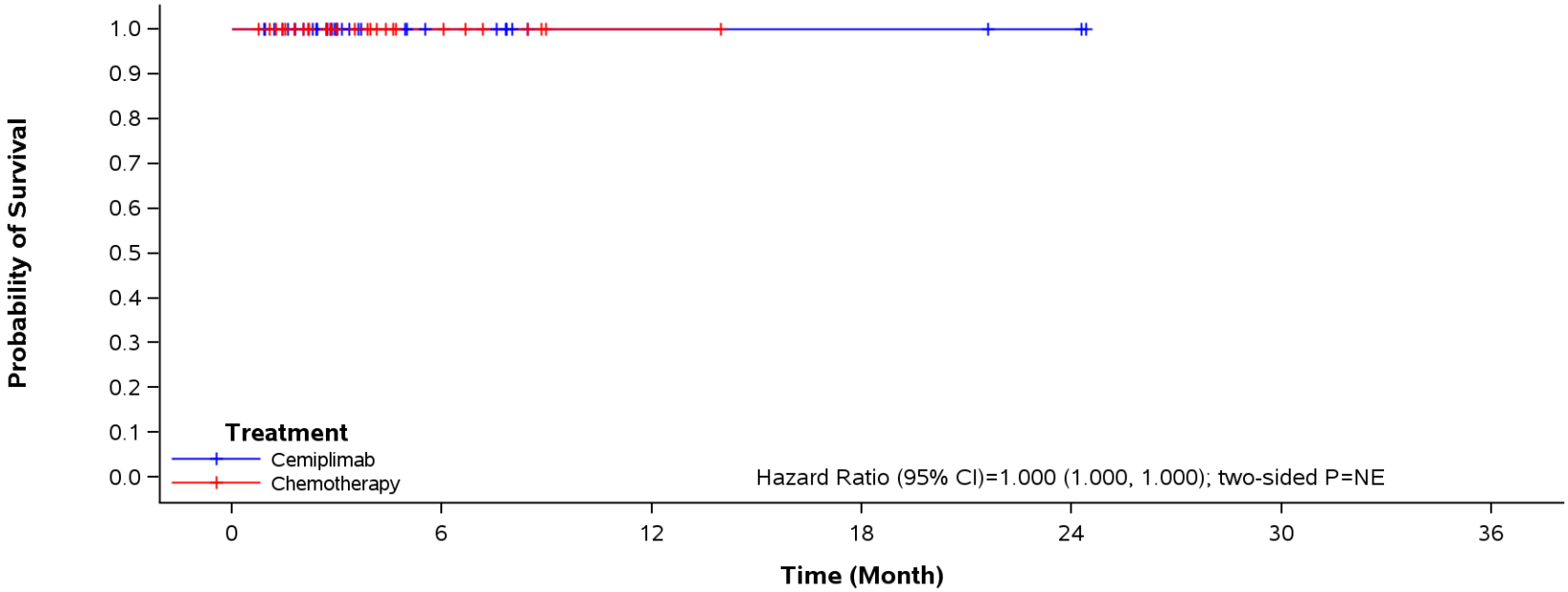

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Endocrine disorders



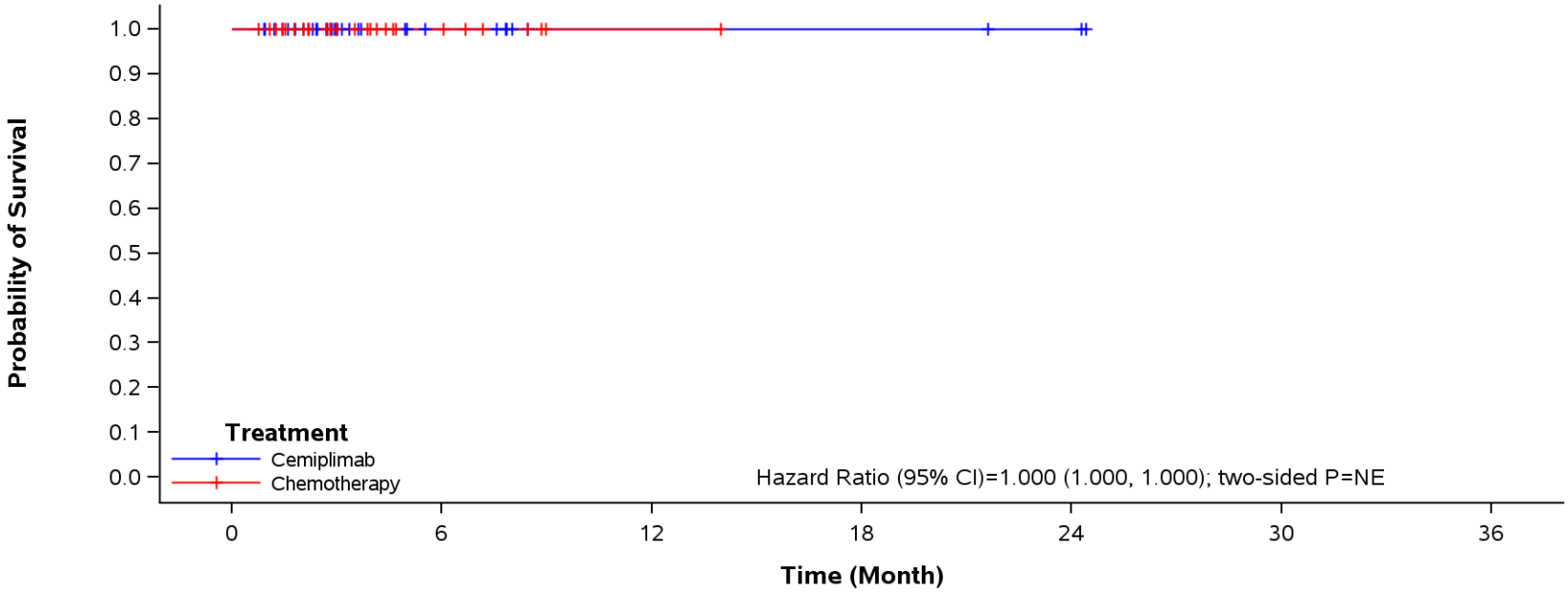

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Endocrine disorders
PT: Hypothyroidism



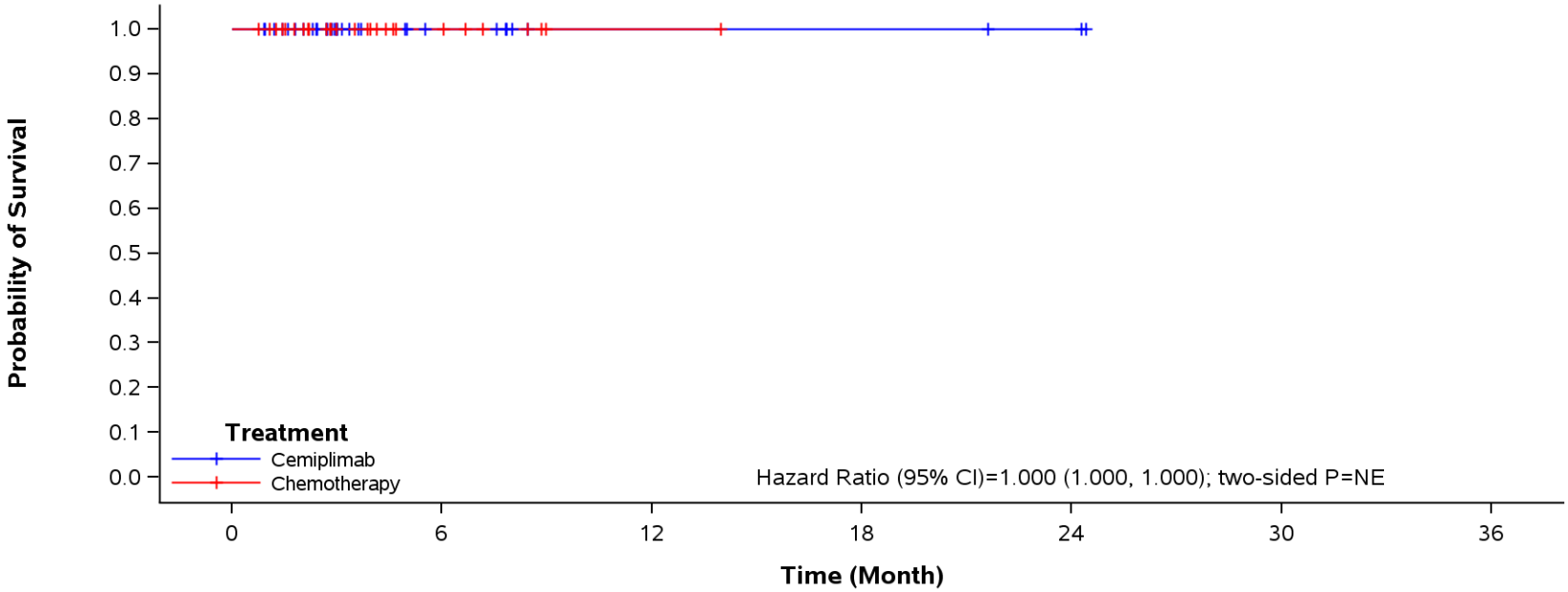

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders



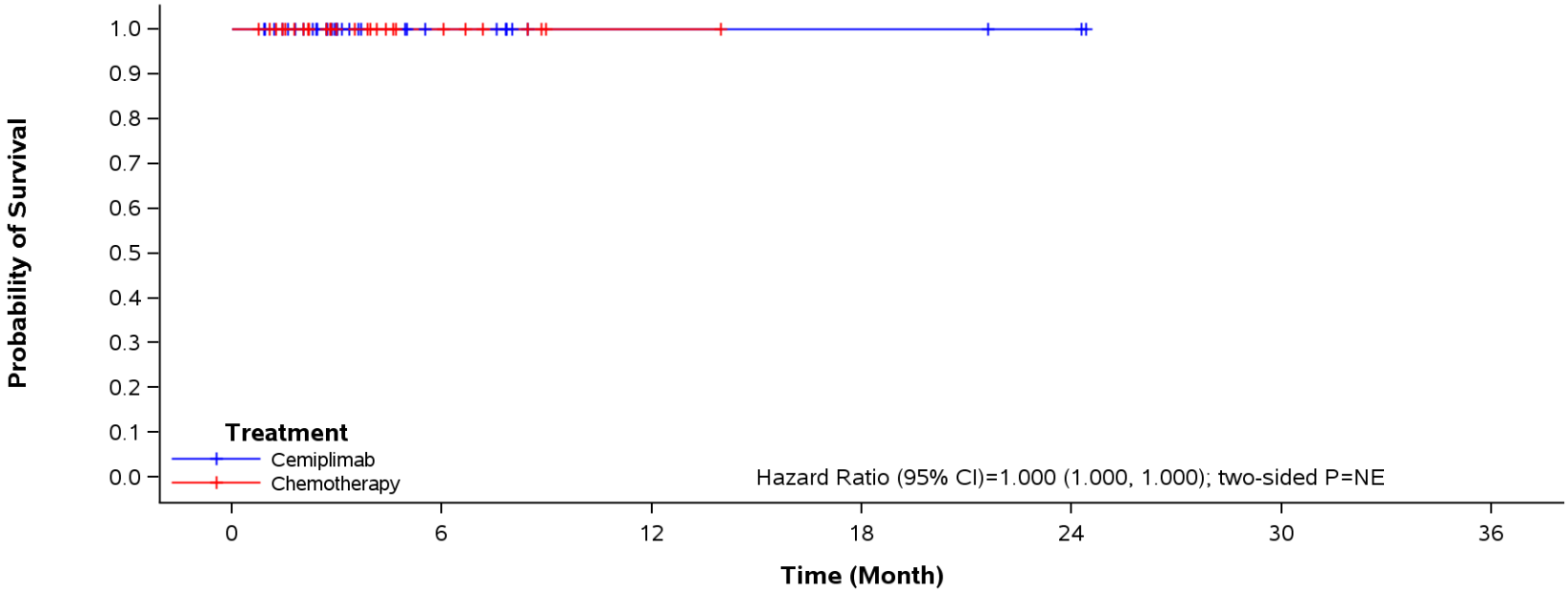

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders
PT: Colitis



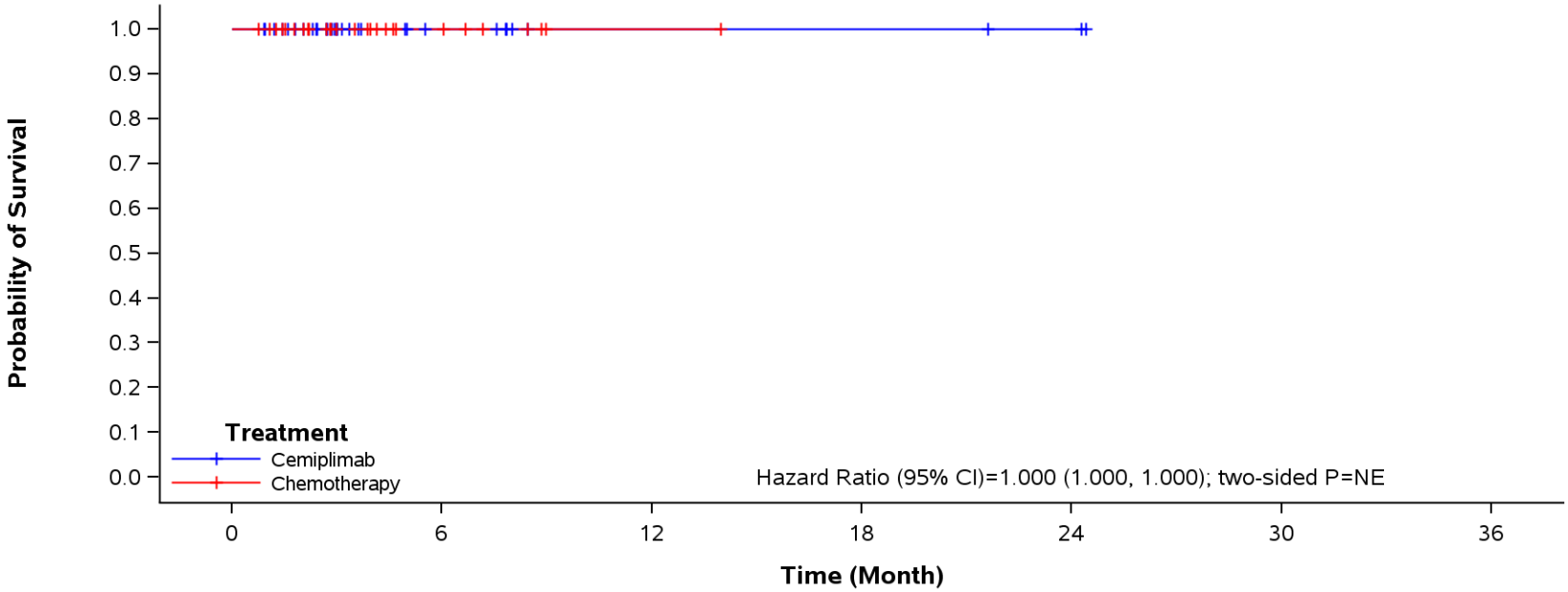

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders
PT: Diverticular perforation



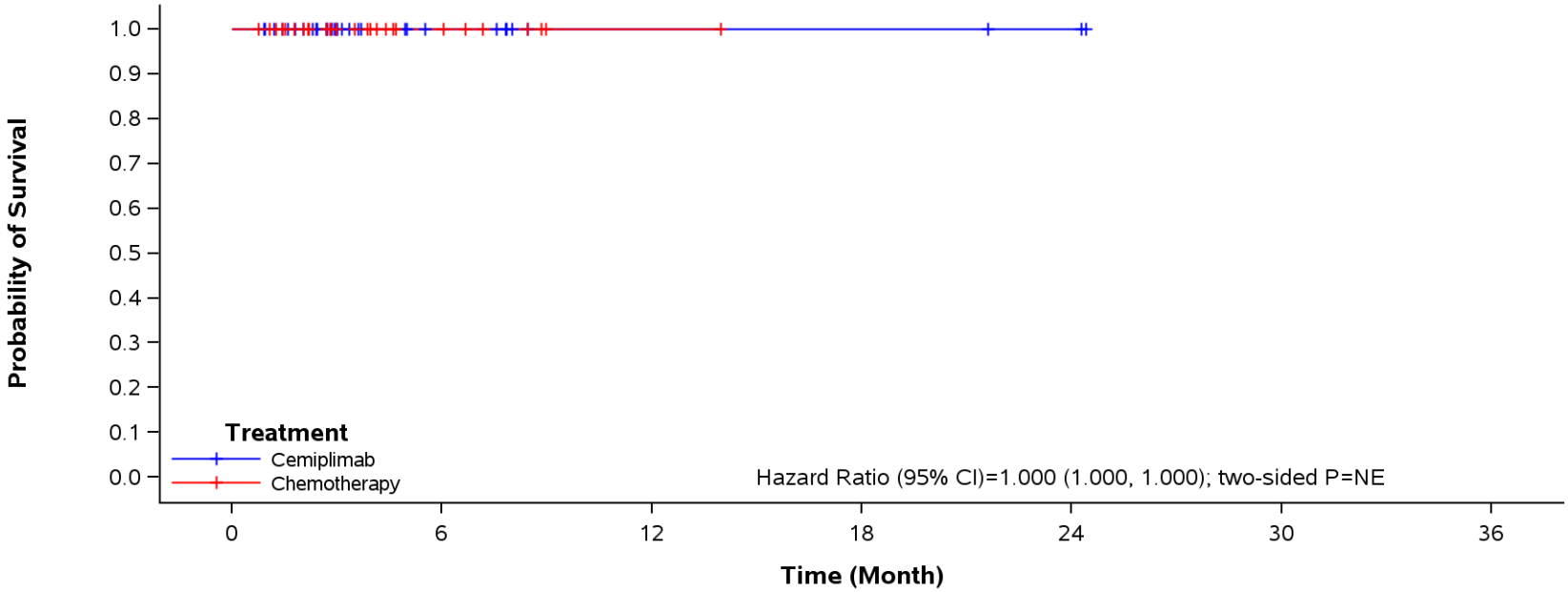

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders
PT: Pancreatic mass



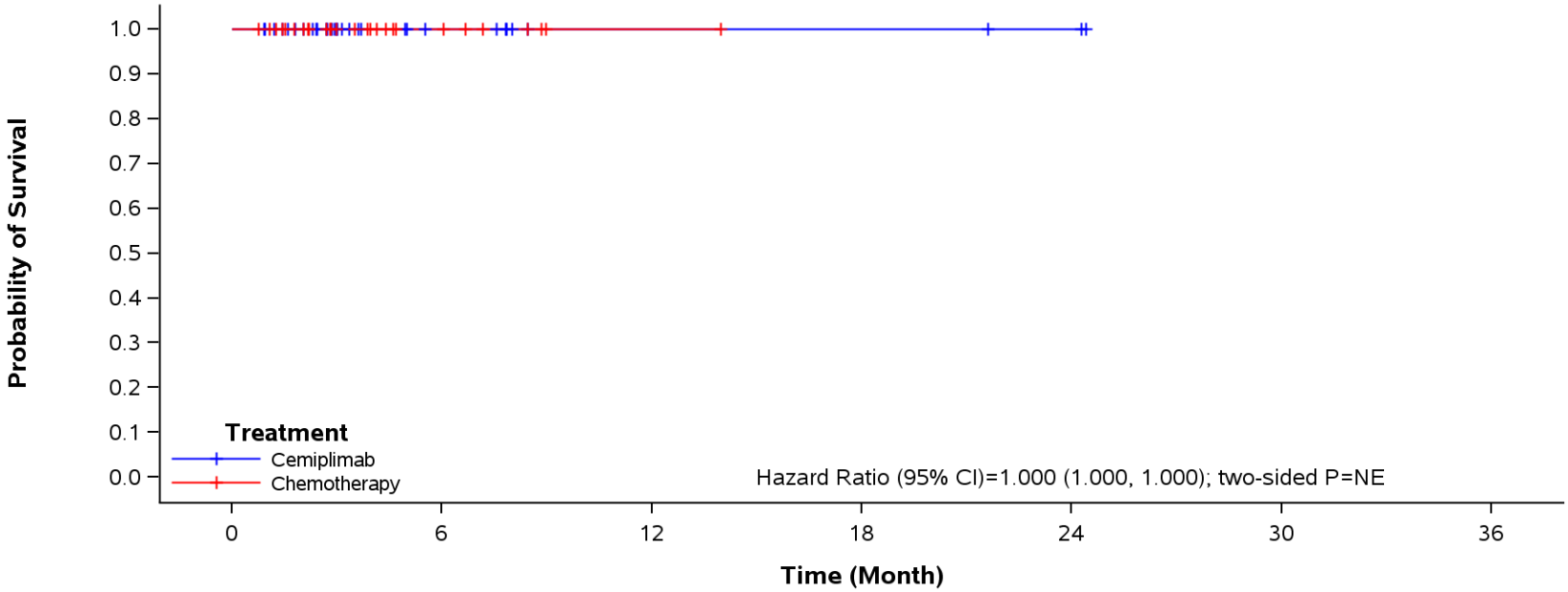

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders
PT: Pancreatitis chronic



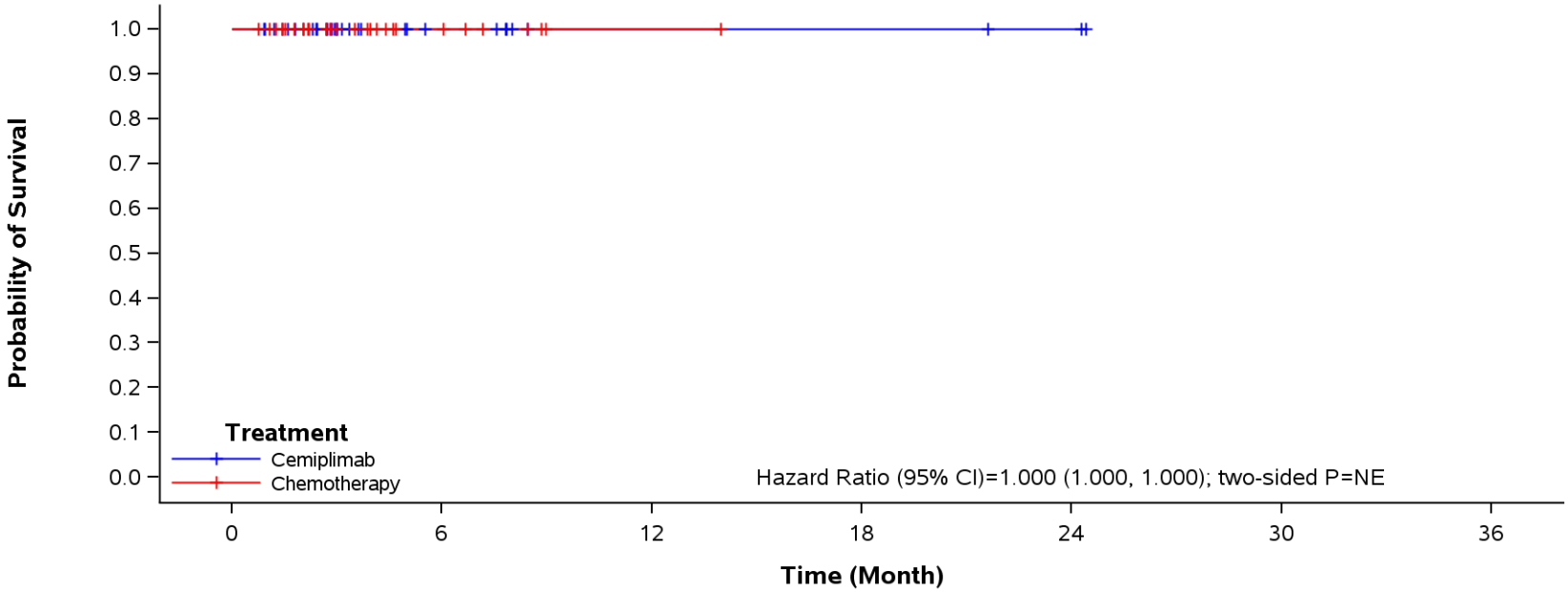

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Gastrointestinal disorders
PT: Proctalgia



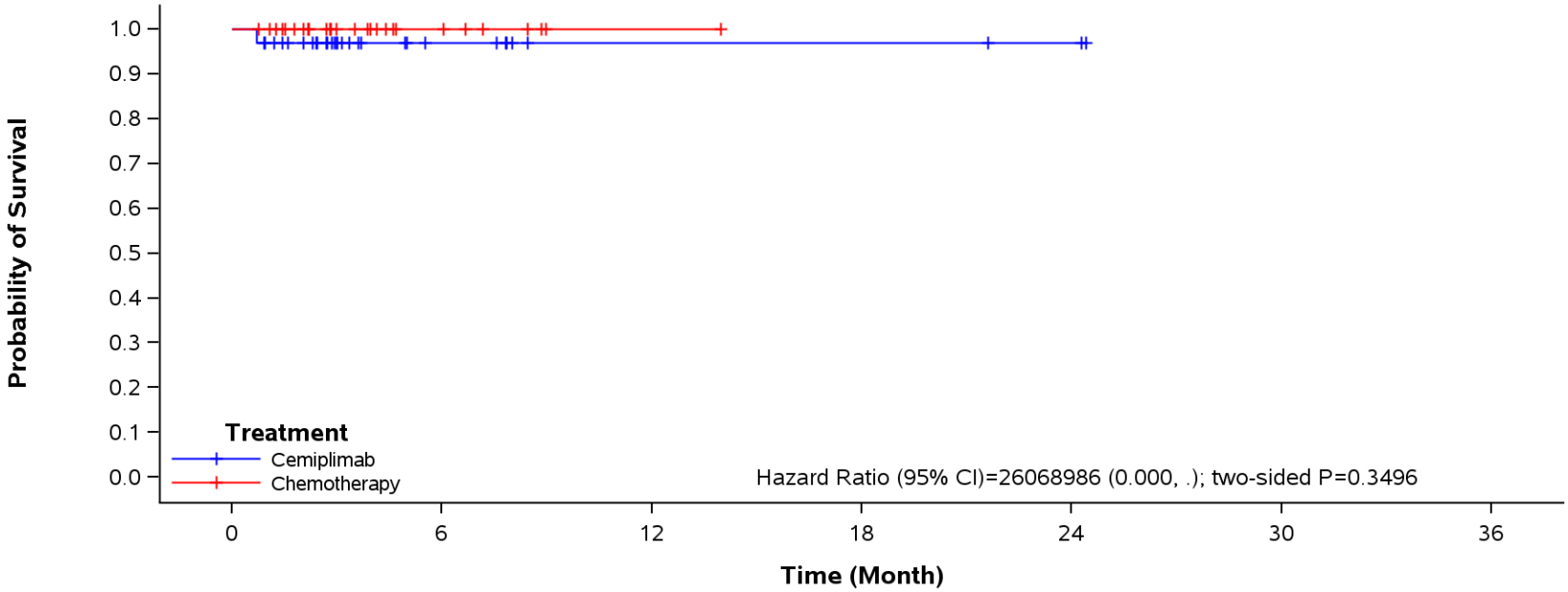

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: General disorders and administration site conditions



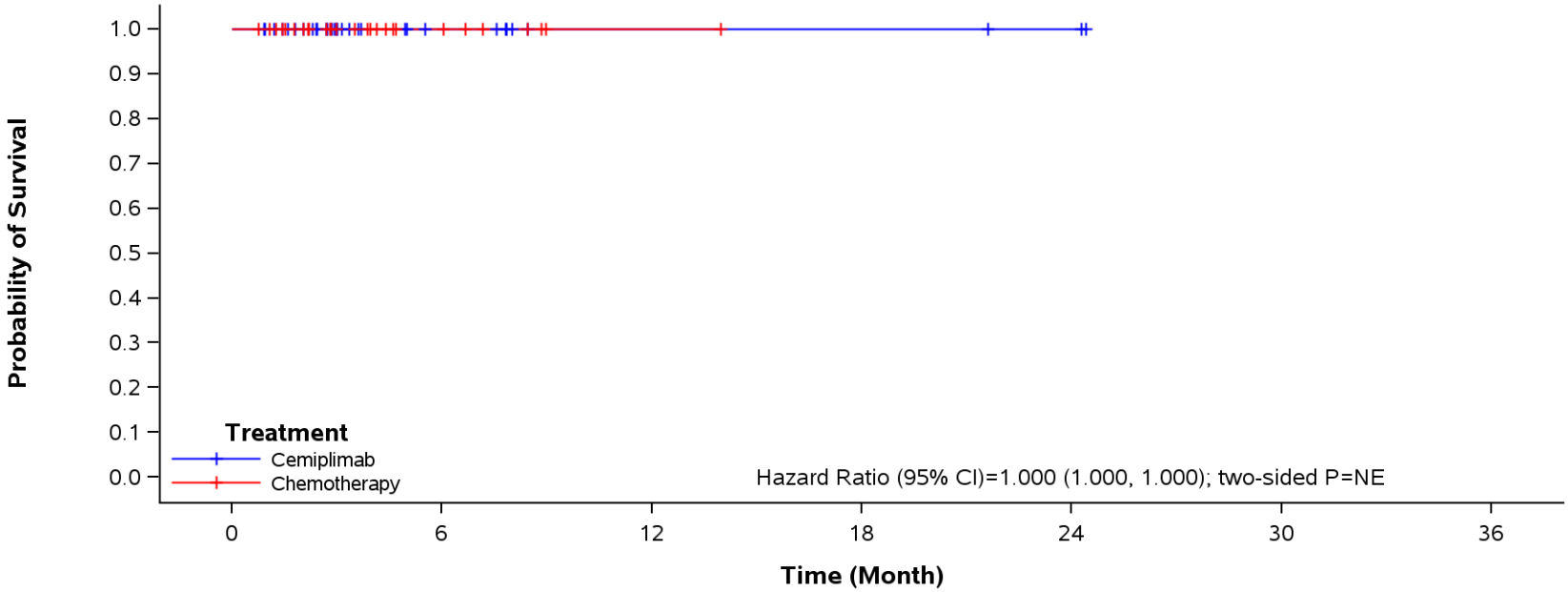

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: General disorders and administration site conditions
PT: Malaise



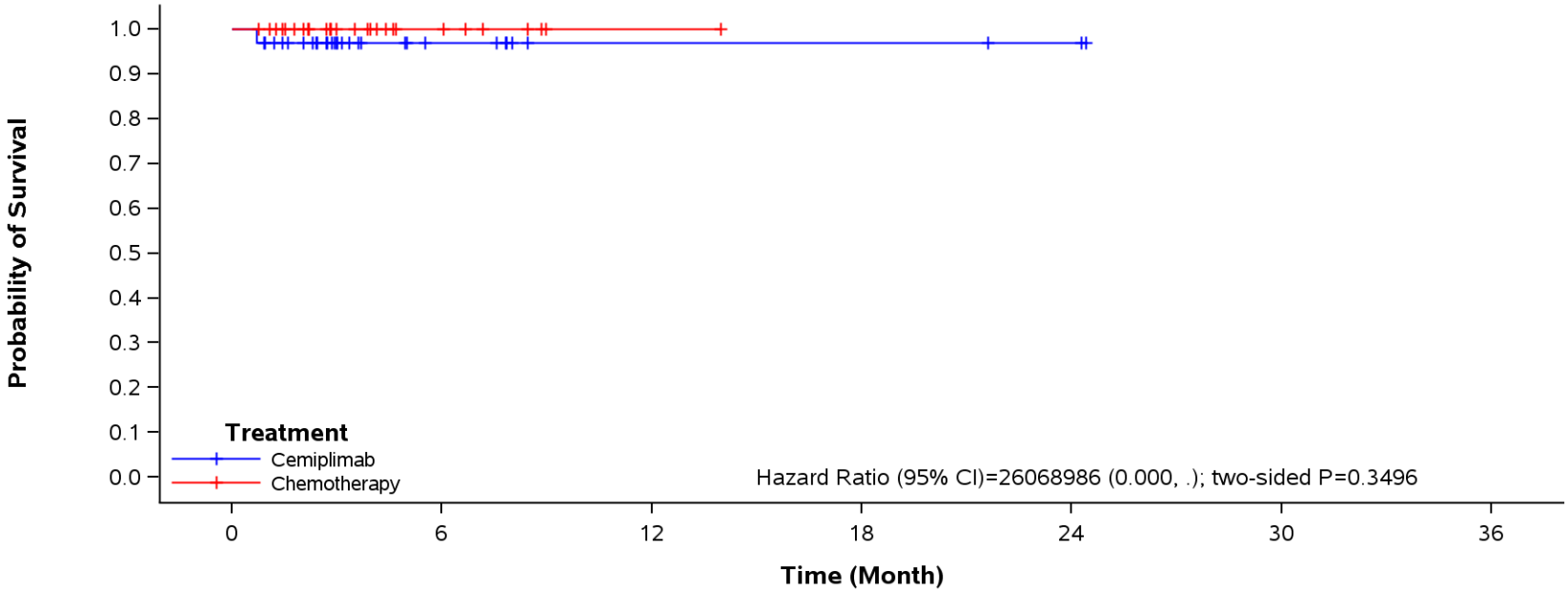

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: General disorders and administration site conditions
PT: Non-cardiac chest pain



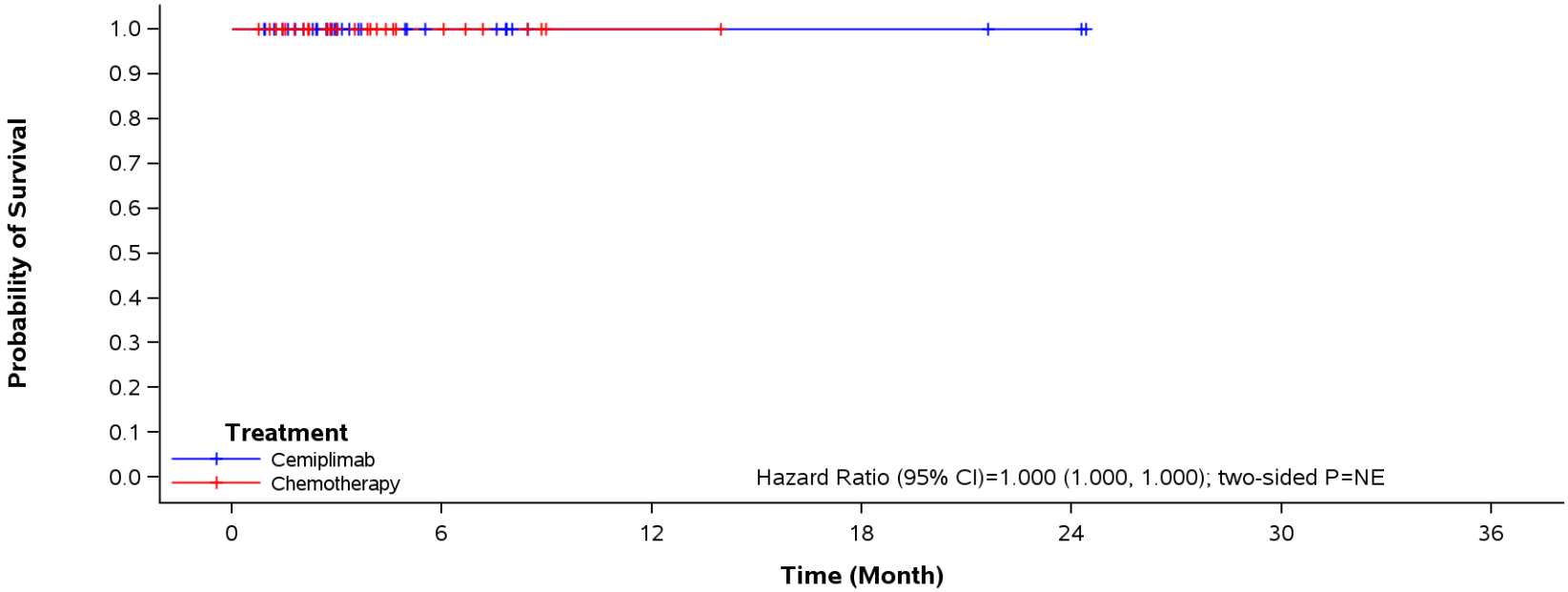

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Hepatobiliary disorders



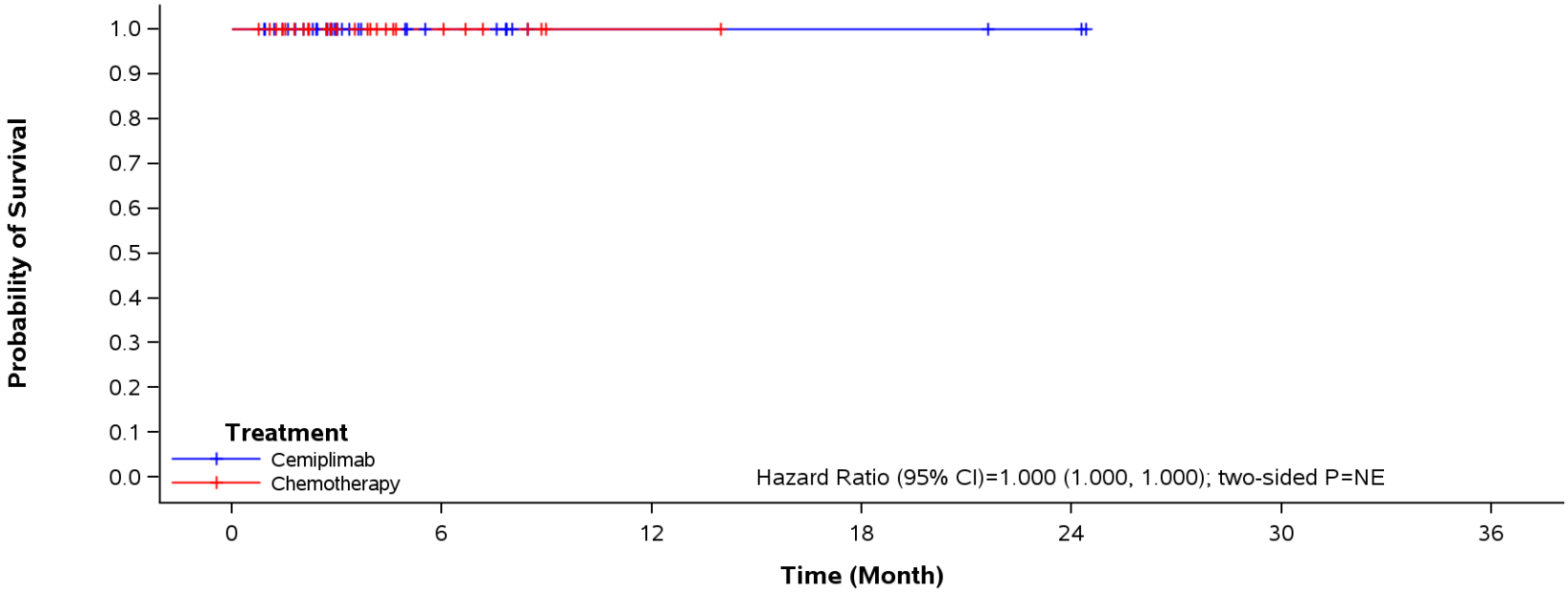

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Hepatobiliary disorders
PT: Autoimmune hepatitis



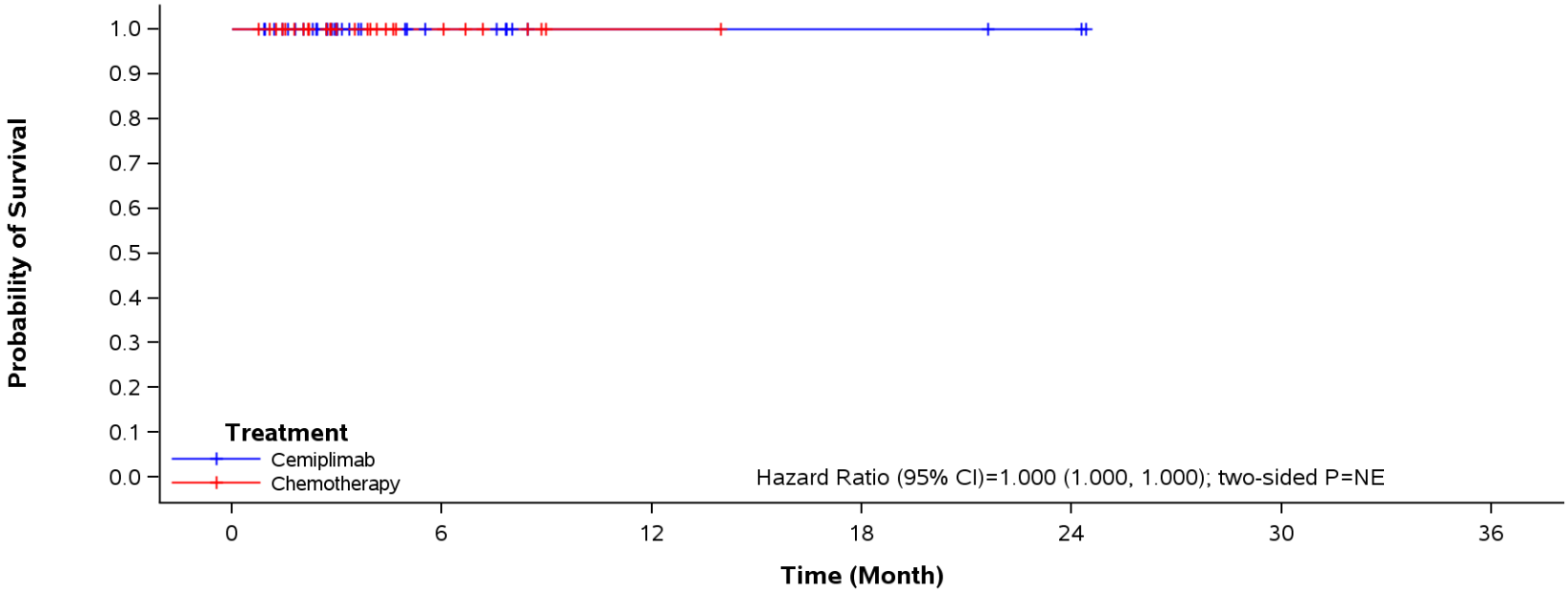

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Hepatobiliary disorders
PT: Hepatic function abnormal




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

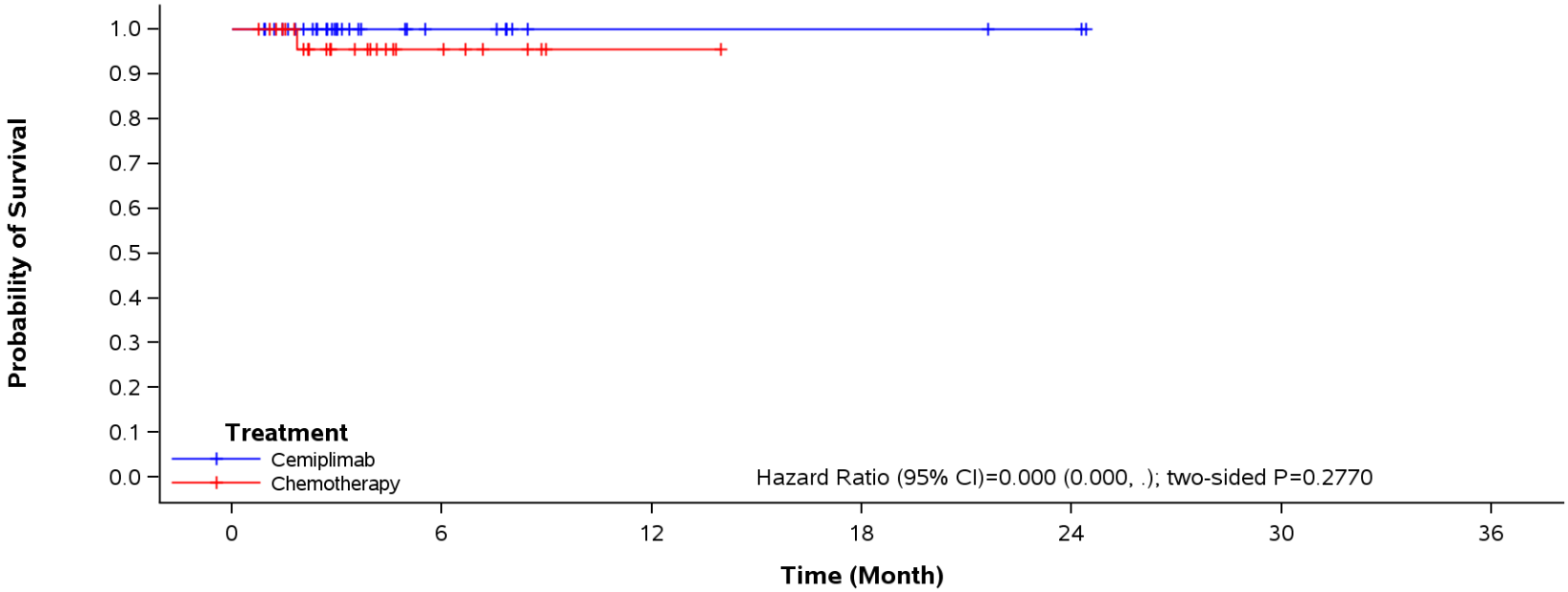
Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Hepatobiliary disorders
PT: Hepatitis

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Nervous system disorders



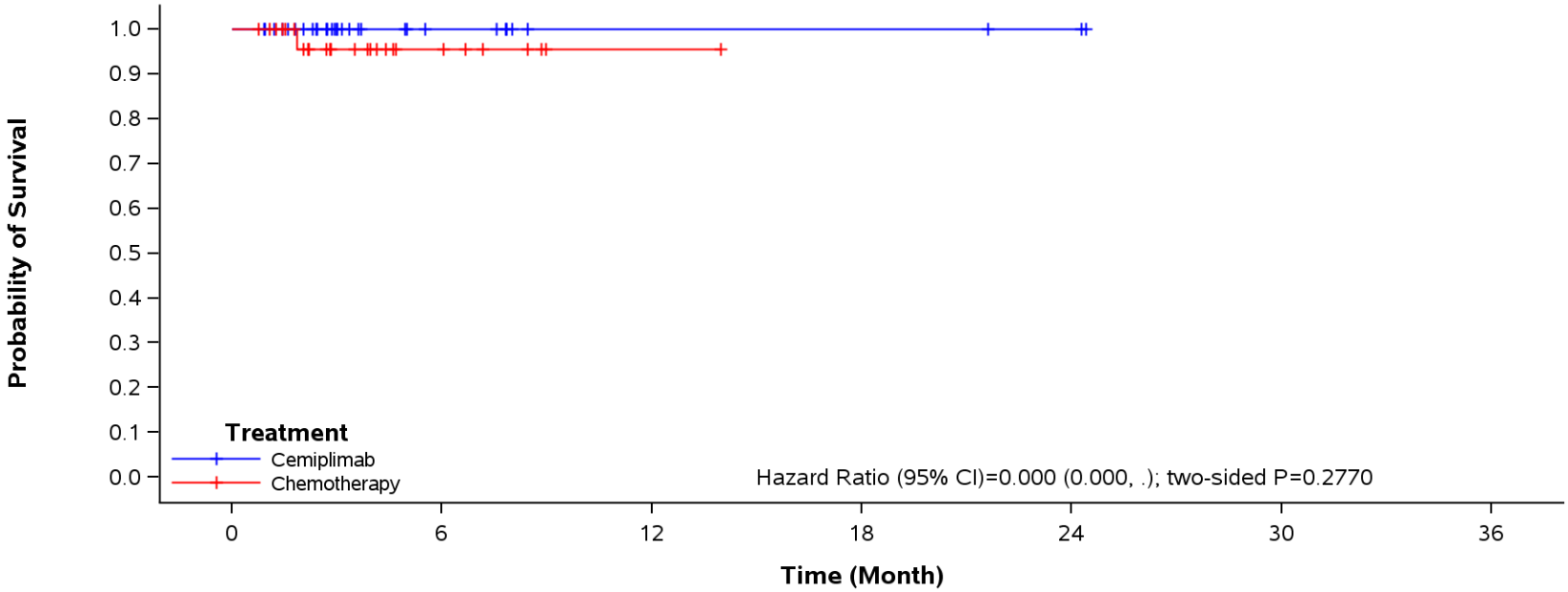

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Nervous system disorders
PT: Neurotoxicity



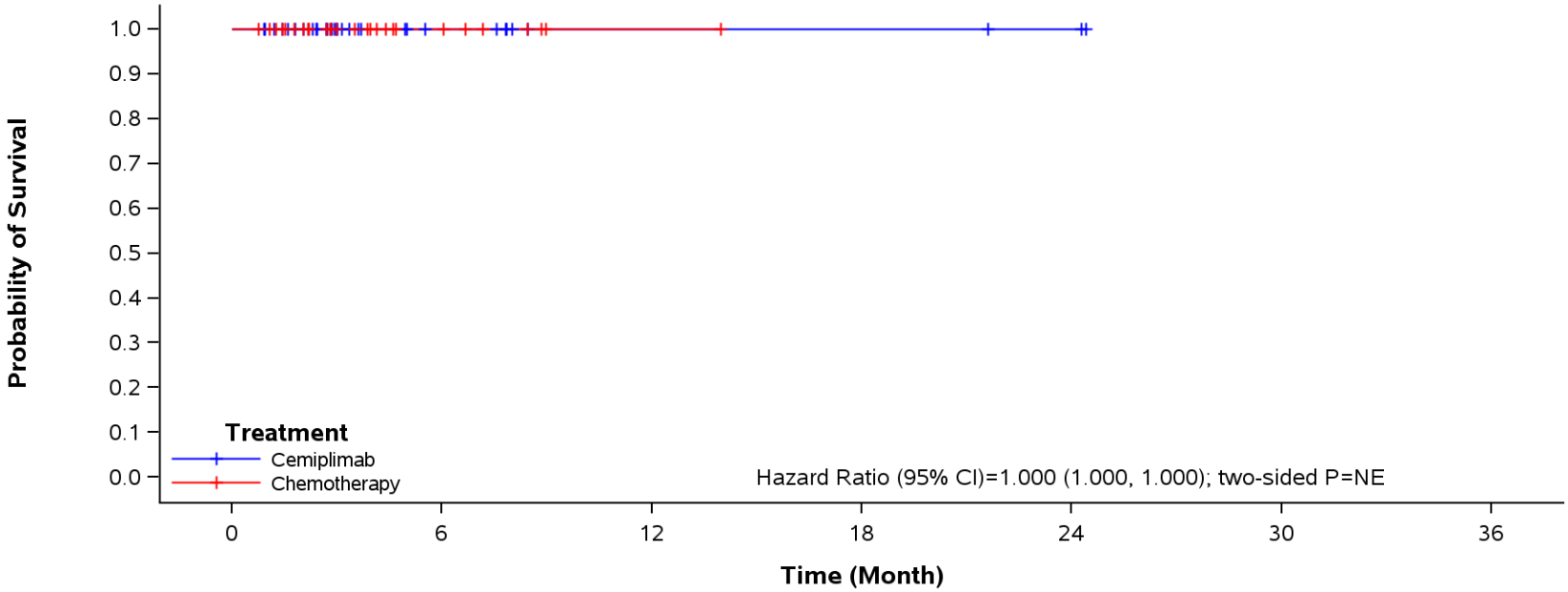

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Nervous system disorders
PT: Transient ischaemic attack



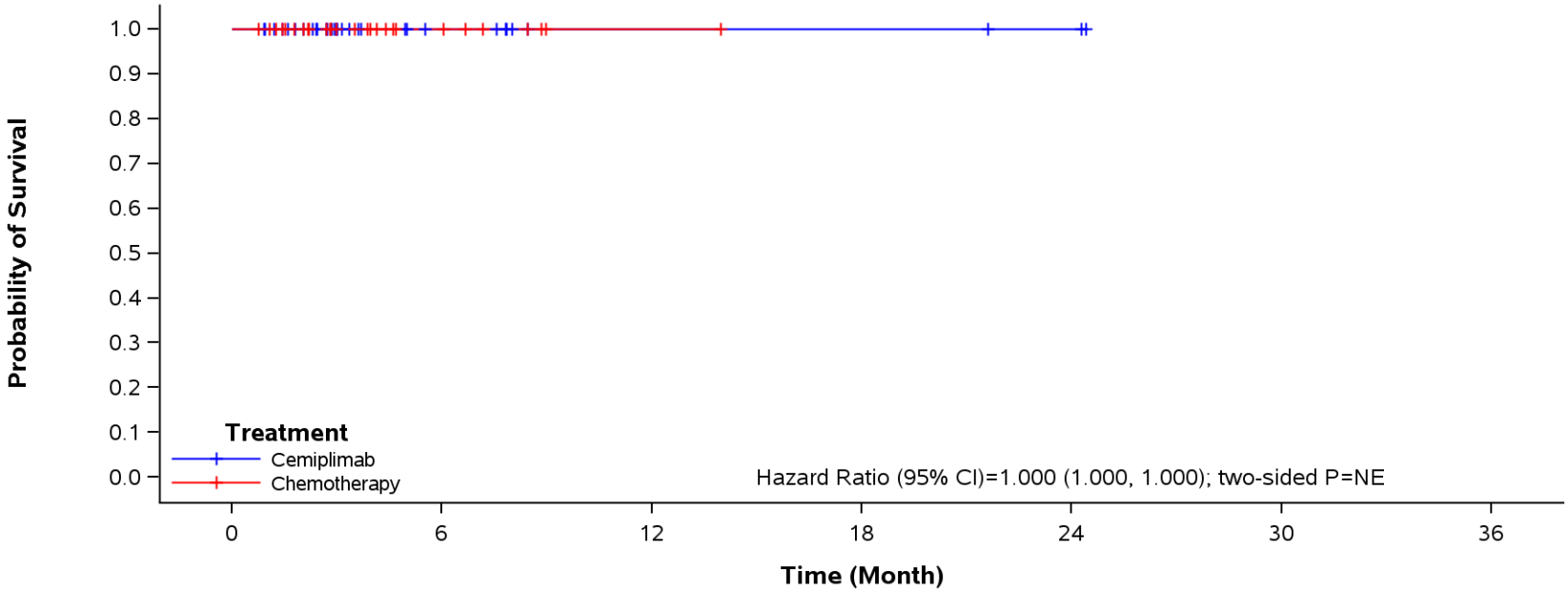

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Psychiatric disorders



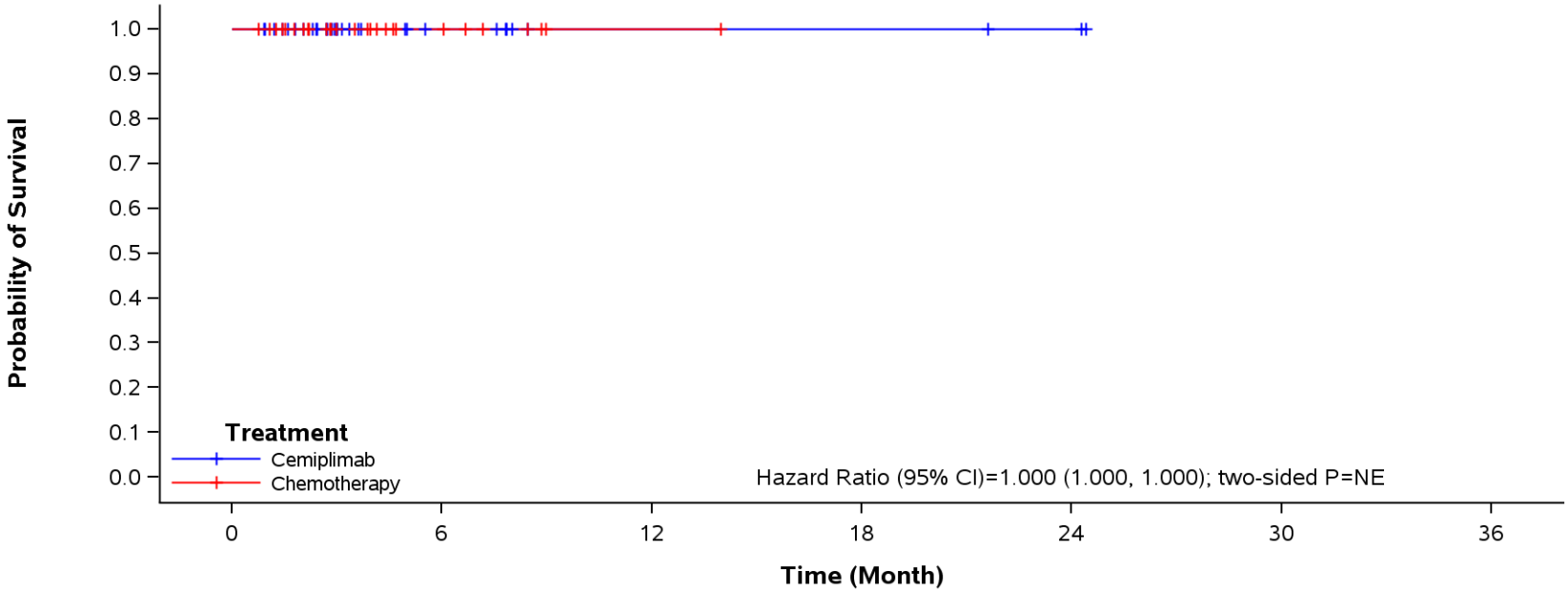

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Psychiatric disorders
PT: Agoraphobia



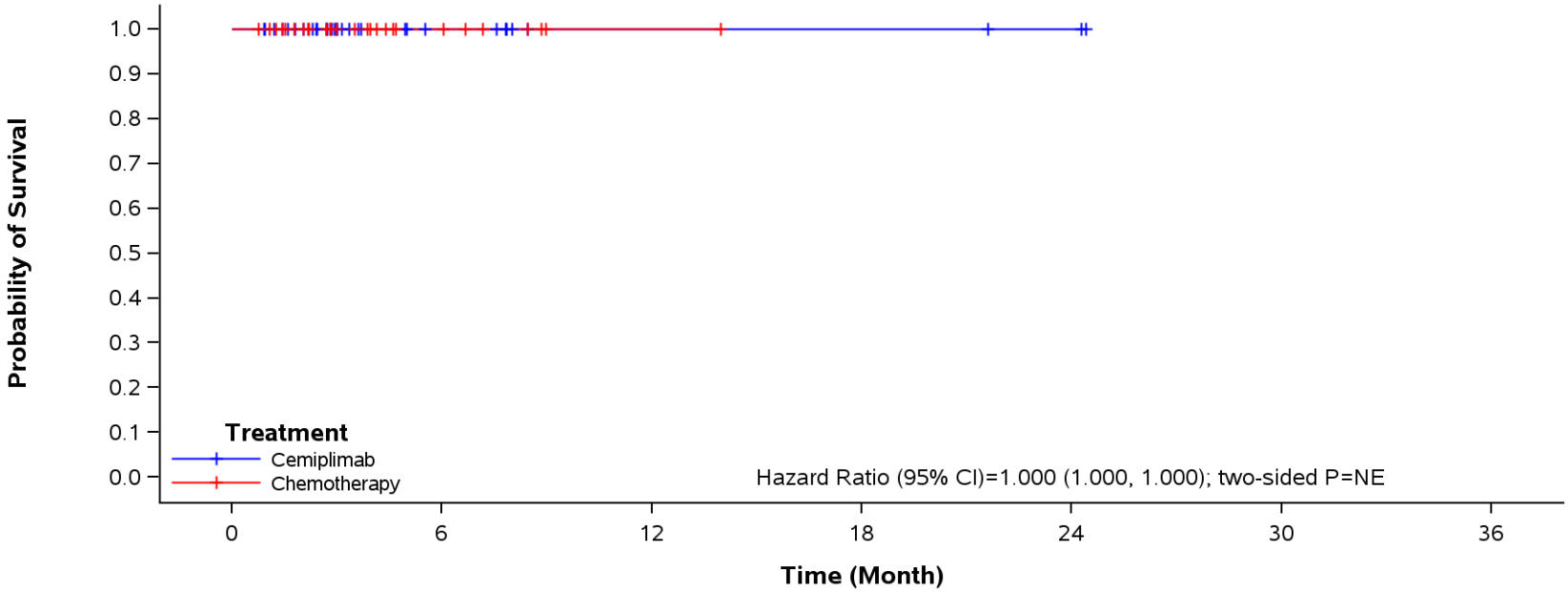

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Renal and urinary disorders



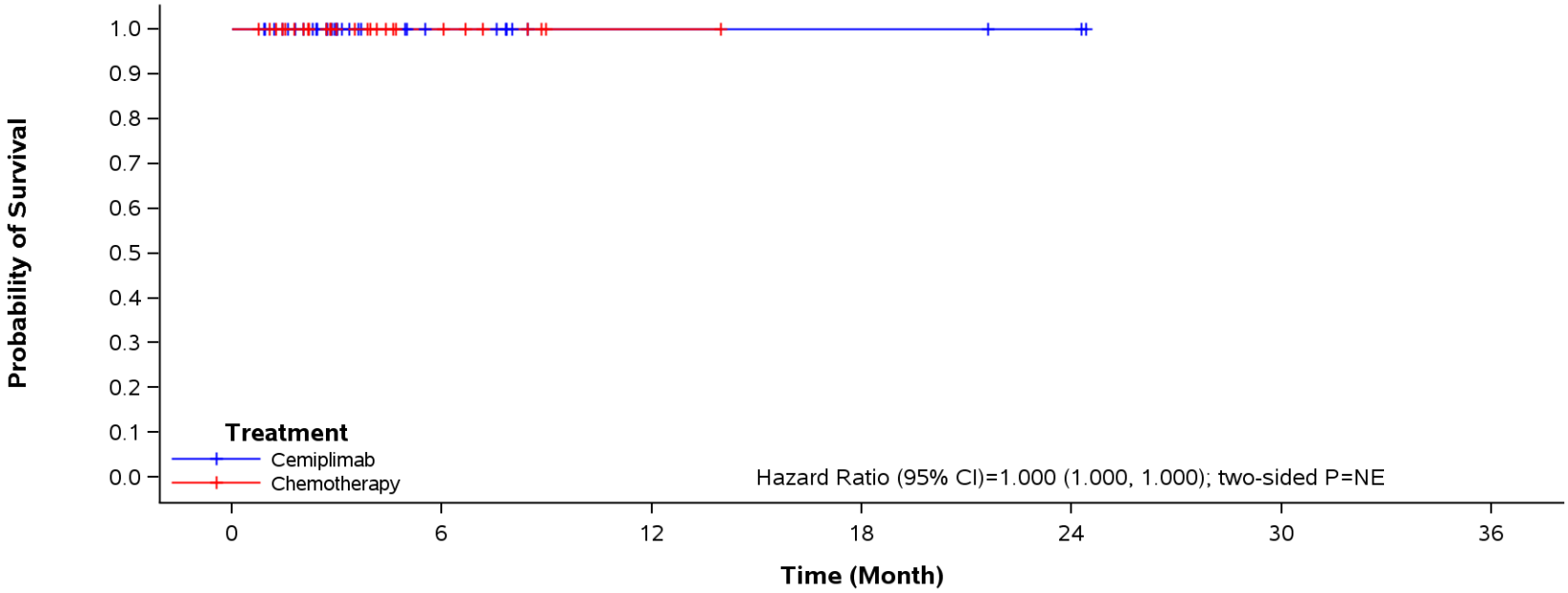

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Renal and urinary disorders
PT: Renal failure



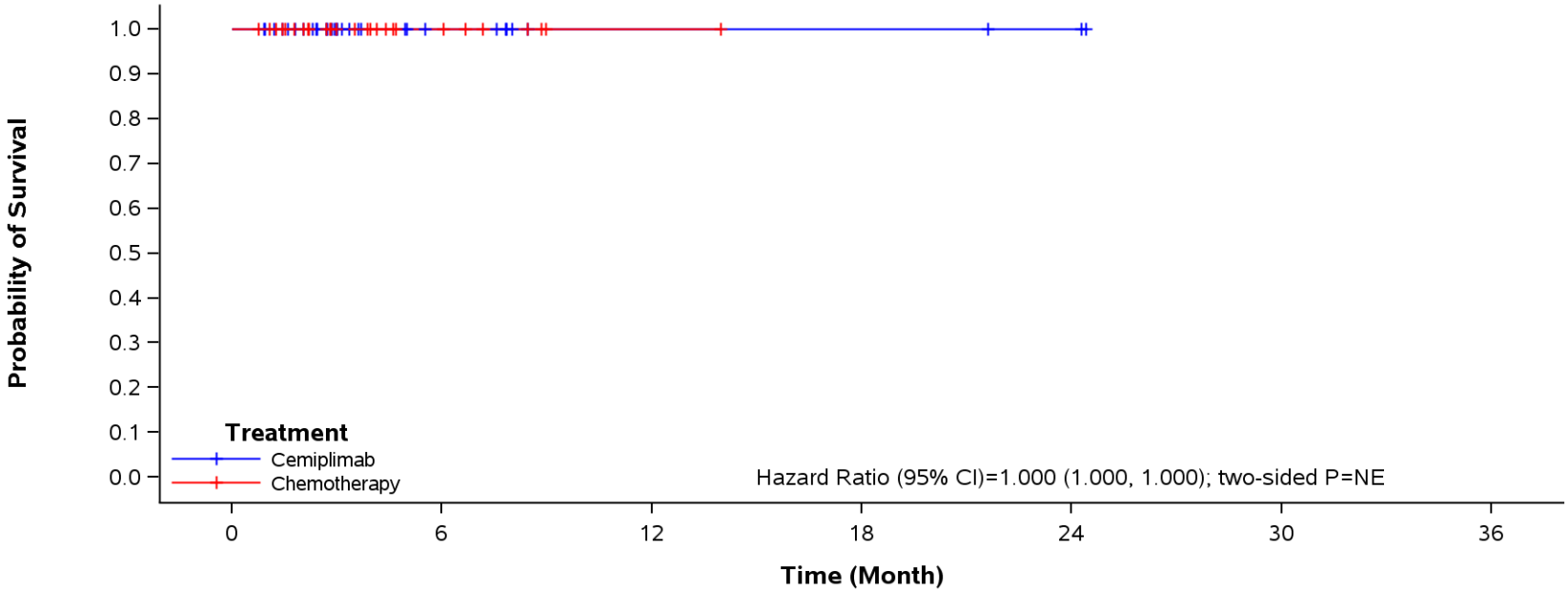

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Respiratory, thoracic and mediastinal disorders



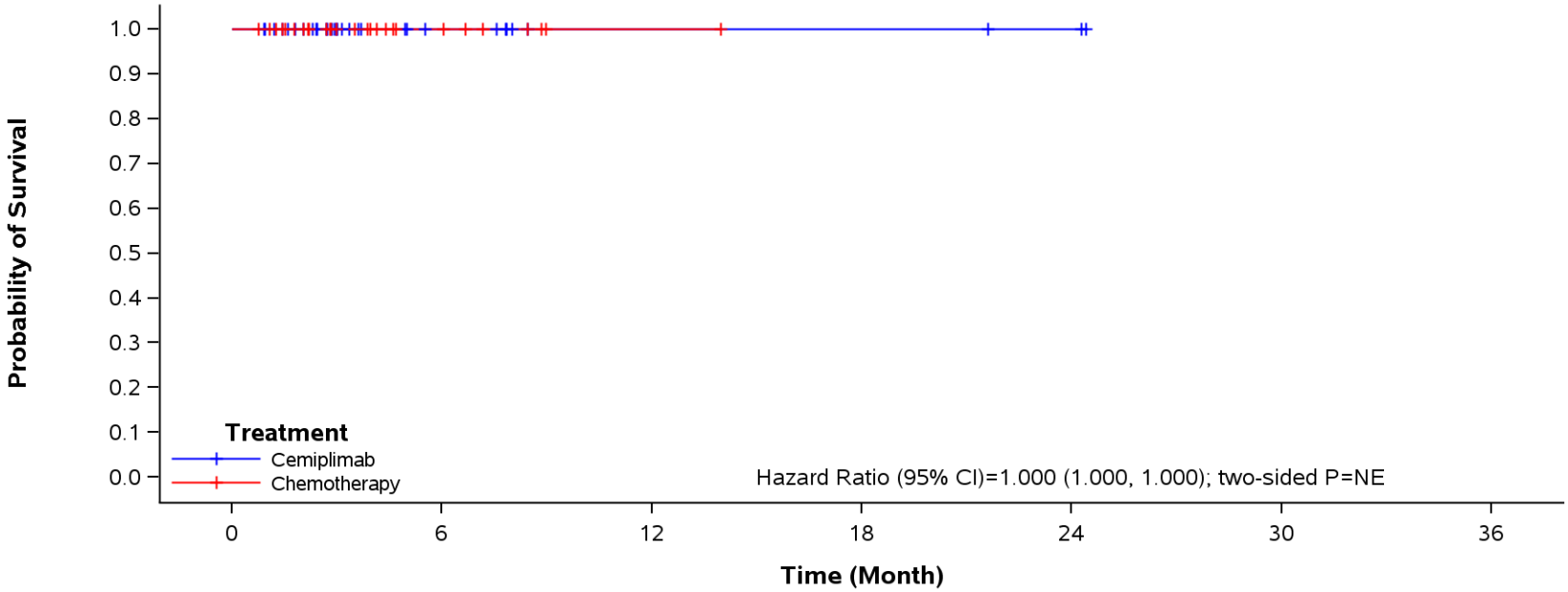

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumonitis



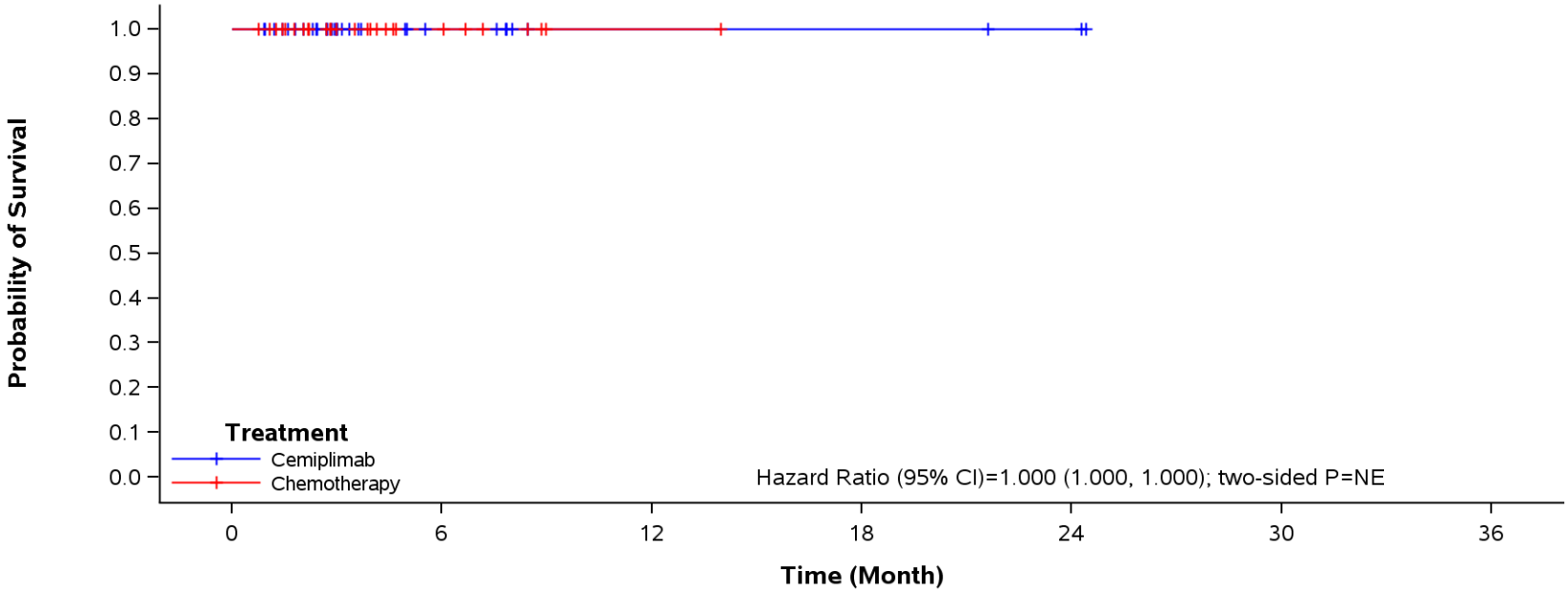

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1 (Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Vascular disorders



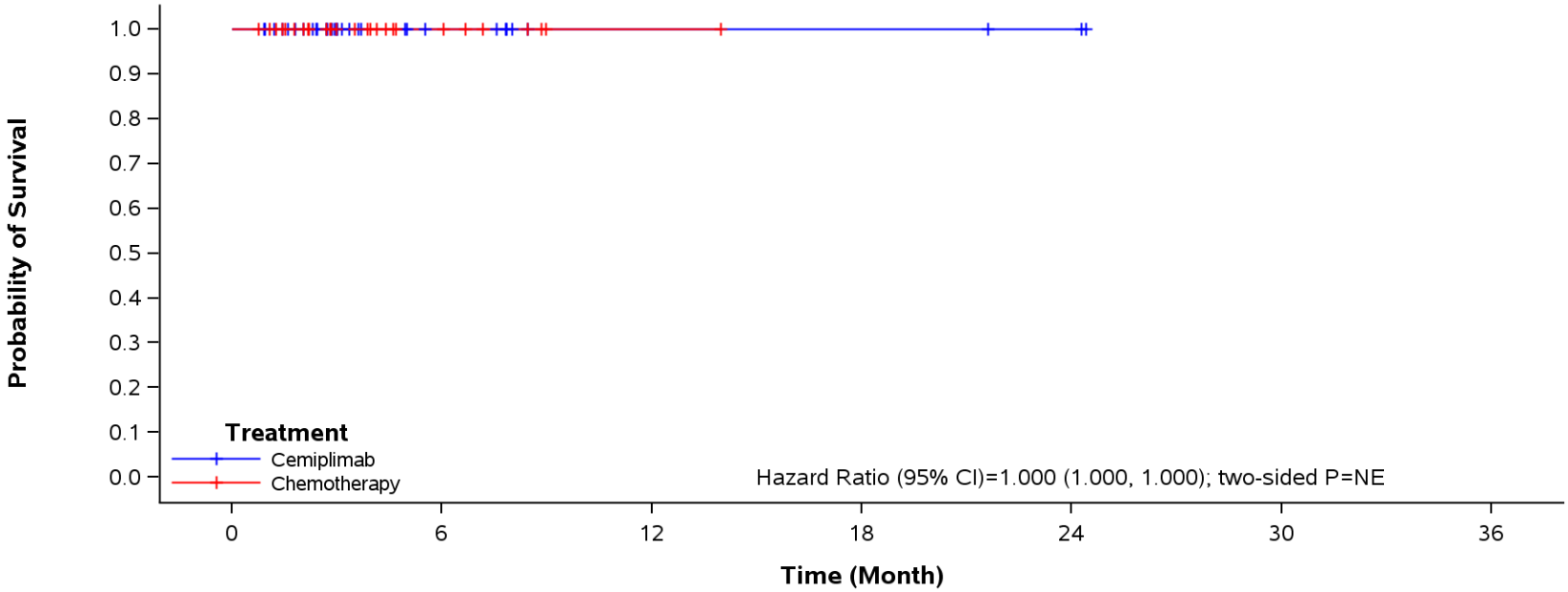

**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Figure 4.2.8. Time to First Any TEAE leading to discontinuation by System Organ Class and Preferred Term by Subgroup without PD-L1
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

Choice of IC chemotherapy: Vinorelbine
SOC: Vascular disorders
PT: Deep vein thrombosis




**Number of Subjects at risk**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Cemiplimab | 32 | 8 | 3 | 3 | 2 | 0 | 0 |
| Chemotherapy | 28 | 7 | 1 | 0 | 0 | 0 | 0 |

Data cut-off as of Jan 4th, 2022.
Hazard ratio is based on unstratified proportional hazards model (cemiplimab vs chemotherapy). Two-sided p-value is from unstratified log-rank test.

Table 12.2.4. Time to First Any Treatment-Emergent Adverse Events of Interest - Immune-Related AE (Grade 3)
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 24 (12.3%) | 0 |
| Censored Patients, n (%) | 171 (87.7%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | <0.0001 | |
| HR (95% CI) [c] | 24134715 (0.000, NE) | |
| HR P-Value [c] | 0.9882 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 85.4 (78.0, 90.4) | 100.0 (100.0, 100.0) |
| 12 months | 82.8 (74.6, 88.6) | 100.0 (100.0, 100.0) |
| 18 months | 80.4 (70.8, 87.2) | 100.0 (100.0, 100.0) |
| 24 months | 80.4 (70.8, 87.2) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.5. Time to First Any Treatment-Emergent Adverse Events of Interest - Infusion-Related Reactions (Grade >=2)
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 3 (1.5%) | 0 |
| Censored Patients, n (%) | 192 (98.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.1033 | |
| HR (95% CI) [c] | 26324080 (0.000, NE) | |
| HR P-Value [c] | 0.9957 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 98.5 (95.3, 99.5) | 100.0 (100.0, 100.0) |
| 12 months | 98.5 (95.3, 99.5) | 100.0 (100.0, 100.0) |
| 18 months | 98.5 (95.3, 99.5) | 100.0 (100.0, 100.0) |
| 24 months | 98.5 (95.3, 99.5) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).

Table 12.2.6. Time to First Any Treatment-Emergent Adverse Events of Interest - Allergic/Hypersensitivity Reactions (Grade >=2)
(Safety Analysis Set Exclude Patients Assigned to Gemcitabine)

| | Cemiplimab (N=195) | Chemotherapy (N=172) |
|---|---|---|
| Patients with event, n (%) | 1 (0.5%) | 0 |
| Censored Patients, n (%) | 194 (99.5%) | 172 (100.0%) |
| Median (95% CI), (Months) [a] | NE (NE, NE) | NE (NE, NE) |
| Unstratified log-rank test 2-sided p-value [b] | 0.3476 | |
| HR (95% CI) [c] | 26258353 (0.000, NE) | |
| HR P-Value [c] | 0.9975 | |
| Estimated Event-Free Probability, %(95% CI)[a] | | |
| 6 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 12 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 18 months | 99.5 (96.4, 99.9) | 100.0 (100.0, 100.0) |
| 24 months | 99.5 (96.4, 99.9) | NE (NE, NE) |
| 30 months | NE (NE, NE) | NE (NE, NE) |

Data cut-off as of Jan 4th, 2022.
[a] Based on Kaplan-Meier method.
[b] Two-sided p-value is from unstratified log-rank test.
[c] Based on unstratified proportional hazards model (cemiplimab vs chemotherapy).